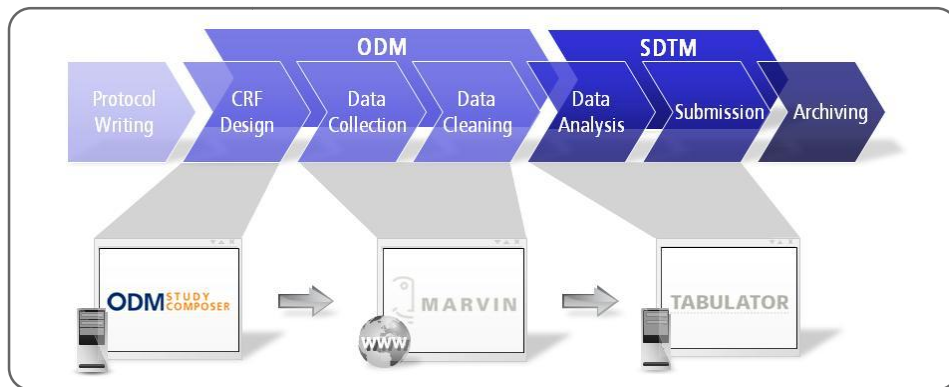




ODM STUDY COMPOSER – OVERVIEW

The ODM STUDY COMPOSER is part of Xclinical’s product suite used in the full CDISC-based End-To-End process. The ODM STUDY COMPOSER provides an intuitive graphical point-and-click interface for study definition and the creation of relevant metadata.

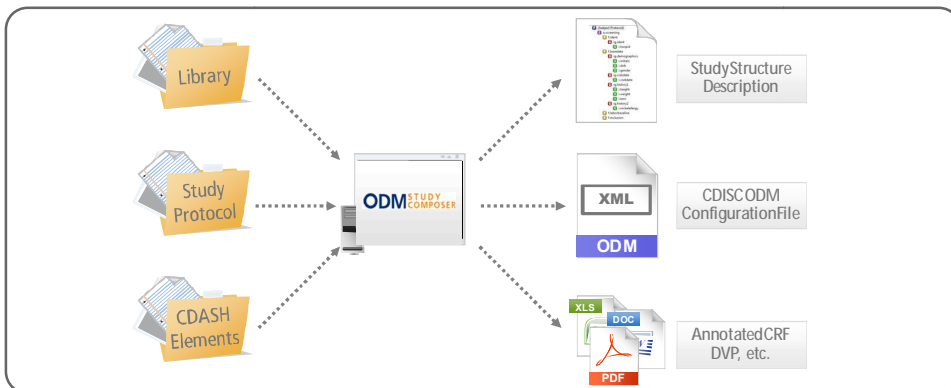


Data managers get a feature-rich, powerful environment for configuring dynamic eCRFs, including complex validation checks. The XML structure based on the CDISC ODM standard is automatically generated in the background.

Through the use of Xclinical's ODM STUDY COMPOSER, eCRF design, the creation of an annotated CRF and MARVIN configuration are done simultaneously. This ultimately saves time, cuts costs and boosts quality because transcription errors are avoided.

The ODM STUDY COMPOSER is an important contribution towards efficient TechTransfer for sponsors and CRO partners.

ODM STUDY COMPOSER – CENTRAL STUDY DEFINITION





ODM STUDY COMPOSER – GENERAL CHARACTERISTICS

- Intuitive and fast study set-up thanks to a graphical interface
- Concise overview of the study structure through clear ODM hierarchy
- Smart copy functionality allows the creation of a full module library
- Generates fully annotated CRFs as PDF files
- Integrated “Actions Editor” for complex validation checks and dynamic study workflow elements
- Easy and fast set-up of amendments
- Generates and validates a 100% ODM-compliant file (ready for import into MARVIN, the first CDISC ODM-certified EDC software)
- Modification of ODM-compliant files from other EDC system vendors



ODM STUDY COMPOSER – ODM HIERARCHY

- P** = Protocol
- E** = Event
- F** = Form
- G** = ItemGroup
- T** = Item
- C** = Code List, e.g. yes / no
- M** = Measurement Unit, e.g. kg