



Define R³
Regulatory * Review * Report

A tool to create Define.xml for Regulatory Submission



WHAT IS DEFINE.XML

The Define.xml will provide a navigation between the Data Definition (information about the data, the origin of the data, and derivation in the comment section), Annotated CRF, and the dataset.

The Definition of Data consists of Metadata about the SAS Datasets that are being submitted to the FDA, origin of the data (CRF Page number or Derived), derivation of the data, if it is derived.

It also contains value level metadata that are possible. The Define.xml package includes the definition file, Annotated CRF, SAS transport files for each domain that are included in the submission, reviewers guide and a navigation to all from Definition file with xml back bone.

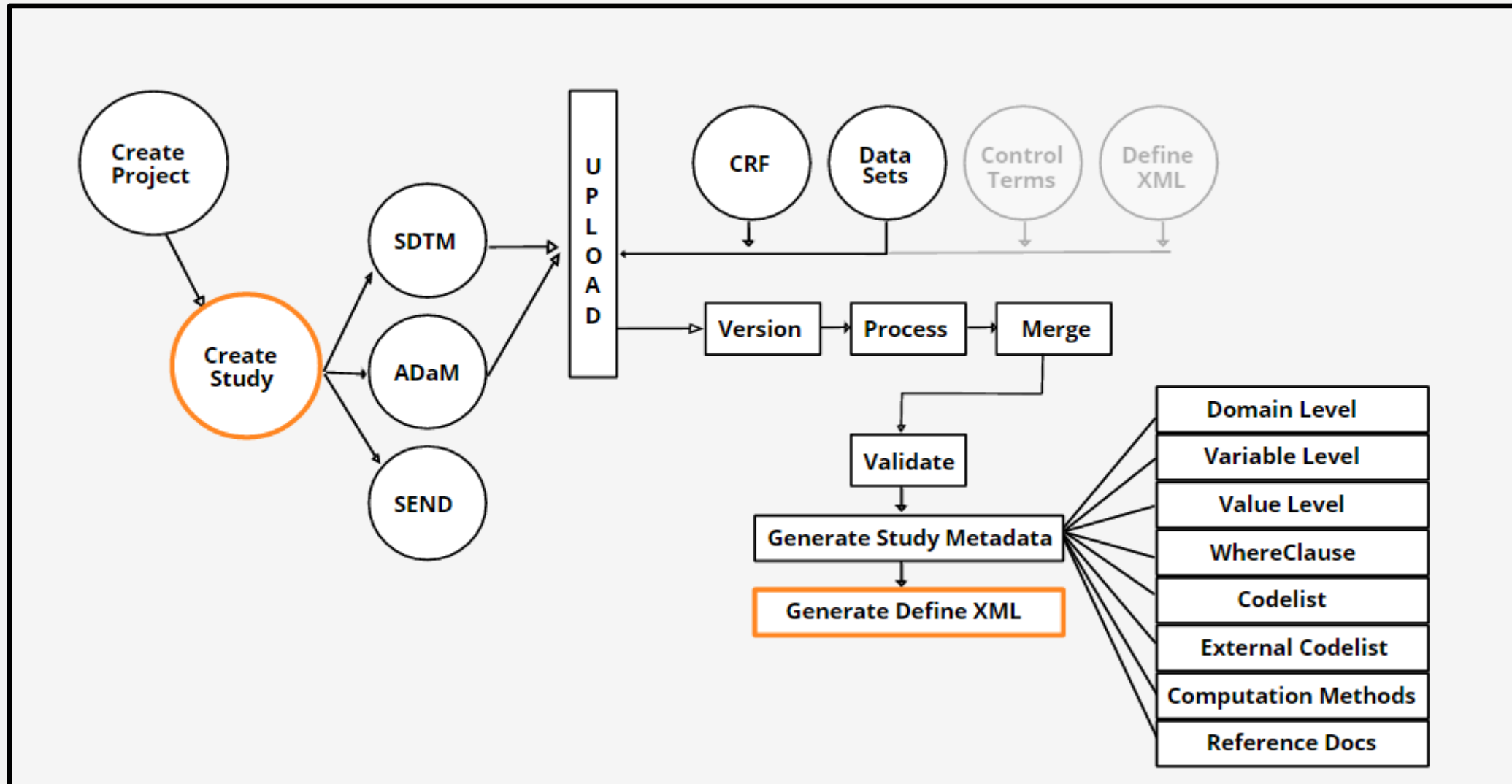
WHY DEFINE R3

- Tool saves significant time in define.xml creation process.
- Effective use and reuse of existing/previous Study and Project Metadata.
- Mapping and reuse of Metadata between CDISC Metadata and Sponsor designed standards (including metadata, IE Version, PDF Version, Control Terminologies, etc.)
- Comes preloaded with CDISC/Sponsor defined Metadata and Control Terminologies.
- Ease of upload on various versions of CDISC Metadata with Sponsor Defined Metadata for use across changes in versions.
- Easy Integration of new CDISC Metadata Standards/sponsor defined standards and Control Terminologies versions/releases.
- Facilitates Consistent and Predictable time/effort from Study Creation to Define.xml.

WHAT ARE THE DIFFERENTIATORS

- Application can be installed as a Standalone Client Application or accessed as a Cloud based Web Application supporting study types - SDTM/ADaM.
- Comes pre-loaded with the CDISC Metadata and Control Terminologies
- Easily map and reuse Sponsor Defined Metadata standards with CDISC Metadata.
- Supports single user and multi user environments with connectivity to a variety of databases.
- **Create Study** > Upload XPTs and Annotated CRF > Process and **View as Define XML** - in minutes.
- Reverse Engineer Define XML from related studies for reuse in Study Metadata.
- Progressively Add XPTs/Edit Study Metadata/Edit Exception Report and view in Define XML specification format.
- View and Edit all Exceptions, Study Metadata - Domain, Variable, Value, WhereClause, Codelist, External Codelist, Computation Methods and Reference Docs in place
- Eliminate manual task significantly

OUR PROCESS



REVIEWER'S GUIDE

- Pre-defined or Customized template for your Study or Submission data
- Accurate justifications – noted from Data Issues items
- Auto adjustment for linking and formatting in a final document

ANALYSIS RESULT METADATA

- UI Driven ARM
- Automated Codelist, SAS Program and supplemental document ingestion to ARM

DATABASE SPECIFICATION

- Generate Specification using standard SDTM / Sponsor defined Metadata
- Study database specification can be auto generated (define without data)

DEMO

Welcome to Define R3

User - sysadmin

Username sysadmin Password ****

Define R³ Regulatory • Review • Report

User Admin Projects Study Search

Oncology / Onc-1 / SDTM

CRF-annotatedCRF.pdf

Standard Version CT Release Date CT (Study) Blank Define SAS Data * Mandatory upload Current Upload

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User Admin Projects Study Search

Oncology / Onc-1 / SDTM

CRF-annotatedCRF.pdf

Reprocess Promote to PMD Compare

Domain	Variable	Value	Where Clauses	Code List	External Code List	Computation Methods	
AE	Adverse Events	Tabulation	Yes	Yes	One record per ad...	STUD	
CM	Concomitant Medi...	Tabulation	Yes	Yes	One record per rec...	STUD	
CO	Comments	Tabulation	Yes	Yes	One record per co...	STUD	
DM	Demographics	Tabulation	No	No	One record per su...	STUD	
DS	Disposition	Tabulation	Yes	Yes	One record per dis...	STUD	
DV	Protocol Deviations	Tabulation	Yes	Yes	One record per pr...	STUD	
EX	Exposure	Tabulation	Yes	Yes	One record per co...	STUD	
FA	Findings About Ev...	Tabulation	Yes	Yes	One record per fin...	STUD	
IE	Inclusion/Exclusio...	Tabulation	Yes	Yes	One record per inc...	STUD	
LB	Laboratory Test R...	Tabulation	Yes	Yes	One record per lab...	STUD	
MH	Medical History	Tabulation	Yes	Yes	One record per me...	STUD	

QUESTIONS