BEFORE STARTING WITH osse

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1 INFORMATION AND USEFUL LINKS

1.1 ABOUT THIS DOCUMENT

This document will help you plan the realization of your registry using the OSSE registry software. It also contains an overview of all the documents that provide information on the setup and functionalities of the OSSE registry software as well as a list of questions that should be answered before you start.

The information and recommendations regarding the data protection concept and required consent declarations comply with the legal requirements and recommendations in Germany. Please observe the legal requirements and recommendations for your country.

1.2 INFORMATION ON OSSE

From time to time, please visit the OSSE website at https://www.osse-register.de/en/. There, you will find the following documents:

- an overview of the OSSE concepts (OSSE_Executive_Summary.pdf)
- an overview of the components of OSSE as well as their functionality and interaction (…); this document is aimed at decision makers who are considering using OSSE as well as IT specialists who want to participate in developing OSSE open source software
- brief instructions on the installation, setup and use of an OSSE patient registry (…)

2 REQUIREMENTS

Before you can start using OSSE to set up a patient registry and collect patient data, you should meet the following requirements:

- The contents of the registry and its organization are coordinated and agreed on within the research network. This includes the *data schema* and its structure in one-time or periodically repeated forms for documentation as well as the collection of *locations* and the different *users* who use the system in different *functions.*
- Contractual regulations regarding the operation of OSSE software and, possibly, identity management are applicable.
- The data protection concept, the patient consent forms and a positive response from the responsible ethics committees are on hand.

The following sections should assist you in fulfilling the requirements:

2.1 WHICH DATA SHOULD BE COLLECTED IN THE REGISTRY?

All data content that you want to collect and save in the registry is first defined and saved in the OSSE Metadata Repository (MDR). The following information must be provided for the definition:

- What is the name of the data element? Normally, the name will appear as a label in forms.
- What is the meaning of this data element? This description should be precise enough that even similar data elements can be differentiated from one another (for example, “blood pressure measured while lying down” and “blood pressure measured while sitting”).
- What type of data is collected? This can be a number, a value from a list, a date or time, a text.

- The unit that should be used to collect the value (if applicable).
- A value range in which the value should be (if applicable).
- A value set which can be used to select data during data entry (if applicable); for every value, there can be a difference between the way the value is stored in the database and the way it is shown in the form (data field “Sex” with the manifestations of “M” / “male”, “F” / “female”).

In some cases, it makes sense to group data elements that have been defined on a more abstract level together in a particular context. For this, the MDR provides composite data types (records). All information can be saved in different languages.

Once you have defined the data elements, they can be used to draft data entry forms. OSSE differentiates between basic data forms (which are collected once) and longitudinal data forms (which are repeatedly collected in defined time periods).

Assistance for defining the data content in the MDR and the design of forms can be found in the OSSE user guide on the website.

When defining the content of your registry in the MDR, please check whether suitable data elements already exist, for example in the “Common Data Set for Rare Disease Registries” (OSSE-CDS), in the GRDR common data elements or in the namespaces of other registries. The more data elements are used jointly by several registries, the easier it will be to network the registries in the future in terms of interoperability.

2.2 What is your authorisation concept?

Using OSSE, you can define users and assign roles appropriate to their function and location. The current version of OSSE contains predefined sets of permissions that can be assigned to roles. In a later version there will be an enhanced interface for a more fine-grained definition of permissions.

Plan your authorisation concept:

- Who is allowed to see which data and execute which actions?
- Which locations are part of the registry?

2.3 Who operates the identity management?

In accordance with the recommendations to implement German data protection laws, in general no identifying data from the patients should be saved in OSSE. If you want to jointly operate an identity management system for all locations in the network, OSSE offers an interface to the “Mainzelliste”, an identity management system in which the identifying data are directly transferred to OSSE when creating a new patient. OSSE only saves the pseudonym that it receives from the Mainzelliste. The advantage of this is that even if patients transfer from one location to another (for example, if they move), you can allocate data correctly and not create duplicates.

2.4 Who operates the OSSE software?

If you do not operate the OSSE registry software yourself, conclude a contract for commissioned data processing. If this is not the case, you can find instructions how to install the OSSE software and the necessary system requirements in the OSSE user guide on the website. In general, we recommend having the server (for OSSE as well as Mainzelliste) operated by professional providers.

2.5 Requirements for hardware, software and personnel resources for the operation of the OSSE components

In the following, you can see an estimation of the effort required to run the software yourself; please note that these are estimations only and are not based on concrete experience:

- Hardware — The **OSSE registry software,** a (virtual) server; for operation with (among others) ISO data minimum of 2GB RAM.
  For **Mainzelliste**, a second (virtual) server; also a minimum of 2GB RAM
- Software — You can download the **CD image** (ISO format) here for free: http://osse-register.de. It contains an operating system including necessary software.
  SSL-/TLS certificate fees for OSSE and Mainzelliste start at roughly €15 per year
- Personnel — One-time 10 PT for installation, configuration, definition of data elements and creation of the forms; this may be more for comprehensive registries.
  On-going 30 PT p.a. for availability and security of the server as well as system maintenance and occasional configuration.

2.6 Data protection concept

2.7 Patient consent forms