

The **osse**-Registry Framework Component Reference

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1 OVERVIEW: COMPONENTS AND INTERFACES

The OSSE registry framework is a toolbox that supports the setup of disease-related registries in the area of rare diseases. The framework consists of several **local components** that each registry compound runs by itself and **overall components** that are operated centrally for several (ideally all) OSSE-type registries (see figure 1).

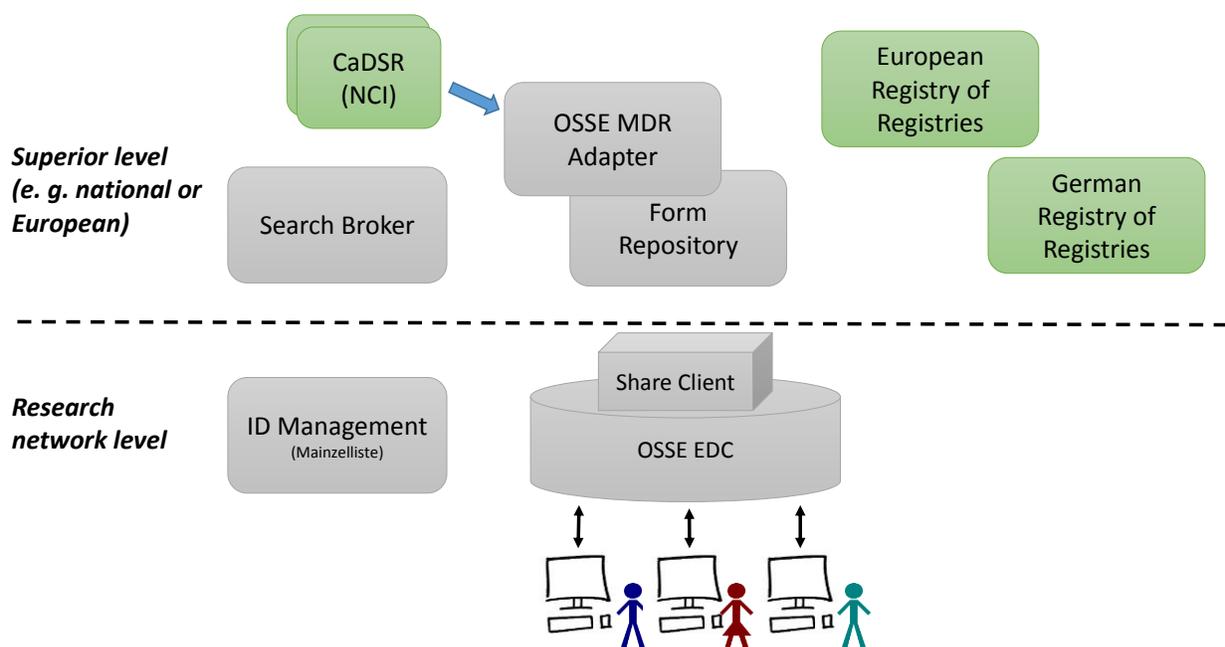


Figure 1: Components of the OSSE registry framework (blue) and systems that are interfaced (green)

Local Components

Each registry compound runs an **OSSE data management** component (OSSE.EDC) for the recording and storage of patient data and a **share client component** (OSSE.Share.Client) with which the registry can participate in **decentralized search**, a network infrastructure used to respond to cross-registry questions. Generally, each compound also operates its own **identity management** for the pseudonymization of documented patients according to data protection rules. This could e.g. involve one instance of the *Mainzliste*¹, which, in the context of the informational separation of powers, should be operated by a trusted third party.

Overall Components

The **metadata repository** (MDR) serves the harmonization of data elements, i.e. the precise definition of which data are being recorded in a registry, and is operated together with the **form repository**

¹ More about the Mainzliste pseudonymization software see at www.mainzliste.de

commonly preferably for all² OSSE registries in order to achieve a high degree of comparable data. The **OSSE MDR adapter** can be used as a standalone MDR, but it also has interfaces to e.g. the TMF (a German platform and umbrella organization for networked medical research) metadata repository and the National Cancer Institute's caDSR by means of which it can take over data elements.

The **search broker** (OSSE.Share.Broker) is an overall component for inquiries. All OSSE-type registries wishing to participate in the “decentralized search” have to register with this search broker.

Registries of Registries

The OSSE data management supports a registry's reporting to various **registries of registries** such as the German national registry portal run by TMF and the European Registry of Registries for Rare Diseases. Thus, basic information on the registry such as its name, goals, inclusion and exclusion criteria to describe the patient collective, etc. is recorded and displayed in a kind of public “showcase”.

1.1 THE METADATA REPOSITORY (OSSE MDR ADAPTER)

The MDR serves the harmonization of data content. The more registries define their data elements in a comprehensible way and use identical data definitions, the easier it is to use the data for overarching questions. The MDR contains a collection of metadata (definitions of data elements), which the compounds (not necessarily only OSSE-type registry compounds) record or take over from other MDRs. In defining the data elements, it is important that their meaning is described accurately and that existing data elements are used if possible. Due to namespaces and version control (see below), there is no danger that data elements already in use in a registry change without notice when edited in the MDR.

1.1.1 Features

Namespaces and Access Control

Each registered user (person or registry) receives his/her own *namespace* in which he/she can define data elements. Data elements from external namespaces are visible and can be taken over into one's own namespace. Data elements from one's own namespace can be used to generate forms.

Generating Groups and Data Elements

The OSSE MDR adapter allows the definition of data elements in compliance with ISO/IEC11179. This includes the specification of the following values for each data element:

- *Name*: The name of the data element is automatically used as a label for the corresponding input field in the entry form.
- *Definition*: Each data element is described as precisely as possible. This also includes, e.g., information on how and under which conditions a value was measured.
- *Data type*: Valid data types include DATE, TIME, DATETIME, INTEGER, FLOAT, BOOLEAN, STRING, ENUMERATED VALUE DOMAIN (enumeration type).
- *Value range*: Value ranges can be specified for the data types INTEGER and FLOAT.
- *Value set*: The data type ENUMERATED VALUE DOMAIN requires the specification of a value set (numbered list of parameter identifiers).

² It will generally also be possible for each registry to run these components individually by itself.

Apart from the above data types, *composite data types (RECORD)* can be defined as well. For this purpose, each record component needs to have been created previously as a data element. In queries, similar data elements are recognized as comparable regardless of whether they are used in the context of a record or independently.

Data elements can be assigned to predefined *groups*. In contrast to the record definition, this grouping only serves the structuring and better findability of data elements in the MDR.

Version Control

As soon as a user edits (creates or changes) a data element, it enters DRAFT status. In this status, the data element or its current version, respectively, is not yet available for form definition. Once the data element is released (RELEASED status), it receives a version number; the version number of existing data elements is incremented. Elements in OUTDATED status shall no longer be used in forms.

Multi-language Ability

All attributes of the data elements can be (simultaneously) recorded in different languages.

Data Element Search

Data elements are searchable based on word parts of identifier and description.

1.1.2 Interfaces

The MDR offers a REST interface with which data elements and their attributes can be queried.

1.2 FORM EDITOR AND FORM REPOSITORY

1.2.1 Features

Creating and Managing Forms

For the creation of entry forms, the form editor allows the choice of data elements from the MDR namespace of the registered registry. Each element may be chosen to be optional or required and repeatable. Furthermore, the form editor offers design elements (formattable labels, separators, hyperlinks) to structure the form and include additional information. Each form must be named (e.g. therapy, lab) and the name is shown on the form in the OSSE data management.

Version Control

While it is generated or as soon as it is edited, a form enters draft mode. Through active approval (published), it receives the next version number and is available for import into the registry.

Access Control

Forms are stored centrally in the form repository for all registries. Each registry can create and edit forms in its domain.

1.2.2 Interfaces

The form repository offers a REST interface through which a list of forms available in each registry can be displayed and XML-based definition structures can be taken over.

1.3 OSSE DATA MANAGEMENT

The OSSE data management component includes the data management as well as administrative features with which specific settings for the operation can be determined.

1.3.1 Configuration

The OSSE installation and configuration are carried out by an administrator in charge. Running the OSSE data management first requires the following settings to be defined:

Connections to other Components

Connection data of the metadata/form repository, the registries of registries, and the identity management

Information on the Registry to be reported to the Registries of Registries

Information on the registry is stored in the data management and can be updated as necessary. It has to be determined whether the registry actually reports to a registry of registries, and if so, how frequently values to be calculated dynamically, such as the number of cases in the registry, should be updated in the registry of registries.

Workflow

The configuration contains a preconfigured³ workflow through which each form can receive one of the following status values:

- *Open*: the form is being edited
- *Reported*: editing of the form is complete
- *Validated*: the entries were checked and considered valid

The following status transitions are possible: open → reported, reported → validated, validated → open.

Locations

The OSSE administrator records and manages a list of locations (e.g. centers, practices) of the compound including the following information: location name; (location type;) list of contact persons with name, address, e-mail address, and phone numbers. Each location has a location administrator who is set up by the registry administrator. The location administrator, on the other hand, creates the users at the location and assigns them the predefined roles (see “Roles and Permissions”).

³ In version 1.0 there is no workflow support yet, from version 1.2 the workflow will be configurable, i.e. the status values and status transitions will be freely selectable.

Roles and Permissions

The registry administrator creates the roles defined in the registry compound's authorization scheme and provides them with the necessary permissions. For each role that can enter data, the location to which the data are to be allocated is defined. The respective permissions have the following structure: each permission contains the definition of a data class and which action can be executed on it. Valid actions include:

- *Creating data sets*
- *Editing data*
- *Reading*
- *Changing the form status*

Data classes are:

- *Patient data* (this refers to the identity data in the identity management and the structural patient data generated when entering a new patient into the registry)
- *Episodes*
- *Forms*

Each of these general data classes can be narrowed by indicating filter attributes, e.g. by *affiliation with a particular location, status* (for forms), *form type* (e.g. only pathology data as a permission for the reference pathologist), but also by specifying a particular patient ID.

A set of predefined permissions is provided instead of an user interface to define permissions. The user interface will be available in a future version.

Users

Users are set up and managed across locations by the registry administrator or for a particular location by the location administrator. Each user receives one or several roles defining his access authorization.

Data Elements and Entry Forms

The OSSE MDR adapter and the form editor can be launched from the configuration menu. The forms created are shown and can be taken over, and their use as basic data forms or longitudinal data forms is specified in the process. The user interface and the data schema are created automatically based on the form definitions.

1.3.2 Data Management Features

After registering with the OSSE data management, the following features are available for the user depending on his/her role and the rights associated with it:

Creating and Managing Patients

The user receives a list of patients he/she can choose from. On this list, the patients of his/her own location are shown with identity data (usually last name and first name) in order to avoid

misallocations.⁴ All other patients in the registry show up in the list with a non-speaking pseudonym. If a new patient has to be entered, the user is redirected to the entry mask of the identity management, where he/she enters the patient's identity data. The identity management returns a pseudonym to the data management under which the patient is entered. At the same time, for new patients, the pseudonym for the display of their data in other locations is created and stored in the identity management together with the identity data. Faulty identity data can generally be corrected. However, this feature should be used with great caution, as it could lead to homonym errors in the worst case.

Creating and Managing Episodes

Historical data are attributed to one particular episode each. One episode corresponds to one point in time or interval at or during which data were collected. The same forms (historical data forms) are completed in each new episode. In the patient view, new episodes can be recorded and episodes can be selected.

Editing Forms

Forms are collections of entry fields usually sorted thematically or according to the documentation workflow and to be completed by different persons if necessary. In order to avoid collisions if several users (of the same role) are involved in the editing process, a form must first be moved from the read-only to the editing mode in order to be processed. It is then locked and cannot be edited by any other person. The entries can be saved or discarded. Furthermore, the form's status can be set according to the defined workflow. A new version of the data is generated for each intermediate stage. Depending on which forms were defined and imported for a registry, there are basic data forms shown in the patient view and longitudinal data forms accessible through the episode view.

1.3.3 Interfaces

Exporting Data

Data can be exported e.g. for the purpose of analysis with statistics software. To narrow down the data volume, a time interval can be specified during which the data were collected. The data are exported fully for this period and contain non-speaking one-time pseudonyms. The export format can be selected as XML or CSV.

1.4 THE SHARE CLIENT

The share client as an interface to decentralized search is not yet available.

⁴ Identifying and medical data are combined exclusively in the authorized user's web browser. There is no (not even a temporary) combination on the server side.