

10.2 Limitations on Support for Generated and Received ODM Files

OpenClinica has the following limitations on its support for generated and received ODM files:

OpenClinica acts as a receiving system via its Data Import functionality. In this case it selectively ignores information as allowed by the conformity requirements. In particular:

- Receiving files for data import ignores any information under the Study AdminData, ReferenceData, and Association nodes. When receiving files OpenClinica only deals with ClinicalData
- OpenClinica does not support the typed data transmission construct in ClinicalData (see ODM section 2.5.1 - Typed Data Transmission). All files generated by OpenClinica use the generic ItemData tag rather than ItemData[TYPE]. If when receiving files (ie in Data Import), OpenClinica encounters ClinicalData using ItemData[TYPE] tags, these entities are ignored. They will pass through schema validation, but the data will not be imported, as OpenClinica wont be able to generate the necessary Java objects to put data into the database.
- OpenClinica does not support the same set of Item Data types as specified in the ODM definition. For generation of ODM, the types supported are defined in the table Item Data Types in this document. For receiving ODM, since only ClinicalData is recognized, and Item Data Types defined as part of the incoming ODM file will be ignored. Incoming ItemData values will be validated based on the OpenClinica data type of the specified Item OID.

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