CERTARA | PINNACLE 21

DEFINE.XML 2.0 DESIGNER

NOW WITH ANALYSIS RESULT METADATA

THE ABILITY TO CREATE DEFINE.XML 2.0 FILES THAT WILL ASSIST REVIEWERS & EASE YOUR SUBMISSION PROCESS

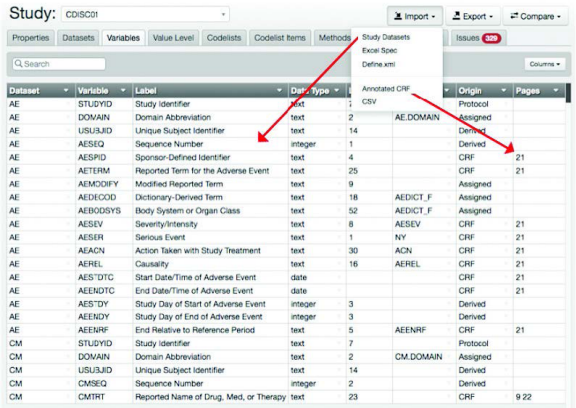
A sufficiently documented Define file allows reviewers to interpret your datasets faster, which results in a submission that's structured to move through the process more quickly. Yet reviewers frequently report that Define.xml files are deficient. And sponsors continue to struggle creating FDA-compliant Define files due to a lack of useful tools.

Until now.

Pinnacle 21's Define.xml 2.0 Designer gives you everything you need to create and manage Define files. The result? Easier transmission of metadata for SDTM, SEND and ADaM datasets … and, ultimately, faster time to market.

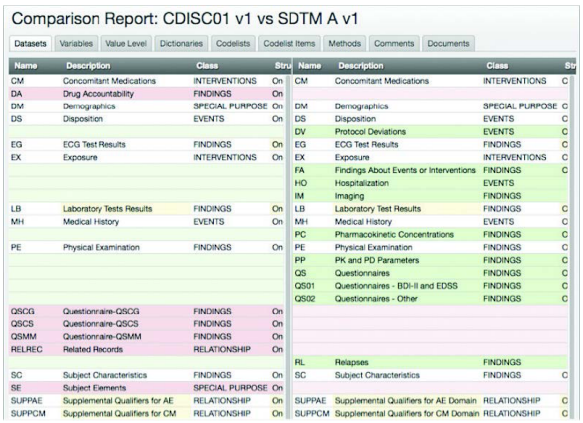
With Define.xml 2.0 Designer, you can:

- Create Define.xml 2.0 for SDTM, SEND and ADaM datasets
- Create Define.xml 2.0 with Analysis Results Metadata (ARM)
- Automatically extract metadata from SAS datasets
- Automatically extract origin page numbers from annotated CRFs
- Easily convert Define.xml 1.0 files into Define.xml 2.0
- Merge metadata from external specifications, standards, or previous studies
- Generate Define.pdf in a single click
- Validate Define.xml and its consistency with study data
- Compare Define.xml content with standards and other studies
- Create, manage, and track changes between multiple versions



Extract metadata and merge with standards

Scan datasets to extract domain, variable, codelist, and value level metadata and then merge it with standards. Finally, scan annotated CRFs to automatically populate origin page numbers.

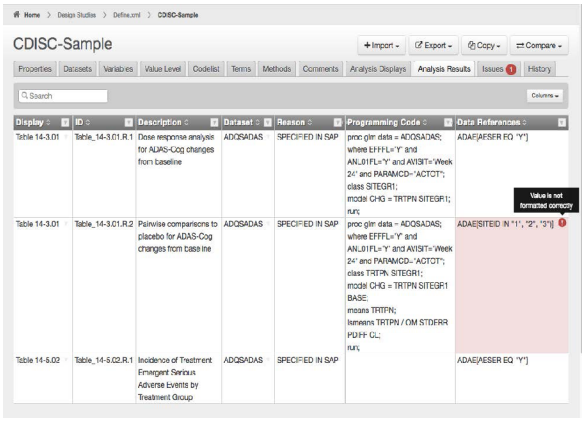


Compare studies and versions

Compare two studies to see the differences between them. You can even compare two versions of the same study to see how it changes over time.

Analysis Results Metadata (ARM)

Define traceability from results in a statistical display to the data in the analysis datasets. Ensure your ARM metadata is compliant with real-time validation.



About Certara

Certara accelerates medicines using biosimulation software and technology to transform traditional drug discovery and development. Its clients include more than 1,650 global biopharmaceutical companies, leading academic institutions, and key regulatory agencies across 61 countries.

For more information, visit **www.certara.com**.