10 CDISC ODM Representation in OpenClinica

The Clinical Data Interchange Standards Consortium (CDISC) is a clinical research standards body formed to encourage maximum sharing of information and minimum duplication of efforts. One of the standards CDISC has created and endorsed is the Operational Data Model (ODM), which facilitates the archive and interchange of the metadata and data for clinical research. ODM is represented in XML format and is designed to collect data from many different sources into one document.

Purpose of this document

OpenClinica provides and/or consumes CDISC ODM XML representations in its Extract Data and Import Data modules and other parts of the software. This document describes how OpenClinica represents study metadata and data that is stored in its internal database as CDISC ODM XML documents. It assumes a working knowledge of CDISC ODM 1.3 and of OpenClinica, and attempts to describe how each OpenClinica field or element is represented in ODM, and under what conditions. The document is best read when accompanied by the CDISC ODM standard. It is geared towards developers, but is also intended for data managers who want to know more about the capabilities of ODM XML export in OpenClinica. Additionally, parts of this document will find its way into the online documentation, for all end users.

OpenClinicas ODM representation has changed iteratively from version to version of OpenClinica, and the appendix to this document charts these changes since version 2.5 and the addition of the custom extension to the ODM, introduced with OpenClinica 3.0.

Scope of this document

This document provides a detailed specification of the OpenClinica CDISC ODM XML version 1.3 with OpenClinica Extensions as implemented in the OpenClinica 3.1 and later releases.

Definitions and acronyms

- CDISC Clinical Data Interchange Standards Consortium
- DOM Document Object Model
- ODM CDISC Operational Data Model
- XML Extensible Markup Language
- XSL Extensible Stylesheet Language, a language for displaying an XML file as a given type.

10.1 CDISC ODM - General Issues

CDISC defines its Operational Data Model, version 1.3, as a vendor neutral, platform independent format for interchange and archive of clinical trials data. The model includes the clinical data along with its associated metadata, administrative data, reference data and audit information. All of the information that needs to be shared among different software systems during the setup, operation, analysis, submission or for long term retention as part of an archive is included in the model.

An XML document must meet certain basic criteria to be considered conformant to the ODM standard. These are briefly discussed below:

10.1.1 Syntatic Constraints

The syntactic constraints defined by the ODM standard are

1. The ODM file must be a well-formed XML file. See the XML standard for details.

2. The ODM file must conform to the XML Namespace standard. See the XML Namespace standard for details.

3. The ODM file must contain only elements and attributes defined in the ODM standard schema or in a valid vendor extension schema, and must satisfy the rules about element nesting and the formats of attribute values and element bodies.

4. The ODM file must contain a prolog and a single (top-level) ODM element.

5. The namespace for version 1.3 of the ODM is http://www.cdisc.org/ns/odm/v1.3.

OpenClinica ODM Exports from the Extract Data module meets these constraints.

Currently, the ODM study definition file (available from the View Study page at the URL /DownloadStudyMetadata?studyId=#) does not meet these requirements for the following reasons:

1. The file generated from the View Study page is only a fragment of XML, and does not contain the initial tag which defines the character set and version, i.e. <?xml version="1.0" encoding="UTF-8"?>.
2. The file generated does not contain references to any XML Namespaces, including the namespace for version 1.3 of the ODM itself.
3. The file generated does contain elements defined in the ODM standard schema, but lacks the single top-level ODM element.
4. The files suffix is txt instead of xml.

OpenClinica ODM Data Import meets the above constraints, but note that OpenClinica parses everything within the ClinicalData element only, and it does not read anything in the Study element,

and, as such, cannot import Study metadata at this time.

10.1.2 System Conformity

A computing system that processes information in ODM format can claim conformance to this standard only if it obeys the following rules.

1. Generated ODM files must satisfy all the correctness rules in the standard, both syntactic and semantic.

2. A receiving system must be able to read any ODM file that satisfies all the correctness rules in this standard, both syntactic and semantic.

3. ODM files must validate against the ODM schema for the ODM version indicated in the ODM root element.

4. Information included in generated ODM files must be accurate according to the rules of this standard as defined in this specification.

5. A receiving system must interpret information read from an ODM file accurately according to the rules of this standard as defined in this specification.

6. Generated ODM files need not include information that is not normally handled or stored by the generating system.

7. A receiving system may selectively ignore information read from an ODM file if that information is not normally handled or stored by the receiving system.

8. A receiving system may constrain the range of data values, keys, names, and so on, that it is capable of handling or storing.

9. Systems that receive ODM clinical data files but do not normally support one or more of the datatypes specified in section 2.14, should accept clinical data of the unsupported types as text.

10. All system limitations (rules 6 through 9) must be documented.

11. If conformity is dependent on certain modes or settings, this must also be documented.

OpenClinicas support for generated and received meets these constraints, including documentation of limitations (#10). The limitations are described in the Limitations section of this document.

10.1.3 Vendor Extensions

Requirements for Vendor extensions to the ODM model are:

1. The vendor must supply a XML Schema fully describing their extended ODM format.

2. Extended ODM files should reference the proper extension Schema.

3. The extension may add new XML elements and attributes, but may not render any standard ODM elements or attributes obsolete. Vendor extensions cannot be used for information that is normally expressed using other ODM elements.

4. All new element and attribute names must use distinct XML namespaces to insure that there are no naming conflicts with other vendor extensions.

5. Removing all vendor extensions from an extended ODM file must result in a meaningful and accurate standard ODM file.

6. Vendors should be able to produce ODM files free of any vendor extensions upon request.

OpenClinica meets these requirements in its use of vendor extensions.

10.2 Limitations on Support for Generated and Received ODM Files

OpenClinica has the following limitations on its support for generated and received ODM files:

OpenClinica acts as a receiving system via its Data Import functionality. In this case it selectively ignores information as allowed by the conformity requirements. In particular:

- Receiving files for data import ignores any information under the Study AdminData, ReferenceData, and Association nodes. When receiving files OpenClinica only deals with ClinicalData
- OpenClinica does not support the typed data transmission construct in ClinicalData (see ODM section 2.5.1 - Typed Data Transmission). All files generated by OpenClinica use the generic ItemData tag rather than ItemData[TYPE]. If when receiving files (ie in Data Import), OpenClinica encounters ClinicalData using ItemData[TYPE] tags, these entities are ignored. They will pass through schema validation, but the data will not be imported, as OpenClinica wont be able to generate the necessary Java objects to put data into the database.
- OpenClinica does not support the same set of Item Data types as specified in the ODM definition. For generation of ODM, the types supported are defined in the table Item Data Types in this document. For receiving ODM, since only ClinicalData is recognized, and Item Data Types defined as part of the incoming ODM file will be ignored. Incoming ItemData values will be validated based on the OpenClinica data type of the specified Item OID.

10.3 Entities and Elements

Entities and elements in OpenClinica use the same names as their counterparts in ODM. For example, the ODM definitions for study event and Study Event Definition are valid for the entities of the same name in OpenClinica (see Section 2.6, Entities and Elements, of the ODM specification):

- A *study event* is a reusable package of forms usually corresponding to a study data-collection event.
- A *Study Event Definition* describes a particular type of study event (mostly by listing the types

of forms it can contain).
- The clinical data of a study will typically have many actual study events corresponding to each StudyEventDef,

Where the usage of these entity names in OpenClinica diverges from the ODM definition, it will be noted in this document.

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10.4 OIDs and Clinical Data Keys

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10.4.1 Generation of OIDs

OpenClinica uses Object Identifiers (OIDs, sometimes referred to as OpenClinica IDs) to link objects to one another, and enforce uniqueness within an instance of OpenClinica (with the exception of Rule OIDs, which must only be unique within a study). We currently utilize OIDs for the following objects in OpenClinica:

- CRFs
- CRF Versions
- Item Groups
- Items
- Measurement Units
- Rules
- Study Event Definitions
- Studies
- Sites
- Study Subjects

Each OID generated by OpenClinica starts with a prefix based on the type of entity, followed by *n* characters taken from the start of the proper name of the object (alpha-numeric only and converted to all caps), plus a random number at the end if the OID already exists in the database. This random number is generally 3-4 characters long (345, 5678, etc). Each part of the OID is separated by underscores. Using this scheme, we generate the following OIDs for objects:

- CRF: F + first 12 alpha-numeric characters in the CRF Name + random number if necessary (e.g. F_PHYSEXAM_7133)

- CRF Version: the CRF OID + the first 10 alpha-numeric characters in the CRF Version Name + random number if necessary
- Item Group: IG + first 5 alpha-numeric characters in the CRF Name + all the alpha-numeric characters in the Item Group Label + random number if necessary
- Item: I + first 5 alpha-numeric characters in the CRF Name + first 26 alpha-numeric characters in the Item Label + random number if necessary
- Measurement Unit: MU + first 37 alpha-numeric characters in the measurement unit name + random number if necessary
- Rule: generated by user input at the Import Rules stage of OpenClinica. Must be alpha-numeric and all caps (underscores allowed) with a maximum 40 characters. Each Rule OID must be unique within the study that it is uploaded to.
- Study Event Definition: SE + first 28 alpha-numeric characters in study event definition name + random number if necessary
- Study: S + first 8 alpha-numeric characters in the Studys Unique Protocol ID + random number if necessary
- Site: S + first 8 alpha-numeric characters in the Studys Unique Protocol ID + random number if necessary
- Study Subject: SS + all alpha-numeric characters in the Study Subject ID + random number if necessary. Each Study Subject OID will be unique within the entire OpenClinica instance. In ODM, Study Subjects are given a SubjectKey to identify a specific subject that is unique within the study, while OpenClinica Study Subject OIDs are unique across all studies in the instance.

10.4.2 OID Scope, Context and Uniqueness Constraints

ODM defines a system of OID uniqueness constraints for Element Identifiers and references, which only require uniqueness within certain contexts. For example, the Study OID has to be unique within a series of ODM documents, while an OID for ItemGroup has to be unique within its Study only. Aside from that, notable requirements for ODM OID uniqueness include the following:

- ODM OIDs for each element type inside a MetaDataVersion must be unique for that scope of the MetaDataVersion.
- MetaDataVersion OIDs must be unique within the containing Study.
- ArchiveLayout OIDs, while not used in OpenClinica yet, must be unique within a single FormDef.
- Study OIDs must be unique within the containing ODM.
- Measurement Unit OIDs must be unique within the containing Study.
- User, Location and Signature OIDs, while not used in OpenClinica yet, must be unique within the containing AdminData.

OpenClinica generally adheres to these contraints, but OpenClinica OIDs are also unique across all studies in a single instance of OpenClinica. Because of this, an entity (such as a CRF) loaded into a separate instance of OpenClinica may not have the same OIDs in the new instance since those OIDs may already be assigned. This has drawbacks for reuse of CRFs and Rules across instances (such as

porting a study definition from test to production) because the OIDs of items, groups, forms, and events that are referenced in the Rules may change when loaded into the new instance.

10.4.3 Clinical Data Keys

The ODM standard uses the concept of Internal Clinical Data Keys to uniquely address clinical data entities within the model. The following table details the key, or combination of entity identifiers, that you would need to uniquely and specifically address a clinical data entity.

Kind of Entity	**Identifying Keys (ODM)**	**Identifying Keys (OpenClinica ODM)**
study	StudyOID	Same as ODM
subject	above plus SubjectKey	Same as ODM
study event	above plus StudyEventOID and StudyEventRepeatKey	Same as ODM
Form	above plus FormOID and FormRepeatKey	Same as ODM, however repeating forms are not supported so no FormRepeatKey is necessary
Item group	above plus ItemGroupOID and ItemGroupRepeatKey	Same as ODM
item	above plus ItemOID	Same as ODM
annotation	keys for the annotated entity plus SeqNum	Not used in OpenClinica

For example, an XPath query to retrieve a specific item data value in an OpenClinica ODM Extract would be of the form:

/odm:ODM/odm:ClinicalData[@StudyOID='S_P12345_2818']/odm:SubjectData[@SubjectKey='SS_101']/odm:StudyEventData[@StudyEventOID='SE_INITIALT' and @StudyEventRepeatKey='1']/odm:FormData[@FormOID='F_AGEN_V10']/odm:ItemGroupData[@ItemGroupOID='IG_AGEN_DOSETABLE-F_AGEN_V10' and @ItemGroupRepeatKey='1']/odm:ItemData[@ItemOID='I_AGEN_AGENT_NAME']/@Value

In the image below you can see that the latter half of the XML file (the part contained in the <ClinicalData> tags) links to specific tables in the OpenClinica database. We then link back to the Study metadata through those OIDs. Internally we dont use OIDs in those tables, but instead the conventional methods of primary keys and foreign keys in the database is good enough. For more on how ODM, OIDs, and Clinical Data Keys are implemented in OpenClinica see the blog post, "Thoughts on Code: OpenClinica and Open Standards with CDISC".

10.5 File Properties, Transactions and Element Ordering

ODM and OpenClinica support versioning of files with a FileOID attribute which is meant to uniquely identify the document. The OID is generated in OpenClinica Extract Data module, from the file name which contains a timestamp down to the millisecond. No effort is made to parse or connect this FileOID upon Bulk Data Import, however.

ODM and OpenClinica both support the FileType attribute, which is automatically set to Snapshot in Extract Data.

ODM also supports an optional Archival attribute, but OpenClinica does not generate or support this attribute currently.

In ODM, each data attribute has an optional TransactionType attribute. This attribute can be one of Insert, Update, Remove or Upsert. OpenClinicas Extract Data always outputs TransactionTypes of Insert. OpenClinicas Data Import module always processes data as if it were a TransactionType of Upsert, and ignores any TransactionType attributes specified in the ODM.

ODM also supports the concept of Element Ordering: where all time stamps on each element must precede the CreationDateTime of the ODM file. Currently, OpenClinica does not have any logic which monitors date correctness in ODM files, during Import or Extract.

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.

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10.7 Data Representations in ODM XML (Extract)

When OpenClinica outputs ODM XML, the five basic XML entities (gt, lt, quot, amp, apos) are escaped using XML Entity notation (For example: "bread" & "butter" => "bread" & "butter").

Whitespace is represented literally linebreaks and tabs in ItemData values and other fields will be preserved. Note that, while tabs and carriage returns are limited in the data entry side of the application, (tabs will automatically shift focus from one Item to the next, for example) all spaces and linebreaks are saved to the database, and will export into ODM XML.

Items saved in the database with non-ASCII characters will be extracted to XML entities using their ASCII decimal value equivalents; please see the next section, "OpenClinica Data Representations in ODM XML (Extract)" for an example of this.

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10.8 Data Representations in ODM XML (Import)

ItemData values being imported are validated against data type and length.

During data import the XML Entity representation of characters in ItemData values are treated as literals. So an Item Data value of

"bread" & "butter"

would be exported as

"bread" & "butter"

and if it were then imported back into OpenClinica would be saved as

"bread" & "butter"

Whitespace, including linebreaks and tabs in ItemData values are preserved, but the validations on different data types react differently to whitespace. Single-select and multi-select values do not accept whitespace upon import, instead generating the hard validation check error message, This is not in the correct response set. Whitespace generated in date types passes validation, but is stripped out and does not re-export; tabs are kept in other data types, but returns are not kept.

For example, a set of Items in XML that is imported as the following:

```
<ItemData ItemOID="I_GROU_TC_ADV_PRIMARY_06" Value="Heart Attack      "/>

 <ItemData ItemOID="I_GROU_TC_ADV_PRIMARY_07" Value="2009-12-16       "/>

 <ItemData ItemOID="I_GROU_TC_ADV_PRIMARY_08" Value="11/02/2009        "/>
```

Will be returned as the following:

```
 <ItemData ItemOID="I_GROU_TC_ADV_PRIMARY_06" Value="Heart Attack"/>

 <ItemData ItemOID="I_GROU_TC_ADV_PRIMARY_07" Value="2009-12-16"/>

 <ItemData ItemOID="I_GROU_TC_ADV_PRIMARY_08" Value="11/02/2009"/>
```

Items imported with non-ASCII characters will be exported using escaped ASCII codes. For example, the following line

```
<ItemData ItemOID="I_GROU_TC_ADV_PRIMARY_06" Value="??? ????"/>
```

Will be returned as the following:

<ItemData ItemOID="I_GROU_TC_ADV_PRIMARY_06" Value="про
ыуиу "/>

Note that, if the above ASCII values are copied and inserted back into the database, they are still saved as UTF-8 values, and will be exported the same way, without any degradation (as in the above example with XML escaped characters).

10.9 Item Data Types

OpenClinica supports a subset of the Item Data Types defined in ODM. The data type mapping is shown below, along with the allowed string pattern used to validate item values for a given data type. Note that a listing of no definition in the table below means that the data type is not supported in OpenClinica.

Item Data Types

CDISC Item Data Type	***OpenClinica Data Type***	***Allowed Values (Data Import)***	***Representation of Values (Extract)***
text	ST	Any sequence of characters up to the maximum allowed number of characters (currently 4000). If the value is greater than the width is specified in the items width_decimal property (or 255, whichever is less), a discrepancy note will be created but the data will be allowed.	
partialDate	PDATE	A date represented according to the XML schema date datatype, which is based on the ISO8601 standard (YYYY-MM-DD).	A date represented according to the XML schema date datatype, which is based on the ISO8601 standard (YYYY-MM-DD). Partial Dates can be YYYY-MM or YYYY and will be exported as YYYY-MM or YYYY.
text	FILE	Files cannot be imported into ODM at this time.	A string representing the file name of the stored file, up to the maximum allowed number of characters (currently 4000).
integer	INT	-?digit+ If the value is greater than the width specified in the items width_decimal property (or 255, whichever is less), a discrepancy note will be created but the data will be allowed.	
float	REAL	-?digit+(.digit+)? If the value is greater than the width is specified in the items width_decimal property (or 255, whichever is less), a discrepancy note will be created but the data will be allowed. Float values will only be rounded for calculations, based on the decimal specified in the items width_decimal property if it exists. If no width_decimal is provided it will round to the 4th decimal place. For example, if someone entered a value like 6.987398 into a field that is not a calculation, the number will not be rounded to the 4th decimal place.	
date	DATE	A date represented according to the XML schema date datatype, which is based on the ISO8601 standard (YYYY-MM-DD).	A date represented according to the XML schema date datatype, which is based on the ISO8601 standard (YYYY-MM-DD).
time	No definition		
datetime	No definition		
string	No definition		
boolean	No definition		
double	No definition		
hexBinary	No definition		
base64Binary	No definition		
hexFloat	No definition		
base64Float	No definition		

partialTime	No definition		
partialDatetime	No definition		
durationDatetime	No definition		
intervalDatetime	No definition		
incompleteDatetime	No definition		
URI	No definition		

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10.10 Mapping of OpenClinica Elements to ODM

CDISC ODM	OpenClinica Data Schema (table.column_name)	OpenClinica CRF Spreadsheet	Example Values (Comments)	Added to 3.1?
ODM				
FileOID	dataset.name-D-creationDateTime		Intervention_DatasetD20100924143323+0300	
CreationDateTime			2010-09-24T14:33:23+03:00	
FileType			Snapshot (generated automatically)	
ODMVersion			1.3	
xsi:schemaLocation			http://www.cdisc.org/ns/odm/v1.3 OpenClinica-ODM1-3-0-OC2-0.xsd	
Study				
OID	study.oc_oid		S_DEMO123	
StudyName	study.name		Demonstration Study	
StudyDescription	study.summary		This study is used for demonstrational purposes	
ProtocolName	study.unique_identifier		Demo123	
MeasurementUnit				
OID	measurement_unit.oc_oid		MU_HG	
Name	measurement_unit.name	UNITS	Hg	
Symbol				
TranslatedText	item.units	UNITS	Hg	
MetaDataVersion				
OID	dataset.odm_metadataversion_oid		v1.0.0 (defined at dataset creation time)	
Name	dataset.odm_metadataversion_name		MetaDataVersion_v1.0.0	
StudyEventRef				
StudyEventOID	study_event_definition.oc_oid		Systematically generated when a study event definition is created. Refer to section 2.4.1	
OrderNumber	study_event.sample_ordinal		The order the event definitions appear in the system. These values can be rearranged by certain users.	
Mandatory	event_definition_crf.required_crf		If at least one CRF in the event definition is set to Required, the event itself becomes required.	
StudyEventDef				
OID	study_event_definition.oc_oid		Systematically generated when a study event definition is created. Refer to section 2.4.1	
Name	study_event_definition.name		Initial Visit	
Repeating	study_event_definition.repeating		Yes, No	
Type	study_event_definition.type		Scheduled, Unscheduled, Common. The values conform to CDISC terms.	
FormRef				
FormOID	crf_version.oc_oid		F_DEMOGRAPHICS_1	
Mandatory	event_defintion_crf.required_crf		Yes, No	
FormDef				
OID	crf_version.oc_oid		F_DEMOGRAPHICS_1	
Name	crf.name + crf_version.name	CRF_NAME + VERSION	Demographics-Dynamics - 1	
Repeating			No (generated automatically)	
ItemGroupRef				
ItemGroupOID	item_group.oc_oid		IG_DEMOG_UNGROUPED	
Mandatory	Same as ItemRef Mandatory		Yes, No	
OpenClinica:FormDetails				
FormOID	crf_version.oc_oid		F_DEMOG_1	
ParentFormOID	crf.name	CRF_NAME	DEMOG	Y
VersionDescription	crf_version.description	VERSION_DESCRIPTION	This CRF version contains 2 additional items	Y
RevisionNotes	crf_version.revision_notes	REVISION_NOTES	I revised this CRF and created this new version.	Y
OpenClinica:SectionDetails				
OpenClinica:Section				
SectionLabel	section.label	SECTION_LABEL		
SectionTitle	section.title	SECTION_TITLE		
SectionSubtitle	section.subtitle	SUBTITLE		
SectionInstructions	section.instructions	INSTRUCTIONS		
SectionPageNumber	section.page_number_label	PAGE_NUMBER		
OpenClinica:PresentInEventDefinition				Y
StudyEventOID	study_event_definition.oc_oid		Systematically generated when a study event definition is created. Refer to section 2.4.1	Y
IsDefaultVersion	event_definition_crf.default_version_id		True, False	Y
PasswordRequired	event_definition_crf.electronic_signature		True, False	Y

DoubleDataEntry	event_definition_crf.double_entry		True, False	Y
HideCRF	event_definition_crf.hide_crf		True, False	Y
SourceDataVerification	event_definition_crf.source_data_verification		100% Required, Partial Required, Not Required, Not Applicable	Y
ItemGroupDef				
OID	item_group.oc_oid		IG_DEMOG_UNGROUPED	
Name	item_group.name	GROUP_LABEL	Ungrouped (if the items are ungrouped)	
Repeating	item_group_metadata.repeating_group	GROUP_LAYOUT	Yes, No	
Comment	item_group_metadata.header	GROUP_HEADER		
SASDatasetName			UNGRO044 (generated automatically; take the item_group.name, switch to all caps, and truncate to eight characters, adding integers and alpha characters to the end to make unique)	Y
ItemRef				
ItemOID	item.oc_oid		I_THAP_BLOODPRODTYP	
OrderNumber	item_form_metadata.ordinal		1, 2, 3, etc.	
Mandatory	item_form_metadata.required	REQUIRED	Yes, No	
OpenClinicaItemGroupDetails				
ItemGroupOID	item_group.oc_oid		IG_DEMOG_UNGROUPED	
OpenClinica:PresentInForm				
FormOID	crf_version.oc_oid			
ShowGroup	item_group_metadata.show_group	GROUP_DISPLAY_STATUS	HIDE, SHOW	Y
OpenClinica:ItemGroupRepeat				Y
RepeatNumber	item_group_metadata.repeat_number	GROUP_REPEAT_NUMBER		Y
RepeatMax	item_group_metadata.repeat_max	GROUP_REPEAT_MAX		Y
ItemDef				
OID	item.oc_oid		I_THAP_BLOODPRODTYP	
Name	item.name	ITEM_NAME	BloodProdTyp	
DataType	item_data_type.name	DATA_TYPES	Text, float, integer, etc.	
Length	item_form_metadata.width_decimal	WIDTH_DECIMAL*	(For ODM float data types, the length is based on the width parameter specified in the WIDTH_DECIMAL field in the spreadsheet (if it is provided). For other data types, length is calculated based on the maximum length of all the values for the item.)	
SignificantDigits	item_form_metadata.width_decimal	WIDTH_DECIMAL*	(For ODM float data types, the SignificantDigits is based on the decimal parameter specified in the WIDTH_DECIMAL field in the spreadsheet. For other data types, SignificantDigits is not used.)	
SASFieldName			Blood301 (again, generated from the item.name, but truncated to eight characters with an integer at the end to enforce uniqueness)	
Comment	item.description	DESCRIPTION_LABEL		
OpenClinica:FormOIDs	crf_version.oc_oid		F_THAP_V10 (comma-separated list of CRF version OIDs where the item is found)	
Question				
OpenClinica:QuestionNumber	item_form_metadata.question_number	QUESTION_NUMBER		Y
TranslatedText	item_form_metadata.header + item_form_metadata.left_item_text + item_form_metadata.right_item_text	LEFT_ITEM_TEXT RIGHT_ITEM_TEXT HEADER SUB_HEADER	Amount of blood product (ml)	
MeasurementUnitRef				
MeasurementUnitOID	measurement_unit.oc_oid		Systematically generated when a CRF Version is uploaded containing an item with a value in the UNITS cell.	
CodeListRef				
CodeListOID	response_set.response_set_id		CL_233 (OID generated automatically by adding the prefix CL_ to the primary key)	
RangeCheck				
Comparator	item_form_metadata.regexp (if "func:")	VALIDATION	LE, GE, EQ, etc.	
SoftHard			Soft, Hard (based on study parameter values governing discrepancy note generation)	
CheckValue	Item_form_metadata the value in the function. For example, 95 if the check is for greater than 95,	VALIDATION	100	
ErrorMessage				
TranslatedText	item_form_metadata.regexp_error_msg (if "func:")	VALIDATION_ERROR_MESSAGE	Please specify a value between 0 and 100	
OpenClinica:ItemDetails				
ItemOID	item.oc_oid		Systematically generated when a CRF Version is uploaded to OpenClinica	
OpenClinica:PresentInForm				
FormOID	crf_version.oc_oid			
ParentItemOID	item.oc_oid		Items can contain links to other items that are their parents. The value would reflect an OID for an item present in the same section of the same form.	Y
ColumnNumber	item_form_metadata.column_number	COLUMN_NUMBER	1, 2, 3 etc.	Y
PageNumber	item_form_metadata.page_number	PAGE_NUMBER	1, 2, 3 etc.	Y
PHI	item.phi_status	PHI	1, 0	Y
ShowItem	item_form_metadata.show_item	ITEM_DISPLAY_STATUS	SHOW, HIDE	Y
OrderInForm	item_form_metadata.ordinal		The items order shown in UI from view crf page.	
OpenClinica:LeftItemText	item_form_metadata.left_item_text	LEFT_ITEM_TEXT	Height	Y
OpenClinica:RightItemText	item_form_metadata.right_item_text	RIGHT_ITEM_TEXT	Height	Y
OpenClinica:ItemHeader	item_form_metadata.header	HEADER	This field captures Height	Y
OpenClinica:ItemSubHeader	item_form_metadata.subheader	SUB_HEADER	Please provide the Height in inches.	Y
OpenClinica:SectionLabel	section.label	SECTION_LABEL		Y
OpenClinica:ItemResponse	response_type.name	RESPONSE_TYPE		Y
CodeList				
OID	response_set.response_set_id		CL_233 (OID generated automatically by adding the prefix CL_ to the primary key)	

Name	response_set.label	RESPONSE_LABEL	yn	
DataType	item_data_type.name	DATA_TYPES	Text, float, integer, etc.	
SASFormatName			$YN54X (generated, with Name in all caps with a $ and an extra suffix to be unique)	
CodeListItem				
CodedValue	response_set.options_values	REPONSE_VALUES_OR_CALCULATIONS	1, 2, 3, etc.	
Decode				
TranslatedText	response_set.options_text	RESPONSE_OPTIONS_TEXT	Yes, No, etc.	
OpenClinica:MultiSelectList				
OpenClinica:ID	response_set.response_set_id		MSL_54 (generate an OID on the fly by adding the prefix MSL_ to the iprimary key)	
OpenClinica:Name	response_set.label	RESPONSE_LABEL	OptionsList	
OpenClinica:DataType	response_type.name		text, (the DataType value is always text)	
OpenClinica:ActualDataType	response_type.name	DATA_TYPE	text, float, integer	
OpenClinica:MultiSelectListItem				
OpenClinica:CodedOptionValue	response_set.options_values	RESPONSE_VALUES_OR_CALCULATIONS	1, 2, 3, etc.	
OpenClinica:StudyGroupClassList				
OpenClinica:ID	study_group_class.study_group_class_id		SGC_1 (SGC_ prefix automatically appended)	
OpenClinica:Name	study_group_class.name		Age Classification	
OpenClinica:Status	status.name		Available	
OpenClinica:Type	group_class_types.name		Arm, Demographic, etc.	
OpenClinica:SubjectAssignment	study_group_class.subject_assignment		Optional	
OpenClinica:StudyGroupItem				
OpenClinica:Name	study_group.name		Young Adult	
OpenClinica:Description	study_group.description		12-18	
OpenClinica:StudyDetails				
StudyOID	study.oc_oid			
SiteName	study.name		Present only when extracting site level ODM.	Y
ParentStudyName	study.name		Gives the name of study which this site is part of. Tag is present only when the ODM is retrieved at site level.	Y
OpenClinica:StudyDescriptionStatus				Y
OfficialTitle	study.official_title			Y
SecondaryIDs	study.secondary_identifier			Y
DateCreated	study.date_created		2011-01-01	Y
StartDate	study.date_planned_start		2011-01-01	Y
StudyCompletionDate	study.date_planned_end		2011-12-31	Y
OpenClinica:StudySystemStatus	study.status_id		Available, Pending, Locked, Frozen	Y
OpenClinica:PrincipalInvestigator	study.principal_investigator		John Smith	Y
OpenClinica:DetailedDescription	study.protocol_description		This is a demonstration study.	Y
OpenClinica:Sponsor	study.sponsor		Drug Company A	Y
OpenClinica:Collaborators	study.collaborators		This can be a list of different organizations	Y
OpenClinica:StudyPhase	study.phase		N/A, Phase I, Phase I/Phase II, Phase II, Phase II/Phase III, Phase III, Phase III/Phase IV, Phase IV	Y
OpenClinica:ProtocolType	study.protocol_type		Interventional, Observational	Y
OpenClinica:ProtocolVerificationDate	study.protocol_date_verification		2011-01-01	Y
OpenClinica:Purpose	study.purpose		Treatment, Prevention, Diagnosis, Supportive Care, Screening, Health Services Research, Basic Science, Other	Y
OpenClinica:Allocation	study.allocation		Randomized Clinical Trial, Non-Randomized Clinical Trial, N/A	Y
OpenClinica:Masking	study.masking		Open, Single Blind, Double Blind	Y
OpenClinica:Control	study.control			Y
OpenClinica:InverventionModel	study.interventions			Y
OpenClinica:ConditionsAndEligibility	study.eligibility			Y
OpenClinica:Conditions	study.conditions			Y
OpenClinica:Keywords	study.keywords			Y
OpenClinica:EligibilityCriteria				Y
OpenClinica:Sex	study.gender			Y
OpenClinica:Age				Y
MinimumAge	study.age_min			Y
MaximumAge	study.age_max			Y
OpenClinica:HealthyVolunteersAccepted	study.healthy_volunteers			Y
OpenClinica:ExpectedTotalEnrollment	study.expected_total_enrollment			Y
OpenClinica:FaciltyInformation				Y
OpenClinica:FacilityName	study.facility_name			Y
OpenClinica:FacilityCity	study.facility_city			Y
OpenClinica:FacilityState	study.facility_state			Y
OpenClinica:PostalCode	study.facility_zip			Y
OpenClinica:FacilityCountry	study.facility_country			Y
OpenClinica:FacilityContactName	study.facility_contact_name			Y
OpenClinica:FacilityContactPhone	study.facility_contact_phone			Y
OpenClinica:FacilityContactEmail	study.facility_contact_email			Y
OpenClinica:RelatedInformation				Y
OpenClinica:MEDLINEIdentifier	study.medline_identifier			Y
OpenClinica:ResultsReference	study.results_reference			Y
OpenClinica:URLReference	study.url			Y
OpenClinica:URLDescription	study.url_description			Y
OpenClinica:StudyParameterConfiguration				Y
OpenClinica:StudyParameterListRef				Y
StudyParameterListID	study_parameter.name			Y
Value	study_parameter_value.value			Y
OpenClincia:StudyParameterListItem				Y
CodedParameterValue	study_parameter.name			Y
RuleImport			Rules are a separate vendor extensions from the OpenClinica: namespace.	Y
RuleAssignment				Y
RuleRef				Y
OID	rule.oc_oid			Y
ShowAction	rule_action.action_type			Y
ifExpressionEvaluates	rule_action.expression_evaluates_to			Y
HideAction	rule_action.action_type			Y
ifExpressionEvaluates	rule_action.expression_evaluates_to		TRUE or FALSE	Y
EmailAction	rule_action.action_type			Y
ifExpressionEvaluates	rule_action.expression_evaluates_to		TRUE or FALSE	Y
DiscrepancyNoteAction	rule_action.action_type			Y
ifExpressionEvaluates	rule_action.expression_evaluates_to		TRUE or FALSE	Y

InsertAction	rule_action.action_type			Y
ifExpressionEvaluates	rule_action.expression_evaluates_to		TRUE or FALSE	Y
Run				Y
AdministrativeEditing	rule_action.administrative_data_entry		TRUE or FALSE	Y
InitialDataEntry	rule_action.initial_data_entry		TRUE or FALSE	Y
DoubleDataEntry	rule_action.double_data_entry		TRUE or FALSE	Y
Batch	rule_action.batch		TRUE or FALSE	Y
Message	rule_action.message		The values do not match, please verify the data provided.	Y
DestinationProperty				Y
OID	rule_action_property.oc_oid		This will be an OID. If the item is part of the same group, then the user should	Y
RuleDef				Y
OID	rule.oc_oid		All capital letters or integers. This is user defined	Y
Name	rule.name			Y
Description	rule.description		Describe the rule to put it into a context you will recognize.	Y
Expression	rule_expression.value		The expression is used to validate data values to then decide if an action should be taken.	Y
AdminData				Y
StudyOID	study.oc_oid			Y
User				Y
OID			Generated automatically by taking the value in user_account.user_id and appending USR_ to the front	Y
FullName	user.user_name		jsmith	Y
FirstName	user.first_name		John	Y
LastName	user.last_name		Smith	Y
Organization	user.institutional_affiliation		Enterprise Organization	Y
ClinicalData				Y
StudyOID	study.oc_oid		S_DEMO123	
MetaDataVersionOID	dataset.odm_metadataversion_oid		v1.0.0	
SubjectData				
SubjectKey	study_subject.oc_oid		SS_101	
OpenClinica:StudySubjectId	study_subject.label		101	
OpenClinica:UniqueIdentifier	subject.unique_identifier			
OpenClinica:Status	status.name		available	
OpenClinica:SecondaryId	study_subject.secondary_label			
OpenClinica:YearOfBirth	subject.date_of_birth		2001 (depends on the study parameters; if study does not require date of birth or records full date of birth, this is not included)	
OpenClinica:DateOfBirth	subject.date_of_birth		2001-01-01 (depends on the study parameters; if subject is year only or if date of dirth is not recorded, this is not included)	
OpenClinica:Sex	subject.gender		m, f	
StudyEventData				
StudyEventOID	study_event_definition.oc_oid		SE_OBSERVAT	
StudyEventRepeatKey			1, 2, 3, etc. (optional, not included if not repeating)	
OpenClinica:StudyEventLocation	study_event.location		Boston, MA	
OpenClinica:StartDate	study_event.date_start		2010-10-10	
OpenClinica:EndDate	study_event.date_end		2010-12-31 (optional, not included if left blank)	
OpenClinica:Status	status.name		signed, available, etc.	
OpenClinica:SubjectAgeAtEvent			13 (calculated automatically)	
FormData				
FormOID	crf_version.oc_oid		F_GROU_V22	
OpenClinica:Version	crf_version.name			
OpenClinica:InterviewerName	event_crf.interviewer_name			
OpenClinica:InterviewDate	event_crf.date_interviewed		2010-10-10	
OpenClinica:Status	status.name			
ItemGroupData				
ItemGroupOID	item_group.oc_oid		IG_GROU_GROUP_1	
TransactionType			Insert (generated by default)	
ItemGroupRepeatKey	item_data.ordinal if repeating		1, 2, 3, etc. (optional)	
ItemData				
ItemOID	item.oc_oid		I_GROU_TC_ADV_PRIMARY_03	
Value	item_data.value			
IsNull			Yes (only generated if the item is null)	
OpenClinica:ReasonForNull	item_data.value		(only generated if the item is null)	
OpenClinica:AuditLogs				Y
EntityID			Form OID, Item OID, Event OID, Study Subject OID	Y
OpenClinica:AuditLog				Y
ID			System generated ID taken from the audit_log_event.audit_id and appending AL_ to the beginning	Y
UserID			References the value for User OID	Y
DateTimeStamp	audit_log_event.audit_date		1000-11-16T10:15:37	Y
AuditType	audit_log_event_type.name		The audit log type	Y
OldValue	audit_log_event.old_value			Y
NewValue	audit_log_event.new value			Y
OpenClinica:DiscrepancyNotes				Y
EntityID			Item OID, Event OID, Study Subject OID	Y
OpenClinica:DiscrepancyNote				Y
ID			System generated by appending DN_ to the value from discrepancy_note.discrepancy_note_id	Y
Status	resolution_status.name		New, Updated, Resolution Proposed, Closed, Not Applicable	Y
NoteType	discrepancy_note_type.name		Query, Failed Validation Check, Reason for Change, Annotation	Y
DateUpdated	discrepancy_note.date_created for a child note			Y
NumberOfChildren			Adds up the number of child notes that exist in the thread.	Y
OpenClinica:ChildNote				Y

Status	resolution_status.name		New, Updated, Resolution Proposed, Closed, Not Applicable	Y
DateCreated	discrepancy_note.date_created			Y
OpenClinica:Description	discrepancy_note.description		Value outside of range	Y
OpenClinica:DetailedNote	discrepancy_note.detailed_note		This value was outside of the range that is accepted. Please follow up with this subject and see if they should be enrolled or not.	Y
UserRef				Y
UserOID				Y
OpenClinica:SubjectGroupData				
OpenClinica:StudyGroupClassID	study_group_class.study_group_class_id		SGC_1	
OpenClinica:StudyGroupClassName	study_group_class.name		Age Classification	
OpenClinica:StudyGroupName	study_group.name		Young Adult	

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10.11 CDISC ODM XML Schema

The schema for CDISC ODM, as implemented natively by OpenClinica (ODM 1.3, including vendor extensions) can be found at https://dev.openclinica.com/tools/odm-doc/. This page provides an overview of the schemas/namespaces that are used in an OpennClinica ODM document. Click on the 'schema location' for each individual schema to get the raw XSD. You can also see a visualization of the data structures here.

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10.12 Global Case Report Form in ODM repesentation

Starting in OpenClinica 3.1.4, the print module has been revamped. The Printable CRF functionality uses javascript and CSS code applied to CDISC ODM data served by the REST API format to print the CRFs with and without data.

The CDISC-ODM model is based around a study protocol, and represents CRFs as part of a protocol. It does not cover CRFs when they are not part of a protocol, even if they are CRFs in the OpenClinica instance. To do this, and therefore allow printable views of non-study specific CRFs, we generate in the REST API calls a "fake" set of OIDs, starting with "OC_FORM_LIB" in the CDISC-ODM xml.

As an example:

<GlobalVariables><StudyName>OC_FORM_LIB_STUDY</StudyName><StudyDescription>

</StudyDescription><ProtocolName/></GlobalVariables><MetaDataVersion OID="v1.0.0" Name="MetaDataVersion_v1.0.0"><Protocol>
</Protocol><StudyEventDef OID="OC_FORM_LIB_SE" Name="OC_FORM_LIB_SE_NAME" Repeating="NO" Type="null">
<FormRef FormOID="F_0000ARTESTRE_12" Mandatory="null"/>
</StudyEventDef>
<FormDef OID="F_0000ARTESTRE_12" Name="1.2" Repeating="No">
<OpenClinica:FormDetails FormOID="F_0000ARTESTRE_12" ParentFormOID="F_TEST_FIELD_R">....