

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	
CreationDate/Time			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_definition_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
<i>OpenClinica:SectionDetails</i>				
<i>OpenClinica:Section</i>				
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		
<i>OpenClinica:PresentInEventDefinition</i>				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	

OpenClinicalItemGroupDetails				
ItemGroupOID	item_group.oc_oid		IG DEMOG UNGROUPED	
<i>OpenClinica:PresentInForm</i>				
FormOID	crf_version.oc_oid			
ShowGroup	item_group_metadata.show_group	GROUP DISPLAY STATUS	HIDE, SHOW	Y
<i>OpenClinica:ItemGroupRepeat</i>				
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	
Data Type	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	
Error Message				
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	
<i>OpenClinica:PresentInForm</i>				
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.	
<i>OpenClinica:LeftItemText</i>	item_form_metadata.left_item_text	LEFT_ITEM_TEXT	Height	Y
<i>OpenClinica:RightItemText</i>	item_form_metadata.right_item_text	RIGHT_ITEM_TEXT	Height	Y
<i>OpenClinica:ItemHeader</i>	item_form_metadata.header	HEADER	This field captures Height	Y
<i>OpenClinica:ItemSubHeader</i>	item_form_metadata.subheader	SUB HEADER	Please provide the Height in inches.	Y
<i>OpenClinica:SectionLabel</i>	section.label	SECTION LABEL		Y
<i>OpenClinica:ItemResponse</i>	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	
Data Type	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	RESPONSE_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 primary 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
<i>OpenClinica:StudyDescriptionStatus</i>			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
<i>OpenClinica:StudySystemStatus</i>	study.status_id	Available, Pending, Locked, Frozen	Y
<i>OpenClinica:PrincipalInvestigator</i>	study.principal_investigator	John Smith	Y
<i>OpenClinica:DetailedDescription</i>	study.protocol_description	This is a demonstration study.	Y
<i>OpenClinica:Sponsor</i>	study.sponsor	Drug Company A	Y
<i>OpenClinica:Collaborators</i>	study.collaborators	This can be a list of different organizations	Y
<i>OpenClinica:StudyPhase</i>	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
<i>OpenClinica:ProtocolType</i>	study.protocol_type	Interventional, Observational	Y
<i>OpenClinica:ProtocolVerificationDate</i>	study.protocol_date_verification	2011-01-01	Y
<i>OpenClinica:Purpose</i>	study.purpose	Treatment, Prevention, Diagnosis, Supportive Care, Screening, Health Services Research, Basic Science, Other	Y
<i>OpenClinica:Allocation</i>	study.allocation	Randomized Clinical Trial, Non-Randomized Clinical Trial, N/A	Y
<i>OpenClinica:Masking</i>	study.masking	Open, Single Blind, Double Blind	Y
<i>OpenClinica:Control</i>	study.control		Y
<i>OpenClinica:InerventionModel</i>	study.interventions		Y
<i>OpenClinica:ConditionsAndEligibility</i>	study.eligibility		Y
<i>OpenClinica:Conditions</i>	study.conditions		Y
<i>OpenClinica:Keywords</i>	study.keywords		Y
OpenClinica:EligibilityCriteria			Y
<i>OpenClinica:Sex</i>	study.gender		Y
<i>OpenClinica:Age</i>			Y
<i>MinimumAge</i>	study.age_min		Y
<i>MaximumAge</i>	study.age_max		Y
<i>OpenClinica:HealthyVolunteersAccepted</i>	study.healthy_volunteers		Y
<i>OpenClinica:ExpectedTotalEnrollment</i>	study.expected_total_enrollment		Y
OpenClinica:FacilityInformation			Y
<i>OpenClinica:FacilityName</i>	study.facility_name		Y
<i>OpenClinica:FacilityCity</i>	study.facility_city		Y
<i>OpenClinica:FacilityState</i>	study.facility_state		Y
<i>OpenClinica:PostalCode</i>	study.facility_zip		Y
<i>OpenClinica:FacilityCountry</i>	study.facility_country		Y
<i>OpenClinica:FacilityContactName</i>	study.facility_contact_name		Y
<i>OpenClinica:FacilityContactPhone</i>	study.facility_contact_phone		Y
<i>OpenClinica:FacilityContactEmail</i>	study.facility_contact_email		Y
OpenClinica:RelatedInformation			Y
<i>OpenClinica:MEDLINEIdentifier</i>	study.medline_identifier		Y
<i>OpenClinica:ResultsReference</i>	study.results_reference		Y
<i>OpenClinica:URLReference</i>	study.url		Y
<i>OpenClinica:URLDescription</i>	study.url_description		Y
OpenClinica:StudyParameterConfiguration			Y
OpenClinica:StudyParameterListRef			Y
<i>StudyParameterListID</i>	study_parameter.name		Y
<i>Value</i>	study_parameter.value.value		Y
OpenClinica:StudyParameterListItem			Y
<i>CodedParameterValue</i>	study_parameter.name		Y
RuleImport		Rules are a separate vendor extensions from the OpenClinica: namespace.	Y
RuleAssignment			Y
RuleRef			Y
<i>OID</i>	rule.oc_oid		Y
<i>ShowAction</i>	rule.action.action_type		Y
<i>ifExpressionEvaluates</i>	rule.action.expression evaluates to		Y
<i>HideAction</i>	rule.action.action_type		Y
<i>ifExpressionEvaluates</i>	rule.action.expression evaluates to	TRUE or FALSE	Y
<i>EmailAction</i>	rule.action.action_type		Y
<i>ifExpressionEvaluates</i>	rule.action.expression evaluates to	TRUE or FALSE	Y
<i>DiscrepancyNoteAction</i>	rule.action.action_type		Y
<i>ifExpressionEvaluates</i>	rule.action.expression evaluates to	TRUE or FALSE	Y
<i>InsertAction</i>	rule.action.action_type		Y
<i>ifExpressionEvaluates</i>	rule.action.expression evaluates to	TRUE or FALSE	Y
<i>Run</i>			Y
<i>AdministrativeEditing</i>	rule.action.administrative data entry	TRUE or FALSE	Y
<i>InitialDataEntry</i>	rule.action.initial data entry	TRUE or FALSE	Y
<i>DoubleDataEntry</i>	rule.action.double data entry	TRUE or FALSE	Y
<i>Batch</i>	rule.action.batch	TRUE or FALSE	Y
<i>Message</i>	rule.action.message	The values do not match, please verify the data provided.	Y
<i>DestinationProperty</i>			Y
<i>OID</i>	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
<i>OID</i>	rule.oc_oid	All capital letters or integers. This is user defined	Y
<i>Name</i>	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				
StudyOID	study.oc_oid			Y
User				
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				
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 birth 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				
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				
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	

Approved for publication by Cal Collins. Signed on 2014-04-02 3:48PM

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