

Generate, don't program!

Mission

In Entimo Integrated Clinical Environment (entimICE[®]), a dedicated generator allows define.xml for SDTM, ADaM and other datasets to be created with a few clicks from metadata domain definitions.

Benefits of Entimo's Define.xml Generator

1. Rapid creation without programming:

Reusable metadata templates and comfortable GUI allow rapid creation without programming a single line of code.

2. Up-to-date information:

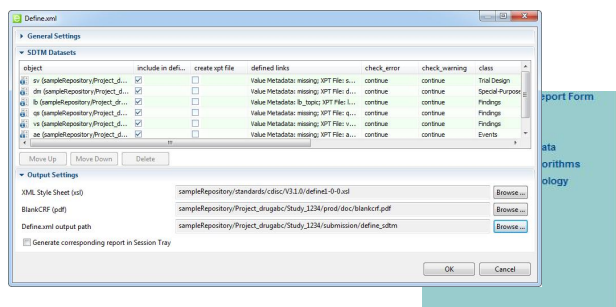
Central repository maintains up-to-date information including templates accessible to all users.

3. Consistent definition:

Controlled links between versioned elements provide for consistent definition.

4. Universal approach for SDTM and ADaM define:

Metadata driven concept allows to create define for SDTM, ADaM and even custom structures.



Dataset	Description	Class	Structure
sv	Subject Visits	Trial Design	One record per subject per actual visit
dm	Demographics	Special-Purpose	One record per subject
lb	Laboratory Test Results	Findings	One record per lab test per time point per visit per subject
qs	Questionnaires	Findings	One record per question per time point per visit per subject
vs	Vital Signs	Findings	One record per vital sign measurement per time point per visit per subject
ae	Adverse Events	Events	One record per adverse event per subject

4 steps to Define.xml:

Only four steps are required to generate define.xml for SDTM or ADaM:

1. Use Metadata Templates

Entimo provides you with a set of standard SDTM domains saving your precious time. The templates can be used as they are or adjusted to customer specific models. Domain level metadata is already preconfigured for standard SDTM domain definitions. Standard SDTM controlled terminology is available.

2. Define Data Elements

You can comfortably create and maintain additional data elements such as value level metadata and algorithms using a robust data grid with filtering and query definition dialog. All information is stored in the central repository and is subject to full-fledged traceability, version control and lifecycle management. If available, you can load datasets with the required information by using dedicated file and database wizards.

3. Define Dependencies and Links

Drag-and-drop GUI allows you to define necessary links between the metadata and all required data elements. A highlight of the tool is the aCRF page extractor which automatically scans aCRF for page numbers where domain attributes are referenced and stores them in domain metadata.

4. Create Define.xml

As the last step, you need only to select domains to be included – define.xml is automatically created in a specified location. Controlled terminology and other data elements are included into define.xml on the fly and are up-to-date with consistent links. If some data elements have changed, you just need to press the button again.