



USER GUIDE REGISTRY DESIGN

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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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UNIVERSITÄTS**medizin.**
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Gefördert durch:



Bundesministerium
für Gesundheit

aufgrund eines Beschlusses
des Deutschen Bundestages

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1 REGISTRY DESIGN

1.1 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 1).

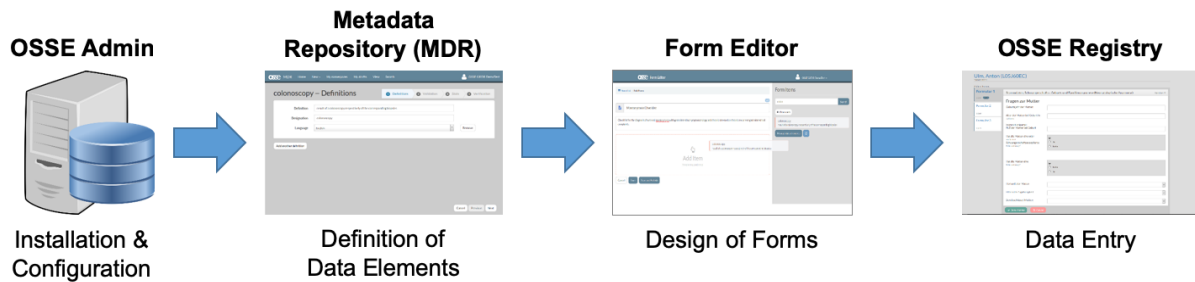


Figure 1

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 2). 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.

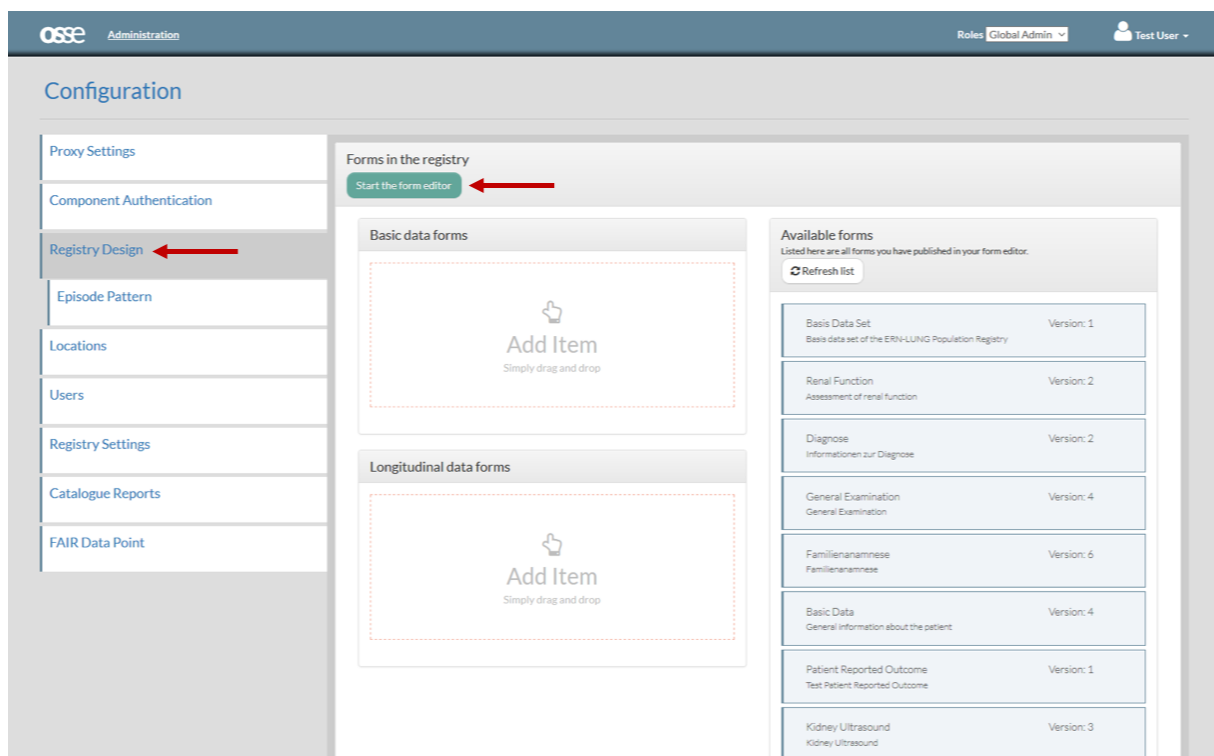


Figure 2

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 3).

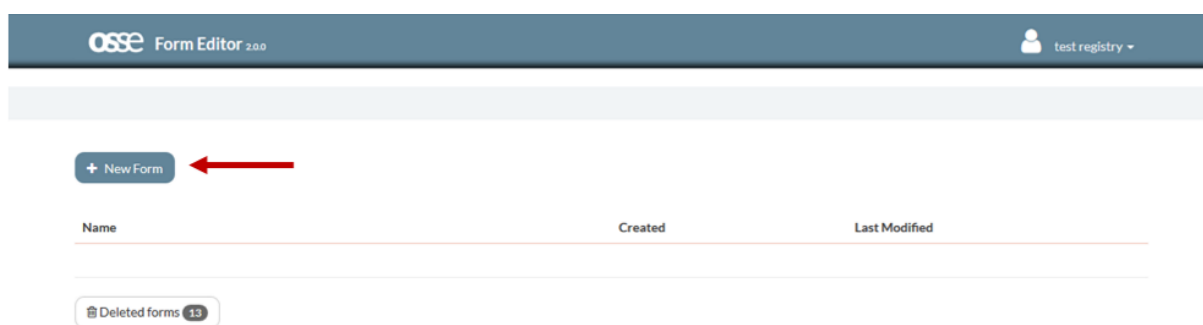


Figure 3

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 4), 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.

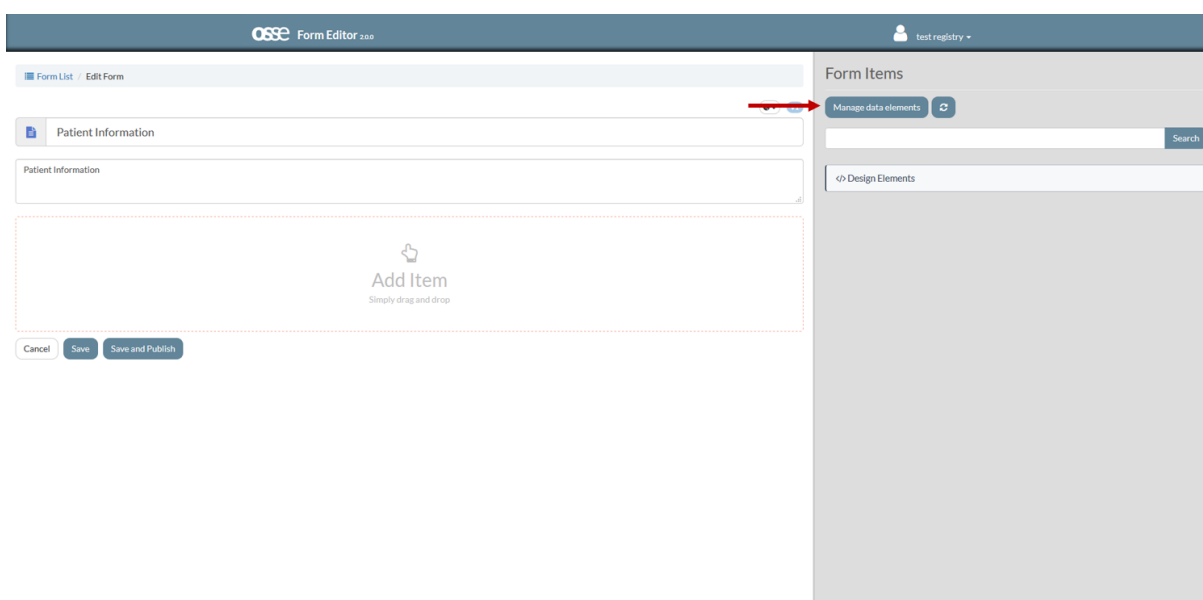


Figure 4

1.2 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 5). 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 6).

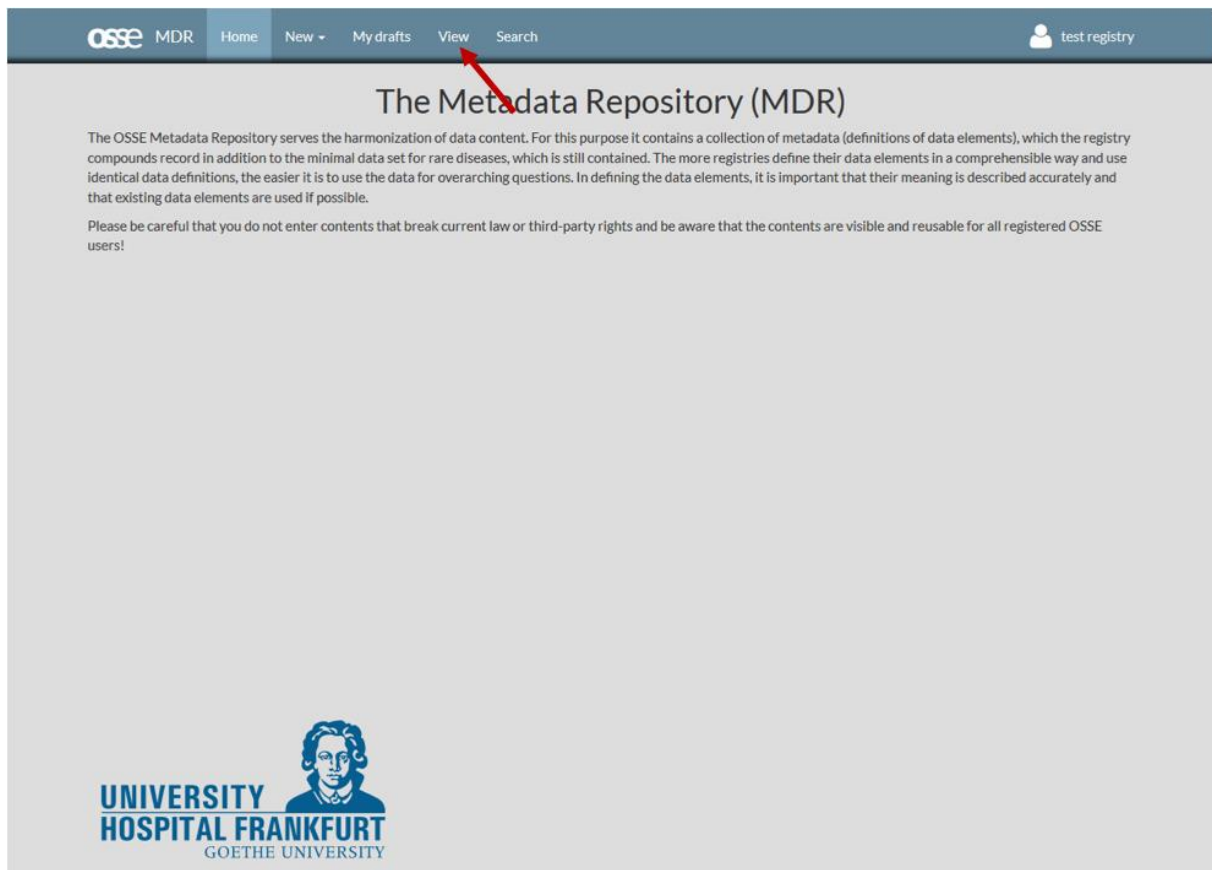


Figure 5

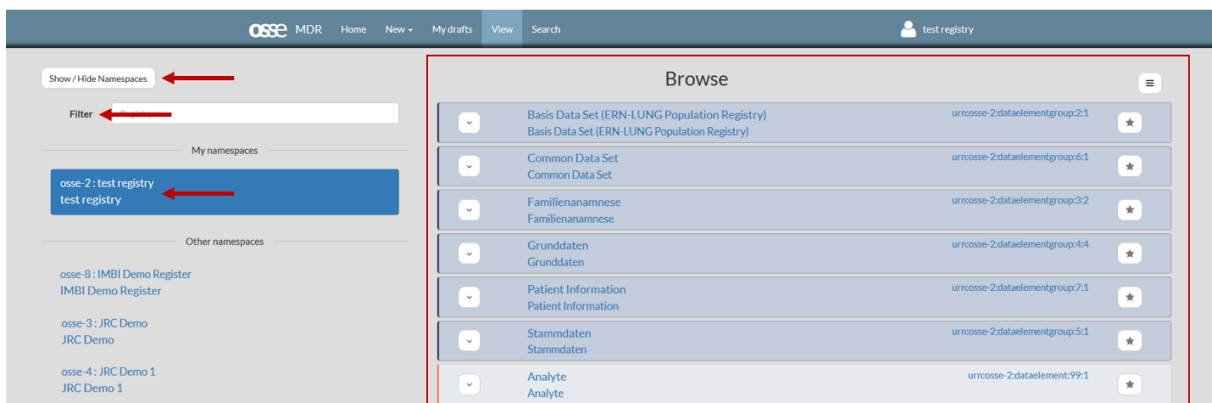


Figure 6

1.2.1 ADDING DATA ELEMENTS

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

1.2.1.1 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 7). A copy of this data element will now be available in your own namespace.

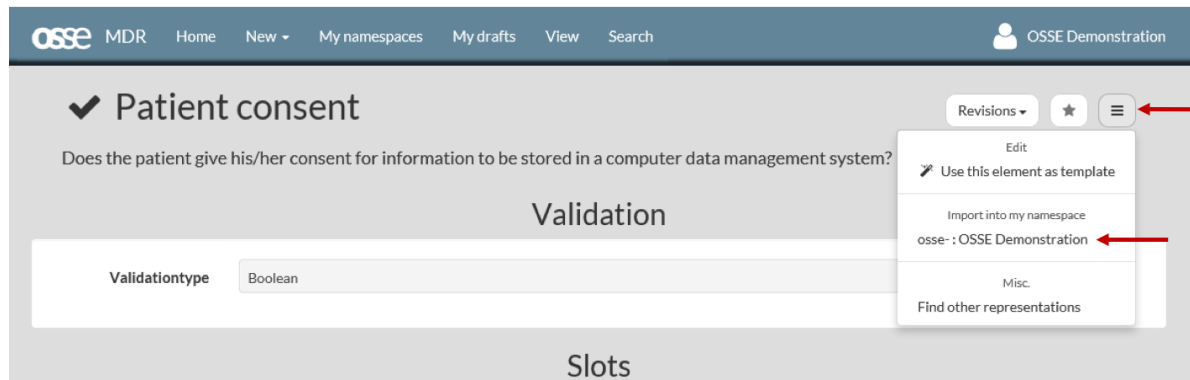


Figure 7

1.2.1.2 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 8). 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.

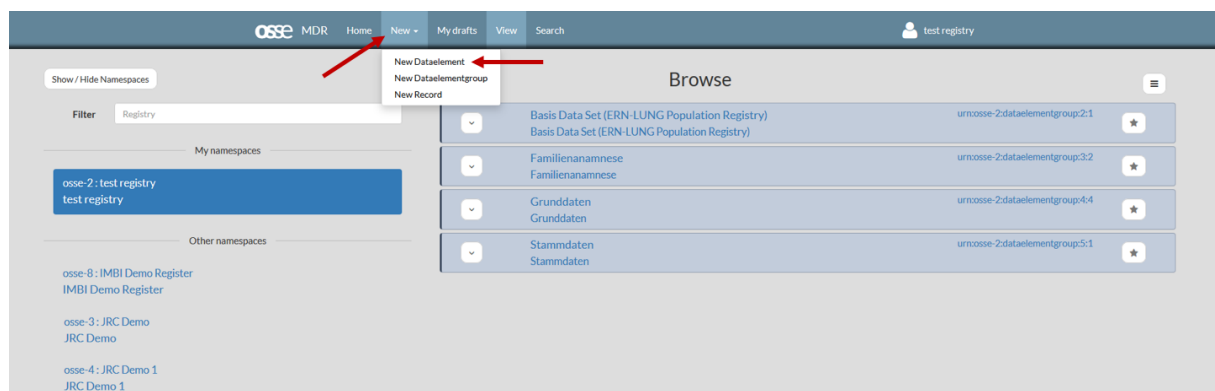


Figure 8

1. Definitions

Select a designation, or name, for the data element (Figure 9). 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).

Definitions

1 Definitions 2 Validation 3 Slots 4 Verification

Designation: Consent

Definition: Patient's consent exists for participation in the study

Language: English

Remove

Add another definition

Cancel Previous Next

Figure 9

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 10). 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.

Test – Validation

1 Definitions 2 Validation 3 Slots 4 Verification

Validationtype: Integer

Within range: List of permitted values

Range (from - to): Integer

Unit of measure: Float

Boolean

String

Date

Datetime

Figure 10

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 11)

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 with the 'Validationtype' dropdown set to 'List of permitted values'. Below this, there is a table of permitted values. The first row shows 'Male' as the permitted value, with 'Male' as the designation and definition, and 'English' as the language. There are 'Remove' buttons for each row. At the bottom, there is an 'Add another permitted value' button. Red arrows point to the 'List of permitted values' dropdown, the 'Male' permitted value input, and the 'Add another permitted value' button.

Figure 11

Strings (Figure 12)

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 with the 'Validationtype' dropdown set to 'String'. Below this, there are two checkboxes: 'Max length' and 'Use Regex'. The 'Max length' checkbox is checked, and the value '0' is entered in the adjacent input field. The 'Use Regex' checkbox is unchecked. A red arrow points to the 'String' dropdown.

Figure 12

Integers / Float (Figure 13)

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 13

Date (Figure 14)

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 14

Time (Figure 15)

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 15

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 16).

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 17).

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 16

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 17

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 18). 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.

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 18

1.2.1.3 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 19). Proceed through the wizard as described above; all parameters of the new element can now be edited at will.

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 19

1.2.2 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 20). 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.

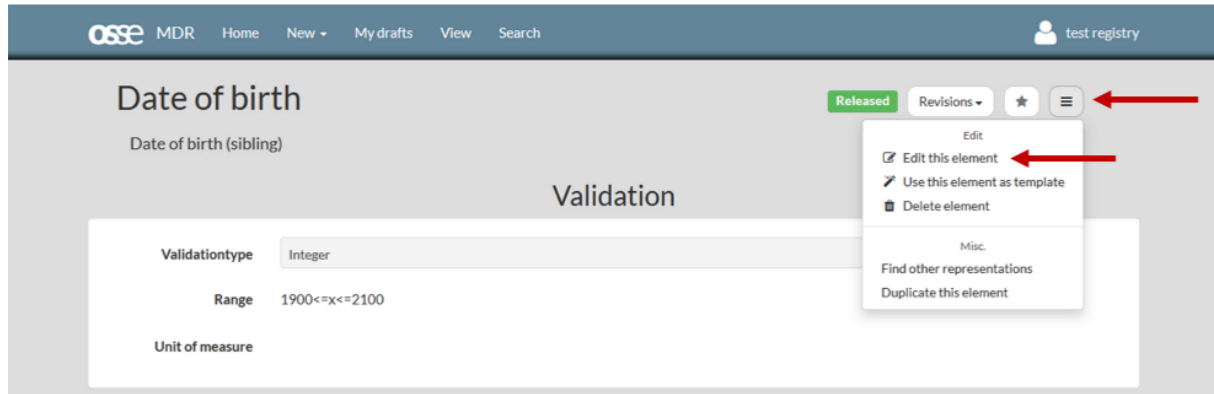


Figure 20

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.

1.2.3 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.

1.2.4 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 21).

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 22).

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 21

osse MDR Home New My drafts View Search test.registry

Laboratory analysis – Assign record entries

1 Date urn:osse-2:dataelement:98:1

1 Analyte urn:osse-2:dataelement:99:1

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) urn:osse-2:dataelementgroup:2:1 (ERN-LUNG Population Registry)

Common Data Set urn:osse-2:dataelementgroup:6:1

Familienanamnese urn:osse-2:dataelementgroup:3:2

Grunddaten urn:osse-2:dataelementgroup:4:4

Stammdaten urn:osse-2:dataelementgroup:5:1

Analyte urn:osse-2:dataelement:99:1

Consent urn:osse-2:dataelement:85:1 Patient's consent exists for participation in the study

Date urn:osse-2:dataelement:98:1

Cancel Previous Next

Figure 22

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.

1.2.5 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.

1.3 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 23). 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 23). 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 24).

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 24).

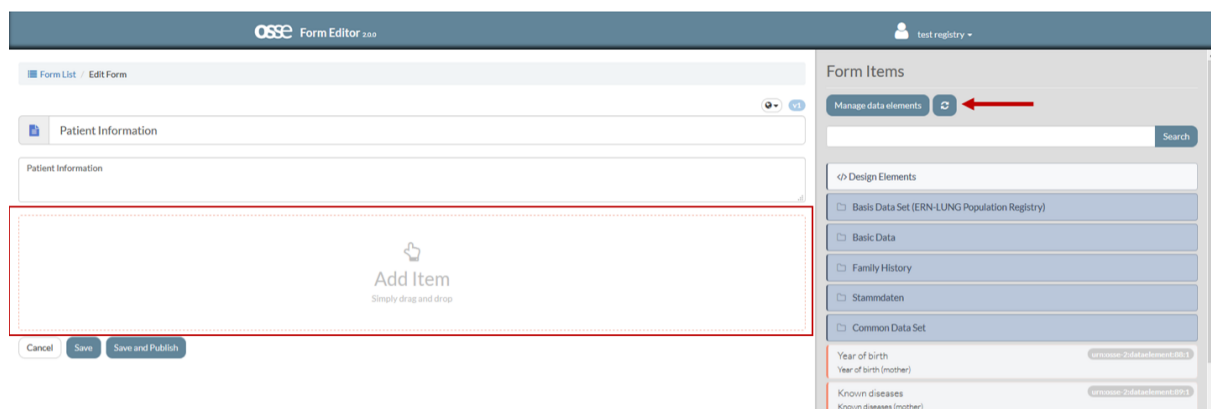


Figure 23

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 24

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 25).

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 25

1.4 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 26). 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 27).

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'.

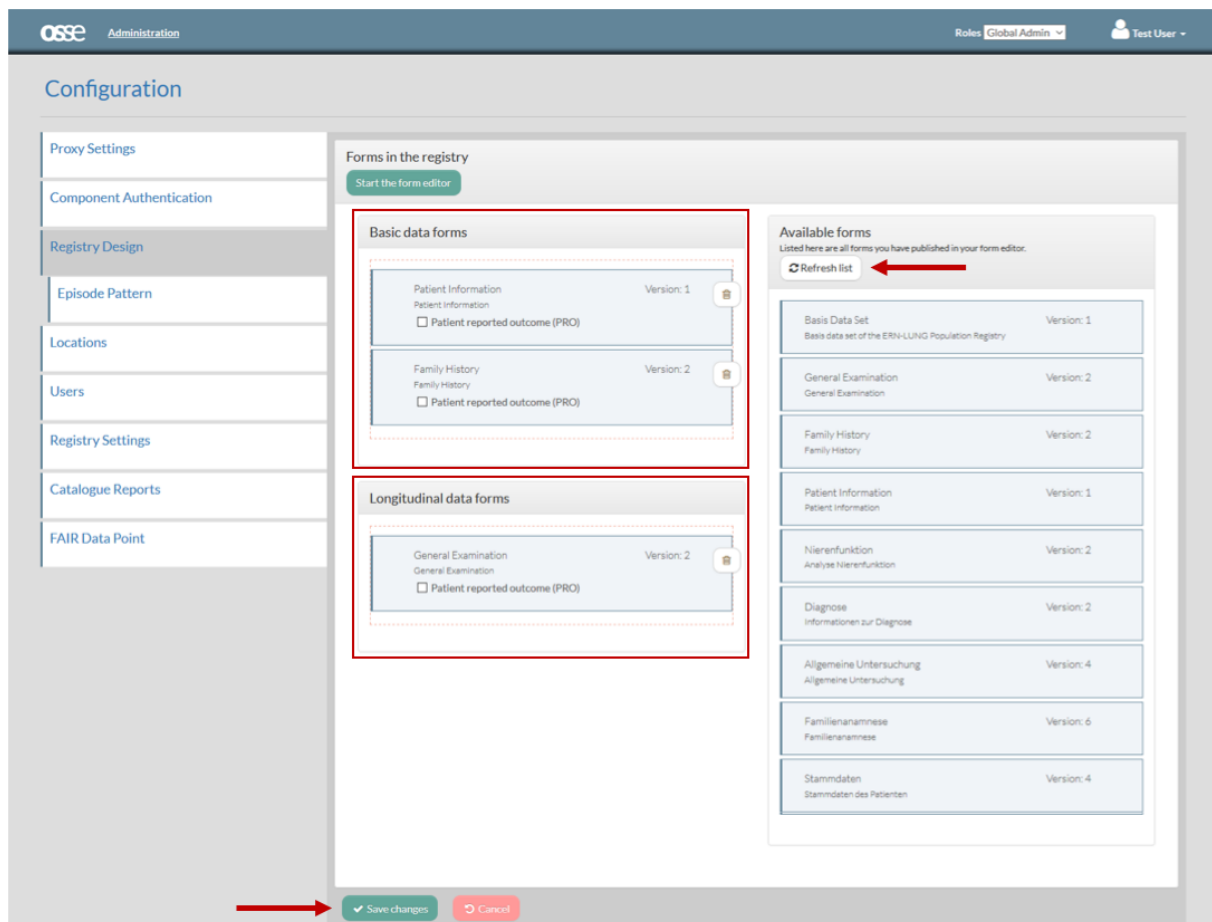


Figure 26

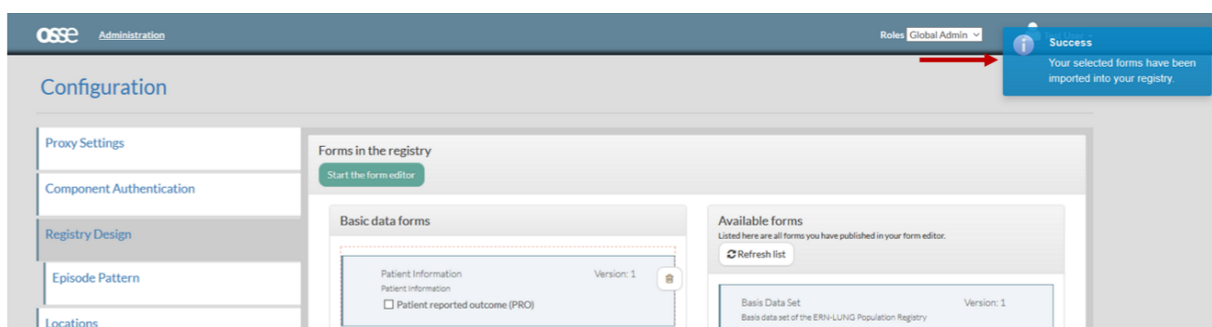


Figure 27