

Appendix 16.1.1. Protocol and Amendments

1. 8822-001 Protocol Amendment 1 2015 JAN 12
2. 8822-001 Protocol Amendment 1 Description 2015 JAN 12
3. 8822-001 Protocol 2014 SEP 17

Post-authorisation Safety Study Protocol: Study 8822-001

Title	A Multicenter, Non-interventional, Observational, Post-Approval Safety Study of Updated ACCUSOL 35 Solutions in Continuous Renal Replacement Therapy (ACCUPASS)
Protocol version	Amendment 1 (2015Jan12)
EU PAS register number	ENCEPP/SDPP/6800
Active substances	Calcium chloride dihydrate, magnesium chloride hexahydrate, sodium chloride and sodium bicarbonate in all 3 formulations; and potassium chloride and glucose monohydrate in 2 of the 3 formulations
Medicinal products	ACCUSOL 35; ACCUSOL 35 Potassium 2 mmol/L; and ACCUSOL 35 Potassium 4 mmol/L
Product references	UK license numbers: PL 00116/0414; PL 00116/0415; and PL 00116/0416
Procedure numbers	MRP numbers: UK/H/0813/001; UK/H/0839/001; and UK/H/0839/002
Marketing authorisation holder	Baxter Healthcare Limited Caxton Way, Thetford, Norfolk, UK IP243SE
Joint PASS	No
Research question and objectives	As a result of prior reports of visible calcium carbonate precipitate in continuous renal replacement therapy (CRRT) lines during administration of ACCUSOL 35 solutions, the formulations of the products were updated. The objective of this study is to confirm the prevention of precipitate formation during CRRT by the use of the updated ACCUSOL 35 solutions.
Countries of study	4 to 5 EU countries (possible candidates include Austria, Belgium, Czech Republic, Denmark, France, Germany, Ireland, Netherlands, Spain, Sweden and United Kingdom)
Author	Drew S. Jones, MD, MPH, MBA Senior Medical Director Baxter Healthcare Corporation Round Lake, IL, USA Telephone: +1 (224) 270 2659
MAH contact person	James D. Motley Director, Pharmacovigilance, UK, Ireland and Malta Direct telephone: +44 (0) 1635 206437 Mobile telephone: +44 (0) 7717 542284 Direct fax: +44 (0) 1635 206281 e-mail: james_motley@baxter.com

Confidentiality Statement

This protocol contains confidential information belonging to Baxter Healthcare Limited. Acceptance of this document constitutes an agreement by the recipient that information will be held in confidence and will not be disclosed to others without prior written authorization from Baxter Healthcare Limited, except to the extent necessary to obtain approval of the responsible Ethics Committee and, if required, the responsible health authority, or as otherwise required by law.

1. TABLE OF CONTENTS

1. TABLE OF CONTENTS	2
2. LIST OF ABBREVIATIONS	5
3. RESPONSIBLE PARTIES	6
4. ABSTRACT.....	7
Title	7
Rationale and Background	7
Research Question and Objectives.....	7
Study Design.....	7
Population.....	8
Variables	8
Data Sources.....	9
Study Size.....	9
Data Analysis.....	9
Milestones	9
5. AMENDMENTS AND UPDATES.....	10
6. MILESTONES	10
7. RATIONALE AND BACKGROUND	10
8. RESEARCH QUESTION AND OBJECTIVES	11
9. RESEARCH METHODS.....	11
9.1 Study Design.....	11
9.2 Setting	12
9.2.1 Study Treatment	12
9.2.1.1 Study Drug	12
9.2.1.2 Concomitant Therapy	13
9.2.2 Study Population.....	13
9.2.2.1 Inclusion Criteria.....	14
9.2.2.2 Exclusion Criteria.....	14
9.2.2.3 Patient Withdrawal from the Study.....	14
9.2.2.4 Study Termination.....	15
9.3 Variables	15
9.3.1 Demographic and Baseline Data	15

9.3.2 Concomitant Medication	15
9.3.3 CRRT Details	16
9.3.4 ACCUSOL 35 Administration.....	16
9.4 Data Sources	17
9.5 Study Size.....	17
9.6 Data Management.....	18
9.7 Data Analysis.....	19
9.7.1 General Considerations.....	19
9.7.2 Analysis Populations.....	19
9.7.3 Primary Analysis	19
9.7.4 Other Assessments and Analyses	20
9.7.5 Potential Exploratory Analyses	20
9.8 Quality Control	21
9.8.1 Investigator's Responsibility.....	21
9.8.2 Direct Access to Source Data/Documents.....	21
9.8.3 Training	21
9.8.4 Monitoring.....	21
9.8.5 Auditing	21
9.8.6 Non-compliance with the Protocol	22
9.9 Limitations of the Research Methods	22
9.10 Other Aspects	22
 10. PROTECTION OF HUMAN SUBJECTS	 22
10.1 Ethical Conduct of the Study.....	22
10.2 Ethics Committee Approval.....	22
10.3 Patient Information and Consent.....	23
10.4 Patient Confidentiality	24
 11. MANAGEMENT AND REPORTING OF ADVERSE EVENTS/ADVERSE REACTIONS.....	 24
11.1 Definitions.....	24
11.2 Recording of Adverse Reactions.....	25
11.2.1 Relationship to Study Drug.....	26
11.2.2 Severity	26
11.3 Expedited Reporting of Adverse Reactions, Precipitate Observation and Pregnancy	27
11.3.1 Adverse Reactions.....	27
11.3.2 Precipitate Observation.....	27
11.3.3 Pregnancy	27
 12. PLANS FOR DISSEMINATING AND COMMUNICATING STUDY RESULTS	 27

13. REFERENCES.....	29
14. ANNEXES	30
14.1 List of Stand-alone Documents	30
14.2 ENCePP Checklist for Study Protocol.....	31
14.3 Additional Information	37
Investigator Acknowledgement	37

2. LIST OF ABBREVIATIONS

CRF	case report form
CRRT	continuous renal replacement therapy
EC	ethics committee
ICH GCP	International Conference on Harmonisation guidelines for Good Clinical Practice
ICU	intensive care unit
KCl	potassium chloride
MedDRA	Medical Dictionary for Regulatory Activities dictionary
WHODRUG	World Health Organization drug dictionary

3. RESPONSIBLE PARTIES

Protocol Author and Sponsor Medical Monitor	Drew S. Jones, MD, MPH, MBA Senior Medical Director Baxter Healthcare Corporation Round Lake, IL, USA Direct telephone: +1 (224) 270 2659
Qualified Person in Pharmacovigilance	Johan Hellmér, MD, PhD Deputy EU Qualified Person for Pharmacovigilance Baxter Medical AB Kista, Sweden Direct telephone: +46 (0) 8 632 64 68) Direct fax: +46 (0) 8 752 01 12

The list of investigators and contact information for them will be maintained by the study Sponsor in a separate document (see Section [14.1](#)).

4. ABSTRACT

Title

A Multicenter, Non-interventional, Observational, Post-Approval Safety Study of Updated ACCUSOL 35 Solutions in Continuous Renal Replacement Therapy (ACCUPASS)

Study Number: 8822-001

Version: Original (2014Sep17)

Author: Drew S. Jones, MD, MPH, MBA
Senior Medical Director
Baxter Healthcare Corporation
Round Lake, IL, USA
phone: +1 224-270-2659

Rationale and Background

ACCUSOL 35 solutions are indicated for the treatment of acute and chronic renal failure, as substitution solution in haemofiltration and haemodiafiltration, and as dialysis solution in haemodialysis and haemodiafiltration. Due to an increase in the number of product quality complaint reports related to the presence of white precipitate (calcium carbonate) formed during continuous veno-venous haemofiltration and continuous veno-venous haemodiafiltration in the continuous renal replacement therapy (CRRT) lines during the use of ACCUSOL 35 solutions, Baxter Healthcare Corporation updated the formulations of the products. The marketing authorization holder subsequently committed to perform this post-approval safety study with the updated solutions to monitor the safety of the updated formulations, specifically to address the risk of calcium carbonate precipitate formation.

Research Question and Objectives

The updated ACCUSOL 35 formulations were developed to prevent calcium carbonate precipitate formation during CRRT administration. The objective of this study is to confirm the prevention of calcium carbonate precipitate formation during CRRT by the use of the updated ACCUSOL 35 solutions under normal clinical use conditions.

Study Design

This is a multicenter, non-interventional, single-arm, observational, post-approval safety study in adult patients undergoing CRRT using any ACCUSOL 35 solution(s).

CRRT therapy will be administered in accordance with the intensive care unit's usual clinical practice and the recommendations in the current labeling for the ACCUSOL 35 solutions. Addition of antibiotics or any other medications to the ACCUSOL 35 solution bag, except for potassium chloride (KCl) supplementation, will not be allowed (see "Population"). The CRRT lines will be inspected every 30 minutes for the duration of the therapy, as described in the labeling for ACCUSOL 35 solutions.

Study staff will record the study data (see "Variables") during administration of CRRT with ACCUSOL 35 solution. The planned maximum study observation period is 32 hours: from 40 hours after CRRT with the current circuit was started until 72 hours of treatment has been administered using that same circuit.

Population

The study will include approximately 240 adult patients enrolled at approximately 20 to 25 hospitals, with medical or surgical ICUs that regularly treat CRRT patients using ACCUSOL 35 solutions, in 4 to 5 European Union countries (possible candidates include Austria, Belgium, Czech Republic, Denmark, France, Germany, Ireland, Netherlands, Spain, Sweden and United Kingdom).

Male and non-pregnant female patients will be eligible for enrollment if they are at least 18 years of age and have been undergoing CRRT using any ACCUSOL 35 solution (without any concomitant medication added to the solution, except for supplemental potassium chloride, if needed), with the same CRRT circuit for at least 40 hours. Patients with any contraindication to treatment with an ACCUSOL 35 solution, patients involved in any study with another investigational product or therapy (in the prior 30 days or during participation in this study), and patients who were previously included in the study will be excluded.

Variables

The key safety variables to be collected for analysis include:

- Amount of ACCUSOL 35 solution delivered through the CRRT circuit observed during the study
- Start- and end-of use times for the CRRT circuit used during the study
- Presence or absence of visible precipitate in the CRRT lines used during the study
- Time of observation of visible precipitate (if applicable)
- Color of precipitate observed (if applicable)

- Reason for terminating the use of the CRRT circuit, if during the study
- Reason for terminating the CRRT, if during the study
- Reason for end of patient's study participation

Data Sources

Data will be collected from the medical records of the enrolled patients and from observation of the patients and CRRT lines during the study period.

Study Size

The study will enroll approximately 240 patients. Data from at least 58 evaluable CRRT patients (ie, those whose CRRT circuits remained precipitate-free for 72 hours and those in whose circuits visible precipitate was observed within 72-hours) are needed to meet the study objective (see "Data Analysis").

Data Analysis

The primary analysis will be to generate the upper bound of the 95% confidence interval on the true proportion of treatments having precipitate formation, based on the data from the evaluable treatments. If no visible precipitate is observed in at least 58 evaluable treatments, the study will have provided 95% confidence that the probability of visible precipitate formation during 72 hours of CRRT with ACCUSOL 35 solution using the same CRRT circuit is not more than 5.0%. Based on the assumption that only 10% of all CRRT treatments will last 72 hours (regardless of whether the same circuit is in use the whole time), and combining the probabilities of both having a treatment last 72 hours and also having visible particulate formation, the result will have demonstrated with 95% confidence that the probability of visible precipitate formation in all CRRT treatments of any length with ACCUSOL 35 solutions, is not more than 0.5%.

Appropriate summary statistics will be calculated for other applicable variables to describe the variability of the therapy methods and materials involved in the study.

Milestones

Planned registration in the EU PAS register: June 2014

Planned start of data collection: October 2014

Planned end of data collection: April 2016

Planned final report of study results: August 2016

5. AMENDMENTS AND UPDATES

Number	Date	Section(s) of Study Protocol	Amendment or Update	Reason
1	2015Jan12	4. Abstract (Study Population) 9.2.2 Study Population 9.2.2.1 Inclusion Criteria (Item 1)	Exclusion of pregnant females from study participation	Request from the responsible ethics committee

6. MILESTONES

Milestone	Planned Date
Registration in EU PAS Register	June 2014
Start of data collection	October 2014
End of data collection	April 2016
Final Report of Study Results	August 2016

7. RATIONALE AND BACKGROUND

ACCUSOL 35 solutions are indicated for the treatment of acute and chronic renal failure, as substitution solution in haemofiltration and haemodiafiltration, and as dialysis solution in haemodialysis and haemodiafiltration. The product is presented in 3 formulations, 1 without potassium chloride (KCl) and 2 containing KCl (at concentrations of 2 mmol/L and 4 mmol/L). All 3 formulations contain calcium chloride dihydrate, magnesium chloride hexahydrate, sodium chloride and sodium bicarbonate. The 2 KCl formulations also contain glucose monohydrate.

In 2008, Baxter Healthcare Corporation (Baxter; the manufacturer of ACCUSOL 35 solutions) received an increased number of product quality complaint reports related to the presence of white precipitate observed in the continuous renal replacement (CRRT) lines during continuous veno-venous haemofiltration and continuous veno-venous haemodiafiltration during the use of ACCUSOL 35 solutions. In 2009, Baxter's root cause investigation identified that the precipitate was calcium carbonate, and a change in the pH of the mixed solution (supersaturation) was acknowledged as the major contributing factor to precipitate formation. Further investigation revealed that the addition of a low amount of phosphate salt as an excipient and lowering the pH of the mixed solution could inhibit the formation of calcium carbonate.

As part of their responses on 27 August 2009, Baxter made a commitment to the Pharmacovigilance Working Party to perform a post-approval safety study with the updated solution to monitor the safety of the updated formulation, specifically to address the risk of calcium carbonate precipitate formation.

This protocol presents the details of the post-approval safety study designed to verify the successful minimization of the risk of precipitate formation with the updated ACCUSOL 35 solution. The confirmation of the prevention of precipitate formation will support a proposal for removal of the current recommendation (presented in the labeling for the ACCUSOL 35 solutions) to inspect the CRRT lines every 30 minutes for the presence of precipitate during the use of the products.

8. RESEARCH QUESTION AND OBJECTIVES

The updated ACCUSOL 35 formulations were developed to prevent calcium carbonate precipitate formation during CRRT administration. The objective of this study is to confirm the prevention of calcium carbonate precipitate formation during CRRT by the use of the updated ACCUSOL 35 solutions.

9. RESEARCH METHODS

9.1 Study Design

This study is a prospective, multicenter, non-interventional, uncontrolled, open-label, observational study in adult patients undergoing CRRT using any of the updated ACCUSOL 35 solutions. The study is intended to capture data on the absence or presence of visible precipitate during 72 hours of use of ACCUSOL 35 solution with a single CRRT circuit.

Study centers will use the ACCUSOL 35 solutions from their available inventory; no ACCUSOL 35 solutions or any other approved medications or investigational products will be provided to the study centers by the Sponsor. CRRT therapy will be administered in accordance with the intensive care unit's (ICU) usual clinical practice and the recommendations in the current labeling for ACCUSOL 35 solutions. Addition of antibiotics or any other medications to the ACCUSOL 35 solution bag, except for KCl supplementation, will not be allowed.

There will be no randomized or non-randomized treatment assignments; no diagnostic, therapeutic, or experimental interventions; and no restrictions on use of concomitant medications or other treatments, except as noted above for the restriction on addition of medications other than KCl supplementation to the ACCUSOL 35 solution bag. Study patients will be prospectively identified in that study data will only be collected from

patients treated after study enrollment at a site has been authorized by the responsible ethics committee (EC) and the Sponsor.

Data will be collected at patient enrollment (at approximately 40 hours of CRRT with the same CRRT circuit) and periodically up to 72 hours of CRRT with the same circuit, or until the CRRT circuit needs to be changed or CRRT is completed (if either occurs sooner than 72 hours). The CRRT lines will be inspected every 30 minutes for the duration of the therapy, as recommended in the labeling for the ACCUSOL 35 solutions.

Observation of the CRRT circuit for precipitate through 72 hours of use is intended to represent a worst-case situation, since 72 hours is the maximum intended use period for a single CRRT circuit. Enrollment of patients whose CRRT circuit has already been in use for 40 hours is intended to maximize the possibility of the studied CRRT circuits reaching 72 hours of use for inclusion in the primary analysis (see Section 9.5), while maintaining a reasonable overall study size by reducing the number of patients enrolled.

If precipitate is seen in a CRRT line during therapy administration, the therapy will be stopped and proper procedures and monitoring (as recommended in the current ACCUSOL 35 solutions labeling) will be performed in order to return the circuit blood back to the patient and immediately set up a new CRRT circuit to continue therapy.

This study is strictly a non-interventional observational safety study assessing the presence or absence of visible precipitate in the CRRT lines with the specific products being studied. Therefore, no control group is considered necessary to achieve the study objectives.

9.2 Setting

9.2.1 Study Treatment

9.2.1.1 Study Drug

Patients enrolled in the study can be treated with ACCUSOL 35, ACCUSOL 35 Potassium 2 mmol/L, ACCUSOL 35 Potassium 4 mmol/L, or any combination of the solutions. Given the observational nature of this study, no ACCUSOL 35 solutions, or any other approved medications or investigational products, will be provided to study sites. All patients will be treated with ACCUSOL 35 solutions according to the patients' medical needs and the standard of care at the participating ICU.

No ACCUSOL 35 solution bag should be used for more than 24 hours after mixing of the two chambers as indicated in the approved labeling for the products.

9.2.1.2 Concomitant Therapy

There will be no restrictions on the use of concomitant medications or non-drug therapies, with the single exception being that only supplemental KCl may be added directly to the ACCUSOL 35 solution bag being used to treat a study patient. All patients will otherwise be treated according to their medical needs and the standard of care at the participating ICU.

9.2.2 Study Population

The study will include approximately 240 adult patients enrolled at approximately 20 to 25 hospitals, with medical or surgical ICUs that regularly treat CRRT patients using ACCUSOL 35 solutions, in 4 to 5 European Union countries (possible candidates include Austria, Belgium, Czech Republic, Denmark, France, Germany, Ireland, Netherlands, Spain, Sweden and United Kingdom). Patient enrollment in the study will be terminated when it has been confirmed that data have been collected from 58 evaluable patients (ie, those whose CRRT circuits remained precipitate-free for 72 hours, and those in whose circuits visible precipitate was observed within 72 hours; see Section 9.7.3). The number of patients to be enrolled at each site will be pre-specified to ensure that a small number of sites do not dominate the overall study enrollment.

Male and non-pregnant female patients will be eligible for enrollment if they are at least 18 years of age and have been undergoing CRRT using ACCUSOL 35 solution(s), without any concomitant medication added to the solution (except for supplemental KCl, if required), with the same CRRT circuit for at least 40 hours. Patients with any contraindication to treatment with an ACCUSOL 35 solution, and patients involved in any study with another investigational product or therapy (in the prior 30 days or during participation in this study) will be excluded. The specific inclusion and exclusion criteria are listed below.

9.2.2.1 Inclusion Criteria

Each patient must meet the following criteria to be enrolled in this study.

1. The patient is male or non-pregnant female and at least 18 years of age.
2. The patient is undergoing CRRT using ACCUSOL 35 solution(s).
3. The patient's CRRT has been ongoing for 40 hours using the same CRRT circuit; and the CRRT is anticipated to be continued for at least another 32 hours with the same circuit.
4. The patient, or their legally authorized representative, has provided informed consent for inclusion of their medical data in the study (unless the responsible EC has provided the Investigator a written waiver of the need to obtain consent due to the observational nature of the study).

9.2.2.2 Exclusion Criteria

Patients who meet any of the following criteria will be excluded from the study.

1. The patient has any contraindication(s) to treatment with ACCUSOL 35 solution(s).
2. An antibiotic or other medication (other than supplemental KCl) has been added to the ACCUSOL 35 solution(s) used for the patient's CRRT.
3. The patient previously participated in the study (ie, one of the patient's CRRT circuits has already been observed as part of this study).
4. The patient is currently, or was within the preceding 30 days, involved in a study of an investigational product or therapy.

9.2.2.3 Patient Withdrawal from the Study

Patients, or their legally authorized representatives, may terminate their consent for collection of their medical data for use in the study at any time. Should a patient or their legally authorized representative do so, site study personnel will record the time of and the reason provided for the withdrawal. The data collected on withdrawn patients will be used in the analyses, as applicable, and included in the clinical study report.

9.2.2.4 Study Termination

The Sponsor may prematurely terminate this study at any time for any reason. It may also terminate a single study center from participation in the study at any time for various reasons such as:

- inadequate rate of patient enrollment into the study
- noncompliance with protocol requirements or data collection methods
- noncompliance with Good Clinical Practice guidelines; applicable national and local laws; and/or applicable guidelines or regulations for protecting the rights, safety, and welfare of patients
- knowingly submitting false information to the Sponsor or designee.

If the study is prematurely terminated, all collected study data must be provided to the Sponsor.

9.3 Variables

Data will be collected at patient enrollment (at approximately 40 hours of CRRT with the same CRRT circuit) and periodically up to 72 hours of CRRT with the same circuit, or until the CRRT circuit needs to be changed or CRRT is terminated (if either occurs sooner than 72 hours).

9.3.1 Demographic and Baseline Data

The following data will be obtained from the patient's medical record:

- age
- gender
- weight

9.3.2 Concomitant Medication

Details (product, dosage and timing) of any anticoagulants used will be collected.

The concentration of any supplemental KCl added to the ACCUSOL 35 solution(s) will be recorded.

No other concomitant medications data will be collected on the study CRF for study analysis. However, details of concomitant medications will be included on the report form used for expedited reporting of any of adverse reactions (see Section 11.3)

9.3.3 CRRT Details

The following information about the patient's CRRT will be collected:

- the manufacturer and model of the CRRT monitor used
- the manufacturer and model of the CRRT lines used
- the manufacturer and model of the haemofilter used
- the CRRT mode employed
- the ultrafiltration rate(s) used

9.3.4 ACCUSOL 35 Administration

The following data on the administration of ACCUSOL 35 and the presence or absence of visible precipitate will be collected:

- the formulation(s) (ACCUSOL 35, ACCUSOL 35 Potassium 2 mmol/L, ACCUSOL 35 Potassium 4 mmol/L) and lot number(s) of ACCUSOL 35 solution(s) administered
- the ACCUSOL 35 solution dose rate(s) (mL/kg/hr) by site of introduction (pre- or post-filter or as dialysate)
- the start- and end-of-use times for the CRRT circuit used during the study
- the presence or absence of visible precipitate in the CRRT lines used during the study
- the time of observation of the observed precipitate, if applicable
- the formulation (ACCUSOL 35, ACCUSOL 35 Potassium 2 mmol/L or ACCUSOL 35 Potassium 4 mmol/L) and lot number of the ACCUSOL 35 solution in use at the time of the observation of the precipitate, if applicable
- the color of the observed precipitate, if applicable
- the reason for termination of the use of the CRRT circuit used during the study, if it occurs during the study (ie, before 72 hours of use are completed)

- the reason for termination of CRRT, if during the study (ie, before 72 hours of CRRT are completed)
- the reason for the end of the patient's study participation

9.4 Data Sources

Source data are defined as all information in original records and certified copies of original records of clinical findings, observations, or other activities in a clinical study that are necessary for the reconstruction and evaluation of the study. Source data are contained in source documents (original records or certified copies), which may be in paper and/or electronic format. Source data for this study may comprise any of the following: hospital records, medical records, clinical and office charts, laboratory notes, memoranda, outcomes reported by subjects, pharmacy dispensing records, recorded data from automated instruments, copies or transcriptions certified after verification as being accurate copies, microfiches, photographic negatives, microfilm or magnetic media, X-rays, study patient files and worksheets, and records kept at the pharmacy, at the laboratories, and at medico-technical departments involved in the clinical study.

9.5 Study Size

Based on published CRRT studies[1-5], it is estimated that of those CRRT treatments that have reached 40 hours with the same CRRT circuit, 25% will continue with the same circuit through 72 hours of use. It is expected, therefore, that about 240 enrolled patients will provide data on approximately 60 treatments that last 72 hours without CRRT circuit changes. If no visible precipitate is observed within that time in at least 58 evaluable treatments (ie, those in which CRRT circuits remains precipitate-free for 72 hours, and those in which visible precipitate is observed within 72-hours), the study will have provided 95% confidence that the probability of visible precipitate formation during 72 hours of CRRT with ACCUSOL 35 solution using the same CRRT circuit is not more than 5.0%.

It is also reasonable to assume (based on the published studies[1-5]) that approximately 10% of all CRRT treatments will last 72 hours, regardless of whether the same CRRT circuit is in use the whole time. Combining the probabilities of both having a treatment last 72 hours and also having visible particulate formation reduces the risk from 5% to 0.5%. Thus a sample size of 58 treatments with no observed precipitate will demonstrate, with 95% confidence, that the probability of precipitate formation in all CRRT treatments with ACCUSOL 35 solutions of any length (and not necessarily with the same CRRT circuit) is not more than 0.5%.

9.6 Data Management

The Investigator is responsible for the procurement of data and for the quality of data recorded on the patient's case report form (CRF). CRFs will be provided by the Sponsor in paper or electronic form. Detailed instructions for completing the CRF will be provided by the Sponsor. All study personnel will be trained on the protocol, study, and proper completion of the CRF. Data will be obtained from the patient's medical record and, if applicable, study-specific worksheets.

The Investigator will comply with the procedures for data recording and reporting. Any corrections to paper study documentation must be performed as follows: 1) the first entry will be crossed out entirely, remaining legible; and 2) each correction must be dated and initialed by the person correcting the entry; the use of correction fluid and erasing are prohibited.

All information transcribed onto the CRF is expected to accurately reflect original data recorded in the patient's medical record and any applicable study worksheets. These must be available to the Sponsor or designee and/or appropriate health authorities.

If paper-format CRFs are provided by the Sponsor, all required study data, including corrections, will be clearly and accurately recorded by authorized study site personnel on the CRFs. The CRFs will remain at the site until they are reviewed by the Sponsor's study monitor. All original CRFs will be collected by the study monitor, and an identical copy of the complete set of CRFs for each subject will remain in the investigator file at the study site.

If electronic-format CRFs are provided by the Sponsor, only authorized study site personnel will record or change data on the CRFs. Changes to a CRF will require documentation of the reason for each change, and an audit trail will be created for all changes. An identical (electronic/paper) version of the complete set of CRFs for each subject will remain in the investigator file at the study site.

The handling of data by the Sponsor, including data quality assurance, will comply with regulatory guidelines and the Sponsor's, or designee's, standard operating procedures. Data management and control processes and data management software specific to the study will be described in a data management plan (see Section 14.1).

A study database will be created from the data on the CRFs, using the Medical Dictionary for Regulatory Activities dictionary (MedDRA) for adverse event coding and the World Health Organization drug dictionary (WHODRUG) for coding concomitant medications.

Programmatic and manual review of the database will be performed to detect missing data, errors and inconsistencies. Queries on the detected problems will be forwarded to the site, and the responses returned from the site will be used by data management personnel to update the database as needed.

After all database updates are completed and prior to any statistical analyses, the database will be locked.

Quality assurance department representatives from the Sponsor and/or a contract research organization designated by the Sponsor, may visit a study site during or after the study to conduct a quality assurance audit. During a visit, EC and informed consent documentation, data entry and validation processes, and adverse event reporting may be reviewed. Processes may be reviewed to ensure the study is conducted in compliance with the protocol, standard operating procedures, and all applicable legal requirements. During these visits, the Investigator is obligated to provide direct access to all relevant documents and to allocate adequate time to discuss findings and relevant issues and, after the visit, to complete appropriate corrective actions when necessary.

9.7 Data Analysis

9.7.1 General Considerations

The methods and software to be used for the analyses and the responsible individual(s) who will perform these analyses will be identified in a data analysis plan (see Section 14.1) prior to database lock. Deviations from the planned analyses, if any, will be described in the clinical study report.

All data collected (see Sections 9.3 and 11) will be presented in data listings.

9.7.2 Analysis Populations

The enrolled population will be patients expected to receive CRRT with ACCUSOL 35 solution(s) using the same CRRT circuit for at least 72 hours. All analyses will be performed on the enrolled population, except as otherwise noted below.

9.7.3 Primary Analysis

For purposes of this study, the incidence of visible precipitate in the CRRT lines during 72 hours of use of the CRRT circuit will be examined. Data from the evaluable patients (ie, those whose CRRT circuits remains precipitate-free for 72 hours, and those in whose circuits visible precipitate is observed within 72-hours) will be used for this analysis. Data from patients whose CRRT was interrupted or terminated prior to 72 hours with no

observation of visible precipitate in the lines (ie, non-evaluable patients) will be excluded from this analysis.

The primary analysis will be to estimate the upper bound of a 95% confidence interval on the true proportion of treatments having precipitate formation. If the upper bound of the 95% confidence interval is 5% or less, then the primary objective of the study will have been achieved. That result will have demonstrated, with 95% confidence, that the probability of visible precipitate formation in all CRRT treatments with ACCUSOL 35 solutions of any length (and not necessarily with the same CRRT circuit), is not more than 0.5%. (see Section 9.5).

9.7.4 Other Assessments and Analyses

Categorical data (eg, gender) will be summarized using counts and percentages. Continuous data (eg, age) will be summarized using descriptive statistics for measures of central tendency and dispersion (number of patients, mean, standard deviation, minimum, median, maximum, and number missing).

Demographic and baseline characteristics include age, gender, and weight. Frequency and percentages will be provided for age as a categorical variable (eg, 18-35 years, 36-45 years, 46-55 years, 56-65 years and > 65 years) and gender. Weight will be summarized by descriptive statistics for measures of central tendency and dispersion.

Adverse reactions will be summarized both by the total frequency of reactions and by the frequency and percentage of subjects having at least one reaction. These adverse reaction summaries will be done overall and by MedDRA system organ class and preferred term.

Other data recorded (eg, concomitant anticoagulant used, CRRT details, ACCUSOL 35 administration details other than occurrence of precipitate) will not be summarized.

9.7.5 Potential Exploratory Analyses

If visible precipitate is observed, the time to first occurrence will be calculated (time from start of use of the CRRT circuit to time of observation of precipitate). In addition, further analyses may be performed to explore contributing factors (eg, ACCUSOL 35 solution formulation(s) and lot(s) administered; dose rate(s) and amount of ACCUSOL 35 delivered through the circuit; frequency of use and concentration of KCl add to the ACCUSOL 35 solution; manufacturer and model of CRRT lines used; haemofilter used; use and type of anticoagulant; CRRT mode; or ultrafiltration rate), as appropriate.

9.8 Quality Control

9.8.1 Investigator's Responsibility

The Investigator will comply with the protocol, the International Conference on Harmonisation guidelines for Good Clinical Practice (ICH GCP), and applicable regulatory requirements. The Investigator is ultimately responsible for the conduct of all aspects of the study at the study site and verifies by signature the integrity of all data transmitted to the responsible party. The term "Investigator" as used in this protocol as well as in other study documents, refers to the Investigator or authorized study personnel that the Investigator has designated to perform certain duties. Sub-investigators or other authorized study personnel are eligible to sign for the Investigator, except where the Investigator's signature is specifically required.

9.8.2 Direct Access to Source Data/Documents

The Investigator/study site will cooperate and provide direct access to study documents and data, including source documentation for monitoring by the study monitor, audits by the Sponsor or its designee, review by the EC, and inspections by applicable regulatory authorities.

9.8.3 Training

The study monitor will ensure that the Investigator and study site personnel understand all requirements of the protocol and his/her regulatory responsibilities as an investigator. Training may be provided at an investigator's meeting, at the study site, and/or by instruction manuals. In addition, the study monitor will be available for consultation with the Investigator and will serve as the liaison between the study site and the Sponsor.

9.8.4 Monitoring

The study monitor is responsible for ensuring and verifying that each study site conducts the study according to the protocol, standard operating procedures, other written instructions/agreements, and applicable regulatory guidelines/requirements. The Investigator will permit the study monitor to visit the study site at appropriate intervals. Monitoring processes specific to the study will be described in the Clinical Operations Plan (see Section [14.1](#)).

9.8.5 Auditing

The Sponsor and/or their designee may conduct audits to evaluate study conduct and compliance with the protocol, standard operating procedures, other written instructions/agreements, ICH GCP, and applicable regulatory guidelines/requirements. The investigator will permit auditors to visit the study site.

9.8.6 Non-compliance with the Protocol

If monitoring and/or auditing identify serious and/or persistent non-compliance with the protocol, the Sponsor may terminate the investigator's participation. The Sponsor will notify the responsible EC and applicable regulatory authorities of any such investigator termination.

9.9 Limitations of the Research Methods

The non-controlled observational study design is considered suitable to achieve the study purpose, which is to confirm that the updated ACCUSOL 35 solutions do not present a significant risk of calcium carbonate precipitate formation. If there are statistical limitations, it is the inability to generalize to any specific CRRT patient population, which is typically the case for an observational study.

If precipitate is actually observed during the study, the study data will not be adequate to determine the cause of that occurrence, although the data collected may be helpful in developing hypotheses for further in vitro or clinical studies.

9.10 Other Aspects

Not applicable; all aspects of the study are described in the other sections of this protocol.

10. PROTECTION OF HUMAN SUBJECTS

10.1 Ethical Conduct of the Study

This study will be conducted in compliance with the ethical principles that have their origin in the Declaration of Helsinki and its revisions, ICH GCP, good pharmacovigilance practices and all national and local laws. The Investigator will be responsible for ensuring that this study is conducted according to the investigational plan and for protecting the rights, safety, and welfare of study patients under the Investigator's care.

10.2 Ethics Committee Approval

Prior to enrolling any patients in the study, the Investigator must obtain approval from the responsible EC and, if required, the responsible health authority for the protocol and any amendments, the informed consent form (if applicable), and any other information intended to be presented to the patient in order to obtain informed consent (if applicable). All changes in the research activity and all unanticipated problems involving risk to study patients or others will be reported to the responsible EC and, if required, to the responsible health authority. No changes in the research will be implemented without the

responsible EC's and, if required, to the responsible health authority's prior approval, except where necessary to eliminate apparent immediate hazards to study patients.

10.3 Patient Information and Consent

Written informed consent will be obtained from each patient or (if the patient is unable to provide informed consent) the patient's legally authorized representative prior to the patient's participation in the study, unless the responsible EC has granted a waiver from the requirement for informed consent based on the observational nature of the study.

In obtaining and documenting informed consent, the Investigator will comply with all Good Clinical Practice and applicable legal requirements, and with the ethical principles that have their origin in the Declaration of Helsinki. Neither the Investigator, nor the site staff, will coerce or unduly influence a patient or their representative, to participate or to continue to participate in the study. The patients or the patient's representative may refuse participation or withdraw consent at any time and for any reason during the study.

Neither the written informed consent form, nor any other information presented to the patient or the patient's representative in order to obtain consent for participation in the study, will contain language that causes the patient or their representative to waive or to appear to waive any legal rights, or that releases the Investigator, the institution, or their agents from liability for negligence.

The Investigator or designee will fully inform the patient or the patient's representative of all pertinent aspects of the study. Before informed consent is obtained, the Investigator or their designee will answer all questions about the study to the satisfaction of the patient or the patient's representative. The Investigator or designee will inform the patient or the patient's representative that they are free to refuse to participate in the study without affecting the quality of the patient's medical care. The language used in all communications regarding the study will be as non-technical as practical so that it is understandable to the patient or the patient's representative.

If a patient is unable to read or to provide written informed consent by him/herself, the patient's representative will sign on behalf of the patient; in addition to which an impartial witness, who was present throughout the informed consent process, will also sign and date the form. Prior to the patient's participation in the study, the patient or the patient's representative will be given a copy of the signed and dated written informed consent form and any other written information intended to be provided to the patient.

10.4 Patient Confidentiality

Every effort will be made to maintain confidentiality of all patient data included in the CRF. At the time of study enrollment study personnel will assign each patient a patient identification number, which will be used to identify the patient in the CRF. The Investigator will maintain a patient identification list (patient study identification numbers with the corresponding patient names) to enable source records to be identified.

Patients will be informed that information about them is being entered into the study database. Patients will be informed that all protected health information and clinical data will be maintained in a confidential manner.

All study data will be stored in electronic databases that are confidential, password-protected, and access-restricted. Information that may be made available for inspection by authorized health authorities will be handled in the strictest confidence. No information that could uniquely identify individual patients will be submitted to the Sponsor.

11. MANAGEMENT AND REPORTING OF ADVERSE EVENTS/ADVERSE REACTIONS

11.1 Definitions

An *adverse event* is any untoward medical occurrence in a patient administered a medicinal product and which does not necessarily have to have a causal relationship with this treatment. An adverse event can therefore be any unfavorable and unintended sign (eg, an abnormal laboratory finding), symptom (eg, rash, pain, discomfort, fever, dizziness, etc), disease (eg, peritonitis, bacteremia, etc) or outcome of death temporally associated with the use of a medicinal product, whether or not considered associated with this medicinal product. Other events that, while not necessarily meeting the definition of adverse events, should be treated as such because they may be reportable to regulatory authorities according to adverse event reporting requirements, whether or not considered causally associated with drug or biologic treatment, include the following:

- drug or biologic overdose, whether accidental or intentional
- drug or biologic abuse
- an event occurring from drug or biologic withdrawal
- any failure of expected pharmacological action
- exposure to a drug or biologic during pregnancy

- inadvertent or accidental drug or biologic exposure (eg, product leaking or being spilled onto a patient or caregiver)
- unexpected therapeutic or clinical benefit from the drug or biologic product
- medication errors (eg, incorrect route of administration, incorrect dosage, use of incorrect product)

An *adverse reaction* is a response to a medicinal product which is noxious and unintended. Response in this context means that a causal relationship between a medicinal product and an adverse event is, at least, a reasonable possibility.

A *serious adverse reaction* is one that meets one or more of the following criteria:

- results in death (including fetal death);
- is life-threatening (Note: “life-threatening” in the definition of “serious” refers to an adverse reaction in which the patient was at risk of immediate death at the time of the reaction. It does not refer to a reaction that might have caused death if it were more severe);
- requires inpatient hospitalization (Note: inpatient hospitalization refers to any inpatient admission, regardless of length of stay);
- results in prolongation of ongoing hospitalization;
- results in persistent or significant disability/incapacity (ie, a substantial disruption of a person’s ability to conduct normal life functions);
- is a congenital anomaly/birth defect; or
- is a medically important reaction that may not be immediately life-threatening or result in death or hospitalization, but may jeopardize the patient or requires intervention to prevent one of the other outcomes listed above (eg, intensive treatment in an emergency room or at home for allergic bronchospasm, blood dyscrasias or convulsions that do not result in hospitalization; or development of drug dependence or drug abuse).

11.2 Recording of Adverse Reactions

Details of any adverse reaction (non-serious or serious) that is noted in or reported by the study patient during the study data collection period (see Section 9.3) will be collected in the CRF.

Whenever possible, the Investigator will present a diagnosis based on the presenting signs and symptoms, rather than just presenting a sign or symptom.

11.2.1 Relationship to Study Drug

The Investigator will indicate their opinion on the relationship of the reaction to ACCUSOL 35 according to the following definitions.

Possibly related:

The reaction follows a reasonable temporal relationship to the administration of the study drug, and an alternative etiology is equally or less likely compared to the potential relationship to the study drug.

Probably related:

The reaction has a strong temporal relationship to the administration of the study drug and an alternative etiology is unlikely or significantly less likely compared to the potential relationship to the study drug.

11.2.2 Severity

The severity of an adverse reaction is defined as a qualitative assessment by the Investigator of the degree of intensity of the adverse reaction observed or reported to him/her by the patient. The Investigator will indicate their opinion on the severity of the event or reaction according to the following definitions. The assessment of severity will be made irrespective of drug relationship or seriousness.

Mild:

- The reaction is a transient discomfort and does not interfere in a significant manner with the subject's normal functioning level.
- The reaction resolves spontaneously or may require minimal therapeutic intervention.

Moderate:

- The reaction produces limited impairment of function and may require therapeutic intervention.
- The reaction produces no sequela(e).

Severe:

- The reaction results in a marked impairment of function and may lead to temporary inability to resume usual life pattern.

- The reaction produces sequela(e), which require(s) (prolonged) therapeutic intervention.

11.3 Expedited Reporting of Adverse Reactions, Precipitate Observation and Pregnancy

11.3.1 Adverse Reactions

All adverse reactions (non-serious or serious) must be reported to the Sponsor or designee within one business day of observation or notification of the event. Instructions and forms for reporting an adverse reaction will be provided to the Investigator, including the name(s) and contact details of the individual(s) who should be contacted regarding safety issues or questions regarding the study.

An adverse reaction form will be completed that provides detailed information about the reaction and will be promptly forwarded to the Sponsor or designee as indicated in the instructions. The Sponsor or designee will be responsible for appropriate reporting of adverse reactions that occur in patients exposed to an ACCUSOL 35 solution to health authorities. The Investigator will promptly notify the responsible EC of all adverse reactions occurring at the Investigator's site, in accordance with the requirements of the EC, including any significant follow-up information.

11.3.2 Precipitate Observation

If the Investigator or study staff observes visible precipitate in any study CRRT line, it will be reported within one business day of becoming aware of the precipitate observation. Instructions and forms for expedited reporting of precipitate observation will be provided to the Investigator.

11.3.3 Pregnancy

Although it is not expected based on the population included in this study, if the Investigator or study staff becomes aware of the pregnancy of a study patient during their study participation, the pregnancy will be reported within one business day of becoming aware of the pregnancy, and the pregnancy will be followed-up at 1 year post-delivery, if feasible. Instructions and forms for reporting pregnancy will be provided to the Investigator.

12. PLANS FOR DISSEMINATING AND COMMUNICATING STUDY RESULTS

Information concerning study treatment, patent applications, formulation, manufacturing processes, unpublished scientific data, and other pertinent information is confidential and remains the property of the Sponsor. Details will be disclosed only to persons involved in

the conduct of the study. The Investigator may use this information for the purposes of the study only.

It is understood by the Investigator that the Sponsor may use the information derived from this study and may share this information, as required, with other clinical investigators or health authorities. To allow for the use of the information and to ensure complete and thorough analysis, the Investigator is obligated to provide the Sponsor with complete study data.

The results of this study may be considered for publication or presentation at symposia and congresses. Individual investigators are encouraged to publish or disclose the data generated at their respective sites; but only after the collective data are presented or published as a single study, or two years following either the conclusion of the study at all sites or database lock, whichever occurs first. All publication manuscripts, abstracts, prepared transcripts, and texts and visual material for presentation (eg, slide sets) must be submitted to the Sponsor at least 60 days prior to the intended submission. This is necessary to prevent premature disclosure of trade secrets or patent-protected information, and is in no way intended to restrict publication of facts or opinions formulated by the Investigator. The Sponsor will inform the Investigator in writing of any objections or questions arising within 30 days of receipt of the proposed presentation materials.

The results of the study will be summarized on the EU PAS register after completion of the study report.

13. REFERENCES

1. Monchi M, Berghmans D, Ledoux D, Canivet J-L, Dubois B, Damas P. Citrate vs. heparin for anticoagulation in continuous venovenous hemofiltration: a prospective randomized study. *Intensive Care Med.* 2004;30:260-265. doi:10.1007/s00134-003-2047-x.
2. Kutsogiannis DJ, Gibney RT, Stollery D, Gao J. Regional citrate versus systemic heparin anticoagulation for continuous renal replacement in critically ill patients. *Kidney Int.* 2005;67:2361-2367. doi:10.1111/j.1523-1755.2005.00342.x
3. Morabito S, Pistolesi V, Tritapepe L, et al. Regional citrate anticoagulation in cardiac surgery patients at high risk of bleeding: a continuous veno-venous hemofiltration protocol with a low concentration citrate solution. *Critical Care.* 2012;16:R1111. doi:10.1186/cc11403.
4. Hetzel GR, Schmitz M, Wissing H, et al. Regional citrate versus systemic heparin for anticoagulation in critically ill patients on continuous venovenous haemofiltration: a prospective randomized multicentre trial. *Nephrol Dial Transplant.* 26(1):232-239. doi:10.1093/ndt/gfq575.
5. Betjes MGH, van Oosterom D, van Agteren M, van de Wetering J. Regional citrate versus heparin anticoagulation during venovenous hemofiltration in patients at low risk for bleeding: similar hemofilter survival but significantly less bleeding. *J Nephrol.* 2007;20(5):602-608.

14. ANNEXES

14.1 List of Stand-alone Documents

Number	Document Reference Number	Date	Title
1	to be assigned	to be determined	Study Investigators
2	to be assigned	to be determined	Clinical Operations Plan
3	to be assigned	to be determined	Data Management Plan
4	to be assigned	to be determined	Statistical Analysis Plan
5	to be assigned	to be determined	Safety Plan

14.2 ENCePP Checklist for Study Protocol



Doc.Ref. EMA/540136/2009

European Network of Centres for
Pharmacoepidemiology and
Pharmacovigilance

ENCePP Checklist for Study Protocols (Revision 2, amended)

Adopted by the ENCePP Steering Group on 14/01/2013

The [European Network of Centres for Pharmacoepidemiology and Pharmacovigilance \(ENCePP\)](#) welcomes innovative designs and new methods of research. This Checklist has been developed by ENCePP to stimulate consideration of important principles when designing and writing a pharmacoepidemiological or pharmacovigilance study protocol. The Checklist is intended to promote the quality of such studies, not their uniformity. The user is also referred to the [ENCePP Guide on Methodological Standards in Pharmacoepidemiology](#) which reviews and gives direct electronic access to guidance for research in pharmacoepidemiology and pharmacovigilance.

For each question of the Checklist, the investigator should indicate whether or not it has been addressed in the study protocol. If the answer is "Yes", the page number(s) of the protocol where this issue has been discussed should be specified. It is possible that some questions do not apply to a particular study (for example in the case of an innovative study design). In this case, the answer 'N/A' (Not Applicable) can be checked and the "Comments" field included for each section should be used to explain why. The "Comments" field can also be used to elaborate on a "No" answer.

This Checklist should be included as an Annex by marketing authorisation holders when submitting the protocol of a non-interventional post-authorisation safety study (PASS) to a regulatory authority (see the [Guidance on the format and content of the protocol of non-interventional post-authorisation safety studies](#)). Note, the Checklist is a supporting document and does not replace the format of the protocol for PASS as recommended in the Guidance and Module VIII of the Good pharmacovigilance practices (GVP).

Study title:
A Multicenter, Non-interventional, Observational, Post-Approval Safety Study of Updated ACCUSOL 35 Solutions in Continuous Renal Replacement Therapy (ACCUPASS)

Study reference number:
8822-001

Section 1: Milestones	Yes	No	N/A	Page Number(s)
1.1 Does the protocol specify timelines for				
1.1.1 Start of data collection ¹	☐	☒	☐	10
1.1.2 End of data collection ²	☐	☒	☐	10
1.1.3 Study progress report(s)	☐	☐	☒	
1.1.4 Interim progress report(s)	☐	☐	☒	
1.1.5 Registration in the EU PAS register	☐	☒	☐	10
1.1.6 Final report of study results.	☐	☒	☐	10

Comments:

No study progress or interim progress reports were requested by the responsible regulatory authority.

¹ Date from which information on the first study is first recorded in the study dataset or, in the case of secondary use of data, the date from which data extraction starts.

² Date from which the analytical dataset is completely available.

ENCePP Checklist for Study Protocols (Revision 2)

Section 2: Research question	Yes	No	N/A	Page Number(s)
2.1 Does the formulation of the research question and objectives clearly explain:				
2.1.1 Why the study is conducted? (e.g. to address an important public health concern, a risk identified in the risk management plan, an emerging safety issue)	☒	☐	☐	7
2.1.2 The objective(s) of the study?	☒	☐	☐	7
2.1.3 The target population? (i.e. population or subgroup to whom the study results are intended to be generalised)	☒	☐	☐	13-14
2.1.4 Which formal hypothesis(-es) is (are) to be tested?	☐	☐	☒	
2.1.5 If applicable, that there is no <i>a priori</i> hypothesis?	☐	☐	☒	

Comments:

This study is observational and therefore does not include hypothesis testing.

Section 3: Study design	Yes	No	N/A	Page Number(s)
3.1 Is the study design described? (e.g. cohort, case-control, randomised controlled trial, new or alternative design)	☒	☐	☐	11-12
3.2 Does the protocol specify the primary and secondary (if applicable) endpoint(s) to be investigated?	☒	☐	☐	19-20
3.3 Does the protocol describe the measure(s) of effect? (e.g. relative risk, odds ratio, deaths per 1000 person-years, absolute risk, excess risk, incidence rate ratio, hazard ratio, number needed to harm (NNH) per year)	☒	☐	☐	19

Comments:

Section 4: Source and study populations	Yes	No	N/A	Page Number(s)
4.1 Is the source population described?	☒	☐	☐	13
4.2 Is the planned study population defined in terms of:				
4.2.1 Study time period?	☒	☐	☐	11-12
4.2.2 Age and sex?	☒	☐	☐	13
4.2.3 Country of origin?	☒	☐	☐	13
4.2.4 Disease/indication?	☒	☐	☐	13
4.2.5 Co-morbidity?	☒	☐	☐	13-14
4.2.6 Seasonality?	☐	☐	☒	
4.3 Does the protocol define how the study population will be sampled from the source population? (e.g. event or inclusion/exclusion criteria)	☒	☐	☐	13-14

Comments:

Seasonality has no bearing on this study's population or design.

Section 5: Exposure definition and measurement	Yes	No	N/A	Page Number(s)
5.1 Does the protocol describe how exposure is defined and measured? (e.g. operational details for defining and categorising exposure)	☒	☐	☐	16

Section 5: Exposure definition and measurement	Yes	No	N/A	Page Number(s)
5.2 Does the protocol discuss the validity of exposure measurement? (e.g. precision, accuracy, prospective ascertainment, exposure information recorded before the outcome occurred, use of validation sub-study)	☐	☐	☒	
5.3 Is exposure classified according to time windows? (e.g. current user, former user, non-use)	☐	☐	☒	
5.4 Is exposure classified based on biological mechanism of action and taking into account the pharmacokinetics and pharmacodynamics of the drug?	☐	☐	☒	
5.5 Does the protocol specify whether a dose-dependent or duration-dependent response is measured?	☐	☐	☒	

Comments:

The time during which direct observations are made for the occurrence of the study endpoint is fixed. Based on the endpoint, the use of time windows is not appropriate for the planned analyses. The study does not examine in-vivo exposure and the endpoint is not based on a pharmacologic response.

Section 6: Endpoint definition and measurement	Yes	No	N/A	Page Number(s)
6.1 Does the protocol describe how the endpoints are defined and measured?	☒	☐	☐	15-16
6.2 Does the protocol discuss the validity of endpoint measurement? (e.g. precision, accuracy, sensitivity, specificity, positive predictive value, prospective or retrospective ascertainment, use of validation sub-study)	☒	☐	☐	17

Comments:

Section 7: Confounders and effect modifiers	Yes	No	N/A	Page Number(s)
7.1 Does the protocol address known confounders? (e.g. collection of data on known confounders, methods of controlling for known confounders)	☐	☐	☒	
7.2 Does the protocol address known effect modifiers? (e.g. collection of data on known effect modifiers, anticipated direction of effect)	☐	☐	☒	

Comments:

The primary study endpoint is absence or observation of a physicochemical phenomenon in the study product outside the patient, rather than a therapeutic or pharmacologic effect on the patient.

Section 8: Data sources	Yes	No	N/A	Page Number(s)
8.1 Does the protocol describe the data source(s) used in the study for the ascertainment of:				
8.1.1 Exposure? (e.g. pharmacy dispensing, general practice prescribing, claims data, self-report, face-to-face interview, etc.)	☒	☐	☐	16-17
8.1.2 Endpoints? (e.g. clinical records, laboratory markers or values, claims data, self-report, patient interview including scales and questionnaires, vital statistics, etc.)	☒	☐	☐	16-17
8.1.3 Covariates?	☒	☐	☐	16-17
8.2 Does the protocol describe the information available from the data source(s) on:				

Section 8: Data sources	Yes	No	N/A	Page Number(s)
8.2.1 Exposure? (e.g. date of dispensing, drug quantity, dose, number of days of supply prescription, daily dosage, prescriber)	☒	☐	☐	15-16
8.2.2 Endpoints? (e.g. date of occurrence, multiple event, severity measures related to event)	☒	☐	☐	15-16
8.2.3 Covariates? (e.g. age, sex, clinical and drug use history, co-morbidity, co-medications, life style, etc.)	☒	☐	☐	15-16
8.3 Is a coding system described for:				
8.3.1 Diseases? (e.g. International Classification of Diseases (ICD)-10)	☐	☐	☒	
8.3.2 Endpoints? (e.g. Medical Dictionary for Regulatory Activities (MedDRA) for adverse events)	☒	☐	☐	18
8.3.3 Exposure? (e.g. WHO Drug Dictionary, Anatomical Therapeutic Chemical (ATC) Classification System)	☒	☐	☐	18
8.4 Is the linkage method between data sources described? (e.g. based on a unique identifier or other)	☒	☐	☐	23

Comments:

Based on study design, data on the patients' diseases are not collected for analysis.

Section 9: Study size and power	Yes	No	N/A	Page Number(s)
9.1 Is sample size and/or statistical power calculated?	☒	☐	☐	17

Comments:

Section 10: Analysis plan	Yes	No	N/A	Page Number(s)
10.1 Does the plan include measurement of excess risks?	☐	☐	☒	
10.2 Is the choice of statistical techniques described?	☒	☐	☐	19-20
10.3 Are descriptive analyses included?	☒	☐	☐	19-20
10.4 Are stratified analyses included?	☐	☐	☒	
10.5 Does the plan describe methods for adjusting for confounding?	☐	☐	☒	
10.6 Does the plan describe methods addressing effect modification?	☐	☐	☒	

Comments:

The primary study endpoint is absence or observation of a physicochemical phenomenon in the study product outside the patient, rather than a therapeutic or pharmacologic effect on the patient.

Section 11: Data management and quality control	Yes	No	N/A	Page Number(s)
11.1 Is information provided on the management of missing data?	☐	☐	☒	
11.2 Does the protocol provide information on data storage? (e.g. software and IT environment, database maintenance and anti-fraud protection, archiving)	☒	☐	☐	17-18
11.3 Are methods of quality assurance described?	☒	☐	☐	17-18

Section 11: Data management and quality control	Yes	No	N/A	Page Number(s)
11.4 Does the protocol describe possible quality issues related to the data source(s)?	☐	☐	☒	
11.5 Is there a system in place for independent review of study results?	☐	☐	☒	

Comments:

The primary study endpoint is absence or observation of a physicochemical phenomenon in the study product outside the patient, rather than a therapeutic or pharmacologic effect on the patient.

Section 12: Limitations	Yes	No	N/A	Page Number(s)
12.1 Does the protocol discuss: 12.1.1 Selection biases? 12.1.2 Information biases? (e.g. anticipated direction and magnitude of such biases, validation sub-study, use of validation and external data, analytical methods)	☐ ☐	☐ ☐	☒ ☒	
12.2 Does the protocol discuss study feasibility? (e.g. sample size, anticipated exposure, duration of follow-up in a cohort study, patient recruitment)	☐	☐	☒	
12.3 Does the protocol address other limitations?	☒	☐	☐	21-22

Comments:

Section 13: Ethical issues	Yes	No	N/A	Page Number(s)
13.1 Have requirements of Ethics Committee/Institutional Review Board approval been described?	☒	☐	☐	22
13.2 Has any outcome of an ethical review procedure been addressed?	☐	☐	☒	
13.3 Have data protection requirements been described?	☒	☐	☐	23-24

Comments:

Section 14: Amendments and deviations	Yes	No	N/A	Page Number(s)
14.1 Does the protocol include a section to document future amendments and deviations?	☒	☐	☐	10

Comments:

Section 15: Plans for communication of study results	Yes	No	N/A	Page Number(s)
15.1 Are plans described for communicating study results (e.g. to regulatory authorities)?	☒	☐	☐	7, 27
15.2 Are plans described for disseminating study results externally, including publication?	☒	☐	☐	27-28

Comments:

Name of the main author of the protocol: Drew S Jones MD

Date: 16 July 2014

Signature: Drew S Jones MD

14.3 Additional Information

Investigator Acknowledgement

Study Title: A Multicenter, Non-interventional, Observational, Post-Approval Safety Study of Updated ACCUSOL 35 Solutions in Continuous Renal Replacement Therapy (ACCUPASS)

Study Number: 8822-001

Version: Amendment 1

Date: 2015Jan12

I have read the protocol described above, and I agree to abide by all provisions set forth therein.

I agree to obtain written and dated approval from the responsible Ethics Committee (EC) and, if required, the responsible health authority for the protocol and (unless the EC has granted a written waiver of the requirement for informed consent) the informed consent form, any consent form updates, and any other written information to be provided to the patients before collection of their medical information for use in this study.

I agree to provide sufficient resources for the foreseen duration of the study and to conduct the study properly, ethically, and safely. I agree to ensure that all persons assisting in this study are adequately informed about the protocol and I agree to permit direct monitoring and auditing by the Sponsor, Sponsor's representatives, and authorized health authorities.

I agree to ensure that the confidential information contained in this document will not be disclosed to others without prior written authorization from Baxter Healthcare Limited, except to the extent necessary to obtain approval of the EC and, if required, the responsible health authority.

Signed: _____ Date: _____

Printed Name: _____

8822-001 Protocol Amendment 1 Description

A Multicenter, Non-interventional, Observational, Post-Approval Safety Study of
Updated ACCUSOL 35 Solutions in Continuous Renal Replacement Therapy
(ACCUPASS)

Amendment Date: 2015Jan12

GENERAL INFORMATION

Justification for the Amendment:

The protocol is being amended, at the request of the responsible ethics committee, to exclude the participation of pregnant patients in the study.

Purpose of the Amendment:

The amendment is being made to exclude the participation of pregnant patients, and to include an editorial change to the confidentiality statement in the document footer.

Type of Amendment:

Minor.

Statistical Implications:

There is no effect on the planned sample size or the planned analyses.

Patient Enrollment:

There is no effect on the number of patients to be enrolled.

Informed Consent:

The informed consent reflects the exclusion of pregnant patients.

Randomization:

This is a non-randomized study.

Clinical Supplies:

No clinical supplies are being provided for this study.

Case Report Form:

The inclusion criteria section of the CRF will reflect this change.

Safety Reporting:

There is no change to the planned safety reporting scheme.

Timing of the Amendment:

The amendment is being made prior to the start of study enrollment.

SPECIFIC PROTOCOL CHANGES

1. In the 2nd paragraph in the Population subsection of Section 4, the 2nd paragraph in Section 9.2.2 (Study Population), and the 1st inclusion criterion in Section 9.2.2.1 (Inclusion Criteria), the underlined word “non-pregnant” is added before the word “female” in the descriptions of the types of patients to be included in the study.
2. The “protocol version” section of the title page (Page 1), Section 5 (Amendments and Updates), the “version” and “date” sections of the investigator acknowledgement page in Section 14.3 (Additional Information), and the header on all pages are revised appropriately to reflect this amendment.
3. The wording “Restricted. Do not distribute without prior approval.” is added to the confidentiality statement in the footer on all pages to meet Baxter internal requirements.

Post-authorisation Safety Study Protocol: Study 8822-001

Title	A Multicenter, Non-interventional, Observational, Post-Approval Safety Study of Updated ACCUSOL 35 Solutions in Continuous Renal Replacement Therapy (ACCUPASS)
Protocol version	Original (2014Sep17)
EU PAS register number	ENCEPP/SDPP/6800
Active substances	Calcium chloride dihydrate, magnesium chloride hexahydrate, sodium chloride and sodium bicarbonate in all 3 formulations; and potassium chloride and glucose monohydrate in 2 of the 3 formulations
Medicinal products	ACCUSOL 35; ACCUSOL 35 Potassium 2 mmol/L; and ACCUSOL 35 Potassium 4 mmol/L
Product references	UK license numbers: PL 00116/0414; PL 00116/0415; and PL 00116/0416
Procedure numbers	MRP numbers: UK/H/0813/001; UK/H/0839/001; and UK/H/0839/002
Marketing authorisation holder	Baxter Healthcare Limited Caxton Way, Thetford, Norfolk, UK IP243SE
Joint PASS	No
Research question and objectives	As a result of prior reports of visible calcium carbonate precipitate in continuous renal replacement therapy (CRRT) lines during administration of ACCUSOL 35 solutions, the formulations of the products were updated. The objective of this study is to confirm the prevention of precipitate formation during CRRT by the use of the updated ACCUSOL 35 solutions.
Countries of study	4 to 5 EU countries (possible candidates include Austria, Belgium, Czech Republic, Denmark, France, Germany, Ireland, Netherlands, Spain, Sweden and United Kingdom)
Author	Drew S. Jones, MD, MPH, MBA Senior Medical Director Baxter Healthcare Corporation Round Lake, IL, USA Telephone: +1 (224) 270 2659
MAH contact person	James D. Motley Director, Pharmacovigilance, UK, Ireland and Malta Direct telephone: +44 (0) 1635 206437 Mobile telephone: +44 (0) 7717 542284 Direct fax: +44 (0) 1635 206281 e-mail: james_motley@baxter.com

Confidentiality Statement

This protocol contains confidential information belonging to Baxter Healthcare Limited. Acceptance of this document constitutes an agreement by the recipient that information will be held in confidence and will not be disclosed to others without prior written authorization from Baxter Healthcare Limited, except to the extent necessary to obtain approval of the responsible Ethics Committee and, if required, the responsible health authority, or as otherwise required by law.

1. TABLE OF CONTENTS

1. TABLE OF CONTENTS	2
2. LIST OF ABBREVIATIONS	5
3. RESPONSIBLE PARTIES	6
4. ABSTRACT.....	7
Title	7
Rationale and Background	7
Research Question and Objectives.....	7
Study Design.....	7
Population.....	8
Variables	8
Data Sources.....	9
Study Size.....	9
Data Analysis.....	9
Milestones	9
5. AMENDMENTS AND UPDATES.....	10
6. MILESTONES	10
7. RATIONALE AND BACKGROUND	10
8. RESEARCH QUESTION AND OBJECTIVES	11
9. RESEARCH METHODS.....	11
9.1 Study Design.....	11
9.2 Setting	12
9.2.1 Study Treatment	12
9.2.1.1 Study Drug	12
9.2.1.2 Concomitant Therapy	12
9.2.2 Study Population.....	13
9.2.2.1 Inclusion Criteria.....	13
9.2.2.2 Exclusion Criteria.....	14
9.2.2.3 Patient Withdrawal from the Study.....	14
9.2.2.4 Study Termination.....	14
9.3 Variables	15
9.3.1 Demographic and Baseline Data	15

9.3.2 Concomitant Medication	15
9.3.3 CRRT Details	15
9.3.4 ACCUSOL 35 Administration.....	16
9.4 Data Sources	16
9.5 Study Size.....	17
9.6 Data Management.....	17
9.7 Data Analysis.....	19
9.7.1 General Considerations.....	19
9.7.2 Analysis Populations.....	19
9.7.3 Primary Analysis	19
9.7.4 Other Assessments and Analyses	19
9.7.5 Potential Exploratory Analyses	20
9.8 Quality Control	20
9.8.1 Investigator's Responsibility.....	20
9.8.2 Direct Access to Source Data/Documents.....	20
9.8.3 Training	21
9.8.4 Monitoring.....	21
9.8.5 Auditing	21
9.8.6 Non-compliance with the Protocol	21
9.9 Limitations of the Research Methods	21
9.10 Other Aspects	22
 10. PROTECTION OF HUMAN SUBJECTS	 22
10.1 Ethical Conduct of the Study	22
10.2 Ethics Committee Approval.....	22
10.3 Patient Information and Consent.....	22
10.4 Patient Confidentiality	23
 11. MANAGEMENT AND REPORTING OF ADVERSE EVENTS/ADVERSE REACTIONS.....	 24
11.1 Definitions.....	24
11.2 Recording of Adverse Reactions.....	25
11.2.1 Relationship to Study Drug.....	25
11.2.2 Severity	26
11.3 Expedited Reporting of Adverse Reactions, Precipitate Observation and Pregnancy	26
11.3.1 Adverse Reactions.....	26
11.3.2 Precipitate Observation.....	27
11.3.3 Pregnancy	27
 12. PLANS FOR DISSEMINATING AND COMMUNICATING STUDY RESULTS	 27

13. REFERENCES.....29

14. ANNEXES 30

14.1 List of Stand-alone Documents 30

14.2 ENCePP Checklist for Study Protocol.....31

14.3 Additional Information 37

Investigator Acknowledgement 37

2. LIST OF ABBREVIATIONS

CRF	case report form
CRRT	continuous renal replacement therapy
EC	ethics committee
ICH GCP	International Conference on Harmonisation guidelines for Good Clinical Practice
ICU	intensive care unit
KCl	potassium chloride
MedDRA	Medical Dictionary for Regulatory Activities dictionary
WHODRUG	World Health Organization drug dictionary

3. RESPONSIBLE PARTIES

Protocol Author and Sponsor Medical Monitor	Drew S. Jones, MD, MPH, MBA Senior Medical Director Baxter Healthcare Corporation Round Lake, IL, USA Direct telephone: +1 (224) 270 2659
Qualified Person in Pharmacovigilance	Johan Hellmér, MD, PhD Deputy EU Qualified Person for Pharmacovigilance Baxter Medical AB Kista, Sweden Direct telephone: +46 (0) 8 632 64 68) Direct fax: +46 (0) 8 752 01 12

The list of investigators and contact information for them will be maintained by the study Sponsor in a separate document (see Section [14.1](#)).

4. ABSTRACT

Title

A Multicenter, Non-interventional, Observational, Post-Approval Safety Study of Updated ACCUSOL 35 Solutions in Continuous Renal Replacement Therapy (ACCUPASS)

Study Number: 8822-001

Version: Original (2014Sep17)

Author: Drew S. Jones, MD, MPH, MBA
Senior Medical Director
Baxter Healthcare Corporation
Round Lake, IL, USA
phone: +1 224-270-2659

Rationale and Background

ACCUSOL 35 solutions are indicated for the treatment of acute and chronic renal failure, as substitution solution in haemofiltration and haemodiafiltration, and as dialysis solution in haemodialysis and haemodiafiltration. Due to an increase in the number of product quality complaint reports related to the presence of white precipitate (calcium carbonate) formed during continuous veno-venous haemofiltration and continuous veno-venous haemodiafiltration in the continuous renal replacement therapy (CRRT) lines during the use of ACCUSOL 35 solutions, Baxter Healthcare Corporation updated the formulations of the products. The marketing authorization holder subsequently committed to perform this post-approval safety study with the updated solutions to monitor the safety of the updated formulations, specifically to address the risk of calcium carbonate precipitate formation.

Research Question and Objectives

The updated ACCUSOL 35 formulations were developed to prevent calcium carbonate precipitate formation during CRRT administration. The objective of this study is to confirm the prevention of calcium carbonate precipitate formation during CRRT by the use of the updated ACCUSOL 35 solutions under normal clinical use conditions.

Study Design

This is a multicenter, non-interventional, single-arm, observational, post-approval safety study in adult patients undergoing CRRT using any ACCUSOL 35 solution(s).

CRRT therapy will be administered in accordance with the intensive care unit's usual clinical practice and the recommendations in the current labeling for the ACCUSOL 35 solutions. Addition of antibiotics or any other medications to the ACCUSOL 35 solution bag, except for potassium chloride (KCl) supplementation, will not be allowed (see "Population"). The CRRT lines will be inspected every 30 minutes for the duration of the therapy, as described in the labeling for ACCUSOL 35 solutions.

Study staff will record the study data (see "Variables") during administration of CRRT with ACCUSOL 35 solution. The planned maximum study observation period is 32 hours: from 40 hours after CRRT with the current circuit was started until 72 hours of treatment has been administered using that same circuit.

Population

The study will include approximately 240 adult patients enrolled at approximately 20 to 25 hospitals, with medical or surgical ICUs that regularly treat CRRT patients using ACCUSOL 35 solutions, in 4 to 5 European Union countries (possible candidates include Austria, Belgium, Czech Republic, Denmark, France, Germany, Ireland, Netherlands, Spain, Sweden and United Kingdom).

Male and female patients will be eligible for enrollment if they are at least 18 years of age and have been undergoing CRRT using any ACCUSOL 35 solution (without any concomitant medication added to the solution, except for supplemental potassium chloride, if needed), with the same CRRT circuit for at least 40 hours. Patients with any contraindication to treatment with an ACCUSOL 35 solution, patients involved in any study with another investigational product or therapy (in the prior 30 days or during participation in this study), and patients who were previously included in the study will be excluded.

Variables

The key safety variables to be collected for analysis include:

- Amount of ACCUSOL 35 solution delivered through the CRRT circuit observed during the study
- Start- and end-of use times for the CRRT circuit used during the study
- Presence or absence of visible precipitate in the CRRT lines used during the study
- Time of observation of visible precipitate (if applicable)
- Color of precipitate observed (if applicable)

- Reason for terminating the use of the CRRT circuit, if during the study
- Reason for terminating the CRRT, if during the study
- Reason for end of patient's study participation

Data Sources

Data will be collected from the medical records of the enrolled patients and from observation of the patients and CRRT lines during the study period.

Study Size

The study will enroll approximately 240 patients. Data from at least 58 evaluable CRRT patients (ie, those whose CRRT circuits remained precipitate-free for 72 hours and those in whose circuits visible precipitate was observed within 72-hours) are needed to meet the study objective (see "Data Analysis").

Data Analysis

The primary analysis will be to generate the upper bound of the 95% confidence interval on the true proportion of treatments having precipitate formation, based on the data from the evaluable treatments. If no visible precipitate is observed in at least 58 evaluable treatments, the study will have provided 95% confidence that the probability of visible precipitate formation during 72 hours of CRRT with ACCUSOL 35 solution using the same CRRT circuit is not more than 5.0%. Based on the assumption that only 10% of all CRRT treatments will last 72 hours (regardless of whether the same circuit is in use the whole time), and combining the probabilities of both having a treatment last 72 hours and also having visible particulate formation, the result will have demonstrated with 95% confidence that the probability of visible precipitate formation in all CRRT treatments of any length with ACCUSOL 35 solutions, is not more than 0.5%.

Appropriate summary statistics will be calculated for other applicable variables to describe the variability of the therapy methods and materials involved in the study.

Milestones

Planned registration in the EU PAS register: June 2014

Planned start of data collection: October 2014

Planned end of data collection: April 2016

Planned final report of study results: August 2016

5. AMENDMENTS AND UPDATES

None; this is the original approved version of the protocol.

6. MILESTONES

Milestone	Planned Date
Registration in EU PAS Register	June 2014
Start of data collection	October 2014
End of data collection	April 2016
Final Report of Study Results	August 2016

7. RATIONALE AND BACKGROUND

ACCUSOL 35 solutions are indicated for the treatment of acute and chronic renal failure, as substitution solution in haemofiltration and haemodiafiltration, and as dialysis solution in haemodialysis and haemodiafiltration. The product is presented in 3 formulations, 1 without potassium chloride (KCl) and 2 containing KCl (at concentrations of 2 mmol/L and 4 mmol/L). All 3 formulations contain calcium chloride dihydrate, magnesium chloride hexahydrate, sodium chloride and sodium bicarbonate. The 2 KCl formulations also contain glucose monohydrate.

In 2008, Baxter Healthcare Corporation (Baxter; the manufacturer of ACCUSOL 35 solutions) received an increased number of product quality complaint reports related to the presence of white precipitate observed in the continuous renal replacement (CRRT) lines during continuous veno-venous haemofiltration and continuous veno-venous haemodiafiltration during the use of ACCUSOL 35 solutions. In 2009, Baxter's root cause investigation identified that the precipitate was calcium carbonate, and a change in the pH of the mixed solution (supersaturation) was acknowledged as the major contributing factor to precipitate formation. Further investigation revealed that the addition of a low amount of phosphate salt as an excipient and lowering the pH of the mixed solution could inhibit the formation of calcium carbonate.

As part of their responses on 27 August 2009, Baxter made a commitment to the Pharmacovigilance Working Party to perform a post-approval safety study with the updated solution to monitor the safety of the updated formulation, specifically to address the risk of calcium carbonate precipitate formation.

This protocol presents the details of the post-approval safety study designed to verify the successful minimization of the risk of precipitate formation with the updated ACCUSOL 35 solution. The confirmation of the prevention of precipitate formation will

support a proposal for removal of the current recommendation (presented in the labeling for the ACCUSOL 35 solutions) to inspect the CRRT lines every 30 minutes for the presence of precipitate during the use of the products.

8. RESEARCH QUESTION AND OBJECTIVES

The updated ACCUSOL 35 formulations were developed to prevent calcium carbonate precipitate formation during CRRT administration. The objective of this study is to confirm the prevention of calcium carbonate precipitate formation during CRRT by the use of the updated ACCUSOL 35 solutions.

9. RESEARCH METHODS

9.1 Study Design

This study is a prospective, multicenter, non-interventional, uncontrolled, open-label, observational study in adult patients undergoing CRRT using any of the updated ACCUSOL 35 solutions. The study is intended to capture data on the absence or presence of visible precipitate during 72 hours of use of ACCUSOL 35 solution with a single CRRT circuit.

Study centers will use the ACCUSOL 35 solutions from their available inventory; no ACCUSOL 35 solutions or any other approved medications or investigational products will be provided to the study centers by the Sponsor. CRRT therapy will be administered in accordance with the intensive care unit's (ICU) usual clinical practice and the recommendations in the current labeling for ACCUSOL 35 solutions. Addition of antibiotics or any other medications to the ACCUSOL 35 solution bag, except for KCl supplementation, will not be allowed.

There will be no randomized or non-randomized treatment assignments; no diagnostic, therapeutic, or experimental interventions; and no restrictions on use of concomitant medications or other treatments, except as noted above for the restriction on addition of medications other than KCl supplementation to the ACCUSOL 35 solution bag. Study patients will be prospectively identified in that study data will only be collected from patients treated after study enrollment at a site has been authorized by the responsible ethics committee (EC) and the Sponsor.

Data will be collected at patient enrollment (at approximately 40 hours of CRRT with the same CRRT circuit) and periodically up to 72 hours of CRRT with the same circuit, or until the CRRT circuit needs to be changed or CRRT is completed (if either occurs sooner than 72 hours). The CRRT lines will be inspected every 30 minutes for the duration of the therapy, as recommended in the labeling for the ACCUSOL 35 solutions.

Observation of the CRRT circuit for precipitate through 72 hours of use is intended to represent a worst-case situation, since 72 hours is the maximum intended use period for a single CRRT circuit. Enrollment of patients whose CRRT circuit has already been in use for 40 hours is intended to maximize the possibility of the studied CRRT circuits reaching 72 hours of use for inclusion in the primary analysis (see Section 9.5), while maintaining a reasonable overall study size by reducing the number of patients enrolled.

If precipitate is seen in a CRRT line during therapy administration, the therapy will be stopped and proper procedures and monitoring (as recommended in the current ACCUSOL 35 solutions labeling) will be performed in order to return the circuit blood back to the patient and immediately set up a new CRRT circuit to continue therapy.

This study is strictly a non-interventional observational safety study assessing the presence or absence of visible precipitate in the CRRT lines with the specific products being studied. Therefore, no control group is considered necessary to achieve the study objectives.

9.2 Setting

9.2.1 Study Treatment

9.2.1.1 Study Drug

Patients enrolled in the study can be treated with ACCUSOL 35, ACCUSOL 35 Potassium 2 mmol/L, ACCUSOL 35 Potassium 4 mmol/L, or any combination of the solutions. Given the observational nature of this study, no ACCUSOL 35 solutions, or any other approved medications or investigational products, will be provided to study sites. All patients will be treated with ACCUSOL 35 solutions according to the patients' medical needs and the standard of care at the participating ICU.

No ACCUSOL 35 solution bag should be used for more than 24 hours after mixing of the two chambers as indicated in the approved labeling for the products.

9.2.1.2 Concomitant Therapy

There will be no restrictions on the use of concomitant medications or non-drug therapies, with the single exception being that only supplemental KCl may be added directly to the ACCUSOL 35 solution bag being used to treat a study patient. All patients will otherwise be treated according to their medical needs and the standard of care at the participating ICU.

9.2.2 Study Population

The study will include approximately 240 adult patients enrolled at approximately 20 to 25 hospitals, with medical or surgical ICUs that regularly treat CRRT patients using ACCUSOL 35 solutions, in 4 to 5 European Union countries (possible candidates include Austria, Belgium, Czech Republic, Denmark, France, Germany, Ireland, Netherlands, Spain, Sweden and United Kingdom). Patient enrollment in the study will be terminated when it has been confirmed that data have been collected from 58 evaluable patients (ie, those whose CRRT circuits remained precipitate-free for 72 hours, and those in whose circuits visible precipitate was observed within 72 hours; see Section 9.7.3). The number of patients to be enrolled at each site will be pre-specified to ensure that a small number of sites do not dominate the overall study enrollment.

Male and female patients will be eligible for enrollment if they are at least 18 years of age and have been undergoing CRRT using ACCUSOL 35 solution(s), without any concomitant medication added to the solution (except for supplemental KCl, if required), with the same CRRT circuit for at least 40 hours. Patients with any contraindication to treatment with an ACCUSOL 35 solution, and patients involved in any study with another investigational product or therapy (in the prior 30 days or during participation in this study) will be excluded. The specific inclusion and exclusion criteria are listed below.

9.2.2.1 Inclusion Criteria

Each patient must meet the following criteria to be enrolled in this study.

1. The patient is male or female and at least 18 years of age.
2. The patient is undergoing CRRT using ACCUSOL 35 solution(s).
3. The patient's CRRT has been ongoing for 40 hours using the same CRRT circuit; and the CRRT is anticipated to be continued for at least another 32 hours with the same circuit.
4. The patient, or their legally authorized representative, has provided informed consent for inclusion of their medical data in the study (unless the responsible EC has provided the Investigator a written waiver of the need to obtain consent due to the observational nature of the study).

9.2.2.2 Exclusion Criteria

Patients who meet any of the following criteria will be excluded from the study.

1. The patient has any contraindication(s) to treatment with ACCUSOL 35 solution(s).
2. An antibiotic or other medication (other than supplemental KCl) has been added to the ACCUSOL 35 solution(s) used for the patient's CRRT.
3. The patient previously participated in the study (ie, one of the patient's CRRT circuits has already been observed as part of this study).
4. The patient is currently, or was within the preceding 30 days, involved in a study of an investigational product or therapy.

9.2.2.3 Patient Withdrawal from the Study

Patients, or their legally authorized representatives, may terminate their consent for collection of their medical data for use in the study at any time. Should a patient or their legally authorized representative do so, site study personnel will record the time of and the reason provided for the withdrawal. The data collected on withdrawn patients will be used in the analyses, as applicable, and included in the clinical study report.

9.2.2.4 Study Termination

The Sponsor may prematurely terminate this study at any time for any reason. It may also terminate a single study center from participation in the study at any time for various reasons such as:

- inadequate rate of patient enrollment into the study
- noncompliance with protocol requirements or data collection methods
- noncompliance with Good Clinical Practice guidelines; applicable national and local laws; and/or applicable guidelines or regulations for protecting the rights, safety, and welfare of patients
- knowingly submitting false information to the Sponsor or designee.

If the study is prematurely terminated, all collected study data must be provided to the Sponsor.

9.3 Variables

Data will be collected at patient enrollment (at approximately 40 hours of CRRT with the same CRRT circuit) and periodically up to 72 hours of CRRT with the same circuit, or until the CRRT circuit needs to be changed or CRRT is terminated (if either occurs sooner than 72 hours).

9.3.1 Demographic and Baseline Data

The following data will be obtained from the patient's medical record:

- age
- gender
- weight

9.3.2 Concomitant Medication

Details (product, dosage and timing) of any anticoagulants used will be collected.

The concentration of any supplemental KCl added to the ACCUSOL 35 solution(s) will be recorded.

No other concomitant medications data will be collected on the study CRF for study analysis. However, details of concomitant medications will be included on the report form used for expedited reporting of any of adverse reactions (see Section [11.3](#))

9.3.3 CRRT Details

The following information about the patient's CRRT will be collected:

- the manufacturer and model of the CRRT monitor used
- the manufacturer and model of the CRRT lines used
- the manufacturer and model of the haemofilter used
- the CRRT mode employed
- the ultrafiltration rate(s) used

9.3.4 ACCUSOL 35 Administration

The following data on the administration of ACCUSOL 35 and the presence or absence of visible precipitate will be collected:

- the formulation(s) (ACCUSOL 35, ACCUSOL 35 Potassium 2 mmol/L, ACCUSOL 35 Potassium 4 mmol/L) and lot number(s) of ACCUSOL 35 solution(s) administered
- the ACCUSOL 35 solution dose rate(s) (mL/kg/hr) by site of introduction (pre- or post-filter or as dialysate)
- the start- and end-of-use times for the CRRT circuit used during the study
- the presence or absence of visible precipitate in the CRRT lines used during the study
- the time of observation of the observed precipitate, if applicable
- the formulation (ACCUSOL 35, ACCUSOL 35 Potassium 2 mmol/L or ACCUSOL 35 Potassium 4 mmol/L) and lot number of the ACCUSOL 35 solution in use at the time of the observation of the precipitate, if applicable
- the color of the observed precipitate, if applicable
- the reason for termination of the use of the CRRT circuit used during the study, if it occurs during the study (ie, before 72 hours of use are completed)
- the reason for termination of CRRT, if during the study (ie, before 72 hours of CRRT are completed)
- the reason for the end of the patient's study participation

9.4 Data Sources

Source data are defined as all information in original records and certified copies of original records of clinical findings, observations, or other activities in a clinical study that are necessary for the reconstruction and evaluation of the study. Source data are contained in source documents (original records or certified copies), which may be in paper and/or electronic format. Source data for this study may comprise any of the following: hospital records, medical records, clinical and office charts, laboratory notes, memoranda, outcomes reported by subjects, pharmacy dispensing records, recorded data from automated instruments, copies or transcriptions certified after verification as being accurate copies, microfiches, photographic negatives, microfilm or magnetic media,

X-rays, study patient files and worksheets, and records kept at the pharmacy, at the laboratories, and at medico-technical departments involved in the clinical study.

9.5 Study Size

Based on published CRRT studies[1-5], it is estimated that of those CRRT treatments that have reached 40 hours with the same CRRT circuit, 25% will continue with the same circuit through 72 hours of use. It is expected, therefore, that about 240 enrolled patients will provide data on approximately 60 treatments that last 72 hours without CRRT circuit changes. If no visible precipitate is observed within that time in at least 58 evaluable treatments (ie, those in which CRRT circuits remains precipitate-free for 72 hours, and those in which visible precipitate is observed within 72-hours), the study will have provided 95% confidence that the probability of visible precipitate formation during 72 hours of CRRT with ACCUSOL 35 solution using the same CRRT circuit is not more than 5.0%.

It is also reasonable to assume (based on the published studies[1-5]) that approximately 10% of all CRRT treatments will last 72 hours, regardless of whether the same CRRT circuit is in use the whole time. Combining the probabilities of both having a treatment last 72 hours and also having visible particulate formation reduces the risk from 5% to 0.5%. Thus a sample size of 58 treatments with no observed precipitate will demonstrate, with 95% confidence, that the probability of precipitate formation in all CRRT treatments with ACCUSOL 35 solutions of any length (and not necessarily with the same CRRT circuit) is not more than 0.5%.

9.6 Data Management

The Investigator is responsible for the procurement of data and for the quality of data recorded on the patient's case report form (CRF). CRFs will be provided by the Sponsor in paper or electronic form. Detailed instructions for completing the CRF will be provided by the Sponsor. All study personnel will be trained on the protocol, study, and proper completion of the CRF. Data will be obtained from the patient's medical record and, if applicable, study-specific worksheets.

The Investigator will comply with the procedures for data recording and reporting. Any corrections to paper study documentation must be performed as follows: 1) the first entry will be crossed out entirely, remaining legible; and 2) each correction must be dated and initialed by the person correcting the entry; the use of correction fluid and erasing are prohibited.

All information transcribed onto the CRF is expected to accurately reflect original data recorded in the patient's medical record and any applicable study worksheets. These must be available to the Sponsor or designee and/or appropriate health authorities.

If paper-format CRFs are provided by the Sponsor, all required study data, including corrections, will be clearly and accurately recorded by authorized study site personnel on the CRFs. The CRFs will remain at the site until they are reviewed by the Sponsor's study monitor. All original CRFs will be collected by the study monitor, and an identical copy of the complete set of CRFs for each subject will remain in the investigator file at the study site.

If electronic-format CRFs are provided by the Sponsor, only authorized study site personnel will record or change data on the CRFs. Changes to a CRF will require documentation of the reason for each change, and an audit trail will be created for all changes. An identical (electronic/paper) version of the complete set of CRFs for each subject will remain in the investigator file at the study site.

The handling of data by the Sponsor, including data quality assurance, will comply with regulatory guidelines and the Sponsor's, or designee's, standard operating procedures. Data management and control processes and data management software specific to the study will be described in a data management plan (see Section 14.1).

A study database will be created from the data on the CRFs, using the Medical Dictionary for Regulatory Activities dictionary (MedDRA) for adverse event coding and the World Health Organization drug dictionary (WHODRUG) for coding concomitant medications.

Programmatic and manual review of the database will be performed to detect missing data, errors and inconsistencies. Queries on the detected problems will be forwarded to the site, and the responses returned from the site will be used by data management personnel to update the database as needed.

After all database updates are completed and prior to any statistical analyses, the database will be locked.

Quality assurance department representatives from the Sponsor and/or a contract research organization designated by the Sponsor, may visit a study site during or after the study to conduct a quality assurance audit. During a visit, EC and informed consent documentation, data entry and validation processes, and adverse event reporting may be reviewed. Processes may be reviewed to ensure the study is conducted in compliance with the protocol, standard operating procedures, and all applicable legal requirements.

During these visits, the Investigator is obligated to provide direct access to all relevant documents and to allocate adequate time to discuss findings and relevant issues and, after the visit, to complete appropriate corrective actions when necessary.

9.7 Data Analysis

9.7.1 General Considerations

The methods and software to be used for the analyses and the responsible individual(s) who will perform these analyses will be identified in a data analysis plan (see Section 14.1) prior to database lock. Deviations from the planned analyses, if any, will be described in the clinical study report.

All data collected (see Sections 9.3 and 11) will be presented in data listings.

9.7.2 Analysis Populations

The enrolled population will be patients expected to receive CRRT with ACCUSOL 35 solution(s) using the same CRRT circuit for at least 72 hours. All analyses will be performed on the enrolled population, except as otherwise noted below.

9.7.3 Primary Analysis

For purposes of this study, the incidence of visible precipitate in the CRRT lines during 72 hours of use of the CRRT circuit will be examined. Data from the evaluable patients (ie, those whose CRRT circuits remains precipitate-free for 72 hours, and those in whose circuits visible precipitate is observed within 72-hours) will be used for this analysis. Data from patients whose CRRT was interrupted or terminated prior to 72 hours with no observation of visible precipitate in the lines (ie, non-evaluable patients) will be excluded from this analysis.

The primary analysis will be to estimate the upper bound of a 95% confidence interval on the true proportion of treatments having precipitate formation. If the upper bound of the 95% confidence interval is 5% or less, then the primary objective of the study will have been achieved. That result will have demonstrated, with 95% confidence, that the probability of visible precipitate formation in all CRRT treatments with ACCUSOL 35 solutions of any length (and not necessarily with the same CRRT circuit), is not more than 0.5%. (see Section 9.5).

9.7.4 Other Assessments and Analyses

Categorical data (eg, gender) will be summarized using counts and percentages. Continuous data (eg, age) will be summarized using descriptive statistics for measures of

central tendency and dispersion (number of patients, mean, standard deviation, minimum, median, maximum, and number missing).

Demographic and baseline characteristics include age, gender, and weight. Frequency and percentages will be provided for age as a categorical variable (eg, 18-35 years, 36-45 years, 46-55 years, 56-65 years and > 65 years) and gender. Weight will be summarized by descriptive statistics for measures of central tendency and dispersion.

Adverse reactions will be summarized both by the total frequency of reactions and by the frequency and percentage of subjects having at least one reaction. These adverse reaction summaries will be done overall and by MedDRA system organ class and preferred term.

Other data recorded (eg, concomitant anticoagulant used, CRRT details, ACCUSOL 35 administration details other than occurrence of precipitate) will not be summarized.

9.7.5 Potential Exploratory Analyses

If visible precipitate is observed, the time to first occurrence will be calculated (time from start of use of the CRRT circuit to time of observation of precipitate). In addition, further analyses may be performed to explore contributing factors (eg, ACCUSOL 35 solution formulation(s) and lot(s) administered; dose rate(s) and amount of ACCUSOL 35 delivered through the circuit; frequency of use and concentration of KCl add to the ACCUSOL 35 solution; manufacturer and model of CRRT lines used; haemofilter used; use and type of anticoagulant; CRRT mode; or ultrafiltration rate), as appropriate.

9.8 Quality Control

9.8.1 Investigator's Responsibility

The Investigator will comply with the protocol, the International Conference on Harmonisation guidelines for Good Clinical Practice (ICH GCP), and applicable regulatory requirements. The Investigator is ultimately responsible for the conduct of all aspects of the study at the study site and verifies by signature the integrity of all data transmitted to the responsible party. The term "Investigator" as used in this protocol as well as in other study documents, refers to the Investigator or authorized study personnel that the Investigator has designated to perform certain duties. Sub-investigators or other authorized study personnel are eligible to sign for the Investigator, except where the Investigator's signature is specifically required.

9.8.2 Direct Access to Source Data/Documents

The Investigator/study site will cooperate and provide direct access to study documents and data, including source documentation for monitoring by the study monitor, audits by

the Sponsor or its designee, review by the EC, and inspections by applicable regulatory authorities.

9.8.3 Training

The study monitor will ensure that the Investigator and study site personnel understand all requirements of the protocol and his/her regulatory responsibilities as an investigator. Training may be provided at an investigator's meeting, at the study site, and/or by instruction manuals. In addition, the study monitor will be available for consultation with the Investigator and will serve as the liaison between the study site and the Sponsor.

9.8.4 Monitoring

The study monitor is responsible for ensuring and verifying that each study site conducts the study according to the protocol, standard operating procedures, other written instructions/agreements, and applicable regulatory guidelines/requirements. The Investigator will permit the study monitor to visit the study site at appropriate intervals. Monitoring processes specific to the study will be described in the Clinical Operations Plan (see Section [14.1](#)).

9.8.5 Auditing

The Sponsor and/or their designee may conduct audits to evaluate study conduct and compliance with the protocol, standard operating procedures, other written instructions/agreements, ICH GCP, and applicable regulatory guidelines/requirements. The investigator will permit auditors to visit the study site.

9.8.6 Non-compliance with the Protocol

If monitoring and/or auditing identify serious and/or persistent non-compliance with the protocol, the Sponsor may terminate the investigator's participation. The Sponsor will notify the responsible EC and applicable regulatory authorities of any such investigator termination.

9.9 Limitations of the Research Methods

The non-controlled observational study design is considered suitable to achieve the study purpose, which is to confirm that the updated ACCUSOL 35 solutions do not present a significant risk of calcium carbonate precipitate formation. If there are statistical limitations, it is the inability to generalize to any specific CRRT patient population, which is typically the case for an observational study.

If precipitate is actually observed during the study, the study data will not be adequate to determine the cause of that occurrence, although the data collected may be helpful in developing hypotheses for further in vitro or clinical studies.

9.10 Other Aspects

Not applicable; all aspects of the study are described in the other sections of this protocol.

10. PROTECTION OF HUMAN SUBJECTS

10.1 Ethical Conduct of the Study

This study will be conducted in compliance with the ethical principles that have their origin in the Declaration of Helsinki and its revisions, ICH GCP, good pharmacovigilance practices and all national and local laws. The Investigator will be responsible for ensuring that this study is conducted according to the investigational plan and for protecting the rights, safety, and welfare of study patients under the Investigator's care.

10.2 Ethics Committee Approval

Prior to enrolling any patients in the study, the Investigator must obtain approval from the responsible EC and, if required, the responsible health authority for the protocol and any amendments, the informed consent form (if applicable), and any other information intended to be presented to the patient in order to obtain informed consent (if applicable). All changes in the research activity and all unanticipated problems involving risk to study patients or others will be reported to the responsible EC and, if required, to the responsible health authority. No changes in the research will be implemented without the responsible EC's and, if required, to the responsible health authority's prior approval, except where necessary to eliminate apparent immediate hazards to study patients.

10.3 Patient Information and Consent

Written informed consent will be obtained from each patient or (if the patient is unable to provide informed consent) the patient's legally authorized representative prior to the patient's participation in the study, unless the responsible EC has granted a waiver from the requirement for informed consent based on the observational nature of the study.

In obtaining and documenting informed consent, the Investigator will comply with all Good Clinical Practice and applicable legal requirements, and with the ethical principles that have their origin in the Declaration of Helsinki. Neither the Investigator, nor the site staff, will coerce or unduly influence a patient or their representative, to participate or to

continue to participate in the study. The patients or the patient's representative may refuse participation or withdraw consent at any time and for any reason during the study.

Neither the written informed consent form, nor any other information presented to the patient or the patient's representative in order to obtain consent for participation in the study, will contain language that causes the patient or their representative to waive or to appear to waive any legal rights, or that releases the Investigator, the institution, or their agents from liability for negligence.

The Investigator or designee will fully inform the patient or the patient's representative of all pertinent aspects of the study. Before informed consent is obtained, the Investigator or their designee will answer all questions about the study to the satisfaction of the patient or the patient's representative. The Investigator or designee will inform the patient or the patient's representative that they are free to refuse to participate in the study without affecting the quality of the patient's medical care. The language used in all communications regarding the study will be as non-technical as practical so that it is understandable to the patient or the patient's representative.

If a patient is unable to read or to provide written informed consent by him/herself, the patient's representative will sign on behalf of the patient; in addition to which an impartial witness, who was present throughout the informed consent process, will also sign and date the form. Prior to the patient's participation in the study, the patient or the patient's representative will be given a copy of the signed and dated written informed consent form and any other written information intended to be provided to the patient.

10.4 Patient Confidentiality

Every effort will be made to maintain confidentiality of all patient data included in the CRF. At the time of study enrollment study personnel will assign each patient a patient identification number, which will be used to identify the patient in the CRF. The Investigator will maintain a patient identification list (patient study identification numbers with the corresponding patient names) to enable source records to be identified.

Patients will be informed that information about them is being entered into the study database. Patients will be informed that all protected health information and clinical data will be maintained in a confidential manner.

All study data will be stored in electronic databases that are confidential, password-protected, and access-restricted. Information that may be made available for inspection by authorized health authorities will be handled in the strictest confidence. No

information that could uniquely identify individual patients will be submitted to the Sponsor.

11. MANAGEMENT AND REPORTING OF ADVERSE EVENTS/ADVERSE REACTIONS

11.1 Definitions

An *adverse event* is any untoward medical occurrence in a patient administered a medicinal product and which does not necessarily have to have a causal relationship with this treatment. An adverse event can therefore be any unfavorable and unintended sign (eg, an abnormal laboratory finding), symptom (eg, rash, pain, discomfort, fever, dizziness, etc), disease (eg, peritonitis, bacteremia, etc) or outcome of death temporally associated with the use of a medicinal product, whether or not considered associated with this medicinal product. Other events that, while not necessarily meeting the definition of adverse events, should be treated as such because they may be reportable to regulatory authorities according to adverse event reporting requirements, whether or not considered causally associated with drug or biologic treatment, include the following:

- drug or biologic overdose, whether accidental or intentional
- drug or biologic abuse
- an event occurring from drug or biologic withdrawal
- any failure of expected pharmacological action
- exposure to a drug or biologic during pregnancy
- inadvertent or accidental drug or biologic exposure (eg, product leaking or being spilled onto a patient or caregiver)
- unexpected therapeutic or clinical benefit from the drug or biologic product
- medication errors (eg, incorrect route of administration, incorrect dosage, use of incorrect product)

An *adverse reaction* is a response to a medicinal product which is noxious and unintended. Response in this context means that a causal relationship between a medicinal product and an adverse event is, at least, a reasonable possibility.

A *serious adverse reaction* is one that meets one or more of the following criteria:

- results in death (including fetal death);

- is life-threatening (Note: “life-threatening” in the definition of “serious” refers to an adverse reaction in which the patient was at risk of immediate death at the time of the reaction. It does not refer to a reaction that might have caused death if it were more severe);
- requires inpatient hospitalization (Note: inpatient hospitalization refers to any inpatient admission, regardless of length of stay);
- results in prolongation of ongoing hospitalization;
- results in persistent or significant disability/incapacity (ie, a substantial disruption of a person’s ability to conduct normal life functions);
- is a congenital anomaly/birth defect; or
- is a medically important reaction that may not be immediately life-threatening or result in death or hospitalization, but may jeopardize the patient or requires intervention to prevent one of the other outcomes listed above (eg, intensive treatment in an emergency room or at home for allergic bronchospasm, blood dyscrasias or convulsions that do not result in hospitalization; or development of drug dependence or drug abuse).

11.2 Recording of Adverse Reactions

Details of any adverse reaction (non-serious or serious) that is noted in or reported by the study patient during the study data collection period (see Section 9.3) will be collected in the CRF.

Whenever possible, the Investigator will present a diagnosis based on the presenting signs and symptoms, rather than just presenting a sign or symptom.

11.2.1 Relationship to Study Drug

The Investigator will indicate their opinion on the relationship of the reaction to ACCUSOL 35 according to the following definitions.

Possibly related:

The reaction follows a reasonable temporal relationship to the administration of the study drug, and an alternative etiology is equally or less likely compared to the potential relationship to the study drug.

Probably related:

The reaction has a strong temporal relationship to the administration of the study drug and an alternative etiology is unlikely or significantly less likely compared to the potential relationship to the study drug.

11.2.2 Severity

The severity of an adverse reaction is defined as a qualitative assessment by the Investigator of the degree of intensity of the adverse reaction observed or reported to him/her by the patient. The Investigator will indicate their opinion on the severity of the event or reaction according to the following definitions. The assessment of severity will be made irrespective of drug relationship or seriousness.

Mild:

- The reaction is a transient discomfort and does not interfere in a significant manner with the subject's normal functioning level.
- The reaction resolves spontaneously or may require minimal therapeutic intervention.

Moderate:

- The reaction produces limited impairment of function and may require therapeutic intervention.
- The reaction produces no sequela(e).

Severe:

- The reaction results in a marked impairment of function and may lead to temporary inability to resume usual life pattern.
- The reaction produces sequela(e), which require(s) (prolonged) therapeutic intervention.

11.3 Expedited Reporting of Adverse Reactions, Precipitate Observation and Pregnancy

11.3.1 Adverse Reactions

All adverse reactions (non-serious or serious) must be reported to the Sponsor or designee within one business day of observation or notification of the event. Instructions and forms for reporting an adverse reaction will be provided to the Investigator, including the name(s) and contact details of the individual(s) who should be contacted regarding safety issues or questions regarding the study.

An adverse reaction form will be completed that provides detailed information about the reaction and will be promptly forwarded to the Sponsor or designee as indicated in the instructions. The Sponsor or designee will be responsible for appropriate reporting of adverse reactions that occur in patients exposed to an ACCUSOL 35 solution to health authorities. The Investigator will promptly notify the responsible EC of all adverse reactions occurring at the Investigator's site, in accordance with the requirements of the EC, including any significant follow-up information.

11.3.2 Precipitate Observation

If the Investigator or study staff observes visible precipitate in any study CRRT line, it will be reported within one business day of becoming aware of the precipitate observation. Instructions and forms for expedited reporting of precipitate observation will be provided to the Investigator.

11.3.3 Pregnancy

Although it is not expected based on the population included in this study, if the Investigator or study staff becomes aware of the pregnancy of a study patient during their study participation, the pregnancy will be reported within one business day of becoming aware of the pregnancy, and the pregnancy will be followed-up at 1 year post-delivery, if feasible. Instructions and forms for reporting pregnancy will be provided to the Investigator.

12. PLANS FOR DISSEMINATING AND COMMUNICATING STUDY RESULTS

Information concerning study treatment, patent applications, formulation, manufacturing processes, unpublished scientific data, and other pertinent information is confidential and remains the property of the Sponsor. Details will be disclosed only to persons involved in the conduct of the study. The Investigator may use this information for the purposes of the study only.

It is understood by the Investigator that the Sponsor may use the information derived from this study and may share this information, as required, with other clinical investigators or health authorities. To allow for the use of the information and to ensure complete and thorough analysis, the Investigator is obligated to provide the Sponsor with complete study data.

The results of this study may be considered for publication or presentation at symposia and congresses. Individual investigators are encouraged to publish or disclose the data generated at their respective sites; but only after the collective data are presented or published as a single study, or two years following either the conclusion of the study at

all sites or database lock, whichever occurs first. All publication manuscripts, abstracts, prepared transcripts, and texts and visual material for presentation (eg, slide sets) must be submitted to the Sponsor at least 60 days prior to the intended submission. This is necessary to prevent premature disclosure of trade secrets or patent-protected information, and is in no way intended to restrict publication of facts or opinions formulated by the Investigator. The Sponsor will inform the Investigator in writing of any objections or questions arising within 30 days of receipt of the proposed presentation materials.

The results of the study will be summarized on the EU PAS register after completion of the study report.

13. REFERENCES

1. Monchi M, Berghmans D, Ledoux D, Canivet J-L, Dubois B, Damas P. Citrate vs. heparin for anticoagulation in continuous venovenous hemofiltration: a prospective randomized study. *Intensive Care Med.* 2004;30:260-265. doi:10.1007/s00134-003-2047-x.
2. Kutsogiannis DJ, Gibney RT, Stollery D, Gao J. Regional citrate versus systemic heparin anticoagulation for continuous renal replacement in critically ill patients. *Kidney Int.* 2005;67:2361-2367. doi:10.1111/j.1523-1755.2005.00342.x
3. Morabito S, Pistolesi V, Tritapepe L, et al. Regional citrate anticoagulation in cardiac surgery patients at high risk of bleeding: a continuous veno-venous hemofiltration protocol with a low concentration citrate solution. *Critical Care.* 2012;16:R1111. doi:10.1186/cc11403.
4. Hetzel GR, Schmitz M, Wissing H, et al. Regional citrate versus systemic heparin for anticoagulation in critically ill patients on continuous venovenous haemofiltration: a prospective randomized multicentre trial. *Nephrol Dial Transplant.* 26(1):232-239. doi:10.1093/ndt/gfq575.
5. Betjes MGH, van Oosterom D, van Agteren M, van de Wetering J. Regional citrate versus heparin anticoagulation during venovenous hemofiltration in patients at low risk for bleeding: similar hemofilter survival but significantly less bleeding. *J Nephrol.* 2007;20(5):602-608.

14. ANNEXES

14.1 List of Stand-alone Documents

Number	Document Reference Number	Date	Title
1	to be assigned	to be determined	Study Investigators
2	to be assigned	to be determined	Clinical Operations Plan
3	to be assigned	to be determined	Data Management Plan
4	to be assigned	to be determined	Statistical Analysis Plan
5	to be assigned	to be determined	Safety Plan

14.2 ENCePP Checklist for Study Protocol



Doc.Ref. EMA/540136/2009

European Network of Centres for
Pharmacoepidemiology and
Pharmacovigilance

ENCePP Checklist for Study Protocols (Revision 2, amended)

Adopted by the ENCePP Steering Group on 14/01/2013

The [European Network of Centres for Pharmacoepidemiology and Pharmacovigilance \(ENCePP\)](#) welcomes innovative designs and new methods of research. This Checklist has been developed by ENCePP to stimulate consideration of important principles when designing and writing a pharmacoepidemiological or pharmacovigilance study protocol. The Checklist is intended to promote the quality of such studies, not their uniformity. The user is also referred to the [ENCePP Guide on Methodological Standards in Pharmacoepidemiology](#) which reviews and gives direct electronic access to guidance for research in pharmacoepidemiology and pharmacovigilance.

For each question of the Checklist, the investigator should indicate whether or not it has been addressed in the study protocol. If the answer is "Yes", the page number(s) of the protocol where this issue has been discussed should be specified. It is possible that some questions do not apply to a particular study (for example in the case of an innovative study design). In this case, the answer 'N/A' (Not Applicable) can be checked and the "Comments" field included for each section should be used to explain why. The "Comments" field can also be used to elaborate on a "No" answer.

This Checklist should be included as an Annex by marketing authorisation holders when submitting the protocol of a non-interventional post-authorisation safety study (PASS) to a regulatory authority (see the [Guidance on the format and content of the protocol of non-interventional post-authorisation safety studies](#)). Note, the Checklist is a supporting document and does not replace the format of the protocol for PASS as recommended in the Guidance and Module VIII of the Good pharmacovigilance practices (GVP).

Study title:
A Multicenter, Non-interventional, Observational, Post-Approval Safety Study of Updated ACCUSOL 35 Solutions in Continuous Renal Replacement Therapy (ACCUPASS)

Study reference number:
8822-001

Section 1: Milestones	Yes	No	N/A	Page Number(s)
1.1 Does the protocol specify timelines for				
1.1.1 Start of data collection ¹	☐	☒	☐	10
1.1.2 End of data collection ²	☐	☒	☐	10
1.1.3 Study progress report(s)	☐	☐	☒	
1.1.4 Interim progress report(s)	☐	☐	☒	
1.1.5 Registration in the EU PAS register	☐	☒	☐	10
1.1.6 Final report of study results.	☐	☒	☐	10

Comments:

No study progress or interim progress reports were requested by the responsible regulatory authority.

¹ Date from which information on the first study is first recorded in the study dataset or, in the case of secondary use of data, the date from which data extraction starts.

² Date from which the analytical dataset is completely available.

ENCePP Checklist for Study Protocols (Revision 2)

Section 2: Research question	Yes	No	N/A	Page Number(s)
2.1 Does the formulation of the research question and objectives clearly explain:				
2.1.1 Why the study is conducted? (e.g. to address an important public health concern, a risk identified in the risk management plan, an emerging safety issue)	☒	☐	☐	7
2.1.2 The objective(s) of the study?	☒	☐	☐	7
2.1.3 The target population? (i.e. population or subgroup to whom the study results are intended to be generalised)	☒	☐	☐	13-14
2.1.4 Which formal hypothesis(-es) is (are) to be tested?	☐	☐	☒	
2.1.5 If applicable, that there is no <i>a priori</i> hypothesis?	☐	☐	☒	

Comments:

This study is observational and therefore does not include hypothesis testing.

Section 3: Study design	Yes	No	N/A	Page Number(s)
3.1 Is the study design described? (e.g. cohort, case-control, randomised controlled trial, new or alternative design)	☒	☐	☐	11-12
3.2 Does the protocol specify the primary and secondary (if applicable) endpoint(s) to be investigated?	☒	☐	☐	19-20
3.3 Does the protocol describe the measure(s) of effect? (e.g. relative risk, odds ratio, deaths per 1000 person-years, absolute risk, excess risk, incidence rate ratio, hazard ratio, number needed to harm (NNH) per year)	☒	☐	☐	19

Comments:

Section 4: Source and study populations	Yes	No	N/A	Page Number(s)
4.1 Is the source population described?	☒	☐	☐	13
4.2 Is the planned study population defined in terms of:				
4.2.1 Study time period?	☒	☐	☐	11-12
4.2.2 Age and sex?	☒	☐	☐	13
4.2.3 Country of origin?	☒	☐	☐	13
4.2.4 Disease/indication?	☒	☐	☐	13
4.2.5 Co-morbidity?	☒	☐	☐	13-14
4.2.6 Seasonality?	☐	☐	☒	
4.3 Does the protocol define how the study population will be sampled from the source population? (e.g. event or inclusion/exclusion criteria)	☒	☐	☐	13-14

Comments:

Seasonality has no bearing on this study's population or design.

Section 5: Exposure definition and measurement	Yes	No	N/A	Page Number(s)
5.1 Does the protocol describe how exposure is defined and measured? (e.g. operational details for defining and categorising exposure)	☒	☐	☐	16

Section 5: Exposure definition and measurement	Yes	No	N/A	Page Number(s)
5.2 Does the protocol discuss the validity of exposure measurement? (e.g. precision, accuracy, prospective ascertainment, exposure information recorded before the outcome occurred, use of validation sub-study)	☐	☐	☒	
5.3 Is exposure classified according to time windows? (e.g. current user, former user, non-use)	☐	☐	☒	
5.4 Is exposure classified based on biological mechanism of action and taking into account the pharmacokinetics and pharmacodynamics of the drug?	☐	☐	☒	
5.5 Does the protocol specify whether a dose-dependent or duration-dependent response is measured?	☐	☐	☒	

Comments:

The time during which direct observations are made for the occurrence of the study endpoint is fixed. Based on the endpoint, the use of time windows is not appropriate for the planned analyses. The study does not examine in-vivo exposure and the endpoint is not based on a pharmacologic response.

Section 6: Endpoint definition and measurement	Yes	No	N/A	Page Number(s)
6.1 Does the protocol describe how the endpoints are defined and measured?	☒	☐	☐	15-16
6.2 Does the protocol discuss the validity of endpoint measurement? (e.g. precision, accuracy, sensitivity, specificity, positive predictive value, prospective or retrospective ascertainment, use of validation sub-study)	☒	☐	☐	17

Comments:

Section 7: Confounders and effect modifiers	Yes	No	N/A	Page Number(s)
7.1 Does the protocol address known confounders? (e.g. collection of data on known confounders, methods of controlling for known confounders)	☐	☐	☒	
7.2 Does the protocol address known effect modifiers? (e.g. collection of data on known effect modifiers, anticipated direction of effect)	☐	☐	☒	

Comments:

The primary study endpoint is absence or observation of a physicochemical phenomenon in the study product outside the patient, rather than a therapeutic or pharmacologic effect on the patient.

Section 8: Data sources	Yes	No	N/A	Page Number(s)
8.1 Does the protocol describe the data source(s) used in the study for the ascertainment of:				
8.1.1 Exposure? (e.g. pharmacy dispensing, general practice prescribing, claims data, self-report, face-to-face interview, etc.)	☒	☐	☐	16-17
8.1.2 Endpoints? (e.g. clinical records, laboratory markers or values, claims data, self-report, patient interview including scales and questionnaires, vital statistics, etc.)	☒	☐	☐	16-17
8.1.3 Covariates?	☒	☐	☐	16-17
8.2 Does the protocol describe the information available from the data source(s) on:				

Section 8: Data sources	Yes	No	N/A	Page Number(s)
8.2.1 Exposure? (e.g. date of dispensing, drug quantity, dose, number of days of supply prescription, daily dosage, prescriber)	☒	☐	☐	15-16
8.2.2 Endpoints? (e.g. date of occurrence, multiple event, severity measures related to event)	☒	☐	☐	15-16
8.2.3 Covariates? (e.g. age, sex, clinical and drug use history, co-morbidity, co-medications, life style, etc.)	☒	☐	☐	15-16
8.3 Is a coding system described for:				
8.3.1 Diseases? (e.g. International Classification of Diseases (ICD)-10)	☐	☐	☒	
8.3.2 Endpoints? (e.g. Medical Dictionary for Regulatory Activities (MedDRA) for adverse events)	☒	☐	☐	18
8.3.3 Exposure? (e.g. WHO Drug Dictionary, Anatomical Therapeutic Chemical (ATC) Classification System)	☒	☐	☐	18
8.4 Is the linkage method between data sources described? (e.g. based on a unique identifier or other)	☒	☐	☐	23

Comments:

Based on study design, data on the patients' diseases are not collected for analysis.

Section 9: Study size and power	Yes	No	N/A	Page Number(s)
9.1 Is sample size and/or statistical power calculated?	☒	☐	☐	17

Comments:

Section 10: Analysis plan	Yes	No	N/A	Page Number(s)
10.1 Does the plan include measurement of excess risks?	☐	☐	☒	
10.2 Is the choice of statistical techniques described?	☒	☐	☐	19-20
10.3 Are descriptive analyses included?	☒	☐	☐	19-20
10.4 Are stratified analyses included?	☐	☐	☒	
10.5 Does the plan describe methods for adjusting for confounding?	☐	☐	☒	
10.6 Does the plan describe methods addressing effect modification?	☐	☐	☒	

Comments:

The primary study endpoint is absence or observation of a physicochemical phenomenon in the study product outside the patient, rather than a therapeutic or pharmacologic effect on the patient.

Section 11: Data management and quality control	Yes	No	N/A	Page Number(s)
11.1 Is information provided on the management of missing data?	☐	☐	☒	
11.2 Does the protocol provide information on data storage? (e.g. software and IT environment, database maintenance and anti-fraud protection, archiving)	☒	☐	☐	17-18
11.3 Are methods of quality assurance described?	☒	☐	☐	17-18

Section 11: Data management and quality control	Yes	No	N/A	Page Number(s)
11.4 Does the protocol describe possible quality issues related to the data source(s)?	☐	☐	☒	
11.5 Is there a system in place for independent review of study results?	☐	☐	☒	

Comments:

The primary study endpoint is absence or observation of a physicochemical phenomenon in the study product outside the patient, rather than a therapeutic or pharmacologic effect on the patient.

Section 12: Limitations	Yes	No	N/A	Page Number(s)
12.1 Does the protocol discuss: 12.1.1 Selection biases? 12.1.2 Information biases? (e.g. anticipated direction and magnitude of such biases, validation sub-study, use of validation and external data, analytical methods)	☐	☐	☒	
12.2 Does the protocol discuss study feasibility? (e.g. sample size, anticipated exposure, duration of follow-up in a cohort study, patient recruitment)	☐	☐	☒	
12.3 Does the protocol address other limitations?	☒	☐	☐	21-22

Comments:

Section 13: Ethical issues	Yes	No	N/A	Page Number(s)
13.1 Have requirements of Ethics Committee/Institutional Review Board approval been described?	☒	☐	☐	22
13.2 Has any outcome of an ethical review procedure been addressed?	☐	☐	☒	
13.3 Have data protection requirements been described?	☒	☐	☐	23-24

Comments:

Section 14: Amendments and deviations	Yes	No	N/A	Page Number(s)
14.1 Does the protocol include a section to document future amendments and deviations?	☒	☐	☐	10

Comments:

Section 15: Plans for communication of study results	Yes	No	N/A	Page Number(s)
15.1 Are plans described for communicating study results (e.g. to regulatory authorities)?	☒	☐	☐	7, 27
15.2 Are plans described for disseminating study results externally, including publication?	☒	☐	☐	27-28

Comments:

Name of the main author of the protocol: Drew S Jones MD

Date: 16 July 2014

Signature: Drew S Jones MD

14.3 Additional Information

Investigator Acknowledgement

Study Title: A Multicenter, Non-interventional, Observational, Post-Approval Safety Study of Updated ACCUSOL 35 Solutions in Continuous Renal Replacement Therapy (ACCUPASS)

Study Number: 8822-001

Version: Original

Date: 2014Sep17

I have read the protocol described above, and I agree to abide by all provisions set forth therein.

I agree to obtain written and dated approval from the responsible Ethics Committee (EC) and, if required, the responsible health authority for the protocol and (unless the EC has granted a written waiver of the requirement for informed consent) the informed consent form, any consent form updates, and any other written information to be provided to the patients before collection of their medical information for use in this study.

I agree to provide sufficient resources for the foreseen duration of the study and to conduct the study properly, ethically, and safely. I agree to ensure that all persons assisting in this study are adequately informed about the protocol and I agree to permit direct monitoring and auditing by the Sponsor, Sponsor's representatives, and authorized health authorities.

I agree to ensure that the confidential information contained in this document will not be disclosed to others without prior written authorization from Baxter Healthcare Limited, except to the extent necessary to obtain approval of the EC and, if required, the responsible health authority.

Signed: _____ Date: _____

Printed Name: _____

Appendix 16.1.2. Sample Case Report Form

V2.000 AT 19AUG2015: ALL_FORMS_PDF

Project Name: 8822001

Form: Informed Consent

Generated On: 19 Aug 2015 07:51:46

Date of consent given to enter the trial _____ ①

Time of consent to enter the trial _____ ②

(24hr clock) _____

Type of consent _____ Phone ☐ ③
Written ☐

Who gave consent? _____ Patient ☐ ④
Next of Kin/Relative ☐
Legally Authorised Representative ☐

Was additional written, informed consent later obtained? _____ Yes ☐ ⑤
No ☐

Who gave written, informed consent? _____ Patient ☐ ⑥
Next of Kin/Relative ☐
Legally Authorised Representative ☐

If Yes, date of written, informed consent _____ ⑦

If Yes, time of written, informed consent _____ ⑧

(24hr clock) _____

Date and Time Informed Consent was signed (Derived, hidden) _____ ⑨

V2.000 AT 19AUG2015: ALL_FORMS_PDF

Project Name: 8822001

Form: Informed Consent

Generated On: 19 Aug 2015 07:51:46

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
①	ICDAT	dd MMM yyyy				ICDAT
②	ICTIM	HH:nn				ICTIM
③	IC_TYPE	\$10		PHONE = Phone WRITTEN = Written		IC_TYPE
④	CONSENT_B 1 Y			1 = Patient 2 = Next of Kin/Relative 3 = Legally Authorised Representative		CONSENT_B Y
⑤	WRITTENIC_\$1 YN			Y = Yes N = No		WRITTENIC_ YN
⑥	CONSENT_B 1 Y2			1 = Patient 2 = Next of Kin/Relative 3 = Legally Authorised Representative		CONSENT_B Y2
⑦	ICDAT2	dd MMM yyyy				ICDAT2

V2.000 AT 19AUG2015: ALL_FORMS_PDF

Project Name: 8822001

Form: Informed Consent

Generated On: 19 Aug 2015 07:51:46

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
⑧	ICTIM2	HH:nn				ICTIM2
⑨	ICDATTM	dd MMM yyyy HH:nn				ICDATTM

V2.000 AT 19AUG2015: ALL_FORMS_PDF

Project Name: 8822001

Form: Demographics

Generated On: 19 Aug 2015 07:51:46

Sex

Male ☐ ①
Female ☐

Age

_____ ②

Baxter evaluable subject

Yes ☒ ③
No ☐

Baxter evaluable date

_____ ④

V2.000 AT 19AUG2015: ALL_FORMS_PDF

Project Name: 8822001

Form: Demographics

Generated On: 19 Aug 2015 07:51:46

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
① SEX	\$1		M = Male F = Female		SEX
② AGE	3				AGE
③ BAXTER_EV \$1			Y = Yes N = No		BAXTER_EV
④ BAXTER_EV dd MMM _DAT yyyy					BAXTER_EV _DAT

V2.000 AT 19AUG2015: ALL_FORMS_PDF

Project Name: 8822001

Form: Inclusion/Exclusion

Generated On: 19 Aug 2015 07:51:46

Protocol Version

Amendment 1 (12Jan2015) ☐ ①

Did the subject meet all eligibility requirements for the study?

Yes ☐ ②
No ☐

If No, specify which Inclusion criteria was not met or which Exclusion criteria was met

Inclusion 1 ☐ ④
Inclusion 2 ☐
Inclusion 3 ☐
Inclusion 4 ☐
Exclusion 1 ☐
Exclusion 2 ☐
Exclusion 3 ☐
Exclusion 4 ☐

Failed

⑤

V2.000 AT 19AUG2015: ALL_FORMS_PDF

Project Name: 8822001

Form: Inclusion/Exclusion

Generated On: 19 Aug 2015 07:51:46

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
①	PROTVER	\$30		AMENDMEN T 1 = Amendment 1 (12Jan2015)		PROTVER
②	ELIG_YN	\$1		Y = Yes N = No		ELIG_YN
④	FAILED_IE	\$15		INCLUSION 1: Inclusion 1 1 = Inclusion 2: Inclusion 2 1 3: Inclusion 3 INCLUSION 4: Inclusion 4 2 = Inclusion 5: Exclusion 1 2 6: Exclusion 2 INCLUSION 7: Exclusion 3 3 = Inclusion 8: Exclusion 4 3 INCLUSION 4 = Inclusion 4 EXCLUSION 1 = Exclusion 1 EXCLUSION 2 = Exclusion 2 EXCLUSION 3 = Exclusion 3 EXCLUSION 4 = Exclusion 4		FAILED_IE
⑤	FAILED	1				FAILED

V2.000 AT 19AUG2015: ALL_FORMS_PDF

Project Name: 8822001

Form: Subject Enrollment

Generated On: 19 Aug 2015 07:51:46

Was the subject enrolled into the study?

Yes ☐ ①
No ☐

If Yes, Date of Enrollment

_____ ②

If Yes, Time of Enrollment

③

(24hr clock)

Date and Time of Enrollment (Derived, hidden)

_____ ④

V2.000 AT 19AUG2015: ALL_FORMS_PDF

Project Name: 8822001

Form: Subject Enrollment

Generated On: 19 Aug 2015 07:51:46

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
① ENROLL_YN\$1			Y = Yes N = No		ENROLL_YN
② ENROLLDATdd MMM yyyy					ENROLLDAT
③ ENROLLTIM HH:nn					ENROLLTIM
④ ENROLLDATdd MMM TM	yyyy HH:nn				ENROLLDAT TM

V2.000 AT 19AUG2015: ALL_FORMS_PDF

Project Name: 8822001

Form: Screening Failures

Generated On: 19 Aug 2015 07:51:46

Was the subject a Screening Failure?

Yes ☐ ①

Date of Screen Failure

②

Reason for Screen Failure

Failure to meet Eligibility Criteria ☐ ③

Death ☐

Withdrawal by Subject ☐

Other, specify ☐

V2.000 AT 19AUG2015: ALL_FORMS_PDF

Project Name: 8822001

Form: Screening Failures

Generated On: 19 Aug 2015 07:51:46

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
① SCRFLR_YN \$1			Y = Yes		SCRFLR_YN
② SCRFLRDAT dd MMM yyyy					SCRFLRDAT
③ SCRFLR_RE 1 AS			1 = Failure to meet Eligibility Criteria 3 = Death 4 = Withdrawal by Subject 9 = Other, specify		SCRFLR_RE AS

V2.000 AT 19AUG2015: ALL_FORMS_PDF

Project Name: 8822001

Form: Weight

Generated On: 19 Aug 2015 07:51:46

Date of Assessment		①
Type of measurement	Actual ☐ Ideal ☐ Unknown ☐	②
Weight	kg ☐ lb ☐	③
Standard Weight in KG (Derived, hidden)		④
User Value entered in KG (Derived, hidden)		⑤

V2.000 AT 19AUG2015: ALL_FORMS_PDF

Project Name: 8822001

Form: Weight

Generated On: 19 Aug 2015 07:51:46

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
① WEIGHTDATdd- yyyy					WEIGHTDAT
② M_TYPE	1		1 = Actual 2 = Ideal 3 = Unknown		M_TYPE
③ WEIGHT	5.2	KG = kg LB = lb			WEIGHT
④ STD_WEIGHT T	5.2				STD_WEIGHT T
⑤ USER_WEIGHT HT	5.2				USER_WEIGHT HT

V2.000 AT 19AUG2015: ALL_FORMS_PDF

Project Name: 8822001

Form: Dialysis Session

Generated On: 19 Aug 2015 07:51:46

Start Date of current CRRT circuit _____ ①

Start Time of current CRRT circuit _____ ②

(24hr clock) _____

Manufacturer of CRRT Monitor
Nikkiso ☐ ③
Edwards ☐
Other, specify ☐

Model of CRRT Monitor
Aquarius ☐ ④
Other, specify ☐

Manufacturer of CRRT Lines
Haemotronic ☐ ⑤
Nikkiso ☐
Other, specify ☐

Model of CRRT Lines
Aqualine ☐ ⑥
Aqualine S ☐
Aqualine C ☐
Other, specify ☐

Manufacturer of Haemofilter _____ ⑦

Model of Haemofilter _____ ⑧

CRRT mode employed
Continuous Venovenous Hemofiltration (CVVH) ☐ ⑨
Continuous Venovenous Hemodialysis (CVVHD) ☐
Continuous Venovenous Hemodiafiltration (CVVHDF) ☐
Slow Continuous Ultrafiltration (SCUF) ☐
Arteriovenous Modes of CRRT ☐
Other, please specify ☐

V2.000 AT 19AUG2015: ALL_FORMS_PDF

Project Name: 8822001

Form: Dialysis Session

Generated On: 19 Aug 2015 07:51:46

Ultrafiltration Rate (L/h) _____ (10)

End Date of current CRRT circuit _____ (11)

End Time of current CRRT circuit _____ (12)
(24hr clock) _____

Was the circuit interrupted? Yes ☐ (13)
No ☐

Number of interruptions _____ (14)

TOTAL time of interruption _____ Fixed Unit: minutes (15)

Reason for interruption _____ (16)

Was the CRRT circuit changed while the subject was on study? Yes ☐ (17)
No ☐

If yes, specify reason _____
Malfunction in circuit ☐ (18)
Access issues ☐
Interruption for other procedure ☐
Other, specify ☐

Was CRRT terminated while the subject was on study? Yes ☐ (19)
No ☐

If yes, specify reason _____
CRRT no longer required (Patient status improved) ☐ (20)
Death ☐
Other, specify ☐

Start Date and Time of current CRRT circuit (Derived, hidden) _____ (21)

V2.000 AT 19AUG2015: ALL_FORMS_PDF

Project Name: 8822001

Form: Dialysis Session

Generated On: 19 Aug 2015 07:51:46

End Date and Time of current CRRT circuit (Derived, hidden)

22

V2.000 AT 19AUG2015: ALL_FORMS_PDF

Project Name: 8822001

Form: Dialysis Session

Generated On: 19 Aug 2015 07:51:46

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
①	CRRT_STDA T	dd MMM yyyy				CRRT_STDA T
②	CRRT_STTI M	HH:nn M				CRRT_STTI M
③	CRRT_MNF	\$30		NIKKISO = Nikkiso EDWARDS = Edwards OTHER = Other, specify		CRRT_MNF
④	CRRT_MOD EL	\$30		AQUARIUS = Aquarius OTHER = Other, specify		CRRT_MOD EL
⑤	CRRT_L_MN F	\$30		HAEMOTRO NIC = Haemotronic NIKKISO = Nikkiso OTHER = Other, specify		CRRT_L_MN F
⑥	CRRT_L_MO DEL	\$30		AQUALINE = Aqualine AQUALINE S = Aqualine S AQUALINE C = Aqualine C		CRRT_L_MO DEL

V2.000 AT 19AUG2015: ALL_FORMS_PDF

Project Name: 8822001

Form: Dialysis Session

Generated On: 19 Aug 2015 07:51:46

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
OTHER = Other, specify					
⑦ HFILT_MNF	\$80				HFILT_MNF
⑧ HFILT_MOD EL	\$80				HFILT_MOD EL
⑨ CRRT_MOD E	1		1 = Continuous Venovenous Hemofiltration (CVVH) 2 = Continuous Venovenous Hemodialysis (CVVHD) 3 = Continuous Venovenous Hemodiafiltrat ion (CVVHDF) 4 = Slow Continuous Ultrafiltration (SCUF) 5 = Arteriovenous Modes of CRRT 9 = Other, please specify		CRRT_MOD E

V2.000 AT 19AUG2015: ALL_FORMS_PDF

Project Name: 8822001

Form: Dialysis Session

Generated On: 19 Aug 2015 07:51:46

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
10	CRRT_UFRA TE	\$20				CRRT_UFRA TE
11	CRRT_SPDA T	dd MMM yyyy				CRRT_SPDA T
12	CRRT_SPTI M	HH:nn M				CRRT_SPTI M
13	CRRTINT_Y N	\$1		Y = Yes N = No		CRRTINT_Y N
14	NO_INTS	2				NO_INTS
15	TIME_INTS	3				TIME_INTS
16	REAS_INTS	\$200				REAS_INTS
17	CRRTCH_YN\$1			Y = Yes N = No		CRRTCH_YN
18	CRRTCH_RE A	\$40		MALFUNCTION IN CIRCUIT = Malfunction in circuit ACCESS ISSUES = Access issues INTERRUPTION FOR OTHER PROCEDURE = Interruption for other procedure		CRRTCH_RE A

V2.000 AT 19AUG2015: ALL_FORMS_PDF

Project Name: 8822001

Form: Dialysis Session

Generated On: 19 Aug 2015 07:51:46

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
OTHER = Other, specify					
19 CRRTERM_\$1 YN			Y = Yes N = No		CRRTERM_ YN
20 CRRTERM_\$40 REA			CRRT NO LONGER REQUIRED = CRRT no longer required (Patient status improved) DEATH = Death OTHER = Other, specify		CRRTERM_ REA
21 CRRT_STDT TM	dd MMM yyyy HH:nn				CRRT_STDT TM
22 CRRT_SPDT TM	dd MMM yyyy HH:nn				CRRT_SPDT TM

V2.000 AT 19AUG2015: ALL_FORMS_PDF

Project Name: 8822001

Form: Accusol Administration

Generated On: 19 Aug 2015 07:51:46

Dialysis Solution used	ACCUSOL 35 ☐ ①
	ACCUSOL 35 Potassium 2 mmol/L ☐
	ACCUSOL 35 Potassium 4 mmol/L ☐
Lot Number	_____ ②
Site of Introduction	Pre-filter ☐ ③
	Post-filter ☐
	As dialysate ☐
	Other, specify ☐
Start Date	_____ ④
Start Time	_____ ⑤
(24hr clock)	_____
End Date	_____ ⑥
End Time	_____ ⑦
(24hr clock)	_____
Dialysis dose (ml/kg/hr)	_____ ⑧
Amount administered (L)	_____ ⑨
Start Date and Time (Derived, hidden)	_____ ⑩
End Date and Time (Derived, hidden)	_____ ⑪
First Accusol Administration Start Date and Time (Derived, hidden)	_____ ⑫

V2.000 AT 19AUG2015: ALL_FORMS_PDF

Project Name: 8822001

Form: Accusol Administration

Generated On: 19 Aug 2015 07:51:46

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
① DIALSOL	1		1 = ACCUSOL 35 2 = ACCUSOL 35 Potassium 2 mmol/L 4 = ACCUSOL 35 Potassium 4 mmol/L		DIALSOL
② LOTNO	\$20				LOTNO
③ SITE	1		1 = Pre-filter 2 = Post-filter 3 = As dialysate 9 = Other, specify		SITE
④ ADM_STDA T	dd MMM yyyy				ADM_STDA T
⑤ ADM_STTIM	HH:nn				ADM_STTIM
⑥ ADM_STPDAdd T	dd MMM yyyy				ADM_STPDA T
⑦ ADM_SPTIM	HH:nn				ADM_SPTIM
⑧ DIAL_DOSE	4.2				DIAL_DOSE

V2.000 AT 19AUG2015: ALL_FORMS_PDF

Project Name: 8822001

Form: Accusol Administration

Generated On: 19 Aug 2015 07:51:46

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
9	AMOUNT_A	4.2				AMOUNT_A DM
10	ADM_STDTT	dd MMM M		yyyy HH:nn		ADM_STDTT M
11	ADM_STPDT	dd MMM TM		yyyy HH:nn		ADM_STPDT TM
12	ADM_STDTT	dd MMM M1		yyyy HH:nn		ADM_STDTT M1

V2.000 AT 19AUG2015: ALL_FORMS_PDF

Project Name: 8822001

Form: Precipitate Observation

Generated On: 19 Aug 2015 07:51:46

Date of Final Observation	_____	①
Time of Final Observation	_____	②
(24hr clock)	_____	
Was any precipitate observed in the CRRT lines?	Yes ☐ No ☐	③
If Yes:		
Colour of precipitate	White ☐ Other, specify ☐	⑤
Solution in use at the time precipitate was observed	ACCUSOL 35 ☐ ACCUSOL 35 Potassium 2 mmol/L ☐ ACCUSOL 35 Potassium 4 mmol/L ☐	⑥
Lot number of solution in use at the time precipitate was observed	_____	⑦
Observation Date/Time (Derived, Hidden)	_____	⑧

V2.000 AT 19AUG2015: ALL_FORMS_PDF

Project Name: 8822001

Form: Precipitate Observation

Generated On: 19 Aug 2015 07:51:46

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
①	OBS_DAT	dd MMM yyyy				OBS_DAT
②	OBS_TIM	HH:nn				OBS_TIM
③	PREC_YN	\$1		Y = Yes N = No		PREC_YN
⑤	PREC_CLR	1		1 = White 9 = Other, specify		PREC_CLR
⑥	PREC_SOL	1		1 = ACCUSOL 35 2 = ACCUSOL 35 Potassium 2 mmol/L 4 = ACCUSOL 35 Potassium 4 mmol/L		PREC_SOL
⑦	PREC_LOTN O	\$20				PREC_LOTN O
⑧	OBSDTTM	dd MMM yyyy HH:nn				OBSDTTM

V2.000 AT 19AUG2015: ALL_FORMS_PDF

Project Name: 8822001

Form: Study Completion

Generated On: 19 Aug 2015 07:51:46

Completion or Discontinuation date _____ ①

Completion or Discontinuation time _____ ②

Status _____ ③

Completed	☐
CRRT Terminated	☐
CRRT Circuit Changed	☐
Adverse Reaction	☐
Lost to Follow-Up	☐
Withdrawal by Subject	☐
Study Terminated by Sponsor	☐
Physician Decision	☐
Protocol Violation	☐
Death	☐
Other	☐

If Other, specify _____ ④

Completion or Discontinuation date and time (Derived, hidden) _____ ⑤

V2.000 AT 19AUG2015: ALL_FORMS_PDF

Project Name: 8822001

Form: Study Completion

Generated On: 19 Aug 2015 07:51:46

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
①	EOSDAT	dd MMM yyyy				EOSDAT
②	EOSTIM	HH:nn				EOSTIM
③	WTHREAS	2		1 = Completed 9 = CRRT Terminated 10 = CRRT Circuit Changed 2 = Adverse Reaction 3 = Lost to Follow-Up 4 = Withdrawal by Subject 5 = Study Terminated by Sponsor 6 = Physician Decision 7 = Protocol Violation 8 = Death 99 = Other		WTHREAS
④	OTHER	\$200				OTHER
⑤	EOSDTTM	dd MMM yyyy HH:nn				EOSDTTM

V2.000 AT 19AUG2015: ALL_FORMS_PDF

Project Name: 8822001

Form: Adverse Reactions

Generated On: 19 Aug 2015 07:51:46

Did the subject experience any Adverse Reactions during the study?

Yes ☐ ①
No ☐

(From subject enrollment (approx. 40 hours after starting CRRT circuit until 72 hours with the same circuit or until the CRRT circuit needs to be changed or CRRT is terminated)

Adverse Reaction description

②

Onset Date

③

Resolution Date

④

Check if ongoing

⑤

Severity

Mild ☐ ⑥
Moderate ☐
Severe ☐

Treatment required?

Yes ☐ ⑦
No ☐

Drug treatment given

⑧

Non-drug treatment given

⑨

Other

⑩

Specify

⑪

Relationship to ACCUSOL 35

Possibly Related ☐ ⑫
Probably Related ☐

Action taken with study drug
(record all that apply)

⑬

Treatment Not Changed

V2.000 AT 19AUG2015: ALL_FORMS_PDF

Project Name: 8822001

Form: Adverse Reactions

Generated On: 19 Aug 2015 07:51:46

Dose increased _____ (14)

Dose reduced _____ (15)

Treatment interrupted _____ (16)

Treatment withdrawn _____ (17)

Not Applicable _____ (18)

Unknown _____ (19)

Serious? Yes ☐ (20)
No ☐

Reason for seriousness (Please tick all that apply) (21)

Death _____

Life threatening _____ (22)

Hospitalization _____ (23)

Significant Disability _____ (24)

Congenital Anomaly or Birth Defect _____ (25)

Other Medically Important Event _____ (26)

Outcome Resolved/ Recovered ☐ (27)
Recovering/ Resolving ☐
Not Recovered/ Not Resolved ☐
Recovered/ Resolved with sequelae ☐
Fatal ☐
Unknown ☐

V2.000 AT 19AUG2015: ALL_FORMS_PDF

Project Name: 8822001

Form: Adverse Reactions

Generated On: 19 Aug 2015 07:51:46

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
①	AE_YN	\$1		Y = Yes N = No		AE_YN
②	AETERM	\$200				AETERM
③	AESTDAT	dd MMM yyyy				AESTDAT
④	AEENDAT	dd MMM yyyy				AEENDAT
⑤	AEONG	1				AEONG
⑥	AESEV	1		1 = Mild 2 = Moderate 3 = Severe		AESEV
⑦	AETRT	\$1		Y = Yes N = No		AETRT
⑧	AETRT_1	1				AETRT_1
⑨	AETRT_2	1				AETRT_2
⑩	AETRT_3	1				AETRT_3
⑪	AETRT_O	\$100				AETRT_O
⑫	AEREL	\$20		POSSIBLY RELATED = Possibly Related		AEREL

V2.000 AT 19AUG2015: ALL_FORMS_PDF

Project Name: 8822001

Form: Adverse Reactions

Generated On: 19 Aug 2015 07:51:46

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			PROBABLY RELATED = Probably Related		
13 AEACTION_1	1				AEACTION_1
14 AEACTION_6	1				AEACTION_6
15 AEACTION_7	1				AEACTION_7
16 AEACTION_2	1				AEACTION_2
17 AEACTION_3	1				AEACTION_3
18 AEACTION_4	1				AEACTION_4
19 AEACTION_5	1				AEACTION_5
20 SAE	\$1		Y = Yes N = No		SAE
21 SAE_REAS1	1				SAE_REAS1
22 SAE_REAS2	1				SAE_REAS2
23 SAE_REAS3	1				SAE_REAS3
24 SAE_REAS4	1				SAE_REAS4

V2.000 AT 19AUG2015: ALL_FORMS_PDF

Project Name: 8822001

Form: Adverse Reactions

Generated On: 19 Aug 2015 07:51:46

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
25	SAE_REAS5	1				SAE_REAS5
26	SAE_REAS6	1				SAE_REAS6
27	AEOUT	\$30		RECOVERED = Resolved/ Recovered RECOVERIN G = Recovering/ Resolving NOT RECOVERED = Not Recovered/ Not Resolved RECOVERED WITH SEQUELAE = Recovered/ Resolved with sequelae FATAL = Fatal UNKNOWN = Unknown		AEOUT

V2.000 AT 19AUG2015: ALL_FORMS_PDF

Project Name: 8822001

Form: Anti-Coagulant Administration

Generated On: 19 Aug 2015 07:51:46

Did the subject take any anti-coagulants during the study?

Yes ☐ ①
No ☐

Anti-coagulant Name
(generic name preferred,
if combination product,
use trade name)

②

Date of Administration

③

Time of Administration

④

(24hr clock)

Route

IV ☐ ⑤
IM ☐
SC ☐
Other, specify ☐

Dose per administration

⑥

Units

mg ☐ ⑦
mg/kg ☐
units/mL ☐
Other, specify ☐

Date and Time of Administration (Derived, hidden)

⑧

V2.000 AT 19AUG2015: ALL_FORMS_PDF

Project Name: 8822001

Form: Anti-Coagulant Administration

Generated On: 19 Aug 2015 07:51:46

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
①	COAG_YN	\$1		Y = Yes N = No		COAG_YN
②	COAGTERM	\$200				COAGTERM
③	COAGDAT	dd MMM yyyy				COAGDAT
④	COAGTIM	HH:nn				COAGTIM
⑤	COAGROUT E	\$15		IV = IV IM = IM SC = SC OTHER = Other, specify		COAGROUT E
⑥	COAGDOSE	\$10				COAGDOSE
⑦	COAGUNIT	\$15		MG = mg MG/KG = mg/kg UNITS/ML = units/mL OTHER = Other, specify		COAGUNIT
⑧	COAGDTTM	dd MMM yyyy HH:nn				COAGDTTM

V2.000 AT 19AUG2015: ALL_FORMS_PDF

Project Name: 8822001

Form: Potassium Chloride Administration

Generated On: 19 Aug 2015 07:51:46

Did the subject have any additional Potassium Chloride added to their dialysate fluid during the study?

Yes ☐ ①
No ☐

Drug name

②

Date of Administration

③

Time of Administration

④

(24hr clock)

Concentration

⑤

Units

meq/L ☐ ⑥
g/mL ☐
Other, specify ☐

Date and Time of Administration (Derived, hidden)

⑦

V2.000 AT 19AUG2015: ALL_FORMS_PDF
Project Name: 8822001
Form: Potassium Chloride Administration
Generated On: 19 Aug 2015 07:51:46

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
①	PCHL_YN	\$1		Y = Yes N = No		PCHL_YN
②	PCHLTERM	\$200				PCHLTERM
③	PCHLDAT	dd MMM yyyy				PCHLDAT
④	PCHLTIM	HH:nn				PCHLTIM
⑤	PCHLCONC	\$10				PCHLCONC
⑥	PCHLUNIT	\$15		MEQ/L = meq/L G/ML = g/mL OTHER = Other, specify		PCHLUNIT
⑦	PCHLDTTM	dd MMM yyyy HH:nn				PCHLDTTM

V2.000 AT 19AUG2015: ALL_FORMS_PDF

Project Name: 8822001

Form: Death Report

Generated On: 19 Aug 2015 07:51:46

Date of Death		①
Time of Death		②
Primary Cause of Death		③
Death Date/Time (Derived, Hidden)		④

V2.000 AT 19AUG2015: ALL_FORMS_PDF

Project Name: 8822001

Form: Death Report

Generated On: 19 Aug 2015 07:51:46

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
①	DTHDAT	dd MMM yyyy				DTHDAT
②	DTHTIM	HH:nn				DTHTIM
③	DTHCAUSE	\$200				DTHCAUSE
④	DTHDATTM	dd MMM yyyy HH:nn				DTHDATTM

Appendix 16.1.4. Descriptions of Investigators Qualifications

Center Number	Investigator (blue text links to investigator CV)	Institution
001	Kiran Salaunkey, MBBS, MD, DNB, FRCA	Papworth Hospital Cambridge, UK
002	Philip Watt, MB, BS, FRCA, FFICM	Kettering General Hospital Kettering, UK
003	Maurizio Cecconi, MD, FRCA, FFICM	St. George's Hospital, General Intensive Care Unit London, UK
004	David Brealey, BSc, PhD, MRCP, FRCA, FFICM	University College Hospital London, UK
005	Christopher Thompson, MBChB, MRCP	Royal Stoke University Hospital Stoke on Trent, UK
007	Ingeborg Welters, MD, PhD	Royal Liverpool University Hospital, Intensive Care Unit Liverpool, UK
008	Jonathan Bannard-Smith, MBChB, FRCA, FFICM	Manchester Royal Infirmary, Department of Adult Critical Care Manchester, UK
009	Daniel Martin, MBChB, FRCA, FFICM, PhD	Royal Free Hospital, Intensive Care Unit London, UK
010	Mohamed Ramali, MBBS, MD, FRCA, FFICM	Colchester General Hospital, Intensive Treatment Unit Colchester, UK
011	Catherine Plowright, MScN, MA	Medway Maritime Hospital Gillingham, UK
012	Joyce Yeung, MBChB, FRCA, PhD	Birmingham Heartlands Hospital, Academic Department of Anesthesia, Critical Care, Resuscitation, and Pain Birmingham, UK
014		Good Hope Hospital, Intensive Care Unit Birmingham, UK
013	Simon Fletcher, MBBS, FRCA, FRCPE	Norfolk and Norwich University Hospital, Critical Care Complex Norwich, UK
015	Julius Cranshaw, MBChB, MRCP, FRCA, PhD	Royal Bournemouth Hospital Bournemouth, UK

Center Number	Investigator (blue text links to investigator CV)	Institution
016	Stuart McKechnie, MBChB, FRCA, PhD, DICM, FFICM	John Radcliffe Hospital Oxford, UK
017	Robin Hollands, MBChB, DCH, FRCA	Royal Shrewsbury Hospital Shrewsbury, UK

Note: No patients were enrolled at Center 006.

Curriculum Vitae

Dr. Kiran Salaunkey
MBBS, MD, DNB (Anaesthetics); FRCA



06 OCT 2014

In support of Consultant Anaesthetist and Intensivist's
post at Papworth Hospital NHS Foundation Trust.

Personal Details:

Name : Kiran Salaunkey
Address : 40 Bascombe Grove, Crayford, DA1 3RJ.
Date of birth : 02 March 1977.
E-mail : drksal@gmail.com.
Phone : 07970604133.
GMC Registration No : 6067330 fully registered with Fitness to practice.

Academic Qualifications:

FRCA	Royal College of Anaesthetists, London. Jun 2008
DNB (Anaesthetics)	Diplomate National Board, New Delhi, India. November 2005.
M. D (Anaesthetics)	Gujarat University, Ahmedabad, India. April 2004.
M. B. B. S	Bangalore University, Bangalore, India. December 2000.

Membership of professional bodies:

1. Member of the Royal college of Anaesthetists.
2. Member of the Intensive Care Society & European society of Intensive Care Medicine.
3. Member of Association of Cardiothoracic anaesthetists
4. Member of American Society of Anaesthesiology.

Present Post:

Locum Consultant
(from May 2013)

Papworth Hospital NHS Foundation Trust, Papworth
Cambridgeshire, UK.

Previous Appointments:

Vascular Research Fellow

King's College Hospital, Denmark Hill, London, UK
Aug 2012- Apr 2013

Clinical Fellow
Cardiothoracic anaesthesia

Papworth Hospitals NHS foundation Trust, Papworth, UK
Aug 2011 – July 2012.

ST6 Anaesthetics
(6Months)

Royal Brompton Hospitals, London, UK
Feb 2011- Aug 2011

ST5 Anaesthetics
(6months/hospital)

Kent and Canterbury Hospitals, Canterbury, Kent, UK
Medway Maritime Hospitals, Gillingham, Kent, UK
Aug 2009 to Aug 2010.

ST4 Anaesthetics
(1 Year)

Guy's and St. Thomas hospitals NHS Trust, London, UK.
Aug 2008 to Jul 2009

ST3 Anaesthetics
(1 year)

William Harvey Hospitals, Ashford, Kent.
Aug 2007 to Jul 2008.

Senior SHO Anaesthetics
(2 years)

Whipps Cross University Hospitals, Leytonstone, London, UK
Aug 2005 to Jul 2007.

SHO Anaesthetics
(5 months)

Sunderland Royal Hospitals, Sunderland, Tyne and Wear, UK
Mar 2005 to Jul 2005.

Locum SHO Anaesthetics
(2 Months)

Whittington Hospitals, London, UK
Jan 2005 to Mar 2005.

Registrar Anaesthetics
(4 Months)

M S Ramiah Medical College, Bangalore, India
Jul 2004 to Oct 2004.

Resident Anaesthesia
(3 years)

B J Medical College and Post graduate centre, Ahmedabad, India
May 2001 to Jul 2004.

House Surgeon
(1 year)

Bangalore Medical College, Bangalore, India
Sep 1999 to Sep 2000.

Clinical Experience:

Cardiac Anaesthesia: (32 months in the UK)

I completed my basic, intermediate & advanced modules at Guy's and St. Thomas hospitals, The Royal Brompton hospital and Papworth hospitals respectively and have 8 months experience as a Locum Consultant.

I have anaesthetised around 700 patients requiring cardiopulmonary bypass of various complexities including Pulmonary Thromboendarterectomies, Heart and Lung transplants, placement of mechanical circulatory devices for Heart failure and adult congenital heart diseases apart from routine procedures such as CABG & valve replacements. I have been exposed to the complexities of paediatric cardiac anaesthesia too.

~~I have anaesthetised over 250 patients for thoracic surgery which mainly included lung resections and VATS. I have a substantial exposure to major thoracic surgery like chest wall resection and lung volume reduction.~~

I have also anaesthetised patients for electrophysiological procedures, TAVI's and ASD closures.

I have gained sufficient experience in the post-operative management complex cardiothoracic patients, especially in the field of extracorporeal support and invasive cardiac monitoring

I have performed >300 Transesophageal ECHO examination and have obtain full TOE accreditation.

My present responsibilities in the post of a Locum Consultant include providing a consultant service for routine cardiothoracic anaesthesia including major aortic surgery, out of hours ECMO retrieval (as a part of 1:5 on call rota) for the respiratory ECMO service and covering the cardiac post operative recovery unit and high dependency units.

Intensive Care: (9 months SpR+ 3 Months SHO+ 6 months Post cardiac surgical recovery)

I have completed my intermediate module of general intensive care medicine training at Guy's and St. Thomas hospitals. I have gained experience of managing sick patients, task prioritisation, hemodynamic monitoring & appropriate resource utilisation on this job. I also understood the importance of communication and importance of protocolised care.

I was exposed to pure Cardiothoracic Intensive care mainly at Papworth, where I learnt the principles and practice of post cardiac surgical care, extracorporeal circulation and management of mechanical cardiovascular support devices.

I have covered to the “overnight intensive recovery” unit at St. Thomas which caters primarily for post cardiac surgical patients for 6 months during on calls apart from core intensive care training for 12 months.

Vascular Anaesthesia: (15 months in UK)

I completed my intermediate modules of 3 months each in Kent & Canterbury hospitals, Medway maritime hospitals. I am presently pursuing an advanced vascular module coupled with research in hemodynamic monitoring techniques at King’s College hospital.

I have anaesthetised over 200 patients for vascular surgery which includes complex vascular reconstructions, carotid endarterectomies, open AAA repairs and Endovascular AAA repairs.

Paediatric Anaesthesia: (4 months)

I completed my basic and intermediate modules in Medway and King’s college hospital respectively.

I have performed over 40 neonatal laparotomies. However my major experience with sick neonates has been while anaesthetising them for congenital heart diseases and their perioperative care for Tetralogy repairs, Correction of co-arcations, arterial switch procedures etc.

Airway module: (3 months)

I completed this at Guy’s hospital, where I have performed 25 awake fibre-optic intubations, 20 asleep fibre-optic intubations and used different techniques of direct and indirect laryngoscopy to secure the difficult airway.

Neuroanaesthesia: (2months)

I completed this at King’s college hospital, which being a major trauma centre for London presented numerous patients with traumatic brain injury which is a challenge to manage. I have conducted over 60 cases of elective and emergency neurosurgery. This placement also taught me the issues surrounding remote site anaesthesia for MRI/CT scans and for aneurysmal clippings.

Chronic Pain: (3 months)

I completed this module at St.Thomas hospital. The Intermediate pain module improved my interview skills in evaluation of a chronic pain patient and performance of regional techniques. It exposed me to central and peripheral neuro modulatory techniques of pain management.

General: (Urology, Gynaecology, Orthopaedics, Day case, Obstetrics, Ophthalmology) – 14 months

Urology module gave me good exposure to anaesthesia for advance urological procedures such as robotic radical prostatectomy, laser endourology, and donor nephrectomies.

Regional Anaesthesia: I have learnt the art of USG guided regional techniques here and management of elderly patients coming in for surgeries with multiple co-morbidities. Conducting both the elective and trauma Orthopaedic lists has given me an opportunity to hone my skills in regional anaesthetic techniques. I have performed femoral blocks, sciatic blocks, interscalene blocks and axillary nerve blocks during my time here. Exposure to Orthogeriatrics has made me more confident in anaesthetising sick elderly patients, management of blood loss.

ENT: The difference from other hospitals regarding the ENT module here is the widespread use of jet ventilation for pan endoscopies.

Day Case Surgery: The challenge of maintaining a rapid list turnover with a balanced anaesthetic technique to facilitate early recovery and discharge is unique to day case surgery. Laparoscopic Cholecystectomy, Gynaecological laparoscopies hysteroscopies, arthroscopies, and Paediatric ENT procedures like adenotonsillectomy.

General Surgery/Gynaecologic Surgery: I have gained invaluable experience anaesthetising major laparoscopic upper GI and lower GI procedures, and also their post op management on the intensive care unit.

Experience in India:

I completed my postgraduate training in anaesthetics in at the Civil hospital at Ahmedabad, which is the regional centre for cardiology, oncology and nephro/urology for Western India and is located in the state of Gujarat. It had about 2000 inpatient beds and the anaesthetic department managed 25 operating theatres, the general intensive care unit and trauma intensive care unit of

twelve beds. We also provided support to the post Cardiothoracic/vascular and Neuro ITU which had 12 beds between them.

All of the surgical specialties and super specialties like general surgery, orthopaedics, ENT, Plastics, Max Fax, O&G, Cardiothoracic, advanced oncology and urology were well represented. The training was modular and we spent about 2-3 months doing each module.

Research:

Present Project:

Survey of Cardio-thoracic intensive care practices in the United Kingdom:

I designed this survey based on the CANCARE survey in Canada and submitted it to the Association of Cardiothoracic anaesthetists for their approval and dissemination among their members. The survey aims to gauge the staffing levels, the level of standardisation of various ITU protocols to obtain a consensus amongst the members of the CIA (cardiothoracic anaesthetists in intensive care). Presented at the AAGBI –CIA national meeting at London in October. Manuscript being prepared for submission to JICS.

1. Impact of NICE guidelines for Infective Endocarditis prophylaxis on incidence and severity of Infective Endocarditis at Papworth hospital: I initiated this project, got ethical approval, collected and analysed data of all 180 patients admitted to Papworth with Infective Endocarditis over the last 6 years. This showed that since the guidelines were introduced our rates of infective endocarditis on bicuspid aortic valves, repaired mitral valves and pacing devices has increased significantly. Streptococci are the most common organisms as opposed to the expected Staphylococci and the mortality of patients has increased. Manuscript submitted to European Journal of Cardiothoracic surgery.

2. Concordance of invasive arterial pressure with Continuous non invasive arterial pressure. We have completed this prospective study comparing the readings between the two monitors in 50 patients. Results reveal that there is good concordance with changes in arterial pressure across the two monitoring techniques but the absolute values do vary. Results were presented at the ASA meeting in San Francisco 2013.

3. Use of Cerebral Oximetry (rSO₂) and LiDCO rapid for carotid endarterectomies: This prospective research project where 65 patients were recruited and underwent awake carotid endarterectomies revealed that a drop in rSO₂ > 20% is a very good predictor of shunt requirement prior to manifestation of clinical signs of cerebral hypoxia. The hemodynamic monitor in combination with rSO₂ helps us to manipulate haemodynamics to improve cerebral oxygenation and thus prevent shunt insertion which in itself has a ~4% risk of strokes. Presented at South-eastern society of anaesthesia meeting, 2012 – secured 3rd place for oral presentation. The abstract has been submitted to EACTA 2013. Manuscript submitted to the International Journal of Surgery.

- 4. Reduction of Post operative cognitive dysfunction after cardiac surgery with combined monitoring techniques.** Have recruited patients for this prospective randomised controlled study which hypothesises that optimising cerebral oxygenation with the use of rSO₂ and the use of Bi-spectral index (BIS) to prevent neurotoxic effects from excessive anaesthetic administration. I am presently co-ordinating this study.

Protocol presented to the London research society meeting. The preliminary findings were presented as a podium presentation at EACTA Barcelona 2013.

- 5. Cerebral Oximetry post cardiac surgery:** As a part of the above trial we have analysed postoperative rSO₂ data from the first 80 patients recruited which revealed a >20% drop in over 50% of the patients. This is a significant decrease in rSO₂ postoperatively which we hypothesise might be responsible for post operative delirium and cognitive dysfunction. This preliminary data was presented as a podium presentation at EACTA Barcelona 2013. Manuscript being prepared for submission.

- 6. Training Opportunities in Cardiothoracic Intensive Care at Papworth hospital for Foundation Year (FY) Doctors:** Sep 2011 Conducted an online anonymous survey of all FY doctors in Papworth over two years. The results showed that close senior supervision and encouragement will influence career choices and lead to better talent retention in Intensive Care. Presented as an Oral Presentation in European Association of Cardiothoracic Anaesthetists, Amsterdam, May 2012.

- 7. EVAR experience of 1 year: Dec 2009:** Retrospectively analysed data for all patients undergoing EVAR for 1 year, specifically looking into 30 day mortality, morbidity such as renal failure, prolonged ITU stay and post op endovascular leaks. Presented as a poster at the VASGBI meeting in Aug 2010.

- 8. Intranasal midazolam for premedication in children:** This was the topic for my MD thesis; We compared the comparative efficacy of this route with oral and IM routes regarding acceptability, time of onset, adverse events and morbidity. It was found that intranasal midazolam was not the preferred route due to discomfort caused in spite of having favourable onset times and predictability of sedation.

Audits/Service Evaluation:

- 1. Post – thoracotomy analgesia- Efficacy with enhanced thoracic recovery and patient satisfaction: Nov 2013:** Primary investigator, I designed and set up this audit to look at the efficacy of our post operative analgesic regimen. Data collection was completed yesterday.
- 2. Outcome of repatriated ITU patients from Papworth Hospital- Jul 2013:** I collected and analysed data for the last one year of the outcomes of all repatriated patients from Papworth's intensive care unit. The findings are due to be presented at the hospital wide audit meeting in March 2014.

2. Thoracic Surgical Readmissions to Intensive Care at Guy's & St.Thomas

Hospital: Feb 2011, Primary investigator, designed and set up this audit to determine the extent of the problem and the causes for readmissions to Intensive care. Preliminary data of 350 patients followed up over 2 years shows a 12% rate of readmissions and unsurprisingly the outcome of readmitted patients is poor.

3. Antenatal anaesthetic clinic's influence on Morbidly obese parturient, Sep 2010: Primary Investigator, We followed 50 consecutive morbidly obese parturients attending the antenatal anaesthetic clinic and found epidural uptake rates improved & airway complication rates were not high as predicted in the antenatal clinic. Accepted as a poster at ESRA 2011.

4. Efficacy of Non Obstetric Epidurals Aug 2010: Performed a retrospective audit spanning over three months regarding the efficacy of non obstetric epidurals and found that ~40% do NOT have a satisfactory outcome but the outcome improves if they are diligently followed up on the 1st postoperative day for 24 hrs. Accepted as a poster at ESRA 2011.

5. Post Hysterectomy pain relief: Jul 2010: Primary investigator. Studied the practices of anaesthesia and post op analgesia protocol for 3 months in patients who have had an open abdominal hysterectomy and have recommended the use of regional anaesthesia especially neuraxial anaesthesia to be advocated to patients to improve pain scores, PONV and their satisfaction.

Presented as a poster in International Conference of Pain & Regional Anaesthesia 2010.

6. Thromboprophylaxis post elective hip and knee arthroplasties: Mar 2010: Looked at the practice of risk assessment, tools for risk assessment and compliance of the medical staff with risk assessment and prescription of thromboprophylaxis comparing with the recent NICE guidelines and have recommended that the guidelines should be followed as we found the prescription rate for thromboprophylaxis to be fairly poor.

7. Information on post operative pain Aug 2009: We audited our practice and the system in place to disseminate information to patients regarding anaesthesia and post op pain. We found that about 24% of patients had received prior information about post op pain and techniques for its relief. There was a revamp of the system after this audit and now there is a leaflet in place which patients get when they present for preassessment.

8. Epidural analgesia for post operative pain relief: Mar 2009: looked into the success rate, problems and difficulties of managing post op epidural analgesia at St Thomas hospital. This was presented as a poster at the NYSORA conference in Dubai 2010.

9. High risk pregnancy clinic at Whipps Cross: Jan 2007: have looked into the reasons for referral to this clinic, recognition and management of potentially difficult cases and followed up patients for three months and specifically looked at the outcome and satisfaction profile of patients from this service. Presented as a Poster in ESRA 2008

10. Pattern of use of Emergency drugs at Whipps Cross University Hospitals: Aug 2006: after looking into the frequency of use and wastage of emergency drugs in theatres, at the joint audit meeting of Surgeons and Anaesthetists at Whipps Cross hospital.

11. Practice of regional Anaesthesia at the Whittington Hospital: Feb 2005: after evaluating effectiveness, economic benefits, patient acceptability & satisfaction of Regional anaesthesia in comparison to General anaesthetic.

Publications:

Case Report: Successful management of a parturient in labour with hereditary angioedema: Dr M Thirukkamu, Dr K Salaunkey, Dr S Walker; Internet journal of anesthesiology 2010, Vol 27: 2.

Review: Dr K Salaunkey, Dr F Falter, Dr S W Webb; Extracorporeal Membrane Oxygenation- A Review, British Journal of Intensive Care, Feb 2013, Vol 22, Number 4- 107-112.

Review: Mechanical Cardio Vascular Support for Advanced Heart Failure, Dr K Salaunkey, Dr J Parameshwar, Dr K Valchanov, Dr A Vuylsteke, Journal of Intensive Care Society, Jul 2013, Vol 14, Number 3- 220-225.

Book Chapter: Transoesophageal ECHO for the book Core topics in Cardiac surgery (in print)

Article: Papworth ECMO course; ACTA news letter Feb 2013.

Courses/Meetings Attended:

1. 3D Echocardiography course – Jan 2014 – London.
2. ASA annual conference – October 2013 – San Francisco
3. AAGBI-CIA annual Meeting – October 2013- London.
4. ACTA spring meeting – Cambridge- June 2013.
5. EACTA June 2013 – Barcelona.
6. Hammersmith Interview skills course – Feb 2013.
7. Keele clinical management course for SpRs – Jan 2013
8. Supervisory skills equality and diversity workshop –Dec 2012
9. Future directions in perioperative research – Nov 2012.
10. Papworth ECMO course – Nov 2012.
11. Annual conference of Indian society of Anaesthesiologists – Oct 2012
12. South east thames school of anaesthesia meeting – Oct 2012.
13. Good clinical practice and the medicines for human use regulations – Aug 2012.
14. Perioperative procedures in organ donation- Aug 2012.
15. Care of the critically ill surgical patient course – May 2012(as a facilitator)
16. EACTA May 2012.
17. London deanery WPBA training day Jan 2012
18. East Anglian Intensive Care Group meeting – Nov 2011.
19. Cardiac advanced life support course- Nov 2011.

20. Annual meeting of Association of Cardiothoracic Anaesthetists – Nov 2011
21. NHS management issues – Sep 2011.
22. Improving Clinical Leadership skills – July 2011.
23. Medical Statistics Course – Imperial college & Royal Brompton Hospitals, Jun 2011.
24. Transesophageal ECHO generic simulator training day – May 2011.
25. Research Methodology Course – Royal society of Medicine, Apr 2011.
26. Patient safety training workshop – Apr 2011
27. Transesophageal Echocardiography course, Papworth, Nov 2010.
28. International Pain and Regional Anaesthesia Conference, Morocco, Nov 2010
29. NYSORA World anaesthesia Conference, Dubai, March 2010
30. Difficult airway management, Guy's hospital, Dec 2009.
31. Advanced Life Support, King's college hospital, London. Apr 2009.
32. Ultrasound in regional anaesthesia, RCoA, Mar 2009.
33. Annual Obstetric Anaesthesia update, RCoA, Apr 2009.
34. ICS annual meeting, Manchester, May 2008.

Teaching Skills:

1. **Cardiac Advanced Life support Course:** Instructor on this course and have helped in the organisation and conduct of three Cardiac advanced life support courses at Papworth hospital, in Nov 2011, May 2012 and May 2013.
2. **Transesophageal ECHO courses:**
 - a. King's College Hospital: Set up and facilitated the conduct of the inaugural TOE course at King's college hospital and ran in the course as an instructor.
 - b. Papworth Hospital: Instructor on the Papworth hospital ECHO course and have facilitated the conduct of two courses during my tenure as a Locum Consultant.
3. **ICU Simulation course:** Collaborating with the director of the simulation centre at Addenbrookes to set up a simulator based ICU course and am responsible for inputs/scenarios from the cardiothoracic ICU.
4. **Faculty Observer:** Care of the Critically Ill surgical Patient, Have observed and facilitated this course at Addenbrookes hospital, Cambridgeshire in May 2012 with a view to become a full instructor on this course.
5. **Exam Courses:** I facilitated the organisation and conduct of the primary FRCA course for the KSS deanery students at Medway hospitals in Mar 2010 & been a viva examiner at the St. Thomas hospital's VIVA course.

I have completed all the teaching and faculty development modules of London deanery and am eligible to be a clinical trainer and clinical supervisor.

IT Skills:

Proficient in handling MS Office, Internet and the use of online medical resources.

Career Objectives:

Obtaining a full time Consultant position in Cardiothoracic anaesthesia with a special interest in Transesophageal ECHO and cardiac post operative care.

References:**Dr Sunit Ghosh****Consultant Anaesthetist**

Papworth Hospital NHS Foundation Trust

Papworth Everard, Cambridgeshire, UK

Phone: 00441480830541

Fax:

E-Mail: davidgreen1@nhs.net

Dr. Gudrun Kunst**Consultant Anaesthetist & College Tutor**

Kings College Hospital, Denmark Hill, London

Phone: 0044203299000

Fax:

E-Mail: Gudrun.kunst@nhs.net

Dr Kamen Valchanov**Consultant Anaesthetist & College Tutor**

Papworth Hospital NHS Foundation Trust

Papworth Everard, Cambridgeshire, UK

Phone: 00441480830541

E-mail: kamen.valchanov@nhs.net.

Dr. Dharshini Radhakrishnan**Consultant Anaesthetist**

Whipps Cross University Hospitals NHS Trust

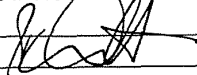
Leytonstone, London, E11 1NR.

Phone: 02085356614.

Fax: 02085356467.

E-Mail: d.radha@whippsx.nhs.uk

CURRICULUM VITAE

Name: Dr Philip Watt	
Present appointment: <i>(Job title, department, and organisation.)</i> Consultant Anaesthetist with interest in Critical Care, Department of Anaesthetics, Kettering General Hospital, NHS Foundation Trust.	
Work Address Kettering General Hospital, NHS Foundation Trust. Rothwell Road, Kettering NHS Foundation Trust, NN16 8UZ	
*Telephone number: 01536 492016	*Email address: Phil.watt@kgh.nhs.uk
*Fax number: 01536 492757	
Qualifications: MB BS FRCA FFICM	
Professional registration: <i>(Name of body, registration number and date of registration.)</i> GMC. Reg. No. 4204341	
Previous and other appointments: <i>(Include previous appointments in the last 5 years and other current appointments.)</i> Feb. 2000-Feb.2005 SpR Anaesthetics Leicester Rotation. Feb.2005-Apr. 2005.Locum Consultant Anaesthetics. Apr.2005-present. Consultant Anaesthetist Kettering General Hospital.	
Research experience: <i>(Summary of research experience, including the extent of your involvement. Refer to any specific clinical or research experience relevant to the current application.)</i> Principal Investigator for the Promise, Gains, Spotlight, Spotid, Obtain, Etpos, Las Vegas, ISARIC, ACCUPASS, Leopards trials (NIHR portfolio studies). Co-Investigator for the Relief study (NIHR portfolio studies). Had involvement in the anaesthetic academic department at Leicester University during SpR training. Undertook four month research module within SpR training. Involved in several studies at different stages, from ethics submissions, recruitment, data collation, presentation and publication. Contributed Data to SwiFT study. See list of publications.	
Research training: <i>(Details of any relevant training in the design or conduct of research, for example in the Clinical Trials Regulations, Good Clinical Practice, consent or other training appropriate to non-clinical research. Give the date of the training.)</i> ICH GCP Training- 26/06/2014	
Relevant publications: <i>(Give references to all publications in the last two years plus other publications relevant to the current application.)</i> Anaesthesia and Analgesia 2003, 97, 5:1501-3 Thompson JP, Watt, P. A comparison of cerebrospinal fluid and plasma Urotensin II concentrations in normotensive and hypertensive patients undergoing urological surgery during spinal anaesthesia: A pilot study. Br. J. Anaesth., 2002 89:670-681 Watt P et al. Recording pain in ambulatory surgery: Further evaluation of a revised electronic data collection device.	
Signature: 	Date: 26/08/15

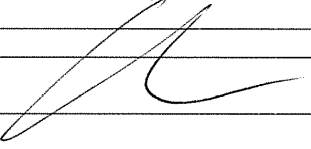
* Compulsory Field

CURRICULUM VITAE

Name: Dr Maurizio Cecconi	
Present appointment:	
St Georges Healthcare NHS Trust- Consultant and Honorary Senior Lecturer in Critical Care and Anaesthesia Head of Critical Care Research	
Address:	
GICU, St Georges Hospital, Blackshaw Road, Tooting, London, SW170QT	
Telephone number:	Email address:
0208 725 0879	m.cecconi@nhs.net
Qualifications:	
MD (It) FRCA FICM MD(Res UK)	
Professional registration:	
GMC-6118600	
Previous and other appointments:	
Consultant in Intensive Care and Anaesthetics- Udine Italy Medical training	
Research experience: <i>(Summary of research experience, including the extent of your involvement. Refer to any specific clinical or research experience relevant to the current application.)</i>	
Extensive first author publications in peer reviewed high impact journals.	
Research training: <i>(Details of any relevant training in the design or conduct of research, for example in the Clinical Trials Regulations, Good Clinical Practice, consent or other training appropriate to non-clinical research. Give the date of the training.)</i>	
Completed the Global Clinical Scholar Research training at Harvard (2015) GCP trained	
Relevant publications: <i>(Give references to all publications in the last two years plus other publications relevant to the current application.)</i>	
Selection of 10 Publications since 2009: 1. Cecconi M, Monge García MI, Gracia Romero M, Mellinshoff J, Caliandro F, Grounds RM, Rhodes A. The use of pulse pressure variation and stroke volume variation in spontaneously breathing patients to assess dynamic arterial elastance and to predict arterial pressure response to fluid administration. <i>Anesth Analg</i>. 2015 Jan;120(1):76-8 2. Mebazaa A, Tolppanen H, Mueller C, Lassus J, DiSomma S, Bakstye G, Cecconi M, Choi DJ, Cohen Solal A, Christ M, Masip J, Arrigo M, Noura S, Ojji D, Peacock F, Richards M, Sato N, Sliwa K, Spinar J, Thiele H, Yilmaz MB, Januzzi J. Acute heart failure and cardiogenic shock: a multidisciplinary practical guidance. <i>Intensive Care Med</i>. 2015 Sep 14. [Epub ahead of print] PubMed PMID: 26370690. 3. Cecconi M, De Backer D, Antonelli M, Beale R, Bakker J, Hofer C, Jaeschke R, Mebazaa A, Pinsky MR, Teboul JL, Vincent JL, Rhodes A. Cecconi M, Consensus on circulatory shock and hemodynamic monitoring. Task force of the European Society of Intensive Care Medicine. <i>Intensive Care Med</i>. 2014 Dec;40(12):1795-815. doi: 10.1007/s00134-014-3525-z. Epub 2014 Nov 13. 4. Ackland GL, Iqbal S, Gallego Paredes L, Toner A, Lyness C, Jenkins N, Bodger P, Karmali S, Whittle J, Reyes A, Singer M, Hamilton M, Cecconi M, Pearse R, Mallett SV, Omar Z Individualised oxygen delivery targeted haemodynamic therapy in high-risk surgical patients: a multicentre, randomised, double-blind, controlled, mechanistic trial 2015 Jan;3(1):33-41. doi: 10.1016/S2213-2600(14)70205-X	

5. **Cecconi M**, Aya Bernal DH, Geisen M, Ebm C, Fletcher N, Grounds RM, Rhodes A Changes in mean systemic filling pressure during a fluid challenge in post surgical intensive care patients. ICM April 2013
6. **Cecconi M**, Corredor C, Arulkumaran N, Abuela G, Ball J, Grounds RM, Hamilton M, Rhodes A. Clinical review: Goal directed therapy-what is the evidence in surgical patients? The effect on different risk groups Crit Care 2012, 17:209 (5 March 2013)
7. **Cecconi M**, Fasano N, Langiano N, Divella M, Costa MG, Rhodes A, Rocca GD. Goal-directed haemodynamic therapy during elective total hip arthroplasty under regional anaesthesia. Crit Care. 2011;15(3):R132. Epub 2011 May 30.
8. Hamilton MA, **Cecconi M**, Rhodes A. A systematic review and meta-analysis on the use of preemptive hemodynamic intervention to improve postoperative outcomes in moderate and high-risk surgical patients. Anesth Analg. 2011 Jun;112(6):1392-402.
9. Rhodes A, **Cecconi M**, Hamilton M, Poloniecki J, Woods J, Boyd O, Bennett D, Grounds RM: Goal-directed therapy in high-risk surgical patients: a 15-year follow-up study. *Intensive Care Med* 2010, 36(8):1327-1332.
10. **Cecconi M**, Rhodes A, Poloniecki J, Della Rocca G, Grounds RM Bench-to-bedside review: The importance of the precision of the reference technique in method comparison studies – with specific reference to the measurement of cardiac output. Crit Care 2009, Jan 13:13(1):201 [Epub ahead of print]

This is a small selection of publications

Signature:	Date:
	28/01/2016

Dr David A Brealey

BSc, PhD, MRCP, FRCA, FFICM

Curriculum Vitae

August 2014

Consultant in Intensive Care Medicine and

Anaesthesia

University College Hospital

A handwritten signature in black ink, appearing to be 'DB', with a long horizontal stroke extending to the right.

13 NOV 14

Personal Details and Qualifications

Personal Details

Address: Hampermill Cottage, Hampermill Lane, Watford
Home telephone: 01923 819 525
Mobile: 07941 054624
E mail: david.brealey@uclh.nhs.uk

Professional Bodies

GMC: N° 4096436
Royal College of Anaesthetists: N° 634010
Intensive Care Society since 1998

Personal Profile

Clinician with a diverse range of skills and expertise. Proven track record in biomedical research, anaesthesia, intensive care and acute medicine.

Qualifications

2011 **FFICM**
2006 **FRCA**
2004 **PhD** (Clinical Medicine) University of London
1997 **MRCP** London
1994 **MB BS** University College London Medical School
1991 **BSc** (2:1) Cellular Pathology, University College London

Awards

2012 **Local clinical excellence award, level 1**
2003 **Intensive Care Society** runner-up, Research Gold Medal
1999 **London Intensive Care Group** Travel Scholarship

Current Position

Consultant (substantive) in Anaesthesia and Intensive Care Medicine
University College Hospital, London: Dec 2010 – present:

Trust Lead

NIHR portfolio adopted critical care and anaesthesia research across the trust

Departmental Lead

- Critical Care Clinical Research: I successfully lead an expanding team of research nurses to attract and deliver a wide ranging portfolio of clinical trials.
- Hyper Acute Stroke Unit (HASU): I lead a highly interventional critical care response relating to the critically ill stroke patient in the UKs busiest HASU. The critical care outcomes have become some of the best within Europe
- Patient Emergency Resuscitation Response Team (PERRT): I aided the merging of the resuscitation and PERT services with the generation of a new nursing lead. During this period there has been a 50% reduction in avoidable cardiac arrests within UCH.
- Organ donation and Emergency Department link.

Research Activity

Clinical Trials

I lead the highly successful Critical Care Clinical Trials Team. I have expanded the team from 2 to 5.3 research nurses and created a 7 day/week presence. Over the past two years we have run 14 protocols, recruiting over 400 patients/year. We have expertise in early phase work with medicinal products and monitoring devices. This expansion has enabled:

- Central East London Research Network to become the highest recruiting critical care network in the UK. A 70% increase in recruits to portfolio studies in the last year
- The team to be recognized within the Trust as a high performing area, I now lead the Critical Care and Anaesthesia research hub
- Recognized as a research active area involved in experimental medicine within the CBRC

The research programme involves a high proportion of experimental medicine studies and funding is obtained from academic/charitable grants, NIHR, CBRC and industry. We pride ourselves on high recruitment rates and high data quality.

I work with commercial and academic sponsors on:

- Advisory Boards (GSK, Abbott, ImmunExpress, Defence Science and Technology Laboratory)
- Protocol design
- IRAS submissions
- Representation at ethics committee meetings

I am **Principal Investigator** on:

- **POPPI**. psychological support in the critically ill (in set-up)
- **LeoPARDS**. Phase 2b trial of Levosimendan in septic shock
- **Pelorus**. A pharmacokinetic study of propofol in the critically ill
- **CIGMA**. First in patient study of immunoglobulin in severe community acquired pneumonia

- **ProMISe**. Protocolised Management in Sepsis. A national, NIHR funded study of early goal directed therapy in sepsis.
- **CALORIES**. An open randomised trial to assess the clinical and cost effectiveness of enteral versus parenteral feeding in critically ill patients. Our recruitment rates are in the top 10% within the UK (in close down)
- **OASIS**. A randomised placebo, controlled trial of recombinant Talactoferrin in severe sepsis. UCH was the only UK site to recruit to this study.
- **RADICAL**. An observational study investigating the utility of a new rapid pathogen detection system
- **CAP-ARDS**. an academic observational study investigating the role of proteinases in ARDS

I am **Co-Investigator** on:

- **SPOT(id)**. Observational study investigating trajectory of illness in patients with pneumonia and receiving chemotherapy. A cross theme/BRC cutting project, part commercially funded.
- **HALT-IT**. Phase 3 study of tranexamic acid in gastrointestinal bleeding
- **Immune modulators in early sepsis**. An investigation of potential new biomarkers for sepsis.
- **PREVENTT**: a randomised, placebo controlled study of intravenous iron in anaemic patient prior to major surgery
- **Stress**. Relationship between physical and psychological stress on the critical care unit
- **OSCAR**. High frequency versus conventional ventilation in acute lung injury, UCH being the second highest recruiting site within the UK (finished 2012)
- **GAINS**. Genomics in sepsis (finished 2013)
- **Zanamivir**. Commercial, open label phase II study of iv zanamavir in patients with influenza A. Highest recruiting unit in UK (finished April 2012)

Other Current Projects

NIHR Critical Care Health Informatics Collaborative. I co-lead a team of investigators aiming to link routine clinical data from the five CBRCs, to improve clinical and research outcomes.

Assessment of the Deltex Combi Oesophageal Doppler Monitor. A new device combining pulse contour/pulse power analysis and oesophageal Doppler cardiac output monitoring

Investigation of ubiquinone levels in critically ill patients on statins.

Investigation of the impact of simvastatin on ubiquinone in critically ill patients and a septic animal model. A collaboration Neurometabolic Laboratory at National Hospital for Neurology and Neurosurgery and with Queens University, Belfast.

Future Projects

SOAP-BOX: Surrogate of Adequate Perfusion – Bladder Oxygenation, first time in man investigation of a new monitoring device developed at UCL (Prof Singer). Fully funded awaiting regulatory approval..

Haemabsorption in septic shock: in conjunction with CytoSorbents GmbH (Berlin) and Michael Bauer (Jena University), I am developing a multi-centre trial to examine the effects of haemabsorption on this group of patients

Interventional study on oral health. A collaboration with the Eastman Dental Institute (Prof Needleman) following a successful observational study, in early design stage.

Translational and Basic Science Experience

For my PhD thesis, I was the first to demonstrate mitochondrial dysfunction in human sepsis and relate this to outcomes. This markedly changed the perception of the intensive care community's view of the pathogenesis of the associated organ dysfunction (*Brealey DA. Lancet 2002*). In tandem, I developed a unique long-term animal model of sepsis and organ dysfunction (*Brealey DA. Am J Physiol. 2004*). This verified my findings in the patients and continues to be used for the investigation of potential therapeutic compounds.

Previous Clinical Positions: Intensive Care

Step 2

University College Hospital: Feb 2009- Aug 2009

Guy's and St Thomas' Hospitals: Aug 2008-Feb 2009

Step 1

Royal Free Hospital: Sept 2006 – Dec 2006.

North Middlesex University Hospital: June 2005 – Sept 2005

Clinical Lecturer Intensive Care Medicine

University College Hospitals, London: June 1998 – Mar 2003

Experience

I am proficient in a wide range of advanced monitoring, organ support techniques and non-clinical skills, with particular expertise in:

- ARDS and sepsis
- High risk general surgery
- Haem-oncology
- Neurosurgical and neuromedical
- Cardio-thoracic

Previous Clinical Positions: Anaesthesia

SpR Rotation:

North Thames Central School of Anaesthesia: May 2003 – December 2010.

SHO Rotation:

A two year rotation with the Central London School of Anaesthesia, including Royal Free, Barnet and Lister, Stevenage Hospitals, June 2003 – June 2005. A stand alone post at Ealing Hospital, October 1997-June 1998

Previous Clinical Positions: Medicine

A two year SHO rotation at Harefield, Edgware and Barnet Hospitals: August 1995-August 1997.

Teaching

Organisation

I organise the local Critical Care weekly academic meeting and deliver bed-side teaching to medical students and junior doctors in anaesthesia and intensive care.

National and International Courses

I have taught on:

1. **RCoA annual and regional conferences**, 2011, 2012, 2013
2. **An Introduction to ICU for Industry**, 2012, 2013
3. **UCL Introduction to Intensive Care**. 2011, 2012, 2013
4. **UCL Critical Care Masterclass**: 2011, 2013
5. **Masterclass for Critical Care Pharmacists**: 2011
6. **European Soc. Intensive Care Medicine, Summer School, Brijuni**: 2011
7. **UCH FRCA Pt 1 and Finals course**. OSCE examiner, 2010 and 2009
8. **UCL Medical Emergencies Course for Trainee Doctors: 2001 - 2014**
9. **St Thomas' MRCS course**. OSCE examiner, Feb and April 2009, Feb 2010
10. **Medical Emergencies Course**. London, Birmingham and Manchester. Management of Sepsis, 2006
11. Courses aimed at members of industry, nursing, physiotherapy on a diverse array of subjects including blast injuries, oxygen delivery and introduction to intensive care, 1999-2014

Original Papers

1. Sachdev M, Ready D, **Brealey D**, *et-al*. Changes in dental plaque following hospitalisation in a critical care unit: an observational study. *Crit Care*. 2013; 17: 189.
2. Marty FM, Man CY, van der Horst C, Francois B, Garot D, Mánez R, Thamlikitkul V, Lorente JA, Alvarez-Lerma F, **Brealey D**, *et-al*. Safety and Pharmacokinetics of Intravenous Zanamivir Treatment in Hospitalized Adults with Influenza: An Open-label, Multicenter, Single-Arm, Phase II Study. *J Infect Dis*. 2013
3. Needleman I, Hyun-Ryu J, **Brealey D**, *et-al*. The impact of hospitalization on dental plaque accumulation: an observational study. *J Clin Periodontol*. 2012
4. Atlas G, **Brealey D**, Dhar S, *et-al*. Additional hemodynamic measurements with an esophageal Doppler monitor: a preliminary report of compliance, force, kinetic energy, and afterload in the clinical setting. *J Clin Monit Comput*. 2012
5. Taylor CJ , Robertson F, **Brealey D**, *et-al*. Outcome from endovascular coiling of aneurysms in poor grade subarachnoid haemorrhage patients. Accepted for publication *Neurocritical Care*. 2010.
6. Svistunenko DA, Davies N, **Brealey D**, *et-al*. Mitochondrial dysfunction in patients with severe sepsis: an EPR interrogation of individual respiratory chain components. *Biochim Biophys Acta*. 2006; 175: 262-72.
7. Davies NA, **Brealey DA**, Stidwill R, *et-al*. Nitrosyl heme production compared in endotoxemic & hemorrhagic shock. *Free Radic Biol Med*. 2005;38:41-9.
8. Rabuel C, Renaud E, **Brealey D**, *et-al*. Human septic myopathy: induction of cyclooxygenase, heme oxygenase and activation of the ubiquitin proteolytic pathway. *Anesthesiology*. 2004;101:583-9.

9. **Brealey D**, Karyampudi S, Jacques TS, *et-al*. Mitochondrial dysfunction in a long-term rodent model of sepsis and organ failure. *Am J Physiol Regul Integr Comp Physiol*. 2004;286:R491-7.
10. **Brealey DA**, Brand M, Hargreaves I, *et-al*.
Association between mitochondrial dysfunction and severity and outcome of septic shock. *Lancet*. 2002; 360: 219-223.
11. Venn RM, Bradshaw CJ, Spencer R, **Brealey D**, *et-al*.
Preliminary UK experience of dexmedetomidine, a novel agent for postoperative sedation in the ICU. *Anaesthesia*. 1999; 54: 1136-42.

Books and Reviews

1. **Brealey DA**, Hirsch N. Guillain-Barré Syndrome. Commissioned by Anaesthesia.
2. Singer M, **Brealey D**. Another nail in the hammer's coffin? *Crit Care*. 2011
3. The Handbook of Clinical Anaesthesia, 3rd Edition. Editor: Brian Pollard:
Anaesthetic considerations for:
 - Primary neuromuscular diseases
 - Neuromuscular Junction Disorders
 - Polyneuropathies.
4. **Brealey DA**, Singer M, Terblanche M. Metabolic consequences of statin therapy in the critically ill. *Critical Care Medicine* 2011.
5. **Brealey DA**, Singer M. So you want to be...a critical care physician. *Br J Hosp Med*. 2010.
6. **Brealey DA**, Singer M. Hyperglycemia in Critical illness. *J Diabetes Sci Technol*. 2009.
7. **Brealey DA**, Singer M. Mitochondrial Dysfunction in Sepsis. *Curr Infect Dis Rep*. 2003.

8. **Brealey DA**, Singer M. Cytopathic dysoxia revisited. Crit Care and Shock. 2002; 5: 1-10.
9. **Brealey DA**, Singer M. Multi organ dysfunction in the critically ill: epidemiology, pathophysiology and management. J R Coll Phys Lond 2000. 34: 424-427.
10. **Brealey DA**, Singer M. Multi organ dysfunction in the critically ill: effects on different organs. J R Coll Phys Lond. 2000. 34: 428-431.
11. Singer M, **Brealey DA**. Mitochondrial dysfunction in sepsis. Biochem Soc Symp. 1999; 66: 149-166.
12. **Brealey DA**, Singer M. Tissue oxygenation in sepsis. Sepsis. 1998; 2: 291-302.

National & International Presentations

1. Stroke – not as bad as you think. Invited speaker, State of the Art, Intensive Care Society Annual Meeting. London 2013
2. Plasma ubiquinone levels are unaffected by simvastatin in acute lung injury. European Society of Intensive Care Medicine. Lisbon 2012
3. The axonal variant of severe Guillain-Barré syndrome (GBS) is associated with prolonged ICU stay and long-term disability. Intensive Care Society. London 2010.
4. Reasons for delay in transferring patients with head injury to a neurosurgical centre. Neuroanaesthesia Society of Great Britain and Ireland. Bristol, 2005.
5. Sepsis induced organ dysfunction—a failure of mitochondrial respiration? Intensive Care Society, London, 2004.
6. Soho pub bomb. Herts and Beds Anaesthetic Society, 2003.
7. Recovery from organ failure is associated with improved mitochondrial function in septic patients. European Society of Intensive Care Medicine, Amsterdam, 2003.

8. Mitochondrial dysfunction in a rodent model of sepsis and multi organ dysfunction. European Society of Intensive Care Medicine, Barcelona, 2002.
9. iNOS expression & peroxynitrite production is associated with mitochondrial dysfunction in skeletal muscle of severe sepsis. European Society of Intensive Care Medicine, Barcelona. 2002.
10. Invited speaker: Mitochondrial dysfunction and sepsis. Intensive Care Society, Edinburgh, 2002.
11. Mitochondrial inhibition is associated with the severity of human septic shock. European Society of Intensive Care Medicine, Geneva, 2001.
12. Muscle ATP levels in early septic shock predict outcome. European Society of Intensive Care Medicine. Rome, 2000.
13. Mitochondrial dysfunction in human septic shock. European Society of Intensive Care Medicine, Berlin, 1999.
14. Mitochondrial dysfunction in human septic shock. Intensive Care Society. London, 1998.

Interests

Now the father of three small children, but when the opportunity arises I enjoy snowboarding, horse riding, windsurfing and alpine mountaineering (Summits include Mont Blanc, Monch and Weismiess).

CURRICULUM VITAE

Name:	
Dr Christopher Thompson	
Present appointment: <i>(Job title, department, and organisation.)</i>	
Consultant in Renal and Intensive Care Medicine	
Address: <i>(Full work address.)</i>	
University Hospitals of North Midlands NHS Trust Royal Stoke University Hospital, Newcastle Road, Stoke-on-Trent, ST4 6QG	
Telephone number:	Email address:
01782676346 or 01782675500	christopher.thompson@uhns.nhs.uk
Qualifications:	
MBChB 1996 (Dundee), MRCP(UK)2000	
Professional registration: <i>(Name of body, registration number and date of registration.)</i>	
Date of registration: 07/1996	
GMC number: 4315483	
GMC Specialties: Intensive Care Medicine Renal Medicine General Internal Medicine	
Previous and other appointments: <i>(Include previous appointments in the last 5 years and other current appointments.)</i>	
Consultant in Renal and Intensive Care Medicine 05/07 - date, University Hospital of North Midlands NHS Trust, Royal Stoke University Hospital Newcastle Road Stoke-on-Trent ST4 6QG	
Research experience: <i>(Summary of research experience, including the extent of your involvement. Refer to any specific clinical or research experience relevant to the current application.)</i>	
Research "D-dimers and Microalbuminuria in Critical Illness" conducted UHNS 2006-2007. LREC approval granted, completed, Abstract Published Journal of Intensive care Society. UHNH PI for Swine flu triage Study (study closed recruited 21 patients) UHNH PI and Member of trial Steering committee Eurotherm3235 (Closed to recruitment - ongoing) UHNH Co-investigator CRASH3 study (Open) UHNH PI European Surgical Outcomes Study (closed) UHNH PI ISARIC Pandemic Flu study (Hibernating) UHNH Co-investigator ASAP Pandemic Flu study (Hibernating) UHNH PI DIRECT Acute kidney injury Study (Open Recruiting – ongoing) UHNH PI Accusol 35 Post-authorisation Safety Study Protocol: Study 8822-001 (Industry in set-up) Co-lead WMN CLRN Critical Care CSG 12/09 to 12/2013.	
Research training: <i>(Details of any relevant training in the design or conduct of research, for example in the Clinical Trials Regulations, Good Clinical Practice, consent or other training appropriate to non-clinical research. Give the date of the training.)</i>	
ICR eLearning module Principles of ICH GCP completed 03/07/2009 UHNS Principles of ICH GCP update 10/2013	

Relevant publications: <i>(Give references to all publications in the last two years plus other publications relevant to the current application.)</i>	
nil	
Signature:	Date:
	23/12/14

Curriculum Vitae

Family name:	Welters
First names:	Ingeborg Dorothea Maria
Date of birth:	22 nd February 1968
Place of birth:	Bonn, Germany
Nationality:	German

Academic distinctions:

10/2009:	Honorary Professor in Anaesthesia and Intensive Care, Justus-Liebig-Universität, Giessen, Germany
02/2002	Assistant Professor in Anaesthesia and Intensive Care Justus-Liebig-Universität Giessen, Germany

Academic degrees:

05/2008	Master of Arts	Management of Health Care Organisations (honours)
01/2002	PhD (Habilitation)	Thesis: Effects of morphine, fentanyl, and ketamine on leukocyte function and gene transcription
05/1996	MD (Dr. med.)	Thesis: Haemostatic and immunologic changes during heart surgery: Influence of different priming solution, age, and gender
11/1993	State Exam Med	Justus-Liebig-Universität Giessen, Germany

Education:

1987 – 1993	Medical School	Justus-Liebig-Universität, Giessen, Germany

Grants, Fellowships and Awards

11/2010 and 4/2014	Clinical Excellence Award	Royal Liverpool and Broadgreen University Hospitals, NHS Trust
11/2003	Travel Grant	Oxford Radcliffe Hospitals NHS Trust
06/2003 – 10/2003	Clinical Research Fellow	John Radcliffe Hospital, University of Oxford, UK
11/1999 – 06/2000	Senior Research Scientist	Mind/Body Medical Institute Harvard Medical School, Boston, MA, USA
06/1999 – 05/2000	German Research Council	Neuroscience Research Institute State University of New York Old Westbury, NY, USA
09/1998 – 12/1998	NIH Fogarty Fellowship	Neuroscience Research Institute State University of New York Old Westbury, NY, USA

Specialist Training and professional activities

Since 10/2005	Senior Clinical Lecturer and Honorary Consultant, School of Clinical Science, University of Liverpool, UK
12/ 2003 – 09/2005	Consultant in Anaesthesia and Cardiac Anaesthesia Department of Anaesthesia and Intensive Care Justus-Liebig-Universität, Giessen, Germany
06/2003 – 10/003	Clinical Research Fellow in Intensive Care Medicine John Radcliffe Hospital, University of Oxford
10/2001 – 04/2003	Advanced training in Cardiac Anaesthesia, Department of Anaesthesia and Intensive Care, Justus-Liebig-Universität, Giessen, Germany
06/2000 – 04/2003	Consultant Anaesthesiologist, Department of Anaesthesia and Intensive Care, Justus-Liebig-Universität, Giessen, Germany
06/1999 – 05/2000	Visiting Scholar, State University of New York
06/1999	Accreditation as Specialist for Anaesthesiology
12/1993 – 05/1999:	Specialist training in Anaesthesiology Department of Anaesthesia and Intensive Care Justus-Liebig-Universität, Giessen, Germany

Funded Research Projects:

Since 2014 (Co-Investigator)	British Heart Foundation, (230 000 £) The Role of Circulating Histones in the Cardiac Dysfunction of Sepsis.
2011-2012: (Co-Investigator)	National Institute of Health Research, Biomedical Research Centre (165 000 £) A Prospective Study of the aPTT Waveform and Lipoprotein- Complexed C Reactive Protein Assays in the Early Diagnosis and Prognosis of Sepsis
2009-2011: (Principal Investigator)	National Institute of Health Research (200 000 £) Plasma GLP-1 and GIP levels in sepsis/SIRS patients with acute necrotising pancreatitis" (Part of BRU application)
2008 - 2010: (Co-Investigator)	National Institute of Health Research, Biomedical Research Centre (330 000 £) A Prospective Study of the aPTT Waveform and Lipoprotein- Complexed C Reactive Protein Assays in the Early Diagnosis and Prognosis of Sepsis
2007 - 2009: (Principal Investigator)	Mersey School of Anaesthesia (13 833 £) Toll-like receptor expression during cardiac surgery
2006 - 2007: (Principal Investigator)	University of Liverpool R&D Fund (6000 £) Influence of Activated Protein C in Free or Microparticulate Form on Endothelial Protein C Receptor Expression and Function in Neutrophils
1999 – 2001: (Principal Investigator)	B. Braun, Melsungen (50 000 DM, ca. 25 000 £) Colloids and neutrophil function
1999 – 2000: (Principal Investigator)	German Research Fund (DFG) (68 000 DM, ca. 34 000 £) NF- κ B in Opioid-mediated immune modulation
1996 – 2000: (Principal Investigator)	Yamanouchi Pharma, (28 000 DM, ca. 14 000 £) Postoperative vomiting in children
09/98 – 12/1998: (Co-Investigator)	Fogarty Fellowship, National Institute of Health (5000 USD) Nitric Oxide and calcium as second messengers in opioid- induced immune changes

Patents:

- 2008: Endogenous morphine or a naturally occurring metabolite thereof as a marker for infection
2012: Use of Serum or Lithium Heparinate Plasma for the Measurement of Endogenous and Exogenous Morphine Levels

Additional Clinical Qualifications:

- 2005 Subspecialty training in Emergency Medicine (Weiterbildung Notfallmedizin, Germany)
2005 Subspecialty training in Pain Medicine (Weiterbildung Schmerztherapie, Germany)
2004 European Diploma of Intensive Care Medicine (EDIC)
2004 Subspecialty training in Intensive Care (Spezielle Anästhesiologische Intensivmedizin)
2003 Transoesophageal Echocardiography (German Society for Anaesthesia and Intensive Care)

Current Professional Memberships:

DGAI (German Society of Anaesthesia and Intensive Care Medicine)
ESICM (European Society of Intensive Care Medicine)
ICS (Intensive Care Society)
BMA (British Medical Association)

Main publications as First or Senior Author:

1. Steele T, Kolamunnage-Dona R, Downey C, Toh CH, Welters I. Assessment and clinical course of hypocalcemia in critical illness. Crit Care. 2013 Jun 4;17(3):R106
2. Welters ID, Gibson J, Mogk M, Wenstone R. Major sources of critical incidents in intensive care. Crit Care. 2011;15(5):R232.
3. Welters ID, Feurer MK, Preiss V, Müller M, Scholz S, Kwapisz M, Mogk M, Neuhäuser C. Continuous S-(+)-ketamine administration during elective coronary artery bypass graft surgery attenuates pro-inflammatory cytokine response during and after cardiopulmonary bypass. Br J Anaesth. 2011 Feb;106(2):172-9. Epub 2010 Dec 7
4. Glattard E, Welters ID, Lavaux T, Muller A, Zhang D, Laux A, Schmidt AR, Delande F, Colin DA, Van Dorselaer A, Aunis D, Metz-Boutigue MH, Schneider F, Goumon Y. Endogenous Morphine Levels are Increased in Sepsis. PlosOne 2010 Jan 20;5(1):e8791
5. Welters ID, Hafer G, Menzebach A, Mühling J, Neuhäuser C, Browning P, Goumon Y. Ketamine inhibits transcription factors AP-1 and NF- κ B, IL-8 production, as well as CD11b and CD16 expression: Studies in human leukocytes and leukocytic cell lines. Anesth Analg 2010;110:934-41
6. Neuhäuser C, Preiss V, Feurer MK, Müller M, Scholz S, Kwapisz M, Mogk M, Welters ID. Comparison of S-(+)-ketamine- with sufentanil-based anaesthesia for elective coronary artery bypass graft surgery: effect on troponin T levels. Br J Anaesth. 2008;100:765-71
7. Welters ID, Menzebach A, Goumon Y, Langefeld TW, Harbach H, Mühling J, Cadet P, Stefano GB. Morphine inhibits AP-1 activity and CD14 expression in leukocytes by a nitric oxide and opioid receptor dependent mechanism. Eur J Anaesth 2007;24:958-65
8. Harbach H, Hempelmann G, Matejec R, Langefeld TW, Menzebach A, Welters ID. Funktionelle Bedeutung von ACTH und β -Endorphin für die Proopiomelanocortin- und Immunantwort bei Stress. Anaesth Intensivmed 2007;11:592-603
9. Welters ID, Hirsch J, Menzebach A, Hempelmann G, Müller M. Activation of granulocytes and antiproteases in open heart surgery. Anesthesiol.Intensivmed.Notfallmed.Schmerzther. 2005;40:164-72.
10. Menzebach A, Hirsch J, Nöst R, Mogk M, Hempelmann G, Welters ID. Morphine inhibits complement receptor expression, phagocytosis and oxidative burst by a nitric oxide dependent mechanism. Anesthesiol.Intensivmed.Notfallmed.Schmerzther. 2004;39:204-11.

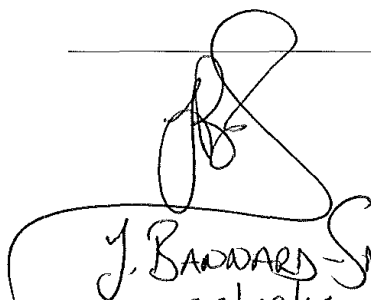
Liverpool, 23.November 2014

J. Welters

DR. JONATHAN BANNARD-SMITH
MB ChB FRCA FFICM

Curriculum Vitae

March 2015



J. BANNARD-SMITH
05/03/15.

CONTENTS

Personal Details	3
Career Aspirations	4
Qualifications	5
Current Employment	5
Previous Employment	6-9
International Experience	10
Pre-hospital Care Experience	10
Practical Skills	11
Audit	12
Research	13
Teaching	14
Management & Service Development	15
Publications	16
Prizes	17
Oral Presentations & Workshops	17
Poster Presentations	18
Courses	19
Personal Statement	20
Referees	21

PERSONAL DETAILS

Name:	Dr. Jonathan Paul Bannard-Smith
Address:	265, Manchester Road, Heaton Chapel, Stockport, Cheshire, SK4 5EB UNITED KINGDOM
Telephone:	+44 (0)7887 622992
Email:	jonbannardsmith@doctors.org.uk
Date of Birth:	26 th May 1980
Place of Birth:	Chichester, England
Nationality:	British
Marital Status:	Married
General Medical Council registration number:	6105314 (Full registration)
Date of entry to specialist register:	1 st August 2013 (Dual-CCT in Intensive Care Medicine & Anaesthesia)
Postgraduate Fellowships:	Royal College of Anaesthetists (FRCA) Faculty of Intensive Care Medicine (FFICM)
Other Memberships:	European Society of Intensive Care Medicine Intensive Care Society Association of Northwest Intensive Care Units (ANWICU)

QUALIFICATIONS

Primary Medical Degree:

MB ChB: University of Manchester, July 2004

Fellowship of the Royal College of Anaesthetists (FRCA):

Final FRCA: Passed June 2009 (1st attempt)

Primary FRCA: Passed October 2007 (1st attempt)

Fellowship of the Faculty of Intensive Care Medicine (FFICM, inaugural exam sitting):

Final FFICM MCQ: Passed January 2013 (1st attempt)

Final FFICM OSCE & SOE: Passed March 2013 (1st attempt)

Postgraduate Certificate in workplace based postgraduate medical education (PGCert):

Edge Hill University, June 2012 – 60 masters credits, passed with merit.

CURRENT EMPLOYMENT

Consultant in Critical Care & Anaesthesia – Manchester Royal Infirmary, Central Manchester University Hospitals, Oxford Road, Manchester M13 9WL

PREVIOUS EMPLOYMENT

Aug 2013 - Aug 2014

Austin Hospital, Melbourne, Australia - Clinical Research Fellowship

Research Supervisor: Prof Rinaldo Bellomo

I worked as a senior fellow in a large 20 bed ICU offering specialists services in Liver failure and transplantation and spinal cord injuries for the states of Victoria and Tasmania. I completed an observational study into the physiological responses to fluid bolus therapy. I gained experience in the collaborative approach to conducting large clinical studies utilised by members of the Australia and New Zealand Intensive Care Society Clinical Trials Group. This invaluable experience has assisted me leading research as a consultant and provide an insight into strategic healthcare developments, such as the centralised provision of 24/7 services and the introduction of medical emergency teams.

PREVIOUS EMPLOYMENT Ctd.

Nov 2011 – Feb 2012

Manchester Royal Infirmary, Specialist Registrar Anaesthesia (ST6)

Educational supervisor: Dr P Foster

Aug 2011 - Nov 2011

Royal Manchester Children's Hospital, Specialist Registrar Anaesthesia (ST6)

Educational supervisor: Dr D Fines

Nov 2010 – Aug 2011

Royal Blackburn Hospital, Specialist Registrar Anaesthesia (ST5)

Educational supervisor: Dr D Watson

Aug 2010 - Nov 2010

Royal Blackburn Hospital, Specialist Registrar Intensive Care (2nd Intermediate block)

Educational supervisor: Dr S Clarke

May 2010 – Aug 2010

Stepping Hill Hospital, Specialist Registrar Anaesthesia (ST4)

Educational supervisor: Dr S Latif

Feb 2010 – May 2010

Stepping Hill Hospital, Specialist Registrar Intensive Care (1st Intermediate block)

Educational supervisor: Dr L Evans

Aug 2009 – Feb 2010

University Hospitals South Manchester, Specialist Registrar Anaesthesia (ST4)

Educational supervisor: Dr G Briggs

May 2009 – Aug 2009

University Hospitals South Manchester, Specialist Registrar Cardiothoracic Anaesthesia (ST3)

Educational Supervisor: Dr A Szabo-Barnes

Feb 2009 - May 2009

Rotation between: Royal Manchester Children's Hospital Pendlebury, Booth Hall Hospital & St Mary's Hospital, Specialist Registrar Paediatric Anaesthesia (ST3)

Educational Supervisor: Dr R Vashisht

Nov 2008 - Feb 2009

Stepping Hill Hospital, Specialist Registrar Obstetric Anaesthesia (ST3)

Educational Supervisor: Dr C Hardy

Aug 2008 – Nov 2008

Hope Hospital, Specialist Registrar Neuroanaesthesia (ST3)

Educational Supervisor: Dr P Eadesforth

Aug 2007 – Aug 2008

Royal Oldham Hospital, Specialist Trainee Anaesthesia (ST2)

Including 3 months secondment in Acute Medicine at Fairfield General Hospital, Bury.

Educational Supervisors: Dr A Richards (Anaesthesia), Dr Raw (Acute Medicine)

Feb 2007 - Aug 2007

Royal Blackburn Hospital, Senior House Officer Anaesthesia

Educational Supervisor: Dr R Emmott

Nov 2006 – Feb 2007

Burnley General Hospital, Senior House Officer Intensive Care (Basic level training)

Educational Supervisor: Dr S Price

PREVIOUS EMPLOYMENT Ctd.

Feb 2006 – Nov 2006

Burnley General Hospital, Senior House Officer Anaesthesia

Educational Supervisor: Dr C Calow

Aug 2005 – Feb 2006

Royal Oldham Hospital, Senior House Officer Accident & Emergency

Educational Supervisor: Dr S Derbyshire

Aug 2004 – Aug 2005

Royal Oldham Hospital, House Officer

Educational Supervisors: Dr I Brocklehurst, Mr A Rate, Dr S Solomon

A 12 month pre-registration post comprising 3 x 4 months in: Anaesthetics & Intensive Care,
Colorectal Surgery and General Medicine/Haematology

PRACTICAL SKILLS

I have extensive skills and experience enabling me to perform the following independently and completely (from explanation, consent, performance and management of complications):

Advanced airway management

- Supraglottic airway devices
- Endotracheal intubation
- Fiberoptic intubation (awake and asleep)
- Percutaneous tracheostomy
- Cricothyroidotomy (emergency and elective)
- Video laryngoscopy

Intravascular access

- Peripheral intravenous cannulation (including ultrasound guided)
- Central venous cannulation (internal jugular, subclavian, axillary and femoral)
- Pulmonary artery catheter
- Peripherally inserted central catheter (PICC line)
- Arterial line insertion (radial, brachial, femoral and dorsalis pedis)

Cardiorespiratory

- Bronchoscopy (diagnostic and therapeutic)
- Thoracic ultrasound (diagnostic and guided drain insertion)
- Transthoracic echocardiography (FATE accredited & FICE accreditation pending)
- Use of cardiac output monitors (bio-impedance, arterial waveform analysis and oesophageal Doppler)

Regional anaesthesia

- Neuraxial blockade (lumbar spinal, paravertebral, thoracic and lumbar epidural)
- Ultrasound guided peripheral nerve blocks (ankle, femoral, interscalene, supraclavicular, axillary)
- Thoraco-abdominal blocks (ilioinguinal, trans-abdominal plane, rectus sheath, intercostal)

INTERNATIONAL EXPERIENCE

- ❶ **Mure Memorial Hospital, Nagpur, India. Jan 2012:** As part of a charitable team of 42 surgeons, anaesthetists and nurses, we performed cleft lip and palate surgery on 102 patients. This intriguing experience required dedicated enthusiasm and effective teamwork in order to safely achieve our objectives with relatively limited resources available.
- ❷ **Colombo General Hospital & Lady Ridgewell Hospital for Women and Children, Colombo, Sri Lanka. Jan-March 2004:** During my final year as an undergraduate I spent 8 weeks at Sri Lanka's largest government funded hospitals. Here I witnessed healthcare delivery in a third world setting and a variety of tropical pathology rarely seen in the UK.
- ❸ **Hospital for Sick Kids, Toronto, Canada. June 2002:** During a summer break at medical school I spent three weeks as a student on a paediatric respiratory firm. The team's principle interest was asthma and allergy medicine, but also had daily involvement with children suffering with respiratory disease on the paediatric ICU.

PRE-HOSPITAL CARE EXPERIENCE

- ❶ **Professional Beauty National Show. Manchester Central Exhibition Centre, October 2012:** I provided statutory medical cover for this beauty industry event. My principle role was to regulate and ensure best practice guidelines were achieved with regard to infection control precautions taken during invasive procedures.
 - ❷ **Blenheim Palace International Horse Trials. Oxfordshire, September 2012:** I led a team of paramedics, emergency medicine doctors and veterinary practitioners in order to ensure the safety and good health of professional athletes, their horses and spectators at this international sporting event.
-

CLINICAL GOVERNANCE: AUDIT PROJECTS

- ❶ The use and compliance with the World Health Organisation Surgical Safety Checklist. Manchester Royal Infirmary, March-April 2013
 - ❷ The use of sedation holds and scores in critical care: An audit of practice against a trial protocol. Manchester Royal Infirmary, April 2012 & re-audit January 2013
 - ❸ The influence of transverse abdominal plane (TAP) blocks on the duration of hospital stay following laparoscopic colorectal surgery in an enhanced recovery programme. Royal Blackburn Hospital, July 2011
 - ❹ Epidural failure and a rescue protocol: influence on hospital stay in a colorectal enhanced recovery programme. Royal Blackburn Hospital, July 2011
 - ❺ Early versus late renal replacement therapy in patients with acute kidney injury. Royal Blackburn Hospital, May 2011
 - ❻ Scrubbing up: are trainee anaesthetists formally taught in the UK? National Survey, May 2010.
 - ❼ Effect of the 48 hour week on training in Anaesthesia. North West School of Anaesthesia, March 2009
 - ❽ Quality of patient handover on intensive care units in Northwest England. North West School of Anaesthesia, July 2008
 - ❾ The use of transthoracic echocardiography in northwest Intensive Care Units. Regional survey, November 2007
 - ❿ Thromboprophylaxis in patients following caesarean section. Royal Blackburn Hospital, June 2007
 - ⓫ Out-of-hours acute pain referrals to the 1st on-call anaesthetist. Burnley General Hospital, November 2006
 - ⓬ The use of blood products in the management of acute gastrointestinal haemorrhage. Royal Oldham Hospital, September 2005
 - ⓭ Assessment of appropriateness of GP referrals for patients with symptoms suggestive of bowel cancer. Royal Oldham Hospital, February 2005
-

RESEARCH

I am a principal investigator (PI) for:

1. ACCUPASS – A post marketing surveillance study on the use of Accusol 35 solution and the development of precipitate in renal replacement therapy circuits in intensive care
2. VAPRAPID 2 – A multicentred randomised controlled trial of biomarker guided early exclusion of VAP in ventilated intensive care patients

I am a sub-investigator (sub-I) for:

3. LEOPARDS – A multicentred randomised controlled trial of levosimendan versus placebo for the prevention of acute organ dysfunction in sepsis
4. REMPEX - A multicentred randomised controlled trial of a novel antibiotic preparation versus standard care for patients with carbapenemase resistant infections

My previous projects include:

- ❖ Time of hospital admission and its bearing on outcomes for the critically ill
Supervisor: Dr J Eddlestone, Consultant Critical Care & Anaesthesia
 - ❖ Aspirations for Intensive Care Training
Supervisor: Dr M Holland, Consultant Physician Acute Medicine
 - ❖ CPEX measures and hospital stay in patients undergoing major surgery
Supervisor: Dr N Wisely, Consultant Anaesthetist
 - ❖ Trends in lipoprotein profile after renal transplantation: A five-year prospective study
Supervisor: Dr C Short, Consultant Nephrologist
-

TEACHING

Throughout my medical career I have always been heavily interested and involved in education. Nationally I am qualified to teach on a number of life support courses including ALS and APLS. I have presented educational research at national academic meetings.

Regionally I have led workshops for trainers providing effective feedback to their trainees and also a careers day for anaesthetic trainees. I regularly contribute to regional teaching and practice examinations of trainees working towards their FRCA. I am an accredited tutor in problem based learning and have formally co-supervised undergraduate students during their placements in critical care.

Locally I take every opportunity to teach others including allied health professionals and medical staff from other specialities. The demands of providing good clinical care under the pressures of working time directives require a dynamic approach in order to maximise educational opportunities.

In 2009 I was appointed a Deanery Medical Education Fellow. The two year fellowship offered numerous opportunities to develop my knowledge, skills and understanding of the world of medical education. It also presented leadership opportunities as an educator and experience in qualitative research methods. Following completion of the Edge Hill postgraduate certificate I am now formally trained beyond the level of Educational Supervisor as required by the GMC. My particular areas of interest include methods of assessment and curriculum mapping.

PUBLICATIONS: ORIGINAL ARTICLES

1. Bannard-Smith J, Bishop S, Gawne S, Halder N. Twelve Tips for Junior Doctors Interested in Medical Education. *Medical Teacher* 2012; 34(12): 1012-16
2. Bannard-Smith J, Washington SJ, Yuill G. Which Vasopressor for Caesarean Section? *British Journal of Hospital Medicine* 2009; 70(12): 725
3. Bannard-Smith J, Booth CMA, Saha B, Washington SJ. Quality of patient handover on intensive care units in northwest England. *Journal of the Intensive Care Society* 2009; 10(3): 186-188
4. Watts J, Bannard-Smith J. My Modernised Career. *Clinical Leader* 2009; 2(1): 47-8
5. Bannard-Smith J, Campo E, Ho A, Watts J. Modernising my career: the view from inside or a farewell from distant SHOs? *Clinician in Management* 2007; 14(6): 157-162

PUBLICATIONS: LETTERS

6. Bannard-Smith J, Carroll I, Nichani R, Sharma R. Anthrax infection in intra-venous drug users. *Intensive Care Medicine* 2013; 39(3): 530
7. Bannard-Smith J, Mousdale S. Early versus late renal replacement therapy in acute kidney injury: The search for a definition on timing continues. *Critical Care* 2011; 15: 437

-
8. Clayton RA, Bannard-Smith JP, Washington SJ, Wisely N, Columb M, Rees L. Cardiopulmonary exercise testing and length of stay in patients undergoing major surgery. *Anaesthesia* 2011; 66(5): 393-394
 9. Booth CMA, Bannard-Smith J, Tomlinson S. Effect of the 48-hour week on training in anaesthesia. *Anaesthesia* 2009; 64: 915
-

PRIZES

- ❶ Association of Northwest Intensive Care Units (ANWICU) Annual Trainee Prize for Research: 1st Prize for: "*Aspirations for Intensive Care Training in Northwest England*" Bolton, November 2010
 - ❷ Academy of Medical Educators (AoME) Annual Academic Meeting, Poster Competition for Original Educational Research/Audit: 1st Prize for: "*Qualitative evaluation of experiences of the North Western Medical Education Fellows*" London, January 2011
-

ORAL PRESENTATIONS

1. **The Medical Emergency Team: Hospital Outcomes after a Day (METHOD) Study results** – The UK National Outreach Forum, Taunton, Somerset, March 2015
 2. **Physiological Effects of 4% versus 20% Human Albumin Solution for Fluid Bolus Therapy in Critically Ill Adults** – The ICF Research Free Paper Prize, The ICS State of the Art Meeting, London Dec 2014
 3. **Critical Care Nephrology for the FFICM** – A regional study day led by expert speakers for senior critical care trainees from both the North Western and Mersey Deaneries. Manchester Royal Infirmary, June 2013
 4. **Tracheostomies for Critical Care and Ward Staff (Courtesy of the National Tracheostomy Safety Project)** – A simulation based training day for allied health professionals who look after patients with tracheostomies. Royal Preston Hospital, January 2013
 5. **Targeting Trainees: The Supervisors of the Future** – A new initiative to provide all specialist trainees with formal training and accreditation in clinical supervision. Association of Study in Medical Education (ASME) Annual Conference. Edinburgh, July 2011
 6. **Your Future Career in Anaesthesia: A Study Day for Trainees** – An overview of the Anaesthetic sub-specialties and an opportunity for self-assessment and career planning. Hope Hospital, May 2011
 7. **Providing effective feedback in the clinical workplace** – A workshop for clinicians delivering postgraduate training. The North Western Deanery Annual Medical Education Conference. The Reebok Stadium, Bolton, September 2010
 8. **Trends in lipoprotein profile after renal transplantation: A five-year prospective study.** Northern Alliance of Transplant Specialists Annual Meeting. Manchester, Sept 2003
-

POSTER PRESENTATIONS

1. **Influence of out-of-hours admission and onset of critical illness on hospital mortality at a large teaching hospital.** The Intensive Care Society (ICS) State of the Art Meeting. London, December 2013
 2. **Short term outcomes following RRT review: a prospective international multi-centre study.** Rapid Response Systems and Medical Emergency Teams – 10th International Conference. Miami, Florida, USA, May 2014
 3. **Timing of Renal Replacement Therapy according to the AKIN score.** International Symposium on Intensive Care and Emergency Medicine. Brussels, March 2012
 4. **Acute Kidney Injury in elderly emergency abdominal surgery patients** The Intensive Care Society (ICS) State of the Art Meeting. London, December 2011
 5. **Aspirations for Intensive Care Training in Northwest England** Association of Study in Medical Education (ASME) annual meeting. Edinburgh, July 2011
 6. **The influence of transverse abdominal Plane (TAP) blocks on the duration of hospital stay following laparoscopic colorectal surgery in an enhanced recovery programme.** Evidenced Based Perioperative Medicine (EBPOM) World Congress. London, July 2011
 7. **Epidural failure and a rescue protocol: influence on hospital stay in a colorectal enhanced recovery programme.** Evidenced Based Perioperative Medicine (EBPOM) World Congress. London, July 2011
 8. **Qualitative evaluation of experiences of the North Western Deanery Medical Education Fellows.** Academy of Medical Educators (AoME) 3rd Annual Academic Meeting. London, January 2011
 9. **The Edge Hill Experience.** Academy of Medical Educators (AoME) 3rd Annual Academic Meeting. London, January 2011
 10. **The Genesis of the Medical Education Fellow (MEF) Role.** The North Western Deanery Annual Medical Education Conference. Bolton, September 2010
 11. **Effect of the 48 hour week on training in Anaesthesia.** The Group of Anaesthetists in Training (GAT) Annual Meeting. Cambridge, July 2009
 12. **Quality of patient handover on intensive care units in Northwest England.** The Intensive Care Society (ICS) State of the Art Meeting. London, December 2008
 13. **The use of transthoracic echocardiography in intensive care units in Northwest England** The Group of Anaesthetists in Training (GAT) Annual Meeting. Liverpool, July 2008
-

COURSES

- ❶ Non-technical skills in Anaesthesia. The Northwest School of Anaesthesia. July 2012
 - ❷ Tracheostomies for Medical Trainees. The National Tracheostomy Safety Project. March 2011
 - ❸ Focused Assessed Transthoracic Echocardiography (FATE) Course. November 2011
 - ❹ Problem Based Learning for new tutors. The University of Manchester. July 2010
 - ❺ Statistical Data Analysis Course. Data Solutions Services on behalf of the North Western Deanery. March-May 2010
 - ❻ Training for Transport of the Critically Ill. April 2007
 - ❼ Generic Instructors Course (GIC) for APLS & ALS instructor. February 2007
 - ❽ Advanced Paediatric Life Support (APLS course). November 2005
APLS Resuscitation update: Feb 2009 & Aug 2011
 - ❾ Advanced Life Support (ALS course). Sept 2006 & 2004
ALS Resuscitation update: Aug 2008, May 2009, Aug 2010, Feb 2012 & Feb 2013
 - ❿ Acute Pain and its Management (inc. BOC training in the use of Entonox for painful procedures). Royal Oldham Hospital, Nov 2004
 - ⓫ Trafford Introduction to Elementary Surgery (TIES course). July 2004
 - ⓬ Greater Manchester Acute Illness Management (GMAIM) Course. June 2004
 - ⓭ Non-abusive psychological and physical intervention (NAPPI) course. June 2000
-

PERSONAL STATEMENT

The attributes of a good doctor are numerous and complex, but I can profess to have many of them and work hard in cultivating others. I enjoy solving problems particularly as part of a team, which has become an integral theme and approach to treating patients in today's NHS. I am an enthusiastic, hard-working individual, proficient in communicating with fellow colleagues, patients and their relatives in a variety of situations under the greatest of pressures.

I possess excellent organisational skills and have been elected as senior trainee representative for the regional speciality training committee for Anaesthesia. My role involved representing the interests of my fellow trainees, along with initiating, reviewing and developing a number of projects relevant to training in anaesthesia. My own initiatives in this role have included: the launch of a quarterly trainee newsletter, a trainee careers day and formal reform of the trainee representative role. I possess comprehensive IT skills in word processing, database management and inferential statistical analysis of data.

Outside of medicine, I am a keen cyclist. I have organised two charity cycle rides across Europe whereby I planned routes and itineraries, leading a group of volunteers in their efforts to raise over £10,000. I am a professional mentor for pupils at a local school. I work to raise aspirations and achievement of 12-16 year olds who come from a background of low aspirations, thereby encouraging advancement to Higher Education. I enjoy spending the majority of my spare time with my wife and two children, and when they permit competing on the bike in road sportive events.

Curriculum Vitae

Name: Dr Daniel Stuart Martin	
Present appointment: Senior Lecturer, UCL Division of Surgery and Interventional Science Consultant in Anaesthesia and Critical Care Medicine, Royal Free Hospital, London.	
Address: Royal Free Perioperative Research Office, Anaesthetic Department, 3 rd Floor, Royal Free Hospital, Pond Street, London, NW3 2QG.	
Telephone number: 020 7794 0500 ext 35047	Email address: daniel.martin@ucl.ac.uk
Qualifications: BSc, MBChB, FRCA, FFICM, PhD	
Professional registration: GMC: 4437925 (From July 1997)	
Previous and other appointments: Nov 2010 – May 2011: Anaesthetics, Whittington Hospital, London Aug 2010 – Oct 2010: Research Fellow CASE Medicine, University College London Feb 2010 – Aug 2010: Intensive Care Medicine, University College London Hospital Aug 2009 – Feb 2010: Intensive Care Medicine, Royal Free Hospital, London	
Research experience: 1. Molecular biology research degree (intercalated) at the University of Leicester - angiotensin-converting enzyme gene insertion/deletion polymorphism and other potential genetic markers of cardiovascular disease. 2. Extreme Everest Oxygen Research Consortium – A series of studies at high altitude and sea level laboratories to discover more about human adaptation to hypoxia, as part of a translational research programme to improve outcome in hypoxic critically ill patients. 3. PhD in applied physiology, UCL (2013) 4. PI for numerous NIHR CRN Portfolio studies at the Royal Free Hospital 5. CI of studies looking at cardiopulmonary exercise testing in patients and mechanisms of Critical Illness	
Research training: GCP Course Sept 2013 Practical statistics for medical research 2009 Extensive experience in study design and patient consenting since 1993.	
Relevant publications: Primary research: - Levett DZ1, Viganò A, Capitanio D, Vasso M, De Palma S, Moriggi M, Martin DS, Murray AJ, Cerretelli P, Grocott MP and Gelfi C. Changes in muscle proteomics in the course of the Caudwell Research Expedition to Mt. Everest. Proteomics. 2014 Nov 5. [Epub ahead of print] Martin DS, Cobb A, Meale P, Mitchell K, Edsell M, Mythen M and Grocott MPW. Systemic oxygen extraction during exercise at high altitude. Br J Anaesth. 2014 Dec 13. - Gilbert-Kawai ET, Mitchell K, Martin D, Carlisle J, Grocott MP. Permissive hypoxaemia versus normoxaemia for mechanically ventilated critically ill patients. Cochrane Database Syst Rev. 2014 May 7;5:CD009931.	

- Siervo M, Riley H, Fernandez B, Leckstrom C, **Martin D**, et al. Effects of Prolonged Exposure to Hypobaric Hypoxia on Oxidative Stress, Inflammation and Gluco-Insular Regulation: The Not-So-Sweet Price for Good Regulation. *PLOS ONE*. April 2014
- Holloway CJ, Murray AJ, Mitchell K, **Martin DS**, Johnson AW, Cochlin LE, Codreanu I, Dhillon S, Rodway GW, Ashmore T, Levett DZH, Neubauer S, Montgomery HE, Grocott MPW and Clarke K. Oral coenzyme Q10 supplementation does not prevent cardiac alterations during a high altitude trek to Everest Base Camp. *High Alt Med Biol*. 2014, Vol 15.
- **Martin DS**, Pate JS, Vercueil A, Doyle PW, Mythen MG and Grocott MPW Reduced coagulation at high altitude identified by thromboelastography. *Thrombosis and Haemostasis* 2012 May 31;107(6):1066-1071
- Levett DZ, Radford EJ, Menassa DA, Graber EF, Morash AJ, Hoppeler H, Clarke K, **Martin DS**, Ferguson-Smith AC, Montgomery HE, Grocott MP, Murray AJ; the Caudwell Xtreme Everest Research Group. Acclimatization of skeletal muscle mitochondria to high-altitude hypoxia during an ascent of Everest. *FASEB J*. 2012 Apr;26(4):1431-41.
- Levett DZ, Fernandez BO, Riley H, **Martin DS**, Mitchell K, Leckstrom CA, Ince C, Whipp BJ, Mythen MG, Montgomery HE, Grocott MPW, & Feelisch M. The role of nitrogen oxides in human adaptation to hypoxia. *Scientific Reports* 2011. 1:109
- Wilson MH, Edsell MEG, Davagnanam I, Hirani SP, **Martin DS**, Levett DZH, Thornton JS, Golay X, Strycharczuk L, Newman SP, Montgomery HE, Grocott MPW and Imray CHE. Cerebral artery dilatation maintains cerebral oxygenation at extreme altitude and in acute hypoxia—an ultrasound and MRI study. *J Cereb Blood Flow Metab*. 2011 Oct;31(10):2019-2029
- Levett DZ, **Martin DS**, Wilson MH, Mitchell K, Dhillon S, Rigat F, Montgomery HE, Mythen MM and Grocott MP. Design and conduct of Caudwell Xtreme Everest: an observational cohort study of variation in human adaptation to progressive environmental hypoxia. *BMC Med Res Methodol*. 2010 Oct 21;10(1):98.
- Grocott MPW, **Martin DS**, Wilson MH, Mitchell K, Dhillon S, Mythen MG, Montgomery HE and Levett DZH. Caudwell Xtreme Everest Expedition. *High Alt Med Biol*. Volume 11, Number 2, 2010
- **Martin DS**, Goedhart P, Vercueil A, Ince C, Levett DZH, Grocott MPW. Changes in sublingual microcirculatory flow index and vessel density on ascent to altitude. *Exp Physiol* 95.8 pp 880–891
- Bezemer R, Karemaker JM, Klijn E, **Martin D**, Mitchell K, Grocott M, Heger M and Ince C. Simultaneous multi-depth assessment of tissue oxygen saturation in the hand and forearm using near-infrared spectroscopy during a simple cardiovascular challenge. *Critical Care* 2009, 13(Suppl 5):S5
- **Martin DS**, Levett DZH, Mythen M and Grocott MPW, for the Caudwell Xtreme Everest Research Group. Changes in skeletal muscle oxygenation during exercise measured by near-infrared spectroscopy on ascent to altitude. *Critical Care* 2009, 13(Suppl 5):S7
- Scrase E, Lavery A, Gavlak JCD, Sonnappa S, Levett DZH, **Martin D**, Grocott MPW, and Stocks J. The Young Everest Study: Effects of hypoxia at high altitude on cardio-respiratory function and general well-being in healthy children. *Arch. Dis. Child*. 2009 Aug;94(8):621-6.
- **Martin DS**, Ince C, Goedhart P, Levett DZ, Grocott MP for the Caudwell Xtreme Everest Research Group. Abnormal blood flow in the sublingual microcirculation at high altitude. *Eur J Appl Physiol*. 2009 Jun; 106(3):473-8.

- Grocott M and Martin D, Levett D, McMorow R, Windsor W, Montgomery H and the Caudwell Xtreme Everest Research Group. Arterial blood gases and oxygen content in climbers on Mount Everest. <i>N Engl J Med</i>. 2009 Jan 8;360(2):140-149. Martin D, McCorkell S, Vercueil A, Gunning P, Cox M, Dick J, Mythen M, Grocott M. Increased gastric-end tidal PCO₂ gap during exercise at high altitude measured by gastric tonometry. <i>High Alt Med Biol</i>. 2007 Spring;8(1):50-5.	
Signature: 	Date: 17/8/15
Daniel S. Martin	

CURRICULUM VITAE

DR MOHAMED RAMALI MOHAMED MASHOOR.

(MBBS MD Anaesthesiology FRCA FICM)

FEBRUARY 2015

Contents

Personal

Personal Details	3
Education and Qualifications	3
Resuscitation Training	4
Prizes and Grants	4
Personal Statement	4

Employment History

Current Employment	5
Previous Employment	5 - 6
Clinical Experience	7-8

Core Skills

Clinical Governance and Audit	9
Management	10
Teaching	10
Information Technology	11
Publications	11
References	12

PERSONAL

Personal Details:

Full name: Mohamed Ramali Mohamed Mashoor
Permanent Address: 27, Titus Way, Colchester, CO4 9WH. UK
Home telephone: +44 1206852269
Mobile: +44 7877810747
Email: ramalimashoor@yahoo.com
Date of birth: 6th February 1964
Marital status: Married
Nationality: British
GMC registration: 5204041 (Full) (Specialist Register)
CCT: 06th May 2005
Revalidation date: December 2019

Education:

1971- 1978 Zahira College, Colombo, Sri Lanka.
1978-1982 St. Peters College, Colombo, Sri Lanka

Qualifications:

1991 MBBS North Colombo Medical College, Sri Lanka
2001 FRCA Royal College of Anaesthetists, London
2002 MD Anaesthesiology, Postgraduate Institute of Medicine
Sri Lanka
2005 CCT
2010 FICM

Learned Bodies: Royal College of Anaesthetists, London
Obstetric Anaesthetists Association, UK
Association of Anaesthetists of Great Britain and Ireland
British society of orthopaedic Anaesthetists
Intensive Care Society, UK
Society for Computing and Technology in Anaesthesia.
British Society of Bariatric Anaesthetists

Prizes and Grants: 1999 .LMV Attygalle Prize for the best scientific paper presented
by a registrar at the scientific sessions.

Life support Certifications: Advanced Life Support (ALS) 2005. Attended yearly mandatory
refresher sessions since 2007)
Advanced Trauma Life support (ATLS) 2001.
Advanced Paediatric Life Support .(Attended yearly mandatory
refresher sessions since 2008)

Personal Statement: I am an experienced, enthusiastic, conscientious anaesthetist with a
sound training back ground from two health care systems and 10 years of experience at the
level of a Consultant Anaesthetist with special interest in critical care. At present I work in a
twelve bedded critical care unit. We care for both level two and three patients. Patient safety
is of paramount in our unit and we work very hard to achieve this as a team. We care for
both post surgical and medical patients.

EMPLOYMENT HISTORY

CURRENT EMPLOYMENT

October 2005 – Present Consultant Anaesthetist with special interest in critical care.

Colchester Hospital University NHS Foundation Trust, Colchester UK

PREVIOUS EMPLOYMENT

September 2005-October 2005 Specialist Registrar, Anaesthetics and critical care, Southend

General Hospital UK

March 2005 - August 2005 Specialist Registrar, Cardiothoracic Anaesthesia and critical

care, St. Bartholomews Teaching Hospital, London, UK

August 2004 - February 2005. Clinical fellow in obstetric anaesthesia, Royal Free Teaching

Hospital, London, UK

March 2004 - July 2004 Specilaist Registrar in Anaesthetics, Royal Free Teaching

Hospital, London, UK

March 2003-February 2004 Specialist Registrar in Anaesthetics and critical care, Colchester

General Hospital, UK

December 2002- February 2004 Acting Consultant Anaesthetist , Wathupitiwala Base

Hospital, Sri Lanka.

September 2002- November 2002 Senior Registrar, Anuradhapura General Hospital, Sri Lanka

January 2002 - August 2002 Senior Registrar, Neuroanaesthesia and Neurocritical Care,

National Hospital, Colombo, Sri Lanka

September 2001 - December 2001 Specialist Registrar in paediatric anaesthesia, Great

Ormond Street Hospital For Children, London, UK

March 2001 - August 2001. Specialist Registrar in Neuroanaesthesia and neurocritical Care National Hospital For Neurosurgery and Neurology, London, UK

March 2000 - February 2001. Senior House Officer in Anaesthesia, Barnet General Hospital,

December 1999 - February 2000. Senior House Officer in Anaesthesia, University College Hospital, London, UK

January 1996 - November 1999- Senior Registrar in Anaesthetics, National Hospital Of Sri Lanka. Colombo

January 1995 - December 1995. Senior House Officer in Neuroanaesthesia and neurocritical care. National Hospital of Sri Lanka. Colombo

January 1994 - December 1994- Senior House Officer in Anaesthesia. Base Hospital Avissawella. Sri Lanka

June 1993 - December 1993- Senior House Officer in Anaesthesia. Base Hospital Matara. Sri Lanka.

June 1992 - November 1992- House Officer in Paediatrics. Base Hospital Avissawella. Sri Lanka.

December 1992 - May 1993- House Officer in Obstetrics and Gynaecology. Base Hospital Avissawella. Sri Lanka.

CLINICAL EXPERIENCE

I have over 20 years of experience in Anaesthetics in total. I commenced my career as an anaesthetist in 1993. In 1996 I entered a comprehensive residency training programme, which brought me to the United Kingdom in 1999 to complete my postgraduate training. I was very fortunate to undergo further training in one of the best schools of anaesthesia, which comprised of University College Hospital London, Great Ormond Street Hospital for Children and National Hospital for Neurology and Neurosurgery. In 2002 I was board certified as anaesthetist with special interest in Neuroanaesthesia. I was back in UK in 2003 to complete my CCT in Anaesthesia and progressed quickly through the competency based modular training to complete the higher specialist training and obtained CCT in May 2005 and on specialist register of GMC since. During my training years I worked both at district general hospitals and university teaching hospitals and gained a broad experience in all sub-specialties of anaesthesia e.g. Neuro anaesthesia, Cardiac and thoracic anaesthesia, Paediatric anaesthesia, Obstetric anaesthesia, regional anaesthesia, critical care medicine etc. I am experienced in all commonly performed procedures in anaesthesia e.g. neuraxial blocks, ultra sound guided nerve blocks, arterial and central venous cannulations, fibre optic intubation(both awake and asleep), use of double lumen ET tubes, using advanced monitoring techniques like BIS monitor, various invasive, semi invasive and non-invasive cardiac output monitors etc.

I am currently working as a consultant anaesthetist with special interest in critical care since October 2005 at Colchester Hospital University NHS Foundation Trust.

Colchester General Hospital is a district general hospital with 670 beds, 17 operating theatres and 14 bed critical care unit which caters for a population of approximately 400,000. Anaesthetic department provides anaesthetic services to General surgery (major laparoscopic centre), Urology (major cancer centre), Vascular surgery (Regional vascular unit serving north east Essex and Suffolk), Obstetrics (over 4000 deliveries per year), Gynaecology, ENT, dental and Orthopaedics. I am one of ten Consultant anaesthetists covering critical care.

My routine work involves a week in critical care and three weeks in anaesthetics. This cycle is repeated. My critical care work involves leading the multidisciplinary morning critical care ward round. During this time I will also be taking acute referrals including post trauma and cardiac arrests. I will also be advising the outreach team. I will also take part in a microbiology and rehabilitation ward round during the afternoon. The last ward round of the day is during the handover to the night team.

I am passionate about patient safety. The morning ward round starts with a critical care safety check list. Staffing levels, patients with special problems, and any outliers are discussed. All critical care intubations and extubations will have a check list to ensure safety. We have a range of quality measures to monitor and compare with other units locally and nationally.(ICNARC).

We follow care bundles in our unit such as ventilation, sepsis, sedation hold, VAP and central line. We also monitor readmissions, non clinical transfers and out of hours discharges.

I also regularly anaesthetise patients from various other surgical lists like general surgery (Colchester general hospital is a major laparoscopic centre in UK), Urology, Gynaecology, ENT, maxillofacial, vascular and paediatrics to keep my skills up to date and meet the revalidation requirements of GMC. I participate in 1in 8 out of hour's non-resident consultant on call rota covering .critical care.

I have updated my personal practices and knowledge by reflective practice and self-directed learning, as well as attending internal and external seminars, courses and meetings. I participate actively in teaching and supervising anaesthetic trainees, audit, clinical governance, managerial and service improvement activities in the department. I participate actively in the annual appraisals and kept my portfolio up-to-date.

Clinical Governance and Audit

I attend departmental clinical governance and management group meetings and have experience of clinical incident reporting and investigating. I am aware of major incident strategies and have been trained in responding to these.

Audit

I am fully committed to clinical audit and understand its role in driving clinical excellence.

Audits completed in the past 4 years:

February 2015. I audited the use of sepsis tool and its implementation in the hospital. Recommendations were made to improve use of the tool and treating septic patients.

January 2015. Audit of contents of the emergency drug boxes and its contents in critical care and accident and emergency department.

December 2014. Audit of tidal volumes patients received in critical care and its compliance with lung protective ventilation strategies.

January 2014. Audit of communication and documentation in critical care.

2013 Audit on readmission rates to critical care unit within 72 hours of discharge.

2010- Audit on data protection in the anaesthetic department.

Management

I enjoy organisational responsibilities, and consider myself to be an organised and capable person who can be effective, motivate others and achieve set targets. I have also learnt to set time scales and manage my own workload effectively in my present post.

I have the following responsibilities and lead roles in the department.

- Lead for infection control. I am overall responsible for preventing and minimising catheter related blood stream infections and ventilator associated pneumonia. I was part of the team which introduced central venous line and VAP care bundles. I was also the lead for the matching Michigan project to minimise catheter related blood stream infections.
- Audit lead for critical care and anaesthetics
- Research lead for critical care.
- I represented anaesthetic department in various meetings in the organisation.

• Teaching

I am one of the designated educational supervisors for anaesthetic trainees and foundation year doctors. I am also designated undergraduate tutor in anaesthetics for medical students from Queen Mary University London. I am also involved in interviewing prospective medical students for the same university.

I have always enjoyed teaching, and have developed my experience in a number of different areas, which include teaching medical students and trainees both formally and informally. I use a range of teaching styles appropriate to the subject and audience.

I always try to use the management of emergency cases as teaching opportunities. As well as theory, I enjoy teaching and supervising practical skills. I am a designated educational supervisor for trainees coming from London and East of England deaneries. As an educational supervisor I have to ensure that my trainees are supported and progressing well throughout their placement in the department and provide structured reports to deanery about their progress.

Information Technology

I am familiar with hospital information management systems. I am a competent user of computers and software. I am fully literate with the Office suite of programmes including access and have Microsoft-accredited training in Excel, PowerPoint and Word and hold European Computer deriving licence (ECDL).

Publications

1. Poster. Audit on readmission rates to critical care unit at the Colchester General Hospital. Intensive care society state of the art meeting, London

Referees

Dr Gerald Timmins

Consultant Anaesthetist

Colchester General Hospital

Colchester Hospital University NHS Trust

Turner Road

Colchester CO4 9FF United Kingdom

Phone: +44 (0)1206744287

Fax: +44 (0)01206742938

Email: Andrew.timmins@colchesterhospital.nhs.uk

Dr David Thomas

Consultant Anaesthetist

Colchester General Hospital

Colchester Hospital University NHS Trust

Turner Road

Colchester CO4 9FF United Kingdom

Phone: +44 (0)1206744287

Fax: +44 (0)01206742938

Email: david.thomas@colchesterhospital.nhs.uk

m. Kennel
14/04/15

Curriculum Vitae

Access template CV for other staff [here](#).

Title:	Forename/Initials	Surname
Mrs	Catherine I	Plowright

Present appointment: *(Job title, department, and organisation.)*

Consultant Nurse Critical Care
Medway NHS Foundation Trust

Start date for present appointment:

May 2003

Address: *(Full work address.)*

c/o Anaesthetic Department

Medway Hospital

Windmill Road, Gillingham

Postcode:

ME7 5NY

Telephone number:

01634 833725

Email address:

catherine.plowright@nhs.net

Qualifications:

- Registered Nurse
- BSc & MSc Nursing
- MA in Applied Professional Research
- Intensive Care Nursing ENB 100
- Teaching & Assessing ENB998
- Further & Adult Education Teaching Certificate
- Diploma in Management Studies

Professional registration: *(Name of body, registration number and date of registration.)*

Nursing & Midwifery Council
Registration number 8110439S
Date of registration 1985

Previous and other appointments: *(Include previous appointments in the last 5 years and other current appointments.)*

Critical Care Lead – Kent, Surrey & Sussex Clinical Research Network

Honorary Lecturer Canterbury Christ Church University
May 2003 to date

Visiting Lecturer University of Greenwich 2011 to date

Lead Senior Nurse Critical Care
East Kent Hospitals NHS Trust
December 1996 to May 2003

Research experience: *(Summary of research experience, including the extent of your involvement. Refer to any specific clinical or research experience relevant to the current application.)*

I have been the local Principle Investigator for numerous trials: TracMan, OSCAR, Spot(light, SPOT(id),Pre-deliric, ICON3, the Organ donation: an evaluation of health workers' knowledge & education trial, POPPI etc

I have had experience of undertaking interviews as part of my MSc (this was completed in 1996) and in local project work / research within NHS workplace. Also as part of my research MA. As part of daily work, I meet with patients, relatives and staff and undertake a variety of different interviews with them.

Research training: *(Details of any relevant training in the design or conduct of research, for example in the Clinical Trials Regulations, Good Clinical Practice or other training appropriate to non-clinical research. Give the date of the training.)*

I completed my MA in Applied Professional Research at University of Brighton in 2011

I have attended Good Clinical Practice Training on 3rd November 2009, 7th December 2011 and 5th June 2014

Relevant publications: *(Give references to all publications in the last two years plus other publications relevant to the current application.)*

van den Boogaard M, Schoonhoven L, Maseda E, Plowright C, Jones C, Luetz A, Sackey PV, Jorens PG, Aitken LM, van Haren F, van der Hoeven JG, Pickkers P (2013) International validation of the delirium prediction model for ICU patients (PRE-DELIRIC); a multicenter observational study. Critical Care Medicine

Gibson V, Plowright C, Collin T, Dawson D, Evans S, Gibb P, Lynch F, Mitchell K, Page P, Sturmey G 2012. Position Statement on visiting in adult critical care units in the UK. Nursing in Critical Care. 17(4): 213 – 218.

Plowright C 2009 National Institute for Health and Clinical Effectiveness announces guideline on critical illness rehabilitation Nursing in Critical Care 14(4):1-3

Price AM, Plowright C, Makowski A, Misztal B 2008 Using a high flow respiratory system (Vapotherm) within a high dependency setting Nursing in Critical Care 13(6):298-304

Signature: C Plowright

Date: 7/8/14

DR JOYCE YEUNG

27/08/1977

GMC 6025363

www.birmingham.ac.uk/joyce_yeung

j.yeung@bham.ac.uk

**Academic Department of Anaesthesia, Critical Care, Resuscitation and Pain,
1/F MIDRU Building, Birmingham Heartlands Hospital, Birmingham B9 5SS**

Degrees

2012 PhD Strategies to improve quality of CPR University of Warwick

2006 FRCA Anaesthesia Royal College of Anaesthetists

2001 MBChB Medicine University of Birmingham

Present and previous positions held/Professional Experience

01/01/2015 – NIHR Post-Doctoral Fellow

01/09/2013 – Clinician Scientist/Senior Lecturer, University of Birmingham, Honorary
Consultant anaesthetist, Heart of England NHS Foundation Trust

01/03/2012 01/09/2013 NIHR Clinical Lecturer in Anaesthesia, University of Birmingham

01/02/2012 01/03/2012 Specialist Registrar in Anaesthesia and Critical Care, Heart Of
England NHS Foundation Trust

01/11/2011 01/02/2012 Specialist Registrar in Anaesthesia and Critical Care, Birmingham
Children's Hospital NHS Foundation Trust

01/08/2011 01/11/2011 Specialist Registrar in Anaesthesia and Critical Care, University
Hospitals Coventry and Warwickshire NHS Trust

01/08/2007 01/08/2011 Specialist Registrar in Anaesthesia and Critical Care, Heart Of
England NHS Foundation Trust

01/08/2006 01/08/2007 Specialist Registrar in Anaesthesia and Critical Care, University
Hospitals Coventry and Warwickshire NHS Trust

01/08/2005 01/08/2006 Senior House Officer in Anaesthesia Burton Hospitals NHS
Foundation Trust

01/02/2005 01/08/2005 Senior House Officer in Intensive Care, Medicine Heart Of England NHS Foundation Trust

01/02/2004 01/02/2005 Senior House Officer in Anaesthesia, Worcestershire Acute Hospitals NHS Trust

01/02/2003 01/02/2004 Senior House Officer in Anaesthesia, South Warwickshire NHS Foundation Trust

01/08/2002 01/02/2003 Senior House officer in Emergency Medicine, Heart Of England NHS Foundation Trust

01/08/2001 01/08/2002 PRHO in medicine, surgery and paediatrics, University Hospital of North Staffordshire NHS Trust

Current research projects

In elderly patients undergoing fractured neck of femur fixation, does the use of regional anaesthesia compared to general anaesthesia reduce incidence of post-operative delirium (GeRAFFE)? A programme of research – CI

A randomised controlled trial to investigate the effectiveness of thoracic epidural and paravertebral blockade in reducing chronic post-thoracotomy pain – TOPIC pilot study. Co-applicant

Effect of non-technical skills teaching on performance– an evaluation of new ALS course Resuscitation Council UK, CI

IV iron and impact on anaemia in patients with hip fracture (IVANOF1) – PI

Prevention of acute lung injury post oesophagectomy – PI

Use of monoclonal oxidase inhibitor in severe flu – PI

Research award(s) held

01/01/2015 4 years NIHR Post Doctoral Fellowship

In elderly patients undergoing fractured neck of femur fixation, does the use of regional anaesthesia compared to general anaesthesia reduce incidence of post-operative delirium (GeRAFFE)? A programme of research

01/02/2015 12 months £22435.00

Evaluation of instructor-led debriefing in Advanced Life Support course (ATEAM-II) – A program of research. Resuscitation Council, CI

01/02/2014 24months £223454.00

A randomised controlled trial to investigate the effectiveness of thoracic epidural and paravertebral blockade in reducing chronic post-thoracotomy pain – TOPIC pilot study. NIHR RFPB Co-applicant

01/01/2014 12months £19772.00

Effect of non-technical skills teaching on performance– an evaluation of new ALS course
Resuscitation Council UK, Chief Investigator

01/12/2012 6months £450.00 Pre-protocol PPI bursary Birmingham RDS Chief investigator

01/03/2012 24months £150000.00 NIHR Clinical Lecturer in Anaesthesia NIHR Clinical Lecturership Clinical Lecturer

01/10/2010 £5000 University Hospital Birmingham Charities. Cochrane review Paravertebral blockade versus thoracic epidural blockade in adults undergoing thoracotomy

03/07/2009 £4000 Evaluation of fluid warming devices for Innovation Factory.

01/09/2008 36months £9000.00 Strategies to improve quality of cardiopulmonary resuscitation, Resuscitation Council UK PhD fellow

Prizes

2011 European Resuscitation Council Young Investigator Runner up

2010 and 2011 Resuscitation Council UK Young Investigator Runner up

2011 Intensive Care Society Gold Medal runner up

2012 Maurice Hudson Prize, Royal College of Anaesthetists

Signature

A handwritten signature in black ink, appearing to read 'D. Gray', is written over a horizontal line.

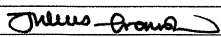
Date

5th December 2014

CURRICULUM VITAE

Name:	
Simon Fletcher	
Present appointment:	
Consultant in Anaesthesia and Intensive Care	
Address:	
Critical Care Complex Level 3 East Block, Norfolk & Norwich University Hospitals NHS Foundation Trust Colney Lane, Norwich NR4 7UY Norfolk	
Telephone number:	Email address:
01603 286200	simon.fletcher@nnuh.nhs.uk
Qualifications:	
MBBS, 1983, Guy's Hospital Medical School, London FRCA, 1988, London FRCPE, 2007, Edinburgh	
Professional registration:	
GMC Registration 2836845	
Previous and other appointments:	
Research experience:	
I have been involved in clinical trials for nearly 20 years (phase 2 and 3) and have been principal investigator for approximately 10 years. Recent studies include: • Genomic Advances in Sepsis (GAinS) – Principal Investigator • Atryn in patients with DIC associated with severe sepsis (phase 2) – principal investigator • TAK 242 in sepsis (phase 3) – principal investigator • Calories – sub-investigator • Harp 2 – sub-investigator	
Research training:	
GCP training 11/08/2014	
Relevant publications: <i>(Give references to all publications in the last two years plus other publications relevant to the current application.)</i>	
2 letters, 6 reviews, 6 papers, 2 abstracts and 2 chapters mainly concerning the following therapeutic areas: Anaesthesiology, care of critically ill patients and the respiratory system	
Signature:	Date:
	77-12-14

CURRICULUM VITAE

Name:	
Dr Julius Cranshaw	
Present appointment:	
Consultant Anaesthetics and Intensive Care Royal Bournemouth & Christchurch Hospital	
Address:	
Royal Bournemouth Hospital Castle Lane East Bournemouth BH7 7DW	
Telephone number:	Email address:
W:01202 303626 M: 07789004329	julius.cranshaw@rbch.nhs.uk
Qualifications:	
1989	BSc(Hons) Cellular and Molecular Pathology, University of Bristol
1992	MBChB (Hons), University of Bristol
1997	MRCP
1998	FRCA
2004	PhD (Imperial College of Science Technology and Medicine, London)
2005	Diploma of Intensive Care Medicine (UK)
2005	European Diploma of Intensive Care
Professional registration:	
GMC No: 3565490, Specialist Registration: 21 st January 2005 (Full)	
Previous and other appointments:	
As current position	
Research experience:	
• 1998-1989 BSc(Hons) Cellular and Molecular Pathology, University of Bristol • 2008-2009 Local Investigator for UK multi-centre TracMan Trial • 2000-2003 PhD student • 2011-2013 Principle Investigator for International TTM Interventional Trial • 2011-2014 Local Investigator for ProMiSe Interventional Trial • 2012-2013 Principle Investigator for ELOISE observational study • 2013-2014 Local Investigator for VANISH • 2015 - PI for BALANCED study due to start May 2015	
Research training:	
• 28th April 2011 & 20th May 2013 • 2000-2003 PhD Student involving experience with study design, data collection, analysis, consent process and ethical approval • 1988-1989 BSc (Hons) Cellular and Molecular Pathology involved experience with study design, data collection, analysis and ethical approval	
Relevant publications:	
Short and long term outcomes for elderly patients managed with induced hypothermia after VF and pulseless VT may be as good as for younger patients. Abstract 1307. J. Cranshaw, A Vaughton, T.J. Perkins. European Society of Intensive Care Medicine 2010. Litigation related to drug errors in anaesthesia: an analysis of claims against the NHS in England 1995-2007. Cranshaw J, Gupta KJ, Cook TM, Anaesthesia. 2009 Dec; 64 (12): 1317-23. A national survey of single-use and reusable laryngeal mask use in England. Gregory T, Golding J, Cranshaw J. European Journal of Anaesthesiology. 2008 May;25(5); 432-4 Treatment of severe local anaesthetic toxicity. Mathieu S, Cranshaw J. Anaesthesia. 2008 Feb; 63(2) 202-3.	
Signature: 	Date: 19/2/15.

STUART MCKECHNIE RESEARCH CURRICULUM VITAE

Name:	
Stuart McKechnie	
Present appointment: <i>(Job title, department, and organisation.)</i>	
Consultant, Intensive Care Medicine & Anaesthetics, Oxford University Hospitals NHS Trust	
Address: <i>(Full work address.)</i>	
Adult Intensive Care Unit John Radcliffe Hospital Headley Way Oxford OX3 9DU	
Telephone number:	Email address:
01865 220621	stuartmckechnie@mac.com stuart.mckechnie@ouh.nhs.uk
Qualifications:	
MBChB BSc (Hons) FRCA PhD DICM FFICM	
Professional registration: <i>(Name of body, registration number and date of registration.)</i>	
GMC 4228600; Royal College of Anaesthetists 564874; Faculty of Intensive Care Medicine	
Previous and other appointments: <i>(Include previous appointments in the last 5 years and other current appointments.)</i>	
Specialist Registrar Anaesthetics, SE Scotland May 2001 – May 2009 Wellcome Trust Clinical Research Fellow 2002 - 2005	
Research experience: <i>(Summary of research experience, including the extent of your involvement. Refer to any specific clinical or research experience relevant to the current application.)</i>	
1. Principal Investigator: Age of Blood Evaluation study (ABLE). 2012 – Current. Oxford University Hospitals NHS Trust 2. Principal Investigator: Intensive Care Study of Coagulopathy (ISOC-2). 2012 – Current. Oxford University Hospitals NHS Trust 3. Principal Investigator: Genetic Advances in Sepsis (GAInS) study. 2011 – Current. Oxford University Hospitals NHS Trust 4. Supervisor: Shoulder dysfunction in survivors of critical care. 2013 – Current. Oxford University Hospitals NHS Trust 4. Wellcome Trust Clinical Research Fellow 2002 – 2005. Edinburgh University Three years translational research investigating the roles of hyperoxia and mechanical deformation in alveolar epithelial injury and repair. Based in the MRC Centre of Inflammation Research at the University of Edinburgh. Funded by the award of a Wellcome Trust Clinical Research Fellowship, culminating in the degree of Doctor of Philosophy.	

Research training: *(Details of any relevant training in the design or conduct of research, for example in the Clinical Trials Regulations, Good Clinical Practice, consent or other training appropriate to non-clinical research. Give the date of the training.)*

Good Clinical Practice Training 08.10.2014

Wellcome Trust Clinical Research Fellow 2002 - 2005

Relevant publications: *(Give references to all publications in the last two years plus other publications relevant to the current application.)*

Tridente A, Clarke GM, Walden A, McKechnie S, Hutton P, Mills GH, Gordon AC, Holloway PA, Chiche JD, Bion J, Stuber F, Garrard C, Hinds CJ; GenOSept Investigators. Patients with faecal peritonitis admitted to European intensive care units: an epidemiological survey of the GenOSept cohort. *Intensive Care Med.* 2014 Feb;40(2):202-10.

Walden AP, Clarke GM, McKechnie S, Hutton P, Gordon AC, Rello J, Chiche JD, Stueber F, Garrard CS, Hinds CJ. Patients with community acquired pneumonia admitted to European Intensive Care Units: an epidemiological survey of the GenOSept cohort. *Crit Care.* 2014 Apr 1;18(2):R58.

Garry DA, McKechnie SR, Culliford DJ, Ezra M, Garry PS, Loveland RC, Sharma VV, Walden AP, Keating LM; PREVENT group. A prospective multicentre observational study of adverse iatrogenic events and substandard care preceding intensive care unit admission (PREVENT). *Anaesthesia.* 2014 Feb;69(2):137-42.

Retter A, Wyncoll D, Pearse R, Carson D, McKechnie S, Stanworth S, Allard S, Thomas D, Walsh T; British Committee for Standards in Haematology. Guidelines on the management of anaemia and red cell transfusion in adult critically ill patients. *Br J Haematol.* 2013 Feb;160(4):445-64. doi: 10.1111/bjh.12143. Epub 2012 Dec 27. Review.

S. M. Alderson, S. R. McKechnie. Unrecognised, undertreated, pain in ICU: Causes, effects, and how to do better. *Open Journal of Nursing*, 2013, 3, 108-113

A. Cumpstey, S. Benzie, S. McKechnie. Tracheostomy management. *Student BMJ* 2012;20:e6016

C Tyrell, S McKechnie, M Beers, R Mitchell, M McElroy. Differential alveolar epithelial injury & protein expression in Pneumococcal pneumonia. *Experimentla Lung Research* 2012. In press.

D Garry, S McKechnie, D Culliford, M Ezra, P Garry, R Loveland, V Sharma, A Walden and L Keating. A prospective multicentre observational study of iatrogenic events preceding intensive care unit admission (PREVENT). *JICS* 2012; 13(1): 65.

Watkinson P, McKechnie S, Wilkinson D, Salmon J, Young D. Actively delaying death to increase organ donation. *BMJ.* 2012 Feb 17;344.

Hatch R, McKechnie S, Griffiths J. Psychological intervention to prevent ICU-related PTSD: who, when and for how long? *Crit Care* 2011; 15(2): 141.

McKechnie SR, Drummond GB. Cytokines, neurokinins or both? Mixed mechanisms of

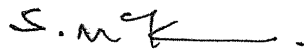
mechanical lung injury. J Physiol. 2010 Jun 1;588(Pt 11):1813-4.

McKechnie SR. The effect of hyperoxia on alveolar epithelial injury and repair. JICS 2008; 9(1): 94.

Clegg GR, Tyrrell C, McKechnie SR, Beers MF, Harrison DJ and McElroy MC.
Coexpression of RTI40 with alveolar epithelial type II cell proteins in lungs following injury: identification of alveolar intermediate cell types. Am J Physiol Lung Cell Mol Physiol. 2005 Sep; 289(3): L382-90.

Signature:

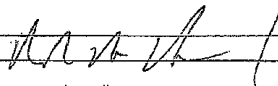
Date:



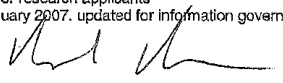
14th Oct 2014

Stuart McKechnie

CURRICULUM VITAE

Name: Dr Robin Hollands	
Present appointment:	
Job title: Consultant in Anaesthesia and Intensive Care Dept: Anaesthesia Start date: 2002 Employer: The Shrewsbury and Telford Hospital NHS Trust	
Address: (Full work address.) Dept Anaesthesia Royal Shrewsbury Hospital Shrewsbury SY3 8XQ	
Telephone number: 01743261196	Email address: robin.hollands@sath.nhs.uk
Qualifications (Please include university names and locations where qualifications obtained and also dates of qualifications): MBChB 1991 University of Birmingham Medical School DCH 1995 FRCA 1998	
Professional registration: (Name of body, registration number and date of registration.) GMC 3466371 1991	
Previous and other appointments: (Include job titles and dates of previous appointments in the last 5 years and other current appointments.) 	
Research experience: (Summary of research experience, including the extent of your involvement. Refer to any specific clinical or research experience relevant to the current application.) No research experience	
Research training: (Details of Clinical Trials Good Clinical Practice, Information Governance and any relevant training in the design or conduct of research including consent or other training appropriate to research. Give the date of the training.) GCP training date: 16/07/2013 Information Governance training date: 20/10/2011	
Relevant publications if applicable: (Give references to any publications in the last two years plus other publications relevant to the current application.) 	
Signature: 	Date (Please hand-write and use format dd month year) 8 th August 2013

Template CV for research applicants
Version 2, January 2007, updated for information governance MA Aug 11

 5-10-2015 4-11-15

Appendix 16.1.5. Report Signature Sheet

8822-001 Clinical Study Report 2016 SEP 08 Signatures

A Multicenter, Non-interventional, Observational, Post-Approval Safety Study of
Updated ACCUSOL 35 Solutions in Continuous Renal Replacement Therapy
(ACCUPASS)

*I hereby confirm that, to the best of my knowledge, this report accurately describes the
conduct and results of the study.*



Drew S. Jones, MD, MPH, MBA
Clinical Development Lead (Author)
Baxter Healthcare Corporation



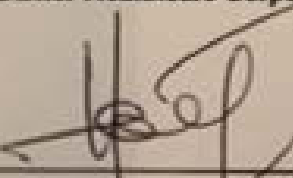
Date



Michael Amdahl
Statistical Specialist
Baxter Healthcare Corporation



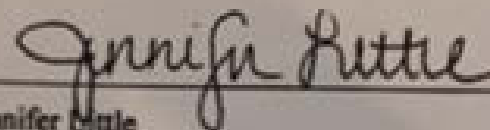
Date



Klaus Hoersuf, MD, PhD
Global Head Therapeutic Areas - Medical Affairs
Baxter Healthcare Corporation



Date



Jennifer Little
Director, Regulatory Affairs
Baxter Healthcare Corporation



Date

Appendix 16.1.8. Audit Certificate



Audit Certificate

This Certificate is issued by PSI Quality Management to document that a Quality Assurance Audit has been conducted on the study

8822-001

A MULTICENTER, NON-INTERVENTIONAL, OBSERVATIONAL, POST-APPROVAL SAFETY STUDY OF UPDATED ACCUSOL 35 SOLUTIONS IN CONTINUOUS RENAL REPLACEMENT THERAPY (ACCUPASS)

Audit date:

19 July 2016

Audit type:

Quality Assurance Onsite Study Audit

Investigator:

Dr. Bannard-Smith

Site number/investigator number:

008

Site name and address:

Manchester Royal Infirmary, Department of Adult Critical Care, Oxford Road, M13 9WL, Manchester, UK

Elena Chestikova
Senior QA Manager
Quality Management

Date

24-SEP-2016

Appendix 16.1.9. Documentation of Statistical Methods

1. [8822-001 Statistical Analysis Plan Version 2.0 2016 MAY 11](#)
2. [8822-001 Statistical Analysis Plan 2016 JAN 2016](#)

Statistical Analysis Plan: 8822-001

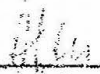
Study Title:	A Multicenter, Non-interventional, Observational, Post-Approval Safety Study of Updated ACCUSOL 35 Solutions in Continuous Renal Replacement Therapy (ACCUPASS)
Study Number:	8822-001
Study Design	Multicenter, non-interventional, single-arm, observational, post-approval safety study
Product Name:	ACCUSOL 35 Solutions
Statistician:	Michael Amdahl Senior Manager, Biostatistics Baxter Healthcare Corporation
Sponsor:	Baxter Healthcare Corporation One Baxter Parkway Deerfield, IL 60015 USA
Responsible Medical Officer:	Drew S. Jones, MD, MPH, MBA Senior Medical Director Baxter Healthcare Corporation
Final Date:	11 May 2016

1. SIGNATURE PAGE

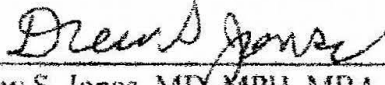
Study Title: A Multicenter, Non-interventional, Observational, Post-Approval Safety Study of Updated ACCUSOL 35 Solutions in Continuous Renal Replacement Therapy (ACCUPASS)
Study Number: 8822-001
Statisticians: Michael Amdahl

I have read this report and confirm that to the best of my knowledge it accurately describes the intended analyses of results of the study.

Prepared by:  Date: 16 May 2016
Jürgen Deinhard
Senior Statistician
PSI CRO Deutschland GmbH

Approved by:  Date: 17 MAY-2016
Anna Ignatenko, PhD
Senior Statistician
PSI

Approved by:  Date: 12-MAY-2016
Nigel Smeaton
Project Manager
PSI

Approved by:  Date: 11 May 2016
Drew S. Jones, MD, MPH, MBA
Senior Medical Director, Clinical Lead
Life Sciences & Operations
Chief Scientific Office
Baxter Healthcare Corporation

Approved by:  Date: 11 May 2016
Michael Amdahl
Sr. Manager, Biostatistics
Life Sciences & Operations
Chief Scientific Office
Baxter Healthcare Corporation

Document History

First final version was approved on January 12 2016.

Following the test-run performed on 20 April 2016 the following changes were implemented to the SAP based on the comments to the test-run. Version 2 of the SAP has been finalized before database lock and the following changes were made: Layout changes have been made to Table 14.1.4, Table 14.1.5.3, Table 14.3.1.2.1 and Table 14.3.1.2.2. A footnote has been added to Table 14.1.3.1. Data Listing 16.2.3.1 and Data Listing 16.2.3.2 have been added. Data Listing 16.2.4 has been renumbered. Data Listing 16.2.5.1 has been deleted as it comprises Anti-coagulant (Data Listing 16.2.5.2) and potassium chloride administration (Data Listing 16.2.5.3) and the remaining tables have been renumbered accordingly.

The SAP final version 2.0 was approved prior to DBL.

Table of Contents

1. SIGNATURE PAGE.....	2
2. LIST OF ABBREVIATIONS AND DEFINITIONS OF TERMS	8
3. INTRODUCTION.....	9
4. TRIAL OBJECTIVES	10
5. STUDY DESIGN AND CONDUCT CONSIDERATIONS	10
5.1 Study Design.....	10
5.2 Sample Size.....	11
5.3 Safety Measures	12
5.4 Completion and Discontinuation.....	12
5.4.1 Patient Withdrawal from the Study.....	12
5.4.2 Study Termination.....	13
6. STUDY POPULATIONS	13
6.1 Analysis Populations.....	13
6.1.1 Enrolled Population.....	13
6.1.2 Evaluable Patient Population (Per-Protocol Population)	13
7. STATISTICAL ANALYSIS	14
7.1 General.....	14
7.2 Handling of Missing Data.....	14
7.3 Interim Analysis.....	14
7.4 Pooling Strategy for Study Sites.....	14
7.5 Visit Windows/Unscheduled Visits.....	14
7.6 Other Issues	14
7.7 Changes to Planned Analyses Described in the Protocol	14
8. PATIENT DISPOSITION	14
9. PROTOCOL DEVIATIONS	15
10. DEMOGRAPHICS AND BASELINE CHARACTERISTICS	15
11. TREATMENT COMPLIANCE AND EXPOSURE	15

12. SAFETY	15
12.1 Primary Analysis	15
12.2 Adverse Reactions	16
12.3 Laboratory Parameters	16
12.4 Exploratory Analyses	16
13. OTHER RELEVANT DATA ANALYSES/SUMMARIES	17
14. SUBGROUP ANALYSES	17
15. REFERENCES	18
16. LISTS OF TABLES AND LISTINGS	19
16.1 Tables	19
16.2 Data Listings	20
17. MOCK TABLES AND LISTINGS	21
17.1 Tables	21
17.2 Data Listings	49
18. APPENDICES	65
Data Presentation	65
Table Specifications	65
Listing Specifications	66
List of Tables and Listings	
Table 14.1.1. Patient Disposition - All Screened Patients	21
Table 14.1.2 Patients Excluded From the Per-Protocol Population - Enrolled Population	22
Table 14.1.3.1 Summary of Demographic and Baseline Characteristics - Enrolled Population	23
Table 14.1.3.2 Summary of Demographic and Baseline Characteristics Per-Protocol Population.	24
Table 14.1.4 Anti-coagulant and potassium chloride administration - Enrolled Population	25
Table 14.1.5.1 CRRT Details: Ultrafiltration Rate - Enrolled Population	26
Table 14.1.5.2 CRRT Details: CRRT Mode - Enrolled Population	27

Table 14.1.5.3 ACCUSOL 35 Administration: Formulation Used - Enrolled Population	28
Table 14.1.5.4 ACCUSOL 35 Administration: Dose Rate by Site of Introduction - Enrolled Population.....	29
Table 14.1.5.5 ACCUSOL 35 Administration: Amount Administered - Enrolled Population	30
Table 14.1.5.6 ACCUSOL 35 Administration: Incidence of Major Protocol Deviations - Enrolled Population.....	31
Table 14.3.1.1 Analysis of Precipitate Formation - Per-Protocol Population	32
Table 14.3.1.2.1 Overview of Adverse Reactions on Patient Level - Enrolled Population	33
Table 14.3.1.2.2 Overview of Total Adverse Reactions - Enrolled Population	34
Table 14.3.1.3.1 Summary of Adverse Reactions - Enrolled Population	35
Table 14.3.1.3.2 Summary of Adverse Reactions (by Frequency of Reactions) - Enrolled Population	36
Table 14.3.1.4.1 Summary of Adverse Reactions by Severity - Enrolled Population	37
Table 14.3.1.4.2 Summary of Adverse Reactions by Severity (by Frequency of Reactions) - Enrolled Population.....	38
Table 14.3.1.5.1 Summary of Adverse Reactions by Relationship to Study Drug - Enrolled Population	39
Table 14.3.1.5.2 Summary of Adverse Reactions by Relationship to Study Drug (by Frequency of Reactions) - Enrolled Population.....	40
Table 14.3.2.1.1 Summary of Serious Adverse Reactions - Enrolled Population	41
Table 14.3.2.1.2 Summary of Serious Adverse Reactions (by Frequency of Reactions) - Enrolled Population.....	42
Table 14.3.2.2.1 Summary of Serious Adverse Reactions by Severity - Enrolled Population	43
Table 14.3.2.2.2 Summary of Serious Adverse Reactions by Severity (by Frequency of Reactions) - Enrolled Population	44
Table 14.3.2.3.1 Summary of Serious Adverse Reactions by Relationship to Study Drug - Enrolled Population.....	45
Table 14.3.2.3.2 Summary of Serious Adverse Reactions by Relationship to Study Drug (by Frequency of Reactions) - Enrolled Population.....	46
Table 14.3.3.1 Exploratory Analysis: Time to First Occurrence of Precipitate – Per-Protocol Population	47

Table 14.3.3.2 Exploratory Analysis: Precipitate Formation by Dialysis Solution Used at Time of Observation – Per-Protocol Population	48
Data Listing 16.2.1 Patient Disposition: Completion/Discontinuation from study - Enrolled Population.....	49
Data Listing 16.2.2 Protocol Deviations - Enrolled Population	50
Data Listing 16.2.3.1 Patients excluded from Per-Protocol Population - Enrolled Population	51
Data Listing 16.2.3.2 Inclusion/Exclusion – Screened Population.....	52
Data Listing 16.2.4 Demographic and Baseline Characteristics - Enrolled Population	53
Data Listing 16.2.5.1 Anti-Coagulant Administration - Enrolled Population	54
Data Listing 16.2.5.2 Potassium Chloride Administration - Enrolled population.....	55
Data Listing 16.2.5.3 ACCUSOL 35 Administration - Enrolled Population.....	56
Data Listing 16.2.5.4 Dialysis Session - Enrolled Population.....	57
Data Listing 16.2.5.5 Dialysis Session – Interruptions - Enrolled Population	58
Data Listing 16.2.7.1 Precipitate Observation - Enrolled Population.....	59
Data Listing 16.2.7.2.1 Adverse Reactions - Enrolled Population.....	60
Data Listing 16.2.7.2.2 Adverse Reactions - Details - Enrolled Population.....	61
Data Listing 16.2.7.3.1 Serious Adverse Reactions - Enrolled Population	62
Data Listing 16.2.7.3.2 Serious Adverse Reactions - Details - Enrolled Population ..	63
Data Listing 16.2.7.4 Deaths - Enrolled Population.....	64
 List of Appendices	
Appendix 1 Programming Specifications	65

2. LIST OF ABBREVIATIONS AND DEFINITIONS OF TERMS

KCl	potassium chloride
CRRT	continuous renal replacement
AR	adverse reaction
CI	confidence interval
DP	Decimal place
MedDRA	Medical Dictionary for Regulatory Activities
SAR	serious adverse reaction
SD	standard deviation
SAP	Statistical Analysis Plan
SAS	Statistical Analysis System

3. INTRODUCTION

ACCUSOL 35 solutions are indicated for the treatment of acute and chronic renal failure, as substitution solution in haemofiltration and haemodiafiltration, and as dialysis solution in haemodialysis and haemodiafiltration. The product is presented in 3 formulations, 1 without potassium chloride (KCl) and 2 containing KCl (at concentrations of 2 mmol/L and 4 mmol/L). All 3 formulations contain calcium chloride dihydrate, magnesium chloride hexahydrate, sodium chloride and sodium bicarbonate. The 2 KCl formulations also contain glucose monohydrate.

In 2008, Baxter Healthcare Corporation (Baxter; the manufacturer of ACCUSOL 35 solutions) received an increased number of product quality complaint reports related to the presence of white precipitate observed in the continuous renal replacement (CRRT) lines during continuous veno-venous haemofiltration and continuous veno-venous haemodiafiltration during the use of ACCUSOL 35 solutions. In 2009, Baxter's root cause investigation identified that the precipitate was calcium carbonate, and a change in the pH of the mixed solution (supersaturation) was acknowledged as the major contributing factor to precipitate formation. Further investigation revealed that the addition of a low amount of phosphate salt as an excipient and lowering the pH of the mixed solution could inhibit the formation of calcium carbonate.

As part of their responses on 27 August 2009, Baxter made a commitment to the Pharmacovigilance Working Party to perform a post-approval safety study with the updated solution to monitor the safety of the updated formulation, specifically to address the risk of calcium carbonate precipitate formation.

This post-approval safety study is designed to verify the successful minimization of the risk of precipitate formation with the updated ACCUSOL 35 solution. The confirmation of the prevention of precipitate formation will support a proposal for removal of the current recommendation (presented in the labelling for the ACCUSOL 35 solutions) to inspect the CRRT lines every 30 minutes for the presence of precipitate during the use of the products.

The statistical analysis plan (SAP) is created based on Study protocol 8822-01 dated 12 Jan 2015. All analyses will be performed using SAS statistical analysis software (SAS, SAS/GRAPH and SAS/STAT; version 9.4 or higher of SAS for Windows [SAS Institute Inc; Cary, NC, USA]). Data listings will be created to display the raw clinical data collected in this study.

This SAP describes all analyses to be conducted by PSI. This document describes the patient populations that will be analyzed, the variables that will be used for the analyses, the statistical methods that will be employed, and the analysis conventions that will be used to guide statistical programming. The intention of the SAP is to expand on the details of the planned statistical methods described in the study protocol.

4. TRIAL OBJECTIVES

The updated ACCUSOL 35 formulations were developed to prevent calcium carbonate precipitate formation during CRRT administration. The objective of this study is to confirm the prevention of calcium carbonate precipitate formation during CRRT by the use of the updated ACCUSOL 35 solutions.

5. STUDY DESIGN AND CONDUCT CONSIDERATIONS

5.1 Study Design

This study is a prospective, multicenter, non-interventional, uncontrolled, open-label, observational study in adult patients undergoing CRRT using any of the updated ACCUSOL 35 solutions. The study is intended to capture data on the absence or presence of visible precipitate during 72 hours of use of ACCUSOL 35 solution with a single CRRT circuit.

Study centers will use the ACCUSOL 35 solutions from their available inventory; no ACCUSOL 35 solutions or any other approved medications or investigational products will be provided to the study centers by the Sponsor. CRRT therapy will be administered in accordance with the intensive care unit's (ICU) usual clinical practice and the recommendations in the current labeling for ACCUSOL 35 solutions. Addition of antibiotics or any other medications to the ACCUSOL 35 solution bag, except for KCl supplementation, will not be allowed.

There will be no randomized or non-randomized treatment assignments; no diagnostic, therapeutic, or experimental interventions; and no restrictions on use of concomitant medications or other treatments, except as noted above for the restriction on addition of medications other than KCl supplementation to the ACCUSOL 35 solution bag. Study patients will be prospectively identified in that study data will only be collected from patients treated after study enrollment at a site has been authorized by the responsible ethics committee (EC) and the Sponsor.

Data will be collected at patient enrollment (at approximately 40 hours of CRRT with the same CRRT circuit) and periodically up to 72 hours of CRRT with the same circuit, or until the CRRT circuit needs to be changed or CRRT is completed (if either occurs

sooner than 72 hours). The CRRT lines will be inspected every 30 minutes for the duration of the therapy, as recommended in the labeling for the ACCUSOL 35 solutions.

Observation of the CRRT circuit for precipitate through 72 hours of use is intended to represent a worst-case situation, since 72 hours is the maximum intended use period for a single CRRT circuit. Enrollment of patients whose CRRT circuit has already been in use for 40 hours is intended to maximize the possibility of the studied CRRT circuits reaching 72 hours of use for inclusion in the primary analysis (see Section 9.5), while maintaining a reasonable overall study size by reducing the number of patients enrolled.

If precipitate is seen in a CRRT line during therapy administration, the therapy will be stopped and proper procedures and monitoring (as recommended in the current ACCUSOL 35 solutions labeling) will be performed in order to return the circuit blood back to the patient and immediately set up a new CRRT circuit to continue therapy.

This study is strictly a non-interventional observational safety study assessing the presence or absence of visible precipitate in the CRRT lines with the specific products being studied. Therefore, no control group is considered necessary to achieve the study objectives.

5.2 Sample Size

Based on published CRRT studies[1-5], it is estimated that of those CRRT treatments that have reached 40 hours with the same CRRT circuit, 25% will continue with the same circuit through 72 hours of use. It is expected, therefore, that about 240 enrolled patients will provide data on approximately 60 treatments that last 72 hours without CRRT circuit changes. If no visible precipitate is observed within that time in at least 58 evaluable treatments (ie, those in which CRRT circuits remains precipitate-free for 72 hours, and those in which visible precipitate is observed within 72-hours), the study will have provided 95% confidence that the probability of visible precipitate formation during 72 hours of CRRT with ACCUSOL 35 solution using the same CRRT circuit is not more than 5.0%.

It is also reasonable to assume (based on the published studies[1-5]) that approximately 10% of all CRRT treatments will last 72 hours, regardless of whether the same CRRT circuit is in use the whole time. Combining the probabilities of both having a treatment last 72 hours and also having visible particulate formation reduces the risk from 5% to 0.5%. Thus a sample size of 58 treatments with no observed precipitate will demonstrate, with 95% confidence, that the probability of precipitate formation in all CRRT treatments

with ACCUSOL 35 solutions of any length (and not necessarily with the same CRRT circuit) is not more than 0.5%.

5.3 Safety Measures

The key safety variables to be collected for analysis include:

- Amount of ACCUSOL 35 solution delivered through the CRRT circuit observed during the study
- Start- and end-of use times for the CRRT circuit used during the study
- Presence or absence of visible precipitate in the CRRT lines used during the study
- Time of observation of visible precipitate (if applicable)
- Color of precipitate observed (if applicable)
- Reason for terminating the use of the CRRT circuit, if during the study
- Reason for terminating the CRRT, if during the study
- Reason for end of patient's study participation

In addition, adverse reactions will be recorded.

5.4 Completion and Discontinuation

The planned maximum study observation period is 32 hours: from 40 hours after CRRT with the current circuit was started until 72 hours of treatment has been administered using that same circuit.

The following reasons for patients' early termination are collected on the electronic case report form: termination of CRRT, change of CRRT circuit, adverse reaction, loss to follow up, withdrawal by patient, study termination by sponsor, physician decision, protocol violation, death, other (to be specified).

5.4.1 Patient Withdrawal from the Study

Patients, or their legally authorized representatives, may terminate their consent for collection of their medical data for use in the study at any time. Should a patient or their legally authorized representative do so, site study personnel will record the time of and the reason provided for the withdrawal. The data collected on withdrawn patients will be used in the analyses, as applicable, and included in the clinical study report.

5.4.2 Study Termination

The Sponsor may prematurely terminate this study at any time for any reason. It may also terminate a single study centre from participation in the study at any time for various reasons such as:

- Inadequate rate of patient enrollment into the study
- Noncompliance with protocol requirements or data collection methods
- Noncompliance with Good Clinical Practice guidelines; applicable national and local laws; and/or applicable guidelines or regulations for protecting the rights, safety, and welfare of patients
- Knowingly submitting false information to the Sponsor or designee.

If the study is prematurely terminated, all collected study data must be provided to the Sponsor.

6. STUDY POPULATIONS

6.1 Analysis Populations

6.1.1 Enrolled Population

The enrolled population will be patients expected to receive CRRT with ACCUSOL 35 solution(s) using the same CRRT circuit for at least 72 hours. All analyses will be performed on the enrolled population, except as otherwise noted below.

6.1.2 Evaluable Patient Population (Per-Protocol Population)

The evaluable patient population (per-protocol population) will be used for the primary analysis of this study. Although not specifically stated in the protocol, the evaluable patient population includes patients:

- Who were treated with a single CRRT circuit and whose circuits remained precipitate-free for 72 hours, or in whose circuits visible precipitate was observed within 72 hours and
- Whose study participation and treatment were not subject to any protocol deviations that may have substantially affected the primary safety endpoints (e.g., missing information on precipitate at 72 hours, or at least 25% of planned time points)

The final decision on the exact criteria for exclusion from the evaluable patient population will be made in a data review meeting prior to database lock.

7. STATISTICAL ANALYSIS

7.1 General

All analyses will be performed using SAS statistical analysis software (SAS, SAS/GRAPH and SAS/STAT; version 9.4 or higher of SAS for Windows [SAS Institute Inc; Cary, NC, USA]).

7.2 Handling of Missing Data

No imputation of missing values will be performed.

7.3 Interim Analysis

A formal interim analysis is not planned for this study.

7.4 Pooling Strategy for Study Sites

This is a multicenter study. Data will be pooled across clinical centers and no adjustment will be made for centers in the analyses.

7.5 Visit Windows/Unscheduled Visits

Data will be collected at patient enrollment (at approximately 40 hours of CRRT with the same CRRT circuit) and periodically up to 72 hours of CRRT with the same circuit, or until the CRRT circuit needs to be changed or CRRT is completed (if either occurs sooner than 72 hours). The CRRT lines will be inspected every 30 minutes for the duration of the therapy, as recommended in the labeling for the ACCUSOL 35 solutions.

7.6 Other Issues

No other issues have been identified.

7.7 Changes to Planned Analyses Described in the Protocol

Any changes made to analysis described in the final SAP will be documented in the clinical study report.

8. PATIENT DISPOSITION

The patients who were screened, in the enrolled population, and in the per-protocol population will be summarized for each of these categories using number (n) and percentage (%). In addition, the patients who are screen failures or prematurely terminated will be summarized using number (n) and percentage (%) for each discontinuation category specified on the electronic case report forms. A data listing will be provided for the patients' study disposition status with reasons for discontinuation.

9. PROTOCOL DEVIATIONS

A data listing of protocol deviations will be provided.

10. DEMOGRAPHICS AND BASELINE CHARACTERISTICS

Demographic and baseline characteristics such as age (years) and weight (kg) will be summarized for the Enrolled Population and the Per-Protocol Population using descriptive statistics such as n, mean, standard deviation (SD), median, Min, Max and number missing. Number (n) and percentage (%) will be summarized for gender and age (years) categories 18-35 years, 36-45 years, 46-55 years, 56-65 years and > 65 years.

Data listings will be provided for demographic and baseline characteristics.

11. TREATMENT COMPLIANCE AND EXPOSURE

Duration (hours) of current CRRT circuit use will be calculated using the time from the start of use of the current CRRT circuit to the time of end of the current CRRT circuit (i.e., derived from time of the end of current CRRT circuit –time of start of the current CRRT circuit). Duration (hours) of current CRRT circuit use and the amount of ACCUSOL 35 solution delivered through the CRRT circuit observed during the study, the ultrafiltration rate, and dose rate by site of introduction (if there is no unique value for a patient, the arithmetic mean will be used) will be summarized descriptively using n, mean, standard deviation (SD), median, Min, Max and number missing. The frequency and percentage of ACCUSOL 35 formulations and CRRT mode used will be tabulated.

In addition, the incidence of major protocol deviations related to ACCUSOL 35 solution administration will be summarized.

Data listings will be provided for CRRT administration and exposure to ACCUSOL 35 solution administration. They will include the manufacturer and model of the CRRT monitor and lines and of the haemofilter used, the CRRT mode employed and the ultrafiltration rate(s) used, the formulations and lot numbers of ACCUSOL 24 solutions administered, ACCUSOL 35 dose rate(s) and site of introduction as well as the start and end times of the CRRT circuit used during the study.

12. SAFETY

12.1 Primary Analysis

The primary analysis for this study will be to evaluate the incidence of visible precipitate in the CRRT lines during 72 hours of use of the single CRRT circuit. If the upper bound of the 95% confidence interval on the true proportion of treatments having precipitate

formation is 5% or less, then the primary objective of the study will have been achieved. Jeffrey's method [6] has been selected for generating the upper bound because normal approximation is not feasible when a zero rate is expected, and Jeffrey's method is considered appropriate for the planned sample size.

Number (n) and proportion of patients with visible precipitate in the CRRT lines during 72 hours of use of the single CRRT circuit will be summarized and presented along with the corresponding Jeffrey's 95% confidence interval for proportion.

In addition, a data listing will be provided for precipitate observation.

12.2 Adverse Reactions

Adverse reactions will be coded to a Medical Dictionary for Regulatory Activities (MedDRA; Version 17.1) system organ class and preferred term. Adverse reactions will be summarized both by the total frequency of reactions and by the frequency and percentage of patients having at least one reaction. These adverse reaction summaries will be done overall and by MedDRA system organ class and preferred term. The specific adverse reactions will be summarized by system organ class and preferred term; Adverse reactions by system organ class, preferred term and severity; and adverse reactions by system organ class, preferred term and Relationship with study drug. The serious adverse reactions will be summarized by system organ class and preferred term; serious adverse reactions by system organ class, preferred term and severity; and serious adverse reactions by system organ class and preferred term and relationship with study drug. Data listings will be provided for adverse reactions.

The number (n) and percentage (%) of patients with at least one adverse reaction or serious adverse reaction will be presented.

12.3 Laboratory Parameters

No clinical laboratory test results were collected in this study.

12.4 Exploratory Analyses

Exploratory analysis will be done only if visible precipitate is observed during 72 hours of use of ACCUSOL 35 solution with a single CRRT circuit.

The time to first occurrence will be calculated (time from start of use of the CRRT circuit to time of observation of precipitate) and summarized using Kaplan-Meier methodology. In addition, further analyses may be performed to explore contributing factors (e.g., ACCUSOL 35 solution formulation(s) and lot(s) administered; dose rate(s) and amount

of ACCUSOL 35 delivered through the circuit; frequency of use and concentration of KCl added to the ACCUSOL 35 solution; manufacturer and model of CRRT lines used; haemofilter used; use and type of anticoagulant; CRRT mode; or ultrafiltration rate) by summary statistics, as appropriate.

Time to first occurrence (hours) = time of observation of precipitate - time of start of use of the CRRT circuit.

Additional exploratory analyses pertaining to visible precipitate may be performed.

13. OTHER RELEVANT DATA ANALYSES/SUMMARIES

Concomitant medications (anticoagulant administration and any supplemental KCl added to the ACCUSOL 35 solution[s]) will be coded using the World Health Organization drug dictionary (WHODrug, September 2014). Concomitant medications within each therapeutic category will be summarized using number (n) and percentage (%) of patients receiving concomitant medication at the anatomic therapeutic class (ATC) Level 2 and preferred term level. A summary table will be provided for patients' concomitant medications combining the categories above.

In addition, data listings will be provided for anticoagulant administration and potassium chloride administration.

14. SUBGROUP ANALYSES

No subgroup analysis is planned beyond the possible exploratory analyses described above (see Section 12.4).

15. REFERENCES

1. Monchi M, Berghmans D, Ledoux D, Canivet J-L, Dubois B, Damas P. Citrate vs. heparin for anticoagulation in continuous venovenous hemofiltration: a prospective randomized study. *Intensive Care Med.* 2004;30:260-265. doi:10.1007/s00134-003-2047-x.
2. Kutsogiannis DJ, Gibney RT, Stollery D, Gao J. Regional citrate versus systemic heparin anticoagulation for continuous renal replacement in critically ill patients. *Kidney Int.* 2005;67:2361-2367. doi:10.1111/j.1523-1755.2005.00342.x
3. Morabito S, Pistolesi V, Tritapepe L, et al. Regional citrate anticoagulation in cardiac surgery patients at high risk of bleeding: a continuous veno-venous hemofiltration protocol with a low concentration citrate solution. *Critical Care.* 2012;16:R1111. doi:10.1186/cc11403.
4. Hetzel GR, Schmitz M, Wissing H, et al. Regional citrate versus systemic heparin for anticoagulation in critically ill patients on continuous venovenous haemofiltration: a prospective randomized multicentre trial. *Nephrol Dial Transplant.* 26(1):232-239. doi:10.1093/ndt/gfq575.
5. Betjes MGH, van Oosterom D, van Agteren M, van de Wetering J. Regional citrate versus heparin anticoagulation during venovenous hemofiltration in patients at low risk for bleeding: similar hemofilter survival but significantly less bleeding. *J Nephrol.* 2007;20(5):602-608.
6. Brown LD, Cai TT, DasGupta A. Interval estimation for a binomial proportion. *Stat Sci.* 2001;16(2):101-117.

16. LISTS OF TABLES AND LISTINGS

16.1 Tables

Patient Disposition, Demographics and Other Baseline Characteristics

Table 14.1.1	Patient Disposition - All Screened Patients
Table 14.1.2	Patients Excluded From the Per-Protocol Population - Enrolled Population
Table 14.1.3.1	Summary of Demographic and Baseline Characteristics - Enrolled Population
Table 14.1.3.2	Summary of Demographic and Baseline Characteristics - Per-Protocol Population
Table 14.1.4	Anti-coagulant and potassium chloride administration - Enrolled Population
Table 14.1.5.1	CRRT Details: Ultrafiltration Rate - Enrolled Population
Table 14.1.5.2	CRRT Details: CRRT Mode - Enrolled Population
Table 14.1.5.3	ACCUSOL 35 Administration: Formulation Used – Enrolled Population
Table 14.1.5.4	ACCUSOL 35 Administration: Dose Rate by Site of Introduction - Enrolled Population
Table 14.1.5.5	ACCUSOL 35 Administration: Amount Administered - Enrolled Population
Table 14.1.5.6	ACCUSOL 35 Administration: Major Protocol Deviations - Enrolled Population

Safety Analysis

Table 14.3.1.1	Analysis of Precipitate Formation – Per-Protocol Population
Table 14.3.1.2.1	Overview of Adverse Reactions on Patient Level - Enrolled Population
Table 14.3.1.2.2	Overview of Total Adverse Reactions - Enrolled Population
Table 14.3.1.3.1	Summary of Adverse Reactions - Enrolled Population
Table 14.3.1.3.2	Summary of Adverse Reactions (by Frequency of Reactions) - Enrolled Population
Table 14.3.1.4.1	Summary of Adverse Reactions by Severity - Enrolled Population
Table 14.3.1.4.2	Summary of Adverse Reactions by Severity (by Frequency of Reactions) - Enrolled Population
Table 14.3.1.5.1	Summary of Adverse Reactions by Relationship with Study Drug - Enrolled Population
Table 14.3.1.5.2	Summary of Adverse Reactions by Relationship with Study Drug (by Frequency of Reactions) - Enrolled Population
Table 14.3.2.1.1	Summary of Serious Adverse Reactions - Enrolled Population
Table 14.3.2.1.2	Summary of Serious Adverse Reactions (by Frequency of Reactions) - Enrolled Population
Table 14.3.2.2.1	Summary of Serious Adverse Reactions by Severity - Enrolled Population

Safety Analysis

Table 14.3.2.2.2	Summary of Serious Adverse Reactions by Severity (by Frequency of Reactions) - Enrolled Population
Table 14.3.2.3.1	Summary of Serious Adverse Reactions by Relationship to Study Drug - Enrolled Population
Table 14.3.2.3.2	Summary of Serious Adverse Reactions by Relationship to Study Drug (by Frequency of Reactions) - Enrolled Population

Exploratory Analysis

Table 14.3.3.1	Exploratory Analysis: Time to First Occurrence of Precipitate - Per-Protocol Population
Table 14.3.3.2	Exploratory Analysis: Precipitate Formation by Dialysis Solution Used at Time of Observation - Per-Protocol Population

16.2 Data Listings

Patient Disposition

Data Listing 16.2.1	Patient Disposition: Completion/ Discontinuation from Study - Enrolled Population
Data Listing 16.2.2	Protocol Deviations - Enrolled Population
Data Listing 16.2.3.1	Patients excluded from Per-Protocol Population - Enrolled Population
Data Listing 16.2.3.2	Inclusion/Exclusion – Screened Population

Demographic/Baseline Characteristics

Data Listing 16.2.4	Demographic and Baseline Characteristics - Enrolled Population
Data Listing 16.2.5.1	Anti-Coagulant Administration - Enrolled Population
Data Listing 16.2.5.2	Potassium Chloride Administration - Enrolled Population
Data Listing 16.2.5.3	ACCUSOL 35 Administration - Enrolled Population
Data Listing 16.2.5.4	Dialysis Session - Enrolled Population
Data Listing 16.2.5.5	Dialysis Session - Interruptions - Enrolled Population

Safety Data

Data Listing 16.2.7.1	Precipitate Observation - Enrolled Population
Data Listing 16.2.7.2	Adverse Reactions - Enrolled Population
Data Listing 16.2.7.3	Serious Adverse Reactions - Enrolled Population
Data Listing 16.2.7.4	Deaths - Enrolled Population

17. MOCK TABLES AND LISTINGS

17.1 Tables

Page x of y

Table 14.1.1. Patient Disposition - All Screened Patients

	Total n (%)
Patients screened (a)	xxx
Number of screen failures	xx
Reason if screen failure	
Failure to meet eligibility criteria	xx (xx.x)
Death	xx (xx.x)
...to be continued	
Patients enrolled (b)	xxx
Patients in Per-Protocol population	xx (xx.x)
Patients completed the study	xx (xx.x)
Patients prematurely discontinued	xx (xx.x)
Reason if discontinued	
Reason 1	xx (xx.x)
Reason 2	xx (xx.x)

(a) Denominator of the percentages is the number of patients screened.

(b) Denominator of the percentages is the number of patients enrolled.

Program \\xxxxxxx\yyyyyyy\zzzzzzz.sas Output: \\xxxxxxx\yyyyyyy\zzzzzzzzzz.txt Data: xxFEB2016
Table Generation: DDMMYYYY, Version: Draft Programmer ID: xxxxxx

Table 14.1.2 Patients Excluded From the Per-Protocol Population - Enrolled Population

	Total n (%)
Patients in Enrolled Population	xxx
Patients Excluded from Per-Protocol Population	xxx (xx.x)
Reason, if excluded	
xxxxxxxxxx	xxx (xx.x)
xxxxxxxxxx	xxx (xx.x)

Denominator of the percentage is the number of patients enrolled.
Source Data: Listing 16.xx

Program \\xxxxxxx\yyyyyyyy\zzzzzzz.sas Output: \\xxxxxxx\yyyyyyyy\zzzzzzzzzz.txt Data: xxFEB2016
Table Generation: DDMMYYYY, Version: Draft Programmer ID: xxxxxx

Table 14.1.3.1 Summary of Demographic and Baseline Characteristics - Enrolled Population

	Statistics	ACCUSOL 35 (N=XXX)
Gender		
Male	n (%)	xx (xx.x)
Female	n (%)	xx (xx.x)
missing	n (%)	xx (xx.x)
Age (years)		
18-35	n (%)	xx (xx.x)
36-45	n (%)	xx (xx.x)
46-55	n (%)	xx (xx.x)
56-65	n (%)	xx (xx.x)
> 65	n (%)	xx (xx.x)
missing	n (%)	xx (xx.x)
	n	xxx
	Mean (SD)	xx.x (xx.xx)
	Median	xx.x
	Min, Max	xx.x, xx.x
	Missing	xx
Weight (kg)		
	n	xxx
	Mean (SD)	xx.x (xx.xx)
	Median	xx.x
	Min, Max	xx.x, xx.x
	Missing	xx

Table 14.1.3.1 Summary of Demographic and Baseline Characteristics - Enrolled Population

Statistics	ACCUSOL 35 (N=XXX)

Denominator of the percentage is the number of patients in the Enrolled Population.

N:number of enrolled patients

Demographic data is missing for some patients because informed consent was not obtained from the patient personally.

Program \\xxxxxxx\yyyyyyyy\zzzzzzzz.sas Output: \\xxxxxxx\yyyyyyyy\zzzzzzzzzz.txt Data: xxFEB2016

Table Generation: DDMMYY, Version: Draft Programmer ID: xxxxxx

"Missing" categories to be shown if applicable

Table 14.1.3.2 Summary of Demographic and Baseline Characteristics Per-Protocol Population.

Table 14.1.3.2 is similar to Table 14.1.3.1.

Table 14.1.4 Anti-coagulant and potassium chloride administration - Enrolled Population

ATC Level 2	ACCUSOL 35
Preferred Term	(N=XXX)
	n (%)
XXXXXXXXXXXXXXXXXXXXXXXXXXXX	xxx (xx.x)
XXXXXXXXXXXXXXXXXXXXXXXXXXXX	xxx (xx.x)
XXXXXXXXXXXXXXXXXXXXXXXXXXXX	xxx (xx.x)
XXXXXXXXXXXXXXXXXXXXXXXXXXXX	xxx (xx.x)
XXXXXXXXXXXXXXXXXXXXXXXXXXXX	xxx (xx.x)
XXXXXXXXXXXXXXXXXXXXXXXXXXXX	xxx (xx.x)
XXXXXXXXXXXXXXXXXXXXXXXXXXXX	xxx (xx.x)

Note: Every patient is counted a single time for each applicable specific anti-coagulant and potassium chloride administration. A patient with multiple medications within a medication category is counted a single time for that category.
N: number of patients in the enrolled population.

Program \\xxxxxxx\yyyyyyyy\zzzzzzzz.sas Output: \\xxxxxxx\yyyyyyyy\zzzzzzzzzz.txt Data: xxFEB2016
Table Generation: DDMMYYYY, Version: Draft Programmer ID: xxxxxx

Table 14.1.5.1 CRRT Details: Ultrafiltration Rate - Enrolled Population

	Statistics	ACCUSOL 35 (N=XXX)
Ultrafiltration rate (L/h)	n	xxx
	Mean (SD)	xx.x (xx.xx)
	Median	xx.x
	Min, Max	xx.x, xx.x
	Missing	xx

Program \\xxxxxxx\yyyyyyyy\zzzzzzzz.sas Output: \\xxxxxxx\yyyyyyyy\zzzzzzzzzzzz.txt Data: xxFEB2016
Table Generation: DDMMYYYY, Version: Draft Programmer ID: xxxxxx

Table 14.1.5.2 CRRT Details: CRRT Mode - Enrolled Population

	Statistics	ACCUSOL 35 (N=XXX)
Continuous Venovenous Hemofiltration (CVVH)	n (%)	xx (xx.x)
Continuous Venovenous Hemodialysis (CVVHD)	n (%)	xx (xx.x)
Continuous Venovenous Hemodiafiltration (CVVHDF)	n (%)	xx (xx.x)
Slow Continuous Ultrafiltration (SCUF)	n (%)	xx (xx.x)
Arteriovenous Modes of CRRT	n (%)	xx (xx.x)
Other	n (%)	xx (xx.x)

Program \xxxxxxx\yyyyyyyy\zzzzzzzz.sas Output: \xxxxxxx\yyyyyyyy\zzzzzzzzzz.txt Data: xxFEB2016
Table Generation: DDMMYYYY, Version: Draft Programmer ID: xxxxxx

Table 14.1.5.3 ACCUSOL 35 Administration: Formulation Used - Enrolled Population

	Statistics	ACCUSOL 35 (N=XXX)
ACCUSOL 35	n (%)	xx (xx.x)
ACCUSOL 35 Potassium 2 mmol/L	n (%)	xx (xx.x)
ACCUSOL 35 Potassium 4 mmol/L	n (%)	xx (xx.x)
ACCUSOL 35 and ACCUSOL 35 Potassium 2 mmol/L	n (%)	xx (xx.x)
ACCUSOL 35 and ACCUSOL 35 Potassium 4 mmol/L	n (%)	xx (xx.x)
ACCUSOL 35 Potassium 2 mmol/L and ACCUSOL 35 Potassium 4 mmol/L	n (%)	xx (xx.x)

Program \\xxxxxxx\yyyyyyy\zzzzzzz.sas Output: \\xxxxxxx\yyyyyyy\zzzzzzzzzz.txt Data: xxFEB2016

Table Generation: DDMMYYYY, Version: Draft Programmer ID: xxxxxx

Table 14.1.5.4 ACCUSOL 35 Administration: Dose Rate by Site of Introduction - Enrolled Population

	Statistics	ACCUSOL 35 (N=XXX)
Dose rate - Pre-filter (ml/kg/hr)	n	xxx
	Mean (SD)	xx.x (xx.xx)
	Median	xx.x
	Min, Max	xx.x, xx.x
	Missing	xx
Dose rate - Post-filter (ml/kg/hr)		
Dose rate – As dialysate (ml/kg/hr)		
Dose rate - Other (ml/kg/hr)		
Dose rate – Combination (ml/kg/hr)		

Program \\xxxxxxx\yyyyyyyy\zzzzzzzz.sas Output: \\xxxxxxx\yyyyyyyy\zzzzzzzzzz.txt Data: xxFEB2016
Table Generation: DDMMYYYY, Version: Draft Programmer ID: xxxxxx

Table 14.1.5.5 ACCUSOL 35 Administration: Amount Administered - Enrolled Population

	Statistics	ACCUSOL 35 (N=XXX)
Amount administered (L)	n	xxx
	Mean (SD)	xx.x (xx.xx)
	Median	xx.x
	Min, Max	xx.x, xx.x
	Missing	xx

Program \\xxxxxxx\yyyyyyyy\zzzzzzzz.sas Output: \\xxxxxxx\yyyyyyyy\zzzzzzzzzz.txt Data: xxFEB2016
Table Generation: DDMMYYYY, Version: Draft Programmer ID: xxxxxx

Table 14.1.5.6 ACCUSOL 35 Administration: Incidence of Major Protocol Deviations - Enrolled Population

	Statistics	ACCUSOL 35 (N=XXX)
Deviation 1	n (%)	xx (xx.x)
Deviation 2	n (%)	xx (xx.x)
Deviation 3	n (%)	xx (xx.x)

Program \\xxxxxxx\yyyyyyy\zzzzzzzz.sas Output: \\xxxxxxx\yyyyyyy\zzzzzzzzzzzz.txt Data: xxFEB2016
Table Generation: DDMMYYYY, Version: Draft Programmer ID: xxxxxx

Page X of Y

Table 14.3.1.1 Analysis of Precipitate Formation - Per-Protocol Population

	ACCUSOL 35 (N=XXX)	
	n (%)	95% CI
Proportion of patients with visible precipitate during 72 hours of use of ACCUSOL 35 solution with a single CRRT circuit	xx (xx.x)	(x. xxx, x.xxx)

N:number of evaluable patients

CI: Confidence Interval. Jeffrey's method is used to derive the confidence interval.

Program \\xxxxxxx\yyyyyyyy\zzzzzzzz.sas Output: \\xxxxxxx\yyyyyyyy\zzzzzzzzzz.txt Data: xxFEB2016
Table Generation: DDMMYY, Version: Draft Programmer ID: xxxxxx

Page X of Y

Table 14.3.1.2.1 Overview of Adverse Reactions on Patient Level - Enrolled Population

	ACCUSOL 35 (N=XXX)
	n (%)
Patients with at least one AR	xx (xx.x)
Patients with at least one Serious AR	xx (xx.x)
Patients with at least one Drug-Related AR	xx (xx.x)
Patients with at least one serious Drug-related adverse reactions	xx (xx.x)
Patients with AR leading to discontinuation	xx (xx.x)
Patients with SAR leading to discontinuation	xx (xx.x)

N: number of patients in the enrolled population

Program \\xxxxxxx\yyyyyyyy\zzzzzzzz.sas Output: \\xxxxxxx\yyyyyyyy\zzzzzzzzzzzz.txt Data: xxFEB2016
Table Generation: DDMMYYYY, Version: Draft Programmer ID: xxxxxx

Table 14.3.1.2.2 Overview of Total Adverse Reactions - Enrolled Population

	ACCUSOL 35 (N=XXX) n
Total Number of ARs	xx
Total Number of Serious ARs	xx
Total Number of Drug-Related ARs	xx
Total Number of serious Drug-related adverse reactions	xx

N: number of patients in the enrolled population

Program \\xxxxxxx\yyyyyyy\zzzzzzz.sas Output: \\xxxxxxx\yyyyyyy\zzzzzzzzzz.txt Data: xxFEB2016
Table Generation: DDMMYYYY, Version: Draft Programmer ID: xxxxxx

Table 14.3.1.3.1 Summary of Adverse Reactions - Enrolled Population

System Organ Class	ACCUSOL 35 (N=XXX)
Preferred Term	n (%)
Patients with one or more adverse reactions	xxx (xx.x)
XXXXXXXXXXXXXXXXXXXXXXXXXXXX	xxx (xx.x)
XXXXXXXXXXXXXXXXXXXXXXXXXXXX	xxx (xx.x)
XXXXXXXXXXXXXXXXXXXXXXXXXXXX	xxx (xx.x)
XXXXXXXXXXXXXXXXXXXXXXXXXXXX	xxx (xx.x)
XXXXXXXXXXXXXXXXXXXXXXXXXXXX	xxx (xx.x)
XXXXXXXXXXXXXXXXXXXXXXXXXXXX	xxx (xx.x)
XXXXXXXXXXXXXXXXXXXXXXXXXXXX	xxx (xx.x)
XXXXXXXXXXXXXXXXXXXXXXXXXXXX	xxx (xx.x)

Denominator of the percentage is the number of patients in the enrolled population.

Every patient is counted a single time for each applicable specific adverse reaction. A patient with multiple adverse reactions within a system organ class is counted a single time for that system organ class. A patient may appear more than once in different System Organ Class categories.

N: number of patients in the enrolled population.

Program \\xxxxxxx\yyyyyyyy\zzzzzzzz.sas Output: \\xxxxxxx\yyyyyyyy\zzzzzzzzzz.txt Data: xxFEB2016

Table Generation: DDMMYYYY, Version: Draft Programmer ID: xxxxxx

Table 14.3.1.3.2 Summary of Adverse Reactions (by Frequency of Reactions) - Enrolled Population

System Organ Class	ACCUSOL 35 (N=XXX)
Preferred Term	n (%)
Total number of adverse reactions	xxx (100.0)
XXXXXXXXXXXXXXXXXXXXXXXXXXXX	xxx (xx.x)
XXXXXXXXXXXXXXXXXXXXXXXXXXXX	xxx (xx.x)
XXXXXXXXXXXXXXXXXXXXXXXXXXXX	xxx (xx.x)
XXXXXXXXXXXXXXXXXXXXXXXXXXXX	xxx (xx.x)
XXXXXXXXXXXXXXXXXXXXXXXXXXXX	xxx (xx.x)
XXXXXXXXXXXXXXXXXXXXXXXXXXXX	xxx (xx.x)
XXXXXXXXXXXXXXXXXXXXXXXXXXXX	xxx (xx.x)
XXXXXXXXXXXXXXXXXXXXXXXXXXXX	xxx (xx.x)
XXXXXXXXXXXXXXXXXXXXXXXXXXXX	xxx (xx.x)

Denominator of the percentage is the total number of adverse reactions.

N: number of patients in the enrolled population.

Program \\xxxxxxx\yyyyyyyy\zzzzzzz.sas Output: \\xxxxxxx\yyyyyyyy\zzzzzzzzzz.txt Data: xxFEB2016

Table Generation: DDMMYYYY, Version: Draft Programmer ID: xxxxxx

Table 14.3.1.4.1 Summary of Adverse Reactions by Severity - Enrolled Population

System Organ Class Preferred Term	ACCUSOL 35 (N=XXX)		
	Mild n (%)	Moderate n (%)	Severe n (%)
Patients with one or more adverse reactions	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)

Denominator of the percentage is the number of patients in the enrolled population.

Every patient is counted a single time for each applicable specific adverse reaction with highest severity. A patient with multiple adverse reactions within a system organ class is counted a single time for that system organ class. A patient may appear more than once in different System Organ Class categories.

N: number of patients in the enrolled population.

Program \\xxxxxxx\yyyyyyyy\zzzzzzzz.sas Output: \\xxxxxxx\yyyyyyyy\zzzzzzzzzz.txt Data: xxFEB2016

Table Generation: DDMMYY, Version: Draft Programmer ID: xxxxxx

Table 14.3.1.4.2 Summary of Adverse Reactions by Severity (by Frequency of Reactions) - Enrolled Population

System Organ Class Preferred Term	ACCUSOL 35 (N=XXX)		
	Mild n (%)	Moderate n (%)	Severe n (%)
Total number of adverse reactions	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)

Denominator of the percentage is the total number of adverse reactions in the treatment group.
N: number of patients in the enrolled population.

Program \\xxxxxxx\yyyyyyyy\zzzzzzzz.sas Output: \\xxxxxxx\yyyyyyyy\zzzzzzzzzz.txt Data: xxFEB2016
Table Generation: DDMMYYYY, Version: Draft Programmer ID: xxxxxxx

Table 14.3.1.5.1 Summary of Adverse Reactions by Relationship to Study Drug - Enrolled Population

System Organ Class Preferred Term	ACCUSOL 35 (N=XXX)	
	Possibly Related n (%)	Probably Related n (%)
Patients with one or more adverse reactions	xxx (xx.x)	xxx (xx.x)
xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx	xxx (xx.x)	xxx (xx.x)
xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx	xxx (xx.x)	xxx (xx.x)
xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx	xxx (xx.x)	xxx (xx.x)
xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx	xxx (xx.x)	xxx (xx.x)
xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx	xxx (xx.x)	xxx (xx.x)
xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx	xxx (xx.x)	xxx (xx.x)
xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx	xxx (xx.x)	xxx (xx.x)

Denominator of the percentage is the number of patients in the enrolled population.

Every patient is counted a single time for each applicable specific adverse reaction. A patient with multiple adverse reactions within a system organ class is counted a single time for that system organ class. A patient may appear more than once in different System Organ Class categories.

N: number of patients in the enrolled population.

Program \\xxxxxxx\yyyyyyyy\zzzzzzzz.sas Output: \\xxxxxxx\yyyyyyyy\zzzzzzzzzz.txt Data: xxFEB2016

Table Generation: DDDMMYYY, Version: Draft Programmer ID: xxxxxxx

Table 14.3.1.5.2 Summary of Adverse Reactions by Relationship to Study Drug (by Frequency of Reactions) - Enrolled Population

System Organ Class	ACCUSOL 35 (N=XXX)	
	Possibly Related n (%)	Probably Related n (%)
Preferred Term		
Total number of reactions	xxx (xx.x)	xxx (xx.x)
xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx	xxx (xx.x)	xxx (xx.x)
xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx	xxx (xx.x)	xxx (xx.x)
xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx	xxx (xx.x)	xxx (xx.x)
xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx	xxx (xx.x)	xxx (xx.x)
xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx	xxx (xx.x)	xxx (xx.x)
xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx	xxx (xx.x)	xxx (xx.x)
xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx	xxx (xx.x)	xxx (xx.x)

Denominator of the percentage is the total number of adverse reactions.
N: number of patients in the enrolled population.

Program \\xxxxxxx\yyyyyyyy\zzzzzzzz.sas Output: \\xxxxxxx\yyyyyyyy\zzzzzzzzzz.txt Data: xxFEB2016
Table Generation: DDMMYYYY, Version: Draft Programmer ID: xxxxxxx

X of Y

Table 14.3.2.1.1 Summary of Serious Adverse Reactions - Enrolled Population

System Organ Class	ACCUSOL 35 (N=XXX)
Preferred Term	n (%)
Patients with any SAR	xxx (xx.x)
xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx	xxx (xx.x)
xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx	xxx (xx.x)
xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx	xxx (xx.x)
xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx	xxx (xx.x)
xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx	xxx (xx.x)
xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx	xxx (xx.x)
xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx	xxx (xx.x)
xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx	xxx (xx.x)

Denominator of the percentage is the number of patients in the enrolled population.
Every patient is counted a single time for each applicable specific adverse reaction. A patient with multiple adverse reactions within a system organ class is counted a single time for that system organ class. A patient may appear more than once in different System Organ Class categories.
N: number of patients in the enrolled population.

Program \\xxxxxxx\yyyyyyyy\zzzzzzz.sas Output: \\xxxxxxx\yyyyyyyy\zzzzzzzzzz.txt Data: xxFEB2016
Table Generation: DDMMYY, Version: Draft Programmer ID: xxxxxx

Table 14.3.2.1.2 Summary of Serious Adverse Reactions (by Frequency of Reactions) - Enrolled Population

System Organ Class	ACCUSOL 35 (N=XXX)
Preferred Term	n (%)
Total number of serious adverse reactions	xxx (100.0)
xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx	xxx (xx.x)
xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx	xxx (xx.x)
xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx	xxx (xx.x)
xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx	xxx (xx.x)
xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx	xxx (xx.x)
xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx	xxx (xx.x)
xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx	xxx (xx.x)

Denominator of the percentage is the total number of serious adverse reactions in the treatment group.

N: number of patients in the enrolled population.

Program \\xxxxxxx\yyyyyyyy\zzzzzzzz.sas Output: \\xxxxxxx\yyyyyyyy\zzzzzzzzzz.txt Data: xxFEB2016
Table Generation: DDMMYY, Version: Draft Programmer ID: xxxxxx

Table 14.3.2.1 Summary of Serious Adverse Reactions by Severity - Enrolled Population

System Organ Class Preferred Term	ACCUSOL 35 (N=XXX)		
	Mild n (%)	Moderate n (%)	Severe n (%)
Patients with any SAR	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
xxxxxxxxxxxxxxxxxxxxxxxxxxxx	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
xxxxxxxxxxxxxxxxxxxxxxxxxxxx	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
xxxxxxxxxxxxxxxxxxxxxxxxxxxx	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
xxxxxxxxxxxxxxxxxxxxxxxxxxxx	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
xxxxxxxxxxxxxxxxxxxxxxxxxxxx	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
xxxxxxxxxxxxxxxxxxxxxxxxxxxx	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)

Denominator of the percentage is the number of patients in the enrolled population.

Every patient is counted a single time for each applicable specific serious adverse reaction with highest severity. A patient with multiple adverse reactions within a system organ class is counted a single time for that system organ class. A patient may appear more than once in different System Organ Class categories.

N: number of patients in the enrolled population.

Program \\xxxxxxx\yyyyyyyy\zzzzzzzz.sas Output: \\xxxxxxx\yyyyyyyy\zzzzzzzzzz.txt Data: xxFEB2016

Table Generation: DDMMYY, Version: Draft Programmer ID: xxxxxx

Table 14.3.2.2.2 Summary of Serious Adverse Reactions by Severity (by Frequency of Reactions) - Enrolled Population

System Organ Class Preferred Term	ACCUSOL 35 (N=XXX)		
	Mild n (%)	Moderate n (%)	Severe n (%)
Total number of serious adverse reactions	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
xxxxxxxxxxxxxxxxxxxxxxxxxxxxxx	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
xxxxxxxxxxxxxxxxxxxxxxxxxxxxxx	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
xxxxxxxxxxxxxxxxxxxxxxxxxxxxxx	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
xxxxxxxxxxxxxxxxxxxxxxxxxxxxxx	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
xxxxxxxxxxxxxxxxxxxxxxxxxxxxxx	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
xxxxxxxxxxxxxxxxxxxxxxxxxxxxxx	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
xxxxxxxxxxxxxxxxxxxxxxxxxxxxxx	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
xxxxxxxxxxxxxxxxxxxxxxxxxxxxxx	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)

Denominator of the percentage is the total number of serious adverse reactions in the treatment group.
N: number of patients in the enrolled population.

Program \\xxxxxxx\yyyyyyyy\zzzzzzzz.sas Output: \\xxxxxxx\yyyyyyyy\zzzzzzzzzz.txt Data: xxFEB2016
Table Generation: DDMMYYYY, Version: Draft Programmer ID: xxxxxx

Table 14.3.2.3.1 Summary of Serious Adverse Reactions by Relationship to Study Drug - Enrolled Population

System Organ Class Preferred Term	ACCUSOL 35 (N=XXX)	
	Possibly Related n (%)	Probably Related n (%)
Patients with any SAR	xxx (xx.x)	xxx (xx.x)
XXXXXXXXXXXXXXXXXXXXXXXXXXXX	xxx (xx.x)	xxx (xx.x)
XXXXXXXXXXXXXXXXXXXXXXXXXXXX	xxx (xx.x)	xxx (xx.x)
XXXXXXXXXXXXXXXXXXXXXXXXXXXX	xxx (xx.x)	xxx (xx.x)
XXXXXXXXXXXXXXXXXXXXXXXXXXXX	xxx (xx.x)	xxx (xx.x)
XXXXXXXXXXXXXXXXXXXXXXXXXXXX	xxx (xx.x)	xxx (xx.x)
XXXXXXXXXXXXXXXXXXXXXXXXXXXX	xxx (xx.x)	xxx (xx.x)
XXXXXXXXXXXXXXXXXXXXXXXXXXXX	xxx (xx.x)	xxx (xx.x)
XXXXXXXXXXXXXXXXXXXXXXXXXXXX	xxx (xx.x)	xxx (xx.x)

Denominator of the percentage is the number of patients in the enrolled population. Every patient is counted a single time for each applicable specific adverse reaction. A patient with multiple adverse reactions within a system organ class is counted a single time for that system organ class. A patient may appear more than once in different System Organ Class categories.
N: number of patients in the enrolled population.

Program \\xxxxxxx\yyyyyyyy\zzzzzzzz.sas Output: \\xxxxxxx\yyyyyyyy\zzzzzzzzzz.txt Data: xxFEB2016
Table Generation: DDMMYYYY, Version: Draft Programmer ID: xxxxxx

Table 14.3.2.3.2 Summary of Serious Adverse Reactions by Relationship to Study Drug (by Frequency of Reactions) - Enrolled Population

System Organ Class Preferred Term	ACCUSOL 35 (N=XXX)	
	Possibly Related n (%)	Probably Related n (%)
Total number of serious adverse reactions	xxx (xx.x)	xxx (xx.x)
xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx	xxx (xx.x)	xxx (xx.x)
xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx	xxx (xx.x)	xxx (xx.x)
xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx	xxx (xx.x)	xxx (xx.x)
xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx	xxx (xx.x)	xxx (xx.x)
xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx	xxx (xx.x)	xxx (xx.x)
xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx	xxx (xx.x)	xxx (xx.x)
xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx	xxx (xx.x)	xxx (xx.x)
xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx	xxx (xx.x)	xxx (xx.x)

Denominator of the percentage is the total number of serious adverse reactions in the treatment group.

N: number of patients in the enrolled population.

Program \\xxxxxxx\yyyyyyy\zzzzzzz.sas Output: \\xxxxxxx\yyyyyyy\zzzzzzzzzz.txt Data: xxFEB2016

Table Generation: DDMMYYYY, Version: Draft Programmer ID: xxxxxx

Table 14.3.3.1 Exploratory Analysis: Time to First Occurrence of Precipitate – Per-Protocol Population

	Statistics	ACCUSOL 35 (N=XXX)
Time to First Occurrence of Precipitate (h)	Events observed	x
	Subjects censored	xx
	1st quartile	xx.x
	95% CI	(xx.xx, xx.xx)
	Median	xx.x
	95% CI	(xx.xx, xx.xx)
	3rd quartile	xx.x
	95% CI	(xx.xx, xx.xx)

CI: Confidence Interval

Program \\xxxxxxx\yyyyyyyy\zzzzzzzz.sas Output: \\xxxxxxx\yyyyyyyy\zzzzzzzzzz.txt Data: xxFEB2016
Table Generation: DDMMYYYY, Version: Draft Programmer ID: xxxxxx

Table 14.3.3.2 Exploratory Analysis: Precipitate Formation by Dialysis Solution Used at Time of Observation – Per-Protocol Population

	ACCUSOL 35 (N=XXX)		
	n treated	n (%) with precipitate	95% CI
Proportion of patients with visible precipitate during 72 hours of use of ACCUSOL 35 solution with a single CRRT circuit (ACCUSOL 35)	xx	x (x.x)	(x.xxx, x.xxx)
Proportion of patients with visible precipitate during 72 hours of use of ACCUSOL 35 solution with a single CRRT circuit (ACCUSOL 35 Potassium 2 mmol/L)	xx	x (x.x)	(x.xxx, x.xxx)
Proportion of patients with visible precipitate during 72 hours of use of ACCUSOL 35 solution with a single CRRT circuit (ACCUSOL 35 Potassium 4 mmol/L)	xx	x (x.x)	(x.xxx, x.xxx)

N:number of evaluable patients

CI: Confidence Interval. Jeffrey's method is used to derive the confidence interval.

Program \\xxxxxxx\yyyyyyyy\zzzzzzzz.sas Output: \\xxxxxxx\yyyyyyyy\zzzzzzzzzzzz.txt Data: xxFEB2016

Table Generation: DDMMYY, Version: Draft Programmer ID: xxxxxx

Note: In case of precipitate observation similar tables will be produced for the other parameters mentioned in section 11.4 as required.

17.2 Data Listings

Page X of Y

Data Listing 16.2.1 Patient Disposition: Completion/Discontinuation from study - Enrolled Population

Patient Number	Age(Years) /Gender	Date and Time of Informed Consent	Written Consent by Whom	Date and Time of Informed Consent was Signed	Date and Time of Completion/ Discontinuation	Patient's Disposition Status	Specify, If Others
xxxxxx	xx/xxxx	ddMMMyyyy HH:nn	xxxxxxx	ddMMMyyyy HH:nn	ddMMMyyyy HH:nn	xxxxxxxxxx	xxxxxxx
xxxxxx	xx/xxxx	ddMMMyyyy HH:nn	xxxxxxx	ddMMMyyyy HH:nn	ddMMMyyyy HH:nn	xxxxxxxxxx	xxxxxxx
xxxxxx	xx/xxxx	ddMMMyyyy HH:nn	xxxxxxx	ddMMMyyyy HH:nn	ddMMMyyyy HH:nn	xxxxxxxxxx	xxxxxxx
xxxxxx	xx/xxxx	ddMMMyyyy HH:nn	xxxxxxx	ddMMMyyyy HH:nn	ddMMMyyyy HH:nn	xxxxxxxxxx	xxxxxxx
xxxxxx	xx/xxxx	ddMMMyyyy HH:nn	xxxxxxx	ddMMMyyyy HH:nn	ddMMMyyyy HH:nn	xxxxxxxxxx	xxxxxxx
xxxxxx	xx/xxxx	ddMMMyyyy HH:nn	xxxxxxx	ddMMMyyyy HH:nn	ddMMMyyyy HH:nn	xxxxxxxxxx	xxxxxxx

Program \\xxxxxxx\yyyyyyyy\zzzzzzzz.sas Output: \\xxxxxxx\yyyyyyyy\zzzzzzzzzz.txt Data: xxFEB2016

Listing Generation: DDMMYYYY, Version: Draft Programmer ID: xxxxxx

Data Listing 16.2.2 Protocol Deviations - Enrolled Population

Patient Number	Age(Years) /Gender	Protocol Deviation	Major or Minor
xxxxxx	xx/xxxx	xxxxxxxxxxxxxxxxxxxx	xxxxx
xxxxxx	xx/xxxx	xxxxxxxxxxxxxxxxxxxx	xxxxx
xxxxxx	xx/xxxx	xxxxxxxxxxxxxxxxxxxx	xxxxx
xxxxxx	xx/xxxx	xxxxxxxxxxxxxxxxxxxx	xxxxx
xxxxxx	xx/xxxx	xxxxxxxxxxxxxxxxxxxx	xxxxx
xxxxxx	xx/xxxx	xxxxxxxxxxxxxxxxxxxx	xxxxx
Program \\xxxxxxx\yyyyyyyy\zzzzzzz.sas Output: \\xxxxxxx\yyyyyyyy\zzzzzzzzzz.txt Data: xxFEB2016 Listing Generation: DDMMYYYY, Version: Draft Programmer ID: xxxxxxx			

Data Listing 16.2.3.1 Patients excluded from Per-Protocol Population - Enrolled Population

Patient Number	Reason for exclusion from PP Population
XXXXXX	XXXXXXXXXXXXXXXXXXXXXXXXXXXX
XXXXXX	XXXXXXXXXXXXXXXXXXXXXXXXXXXX
XXXXXX	XXXXXXXXXXXXXXXXXXXXXXXXXXXX
XXXXXX	XXXXXXXXXXXXXXXXXXXXXXXXXXXX
XXXXXX	XXXXXXXXXXXXXXXXXXXXXXXXXXXX
XXXXXX	XXXXXXXXXXXXXXXXXXXXXXXXXXXX
Program \\xxxxxxx\yyyyyyyy\zzzzzzz.sas Output: \\xxxxxxx\yyyyyyyy\zzzzzzzzzz.txt Data: xxFEB2016 Listing Generation: DDMMYYYY, Version: Draft Programmer ID: xxxxxx	

Data Listing 16.2.3.2 Inclusion/Exclusion – Screened Population

Patient Number	Category	Inclusion/Exclusion Criterion
XXXXXX	XXXXXX	XXXXXXXXXXXXXXXXXXXX
XXXXXX	XXXXXX	XXXXXXXXXXXXXXXXXXXX
XXXXXX	XXXXXX	XXXXXXXXXXXXXXXXXXXX
XXXXXX	XXXXXX	XXXXXXXXXXXXXXXXXXXX
XXXXXX	XXXXXX	XXXXXXXXXXXXXXXXXXXX

Note: Only exclusion criteria met or inclusion criteria did not fulfill are included in this listing.

Program \\xxxxxxx\yyyyyyyy\zzzzzzzz.sas Output: \\xxxxxxx\yyyyyyyy\zzzzzzzzzz.txt Data: xxFEB2016
Listing Generation: DDMMYYYY, Version: Draft Programmer ID: xxxxxxx

Data Listing 16.2.4 Demographic and Baseline Characteristics - Enrolled Population

Patient Number	Age(Years)/ Gender	Weight(kg)	Baxter Evaluable Patient	Baxter Evaluable date, if Yes
xxxxxx	xx/xxxx	xx	xxx	ddMMMyyyy
xxxxxx	xx/xxxx	xx	xxx	ddMMMyyyy
xxxxxx	xx/xxxx	xx	xxx	ddMMMyyyy
xxxxxx	xx/xxxx	xx	xxx	ddMMMyyyy
xxxxxx	xx/xxxx	xx	xxx	ddMMMyyyy
xxxxxx	xx/xxxx	xx	xxx	ddMMMyyyy
xxxxxx	xx/xxxx	xx	xxx	ddMMMyyyy
xxxxxx	xx/xxxx	xx	xxx	ddMMMyyyy
Demographic data is missing for some patients because informed consent was not obtained from the patient personally.				
Program \\xxxxxxx\yyyyyyyy\zzzzzzzz.sas Output: \\xxxxxxx\yyyyyyyy\zzzzzzzzzz.txt Data: xxFEB2016				
Listing Generation: DDMMYYYY, Version: Draft Programmer ID: xxxxxx				

Data Listing 16.2.5.1 Anti-Coagulant Administration - Enrolled Population

Patient Number	Age (Years) / Gender	Anti-Coagulant Medication Taken	ATC Term/ Preferred Term/ Reported Term	Date and Time of Administration	Route. Specify, if Other	Dose per Administration	Unit. Specify, if Other
xxxxxx	xx/xxxx	xxxx	xxxxxxx/ xxxxxxx/ xxxxxxx	ddMMMyyyy HH:nn	xx	xxx	xxx
			xxxxxxx/ xxxxxxx/ xxxxxxx	ddMMMyyyy HH:nn	xx	xxx	xxx
xxxxxx	xx/xxxx	xxxx	xxxxxxx/ xxxxxxx/ xxxxxxx	ddMMMyyyy HH:nn	xx	xxx	xxx
			xxxxxxx/ xxxxxxx/ xxxxxxx	ddMMMyyyy HH:nn	xx	xxx	xxx

Program \\xxxxxxx\yyyyyyyy\zzzzzzz.sas Output: \\xxxxxxx\yyyyyyyy\zzzzzzzzzz.txt Data: xxFEB2016
Listing Generation: DDMMYYYY, Version: Draft Programmer ID: xxxxxxx

Page X of Y

Data Listing 16.2.5.2 Potassium Chloride Administration - Enrolled population

Patient Number	Age (Years) / Gender	Did the Patient have any additional Potassium Chloride added to their Dialysate fluid?	ATC Term/ Preferred Term/Reported Term	Date and Time of Administration	Concentration	Unit
xxxxxx	xx/xxxx	xxxx	xxxxxxxx/ xxxxxxxx/ xxxxxxxx	ddMMMyyyy HH:nn	xx	xxx
			xxxxxxxx/ xxxxxxxx/ xxxxxxxx	ddMMMyyyy HH:nn	xx	xxx
xxxxxx	xx/xxxx	xxxx	xxxxxxxx/ xxxxxxxx/ xxxxxxxx	ddMMMyyyy HH:nn	xx	xxx
			xxxxxxxx/ xxxxxxxx/ xxxxxxxx	ddMMMyyyy HH:nn	xx	xxx

Program \\xxxxxxx\yyyyyyyy\zzzzzzz.sas Output: \\xxxxxxx\yyyyyyyy\zzzzzzzzzz.txt Data: xxFEB2016
Listing Generation: DDMMYYYY, Version: Draft Programmer ID: xxxxxxx

Page X of Y

Data Listing 16.2.5.3 ACCUSOL 35 Administration - Enrolled Population

Patient Number	Age (Years) / Gender	First Accusol Administration Start Date/Time	Dialysis Solution used	Lot Number	Site of Introduction	Start Date and Time / End Date and Time	Dialysis Dose (ml/kg/hr)	Amount Administered (L)
xxxxxx	xx/xxxx	ddMMMyyyy HH:nn	xxx	xx	xxx	ddMMMyyyy HH:nn/ ddMMMyyyy HH:nn	xxx	xxx
xxxxxx	xx/xxxx	ddMMMyyyy HH:nn	xxx	xx	xxx	ddMMMyyyy HH:nn/ ddMMMyyyy HH:nn	xxx	xxx
xxxxxx	xx/xxxx	ddMMMyyyy HH:nn	xxx	xx	xxx	ddMMMyyyy HH:nn/ ddMMMyyyy HH:nn	xxx	xxx
xxxxxx	xx/xxxx	ddMMMyyyy HH:nn	xxx	xx	xxx	ddMMMyyyy HH:nn/ ddMMMyyyy HH:nn	xxx	xxx

Abbreviations: xxx

Program \\\xxxxxxx\yyyyyyyy\zzzzzzz.sas Output: \\\xxxxxxx\yyyyyyyy\zzzzzzzzzz.txt Data: xxFEB2016

Listing Generation: DDMMYYYY, Version: Draft Programmer ID: xxxxxxx

Note: Abbreviations can be used for Dialysis solution used and site of introduction to save space. Abbreviations will be explained in a footnote.

Data Listing 16.2.5.4 Dialysis Session - Enrolled Population

Patient Number	Age (Years) / Gender	Start Date and Time of Current CRRT Circuit /End Date and Time of Current CRRT Circuit	Manufacturer of CRRT Monitor/ Model of CRRT Monitor	Manufacturer of CRRT Lines/ Model of CRRT Lines	Manufacturer of Haemofilter / Model of Haemofilter	CRRT Mode Employed	Ultrafiltration Rate (L/h)
xxxxxx	xx/xxxx	ddMMMyyyy HH:nn/ ddMMMyyyy HH:nn	xxxxxxx/ xxxxxxx	xxxxxxx/ xxxxxxx	xxxxxxx/ xxxxxxx	xxxxxxx	xxx
xxxxxx	xx/xxxx	ddMMMyyyy HH:nn/ ddMMMyyyy HH:nn	xxxxxxx/ xxxxxxx	xxxxxxx/ xxxxxxx	xxxxxxx/ xxxxxxx	xxxxxxx	xxx

Abbreviations: xxx

Program \\xxxxxxx\yyyyyyyy\zzzzzzzz.sas Output: \\xxxxxxx\yyyyyyyy\zzzzzzzzzz.txt Data: xxFEB2016

Listing Generation: DDMMYYYY, Version: Draft Programmer ID: xxxxxxx

Note: Abbreviations can be used for manufacturers and models of CRRT circuits and monitors and of haemofilters to save space. Abbreviations will be explained in a footnote.

Data Listing 16.2.5.5 Dialysis Session – Interruptions - Enrolled Population

Patient Number	Age (Years) / Gender	Circuit Interrupted	No.of Interruptions	Total Time of Interruption	Reason for Interruption	Was the CRRT Circuit Changed while the Patient was on Study?	If yes, Specify Reason	Was CRRT Terminated while the Patient was on Study?	If yes, Specify Reason
xxxxxx	xx/xxxx	xxx	xx	xx	xxx	xxx	xxx	xxx	xxxxxx
xxxxxx	xx/xxxx	xxx	xx	xx	xxx	xxx	xxx	xxx	xxxxxx
xxxxxx	xx/xxxx	xxx	xx	xx	xxx	xxx	xxx	xxx	xxxxxx
xxxxxx	xx/xxxx	xxx	xx	xx	xxx	xxx	xxx	xxx	xxxxxx

Program \\xxxxxxx\yyyyyyyy\zzzzzzzz.sas Output: \\xxxxxxx\yyyyyyyy\zzzzzzzzzz.txt Data: xxFEB2016
Listing Generation: DDMMYYYY, Version: Draft Programmer ID: xxxxxxx

Data Listing 16.2.7.1 Precipitate Observation - Enrolled Population

Patient Number	Age (Years) / Gender	Date and Time(24hr Clock) of Final Observation/ Time since start of CRRT	Any Precipitate Observed in the CRRT Lines	If Yes, Colour of the Precipitate	Solution in Use at the Time Precipitate was Observed	Lot Number of Solution in Use at the Time Precipitate was Observed
xxxxxx	xx/xxxx	ddMMMyyyy HH:nn/HH:mm	xxx	xxxxxxx	xxxxxxx	xxx
xxxxxx	xx/xxxx	ddMMMyyyy HH:nn/HH:mm	xxx	xxxxxxx	xxxxxxx	xxx
xxxxxx	xx/xxxx	ddMMMyyyy HH:nn/HH:mm	xxx	xxxxxxx	xxxxxxx	xxx
xxxxxx	xx/xxxx	ddMMMyyyy HH:nn/HH:mm	xxx	xxxxxxx	xxxxxxx	xxx

Program \\xxxxxxx\yyyyyyyy\zzzzzzzz.sas Output: \\xxxxxxx\yyyyyyyy\zzzzzzzzzz.txt Data: xxFEB2016
Listing Generation: DDMMMYYYY, Version: Draft Programmer ID: xxxxxxx

Data Listing 16.2.7.2.1 Adverse Reactions - Enrolled Population

Patient Number	Age (Years) /Sex	Did the Patient Experience any AR?	Adverse Reaction Description/ System Organ Class/ Preferred Term	Onset Date/ Resolution Date	Ongoing	Severity	Treatment Required	Treatment Given. Specify, if Other
xxxxxx	xx/xxx	xxxx	xxxxxxxxxxx/ xxxxxxxx/ xxxxxx	ddMMMyyyy/ ddMMMyyyy	xxxx	xxxxxx	xxx	xxxxxxx
			xxxxxxxxxxx/ xxxxxxxx/ xxxxxx	ddMMMyyyy/ ddMMMyyyy	xxxx	xxxxxx	xxx	xxxxxxx
xxxxxx	xx/xxx	xxxx	xxxxxxxxxxx/ xxxxxxxx/ xxxxxx	ddMMMyyyy/ ddMMMyyyy	xxxx	xxxxxx	xxx	xxxxxxx
			xxxxxxxxxxx/ xxxxxxxx/ xxxxxx	ddMMMyyyy/ ddMMMyyyy	xxxx	xxxxxx	xxx	xxxxxxx
xxxxxx	xx/xxx	xxxx	xxxxxxxxxxx/ xxxxxxxx/ xxxxxx	ddMMMyyyy/ ddMMMyyyy	xxxx	xxxxxx	xxx	xxxxxxx

Program \\xxxxxxx\yyyyyyyy\zzzzzzzz.sas Output: \\xxxxxxx\yyyyyyyy\zzzzzzzzzz.txt Data: xxFEB2016

Listing Generation: DDMMYYYY, Version: Draft Programmer ID: xxxxxx

Data Listing 16.2.7.2.2 Adverse Reactions - Details - Enrolled Population

Patient Number	Age (Years) /Sex	Did the Patient Experience any AR?	Adverse Reaction Description/ System Organ Class/ Preferred Term	Onset Date/ Resolution Date	Relationship to ACCUSOL 35	Action Taken with Study Drug	Outcome of AR	Serious Adverse Reaction
xxxxxx	xx/xxx	xxxx	xxxxxxxxxxx/ xxxxxxxx/ xxxxxx	ddMMMyyyy/ ddMMMyyyy	xxxxxxx	xxxxxxx	xxxxxxx	xxx
			xxxxxxxxxxx/ xxxxxxxx/ xxxxxx	ddMMMyyyy/ ddMMMyyyy	xxxxxxx	xxxxxxx	xxxxxxx	xxx
xxxxxx	xx/xxx	xxxx	xxxxxxxxxxx/ xxxxxxxx/ xxxxxx	ddMMMyyyy/ ddMMMyyyy	xxxxxxx	xxxxxxx	xxxxxxx	xxx
			xxxxxxxxxxx/ xxxxxxxx/ xxxxxx	ddMMMyyyy/ ddMMMyyyy	xxxxxxx	xxxxxxx	xxxxxxx	xxx
xxxxxx	xx/xxx	xxxx	xxxxxxxxxxx/ xxxxxxxx/ xxxxxx	ddMMMyyyy/ ddMMMyyyy	xxxxxxx	xxxxxxx	xxxxxxx	xxx

Program \\xxxxxxx\yyyyyyyy\zzzzzzz.sas Output: \\xxxxxxx\yyyyyyyy\zzzzzzzzzz.txt Data: xxFEB2016

Listing Generation: DDMMYYYY, Version: Draft Programmer ID: xxxxxx

Data Listing 16.2.7.3.1 Serious Adverse Reactions - Enrolled Population

Patient Number	Age (Years) /Sex	Did the Patient Experience any AR?	Adverse Reaction Description/ System Organ Class/ Preferred Term	Onset Date/ Resolution Date	Ongoing	Severity	Treatment Required	Treatment Given. Specify, if Other
xxxxxx	xx/xxx	xxxx	xxxxxxxxxxx/ xxxxxxxx/ xxxxxx	ddMMMyyyy/ ddMMMyyyy	xxxx	xxxxxx	xxx	xxxxxxx
			xxxxxxxxxxx/ xxxxxxxx/ xxxxxx	ddMMMyyyy/ ddMMMyyyy	xxxx	xxxxxx	xxx	xxxxxxx
xxxxxx	xx/xxx	xxxx	xxxxxxxxxxx/ xxxxxxxx/ xxxxxx	ddMMMyyyy/ ddMMMyyyy	xxxx	xxxxxx	xxx	xxxxxxx
			xxxxxxxxxxx/ xxxxxxxx/ xxxxxx	ddMMMyyyy/ ddMMMyyyy	xxxx	xxxxxx	xxx	xxxxxxx
xxxxxx	xx/xxx	xxxx	xxxxxxxxxxx/ xxxxxxxx/ xxxxxx	ddMMMyyyy/ ddMMMyyyy	xxxx	xxxxxx	xxx	xxxxxxx

Program \\xxxxxxx\yyyyyyyy\zzzzzzz.sas Output: \\xxxxxxx\yyyyyyyy\zzzzzzzzzz.txt Data: xxFEB2016

Listing Generation: DDMMMYYYY, Version: Draft Programmer ID: xxxxxxxx

Data Listing 16.2.7.3.2 Serious Adverse Reactions - Details - Enrolled Population

Patient Number	Age (Years) /Sex	Did the Patient Experience any AR	Adverse Reaction Description/ System Organ Class/ Preferred Term	Onset Date/ Resolution Date	Relationship to ACCUSOL 35	Action Taken with Study Drug	Outcome of SAR
xxxxxx	xx/xxx	xxxx	xxxxxxxxxxx/ xxxxxxxx/ xxxxxxx	ddMMMyyyy/ ddMMMyyyy	xxxxxxx	xxxxxxx	xxxxxxx
			xxxxxxxxxxx/ xxxxxxxx/ xxxxxxx	ddMMMyyyy/ ddMMMyyyy	xxxxxxx	xxxxxxx	xxxxxxx
xxxxxx	xx/xxx	xxxx	xxxxxxxxxxx/ xxxxxxxx/ xxxxxxx	ddMMMyyyy/ ddMMMyyyy	xxxxxxx	xxxxxxx	xxxxxxx
			xxxxxxxxxxx/ xxxxxxxx/ xxxxxxx	ddMMMyyyy/ ddMMMyyyy	xxxxxxx	xxxxxxx	xxxxxxx
xxxxxx	xx/xxx	xxxx	xxxxxxxxxxx/ xxxxxxxx/ xxxxxxx	ddMMMyyyy/ ddMMMyyyy	xxxxxxx	xxxxxxx	xxxxxxx

Program \\xxxxxxx\yyyyyyyy\zzzzzzz.sas Output: \\xxxxxxx\yyyyyyyy\zzzzzzzzzz.txt Data: xxFEB2016

Listing Generation: DDMMYYYY, Version: Draft Programmer ID: xxxxxxx

Data Listing 16.2.7.4 Deaths - Enrolled Population

Patient Number	Age (Years) /Sex	Date of Death	Time of death	Primary Cause of Death
xxxxxx	xx/xxx	ddMMMyyyy	XX:XX	xxxxxxx
xxxxxx	xx/xxx	ddMMMyyyy	XX:XX	xxxxxxx

Program \\xxxxxxx\yyyyyyyy\zzzzzzzz.sas Output: \\xxxxxxx\yyyyyyyy\zzzzzzzzzz.txt Data: xxFEB2016
Listing Generation: DDMMYYYY, Version: Draft Programmer ID: xxxxxxListing

18. APPENDICES

Appendix 1 Programming Specifications

Data Presentation

- The TLF title will be center aligned and the last row of the title should indicate the population, unless specified.
- The column titles should be aligned top left and the contents in the TLF should be aligned left, unless specified.
- TLF will be produced as RTF files using PROC REPORT in Times New Roman font and font size 10 in landscape orientation.
- The footnotes will be presented in the order as seen in SAP. No programming notes will be presented in the TLF.
- Version: X will be replaced with Version: Draft or Final accordingly in all the tables and listings.
- All outputs will show the name of the SAS program and its location, the name of the program output and its location, the date of used data sets, e.g., a snapshot date or a database lock date, the date of output production and programmer ID in a footnote

Table Specifications

The following rules will apply when creating the tables.

- The values will be aligned on decimal places.
- Number (n) and percentage (%) will be presented in the format n (%).
- Ordering of statistics – N, Mean (SD), Median, Min, Max, and Missing.

Number of decimal places (DP)

- For minimum and maximum the DPs will be the same as the raw data.
- For mean the DPs will be one more than the raw data.
- For SD the DPs will be one more than the mean.
- Percentages (%) will be displayed with one DP.

Listing Specifications

The following rules will apply when creating the listings.

- The values presented in the listing will be left aligned.
- The listings will be presented by patient number and age (years) /gender.
- Time will be presented as 24 hour clock.

Number of DPs

The number of DPs must be same as in the raw data.

Statistical Analysis Plan: 8822-001

Study Title:	A Multicenter, Non-interventional, Observational, Post-Approval Safety Study of Updated ACCUSOL 35 Solutions in Continuous Renal Replacement Therapy (ACCUPASS)
Study Number:	8822-001
Study Design	Multicenter, non-interventional, single-arm, observational, post-approval safety study
Product Name:	ACCUSOL 35 Solutions
Statistician:	Michael Amdahl Senior Manager, Biostatistics Baxter Healthcare Corporation
Sponsor:	Baxter Healthcare Corporation One Baxter Parkway Deerfield, IL 60015 USA
Responsible Medical Officer:	Drew S. Jones, MD, MPH, MBA Senior Medical Director Baxter Healthcare Corporation
Final Date:	12 January 2016

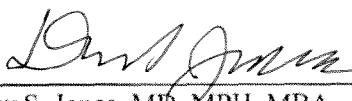
1. SIGNATURE PAGE

Study Title: A Multicenter, Non-interventional, Observational, Post-Approval
Safety Study of Updated ACCUSOL 35 Solutions in Continuous
Renal Replacement Therapy (ACCUPASS)
Study Number: 8822-001
Statisticians: Michael Amdahl

I have read this report and confirm that to the best of my knowledge it accurately describes the intended analyses of results of the study.

Prepared by:  Date: 14-Jan-2016
Jürgen Deinhard
Senior Statistician
PSI CRO Deutschland GmbH

Approved by:  Date: 14-Jan-2016
Anna Ignatenko, PhD
Senior Statistician
PSI

Approved by:  Date: 20 Jan 2016
Drew S. Jones, MD, MPH, MBA
Senior Medical Director, Clinical Lead
Life Sciences & Operations
Chief Scientific Office
Baxter Healthcare Corporation

Approved by:  Date: 19 Jan 2016
Michael Amdahl
Sr. Manager, Biostatistics
Life Sciences & Operations
Chief Scientific Office
Baxter Healthcare Corporation

Baxter Confidential - Restricted: Do not distribute without prior approval.

Table of Contents

1. SIGNATURE PAGE	2
2. LIST OF ABBREVIATIONS AND DEFINITIONS OF TERMS	7
3. INTRODUCTION	8
4. TRIAL OBJECTIVES	9
5. STUDY DESIGN AND CONDUCT CONSIDERATIONS	9
5.1 Study Design	9
5.2 Sample Size	10
5.3 Safety Measures	11
5.4 Completion and Discontinuation	11
5.4.1 Patient Withdrawal from the Study	11
5.4.2 Study Termination	12
6. STUDY POPULATIONS	12
6.1 Analysis Populations	12
6.1.1 Enrolled Population	12
6.1.2 Evaluable Patient Population (Per-Protocol Population)	12
7. STATISTICAL ANALYSIS	13
7.1 General	13
7.2 Handling of Missing Data	13
7.3 Interim Analysis	13
7.4 Pooling Strategy for Study Sites	13
7.5 Visit Windows/Unscheduled Visits	13
7.6 Other Issues	13
7.7 Changes to Planned Analyses Described in the Protocol	13
8. PATIENT DISPOSITION	13
9. PROTOCOL DEVIATIONS	14
10. DEMOGRAPHICS AND BASELINE CHARACTERISTICS	14
11. TREATMENT COMPLIANCE AND EXPOSURE	14

12. SAFETY	15
12.1 Primary Analysis	15
12.2 Adverse Reactions	15
12.3 Laboratory Parameters	15
12.4 Exploratory Analyses	16
13. OTHER RELEVANT DATA ANALYSES/SUMMARIES	16
14. SUBGROUP ANALYSES	16
15. REFERENCES	17
16. LISTS OF TABLES AND LISTINGS	18
16.1 Tables	18
16.2 Data Listings	19
17. MOCK TABLES AND LISTINGS	20
17.1 Tables	20
17.2 Data Listings	48
18. APPENDICES	63
Data Presentation	63
Table Specifications	63
Listing Specifications	64
List of Tables and Listings	
Table 14.1.1. Patient Disposition - All Screened Patients	20
Table 14.1.2 Patients Excluded From the Per-Protocol Population - Enrolled Population	21
Table 14.1.3.1 Summary of Demographic and Baseline Characteristics - Enrolled Population	22
Table 14.1.3.2 Summary of Demographic and Baseline Characteristics Per-Protocol Population.	23
Table 14.1.4 Concomitant Medications - Enrolled Population	24
Table 14.1.5.1 CRRT Details: Ultrafiltration Rate - Enrolled Population	25
Table 14.1.5.2 CRRT Details: CRRT Mode - Enrolled Population	26
Table 14.1.5.3 ACCUSOL 35 Administration: Formulation Used - Enrolled Population	27

Table 14.1.5.4 ACCUSOL 35 Administration: Dose Rate by Site of Introduction - Enrolled Population.....	28
Table 14.1.5.5 ACCUSOL 35 Administration: Amount Administered - Enrolled Population	29
Table 14.1.5.6 ACCUSOL 35 Administration: Incidence of Major Protocol Deviations - Enrolled Population.....	30
Table 14.3.1.1 Analysis of Precipitate Formation - Per-Protocol Population	31
Table 14.3.1.2.1 Overview of Adverse Reactions on Patient Level - Enrolled Population	32
Table 14.3.1.2.2 Overview of Total Adverse Reactions - Enrolled Population	33
Table 14.3.1.3.1 Summary of Adverse Reactions - Enrolled Population	34
Table 14.3.1.3.2 Summary of Adverse Reactions (by Frequency of Reactions) - Enrolled Population	35
Table 14.3.1.4.1 Summary of Adverse Reactions by Severity - Enrolled Population	36
Table 14.3.1.4.2 Summary of Adverse Reactions by Severity (by Frequency of Reactions) - Enrolled Population.....	37
Table 14.3.1.5.1 Summary of Adverse Reactions by Relationship to Study Drug - Enrolled Population	38
Table 14.3.1.5.2 Summary of Adverse Reactions by Relationship to Study Drug (by Frequency of Reactions) - Enrolled Population.....	39
Table 14.3.2.1.1 Summary of Serious Adverse Reactions - Enrolled Population	40
Table 14.3.2.1.2 Summary of Serious Adverse Reactions (by Frequency of Reactions) - Enrolled Population.....	41
Table 14.3.2.2.1 Summary of Serious Adverse Reactions by Severity - Enrolled Population	42
Table 14.3.2.2.2 Summary of Serious Adverse Reactions by Severity (by Frequency of Reactions) - Enrolled Population	43
Table 14.3.2.3.1 Summary of Serious Adverse Reactions by Relationship to Study Drug - Enrolled Population	44
Table 14.3.2.3.2 Summary of Serious Adverse Reactions by Relationship to Study Drug (by Frequency of Reactions) - Enrolled Population.....	45
Table 14.3.3.1 Exploratory Analysis: Time to First Occurrence of Precipitate – Per-Protocol Population	46
Table 14.3.3.2 Exploratory Analysis: Precipitate Formation by Dialysis Solution Used at Time of Observation – Per-Protocol Population	47

Data Listing 16.2.1 Patient Disposition: Completion/Discontinuation from study - Enrolled Population.....	48
Data Listing 16.2.2 Protocol Deviations - Enrolled Population	49
Data Listing 16.2.4.1 Demographic and Baseline Characteristics - Enrolled Population	50
Data Listing 16.2.5.1 Concomitant Medications - Enrolled Population	51
Data Listing 16.2.5.2 Anti-Coagulant Administration - Enrolled Population	52
Data Listing 16.2.5.3 Potassium Chloride Administration - Enrolled population.....	53
Data Listing 16.2.5.4 ACCUSOL 35 Administration - Enrolled Population.....	54
Data Listing 16.2.5.5 Dialysis Session - Enrolled Population.....	55
Data Listing 16.2.5.6 Dialysis Session – Interruptions - Enrolled Population	56
Data Listing 16.2.7.1 Precipitate Observation - Enrolled Population.....	57
Data Listing 16.2.7.2.1 Adverse Reactions - Enrolled Population.....	58
Data Listing 16.2.7.2.2 Adverse Reactions - Details - Enrolled Population.....	59
Data Listing 16.2.7.3.1 Serious Adverse Reactions - Enrolled Population	60
Data Listing 16.2.7.3.2 Serious Adverse Reactions - Details - Enrolled Population ..	61
Data Listing 16.2.7.4 Deaths - Enrolled Population.....	62
 List of Appendices	
Appendix 1 Programming Specifications	63

2. LIST OF ABBREVIATIONS AND DEFINITIONS OF TERMS

KCl	potassium chloride
CRRT	continuous renal replacement
AR	adverse reaction
CI	confidence interval
DP	Decimal place
MedDRA	Medical Dictionary for Regulatory Activities
SAR	serious adverse reaction
SD	standard deviation
SAP	Statistical Analysis Plan
SAS	Statistical Analysis System

3. INTRODUCTION

ACCUSOL 35 solutions are indicated for the treatment of acute and chronic renal failure, as substitution solution in haemofiltration and haemodiafiltration, and as dialysis solution in haemodialysis and haemodiafiltration. The product is presented in 3 formulations, 1 without potassium chloride (KCl) and 2 containing KCl (at concentrations of 2 mmol/L and 4 mmol/L). All 3 formulations contain calcium chloride dihydrate, magnesium chloride hexahydrate, sodium chloride and sodium bicarbonate. The 2 KCl formulations also contain glucose monohydrate.

In 2008, Baxter Healthcare Corporation (Baxter; the manufacturer of ACCUSOL 35 solutions) received an increased number of product quality complaint reports related to the presence of white precipitate observed in the continuous renal replacement (CRRT) lines during continuous veno-venous haemofiltration and continuous veno-venous haemodiafiltration during the use of ACCUSOL 35 solutions. In 2009, Baxter's root cause investigation identified that the precipitate was calcium carbonate, and a change in the pH of the mixed solution (supersaturation) was acknowledged as the major contributing factor to precipitate formation. Further investigation revealed that the addition of a low amount of phosphate salt as an excipient and lowering the pH of the mixed solution could inhibit the formation of calcium carbonate.

As part of their responses on 27 August 2009, Baxter made a commitment to the Pharmacovigilance Working Party to perform a post-approval safety study with the updated solution to monitor the safety of the updated formulation, specifically to address the risk of calcium carbonate precipitate formation.

This post-approval safety study is designed to verify the successful minimization of the risk of precipitate formation with the updated ACCUSOL 35 solution. The confirmation of the prevention of precipitate formation will support a proposal for removal of the current recommendation (presented in the labelling for the ACCUSOL 35 solutions) to inspect the CRRT lines every 30 minutes for the presence of precipitate during the use of the products.

The statistical analysis plan (SAP) is created based on Study protocol 8822-01 dated 12 Jan 2015. All analyses will be performed using SAS statistical analysis software (SAS, SAS/GRAPH and SAS/STAT; version 9.4 or higher of SAS for Windows [SAS Institute Inc; Cary, NC, USA]). Data listings will be created to display the raw clinical data collected in this study.

This SAP describes all analyses to be conducted by PSI. This document describes the patient populations that will be analyzed, the variables that will be used for the analyses, the statistical methods that will be employed, and the analysis conventions that will be used to guide statistical programming. The intention of the SAP is to expand on the details of the planned statistical methods described in the study protocol.

4. TRIAL OBJECTIVES

The updated ACCUSOL 35 formulations were developed to prevent calcium carbonate precipitate formation during CRRT administration. The objective of this study is to confirm the prevention of calcium carbonate precipitate formation during CRRT by the use of the updated ACCUSOL 35 solutions.

5. STUDY DESIGN AND CONDUCT CONSIDERATIONS

5.1 Study Design

This study is a prospective, multicenter, non-interventional, uncontrolled, open-label, observational study in adult patients undergoing CRRT using any of the updated ACCUSOL 35 solutions. The study is intended to capture data on the absence or presence of visible precipitate during 72 hours of use of ACCUSOL 35 solution with a single CRRT circuit.

Study centers will use the ACCUSOL 35 solutions from their available inventory; no ACCUSOL 35 solutions or any other approved medications or investigational products will be provided to the study centers by the Sponsor. CRRT therapy will be administered in accordance with the intensive care unit's (ICU) usual clinical practice and the recommendations in the current labeling for ACCUSOL 35 solutions. Addition of antibiotics or any other medications to the ACCUSOL 35 solution bag, except for KCl supplementation, will not be allowed.

There will be no randomized or non-randomized treatment assignments; no diagnostic, therapeutic, or experimental interventions; and no restrictions on use of concomitant medications or other treatments, except as noted above for the restriction on addition of medications other than KCl supplementation to the ACCUSOL 35 solution bag. Study patients will be prospectively identified in that study data will only be collected from patients treated after study enrollment at a site has been authorized by the responsible ethics committee (EC) and the Sponsor.

Data will be collected at patient enrollment (at approximately 40 hours of CRRT with the same CRRT circuit) and periodically up to 72 hours of CRRT with the same circuit, or

until the CRRT circuit needs to be changed or CRRT is completed (if either occurs sooner than 72 hours). The CRRT lines will be inspected every 30 minutes for the duration of the therapy, as recommended in the labeling for the ACCUSOL 35 solutions.

Observation of the CRRT circuit for precipitate through 72 hours of use is intended to represent a worst-case situation, since 72 hours is the maximum intended use period for a single CRRT circuit. Enrollment of patients whose CRRT circuit has already been in use for 40 hours is intended to maximize the possibility of the studied CRRT circuits reaching 72 hours of use for inclusion in the primary analysis (see Section 9.5), while maintaining a reasonable overall study size by reducing the number of patients enrolled.

If precipitate is seen in a CRRT line during therapy administration, the therapy will be stopped and proper procedures and monitoring (as recommended in the current ACCUSOL 35 solutions labeling) will be performed in order to return the circuit blood back to the patient and immediately set up a new CRRT circuit to continue therapy.

This study is strictly a non-interventional observational safety study assessing the presence or absence of visible precipitate in the CRRT lines with the specific products being studied. Therefore, no control group is considered necessary to achieve the study objectives.

5.2 Sample Size

Based on published CRRT studies[1-5], it is estimated that of those CRRT treatments that have reached 40 hours with the same CRRT circuit, 25% will continue with the same circuit through 72 hours of use. It is expected, therefore, that about 240 enrolled patients will provide data on approximately 60 treatments that last 72 hours without CRRT circuit changes. If no visible precipitate is observed within that time in at least 58 evaluable treatments (ie, those in which CRRT circuits remains precipitate-free for 72 hours, and those in which visible precipitate is observed within 72-hours), the study will have provided 95% confidence that the probability of visible precipitate formation during 72 hours of CRRT with ACCUSOL 35 solution using the same CRRT circuit is not more than 5.0%.

It is also reasonable to assume (based on the published studies[1-5]) that approximately 10% of all CRRT treatments will last 72 hours, regardless of whether the same CRRT circuit is in use the whole time. Combining the probabilities of both having a treatment last 72 hours and also having visible particulate formation reduces the risk from 5% to 0.5%. Thus a sample size of 58 treatments with no observed precipitate will demonstrate,

with 95% confidence, that the probability of precipitate formation in all CRRT treatments with ACCUSOL 35 solutions of any length (and not necessarily with the same CRRT circuit) is not more than 0.5%.

5.3 Safety Measures

The key safety variables to be collected for analysis include:

- Amount of ACCUSOL 35 solution delivered through the CRRT circuit observed during the study
- Start- and end-of use times for the CRRT circuit used during the study
- Presence or absence of visible precipitate in the CRRT lines used during the study
- Time of observation of visible precipitate (if applicable)
- Color of precipitate observed (if applicable)
- Reason for terminating the use of the CRRT circuit, if during the study
- Reason for terminating the CRRT, if during the study
- Reason for end of patient's study participation

In addition, adverse reactions will be recorded.

5.4 Completion and Discontinuation

The planned maximum study observation period is 32 hours: from 40 hours after CRRT with the current circuit was started until 72 hours of treatment has been administered using that same circuit.

The following reasons for patients' early termination are collected on the electronic case report form: termination of CRRT, change of CRRT circuit, adverse reaction, loss to follow up, withdrawal by patient, study termination by sponsor, physician decision, protocol violation, death, other (to be specified).

5.4.1 Patient Withdrawal from the Study

Patients, or their legally authorized representatives, may terminate their consent for collection of their medical data for use in the study at any time. Should a patient or their legally authorized representative do so, site study personnel will record the time of and

the reason provided for the withdrawal. The data collected on withdrawn patients will be used in the analyses, as applicable, and included in the clinical study report.

5.4.2 Study Termination

The Sponsor may prematurely terminate this study at any time for any reason. It may also terminate a single study centre from participation in the study at any time for various reasons such as:

- Inadequate rate of patient enrollment into the study
- Noncompliance with protocol requirements or data collection methods
- Noncompliance with Good Clinical Practice guidelines; applicable national and local laws; and/or applicable guidelines or regulations for protecting the rights, safety, and welfare of patients
- Knowingly submitting false information to the Sponsor or designee.

If the study is prematurely terminated, all collected study data must be provided to the Sponsor.

6. STUDY POPULATIONS

6.1 Analysis Populations

6.1.1 Enrolled Population

The enrolled population will be patients expected to receive CRRT with ACCUSOL 35 solution(s) using the same CRRT circuit for at least 72 hours. All analyses will be performed on the enrolled population, except as otherwise noted below.

6.1.2 Evaluable Patient Population (Per-Protocol Population)

The evaluable patient population (per-protocol population) will be used for the primary analysis of this study. Although not specifically stated in the protocol, the evaluable patient population includes patients:

- Who were treated with a single CRRT circuit and whose circuits remained precipitate-free for 72 hours, or in whose circuits visible precipitate was observed within 72 hours and
- Whose study participation and treatment were not subject to any protocol deviations that may have substantially affected the primary safety endpoints (e.g., missing information on precipitate at 72 hours, or at least 25% of planned time points)

The final decision on the exact criteria for exclusion from the evaluable patient population will be made in a data review meeting prior to database lock.

7. STATISTICAL ANALYSIS

7.1 General

All analyses will be performed using SAS statistical analysis software (SAS, SAS/GRAPH and SAS/STAT; version 9.4 or higher of SAS for Windows [SAS Institute Inc; Cary, NC, USA]).

7.2 Handling of Missing Data

No imputation of missing values will be performed.

7.3 Interim Analysis

A formal interim analysis is not planned for this study.

7.4 Pooling Strategy for Study Sites

This is a multicenter study. Data will be pooled across clinical centers and no adjustment will be made for centers in the analyses.

7.5 Visit Windows/Unscheduled Visits

Data will be collected at patient enrollment (at approximately 40 hours of CRRT with the same CRRT circuit) and periodically up to 72 hours of CRRT with the same circuit, or until the CRRT circuit needs to be changed or CRRT is completed (if either occurs sooner than 72 hours). The CRRT lines will be inspected every 30 minutes for the duration of the therapy, as recommended in the labeling for the ACCUSOL 35 solutions.

7.6 Other Issues

No other issues have been identified.

7.7 Changes to Planned Analyses Described in the Protocol

Any changes made to analysis described in the final SAP will be documented in the clinical study report.

8. PATIENT DISPOSITION

The patients who were screened, in the enrolled population, and in the per-protocol population will be summarized for each of these categories using number (n) and percentage (%). In addition, the patients who are screen failures or prematurely terminated will be summarized using number (n) and percentage (%) for each

discontinuation category specified on the electronic case report forms. A data listing will be provided for the patients' study disposition status with reasons for discontinuation.

9. PROTOCOL DEVIATIONS

A data listing of protocol deviations will be provided.

10. DEMOGRAPHICS AND BASELINE CHARACTERISTICS

Demographic and baseline characteristics such as age (years) and weight (kg) will be summarized for the Enrolled Population and the Per-Protocol Population using descriptive statistics such as n, mean, standard deviation (SD), median, Min, Max and number missing. Number (n) and percentage (%) will be summarized for gender and age (years) categories 18-35 years, 36-45 years, 46-55 years, 56-65 years and > 65 years.

Data listings will be provided for demographic and baseline characteristics.

11. TREATMENT COMPLIANCE AND EXPOSURE

Duration (hours) of current CRRT circuit use will be calculated using the time from the start of use of the current CRRT circuit to the time of end of the current CRRT circuit (i.e., derived from time of the end of current CRRT circuit –time of start of the current CRRT circuit). Duration (hours) of current CRRT circuit use and the amount of ACCUSOL 35 solution delivered through the CRRT circuit observed during the study, the ultrafiltration rate, and dose rate by site of introduction (if there is no unique value for a patient, the arithmetic mean will be used) will be summarized descriptively using n, mean, standard deviation (SD), median, Min, Max and number missing. The frequency and percentage of ACCUSOL 35 formulations and CRRT mode used will be tabulated.

In addition, the incidence of major protocol deviations related to ACCUSOL 35 solution administration will be summarized.

Data listings will be provided for CRRT administration and exposure to ACCUSOL 35 solution administration. They will include the manufacturer and model of the CRRT monitor and lines and of the haemofilter used, the CRRT mode employed and the ultrafiltration rate(s) used, the formulations and lot numbers of ACCUSOL 24 solutions administered, ACCUSOL 35 dose rate(s) and site of introduction as well as the start and end times of the CRRT circuit used during the study.

12. SAFETY

12.1 Primary Analysis

The primary analysis for this study will be to evaluate the incidence of visible precipitate in the CRRT lines during 72 hours of use of the single CRRT circuit. If the upper bound of the 95% confidence interval on the true proportion of treatments having precipitate formation is 5% or less, then the primary objective of the study will have been achieved. Jeffrey's method [6] has been selected for generating the upper bound because normal approximation is not feasible when a zero rate is expected, and Jeffrey's method is considered appropriate for the planned sample size.

Number (n) and proportion of patients with visible precipitate in the CRRT lines during 72 hours of use of the single CRRT circuit will be summarized and presented along with the corresponding Jeffrey's 95% confidence interval for proportion.

In addition, a data listing will be provided for precipitate observation.

12.2 Adverse Reactions

Adverse reactions will be coded to a Medical Dictionary for Regulatory Activities (MedDRA; Version 17.1) system organ class and preferred term. Adverse reactions will be summarized both by the total frequency of reactions and by the frequency and percentage of patients having at least one reaction. These adverse reaction summaries will be done overall and by MedDRA system organ class and preferred term. The specific adverse reactions will be summarized by system organ class and preferred term; Adverse reactions by system organ class, preferred term and severity; and adverse reactions by system organ class, preferred term and Relationship with study drug. The serious adverse reactions will be summarized by system organ class and preferred term; serious adverse reactions by system organ class, preferred term and severity; and serious adverse reactions by system organ class and preferred term and relationship with study drug. A data listing will be provided for adverse reactions.

The number (n) and percentage (%) of patients with at least one adverse reaction or serious adverse reaction will be presented.

12.3 Laboratory Parameters

No clinical laboratory test results were collected in this study.

12.4 Exploratory Analyses

Exploratory analysis will be done only if visible precipitate is observed during 72 hours of use of ACCUSOL 35 solution with a single CRRT circuit.

The time to first occurrence will be calculated (time from start of use of the CRRT circuit to time of observation of precipitate) and summarized using Kaplan-Meier methodology. In addition, further analyses may be performed to explore contributing factors (e.g., ACCUSOL 35 solution formulation(s) and lot(s) administered; dose rate(s) and amount of ACCUSOL 35 delivered through the circuit; frequency of use and concentration of KCl added to the ACCUSOL 35 solution; manufacturer and model of CRRT lines used; haemofilter used; use and type of anticoagulant; CRRT mode; or ultrafiltration rate) by summary statistics, as appropriate.

Time to first occurrence (hours) = time of observation of precipitate - time of start of use of the CRRT circuit.

Additional exploratory analyses pertaining to visible precipitate may be performed.

13. OTHER RELEVANT DATA ANALYSES/SUMMARIES

Concomitant medications (anticoagulant administration and any supplemental KCl added to the ACCUSOL 35 solution[s]) will be coded using the World Health Organization drug dictionary (WHODrug, September 2014). Concomitant medications within each therapeutic category will be summarized using number (n) and percentage (%) of patients receiving concomitant medication at the anatomic therapeutic class (ATC) Level 2 and preferred term level. A summary table will be provided for patients' concomitant medications combining the categories above.

In addition, data listings will be provided for anticoagulant administration and potassium chloride administration.

14. SUBGROUP ANALYSES

No subgroup analysis is planned beyond the possible exploratory analyses described above (see Section 12.4).

15. REFERENCES

1. Monchi M, Berghmans D, Ledoux D, Canivet J-L, Dubois B, Damas P. Citrate vs. heparin for anticoagulation in continuous venovenous hemofiltration: a prospective randomized study. *Intensive Care Med.* 2004;30:260-265. doi:10.1007/s00134-003-2047-x.
2. Kutsogiannis DJ, Gibney RT, Stollery D, Gao J. Regional citrate versus systemic heparin anticoagulation for continuous renal replacement in critically ill patients. *Kidney Int.* 2005;67:2361-2367. doi:10.1111/j.1523-1755.2005.00342.x
3. Morabito S, Pistolesi V, Tritapepe L, et al. Regional citrate anticoagulation in cardiac surgery patients at high risk of bleeding: a continuous veno-venous hemofiltration protocol with a low concentration citrate solution. *Critical Care.* 2012;16:R1111. doi:10.1186/cc11403.
4. Hetzel GR, Schmitz M, Wissing H, et al. Regional citrate versus systemic heparin for anticoagulation in critically ill patients on continuous venovenous haemofiltration: a prospective randomized multicentre trial. *Nephrol Dial Transplant.* 26(1):232-239. doi:10.1093/ndt/gfq575.
5. Betjes MGH, van Oosterom D, van Agteren M, van de Wetering J. Regional citrate versus heparin anticoagulation during venovenous hemofiltration in patients at low risk for bleeding: similar hemofilter survival but significantly less bleeding. *J Nephrol.* 2007;20(5):602-608.
6. Brown LD, Cai TT, DasGupta A. Interval estimation for a binomial proportion. *Stat Sci.* 2001;16(2):101-117.

16. LISTS OF TABLES AND LISTINGS

16.1 Tables

Patient Disposition, Demographics and Other Baseline Characteristics

Table 14.1.1	Patient Disposition - All Screened Patients
Table 14.1.2	Patients Excluded From the Per-Protocol Population - Enrolled Population
Table 14.1.3.1	Summary of Demographic and Baseline Characteristics - Enrolled Population
Table 14.1.3.2	Summary of Demographic and Baseline Characteristics - Per-Protocol Population
Table 14.1.4	Concomitant Medications - Enrolled Population
Table 14.1.5.1	CRRT Details: Ultrafiltration Rate - Enrolled Population
Table 14.1.5.2	CRRT Details: CRRT Mode - Enrolled Population
Table 14.1.5.3	ACCUSOL 35 Administration: Formulation Used – Enrolled Population
Table 14.1.5.4	ACCUSOL 35 Administration: Dose Rate by Site of Introduction - Enrolled Population
Table 14.1.5.5	ACCUSOL 35 Administration: Amount Administered - Enrolled Population
Table 14.1.5.6	ACCUSOL 35 Administration: Major Protocol Deviations - Enrolled Population

Safety Analysis

Table 14.3.1.1	Analysis of Precipitate Formation – Per-Protocol Population
Table 14.3.1.2.1	Overview of Adverse Reactions on Patient Level - Enrolled Population
Table 14.3.1.2.2	Overview of Total Adverse Reactions - Enrolled Population
Table 14.3.1.3.1	Summary of Adverse Reactions - Enrolled Population
Table 14.3.1.3.2	Summary of Adverse Reactions (by Frequency of Reactions) - Enrolled Population
Table 14.3.1.4.1	Summary of Adverse Reactions by Severity - Enrolled Population
Table 14.3.1.4.2	Summary of Adverse Reactions by Severity (by Frequency of Reactions) - Enrolled Population
Table 14.3.1.5.1	Summary of Adverse Reactions by Relationship with Study Drug - Enrolled Population
Table 14.3.1.5.2	Summary of Adverse Reactions by Relationship with Study Drug (by Frequency of Reactions) - Enrolled Population
Table 14.3.2.1.1	Summary of Serious Adverse Reactions - Enrolled Population
Table 14.3.2.1.2	Summary of Serious Adverse Reactions (by Frequency of Reactions) - Enrolled Population
Table 14.3.2.2.1	Summary of Serious Adverse Reactions by Severity - Enrolled Population

Safety Analysis

Table 14.3.2.2.2	Summary of Serious Adverse Reactions by Severity (by Frequency of Reactions) - Enrolled Population
Table 14.3.2.3.1	Summary of Serious Adverse Reactions by Relationship to Study Drug - Enrolled Population
Table 14.3.2.3.2	Summary of Serious Adverse Reactions by Relationship to Study Drug (by Frequency of Reactions) - Enrolled Population

Exploratory Analysis

Table 14.3.3.1	Exploratory Analysis: Time to First Occurrence of Precipitate - Per-Protocol Population
Table 14.3.3.2	Exploratory Analysis: Precipitate Formation by Dialysis Solution Used at Time of Observation - Per-Protocol Population

16.2 Data Listings

Patient Disposition

Data Listing 16.2.1	Patient Disposition: Completion/ Discontinuation from Study - Enrolled Population
Data Listing 16.2.2	Protocol Deviations - Enrolled Population

Demographic/Baseline Characteristics

Data Listing 16.2.4.1	Demographic and Baseline Characteristics - Enrolled Population
Data Listing 16.2.5.1	Concomitant Medication - Enrolled Population
Data Listing 16.2.5.2	Anti-Coagulant Administration - Enrolled Population
Data Listing 16.2.5.3	Potassium Chloride Administration - Enrolled Population
Data Listing 16.2.5.4	ACCUSOL 35 Administration - Enrolled Population
Data Listing 16.2.5.5	Dialysis Session - Enrolled Population
Data Listing 16.2.5.6	Dialysis Session - Interruptions - Enrolled Population

Safety Data

Data Listing 16.2.7.1	Precipitate Observation - Enrolled Population
Data Listing 16.2.7.2	Adverse Reactions - Enrolled Population
Data Listing 16.2.7.3	Serious Adverse Reactions - Enrolled Population
Data Listing 16.2.7.4	Deaths - Enrolled Population

17. MOCK TABLES AND LISTINGS

17.1 Tables

Page x of y

Table 14.1.1. Patient Disposition - All Screened Patients

	Total n (%)
Patients screened (a)	xxx
Number of screen failures	xx
Reason if screen failure	
Failure to meet eligibility criteria	xx (xx.x)
Death	xx (xx.x)
...to be continued	
Patients enrolled (b)	xxx
Patients in Per-Protocol population	xx (xx.x)
Patients completed the study	xx (xx.x)
Patients prematurely discontinued	xx (xx.x)
Reason if discontinued	
Reason 1	xx (xx.x)
Reason 2	xx (xx.x)

(a) Denominator of the percentages is the number of patients screened.

(b) Denominator of the percentages is the number of patients enrolled.

Program \\xxxxxxx\yyyyyyy\zzzzzzz.sas Output: \\xxxxxxx\yyyyyyy\zzzzzzzzzz.txt Data: xxFEB2016
Table Generation: DDMMYYYY, Version: Draft Programmer ID: xxxxxx

Table 14.1.2 Patients Excluded From the Per-Protocol Population - Enrolled Population

	Total n (%)
Patients in Enrolled Population	xxx
Patients Excluded from Per-Protocol Population	xxx (xx.x)
Reason, if excluded	
xxxxxxxxxx	xxx (xx.x)
xxxxxxxxxx	xxx (xx.x)

Denominator of the percentage is the number of patients enrolled.
Source Data: Listing 16.xx

Program \\xxxxxxx\yyyyyyyy\zzzzzzz.sas Output: \\xxxxxxx\yyyyyyyy\zzzzzzzzzz.txt Data: xxFEB2016
Table Generation: DDMMYYYY, Version: Draft Programmer ID: xxxxxx

Table 14.1.3.1 Summary of Demographic and Baseline Characteristics - Enrolled Population

	Statistics	ACCUSOL 35 (N=XXX)
Gender		
Male	n (%)	xx (xx.x)
Female	n (%)	xx (xx.x)
missing	n (%)	xx (xx.x)
Age (years)		
18-35	n (%)	xx (xx.x)
36-45	n (%)	xx (xx.x)
46-55	n (%)	xx (xx.x)
56-65	n (%)	xx (xx.x)
> 65	n (%)	xx (xx.x)
missing	n (%)	xx (xx.x)
	n	xxx
	Mean (SD)	xx.x (xx.xx)
	Median	xx.x
	Min, Max	xx.x, xx.x
	Missing	xx
Weight (kg)		
	n	xxx
	Mean (SD)	xx.x (xx.xx)
	Median	xx.x
	Min, Max	xx.x, xx.x
	Missing	xx

Page X of Y

Table 14.1.3.1 Summary of Demographic and Baseline Characteristics - Enrolled Population

Statistics	ACCUSOL 35 (N=XXX)

Denominator of the percentage is the number of patients in the Enrolled Population.

N:number of enrolled patients

Program \\xxxxxxx\yyyyyyyy\zzzzzzz.sas Output: \\xxxxxxx\yyyyyyyy\zzzzzzzzzz.txt Data: xxFEB2016

Table Generation: DDMMYYYY, Version: Draft Programmer ID: xxxxxx

"Missing" categories to be shown if applicable

Table 14.1.3.2 Summary of Demographic and Baseline Characteristics Per-Protocol Population.

Table 14.1.3.2 is similar to Table 14.1.3.1.

Table 14.1.4 Concomitant Medications - Enrolled Population

ATC Level 2 Preferred Term	ACCUSOL 35 (N=XXX) n (%)
Patients with one or more concomitant medications	xxx (xx.x)
xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx	xxx (xx.x)
xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx	xxx (xx.x)
xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx	xxx (xx.x)
xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx	xxx (xx.x)
xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx	xxx (xx.x)
xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx	xxx (xx.x)
xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx	xxx (xx.x)
xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx	xxx (xx.x)

Note: This table includes anti-coagulant and potassium chloride administration.
Every patient is counted a single time for each applicable specific concomitant medication. A patient with multiple concomitant medications within a medication category is counted a single time for that category.
N: number of patients in the enrolled population.

Program \\xxxxxxx\yyyyyyy\zzzzzzz.sas Output: \\xxxxxxx\yyyyyyy\zzzzzzzzzz.txt Data: xxFEB2016
Table Generation: DDMMYYYY, Version: Draft Programmer ID: xxxxxx

Page X of Y

Table 14.1.5.1 CRRT Details: Ultrafiltration Rate - Enrolled Population

	Statistics	ACCUSOL 35 (N=XXX)
Ultrafiltration rate (L/h)	n	xxx
	Mean (SD)	xx.x (xx.xx)
	Median	xx.x
	Min, Max	xx.x, xx.x
	Missing	xx

Program \\xxxxxxx\yyyyyyyy\zzzzzzzz.sas Output: \\xxxxxxx\yyyyyyyy\zzzzzzzzzzzz.txt Data: xxFEB2016
Table Generation: DDMMYYYY, Version: Draft Programmer ID: xxxxxx

Page X of Y

Table 14.1.5.2 CRRT Details: CRRT Mode - Enrolled Population

	Statistics	ACCUSOL 35 (N=XXX)
Continuous Venovenous Hemofiltration (CVVH)	n (%)	xx (xx.x)
Continuous Venovenous Hemodialysis (CVVHD)	n (%)	xx (xx.x)
Continuous Venovenous Hemodiafiltration (CVVHDF)	n (%)	xx (xx.x)
Slow Continuous Ultrafiltration (SCUF)	n (%)	xx (xx.x)
Arteriovenous Modes of CRRT	n (%)	xx (xx.x)
Other	n (%)	xx (xx.x)

Program \xxxxxxx\yyyyyyyy\zzzzzzzz.sas Output: \xxxxxxx\yyyyyyyy\zzzzzzzzzz.txt Data: xxFEB2016
Table Generation: DDMMYYYY, Version: Draft Programmer ID: xxxxxx

Table 14.1.5.3 ACCUSOL 35 Administration: Formulation Used - Enrolled Population

	Statistics	ACCUSOL 35 (N=XXX)
ACCUSOL 35	n (%)	xx (xx.x)
ACCUSOL 35 Potassium 2 mmol/L	n (%)	xx (xx.x)
ACCUSOL 35 Potassium 4 mmol/L	n (%)	xx (xx.x)

Program \\xxxxxxx\yyyyyyy\zzzzzzzz.sas Output: \\xxxxxxx\yyyyyyy\zzzzzzzzzzzz.txt Data: xxFEB2016
Table Generation: DDMMYYYY, Version: Draft Programmer ID: xxxxxx

Table 14.1.5.4 ACCUSOL 35 Administration: Dose Rate by Site of Introduction - Enrolled Population

	Statistics	ACCUSOL 35 (N=XXX)
Dose rate - Pre-filter (ml/kg/hr)	n	xxx
	Mean (SD)	xx.x (xx.xx)
	Median	xx.x
	Min, Max	xx.x, xx.x
	Missing	xx
Dose rate - Post-filter (ml/kg/hr)		
Dose rate – As dislysate (ml/kg/hr)		
Dose rate - Other (ml/kg/hr)		
Dose rate – Combination (ml/kg/hr)		

Program \\xxxxxxx\yyyyyyyy\zzzzzzz.sas Output: \\xxxxxxx\yyyyyyyy\zzzzzzzzzz.txt Data: xxFEB2016
Table Generation: DDMMYY, Version: Draft Programmer ID: xxxxxx

Table 14.1.5.5 ACCUSOL 35 Administration: Amount Administered - Enrolled Population

	Statistics	ACCUSOL 35 (N=XXX)
Amount administered (L)	n	xxx
	Mean (SD)	xx.x (xx.xx)
	Median	xx.x
	Min, Max	xx.x, xx.x
	Missing	xx

Program \\xxxxxxx\yyyyyyyy\zzzzzzzz.sas Output: \\xxxxxxx\yyyyyyyy\zzzzzzzzzz.txt Data: xxFEB2016
Table Generation: DDMMYYYY, Version: Draft Programmer ID: xxxxxxx

Table 14.1.5.6 ACCUSOL 35 Administration: Incidence of Major Protocol Deviations - Enrolled Population

	Statistics	ACCUSOL 35 (N=XXX)
Deviation 1	n (%)	xx (xx.x)
Deviation 2	n (%)	xx (xx.x)
Deviation 3	n (%)	xx (xx.x)

Program \\xxxxxxx\yyyyyyyy\zzzzzzzz.sas Output: \\xxxxxxx\yyyyyyyy\zzzzzzzzzzzz.txt Data: xxFEB2016
Table Generation: DDMMYYYY, Version: Draft Programmer ID: xxxxxx

Page X of Y

Table 14.3.1.1 Analysis of Precipitate Formation - Per-Protocol Population

	ACCUSOL 35 (N=XXX)	
	n (%)	95% CI
Proportion of patients with visible precipitate during 72 hours of use of ACCUSOL 35 solution with a single CRRT circuit	xx (xx.x)	(xx.x, xx.x)

N:number of evaluable patients

CI: Confidence Interval. Jeffrey's method is used to derive the confidence interval.

Program \\xxxxxxx\yyyyyyyy\zzzzzzzz.sas Output: \\xxxxxxx\yyyyyyyy\zzzzzzzzzzzz.txt Data: xxFEB2016
Table Generation: DDMMYY, Version: Draft Programmer ID: xxxxxx

Page X of Y

Table 14.3.1.2.1 Overview of Adverse Reactions on Patient Level - Enrolled Population

	ACCUSOL 35 (N=XXX) n (%)
Patients with at least one AR	xx (xx.x)
Patients with at least one Serious AR	xx (xx.x)
Patients with at least one Drug-Related AR	xx (xx.x)
Patients with at least one serious Drug-related adverse reactions	xx (xx.x)
Patients with AR leading to discontinuation	xx (xx.x)
Patients with SAR leading to discontinuation	xx (xx.x)
Patients who died	xx (xx.x)

N: number of patients in the enrolled population

Program \\xxxxxxx\yyyyyyyy\zzzzzzzz.sas Output: \\xxxxxxx\yyyyyyyy\zzzzzzzzzzzz.txt Data: xxFEB2016
Table Generation: DDMMYYYY, Version: Draft Programmer ID: xxxxxx

Page X of Y

Table 14.3.1.2.2 Overview of Total Adverse Reactions - Enrolled Population

	ACCUSOL 35 (N=XXX) n
Total Number of ARs	xx
Total Number of Serious ARs	xx
Total Number of Drug-Related ARs	xx
Total Number of serious Drug-related adverse reactions	xx
Total Number of ARs leading to discontinuation	xx
Total Number of SARs leading to discontinuation	xx

N: number of patients in the enrolled population

Program \\xxxxxxx\yyyyyyy\zzzzzzz.sas Output: \\xxxxxxx\yyyyyyy\zzzzzzzzzz.txt Data: xxFEB2016
Table Generation: DDMMYY, Version: Draft Programmer ID: xxxxxx

Table 14.3.1.3.1 Summary of Adverse Reactions - Enrolled Population

System Organ Class	ACCUSOL 35 (N=XXX)
Preferred Term	n (%)
Patients with one or more adverse reactions	xxx (xx.x)
XXXXXXXXXXXXXXXXXXXXXXXXXXXX	xxx (xx.x)
XXXXXXXXXXXXXXXXXXXXXXXXXXXX	xxx (xx.x)
XXXXXXXXXXXXXXXXXXXXXXXXXXXX	xxx (xx.x)
XXXXXXXXXXXXXXXXXXXXXXXXXXXX	xxx (xx.x)
XXXXXXXXXXXXXXXXXXXXXXXXXXXX	xxx (xx.x)
XXXXXXXXXXXXXXXXXXXXXXXXXXXX	xxx (xx.x)
XXXXXXXXXXXXXXXXXXXXXXXXXXXX	xxx (xx.x)
XXXXXXXXXXXXXXXXXXXXXXXXXXXX	xxx (xx.x)

Denominator of the percentage is the number of patients in the enrolled population.

Every patient is counted a single time for each applicable specific adverse reaction. A patient with multiple adverse reactions within a system organ class is counted a single time for that system organ class. A patient may appear more than once in different System Organ Class categories.

N: number of patients in the enrolled population.

Program \\xxxxxxx\yyyyyyyy\zzzzzzzz.sas Output: \\xxxxxxx\yyyyyyyy\zzzzzzzzzz.txt Data: xxFEB2016

Table Generation: DDMMYY, Version: Draft Programmer ID: xxxxxx

Table 14.3.1.3.2 Summary of Adverse Reactions (by Frequency of Reactions) - Enrolled Population

System Organ Class	ACCUSOL 35 (N=XXX)
Preferred Term	n (%)
Total number of adverse reactions	xxx (100.0)
XXXXXXXXXXXXXXXXXXXXXXXXXXXX	xxx (xx.x)
XXXXXXXXXXXXXXXXXXXXXXXXXXXX	xxx (xx.x)
XXXXXXXXXXXXXXXXXXXXXXXXXXXX	xxx (xx.x)
XXXXXXXXXXXXXXXXXXXXXXXXXXXX	xxx (xx.x)
XXXXXXXXXXXXXXXXXXXXXXXXXXXX	xxx (xx.x)
XXXXXXXXXXXXXXXXXXXXXXXXXXXX	xxx (xx.x)
XXXXXXXXXXXXXXXXXXXXXXXXXXXX	xxx (xx.x)
XXXXXXXXXXXXXXXXXXXXXXXXXXXX	xxx (xx.x)
XXXXXXXXXXXXXXXXXXXXXXXXXXXX	xxx (xx.x)

Denominator of the percentage is the total number of adverse reactions.

N: number of patients in the enrolled population.

Program \\xxxxxxx\yyyyyyyy\zzzzzzzz.sas Output: \\xxxxxxx\yyyyyyyy\zzzzzzzzzz.txt Data: xxFEB2016

Table Generation: DDMMYYYY, Version: Draft Programmer ID: xxxxxx

Table 14.3.1.4.1 Summary of Adverse Reactions by Severity - Enrolled Population

System Organ Class Preferred Term	ACCUSOL 35 (N=XXX)		
	Mild n (%)	Moderate n (%)	Severe n (%)
Patients with one or more adverse reactions	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)

Denominator of the percentage is the number of patients in the enrolled population.

Every patient is counted a single time for each applicable specific adverse reaction with highest severity. A patient with multiple adverse reactions within a system organ class is counted a single time for that system organ class. A patient may appear more than once in different System Organ Class categories.

N: number of patients in the enrolled population.

Program \\xxxxxxx\yyyyyyyy\zzzzzzzz.sas Output: \\xxxxxxx\yyyyyyyy\zzzzzzzzzz.txt Data: xxFEB2016

Table Generation: DDMMYY, Version: Draft Programmer ID: xxxxxx

Table 14.3.1.4.2 Summary of Adverse Reactions by Severity (by Frequency of Reactions) - Enrolled Population

System Organ Class Preferred Term	ACCUSOL 35 (N=XXX)		
	Mild n (%)	Moderate n (%)	Severe n (%)
Total number of adverse reactions	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)

Denominator of the percentage is the total number of adverse reactions in the treatment group.
N: number of patients in the enrolled population.

Program \\xxxxxxx\yyyyyyyy\zzzzzzz.sas Output: \\xxxxxxx\yyyyyyyy\zzzzzzzzzz.txt Data: xxFEB2016
Table Generation: DDMMYYYY, Version: Draft Programmer ID: xxxxxxx

Table 14.3.1.5.1 Summary of Adverse Reactions by Relationship to Study Drug - Enrolled Population

System Organ Class Preferred Term	ACCUSOL 35 (N=XXX)	
	Possibly Related n (%)	Probably Related n (%)
Patients with one or more adverse reactions	xxx (xx.x)	xxx (xx.x)
xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx	xxx (xx.x)	xxx (xx.x)
xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx	xxx (xx.x)	xxx (xx.x)
xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx	xxx (xx.x)	xxx (xx.x)
xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx	xxx (xx.x)	xxx (xx.x)
xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx	xxx (xx.x)	xxx (xx.x)
xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx	xxx (xx.x)	xxx (xx.x)
xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx	xxx (xx.x)	xxx (xx.x)

Denominator of the percentage is the number of patients in the enrolled population.

Every patient is counted a single time for each applicable specific adverse reaction. A patient with multiple adverse reactions within a system organ class is counted a single time for that system organ class. A patient may appear more than once in different System Organ Class categories.

N: number of patients in the enrolled population.

Program \\xxxxxxx\yyyyyyyy\zzzzzzzz.sas Output: \\xxxxxxx\yyyyyyyy\zzzzzzzzzz.txt Data: xxFEB2016

Table Generation: DDDMMYYY, Version: Draft Programmer ID: xxxxxxx

Table 14.3.1.5.2 Summary of Adverse Reactions by Relationship to Study Drug (by Frequency of Reactions) - Enrolled Population

System Organ Class	ACCUSOL 35 (N=XXX)	
	Possibly Related n (%)	Probably Related n (%)
Preferred Term		
Total number of reactions	xxx (xx.x)	xxx (xx.x)
xxxxxxxxxxxxxxxxxxxxxxxxxxxx	xxx (xx.x)	xxx (xx.x)
xxxxxxxxxxxxxxxxxxxxxxxxxxxx	xxx (xx.x)	xxx (xx.x)
xxxxxxxxxxxxxxxxxxxxxxxxxxxx	xxx (xx.x)	xxx (xx.x)
xxxxxxxxxxxxxxxxxxxxxxxxxxxx	xxx (xx.x)	xxx (xx.x)
xxxxxxxxxxxxxxxxxxxxxxxxxxxx	xxx (xx.x)	xxx (xx.x)
xxxxxxxxxxxxxxxxxxxxxxxxxxxx	xxx (xx.x)	xxx (xx.x)
xxxxxxxxxxxxxxxxxxxxxxxxxxxx	xxx (xx.x)	xxx (xx.x)

Denominator of the percentage is the total number of adverse reactions.
N: number of patients in the enrolled population.

Program \\xxxxxxx\yyyyyyyy\zzzzzzzz.sas Output: \\xxxxxxx\yyyyyyyy\zzzzzzzzzz.txt Data: xxFEB2016
Table Generation: DDMMYYYY, Version: Draft Programmer ID: xxxxxx

X of Y

Table 14.3.2.1.1 Summary of Serious Adverse Reactions - Enrolled Population

System Organ Class	ACCUSOL 35 (N=XXX)
Preferred Term	n (%)
Patients with any SAR	xxx (xx.x)
xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx	xxx (xx.x)
xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx	xxx (xx.x)
xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx	xxx (xx.x)
xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx	xxx (xx.x)
xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx	xxx (xx.x)
xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx	xxx (xx.x)
xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx	xxx (xx.x)
xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx	xxx (xx.x)

Denominator of the percentage is the number of patients in the enrolled population.
Every patient is counted a single time for each applicable specific adverse reaction. A patient with multiple adverse reactions within a system organ class is counted a single time for that system organ class. A patient may appear more than once in different System Organ Class categories.
N: number of patients in the enrolled population.

Program \\xxxxxxx\yyyyyyyy\zzzzzzz.sas Output: \\xxxxxxx\yyyyyyyy\zzzzzzzzzz.txt Data: xxFEB2016
Table Generation: DDMMYY, Version: Draft Programmer ID: xxxxxx

Table 14.3.2.1.2 Summary of Serious Adverse Reactions (by Frequency of Reactions) - Enrolled Population

System Organ Class	ACCUSOL 35 (N=XXX)
Preferred Term	n (%)
Total number of serious adverse reactions	xxx (100.0)
xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx	xxx (xx.x)
xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx	xxx (xx.x)
xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx	xxx (xx.x)
xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx	xxx (xx.x)
xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx	xxx (xx.x)
xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx	xxx (xx.x)
xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx	xxx (xx.x)

Denominator of the percentage is the total number of serious adverse reactions in the treatment group.

N: number of patients in the enrolled population.

Program \\xxxxxxx\yyyyyyyy\zzzzzzzz.sas Output: \\xxxxxxx\yyyyyyyy\zzzzzzzzzz.txt Data: xxFEB2016
Table Generation: DDMMYY, Version: Draft Programmer ID: xxxxxx

Table 14.3.2.2.1 Summary of Serious Adverse Reactions by Severity - Enrolled Population

System Organ Class Preferred Term	ACCUSOL 35 (N=XXX)		
	Mild n (%)	Moderate n (%)	Severe n (%)
Patients with any SAR	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
xxxxxxxxxxxxxxxxxxxxxxxxxxxx	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
xxxxxxxxxxxxxxxxxxxxxxxxxxxx	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
xxxxxxxxxxxxxxxxxxxxxxxxxxxx	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
xxxxxxxxxxxxxxxxxxxxxxxxxxxx	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
xxxxxxxxxxxxxxxxxxxxxxxxxxxx	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
xxxxxxxxxxxxxxxxxxxxxxxxxxxx	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)

Denominator of the percentage is the number of patients in the enrolled population.

Every patient is counted a single time for each applicable specific serious adverse reaction with highest severity. A patient with multiple adverse reactions within a system organ class is counted a single time for that system organ class. A patient may appear more than once in different System Organ Class categories.

N: number of patients in the enrolled population.

Program \\xxxxxxx\yyyyyyyy\zzzzzzzz.sas Output: \\xxxxxxx\yyyyyyyy\zzzzzzzzzz.txt Data: xxFEB2016

Table Generation: DDMMYY, Version: Draft Programmer ID: xxxxxx

Table 14.3.2.2.2 Summary of Serious Adverse Reactions by Severity (by Frequency of Reactions) - Enrolled Population

System Organ Class Preferred Term	ACCUSOL 35 (N=XXX)		
	Mild n (%)	Moderate n (%)	Severe n (%)
Total number of serious adverse reactions	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
xxxxxxxxxxxxxxxxxxxxxxxxxxxxxx	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
xxxxxxxxxxxxxxxxxxxxxxxxxxxxxx	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
xxxxxxxxxxxxxxxxxxxxxxxxxxxxxx	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
xxxxxxxxxxxxxxxxxxxxxxxxxxxxxx	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
xxxxxxxxxxxxxxxxxxxxxxxxxxxxxx	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
xxxxxxxxxxxxxxxxxxxxxxxxxxxxxx	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
xxxxxxxxxxxxxxxxxxxxxxxxxxxxxx	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
xxxxxxxxxxxxxxxxxxxxxxxxxxxxxx	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)

Denominator of the percentage is the total number of serious adverse reactions in the treatment group.
N: number of patients in the enrolled population.

Program \\xxxxxxx\yyyyyyyy\zzzzzzzz.sas Output: \\xxxxxxx\yyyyyyyy\zzzzzzzzzz.txt Data: xxFEB2016
Table Generation: DDMMYYYY, Version: Draft Programmer ID: xxxxxx

Table 14.3.2.3.1 Summary of Serious Adverse Reactions by Relationship to Study Drug - Enrolled Population

System Organ Class Preferred Term	ACCUSOL 35 (N=XXX)	
	Possibly Related n (%)	Probably Related n (%)
Patients with any SAR	xxx (xx.x)	xxx (xx.x)
xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx	xxx (xx.x)	xxx (xx.x)
xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx	xxx (xx.x)	xxx (xx.x)
xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx	xxx (xx.x)	xxx (xx.x)
xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx	xxx (xx.x)	xxx (xx.x)
xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx	xxx (xx.x)	xxx (xx.x)
xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx	xxx (xx.x)	xxx (xx.x)
xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx	xxx (xx.x)	xxx (xx.x)
xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx	xxx (xx.x)	xxx (xx.x)

Denominator of the percentage is the number of patients in the enrolled population. Every patient is counted a single time for each applicable specific adverse reaction. A patient with multiple adverse reactions within a system organ class is counted a single time for that system organ class. A patient may appear more than once in different System Organ Class categories.
N: number of patients in the enrolled population.

Program \\xxxxxxx\yyyyyyyy\zzzzzzzz.sas Output: \\xxxxxxx\yyyyyyyy\zzzzzzzzzz.txt Data: xxFEB2016
Table Generation: DDMMYYYY, Version: Draft Programmer ID: xxxxxx

Table 14.3.2.3.2 Summary of Serious Adverse Reactions by Relationship to Study Drug (by Frequency of Reactions) - Enrolled Population

System Organ Class Preferred Term	ACCUSOL 35 (N=XXX)	
	Possibly Related n (%)	Probably Related n (%)
Total number of serious adverse reactions	xxx (xx.x)	xxx (xx.x)
XXXXXXXXXXXXXXXXXXXXXXXXXXXX	xxx (xx.x)	xxx (xx.x)
XXXXXXXXXXXXXXXXXXXXXXXXXXXX	xxx (xx.x)	xxx (xx.x)
XXXXXXXXXXXXXXXXXXXXXXXXXXXX	xxx (xx.x)	xxx (xx.x)
XXXXXXXXXXXXXXXXXXXXXXXXXXXX	xxx (xx.x)	xxx (xx.x)
XXXXXXXXXXXXXXXXXXXXXXXXXXXX	xxx (xx.x)	xxx (xx.x)
XXXXXXXXXXXXXXXXXXXXXXXXXXXX	xxx (xx.x)	xxx (xx.x)
XXXXXXXXXXXXXXXXXXXXXXXXXXXX	xxx (xx.x)	xxx (xx.x)
XXXXXXXXXXXXXXXXXXXXXXXXXXXX	xxx (xx.x)	xxx (xx.x)

Denominator of the percentage is the total number of serious adverse reactions in the treatment group.

N: number of patients in the enrolled population.

Program \\xxxxxxx\yyyyyyy\zzzzzzz.sas Output: \\xxxxxxx\yyyyyyy\zzzzzzzzzz.txt Data: xxFEB2016

Table Generation: DDMMYYYY, Version: Draft Programmer ID: xxxxxx

Table 14.3.3.1 Exploratory Analysis: Time to First Occurrence of Precipitate – Per-Protocol Population

	Statistics	ACCUSOL 35 (N=XXX)
Time to First Occurrence of Precipitate (h)	Events observed	x
	Subjects censored	xx
	1st quartile	xx.x
	95% CI	(xx.xx, xx.xx)
	Median	xx.x
	95% CI	(xx.xx, xx.xx)
	3rd quartile	xx.x
	95% CI	(xx.xx, xx.xx)

CI: Confidence Interval

Program \\xxxxxxx\yyyyyyyy\zzzzzzzz.sas Output: \\xxxxxxx\yyyyyyyy\zzzzzzzzzz.txt Data: xxFEB2016
Table Generation: DDMMYYYY, Version: Draft Programmer ID: xxxxxx

Table 14.3.3.2 Exploratory Analysis: Precipitate Formation by Dialysis Solution Used at Time of Observation – Per-Protocol Population

	ACCUSOL 35 (N=XXX)		
	n treated	n (%) with precipitate	95% CI
Proportion of patients with visible precipitate during 72 hours of use of ACCUSOL 35 solution with a single CRRT circuit (ACCUSOL 35)	xx	x (x.x)	(xx.x, xx.x)
Proportion of patients with visible precipitate during 72 hours of use of ACCUSOL 35 solution with a single CRRT circuit (ACCUSOL 35 Potassium 2 mmol/L)	xx	x (x.x)	(xx.x, xx.x)
Proportion of patients with visible precipitate during 72 hours of use of ACCUSOL 35 solution with a single CRRT circuit (ACCUSOL 35 Potassium 4 mmol/L)	xx	x (x.x)	(xx.x, xx.x)

N:number of evaluable patients

CI: Confidence Interval. Jeffrey's method is used to derive the confidence interval.

Program \\xxxxxxx\yyyyyyyy\zzzzzzzz.sas Output: \\xxxxxxx\yyyyyyyy\zzzzzzzzzzzz.txt Data: xxFEB2016

Table Generation: DDMMYY, Version: Draft Programmer ID: xxxxxx

Note: In case of precipitate observation similar tables will be produced for the other parameters mentioned in section 11.4 as required.

17.2 Data Listings

Page X of Y

Data Listing 16.2.1 Patient Disposition: Completion/Discontinuation from study - Enrolled Population

Patient Number	Age(Years) /Gender	Date and Time of Informed Consent	Written Consent by Whom	Date and Time of Informed Consent was Signed	Date and Time of Completion/ Discontinuation	Patient's Disposition Status	Specify, If Others
xxxxxx	xx/xxxx	ddMMMyyyy HH:nn	xxxxxxx	ddMMMyyyy HH:nn	ddMMMyyyy HH:nn	xxxxxxxxxx	xxxxxxx
xxxxxx	xx/xxxx	ddMMMyyyy HH:nn	xxxxxxx	ddMMMyyyy HH:nn	ddMMMyyyy HH:nn	xxxxxxxxxx	xxxxxxx
xxxxxx	xx/xxxx	ddMMMyyyy HH:nn	xxxxxxx	ddMMMyyyy HH:nn	ddMMMyyyy HH:nn	xxxxxxxxxx	xxxxxxx
xxxxxx	xx/xxxx	ddMMMyyyy HH:nn	xxxxxxx	ddMMMyyyy HH:nn	ddMMMyyyy HH:nn	xxxxxxxxxx	xxxxxxx
xxxxxx	xx/xxxx	ddMMMyyyy HH:nn	xxxxxxx	ddMMMyyyy HH:nn	ddMMMyyyy HH:nn	xxxxxxxxxx	xxxxxxx
xxxxxx	xx/xxxx	ddMMMyyyy HH:nn	xxxxxxx	ddMMMyyyy HH:nn	ddMMMyyyy HH:nn	xxxxxxxxxx	xxxxxxx

Program \\xxxxxxx\yyyyyyyy\zzzzzzz.sas Output: \\xxxxxxx\yyyyyyyy\zzzzzzzzzz.txt Data: xxFEB2016

Listing Generation: DDMMMYYYY, Version: Draft Programmer ID: xxxxxx

Data Listing 16.2.2 Protocol Deviations - Enrolled Population

Patient Number	Age(Years) /Gender	Protocol Deviation	Major or Minor
xxxxxx	xx/xxxx	xxxxxxxxxxxxxxxxxxxx	xxxxx
xxxxxx	xx/xxxx	xxxxxxxxxxxxxxxxxxxx	xxxxx
xxxxxx	xx/xxxx	xxxxxxxxxxxxxxxxxxxx	xxxxx
xxxxxx	xx/xxxx	xxxxxxxxxxxxxxxxxxxx	xxxxx
xxxxxx	xx/xxxx	xxxxxxxxxxxxxxxxxxxx	xxxxx
xxxxxx	xx/xxxx	xxxxxxxxxxxxxxxxxxxx	xxxxx
Program \\xxxxxxx\yyyyyyyy\zzzzzzz.sas Output: \\xxxxxxx\yyyyyyyy\zzzzzzzzzz.txt Data: xxFEB2016 Listing Generation: DDMMYYYY, Version: Draft Programmer ID: xxxxxxx			

Data Listing 16.2.4.1 Demographic and Baseline Characteristics - Enrolled Population

Patient Number	Age(Years)/ Gender	Weight(kg)	Baxter Evaluable Patient	Baxter Evaluable date, if Yes
xxxxxx	xx/xxxx	xx	xxx	ddMMMyyyy
xxxxxx	xx/xxxx	xx	xxx	ddMMMyyyy
xxxxxx	xx/xxxx	xx	xxx	ddMMMyyyy
xxxxxx	xx/xxxx	xx	xxx	ddMMMyyyy
xxxxxx	xx/xxxx	xx	xxx	ddMMMyyyy
xxxxxx	xx/xxxx	xx	xxx	ddMMMyyyy
xxxxxx	xx/xxxx	xx	xxx	ddMMMyyyy
xxxxxx	xx/xxxx	xx	xxx	ddMMMyyyy
Program \\xxxxxxx\yyyyyyyy\zzzzzzz.sas Output: \\xxxxxxxx\yyyyyyyy\zzzzzzzzzz.txt Data: xxFEB2016 Listing Generation: DDMMYYYY, Version: Draft Programmer ID: xxxxxxx				

Data Listing 16.2.5.1 Concomitant Medications - Enrolled Population

Patient Number	Age (Years) / Gender	Concomitant Medication Taken	ATC Term/ Preferred Term/ Reported Term
xxxxxx	xx/xxxx	yes	xxxxxxx/ xxxxxxx/ xxxxxxx xxxxxxx/ xxxxxxx/ xxxxxxx
xxxxxx	xx/xxxx	xxx	xxxxxxx/ xxxxxxx/ xxxxxxx xxxxxxx/ xxxxxxx/ xxxxxxx

Note: This listing summarizes anti-coagulant and potassium chloride administration

Program \\xxxxxxx\yyyyyyy\zzzzzzz.sas Output: \\xxxxxxx\yyyyyyy\zzzzzzzzzz.txt Data: xxFEB2016
Listing Generation: DDMMYYYY, Version: Draft Programmer ID: xxxxxx

Data Listing 16.2.5.2 Anti-Coagulant Administration - Enrolled Population

Patient Number	Age (Years) / Gender	Anti-Coagulant Medication Taken	ATC Term/ Preferred Term/ Reported Term	Date and Time of Administration	Route. Specify, if Other	Dose per Administration	Unit. Specify, if Other
xxxxxx	xx/xxxx	xxxx	xxxxxxx/ xxxxxxx/ xxxxxxx	ddMMMyyyy HH:nn	xx	xxx	xxx
			xxxxxxx/ xxxxxxx/ xxxxxxx	ddMMMyyyy HH:nn	xx	xxx	xxx
xxxxxx	xx/xxxx	xxxx	xxxxxxx/ xxxxxxx/ xxxxxxx	ddMMMyyyy HH:nn	xx	xxx	xxx
			xxxxxxx/ xxxxxxx/ xxxxxxx	ddMMMyyyy HH:nn	xx	xxx	xxx

Program \\xxxxxxx\yyyyyyyy\zzzzzzzz.sas Output: \\xxxxxxx\yyyyyyyy\zzzzzzzzzz.txt Data: xxFEB2016
Listing Generation: DDMMMYYYY, Version: Draft Programmer ID: xxxxxx

Page X of Y

Data Listing 16.2.5.3 Potassium Chloride Administration - Enrolled population

Patient Number	Age (Years) / Gender	Did the Patient have any additional Potassium Chloride added to their Dialysate fluid?	ATC Term/ Preferred Term/Reported Term	Date and Time of Administration	Concentration	Unit
xxxxxx	xx/xxxx	xxxx	xxxxxxxx/ xxxxxxxx/ xxxxxxxx	ddMMMyyyy HH:nn	xx	xxx
			xxxxxxxx/ xxxxxxxx/ xxxxxxxx	ddMMMyyyy HH:nn	xx	xxx
xxxxxx	xx/xxxx	xxxx	xxxxxxxx/ xxxxxxxx/ xxxxxxxx	ddMMMyyyy HH:nn	xx	xxx
			xxxxxxxx/ xxxxxxxx/ xxxxxxxx	ddMMMyyyy HH:nn	xx	xxx

Program \\xxxxxxx\yyyyyyyy\zzzzzzz.sas Output: \\xxxxxxx\yyyyyyyy\zzzzzzzzzz.txt Data: xxFEB2016
Listing Generation: DDMMYYYY, Version: Draft Programmer ID: xxxxxxx

Page X of Y

Data Listing 16.2.5.4 ACCUSOL 35 Administration - Enrolled Population

Patient Number	Age (Years) / Gender	First Accusol Administration Start Date/Time	Dialysis Solution used	Lot Number	Site of Introduction	Start Date and Time / End Date and Time	Dialysis Dose (ml/kg/hr)	Amount Administered (L)
xxxxxx	xx/xxxx	ddMMMyyyy HH:nn	xxx	xx	xxx	ddMMMyyyy HH:nn/ ddMMMyyyy HH:nn	xxx	xxx
xxxxxx	xx/xxxx	ddMMMyyyy HH:nn	xxx	xx	xxx	ddMMMyyyy HH:nn/ ddMMMyyyy HH:nn	xxx	xxx
xxxxxx	xx/xxxx	ddMMMyyyy HH:nn	xxx	xx	xxx	ddMMMyyyy HH:nn/ ddMMMyyyy HH:nn	xxx	xxx
xxxxxx	xx/xxxx	ddMMMyyyy HH:nn	xxx	xx	xxx	ddMMMyyyy HH:nn/ ddMMMyyyy HH:nn	xxx	xxx

Abbreviations: xxx

Program \\\xxxxxxx\yyyyyyyy\zzzzzzz.sas Output: \\\xxxxxxx\yyyyyyyy\zzzzzzzzzz.txt Data: xxFEB2016

Listing Generation: DDMMYYYY, Version: Draft Programmer ID: xxxxxxx

Note: Abbreviations can be used for Dialysis solution used and site of introduction to save space. Abbreviations will be explained in a footnote.

Data Listing 16.2.5.5 Dialysis Session - Enrolled Population

Patient Number	Age (Years) / Gender	Start Date and Time of Current CRRT Circuit /End Date and Time of Current CRRT Circuit	Manufacturer of CRRT Monitor/ Model of CRRT Monitor	Manufacturer of CRRT Lines/ Model of CRRT Lines	Manufacturer of Haemofilter / Model of Haemofilter	CRRT Mode Employed	Ultrafiltration Rate (L/h)
xxxxxx	xx/xxxx	ddMMMyyyy HH:nn/ ddMMMyyyy HH:nn	xxxxxxx/ xxxxxxx	xxxxxxx/ xxxxxxx	xxxxxxx/ xxxxxxx	xxxxxxx	xxx
xxxxxx	xx/xxxx	ddMMMyyyy HH:nn/ ddMMMyyyy HH:nn	xxxxxxx/ xxxxxxx	xxxxxxx/ xxxxxxx	xxxxxxx/ xxxxxxx	xxxxxxx	xxx

Abbreviations: xxx

Program \\xxxxxxx\yyyyyyy\zzzzzzz.sas Output: \\xxxxxxx\yyyyyyy\zzzzzzzzzz.txt Data: xxFEB2016

Listing Generation: DDMMYYYY, Version: Draft Programmer ID: xxxxxx

Note: Abbreviations can be used for manufacturers and models of CRRT circuits and monitors and of haemofilters to save space. Abbreviations will be explained in a footnote.

Data Listing 16.2.5.6 Dialysis Session – Interruptions - Enrolled Population

Patient Number	Age (Years) / Gender	Circuit Interrupted	No.of Interruptions	Total Time of Interruption	Reason for Interruption	Was the CRRT Circuit Changed while the Patient was on Study?	If yes, Specify Reason	Was CRRT Terminated while the Patient was on Study?	If yes, Specify Reason
xxxxxx	xx/xxxx	xxx	xx	xx	xxx	xxx	xxx	xxx	xxxxxx
xxxxxx	xx/xxxx	xxx	xx	xx	xxx	xxx	xxx	xxx	xxxxxx
xxxxxx	xx/xxxx	xxx	xx	xx	xxx	xxx	xxx	xxx	xxxxxx
xxxxxx	xx/xxxx	xxx	xx	xx	xxx	xxx	xxx	xxx	xxxxxx

Program \\xxxxxxx\yyyyyyyy\zzzzzzzz.sas Output: \\xxxxxxx\yyyyyyyy\zzzzzzzzzz.txt Data: xxFEB2016
Listing Generation: DDMMYYYY, Version: Draft Programmer ID: xxxxxxx

Data Listing 16.2.7.1 Precipitate Observation - Enrolled Population

Patient Number	Age (Years) / Gender	Date and Time(24hr Clock) of Final Observation/ Time since start of CRRT	Any Precipitate Observed in the CRRT Lines	If Yes, Colour of the Precipitate	Solution in Use at the Time Precipitate was Observed	Lot Number of Solution in Use at the Time Precipitate was Observed
xxxxxx	xx/xxxx	ddMMMyyyy HH:nn/HH:mm	xxx	xxxxxxx	xxxxxxx	xxx
xxxxxx	xx/xxxx	ddMMMyyyy HH:nn/HH:mm	xxx	xxxxxxx	xxxxxxx	xxx
xxxxxx	xx/xxxx	ddMMMyyyy HH:nn/HH:mm	xxx	xxxxxxx	xxxxxxx	xxx
xxxxxx	xx/xxxx	ddMMMyyyy HH:nn/HH:mm	xxx	xxxxxxx	xxxxxxx	xxx

Program \\xxxxxxx\yyyyyyyy\zzzzzzzz.sas Output: \\xxxxxxx\yyyyyyyy\zzzzzzzzzz.txt Data: xxFEB2016
Listing Generation: DDMMYYYY, Version: Draft Programmer ID: xxxxxxx

Data Listing 16.2.7.2.1 Adverse Reactions - Enrolled Population

Patient Number	Age (Years) /Sex	Did the Patient Experience any AR?	Adverse Reaction Description/ System Organ Class/ Preferred Term	Onset Date/ Resolution Date	Ongoing	Severity	Treatment Required	Treatment Given. Specify, if Other
xxxxxx	xx/xxx	xxxx	xxxxxxxxxx/ xxxxxxxx/ xxxxxx	ddMMMyyyy/ ddMMMyyyy	xxxx	xxxxxx	xxx	xxxxxxx
			xxxxxxxxxx/ xxxxxxxx/ xxxxxx	ddMMMyyyy/ ddMMMyyyy	xxxx	xxxxxx	xxx	xxxxxxx
xxxxxx	xx/xxx	xxxx	xxxxxxxxxx/ xxxxxxxx/ xxxxxx	ddMMMyyyy/ ddMMMyyyy	xxxx	xxxxxx	xxx	xxxxxxx
			xxxxxxxxxx/ xxxxxxxx/ xxxxxx	ddMMMyyyy/ ddMMMyyyy	xxxx	xxxxxx	xxx	xxxxxxx
xxxxxx	xx/xxx	xxxx	xxxxxxxxxx/ xxxxxxxx/ xxxxxx	ddMMMyyyy/ ddMMMyyyy	xxxx	xxxxxx	xxx	xxxxxxx

Program \\xxxxxxx\yyyyyyyy\zzzzzzzz.sas Output: \\xxxxxxx\yyyyyyyy\zzzzzzzzzz.txt Data: xxFEB2016

Listing Generation: DDMMYYYY, Version: Draft Programmer ID: xxxxxx

Data Listing 16.2.7.2.2 Adverse Reactions - Details - Enrolled Population

Patient Number	Age (Years) /Sex	Did the Patient Experience any AR?	Adverse Reaction Description/ System Organ Class/ Preferred Term	Onset Date/ Resolution Date	Relationship to ACCUSOL 35	Action Taken with Study Drug	Outcome of AR	Serious Adverse Reaction
xxxxxx	xx/xxx	xxxx	xxxxxxxxxxx/ xxxxxxxx/ xxxxxx	ddMMMyyyy/ ddMMMyyyy	xxxxxxx	xxxxxxx	xxxxxxx	xxx
			xxxxxxxxxxx/ xxxxxxxx/ xxxxxx	ddMMMyyyy/ ddMMMyyyy	xxxxxxx	xxxxxxx	xxxxxxx	xxx
xxxxxx	xx/xxx	xxxx	xxxxxxxxxxx/ xxxxxxxx/ xxxxxx	ddMMMyyyy/ ddMMMyyyy	xxxxxxx	xxxxxxx	xxxxxxx	xxx
			xxxxxxxxxxx/ xxxxxxxx/ xxxxxx	ddMMMyyyy/ ddMMMyyyy	xxxxxxx	xxxxxxx	xxxxxxx	xxx
xxxxxx	xx/xxx	xxxx	xxxxxxxxxxx/ xxxxxxxx/ xxxxxx	ddMMMyyyy/ ddMMMyyyy	xxxxxxx	xxxxxxx	xxxxxxx	xxx

Program \\xxxxxxx\yyyyyyyy\zzzzzzz.sas Output: \\xxxxxxx\yyyyyyyy\zzzzzzzzzz.txt Data: xxFEB2016

Listing Generation: DDMMYYYY, Version: Draft Programmer ID: xxxxxx

Data Listing 16.2.7.3.1 Serious Adverse Reactions - Enrolled Population

Patient Number	Age (Years) /Sex	Did the Patient Experience any AR?	Adverse Reaction Description/ System Organ Class/ Preferred Term	Onset Date/ Resolution Date	Ongoing	Severity	Treatment Required	Treatment Given. Specify, if Other
xxxxxx	xx/xxx	xxxx	xxxxxxxxxxx/ xxxxxxxx/ xxxxxx	ddMMMyyy/ ddMMMyyy	xxxx	xxxxxx	xxx	xxxxxxx
			xxxxxxxxxxx/ xxxxxxxx/ xxxxxx	ddMMMyyy/ ddMMMyyy	xxxx	xxxxxx	xxx	xxxxxxx
xxxxxx	xx/xxx	xxxx	xxxxxxxxxxx/ xxxxxxxx/ xxxxxx	ddMMMyyy/ ddMMMyyy	xxxx	xxxxxx	xxx	xxxxxxx
			xxxxxxxxxxx/ xxxxxxxx/ xxxxxx	ddMMMyyy/ ddMMMyyy	xxxx	xxxxxx	xxx	xxxxxxx
xxxxxx	xx/xxx	xxxx	xxxxxxxxxxx/ xxxxxxxx/ xxxxxx	ddMMMyyy/ ddMMMyyy	xxxx	xxxxxx	xxx	xxxxxxx

Program \\xxxxxxx\yyyyyyyy\zzzzzzz.sas Output: \\xxxxxxx\yyyyyyyy\zzzzzzzzzz.txt Data: xxFEB2016

Listing Generation: DDMMYYYY, Version: Draft Programmer ID: xxxxxxxx

Data Listing 16.2.7.3.2 Serious Adverse Reactions - Details - Enrolled Population

Patient Number	Age (Years) /Sex	Did the Patient Experience any AR	Adverse Reaction Description/ System Organ Class/ Preferred Term	Onset Date/ Resolution Date	Relationship to ACCUSOL 35	Action Taken with Study Drug	Outcome of SAR
xxxxxx	xx/xxx	xxxx	xxxxxxxxxxx/ xxxxxxxx/ xxxxxxx	ddMMMyyyy/ ddMMMyyyy	xxxxxxx	xxxxxxx	xxxxxxx
			xxxxxxxxxxx/ xxxxxxxx/ xxxxxxx	ddMMMyyyy/ ddMMMyyyy	xxxxxxx	xxxxxxx	xxxxxxx
xxxxxx	xx/xxx	xxxx	xxxxxxxxxxx/ xxxxxxxx/ xxxxxxx	ddMMMyyyy/ ddMMMyyyy	xxxxxxx	xxxxxxx	xxxxxxx
			xxxxxxxxxxx/ xxxxxxxx/ xxxxxxx	ddMMMyyyy/ ddMMMyyyy	xxxxxxx	xxxxxxx	xxxxxxx
xxxxxx	xx/xxx	xxxx	xxxxxxxxxxx/ xxxxxxxx/ xxxxxxx	ddMMMyyyy/ ddMMMyyyy	xxxxxxx	xxxxxxx	xxxxxxx

Program \\xxxxxxx\yyyyyyyy\zzzzzzz.sas Output: \\xxxxxxx\yyyyyyyy\zzzzzzzzzz.txt Data: xxFEB2016

Listing Generation: DDMMYYYY, Version: Draft Programmer ID: xxxxxxx

Data Listing 16.2.7.4 Deaths - Enrolled Population

Patient Number	Age (Years) /Sex	Date of Death	Time of death	Primary Cause of Death
xxxxxx	xx/xxx	ddMMMyyyy	XX:XX	xxxxxxx
xxxxxx	xx/xxx	ddMMMyyyy	XX:XX	xxxxxxx

Program \\xxxxxxx\yyyyyyyy\zzzzzzzz.sas Output: \\xxxxxxx\yyyyyyyy\zzzzzzzzzz.txt Data: xxFEB2016
Listing Generation: DDMMYYYY, Version: Draft Programmer ID: xxxxxxListing

18. APPENDICES

Appendix 1 Programming Specifications

Data Presentation

- The TLF title will be center aligned and the last row of the title should indicate the population, unless specified.
- The column titles should be aligned top left and the contents in the TLF should be aligned left, unless specified.
- TLF will be produced as RTF files using PROC REPORT in Times New Roman font and font size 10 in landscape orientation.
- The footnotes will be presented in the order as seen in SAP. No programming notes will be presented in the TLF.
- Version: X will be replaced with Version: Draft or Final accordingly in all the tables and listings.
- All outputs will show the name of the SAS program and its location, the name of the program output and its location, the date of used data sets, e.g., a snapshot date or a database lock date, the date of output production and programmer ID in a footnote

Table Specifications

The following rules will apply when creating the tables.

- The values will be aligned on decimal places.
- Number (n) and percentage (%) will be presented in the format n (%).
- Ordering of statistics – N, Mean (SD), Median, Min, Max, and Missing.

Number of decimal places (DP)

- For minimum and maximum the DPs will be the same as the raw data.
- For mean the DPs will be one more than the raw data.
- For SD the DPs will be one more than the mean.
- Percentages (%) will be displayed with one DP.

Listing Specifications

The following rules will apply when creating the listings.

- The values presented in the listing will be left aligned.
- The listings will be presented by patient number and age (years) /gender.
- Time will be presented as 24 hour clock.

Number of DPs

The number of DPs must be same as in the raw data.

Appendix 16.2.1. Patient Disposition

Data Listing 16.2.1. Patient Disposition: Completion/Discontinuation from Study - Enrolled Population

Patient Number	Age (Years)/ Gender	Date and Time of Informed Consent/ by Whom	Additional written consent (Y/N)/ If Yes, Written Consent by Whom	Date and Time of Additional Informed Consent was Signed	Date and Time of Completion/ Discontinuation	Patient's Disposition Status	Specify, If Others
001-001	57/Female	04JUN2015 14:50 / PATIENT	N		05JUN2015 23:00	COMPLETED	
001-002	50/Male	12JUN2015 13:32 / PATIENT	N		13JUN2015 23:04	COMPLETED	
001-003	68/Female	14AUG2015 12:25 / NEXT OF KIN/RELATIVE	N		15AUG2015 02:30	CRRT CIRCUIT CHANGED	
001-004	78/Female	18SEP2015 14:17 / NEXT OF KIN/RELATIVE	N		20SEP2015 04:01	COMPLETED	
001-005	33/Female	28OCT2015 15:34 / NEXT OF KIN/RELATIVE	Y / PATIENT	13JAN2016 13:50	30OCT2015 14:10	COMPLETED	
001-006		12NOV2015 15:25 / NEXT OF KIN/RELATIVE	N		13NOV2015 15:50	CRRT TERMINATED	
001-007	56/Male	22DEC2015 13:32 / PATIENT			24DEC2015 03:33	COMPLETED	

Data Listing 16.2.1. Patient Disposition: Completion/Discontinuation from Study - Enrolled Population

Patient Number	Age (Years)/ Gender	Date and Time of Informed Consent/ by Whom	Additional written consent (Y/N)/ If Yes, Written Consent by Whom	Date and Time of Additional Informed Consent was Signed	Date and Time of Completion/ Discontinuation	Patient's Disposition Status	Specify, If Others
001-008	57/Male	29JAN2016 12:40 / NEXT OF KIN/RELATIVE	Y / NEXT OF KIN/RELATIVE	01FEB2016 16:07	31JAN2016 01:00	COMPLETED	
002-002	56/Male	21APR2015 15:20 / NEXT OF KIN/RELATIVE	Y / PATIENT	25JUN2015 11:30	27APR2015 10:25	COMPLETED	
002-003	68/Female	25APR2015 15:45 / NEXT OF KIN/RELATIVE	N		05MAY2015 09:50	CRRT TERMINATED	
002-005	44/Male	12MAY2015 18:40 / NEXT OF KIN/RELATIVE	Y / PATIENT	18MAY2015 15:40	16MAY2015 18:20	CRRT TERMINATED	
002-007	61/Male	26MAY2015 16:53 / NEXT OF KIN/RELATIVE	N		24JUN2015 18:00	CRRT TERMINATED	
002-009	58/Female	15JUN2015 15:18 / NEXT OF KIN/RELATIVE	N		20JUN2015 17:00	CRRT TERMINATED	
002-011	63/Female	19AUG2015 15:15 / NEXT OF KIN/RELATIVE	Y / PATIENT	04SEP2015 13:30	21AUG2015 15:00	COMPLETED	
002-012		27AUG2015 17:40 / NEXT OF KIN/RELATIVE	N		30AUG2015 12:45	CRRT TERMINATED	

Data Listing 16.2.1. Patient Disposition: Completion/Discontinuation from Study - Enrolled Population

Patient Number	Age (Years)/ Gender	Date and Time of Informed Consent/ by Whom	Additional written consent (Y/N)/ If Yes, Written Consent by Whom	Date and Time of Additional Informed Consent was Signed	Date and Time of Completion/ Discontinuation	Patient's Disposition Status	Specify, If Others
002-014	59/Male	01SEP2015 15:07 / NEXT OF KIN/RELATIVE	N		03SEP2015 19:35	CRRT TERMINATED	
002-016	83/Female	03SEP2015 14:50 / NEXT OF KIN/RELATIVE	Y / PATIENT	11SEP2015 12:30	03SEP2015 18:30	CRRT TERMINATED	
002-017	73/Male	12OCT2015 14:30 / PATIENT			12OCT2015 18:30	CRRT TERMINATED	
002-018	91/Female	21OCT2015 15:30 / NEXT OF KIN/RELATIVE	N		23OCT2015 11:00	CRRT TERMINATED	
002-019	70/Male	09OCT2015 16:40 / NEXT OF KIN/RELATIVE	N		10NOV2015 21:35	OTHER	IMMINENT DEATH
002-021	73/Male	08DEC2015 12:00 / NEXT OF KIN/RELATIVE	Y / PATIENT	24DEC2015 12:55	11DEC2015 12:10	CRRT TERMINATED	
003-001	77/Male	30MAR2015 15:00 / PATIENT			30MAR2015 20:30	CRRT TERMINATED	
003-002	67/Male	13MAY2015 11:15 / NEXT OF KIN/RELATIVE	N		16MAY2015 08:30	CRRT CIRCUIT CHANGED	

Data Listing 16.2.1. Patient Disposition: Completion/Discontinuation from Study - Enrolled Population

Patient Number	Age (Years)/ Gender	Date and Time of Informed Consent/ by Whom	Additional written consent (Y/N)/ If Yes, Written Consent by Whom	Date and Time of Additional Informed Consent was Signed	Date and Time of Completion/ Discontinuation	Patient's Disposition Status	Specify, If Others
003-003	57/Female	27AUG2015 18:00 / NEXT OF KIN/RELATIVE	Y / PATIENT	08OCT2015 11:00	28AUG2015 13:30	CRRT TERMINATED	
003-004	66/Male	07SEP2015 11:20 / NEXT OF KIN/RELATIVE	N		08SEP2015 20:35	CRRT TERMINATED	
003-007	60/Male	05OCT2015 11:00 / NEXT OF KIN/RELATIVE	N		06OCT2015 22:00	COMPLETED	
003-008	47/Male	20OCT2015 17:15 / PATIENT			21OCT2015 16:30	CRRT TERMINATED	
003-009		26OCT2015 16:30 / NEXT OF KIN/RELATIVE	Y / PATIENT	27OCT2015 12:00	27OCT2015 13:30	COMPLETED	
003-010	79/Male	29NOV2015 16:00 / NEXT OF KIN/RELATIVE	N		01DEC2015 10:00	COMPLETED	
003-011	69/Male	22DEC2015 18:30 / NEXT OF KIN/RELATIVE	Y / PATIENT	29DEC2015 13:30	24DEC2015 11:00	COMPLETED	
003-012	88/Male	23JAN2016 07:30 / PATIENT			23JAN2016 14:00	CRRT TERMINATED	

Data Listing 16.2.1. Patient Disposition: Completion/Discontinuation from Study - Enrolled Population

Patient Number	Age (Years)/ Gender	Date and Time of Informed Consent/ by Whom	Additional written consent (Y/N)/ If Yes, Written Consent by Whom	Date and Time of Additional Informed Consent was Signed	Date and Time of Completion/ Discontinuation	Patient's Disposition Status	Specify, If Others
004-001		22APR2015 19:05 / LEGALLY AUTHORISED REPRESENTATIVE	N		23APR2015 21:00	CRRT TERMINATED	
004-002		16MAY2015 15:20 / NEXT OF KIN/RELATIVE	N		19MAY2015 06:00	CRRT CIRCUIT CHANGED	
004-003	45/Female	01JUN2015 11:30 / NEXT OF KIN/RELATIVE	N		02JUN2015 20:00	CRRT CIRCUIT CHANGED	
004-005	20/Female	21JUN2015 19:15 / NEXT OF KIN/RELATIVE	Y / PATIENT	08JUL2015 16:45	24JUN2015 12:00	COMPLETED	
004-006	30/Male	04JUL2015 16:40 / LEGALLY AUTHORISED REPRESENTATIVE	N		06JUL2015 15:00	COMPLETED	
004-009	59/Female	22JUL2015 12:30 / NEXT OF KIN/RELATIVE	Y / NEXT OF KIN/RELATIVE	24JUL2015 15:55	25JUL2015 23:00	COMPLETED	
004-010	55/Male	28JUL2015 10:20 / PATIENT			29JUL2015 08:00	CRRT TERMINATED	

Data Listing 16.2.1. Patient Disposition: Completion/Discontinuation from Study - Enrolled Population

Patient Number	Age (Years)/ Gender	Date and Time of Informed Consent/ by Whom	Additional written consent (Y/N)/ If Yes, Written Consent by Whom	Date and Time of Additional Informed Consent was Signed	Date and Time of Completion/ Discontinuation	Patient's Disposition Status	Specify, If Others
004-013	79/Male	13AUG2015 16:12 / LEGALLY AUTHORISED REPRESENTATIVE	N		15AUG2015 01:00	CRRT CIRCUIT CHANGED	
004-014	65/Male	22AUG2015 16:55 / NEXT OF KIN/RELATIVE	N		23AUG2015 17:00	CRRT CIRCUIT CHANGED	
004-016	47/Female	18SEP2015 16:25 / NEXT OF KIN/RELATIVE	N		19SEP2015 09:00	CRRT CIRCUIT CHANGED	
004-017	67/Male	24SEP2015 15:10 / NEXT OF KIN/RELATIVE	N		26SEP2015 01:00	COMPLETED	
004-018	40/Male	25SEP2015 11:30 / LEGALLY AUTHORISED REPRESENTATIVE	N		27SEP2015 02:30	CRRT CIRCUIT CHANGED	
005-002	68/Female	20MAR2015 14:25 / NEXT OF KIN/RELATIVE	Y / PATIENT	06MAY2015 13:14	22MAR2015 12:00	CRRT TERMINATED	
005-003	65/Female	23MAR2015 15:00 / NEXT OF KIN/RELATIVE	Y / NEXT OF KIN/RELATIVE	24MAR2015 13:10	25MAR2015 13:00	CRRT TERMINATED	

Data Listing 16.2.1. Patient Disposition: Completion/Discontinuation from Study - Enrolled Population

Patient Number	Age (Years)/ Gender	Date and Time of Informed Consent/ by Whom	Additional written consent (Y/N)/ If Yes, Written Consent by Whom	Date and Time of Additional Informed Consent was Signed	Date and Time of Completion/ Discontinuation	Patient's Disposition Status	Specify, If Others
005-004	81/Male	26MAR2015 19:30 / NEXT OF KIN/RELATIVE	Y / NEXT OF KIN/RELATIVE	26MAR2015 19:40	28MAR2015 07:00	CRRT TERMINATED	
005-006	38/Male	22APR2015 09:30 / NEXT OF KIN/RELATIVE	Y / NEXT OF KIN/RELATIVE	22APR2015 14:05	23APR2015 11:10	CRRT TERMINATED	
005-007	63/Male	23APR2015 20:00 / NEXT OF KIN/RELATIVE	Y / PATIENT	22JUN2015 13:30	25APR2015 04:00	COMPLETED	
005-008	74/Female	08MAY2015 14:40 / NEXT OF KIN/RELATIVE	N		10MAY2015 03:00	CRRT TERMINATED	
005-010	42/Male	13MAY2015 11:50 / NEXT OF KIN/RELATIVE	Y / PATIENT	08JUN2015 15:00	15MAY2015 18:00	COMPLETED	
005-011	78/Female	14MAY2015 14:20 / NEXT OF KIN/RELATIVE	N		15MAY2015 16:00	CRRT TERMINATED	
005-012		16MAY2015 11:20 / NEXT OF KIN/RELATIVE	N		17MAY2015 21:00	COMPLETED	
005-014	65/Male	04JUN2015 19:45 / NEXT OF KIN/RELATIVE	Y / PATIENT	19JAN2016 12:00	06JUN2015 08:20	CRRT TERMINATED	

Data Listing 16.2.1. Patient Disposition: Completion/Discontinuation from Study - Enrolled Population

Patient Number	Age (Years)/ Gender	Date and Time of Informed Consent/ by Whom	Additional written consent (Y/N)/ If Yes, Written Consent by Whom	Date and Time of Additional Informed Consent was Signed	Date and Time of Completion/ Discontinuation	Patient's Disposition Status	Specify, If Others
005-015	78/Male	20JUN2015 17:30 / NEXT OF KIN/RELATIVE	Y / NEXT OF KIN/RELATIVE	21JUN2015 11:00	22JUN2015 05:00	COMPLETED	
005-016		14JUL2015 14:15 / NEXT OF KIN/RELATIVE	N		16JUL2015 03:50	COMPLETED	
005-018	67/Male	28AUG2015 14:15 / NEXT OF KIN/RELATIVE	N		29AUG2015 18:00	CRRT CIRCUIT CHANGED	
005-019	69/Male	15SEP2015 12:45 / NEXT OF KIN/RELATIVE	Y / PATIENT	29DEC2015 12:50	16SEP2015 23:30	COMPLETED	
005-020		15SEP2015 13:20 / NEXT OF KIN/RELATIVE	N		17SEP2015 19:30	COMPLETED	
005-021	58/Male	15SEP2015 14:25 / NEXT OF KIN/RELATIVE	N		17SEP2015 16:30	COMPLETED	
005-022		05OCT2015 14:00 / NEXT OF KIN/RELATIVE	N		07OCT2015 12:30	COMPLETED	
005-023	66/Male	10NOV2015 11:30 / PATIENT	N		11NOV2015 18:00	CRRT TERMINATED	

Data Listing 16.2.1. Patient Disposition: Completion/Discontinuation from Study - Enrolled Population

Patient Number	Age (Years)/ Gender	Date and Time of Informed Consent/ by Whom	Additional written consent (Y/N)/ If Yes, Written Consent by Whom	Date and Time of Additional Informed Consent was Signed	Date and Time of Completion/ Discontinuation	Patient's Disposition Status	Specify, If Others
005-024	41/Female	25NOV2015 09:20 / NEXT OF KIN/RELATIVE	Y / PATIENT	11DEC2015 13:30	26NOV2015 19:00	COMPLETED	
005-025		25NOV2015 13:05 / NEXT OF KIN/RELATIVE	N		26NOV2015 20:45	CRRT TERMINATED	
005-026	64/Male	01DEC2015 12:40 / NEXT OF KIN/RELATIVE	Y / PATIENT	19JAN2016 14:45	03DEC2015 10:45	CRRT TERMINATED	
005-027		01DEC2015 15:40 / NEXT OF KIN/RELATIVE	N		03DEC2015 12:00	CRRT TERMINATED	
005-028		08DEC2015 15:00 / NEXT OF KIN/RELATIVE	N		10DEC2015 15:40	CRRT TERMINATED	
005-029	68/Male	10DEC2015 12:20 / NEXT OF KIN/RELATIVE	Y / PATIENT	29DEC2015 12:20	12DEC2015 15:30	COMPLETED	
005-030	61/Male	14DEC2015 12:20 / NEXT OF KIN/RELATIVE	Y / PATIENT	17MAR2016 10:30	18DEC2015 17:00	CRRT TERMINATED	
005-032	49/Male	31DEC2015 13:05 / NEXT OF KIN/RELATIVE	Y / PATIENT	01MAR2016 13:52	01JAN2016 18:00	CRRT TERMINATED	

Data Listing 16.2.1. Patient Disposition: Completion/Discontinuation from Study - Enrolled Population

Patient Number	Age (Years)/ Gender	Date and Time of Informed Consent/ by Whom	Additional written consent (Y/N)/ If Yes, Written Consent by Whom	Date and Time of Additional Informed Consent was Signed	Date and Time of Completion/ Discontinuation	Patient's Disposition Status	Specify, If Others
005-034	70/Male	13JAN2016 12:25 / NEXT OF KIN/RELATIVE	Y / PATIENT	01FEB2016 10:10	14JAN2016 14:00	CRRT TERMINATED	
005-036	51/Female	13JAN2016 14:30 / NEXT OF KIN/RELATIVE	Y / PATIENT	21JAN2016 10:32	15JAN2016 09:15	COMPLETED	
005-037	53/Female	29JAN2016 12:15 / NEXT OF KIN/RELATIVE	N		30JAN2016 23:00	COMPLETED	
005-038		29JAN2016 12:45 / NEXT OF KIN/RELATIVE	N		29JAN2016 22:10	CRRT TERMINATED	
007-001	61/Male	10APR2015 14:00 / NEXT OF KIN/RELATIVE	Y / PATIENT	12MAY2015 14:00	11APR2015 09:30	CRRT TERMINATED	
007-002		19MAY2015 12:50 / NEXT OF KIN/RELATIVE	N		20MAY2015 11:00	CRRT TERMINATED	
007-003	64/Male	25JUN2015 12:50 / NEXT OF KIN/RELATIVE	Y / PATIENT	02JUL2015 11:05	27JUN2015 08:00	CRRT TERMINATED	
007-004	72/Male	27JUN2015 13:10 / NEXT OF KIN/RELATIVE	N		28JUN2015 20:30	CRRT TERMINATED	

Data Listing 16.2.1. Patient Disposition: Completion/Discontinuation from Study - Enrolled Population

Patient Number	Age (Years)/ Gender	Date and Time of Informed Consent/ by Whom	Additional written consent (Y/N)/ If Yes, Written Consent by Whom	Date and Time of Additional Informed Consent was Signed	Date and Time of Completion/ Discontinuation	Patient's Disposition Status	Specify, If Others
007-005	24/Male	17JUL2015 13:22 / NEXT OF KIN/RELATIVE	Y / PATIENT	06AUG2015 14:15	19JUL2015 11:00	CRRT TERMINATED	
007-006	73/Female	26JUL2015 13:02 / NEXT OF KIN/RELATIVE	Y / PATIENT	24SEP2015 10:00	28JUL2015 04:30	COMPLETED	
007-007	83/Male	30JUL2015 13:30 / NEXT OF KIN/RELATIVE	Y / PATIENT	25AUG2015 11:00	03AUG2015 04:10	CRRT TERMINATED	
007-008	79/Male	12AUG2015 14:00 / NEXT OF KIN/RELATIVE	N		13AUG2015 09:45	CRRT TERMINATED	
007-010	70/Male	31AUG2015 13:05 / NEXT OF KIN/RELATIVE	N		01SEP2015 10:00	CRRT TERMINATED	
007-011	64/Female	31AUG2015 14:55 / NEXT OF KIN/RELATIVE	Y / PATIENT	24NOV2015 12:00	02SEP2015 13:30	COMPLETED	
007-012	36/Male	07SEP2015 15:30 / NEXT OF KIN/RELATIVE	Y / PATIENT	24SEP2015 10:25	09SEP2015 01:30	COMPLETED	
007-014	74/Female	24SEP2015 14:10 / NEXT OF KIN/RELATIVE	N		28SEP2015 07:45	CRRT TERMINATED	

Data Listing 16.2.1. Patient Disposition: Completion/Discontinuation from Study - Enrolled Population

Patient Number	Age (Years)/ Gender	Date and Time of Informed Consent/ by Whom	Additional written consent (Y/N)/ If Yes, Written Consent by Whom	Date and Time of Additional Informed Consent was Signed	Date and Time of Completion/ Discontinuation	Patient's Disposition Status	Specify, If Others
007-015	73/Female	13DEC2015 18:30 / NEXT OF KIN/RELATIVE	N		15DEC2015 01:50	CRRT TERMINATED	
007-016	71/Male	04JAN2016 14:00 / NEXT OF KIN/RELATIVE	Y / NEXT OF KIN/RELATIVE	05JAN2016 14:50	05JAN2016 10:20	CRRT TERMINATED	
008-001	26/Male	19MAR2015 08:55 / NEXT OF KIN/RELATIVE	N		20MAR2015 20:05	COMPLETED	
008-002	31/Male	13APR2015 16:50 / NEXT OF KIN/RELATIVE	Y / PATIENT	11FEB2016 09:20	15APR2015 21:00	COMPLETED	
008-003	25/Female	15APR2015 14:40 / NEXT OF KIN/RELATIVE	N		22APR2015 04:00	COMPLETED	
008-004	46/Male	06MAY2015 16:45 / NEXT OF KIN/RELATIVE	Y / PATIENT	22JUN2015 11:58	06MAY2015 23:45	CRRT CIRCUIT CHANGED	
008-005	82/Male	21MAY2015 16:20 / NEXT OF KIN/RELATIVE	N		22MAY2015 10:55	CRRT TERMINATED	
008-006	70/Male	27MAY2015 15:43 / NEXT OF KIN/RELATIVE	N		28MAY2015 13:00	CRRT CIRCUIT CHANGED	

Data Listing 16.2.1. Patient Disposition: Completion/Discontinuation from Study - Enrolled Population

Patient Number	Age (Years)/ Gender	Date and Time of Informed Consent/ by Whom	Additional written consent (Y/N)/ If Yes, Written Consent by Whom	Date and Time of Additional Informed Consent was Signed	Date and Time of Completion/ Discontinuation	Patient's Disposition Status	Specify, If Others
008-007	74/Male	27MAY2015 16:39 / PATIENT	N		28MAY2015 21:50	CRRT CIRCUIT CHANGED	
008-012	71/Male	20JUL2015 12:25 / PATIENT			20JUL2015 20:30	CRRT TERMINATED	
008-013	68/Male	20JUL2015 13:00 / NEXT OF KIN/RELATIVE	N		21JUL2015 14:45	CRRT CIRCUIT CHANGED	
008-014	65/Female	24JUL2015 17:30 / LEGALLY AUTHORISED REPRESENTATIVE	N		25JUL2015 11:00	CRRT CIRCUIT CHANGED	
008-016	34/Male	13AUG2015 09:00 / LEGALLY AUTHORISED REPRESENTATIVE	Y / PATIENT	05NOV2015 13:57	13AUG2015 14:00	CRRT TERMINATED	
008-017	52/Female	21AUG2015 10:20 / LEGALLY AUTHORISED REPRESENTATIVE	N		22AUG2015 05:55	CRRT CIRCUIT CHANGED	
008-018	65/Male	05OCT2015 12:15 / PATIENT	N		05OCT2015 22:55	CRRT TERMINATED	

Data Listing 16.2.1. Patient Disposition: Completion/Discontinuation from Study - Enrolled Population

Patient Number	Age (Years)/ Gender	Date and Time of Informed Consent/ by Whom	Additional written consent (Y/N)/ If Yes, Written Consent by Whom	Date and Time of Additional Informed Consent was Signed	Date and Time of Completion/ Discontinuation	Patient's Disposition Status	Specify, If Others
008-019	69/Female	09OCT2015 16:30 / LEGALLY AUTHORISED REPRESENTATIVE	Y / PATIENT	10OCT2015 12:50	10OCT2015 02:00	CRRT TERMINATED	
008-020	60/Male	19OCT2015 18:35 / NEXT OF KIN/RELATIVE	Y / LEGALLY AUTHORISED REPRESENTATIVE	19OCT2015 18:30	21OCT2015 15:30	COMPLETED	
008-021	66/Male	20OCT2015 14:05 / LEGALLY AUTHORISED REPRESENTATIVE	N		20OCT2015 18:10	CRRT CIRCUIT CHANGED	
008-022	43/Male	20OCT2015 15:20 / NEXT OF KIN/RELATIVE	Y / LEGALLY AUTHORISED REPRESENTATIVE	20OCT2015 18:00	22OCT2015 05:00	COMPLETED	
008-023		20OCT2015 18:00 / LEGALLY AUTHORISED REPRESENTATIVE	Y / PATIENT	05NOV2015	21OCT2015 16:45	CRRT CIRCUIT CHANGED	
008-024	27/Male	27OCT2015 11:35 / LEGALLY AUTHORISED REPRESENTATIVE	Y / PATIENT	19NOV2015 15:40	28OCT2015 20:00	COMPLETED	

Data Listing 16.2.1. Patient Disposition: Completion/Discontinuation from Study - Enrolled Population

Patient Number	Age (Years)/ Gender	Date and Time of Informed Consent/ by Whom	Additional written consent (Y/N)/ If Yes, Written Consent by Whom	Date and Time of Additional Informed Consent was Signed	Date and Time of Completion/ Discontinuation	Patient's Disposition Status	Specify, If Others
008-025	68/Male	30OCT2015 10:45 / LEGALLY AUTHORISED REPRESENTATIVE	N		30OCT2015 11:30	CRRT CIRCUIT CHANGED	
008-026	30/Female	05NOV2015 09:50 / LEGALLY AUTHORISED REPRESENTATIVE	N		05NOV2015 19:00	CRRT TERMINATED	
008-027	71/Male	12OCT2015 18:15 / NEXT OF KIN/RELATIVE	Y / PATIENT	24DEC2015 10:30	13NOV2015 18:00	CRRT CIRCUIT CHANGED	
008-028	72/Male	30NOV2015 12:25 / PATIENT			01DEC2015 10:30	CRRT CIRCUIT CHANGED	
008-029	66/Female	08DEC2015 18:12 / LEGALLY AUTHORISED REPRESENTATIVE	N		09DEC2015 20:00	CRRT CIRCUIT CHANGED	
008-030	63/Female	11JAN2016 16:05 / NEXT OF KIN/RELATIVE	N		12JAN2016 18:00	CRRT TERMINATED	
008-031	23/Male	26JAN2016 17:18 / NEXT OF KIN/RELATIVE	N		28JAN2016 04:10	CRRT CIRCUIT CHANGED	

Data Listing 16.2.1. Patient Disposition: Completion/Discontinuation from Study - Enrolled Population

Patient Number	Age (Years)/ Gender	Date and Time of Informed Consent/ by Whom	Additional written consent (Y/N)/ If Yes, Written Consent by Whom	Date and Time of Additional Informed Consent was Signed	Date and Time of Completion/ Discontinuation	Patient's Disposition Status	Specify, If Others
009-001	64/Male	31MAR2015 14:45 / NEXT OF KIN/RELATIVE	Y / PATIENT	13APR2015 08:30	02APR2015 15:15	CRRT CIRCUIT CHANGED	
009-002		08APR2015 14:45 / NEXT OF KIN/RELATIVE	N		09APR2015 12:00	CRRT CIRCUIT CHANGED	
009-003	75/Male	09APR2015 14:00 / NEXT OF KIN/RELATIVE	N		15APR2015 19:00	COMPLETED	
009-006	58/Female	22APR2015 14:30 / NEXT OF KIN/RELATIVE	N		23APR2015 10:00	CRRT CIRCUIT CHANGED	
009-008	31/Male	24APR2015 14:07 / LEGALLY AUTHORISED REPRESENTATIVE	N		01MAY2015 01:00	COMPLETED	
009-009		30APR2015 13:00 / NEXT OF KIN/RELATIVE	N		01MAY2015 16:50	CRRT CIRCUIT CHANGED	
009-011	75/Female	19MAY2015 14:20 / NEXT OF KIN/RELATIVE	N		21MAY2015 12:55	CRRT CIRCUIT CHANGED	

Data Listing 16.2.1. Patient Disposition: Completion/Discontinuation from Study - Enrolled Population

Patient Number	Age (Years)/ Gender	Date and Time of Informed Consent/ by Whom	Additional written consent (Y/N)/ If Yes, Written Consent by Whom	Date and Time of Additional Informed Consent was Signed	Date and Time of Completion/ Discontinuation	Patient's Disposition Status	Specify, If Others
009-013	60/Female	10JUN2015 14:53 / NEXT OF KIN/RELATIVE	N		12JUN2015 01:00	CRRT TERMINATED	
009-015	29/Male	15JUL2015 15:15 / NEXT OF KIN/RELATIVE	Y / PATIENT	20JUL2015 15:30	17JUL2015 18:35	CRRT CIRCUIT CHANGED	
009-016	83/Male	21JUL2015 12:30 / NEXT OF KIN/RELATIVE	N		21JUL2015 13:20	CRRT CIRCUIT CHANGED	
009-017	51/Male	21JUL2015 13:30 / NEXT OF KIN/RELATIVE	N		23JUL2015 21:45	DEATH	
009-018	44/Male	23JUL2015 16:30 / NEXT OF KIN/RELATIVE	Y / PATIENT	28SEP2015 14:00	25JUL2015 02:00	COMPLETED	
009-019	84/Male	24JUL2015 17:30 / PATIENT			28JUL2015 11:40	CRRT CIRCUIT CHANGED	
009-021	51/Male	30JUL2015 14:10 / NEXT OF KIN/RELATIVE	N		04AUG2015 01:00	COMPLETED	
009-022		31JUL2015 12:40 / NEXT OF KIN/RELATIVE	N		01AUG2015 19:40	CRRT CIRCUIT CHANGED	

Data Listing 16.2.1. Patient Disposition: Completion/Discontinuation from Study - Enrolled Population

Patient Number	Age (Years)/ Gender	Date and Time of Informed Consent/ by Whom	Additional written consent (Y/N)/ If Yes, Written Consent by Whom	Date and Time of Additional Informed Consent was Signed	Date and Time of Completion/ Discontinuation	Patient's Disposition Status	Specify, If Others
009-024	49/Female	28AUG2015 13:00 / PATIENT			31AUG2015 03:00	COMPLETED	
009-026	76/Female	01OCT2015 14:45 / NEXT OF KIN/RELATIVE	N		08OCT2015 16:00	COMPLETED	
009-027	53/Male	12OCT2015 16:30 / NEXT OF KIN/RELATIVE	N		13OCT2015 08:00	CRRT TERMINATED	
009-028		23NOV2015 16:55 / NEXT OF KIN/RELATIVE	N		26NOV2015 10:30	CRRT CIRCUIT CHANGED	
009-030	75/Male	15DEC2015 14:45 / NEXT OF KIN/RELATIVE	N		18DEC2015 23:00	COMPLETED	
009-031	34/Male	27JAN2016 16:45 / NEXT OF KIN/RELATIVE	N		28JAN2016 19:10	CRRT CIRCUIT CHANGED	
009-032	59/Male	27JAN2016 17:30 / LEGALLY AUTHORISED REPRESENTATIVE	N		29JAN2016 12:00	CRRT TERMINATED	
010-002	57/Male	08MAY2015 10:31 / NEXT OF KIN/RELATIVE	Y / PATIENT	23MAY2015 11:55	09MAY2015 17:00	COMPLETED	

Data Listing 16.2.1. Patient Disposition: Completion/Discontinuation from Study - Enrolled Population

Patient Number	Age (Years)/ Gender	Date and Time of Informed Consent/ by Whom	Additional written consent (Y/N)/ If Yes, Written Consent by Whom	Date and Time of Additional Informed Consent was Signed	Date and Time of Completion/ Discontinuation	Patient's Disposition Status	Specify, If Others
010-003		09MAY2015 10:47 / NEXT OF KIN/RELATIVE	N		09MAY2015 14:50	CRRT TERMINATED	
010-005	78/Male	04JUN2015 18:20 / NEXT OF KIN/RELATIVE	N		06JUN2015 23:00	COMPLETED	
010-006	80/Male	10JUN2015 14:30 / NEXT OF KIN/RELATIVE	N		12JUN2015 23:00	COMPLETED	
010-008	70/Female	28JUN2015 12:00 / PATIENT	N		29JUN2015 01:00	CRRT TERMINATED	
010-009	69/Male	28JUN2015 18:00 / NEXT OF KIN/RELATIVE	Y / PATIENT	10JUL2015 13:40	28JUN2015 22:30	CRRT TERMINATED	
010-010	52/Female	01SEP2015 16:20 / NEXT OF KIN/RELATIVE	N		03SEP2015 12:20	COMPLETED	
010-011		30SEP2015 15:35 / NEXT OF KIN/RELATIVE	N		30SEP2015 17:00	CRRT TERMINATED	
010-014	79/Female	12JAN2016 11:51 / PATIENT			12JAN2016 21:20	CRRT TERMINATED	
011-001	53/Male	29APR2015 13:45 / PATIENT			30APR2015 10:10	CRRT TERMINATED	

Data Listing 16.2.1. Patient Disposition: Completion/Discontinuation from Study - Enrolled Population

Patient Number	Age (Years)/ Gender	Date and Time of Informed Consent/ by Whom	Additional written consent (Y/N)/ If Yes, Written Consent by Whom	Date and Time of Additional Informed Consent was Signed	Date and Time of Completion/ Discontinuation	Patient's Disposition Status	Specify, If Others
011-002	75/Male	29APR2015 19:07 / NEXT OF KIN/RELATIVE	N		30APR2015 12:00	CRRT TERMINATED	
011-003	80/Male	04JUN2015 14:15 / PATIENT	N		05JUN2015 09:30	CRRT TERMINATED	
011-004	80/Female	08JUN2015 18:00 / NEXT OF KIN/RELATIVE	Y / PATIENT	19JUN2015 11:15	10JUN2015 15:00	COMPLETED	
011-005	78/Male	10JUN2015 15:21 / NEXT OF KIN/RELATIVE	N		11JUN2015 11:31	CRRT TERMINATED	
011-006	77/Male	04JUL2015 08:37 / PATIENT	N		05JUL2015 06:00	CRRT TERMINATED	
011-007	62/Female	01OCT2015 16:01 / NEXT OF KIN/RELATIVE	N		02OCT2015 06:05	CRRT TERMINATED	
011-008	61/Male	05OCT2015 09:20 / PATIENT	N		05OCT2015 11:30	CRRT TERMINATED	
011-009	71/Female	06OCT2015 17:30 / NEXT OF KIN/RELATIVE	N		06OCT2015 22:30	CRRT TERMINATED	
011-010	47/Male	12OCT2015 10:50 / NEXT OF KIN/RELATIVE	N		12OCT2015 17:00	CRRT TERMINATED	

Data Listing 16.2.1. Patient Disposition: Completion/Discontinuation from Study - Enrolled Population

Patient Number	Age (Years)/ Gender	Date and Time of Informed Consent/ by Whom	Additional written consent (Y/N)/ If Yes, Written Consent by Whom	Date and Time of Additional Informed Consent was Signed	Date and Time of Completion/ Discontinuation	Patient's Disposition Status	Specify, If Others
011-011	77/Male	14OCT2015 15:55 / NEXT OF KIN/RELATIVE	N		16OCT2015 11:00	CRRT TERMINATED	
011-012	74/Male	19OCT2015 18:40 / NEXT OF KIN/RELATIVE	Y / PATIENT	27OCT2015 15:43	21OCT2015 11:45	COMPLETED	
011-013	71/Female	26OCT2015 15:55 / NEXT OF KIN/RELATIVE	Y / PATIENT	04NOV2015 12:00	28OCT2015 01:00	COMPLETED	
011-014	79/Female	03NOV2015 15:16 / PATIENT	N		04NOV2015 02:30	CRRT TERMINATED	
011-015	77/Female	20NOV2015 19:10 / NEXT OF KIN/RELATIVE	Y / PATIENT	01DEC2015 09:25	22NOV2015 08:30	CRRT TERMINATED	
011-016	72/Female	08JAN2016 11:15 / NEXT OF KIN/RELATIVE	Y / PATIENT	22JAN2016 14:20	10JAN2016 15:30	COMPLETED	
012-001	59/Male	01APR2015 12:45 / NEXT OF KIN/RELATIVE	N		02APR2015 22:00	COMPLETED	
012-002	67/Male	08APR2015 11:47 / NEXT OF KIN/RELATIVE	N		09APR2015 21:00	COMPLETED	

Data Listing 16.2.1. Patient Disposition: Completion/Discontinuation from Study - Enrolled Population

Patient Number	Age (Years)/ Gender	Date and Time of Informed Consent/ by Whom	Additional written consent (Y/N)/ If Yes, Written Consent by Whom	Date and Time of Additional Informed Consent was Signed	Date and Time of Completion/ Discontinuation	Patient's Disposition Status	Specify, If Others
012-003	63/Male	16APR2015 16:30 / NEXT OF KIN/RELATIVE	N		18APR2015 02:30	CRRT TERMINATED	
012-004	59/Female	20JUL2015 08:30 / NEXT OF KIN/RELATIVE	N		21JUL2015 12:35	CRRT CIRCUIT CHANGED	
012-005	41/Male	27JUL2015 15:10 / NEXT OF KIN/RELATIVE	Y / PATIENT	14AUG2015 10:00	29JUL2015 07:15	COMPLETED	
012-006	44/Male	30AUG2015 19:00 / NEXT OF KIN/RELATIVE	N		31AUG2015 06:15	CRRT TERMINATED	
012-007	82/Male	11OCT2015 12:25 / NEXT OF KIN/RELATIVE	Y / PATIENT	28OCT2015 14:30	12OCT2015 14:00	CRRT TERMINATED	
012-008	59/Male	16OCT2015 09:50 / PATIENT	Y / PATIENT	16OCT2015 10:00	17OCT2015 10:45	CRRT TERMINATED	
012-009	70/Male	04NOV2015 16:15 / PATIENT	Y / PATIENT	15DEC2015 15:40	05NOV2015 11:05	CRRT TERMINATED	
012-010	72/Male	04NOV2015 11:00 / NEXT OF KIN/RELATIVE	N		07NOV2015 18:00	COMPLETED	

Data Listing 16.2.1. Patient Disposition: Completion/Discontinuation from Study - Enrolled Population

Patient Number	Age (Years)/ Gender	Date and Time of Informed Consent/ by Whom	Additional written consent (Y/N)/ If Yes, Written Consent by Whom	Date and Time of Additional Informed Consent was Signed	Date and Time of Completion/ Discontinuation	Patient's Disposition Status	Specify, If Others
012-011	58/Female	16DEC2015 11:05 / NEXT OF KIN/RELATIVE	N		17DEC2015 17:50	CRRT CIRCUIT CHANGED	
012-012	69/Male	11JAN2016 16:10 / NEXT OF KIN/RELATIVE	Y / PATIENT	24FEB2016 09:15	16JAN2016 18:00	COMPLETED	
012-013	77/Female	18JAN2016 11:30 / NEXT OF KIN/RELATIVE	N		20JAN2016 08:00	CRRT TERMINATED	
013-002	70/Male	30JUN2015 16:17 / NEXT OF KIN/RELATIVE	N		02JUL2015 14:00	COMPLETED	
013-003	69/Male	29JUL2015 14:05 / NEXT OF KIN/RELATIVE	Y / NEXT OF KIN/RELATIVE	29JUL2015 15:55	29JUL2015 16:30	CRRT TERMINATED	
013-004	64/Female	08SEP2015 16:40 / NEXT OF KIN/RELATIVE	N		09SEP2015 10:00	CRRT TERMINATED	
013-005		17SEP2015 12:33 / NEXT OF KIN/RELATIVE	Y / NEXT OF KIN/RELATIVE	17SEP2015 15:15	18SEP2015 21:00	COMPLETED	
013-010	76/Female	04DEC2015 18:30 / NEXT OF KIN/RELATIVE	N		06DEC2015 15:00	COMPLETED	

Data Listing 16.2.1. Patient Disposition: Completion/Discontinuation from Study - Enrolled Population

Patient Number	Age (Years)/ Gender	Date and Time of Informed Consent/ by Whom	Additional written consent (Y/N)/ If Yes, Written Consent by Whom	Date and Time of Additional Informed Consent was Signed	Date and Time of Completion/ Discontinuation	Patient's Disposition Status	Specify, If Others
014-001	75/Female	16APR2015 17:00 / PATIENT	N		18APR2015 20:00	COMPLETED	
014-002	47/Male	27APR2015 14:10 / NEXT OF KIN/RELATIVE	N		30APR2015 02:40	DEATH	
014-003	63/Female	12JUN2015 13:25 / NEXT OF KIN/RELATIVE	Y / PATIENT	23JUN2015 10:45	12JUN2015 20:30	CRRT CIRCUIT CHANGED	
014-004	33/Female	01SEP2015 14:30 / NEXT OF KIN/RELATIVE	N		02SEP2015 23:00	CRRT TERMINATED	
014-007	34/Female	08SEP2015 16:40 / NEXT OF KIN/RELATIVE	N		10SEP2015 08:00	CRRT CIRCUIT CHANGED	
015-001	77/Female	27APR2015 10:05 / PATIENT	N		28APR2015 16:20	CRRT TERMINATED	
015-002	60/Male	24MAY2015 12:45 / NEXT OF KIN/RELATIVE	Y / PATIENT	13JUL2015 13:00	26MAY2015 03:00	COMPLETED	
015-003	57/Male	28MAY2015 15:00 / NEXT OF KIN/RELATIVE	Y / PATIENT	01JUN2015 15:00	29MAY2015 18:30	CRRT TERMINATED	

Data Listing 16.2.1. Patient Disposition: Completion/Discontinuation from Study - Enrolled Population

Patient Number	Age (Years)/ Gender	Date and Time of Informed Consent/ by Whom	Additional written consent (Y/N)/ If Yes, Written Consent by Whom	Date and Time of Additional Informed Consent was Signed	Date and Time of Completion/ Discontinuation	Patient's Disposition Status	Specify, If Others
015-004	85/Male	19JUN2015 17:00 / NEXT OF KIN/RELATIVE	Y / PATIENT	23JUN2015 13:40	21JUN2015 15:30	COMPLETED	
015-005	76/Male	06JUL2015 17:29 / NEXT OF KIN/RELATIVE	Y / PATIENT	04SEP2015 19:30	08JUL2015 03:13	COMPLETED	
015-006	84/Female	14AUG2015 16:00 / NEXT OF KIN/RELATIVE	N		16AUG2015 15:10	COMPLETED	
015-009	76/Female	06JAN2016 15:09 / NEXT OF KIN/RELATIVE	Y / PATIENT	21JAN2016 14:00	08JAN2016 03:45	COMPLETED	
015-010		09JAN2016 15:50 / NEXT OF KIN/RELATIVE	N		11JAN2016 10:50	CRRT TERMINATED	
015-011		22JAN2016 14:30 / NEXT OF KIN/RELATIVE	N		23JAN2016 20:05	CRRT TERMINATED	
016-002		03SEP2015 14:50 / NEXT OF KIN/RELATIVE	N		04SEP2015 12:15	CRRT TERMINATED	

Data Listing 16.2.1. Patient Disposition: Completion/Discontinuation from Study - Enrolled Population

Patient Number	Age (Years)/ Gender	Date and Time of Informed Consent/ by Whom	Additional written consent (Y/N)/ If Yes, Written Consent by Whom	Date and Time of Additional Informed Consent was Signed	Date and Time of Completion/ Discontinuation	Patient's Disposition Status	Specify, If Others
016-004	55/Male	02DEC2015 16:20 / LEGALLY AUTHORISED REPRESENTATIVE	Y / PATIENT	11JAN2016 16:00	03DEC2015 12:00	CRRT TERMINATED	
017-003	92/Female	13JUL2015 16:00 / NEXT OF KIN/RELATIVE	N		13JUL2015 19:20	CRRT TERMINATED	
017-004	74/Male	17JUL2015 15:50 / NEXT OF KIN/RELATIVE	N		19JUL2015 17:30	COMPLETED	
017-005	77/Male	13AUG2015 15:12 / NEXT OF KIN/RELATIVE	Y / PATIENT	19AUG2015 14:30	14AUG2015 09:00	CRRT TERMINATED	
017-007	66/Male	01SEP2015 16:14 / NEXT OF KIN/RELATIVE	Y / PATIENT	14SEP2015 12:22	03SEP2015 15:30	COMPLETED	
017-008		25SEP2015 15:06 / NEXT OF KIN/RELATIVE	N		28SEP2015 00:20	CRRT TERMINATED	
017-010	54/Male	19NOV2015 12:27 / PATIENT	N		20NOV2015 10:30	CRRT TERMINATED	
017-011	49/Male	19NOV2015 16:10 / NEXT OF KIN/RELATIVE	N		23NOV2015 15:30	COMPLETED	

Appendix 16.2.2. Protocol Deviations

Data Listing 16.2.2 Protocol Deviations - Enrolled Population

Patient Number	Age(Years)/Gender	Protocol Deviation	Major or Minor
001-001	57/Female	Study procedure or assessment: The monitor noticed that the site was missing quite a few observation readings for patient 001-001 and all patients had precipitate observation readings that were significantly out of window (3min to 14minutes beyond the half hourly checks). The monitor raised this with the PI who indicated that a precipitate checkbox had been built into the Clinical Information System in order to prompt bedside nurses to record the precipitate observation but that real life emergency situations have caused medical staff to prioritize actions to save the lives of patients. The monitor has asked the PI to step in to remedy this situation and try to improve site's performance on recording observations.	Major
001-006		Study procedure or assessment: CVVH Start = 02:30, 11NOV2015 Enrollment = 18:30, 12NOV2015, thereafter precipitate reading were taken every 30mins. However, upon inspection of the electronic ICU Observation Chart, JU noticed that CVVH for this patient started at 02:03 on 11NOV2015 which means that the patient should have been enrolled at 18:03 instead of 18:30 on 12NOV2015. While in a discussion about this issue, FB showed JU an annotation on the electronic Observation Chart which seemed to indicate that CVVH started at 02:30 but on closer review, this was not the case. JU has deduced that this error was purely human and unintended. FB indicated that she will continue to make effort to enroll at exactly 40 hours into CRRT.	Minor
		Informed consent: No retrospective patient consent has been obtained since the patient was discharged from the Trust with no follow up visits schedule to return.	Minor
002-005	44/Male	Study procedure or assessment: The final but pre-mature precipitate observation was taken 10 minutes before the circuit had run for a complete 72-hour period. Circuit was also terminated at the time of final observation, 71hrs 50mins. Observations were recorded by a Critical Care Nurse and she cannot remember why the circuit was stopped prematurely.	Minor

Data Listing 16.2.2 Protocol Deviations - Enrolled Population

Patient Number	Age(Years)/Gender	Protocol Deviation	Major or Minor
002-012		Informed consent: Retrospective consent was not able to be obtained prior to patient's discharge.	Minor
002-018	91/Female	Study procedure or assessment: For this patient CVVH was not terminated until 11:00 (23OCT2015) however, the last precipitate observation ended at 09:05 (23OCT2015). Source notes correctly indicate that the last 3 precipitate observations were missed. Reasons for ending observations according to PR are evidenced by annotations in the medical notes which clearly shows that death was imminent and care for the patient was transitioned from 'treatment' to 'palliative'. Patient died at 14:52 (23OCT2015). PR has followed up with ICU nurses and has asked that observations should continue to be made regardless of the patient's medical situation.	Major
003-001	77/Male	Informed consent: During verification of the signed ICF of Patient 003-001, it was noticed that the patient had not initialled the boxes (page 6 of 7 master v 1.1) of the ICF, but had ticked the boxes in error. The ICF was also missing page 7 which includes the signature of the principal investigator/designee who took consent. On discussion with Christine, it was Christine herself who took consent for this patient and she should therefore sign page 7 of the ICF.	Minor
003-002	67/Male	Study procedure or assessment: Precipitate observation data collection began before CRRT had been ongoing for 40 hours. The patient was initially enrolled onto the study at 08:00 on 15-May-2015. They started CRRT on 13-May-2015 at 16:54 so enrollment was at less than 40 hours. This was done in error by the site and it was noted that the current protocol (amendment 1 dated 12-Jan-2015) is unclear since on page 15 it states enrollment is at "approximately 40 hours of CRRT" and else where is states "at least 40 hours".	Minor

Data Listing 16.2.2 Protocol Deviations - Enrolled Population

Patient Number	Age(Years)/Gender	Protocol Deviation	Major or Minor
003-003	57/Female	Study procedure or assessment: Precipitate observation data collection began before CRRT had been ongoing for 40 hours. The patient was initially enrolled onto the study at 07:00 on 28-Aug-2015. They started CRRT on 26-Aug-2015 at 16:00 so enrollment was at less than 40 hours. This was done in error by the site and it was noted that the current protocol (amendment 1 dated 12-Jan-2015) is unclear since on page 15 it states enrolment is at "approximately 40 hours of CRRT" and else where is states "at least 40 hours".	Minor
003-004	66/Male	Study procedure or assessment: Precipitate observation data collection began before CRRT had been ongoing for 40 hours. The patient was initially enrolled onto the study at 12:00 on 07-Sep-2015. They started CRRT on 05-Sep-2015 at 21:00 so enrollment was at less than 40 hours. This was done in error by the site and it was noted that the current protocol (amendment 1 dated 12-Jan-2015) is unclear since on page 15 it states enrolment is at "approximately 40 hours of CRRT" and else where is states "at least 40 hours".	Minor
003-008	47/Male	Informed consent: Patient 003-008 signed the patient master ICF v 2.1 but his hands were shaky so he was unable to print his name, initial the boxes or write the date and time. An impartial witness signature was used, however the monitor noted that the impartial witnesses was the patient's next of kin. Patient 003-008 has since been discharged.	Minor

Data Listing 16.2.2 Protocol Deviations - Enrolled Population

Patient Number	Age(Years)/Gender	Protocol Deviation	Major or Minor
003-009		Informed consent: It was documented in the patient notes with a full description, that this patient gave verbal consent at 05:00 on 26-Oct-2015 before being enrolled at 05:30. It was also documented that an impartial nurse witness this consenting process. There was however no consent form signed. Later that day at 16:30, consultee form v 2.1 was signed by the patient's next of kin. On the 27th October, the patient gave retrospective consent on the master ICF v 2.1 and signed the document. The patient was however still very weak and could only tick the boxes on the ICF. It is noted that Research Nurse Christine Ryan, who took consent printed the name of the patient and wrote the date and the time for the patient. No impartial witness signature was used. The patient has now been discharged so the site are not able to get re-consent. Consent process is described fully within the patient's notes.	Minor
		Informed consent: Due to the consenting issues described within an early deviation, demographics were removed.	Minor
003-012	88/Male	Informed consent: Patient 003-012 had given consent personally on 23-Jan-2016 however although the PIS was the correct Patient PIS v 2.1, the ICF signed by the patient was the incorrect consultee form v 2.1. The research nurse who took the consent ensured the patient provided the required details as required by the patient ICF v 2.1, she just used the wrong form. The patient has since died so will not be able to sign the correct ICF.	Minor
004-001		Informed consent: Patient was discharged before retrospective consent could be obtained.	Minor
004-002		Informed consent: Patient's consultee form is missing 1 signature. Second signature has been obtained under consultee statement. Patient has been discharged, but the site will try and obtain a retrospective correction is not possible. Site to produce MTF explaining the situation if they cannot obtain the signature.	Minor
		Informed consent: Patient was transferred to another hospital before retrospective consent could be obtained.	Minor
005-002	68/Female	Other: Precipitate Observation: One observation missed at 10:30 on 22MAR2015	Minor

Data Listing 16.2.2 Protocol Deviations - Enrolled Population

Patient Number	Age(Years)/Gender	Protocol Deviation	Major or Minor
005-003	65/Female	Other: Patient was enrolled at 40hrs 30mins after CRRT	Minor
005-011	78/Female	Study procedure or assessment: This patient was enrolled at 08:25 but precipitate observation commenced at 08:30. The RN indicated that this deviation occurred because it was more conducive to collect data on the hour and every 30 minute after.	Minor
005-012		Informed consent: Phone consent obtained before observations and data collection began but hard copy of written consent was lost. Site claim that the consultee signed only one portion of the consultee form. Consultee Form sent to the consultee by another family member for completing signature process. Consultee form never returned to site.	Minor
		Informed consent: Retrospective consent from the patient since the patient died. Only phone consent is available. Demographics have been removed from eCRF.	Minor
005-016		Informed consent: Retrospective consent was not obtained as patient was discharged home on 03/08/15. Demographic data has been removed from eCRF.	Minor
005-020		Informed consent: Retrospective consent was not obtained as patient was discharged on 07/10/15. Demographics have been removed from eCRF	Minor
005-022		Informed consent: Patient was discharged before retrospective patient consent could be obtained. Demographics have been removed from eCRF.	Minor
005-025		Informed consent: Patient was discharged before retrospective patient consent could be obtained. Demographics have been removed from eCRF	Minor
005-027		Informed consent: Patient was discharged before retrospective consent could be obtained from the patient. Demographic data has been removed from eCRF	Minor

Data Listing 16.2.2 Protocol Deviations - Enrolled Population

Patient Number	Age(Years)/Gender	Protocol Deviation	Major or Minor
005-028		Informed consent: No retrospective consent was collected from 005-028 as last entry in EDC indicates that the patient was not mentally competent. These patients in critical care are either mentally incompetent, too traumatized to be approached for consent or they die before study team can obtain consent from them.	Minor
		Study procedure or assessment: This patient had almost reached the requisite 72 hours on the filter when treatment was stopped for no apparent reason. The monitor reviewed the notes and there were no annotations or plans by the physician to stop treatment. There was no recorded 'high filter pressure'. There were no clots in the filter. There was no link established between the patients medical status and the decision to stop the filter. No explanation could be given by the study team on reason(s) why this happened given that this patient could have added to our pool of 'completed' patients.	Minor
005-038		Informed consent: No retrospective consent was collected from 005-038 as last entry in EDC indicates that the patient did not regain mentally capacity. These patients in critical care are either mentally incompetent, too traumatized to be approached for consent or they die before study team can obtain consent from them.	Minor
007-002		Informed consent: Retrospective consent was not obtained as patient was discharged home. Demographics have been removed from eCRF	Minor
007-004	72/Male	Study procedure or assessment: More than 6 precipitate observations were missed. This occurred because the site were only recording the precipitate observations on an hourly basis rather than half-hourly. This issue was identified by the monitor during RMV #1 on 06AUG2015 and has been brought to the attention of the PI and the research team.	Major

Data Listing 16.2.2 Protocol Deviations - Enrolled Population

Patient Number	Age(Years)/Gender	Protocol Deviation	Major or Minor
007-005	24/Male	Study procedure or assessment: Exactly 6 precipitate observations were missed. In this instance, the ICU nurse was willing and able to record the half-hourly observations (out of 63 possible observations, 6 were not recorded). This issue was identified by the monitor during RMV #1 on 06AUG2015 as a site level deficiency and brought to the attention of the PI and the research team. It was discussed again with the PI during the RMV #2 on 15OCT2015 on a patient. The reluctance of the ICU Nurses to record these mandatory observations was identified as the root cause and the PI is aware of this problem. A follow up letter to the site will highlight this issue once more and offer the PI clear guidance on what to do to remedy this situation and the EC-reporting consequence of non-compliance.	Major
007-006	73/Female	Study procedure or assessment: More than 6 precipitate observations were missed (out of 65 possible observations, 45 observations were not recorded). This occurred because the site was only recording the precipitate observations on an hourly basis rather than half-hourly. This issue was identified by the monitor during RMV #1 on 06AUG2015 and was brought to the attention of the PI and the research team. The monitor also reiterated this issue to the PI during RMV #2 on 15OCT2015. The PI was told to directly intervene if this issue persists. The PI was told to convey to the ICU Nurses that the half-hourly observation was the most important aspect of this trial and needed to be collected. The PI concurred and indicated that she will personally attend to this issue.	Major
007-007	83/Male	Study procedure or assessment: This patient was an 'Early Terminator' and lasted on the study from 03AUG @ 01:50 - 03AUG @ 04:10. If precipitate observations were performed as they should have, there would have been observation readings at 01:50, 02:20, 02:50, 03:20 & 03:50. This was not the case - Instead what we had were precipitate observation readings at 02:00, 03:00 & 04:00. Under this scenario, the deviations to the protocol which occurred, were as follows: 1. Precipitate Observations were made hourly. 2. Initial precipitate observation was made at 02:00 rather than 01:50. This patient is not a new patient and data from this patient falls into the bracket of series of deviations other deviations like this which have occurred previously and have been reported in previous MVRs and have been discussed with the site team.	Minor

Data Listing 16.2.2 Protocol Deviations - Enrolled Population

Patient Number	Age(Years)/Gender	Protocol Deviation	Major or Minor
007-011	64/Female	Study procedure or assessment: There were 2 missed observations at 20:30 (01SEP2015) & 05:00 (02SEP2015).	Minor
007-014	74/Female	Study procedure or assessment: The first three precipitate observation should have been carried out by 06:40, 07:10 & 07:40 (28SEP) but ICU Nurse collected data at 07:00 & 07:30 (28SEP). When JU asked KW why data was collected this way, she said that on the Renal Prescription Sheet, details of CVVH are usually captured on the hour and 30 minutes after. JU pointed out that this was a deviation and will e reported as so. JU also said that the worksheet which was provided will now have to be used to avoid this happening again. JU instructed KW to pre-fill the worksheet with the Study enrollment time once known and to populate it with the times for the required observation. Therefore, all the ICU nurses need to do is to append a tick next to the time indicated. KW agreed and so did the IW whom JU has asked to personally approach the Lead Nurse and speak about the haphazard manner in which data is being collected. The worksheet will now be used to collect half hourly observations.	Minor
008-001	26/Male	Study procedure or assessment: Amount of Accusol administered on 19-Mar-2015 from 12:05 to 14:10 and 20-Mar-2015 from 19:00 to 20:05 was not documented and therefore listed as "UNK"	Minor
		Study procedure or assessment: Lot numbers of Accusol bags used on 20-Mar-2015 at 00:20, 01:55, 03:40, 08:40 were not documented and are therefore listed as "UNK" in eCRF.	Minor
008-002	31/Male	Study procedure or assessment: Amount of Accusol administered on 14-Apr-2015 from 13:00 to 17:00 and on 15-Apr-2015 from 20:50 to 21:00 was not documented and is therefore listed as "UNK"	Minor

Data Listing 16.2.2 Protocol Deviations - Enrolled Population

Patient Number	Age(Years)/Gender	Protocol Deviation	Major or Minor
008-003	25/Female	Study procedure or assessment: Lot numbers of bag are listed as "unknown" between 11:30 and 14:00 on 21-Apr-2015 and 20:00 to 22:00 on 20-Apr-2015 due to oversight by the site, having not documented them.	Minor
		Study procedure or assessment: Amount of accusol administered is not documented between the following times: 03:25 - 04:00 on 22-Apr-2015 and 20:00 - 22:00 on 20-Apr-2015. This is due to oversight.	Minor
008-004	46/Male	Study procedure or assessment: Lot number of Accusol bag used on 22-May-2015 from 08:20 was not documented and therefore listed as "UNK" in eCRF	Minor
		Study procedure or assessment: Amount of Accusol administered is "UNK" for both bags used on 22-May-2015 as they were not documented within the source.	Minor
008-005	82/Male	Study procedure or assessment: On Accusol Admin page, amount of Accusol administered was not documented within the source notes throughout 32 hours of observations. Lot number of bag also missing for bag used between 08:20 and 09:30 on 22-May-2015. This is due to oversight.	Minor
008-007	74/Male	Study procedure or assessment: Lot number of Accusol bag used from 06:20 on 28-May-2015 was not documented and was therefore added into eCRF as "UNK"	Minor
		Study procedure or assessment: Amount of Accusol administered from 07:40 to 10:15 on 28-May-2015 and from 06:20 to 07:40 on 28-May-2015 were not documented and therefore were entered into eCRF as "UNK"	Minor

Data Listing 16.2.2 Protocol Deviations - Enrolled Population

Patient Number	Age(Years)/Gender	Protocol Deviation	Major or Minor
008-012	71/Male	Study procedure or assessment: Amount of Accusol administered on 20-Jul-2015 at 18:00 was not documented and is therefore entered into eCRF as "UNK"	Minor
		Study procedure or assessment: All lot numbers of Accusol administered were not documented and have therefore been entered as "UNK" in eCRF	Minor
		Informed consent: Within the source notes, it was documented that only a copy of the signed ICF was given to the patient 008-012, not an original as per instructions within the ICF. The monitor spoke to the research nurse regarding this and the RN noticed that due to the patient's conditions, it is very hard for them to sign just one original, let alone two. Site does not systematically comply with the requirement to obtain two original consent forms. Site to have two original ICFs signed – one should be kept with the patient notes and the other should be given to the patient.	Minor
008-013	68/Male	Study procedure or assessment: All lot numbers of Accusol administered were not documented and have therefore been entered as "UNK" in eCRF	Minor
		Study procedure or assessment: Amount of accusol administered from 06:00 and 14:45 on 21-Jul-2015 was not documented and therefore entered into eCRF as "UNK"	Minor
008-014	65/Female	Study procedure or assessment: Amount of Accusol administered from 10:35 on 25-Jul-2015 was not estimated and documented so remains "UNK" in eCRF.	Minor
008-016	34/Male	Study procedure or assessment: Lot numbers were not documented for all bags and are entered into eCRF as "UNK"	Minor
		Study procedure or assessment: Amount of Accusol Administered from 10:00, 10:10 and 13:40 on the 13th Aug 2015 were not documented so entered as "UNK" in eCRF.	Minor
008-017	52/Female	Study procedure or assessment: No lot numbers for accusol bags were documented and therefore these are logged as "UNK" in eCRF	Minor
		Study procedure or assessment: Amount of accusol administered between 13:25 and 13:40 on 21-Aug-2015 and 04:30 and 05:55 on 22-Aug-2015 was not documented and therefore was added as "UNK" in eCRF	Minor

Data Listing 16.2.2 Protocol Deviations - Enrolled Population

Patient Number	Age(Years)/Gender	Protocol Deviation	Major or Minor
008-018	65/Male	Study procedure or assessment: Site did not estimate amount of accusol administered from 22:10 to 22:55 on 05-Oct-2015. This value was not documented in the source and has therefore been listed as "UNK"	Minor
008-019	69/Female	Study procedure or assessment: Amount of Accusol administered not documented within patient notes between 20:15 and 20:30 on 9th October 2015. This is due to oversight.	Minor
008-020	60/Male	Study procedure or assessment: Some of the Accusol lot numbers were blank in the source records and were incorrectly entered into eCRF as the same number as the previous entry. The research nurse noted that although not documented, the bags would have been the same lot since they came from the same box. The research nurse updated eCRF accordingly to mark these sections of the eCRF as "unknown".	Minor
		Study procedure or assessment: The nurse had not written down the end date or time of the last used Accusol bag, or the amount administered/estimate of the amount left in the bag. The eCRF was therefore updated to state these fields as "unknown".	Minor
008-021	66/Male	Study procedure or assessment: Accusol amount administered from 16:00 on 20-Oct-2015 was not approximated or documented and therefore is listed in eCRF as "UNK"	Minor
008-022	43/Male	Study procedure or assessment: Accusol lot numbers were not documented within the source and therefore are listed as "unknown" in eCRF except for bags used at 08:35 on 21-Oct-2015 and 11:30 on 21-Oct-2015.	Minor
		Study procedure or assessment: Amount of Accusol administered at enrolment and at time of completion were not documented and are therefore listed as "unknown in eCRF".	Minor
008-023		Informed consent: Retrospective consent was obtained for patient 008-023 but in the monitor's opinion the time on the consent form is illegible.	Minor

Data Listing 16.2.2 Protocol Deviations - Enrolled Population

Patient Number	Age(Years)/Gender	Protocol Deviation	Major or Minor
008-024	27/Male	Study procedure or assessment: Lot numbers of Accusol bags used at 14:00 and 16:15 on 28-Oct-2015 are not documented within the source notes and are therefore listed as "unknown" in eCRF. of Accusol administered at enrolment and at time of completion were not documented and are therefore listed as "unknown in eCRF".	Minor
008-025	68/Male	Study procedure or assessment: Lot number and amount administered of Accusol bag used from 11:15 on 30-Oct-2015 was not documented and therefore are listed as "UNK"	Minor
008-026	30/Female	Study procedure or assessment: Lot number of bags used from 15:30 on 05-Nov-2015 and 18:10 on 05-Nov-2015 were not documented in the source and therefore have been listed in eCRF as "UNK"	Minor
008-027	71/Male	Study procedure or assessment: Amount administered between 09:00 and 09:55 was not documented and therefore is listed as "unknown"	Minor
		Study procedure or assessment: The Accusol Admin page does not cover the total 32 hour observation period. There is missing information from 14:30 to 18:00 on 13-Nov-2015. The site state there is no further information available between this time period.	Minor
008-028	72/Male	Study procedure or assessment: Amount of Accusol Administered between 12:30 to 14:25 and 09:30 to 10:00 was not documented and therefore was listed as "Unknown"	Minor
		Study procedure or assessment: Lot numbers used from 22:00 on 30-Nov-2015 and 01:20 on 01-Dec-2015 were not present in the source and therefore entered as "UNK"	Minor
008-029	66/Female	Study procedure or assessment: Site have entered all lot numbers as "UNK" since they are not present or legible within the source.	Minor
008-030	63/Female	Study procedure or assessment: Patient was an early terminator due to the treatment being withdrawn by the medical staff at 18:00 on 12-Jan-2016. The last observation was at 17.25 so there should have been another observation at 17.55 but this was missed.	Minor
		Study procedure or assessment: Lot number of bag used at 16:35 on 12-Jan-2016 was not documented and therefore entered as "UNK"	Minor

Data Listing 16.2.2 Protocol Deviations - Enrolled Population

Patient Number	Age(Years)/Gender	Protocol Deviation	Major or Minor
008-031	23/Male	Study procedure or assessment: This patient was an early terminator. For an unknown reason the system alarmed and the nurse terminated the circuit because she thought the 72 hours was complete.	Minor
009-001	64/Male	Informed consent: Patient 009-001 did not have a full control of his hands therefore his signature is not eligible on the form and none of the initial boxes were initialled by the patient.	Minor
009-002		Informed consent: 4 attempts made to obtain consent from patient after enrolment. Patient discharged from hospital on 24/04/2015 prior to giving retrospective patient consent.	Minor
009-009		Informed consent: Patient discharged from hospital prior to obtaining retrospective patient consent. Site attempted to get consent prior to discharge but it was not possible.	Minor
009-015	29/Male	Informed consent: The Next-of-Kin consented to patient 009-015 being on the ACCUPASS study using v1.1 instead of newly approved v2.1 Consultee ICF	Major
009-022		Informed consent: During verification it was noted that the patient's consultee signed the consultee consent form with a date of 31-07-2014.	Major
		Informed consent: Patient discharged from hospital, site unable to obtain retrospective consent prior to this.	Minor
009-028		Informed consent: Patient is still in the unit but does not have the mental capacity to give retrospective patient consent. The site does not think she will re-gain capacity before the study ends.	Minor
010-002	57/Male	Informed consent: Data collection started before the patient or next of kin had given consent. The mandatory 40 hour screening period was reached at 09:30 on 08MAY2015. Enrollment unto the study and data collection followed at 09:30 on 08MAY2015 without written consent. Written consent was obtained 60 minutes later at 10:30 on 08MAY2015. Research staff informed the monitor that verbal consent was given by nominated consultee on 07MAY2015 and documented in patient's medical notes.	Minor

Data Listing 16.2.2 Protocol Deviations - Enrolled Population

Patient Number	Age(Years)/Gender	Protocol Deviation	Major or Minor
010-003		Informed consent: Data collection started before the patient or next of kin had given consent. The mandatory 40 hour screening period was reached at 10:00 on 09MAY2015. Enrollment unto the study and data collection followed at 10:00 on 09MAY2015 without written consent. Written consent was obtained 47 minutes later at 10:47 on 09MAY2015. Research staff informed the monitor that Consultee form was presented to the nominated consultee on the 08MAY2015 and documented in patient's medical notes.	Major
010-005	78/Male	Study procedure or assessment: Patient 010-005 was previously reported as being enrolled at 39 hours. It was also previously thought that after the initial 39 hours, that the patient was then on the filter for the study-mandated 32 hours. However, upon closer inspection of the ICU Observation charts, the Monitor can confirm that this patient's circuit ran from 03JUN2015 (@23:00) - 07JUN2015 (@ 02:50). This means that site began precipitate observation an hour early and missed the last 2 observations at 22:30 and 23:00 on 06JUN2015.	Major
010-009	69/Male	Informed consent: The monitor can confirm that a signed retrospective consent was obtained from patient 010-009. However a description of the consent process was not duly described in the source notes. Alison Wright was notified and she explained that this must have been an oversight and that she will approach Dr Ramali to get an explanation in order to remedy this anomaly. The monitor will highlight this issue in a follow up letter and will verify that this has been done at the next visit.	Minor
		Study procedure or assessment: Precipitate observation data collection began before CRRT had been ongoing for 40 hours. Patient 010-009 was placed on CRRT at 0400 on 27JUN2015. At 1630 on 27JUN2015, the patient was taken for a CT Scan. The CRRT circuit was not changed; It was placed in 'recirculation mode'. CT Scan took 50minutes and CRRT recommenced on the same circuit. at 1720 on 27JUN2015. The patient was enrolled at 2000 on 28JUN2015	Minor
		Study procedure or assessment: This patient was recruited on 28JUN2015 @ 20:00. This patient was on the study until 22:30 on the same day. There were no observations made in the 150 minutes that the patient was on the study - i.e. all 6 precipitate observations were missed	Major

Data Listing 16.2.2 Protocol Deviations - Enrolled Population

Patient Number	Age(Years)/Gender	Protocol Deviation	Major or Minor
010-010	52/Female	Study procedure or assessment: All Accusol Administration data is listed as "Unknown"	Major
010-011		Informed consent: Patient did not re-gain capacity to give retrospective patient consent and therefore demographic data was removed in eCRF	Minor
011-005	78/Male	Other: Patient was enrolled at 10:00 on 11JUN2015 and terminated from the study at 11:31 on 11JUN2015. There should have been 4 observations but only 3 were made due to the nurses attention to the patient's condition - pancreatitis.	Minor
011-007	62/Female	Informed consent: Phone consent was obtained from the patients next-of-kin (daughter). Written consent from 'personal consultee' not obtained because daughter lives far from site and did not come in to see mother in hospital. Medical notes show that daughter kept in touch with mother's progress over the phone. Between 01OCT2015 (study end) and 19OCT2015 (patient death), the patient was continuously ventilated and sedated according to the medical notes and never regained capacity.	Minor
011-015	77/Female	Study procedure or assessment: on the ITU Observation chart, JU could see that CRRT termination time was neither documented on the ITU Observation chart nor on the Nursing notes, however, the study worksheet clearly shows that this patient's CVVH session ended at 08:26 on 22NOV2015. Normal ITU practice encourages ITU Nurses to indicate start and stop times of CRRT on ITU Observation charts, within the nursing notes or both. The RN Nurse, James CULLINANE, indicated that the ITU dept. at Medway Maritime are using this study to improve practices but indicated that they are working hard to make all their ITU Nurses fully compliant.	Minor
012-007	82/Male	Study procedure or assessment: Patient was enrolled at 12:45(09OCT2015) but the first observation took place 30 minutes after at 13:15(09OCT2015).	Minor

Data Listing 16.2.2 Protocol Deviations - Enrolled Population

Patient Number	Age(Years)/Gender	Protocol Deviation	Major or Minor
012-008	59/Male	Informed consent: ICF v1.1 was used to consent this patient on 16OCT2015. Error was noticed and on 28OCT2015 this patient was approached with ICF v2.1. Patient was understanding about the error and was happy to sign ICF v2.1 with a date matching the previously signed ICF. Medical notes does however indicate that the patient was given the ICF on 28OCT2015. All hardcopies of ICFv1.1 were previously superseded in the OSF so the root cause of this problem was printing off an electronic ICF. JG has been told to make copies of ICF v2.1 from the OSF instead of using electronic versions of the ICF.	Minor
012-009	70/Male	Study procedure or assessment: This patient was an Early Terminator. The initial 40 hours on the filter was reached at 05:30 (05NOV2015) - the first precipitate observation should have been made at this time. Instead, data collection commenced at 08:00(05NOV2015) therefore a total of 5 readings were not taken. The Research Nurse, Jo Gresty (JG) informed the monitor, James Uchuno (JU) that clear instructions had been left for the ICU Nurses to commence data collection at 05:30. A review of the worksheet by JU also supports the fact that data collection should have begun at 05:30. JG informed JU that when the ICU Nursing team were questioned, it appeared that the nurses forgot to collect data at the stipulated time but then realized the error of omission and began collecting data at 08:00. JU is of the opinion that this was a single instance of this kind of error and categorizes this deviation as an oversight by the ICU Nursing team. The nursing team noticed the error and mitigated it by following through with the rest of the precipitate observations so no additional training was needed.	Minor
013-002	70/Male	Study procedure or assessment: There was a missed observation (observation #29) at 20:00 on the 01JUL2015.	Minor
013-005		Informed consent: Patient was discharged before retrospective patient consent was obtained. Demographics have been removed from the eCRF	Minor

Data Listing 16.2.2 Protocol Deviations - Enrolled Population

Patient Number	Age(Years)/Gender	Protocol Deviation	Major or Minor
013-010	76/Female	Informed consent: Dr Irvine has consented the next of kin to patient 013-010. This individual is neither on the delegation log nor on the training log and has submitted no essential documents to the study team. An enquiry was placed by the Monitor, James Uchuno (JU) into this case and forwarded to the Study Nurses, Kirsti Withington (KW) & Georgina Glister (GG) for a full explanation of how this occurred. JU has asked for a full explanation of why documentation of training or PI authorization is not on file. JU has also asked if lack of documentation was an oversight and asked if the PI is aware that Dr Irvine has undertaken study-related activities. JU has also asked if the PI, had at least, verbalized his intent to include Dr Irvine on this study. KW and GG have been encouraged to forward documentation for Dr Irvine and to follow up with PI and get back to JU with an update.	Major
014-003	63/Female	Informed consent: On 12JUN2015, the PI used a Patient ICF which was localized for Good Hope Hospital, to consent the next of kin (the Consultee ICF was not used). All signatories signed in the wrong place. The next of kin wrote the patients name in the correct space but signed on the PI line. and the PI, then signed on the Impartial Witness line. A retrospective consent was obtained from the patient on 23JUN2015 but this time, the Main Patient ICF which was localized for Birmingham Heartlands Hospital was used. This error occurred because the PI was in a hurry to secure a consent before the patient crossed the required 40 hours on the filter and could not find the Consultee ICF within the Onsite Study File (OSF). The monitor has reviewed the OSF and can confirm that the Consultee ICF v1.1 (now superseded by v2.1) is present in the OSF. There was no record of the consent process within the patient's medical notes. The PI, Joyce Young was not available for this visit so the monitor will schedule a training session in 'Informed Consent Procedure' and also get a first hand account of all that went wrong during the informed consent process. A follow up letter from the monitor will be sent to site giving a summary of the issues that were revealed and a request will be made for a scheduled training session. Details of the aforementioned call will be summarized in both a communication report and the next Routine Monitoring Visit Report.	Minor
015-001	77/Female	Study procedure or assessment: The Lot number of the first Accusol bag used at 13:00 on 27-Apr-2015 was not documented and therefore listed as unknown	Minor

Data Listing 16.2.2 Protocol Deviations - Enrolled Population

Patient Number	Age(Years)/Gender	Protocol Deviation	Major or Minor
015-002	60/Male	Study procedure or assessment: Study staff did not document ACCUSOL bags used for the duration of the study. Lot numbers and times the bags were changed were not documented and therefore are unknown. Research staff relies on ICU nurses completing documentation and in this instance it was not performed with due diligence.	Major
015-003	57/Male	Study procedure or assessment: Study staff did not document ACCUSOL bags used for the duration of the study. Lot numbers and times the bags were changed were not documented and therefore are unknown. Research staff relies on ICU nurses completing documentation and in this instance it was not performed with due diligence.	Minor
015-004	85/Male	Study procedure or assessment: The lot numbers for Accusol bags starting at 23:00 on 20-Jun-2015 and 07:00 on 21-Jun-2015 were not documented and are therefore listed as unknown in eCRF	Minor
015-005	76/Male	Informed consent: Patient was re-consented onto Patient ICF v 2.1, however the monitor deemed the patient's printed name and date to be illegible. There was an impartial witness signature on the ICF, but the impartial witness was study nurse, Sally Pitts.	Major
015-006	84/Female	Study procedure or assessment: End date and times missing from source data for Accusol bags used from 07:05 on 16-Aug-2015 due to nurse oversight.	Minor
015-010		Informed consent: Patient transferred to another hospital before regaining capacity and providing retrospective patient consent.	Minor
015-011		Study procedure or assessment: For the first three Accusol bags used (Between 09:39 and 10:40 on 23-Jan-2016) the lot numbers are unknown. This is due to CDU nurse error as they did not record them in the source data	Minor
		Informed consent: The patient has since been moved to another unit for palliative care and is therefore unable to provide retrospective patient consent.	Minor

Data Listing 16.2.2 Protocol Deviations - Enrolled Population

Patient Number	Age(Years)/Gender	Protocol Deviation	Major or Minor
016-002		Study medication: Patient 016-002 was enrolled at 19:10 on 04SEP2015 Precipitate observation should have begun at 19:10 but was started 10min earlier due to human error in the calculation of enrollment time. Thus, observations began at 11:00 (04SEP2015) and continued through 11:30 & 12:00. JU reminded PH that according to the protocol enrollment and precipitate observation should commence together after initial 40 hours on CRRT.	Minor
		Informed consent: Patient was discharged before retrospective patient consent was obtained. Demographics have been removed from the eCRF	Minor
017-005	77/Male	Study procedure or assessment: Where there should have been about 28 half hourly precipitate observation readings, ICU nurses were only able to capture 19. This deviation occurred because of the patients acute condition and the need for close medical observation (this is despite the fact that the records also show that the patient began to improve and no longer required CRRT)	Minor
017-008		Informed consent: Patient was discharged before retrospective consent was obtained. Demographics have been removed from the eCRF	Minor
		Study procedure or assessment: This patient was recruited at 1624 on 26SEP2016. This was also the same time that the first precipitate observation was made. 30-minute observations continued to be made up until and including 19:24, 26SEP2016. Thereafter, an observation was made at 19:56, 26SEP2016 (instead of 19:54) which is a 2-minute deviation. Between 19:56, 26SEP2016 & 07:56, 27SEP2016 1hr observations were made. JU then noticed that the following observation made after this was at 08:30, 27SEP2016 - under normal circumstances, the observation made at 08:30, would have been made at 08:24 thereby increasing the deviation by 6 minutes. Further deviations noticed include only 1 observation made between 14:00 and 15:00 on 27SEP2016.	Minor

Data Listing 16.2.2 Protocol Deviations - Enrolled Population

Patient Number	Age(Years)/Gender	Protocol Deviation	Major or Minor
017-010	54/Male	Study procedure or assessment: This patient was recruited at 14:10. The next observations that were made were at 14:40 and then at 15:00 instead of 15:10. Subsequent observations were made half hourly from 15:00. The deviation at 15:00 appeared to have been done deliberately to make it easier for the ICU nurses to collect data.	Minor
		Study procedure or assessment: Study was initially indicated in EDC to have ended at 10:00 on 20NOV2015. Upon closer examination, annotations on the study worksheet indicated that the study ended at 10:30. There was no corresponding precipitate observation at that time.	Minor

Appendix 16.2.3. Patients Excluded from Analysis

Data Listing 16.2.3.1. Patients Excluded from Per-Protocol Population - Enrolled Population

Patient Number	Reason for Exclusion from PP Population
001-001	LAST 4 HOURS OF OBSERVATION MISSED. ALSO NOT ABLE TO SDV ACCUSOL ADMINISTRATION - RECORDS INCOMPLETE
001-003	CRRT CIRCUIT CHANGED
001-006	CRRT TERMINATED
002-003	CRRT TERMINATED
002-005	CRRT TERMINATED
002-007	CRRT TERMINATED
002-009	CRRT TERMINATED
002-012	CRRT TERMINATED
002-014	CRRT TERMINATED
002-016	CRRT TERMINATED
002-017	CRRT TERMINATED
002-018	CRRT TERMINATED
002-019	OTHER: IMMINENT DEATH
002-021	CRRT TERMINATED
003-001	CRRT TERMINATED
003-002	CRRT CIRCUIT CHANGED
003-003	CRRT TERMINATED
003-004	CRRT TERMINATED
003-008	CRRT TERMINATED
003-012	CRRT TERMINATED
004-001	CRRT TERMINATED
004-002	CRRT CIRCUIT CHANGED
004-003	CRRT CIRCUIT CHANGED
004-010	CRRT TERMINATED
004-013	CRRT CIRCUIT CHANGED
004-014	CRRT CIRCUIT CHANGED
004-016	CRRT CIRCUIT CHANGED

**Data Listing 16.2.3.1. Patients Excluded from Per-Protocol Population -
Enrolled Population**

Patient Number	Reason for Exclusion from PP Population
004-018	CRRT CIRCUIT CHANGED
005-002	CRRT TERMINATED
005-003	CRRT TERMINATED
005-004	CRRT TERMINATED
005-006	CRRT TERMINATED
005-008	CRRT TERMINATED
005-011	CRRT TERMINATED
005-014	CRRT TERMINATED
005-018	CRRT CIRCUIT CHANGED
005-023	CRRT TERMINATED
005-025	CRRT TERMINATED
005-026	CRRT TERMINATED
005-027	CRRT TERMINATED
005-028	CRRT TERMINATED
005-030	CRRT TERMINATED
005-032	CRRT TERMINATED
005-034	CRRT TERMINATED
005-038	CRRT TERMINATED
007-001	CRRT TERMINATED
007-002	CRRT TERMINATED
007-003	CRRT TERMINATED
007-004	CRRT TERMINATED
007-005	CRRT TERMINATED
007-006	>25% OBSERVATIONS MISSED
007-007	CRRT TERMINATED
007-008	CRRT TERMINATED
007-010	CRRT TERMINATED
007-014	CRRT TERMINATED
007-015	CRRT TERMINATED
007-016	CRRT TERMINATED

**Data Listing 16.2.3.1. Patients Excluded from Per-Protocol Population -
Enrolled Population**

Patient Number	Reason for Exclusion from PP Population
008-004	CRRT CIRCUIT CHANGED
008-005	CRRT TERMINATED
008-006	CRRT CIRCUIT CHANGED
008-007	CRRT CIRCUIT CHANGED
008-012	CRRT TERMINATED
008-013	CRRT CIRCUIT CHANGED
008-014	CRRT CIRCUIT CHANGED
008-016	CRRT TERMINATED
008-017	CRRT CIRCUIT CHANGED
008-018	CRRT TERMINATED
008-019	CRRT TERMINATED
008-021	CRRT CIRCUIT CHANGED
008-023	CRRT CIRCUIT CHANGED
008-025	CRRT CIRCUIT CHANGED
008-026	CRRT TERMINATED
008-027	CRRT CIRCUIT CHANGED
008-028	CRRT CIRCUIT CHANGED
008-029	CRRT CIRCUIT CHANGED
008-030	CRRT TERMINATED
008-031	CRRT CIRCUIT CHANGED
009-001	CRRT CIRCUIT CHANGED
009-002	CRRT CIRCUIT CHANGED
009-006	CRRT CIRCUIT CHANGED
009-009	CRRT CIRCUIT CHANGED
009-011	CRRT CIRCUIT CHANGED
009-013	CRRT TERMINATED
009-015	CRRT CIRCUIT CHANGED
009-016	CRRT CIRCUIT CHANGED
009-017	DEATH
009-019	CRRT CIRCUIT CHANGED

**Data Listing 16.2.3.1. Patients Excluded from Per-Protocol Population -
Enrolled Population**

Patient Number	Reason for Exclusion from PP Population
009-022	CRRT CIRCUIT CHANGED
009-027	CRRT TERMINATED
009-028	CRRT CIRCUIT CHANGED
009-031	CRRT CIRCUIT CHANGED
009-032	CRRT TERMINATED
010-003	CRRT TERMINATED
010-005	LAST OBSERVATION MISSED (LAST 2)
010-008	CRRT TERMINATED
010-009	CRRT TERMINATED
010-010	ACCUSOL ADMINISTRATION NOT DOCUMENTED
010-011	CRRT TERMINATED
010-014	CRRT TERMINATED
011-001	CRRT TERMINATED
011-002	CRRT TERMINATED
011-003	CRRT TERMINATED
011-005	CRRT TERMINATED
011-006	CRRT TERMINATED
011-007	CRRT TERMINATED
011-008	CRRT TERMINATED
011-009	CRRT TERMINATED
011-010	CRRT TERMINATED
011-011	CRRT TERMINATED
011-014	CRRT TERMINATED
011-015	CRRT TERMINATED
012-003	CRRT TERMINATED
012-004	CRRT CIRCUIT CHANGED
012-006	CRRT TERMINATED
012-007	CRRT TERMINATED
012-008	CRRT TERMINATED
012-009	CRRT TERMINATED

**Data Listing 16.2.3.1. Patients Excluded from Per-Protocol Population -
Enrolled Population**

Patient Number	Reason for Exclusion from PP Population
012-011	CRRT CIRCUIT CHANGED
012-013	CRRT TERMINATED
013-003	CRRT TERMINATED
013-004	CRRT TERMINATED
014-002	DEATH
014-003	CRRT CIRCUIT CHANGED
014-004	CRRT TERMINATED
014-007	CRRT CIRCUIT CHANGED
015-001	CRRT TERMINATED
015-002	ACCUSOL ADMINISTRATION NOT DOCUMENTED
015-003	CRRT TERMINATED
015-010	CRRT TERMINATED
015-011	CRRT TERMINATED
016-002	CRRT TERMINATED
016-004	CRRT TERMINATED
017-003	CRRT TERMINATED
017-005	CRRT TERMINATED
017-008	CRRT TERMINATED
017-010	CRRT TERMINATED

Data Listing 16.2.3.2. Inclusion/Exclusion – Enrolled Population

Patient Number	All Eligibility Requirements Met?	Inclusion/Exclusion Criterion
001-001	Yes	
001-002	Yes	
001-003	Yes	
001-004	Yes	
001-005	Yes	
001-006	Yes	
001-007	Yes	
001-008	Yes	
002-002	Yes	
002-003	Yes	
002-005	Yes	
002-007	Yes	
002-009	Yes	
002-011	Yes	
002-012	Yes	
002-014	Yes	
002-016	Yes	
002-017	Yes	
002-018	Yes	
002-019	Yes	
002-021	Yes	
003-001	Yes	
003-002	Yes	
003-003	Yes	
003-004	Yes	
003-007	Yes	
003-008	Yes	
003-009	Yes	
003-010	Yes	
003-011	Yes	

Data Listing 16.2.3.2. Inclusion/Exclusion – Enrolled Population

Patient Number	All Eligibility Requirements Met?	Inclusion/Exclusion Criterion
003-012	Yes	
004-001	Yes	
004-002	Yes	
004-003	Yes	
004-005	Yes	
004-006	Yes	
004-009	Yes	
004-010	Yes	
004-013	Yes	
004-014	Yes	
004-016	Yes	
004-017	Yes	
004-018	Yes	
005-002	Yes	
005-003	Yes	
005-004	Yes	
005-006	Yes	
005-007	Yes	
005-008	Yes	
005-010	Yes	
005-011	Yes	
005-012	Yes	
005-014	Yes	
005-015	Yes	
005-016	Yes	
005-018	Yes	
005-019	Yes	
005-020	Yes	
005-021	Yes	
005-022	Yes	

Data Listing 16.2.3.2. Inclusion/Exclusion – Enrolled Population

Patient Number	All Eligibility Requirements Met?	Inclusion/Exclusion Criterion
005-023	Yes	
005-024	Yes	
005-025	Yes	
005-026	Yes	
005-027	Yes	
005-028	Yes	
005-029	Yes	
005-030	Yes	
005-032	Yes	
005-034	Yes	
005-036	Yes	
005-037	Yes	
005-038	Yes	
007-001	Yes	
007-002	Yes	
007-003	Yes	
007-004	Yes	
007-005	Yes	
007-006	Yes	
007-007	Yes	
007-008	Yes	
007-010	Yes	
007-011	Yes	
007-012	Yes	
007-014	Yes	
007-015	Yes	
007-016	Yes	
008-001	Yes	
008-002	Yes	
008-003	Yes	

Data Listing 16.2.3.2. Inclusion/Exclusion – Enrolled Population

Patient Number	All Eligibility Requirements Met?	Inclusion/Exclusion Criterion
008-004	Yes	
008-005	Yes	
008-006	Yes	
008-007	Yes	
008-012	Yes	
008-013	Yes	
008-014	Yes	
008-016	Yes	
008-017	Yes	
008-018	Yes	
008-019	Yes	
008-020	Yes	
008-021	Yes	
008-022	Yes	
008-023	Yes	
008-024	Yes	
008-025	Yes	
008-026	Yes	
008-027	Yes	
008-028	Yes	
008-029	Yes	
008-030	Yes	
008-031	Yes	
009-001	Yes	
009-002	Yes	
009-003	Yes	
009-006	Yes	
009-008	Yes	
009-009	Yes	
009-011	Yes	

Data Listing 16.2.3.2. Inclusion/Exclusion – Enrolled Population

Patient Number	All Eligibility Requirements Met?	Inclusion/Exclusion Criterion
009-013	Yes	
009-015	Yes	
009-016	Yes	
009-017	Yes	
009-018	Yes	
009-019	Yes	
009-021	Yes	
009-022	Yes	
009-024	Yes	
009-026	Yes	
009-027	Yes	
009-028	Yes	
009-030	Yes	
009-031	Yes	
009-032	Yes	
010-002	Yes	
010-003	Yes	
010-005	Yes	
010-006	Yes	
010-008	Yes	
010-009	Yes	
010-010	Yes	
010-011	Yes	
010-014	Yes	
011-001	Yes	
011-002	Yes	
011-003	Yes	
011-004	Yes	
011-005	Yes	
011-006	Yes	

Data Listing 16.2.3.2. Inclusion/Exclusion – Enrolled Population

Patient Number	All Eligibility Requirements Met?	Inclusion/Exclusion Criterion
011-007	Yes	
011-008	Yes	
011-009	Yes	
011-010	Yes	
011-011	Yes	
011-012	Yes	
011-013	Yes	
011-014	Yes	
011-015	Yes	
011-016	Yes	
012-001	Yes	
012-002	Yes	
012-003	Yes	
012-004	Yes	
012-005	Yes	
012-006	Yes	
012-007	Yes	
012-008	Yes	
012-009	Yes	
012-010	Yes	
012-011	Yes	
012-012	Yes	
012-013	Yes	
013-002	Yes	
013-003	Yes	
013-004	Yes	
013-005	Yes	
013-010	Yes	
014-001	Yes	
014-002	Yes	

Data Listing 16.2.3.2. Inclusion/Exclusion – Enrolled Population

Patient Number	All Eligibility Requirements Met?	Inclusion/Exclusion Criterion
014-003	Yes	
014-004	Yes	
014-007	Yes	
015-001	Yes	
015-002	Yes	
015-003	Yes	
015-004	Yes	
015-005	Yes	
015-006	Yes	
015-009	Yes	
015-010	Yes	
015-011	Yes	
016-002	Yes	
016-004	Yes	
017-003	Yes	
017-004	Yes	
017-005	Yes	
017-007	Yes	
017-008	Yes	
017-010	Yes	
017-011	Yes	

Note: Only exclusion criteria met or inclusion criteria not fulfilled are included in this listing.

Appendix 16.2.4. Demographic Data and Other Baseline Characteristics

Data Listing 16.2.4. Demographic and Baseline Characteristics - Enrolled Population

Patient Number	Age (Years)/Gender	Weight (kg)
001-001	57/Female	59.5
001-002	50/Male	102.5
001-003	68/Female	80
001-004	78/Female	54.5
001-005	33/Female	84.6
001-006		100
001-007	56/Male	70.3
001-008	57/Male	83.8
002-002	56/Male	91
002-003	68/Female	65.5
002-005	44/Male	105
002-007	61/Male	85.5
002-009	58/Female	123
002-011	63/Female	93
002-012		72.5
002-014	59/Male	70
002-016	83/Female	70
002-017	73/Male	158
002-018	91/Female	61
002-019	70/Male	79
002-021	73/Male	72
003-001	77/Male	67
003-002	67/Male	95
003-003	57/Female	60
003-004	66/Male	65
003-007	60/Male	65
003-008	47/Male	62
003-009		77

**Data Listing 16.2.4. Demographic and Baseline Characteristics -
Enrolled Population**

Patient Number	Age (Years)/Gender	Weight (kg)
003-010	79/Male	109
003-011	69/Male	70
003-012	88/Male	73
004-001		80
004-002		63.5
004-003	45/Female	62
004-005	20/Female	69
004-006	30/Male	38
004-009	59/Female	70
004-010	55/Male	85
004-013	79/Male	75
004-014	65/Male	108
004-016	47/Female	70
004-017	67/Male	77
004-018	40/Male	80
005-002	68/Female	72.5
005-003	65/Female	119.5
005-004	81/Male	89
005-006	38/Male	82
005-007	63/Male	177
005-008	74/Female	60
005-010	42/Male	126
005-011	78/Female	109.5
005-012		90
005-014	65/Male	153
005-015	78/Male	93.5
005-016		74
005-018	67/Male	98.5
005-019	69/Male	117
005-020		89
005-021	58/Male	76

**Data Listing 16.2.4. Demographic and Baseline Characteristics -
Enrolled Population**

Patient Number	Age (Years)/Gender	Weight (kg)
005-022		130
005-023	66/Male	95.5
005-024	41/Female	118.5
005-025		80
005-026	64/Male	70
005-027		68
005-028		76
005-029	68/Male	69
005-030	61/Male	114
005-032	49/Male	116
005-034	70/Male	53
005-036	51/Female	117
005-037	53/Female	85
005-038		54
007-001	61/Male	107
007-002		45
007-003	64/Male	116.5
007-004	72/Male	60
007-005	24/Male	104
007-006	73/Female	107.6
007-007	83/Male	62
007-008	79/Male	67
007-010	70/Male	102
007-011	64/Female	79
007-012	36/Male	77.8
007-014	74/Female	103
007-015	73/Female	65
007-016	71/Male	82.55
008-001	26/Male	84
008-002	31/Male	71.6
008-003	25/Female	30

**Data Listing 16.2.4. Demographic and Baseline Characteristics -
Enrolled Population**

Patient Number	Age (Years)/Gender	Weight (kg)
008-004	46/Male	103.4
008-005	82/Male	98
008-006	70/Male	92.5
008-007	74/Male	87
008-012	71/Male	83
008-013	68/Male	68
008-014	65/Female	102
008-016	34/Male	69
008-017	52/Female	54.5
008-018	65/Male	106
008-019	69/Female	46.3
008-020	60/Male	80.5
008-021	66/Male	61
008-022	43/Male	71
008-023		114
008-024	27/Male	71.5
008-025	68/Male	87.1
008-026	30/Female	53.5
008-027	71/Male	111.5
008-028	72/Male	120
008-029	66/Female	95.5
008-030	63/Female	46.3
008-031	23/Male	57
009-001	64/Male	88
009-002		65
009-003	75/Male	90
009-006	58/Female	60
009-008	31/Male	89.2
009-009		65
009-011	75/Female	55
009-013	60/Female	85

**Data Listing 16.2.4. Demographic and Baseline Characteristics -
Enrolled Population**

Patient Number	Age (Years)/Gender	Weight (kg)
009-015	29/Male	60
009-016	83/Male	65
009-017	51/Male	50
009-018	44/Male	85
009-019	84/Male	65
009-021	51/Male	77
009-022		70
009-024	49/Female	62.8
009-026	76/Female	55
009-027	53/Male	67
009-028		60
009-030	75/Male	61
009-031	34/Male	84.2
009-032	59/Male	67.84
010-002	57/Male	77
010-003		60
010-005	78/Male	70
010-006	80/Male	66
010-008	70/Female	57
010-009	69/Male	114
010-010	52/Female	70
010-011		83
010-014	79/Female	70
011-001	53/Male	66
011-002	75/Male	120
011-003	80/Male	80
011-004	80/Female	75
011-005	78/Male	95
011-006	77/Male	65
011-007	62/Female	100
011-008	61/Male	85

**Data Listing 16.2.4. Demographic and Baseline Characteristics -
Enrolled Population**

Patient Number	Age (Years)/Gender	Weight (kg)
011-009	71/Female	65
011-010	47/Male	60
011-011	77/Male	156
011-012	74/Male	110
011-013	71/Female	70
011-014	79/Female	69
011-015	77/Female	83
011-016	72/Female	90
012-001	59/Male	82.6
012-002	67/Male	84
012-003	63/Male	95
012-004	59/Female	66
012-005	41/Male	85
012-006	44/Male	65
012-007	82/Male	83
012-008	59/Male	98
012-009	70/Male	79
012-010	72/Male	66.6
012-011	58/Female	92.7
012-012	69/Male	70
012-013	77/Female	53
013-002	70/Male	92
013-003	69/Male	85
013-004	64/Female	165
013-005		54
013-010	76/Female	55.2
014-001	75/Female	75
014-002	47/Male	58
014-003	63/Female	80
014-004	33/Female	60
014-007	34/Female	70

**Data Listing 16.2.4. Demographic and Baseline Characteristics -
Enrolled Population**

Patient Number	Age (Years)/Gender	Weight (kg)
015-001	77/Female	57
015-002	60/Male	73.6
015-003	57/Male	66
015-004	85/Male	66
015-005	76/Male	80
015-006	84/Female	52
015-009	76/Female	62
015-010		80
015-011		52
016-002		70
016-004	55/Male	75
017-003	92/Female	66
017-004	74/Male	80
017-005	77/Male	100
017-007	66/Male	80
017-008		60
017-010	54/Male	90
017-011	49/Male	60

Demographic data is missing for some patients because informed consent was not obtained from the patient personally.

Appendix 16.2.5. Product Exposure, Compliance and Concentration Data

Data Listing 16.2.5.1. Anti-Coagulant Administration - Enrolled Population

Patient Number	Age (Years)/ Gender	Anti-Coagulant Medication Taken	ATC Term/Preferred Term/Reported Term	Date and Time of Administration	Route. Specify, if Other	Dose per Administration	Unit. Specify, if Other
001-001	57/Female	Yes	ANTITHROMBOTIC AGENTS/HEPARIN SODIUM/HEPARIN SODIUM	04JUN2015 15:00	ADMINISTERED VIA THE FILTRATION MACHINE	2	ML/HR
001-001	57/Female	Yes	ANTITHROMBOTIC AGENTS/HEPARIN/HEPARIN	04JUN2015 20:46	VIA FILTRATION LINE	2.5	ML/HR
001-001	57/Female	Yes	ANTITHROMBOTIC AGENTS/HEPARIN/HEPARIN	05JUN2015 18:15	VIA FILTRATION	2	ML/HR
001-002	50/Male	Yes	ANTITHROMBOTIC AGENTS/HEPARIN/HEPARIN	12JUN2015 15:00	VIA FILTER	2.5	ML/HR
001-002	50/Male	Yes	ANTITHROMBOTIC AGENTS/HEPARIN/HEPARIN	13JUN2015 06:13	VIA FILTER	3	ML/HR
001-003	68/Female	Yes	ANTITHROMBOTIC AGENTS/HEPARIN SODIUM/HEPARIN SODIUM	14AUG2015 14:06	INTRAVENOUS	2.4	ML/HR
001-004	78/Female	No					

Data Listing 16.2.5.1. Anti-Coagulant Administration - Enrolled Population

Patient Number	Age (Years)/ Gender	Anti-Coagulant Medication Taken	ATC Term/Preferred Term/Reported Term	Date and Time of Administration	Route. Specify, if Other	Dose per Administration	Unit. Specify, if Other
001-005	33/Female	Yes	ANTITHROMBOTIC AGENTS/HEPARIN SODIUM/HEPARIN SODIUM	29OCT2015 06:10	VIA IV	3	ML/HR
001-005	33/Female	Yes	ANTITHROMBOTIC AGENTS/HEPARIN SODIUM/HEPARIN SODIUM	29OCT2015 06:10	VIA IV	3	ML/HR
001-005	33/Female	Yes	ANTITHROMBOTIC AGENTS/HEPARIN SODIUM/HEPARIN SODIUM	29OCT2015 06:10	VIA FILTRATION	1.5	ML/HR
001-005	33/Female	Yes	ANTITHROMBOTIC AGENTS/HEPARIN SODIUM/HEPARIN SODIUM	29OCT2015 07:20	VIA FILTRATION	1.6	ML/HR
001-005	33/Female	Yes	ANTITHROMBOTIC AGENTS/HEPARIN SODIUM/HEPARIN SODIUM	29OCT2015 12:41	VIA FILTRATION	1.8	ML/HR
001-005	33/Female	Yes	ANTITHROMBOTIC AGENTS/HEPARIN SODIUM/HEPARIN SODIUM	29OCT2015 17:45	VIA FILTRATION	2	ML/HR

Data Listing 16.2.5.1. Anti-Coagulant Administration - Enrolled Population

Patient Number	Age (Years)/ Gender	Anti-Coagulant Medication Taken	ATC Term/Preferred Term/Reported Term	Date and Time of Administration	Route. Specify, if Other	Dose per Administration	Unit. Specify, if Other
001-005	33/Female	Yes	ANTITHROMBOTIC AGENTS/HEPARIN SODIUM/HEPARIN SODIUM	29OCT2015 18:03	VIA FILTRATION	2.2	ML/HR
001-006		Yes	ANTITHROMBOTIC AGENTS/HEPARIN SODIUM/HEPARIN SODIUM	12NOV2015 18:30	VIA FILTRATION MACHINE	3	ML/HR
001-006		Yes	ANTITHROMBOTIC AGENTS/HEPARIN SODIUM/HEPARIN SODIUM	13NOV2015 04:00	VIA FILTRATION MACHINE	3	ML/HR
001-007	56/Male	Yes	ANTITHROMBOTIC AGENTS/HEPARIN/HEP ARIN	22DEC2015 19:33	INTRAVENOUS	1.5	ML/HR
001-008	57/Male	Yes	ANTITHROMBOTIC AGENTS/HEPARIN/HEP ARIN	29JAN2016 17:00	INTRAVENOUS	1.7	U/mL
001-008	57/Male	Yes	ANTITHROMBOTIC AGENTS/HEPARIN/HEP ARIN	30JAN2016 18:19	INTRAVENOUS	1.4	U/mL
002-002	56/Male	Yes	ANTITHROMBOTIC AGENTS/HEPARIN/HEP ARIN	26APR2015 02:25	INTRAVENOUS	1000	U/mL

Data Listing 16.2.5.1. Anti-Coagulant Administration - Enrolled Population

Patient Number	Age (Years)/ Gender	Anti-Coagulant Medication Taken	ATC Term/Preferred Term/Reported Term	Date and Time of Administration	Route. Specify, if Other	Dose per Administration	Unit. Specify, if Other
002-003	68/Female	Yes	ANTITHROMBOTIC AGENTS/EPOPROSTENOL SODIUM/FLOLAN	05MAY2015 01:20	INTRAVENOUS	10000	NANOGRAM PER MILILITERS
002-005	44/Male	Yes	ANTITHROMBOTIC AGENTS/EPOPROSTENOL SODIUM/FLOLAN	15MAY2015 10:30	INTRAVENOUS	10000	NANOGRAM/MILLI LITRE
002-007	61/Male	Yes	ANTITHROMBOTIC AGENTS/HEPARIN/HEPARIN	24JUN2015 15:22	INTRAVENOUS	1000	U/mL
002-009	58/Female	Yes	ANTITHROMBOTIC AGENTS/HEPARIN/HEPARIN	19JUN2015 12:50	INTRAVENOUS	1000	U/mL
002-009	58/Female	Yes	ANTITHROMBOTIC AGENTS/EPOPROSTENOL SODIUM/FLOLAN	19JUN2015 12:50	INTRAVENOUS	1000	U/mL
002-011	63/Female	Yes	ANTITHROMBOTIC AGENTS/HEPARIN/HEPARIN	20AUG2015 07:00	INTRAVENOUS	1000	U/mL
002-012		Yes	ANTITHROMBOTIC AGENTS/HEPARIN/HEPARIN	30AUG2015 03:40	INTRAVENOUS	1000	U/mL
002-014	59/Male	Yes	ANTITHROMBOTIC AGENTS/HEPARIN/HEPARIN	02SEP2015 16:00	INTRAVENOUS	1000	U/mL

Data Listing 16.2.5.1. Anti-Coagulant Administration - Enrolled Population

Patient Number	Age (Years)/ Gender	Anti-Coagulant Medication Taken	ATC Term/Preferred Term/Reported Term	Date and Time of Administration	Route. Specify, if Other	Dose per Administration	Unit. Specify, if Other
002-016	83/Female	Yes	ANTITHROMBOTIC AGENTS/EPOPROSTENOL SODIUM/FLOLAN	03SEP2015 15:55	INTRAVENOUS	1000	NANOGRAM/MILLI LITRE
002-017	73/Male	Yes	ANTITHROMBOTIC AGENTS/HEPARIN/HEPARIN	12OCT2015 17:30	INTRAVENOUS	1000	U/mL
002-018	91/Female	Yes	ANTITHROMBOTIC AGENTS/HEPARIN/HEPARIN	22OCT2015 15:05	INTRAVENOUS	1000	U/mL
002-019	70/Male	Yes	ANTITHROMBOTIC AGENTS/EPOPROSTENOL SODIUM/FLOLAN	10NOV2015 05:05	INTRAVENOUS	10000	NG/ML
002-021	73/Male	Yes	ANTITHROMBOTIC AGENTS/HEPARIN/HEPARIN	10DEC2015 05:00	INTRAVENOUS	1000	U/mL
003-001	77/Male	No					
003-002	67/Male	Yes	ANTITHROMBOTIC AGENTS/HEPARIN/HEPARIN-CONTINUOUS INFUSION	15MAY2015 09:00	INTRAVENOUS	CONTINUOUS	2700 IU PER HOUR
003-003	57/Female	No					
003-004	66/Male	Yes	ANTITHROMBOTIC AGENTS/HEPARIN/HEPARIN	07SEP2015 13:00	VIA FILTER IV	100 U/HR	UNITS PER HOUR

Data Listing 16.2.5.1. Anti-Coagulant Administration - Enrolled Population

Patient Number	Age (Years)/ Gender	Anti-Coagulant Medication Taken	ATC Term/Preferred Term/Reported Term	Date and Time of Administration	Route. Specify, if Other	Dose per Administration	Unit. Specify, if Other
003-004	66/Male	Yes	ANTITHROMBOTIC AGENTS/HEPARIN/HEPARIN	07SEP2015 15:53	IV VIA FILTER	100U/HR	UNITS/HOUR
003-007	60/Male	Yes	ANTITHROMBOTIC AGENTS/HEPARIN/HEPARIN	05OCT2015 14:00	CONTINUOUS IV ADMIN AT 1000 IU/HR	1000	U/mL
003-008	47/Male	Yes	ANTITHROMBOTIC AGENTS/HEPARIN/HEPARIN	21OCT2015 11:30	INTRAVENOUS	1200	UNITS PER HOUR CONTINUOUS
003-009		Yes	ANTITHROMBOTIC AGENTS/HEPARIN/HEPARIN	26OCT2015 05:30	INTRAVENOUS	400 U/HR	UNITS PER HOUR CONTINUOUS
003-009		Yes	ANTITHROMBOTIC AGENTS/HEPARIN/HEPARIN	26OCT2015 13:40	VIA FILTER	600	UNITS PER HOUR CONTINUOUS
003-009		Yes	ANTITHROMBOTIC AGENTS/HEPARIN/HEPARIN	27OCT2015 07:50	VIA FILTER	600	UNITS PER HOUR CONTINUOUS
003-010	79/Male	Yes	ANTITHROMBOTIC AGENTS/HEPARIN/HEPARIN	30NOV2015 02:00	VIA CVVH	2600	UNITS PER HOUR CONTINUOUS

Data Listing 16.2.5.1. Anti-Coagulant Administration - Enrolled Population

Patient Number	Age (Years)/ Gender	Anti-Coagulant Medication Taken	ATC Term/Preferred Term/Reported Term	Date and Time of Administration	Route. Specify, if Other	Dose per Administration	Unit. Specify, if Other
003-011	69/Male	Yes	ANTITHROMBOTIC AGENTS/HEPARIN/HEPARIN	23DEC2015 03:00	VIA FILTER	400	400 UNITS OF HEPARIN PER HOUR FOR THE DURATION OF STUDY
003-012	88/Male	Yes	ANTITHROMBOTIC AGENTS/HEPARIN/HEPARIN	23JAN2016 08:00	VIA FILTER	600	UNITS PER HOUR CONTINUOUS
004-001		Yes	ANTITHROMBOTIC AGENTS/HEPARIN/HEPARIN	23APR2015 08:00	IV RUNNING THROUGH FILTER	500	UNITS/HR
004-002		Yes	ANTITHROMBOTIC AGENTS/HEPARIN/HEPARIN	18MAY2015 18:00	INTRAVENOUS	600	UNITS/ HR
004-003	45/Female	Yes	ANTITHROMBOTIC AGENTS/HEPARIN SODIUM/HEPARIN SODIUM	01JUN2015 14:00	INTRAVENOUS	1000	UNIT/HOUR
004-005	20/Female	Yes	ANTITHROMBOTIC AGENTS/HEPARIN SODIUM/HEPARIN SODIUM	23JUN2015 07:10	VIA FILTER	1400	UNITS/HOUR
004-005	20/Female	Yes	ANTITHROMBOTIC AGENTS/HEPARIN SODIUM/HEPARIN SODIUM	23JUN2015 21:15	VIA FILTER	1400	UNITS/HOUR

Data Listing 16.2.5.1. Anti-Coagulant Administration - Enrolled Population

Patient Number	Age (Years)/ Gender	Anti-Coagulant Medication Taken	ATC Term/Preferred Term/Reported Term	Date and Time of Administration	Route. Specify, if Other	Dose per Administration	Unit. Specify, if Other
004-006	30/Male	Yes	ANTITHROMBOTIC AGENTS/HEPARIN/HEPARIN	05JUL2015 07:00	VIA FILTER	300	UNITS PER HOUR
004-006	30/Male	Yes	ANTITHROMBOTIC AGENTS/HEPARIN/HEPARIN	06JUL2015 00:15	VIA FILTER	300	UNITS PER HOUR
004-009	59/Female	Yes	ANTITHROMBOTIC AGENTS/EPOPROSTENOL SODIUM/FLOLAN	24JUL2015 15:00	VIA FILTER	2.4	NG/KG/MIN
004-010	55/Male	No					
004-013	79/Male	Yes	ANTITHROMBOTIC AGENTS/EPOPROSTENOL SODIUM/EPOPROSTENOL (FLOLAN)	14AUG2015 08:00	VIA FILTER	8.9	NG/KG/MIN
004-014	65/Male	No					
004-016	47/Female	Yes	ANTITHROMBOTIC AGENTS/HEPARIN SODIUM/HEPARIN SODIUM	19SEP2015 03:00	INTRAVENOUS	700	U/mL
004-017	67/Male	Yes	ANTITHROMBOTIC AGENTS/HEPARIN/HEPARIN	24SEP2015 17:00	IV VIA FILTER	500	UNITS/HR

Data Listing 16.2.5.1. Anti-Coagulant Administration - Enrolled Population

Patient Number	Age (Years)/ Gender	Anti-Coagulant Medication Taken	ATC Term/Preferred Term/Reported Term	Date and Time of Administration	Route. Specify, if Other	Dose per Administration	Unit. Specify, if Other
004-017	67/Male	Yes	ANTITHROMBOTIC AGENTS/HEPARIN/HEP ARIN	25SEP2015 23:00	IV VIA FILTER	500	UNITS/HR
004-018	40/Male	Yes	ANTITHROMBOTIC AGENTS/EPOPROSTENO L SODIUM/FLOLAN, EPOPROSTENOL	25SEP2015 20:00	IV VIA FILTER	2.5	NG/KG/MIN
005-002	68/Female	Yes	ANTITHROMBOTIC AGENTS/HEPARIN/HEP ARIN	21MAR2015 18:30	INTRAVENOUS	3.5 MLS/HR	20,000 UNITS HEPARIN IN 40MLS NORMAL SALINE
005-002	68/Female	Yes	ANTITHROMBOTIC AGENTS/HEPARIN/HEP ARIN	21MAR2015 20:15	INTRAVENOUS	3.5	MLS/HR
005-003	65/Female	Yes	ANTITHROMBOTIC AGENTS/HEPARIN/HEP ARIN	24MAR2015 12:59	INTRAVENOUS	2.6	MLS/HR
005-004	81/Male	No					
005-006	38/Male	No					
005-007	63/Male	Yes	ANTITHROMBOTIC AGENTS/HEPARIN/HEP ARIN	23APR2015 20:00	INTRAVENOUS	3.5 MLS/HR	20,000 UNITS IN 40 MLS OF NORMAL SALINE
005-007	63/Male	Yes	ANTITHROMBOTIC AGENTS/HEPARIN/HEP ARIN	24APR2015 04:10	INTRAVENOUS	3.5 MLS/HR	20,000 UNITS IN 40MLS NORMAL SALINE

Data Listing 16.2.5.1. Anti-Coagulant Administration - Enrolled Population

Patient Number	Age (Years)/ Gender	Anti-Coagulant Medication Taken	ATC Term/Preferred Term/Reported Term	Date and Time of Administration	Route. Specify, if Other	Dose per Administration	Unit. Specify, if Other
005-007	63/Male	Yes	ANTITHROMBOTIC AGENTS/HEPARIN/HEP ARIN	24APR2015 17:00	INTRAVENOUS	3.7 MLS/HR	20,000 UNITS IN 40 MLS NORMAL SALINE
005-007	63/Male	Yes	ANTITHROMBOTIC AGENTS/HEPARIN/HEP ARIN	25APR2015 03:10	INTRAVENOUS	3.7 MLS/HR	20,000 UNITS IN 40 MLS NORMAL SALINE
005-008	74/Female	Yes	ANTITHROMBOTIC AGENTS/HEPARIN/HEP ARIN	09MAY2015 09:00	CVVHDF	1.8 MLS/HR	20,000 UNITS OF HEPARIN IN 40 MLS OF NORMAL SALINE
005-008	74/Female	Yes	ANTITHROMBOTIC AGENTS/HEPARIN/HEP ARIN	09MAY2015 16:38	CVVHDF	2 MLS/HR	20,000 UNITS IN 40 MLS NORMAL SALINE
005-010	42/Male	Yes	ANTITHROMBOTIC AGENTS/HEPARIN/HEP ARIN	14MAY2015 10:00	CVVHDF	3.6 MLS/HR	20,000 UNITS IN 40 MLS HEPARIN
005-010	42/Male	Yes	ANTITHROMBOTIC AGENTS/HEPARIN/HEP ARIN	14MAY2015 12:05	CVVHDF	3.6 MLS/HR	20,000 UNITS IN 40 MLS NORMAL SALINE
005-010	42/Male	Yes	ANTITHROMBOTIC AGENTS/HEPARIN/HEP ARIN	14MAY2015 14:00	CVVHDF	3.8 MLS/HR	20,000 UNITS IN 40 MLS HEPARIN
005-010	42/Male	Yes	ANTITHROMBOTIC AGENTS/HEPARIN/HEP ARIN	14MAY2015 21:45	CVVHDF	4.0 MLS/HR	20,000 UNITS IN 40 MLS NORMAL SALINE

Data Listing 16.2.5.1. Anti-Coagulant Administration - Enrolled Population

Patient Number	Age (Years)/ Gender	Anti-Coagulant Medication Taken	ATC Term/Preferred Term/Reported Term	Date and Time of Administration	Route. Specify, if Other	Dose per Administration	Unit. Specify, if Other
005-010	42/Male	Yes	ANTITHROMBOTIC AGENTS/HEPARIN/HEP ARIN	15MAY2015 08:30	CVVHDF	4.0 MLS/HR	20,000 UNITS IN 40 MLS NORMAL SALINE
005-011	78/Female	No					
005-012		No					
005-014	65/Male	Yes	ANTITHROMBOTIC AGENTS/HEPARIN/HEP ARIN	05JUN2015 15:35	CVVHDF	5 MLS/HR	20,000 IN 40 MLS NORMAL SALINE
005-014	65/Male	Yes	ANTITHROMBOTIC AGENTS/HEPARIN/HEP ARIN	05JUN2015 22:50	CVVHDF	5 MLS/HR	20,000 UNITS IN 40 MLS NORMAL SALINE
005-014	65/Male	Yes	ANTITHROMBOTIC AGENTS/HEPARIN/HEP ARIN	06JUN2015 06:45	CVVHDF	5 MLS/HR	20,000 UNITS IN 40 MLS NORMAL SALINE
005-014	65/Male	Yes	ANTITHROMBOTIC AGENTS/HEPARIN/HEP ARIN	05JUN2015 09:30	CVVHDF	5 MLS/HR	20,000 UNIT IN 40 MLS NORMAL SALINE
005-015	78/Male	Yes	ANTITHROMBOTIC AGENTS/HEPARIN/HEP ARIN	20JUN2015 21:00	CVVHDF	2.2 MLS/HR	20000 UNITS IN 40 MLS NORMAL SALINE
005-015	78/Male	Yes	ANTITHROMBOTIC AGENTS/HEPARIN/HEP ARIN	21JUN2015 05:00	CVVHDF	2.2 MLS/HR	20000 UNITS IN 40 MLS. NORMAL SALINE

Data Listing 16.2.5.1. Anti-Coagulant Administration - Enrolled Population

Patient Number	Age (Years)/ Gender	Anti-Coagulant Medication Taken	ATC Term/Preferred Term/Reported Term	Date and Time of Administration	Route. Specify, if Other	Dose per Administration	Unit. Specify, if Other
005-015	78/Male	Yes	ANTITHROMBOTIC AGENTS/HEPARIN/HEPARIN	21JUN2015 23:00	CVVHDF	2.2 MLS/HR	20000 UNITS IN 40 MLS NORMAL SALINE
005-016		Yes	ANTITHROMBOTIC AGENTS/HEPARIN/HEPARIN	15JUL2015 20:20	CVVHDF	2.3 MLS/HR	20,000 UNITS IN 40 MLS NORMAL SALINE
005-018	67/Male	Yes	ANTITHROMBOTIC AGENTS/HEPARIN/HEPARIN	29AUG2015 07:30	CVVHDF	1.2 MLS/HR	20,000 UNITS IN 40 MLS NORMAL SALINE
005-018	67/Male	Yes	ANTITHROMBOTIC AGENTS/HEPARIN/HEPARIN	29AUG2015 16:41	CVVHDF	1.4 MLS/HR	20,000 UNITS IN 40 MLS NORMAL SALINE
005-019	69/Male	Yes	ANTITHROMBOTIC AGENTS/HEPARIN/HEPARIN	15SEP2015 15:30	CVVHDF	1.0 MLS/HR	20,000 UNITS IN 40 MLS OF NORMAL SLAINE
005-019	69/Male	Yes	ANTITHROMBOTIC AGENTS/HEPARIN/HEPARIN	15SEP2015 23:54	CVVHDF	1.4 MLS/HR	20,000 UNITS IN 40 MLS OF NORMAL SALINE
005-019	69/Male	Yes	ANTITHROMBOTIC AGENTS/HEPARIN/HEPARIN	16SEP2015 09:30	CVVHDF	2.2 MLS/HR	20,000 UNITS IN 40 MLS OF NORMAL SALINE
005-019	69/Male	Yes	ANTITHROMBOTIC AGENTS/HEPARIN/HEPARIN	16SEP2015 13:59	CVVHDF	3.0 MLS/HR	20,000 UNITS IN 40 MLS IN NORMAL SALINE

Data Listing 16.2.5.1. Anti-Coagulant Administration - Enrolled Population

Patient Number	Age (Years)/ Gender	Anti-Coagulant Medication Taken	ATC Term/Preferred Term/Reported Term	Date and Time of Administration	Route. Specify, if Other	Dose per Administration	Unit. Specify, if Other
005-020		Yes	ANTITHROMBOTIC AGENTS/HEPARIN/HEP ARIN	16SEP2015 11:30	CVVHDF	2.8 MLS/HR	20,000 UNITS IN 40 MLS NORMAL SALINE
005-020		Yes	ANTITHROMBOTIC AGENTS/HEPARIN/HEP ARIN	16SEP2015 11:50	CVVHDF	2.8 MLS/HR	20,000 UNITS IN 40 MLS NORMAL SALINE
005-020		Yes	ANTITHROMBOTIC AGENTS/HEPARIN/HEP ARIN	16SEP2015 15:30	CVVHDF	2.8 MLS/HR	20,000 UNITS IN 40 MLS NORMAL SALINE
005-021	58/Male	Yes	ANTITHROMBOTIC AGENTS/HEPARIN/HEP ARIN	16SEP2015 08:30	CVVHDF	1.8 MLS/HR	20,000 UNITS IN 40 MLS NORMAL SALINE
005-021	58/Male	Yes	ANTITHROMBOTIC AGENTS/HEPARIN/HEP ARIN	17SEP2015 00:04	CVVHDF	2.0 MLS/HR	20,000 UNITS HEPARIN IN 20 MLS OF NORMAL SALINE
005-022		Yes	ANTITHROMBOTIC AGENTS/HEPARIN/HEP ARIN	06OCT2015 04:30	CVVHDF	3.5 MLS/HR	20,000 UNITS HEPARIN IN 40 MLS NORMAL SALINE
005-022		Yes	ANTITHROMBOTIC AGENTS/HEPARIN/HEP ARIN	06OCT2015 20:15	CVVHDF	3.5 MLS/HR	20,000 UNITS HEPARIN IN 40 MLS NORMAL SALINE

Data Listing 16.2.5.1. Anti-Coagulant Administration - Enrolled Population

Patient Number	Age (Years)/ Gender	Anti-Coagulant Medication Taken	ATC Term/Preferred Term/Reported Term	Date and Time of Administration	Route. Specify, if Other	Dose per Administration	Unit. Specify, if Other
005-022		Yes	ANTITHROMBOTIC AGENTS/HEPARIN/HEP ARIN	07OCT2015 07:45	CVVHDF	3.5 MLS/HR	20,000 UNITS HEPARIN IN 40MLS NORMAL SALINE
005-023	66/Male	No					
005-024	41/Female	Yes	ANTITHROMBOTIC AGENTS/HEPARIN/HEP ARIN	25NOV2015 11:00	CVVHDF	3.1 MLS/HR	20,000 UNITS IN 40MLS NORMAL SALINE
005-024	41/Female	Yes	ANTITHROMBOTIC AGENTS/HEPARIN/HEP ARIN	25NOV2015 21:11	CVVHDF	3.5 MLS/HR	20,000 UNITS IN 40MLS NORMAL SALINE
005-024	41/Female	Yes	ANTITHROMBOTIC AGENTS/HEPARIN/HEP ARIN	25NOV2015 14:00	CVVHDF	3.3 MLS/HR	20,000 UNITS IN 40 MLS NORMAL SALINE
005-025		Yes	ANTITHROMBOTIC AGENTS/HEPARIN/HEP ARIN	25NOV2015 20:00	CVVHDF	2.8MLS/HR	20,000 UNITS IN 40MLS OF NORMAL SALINE
005-025		Yes	ANTITHROMBOTIC AGENTS/HEPARIN/HEP ARIN	25NOV2015 22:05	CVVHDF	2.8MLS/HR	20,000 UNITS IN 40 MLS OF NORMAL SALINE
005-026	64/Male	Yes	ANTITHROMBOTIC AGENTS/HEPARIN/HEP ARIN	02DEC2015 05:00	CVVHDF	3.8MLS/HR	20,000 UNITS IN 40 MLS NORMAL SALINE

Data Listing 16.2.5.1. Anti-Coagulant Administration - Enrolled Population

Patient Number	Age (Years)/ Gender	Anti-Coagulant Medication Taken	ATC Term/Preferred Term/Reported Term	Date and Time of Administration	Route. Specify, if Other	Dose per Administration	Unit. Specify, if Other
005-027		Yes	ANTITHROMBOTIC AGENTS/HEPARIN/HEP ARIN	02DEC2015 21:00	CVVHDF	3.1 MLS/HR	20,000 UNITS IN 40 MLS NORMAL SALINE
005-027		Yes	ANTITHROMBOTIC AGENTS/HEPARIN/HEP ARIN	02DEC2015 22:00	CVVHDF	3.3 MLS/HR	20,000 UNITS IN 40 MLS NORMAL SALINE
005-028		Yes	ANTITHROMBOTIC AGENTS/HEPARIN/HEP ARIN	09DEC2015 08:00	CVVHDF	2.9 MLS/HR	20,000 UNITS IN 40 MLS NORMAL SALINE
005-028		Yes	ANTITHROMBOTIC AGENTS/HEPARIN/HEP ARIN	10DEC2015 01:15	CVVHDF	2.9 MLS/HR	20,000 UNITS IN 40 MLS NORMAL SALINE
005-029	68/Male	Yes	ANTITHROMBOTIC AGENTS/HEPARIN/HEP ARIN	11DEC2015 07:30	CVVHDF	2.4 MLS/HR	20,000 UNITS HEPARIN IN 40 MLS NORMAL SALINE
005-029	68/Male	Yes	ANTITHROMBOTIC AGENTS/HEPARIN/HEP ARIN	12DEC2015 04:52	CVVHDF	2.3 MLS/HR	20,000 UNITS HEPARIN IN 40 MLS NORMAL SALINE
005-030	61/Male	Yes	ANTITHROMBOTIC AGENTS/HEPARIN/HEP ARIN	18DEC2015 11:00	CVVHDF	4.4 MLS/HR	20,000 UNITS HEPARIN IN 40 MLS NORMAL SALINE

Data Listing 16.2.5.1. Anti-Coagulant Administration - Enrolled Population

Patient Number	Age (Years)/ Gender	Anti-Coagulant Medication Taken	ATC Term/Preferred Term/Reported Term	Date and Time of Administration	Route. Specify, if Other	Dose per Administration	Unit. Specify, if Other
005-030	61/Male	Yes	ANTITHROMBOTIC AGENTS/HEPARIN/HEPARIN	18DEC2015 14:25	CVVHDF	4.6MLS/HR	20,000 UNITS HEPARIN IN 40 MLS OR NORMAL SALINE
005-032	49/Male	Yes	ANTITHROMBOTIC AGENTS/HEPARIN/HEPARIN	01JAN2016 07:20	CVVHDF	4.4 MLS/HR	20,000 UNITS IN 40 MLS NORMAL SALINE
005-032	49/Male	Yes	ANTITHROMBOTIC AGENTS/HEPARIN/HEPARIN	01JAN2016 15:06	CVVHDF	4.6 MLS/HR	20,000 UNITS IN 40 MLS NORMAL SALINE
005-034	70/Male	Yes	ANTITHROMBOTIC AGENTS/HEPARIN/HEPARIN	13JAN2016 18:40	CVVHDF	1.4 MLS/HR	20,000 UNITS IN 40 MLS NORMAL SALINE
005-036	51/Female	Yes	ANTITHROMBOTIC AGENTS/HEPARIN/HEPARIN	14JAN2016 01:15	CVVHDF	5.6 MLS/HR	20,000 UNITS OF HEPARIN IN 40 MLS NORMAL SALINE
005-036	51/Female	Yes	ANTITHROMBOTIC AGENTS/HEPARIN/HEPARIN	14JAN2016 01:45	CVVHDF	5.6 MLS/HR	20,000 UNITS OF HEPARIN IN 40 MLS NORMAL SALINE
005-036	51/Female	Yes	ANTITHROMBOTIC AGENTS/HEPARIN/HEPARIN	14JAN2016 08:35	CVVHDF	5.6 MLS/HR	20,000 UNITS HEPARIN IN 40 MLS NORMAL SALINE

Data Listing 16.2.5.1. Anti-Coagulant Administration - Enrolled Population

Patient Number	Age (Years)/ Gender	Anti-Coagulant Medication Taken	ATC Term/Preferred Term/Reported Term	Date and Time of Administration	Route. Specify, if Other	Dose per Administration	Unit. Specify, if Other
005-036	51/Female	Yes	ANTITHROMBOTIC AGENTS/HEPARIN/HEP ARIN	14JAN2016 15:40	CVVHDF	5.6 MLS/HR	20,000 UNITS HEPARIN IN 40 MLS NORMLA SALINE
005-036	51/Female	Yes	ANTITHROMBOTIC AGENTS/HEPARIN/HEP ARIN	14JAN2016 22:55	CVVHDF	5.6 MLS/HR	20,000 UNITS HEPARIN IN 40 MLS NORMAL SALINE
005-036	51/Female	Yes	ANTITHROMBOTIC AGENTS/HEPARIN/HEP ARIN	15JAN2016 06:30	CVVHDF	5.8 MLS/HR	20,000 UNITS HEPARININ 40 MLS NORMAL SALINE
005-036	51/Female	Yes	ANTITHROMBOTIC AGENTS/HEPARIN/HEP ARIN	15JAN2016 08:45	CVVHDF	5.8 MLS/HR	20,000 UNITS HEPARIN IN 40 MLS NORMAL SALINE
005-036	51/Female	Yes	ANTITHROMBOTIC AGENTS/HEPARIN/HEP ARIN	15JAN2016 05:12	CVVHDF	5.8 MLS/HR	20,000 UNITS IN 40 MLS IN NORMAL SALINE
005-037	53/Female	No					
005-038		No					
007-001	61/Male	Yes	ANTITHROMBOTIC AGENTS/HEPARIN/HEP ARIN	11APR2015 08:30	CONTINUOUS VIA AQUARIUS CIRCUIT	2	MLS/HR

Data Listing 16.2.5.1. Anti-Coagulant Administration - Enrolled Population

Patient Number	Age (Years)/ Gender	Anti-Coagulant Medication Taken	ATC Term/Preferred Term/Reported Term	Date and Time of Administration	Route. Specify, if Other	Dose per Administration	Unit. Specify, if Other
007-002		Yes	ANTITHROMBOTIC AGENTS/HEPARIN/HEP ARIN	19MAY2015 17:00	CONTINUOUS VIA AQUARIUS CIRCUIT.	2	MLS/HR
007-002		Yes	ANTITHROMBOTIC AGENTS/HEPARIN/HEP ARIN	19MAY2015 23:35	CONTINUOUS VIA AQUARIUS CIRCUIT	3	MLS/HR
007-003	64/Male	Yes	ANTITHROMBOTIC AGENTS/HEPARIN/HEP ARIN	26JUN2015 09:00	CONTINUOUS VIA AQUARIUS CIRCUIT	2	MLS/HR
007-003	64/Male	Yes	ANTITHROMBOTIC AGENTS/HEPARIN/HEP ARIN	27JUN2015 05:45	CONTINUOUS VIA AQUARIUS CIRCUIT	3	MLS/HR
007-004	72/Male	Yes	ANTITHROMBOTIC AGENTS/HEPARIN/HEP ARIN	27JUN2015 17:50	CONTINUOUS VIA AQUARIUS CIRCUIT	4	MLS/HR
007-004	72/Male	Yes	ANTITHROMBOTIC AGENTS/HEPARIN/HEP ARIN	28JUN2015 04:25	CONTINUOUS VIA AQUARIUS CIRCUIT	2	MLS/HR
007-005	24/Male	No					
007-006	73/Female	Yes	ANTITHROMBOTIC AGENTS/HEPARIN/HEP ARIN	26JUL2015 20:30	CONTINUOUS VIA AQUARIUS CIRCUIT	6	MLS/HR
007-006	73/Female	Yes	ANTITHROMBOTIC AGENTS/HEPARIN/HEP ARIN	27JUL2015 06:35	CONTINUOUS VIA AQUARIUS CIRCUIT	7	MLS/HR

Data Listing 16.2.5.1. Anti-Coagulant Administration - Enrolled Population

Patient Number	Age (Years)/ Gender	Anti-Coagulant Medication Taken	ATC Term/Preferred Term/Reported Term	Date and Time of Administration	Route. Specify, if Other	Dose per Administration	Unit. Specify, if Other
007-007	83/Male	Yes	ANTITHROMBOTIC AGENTS/HEPARIN/HEP ARIN	03AUG2015 01:50	CONTINUOUS VIA AQUARIUS CIRCUIT	2	MLS/HR
007-008	79/Male	Yes	ANTITHROMBOTIC AGENTS/HEPARIN/HEP ARIN	13AUG2015 07:00	CONTINUOUS VIA AQUARIUS CIRCUIT	5	MLS/HR
007-010	70/Male	Yes	ANTITHROMBOTIC AGENTS/HEPARIN/HEP ARIN	01SEP2015 07:40	VIA AQUARIUS CIRCUIT	8	MLS/HR
007-011	64/Female	Yes	ANTITHROMBOTIC AGENTS/HEPARIN/HEP ARIN	01SEP2015 05:30	CONTINUOUS VIA AQUARIUS CIRCUIT	3	MLS/HR
007-011	64/Female	Yes	ANTITHROMBOTIC AGENTS/HEPARIN/HEP ARIN	02SEP2015 09:48	CONTINUOUS VIA AQUARIUS CIRCUIT	1	MLS/HR
007-012	36/Male	Yes	ANTITHROMBOTIC AGENTS/HEPARIN/HEP ARIN	07SEP2015 17:30	VIA CIRCUIT	5	MLS/HR
007-014	74/Female	Yes	ANTITHROMBOTIC AGENTS/HEPARIN/HEP ARIN	28SEP2015 06:40	VIA AQUARIUS CIRCUIT	4	MLS/HR
007-015	73/Female	Yes	ANTITHROMBOTIC AGENTS/HEPARIN/HEP ARIN	14DEC2015 06:50	VIA AQUARIUS CIRCUIT	1	MLS/HR

Data Listing 16.2.5.1. Anti-Coagulant Administration - Enrolled Population

Patient Number	Age (Years)/ Gender	Anti-Coagulant Medication Taken	ATC Term/Preferred Term/Reported Term	Date and Time of Administration	Route. Specify, if Other	Dose per Administration	Unit. Specify, if Other
007-015	73/Female	Yes	ANTITHROMBOTIC AGENTS/HEPARIN/HEPARIN	14DEC2015 20:45	VIA AQUARIUS CIRCUIT	2	MLS/HR
007-016	71/Male	Yes	ANTITHROMBOTIC AGENTS/HEPARIN/HEPARIN	05JAN2016 06:35	VIA CIRCUIT	4	MLS/HR
007-016	71/Male	Yes	ANTITHROMBOTIC AGENTS/HEPARIN/HEPARIN	05JAN2016 08:54	VIA CIRCUIT	5	MLS/HR
008-001	26/Male	No					
008-002	31/Male	Yes	ANTITHROMBOTIC AGENTS/DALTEPARIN/DALTEPARIN	14APR2015 21:30	SUBCUTANEOUS	2500	U/mL
008-002	31/Male	Yes	ANTITHROMBOTIC AGENTS/HEPARIN/HEPARIN	15APR2015 00:00	INTRAVENOUS	2	MLS/HR
008-002	31/Male	Yes	ANTITHROMBOTIC AGENTS/HEPARIN/HEPARIN	15APR2015 18:30	INTRAVENOUS	2.2	MLS/HR
008-002	31/Male	Yes	ANTITHROMBOTIC AGENTS/DALTEPARIN/DALTEPARIN	14APR2015 13:00	SUBCUTANEOUS	2500	U/mL
008-002	31/Male	Yes	ANTITHROMBOTIC AGENTS/HEPARIN/HEPARIN	14APR2015 13:00	INTRAVENOUS	2	MLS/HR

Data Listing 16.2.5.1. Anti-Coagulant Administration - Enrolled Population

Patient Number	Age (Years)/ Gender	Anti-Coagulant Medication Taken	ATC Term/Preferred Term/Reported Term	Date and Time of Administration	Route. Specify, if Other	Dose per Administration	Unit. Specify, if Other
008-003	25/Female	Yes	ANTITHROMBOTIC AGENTS/HEPARIN/HEPARIN	20APR2015 20:00	INTRAVENOUS	500	IU PER ML CONTINUOUS INFUSION
008-004	46/Male	Yes	ANTITHROMBOTIC AGENTS/HEPARIN/HEPARIN	06MAY2015 18:00	INTRAVENOUS	20000	2MLS PER HOUR
008-005	82/Male	Yes	ANTITHROMBOTIC AGENTS/HEPARIN/HEPARIN	22MAY2015 08:20	CONTINUOUS IV INFUSION	1.4	U/mL
008-006	70/Male	Yes	ANTITHROMBOTIC AGENTS/HEPARIN/HEPARIN	27MAY2015 18:00	INTRAVENOUS	600	UNITS /HR
008-007	74/Male	Yes	ANTITHROMBOTIC AGENTS/HEPARIN/HEPARIN	28MAY2015 17:40	INTRAVENOUS	1.4	20,000 UNITS IN 40MLS RUNNING AT 1.4MLS/HR
008-012	71/Male	No					
008-013	68/Male	No					
008-014	65/Female	No					
008-016	34/Male	No					
008-017	52/Female	Yes	ANTITHROMBOTIC AGENTS/DALTEPARIN/DALTEPARIN	21AUG2015 18:00	SUBCUTANEOUS	2500	IU

Data Listing 16.2.5.1. Anti-Coagulant Administration - Enrolled Population

Patient Number	Age (Years)/ Gender	Anti-Coagulant Medication Taken	ATC Term/Preferred Term/Reported Term	Date and Time of Administration	Route. Specify, if Other	Dose per Administration	Unit. Specify, if Other
008-018	65/Male	Yes	ANTITHROMBOTIC AGENTS/DALTEPARIN/ DALTEPARIN	05OCT2015 22:00	SUBCUTANEOUS	9000	INTERNATIONAL UNITS
008-019	69/Female	Yes	ANTITHROMBOTIC AGENTS/HEPARIN/HEPARIN	10OCT2015 01:10	INTRAVENOUS	1.2	20000 UNITS IN 40MLS OF SALINE RUNNING AS A CONTINUOUS INFUSION
008-020	60/Male	Yes	ANTITHROMBOTIC AGENTS/HEPARIN/HEPARIN	20OCT2015 11:00	INTRAVENOUS	1.6	MLS /HR
008-020	60/Male	Yes	ANTITHROMBOTIC AGENTS/HEPARIN/HEPARIN	20OCT2015 20:30	INTRAVENOUS	1.8	MLS/HR
008-020	60/Male	Yes	ANTITHROMBOTIC AGENTS/HEPARIN/HEPARIN	21OCT2015 03:54	INTRAVENOUS	2	MLS/HR
008-020	60/Male	Yes	ANTITHROMBOTIC AGENTS/HEPARIN/HEPARIN	21OCT2015 14:00	INTRAVENOUS	2.2	MLS/HR
008-021	66/Male	No					
008-022	43/Male	Yes	ANTITHROMBOTIC AGENTS/DALTEPARIN/ DALTEPARIN	21OCT2015 18:00	SUBCUTANEOUS	2500	INTERNATIONAL UNITS

Data Listing 16.2.5.1. Anti-Coagulant Administration - Enrolled Population

Patient Number	Age (Years)/ Gender	Anti-Coagulant Medication Taken	ATC Term/Preferred Term/Reported Term	Date and Time of Administration	Route. Specify, if Other	Dose per Administration	Unit. Specify, if Other
008-022	43/Male	Yes	ANTITHROMBOTIC AGENTS/HEPARIN/HEPARIN	21OCT2015 09:00	INTRAVENOUS	0.8	20000 UNITS IN 40 MLS CONTINUOUS INFUSION
008-023		No					
008-024	27/Male	Yes	ANTITHROMBOTIC AGENTS/DALTEPARIN/DALTEPARIN	27OCT2015 18:00	SUBCUTANEOUS	2500	IU
008-025	68/Male	No					
008-026	30/Female	Yes	ANTITHROMBOTIC AGENTS/HEPARIN/HEPARIN	05NOV2015 13:45	INTRAVENOUS	5.8	MLS /HR - 5000 UNITS IN 50 MLS SALINE
008-027	71/Male	No					
008-028	72/Male	Yes	ANTITHROMBOTIC AGENTS/HEPARIN/HEPARIN	30NOV2015 12:30	INTRAVENOUS	2	MLS / HR CONTINUOUS IFUSION - 20,000 UNITS IN 40MLS SALINE
008-029	66/Female	Yes	ANTITHROMBOTIC AGENTS/HEPARIN/HEPARIN	08DEC2015 23:40	INTRAVENOUS	1.2	MLS/HR - 20000 UNITS IN 40MLS CONTINUOUS INFUSION
008-030	63/Female	Yes	ANTITHROMBOTIC AGENTS/HEPARIN/HEPARIN	11JAN2016 16:50	INTRAVENOUS	3.6MLS	CONTINUOUS INFUSION 20000 UNITS IN 40 MLS

Data Listing 16.2.5.1. Anti-Coagulant Administration - Enrolled Population

Patient Number	Age (Years)/ Gender	Anti-Coagulant Medication Taken	ATC Term/Preferred Term/Reported Term	Date and Time of Administration	Route. Specify, if Other	Dose per Administration	Unit. Specify, if Other
008-030	63/Female	Yes	ANTITHROMBOTIC AGENTS/HEPARIN/HEPARIN	12JAN2016 02:55	INTRAVENOUS	3.6 MLS/HR	20000 UNITS IN 40MLS SALINE CONINUOUS INFUSION
008-030	63/Female	Yes	ANTITHROMBOTIC AGENTS/HEPARIN/HEPARIN	12JAN2016 14:00	INTRAVENOUS	3.6 MLS/HR	20000 UNITS IN 40MLS SALINE CONTINUOUS INFUSION
008-031	23/Male	Yes	ANTITHROMBOTIC AGENTS/HEPARIN/HEPARIN	27JAN2016 08:00	INTRAVENOUS	1.5MLS	CONTINUOUS INFUSION OF 20000 UNITS IN 40 MLS SALINE
008-031	23/Male	Yes	ANTITHROMBOTIC AGENTS/HEPARIN/HEPARIN	27JAN2016 20:15	INTRAVENOUS	2.1 MLS/HR	20000 UNITS IN 40 MLS SALINE CONTINUOUS INFUSION
009-001	64/Male	Yes	ANTITHROMBOTIC AGENTS/HEPARIN/HEPARIN - CONTINUOUS INFUSION	02APR2015 15:00	INTRAVENOUS	2100	UNITS PER HOUR
009-002		Yes	ANTITHROMBOTIC AGENTS/HEPARIN/HEPARIN INFUSION- VIA CRRT	09APR2015 01:00	VIA CRRT	400	UNITS PER HOUR

Data Listing 16.2.5.1. Anti-Coagulant Administration - Enrolled Population

Patient Number	Age (Years)/ Gender	Anti-Coagulant Medication Taken	ATC Term/Preferred Term/Reported Term	Date and Time of Administration	Route. Specify, if Other	Dose per Administration	Unit. Specify, if Other
009-002		Yes	ANTITHROMBOTIC AGENTS/HEPARIN/HEP ARIN - INFUSION	09APR2015 03:00	VIA CVVH	400	IU/HOUR
009-003	75/Male	Yes	ANTITHROMBOTIC AGENTS/HEPARIN/HEP ARIN INFUSION	14APR2015 11:00	VIA CRRT ONGOING INFUSION	500	UNITS PER HOUR
009-003	75/Male	Yes	ANTITHROMBOTIC AGENTS/TINZAPARIN/T INZAPARIN	14APR2015 18:00	SUBCUTANEOUS	4500	UNITS
009-003	75/Male	Yes	ANTITHROMBOTIC AGENTS/TINZAPARIN/T INZAPARIN	15APR2015 18:00	SUBCUTANEOUS	4500	UNITS
009-006	58/Female	No					
009-008	31/Male	No					
009-009		Yes	ANTITHROMBOTIC AGENTS/TINZAPARIN/T INZAPARIN	30APR2015 18:00	SUBCUTANEOUS	4500	INTERNATIONAL UNITS
009-011	75/Female	Yes	ANTITHROMBOTIC AGENTS/TINZAPARIN/T INZAPARIN	21MAY2015 06:00	SUBCUTANEOUS	4500	UNITS
009-013	60/Female	Yes	ANTITHROMBOTIC AGENTS/HEPARIN/HEP ARIN	11JUN2015 10:00	VIA CRRT	500	IU/HR

Data Listing 16.2.5.1. Anti-Coagulant Administration - Enrolled Population

Patient Number	Age (Years)/ Gender	Anti-Coagulant Medication Taken	ATC Term/Preferred Term/Reported Term	Date and Time of Administration	Route. Specify, if Other	Dose per Administration	Unit. Specify, if Other
009-013	60/Female	Yes	ANTITHROMBOTIC AGENTS/TINZAPARIN/T INZAPARIN	11JUN2015 18:00	SUBCUTANEOUS	4500	UNITS
009-013	60/Female	Yes	ANTITHROMBOTIC AGENTS/EPOPROSTENO L SODIUM/FLOLAN	11JUN2015 22:00	VIA CRRT CIRCUIT	5	NG/KG/MIN
009-015	29/Male	No					
009-016	83/Male	No					
009-017	51/Male	No					
009-018	44/Male	No					
009-019	84/Male	Yes	ANTITHROMBOTIC AGENTS/TINZAPARIN/T INZAPARIN	27JUL2015 18:00	SUBCUTANEOUS	4500	INTERNATIONAL UNITS
009-021	51/Male	No					
009-022		No					
009-024	49/Female	No					
009-026	76/Female	Yes	ANTITHROMBOTIC AGENTS/EPOPROSTENO L SODIUM/FLOLAN (EPOPROSTENOL)	07OCT2015 08:00	VIA CRRT CIRCUIT	4.5	NG/KG/MIN
009-027	53/Male	Yes	ANTITHROMBOTIC AGENTS/HEPARIN/HEP ARIN	12OCT2015 22:00	VIA CRRT CIRCUIT	300	IU/HR

Data Listing 16.2.5.1. Anti-Coagulant Administration - Enrolled Population

Patient Number	Age (Years)/ Gender	Anti-Coagulant Medication Taken	ATC Term/Preferred Term/Reported Term	Date and Time of Administration	Route. Specify, if Other	Dose per Administration	Unit. Specify, if Other
009-028		Yes	ANTITHROMBOTIC AGENTS/HEPARIN/HEPARIN	25NOV2015 21:00	VIA CRRT	200	IU/HR
009-030	75/Male	Yes	ANTITHROMBOTIC AGENTS/TINZAPARIN/TINZAPARIN	17DEC2015 18:00	SUBCUTANEOUS	4500	IU
009-030	75/Male	Yes	ANTITHROMBOTIC AGENTS/TINZAPARIN/TINZAPARIN	18DEC2015 18:00	SUBCUTANEOUS	4500	IU
009-031	34/Male	No					
009-032	59/Male	No					
010-002	57/Male	Yes	ANTITHROMBOTIC AGENTS/HEPARIN/HEPARIN	08MAY2015 09:00	VIA CVVH	49ML	200 UNITS\ML
010-002	57/Male	Yes	ANTITHROMBOTIC AGENTS/HEPARIN/HEPARIN	08MAY2015 15:00	VIA CVVH	49ML	200 UNITS\ML
010-002	57/Male	Yes	ANTITHROMBOTIC AGENTS/HEPARIN/HEPARIN	08MAY2015 21:45	VIA CVVH	46ML	200 UNITS\ML
010-002	57/Male	Yes	ANTITHROMBOTIC AGENTS/HEPARIN/HEPARIN	09MAY2015 04:30	VIA CVVH	50ML	200 UNITS\ML

Data Listing 16.2.5.1. Anti-Coagulant Administration - Enrolled Population

Patient Number	Age (Years)/ Gender	Anti-Coagulant Medication Taken	ATC Term/Preferred Term/Reported Term	Date and Time of Administration	Route. Specify, if Other	Dose per Administration	Unit. Specify, if Other
010-002	57/Male	Yes	ANTITHROMBOTIC AGENTS/HEPARIN/HEPARIN	09MAY2015 11:00	VIA CVVH	40ML	200 UNITS\ML
010-003		Yes	ANTITHROMBOTIC AGENTS/HEPARIN/HEPARIN	09MAY2015 10:00	VIA CVVH	3800	U/mL
010-005	78/Male	Yes	ANTITHROMBOTIC AGENTS/HEPARIN/HEPARIN	05JUN2015 15:00	INTRAVENOUS	28ML	200 UNITS\ML
010-005	78/Male	Yes	ANTITHROMBOTIC AGENTS/HEPARIN/HEPARIN	05JUN2015 20:00	INTRAVENOUS	43ML	200 UNITS\ML
010-005	78/Male	Yes	ANTITHROMBOTIC AGENTS/HEPARIN/HEPARIN	06JUN2015 05:30	INTRAVENOUS	49ML	200 UNITS\ML
010-005	78/Male	Yes	ANTITHROMBOTIC AGENTS/HEPARIN/HEPARIN	06JUN2015 14:30	INTRAVENOUS	49ML	200 UNITS\ML
010-005	78/Male	Yes	ANTITHROMBOTIC AGENTS/HEPARIN/HEPARIN	06JUN2015 22:00	INTRAVENOUS	5ML	200 UNITS\ML
010-006	80/Male	Yes	ANTITHROMBOTIC AGENTS/HEPARIN/HEPARIN	11JUN2015 15:00	INTRAVENOUS	37.5ML	200 UNITS\ML

Data Listing 16.2.5.1. Anti-Coagulant Administration - Enrolled Population

Patient Number	Age (Years)/ Gender	Anti-Coagulant Medication Taken	ATC Term/Preferred Term/Reported Term	Date and Time of Administration	Route. Specify, if Other	Dose per Administration	Unit. Specify, if Other
010-006	80/Male	Yes	ANTITHROMBOTIC AGENTS/HEPARIN/HEP ARIN	12JUN2015 00:30	INTRAVENOUS	35.5ML	200 UNITS\ML
010-006	80/Male	Yes	ANTITHROMBOTIC AGENTS/HEPARIN/HEP ARIN	12JUN2015 12:30	INTRAVENOUS	30ML	200 UNITS\ML
010-008	70/Female	Yes	ANTITHROMBOTIC AGENTS/HEPARIN/HEP ARIN	28JUN2015 21:00	SYRINGE DRIVER/HAEMOF ILTER	22ML	200 UNITS\ML
010-009	69/Male	Yes	ANTITHROMBOTIC AGENTS/HEPARIN/HEP ARIN	28JUN2015 20:00	CVVH	4ML	200 UNITS\ML
010-009	69/Male	Yes	ANTITHROMBOTIC AGENTS/HEPARIN/HEP ARIN	28JUN2015 21:00	VIA CVVH	4ML	200 UNITS\ML
010-010	52/Female	No					
010-011		No					
010-014	79/Female	Yes	ANTITHROMBOTIC AGENTS/HEPARIN/HEP ARIN	12JAN2016 12:00	VIA CVVH	47ML	200 UNITS\ML
010-014	79/Female	Yes	ANTITHROMBOTIC AGENTS/HEPARIN/HEP ARIN	12JAN2016 19:00	VIA CVVH	4ML	200 UNITS\ML

Data Listing 16.2.5.1. Anti-Coagulant Administration - Enrolled Population

Patient Number	Age (Years)/ Gender	Anti-Coagulant Medication Taken	ATC Term/Preferred Term/Reported Term	Date and Time of Administration	Route. Specify, if Other	Dose per Administration	Unit. Specify, if Other
011-001	53/Male	Yes	ANTITHROMBOTIC AGENTS/HEPARIN/HEP ARIN	30APR2015 09:40	INTRAVENOUS	1	ML/HR
011-002	75/Male	Yes	ANTITHROMBOTIC AGENTS/HEPARIN SODIUM/HEPARIN SODIUM	30APR2015 07:00	INTRAVENOUS	4	ML/HR
011-002	75/Male	Yes	ANTITHROMBOTIC AGENTS/HEPARIN SODIUM/HEPARIN SODIUM	30APR2015 09:00	INTRAVENOUS	5	ML/HR
011-003	80/Male	Yes	ANTITHROMBOTIC AGENTS/HEPARIN/HEP ARIN	04JUN2015 14:45	INTRAVENOUS	1	ML/HR
011-004	80/Female	Yes	ANTITHROMBOTIC AGENTS/HEPARIN SODIUM/HEPARIN SODIUM	09JUN2015 07:00	INTRAVENOUS	2	ML/HR
011-004	80/Female	Yes	ANTITHROMBOTIC AGENTS/HEPARIN SODIUM/HEPARIN SODIUM	09JUN2015 14:00	INTRAVENOUS	3	ML/HR

Data Listing 16.2.5.1. Anti-Coagulant Administration - Enrolled Population

Patient Number	Age (Years)/ Gender	Anti-Coagulant Medication Taken	ATC Term/Preferred Term/Reported Term	Date and Time of Administration	Route. Specify, if Other	Dose per Administration	Unit. Specify, if Other
011-004	80/Female	Yes	ANTITHROMBOTIC AGENTS/EPOPROSTENO L SODIUM/EPOPROSTENO L (FLOLAN)	10JUN2015 14:10	INTRAVENOUS	5	NG/KG/MIN
011-005	78/Male	No					
011-006	77/Male	Yes	ANTITHROMBOTIC AGENTS/HEPARIN SODIUM/HEPARIN SODIUM	04JUL2015 12:30	INTRAVENOUS	1	ML/HR
011-007	62/Female	Yes	ANTITHROMBOTIC AGENTS/HEPARIN SODIUM/HEPARIN SODIUM	02OCT2015 05:00	INTRAVENOUS	1	ML/HR
011-008	61/Male	Yes	ANTITHROMBOTIC AGENTS/HEPARIN SODIUM/HEPARIN SODIUM	05OCT2015 10:00	INTRAVENOUS	2.5	ML/HR
011-009	71/Female	Yes	ANTITHROMBOTIC AGENTS/EPOPROSTENO L/EPOPROSTENOL	06OCT2015 18:00	INTRAVENOUS	5	NG/KG/MIN
011-010	47/Male	Yes	ANTITHROMBOTIC AGENTS/EPOPROSTENO L SODIUM/EPOPROSTENO L (FLOLAN)	12OCT2015 10:50	INTRAVENOUS	5	NG/KG/MIN

Data Listing 16.2.5.1. Anti-Coagulant Administration - Enrolled Population

Patient Number	Age (Years)/ Gender	Anti-Coagulant Medication Taken	ATC Term/Preferred Term/Reported Term	Date and Time of Administration	Route. Specify, if Other	Dose per Administration	Unit. Specify, if Other
011-011	77/Male	Yes	ANTITHROMBOTIC AGENTS/HEPARIN SODIUM/HEPARIN SODIUM	15OCT2015 09:00	INTRAVENOUS	4	ML/HR
011-011	77/Male	Yes	ANTITHROMBOTIC AGENTS/HEPARIN SODIUM/HEPARIN SODIUM	15OCT2015 10:00	INTRAVENOUS	1.5	ML/HR
011-011	77/Male	Yes	ANTITHROMBOTIC AGENTS/HEPARIN SODIUM/HEPARIN SODIUM	15OCT2015 18:00	INTRAVENOUS	3	ML/HR
011-011	77/Male	Yes	ANTITHROMBOTIC AGENTS/HEPARIN SODIUM/HEPARIN SODIUM	16OCT2015 10:00	INTRAVENOUS	4	ML/HR
011-012	74/Male	Yes	ANTITHROMBOTIC AGENTS/HEPARIN SODIUM/HEPARIN SODIUM	20OCT2015 03:45	INTRAVENOUS	2.5	ML/HR
011-012	74/Male	Yes	ANTITHROMBOTIC AGENTS/HEPARIN SODIUM/HEPARIN SODIUM	20OCT2015 10:00	INTRAVENOUS	3	ML/HR

Data Listing 16.2.5.1. Anti-Coagulant Administration - Enrolled Population

Patient Number	Age (Years)/ Gender	Anti-Coagulant Medication Taken	ATC Term/Preferred Term/Reported Term	Date and Time of Administration	Route. Specify, if Other	Dose per Administration	Unit. Specify, if Other
011-012	74/Male	Yes	ANTITHROMBOTIC AGENTS/HEPARIN SODIUM/HEPARIN SODIUM	20OCT2015 19:00	INTRAVENOUS	2.5	ML/HR
011-013	71/Female	Yes	ANTITHROMBOTIC AGENTS/HEPARIN SODIUM/HEPARIN SODIUM	26OCT2015 17:00	INTRAVENOUS	1	ML/HR
011-013	71/Female	Yes	ANTITHROMBOTIC AGENTS/HEPARIN SODIUM/HEPARIN SODIUM	26OCT2015 19:00	INTRAVENOUS	0.5	ML/HR
011-013	71/Female	Yes	ANTITHROMBOTIC AGENTS/HEPARIN SODIUM/HEPARIN SODIUM	27OCT2015 11:00	INTRAVENOUS	1	ML/HR
011-013	71/Female	Yes	ANTITHROMBOTIC AGENTS/HEPARIN SODIUM/HEPARIN SODIUM	27OCT2015 18:00	INTRAVENOUS	1.5	ML/HR
011-014	79/Female	Yes	ANTITHROMBOTIC AGENTS/EPOPROSTENO L SODIUM/EPOPROSTENO L (FLOLAN)	03NOV2015 19:00	INTRAVENOUS	5	NG/KG/MIN

Data Listing 16.2.5.1. Anti-Coagulant Administration - Enrolled Population

Patient Number	Age (Years)/ Gender	Anti-Coagulant Medication Taken	ATC Term/Preferred Term/Reported Term	Date and Time of Administration	Route. Specify, if Other	Dose per Administration	Unit. Specify, if Other
011-015	77/Female	Yes	ANTITHROMBOTIC AGENTS/HEPARIN SODIUM/HEPARIN SODIUM	21NOV2015 08:56	INTRAVENOUS	4	ML/HR
011-015	77/Female	Yes	ANTITHROMBOTIC AGENTS/HEPARIN SODIUM/HEPARIN SODIUM	21NOV2015 09:00	INTRAVENOUS	3.5	ML/HR
011-015	77/Female	Yes	ANTITHROMBOTIC AGENTS/HEPARIN SODIUM/HEPARIN SODIUM	21NOV2015 16:00	INTRAVENOUS	3	ML/HR
011-015	77/Female	Yes	ANTITHROMBOTIC AGENTS/HEPARIN SODIUM/HEPARIN SODIUM	21NOV2015 20:00	INTRAVENOUS	2.5	ML/HR
011-016	72/Female	Yes	ANTITHROMBOTIC AGENTS/HEPARIN SODIUM/HEPARIN SODIUM	09JAN2016 07:30	INTRAVENOUS	1.5	ML/HR
011-016	72/Female	Yes	ANTITHROMBOTIC AGENTS/HEPARIN SODIUM/HEPARIN SODIUM	09JAN2016 15:00	INTRAVENOUS	2	ML/HR

Data Listing 16.2.5.1. Anti-Coagulant Administration - Enrolled Population

Patient Number	Age (Years)/ Gender	Anti-Coagulant Medication Taken	ATC Term/Preferred Term/Reported Term	Date and Time of Administration	Route. Specify, if Other	Dose per Administration	Unit. Specify, if Other
011-016	72/Female	Yes	ANTITHROMBOTIC AGENTS/HEPARIN SODIUM/HEPARIN SODIUM	10JAN2016 04:00	INTRAVENOUS	1.5	ML/HR
012-001	59/Male	Yes	ANTITHROMBOTIC AGENTS/HEPARIN/HEP ARIN	01APR2015 16:45	VIA FILTER	0.4	MLS/HR
012-001	59/Male	Yes	ANTITHROMBOTIC AGENTS/HEPARIN/HEP ARIN	02APR2015 16:20	VIA FILTER	0.45	MLS/HR
012-002	67/Male	No					
012-003	63/Male	Yes	ANTITHROMBOTIC AGENTS/HEPARIN/HEP ARIN	17APR2015	VIA CVVH	0.85	U/mL
012-004	59/Female	Yes	ANTITHROMBOTIC AGENTS/EPOPROSTENO L/EPOPROSTENOL	20JUL2015 10:00	VIA FILTER	4	NANOGRAMS/KG /MINUTE
012-005	41/Male	Yes	ANTITHROMBOTIC AGENTS/HEPARIN/HEP ARIN	28JUL2015 00:45	VIA FILTER	1,000	U/mL
012-005	41/Male	Yes	ANTITHROMBOTIC AGENTS/HEPARIN/HEP ARIN	28JUL2015 10:00	VIA FILTER	1,000	U/mL

Data Listing 16.2.5.1. Anti-Coagulant Administration - Enrolled Population

Patient Number	Age (Years)/ Gender	Anti-Coagulant Medication Taken	ATC Term/Preferred Term/Reported Term	Date and Time of Administration	Route. Specify, if Other	Dose per Administration	Unit. Specify, if Other
012-005	41/Male	Yes	ANTITHROMBOTIC AGENTS/HEPARIN/HEP ARIN	28JUL2015 18:00	VIA FILTER	1,000	U/mL
012-005	41/Male	Yes	ANTITHROMBOTIC AGENTS/HEPARIN/HEP ARIN	29JUL2015 01:45	VIA FILTER	1,000	U/mL
012-005	41/Male	Yes	ANTITHROMBOTIC AGENTS/HEPARIN/HEP ARIN	27JUL2015 23:15	VIA FILTER	1,000	U/mL
012-006	44/Male	Yes	ANTITHROMBOTIC AGENTS/HEPARIN/HEP ARIN	30AUG2015 19:30	VIA CVVH	1.25	MLS/HR
012-006	44/Male	Yes	ANTITHROMBOTIC AGENTS/HEPARIN/HEP ARIN	31AUG2015 03:20	VIA CVVH	1.4	MLS/HR
012-007	82/Male	Yes	ANTITHROMBOTIC AGENTS/HEPARIN/HEP ARIN	11OCT2015 13:15	VIA FILTER	1000	U/mL
012-008	59/Male	Yes	ANTITHROMBOTIC AGENTS/HEPARIN/HEP ARIN	17OCT2015 07:00	VIA CVVH	1000	U/mL
012-009	70/Male	Yes	ANTITHROMBOTIC AGENTS/HEPARIN/HEP ARIN	05NOV2015 05:30	VIA FILTER	1,000	U/mL

Data Listing 16.2.5.1. Anti-Coagulant Administration - Enrolled Population

Patient Number	Age (Years)/ Gender	Anti-Coagulant Medication Taken	ATC Term/Preferred Term/Reported Term	Date and Time of Administration	Route. Specify, if Other	Dose per Administration	Unit. Specify, if Other
012-010	72/Male	Yes	ANTITHROMBOTIC AGENTS/HEPARIN/HEP ARIN	06NOV2015 10:00	VIA FILTER	1,000	U/mL
012-011	58/Female	Yes	ANTITHROMBOTIC AGENTS/HEPARIN/HEP ARIN	16DEC2015 20:45	VIA CVVH	1,000	U/mL
012-011	58/Female	Yes	ANTITHROMBOTIC AGENTS/HEPARIN/HEP ARIN	17DEC2015 15:50	VIA CVVH	1,000	U/mL
012-012	69/Male	Yes	ANTITHROMBOTIC AGENTS/HEPARIN/HEP ARIN	15JAN2016 10:00	VIA FILTER	1,000	U/mL
012-012	69/Male	Yes	ANTITHROMBOTIC AGENTS/HEPARIN/HEP ARIN	16JAN2016 17:30	VIA FILTER	1,000	U/mL
012-013	77/Female	Yes	ANTITHROMBOTIC AGENTS/HEPARIN/HEP ARIN	19JAN2016 18:15	VIA FILTER	1,000	U/mL
013-002	70/Male	Yes	ANTITHROMBOTIC AGENTS/EPOPROSTENO L/EPOPROSTENOL	01JUL2015 06:00	INTRAVENOUS	2.7	NG/KG/MIN
013-002	70/Male	Yes	ANTITHROMBOTIC AGENTS/EPOPROSTENO L/EPOPROSTENOL	01JUL2015 18:39	INTRAVENOUS	2.7	NG/KG/MIN

Data Listing 16.2.5.1. Anti-Coagulant Administration - Enrolled Population

Patient Number	Age (Years)/ Gender	Anti-Coagulant Medication Taken	ATC Term/Preferred Term/Reported Term	Date and Time of Administration	Route. Specify, if Other	Dose per Administration	Unit. Specify, if Other
013-003	69/Male	Yes	ANTITHROMBOTIC AGENTS/TIROFIBAN/TI ROFIBAN	29JUL2015 15:00	INTRAVENOUS	0.08	MCG/KG/MIN
013-004	64/Female	Yes	ANTITHROMBOTIC AGENTS/HEPARIN/HEP ARIN	09SEP2015 04:00	INTRAVENOUS	1500	IU/HR
013-005		Yes	ANTITHROMBOTIC AGENTS/EPOPROSTENO L SODIUM/FLOLAN	17SEP2015 13:00	INTRAVENOUS	4.59	NG/KG/MIN
013-005		Yes	ANTITHROMBOTIC AGENTS/EPOPROSTENO L SODIUM/FLOLAN	18SEP2015 17:40	INTRAVENOUS	4.63	NG/KG/MIN
013-010	76/Female	Yes	ANTITHROMBOTIC AGENTS/HEPARIN/HEP ARIN	05DEC2015 07:00	INTRAVENOUS	14	IU/KG/HR
014-001	75/Female	Yes	ANTITHROMBOTIC AGENTS/HEPARIN/HEP ARIN	18APR2015 19:05	VIA FILTER	1,000	U/mL
014-001	75/Female	Yes	ANTITHROMBOTIC AGENTS/HEPARIN/HEP ARIN	18APR2015 00:40	VIA FILTER	1,000	U/mL
014-002	47/Male	Yes	ANTITHROMBOTIC AGENTS/HEPARIN/HEP ARIN	28APR2015 21:00	VIA FILTER	750	UNITS/HOUR

Data Listing 16.2.5.1. Anti-Coagulant Administration - Enrolled Population

Patient Number	Age (Years)/ Gender	Anti-Coagulant Medication Taken	ATC Term/Preferred Term/Reported Term	Date and Time of Administration	Route. Specify, if Other	Dose per Administration	Unit. Specify, if Other
014-003	63/Female	Yes	ANTITHROMBOTIC AGENTS/EPOPROSTENO L/EPOPROSTENAL	12JUN2015 17:30	VIA CVVH	1.25	NG/KG/MIN
014-004	33/Female	No					
014-007	34/Female	No					
015-001	77/Female	Yes	ANTITHROMBOTIC AGENTS/HEPARIN/HEP ARIN	27APR2015 13:00	INTRAVENOUS	4000	UNITS
015-001	77/Female	Yes	ANTITHROMBOTIC AGENTS/HEPARIN/HEP ARIN	27APR2015 20:00	INTRAVENOUS	19,770	UNITS
015-002	60/Male	Yes	ANTITHROMBOTIC AGENTS/HEPARIN/HEP ARIN	24MAY2015 19:00	INTRAVENOUS	3600	UNITS
015-002	60/Male	Yes	ANTITHROMBOTIC AGENTS/DALTEPARIN SODIUM/FRAGMIN	24MAY2015 19:30	SUBCUTANEOUS	5000	UNITS
015-002	60/Male	Yes	ANTITHROMBOTIC AGENTS/HEPARIN/HEP ARIN	25MAY2015 01:00	INTRAVENOUS	5000	UNITS
015-002	60/Male	Yes	ANTITHROMBOTIC AGENTS/DALTEPARIN SODIUM/FRAGMIN	25MAY2015 08:00	SUBCUTANEOUS	5000	UNITS

Data Listing 16.2.5.1. Anti-Coagulant Administration - Enrolled Population

Patient Number	Age (Years)/ Gender	Anti-Coagulant Medication Taken	ATC Term/Preferred Term/Reported Term	Date and Time of Administration	Route. Specify, if Other	Dose per Administration	Unit. Specify, if Other
015-002	60/Male	Yes	ANTITHROMBOTIC AGENTS/HEPARIN/HEP ARIN	25MAY2015 08:00	INTRAVENOUS	5000	UNITS
015-002	60/Male	Yes	ANTITHROMBOTIC AGENTS/HEPARIN/HEP ARIN	25MAY2015 23:00	INTRAVENOUS	2800	UNITS
015-003	57/Male	Yes	ANTITHROMBOTIC AGENTS/HEPARIN/HEP ARIN	29MAY2015 05:40	INTRAVENOUS	3900	UNITS
015-003	57/Male	Yes	ANTITHROMBOTIC AGENTS/HEPARIN/HEP ARIN	29MAY2015 12:00	INTRAVENOUS	4070	UNITS
015-004	85/Male	Yes	ANTITHROMBOTIC AGENTS/HEPARIN/HEP ARIN	20JUN2015 07:30	INTRAVENOUS	1375	UNITS
015-004	85/Male	Yes	ANTITHROMBOTIC AGENTS/HEPARIN/HEP ARIN	20JUN2015 13:10	INTRAVENOUS	1167	UNITS
015-004	85/Male	Yes	ANTITHROMBOTIC AGENTS/HEPARIN/HEP ARIN	20JUN2015 15:30	INTRAVENOUS	5000	UNITS
015-004	85/Male	Yes	ANTITHROMBOTIC AGENTS/HEPARIN/HEP ARIN	21JUN2015 02:20	INTRAVENOUS	5000	UNITS

Data Listing 16.2.5.1. Anti-Coagulant Administration - Enrolled Population

Patient Number	Age (Years)/ Gender	Anti-Coagulant Medication Taken	ATC Term/Preferred Term/Reported Term	Date and Time of Administration	Route. Specify, if Other	Dose per Administration	Unit. Specify, if Other
015-004	85/Male	Yes	ANTITHROMBOTIC AGENTS/HEPARIN/HEP ARIN	21JUN2015 14:00	INTRAVENOUS	1000	UNITS
015-005	76/Male	Yes	ANTITHROMBOTIC AGENTS/HEPARIN/HEP ARIN	06JUL2015 19:13	INTRAVENOUS	10,000	UNITS
015-005	76/Male	Yes	ANTITHROMBOTIC AGENTS/HEPARIN/HEP ARIN	07JUL2015 04:28	INTRAVENOUS	9600	UNITS
015-006	84/Female	Yes	ANTITHROMBOTIC AGENTS/HEPARIN/HEP ARIN	15AUG2015 08:20	INTRAVENOUS	4625	IU
015-006	84/Female	Yes	ANTITHROMBOTIC AGENTS/HEPARIN/HEP ARIN	15AUG2015 07:10	INTRAVENOUS	175	IU
015-009	76/Female	Yes	ANTITHROMBOTIC AGENTS/HEPARIN/HEP ARIN	06JAN2016 19:45	INTRAVENOUS	690	IU
015-009	76/Female	Yes	ANTITHROMBOTIC AGENTS/HEPARIN/HEP ARIN	06JAN2016 20:30	INTRAVENOUS	5000	IU
015-009	76/Female	Yes	ANTITHROMBOTIC AGENTS/HEPARIN/HEP ARIN	07JAN2016 02:10	INTRAVENOUS	5000	IU

Data Listing 16.2.5.1. Anti-Coagulant Administration - Enrolled Population

Patient Number	Age (Years)/ Gender	Anti-Coagulant Medication Taken	ATC Term/Preferred Term/Reported Term	Date and Time of Administration	Route. Specify, if Other	Dose per Administration	Unit. Specify, if Other
015-009	76/Female	Yes	ANTITHROMBOTIC AGENTS/HEPARIN/HEP ARIN	07JAN2016 07:05	INTRAVENOUS	5000	IU
015-009	76/Female	Yes	ANTITHROMBOTIC AGENTS/HEPARIN/HEP ARIN	07JAN2016 11:30	INTRAVENOUS	5000	IU
015-009	76/Female	Yes	ANTITHROMBOTIC AGENTS/HEPARIN/HEP ARIN	07JAN2016 16:30	INTRAVENOUS	5000	IU
015-009	76/Female	Yes	ANTITHROMBOTIC AGENTS/HEPARIN/HEP ARIN	07JAN2016 21:30	INTRAVENOUS	5000	IU
015-009	76/Female	Yes	ANTITHROMBOTIC AGENTS/HEPARIN/HEP ARIN	08JAN2016 01:40	INTRAVENOUS	2542	IU
015-010		Yes	ANTITHROMBOTIC AGENTS/HEPARIN/HEP ARIN	10JAN2016 14:15	INTRAVENOUS	2475	IU
015-010		Yes	ANTITHROMBOTIC AGENTS/HEPARIN/HEP ARIN	10JAN2016 16:30	INTRAVENOUS	5000	IU
015-010		Yes	ANTITHROMBOTIC AGENTS/HEPARIN/HEP ARIN	10JAN2016 20:00	SUBCUTANEOUS	5000	IU

Data Listing 16.2.5.1. Anti-Coagulant Administration - Enrolled Population

Patient Number	Age (Years)/ Gender	Anti-Coagulant Medication Taken	ATC Term/Preferred Term/Reported Term	Date and Time of Administration	Route. Specify, if Other	Dose per Administration	Unit. Specify, if Other
015-010		Yes	ANTITHROMBOTIC AGENTS/HEPARIN/HEPARIN	10JAN2016 22:00	INTRAVENOUS	5000	IU
015-010		Yes	ANTITHROMBOTIC AGENTS/HEPARIN/HEPARIN	11JAN2016 02:05	INTRAVENOUS	5000	IU
015-010		Yes	ANTITHROMBOTIC AGENTS/HEPARIN/HEPARIN	11JAN2016 06:25	INTRAVENOUS	5000	IU
015-010		Yes	ANTITHROMBOTIC AGENTS/HEPARIN/HEPARIN	11JAN2016 08:00	SUBCUTANEOUS	5000	IU
015-011		Yes	ANTITHROMBOTIC AGENTS/HEPARIN/HEPARIN	23JAN2016 09:30	INTRAVENOUS	1662.5	IU
016-002		Yes	ANTITHROMBOTIC AGENTS/HEPARIN/HEPARIN	04SEP2015 11:10	CVVHDF	600	UNITS/HR
016-004	55/Male	No					
017-003	92/Female	Yes	ANTITHROMBOTIC AGENTS/HEPARIN/HEPARIN	13JUL2015 18:00	VIA CIRCUIT	1000	U/mL
017-004	74/Male	Yes	ANTITHROMBOTIC AGENTS/HEPARIN/HEPARIN	18JUL2015 09:30	VIA CVVH	1000	U/mL

Data Listing 16.2.5.1. Anti-Coagulant Administration - Enrolled Population

Patient Number	Age (Years)/ Gender	Anti-Coagulant Medication Taken	ATC Term/Preferred Term/Reported Term	Date and Time of Administration	Route. Specify, if Other	Dose per Administration	Unit. Specify, if Other
017-005	77/Male	Yes	ANTITHROMBOTIC AGENTS/HEPARIN/HEP ARIN	13AUG2015 18:45	VIA CIRCUIT	2	ML/HR
017-007	66/Male	Yes	ANTITHROMBOTIC AGENTS/HEPARIN/HEP ARIN	02SEP2015 07:30	INTRAVENOUS	2.5	ML/HR
017-007	66/Male	Yes	ANTITHROMBOTIC AGENTS/HEPARIN/HEP ARIN	02SEP2015 08:30	INTRAVENOUS	2	ML/HR
017-007	66/Male	Yes	ANTITHROMBOTIC AGENTS/HEPARIN/HEP ARIN	02SEP2015 17:10	INTRAVENOUS	1.5	ML/HR
017-008		Yes	ANTITHROMBOTIC AGENTS/HEPARIN/HEP ARIN	26SEP2015 16:24	VIA CIRCUIT	1	ML/HR
017-008		Yes	ANTITHROMBOTIC AGENTS/HEPARIN/HEP ARIN	26SEP2015 18:15	VIA CIRCUIT	1	ML/HR
017-008		Yes	ANTITHROMBOTIC AGENTS/HEPARIN/HEP ARIN	27SEP2015 00:00	VIA CIRCUIT	1.5	ML/HR
017-008		Yes	ANTITHROMBOTIC AGENTS/HEPARIN/HEP ARIN	27SEP2015 01:00	VIA CIRCUIT	0.5	ML/HR

Data Listing 16.2.5.1. Anti-Coagulant Administration - Enrolled Population

Patient Number	Age (Years)/ Gender	Anti-Coagulant Medication Taken	ATC Term/Preferred Term/Reported Term	Date and Time of Administration	Route. Specify, if Other	Dose per Administration	Unit. Specify, if Other
017-008		Yes	ANTITHROMBOTIC AGENTS/HEPARIN/HEPARIN	27SEP2015 04:00	VIA CIRCUIT	1	ML/HR
017-010	54/Male	Yes	ANTITHROMBOTIC AGENTS/HEPARIN/HEPARIN	19NOV2015 14:45	VIA CRRT CIRCUIT	1.5	MLS/HR
017-010	54/Male	Yes	ANTITHROMBOTIC AGENTS/HEPARIN/HEPARIN	19NOV2015 18:00	VIA CRRT CIRCUIT	2	MLS/HR
017-010	54/Male	Yes	ANTITHROMBOTIC AGENTS/HEPARIN/HEPARIN	19NOV2015 20:00	VIA CRRT CIRCUIT	2.5	MLS/HR
017-010	54/Male	Yes	ANTITHROMBOTIC AGENTS/HEPARIN/HEPARIN	20NOV2015 03:00	VIA CRRT CIRCUIT	2	MLS/HR
017-010	54/Male	Yes	ANTITHROMBOTIC AGENTS/HEPARIN/HEPARIN	20NOV2015 09:00	VIA CRRT CIRCUIT	2.5	MLS/HR
017-011	49/Male	Yes	ANTITHROMBOTIC AGENTS/HEPARIN/HEPARIN	22NOV2015 09:00	VIA CIRCUIT	1	MLS/HR
017-011	49/Male	Yes	ANTITHROMBOTIC AGENTS/HEPARIN/HEPARIN	22NOV2015 11:00	VIA CIRCUIT	1.5	MLS/HR

Data Listing 16.2.5.1. Anti-Coagulant Administration - Enrolled Population

Patient Number	Age (Years)/ Gender	Anti-Coagulant Medication Taken	ATC Term/Preferred Term/Reported Term	Date and Time of Administration	Route. Specify, if Other	Dose per Administration	Unit. Specify, if Other
017-011	49/Male	Yes	ANTITHROMBOTIC AGENTS/HEPARIN/HEPARIN	22NOV2015 16:00	VIA CIRCUIT	0.5	MLS/HR
017-011	49/Male	Yes	ANTITHROMBOTIC AGENTS/HEPARIN/HEPARIN	22NOV2015 18:00	VIA CIRCUIT	1	MLS/HR
017-011	49/Male	Yes	ANTITHROMBOTIC AGENTS/HEPARIN/HEPARIN	22NOV2015 19:00	VIA CIRCUIT	0.5	MLS/HR
017-011	49/Male	Yes	ANTITHROMBOTIC AGENTS/HEPARIN/HEPARIN	23NOV2015 01:00	VIA CIRCUIT	1	MLS/HR
017-011	49/Male	Yes	ANTITHROMBOTIC AGENTS/HEPARIN/HEPARIN	23NOV2015 04:00	VIA CIRCUIT	1.5	MLS/HR
017-011	49/Male	Yes	ANTITHROMBOTIC AGENTS/HEPARIN/HEPARIN	23NOV2015 09:00	VIA CIRCUIT	1.5	MLS/HR
017-011	49/Male	Yes	ANTITHROMBOTIC AGENTS/HEPARIN/HEPARIN	23NOV2015 10:00	VIA CIRCUIT	0.5	MLS/HR
017-011	49/Male	Yes	ANTITHROMBOTIC AGENTS/HEPARIN/HEPARIN	23NOV2015 14:00	VIA CIRCUIT	1	MLS/HR

Data Listing 16.2.5.2. Potassium Chloride Administration - Enrolled population

Patient Number	Age (Years)/ Gender	Did the Patient have any additional Potassium Chloride added to their Dialysate fluid?	ATC Term/Preferred Term/ Reported Term	Date and Time of Administration	Concentration	Unit
001-001	57/Female	No				
001-002	50/Male	No				
001-003	68/Female	No				
001-004	78/Female	No				
001-005	33/Female	No				
001-006		No				
001-007	56/Male	No				
001-008	57/Male	No				
002-002	56/Male	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHORIDE	26APR2015 02:25	4	mmol/L
002-002	56/Male	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	26APR2015 02:25	4	mmol/L
002-002	56/Male	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	26APR2015 02:25	4	mmol/L

Data Listing 16.2.5.2. Potassium Chloride Administration - Enrolled population

Patient Number	Age (Years)/ Gender	Did the Patient have any additional Potassium Chloride added to their Dialysate fluid?	ATC Term/Preferred Term/ Reported Term	Date and Time of Administration	Concentration	Unit
002-002	56/Male	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	26APR2015 07:55	4	mmol/L
002-002	56/Male	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	26APR2015 07:55	4	mmol/L
002-002	56/Male	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	26APR2015 07:55	4	mmol/L
002-002	56/Male	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	26APR2015 17:15	4	mmol/L
002-002	56/Male	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	26APR2015 17:15	4	mmol/L

Data Listing 16.2.5.2. Potassium Chloride Administration - Enrolled population

Patient Number	Age (Years)/ Gender	Did the Patient have any additional Potassium Chloride added to their Dialysate fluid?	ATC Term/Preferred Term/ Reported Term	Date and Time of Administration	Concentration	Unit
002-002	56/Male	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	26APR2015 17:15	4	mmol/L
002-002	56/Male	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	27APR2015 01:00	4	mmol/L
002-002	56/Male	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	27APR2015 01:00	4	mmol/L
002-003	68/Female	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	05MAY2015 01:20	4	mmol/L
002-005	44/Male	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	15MAY2015 10:30	4	mmol/L

Data Listing 16.2.5.2. Potassium Chloride Administration - Enrolled population

Patient Number	Age (Years)/ Gender	Did the Patient have any additional Potassium Chloride added to their Dialysate fluid?	ATC Term/Preferred Term/ Reported Term	Date and Time of Administration	Concentration	Unit
002-005	44/Male	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	15MAY2015 10:30	4	mmol/L
002-005	44/Male	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	15MAY2015 10:30	4	mmol/L
002-005	44/Male	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	15MAY2015 15:20	4	mmol/L
002-005	44/Male	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	15MAY2015 15:20	4	mmol/L
002-005	44/Male	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	15MAY2015 15:20	4	mmol/L

Data Listing 16.2.5.2. Potassium Chloride Administration - Enrolled population

Patient Number	Age (Years)/ Gender	Did the Patient have any additional Potassium Chloride added to their Dialysate fluid?	ATC Term/Preferred Term/ Reported Term	Date and Time of Administration	Concentration	Unit
002-005	44/Male	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	15MAY2015 21:05	4	mmol/L
002-005	44/Male	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	15MAY2015 21:05	4	mmol/L
002-005	44/Male	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	15MAY2015 21:05	4	mmol/L
002-005	44/Male	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	16MAY2015 02:45	4	mmol/L
002-005	44/Male	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	16MAY2015 02:45	4	mmol/L

Data Listing 16.2.5.2. Potassium Chloride Administration - Enrolled population

Patient Number	Age (Years)/ Gender	Did the Patient have any additional Potassium Chloride added to their Dialysate fluid?	ATC Term/Preferred Term/ Reported Term	Date and Time of Administration	Concentration	Unit
002-005	44/Male	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	16MAY2015 04:00	4	mmol/L
002-005	44/Male	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	16MAY2015 02:45	4	mmol/L
002-005	44/Male	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	16MAY2015 04:00	4	mmol/L
002-005	44/Male	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	16MAY2015 04:00	4	mmol/L
002-005	44/Male	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	16MAY2015 13:40	4	mmol/L

Data Listing 16.2.5.2. Potassium Chloride Administration - Enrolled population

Patient Number	Age (Years)/ Gender	Did the Patient have any additional Potassium Chloride added to their Dialysate fluid?	ATC Term/Preferred Term/ Reported Term	Date and Time of Administration	Concentration	Unit
002-005	44/Male	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	16MAY2015 13:40	4	mmol/L
002-005	44/Male	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	16MAY2015 13:40	4	mmol/L
002-007	61/Male	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	24JUN2015 15:22	4	mmol/L
002-007	61/Male	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	24JUN2015 15:22	4	mmol/L
002-009	58/Female	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	19JUN2015 12:50	UNK	UNK

Data Listing 16.2.5.2. Potassium Chloride Administration - Enrolled population

Patient Number	Age (Years)/ Gender	Did the Patient have any additional Potassium Chloride added to their Dialysate fluid?	ATC Term/Preferred Term/ Reported Term	Date and Time of Administration	Concentration	Unit
002-009	58/Female	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	20JUN2015 13:15	4	mmol/L
002-011	63/Female	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	20AUG2015 07:00	4	mmol/L
002-011	63/Female	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	20AUG2015 07:00	4	mmol/L
002-011	63/Female	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	20AUG2015 07:00	4	mmol/L
002-011	63/Female	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	20AUG2015 13:15	4	mmol/L

Data Listing 16.2.5.2. Potassium Chloride Administration - Enrolled population

Patient Number	Age (Years)/ Gender	Did the Patient have any additional Potassium Chloride added to their Dialysate fluid?	ATC Term/Preferred Term/ Reported Term	Date and Time of Administration	Concentration	Unit
002-011	63/Female	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	20AUG2015 13:15	4	mmol/L
002-011	63/Female	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	20AUG2015 13:15	4	mmol/L
002-011	63/Female	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	20AUG2015 22:00	4	mmol/L
002-011	63/Female	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	20AUG2015 22:00	4	mmol/L
002-011	63/Female	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	20AUG2015 22:00	4	mmol/L

Data Listing 16.2.5.2. Potassium Chloride Administration - Enrolled population

Patient Number	Age (Years)/ Gender	Did the Patient have any additional Potassium Chloride added to their Dialysate fluid?	ATC Term/Preferred Term/ Reported Term	Date and Time of Administration	Concentration	Unit
002-011	63/Female	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	21AUG2015 09:20	4	mmol/L
002-011	63/Female	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	21AUG2015 09:20	4	mmol/L
002-011	63/Female	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	21AUG2015 09:20	4	mmol/L
002-012		Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	30AUG2015 03:40	4	mmol/L
002-012		Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	30AUG2015 05:30	4	mmol/L

Data Listing 16.2.5.2. Potassium Chloride Administration - Enrolled population

Patient Number	Age (Years)/ Gender	Did the Patient have any additional Potassium Chloride added to their Dialysate fluid?	ATC Term/Preferred Term/ Reported Term	Date and Time of Administration	Concentration	Unit
002-012		Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	30AUG2015 11:00	4	mmol/L
002-014	59/Male	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	02SEP2015 16:00	4	mmol/L
002-014	59/Male	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	02SEP2015 17:30	4	mmol/L
002-014	59/Male	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	03SEP2015 00:00	4	mmol/L
002-014	59/Male	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	03SEP2015 00:00	4	mmol/L

Data Listing 16.2.5.2. Potassium Chloride Administration - Enrolled population

Patient Number	Age (Years)/ Gender	Did the Patient have any additional Potassium Chloride added to their Dialysate fluid?	ATC Term/Preferred Term/ Reported Term	Date and Time of Administration	Concentration	Unit
002-014	59/Male	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	03SEP2015 06:00	4	mmol/L
002-014	59/Male	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	03SEP2015 06:00	4	mmol/L
002-014	59/Male	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	03SEP2015 11:45	4	mmol/L
002-014	59/Male	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	03SEP2015 11:45	4	mmol/L
002-014	59/Male	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	03SEP2015 18:30	4	mmol/L

Data Listing 16.2.5.2. Potassium Chloride Administration - Enrolled population

Patient Number	Age (Years)/ Gender	Did the Patient have any additional Potassium Chloride added to their Dialysate fluid?	ATC Term/Preferred Term/ Reported Term	Date and Time of Administration	Concentration	Unit
002-014	59/Male	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	03SEP2015 18:30	4	mmol/L
002-016	83/Female	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	03SEP2015 15:55	4	mmol/L
002-016	83/Female	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	03SEP2015 15:55	4	mmol/L
002-016	83/Female	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	03SEP2015 15:55	4	mmol/L
002-017	73/Male	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	12OCT2015 17:30	4	mmol/L

Data Listing 16.2.5.2. Potassium Chloride Administration - Enrolled population

Patient Number	Age (Years)/ Gender	Did the Patient have any additional Potassium Chloride added to their Dialysate fluid?	ATC Term/Preferred Term/ Reported Term	Date and Time of Administration	Concentration	Unit
002-017	73/Male	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	12OCT2015 17:30	4	mmol/L
002-018	91/Female	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	22OCT2015 15:05	4	mmol/L
002-018	91/Female	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	22OCT2015 15:05	4	mmol/L
002-018	91/Female	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	22OCT2015 15:05	4	mmol/L
002-018	91/Female	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	22OCT2015 20:45	4	mmol/L

Data Listing 16.2.5.2. Potassium Chloride Administration - Enrolled population

Patient Number	Age (Years)/ Gender	Did the Patient have any additional Potassium Chloride added to their Dialysate fluid?	ATC Term/Preferred Term/ Reported Term	Date and Time of Administration	Concentration	Unit
002-018	91/Female	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	22OCT2015 20:45	4	mmol/L
002-018	91/Female	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	22OCT2015 20:45	4	mmol/L
002-018	91/Female	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	23OCT2015 06:00	4	mmol/L
002-018	91/Female	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	23OCT2015 06:00	4	mmol/L
002-018	91/Female	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	23OCT2015 06:00	4	mmol/L

Data Listing 16.2.5.2. Potassium Chloride Administration - Enrolled population

Patient Number	Age (Years)/ Gender	Did the Patient have any additional Potassium Chloride added to their Dialysate fluid?	ATC Term/Preferred Term/ Reported Term	Date and Time of Administration	Concentration	Unit
002-019	70/Male	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	10NOV2015 05:05	4	mmol/L
002-019	70/Male	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	10NOV2015 05:05	4	mmol/L
002-019	70/Male	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	10NOV2015 05:05	4	mmol/L
002-019	70/Male	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	10NOV2015 07:00	4	mmol/L
002-019	70/Male	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	10NOV2015 07:00	4	mmol/L

Data Listing 16.2.5.2. Potassium Chloride Administration - Enrolled population

Patient Number	Age (Years)/ Gender	Did the Patient have any additional Potassium Chloride added to their Dialysate fluid?	ATC Term/Preferred Term/ Reported Term	Date and Time of Administration	Concentration	Unit
002-019	70/Male	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	10NOV2015 07:00	4	mmol/L
002-019	70/Male	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	10NOV2015 11:10	4	mmol/L
002-019	70/Male	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	10NOV2015 11:10	4	mmol/L
002-021	73/Male	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	10DEC2015 05:00	4	mmol/L
002-021	73/Male	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	10DEC2015 05:00	4	mmol/L

Data Listing 16.2.5.2. Potassium Chloride Administration - Enrolled population

Patient Number	Age (Years)/ Gender	Did the Patient have any additional Potassium Chloride added to their Dialysate fluid?	ATC Term/Preferred Term/ Reported Term	Date and Time of Administration	Concentration	Unit
002-021	73/Male	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	10DEC2015 05:00	4	mmol/L
002-021	73/Male	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	10DEC2015 09:40	4	mmol/L
002-021	73/Male	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	10DEC2015 09:40	4	mmol/L
002-021	73/Male	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	10DEC2015 16:30	4	mmol/L
002-021	73/Male	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	10DEC2015 16:30	4	mmol/L

Data Listing 16.2.5.2. Potassium Chloride Administration - Enrolled population

Patient Number	Age (Years)/ Gender	Did the Patient have any additional Potassium Chloride added to their Dialysate fluid?	ATC Term/Preferred Term/ Reported Term	Date and Time of Administration	Concentration	Unit
002-021	73/Male	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	10DEC2015 16:30	4	mmol/L
002-021	73/Male	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	10DEC2015 22:30	4	mmol/L
002-021	73/Male	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	10DEC2015 22:30	4	mmol/L
002-021	73/Male	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	10DEC2015 22:30	4	mmol/L
002-021	73/Male	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	11DEC2015 06:45	4	mmol/L

Data Listing 16.2.5.2. Potassium Chloride Administration - Enrolled population

Patient Number	Age (Years)/ Gender	Did the Patient have any additional Potassium Chloride added to their Dialysate fluid?	ATC Term/Preferred Term/ Reported Term	Date and Time of Administration	Concentration	Unit
002-021	73/Male	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	11DEC2015 06:45	4	mmol/L
002-021	73/Male	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	11DEC2015 06:45	4	mmol/L
003-001	77/Male	No				
003-002	67/Male	No				
003-003	57/Female	No				
003-004	66/Male	No				
003-007	60/Male	No				
003-008	47/Male	No				
003-009		No				
003-010	79/Male	No				
003-011	69/Male	No				
003-012	88/Male	No				
004-001		No				

Data Listing 16.2.5.2. Potassium Chloride Administration - Enrolled population

Patient Number	Age (Years)/ Gender	Did the Patient have any additional Potassium Chloride added to their Dialysate fluid?	ATC Term/Preferred Term/ Reported Term	Date and Time of Administration	Concentration	Unit
004-002		No				
004-003	45/Female	No				
004-005	20/Female	No				
004-006	30/Male	No				
004-009	59/Female	No				
004-010	55/Male	No				
004-013	79/Male	No				
004-014	65/Male	No				
004-016	47/Female	No				
004-017	67/Male	No				
004-018	40/Male	No				
005-002	68/Female	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/KCL	21MAR2015 19:30	4	mmols/l
005-002	68/Female	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/KCL	21MAR2015 21:45	4	mmols/l

Data Listing 16.2.5.2. Potassium Chloride Administration - Enrolled population

Patient Number	Age (Years)/ Gender	Did the Patient have any additional Potassium Chloride added to their Dialysate fluid?	ATC Term/Preferred Term/ Reported Term	Date and Time of Administration	Concentration	Unit
005-002	68/Female	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/KCL	22MAR2015 00:10	8	mmols/l
005-002	68/Female	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/KCL	22MAR2015 02:35	8	mmols/l
005-002	68/Female	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/KCL	22MAR2015 05:00	4	mmols/l
005-002	68/Female	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/KCL	22MAR2015 07:30	4	mmols/l
005-002	68/Female	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/KCL	21MAR2015 18:30	4	mmols/L
005-003	65/Female	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/KCL	24MAR2015 10:45	4	MMOLS/L

Data Listing 16.2.5.2. Potassium Chloride Administration - Enrolled population

Patient Number	Age (Years)/ Gender	Did the Patient have any additional Potassium Chloride added to their Dialysate fluid?	ATC Term/Preferred Term/ Reported Term	Date and Time of Administration	Concentration	Unit
005-003	65/Female	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/KCL	24MAR2015 12:15	4	MMOLS/L
005-003	65/Female	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/KCL	24MAR2015 13:50	4	MMOLS/L
005-003	65/Female	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/KCL	24MAR2015 15:30	4	MMOLS/L
005-003	65/Female	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/KCL	24MAR2015 18:36	4	MMOLS/L
005-003	65/Female	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/KCL	24MAR2015 20:20	4	MMOLS/L
005-003	65/Female	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/KCL	25MAR2015 00:50	4	MMOLS/L

Data Listing 16.2.5.2. Potassium Chloride Administration - Enrolled population

Patient Number	Age (Years)/ Gender	Did the Patient have any additional Potassium Chloride added to their Dialysate fluid?	ATC Term/Preferred Term/ Reported Term	Date and Time of Administration	Concentration	Unit
005-003	65/Female	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/KCL	25MAR2015 02:30	4	MMOLS/L
005-003	65/Female	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/KCL	25MAR2015 04:05	4	MMOLS/L
005-003	65/Female	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/KCL	25MAR2015 07:00	4	MMOLS/L
005-003	65/Female	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/KCL	25MAR2015 08:33	4	MMOLS/L
005-003	65/Female	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/KCL	24MAR2015 10:00	4	mmols/L
005-004	81/Male	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/KCL	27MAR2015 09:00	4	MMOLS/L

Data Listing 16.2.5.2. Potassium Chloride Administration - Enrolled population

Patient Number	Age (Years)/ Gender	Did the Patient have any additional Potassium Chloride added to their Dialysate fluid?	ATC Term/Preferred Term/ Reported Term	Date and Time of Administration	Concentration	Unit
005-004	81/Male	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/KCL	27MAR2015 10:45	4	MMOLS/L
005-004	81/Male	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/KCL	27MAR2015 12:40	4	MMOLS/L
005-004	81/Male	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/KCL	27MAR2015 14:35	4	MMOLS/L
005-004	81/Male	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/KCL	27MAR2015 16:40	4	MMOLS/L
005-004	81/Male	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/KCL	27MAR2015 18:35	4	MMOLS/L
005-004	81/Male	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/KCL	27MAR2015 20:40	4	MMOLS/L

Data Listing 16.2.5.2. Potassium Chloride Administration - Enrolled population

Patient Number	Age (Years)/ Gender	Did the Patient have any additional Potassium Chloride added to their Dialysate fluid?	ATC Term/Preferred Term/ Reported Term	Date and Time of Administration	Concentration	Unit
005-004	81/Male	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/KCL	28MAR2015 00:40	4	MMOLS/L
005-004	81/Male	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/KCL	28MAR2015 02:40	4	MMOLS/L
005-004	81/Male	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/KCL	28MAR2015 04:40	4	MMOLS/L
005-004	81/Male	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/KCL	28MAR2015 06:40	4	MMOLS/L
005-006	38/Male	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	22APR2015 12:00	4	MMOLS/L
005-006	38/Male	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	22APR2015 12:15	4	MMOLS/L

Data Listing 16.2.5.2. Potassium Chloride Administration - Enrolled population

Patient Number	Age (Years)/ Gender	Did the Patient have any additional Potassium Chloride added to their Dialysate fluid?	ATC Term/Preferred Term/ Reported Term	Date and Time of Administration	Concentration	Unit
005-006	38/Male	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	22APR2015 14:50	4	MMOLS/L
005-006	38/Male	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	22APR2015 16:55	4	MMOLS/L
005-006	38/Male	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTTASIUM CHLORIDE	22APR2015 19:00	4	MMOLS/L
005-006	38/Male	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	22APR2015 21:00	4	MMOLS/L
005-006	38/Male	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTTASIUM CHLORIDE	22APR2015 23:45	4	MMOLS/L

Data Listing 16.2.5.2. Potassium Chloride Administration - Enrolled population

Patient Number	Age (Years)/ Gender	Did the Patient have any additional Potassium Chloride added to their Dialysate fluid?	ATC Term/Preferred Term/ Reported Term	Date and Time of Administration	Concentration	Unit
005-006	38/Male	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	23APR2015 01:35	4	MMOLS/L
005-006	38/Male	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	23APR2015 03:35	4	MMOLS/L
005-006	38/Male	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	23APR2015 05:30	4	MMOLS/L
005-006	38/Male	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	23APR2015 07:50	4	MMOLS/L
005-006	38/Male	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	23APR2015 10:00	4	MMOLS/L

Data Listing 16.2.5.2. Potassium Chloride Administration - Enrolled population

Patient Number	Age (Years)/ Gender	Did the Patient have any additional Potassium Chloride added to their Dialysate fluid?	ATC Term/Preferred Term/ Reported Term	Date and Time of Administration	Concentration	Unit
005-007	63/Male	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	23APR2015 20:00	4	MMOLS/L
005-007	63/Male	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	23APR2015 21:00	4	MMOLS/L
005-007	63/Male	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	23APR2015 22:00	4	MMOLS/L
005-007	63/Male	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	23APR2015 23:15	4	MMOLS/L
005-007	63/Male	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	24APR2015 00:20	4	MMOLS/L

Data Listing 16.2.5.2. Potassium Chloride Administration - Enrolled population

Patient Number	Age (Years)/ Gender	Did the Patient have any additional Potassium Chloride added to their Dialysate fluid?	ATC Term/Preferred Term/ Reported Term	Date and Time of Administration	Concentration	Unit
005-007	63/Male	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	24APR2015 01:25	4	MMOLS/L
005-007	63/Male	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	24APR2015 02:30	4	MMOLS/L
005-007	63/Male	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	24APR2015 03:30	4	MMOLS/L
005-007	63/Male	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	24APR2015 04:40	4	MMOLS/L
005-007	63/Male	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	24APR2015 05:30	4	MMOLS/L

Data Listing 16.2.5.2. Potassium Chloride Administration - Enrolled population

Patient Number	Age (Years)/ Gender	Did the Patient have any additional Potassium Chloride added to their Dialysate fluid?	ATC Term/Preferred Term/ Reported Term	Date and Time of Administration	Concentration	Unit
005-007	63/Male	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	24APR2015 06:50	4	MMOLS/L
005-007	63/Male	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	24APR2015 08:00	4	MMOLS/L
005-007	63/Male	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	24APR2015 09:00	4	MMOLS/L
005-007	63/Male	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	24APR2015 10:00	4	MMOLS/L
005-007	63/Male	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	24APR2015 11:15	4	MMOLS/L

Data Listing 16.2.5.2. Potassium Chloride Administration - Enrolled population

Patient Number	Age (Years)/ Gender	Did the Patient have any additional Potassium Chloride added to their Dialysate fluid?	ATC Term/Preferred Term/ Reported Term	Date and Time of Administration	Concentration	Unit
005-007	63/Male	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	24APR2015 12:05	4	MMOLS/L
005-007	63/Male	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	24APR2015 13:30	4	MMOLS/L
005-007	63/Male	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	24APR2015 14:30	4	MMOLS/L
005-007	63/Male	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	24APR2015 15:25	4	MMOLS/L
005-007	63/Male	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	24APR2015 16:35	4	MMOLS/L

Data Listing 16.2.5.2. Potassium Chloride Administration - Enrolled population

Patient Number	Age (Years)/ Gender	Did the Patient have any additional Potassium Chloride added to their Dialysate fluid?	ATC Term/Preferred Term/ Reported Term	Date and Time of Administration	Concentration	Unit
005-007	63/Male	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	24APR2015 17:35	4	MMOLS/L
005-007	63/Male	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	24APR2015 18:50	4	MMOLS/L
005-007	63/Male	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	24APR2015 19:50	4	MMOLS/L
005-007	63/Male	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	24APR2015 21:00	4	MMOLS/L
005-007	63/Male	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	24APR2015 22:00	4	MMOLS/L

Data Listing 16.2.5.2. Potassium Chloride Administration - Enrolled population

Patient Number	Age (Years)/ Gender	Did the Patient have any additional Potassium Chloride added to their Dialysate fluid?	ATC Term/Preferred Term/ Reported Term	Date and Time of Administration	Concentration	Unit
005-007	63/Male	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	24APR2015 23:15	4	MMOLS/L
005-007	63/Male	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	25APR2015 00:20	4	MMOLS/L
005-007	63/Male	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	25APR2015 01:25	4	MMOLS/L
005-007	63/Male	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	25APR2015 02:25	4	MMOLS/L
005-007	63/Male	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	25APR2015 03:35	4	MMOLS/L

Data Listing 16.2.5.2. Potassium Chloride Administration - Enrolled population

Patient Number	Age (Years)/ Gender	Did the Patient have any additional Potassium Chloride added to their Dialysate fluid?	ATC Term/Preferred Term/ Reported Term	Date and Time of Administration	Concentration	Unit
005-008	74/Female	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	09MAY2015 09:00	4	MMOLS/L
005-008	74/Female	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	09MAY2015 11:40	4	MMOLS/L
005-008	74/Female	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	09MAY2015 11:40	4	MMOLS/L
005-008	74/Female	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	09MAY2015 14:35	4	MMOLS/L
005-008	74/Female	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	09MAY2015 15:30	4	MMOLS/L

Data Listing 16.2.5.2. Potassium Chloride Administration - Enrolled population

Patient Number	Age (Years)/ Gender	Did the Patient have any additional Potassium Chloride added to their Dialysate fluid?	ATC Term/Preferred Term/ Reported Term	Date and Time of Administration	Concentration	Unit
005-008	74/Female	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	09MAY2015 20:25	4	MMOLS/L
005-008	74/Female	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTTASIUM CHLORIDE	09MAY2015 23:20	4	MMOLS/L
005-010	42/Male	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	14MAY2015 10:00	4	MMOLS/L
005-010	42/Male	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	14MAY2015 11:55	4	MMOLS/L
005-010	42/Male	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	14MAY2015 13:30	4	MMOLS/L

Data Listing 16.2.5.2. Potassium Chloride Administration - Enrolled population

Patient Number	Age (Years)/ Gender	Did the Patient have any additional Potassium Chloride added to their Dialysate fluid?	ATC Term/Preferred Term/ Reported Term	Date and Time of Administration	Concentration	Unit
005-010	42/Male	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	14MAY2015 15:05	4	MMOLS/L
005-010	42/Male	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	14MAY2015 16:30	4	MMOLS/L
005-010	42/Male	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	14MAY2015 18:10	4	MMOLS/L
005-010	42/Male	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	14MAY2015 19:30	4	MMOLS/L
005-010	42/Male	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	14MAY2015 21:05	4	MMOLS/L

Data Listing 16.2.5.2. Potassium Chloride Administration - Enrolled population

Patient Number	Age (Years)/ Gender	Did the Patient have any additional Potassium Chloride added to their Dialysate fluid?	ATC Term/Preferred Term/ Reported Term	Date and Time of Administration	Concentration	Unit
005-010	42/Male	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	14MAY2015 22:35	4	MMOLS/L
005-010	42/Male	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	15MAY2015 00:10	4	MMOLS/L
005-010	42/Male	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	15MAY2015 01:45	4	MMOLS/L
005-010	42/Male	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	15MAY2015 03:15	4	MMOLS/L
005-010	42/Male	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	15MAY2015 04:55	4	MMOLS/L

Data Listing 16.2.5.2. Potassium Chloride Administration - Enrolled population

Patient Number	Age (Years)/ Gender	Did the Patient have any additional Potassium Chloride added to their Dialysate fluid?	ATC Term/Preferred Term/ Reported Term	Date and Time of Administration	Concentration	Unit
005-010	42/Male	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	15MAY2015 06:20	4	MMOLS/L
005-010	42/Male	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	15MAY2015 07:55	4	MMOLS/L
005-010	42/Male	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	15MAY2015 09:20	4	MMOLS/L
005-010	42/Male	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	15MAY2015 11:25	4	MMOLS/L
005-010	42/Male	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	15MAY2015 12:20	4	MMOLS/L

Data Listing 16.2.5.2. Potassium Chloride Administration - Enrolled population

Patient Number	Age (Years)/ Gender	Did the Patient have any additional Potassium Chloride added to their Dialysate fluid?	ATC Term/Preferred Term/ Reported Term	Date and Time of Administration	Concentration	Unit
005-010	42/Male	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	15MAY2015 14:00	4	MMOLS/L
005-010	42/Male	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	15MAY2015 15:40	4	MMOLS/L
005-010	42/Male	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	15MAY2015 17:10	4	MMOLS/L
005-011	78/Female	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	15MAY2015 10:00	4	MMOLS/L
005-011	78/Female	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	15MAY2015 11:45	4	MMOLS/L

Data Listing 16.2.5.2. Potassium Chloride Administration - Enrolled population

Patient Number	Age (Years)/ Gender	Did the Patient have any additional Potassium Chloride added to their Dialysate fluid?	ATC Term/Preferred Term/ Reported Term	Date and Time of Administration	Concentration	Unit
005-011	78/Female	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	15MAY2015 13:20	4	MMOLS/L
005-011	78/Female	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	15MAY2015 15:00	4	MMOLS/L
005-011	78/Female	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	15MAY2015 08:25	4	mmols/L
005-012		Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	16MAY2015 14:20	8	MMOLS/L
005-012		Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	16MAY2015 16:20	8	MMOLS/L

Data Listing 16.2.5.2. Potassium Chloride Administration - Enrolled population

Patient Number	Age (Years)/ Gender	Did the Patient have any additional Potassium Chloride added to their Dialysate fluid?	ATC Term/Preferred Term/ Reported Term	Date and Time of Administration	Concentration	Unit
005-012		Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	16MAY2015 18:30	8	MMOLS/L
005-012		Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	16MAY2015 20:25	4	MMOLS/L
005-012		Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	16MAY2015 22:30	4	MMOLS/L
005-012		Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	17MAY2015 00:30	4	MMOLS/L
005-012		Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	17MAY2015 02:40	4	MMOLS/L

Data Listing 16.2.5.2. Potassium Chloride Administration - Enrolled population

Patient Number	Age (Years)/ Gender	Did the Patient have any additional Potassium Chloride added to their Dialysate fluid?	ATC Term/Preferred Term/ Reported Term	Date and Time of Administration	Concentration	Unit
005-012		Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	17MAY2015 04:40	4	MMOLS/L
005-012		Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	17MAY2015 06:40	4	MMOLS/L
005-012		Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	17MAY2015 08:40	4	MMOLS/L
005-012		Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	17MAY2015 10:45	4	MMOLS/L
005-012		Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	17MAY2015 12:50	4	MMOLS/L

Data Listing 16.2.5.2. Potassium Chloride Administration - Enrolled population

Patient Number	Age (Years)/ Gender	Did the Patient have any additional Potassium Chloride added to their Dialysate fluid?	ATC Term/Preferred Term/ Reported Term	Date and Time of Administration	Concentration	Unit
005-012		Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	17MAY2015 15:00	4	MMOLS/L
005-012		Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	17MAY2015 17:00	4	MMOLS/L
005-012		Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	17MAY2015 18:00	4	MMOLS/L
005-012		Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	17MAY2015 19:00	4	MMOLS/L
005-012		Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	17MAY2015 20:00	4	MMOLS/L

Data Listing 16.2.5.2. Potassium Chloride Administration - Enrolled population

Patient Number	Age (Years)/ Gender	Did the Patient have any additional Potassium Chloride added to their Dialysate fluid?	ATC Term/Preferred Term/ Reported Term	Date and Time of Administration	Concentration	Unit
005-012		Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	16MAY2015 13:00	UNK	unk
005-014	65/Male	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	05JUN2015 09:30	4	MMOLS/L
005-014	65/Male	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	05JUN2015 10:45	4	MMOLS/L
005-014	65/Male	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	05JUN2015 11:45	4	MMOLS/L
005-014	65/Male	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	05JUN2015 13:00	4	MMOLS/L

Data Listing 16.2.5.2. Potassium Chloride Administration - Enrolled population

Patient Number	Age (Years)/ Gender	Did the Patient have any additional Potassium Chloride added to their Dialysate fluid?	ATC Term/Preferred Term/ Reported Term	Date and Time of Administration	Concentration	Unit
005-014	65/Male	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	05JUN2015 15:35	4	MMOLS/L
005-014	65/Male	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	05JUN2015 17:05	4	MMOLS/L
005-014	65/Male	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	05JUN2015 18:00	4	MMOLS/L
005-014	65/Male	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	05JUN2015 19:25	4	MMOLS/L
005-014	65/Male	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	05JUN2015 20:35	4	MMOLS/L

Data Listing 16.2.5.2. Potassium Chloride Administration - Enrolled population

Patient Number	Age (Years)/ Gender	Did the Patient have any additional Potassium Chloride added to their Dialysate fluid?	ATC Term/Preferred Term/ Reported Term	Date and Time of Administration	Concentration	Unit
005-014	65/Male	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	05JUN2015 21:50	4	MMOLS/L
005-014	65/Male	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	05JUN2015 23:10	4	MMOLS/L
005-014	65/Male	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	06JUN2015 00:20	4	MMOLS/L
005-014	65/Male	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	06JUN2015 01:30	4	MMOLS/L
005-014	65/Male	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	06JUN2015 02:40	4	MMOLS/L

Data Listing 16.2.5.2. Potassium Chloride Administration - Enrolled population

Patient Number	Age (Years)/ Gender	Did the Patient have any additional Potassium Chloride added to their Dialysate fluid?	ATC Term/Preferred Term/ Reported Term	Date and Time of Administration	Concentration	Unit
005-014	65/Male	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	06JUN2015 03:55	4	MMOLS/L
005-014	65/Male	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	06JUN2015 05:00	4	MMOLS/L
005-014	65/Male	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	06JUN2015 06:15	4	MMOLS/L
005-014	65/Male	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	06JUN2015 07:20	4	MMOLS/L
005-015	78/Male	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	20JUN2015 21:00	4	MMOLS/L

Data Listing 16.2.5.2. Potassium Chloride Administration - Enrolled population

Patient Number	Age (Years)/ Gender	Did the Patient have any additional Potassium Chloride added to their Dialysate fluid?	ATC Term/Preferred Term/ Reported Term	Date and Time of Administration	Concentration	Unit
005-015	78/Male	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	20JUN2015 21:40	4	MMOLS/L
005-015	78/Male	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	20JUN2015 23:30	4	mmols/L
005-015	78/Male	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	21JUN2015 00:45	4	MMOLS/L
005-015	78/Male	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	21JUN2015 03:20	4	MMOLS/L
005-015	78/Male	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	21JUN2015 07:00	4	MMOLS/L

Data Listing 16.2.5.2. Potassium Chloride Administration - Enrolled population

Patient Number	Age (Years)/ Gender	Did the Patient have any additional Potassium Chloride added to their Dialysate fluid?	ATC Term/Preferred Term/ Reported Term	Date and Time of Administration	Concentration	Unit
005-015	78/Male	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	21JUN2015 08:50	4	MMOLS/L
005-015	78/Male	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	21JUN2015 10:50	4	MMOLS/L
005-015	78/Male	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	21JUN2015 12:35	4	MMOLS/L
005-015	78/Male	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	21JUN2015 14:10	4	MMOLS/L
005-015	78/Male	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	21JUN2015 16:00	4	MMOLS/L

Data Listing 16.2.5.2. Potassium Chloride Administration - Enrolled population

Patient Number	Age (Years)/ Gender	Did the Patient have any additional Potassium Chloride added to their Dialysate fluid?	ATC Term/Preferred Term/ Reported Term	Date and Time of Administration	Concentration	Unit
005-015	78/Male	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	21JUN2015 18:05	4	MMOLS/L
005-015	78/Male	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	21JUN2015 20:05	4	MMOLS/L
005-015	78/Male	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	22JUN2015 02:10	4	MMOLS/L
005-016		Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	14JUL2015 19:50	4	MMOLS/L
005-016		Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	15JUL2015 22:20	4	MMOLS/L

Data Listing 16.2.5.2. Potassium Chloride Administration - Enrolled population

Patient Number	Age (Years)/ Gender	Did the Patient have any additional Potassium Chloride added to their Dialysate fluid?	ATC Term/Preferred Term/ Reported Term	Date and Time of Administration	Concentration	Unit
005-016		Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	15JUL2015 01:00	4	MMOLS/L
005-016		Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	15JUL2015 03:25	4	MMOLS/L
005-016		Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	15JUL2015 06:00	4	MMOLS/L
005-016		Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	15JUL2015 08:30	4	MMOLS/L
005-016		Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	15JUL2015 11:05	4	MMOLS/L

Data Listing 16.2.5.2. Potassium Chloride Administration - Enrolled population

Patient Number	Age (Years)/ Gender	Did the Patient have any additional Potassium Chloride added to their Dialysate fluid?	ATC Term/Preferred Term/ Reported Term	Date and Time of Administration	Concentration	Unit
005-016		Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	15JUL2015 13:30	4	MMOLS/L
005-016		Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	15JUL2015 16:00	4	MMOLS/L
005-016		Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	15JUL2015 18:30	4	MMOLS/L
005-016		Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	15JUL2015 20:45	4	MMOLS/L
005-016		Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	15JUL2015 23:15	4	MMOLS/L

Data Listing 16.2.5.2. Potassium Chloride Administration - Enrolled population

Patient Number	Age (Years)/ Gender	Did the Patient have any additional Potassium Chloride added to their Dialysate fluid?	ATC Term/Preferred Term/ Reported Term	Date and Time of Administration	Concentration	Unit
005-016		Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	15JUL2015 01:40	4	MMOLS/L
005-018	67/Male	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	29AUG2015 07:30	4	mmols/L
005-018	67/Male	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	29AUG2015 10:30	4	mmols/L
005-018	67/Male	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	29AUG2015 12:25	4	mmols/L
005-018	67/Male	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	29AUG2015 14:20	4	mmols/L

Data Listing 16.2.5.2. Potassium Chloride Administration - Enrolled population

Patient Number	Age (Years)/ Gender	Did the Patient have any additional Potassium Chloride added to their Dialysate fluid?	ATC Term/Preferred Term/ Reported Term	Date and Time of Administration	Concentration	Unit
005-018	67/Male	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	29AUG2015 16:20	4	mmols/L
005-019	69/Male	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	15SEP2015 15:30	4	MMOLS/L
005-019	69/Male	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	15SEP2015 16:20	4	MMOLS/L
005-019	69/Male	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	15SEP2015 18:10	4	MMOLS/L
005-019	69/Male	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	15SEP2015 19:45	4	MMOLS/L

Data Listing 16.2.5.2. Potassium Chloride Administration - Enrolled population

Patient Number	Age (Years)/ Gender	Did the Patient have any additional Potassium Chloride added to their Dialysate fluid?	ATC Term/Preferred Term/ Reported Term	Date and Time of Administration	Concentration	Unit
005-019	69/Male	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	15SEP2015 21:20	4	MMOLS/L
005-019	69/Male	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	15SEP2015 23:00	4	MMOLS/L
005-019	69/Male	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	16SEP2015 00:40	4	MMOLS/L
005-019	69/Male	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	16SEP2015 02:20	4	MMOLS/L
005-019	69/Male	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	16SEP2015 03:55	4	MMOLS/L

Data Listing 16.2.5.2. Potassium Chloride Administration - Enrolled population

Patient Number	Age (Years)/ Gender	Did the Patient have any additional Potassium Chloride added to their Dialysate fluid?	ATC Term/Preferred Term/ Reported Term	Date and Time of Administration	Concentration	Unit
005-019	69/Male	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	16SEP2015 05:40	4	MMOLS/L
005-019	69/Male	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	16SEP2015 07:15	4	MMOLS/L
005-019	69/Male	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	16SEP2015 08:50	4	MMOLS/L
005-019	69/Male	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	16SEP2015 10:30	4	MMOLS/L
005-019	69/Male	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	16SEP2015 11:15	4	MMOLS/L

Data Listing 16.2.5.2. Potassium Chloride Administration - Enrolled population

Patient Number	Age (Years)/ Gender	Did the Patient have any additional Potassium Chloride added to their Dialysate fluid?	ATC Term/Preferred Term/ Reported Term	Date and Time of Administration	Concentration	Unit
005-019	69/Male	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	16SEP2015 14:00	4	MMOLS/L
005-019	69/Male	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	16SEP2015 15:40	4	MMOLS/I
005-019	69/Male	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	16SEP2015 17:15	4	MMOLS/I
005-019	69/Male	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	16SEP2015 19:00	4	MMOLS/I
005-019	69/Male	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	16SEP2015 22:10	4	MMOLS/I

Data Listing 16.2.5.2. Potassium Chloride Administration - Enrolled population

Patient Number	Age (Years)/ Gender	Did the Patient have any additional Potassium Chloride added to their Dialysate fluid?	ATC Term/Preferred Term/ Reported Term	Date and Time of Administration	Concentration	Unit
005-020		Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	16SEP2015 11:30	4	MMOLS/L
005-020		Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	16SEP2015 13:30	4	MMOLS/L
005-020		Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	16SEP2015 15:10	4	MMOLS/L
005-020		Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	16SEP2015 17:15	4	MMOLS/L
005-020		Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	16SEP2015 19:10	4	MMOLS/L

Data Listing 16.2.5.2. Potassium Chloride Administration - Enrolled population

Patient Number	Age (Years)/ Gender	Did the Patient have any additional Potassium Chloride added to their Dialysate fluid?	ATC Term/Preferred Term/ Reported Term	Date and Time of Administration	Concentration	Unit
005-020		Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	16SEP2015 21:10	4	MMOLS/L
005-020		Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	16SEP2015 23:10	4	MMOLS/L
005-020		Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	17SEP2015 01:30	4	MMOLS/L
005-020		Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	17SEP2015 03:10	4	MMOLS/L
005-020		Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	17SEP2015 05:05	4	MMOLS/L

Data Listing 16.2.5.2. Potassium Chloride Administration - Enrolled population

Patient Number	Age (Years)/ Gender	Did the Patient have any additional Potassium Chloride added to their Dialysate fluid?	ATC Term/Preferred Term/ Reported Term	Date and Time of Administration	Concentration	Unit
005-020		Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	17SEP2015 07:10	8	MMOLS/L
005-020		Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	17SEP2015 09:10	4	MMOLS/L
005-020		Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	17SEP2015 11:10	4	MMOLS/L
005-020		Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	17SEP2015 13:15	4	MMOLS/L
005-020		Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	17SEP2015 15:20	4	MMOLS/L

Data Listing 16.2.5.2. Potassium Chloride Administration - Enrolled population

Patient Number	Age (Years)/ Gender	Did the Patient have any additional Potassium Chloride added to their Dialysate fluid?	ATC Term/Preferred Term/ Reported Term	Date and Time of Administration	Concentration	Unit
005-020		Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	17SEP2015 17:20	4	MMOLS/L
005-021	58/Male	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	16SEP2015 08:30	4	MMOLS/L
005-021	58/Male	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	16SEP2015 09:45	4	MMOLS/L
005-021	58/Male	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	16SEP2015 12:00	4	mmols/L
005-021	58/Male	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	16SEP2015 14:20	4	mmols/L

Data Listing 16.2.5.2. Potassium Chloride Administration - Enrolled population

Patient Number	Age (Years)/ Gender	Did the Patient have any additional Potassium Chloride added to their Dialysate fluid?	ATC Term/Preferred Term/ Reported Term	Date and Time of Administration	Concentration	Unit
005-021	58/Male	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	16SEP2015 16:30	4	mmols/L
005-021	58/Male	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	16SEP2015 18:50	4	mmols/L
005-021	58/Male	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	16SEP2015 21:00	4	mmols/L
005-021	58/Male	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	16SEP2015 23:20	4	mmols/L
005-021	58/Male	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	17SEP2015 01:30	4	mmols/L

Data Listing 16.2.5.2. Potassium Chloride Administration - Enrolled population

Patient Number	Age (Years)/ Gender	Did the Patient have any additional Potassium Chloride added to their Dialysate fluid?	ATC Term/Preferred Term/ Reported Term	Date and Time of Administration	Concentration	Unit
005-021	58/Male	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	17SEP2015 04:00	4	mmols/l
005-021	58/Male	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	17SEP2015 06:15	4	mmols/L
005-021	58/Male	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	17SEP2015 09:42	4	mmols/L
005-021	58/Male	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	17SEP2015 11:10	4	mmols/L
005-021	58/Male	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	17SEP2015 13:45	4	mmols/L

Data Listing 16.2.5.2. Potassium Chloride Administration - Enrolled population

Patient Number	Age (Years)/ Gender	Did the Patient have any additional Potassium Chloride added to their Dialysate fluid?	ATC Term/Preferred Term/ Reported Term	Date and Time of Administration	Concentration	Unit
005-022		Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	06OCT2015 04:30	8	MMOLS/L
005-022		Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	06OCT2015 06:20	4	MMOLS/L
005-022		Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	06OCT2015 07:45	4	MMOLS/L
005-022		Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	06OCT2015 09:20	8	MMOLS/L
005-022		Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	06OCT2015 10:40	8	MMOLS/L

Data Listing 16.2.5.2. Potassium Chloride Administration - Enrolled population

Patient Number	Age (Years)/ Gender	Did the Patient have any additional Potassium Chloride added to their Dialysate fluid?	ATC Term/Preferred Term/ Reported Term	Date and Time of Administration	Concentration	Unit
005-022		Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	06OCT2015 12:30	4	MMOLS/L
005-022		Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	06OCT2015 13:45	4	MMOLS/L
005-022		Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	06OCT2015 15:00	8	MMOLS/L
005-022		Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	06OCT2015 16:40	8	MMOLS/L
005-022		Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	06OCT2015 18:00	4	mmols/L

Data Listing 16.2.5.2. Potassium Chloride Administration - Enrolled population

Patient Number	Age (Years)/ Gender	Did the Patient have any additional Potassium Chloride added to their Dialysate fluid?	ATC Term/Preferred Term/ Reported Term	Date and Time of Administration	Concentration	Unit
005-022		Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	06OCT2015 19:30	4	mmols/l
005-022		Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	06OCT2015 21:00	8	mmols/l
005-022		Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	06OCT2015 22:30	4	mmols/l
005-022		Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	06OCT2015 23:55	4	mmols/l
005-022		Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	07OCT2015 01:35	8	mmols/l

Data Listing 16.2.5.2. Potassium Chloride Administration - Enrolled population

Patient Number	Age (Years)/ Gender	Did the Patient have any additional Potassium Chloride added to their Dialysate fluid?	ATC Term/Preferred Term/ Reported Term	Date and Time of Administration	Concentration	Unit
005-022		Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	07OCT2015 03:10	8	mmols/l
005-022		Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	07OCT2015 04:40	4	mmols/l
005-022		Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	07OCT2015 06:15	4	mmols/l
005-022		Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	07OCT2015 07:45	4	mmols/l
005-022		Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	07OCT2015 09:05	4	mmols/l

Data Listing 16.2.5.2. Potassium Chloride Administration - Enrolled population

Patient Number	Age (Years)/ Gender	Did the Patient have any additional Potassium Chloride added to their Dialysate fluid?	ATC Term/Preferred Term/ Reported Term	Date and Time of Administration	Concentration	Unit
005-022		Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	07OCT2015 10:35	4	MMOLS/l
005-022		Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	07OCT2015 12:10	4	mmols/l
005-023	66/Male	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	11NOV2015 05:00	4	MMOLS/L
005-023	66/Male	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	11NOV2015 06:30	4	MMOLS/L
005-023	66/Male	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	11NOV2015 08:30	4	MMOLS/L

Data Listing 16.2.5.2. Potassium Chloride Administration - Enrolled population

Patient Number	Age (Years)/ Gender	Did the Patient have any additional Potassium Chloride added to their Dialysate fluid?	ATC Term/Preferred Term/ Reported Term	Date and Time of Administration	Concentration	Unit
005-023	66/Male	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	11NOV2015 10:30	4	MMOLS/L
005-023	66/Male	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	11NOV2015 10:55	4	MMOLS/L
005-023	66/Male	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	11NOV2015 12:50	4	MMOLS/L
005-023	66/Male	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	11NOV2015 15:00	4	MMOLS/L
005-023	66/Male	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	11NOV2015 17:00	4	MMOLS/L

Data Listing 16.2.5.2. Potassium Chloride Administration - Enrolled population

Patient Number	Age (Years)/ Gender	Did the Patient have any additional Potassium Chloride added to their Dialysate fluid?	ATC Term/Preferred Term/ Reported Term	Date and Time of Administration	Concentration	Unit
005-024	41/Female	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	25NOV2015 11:00	4	MMOLS/l
005-024	41/Female	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	25NOV2015 11:55	4	MMOLS/L
005-024	41/Female	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	25NOV2015 13:45	4	MMOLS/L
005-024	41/Female	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	25NOV2015 15:35	4	MMOLS/L
005-024	41/Female	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	25NOV2015 17:20	4	MMOLS/L

Data Listing 16.2.5.2. Potassium Chloride Administration - Enrolled population

Patient Number	Age (Years)/ Gender	Did the Patient have any additional Potassium Chloride added to their Dialysate fluid?	ATC Term/Preferred Term/ Reported Term	Date and Time of Administration	Concentration	Unit
005-024	41/Female	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	25NOV2015 19:10	4	MMOLS/L
005-024	41/Female	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	25NOV2015 21:00	4	MMOLS/L
005-024	41/Female	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	25NOV2015 22:45	4	MMOLS/L
005-024	41/Female	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	26NOV2015 00:30	4	MMOLS/L
005-024	41/Female	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	26NOV2015 02:20	4	MMOLS/L

Data Listing 16.2.5.2. Potassium Chloride Administration - Enrolled population

Patient Number	Age (Years)/ Gender	Did the Patient have any additional Potassium Chloride added to their Dialysate fluid?	ATC Term/Preferred Term/ Reported Term	Date and Time of Administration	Concentration	Unit
005-024	41/Female	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	26NOV2015 04:05	4	MMOLS/L
005-024	41/Female	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	26NOV2015 06:00	8	MMOLS/L
005-024	41/Female	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	26NOV2015 07:45	4	MMOLS/L
005-024	41/Female	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	26NOV2015 09:25	4	MMOLS/L
005-024	41/Female	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	26NOV2015 11:30	8	MMOLS/L

Data Listing 16.2.5.2. Potassium Chloride Administration - Enrolled population

Patient Number	Age (Years)/ Gender	Did the Patient have any additional Potassium Chloride added to their Dialysate fluid?	ATC Term/Preferred Term/ Reported Term	Date and Time of Administration	Concentration	Unit
005-024	41/Female	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	26NOV2015 13:25	8	MMOLS/L
005-024	41/Female	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	26NOV2015 17:05	4	MMOLS/L
005-024	41/Female	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	26NOV2015 18:45	4	MMOLS/L
005-025		Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	25NOV2015 20:00	4	MMOLS/I
005-025		Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	25NOV2015 20:25	4	MMOLS/I

Data Listing 16.2.5.2. Potassium Chloride Administration - Enrolled population

Patient Number	Age (Years)/ Gender	Did the Patient have any additional Potassium Chloride added to their Dialysate fluid?	ATC Term/Preferred Term/ Reported Term	Date and Time of Administration	Concentration	Unit
005-025		Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	25NOV2015 22:05	4	MMOLS/l
005-025		Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	26NOV2015 00:15	4	MMOLS/L
005-025		Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	26NOV2015 02:30	4	MMOLS/L
005-025		Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	26NOV2015 04:45	4	MMOLS/L
005-025		Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	26NOV2015 07:00	4	MMOLS/L

Data Listing 16.2.5.2. Potassium Chloride Administration - Enrolled population

Patient Number	Age (Years)/ Gender	Did the Patient have any additional Potassium Chloride added to their Dialysate fluid?	ATC Term/Preferred Term/ Reported Term	Date and Time of Administration	Concentration	Unit
005-025		Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	26NOV2015 09:13	4	MMOLS/L
005-025		Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	26NOV2015 11:09	4	MMOLS/L
005-025		Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	26NOV2015 13:35	4	MMOLS/L
005-025		Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	26NOV2015 15:50	4	MMOLS/L
005-025		Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	26NOV2015 20:19	4	MMOLS/L

Data Listing 16.2.5.2. Potassium Chloride Administration - Enrolled population

Patient Number	Age (Years)/ Gender	Did the Patient have any additional Potassium Chloride added to their Dialysate fluid?	ATC Term/Preferred Term/ Reported Term	Date and Time of Administration	Concentration	Unit
005-026	64/Male	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	02DEC2015 05:00	4	MMOLS/L
005-026	64/Male	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	02DEC2015 05:45	4	MMOLS/L
005-026	64/Male	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	02DEC2015 07:55	4	MMOLS/L
005-026	64/Male	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	02DEC2015 10:00	4	MMOLS/L
005-026	64/Male	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	02DEC2015 12:00	4	MMOLS/L

Data Listing 16.2.5.2. Potassium Chloride Administration - Enrolled population

Patient Number	Age (Years)/ Gender	Did the Patient have any additional Potassium Chloride added to their Dialysate fluid?	ATC Term/Preferred Term/ Reported Term	Date and Time of Administration	Concentration	Unit
005-026	64/Male	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	02DEC2015 12:00	4	MMOLS/L
005-026	64/Male	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	02DEC2015 14:15	4	MMOLS/L
005-026	64/Male	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	02DEC2015 16:20	4	MMOLS/L
005-026	64/Male	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	02DEC2015 18:30	4	MMOLS/L
005-026	64/Male	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	02DEC2015 20:30	4	MMOLS/L

Data Listing 16.2.5.2. Potassium Chloride Administration - Enrolled population

Patient Number	Age (Years)/ Gender	Did the Patient have any additional Potassium Chloride added to their Dialysate fluid?	ATC Term/Preferred Term/ Reported Term	Date and Time of Administration	Concentration	Unit
005-026	64/Male	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	02DEC2015 22:30	4	MMOLS/L
005-026	64/Male	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	03DEC2015 00:45	4	MMOLS/L
005-026	64/Male	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	03DEC2015 02:30	4	MMOLS/L
005-026	64/Male	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	03DEC2015 04:45	4	MMOLS/L
005-026	64/Male	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	03DEC2015 06:50	4	MMOLS/L

Data Listing 16.2.5.2. Potassium Chloride Administration - Enrolled population

Patient Number	Age (Years)/ Gender	Did the Patient have any additional Potassium Chloride added to their Dialysate fluid?	ATC Term/Preferred Term/ Reported Term	Date and Time of Administration	Concentration	Unit
005-027		Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	02DEC2015 21:00	4	MMOLS/L
005-027		Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	02DEC2015 21:15	4	MMOLS/L
005-027		Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	02DEC2015 23:40	4	MMOLS/L
005-027		Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	03DEC2015 02:00	4	MMOLS/L
005-027		Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	03DEC2015 04:30	4	MMOLS/L

Data Listing 16.2.5.2. Potassium Chloride Administration - Enrolled population

Patient Number	Age (Years)/ Gender	Did the Patient have any additional Potassium Chloride added to their Dialysate fluid?	ATC Term/Preferred Term/ Reported Term	Date and Time of Administration	Concentration	Unit
005-027		Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	03DEC2015 06:50	4	MMOLS/L
005-027		Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	03DEC2015 09:15	4	MMOLS/L
005-028		Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	09DEC2015 08:00	4	MMOLS/L
005-028		Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	09DEC2015 09:30	8	MMOLS/L
005-028		Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	09DEC2015 12:30	4	MMOLS/L

Data Listing 16.2.5.2. Potassium Chloride Administration - Enrolled population

Patient Number	Age (Years)/ Gender	Did the Patient have any additional Potassium Chloride added to their Dialysate fluid?	ATC Term/Preferred Term/ Reported Term	Date and Time of Administration	Concentration	Unit
005-028		Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	09DEC2015 14:45	4	MMOLS/L
005-028		Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	09DEC2015 19:35	4	MMOLS/L
005-028		Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	09DEC2015 22:10	4	MMOLS/L
005-028		Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	10DEC2015 00:30	4	MMOLS/L
005-028		Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	10DEC2015 02:55	4	MMOLS/L

Data Listing 16.2.5.2. Potassium Chloride Administration - Enrolled population

Patient Number	Age (Years)/ Gender	Did the Patient have any additional Potassium Chloride added to their Dialysate fluid?	ATC Term/Preferred Term/ Reported Term	Date and Time of Administration	Concentration	Unit
005-028		Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	10DEC2015 05:20	4	MMOLS/L
005-028		Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	10DEC2015 07:50	4	MMOLS/L
005-028		Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	10DEC2015 10:20	4	MMOLS/L
005-028		Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	10DEC2015 12:50	4	MMOLS/L
005-028		Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	10DEC2015 15:20	4	MMOLS/L

Data Listing 16.2.5.2. Potassium Chloride Administration - Enrolled population

Patient Number	Age (Years)/ Gender	Did the Patient have any additional Potassium Chloride added to their Dialysate fluid?	ATC Term/Preferred Term/ Reported Term	Date and Time of Administration	Concentration	Unit
005-029	68/Male	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	11DEC2015 07:30	4	MMOLS/L
005-029	68/Male	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	11DEC2015 09:00	4	MMOLS/L
005-029	68/Male	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	11DEC2015 11:30	4	MMOLS/L
005-029	68/Male	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	11DEC2015 14:30	4	MMOLS/L
005-029	68/Male	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	11DEC2015 17:15	4	MMOLS/L

Data Listing 16.2.5.2. Potassium Chloride Administration - Enrolled population

Patient Number	Age (Years)/ Gender	Did the Patient have any additional Potassium Chloride added to their Dialysate fluid?	ATC Term/Preferred Term/ Reported Term	Date and Time of Administration	Concentration	Unit
005-029	68/Male	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	11DEC2015 19:55	4	MMOLS/L
005-029	68/Male	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	11DEC2015 22:35	8	MMOLS/L
005-029	68/Male	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	12DEC2015 01:25	4	MMOLS/L
005-029	68/Male	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	12DEC2015 04:10	4	MMOLS/L
005-029	68/Male	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	12DEC2015 07:00	4	MMOLS/L

Data Listing 16.2.5.2. Potassium Chloride Administration - Enrolled population

Patient Number	Age (Years)/ Gender	Did the Patient have any additional Potassium Chloride added to their Dialysate fluid?	ATC Term/Preferred Term/ Reported Term	Date and Time of Administration	Concentration	Unit
005-029	68/Male	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	12DEC2015 09:40	4	MMOLS/L
005-029	68/Male	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	12DEC2015 12:30	4	MMOLS/L
005-030	61/Male	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	18DEC2015 11:00	4	MMOLS/L
005-030	61/Male	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	18DEC2015 11:15	4	MMOLS/L
005-030	61/Male	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	18DEC2015 12:50	4	MMOLS/L

Data Listing 16.2.5.2. Potassium Chloride Administration - Enrolled population

Patient Number	Age (Years)/ Gender	Did the Patient have any additional Potassium Chloride added to their Dialysate fluid?	ATC Term/Preferred Term/ Reported Term	Date and Time of Administration	Concentration	Unit
005-030	61/Male	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	18DEC2015 14:40	4	MMOLS/L
005-030	61/Male	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	18DEC2015 16:30	4	MMOLS/L
005-032	49/Male	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	01JAN2016 07:20	4	MMOLS/L
005-032	49/Male	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	01JAN2016 08:30	4	MMOLS/L
005-032	49/Male	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	01JAN2016 10:10	4	MMOLS/L

Data Listing 16.2.5.2. Potassium Chloride Administration - Enrolled population

Patient Number	Age (Years)/ Gender	Did the Patient have any additional Potassium Chloride added to their Dialysate fluid?	ATC Term/Preferred Term/ Reported Term	Date and Time of Administration	Concentration	Unit
005-032	49/Male	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	01JAN2016 11:45	4	MMOLS/L
005-032	49/Male	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	01JAN2016 13:25	4	MMOLS/L
005-032	49/Male	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	01JAN2016 15:10	4	MMOLS/L
005-032	49/Male	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	01JAN2016 16:50	4	MMOLS/L
005-034	70/Male	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	13JAN2016 18:40	4	MMOLS/L

Data Listing 16.2.5.2. Potassium Chloride Administration - Enrolled population

Patient Number	Age (Years)/ Gender	Did the Patient have any additional Potassium Chloride added to their Dialysate fluid?	ATC Term/Preferred Term/ Reported Term	Date and Time of Administration	Concentration	Unit
005-034	70/Male	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	13JAN2016 21:10	4	MMOLS/L
005-034	70/Male	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	13JAN2016 23:55	4	MMOLS/L
005-034	70/Male	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	14JAN2016 02:30	4	mmols/L
005-034	70/Male	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	14JAN2016 05:35	4	mmols/L
005-034	70/Male	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	14JAN2016 09:15	4	mmols/L

Data Listing 16.2.5.2. Potassium Chloride Administration - Enrolled population

Patient Number	Age (Years)/ Gender	Did the Patient have any additional Potassium Chloride added to their Dialysate fluid?	ATC Term/Preferred Term/ Reported Term	Date and Time of Administration	Concentration	Unit
005-034	70/Male	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	14JAN2016 11:15	4	mmols/L
005-036	51/Female	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	14JAN2016 01:15	4	MMOLS/L
005-036	51/Female	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	14JAN2016 02:55	4	MMOLS/L
005-036	51/Female	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	14JAN2016 05:10	4	MMOLS/L
005-036	51/Female	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	14JAN2016 07:30	4	MMOLS/L

Data Listing 16.2.5.2. Potassium Chloride Administration - Enrolled population

Patient Number	Age (Years)/ Gender	Did the Patient have any additional Potassium Chloride added to their Dialysate fluid?	ATC Term/Preferred Term/ Reported Term	Date and Time of Administration	Concentration	Unit
005-036	51/Female	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	14JAN2016 09:45	4	MMOLS/L
005-036	51/Female	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	14JAN2016 11:45	4	MMOLS/L
005-036	51/Female	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	14JAN2016 13:15	4	MMOLS/L
005-036	51/Female	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	14JAN2016 14:45	4	MMOLS/I
005-036	51/Female	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	14JAN2016 16:20	4	MMOLS/I

Data Listing 16.2.5.2. Potassium Chloride Administration - Enrolled population

Patient Number	Age (Years)/ Gender	Did the Patient have any additional Potassium Chloride added to their Dialysate fluid?	ATC Term/Preferred Term/ Reported Term	Date and Time of Administration	Concentration	Unit
005-036	51/Female	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	14JAN2016 17:50	4	MMOLS/L
005-036	51/Female	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	14JAN2016 19:30	4	MMOLS/L
005-036	51/Female	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	14JAN2016 21:05	4	MMOLS/L
005-036	51/Female	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	14JAN2016 23:00	4	MMOLS/L
005-036	51/Female	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	15JAN2016 00:16	4	MMOLS/L

Data Listing 16.2.5.2. Potassium Chloride Administration - Enrolled population

Patient Number	Age (Years)/ Gender	Did the Patient have any additional Potassium Chloride added to their Dialysate fluid?	ATC Term/Preferred Term/ Reported Term	Date and Time of Administration	Concentration	Unit
005-036	51/Female	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	14JAN2016 01:50	4	MMOLS/L
005-036	51/Female	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	15JAN2016 03:25	4	MMOLS/L
005-036	51/Female	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	15JAN2016 05:00	4	MMOLS/L
005-036	51/Female	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	15JAN2016 06:35	4	MMOLS/L
005-036	51/Female	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	15JAN2016 08:05	4	MMOLS/L

Data Listing 16.2.5.2. Potassium Chloride Administration - Enrolled population

Patient Number	Age (Years)/ Gender	Did the Patient have any additional Potassium Chloride added to their Dialysate fluid?	ATC Term/Preferred Term/ Reported Term	Date and Time of Administration	Concentration	Unit
005-037	53/Female	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	29JAN2016 15:00	4	MMOLS/L
005-037	53/Female	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	29JAN2016 16:40	4	MMOLS/L
005-037	53/Female	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	29JAN2016 18:15	4	MMOLS/L
005-037	53/Female	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	29JAN2016 20:10	4	MMOLS/L
005-037	53/Female	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	29JAN2016 22:15	4	MMOLS/L

Data Listing 16.2.5.2. Potassium Chloride Administration - Enrolled population

Patient Number	Age (Years)/ Gender	Did the Patient have any additional Potassium Chloride added to their Dialysate fluid?	ATC Term/Preferred Term/ Reported Term	Date and Time of Administration	Concentration	Unit
005-037	53/Female	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	30JAN2016 00:15	8	MMOLS/L
005-037	53/Female	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	30JAN2016 02:10	4	MMOLS/L
005-037	53/Female	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	30JAN2016 04:15	4	MMOLS/L
005-037	53/Female	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	30JAN2016 06:15	4	MMOLS/L
005-037	53/Female	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	30JAN2016 08:20	4	MMOLS/L

Data Listing 16.2.5.2. Potassium Chloride Administration - Enrolled population

Patient Number	Age (Years)/ Gender	Did the Patient have any additional Potassium Chloride added to their Dialysate fluid?	ATC Term/Preferred Term/ Reported Term	Date and Time of Administration	Concentration	Unit
005-037	53/Female	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	30JAN2016 10:30	4	MMOLS/L
005-037	53/Female	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	30JAN2016 12:30	4	MMOLS/L
005-037	53/Female	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	30JAN2016 14:30	4	MMOLS/L
005-037	53/Female	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	30JAN2016 16:30	4	MMOLS/L
005-037	53/Female	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	30JAN2016 18:35	4	MMOLS/L

Data Listing 16.2.5.2. Potassium Chloride Administration - Enrolled population

Patient Number	Age (Years)/ Gender	Did the Patient have any additional Potassium Chloride added to their Dialysate fluid?	ATC Term/Preferred Term/ Reported Term	Date and Time of Administration	Concentration	Unit
005-037	53/Female	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	30JAN2016 20:30	4	MMOLS/L
005-037	53/Female	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	30JAN2016 22:20	4	MMOLS/L
005-037	53/Female	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	30JAN2016 22:50	4	MMOLS/L
005-038		Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	29JAN2016 17:30	4	MMOLS/L
005-038		Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	29JAN2016 19:45	4	MMOLS/L
007-001	61/Male	No				

Data Listing 16.2.5.2. Potassium Chloride Administration - Enrolled population

Patient Number	Age (Years)/ Gender	Did the Patient have any additional Potassium Chloride added to their Dialysate fluid?	ATC Term/Preferred Term/ Reported Term	Date and Time of Administration	Concentration	Unit
007-002		No				
007-003	64/Male	No				
007-004	72/Male	No				
007-005	24/Male	No				
007-006	73/Female	No				
007-007	83/Male	No				
007-008	79/Male	No				
007-010	70/Male	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	01SEP2015 07:40	2	mmol/L
007-010	70/Male	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	01SEP2015 07:40	2	mmol/L
007-011	64/Female	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	01SEP2015 05:30	2	mmol/L

Data Listing 16.2.5.2. Potassium Chloride Administration - Enrolled population

Patient Number	Age (Years)/ Gender	Did the Patient have any additional Potassium Chloride added to their Dialysate fluid?	ATC Term/Preferred Term/ Reported Term	Date and Time of Administration	Concentration	Unit
007-011	64/Female	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	01SEP2015 05:30	2	mmol/L
007-011	64/Female	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	01SEP2015 07:50	2	mmol/L
007-011	64/Female	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	01SEP2015 07:50	2	mmol/L
007-011	64/Female	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	01SEP2015 10:30	2	mmol/L
007-011	64/Female	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	01SEP2015 10:30	2	mmol/L

Data Listing 16.2.5.2. Potassium Chloride Administration - Enrolled population

Patient Number	Age (Years)/ Gender	Did the Patient have any additional Potassium Chloride added to their Dialysate fluid?	ATC Term/Preferred Term/ Reported Term	Date and Time of Administration	Concentration	Unit
007-011	64/Female	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	01SEP2015 13:30	2	mmol/L
007-011	64/Female	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	01SEP2015 13:30	2	mmol/L
007-011	64/Female	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	01SEP2015 15:55	2	mmol/L
007-011	64/Female	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	01SEP2015 15:55	2	mmol/L
007-011	64/Female	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	01SEP2015 19:00	2	mmol/L

Data Listing 16.2.5.2. Potassium Chloride Administration - Enrolled population

Patient Number	Age (Years)/ Gender	Did the Patient have any additional Potassium Chloride added to their Dialysate fluid?	ATC Term/Preferred Term/ Reported Term	Date and Time of Administration	Concentration	Unit
007-011	64/Female	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	01SEP2015 19:00	2	mmol/L
007-011	64/Female	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	01SEP2015 21:30	2	mmol/L
007-011	64/Female	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	01SEP2015 21:30	2	mmol/L
007-011	64/Female	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	02SEP2015 00:00	2	mmol/L
007-011	64/Female	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	02SEP2015 00:00	2	mmol/L

Data Listing 16.2.5.2. Potassium Chloride Administration - Enrolled population

Patient Number	Age (Years)/ Gender	Did the Patient have any additional Potassium Chloride added to their Dialysate fluid?	ATC Term/Preferred Term/ Reported Term	Date and Time of Administration	Concentration	Unit
007-011	64/Female	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	02SEP2015 02:50	2	mmol/L
007-011	64/Female	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	02SEP2015 02:50	2	mmol/L
007-011	64/Female	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	02SEP2015 05:30	2	mmol/L
007-011	64/Female	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	02SEP2015 05:30	2	mmol/L
007-011	64/Female	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	02SEP2015 08:20	2	mmol/L

Data Listing 16.2.5.2. Potassium Chloride Administration - Enrolled population

Patient Number	Age (Years)/ Gender	Did the Patient have any additional Potassium Chloride added to their Dialysate fluid?	ATC Term/Preferred Term/ Reported Term	Date and Time of Administration	Concentration	Unit
007-011	64/Female	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	02SEP2015 08:20	2	mmol/L
007-011	64/Female	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	02SEP2015 11:00	2	mmol/L
007-011	64/Female	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	02SEP2015 11:00	2	mmol/L
007-012	36/Male	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	07SEP2015 17:30	2	mmol/L
007-012	36/Male	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	07SEP2015 17:30	2	mmol/L

Data Listing 16.2.5.2. Potassium Chloride Administration - Enrolled population

Patient Number	Age (Years)/ Gender	Did the Patient have any additional Potassium Chloride added to their Dialysate fluid?	ATC Term/Preferred Term/ Reported Term	Date and Time of Administration	Concentration	Unit
007-012	36/Male	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	07SEP2015 19:00	2	mmol/L
007-012	36/Male	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	07SEP2015 19:00	2	mmol/L
007-012	36/Male	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	07SEP2015 22:00	2	mmol/L
007-012	36/Male	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	07SEP2015 22:00	2	mmol/L
007-012	36/Male	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	08SEP2015 01:00	2	mmol/L

Data Listing 16.2.5.2. Potassium Chloride Administration - Enrolled population

Patient Number	Age (Years)/ Gender	Did the Patient have any additional Potassium Chloride added to their Dialysate fluid?	ATC Term/Preferred Term/ Reported Term	Date and Time of Administration	Concentration	Unit
007-012	36/Male	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	08SEP2015 01:00	2	mmol/L
007-012	36/Male	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	08SEP2015 04:00	2	mmol/L
007-012	36/Male	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	08SEP2015 04:00	2	mmol/L
007-012	36/Male	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	08SEP2015 07:00	2	mmol/L
007-012	36/Male	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	08SEP2015 07:00	2	mmol/L

Data Listing 16.2.5.2. Potassium Chloride Administration - Enrolled population

Patient Number	Age (Years)/ Gender	Did the Patient have any additional Potassium Chloride added to their Dialysate fluid?	ATC Term/Preferred Term/ Reported Term	Date and Time of Administration	Concentration	Unit
007-012	36/Male	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	08SEP2015 09:30	2	mmol/L
007-012	36/Male	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	08SEP2015 09:30	2	mmol/L
007-012	36/Male	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	08SEP2015 13:05	2	mmol/L
007-012	36/Male	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	08SEP2015 13:05	2	mmol/L
007-012	36/Male	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	08SEP2015 16:50	2	mmol/L

Data Listing 16.2.5.2. Potassium Chloride Administration - Enrolled population

Patient Number	Age (Years)/ Gender	Did the Patient have any additional Potassium Chloride added to their Dialysate fluid?	ATC Term/Preferred Term/ Reported Term	Date and Time of Administration	Concentration	Unit
007-012	36/Male	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	08SEP2015 16:50	2	mmol/L
007-012	36/Male	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	08SEP2015 20:00	2	mmol/L
007-012	36/Male	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	08SEP2015 20:00	2	mmol/L
007-012	36/Male	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	08SEP2015 23:00	2	mmol/L
007-012	36/Male	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	08SEP2015 23:00	2	mmol/L
007-014	74/Female	No				

Data Listing 16.2.5.2. Potassium Chloride Administration - Enrolled population

Patient Number	Age (Years)/ Gender	Did the Patient have any additional Potassium Chloride added to their Dialysate fluid?	ATC Term/Preferred Term/ Reported Term	Date and Time of Administration	Concentration	Unit
007-015	73/Female	No				
007-016	71/Male	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	05JAN2016 06:35	2	mmol/L
007-016	71/Male	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	05JAN2016 06:35	2	mmol/L
008-001	26/Male	No				
008-002	31/Male	No				
008-003	25/Female	No				
008-004	46/Male	No				
008-005	82/Male	No				
008-006	70/Male	No				
008-007	74/Male	No				
008-012	71/Male	No				
008-013	68/Male	No				
008-014	65/Female	No				

Data Listing 16.2.5.2. Potassium Chloride Administration - Enrolled population

Patient Number	Age (Years)/ Gender	Did the Patient have any additional Potassium Chloride added to their Dialysate fluid?	ATC Term/Preferred Term/ Reported Term	Date and Time of Administration	Concentration	Unit
008-016	34/Male	No				
008-017	52/Female	No				
008-018	65/Male	No				
008-019	69/Female	No				
008-020	60/Male	No				
008-021	66/Male	No				
008-022	43/Male	No				
008-023		No				
008-024	27/Male	No				
008-025	68/Male	No				
008-026	30/Female	No				
008-027	71/Male	No				
008-028	72/Male	No				
008-029	66/Female	No				
008-030	63/Female	No				
008-031	23/Male	No				

Data Listing 16.2.5.2. Potassium Chloride Administration - Enrolled population

Patient Number	Age (Years)/ Gender	Did the Patient have any additional Potassium Chloride added to their Dialysate fluid?	ATC Term/Preferred Term/ Reported Term	Date and Time of Administration	Concentration	Unit
009-001	64/Male	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	02APR2015 15:00	4	mmol/L
009-001	64/Male	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTTASIUM CHLORIDE	02APR2015 15:00	4	mmol/L
009-002		Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	09APR2015 01:25	4	mmol/L
009-002		Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	09APR2015 09:00	4	mmol/L
009-003	75/Male	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	14APR2015 11:00	4	mmol/L

Data Listing 16.2.5.2. Potassium Chloride Administration - Enrolled population

Patient Number	Age (Years)/ Gender	Did the Patient have any additional Potassium Chloride added to their Dialysate fluid?	ATC Term/Preferred Term/ Reported Term	Date and Time of Administration	Concentration	Unit
009-003	75/Male	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	14APR2015 13:00	4	mmol/L
009-003	75/Male	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	14APR2015 16:30	2	mmol/L
009-003	75/Male	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	14APR2015 23:55	2	mmol/L
009-003	75/Male	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	15APR2015 03:30	4	mmol/L
009-003	75/Male	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	15APR2015 07:40	4	mmol/L

Data Listing 16.2.5.2. Potassium Chloride Administration - Enrolled population

Patient Number	Age (Years)/ Gender	Did the Patient have any additional Potassium Chloride added to their Dialysate fluid?	ATC Term/Preferred Term/ Reported Term	Date and Time of Administration	Concentration	Unit
009-003	75/Male	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	15APR2015 11:30	2	mmol/L
009-003	75/Male	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	15APR2015 14:00	2	mmol/L
009-006	58/Female	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	23APR2015 02:00	4	mmol/L
009-006	58/Female	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	23APR2015 06:00	4	mmol/L
009-008	31/Male	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	29APR2015 17:00	4	mmol/L

Data Listing 16.2.5.2. Potassium Chloride Administration - Enrolled population

Patient Number	Age (Years)/ Gender	Did the Patient have any additional Potassium Chloride added to their Dialysate fluid?	ATC Term/Preferred Term/ Reported Term	Date and Time of Administration	Concentration	Unit
009-008	31/Male	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	29APR2015 20:30	4	mmol/L
009-008	31/Male	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	30APR2015 12:00	4	mmol/L
009-008	31/Male	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	30APR2015 16:00	4	mmol/L
009-008	31/Male	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	30APR2015 19:00	4	mmol/L
009-009		Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	30APR2015 14:00	4	mmol/L

Data Listing 16.2.5.2. Potassium Chloride Administration - Enrolled population

Patient Number	Age (Years)/ Gender	Did the Patient have any additional Potassium Chloride added to their Dialysate fluid?	ATC Term/Preferred Term/ Reported Term	Date and Time of Administration	Concentration	Unit
009-009		Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	30APR2015 19:00	4	mmol/L
009-009		Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	30APR2015 23:30	4	mmol/L
009-009		Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	01MAY2015 02:40	4	mmol/L
009-009		Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	01MAY2015 06:45	4	mmol/L
009-009		Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	01MAY2015 10:10	4	mmol/L

Data Listing 16.2.5.2. Potassium Chloride Administration - Enrolled population

Patient Number	Age (Years)/ Gender	Did the Patient have any additional Potassium Chloride added to their Dialysate fluid?	ATC Term/Preferred Term/ Reported Term	Date and Time of Administration	Concentration	Unit
009-009		Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	01MAY2015 13:35	4	mmol/L
009-011	75/Female	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	20MAY2015 20:00	4	mmol/L
009-011	75/Female	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	20MAY2015 23:45	4	mmol/L
009-011	75/Female	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	21MAY2015 04:00	4	mmol/L
009-011	75/Female	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	21MAY2015 08:30	4	mmol/L

Data Listing 16.2.5.2. Potassium Chloride Administration - Enrolled population

Patient Number	Age (Years)/ Gender	Did the Patient have any additional Potassium Chloride added to their Dialysate fluid?	ATC Term/Preferred Term/ Reported Term	Date and Time of Administration	Concentration	Unit
009-013	60/Female	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	11JUN2015 10:00	4	mmol/L
009-013	60/Female	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	11JUN2015 15:00	4	mmol/L
009-013	60/Female	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	11JUN2015 20:20	4	mmol/L
009-015	29/Male	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTTASIAM CHLORIDE	17JUL2015 12:00	4	mmol/L
009-015	29/Male	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTTASIAM CHLORIDE	17JUL2015 15:00	4	mmol/L

Data Listing 16.2.5.2. Potassium Chloride Administration - Enrolled population

Patient Number	Age (Years)/ Gender	Did the Patient have any additional Potassium Chloride added to their Dialysate fluid?	ATC Term/Preferred Term/ Reported Term	Date and Time of Administration	Concentration	Unit
009-016	83/Male	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	21JUL2015 13:00	4	mmol/L
009-017	51/Male	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTTASIUM CHLORIDE	23JUL2015 13:00	4	mmol/L
009-017	51/Male	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	23JUL2015 16:30	4	mmol/L
009-018	44/Male	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	23JUL2015 18:00	4	mmol/L
009-018	44/Male	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	23JUL2015 22:45	4	mmol/L

Data Listing 16.2.5.2. Potassium Chloride Administration - Enrolled population

Patient Number	Age (Years)/ Gender	Did the Patient have any additional Potassium Chloride added to their Dialysate fluid?	ATC Term/Preferred Term/ Reported Term	Date and Time of Administration	Concentration	Unit
009-018	44/Male	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	24JUL2015 04:25	4	mmol/L
009-018	44/Male	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	24JUL2015 08:30	4	mmol/L
009-018	44/Male	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	24JUL2015 13:00	4	mmol/L
009-018	44/Male	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	24JUL2015 17:00	4	mmol/L
009-018	44/Male	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	24JUL2015 22:45	4	mmol/L

Data Listing 16.2.5.2. Potassium Chloride Administration - Enrolled population

Patient Number	Age (Years)/ Gender	Did the Patient have any additional Potassium Chloride added to their Dialysate fluid?	ATC Term/Preferred Term/ Reported Term	Date and Time of Administration	Concentration	Unit
009-019	84/Male	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	27JUL2015 16:30	4	mmol/L
009-019	84/Male	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	28JUL2015 00:00	4	mmol/L
009-021	51/Male	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	02AUG2015 21:20	4	mmol/L
009-021	51/Male	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	03AUG2015 01:15	4	mmol/L
009-021	51/Male	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	03AUG2015 07:54	4	mmol/L

Data Listing 16.2.5.2. Potassium Chloride Administration - Enrolled population

Patient Number	Age (Years)/ Gender	Did the Patient have any additional Potassium Chloride added to their Dialysate fluid?	ATC Term/Preferred Term/ Reported Term	Date and Time of Administration	Concentration	Unit
009-022		Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	01AUG2015 11:05	4	mmol/L
009-022		Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	01AUG2015 11:05	4	mmol/L
009-022		Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	01AUG2015 16:00	4	mmol/L
009-022		Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	01AUG2015 16:00	4	mmol/L
009-024	49/Female	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	29AUG2015 22:00	4	mmol/L

Data Listing 16.2.5.2. Potassium Chloride Administration - Enrolled population

Patient Number	Age (Years)/ Gender	Did the Patient have any additional Potassium Chloride added to their Dialysate fluid?	ATC Term/Preferred Term/ Reported Term	Date and Time of Administration	Concentration	Unit
009-024	49/Female	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	30AUG2015 06:55	4	mmol/L
009-024	49/Female	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	30AUG2015 11:30	4	mmol/L
009-024	49/Female	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	30AUG2015 19:00	4	mmol/L
009-026	76/Female	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	07OCT2015 08:00	4	mmol/L
009-026	76/Female	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	07OCT2015 10:00	4	mmol/L

Data Listing 16.2.5.2. Potassium Chloride Administration - Enrolled population

Patient Number	Age (Years)/ Gender	Did the Patient have any additional Potassium Chloride added to their Dialysate fluid?	ATC Term/Preferred Term/ Reported Term	Date and Time of Administration	Concentration	Unit
009-026	76/Female	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	07OCT2015 14:30	4	mmol/L
009-026	76/Female	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	07OCT2015 20:00	4	mmol/L
009-026	76/Female	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	08OCT2015 00:15	4	mmol/L
009-026	76/Female	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	08OCT2015 06:00	4	mmol/L
009-026	76/Female	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	08OCT2015 11:20	4	mmol/L

Data Listing 16.2.5.2. Potassium Chloride Administration - Enrolled population

Patient Number	Age (Years)/ Gender	Did the Patient have any additional Potassium Chloride added to their Dialysate fluid?	ATC Term/Preferred Term/ Reported Term	Date and Time of Administration	Concentration	Unit
009-027	53/Male	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	12OCT2015 22:00	4	mmol/L
009-027	53/Male	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	12OCT2015 23:30	4	mmol/L
009-027	53/Male	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	13OCT2015 04:30	4	mmol/L
009-028		Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	25NOV2015 21:00	2	mmol/L
009-028		Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	25NOV2015 23:30	4	mmol/L

Data Listing 16.2.5.2. Potassium Chloride Administration - Enrolled population

Patient Number	Age (Years)/ Gender	Did the Patient have any additional Potassium Chloride added to their Dialysate fluid?	ATC Term/Preferred Term/ Reported Term	Date and Time of Administration	Concentration	Unit
009-028		Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	26NOV2015 03:45	4	mmol/L
009-028		Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	26NOV2015 08:30	2	mmol/L
009-030	75/Male	No				
009-031	34/Male	No				
009-032	59/Male	No				
010-002	57/Male	No				
010-003		No				
010-005	78/Male	No				
010-006	80/Male	No				
010-008	70/Female	No				
010-009	69/Male	No				
010-010	52/Female	No				
010-011		No				

Data Listing 16.2.5.2. Potassium Chloride Administration - Enrolled population

Patient Number	Age (Years)/ Gender	Did the Patient have any additional Potassium Chloride added to their Dialysate fluid?	ATC Term/Preferred Term/ Reported Term	Date and Time of Administration	Concentration	Unit
010-014	79/Female	No				
011-001	53/Male	No				
011-002	75/Male	No				
011-003	80/Male	No				
011-004	80/Female	No				
011-005	78/Male	No				
011-006	77/Male	No				
011-007	62/Female	No				
011-008	61/Male	No				
011-009	71/Female	No				
011-010	47/Male	No				
011-011	77/Male	No				
011-012	74/Male	No				
011-013	71/Female	No				
011-014	79/Female	No				
011-015	77/Female	No				
011-016	72/Female	No				
012-001	59/Male	No				

Data Listing 16.2.5.2. Potassium Chloride Administration - Enrolled population

Patient Number	Age (Years)/ Gender	Did the Patient have any additional Potassium Chloride added to their Dialysate fluid?	ATC Term/Preferred Term/ Reported Term	Date and Time of Administration	Concentration	Unit
012-002	67/Male	No				
012-003	63/Male	No				
012-004	59/Female	No				
012-005	41/Male	No				
012-006	44/Male	No				
012-007	82/Male	No				
012-008	59/Male	No				
012-009	70/Male	No				
012-010	72/Male	No				
012-011	58/Female	No				
012-012	69/Male	No				
012-013	77/Female	No				
013-002	70/Male	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	01JUL2015 06:00	4	mmols/l

Data Listing 16.2.5.2. Potassium Chloride Administration - Enrolled population

Patient Number	Age (Years)/ Gender	Did the Patient have any additional Potassium Chloride added to their Dialysate fluid?	ATC Term/Preferred Term/ Reported Term	Date and Time of Administration	Concentration	Unit
013-002	70/Male	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	01JUL2015 06:00	4	mmols/l
013-002	70/Male	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	01JUL2015 14:30	4	mmols/l
013-002	70/Male	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	01JUL2015 14:30	4	mmols/l
013-002	70/Male	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	01JUL2015 14:30	4	mmols/l
013-002	70/Male	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	01JUL2015 16:20	4	mmols/l

Data Listing 16.2.5.2. Potassium Chloride Administration - Enrolled population

Patient Number	Age (Years)/ Gender	Did the Patient have any additional Potassium Chloride added to their Dialysate fluid?	ATC Term/Preferred Term/ Reported Term	Date and Time of Administration	Concentration	Unit
013-002	70/Male	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	01JUL2015 16:20	4	mmols/l
013-002	70/Male	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	02JUL2015 00:05	4	mmols/l
013-002	70/Male	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	02JUL2015 00:05	4	mmols/l
013-002	70/Male	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	02JUL2015 00:05	4	mmols/l
013-002	70/Male	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	02JUL2015 08:00	4	mmols/l

Data Listing 16.2.5.2. Potassium Chloride Administration - Enrolled population

Patient Number	Age (Years)/ Gender	Did the Patient have any additional Potassium Chloride added to their Dialysate fluid?	ATC Term/Preferred Term/ Reported Term	Date and Time of Administration	Concentration	Unit
013-002	70/Male	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	02JUL2015 08:00	4	mmols/l
013-002	70/Male	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	02JUL2015 08:00	4	mmols/l
013-003	69/Male	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	29JUL2015 15:00	4	mmols/L
013-003	69/Male	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	29JUL2015 15:00	4	mmols/L
013-003	69/Male	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	29JUL2015 15:00	4	mmols/L

Data Listing 16.2.5.2. Potassium Chloride Administration - Enrolled population

Patient Number	Age (Years)/ Gender	Did the Patient have any additional Potassium Chloride added to their Dialysate fluid?	ATC Term/Preferred Term/ Reported Term	Date and Time of Administration	Concentration	Unit
013-004	64/Female	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	09SEP2015 04:00	4	mmols/l
013-004	64/Female	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	09SEP2015 04:00	4	mmols/l
013-004	64/Female	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	09SEP2015 05:00	4	mmols/l
013-004	64/Female	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	09SEP2015 05:00	4	mmols/l
013-004	64/Female	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	09SEP2015 08:30	4	mmols/l

Data Listing 16.2.5.2. Potassium Chloride Administration - Enrolled population

Patient Number	Age (Years)/ Gender	Did the Patient have any additional Potassium Chloride added to their Dialysate fluid?	ATC Term/Preferred Term/ Reported Term	Date and Time of Administration	Concentration	Unit
013-004	64/Female	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	09SEP2015 08:30	4	mmols/l
013-005		Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	17SEP2015 13:00	4	mmols/l
013-005		Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/KCL	17SEP2015 13:00	4	mmols/l
013-005		Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/KCL	17SEP2015 13:00	4	mmols/l
013-005		Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/KCL	17SEP2015 19:00	4	mmols/l
013-005		Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/KCL	17SEP2015 19:00	4	mmols/l

Data Listing 16.2.5.2. Potassium Chloride Administration - Enrolled population

Patient Number	Age (Years)/ Gender	Did the Patient have any additional Potassium Chloride added to their Dialysate fluid?	ATC Term/Preferred Term/ Reported Term	Date and Time of Administration	Concentration	Unit
013-005		Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/KCL	17SEP2015 19:00	4	mmols/l
013-005		Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/KCL	18SEP2015 03:30	4	mmols/l
013-005		Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/KCL	18SEP2015 03:30	4	mmols/l
013-005		Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/KCL	18SEP2015 03:30	4	mmols/l
013-005		Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/KCL	18SEP2015 12:00	4	mmols/l
013-005		Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/KCL	18SEP2015 12:00	4	mmols/l

Data Listing 16.2.5.2. Potassium Chloride Administration - Enrolled population

Patient Number	Age (Years)/ Gender	Did the Patient have any additional Potassium Chloride added to their Dialysate fluid?	ATC Term/Preferred Term/ Reported Term	Date and Time of Administration	Concentration	Unit
013-005		Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/KCL	18SEP2015 12:00	4	mmols/l
013-005		Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/KCL	18SEP2015 20:00	4	mmols/l
013-005		Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/KCL	18SEP2015 20:00	4	mmols/l
013-005		Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/KCL	18SEP2015 20:00	4	mmols/l
013-010	76/Female	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	05DEC2015 07:00	4	mmols/l
013-010	76/Female	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	05DEC2015 07:00	4	mmols/l

Data Listing 16.2.5.2. Potassium Chloride Administration - Enrolled population

Patient Number	Age (Years)/ Gender	Did the Patient have any additional Potassium Chloride added to their Dialysate fluid?	ATC Term/Preferred Term/ Reported Term	Date and Time of Administration	Concentration	Unit
013-010	76/Female	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	05DEC2015 07:00	4	mmols/l
013-010	76/Female	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/POTASSIUM CHLORIDE	05DEC2015 16:11	4	mmols/l
013-010	76/Female	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/KCL	05DEC2015 16:11	4	mmols/l
013-010	76/Female	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/KCL	05DEC2015 16:11	4	mmols/l
013-010	76/Female	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/KCL	06DEC2015 00:07	4	mmols/l
013-010	76/Female	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/KCL	06DEC2015 00:07	4	mmols/l

Data Listing 16.2.5.2. Potassium Chloride Administration - Enrolled population

Patient Number	Age (Years)/ Gender	Did the Patient have any additional Potassium Chloride added to their Dialysate fluid?	ATC Term/Preferred Term/ Reported Term	Date and Time of Administration	Concentration	Unit
013-010	76/Female	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/KCL	06DEC2015 00:07	4	mmols/l
013-010	76/Female	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/KCL	06DEC2015 08:10	4	mmols/l
013-010	76/Female	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/KCL	06DEC2015 08:10	4	mmols/l
013-010	76/Female	Yes	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/POTASSIUM CHLORIDE/KCL	06DEC2015 08:10	4	mmols/l
014-001	75/Female	No				
014-002	47/Male	No				
014-003	63/Female	No				
014-004	33/Female	No				
014-007	34/Female	No				
015-001	77/Female	No				
015-002	60/Male	No				

Data Listing 16.2.5.2. Potassium Chloride Administration - Enrolled population

Patient Number	Age (Years)/ Gender	Did the Patient have any additional Potassium Chloride added to their Dialysate fluid?	ATC Term/Preferred Term/ Reported Term	Date and Time of Administration	Concentration	Unit
015-003	57/Male	No				
015-004	85/Male	No				
015-005	76/Male	No				
015-006	84/Female	No				
015-009	76/Female	No				
015-010		No				
015-011		No				
016-002		No				
016-004	55/Male	No				
017-003	92/Female	No				
017-004	74/Male	No				
017-005	77/Male	No				
017-007	66/Male	No				
017-008		No				
017-010	54/Male	No				
017-011	49/Male	No				

Data Listing 16.2.5.3. ACCUSOL 35 Administration - Enrolled Population

Patient Number	Age (Years)/ Gender	First Accusol Administration Start Date/ Time	Dialysis Solution Used	Lot Number	Site of Introduction	Start Date and Time/ End Date and Time	Dialysis Dose (ml/kg/hr)	Amount Administered (L)
001-001	57/Female		ACCUSOL 35 Potassium 4 mmol/L	UNK				.
001-002	50/Male	12JUN2015	ACCUSOL 35 Potassium 4 mmol/L	UNK	POST-FILTER	12JUN2015 / 12JUN2015 15:10	31.21	.
001-002	50/Male	12JUN2015	ACCUSOL 35 Potassium 4 mmol/L	15A08G75	POST-FILTER	12JUN2015 15:10 / 12JUN2015 16:32	31.21	5
001-002	50/Male	12JUN2015	ACCUSOL 35 Potassium 4 mmol/L	15A08G75	POST-FILTER	12JUN2015 16:32 / 12JUN2015 18:28	31.21	5
001-002	50/Male	12JUN2015	ACCUSOL 35 Potassium 4 mmol/L	15C01G70	POST-FILTER	12JUN2015 18:28 / 12JUN2015 20:10	31.21	5
001-002	50/Male	12JUN2015	ACCUSOL 35 Potassium 4 mmol/L	15C01G70	POST-FILTER	12JUN2015 20:10 / 12JUN2015 21:56	31.21	5
001-002	50/Male	12JUN2015	ACCUSOL 35 Potassium 4 mmol/L	18A08G75	POST-FILTER	12JUN2015 21:56 / 12JUN2015 23:34	31.21	5
001-002	50/Male	12JUN2015	ACCUSOL 35 Potassium 4 mmol/L	15A08G75	POST-FILTER	12JUN2015 23:34 / 13JUN2015 01:13	34.15	5
001-002	50/Male	12JUN2015	ACCUSOL 35 Potassium 4 mmol/L	15A08G75	POST-FILTER	13JUN2015 01:13 / 13JUN2015 02:55	34.15	5
001-002	50/Male	12JUN2015	ACCUSOL 35 Potassium 4 mmol/L	15A08G75	POST-FILTER	13JUN2015 02:55 / 13JUN2015 04:26	34.15	5
001-002	50/Male	12JUN2015	ACCUSOL 35 Potassium 4 mmol/L	15A08G75	POST-FILTER	13JUN2015 04:26 / 13JUN2015 06:03	34.15	5

Data Listing 16.2.5.3. ACCUSOL 35 Administration - Enrolled Population

Patient Number	Age (Years)/ Gender	First Accusol Administration Start Date/ Time	Dialysis Solution Used	Lot Number	Site of Introduction	Start Date and Time/ End Date and Time	Dialysis Dose (ml/kg/hr)	Amount Administered (L)
001-002	50/Male	12JUN2015	ACCUSOL 35 Potassium 4 mmol/L	15C01G70	POST-FILTER	13JUN2015 06:03 / 13JUN2015 07:45	34.15	5
001-002	50/Male	12JUN2015	ACCUSOL 35 Potassium 4 mmol/L	15C01G70	POST-FILTER	13JUN2015 07:45 / 13JUN2015 09:21	34.15	5
001-002	50/Male	12JUN2015	ACCUSOL 35 Potassium 4 mmol/L	15A08G75	POST-FILTER	13JUN2015 09:21 / 13JUN2015 11:00	34.15	5
001-002	50/Male	12JUN2015	ACCUSOL 35 Potassium 4 mmol/L	15A08G75	POST-FILTER	13JUN2015 11:00 / 13JUN2015 12:58	34.15	5
001-002	50/Male	12JUN2015	ACCUSOL 35 Potassium 4 mmol/L	15A08G75	POST-FILTER	13JUN2015 12:58 / 13JUN2015 14:40	34.15	5
001-002	50/Male	12JUN2015	ACCUSOL 35 Potassium 4 mmol/L	15A08G75	POST-FILTER	13JUN2015 14:40 / 13JUN2015 16:10	34.15	5
001-002	50/Male	12JUN2015	ACCUSOL 35 Potassium 4 mmol/L	15A08G75	POST-FILTER	13JUN2015 16:10 / 13JUN2015 17:55	34.15	5
001-002	50/Male	12JUN2015	ACCUSOL 35 Potassium 4 mmol/L	15A08G75	POST-FILTER	13JUN2015 17:55 / 13JUN2015 19:35	34.15	5
001-002	50/Male	12JUN2015	ACCUSOL 35 Potassium 4 mmol/L	15A08G75	POST-FILTER	13JUN2015 19:35 / 13JUN2015 21:09	34.15	5
001-002	50/Male	12JUN2015	ACCUSOL 35	15A09G70	POST-FILTER	13JUN2015 21:09 / 13JUN2015 22:49	34.9	5
001-002	50/Male	12JUN2015	ACCUSOL 35 Potassium 4 mmol/L	15B02G70	POST-FILTER	13JUN2015 22:50 / 13JUN2015 23:04	34.9	0.7

Data Listing 16.2.5.3. ACCUSOL 35 Administration - Enrolled Population

Patient Number	Age (Years)/ Gender	First Accusol Administration Start Date/ Time	Dialysis Solution Used	Lot Number	Site of Introduction	Start Date and Time/ End Date and Time	Dialysis Dose (ml/kg/hr)	Amount Administered (L)
001-003	68/Female	14AUG2015 14:06	ACCUSOL 35 Potassium 4 mmol/L	15C02G71	POST-FILTER	14AUG2015 14:06 / 14AUG2015 15:11	35	2.48
001-003	68/Female	14AUG2015 14:06	ACCUSOL 35 Potassium 4 mmol/L	15C02G71	POST-FILTER	14AUG2015 15:11 / 14AUG2015 17:44	35	5
001-003	68/Female	14AUG2015 14:06	ACCUSOL 35 Potassium 4 mmol/L	15C02G71	POST-FILTER	14AUG2015 17:44 / 14AUG2015 19:50	35	5
001-003	68/Female	14AUG2015 14:06	ACCUSOL 35 Potassium 4 mmol/L	15C02G71	POST-FILTER	14AUG2015 19:50 / 14AUG2015 22:10	35	5
001-003	68/Female	14AUG2015 14:06	ACCUSOL 35 Potassium 4 mmol/L	15C02F71	POST-FILTER	14AUG2015 22:10 / 15AUG2015 00:25	35	5
001-003	68/Female	14AUG2015 14:06	ACCUSOL 35 Potassium 4 mmol/L	15D11G70	POST-FILTER	15AUG2015 00:25 / 15AUG2015 02:20	35	5
001-003	68/Female	14AUG2015 14:06	ACCUSOL 35 Potassium 4 mmol/L		POST-FILTER	15AUG2015 02:20 / 15AUG2015 02:30		.
001-004	78/Female	18SEP2015	ACCUSOL 35 Potassium 4 mmol/L	UNK	POST-FILTER	18SEP2015 / 18SEP2015 21:05	38.5	.
001-004	78/Female	18SEP2015	ACCUSOL 35 Potassium 4 mmol/L	15D11G70	POST-FILTER	18SEP2015 21:05 / 19SEP2015 00:25	38.5	5
001-004	78/Female	18SEP2015	ACCUSOL 35 Potassium 4 mmol/L	15D11G70	POST-FILTER	19SEP2015 00:25 / 19SEP2015 03:20	38.5	5
001-004	78/Female	18SEP2015	ACCUSOL 35 Potassium 4 mmol/L	15D11G70	POST-FILTER	19SEP2015 03:20 / 19SEP2015 06:00	38.5	5

Data Listing 16.2.5.3. ACCUSOL 35 Administration - Enrolled Population

Patient Number	Age (Years)/ Gender	First Accusol Administration Start Date/ Time	Dialysis Solution Used	Lot Number	Site of Introduction	Start Date and Time/ End Date and Time	Dialysis Dose (ml/kg/hr)	Amount Administered (L)
001-004	78/Female	18SEP2015	ACCUSOL 35 Potassium 4 mmol/L	15D11G70	POST-FILTER	19SEP2015 06:00 / 19SEP2015 08:45	38.5	5
001-004	78/Female	18SEP2015	ACCUSOL 35 Potassium 4 mmol/L	15D11G70	POST-FILTER	19SEP2015 08:45 / 19SEP2015 11:30	38.5	5
001-004	78/Female	18SEP2015	ACCUSOL 35 Potassium 4 mmol/L	15D11G70	POST-FILTER	19SEP2015 11:30 / 19SEP2015 14:45	38.5	5
001-004	78/Female	18SEP2015	ACCUSOL 35 Potassium 4 mmol/L	15A07G70	POST-FILTER	19SEP2015 14:45 / 19SEP2015 17:40	38.5	5
001-004	78/Female	18SEP2015	ACCUSOL 35 Potassium 4 mmol/L	15A07G70	POST-FILTER	19SEP2015 17:40 / 19SEP2015 22:15	38.5	5
001-004	78/Female	18SEP2015	ACCUSOL 35 Potassium 4 mmol/L	15A07G70	POST-FILTER	19SEP2015 22:15 / 19SEP2015	38.5	5
001-004	78/Female	18SEP2015	ACCUSOL 35 Potassium 4 mmol/L	15A07G70	POST-FILTER	20SEP2015 00:37 / 20SEP2015 03:10	38.5	5
001-004	78/Female	18SEP2015	ACCUSOL 35 Potassium 4 mmol/L	15A07G70	POST-FILTER	20SEP2015 03:10 / 20SEP2015 04:01	38.5	1.76
001-005	33/Female	29OCT2015 06:10	ACCUSOL 35 Potassium 4 mmol/L	UNK	POST-FILTER	29OCT2015 06:10 / 29OCT2015 08:00	30.7	4.77
001-005	33/Female	29OCT2015 06:10	ACCUSOL 35 Potassium 4 mmol/L	15H28G73	POST-FILTER	29OCT2015 08:00 / 29OCT2015 10:15	30.7	5
001-005	33/Female	29OCT2015 06:10	ACCUSOL 35 Potassium 4 mmol/L	15H28G73	POST-FILTER	29OCT2015 10:15 / 29OCT2015 12:15	30.7	5

Data Listing 16.2.5.3. ACCUSOL 35 Administration - Enrolled Population

Patient Number	Age (Years)/ Gender	First Accusol Administration Start Date/ Time	Dialysis Solution Used	Lot Number	Site of Introduction	Start Date and Time/ End Date and Time	Dialysis Dose (ml/kg/hr)	Amount Administered (L)
001-005	33/Female	29OCT2015 06:10	ACCUSOL 35 Potassium 4 mmol/L	15H28G73	POST-FILTER	29OCT2015 12:15 / 29OCT2015 16:15	30.7	5
001-005	33/Female	29OCT2015 06:10	ACCUSOL 35 Potassium 4 mmol/L	15H28G73	POST-FILTER	29OCT2015 16:15 / 29OCT2015 18:20	30.7	5
001-005	33/Female	29OCT2015 06:10	ACCUSOL 35 Potassium 4 mmol/L	15H28G73	POST-FILTER	29OCT2015 18:20 / 29OCT2015 20:30	30.7	5
001-005	33/Female	29OCT2015 06:10	ACCUSOL 35 Potassium 4 mmol/L	15H28G73	POST-FILTER	29OCT2015 20:30 / 29OCT2015 22:23	30.4	5
001-005	33/Female	29OCT2015 06:10	ACCUSOL 35 Potassium 4 mmol/L	15G09G70	POST-FILTER	29OCT2015 22:23 / 30OCT2015 00:52	30.4	5
001-005	33/Female	29OCT2015 06:10	ACCUSOL 35 Potassium 4 mmol/L	15G09G70	POST-FILTER	30OCT2015 00:52 / 30OCT2015 02:58	30.4	5
001-005	33/Female	29OCT2015 06:10	ACCUSOL 35 Potassium 4 mmol/L	15H28G73	POST-FILTER	30OCT2015 02:58 / 30OCT2015 05:15	30.4	5
001-005	33/Female	29OCT2015 06:10	ACCUSOL 35 Potassium 4 mmol/L	15H28G73	POST-FILTER	30OCT2015 05:15 / 30OCT2015 07:20	30.4	5
001-005	33/Female	29OCT2015 06:10	ACCUSOL 35 Potassium 4 mmol/L	15H28G73	POST-FILTER	30OCT2015 07:20 / 30OCT2015 08:40	30.4	5
001-005	33/Female	29OCT2015 06:10	ACCUSOL 35 Potassium 4 mmol/L	15G09G70	POST-FILTER	30OCT2015 08:40 / 30OCT2015 10:35	37.4	5
001-005	33/Female	29OCT2015 06:10	ACCUSOL 35 Potassium 4 mmol/L	15G09G70	POST-FILTER	30OCT2015 10:35 / 30OCT2015 12:42	37.4	5

Data Listing 16.2.5.3. ACCUSOL 35 Administration - Enrolled Population

Patient Number	Age (Years)/ Gender	First Accusol Administration Start Date/ Time	Dialysis Solution Used	Lot Number	Site of Introduction	Start Date and Time/ End Date and Time	Dialysis Dose (ml/kg/hr)	Amount Administered (L)
001-005	33/Female	29OCT2015 06:10	ACCUSOL 35 Potassium 4 mmol/L	15G09G70	POST-FILTER	30OCT2015 12:42 / 30OCT2015 14:10	38.4	4.69
001-006		12NOV2015 18:30	ACCUSOL 35 Potassium 4 mmol/L	UNK	POST-FILTER	12NOV2015 18:30 / 12NOV2015 20:30	40	.
001-006		12NOV2015 18:30	ACCUSOL 35 Potassium 4 mmol/L	15G09G70	POST-FILTER	12NOV2015 20:30 / 12NOV2015 22:16	40	5
001-006		12NOV2015 18:30	ACCUSOL 35 Potassium 4 mmol/L	15G09G70	POST-FILTER	12NOV2015 22:16 / 12NOV2015 23:45	40	5
001-006		12NOV2015 18:30	ACCUSOL 35 Potassium 4 mmol/L	15G09G71	POST-FILTER	12NOV2015 23:45 / 13NOV2015 01:10	40	5
001-006		12NOV2015 18:30	ACCUSOL 35 Potassium 4 mmol/L	15G09G71	POST-FILTER	13NOV2015 01:10 / 13NOV2015 02:40	40	5
001-006		12NOV2015 18:30	ACCUSOL 35 Potassium 4 mmol/L	15G09G71	POST-FILTER	13NOV2015 02:40 / 13NOV2015 04:00	40	5
001-006		12NOV2015 18:30	ACCUSOL 35 Potassium 4 mmol/L	15G09G71	POST-FILTER	13NOV2015 04:00 / 13NOV2015 05:40	40	5
001-006		12NOV2015 18:30	ACCUSOL 35 Potassium 4 mmol/L	15G09G71	POST-FILTER	13NOV2015 05:40 / 13NOV2015 07:20	40	5
001-006		12NOV2015 18:30	ACCUSOL 35 Potassium 4 mmol/L	15G09G71	POST-FILTER	13NOV2015 07:20 / 13NOV2015 08:35	40	5
001-006		12NOV2015 18:30	ACCUSOL 35 Potassium 4 mmol/L	15G09G71	POST-FILTER	13NOV2015 08:35 / 13NOV2015 10:10	40	5

Data Listing 16.2.5.3. ACCUSOL 35 Administration - Enrolled Population

Patient Number	Age (Years)/ Gender	First Accusol Administration Start Date/ Time	Dialysis Solution Used	Lot Number	Site of Introduction	Start Date and Time/ End Date and Time	Dialysis Dose (ml/kg/hr)	Amount Administered (L)
001-006		12NOV2015 18:30	ACCUSOL 35 Potassium 4 mmol/L	15G09G71	POST-FILTER	13NOV2015 10:10 / 13NOV2015 11:33	40	5
001-006		12NOV2015 18:30	ACCUSOL 35 Potassium 4 mmol/L	15G09G71	POST-FILTER	13NOV2015 11:33 / 13NOV2015 12:50	40	5
001-006		12NOV2015 18:30	ACCUSOL 35 Potassium 4 mmol/L	15G09G71	POST-FILTER	13NOV2015 12:50 / 13NOV2015 14:25	34.8	5
001-006		12NOV2015 18:30	ACCUSOL 35 Potassium 4 mmol/L	15G09G71	POST-FILTER	13NOV2015 14:25 / 13NOV2015 15:50	34.8	3.7
001-007	56/Male	22DEC2015 19:33	ACCUSOL 35 Potassium 4 mmol/L	UNK	POST-FILTER	22DEC2015 19:33 / 22DEC2015 21:16	29.87	.
001-007	56/Male	22DEC2015 19:33	ACCUSOL 35 Potassium 4 mmol/L	15H28G72	POST-FILTER	22DEC2015 21:16 / 23DEC2015 00:10	29.87	5
001-007	56/Male	22DEC2015 19:33	ACCUSOL 35 Potassium 4 mmol/L	15H28G72	POST-FILTER	23DEC2015 00:10 / 23DEC2015 02:47	29.87	5
001-007	56/Male	22DEC2015 19:33	ACCUSOL 35 Potassium 4 mmol/L	15H28G72	POST-FILTER	23DEC2015 02:47 / 23DEC2015 05:22	29.87	5
001-007	56/Male	22DEC2015 19:33	ACCUSOL 35 Potassium 4 mmol/L	15H28G72	POST-FILTER	23DEC2015 05:22 / 23DEC2015 08:00	29.87	5
001-007	56/Male	22DEC2015 19:33	ACCUSOL 35 Potassium 4 mmol/L	15H28G72	POST-FILTER	23DEC2015 08:00 / 23DEC2015 10:42	29.87	5
001-007	56/Male	22DEC2015 19:33	ACCUSOL 35 Potassium 4 mmol/L	15H22G72	POST-FILTER	23DEC2015 10:42 / 23DEC2015 13:00	30.22	5

Data Listing 16.2.5.3. ACCUSOL 35 Administration - Enrolled Population

Patient Number	Age (Years)/ Gender	First Accusol Administration Start Date/ Time	Dialysis Solution Used	Lot Number	Site of Introduction	Start Date and Time/ End Date and Time	Dialysis Dose (ml/kg/hr)	Amount Administered (L)
001-007	56/Male	22DEC2015 19:33	ACCUSOL 35 Potassium 4 mmol/L	15I22G72	POST-FILTER	23DEC2015 13:00 / 23DEC2015 15:18	30.22	5
001-007	56/Male	22DEC2015 19:33	ACCUSOL 35 Potassium 4 mmol/L	15I22G72	POST-FILTER	23DEC2015 15:18 / 23DEC2015 18:10	30.22	5
001-007	56/Male	22DEC2015 19:33	ACCUSOL 35 Potassium 4 mmol/L	15I22G72	POST-FILTER	23DEC2015 18:10 / 23DEC2015 20:30	30.22	5
001-007	56/Male	22DEC2015 19:33	ACCUSOL 35 Potassium 4 mmol/L	15H28G72	POST-FILTER	23DEC2015 20:30 / 23DEC2015 23:00	30.22	5
001-007	56/Male	22DEC2015 19:33	ACCUSOL 35	15F02G70	POST-FILTER	23DEC2015 23:00 / 24DEC2015 01:30	30.22	5
001-007	56/Male	22DEC2015 19:33	ACCUSOL 35 Potassium 4 mmol/L	15H28G72	POST-FILTER	24DEC2015 01:30 / 24DEC2015 03:33	30.22	4.4
001-008	57/Male	29JAN2016 17:00	ACCUSOL 35 Potassium 4 mmol/L	UNK	UNKNOWN	29JAN2016 17:00 / 29JAN2016 20:19	UNK	.
001-008	57/Male	29JAN2016 17:00	ACCUSOL 35 Potassium 4 mmol/L	15J13G70	POST-FILTER	29JAN2016 20:19 / 30JAN2016 03:40	33.41	5
001-008	57/Male	29JAN2016 17:00	ACCUSOL 35 Potassium 4 mmol/L	15J15G71	POST-FILTER	29JAN2016 20:19 / 30JAN2016 03:40	33.41	5
001-008	57/Male	29JAN2016 17:00	ACCUSOL 35 Potassium 4 mmol/L	15J15G70	POST-FILTER	29JAN2016 20:19 / 30JAN2016 03:40	33.41	5
001-008	57/Male	29JAN2016 17:00	ACCUSOL 35 Potassium 4 mmol/L	15J15G71	POST-FILTER	29JAN2016 20:19 / 30JAN2016 03:40	33.41	5

Data Listing 16.2.5.3. ACCUSOL 35 Administration - Enrolled Population

Patient Number	Age (Years)/ Gender	First Accusol Administration Start Date/ Time	Dialysis Solution Used	Lot Number	Site of Introduction	Start Date and Time/ End Date and Time	Dialysis Dose (ml/kg/hr)	Amount Administered (L)
001-008	57/Male	29JAN2016 17:00	ACCUSOL 35 Potassium 4 mmol/L	15J13G70	POST-FILTER	30JAN2016 03:40 / 30JAN2016 10:43	33.41	5
001-008	57/Male	29JAN2016 17:00	ACCUSOL 35 Potassium 4 mmol/L	15J13G70	POST-FILTER	30JAN2016 03:40 / 30JAN2016 10:43	33.41	5
001-008	57/Male	29JAN2016 17:00	ACCUSOL 35 Potassium 4 mmol/L	15J13G70	POST-FILTER	30JAN2016 03:40 / 30JAN2016 10:43	33.41	5
001-008	57/Male	29JAN2016 17:00	ACCUSOL 35 Potassium 4 mmol/L	15J13G70	POST-FILTER	30JAN2016 03:40 / 30JAN2016 10:43	33.41	5
001-008	57/Male	29JAN2016 17:00	ACCUSOL 35 Potassium 4 mmol/L	15J13G70	POST-FILTER	30JAN2016 10:43 / 30JAN2016 17:45	33.73	5
001-008	57/Male	29JAN2016 17:00	ACCUSOL 35 Potassium 4 mmol/L	15J13G70	POST-FILTER	30JAN2016 10:43 / 30JAN2016 17:45	33.73	5
001-008	57/Male	29JAN2016 17:00	ACCUSOL 35 Potassium 4 mmol/L	15J13G70	POST-FILTER	30JAN2016 10:43 / 30JAN2016 17:45	33.73	5
001-008	57/Male	29JAN2016 17:00	ACCUSOL 35 Potassium 4 mmol/L	15J13G70	POST-FILTER	30JAN2016 10:43 / 30JAN2016 17:45	33.73	5
001-008	57/Male	29JAN2016 17:00	ACCUSOL 35 Potassium 4 mmol/L	15J13G70	POST-FILTER	30JAN2016 17:45 / 31JAN2016 01:00	33.73	4.89
001-008	57/Male	29JAN2016 17:00	ACCUSOL 35 Potassium 4 mmol/L	15F13G70	POST-FILTER	30JAN2016 17:45 / 31JAN2016 01:00	33.73	4.89
001-008	57/Male	29JAN2016 17:00	ACCUSOL 35 Potassium 4 mmol/L	15F13G70	POST-FILTER	30JAN2016 17:45 / 31JAN2016 01:00	33.73	4.89

Data Listing 16.2.5.3. ACCUSOL 35 Administration - Enrolled Population

Patient Number	Age (Years)/ Gender	First Accusol Administration Start Date/ Time	Dialysis Solution Used	Lot Number	Site of Introduction	Start Date and Time/ End Date and Time	Dialysis Dose (ml/kg/hr)	Amount Administered (L)
001-008	57/Male	29JAN2016 17:00	ACCUSOL 35 Potassium 4 mmol/L	15F13G70	POST-FILTER	30JAN2016 17:45 / 31JAN2016 01:00	33.73	4.89
002-002	56/Male	26APR2015 02:25	ACCUSOL 35	14K11G71	PRE, POST FILTER	26APR2015 02:25 / 26APR2015 07:55	35	3.3
002-002	56/Male	26APR2015 02:25	ACCUSOL 35	14K11G71	PRE/POST FILTER	26APR2015 02:25 / 26APR2015 07:55	35	3.3
002-002	56/Male	26APR2015 02:25	ACCUSOL 35	14K11G71	PRE/POST FILTER	26APR2015 02:25 / 26APR2015 07:55	35	3.3
002-002	56/Male	26APR2015 02:25	ACCUSOL 35	14K11G71	PRE-POST FILTER	26APR2015 07:55 / 26APR2015 17:15	35	5
002-002	56/Male	26APR2015 02:25	ACCUSOL 35	14K13G71	PRE AND POST FILTER	26APR2015 07:55 / 26APR2015 17:15	35	5
002-002	56/Male	26APR2015 02:25	ACCUSOL 35	14K13G71	PRE AND POST FILTER	26APR2015 07:55 / 26APR2015 17:15	35	5
002-002	56/Male	26APR2015 02:25	ACCUSOL 35	14K13G71	PRE AND POST	26APR2015 17:15 / 27APR2015 01:00	35	5
002-002	56/Male	26APR2015 02:25	ACCUSOL 35	14K13G71	PRE AND POST FILTER	26APR2015 17:15 / 27APR2015 01:00	35	5
002-002	56/Male	26APR2015 02:25	ACCUSOL 35	14K13G71	PRE AND POST FILTER	26APR2015 17:15 / 27APR2015 01:00	35	5
002-002	56/Male	26APR2015 02:25	ACCUSOL 35	14K30G70	PRE AND POST FILTER	27APR2015 01:00 / 27APR2015 10:25	35	5

Data Listing 16.2.5.3. ACCUSOL 35 Administration - Enrolled Population

Patient Number	Age (Years)/ Gender	First Accusol Administration Start Date/ Time	Dialysis Solution Used	Lot Number	Site of Introduction	Start Date and Time/ End Date and Time	Dialysis Dose (ml/kg/hr)	Amount Administered (L)
002-002	56/Male	26APR2015 02:25	ACCUSOL 35	14K30G70	PRE AND POST FILTER	27APR2015 01:00 / 27APR2015 10:25	35	5
002-002	56/Male	26APR2015 02:25	ACCUSOL 35	14K30G70	PRE AND POST FILER	27APR2015 01:00 / 27APR2015 10:25	35	5
002-003	68/Female	05MAY2015 01:20	ACCUSOL 35	14K30G70	PRE, POST	05MAY2015 01:20 / 05MAY2015 09:50	35	5
002-003	68/Female	05MAY2015 01:20	ACCUSOL 35	14K30G70	PRE/POST FILTER	05MAY2015 01:20 / 05MAY2015 09:50	35	5
002-003	68/Female	05MAY2015 01:20	ACCUSOL 35	14K30G70	PRE/POST FILTER	05MAY2015 01:20 / 05MAY2015 09:50	35	5
002-005	44/Male	15MAY2015 10:30	ACCUSOL 35	14K30G70	PRE AND POST FILTER	15MAY2015 10:30 / 15MAY2015 15:20	35	4.5
002-005	44/Male	15MAY2015 10:30	ACCUSOL 35	14K30G70	PRE AND POST FILTER	15MAY2015 10:30 / 15MAY2015 15:20	35	4.5
002-005	44/Male	15MAY2015 10:30	ACCUSOL 35	14K30G70	PRE AND POST FILTER	15MAY2015 10:30 / 15MAY2015 15:20	35	4.5
002-005	44/Male	15MAY2015 10:30	ACCUSOL 35	14K30G70	PRE AND POST FILTER	15MAY2015 15:20 / 15MAY2015 21:05	35	5
002-005	44/Male	15MAY2015 10:30	ACCUSOL 35	14K30G70	PREAND POST FILTER	15MAY2015 15:20 / 15MAY2015 21:05	35	5
002-005	44/Male	15MAY2015 10:30	ACCUSOL 35	14K30G70	PRE AND POST FILTER	15MAY2015 15:20 / 15MAY2015 21:05	35	5

Data Listing 16.2.5.3. ACCUSOL 35 Administration - Enrolled Population

Patient Number	Age (Years)/ Gender	First Accusol Administration Start Date/ Time	Dialysis Solution Used	Lot Number	Site of Introduction	Start Date and Time/ End Date and Time	Dialysis Dose (ml/kg/hr)	Amount Administered (L)
002-005	44/Male	15MAY2015 10:30	ACCUSOL 35	14K30G70	PRE AND POST FILTER	15MAY2015 21:05 / 16MAY2015 02:45	35	5
002-005	44/Male	15MAY2015 10:30	ACCUSOL 35	14K30G70	PRE AND POST FILTER	15MAY2015 21:05 / 16MAY2015 02:45	35	5
002-005	44/Male	15MAY2015 10:30	ACCUSOL 35	14K30G70	PRE AND POST FILTER	15MAY2015 21:05 / 16MAY2015 02:45	35	5
002-005	44/Male	15MAY2015 10:30	ACCUSOL 35	14K30G70	PRE AND POST FILTER	16MAY2015 02:45 / 16MAY2015 04:00	35	5
002-005	44/Male	15MAY2015 10:30	ACCUSOL 35	14K30G70	PRE AND POST FILTER	16MAY2015 02:45 / 16MAY2015 04:00	35	5
002-005	44/Male	15MAY2015 10:30	ACCUSOL 35	14K30G70	PRE AND POST FILTER	16MAY2015 02:45 / 16MAY2015 04:00	35	5
002-005	44/Male	15MAY2015 10:30	ACCUSOL 35	14K30G70	PRE AND POST FILTER	16MAY2015 04:00 / 16MAY2015 13:40	35	5
002-005	44/Male	15MAY2015 10:30	ACCUSOL 35	14K30G70	PRE AND POST FILTER	16MAY2015 04:00 / 16MAY2015 13:40	35	5
002-005	44/Male	15MAY2015 10:30	ACCUSOL 35	14K30G70	PRE AND POST FILTER	16MAY2015 04:00 / 16MAY2015 13:40	35	5
002-005	44/Male	15MAY2015 10:30	ACCUSOL 35	14K30G70	PRE AND POST FILTER	16MAY2015 13:40 / 16MAY2015 18:20	35	5
002-005	44/Male	15MAY2015 10:30	ACCUSOL 35	14K30G70	PRE AND POST FILTER	16MAY2015 13:40 / 16MAY2015 18:20	35	5

Data Listing 16.2.5.3. ACCUSOL 35 Administration - Enrolled Population

Patient Number	Age (Years)/ Gender	First Accusol Administration Start Date/ Time	Dialysis Solution Used	Lot Number	Site of Introduction	Start Date and Time/ End Date and Time	Dialysis Dose (ml/kg/hr)	Amount Administered (L)
002-005	44/Male	15MAY2015 10:30	ACCUSOL 35	14K30G70	PRE AND POST FILTER	16MAY2015 13:40 / 16MAY2015 18:20	35	5
002-007	61/Male	24JUN2015 15:22	ACCUSOL 35	15A09G70	PRE/POST FILTER	24JUN2015 15:22 / 24JUN2015 18:00	35	2.5
002-007	61/Male	24JUN2015 15:22	ACCUSOL 35	15A09G70	PRE/POST FILTER	24JUN2015 15:22 / 24JUN2015 18:00	35	2.5
002-007	61/Male	24JUN2015 15:22	ACCUSOL 35	15A09G70	PRE AND POST FILTER	24JUN2015 15:22 / 24JUN2015 18:00	35	2.5
002-009	58/Female	19JUN2015 12:50	ACCUSOL 35	UNK	UNK	19JUN2015 12:50 / 20JUN2015 13:15	UNK	.
002-009	58/Female	19JUN2015 12:50	ACCUSOL 35	14K30G71	AS DIALYSATE	20JUN2015 13:15 / 20JUN2015 17:00	35	5
002-009	58/Female	19JUN2015 12:50	ACCUSOL 35	14K30G71	AS DIALYSATE	20JUN2015 13:15 / 20JUN2015 17:00	35	5
002-009	58/Female	19JUN2015 12:50	ACCUSOL 35	14K30G71	AS DIALYSATE	20JUN2015 13:15 / 20JUN2015 17:00	35	5
002-011	63/Female	20AUG2015 07:00	ACCUSOL 35	15A09G71	PRE-POST FILTER	20AUG2015 07:00 / 20AUG2015 13:15	35	3.9
002-011	63/Female	20AUG2015 07:00	ACCUSOL 35	15A09G71	PRE AND POST FILTER	20AUG2015 07:00 / 20AUG2015 13:15	35	3.9
002-011	63/Female	20AUG2015 07:00	ACCUSOL 35	15A09G71	PRE AND POST FILTER	20AUG2015 07:00 / 20AUG2015 13:15	35	3.9

Data Listing 16.2.5.3. ACCUSOL 35 Administration - Enrolled Population

Patient Number	Age (Years)/ Gender	First Accusol Administration Start Date/ Time	Dialysis Solution Used	Lot Number	Site of Introduction	Start Date and Time/ End Date and Time	Dialysis Dose (ml/kg/hr)	Amount Administered (L)
002-011	63/Female	20AUG2015 07:00	ACCUSOL 35	15A09G71	PRE AND POST FILTER	20AUG2015 13:15 / 20AUG2015 22:00	35	5
002-011	63/Female	20AUG2015 07:00	ACCUSOL 35	15A09G71	PRE AND POST FILTER	20AUG2015 13:15 / 20AUG2015 22:00	35	5
002-011	63/Female	20AUG2015 07:00	ACCUSOL 35	15A09G71	PRE AND POST FILTER	20AUG2015 13:15 / 20AUG2015 22:00	35	5
002-011	63/Female	20AUG2015 07:00	ACCUSOL 35	15A09G71	PRE AND POST FILTER	20AUG2015 22:00 / 21AUG2015 09:20	35	5
002-011	63/Female	20AUG2015 07:00	ACCUSOL 35	15A09G71	PRE AND POST FILTER	20AUG2015 22:00 / 21AUG2015 09:20	35	5
002-011	63/Female	20AUG2015 07:00	ACCUSOL 35	15A09G71	PRE AND POST FILTER	20AUG2015 22:00 / 21AUG2015 09:20	35	5
002-011	63/Female	20AUG2015 07:00	ACCUSOL 35	15A09G71	PRE AND POST FILTER	21AUG2015 09:20 / 21AUG2015 15:00	35	5
002-011	63/Female	20AUG2015 07:00	ACCUSOL 35	15A09G71	PRE AND POST FILTER	21AUG2015 09:20 / 21AUG2015 15:00	35	5
002-011	63/Female	20AUG2015 07:00	ACCUSOL 35	15A09G71	PRE AND POST FILTER	21AUG2015 09:20 / 21AUG2015 15:00	35	5
002-012		30AUG2015 03:40	ACCUSOL 35	15C03G73	PRE-FILTER	30AUG2015 03:40 / 30AUG2015 05:30	35	2
002-012		30AUG2015 03:40	ACCUSOL 35	15C03G73	PRE-FILTER	30AUG2015 05:30 / 30AUG2015 11:00	35	5

Data Listing 16.2.5.3. ACCUSOL 35 Administration - Enrolled Population

Patient Number	Age (Years)/ Gender	First Accusol Administration Start Date/ Time	Dialysis Solution Used	Lot Number	Site of Introduction	Start Date and Time/ End Date and Time	Dialysis Dose (ml/kg/hr)	Amount Administered (L)
002-012		30AUG2015 03:40	ACCUSOL 35	15C03G73	PRE-FILTER	30AUG2015 11:00 / 30AUG2015 12:45	35	1.6
002-014	59/Male	02SEP2015 16:00	ACCUSOL 35	15D12G70	PRE AND POST	02SEP2015 16:00 / 02SEP2015 17:30	35	1.2
002-014	59/Male	02SEP2015 16:00	ACCUSOL 35	15D12G70	PRE AND POST	02SEP2015 16:00 / 02SEP2015 17:30	35	1.2
002-014	59/Male	02SEP2015 16:00	ACCUSOL 35	15D12G70	PRE AND POST	02SEP2015 16:00 / 02SEP2015 17:30	35	1.2
002-014	59/Male	02SEP2015 16:00	ACCUSOL 35	15D12G70	PRE AND POST FILTER	02SEP2015 17:30 / 03SEP2015 00:00	35	5
002-014	59/Male	02SEP2015 16:00	ACCUSOL 35	15D12G70	PRE AND POST FILTER	02SEP2015 17:30 / 03SEP2015 00:00	35	5
002-014	59/Male	02SEP2015 16:00	ACCUSOL 35	15D12G70	PRE AND POST FILTER	02SEP2015 17:30 / 03SEP2015 00:00	35	5
002-014	59/Male	02SEP2015 16:00	ACCUSOL 35	15D12G70	PRE AND POST FILTER	03SEP2015 00:00 / 03SEP2015 06:00	35	5
002-014	59/Male	02SEP2015 16:00	ACCUSOL 35	15D12G70	PRE AND POST FILTER	03SEP2015 00:00 / 03SEP2015 06:00	35	5
002-014	59/Male	02SEP2015 16:00	ACCUSOL 35	15D12G70	PRE AND POST FILTER	03SEP2015 00:00 / 03SEP2015 06:00	35	5
002-014	59/Male	02SEP2015 16:00	ACCUSOL 35	15D12G70	PRE AND POST FILTER	03SEP2015 06:00 / 03SEP2015 11:45	35	5

Data Listing 16.2.5.3. ACCUSOL 35 Administration - Enrolled Population

Patient Number	Age (Years)/ Gender	First Accusol Administration Start Date/ Time	Dialysis Solution Used	Lot Number	Site of Introduction	Start Date and Time/ End Date and Time	Dialysis Dose (ml/kg/hr)	Amount Administered (L)
002-014	59/Male	02SEP2015 16:00	ACCUSOL 35	15G12D70	PRE AND POST FILTER	03SEP2015 06:00 / 03SEP2015 11:45	35	5
002-014	59/Male	02SEP2015 16:00	ACCUSOL 35	15D12G70	PRE AND POST FILTER	03SEP2015 06:00 / 03SEP2015 11:45	35	5
002-014	59/Male	02SEP2015 16:00	ACCUSOL 35	15D12G70	PRE AND POST FILTER	03SEP2015 11:45 / 03SEP2015 18:30	35	5
002-014	59/Male	02SEP2015 16:00	ACCUSOL 35	15D12G70	PRE AND POST FILTER	03SEP2015 11:45 / 03SEP2015 18:30	35	5
002-014	59/Male	02SEP2015 16:00	ACCUSOL 35	15D12G70	PRE AND POST FILTER	03SEP2015 11:45 / 03SEP2015 18:30	35	5
002-014	59/Male	02SEP2015 16:00	ACCUSOL 35	15D12G70	PRE AND POST FILTER	03SEP2015 18:30 / 03SEP2015 19:35	35	0.87
002-014	59/Male	02SEP2015 16:00	ACCUSOL 35	15D12G70	PRE AND POST FILTER	03SEP2015 18:30 / 03SEP2015 19:35	35	0.87
002-014	59/Male	02SEP2015 16:00	ACCUSOL 35	15D12G70	PRE AND POST FILTER	03SEP2015 18:30 / 03SEP2015 19:35	35	0.87
002-016	83/Female	03SEP2015 15:55	ACCUSOL 35	15D12G70	PRE AND POST FILTER	03SEP2015 15:55 / 03SEP2015 17:25	35	5
002-016	83/Female	03SEP2015 15:55	ACCUSOL 35	15D12G70	PRE AND POST FILTER	03SEP2015 15:55 / 03SEP2015 17:25	35	5
002-016	83/Female	03SEP2015 15:55	ACCUSOL 35	15D12G70	PRE AND POST FILTER	03SEP2015 15:55 / 03SEP2015 17:25	35	5

Data Listing 16.2.5.3. ACCUSOL 35 Administration - Enrolled Population

Patient Number	Age (Years)/ Gender	First Accusol Administration Start Date/ Time	Dialysis Solution Used	Lot Number	Site of Introduction	Start Date and Time/ End Date and Time	Dialysis Dose (ml/kg/hr)	Amount Administered (L)
002-017	73/Male	12OCT2015 17:30	ACCUSOL 35	15A09G71	PRE AND POST FILER	12OCT2015 17:30 / 12OCT2015 18:30	35	0.87
002-017	73/Male	12OCT2015 17:30	ACCUSOL 35	15A09G71	PRE AND POST FILTER	12OCT2015 17:30 / 12OCT2015 18:30	35	0.87
002-017	73/Male	12OCT2015 17:30	ACCUSOL 35	15A09G71	PRE AND POST FILTER	12OCT2015 17:30 / 12OCT2015 18:30	35	0.87
002-018	91/Female	22OCT2015 15:05	ACCUSOL 35	15A09G71	PRE AND POST	22OCT2015 15:05 / 22OCT2015 20:45	35	3.71
002-018	91/Female	22OCT2015 15:05	ACCUSOL 35	15A09G71	PRE AND POST	22OCT2015 15:05 / 22OCT2015 20:45	35	3.71
002-018	91/Female	22OCT2015 15:05	ACCUSOL 35	15A09G71	PRE AND POST	22OCT2015 15:05 / 22OCT2015 20:45	35	3.71
002-018	91/Female	22OCT2015 15:05	ACCUSOL 35	15A09G71	PRE AND POST FILTER	22OCT2015 20:45 / 23OCT2015 06:00	35	5
002-018	91/Female	22OCT2015 15:05	ACCUSOL 35	15A09G71	PRE AND POST FILTER	22OCT2015 20:45 / 23OCT2015 06:00	35	5
002-018	91/Female	22OCT2015 15:05	ACCUSOL 35	15A09G71	PRE AND POST FILTER	22OCT2015 20:45 / 23OCT2015 06:00	35	5
002-018	91/Female	22OCT2015 15:05	ACCUSOL 35	15A09G71	PRE AND POST FILTER	23OCT2015 06:00 / 23OCT2015 11:00	35	5
002-018	91/Female	22OCT2015 15:05	ACCUSOL 35	15A09G71	PRE AND POST FILTER	23OCT2015 06:00 / 23OCT2015 11:00	35	5

Data Listing 16.2.5.3. ACCUSOL 35 Administration - Enrolled Population

Patient Number	Age (Years)/ Gender	First Accusol Administration Start Date/ Time	Dialysis Solution Used	Lot Number	Site of Introduction	Start Date and Time/ End Date and Time	Dialysis Dose (ml/kg/hr)	Amount Administered (L)
002-018	91/Female	22OCT2015 15:05	ACCUSOL 35	15A09G71	PRE AND POST FILTER	23OCT2015 06:00 / 23OCT2015 11:00	35	5
002-019	70/Male	10NOV2015 05:05	ACCUSOL 35	15E09G70	PRE AND POST FILTER	10NOV2015 05:05 / 10NOV2015 07:00	35	5
002-019	70/Male	10NOV2015 05:05	ACCUSOL 35	15E09G70	PRE AND POST FILTER	10NOV2015 05:05 / 10NOV2015 07:00	35	5
002-019	70/Male	10NOV2015 05:05	ACCUSOL 35	15E09G70	PRE AND POST FILTER	10NOV2015 05:05 / 10NOV2015 07:00	35	5
002-019	70/Male	10NOV2015 05:05	ACCUSOL 35	15E09G70	PRE AND POST FILTER	10NOV2015 07:00 / 10NOV2015 11:10	35	5
002-019	70/Male	10NOV2015 05:05	ACCUSOL 35	15E09G70	PRE AND POST FILTER	10NOV2015 07:00 / 10NOV2015 11:10	35	5
002-019	70/Male	10NOV2015 05:05	ACCUSOL 35	15E09G70	PRE AND POST FILTER	10NOV2015 07:00 / 10NOV2015 11:10	35	5
002-019	70/Male	10NOV2015 05:05	ACCUSOL 35	15E09G70	PRE AND POST FILTER	10NOV2015 11:10 / 10NOV2015 21:35	35	5
002-019	70/Male	10NOV2015 05:05	ACCUSOL 35	15E09G70	PRE AND POST FILTER	10NOV2015 11:10 / 10NOV2015 21:35	35	5
002-019	70/Male	10NOV2015 05:05	ACCUSOL 35	15E09G70	PRE AND POST FILTER	10NOV2015 11:10 / 10NOV2015 21:35	35	5
002-021	73/Male	10DEC2015 05:00	ACCUSOL 35	15E09G71	PRE AND POST	10DEC2015 05:00 / 10DEC2015 09:40	35	3.5

Data Listing 16.2.5.3. ACCUSOL 35 Administration - Enrolled Population

Patient Number	Age (Years)/ Gender	First Accusol Administration Start Date/ Time	Dialysis Solution Used	Lot Number	Site of Introduction	Start Date and Time/ End Date and Time	Dialysis Dose (ml/kg/hr)	Amount Administered (L)
002-021	73/Male	10DEC2015 05:00	ACCUSOL 35	15E09G71	PRE AND POST	10DEC2015 05:00 / 10DEC2015 09:40	35	3.5
002-021	73/Male	10DEC2015 05:00	ACCUSOL 35	15E09G71	PRE AND POST FILTER	10DEC2015 05:00 / 10DEC2015 09:40	35	3.5
002-021	73/Male	10DEC2015 05:00	ACCUSOL 35	15E09G71	PRE AND POST FILTER	10DEC2015 09:40 / 10DEC2015 16:30	35	5
002-021	73/Male	10DEC2015 05:00	ACCUSOL 35	15E09G71	PRE AND POST FILTER	10DEC2015 09:40 / 10DEC2015 16:30	35	5
002-021	73/Male	10DEC2015 05:00	ACCUSOL 35	15E09G71	PRE AND POST FILTER	10DEC2015 09:40 / 10DEC2015 16:30	35	5
002-021	73/Male	10DEC2015 05:00	ACCUSOL 35	15E09G71	PRE AND POST FILTER	10DEC2015 16:30 / 10DEC2015 22:30	35	5
002-021	73/Male	10DEC2015 05:00	ACCUSOL 35	15E09G71	PRE AND POST FILTER	10DEC2015 16:30 / 10DEC2015 22:30	35	5
002-021	73/Male	10DEC2015 05:00	ACCUSOL 35	15E09G71	PRE AND POST FILTER	10DEC2015 16:30 / 10DEC2015 22:30	35	5
002-021	73/Male	10DEC2015 05:00	ACCUSOL 35	15E09G71	PRE AND POST FILTER	10DEC2015 22:30 / 11DEC2015 06:45	35	5
002-021	73/Male	10DEC2015 05:00	ACCUSOL 35	15E09G71	PRE AND POST FILTER	10DEC2015 22:30 / 11DEC2015 06:45	35	5
002-021	73/Male	10DEC2015 05:00	ACCUSOL 35	15E09G71	PRE AND POST FILTER	10DEC2015 22:30 / 11DEC2015 06:45	35	5

Data Listing 16.2.5.3. ACCUSOL 35 Administration - Enrolled Population

Patient Number	Age (Years)/ Gender	First Accusol Administration Start Date/ Time	Dialysis Solution Used	Lot Number	Site of Introduction	Start Date and Time/ End Date and Time	Dialysis Dose (ml/kg/hr)	Amount Administered (L)
002-021	73/Male	10DEC2015 05:00	ACCUSOL 35	15E09G71	PRE AND POST FILTER	11DEC2015 06:45 / 11DEC2015 12:10	35	5
002-021	73/Male	10DEC2015 05:00	ACCUSOL 35	15E09G71	PRE AND POST FILTER	11DEC2015 06:45 / 11DEC2015 12:10	35	5
002-021	73/Male	10DEC2015 05:00	ACCUSOL 35	15E09G71	PRE AND POST FILTER	11DEC2015 06:45 / 11DEC2015 12:10	35	5
003-001	77/Male	30MAR2015 15:30	ACCUSOL 35 Potassium 4 mmol/L	14K28G71	PRE AND POST	30MAR2015 15:30 / 30MAR2015 19:50	20	1.4
003-001	77/Male	30MAR2015 15:30	ACCUSOL 35 Potassium 4 mmol/L	14K28G71	PRE AND POST	30MAR2015 15:30 / 30MAR2015 19:50	20	5
003-001	77/Male	30MAR2015 15:30	ACCUSOL 35 Potassium 4 mmol/L	14K28G71	PRE AND POST	30MAR2015 19:50 / 30MAR2015 20:30	20	5
003-001	77/Male	30MAR2015 15:30	ACCUSOL 35 Potassium 4 mmol/L	14K28G71	PRE AND POST	30MAR2015 19:50 / 30MAR2015 20:30	20	5
003-002	67/Male	15MAY2015 09:00	ACCUSOL 35	15A07971	PRE AND POST FILTER	15MAY2015 09:00 / 15MAY2015 10:10	20	5
003-002	67/Male	15MAY2015 09:00	ACCUSOL 35	15A07971	PRE AND POST FILTER	15MAY2015 10:10 / 15MAY2015 12:00	20	5
003-002	67/Male	15MAY2015 09:00	ACCUSOL 35	15A07G71	PRE AND POST FILTER	15MAY2015 12:00 / 15MAY2015 13:25	20	5
003-002	67/Male	15MAY2015 09:00	ACCUSOL 35 Potassium 4 mmol/L	14K30G70	PRE AND POST FILTER	15MAY2015 13:25 / 15MAY2015 15:25	20	5

Data Listing 16.2.5.3. ACCUSOL 35 Administration - Enrolled Population

Patient Number	Age (Years)/ Gender	First Accusol Administration Start Date/ Time	Dialysis Solution Used	Lot Number	Site of Introduction	Start Date and Time/ End Date and Time	Dialysis Dose (ml/kg/hr)	Amount Administered (L)
003-002	67/Male	15MAY2015 09:00	ACCUSOL 35	15A07G71	PRE AND POST FILTER	15MAY2015 15:25 / 15MAY2015 17:30	20	5
003-002	67/Male	15MAY2015 09:00	ACCUSOL 35 Potassium 4 mmol/L	14K30G70	PRE AND POST FILTER	15MAY2015 17:30 / 15MAY2015 19:00	20	5
003-002	67/Male	15MAY2015 09:00	ACCUSOL 35 Potassium 4 mmol/L	14K30G70	PRE AND POST	15MAY2015 19:00 / 16MAY2015 00:45	20	5
003-002	67/Male	15MAY2015 09:00	ACCUSOL 35	15A07G71	PRE AND POST FILTER	15MAY2015 20:00 / 16MAY2015 00:45	20	5
003-002	67/Male	15MAY2015 09:00	ACCUSOL 35	15A07G71	PRE AND POST FILTER	15MAY2015 20:00 / 16MAY2015 00:45	20	5
003-002	67/Male	15MAY2015 09:00	ACCUSOL 35	15A07G71	PRE AND POST FILTER	16MAY2015 00:45 / 16MAY2015 06:45	20	5
003-002	67/Male	15MAY2015 09:00	ACCUSOL 35	15A07G71	PRE AND POST FILTER	16MAY2015 00:45 / 16MAY2015 06:45	20	5
003-002	67/Male	15MAY2015 09:00	ACCUSOL 35 Potassium 4 mmol/L	14K30G70	PRE AND POST	16MAY2015 00:45 / 16MAY2015 06:45	20	5
003-002	67/Male	15MAY2015 09:00	ACCUSOL 35	15A07G71	PRE AND POST	16MAY2015 06:45 / 16MAY2015 08:30	20	1
003-002	67/Male	15MAY2015 09:00	ACCUSOL 35	15A07G71	PRE AND POST	16MAY2015 06:45 / 16MAY2015 08:30	20	1
003-002	67/Male	15MAY2015 09:00	ACCUSOL 35 Potassium 4 mmol/L	14K30G70	PRE AND POST	16MAY2015 06:45 / 16MAY2015 08:30	20	1

Data Listing 16.2.5.3. ACCUSOL 35 Administration - Enrolled Population

Patient Number	Age (Years)/ Gender	First Accusol Administration Start Date/ Time	Dialysis Solution Used	Lot Number	Site of Introduction	Start Date and Time/ End Date and Time	Dialysis Dose (ml/kg/hr)	Amount Administered (L)
003-003	57/Female	28AUG2015 08:00	ACCUSOL 35 Potassium 4 mmol/L	15D11G70	PRE-FILTER	28AUG2015 08:00 / 28AUG2015 10:00	17.4	1
003-003	57/Female	28AUG2015 08:00	ACCUSOL 35 Potassium 4 mmol/L	15D11G70	PRE-FILTER	28AUG2015 10:00 / 28AUG2015 13:30	17.4	3
003-004	66/Male	07SEP2015 13:00	ACCUSOL 35 Potassium 4 mmol/L	15C02671	PRE AND POST	07SEP2015 13:00 / 07SEP2015 15:15	30	3
003-004	66/Male	07SEP2015 13:00	ACCUSOL 35 Potassium 4 mmol/L	15C02671	PRE AND POST	07SEP2015 15:15 / 07SEP2015 19:00	30	5
003-004	66/Male	07SEP2015 13:00	ACCUSOL 35 Potassium 4 mmol/L	15C02671	PRE AND POST	07SEP2015 19:00 / 07SEP2015 23:00	30	5
003-004	66/Male	07SEP2015 13:00	ACCUSOL 35 Potassium 4 mmol/L	15D11970	PRE AND POST	07SEP2015 23:00 / 08SEP2015 01:30	30	5
003-004	66/Male	07SEP2015 13:00	ACCUSOL 35 Potassium 4 mmol/L	15D11970	PRE AND POST	08SEP2015 01:30 / 08SEP2015 04:30	30	5
003-004	66/Male	07SEP2015 13:00	ACCUSOL 35 Potassium 4 mmol/L	15D11970	PRE AND POST	08SEP2015 04:30 / 08SEP2015 10:30	30	5
003-004	66/Male	07SEP2015 13:00	ACCUSOL 35 Potassium 4 mmol/L	NOT RECORDED BY NURS	PRE AND POST	08SEP2015 10:30 / 08SEP2015 13:00	30	5
003-004	66/Male	07SEP2015 13:00	ACCUSOL 35 Potassium 4 mmol/L	NOT RECORDED	PRE AND POST	08SEP2015 13:00 / 08SEP2015 17:00	30	5

Data Listing 16.2.5.3. ACCUSOL 35 Administration - Enrolled Population

Patient Number	Age (Years)/ Gender	First Accusol Administration Start Date/ Time	Dialysis Solution Used	Lot Number	Site of Introduction	Start Date and Time/ End Date and Time	Dialysis Dose (ml/kg/hr)	Amount Administered (L)
003-004	66/Male	07SEP2015 13:00	ACCUSOL 35 Potassium 4 mmol/L	NOT RECORDED	PRE AND POST	08SEP2015 17:00 / 08SEP2015 20:35	30	3
003-007	60/Male	05OCT2015 14:00	ACCUSOL 35 Potassium 4 mmol/L	15C02G71	PRE AND POST	05OCT2015 14:00 / 05OCT2015 17:00	15	2.5
003-007	60/Male	05OCT2015 14:00	ACCUSOL 35 Potassium 4 mmol/L	15C02G71	PRE AND POST	05OCT2015 17:00 / 05OCT2015 22:10	15	5
003-007	60/Male	05OCT2015 14:00	ACCUSOL 35 Potassium 4 mmol/L	15H28G72	PRE AND POST	05OCT2015 22:10 / 06OCT2015 02:45	15	5
003-007	60/Male	05OCT2015 14:00	ACCUSOL 35 Potassium 4 mmol/L	15H28G72	PRE AND POST	06OCT2015 02:45 / 06OCT2015 08:05	15	5
003-007	60/Male	05OCT2015 14:00	ACCUSOL 35 Potassium 4 mmol/L	15A07G70	PRE AND POST	06OCT2015 08:05 / 06OCT2015 13:08	15	5
003-007	60/Male	05OCT2015 14:00	ACCUSOL 35 Potassium 4 mmol/L	15A07G70	PRE AND POST	06OCT2015 13:08 / 06OCT2015 17:50	15	5
003-007	60/Male	05OCT2015 14:00	ACCUSOL 35 Potassium 4 mmol/L	15A07G70	PRE AND POST	06OCT2015 17:50 / 06OCT2015 22:00	15	4
003-008	47/Male	21OCT2015 11:30	ACCUSOL 35 Potassium 4 mmol/L	15AD7G70	PRE AND POST	21OCT2015 11:30 / 21OCT2015 14:30	15	2
003-008	47/Male	21OCT2015 11:30	ACCUSOL 35 Potassium 4 mmol/L	15D12G70	PRE AND POST	21OCT2015 14:30 / 21OCT2015 16:30	15	1.5
003-009		26OCT2015 05:30	ACCUSOL 35 Potassium 4 mmol/L	15H28G72	PRE AND POST	26OCT2015 05:30 / 26OCT2015 07:00	30	2

Data Listing 16.2.5.3. ACCUSOL 35 Administration - Enrolled Population

Patient Number	Age (Years)/ Gender	First Accusol Administration Start Date/ Time	Dialysis Solution Used	Lot Number	Site of Introduction	Start Date and Time/ End Date and Time	Dialysis Dose (ml/kg/hr)	Amount Administered (L)
003-009		26OCT2015 05:30	ACCUSOL 35 Potassium 4 mmol/L	15H28G72	PRE AND POST	26OCT2015 07:00 / 26OCT2015 11:20	30	5
003-009		26OCT2015 05:30	ACCUSOL 35 Potassium 4 mmol/L	15H28G72	PRE AND POST	26OCT2015 11:20 / 26OCT2015 15:29	30	5
003-009		26OCT2015 05:30	ACCUSOL 35 Potassium 4 mmol/L	15E07G72	PRE AND POST	26OCT2015 15:29 / 26OCT2015 19:50	30	5
003-009		26OCT2015 05:30	ACCUSOL 35 Potassium 4 mmol/L	15E07G72	PRE AND POST	26OCT2015 19:50 / 27OCT2015 00:00	30	5
003-009		26OCT2015 05:30	ACCUSOL 35 Potassium 4 mmol/L	15E07G72	PRE AND POST	27OCT2015 00:00 / 27OCT2015 04:00	30	5
003-009		26OCT2015 05:30	ACCUSOL 35 Potassium 4 mmol/L	15E07G72	PRE AND POST	27OCT2015 04:00 / 27OCT2015 09:00	30	5
003-009		26OCT2015 05:30	ACCUSOL 35 Potassium 4 mmol/L	15E07G72	PRE AND POST	27OCT2015 09:00 / 27OCT2015 13:15	30	5
003-009		26OCT2015 05:30	ACCUSOL 35 Potassium 4 mmol/L	15E07G72	PRE AND POST	27OCT2015 13:15 / 27OCT2015 13:30	30	0.05
003-010	79/Male	30NOV2015 02:00	ACCUSOL 35 Potassium 4 mmol/L	15G09G71	PRE AND POST	30NOV2015 02:00 / 30NOV2015 02:40	15.7	1
003-010	79/Male	30NOV2015 02:00	ACCUSOL 35	15E09G70	PRE AND POST	30NOV2015 02:40 / 30NOV2015 05:10	15.8	5
003-010	79/Male	30NOV2015 02:00	ACCUSOL 35 Potassium 4 mmol/L	15G09G71	PRE AND POST	30NOV2015 05:10 / 30NOV2015 07:10	15.8	5

Data Listing 16.2.5.3. ACCUSOL 35 Administration - Enrolled Population

Patient Number	Age (Years)/ Gender	First Accusol Administration Start Date/ Time	Dialysis Solution Used	Lot Number	Site of Introduction	Start Date and Time/ End Date and Time	Dialysis Dose (ml/kg/hr)	Amount Administered (L)
003-010	79/Male	30NOV2015 02:00	ACCUSOL 35	15E09G70	PRE AND POST	30NOV2015 07:10 / 30NOV2015 09:34	15.9	5
003-010	79/Male	30NOV2015 02:00	ACCUSOL 35 Potassium 4 mmol/L	15H28G72	PRE AND POST	30NOV2015 09:34 / 30NOV2015 12:15	15.8	5
003-010	79/Male	30NOV2015 02:00	ACCUSOL 35 Potassium 4 mmol/L	15H28G72	PRE AND POST	30NOV2015 12:15 / 30NOV2015 14:20	15.9	5
003-010	79/Male	30NOV2015 02:00	ACCUSOL 35 Potassium 4 mmol/L	15G09G70	PRE AND POST	30NOV2015 14:20 / 30NOV2015 16:30	15.9	5
003-010	79/Male	30NOV2015 02:00	ACCUSOL 35 Potassium 4 mmol/L	15G09G70	PRE AND POST FILTER	30NOV2015 16:30 / 30NOV2015 18:55	15.9	5
003-010	79/Male	30NOV2015 02:00	ACCUSOL 35 Potassium 4 mmol/L	15G09G70	PRE AND POST	30NOV2015 18:55 / 30NOV2015 21:40	15.4	5
003-010	79/Male	30NOV2015 02:00	ACCUSOL 35	15D12G70	PRE AND POST	30NOV2015 21:40 / 30NOV2015 23:55	15.9	5
003-010	79/Male	30NOV2015 02:00	ACCUSOL 35 Potassium 4 mmol/L	15H28G72	PRE AND POST	30NOV2015 23:55 / 01DEC2015 02:30	15.8	5
003-010	79/Male	30NOV2015 02:00	ACCUSOL 35	15D12G70	PRE AND POST	01DEC2015 02:30 / 01DEC2015 05:19	15.8	5
003-010	79/Male	30NOV2015 02:00	ACCUSOL 35 Potassium 4 mmol/L	15G09G71	PRE AND POST	01DEC2015 05:19 / 01DEC2015 07:10	15.8	5
003-010	79/Male	30NOV2015 02:00	ACCUSOL 35 Potassium 4 mmol/L	15G09G71	PRE AND POST	01DEC2015 07:10 / 01DEC2015 10:00	15.8	5

Data Listing 16.2.5.3. ACCUSOL 35 Administration - Enrolled Population

Patient Number	Age (Years)/ Gender	First Accusol Administration Start Date/ Time	Dialysis Solution Used	Lot Number	Site of Introduction	Start Date and Time/ End Date and Time	Dialysis Dose (ml/kg/hr)	Amount Administered (L)
003-011	69/Male	23DEC2015 03:00	ACCUSOL 35 Potassium 4 mmol/L	15H28G73	PRE-FILTER	23DEC2015 03:00 / 23DEC2015 06:20	20	3.5
003-011	69/Male	23DEC2015 03:00	ACCUSOL 35 Potassium 4 mmol/L	15H28G73	PRE-FILTER	23DEC2015 06:20 / 23DEC2015 11:30	20	5
003-011	69/Male	23DEC2015 03:00	ACCUSOL 35 Potassium 4 mmol/L	15H28G73	PRE-FILTER	23DEC2015 11:30 / 23DEC2015 16:45	20	5
003-011	69/Male	23DEC2015 03:00	ACCUSOL 35 Potassium 4 mmol/L	15H28G73	PRE-FILTER	23DEC2015 16:45 / 23DEC2015 21:10	20	5
003-011	69/Male	23DEC2015 03:00	ACCUSOL 35 Potassium 4 mmol/L	15H28G73	PRE-FILTER	23DEC2015 21:10 / 24DEC2015 01:00	20	5
003-011	69/Male	23DEC2015 03:00	ACCUSOL 35 Potassium 4 mmol/L	15H28G73	PRE-FILTER	24DEC2015 01:00 / 24DEC2015 07:00	20	5
003-011	69/Male	23DEC2015 03:00	ACCUSOL 35 Potassium 4 mmol/L	15I27G72	PRE-FILTER	24DEC2015 07:00 / 24DEC2015 11:00	20	1
003-012	88/Male	23JAN2016 08:00	ACCUSOL 35 Potassium 4 mmol/L	15H28G73	PRE AND POST FILTER	23JAN2016 08:00 / 23JAN2016 12:45	11.9	4.9
003-012	88/Male	23JAN2016 08:00	ACCUSOL 35	15E09G70	PRE AND POST FILTER	23JAN2016 12:45 / 23JAN2016 14:00	11.9	3.5
004-001		23APR2015 08:00	ACCUSOL 35 Potassium 4 mmol/L	14K13T72	PRE AND POST	23APR2015 08:00 / 23APR2015 12:30	12.5	5
004-001		23APR2015 08:00	ACCUSOL 35 Potassium 4 mmol/L	14K13G72	BOTH PRE AND POST	23APR2015 12:30 / 23APR2015 21:00	12.5	5

Data Listing 16.2.5.3. ACCUSOL 35 Administration - Enrolled Population

Patient Number	Age (Years)/ Gender	First Accusol Administration Start Date/ Time	Dialysis Solution Used	Lot Number	Site of Introduction	Start Date and Time/ End Date and Time	Dialysis Dose (ml/kg/hr)	Amount Administered (L)
004-002		18MAY2015 18:00	ACCUSOL 35 Potassium 4 mmol/L	14K28671	PRE AND POST	18MAY2015 18:00 / 18MAY2015 21:00	15.74	5
004-002		18MAY2015 18:00	ACCUSOL 35	UNK	BOTH PRE AND POST	18MAY2015 21:00 / 19MAY2015 02:00	15.74	5
004-002		18MAY2015 18:00	ACCUSOL 35 Potassium 4 mmol/L	UNK	BOTH PRE AND POST	19MAY2015 02:00 / 19MAY2015 06:00	15.74	5
004-003	45/Female	01JUN2015 14:00	ACCUSOL 35 Potassium 4 mmol/L	15A07671	BOTH PRE AND POST DILUTION	01JUN2015 14:00 / 01JUN2015 18:40	16.13	5
004-003	45/Female	01JUN2015 14:00	ACCUSOL 35	14I08G71	BOTH PRE AND POST	01JUN2015 18:40 / 02JUN2015 01:14	16.13	5
004-003	45/Female	01JUN2015 14:00	ACCUSOL 35	14K13070	BOTH PRE AND POST	02JUN2015 01:14 / 02JUN2015 06:30	16.13	5
004-003	45/Female	01JUN2015 14:00	ACCUSOL 35	14K13670	BOTH PRE AND POST	02JUN2015 06:30 / 02JUN2015 11:45	16.13	5
004-003	45/Female	01JUN2015 14:00	ACCUSOL 35 Potassium 4 mmol/L	14K286G71	BOTH PRE AND POST	02JUN2015 11:45 / 02JUN2015 17:30	16.13	5
004-003	45/Female	01JUN2015 14:00	ACCUSOL 35	14K13G71	BOTH PRE AND POST	02JUN2015 17:30 / 02JUN2015 20:00	16.13	5
004-005	20/Female	23JUN2015 04:00	ACCUSOL 35 Potassium 4 mmol/L	14K12G70	PRE-POST DILUTION	23JUN2015 04:00 / 23JUN2015 07:40	14.5	5

Data Listing 16.2.5.3. ACCUSOL 35 Administration - Enrolled Population

Patient Number	Age (Years)/ Gender	First Accusol Administration Start Date/ Time	Dialysis Solution Used	Lot Number	Site of Introduction	Start Date and Time/ End Date and Time	Dialysis Dose (ml/kg/hr)	Amount Administered (L)
004-005	20/Female	23JUN2015 04:00	ACCUSOL 35 Potassium 4 mmol/L	14K12G70	PRE-POST DILUTION	23JUN2015 07:40 / 23JUN2015 13:05	14.5	5
004-005	20/Female	23JUN2015 04:00	ACCUSOL 35 Potassium 4 mmol/L	14K28G71	PRE-POST DILUTION	23JUN2015 13:05 / 23JUN2015 18:37	14.5	5
004-005	20/Female	23JUN2015 04:00	ACCUSOL 35 Potassium 4 mmol/L	14K28G71	PRE-POST DILUTION	23JUN2015 18:37 / 23JUN2015 22:40	14.5	5
004-005	20/Female	23JUN2015 04:00	ACCUSOL 35 Potassium 4 mmol/L	14K28G71	PRE-POST DILUTION	23JUN2015 22:40 / 24JUN2015 02:20	14.5	5
004-005	20/Female	23JUN2015 04:00	ACCUSOL 35 Potassium 4 mmol/L	14K28G71	PRE-POST DILUTION	24JUN2015 02:20 / 24JUN2015 05:45	14.5	5
004-005	20/Female	23JUN2015 04:00	ACCUSOL 35 Potassium 4 mmol/L	14K28G71	PRE-POST DILUTION	24JUN2015 05:45 / 24JUN2015 11:10	14.5	5
004-005	20/Female	23JUN2015 04:00	ACCUSOL 35 Potassium 4 mmol/L	14K30G70	PRE-POST DILUTION	24JUN2015 11:10 / 24JUN2015 12:00	14.5	5
004-006	30/Male	05JUL2015 07:00	ACCUSOL 35 Potassium 4 mmol/L	14K28G71	PRE-POST FILTER	05JUL2015 07:00 / 05JUL2015 10:40	52.63	5
004-006	30/Male	05JUL2015 07:00	ACCUSOL 35 Potassium 4 mmol/L	14K28G71	PRE-POST FILTER	05JUL2015 10:40 / 05JUL2015 18:00	52.63	5
004-006	30/Male	05JUL2015 07:00	ACCUSOL 35 Potassium 4 mmol/L	15C01G70	PRE-POST FILTER	05JUL2015 18:00 / 05JUL2015 23:30	52.63	5
004-006	30/Male	05JUL2015 07:00	ACCUSOL 35 Potassium 4 mmol/L	15C01G70	PRE-POST FILTER	05JUL2015 23:30 / 06JUL2015 05:00	52.63	5

Data Listing 16.2.5.3. ACCUSOL 35 Administration - Enrolled Population

Patient Number	Age (Years)/ Gender	First Accusol Administration Start Date/ Time	Dialysis Solution Used	Lot Number	Site of Introduction	Start Date and Time/ End Date and Time	Dialysis Dose (ml/kg/hr)	Amount Administered (L)
004-006	30/Male	05JUL2015 07:00	ACCUSOL 35 Potassium 4 mmol/L	15C01G70	PRE-POST FILTER	06JUL2015 05:00 / 06JUL2015 09:30	52.63	5
004-006	30/Male	05JUL2015 07:00	ACCUSOL 35 Potassium 4 mmol/L	15C01670	PRE-POST FILTER	06JUL2015 09:30 / 06JUL2015 15:00	52.63	5
004-009	59/Female	24JUL2015 15:00	ACCUSOL 35 Potassium 4 mmol/L	15L02971	BOTH PRE & POST	24JUL2015 15:00 / 24JUL2015 16:00	14.28	5
004-009	59/Female	24JUL2015 15:00	ACCUSOL 35 Potassium 4 mmol/L	15L02971	BOTH PRE & POST	24JUL2015 16:00 / 25JUL2015 11:00	14.28	5
004-009	59/Female	24JUL2015 15:00	ACCUSOL 35	14K30G70	BOTH PRE & POST	25JUL2015 11:00 / 25JUL2015 17:00	14.28	5
004-009	59/Female	24JUL2015 15:00	ACCUSOL 35	15C02G71	BOTH PRE & POST	25JUL2015 17:00 / 25JUL2015 23:00	14.28	5
004-010	55/Male	28JUL2015 11:00	ACCUSOL 35 Potassium 4 mmol/L	14K30G70	PRE/POST FILTER	28JUL2015 11:00 / 28JUL2015 16:05	23.52	5
004-010	55/Male	28JUL2015 11:00	ACCUSOL 35 Potassium 4 mmol/L	14K30G70	PRE/POST FILTER	28JUL2015 16:05 / 28JUL2015 22:00	23.52	5
004-010	55/Male	28JUL2015 11:00	ACCUSOL 35 Potassium 4 mmol/L	15C02671	BOTH, PRE AND POST	28JUL2015 16:05 / 28JUL2015 22:00	23.52	5
004-010	55/Male	28JUL2015 11:00	ACCUSOL 35 Potassium 4 mmol/L	15C02G71	BOTH, PRE AND POST	28JUL2015 22:00 / 29JUL2015 08:00	23.52	5
004-010	55/Male	28JUL2015 11:00	ACCUSOL 35 Potassium 4 mmol/L	15C02G71	BOTH, PRE AND POST	28JUL2015 22:00 / 29JUL2015 08:00	23.52	5

Data Listing 16.2.5.3. ACCUSOL 35 Administration - Enrolled Population

Patient Number	Age (Years)/ Gender	First Accusol Administration Start Date/ Time	Dialysis Solution Used	Lot Number	Site of Introduction	Start Date and Time/ End Date and Time	Dialysis Dose (ml/kg/hr)	Amount Administered (L)
004-013	79/Male	14AUG2015 08:00	ACCUSOL 35 Potassium 4 mmol/L	15L02571	BOTH, PRE AND POST	14AUG2015 08:00 / 14AUG2015 10:30	13.33	5
004-013	79/Male	14AUG2015 08:00	ACCUSOL 35 Potassium 4 mmol/L	15L02571	BOTH, PRE AND POST	14AUG2015 10:30 / 14AUG2015 15:30	13.33	5
004-013	79/Male	14AUG2015 08:00	ACCUSOL 35 Potassium 4 mmol/L	15L02971	BOTH, PRE AND POST	14AUG2015 15:30 / 14AUG2015 21:30	13.33	5
004-013	79/Male	14AUG2015 08:00	ACCUSOL 35 Potassium 4 mmol/L	15L02971	BOTH, PRE AND POST	14AUG2015 21:30 / 15AUG2015 01:00	13.33	5
004-014	65/Male	23AUG2015 10:00	ACCUSOL 35 Potassium 4 mmol/L	15C02671	PRE /POST	23AUG2015 10:00 / 23AUG2015 11:15	18.51	5
004-014	65/Male	23AUG2015 10:00	ACCUSOL 35 Potassium 4 mmol/L	15C02671	PRE/POST	23AUG2015 11:15 / 23AUG2015 14:10	18.51	5
004-014	65/Male	23AUG2015 10:00	ACCUSOL 35 Potassium 4 mmol/L	15C02671B	PRE/POST	23AUG2015 14:10 / 23AUG2015 17:00	18.51	5
004-016	47/Female	19SEP2015 03:00	ACCUSOL 35 Potassium 4 mmol/L	15C01670	PRE-POST FILTER	19SEP2015 03:00 / 19SEP2015 06:00	71.4	5
004-016	47/Female	19SEP2015 03:00	ACCUSOL 35 Potassium 4 mmol/L	15D11670	PRE - POST FILTER	19SEP2015 06:00 / 19SEP2015 09:00	71.4	5
004-017	67/Male	24SEP2015 17:00	ACCUSOL 35 Potassium 4 mmol/L	15B02G70	PRE-POST FILTER	24SEP2015 17:00 / 24SEP2015 19:30	12.98	5
004-017	67/Male	24SEP2015 17:00	ACCUSOL 35 Potassium 4 mmol/L	15B02G70	PRE-POST FILTER	24SEP2015 19:30 / 24SEP2015 23:30	12.98	5

Data Listing 16.2.5.3. ACCUSOL 35 Administration - Enrolled Population

Patient Number	Age (Years)/ Gender	First Accusol Administration Start Date/ Time	Dialysis Solution Used	Lot Number	Site of Introduction	Start Date and Time/ End Date and Time	Dialysis Dose (ml/kg/hr)	Amount Administered (L)
004-017	67/Male	24SEP2015 17:00	ACCUSOL 35	14K30G70	PRE-POST FILTER	24SEP2015 23:30 / 25SEP2015 00:40	12.98	5
004-017	67/Male	24SEP2015 17:00	ACCUSOL 35 Potassium 4 mmol/L	14K12971	PRE-POST FILTER	25SEP2015 00:40 / 25SEP2015 03:10	12.98	5
004-017	67/Male	24SEP2015 17:00	ACCUSOL 35 Potassium 4 mmol/L	14K12971	PRE-POST FILTER	25SEP2015 03:10 / 25SEP2015 05:30	12.98	5
004-017	67/Male	24SEP2015 17:00	ACCUSOL 35	15A09G70	PRE-POST FILTER	25SEP2015 05:30 / 25SEP2015 07:30	12.98	5
004-017	67/Male	24SEP2015 17:00	ACCUSOL 35	15A09470	PRE POST FILTER	25SEP2015 07:30 / - -	12.98	5
004-018	40/Male	25SEP2015 20:00	ACCUSOL 35 Potassium 4 mmol/L	15C01G70	PRE/POST	25SEP2015 20:00 / 26SEP2015 04:00	12.5	5
004-018	40/Male	25SEP2015 20:00	ACCUSOL 35 Potassium 4 mmol/L	15C01G70	PRE/POST	26SEP2015 04:00 / 26SEP2015 10:30	12.5	5
004-018	40/Male	25SEP2015 20:00	ACCUSOL 35 Potassium 4 mmol/L	15C01G70	PRE/POST	26SEP2015 10:30 / 26SEP2015 15:30	12.5	5
004-018	40/Male	25SEP2015 20:00	ACCUSOL 35 Potassium 4 mmol/L	L5C01G70	PRE/POST	26SEP2015 15:30 / 26SEP2015 21:00	12.5	5
004-018	40/Male	25SEP2015 20:00	ACCUSOL 35 Potassium 4 mmol/L	L5C01G70	PRE/ POST	26SEP2015 21:00 / 27SEP2015 00:00	12.5	5
004-018	40/Male	25SEP2015 20:00	ACCUSOL 35 Potassium 4 mmol/L	LSB02670M	PRE/POST	27SEP2015 00:00 / 27SEP2015 02:30	12.5	4

Data Listing 16.2.5.3. ACCUSOL 35 Administration - Enrolled Population

Patient Number	Age (Years)/ Gender	First Accusol Administration Start Date/ Time	Dialysis Solution Used	Lot Number	Site of Introduction	Start Date and Time/ End Date and Time	Dialysis Dose (ml/kg/hr)	Amount Administered (L)
005-002	68/Female	21MAR2015 18:30	ACCUSOL 35	UNKNOWN	UNKNOWN	21MAR2015 18:30 / 21MAR2015 19:15	UNK	.
005-002	68/Female	21MAR2015 18:30	ACCUSOL 35	14K13G71	AS DIALYSATE	21MAR2015 19:15 / 21MAR2015 21:30	30.6	5
005-002	68/Female	21MAR2015 18:30	ACCUSOL 35	14K13G71	AS DIALYSATE	21MAR2015 21:30 / 22MAR2015 00:10	30.6	5
005-002	68/Female	21MAR2015 18:30	ACCUSOL 35	14K13G71	AS DIALYSATE	22MAR2015 00:10 / 22MAR2015 02:35	32.5	5
005-002	68/Female	21MAR2015 18:30	ACCUSOL 35	14K13G71	AS DIALYSATE	22MAR2015 02:35 / 22MAR2015 05:00	32.5	5
005-002	68/Female	21MAR2015 18:30	ACCUSOL 35	14K13G71	AS DIALYSATE	22MAR2015 05:00 / 22MAR2015 07:30	63.9	5
005-002	68/Female	21MAR2015 18:30	ACCUSOL 35	14K13G71	AS DIALYSATE	22MAR2015 07:30 / 22MAR2015 12:00	33.7	4.9
005-003	65/Female	24MAR2015 10:00	ACCUSOL 35	14K13G71	AS DIALYSATE	24MAR2015 10:00 / 24MAR2015 10:45	32	2.25
005-003	65/Female	24MAR2015 10:00	ACCUSOL 35	14K13G70	AS DIALYSATE	24MAR2015 10:45 / 24MAR2015 12:15	32	5
005-003	65/Female	24MAR2015 10:00	ACCUSOL 35	14K13G71	AS DIALYSATE	24MAR2015 12:15 / 24MAR2015 13:50	32	5
005-003	65/Female	24MAR2015 10:00	ACCUSOL 35	14K13G71	AS DIALYSATE	24MAR2015 13:50 / 24MAR2015 15:30	31.3	5

Data Listing 16.2.5.3. ACCUSOL 35 Administration - Enrolled Population

Patient Number	Age (Years)/ Gender	First Accusol Administration Start Date/ Time	Dialysis Solution Used	Lot Number	Site of Introduction	Start Date and Time/ End Date and Time	Dialysis Dose (ml/kg/hr)	Amount Administered (L)
005-003	65/Female	24MAR2015 10:00	ACCUSOL 35	14K13G71	AS DIALYSATE	24MAR2015 15:30 / 24MAR2015 18:35	31.3	5
005-003	65/Female	24MAR2015 10:00	ACCUSOL 35	14K13G71	AS DIALYSATE	24MAR2015 18:35 / 24MAR2015 20:20	31.3	5
005-003	65/Female	24MAR2015 10:00	ACCUSOL 35	14K13G71	AS DIALYSATE	24MAR2015 20:20 / 24MAR2015 21:20	40	5
005-003	65/Female	24MAR2015 10:00	ACCUSOL 35	14K13G71	AS DIALYSATE	24MAR2015 21:20 / 24MAR2015 22:00	40	5
005-003	65/Female	24MAR2015 10:00	ACCUSOL 35	14K13G71	AS DIALYSATE	24MAR2015 22:00 / 25MAR2015 00:50	40	5
005-003	65/Female	24MAR2015 10:00	ACCUSOL 35	14K13G71	AS DIALYSATE	25MAR2015 00:50 / 25MAR2015 02:30	31	5
005-003	65/Female	24MAR2015 10:00	ACCUSOL 35	14K13G71	AS DIALYSATE	25MAR2015 02:30 / 25MAR2015 04:05	31	5
005-003	65/Female	24MAR2015 10:00	ACCUSOL 35	14K13G71	AS DIALYSATE	25MAR2015 04:05 / 25MAR2015 07:00	30	5
005-003	65/Female	24MAR2015 10:00	ACCUSOL 35	14K13G71	AS DIALYSATE	25MAR2015 07:00 / 25MAR2015 08:35	30	5
005-003	65/Female	24MAR2015 10:00	ACCUSOL 35	14K13G71	AS DIALYSATE	25MAR2015 08:35 / 25MAR2015 10:00	30	5
005-003	65/Female	24MAR2015 10:00	ACCUSOL 35	BWPE9009	AS DIALYSATE	25MAR2015 10:00 / 25MAR2015 11:35	35.9	5

Data Listing 16.2.5.3. ACCUSOL 35 Administration - Enrolled Population

Patient Number	Age (Years)/ Gender	First Accusol Administration Start Date/ Time	Dialysis Solution Used	Lot Number	Site of Introduction	Start Date and Time/ End Date and Time	Dialysis Dose (ml/kg/hr)	Amount Administered (L)
005-003	65/Female	24MAR2015 10:00	ACCUSOL 35	14K13G71	AS DIALYSATE	25MAR2015 11:35 / 25MAR2015 13:00	35.9	2.55
005-004	81/Male	27MAR2015 09:00	ACCUSOL 35	14K11G70	AS DIALYSATE	27MAR2015 09:00 / 27MAR2015 10:45	49.9	4.38
005-004	81/Male	27MAR2015 09:00	ACCUSOL 35	14K11G70	AS DIALYSATE	27MAR2015 10:45 / 27MAR2015 12:40	45	5
005-004	81/Male	27MAR2015 09:00	ACCUSOL 35	14K13G70	AS DIALYSATE	27MAR2015 12:40 / 27MAR2015 14:40	45	5
005-004	81/Male	27MAR2015 09:00	ACCUSOL 35	14K13G70	AS DIALYSATE	27MAR2015 14:40 / 27MAR2015 16:40	34.5	5
005-004	81/Male	27MAR2015 09:00	ACCUSOL 35	14K13G70	AS DIALYSATE	27MAR2015 16:40 / 27MAR2015 20:40	34.5	5
005-004	81/Male	27MAR2015 09:00	ACCUSOL 35	14K27G73	AS DIALYSATE	27MAR2015 20:40 / 27MAR2015 22:35	37.1	5
005-004	81/Male	27MAR2015 09:00	ACCUSOL 35	14K27G73	AS DIALYSATE	27MAR2015 22:35 / 28MAR2015 00:40	37.1	5
005-004	81/Male	27MAR2015 09:00	ACCUSOL 35	14K27G73	AS DIALYSATE	28MAR2015 00:40 / 28MAR2015 02:40	40	5
005-004	81/Male	27MAR2015 09:00	ACCUSOL 35	14K27G73	AS DIALYSATE	28MAR2015 02:40 / 28MAR2015 04:40	40	5
005-004	81/Male	27MAR2015 09:00	ACCUSOL 35	14K11G70	AS DIALYSATE	28MAR2015 04:40 / 28MAR2015 06:40	40	5

Data Listing 16.2.5.3. ACCUSOL 35 Administration - Enrolled Population

Patient Number	Age (Years)/ Gender	First Accusol Administration Start Date/ Time	Dialysis Solution Used	Lot Number	Site of Introduction	Start Date and Time/ End Date and Time	Dialysis Dose (ml/kg/hr)	Amount Administered (L)
005-004	81/Male	27MAR2015 09:00	ACCUSOL 35	14K11G70	AS DIALYSATE	28MAR2015 06:40 / 28MAR2015 07:00	26.7	0.43
005-006	38/Male	22APR2015 12:00	ACCUSOL 35	14K27G73	AS DIALYSATE	22APR2015 12:00 / 22APR2015 12:15	33.4	0.56
005-006	38/Male	22APR2015 12:00	ACCUSOL 35	14I30G70	AS DIALYSATE	22APR2015 12:15 / 22APR2015 14:50	33.4	5
005-006	38/Male	22APR2015 12:00	ACCUSOL 35	14I30G70	AS DIALYSATE	22APR2015 14:50 / 22APR2015 19:00	34.7	5
005-006	38/Male	22APR2015 12:00	ACCUSOL 35	14K30G70	AS DIALYSATE	22APR2015 19:00 / 22APR2015 21:00	46	5
005-006	38/Male	22APR2015 12:00	ACCUSOL 35	14K30G70	AS DIALYSATE	22APR2015 21:00 / 22APR2015 23:45	46	5
005-006	38/Male	22APR2015 12:00	ACCUSOL 35	14K30G70	AS DIALYSATE	22APR2015 23:45 / 23APR2015 01:35	34.2	5
005-006	38/Male	22APR2015 12:00	ACCUSOL 35	14K30G70	AS DIALYSATE	23APR2015 01:35 / 23APR2015 03:35	34.2	5
005-006	38/Male	22APR2015 12:00	ACCUSOL 35	14K30G70	AS DIALYSATE	23APR2015 03:35 / 23APR2015 05:30	34.2	5
005-006	38/Male	22APR2015 12:00	ACCUSOL 35	14I30G70	AS DIALYSATE	23APR2015 05:30 / 23APR2015 07:50	44	5
005-006	38/Male	22APR2015 12:00	ACCUSOL 35	14I30G70	AS DIALYSATE	23APR2015 07:50 / 23APR2015 10:00	44	5

Data Listing 16.2.5.3. ACCUSOL 35 Administration - Enrolled Population

Patient Number	Age (Years)/ Gender	First Accusol Administration Start Date/ Time	Dialysis Solution Used	Lot Number	Site of Introduction	Start Date and Time/ End Date and Time	Dialysis Dose (ml/kg/hr)	Amount Administered (L)
005-006	38/Male	22APR2015 12:00	ACCUSOL 35	14I30G70	AS DIALYSATE	23APR2015 10:00 / 23APR2015 11:10	44	1.2
005-007	63/Male	23APR2015 20:00	ACCUSOL 35	UNK	UNK	23APR2015 20:00 / 23APR2015 21:00	25.3	.
005-007	63/Male	23APR2015 20:00	ACCUSOL 35	14K11G71	AS DIALYSATE	23APR2015 21:00 / 23APR2015 22:00	30.5	5
005-007	63/Male	23APR2015 20:00	ACCUSOL 35	14K11G71	AS DIALYSATE	23APR2015 22:00 / 23APR2015 23:15	30.5	5
005-007	63/Male	23APR2015 20:00	ACCUSOL 35	14K11G71	AS DIALYSATE	23APR2015 23:15 / 24APR2015 00:20	32.5	5
005-007	63/Male	23APR2015 20:00	ACCUSOL 35	14K11G71	AS DIALYSATE	24APR2015 00:20 / 24APR2015 01:25	32.5	5
005-007	63/Male	23APR2015 20:00	ACCUSOL 35	14K11G71	AS DIALYSATE	24APR2015 01:25 / 24APR2015 02:30	32.5	5
005-007	63/Male	23APR2015 20:00	ACCUSOL 35	14K27G73	AS DIALYSATE	24APR2015 02:30 / 24APR2015 03:30	32.5	5
005-007	63/Male	23APR2015 20:00	ACCUSOL 35	14K13G71	AS DIALYSATE	24APR2015 03:30 / 24APR2015 04:40	30.0	5
005-007	63/Male	23APR2015 20:00	ACCUSOL 35	14K27G73	AS DIALYSATE	24APR2015 04:40 / 24APR2015 05:45	30.0	5
005-007	63/Male	23APR2015 20:00	ACCUSOL 35	14K13G71	AS DIALYSATE	24APR2015 05:45 / 24APR2015 06:50	30.0	5

Data Listing 16.2.5.3. ACCUSOL 35 Administration - Enrolled Population

Patient Number	Age (Years)/ Gender	First Accusol Administration Start Date/ Time	Dialysis Solution Used	Lot Number	Site of Introduction	Start Date and Time/ End Date and Time	Dialysis Dose (ml/kg/hr)	Amount Administered (L)
005-007	63/Male	23APR2015 20:00	ACCUSOL 35	14K11G70	AS DIALYSATE	24APR2015 06:50 / 24APR2015 08:00	30.0	5
005-007	63/Male	23APR2015 20:00	ACCUSOL 35	14I08G71	AS DIALYSATE	24APR2015 08:00 / 24APR2015 09:00	32.9	5
005-007	63/Male	23APR2015 20:00	ACCUSOL 35	14I08G71	AS DIALYSATE	24APR2015 09:00 / 24APR2015 10:00	32.9	5
005-007	63/Male	23APR2015 20:00	ACCUSOL 35	14K11G70	AS DIALYSATE	24APR2015 10:00 / 24APR2015 11:15	32.9	5
005-007	63/Male	23APR2015 20:00	ACCUSOL 35	14K11G70	AS DIALYSATE	24APR2015 11:15 / 24APR2015 12:05	32.9	5
005-007	63/Male	23APR2015 20:00	ACCUSOL 35	14K11G70	AS DIALYSATE	24APR2015 12:05 / 24APR2015 13:30	32.6	5
005-007	63/Male	23APR2015 20:00	ACCUSOL 35	14K11G70	AS DIALYSATE	24APR2015 13:30 / 24APR2015 14:30	32.6	5
005-007	63/Male	23APR2015 20:00	ACCUSOL 35	14K13G71	AS DIALYSATE	24APR2015 14:30 / 24APR2015 15:25	32.6	5
005-007	63/Male	23APR2015 20:00	ACCUSOL 35	14K27G73	AS DIALYSATE	24APR2015 15:25 / 24APR2015 16:35	32.6	5
005-007	63/Male	23APR2015 20:00	ACCUSOL 35	14K11G70	AS DIALYSATE	24APR2015 16:35 / 24APR2015 17:35	32.6	5
005-007	63/Male	23APR2015 20:00	ACCUSOL 35	14K11G70	AS DIALYSATE	24APR2015 17:35 / 24APR2015 18:50	32.6	5

Data Listing 16.2.5.3. ACCUSOL 35 Administration - Enrolled Population

Patient Number	Age (Years)/ Gender	First Accusol Administration Start Date/ Time	Dialysis Solution Used	Lot Number	Site of Introduction	Start Date and Time/ End Date and Time	Dialysis Dose (ml/kg/hr)	Amount Administered (L)
005-007	63/Male	23APR2015 20:00	ACCUSOL 35	14K13G70	AS DIALYSATE	24APR2015 18:50 / 24APR2015 19:50	32.6	5
005-007	63/Male	23APR2015 20:00	ACCUSOL 35	14I30G70	AS DIALYSATE	24APR2015 19:50 / 24APR2015 21:00	32.6	5
005-007	63/Male	23APR2015 20:00	ACCUSOL 35	14I30G70	AS DIALYSATE	24APR2015 21:00 / 24APR2015 22:00	21.6	5
005-007	63/Male	23APR2015 20:00	ACCUSOL 35	14K11G70	AS DIALYSATE	24APR2015 22:00 / 24APR2015 23:15	33.1	5
005-007	63/Male	23APR2015 20:00	ACCUSOL 35	14K11G70	AS DIALYSATE	24APR2015 23:15 / 25APR2015 00:20	33.1	5
005-007	63/Male	23APR2015 20:00	ACCUSOL 35	14K13G71	AS DIALYSATE	25APR2015 00:20 / 25APR2015 01:25	33.1	5
005-007	63/Male	23APR2015 20:00	ACCUSOL 35	14K30G70	AS DIALYSATE	25APR2015 01:25 / 25APR2015 02:25	33.1	5
005-007	63/Male	23APR2015 20:00	ACCUSOL 35	14K30G70	AS DIALYSATE	25APR2015 02:25 / 25APR2015 03:35	33.1	5
005-007	63/Male	23APR2015 20:00	ACCUSOL 35	14K30G70	AS DIALYSATE	25APR2015 03:35 / 25APR2015 04:00	53.3	2.5
005-008	74/Female	09MAY2015 09:00	ACCUSOL 35	14K30G70	AS DIALYSATE	09MAY2015 09:00 / 09MAY2015 11:40	30.6	4.21
005-008	74/Female	09MAY2015 09:00	ACCUSOL 35	14K30G70	AS DIALYSATE	09MAY2015 11:40 / 09MAY2015 11:40	UNK	0

Data Listing 16.2.5.3. ACCUSOL 35 Administration - Enrolled Population

Patient Number	Age (Years)/ Gender	First Accusol Administration Start Date/ Time	Dialysis Solution Used	Lot Number	Site of Introduction	Start Date and Time/ End Date and Time	Dialysis Dose (ml/kg/hr)	Amount Administered (L)
005-008	74/Female	09MAY2015 09:00	ACCUSOL 35	14K30G70	AS DIALYSATE	09MAY2015 11:40 / 09MAY2015 14:35	41.3	5
005-008	74/Female	09MAY2015 09:00	ACCUSOL 35	14K30G70	AS DIALYSATE	09MAY2015 14:35 / 09MAY2015 17:30	31.8	5
005-008	74/Female	09MAY2015 09:00	ACCUSOL 35	14K30G70	AS DIALYSATE	09MAY2015 17:30 / 09MAY2015 20:25	31.8	5
005-008	74/Female	09MAY2015 09:00	ACCUSOL 35	14K30G70	AS DIALYSATE	09MAY2015 20:25 / 09MAY2015 23:20	31.8	5
005-008	74/Female	09MAY2015 09:00	ACCUSOL 35	14K30G70	AS DIALYSATE	09MAY2015 23:20 / 10MAY2015 02:30	32	5
005-008	74/Female	09MAY2015 09:00	ACCUSOL 35	14K30G70	AS DIALYSATE	10MAY2015 02:30 / 10MAY2015 03:00	32	0.45
005-010	42/Male	14MAY2015 10:00	ACCUSOL 35	UNK	UNK	14MAY2015 10:00 / 14MAY2015 10:30	31.1	.
005-010	42/Male	14MAY2015 10:00	ACCUSOL 35	14K27G73	AS DIALYSATE	14MAY2015 10:30 / 14MAY2015 11:55	31.1	5
005-010	42/Male	14MAY2015 10:00	ACCUSOL 35	14K30G70	AS DIALYSATE	14MAY2015 11:55 / 14MAY2015 13:30	31.1	5
005-010	42/Male	14MAY2015 10:00	ACCUSOL 35	14K30G70	AS DIALYSATE	14MAY2015 13:30 / 14MAY2015 15:05	33.2	5
005-010	42/Male	14MAY2015 10:00	ACCUSOL 35	14K30G70	AS DIALYSATE	14MAY2015 15:05 / 14MAY2015 16:30	33.2	5

Data Listing 16.2.5.3. ACCUSOL 35 Administration - Enrolled Population

Patient Number	Age (Years)/ Gender	First Accusol Administration Start Date/ Time	Dialysis Solution Used	Lot Number	Site of Introduction	Start Date and Time/ End Date and Time	Dialysis Dose (ml/kg/hr)	Amount Administered (L)
005-010	42/Male	14MAY2015 10:00	ACCUSOL 35	14K30G70	AS DIALYSATE	14MAY2015 16:30 / 14MAY2015 18:10	31.5	5
005-010	42/Male	14MAY2015 10:00	ACCUSOL 35	14K30G70	AS DIALYSATE	14MAY2015 18:10 / 14MAY2015 19:30	31.5	5
005-010	42/Male	14MAY2015 10:00	ACCUSOL 35	14K27G73	AS DIALYSATE	14MAY2015 19:30 / 14MAY2015 21:05	31.5	5
005-010	42/Male	14MAY2015 10:00	ACCUSOL 35	14K27G73	AS DIALYSATE	14MAY2015 21:05 / 14MAY2015 22:35	31.7	5
005-010	42/Male	14MAY2015 10:00	ACCUSOL 35	14K30G70	AS DIALYSATE	14MAY2015 22:35 / 15MAY2015 00:10	31.7	5
005-010	42/Male	14MAY2015 10:00	ACCUSOL 35	14K27G73	AS DIALYSATE	15MAY2015 00:10 / 15MAY2015 01:45	27.2	5
005-010	42/Male	14MAY2015 10:00	ACCUSOL 35	14K30G70	AS DIALYSATE	15MAY2015 01:45 / 15MAY2015 03:15	27.2	5
005-010	42/Male	14MAY2015 10:00	ACCUSOL 35	14K30G70	AS DIALYSATE	15MAY2015 03:15 / 15MAY2015 04:55	27.2	5
005-010	42/Male	14MAY2015 10:00	ACCUSOL 35	14K30G70	AS DIALYSATE	15MAY2015 04:55 / 15MAY2015 06:25	27.2	5
005-010	42/Male	14MAY2015 10:00	ACCUSOL 35	14K30G70	AS DIALYSATE	15MAY2015 06:25 / 15MAY2015 07:55	26.5	5
005-010	42/Male	14MAY2015 10:00	ACCUSOL 35	14K30G70	AS DIALYSATE	15MAY2015 07:55 / 15MAY2015 09:20	26.5	5

Data Listing 16.2.5.3. ACCUSOL 35 Administration - Enrolled Population

Patient Number	Age (Years)/ Gender	First Accusol Administration Start Date/ Time	Dialysis Solution Used	Lot Number	Site of Introduction	Start Date and Time/ End Date and Time	Dialysis Dose (ml/kg/hr)	Amount Administered (L)
005-010	42/Male	14MAY2015 10:00	ACCUSOL 35	14K30G70	AS DIALYSATE	15MAY2015 09:20 / 15MAY2015 11:25	23.1	5
005-010	42/Male	14MAY2015 10:00	ACCUSOL 35	14K30G70	AS DIALYSATE	15MAY2015 11:25 / 15MAY2015 12:20	23.1	5
005-010	42/Male	14MAY2015 10:00	ACCUSOL 35	14K30G70	AS DIALYSATE	15MAY2015 12:20 / 15MAY2015 14:00	23.1	5
005-010	42/Male	14MAY2015 10:00	ACCUSOL 35	14K30G70	AS DIALYSATE	15MAY2015 14:00 / 15MAY2015 15:40	26.4	5
005-010	42/Male	14MAY2015 10:00	ACCUSOL 35	14K30G70	AS DIALYSATE	15MAY2015 15:40 / 15MAY2015 17:10	26.4	5
005-010	42/Male	14MAY2015 10:00	ACCUSOL 35	14K30G70	AS DIALYSATE	15MAY2015 17:10 / 15MAY2015 18:00	26.4	2.63
005-011	78/Female	15MAY2015 08:25	ACCUSOL 35	14K30G70	AS DIALYSATE	15MAY2015 08:25 / 15MAY2015 10:00	44.6	4.75
005-011	78/Female	15MAY2015 08:25	ACCUSOL 35	14K30G70	AS DIALYSATE	15MAY2015 10:00 / 15MAY2015 11:45	44.6	5
005-011	78/Female	15MAY2015 08:25	ACCUSOL 35	14K30G70	AS DIALYSATE	15MAY2015 11:45 / 15MAY2015 13:20	51.2	5
005-011	78/Female	15MAY2015 08:25	ACCUSOL 35	14K30G70	AS DIALYSATE	15MAY2015 13:20 / 15MAY2015 15:00	51.8	5
005-011	78/Female	15MAY2015 08:25	ACCUSOL 35	14K30G70	AS DIALYSATE	15MAY2015 15:00 / 15MAY2015 16:00	51.2	5

Data Listing 16.2.5.3. ACCUSOL 35 Administration - Enrolled Population

Patient Number	Age (Years)/ Gender	First Accusol Administration Start Date/ Time	Dialysis Solution Used	Lot Number	Site of Introduction	Start Date and Time/ End Date and Time	Dialysis Dose (ml/kg/hr)	Amount Administered (L)
005-012		16MAY2015 13:00	ACCUSOL 35	UNK	UNK	16MAY2015 13:00 / 16MAY2015 14:20	43.6	.
005-012		16MAY2015 13:00	ACCUSOL 35	14K30G70	AS DIALYSATE	16MAY2015 14:20 / 16MAY2015 16:20	43.6	5
005-012		16MAY2015 13:00	ACCUSOL 35	14K30G70	AS DIALYSATE	16MAY2015 16:20 / 16MAY2015 18:30	33	5
005-012		16MAY2015 13:00	ACCUSOL 35	14K30G70	AS DIALYSATE	16MAY2015 18:30 / 16MAY2015 20:25	33	5
005-012		16MAY2015 13:00	ACCUSOL 35	14K30G70	AS DIALYSATE	16MAY2015 20:25 / 16MAY2015 22:30	27.1	5
005-012		16MAY2015 13:00	ACCUSOL 35	14K30G70	AS DIALYSATE	16MAY2015 22:30 / 17MAY2015 00:30	27.1	5
005-012		16MAY2015 13:00	ACCUSOL 35	14K30G70	AS DIALYSATE	17MAY2015 00:30 / 17MAY2015 02:40	43.6	5
005-012		16MAY2015 13:00	ACCUSOL 35	14K30G70	AS DIALYSATE	17MAY2015 02:40 / 17MAY2015 04:40	43.6	5
005-012		16MAY2015 13:00	ACCUSOL 35	14K30G70	AS DIALYSATE	17MAY2015 04:40 / 17MAY2015 06:40	43.6	5
005-012		16MAY2015 13:00	ACCUSOL 35	14K30G70	AS DIALYSATE	17MAY2015 06:40 / 17MAY2015 08:40	43.6	5
005-012		16MAY2015 13:00	ACCUSOL 35	14K30G70	AS DIALYSATE	17MAY2015 08:40 / 17MAY2015 10:45	32.9	5

Data Listing 16.2.5.3. ACCUSOL 35 Administration - Enrolled Population

Patient Number	Age (Years)/ Gender	First Accusol Administration Start Date/ Time	Dialysis Solution Used	Lot Number	Site of Introduction	Start Date and Time/ End Date and Time	Dialysis Dose (ml/kg/hr)	Amount Administered (L)
005-012		16MAY2015 13:00	ACCUSOL 35	14K30G70	AS DIALYSATE	17MAY2015 10:45 / 17MAY2015 12:50	40.1	5
005-012		16MAY2015 13:00	ACCUSOL 35	14K30G70	AS DIALYSATE	17MAY2015 12:50 / 17MAY2015 15:00	40.1	5
005-012		16MAY2015 13:00	ACCUSOL 35	14K30G70	AS DIALYSATE	17MAY2015 15:00 / 17MAY2015 17:00	44.2	5
005-012		16MAY2015 13:00	ACCUSOL 35	14K30G70	AS DIALYSATE	17MAY2015 17:00 / 17MAY2015 18:00	44.2	5
005-012		16MAY2015 13:00	ACCUSOL 35	14K30G70	AS DIALYSATE	17MAY2015 18:00 / 17MAY2015 19:00	44.2	5
005-012		16MAY2015 13:00	ACCUSOL 35	14K30G70	AS DIALYSATE	17MAY2015 19:00 / 17MAY2015 20:00	28.8	5
005-012		16MAY2015 13:00	ACCUSOL 35	14K30G70	AS DIALYSATE	17MAY2015 20:00 / 17MAY2015 21:00	28.8	5
005-014	65/Male	05JUN2015 09:30	ACCUSOL 35	14K30G71	AS DIALYSATE	05JUN2015 09:30 / 05JUN2015 10:45	26.1	5
005-014	65/Male	05JUN2015 09:30	ACCUSOL 35	14K30G71	AS DIALYSATE	05JUN2015 10:45 / 05JUN2015 11:45	26.1	5
005-014	65/Male	05JUN2015 09:30	ACCUSOL 35	14K30G71	AS DIALYSATE	05JUN2015 11:45 / 05JUN2015 13:00	26.1	5
005-014	65/Male	05JUN2015 09:30	ACCUSOL 35	14K30G71	AS DIALYSATE	05JUN2015 13:00 / 05JUN2015 15:35	26.7	5

Data Listing 16.2.5.3. ACCUSOL 35 Administration - Enrolled Population

Patient Number	Age (Years)/ Gender	First Accusol Administration Start Date/ Time	Dialysis Solution Used	Lot Number	Site of Introduction	Start Date and Time/ End Date and Time	Dialysis Dose (ml/kg/hr)	Amount Administered (L)
005-014	65/Male	05JUN2015 09:30	ACCUSOL 35	14K30G71	AS DIALYSATE	05JUN2015 15:35 / 05JUN2015 17:05	26.7	5
005-014	65/Male	05JUN2015 09:30	ACCUSOL 35	14K30G71	AS DIALYSATE	05JUN2015 17:05 / 05JUN2015 18:00	26.7	5
005-014	65/Male	05JUN2015 09:30	ACCUSOL 35	14K30G71	AS DIALYSATE	05JUN2015 18:00 / 05JUN2015 19:25	26.7	5
005-014	65/Male	05JUN2015 09:30	ACCUSOL 35	14K30G71	AS DIALYSATE	05JUN2015 19:25 / 05JUN2015 20:35	26.7	5
005-014	65/Male	05JUN2015 09:30	ACCUSOL 35	14K30G71	AS DIALYSATE	05JUN2015 20:35 / 05JUN2015 21:50	26.7	5
005-014	65/Male	05JUN2015 09:30	ACCUSOL 35	14K30G71	AS DIALYSATE	05JUN2015 21:50 / 05JUN2015 23:10	26.7	5
005-014	65/Male	05JUN2015 09:30	ACCUSOL 35	14K30G71	AS DIALYSATE	05JUN2015 23:10 / 06JUN2015 00:20	32.7	5
005-014	65/Male	05JUN2015 09:30	ACCUSOL 35	14K30G71	AS DIALYSATE	06JUN2015 00:20 / 06JUN2015 01:30	32.7	5
005-014	65/Male	05JUN2015 09:30	ACCUSOL 35	14K30G71	AS DIALYSATE	06JUN2015 01:30 / 06JUN2015 02:40	32.7	5
005-014	65/Male	05JUN2015 09:30	ACCUSOL 35	14K30G71	AS DIALYSATE	06JUN2015 02:40 / 06JUN2015 03:55	32.7	5
005-014	65/Male	05JUN2015 09:30	ACCUSOL 35	14K30G71	AS DIALYSATE	06JUN2015 03:55 / 06JUN2015 05:00	32.8	5

Data Listing 16.2.5.3. ACCUSOL 35 Administration - Enrolled Population

Patient Number	Age (Years)/ Gender	First Accusol Administration Start Date/ Time	Dialysis Solution Used	Lot Number	Site of Introduction	Start Date and Time/ End Date and Time	Dialysis Dose (ml/kg/hr)	Amount Administered (L)
005-014	65/Male	05JUN2015 09:30	ACCUSOL 35	14K30G71	AS DIALYSATE	06JUN2015 05:00 / 06JUN2015 06:15	32.8	5
005-014	65/Male	05JUN2015 09:30	ACCUSOL 35	14K30G71	AS DIALYSATE	06JUN2015 06:15 / 06JUN2015 07:20	32.8	5
005-014	65/Male	05JUN2015 09:30	ACCUSOL 35	14K30G71	AS DIALYSATE	06JUN2015 07:20 / 06JUN2015 08:20	32.8	5
005-015	78/Male	20JUN2015 21:00	ACCUSOL 35	14K30G71	AS DIALYSATE	20JUN2015 21:00 / 20JUN2015 21:40	26.9	1.82
005-015	78/Male	20JUN2015 21:00	ACCUSOL 35	14K30G71	AS DIALYSATE	20JUN2015 21:40 / 20JUN2015 23:30	32.2	5
005-015	78/Male	20JUN2015 21:00	ACCUSOL 35	14K30G71	AS DIALYSATE	20JUN2015 23:30 / 21JUN2015 00:45	31.3	5
005-015	78/Male	20JUN2015 21:00	ACCUSOL 35	14K30G71	AS DIALYSATE	21JUN2015 00:45 / 21JUN2015 03:20	31.3	5
005-015	78/Male	20JUN2015 21:00	ACCUSOL 35	14K30G71	AS DIALYSATE	21JUN2015 03:20 / 21JUN2015 05:15	31.3	5
005-015	78/Male	20JUN2015 21:00	ACCUSOL 35	15A09G70	AS DIALYSATE	21JUN2015 05:15 / 21JUN2015 07:00	47	5
005-015	78/Male	20JUN2015 21:00	ACCUSOL 35	15A09G70	AS DIALYSATE	21JUN2015 07:00 / 21JUN2015 08:50	47	5
005-015	78/Male	20JUN2015 21:00	ACCUSOL 35	15A09G70	AS DIALYSATE	21JUN2015 08:50 / 21JUN2015 10:50	26.9	5

Data Listing 16.2.5.3. ACCUSOL 35 Administration - Enrolled Population

Patient Number	Age (Years)/ Gender	First Accusol Administration Start Date/ Time	Dialysis Solution Used	Lot Number	Site of Introduction	Start Date and Time/ End Date and Time	Dialysis Dose (ml/kg/hr)	Amount Administered (L)
005-015	78/Male	20JUN2015 21:00	ACCUSOL 35	14K30G71	AS DIALYSATE	21JUN2015 10:50 / 21JUN2015 12:35	47.5	5
005-015	78/Male	20JUN2015 21:00	ACCUSOL 35	14K30G71	AS DIALYSATE	21JUN2015 12:35 / 21JUN2015 14:10	26.5	5
005-015	78/Male	20JUN2015 21:00	ACCUSOL 35	14K30G70	AS DIALYSATE	21JUN2015 14:10 / 21JUN2015 16:00	48.9	5
005-015	78/Male	20JUN2015 21:00	ACCUSOL 35	14K30G70	AS DIALYSATE	21JUN2015 16:00 / 21JUN2015 18:05	48.9	5
005-015	78/Male	20JUN2015 21:00	ACCUSOL 35	14K30G71	AS DIALYSATE	21JUN2015 18:05 / 21JUN2015 20:05	28.6	5
005-015	78/Male	20JUN2015 21:00	ACCUSOL 35	14K30G71	AS DIALYSATE	21JUN2015 20:05 / 21JUN2015 22:05	28.6	5
005-015	78/Male	20JUN2015 21:00	ACCUSOL 35	14K30G71	AS DIALYSATE	21JUN2015 22:05 / 22JUN2015 00:00	28.6	5
005-015	78/Male	20JUN2015 21:00	ACCUSOL 35	14K30G71	AS DIALYSATE	22JUN2015 00:00 / 22JUN2015 02:10	35.6	5
005-015	78/Male	20JUN2015 21:00	ACCUSOL 35	14K30G71	AS DIALYSATE	22JUN2015 02:10 / 22JUN2015 05:00	35.6	5
005-016		14JUL2015 19:50	ACCUSOL 35	15A09G71	AS DIALYSATE	14JUL2015 19:50 / 14JUL2015 20:00	28.5	0.18
005-016		14JUL2015 19:50	ACCUSOL 35	15A09G71	AS DIALYSATE	14JUL2015 20:00 / 15JUL2015 22:20	38.9	5

Data Listing 16.2.5.3. ACCUSOL 35 Administration - Enrolled Population

Patient Number	Age (Years)/ Gender	First Accusol Administration Start Date/ Time	Dialysis Solution Used	Lot Number	Site of Introduction	Start Date and Time/ End Date and Time	Dialysis Dose (ml/kg/hr)	Amount Administered (L)
005-016		14JUL2015 19:50	ACCUSOL 35	15A09G71	AS DIALYSATE	14JUL2015 22:20 / 15JUL2015 01:00	22.2	5
005-016		14JUL2015 19:50	ACCUSOL 35	15A09G71	AS DIALYSATE	15JUL2015 01:00 / 15JUL2015 03:25	41.6	5
005-016		14JUL2015 19:50	ACCUSOL 35	15A09G71	AS DIALYSATE	15JUL2015 03:25 / 15JUL2015 06:00	41.6	5
005-016		14JUL2015 19:50	ACCUSOL 35	15A09G71	AS DIALYSATE	15JUL2015 06:00 / 15JUL2015 08:30	43.5	5
005-016		14JUL2015 19:50	ACCUSOL 35	15A09G71	AS DIALYSATE	15JUL2015 08:30 / 15JUL2015 11:05	33.2	5
005-016		14JUL2015 19:50	ACCUSOL 35	15A09G71	AS DIALYSATE	15JUL2015 11:05 / 15JUL2015 13:30	33.2	5
005-016		14JUL2015 19:50	ACCUSOL 35	15A09G71	AS DIALYSATE	15JUL2015 13:30 / 15JUL2015 16:00	43.9	5
005-016		14JUL2015 19:50	ACCUSOL 35	15A09G71	AS DIALYSATE	15JUL2015 16:00 / 15JUL2015 18:30	43.9	5
005-016		14JUL2015 19:50	ACCUSOL 35	15A09G71	AS DIALYSATE	15JUL2015 18:30 / 15JUL2015 20:45	43.4	5
005-016		14JUL2015 19:50	ACCUSOL 35	15A09G71	AS DIALYSATE	15JUL2015 20:45 / 15JUL2015 23:15	43.4	5
005-016		14JUL2015 19:50	ACCUSOL 35	15A09G71	AS DIALYSATE	15JUL2015 23:15 / 16JUL2015 01:40	32.7	5

Data Listing 16.2.5.3. ACCUSOL 35 Administration - Enrolled Population

Patient Number	Age (Years)/ Gender	First Accusol Administration Start Date/ Time	Dialysis Solution Used	Lot Number	Site of Introduction	Start Date and Time/ End Date and Time	Dialysis Dose (ml/kg/hr)	Amount Administered (L)
005-016		14JUL2015 19:50	ACCUSOL 35	15A09G70	AS DIALYSATE	16JUL2015 01:40 / 16JUL2015 03:50	32.7	3.1
005-018	67/Male	29AUG2015 07:30	ACCUSOL 35	15C03G73	AS DIALYSATE	29AUG2015 07:30 / 29AUG2015 08:30	35.2	2.5
005-018	67/Male	29AUG2015 07:30	ACCUSOL 35	15C03G73	AS DIALYSATE	29AUG2015 08:30 / 29AUG2015 10:30	35.2	5
005-018	67/Male	29AUG2015 07:30	ACCUSOL 35	15C03G73	AS DIALYSATE	29AUG2015 10:30 / 29AUG2015 12:25	35.2	5
005-018	67/Male	29AUG2015 07:30	ACCUSOL 35	15C03G73	AS DIALYSATE	29AUG2015 12:25 / 29AUG2015 14:20	28.3	5
005-018	67/Male	29AUG2015 07:30	ACCUSOL 35	15C03G73	AS DIALYSATE	29AUG2015 14:20 / 29AUG2015 16:20	28.3	5
005-018	67/Male	29AUG2015 07:30	ACCUSOL 35	15C03G73	AS DIALYSATE	29AUG2015 16:20 / 29AUG2015 18:00	28.3	5
005-019	69/Male	15SEP2015 15:30	ACCUSOL 35	15D12G70	AS DIALYSATE	15SEP2015 15:30 / 15SEP2015 16:20	26.8	2.94
005-019	69/Male	15SEP2015 15:30	ACCUSOL 35	15A09G71	AS DIALYSATE	15SEP2015 16:20 / 15SEP2015 18:10	26.8	5
005-019	69/Male	15SEP2015 15:30	ACCUSOL 35	15A09G71	AS DIALYSATE	15SEP2015 18:10 / 15SEP2015 19:45	54.1	5
005-019	69/Male	15SEP2015 15:30	ACCUSOL 35	15A09G71	AS DIALYSATE	15SEP2015 19:45 / 15SEP2015 21:20	54.1	5

Data Listing 16.2.5.3. ACCUSOL 35 Administration - Enrolled Population

Patient Number	Age (Years)/ Gender	First Accusol Administration Start Date/ Time	Dialysis Solution Used	Lot Number	Site of Introduction	Start Date and Time/ End Date and Time	Dialysis Dose (ml/kg/hr)	Amount Administered (L)
005-019	69/Male	15SEP2015 15:30	ACCUSOL 35	15A09G71	AS DIALYSATE	15SEP2015 21:20 / 15SEP2015 23:00	36.1	5
005-019	69/Male	15SEP2015 15:30	ACCUSOL 35	15A09G71	AS DIALYSATE	15SEP2015 23:00 / 16SEP2015 00:40	36.1	5
005-019	69/Male	15SEP2015 15:30	ACCUSOL 35	15A09G71	AS DIALYSATE	16SEP2015 00:40 / 16SEP2015 02:20	32.3	5
005-019	69/Male	15SEP2015 15:30	ACCUSOL 35	15A09G71	AS DIALYSATE	16SEP2015 02:20 / 16SEP2015 03:55	32.3	5
005-019	69/Male	15SEP2015 15:30	ACCUSOL 35	15A09G71	AS DIALYSATE	16SEP2015 03:55 / 16SEP2015 05:40	29.6	5
005-019	69/Male	15SEP2015 15:30	ACCUSOL 35	15A09G71	AS DIALYSATE	16SEP2015 05:40 / 16SEP2015 07:15	29.6	5
005-019	69/Male	15SEP2015 15:30	ACCUSOL 35	15A09G71	AS DIALYSATE	16SEP2015 07:15 / 16SEP2015 08:50	29.6	5
005-019	69/Male	15SEP2015 15:30	ACCUSOL 35	15A09G71	AS DIALYSATE	16SEP2015 08:50 / 16SEP2015 10:30	31.9	5
005-019	69/Male	15SEP2015 15:30	ACCUSOL 35	15A09G71	AS DIALYSATE	16SEP2015 10:30 / 16SEP2015 11:15	31.9	5
005-019	69/Male	15SEP2015 15:30	ACCUSOL 35	15A09G71	AS DIALYSATE	16SEP2015 11:15 / 16SEP2015 14:00	31.9	5
005-019	69/Male	15SEP2015 15:30	ACCUSOL 35	15A09G71	AS DIALYSATE	16SEP2015 14:00 / 16SEP2015 15:40	34.9	5

Data Listing 16.2.5.3. ACCUSOL 35 Administration - Enrolled Population

Patient Number	Age (Years)/ Gender	First Accusol Administration Start Date/ Time	Dialysis Solution Used	Lot Number	Site of Introduction	Start Date and Time/ End Date and Time	Dialysis Dose (ml/kg/hr)	Amount Administered (L)
005-019	69/Male	15SEP2015 15:30	ACCUSOL 35	15A09G71	AS DIALYSATE	16SEP2015 15:40 / 16SEP2015 17:15	34.9	5
005-019	69/Male	15SEP2015 15:30	ACCUSOL 35	15A09G71	AS DIALYSATE	16SEP2015 17:15 / 16SEP2015 19:00	34.9	5
005-019	69/Male	15SEP2015 15:30	ACCUSOL 35	15A09G71	AS DIALYSATE	16SEP2015 19:00 / 16SEP2015 22:10	29.6	5
005-019	69/Male	15SEP2015 15:30	ACCUSOL 35	15A09G71	AS DIALYSATE	16SEP2015 22:10 / 16SEP2015 23:30	29.6	4.44
005-020		16SEP2015 11:30	ACCUSOL 35	15A09G71	AS DIALYSATE	16SEP2015 11:30 / 16SEP2015 13:30	42.1	2.6
005-020		16SEP2015 11:30	ACCUSOL 35	15A09G71	AS DIALYSATE	16SEP2015 13:30 / 16SEP2015 15:10	35	5
005-020		16SEP2015 11:30	ACCUSOL 35	15A09G71	AS DIALYSATE	16SEP2015 15:10 / 16SEP2015 17:15	35	5
005-020		16SEP2015 11:30	ACCUSOL 35	15A09G70	AS DIALYSATE	16SEP2015 17:15 / 16SEP2015 19:10	33.7	5
005-020		16SEP2015 11:30	ACCUSOL 35	15A09G70	AS DIALYSATE	16SEP2015 19:10 / 16SEP2015 21:10	33.7	5
005-020		16SEP2015 11:30	ACCUSOL 35	15A09G70	AS DIALYSATE	16SEP2015 21:10 / 16SEP2015 23:10	45.6	5
005-020		16SEP2015 11:30	ACCUSOL 35	15A09G70	AS DIALYSATE	16SEP2015 23:10 / 17SEP2015 01:30	45.6	5

Data Listing 16.2.5.3. ACCUSOL 35 Administration - Enrolled Population

Patient Number	Age (Years)/ Gender	First Accusol Administration Start Date/ Time	Dialysis Solution Used	Lot Number	Site of Introduction	Start Date and Time/ End Date and Time	Dialysis Dose (ml/kg/hr)	Amount Administered (L)
005-020		16SEP2015 11:30	ACCUSOL 35	15A09G70	AS DIALYSATE	17SEP2015 01:30 / 17SEP2015 03:10	45.9	5
005-020		16SEP2015 11:30	ACCUSOL 35	15A09G70	AS DIALYSATE	17SEP2015 03:10 / 17SEP2015 05:05	45.9	5
005-020		16SEP2015 11:30	ACCUSOL 35	15A09G70	AS DIALYSATE	17SEP2015 05:05 / 17SEP2015 07:10	34.5	5
005-020		16SEP2015 11:30	ACCUSOL 35	15A09G70	AS DIALYSATE	17SEP2015 07:10 / 17SEP2015 09:10	34.5	5
005-020		16SEP2015 11:30	ACCUSOL 35	15A09G70	AS DIALYSATE	17SEP2015 09:10 / 17SEP2015 11:10	34.5	5
005-020		16SEP2015 11:30	ACCUSOL 35	15A09G70	AS DIALYSATE	17SEP2015 11:10 / 17SEP2015 13:15	45.3	5
005-020		16SEP2015 11:30	ACCUSOL 35	15A09G70	AS DIALYSATE	17SEP2015 13:15 / 17SEP2015 15:20	45.3	5
005-020		16SEP2015 11:30	ACCUSOL 35	15A09G70	AS DIALYSATE	17SEP2015 15:20 / 17SEP2015 17:20	45.3	5
005-020		16SEP2015 11:30	ACCUSOL 35	15A09G70	AS DIALYSATE	17SEP2015 17:20 / 17SEP2015 19:30	45.3	5
005-021	58/Male	16SEP2015 08:30	ACCUSOL 35	15A09G71	AS DIALYSATE	16SEP2015 08:30 / 16SEP2015 09:45	42.8	2.86
005-021	58/Male	16SEP2015 08:30	ACCUSOL 35	15A09G71	AS DIALYSATE	16SEP2015 09:45 / 16SEP2015 12:00	47.2	5

Data Listing 16.2.5.3. ACCUSOL 35 Administration - Enrolled Population

Patient Number	Age (Years)/ Gender	First Accusol Administration Start Date/ Time	Dialysis Solution Used	Lot Number	Site of Introduction	Start Date and Time/ End Date and Time	Dialysis Dose (ml/kg/hr)	Amount Administered (L)
005-021	58/Male	16SEP2015 08:30	ACCUSOL 35	15A09G71	AS DIALYSATE	16SEP2015 12:00 / 16SEP2015 14:20	47.2	5
005-021	58/Male	16SEP2015 08:30	ACCUSOL 35	15A09G71	AS DIALYSATE	16SEP2015 14:20 / 16SEP2015 16:30	41.5	5
005-021	58/Male	16SEP2015 08:30	ACCUSOL 35	15A09G71	AS DIALYSATE	16SEP2015 16:30 / 16SEP2015 18:50	41.5	5
005-021	58/Male	16SEP2015 08:30	ACCUSOL 35	15A09G70	AS DIALYSATE	16SEP2015 18:50 / 16SEP2015 21:00	47.5	5
005-021	58/Male	16SEP2015 08:30	ACCUSOL 35	15A09G70	AS DIALYSATE	16SEP2015 21:00 / 16SEP2015 23:20	47.4	5
005-021	58/Male	16SEP2015 08:30	ACCUSOL 35	15A09G70	AS DIALYSATE	16SEP2015 23:20 / 17SEP2015 01:30	47.4	5
005-021	58/Male	16SEP2015 08:30	ACCUSOL 35	15A09G70	AS DIALYSATE	17SEP2015 01:30 / 17SEP2015 04:00	49.6	5
005-021	58/Male	16SEP2015 08:30	ACCUSOL 35	15A09G71	AS DIALYSATE	17SEP2015 04:00 / 17SEP2015 06:15	49.6	5
005-021	58/Male	16SEP2015 08:30	ACCUSOL 35	15A09G71	AS DIALYSATE	17SEP2015 06:15 / 17SEP2015 09:42	30.2	5
005-021	58/Male	16SEP2015 08:30	ACCUSOL 35	15A09G71	AS DIALYSATE	17SEP2015 09:42 / 17SEP2015 11:10	30.2	5
005-021	58/Male	16SEP2015 08:30	ACCUSOL 35	15A09G71	AS DIALYSATE	17SEP2015 11:10 / 17SEP2015 13:45	30.2	5

Data Listing 16.2.5.3. ACCUSOL 35 Administration - Enrolled Population

Patient Number	Age (Years)/ Gender	First Accusol Administration Start Date/ Time	Dialysis Solution Used	Lot Number	Site of Introduction	Start Date and Time/ End Date and Time	Dialysis Dose (ml/kg/hr)	Amount Administered (L)
005-021	58/Male	16SEP2015 08:30	ACCUSOL 35	15A09G71	AS DIALYSATE	17SEP2015 13:45 / 17SEP2015 16:30	41.5	5
005-022		06OCT2015 04:30	ACCUSOL 35	15A09G71	AS DIALYSATE	06OCT2015 04:30 / 06OCT2015 06:20	30.6	5
005-022		06OCT2015 04:30	ACCUSOL 35	15D12G70	AS DIALYSATE	06OCT2015 06:20 / 06OCT2015 07:45	42.0	5
005-022		06OCT2015 04:30	ACCUSOL 35	15D12G70	AS DIALYSATE	06OCT2015 07:45 / 06OCT2015 09:20	42.0	5
005-022		06OCT2015 04:30	ACCUSOL 35	15D12G70	AS DIALYSATE	06OCT2015 09:20 / 06OCT2015 10:40	42.0	5
005-022		06OCT2015 04:30	ACCUSOL 35	15D12G70	AS DIALYSATE	06OCT2015 10:40 / 06OCT2015 12:30	38.2	5
005-022		06OCT2015 04:30	ACCUSOL 35	15D12G70	AS DIALYSATE	06OCT2015 12:30 / 06OCT2015 13:45	38.2	5
005-022		06OCT2015 04:30	ACCUSOL 35	15D12G70	AS DIALYSATE	06OCT2015 13:45 / 06OCT2015 15:00	38.2	5
005-022		06OCT2015 04:30	ACCUSOL 35	15D12G70	AS DIALYSATE	06OCT2015 15:00 / 06OCT2015 16:40	37.1	5
005-022		06OCT2015 04:30	ACCUSOL 35	15D12G70	AS DIALYSATE	06OCT2015 16:40 / 06OCT2015 18:00	37.1	5
005-022		06OCT2015 04:30	ACCUSOL 35	15D12G70	AS DIALYSATE	06OCT2015 18:00 / 06OCT2015 21:00	29.3	5

Data Listing 16.2.5.3. ACCUSOL 35 Administration - Enrolled Population

Patient Number	Age (Years)/ Gender	First Accusol Administration Start Date/ Time	Dialysis Solution Used	Lot Number	Site of Introduction	Start Date and Time/ End Date and Time	Dialysis Dose (ml/kg/hr)	Amount Administered (L)
005-022		06OCT2015 04:30	ACCUSOL 35	15D12G70	AS DIALYSATE	06OCT2015 21:00 / 06OCT2015 22:30	29.3	5
005-022		06OCT2015 04:30	ACCUSOL 35	15A09G71	AS DIALYSATE	06OCT2015 22:30 / 06OCT2015 23:55	29.3	5
005-022		06OCT2015 04:30	ACCUSOL 35	15A09G70	AS DIALYSATE	06OCT2015 23:55 / 07OCT2015 01:35	39	5
005-022		06OCT2015 04:30	ACCUSOL 35	15D12G70	AS DIALYSATE	07OCT2015 01:35 / 07OCT2015 03:10	39	5
005-022		06OCT2015 04:30	ACCUSOL 35	15A09G70	AS DIALYSATE	07OCT2015 03:10 / 07OCT2015 04:40	39	5
005-022		06OCT2015 04:30	ACCUSOL 35	15A09G70	AS DIALYSATE	07OCT2015 04:40 / 07OCT2015 06:15	39	5
005-022		06OCT2015 04:30	ACCUSOL 35	15A09G70	AS DIALYSATE	07OCT2015 06:15 / 07OCT2015 07:45	39	5
005-022		06OCT2015 04:30	ACCUSOL 35	15A09G70	AS DIALYSATE	07OCT2015 07:45 / 07OCT2015 09:05	39	5
005-022		06OCT2015 04:30	ACCUSOL 35	15A09G70	AS DIALYSATE	07OCT2015 09:05 / 07OCT2015 10:35	39	5
005-022		06OCT2015 04:30	ACCUSOL 35	15A09G70	AS DIALYSATE	07OCT2015 10:35 / 07OCT2015 12:10	39	5
005-022		06OCT2015 04:30	ACCUSOL 35	15A09G70	AS DIALYSATE	07OCT2015 12:10 / 07OCT2015 12:30	39	0.5

Data Listing 16.2.5.3. ACCUSOL 35 Administration - Enrolled Population

Patient Number	Age (Years)/ Gender	First Accusol Administration Start Date/ Time	Dialysis Solution Used	Lot Number	Site of Introduction	Start Date and Time/ End Date and Time	Dialysis Dose (ml/kg/hr)	Amount Administered (L)
005-023	66/Male	11NOV2015 05:00	ACCUSOL 35	15F08G73	AS DIALYSATE	11NOV2015 05:00 / 11NOV2015 06:30	28.4	2.2
005-023	66/Male	11NOV2015 05:00	ACCUSOL 35	15F08G73	AS DIALYSATE	11NOV2015 06:30 / 11NOV2015 08:30	28.4	5
005-023	66/Male	11NOV2015 05:00	ACCUSOL 35	15F08G73	AS DIALYSATE	11NOV2015 08:30 / 11NOV2015 10:30	28.4	5
005-023	66/Male	11NOV2015 05:00	ACCUSOL 35	UNK	AS DIALYSATE	11NOV2015 10:30 / 11NOV2015 10:55	28.4	0.6
005-023	66/Male	11NOV2015 05:00	ACCUSOL 35	15F08G73	AS DIALYSATE	11NOV2015 10:55 / 11NOV2015 12:50	44.1	5
005-023	66/Male	11NOV2015 05:00	ACCUSOL 35	15F08G73	AS DIALYSATE	11NOV2015 12:50 / 11NOV2015 15:00	23.6	5
005-023	66/Male	11NOV2015 05:00	ACCUSOL 35	15F08G73	AS DIALYSATE	11NOV2015 15:00 / 11NOV2015 17:00	23.6	5
005-023	66/Male	11NOV2015 05:00	ACCUSOL 35	15F08G73	AS DIALYSATE	11NOV2015 17:00 / 11NOV2015 18:00	23.6	5
005-024	41/Female	25NOV2015 11:00	ACCUSOL 35	15D12G70	AS DIALYSATE	25NOV2015 11:00 / 25NOV2015 11:55	33.2	1.3
005-024	41/Female	25NOV2015 11:00	ACCUSOL 35	15D12G70	AS DIALYSATE	25NOV2015 11:55 / 25NOV2015 13:45	26.7	5
005-024	41/Female	25NOV2015 11:00	ACCUSOL 35	15D12G70	AS DIALYSATE	25NOV2015 13:45 / 25NOV2015 15:35	26.7	5

Data Listing 16.2.5.3. ACCUSOL 35 Administration - Enrolled Population

Patient Number	Age (Years)/ Gender	First Accusol Administration Start Date/ Time	Dialysis Solution Used	Lot Number	Site of Introduction	Start Date and Time/ End Date and Time	Dialysis Dose (ml/kg/hr)	Amount Administered (L)
005-024	41/Female	25NOV2015 11:00	ACCUSOL 35	15D12G70	AS DIALYSATE	25NOV2015 15:35 / 25NOV2015 17:20	26.7	5
005-024	41/Female	25NOV2015 11:00	ACCUSOL 35	15D12G70	AS DIALYSATE	25NOV2015 17:20 / 25NOV2015 19:10	35.3	5
005-024	41/Female	25NOV2015 11:00	ACCUSOL 35	15D12G70	AS DIALYSATE	25NOV2015 19:10 / 25NOV2015 21:00	35.3	5
005-024	41/Female	25NOV2015 11:00	ACCUSOL 35	15D12G70	AS DIALYSATE	25NOV2015 21:00 / 25NOV2015 22:45	28.4	5
005-024	41/Female	25NOV2015 11:00	ACCUSOL 35	15D12G70	AS DIALYSATE	25NOV2015 22:45 / 26NOV2015 00:30	28.4	5
005-024	41/Female	25NOV2015 11:00	ACCUSOL 35	15D12G70	AS DIALYSATE	26NOV2015 00:30 / 26NOV2015 02:20	28.4	5
005-024	41/Female	25NOV2015 11:00	ACCUSOL 35	15D12G70	AS DIALYSATE	26NOV2015 02:20 / 26NOV2015 04:05	37.3	5
005-024	41/Female	25NOV2015 11:00	ACCUSOL 35	15D12G70	AS DIALYSATE	26NOV2015 04:05 / 26NOV2015 06:00	37.3	5
005-024	41/Female	25NOV2015 11:00	ACCUSOL 35	15D12G70	AS DIALYSATE	26NOV2015 06:00 / 26NOV2015 07:45	36.9	5
005-024	41/Female	25NOV2015 11:00	ACCUSOL 35	15D12G70	AS DIALYSATE	26NOV2015 07:45 / 26NOV2015 09:25	36.9	5
005-024	41/Female	25NOV2015 11:00	ACCUSOL 35	15D12G70	AS DIALYSATE	26NOV2015 09:25 / 26NOV2015 11:30	36.9	5

Data Listing 16.2.5.3. ACCUSOL 35 Administration - Enrolled Population

Patient Number	Age (Years)/ Gender	First Accusol Administration Start Date/ Time	Dialysis Solution Used	Lot Number	Site of Introduction	Start Date and Time/ End Date and Time	Dialysis Dose (ml/kg/hr)	Amount Administered (L)
005-024	41/Female	25NOV2015 11:00	ACCUSOL 35	15D12G70	AS DIALYSATE	26NOV2015 11:30 / 26NOV2015 13:25	36.9	5
005-024	41/Female	25NOV2015 11:00	ACCUSOL 35	15D12G70	AS DIALYSATE	26NOV2015 13:25 / 26NOV2015 15:20	36.9	5
005-024	41/Female	25NOV2015 11:00	ACCUSOL 35	15D12G70	AS DIALYSATE	26NOV2015 15:20 / 26NOV2015 17:05	36.9	5
005-024	41/Female	25NOV2015 11:00	ACCUSOL 35	15D12G70	AS DIALYSATE	26NOV2015 17:05 / 26NOV2015 18:45	36.9	5
005-024	41/Female	25NOV2015 11:00	ACCUSOL 35	15D12G70	AS DIALYSATE	26NOV2015 18:45 / 26NOV2015 19:00	41.4	0.68
005-025		25NOV2015 20:00	ACCUSOL 35	15D12G70	AS DIALYSATE	25NOV2015 20:00 / 25NOV2015 20:25	29.3	0.58
005-025		25NOV2015 20:00	ACCUSOL 35	15D12G70	AS DIALYSATE	25NOV2015 20:25 / 25NOV2015 22:05	29.3	5
005-025		25NOV2015 20:00	ACCUSOL 35	15D12G70	AS DIALYSATE	25NOV2015 22:05 / 26NOV2015 00:15	29.3	5
005-025		25NOV2015 20:00	ACCUSOL 35	15D12G70	AS DIALYSATE	26NOV2015 00:15 / 26NOV2015 02:30	38.6	5
005-025		25NOV2015 20:00	ACCUSOL 35	15D12G70	AS DIALYSATE	26NOV2015 02:30 / 26NOV2015 04:45	38.6	5
005-025		25NOV2015 20:00	ACCUSOL 35	15D12G70	AS DIALYSATE	26NOV2015 04:45 / 26NOV2015 07:00	9.16	5

Data Listing 16.2.5.3. ACCUSOL 35 Administration - Enrolled Population

Patient Number	Age (Years)/ Gender	First Accusol Administration Start Date/ Time	Dialysis Solution Used	Lot Number	Site of Introduction	Start Date and Time/ End Date and Time	Dialysis Dose (ml/kg/hr)	Amount Administered (L)
005-025		25NOV2015 20:00	ACCUSOL 35	15D12G70	AS DIALYSATE	26NOV2015 07:00 / 26NOV2015 09:13	9.16	5
005-025		25NOV2015 20:00	ACCUSOL 35	15D12G70	AS DIALYSATE	26NOV2015 09:13 / 26NOV2015 11:09	38.6	5
005-025		25NOV2015 20:00	ACCUSOL 35	15D12G70	AS DIALYSATE	26NOV2015 11:09 / 26NOV2015 13:35	38.6	5
005-025		25NOV2015 20:00	ACCUSOL 35	15D12G70	AS DIALYSATE	26NOV2015 13:35 / 26NOV2015 15:50	38.0	5
005-025		25NOV2015 20:00	ACCUSOL 35	15D12G70	AS DIALYSATE	26NOV2015 15:50 / 26NOV2015 20:19	36.5	5
005-025		25NOV2015 20:00	ACCUSOL 35	15D12G70	AS DIALYSATE	26NOV2015 20:19 / 26NOV2015 20:45	36.5	0.6
005-026	64/Male	02DEC2015 05:00	ACCUSOL 35	UNK	AS DIALYSATE	02DEC2015 05:00 / 02DEC2015 05:45	38.4	1.8
005-026	64/Male	02DEC2015 05:00	ACCUSOL 35	15E09G70	AS DIALYSATE	02DEC2015 05:45 / 02DEC2015 07:55	38.4	5
005-026	64/Male	02DEC2015 05:00	ACCUSOL 35	15E09G70	AS DIALYSATE	02DEC2015 07:55 / 02DEC2015 10:00	60	5
005-026	64/Male	02DEC2015 05:00	ACCUSOL 35	15E09G71	AS DIALYSATE	02DEC2015 10:00 / 02DEC2015 12:00	31.0	5
005-026	64/Male	02DEC2015 05:00	ACCUSOL 35	15E09G71	AS DIALYSATE	02DEC2015 12:00 / 02DEC2015 12:00	31.0	0

Data Listing 16.2.5.3. ACCUSOL 35 Administration - Enrolled Population

Patient Number	Age (Years)/ Gender	First Accusol Administration Start Date/ Time	Dialysis Solution Used	Lot Number	Site of Introduction	Start Date and Time/ End Date and Time	Dialysis Dose (ml/kg/hr)	Amount Administered (L)
005-026	64/Male	02DEC2015 05:00	ACCUSOL 35	15E09G71	AS DIALYSATE	02DEC2015 12:00 / 02DEC2015 14:15	31.0	5
005-026	64/Male	02DEC2015 05:00	ACCUSOL 35	15E09G71	AS DIALYSATE	02DEC2015 14:15 / 02DEC2015 16:20	38.1	5
005-026	64/Male	02DEC2015 05:00	ACCUSOL 35	15E09G71	AS DIALYSATE	02DEC2015 16:20 / 02DEC2015 18:30	38.1	5
005-026	64/Male	02DEC2015 05:00	ACCUSOL 35	15E09G71	AS DIALYSATE	02DEC2015 18:30 / 02DEC2015 20:30	64.5	5
005-026	64/Male	02DEC2015 05:00	ACCUSOL 35	15E09G71	AS DIALYSATE	02DEC2015 20:30 / 02DEC2015 22:30	64.5	5
005-026	64/Male	02DEC2015 05:00	ACCUSOL 35	15E09G71	AS DIALYSATE	02DEC2015 22:30 / 03DEC2015 00:45	32.6	5
005-026	64/Male	02DEC2015 05:00	ACCUSOL 35	15E09G71	AS DIALYSATE	03DEC2015 00:45 / 03DEC2015 02:30	32.6	5
005-026	64/Male	02DEC2015 05:00	ACCUSOL 35	15E09G71	AS DIALYSATE	03DEC2015 02:30 / 03DEC2015 04:45	32.6	5
005-026	64/Male	02DEC2015 05:00	ACCUSOL 35	15E09G71	AS DIALYSATE	03DEC2015 04:45 / 03DEC2015 06:50	31.9	5
005-026	64/Male	02DEC2015 05:00	ACCUSOL 35	15E09G71	AS DIALYSATE	03DEC2015 06:50 / 03DEC2015 10:45	31.9	5
005-027		02DEC2015 21:00	ACCUSOL 35	15E09G71	AS DIALYSATE	02DEC2015 21:00 / 02DEC2015 21:15	43.7	0.27

Data Listing 16.2.5.3. ACCUSOL 35 Administration - Enrolled Population

Patient Number	Age (Years)/ Gender	First Accusol Administration Start Date/ Time	Dialysis Solution Used	Lot Number	Site of Introduction	Start Date and Time/ End Date and Time	Dialysis Dose (ml/kg/hr)	Amount Administered (L)
005-027		02DEC2015 21:00	ACCUSOL 35	15E09G71	AS DIALYSATE	02DEC2015 21:15 / 02DEC2015 23:40	44.1	5
005-027		02DEC2015 21:00	ACCUSOL 35	15E09G71	AS DIALYSATE	02DEC2015 23:40 / 03DEC2015 02:00	44.1	5
005-027		02DEC2015 21:00	ACCUSOL 35	15E09G71	AS DIALYSATE	03DEC2015 02:00 / 03DEC2015 04:30	32.7	5
005-027		02DEC2015 21:00	ACCUSOL 35	15E09G71	AS DIALYSATE	03DEC2015 04:30 / 03DEC2015 06:50	32.7	5
005-027		02DEC2015 21:00	ACCUSOL 35	15E09G71	AS DIALYSATE	03DEC2015 06:50 / 03DEC2015 09:15	51.4	5
005-027		02DEC2015 21:00	ACCUSOL 35	15E09G71	AS DIALYSATE	03DEC2015 09:15 / 03DEC2015 12:00	51.4	5
005-028		09DEC2015 08:00	ACCUSOL 35	15D12G70	AS DIALYSATE	09DEC2015 08:00 / 09DEC2015 09:30	30.0	3.75
005-028		09DEC2015 08:00	ACCUSOL 35	15D12G70	AS DIALYSATE	09DEC2015 09:30 / 09DEC2015 12:30	30.0	5
005-028		09DEC2015 08:00	ACCUSOL 35	15D12G70	AS DIALYSATE	09DEC2015 12:30 / 09DEC2015 14:45	28.4	5
005-028		09DEC2015 08:00	ACCUSOL 35	15E09G70	AS DIALYSATE	09DEC2015 14:45 / 09DEC2015 17:15	28.4	5
005-028		09DEC2015 08:00	ACCUSOL 35	15E09G70	AS DIALYSATE	09DEC2015 17:15 / 09DEC2015 19:35	39.4	5

Data Listing 16.2.5.3. ACCUSOL 35 Administration - Enrolled Population

Patient Number	Age (Years)/ Gender	First Accusol Administration Start Date/ Time	Dialysis Solution Used	Lot Number	Site of Introduction	Start Date and Time/ End Date and Time	Dialysis Dose (ml/kg/hr)	Amount Administered (L)
005-028		09DEC2015 08:00	ACCUSOL 35	15E09G70	AS DIALYSATE	09DEC2015 19:35 / 09DEC2015 22:10	41.7	5
005-028		09DEC2015 08:00	ACCUSOL 35	15E09G71	AS DIALYSATE	09DEC2015 22:10 / 10DEC2015 00:30	41.7	5
005-028		09DEC2015 08:00	ACCUSOL 35	15E09G71	AS DIALYSATE	10DEC2015 00:30 / 10DEC2015 02:55	30.2	5
005-028		09DEC2015 08:00	ACCUSOL 35	15E90G71	AS DIALYSATE	10DEC2015 02:55 / 10DEC2015 05:20	30.2	5
005-028		09DEC2015 08:00	ACCUSOL 35	15E09G71	AS DIALYSATE	10DEC2015 05:20 / 10DEC2015 07:50	61.3	5
005-028		09DEC2015 08:00	ACCUSOL 35	15E09G71	AS DIALYSATE	10DEC2015 07:50 / 10DEC2015 10:20	38.6	5
005-028		09DEC2015 08:00	ACCUSOL 35	15E09G71	AS DIALYSATE	10DEC2015 10:20 / 10DEC2015 12:50	38.6	5
005-028		09DEC2015 08:00	ACCUSOL 35	15E09G71	AS DIALYSATE	10DEC2015 12:50 / 10DEC2015 15:20	43.2	5
005-028		09DEC2015 08:00	ACCUSOL 35	15E09G71	AS DIALYSATE	10DEC2015 15:20 / 10DEC2015 15:40	43.2	0.36
005-029	68/Male	11DEC2015 07:30	ACCUSOL 35	15E09G71	AS DIALYSATE	11DEC2015 07:30 / 11DEC2015 09:00	45.7	1.4
005-029	68/Male	11DEC2015 07:30	ACCUSOL 35	15E09G71	AS DIALYSATE	11DEC2015 09:00 / 11DEC2015 11:30	29.8	5

Data Listing 16.2.5.3. ACCUSOL 35 Administration - Enrolled Population

Patient Number	Age (Years)/ Gender	First Accusol Administration Start Date/ Time	Dialysis Solution Used	Lot Number	Site of Introduction	Start Date and Time/ End Date and Time	Dialysis Dose (ml/kg/hr)	Amount Administered (L)
005-029	68/Male	11DEC2015 07:30	ACCUSOL 35	15E09G71	AS DIALYSATE	11DEC2015 11:30 / 11DEC2015 14:30	29.8	5
005-029	68/Male	11DEC2015 07:30	ACCUSOL 35	15D12G70	AS DIALYSATE	11DEC2015 14:30 / 11DEC2015 17:15	29.8	5
005-029	68/Male	11DEC2015 07:30	ACCUSOL 35	15D12G70	AS DIALYSATE	11DEC2015 17:15 / 11DEC2015 19:55	40.1	5
005-029	68/Male	11DEC2015 07:30	ACCUSOL 35	15D12G70	AS DIALYSATE	11DEC2015 19:55 / 11DEC2015 22:35	40.1	5
005-029	68/Male	11DEC2015 07:30	ACCUSOL 35	15E09G71	AS DIALYSATE	11DEC2015 22:35 / 12DEC2015 01:25	33.4	5
005-029	68/Male	11DEC2015 07:30	ACCUSOL 35	15D12G70	AS DIALYSATE	12DEC2015 01:25 / 12DEC2015 04:10	48.9	5
005-029	68/Male	11DEC2015 07:30	ACCUSOL 35	15E09G71	AS DIALYSATE	12DEC2015 04:10 / 12DEC2015 07:00	20.7	5
005-029	68/Male	11DEC2015 07:30	ACCUSOL 35	15E09G71	AS DIALYSATE	12DEC2015 07:00 / 12DEC2015 09:40	47	5
005-029	68/Male	11DEC2015 07:30	ACCUSOL 35	15E09G71	AS DIALYSATE	12DEC2015 09:40 / 12DEC2015 12:30	47	5
005-029	68/Male	11DEC2015 07:30	ACCUSOL 35	15E09G71	AS DIALYSATE	12DEC2015 12:30 / 12DEC2015 15:30	20.7	5
005-030	61/Male	18DEC2015 11:00	ACCUSOL 35	15E09G71	AS DIALYSATE	18DEC2015 11:00 / 18DEC2015 11:15	32.7	0.3

Data Listing 16.2.5.3. ACCUSOL 35 Administration - Enrolled Population

Patient Number	Age (Years)/ Gender	First Accusol Administration Start Date/ Time	Dialysis Solution Used	Lot Number	Site of Introduction	Start Date and Time/ End Date and Time	Dialysis Dose (ml/kg/hr)	Amount Administered (L)
005-030	61/Male	18DEC2015 11:00	ACCUSOL 35	15EO9G71	AS DIALYSATE	18DEC2015 11:15 / 18DEC2015 12:50	32.7	5
005-030	61/Male	18DEC2015 11:00	ACCUSOL 35	15EO9G71	AS DIALYSATE	18DEC2015 12:50 / 18DEC2015 14:40	19.2	5
005-030	61/Male	18DEC2015 11:00	ACCUSOL 35	15EO9G71	AS DIALYSATE	18DEC2015 14:40 / 18DEC2015 16:30	19.2	5
005-030	61/Male	18DEC2015 11:00	ACCUSOL 35	15EO9G71	AS DIALYSATE	18DEC2015 16:30 / 18DEC2015 17:00	19.2	0.6
005-032	49/Male	01JAN2016 07:20	ACCUSOL 35	15F02G70	AS DIALYSATE	01JAN2016 07:20 / 01JAN2016 08:30	42.2	1.9
005-032	49/Male	01JAN2016 07:20	ACCUSOL 35	15F02G70	AS DIALYSATE	01JAN2016 08:30 / 01JAN2016 10:10	42.2	5
005-032	49/Male	01JAN2016 07:20	ACCUSOL 35	15F02G70	AS DIALYSATE	01JAN2016 10:10 / 01JAN2016 11:45	42.2	5
005-032	49/Male	01JAN2016 07:20	ACCUSOL 35	15F02G70	AS DIALYSATE	01JAN2016 11:45 / 01JAN2016 13:25	42.2	5
005-032	49/Male	01JAN2016 07:20	ACCUSOL 35	15F02G70	AS DIALYSATE	01JAN2016 13:25 / 01JAN2016 15:10	14.8	5
005-032	49/Male	01JAN2016 07:20	ACCUSOL 35	15F02G70	AS DIALYSATE	01JAN2016 15:10 / 01JAN2016 16:50	14.8	5
005-032	49/Male	01JAN2016 07:20	ACCUSOL 35	15F02G70	AS DIALYSATE	01JAN2016 16:50 / 01JAN2016 18:00	32.6	5

Data Listing 16.2.5.3. ACCUSOL 35 Administration - Enrolled Population

Patient Number	Age (Years)/ Gender	First Accusol Administration Start Date/ Time	Dialysis Solution Used	Lot Number	Site of Introduction	Start Date and Time/ End Date and Time	Dialysis Dose (ml/kg/hr)	Amount Administered (L)
005-034	70/Male	13JAN2016 18:40	ACCUSOL 35	15F02G71	AS DIALYSATE	13JAN2016 18:40 / 13JAN2016 21:10	34.3	2.2
005-034	70/Male	13JAN2016 18:40	ACCUSOL 35	15F02G71	AS DIALYSATE	13JAN2016 21:10 / 13JAN2016 23:55	34.3	5
005-034	70/Male	13JAN2016 18:40	ACCUSOL 35	15F02G71	AS DIALYSATE	13JAN2016 23:55 / 14JAN2016 02:30	34.5	5
005-034	70/Male	13JAN2016 18:40	ACCUSOL 35	15F02G71	AS DIALYSATE	14JAN2016 02:30 / 14JAN2016 05:35	34.5	5
005-034	70/Male	13JAN2016 18:40	ACCUSOL 35	15F02G71	AS DIALYSATE	14JAN2016 05:35 / 14JAN2016 09:15	34.5	5
005-034	70/Male	13JAN2016 18:40	ACCUSOL 35	15F02G71	AS DIALYSATE	14JAN2016 09:15 / 14JAN2016 11:15	34.5	5
005-034	70/Male	13JAN2016 18:40	ACCUSOL 35	15F02G71	AS DIALYSATE	14JAN2016 11:15 / 14JAN2016 14:00	34.5	4.58
005-036	51/Female	14JAN2016 01:15	ACCUSOL 35	15F02G71	AS DIALYSATE	14JAN2016 01:15 / 14JAN2016 02:55	16.2	3
005-036	51/Female	14JAN2016 01:15	ACCUSOL 35	15F02G71	AS DIALYSATE	14JAN2016 02:55 / 14JAN2016 05:10	28.7	5
005-036	51/Female	14JAN2016 01:15	ACCUSOL 35	15F02G71	AS DIALYSATE	14JAN2016 05:10 / 14JAN2016 07:30	28.7	5
005-036	51/Female	14JAN2016 01:15	ACCUSOL 35	15F02G71	AS DIALYSATE	14JAN2016 07:30 / 14JAN2016 09:45	22.5	5

Data Listing 16.2.5.3. ACCUSOL 35 Administration - Enrolled Population

Patient Number	Age (Years)/ Gender	First Accusol Administration Start Date/ Time	Dialysis Solution Used	Lot Number	Site of Introduction	Start Date and Time/ End Date and Time	Dialysis Dose (ml/kg/hr)	Amount Administered (L)
005-036	51/Female	14JAN2016 01:15	ACCUSOL 35	15F02G71	AS DIALYSATE	14JAN2016 09:45 / 14JAN2016 11:45	22.5	5
005-036	51/Female	14JAN2016 01:15	ACCUSOL 35	15F02G71	AS DIALYSATE	14JAN2016 11:45 / 14JAN2016 13:15	45.8	5
005-036	51/Female	14JAN2016 01:15	ACCUSOL 35	15F02G70	AS DIALYSATE	14JAN2016 13:15 / 14JAN2016 14:45	45.8	5
005-036	51/Female	14JAN2016 01:15	ACCUSOL 35	15F02G70	AS DIALYSATE	14JAN2016 14:45 / 14JAN2016 16:20	35.1	5
005-036	51/Female	14JAN2016 01:15	ACCUSOL 35	15F02G70	AS DIALYSATE	14JAN2016 16:20 / 14JAN2016 17:50	35.1	5
005-036	51/Female	14JAN2016 01:15	ACCUSOL 35	15F02G70	AS DIALYSATE	14JAN2016 17:50 / 14JAN2016 19:30	35.1	5
005-036	51/Female	14JAN2016 01:15	ACCUSOL 35	15F02G70	AS DIALYSATE	14JAN2016 19:30 / 14JAN2016 21:05	33.8	5
005-036	51/Female	14JAN2016 01:15	ACCUSOL 35	15E09G71	AS DIALYSATE	14JAN2016 21:05 / 14JAN2016 23:00	33.8	5
005-036	51/Female	14JAN2016 01:15	ACCUSOL 35	15E09G71	AS DIALYSATE	14JAN2016 23:00 / 15JAN2016 00:16	33.8	5
005-036	51/Female	14JAN2016 01:15	ACCUSOL 35	15E09G71	AS DIALYSATE	15JAN2016 00:16 / 15JAN2016 01:50	33.2	5
005-036	51/Female	14JAN2016 01:15	ACCUSOL 35	15E09G71	AS DIALYSATE	15JAN2016 01:50 / 15JAN2016 03:25	33.2	5

Data Listing 16.2.5.3. ACCUSOL 35 Administration - Enrolled Population

Patient Number	Age (Years)/ Gender	First Accusol Administration Start Date/ Time	Dialysis Solution Used	Lot Number	Site of Introduction	Start Date and Time/ End Date and Time	Dialysis Dose (ml/kg/hr)	Amount Administered (L)
005-036	51/Female	14JAN2016 01:15	ACCUSOL 35	15E09G71	AS DIALYSATE	15JAN2016 03:25 / 15JAN2016 05:00	33.2	5
005-036	51/Female	14JAN2016 01:15	ACCUSOL 35	15E09G71	AS DIALYSATE	15JAN2016 05:00 / 15JAN2016 06:35	37.1	5
005-036	51/Female	14JAN2016 01:15	ACCUSOL 35	15E09G71	AS DIALYSATE	15JAN2016 06:35 / 15JAN2016 08:05	35.1	5
005-036	51/Female	14JAN2016 01:15	ACCUSOL 35	15E09G71	AS DIALYSATE	15JAN2016 08:05 / 15JAN2016 09:15	47.2	5
005-037	53/Female	29JAN2016 15:00	ACCUSOL 35	UNK	AS DIALYSATE	29JAN2016 15:00 / 29JAN2016 15:10	31.1	0.71
005-037	53/Female	29JAN2016 15:00	ACCUSOL 35	15F08G74	AS DIALYSATE	29JAN2016 15:10 / 29JAN2016 16:40	31.1	5
005-037	53/Female	29JAN2016 15:00	ACCUSOL 35	15F08G74	AS DIALYSATE	29JAN2016 16:40 / 29JAN2016 18:15	31.1	5
005-037	53/Female	29JAN2016 15:00	ACCUSOL 35	15F08G74	AS DIALYSATE	29JAN2016 18:15 / 29JAN2016 20:10	31.1	5
005-037	53/Female	29JAN2016 15:00	ACCUSOL 35	15F08G74	AS DIALYSATE	29JAN2016 20:10 / 29JAN2016 22:15	31.1	5
005-037	53/Female	29JAN2016 15:00	ACCUSOL 35	15F02G71	AS DIALYSATE	29JAN2016 22:15 / 30JAN2016 00:15	31.1	5
005-037	53/Female	29JAN2016 15:00	ACCUSOL 35	15F08G74	AS DIALYSATE	30JAN2016 00:15 / 30JAN2016 02:10	36.5	5

Data Listing 16.2.5.3. ACCUSOL 35 Administration - Enrolled Population

Patient Number	Age (Years)/ Gender	First Accusol Administration Start Date/ Time	Dialysis Solution Used	Lot Number	Site of Introduction	Start Date and Time/ End Date and Time	Dialysis Dose (ml/kg/hr)	Amount Administered (L)
005-037	53/Female	29JAN2016 15:00	ACCUSOL 35	15F02G70	AS DIALYSATE	30JAN2016 02:10 / 30JAN2016 04:15	36.5	5
005-037	53/Female	29JAN2016 15:00	ACCUSOL 35	15F02G70	AS DIALYSATE	30JAN2016 04:15 / 30JAN2016 06:15	36.5	5
005-037	53/Female	29JAN2016 15:00	ACCUSOL 35	15F02G70	AS DIALYSATE	30JAN2016 06:15 / 30JAN2016 08:20	36.5	5
005-037	53/Female	29JAN2016 15:00	ACCUSOL 35	15F02G70	AS DIALYSATE	30JAN2016 08:20 / 30JAN2016 10:30	36.6	5
005-037	53/Female	29JAN2016 15:00	ACCUSOL 35	15F02G70	AS DIALYSATE	30JAN2016 10:30 / 30JAN2016 12:30	36.6	5
005-037	53/Female	29JAN2016 15:00	ACCUSOL 35	15F02G70	AS DIALYSATE	30JAN2016 12:30 / 30JAN2016 14:30	36.6	5
005-037	53/Female	29JAN2016 15:00	ACCUSOL 35	15F02G70	AS DIALYSATE	30JAN2016 14:30 / 30JAN2016 16:30	36.6	5
005-037	53/Female	29JAN2016 15:00	ACCUSOL 35	15F02G70	AS DIALYSATE	30JAN2016 16:30 / 30JAN2016 18:35	43.0	5
005-037	53/Female	29JAN2016 15:00	ACCUSOL 35	15F02G70	AS DIALYSATE	30JAN2016 18:35 / 30JAN2016 20:30	43.0	5
005-037	53/Female	29JAN2016 15:00	ACCUSOL 35	15F02G70	AS DIALYSATE	30JAN2016 20:30 / 30JAN2016 22:20	33.9	5
005-037	53/Female	29JAN2016 15:00	ACCUSOL 35	15F02G70	AS DIALYSATE	30JAN2016 22:20 / 30JAN2016 22:50	33.9	0.65

Data Listing 16.2.5.3. ACCUSOL 35 Administration - Enrolled Population

Patient Number	Age (Years)/ Gender	First Accusol Administration Start Date/ Time	Dialysis Solution Used	Lot Number	Site of Introduction	Start Date and Time/ End Date and Time	Dialysis Dose (ml/kg/hr)	Amount Administered (L)
005-037	53/Female	29JAN2016 15:00	ACCUSOL 35	15F02G70	AS DIALYSATE	30JAN2016 22:50 / 30JAN2016 23:00	33.9	0.42
005-038		29JAN2016 17:30	ACCUSOL 35	15F02G70	AS DIALYSATE	29JAN2016 17:30 / 29JAN2016 19:45	46.1	5
005-038		29JAN2016 17:30	ACCUSOL 35	15F02G70	AS DIALYSATE	29JAN2016 19:45 / 29JAN2016 22:10	37.7	5
007-001	61/Male	11APR2015 08:30	ACCUSOL 35 Potassium 4 mmol/L	14K28971	BOTH PRE & POST FILTER	11APR2015 08:30 / 11APR2015 09:30	37.38	2
007-001	61/Male	11APR2015 08:30	ACCUSOL 35 Potassium 4 mmol/L	14K28971	BOTH PRE & POST FILTER	11APR2015 08:30 / 11APR2015 09:30	37.38	2
007-002		19MAY2015 17:00	ACCUSOL 35 Potassium 4 mmol/L	14K28G71	PRE & POST	19MAY2015 17:00 / 19MAY2015 19:50	57.97	3.69
007-002		19MAY2015 17:00	ACCUSOL 35 Potassium 4 mmol/L	14K28G71	PRE & POST	19MAY2015 17:00 / 19MAY2015 19:50	57.97	3.69
007-002		19MAY2015 17:00	ACCUSOL 35 Potassium 4 mmol/L	14I09G70	PRE & POST	19MAY2015 19:50 / 19MAY2015 23:30	60.60	5
007-002		19MAY2015 17:00	ACCUSOL 35 Potassium 4 mmol/L	14K13G73	PRE & POST	19MAY2015 19:50 / 19MAY2015 23:30	60.60	5
007-002		19MAY2015 17:00	ACCUSOL 35 Potassium 4 mmol/L	14K13G73	PRE & POST	19MAY2015 23:30 / 20MAY2015 03:05	62.01	5
007-002		19MAY2015 17:00	ACCUSOL 35 Potassium 4 mmol/L	14K13G73	PRE & POST	19MAY2015 23:30 / 20MAY2015 03:05	62.01	5

Data Listing 16.2.5.3. ACCUSOL 35 Administration - Enrolled Population

Patient Number	Age (Years)/ Gender	First Accusol Administration Start Date/ Time	Dialysis Solution Used	Lot Number	Site of Introduction	Start Date and Time/ End Date and Time	Dialysis Dose (ml/kg/hr)	Amount Administered (L)
007-002		19MAY2015 17:00	ACCUSOL 35 Potassium 4 mmol/L	14K28G71	PRE & POST	20MAY2015 03:05 / 20MAY2015 06:40	62.01	5
007-002		19MAY2015 17:00	ACCUSOL 35 Potassium 4 mmol/L	14K28G71	PRE & POST	20MAY2015 03:05 / 20MAY2015 06:40	62.01	5
007-002		19MAY2015 17:00	ACCUSOL 35 Potassium 4 mmol/L	14K28G71	PRE & POST	20MAY2015 06:40 / 20MAY2015 10:40	55.55	5
007-002		19MAY2015 17:00	ACCUSOL 35 Potassium 4 mmol/L	14K28G71	PRE & POST	20MAY2015 06:40 / 20MAY2015 10:40	55.55	5
007-002		19MAY2015 17:00	ACCUSOL 35 Potassium 4 mmol/L	14K28G71	PRE & POST	20MAY2015 10:40 / 20MAY2015 11:00	62.01	0.4
007-002		19MAY2015 17:00	ACCUSOL 35 Potassium 4 mmol/L	14K28G71	PRE & POST	20MAY2015 10:40 / 20MAY2015 11:00	62.01	0.4
007-003	64/Male	26JUN2015 09:00	ACCUSOL 35 Potassium 4 mmol/L	14K13G73	PRE & POST	26JUN2015 09:00 / 26JUN2015 11:50	25.86	3.5
007-003	64/Male	26JUN2015 09:00	ACCUSOL 35 Potassium 4 mmol/L	14K13G73	PRE & POST	26JUN2015 09:00 / 26JUN2015 11:50	25.86	3.5
007-003	64/Male	26JUN2015 09:00	ACCUSOL 35 Potassium 4 mmol/L	14K28G71	PRE & POST	26JUN2015 11:50 / 26JUN2015 15:20	24.63	5
007-003	64/Male	26JUN2015 09:00	ACCUSOL 35 Potassium 4 mmol/L	14K28G71	PRE & POST	26JUN2015 11:50 / 26JUN2015 15:20	24.63	5
007-003	64/Male	26JUN2015 09:00	ACCUSOL 35 Potassium 4 mmol/L	14K28G71	PRE & POST	26JUN2015 15:20 / 26JUN2015 19:00	23.5	5

Data Listing 16.2.5.3. ACCUSOL 35 Administration - Enrolled Population

Patient Number	Age (Years)/ Gender	First Accusol Administration Start Date/ Time	Dialysis Solution Used	Lot Number	Site of Introduction	Start Date and Time/ End Date and Time	Dialysis Dose (ml/kg/hr)	Amount Administered (L)
007-003	64/Male	26JUN2015 09:00	ACCUSOL 35 Potassium 4 mmol/L	14K28G71	PRE & POST	26JUN2015 15:20 / 26JUN2015 19:00	23.5	5
007-003	64/Male	26JUN2015 09:00	ACCUSOL 35 Potassium 4 mmol/L	14K28G71	PRE & POST	26JUN2015 19:00 / 26JUN2015 22:30	24.63	5
007-003	64/Male	26JUN2015 09:00	ACCUSOL 35 Potassium 4 mmol/L	14K28G71	PRE & POST	26JUN2015 19:00 / 26JUN2015 22:30	24.63	5
007-003	64/Male	26JUN2015 09:00	ACCUSOL 35 Potassium 4 mmol/L	UNKNOWN	UNKNOWN	26JUN2015 22:30 / 27JUN2015 08:00		.
007-004	72/Male	27JUN2015 17:50	ACCUSOL 35 Potassium 4 mmol/L	15A07G71	1000 PRE,2000 POST	27JUN2015 17:50 / 27JUN2015 19:10	20.06	1.6
007-004	72/Male	27JUN2015 17:50	ACCUSOL 35 Potassium 4 mmol/L	15A07G71	PRE & POST	27JUN2015 17:50 / 27JUN2015 19:10	20.06	1.6
007-004	72/Male	27JUN2015 17:50	ACCUSOL 35 Potassium 4 mmol/L	14K28G71	PRE & POST	27JUN2015 19:10 / 27JUN2015 22:40	23.8	5
007-004	72/Male	27JUN2015 17:50	ACCUSOL 35 Potassium 4 mmol/L	14K28G71	PRE & POST	27JUN2015 19:10 / 27JUN2015 22:40	23.8	5
007-004	72/Male	27JUN2015 17:50	ACCUSOL 35 Potassium 4 mmol/L	15A07G71	PRE & POST	27JUN2015 22:40 / 28JUN2015 02:10	23.8	5
007-004	72/Male	27JUN2015 17:50	ACCUSOL 35 Potassium 4 mmol/L	15A07G71	PRE & POST	27JUN2015 22:40 / 28JUN2015 02:10	23.8	5
007-004	72/Male	27JUN2015 17:50	ACCUSOL 35 Potassium 4 mmol/L	14K28G71	PRE & POST	28JUN2015 02:10 / 28JUN2015 06:00	21.73	5

Data Listing 16.2.5.3. ACCUSOL 35 Administration - Enrolled Population

Patient Number	Age (Years)/ Gender	First Accusol Administration Start Date/ Time	Dialysis Solution Used	Lot Number	Site of Introduction	Start Date and Time/ End Date and Time	Dialysis Dose (ml/kg/hr)	Amount Administered (L)
007-004	72/Male	27JUN2015 17:50	ACCUSOL 35 Potassium 4 mmol/L	14K28G71	PRE & POST	28JUN2015 02:10 / 28JUN2015 06:00	21.73	5
007-004	72/Male	27JUN2015 17:50	ACCUSOL 35 Potassium 4 mmol/L	14K28G71	PRE & POST	28JUN2015 06:00 / 28JUN2015 09:55	21.27	5
007-004	72/Male	27JUN2015 17:50	ACCUSOL 35 Potassium 4 mmol/L	14K28G71	PRE & POST	28JUN2015 06:00 / 28JUN2015 09:55	21.27	5
007-004	72/Male	27JUN2015 17:50	ACCUSOL 35 Potassium 4 mmol/L	14K13G73	PRE & POST	28JUN2015 09:55 / 28JUN2015 13:35	22.72	5
007-004	72/Male	27JUN2015 17:50	ACCUSOL 35 Potassium 4 mmol/L	14K13G73	PRE & POST	28JUN2015 09:55 / 28JUN2015 13:35	22.72	5
007-004	72/Male	27JUN2015 17:50	ACCUSOL 35 Potassium 4 mmol/L	14K28G71	PRE & POST	28JUN2015 13:35 / 28JUN2015 17:30	21.27	5
007-004	72/Male	27JUN2015 17:50	ACCUSOL 35 Potassium 4 mmol/L	14K28G71	PRE & POST	28JUN2015 13:35 / 28JUN2015 17:30	21.27	5
007-004	72/Male	27JUN2015 17:50	ACCUSOL 35 Potassium 4 mmol/L	14K28G71	PRE & POST	28JUN2015 17:30 / 28JUN2015 20:30	21.27	3.8
007-004	72/Male	27JUN2015 17:50	ACCUSOL 35 Potassium 4 mmol/L	14K28G71	PRE & POST	28JUN2015 17:30 / 28JUN2015 20:30	21.27	3.8
007-005	24/Male	18JUL2015 04:00	ACCUSOL 35 Potassium 4 mmol/L	14K13G73	PRE&POST	18JUL2015 04:00 / 18JUL2015 06:45	17.48	5
007-005	24/Male	18JUL2015 04:00	ACCUSOL 35 Potassium 4 mmol/L	14K13G73	PRE&POST	18JUL2015 04:00 / 18JUL2015 06:45	17.48	5

Data Listing 16.2.5.3. ACCUSOL 35 Administration - Enrolled Population

Patient Number	Age (Years)/ Gender	First Accusol Administration Start Date/ Time	Dialysis Solution Used	Lot Number	Site of Introduction	Start Date and Time/ End Date and Time	Dialysis Dose (ml/kg/hr)	Amount Administered (L)
007-005	24/Male	18JUL2015 04:00	ACCUSOL 35 Potassium 4 mmol/L	14K13G73	PRE & POST	18JUL2015 06:45 / 18JUL2015 09:30	17.48	5
007-005	24/Male	18JUL2015 04:00	ACCUSOL 35 Potassium 4 mmol/L	14K13G73	PRE & POST	18JUL2015 06:45 / 18JUL2015 09:30	17.48	5
007-005	24/Male	18JUL2015 04:00	ACCUSOL 35 Potassium 4 mmol/L	14K13G73	PRE & POST	18JUL2015 09:30 / 18JUL2015 11:00	32.05	5
007-005	24/Male	18JUL2015 04:00	ACCUSOL 35 Potassium 4 mmol/L	14K13G73	PRE & POST	18JUL2015 09:30 / 18JUL2015 11:00	32.05	5
007-005	24/Male	18JUL2015 04:00	ACCUSOL 35 Potassium 4 mmol/L	15A07G71	PRE & POST	18JUL2015 11:00 / 18JUL2015 14:00	16.02	5
007-005	24/Male	18JUL2015 04:00	ACCUSOL 35 Potassium 4 mmol/L	15A07G71	PRE & POST	18JUL2015 11:00 / 18JUL2015 14:00	16.02	5
007-005	24/Male	18JUL2015 04:00	ACCUSOL 35 Potassium 4 mmol/L	15A07G71	PRE & POST	18JUL2015 14:00 / 18JUL2015 17:30	13.73	5
007-005	24/Male	18JUL2015 04:00	ACCUSOL 35 Potassium 4 mmol/L	15A07G71	PRE & POST	18JUL2015 14:00 / 18JUL2015 17:30	13.73	5
007-005	24/Male	18JUL2015 04:00	ACCUSOL 35 Potassium 4 mmol/L	15A07G71	PRE & POST	18JUL2015 17:30 / 18JUL2015 20:10	18.49	5
007-005	24/Male	18JUL2015 04:00	ACCUSOL 35 Potassium 4 mmol/L	15A07G71	PRE & POST	18JUL2015 17:30 / 18JUL2015 20:10	18.49	5
007-005	24/Male	18JUL2015 04:00	ACCUSOL 35 Potassium 4 mmol/L	15A07G71	PRE & POST	18JUL2015 20:10 / 18JUL2015 23:20	15.18	5

Data Listing 16.2.5.3. ACCUSOL 35 Administration - Enrolled Population

Patient Number	Age (Years)/ Gender	First Accusol Administration Start Date/ Time	Dialysis Solution Used	Lot Number	Site of Introduction	Start Date and Time/ End Date and Time	Dialysis Dose (ml/kg/hr)	Amount Administered (L)
007-005	24/Male	18JUL2015 04:00	ACCUSOL 35 Potassium 4 mmol/L	15A07G71	PRE & POST	18JUL2015 20:10 / 18JUL2015 23:20	15.18	5
007-005	24/Male	18JUL2015 04:00	ACCUSOL 35 Potassium 4 mmol/L	15C02G70	PRE & POST	18JUL2015 23:20 / 19JUL2015 02:20	16.02	5
007-005	24/Male	18JUL2015 04:00	ACCUSOL 35 Potassium 4 mmol/L	15C02G70	PRE & POST	18JUL2015 23:20 / 19JUL2015 02:20	16.02	5
007-005	24/Male	18JUL2015 04:00	ACCUSOL 35 Potassium 4 mmol/L	15C02G70	PRE & POST	19JUL2015 02:20 / 19JUL2015 05:05	17.48	5
007-005	24/Male	18JUL2015 04:00	ACCUSOL 35 Potassium 4 mmol/L	15C02G70	PRE & POST	19JUL2015 02:20 / 19JUL2015 05:05	17.48	5
007-005	24/Male	18JUL2015 04:00	ACCUSOL 35 Potassium 4 mmol/L	15C02G70	PRE & POST	19JUL2015 05:05 / 19JUL2015 07:50	17.48	5
007-005	24/Male	18JUL2015 04:00	ACCUSOL 35 Potassium 4 mmol/L	15C02G70	PRE & POST	19JUL2015 05:05 / 19JUL2015 07:50	17.48	5
007-005	24/Male	18JUL2015 04:00	ACCUSOL 35 Potassium 4 mmol/L	15C02G70	PRE & POST	19JUL2015 07:50 / 19JUL2015 11:00	15.18	5
007-005	24/Male	18JUL2015 04:00	ACCUSOL 35 Potassium 4 mmol/L	15C02G70	PRE & POST	19JUL2015 07:50 / 19JUL2015 11:00	15.18	5
007-006	73/Female	26JUL2015 20:30	ACCUSOL 35 Potassium 4 mmol/L	15C02G70	PRE & POST	26JUL2015 20:30 / 26JUL2015 23:00	35.04	4.68
007-006	73/Female	26JUL2015 20:30	ACCUSOL 35 Potassium 4 mmol/L	15C02G70	PRE & POST	26JUL2015 20:30 / 26JUL2015 23:00	35.04	4.68

Data Listing 16.2.5.3. ACCUSOL 35 Administration - Enrolled Population

Patient Number	Age (Years)/ Gender	First Accusol Administration Start Date/ Time	Dialysis Solution Used	Lot Number	Site of Introduction	Start Date and Time/ End Date and Time	Dialysis Dose (ml/kg/hr)	Amount Administered (L)
007-006	73/Female	26JUL2015 20:30	ACCUSOL 35 Potassium 4 mmol/L	15C02G70	PRE & POST	26JUL2015 23:00 / 27JUL2015 02:15	28.74	5
007-006	73/Female	26JUL2015 20:30	ACCUSOL 35 Potassium 4 mmol/L	15C02G70	PRE & POST	26JUL2015 23:00 / 27JUL2015 02:15	28.74	5
007-006	73/Female	26JUL2015 20:30	ACCUSOL 35 Potassium 4 mmol/L	15C02G70	PRE & POST	27JUL2015 02:15 / 27JUL2015 05:35	28.02	5
007-006	73/Female	26JUL2015 20:30	ACCUSOL 35 Potassium 4 mmol/L	15C02G70	PRE & POST	27JUL2015 02:15 / 27JUL2015 05:35	28.02	5
007-006	73/Female	26JUL2015 20:30	ACCUSOL 35 Potassium 4 mmol/L	15C02G70	PRE & POST	27JUL2015 05:35 / 27JUL2015 09:10	26.08	5
007-006	73/Female	26JUL2015 20:30	ACCUSOL 35 Potassium 4 mmol/L	15C02G70	PRE & POST	27JUL2015 05:35 / 27JUL2015 09:10	26.08	5
007-006	73/Female	26JUL2015 20:30	ACCUSOL 35 Potassium 4 mmol/L	15C02G70	PRE & POST	27JUL2015 09:10 / 27JUL2015 12:30	28.02	5
007-006	73/Female	26JUL2015 20:30	ACCUSOL 35 Potassium 4 mmol/L	15C02G70	PRE & POST	27JUL2015 09:10 / 27JUL2015 12:30	28.02	5
007-006	73/Female	26JUL2015 20:30	ACCUSOL 35 Potassium 4 mmol/L	UNKNOWN	UNKNOWN	27JUL2015 12:30 / 28JUL2015 04:30		.
007-007	83/Male	03AUG2015 01:50	ACCUSOL 35 Potassium 4 mmol/L	15C02G71	PRE & POST	03AUG2015 01:50 / 03AUG2015 04:10	48.43	3.5
007-007	83/Male	03AUG2015 01:50	ACCUSOL 35 Potassium 4 mmol/L	15C02G71	PRE & POST	03AUG2015 01:50 / 03AUG2015 04:10	48.43	3.5

Data Listing 16.2.5.3. ACCUSOL 35 Administration - Enrolled Population

Patient Number	Age (Years)/ Gender	First Accusol Administration Start Date/ Time	Dialysis Solution Used	Lot Number	Site of Introduction	Start Date and Time/ End Date and Time	Dialysis Dose (ml/kg/hr)	Amount Administered (L)
007-008	79/Male	13AUG2015 07:00	ACCUSOL 35 Potassium 4 mmol/L	15C03G75	PRE & POST	13AUG2015 07:00 / 13AUG2015 09:45	44.77	4.1
007-008	79/Male	13AUG2015 07:00	ACCUSOL 35 Potassium 4 mmol/L	15C03G75	PRE & POST	13AUG2015 07:00 / 13AUG2015 09:45	44.77	4.1
007-010	70/Male	01SEP2015 07:40	ACCUSOL 35 Potassium 2 mmol/L	14K10G71	PRE & POST	01SEP2015 07:40 / 01SEP2015 10:00	39.21	5
007-010	70/Male	01SEP2015 07:40	ACCUSOL 35 Potassium 2 mmol/L	14K10G71	PRE & POST	01SEP2015 07:40 / 01SEP2015 10:00	39.21	5
007-011	64/Female	01SEP2015 05:30	ACCUSOL 35 Potassium 2 mmol/L	14K10G71	PRE & POST	01SEP2015 05:30 / 01SEP2015 07:50	48.99	4.5
007-011	64/Female	01SEP2015 05:30	ACCUSOL 35 Potassium 2 mmol/L	14K10G71	PRE 7 POST	01SEP2015 05:30 / 01SEP2015 07:50	48.99	4.5
007-011	64/Female	01SEP2015 05:30	ACCUSOL 35 Potassium 2 mmol/L	14K10G71	PRE & POST	01SEP2015 07:50 / 01SEP2015 10:30	47.46	5
007-011	64/Female	01SEP2015 05:30	ACCUSOL 35 Potassium 2 mmol/L	14K10G71	PRE & POST	01SEP2015 07:50 / 01SEP2015 10:30	47.46	5
007-011	64/Female	01SEP2015 05:30	ACCUSOL 35 Potassium 2 mmol/L	14K10G71	PRE & POST	01SEP2015 10:30 / 01SEP2015 13:30	42.19	5
007-011	64/Female	01SEP2015 05:30	ACCUSOL 35 Potassium 2 mmol/L	14K10G71	PRE & POST	01SEP2015 10:30 / 01SEP2015 13:30	42.19	5
007-011	64/Female	01SEP2015 05:30	ACCUSOL 35 Potassium 2 mmol/L	14K10G71	PRE & POST	01SEP2015 13:30 / 01SEP2015 15:55	52.37	5

Data Listing 16.2.5.3. ACCUSOL 35 Administration - Enrolled Population

Patient Number	Age (Years)/ Gender	First Accusol Administration Start Date/ Time	Dialysis Solution Used	Lot Number	Site of Introduction	Start Date and Time/ End Date and Time	Dialysis Dose (ml/kg/hr)	Amount Administered (L)
007-011	64/Female	01SEP2015 05:30	ACCUSOL 35 Potassium 2 mmol/L	14K10G71	PRE & POST	01SEP2015 13:30 / 01SEP2015 15:55	52.37	5
007-011	64/Female	01SEP2015 05:30	ACCUSOL 35 Potassium 2 mmol/L	14K10G71	PRE & POST	01SEP2015 15:55 / 01SEP2015 19:00	43.49	5
007-011	64/Female	01SEP2015 05:30	ACCUSOL 35 Potassium 2 mmol/L	14K10G71	PRE & POST	01SEP2015 15:55 / 01SEP2015 19:00	43.49	5
007-011	64/Female	01SEP2015 05:30	ACCUSOL 35 Potassium 2 mmol/L	14K10G71	PRE 7 POST	01SEP2015 19:00 / 01SEP2015 21:30	50.63	5
007-011	64/Female	01SEP2015 05:30	ACCUSOL 35 Potassium 2 mmol/L	14K10G71	PRE & POST	01SEP2015 19:00 / 01SEP2015 21:30	50.63	5
007-011	64/Female	01SEP2015 05:30	ACCUSOL 35 Potassium 2 mmol/L	14K10G71	PRE & POST	01SEP2015 21:30 / 02SEP2015 00:00	50.63	5
007-011	64/Female	01SEP2015 05:30	ACCUSOL 35 Potassium 2 mmol/L	14K10G71	PRE & POST	01SEP2015 21:30 / 02SEP2015 00:00	50.63	5
007-011	64/Female	01SEP2015 05:30	ACCUSOL 35 Potassium 2 mmol/L	14K10G71	PRE & POST	02SEP2015 00:00 / 02SEP2015 02:50	44.67	5
007-011	64/Female	01SEP2015 05:30	ACCUSOL 35 Potassium 2 mmol/L	14K10G71	PRE & POST	02SEP2015 00:00 / 02SEP2015 02:50	44.67	5
007-011	64/Female	01SEP2015 05:30	ACCUSOL 35 Potassium 2 mmol/L	14K10G71	PRE & POST	02SEP2015 02:50 / 02SEP2015 05:30	47.46	5
007-011	64/Female	01SEP2015 05:30	ACCUSOL 35 Potassium 2 mmol/L	14K10G71	PRE & POST	02SEP2015 02:50 / 02SEP2015 05:30	47.46	5

Data Listing 16.2.5.3. ACCUSOL 35 Administration - Enrolled Population

Patient Number	Age (Years)/ Gender	First Accusol Administration Start Date/ Time	Dialysis Solution Used	Lot Number	Site of Introduction	Start Date and Time/ End Date and Time	Dialysis Dose (ml/kg/hr)	Amount Administered (L)
007-011	64/Female	01SEP2015 05:30	ACCUSOL 35 Potassium 2 mmol/L	14K10G71	PRE & POST	02SEP2015 05:30 / 02SEP2015 08:20	44.67	5
007-011	64/Female	01SEP2015 05:30	ACCUSOL 35 Potassium 2 mmol/L	14K10G71	PRE 7 POST	02SEP2015 05:30 / 02SEP2015 08:20	44.67	5
007-011	64/Female	01SEP2015 05:30	ACCUSOL 35 Potassium 2 mmol/L	14K10G71	PRE & POST	02SEP2015 08:20 / 02SEP2015 11:00	47.46	5
007-011	64/Female	01SEP2015 05:30	ACCUSOL 35 Potassium 2 mmol/L	14K10G71	PRE & POST	02SEP2015 08:20 / 02SEP2015 11:00	47.46	5
007-011	64/Female	01SEP2015 05:30	ACCUSOL 35 Potassium 2 mmol/L	14K10G71	PRE & POST	02SEP2015 11:00 / 02SEP2015 13:30	50.63	5
007-011	64/Female	01SEP2015 05:30	ACCUSOL 35 Potassium 2 mmol/L	14K10G71	PRE & POST	02SEP2015 11:00 / 02SEP2015 13:30	50.63	5
007-012	36/Male	07SEP2015 17:30	ACCUSOL 35 Potassium 2 mmol/L	14K10G71	PRE 1000, POST 2000	07SEP2015 17:30 / 07SEP2015 19:00	38.56	2.4
007-012	36/Male	07SEP2015 17:30	ACCUSOL 35 Potassium 2 mmol/L	14K10G71	PRE 1000 POST 2000	07SEP2015 17:30 / 07SEP2015 19:00	38.56	2.4
007-012	36/Male	07SEP2015 17:30	ACCUSOL 35 Potassium 2 mmol/L	14K10G71	PRE 1000 POST 2000	07SEP2015 19:00 / 07SEP2015 22:00	42.84	5
007-012	36/Male	07SEP2015 17:30	ACCUSOL 35 Potassium 2 mmol/L	14K10G71	PRE 1000 POST 2000	07SEP2015 19:00 / 07SEP2015 22:00	42.84	5
007-012	36/Male	07SEP2015 17:30	ACCUSOL 35 Potassium 2 mmol/L	14K10G71	PRE 1000 POST 2000	07SEP2015 22:00 / 08SEP2015 01:00	42.84	5

Data Listing 16.2.5.3. ACCUSOL 35 Administration - Enrolled Population

Patient Number	Age (Years)/ Gender	First Accusol Administration Start Date/ Time	Dialysis Solution Used	Lot Number	Site of Introduction	Start Date and Time/ End Date and Time	Dialysis Dose (ml/kg/hr)	Amount Administered (L)
007-012	36/Male	07SEP2015 17:30	ACCUSOL 35 Potassium 2 mmol/L	14K10G71	PRE 1000 POST 2000	07SEP2015 22:00 / 08SEP2015 01:00	42.84	5
007-012	36/Male	07SEP2015 17:30	ACCUSOL 35 Potassium 2 mmol/L	14K10G71	PRE 1000 POST 2000	08SEP2015 01:00 / 08SEP2015 04:00	42.84	5
007-012	36/Male	07SEP2015 17:30	ACCUSOL 35 Potassium 2 mmol/L	14K10G71	PRE 1000 POST 2000	08SEP2015 01:00 / 08SEP2015 04:00	42.84	5
007-012	36/Male	07SEP2015 17:30	ACCUSOL 35 Potassium 2 mmol/L	14K10G71	PRE 1000 POST 2000	08SEP2015 04:00 / 08SEP2015 07:00	42.84	5
007-012	36/Male	07SEP2015 17:30	ACCUSOL 35 Potassium 2 mmol/L	14K10G71	PRE 1000 POST 2000	08SEP2015 04:00 / 08SEP2015 07:00	42.84	5
007-012	36/Male	07SEP2015 17:30	ACCUSOL 35 Potassium 2 mmol/L	14K10G71	PRE 1000 POST 2000	08SEP2015 07:00 / 08SEP2015 09:30	51.41	5
007-012	36/Male	07SEP2015 17:30	ACCUSOL 35 Potassium 2 mmol/L	14K10G71	PRE 1000 POST 2000	08SEP2015 07:00 / 08SEP2015 09:30	51.41	5
007-012	36/Male	07SEP2015 17:30	ACCUSOL 35 Potassium 2 mmol/L	14K10G71	PRE 1000 POST 2000	08SEP2015 09:30 / 08SEP2015 13:05	35.87	5
007-012	36/Male	07SEP2015 17:30	ACCUSOL 35 Potassium 2 mmol/L	14K10G71	PRE 1000 POST 2000	08SEP2015 09:30 / 08SEP2015 13:05	35.87	5
007-012	36/Male	07SEP2015 17:30	ACCUSOL 35 Potassium 2 mmol/L	14K10G71	PRE AND POST	08SEP2015 13:05 / 08SEP2015 16:50	34.27	5
007-012	36/Male	07SEP2015 17:30	ACCUSOL 35 Potassium 2 mmol/L	14K10G71	PRE AND POST	08SEP2015 13:05 / 08SEP2015 16:50	34.27	5

Data Listing 16.2.5.3. ACCUSOL 35 Administration - Enrolled Population

Patient Number	Age (Years)/ Gender	First Accusol Administration Start Date/ Time	Dialysis Solution Used	Lot Number	Site of Introduction	Start Date and Time/ End Date and Time	Dialysis Dose (ml/kg/hr)	Amount Administered (L)
007-012	36/Male	07SEP2015 17:30	ACCUSOL 35 Potassium 2 mmol/L	14K10G71	PRE AND POST	08SEP2015 16:50 / 08SEP2015 20:00	40.58	5
007-012	36/Male	07SEP2015 17:30	ACCUSOL 35 Potassium 2 mmol/L	14K10G71	PRE AND POST	08SEP2015 16:50 / 08SEP2015 20:00	40.58	5
007-012	36/Male	07SEP2015 17:30	ACCUSOL 35 Potassium 2 mmol/L	14K10G71	PRE AND POST	08SEP2015 20:00 / 08SEP2015 23:00	42.84	5
007-012	36/Male	07SEP2015 17:30	ACCUSOL 35 Potassium 2 mmol/L	14K10G71	PRE AND POST	08SEP2015 20:00 / 08SEP2015 23:00	42.84	5
007-012	36/Male	07SEP2015 17:30	ACCUSOL 35 Potassium 2 mmol/L	14K10G71	PRE AND POST	08SEP2015 23:00 / 09SEP2015 01:30	32.13	3.13
007-012	36/Male	07SEP2015 17:30	ACCUSOL 35 Potassium 2 mmol/L	14K10G71	PRE AND POST	08SEP2015 23:00 / 09SEP2015 01:30	32.13	3.13
007-014	74/Female	28SEP2015 06:40	ACCUSOL 35 Potassium 4 mmol/L	15H28G72	1000 PRE,2000 POST	28SEP2015 06:40 / 28SEP2015 07:45	27.22	1.4
007-014	74/Female	28SEP2015 06:40	ACCUSOL 35 Potassium 4 mmol/L	15H28G72	PRE & POST	28SEP2015 06:40 / 28SEP2015 07:45	27.22	1.4
007-015	73/Female	14DEC2015 06:50	ACCUSOL 35 Potassium 4 mmol/L	15H28G73	PRE & POST	14DEC2015 06:50 / 14DEC2015 08:00	51.28	1.9
007-015	73/Female	14DEC2015 06:50	ACCUSOL 35 Potassium 4 mmol/L	15H28G73	PRE & POST	14DEC2015 06:50 / 14DEC2015 08:00	51.28	1.9
007-015	73/Female	14DEC2015 06:50	ACCUSOL 35 Potassium 4 mmol/L	15H28G73	PRE & POST	14DEC2015 08:00 / 14DEC2015 11:30	43.95	5

Data Listing 16.2.5.3. ACCUSOL 35 Administration - Enrolled Population

Patient Number	Age (Years)/ Gender	First Accusol Administration Start Date/ Time	Dialysis Solution Used	Lot Number	Site of Introduction	Start Date and Time/ End Date and Time	Dialysis Dose (ml/kg/hr)	Amount Administered (L)
007-015	73/Female	14DEC2015 06:50	ACCUSOL 35 Potassium 4 mmol/L	15H28G73	PRE & POST	14DEC2015 08:00 / 14DEC2015 11:30	43.95	5
007-015	73/Female	14DEC2015 06:50	ACCUSOL 35 Potassium 4 mmol/L	15H28G73	PRE & POST	14DEC2015 11:30 / 14DEC2015 14:45	47.33	5
007-015	73/Female	14DEC2015 06:50	ACCUSOL 35 Potassium 4 mmol/L	15H28G73	PRE & POST	14DEC2015 11:30 / 14DEC2015 14:45	47.33	5
007-015	73/Female	14DEC2015 06:50	ACCUSOL 35 Potassium 4 mmol/L	15H28G73	PRE & POST	14DEC2015 14:45 / 14DEC2015 18:00	47.33	5
007-015	73/Female	14DEC2015 06:50	ACCUSOL 35 Potassium 4 mmol/L	15H28G73	PRE & POST	14DEC2015 14:45 / 14DEC2015 18:00	47.33	5
007-015	73/Female	14DEC2015 06:50	ACCUSOL 35 Potassium 4 mmol/L	15H28G73	PRE & POST	14DEC2015 18:00 / 14DEC2015 21:30	43.95	5
007-015	73/Female	14DEC2015 06:50	ACCUSOL 35 Potassium 4 mmol/L	15H28G73	PRE & POST	14DEC2015 18:00 / 14DEC2015 21:30	43.95	5
007-015	73/Female	14DEC2015 06:50	ACCUSOL 35 Potassium 4 mmol/L	15H28G73	PRE & POST	14DEC2015 21:30 / 15DEC2015 00:10	57.69	5
007-015	73/Female	14DEC2015 06:50	ACCUSOL 35 Potassium 4 mmol/L	15H28G73	PRE & POST	14DEC2015 21:30 / 15DEC2015 00:10	57.69	5
007-015	73/Female	14DEC2015 06:50	ACCUSOL 35 Potassium 4 mmol/L	15H28G73	PRE & POST	15DEC2015 00:10 / 15DEC2015 01:50	43.95	2.6
007-015	73/Female	14DEC2015 06:50	ACCUSOL 35 Potassium 4 mmol/L	15H28G73	PRE & POST	15DEC2015 00:10 / 15DEC2015 01:50	43.95	2.6

Data Listing 16.2.5.3. ACCUSOL 35 Administration - Enrolled Population

Patient Number	Age (Years)/ Gender	First Accusol Administration Start Date/ Time	Dialysis Solution Used	Lot Number	Site of Introduction	Start Date and Time/ End Date and Time	Dialysis Dose (ml/kg/hr)	Amount Administered (L)
007-016	71/Male	05JAN2016 06:35	ACCUSOL 35 Potassium 2 mmol/L	15E10G72	PRE & POST	05JAN2016 06:35 / 05JAN2016 10:20	32.30	5
007-016	71/Male	05JAN2016 06:35	ACCUSOL 35 Potassium 2 mmol/L	15E10G72	PRE & POST	05JAN2016 06:35 / 05JAN2016 10:20	32.30	5
008-001	26/Male	19MAR2015 12:05	ACCUSOL 35 Potassium 4 mmol/L	14K28G70	PRE/POST MIXTURE	19MAR2015 12:05 / 19MAR2015 14:10	39.28	.
008-001	26/Male	19MAR2015 12:05	ACCUSOL 35 Potassium 4 mmol/L	14K28G70	PRE/POST MIXTURE	19MAR2015 14:10 / 19MAR2015 15:45	39.28	5
008-001	26/Male	19MAR2015 12:05	ACCUSOL 35 Potassium 4 mmol/L	14K28G70	PRE/POST MIXTURE	19MAR2015 15:45 / 19MAR2015 17:20	39.28	5
008-001	26/Male	19MAR2015 12:05	ACCUSOL 35 Potassium 4 mmol/L	14K28G70	PRE /POST	19MAR2015 17:20 / 19MAR2015 19:15	39.28	5
008-001	26/Male	19MAR2015 12:05	ACCUSOL 35 Potassium 4 mmol/L	14K28670	PRE/POST	19MAR2015 19:15 / 19MAR2015 20:50	39.28	5
008-001	26/Male	19MAR2015 12:05	ACCUSOL 35 Potassium 4 mmol/L	14K28G70	PRE/POST	19MAR2015 20:50 / 19MAR2015 22:30	39.28	5
008-001	26/Male	19MAR2015 12:05	ACCUSOL 35 Potassium 4 mmol/L	14K28670	PRE/POST	19MAR2015 22:30 / 20MAR2015 00:20	40.47	5
008-001	26/Male	19MAR2015 12:05	ACCUSOL 35 Potassium 4 mmol/L	UNK	PRE /POST	20MAR2015 00:20 / 20MAR2015 01:55	39.28	5
008-001	26/Male	19MAR2015 12:05	ACCUSOL 35 Potassium 4 mmol/L	UNK	PRE/POST MIXTURE	20MAR2015 01:55 / 20MAR2015 03:40	39.28	5

Data Listing 16.2.5.3. ACCUSOL 35 Administration - Enrolled Population

Patient Number	Age (Years)/ Gender	First Accusol Administration Start Date/ Time	Dialysis Solution Used	Lot Number	Site of Introduction	Start Date and Time/ End Date and Time	Dialysis Dose (ml/kg/hr)	Amount Administered (L)
008-001	26/Male	19MAR2015 12:05	ACCUSOL 35 Potassium 4 mmol/L	UNK	PRE / POST MIXTURE	20MAR2015 03:40 / 20MAR2015 08:40	39.28	5
008-001	26/Male	19MAR2015 12:05	ACCUSOL 35 Potassium 4 mmol/L	UNK	PRE /POST	20MAR2015 08:40 / 20MAR2015 13:55	39.28	5
008-001	26/Male	19MAR2015 12:05	ACCUSOL 35 Potassium 4 mmol/L	14K28G71	PRE /POST	20MAR2015 13:55 / 20MAR2015 14:50	39.28	5
008-001	26/Male	19MAR2015 12:05	ACCUSOL 35 Potassium 4 mmol/L	14K28G71	PRE /POST	20MAR2015 14:50 / 20MAR2015 16:25	39.28	5
008-001	26/Male	19MAR2015 12:05	ACCUSOL 35 Potassium 4 mmol/L	14K28G71	PRE/POST	20MAR2015 16:25 / 20MAR2015 17:45	39.28	5
008-001	26/Male	19MAR2015 12:05	ACCUSOL 35 Potassium 4 mmol/L	14K28671	PRE/POST	20MAR2015 17:45 / 20MAR2015 19:00	39.28	5
008-001	26/Male	19MAR2015 12:05	ACCUSOL 35 Potassium 4 mmol/L	14K28G71	PRE /POST	20MAR2015 19:00 / 20MAR2015 20:05	39.28	.
008-002	31/Male	14APR2015 13:00	ACCUSOL 35 Potassium 4 mmol/L	14K28G70	PRE /POST MIXTURE	14APR2015 13:00 / 14APR2015 17:00	40.50	.
008-002	31/Male	14APR2015 13:00	ACCUSOL 35 Potassium 4 mmol/L	14K28G70	PRE/POST MIXTURE	14APR2015 17:00 / 14APR2015 18:35	40.50	5
008-002	31/Male	14APR2015 13:00	ACCUSOL 35 Potassium 4 mmol/L	14K28G70	PRE/POST MIXTURE	14APR2015 18:35 / 14APR2015 22:25	40.50	5
008-002	31/Male	14APR2015 13:00	ACCUSOL 35 Potassium 4 mmol/L	14K28G70	PRE/POST	14APR2015 22:25 / 15APR2015 00:15	40.50	5

Data Listing 16.2.5.3. ACCUSOL 35 Administration - Enrolled Population

Patient Number	Age (Years)/ Gender	First Accusol Administration Start Date/ Time	Dialysis Solution Used	Lot Number	Site of Introduction	Start Date and Time/ End Date and Time	Dialysis Dose (ml/kg/hr)	Amount Administered (L)
008-002	31/Male	14APR2015 13:00	ACCUSOL 35 Potassium 4 mmol/L	14K28G70	PRE/POST	15APR2015 00:15 / 15APR2015 02:05	40.50	5
008-002	31/Male	14APR2015 13:00	ACCUSOL 35 Potassium 4 mmol/L	14K28G70	PRE/POST	15APR2015 02:05 / 15APR2015 03:55	40.50	5
008-002	31/Male	14APR2015 13:00	ACCUSOL 35 Potassium 4 mmol/L	14K28670	PRE /POST	15APR2015 03:55 / 15APR2015 05:50	40.50	5
008-002	31/Male	14APR2015 13:00	ACCUSOL 35 Potassium 4 mmol/L	14K28G70	PRE/POST	15APR2015 05:50 / 15APR2015 07:50	40.50	5
008-002	31/Male	14APR2015 13:00	ACCUSOL 35 Potassium 4 mmol/L	14K28G70	PRE/POST	15APR2015 07:50 / 15APR2015 09:50	40.50	5
008-002	31/Male	14APR2015 13:00	ACCUSOL 35 Potassium 4 mmol/L	14K28670	PRE/POST	15APR2015 09:50 / 15APR2015 11:20	40.50	5
008-002	31/Male	14APR2015 13:00	ACCUSOL 35 Potassium 4 mmol/L	14K28G70	PRE/POST	15APR2015 11:20 / 15APR2015 13:10	40.50	5
008-002	31/Male	14APR2015 13:00	ACCUSOL 35 Potassium 4 mmol/L	14K28G70	PRE/POST	15APR2015 13:10 / 15APR2015 15:00	40.50	5
008-002	31/Male	14APR2015 13:00	ACCUSOL 35 Potassium 4 mmol/L	14K28G70	PRE/POST	15APR2015 15:00 / 15APR2015 17:00	40.50	5
008-002	31/Male	14APR2015 13:00	ACCUSOL 35 Potassium 4 mmol/L	14K28G70	PRE/POST	15APR2015 17:00 / 15APR2015 19:00	40.50	5
008-002	31/Male	14APR2015 13:00	ACCUSOL 35 Potassium 4 mmol/L	14K28G70	PRE/POST	15APR2015 19:00 / 15APR2015 20:50	40.50	5

Data Listing 16.2.5.3. ACCUSOL 35 Administration - Enrolled Population

Patient Number	Age (Years)/ Gender	First Accusol Administration Start Date/ Time	Dialysis Solution Used	Lot Number	Site of Introduction	Start Date and Time/ End Date and Time	Dialysis Dose (ml/kg/hr)	Amount Administered (L)
008-002	31/Male	14APR2015 13:00	ACCUSOL 35 Potassium 4 mmol/L	14K28G70	PRE/POST	15APR2015 20:50 / 15APR2015 21:00	40.50	.
008-003	25/Female	20APR2015 20:00	ACCUSOL 35 Potassium 4 mmol/L	UNK	PRE/POST MIX	20APR2015 20:00 / 20APR2015 22:00	66	.
008-003	25/Female	20APR2015 20:00	ACCUSOL 35 Potassium 4 mmol/L	14K28G70	PRE /POST	20APR2015 22:00 / 21APR2015 00:15	66	5
008-003	25/Female	20APR2015 20:00	ACCUSOL 35 Potassium 4 mmol/L	14K28G70	PRE /POST	21APR2015 00:15 / 21APR2015 03:15	66	5
008-003	25/Female	20APR2015 20:00	ACCUSOL 35 Potassium 4 mmol/L	15A07G70	PRE /POST	21APR2015 03:15 / 21APR2015 05:30	66	5
008-003	25/Female	20APR2015 20:00	ACCUSOL 35 Potassium 4 mmol/L	15A07G70	PRE /POST FILTER	21APR2015 05:30 / 21APR2015 08:40	66	5
008-003	25/Female	20APR2015 20:00	ACCUSOL 35 Potassium 4 mmol/L	15A07G70	PRE / POST MIXTURE	21APR2015 08:40 / 21APR2015 11:30	66	5
008-003	25/Female	20APR2015 20:00	ACCUSOL 35 Potassium 4 mmol/L	UNK	PRE/POST MIXTURE	21APR2015 11:30 / 21APR2015 14:00	66	5
008-003	25/Female	20APR2015 20:00	ACCUSOL 35 Potassium 4 mmol/L	15A07G70	PRE / POST	21APR2015 14:00 / 21APR2015 16:40	66	5
008-003	25/Female	20APR2015 20:00	ACCUSOL 35 Potassium 4 mmol/L	15A07640	PRE /POST	21APR2015 16:40 / 21APR2015 19:20	66	5
008-003	25/Female	20APR2015 20:00	ACCUSOL 35 Potassium 4 mmol/L	15A07G70	PRE / POST	21APR2015 19:20 / 21APR2015 22:00	66	5

Data Listing 16.2.5.3. ACCUSOL 35 Administration - Enrolled Population

Patient Number	Age (Years)/ Gender	First Accusol Administration Start Date/ Time	Dialysis Solution Used	Lot Number	Site of Introduction	Start Date and Time/ End Date and Time	Dialysis Dose (ml/kg/hr)	Amount Administered (L)
008-003	25/Female	20APR2015 20:00	ACCUSOL 35 Potassium 4 mmol/L	15A07G70	PRE / POST	21APR2015 22:00 / 22APR2015 00:45	66	5
008-003	25/Female	20APR2015 20:00	ACCUSOL 35 Potassium 4 mmol/L	15A07G70	PRE / POST MIXTURE	22APR2015 00:45 / 22APR2015 03:25	66	5
008-003	25/Female	20APR2015 20:00	ACCUSOL 35 Potassium 4 mmol/L	15A07G70	PRE / POST	22APR2015 03:25 / 22APR2015 04:00	66	.
008-004	46/Male	06MAY2015 18:00	ACCUSOL 35 Potassium 4 mmol/L	15A07671	PRE/POST MIXTURE	06MAY2015 18:00 / 06MAY2015 22:00	28	5
008-004	46/Male	06MAY2015 18:00	ACCUSOL 35 Potassium 4 mmol/L	15A07671	PRE/POST	06MAY2015 22:00 / 06MAY2015 23:45	28	.
008-005	82/Male	22MAY2015 08:20	ACCUSOL 35 Potassium 4 mmol/L	UNK	PRE /POST MIX	22MAY2015 08:20 / 22MAY2015 09:30	29	.
008-005	82/Male	22MAY2015 08:20	ACCUSOL 35 Potassium 4 mmol/L	15A07671	PRE / POST MIXTURE	22MAY2015 09:30 / 22MAY2015 10:55	29	.
008-006	70/Male	27MAY2015 19:00	ACCUSOL 35 Potassium 4 mmol/L	15A08G73	PRE /POST	27MAY2015 19:00 / 27MAY2015 21:20	35.7	2.5
008-006	70/Male	27MAY2015 19:00	ACCUSOL 35 Potassium 4 mmol/L	15A08G73	PRE /POST	27MAY2015 21:20 / 27MAY2015 22:45	35.7	2.5
008-006	70/Male	27MAY2015 19:00	ACCUSOL 35 Potassium 4 mmol/L	15A08G73	PRE /POST	27MAY2015 22:45 / 28MAY2015 02:00	35.7	2.5
008-006	70/Male	27MAY2015 19:00	ACCUSOL 35 Potassium 4 mmol/L	15A08G73	PRE /POST	28MAY2015 02:00 / 28MAY2015 04:20	35.7	2.5

Data Listing 16.2.5.3. ACCUSOL 35 Administration - Enrolled Population

Patient Number	Age (Years)/ Gender	First Accusol Administration Start Date/ Time	Dialysis Solution Used	Lot Number	Site of Introduction	Start Date and Time/ End Date and Time	Dialysis Dose (ml/kg/hr)	Amount Administered (L)
008-006	70/Male	27MAY2015 19:00	ACCUSOL 35 Potassium 4 mmol/L	15A08G73	PRE /POST	28MAY2015 04:20 / 28MAY2015 06:50	35.7	2.5
008-006	70/Male	27MAY2015 19:00	ACCUSOL 35	14K29G72	PRE /POST	28MAY2015 06:50 / 28MAY2015 10:30	35.7	2.5
008-006	70/Male	27MAY2015 19:00	ACCUSOL 35 Potassium 4 mmol/L	15A07G67	PRE / POST	28MAY2015 10:30 / 28MAY2015 13:00	35.7	2.5
008-007	74/Male	28MAY2015 06:20	ACCUSOL 35 Potassium 4 mmol/L	UNK	PRE/POST MIX	28MAY2015 06:20 / 28MAY2015 07:40	22.98	.
008-007	74/Male	28MAY2015 06:20	ACCUSOL 35 Potassium 4 mmol/L	15A08G73	PRE /POST MIX	28MAY2015 07:40 / 28MAY2015 10:15	22.98	.
008-007	74/Male	28MAY2015 06:20	ACCUSOL 35 Potassium 4 mmol/L	15A08G73	PRE/POST MIX	28MAY2015 10:15 / 28MAY2015 13:00	22.98	5
008-007	74/Male	28MAY2015 06:20	ACCUSOL 35 Potassium 4 mmol/L	15A08G73	PRE /POST MIX	28MAY2015 13:00 / 28MAY2015 16:00	22.98	5
008-007	74/Male	28MAY2015 06:20	ACCUSOL 35 Potassium 4 mmol/L	15A08G73	PRE / POST MIX	28MAY2015 16:00 / 28MAY2015 19:00	22.98	5
008-007	74/Male	28MAY2015 06:20	ACCUSOL 35 Potassium 4 mmol/L	15A08G73	PRE/ POST MIX	28MAY2015 19:00 / 28MAY2015 22:00	22.98	5
008-012	71/Male	20JUL2015 18:00	ACCUSOL 35 Potassium 4 mmol/L	UNK	PRE/POST	20JUL2015 18:00 / 20JUL2015 20:30	39.75	.
008-013	68/Male	21JUL2015 06:00	ACCUSOL 35 Potassium 4 mmol/L	UNK	PRE /POST MIX	21JUL2015 06:00 / 21JUL2015 06:55	42.64	.

Data Listing 16.2.5.3. ACCUSOL 35 Administration - Enrolled Population

Patient Number	Age (Years)/ Gender	First Accusol Administration Start Date/ Time	Dialysis Solution Used	Lot Number	Site of Introduction	Start Date and Time/ End Date and Time	Dialysis Dose (ml/kg/hr)	Amount Administered (L)
008-013	68/Male	21JUL2015 06:00	ACCUSOL 35 Potassium 4 mmol/L	UNK	MIX PRE / POST	21JUL2015 06:55 / 21JUL2015 14:45	42.64	5
008-013	68/Male	21JUL2015 06:00	ACCUSOL 35 Potassium 4 mmol/L	UNK	PRE/POST	21JUL2015 14:45 / 21JUL2015 14:45	42.64	.
008-014	65/Female	25JUL2015 08:00	ACCUSOL 35 Potassium 4 mmol/L	15A08G74	MIX	25JUL2015 08:00 / 25JUL2015 10:35	19.6	5
008-014	65/Female	25JUL2015 08:00	ACCUSOL 35 Potassium 4 mmol/L	15A08G73	MIX	25JUL2015 10:35 / 25JUL2015 11:00	19.6	.
008-016	34/Male	13AUG2015 10:00	ACCUSOL 35 Potassium 4 mmol/L	UNK	PRE / POST MIX	13AUG2015 10:00 / 13AUG2015 10:10	43.47	.
008-016	34/Male	13AUG2015 10:00	ACCUSOL 35 Potassium 4 mmol/L	UNK	MIX	13AUG2015 10:10 / 13AUG2015 11:45	43.47	.
008-016	34/Male	13AUG2015 10:00	ACCUSOL 35 Potassium 4 mmol/L	UNK	MIX	13AUG2015 11:45 / 13AUG2015 13:40	43.47	5
008-016	34/Male	13AUG2015 10:00	ACCUSOL 35 Potassium 4 mmol/L	UNK	MIX	13AUG2015 13:40 / 13AUG2015 14:00	43.47	.
008-017	52/Female	21AUG2015 13:25	ACCUSOL 35 Potassium 4 mmol/L	UNK	PRE /POST MIX	21AUG2015 13:25 / 21AUG2015 13:40	55.04	.
008-017	52/Female	21AUG2015 13:25	ACCUSOL 35 Potassium 4 mmol/L	UNK	PRE / POST MIX	21AUG2015 13:40 / 21AUG2015 17:20	55.04	5
008-017	52/Female	21AUG2015 13:25	ACCUSOL 35 Potassium 4 mmol/L	UNK	PRE/POST MIX	21AUG2015 17:20 / 21AUG2015 20:50	55.04	5

Data Listing 16.2.5.3. ACCUSOL 35 Administration - Enrolled Population

Patient Number	Age (Years)/ Gender	First Accusol Administration Start Date/ Time	Dialysis Solution Used	Lot Number	Site of Introduction	Start Date and Time/ End Date and Time	Dialysis Dose (ml/kg/hr)	Amount Administered (L)
008-017	52/Female	21AUG2015 13:25	ACCUSOL 35 Potassium 4 mmol/L	UNK	PRE/POST MIX	21AUG2015 20:50 / 21AUG2015 22:50	55.04	5
008-017	52/Female	21AUG2015 13:25	ACCUSOL 35 Potassium 4 mmol/L	UNK	PRE / POST MIX	21AUG2015 22:50 / 22AUG2015 00:45	55.04	5
008-017	52/Female	21AUG2015 13:25	ACCUSOL 35 Potassium 4 mmol/L	UNK	PRE / POST MIX	22AUG2015 00:45 / 22AUG2015 02:30	55.04	5
008-017	52/Female	21AUG2015 13:25	ACCUSOL 35 Potassium 4 mmol/L	UNK	PRE / POST MIX	22AUG2015 02:30 / 22AUG2015 04:30	55.04	5
008-017	52/Female	21AUG2015 13:25	ACCUSOL 35 Potassium 4 mmol/L	UNK	PRE / POST MIX	22AUG2015 04:30 / 22AUG2015 05:55	55.04	.
008-018	65/Male	05OCT2015 16:25	ACCUSOL 35 Potassium 4 mmol/L	15D11G70	PRE /POST	05OCT2015 16:25 / 05OCT2015 18:10	27.35	5
008-018	65/Male	05OCT2015 16:25	ACCUSOL 35 Potassium 4 mmol/L	15D11G70	PRE/POST	05OCT2015 18:10 / 05OCT2015 20:10	27.35	5
008-018	65/Male	05OCT2015 16:25	ACCUSOL 35 Potassium 4 mmol/L	15D11G70	PRE/POST	05OCT2015 20:10 / 05OCT2015 22:10	27.35	5
008-018	65/Male	05OCT2015 16:25	ACCUSOL 35 Potassium 4 mmol/L	15D11G70	PRE/POST	05OCT2015 22:10 / 05OCT2015 22:55	27.35	.
008-019	69/Female	09OCT2015 20:15	ACCUSOL 35 Potassium 4 mmol/L	15D11G07	PRE/POST MIX	09OCT2015 20:15 / 09OCT2015 20:30	62.63	.
008-019	69/Female	09OCT2015 20:15	ACCUSOL 35 Potassium 4 mmol/L	15D11G07	PRE / POST MIX	09OCT2015 20:30 / 09OCT2015 22:05	62.63	5

Data Listing 16.2.5.3. ACCUSOL 35 Administration - Enrolled Population

Patient Number	Age (Years)/ Gender	First Accusol Administration Start Date/ Time	Dialysis Solution Used	Lot Number	Site of Introduction	Start Date and Time/ End Date and Time	Dialysis Dose (ml/kg/hr)	Amount Administered (L)
008-019	69/Female	09OCT2015 20:15	ACCUSOL 35 Potassium 4 mmol/L	15D11GO7	PRE / POST MIX	09OCT2015 22:05 / 09OCT2015 23:59	62.63	5
008-019	69/Female	09OCT2015 20:15	ACCUSOL 35 Potassium 4 mmol/L	15D11G07	MIX	09OCT2015 23:59 / 10OCT2015 02:00	62.63	5
008-020	60/Male	20OCT2015 07:30	ACCUSOL 35 Potassium 4 mmol/L	15H28G73	PRE/POST	20OCT2015 07:30 / 20OCT2015 10:30	36	5
008-020	60/Male	20OCT2015 07:30	ACCUSOL 35 Potassium 4 mmol/L	15H28G73	PRE/POST MIX	20OCT2015 10:30 / 20OCT2015 12:30	36	5
008-020	60/Male	20OCT2015 07:30	ACCUSOL 35 Potassium 4 mmol/L	15H28G73	PRE /POST	20OCT2015 12:30 / 20OCT2015 14:30	36.0	5
008-020	60/Male	20OCT2015 07:30	ACCUSOL 35 Potassium 4 mmol/L	UNKOWN	MIX PRE / POST	20OCT2015 14:30 / 20OCT2015 16:45	36	5
008-020	60/Male	20OCT2015 07:30	ACCUSOL 35 Potassium 4 mmol/L	UNKNOWN	PRE/ POST MIX	20OCT2015 16:45 / 20OCT2015 19:00	36	5
008-020	60/Male	20OCT2015 07:30	ACCUSOL 35 Potassium 4 mmol/L	UNKNOWN	MIX PRE /POST	20OCT2015 19:00 / 20OCT2015 22:15	36	5
008-020	60/Male	20OCT2015 07:30	ACCUSOL 35 Potassium 4 mmol/L	15H28G73	PRE / POST	20OCT2015 22:15 / 21OCT2015 00:15	36	5
008-020	60/Male	20OCT2015 07:30	ACCUSOL 35 Potassium 4 mmol/L	15H28G73	PRE / POST MIX	21OCT2015 00:15 / 21OCT2015 02:15	36	5
008-020	60/Male	20OCT2015 07:30	ACCUSOL 35 Potassium 4 mmol/L	UNKNOWN	PRE/ POST MIX	21OCT2015 02:15 / 21OCT2015 04:20	36	5

Data Listing 16.2.5.3. ACCUSOL 35 Administration - Enrolled Population

Patient Number	Age (Years)/ Gender	First Accusol Administration Start Date/ Time	Dialysis Solution Used	Lot Number	Site of Introduction	Start Date and Time/ End Date and Time	Dialysis Dose (ml/kg/hr)	Amount Administered (L)
008-020	60/Male	20OCT2015 07:30	ACCUSOL 35 Potassium 4 mmol/L	15H28G73	PRE / POST MIX	21OCT2015 04:20 / 21OCT2015 06:25	36	5
008-020	60/Male	20OCT2015 07:30	ACCUSOL 35 Potassium 4 mmol/L	UNKNOWN	PRE/POST MIX	21OCT2015 06:25 / - -	36	.
008-021	66/Male	20OCT2015 16:00	ACCUSOL 35	15E09670	PRE/ POST MIX	20OCT2015 16:00 / 20OCT2015 18:00	32.7	.
008-022	43/Male	20OCT2015 21:00		UNK	PRE/POST MIX	20OCT2015 21:00 / 20OCT2015 23:30	35.2	.
008-022	43/Male	20OCT2015 21:00	ACCUSOL 35 Potassium 4 mmol/L	UNK	PRE / POST MIX	20OCT2015 23:30 / 21OCT2015 01:30	35.2	5
008-022	43/Male	20OCT2015 21:00	ACCUSOL 35 Potassium 4 mmol/L	UNK	PRE/ POST MIX	21OCT2015 01:30 / 21OCT2015 04:00	35.2	5
008-022	43/Male	20OCT2015 21:00	ACCUSOL 35 Potassium 4 mmol/L	UNK	PRE/ POST MIX	21OCT2015 04:00 / 21OCT2015 08:35	35.2	5
008-022	43/Male	20OCT2015 21:00	ACCUSOL 35 Potassium 4 mmol/L	15D11G70	MIX	21OCT2015 08:35 / 21OCT2015 11:30	35.2	5
008-022	43/Male	20OCT2015 21:00	ACCUSOL 35 Potassium 4 mmol/L	15H28G73	MIX	21OCT2015 11:30 / 21OCT2015 13:00	35.2	5
008-022	43/Male	20OCT2015 21:00	ACCUSOL 35 Potassium 4 mmol/L	UNK	MIX	21OCT2015 13:00 / 21OCT2015 15:00	35.2	5
008-022	43/Male	20OCT2015 21:00	ACCUSOL 35 Potassium 4 mmol/L	UNK	MIX	21OCT2015 15:00 / 21OCT2015 18:00	35.2	5

Data Listing 16.2.5.3. ACCUSOL 35 Administration - Enrolled Population

Patient Number	Age (Years)/ Gender	First Accusol Administration Start Date/ Time	Dialysis Solution Used	Lot Number	Site of Introduction	Start Date and Time/ End Date and Time	Dialysis Dose (ml/kg/hr)	Amount Administered (L)
008-022	43/Male	20OCT2015 21:00	ACCUSOL 35 Potassium 4 mmol/L	UNK	MIX	21OCT2015 18:00 / 21OCT2015 20:00	35.2	5
008-022	43/Male	20OCT2015 21:00	ACCUSOL 35 Potassium 4 mmol/L	UNK	MIX	21OCT2015 20:00 / 21OCT2015 22:10	35.2	5
008-022	43/Male	20OCT2015 21:00	ACCUSOL 35 Potassium 4 mmol/L	UNK	MIX	21OCT2015 22:10 / 21OCT2015 23:55	35.2	5
008-022	43/Male	20OCT2015 21:00	ACCUSOL 35 Potassium 4 mmol/L	UNK	MIX	21OCT2015 23:55 / 22OCT2015 02:00	35.2	5
008-022	43/Male	20OCT2015 21:00	ACCUSOL 35 Potassium 4 mmol/L	UNK	MIX	22OCT2015 02:00 / 22OCT2015 04:00	35.2	5
008-022	43/Male	20OCT2015 21:00	ACCUSOL 35 Potassium 4 mmol/L	UNK	MIX	22OCT2015 04:00 / 22OCT2015 05:00	35.2	.
008-023		21OCT2015 09:00	ACCUSOL 35 Potassium 4 mmol/L	115D11G70	PRE / POST MIX	21OCT2015 09:00 / 21OCT2015 09:10	25.4	2.9
008-023		21OCT2015 09:00	ACCUSOL 35 Potassium 4 mmol/L	115D11G70	MIX	21OCT2015 09:10 / 21OCT2015 10:20	25.4	2.9
008-023		21OCT2015 09:00	ACCUSOL 35 Potassium 4 mmol/L	115D11G70	MIX	21OCT2015 10:20 / 21OCT2015 12:30	25.4	2.9
008-023		21OCT2015 09:00	ACCUSOL 35 Potassium 4 mmol/L	115D11G70	MIX	21OCT2015 12:30 / 21OCT2015 14:20	25.4	2.9
008-023		21OCT2015 09:00	ACCUSOL 35 Potassium 4 mmol/L	115D11G70	MIX	21OCT2015 14:20 / 21OCT2015 16:10	25.4	2.9

Data Listing 16.2.5.3. ACCUSOL 35 Administration - Enrolled Population

Patient Number	Age (Years)/ Gender	First Accusol Administration Start Date/ Time	Dialysis Solution Used	Lot Number	Site of Introduction	Start Date and Time/ End Date and Time	Dialysis Dose (ml/kg/hr)	Amount Administered (L)
008-023		21OCT2015 09:00	ACCUSOL 35 Potassium 4 mmol/L	115D11G70	MIX	21OCT2015 16:10 / 21OCT2015 16:45	25.4	2.9
008-024	27/Male	27OCT2015 12:00	ACCUSOL 35 Potassium 4 mmol/L	15H28G73	PRE / POST MIX	27OCT2015 12:00 / 27OCT2015 12:30	34.9	.
008-024	27/Male	27OCT2015 12:00	ACCUSOL 35 Potassium 4 mmol/L	15H28G73	PRE / POST MIX	27OCT2015 12:30 / 27OCT2015 14:30	34.9	.
008-024	27/Male	27OCT2015 12:00	ACCUSOL 35 Potassium 4 mmol/L	15H28G73	MIX	27OCT2015 14:30 / 27OCT2015 16:00	34.9	5
008-024	27/Male	27OCT2015 12:00	ACCUSOL 35 Potassium 4 mmol/L	15H28G73	MIX	27OCT2015 16:00 / 27OCT2015 18:30	34.9	5
008-024	27/Male	27OCT2015 12:00	ACCUSOL 35	15E09G70	MIX	27OCT2015 18:30 / 27OCT2015 20:30	34.9	5
008-024	27/Male	27OCT2015 12:00	ACCUSOL 35	15E09G70	MIX	27OCT2015 20:30 / 27OCT2015 22:55	34.9	5
008-024	27/Male	27OCT2015 12:00	ACCUSOL 35 Potassium 4 mmol/L	15G09G70	MIX	27OCT2015 22:55 / 28OCT2015 00:20	34.9	5
008-024	27/Male	27OCT2015 12:00	ACCUSOL 35 Potassium 4 mmol/L	15G09G70	MIX	28OCT2015 00:20 / 28OCT2015 02:30	34.9	5
008-024	27/Male	27OCT2015 12:00	ACCUSOL 35 Potassium 4 mmol/L	14K28G71	MIX	28OCT2015 02:30 / 28OCT2015 04:45	34.9	5
008-024	27/Male	27OCT2015 12:00	ACCUSOL 35 Potassium 4 mmol/L	14K28G71	MIX	28OCT2015 04:45 / 28OCT2015 07:00	34.9	5

Data Listing 16.2.5.3. ACCUSOL 35 Administration - Enrolled Population

Patient Number	Age (Years)/ Gender	First Accusol Administration Start Date/ Time	Dialysis Solution Used	Lot Number	Site of Introduction	Start Date and Time/ End Date and Time	Dialysis Dose (ml/kg/hr)	Amount Administered (L)
008-024	27/Male	27OCT2015 12:00	ACCUSOL 35 Potassium 4 mmol/L	14K28G71	MIX	28OCT2015 07:00 / 28OCT2015 09:20	34.9	5
008-024	27/Male	27OCT2015 12:00	ACCUSOL 35 Potassium 4 mmol/L	14K28G71	MIX	28OCT2015 09:20 / 28OCT2015 11:30	34.9	5
008-024	27/Male	27OCT2015 12:00	ACCUSOL 35 Potassium 4 mmol/L	14K28G71	MIX	28OCT2015 11:30 / 28OCT2015 14:00	34.9	5
008-024	27/Male	27OCT2015 12:00	ACCUSOL 35 Potassium 4 mmol/L	UNK	PRE / POST MIX	28OCT2015 14:00 / 28OCT2015 16:15	34.9	5
008-024	27/Male	27OCT2015 12:00	ACCUSOL 35 Potassium 4 mmol/L	UNK	MIX	28OCT2015 16:15 / 28OCT2015 18:35	34.9	5
008-024	27/Male	27OCT2015 12:00	ACCUSOL 35 Potassium 4 mmol/L	14K28G71	MIX	28OCT2015 18:35 / 28OCT2015 20:00	34.9	.
008-025	68/Male	30OCT2015 11:15	ACCUSOL 35 Potassium 4 mmol/L	UNK	PRE /POST MIX	30OCT2015 11:15 / 30OCT2015 11:30	28.7	.
008-026	30/Female	05NOV2015 10:00	ACCUSOL 35 Potassium 4 mmol/L	1502G71	PRE /POST MIX	05NOV2015 10:00 / 05NOV2015 11:25	46.7	.
008-026	30/Female	05NOV2015 10:00	ACCUSOL 35 Potassium 4 mmol/L	1502G71	PRE /POST MIX	05NOV2015 11:25 / 05NOV2015 13:20	46.7	5
008-026	30/Female	05NOV2015 10:00	ACCUSOL 35 Potassium 4 mmol/L	1502G71	PRE /POST MIX	05NOV2015 13:20 / 05NOV2015 15:30	46.7	5
008-026	30/Female	05NOV2015 10:00	ACCUSOL 35 Potassium 4 mmol/L	UNK	-PRE / POST MIX	05NOV2015 15:30 / 05NOV2015 18:10	46.7	5

Data Listing 16.2.5.3. ACCUSOL 35 Administration - Enrolled Population

Patient Number	Age (Years)/ Gender	First Accusol Administration Start Date/ Time	Dialysis Solution Used	Lot Number	Site of Introduction	Start Date and Time/ End Date and Time	Dialysis Dose (ml/kg/hr)	Amount Administered (L)
008-026	30/Female	05NOV2015 10:00	ACCUSOL 35 Potassium 4 mmol/L	UNK	PRE /POST MIX	05NOV2015 18:10 / 05NOV2015 19:00	46.7	.
008-027	71/Male	13NOV2015 09:00	ACCUSOL 35 Potassium 4 mmol/L	15G09G70	MIX	13NOV2015 09:00 / 13NOV2015 09:55	32.2	.
008-027	71/Male	13NOV2015 09:00	ACCUSOL 35 Potassium 4 mmol/L	15G09G70	MIX	13NOV2015 09:55 / 13NOV2015 11:30	32.2	5
008-027	71/Male	13NOV2015 09:00	ACCUSOL 35 Potassium 4 mmol/L	15G09G70	MIX	13NOV2015 11:30 / 13NOV2015 13:00	32.2	5
008-027	71/Male	13NOV2015 09:00	ACCUSOL 35 Potassium 4 mmol/L	15G09G70	MIX	13NOV2015 13:00 / 13NOV2015 14:30	32.2	5
008-028	72/Male	30NOV2015 12:30	ACCUSOL 35 Potassium 4 mmol/L	15G09G71	PRE /POST MIX	30NOV2015 12:30 / 30NOV2015 14:25	16.66	.
008-028	72/Male	30NOV2015 12:30	ACCUSOL 35 Potassium 4 mmol/L	15G09G71	PRE / POST MIX	30NOV2015 14:25 / 30NOV2015 17:00	16.66	5
008-028	72/Male	30NOV2015 12:30	ACCUSOL 35 Potassium 4 mmol/L	15G0971	PRE /POST MIX	30NOV2015 17:00 / 30NOV2015 22:00	16.66	5
008-028	72/Male	30NOV2015 12:30	ACCUSOL 35 Potassium 4 mmol/L	UNK	PRE /POST MIX	30NOV2015 22:00 / 01DEC2015 01:20	16.66	5
008-028	72/Male	30NOV2015 12:30	ACCUSOL 35 Potassium 4 mmol/L	UNK	PRE / POST MIX	01DEC2015 01:20 / 01DEC2015 04:00	16.66	5
008-028	72/Male	30NOV2015 12:30	ACCUSOL 35 Potassium 4 mmol/L	15G09G70	PRE /POST MIX	01DEC2015 04:00 / 01DEC2015 09:35	16.66	5

Data Listing 16.2.5.3. ACCUSOL 35 Administration - Enrolled Population

Patient Number	Age (Years)/ Gender	First Accusol Administration Start Date/ Time	Dialysis Solution Used	Lot Number	Site of Introduction	Start Date and Time/ End Date and Time	Dialysis Dose (ml/kg/hr)	Amount Administered (L)
008-028	72/Male	30NOV2015 12:30	ACCUSOL 35 Potassium 4 mmol/L	15G09G70	PRE /POST MIX	01DEC2015 09:35 / 01DEC2015 10:00	16.66	.
008-029	66/Female	08DEC2015 23:40	ACCUSOL 35 Potassium 4 mmol/L	UNK	PRE/POST MIX	08DEC2015 23:40 / 09DEC2015 01:10	26.1	.
008-029	66/Female	08DEC2015 23:40	ACCUSOL 35 Potassium 4 mmol/L	UNK	PRE/POST MIX	09DEC2015 01:10 / 09DEC2015 03:10	26.1	5
008-029	66/Female	08DEC2015 23:40	ACCUSOL 35 Potassium 4 mmol/L	UNK	PRE/POST MIX	09DEC2015 03:10 / 09DEC2015 05:45	26.1	5
008-029	66/Female	08DEC2015 23:40	ACCUSOL 35 Potassium 4 mmol/L	UNK	PRE/POST MIX	09DEC2015 05:45 / 09DEC2015 07:50	26.1	5
008-029	66/Female	08DEC2015 23:40	ACCUSOL 35 Potassium 4 mmol/L	UNK	PRE/POST	09DEC2015 07:50 / 09DEC2015 10:00	26.1	5
008-029	66/Female	08DEC2015 23:40	ACCUSOL 35 Potassium 4 mmol/L	UNK	PRE/POST	09DEC2015 10:00 / 09DEC2015 12:00	26.1	5
008-029	66/Female	08DEC2015 23:40	ACCUSOL 35 Potassium 4 mmol/L	UNK	PRE/POST	09DEC2015 12:00 / 09DEC2015 14:30	26.1	5
008-029	66/Female	08DEC2015 23:40	ACCUSOL 35 Potassium 4 mmol/L	UNK	PRE / POST MIX	09DEC2015 14:30 / 09DEC2015 17:30	26.1	5
008-029	66/Female	08DEC2015 23:40	ACCUSOL 35 Potassium 4 mmol/L	UNK	PRE/POST MIX	09DEC2015 17:30 / 09DEC2015 18:45	26.1	5
008-029	66/Female	08DEC2015 23:40	ACCUSOL 35 Potassium 4 mmol/L	UNK	PRE/POST MIX	09DEC2015 18:45 / 09DEC2015 20:00	26.1	5

Data Listing 16.2.5.3. ACCUSOL 35 Administration - Enrolled Population

Patient Number	Age (Years)/ Gender	First Accusol Administration Start Date/ Time	Dialysis Solution Used	Lot Number	Site of Introduction	Start Date and Time/ End Date and Time	Dialysis Dose (ml/kg/hr)	Amount Administered (L)
008-030	63/Female	11JAN2016 16:25	ACCUSOL 35 Potassium 4 mmol/L	15H28G73	PRE / POST MIX	11JAN2016 16:25 / 11JAN2016 16:45	45.3	.
008-030	63/Female	11JAN2016 16:25	ACCUSOL 35 Potassium 4 mmol/L	15H28G73	PRE/POST MIX	11JAN2016 16:45 / 11JAN2016 19:19	45.3	5
008-030	63/Female	11JAN2016 16:25	ACCUSOL 35 Potassium 4 mmol/L	15H28G73	PRE /POST MIX	11JAN2016 19:19 / 11JAN2016 21:40	45.3	5
008-030	63/Female	11JAN2016 16:25	ACCUSOL 35 Potassium 4 mmol/L	15H28G73	PRE /POST MIX	11JAN2016 21:40 / 11JAN2016 23:15	45.3	5
008-030	63/Female	11JAN2016 16:25	ACCUSOL 35 Potassium 4 mmol/L	15H28G73	PRE/POST MIX	11JAN2016 23:15 / 12JAN2016 02:35	45.3	5
008-030	63/Female	11JAN2016 16:25	ACCUSOL 35 Potassium 4 mmol/L	15H28G73	PRE/POST MIX	12JAN2016 02:35 / 12JAN2016 05:10	45.3	5
008-030	63/Female	11JAN2016 16:25	ACCUSOL 35 Potassium 4 mmol/L	15H28G73	PRE/POST MIX	12JAN2016 05:10 / 12JAN2016 10:10	45.3	5
008-030	63/Female	11JAN2016 16:25	ACCUSOL 35 Potassium 4 mmol/L	15H28G73	PRE /POST MIX	12JAN2016 10:10 / 12JAN2016 12:45	45.3	5
008-030	63/Female	11JAN2016 16:25	ACCUSOL 35 Potassium 4 mmol/L	15H28G73	PRE /POST MIX	12JAN2016 12:45 / 12JAN2016 15:30	45.3	5
008-030	63/Female	11JAN2016 16:25	ACCUSOL 35 Potassium 4 mmol/L	15H28G73	PRE /POST MIX	12JAN2016 15:30 / 12JAN2016 16:35	45.3	5
008-030	63/Female	11JAN2016 16:25	ACCUSOL 35	UNK	PRE/POST MIX	12JAN2016 16:35 / 12JAN2016 18:00	45.3	.

Data Listing 16.2.5.3. ACCUSOL 35 Administration - Enrolled Population

Patient Number	Age (Years)/ Gender	First Accusol Administration Start Date/ Time	Dialysis Solution Used	Lot Number	Site of Introduction	Start Date and Time/ End Date and Time	Dialysis Dose (ml/kg/hr)	Amount Administered (L)
008-031	23/Male	27JAN2016 08:00	ACCUSOL 35 Potassium 4 mmol/L	15J12G71	PRE/ POST MIX	27JAN2016 08:00 / 27JAN2016 09:15	35.08	.
008-031	23/Male	27JAN2016 08:00	ACCUSOL 35 Potassium 4 mmol/L	15H28G72	PRE / POST MIX	27JAN2016 09:15 / 27JAN2016 11:50	35.08	5
008-031	23/Male	27JAN2016 08:00	ACCUSOL 35 Potassium 4 mmol/L	15H28G72	PRE/POST MIX	27JAN2016 11:50 / 27JAN2016 14:30	35.08	5
008-031	23/Male	27JAN2016 08:00	ACCUSOL 35 Potassium 4 mmol/L	15J12G71	PRE / POST MIX	27JAN2016 14:30 / 27JAN2016 17:00	35.08	5
008-031	23/Male	27JAN2016 08:00	ACCUSOL 35 Potassium 4 mmol/L	15J12G71	PRE/POST MIX	27JAN2016 17:00 / 27JAN2016 19:40	35.08	5
008-031	23/Male	27JAN2016 08:00	ACCUSOL 35	15E09G71	PRE /POST MIX	27JAN2016 19:40 / 27JAN2016 22:20	35.08	5
008-031	23/Male	27JAN2016 08:00	ACCUSOL 35 Potassium 4 mmol/L	15J12G71	PRE /POST MIX	27JAN2016 22:20 / 28JAN2016 00:40	35.08	5
008-031	23/Male	27JAN2016 08:00	ACCUSOL 35 Potassium 4 mmol/L	15309G71	PRE /POST MIX	28JAN2016 00:40 / 28JAN2016 03:20	35.08	5
008-031	23/Male	27JAN2016 08:00	ACCUSOL 35 Potassium 4 mmol/L	15J12G71	PRE/POST MIX	28JAN2016 03:20 / 28JAN2016 04:10	35.08	.
009-001	64/Male	02APR2015 15:00	ACCUSOL 35	14K27G73	PRE-FILTER	02APR2015 15:00 / 02APR2015 15:15	20	0.5
009-001	64/Male	02APR2015 15:00	ACCUSOL 35	14K27G73	PRE-FILTER	02APR2015 15:00 / 02APR2015 15:15	20	0.5

Data Listing 16.2.5.3. ACCUSOL 35 Administration - Enrolled Population

Patient Number	Age (Years)/ Gender	First Accusol Administration Start Date/ Time	Dialysis Solution Used	Lot Number	Site of Introduction	Start Date and Time/ End Date and Time	Dialysis Dose (ml/kg/hr)	Amount Administered (L)
009-002		09APR2015 01:00	ACCUSOL 35	14K27973	PRE-FILTER	09APR2015 01:00 / 09APR2015 01:25	20.3	1
009-002		09APR2015 01:00	ACCUSOL 35	14K27973	PRE-FILTER	09APR2015 01:25 / 09APR2015 09:00	20	5
009-002		09APR2015 01:00	ACCUSOL 35	14K27973	PRE-FILTER	09APR2015 09:00 / 09APR2015 12:00	20	4
009-003	75/Male	14APR2015 11:00	ACCUSOL 35	14K13G70	PRE-FILTER	14APR2015 11:00 / 14APR2015 13:00	20	4.5
009-003	75/Male	14APR2015 11:00	ACCUSOL 35	14K13G70	PRE-FILTER	14APR2015 13:00 / 14APR2015 16:30	20	5
009-003	75/Male	14APR2015 11:00	ACCUSOL 35	14K13G71	PRE-FILTER	14APR2015 16:30 / 14APR2015 20:00	20	5
009-003	75/Male	14APR2015 11:00	ACCUSOL 35	14K13G71	PRE-FILTER	14APR2015 20:00 / 14APR2015 23:55	20	5
009-003	75/Male	14APR2015 11:00	ACCUSOL 35	14K13G71	PRE-FILTER	14APR2015 23:55 / 15APR2015 03:30	20	5
009-003	75/Male	14APR2015 11:00	ACCUSOL 35	14K13G71	PRE-FILTER	15APR2015 03:30 / 15APR2015 07:40	20	5
009-003	75/Male	14APR2015 11:00	ACCUSOL 35	14K13G71	PRE-FILTER	15APR2015 07:40 / 15APR2015 11:30	20	5
009-003	75/Male	14APR2015 11:00	ACCUSOL 35	14K29G72	PRE-FILTER	15APR2015 11:30 / 15APR2015 14:00	20	5

Data Listing 16.2.5.3. ACCUSOL 35 Administration - Enrolled Population

Patient Number	Age (Years)/ Gender	First Accusol Administration Start Date/ Time	Dialysis Solution Used	Lot Number	Site of Introduction	Start Date and Time/ End Date and Time	Dialysis Dose (ml/kg/hr)	Amount Administered (L)
009-003	75/Male	14APR2015 11:00	ACCUSOL 35	14K29G72	PRE-FILTER	15APR2015 14:00 / 15APR2015 19:00	20	5
009-006	58/Female	22APR2015 18:00	ACCUSOL 35	14085011	PRE-FILTER	22APR2015 18:00 / 22APR2015 18:30	20	0.5
009-006	58/Female	22APR2015 18:00	ACCUSOL 35	14085011	PRE-FILTER	22APR2015 18:30 / 22APR2015 21:00	20	5
009-006	58/Female	22APR2015 18:00	ACCUSOL 35	14085011	PRE-FILTER	22APR2015 21:00 / 23APR2015 02:00	20	5
009-006	58/Female	22APR2015 18:00	ACCUSOL 35	14085011	PRE-FILTER	23APR2015 02:00 / 23APR2015 06:00	20	5
009-006	58/Female	22APR2015 18:00	ACCUSOL 35	14085011	PRE-FILTER	23APR2015 06:00 / 23APR2015 10:00	20	5
009-008	31/Male	29APR2015 17:00	ACCUSOL 35	UNK	PRE-FILTER	29APR2015 17:00 / 29APR2015 21:30	20	4.5
009-008	31/Male	29APR2015 17:00	ACCUSOL 35	UNK	PRE-FILTER	29APR2015 21:35 / 30APR2015 00:30	20	5
009-008	31/Male	29APR2015 17:00	ACCUSOL 35	UNK	PRE-FILTER	30APR2015 00:30 / 30APR2015 03:30	20	5
009-008	31/Male	29APR2015 17:00	ACCUSOL 35	UNK	PRE-FILTER	30APR2015 03:30 / 30APR2015 08:00	20	5
009-008	31/Male	29APR2015 17:00	ACCUSOL 35	UNK	PRE-FILTER	30APR2015 08:00 / 30APR2015 12:00	20	5

Data Listing 16.2.5.3. ACCUSOL 35 Administration - Enrolled Population

Patient Number	Age (Years)/ Gender	First Accusol Administration Start Date/ Time	Dialysis Solution Used	Lot Number	Site of Introduction	Start Date and Time/ End Date and Time	Dialysis Dose (ml/kg/hr)	Amount Administered (L)
009-008	31/Male	29APR2015 17:00	ACCUSOL 35	UNK	PRE-FILTER	30APR2015 12:00 / 30APR2015 16:00	20	5
009-008	31/Male	29APR2015 17:00	ACCUSOL 35	UNK	PRE-FILTER	30APR2015 16:00 / 30APR2015 19:00	20	5
009-008	31/Male	29APR2015 17:00	ACCUSOL 35	UNK	PRE-FILTER	30APR2015 19:00 / 30APR2015 22:00	20	5
009-008	31/Male	29APR2015 17:00	ACCUSOL 35	UNK	PRE-FILTER	30APR2015 22:00 / 01MAY2015 01:00	20	5
009-009		30APR2015 14:00	ACCUSOL 35	14K29G72	PRE-FILTER	30APR2015 14:00 / 30APR2015 19:00	20	5
009-009		30APR2015 14:00	ACCUSOL 35	14K29G72	PRE-FILTER	30APR2015 19:00 / 30APR2015 23:30	20	5
009-009		30APR2015 14:00	ACCUSOL 35	14I30G71	PRE-FILTER	30APR2015 23:30 / 01MAY2015 02:40	20	5
009-009		30APR2015 14:00	ACCUSOL 35	14I30G71	PRE-FILTER	01MAY2015 02:40 / 01MAY2015 06:45	20	5
009-009		30APR2015 14:00	ACCUSOL 35	14K29G72	PRE-FILTER	01MAY2015 06:45 / 01MAY2015 10:15	20	5
009-009		30APR2015 14:00	ACCUSOL 35	14K29G72	PRE-FILTER	01MAY2015 10:15 / 01MAY2015 13:35	20	5
009-009		30APR2015 14:00	ACCUSOL 35	14K13G71	PRE-FILTER	01MAY2015 13:35 / 01MAY2015 16:50	20	3

Data Listing 16.2.5.3. ACCUSOL 35 Administration - Enrolled Population

Patient Number	Age (Years)/ Gender	First Accusol Administration Start Date/ Time	Dialysis Solution Used	Lot Number	Site of Introduction	Start Date and Time/ End Date and Time	Dialysis Dose (ml/kg/hr)	Amount Administered (L)
009-011	75/Female	20MAY2015 20:00	ACCUSOL 35	14K30G70	PRE-FILTER	20MAY2015 20:00 / 20MAY2015 23:45	20	5
009-011	75/Female	20MAY2015 20:00	ACCUSOL 35	14K30G70	PRE-FILTER	20MAY2015 23:45 / 21MAY2015 04:00	20	5
009-011	75/Female	20MAY2015 20:00	ACCUSOL 35	14K30G70	PRE-FILTER	21MAY2015 04:00 / 21MAY2015 08:30	20	5
009-011	75/Female	20MAY2015 20:00	ACCUSOL 35	14K30G70	PRE-FILTER	21MAY2015 08:30 / 21MAY2015 12:55	20	5
009-013	60/Female	11JUN2015 10:00	ACCUSOL 35	15A09G70	PRE-FILTER	11JUN2015 10:00 / 11JUN2015 15:00	20	4
009-013	60/Female	11JUN2015 10:00	ACCUSOL 35	15A09G70	PRE-FILTER	11JUN2015 15:00 / 11JUN2015 20:20	20	5
009-013	60/Female	11JUN2015 10:00	ACCUSOL 35	14K30G70	PRE-FILTER	11JUN2015 20:20 / 12JUN2015 01:00	20	4.5
009-015	29/Male	17JUL2015 08:00	ACCUSOL 35	UNK	PRE-FILTER	17JUL2015 08:00 / 17JUL2015 12:00	20	5
009-015	29/Male	17JUL2015 08:00	ACCUSOL 35	15A09G71	PRE-FILTER	17JUL2015 12:00 / 17JUL2015 15:00	20	5
009-015	29/Male	17JUL2015 08:00	ACCUSOL 35	15A09G71	PRE-FILTER	17JUL2015 15:00 / 17JUL2015 18:35	20	5
009-016	83/Male	21JUL2015 13:00	ACCUSOL 35	15A09G71	PRE-FILTER	21JUL2015 13:00 / 21JUL2015 13:20	20	1

Data Listing 16.2.5.3. ACCUSOL 35 Administration - Enrolled Population

Patient Number	Age (Years)/ Gender	First Accusol Administration Start Date/ Time	Dialysis Solution Used	Lot Number	Site of Introduction	Start Date and Time/ End Date and Time	Dialysis Dose (ml/kg/hr)	Amount Administered (L)
009-017	51/Male	23JUL2015 13:00	ACCUSOL 35	15A09G71	PRE-FILTER	23JUL2015 13:00 / 23JUL2015 16:30	20	5
009-017	51/Male	23JUL2015 13:00	ACCUSOL 35	15A09G71	PRE-FILTER	23JUL2015 16:30 / 23JUL2015 19:30	20	4
009-018	44/Male	23JUL2015 18:00	ACCUSOL 35	15A09G71	PRE-FILTER	23JUL2015 18:00 / 23JUL2015 22:45	12	4
009-018	44/Male	23JUL2015 18:00	ACCUSOL 35	15A09G71	PRE-FILTER	23JUL2015 22:45 / 24JUL2015 04:25	12	5
009-018	44/Male	23JUL2015 18:00	ACCUSOL 35	15A09G71	PRE-FILTER	24JUL2015 04:25 / 24JUL2015 08:30	12	5
009-018	44/Male	23JUL2015 18:00	ACCUSOL 35	15A09G71	PRE-FILTER	24JUL2015 08:30 / 24JUL2015 13:00	12	5
009-018	44/Male	23JUL2015 18:00	ACCUSOL 35	15A09G71	PRE-FILTER	24JUL2015 13:00 / 24JUL2015 17:00	12	5
009-018	44/Male	23JUL2015 18:00	ACCUSOL 35	15A09G71	PRE-FILTER	24JUL2015 17:00 / 24JUL2015 22:45	12	5
009-018	44/Male	23JUL2015 18:00	ACCUSOL 35	15I04O14	PRE-FILTER	24JUL2015 22:45 / 25JUL2015 02:00	12	4
009-019	84/Male	27JUL2015 07:00	ACCUSOL 35	15A09G71	PRE-FILTER	27JUL2015 07:00 / 27JUL2015 09:30	20	2.5
009-019	84/Male	27JUL2015 07:00	ACCUSOL 35	15A09G71	PRE-FILTER	27JUL2015 09:30 / 27JUL2015 13:30	20	5

Data Listing 16.2.5.3. ACCUSOL 35 Administration - Enrolled Population

Patient Number	Age (Years)/ Gender	First Accusol Administration Start Date/ Time	Dialysis Solution Used	Lot Number	Site of Introduction	Start Date and Time/ End Date and Time	Dialysis Dose (ml/kg/hr)	Amount Administered (L)
009-019	84/Male	27JUL2015 07:00	ACCUSOL 35	15A09G71	PRE-FILTER	27JUL2015 13:30 / 27JUL2015 17:00	20	5
009-019	84/Male	27JUL2015 07:00	ACCUSOL 35	15A09G71	PRE-FILTER	27JUL2015 17:00 / 27JUL2015 21:00	20	5
009-019	84/Male	27JUL2015 07:00	ACCUSOL 35	15A09G71	PRE-FILTER	27JUL2015 21:00 / 28JUL2015 00:30	20	5
009-019	84/Male	27JUL2015 07:00	ACCUSOL 35	15A09G71	PRE-FILTER	28JUL2015 00:30 / 28JUL2015 04:00	20	5
009-019	84/Male	27JUL2015 07:00	ACCUSOL 35	15A09G71	PRE-FILTER	28JUL2015 04:00 / 28JUL2015 09:55	20	5
009-019	84/Male	27JUL2015 07:00	ACCUSOL 35	15A09G71	PRE-FILTER	28JUL2015 09:55 / 28JUL2015 11:40	20	2.5
009-021	51/Male	02AUG2015 17:00	ACCUSOL 35	15A09G70	PRE-FILTER	02AUG2015 17:00 / 02AUG2015 17:41	18.5	0.5
009-021	51/Male	02AUG2015 17:00	ACCUSOL 35	15A09G70	PRE-FILTER	02AUG2015 17:41 / 02AUG2015 21:20	18.5	5
009-021	51/Male	02AUG2015 17:00	ACCUSOL 35	15A09G70	PRE-FILTER	02AUG2015 21:20 / 03AUG2015 01:15	18.5	5
009-021	51/Male	02AUG2015 17:00	ACCUSOL 35	15A09G70	PRE-FILTER	03AUG2015 01:15 / 03AUG2015 04:20	18.5	5
009-021	51/Male	02AUG2015 17:00	ACCUSOL 35	L5A09G70	PRE-FILTER	03AUG2015 04:20 / 03AUG2015 07:54	18.5	5

Data Listing 16.2.5.3. ACCUSOL 35 Administration - Enrolled Population

Patient Number	Age (Years)/ Gender	First Accusol Administration Start Date/ Time	Dialysis Solution Used	Lot Number	Site of Introduction	Start Date and Time/ End Date and Time	Dialysis Dose (ml/kg/hr)	Amount Administered (L)
009-021	51/Male	02AUG2015 17:00	ACCUSOL 35	L5A09G70	PRE-FILTER	03AUG2015 07:54 / 03AUG2015 13:06	18.5	5
009-021	51/Male	02AUG2015 17:00	ACCUSOL 35	L5A09G70	PRE-FILTER	03AUG2015 13:06 / 03AUG2015 15:58	18.5	5
009-021	51/Male	02AUG2015 17:00	ACCUSOL 35	L5A09G70	PRE-FILTER	03AUG2015 15:58 / 03AUG2015 19:50	18.5	5
009-021	51/Male	02AUG2015 17:00	ACCUSOL 35	L5A09G70	PRE-FILTER	03AUG2015 19:50 / 03AUG2015 23:50	18.5	5
009-021	51/Male	02AUG2015 17:00	ACCUSOL 35	L5A09G70	PRE-FILTER	03AUG2015 23:50 / 04AUG2015 01:00	18.5	1.5
009-022		01AUG2015 11:05	ACCUSOL 35	15A09G71	PRE-FILTER	01AUG2015 11:05 / 01AUG2015 16:00	20	5
009-022		01AUG2015 11:05	ACCUSOL 35	15A09G71	PRE-FILTER	01AUG2015 11:05 / 01AUG2015 16:00	20	5
009-022		01AUG2015 11:05	ACCUSOL 35	15A09G71	PRE-FILTER	01AUG2015 16:00 / 01AUG2015 19:40	20	5
009-022		01AUG2015 11:05	ACCUSOL 35	15A09G70	PRE-FILTER	01AUG2015 16:00 / 01AUG2015 19:40	20	5
009-024	49/Female	29AUG2015 19:00	ACCUSOL 35	15C03G73	PRE-FILTER	29AUG2015 19:00 / 29AUG2015 22:00	20	4
009-024	49/Female	29AUG2015 19:00	ACCUSOL 35	15C03G72	PRE-FILTER	29AUG2015 22:00 / 30AUG2015 02:35	20	5

Data Listing 16.2.5.3. ACCUSOL 35 Administration - Enrolled Population

Patient Number	Age (Years)/ Gender	First Accusol Administration Start Date/ Time	Dialysis Solution Used	Lot Number	Site of Introduction	Start Date and Time/ End Date and Time	Dialysis Dose (ml/kg/hr)	Amount Administered (L)
009-024	49/Female	29AUG2015 19:00	ACCUSOL 35	15C03G72	PRE-FILTER	30AUG2015 02:35 / 30AUG2015 06:55	20	5
009-024	49/Female	29AUG2015 19:00	ACCUSOL 35	15C03G72	PRE-FILTER	30AUG2015 06:55 / 30AUG2015 11:30	20	5
009-024	49/Female	29AUG2015 19:00	ACCUSOL 35	15C03G72	PRE-FILTER	30AUG2015 11:30 / 30AUG2015 16:00	20	5
009-024	49/Female	29AUG2015 19:00	ACCUSOL 35	15C03G72	PRE-FILTER	30AUG2015 16:00 / 30AUG2015 19:00	20	5
009-024	49/Female	29AUG2015 19:00	ACCUSOL 35	15C03G72	PRE-FILTER	30AUG2015 19:00 / 30AUG2015 23:40	20	5
009-024	49/Female	29AUG2015 19:00	ACCUSOL 35	15C03G72	PRE-FILTER	30AUG2015 23:40 / 31AUG2015 03:00	20	5
009-026	76/Female	07OCT2015 08:00	ACCUSOL 35	15D12G70	PRE-FILTER	07OCT2015 08:00 / 07OCT2015 10:00	20	2
009-026	76/Female	07OCT2015 08:00	ACCUSOL 35	15D12G70	PRE-FILTER	07OCT2015 10:00 / 07OCT2015 14:30	20	5
009-026	76/Female	07OCT2015 08:00	ACCUSOL 35	15D12G70	PRE-FILTER	07OCT2015 14:30 / 07OCT2015 20:00	20	5
009-026	76/Female	07OCT2015 08:00	ACCUSOL 35	15D12G70	PRE-FILTER	07OCT2015 20:00 / 08OCT2015 00:15	20	5
009-026	76/Female	07OCT2015 08:00	ACCUSOL 35	15D12G70	PRE-FILTER	08OCT2015 00:15 / 08OCT2015 06:00	20	5

Data Listing 16.2.5.3. ACCUSOL 35 Administration - Enrolled Population

Patient Number	Age (Years)/ Gender	First Accusol Administration Start Date/ Time	Dialysis Solution Used	Lot Number	Site of Introduction	Start Date and Time/ End Date and Time	Dialysis Dose (ml/kg/hr)	Amount Administered (L)
009-026	76/Female	07OCT2015 08:00	ACCUSOL 35	15D12G70	PRE-FILTER	08OCT2015 06:00 / 08OCT2015 11:20	20	5
009-026	76/Female	07OCT2015 08:00	ACCUSOL 35	15D12G70	PRE-FILTER	08OCT2015 11:20 / 08OCT2015 16:00	20	5
009-027	53/Male	12OCT2015 22:00	ACCUSOL 35	15D12G70	PRE-FILTER	12OCT2015 22:00 / 12OCT2015 23:30	20	1.5
009-027	53/Male	12OCT2015 22:00	ACCUSOL 35	15D12G70	PRE-FILTER	12OCT2015 23:30 / 13OCT2015 04:30	20	5
009-027	53/Male	12OCT2015 22:00	ACCUSOL 35	15D12G70	PRE-FILTER	13OCT2015 04:30 / 13OCT2015 08:00	20	3.5
009-028		25NOV2015 21:00	ACCUSOL 35	15I04014	PRE-FILTER	25NOV2015 21:00 / 25NOV2015 23:30	20	3
009-028		25NOV2015 21:00	ACCUSOL 35	15I04014	PRE-FILTER	25NOV2015 23:30 / 26NOV2015 03:45	20	5
009-028		25NOV2015 21:00	ACCUSOL 35	15I04014	PRE-FILTER	26NOV2015 03:45 / 26NOV2015 08:30	20	5
009-028		25NOV2015 21:00	ACCUSOL 35	15I04014	PRE-FILTER	26NOV2015 08:30 / 26NOV2015 10:30	20	2.5
009-030	75/Male	17DEC2015 15:00	ACCUSOL 35 Potassium 4 mmol/L	15I22G72	PRE-FILTER	17DEC2015 15:00 / 17DEC2015 19:15	15.7	4.5
009-030	75/Male	17DEC2015 15:00	ACCUSOL 35 Potassium 4 mmol/L	15I22G72	PRE-FILTER	17DEC2015 19:15 / 17DEC2015 23:40	15.7	5

Data Listing 16.2.5.3. ACCUSOL 35 Administration - Enrolled Population

Patient Number	Age (Years)/ Gender	First Accusol Administration Start Date/ Time	Dialysis Solution Used	Lot Number	Site of Introduction	Start Date and Time/ End Date and Time	Dialysis Dose (ml/kg/hr)	Amount Administered (L)
009-030	75/Male	17DEC2015 15:00	ACCUSOL 35 Potassium 4 mmol/L	15I22G72	PRE-FILTER	17DEC2015 23:40 / 18DEC2015 04:00	15.7	5
009-030	75/Male	17DEC2015 15:00	ACCUSOL 35 Potassium 4 mmol/L	15I22G72	PRE-FILTER	18DEC2015 04:00 / 18DEC2015 08:30	15.7	5
009-030	75/Male	17DEC2015 15:00	ACCUSOL 35 Potassium 4 mmol/L	15I22G72	PRE-FILTER	18DEC2015 08:30 / 18DEC2015 13:10	15.7	5
009-030	75/Male	17DEC2015 15:00	ACCUSOL 35 Potassium 4 mmol/L	15I22G72	PRE-FILTER	18DEC2015 13:10 / 18DEC2015 18:00	15.7	5
009-030	75/Male	17DEC2015 15:00	ACCUSOL 35 Potassium 4 mmol/L	15I22G72	PRE-FILTER	18DEC2015 18:00 / 18DEC2015 22:15	15.7	5
009-030	75/Male	17DEC2015 15:00	ACCUSOL 35 Potassium 4 mmol/L	15I22G72	PRE-FILTER	18DEC2015 22:15 / 18DEC2015 23:00	15.7	0.5
009-031	34/Male	28JAN2016 11:00	ACCUSOL 35 Potassium 4 mmol/L	15J13G70	PRE-FILTER	28JAN2016 11:00 / 28JAN2016 15:00	10	5
009-031	34/Male	28JAN2016 11:00	ACCUSOL 35 Potassium 4 mmol/L	15J12G71	PRE-FILTER	28JAN2016 15:00 / 28JAN2016 18:00	10	5
009-031	34/Male	28JAN2016 11:00	ACCUSOL 35 Potassium 4 mmol/L	15I1267T	PRE-FILTER	28JAN2016 18:00 / 28JAN2016 19:10	10	1
009-032	59/Male	28JAN2016 06:00	ACCUSOL 35 Potassium 4 mmol/L	15J13G70	PRE-FILTER	28JAN2016 06:00 / 28JAN2016 07:30	29	4
009-032	59/Male	28JAN2016 06:00	ACCUSOL 35 Potassium 4 mmol/L	15J13G70	PRE-FILTER	28JAN2016 07:30 / 28JAN2016 09:00	29	5

Data Listing 16.2.5.3. ACCUSOL 35 Administration - Enrolled Population

Patient Number	Age (Years)/ Gender	First Accusol Administration Start Date/ Time	Dialysis Solution Used	Lot Number	Site of Introduction	Start Date and Time/ End Date and Time	Dialysis Dose (ml/kg/hr)	Amount Administered (L)
009-032	59/Male	28JAN2016 06:00	ACCUSOL 35 Potassium 4 mmol/L	15J13G70	PRE-FILTER	28JAN2016 09:00 / 28JAN2016 11:30	29	5
009-032	59/Male	28JAN2016 06:00	ACCUSOL 35 Potassium 4 mmol/L	15J13G70	PRE-FILTER	28JAN2016 11:30 / 28JAN2016 14:00	29	5
009-032	59/Male	28JAN2016 06:00	ACCUSOL 35 Potassium 4 mmol/L	15J13G70	PRE-FILTER	28JAN2016 14:00 / 28JAN2016 16:30	29	5
009-032	59/Male	28JAN2016 06:00	ACCUSOL 35 Potassium 4 mmol/L	15J13G70	PRE-FILTER	28JAN2016 16:30 / 28JAN2016 19:00	29	5
009-032	59/Male	28JAN2016 06:00	ACCUSOL 35 Potassium 4 mmol/L	15J13G70	PRE-FILTER	28JAN2016 19:00 / 28JAN2016 21:30	29	5
009-032	59/Male	28JAN2016 06:00	ACCUSOL 35 Potassium 4 mmol/L	15J13G70	PRE-FILTER	28JAN2016 21:30 / 29JAN2016 00:00	29	5
009-032	59/Male	28JAN2016 06:00	ACCUSOL 35 Potassium 4 mmol/L	15J13G70	PRE-FILTER	29JAN2016 00:00 / 29JAN2016 02:30	22	5
009-032	59/Male	28JAN2016 06:00	ACCUSOL 35 Potassium 4 mmol/L	15J13G70	PRE-FILTER	29JAN2016 02:30 / 29JAN2016 05:00	22	5
009-032	59/Male	28JAN2016 06:00	ACCUSOL 35 Potassium 4 mmol/L	15J13G70	PRE-FILTER	29JAN2016 05:00 / 29JAN2016 07:30	22	5
009-032	59/Male	28JAN2016 06:00	ACCUSOL 35 Potassium 4 mmol/L	15J13G70	PRE-FILTER	29JAN2016 07:30 / 29JAN2016 10:30	22	5
009-032	59/Male	28JAN2016 06:00	ACCUSOL 35 Potassium 4 mmol/L	15J13G70	PRE-FILTER	29JAN2016 10:30 / 29JAN2016 12:00	22	4

Data Listing 16.2.5.3. ACCUSOL 35 Administration - Enrolled Population

Patient Number	Age (Years)/ Gender	First Accusol Administration Start Date/ Time	Dialysis Solution Used	Lot Number	Site of Introduction	Start Date and Time/ End Date and Time	Dialysis Dose (ml/kg/hr)	Amount Administered (L)
010-002	57/Male	08MAY2015 09:00	ACCUSOL 35 Potassium 4 mmol/L	14K13G73	PRE AND POST	08MAY2015 09:00 / 08MAY2015 15:15	35.5	4.16
010-002	57/Male	08MAY2015 09:00	ACCUSOL 35 Potassium 4 mmol/L	14K13G73	PRE AND POST	08MAY2015 09:00 / 08MAY2015 15:15	35.5	4.16
010-002	57/Male	08MAY2015 09:00	ACCUSOL 35 Potassium 4 mmol/L	14K13G73	PRE AND POST	08MAY2015 09:00 / 08MAY2015 15:15	35.5	4.16
010-002	57/Male	08MAY2015 09:00	ACCUSOL 35 Potassium 4 mmol/L	14K13G73	PRE AND POST	08MAY2015 15:15 / 08MAY2015 22:00	35.5	5
010-002	57/Male	08MAY2015 09:00	ACCUSOL 35 Potassium 4 mmol/L	14K13G73	PRE AND POST	08MAY2015 15:15 / 08MAY2015 22:00	35.5	5
010-002	57/Male	08MAY2015 09:00	ACCUSOL 35 Potassium 4 mmol/L	14K13G73	PRE AND POST	08MAY2015 15:15 / 08MAY2015 22:00	35.5	5
010-002	57/Male	08MAY2015 09:00	ACCUSOL 35 Potassium 4 mmol/L	14K13G73	PRE AND POST	08MAY2015 22:00 / 09MAY2015 04:45	35.0	5
010-002	57/Male	08MAY2015 09:00	ACCUSOL 35 Potassium 4 mmol/L	14K13G73	PRE AND POST	08MAY2015 22:00 / 09MAY2015 04:45	35.0	5
010-002	57/Male	08MAY2015 09:00	ACCUSOL 35	14K13G70	PRE AND POST	08MAY2015 22:00 / 09MAY2015 04:45	35.0	5
010-002	57/Male	08MAY2015 09:00	ACCUSOL 35 Potassium 4 mmol/L	14K13G73	PRE AND POST	09MAY2015 04:45 / 09MAY2015 11:00	35.0	5
010-002	57/Male	08MAY2015 09:00	ACCUSOL 35 Potassium 4 mmol/L	14K13G73	PRE AND POST	09MAY2015 04:45 / 09MAY2015 11:00	35.0	5

Data Listing 16.2.5.3. ACCUSOL 35 Administration - Enrolled Population

Patient Number	Age (Years)/ Gender	First Accusol Administration Start Date/ Time	Dialysis Solution Used	Lot Number	Site of Introduction	Start Date and Time/ End Date and Time	Dialysis Dose (ml/kg/hr)	Amount Administered (L)
010-002	57/Male	08MAY2015 09:00	ACCUSOL 35 Potassium 4 mmol/L	14K13G73	PRE AND POST	09MAY2015 04:45 / 09MAY2015 11:00	35	5
010-002	57/Male	08MAY2015 09:00	ACCUSOL 35 Potassium 4 mmol/L	14K13G73	PRE AND POST	09MAY2015 11:00 / 09MAY2015 16:20	35.0	5
010-002	57/Male	08MAY2015 09:00	ACCUSOL 35 Potassium 4 mmol/L	14K13G73	PRE AND POST	09MAY2015 11:00 / 09MAY2015 16:20	35.0	5
010-002	57/Male	08MAY2015 09:00	ACCUSOL 35 Potassium 4 mmol/L	14K13G73	PRE AND POST	09MAY2015 11:00 / 09MAY2015 16:20	35.0	5
010-002	57/Male	08MAY2015 09:00	ACCUSOL 35 Potassium 4 mmol/L	14K13G73	PRE AND POST	09MAY2015 16:20 / 09MAY2015 17:00	35.0	2.86
010-003		09MAY2015 10:00	ACCUSOL 35 Potassium 4 mmol/L	14K13G73	PRE AND POST	09MAY2015 10:00 / 09MAY2015 14:20	31.8	3.4
010-003		09MAY2015 10:00	ACCUSOL 35 Potassium 4 mmol/L	14K13G73	PRE AND POST	09MAY2015 10:00 / 09MAY2015 14:20	31.8	3.4
010-003		09MAY2015 10:00	ACCUSOL 35 Potassium 4 mmol/L	14K13G73	PRE AND POST	09MAY2015 10:00 / 09MAY2015 14:20	31.8	3.4
010-003		09MAY2015 10:00	ACCUSOL 35 Potassium 4 mmol/L	14K13G73	PRE AND POST	09MAY2015 14:20 / 09MAY2015 14:50	31.6	0.49
010-003		09MAY2015 10:00	ACCUSOL 35 Potassium 4 mmol/L	14K13G73	PRE AND POST	09MAY2015 14:20 / 09MAY2015 14:50	31.6	0.49
010-003		09MAY2015 10:00	ACCUSOL 35 Potassium 4 mmol/L	14K13G73	PRE AND POST	09MAY2015 14:20 / 09MAY2015 14:50	31.6	0.49

Data Listing 16.2.5.3. ACCUSOL 35 Administration - Enrolled Population

Patient Number	Age (Years)/ Gender	First Accusol Administration Start Date/ Time	Dialysis Solution Used	Lot Number	Site of Introduction	Start Date and Time/ End Date and Time	Dialysis Dose (ml/kg/hr)	Amount Administered (L)
010-005	78/Male	05JUN2015 15:00	ACCUSOL 35 Potassium 4 mmol/L	15A07G71	PRE AND POST	05JUN2015 15:00 / 05JUN2015 18:50	35.5	2.8
010-005	78/Male	05JUN2015 15:00	ACCUSOL 35 Potassium 4 mmol/L	15A07G71	PRE AND POST	05JUN2015 15:00 / 05JUN2015 18:50	35.5	2.8
010-005	78/Male	05JUN2015 15:00	ACCUSOL 35 Potassium 4 mmol/L	15A07G71	PRE AND POST	05JUN2015 15:00 / 05JUN2015 18:50	35.5	2.8
010-005	78/Male	05JUN2015 15:00	ACCUSOL 35 Potassium 4 mmol/L	15A07G71	PRE AND POST	05JUN2015 18:50 / 06JUN2015 00:30	35.5	5
010-005	78/Male	05JUN2015 15:00	ACCUSOL 35 Potassium 4 mmol/L	15A07G71	PRE AND POST	05JUN2015 18:50 / 06JUN2015 00:30	35.5	5
010-005	78/Male	05JUN2015 15:00	ACCUSOL 35 Potassium 4 mmol/L	14I30G70	PRE AND POST	05JUN2015 18:50 / 06JUN2015 00:30	35.5	5
010-005	78/Male	05JUN2015 15:00	ACCUSOL 35 Potassium 4 mmol/L	15A07G71	PRE AND POST	06JUN2015 00:30 / 06JUN2015 06:45	35.5	5
010-005	78/Male	05JUN2015 15:00	ACCUSOL 35 Potassium 4 mmol/L	15A07G71	PRE AND POST	06JUN2015 00:30 / 06JUN2015 06:45	35.5	5
010-005	78/Male	05JUN2015 15:00	ACCUSOL 35 Potassium 4 mmol/L	14I30G70	PRE AND POST	06JUN2015 00:30 / 06JUN2015 06:45	35.5	5
010-005	78/Male	05JUN2015 15:00	ACCUSOL 35 Potassium 4 mmol/L	15A07G71	PRE AND POST	06JUN2015 06:45 / 06JUN2015 13:10	35.5	5
010-005	78/Male	05JUN2015 15:00	ACCUSOL 35 Potassium 4 mmol/L	15A07G71	PRE AND POST	06JUN2015 06:45 / 06JUN2015 13:10	35.5	5

Data Listing 16.2.5.3. ACCUSOL 35 Administration - Enrolled Population

Patient Number	Age (Years)/ Gender	First Accusol Administration Start Date/ Time	Dialysis Solution Used	Lot Number	Site of Introduction	Start Date and Time/ End Date and Time	Dialysis Dose (ml/kg/hr)	Amount Administered (L)
010-005	78/Male	05JUN2015 15:00	ACCUSOL 35 Potassium 4 mmol/L	14I30G71	PRE AND POST	06JUN2015 06:45 / 06JUN2015 13:10	35.5	5
010-005	78/Male	05JUN2015 15:00	ACCUSOL 35 Potassium 4 mmol/L	15D07G71	PRE AND POST	06JUN2015 13:10 / 06JUN2015 19:40	35.5	5
010-005	78/Male	05JUN2015 15:00	ACCUSOL 35 Potassium 4 mmol/L	15D07G71	PRE AND POST	06JUN2015 13:10 / 06JUN2015 19:40	35.5	5
010-005	78/Male	05JUN2015 15:00	ACCUSOL 35 Potassium 4 mmol/L	15D07G71	PRE AND POST	06JUN2015 13:10 / 06JUN2015 19:40	35.5	5
010-005	78/Male	05JUN2015 15:00	ACCUSOL 35 Potassium 4 mmol/L	15A07G71	PRE AND POST	06JUN2015 19:40 / 06JUN2015 23:00	35.5	4.35
010-005	78/Male	05JUN2015 15:00	ACCUSOL 35 Potassium 4 mmol/L	15A07G71	PRE AND POST	06JUN2015 19:40 / 06JUN2015 23:00	35.5	4.35
010-005	78/Male	05JUN2015 15:00	ACCUSOL 35 Potassium 4 mmol/L	15A07G71	PRE AND POST	06JUN2015 19:40 / 06JUN2015 23:00	35.5	4.35
010-006	80/Male	11JUN2015 15:00	ACCUSOL 35 Potassium 4 mmol/L	UNKNOWN	PRE AND POST	11JUN2015 15:00 / 11JUN2015 17:30	UNK	1.67
010-006	80/Male	11JUN2015 15:00	ACCUSOL 35 Potassium 4 mmol/L	UNKNOWN	PRE AND POST	11JUN2015 15:00 / 11JUN2015 17:30	UNK	1.67
010-006	80/Male	11JUN2015 15:00	ACCUSOL 35 Potassium 4 mmol/L	UNKNOWN	PRE AND POST	11JUN2015 15:00 / 11JUN2015 17:30	UNK	1.67
010-006	80/Male	11JUN2015 15:00	ACCUSOL 35 Potassium 4 mmol/L	UNKNOWN	PRE AND POST	11JUN2015 17:30 / 11JUN2015 22:25	UNK	5

Data Listing 16.2.5.3. ACCUSOL 35 Administration - Enrolled Population

Patient Number	Age (Years)/ Gender	First Accusol Administration Start Date/ Time	Dialysis Solution Used	Lot Number	Site of Introduction	Start Date and Time/ End Date and Time	Dialysis Dose (ml/kg/hr)	Amount Administered (L)
010-006	80/Male	11JUN2015 15:00	ACCUSOL 35 Potassium 4 mmol/L	UNKNOWN	PRE AND POST	11JUN2015 17:30 / 11JUN2015 22:25	UNK	5
010-006	80/Male	11JUN2015 15:00	ACCUSOL 35 Potassium 4 mmol/L	UNKNOWN	PRE AND POST	11JUN2015 17:30 / 11JUN2015 22:25	UNK	5
010-006	80/Male	11JUN2015 15:00	ACCUSOL 35 Potassium 4 mmol/L	UNKNOWN	PRE AND POST	11JUN2015 22:25 / 12JUN2015 05:00	UNK	5
010-006	80/Male	11JUN2015 15:00	ACCUSOL 35 Potassium 4 mmol/L	UNKNOWN	PRE AND POST	11JUN2015 22:25 / 12JUN2015 05:00	UNK	5
010-006	80/Male	11JUN2015 15:00	ACCUSOL 35 Potassium 4 mmol/L	UNKNOWN	PRE AND POST	11JUN2015 22:25 / 12JUN2015 05:00	UNK	5
010-006	80/Male	11JUN2015 15:00	ACCUSOL 35 Potassium 4 mmol/L	UNKNOWN	PRE AND POST	12JUN2015 05:00 / 12JUN2015 10:45	UNK	5
010-006	80/Male	11JUN2015 15:00	ACCUSOL 35 Potassium 4 mmol/L	UNKNOWN	PRE AND POST	12JUN2015 05:00 / 12JUN2015 10:45	UNK	5
010-006	80/Male	11JUN2015 15:00	ACCUSOL 35 Potassium 4 mmol/L	UNKNOWN	PRE AND POST	12JUN2015 05:00 / 12JUN2015 10:45	UNK	5
010-006	80/Male	11JUN2015 15:00	ACCUSOL 35 Potassium 4 mmol/L	UNKNOWN	PRE AND POST	12JUN2015 10:45 / 12JUN2015 20:25	UNK	5
010-006	80/Male	11JUN2015 15:00	ACCUSOL 35 Potassium 4 mmol/L	UNKNOWN	PRE AND POST	12JUN2015 10:45 / 12JUN2015 20:25	UNK	5
010-006	80/Male	11JUN2015 15:00	ACCUSOL 35 Potassium 4 mmol/L	UNKNOWN	PRE AND POST	12JUN2015 10:45 / 12JUN2015 20:25	UNK	5

Data Listing 16.2.5.3. ACCUSOL 35 Administration - Enrolled Population

Patient Number	Age (Years)/ Gender	First Accusol Administration Start Date/ Time	Dialysis Solution Used	Lot Number	Site of Introduction	Start Date and Time/ End Date and Time	Dialysis Dose (ml/kg/hr)	Amount Administered (L)
010-006	80/Male	11JUN2015 15:00	ACCUSOL 35 Potassium 4 mmol/L	UNKNOWN	PRE AND POST	12JUN2015 20:25 / 12JUN2015 23:00	UNK	1.96
010-006	80/Male	11JUN2015 15:00	ACCUSOL 35 Potassium 4 mmol/L	UNKNOWN	PRE AND POST	12JUN2015 20:25 / 12JUN2015 23:00	UNK	1.96
010-006	80/Male	11JUN2015 15:00	ACCUSOL 35 Potassium 4 mmol/L	UNKNOWN	PRE AND POST	12JUN2015 20:25 / 12JUN2015 23:00	UNK	1.96
010-008	70/Female	28JUN2015 21:00	ACCUSOL 35 Potassium 4 mmol/L	15C02G70	PRE/POST FILTER	28JUN2015 21:00 / 29JUN2015 01:00	35	2.11
010-008	70/Female	28JUN2015 21:00	ACCUSOL 35 Potassium 4 mmol/L	15C02G70	PRE/POST FILTER	28JUN2015 21:00 / 29JUN2015 01:00	35	2.11
010-008	70/Female	28JUN2015 21:00	ACCUSOL 35 Potassium 4 mmol/L	15C02G70	PRE/POST FILTER	28JUN2015 21:00 / 29JUN2015 01:00	35	2.11
010-009	69/Male	28JUN2015 20:00	ACCUSOL 35 Potassium 4 mmol/L	15C02G70	PRE-POST FILTER	28JUN2015 20:00 / 28JUN2015 22:30	UNK	1.92
010-009	69/Male	28JUN2015 20:00	ACCUSOL 35 Potassium 4 mmol/L	15C02G70	PRE/POST FILTER	28JUN2015 20:00 / 28JUN2015 22:30	UNK	1.92
010-009	69/Male	28JUN2015 20:00	ACCUSOL 35 Potassium 4 mmol/L	15C02G70	PRE/POST FILTER	28JUN2015 20:00 / 28JUN2015 22:30	UNK	1.92
010-010	52/Female			UNK	UNKNOWN		UNK	.
010-011		30SEP2015 16:15	ACCUSOL 35 Potassium 4 mmol/L	15C03G75	PRE AND POST	30SEP2015 16:15 / 30SEP2015 17:00	35	1.61

Data Listing 16.2.5.3. ACCUSOL 35 Administration - Enrolled Population

Patient Number	Age (Years)/ Gender	First Accusol Administration Start Date/ Time	Dialysis Solution Used	Lot Number	Site of Introduction	Start Date and Time/ End Date and Time	Dialysis Dose (ml/kg/hr)	Amount Administered (L)
010-011		30SEP2015 16:15	ACCUSOL 35 Potassium 4 mmol/L	15C03G75	PRE AND POST	30SEP2015 16:15 / 30SEP2015 17:00	35	1.61
010-011		30SEP2015 16:15	ACCUSOL 35 Potassium 4 mmol/L	15C03G75	PRE AND POST	30SEP2015 16:15 / 30SEP2015 17:00	35	1.61
010-014	79/Female	12JAN2016 12:00	ACCUSOL 35 Potassium 4 mmol/L	15S12G71	PRE AND POST	12JAN2016 12:00 / 12JAN2016 15:42	35	2.66
010-014	79/Female	12JAN2016 12:00	ACCUSOL 35 Potassium 4 mmol/L	15S12G71	PRE AND POST	12JAN2016 12:00 / 12JAN2016 15:42	35	2.66
010-014	79/Female	12JAN2016 12:00	ACCUSOL 35 Potassium 4 mmol/L	15S12G71	PRE AND POST	12JAN2016 12:00 / 12JAN2016 15:42	35	2.66
010-014	79/Female	12JAN2016 12:00	ACCUSOL 35 Potassium 4 mmol/L	15S12G71	PRE AND POST	12JAN2016 15:42 / 12JAN2016 21:20	35	4.05
010-014	79/Female	12JAN2016 12:00	ACCUSOL 35 Potassium 4 mmol/L	15S12G71	PRE AND POST	12JAN2016 15:42 / 12JAN2016 21:20	35	4.05
010-014	79/Female	12JAN2016 12:00	ACCUSOL 35 Potassium 4 mmol/L	15S12G71	PRE AND POST	12JAN2016 15:42 / 12JAN2016 21:20	35	4.05
011-001	53/Male	30APR2015 07:00	ACCUSOL 35	14K28G70	AS DIALYSATE	30APR2015 07:00 / 30APR2015 09:05	40	4.5
011-001	53/Male	30APR2015 07:00	ACCUSOL 35 Potassium 4 mmol/L	14K28G70	AS DIALYSATE	30APR2015 09:05 / 30APR2015 10:10	40	2
011-002	75/Male	30APR2015 07:00	ACCUSOL 35 Potassium 4 mmol/L	14K12G70	AS DIALYSATE	30APR2015 07:00 / 30APR2015 08:00	40	1

Data Listing 16.2.5.3. ACCUSOL 35 Administration - Enrolled Population

Patient Number	Age (Years)/ Gender	First Accusol Administration Start Date/ Time	Dialysis Solution Used	Lot Number	Site of Introduction	Start Date and Time/ End Date and Time	Dialysis Dose (ml/kg/hr)	Amount Administered (L)
011-002	75/Male	30APR2015 07:00	ACCUSOL 35 Potassium 4 mmol/L	14K28G70	PRE AND POST FILTER	30APR2015 08:00 / 30APR2015 10:15	40	5
011-002	75/Male	30APR2015 07:00	ACCUSOL 35 Potassium 4 mmol/L	14K12G70	PRE AND POST FILTER	30APR2015 10:15 / 30APR2015 12:00	40	5
011-003	80/Male	04JUN2015 14:45	ACCUSOL 35 Potassium 4 mmol/L	14K28G70	AS DIALYSATE	04JUN2015 14:45 / 04JUN2015 15:10	29.0	0.5
011-003	80/Male	04JUN2015 14:45	ACCUSOL 35	14K13670	AS DIALYSATE	04JUN2015 15:10 / 04JUN2015 17:15	29.2	5
011-003	80/Male	04JUN2015 14:45	ACCUSOL 35	14G15670	AS DIALYSATE	04JUN2015 17:15 / 04JUN2015 19:31	29.1	5
011-003	80/Male	04JUN2015 14:45	ACCUSOL 35 Potassium 4 mmol/L	15A07671	AS DIALYSATE	04JUN2015 19:31 / 04JUN2015 21:40	29.0	5
011-003	80/Male	04JUN2015 14:45	ACCUSOL 35 Potassium 4 mmol/L	15A07671	AS DIALYSATE	04JUN2015 21:40 / 04JUN2015 23:45	29.0	5
011-003	80/Male	04JUN2015 14:45	ACCUSOL 35 Potassium 4 mmol/L	14K28970	AS DIALYSATE	04JUN2015 23:45 / 05JUN2015 01:55	29.0	5
011-003	80/Male	04JUN2015 14:45	ACCUSOL 35 Potassium 4 mmol/L	14K28970	AS DIALYSATE	05JUN2015 01:55 / 05JUN2015 04:00	28.9	5
011-003	80/Male	04JUN2015 14:45	ACCUSOL 35 Potassium 4 mmol/L	14K28970	AS DIALYSATE	05JUN2015 04:00 / 05JUN2015 06:00	30.2	5
011-003	80/Male	04JUN2015 14:45	ACCUSOL 35 Potassium 4 mmol/L	14K28970	AS DIALYSATE	05JUN2015 06:00 / 05JUN2015 08:15	28.8	5

Data Listing 16.2.5.3. ACCUSOL 35 Administration - Enrolled Population

Patient Number	Age (Years)/ Gender	First Accusol Administration Start Date/ Time	Dialysis Solution Used	Lot Number	Site of Introduction	Start Date and Time/ End Date and Time	Dialysis Dose (ml/kg/hr)	Amount Administered (L)
011-003	80/Male	04JUN2015 14:45	ACCUSOL 35 Potassium 4 mmol/L	14K28970	AS DIALYSATE	05JUN2015 08:15 / 05JUN2015 09:30	28.8	5
011-004	80/Female	09JUN2015 07:00	ACCUSOL 35 Potassium 4 mmol/L	14K28G70	AS DIALYSATE	09JUN2015 07:00 / 09JUN2015 08:40	40	1
011-004	80/Female	09JUN2015 07:00	ACCUSOL 35 Potassium 4 mmol/L	14K28G72	AS DIALYSATE	09JUN2015 07:00 / 09JUN2015 08:40	40	1
011-004	80/Female	09JUN2015 07:00	ACCUSOL 35 Potassium 4 mmol/L	14K28G71	AS DIALYSATE	09JUN2015 07:00 / 09JUN2015 08:40	40	1
011-004	80/Female	09JUN2015 07:00	ACCUSOL 35 Potassium 4 mmol/L	15A07G71	AS DIALYSATE	09JUN2015 08:40 / 09JUN2015 14:55	40	5
011-004	80/Female	09JUN2015 07:00	ACCUSOL 35 Potassium 4 mmol/L	15A07G71	AS DIALYSATE	09JUN2015 08:40 / 09JUN2015 14:55	40	5
011-004	80/Female	09JUN2015 07:00	ACCUSOL 35 Potassium 4 mmol/L	15A07G71	AS DIALYSATE	09JUN2015 08:40 / 09JUN2015 14:55	40	5
011-004	80/Female	09JUN2015 07:00	ACCUSOL 35 Potassium 4 mmol/L	15A07G71	AS DIALYSATE	09JUN2015 14:55 / 09JUN2015 21:30	40	5
011-004	80/Female	09JUN2015 07:00	ACCUSOL 35 Potassium 4 mmol/L	15A07G71	AS DIALYSATE	09JUN2015 14:55 / 09JUN2015 21:30	40	5
011-004	80/Female	09JUN2015 07:00	ACCUSOL 35	14K29G72	AS DIALYSATE	09JUN2015 14:55 / 09JUN2015 21:30	40	5
011-004	80/Female	09JUN2015 07:00	ACCUSOL 35 Potassium 4 mmol/L	15A07G71	AS DIALYSATE	09JUN2015 21:30 / 10JUN2015 02:30	40	5

Data Listing 16.2.5.3. ACCUSOL 35 Administration - Enrolled Population

Patient Number	Age (Years)/ Gender	First Accusol Administration Start Date/ Time	Dialysis Solution Used	Lot Number	Site of Introduction	Start Date and Time/ End Date and Time	Dialysis Dose (ml/kg/hr)	Amount Administered (L)
011-004	80/Female	09JUN2015 07:00	ACCUSOL 35 Potassium 4 mmol/L	15A07G71	AS DIALYSATE	09JUN2015 21:30 / 10JUN2015 02:30	40	5
011-004	80/Female	09JUN2015 07:00	ACCUSOL 35	14K29G72	AS DIALYSATE	09JUN2015 21:30 / 10JUN2015 02:30	40	5
011-004	80/Female	09JUN2015 07:00	ACCUSOL 35 Potassium 4 mmol/L	15802G70	AS DIALYSATE	10JUN2015 02:30 / 10JUN2015 08:15	40	5
011-004	80/Female	09JUN2015 07:00	ACCUSOL 35 Potassium 4 mmol/L	15802G70	AS DIALYSATE	10JUN2015 02:30 / 10JUN2015 08:15	40	5
011-004	80/Female	09JUN2015 07:00	ACCUSOL 35	14K29G72	AS DIALYSATE	10JUN2015 02:30 / 10JUN2015 08:15	40	5
011-004	80/Female	09JUN2015 07:00	ACCUSOL 35 Potassium 4 mmol/L	15B02G70	AS DIALYSATE	10JUN2015 08:15 / 10JUN2015 14:35	40	5
011-004	80/Female	09JUN2015 07:00	ACCUSOL 35	14K29G72	AS DIALYSATE	10JUN2015 08:15 / 10JUN2015 14:35	40	5
011-004	80/Female	09JUN2015 07:00	ACCUSOL 35 Potassium 4 mmol/L	15A07G71	AS DIALYSATE	10JUN2015 08:15 / 10JUN2015 14:35	40	5
011-004	80/Female	09JUN2015 07:00	ACCUSOL 35 Potassium 4 mmol/L	15B02G70	AS DIALYSATE	10JUN2015 14:35 / 10JUN2015 15:00	40	0.5
011-004	80/Female	09JUN2015 07:00	ACCUSOL 35 Potassium 4 mmol/L	15B02G70	AS DIALYSATE	10JUN2015 14:35 / 10JUN2015 15:00	40	0.5
011-004	80/Female	09JUN2015 07:00	ACCUSOL 35	14K29G72	AS DIALYSATE	10JUN2015 14:35 / 10JUN2015 15:00	40	0.5

Data Listing 16.2.5.3. ACCUSOL 35 Administration - Enrolled Population

Patient Number	Age (Years)/ Gender	First Accusol Administration Start Date/ Time	Dialysis Solution Used	Lot Number	Site of Introduction	Start Date and Time/ End Date and Time	Dialysis Dose (ml/kg/hr)	Amount Administered (L)
011-005	78/Male	11JUN2015 10:00	ACCUSOL 35 Potassium 4 mmol/L	NOT RECORDED	AS DIALYSATE	11JUN2015 10:00 / 11JUN2015 11:31	40	1
011-006	77/Male	04JUL2015 09:00	ACCUSOL 35 Potassium 4 mmol/L	L5B02G70	AS DIALYSATE	04JUL2015 09:00 / 04JUL2015 10:00	40	1
011-006	77/Male	04JUL2015 09:00	ACCUSOL 35 Potassium 4 mmol/L	L5B02G70	AS DIALYSATE	04JUL2015 10:00 / 04JUL2015 12:20	40	5
011-006	77/Male	04JUL2015 09:00	ACCUSOL 35 Potassium 4 mmol/L	L5B02G70	AS DIALYSATE	04JUL2015 12:20 / 04JUL2015 14:30	40	5
011-006	77/Male	04JUL2015 09:00	ACCUSOL 35 Potassium 4 mmol/L	L5B02G70	AS DIALYSATE	04JUL2015 14:30 / 04JUL2015 16:40	40	5
011-006	77/Male	04JUL2015 09:00	ACCUSOL 35 Potassium 4 mmol/L	L4K28G70	AS DIALYSATE	04JUL2015 16:40 / 04JUL2015 19:00	40	5
011-006	77/Male	04JUL2015 09:00	ACCUSOL 35 Potassium 4 mmol/L	L5B02G70	AS DIALYSATE	04JUL2015 19:00 / 04JUL2015 21:05	31	5
011-006	77/Male	04JUL2015 09:00	ACCUSOL 35 Potassium 4 mmol/L	L5B02G70	AS DIALYSATE	04JUL2015 21:05 / 04JUL2015 23:30	25	5
011-006	77/Male	04JUL2015 09:00	ACCUSOL 35 Potassium 4 mmol/L	L5B02G70	AS DIALYSATE	04JUL2015 23:30 / 05JUL2015 02:20	25	5
011-006	77/Male	04JUL2015 09:00	ACCUSOL 35 Potassium 4 mmol/L	L5B02G70	AS DIALYSATE	05JUL2015 02:20 / 05JUL2015 06:00	25	5
011-007	62/Female	02OCT2015 05:00	ACCUSOL 35 Potassium 4 mmol/L	UNK	AS DIALYSATE	02OCT2015 05:00 / 02OCT2015 06:05	40	2

Data Listing 16.2.5.3. ACCUSOL 35 Administration - Enrolled Population

Patient Number	Age (Years)/ Gender	First Accusol Administration Start Date/ Time	Dialysis Solution Used	Lot Number	Site of Introduction	Start Date and Time/ End Date and Time	Dialysis Dose (ml/kg/hr)	Amount Administered (L)
011-008	61/Male	05OCT2015 10:00	ACCUSOL 35 Potassium 4 mmol/L	15C01G70	AS DIALYSATE	05OCT2015 10:00 / 05OCT2015 11:30	40	2
011-009	71/Female	06OCT2015 18:00	ACCUSOL 35 Potassium 4 mmol/L	15C02G70	AS DIALYSATE	06OCT2015 18:00 / 06OCT2015 19:05	40	2.5
011-009	71/Female	06OCT2015 18:00	ACCUSOL 35 Potassium 4 mmol/L	15C02G71	AS DIALYSATE	06OCT2015 19:05 / 06OCT2015 21:20	40	5
011-009	71/Female	06OCT2015 18:00	ACCUSOL 35	15D12G70	AS DIALYSATE	06OCT2015 21:20 / 06OCT2015 22:30	40	1
011-010	47/Male	12OCT2015 10:50	ACCUSOL 35 Potassium 4 mmol/L	15C02G71	AS DIALYSATE	12OCT2015 10:50 / 12OCT2015 12:10	40	5
011-010	47/Male	12OCT2015 10:50	ACCUSOL 35 Potassium 4 mmol/L	15C02G71	AS DIALYSATE	12OCT2015 12:10 / 12OCT2015 14:00	40	5
011-010	47/Male	12OCT2015 10:50	ACCUSOL 35 Potassium 4 mmol/L	15C02G71	AS DIALYSATE	12OCT2015 14:00 / 12OCT2015 16:20	40	5
011-010	47/Male	12OCT2015 10:50	ACCUSOL 35 Potassium 4 mmol/L	15C02G71	AS DIALYSATE	12OCT2015 16:20 / 12OCT2015 17:00	40	1
011-011	77/Male	15OCT2015 09:00	ACCUSOL 35	UNKNOWN	AS DIALYSATE	15OCT2015 09:00 / 15OCT2015 11:00	40	5
011-011	77/Male	15OCT2015 09:00	ACCUSOL 35 Potassium 4 mmol/L	UNKNOWN	AS DIALYSATE	15OCT2015 11:00 / 15OCT2015 13:00	40	5
011-011	77/Male	15OCT2015 09:00	ACCUSOL 35 Potassium 4 mmol/L	UNKNOWN	AS DIALYSATE	15OCT2015 13:00 / 15OCT2015 15:45	40	5

Data Listing 16.2.5.3. ACCUSOL 35 Administration - Enrolled Population

Patient Number	Age (Years)/ Gender	First Accusol Administration Start Date/ Time	Dialysis Solution Used	Lot Number	Site of Introduction	Start Date and Time/ End Date and Time	Dialysis Dose (ml/kg/hr)	Amount Administered (L)
011-011	77/Male	15OCT2015 09:00	ACCUSOL 35 Potassium 4 mmol/L	UNKNOWN	AS DIALYSATE	15OCT2015 15:45 / 15OCT2015 18:30	40	5
011-011	77/Male	15OCT2015 09:00	ACCUSOL 35 Potassium 4 mmol/L	UNKNOWN	AS DIALYSATE	15OCT2015 18:30 / 15OCT2015 20:10	40	5
011-011	77/Male	15OCT2015 09:00	ACCUSOL 35 Potassium 4 mmol/L	UNKNOWN	AS DIALYSATE	15OCT2015 20:10 / 15OCT2015 21:15	40	5
011-011	77/Male	15OCT2015 09:00	ACCUSOL 35 Potassium 4 mmol/L	UNKNOWN	AS DIALYSATE	15OCT2015 21:15 / 15OCT2015 22:00	40	5
011-011	77/Male	15OCT2015 09:00	ACCUSOL 35 Potassium 4 mmol/L	UNKNOWN	AS DIALYSATE	15OCT2015 22:00 / 16OCT2015 00:15	40	5
011-011	77/Male	15OCT2015 09:00	ACCUSOL 35 Potassium 4 mmol/L	UNKNOWN	AS DIALYSATE	16OCT2015 00:15 / 16OCT2015 02:30	40	5
011-011	77/Male	15OCT2015 09:00	ACCUSOL 35 Potassium 4 mmol/L	UNKNOWN	AS DIALYSATE	16OCT2015 02:30 / 16OCT2015 03:35	40	5
011-011	77/Male	15OCT2015 09:00	ACCUSOL 35 Potassium 4 mmol/L	UNKNOWN	AS DIALYSATE	16OCT2015 03:35 / 16OCT2015 04:45	40	5
011-011	77/Male	15OCT2015 09:00	ACCUSOL 35 Potassium 4 mmol/L	UNKNOWN	AS DIALYSATE	16OCT2015 04:45 / 16OCT2015 06:50	40	5
011-011	77/Male	15OCT2015 09:00	ACCUSOL 35 Potassium 4 mmol/L	UNKNOWN	AS DIALYSATE	16OCT2015 06:50 / 16OCT2015 09:25	40	5
011-011	77/Male	15OCT2015 09:00	ACCUSOL 35 Potassium 4 mmol/L	15D12G70	AS DIALYSATE	16OCT2015 09:25 / 16OCT2015 11:00	40	3

Data Listing 16.2.5.3. ACCUSOL 35 Administration - Enrolled Population

Patient Number	Age (Years)/ Gender	First Accusol Administration Start Date/ Time	Dialysis Solution Used	Lot Number	Site of Introduction	Start Date and Time/ End Date and Time	Dialysis Dose (ml/kg/hr)	Amount Administered (L)
011-012	74/Male	20OCT2015 03:45	ACCUSOL 35 Potassium 4 mmol/L	15D12G70	AS DIALYSATE	20OCT2015 03:45 / 20OCT2015 05:12	27.6	3
011-012	74/Male	20OCT2015 03:45	ACCUSOL 35	15H28G72	AS DIALYSATE	20OCT2015 05:12 / 20OCT2015 07:20	27.6	5
011-012	74/Male	20OCT2015 03:45	ACCUSOL 35	15D12G70	AS DIALYSATE	20OCT2015 07:20 / 20OCT2015 09:25	27.6	5
011-012	74/Male	20OCT2015 03:45	ACCUSOL 35	15D12G70	AS DIALYSATE	20OCT2015 09:25 / 20OCT2015 11:40	27.5	5
011-012	74/Male	20OCT2015 03:45	ACCUSOL 35 Potassium 4 mmol/L	15H28G72	AS DIALYSATE	20OCT2015 11:40 / 20OCT2015 13:45	27.5	5
011-012	74/Male	20OCT2015 03:45	ACCUSOL 35 Potassium 4 mmol/L	15H28G72	AS DIALYSATE	20OCT2015 13:45 / 20OCT2015 15:55	27.5	5
011-012	74/Male	20OCT2015 03:45	ACCUSOL 35	15D12G70	AS DIALYSATE	20OCT2015 15:55 / 20OCT2015 18:30	27.4	5
011-012	74/Male	20OCT2015 03:45	ACCUSOL 35 Potassium 4 mmol/L	15H28G72	AS DIALYSATE	20OCT2015 18:30 / 20OCT2015 20:30	27.3	5
011-012	74/Male	20OCT2015 03:45	ACCUSOL 35 Potassium 4 mmol/L	15H28G72	AS DIALYSATE	20OCT2015 20:30 / 20OCT2015 22:40	27.3	5
011-012	74/Male	20OCT2015 03:45	ACCUSOL 35 Potassium 4 mmol/L	15H28G72	AS DIALYSATE	20OCT2015 22:40 / 21OCT2015 00:50	27.3	5
011-012	74/Male	20OCT2015 03:45	ACCUSOL 35	15D12G70	AS DIALYSATE	21OCT2015 00:50 / 21OCT2015 02:52	27.4	5

Data Listing 16.2.5.3. ACCUSOL 35 Administration - Enrolled Population

Patient Number	Age (Years)/ Gender	First Accusol Administration Start Date/ Time	Dialysis Solution Used	Lot Number	Site of Introduction	Start Date and Time/ End Date and Time	Dialysis Dose (ml/kg/hr)	Amount Administered (L)
011-012	74/Male	20OCT2015 03:45	ACCUSOL 35 Potassium 4 mmol/L	15H28G72	AS DIALYSATE	21OCT2015 02:52 / 21OCT2015 05:05	27.4	5
011-012	74/Male	20OCT2015 03:45	ACCUSOL 35 Potassium 4 mmol/L	15H28G72	AS DIALYSATE	21OCT2015 05:05 / 21OCT2015 07:10	27.4	5
011-012	74/Male	20OCT2015 03:45	ACCUSOL 35 Potassium 4 mmol/L	15H28G72	AS DIALYSATE	21OCT2015 07:10 / 21OCT2015 09:17	27.4	5
011-012	74/Male	20OCT2015 03:45	ACCUSOL 35 Potassium 4 mmol/L	15H28G72	AS DIALYSATE	21OCT2015 09:17 / 21OCT2015 11:31	27.5	5
011-012	74/Male	20OCT2015 03:45	ACCUSOL 35 Potassium 4 mmol/L	15H28G72	AS DIALYSATE	21OCT2015 11:31 / 21OCT2015 11:45	27.5	0.5
011-013	71/Female	26OCT2015 17:00	ACCUSOL 35 Potassium 4 mmol/L	15E07G72	AS DIALYSATE	26OCT2015 17:00 / 26OCT2015 18:10	40	2.5
011-013	71/Female	26OCT2015 17:00	ACCUSOL 35 Potassium 4 mmol/L	15E07G72	AS DIALYSATE	26OCT2015 18:10 / 26OCT2015 19:30	40	5
011-013	71/Female	26OCT2015 17:00	ACCUSOL 35 Potassium 4 mmol/L	15E07G72	AS DIALYSATE	26OCT2015 19:30 / 26OCT2015 20:55	40	5
011-013	71/Female	26OCT2015 17:00	ACCUSOL 35 Potassium 4 mmol/L	15E07G72	AS DIALYSATE	26OCT2015 20:55 / 26OCT2015 22:35	40	5
011-013	71/Female	26OCT2015 17:00	ACCUSOL 35 Potassium 4 mmol/L	15E07G72	AS DIALYSATE	26OCT2015 22:35 / 27OCT2015 00:05	40	5
011-013	71/Female	26OCT2015 17:00	ACCUSOL 35 Potassium 4 mmol/L	15E07G72	AS DIALYSATE	27OCT2015 00:05 / 27OCT2015 01:30	40	5

Data Listing 16.2.5.3. ACCUSOL 35 Administration - Enrolled Population

Patient Number	Age (Years)/ Gender	First Accusol Administration Start Date/ Time	Dialysis Solution Used	Lot Number	Site of Introduction	Start Date and Time/ End Date and Time	Dialysis Dose (ml/kg/hr)	Amount Administered (L)
011-013	71/Female	26OCT2015 17:00	ACCUSOL 35 Potassium 4 mmol/L	15E07G72	AS DIALYSATE	27OCT2015 01:30 / 27OCT2015 03:00	40	5
011-013	71/Female	26OCT2015 17:00	ACCUSOL 35 Potassium 4 mmol/L	15E07G72	AS DIALYSATE	27OCT2015 03:00 / 27OCT2015 04:35	40	5
011-013	71/Female	26OCT2015 17:00	ACCUSOL 35 Potassium 4 mmol/L	15E07G72	AS DIALYSATE	27OCT2015 04:35 / 27OCT2015 06:05	40	5
011-013	71/Female	26OCT2015 17:00	ACCUSOL 35 Potassium 4 mmol/L	15E07G72	AS DIALYSATE	27OCT2015 06:05 / 27OCT2015 07:45	40	5
011-013	71/Female	26OCT2015 17:00	ACCUSOL 35 Potassium 4 mmol/L	15E07G72	AS DIALYSATE	27OCT2015 07:45 / 27OCT2015 09:15	40	5
011-013	71/Female	26OCT2015 17:00	ACCUSOL 35 Potassium 4 mmol/L	15E07G72	AS DIALYSATE	27OCT2015 09:15 / 27OCT2015 11:00	40	5
011-013	71/Female	26OCT2015 17:00	ACCUSOL 35 Potassium 4 mmol/L	15E07G72	AS DIALYSATE	27OCT2015 11:00 / 27OCT2015 13:00	40	5
011-013	71/Female	26OCT2015 17:00	ACCUSOL 35 Potassium 4 mmol/L	15E07G72	AS DIALYSATE	27OCT2015 13:00 / 27OCT2015 15:20	40	5
011-013	71/Female	26OCT2015 17:00	ACCUSOL 35 Potassium 4 mmol/L	15E07G72	AS DIALYSATE	27OCT2015 15:20 / 27OCT2015 17:15	40	5
011-013	71/Female	26OCT2015 17:00	ACCUSOL 35 Potassium 4 mmol/L	15E07G72	AS DIALYSATE	27OCT2015 17:15 / 27OCT2015 19:15	40	5
011-013	71/Female	26OCT2015 17:00	ACCUSOL 35 Potassium 4 mmol/L	15E07G72	AS DIALYSATE	27OCT2015 19:15 / 27OCT2015 21:55	40	5

Data Listing 16.2.5.3. ACCUSOL 35 Administration - Enrolled Population

Patient Number	Age (Years)/ Gender	First Accusol Administration Start Date/ Time	Dialysis Solution Used	Lot Number	Site of Introduction	Start Date and Time/ End Date and Time	Dialysis Dose (ml/kg/hr)	Amount Administered (L)
011-013	71/Female	26OCT2015 17:00	ACCUSOL 35 Potassium 4 mmol/L	15E07G72	AS DIALYSATE	27OCT2015 21:55 / 28OCT2015 00:10	40	5
011-013	71/Female	26OCT2015 17:00	ACCUSOL 35 Potassium 4 mmol/L	15E07G72	AS DIALYSATE	28OCT2015 00:10 / 28OCT2015 01:00	40	2.5
011-014	79/Female	03NOV2015 18:30	ACCUSOL 35 Potassium 4 mmol/L	15E07G72	AS DIALYSATE	03NOV2015 18:30 / 03NOV2015 19:25	32.7	1
011-014	79/Female	03NOV2015 18:30	ACCUSOL 35 Potassium 4 mmol/L	15H28G72	AS DIALYSATE	03NOV2015 19:25 / 03NOV2015 22:00	32.6	5
011-014	79/Female	03NOV2015 18:30	ACCUSOL 35 Potassium 4 mmol/L	15E07G72	AS DIALYSATE	03NOV2015 22:00 / 03NOV2015 23:20	32.7	5
011-014	79/Female	03NOV2015 18:30	ACCUSOL 35	15D16G70	AS DIALYSATE	03NOV2015 23:20 / 04NOV2015 01:30	32.5	5
011-014	79/Female	03NOV2015 18:30	ACCUSOL 35 Potassium 4 mmol/L	15H28G72	AS DIALYSATE	04NOV2015 01:30 / 04NOV2015 02:30	32.6	1
011-015	77/Female	21NOV2015 08:56	ACCUSOL 35 Potassium 4 mmol/L	15G09G70	AS DIALYSATE	21NOV2015 08:56 / 21NOV2015 10:10	40	3
011-015	77/Female	21NOV2015 08:56	ACCUSOL 35 Potassium 4 mmol/L	15G09G70	AS DIALYSATE	21NOV2015 10:10 / 21NOV2015 12:00	40	5
011-015	77/Female	21NOV2015 08:56	ACCUSOL 35 Potassium 4 mmol/L	15G09G70	AS DIALYSATE	21NOV2015 12:00 / 21NOV2015 13:55	40	5
011-015	77/Female	21NOV2015 08:56	ACCUSOL 35 Potassium 4 mmol/L	15G09G70	AS DIALYSATE	21NOV2015 13:55 / 21NOV2015 15:50	40	5

Data Listing 16.2.5.3. ACCUSOL 35 Administration - Enrolled Population

Patient Number	Age (Years)/ Gender	First Accusol Administration Start Date/ Time	Dialysis Solution Used	Lot Number	Site of Introduction	Start Date and Time/ End Date and Time	Dialysis Dose (ml/kg/hr)	Amount Administered (L)
011-015	77/Female	21NOV2015 08:56	ACCUSOL 35 Potassium 4 mmol/L	15G09G70	AS DIALYSATE	21NOV2015 15:50 / 21NOV2015 17:40	40	5
011-015	77/Female	21NOV2015 08:56	ACCUSOL 35 Potassium 4 mmol/L	15G09G70	AS DIALYSATE	21NOV2015 17:40 / 21NOV2015 19:35	40	5
011-015	77/Female	21NOV2015 08:56	ACCUSOL 35 Potassium 4 mmol/L	15G09G70	AS DIALYSATE	21NOV2015 19:35 / 21NOV2015 21:35	40	5
011-015	77/Female	21NOV2015 08:56	ACCUSOL 35 Potassium 4 mmol/L	15G09G70	AS DIALYSATE	21NOV2015 21:35 / 21NOV2015 23:25	40	5
011-015	77/Female	21NOV2015 08:56	ACCUSOL 35 Potassium 4 mmol/L	15G09G70	AS DIALYSATE	21NOV2015 23:25 / 22NOV2015 01:25	40	5
011-015	77/Female	21NOV2015 08:56	ACCUSOL 35 Potassium 4 mmol/L	15G09G70	AS DIALYSATE	22NOV2015 01:25 / 22NOV2015 03:20	40	5
011-015	77/Female	21NOV2015 08:56	ACCUSOL 35 Potassium 4 mmol/L	15G09G70	AS DIALYSATE	22NOV2015 03:20 / 22NOV2015 05:12	40	5
011-015	77/Female	21NOV2015 08:56	ACCUSOL 35 Potassium 4 mmol/L	15G09G70	AS DIALYSATE	22NOV2015 05:12 / 22NOV2015 07:15	40	5
011-015	77/Female	21NOV2015 08:56	ACCUSOL 35 Potassium 4 mmol/L	15G09G70	AS DIALYSATE	22NOV2015 07:15 / 22NOV2015 08:30	40	2
011-016	72/Female	09JAN2016 07:30	ACCUSOL 35 Potassium 4 mmol/L	15E09G70	AS DIALYSATE	09JAN2016 07:30 / 09JAN2016 09:46	40	5
011-016	72/Female	09JAN2016 07:30	ACCUSOL 35 Potassium 4 mmol/L	15G09G71	AS DIALYSATE	09JAN2016 09:46 / 09JAN2016 11:30	40	5

Data Listing 16.2.5.3. ACCUSOL 35 Administration - Enrolled Population

Patient Number	Age (Years)/ Gender	First Accusol Administration Start Date/ Time	Dialysis Solution Used	Lot Number	Site of Introduction	Start Date and Time/ End Date and Time	Dialysis Dose (ml/kg/hr)	Amount Administered (L)
011-016	72/Female	09JAN2016 07:30	ACCUSOL 35	15E09G70	AS DIALYSATE	09JAN2016 11:30 / 09JAN2016 13:25	40	5
011-016	72/Female	09JAN2016 07:30	ACCUSOL 35 Potassium 4 mmol/L	15G09G71	AS DIALYSATE	09JAN2016 13:25 / 09JAN2016 15:30	40	5
011-016	72/Female	09JAN2016 07:30	ACCUSOL 35	15E09G70	AS DIALYSATE	09JAN2016 15:30 / 09JAN2016 17:10	40	5
011-016	72/Female	09JAN2016 07:30	ACCUSOL 35 Potassium 4 mmol/L	15G09G71	AS DIALYSATE	09JAN2016 17:10 / 09JAN2016 18:20	40	5
011-016	72/Female	09JAN2016 07:30	ACCUSOL 35 Potassium 4 mmol/L	15G09G71	AS DIALYSATE	09JAN2016 18:20 / 09JAN2016 19:40	40	5
011-016	72/Female	09JAN2016 07:30	ACCUSOL 35	15E09G70	AS DIALYSATE	09JAN2016 19:40 / 09JAN2016 21:45	40	5
011-016	72/Female	09JAN2016 07:30	ACCUSOL 35 Potassium 4 mmol/L	15G09G71	AS DIALYSATE	09JAN2016 21:45 / 09JAN2016 23:45	40	5
011-016	72/Female	09JAN2016 07:30	ACCUSOL 35 Potassium 4 mmol/L	15G09G71	AS DIALYSATE	09JAN2016 23:45 / 10JAN2016 01:50	40	5
011-016	72/Female	09JAN2016 07:30	ACCUSOL 35	15E09G70	AS DIALYSATE	10JAN2016 01:50 / 10JAN2016 03:56	40	5
011-016	72/Female	09JAN2016 07:30	ACCUSOL 35 Potassium 4 mmol/L	15G09G71	AS DIALYSATE	10JAN2016 03:56 / 10JAN2016 06:02	40	5
011-016	72/Female	09JAN2016 07:30	ACCUSOL 35 Potassium 4 mmol/L	15G09G71	AS DIALYSATE	10JAN2016 06:02 / 10JAN2016 08:10	40	5

Data Listing 16.2.5.3. ACCUSOL 35 Administration - Enrolled Population

Patient Number	Age (Years)/ Gender	First Accusol Administration Start Date/ Time	Dialysis Solution Used	Lot Number	Site of Introduction	Start Date and Time/ End Date and Time	Dialysis Dose (ml/kg/hr)	Amount Administered (L)
011-016	72/Female	09JAN2016 07:30	ACCUSOL 35 Potassium 4 mmol/L	15G09G71	AS DIALYSATE	10JAN2016 08:10 / 10JAN2016 10:20	40	5
011-016	72/Female	09JAN2016 07:30	ACCUSOL 35 Potassium 4 mmol/L	15G09G71	AS DIALYSATE	10JAN2016 10:20 / 10JAN2016 12:25	40	5
011-016	72/Female	09JAN2016 07:30	ACCUSOL 35 Potassium 4 mmol/L	15G09G71	AS DIALYSATE	10JAN2016 12:25 / 10JAN2016 14:33	40	5
011-016	72/Female	09JAN2016 07:30	ACCUSOL 35 Potassium 4 mmol/L	15G09G71	AS DIALYSATE	10JAN2016 14:33 / 10JAN2016 15:30	40	2
012-001	59/Male	01APR2015 14:00		DATA NOT CAPTURED	DATA NOT CAPTURED	01APR2015 14:00 / 01APR2015 15:10	UNK	.
012-001	59/Male	01APR2015 14:00	ACCUSOL 35 Potassium 4 mmol/L	L4J02G70	PRE AND POST FILTER	01APR2015 15:10 / 01APR2015 19:15	30	5
012-001	59/Male	01APR2015 14:00	ACCUSOL 35 Potassium 4 mmol/L	L4J02G70	PRE AND POST FILTER	01APR2015 19:15 / 01APR2015 23:25	30	5
012-001	59/Male	01APR2015 14:00	ACCUSOL 35 Potassium 4 mmol/L	L4J02G70	PRE AND POST FILTER	01APR2015 23:25 / 02APR2015 03:30	30	5
012-001	59/Male	01APR2015 14:00	ACCUSOL 35 Potassium 4 mmol/L	L4J02G70	PRE AND POST FILTER	02APR2015 03:30 / 02APR2015 07:30	30	5
012-001	59/Male	01APR2015 14:00	ACCUSOL 35 Potassium 4 mmol/L	L4J02G70	PRE AND POST FILTER	02APR2015 07:30 / 02APR2015 11:30	30	5
012-001	59/Male	01APR2015 14:00	ACCUSOL 35 Potassium 4 mmol/L	L4I09G71	PRE AND POST FILTER	02APR2015 11:30 / 02APR2015 15:20	30	5

Data Listing 16.2.5.3. ACCUSOL 35 Administration - Enrolled Population

Patient Number	Age (Years)/ Gender	First Accusol Administration Start Date/ Time	Dialysis Solution Used	Lot Number	Site of Introduction	Start Date and Time/ End Date and Time	Dialysis Dose (ml/kg/hr)	Amount Administered (L)
012-001	59/Male	01APR2015 14:00	ACCUSOL 35 Potassium 4 mmol/L	L4I09G71	PRE AND POST FILTER	02APR2015 15:20 / 02APR2015 19:15	30	5
012-001	59/Male	01APR2015 14:00	ACCUSOL 35 Potassium 4 mmol/L	L4I09G71	PRE AND POST FILTER	02APR2015 19:15 / 02APR2015 22:00	30	5
012-002	67/Male	08APR2015 13:00	ACCUSOL 35 Potassium 4 mmol/L	14I09G71	PRE AND POST FILTER	08APR2015 13:00 / 08APR2015 15:30	30	3.06
012-002	67/Male	08APR2015 13:00	ACCUSOL 35 Potassium 4 mmol/L	14I09G71	PRE AND POST FILTER	08APR2015 15:30 / 08APR2015 17:35	30	5
012-002	67/Male	08APR2015 13:00	ACCUSOL 35 Potassium 4 mmol/L	14I09G71	PRE AND POST FILTER	08APR2015 17:35 / 08APR2015 19:30	30	5
012-002	67/Male	08APR2015 13:00	ACCUSOL 35 Potassium 4 mmol/L	14I09G71	PRE AND POST FILTER	08APR2015 19:30 / 08APR2015 22:10	30	5
012-002	67/Male	08APR2015 13:00	ACCUSOL 35	14K27G73	PRE AND POST FILTER	08APR2015 22:10 / 08APR2015 23:50	30	5
012-002	67/Male	08APR2015 13:00	ACCUSOL 35	14K27G73	PRE AND POST FILTER	08APR2015 23:50 / 09APR2015 02:00	30	5
012-002	67/Male	08APR2015 13:00	ACCUSOL 35 Potassium 4 mmol/L	14I09G71	PRE AND POST FILTER	09APR2015 02:00 / 09APR2015 04:15	30	5
012-002	67/Male	08APR2015 13:00	ACCUSOL 35 Potassium 4 mmol/L	14I09G71	PRE AND POST FILTER	09APR2015 04:15 / 09APR2015 06:15	30	5
012-002	67/Male	08APR2015 13:00	ACCUSOL 35 Potassium 4 mmol/L	14I27G73	PRE AND POST FILTER	09APR2015 06:15 / 09APR2015 07:50	30	5

Data Listing 16.2.5.3. ACCUSOL 35 Administration - Enrolled Population

Patient Number	Age (Years)/ Gender	First Accusol Administration Start Date/ Time	Dialysis Solution Used	Lot Number	Site of Introduction	Start Date and Time/ End Date and Time	Dialysis Dose (ml/kg/hr)	Amount Administered (L)
012-002	67/Male	08APR2015 13:00	ACCUSOL 35	14K27G73	PRE AND POST FILTER	09APR2015 07:50 / 09APR2015 10:20	30	5
012-002	67/Male	08APR2015 13:00	ACCUSOL 35 Potassium 4 mmol/L	14I09G71	PRE AND POST FILTER	09APR2015 10:20 / 09APR2015 12:30	30	5
012-002	67/Male	08APR2015 13:00	ACCUSOL 35 Potassium 4 mmol/L	14I09G71	PRE AND POST FILTER	09APR2015 12:30 / 09APR2015 14:45	30	5
012-002	67/Male	08APR2015 13:00	ACCUSOL 35 Potassium 4 mmol/L	14I09G71	PRE AND POST FILTER	09APR2015 14:45 / 09APR2015 18:30	30	5
012-002	67/Male	08APR2015 13:00	ACCUSOL 35 Potassium 4 mmol/L	14K27G73	PRE AND POST FILTER	09APR2015 18:30 / 09APR2015 21:00	30	5
012-003	63/Male	17APR2015	ACCUSOL 35 Potassium 4 mmol/L	14I09G71	PRE AND POST FILTER	17APR2015 / 17APR2015	30	5
012-003	63/Male	17APR2015	ACCUSOL 35 Potassium 4 mmol/L	14I09G71	PRE AND POST DIALYSIS	17APR2015 / 17APR2015	30	5
012-003	63/Male	17APR2015	ACCUSOL 35 Potassium 4 mmol/L	14I09G71	PRE AND POST FILTER	17APR2015 05:50 / 17APR2015	30	5
012-003	63/Male	17APR2015	ACCUSOL 35 Potassium 4 mmol/L	14I09G71	PRE AND POST FILTER	17APR2015 13:20 / 17APR2015	30	5
012-003	63/Male	17APR2015	ACCUSOL 35 Potassium 4 mmol/L	14I09G71	PRE AND POST FILTER	17APR2015 13:20 / 17APR2015 21:20	30	5
012-003	63/Male	17APR2015	ACCUSOL 35 Potassium 4 mmol/L	14I09G71	PRE AND POST FILTER	17APR2015 13:20 / 17APR2015 21:20	30	5

Data Listing 16.2.5.3. ACCUSOL 35 Administration - Enrolled Population

Patient Number	Age (Years)/ Gender	First Accusol Administration Start Date/ Time	Dialysis Solution Used	Lot Number	Site of Introduction	Start Date and Time/ End Date and Time	Dialysis Dose (ml/kg/hr)	Amount Administered (L)
012-003	63/Male	17APR2015	ACCUSOL 35 Potassium 4 mmol/L	14I09G71	PRE AND POST FILTER	17APR2015 21:20 / - -	30	5
012-003	63/Male	17APR2015	ACCUSOL 35 Potassium 4 mmol/L	14I09G71	PRE AND POST FILTER	17APR2015 21:20 / 18APR2015 02:30	30	5
012-004	59/Female	20JUL2015 10:00		UNK	AS DIALYSATE	20JUL2015 10:00 / 20JUL2015 11:45	30	5
012-004	59/Female	20JUL2015 10:00	ACCUSOL 35 Potassium 4 mmol/L	14I09G71	PRE AND POST FILTER	20JUL2015 11:45 / 20JUL2015 14:50	30	5
012-004	59/Female	20JUL2015 10:00	ACCUSOL 35 Potassium 4 mmol/L	14I09671	PRE AND POST FILTER	20JUL2015 14:50 / 20JUL2015 17:30	30	5
012-004	59/Female	20JUL2015 10:00	ACCUSOL 35 Potassium 4 mmol/L	14I09671	PRE AND POST FILTER	20JUL2015 17:30 / 20JUL2015 20:05	30	5
012-004	59/Female	20JUL2015 10:00	ACCUSOL 35 Potassium 4 mmol/L	14I09G71	PRE AND POST FILTER	20JUL2015 20:05 / 20JUL2015 22:30	30	5
012-004	59/Female	20JUL2015 10:00	ACCUSOL 35	15A09G70	PRE AND POST	20JUL2015 22:30 / 21JUL2015 01:15	30	5
012-004	59/Female	20JUL2015 10:00	ACCUSOL 35	15A09G70	PRE AND POST FILTER	21JUL2015 01:15 / 21JUL2015 04:05	30	5
012-004	59/Female	20JUL2015 10:00	ACCUSOL 35	15A09G70	PRE AND POST FILTER	21JUL2015 04:05 / 21JUL2015 06:40	30	5
012-004	59/Female	20JUL2015 10:00	ACCUSOL 35	15A09G70	PRE AND POST FILTER	21JUL2015 06:40 / 21JUL2015 09:20	30	5

Data Listing 16.2.5.3. ACCUSOL 35 Administration - Enrolled Population

Patient Number	Age (Years)/ Gender	First Accusol Administration Start Date/ Time	Dialysis Solution Used	Lot Number	Site of Introduction	Start Date and Time/ End Date and Time	Dialysis Dose (ml/kg/hr)	Amount Administered (L)
012-004	59/Female	20JUL2015 10:00	ACCUSOL 35 Potassium 4 mmol/L	14I09671	PRE AND POST FILTER	21JUL2015 09:20 / 21JUL2015 12:35	30	5
012-005	41/Male	27JUL2015 23:15		UNK	UNK	27JUL2015 23:15 / 28JUL2015 03:20	UNK	.
012-005	41/Male	27JUL2015 23:15	ACCUSOL 35	15A09G70	PRE AND POST FILTER	28JUL2015 03:20 / 28JUL2015 07:28	30	5
012-005	41/Male	27JUL2015 23:15	ACCUSOL 35	15A09G70	PRE AND POST FILTER	28JUL2015 03:20 / 28JUL2015 07:28	30	5
012-005	41/Male	27JUL2015 23:15	ACCUSOL 35	15A09G70	PRE AND POST FILTER	28JUL2015 07:28 / 28JUL2015 10:25	30	5
012-005	41/Male	27JUL2015 23:15	ACCUSOL 35	15A09G70	PRE AND POST FILTER	28JUL2015 07:28 / 28JUL2015 10:25	30	5
012-005	41/Male	27JUL2015 23:15	ACCUSOL 35 Potassium 4 mmol/L	15A08G74	PRE AND POST FILTER	28JUL2015 10:25 / 28JUL2015 14:30	30	5
012-005	41/Male	27JUL2015 23:15	ACCUSOL 35 Potassium 4 mmol/L	15A08G74	PRE AND POST FILTER	28JUL2015 10:25 / 28JUL2015 14:30	30	5
012-005	41/Male	27JUL2015 23:15	ACCUSOL 35	15A08G70	PRE AND POST FILTER	28JUL2015 14:30 / 28JUL2015 18:30	30	5
012-005	41/Male	27JUL2015 23:15	ACCUSOL 35	15A09G70	PRE AND POST FILTER	28JUL2015 14:30 / 28JUL2015 18:30	30	5
012-005	41/Male	27JUL2015 23:15	ACCUSOL 35	15A09G70	PRE AND POST FILTER	28JUL2015 18:30 / 28JUL2015 20:50	30	5

Data Listing 16.2.5.3. ACCUSOL 35 Administration - Enrolled Population

Patient Number	Age (Years)/ Gender	First Accusol Administration Start Date/ Time	Dialysis Solution Used	Lot Number	Site of Introduction	Start Date and Time/ End Date and Time	Dialysis Dose (ml/kg/hr)	Amount Administered (L)
012-005	41/Male	27JUL2015 23:15	ACCUSOL 35	15A09G70	PRE AND POST FILTER	28JUL2015 18:30 / 28JUL2015 20:50	30	5
012-005	41/Male	27JUL2015 23:15	ACCUSOL 35 Potassium 4 mmol/L	15A08G74	PRE AND POST FILTER	28JUL2015 20:50 / 29JUL2015 01:20	30	5
012-005	41/Male	27JUL2015 23:15	ACCUSOL 35 Potassium 4 mmol/L	15A08G74	PRE AND POST FILTER	28JUL2015 20:50 / 29JUL2015 01:20	30	5
012-005	41/Male	27JUL2015 23:15	ACCUSOL 35 Potassium 4 mmol/L	15A08G74	PRE AND POST FILTER	29JUL2015 01:20 / 29JUL2015 05:40	30	5
012-005	41/Male	27JUL2015 23:15	ACCUSOL 35 Potassium 4 mmol/L	15A08G74	PRE AND POST FILTER	29JUL2015 01:20 / 29JUL2015 05:40	30	5
012-005	41/Male	27JUL2015 23:15	ACCUSOL 35 Potassium 4 mmol/L	15L02G70	PRE AND POST FILTER	29JUL2015 05:40 / 29JUL2015 07:15	30	5
012-005	41/Male	27JUL2015 23:15	ACCUSOL 35 Potassium 4 mmol/L	15L02G70	PRE AND POST FILTER	29JUL2015 05:40 / 29JUL2015 07:15	30	5
012-006	44/Male	30AUG2015 19:30		UNKNOWN	AS DIALYSATE	30AUG2015 19:30 / 30AUG2015 21:10	30	5
012-006	44/Male	30AUG2015 19:30	ACCUSOL 35 Potassium 4 mmol/L	FA08G74	AS DIALYSATE	30AUG2015 21:10 / 31AUG2015 03:05	30	5
012-006	44/Male	30AUG2015 19:30	ACCUSOL 35 Potassium 4 mmol/L	FA08G74	AS DIALYSATE	30AUG2015 21:10 / 31AUG2015 03:05	30	5
012-006	44/Male	30AUG2015 19:30	ACCUSOL 35 Potassium 4 mmol/L	15002G70	AS DIALYSATE	31AUG2015 03:05 / 31AUG2015 06:15	30	5

Data Listing 16.2.5.3. ACCUSOL 35 Administration - Enrolled Population

Patient Number	Age (Years)/ Gender	First Accusol Administration Start Date/ Time	Dialysis Solution Used	Lot Number	Site of Introduction	Start Date and Time/ End Date and Time	Dialysis Dose (ml/kg/hr)	Amount Administered (L)
012-006	44/Male	30AUG2015 19:30	ACCUSOL 35 Potassium 4 mmol/L	15002G70	AS DIALYSATE	31AUG2015 03:05 / 31AUG2015 06:15	30	5
012-007	82/Male	11OCT2015 13:15		DATA NOT CAPTURED	PRE AND POST FILTER	11OCT2015 13:15 / 11OCT2015 15:30	30	5
012-007	82/Male	11OCT2015 13:15	ACCUSOL 35 Potassium 4 mmol/L	15002670	AS DIALYSATE	11OCT2015 15:30 / - -	30	5
012-007	82/Male	11OCT2015 13:15	ACCUSOL 35	15A09G71	AS DIALYSATE	12OCT2015 10:45 / - -	30	5
012-008	59/Male	17OCT2015 07:00	ACCUSOL 35	15A09G71B 1	AS DIALYSATE	17OCT2015 07:00 / 17OCT2015 10:15	30	5
012-008	59/Male	17OCT2015 07:00	ACCUSOL 35	15A09G71B 1	AS DIALYSATE	17OCT2015 07:00 / 17OCT2015 10:15	30	5
012-008	59/Male	17OCT2015 07:00	ACCUSOL 35 Potassium 4 mmol/L	15A08G74	AS DIALYSATE	17OCT2015 10:15 / 17OCT2015 10:45	30	5
012-008	59/Male	17OCT2015 07:00	ACCUSOL 35 Potassium 4 mmol/L	15A08G74	AS DIALYSATE	17OCT2015 10:15 / 17OCT2015 10:45	30	5
012-009	70/Male	05NOV2015 05:30	ACCUSOL 35	DATA NOT CAPTURED	PRE AND POST FILTER	05NOV2015 05:30 / 05NOV2015 09:30	30	5
012-009	70/Male	05NOV2015 05:30	ACCUSOL 35 Potassium 4 mmol/L	15H28G72	PRE/POST FILTER	05NOV2015 09:30 / 05NOV2015 11:05	30	5
012-010	72/Male	06NOV2015 10:00	ACCUSOL 35 Potassium 4 mmol/L	15A08G74	PRE AND POST FILTER	06NOV2015 10:00 / 06NOV2015 12:25	30	5

Data Listing 16.2.5.3. ACCUSOL 35 Administration - Enrolled Population

Patient Number	Age (Years)/ Gender	First Accusol Administration Start Date/ Time	Dialysis Solution Used	Lot Number	Site of Introduction	Start Date and Time/ End Date and Time	Dialysis Dose (ml/kg/hr)	Amount Administered (L)
012-010	72/Male	06NOV2015 10:00	ACCUSOL 35 Potassium 4 mmol/L	15A08G74	PRE AND POST FILTER	06NOV2015 12:25 / 06NOV2015 15:15	30	5
012-010	72/Male	06NOV2015 10:00	ACCUSOL 35 Potassium 4 mmol/L	15C02G71	PRE AND POST FILTER	06NOV2015 15:15 / 06NOV2015 18:30	30	5
012-010	72/Male	06NOV2015 10:00	ACCUSOL 35 Potassium 4 mmol/L	15C02G71	PRE AND POST FILTER	06NOV2015 18:30 / 06NOV2015 21:00	30	5
012-010	72/Male	06NOV2015 10:00	ACCUSOL 35 Potassium 4 mmol/L	15C02G71	PRE AND POST FILTER	06NOV2015 21:00 / 06NOV2015 23:55	30	5
012-010	72/Male	06NOV2015 10:00	ACCUSOL 35 Potassium 4 mmol/L	15C02G71	PRE AND POST FILTER	06NOV2015 23:55 / 07NOV2015 02:25	30	5
012-010	72/Male	06NOV2015 10:00	ACCUSOL 35 Potassium 4 mmol/L	15C02G71	PRE AND POST FILTER	07NOV2015 02:25 / 07NOV2015 05:00	30	5
012-010	72/Male	06NOV2015 10:00	ACCUSOL 35 Potassium 4 mmol/L	15C02G71	PRE AND POST FILTER	07NOV2015 05:00 / 07NOV2015 08:00	30	5
012-010	72/Male	06NOV2015 10:00	ACCUSOL 35 Potassium 4 mmol/L	15C02G71	PRE AND POST FILTER	07NOV2015 08:00 / 07NOV2015 11:00	30	5
012-010	72/Male	06NOV2015 10:00	ACCUSOL 35 Potassium 4 mmol/L	15C02G71	PRE AND POST FILTER	07NOV2015 11:00 / 07NOV2015 14:00	30	5
012-010	72/Male	06NOV2015 10:00	ACCUSOL 35 Potassium 4 mmol/L	15C02G71	PRE AND POST FILTER	07NOV2015 14:00 / 07NOV2015 16:20	30	5
012-010	72/Male	06NOV2015 10:00	ACCUSOL 35 Potassium 4 mmol/L	15H28G72	PRE AND POST FILTER	07NOV2015 16:20 / 07NOV2015 18:00	30	3.13

Data Listing 16.2.5.3. ACCUSOL 35 Administration - Enrolled Population

Patient Number	Age (Years)/ Gender	First Accusol Administration Start Date/ Time	Dialysis Solution Used	Lot Number	Site of Introduction	Start Date and Time/ End Date and Time	Dialysis Dose (ml/kg/hr)	Amount Administered (L)
012-011	58/Female	16DEC2015 20:45		UNKNOWN	AS DIALYSATE	16DEC2015 20:45 / 16DEC2015 21:15	30	.
012-011	58/Female	16DEC2015 20:45	ACCUSOL 35	15D12G70	AS DIALYSATE	16DEC2015 21:15 / 16DEC2015 23:00	30	5
012-011	58/Female	16DEC2015 20:45	ACCUSOL 35	15D12G70	AS DIALYSATE	16DEC2015 23:00 / 17DEC2015 02:05	30	5
012-011	58/Female	16DEC2015 20:45	ACCUSOL 35 Potassium 4 mmol/L	15G09G71	AS DIALYSATE	17DEC2015 02:05 / 17DEC2015 03:00	30	5
012-011	58/Female	16DEC2015 20:45	ACCUSOL 35 Potassium 4 mmol/L	15G09G71	AS DIALYSATE	17DEC2015 03:00 / 17DEC2015 05:00	30	5
012-011	58/Female	16DEC2015 20:45	ACCUSOL 35 Potassium 4 mmol/L	15H28G72	AS DIALYSATE	17DEC2015 05:00 / 17DEC2015 07:00	30	5
012-011	58/Female	16DEC2015 20:45	ACCUSOL 35 Potassium 4 mmol/L	15H28G72	AS DIALYSATE	17DEC2015 07:00 / 17DEC2015 09:10	30	5
012-011	58/Female	16DEC2015 20:45	ACCUSOL 35 Potassium 4 mmol/L	15G09G71	AS DIALYSATE	17DEC2015 09:10 / 17DEC2015 11:10	30	5
012-011	58/Female	16DEC2015 20:45	ACCUSOL 35 Potassium 4 mmol/L	15G09G71	AS DIALYSATE	17DEC2015 11:10 / 17DEC2015 13:25	30	5
012-011	58/Female	16DEC2015 20:45	ACCUSOL 35 Potassium 4 mmol/L	15G09G71	AS DIALYSATE	17DEC2015 13:25 / 17DEC2015 15:30	30	5
012-011	58/Female	16DEC2015 20:45	ACCUSOL 35 Potassium 4 mmol/L	15G09G71	AS DIALYSATE	17DEC2015 15:30 / 17DEC2015 17:50	30	5

Data Listing 16.2.5.3. ACCUSOL 35 Administration - Enrolled Population

Patient Number	Age (Years)/ Gender	First Accusol Administration Start Date/ Time	Dialysis Solution Used	Lot Number	Site of Introduction	Start Date and Time/ End Date and Time	Dialysis Dose (ml/kg/hr)	Amount Administered (L)
012-012	69/Male	15JAN2016 10:00	ACCUSOL 35 Potassium 4 mmol/L	15G09G71	AS DIALYSATE	15JAN2016 10:00 / 15JAN2016 12:05	30	5
012-012	69/Male	15JAN2016 10:00	ACCUSOL 35 Potassium 4 mmol/L	15G09G71	AS DIALYSATE	15JAN2016 12:05 / 15JAN2016 14:45	30	5
012-012	69/Male	15JAN2016 10:00	ACCUSOL 35 Potassium 4 mmol/L	15G09G71	AS DIALYSATE	15JAN2016 14:45 / 15JAN2016 17:15	30	5
012-012	69/Male	15JAN2016 10:00	ACCUSOL 35 Potassium 4 mmol/L	15H28G72	AS DIALYSATE	15JAN2016 17:15 / 15JAN2016 19:45	30	5
012-012	69/Male	15JAN2016 10:00	ACCUSOL 35 Potassium 4 mmol/L	15H28G72	AS DIALYSATE	15JAN2016 19:45 / 15JAN2016 22:30	30	5
012-012	69/Male	15JAN2016 10:00	ACCUSOL 35	15D12G72	AS DIALYSATE	15JAN2016 22:30 / 16JAN2016 01:10	30	5
012-012	69/Male	15JAN2016 10:00	ACCUSOL 35	15D12G72	AS DIALYSATE	16JAN2016 01:10 / 16JAN2016 03:50	30	5
012-012	69/Male	15JAN2016 10:00	ACCUSOL 35 Potassium 4 mmol/L	15G09G71	AS DIALYSATE	16JAN2016 03:50 / 16JAN2016 06:25	30	5
012-012	69/Male	15JAN2016 10:00	ACCUSOL 35 Potassium 4 mmol/L	15G09G71	AS DIALYSATE	16JAN2016 06:25 / 16JAN2016 08:55	30	5
012-012	69/Male	15JAN2016 10:00	ACCUSOL 35 Potassium 4 mmol/L	15H28G72	AS DIALYSATE	16JAN2016 08:55 / 16JAN2016 11:30	30	5
012-012	69/Male	15JAN2016 10:00	ACCUSOL 35 Potassium 4 mmol/L	15H28G72	AS DIALYSATE	16JAN2016 11:30 / 16JAN2016 14:00	30	5

Data Listing 16.2.5.3. ACCUSOL 35 Administration - Enrolled Population

Patient Number	Age (Years)/ Gender	First Accusol Administration Start Date/ Time	Dialysis Solution Used	Lot Number	Site of Introduction	Start Date and Time/ End Date and Time	Dialysis Dose (ml/kg/hr)	Amount Administered (L)
012-012	69/Male	15JAN2016 10:00	ACCUSOL 35 Potassium 4 mmol/L	15H28G72	AS DIALYSATE	16JAN2016 14:00 / 16JAN2016 16:40	30	5
012-012	69/Male	15JAN2016 10:00	ACCUSOL 35	15H09G71	AS DIALYSATE	16JAN2016 16:40 / 16JAN2016 18:00	30	2.67
012-013	77/Female	19JAN2016 18:15		UNK	AS DIALYSATE	19JAN2016 18:15 / 19JAN2016 22:45	30	5
012-013	77/Female	19JAN2016 18:15	ACCUSOL 35 Potassium 4 mmol/L	15I22G73	AS DIALYSATE	19JAN2016 22:45 / 20JAN2016 04:20	30	5
012-013	77/Female	19JAN2016 18:15	ACCUSOL 35 Potassium 4 mmol/L	15I22G73	AS DIALYSATE	19JAN2016 22:45 / 20JAN2016 04:20	30	5
012-013	77/Female	19JAN2016 18:15	ACCUSOL 35 Potassium 4 mmol/L	15I22G73	AS DIALYSATE	20JAN2016 04:20 / 20JAN2016 08:00	30	5
012-013	77/Female	19JAN2016 18:15	ACCUSOL 35 Potassium 4 mmol/L	15I22G73	AS DIALYSATE	20JAN2016 04:20 / 20JAN2016 08:00	30	5
013-002	70/Male	01JUL2015 06:00	ACCUSOL 35	14K27G73	PRE AND POST FILTER	01JUL2015 06:00 / 01JUL2015 14:30	22.7	4.87
013-002	70/Male	01JUL2015 06:00	ACCUSOL 35	14K27G73	PRE AND POST FILTER	01JUL2015 06:00 / 01JUL2015 14:30	22.7	4.87
013-002	70/Male	01JUL2015 06:00	ACCUSOL 35	14K27G73	PRE AND POST FILTER	01JUL2015 06:00 / 01JUL2015 14:30	22.7	4.87
013-002	70/Male	01JUL2015 06:00	ACCUSOL 35	14K30G70	PRE AND POST FILTER	01JUL2015 14:30 / 01JUL2015 16:20	22.7	5

Data Listing 16.2.5.3. ACCUSOL 35 Administration - Enrolled Population

Patient Number	Age (Years)/ Gender	First Accusol Administration Start Date/ Time	Dialysis Solution Used	Lot Number	Site of Introduction	Start Date and Time/ End Date and Time	Dialysis Dose (ml/kg/hr)	Amount Administered (L)
013-002	70/Male	01JUL2015 06:00	ACCUSOL 35	14K30G70	PRE AND POST FILTER	01JUL2015 14:30 / 01JUL2015 16:20	22.7	5
013-002	70/Male	01JUL2015 06:00	ACCUSOL 35	14K30G70	PRE AND POST FILTER	01JUL2015 14:30 / 01JUL2015 16:20	22.7	5
013-002	70/Male	01JUL2015 06:00	ACCUSOL 35	14K30G70	PRE AND POST FILTER	01JUL2015 16:20 / 02JUL2015 00:10	22.7	5
013-002	70/Male	01JUL2015 06:00	ACCUSOL 35	14K30G70	PRE AND POST FILTER	01JUL2015 16:20 / 02JUL2015 00:10	22.7	5
013-002	70/Male	01JUL2015 06:00	ACCUSOL 35	14K30G70	PRE AND POST FILTER	01JUL2015 16:20 / 02JUL2015 00:10	22.7	5
013-002	70/Male	01JUL2015 06:00	ACCUSOL 35	14K30G70	PRE AND POST FILTER	02JUL2015 00:10 / 02JUL2015 08:05	21.8	5
013-002	70/Male	01JUL2015 06:00	ACCUSOL 35	14K30G70	PRE AND POST FILTER	02JUL2015 00:10 / 02JUL2015 08:05	21.8	5
013-002	70/Male	01JUL2015 06:00	ACCUSOL 35	14K30G70	PRE AND POST FILTER	02JUL2015 00:10 / 02JUL2015 08:05	21.8	5
013-002	70/Male	01JUL2015 06:00	ACCUSOL 35	14K30G70	PRE AND POST FILTER	02JUL2015 08:05 / 02JUL2015 14:00	21.6	5
013-002	70/Male	01JUL2015 06:00	ACCUSOL 35	14K30G70	PRE AND POST FILTER	02JUL2015 08:05 / 02JUL2015 14:00	21.6	5
013-002	70/Male	01JUL2015 06:00	ACCUSOL 35	14K30G70	PRE AND POST FILTER	02JUL2015 08:05 / 02JUL2015 14:00	21.6	5

Data Listing 16.2.5.3. ACCUSOL 35 Administration - Enrolled Population

Patient Number	Age (Years)/ Gender	First Accusol Administration Start Date/ Time	Dialysis Solution Used	Lot Number	Site of Introduction	Start Date and Time/ End Date and Time	Dialysis Dose (ml/kg/hr)	Amount Administered (L)
013-003	69/Male	29JUL2015 15:00	ACCUSOL 35	14K11G70	PRE AND POST FILTER	29JUL2015 15:00 / 29JUL2015 16:30	31.7	2
013-003	69/Male	29JUL2015 15:00	ACCUSOL 35	14K11G70	PRE & POST FILTER	29JUL2015 15:00 / 29JUL2015 16:30	31.7	2
013-003	69/Male	29JUL2015 15:00	ACCUSOL 35	14K11G71	PRE & POST FILTER	29JUL2015 15:00 / 29JUL2015 16:30	31.7	2
013-004	64/Female	09SEP2015 04:00	ACCUSOL 35	15AO9G70	PRE AND POST FILTER	09SEP2015 04:00 / 09SEP2015 05:00	25	1.54
013-004	64/Female	09SEP2015 04:00	ACCUSOL 35	15AO9G70	PRE & POST FILTER	09SEP2015 04:00 / 09SEP2015 05:00	25	1.54
013-004	64/Female	09SEP2015 04:00	ACCUSOL 35	15AO9G70	PRE & POST FILTER	09SEP2015 04:00 / 09SEP2015 05:00	25	1.54
013-004	64/Female	09SEP2015 04:00	ACCUSOL 35	15AO9G71	PRE & POST FILTER	09SEP2015 05:00 / 09SEP2015 08:30	25	5
013-004	64/Female	09SEP2015 04:00	ACCUSOL 35	14K30G71	PRE & POST FILTER	09SEP2015 05:00 / 09SEP2015 08:30	25	5
013-004	64/Female	09SEP2015 04:00	ACCUSOL 35	14K30G71	PRE & POST FILTER	09SEP2015 05:00 / 09SEP2015 08:30	25	5
013-004	64/Female	09SEP2015 04:00	ACCUSOL 35	15AO9G71	PRE & POST FILTER	09SEP2015 08:30 / 09SEP2015 10:00	25	2.9
013-004	64/Female	09SEP2015 04:00	ACCUSOL 35	15AO9G71	PRE & POST FILTER	09SEP2015 08:30 / 09SEP2015 10:00	25	2.9

Data Listing 16.2.5.3. ACCUSOL 35 Administration - Enrolled Population

Patient Number	Age (Years)/ Gender	First Accusol Administration Start Date/ Time	Dialysis Solution Used	Lot Number	Site of Introduction	Start Date and Time/ End Date and Time	Dialysis Dose (ml/kg/hr)	Amount Administered (L)
013-004	64/Female	09SEP2015 04:00	ACCUSOL 35	15A09G70	PRE & POST FILTER	09SEP2015 08:30 / 09SEP2015 10:00	25	2.9
013-005		17SEP2015 13:00	ACCUSOL 35	15C03G73	PRE AND POST FILTER	17SEP2015 13:00 / 17SEP2015 19:00	31.9	2.7
013-005		17SEP2015 13:00	ACCUSOL 35	15C03G73	PRE AND POST FILTER	17SEP2015 13:00 / 17SEP2015 19:00	31.9	2.7
013-005		17SEP2015 13:00	ACCUSOL 35	15C03G73	PRE AND POST FILTER	17SEP2015 13:00 / 17SEP2015 19:00	31.9	2.7
013-005		17SEP2015 13:00	ACCUSOL 35	15A09G71	PRE AND POST FILTER	17SEP2015 19:00 / 18SEP2015 03:30	32.5	5
013-005		17SEP2015 13:00	ACCUSOL 35	15A09G71	PRE AND POST FILTER	17SEP2015 19:00 / 18SEP2015 03:30	32.5	5
013-005		17SEP2015 13:00	ACCUSOL 35	15A09G71	PRE AND POST FILTER	17SEP2015 19:00 / 18SEP2015 03:30	32.5	5
013-005		17SEP2015 13:00	ACCUSOL 35	15C03G73	PRE AND POST	18SEP2015 03:30 / 18SEP2015 12:00	33	5
013-005		17SEP2015 13:00	ACCUSOL 35	15A09G71	PRE AND POST	18SEP2015 03:30 / 18SEP2015 12:00	33	5
013-005		17SEP2015 13:00	ACCUSOL 35	15C03673	PRE AND POST	18SEP2015 03:30 / 18SEP2015 12:00	33	5
013-005		17SEP2015 13:00	ACCUSOL 35	15A09G71	PRE AND POST	18SEP2015 12:00 / 18SEP2015 20:00	33.3	5

Data Listing 16.2.5.3. ACCUSOL 35 Administration - Enrolled Population

Patient Number	Age (Years)/ Gender	First Accusol Administration Start Date/ Time	Dialysis Solution Used	Lot Number	Site of Introduction	Start Date and Time/ End Date and Time	Dialysis Dose (ml/kg/hr)	Amount Administered (L)
013-005		17SEP2015 13:00	ACCUSOL 35	15C03G73	PRE AND POST	18SEP2015 12:00 / 18SEP2015 20:00	33.3	5
013-005		17SEP2015 13:00	ACCUSOL 35	15C03G73	PRE AND POST	18SEP2015 12:00 / 18SEP2015 20:00	33.3	5
013-005		17SEP2015 13:00	ACCUSOL 35	15A09G71	PRE AND POST	18SEP2015 20:00 / 18SEP2015 21:00	33.5	1.25
013-005		17SEP2015 13:00	ACCUSOL 35	15A09G71	PRE AND POST	18SEP2015 20:00 / 18SEP2015 21:00	33.5	1.25
013-005		17SEP2015 13:00	ACCUSOL 35	15A09G71	PRE AND POST	18SEP2015 20:00 / 18SEP2015 21:00	33.5	1.25
013-010	76/Female	05DEC2015 07:00	ACCUSOL 35	PA1671221	PRE AND POST	05DEC2015 07:00 / 05DEC2015 08:00	35	0.63
013-010	76/Female	05DEC2015 07:00	ACCUSOL 35	PA1671221	PRE AND POST	05DEC2015 07:00 / 05DEC2015 08:00	35	0.63
013-010	76/Female	05DEC2015 07:00	ACCUSOL 35	PA1671221	PRE AND POST	05DEC2015 07:00 / 05DEC2015 08:00	35	0.63
013-010	76/Female	05DEC2015 07:00	ACCUSOL 35	PA1671221	PRE AND POST	05DEC2015 08:00 / 05DEC2015 16:11	35	5
013-010	76/Female	05DEC2015 07:00	ACCUSOL 35	PA1671221	PRE AND POST	05DEC2015 08:00 / 05DEC2015 16:11	35	5
013-010	76/Female	05DEC2015 07:00	ACCUSOL 35	PA1671221	PRE AND POST	05DEC2015 08:00 / 05DEC2015 16:11	35	5

Data Listing 16.2.5.3. ACCUSOL 35 Administration - Enrolled Population

Patient Number	Age (Years)/ Gender	First Accusol Administration Start Date/ Time	Dialysis Solution Used	Lot Number	Site of Introduction	Start Date and Time/ End Date and Time	Dialysis Dose (ml/kg/hr)	Amount Administered (L)
013-010	76/Female	05DEC2015 07:00	ACCUSOL 35	15E09G70	PRE AND POST	05DEC2015 16:11 / 06DEC2015 00:07	35	5
013-010	76/Female	05DEC2015 07:00	ACCUSOL 35	15E09G70	PRE AND POST	05DEC2015 16:11 / 06DEC2015 00:07	35	5
013-010	76/Female	05DEC2015 07:00	ACCUSOL 35	15E09G70	PRE AND POST	05DEC2015 16:11 / 06DEC2015 00:07	35	5
013-010	76/Female	05DEC2015 07:00	ACCUSOL 35	15E09G70	PRE AND POST	06DEC2015 00:07 / 06DEC2015 08:10	35	5
013-010	76/Female	05DEC2015 07:00	ACCUSOL 35	15E09G70	PRE AND POST	06DEC2015 00:07 / 06DEC2015 08:10	35	5
013-010	76/Female	05DEC2015 07:00	ACCUSOL 35	15E09G70	PRE AND POST	06DEC2015 00:07 / 06DEC2015 08:10	35	5
013-010	76/Female	05DEC2015 07:00	ACCUSOL 35	15E09G70	PRE AND POST	06DEC2015 08:10 / 06DEC2015 15:00	35	4.66
013-010	76/Female	05DEC2015 07:00	ACCUSOL 35	15E09G70	PRE AND POST	06DEC2015 08:10 / 06DEC2015 15:00	35	4.66
013-010	76/Female	05DEC2015 07:00	ACCUSOL 35	15E09G70	PRE AND POST	06DEC2015 08:10 / 06DEC2015 15:00	35	4.66
014-001	75/Female	17APR2015 12:00		UNK	PRE-FILTER	17APR2015 12:00 / 17APR2015 13:45	30	.
014-001	75/Female	17APR2015 12:00	ACCUSOL 35 Potassium 4 mmol/L	14J02G70B1	PRE-FILTER	17APR2015 13:45 / 17APR2015 18:30	30	5

Data Listing 16.2.5.3. ACCUSOL 35 Administration - Enrolled Population

Patient Number	Age (Years)/ Gender	First Accusol Administration Start Date/ Time	Dialysis Solution Used	Lot Number	Site of Introduction	Start Date and Time/ End Date and Time	Dialysis Dose (ml/kg/hr)	Amount Administered (L)
014-001	75/Female	17APR2015 12:00	ACCUSOL 35 Potassium 4 mmol/L	14J02G70	PRE-FILTER	17APR2015 18:30 / 17APR2015 23:00	30	5
014-001	75/Female	17APR2015 12:00	ACCUSOL 35 Potassium 4 mmol/L	14J02G70	PRE-FILTER	17APR2015 23:00 / 18APR2015 04:10	30	5
014-001	75/Female	17APR2015 12:00	ACCUSOL 35 Potassium 4 mmol/L	14J02G70	PRE-FILTER	18APR2015 04:10 / 18APR2015 09:45	30	5
014-001	75/Female	17APR2015 12:00	ACCUSOL 35 Potassium 4 mmol/L	14J02G70	PRE-FILTER	18APR2015 09:45 / 18APR2015 14:30	30	5
014-001	75/Female	17APR2015 12:00	ACCUSOL 35 Potassium 4 mmol/L	14J02G70	PRE-FILTER	18APR2015 14:30 / 18APR2015 19:05	30	5
014-001	75/Female	17APR2015 12:00	ACCUSOL 35 Potassium 4 mmol/L	14J02G70	PRE-FILTER	18APR2015 19:05 / 18APR2015 20:00	30	5
014-002	47/Male	28APR2015 21:00		UNK	AS DIALYSATE	28APR2015 21:00 / 28APR2015 23:20	30	.
014-002	47/Male	28APR2015 21:00	ACCUSOL 35 Potassium 4 mmol/L	14I09G71	PRE-FILTER	28APR2015 23:20 / 29APR2015 03:40	30	5
014-002	47/Male	28APR2015 21:00	ACCUSOL 35 Potassium 4 mmol/L	14I09G71	AS DIALYSATE	28APR2015 23:20 / 29APR2015 03:40	30	5
014-002	47/Male	28APR2015 21:00	ACCUSOL 35 Potassium 4 mmol/L	14I09G71	AS DIALYSATE	29APR2015 03:40 / 29APR2015 05:30	30	5
014-002	47/Male	28APR2015 21:00	ACCUSOL 35 Potassium 4 mmol/L	14I09G71	PRE-FILTER	29APR2015 03:40 / 29APR2015 05:30	30	5

Data Listing 16.2.5.3. ACCUSOL 35 Administration - Enrolled Population

Patient Number	Age (Years)/ Gender	First Accusol Administration Start Date/ Time	Dialysis Solution Used	Lot Number	Site of Introduction	Start Date and Time/ End Date and Time	Dialysis Dose (ml/kg/hr)	Amount Administered (L)
014-002	47/Male	28APR2015 21:00	ACCUSOL 35	14K27G73	AS DIALYSATE	29APR2015 05:30 / 29APR2015 09:30	30	5
014-002	47/Male	28APR2015 21:00	ACCUSOL 35	14K27G73	PRE-FILTER	29APR2015 05:30 / 29APR2015 09:30	30	5
014-002	47/Male	28APR2015 21:00	ACCUSOL 35 Potassium 4 mmol/L	14I09G71	PRE-FILTER	29APR2015 09:30 / 29APR2015 15:20	30	5
014-002	47/Male	28APR2015 21:00	ACCUSOL 35 Potassium 4 mmol/L	14I09G71	PRE-FILTER	29APR2015 15:20 / 29APR2015 21:00	30	5
014-002	47/Male	28APR2015 21:00	ACCUSOL 35 Potassium 4 mmol/L	14I09G71	PRE-FILTER	29APR2015 21:00 / 30APR2015 01:00	30	5
014-002	47/Male	28APR2015 21:00	ACCUSOL 35	14K27G73	PRE-FILTER	30APR2015 01:00 / 30APR2015 01:30	30	5
014-003	63/Female	12JUN2015 17:30		UNK	PRE AND POST	12JUN2015 17:30 / 12JUN2015 17:45	30	.
014-003	63/Female	12JUN2015 17:30	ACCUSOL 35	14J02670	PRE-FILTER	12JUN2015 17:45 / 12JUN2015 20:30	30	5
014-004	33/Female	02SEP2015 11:15	ACCUSOL 35	15A08G74	AS DIALYSATE	02SEP2015 11:15 / 02SEP2015 14:15	30	4
014-004	33/Female	02SEP2015 11:15	ACCUSOL 35	15A08G74	AS DIALYSATE	02SEP2015 11:15 / 02SEP2015 14:15	30	4
014-004	33/Female	02SEP2015 11:15	ACCUSOL 35	15A08G74	AS DIALYSATE	02SEP2015 14:15 / 02SEP2015 18:00	30	5

Data Listing 16.2.5.3. ACCUSOL 35 Administration - Enrolled Population

Patient Number	Age (Years)/ Gender	First Accusol Administration Start Date/ Time	Dialysis Solution Used	Lot Number	Site of Introduction	Start Date and Time/ End Date and Time	Dialysis Dose (ml/kg/hr)	Amount Administered (L)
014-004	33/Female	02SEP2015 11:15	ACCUSOL 35 Potassium 4 mmol/L	15A08G74	AS DIALYSATE	02SEP2015 14:15 / 02SEP2015 18:00	30	5
014-004	33/Female	02SEP2015 11:15	ACCUSOL 35	15A08G74	AS DIALYSATE	02SEP2015 18:00 / 02SEP2015 22:15	30	5
014-004	33/Female	02SEP2015 11:15	ACCUSOL 35	15A8G74	AS DIALYSATE	02SEP2015 18:00 / 02SEP2015 22:15	30	5
014-004	33/Female	02SEP2015 11:15	ACCUSOL 35	15C02G70	AS DIALYSATE	02SEP2015 22:15 / 02SEP2015 23:00	30	5
014-004	33/Female	02SEP2015 11:15	ACCUSOL 35	15C02G70	AS DIALYSATE	02SEP2015 22:15 / 02SEP2015 23:00	30	5
014-007	34/Female	09SEP2015 05:00		UNK	UNK	09SEP2015 05:00 / 09SEP2015 06:05	UNK	.
014-007	34/Female	09SEP2015 05:00	ACCUSOL 35 Potassium 4 mmol/L	15C02G70B	AS DIALYSATE	09SEP2015 06:05 / 09SEP2015 10:30	30	5
014-007	34/Female	09SEP2015 05:00	ACCUSOL 35 Potassium 4 mmol/L	15C02G70B	AS DIALYSATE	09SEP2015 06:05 / 09SEP2015 10:30	30	5
014-007	34/Female	09SEP2015 05:00	ACCUSOL 35 Potassium 4 mmol/L	15C02G70B	AS DIALYSATE	09SEP2015 10:30 / 09SEP2015 15:15	30	5
014-007	34/Female	09SEP2015 05:00	ACCUSOL 35 Potassium 4 mmol/L	15C02G70B	AS DIALYSATE	09SEP2015 10:30 / 09SEP2015 15:15	30	5
014-007	34/Female	09SEP2015 05:00	ACCUSOL 35 Potassium 4 mmol/L	15C02G70B	AS DIALYSATE	09SEP2015 15:15 / 09SEP2015 20:15	30	5

Data Listing 16.2.5.3. ACCUSOL 35 Administration - Enrolled Population

Patient Number	Age (Years)/ Gender	First Accusol Administration Start Date/ Time	Dialysis Solution Used	Lot Number	Site of Introduction	Start Date and Time/ End Date and Time	Dialysis Dose (ml/kg/hr)	Amount Administered (L)
014-007	34/Female	09SEP2015 05:00	ACCUSOL 35 Potassium 4 mmol/L	15C02G70B	AS DIALYSATE	09SEP2015 15:15 / 09SEP2015 20:15	30	5
014-007	34/Female	09SEP2015 05:00	ACCUSOL 35 Potassium 4 mmol/L	15C02G70B	AS DIALYSATE	09SEP2015 20:15 / 10SEP2015 02:00	30	5
014-007	34/Female	09SEP2015 05:00	ACCUSOL 35 Potassium 4 mmol/L	15C02G70B	AS DIALYSATE	09SEP2015 20:15 / 10SEP2015 02:00	30	5
014-007	34/Female	09SEP2015 05:00	ACCUSOL 35 Potassium 4 mmol/L	15C02G70B	AS DIALYSATE	10SEP2015 02:00 / 10SEP2015 06:00	30	5
014-007	34/Female	09SEP2015 05:00	ACCUSOL 35 Potassium 4 mmol/L	15C02G70B	AS DIALYSATE	10SEP2015 02:00 / 10SEP2015 06:00	30	5
014-007	34/Female	09SEP2015 05:00	ACCUSOL 35 Potassium 4 mmol/L	15C02G70B	AS DIALYSATE	10SEP2015 06:00 / 10SEP2015 08:00	30	5
014-007	34/Female	09SEP2015 05:00	ACCUSOL 35 Potassium 4 mmol/L	15C02G70B	AS DIALYSATE	10SEP2015 06:00 / 10SEP2015 08:00	30	5
015-001	77/Female	27APR2015 13:00	ACCUSOL 35	UNK	PRE & POST	27APR2015 13:00 / 27APR2015 15:00	35	1.33
015-001	77/Female	27APR2015 13:00	ACCUSOL 35 Potassium 4 mmol/L	14K13G73	PRE & POST	27APR2015 13:00 / 27APR2015 15:00	35	1.33
015-001	77/Female	27APR2015 13:00	ACCUSOL 35 Potassium 4 mmol/L	14K13G73	PRE & POST	27APR2015 13:00 / 27APR2015 15:00	35	1.33
015-001	77/Female	27APR2015 13:00	ACCUSOL 35 Potassium 4 mmol/L	14K13G73	PRE & POST	27APR2015 15:00 / 27APR2015 22:15	35	5

Data Listing 16.2.5.3. ACCUSOL 35 Administration - Enrolled Population

Patient Number	Age (Years)/ Gender	First Accusol Administration Start Date/ Time	Dialysis Solution Used	Lot Number	Site of Introduction	Start Date and Time/ End Date and Time	Dialysis Dose (ml/kg/hr)	Amount Administered (L)
015-001	77/Female	27APR2015 13:00	ACCUSOL 35 Potassium 4 mmol/L	14K12G71	PRE & POST	27APR2015 15:00 / 27APR2015 22:15	35	5
015-001	77/Female	27APR2015 13:00	ACCUSOL 35 Potassium 4 mmol/L	14K12G71	PRE & POST	27APR2015 15:00 / 27APR2015 22:15	35	5
015-001	77/Female	27APR2015 13:00	ACCUSOL 35 Potassium 4 mmol/L	14K13G73	PRE & POST	27APR2015 22:15 / 28APR2015 05:25	35	5
015-001	77/Female	27APR2015 13:00	ACCUSOL 35 Potassium 4 mmol/L	14K13G73	PRE & POST	27APR2015 22:15 / 28APR2015 05:25	35	5
015-001	77/Female	27APR2015 13:00	ACCUSOL 35 Potassium 4 mmol/L	14K13G73	PRE & POST	27APR2015 22:15 / 28APR2015 05:25	35	5
015-001	77/Female	27APR2015 13:00	ACCUSOL 35 Potassium 4 mmol/L	14K12G71	PRE & POST	28APR2015 05:25 / 28APR2015 15:00	35	5
015-001	77/Female	27APR2015 13:00	ACCUSOL 35 Potassium 4 mmol/L	14K12G71	PRE & POST	28APR2015 05:25 / 28APR2015 15:00	35	5
015-001	77/Female	27APR2015 13:00	ACCUSOL 35 Potassium 4 mmol/L	14K13G73	PRE & POST	28APR2015 05:25 / 28APR2015 15:00	35	5
015-001	77/Female	27APR2015 13:00	ACCUSOL 35 Potassium 4 mmol/L	14K1342	PRE & POST	28APR2015 15:00 / 28APR2015 16:20	35	0.9
015-001	77/Female	27APR2015 13:00	ACCUSOL 35 Potassium 4 mmol/L	14K1342	PRE & POST	28APR2015 15:00 / 28APR2015 16:20	35	0.9
015-001	77/Female	27APR2015 13:00	ACCUSOL 35 Potassium 4 mmol/L	14K1342	PRE & POST	28APR2015 15:00 / 28APR2015 16:20	35	0.9

Data Listing 16.2.5.3. ACCUSOL 35 Administration - Enrolled Population

Patient Number	Age (Years)/ Gender	First Accusol Administration Start Date/ Time	Dialysis Solution Used	Lot Number	Site of Introduction	Start Date and Time/ End Date and Time	Dialysis Dose (ml/kg/hr)	Amount Administered (L)
015-002	60/Male	24MAY2015 19:00		UNK	PRE & POST	24MAY2015 19:00 / --	UNK	.
015-002	60/Male	24MAY2015 19:00		UNK	PRE & POST	24MAY2015 19:00 / --	UNK	.
015-002	60/Male	24MAY2015 19:00		UNK	PRE & POST	24MAY2015 19:00 / --	UNK	.
015-002	60/Male	24MAY2015 19:00	ACCUSOL 35 Potassium 4 mmol/L	E9011	PRE & POST	25MAY2015 20:30 / --	UNK	4.3
015-002	60/Male	24MAY2015 19:00	ACCUSOL 35 Potassium 4 mmol/L	E9011	PRE & POST	25MAY2015 20:30 / --	UNK	4.3
015-002	60/Male	24MAY2015 19:00	ACCUSOL 35 Potassium 4 mmol/L	E9011	PRE & POST	25MAY2015 20:30 / --	UNK	4.3
015-003	57/Male	29MAY2015		UNK	PRE & POST	29MAY2015 / --	30	.
015-003	57/Male	29MAY2015		UNK	PRE & POST	29MAY2015 05:40 / --	30	5
015-003	57/Male	29MAY2015		UNK	PRE & POST	29MAY2015 05:40 / --	30	5
015-003	57/Male	29MAY2015		UNK	PRE & POST	29MAY2015 05:40 / --	30	5
015-004	85/Male	20JUN2015 07:30	ACCUSOL 35 Potassium 4 mmol/L	14K13G73	PRE & POST	20JUN2015 07:30 / 20JUN2015 14:00	30	5

Data Listing 16.2.5.3. ACCUSOL 35 Administration - Enrolled Population

Patient Number	Age (Years)/ Gender	First Accusol Administration Start Date/ Time	Dialysis Solution Used	Lot Number	Site of Introduction	Start Date and Time/ End Date and Time	Dialysis Dose (ml/kg/hr)	Amount Administered (L)
015-004	85/Male	20JUN2015 07:30	ACCUSOL 35 Potassium 4 mmol/L	14K13G73	PRE & POST	20JUN2015 07:30 / 20JUN2015 14:00	30	5
015-004	85/Male	20JUN2015 07:30	ACCUSOL 35 Potassium 4 mmol/L	14K13G73	PRE & POST	20JUN2015 07:30 / 20JUN2015 14:00	30	5
015-004	85/Male	20JUN2015 07:30	ACCUSOL 35 Potassium 4 mmol/L	14K13G73	PRE & POST	20JUN2015 14:00 / 20JUN2015 23:00	30	5
015-004	85/Male	20JUN2015 07:30	ACCUSOL 35 Potassium 4 mmol/L	14K13G73	PRE & POST	20JUN2015 14:00 / 20JUN2015 23:00	30	5
015-004	85/Male	20JUN2015 07:30	ACCUSOL 35 Potassium 4 mmol/L	14K13G73	PRE & POST	20JUN2015 14:00 / 20JUN2015 23:00	30	5
015-004	85/Male	20JUN2015 07:30	ACCUSOL 35 Potassium 4 mmol/L	UNK	PRE & POST	20JUN2015 23:00 / 21JUN2015 07:00	30	5
015-004	85/Male	20JUN2015 07:30	ACCUSOL 35 Potassium 4 mmol/L	UNK	PRE & POST	20JUN2015 23:00 / 21JUN2015 07:00	30	5
015-004	85/Male	20JUN2015 07:30	ACCUSOL 35 Potassium 4 mmol/L	UNK	PRE & POST	20JUN2015 23:00 / 21JUN2015 07:00	30	5
015-004	85/Male	20JUN2015 07:30	ACCUSOL 35 Potassium 4 mmol/L	UNK	PRE & POST	21JUN2015 07:00 / 21JUN2015 15:30	30	5
015-004	85/Male	20JUN2015 07:30	ACCUSOL 35 Potassium 4 mmol/L	UNK	PRE & POST	21JUN2015 07:00 / 21JUN2015 15:30	30	5
015-004	85/Male	20JUN2015 07:30	ACCUSOL 35 Potassium 4 mmol/L	UNK	PRE & POST	21JUN2015 07:00 / 21JUN2015 15:30	30	5

Data Listing 16.2.5.3. ACCUSOL 35 Administration - Enrolled Population

Patient Number	Age (Years)/ Gender	First Accusol Administration Start Date/ Time	Dialysis Solution Used	Lot Number	Site of Introduction	Start Date and Time/ End Date and Time	Dialysis Dose (ml/kg/hr)	Amount Administered (L)
015-005	76/Male	06JUL2015 19:13	ACCUSOL 35 Potassium 4 mmol/L	15A08G74	PRE & POST	06JUL2015 19:13 / 07JUL2015 01:25	25	4.33
015-005	76/Male	06JUL2015 19:13	ACCUSOL 35 Potassium 4 mmol/L	15A08G74	PRE & POST	06JUL2015 19:13 / 07JUL2015 01:25	25	4.33
015-005	76/Male	06JUL2015 19:13	ACCUSOL 35 Potassium 4 mmol/L	15A08G74	PRE & POST	06JUL2015 19:13 / 07JUL2015 01:25	25	4.33
015-005	76/Male	06JUL2015 19:13	ACCUSOL 35 Potassium 4 mmol/L	14K13G73	PRE & POST	07JUL2015 01:25 / 07JUL2015 09:15	25	5
015-005	76/Male	06JUL2015 19:13	ACCUSOL 35 Potassium 4 mmol/L	14K13G73	PRE & POST	07JUL2015 01:25 / 07JUL2015 09:15	25	5
015-005	76/Male	06JUL2015 19:13	ACCUSOL 35 Potassium 4 mmol/L	14K13G73	PRE & POST	07JUL2015 01:25 / 07JUL2015 09:15	25	5
015-005	76/Male	06JUL2015 19:13	ACCUSOL 35 Potassium 4 mmol/L	14K13G73	PRE & POST	07JUL2015 09:15 / 07JUL2015 17:10	25	5
015-005	76/Male	06JUL2015 19:13	ACCUSOL 35 Potassium 4 mmol/L	14K13G73	PRE & POST	07JUL2015 09:15 / 07JUL2015 17:10	25	5
015-005	76/Male	06JUL2015 19:13	ACCUSOL 35 Potassium 4 mmol/L	14K13G73	PRE & POST	07JUL2015 09:15 / 07JUL2015 17:10	25	5
015-005	76/Male	06JUL2015 19:13	ACCUSOL 35 Potassium 4 mmol/L	15A08G74	PRE & POST	07JUL2015 17:10 / 07JUL2015 23:50	25	5
015-005	76/Male	06JUL2015 19:13	ACCUSOL 35 Potassium 4 mmol/L	15A08G74	PRE & POST	07JUL2015 17:10 / 07JUL2015 23:50	25	5

Data Listing 16.2.5.3. ACCUSOL 35 Administration - Enrolled Population

Patient Number	Age (Years)/ Gender	First Accusol Administration Start Date/ Time	Dialysis Solution Used	Lot Number	Site of Introduction	Start Date and Time/ End Date and Time	Dialysis Dose (ml/kg/hr)	Amount Administered (L)
015-005	76/Male	06JUL2015 19:13	ACCUSOL 35 Potassium 4 mmol/L	14K13G73	PRE & POST	07JUL2015 17:10 / 07JUL2015 23:50	25	5
015-005	76/Male	06JUL2015 19:13	ACCUSOL 35 Potassium 4 mmol/L	14K13G73	PRE & POST	07JUL2015 23:50 / 08JUL2015 03:13	25	2
015-005	76/Male	06JUL2015 19:13	ACCUSOL 35 Potassium 4 mmol/L	14K13G73	PRE & POST	07JUL2015 23:50 / 08JUL2015 03:13	25	2
015-005	76/Male	06JUL2015 19:13	ACCUSOL 35 Potassium 4 mmol/L	14K13G73	PRE & POST	07JUL2015 23:50 / 08JUL2015 03:13	25	2
015-006	84/Female	15AUG2015 07:10	ACCUSOL 35 Potassium 4 mmol/L	15A08G74	PRE & POST	15AUG2015 07:10 / 15AUG2015 14:15	38	4.33
015-006	84/Female	15AUG2015 07:10	ACCUSOL 35 Potassium 4 mmol/L	14K13G73	PRE & POST	15AUG2015 07:10 / 15AUG2015 14:15	38	4.33
015-006	84/Female	15AUG2015 07:10	ACCUSOL 35 Potassium 4 mmol/L	14K13G73	PRE & POST	15AUG2015 07:10 / 15AUG2015 14:15	38	4.33
015-006	84/Female	15AUG2015 07:10	ACCUSOL 35 Potassium 4 mmol/L	15A08G74	PRE & POST	15AUG2015 14:15 / 15AUG2015 22:45	38	5
015-006	84/Female	15AUG2015 07:10	ACCUSOL 35 Potassium 4 mmol/L	15A08G74	PRE & POST	15AUG2015 14:15 / 15AUG2015 22:45	38	5
015-006	84/Female	15AUG2015 07:10	ACCUSOL 35 Potassium 4 mmol/L	15A08G74	PRE & POST	15AUG2015 14:15 / 15AUG2015 22:45	38	5
015-006	84/Female	15AUG2015 07:10	ACCUSOL 35 Potassium 4 mmol/L	15A08G74	PRE & POST	15AUG2015 22:45 / 16AUG2015 07:05	38	5

Data Listing 16.2.5.3. ACCUSOL 35 Administration - Enrolled Population

Patient Number	Age (Years)/ Gender	First Accusol Administration Start Date/ Time	Dialysis Solution Used	Lot Number	Site of Introduction	Start Date and Time/ End Date and Time	Dialysis Dose (ml/kg/hr)	Amount Administered (L)
015-006	84/Female	15AUG2015 07:10	ACCUSOL 35 Potassium 4 mmol/L	14K13G73	PRE & POST	15AUG2015 22:45 / 16AUG2015 07:05	38	5
015-006	84/Female	15AUG2015 07:10	ACCUSOL 35 Potassium 4 mmol/L	14K13G73	PRE & POST	15AUG2015 22:45 / 16AUG2015 07:05	38	5
015-006	84/Female	15AUG2015 07:10	ACCUSOL 35 Potassium 4 mmol/L	15A07G71	PRE & POST	16AUG2015 07:05 / 16AUG2015 14:15	38	5
015-006	84/Female	15AUG2015 07:10	ACCUSOL 35 Potassium 4 mmol/L	14K13G73	PRE & POST	16AUG2015 07:05 / 16AUG2015 14:15	38	5
015-006	84/Female	15AUG2015 07:10	ACCUSOL 35 Potassium 4 mmol/L	14K13G73	PRE & POST	16AUG2015 07:05 / 16AUG2015 14:15	38	5
015-006	84/Female	15AUG2015 07:10	ACCUSOL 35 Potassium 4 mmol/L	15A07G71	PRE & POST	16AUG2015 14:15 / 16AUG2015 15:10	38	1.83
015-009	76/Female	06JAN2016 19:45	ACCUSOL 35	15D12G70	PRE & POST	06JAN2016 19:45 / 06JAN2016 22:25	32	1.78
015-009	76/Female	06JAN2016 19:45	ACCUSOL 35 Potassium 4 mmol/L	15C02G70	PRE & POST	06JAN2016 19:45 / 06JAN2016 22:25	32	1.78
015-009	76/Female	06JAN2016 19:45	ACCUSOL 35 Potassium 4 mmol/L	15C02G70	PRE&POST	06JAN2016 19:45 / 06JAN2016 22:25	32	1.78
015-009	76/Female	06JAN2016 19:45	ACCUSOL 35	15E09G70	PRE & POST	06JAN2016 22:25 / 07JAN2016 05:15	32	5
015-009	76/Female	06JAN2016 19:45	ACCUSOL 35 Potassium 4 mmol/L	15C02G71	PRE & POST	06JAN2016 22:25 / 07JAN2016 05:15	32	5

Data Listing 16.2.5.3. ACCUSOL 35 Administration - Enrolled Population

Patient Number	Age (Years)/ Gender	First Accusol Administration Start Date/ Time	Dialysis Solution Used	Lot Number	Site of Introduction	Start Date and Time/ End Date and Time	Dialysis Dose (ml/kg/hr)	Amount Administered (L)
015-009	76/Female	06JAN2016 19:45	ACCUSOL 35 Potassium 4 mmol/L	15C02G71	PRE & POST	06JAN2016 22:25 / 07JAN2016 05:15	32	5
015-009	76/Female	06JAN2016 19:45	ACCUSOL 35	15E09G70	PRE & POST	07JAN2016 05:15 / 07JAN2016 13:00	32	5
015-009	76/Female	06JAN2016 19:45	ACCUSOL 35 Potassium 4 mmol/L	15C02G71	PRE & POST	07JAN2016 05:15 / 07JAN2016 13:00	32	5
015-009	76/Female	06JAN2016 19:45	ACCUSOL 35 Potassium 4 mmol/L	15C02G71	PRE & POST	07JAN2016 05:15 / 07JAN2016 13:00	32	5
015-009	76/Female	06JAN2016 19:45	ACCUSOL 35 Potassium 4 mmol/L	15C02G70	PRE & POST	07JAN2016 13:00 / 07JAN2016 23:35	32	5
015-009	76/Female	06JAN2016 19:45	ACCUSOL 35 Potassium 4 mmol/L	15C02G70	PRE & POST	07JAN2016 13:00 / 07JAN2016 23:35	32	5
015-009	76/Female	06JAN2016 19:45	ACCUSOL 35	15E09G70	PRE & POST	07JAN2016 13:00 / 07JAN2016 17:40	32	3.06
015-009	76/Female	06JAN2016 19:45	ACCUSOL 35 Potassium 4 mmol/L	15C02G70	PRE & POST	07JAN2016 17:40 / 07JAN2016 23:35	32	5
015-009	76/Female	06JAN2016 19:45	ACCUSOL 35	15E09G70	PRE & POST	07JAN2016 23:35 / 08JAN2016 03:45	32	2.78
015-009	76/Female	06JAN2016 19:45	ACCUSOL 35 Potassium 4 mmol/L	15C02G71	PRE & POST	07JAN2016 23:35 / 08JAN2016 03:45	32	2.78
015-009	76/Female	06JAN2016 19:45	ACCUSOL 35 Potassium 4 mmol/L	15C02G71	PRE & POST	07JAN2016 23:35 / 08JAN2016 03:45	32	2.78

Data Listing 16.2.5.3. ACCUSOL 35 Administration - Enrolled Population

Patient Number	Age (Years)/ Gender	First Accusol Administra- tion Start Date/ Time	Dialysis Solution Used	Lot Number	Site of Introduction	Start Date and Time/ End Date and Time	Dialysis Dose (ml/kg/hr)	Amount Administer- ed (L)
015-010		10JAN2016 14:15	ACCUSOL 35	15E09G70	PRE & POST	10JAN2016 14:15 / 10JAN2016 19:50	25	4.83
015-010		10JAN2016 14:15	ACCUSOL 35	15E09G70	PRE & POST	10JAN2016 14:15 / 10JAN2016 19:50	25	4.83
015-010		10JAN2016 14:15	ACCUSOL 35	15E09G70	PRE & POST	10JAN2016 14:15 / 10JAN2016 19:50	25	4.83
015-010		10JAN2016 14:15	ACCUSOL 35	15E09G70	PRE & POST	10JAN2016 19:50 / 11JAN2016 01:35	25	5
015-010		10JAN2016 14:15	ACCUSOL 35	15E09G70	PRE & POST	10JAN2016 19:50 / 11JAN2016 01:35	25	5
015-010		10JAN2016 14:15	ACCUSOL 35 Potassium 4 mmol/L	15C02G70	PRE & POST	10JAN2016 19:50 / 11JAN2016 01:35	25	5
015-010		10JAN2016 14:15	ACCUSOL 35	15E09G70	PRE & POST	11JAN2016 01:35 / 11JAN2016 06:10	25	5
015-010		10JAN2016 14:15	ACCUSOL 35	15E09G70	PRE & POST	11JAN2016 01:35 / 11JAN2016 06:10	25	5
015-010		10JAN2016 14:15	ACCUSOL 35 Potassium 4 mmol/L	15C02G70	PRE & POST	11JAN2016 01:35 / 11JAN2016 06:10	25	5
015-010		10JAN2016 14:15	ACCUSOL 35	15E09G70	PRE & POST	11JAN2016 06:10 / 11JAN2016 10:50	25	5
015-010		10JAN2016 14:15	ACCUSOL 35	15E09G70	PRE & POST	11JAN2016 06:10 / 11JAN2016 10:50	25	5

Data Listing 16.2.5.3. ACCUSOL 35 Administration - Enrolled Population

Patient Number	Age (Years)/ Gender	First Accusol Administration Start Date/ Time	Dialysis Solution Used	Lot Number	Site of Introduction	Start Date and Time/ End Date and Time	Dialysis Dose (ml/kg/hr)	Amount Administered (L)
015-011		23JAN2016 09:30	ACCUSOL 35 Potassium 4 mmol/L	UNKNOWN	PRE & POST	23JAN2016 09:30 / 23JAN2016 10:40	38	0.78
015-011		23JAN2016 09:30	ACCUSOL 35 Potassium 4 mmol/L	UNKNOWN	PRE & POST	23JAN2016 09:30 / 23JAN2016 10:40	38	0.78
015-011		23JAN2016 09:30	ACCUSOL 35 Potassium 4 mmol/L	UNKNOWN	PRE & POST	23JAN2016 09:30 / 23JAN2016 10:40	38	0.78
015-011		23JAN2016 09:30	ACCUSOL 35 Potassium 4 mmol/L	15J12G71	PRE & POST	23JAN2016 10:40 / 23JAN2016 18:30	38	5
015-011		23JAN2016 09:30	ACCUSOL 35 Potassium 4 mmol/L	15J12G71	PRE & POST	23JAN2016 10:40 / 23JAN2016 18:30	38	5
015-011		23JAN2016 09:30	ACCUSOL 35 Potassium 4 mmol/L	15J12G71	PRE & POST	23JAN2016 10:40 / 23JAN2016 18:30	38	5
015-011		23JAN2016 09:30	ACCUSOL 35 Potassium 4 mmol/L	15J12G71	PRE & POST	23JAN2016 18:30 / 23JAN2016 20:05	38	0.72
015-011		23JAN2016 09:30	ACCUSOL 35 Potassium 4 mmol/L	15J12G71	PRE & POST	23JAN2016 18:30 / 23JAN2016 20:05	38	0.72
015-011		23JAN2016 09:30	ACCUSOL 35 Potassium 4 mmol/L	15J12G71	PRE & POST	23JAN2016 18:30 / 23JAN2016 20:05	38	0.72
016-002		04SEP2015 11:10	ACCUSOL 35 Potassium 4 mmol/L	15C02G70	PRE AND POST DILUTION	04SEP2015 11:10 / 04SEP2015 12:15	35	0.9
016-002		04SEP2015 11:10	ACCUSOL 35 Potassium 4 mmol/L	15A07G71	PRE AND POST FILTER	04SEP2015 11:10 / 04SEP2015 12:15	35	0.9

Data Listing 16.2.5.3. ACCUSOL 35 Administration - Enrolled Population

Patient Number	Age (Years)/ Gender	First Accusol Administration Start Date/ Time	Dialysis Solution Used	Lot Number	Site of Introduction	Start Date and Time/ End Date and Time	Dialysis Dose (ml/kg/hr)	Amount Administered (L)
016-004	55/Male	03DEC2015 09:30	ACCUSOL 35 Potassium 4 mmol/L	15H28G73	PRE AND POST FILTER	03DEC2015 09:30 / 03DEC2015 12:00	32.75	5
016-004	55/Male	03DEC2015 09:30	ACCUSOL 35 Potassium 4 mmol/L	15H28G73	PRE AND POST FILTER	03DEC2015 09:30 / 03DEC2015 12:00	32.75	5
017-003	92/Female	13JUL2015 18:00	ACCUSOL 35	15A09G71B	PRE AND POST FILTER	13JUL2015 18:00 / 13JUL2015 19:20	37	4.8
017-004	74/Male	18JUL2015 09:30	ACCUSOL 35	UNK	UNK	18JUL2015 09:30 / 18JUL2015 11:05	UNK	.
017-004	74/Male	18JUL2015 09:30	ACCUSOL 35	15A09G71	PRE-FILTER	18JUL2015 11:05 / 18JUL2015 15:15	46.6	5
017-004	74/Male	18JUL2015 09:30	ACCUSOL 35	15A09G71	PRE-FILTER	18JUL2015 11:05 / 18JUL2015 15:15	46.6	5
017-004	74/Male	18JUL2015 09:30	ACCUSOL 35	15A09G71	PRE-FILTER	18JUL2015 15:15 / 18JUL2015 19:00	46.6	5
017-004	74/Male	18JUL2015 09:30	ACCUSOL 35	15A09G71	PRE-FILTER	18JUL2015 15:15 / 18JUL2015 19:00	46.6	5
017-004	74/Male	18JUL2015 09:30	ACCUSOL 35	15A09G71	PRE-FILTER	18JUL2015 19:00 / 18JUL2015 22:45	46.6	5
017-004	74/Male	18JUL2015 09:30	ACCUSOL 35	15A09G71	PRE-FILTER	18JUL2015 19:00 / 18JUL2015 22:45	46.6	5
017-004	74/Male	18JUL2015 09:30	ACCUSOL 35	15A09G71	PRE-FILTER	18JUL2015 22:45 / 19JUL2015 02:25	46.6	5

Data Listing 16.2.5.3. ACCUSOL 35 Administration - Enrolled Population

Patient Number	Age (Years)/ Gender	First Accusol Administration Start Date/ Time	Dialysis Solution Used	Lot Number	Site of Introduction	Start Date and Time/ End Date and Time	Dialysis Dose (ml/kg/hr)	Amount Administered (L)
017-004	74/Male	18JUL2015 09:30	ACCUSOL 35	15A09G71	PRE-FILTER	18JUL2015 22:45 / 19JUL2015 02:25	46.6	5
017-004	74/Male	18JUL2015 09:30	ACCUSOL 35	15A09G71	PRE-FILTER	19JUL2015 02:25 / 19JUL2015 05:40	46.6	5
017-004	74/Male	18JUL2015 09:30	ACCUSOL 35	15A09G71	PRE-FILTER	19JUL2015 02:25 / 19JUL2015 05:40	46.6	5
017-004	74/Male	18JUL2015 09:30	ACCUSOL 35	15A09G71	PRE-FILTER	19JUL2015 05:40 / 19JUL2015 09:55	46.6	5
017-004	74/Male	18JUL2015 09:30	ACCUSOL 35	15A09G71	PRE-FILTER	19JUL2015 05:40 / 19JUL2015 09:55	46.6	5
017-004	74/Male	18JUL2015 09:30	ACCUSOL 35	15A09G71	PRE-FILTER	19JUL2015 09:55 / 19JUL2015 13:56	46.6	5
017-004	74/Male	18JUL2015 09:30	ACCUSOL 35	15A09G71	PRE-FILTER	19JUL2015 09:55 / 19JUL2015 13:56	46.6	5
017-004	74/Male	18JUL2015 09:30	ACCUSOL 35	15A09671	PRE-FILTER	19JUL2015 13:56 / 19JUL2015 17:30	46.6	5
017-004	74/Male	18JUL2015 09:30	ACCUSOL 35	15A09G71	PRE-FILTER	19JUL2015 13:56 / 19JUL2015 17:30	46.6	5
017-005	77/Male	13AUG2015 18:45	ACCUSOL 35	UNKNOWN	UNKNOWN	13AUG2015 18:45 / 13AUG2015 19:15	UNK	.
017-005	77/Male	13AUG2015 18:45	ACCUSOL 35	14K30G71	PRE & POST	13AUG2015 19:15 / 13AUG2015 22:30	33.3	5

Data Listing 16.2.5.3. ACCUSOL 35 Administration - Enrolled Population

Patient Number	Age (Years)/ Gender	First Accusol Administration Start Date/ Time	Dialysis Solution Used	Lot Number	Site of Introduction	Start Date and Time/ End Date and Time	Dialysis Dose (ml/kg/hr)	Amount Administered (L)
017-005	77/Male	13AUG2015 18:45	ACCUSOL 35	14K30G71	PRE & POST	13AUG2015 19:15 / 13AUG2015 22:30	33.3	5
017-005	77/Male	13AUG2015 18:45	ACCUSOL 35	14K30G71	PRE & POST	13AUG2015 22:30 / 14AUG2015 01:15	33.3	5
017-005	77/Male	13AUG2015 18:45	ACCUSOL 35	14K30G71	PRE & POST	13AUG2015 22:30 / 14AUG2015 01:15	33.3	5
017-005	77/Male	13AUG2015 18:45	ACCUSOL 35	14K30G71	PRE & POST	14AUG2015 01:15 / 14AUG2015 04:10	33.3	5
017-005	77/Male	13AUG2015 18:45	ACCUSOL 35	14K30G71	PRE & POST	14AUG2015 01:15 / 14AUG2015 04:10	33.3	5
017-005	77/Male	13AUG2015 18:45	ACCUSOL 35	14K30G71	PRE & POST	14AUG2015 04:10 / 14AUG2015 07:10	33.3	5
017-005	77/Male	13AUG2015 18:45	ACCUSOL 35	14K30G71	PRE & POST	14AUG2015 04:10 / 14AUG2015 07:10	33.3	5
017-005	77/Male	13AUG2015 18:45	ACCUSOL 35	14K30G71	PRE & POST	14AUG2015 07:10 / 14AUG2015 09:00	33.3	5
017-005	77/Male	13AUG2015 18:45	ACCUSOL 35	14K30G71	PRE & POST	14AUG2015 07:10 / 14AUG2015 09:00	33.3	5
017-007	66/Male	02SEP2015 07:30	ACCUSOL 35	15D12G70	PRE-FILTER	02SEP2015 07:30 / 02SEP2015 11:10	35	5
017-007	66/Male	02SEP2015 07:30	ACCUSOL 35	15D12G70	PRE-FILTER	02SEP2015 07:30 / 02SEP2015 11:10	35	5

Data Listing 16.2.5.3. ACCUSOL 35 Administration - Enrolled Population

Patient Number	Age (Years)/ Gender	First Accusol Administration Start Date/ Time	Dialysis Solution Used	Lot Number	Site of Introduction	Start Date and Time/ End Date and Time	Dialysis Dose (ml/kg/hr)	Amount Administered (L)
017-007	66/Male	02SEP2015 07:30	ACCUSOL 35	15D12G70	PRE-FILTER	02SEP2015 11:10 / 02SEP2015 14:35	35	5
017-007	66/Male	02SEP2015 07:30	ACCUSOL 35	15D12G70	PRE-FILTER	02SEP2015 11:10 / 02SEP2015 14:35	35	5
017-007	66/Male	02SEP2015 07:30	ACCUSOL 35	15D12G70	PRE-FILTER	02SEP2015 14:35 / 02SEP2015 18:35	35	5
017-007	66/Male	02SEP2015 07:30	ACCUSOL 35	15D12G70	PRE-FILTER	02SEP2015 14:35 / 02SEP2015 18:35	35	5
017-007	66/Male	02SEP2015 07:30	ACCUSOL 35	15D12G70	PRE-FILTER	02SEP2015 18:35 / 02SEP2015 22:30	35	5
017-007	66/Male	02SEP2015 07:30	ACCUSOL 35	15D12G70	PRE-FILTER	02SEP2015 18:35 / 02SEP2015 22:30	35	5
017-007	66/Male	02SEP2015 07:30	ACCUSOL 35	15D12G70	PRE-FILTER	02SEP2015 22:30 / 03SEP2015 01:55	35	5
017-007	66/Male	02SEP2015 07:30	ACCUSOL 35	15D12G70	PRE-FILTER	02SEP2015 22:30 / 03SEP2015 01:55	35	5
017-007	66/Male	02SEP2015 07:30	ACCUSOL 35	15D12G70	PRE-FILTER	03SEP2015 01:55 / 03SEP2015 05:30	35	5
017-007	66/Male	02SEP2015 07:30	ACCUSOL 35	15D12G70	PRE-FILTER	03SEP2015 01:55 / 03SEP2015 05:30	35	5
017-007	66/Male	02SEP2015 07:30	ACCUSOL 35	15D12G70	PRE-FILTER	03SEP2015 05:30 / 03SEP2015 08:45	35	5

Data Listing 16.2.5.3. ACCUSOL 35 Administration - Enrolled Population

Patient Number	Age (Years)/ Gender	First Accusol Administration Start Date/ Time	Dialysis Solution Used	Lot Number	Site of Introduction	Start Date and Time/ End Date and Time	Dialysis Dose (ml/kg/hr)	Amount Administered (L)
017-007	66/Male	02SEP2015 07:30	ACCUSOL 35	15D12G70	PRE-FILTER	03SEP2015 05:30 / 03SEP2015 08:45	35	5
017-007	66/Male	02SEP2015 07:30	ACCUSOL 35	15D12G70	PRE-FILTER	03SEP2015 08:45 / 03SEP2015 12:50	35	5
017-007	66/Male	02SEP2015 07:30	ACCUSOL 35	15D12G70	PRE-FILTER	03SEP2015 08:45 / 03SEP2015 12:50	35	5
017-007	66/Male	02SEP2015 07:30	ACCUSOL 35	15D12G70	PRE-FILTER	03SEP2015 12:50 / 03SEP2015 15:30	35	5
017-007	66/Male	02SEP2015 07:30	ACCUSOL 35	15D12G70	PRE-FILTER	03SEP2015 12:50 / 03SEP2015 15:30	35	5
017-008		26SEP2015 16:24	ACCUSOL 35	14K 11 G71	PRE-FILTER	26SEP2015 16:24 / 26SEP2015 21:00	35	5
017-008		26SEP2015 16:24	ACCUSOL 35	14K11G70	PRE/POST FILTER	26SEP2015 16:24 / 26SEP2015 21:00	35	5
017-008		26SEP2015 16:24	ACCUSOL 35	14K11G71	PRE-FILTER	26SEP2015 21:00 / 27SEP2015 01:50	35	5
017-008		26SEP2015 16:24	ACCUSOL 35	14K11G71	PRE-FILTER	26SEP2015 21:00 / 27SEP2015 01:50	35	5
017-008		26SEP2015 16:24	ACCUSOL 35	14K11G71	PRE-FILTER	27SEP2015 01:50 / 27SEP2015 06:30	35	5
017-008		26SEP2015 16:24	ACCUSOL 35	14K11G71	PRE-FILTER	27SEP2015 01:50 / 27SEP2015 06:30	35	5

Data Listing 16.2.5.3. ACCUSOL 35 Administration - Enrolled Population

Patient Number	Age (Years)/ Gender	First Accusol Administration Start Date/ Time	Dialysis Solution Used	Lot Number	Site of Introduction	Start Date and Time/ End Date and Time	Dialysis Dose (ml/kg/hr)	Amount Administered (L)
017-008		26SEP2015 16:24	ACCUSOL 35	14K11G71	PRE-FILTER	27SEP2015 06:30 / 27SEP2015 12:30	35	5
017-008		26SEP2015 16:24	ACCUSOL 35	14K11G71	PRE-FILTER	27SEP2015 06:30 / 27SEP2015 12:30	35	5
017-008		26SEP2015 16:24	ACCUSOL 35	14K11G71	PRE-FILTER	27SEP2015 12:30 / 27SEP2015 17:00	35	5
017-008		26SEP2015 16:24	ACCUSOL 35	14K11G71	PRE-FILTER	27SEP2015 12:30 / 27SEP2015 17:00	35	5
017-008		26SEP2015 16:24	ACCUSOL 35	14K11G71	PRE-FILTER	27SEP2015 17:00 / 27SEP2015 21:50	35	5
017-008		26SEP2015 16:24	ACCUSOL 35	14K11G71	PRE-FILTER	27SEP2015 17:00 / 27SEP2015 21:50	35	5
017-008		26SEP2015 16:24	ACCUSOL 35	14K11G71	PRE-FILTER	27SEP2015 21:50 / 28SEP2015 00:20	35	5
017-008		26SEP2015 16:24	ACCUSOL 35	14K11G71	PRE-FILTER	27SEP2015 21:50 / 28SEP2015 00:20	35	5
017-010	54/Male	19NOV2015 14:10	ACCUSOL 35	UNK	UNKNOWN	19NOV2015 14:10 / 20NOV2015 09:30	UNK	.
017-010	54/Male	19NOV2015 14:10	ACCUSOL 35	15A09G71	PRE & POST	20NOV2015 09:30 / 20NOV2015 10:30	31.5	1.4
017-010	54/Male	19NOV2015 14:10	ACCUSOL 35	15A09G71	PRE & POST	20NOV2015 09:30 / 20NOV2015 10:30	31.5	1.4

Data Listing 16.2.5.3. ACCUSOL 35 Administration - Enrolled Population

Patient Number	Age (Years)/ Gender	First Accusol Administration Start Date/ Time	Dialysis Solution Used	Lot Number	Site of Introduction	Start Date and Time/ End Date and Time	Dialysis Dose (ml/kg/hr)	Amount Administered (L)
017-011	49/Male	22NOV2015 07:30	ACCUSOL 35	UNK		22NOV2015 07:30 / 22NOV2015 09:00	UNK	.
017-011	49/Male	22NOV2015 07:30	ACCUSOL 35	15A09G71	PRE & POST	22NOV2015 09:00 / 22NOV2015 13:00	32.7	5
017-011	49/Male	22NOV2015 07:30	ACCUSOL 35	15A09G71	PRE & POST	22NOV2015 13:00 / 22NOV2015 17:00	32.7	5
017-011	49/Male	22NOV2015 07:30	ACCUSOL 35	UNK		22NOV2015 17:00 / 22NOV2015 21:00	UNK	.
017-011	49/Male	22NOV2015 07:30	ACCUSOL 35	15A09G71	PRE & POST	22NOV2015 21:00 / 23NOV2015 01:00	32.7	5
017-011	49/Male	22NOV2015 07:30	ACCUSOL 35	UNK		23NOV2015 01:00 / 23NOV2015 05:00	UNK	.
017-011	49/Male	22NOV2015 07:30	ACCUSOL 35	15A09G71	PRE & POST	23NOV2015 05:00 / 23NOV2015 09:00	32.7	5
017-011	49/Male	22NOV2015 07:30	ACCUSOL 35	15A09G71	PRE & POST	23NOV2015 09:00 / 23NOV2015 13:00	32.7	5
017-011	49/Male	22NOV2015 07:30	ACCUSOL 35	UNK		23NOV2015 13:00 / 23NOV2015 15:30	UNK	.

Data Listing 16.2.5.4. Dialysis Session - Enrolled Population

Patient Number	Age (Years)/ Gender	Start Date and Time of Current CRRT Circuit/ End Date and Time of Current CRRT Circuit	Manufacturer of CRRT Monitor/ Model of CRRT Monitor	Manufacturer of CRRT Lines/ Model of CRRT Lines	Manufacturer of Haemofilter/ Model of Haemofilter	CRRT Mode Employed	Ultrafiltration Rate (L/h)
001-001	57/Female	02JUN2015 22:53 / 06JUN2015 02:53	EDWARDS / AQUARIUS	HAEMOTRONIC / AQUALINE	BELLCO / AQUAMAX	CONTINUOUS VENOVENOUS HEMOFILTRATION (CVVH)	2.10
001-002	50/Male	10JUN2015 23:00 / 13JUN2015 23:15	EDWARDS / AQUARIUS	HAEMOTRONIC / AQUALINE	BELLCO / AQUAMAX	CONTINUOUS VENOVENOUS HEMOFILTRATION (CVVH)	3.2
001-003	68/Female	12AUG2015 22:06 / 15AUG2015 02:30	EDWARDS / AQUARIUS	HAEMOTRONIC / AQUALINE	BELLCO / AQUAMAX	CONTINUOUS VENOVENOUS HEMOFILTRATION (CVVH)	2.8
001-004	78/Female	17SEP2015 04:01 / 20SEP2015 05:53	EDWARDS / AQUARIUS	HAEMOTRONIC / AQUALINE	BELLCO / AQUAMAX	CONTINUOUS VENOVENOUS HEMOFILTRATION (CVVH)	2.1
001-005	33/Female	27OCT2015 14:10 / 30OCT2015 14:40	EDWARDS / AQUARIUS	HAEMOTRONIC / AQUALINE	BELLCO / AQUAMAX	CONTINUOUS VENOVENOUS HEMOFILTRATION (CVVH)	2.6
001-006		11NOV2015 02:03 / 13NOV2015 15:50	EDWARDS / AQUARIUS	HAEMOTRONIC / AQUALINE	BELLCO / AQUAMAX	CONTINUOUS VENOVENOUS HEMOFILTRATION (CVVH)	4

Data Listing 16.2.5.4. Dialysis Session - Enrolled Population

Patient Number	Age (Years)/ Gender	Start Date and Time of Current CRRT Circuit/ End Date and Time of Current CRRT Circuit	Manufacturer of CRRT Monitor/ Model of CRRT Monitor	Manufacturer of CRRT Lines/ Model of CRRT Lines	Manufacturer of Haemofilter/ Model of Haemofilter	CRRT Mode Employed	Ultrafiltration Rate (L/h)
001-007	56/Male	21DEC2015 03:33 / 24DEC2015 07:20	EDWARDS / AQUARIUS	HAEMOTRONIC / AQUALINE	BELLCO / AQUAMAX	CONTINUOUS VENOVENOUS HEMOFILTRATION (CVVH)	2.1
001-008	57/Male	28JAN2016 01:00 / 31JAN2016 15:00	EDWARDS / AQUARIUS	HAEMOTRONIC / AQUALINE	BELLCO / AQUAMAX	CONTINUOUS VENOVENOUS HEMOFILTRATION (CVVH)	2.8
002-002	56/Male	24APR2015 10:25 / 27APR2015 10:25	EDWARDS / AQUARIUS	HAEMOTRONIC / AQUALINE	BELLCO / AQUAMAX HF12	CONTINUOUS VENOVENOUS HEMOFILTRATION (CVVH)	2
002-003	68/Female	03MAY2015 09:20 / 05MAY2015 09:50	EDWARDS / AQUARIUS	HAEMOTRONIC / AQUALINE	BELLCO / AQUAMAX HF12	CONTINUOUS VENOVENOUS HEMOFILTRATION (CVVH)	2.1
002-005	44/Male	13MAY2015 18:30 / 16MAY2015 18:20	EDWARDS / AQUARIUS	HAEMOTRONIC / AQUALINE	BELLCO / AQUAMAX HF12	CONTINUOUS VENOVENOUS HEMOFILTRATION (CVVH)	3
002-007	61/Male	22JUN2015 23:22 / 24JUN2015 18:00	EDWARDS / AQUARIUS	HAEMOTRONIC / AQUALINE	BELLCO / AQUAMAXHF 12	CONTINUOUS VENOVENOUS HEMOFILTRATION (CVVH)	3.1

Data Listing 16.2.5.4. Dialysis Session - Enrolled Population

Patient Number	Age (Years)/ Gender	Start Date and Time of Current CRRT Circuit/ End Date and Time of Current CRRT Circuit	Manufacturer of CRRT Monitor/ Model of CRRT Monitor	Manufacturer of CRRT Lines/ Model of CRRT Lines	Manufacturer of Haemofilter/ Model of Haemofilter	CRRT Mode Employed	Ultrafiltration Rate (L/h)
002-009	58/Female	17JUN2015 20:50 / 20JUN2015 17:00	EDWARDS / AQUARIUS	HAEMOTRONIC / AQUALINE	BELLCO / AQUAMAX HF12	CONTINUOUS VENOVENOUS HEMODIAFILTRATION (CVVHDF)	1.5
002-011	63/Female	18AUG2015 15:00 / 21AUG2015 15:00	EDWARDS / AQUARIUS	HAEMOTRONIC / AQUALINE	BELLCO / AQUAMAX	CONTINUOUS VENOVENOUS HEMOFILTRATION (CVVH)	3.2
002-012		28AUG2015 11:40 / 30AUG2015 12:45	GAMBRO / PRISMA	GAMBRO / PRISMA	GAMBRO / PRISMA	CONTINUOUS VENOVENOUS HEMOFILTRATION (CVVH)	1
002-014	59/Male	01SEP2015 00:00 / 03SEP2015 19:35	EDWARDS / AQUARIUS	HAEMOTRONIC / AQUALINE	BELLCO / AQUAMAX HF12	CONTINUOUS VENOVENOUS HEMOFILTRATION (CVVH)	2.5
002-016	83/Female	01SEP2015 23:55 / 03SEP2015 18:30	EDWARDS / AQUARIUS	HAEMOTRONIC / AQUALINE	BELLCO / AQUAMAX HF12	CONTINUOUS VENOVENOUS HEMOFILTRATION (CVVH)	2.5
002-017	73/Male	11OCT2015 01:30 / 12OCT2015 18:30	EDWARDS / AQUARIUS	HAEMOTRONIC / AQUALINE	BELLCO / AQUAMAX HF12	CONTINUOUS VENOVENOUS HEMOFILTRATION (CVVH)	3.5

Data Listing 16.2.5.4. Dialysis Session - Enrolled Population

Patient Number	Age (Years)/ Gender	Start Date and Time of Current CRRT Circuit/ End Date and Time of Current CRRT Circuit	Manufacturer of CRRT Monitor/ Model of CRRT Monitor	Manufacturer of CRRT Lines/ Model of CRRT Lines	Manufacturer of Haemofilter/ Model of Haemofilter	CRRT Mode Employed	Ultrafiltration Rate (L/h)
002-018	91/Female	20OCT2015 23:05 / 23OCT2015 11:00	EDWARDS / AQUARIUS	HAEMOTRONIC / AQUALINE	BELLCO / AQUAMAX HF 12	CONTINUOUS VENOVENOUS HEMOFILTRATION (CVVH)	2.1
002-019	70/Male	08NOV2015 13:05 / 10NOV2015 21:35	EDWARDS / AQUARIUS	HAEMOTRONIC / AQUALINE	BELLCO / AQUAMAX HF12	CONTINUOUS VENOVENOUS HEMOFILTRATION (CVVH)	2.8
002-021	73/Male	08DEC2015 13:00 / 11DEC2015 12:10	EDWARDS / AQUARIUS	HAEMOTRONIC / AQUALINE	BELLCO / AQUAMAX HF 12	CONTINUOUS VENOVENOUS HEMOFILTRATION (CVVH)	2.5
003-001	77/Male	28MAR2015 23:30 / 30MAR2015 20:30	EDWARDS / AQUARIUS	NIKKISO / AQUALINE	BELLCO / AQUAMAX HF12	CONTINUOUS VENOVENOUS HEMOFILTRATION (CVVH)	1.4
003-002	67/Male	13MAY2015 16:54 / 16MAY2015 08:30	EDWARDS / AQUARIUS	NIKKISO / AQUALINE	BELLCO / AQUAMAX 12	CONTINUOUS VENOVENOUS HEMOFILTRATION (CVVH)	3
003-003	57/Female	26AUG2015 16:00 / 28AUG2015 13:30	EDWARDS / AQUARIUS	NIKKISO / AQUALINE	BELLCO / AQUAMAX 12	CONTINUOUS VENOVENOUS HEMOFILTRATION (CVVH)	1

Data Listing 16.2.5.4. Dialysis Session - Enrolled Population

Patient Number	Age (Years)/ Gender	Start Date and Time of Current CRRT Circuit/ End Date and Time of Current CRRT Circuit	Manufacturer of CRRT Monitor/ Model of CRRT Monitor	Manufacturer of CRRT Lines/ Model of CRRT Lines	Manufacturer of Haemofilter/ Model of Haemofilter	CRRT Mode Employed	Ultrafiltration Rate (L/h)
003-004	66/Male	05SEP2015 21:00 / 08SEP2015 20:35	EDWARDS / AQUARIUS	NIKKISO / AQUALINE	BELLCO / AQUAMAX HF12	CONTINUOUS VENOVENOUS HEMOFILTRATION (CVVH)	2.2
003-007	60/Male	03OCT2015 22:00 / 07OCT2015 01:00	EDWARDS / AQUARIUS	NIKKISO / AQUALINE	BELLCO / AQUAMAX HF12	CONTINUOUS VENOVENOUS HEMOFILTRATION (CVVH)	1
003-008	47/Male	19OCT2015 19:30 / 21OCT2015 16:30	EDWARDS / AQUARIUS	NIKKISO / AQUALINE	BELLCO / AQUAMAX HF 12	CONTINUOUS VENOVENOUS HEMOFILTRATION (CVVH)	1
003-009		24OCT2015 12:30 / 27OCT2015 15:00	EDWARDS / AQUARIUS	NIKKISO / AQUALINE	BELLCO / AQUAMAX HF 12	CONTINUOUS VENOVENOUS HEMOFILTRATION (CVVH)	2.2
003-010	79/Male	28NOV2015 10:00 / 01DEC2015 12:20	EDWARDS / AQUARIUS	NIKKISO / AQUALINE	BELLCO / AQUAMAX HF12	CONTINUOUS VENOVENOUS HEMOFILTRATION (CVVH)	2
003-011	69/Male	21DEC2015 10:50 / 24DEC2015 13:30	EDWARDS / AQUARIUS	NIKKISO / AQUALINE	BELLCO / AQUAMAX HF12	CONTINUOUS VENOVENOUS HEMOFILTRATION (CVVH)	1.1

Data Listing 16.2.5.4. Dialysis Session - Enrolled Population

Patient Number	Age (Years)/ Gender	Start Date and Time of Current CRRT Circuit/ End Date and Time of Current CRRT Circuit	Manufacturer of CRRT Monitor/ Model of CRRT Monitor	Manufacturer of CRRT Lines/ Model of CRRT Lines	Manufacturer of Haemofilter/ Model of Haemofilter	CRRT Mode Employed	Ultrafiltration Rate (L/h)
003-012	88/Male	21JAN2016 14:30 / 23JAN2016 14:00	EDWARDS / AQUARIUS	NIKKISO / AQUALINE	BELLCO / AQUAMAX HF12	CONTINUOUS VENOVENOUS HEMOFILTRATION (CVVH)	1.1
004-001		21APR2015 16:00 / 23APR2015 21:00	EDWARDS / AQUARIUS	HAEMOTRONIC / AQUALINE	BELLCO / AQUAMAX HF12	CONTINUOUS VENOVENOUS HEMOFILTRATION (CVVH)	1
004-002		17MAY2015 02:00 / 19MAY2015 06:00	EDWARDS / AQUARIUS	HAEMOTRONIC / AQUALINE	BELLCO / AQUARIUS HF12	CONTINUOUS VENOVENOUS HEMODIAFILTRATION (CVVHDF)	2
004-003	45/Female	30MAY2015 22:00 / 02JUN2015 20:00	EDWARDS / AQUARIUS	HAEMOTRONIC / AQUALINE	BELLCO / AQUARIUS HF12	CONTINUOUS VENOVENOUS HEMODIAFILTRATION (CVVHDF)	1
004-005	20/Female	21JUN2015 12:00 / 24JUN2015 12:00	EDWARDS / AQUARIUS	HAEMOTRONIC / AQUALINE	BELLCO / AQUAMAX HF12	CONTINUOUS VENOVENOUS HEMOFILTRATION (CVVH)	1
004-006	30/Male	03JUL2015 15:00 / 06JUL2015 15:00	EDWARDS / AQUARIUS	HAEMOTRONIC / AQUALINE	BELLCO / AQUAMAX HF12	CONTINUOUS VENOVENOUS HEMOFILTRATION (CVVH)	2

Data Listing 16.2.5.4. Dialysis Session - Enrolled Population

Patient Number	Age (Years)/ Gender	Start Date and Time of Current CRRT Circuit/ End Date and Time of Current CRRT Circuit	Manufacturer of CRRT Monitor/ Model of CRRT Monitor	Manufacturer of CRRT Lines/ Model of CRRT Lines	Manufacturer of Haemofilter/ Model of Haemofilter	CRRT Mode Employed	Ultrafiltration Rate (L/h)
004-009	59/Female	22JUL2015 23:00 / 25JUL2015 23:00	EDWARDS / AQUARIUS	HAEMOTRONIC / AQUALINE	BELLCO / AQUAMAXHF 12	CONTINUOUS VENOVENOUS HEMOFILTRATION (CVVH)	1
004-010	55/Male	26JUL2015 19:00 / 29JUL2015 08:00	EDWARDS / AQUARIUS	HAEMOTRONIC / AQUALINE	BELLCO / AQUAMAX HF12	CONTINUOUS VENOVENOUS HEMOFILTRATION (CVVH)	2
004-013	79/Male	12AUG2015 16:00 / 15AUG2015 01:00	EDWARDS / AQUARIUS	HAEMOTRONIC / AQUALINE	BELLCO / AQUAMAX HF12	CONTINUOUS VENOVENOUS HEMOFILTRATION (CVVH)	1
004-014	65/Male	21AUG2015 18:00 / 23AUG2015 17:00	EDWARDS / AQUARIUS	HAEMOTRONIC / AQUALINE	BELLCO / AQUAMAX HF12	CONTINUOUS VENOVENOUS HEMOFILTRATION (CVVH)	2
004-016	47/Female	17SEP2015 11:00 / 19SEP2015 09:00	EDWARDS / AQUARIUS	HAEMOTRONIC / AQUALINE	BELLCO / AQUAMAX HF12	CONTINUOUS VENOVENOUS HEMODIAFILTRATION (CVVHDF)	3
004-017	67/Male	23SEP2015 01:00 / 26SEP2015 01:00	EDWARDS / AQUARIUS	HAEMOTRONIC / AQUALINE	BELLCO / AQUAMAX HF12	CONTINUOUS VENOVENOUS HEMODIAFILTRATION (CVVHDF)	1

Data Listing 16.2.5.4. Dialysis Session - Enrolled Population

Patient Number	Age (Years)/ Gender	Start Date and Time of Current CRRT Circuit/ End Date and Time of Current CRRT Circuit	Manufacturer of CRRT Monitor/ Model of CRRT Monitor	Manufacturer of CRRT Lines/ Model of CRRT Lines	Manufacturer of Haemofilter/ Model of Haemofilter	CRRT Mode Employed	Ultrafiltration Rate (L/h)
004-018	40/Male	24SEP2015 04:00 / 27SEP2015 02:30	EDWARDS / AQUARIUS	HAEMOTRONIC / AQUALINE	BELLCO / AQUA MAX HF 12	CONTINUOUS VENOVENOUS HEMOFILTRATION (CVVH)	1
005-002	68/Female	20MAR2015 02:30 / 22MAR2015 12:00	NIKKISO / AQUARIUS	HAEMOTRONIC / AQUALINE	BELLCO / AQUAMAX HF19	CONTINUOUS VENOVENOUS HEMODIAFILTRATION (CVVHDF)	1.1
005-003	65/Female	22MAR2015 17:30 / 25MAR2015 13:00	NIKKISO / AQUARIUS	HAEMOTRONIC / AQUALINE	BELLCO / AQUAMAX HF19	CONTINUOUS VENOVENOUS HEMODIAFILTRATION (CVVHDF)	1.8
005-004	81/Male	25MAR2015 17:00 / 28MAR2015 07:00	NIKKISO / AQUARIUS	HAEMOTRONIC / AQUALINE	BELLCO / AQUAMAX HF-19	CONTINUOUS VENOVENOUS HEMODIAFILTRATION (CVVHDF)	1.3
005-006	38/Male	20APR2015 20:00 / 23APR2015 11:10	NIKKISO / AQUARIUS	HAEMOTRONIC / AQUALINE	BELLCO / AQUAMAX HF-19	CONTINUOUS VENOVENOUS HEMODIAFILTRATION (CVVHDF)	1.2
005-007	63/Male	22APR2015 04:00 / 25APR2015 04:40	NIKKISO / AQUARIUS	HAEMOTRONIC / AQUALINE	BELLCO / AQUAMAX HF-19	CONTINUOUS VENOVENOUS HEMODIAFILTRATION (CVVHDF)	2.6

Data Listing 16.2.5.4. Dialysis Session - Enrolled Population

Patient Number	Age (Years)/ Gender	Start Date and Time of Current CRRT Circuit/ End Date and Time of Current CRRT Circuit	Manufacturer of CRRT Monitor/ Model of CRRT Monitor	Manufacturer of CRRT Lines/ Model of CRRT Lines	Manufacturer of Haemofilter/ Model of Haemofilter	CRRT Mode Employed	Ultrafiltration Rate (L/h)
005-008	74/Female	07MAY2015 17:00 / 10MAY2015 03:00	NIKKISO / AQUARIUS	HAEMOTRONIC / AQUALINE	BELLCO / AQUAMAX HF-19	CONTINUOUS VENOVENOUS HEMODIAFILTRATION (CVVHDF)	0.9
005-010	42/Male	12MAY2015 18:00 / 15MAY2015 18:45	NIKKISO / AQUARIUS	HAEMOTRONIC / AQUALINE	BELLCO / AQUAMAX HF19	CONTINUOUS VENOVENOUS HEMODIAFILTRATION (CVVHDF)	1.9
005-011	78/Female	13MAY2015 16:25 / 15MAY2015 16:00	NIKKISO / AQUARIUS	HAEMOTRONIC / AQUALINE	BELLCO / AQUAMAX HF 19	CONTINUOUS VENOVENOUS HEMODIAFILTRATION (CVVHDF)	1.7
005-012		14MAY2015 21:00 / 17MAY2015 21:00	NIKKISO / AQUARIUS	HAEMOTRONIC / AQUALINE	BELLCO / AQUAMAX HF19	CONTINUOUS VENOVENOUS HEMODIAFILTRATION (CVVHDF)	1.4
005-014	65/Male	03JUN2015 17:30 / 06JUN2015 08:20	NIKKISO / AQUARIUS	HAEMOTRONIC / AQUALINE	BELLCO / AQUAMAX HF 19	CONTINUOUS VENOVENOUS HEMODIAFILTRATION (CVVHDF)	2.3
005-015	78/Male	19JUN2015 05:00 / 22JUN2015 05:55	NIKKISO / AQUARIUS	HAEMOTRONIC / AQUALINE	BELLCO / AQUAMAX HF19	CONTINUOUS VENOVENOUS HEMODIAFILTRATION (CVVHDF)	1.4

Data Listing 16.2.5.4. Dialysis Session - Enrolled Population

Patient Number	Age (Years)/ Gender	Start Date and Time of Current CRRT Circuit/ End Date and Time of Current CRRT Circuit	Manufacturer of CRRT Monitor/ Model of CRRT Monitor	Manufacturer of CRRT Lines/ Model of CRRT Lines	Manufacturer of Haemofilter/ Model of Haemofilter	CRRT Mode Employed	Ultrafiltration Rate (L/h)
005-016		13JUL2015 03:50 / 16JUL2015 06:45	NIKKISO / AQUARIUS	HAEMOTRONIC / AQUALINE	BELLCO / AQUAMAX HF19	CONTINUOUS VENOVENOUS HEMODIAFILTRATION (CVVHDF)	1.1
005-018	67/Male	27AUG2015 15:30 / 29AUG2015 18:00	NIKKISO / AQUARIUS	HAEMOTRONIC / AQUALINE	BELLCO / AQUAMAX HF19	CONTINUOUS VENOVENOUS HEMODIAFILTRATION (CVVHDF)	1.5
005-019	69/Male	13SEP2015 23:30 / 16SEP2015 23:40	NIKKISO / AQUARIUS	HAEMOTRONIC / AQUALINE	BELLCO / AQUAMAX HF19	CONTINUOUS VENOVENOUS HEMODIAFILTRATION (CVVHDF)	1.8
005-020		14SEP2015 19:30 / 17SEP2015 19:30	NIKKISO / AQUARIUS	HAEMOTRONIC / AQUALINE	BELLCO / AQUAMAX HF19	CONTINUOUS VENOVENOUS HEMODIAFILTRATION (CVVHDF)	1.3
005-021	58/Male	14SEP2015 16:30 / 17SEP2015 16:30	NIKKISO / AQUARIUS	HAEMOTRONIC / AQUALINE	BELLCO / AQUAMAX HF19	CONTINUOUS VENOVENOUS HEMODIAFILTRATION (CVVHDF)	1.2
005-022		04OCT2015 12:30 / 07OCT2015 15:30	NIKKISO / AQUARIUS	HAEMOTRONIC / AQUALINE	BELLCO / AQUAMAX HF19	CONTINUOUS VENOVENOUS HEMODIAFILTRATION (CVVHDF)	1.8

Data Listing 16.2.5.4. Dialysis Session - Enrolled Population

Patient Number	Age (Years)/ Gender	Start Date and Time of Current CRRT Circuit/ End Date and Time of Current CRRT Circuit	Manufacturer of CRRT Monitor/ Model of CRRT Monitor	Manufacturer of CRRT Lines/ Model of CRRT Lines	Manufacturer of Haemofilter/ Model of Haemofilter	CRRT Mode Employed	Ultrafiltration Rate (L/h)
005-023	66/Male	09NOV2015 13:00 / 11NOV2015 18:00	NIKKISO / AQUARIUS	HAEMOTRONIC / AQUALINE	BELLCO / AQUAMAX HF 19	CONTINUOUS VENOVENOUS HEMODIAFILTRATION (CVVHDF)	1.5
005-024	41/Female	23NOV2015 19:00 / 26NOV2015 22:00	NIKKISO / AQUARIUS	HAEMOTRONIC / AQUALINE	BELLCO / AQUAMAX HF 19	CONTINUOUS VENOVENOUS HEMODIAFILTRATION (CVVHDF)	1.8
005-025		24NOV2015 04:00 / 26NOV2015 20:45	NIKKISO / AQUARIUS	HAEMOTRONIC / AQUALINE	BELLCO / AQUAMAX HF 19	CONTINUOUS VENOVENOUS HEMODIAFILTRATION (CVVHDF)	1.4
005-026	64/Male	30NOV2015 13:00 / 03DEC2015 10:45	NIKKISO / AQUARIUS	HAEMOTRONIC / AQUALINE	BELLCO / AQUAMAX HF 19	CONTINUOUS VENOVENOUS HEMODIAFILTRATION (CVVHDF)	1.3
005-027		01DEC2015 05:00 / 03DEC2015 12:00	NIKKISO / AQUARIUS	HAEMOTRONIC / AQUALINE	BELLCO / AQUAMAX HF19	CONTINUOUS VENOVENOUS HEMODIAFILTRATION (CVVHDF)	1.1
005-028		07DEC2015 16:00 / 10DEC2015 15:40	NIKKISO / AQUARIUS	HAEMOTRONIC / AQUALINE	BELLCO / AQUAMAX HF 19	CONTINUOUS VENOVENOUS HEMODIAFILTRATION (CVVHDF)	1.1

Data Listing 16.2.5.4. Dialysis Session - Enrolled Population

Patient Number	Age (Years)/ Gender	Start Date and Time of Current CRRT Circuit/ End Date and Time of Current CRRT Circuit	Manufacturer of CRRT Monitor/ Model of CRRT Monitor	Manufacturer of CRRT Lines/ Model of CRRT Lines	Manufacturer of Haemofilter/ Model of Haemofilter	CRRT Mode Employed	Ultrafiltration Rate (L/h)
005-029	68/Male	09DEC2015 15:30 / 12DEC2015 15:30	NIKKISO / AQUARIUS	HAEMOTRONIC / AQUALINE	BELLCO / AQUAMAX HF19	CONTINUOUS VENOVENOUS HEMODIAFILTRATION (CVVHDF)	1
005-030	61/Male	16DEC2015 19:00 / 18DEC2015 17:00	NIKKISO / AQUARIUS	HAEMOTRONIC / AQUALINE	BELLCO / AQUAMAX	CONTINUOUS VENOVENOUS HEMODIAFILTRATION (CVVHDF)	1.5
005-032	49/Male	30DEC2015 15:20 / 01JAN2016 18:00	NIKKISO / AQUARIUS	HAEMOTRONIC / AQUALINE	BELLCO / AQUAMAX HF 19	CONTINUOUS VENOVENOUS HEMODIAFILTRATION (CVVHDF)	1.7
005-034	70/Male	12JAN2016 02:40 / 14JAN2016 14:00	NIKKISO / AQUARIUS	HAEMOTRONIC / AQUALINE	BELLCO / AQUAMAX HF19	CONTINUOUS VENOVENOUS HEMODIAFILTRATION (CVVHDF)	0.9
005-036	51/Female	12JAN2016 09:15 / 15JAN2016 09:30	NIKKISO / AQUARIUS	HAEMOTRONIC / AQUALINE	BELLCO / AQUAMAX HF19	CONTINUOUS VENOVENOUS HEMODIAFILTRATION (CVVHDF)	1.8
005-037	53/Female	27JAN2016 23:00 / 31JAN2016 01:45	NIKKISO / AQUARIUS	HAEMOTRONIC / AQUALINE	BELLCO / AQUAMAX HF 19	CONTINUOUS VENOVENOUS HEMODIAFILTRATION (CVVHDF)	1.3

Data Listing 16.2.5.4. Dialysis Session - Enrolled Population

Patient Number	Age (Years)/ Gender	Start Date and Time of Current CRRT Circuit/ End Date and Time of Current CRRT Circuit	Manufacturer of CRRT Monitor/ Model of CRRT Monitor	Manufacturer of CRRT Lines/ Model of CRRT Lines	Manufacturer of Haemofilter/ Model of Haemofilter	CRRT Mode Employed	Ultrafiltration Rate (L/h)
005-038		28JAN2016 01:30 / 29JAN2016 22:10	NIKKISO / AQUARIUS	HAEMOTRONIC / AQUALINE	BELLCO / AQUAMAX HF 19	CONTINUOUS VENOVENOUS HEMODIAFILTRATION (CVVHDF)	0.9
007-001	61/Male	09APR2015 16:30 / 11APR2015 09:30	EDWARDS / AQUARIUS	HAEMOTRONIC / AQUALINE	BELLCO / AQUAMAX HF12	CONTINUOUS VENOVENOUS HEMOFILTRATION (CVVH)	4
007-002		18MAY2015 01:00 / 20MAY2015 11:00	EDWARDS / AQUARIUS	HAEMOTRONIC / AQUALINE	BELLCO / AQUAMAX	CONTINUOUS VENOVENOUS HEMOFILTRATION (CVVH)	3
007-003	64/Male	24JUN2015 17:00 / 27JUN2015 08:00	EDWARDS / AQUARIUS	HAEMOTRONIC / AQUALINE	BELLCO / AQUAMAX	CONTINUOUS VENOVENOUS HEMOFILTRATION (CVVH)	3
007-004	72/Male	26JUN2015 01:50 / 28JUN2015 20:30	EDWARDS / AQUARIUS	HAEMOTRONIC / AQUALINE	BELLCO / AQUAMAX	CONTINUOUS VENOVENOUS HEMOFILTRATION (CVVH)	3
007-005	24/Male	16JUL2015 12:00 / 19JUL2015 11:00	EDWARDS / AQUARIUS	HAEMOTRONIC / AQUALINE	BELLCO / AQUAMAX	CONTINUOUS VENOVENOUS HEMOFILTRATION (CVVH)	4

Data Listing 16.2.5.4. Dialysis Session - Enrolled Population

Patient Number	Age (Years)/ Gender	Start Date and Time of Current CRRT Circuit/ End Date and Time of Current CRRT Circuit	Manufacturer of CRRT Monitor/ Model of CRRT Monitor	Manufacturer of CRRT Lines/ Model of CRRT Lines	Manufacturer of Haemofilter/ Model of Haemofilter	CRRT Mode Employed	Ultrafiltration Rate (L/h)
007-006	73/Female	25JUL2015 04:30 / 28JUL2015 04:30	EDWARDS / AQUARIUS	HAEMOTRONIC / AQUALINE	BELLCO / AQUAMAX	CONTINUOUS VENOVENOUS HEMOFILTRATION (CVVH)	3
007-007	83/Male	01AUG2015 09:50 / 03AUG2015 04:10	EDWARDS / AQUARIUS	HAEMOTRONIC / AQUALINE	BELLCO / AQUAMAX	CONTINUOUS VENOVENOUS HEMOFILTRATION (CVVH)	3
007-008	79/Male	11AUG2015 15:00 / 13AUG2015 09:45	EDWARDS / AQUARIUS	HAEMOTRONIC / AQUALINE	BELLCO / AQUAMAX	CONTINUOUS VENOVENOUS HEMOFILTRATION (CVVH)	3
007-010	70/Male	30AUG2015 15:40 / 01SEP2015 10:00	EDWARDS / AQUARIUS	HAEMOTRONIC / AQUALINE	BELLCO / AQUAMAX	CONTINUOUS VENOVENOUS HEMOFILTRATION (CVVH)	4
007-011	64/Female	30AUG2015 13:30 / 02SEP2015 13:30	EDWARDS / AQUARIUS	HAEMOTRONIC / AQUALINE	BELLCO / AQUAMAX	CONTINUOUS VENOVENOUS HEMOFILTRATION (CVVH)	4
007-012	36/Male	06SEP2015 01:30 / 09SEP2015 03:00	EDWARDS / AQUARIUS	HAEMOTRONIC / AQUALINE	BELLCO / AQUAMAX	CONTINUOUS VENOVENOUS HEMOFILTRATION (CVVH)	3

Data Listing 16.2.5.4. Dialysis Session - Enrolled Population

Patient Number	Age (Years)/ Gender	Start Date and Time of Current CRRT Circuit/ End Date and Time of Current CRRT Circuit	Manufacturer of CRRT Monitor/ Model of CRRT Monitor	Manufacturer of CRRT Lines/ Model of CRRT Lines	Manufacturer of Haemofilter/ Model of Haemofilter	CRRT Mode Employed	Ultrafiltration Rate (L/h)
007-014	74/Female	26SEP2015 14:40 / 28SEP2015 07:45	EDWARDS / AQUARIUS	HAEMOTRONIC / AQUALINE	BELLCO / AQUAMAX	CONTINUOUS VENOVENOUS HEMOFILTRATION (CVVH)	3
007-015	73/Female	12DEC2015 14:50 / 15DEC2015 01:50	EDWARDS / AQUARIUS	HAEMOTRONIC / AQUALINE	BELLCO / AQUAMAX	CONTINUOUS VENOVENOUS HEMOFILTRATION (CVVH)	3
007-016	71/Male	03JAN2016 14:35 / 05JAN2016 10:20	EDWARDS / AQUARIUS	HAEMOTRONIC / AQUALINE	BELLCO / AQUAMAX	CONTINUOUS VENOVENOUS HEMOFILTRATION (CVVH)	3
008-001	26/Male	17MAR2015 20:05 / 20MAR2015 20:05	NIKKISO / AQUARIUS	HAEMOTRONIC / AQUALINE	BELLCO / AQUAMAX HF12	CONTINUOUS VENOVENOUS HEMOFILTRATION (CVVH)	3.3
008-002	31/Male	12APR2015 21:00 / 15APR2015 21:00	NIKKISO / AQUARIUS	HAEMOTRONIC / AQUALINE	BELLCO / AQUAMAX HF12	CONTINUOUS VENOVENOUS HEMOFILTRATION (CVVH)	2.9
008-003	25/Female	19APR2015 04:00 / 22APR2015 04:00	NIKKISO / AQUARIUS	HAEMOTRONIC / AQUALINE	BELLCO / AQUAMAX HF 12	CONTINUOUS VENOVENOUS HEMOFILTRATION (CVVH)	2

Data Listing 16.2.5.4. Dialysis Session - Enrolled Population

Patient Number	Age (Years)/ Gender	Start Date and Time of Current CRRT Circuit/ End Date and Time of Current CRRT Circuit	Manufacturer of CRRT Monitor/ Model of CRRT Monitor	Manufacturer of CRRT Lines/ Model of CRRT Lines	Manufacturer of Haemofilter/ Model of Haemofilter	CRRT Mode Employed	Ultrafiltration Rate (L/h)
008-004	46/Male	05MAY2015 02:00 / 06MAY2015 23:45	NIKKISO / AQUARIUS	HAEMOTRONIC / AQUALINE	BELLCO / AQUAMAX HF 12	CONTINUOUS VENOVENOUS HEMOFILTRATION (CVVH)	2.9
008-005	82/Male	20MAY2015 16:20 / 22MAY2015 10:55	NIKKISO / AQUARIUS	HAEMOTRONIC / AQUALINE	BELLCO / AQUAMAX HF 12	CONTINUOUS VENOVENOUS HEMOFILTRATION (CVVH)	2.5
008-006	70/Male	26MAY2015 02:00 / 28MAY2015 13:00	NIKKISO / AQUARIUS	HAEMOTRONIC / AQUALINE	BELLCO / AQUAMAX HF 2015	CONTINUOUS VENOVENOUS HEMOFILTRATION (CVVH)	2.5
008-007	74/Male	26MAY2015 14:20 / 28MAY2015 22:00	NIKKISO / AQUARIUS	HAEMOTRONIC / AQUALINE	BELLCO / AQUAMAX HF 12	CONTINUOUS VENOVENOUS HEMOFILTRATION (CVVH)	2
008-012	71/Male	19JUL2015 02:00 / 20JUL2015 20:30	NIKKISO / AQUARIUS	HAEMOTRONIC / AQUALINE	BELLCO / AQUAMAX HF 12	CONTINUOUS VENOVENOUS HEMOFILTRATION (CVVH)	3.3
008-013	68/Male	19JUL2015 14:00 / 21JUL2015 14:45	NIKKISO / AQUARIUS	HAEMOTRONIC / AQUALINE	BELLCO / AQUAMAX HF 12	CONTINUOUS VENOVENOUS HEMOFILTRATION (CVVH)	2.9

Data Listing 16.2.5.4. Dialysis Session - Enrolled Population

Patient Number	Age (Years)/ Gender	Start Date and Time of Current CRRT Circuit/ End Date and Time of Current CRRT Circuit	Manufacturer of CRRT Monitor/ Model of CRRT Monitor	Manufacturer of CRRT Lines/ Model of CRRT Lines	Manufacturer of Haemofilter/ Model of Haemofilter	CRRT Mode Employed	Ultrafiltration Rate (L/h)
008-014	65/Female	23JUL2015 16:00 / 25JUL2015 11:00	NIKKISO / AQUARIUS	HAEMOTRONIC / AQUALINE	BELLCO / AQUAMAX HF 12	CONTINUOUS VENOVENOUS HEMOFILTRATION (CVVH)	2
008-016	34/Male	11AUG2015 18:00 / 13AUG2015 14:00	NIKKISO / AQUARIUS	HAEMOTRONIC / AQUALINE	BELLCO / AQUAMAX HF 12	CONTINUOUS VENOVENOUS HEMOFILTRATION (CVVH)	3
008-017	52/Female	19AUG2015 19:00 / 22AUG2015 05:55	NIKKISO / AQUARIUS	HAEMOTRONIC / AQUALINE	BELLCO / AQUAMAX HF12	CONTINUOUS VENOVENOUS HEMOFILTRATION (CVVH)	3
008-018	65/Male	04OCT2015 00:25 / 05OCT2015 23:55	NIKKISO / AQUARIUS	HAEMOTRONIC / AQUALINE	BELLCO / AQUAMAX HF 12	CONTINUOUS VENOVENOUS HEMOFILTRATION (CVVH)	2.9
008-019	69/Female	08OCT2015 04:15 / 10OCT2015 02:00	NIKKISO / AQUARIUS	HAEMOTRONIC / AQUALINE	BELLCO / AQUAMAX HF 12	CONTINUOUS VENOVENOUS HEMOFILTRATION (CVVH)	2.9
008-020	60/Male	18OCT2015 15:30 / 21OCT2015 16:30	NIKKISO / AQUARIUS	HAEMOTRONIC / AQUALINE	BELLCO / AQUAMAX HF 12	CONTINUOUS VENOVENOUS HEMOFILTRATION (CVVH)	2.9

Data Listing 16.2.5.4. Dialysis Session - Enrolled Population

Patient Number	Age (Years)/ Gender	Start Date and Time of Current CRRT Circuit/ End Date and Time of Current CRRT Circuit	Manufacturer of CRRT Monitor/ Model of CRRT Monitor	Manufacturer of CRRT Lines/ Model of CRRT Lines	Manufacturer of Haemofilter/ Model of Haemofilter	CRRT Mode Employed	Ultrafiltration Rate (L/h)
008-021	66/Male	19OCT2015 00:00 / 20OCT2015 18:10	NIKKISO / AQUARIUS	HAEMOTRONIC / AQUALINE	BELLCO / AQUAMAX HF 12	CONTINUOUS VENOVENOUS HEMOFILTRATION (CVVH)	2
008-022	43/Male	19OCT2015 05:00 / 22OCT2015 09:00	NIKKISO / AQUARIUS	HAEMOTRONIC / AQUALINE	BELLCO / AQUAMAX HF 12	CONTINUOUS VENOVENOUS HEMOFILTRATION (CVVH)	2.5
008-023		19OCT2015 17:00 / 21OCT2015 16:45	NIKKISO / AQUARIUS	HAEMOTRONIC / AQUALINE	BELLCO / AQUAMAX HF 12	CONTINUOUS VENOVENOUS HEMOFILTRATION (CVVH)	2
008-024	27/Male	25OCT2015 20:00 / 29OCT2015 00:00	NIKKISO / AQUARIUS	HAEMOTRONIC / AQUALINE	BELLCO / AQUAMAX HF 12	CONTINUOUS VENOVENOUS HEMOFILTRATION (CVVH)	2.5
008-025	68/Male	28OCT2015 19:15 / 30OCT2015 11:30	NIKKISO / AQUARIUS	HAEMOTRONIC / AQUALINE	BELLCO / AQUAMAX HF 12	CONTINUOUS VENOVENOUS HEMOFILTRATION (CVVH)	2.9
008-026	30/Female	03NOV2015 18:00 / 05NOV2015 19:00	NIKKISO / AQUARIUS	HAEMOTRONIC / AQUALINE	BELLCO / AQUAMAX HF12	CONTINUOUS VENOVENOUS HEMOFILTRATION (CVVH)	2.5

Data Listing 16.2.5.4. Dialysis Session - Enrolled Population

Patient Number	Age (Years)/ Gender	Start Date and Time of Current CRRT Circuit/ End Date and Time of Current CRRT Circuit	Manufacturer of CRRT Monitor/ Model of CRRT Monitor	Manufacturer of CRRT Lines/ Model of CRRT Lines	Manufacturer of Haemofilter/ Model of Haemofilter	CRRT Mode Employed	Ultrafiltration Rate (L/h)
008-027	71/Male	11NOV2015 17:00 / 13NOV2015 18:00	NIKKISO / AQUARIUS	HAEMOTRONIC / AQUALINE	BELLCO / AQUAMAX HF 12	CONTINUOUS VENOVENOUS HEMOFILTRATION (CVVH)	3.6
008-028	72/Male	28NOV2015 20:30 / 01DEC2015 10:30	NIKKISO / AQUARIUS	HAEMOTRONIC / AQUALINE	BELLCO / AQUAMAX 12 HF	CONTINUOUS VENOVENOUS HEMOFILTRATION (CVVH)	2
008-029	66/Female	07DEC2015 07:40 / 09DEC2015 20:00	NIKKISO / AQUARIUS	HAEMOTRONIC / AQUALINE	BELLCO / AQUAMAX HF12	CONTINUOUS VENOVENOUS HEMOFILTRATION (CVVH)	2.5
008-030	63/Female	10JAN2016 00:25 / 12JAN2016 18:00	NIKKISO / AQUARIUS	HAEMOTRONIC / AQUALINE	BELLCO / AQUAMAX HF 12	CONTINUOUS VENOVENOUS HEMOFILTRATION (CVVH)	2.1
008-031	23/Male	25JAN2016 16:00 / 28JAN2016 04:10	NIKKISO / AQUARIUS	HAEMOTRONIC / AQUALINE	BELLCO / AQUAMAX HF 12	CONTINUOUS VENOVENOUS HEMOFILTRATION (CVVH)	2
009-001	64/Male	31MAR2015 23:00 / 02APR2015 15:15	NIKKISO / AQUARIUS	HAEMOTRONIC / AQUALINE	BELLCO / AQUAMAX	CONTINUOUS VENOVENOUS HEMOFILTRATION (CVVH)	1.5

Data Listing 16.2.5.4. Dialysis Session - Enrolled Population

Patient Number	Age (Years)/ Gender	Start Date and Time of Current CRRT Circuit/ End Date and Time of Current CRRT Circuit	Manufacturer of CRRT Monitor/ Model of CRRT Monitor	Manufacturer of CRRT Lines/ Model of CRRT Lines	Manufacturer of Haemofilter/ Model of Haemofilter	CRRT Mode Employed	Ultrafiltration Rate (L/h)
009-002		07APR2015 09:40 / 09APR2015 12:00	NIKKISO / AQUARIUS	HAEMOTRONIC / AQUALINE	BELLCO / AQUAMAX	CONTINUOUS VENOVENOUS HEMOFILTRATION (CVVH)	1.5
009-003	75/Male	12APR2015 19:00 / 15APR2015 19:00	NIKKISO / AQUARIUS	HAEMOTRONIC / AQUALINE	BELLCO / AQUAMAX	CONTINUOUS VENOVENOUS HEMOFILTRATION (CVVH)	2
009-006	58/Female	21APR2015 02:00 / 23APR2015 10:00	NIKKISO / AQUARIUS	HAEMOTRONIC / AQUALINE	BELLCO / AQUAMAX	CONTINUOUS VENOVENOUS HEMOFILTRATION (CVVH)	1
009-008	31/Male	28APR2015 01:00 / 01MAY2015 01:00	NIKKISO / AQUARIUS	HAEMOTRONIC / AQUALINE	BELLCO / AQUAMAX	CONTINUOUS VENOVENOUS HEMOFILTRATION (CVVH)	1.5
009-009		28APR2015 22:00 / 01MAY2015 16:50	NIKKISO / AQUARIUS	HAEMOTRONIC / AQUALINE	BELLCO / AQUAMAX	CONTINUOUS VENOVENOUS HEMOFILTRATION (CVVH)	1.5
009-011	75/Female	19MAY2015 04:00 / 21MAY2015 12:55	NIKKISO / AQUARIUS	HAEMOTRONIC / AQUALINE	BELLCO / AQUAMAX	CONTINUOUS VENOVENOUS HEMOFILTRATION (CVVH)	2

Data Listing 16.2.5.4. Dialysis Session - Enrolled Population

Patient Number	Age (Years)/ Gender	Start Date and Time of Current CRRT Circuit/ End Date and Time of Current CRRT Circuit	Manufacturer of CRRT Monitor/ Model of CRRT Monitor	Manufacturer of CRRT Lines/ Model of CRRT Lines	Manufacturer of Haemofilter/ Model of Haemofilter	CRRT Mode Employed	Ultrafiltration Rate (L/h)
009-013	60/Female	09JUN2015 18:00 / 12JUN2015 01:00	NIKKISO / AQUARIUS	HAEMOTRONIC / AQUALINE	BELLCO / AQUAMAX	CONTINUOUS VENOVENOUS HEMOFILTRATION (CVVH)	1
009-015	29/Male	15JUL2015 16:00 / 17JUL2015 18:35	NIKKISO / AQUARIUS	HAEMOTRONIC / AQUALINE	BELLCO / AQUAMAX	CONTINUOUS VENOVENOUS HEMOFILTRATION (CVVH)	2
009-016	83/Male	19JUL2015 21:00 / 21JUL2015 13:20	NIKKISO / AQUARIUS	HAEMOTRONIC / AQUALINE	BELLCO / AQUAMAX	CONTINUOUS VENOVENOUS HEMOFILTRATION (CVVH)	1.5
009-017	51/Male	21JUL2015 21:00 / 23JUL2015 19:30	NIKKISO / AQUARIUS	HAEMOTRONIC / AQUALINE	BELLCO / AQUAMAX	CONTINUOUS VENOVENOUS HEMOFILTRATION (CVVH)	2
009-018	44/Male	22JUL2015 02:00 / 25JUL2015 02:00	NIKKISO / AQUARIUS	HAEMOTRONIC / AQUALINE	BELLCO / AQUAMAX	CONTINUOUS VENOVENOUS HEMOFILTRATION (CVVH)	1
009-019	84/Male	25JUL2015 15:00 / 28JUL2015 11:40	NIKKISO / AQUARIUS	HAEMOTRONIC / AQUALINE	BELLCO / AQUAMAX	CONTINUOUS VENOVENOUS HEMOFILTRATION (CVVH)	1.5

Data Listing 16.2.5.4. Dialysis Session - Enrolled Population

Patient Number	Age (Years)/ Gender	Start Date and Time of Current CRRT Circuit/ End Date and Time of Current CRRT Circuit	Manufacturer of CRRT Monitor/ Model of CRRT Monitor	Manufacturer of CRRT Lines/ Model of CRRT Lines	Manufacturer of Haemofilter/ Model of Haemofilter	CRRT Mode Employed	Ultrafiltration Rate (L/h)
009-021	51/Male	01AUG2015 01:00 / 04AUG2015 02:00	NIKKISO / AQUARIUS	HAEMOTRONIC / AQUALINE	BELLCO / AQUAMAX	CONTINUOUS VENOVENOUS HEMOFILTRATION (CVVH)	1.5
009-022		30JUL2015 19:00 / 01AUG2015 19:40	NIKKISO / AQUARIUS	HAEMOTRONIC / AQUALINE	BELLCO / AQUAMAX	CONTINUOUS VENOVENOUS HEMOFILTRATION (CVVH)	2
009-024	49/Female	28AUG2015 03:00 / 31AUG2015 03:00	NIKKISO / AQUARIUS	HAEMOTRONIC / AQUALINE	BELLCO / AQUAMAX	CONTINUOUS VENOVENOUS HEMOFILTRATION (CVVH)	1.5
009-026	76/Female	05OCT2015 16:00 / 08OCT2015 21:00	NIKKISO / AQUARIUS	HAEMOTRONIC / AQUALINE	BELLCO / AQUAMAX	CONTINUOUS VENOVENOUS HEMOFILTRATION (CVVH)	1.5
009-027	53/Male	11OCT2015 06:00 / 13OCT2015 08:00	NIKKISO / AQUARIUS	HAEMOTRONIC / AQUALINE	BELLCO / AQUAMAX	CONTINUOUS VENOVENOUS HEMOFILTRATION (CVVH)	1.5
009-028		24NOV2015 05:00 / 26NOV2015 10:30	NIKKISO / AQUARIUS	HAEMOTRONIC / AQUALINE	BELLCO / AQUAMAX	CONTINUOUS VENOVENOUS HEMOFILTRATION (CVVH)	1.5

Data Listing 16.2.5.4. Dialysis Session - Enrolled Population

Patient Number	Age (Years)/ Gender	Start Date and Time of Current CRRT Circuit/ End Date and Time of Current CRRT Circuit	Manufacturer of CRRT Monitor/ Model of CRRT Monitor	Manufacturer of CRRT Lines/ Model of CRRT Lines	Manufacturer of Haemofilter/ Model of Haemofilter	CRRT Mode Employed	Ultrafiltration Rate (L/h)
009-030	75/Male	15DEC2015 23:00 / 19DEC2015 03:30	NIKKISO / AQUARIUS	HAEMOTRONIC / AQUALINE	BELLCO / AQUAMAX	CONTINUOUS VENOVENOUS HEMOFILTRATION (CVVH)	1.5
009-031	34/Male	26JAN2016 19:00 / 28JAN2016 19:10	NIKKISO / AQUARIUS	HAEMOTRONIC / AQUALINE	BELLCO / AQUAMAX	CONTINUOUS VENOVENOUS HEMOFILTRATION (CVVH)	1
009-032	59/Male	26JAN2016 14:00 / 29JAN2016 12:00	NIKKISO / AQUARIUS	HAEMOTRONIC / AQUALINE	BELLCO / AQUAMAX	CONTINUOUS VENOVENOUS HEMOFILTRATION (CVVH)	2
010-002	57/Male	06MAY2015 17:00 / 09MAY2015 17:00	EDWARDS / AQUARIUS	HAEMOTRONIC / AQUALINE	BELLCO / AQUAMAX HF-12	CONTINUOUS VENOVENOUS HEMOFILTRATION (CVVH)	UNK
010-003		07MAY2015 18:00 / 09MAY2015 14:50	EDWARDS / AQUARIUS	HAEMOTRONIC / AQUALINE	BELLCO / AQUAMAX HF12	CONTINUOUS VENOVENOUS HEMOFILTRATION (CVVH)	UNK
010-005	78/Male	03JUN2015 23:00 / 07JUN2015 02:50	EDWARDS / AQUARIUS	HAEMOTRONIC / AQUALINE	BELLCO / AQUAMAX HF12	CONTINUOUS VENOVENOUS HEMOFILTRATION (CVVH)	UNK

Data Listing 16.2.5.4. Dialysis Session - Enrolled Population

Patient Number	Age (Years)/ Gender	Start Date and Time of Current CRRT Circuit/ End Date and Time of Current CRRT Circuit	Manufacturer of CRRT Monitor/ Model of CRRT Monitor	Manufacturer of CRRT Lines/ Model of CRRT Lines	Manufacturer of Haemofilter/ Model of Haemofilter	CRRT Mode Employed	Ultrafiltration Rate (L/h)
010-006	80/Male	09JUN2015 23:00 / 13JUN2015 01:00	EDWARDS / AQUARIUS	HAEMOTRONIC / AQUALINE	BELLCO / AQUAMAX HF12	CONTINUOUS VENOVENOUS HEMOFILTRATION (CVVH)	UNKNOWN
010-008	70/Female	27JUN2015 05:00 / 29JUN2015 01:00	EDWARDS / AQUARIUS	HAEMOTRONIC / AQUALINE	BELLCO / AQUAMAX HF12	CONTINUOUS VENOVENOUS HEMOFILTRATION (CVVH)	UNKNOWN
010-009	69/Male	27JUN2015 04:00 / 28JUN2015 22:30	EDWARDS / AQUARIUS	HAEMOTRONIC / AQUALINE	BELLCO / AQUAMAX HF12	CONTINUOUS VENOVENOUS HEMOFILTRATION (CVVH)	UNK
010-010	52/Female	31AUG2015 12:20 / 03SEP2015 12:20	EDWARDS / AQUARIUS	HAEMOTRONIC / AQUALINE	BELLCO / AQUARMAX HF12	CONTINUOUS VENOVENOUS HEMOFILTRATION (CVVH)	2.5
010-011		29SEP2015 00:15 / 30SEP2015 17:00	EDWARDS / AQUARIUS	HAEMOTRONIC / AQUALINE	BELLCO / AQUAMAX HF12	CONTINUOUS VENOVENOUS HEMOFILTRATION (CVVH)	2.8
010-014	79/Female	10JAN2016 20:00 / 12JAN2016 21:20	EDWARDS / AQUARIUS	HAEMOTRONIC / AQUALINE	BELLCO / AQUAMAX HF12	CONTINUOUS VENOVENOUS HEMOFILTRATION (CVVH)	2.1

Data Listing 16.2.5.4. Dialysis Session - Enrolled Population

Patient Number	Age (Years)/ Gender	Start Date and Time of Current CRRT Circuit/ End Date and Time of Current CRRT Circuit	Manufacturer of CRRT Monitor/ Model of CRRT Monitor	Manufacturer of CRRT Lines/ Model of CRRT Lines	Manufacturer of Haemofilter/ Model of Haemofilter	CRRT Mode Employed	Ultrafiltration Rate (L/h)
011-001	53/Male	28APR2015 15:00 / 30APR2015 10:10	EDWARDS / AQUARIUS	HAEMOTRONIC / AQUALINE	BELLCO / AQUAMAX	CONTINUOUS VENOVENOUS HEMOFILTRATION (CVVH)	2.5
011-002	75/Male	28APR2015 15:00 / 30APR2015 12:00	EDWARDS / AQUARIUS	HAEMOTRONIC / AQUALINE	BELLCO / AQUAMAX	CONTINUOUS VENOVENOUS HEMOFILTRATION (CVVH)	2.5
011-003	80/Male	02JUN2015 22:45 / 05JUN2015 09:30	EDWARDS / AQUARIUS	HAEMOTRONIC / AQUALINE	BELLCO / AQUAMAX	CONTINUOUS VENOVENOUS HEMOFILTRATION (CVVH)	2.5
011-004	80/Female	07JUN2015 15:00 / 10JUN2015 20:00	EDWARDS / AQUARIUS	HAEMOTRONIC / AQUALINE	BELLCO / AQUAMAX	CONTINUOUS VENOVENOUS HEMOFILTRATION (CVVH)	2.5
011-005	78/Male	09JUN2015 18:00 / 11JUN2015 11:31	EDWARDS / AQUARIUS	HAEMOTRONIC / AQUALINE	BELLCO / AQUAMAX	CONTINUOUS VENOVENOUS HEMOFILTRATION (CVVH)	2.5
011-006	77/Male	02JUL2015 17:00 / 05JUL2015 06:00	EDWARDS / AQUARIUS	HAEMOTRONIC / AQUALINE	BELLCO / AQUAMAX	CONTINUOUS VENOVENOUS HEMOFILTRATION (CVVH)	2.5

Data Listing 16.2.5.4. Dialysis Session - Enrolled Population

Patient Number	Age (Years)/ Gender	Start Date and Time of Current CRRT Circuit/ End Date and Time of Current CRRT Circuit	Manufacturer of CRRT Monitor/ Model of CRRT Monitor	Manufacturer of CRRT Lines/ Model of CRRT Lines	Manufacturer of Haemofilter/ Model of Haemofilter	CRRT Mode Employed	Ultrafiltration Rate (L/h)
011-007	62/Female	30SEP2015 13:00 / 02OCT2015 06:05	EDWARDS / AQUARIUS	HAEMOTRONIC / AQUALINE	BELLCO / AQUAMAX	CONTINUOUS VENOVENOUS HEMOFILTRATION (CVVH)	2.5
011-008	61/Male	03OCT2015 18:00 / 05OCT2015 11:30	EDWARDS / AQUARIUS	HAEMOTRONIC / AQUALINE	BELLCO / AQUAMAX	CONTINUOUS VENOVENOUS HEMOFILTRATION (CVVH)	2.5
011-009	71/Female	05OCT2015 02:00 / 06OCT2015 22:30	EDWARDS / AQUARIUS	HAEMOTRONIC / AQUALINE	BELLCO / AQUAMAX	CONTINUOUS VENOVENOUS HEMOFILTRATION (CVVH)	2.5
011-010	47/Male	10OCT2015 18:50 / 12OCT2015 17:00	EDWARDS / AQUARIUS	HAEMOTRONIC / AQUALINE	BELLCO / AQUAMAX	CONTINUOUS VENOVENOUS HEMOFILTRATION (CVVH)	2.5
011-011	77/Male	13OCT2015 17:00 / 16OCT2015 11:00	EDWARDS / AQUARIUS	HAEMOTRONIC / AQUALINE	BELLCO / AQUAMAX	CONTINUOUS VENOVENOUS HEMOFILTRATION (CVVH)	2.5
011-012	74/Male	18OCT2015 11:45 / 21OCT2015 15:00	EDWARDS / AQUARIUS	HAEMOTRONIC / AQUALINE	BELLCO / AQUAMAX	CONTINUOUS VENOVENOUS HEMOFILTRATION (CVVH)	2.5

Data Listing 16.2.5.4. Dialysis Session - Enrolled Population

Patient Number	Age (Years)/ Gender	Start Date and Time of Current CRRT Circuit/ End Date and Time of Current CRRT Circuit	Manufacturer of CRRT Monitor/ Model of CRRT Monitor	Manufacturer of CRRT Lines/ Model of CRRT Lines	Manufacturer of Haemofilter/ Model of Haemofilter	CRRT Mode Employed	Ultrafiltration Rate (L/h)
011-013	71/Female	25OCT2015 01:00 / 28OCT2015 02:05	EDWARDS / AQUARIUS	HAEMOTRONIC / AQUALINE	BELLCO / AQUAMAX	CONTINUOUS VENOVENOUS HEMOFILTRATION (CVVH)	3.5
011-014	79/Female	02NOV2015 02:30 / 04NOV2015 02:30	EDWARDS / AQUARIUS	HAEMOTRONIC / AQUALINE	BELLCO / AQUAMAX	CONTINUOUS VENOVENOUS HEMOFILTRATION (CVVH)	2.5
011-015	77/Female	19NOV2015 16:56 / 22NOV2015 08:30	EDWARDS / AQUARIUS	HAEMOTRONIC / AQUALINE	BELLCO / AQUAMAX	CONTINUOUS VENOVENOUS HEMOFILTRATION (CVVH)	3.5
011-016	72/Female	07JAN2016 15:30 / 10JAN2016 19:00	EDWARDS / AQUARIUS	HAEMOTRONIC / AQUALINE	BELLCO / AQUAMAX	CONTINUOUS VENOVENOUS HEMOFILTRATION (CVVH)	2.5
012-001	59/Male	30MAR2015 22:00 / 02APR2015 22:00	NIKKISO / AQUARIUS	HAEMOTRONIC / AQUALINE	BELLCO / AQUAMAX HF12	CONTINUOUS VENOVENOUS HEMOFILTRATION (CVVH)	2.4
012-002	67/Male	06APR2015 21:00 / 09APR2015 21:00	NIKKISO / AQUARIUS	HAEMOTRONIC / AQUALINE	BELLCO / AQUAMAX HF12	CONTINUOUS VENOVENOUS HEMOFILTRATION (CVVH)	2.6

Data Listing 16.2.5.4. Dialysis Session - Enrolled Population

Patient Number	Age (Years)/ Gender	Start Date and Time of Current CRRT Circuit/ End Date and Time of Current CRRT Circuit	Manufacturer of CRRT Monitor/ Model of CRRT Monitor	Manufacturer of CRRT Lines/ Model of CRRT Lines	Manufacturer of Haemofilter/ Model of Haemofilter	CRRT Mode Employed	Ultrafiltration Rate (L/h)
012-003	63/Male	15APR2015 13:50 / 18APR2015 02:30	NIKKISO / AQUARIUS	HAEMOTRONIC / AQUALINE	BELLCO / AQUAMAX HF12	CONTINUOUS VENOVENOUS HEMOFILTRATION (CVVH)	2.9
012-004	59/Female	18JUL2015 18:00 / 21JUL2015 12:35	NIKKISO / AQUARIUS	HAEMOTRONIC / AQUALINE	BELLCO / AQUAMAX HF12	CONTINUOUS VENOVENOUS HEMOFILTRATION (CVVH)	2
012-005	41/Male	26JUL2015 07:15 / 29JUL2015 07:15	NIKKISO / AQUARIUS	HAEMOTRONIC / AQUALINE	BELLCO / AQUAMAX HF12	CONTINUOUS VENOVENOUS HEMOFILTRATION (CVVH)	2.6
012-006	44/Male	29AUG2015 03:30 / 31AUG2015 06:15	NIKKISO / AQUARIUS	HAEMOTRONIC / AQUALINE	BELLCO / AQUAMAX HF12	CONTINUOUS VENOVENOUS HEMODIAFILTRATION (CVVHDF)	2
012-007	82/Male	09OCT2015 20:45 / 12OCT2015 14:00	EDWARDS / AQUARIUS	HAEMOTRONIC / AQUALINE	BELLCO / AQUAMAX HF12	CONTINUOUS VENOVENOUS HEMOFILTRATION (CVVH)	2.4
012-008	59/Male	15OCT2015 15:00 / 17OCT2015 10:45	EDWARDS / AQUARIUS	HAEMOTRONIC / AQUALINE	BELLCO / AQUAMAX HF12	CONTINUOUS VENOVENOUS HEMOFILTRATION (CVVH)	2.9

Data Listing 16.2.5.4. Dialysis Session - Enrolled Population

Patient Number	Age (Years)/ Gender	Start Date and Time of Current CRRT Circuit/ End Date and Time of Current CRRT Circuit	Manufacturer of CRRT Monitor/ Model of CRRT Monitor	Manufacturer of CRRT Lines/ Model of CRRT Lines	Manufacturer of Haemofilter/ Model of Haemofilter	CRRT Mode Employed	Ultrafiltration Rate (L/h)
012-009	70/Male	03NOV2015 13:30 / 05NOV2015 11:05	EDWARDS / AQUARIUS	HAEMOTRONIC / AQUALINE	BELLCO / AQUAMAX HF12	CONTINUOUS VENOVENOUS HEMOFILTRATION (CVVH)	2.4
012-010	72/Male	04NOV2015 18:00 / 07NOV2015 21:20	EDWARDS / AQUARIUS	HAEMOTRONIC / AQUALINE	BELLCO / AQUAMAX HF12	CONTINUOUS VENOVENOUS HEMOFILTRATION (CVVH)	2
012-011	58/Female	15DEC2015 04:45 / 17DEC2015 17:50	NIKKISO / AQUARIUS	HAEMOTRONIC / AQUALINE	BELLCO / AQUAMAX HF12	CONTINUOUS VENOVENOUS HEMOFILTRATION (CVVH)	2.7
012-012	69/Male	13JAN2016 18:00 / 16JAN2016 21:15	EDWARDS / AQUARIUS	HAEMOTRONIC / AQUALINE	BELLCO / AQUAMAX HF12	CONTINUOUS VENOVENOUS HEMOFILTRATION (CVVH)	2.1
012-013	77/Female	18JAN2016 02:15 / 20JAN2016 08:00	EDWARDS / AQUARIUS	HAEMOTRONIC / AQUALINE	BELLCO / AQUAMAX HF12	CONTINUOUS VENOVENOUS HEMOFILTRATION (CVVH)	1.7
013-002	70/Male	29JUN2015 14:00 / 02JUL2015 14:00	EDWARDS / AQUARIUS	HAEMOTRONIC / AQUALINE	BELLCO / AQUAMAX	CONTINUOUS VENOVENOUS HEMOFILTRATION (CVVH)	2.3

Data Listing 16.2.5.4. Dialysis Session - Enrolled Population

Patient Number	Age (Years)/ Gender	Start Date and Time of Current CRRT Circuit/ End Date and Time of Current CRRT Circuit	Manufacturer of CRRT Monitor/ Model of CRRT Monitor	Manufacturer of CRRT Lines/ Model of CRRT Lines	Manufacturer of Haemofilter/ Model of Haemofilter	CRRT Mode Employed	Ultrafiltration Rate (L/h)
013-003	69/Male	27JUL2015 23:00 / 29JUL2015 16:30	EDWARDS / AQUARIUS	HAEMOTRONIC / AQUALINE	BELLCO / AQUAMAX	CONTINUOUS VENOVENOUS HEMOFILTRATION (CVVH)	3.0
013-004	64/Female	07SEP2015 12:00 / 09SEP2015 10:00	EDWARDS / AQUARIUS	HAEMOTRONIC / AQUALINE	BELLCO / AQUAMAX	CONTINUOUS VENOVENOUS HEMOFILTRATION (CVVH)	4.2
013-005		15SEP2015 21:00 / 19SEP2015 01:00	EDWARDS / AQUARIUS	HAEMOTRONIC / AQUALINE	BELLCO / AQUAMAX	CONTINUOUS VENOVENOUS HEMOFILTRATION (CVVH)	2
013-010	76/Female	03DEC2015 15:00 / 06DEC2015 15:30	EDWARDS / AQUARIUS	HAEMOTRONIC / AQUALINE	BELLCO / AQUAMAX	CONTINUOUS VENOVENOUS HEMOFILTRATION (CVVH)	2
014-001	75/Female	15APR2015 20:00 / 19APR2015 00:00	NIKKISO / AQUARIUS	HAEMOTRONIC / AQUALINE	BELLCO / AQUAMAX HF12	CONTINUOUS VENOVENOUS HEMOFILTRATION (CVVH)	2.3
014-002	47/Male	27APR2015 05:00 / 30APR2015 01:30	NIKKISO / AQUARIUS	HAEMOTRONIC / AQUALINE	BELLCO / AQUAMAX HF12	CONTINUOUS VENOVENOUS HEMOFILTRATION (CVVH)	1.8

Data Listing 16.2.5.4. Dialysis Session - Enrolled Population

Patient Number	Age (Years)/ Gender	Start Date and Time of Current CRRT Circuit/ End Date and Time of Current CRRT Circuit	Manufacturer of CRRT Monitor/ Model of CRRT Monitor	Manufacturer of CRRT Lines/ Model of CRRT Lines	Manufacturer of Haemofilter/ Model of Haemofilter	CRRT Mode Employed	Ultrafiltration Rate (L/h)
014-003	63/Female	11JUN2015 01:30 / 12JUN2015 20:30	NIKKISO / AQUARIUS	HAEMOTRONIC / AQUALINE	BELLCO / AQUAMAX HF12	CONTINUOUS VENOVENOUS HEMOFILTRATION (CVVH)	2.4
014-004	33/Female	31AUG2015 19:15 / 02SEP2015 23:00	NIKKISO / AQUARIUS	HAEMOTRONIC / AQUALINE	BELLCO / AQUAMAX HF12	CONTINUOUS VENOVENOUS HEMODIAFILTRATION (CVVHDF)	1.8
014-007	34/Female	07SEP2015 13:00 / 10SEP2015 08:00	NIKKISO / AQUARIUS	HAEMOTRONIC / AQUALINE	BELLCO / AQUAMAX HF12	CONTINUOUS VENOVENOUS HEMOFILTRATION (CVVH)	2.1
015-001	77/Female	25APR2015 21:00 / 28APR2015 16:20	EDWARDS / AQUARIUS	HAEMOTRONIC / AQUALINE	BELLCO / AQUAMAX HF12	CONTINUOUS VENOVENOUS HEMOFILTRATION (CVVH)	2
015-002	60/Male	23MAY2015 03:00 / 26MAY2015 03:00	EDWARDS / AQUARIUS	HAEMOTRONIC / AQUALINE	BELLCO / AQUAMAX HF12	CONTINUOUS VENOVENOUS HEMOFILTRATION (CVVH)	2
015-003	57/Male	27MAY2015 13:40 / 29MAY2015 18:30	EDWARDS / AQUARIUS	HAEMOTRONIC / AQUALINE	BELLCO / AQUAMAX HF12	CONTINUOUS VENOVENOUS HEMOFILTRATION (CVVH)	2

Data Listing 16.2.5.4. Dialysis Session - Enrolled Population

Patient Number	Age (Years)/ Gender	Start Date and Time of Current CRRT Circuit/ End Date and Time of Current CRRT Circuit	Manufacturer of CRRT Monitor/ Model of CRRT Monitor	Manufacturer of CRRT Lines/ Model of CRRT Lines	Manufacturer of Haemofilter/ Model of Haemofilter	CRRT Mode Employed	Ultrafiltration Rate (L/h)
015-004	85/Male	18JUN2015 15:30 / 21JUN2015 15:30	EDWARDS / AQUARIUS	HAEMOTRONIC / AQUALINE	BELLCO / AQUAMAX HF12	CONTINUOUS VENOVENOUS HEMOFILTRATION (CVVH)	2
015-005	76/Male	05JUL2015 03:13 / 08JUL2015 04:00	EDWARDS / AQUARIUS	HAEMOTRONIC / AQUALINE	BELLCO / AQUAMAX HF12	CONTINUOUS VENOVENOUS HEMOFILTRATION (CVVH)	2
015-006	84/Female	13AUG2015 15:10 / 16AUG2015 15:10	EDWARDS / AQUARIUS	HAEMOTRONIC / AQUALINE	BELLCO / AQUAMAX HF12	CONTINUOUS VENOVENOUS HEMOFILTRATION (CVVH)	2
015-009	76/Female	05JAN2016 03:45 / 08JAN2016 03:45	EDWARDS / AQUARIUS	HAEMOTRONIC / AQUALINE	BELLCO / AQUAMAX HF12	CONTINUOUS VENOVENOUS HEMOFILTRATION (CVVH)	2
015-010		08JAN2016 22:15 / 11JAN2016 10:50	EDWARDS / AQUARIUS	HAEMOTRONIC / AQUALINE	BELLCO / AQUAMAX HF12	CONTINUOUS VENOVENOUS HEMOFILTRATION (CVVH)	2
015-011		21JAN2016 17:30 / 23JAN2016 20:05	EDWARDS / AQUARIUS	HAEMOTRONIC / AQUALINE	BELLCO / AQUAMAX HF12	CONTINUOUS VENOVENOUS HEMOFILTRATION (CVVH)	2

Data Listing 16.2.5.4. Dialysis Session - Enrolled Population

Patient Number	Age (Years)/ Gender	Start Date and Time of Current CRRT Circuit/ End Date and Time of Current CRRT Circuit	Manufacturer of CRRT Monitor/ Model of CRRT Monitor	Manufacturer of CRRT Lines/ Model of CRRT Lines	Manufacturer of Haemofilter/ Model of Haemofilter	CRRT Mode Employed	Ultrafiltration Rate (L/h)
016-002		02SEP2015 19:10 / 04SEP2015 12:15	EDWARDS / AQUARIUS	HAEMOTRONIC / AQUALINE	BELLCO / AQUAMAX HF12	CONTINUOUS VENOVENOUS HEMODIAFILTRATION (CVVHDF)	2.4
016-004	55/Male	01DEC2015 17:30 / 03DEC2015 12:00	EDWARDS / AQUARIUS	HAEMOTRONIC / AQUALINE	BELLCO / AQUAMAX HF12	CONTINUOUS VENOVENOUS HEMODIAFILTRATION (CVVHDF)	2.6
017-003	92/Female	12JUL2015 02:00 / 13JUL2015 19:20	EDWARDS / AQUARIUS	HAEMOTRONIC / AQUALINE	BELLCO / AQUAMAX HF12	CONTINUOUS VENOVENOUS HEMOFILTRATION (CVVH)	2.5
017-004	74/Male	16JUL2015 17:30 / 19JUL2015 17:30	EDWARDS / AQUARIUS	HAEMOTRONIC / AQUALINE	BELLCO / AQUAMAX HF12	CONTINUOUS VENOVENOUS HEMOFILTRATION (CVVH)	2.8
017-005	77/Male	12AUG2015 02:45 / 14AUG2015 09:00	EDWARDS / AQUARIUS	HAEMOTRONIC / AQUALINE	BELLCO / AQUAMAX HF12	CONTINUOUS VENOVENOUS HEMOFILTRATION (CVVH)	3.5
017-007	66/Male	31AUG2015 15:30 / 03SEP2015 15:30	EDWARDS / AQUARIUS	HAEMOTRONIC / AQUALINE	BELLCO / AQUAMAX HF12	CONTINUOUS VENOVENOUS HEMOFILTRATION (CVVH)	2.8

Data Listing 16.2.5.4. Dialysis Session - Enrolled Population

Patient Number	Age (Years)/ Gender	Start Date and Time of Current CRRT Circuit/ End Date and Time of Current CRRT Circuit	Manufacturer of CRRT Monitor/ Model of CRRT Monitor	Manufacturer of CRRT Lines/ Model of CRRT Lines	Manufacturer of Haemofilter/ Model of Haemofilter	CRRT Mode Employed	Ultrafiltration Rate (L/h)
017-008		25SEP2015 00:24 / 28SEP2015 00:20	EDWARDS / AQUARIUS	HAEMOTRONIC / AQUALINE	BELLCO / AQUAMAX HF12	CONTINUOUS VENOVENOUS HEMOFILTRATION (CVVH)	2.1
017-010	54/Male	17NOV2015 22:10 / 20NOV2015 10:30	EDWARDS / AQUARIUS	HAEMOTRONIC / AQUALINE	BELLCO / AQUAMAX	CONTINUOUS VENOVENOUS HEMOFILTRATION (CVVH)	3.2
017-011	49/Male	20NOV2015 15:30 / 23NOV2015 15:45	EDWARDS / AQUARIUS	HAEMOTRONIC / AQUALINE	BELLCO / AQUAMAX	CONTINUOUS VENOVENOUS HEMOFILTRATION (CVVH)	2.1

Data Listing 16.2.5.5. Dialysis Session – Interruptions - Enrolled Population

Patient Number	Age(Years) /Gender	Circuit Interrupted	No.of Interruptions	Total Time of Interruption	Reason for Interruption	Was the CRRT Circuit Changed while the Patient was on Study?	If yes, Specify Reason	Was CRRT Terminated while the Patient was on Study?	If yes, Specify Reason
001-001	57/Female	N				N		N	
001-002	50/Male	N				N		N	
001-003	68/Female	N				Y	STOPPED TO CHANGE THE FILTER	N	
001-004	78/Female	N				N		N	
001-005	33/Female	N				N		N	
001-006		N				N		Y	DECANNULATION OF THE ECMO MACHINE
001-007	56/Male	N				N		N	
001-008	57/Male	N				N		N	
002-002	56/Male	N				N		N	
002-003	68/Female	N				N		Y	FILTER CLOTTED
002-005	44/Male	N				N		Y	UNKNOWN
002-007	61/Male	N				N		Y	FILTER CLOTTED
002-009	58/Female	N				N		Y	FILTER CLOTTED
002-011	63/Female	N				N		N	
002-012		N				N		Y	CT SCAN
002-014	59/Male	N				N		Y	FILTER CLOTTED

Data Listing 16.2.5.5. Dialysis Session – Interruptions - Enrolled Population

Patient Number	Age(Years) /Gender	Circuit Interrupted	No.of Interruptions	Total Time of Interruption	Reason for Interruption	Was the CRRT Circuit Changed while the Patient was on Study?	If yes, Specify Reason	Was CRRT Terminated while the Patient was on Study?	If yes, Specify Reason
002-016	83/Female	N				N		Y	FLITER CLOTTED
002-017	73/Male	N				N		Y	CLINICAL DECISION TO STOP THE FILTER
002-018	91/Female	N				N		Y	FILTER CLOTTED
002-019	70/Male	N				N		Y	IMMINENT DEATH
002-021	73/Male	N				N		Y	FILTER CLOTTED
003-001	77/Male	N				N		Y	FILTER CLOT
003-002	67/Male	N				Y	ACCESS ISSUES	N	
003-003	57/Female	N				N		Y	SPECIFY PATIENT NEEDED A LINE CHANGE
003-004	66/Male	N				N		Y	NURSE ERROR
003-007	60/Male	N				N		N	
003-008	47/Male	N				N		Y	SPECIFY TRANSFERRED
003-009		N				N		N	
003-010	79/Male	N				N		N	
003-011	69/Male	N				N		N	
003-012	88/Male	N				N		Y	FILTER CLOTTED

Data Listing 16.2.5.5. Dialysis Session – Interruptions - Enrolled Population

Patient Number	Age(Years) /Gender	Circuit Interrupted	No.of Interruptions	Total Time of Interruption	Reason for Interruption	Was the CRRT Circuit Changed while the Patient was on Study?	If yes, Specify Reason	Was CRRT Terminated while the Patient was on Study?	If yes, Specify Reason
004-001		N				N		Y	FILTER CLOTTED, AND NO FURTHER NEED
004-002		N				Y	PATIENT BECAME AGITATED AND NOT SAFE.CRRT STOPPED AND RESTARTED.	N	
004-003	45/Female	N				Y	FILTER SET WAS CLOTTED	N	
004-005	20/Female	N				N		N	
004-006	30/Male	N				N		N	
004-009	59/Female	N				N		N	
004-010	55/Male	N				N		Y	CRRT NO LONGER REQUIRED (PATIENT STATUS IMPROVED)
004-013	79/Male	N				Y	ACCESS ISSUES	N	
004-014	65/Male	N				Y	FILTER CLOTTED	N	
004-016	47/Female	N				Y	ACCESS ISSUES	N	
004-017	67/Male	N				N		N	

Data Listing 16.2.5.5. Dialysis Session – Interruptions - Enrolled Population

Patient Number	Age(Years) /Gender	Circuit Interrupted	No.of Interruptions	Total Time of Interruption	Reason for Interruption	Was the CRRT Circuit Changed while the Patient was on Study?	If yes, Specify Reason	Was CRRT Terminated while the Patient was on Study?	If yes, Specify Reason
004-018	40/Male	N				Y	CRRT CIRCUIT CHANGED, DUE TO BEDSIDE NURSE ERROR	N	
005-002	68/Female	N				N		Y	FILTER CLOTTED AND DOCTOR'S DECISION NOT TO RESTART FILTER
005-003	65/Female	N				N		Y	PATIENT WAS DISCONNECTED TO PREPARE HIM FOR CT SCAN
005-004	81/Male	N				N		Y	FILTER CLOTTED
005-006	38/Male	N				N		Y	FILTER HAS CLOTTED
005-007	63/Male	N				N		N	
005-008	74/Female	N				N		Y	CRRT HAS CLOTTED
005-010	42/Male	N				N		N	
005-011	78/Female	N				N		Y	FILTER CLOTTED
005-012		N				N		N	
005-014	65/Male	N				N		Y	CRRT CLOTTED @08:20

Data Listing 16.2.5.5. Dialysis Session – Interruptions - Enrolled Population

Patient Number	Age(Years) /Gender	Circuit Interrupted	No.of Interruptions	Total Time of Interruption	Reason for Interruption	Was the CRRT Circuit Changed while the Patient was on Study?	If yes, Specify Reason	Was CRRT Terminated while the Patient was on Study?	If yes, Specify Reason
005-015	78/Male	N				N		N	
005-016		N				N		N	
005-018	67/Male	N				Y	MALFUNCTION IN CIRCUIT	N	
005-019	69/Male	N				N		N	
005-020		N				N		N	
005-021	58/Male	N				N		N	
005-022		N				N		N	
005-023	66/Male	N				N		Y	CRRT WAS TERMINATED BECAUSE PATIENT WAS TO BE TRANSFERRED TO WARD 124
005-024	41/Female	N				N		N	
005-025		N				N		Y	SPECIFY(CRRT CLOTTED @ 20:45)
005-026	64/Male	N				N		Y	CRRT WAS TERMINATED AND PATIENT DISCONNECTED AS HE WAS GOING FOR AN MRI

Data Listing 16.2.5.5. Dialysis Session – Interruptions - Enrolled Population

Patient Number	Age(Years) /Gender	Circuit Interrupted	No.of Interruptions	Total Time of Interruption	Reason for Interruption	Was the CRRT Circuit Changed while the Patient was on Study?	If yes, Specify Reason	Was CRRT Terminated while the Patient was on Study?	If yes, Specify Reason
005-027		N				N		Y	FILTER CLOTTED
005-028		N				N		Y	FILTER OFF
005-029	68/Male	N				N		N	
005-030	61/Male	N				N		Y	CRRT CLOTTED
005-032	49/Male	N				N		Y	FILTER STOPPED, FOR NEW LINE INSERTION
005-034	70/Male	N				N		Y	CRRT CLOTTED
005-036	51/Female	N				N		N	
005-037	53/Female	N				N		N	
005-038		N				N		Y	FILTER CLOTTED
007-001	61/Male	N				N		Y	CLOTTED
007-002		N				N		Y	CRRT NO LONGER REQUIRED (PATIENT STATUS IMPROVED)
007-003	64/Male	N				N		Y	CLOTTED
007-004	72/Male	N				N		Y	CLOTTED
007-005	24/Male	N				N		N	
007-006	73/Female	N				N		N	

Data Listing 16.2.5.5. Dialysis Session – Interruptions - Enrolled Population

Patient Number	Age(Years) /Gender	Circuit Interrupted	No.of Interruptions	Total Time of Interruption	Reason for Interruption	Was the CRRT Circuit Changed while the Patient was on Study?	If yes, Specify Reason	Was CRRT Terminated while the Patient was on Study?	If yes, Specify Reason
007-007	83/Male	N				N		Y	TERMINATED PREMATURELY
007-008	79/Male	N				N		Y	CRRT NO LONGER REQUIRED (PATIENT STATUS IMPROVED)
007-010	70/Male	N				N		Y	TO ATTEND CT SCAN
007-011	64/Female	N				N		N	
007-012	36/Male	N				N		N	
007-014	74/Female	N				N		Y	CLOTTED
007-015	73/Female	N				N		Y	LABILE BLOOD PRESSURE
007-016	71/Male	N				N		Y	MEDICAL DECISION TO STOP THERAPY
008-001	26/Male	N				N		N	
008-002	31/Male	N				N		N	
008-003	25/Female	N				N		N	
008-004	46/Male	N				Y	MALFUNCTION IN CIRCUIT	N	

Data Listing 16.2.5.5. Dialysis Session – Interruptions - Enrolled Population

Patient Number	Age(Years) /Gender	Circuit Interrupted	No.of Interruptions	Total Time of Interruption	Reason for Interruption	Was the CRRT Circuit Changed while the Patient was on Study?	If yes, Specify Reason	Was CRRT Terminated while the Patient was on Study?	If yes, Specify Reason
008-005	82/Male	N				N		Y	CRRT NO LONGER REQUIRED (PATIENT STATUS IMPROVED)
008-006	70/Male	N				Y	INTERRUPTION FOR OTHER PROCEDURE	N	
008-007	74/Male	N				Y	CLOTTED OFF	N	
008-012	71/Male	N				N		Y	CRRT NO LONGER REQUIRED (PATIENT STATUS IMPROVED)
008-013	68/Male	N				Y	CLOTTED	N	
008-014	65/Female	N				Y	MALFUNCTION IN CIRCUIT	N	
008-016	34/Male	N				N		Y	SCAN
008-017	52/Female	N				Y	CLOTTED	N	
008-018	65/Male	N				N		Y	CRRT NO LONGER REQUIRED (PATIENT STATUS IMPROVED)
008-019	69/Female	N				N		Y	CLOTTED
008-020	60/Male	N				N		N	

Data Listing 16.2.5.5. Dialysis Session – Interruptions - Enrolled Population

Patient Number	Age(Years) /Gender	Circuit Interrupted	No.of Interruptions	Total Time of Interruption	Reason for Interruption	Was the CRRT Circuit Changed while the Patient was on Study?	If yes, Specify Reason	Was CRRT Terminated while the Patient was on Study?	If yes, Specify Reason
008-021	66/Male	N				Y	CLOTTED OFF	N	
008-022	43/Male	N				N		N	
008-023		N				Y	MALFUNCTION IN CIRCUIT	N	
008-024	27/Male	N				N		N	
008-025	68/Male	N				Y	CLOTTED OFF	N	
008-026	30/Female	N				N		Y	CRRT NO LONGER REQUIRED (PATIENT STATUS IMPROVED)
008-027	71/Male	N				Y	MALFUNCTION IN CIRCUIT	N	
008-028	72/Male	N				Y	CLOTTED OFF	N	
008-029	66/Female	N				Y	CLOTTED OFF	N	
008-030	63/Female	N				N		Y	TREATMENT WITHDRAWN BY MEDICAL STAFF
008-031	23/Male	N				Y	NURSES THOUGHT 72HRS HAD BEEN ACHIEVED ON CIRCUIT	N	

Data Listing 16.2.5.5. Dialysis Session – Interruptions - Enrolled Population

Patient Number	Age(Years) /Gender	Circuit Interrupted	No.of Interruptions	Total Time of Interruption	Reason for Interruption	Was the CRRT Circuit Changed while the Patient was on Study?	If yes, Specify Reason	Was CRRT Terminated while the Patient was on Study?	If yes, Specify Reason
009-001	64/Male	N				Y	PERIOD OF RECIRCULATION EXCEEDED 2 HOURS	N	
009-002		N				Y	BEDSIDE MISCOMMUNICATION RESULTED IN EARLY TERMINATION OF CURRENT CIRCUIT	N	
009-003	75/Male	N				N		N	
009-006	58/Female	N				Y	LARGE BLOOD CLOT IN THE RETURN CHAMBER	N	
009-008	31/Male	N				N		N	
009-009		N				Y	LARGE BLOOD CLOT PRESENT IN CHAMBER, NEW CIRCUIT REQUIRED	N	
009-011	75/Female	N				Y	MALFUNCTION IN CIRCUIT	N	

Data Listing 16.2.5.5. Dialysis Session – Interruptions - Enrolled Population

Patient Number	Age(Years) /Gender	Circuit Interrupted	No.of Interruptions	Total Time of Interruption	Reason for Interruption	Was the CRRT Circuit Changed while the Patient was on Study?	If yes, Specify Reason	Was CRRT Terminated while the Patient was on Study?	If yes, Specify Reason
009-013	60/Female	N				N		Y	FILTER CLOTTED, NOT TO BE RESTARTED IN EVENT OF.
009-015	29/Male	N				Y	FILTER CLOTTED	N	
009-016	83/Male	N				Y	LARGE CLOT IN RETURN CHAMBER	N	
009-017	51/Male	N				N		Y	ANTICIPATION OF PATIENTS DEATH
009-018	44/Male	N				N		N	
009-019	84/Male	N				Y	HIGH PRE FILTER PRESSURE	N	
009-021	51/Male	N				N		N	
009-022		N				Y	LARGE CLOT IN RETURN CHAMBER	N	
009-024	49/Female	N				N		N	
009-026	76/Female	N				N		N	
009-027	53/Male	N				N		Y	PATIENT TAKEN TO THEATRE

Data Listing 16.2.5.5. Dialysis Session – Interruptions - Enrolled Population

Patient Number	Age(Years) /Gender	Circuit Interrupted	No.of Interruptions	Total Time of Interruption	Reason for Interruption	Was the CRRT Circuit Changed while the Patient was on Study?	If yes, Specify Reason	Was CRRT Terminated while the Patient was on Study?	If yes, Specify Reason
009-028		N				Y	HIGH PRE FILTER PRESSURE	N	
009-030	75/Male	N				N		N	
009-031	34/Male	N				Y	FILTER CLOTTED	N	
009-032	59/Male	N				N		Y	FILTER CLOTTED
010-002	57/Male	N				N		N	
010-003		N				N		Y	CLOTTED
010-005	78/Male	N				N		N	
010-006	80/Male	N				N		N	
010-008	70/Female	N				N		Y	BACK FILL IN FILTER MACHINE
010-009	69/Male	Y	1	50	CT SCAN	N		Y	FILTER CLOTTED
010-010	52/Female	N				N		N	
010-011		N				N		Y	HIGH FILTER PRESSURE
010-014	79/Female	N				N		Y	FILTER CLOTTED

Data Listing 16.2.5.5. Dialysis Session – Interruptions - Enrolled Population

Patient Number	Age(Years) /Gender	Circuit Interrupted	No.of Interruptions	Total Time of Interruption	Reason for Interruption	Was the CRRT Circuit Changed while the Patient was on Study?	If yes, Specify Reason	Was CRRT Terminated while the Patient was on Study?	If yes, Specify Reason
011-001	53/Male	N				N		Y	CRRT NO LONGER REQUIRED (PATIENT STATUS IMPROVED)
011-002	75/Male	N				N		Y	CRRT NO LONGER REQUIRED (PATIENT STATUS IMPROVED)
011-003	80/Male	N				N		Y	CRRT NO LONGER REQUIRED (PATIENT STATUS IMPROVED)
011-004	80/Female	N				N		N	
011-005	78/Male	N				N		Y	HIGH RETURN PRESSURES
011-006	77/Male	N				N		Y	CRRT NO LONGER REQUIRED (PATIENT STATUS IMPROVED)
011-007	62/Female	N				N		Y	5+ BALANCE ALARMS

Data Listing 16.2.5.5. Dialysis Session – Interruptions - Enrolled Population

Patient Number	Age(Years) /Gender	Circuit Interrupted	No.of Interruptions	Total Time of Interruption	Reason for Interruption	Was the CRRT Circuit Changed while the Patient was on Study?	If yes, Specify Reason	Was CRRT Terminated while the Patient was on Study?	If yes, Specify Reason
011-008	61/Male	N				N		Y	PATIENT TRANSFERRED TO ANOTHER HOSPITAL
011-009	71/Female	N				N		Y	HIGH PRE-FILTER PRESSURES
011-010	47/Male	N				N		Y	HAEMOFILTRATION HOLIDAY
011-011	77/Male	N				N		Y	HIGH PRE-FILTER PRESSURES
011-012	74/Male	N				N		N	
011-013	71/Female	N				N		N	
011-014	79/Female	N				N		Y	FILTER CLOTTED OFF - HIGH TMP PRESSURES
011-015	77/Female	N				N		Y	HIGH PRE-FILTER PRESSURE ALARMS
011-016	72/Female	N				N		N	
012-001	59/Male	N				N		N	
012-002	67/Male	N				N		N	

Data Listing 16.2.5.5. Dialysis Session – Interruptions - Enrolled Population

Patient Number	Age(Years) /Gender	Circuit Interrupted	No.of Interruptions	Total Time of Interruption	Reason for Interruption	Was the CRRT Circuit Changed while the Patient was on Study?	If yes, Specify Reason	Was CRRT Terminated while the Patient was on Study?	If yes, Specify Reason
012-003	63/Male	N				N		Y	CRRT NO LONGER REQUIRED (PATIENT STATUS IMPROVED)
012-004	59/Female	N				Y	FILTER CLOTTED	N	
012-005	41/Male	N				N		N	
012-006	44/Male	N				N		Y	CRRT NO LONGER REQUIRED (PATIENT STATUS IMPROVED)
012-007	82/Male	N				N		Y	CRRT NO LONGER REQUIRED (PATIENT STATUS IMPROVED)
012-008	59/Male	N				N		Y	FILTER CLOTTED
012-009	70/Male	N				N		Y	CRRT NO LONGER REQUIRED (PATIENT STATUS IMPROVED)
012-010	72/Male	N				N		N	
012-011	58/Female	N				Y	CVVH CLOTTED	N	
012-012	69/Male	N				N		N	

Data Listing 16.2.5.5. Dialysis Session – Interruptions - Enrolled Population

Patient Number	Age(Years) /Gender	Circuit Interrupted	No.of Interruptions	Total Time of Interruption	Reason for Interruption	Was the CRRT Circuit Changed while the Patient was on Study?	If yes, Specify Reason	Was CRRT Terminated while the Patient was on Study?	If yes, Specify Reason
012-013	77/Female	N				N		Y	CVVH CLOTTED
013-002	70/Male	N				N		N	
013-003	69/Male	N				N		Y	CLOTTED CIRCUIT
013-004	64/Female	N				N		Y	PATIENT REQUIRED EMERGENCY OPERATION
013-005		N				N		N	
013-010	76/Female	N				N		N	
014-001	75/Female	N				N		N	
014-002	47/Male	N				N		Y	PATIENT WITHDRAWN FROM STUDY IN ANTICIPATION OF DEATH
014-003	63/Female	N				Y	MALFUNCTION IN CIRCUIT	N	
014-004	33/Female	N				N		Y	FILTER CLOTTED
014-007	34/Female	N				Y	FILTER CLOTTED	N	
015-001	77/Female	N				N		Y	FILTER CLOT
015-002	60/Male	N				N		N	

Data Listing 16.2.5.5. Dialysis Session – Interruptions - Enrolled Population

Patient Number	Age(Years) /Gender	Circuit Interrupted	No.of Interruptions	Total Time of Interruption	Reason for Interruption	Was the CRRT Circuit Changed while the Patient was on Study?	If yes, Specify Reason	Was CRRT Terminated while the Patient was on Study?	If yes, Specify Reason
015-003	57/Male	N				N		Y	POSITIONAL VASCATH, HIGH ACCESS PRESSURES AND CLOT
015-004	85/Male	N				N		N	
015-005	76/Male	N				N		N	
015-006	84/Female	N				N		N	
015-009	76/Female	N				N		N	
015-010		N				N		Y	AIR IN LINE
015-011		N				N		Y	HIGH PRE-FILTER PRESSURE
016-002		N				N		Y	CLOTTED
016-004	55/Male	N				N		Y	DISCONTINUED FOR THEATRE
017-003	92/Female	N				N		Y	CLINICAL DECISION
017-004	74/Male	N				N		N	
017-005	77/Male	N				N		Y	CRRT NO LONGER REQUIRED (PATIENT STATUS IMPROVED)

Data Listing 16.2.5.5. Dialysis Session – Interruptions - Enrolled Population

Patient Number	Age(Years) /Gender	Circuit Interrupted	No.of Interruptions	Total Time of Interruption	Reason for Interruption	Was the CRRT Circuit Changed while the Patient was on Study?	If yes, Specify Reason	Was CRRT Terminated while the Patient was on Study?	If yes, Specify Reason
017-007	66/Male	N				N		N	
017-008		N				N		Y	CRRT NO LONGER REQUIRED (PATIENT STATUS IMPROVED)
017-010	54/Male	N				N		Y	CRRT NO LONGER REQUIRED (PATIENT STATUS IMPROVED)
017-011	49/Male	N				N		N	

Appendix 16.2.7. Safety Data

Data Listing 16.2.7.1. Precipitate Observation - Enrolled Population

Patient Number	Age (Years)/ Gender	Date and Time (24-hr Clock) of Final Observation/ Time since start of CRRT (hours)	Any Precipitate Observed in the CRRT Lines	If Yes, Colour of the Precipitate	Solution in Use at the Time Precipitate was Observed	Lot Number of Solution in Use at the Time Precipitate was Observed
001-001	57/Female	05JUN2015 19:00 / 68:07	No	NA	NA	NA
001-002	50/Male	13JUN2015 23:04 / 72:04	No	NA	NA	NA
001-003	68/Female	15AUG2015 02:04 / 51:58	No	NA	NA	NA
001-004	78/Female	20SEP2015 04:01 / 72:00	No	NA	NA	NA
001-005	33/Female	30OCT2015 14:10 / 72:00	No	NA	NA	NA
001-006		13NOV2015 15:30 / 61:27	No	NA	NA	NA
001-007	56/Male	24DEC2015 03:33 / 72:00	No	NA	NA	NA
001-008	57/Male	31JAN2016 01:00 / 72:00	No	NA	NA	NA
002-002	56/Male	27APR2015 10:25 / 72:00	No	NA	NA	NA

Data Listing 16.2.7.1. Precipitate Observation - Enrolled Population

Patient Number	Age (Years)/ Gender	Date and Time (24-hr Clock) of Final Observation/ Time since start of CRRT (hours)	Any Precipitate Observed in the CRRT Lines	If Yes, Colour of the Precipitate	Solution in Use at the Time Precipitate was Observed	Lot Number of Solution in Use at the Time Precipitate was Observed
002-003	68/Female	05MAY2015 09:50 / 48:30	No	NA	NA	NA
002-005	44/Male	16MAY2015 18:20 / 71:50	No	NA	NA	NA
002-007	61/Male	24JUN2015 17:52 / 42:30	No	NA	NA	NA
002-009	58/Female	20JUN2015 16:50 / 68:00	No	NA	NA	NA
002-011	63/Female	21AUG2015 15:00 / 72:00	No	NA	NA	NA
002-012		30AUG2015 12:10 / 48:30	No	NA	NA	NA
002-014	59/Male	03SEP2015 19:30 / 67:30	No	NA	NA	NA
002-016	83/Female	03SEP2015 17:25 / 41:30	No	NA	NA	NA
002-017	73/Male	12OCT2015 18:30 / 41:00	No	NA	NA	NA
002-018	91/Female	23OCT2015 09:05 / 58:00	No	NA	NA	NA
002-019	70/Male	10NOV2015 21:05 / 56:00	No	NA	NA	NA

Data Listing 16.2.7.1. Precipitate Observation - Enrolled Population

Patient Number	Age (Years)/ Gender	Date and Time (24-hr Clock) of Final Observation/ Time since start of CRRT (hours)	Any Precipitate Observed in the CRRT Lines	If Yes, Colour of the Precipitate	Solution in Use at the Time Precipitate was Observed	Lot Number of Solution in Use at the Time Precipitate was Observed
002-021	73/Male	11DEC2015 12:00 / 71:00	No	NA	NA	NA
003-001	77/Male	30MAR2015 20:30 / 45:00	No	NA	NA	NA
003-002	67/Male	16MAY2015 08:30 / 63:36	No	NA	NA	NA
003-003	57/Female	28AUG2015 13:30 / 45:30	No	NA	NA	NA
003-004	66/Male	08SEP2015 20:30 / 71:30	No	NA	NA	NA
003-007	60/Male	06OCT2015 22:00 / 72:00	No	NA	NA	NA
003-008	47/Male	21OCT2015 16:30 / 45:00	No	NA	NA	NA
003-009		27OCT2015 13:30 / 73:00	No	NA	NA	NA
003-010	79/Male	01DEC2015 10:00 / 72:00	No	NA	NA	NA
003-011	69/Male	24DEC2015 11:00 / 72:10	No	NA	NA	NA
003-012	88/Male	23JAN2016 14:00 / 47:30	No	NA	NA	NA

Data Listing 16.2.7.1. Precipitate Observation - Enrolled Population

Patient Number	Age (Years)/ Gender	Date and Time (24-hr Clock) of Final Observation/ Time since start of CRRT (hours)	Any Precipitate Observed in the CRRT Lines	If Yes, Colour of the Precipitate	Solution in Use at the Time Precipitate was Observed	Lot Number of Solution in Use at the Time Precipitate was Observed
004-001		23APR2015 20:30 / 52:30	No	NA	NA	NA
004-002		19MAY2015 06:00 / 52:00	No	NA	NA	NA
004-003	45/Female	02JUN2015 20:00 / 70:00	No	NA	NA	NA
004-005	20/Female	24JUN2015 12:00 / 72:00	No	NA	NA	NA
004-006	30/Male	06JUL2015 15:00 / 72:00	No	NA	NA	NA
004-009	59/Female	25JUL2015 23:00 / 72:00	No	NA	NA	NA
004-010	55/Male	29JUL2015 08:00 / 61:00	No	NA	NA	NA
004-013	79/Male	15AUG2015 01:00 / 57:00	No	NA	NA	NA
004-014	65/Male	23AUG2015 17:00 / 47:00	No	NA	NA	NA
004-016	47/Female	19SEP2015 09:00 / 46:00	No	NA	NA	NA
004-017	67/Male	26SEP2015 01:00 / 72:00	No	NA	NA	NA

Data Listing 16.2.7.1. Precipitate Observation - Enrolled Population

Patient Number	Age (Years)/ Gender	Date and Time (24-hr Clock) of Final Observation/ Time since start of CRRT (hours)	Any Precipitate Observed in the CRRT Lines	If Yes, Colour of the Precipitate	Solution in Use at the Time Precipitate was Observed	Lot Number of Solution in Use at the Time Precipitate was Observed
004-018	40/Male	27SEP2015 02:30 / 70:30	No	NA	NA	NA
005-002	68/Female	22MAR2015 12:00 / 57:30	No	NA	NA	NA
005-003	65/Female	25MAR2015 13:00 / 67:30	No	NA	NA	NA
005-004	81/Male	28MAR2015 07:00 / 62:00	No	NA	NA	NA
005-006	38/Male	23APR2015 11:00 / 63:00	No	NA	NA	NA
005-007	63/Male	25APR2015 04:00 / 72:00	No	NA	NA	NA
005-008	74/Female	10MAY2015 03:00 / 58:00	No	NA	NA	NA
005-010	42/Male	15MAY2015 18:00 / 72:00	No	NA	NA	NA
005-011	78/Female	15MAY2015 16:00 / 47:35	No	NA	NA	NA
005-012		17MAY2015 21:00 / 72:00	No	NA	NA	NA
005-014	65/Male	06JUN2015 08:00 / 62:30	No	NA	NA	NA

Data Listing 16.2.7.1. Precipitate Observation - Enrolled Population

Patient Number	Age (Years)/ Gender	Date and Time (24-hr Clock) of Final Observation/ Time since start of CRRT (hours)	Any Precipitate Observed in the CRRT Lines	If Yes, Colour of the Precipitate	Solution in Use at the Time Precipitate was Observed	Lot Number of Solution in Use at the Time Precipitate was Observed
005-015	78/Male	22JUN2015 05:00 / 72:00	No	NA	NA	NA
005-016		16JUL2015 03:50 / 72:00	No	NA	NA	NA
005-018	67/Male	29AUG2015 18:00 / 50:30	No	NA	NA	NA
005-019	69/Male	16SEP2015 23:30 / 72:00	No	NA	NA	NA
005-020		17SEP2015 19:30 / 72:00	No	NA	NA	NA
005-021	58/Male	17SEP2015 16:30 / 72:00	No	NA	NA	NA
005-022		07OCT2015 12:30 / 72:00	No	NA	NA	NA
005-023	66/Male	11NOV2015 17:30 / 52:30	No	NA	NA	NA
005-024	41/Female	26NOV2015 19:00 / 72:00	No	NA	NA	NA
005-025		26NOV2015 20:30 / 64:30	No	NA	NA	NA
005-026	64/Male	03DEC2015 10:30 / 69:30	No	NA	NA	NA

Data Listing 16.2.7.1. Precipitate Observation - Enrolled Population

Patient Number	Age (Years)/ Gender	Date and Time (24-hr Clock) of Final Observation/ Time since start of CRRT (hours)	Any Precipitate Observed in the CRRT Lines	If Yes, Colour of the Precipitate	Solution in Use at the Time Precipitate was Observed	Lot Number of Solution in Use at the Time Precipitate was Observed
005-027		03DEC2015 12:00 / 55:00	No	NA	NA	NA
005-028		10DEC2015 15:30 / 71:30	No	NA	NA	NA
005-029	68/Male	12DEC2015 15:30 / 72:00	No	NA	NA	NA
005-030	61/Male	18DEC2015 17:00 / 46:00	No	NA	NA	NA
005-032	49/Male	01JAN2016 17:50 / 50:30	No	NA	NA	NA
005-034	70/Male	14JAN2016 13:40 / 59:00	No	NA	NA	NA
005-036	51/Female	15JAN2016 09:15 / 72:00	No	NA	NA	NA
005-037	53/Female	30JAN2016 23:00 / 72:00	No	NA	NA	NA
005-038		29JAN2016 22:00 / 44:30	No	NA	NA	NA
007-001	61/Male	11APR2015 09:00 / 40:30	No	NA	NA	NA
007-002		20MAY2015 11:00 / 58:00	No	NA	NA	NA

Data Listing 16.2.7.1. Precipitate Observation - Enrolled Population

Patient Number	Age (Years)/ Gender	Date and Time (24-hr Clock) of Final Observation/ Time since start of CRRT (hours)	Any Precipitate Observed in the CRRT Lines	If Yes, Colour of the Precipitate	Solution in Use at the Time Precipitate was Observed	Lot Number of Solution in Use at the Time Precipitate was Observed
007-003	64/Male	27JUN2015 08:00 / 63:00	No	NA	NA	NA
007-004	72/Male	28JUN2015 20:00 / 66:10	No	NA	NA	NA
007-005	24/Male	19JUL2015 10:30 / 70:30	No	NA	NA	NA
007-006	73/Female	28JUL2015 04:00 / 71:30	No	NA	NA	NA
007-007	83/Male	03AUG2015 04:00 / 42:10	No	NA	NA	NA
007-008	79/Male	13AUG2015 09:45 / 42:45	No	NA	NA	NA
007-010	70/Male	01SEP2015 10:00 / 42:20	No	NA	NA	NA
007-011	64/Female	02SEP2015 13:00 / 71:30	No	NA	NA	NA
007-012	36/Male	09SEP2015 01:30 / 72:00	No	NA	NA	NA
007-014	74/Female	28SEP2015 07:30 / 40:50	No	NA	NA	NA
007-015	73/Female	15DEC2015 01:50 / 59:00	No	NA	NA	NA

Data Listing 16.2.7.1. Precipitate Observation - Enrolled Population

Patient Number	Age (Years)/ Gender	Date and Time (24-hr Clock) of Final Observation/ Time since start of CRRT (hours)	Any Precipitate Observed in the CRRT Lines	If Yes, Colour of the Precipitate	Solution in Use at the Time Precipitate was Observed	Lot Number of Solution in Use at the Time Precipitate was Observed
007-016	71/Male	05JAN2016 10:05 / 43:30	No	NA	NA	NA
008-001	26/Male	20MAR2015 20:05 / 72:00	No	NA	NA	NA
008-002	31/Male	15APR2015 21:00 / 72:00	No	NA	NA	NA
008-003	25/Female	22APR2015 04:00 / 72:00	No	NA	NA	NA
008-004	46/Male	06MAY2015 23:30 / 45:30	No	NA	NA	NA
008-005	82/Male	22MAY2015 10:50 / 42:30	No	NA	NA	NA
008-006	70/Male	28MAY2015 13:00 / 59:00	No	NA	NA	NA
008-007	74/Male	28MAY2015 21:50 / 55:30	No	NA	NA	NA
008-012	71/Male	20JUL2015 20:30 / 42:30	No	NA	NA	NA
008-013	68/Male	21JUL2015 14:30 / 48:30	No	NA	NA	NA
008-014	65/Female	25JUL2015 11:00 / 43:00	No	NA	NA	NA

Data Listing 16.2.7.1. Precipitate Observation - Enrolled Population

Patient Number	Age (Years)/ Gender	Date and Time (24-hr Clock) of Final Observation/ Time since start of CRRT (hours)	Any Precipitate Observed in the CRRT Lines	If Yes, Colour of the Precipitate	Solution in Use at the Time Precipitate was Observed	Lot Number of Solution in Use at the Time Precipitate was Observed
008-016	34/Male	13AUG2015 14:00 / 44:00	No	NA	NA	NA
008-017	52/Female	22AUG2015 05:55 / 58:55	No	NA	NA	NA
008-018	65/Male	05OCT2015 22:55 / 46:30	No	NA	NA	NA
008-019	69/Female	10OCT2015 02:00 / 45:45	No	NA	NA	NA
008-020	60/Male	21OCT2015 15:30 / 72:00	No	NA	NA	NA
008-021	66/Male	20OCT2015 18:00 / 42:00	No	NA	NA	NA
008-022	43/Male	22OCT2015 05:00 / 72:00	No	NA	NA	NA
008-023		21OCT2015 16:30 / 47:30	No	NA	NA	NA
008-024	27/Male	28OCT2015 20:00 / 72:00	No	NA	NA	NA
008-025	68/Male	30OCT2015 11:15 / 40:00	No	NA	NA	NA
008-026	30/Female	05NOV2015 19:00 / 49:00	No	NA	NA	NA

Data Listing 16.2.7.1. Precipitate Observation - Enrolled Population

Patient Number	Age (Years)/ Gender	Date and Time (24-hr Clock) of Final Observation/ Time since start of CRRT (hours)	Any Precipitate Observed in the CRRT Lines	If Yes, Colour of the Precipitate	Solution in Use at the Time Precipitate was Observed	Lot Number of Solution in Use at the Time Precipitate was Observed
008-027	71/Male	13NOV2015 17:30 / 48:30	No	NA	NA	NA
008-028	72/Male	01DEC2015 10:00 / 61:30	No	NA	NA	NA
008-029	66/Female	09DEC2015 19:40 / 60:00	No	NA	NA	NA
008-030	63/Female	12JAN2016 17:25 / 65:00	No	NA	NA	NA
008-031	23/Male	28JAN2016 03:30 / 59:30	No	NA	NA	NA
009-001	64/Male	02APR2015 15:00 / 40:00	No	NA	NA	NA
009-002		09APR2015 12:00 / 50:20	No	NA	NA	NA
009-003	75/Male	15APR2015 19:00 / 72:00	No	NA	NA	NA
009-006	58/Female	23APR2015 10:00 / 56:00	No	NA	NA	NA
009-008	31/Male	01MAY2015 01:00 / 72:00	No	NA	NA	NA
009-009		01MAY2015 16:30 / 66:30	No	NA	NA	NA

Data Listing 16.2.7.1. Precipitate Observation - Enrolled Population

Patient Number	Age (Years)/ Gender	Date and Time (24-hr Clock) of Final Observation/ Time since start of CRRT (hours)	Any Precipitate Observed in the CRRT Lines	If Yes, Colour of the Precipitate	Solution in Use at the Time Precipitate was Observed	Lot Number of Solution in Use at the Time Precipitate was Observed
009-011	75/Female	21MAY2015 12:30 / 56:30	No	NA	NA	NA
009-013	60/Female	12JUN2015 01:00 / 55:00	No	NA	NA	NA
009-015	29/Male	17JUL2015 18:30 / 50:30	No	NA	NA	NA
009-016	83/Male	21JUL2015 13:00 / 40:00	No	NA	NA	NA
009-017	51/Male	23JUL2015 19:30 / 46:30	No	NA	NA	NA
009-018	44/Male	25JUL2015 02:00 / 72:00	No	NA	NA	NA
009-019	84/Male	28JUL2015 11:30 / 68:30	No	NA	NA	NA
009-021	51/Male	04AUG2015 01:00 / 72:00	No	NA	NA	NA
009-022		01AUG2015 19:30 / 48:30	No	NA	NA	NA
009-024	49/Female	31AUG2015 03:00 / 72:00	No	NA	NA	NA
009-026	76/Female	08OCT2015 16:00 / 72:00	No	NA	NA	NA

Data Listing 16.2.7.1. Precipitate Observation - Enrolled Population

Patient Number	Age (Years)/ Gender	Date and Time (24-hr Clock) of Final Observation/ Time since start of CRRT (hours)	Any Precipitate Observed in the CRRT Lines	If Yes, Colour of the Precipitate	Solution in Use at the Time Precipitate was Observed	Lot Number of Solution in Use at the Time Precipitate was Observed
009-027	53/Male	13OCT2015 08:00 / 50:00	No	NA	NA	NA
009-028		26NOV2015 10:30 / 53:30	No	NA	NA	NA
009-030	75/Male	18DEC2015 23:00 / 72:00	No	NA	NA	NA
009-031	34/Male	28JAN2016 19:00 / 48:00	No	NA	NA	NA
009-032	59/Male	29JAN2016 12:00 / 70:00	No	NA	NA	NA
010-002	57/Male	09MAY2015 17:00 / 72:00	No	NA	NA	NA
010-003		09MAY2015 14:30 / 44:30	No	NA	NA	NA
010-005	78/Male	06JUN2015 22:00 / 71:00	No	NA	NA	NA
010-006	80/Male	12JUN2015 23:00 / 72:00	No	NA	NA	NA
010-008	70/Female	29JUN2015 01:00 / 44:00	No	NA	NA	NA
010-009	69/Male			NA	NA	NA

Data Listing 16.2.7.1. Precipitate Observation - Enrolled Population

Patient Number	Age (Years)/ Gender	Date and Time (24-hr Clock) of Final Observation/ Time since start of CRRT (hours)	Any Precipitate Observed in the CRRT Lines	If Yes, Colour of the Precipitate	Solution in Use at the Time Precipitate was Observed	Lot Number of Solution in Use at the Time Precipitate was Observed
010-010	52/Female	03SEP2015 12:20 / 72:00	No	NA	NA	NA
010-011		30SEP2015 17:00 / 40:45	No	NA	NA	NA
010-014	79/Female	12JAN2016 20:00 / 48:00	No	NA	NA	NA
011-001	53/Male	30APR2015 10:00 / 43:00	No	NA	NA	NA
011-002	75/Male	30APR2015 12:00 / 45:00	No	NA	NA	NA
011-003	80/Male	05JUN2015 09:15 / 58:30	No	NA	NA	NA
011-004	80/Female	10JUN2015 15:00 / 72:00	No	NA	NA	NA
011-005	78/Male	11JUN2015 11:30 / 41:30	No	NA	NA	NA
011-006	77/Male	05JUL2015 06:00 / 61:00	No	NA	NA	NA
011-007	62/Female	02OCT2015 06:00 / 41:00	No	NA	NA	NA
011-008	61/Male	05OCT2015 11:30 / 41:30	No	NA	NA	NA

Data Listing 16.2.7.1. Precipitate Observation - Enrolled Population

Patient Number	Age (Years)/ Gender	Date and Time (24-hr Clock) of Final Observation/ Time since start of CRRT (hours)	Any Precipitate Observed in the CRRT Lines	If Yes, Colour of the Precipitate	Solution in Use at the Time Precipitate was Observed	Lot Number of Solution in Use at the Time Precipitate was Observed
011-009	71/Female	06OCT2015 22:30 / 44:30	No	NA	NA	NA
011-010	47/Male	12OCT2015 16:50 / 46:00	No	NA	NA	NA
011-011	77/Male	16OCT2015 11:00 / 66:00	No	NA	NA	NA
011-012	74/Male	21OCT2015 11:45 / 72:00	No	NA	NA	NA
011-013	71/Female	28OCT2015 01:00 / 72:00	No	NA	NA	NA
011-014	79/Female	04NOV2015 02:30 / 48:00	No	NA	NA	NA
011-015	77/Female	22NOV2015 08:26 / 63:30	No	NA	NA	NA
011-016	72/Female	10JAN2016 15:30 / 72:00	No	NA	NA	NA
012-001	59/Male	02APR2015 22:00 / 72:00	No	NA	NA	NA
012-002	67/Male	09APR2015 21:00 / 72:00	No	NA	NA	NA
012-003	63/Male	18APR2015 02:20 / 60:30	No	NA	NA	NA

Data Listing 16.2.7.1. Precipitate Observation - Enrolled Population

Patient Number	Age (Years)/ Gender	Date and Time (24-hr Clock) of Final Observation/ Time since start of CRRT (hours)	Any Precipitate Observed in the CRRT Lines	If Yes, Colour of the Precipitate	Solution in Use at the Time Precipitate was Observed	Lot Number of Solution in Use at the Time Precipitate was Observed
012-004	59/Female	21JUL2015 12:30 / 66:30	No	NA	NA	NA
012-005	41/Male	29JUL2015 07:15 / 72:00	No	NA	NA	NA
012-006	44/Male	31AUG2015 06:00 / 50:30	No	NA	NA	NA
012-007	82/Male	12OCT2015 13:45 / 65:00	No	NA	NA	NA
012-008	59/Male	17OCT2015 10:30 / 43:30	No	NA	NA	NA
012-009	70/Male	05NOV2015 11:00 / 45:30	No	NA	NA	NA
012-010	72/Male	07NOV2015 18:00 / 72:00	No	NA	NA	NA
012-011	58/Female	17DEC2015 17:45 / 61:00	No	NA	NA	NA
012-012	69/Male	16JAN2016 18:00 / 72:00	No	NA	NA	NA
012-013	77/Female	20JAN2016 07:45 / 53:30	No	NA	NA	NA
013-002	70/Male	02JUL2015 14:00 / 72:00	No	NA	NA	NA

Data Listing 16.2.7.1. Precipitate Observation - Enrolled Population

Patient Number	Age (Years)/ Gender	Date and Time (24-hr Clock) of Final Observation/ Time since start of CRRT (hours)	Any Precipitate Observed in the CRRT Lines	If Yes, Colour of the Precipitate	Solution in Use at the Time Precipitate was Observed	Lot Number of Solution in Use at the Time Precipitate was Observed
013-003	69/Male	29JUL2015 16:30 / 41:30	No	NA	NA	NA
013-004	64/Female	09SEP2015 10:00 / 46:00	No	NA	NA	NA
013-005		18SEP2015 21:00 / 72:00	No	NA	NA	NA
013-010	76/Female	06DEC2015 15:00 / 72:00	No	NA	NA	NA
014-001	75/Female	18APR2015 20:00 / 72:00	No	NA	NA	NA
014-002	47/Male	30APR2015 01:30 / 68:30	No	NA	NA	NA
014-003	63/Female	12JUN2015 20:30 / 43:00	No	NA	NA	NA
014-004	33/Female	02SEP2015 22:45 / 51:30	No	NA	NA	NA
014-007	34/Female	10SEP2015 08:00 / 67:00	No	NA	NA	NA
015-001	77/Female	28APR2015 16:20 / 67:20	No	NA	NA	NA
015-002	60/Male	26MAY2015 03:00 / 72:00	No	NA	NA	NA

Data Listing 16.2.7.1. Precipitate Observation - Enrolled Population

Patient Number	Age (Years)/ Gender	Date and Time (24-hr Clock) of Final Observation/ Time since start of CRRT (hours)	Any Precipitate Observed in the CRRT Lines	If Yes, Colour of the Precipitate	Solution in Use at the Time Precipitate was Observed	Lot Number of Solution in Use at the Time Precipitate was Observed
015-003	57/Male	29MAY2015 18:30 / 52:50	No	NA	NA	NA
015-004	85/Male	21JUN2015 15:30 / 72:00	No	NA	NA	NA
015-005	76/Male	08JUL2015 03:13 / 72:00	No	NA	NA	NA
015-006	84/Female	16AUG2015 15:10 / 72:00	No	NA	NA	NA
015-009	76/Female	08JAN2016 03:45 / 72:00	No	NA	NA	NA
015-010		11JAN2016 10:45 / 60:30	No	NA	NA	NA
015-011		23JAN2016 20:00 / 50:30	No	NA	NA	NA
016-002		04SEP2015 12:00 / 40:50	No	NA	NA	NA
016-004	55/Male	03DEC2015 12:00 / 42:30	No	NA	NA	NA
017-003	92/Female	13JUL2015 19:20 / 41:20	No	NA	NA	NA
017-004	74/Male	19JUL2015 17:30 / 72:00	No	NA	NA	NA

Data Listing 16.2.7.1. Precipitate Observation - Enrolled Population

Patient Number	Age (Years)/ Gender	Date and Time (24-hr Clock) of Final Observation/ Time since start of CRRT (hours)	Any Precipitate Observed in the CRRT Lines	If Yes, Colour of the Precipitate	Solution in Use at the Time Precipitate was Observed	Lot Number of Solution in Use at the Time Precipitate was Observed
017-005	77/Male	14AUG2015 09:00 / 54:15	No	NA	NA	NA
017-007	66/Male	03SEP2015 15:30 / 72:00	No	NA	NA	NA
017-008		28SEP2015 00:00 / 71:36	No	NA	NA	NA
017-010	54/Male	20NOV2015 10:00 / 59:50	No	NA	NA	NA
017-011	49/Male	23NOV2015 15:30 / 72:00	No	NA	NA	NA

Data Listing 16.2.7.2.1. Adverse Reactions - Enrolled Population

Patient Number	Age(Years)/ Gender	Did the Patient Experience any AR?	Adverse Reaction Description/ System Organ Class/ Preferred Term	Onset Date/ Resolution Date	Ongoing	Severity	Treatment Required	Treatment Given. Specify, if Other

No adverse reactions were reported in this study

Data Listing 16.2.7.3.1. Serious Adverse Reactions - Enrolled Population

Patient Number	Age(Years)/ Gender	Did the Patient Experience any AR?	Adverse Reaction Description/ System Organ Class/ Preferred Term	Onset Date/ Resolution Date	Ongoing	Severity	Treatment Required	Treatment Given. Specify, if Other

No adverse reactions were reported in this study

Data Listing 16.2.7.4. Deaths - Enrolled Population

Patient Number	Age (Years)/ Gender	Date of Death	Time of Death	Primary Cause of Death
009-017	51/Male	23JUL2015	21:45	GASTROINTESTINAL HAEMMORHAGE & PNEUMONIA
014-002	47/Male	30APR2015	2:40	MULTIORGAN FAILURE