


Release notes for ODM Version 1.1 Final

In response to feedback from reviewers, Version 1.1 contains the following changes to the Version 1.1 Draft ODM model published in November 2001:

1. **Change:** Element names with the ID suffix have been renamed to have the suffix OID.

Source: 23-Jan-2002 Face to Face Meeting stemming from discussion of Thierry Parent Discussion Forum posting about ID and IDREF on 6-Nov-2001.

Rationale: The underlying issue raised in the posting is that "ID" has a special meaning in XML, so ODM's use of "ID" is confusing. We discussed using "KEY" instead of "ID", but "KEY" also has a special meaning in XML schemas. So the team decided to use OID which stands for ODM ID instead of ID; change all data names in the model with a suffix of "ID" to "OID". We'll look into creating a custom "strict" DTD that converts these into XML IDs.

Business requirements for clinical data handling have led to the common practice  separating Metadata and Data transmissions. XML IDs cannot be used to support this practice since the XML standard requires that IDREFs be resolved within a transmission. Our use of OIDs is consistent with ISO definition although a registry of object names has not yet been established. This will be done as a follow on effort.

2. The attributes of the ODM element have been updated.

- **Change:** A DESCRIPTION attribute was added
- **Change:** The FileType attribute was added in place of the TransferType attribute. It can be defined as 'Snapshot' or 'Transactional'.

Source: 1-Mar-2002 ODM Teleconference and several discussions among subgroups of team members.

Rationale: Archival is not needed as a distinct FileType as an Archival transfer is no different from a set of Transactional Transfers with the Archival attribute set (see below).

- **Change:** The Granularity attribute was modified. It can now take values: 'All', 'MetaData', 'AdminData', 'ReferenceData', 'AllClinicalData', 'SingleSite' or 'SingleSubject'.

Source: 1-Mar-2002 ODM Teleconference

Rationale: MetaData includes both Metadata elements and AdminData.

ReferenceData includes both the MetaData and ReferenceData.ItemGroupData.

This series of attribute values was determined by the group to be more descriptive and less ambiguous than the set of values listed in the draft model

(MetaDataOnly, Site, Subject). It also covers the full range of likely transfer scenarios.

Change: The Archival attribute was added.

Source: 8-Mar-2002 ODM team teleconference

Rationale: The Archival attribute indicates that the file is intended to meet the requirements of an electronic record according to 21 CFR 11. The file must unambiguously establish a complete and non-redundant set of entries, updates or deletions to data values where each transaction is associated with signature information and any changes or deletions are marked with a reason for change.

- **Change:** The AsOfDateTime attribute was added to mark the date as of which the clinical data in the transmission is current.

```
<IATTLIST ODM
  Description CDATA #IMPLIED
  FileType ( Snapshot | Transactional ) #REQUIRED
  Granularity ( All
    | Metadata
    | AdminData
    | ReferenceData
    | AllClinicalData
    | SingleSite
    | SingleSubject
  ) #IMPLIED
  Archival (Yes) #IMPLIED
  FileOID CDATA #REQUIRED
  CreationDateTime CDATA #REQUIRED
  PriorFileOID CDATA #IMPLIED
  AsOfDateTime CDATA #IMPLIED
>
```

Source: 23-Jan-2002 Face to Face Meeting; stemming from discussion of V1.1 example transaction types and the idea of a "chain" of transfers.

Rationale: For transactional transfers, there might be a request to ship the data that was current as of a specific date. In this case, the AsOfDateTime would be the last date reflected in the data, even if the data file itself was generated much later.

3. Two changes were made to the ItemDef element to improve support for SDM model:
 - **Change:** Add Role element in ItemDef to replace Role Attribute since in the SDM model, a variable can have multiple roles.
Source: 14-Dec-2001 Discussion Forum posting by Geoff Gordon
Rationale: The posting: "Currently ODM has defined Role as an attribute of ItemDef. Since it now appears that a single data item can assume multiple roles (one for submissions, another for analysis, still others for driving standard FDA

applications such as Patient Profiles), it should be used as a * subelement of ItemDef instead.”

- **Change:** Add SDSVARName attribute to ItemDef

Source: 14-Dec-2001 Discussion Forum posting by Geoff Gordon

Rationale: The posting: “At the November ODM meeting in Boston I raised the specific issue that in ODM 1.1 we define all ID values (such as SubjectID) as specifically being internal, unchangeable values. This was done to make the audit trail issues work: if the SubjectID in the model were the external subjectID (or randomization ID) of a patient and that value is sent incorrectly in one transmission, there would be no way to correct the mistake in a follow-up transition. In doing this we stated that the external subject keys (and other study key variables) should be defined as Items in the metadata and then can be modified through the ODM audit trail. While this solved the problem of supporting modifications of study keys, we did not define a way to identify which ItemDefs have special meaning or what the meaning is. The most obvious place where this is a problem is in matching up patients when loading data from an external source. If you can't find the patient id how do you do it?

We discussed several alternatives, and the people present agreed on the following plan: Create a new, optional, attribute of ItemDef called SDSVarName which can optionally be used to tag the variable as being one of the variables defined in the Submissions Data Model (version 2.0). Software can therefore check for specific values to the SDSVarName variable to search for standard, frequently used variables. The use of this attribute is restricted to a variable defined in the SDS V2.0 model, and in tagging a variable; you are identifying it as being properly defined by the SDS V2.0 definition for that variable. A partial list of commonly used values includes:

SITEID (Center or Site ID),
SUBJID (Subject ID, usually the Randomization ID),
SCSUBJID (Screening SubjectID)
SEX (Sex or Gender, coded value),
VISIT (visit name),
DMACTDT (actual date of visit)
DMREFDT (subject reference date)
BIRTHDT (date of birth),
SUUBJINIT (subject initials)

See the SDS V2.0 definition for definitions and additional choices.”

4. **Change:** Added UserType attribute to AdminData User element. It can take values ‘Sponsor’, ‘Investigator’, ‘Lab’ or ‘Other’

<!ATTLIST User

OID CDATA #REQUIRED

UserType (Sponsor | Investigator | Lab | Other) #IMPLIED

>

Source: 14-Nov-2001 ODM Team Meeting – documented in meeting minutes

Rationale: This facilitates identifying originators of clinical data (especially investigators, who need to be associated with patients) from sponsor data transcribers.

5. Change: At each level of the Clinical Data hierarchy, the Audit, Signature and Annotations sub-elements have been reordered. For example, in the final version, the FormData element is defined as:

```
<!Element FormData (AuditRecord?, Signature?, Annotation*, ItemGroupData*)>
```

Source: 15-Nov-2001 Discussion Forum Posting by Barry Drummond

Rationale: The posting: “At yesterday's ODM meeting (14-NOV-2001), we discussed a request to reorder the clinical data elements. It was suggested that the AuditRecord element be moved to the beginning of each record as it is potentially inherited by other child elements within the hierarchy. Moving it to the beginning would facilitate SAX parsing.

During our discussion, we came to the conclusion that other elements also create a context for the child data elements. The participants agreed to propose the following changes:

- 1) The AuditRecord element would be the first element.
- 2) The Signature element would become the second element.
- 3) All singular elements would precede any elements that can have multiple occurrences.
- 4) The child 'data' element would be the last element, immediately preceded by the Annotation element.

This results in changes to five elements.

Current 1.1 draft version:

```
<!ELEMENT SubjectData (StudyEventData*, InvestigatorRef?, SiteRef?,  
Annotation*, Signature?, AuditRecord?) >  
<!ELEMENT StudyEventData (FormData*, ExpectedTime?, ActualTime?,  
Annotation*, Signature?, AuditRecord?) >  
<!ELEMENT FormData (ItemGroupData*, ArchiveLayoutRef?, Annotation*,  
Signature?, AuditRecord?) >  
<!ELEMENT ItemGroupData (ItemData*, Annotation*, Signature?,  
AuditRecord?) >  
<!ELEMENT ItemData (Value?, MeasurementUnitRef?, Annotation*,  
Signature?, AuditRecord?) >
```

Proposed changes:

```

<!ELEMENT SubjectData (AuditRecord?, Signature?, InvestigatorRef?,
SiteRef?, Annotation*, StudyEventData*) >
<!ELEMENT StudyEventData (AuditRecord?, Signature?, ExpectedTime?,
ActualTime?, Annotation*, FormData*) >
<!ELEMENT FormData (AuditRecord?, Signature?, ArchiveLayoutRef?,
Annotation*, ItemGroupData*) >
<!ELEMENT ItemGroupData (AuditRecord?, Signature?, Annotation*,
ItemData*) >
<!ELEMENT ItemData (AuditRecord?, Signature?, Value?,
MeasurementUnitRef?, Annotation*) >

```

There are no proposed changes to the attribute lists or other elements in the other elements in the ClinicalData hierarchy.”

6. **Change:** The ExpectedTime, ActualTime subelements of StudyEventData have been removed. Common practice is to simply include these values as ItemData.
Source: Discussion Forum posting by Geoff Gordon on 14-Dec-2001
Rationale: The posting: “The StudyEventData elements include elements of ActualTime and ExpectedTime. I believe that this is inappropriate because to the extent that the actual date and/or expected date of a visit are collected, they would normally be collected on a CRF form and thus would properly be defined as ItemDefs and included in an ItemGroupDef. Prior to having the capability of tagging ItemDefs as special it may have been seemed necessary to include this within the model itself, but with the SDSVarName attribute, there is now a way to identify this information in the ItemData.
I believe these should be removed from the model. (This is similar to removing the patient demographic attributes/elements from the PatientData element).”

7. The ItemData element has been restructured.

- **Change:** The Value sub element has been removed. In its place, two new ItemData attributes have been defined – Value and IsNull.

Source: 1-Mar-2002 ODM Team teleconference.

Rationale: This change facilitates processing with the SAX parser.

- **Change:** ‘Context’ has been added to the list of valid values for the TransactionType attribute. If ItemData has TransactionType Context, it is being provided to add context to other data in the transmission – but is assumed to be already present in the receiving database and therefore not loaded.

```

<!ATTLIST ItemData
    ItemOID CDATA #REQUIRED
    TransactionType (Insert | Update | Remove | Upsert | Context) #IMPLIED
    Value CDATA #IMPLIED
    IsNull (Yes) #IMPLIED
>

```

Source: 14-Dec-2001 Discussion Forum posting by Geoff Gordon

Rationale: The posting: “At the Nov ODM meeting we discussed the need to sometimes resend contextual information in an incremental transfer to enable matching up of internal ID against externally identifying information. A typical case of this would be to send demographic information (including external patient identifiers) in an incremental transfer. This has been a standard way of sending external data to be loaded, such as lab data. This was discussed in the context of adding a method of identifying key or special variables to the model (see posting on SDSVarName).

While it might seem that this information could simply be sent as a superfluous edit/upsert, that would actually not work since the receiving system would have no way to distinguish the case in which an exact match of this contextual information is required against the case in which it is actually being edited.

We discussed several alternatives and agreed on the idea that we would define an additional TransactionType called Context. The rules on use of Context information are: it must be information that has been sent before and all context transactions must be before any other transactions within a given level, and there should be no other transactions inside an object marked with a transaction type of Context.

So, for example to include the Demo ItemGroupData for a PatientData, the first StudyEventData in the PatientData would be marked with a TransactionType of Context. This StudyEventData would have a single FormData, which would have a single ItemGroupData (the Demog ItemGroupData).”