

SA08

Efficient Conversion of SDTM/ADaM Specifications from Excel to Define.xml v2.1 Using Pinnacle 21 Community

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Agenda

- Scenarios Considered
- Method Chosen for This Study
- Result
- Key Insights and Challenges
- Role of each sheet and column in Define.xml Excel spec
- Key Considerations for High-Quality Define.xml
- Pinnacle 21 Community vs. Enterprise
- Conclusion and Insights

Scenarios Considered

Pattern 1

- A trial with acquired product
- SDTM and ADaM datasets and specs available
- Need to create Define.xml for submission

Pattern 2

- A past trial unexpectedly included submission
- Required creation of Define.xml after preparing datasets and reports

Method Chosen for This Study

- Pinnacle 21 Community: No-code solution for Define.xml creation
- Initial Assumptions
 - XPT dataset and its dataset specifications were available
 - Define.xml was not available
- Process Overview
 - Registered XPT files in Pinnacle 21 Community
 - Exported an Define.xml Excel spec
 - Added necessary information to the Excel spec
 - Re-registered the updated file to generate Define.xml
- Validation
 - Conducted using Pinnacle 21 Community

Results

- Successful Creation
 - Define.xml was successfully created by updating the Excel spec from Pinnacle 21 Community
- Validation Outcome
 - Passed PMDA's validation rules, avoiding rejection
 - Some errors remained but were addressable in the Reviewer's Guide

Key Insights and Challenges

- Key Insights
 - Met minimum submission requirements
- Challenges
 - Understanding each sheet and column in the Excel spec was crucial for accurate information input
 - The creation of Define.xml involves numerous necessary elements and a substantial amount of information

Role of each sheet and column in Define.xml

Excel spec [1]

- To address the changes in Define.xml v2.1 using Pinnacle 21 Community, it is essential to accurately understand the role of each sheet and column in the Define.xml Excel spec in addition to those columns newly added in define.xml v2.1 and input the data accordingly
- Overview
 - Provides a column-by-column summary of pre-generated content in the Define.xml Excel spec
 - Highlights content that needs review and updates

Role of each sheet and column in Define.xml Excel spec [2]

- DATASETS sheet
 - Dataset/ Label/ Class column
 - Output based on XPT file by Pinnacle 21 Community
 - Class column needs to be updated if necessary
 - Subclass column ***New in v2.1***
 - Provided as null
 - Necessary to define the subclass for the corresponding dataset.
 - For ADaM, Subclass is defined in Define CT

This slide provides a brief overview. For detailed information, please refer to the paper.

Role of each sheet and column in Define.xml Excel spec [3]

- DATASETS sheet (continued)
 - Standard column *New in v2.1*
 - Output based on the configured version
 - Update if referring to a different IG version since the validation is performed based on the IG version set in this column.
 - Has no data column *New in v2.1*
 - If the final dataset is empty, it needs to be set to "Yes".
 - Need to add a reason in comment

This slide provides a brief overview. For detailed information, please refer to the paper.

Role of each sheet and column in Define.xml Excel spec [4]

- VARIABLES sheet
 - Format Column
 - Shows the display format from the XPT dataset
 - Ensure this format is only used for Float variables and ADaM SAS date variables
 - Mandatory Column
 - Set to “Yes” for variables that null values are not allowed
 - Origin & Source Column **New in v2.1**
 - Provide the name according to Define-XML v2.1.pdf
 - 4.3.2.1 Origin for SDTM Datasets
 - 4.3.2.2 Origin for ADaM Datasets

This slide provides a brief overview. For detailed information, please refer to the paper.

Role of each sheet and column in Define.xml

Excel spec [5]

- Manual Completion Required for Specific Sheets
 - The following sheets are not automatically filled by Pinnacle 21 Community. All columns need to be completed manually
 - VALUELEVEL
 - CODELISTS
 - DICTIONARIES
 - METHODS
 - COMMENTS
 - DOCUMENTS
 - ANALYSIS DISPLAYS
 - ANALYSIS RESULTS

This slide provides a brief overview. For detailed information, please refer to the paper.

Key Considerations for High-Quality Define.xml

1.Accuracy	The structure of datasets, variables, codelists, and other metadata are accurately described
2.Consistency	The info within the define.xml is consistent with the actual datasets and other related documents
3.Clarity	Definitions of variables and code lists are clear, allowing users to easily understand them
4.Completeness	All necessary metadata is included, with no omission
5.Standard Compliance	It adheres to CDISC standards
6.Readability	The XML file is properly formatted, making it readable and understandable
7.Validation	The XML has technically correct syntax and doesn't produce errors when using validation tools



Validator



Define.xml
Generator

Pinnacle 21 Community vs. Enterprise (Define Creation)

	P21 Community	P21 Enterprise
Creation Method	Generate from excel spec	6 different options (including generating from xpt files used for validation, importing xlsx, importing xml, copying study, copying standard, or starting with a blank template and manually entering)
Preview	N/A	Can see the preview of define.xml by clicking “Preview” button
Validation	Need to run a validation including define.xml	Checks run automatically in define designer and the user can click on “view issues” which direct to the cells where the issues need to be resolved.
Compare	N/A	Can compare to previous versions, other standards, or other defines
Merge	N/A	Merge xpt info used for validation with the define file.
aCRF import	N/A	Page numbers are populated in Pages column in Variable and Value levels for SDTM define by importing acrf.pdf.
Versioning	N/A	Included in the system

Summary

➤ Purpose

- Outline steps and tips for sufficient creation of Define.xml

➤ Importance

- Essential for electronic data submissions
 - Details metadata for clinical trial datasets
 - Crucial for SDTM and ADaM standards

➤ Challenges

- Enter all required items in the Excel spec
- Complexity in generation Define.xml
- Understand and meet XML and regulation requirements



Conclusion and Insights

- Pinnacle 21 Community is an easy-to-use tool for Define.xml creation
 - Understanding the roles of each sheet and column is crucial
 - Knowing each sheet and column's role makes updating the specs easier and generating define.xml simpler
 - Enables efficient and consistent outputs
- Insights for updating from v2.0 to v2.1





Thank you

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