



# 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? |
|---|---|-----------------------------|--|---------------|
| <b>ODM</b>                                  |   |                             |  |               |
| 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<br>OpenClinica-ODM1-3-0-OC2-0.xsd   |               |
| <b>Study</b>                                |   |                             |  |               |
| 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  |               |
| <b>MeasurementUnit</b>                      |   |                             |  |               |
| OID   | measurement_unit.oc_oid                       |                             | MU HG  |               |
| Name  | measurement_unit.name                         | UNITS                       | Hg   |               |
| <b>Symbol</b>                               |   |                             |  |               |
| TranslatedText                              | item.units                                    | UNITS                       | Hg   |               |
| <b>MetaDataVersion</b>                      |   |                             |  |               |
| OID   | dataset.odm_metadataversion_oid               |                             | v1.0.0 (defined at dataset creation time)  |               |
| Name  | dataset.odm_metadataversion_name              |                             | MetaDataVersion v1.0.0   |               |
| <b>StudyEventRef</b>                        |   |                             |  |               |
| 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.   |               |
| <b>StudyEventDef</b>                        |   |                             |  |               |
| 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.   |               |
| <b>FormRef</b>                              |   |                             |  |               |
| FormOID                                     | crf_version.oc_oid                            |                             | F DEMOGRAPHICS_1   |               |
| Mandatory                                   | event_definition_crf.required_crf             |                             | Yes, No  |               |
| <b>FormDef</b>                              |   |                             |  |               |
| OID   | crf_version.oc_oid                            |                             | F DEMOGRAPHICS_1   |               |
| Name  | crf.name + crf_version.name                   | CRF NAME + VERSION          | Demographics-Dynamics - 1  |               |
| Repeating                                   |   |                             | No (generated automatically)   |               |
| <b>ItemGroupRef</b>                         |   |                             |  |               |
| ItemGroupOID                                | item_group.oc_oid                             |                             | IG DEMOG UNGROUPED   |               |
| Mandatory                                   | Same as ItemRef Mandatory                     |                             | Yes, No  |               |
| <b>OpenClinica:FormDetails</b>              |   |                             |  |               |
| 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> |   |                             |  |               |
| 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             |
| <b>ItemGroupDef</b>                         |   |                             |  |               |
| 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             |
| <b>ItemRef</b>                              |   |                             |  |               |
| ItemOID                                     | item.oc_oid                                   |                             | I THAP BLOODPRODTYP  |               |
| OrderNumber                                 | item_form_metadata.ordinal                    |                             | 1, 2, 3, etc.  |               |
| Mandatory                                   | item_form_metadata.required                   | REQUIRED                    | Yes, No  |               |
| <b>OpenClinicaItemGroupDetails</b>          |   |                             |  |               |
| 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>     |  |   |   | Y |
| RepeatNumber                           | item_group_metadata.repeat_number  | GROUP REPEAT NUMBER                                       |   | Y |
| RepeatMax                              | item_group_metadata.repeat_max   | GROUP REPEAT MAX  |   | Y |
| <b>ItemDef</b>                         |  |   |   |   |
| 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).<br><br>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.<br><br>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)   |   |
| <b>Question</b>                        |  |   |   |   |
| OpenClinica:QuestionNumber             | item_form_metadata.question_number   | QUESTION NUMBER   |   | Y |
| TranslatedText                         | item_form_metadata.header +<br>item_form_metadata.left_item_text +<br>item_form_metadata.right_item_text | LEFT_ITEM_TEXT<br>RIGHT_ITEM_TEXT<br>HEADER<br>SUB HEADER | Amount of blood product (ml)  |   |
| <b>MeasurementUnitRef</b>              |  |   |   |   |
| MeasurementUnitOID                     | measurement_unit.oc_oid  |   | Systematically generated when a CRF Version is uploaded containing an item with a value in the UNITS cell.  |   |
| <b>CodeListRef</b>                     |  |   |   |   |
| CodeListOID                            | response_set.response_set_id   |   | CL_233 (OID generated automatically by adding the prefix CL_ to the primary key)  |   |
| <b>RangeCheck</b>                      |  |   |   |   |
| Comparator                             | item_form_metadata.regexp (if "func:")   | VALIDATION  | LE, GE, EQ, etc.  |   |
| SoftHard                               |  |   | Soft, Hard (based on study parameter values governing discrepancy note generation)  |   |
| <b>CheckValue</b>                      | Item_form_metadata the value in the function. For example, 95 if the check is for greater than 95,       | VALIDATION  | 100   |   |
| <b>ErrorMessage</b>                    |  |   |   |   |
| TranslatedText                         | item_form_metadata.regexp_error_msg (if "func:")   | VALIDATION_ERROR_MESSAGE                                  | Please specify a value between 0 and 100  |   |
| <b>OpenClinica:ItemDetails</b>         |  |   |   |   |
| 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 |
| <b>CodeList</b>                        |  |   |   |   |
| 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)   |   |
| <b>CodeListItem</b>                    |  |   |   |   |
| CodedValue                             | response_set.options values  | RESPONSE VALUES OR CALCULATIONS                           | 1, 2, 3, etc.   |   |
| <b>Decode</b>                          |  |   |   |   |
| TranslatedText                         | response_set.options text  | RESPONSE OPTIONS TEXT                                     | Yes, No, etc.   |   |
| <b>OpenClinica:MultiSelectList</b>     |  |   |   |   |
| 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:Data Type                  | response_type.name   |   | text, (the DataType value is always text)   |   |
| OpenClinica:ActualData Type            | response_type.name   | DATA TYPE   | text, float, integer  |   |
| <b>OpenClinica:MultiSelectListItem</b> |  |   |   |   |
| OpenClinica:CodedOptionValue           | response_set.options values  | RESPONSE VALUES OR CALCULATIONS                           | 1, 2, 3, etc.   |   |
| <b>OpenClinica:StudyGroupClassList</b> |  |   |   |   |
| 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   |   |
| <b>OpenClinica:StudyGroupItem</b>              |                                       |  |   |
| OpenClinica:Name                               | study_group.name                      | Young Adult  |   |
| OpenClinica:Description                        | study_group.description               | 12-18  |   |
| <b>OpenClinica:StudyDetails</b>                |                                       |  |   |
| 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:InverventionModel</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 |
| <b>OpenClinica:EligibilityCriteria</b>         |                                       |  | 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 |
| <b>OpenClinica:FacilityInformation</b>         |                                       |  | 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 |
| <b>OpenClinica:RelatedInformation</b>          |                                       |  | 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 |
| <b>OpenClinica:StudyParameterConfiguration</b> |                                       |  | Y |
| <b>OpenClinica:StudyParameterListRef</b>       |                                       |  | Y |
| <i>StudyParameterListID</i>                    | study_parameter.name                  |  | Y |
| <i>Value</i>                                   | study_parameter.value.value           |  | Y |
| <b>OpenClinica:StudyParameterListItem</b>      |                                       |  | Y |
| <i>CodedParameterValue</i>                     | study_parameter.name                  |  | Y |
| <b>RuleImport</b>                              |                                       | Rules are a separate vendor extensions from the OpenClinica: namespace.  | Y |
| <b>RuleAssignment</b>                          |                                       |  | Y |
| <b>RuleRef</b>                                 |                                       |  | 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 |
| <b>RuleDef</b>                                 |                                       |  | Y |
| <i>OID</i>                                     | rule.oc_oid                           | All capital letters or integers. This is user defined  | Y |
| <i>Name</i>                                    | rule.name                             |  | Y |
| <i>Description</i>                             | 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 |
| <b>AdminData</b>                    |  |  |   | Y |
| StudyOID                            | study.oc_oid                                   |  |   | Y |
| <b>User</b>                         |  |  |   | 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 |
| <b>ClinicalData</b>                 |  |  |   | Y |
| StudyOID                            | study.oc_oid                                   |  | S DEMO123   |   |
| MetaDataVersionOID                  | dataset.odm_metadataversion_oid                |  | v1.0.0  |   |
| <b>SubjectData</b>                  |  |  |   |   |
| 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  |   |
| <b>StudyEventData</b>               |  |  |   |   |
| 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)   |   |
| <b>FormData</b>                     |  |  |   |   |
| 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                                    |  |   |   |
| <b>ItemGroupData</b>                |  |  |   |   |
| 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)  |   |
| <b>ItemData</b>                     |  |  |   |   |
| 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)  |   |
| <b>OpenClinica:AuditLogs</b>        |  |  |   | 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 |
| <b>OpenClinica:DiscrepancyNotes</b> |  |  |   | 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 |
| <b>OpenClinica:SubjectGroupData</b> |  |  |   |   |
| 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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