

Management and Enforcement of Custom Standards and Terminologies with Pinnacle 21 Enterprise

PINNACLE²¹

About Me

- > Brad Moran
- > Software Engineer
- > Phuse Reviewer's Guide XML Team
- > Qualifications



Current Standard Management Practices

- > Excel Spreadsheet
- > MDR Vendor
- > Nothing
- > Pinnacle 21

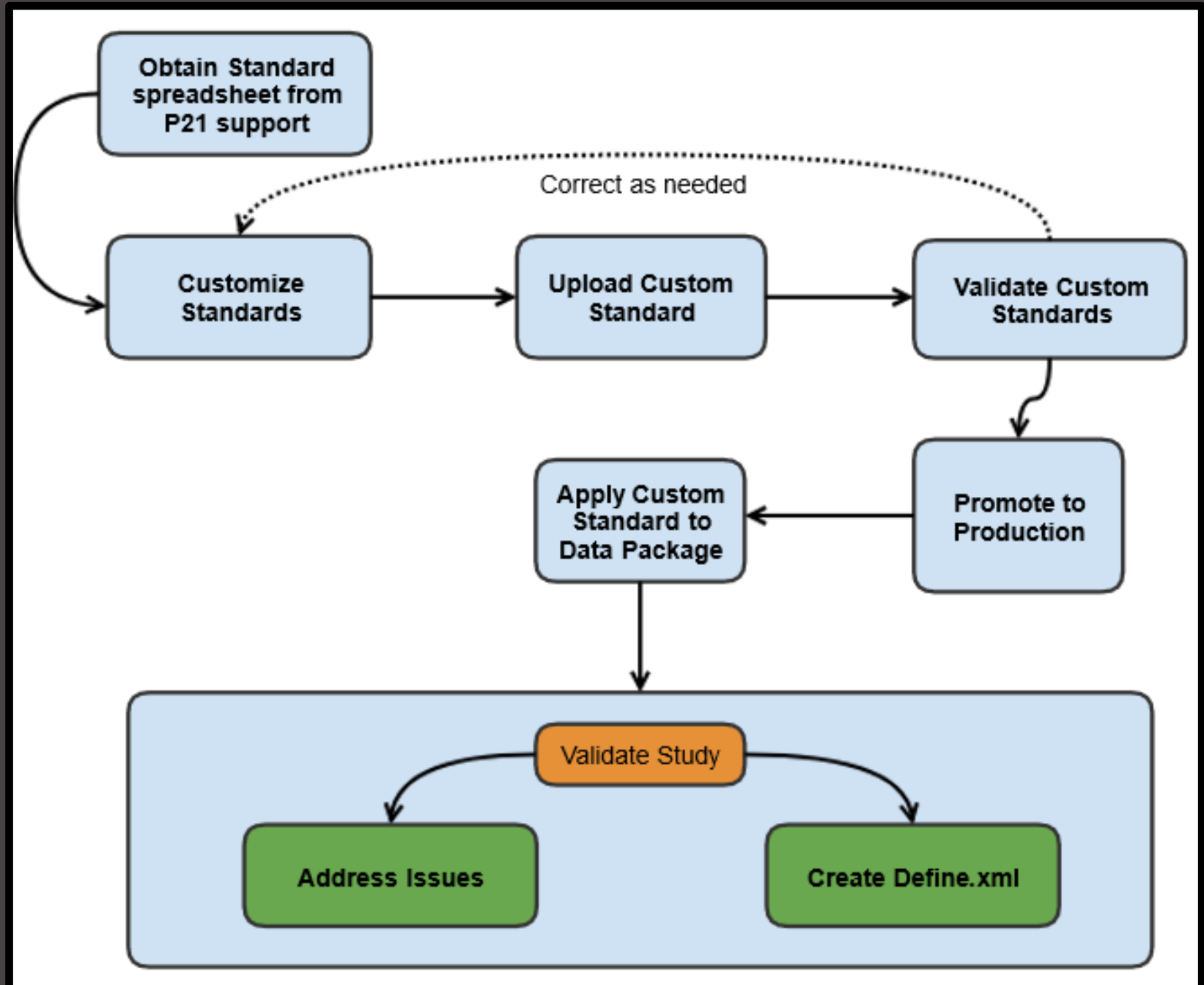
How do we enforce quality of our custom standards?

- > Validate our standards
- > Use our standards to validate our data

Benefits of Validating Against a Custom Standard

- > Reliability across studies and submissions
- > Consistency for business partners, CRO's, and even internal distributed teams
- > Efficiency of shared metadata

Demo



Standard Validation

- > MD---- rules
- > Enforce high quality standards
- > Issues should be resolved

The screenshot displays the PINNACLE Z1 ENTERPRISE web application. The left sidebar contains navigation links: Home, Configure, Design Studies, Manage Metadata, Standards, Terminologies, Issue Filters, and Validate. The main content area shows the 'Manage Metadata' section for 'My_Organization_SDTM-IG 2'. A 'Standard' dropdown is set to 'My_Organization_SDTM-IG 2'. Below it, there are filters for 'Datasets' (2), 'Variables' (2931), 'Value Level', and 'Methods' (2). A search bar is present. A table lists variables with columns: Order, Dataset, Name, Label, Type, and others. The table shows several rows, including 'AESEQ' with a red error icon in the 'Label' column. A 'Validation Issues' dialog box is open, displaying the message: 'MD0031: Missing Label value' and 'Label value is required for each variable.' with a red information icon. A 'Close' button is at the bottom right of the dialog.

Order	Dataset	Name	Label	Type
6	AE	AESEQ		integer
7	AE	AEGRPID	Group ID	text
8	AE	AEREFID	Reference ID	text

Data Validation

- > SP---- rules
- > Issues should be resolved
- > Doesn't change agency results
- > Doesn't change validation score

Dashboard

Analysis Support

Datasets

Issues

History

More Reports

⌵

Actions ▾

🔍

sp00

Filters

Status ▾

Risk ▾

Assign

☐

⌵

Rule ▴

Message ▴

AE - Adverse Events (2 Issues)

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SP0057

Sponsor Expected variable AEBDSYCD not found

☐

SP0063

Sponsor/dataset variable label mismatch

DM - Demographics (2 Issues)

☐

SP0056

Sponsor Required variable ACTARM not found

☐

SP0057

Sponsor Expected variable RFXSTDTC not found

SUPPCM - Supplemental Qualifiers (1 Issues)

☐

SP0055

Sponsor/dataset variable type mismatch

Adapters

> Save time and effort

Import Excel Terminology Template

Please select the template

☒ Sp.A ☐ Pinnacle 21

Please select the standard

☐ SDTM ☐ ADaM

Please select the define version compatibility

☐ Define 1.0 ☐ Define 2.0

Please select .xls,.xlsx spec file(s) to import

If you need a blank template, [download it here.](#)

Problems to Solve

- > Allow editing in system with improved audit trail
- > Integrations with popular MDR vendors
- > Public API

Questions?

Brad Moran

Lead Software Engineer

bmoran@pinnacle21.com

