Specialist Cohort Event Monitoring

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Data source | Human | Hospital inpatient records | Hospital outpatient visit records | Other | Primary care medical records

Administrative details

Administrative details

Data source ID

1111163

Data source acronym

SCEM

Data holder

Drug Safety Research Unit (DSRU)

Data source type

Hospital inpatient records

Hospital outpatient visit records

Other

Primary care medical records

Data source type, other

Electronic healthcare records

Main financial support

Funding from industry or contract research

Care setting

Hospital inpatient care

Hospital outpatient care

Primary care – GP, community pharmacist level

Primary care – specialist level (e.g. paediatricians)

Secondary care – specialist level (ambulatory)

Data source qualification

If the data source has successfully undergone a formal qualification process (e.g., from the EMA, ISO or other certifications), this should be described.

Yes

Description of the qualification

SCEM studies are assessed by NHS Health Research Authority prior to approval.

Data source website

https://www.dsru.org/conducting-studies/event-monitoring-studies/

Contact details

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Main

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Data source regions and languages

Data source countries

United Kingdom

Data source languages

English

Data source establishment

Data source established

15/06/2010

Publications

Data source publications

Specialist Cohort Event Monitoring Studies: A New Study Method for Risk Management in Pharmacovigilance

Rationale and design of a European epidemiological post-authorization safety study (PASS) program: rivaroxaban use in routine clinical practice

Evaluation of the incidence of bleeding in patients prescribed rivaroxaban for the treatment and prevention of deep vein thrombosis and pulmonary embolism in UK secondary care: an observational cohort study

Observational assessment of safety in seroquel (OASIS): a specialist cohort event monitoring (SCEM) study in England

Incidence of major and clinically relevant non-major bleeding in patients prescribed rivaroxaban for stroke prevention in non-valvular atrial fibrillation in secondary care: Results from the Rivaroxaban Observational Safety Evaluation (ROSE) study

Data elements collected

The data source contains the following

Disease information

Does the data source collect information with a focus on a specific disease? This might be a patient registry or other similar initiatives.

Yes

Disease details (other)

SCEM methodology facilitates involvement of HCPs from any chosen speciality, depending on the medicinal product being studied. The HCPs can provide any disease information that we request from the patient medical records.

Rare diseases

Are rare diseases captured? In the European Union a rare disease is one that affects no more than 5 people in 10,000.

Yes

Pregnancy and/or neonates

Does the data source collect information on pregnant women and/or neonatal subpopulation (under 28 days of age)?

Yes

Hospital admission and/or discharge

Yes

ICU admission

Is information on intensive care unit admission available?

Yes

Cause of death

Captured

Cause of death vocabulary

Not coded (Free text)

Other

Cause of death vocabulary, other

Based on study requirements.

Prescriptions of medicines

Captured

Prescriptions vocabulary

other

Prescriptions vocabulary, other

Based on study requirements.

Dispensing of medicines

Captured

Advanced therapy medicinal products (ATMP)

Is information on advanced therapy medicinal products included? A medicinal product for human use that is either a gene therapy medicinal product, a somatic cell therapy product or a tissue engineered products as defined in Regulation (EC) No 1394/2007 [Reg (EC) No 1394/2007 Art 1(1)].

Yes

Contraception

Is information on the use of any type of contraception (oral, injectable, devices etc.) available?

Yes

Indication for use

Does the data source capture information on the therapeutic indication for the use of medicinal products?

Captured

Indication vocabulary

Not coded (Free text)

Other

Indication vocabulary, other

Based on study requirements.

Medical devices

Is information on medicinal devices (e.g., pens, syringes, inhalers) available?

Yes

Administration of vaccines

Yes

Procedures

Does the data source capture information on procedures (e.g., diagnostic tests, therapeutic, surgical interventions)?

Captured

Procedures vocabulary

Other

Procedures vocabulary, other

Based on study requirements.

Healthcare provider

Is information on the person providing healthcare (e.g., physician, pharmacist, specialist) available? The healthcare provider refers to individual health professionals or a health facility organisation licensed to provide health care diagnosis and treatment services including medication, surgery and medical devices.

Yes

Clinical measurements

Is information on clinical measurements (e.g., BMI, blood pressure, height) available?

Yes

Genetic data

Are data related to genotyping, genome sequencing available?

Not Captured

Biomarker data

Does the data source capture biomarker information? The term “biomarker” refers to a broad subcategory of medical signs (objective indications of medical state observed from outside the patient), which can be measured accurately and reproducibly. For example, haematological assays, infectious disease markers or metabolomic biomarkers.

Not Captured

Patient-reported outcomes

Is information on patient-reported outcomes (e.g., quality of life) available?

Yes

Patient-generated data

Is patient-generated information (e.g., from wearable devices) available?

Yes

Units of healthcare utilisation

Are units of healthcare utilisation (e.g., number of visits to GP per year, number of hospital days) available or can they be derived? Units of healthcare utilisation refer to the quantification of the use of services for the purpose of preventing or curing health problems.

Yes

Unique identifier for persons

Are patients uniquely identified in the data source?

Yes

Diagnostic codes

Captured

Diagnosis / medical event vocabulary

Other

Diagnosis / medical event vocabulary, other

Based on study requirements.

Medicinal product information

Captured

Medicinal product information collected

Batch number

Brand name

Dosage regime

Dose

Route of administration

Medicinal product vocabulary

Not coded (Free text)

Other

If 'other,' what vocabulary is used?

Based on study requirements.

Quality of life measurements

Captured

Quality of life measurements vocabulary

other

Quality of life measurements, other

Study specific.

Lifestyle factors

Captured

Lifestyle factors

Alcohol use

Diet

Frequency of exercise

Tobacco use

Sociodemographic information

Captured

Sociodemographic information collected

Age

Country of origin

Deprivation index

Ethnicity

Gender

Marital status

Socioeconomic status

Quantitative descriptors

Population Qualitative Data

Population age groups

Paediatric Population (< 18 years)

Preterm newborn infants (0 – 27 days)

Term newborn infants (0 – 27 days)

Infants and toddlers (28 days – 23 months)

Children (2 to < 12 years)

Adolescents (12 to < 18 years)

Adults (18 to < 46 years)

Adults (46 to < 65 years)

Elderly (≥ 65 years)

Adults (65 to < 75 years)

Adults (75 to < 85 years)

Adults (85 years and over)

Estimated percentage of the population covered by the data source in the catchment area

100%

Description of the population covered by the data source in the catchment area whose data are not collected (e.g., people who are

registered only for private care)

Patients who do not provide consent

Family linkage

Family linkage available in the data source permanently or can be created on an ad hoc basis

Ad hoc

Data flows and management

Access and validation

Governance details

Documents or webpages that describe the overall governance of the data source and processes and procedures for data capture and management, data quality check and validation results (governing data access or utilisation for research purposes).

https://doi.org/10.1007/s40264-014-0260-x

Biospecimen access

Are biospecimens available in the data source (e.g., tissue samples)?

Yes

Biospecimen access conditions

Patient consent, ethical approval and payment of HCP

Access to subject details

Can individual patients/practitioners/practices included in the data source be contacted?

Yes

Description of data collection

A key benefit of SCEM studies is their adoption by the National Institute for Health Research (NIHR) which provides the opportunity for assistance from the Clinical Research Network (CRN). The CRN facilitates high quality research in the NHS and comprises both local CRNs and 30 speciality groups of research-active specialist healthcare professionals (HCPs), so that research can be supported both geographically and by therapy area, depending on the drug of interest.

In a SCEM study the DSRU study team first establishes a cohort of specialists prescribing the study drug, assisted by the NIHR CRN. The specialist HCP makes the clinical decision to prescribe the study drug and registers on the DSRU's study recruitment website. The HCP or care team obtain informed consent from the patient to include them in the study and completes the baseline questionnaire using the patient's medical records and returns to the DSRU study team for processing. After the index date (e.g. 3, 6 or 12 months after first prescription, the exact period depends on the study) a bespoke follow-up questionnaire is completed by the HCP using the patient's medical records, then returned to the study team for processing. Selected events of medical interest, deaths and pregnancies are followed up. Data is collated and analysed.

Event triggering registration

Event triggering registration of a person in the data source

Start of treatment

Event triggering de-registration of a person in the data source

Death

Loss to follow up

Practice deregistration

Event triggering creation of a record in the data source

HCP prescribes drug of interest to patient then obtains patient consent to take part in study and regsiters patient for study.

Data source linkage

Linkage

Is the data source described created by the linkage of other data sources (prelinked data source) and/or can the data source be linked to other data source on an ad-hoc basis?

Yes

Linkage description, possible linkage

If prescribing of drug of interest is transferred from secondary/ specialist care to primary care, patient's GP is asked to provide data from primary care medical record. Patient provides GP contact details on consent form.

Linked data sources

Pre linked

Is the data source described created by the linkage of other data sources?

No

Data source, other

Linkage to GP records.

Linkage completeness

Study dependent

Data management specifications that apply for the data source

Informed consent for use of data for research

Required for all studies

Possibility of data validation

Can validity of the data in the data source be verified (e.g., access to original medical charts)?

Yes

Data source preservation

Are records preserved in the data source indefinitely?

No

Data source preservation length (years)

15 years

Approval for publication

Is an approval needed for publishing the results of a study using the data source?

Yes

Common Data Model (CDM) mapping

CDM mapping

Has the data source been converted (ETL-ed) to a common data model?

Yes

CDM Mappings

CDM name (other)

Other

Data source ETL CDM version

The study design and case report forms developed would allow the collection of data in the format required to allow for mapping to any CDM.