Specifications for the registry "Liver Transplantation in Children and Adolescents", the **CERTAIN-LI registry**, of the Society for Paediatric Gastroenterology and Nutrition (GPGE)

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Contents

Target definition

As there is currently no specific registry in Europe, and particularly in German-speaking countries, for recording liver transplant data in children and adolescents, the Society for Paediatric Gastroenterology and Nutrition (GPGE) decided to provide such a system in order to support and enable scientific evaluation and quality assurance in the field of paediatric liver transplantation. The inaugurated project "CERTAIN-LI Registry" (Cooperative European Paediatric Transplant Initiative Liver) is being implemented by the GPGE's Liver Transplantation Working Group, with the technical implementation and commissioning of the system taking place in Heidelberg.

The registry to be developed as part of the project will serve to collect relevant data on paediatric liver transplantation for research purposes and quality assurance. The registry will take the form of a web application and enable members of the GPGE and Europe to centrally record basic and follow-up data on paediatric liver transplants via the internet, thereby documenting long-term outcomes (in particular patient survival, graft survival, graft function, therapy and complications). In addition to this pure data collection, the registry will offer the following 'service functions' for the individual centres:

- Overview of the various treatment strategies and their success
- Automated transfer of defined data to other systems (Eurotransplant)
- In the next stage of development, the possibility of recording data for studies by members of the CERTAIN-LI research network, thereby simplifying their implementation.

The medical staff of the participating centres are the target group of the CERTAIN-LI Registry. In future, the registry will enable prospective studies to be carried out, which is why the system will also be geared 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 therapy in the form of a database and, depending on the data it contains, can be used to perform various tasks such as quality assurance, therapy improvement or answering health economic questions.

As the CERTAIN-LI Registry is implemented as an internet web application, it can be accessed from anywhere and only requires a current, standard internet browser (such as Edge, Firefox, Safari or Chrome) to use. All that is needed 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 the submitted documents have been checked. Once you have a user account, you can log into the system and enter your data. The registry data, which includes the basic and historical data of a liver transplant patient, is entered at fixed intervals. The data to be entered depends on the respective time of entry. The data is checked for errors or implausibilities during entry; if any are found, the user is notified. In order to allow the data to be corrected at a later date, it is possible to store erroneous data in the system – however, this data is marked accordingly. The data can also be changed at any time, as long as it is not used for 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.

Data entry times:
- Initial entry – transplant
- 30 days after transplantation
- 3 months after transplantation
- 6 months after transplantation
- 1 year after transplantation
- Thereafter annually

In order to avoid multiple entries of the same data, the registry will forward some of its own data to other systems, thereby reducing the data entry workload in the participating centres. The data will be forwarded to the following systems/organisations:

- Eurotransplant
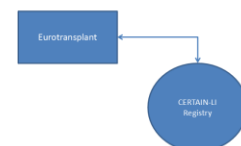
Data exchange with Eurotransplant will be bidirectional, enabling the system to gain access to donor data and older transplant data.

Users will also have access to predefined graphical and tabular analyses of their own data (data from the associated centre). Their own data can also be exported from the system at any time in a predefined format. Analyses of the total amount of registry data require the approval of the Registry Steering Committee. Once this has been obtained, the registry data will be made available.

In addition to data collection and analysis, the registry will offer its users access to GPGE therapy standards, dosage regimens, etc.; users can download these documents via the system.

## User groups

The individual functions of the application should be as intuitive as possible for people with different professional qualifications to use without extensive training. The system should distinguish between the following user groups:

Model of the scope of application

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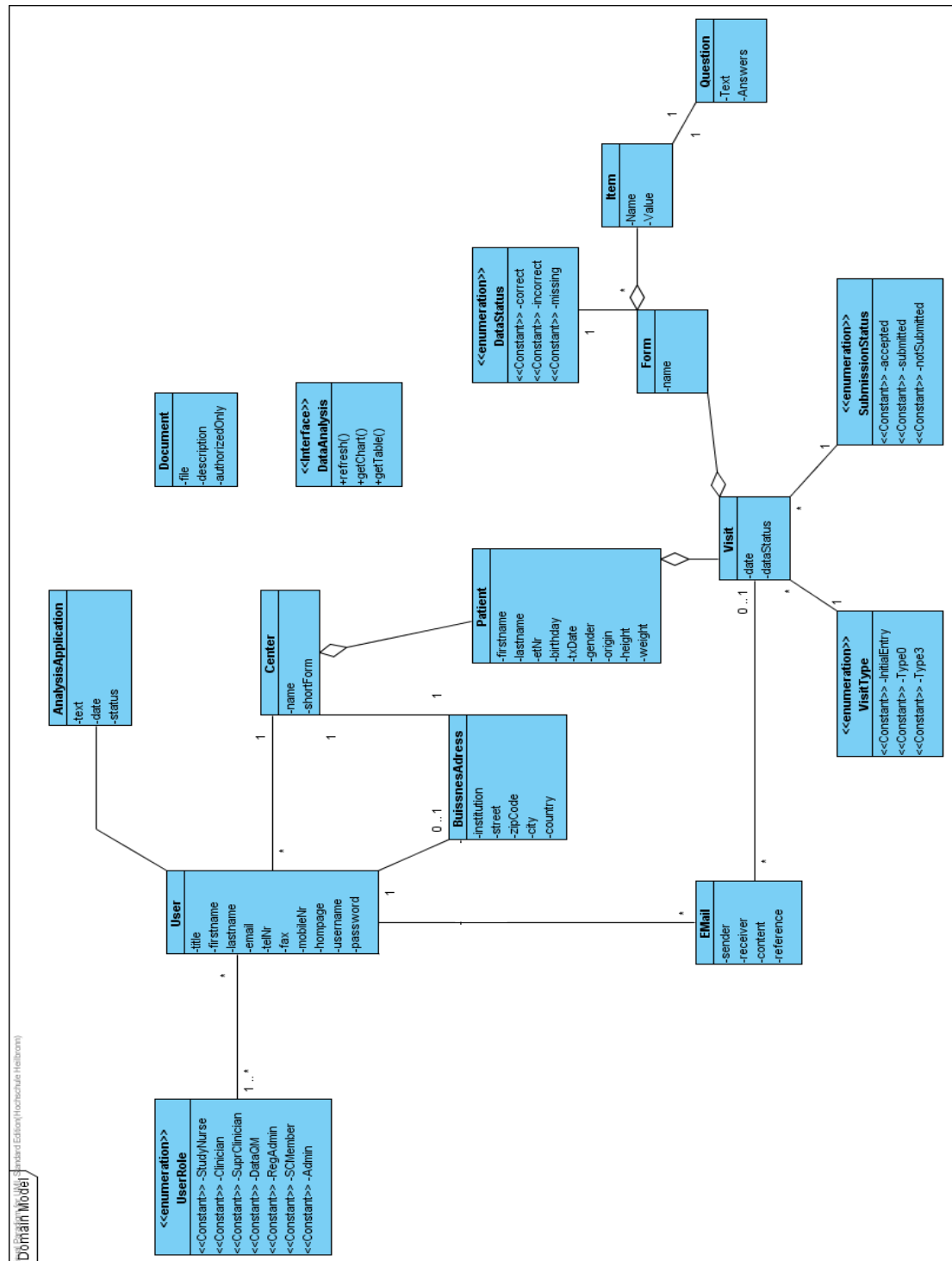
Glossary

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 link between a computer or network and the Internet.

Internet browser – or web browser; a special computer programme for viewing web pages on the World Wide Web or, more generally, documents and data.

GPGE – Society for Paediatric Gastroenterology and Nutrition (https://gpge.de)

Eurotransplant – a non-profit organisation whose main goal is to promote organ transplantation. Eurotransplant arranges and coordinates the international exchange of donor organs in a catchment area with a population of 124 million (https://eurotransplant.org).

Data flow

The registry data is entered either conventionally by registered users (employees of the cooperating centres) or automatically with the help of 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 control and can be divided 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 permission from the Registry Steering Committee).

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

Datenfluss
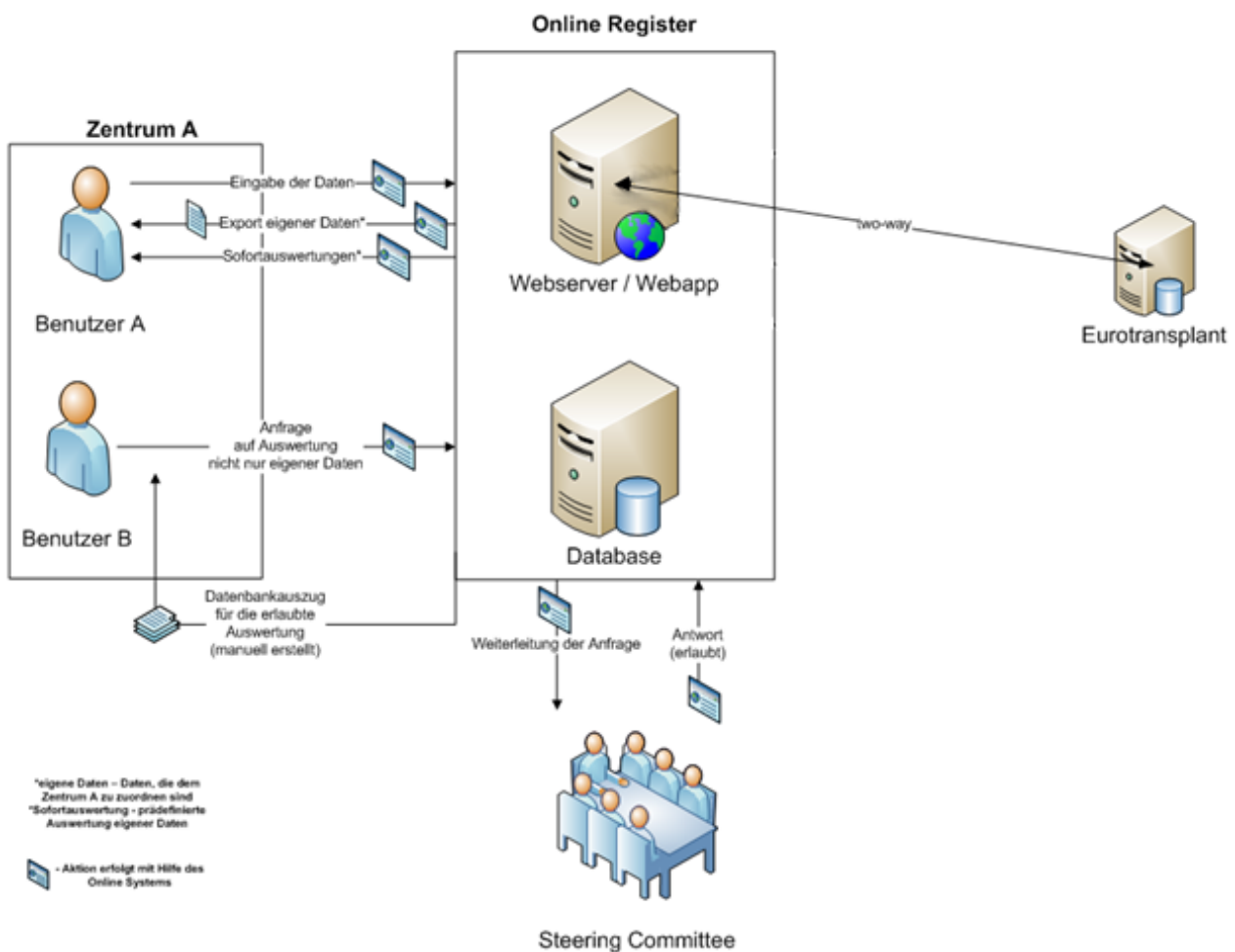
Functions and use cases

The following diagram shows the most important functions, functional areas and 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 does not have 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 evaluation and export functionality.

- **Supervising clinician** – a registered user – physician from the cooperating centre who is responsible for the quality of the data entered by the employees of his centre. A supervising clinician is the only user who can mark the data as "final".

- **Data quality manager** – a user – employee of the registry centre whose main task is to monitor data quality. They are notified when finalised data arrives, which is either marked as accepted or as requiring revision after they have checked it.

- **Register administrator** – a user – employee of the registry centre who is responsible for the technical administration of the registry. They set up user accounts and centres, manage documents and can monitor the activities of other users.

- **Steering Committee member** – a user – member of the Registry Steering Committee who is authorised to assess evaluation requests. The composition of the Steering Committee is specified in §3.3 of the CERTAIN-LI Registry Statutes and Rules of Procedure as follows: "The CERTAIN-LI Steering Committee consists of one member from each participating centre that has actively contributed patient data to the registry in the 12 months prior to the respective meeting. Each centre appoints this member independently. The chair of the GPGE Liver Transplantation Working Group, his deputy and a representative of the registry centre are members of the Steering Committee by virtue of their office."

- **IT administrator** – a user – employee of the registry centre who is responsible for the maintenance and configuration of the web application.
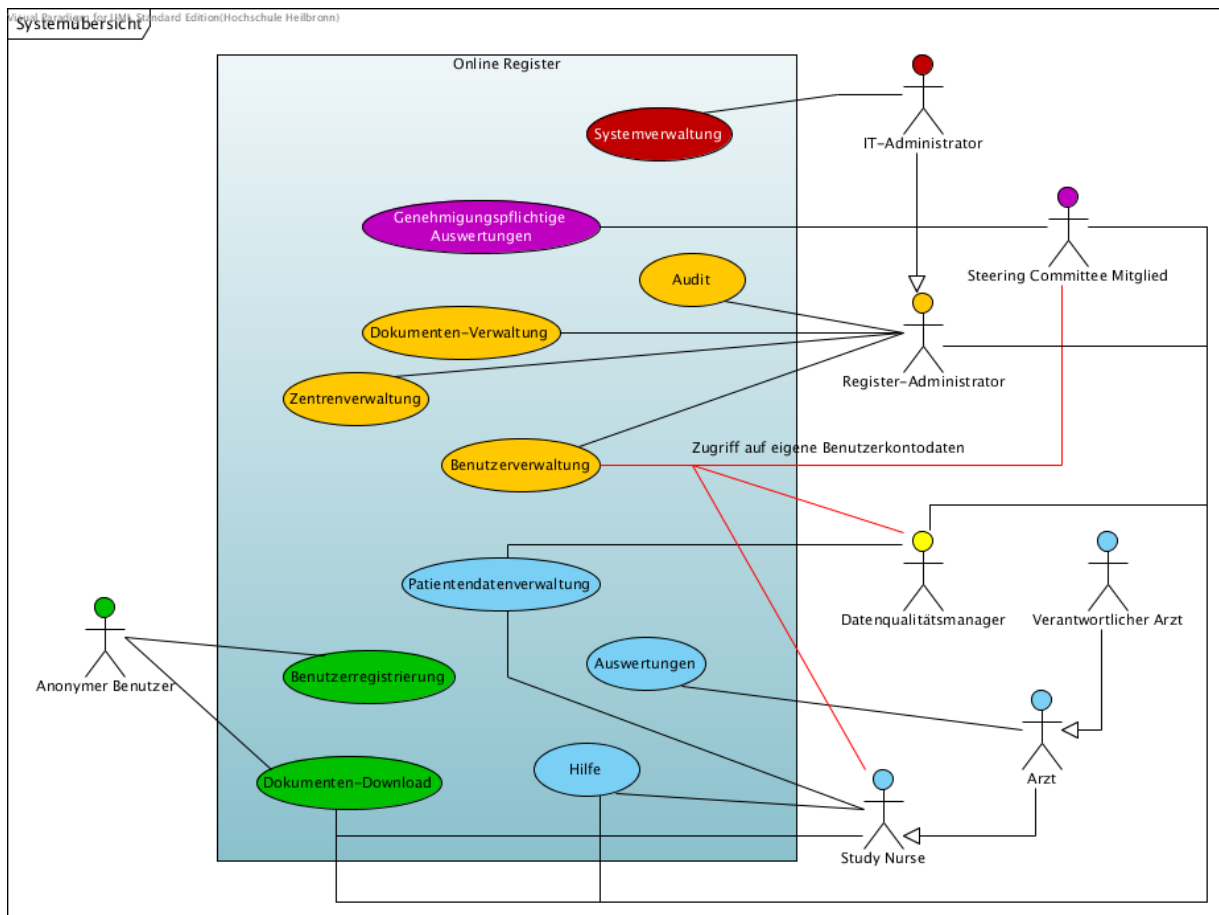
Functions not requiring registration

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 publicly available register documents.

User registration

Name of the use case
User registration

Subsystem
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Actors
Anonymous user

Context and preconditions
The actor has an internet connection and an up-to-date internet browser.
The system is online and accessible to the actor on the Internet.

Normal procedure
1. The actor accesses the registry's website and selects the "Sign up" option.
2. The forms available in the "Sign up" area (online or Word) are filled out by the actor.
3. For a new centre, the Word form is then signed and returned to the registry centre (either by post or scanned and sent by email).
4. The documents are checked at the registry centre and a new user account is set up (see Use Case: *Create user*).

Normal result
The actor receives a notification at their confirmed email address to set their password.

Alternative procedure
3a. Once the online form has been completed, the centre's contact person must verify the new account and the registration centre receives a notification of the registration and verification. (Standard case for centres that have already been created)
4a. The data provided is incorrect – the registry centre contacts the actor and informs them of the necessary corrections. Continue with 3. The process can also be terminated at this point.

Non-functional requirements
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Notes
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Document download

Name of 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
The actor has an internet connection and an up-to-date internet browser.
The system is online and accessible to the actor via the internet.
(To access non-public documents, the user must be logged into the system).

Normal procedure
1. The actor accesses the registry's website and selects the "Resources" item.
2. The actor is presented with the publicly available files in the "Resources" area.
3. The actor selects the files they are interested in and downloads them.

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

Alternative procedure
2a. If the actor is also a registered user, they may also access and download documents that are not publicly available.

Non-functional requirements
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Notes
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Functions requiring registration

Functions requiring registration are only available to users who have a valid user account and depend on the respective roles of the user. These functions can be classified into the following groups:

- Patient data management – this area provides, among other things, 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 analyses of the registry data.

- User management – encapsulates the functionality that enables the creation, editing and management of user accounts.

- Centre management – encapsulates the functionality that enables the creation, editing and management of centres.

- Document management – functions that enable documents to be published and managed.

- Audit – this area encapsulates the monitoring functionality that provides corresponding lists of user actions.

- Analyses requiring approval – functional area that enables the recording of requests for analyses requiring approval, their transmission and processing.

- System administration – Functions necessary for system maintenance and configuration.

- Help – not a function group, but context-dependent access to user help.

Help

Name of the use case
Help

Subsystem
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Actors
Study nurse, clinician, supervising clinician, data quality manager, registry 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-sensitive help text (depending on the currently selected registry function) is displayed to the user in a separate window.
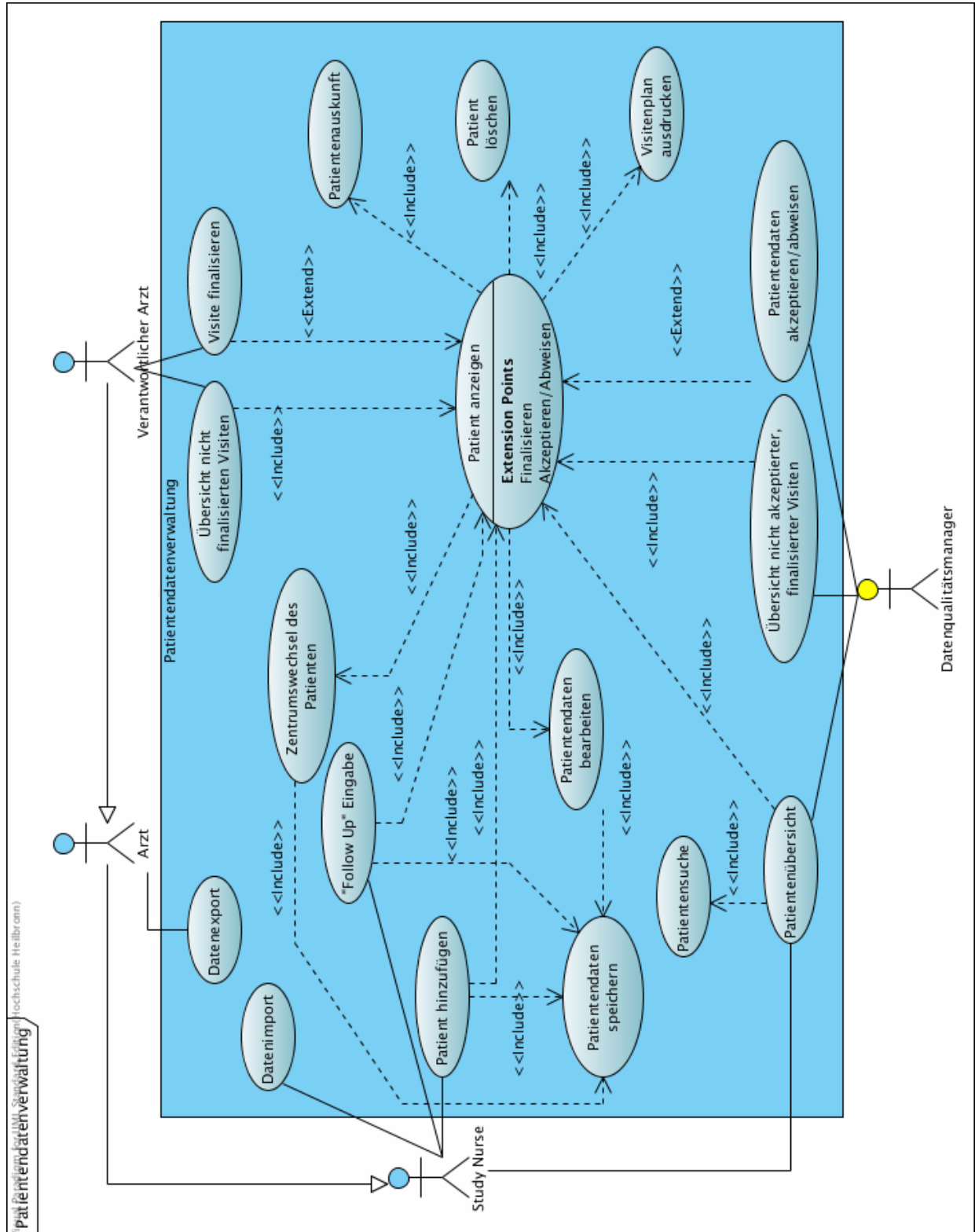
Alternative procedure
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Non-functional requirements
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Notes
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Patient data management

Add patient

Name of 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 them to enter the "Month 0" data (see registry data set).
3. The actor enters the data.
4. The system checks that the data entered is correct.
5. The actor clicks on the "Done" button.
6. The system checks the data for any redundancy.

Normal result
Continue with the use case "*Save patient data*".

Alternative sequence
5a. The data entered is incorrect and is marked as erroneous. The user is advised to check the data entered. Continue with 3 or 5.
7a. The same patient already exists in the system. The actor is notified and can either change the data (continue with 3) or cancel the process and display the patient found (continue with use case *Show patient*).
7b. The same patient already exists in the system, but is assigned to a different centre. The actor is notified of this – a centre change must be carried out. The process is cancelled.

Non-functional requirements
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Notes
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Save patient data

Name of use case
Save patient data

Subsystem
Patient data management

Actors
Study nurse, clinician, supervising clinician

Context and preconditions
The 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 necessary data is present and that the data does not contain any errors (see register data).
3. The system performs the desired operation.

Normal result
The actor is shown a message that the process has been completed successfully. The data is marked as "correct/not completed".

Alternative sequence
3a. Not all necessary data has been entered, or some of the data entered is incorrect. A corresponding message is displayed to the actor, who decides whether to correct the data (return to the original use case) or to proceed with the operation anyway (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 visit

Name of use case
Finalise visit

Subsystem
Patient data management

Actors
Supervising clinician

Context and preconditions
The "*Display patient*" use case has been called up.

Normal procedure
1. Actor clicks on the "Complete" button.
2. The system checks that all necessary data is present and that the data does not contain any errors (see registry data set).
3. The system performs the desired operation.

Normal result
The actor is shown a message indicating that the process has been completed successfully. The visit is marked as "complete".

Alternative procedure
3a. Not all necessary data has been entered or some of the data entered is incorrect.

The actor is shown a corresponding message; they decide whether they want to correct the data (continue with *the Edit Patient* use case) or whether they want to perform the operation anyway (only possible in the case of warnings, continue with 3b). The process can also be cancelled at this point (return to the original use case).
3b. The actor must justify their 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 – the actor can either edit the data (continue with *the Edit Patient* use case) or cancel the process.

Non-functional requirements
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Notes
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Overview of non-finalized visits

Name of use case
Overview of non-finalized 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. The actor can display the respective elements (continue with use case *Show 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" entry

Name of use case
"Follow up" entry
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. The user selects a patient.
4. The selected patient is displayed (see use case *Show Patient*). The user clicks on the active "Follow up" button.
5. The operator is shown a screen that allows them to enter the "30-day" data (see registry data set).
6. The operator enters the data.
7. The system checks that the data entered is correct.
8. The operator clicks on the "Done" button.

Normal result
Continue with the 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 incorrect and is marked as erroneous. The actor is advised to check the data entered. Continue with 6 or 8.
Non-functional requirements
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Notes
Follow-up entries will be possible from the following points in time:
- 30-day entry – from 14 days before and 30 days after the actual date
- 3, 6, and 12 months input: +/- 90 days before/after the actual date
- Annual entry: +/- 6 months before/after the actual date

Patient overview

Name of 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 to whom the actor is authorised to access.

Normal result
The overview of patients is displayed. The actor can select a patient and display it (see use case *Show patient*). The actor can limit the number of patients displayed by entering search criteria (see use case *Patient search*) 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 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-finalized data* or *overview of non-accepted, finalised data* was called up.

Normal procedure
1. A view with the data groups (see registry data set), the input status and the pending and existing entries is presented to the actor.
2. The actor selects a data group.

Normal result
The selected data is displayed. The actor can either attempt to edit the data (if possible – continue with *the patient data editing* use case) or return to the patient data overview (continue with 1).

The actor can also initialise the centre change process at this point (continue with use case *Centre change for the patient*). The actor also has the option "Follow-up schedule" (continue with Use Case "*Print visit* schedule").

Alternative procedure
2a. The actor is a data quality manager and decides to accept the data by clicking on the "Accept" button (continue with *the Accept patient data* use case).
2b. The actor is a responsible physician and decides to finalise the data by clicking on the "Complete" button (continue with use case *Finalise visit*).

Non-functional requirements
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Notes
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Delete patient

Name of use case
Delete patient

Subsystem
Patient data management

Actors
Clinician, supervising clinician

Context and preconditions
The "*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. The user justifies 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 will no longer be found in the system. However, the medical data entered over time will still be available for evaluation.

Alternative procedure
4a. Actor has not confirmed the process. Abort.

Non-functional requirements
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Notes
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Change of centre for the patient

Name of use case
   Change of centre for the patient
Subsystem
   Patient data management
Actors
   Study nurse, clinician, supervising clinician
Context and preconditions
   The "*Show patient*" use case was 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. The user selects the new centre.
4. The patient is assigned to the selected centre.

Normal result
   The patient is now available in the new centre. Both centres (the old and the new) will be able to access all patient data. The old centre can edit data that has not yet been finalised. New entries are only 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 use case
   Patient information
Subsystem
   Patient data management
Actors
   Study nurse, clinician, supervising clinician
Context and preconditions
   The "*Show patient*" use case was called up.
Normal procedure
1. Actor clicks on the button
2. "Patient information" button.
3. The system generates the file containing all patient 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 use case
Accept/reject patient data
Subsystem
Patient data management
Actors
Data quality manager
Context and preconditions
The "*Show patient*" use case has been called up.
Normal procedure
1. The data marked as "completed" is presented to the actor.
2. The actor carefully checks the data.
3. Actor clicks on the "Accept" button.
4. The system marks the data as "accepted".
Normal result
The data is released for evaluation.

Alternative procedure
3a. The actor clicks on the "Reject the data" button; a message (query) to the responsible user is formulated. A mask in which the message can be entered is displayed to the actor. The data record is marked as "revision required". The query is stored in the system and can be viewed by the responsible physician at any time. The query is assigned to a specific visit, so no identifying data is required for communication. If communication takes place via email, this is also done without identifying data, as the actor has no access to this – instead, a 6-digit, random, alphanumeric code generated by the application is used.
4a. The data record contains errors. The actor is notified of these. The reason given by the responsible user is also displayed to him. 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 use case
Patient search
Subsystem
Patient data management
Actors
Study nurse, clinician, supervising clinician, data quality manager
Context and prerequisites
Use case *Patient overview* was called up.
Normal procedure
1. The 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 transplant
- Last name/first name
- ET number or equivalent number

Edit patient data

Name of use case
Edit patients

Subsystem
Patient data management

Actors
Study nurse, clinician, supervising clinician

Context and preconditions
The "*Display patient*" use case was 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. The actor edits the data.
3. The system checks the correctness of the entered data.
4. The actor clicks on the "Done" button.

Normal result
Continue with the use case "*Save patient data*".

Alternative procedure
4a. The data entered is incorrect and is marked as erroneous. The actor is advised to check the data entered. Continue with 2 or 4.

Non-functional requirements
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Notes
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Data import

Name of 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 "Data import" button.
2. A mask is displayed, which the actor can use to select the desired file.
3. The author clicks on the "Upload" button.
4. The system checks the correctness of the file contents.
5. A list of recognised patient data ready for import is presented to the user.
6. The user clicks on the "Import" button.
7. The system imports the data.

Normal result
The user is shown a message indicating that the process has been completed successfully. The imported patient data is marked as "imported" and "not completed".

Alternative procedure
5a. The file does not contain any interpretable data. The actor can either select another file (continue with 2) or cancel the process.
5b. Some of the data contained in the file is incorrect or incomplete. The actor is shown a corresponding message; another file must be uploaded (continue with 2).

Non-functional requirements
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Notes
The upload mask allows files in supported formats to be uploaded.

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 supported file formats is displayed.
3. The 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
The actor downloads the file containing the patient data.
Alternative procedure
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Non-functional requirements
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Notes
Only relevant medical data is exported – no registry-internal attributes.
Supported formats:
- CSV
- MS Excel

Overview of unaccepted, finalised visits

Name of 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 items from all centres in the system.

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

Name of use case
Print out visit schedule

Subsystem
Patient data management

Actors
Study nurse, clinician, supervising clinician

Context and preconditions
The "*Show patient*" use case was called up.

Normal pocedure
1. Actor clicks on the button
   "Follow-up schedule" button.
2. The system generates the follow-up visit
   schedule for the current patient.

Normal result
The visit schedule is displayed to the user,
who can print it out and store it locally.
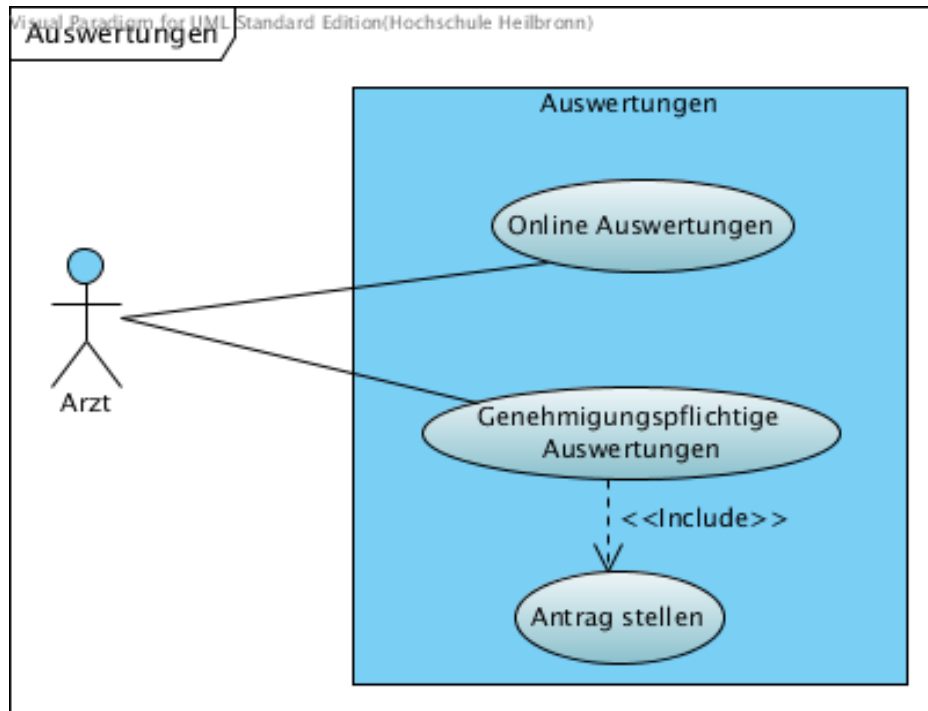
Alternative procedure
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Non-functional requirements
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Notes
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Analyses

Online analyses

Name of use case
Online analyses

Subsystem
Evaluations

Actors
Clinician, supervising clinician

Context and prerequisites
Actor has successfully logged into the system.

Normal procedure
1. The actor clicks on the "Data analysis" button and selects the "Online analysis" option.
2. The actor is presented with the possible analyses and selects one.

Normal result
The desired evaluation 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 marked with a copyright notice.

Analyses requiring approval

Name of the use case
Analyses requiring approval

Subsystem
Evaluations

Actors
Registered user

Context and preconditions
Actor has successfully logged into the system.

Normal procedure
The user clicks on the 'Data analysis' button and selects the 'Request analysis' option.

Normal result
The "Submit request" use case is called up.

**Alternative procedure**
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Non-functional requirements
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Notes
Any analysis that is to be created using all or not only own registry data is considered an analysis requiring approval. The Steering Committee decides whether access to the desired registry data will be granted. If the answer is positive, the actor is informed and the desired data is made available to them.

User management
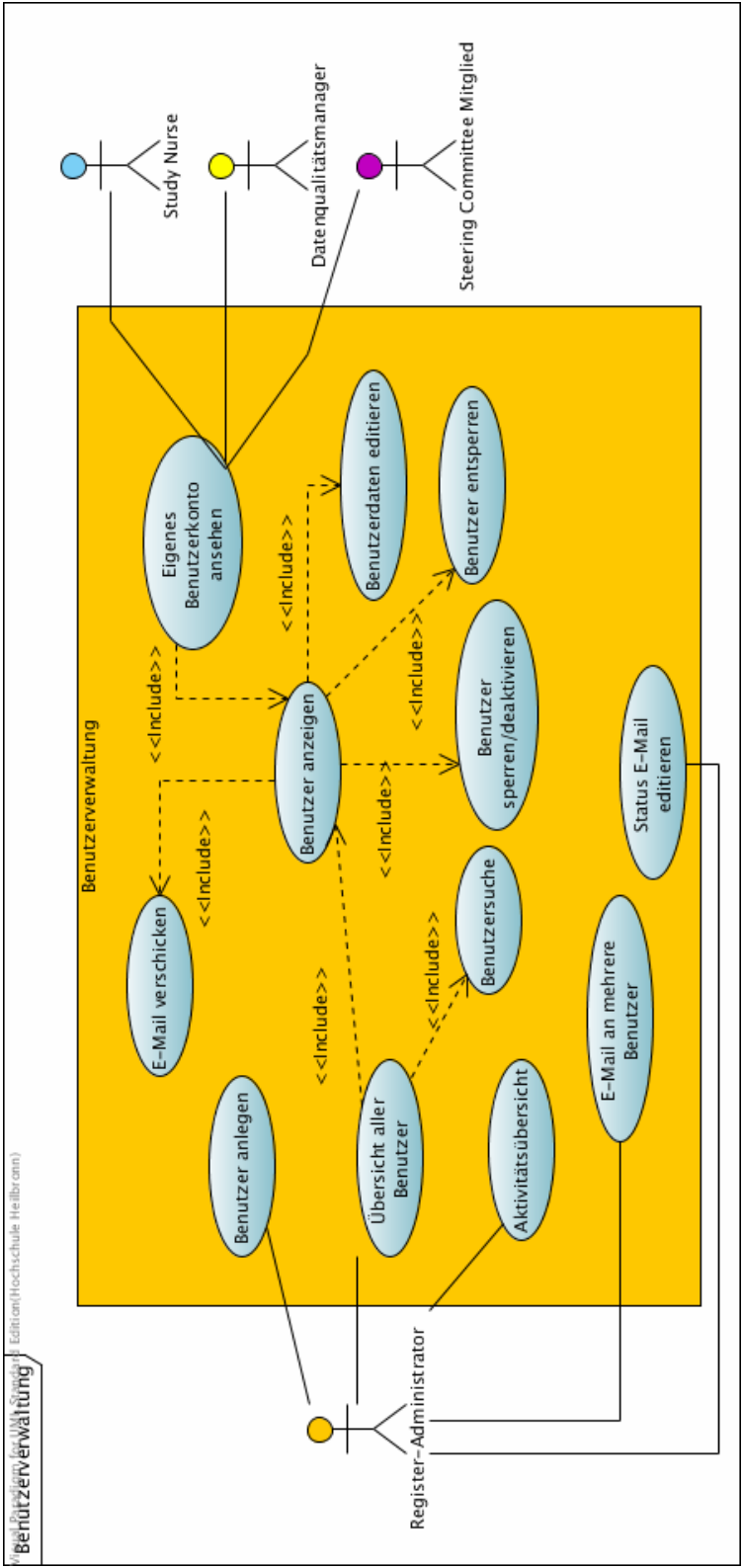
Create user

Name of the use case
Create user

Subsystem
User management

Actors
Register administrator

Context and preconditions
Actor has successfully logged into the system.

Normal procedure
1. The actor clicks on the "Create new user account" button.
2. A form appears in which the user data can be entered.
3. The user enters the data.
4. The system checks that the data entered is correct.
5. The user selects the user role.
6. The user clicks on "Create".
7. The system checks the data for redundancy.
8. The system checks whether all necessary data has been entered.
9. The system saves the new user.

Normal result
The actor is shown a 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 for setting a personal password.

Alternative procedure
5a. The data entered is incorrect and is marked as such. The actor is asked to correct the data (continue with 3).
6a. The actor has not selected a role and is asked to do so (continue with 5).
8a. The same user already exists in the system. The actor is notified of this and can either edit the data (continue with 3) or cancel the process and display the user found

(continue with *the Show User* use case).
9a. Not all necessary data has been entered; the actor is notified of this (continue with 3).

Non-functional requirements
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Notes
The register administrator only creates new users if the centre has not yet been created. In other cases, online registration applies, as described in *User Registration* Step 3a.

User data includes:
- User
- Password (automatically generated when the user account is created)
- Centre code
- Role(s)
- Title
- Last name
- First name
- Email
- Consent to status email
- Telephone number
- Fax
- Mobile number*
- Homepage
- Date of birth
- Business address*
    - o   Institution/centre
    - o   Street
    - o   Postcode
    - o   Town
    - o   Country

Overview of all users

Name of use case
Overview of all users
Subsystem
User management
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
The actor is presented with an overview of all user accounts in the form of a list. This list can be sorted or filtered by entering the

Search criteria can be restricted (continue with use case *User Search*). The actor can also click on a user account to display it (continue with use case *Display User*).
Alternative procedure
--
Non-functional requirements
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Notes
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Display users

Name of the use case
Display user
Subsystem
User management
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* has been called up.
Normal procedure
1. The user data and the list of the user's recent activities are displayed to the actor.
Normal result
The user account is presented to the actor, who can edit the data by clicking 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 an email" button (continue with use case *Send email)*.
Alternative procedure
--
Non-functional requirements
--
Notes
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View your own user account

Name of the use case
View your own user account
Subsystem
User management
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. The actor clicks on the "My Account" button.

Normal result
Continue with the "*Display user*" use case.
Alternative procedure
--
Non-functional requirements
--
Notes
--

Edit user data

Name of use case
Edit user data
Subsystem
User management
Actors
Register administrator, registered user, data quality manager
Context and preconditions
The 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. The actor edits the data.
3. The system checks the correctness of the entered data.
4. The actor clicks on the "Save" button.

Normal result
The changes are applied and saved by the system.
Alternative procedure
4a. The newly entered data is incorrect and is marked as such. The user is instructed to correct the data (continue with 2).
Non-functional requirements
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Notes
The user's password and role can be changed at this point.

Block/deactivate user

Name of use case
Block/deactivate user

Subsystem
User management

Actors
Register administrator

Context and preconditions
Use case *'Display users'* has been called up.

Normal procedure
1. The actor clicks on the "Block/Deactivate the account" button.
2. A window appears in which the reason for the operation can be entered.
3. The actor enters 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. In the case of an account block, the reason is also sent to the blocked user.

Alternative procedure
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Non-functional requirements
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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 reversed by unblocking the user account.
A user account can only be deactivated once – this cannot be reversed and means that the user account is no longer needed.

Unblock user

Name of use case
Unblock user

Subsystem
User management

Actors
Register administrator

Context and preconditions
The use case "*Display users"* has been called.

Normal procedure
1. Actor clicks on the "Unblock the account" button
2. A window appears in which the relevant reason for the operation can be entered.
3. The actor enters the reason.
4. The system performs the operation.

Normal result
The selected user account is unblocked. The affected user is notified.

Alternative procedure
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Non-functional requirements
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Notes
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User search

Name of use case
User search

Subsystem
User management

Actors
Register administrator

Context and preconditions
Use case *Overview of all users*.

Normal procedure
1. The actor enters the search criteria into 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
- Email
- Last name, first name
- Centre/institution

Activity overview

Name of use case
Activity overview

Subsystem
User management

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
The actor is shown a list of user actions. 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 process
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Non-functional requirements
--

Notes
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Send e-mail

Name of use case
Send e-mail

Subsystem
User management

Actors
Register administrator

Context and preconditions
The "Display user" use case has been called.

Normal procedure
1. The actor clicks on the "Send an email" button.
2. The actor's default email programme is called up.

Normal result
The actor can compose the email to the respective user in their default email programme and then send it.

Alternative procedure
--

Non-functional requirements
--

Notes
Standard e-mail programme – the programme that is used by default for composing and receiving e-mails and has been configured as such in the operating system.

Status e-mail

Name of the use case
Status e-mail
Subsystem
User management
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 email template.
3. Actor edits the template.
4. The actor optionally adds an attachment.
5. Actor clicks on "Send".

Normal result
The new content of the status email is saved.
Alternative sequence
--
Non-functional requirements
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Notes
The status email is a message that is sent several times a year to all users of the register who have consented to receive it. It contains the most important register-related news and information, as well as an overview of all the user's to-do items.

Email to multiple users

Name of use case
Email to multiple users
Subsystem
User management
Actors
Register administrator
Context and preconditions
Actor has successfully logged into the system.
Normal procedure
1. Actor clicks on the "Mass email" button.
2. The actor selects the user group that should receive their email:
   - All data quality managers
   - all Steering Committee members
   - all users
3. The actor's default email programme is launched.

Normal result
The actor can compose the email to the respective users in their default email programme and then send it.
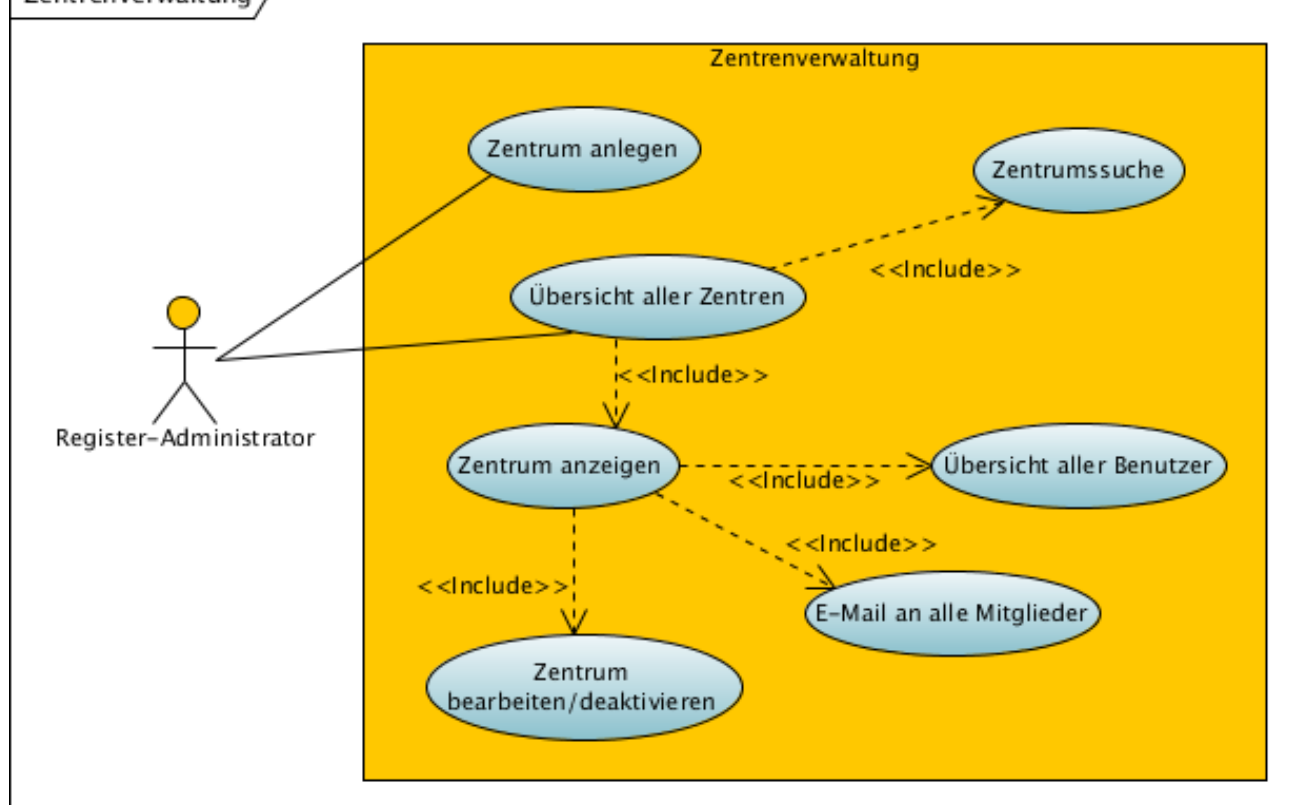**Alternative procedure**
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Non-functional requirements
--
Notes
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Centre management

Create centre

Name of use case
Create centre

Subsystem
Centre management

Actors
Register administrator

Context and preconditions
Actuator has successfully logged into the system.

Normal procedure
1. The operator clicks on the "Create new centre" button.
2. A mask appears in which the centre data can be entered.
3. The operator enters the data.
4. The system checks that the data entered is correct.
5. The user clicks on "Create".
6. The system checks the data for redundancy.
7. The system checks whether all necessary data has been entered.
8. The system saves the new centre.

Normal result
The actor is shown a message indicating that the process has been successfully completed.

Alternative procedure
5a. The data entered is incorrect and is flagged as such. The operator is asked 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 use case *Display Centre*).
8a. Not all necessary data has been entered; the actor is notified of this (continue with 3).

Non-functional requirements
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Notes
Centre data:
Name of centre
Centre abbreviation
Street
Town
Telephone number
Fax
Homepage
Manager
    Title
    Last name
    First name
    Telephone
    Fax
    Email address

* Optional information

Overview of all centres

Name of use case
Overview of all centres

Subsystem
Centre management

Actors
Register administrator

Context and preconditions
Actuator 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
The actor is presented with an overview of all centres stored in the system in the form of a list. This list can be sorted or restricted by entering search criteria (continue with *the centre search* use case). Clicking on a centre calls up the *display centre* use case.

Alternative procedure
--

Non-functional requirements
--

Notes
--

Centre search

Name of 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. The actor enters the search criteria in the mask.
2. The system generates a list of centres that match the search criteria.

Normal result
The centre overview displayed is adapted to the search criteria (all centres listed meet the required criteria).

Alternative procedure
--

Non-functional requirements
--

Notes
Possible search criteria:
- Centre name
- Centre abbreviation
- Location
- Name of the manager (first and last name)

Show centre

Name of use case
Show centre

Subsystem
Centre administration

Actors
Register administrator

Context and preconditions
Use case *overview of all centres* was called up.

Normal procedure
1. The data for the selected centre is presented to the actor.

Normal result
The stored centre is presented to the actor, who can edit the centre data by clicking on the "Edit" button (continue with use case *Edit/deactivate centre*). The actor can also display the users assigned to the centre shown (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 use case
Edit/deactivate centre

Subsystem
Centre management

Actors
Register administrator

Context and preconditions
The "Display Centre" use case has been called.

Normal procedure
1. The centre data is presented to the actor; those that are editable can be changed by the actor.
2. The actor edits the data.
3. The system checks the correctness of the entered data.
4. Actor clicks on "Save".

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

Alternative procedure
2a. The operator wants to deactivate the centre and clicks on the "Deactivate" button – a window appears in which the reason for the operation is entered and the process is confirmed. The system carries out the desired operation.

4a. The newly entered data is incorrect and is marked as such. The actor is instructed to correct the data (continue with 2).

Non-functional requirements
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Notes
Deactivating the centre is an irrevocable operation that deactivates the centre, including all assigned users.

Email to all members

Name of use case
Email to all members

Subsystem
User management

Actors
Register administrator

Context and preconditions
The "Display Centre" use case has been called up.

Normal procedure
1. Actor clicks on the "Mass email" button.
2. The actor's default email programme is called up.

Normal result
The actor can compose the email to all users of the centre in their default email programme and then send it.
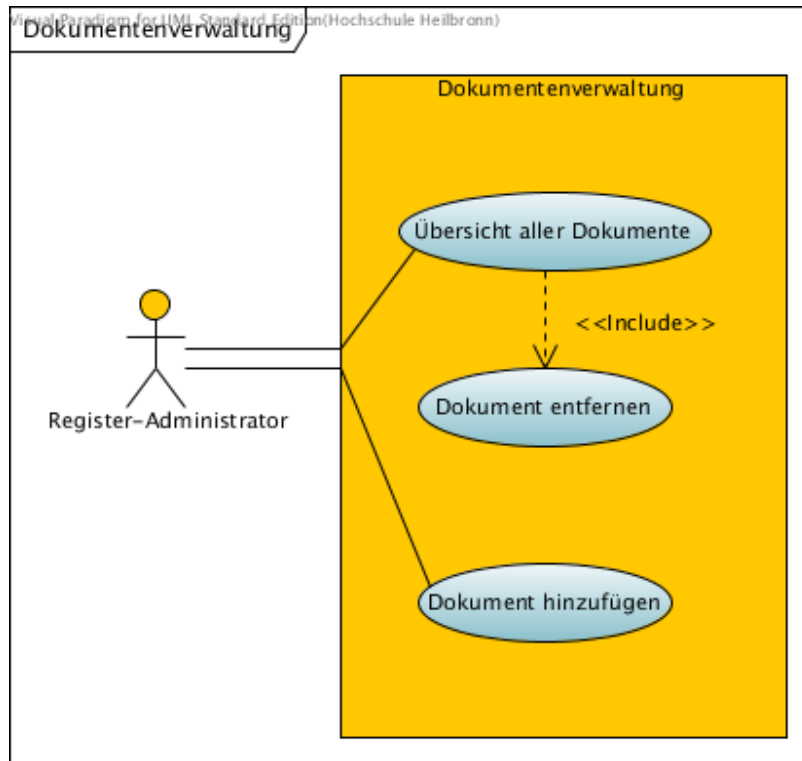
Alternative procedure
--

Non-functional requirements
--

Notes
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Document management

Overview of all documents

Name of 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 *the "Remove document" use case*).

Alternative procedure
　--

Non-functional requirements
　--

Notes
　--

Remove document

Name of 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
1. The actor clicks on the "Delete" button.
2. The system displays a window in which the actor must confirm their decision.
3. The document(s) is/are 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
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Notes
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Add document

Name of 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 stored on their local hard drive.
3. The user clicks on the 'Upload' button.
4. The document is transferred to the server and stored there.
5. The system displays a message confirming that the upload was successful. A short description of the new document must be entered in the same window.
6. The user describes the document.
7. The user decides whether the document should be available internally or publicly.
8. The system saves the information.

Normal result
The document is available in the system (and can also be downloaded).

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).
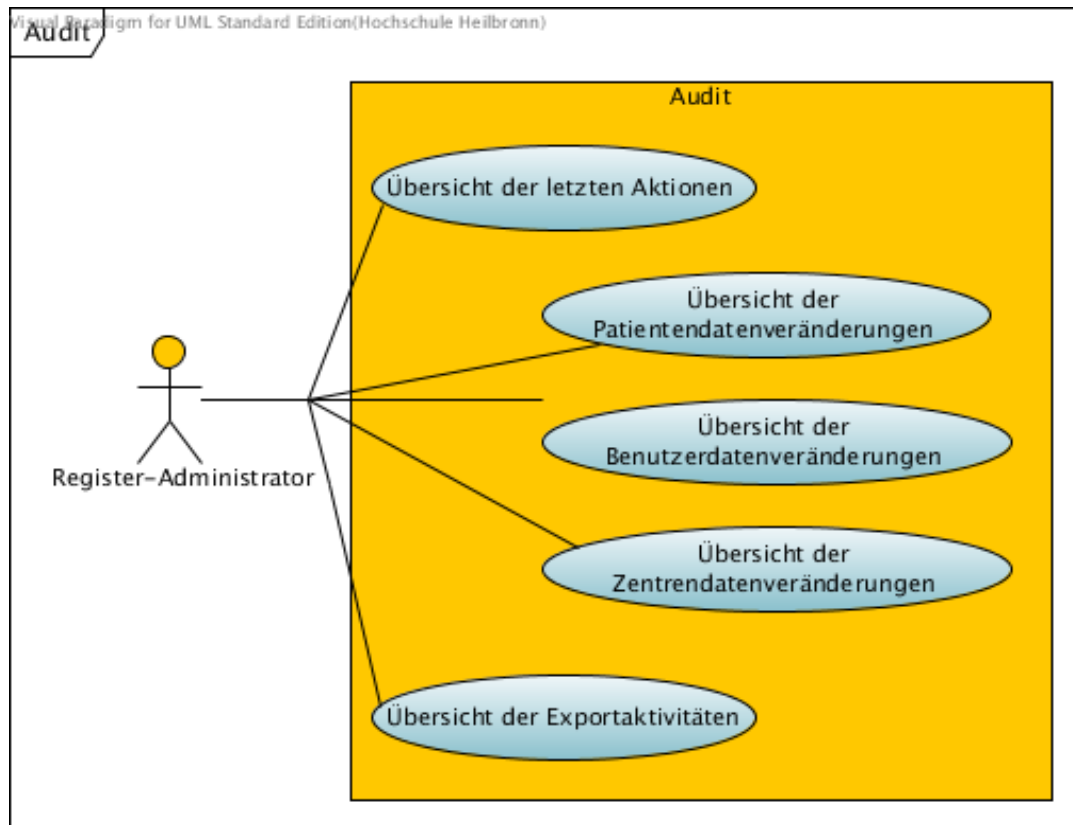
Non-functional requirements
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Notes
The upload mask only allows certain file types to be uploaded:
- PDF
- DOC

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 performed 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 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. The actor clicks on the "Audit/Patient data changes" button.
2. The system generates a list of all actions that have been performed 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 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 performed 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 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. The actor clicks on the "Audit/Centre data changes" button.
2. The system generates a list of all actions that have been performed in the system.

Normal result
The list of all actions that 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 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.
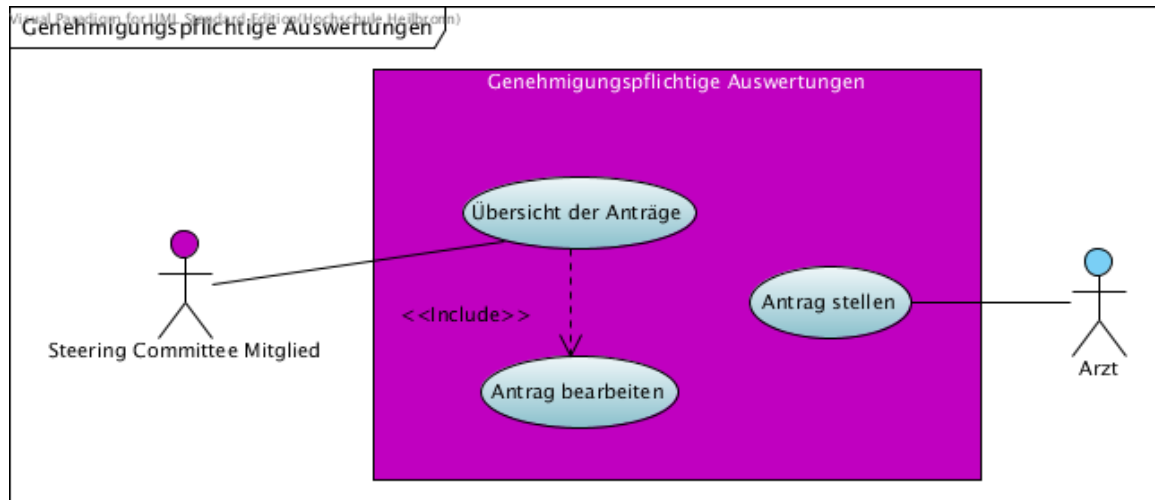
Alternative procedure

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Non-functional requirements

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Notes

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

Analyses requiring approval

Overview of all applications

Name of use case
Overview of all applications

Subsystem
Analyses requiring approval

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 applications, including their status. An item that has not yet been processed by the actor can be selected, which causes the *"Process application"* use case to be called up.

Alternative procedure
--

Non-functional requirements
--

Notes
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Edit application

Name of use case
Edit application

Subsystem
Analyses requiring approval

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. The actor processes the application 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. The actor justifies his decision.
4. Actor clicks on "Submit"
5. The system saves the decision

Normal result
The decision of the Steering Committee member is saved. Once all members have submitted their decisions, the registry administrator is notified (a corresponding email is sent to them).

Alternative procedure
--

Non-functional requirements
--

Notes
--

Submit application

Name of use case
Submit application

Subsystem
Analyses requiring approval

Actors
Clinician, supervising clinician

Context and preconditions
Use case *Analysis requiring approval* has been called up.

Normal procedure
1. The actor is shown a screen in which they can write an analysis application to the Steering Committee.
2. The actor writes the application.
3. Actor clicks on "Submit".
4. The system saves the application.

Normal result
The application for the analyses requiring approval is saved in the system and released to the Steering Committee for processing.
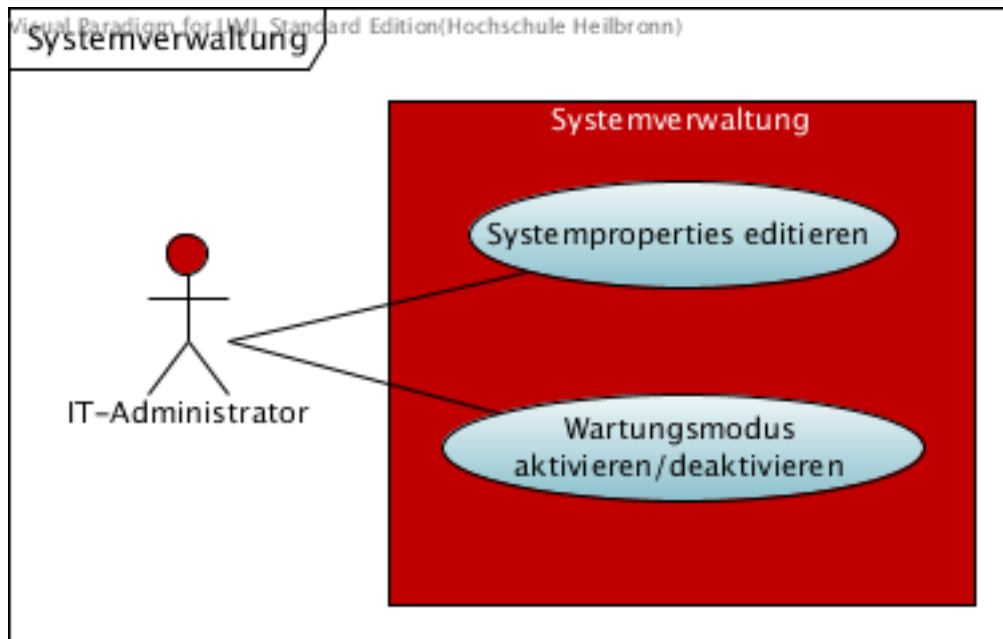
Alternative procedure
--

Non-functional requirements
--

Notes
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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. The actor clicks on the "System Properties" button.
2. A screen displaying all defined system properties is shown to the actor.
3. The user adjusts the desired properties.
4. The system applies the new properties.

Normal result
The system adopts the new properties.
Alternative procedure
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Non-functional requirements
--
Notes
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Activate/deactivate maintenance mode

Name of 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. The actor clicks on the "Maintenance Mode" button.
2. The operator 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
When maintenance mode is activated, it will not be possible to log in to the system, and all visitors to the registry website will see a corresponding message.

Possible status of the data

As already indicated in the previous chapter (Specification of register functions), a distinction is made between the following statuses of register data:

1. **correct / not completed** – the data has been entered and stored in the system. No errors or missing information have been identified. 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 stored 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 has been checked by the data quality manager, but sent back to the centre for correction because 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 is error-free and has been checked by the responsible physician and released for review at the registry centre. The data is not yet included in any analyses.

5. **Accepted** – the data has been checked by the data quality manager at the registry centre and, as it is plausible, has also been accepted (released) for analyses.

Appendix I: Registry data set & data validation plan
See Appendix I.

Appendix II: Data protection concept
See Appendix II.

Heidelberg, 23 May 2025

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Place, date   Signature of project director

                                           Prof. Dr. Burkhard Tönshoff