Getting started with the osse-Registry Toolkit

Authors   Dr. Marita Muscholl and Dennis Kadioglu
                 Johannes Gutenberg University Medical Center Mainz
                 Institute of Medical Biometrics, Epidemiology, and Informatics
                 55101 Mainz
                 Germany

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1 BEFORE YOU START

Please make sure that you have access to the following OSSE-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
- This Getting Started Guide describing steps to set-up an environment and steps to configure and use your first registry.

Before continuing, please be sure you have an understanding of the following concepts. This document will reference to those without further introduction:

- **Registry** with attributes like *short name* and *email address* for identification and for 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. For the creation of data entry forms, the **OSSE.FormEditor** allows to choose from the data elements defined in the MDR namespace of the registered registry. Preferably there is only one single instance of both systems to foster the reuse of data elements among different registries to achieve a high degree of comparable data.
- **Locations**, that are centres, clinical departments or medical practices of a research network, who share a registry. Each location may have a location administrator who is set up by the registry administrator.
- **Users, roles and permissions:** *Permissions* are defined on data classes (for ex. Forms), while *roles* are collections of permissions. A *user* can logon to a registry. The user has *roles* that provide him with the needed *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 Institute for Medical Biostatistics, Epidemiology and Informatics (IMBEI) at Mainz University Medical Center, Germany.
- For announcing the registry as rare diseases registry a registration form is currently supported for the coming German **Registry of Registers (RoR)**.

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

- According to the 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 data without showing the patients 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. Therefor 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 can't 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 like 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 update[1]
   ```
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 e-mail) 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 don't 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 the web browser will show a warning which has to be ignored until you install a valid certificate on the server.

If you don't have a running Ubuntu Server, you can download the ISO image and use it for the installation like 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 Mainzelliste has to be entered during the installation of the registry!)

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

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 don't 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 timezone 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've got an empty hard drive there won't 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 don't 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 case of that 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 begin[2]. 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 e-mail) 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 don't 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

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[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.

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've 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.

5 CONFIGURATION

5.1 LOGGING IN AS ADMINISTRATOR

Open your 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 should ask you 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 a SSL-certificate from your IT department or one of the certification authorities on the market.

After the webpage is loaded you have to log in as administrator with

username: *"admin"*

password: *"admin"*

to set up your registry. Please keep in mind to change the password as soon as possible via the administrators profile by clicking on the small white head in the upper right corner of the page.

You're now in the configuration area of your registry. As you've started it for the first time you will only see one tab called "Registry".

5.2 REGISTER YOUR 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 (*Figure 1*). The *email* address and the *short name* of your registry will be used to authenticate your registry against other OSSE components (metadata repository, form repository).

Figure 1

5.3 DESIGNING DATA ELEMENTS AND FORMS FOR YOUR REGISTRY

Go to the "Registry Design" page to define data elements and forms for your registry. As you've just started to set up a new registry there won't be any forms to choose from. By clicking on "Start the form editor" a new browser window or tab will be opened (*Figure 2*).
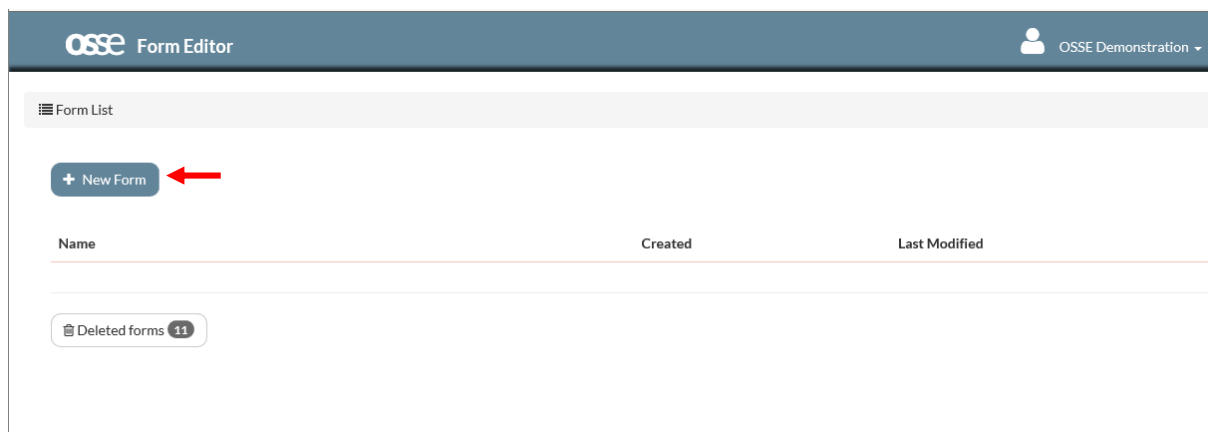
Figure 2

As already mentioned there won't be any forms in the form editor, too. So you will have to create at least one new form by clicking on 'New Form' (

Figure 3).
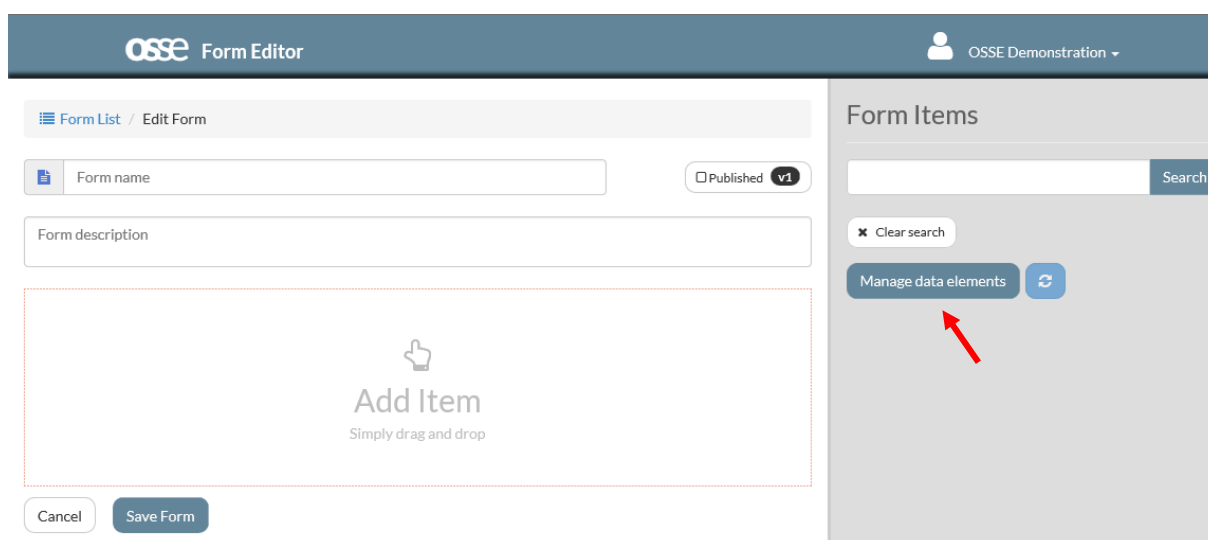
Figure 3

During the creation process of a new form you can then go to the MDR ("Manage data elements" button) in order to define data elements either by creating new ones or by deriving them from existing data elements. By clicking on *My namespaces* you can see all data elements of your own namespaces (*Figure 4*). The current MDR version provides only one namespace per OSSE registry, which is named "osse-:< *registered name of your registry* >". Other namespaces are available with the "View" menu. To copy a data element from other namespaces into your own namespace you have to open the data element and select your namespace identifier under "import into my namespace" in the options menu (*Figure 5*).
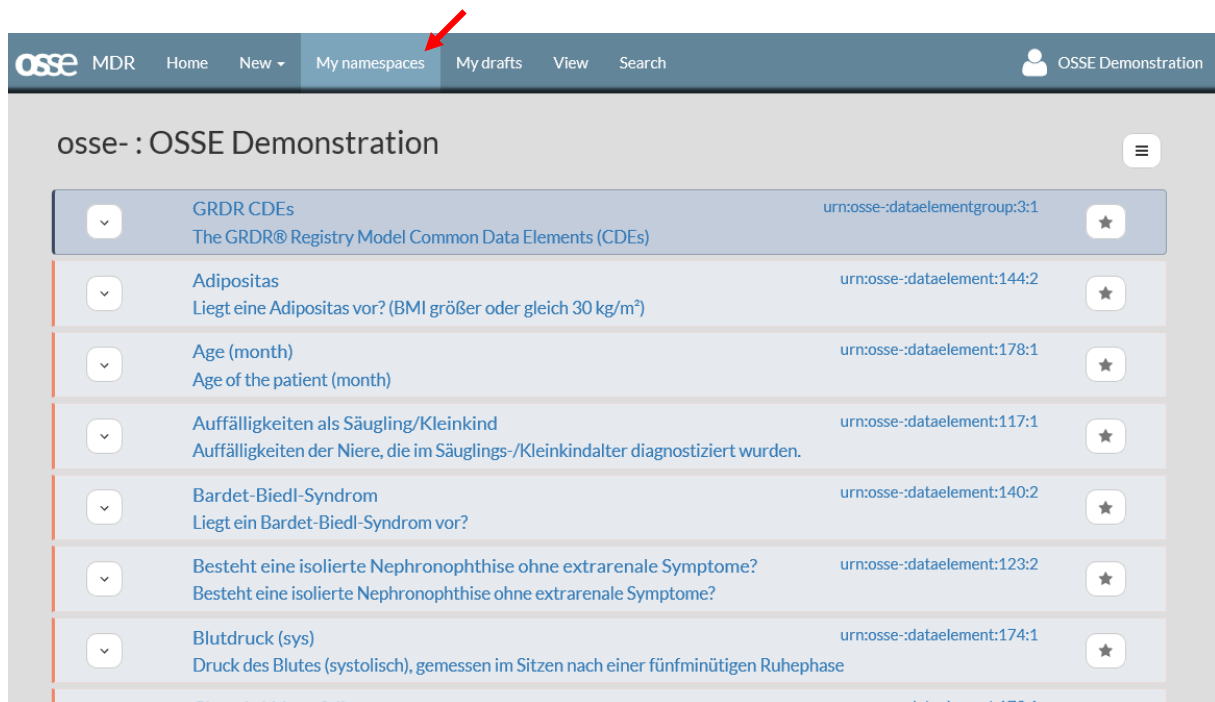
Figure 4
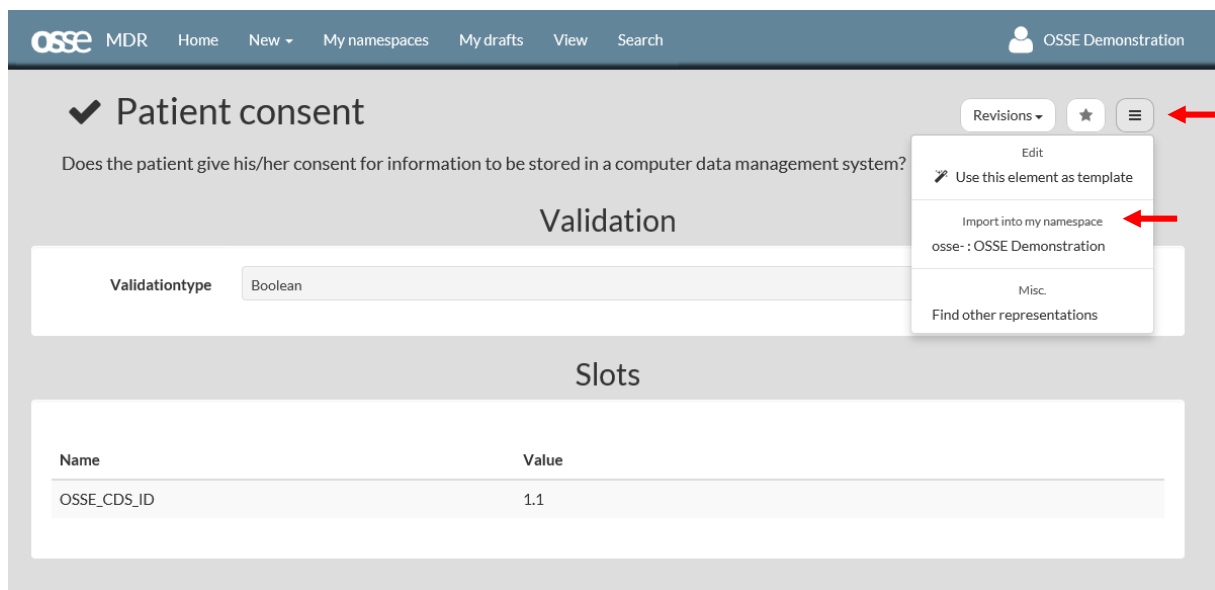
Figure 5

If you can't find an appropriate data element you can create a new one. To do that click on 'New' at the top and choose 'New Dataelement'. Afterwards follow the wizard on your screen to name and define the data element as well as to specify the value domain. You can ignore step 3 ('Slots') for now. In step 4 ('Verification') you only need to click on one of the two 'Finish' buttons. It is important that you release all data elements you want to use in your forms later on (

Figure 6).

Figure 6

After defining your data elements you can go back to the *form editor* and click on the refresh icon to update the list on the right. By simply dragging and dropping data elements and design elements (formatted text, horizontal rules etc.) to the form area on the left you can build your form according to your needs. Just as it is necessary to release the required data elements it is necessary to release the forms you want to use in your registry later on! For this check the "Published" box and(!) save the form (*Figure 7*Figure 8).

Figure 7

Figure 8

After you've finished designing your forms go back to the registry administration page and refresh the list of your forms. Import the forms you have designed as basic data forms or longitudinal data forms in your registry by simply dragging and dropping them from the right to the upper (*basic data*) or lower (*longitudinal data*) left area (*Figure 8*). After saving the forms they will be ready to use in the data management.

5.4   DEFINING LOCATIONS

Before you can start with the data management you have to enter your access policy. First you need to define the different locations (centres, clinical departments or medical practices) where patient data will be entered. Go to the "Locations" page, press 'Add new location' and enter the location name and address for each location (*Figure 9*).
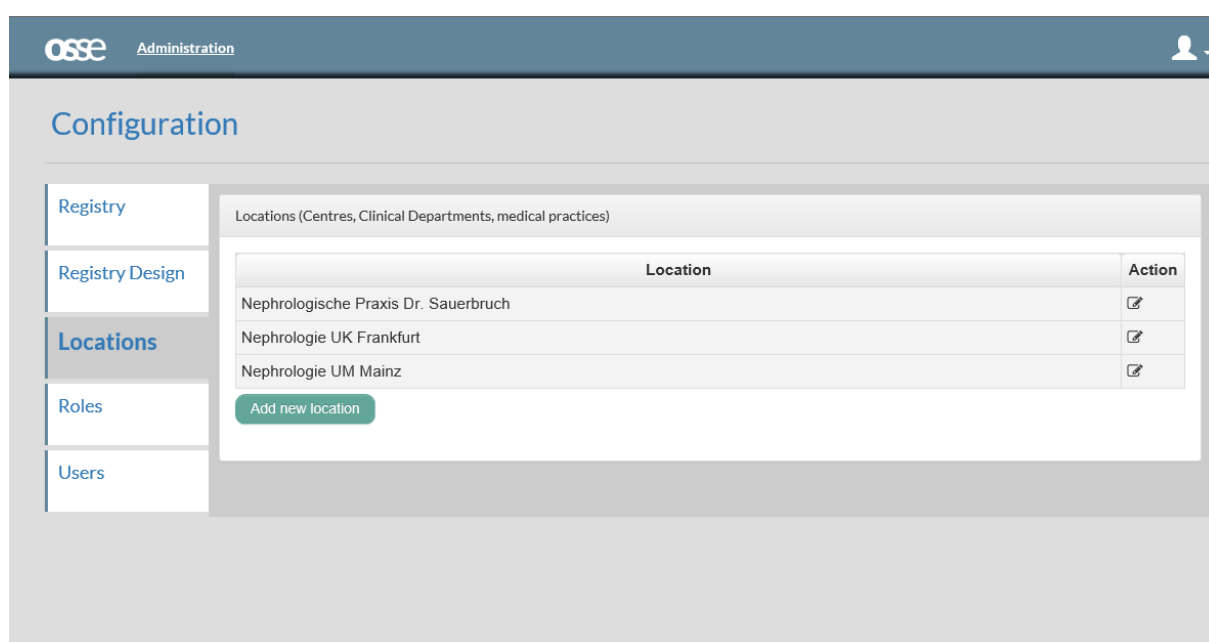
Figure 9

5.5   DEFINING ROLES

Define the necessary roles in order to assign the appropriate permissions to all of your users (who will be defined in the next step) according to their tasks (*Figure 10*). First enter a role name and the location domain for your role. In this version OSSE provides predefined permission sets that you can assign to a role. In a later version there will be an enhanced interface for a more fine-grained definition of permissions.

The following permission sets are available:

- "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

It is possible to assign combinations of those permission sets to a role.

Figure 10

5.6 DEFINING USERS

Go to the "Users" page to enter registry users by clicking on 'Add user'. For each new user enter the real name and a user name. Each user can hold one or more roles. Add as many roles to the user as necessary. Enter and repeat a password and save the user (*Figure 11*).

Figure 11

5.7 DELEGATE THE USER MANAGEMENT AT THE LOCATIONS TO LOCAL ADMINISTRATORS

As registry administrator you can define local administrators. Enter the users intended for this task and assign the corresponding location administrator roles that were automatically created. The local administrators will be able to create location users and assign roles to them.

6 DATA MANAGEMENT

Login as an user with data access permissions.

6.1 MANAGING PATIENT DATA

All patients of the registry will be presented in the patient list. The first column contains either only the PID or the name and the PID of a patient, depending on the location of your role. To open the dataset of a patient simply click on the name or the PID.

After opening a patient dataset (*Figure 12*) you will see all basic data forms. Above you will find a carousel which contains all episodes of the patient. Using the arrows on the left or right you can go through them. To open an episode simply click on the episode date and all episode forms with the longitudinal data of the patient will show up.

Entering or changing data in a form is as simple as just filling in the appropriate values and clicking on the button 'Save changes'.

Figure 12

6.2 ADDING NEW PATIENTS

Pressing the "Add New Patient" button leads you to the user interface of the *Mainzelliste* pseudonymization software where you have to enter the name, first name, birth name (optional), birthdate, zip code (optional) and city (optional) of the patient. With the "Add Patient" button a pseudonym will be requested for the corresponding patient (*Figure 13*). If the patient already exists in the Mainzelliste the existing pseudonym is returned, otherwise a new one will be created. Accept the verification dialog to save the patient in your OSSE data management.

Figure 13

6.3 CHANGING PATIENT DATA

To modify patient data press the patients edit symbol in the patient list (*Figure 14*). Please be aware, that you modify the patient data in the *Mainzelliste* pseudonymization server, where patients are registered for all locations of the registry. The modification of patient data might have side effects for other locations.

Figure 14

6.4 ADDING NEW EPISODES

Episodes structure the entry of longitudinal data. Each episode represents a time or short period where data are collected. These data are documented in one or more longitudinal data forms. Press "+ NEW EPISODE" to add a new episode and enter the date. After saving the episode all longitudinal data forms are shown and data can be entered.