Specification for the registry "Renal Transplantation in Children and Adolescents", the **CERTAIN registry**, of the German Society for Pediatric Nephrology (GPN) and the European Society for Paediatric Nephrology (ESPN)

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Contents

Target definition

As there is currently no specific registry for recording kidney transplantation data in children and adolescents in Europe, and particularly in German-speaking countries, the German Society for Pediatric Nephrology (GPN) and the European Society for Paediatric Nephrology (ESPN) decided to provide such a system to support and enable scientific analyses and quality assurance in the field of paediatric kidney transplantation. The inaugurated project "CERTAIN registry" (Cooperative European Paediatric Renal Transplant Initiative) will be implemented by the Working Group Kidney Transplantation of the GPN and the "Working Group Transplantation" of the European Society for Paediatric Nephrology (ESPN), whereby the technical realisation and commissioning of the system will take place in Heidelberg.

The registry to be developed as part of the project is intended to collect relevant data on paediatric kidney transplantation for research purposes and for quality assurance. The registry is to be implemented in the form of a web application and give the members of the GPN and ESPN in Europe the opportunity to record basic and follow-up data on paediatric kidney transplantation centrally via the Internet in order to document the long-term course (in particular patient survival, graft survival, graft function, therapy, complications). In addition to this pure data collection, the registry should offer the following 'service functions' for the individual centres:

- Overview of the various therapy strategies and their success
- Automated transfer of defined data to other systems (Eurotransplant, CTS, ESPN)
- In the next expansion stage, it will be possible to record the data for studies by members of the CERTAIN research network, thereby simplifying their implementation.

The medical staff of the participating centres is the target group of the CERTAIN registry. In future, the registry will enable prospective studies to be conducted, which is why the system will also be orientated towards study implementation processes. As the success of the system depends on data quality, the aspects of data completeness and integrity as well as system security will play a central role in its development.

Product use

Area of application

A medical registry is a systematic collection of information on a specific clinical picture or a specific therapy in the form of a database and, depending on the data it contains, can be used to fulfil various tasks such as quality assurance, therapy improvement or answering health economic questions.

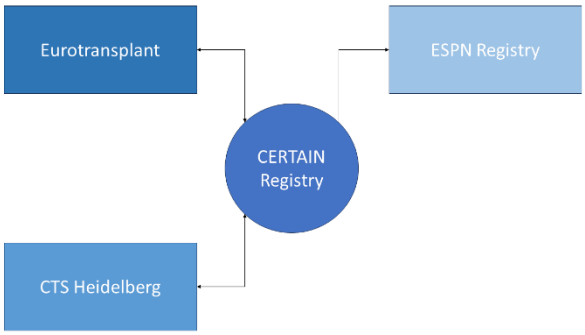
Since the CERTAIN registry is realised as an Internet web application, its accessibility is guaranteed regardless of location, and its use only requires a current, common Internet browser (such as Edge, Firefox, Safari or Chrome). All you need to interact with the system is a valid registry user account. Access to the application (creation of the user account) is granted by the registry centre after verification of the documents submitted. Once you have a user account, you can log in to the system and enter your data. The data entry of the registry data, which includes basic and follow-up data of a kidney transplantation patient, takes place at fixed intervals. The data to be entered depends on the respective time of entry. The data is checked for errors or implausibility while it is being entered; if any are found, the user is notified. Data containing errors can be saved in the system so that they can be corrected later - however, these are labelled accordingly. The data can also be changed at any time as long as it is not used for the analyses - however, the changes must always be justified by the user, which is also noted in the system and made available to the operators of the registry in the form of an audit function.

Times of data entry:

- Initial input - Transplantation
- 30 days after transplantation
- 3 months after transplantation
- 6 months after transplantation
- 9 months after transplantation
- 1 year after transplantation
- thereafter every six months

In order to avoid multiple entries of the same data, the registry will forward some of its own data to other systems and reduce the data entry effort in the participating centres through this service. The data will be forwarded to the following systems/organisations:

- CTS registry
- Eurotransplant
- ESPN registry



Data exchange with Eurotransplant and CTS will be bidirectional, allowing the system to gain donor data and older transplant data.
The user also has access to predefined graphical and tabular analyses of their own data (data from the associated centre). The user's own data can also be exported from the system at any time in a predefined format. Analyses of the entire registry data require the approval of the registry Steering Committee. As soon as this has been granted, the registry data will be made available.
In addition to data collection and analysis, the registry will offer its users access to GPN therapy standards, dosing regimens, etc.; users will be able to download these documents via the system.

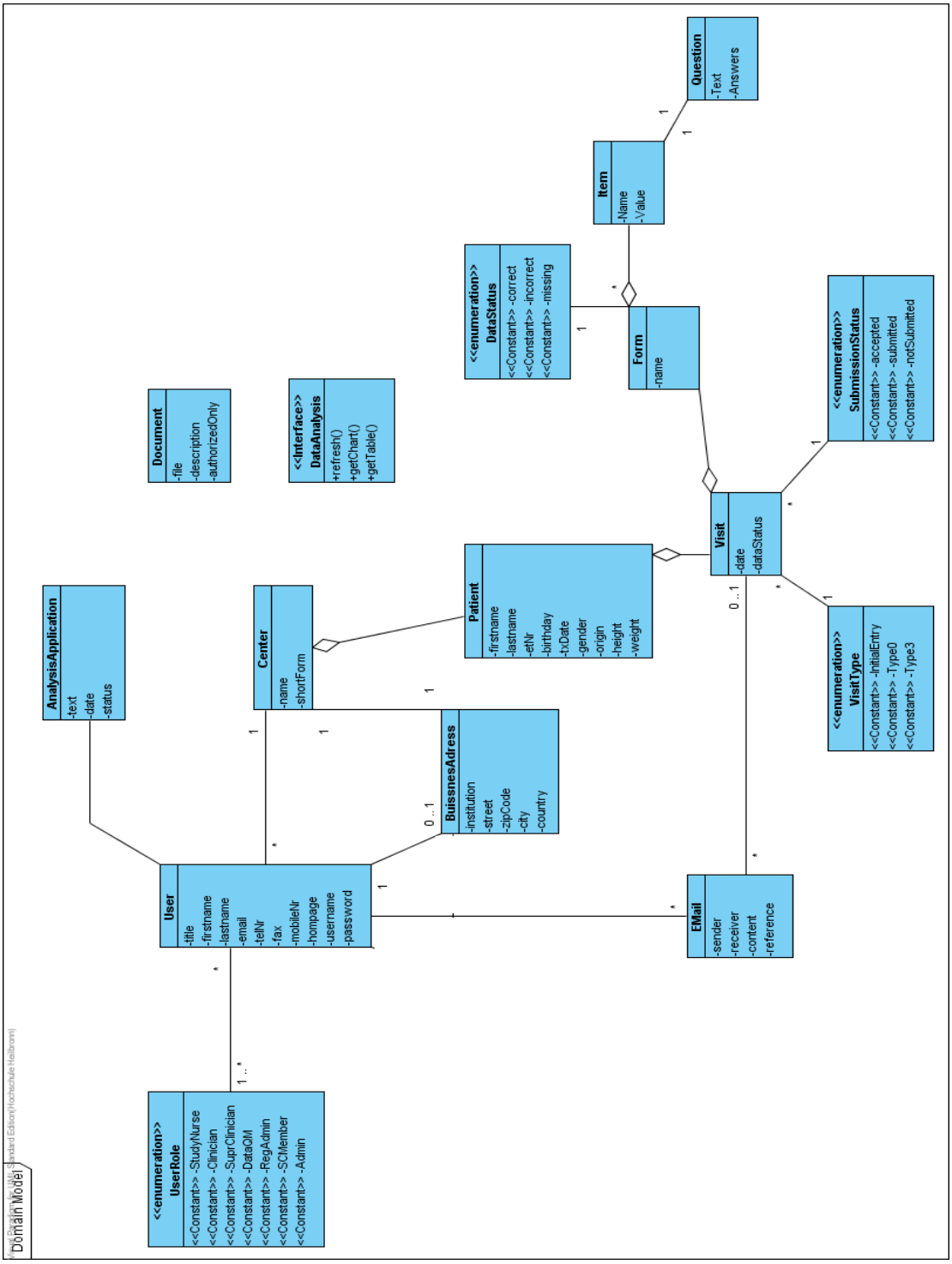
User groups

The individual functions of the application should be able to be used as intuitively as possible by people with different professional qualifications without extensive training. The system should differentiate between the following user groups:

▪ Anonymous user ▪ Study Nurse/Document Assistant ▪ Clinician ▪ Supervising clinician	**Centre**
▪ Data Quality Manager ▪ Register administrator ▪ IT administrator	**Register centre**
▪ Steering Committee member	**Steering Committee**

Model of the application area

The most important elements, their structure and the relationships between them can be seen in the following diagram.



Glossary

Registry - a systematic collection of information about a group of objects, usually in the form of a database.

Web application - a software application that does not require any installation and is used entirely via a web browser.

Internet connection - or Internet access generally refers to the communication connection of a computer or a network to the Internet.

Internet browser - or web browser; a special computer programme for viewing websites on the World Wide Web or documents and data in general.

GPN – German Society for Pediatric Nephrology (https://gpn.de)

CTS - Collaborative Transplant Study is a large-scale research initiative in the field of organ transplantation, which has been running an international transplant registry since the 1980s (https://ctstransplant.org).

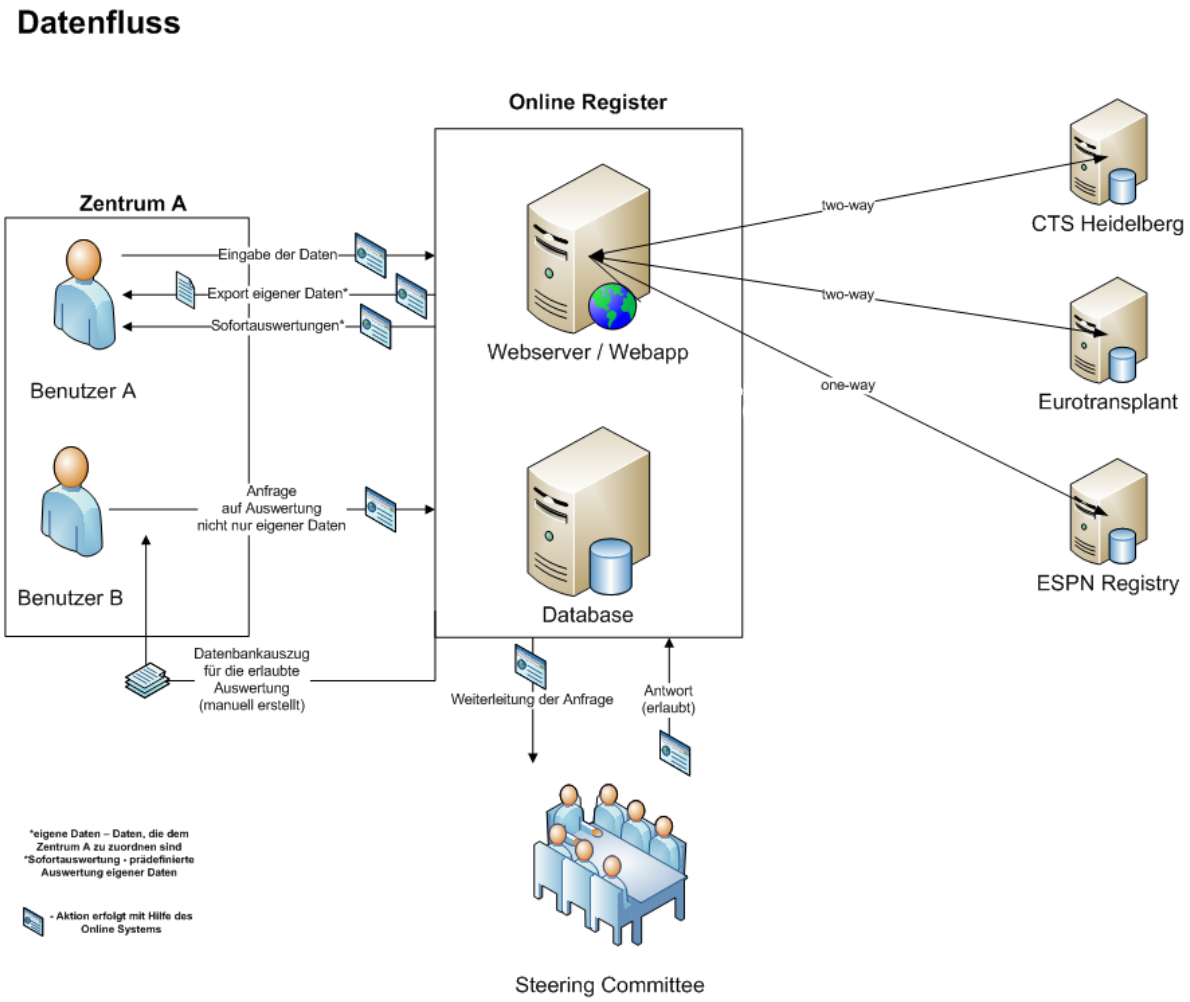
Eurotransplant - a non-profit organisation that has set itself the most important goal of promoting organ transplantation. Eurotransplant arranges and coordinates the international exchange of donor organs in a catchment area in which 124 million people live (https://eurotransplant.org).

Data flow

The registry data is entered either conventionally by the registered users (employees of the cooperating centres) or automatically with the help of the interfaces to other systems. In addition, to prevent double entry, the data is automatically made available to other systems. The use of the collected data is subject to strict controls and can be categorised into two cases:

- Use of own data - data from own centre (always possible)
- Use of the complete registry database or part of the database (requires authorisation from the registry Steering Committee).

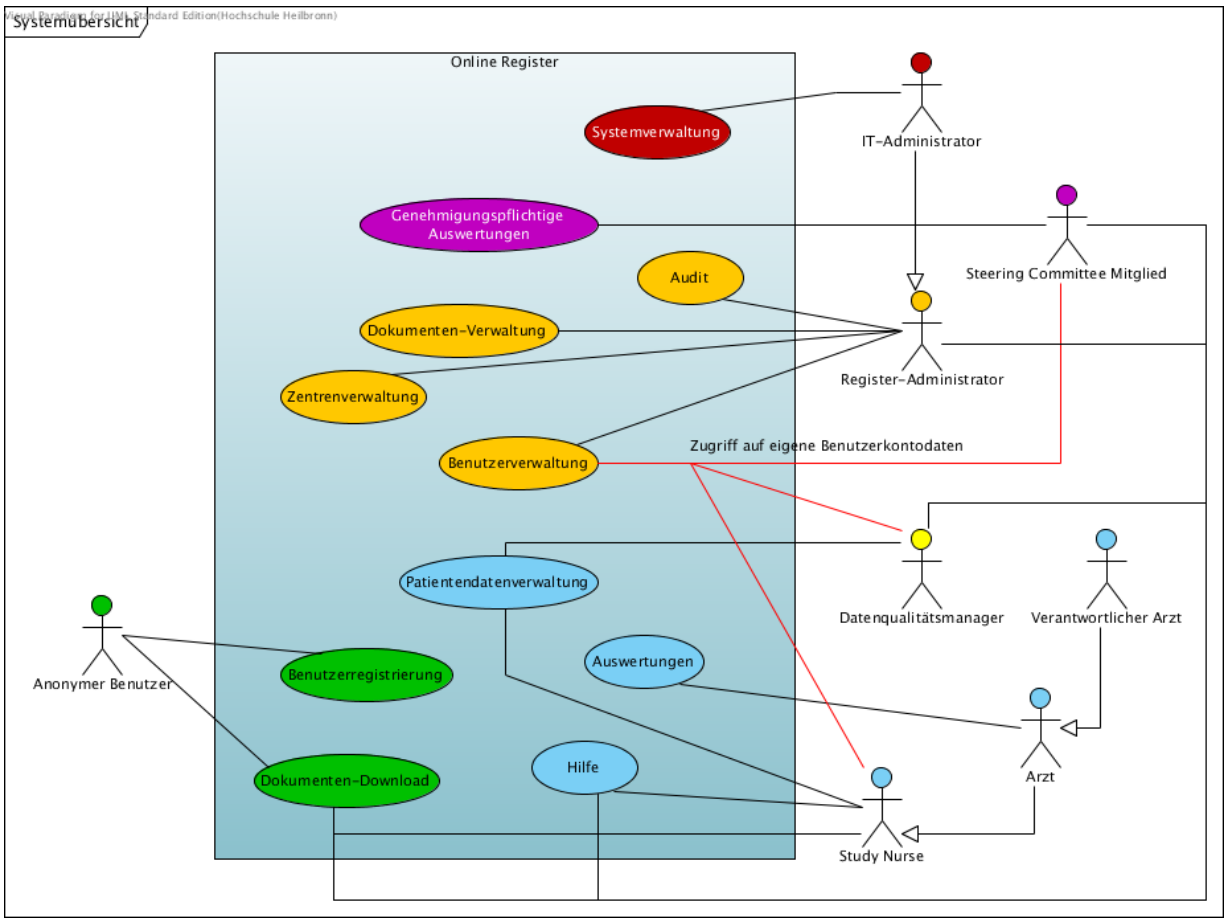
The planned data flow can be seen in the following diagram.



Functions and use cases

The following graphic shows the most important functions, functional areas and the different user types of the software. The users presented can be assigned to the user groups from the previous section and are to be interpreted as follows:

- **Anonymous user** - a user who is not yet registered in the system and therefore has no access to the actual registry.
- **Study nurse** or **documentation assistant -** a registered user who is assigned to a cooperating centre - e.g. an employee of the centre. The main task of this user is to enter and maintain patient data.
- **Clinician** - a registered user, a doctor from the cooperating centre; in addition to entering and maintaining patient data, this user can also access the online analyses and export functionality.
- **Supervising clinician** - a registered user - a doctor from the cooperating centre who is responsible for the quality of the data entered by the employees of his/her centre. A supervising clinician is the only user who can mark the data as "final".
- **Data quality manager** - a user - an employee of the registry centre whose main task is to check data quality. The data quality manager is notified when finalised data arrives, which is either marked as accepted or as requiring revision following his or her review.
- **Register administrator** - a user - an employee of the registry centre who is responsible for the technical administration of the registry. He sets up the user accounts and centres, manages the documents and can monitor the activities of other users.
- **Steering Committee member** - a user - member of the Register Steering Committee who is authorised to assess the analysis requests.
- **IT administrator** - a user - an employee of the registry centre who is responsible for the maintenance and configuration of the web application.



Functions not subject to registration

Two functions of the software do not require authentication and are therefore available to everyone:

- User registration - Applying for a registry user account
- Document download - Access to the publicly available registry documents.

User registration

Name of the use case
User registration
Subsystem
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Actors
Anonymous user
Context and preconditions
Actor has an Internet connection and an up-to-date Internet browser.
The system is online and can be accessed by the actor on the Internet.
Normal procedure
1. Actor calls up the website of the register and selects "Sign up ".
2. The forms available in the "Sign up" area (online or Word) are filled in by the actor.
3. For a new centre, the Word form is then signed and sent back to the registry (either by post or scanned in by e-mail).
4. The documents are checked in the registry centre and a new user account is set up (see Use Case: *Create user*)

Normal result
Actor receives a notification to their confirmed e-mail address to set a personal password.
Alternative procedure
3a. Once the online form has been completed, the centre's contact person must verify the new account and the registry centre receives notification of the registration and verification. (Standard case for centres that have already been created)
4a. The specified data is not correct - the registration centre contacts the actor and informs it what corrections need to be made. Continue with 3, the process can also be cancelled at this point.
Non-functional requirements
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Notes
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Document download

Name of the use case
Document download
Subsystem
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Actors
Anonymous user, Study Nurse, Data Quality manager, Registry administrator, Steering Committee member
Context and preconditions
Actor has an Internet connection and an up-to-date Internet browser.
The system is online and can be accessed by the actor on the Internet.
(The user must be logged into the system to access the non-public documents)
Normal procedure
1. Actor calls up the website of the registry and selects the "Resources" item.
2. The publicly available files in the "Resources" area are presented to the actor
3. Actor selects the files it is interested in and downloads them

Normal result

The selected documents have been downloaded and are available to the actor locally.

Alternative procedure
2a. If the actor is also a registered user, they can also access and download the non-publicly available documents.
Non-functional requirements
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Notes
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Functions requiring registration

The functions requiring login are only available to users who have a valid user account and depend on the user's respective roles. These functions can be categorised into the following groups:

- Patient data management - among other things, this area provides all the necessary functions for entering and editing patient data both directly in the web application and automatically using the import function.
- Analyses - Functions that enable the registry data to be analysed.
- User management - encapsulates the functionality that enables the creation, editing and management of user accounts.
- Centre management - encapsulates the functionality that enables centres to be created, edited and managed.
- Document management - functions that enable documents to be published and managed.
- Audit - this area encapsulates the monitoring functionality, which provides corresponding lists of user actions.
- Analyses subject to authorisation - functional area that enables the entry of the request for an analysis subject to authorisation, its transmission and processing.
- System administration - Functions that are necessary for the maintenance and configuration of the system.
- Help - not a function group, but context-dependent access to the user help.

Help

Name of the use case
Help
Subsystem
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Actors
Study nurse, clinician, supervising clinician, data quality manager, register administrator, steering committee member
Context and preconditions
Actor has successfully logged into the system.
Normal procedure
1. Actor clicks on the "Help" button.

Normal result
The context-dependent (depending on the currently selected tab function) help text is displayed to the actor in a separate window.
Alternative procedure
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Non-functional requirements
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Notes
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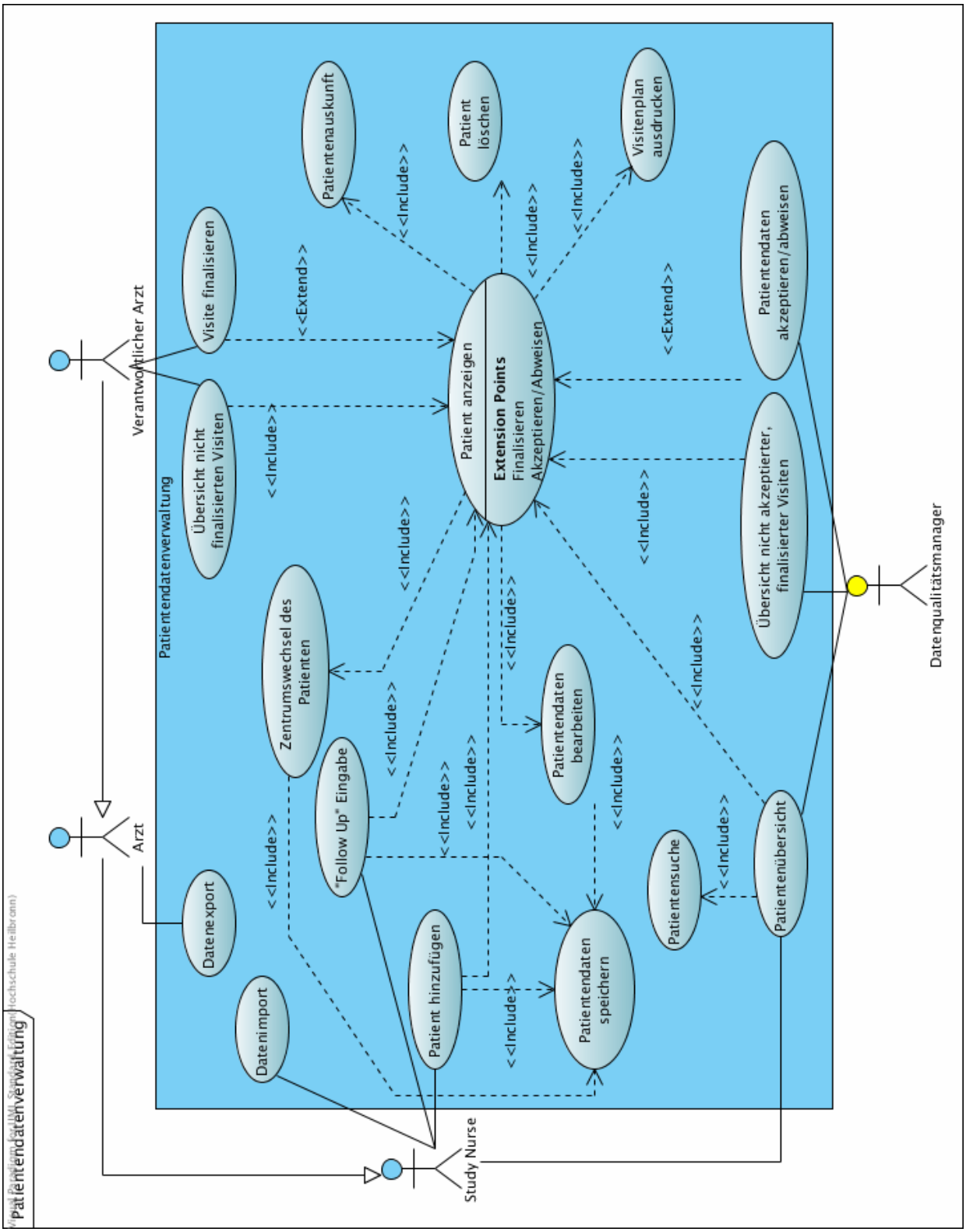
Patient data management



Add patient

Name of the use case
Add patient
Subsystem
Patient data management
Actors
Study nurse, clinician, supervising clinician
Context and preconditions
Actor has successfully logged into the system.
Normal procedure
1. Actor clicks on the "Enrolment" button.
2. The actor is shown a screen that allows the "Month 0" data to be entered (see registry data).
3. Actor enters the data.
4. The system checks the correctness of the data entered.
5. Actor clicks on the "Done" button.
6. The system checks the possible redundancy of the data.

Normal result
Continue with Use Case *Save patient data*.
Alternative procedure
5a. The data entered is not correct and is marked as incorrect. Actor is advised to check the data entered. Continue with 3 or with 5.
7a. The same patient already exists in the system. Actor is informed of this and can either change the data (continue with 3) or cancel the process and display the patient found (continue with *Display patient* use case).
7b. The same patient already exists in the system, but is assigned to a different centre. Actor is informed of this - a change of centre must be carried out. Process is cancelled.
Non-functional requirements
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Notes
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Save patient data

Name of the use case
Save patient data
Subsystem
Patient data management
Actors
Study nurse, clinician, supervising clinician
Context and preconditions
Use Case *Add patient* or *Edit patient has been called up*.
Normal procedure
1. Actor clicks on the "Save" button.
2. The system checks that all the necessary data is available and whether the data contains errors (see registry data).
3. System performs the desired operation.

Normal result
A message is displayed to the actor that the process has been successfully completed. The data is labelled as "correct/not completed".

Alternative procedure
3a. Not all the necessary data has been entered or some of the data entered is incorrect. A corresponding message is displayed to the actor; it decides whether it wants to correct the data (back to the original use case) or whether it still wants to perform the operation (continue with 3b)
3b. The data record is marked as "incorrect/not completed" and the operation is executed (continue with 3).
Non-functional requirements
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Notes
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Finalise the visit

Name of the use case
Finalise the visit
Subsystem
Patient data management
Actors
Supervising clinician
Context and preconditions
Display patient use case has been called up.
Normal procedure
1. Actor clicks on the "Complete" button.
2. The system checks that all the necessary data is available and whether the data contains errors (see registry data).
3. System performs the desired operation.

Normal result
A message is displayed to the actor that the process has been successfully completed. The visit is labelled as "completed".
Alternative procedure
3a. Not all the necessary data has been entered or some of the entered data are incorrect.
A corresponding message is displayed to the actor; it decides whether it wants to improve the data (continue with *Edit patient* use case) or whether it still wants to perform the operation (only possible for warnings, continue with 3b). The process can also be cancelled at this point (back to the original use case)
3b. The actor must justify its decision - a corresponding window with a mask is displayed. (continue with 3).
3c. The data contains errors that cannot be justified under any circumstances (see data validation plan). Finalisation is not possible - actor can either edit the data (continue with *Edit patient* use case) or cancel the process.
Non-functional requirements
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Notes
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Overview of non-finalised visits

Name of the use case
Overview of non-finalised visits
Subsystem
Patient data management
Actors
Supervising clinician
Context and preconditions
Actor has successfully logged into the system.
Normal procedure
1. Actor clicks on the "Not completed data" button.
2. The system generates an overview of all visits from the actor’s centre that have not yet been finalised.

Normal result
The overview is displayed to the actor. They can display the respective elements (continue with *Display* use case *patient*). Those elements that have already been finalised but have been rejected by the data quality manager are specially marked.
Alternative procedure
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Non-functional requirements
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Notes
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"Follow Up" input

Name of the use case
"Follow Up" input
Subsystem
Patient data management
Actors
Study nurse, clinician, supervising clinician
Context and preconditions
Actor has successfully logged into the system.
Normal procedure
1. Actor clicks on the "Follow Up" button.
2. The system displays a list of all patients for whom follow-up entry is possible.
3. Actor selects a patient.
4. The selected patient is displayed (see *Show patient* use case). Actor clicks on the active "Follow Up" button.
5. The actor is shown a screen that allows the "30 day" data to be entered (see registry data).
6. Actor enters the data.
7. The system checks the correctness of the data entered.
8. Actor clicks on the "Done" button.

Normal result
Continue with Use Case *Save patient data*.
Alternative procedure
2a. There are no patients for whom a Follow Up entry is possible; a corresponding message is displayed to the user. The process is cancelled.
8a. The data entered is not correct and is marked as incorrect. The actor is advised to check the data entered. Continue with 6 or with 8.
Non-functional requirements
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Notes
"Follow Up" input will be possible from the following dates:
- 30 days input - from 14 days before and 30 days after the actual date
- 3-, 6-, 9- and 12-months input: +/- 90 days before/after the actual date
- Semi-annual entry: +/- 3 months before/after the actual date

Patient overview

Name of the use case
Patient overview
Subsystem
Patient data management
Actors
Study nurse, clinician, supervising clinician, data quality manager
Context and preconditions
Actor has successfully logged into the system.
Normal procedure
1. Actor clicks on the "Patients' list" button.
2. The system generates an overview of all patients that the actor is authorised to access.

Normal result
The overview of patients is displayed. Actor can select and display a patient (see *Display patient* use case). Actor can limit the number of patients displayed by entering search criteria (see *Patient search* use case) or sort the existing list.
Alternative procedure
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Non-functional requirements
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Notes
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Show patient

Name of the use case
Show patient
Subsystem
Patient data management
Actors
Study nurse, clinician, supervising clinician, data quality manager
Context and preconditions
Use case *Patient overview*, *Follow-up entry*, *Overview of non-finalised data* or *Overview of non-accepted, finalised data* was called up.
Normal procedure
1. A view with the data groups (see registry data), the input status and the pending and existing inputs is presented to the actor.
2. Actor selects a data group.

Normal result
The selected data is displayed. Actor can either try to edit the data (if possible - continue with the *Edit patient data* use case) or return to the patient data overview (continue with 1). Actor can also initialise the centre change process at this point (continue with Use Case *Patient centre change*). The "Follow-up schedule" option is also available to the actor (continue with the "*Print visit schedule*" use case)

Alternative procedure
2a. Actor is a data quality manager and decides to accept the data by clicking on the "Accept" button (continue with Use Case *Accept patient data*)
2b. Actor is a supervising clinician and decides to finalise the data by clicking on the "Complete" button (continue with *Finalise visit* use case)
Non-functional requirements
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Notes
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Delete patient

Name of the use case
Delete patient
Subsystem
Patient data management
Actors
Clinician, supervising clinician
Context and preconditions
Display patient use case has been called up.
Normal procedure
1. Actor clicks on the "Delete patient" button.
2. A window with information and notes as well as the reason for deletion and a confirmation option is displayed.
3. Actor establishes and confirms the process.
4. The data quality manager checks and confirms the deletion request to prevent accidental deletions.
5. The patient is removed from the system.

Normal result
The patient is removed from the system. This means that it will no longer be possible to enter new data and that the patient can no longer be found in the system. However, the medical data entered over time will still be analysable.
Alternative procedure
3a. Actor has not confirmed the process. Cancelled.
4a. Data quality manager rejects deletion request. Cancellation.
Non-functional requirements
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Notes
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Change of centre of the patient

Name of the use case
Change of centre of the patient
Subsystem
Patient data management
Actors
Study nurse, clinician, supervising clinician
Context and preconditions
Display patient use case has been called up.
Normal procedure
1. Actor clicks on the "Change the centre" button.
2. A window with information and notes as well as a selection option for the new centre is displayed.
3. Actor selects the new centre.
4. The patient is assigned to the selected centre.

Normal result
The patient will immediately be available at the new centre. Both centres (both the old and the new) will have access to all patient data. The old centre can process the data that has not yet been finalised. New entries will only be made in the new centre.
Alternative procedure
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Non-functional requirements
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Notes
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Patient information

Name of the use case
Patient information
Subsystem
Patient data management
Actors
Study nurse, clinician, supervising clinician
Context and preconditions
Display patient use case has been called up.
Normal procedure
1. Actor clicks on the button "Patient information".
2. The system generates the file containing all the patient's data

Normal result
The user downloads the generated file. This contains an overview of all data stored in the system for the specific patient.
Alternative procedure
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Non-functional requirements
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Notes
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Accept/reject patient data

Name of the use case
Accept/reject patient data
Subsystem
Patient data management
Actors
Data quality manager
Context and preconditions
Display patient use case has been called up.
Normal procedure
1. The data labelled as "completed" is presented to the actor.
2. Actor carefully checks the data.
3. Actor clicks on the "Accept" button.
4. The system flags the data as "accepted".

Normal result
The data is released for the analyses.

Alternative procedure
3a. Actor clicks on the "Reject" button; a message (query) is formulated for the respective responsible user. A screen in which the message can be entered is displayed to the actor. The data record is labelled as "revision required". The query is sent to the supervising clinician by e-mail and saved in the system.
4a. The data record contains errors. Actor is notified of these. The reason given by the responsible user is also displayed. The actor can either accept the data (continue with 3) or reject it (continue with 2a).

Non-functional requirements
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Notes
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Patient search

Name of the use case
Patient search
Subsystem
Patient data management
Actors
Study nurse, clinician, supervising clinician, data quality manager
Context and preconditions
Use case *patient overview* was called up.
Normal procedure
1. Actor enters the search criteria in the mask.
2. The system updates the patient overview.

Normal result
All patients displayed match the search criteria entered.

Alternative procedure
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Non-functional requirements
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Notes
Search criteria:
- Date of birth (partial search also possible)
- Date of transplantation
- Surname/First name
- ET number or the pendant number

Edit patient data

Name of the use case
Edit patients
Subsystem
Patient data management
Actors
Study nurse, clinician, supervising clinician
Context and preconditions
Display patient use case has been called up.
Normal procedure
1. The patient data is presented to the actor. The data that can be changed can also be edited by the actor.
2. Actor edits the data.
3. The system checks the correctness of the data entered.
4. Actor clicks on the "Done" button.

Normal result
Continue with Use Case *Save patient data*.
Alternative procedure
4a. The data entered is not correct and is marked as incorrect. Actor is advised to check the data entered. Continue with 2 or with 4.
Non-functional requirements
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Notes
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Data import

Name of the use case
Data import
Subsystem
Patient data management
Actors
Study nurse, clinician, supervising clinician
Context and preconditions
Actor has successfully logged into the system.
Normal procedure
1. Actor clicks on the "Import data" button.
2. A screen is displayed which the actor can use to select the desired file.
3. Author clicks on the "Upload" button.
4. The system checks the correctness of the file content.
5. A list of the patient data recognised and ready for import is presented to the user.
6. Actor clicks on the "Import" button.
7. The system imports the data.

Normal result
The actor is shown a message that the process has been successfully completed. The imported patient data is labelled as "imported" and "not completed".
Alternative procedure
5a. The content of the file does not contain any interpretable data. Actor can either select another file (continue with 2) or cancel the process.
5b. The data contained in the file is partially incorrect or incomplete. A corresponding message is displayed to the actor; another file must be uploaded (continue with 2)
Non-functional requirements
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Notes
The upload screen allows you to upload files whose formats are supported.

Data export

Name of the use case
Data export
Subsystem
Patient data management
Actors
Clinician, supervising clinician
Context and preconditions
Actor has successfully logged into the system.
Normal procedure
1. Actor clicks on the "Data export" button.
2. An overview of the supported file formats is displayed.
3. Author selects a file format.
4. The system generates the file containing all patient data that may be made available to the actor.

Normal result
Actor downloads the file with the patient data.
Alternative procedure
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Non-functional requirements
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Notes
Only the relevant medical data is exported - no internal register attributes.
Supported formats:
- CSV
- MS Excel

Overview of unaccepted, finalised visits

Name of the use case
Overview of unaccepted, finalised visits
Subsystem
Patient data management
Actors
Data quality manager
Context and preconditions
Actor has successfully logged into the system.
Normal procedure
1. Actor clicks on the "Not accepted data" button.
2. The system generates an overview of all visits that have already been finalised but not yet accepted. The list contains elements from all centres in the system.

Normal result
The overview is displayed to the actor. They can display the respective elements (continue with *Display patient* use case).
Alternative procedure
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Non-functional requirements
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Notes
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Print visit schedule

Name of the use case
Print visit schedule
Subsystem
Patient data management
Actors
Study nurse, clinician, supervising clinician
Context and preconditions
Display patient use case has been called up.
Normal procedure
1. Actor clicks on the button "Follow-up schedule".
2. The system generates the schedule of follow-up visits for the current patient.

Normal result
The user is shown the visit schedule - this can be printed out and stored locally.
Alternative procedure
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Non-functional requirements
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Notes
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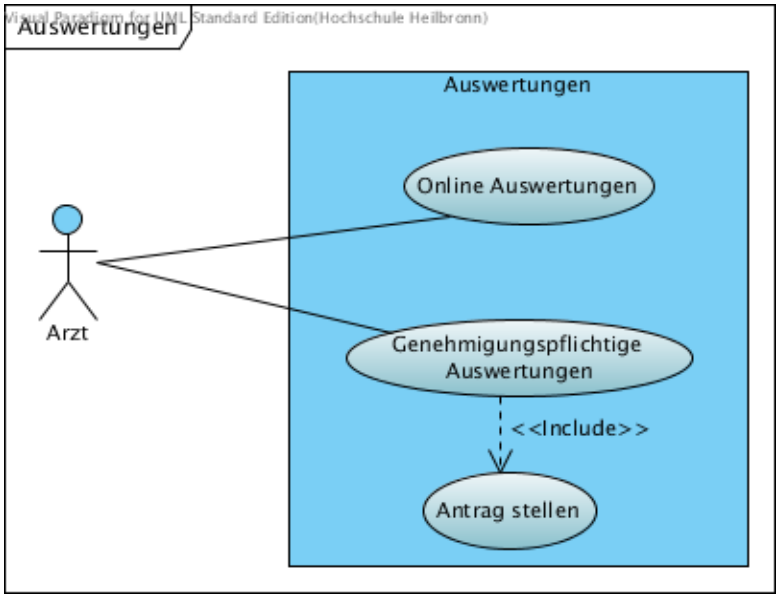
Analyses



Online analyses

Name of the use case
Online analyses
Subsystem
Analyses
Actors
Clinician, supervising clinician
Context and preconditions
Actor has successfully logged into the system.
Normal procedure
1. Actor clicks on the "Data analysis" button and selects the "Online analysis" item.
2. The actor is presented with the possible analyses and selects one.

Normal result
The desired analysis is presented to the actor in the system either as a diagram or in tabular form.
Alternative procedure
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Non-functional requirements
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Notes
The generated analyses are provided with a copyright notice.

Analyses requiring authorisation

Name of the use case
Analyses requiring authorisation
Subsystem
Analyses
Actors
Registered user
Context and preconditions
Actor has successfully logged into the system.
Normal procedure
1. Actor clicks on the "Data analysis" button and selects the "Request analysis" item.

Normal result
Use Case *Submit request* is called up.
Alternative procedure
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Non-functional requirements
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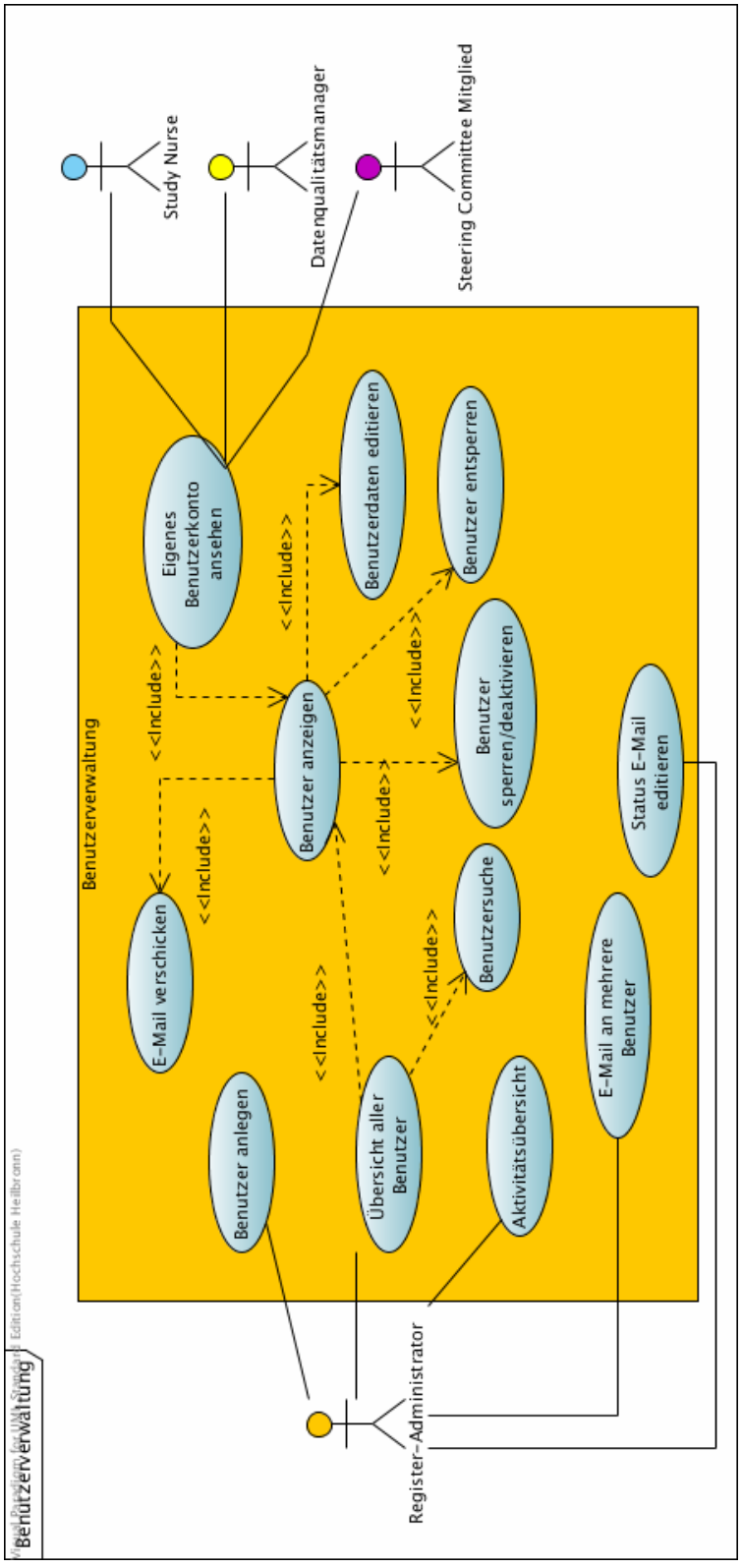
Notes
An analysis requiring authorisation is any analysis that is to be produced with the help of all or not only own registry data. The Steering Committee decides whether access to the desired register data is guaranteed. In the event of a positive response, the actor is informed and the requested data is made available to them.

User administration



Create user

Name of the use case
Create user
Subsystem
User administration
Actors
Register administrator
Context and preconditions
Actor has successfully logged into the system.
Normal procedure
1. Actor clicks on the "Create new user account" button.
2. A screen is displayed in which the user data can be entered.
3. Actor enters the data.
4. The system checks the correctness of the data entered.
5. Actor selects the user role.
6. Actor clicks on "Create".
7. The system checks the data for redundancy.
8. The system checks whether all the necessary data has been entered.
9. The system saves the new user.

Normal result
The actor is shown the message that the process has been successfully completed. The system informs the new user by e-mail that a user account has been set up for them. The e-mail contains a link to set a personal password.
Alternative procedure
5a. The data entered is incorrect and is labelled as such. Actor is asked to correct the data (continue with 3).
6a. Actor has not selected a role and is asked to do so (continue with 5).
8a. The same user already exists in the system. Actor is informed of this and can either edit the data (continue with 3) or cancel the process and view the user found.
(continue with *Display user* use case).
9a. Not all necessary data has been entered, the actor is informed of this (continue with 3).
Non-functional requirements
--
Notes
Register administrator only creates new users if the centre has not yet been created. In other cases, online registration takes effect as described in *user registration* step 3a.

The user data includes
- User name
- Password (automatically generated when the user account is created)
- Centre abbreviation
- Role(s)
- Title*
- Name
- First name
- E-mail address
- Consent to status e-mail
- Telephone number*
- Fax*
- Mobile phone number*
- Homepage*
- Date of birth*
- Business address*
    - Institution/Centre
    - Street
    - Postcode
    - Location
    - Country

*facultative data

Overview of all users

Name of the use case
Overview of all users
Subsystem
User administration
Actors
Register administrator
Context and preconditions
Actor has successfully logged into the system.
Normal procedure
1. Actor clicks on the "Users' list" button.
2. The system generates a sortable list of all users.

Normal result
An overview of all user accounts is presented to the actor in the form of a list. This can be sorted or sorted by entering the
Search criteria can be restricted (continue with Use Case *User search*). Actor can also click on a user account to display it (continue with Use Case *Display user*).
Alternative procedure
--
Non-functional requirements
--
Notes
--

Show users

Name of the use case
Show users
Subsystem
User administration
Actors
Register administrator, study nurse, clinician, supervising clinician, data quality manager, steering committee member
Context and preconditions
Use case *Overview of all users* or *View own user account* was called up.
Normal procedure
1. The user data and the list of the user's last activities are displayed to the actor.

Normal result
The actor is presented with the user account and can edit the data by clicks on the “Edit”-button (continue with Use Case *Edit user data*). If the actor is a register administrator, they can also block or deactivate the displayed user account by clicking on the "Block/Deactivate" button (continue with Use case *Block/deactivate user*). The register administrator can also send an email to the user by clicking on the "Send to email" button (continue with Use case *Send email*).
Alternative procedure
--
Non-functional requirements
--
Notes
--

View own user account

Name of the use case
View own user account
Subsystem
User administration
Actors
Study nurse, clinician, supervising clinician, data quality manager, steering committee member, register administrator
Context and preconditions
Actor is logged into the system.
Normal procedure
1. Actor clicks on the "My Account" button.

Normal result
Continue with Use Case *Display user*.
Alternative procedure
--
Non-functional requirements
--
Notes
--

Edit user data

Name of the use case
Edit user data
Subsystem
User administration
Actors
Register administrator, Registered user, Data quality manager
Context and preconditions
Use Case *Display user* has been called.
Normal procedure
1. The user data is presented to the actor; those that are editable can be changed by the actor.
2. Actor edits the data.
3. The system checks the correctness of the data entered.
4. Actor clicks on the "Save" button.

Normal result
The changes are accepted and saved by the system.
Alternative procedure
4a. The newly entered data is not correct and is marked as such. Actor is advised to correct the data (continue with 2).
Non-functional requirements
--
Notes
The password and the role of the user can be changed at this point.

Block/deactivate user

Name of the use case
Block/deactivate user
Subsystem
User administration
Actors
Register administrator
Context and preconditions
Use Case *Display user* was called.
Normal procedure
1. Actor clicks on the "Block/Deactivate the account" button.
2. A window is displayed in which the corresponding reason for the operation can be entered.
3. Actor writes the reason and selects the exact operation: "Block" or "Deactivate".
4. The system performs the operation.

Normal result
The selected user account is either blocked or deactivated. If the account is blocked, the reason is also sent to the blocked user.
Alternative procedure
--
Non-functional requirements
--
Notes
A user account can be blocked - this means that it is not possible to log in to the system and therefore not possible to use the registry. This action can be cancelled by unblocking the user account.
A user account can only be deactivated once - this cannot be cancelled and means that the user account is no longer needed.

Unblock user

Name of the use case
Unblock user
Subsystem
User administration
Actors
Register administrator
Context and preconditions
Use Case *Display user* was called.
Normal procedure
1. Actor clicks on the "Unblock the account" button
2. A window is displayed in which the corresponding reason for the operation can be entered.
3. Actor writes the justification.
4. The system performs the operation.

Normal result
The selected user account is unblocked. The affected user is notified.
Alternative procedure
--
Non-functional requirements
--
Notes
--

User search

Name of the use case
User search
Subsystem
User administration
Actors
Register administrator
Context and preconditions
Use case *overview of all users*.
Normal procedure
1. Actor enters the search criteria in the mask.
2. The system updates the overview of all users.

Normal result
The users displayed correspond to the search criteria entered.

Alternative procedure
--
Non-functional requirements
--
Notes
Possible search criteria:
- User name
- e-mail
- Surname, first name
- Centre/institution

Activity overview

Name of the use case
Activity overview
Subsystem
User administration
Actors
Register administrator
Context and preconditions
Actor has successfully logged into the system.
Normal procedure
1. Actor clicks on the "Users' actions' overview" button
2. The system generates the list of user actions.

Normal result
A list of user actions is displayed to the actor. By default, the actions that have been performed within the last month are displayed. However, this can be changed by the actor by entering the time window.
Alternative procedure
--
Non-functional requirements
--
Notes
--

Send e-mail

Name of the use case
Send e-mail
Subsystem
User administration
Actors
Register administrator
Context and preconditions
Use Case *Display user* has been called.
Normal procedure
1. Actor clicks on the "Send to email" button.
2. The standard e-mail programme of the actor is called up.

Normal result
Actor can compose the e-mail to the respective user in their standard e-mail programme and then send it.
Alternative procedure
--
Non-functional requirements
--
Notes
Default e-mail programme - the programme that is used by default for composing and receiving e-mails and has been configured in the operating system.

Status e-mail

Name of the use case
Status e-mail
Subsystem
User administration
Actors
Register administrator
Context and preconditions
Actor has successfully logged into the system.
Normal procedure
1. Actor clicks on the "Status email" button.
2. The system displays the e-mail template.
3. Actor edits the template.
4. Actor optionally adds an attachment.
5. Actor clicks on "Send".

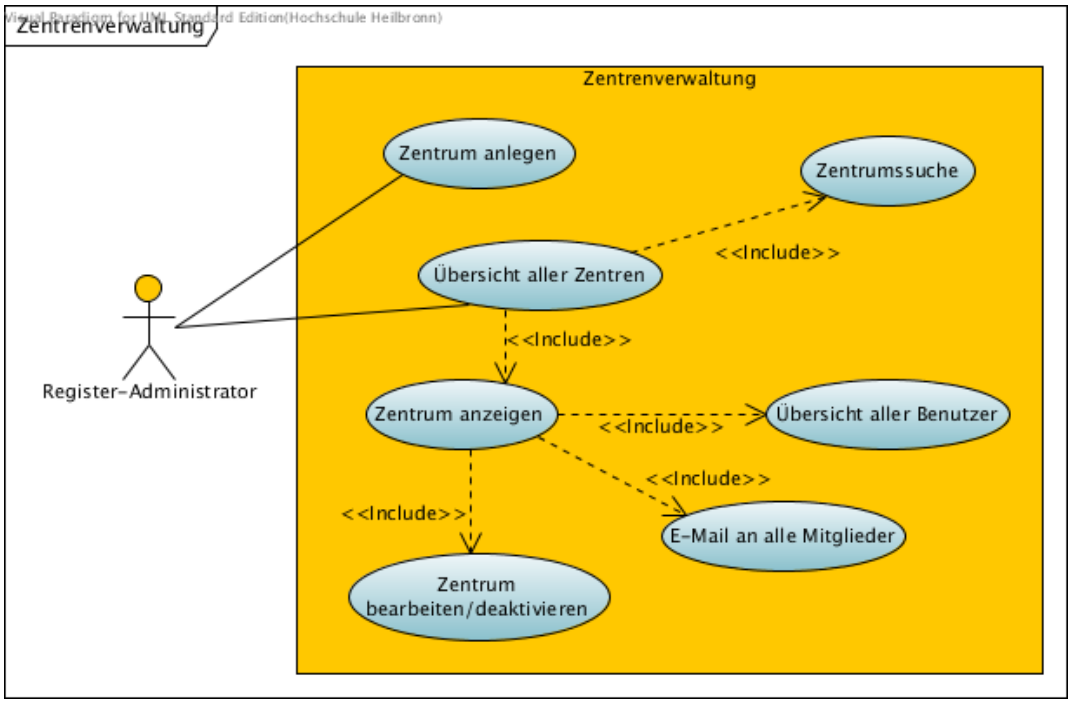
Normal result
The content of the status e-mail is saved and sent to the recipients.
Alternative procedure
--
Non-functional requirements
--
Notes
The status e-mail is a message that is sent several times a year to all users of the register who have agreed to receive the status e-mail. It contains the most important news and information relevant to the registry as well as an overview of all to-do's for the respective user.

E-mail to multiple users

Name of the use case
E-mail to multiple users
Subsystem
User administration
Actors
Register administrator
Context and preconditions
Actor has successfully logged into the system.
Normal procedure
1. Actor clicks on the "Mass email" button.
2. Actor selects the user group that should contain its e-mail:
    a. all data quality managers
    b. all Steering Committee members
    c. All users
3. The standard e-mail programme of the actor is called up.

Normal result
Actor can compose the e-mail to the respective users in its standard e-mail programme and then send it.
Alternative procedure
--
Non-functional requirements
--
Notes
--

Centre management



Create centre

Name of the use case
Create centre
Subsystem
Centre management
Actors
Register administrator
Context and preconditions
Actor has successfully logged into the system.
Normal procedure
1. Actor clicks on the "Create new centre" button.
2. A screen is displayed in which the centre data can be entered.
3. Actor enters the data.
4. The system checks the correctness of the data entered.
5. Actor clicks on "Create"
6. The system checks the data for redundancy.
7. The system checks whether all the necessary data has been entered.
8. The system saves the new centre.

Normal result
A message about the successfully completed process is displayed to the actor.
Alternative procedure
5a. The data entered is incorrect and is labelled as such. Actor is requested to correct the data (continue with 3).
7a. The same centre already exists in the system. The actor is informed of this and can either change the data entered (continue with 3) or cancel the process and display the existing centre (continue with *Display centre* use case).
8a. Not all necessary data has been entered; this is pointed out to the actor (continue with 3).
Non-functional requirements
--
Notes
Centre data:
Name of the centre
Centre abbreviation
Street
Place
Telephone number*
Fax*
Homepage*
Head of department
- Title
- Name
- First name
- Telephone number
- Fax
- E-mail address

* Optional information

Overview of all centres

Name of the use case
Overview of all centres
Subsystem
Centre management
Actors
Register administrator
Context and preconditions
Actor has successfully logged into the system.
Normal procedure
1. Actor clicks on the "Centres' list" button.
2. The system generates a sortable list of all centres.

Normal result
An overview of all centres stored in the system is presented to the actor in the form of a list. This can be sorted or restricted by entering the search criteria (continue with use case *Centre search*). Clicking on a centre calls up the *Display centre* use case.
Alternative procedure
--
Non-functional requirements
--
Notes
--

Centre search

Name of the use case
Centre search
Subsystem
Centre management
Actors
Register administrator
Context and preconditions
Use case *overview of all centres* was called up.
Normal procedure
1. Actor enters the search criteria in the mask.
2. The system generates a list of centres corresponding to the search criteria.

Normal result
The centre overview displayed will show the search criteria adjusted (all listed centres fulfil the search criteria).
Alternative procedure
--
Non-functional requirements
--
Notes
Possible search criteria:
- Centre name
- Centre abbreviation
- Location
- Head of department (first name and surname)

Show centre

Name of the use case
Show centre
Subsystem
Centre management
Actors
Register administrator
Context and preconditions
Use case *overview of all centres* was called up.
Normal procedure
1. The data of the selected centre is presented to the actor.

Normal result
The saved centre is presented to the actor, who can edit the centre data by clicking on the "Edit" button (continue with *Edit/deactivate centre* use case). The actor can also display the users who are assigned to the displayed centre (button: "Users" - continue with Use Case *Overview of all users*). By clicking on the "Mass email" button, the actor can send an email to all users of the displayed centre (continue with Use Case *Email to all members*)

Alternative procedure
--
Non-functional requirements
--
Notes
--

Edit/deactivate centre

Name of the use case
Edit/deactivate centre
Subsystem
Centre management
Actors
Register administrator
Context and preconditions
Display centre use case has been called up.
Normal procedure
1. The actor is presented with the centre data; those that are editable can be changed by the actor.
2. Actor edits the data.
3. The system checks the correctness of the data entered.
4. Actor clicks on "Save"

Normal result
The changes are accepted and saved by the system.

Alternative procedure
2a. Actor wants to deactivate the centre and clicks on the "Deactivate" button - a window is displayed in which the reason for the operation is written and the process is confirmed. System performs the desired operation.
4a. The newly entered data is not correct and is marked as such. Actor is advised to improve the data (continue with 2)

Non-functional requirements
--

Notes
Deactivating the centre is an irrevocable operation that deactivates the centre including all assigned users.

E-mail to all members

Name of the use case
E-mail to all members
Subsystem
User administration
Actors
Register administrator
Context and preconditions
Display centre use case has been called up.
Normal procedure
1. Actor clicks on the "Mass email" button.
2. The actor's standard e-mail programme is called up.

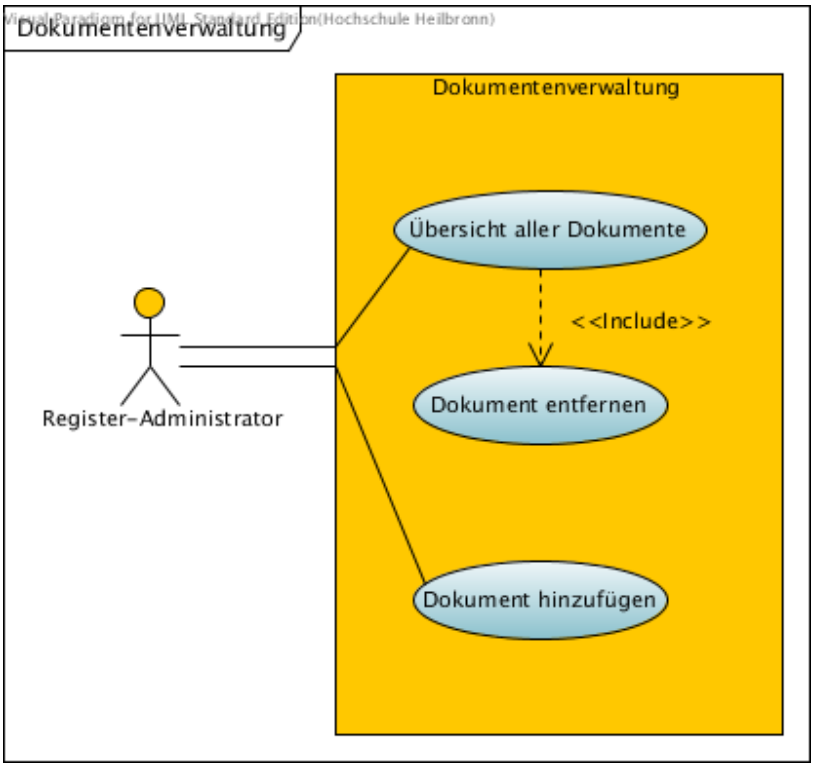
Normal result
Actor can compose the e-mail to all users of the centre in its standard e-mail program and then send it.

Alternative procedure
--

Non-functional requirements
--

Notes
--

Document management



Overview of all documents

Name of the use case
Overview of all documents
Subsystem
Document management
Actors
Register administrator
Context and preconditions
Actor has successfully logged into the system.
Normal procedure
1. Actor clicks on the "Documents overview" button.
2. The system generates a list of existing documents.

Normal result
A list of all documents stored on the server is displayed to the actor. The actor can select one (or more) documents and have them removed (continue with Use Case *Remove document*).
Alternative procedure
--
Non-functional requirements
--
Notes
--

Remove document

Name of the use case
Remove document
Subsystem
Document management
Actors
Register administrator
Context and preconditions
Use case *overview of all documents* has been called up and at least one document has been selected.
Normal procedure
1. Actor clicks on the "Delete" button.
2. The system displays a window in which the actor must confirm its decision.
3. The document(s) selected will be removed from the system.

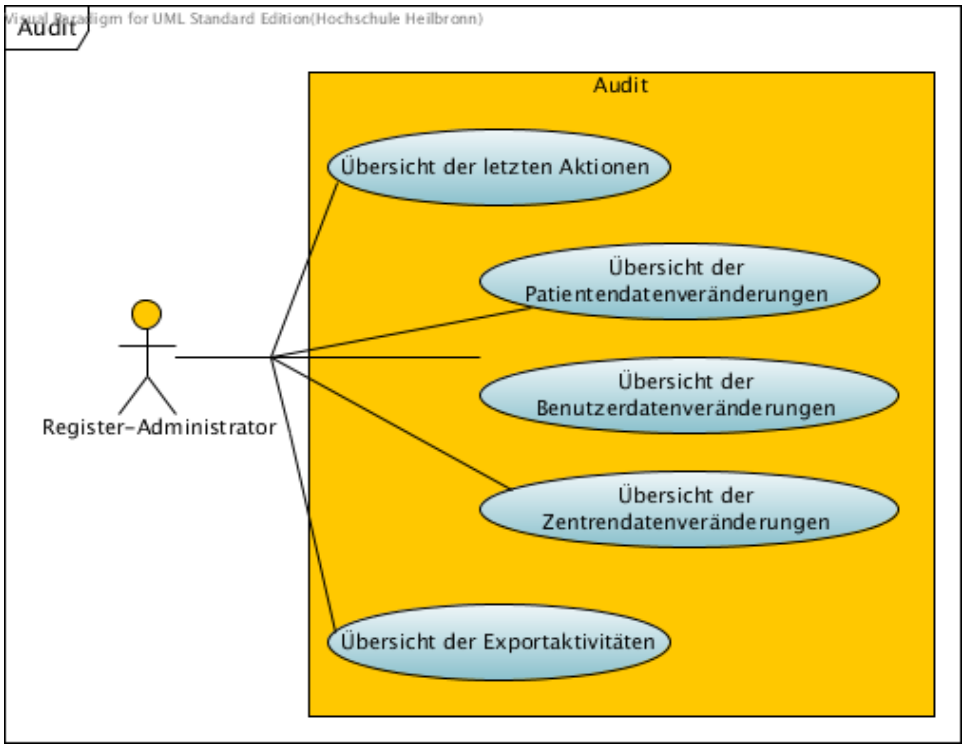
Normal result
The deleted documents are no longer available in the system and can therefore no longer be downloaded.
Alternative procedure
3a. Actor does not confirm the process - no document is deleted; process is cancelled (continue with use case *overview of all documents*)
Non-functional requirements
--
Notes
--

Add document

Name of the use case
Add document
Subsystem
Document management
Actors
Register administrator
Context and preconditions
Actor has successfully logged into the system.
Normal procedure
1. Actor clicks on the "New Document" button.
2. The system displays a window in which the actor can select a document saved on its local hard drive.
3. Actor clicks on the "Upload" button.
4. The document is transferred to the server and saved there.
5. The system displays the upload success message. A short description of the new document must be written in the same window.
6. Actor describes the document.
7. Actor decides whether the document should only be available internally or publicly.
8. The system saves the information.

Normal result
The document is available in the system (i.e. also for download).
Alternative procedure
5a. The document could not be transferred to the server (continue with 2).
7a. Actor has not written a description (continue with 6).
Non-functional requirements
--
Notes
The upload mask only allows certain file types to be uploaded:
- PDF
- DOC

Audit



Overview of recent actions

Name of the use case
Overview of recent actions

Subsystem
Audit

Actors
Register administrator

Context and preconditions
Actor has successfully logged into the system.

Normal procedure
1. Actor clicks on the "Audit/Last actions" button.
2. The system generates a list of the last 50 actions that have been carried out in the system.

Normal result
The list of the last 50 actions is presented to the actor. The actor can also display actions from a specific time window.

Alternative procedure
--

Non-functional requirements
--

Notes
Each action is displayed as the following element in the list:
User(Who?)|Time (When?)|Type of operation (What?)|Reason (Why`?)*

*The reason is not available for every action (e.g. log in/log out).

Overview of patient data changes

Name of the use case
Overview of patient data changes
Subsystem
Audit
Actors
Register administrator
Context and preconditions
Actor has successfully logged into the system.
Normal procedure
1. Actor clicks on the "Audit/Patient data changes" button.
2. The system generates a list of all actions that have been carried out in the system.

Normal result
The list of all actions that have affected any patient data is presented to the actor.
Alternative procedure
--
Non-functional requirements
--
Notes
Each action is displayed as the following element in the list:
User (Who?)|Time (When?)|Type of operation (What?)|Reason (Why?)

Overview of user data changes

Name of the use case
Overview of user data changes
Subsystem
Audit
Actors
Register administrator
Context and preconditions
Actor has successfully logged into the system.
Normal procedure
1. Actor clicks on the "Audit/User data changes" button.
2. The system generates a list of all actions that have been carried out in the system.

Normal result
The list of all actions that have affected any user data is presented to the actor.
Alternative procedure
--
Non-functional requirements
--
Notes
Each action is displayed as the following element in the list:
User (Who?)|Time (When?)|Type of operation (What?)|Reason (Why?)

Overview of centre data changes

Name of the use case
Overview of centre data changes
Subsystem
Audit
Actors
Register administrator
Context and preconditions
Actor has successfully logged into the system.
Normal procedure
1. Actor clicks on the "Audit/Centre data changes" button.
2. The system generates a list of all actions that have been carried out in the system.

Normal result
The list of all actions that have affected any centre data is presented to the actor.
Alternative procedure
--
Non-functional requirements
--
Notes
Each action is displayed as the following element in the list:
User (Who?)|Time (When?)|Type of operation (What?)|Reason (Why?)

Overview of export activities

Name of the use case
Overview of export activities

Subsystem
Audit

Actors
Register administrator

Context and preconditions
Actor has successfully logged into the system.

Normal procedure
1. Actor clicks on the "Audit/Export activity" button.
2. The system generates the list of export activities.

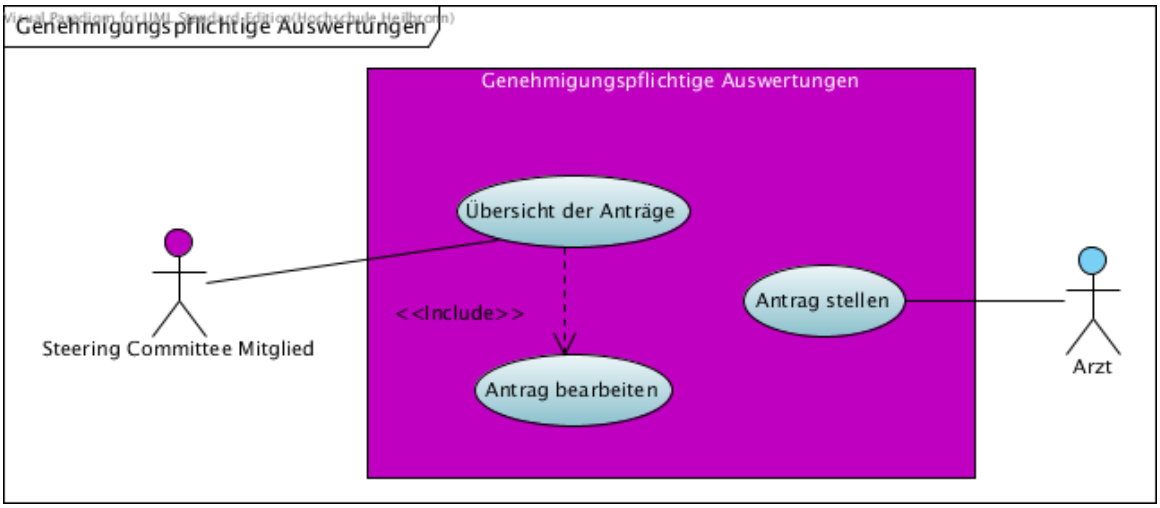
Normal result
The list of all data export processes is presented to the actor.

Alternative procedure
--

Non-functional requirements
--

Notes
An entry in the list has the following form:
Type of exported data | User | Time

Analyses requiring authorisation



Overview of applications

Name of the use case
Overview of all applications
Subsystem
Analyses requiring authorisation
Actors
Steering Committee member
Context and preconditions
Actor has successfully logged into the system.
Normal procedure
1. Actor clicks on the "Applications" button.
2. The system generates a list of applications.

Normal result
The actor is shown a list of requests including their status. An element that has not yet been processed by the actor can be selected, which calls up the *Edit request* use case.
Alternative procedure
--
Non-functional requirements
--
Notes
--

Edit request

Name of the use case
Edit request
Subsystem
Analyses requiring authorisation
Actors
Steering Committee member
Context and preconditions
Use case *overview of all applications* was called up.
Normal procedure
1. The system displays the selected application.
2. Actor processes the request by selecting one of the following options:
    a. Yes, allow the analysis
    b. No, deny the analysis
    c. Need to be discussed with other SC members
    d. Need more information.
3. Actor justifies its decision.
4. Actor clicks on "Submit"
5. The system saves the decision.

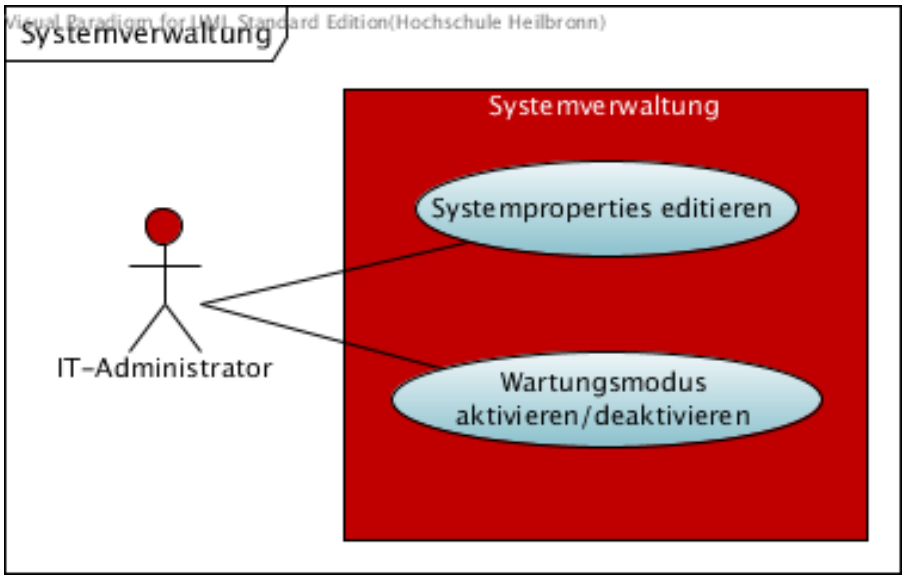
Normal result
The decision of the Steering Committee member is saved. As soon as all members have submitted their decision, the register administrator is informed (a corresponding e-mail is sent to him/her).
Alternative procedure
--
Non-functional requirements
--
Notes
--

Submit an application

Name of the use case
Submit an application
Subsystem
Analyses requiring authorisation
Actors
Clinician, supervising clinician
Context and preconditions
Use case *Analyses requiring authorisation* was called up.
Normal procedure
1. The actor is shown a screen in which they can create an analysis request for the Steering Committee.
2. Actor drafts the application.
3. Actor clicks on "Submit"
4. The system saves the application.

Normal result
The application for the analysis requiring authorisation is stored in the system and released to the Steering Committee for processing.
Alternative procedure
--
Non-functional requirements
--
Notes
--

System administration



Edit system properties

Name of the use case
Edit system properties
Subsystem
System administration
Actors
IT administrator
Context and preconditions
Actor has successfully logged into the system.
Normal procedure
1. Actor clicks on the "System properties" button.
2. A screen with all defined system properties is displayed to the actor.
3. Actor adapts the desired properties.
4. The system adopts the new properties.

Normal result
The system adopts the new properties
Alternative procedure
--
Non-functional requirements
--
Notes
--

Activate/deactivate maintenance mode

Name of the use case
Activate/deactivate maintenance mode

Subsystem
System administration

Actors
IT administrator

Context and preconditions
Actor has successfully logged into the system.

Normal procedure
1. Actor clicks on the "Maintenance Mode" button.
2. Actor activates/deactivates maintenance mode by clicking on the "ON/OFF" button.

Normal result
The system is in maintenance mode/normal mode.

Alternative procedure
--

Non-functional requirements
--

Notes
If maintenance mode is switched on, it will not be possible to log into the system and all visitors to the Register website will see a corresponding message.

Possible status of the data

As already shown in the previous chapter (specification of registry functions), a distinction is made between the following statuses of the registry data:

1. **correct / not completed** - the data has been entered and saved in the system. No errors or missing information were found. However, the data has not yet been released for the review process at the registry centre and will not be included in any analyses.

2. **incorrect / not completed** - the data has been entered and saved in the system. However, errors or missing information have been detected. The data has not yet been released for the review process at the registry centre and will not be included in any analyses.

3. **revision required** - the data was checked by the data quality manager but sent back to the centre for correction as there were still queries about the data set. This may be the case if the data set contained errors that were not found by the automatic validation. The data is not yet included in any analyses.

4. **completed** - the data are error-free and have been checked by the supervising clinician and approved for review at the registry centre. The data are not yet included in any analyses.

5. **accepted** - the data were checked by the data quality manager at the registry centre and, as they are plausible, were also accepted (released) for the analyses.

Appendix I: Registry data set & data validation plan

See Appendix I.

Appendix II: Data protection concept

See Appendix II.