10.6 Study Metadata Versions and Sites

Within the study metadata file generated by OpenClinica, we contain CRF Versions inside of each FormRef called inside the StudyEventDef element of the ODM document. Since CRF Versions can appear in different study event definitions in OpenClinica, we allow duplicate calls to the same definition in this part of the file.

OpenClinica also supports inclusion of multiple instances of the MetadataVersion tag in its documents. This means that one ODM document can hold multiple sets of study metadata, detailing a study and one or more of its sites, for example. Each MetadataVersion has an automatically-generated OID, which can then be attached to any group of ClinicalData that is also contained in the same document.

The OID is generated automatically with the ODM Metadata Version number that is set in the Dataset, typically v1.0.0-, plus the Study OID. Part of the metadata which is central to all Studies is generated with only the ODM Metadata Version number, and then other versions (Sites) can access the metadata using an Include tag, which generally looks like this:

<Include StudyOID ="S_OID_HERE" MetaDataVersionOID="v1.0.0"/>

The Include tag allows Studies to share a collection of metadata, such as CRFs, CRF versions, etc. Typically, a parent Study would contain this metadata, and each Site would then reference it via the Include tag.

Approved for publication by Cal Collins. Signed on 2014-04-02 3:36PM

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