What’s New in Enterprise 3.4

Bringing efficiencies to your data standardization and compliance efforts

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April 23, 2018
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
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

<table>
<thead>
<tr>
<th>Rule ID</th>
<th>Message</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>SD0055</td>
<td>SDTM/dataset variable type mismatch</td>
<td>Variable Data Types in the dataset should match the variable data types described in SDTM.</td>
</tr>
<tr>
<td>SP0055</td>
<td>Sponsor/dataset variable type mismatch</td>
<td>Variable Data Types in the dataset must match the variable data types described in Sponsor standard.</td>
</tr>
<tr>
<td>CT2001</td>
<td>Variable value not found in non-extensible codelist</td>
<td>Variable must be populated with terms from its CDISC controlled terminology codelist. New terms cannot be added into non-extensible codelists.</td>
</tr>
<tr>
<td>SP2001</td>
<td>Variable value not found in Sponsor non-extensible codelist</td>
<td>Variable must be populated with terms from assigned Sponsor non-extensible codelist. New terms cannot be added into non-extensible codelists.</td>
</tr>
</tbody>
</table>
How does it work?

 › Import sponsor standards and terminologies
 › Assign to data package
 › Validate
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.”
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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