

Status: ODM v2.0 has completed Public Review; the team is finalizing the specification and schema for final release in Q2 2023.

Overview: ODM v2.0 is a major new version that modernizes ODM and builds on its acknowledged strengths. ODM v2.0 breaks backwards compatibility with the current version, v1.3.2, published in 2013.

Supplements: CDISC will publish a number of supplements that build on the ODM v2.0 standard and play an important role in how it is applied, including:

- API specification
- ODMPATH
- JSON schemas
- Examples library
- Conformance rules
- Compressed ODM
- Streaming ODM

New Feature	Brief Description
Study design and workflow	Provides rigorous, machine-readable, interchangeable descriptions of study designs, including treatment plans, study design parameters, eligibility, and times and events.
StudyEventGroupDef	Groups of StudyEventGroups or StudyEvents, allows nesting of StudyEventGroups. Can be used to define "study cells", or crossings of epochs and arms.
Improved semantics	The Coding element references a symbol from a defined code system. It uses a code defined in a terminology system to associate semantics with a given term, codelist, variable, or group of variables. The presence of a Coding element associates a meaning to its parent element.
JSON serialization	ODM may be serialized as XML or JSON.
Traceability support	Machine-readable, end-to-end metadata traceability adapted from the Trace-XML extension.
Data query support	Explicit support for data queries and the data query lifecycle.
Nested ItemGroups	Groups of ItemGroupRefs or ItemsRefs allow nested structures that can represent a more diverse range of data structures and enable more flexible re-use of groups of items (e.g., defining semantics when items share a common relationship or grouping common behaviors such as skip logic or pre-population).
Enhanced data capture	Repeating ItemGroup based on a code list so that each term in the code list represents one or more questions on a CRF. Support for matrix style forms.
HL7 FHIR interoperability	Provides the metadata needed to retrieve data from a FHIR resource to populate a variable referenced by an ItemRef.
Formatted text	TranslatedText supports alternative media-types, for example XHTML, which can be used to enhance text displays.
Enhanced MethodDef	Improved traceability and checking added with a method signature and a return datatype(s). FormalExpression can reference code in an external library.
Define-XML content	Most elements and attributes in the Define-XML v2.1 extension have been incorporated into ODM v2.0.
Operational datasets	Reference implementation that uses ODM v2.0 to represent datasets for the exchange of tabular raw data, such as sending tabular datasets to a sponsor.
Biomedical concepts	Allows representation of biomedical concepts using new features such as nested ItemGroupDefs and Coding.
Enhanced AdminData	Elements improved based on input from usage experience and updated for compatibility with CTR-XML and SDM-XML.
Multi-lingual support	Expanded use of TranslatedText to provide broader multi-lingual support.
New Origin element	An Origin element that replaces and enhances the functionality offered by the @Origin attribute. The Origin information has been moved to the ItemRef element, so that an Item can have a different Origin depending on where it is used.
Dataset-JSON	Dataset-JSON is an updated version of Dataset-XML serialized using JSON.
Null flavors	Provides a standard way to indicate the reason for incomplete subject data, including the use HL7 standard NullFlavor codes.
Units relationship	ItemRef attribute UnitsItemOID provides the ItemDef OID for the associated units variable

Use Cases:

- Automated EDC/ePRO/CDM setup
- Data transmission/exchange
- Study design automation
- Clinical data archiving
- Data lakes
- EHR integration
- Dataset data exchange
- Machine-readable traceability
- Data query transfer and reporting
- Metadata repositories
- End-to-end standards implementation

Deprecated:

- FormDef
- @Origin
- @SASFormatName
- ItemData[Type]
- BasicDefinitions
- Presentation
- Certificate
- @SDSVarName
- @SASFieldName
- @SignificantDigits
- @SASDatasetName
- GlobalVariables
- MeasurementUnitRef