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

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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
Obtain Standard spreadsheet from P21 support

Customize Standards

Upload Custom Standard

Validate Custom Standards

Apply Custom Standard to Data Package

Promote to Production

Validate Study

Address Issues

Create Define.xml
Standard Validation

- MD---- rules
- Enforce high quality standards
- Issues should be resolved
Data Validation

- SP---- rules
- Issues should be resolved
- Doesn’t change agency results
- Doesn’t change validation score
Adapters

> Save time and effort
Problems to Solve

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

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