2.5.6 CDISC ODM Formats

When you select one of the CDISC ODM formats for the dataset, OpenClinica exports the dataset to an .xml file that complies with the Operational Data Model (ODM) of the Clinical Data Interchange Standards Consortium (CDISC) standard. These are the different parameters for the available ODM formats:

- **1.3 or 1.2:** refers to the version of the ODM specification.
- **With extensions:** Includes OpenClinica entities that are not part of the ODM specification, such as the Subject Group Class and its attributes.
- **Full:** Includes Discrepancy Notes and the Audit Log.

CDISC ODM is a vendor neutral, platform independent format for interchange and archive of data collected in clinical trials. The model represents study metadata, data, and administrative data associated with a clinical trial. The ODM has been designed to be compliant with guidance and regulations published by the FDA for computer systems used in clinical trials.

The ODM model categorizes a clinical study's data into several kinds of entities including subjects, study events, forms, item groups, items, and annotations. The metadata of a study describes the types of study events, forms, item groups, and items that are allowed in the study. The clinical data of a study will typically have many actual entities corresponding to their definitions described in the metadata.

Like any XML file, an ODM file consists of a tree of elements that correspond to entities. Each element consists of required attributes and optional attributes. An ODM file type must be either Snapshot or Transactional. A Snapshot file shows the current state of the included data. A Transactional file shows both latest state and (optionally) some prior states of an included entity. An ODM file has a Granularity attribute which describes the coverage information of the ODM file.

The ODM file consists of two parts: metadata followed by Subject data. The metadata provides OIDs for the Study, units (as defined when the CRFs were created), Event information, CRF information including Item Groups and Items with information about validations, and user account information. The Subject data provides Subject information, Event information, CRF information, and then the values.

CDISC ODM Format XML File - Metadata Section (Partial View):

```
1   <?xml version="1.0" encoding="US-ASCII"?><ODM xmlns="http://www.cdisc.org/ns/odm/v1.3"
    xmlns:OpenClinica="http://www.openclinica.org/ns/odm_ext_v130/v3.1" xmlns:OpenClinicaRules=
    "http://www.openclinica.org/ns/rules/v3.1" xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"
    FileOID="HeightWeightD20120224141343-0500" Description="Height and Weight" CreationDateTime=
    "2012-02-24T14:13:43-05:00" FileType="Snapshot" ODMVersion="1.3" xsi:schemaLocation=
    "http://www.cdisc.org/ns/odm/v1.3 OpenClinica-ODM1-3-0-OC2-0.xsd">
2       <Study OID="S_R0112345">
3           <GlobalVariables>
4               <StudyName>Docetaxel in Patients With Completely Resected NSCLC </StudyName>
5               <StudyDescription>
6                   Administering chemotherapy drugs such as Docetaxel after surgery, may kill any tumor
    cells that remain post surgery.
7               </StudyDescription>
8               <ProtocolName>R01-123456</ProtocolName>
9           </GlobalVariables>
10          <BasicDefinitions>
11              <MeasurementUnit OID="MU_F" Name="F">
12                  <Symbol>
13                      <TranslatedText>F</TranslatedText>
14                  </Symbol>
15              </MeasurementUnit>
16              <MeasurementUnit OID="MU_HG" Name="Hg">
17                  <Symbol>
18                      <TranslatedText>Hg</TranslatedText>
19                  </Symbol>
20              </MeasurementUnit>
21              <MeasurementUnit OID="MU_HHMM24HRFORMAT" Name="HH:MM (24 hr format)">
22                  <Symbol>
23                      <TranslatedText>HH:MM (24 hr format)</TranslatedText>
24                  </Symbol>
25              </MeasurementUnit>
26              <MeasurementUnit OID="MU_IN" Name="in">
27                  <Symbol>
28                      <TranslatedText>in</TranslatedText>
```

CDISC ODM Format XML File - Subject Data Section (Partial View):

```
4837        <ClinicalData StudyOID="S_R0112345_8478" MetaDataVersionOID="v1.0.0-S_R0112345_8478">
4838            <SubjectData SubjectKey="SS_SMC101" OpenClinica:StudySubjectID="SMC101">
4839                <StudyEventData StudyEventOID="SE_INITIALTREATMENT">
4840                    <FormData FormOID="F_PHYSICALEXAM_ENGLISH">
4841                        <ItemGroupData ItemGroupOID="IG_PHYSI_UNGROUPED" TransactionType="Insert">
4842                            <ItemData ItemOID="I_PHYSI_PEDAT" Value="2011-06-01"/>
4843                            <ItemData ItemOID="I_PHYSI_HEIGHT" Value="86">
4844                                <MeasurementUnitRef MeasurementUnitOID="MU_IN"/>
4845                            </ItemData>
4846                            <ItemData ItemOID="I_PHYSI_WEIGHT" Value="190">
4847                                <MeasurementUnitRef MeasurementUnitOID="MU_LB"/>
4848                            </ItemData>
4849                        </ItemGroupData>
4850                        <OpenClinica:AuditLogs EntityID="F_PHYSICALEXAM_ENGLISH">
4851                            <OpenClinica:AuditLog ID="AL_1409" UserID="USR_2" DateTimeStamp=
    "2011-07-06T15:19:12" Type="Event CRF marked complete" OldValue="available" NewValue=
    "unavailable"/>
4852                        </OpenClinica:AuditLogs>
4853                    </FormData>
4854                    <OpenClinica:AuditLogs EntityID="SE_INITIALTREATMENT">
4855                        <OpenClinica:AuditLog ID="AL_1309" UserID="USR_2" DateTimeStamp=
    "2011-07-06T14:47:04" Type="Study Event scheduled" OldValue="invalid" NewValue="scheduled"/>
4856                        <OpenClinica:AuditLog ID="AL_1318" UserID="USR_2" DateTimeStamp=
    "2011-07-06T14:59:20" Type="Study Event data entry started" OldValue="scheduled" NewValue="data
    entry started"/>
4857                        <OpenClinica:AuditLog ID="AL_1476" UserID="USR_2" DateTimeStamp=
    "2011-07-06T15:22:13" Type="Study Event completed" OldValue="data entry started" NewValue=
    "completed"/>
4858                    </OpenClinica:AuditLogs>
4859                </StudyEventData>
4860                <OpenClinica:AuditLogs EntityID="SS_SMC101">
4861                    <OpenClinica:AuditLog ID="AL_826" UserID="USR_2" DateTimeStamp=
    "2011-07-06T11:30:10" Type="Subject Group Assignment" NewValue="Regimen I"/>
4862                    <OpenClinica:AuditLog ID="AL_1305" UserID="USR_2" DateTimeStamp=
    "2011-07-06T14:46:36" Type="Subject created"/>
4863                    <OpenClinica:AuditLog ID="AL_1306" UserID="USR_2" DateTimeStamp=
    "2011-07-06T14:46:36" Type="Study subject created"/>
4864                </OpenClinica:AuditLogs>
4865            </SubjectData>
4866        </ClinicalData>
4867    </ODM>
```

For more details about the ODM specification and its use in OpenClinica, see CDISC ODM Representation in OpenClinica in the OpenClinica Technical Documentation, and the ODM Final Version 1.3 for Implementation at the CDISC web site.

This page is not approved for publication.