



Step Up Your ADaM Compliance Game

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Agenda

- ❖ Regulatory Requirement
- ❖ Current Situation
- ❖ iACE-Toolbox
- ❖ 3 Step Process
- ❖ Macros
- ❖ Types of Issues
- ❖ Assumptions & Limitations
- ❖ Benefits

Introduction

Regulatory Requirement:

- ❑ Required standards for data submissions to FDA (US) and PMDA (Japan).
- ❑ Timely and efficient review as the reviewers could utilize standardized tools.
- ❑ Fewer questions and faster approval.

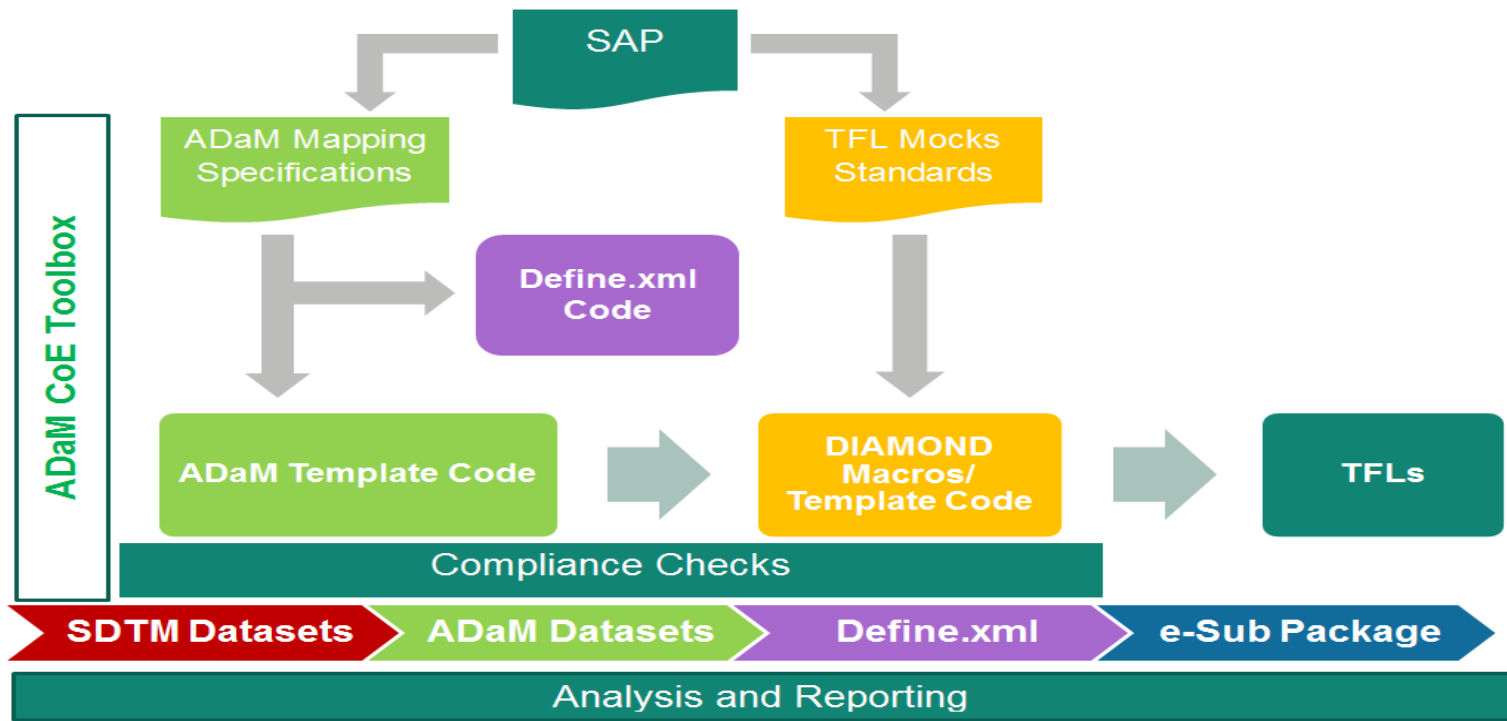


Current Situation

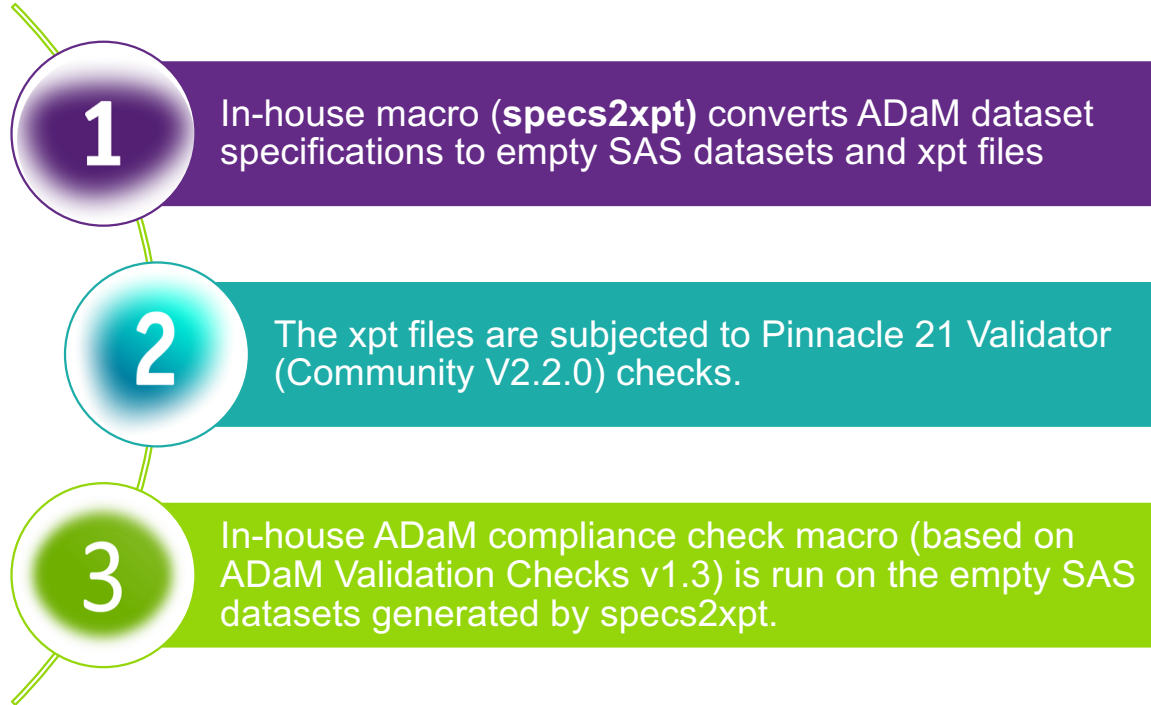
- ❑ Compliance check tools require datasets as an input and therefore checked at later stage.
- ❑ Rework resulting in timeline and cost implication.
- ❑ Certain validation checks not covered by P21C (V2.2.0).

PINNACLE²¹

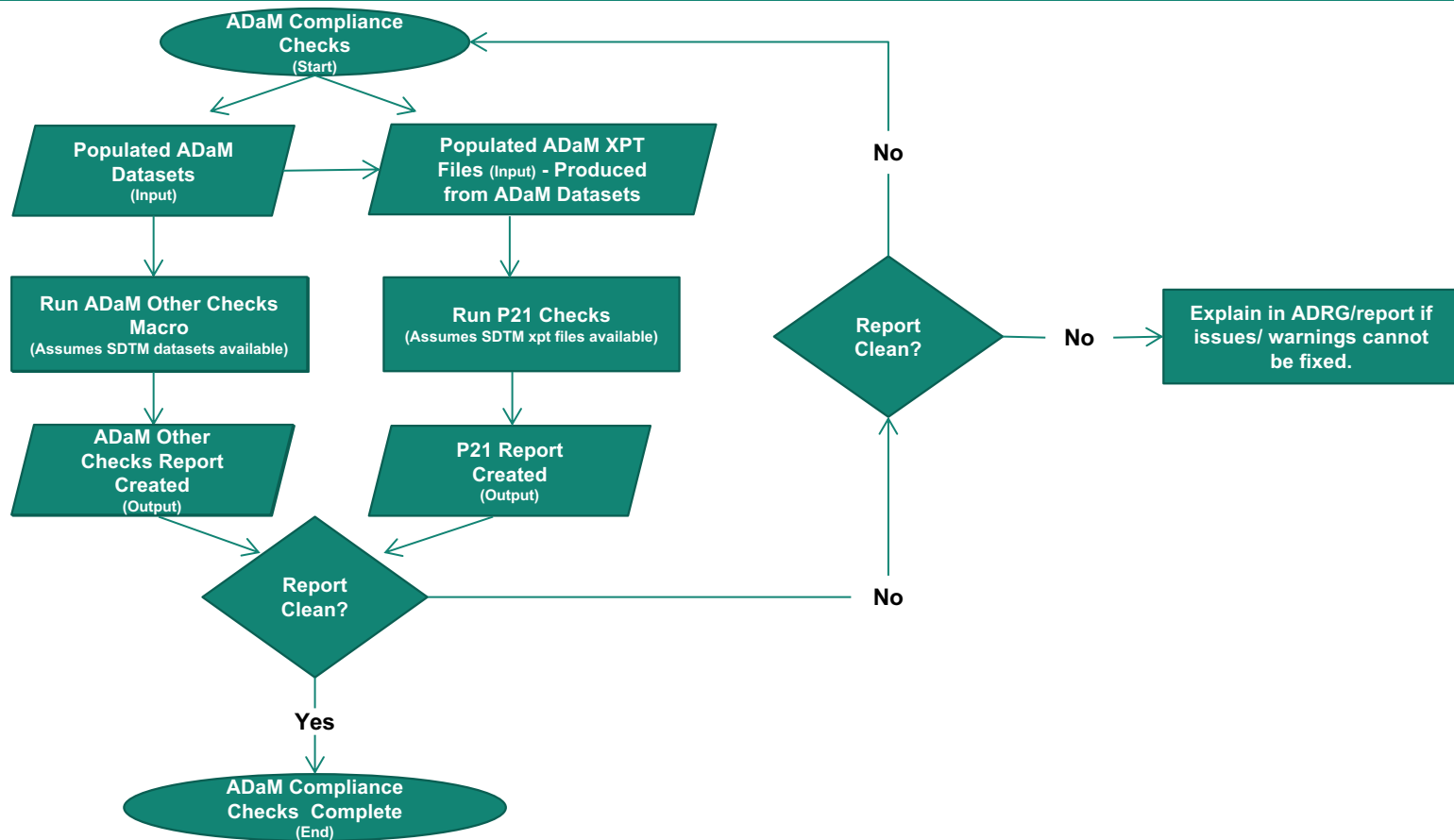
iACE (ICON ADaM Capabilities and Expertise) – Toolbox

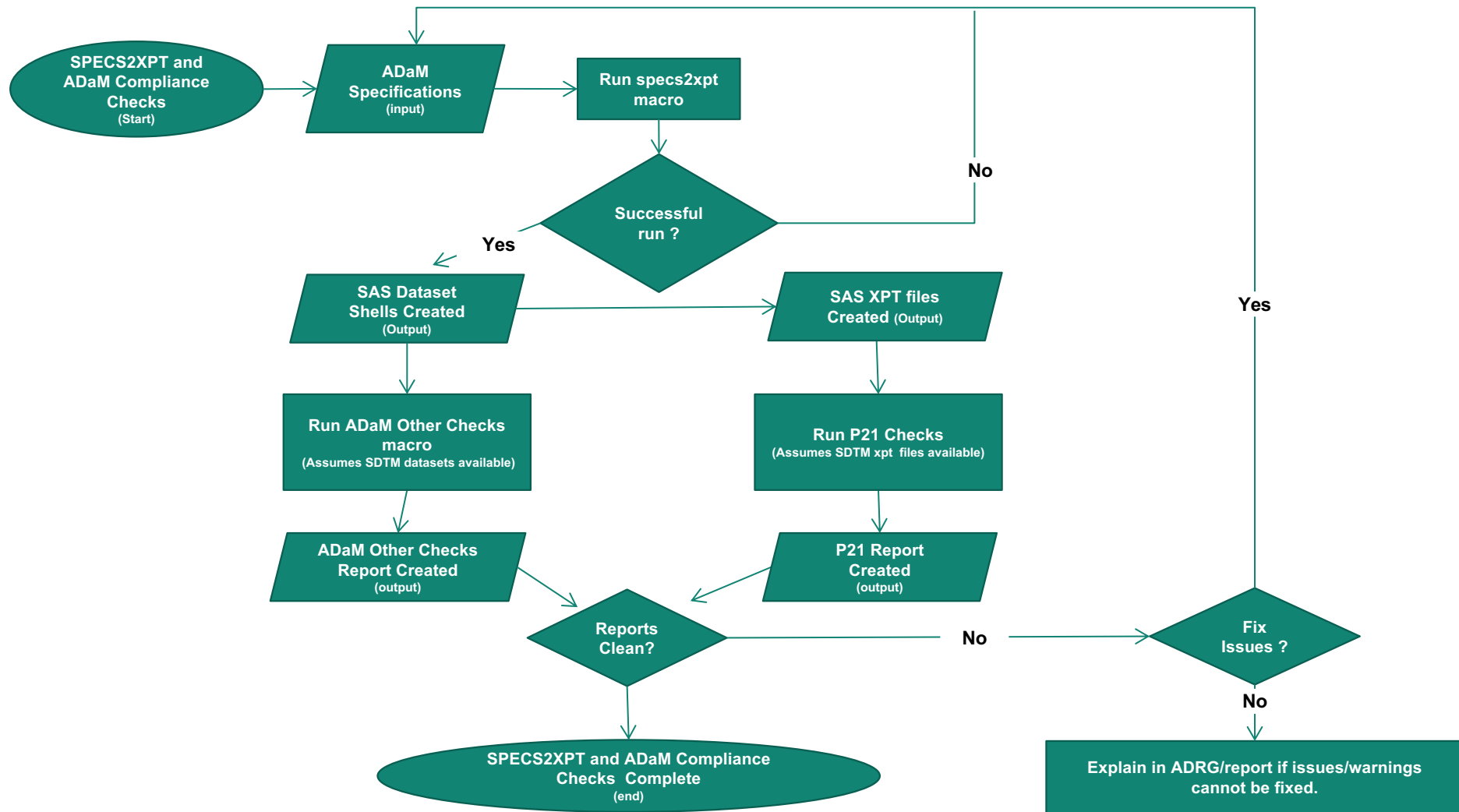


3 Step Process



Process





SPECS2XPT

- ☐ Work with ICON ADaM Specs template.
- ☐ Structural checks before creating output files.

Input

- ☐ ADaM Specs – XL file, including metadata sheet.

Output

- ☐ Empty datasets and XPT files.

Errors and Warnings printed in log if

- ☐ Metadata sheet and ADaM specs not in sync wrt to dataset name.
- ☐ Variable attributes not as expected or missing.

WARNING: For variable UFTIME label mentioned in the ADSL is greater than 40 characters.

```
NOTE: Line generated by the macro variable "FOR49".  
1    time5.  
-----  
48
```

ERROR 48-59: The format \$TIME was not found or could not be loaded.

NOTE: The SAS System stopped processing this step because of errors.

WARNING: The data set SHLL_OUT.ADSL may be incomplete. When this step was stopped there were 0 observations and 72 variables.

WARNING: Data set SHLL_OUT.ADSL was not replaced because this step was stopped.

ADaM Compliance Check Macro

- ❑ Used with empty or populated datasets.

Input

- ❑ Analysis datasets following ADaM standards.

Output

- ❑ Temporary work dataset and a report showing status.

	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

- ❑ Many of these findings are not easily identifiable by manual checks.
- ❑ ICON's in-house macros identify potential structural issues in specs early on.
 - Missing metadata
 - Incorrect variable data type/format
 - Inconsistency in attributes
 - Variable name and label mismatches
 - Variables labels or names over allowed lengths
 - Missing required variables



Assumptions & Limitations

SPECS2XPT

- ☐ Assumes ICON ADaM Specs template as input.

ADaM Compliance Check Macro

- ☐ 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

- ❑ Reduced 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.





Thank You

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