

Step up your ADaM Compliance Game

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ABSTRACT

The importance of ensuring CDISC dataset compliance for submission is critical throughout the Pharmaceutical industry. Open Source Tools such as Pinnacle 21 Validator are used to assess CDISC compliance but currently not all checks documented in CDISC ADaM Validation Checks v1.3 are covered by Pinnacle 21 Validator (Community v2.2.0). In addition, checks based on ADaM IG v1.1 and OCCDS v1.0 are not included and checks do not run at all on some datasets.

At ICON we developed a process which incorporates two macros to help ensure ADaM compliance and will supplement the checks available within the Pinnacle 21 Validator. The macros can either be used at an early stage to check metadata compliance prior to programming using empty datasets created from the ADaM dataset specifications or with populated datasets once data is available.

INTRODUCTION

At ICON we developed a process and tools to check ADaM metadata compliance which will reduce rework downstream, due to early identification and resolution of compliance issues. It is a three-step process :-

- 1) In-house macro (specs2xpt) converts ADaM dataset specifications to empty SAS datasets and xpt files.
- 2) The xpt files are subjected to Pinnacle 21 Validator (Community V2.2.0) checks.
- 3) In-house ADaM compliance check macro (based on ADaM Validation Checks v1.3) is run on the empty SAS datasets generated by specs2xpt. This macro supplements the checks available in Pinnacle 21 Validator (Community v2.2.0). Note: The macro can either be used at the early stage with empty datasets created from the ADaM dataset specifications to ensure metadata compliance prior to beginning programming or at a later stage when datasets are populated with live data.

This paper will cover :-

- The rationale and process for our enhanced checks on ADaM compliance
- Types of issues found when checking compliance
- Assumptions and limitations
- The benefits realized

RATIONALE

In-house macros were developed because available tools such as Pinnacle 21 Validator (Community v2.2.0) do not currently cover all of the ADaM validation checks described in the ADaM Validation Checks v1.3 document.

The specs2xpt macro was developed primarily to enable us to check ADaM metadata compliance prior to programming. The tool creates empty xpt files and empty SAS datasets from ADaM dataset specifications.. Specs2xpt assumes that the ICON ADaM dataset specification template is used and performs a number of preliminary checks prior to creating the empty xpt files/datasets.

The ADaM compliance check macro was developed so that it can be used on any study following ADaM standards to review either empty SAS datasets or populated SAS datasets. The macro was written based upon the compliance check descriptions in the ADaM Validation Checks v1.3, as released by CDISC. 26 specific validation checks not covered by Pinnacle 21 Validator were identified and programmed.

ICON's in-house macros are used in addition to Pinnacle 21 Validator (Community v2.2.0) to help ensure ADaM datasets are CDISC compliant. 17 of the 26 validation checks programmed in the ADaM compliance check macro will review dataset metadata for ADaM compliance.

PROCESS

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Please refer to appendix A1 and A2 for the process flowcharts.

MACROS

SPECS2XPT MACRO

The specs2xpt macro has been written specifically to work with the ICON ADaM specification template. The ICON ADaM template has fixed structures which can accommodate any type of ADaM dataset. The specs2xpt macro performs a number of structural checks before creating the empty datasets and xpt files.

Input File

The input file is the ADaM Dataset Specification file, a Microsoft Excel file. It must include a sheet called Metadata. For each dataset listed on the Metadata sheet there must be one sheet in the file which is named with the dataset name and which contains the detailed variable information for the given dataset.

Macro variables are created for each variable in each dataset specified and for attributes like name, label, length, etc. An empty dataset is created using all the macro variables created in above step, then the dataset is converted to .xpt file and saved.

Warnings are printed in the log for the following :-

- If dataset name is present in Metadata sheet and a corresponding dataset sheet is not present in Analysis Dataset Specification file, as well as the reverse situation
- If invalid data types are encountered or data type is missing
- If variable label is greater than 40 characters or missing
- If variable name is greater than 8 characters or missing
- If variable length is missing

Output Files

The output files generated will be one xpt file and one empty SAS dataset per analysis dataset described in the specification file. The xpt files and empty datasets will be created in a subfolder of the folder where the driver program for the macro is saved and executed.

ADAM COMPLIANCE CHECK MACRO

The ADaM compliance check macro was developed so that it can be used with either empty or populated SAS datasets.

Input Files

The macro requires SAS analysis datasets which follow ADaM standards.

Output Files

A temporary work dataset is created when all checks have been run and is used to output the following reports.

A report is produced in Microsoft Excel and as a SAS list file to show the status of each check and display details of the check along with reasons why a check has passed or failed. Example of the Excel output is shown below.

	1	2	3	4	5	6	7	8	9	10
ADaM Validation Check Report										
1										
2										
3	Check Number	ADaM IG 1.0 Section Number	Text from ADaM IG	ADaM Structur Group	Functional Group	ADaM Variable Group	Machine-Testable Failure Criteria	Pass/Fail	Reason	Additional Information
4										
5										
6										
7	5 S3		The names of all other character flag (or indicator) variables end in FL	ALL	Controlled Terminology	Flag Variables	A variable with a suffix of FL has a value that is not Y, N or null	Failed	A variable with a suffix of FL has a value that is not Y, N or null	
8	6 S3		The names of the corresponding numeric flag (or indicator) variables end in FN	ALL	Controlled Terminology	Flag Variables	A variable with a suffix of FN has a value that is not 0, 1 or null	Passed	Variable with a suffix of FN not present	
9	7 S3		If the numeric flag is used, the character version ("FL") is required	ALL	Present/Populated	Flag Variables	A variable with a suffix of FN is present but a variable with the same root and a suffix of FL is not present	Passed	Variable with a suffix of FN not present thus variable with the same root and a suffix of FL cannot be compared.	

TYPES OF ISSUES FOUND

Many compliance findings are not easily identified by manual checks, and manual review of dataset specifications is time-consuming. ICON's in-house macros are able to quickly identify potential structural issues within the ADaM specifications and datasets.

- Missing metadata e.g. Work sheet available for ADxx which was not specified in Metadata tab of the ADaM specification file or vice versa
- Incorrect data type/format for variables

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- Inconsistency in attributes
- Variable name and label mismatches compared to the standard
- Variable labels or names over allowed lengths
- Missing required variables

ASSUMPTIONS AND LIMITATIONS

SPECS2XPT MACRO

- Only used for studies with analysis dataset specifications that follow the ICON ADaM dataset specification template.

ADAM COMPLIANCE CHECK MACRO

- Only used for studies that create SAS analysis datasets following CDISC ADaM standards.
- Programmed utilizing the SASHELP tables VTABLE and VCOLUMN in conjunction with ADaM datasets.
- Checks are based on ADaM Validation Checks v1.3, as released by CDISC.
- Will need to be updated when CDISC releases a new version of Validation Checks depending on whether or not all checks in that version will be covered by Pinnacle 21 Validator (Community).

BENEFITS

The tools have brought a number of benefits to the clinical study teams :-

- Reliable automated tools reduce reliance on manual compliance checks.
- Ability to check metadata compliance prior to sending ADaM specification for internal or external review.
- Reduction in time in the reporting process by capturing metadata issues as early as possible instead of later in the study.
- Collection of metrics to identify common findings across studies.
- Addressing gaps where checks are not available in Pinnacle 21.
- Performs at least some validation checks on all types of ADaM datasets.

CONCLUSION

The release of this process and these two macros has proved to be of benefit to study teams in many ways. ADaM metadata issues are caught early in the dataset development process, prior to specifications being sent for review and prior to dataset programming. Review for compliance issues is simplified and more reliable due to use of automated tools. All types of ADaM datasets will undergo some amount of compliance checking.

Overall ICON has seen improvements in our ADaM dataset creation process in direct support of our “first time right” approach.

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CONTACT INFORMATION

Your comments and questions are valued and encouraged. Contact the author at:

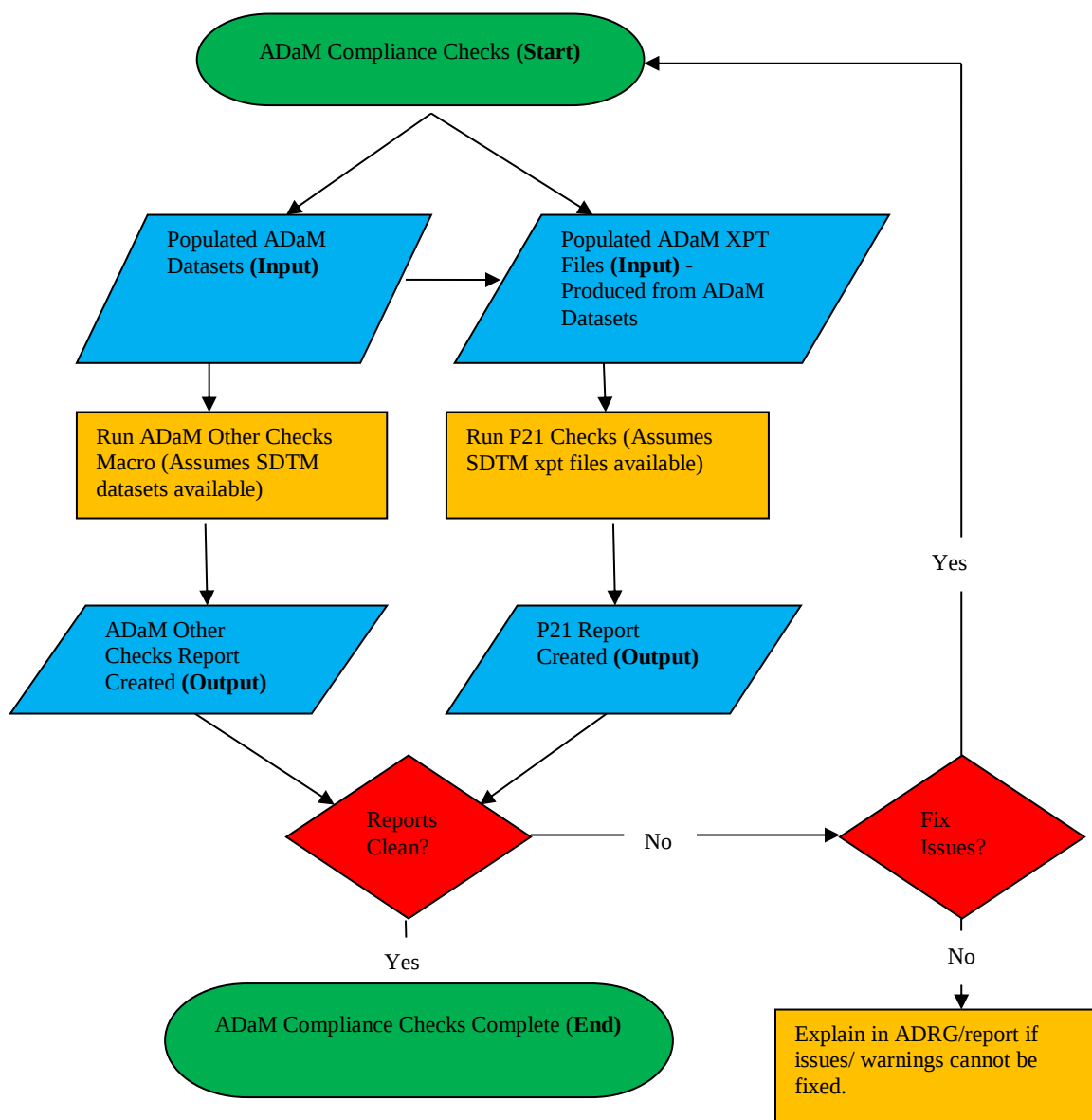
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APPENDIX A1

Flowchart to describe the process of running the ICON ADaM compliance check macro and Pinnacle 21 checks to validate populated ADaM datasets/xpt files, prior to finalizing the ADaM datasets.



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APPENDIX A2

Flowchart to describe the process of running the specs2xpt tool followed by ICON ADaM Compliance checks and P21 to validate the empty datasets/xpt files, prior to finalizing the ADaM dataset specifications.

