

What's New in Enterprise 3.4

Bringing efficiencies to your data standardization and compliance efforts

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Customer Success Team

Oleg Zvenigorodsky



- › Director Customer Success
- › Joined P21 in March 2016
- › Prior experience: 8 years at Janssen (Drug Safety, Clinical Development, Data Management)

Jung Kim



- › Customer Success Manager
- › Joined P21 in January 2018
- › Prior Experience: 2 years direct patient contact, 3 years client account management and Healthcare IT

Customer Success in 2018

- › Objective: Help Enterprise users achieve daily & long-term goals
- › Proactive engagement and communication
 - › Understand users' specific needs
- › Access to additional resources
 - › Webinars, Knowledge Base, Best Practices, etc.
- › Customer Journey
 - › Improvements at every stage of adoption
- › Optimize Enterprise's value

The background of the image is a teal-tinted photograph of the Philadelphia skyline, featuring several prominent skyscrapers and a river in the foreground. A multi-lane highway with traffic is visible on the left side. Overlaid on this background is a large white logo consisting of a square containing the text 'P21' and the word 'LIVE' in a large, bold, sans-serif font to its right. Below 'LIVE' is the text 'PHILLY 2018' in a smaller, white, sans-serif font.

P21 LIVE
PHILLY 2018

September 17-19, 2018

Hilton Philadelphia at Penn's Landing

<http://mailchi.mp/pinnacle21/p21-live-2018>

Presenter – Max Kanevsky



- › Founder of OpenCDISC
- › CEO of Pinnacle 21
- › Validation tool implementer at FDA and PMDA
- › SME on FDA JumpStart Service

What's New in Enterprise 3.4

- › Validation against sponsor standards and terminologies
- › New rules and standards
- › Where Clause Builder
- › Other enhancements

Validation Against Sponsor Standards and Terminologies

- › Added 15 new rules (SPXXXX)
- › Align to existing rules that validate against CDISC standards and CT

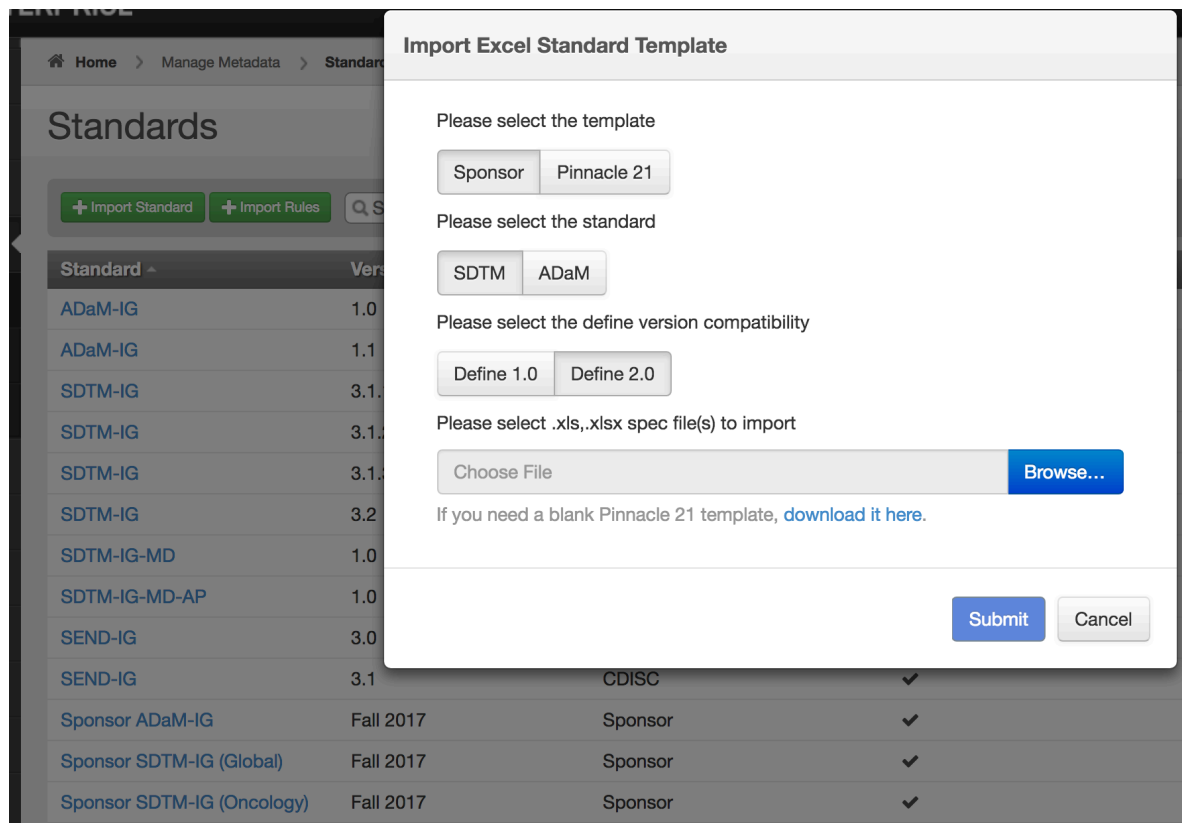
Sponsor Rules Examples

Rule ID	Message	Description
SD0055	SDTM/dataset variable type mismatch	Variable Data Types in the dataset should match the variable data types described in SDTM.
SP0055	Sponsor/dataset variable type mismatch	Variable Data Types in the dataset must match the variable data types described in Sponsor standard.

Rule ID	Message	Description
CT2001	Variable value not found in non-extensible codelist	Variable must be populated with terms from its CDISC controlled terminology codelist. New terms cannot be added into non-extensible codelists.
SP2001	Variable value not found in Sponsor non-extensible codelist	Variable must be populated with terms from assigned Sponsor non-extensible codelist. New terms cannot be added into non-extensible codelists.

How does it work?

- › Import sponsor standards and terminologies
- › Assign to data package
- › Validate



IMPORTING SPONSOR STANDARD

Enterprise provides two methods to import sponsor standards and terminologies. You can either use the Pinnacle 21 Excel template or your own template via a custom adapter.

New Rules and Standards

- › 90 new SDTM-IG 3.2 rules
 - › SD1143-SD1145, SD1238-SD1329
- › ADaM-IG 1.1
- › SEND-IG 3.1

SDTM-IG 3.2 Conformance Rules

- › 410 total rules published by CDISC
- › 356 are “Programmable”
 - › Can be implemented as automated check
- › 304 are implemented in Enterprise 3.4
- › 52 are pending due to
 - › Waiting on clarification from CDISC and/or FDA
 - › Waiting on Validator upgrades

ADaM-IG 1.1 Support

- › FDA started accepting ADaM-IG 1.1 on March 15, 2018
- › CDISC is still working on the rules
 - › Public review – August/September
 - › Final – December
- › Enterprise 3.4 adds support for ADaM-IG 1.1 (beta until CDISC finalizes)

ADaM-IG 1.1 Interesting Facts (1)

- › Supported datasets
 - › ADSL, ADAE
 - › BDS – any dataset with PARAMCD, AVAL
 - › OCCDS – any dataset with *TRT, *TERM, but no PARAMCD
 - › ADaM OTHER – any other dataset that starts with “ad”

ADaM-IG 1.1 Interesting Facts (2)

- › 45 new business rules
 - › AD0323-AD0364
- › 79 business rules deprecated
 - › All Time-to-Event (TTE) rules
 - › Other rules that could produce exceptions. For example, “TR01SDT does not equal TRTSDT”

ADaM-IG 1.1 Interesting Facts (3)

- › Algorithms of many existing business rules changed, for example
 - › 48 “Inconsistent value” checks apply only to records where values for both related variables are populated
 - › New AD0096B: “Within a study, all TRTA values must be the same for each unique value of TRTAN, **considering only those rows on which both variables are populated.**”
 - › Original AD0096: “Within a study, all TRTA values must be the same for each unique value of TRTAN, **when primary variable TRTA is populated.**”

Selection Criteria Builder

Dataset	Variable	Comparator	Value		
ADAE	AESER	EQ	Y	and	
ADAE	TRTEMFL	EQ	Y	and	
ADQSADAS	EFFFL	EQ	Y	and	
ADQSADAS	AVISIT	EQ	Week 24	and	
ADQSADAS	PARAMCD	EQ	ACTOT	and	
ADQSADAS	ANL01FL	EQ	Y	and	

Selection Criteria

ADAE[AESER EQ Y and TRTEMFL EQ Y]

ADQSADAS[EFFFL EQ Y and AVISIT EQ Week 24 and PARAMCD EQ ACTOT and ANL01FL EQ Y]

Submit

Cancel

WHERE CLAUSE BUILDER

Enterprise 3.4 adds a new widget to help users define complex Where Clauses for value level metadata or Selection Criteria for analysis results metadata.

Summary & Questions

- › Next steps with Enterprise 3.4
 - › Release notes available
 - › Submit request for upgrade via Service Desk
 - › Contact your Customer Success team for additional details
- › Blog post with additional information will be posted next week

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