

osse USER GUIDE

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Version 2.0
02-Jan-2020

Previous versions

- 1.1 06-Nov-2015 Dr. Marita Muscholl / Dennis Kadioglu

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1 BEFORE YOU START

Please make sure that you have access to the following documents in their latest published version:

- Executive summary – project overview of OSSE (Open Source Registry System for Rare Diseases in the EU)
- Technical Reference – description of the core concepts of OSSE
- Getting Started Guide – instructions how to set up an environment and how to configure and use your first registry

Before continuing, please make sure that you are familiar with the following concepts. This document will refer to those without further introduction:

- **Registry**, with attributes like *short name* and *email address* for identification and further contact. It will be configured with a selection of data entry *forms* for *basic* or *longitudinal data*.
- The **Metadata Repository (OSSE.MDR)** allows the precise definition of the *data elements* which will be stored in a registry. The **OSSE.FormEditor** allows the selection of data elements defined in the MDR namespace of the registry to create data entry *forms*. Preferably there is only one single instance of both systems to foster the reuse of *data elements* among different registries and achieve a high degree of comparable data.
- **Locations** of a research network, including centres, clinical departments or medical practices, who share a registry. Each location may have a location administrator who is appointed by the registry administrator.
- **Users, roles and permissions:** *Permissions* are defined on data classes (e.g. forms), while *roles* are collections of *permissions*. A user can log on to a registry and has *roles* that provide him with the required *permissions* to perform data entry and retrieval tasks in a registry.
- The central OSSE components (OSSE.MDR, OSSE.FormEditor, ...) are shared between multiple research networks and are hosted by the Medical Informatics Group, University Hospital Frankfurt.

Once the registry has been set up, users need to understand only the following concepts:

- According to European data protection rules and in order to irreversibly prevent the identification of documented patients, a pseudonymization software or **identity management** called *Mainzelliste* is provided.
- A patient is represented by a pseudonym called **PID**. Users from other *locations* see entered medical data without accessing the patient's personal data.

2 SYSTEM REQUIREMENTS

The components of the OSSE registry framework are Java applications which can be accessed and used through a web browser. Therefore, the following general requirements have to be fulfilled:

Client:

A recent web browser (Firefox 42, Internet Explorer 11 and Chrome 46 have been tested)

Server:

Registry and patient list (installed from OSSE CD):

- (Virtualized) server or PC (recent hardware should be sufficient in any case but, we recommend at least 1024 MB of RAM (2048 MB of RAM for a desktop PC))

Registry and patient list (installed from OSSE package repository):

- (Virtualized) server or PC (recent hardware should be sufficient in any case but, we recommend at least 1024 MB of RAM (2048 MB of RAM for a desktop PC))
- Ubuntu 14.04 LTS (other Linux distributions or Windows may also work)
- Java 7
- Apache Tomcat 7
- Postgresql 9.3

Productive vs demo use:

For demo purposes the registry and the patient list can be hosted on the same server. In any case of productive usage two separated servers (fulfilling the requirements as stated above) are strongly recommended! Furthermore, you also should have valid certificates for both servers to ensure secure connections between them as well as with the web browsers accessing the registry. Either your IT-department/-professional or your hosting provider can support you in obtaining them.

Required Knowledge:

- Boot your server or PC from CD/ISO image (OSSE CD)
- Add a package repository and install new software in your Ubuntu based server or PC (OSSE package repository)
- Configure your server or PC appropriately to make it accessible from the internet (reachable IP address, resolvable host name)
- Edit configuration files using the shell in Ubuntu

3 DOWNLOAD & INSTALLATION

You can either download an ISO image or add our Ubuntu package repository to your package sources. In both cases you can decide if you want to set up a demo instance or a productive one.

If you cannot install OSSE on an existing Ubuntu Server 14.04 we recommend you to download the ISO image. You can find the most recent version at <http://osse-register.de>.

If you already have one (demo) or two (productive) running Ubuntu server(s) you can just add our repository as follows:

1. Open a terminal
2. Add our repository to your sources.list.d directory
For OSSE demo please run

```
echo -e '\n#OSSE Demo package repository\ndeb http://packages.osse-register.de/apt/debian/osse-demo trusty main\n' >> /etc/apt/sources.list.d/osse.list
```


For OSSE productive please run

```
echo -e '\n#OSSE Productive package repository\ndeb http://packages.osse-register.de/apt/debian/osse trusty main\n' >> /etc/apt/sources.list.d/osse.list
```
3. Download and add the key of our repository

```
wget -O - http://packages.osse-register.de/apt/debian/osse/osserepo.gpg.key | apt-key add -
```
4. Update the package lists

```
apt-get update1
```
5. Install OSSE demo

```
apt-get install osse-demo
```


Or install OSSE productive (**Please install the ID management first, as the URL of the Mainzelliste has to be entered during the installation of the registry!**)

```
apt-get install osse-idmanagement respectively apt-get install osse-datamanagement
```
6. During the installation process you will have to answer some questions. As the questions depend on the package you install, you may not be asked all of the following questions:
 - a. Enter the contact data (e.g. name, phone number and email) for a person responsible for the Mainzelliste (if it is installed on this machine or in case of the demo installation).
 - b. Enter the URL of your Mainzelliste installation or do not enter anything if you are running OSSE-demo.
 - c. If necessary, enter your proxy settings in the next dialogs. If you do not know what to enter here, just leave it blank. If there is an error, your local administrator should be able to give you support.
7. When the installation is finished, you can start your web browser and open the newly installed registry by entering either the URL `https://<IPofYourServer>:<Port>` or `https://<nameOfYourServer.tld>:<Port>`. As there is only a temporary self-signed certificate

¹ If this step fails, the Ubuntu package repository servers might be updated at the moment. Please wait and retry it later.

the web browser will show a warning which has to be ignored until you install a valid certificate on the server.

If you do not have a running Ubuntu Server, you can download the ISO image and use it for the installation as follows:

1. Either burn the image on a CD and boot your server from there or mount the ISO image in a virtual machine and boot it from there, e.g. in VirtualBox
2. During the boot process you can choose the language for the installation process as well as either “Install Ubuntu Server with OSSE Registry”, “Install Ubuntu Server with OSSE ID-Management” or “Install Ubuntu Server with OSSE Demo” (**Please install the ID management first, as the URL of the Mainzliste has to be entered during the installation of the registry!**)
3. During the installation process you will have to answer several questions which should either be self-explanatory or will be explained in the next steps.
4. You can answer the following 3 to 7 questions concerning your locale settings according to your preferences.
5. The next question is about the hostname of your server. If you do not have an internet domain for the server you can accept the default value ‘ubuntu’ or change it to something else, e.g. ‘ossedatamanagement’ or ‘osseidmanagement’. If you have one, e.g. www.servername.de, you only need the domain name here and thus should enter ‘servername’.
6. In the next 4 to 5 dialogs you will have to define the first user account for your server. Just follow the instructions on your screen.
7. Usually it should be safe to accept the suggestion for your time zone settings but, we still recommend you to check and correct it, if necessary.
8. The next step will be the preparation of the hard drive in your server. If the hard drive already contains data, you will be asked if the partitions on that hard drive should be unmounted or not. We recommend you to say ‘Yes’ and choose ‘Guided – use entire disk’ in the next dialog. If you have an empty hard drive, there will not be any question about unmounting partitions. Afterwards please select the partition where OSSE should be installed on. The last question asks for your final approval to format the hard drive. **KEEP IN MIND: If you choose ‘Yes’ your hard drive will be emptied which means ALL DATA will be gone! If you need that data, you will have to cancel the installation to do a backup. Afterwards you can start the installation again.**
9. If necessary, you will have to enter your proxy settings in the next dialog. If you do not know what to enter here, just leave it blank. If there is an error, then your local administrator should be able to support you.
10. If you installed OSSE on an empty hard drive or chose to empty it during the installation, it should be safe to answer the question ‘Install the GRUB boot loader on a hard disk’ with ‘Yes’. If not you should keep in mind that already existing operating systems, e.g. Windows, may not boot anymore after this step. In that case your local administrator should be able to support you.
11. If all went well the installation should be finished now and you can reboot the system by choosing ‘Continue’.

12. After the server has booted up again the second part of the OSSE installation will begin². During that you will have to answer some more questions. Some questions depend on the package, so you may not be asked all of the following questions:
 - a. Enter contact data (e.g. name, phone number and email) for a responsible person for the Mainzelliste (if it is installed on this machine or in case of the demo installation).
 - b. Enter the URL of your Mainzelliste or enter nothing, if you've installed OSSE demo.
 - c. If necessary, enter your proxy settings in the next dialogs. If you do not know what to enter here, just leave it blank. If there is an error, then your local administrator should be able to support you.
13. When the installation is finished, you can start your web browser and open the newly installed registry by entering either the URL `https://<IPofYourServer>:<Port>` or `https://<nameOfYourServer.tld>:<Port>`. As there is only a temporary self-signed certificate the web browser will show a warning which has to be ignored until you install a valid certificate on the server.

4 MAINTENANCE & UPDATES

As the OSSE software components as well as the underlying operating system Ubuntu evolve you should update your system regularly. This is especially important in the light of security risks!

We have decided to use the same mechanism for the distribution of the OSSE software components as Ubuntu uses, the Debian package management system. As of that it is quite easy to keep your system up to date:

For OSSE productive you can use

- `sudo apt-get update; apt-get install osse-idmanagement` to keep the system serving the Mainzelliste up to date or
- `sudo apt-get update; apt-get install osse-datamanagement` for OSSE.EDC.

For OSSE Demo you can use

- `sudo apt-get update; apt-get install osse-demo` to keep the demo system up to date.

² If this step fails, the Ubuntu servers might be updated at the moment. Please wait and retry it later beginning with step 4 of the above guide for an already running Ubuntu server.

5 CONFIGURATION

5.1 LOGGING IN AS ADMINISTRATOR

Open a web browser and enter the address of your newly installed OSSE server into the URL bar.

Opening the registry for the first time will produce a certificate error and the browser will ask if you want to open the webpage anyways. It is safe to do that in this case as the respective server is under your control. To omit this error, you will have to acquire an SSL-certificate from your IT department or one of the certification authorities on the market.

After loading the webpage, you have to log in as administrator with the following details to set up the registry:

username: *“admin”*

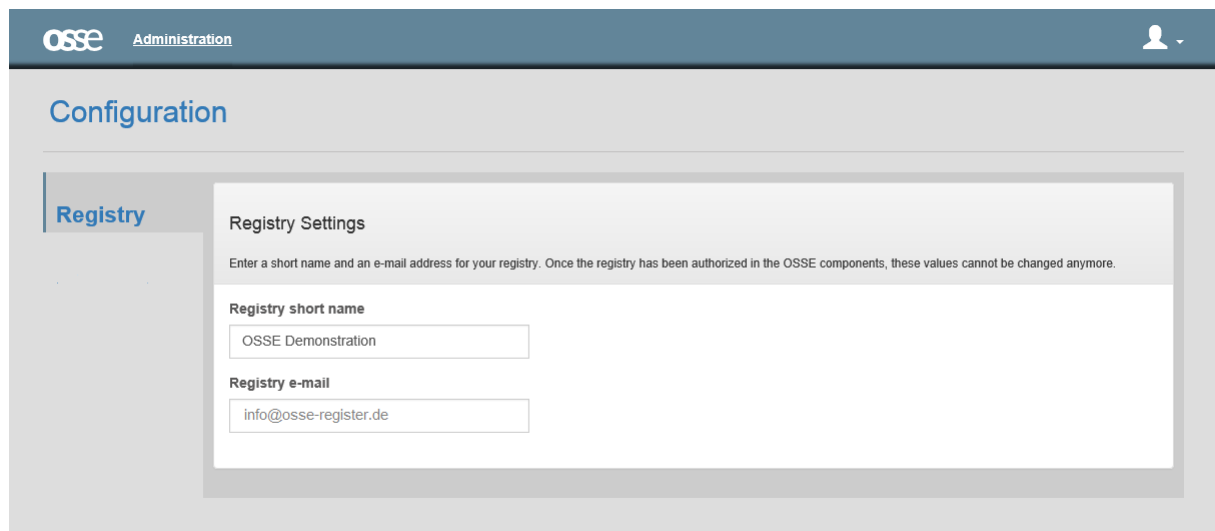
password: *“admin”*

Please remember to change the password as soon as possible via the administrator’s profile by clicking on the small white head in the upper right corner of the page.

5.2 REGISTERING YOUR REGISTRY

After starting a registry for the first time, the configuration area only contains one tab called “Registry”.

Enter a *short name* for your registry and a registry-specific *email address* and click on ‘Save’. Your registry will automatically register at the central authentication service (**Fehler! Verweisquelle konnte nicht gefunden werden.**). The *email address* and the *short name* of your registry will be used to authenticate your registry against other OSSE components (Metadata Repository, OSSE Form Editor).



The screenshot shows the OSSE Administration interface. At the top, there is a dark blue header with the OSSE logo and the word 'Administration'. Below this is a light blue bar with the word 'Configuration'. On the left side, there is a sidebar with a blue bar and the word 'Registry'. The main content area is white and contains a form titled 'Registry Settings'. Below the title, there is a note: 'Enter a short name and an e-mail address for your registry. Once the registry has been authorized in the OSSE components, these values cannot be changed anymore.' The form has two input fields: 'Registry short name' with the value 'OSSE Demonstration' and 'Registry e-mail' with the value 'info@osse-register.de'.

Figure 1

6 REGISTRY DESIGN

6.1 ACCESSING THE FORM EDITOR AND METADATA REPOSITORY

Designing a registry is a multistep process that involves the definition of data elements in the Metadata Repository (MDR), the creation of data entry forms in the OSSE Form Editor and the final configuration of the registry (Figure 2).

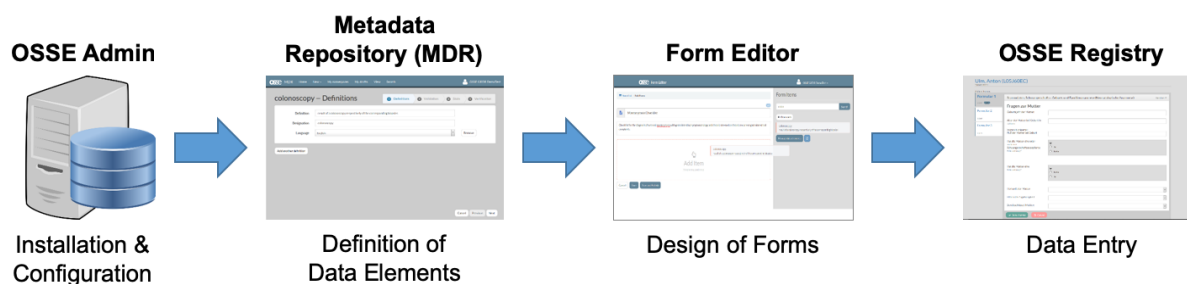


Figure 2

After logging into a registry with administrator rights, access the ‘Registry Design’ page where you can import data entry forms into the registry as either basic or longitudinal data forms (Figure 3). When setting up a new registry the list is empty and you first need to start by building forms and defining the required data elements.

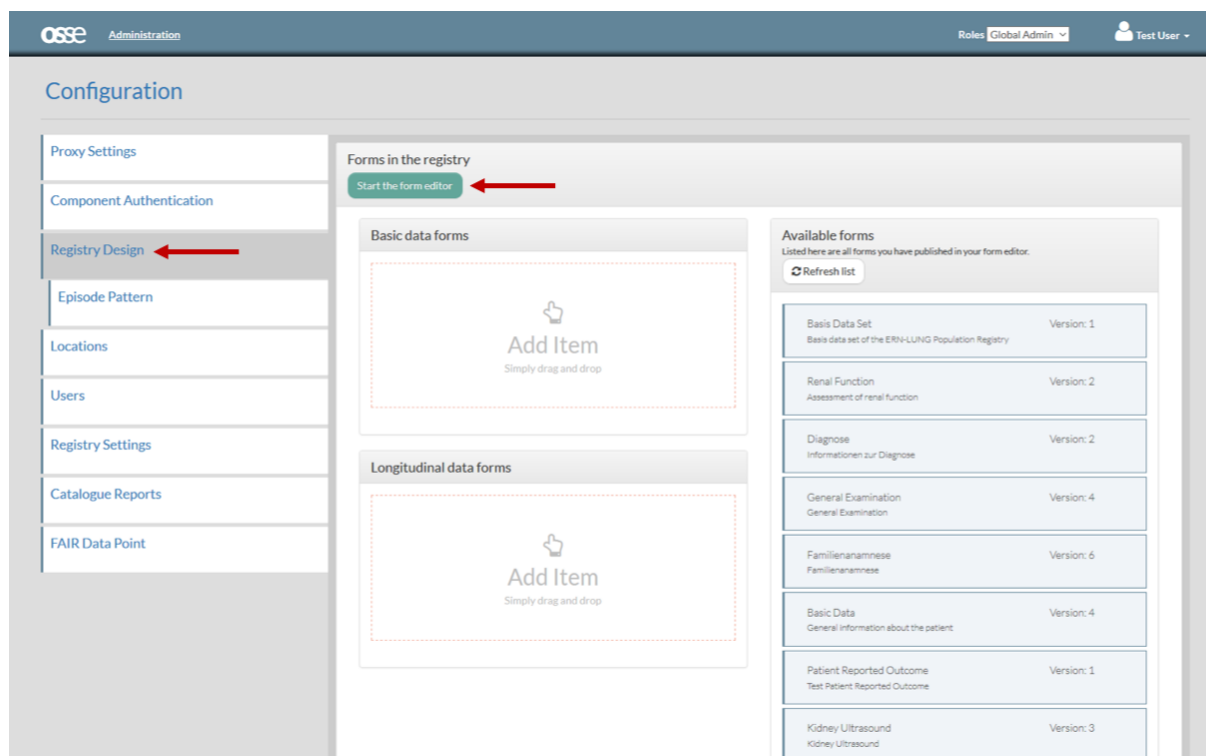


Figure 3

Click on ‘Start the form editor’ to open the OSSE Form Editor in a new browser window or tab. To create a new form, click on ‘New Form’ and enter a form name and a short description (Figure 4).

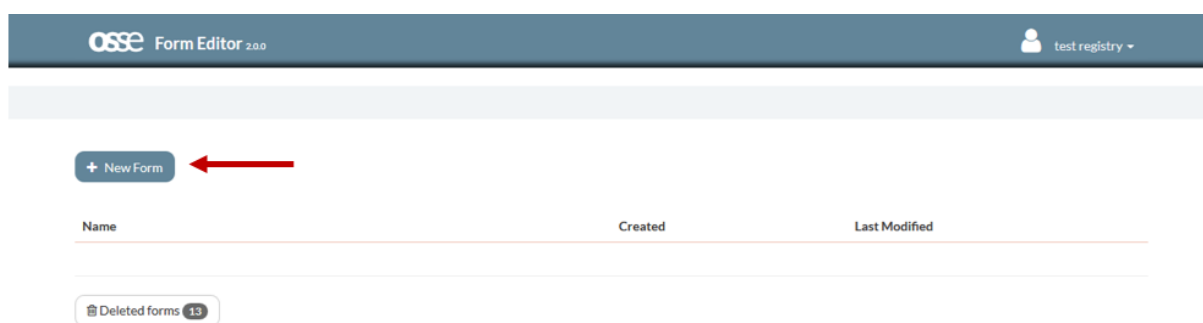


Figure 4

A list of available data elements to add to your forms is displayed on the right under “Form Items”. To define new data elements in the Metadata Repository (MDR) click ‘Manage data elements’ at the top of the list (Figure 5), which will open the MDR in a new browser window or tab. Please note that in older versions of the Form Editor the ‘Manage data elements’ button may be located at the bottom of the list.

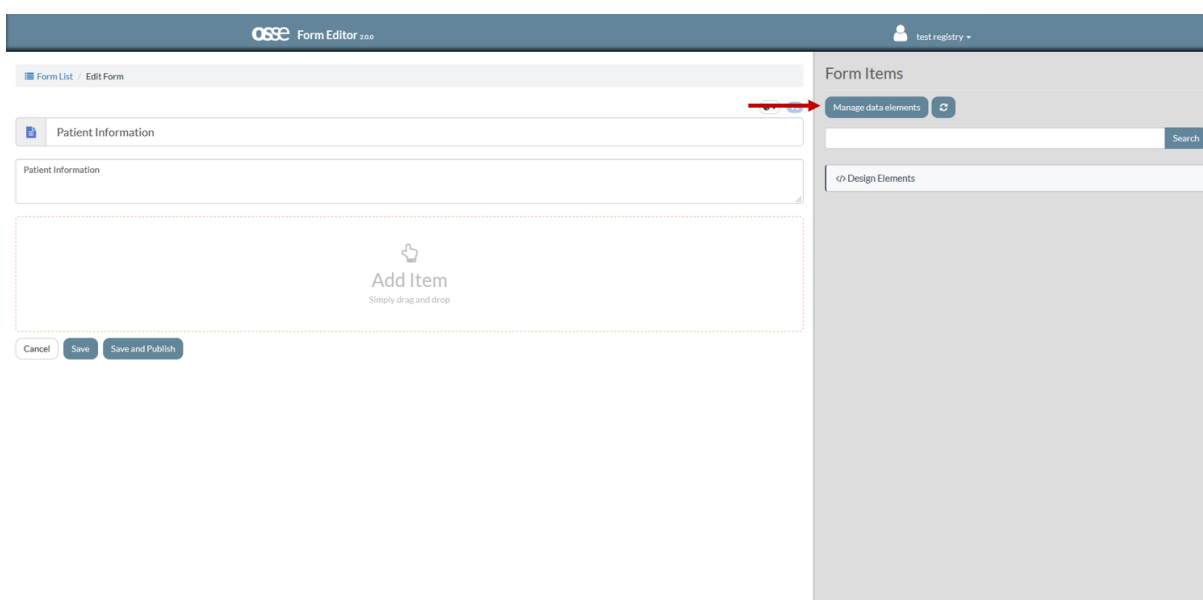


Figure 5

6.2 DEFINING DATA ELEMENTS IN THE MDR

Click ‘View’ in the navigation menu at the top to access previously created data elements in all available namespaces (Figure 6). The current MDR version provides one namespace per OSSE registry, which is named “osse-<registry ID>:<registry name>”. It is displayed as the first entry on the left under “My namespaces”, while other namespaces (i.e. data elements from other registries) are available in the corresponding section below. The list can be hidden via the ‘Show / Hide Namespaces’ button and filtered by entering a registry name in the search box. Selecting a namespace allows you to browse all data elements contained within that namespace (Figure 7).

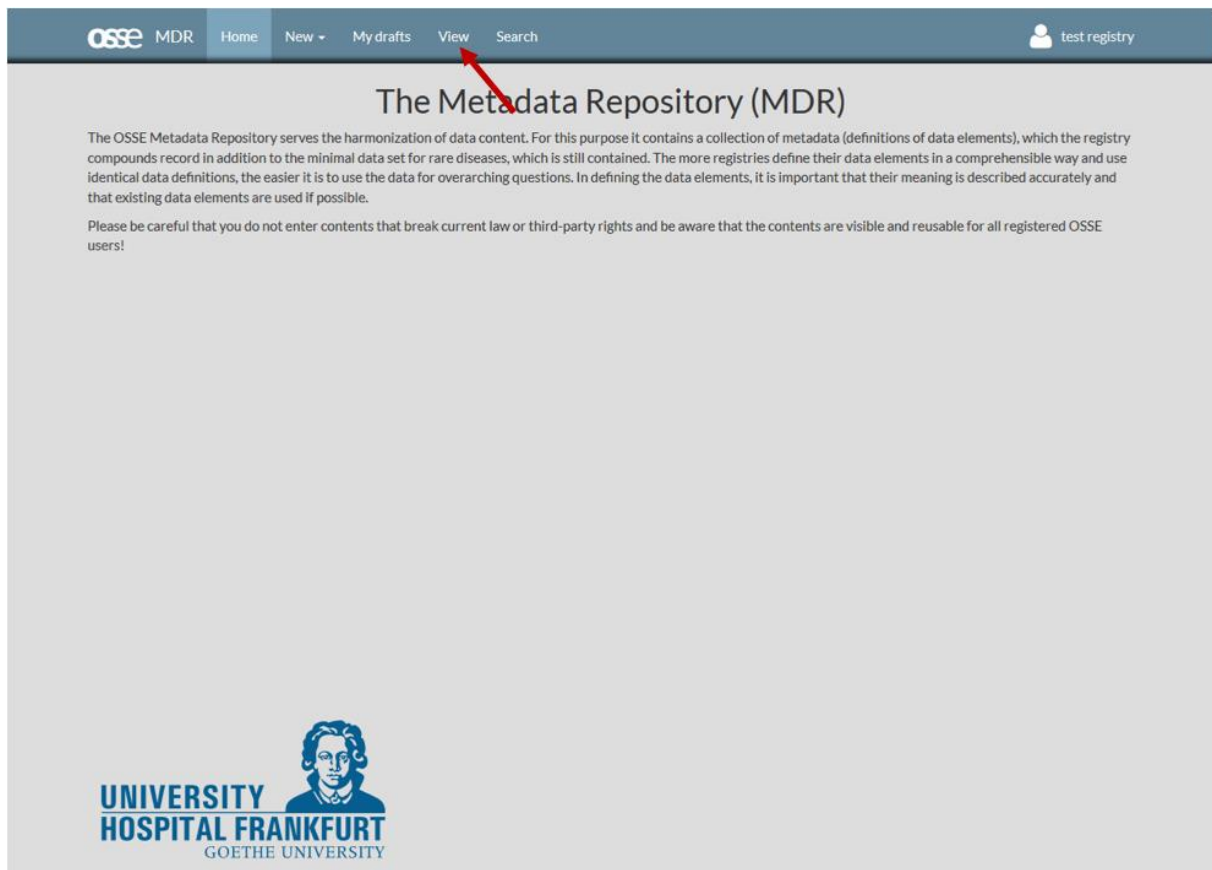


Figure 6

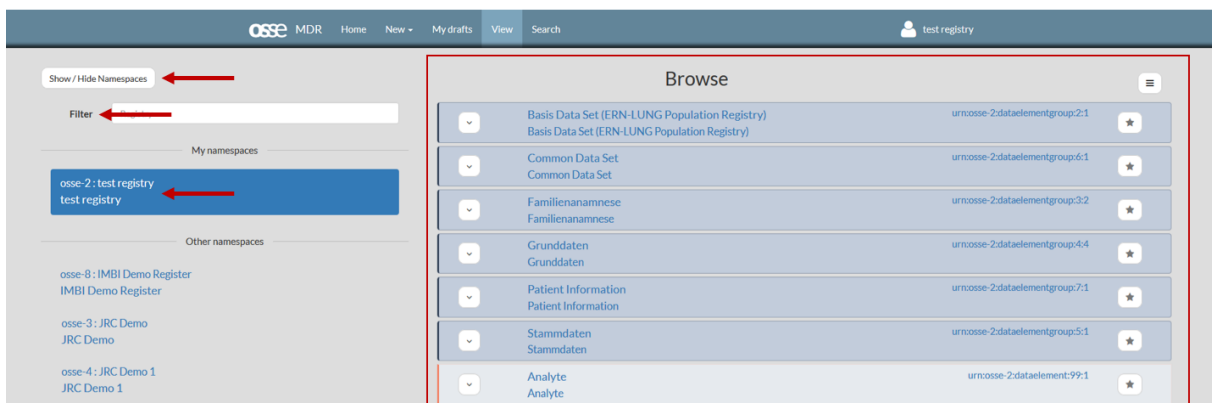


Figure 7

6.2.1 ADDING DATA ELEMENTS

There are several ways to add data elements to your namespace:

6.2.1.1 REUSING EXISTING DATA ELEMENTS FROM OTHER REGISTRIES

To copy a data element from another registry into your namespace select the respective namespace, open the data element and select your namespace under “Import into my namespace” in the options menu (Figure 8). A copy of this data element will now be available in your own namespace.

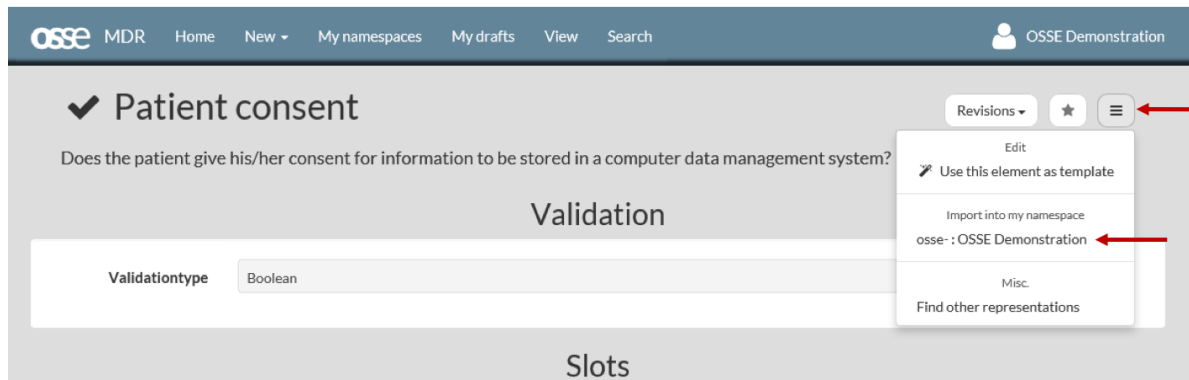


Figure 8

6.2.1.2 CREATING NEW DATA ELEMENTS

If you are unable to find a suitable data element you can create a new one. To do so open the ‘New’ menu at the top and select ‘New Dataelement’ (Figure 9). Afterwards follow the wizard on your screen to name and define the data element and specify the value domain. You can navigate through the different steps using the ‘Previous’ and ‘Next’ buttons.

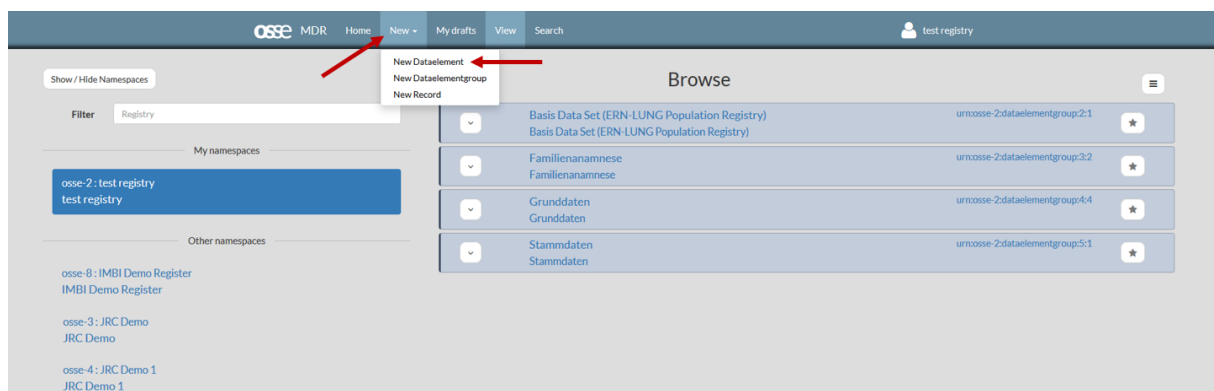


Figure 9

1. Definitions

Select a designation, or name, for the data element (Figure 10). This will be displayed next to the input box and can consist of key words or a written phrase or question (e.g. ‘Details’; ‘Age at diagnosis’; ‘Weight’; ...). Include a definition to add a short explanation or additional information regarding the data element. This is useful especially if the designation is not self-explanatory or ambiguous. The definition will appear as a tooltip in the form when the user hovers the mouse cursor over the label or input field. Both the designation and definition fields have to be completed in order to proceed. You also need to assign a language to the data element from the drop-down menu (currently supporting English, German, French or Spanish).

The screenshot shows the 'Definitions' step of the OSSE process. It includes a progress bar at the top with four steps: 1. Definitions (active), 2. Validation, 3. Slots, and 4. Verification. The main form has three input fields: 'Designation' with the value 'Consent', 'Definition' with the text 'Patient's consent exists for participation in the study', and 'Language' with a dropdown menu set to 'English'. A 'Remove' button is located to the right of the 'Language' field. Below the form is an 'Add another definition' button. At the bottom right, there are three buttons: 'Cancel', 'Previous', and 'Next'. A red arrow points to the 'Next' button.

Figure 10

2. Validation

In this step you have to specify which category the data element belongs to, e.g. whether it is a number, free text or list, and provide further information on the data element, e.g. a range or unit of measure (Figure 11). These properties cannot be modified at a later stage, so it is important to have a clear idea about the data element to be created.

The screenshot shows the 'Test – Validation' step of the OSSE process. It includes a progress bar at the top with four steps: 1. Definitions, 2. Validation (active), 3. Slots, and 4. Verification. The main form has four input fields: 'Validationtype', 'Within range', 'Range (from - to)', and 'Unit of measure'. A dropdown menu is open, showing a list of validation types: Integer, List of permitted values, Integer, Float, Boolean, String, Date (highlighted in blue), and Datetime.

Figure 11

OSSE supports a range of validation types which can be selected from the drop-down menu:

- “List of permitted values”: to select one or more answer options from a pre-defined list of values.
- “Integer”: to enter natural numbers without decimal points.
- “Float”: to enter numbers with one or more decimal points.
- “Boolean”: to make decisions between true and false, i.e. yes-/no-decisions or applicable vs. not applicable
- “String”: to enter any number of arbitrary characters (numbers and letters), e.g. to provide additional details as a free text.
- “Date”: to indicate a date (e.g. ‘date of last examination’) which can be displayed in different formats.
- “Time”: to indicate a time of day in either 12- or 24-hour time format.
- “Datetime”: similar to “Date” but including the precise time in either 12- or 24-hour time format as described in “Time”.
- “Catalogs”: to select data from a structured list of standard values such as the ICD-10 catalogue of medical diagnoses or a list of countries.

List of permitted values (Figure 12)

For each answer option, you have to enter a permitted value (the unique value that is stored in the registry), a designation (the name of the item which is displayed in the form) and a definition (a short explanation which is available in the form when hovering the mouse cursor over the item). In addition, you can specify the language, which is set to the data element's language by default. To add another answer option, click 'Add another permitted value' and complete the details as before. To remove an answer option, click the corresponding 'Remove' button.

The screenshot shows the 'Sex – Validation' form. At the top, there are four tabs: 1 Definitions, 2 Validation (active), 3 Slots, and 4 Verification. Below the tabs, the 'Validationtype' dropdown is set to 'List of permitted values'. Below this, there is a section for 'Permitted value' with a text input field containing 'Male', a 'Remove' button, and fields for 'Designation' (Male), 'Definition' (Male), and 'Language' (English) with another 'Remove' button. At the bottom, there is a button labeled 'Add another permitted value'. Red arrows point to the 'List of permitted values' dropdown, the 'Permitted value' input field, and the 'Add another permitted value' button.

Figure 12

Strings (Figure 13)

For strings you can specify a maximum length or a regular expression that the string has to match. Check the respective box and enter a number or regular expression if required.

The screenshot shows the 'Known diseases – Validation' form. At the top, there are four tabs: 1 Definitions, 2 Validation (active), 3 Slots, and 4 Verification. Below the tabs, the 'Validationtype' dropdown is set to 'String'. Below this, there are two checkboxes: 'Max length' and 'Use Regex'. The 'Max length' checkbox is checked, and the input field next to it contains '0'. The 'Use Regex' checkbox is unchecked. Red arrows point to the 'String' dropdown, the 'Max length' checkbox, and the 'Use Regex' checkbox.

Figure 13

Integers / Float (Figure 14)

For numbers (either with or without decimal points) you can specify whether the value needs to be in a certain range by ticking the 'Within range' box and entering an upper and/or lower limit below with the respective boxes checked. In addition, you can include a unit of measure such as "cm" or "mmol".

Height – Validation

1 Definitions 2 Validation 3 Slots 4 Verification

Validationtype: Integer

Within range: ☒

Range (from - to): ☒ 0 300 ☒

Unit of measure: cm

Figure 14

Date (Figure 15)

For dates you have the choice between different formats to display and store the date (Figure) and can decide whether the day should be included by checking or unchecking the ‘With days’ box.

Date – Validation

1 Definitions 2 Validation 3 Slots 4 Verification

Validationtype: Date

Date representation: YYYY-MM-DD, YYYY-MM (ISO 8601)
The local date format
YYYY-MM-DD, YYYY-MM (ISO 8601)
DD.MM.YYYY, MM.YYYY (DIN 5008, ...)

With days: ☒

Figure 15

Time (Figure 16)

For times you can choose between 12-hour and 24-hour time format and decide whether seconds should be included.

Time – Validation

1 Definitions 2 Validation 3 Slots 4 Verification

Validationtype: Time

Time representation: The local time format
The local time format
The 24 hours time format (22:34:54, 22:34)
The 12 hours time format (11:34:54 PM, 11:34 PM)

With seconds: ☒

Figure 16

3. Slots

This step allows to provide additional details for your data elements in the form of key-value pairs. These are not interpreted by the MDR but used by the OSSE software, for instance, to modify the way that fields are displayed.

Currently, this is only relevant for “List of permitted values” and can be skipped if using any other data type. For “List of permitted values” you now have the choice between different ways to display the answer options. By default, permitted values are presented as a drop-down list from which users can select a specific value. However, values can also be displayed as radio buttons, allowing users to select one option only, or checkboxes, allowing selection of several answer options (Figure 17).

Enter ‘inputType’ into the ‘Name’ field and either ‘SELECT_ONE_RADIO’ for display as radio buttons or ‘SELECT_MANY_CHECKBOX’ for display as checkboxes into the ‘Value’ field (Figure 18).

Dropdown lists

Degree of consanguinity

Siblings

Cousins (2nd degree)
Cousins (1st degree)
Siblings

Radio buttons

Known consanguinity of parents?

☐ Unknown
☐ No
☐ Yes

Checklists

Recent symptoms

☐ Swelling of feet / ankles
☐ Shortness of breath
☐ Chest pain
☐ Persistent itching
☐ Loss of appetite
☐ Fatigue
☐ Hypertension
☐ Vomiting
☐ Nausea
☐ Muscle cramps

Figure 17

osse MDR Home New ▾ My drafts View Search test registry

Status – Slots

1 Definitions 2 Validation 3 Slots 4 Verification

Name	Value	
inputType	SELECT_ONE_RADIO	Remove

Add another slot

osse MDR Home New ▾ My drafts View Search test registry

Recent symptoms – Slots

1 Definitions 2 Validation 3 Slots 4 Verification

Name	Value	
inputType	SELECT_MANY_CHECKBOX	Remove

Add another slot

Figure 18

4. Verification

In this step you can review and check all details before releasing the data element. Click 'Finish as draft' to save the data element but provide the opportunity to edit the data element later via the 'My Drafts' menu at the top. Click 'Finish and release' to release the data element and make it available for use in the Form Editor (Figure 19). Please note that parameters specified in the validation step, including data type, unit of measure and range, can no longer be changed once the element is released.

OSSE MDR Home New ▾ My drafts View Search test registry

BMI – Verification

1 Definitions 2 Validation 3 Slots 4 Verification

Language	Designation	Definition
EN	BMI	BMI (Body Mass Index)

Validation

Validationtype: Integer

Range: $0 \leq x \leq 50$

Unit of measure: kg/m^2

Identification

Identifier *: 59

Revision *: 1

Namespace *: osse-2 : test registry, test registry

Cancel Previous Finish as draft Finish and release

Figure 19

6.2.1.3 DERIVING NEW DATA ELEMENTS FROM EXISTING ONES

Existing data elements can be used as templates if the new element differs from the existing one only in a few details. Open an existing data element and select 'Use this element as template' from the options menu in the upper right corner (Figure 20). Proceed through the wizard as described above; all parameters of the new element can now be edited at will.

OSSE MDR Home New ▾ My drafts View Search test registry

Known diseases

Known diseases (patient)

Released Revisions ▾ ★ ≡

Validation

Validationtype: String

Max length: ☐ 0

Use Regex: ☐

- Edit
- ✎ Edit this element
- ✎ Use this element as template
- 🗑 Delete element
- Misc.
- Find other representations
- Duplicate this element

Figure 20

6.2.2 MODIFYING DATA ELEMENTS

Once a data element has been saved and released only certain properties can be changed via the 'Edit this element' option from the options menu in the upper right corner (Figure 21). These include the definition and designation of the element, the definition and designation (but not the value) of permitted values and any slots assigned to the element.

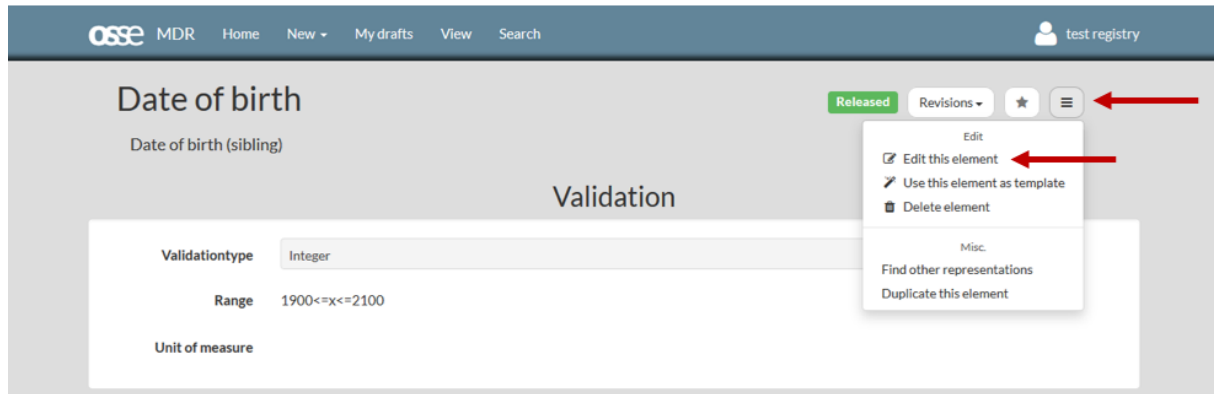


Figure 21

Other modifications, e.g. the data type, ranges or units, are no longer possible once a data element has been released. In order to make such changes you have to create a new data element using the existing version as a template as described above and modify it according to your needs. To avoid confusion and to ensure that you are working with the latest version of a data element, it is recommended to delete the outdated data element from the registry.

Please be aware that data elements are updated only in the MDR but not the registry forms. In order to apply any changes made to a data element, forms have to be revised by removing the outdated version and adding the updated version.

6.2.3 ELEMENT NUMBERS AND REVISIONS

An element number is assigned to each data element in the MDR which is displayed on the right side of each element in the list (e.g. "urn:osse-[ID]:dataelement:150:5"). In the given example the first number (150) represents the element number while the second one (5) indicates the number of revisions. If data elements are edited retrospectively the revision number increases by one. In the MDR, data elements are shown in the most recent version by default. To view earlier versions of data elements, open the element and select a version from the 'Revisions' drop-down list. The current version is indicated by a green bar ('Released') while previous versions are labelled 'Outdated' in orange. Each version can be used as a template for new data elements.

6.2.4 ARRANGING DATA ELEMENTS IN RECORDS

Records can be used to group data elements in major units, which can be used as a cluster in forms. This is especially useful to generate table structures in the registry as described below (Figure 22).

To create a record, go to the MDR and select 'New record' from the 'New' menu. Enter a designation and a definition, which will appear as headings on top of the cluster in the registry form. Click 'Next', select a namespace and drag and drop data elements from the list on the right to the 'Add Item' field. Elements can be deleted from the record using the bin symbol on the right. The double arrows on the left can be used to change the order of elements within the record. Click 'Next', proceed to the verification page (skipping the 'Slots' step) and click 'Finish and release' (Figure 23).

to group data elements

Mother

Year of birth

Ethnicity

Chronic kidney disease?

☒ ☐ Unknown
☐ No
☐ Yes

Other chronic disease?

to create tables (repeatable record)

Laboratory analysis

Date	Analyte	Measurement	Unit of measurement	Further details	Action
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	

[Add new entry](#)

Figure 22

osse MDR Home New My drafts View Search test registry

Laboratory analysis – Assign record entries

Filter Registry

My namespaces

osse-2: test registry
test registry

Other namespaces

osse-8: IMBI Demo Register
IMBI Demo Register

osse-3: JRC Demo
JRC Demo

osse-4: JRC Demo 1
JRC Demo 1

osse-5: ParaReg-Test
ParaReg-Test

osse-6: ParaRegTest
ParaRegTest

Browse

- Basis Data Set (ERN-LUNG Population Registry)
Basis Data Set urnosse-2:dataelementgroup:2:1 (ERN-LUNG Population Registry)
- Common Data Set
Common Data Set urnosse-2:dataelementgroup:6:1
- Familienanamnese
Familienanamnese urnosse-2:dataelementgroup:3:2
- Grunddaten
Grunddaten urnosse-2:dataelementgroup:4:4
- Stammdaten
Stammdaten urnosse-2:dataelementgroup:5:1
- Analyte
Analyte urnosse-2:dataelement:99:1
- Consent
Patient's consent exists for participation in the study urnosse-2:dataelement:85:1
- Date
Date of analysis urnosse-2:dataelement:98:1

Cancel Previous Next

Figure 23

Please note that records are linked to a specific version of a data element and any changes made to data elements will not be applied to the record. To update a record after modifying a data element, you will have to create a new record, either from scratch or using the existing record as a template. Similarly, adding or removing data elements to or from a record retrospectively is currently only possible by creating a new record.

To modify a record using an existing version as a template, select the record and click on 'Use this element as template' from the manual in the upper right corner. In the second step of the wizard you can remove or add data elements as required, e.g. replacing an outdated version of a data element with an updated one. Finish and release the record as described above.

6.2.5 ARRANGING DATA ELEMENTS IN GROUPS

Data elements can be arranged in groups, which is recommended especially for bigger registries to structure the contents. Groups will appear as one item in the MDR and the Form Editor and can be opened by clicking on the folder icon to display data elements within the group.

To create a new data element group, select 'New dataelementgroup' from the 'New' menu in the MDR. Enter a designation and definition and drag and drop elements from your namespace on the right into the field on the left. Click 'Next', ignore the slots step and click 'Finish and release' to save the data element group. Similarly, to records, any changes made to data elements will not automatically apply to the data element group. However, it is possible to retrospectively add or remove data elements to or from a group by selecting 'Edit this element' and making the desired changes.

6.3 DESIGNING FORMS IN THE FORM EDITOR

After defining the required data elements exit the MDR and return to the Form Editor. Click the refresh icon at the top of the page to update the list on the right (Figure 24). Please note that in older versions of the Form Editor the button may be located at the bottom of the list. In contrast to the MDR, where data elements are listed alphabetically, data elements appear in the order of release here..

Forms can be built by dragging and dropping data elements from the list to the form area on the left. To remove a data element from the form, use the bin icon on the right (Figure 24). The order of data elements on the form can be changed using the double arrows on the left and dragging it into the correct position. It is important not to rush this step and to give the page a moment to readjust after adding, removing or repositioning a data element. In addition, the 'Design Elements' button at the top of the list allows inserting design elements such as formatted text or horizontal rules, e.g. to create sub-headings.

Fields that require an input by the user should be checked as 'Mandatory'. Fields that are supposed to be completed several times in the same form can be checked as 'Repeatable'. This is especially useful in order to create tables such as a list of current medication. All data elements to be included in the table (as columns) need to be arranged in a record (see above) which can then be added to the form and marked as 'repeatable' (Figure 25).

Please note that you might be logged out of the Form Editor automatically when you interrupt your work on the form for a while. Similarly, any unsaved changes of the form will be lost if you are leaving the page by mistake. To prevent loss of data, we recommend to use the 'Save' button and save incomplete forms while working on them. To release the final form and enable its use in the registry later on click the 'Save and Publish' button (Figure 25).

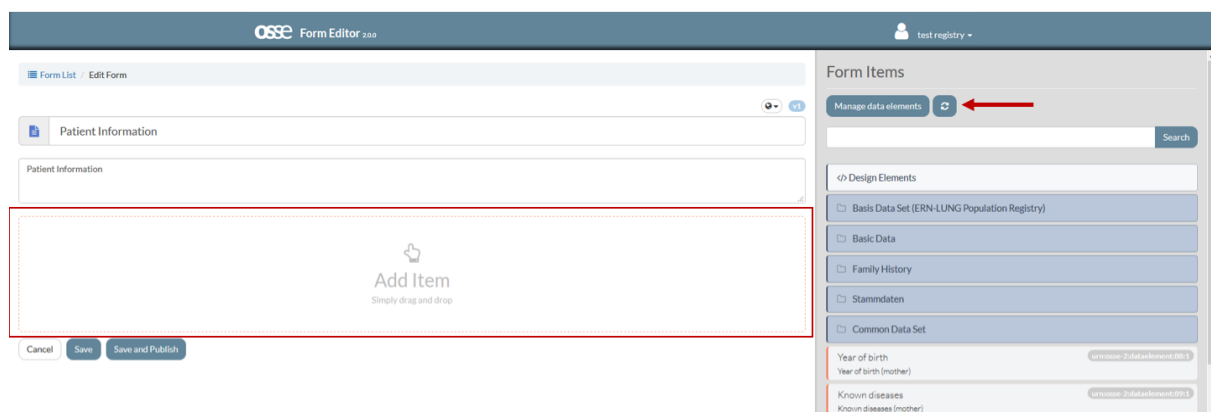


Figure 24

OSSE Form Editor 2.0.0

test registry

Form List / Edit Form

Patient Information

Patient Information

Sex

Consent

Status

Known diseases

Cancel Save Save and Publish

Weight

Recent symptoms

Date

Analyte

Measurement

Unit of measurement

Mother

Father

Siblings

Laboratory analysis

Patient Information

Sex

Consent

Status

Known diseases

Figure 25

You can return to the starting page of the Form Editor by clicking on 'Form List' in the top left corner. Existing forms can be viewed and changed by either selecting the form name or 'Open' in the menu accessible via the arrow on the right. This menu also allows you to view previous versions ('All versions' -> v1 etc.), make a copy or delete the form. The current version of each form and whether it is published for use in the registry is indicated next to the name in the list (Figure 26).

OSSE Form Editor 2.0.0

test registry

+ New Form

Name	Created	Last Modified
Patient Reported Outcome v1 published	Mon, 30 Sep 2019 10:51	Mon, 30 Sep 2019 10:51
Common Data Set v2 published	Mon, 30 Sep 2019 10:09	Mon, 30 Sep 2019 10:09
Familienanamnese v6 published	Mon, 26 Aug 2019 07:29	Fri, 27 Sep 2019 08:27
Diagnose v2 published	Mon, 26 Aug 2019 07:25	Mon, 26 Aug 2019 07:25
Nierenfunktion v2 published	Thu, 22 Aug 2019 09:39	Thu, 22 Aug 2019 09:39
Stammdaten v4 published	Thu, 22 Aug 2019 09:34	Thu, 22 Aug 2019 09:35
Allgemeine Untersuchung v4 published	Thu, 22 Aug 2019 09:29	Thu, 22 Aug 2019 09:29
Nierensonographie v3 published	Thu, 22 Aug 2019 09:27	Thu, 22 Aug 2019 09:27
Basis Data Set v1 published	Tue, 25 Jun 2019 09:19	Tue, 25 Jun 2019 09:19

Deleted forms 13

Figure 26

6.4 IMPORTING FORMS INTO THE REGISTRY

To build your registry return to the registry design page and refresh the list of available forms by clicking 'Refresh list' (Figure 27). Import forms into your registry by simply dragging and dropping them from the list on the right to the upper (*basic data*) or lower (*longitudinal data*) left area. Forms can be removed from the registry by clicking the bin icon. Once you have finished adding forms to your registry click 'Save changes'; a pop-up message will confirm that the forms have been imported and are available to use in data management (Figure 28).

Please note that changes to registry forms made in the Form Editor will not automatically appear in the forms previously imported into the registry. If you modify existing forms you will have to manually remove the outdated form from the registry and replace it with the latest version after clicking 'Refresh list'.

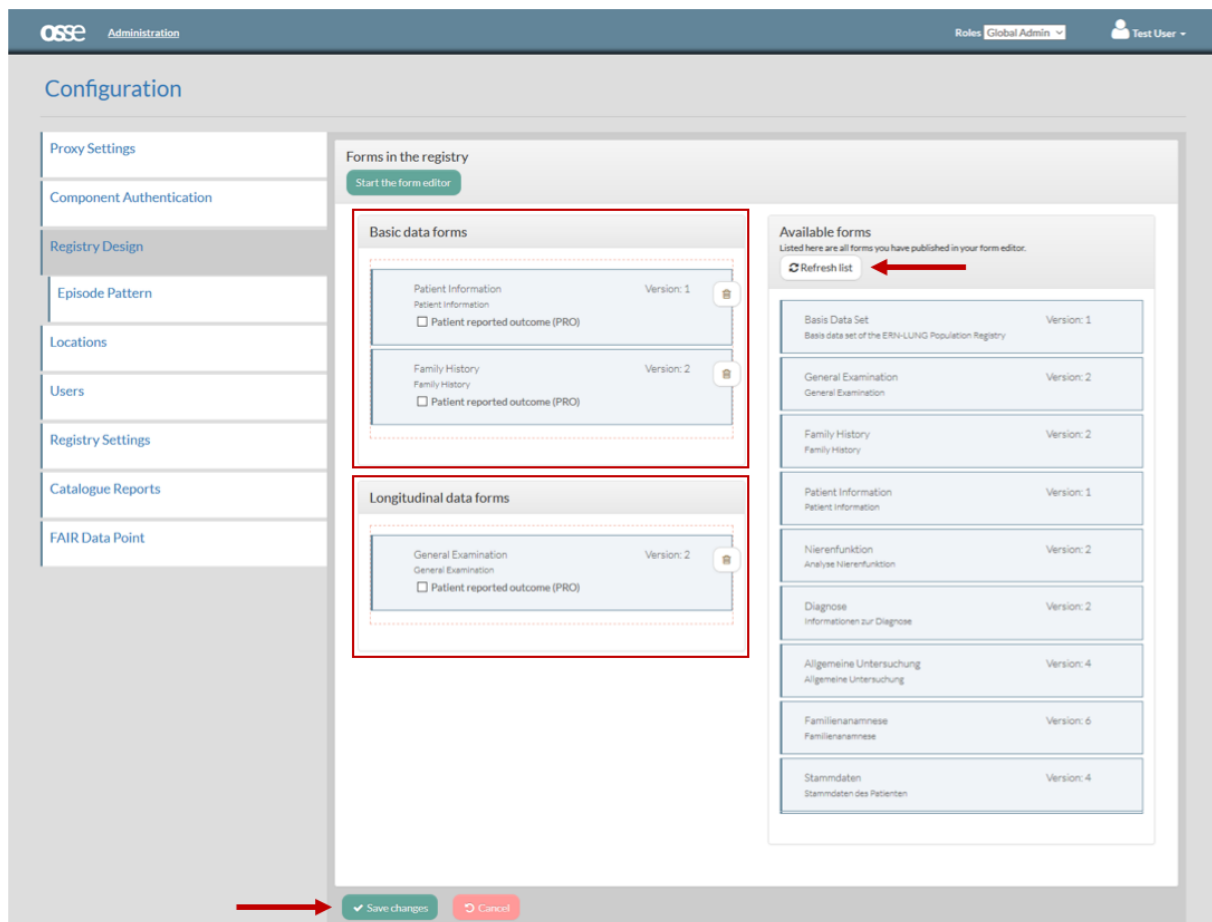


Figure 27

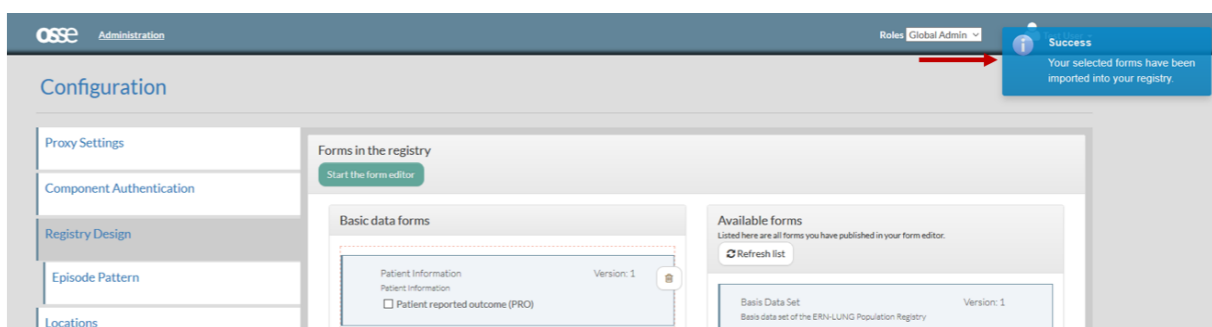


Figure 28

7 USER MANAGEMENT

Before starting to use a registry you have to define your access policy, i.e. define registry locations, assign users and permissions.

7.1 DEFINING LOCATIONS

First you have to define the different locations such as research centres, clinical departments or medical practices where patient data will be entered. Go to the “Locations” page, to access the list of existing locations (Figure 29). Click ‘Add new location’ and enter the location name, address and contact data for each location (Figure 30). Please note that it is not recommended to modify details of a location retrospectively, since this can cause issues regarding the assignment of patients to this location.

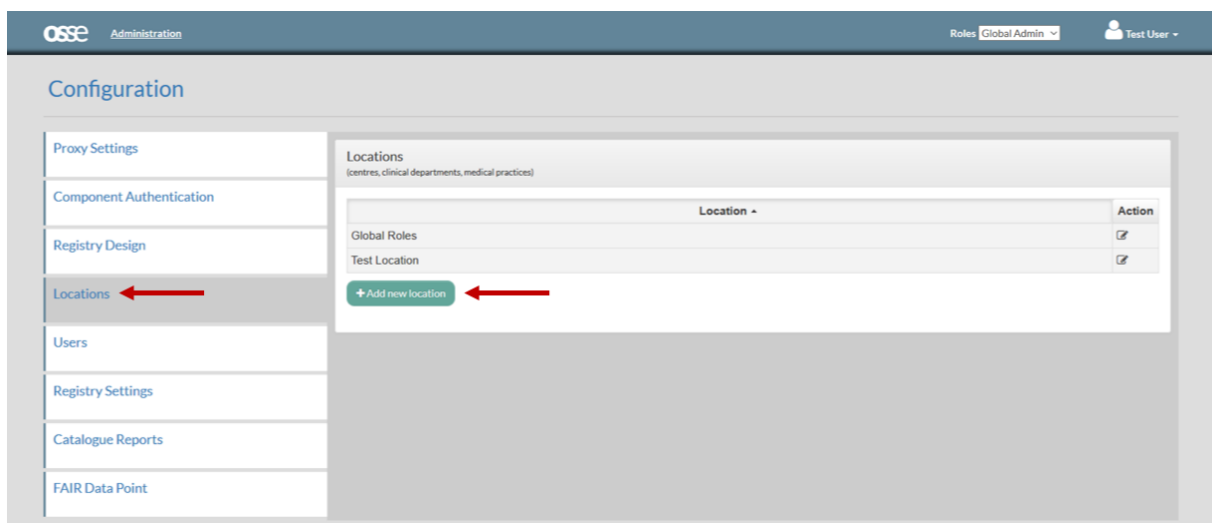


Figure 29

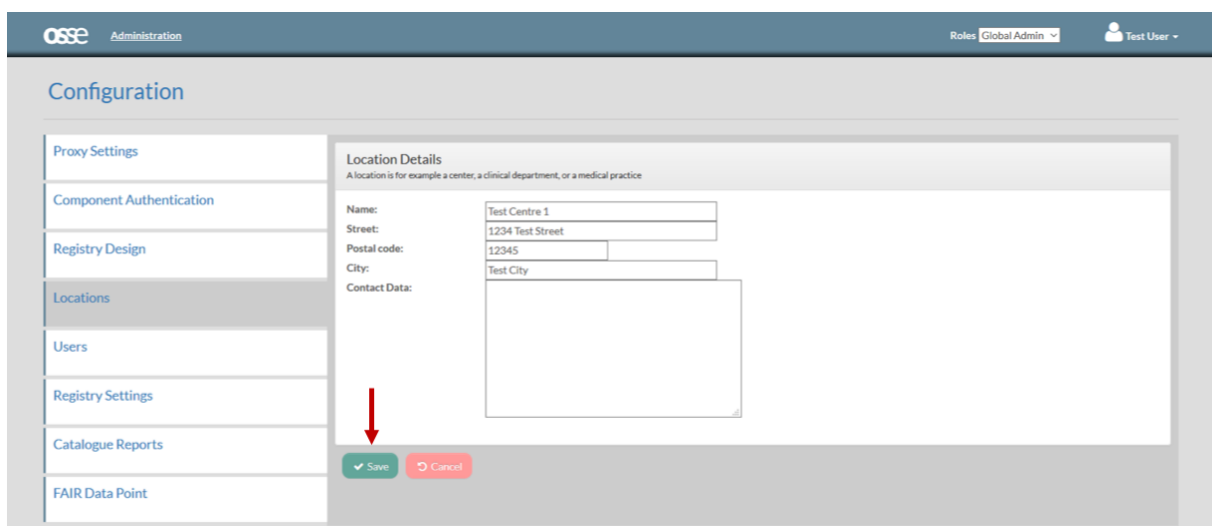


Figure 30

7.2 DEFINING ROLES

Roles are necessary in order to assign the appropriate permissions to registry users according to their tasks and location.

To define a new role, go to the “Users” page, select ‘Roles’ and click on ‘Add new role’ (Figure 31). Here you have to enter a role name and location and select permissions for the role by dragging and dropping items from the list on the right (Figure 32). In the current version OSSE provides pre-defined permission sets; in a later version there will be an enhanced interface for a more fine-grained definition of permissions.

The following permission sets are currently available in OSSE:

- “DataEntry”: permission to read and enter medical data
- “DataEntry+”: permission to add new patients and to read and enter medical data
- “DataRead”: permission to read data
- “DataReport”: permission to change the form status from open to reported
- “DataValidation”: permission to change the form status from reported to validated
- “RemoveValidation”: permission to change the form status from validated to open again
- “DataExport”: permission to export all medical data
- “PatientAccounts”: permission to handle patient accounts
- “See my IDAT”: permission to see the IDAT of patients of your own location
- “See all IDAT”: permission to see the IDAT of any patient, not only those of your own location

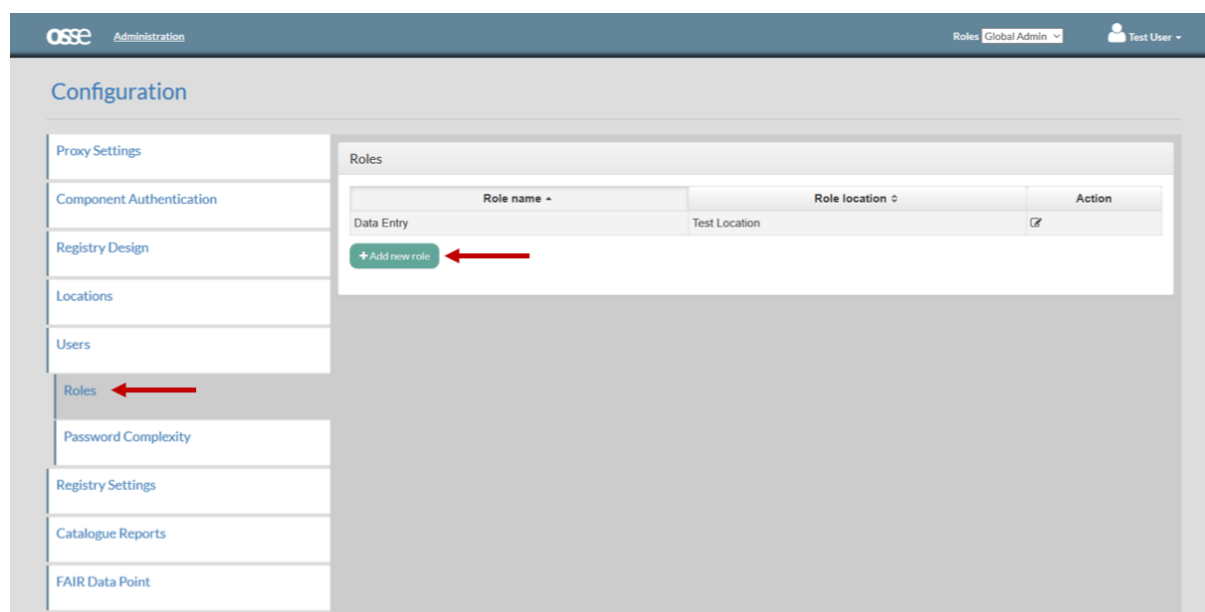


Figure 31

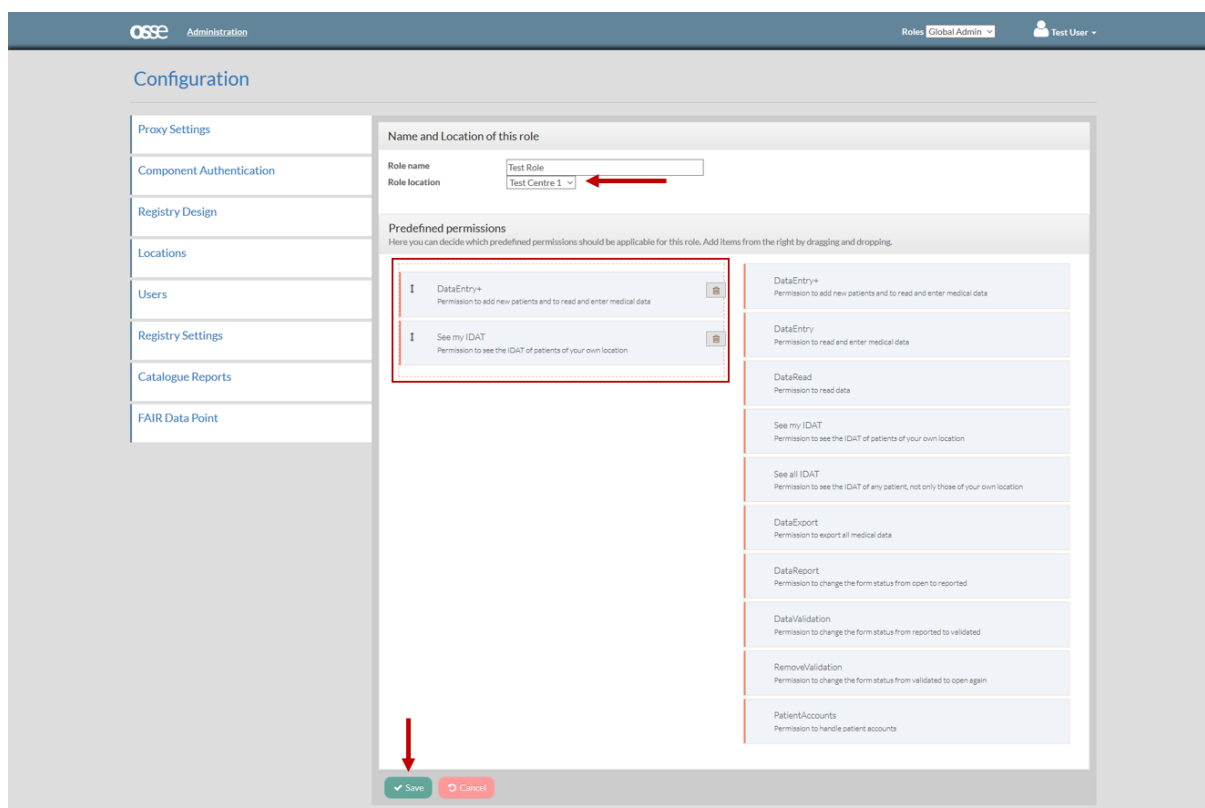


Figure 32

7.3 DEFINING USERS

Go to the “Users” page to add registry users by clicking on ‘Add new user’ (Figure 33). For each new user enter the real name (first name, last name) and a user name and provide an email address in the corresponding field. Assign as many roles to the user as necessary by clicking ‘Add new entry’ and selecting a role from the drop-down list; each user can hold one or more roles. Enter and repeat a password and save the user by clicking ‘Add new user’ (Figure 34).

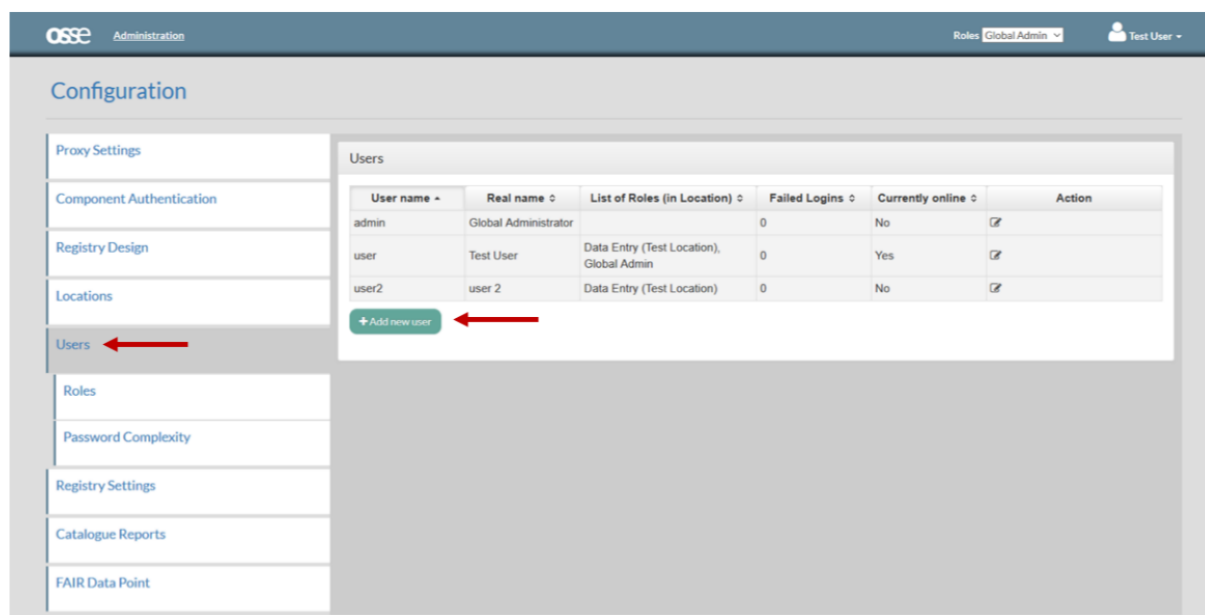


Figure 33

OSSE Administration Roles: Global Admin Test User

Configuration

Proxy Settings
Component Authentication
Registry Design
Locations
Users
Roles
Password Complexity
Registry Settings
Catalogue Reports
FAIR Data Point

User name
Enter the name of the person, the designated username in the registry

Username:
Title:
First name:
Last name:
Email address:

Roles of the user
Define which roles the user shall have in the registry.

Role	Action
Test Role (PRO)	
Test Centre 1 Admin	

Add new entry

Password

Password:
Repeat password:

Add new user Cancel

Figure 34

The password complexity can be defined in the corresponding menu on the left. You can also modify the details or role assignment of existing users or user passwords by selecting a user name from the list on the “Users” page and amending the data accordingly. Click ‘Change user data’ to save any changes made.

7.4 SETTING UP LOCAL ADMINISTRATORS

As registry administrator you can appoint local administrators, who can create users and assign roles at their individual locations. Select the users intended for this task and assign the corresponding location administrator roles that were automatically created.

8 DATA MANAGEMENT

To access and manage patient data, log in to the registry as a user with data access permissions, e.g. 'DataEntry+' (Figure 35). Different roles confer different levels of access (e.g. entering data, exporting data, adding patients), so you should make sure to have the right set of permissions required for your task. Management of users and the respective roles and permissions is performed by (local) registry administrators; please contact them with any access-related issues.

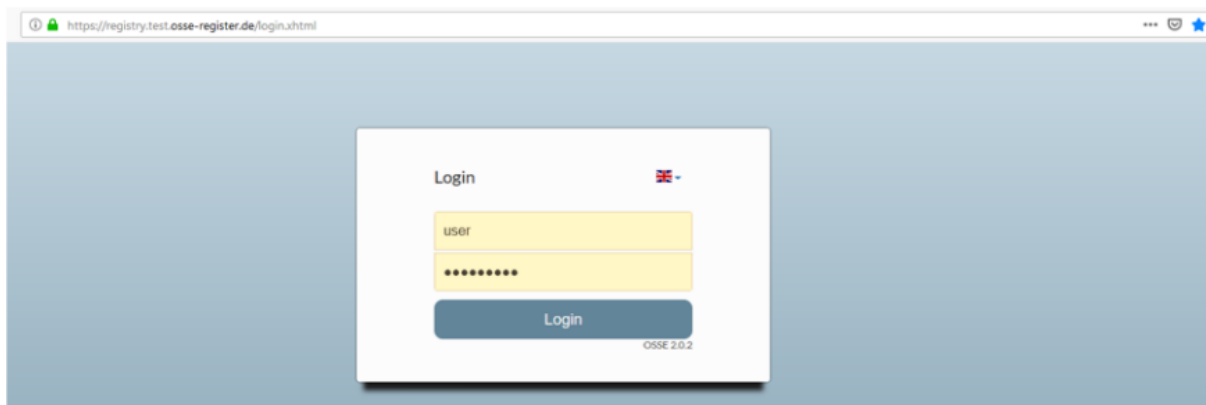


Figure 35

8.1 USER PROFILE

The user profile can be accessed by clicking on the user name in the top right and selecting 'Edit Profile'. It allows users to select a default role and change their own password (Figure 36). Since the password is set by a (local) registry administrator when setting up a user account, it is recommended that users change their password following the first login.

For a user with several roles, e.g. data entry and administration or data entry for different locations, the current role can be changed in the drop-down menu at the top of the page.

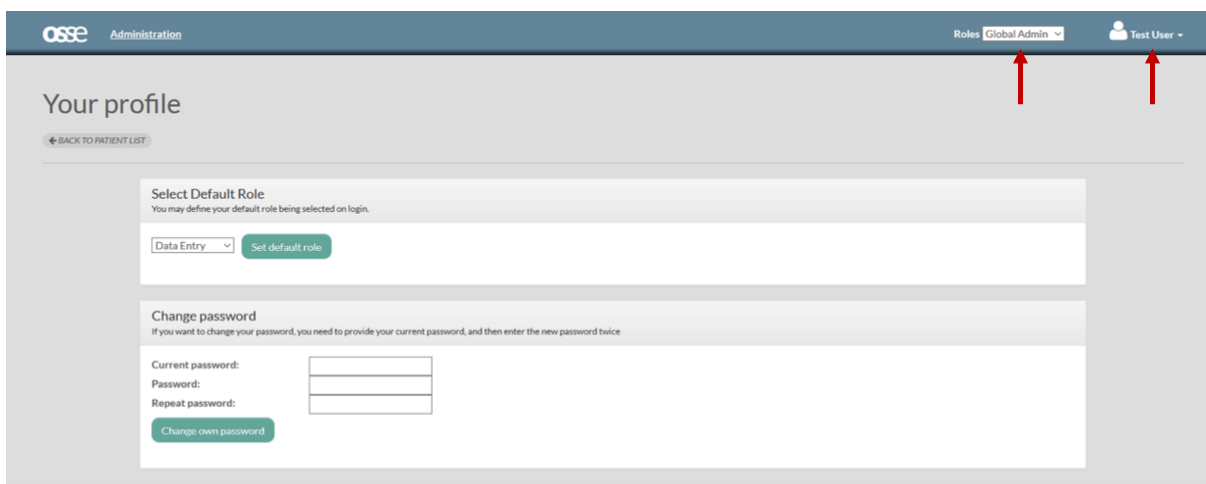


Figure 36

8.2 PATIENT LIST

All patients recorded in the registry are displayed in the patient list (Figure 37). The first column contains either only the PID or the name and the PID of a patient, depending on the location and permission set of your role. The patient's date of birth is displayed in the second column (if available) while the third column contains the location where the patient was added. The icons in the last column allow you to edit, export or delete the patient and his data.

The columns can be sorted in ascending or descending order by either clicking on the column name or the arrows in the top right corner of the title row. You can search the patient list via the text box ('Search'), e.g. for a specific location or patient name, and filter for patients with open or reported forms ('Filter'). From any of the following screens you can return to the patient list by clicking 'Overview' in the top left corner.

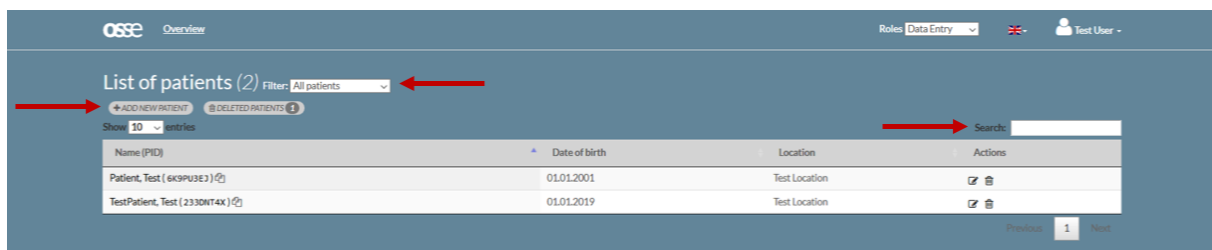


Figure 37

8.2.1 ADDING NEW PATIENTS

To add a new patient to the registry, click the '+ADD NEW PATIENT' button to access the user interface of the Mainzelliste pseudonymization software. Enter the patient's first name(s), name, birth name (optional, if different from last name), birthdate, zip code (optional) and city (optional) and click 'Add patient' (Figure 38). A pseudonym will now be requested for this patient. If the patient already exists in the Mainzelliste, the existing pseudonym (PID) is returned, otherwise a new one will be created. It is not possible to create a new pseudonym for a patient with personal data (name, date of birth) identical to a patient already stored in the Mainzelliste.

The screenshot shows the 'New patient' form. At the top, it says 'OSSE' and 'New patient'. Below this is a section titled 'Personal data'. A paragraph explains that the application produces a patient identifier (PID) based on the entered personal data and that a matching record will be returned if one exists. Below this are four bullet points providing advice on how to enter data. The form fields are: 'First name(s):' with the value 'Test', 'Last name:' with the value 'Patient', 'Birth name:' with the value 'New', 'Date of birth:' with a date picker set to '01 January 2001', and 'City of residence: (Postal code / City)' with two empty input fields. At the bottom, there are two buttons: 'Add patient' (green) and 'Cancel' (red). A red arrow points to the 'Add patient' button.

Figure 38

Sometimes a patient with similar but not exactly matching data is found in the database. In that case you will be asked to either provide additional information if possible via the 'Correct data' button or confirm the details you entered via the 'Confirm data' button (Figure 39).

OSSE

Uncertain case

Personal data

An existing patient with similar data was found in the database. However, the similarity is not sufficient to match the entered data to the existing case.

Please check if your data is correct and if you can provide additional fields.

- Click "Correct data" to go back to the entry form in order to make corrections or to provide additional data.
- If you can assure that the data is correct and the patient has not been entered before, click on "Confirm data" to add a new patient with the entered data.
- If you are confident that this patient already exists in the database, please contact the database administrator in order to resolve the conflict manually.

First name(s): *

Last name: *

Birth name: * (if different)

Date of birth:

City of residence:

(Postal code / City)

Figure 39

After requesting a pseudonym for your patient, make sure to accept the verification dialog by clicking 'Save' or 'Save and another one' to add the patient into your OSSE registry (Figure 40).

OSSE Overview Roles Data Entry Test User

Patient, Test (6K9PU3EJ)

*01.01.2001

You have added the patient Patient, Test (*01.01.2001) to your Mainzliste. With this, the identifying attributes of your patient were pseudo-anonymised and the personal identifier (6K9PU3EJ) was created.

To finalize adding the patient into your registry, press save
In case you do not want to add this patient into your registry, press 'cancel'.

Figure 40

8.2.2 CHANGING PATIENT DETAILS

To modify a patient's personal data, click the corresponding edit symbol in the 'Actions' column of the patient list. Please be aware that you are making changes to patient data stored in the Mainzliste pseudonymization server, where patients for all locations of the registry are recorded. Any modifications made by you might therefore have side effects for other locations. In theory it is possible (but not recommended) to retrospectively modify a patient's name or date of birth without changing the pseudonym. This might result in two patients with identical personal data (name, date of birth) but different pseudonyms.

8.3 PATIENT DATA FORMS

To open the dataset of a patient, click on the patient name or the PID in the first column of the patient list. This will open a new page with two sections: a patient form containing all basic data forms and a carousel of episodes on top of the screen (Figure 41). Each episode represents a point in time or short period of time where longitudinal data is collected. You can navigate through the episodes, which are sorted chronologically, using the arrows on the left and right. Clicking on the date will open an episode and display a list of longitudinal data forms for this episode. To return to the start of the patient data set click on the patient name (or PID) on top of the screen.

The screenshot shows the patient data forms interface. At the top, the patient name and pseudonym are displayed: "TestPatient, Test (233DNT4X)" with a date of birth "01.01.2019". Below this is the "Episodes (2)" section, which includes a "NEW EPISODE" button and a carousel of two episodes: "25/03/2019 Episode 1" and "25/06/2019 Episode 2". The main section is the "Patient Form", which contains a sidebar with a "list of basic data forms" (Basis Data Set, open, Diagnosis, unused, Family History) and a main area with "data entry fields" for "Family History". The "Family History" section includes fields for "Mother" and "Father", each with "Year of birth", "Ethnicity", and "Chronic kidney disease?" (radio buttons for Yes, No, Unknown). There is also a "Known consanguinity of parents?" section with radio buttons for Yes, No, Unknown, and a "Degree of consanguinity" dropdown. At the bottom, there are "Save changes" and "Cancel" buttons. Red arrows point from the annotations to the corresponding elements in the interface.

patient name / pseudonym + date of birth

episode carousel (longitudinal data forms)

form name / description

list of basic data forms

data entry fields

Figure 41

8.3.1 MANAGING EPISODES

To create a new episode, click the '+ NEW EPISODE' button, enter the date and optionally a short text and click 'Save' (Figure 42). The episode is then added to the carousel on top of the screen and a list of empty longitudinal data forms will be displayed (Figure 43).

You have the option of importing one or all longitudinal data forms from the previous episode, i.e. transferring previously recorded data into the current episode. Click the corresponding button above the episode carousel and confirm that you want to proceed with the import; this will overwrite any existing data in the form(s). You will still be able to enter new data or change imported data of course. To delete an episode from the patient dataset, click the 'DELETE CURRENT EPISODE' button and confirm that you want to delete the selected episode in the dialogue.

OSSE Overview Roles: Data Entry Test User

Patient, Test (6K9PU3EJ)
*01.01.2001

Date of Episode * 02/10/2019

Optional text

Save Cancel

Figure 42

OSSE Overview Roles: Data Entry Test User

Patient, Test (6K9PU3EJ)
*01.01.2001

Episodes (2) +NEW EPISODE | OF EDIT CURRENT EPISODE | DELETE CURRENT EPISODE | TRANSFER THIS FORM'S DATA FROM LAST EPISODE | TRANSFER ALL FORM'S DATA FROM LAST EPISODE

02/09/2019 02/10/2019

Episode: 02/10/2019

General Examination
General Examination Version: 2

Height

Weight

Recent symptoms

- ☐ Muscle cramps
- ☐ Nausea
- ☐ Vomiting
- ☐ Hypertension
- ☐ Fatigue
- ☐ Loss of appetite
- ☐ Chest pain
- ☐ Shortness of breath

Laboratory analysis

Date	Analyte	Measurement	Unit of measurement	Action
No entries				

Add new entry

Figure 43

8.3.2 ENTERING PATIENT MEDICAL DATA

To enter medical data for a patient, select a form (its status will change from 'unused' to 'open') and fill in the appropriate values (Figure 44). After clicking the button 'Save changes', a pop up ('Saving succeeded') will confirm that the data you entered has been saved (Figure 45). Please be aware that any data you entered will be lost if you leave the page without successfully saving the changes made to the form. A warning message will appear when trying to leave a form with unsaved changes.

Figure 44

Figure 45

Some notes on entering or changing patient data:

- Hovering the mouse cursor over a field or item will display a tooltip with a short definition or further instructions for completing this field.
- If applicable make sure to enter values corresponding to the indicated unit of measurement (e.g. 'cm' or 'mmol/l').
- Mandatory fields are marked with an asterisk (*) and are highlighted red if you try and save changes without entering data. Please note that none of your data can be saved until all mandatory fields are completed.
- Some fields only allow entering values from a specified range or data type (e.g. whole numbers or decimal numbers). If the data entered exceeds the range or does not correspond to the specified data type, these will be highlighted red and display a short error message when trying to save the form. Please note that none of your data can be saved until any faulty entries are corrected.
- In some cases, additional items or questions will appear depending on the information you provide, e.g. 'How many children?' if you checked 'yes' when queried whether the patient has any children.
- In other cases, e.g. for a list of current medication, you might have to generate a table, providing the information indicated in the headers for each entry. After clicking the 'Add new entry' button, a row of data input fields becomes available for each column of the table. Existing rows can be deleted from the table using the bin icon on the right.