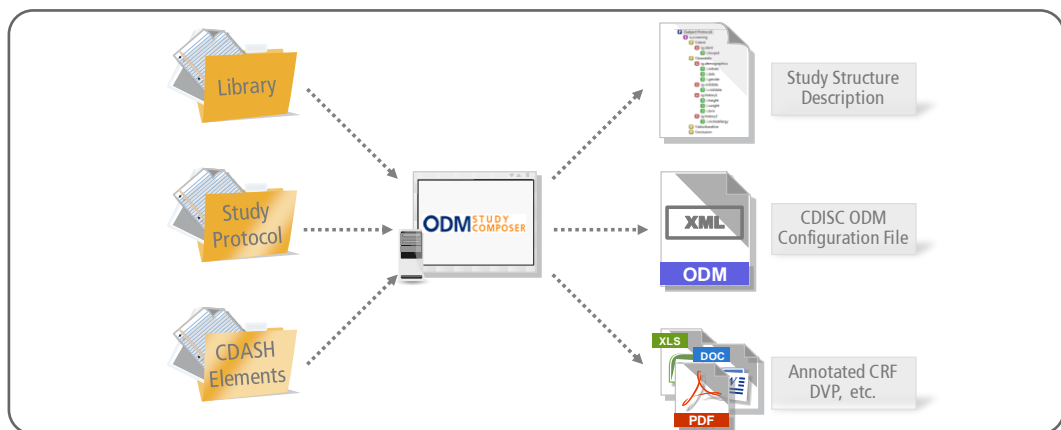


## ODM STUDY COMPOSER – OVERVIEW

The XClinical ODM STUDY COMPOSER provides an intuitive graphical user interface for study set-up including CRF design and data validation plan. As a replacement for MS Word and Excel during the preparation of a clinical trial, the ODM STUDY COMPOSER generates considerable time and cost savings.



Through the use of XClinical’s ODM STUDY COMPOSER, the eCRF design, annotated CRF, data validation plan, visit matrix, database specs and other core documents are automatically derived from a single, central, XML-based set of metadata. This ensures all necessary documents are automatically synchronised, thus eliminating the manual transcription effort to maintain different documents and increasing quality by avoiding inherent error risks.

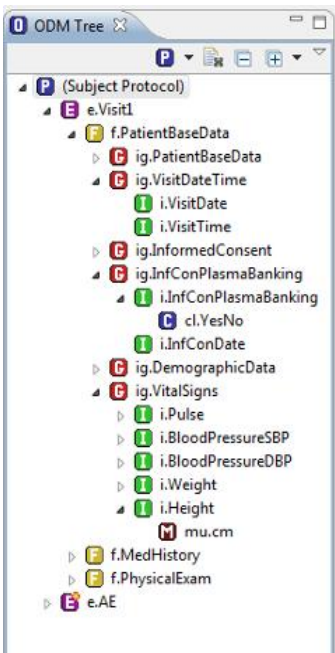
Data managers can utilise the ODM STUDY COMPOSER to build and use an item and CRF library, which enables them to effectively and consistently re-use existing items and CRF definitions. The tool thereby automatically ensures the international CDISC ODM standard format is complied with, enabling the CRF and database design to be exchanged with different systems and organisations, e.g. between sponsors and CROs.








In combination with an EDC/CDM system that can import CDISC ODM metadata, the ODM STUDY COMPOSER supports the automatic set-up of an EDC database. With an EDC/CDM system that does not have this capability, the ODM STUDY COMPOSER still provides the best possible, unambiguous specification of the CRF, database and data validation plan. This guarantees the most efficient communication between different teams and organisations.

## ODM STUDY COMPOSER – FEATURE HIGHLIGHTS

- Intuitive graphical interface for quick and easy study set-up
- Smart search & copy functionality to create and use a library
- Rule and formula editor enables the easy and unambiguous definition of a comprehensive data validation plan
- Automatic output of the annotated CRF, visit matrix and data validation plan in tabular form
- Easy set-up and management of amendments
- Validated, CDISC ODM-compliant storage and export of the CRF design
- Can be used in combination with any EDC system
- Imports third-party vendor extensions without any modifications

## ODM STUDY COMPOSER – CDISC ODM STUDY TREE



	= Protocol
	= Event
	= Form
	= ItemGroup
	= Item
	= Code List, <i>e.g. yes / no</i>
	= Measurement Unit, <i>e.g. kg</i>