

## 3.4.2.3 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 (RESPONSE\_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.

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