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".

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