

5.4.2 OpenClinica eCRF Specifications

OpenClinica provides a template to users for CRF design. This section explains each of the fields in the template and how those fields are either dependent or independent of each other. Best practices are provided as well as some examples of how the CRF Template can be used effectively.

Definitions and acronyms

- CRF Case Report Form, created in OpenClinica by uploading a CRF definition based on the CRF Template Excel file.
- Dynamics Skip Patterns/Skip Logic created using Rules and based on variables in the CRF template.
- Group - A mechanism for logically associating items within a CRF. Items within the same group may repeat together within a CRF.
- Item A variable within a CRF.
- OIDs Object Identifiers uniquely identify a study object such as a CRF, CRF Version, Item Group, or Item and are used to link objects to one another. OIDs for a given class of object are unique within an instance of OpenClinica, with the exception of Rule OIDs, which are only guaranteed to be unique within a study.
- Rules OpenClinica's mechanism to carry out cross form or cross field edit checks, skip logic and inserting data across CRFs. Rules are declared in XML and executed by the OpenClinica Rules Engine. Rules are declared external to the CRF Template but dependent on the variables defined in one or more CRFs.
- SCD Simple Conditional Display. A way of defining skip logic within the CRF Template, without the use of Rules.
- Section A mechanism for organizing items within a CRF for layout purposes. All items in a given section appear on the same page in a CRF. Multiple sections are displayed as tabs within the CRF.
- Tokens A means of displaying a Study Object value for use in a URL (e.g. in a parameterized link) or for use in other scripts (e.g. jquery). Tokens can also be used in Left Item Text, Right Item Text, Header, and/or Subheader to pass item values. The supported tokens are:

`${studySubject}` - Passes the current Subject ID

`${studySubjectOID}` - Passes the OID for the current Subject

`${studyName}` - Passes the current Study Name

`${eventName}` - Passes the current Event Name

`${eventOrdinal}` - For repeating Events, passes the Event repeat number (e.g., 2 for the second repeat)

`${crfName}` - Passes the CRF Name

`${crfVersion}` - Passes the CRF Version

`${item[item_name]}` - Passes the Item value

Approved for publication by Ben Baumann. Signed on 2015-03-03 3:10PM

Not valid unless obtained from the OpenClinica document management system on the day of use.

5.4.2.1 CRF Template - General Constraints

The OpenClinica CRF Template can only be edited and saved as a Microsoft Excel 2003.xls file. OpenOffice spreadsheets and later versions of Microsoft Excel can not be used reliably and may not be successful when uploaded to OpenClinica version 3.1.X.

The CRF Template is used to define the CRF on a client machine with MS Excel. Once the required information has been provided in the template, it must be uploaded to OpenClinica through the Add CRF page. Only certain privileged users are allowed access to this page.

During the upload process, a validation of the CRF design is performed. Errors that are caught at this stage will trigger messages to the user informing him of the error and changes necessary to fix the error.

5.4.2.2 Scope of CRFs and Items

A CRF (with its associated versions, groups, and items) is defined globally within an instance of OpenClinica and may be used in one or more studies. The groups and items defined within a particular CRF exist within the scope of the CRF only (though they will have globally unique OIDs). The CRF Physical Exam may have an item with ITEM_NAME blood_pressure and the CRF Vital Signs can have an item also named blood_pressure. OpenClinica treats these items as separate entities and they will have separate OIDs. Response sets also exist within the scope of the CRF only.

A CRF definition may be shared across OpenClinica instances by loading the CRF template spreadsheet into each instance. Each instance of OpenClinica generates OIDs at CRF upload time and those OIDs must be unique within that instance. Therefore the OIDs for the same CRF and items may be different across OpenClinica instances.

5.4.2.3 CRF Versioning

OpenClinica supports multiple CRF versions being in use at the same time. To create a new version, a user must keep the CRF_NAME field the same as the original, but update the CRF_VERSION field with a new value. This new version is uploaded by selecting the Create New CRF Version icon instead of adding a CRF through the Build Study module. The user does have the ability to overwrite a CRF Version if needed, however the CRF Version cannot have been assigned or used in any event definitions prior to the attempt to remove it.

When a new CRF Version is added, any item with the same ITEM_NAME as an item in a previous version of the CRF is treated as the same variable and will have the same OID, DESCRIPTION, and DATA_TYPE. The value of ITEM_NAME is case-sensitive, so items with ITEM_NAMES 'ItemA' and 'itema' will be considered as different items by OpenClinica.

For Enterprise customers interested in using Datamart:

Please note that Datamart treats items in case-insensitive manner. Please make all ITEM_NAMES case-insensitive if you plan to use Datamart. Special characters and [Postgres reserved words](#) should not be used as item names.

New items that did not exist in prior CRF versions will be added and an appropriate OID generated.

Item metadata vs Item form metadata

Items in a CRF have two types of attributes. Item metadata attributes describe core intrinsic properties of the item. These properties are independent of the CRF Version and cannot change across CRF Versions. These properties include:

ITEM_NAME

DESCRIPTION

DATA_TYPE

GROUP_LABEL

Response Sets (see discussion below)

The properties ITEM_NAME, DATA_TYPE, and RESPONSE_LABEL cannot be changed after the CRF is created.

Item form metadata attributes describe the items representation or behavior on a CRF and may have a different value in each version of a CRF. Most of the attributes in the Items Worksheet in the CRF Template fall into this category.

Response sets

The item properties beginning with RESPONSE_ on the Items worksheet together define a response set in a CRF. The response set is a coded list of allowable values for the item. The response set is given a name (RESPONSE_LABEL) that allows it to be re-used within the CRF if desired, and the set itself is made up of a list of coded values (RESPONSE_VALUES_OR_CALCULATIONS) with corresponding text labels (RESPONSE_OPTIONS_TEXT). Each item in the list of coded values should meet the constraints defined by the item DATA_TYPE and WIDTH_DECIMAL.

Response sets are intended for use in items that utilize a form input control (INPUT_TYPE) that allows the user to select from a constrained list.

* Note that the RESPONSE_VALUES_OR_CALCULATIONS attribute can also be used in a separate context to create calculated/derived items.

Versioning of response sets should not change the mapping RESPONSE_OPTIONS_TEXT -

RESPONSE_VALUES_OR_CALCULATIONS, but it can delete or add new (_OPTIONS_TEXT - RESPONSE_VALUES_OR_CALCULATIONS) pair to existing set of values. For example, an item is a single-select and its RESPONSE_OPTIONS_TEXT defined as Absent,Mild,Moderate,Severe,Life-threatening while

RESPONSE_VALUES_OR_CALCULATIONS defined as 1,2,3,4,5. In another version of CRF it is possible to drop or add several values, but you cannot redefine mapping by setting Absent to have value other than 1.

5.4.2.4 CRF Template Properties

The CRF Template contains five worksheets. Four of the worksheets are intended for input by the user creating the CRF while the fifth worksheet provides instructions about each of the fields of the Template. When a user selects a cell in a column, a tooltip will popup explaining whether the field is Required or not, and other useful instructive text to help the user understand what the field is for.

In some cases HTML elements like Bold (), Italics (<i>), Line Breaks (
), etc. can be used. In the cases where HTML elements are supported, they are designated as such in [CRF Template Elements](#).

In OpenClinica 3.3, Tokens, were introduced. These are available for use in Left or Right Item Text, Header, or Subheader. They can be used to display the Study Object value for use in a URL (as in a Parameterized Link) or for use in other scripts (e.g., jquery). The supported tokens are:

`${studySubject}`

`${studyName}`

`${eventName}`

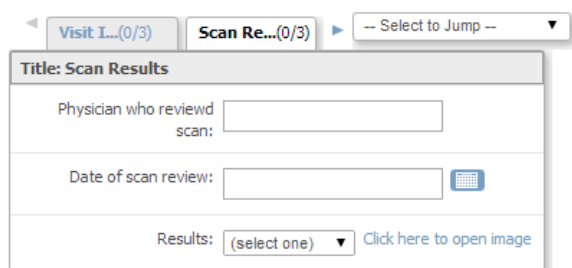
`${eventOrdinal}`

`${crfName}`

`${crfVersion}`

`${item[item_name]}`

Following is an example of a CRF that passes these tokens to a URL to bring up an image:



The screenshot shows a web-based CRF form titled "Scan Results". At the top, there are navigation tabs: "Visit 1...(0/3)" and "Scan Re...(0/3)". Below the tabs, the form contains three main sections: 1. "Physician who reviewed scan:" with a text input field. 2. "Date of scan review:" with a text input field and a calendar icon to its right. 3. "Results: (select one)" with a dropdown menu. To the right of the dropdown menu is a blue link that says "Click here to open image".

When the user clicks on the "Click here to open image" link, based on the following Right Item Text the CRF template, the imaging system (in this case [www.example.com](#)) is accessed and passes the

values for studyName, eventName, crfName, and the SCAN_DATE item for the current Study, Event, and CRF.

Right Item Text:

```
<a  
href="http://www.example.com/${studyName}/${eventName}/${crfName}/${item['SCAN_DATE']}"  
target="_blank">Click here to open image</a>
```

5.4.2.5 CRF Template Elements

Definitions, restrictions and when to use the OpenClinica CRF Template Elements

- [CRF Worksheet](#)
- [Sections Worksheet](#)
- [Groups Worksheet](#)
- [Items Worksheet](#)

[illegible]

