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 with the OSSE registry toolkit. It also contains an overview of all the documents that provide information on the set-up and functions of the OSSE registry toolkit 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 homepage at http://osse-register.de. There, you will find the following documents:

- an overview of the concepts (OSSE_Executive_Summary.pdf),
- an overview of the components of the OSSE architecture as well as their functionality and interaction (2014-12-31_Component Reference);
  this description is aimed at decision makers who are considering using the OSSE registry toolkit as well as IT specialists who want to participate in developing OSSE open source software,
- brief instructions on the installation, configuration and the first steps for the OSSE registry (2015-02-06_Getting_Started.pdf),
- and an overview of the functions of future versions (2015-07-30_CurrentLimitations.pdf).
- In addition, you can find templates and materials for creating data protection concepts and consent declarations aligned with German requirements in the download area on our homepage (some translated into English).

If you want to stay up to date, you can also subscribe to our newsletter:
https://lists.uni-mainz.de/sympa/subscribe/osse-announce.

2 REQUIREMENTS

Before you can start with OSSE data management, the following requirements must be met:

- The contents of the registry and its organisation are coordinated and fixed within the research network. This includes the *data schema* and its structure in one-time or periodically repeated forms for documentation and 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 declarations and a positive response from the responsible committees are on hand.

The following sections should assist you in fulfilling the requirements:

2.1 WHAT CONTENT SHOULD BE COLLECTED IN THE REGISTRY?

All data content that you want to collect and save in the OSSE data management is first defined and saved in a metadata repository. The following characteristics or content must be defined 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? The 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").
- 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 selection options (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.

As soon as you have defined the data elements, you can make a draft of the data entry forms in terms of the content structure in accordance with your work processes. OSSE data management permits differentiating core data forms (which are collected once) from on-going data forms (which are repeatedly collected in defined time periods).

Assistance in entering the data content in the MDR and the definition of forms can be found in the "Getting Started Guide".

When defining the data content 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 date elements are used jointly by a large number of registries, the easier it is to network the registries in the future.

2.2 THE AUTHORISATION CONCEPT

In OSSE data management, you can define users and assign roles appropriate to their function. The authorisations are defined in the roles. The current version of OSSE contains packets of permissions that can be assigned to roles.

Plan your authorisation concept:

- Which groups of people are allowed to see which data and execute which actions?

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 the OSSE data management. If you want to jointly operate an identity management system for all locations in the network, OSSE offers an interface to

"Mainzelliste"[1], 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 Mainzelliste (details on pseudonymisation can be found in the template for creating a data protection concept). 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 doubles.

In order to ensure informational separation of powers, Mainzelliste should be operated by a trusted third party, in particular by an institution that does not have access to the pseudonymised data in OSSE (and vice versa).

Therefore, you should select an appropriate institution that will operate Mainzelliste for you and conclude the necessary contracts.

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 to install the OSSE software and the necessary system requirements in the "Getting Started Guide". 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[2].
	SSL-/TLS certificate fees for OSSE and Mainzelliste start at roughly €15 per year[3].
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.

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[1] cf. Lablans M, Borg A, Ückert F (2015) A RESTful interface to pseudonymization services in modern web applications. BMC Med Inform Decis Mak 15: 2. doi: 10.1186/s12911-014-0123-5. Available at: http://www.biomedcentral.com/1472-6947/15/2.

[2]Alternatively, you can install OSSE via a Debian package repository. Please see the "Getting Started Guide". In this case, Ubuntu 14.04 LTS, Apache Tomcat 7 and Postgresql 9.3 should be installed beforehand.

[3] These are third parties and we don't endorse or generally have any affiliation with them.

2.6 DATA PROTECTION CONCEPT

To create a data protection concept, we provide a template that describes the OSSE-specific system components and data flows, etc. Details pertaining to the architecture of your registry (for example, the interface to a biomaterials bank or different options for identity management) are asked for there, and realisation concepts conforming to data protection requirements are offered.

For the Bridgehead solution, there is a template that offers text passages that can be used to supplement your current data protection concept. Here as well, different realisation options are available.

We recommend that you become familiar with the template and the concepts described in them and keep them in mind for the necessary adaptations for your registry's conditions.

2.7 CONSENT DECLARATIONS

To create a patient consent declaration, we also offer a template with suggestions for use as well as an example consent declaration from the "European Registry and Network for Metabolic Diseases by Intoxication Type – E-IMD".