



Larix – a full service Clinical Research Organisation

N O R D I C • R O B U S T • F L E X I B L E

Pinnacle 21 Enterprise Edition – User Experience

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Aim of this presentation is not about promoting Pinnacle 21 tools but about sharing experience of using the tools in the process of Regulatory submission.

The information and opinions expressed in this presentation are provided for informational purposes only.

Pinnacle 21 Enterprise



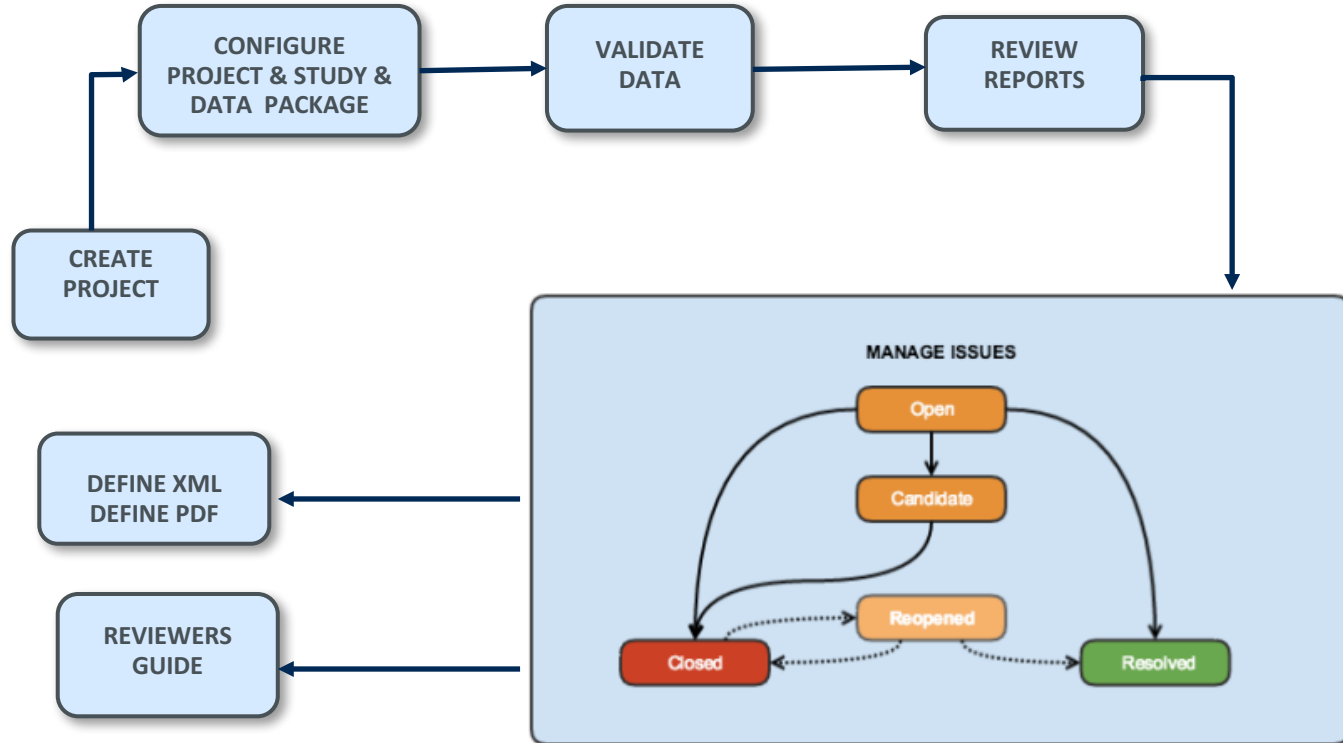
- Web-based application to manage standards compliance over the entire study life-cycle.
- Helps in preparing for a regulatory submission
- The FDA and PMDA also use Pinnacle 21 Enterprise to review incoming submissions (used at FDA under the name “DataFit”).
- Latest version is Enterprise 3.4

Pinnacle 21 Community

- Open Source free version toolkit, which includes Validator, Define.xml Generator, Data Converter, and ClinicalTrials.gov Miner.
- Latest version is v2.2.0 (released on 27-Sep-2016)

P21 Community	P21 Enterprise
Data validation tool	For Regulatory submission, standards management and continuous compliance
Mainly designed for programmers to QC their work for FDA/PMDA submissions	Tool for Programmers and Non-techies
Consists of Validator, Define.xml Generator, Data Converter, and ClinicalTrials.gov Miner	Additional features
Runs on Desktop and Can not be a shared tool among teams	Runs on Cloud and can act as communication tool to collaborate with CROs, developers, and other team members
Dictionary and controlled terminology versions needs to managed manually by Sponser/CRO	Standards, Dictionary and Controlled terminology updates are maintained by Pinnacle21

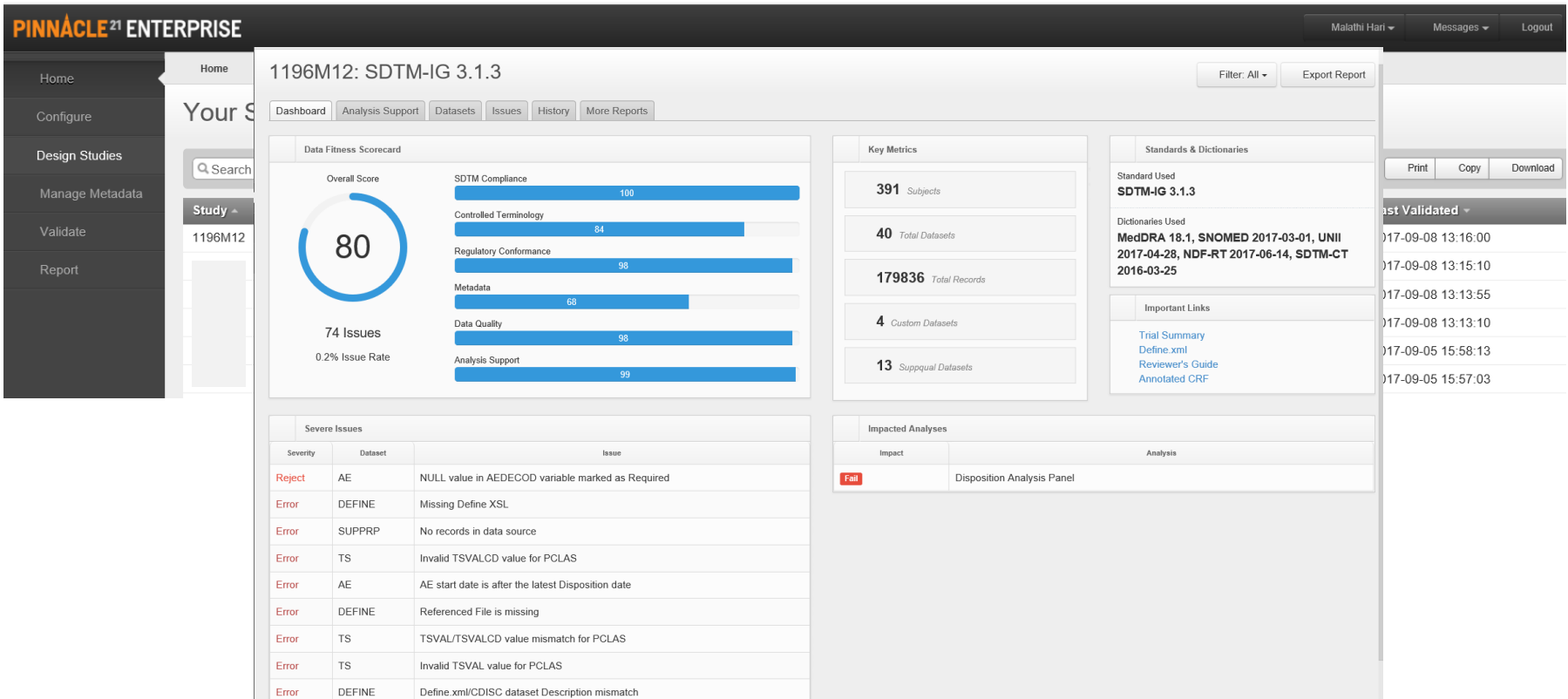
P21 Enterprise- Process Overview



P21 Enterprise Additional features

- ❑ Data Fitness
- ❑ Issue Management and Tracking
- ❑ Additional conformance reports
- ❑ Manage Data issues and collaboration among different teams
- ❑ Manage Custom Standards and custom Terminology
- ❑ Define.xml creation and Issue Management
- ❑ Pre-populated Reviewer's guide
- ❑ Capturing aCRF for SDTM DefineXML

Data Fitness Score



Issue Management and Tracking

Home > Report > 1196M12

1196M12: SDTM-IG 3.1.3

Filter: All Export Report

Dashboard Analysis Support Datasets **Issues** History More Reports

Actions Search Filters Status Risk Assignee Tag Analysis View by Dataset Print Copy Download

Rule	Message	FDA	PMDA	Rate	Risk	Status	Updated
AE - Adverse Events (7 Issues)							
☐ SD0002	NULL value in AEDECOD variable marked as Required	Error	Reject	0.2%		Open	2017-09-08 11:56:36
☐ SD0080	AE start date is after the latest Disposition date	Error	Warning	0.6%		Closed	2018-01-18 13:30:15
☐ SD1031	Value for AEENRF is populated, when RFENDTC is NULL	Warning	Warning	1.4%		Open	2017-09-08 11:56:36
☐ SD1076	Model pe						
Issue Details - SD1031 (AE)							
☐ TS0010	Null valu						
☐ TS0013	Analysis						
☐ TS0013	Analysis						
CE - Clinical Events (2 Issues)							
☐ SD1076	Model pe						
☐ SD1201	Duplicate						
CM - Concomitant Medications (2 Issues)							
☐ CT2002	CMDOS						
☐ SD0031	Missing						
☐ SD1030	Value for						
☐ SD1076	Model pe						
CO - Comments (2 Issues)							
☐ SD1076	Model pe						
☐ SD1203	CODTC						

Details Records

System opened this issue 8 months ago
SD1031: Value for AEENRF is populated, when RFENDTC is NULL

Description: End Relative to Reference Period (-ENRF) should not be populated for subjects with missing value for Reference End Date/Time (RFENDTC).

Structure: AE | Severity: Warning | Category: Consistency | Publisher ID: FDAC138

No one is assigned [Assign](#)

Open

0 comments

Status:

Tags:

Risk:

1) This can be resolved by fixing study data

Close Issue Comment

Issue Management and Tracking

Issue Details - SD1076 (AE)

Details

Records

System opened this issue 8 months ago

SD1076: Model permissible variable added into standard domain

Description: SDTM model variable may be added into standard domains according its domain general class, if there are no restrictions on their usage specified in IG.

Structure: AE | **Severity:** Warning | **Category:** Metadata | **Publisher ID:**

No one is assigned [Assign](#)

Closed Malathi Hari changed the status to closed 7 months ago



Malathi Hari commented

7 months ago

This is a Trial needed variable



Rich text editor toolbar with icons for bold, italic, underline, text color, background color, list, link, unlink, and font size.

2) This can be explained and closed.

These comments will automatically be included in the Data Reviewers Guide.

Reopen Issue

Comment

Closed

1 comment

Status:

Tags:

Risk:

Manage Data issues and collaboration among different teams

Issue Details - SD1201 (CE)

Details

Records

System opened this issue 8 months ago

SD1201: Duplicate records in CE domain

Description: The structure of Events class domains should be one records per Event per subject. No Events with the same Collected Term (--TERM), Decoded Term (--DECOD), Category (--CAT), Subcategory (--SCAT), Severity (--SEV), and Toxicity Grade (--TOXGR) values for the same Subject (USUBJID) and the same Start Date (--STDTC) are expected.

Structure: CE | **Severity:** Warning | **Category:** Consistency | **Publisher ID:** FDAB021

Nils Luxhøj is assigned [Reassign](#) [Unassign](#)



Rich text editor toolbar with icons for bold, italic, underline, link, unlink, list, and text color.

Nils: Can you look into this issue? Please check the data...

Open

0 comments

Status: ⚙️

Tags: ⚙️

study design

data collection

Risk: ⚙️

High

Close Issue

Comment

The issue can be assigned to one or more team members to review, fix, or take other action. The assigned team members will be notified by email and notifications on Home page.

Standards, Dictionary and controlled terminology updates are maintained by Pinnacle21

12 Communication ♦ Proactivity ♦ Quality on time

Custom Standards and Custom Terminology can be uploaded into the system and study data are validated against these specifications

Standard:

Dataset	Description	Class	Structure	Purpose	Key Variables	Prototype
ADAE	Adverse Event Analysis Dataset	ADAM OTHER	One record per subject per each AE recorded in SDTM AE domain	Analysis	STUDYID, USUBJID, AEDECOD, AESEQ	
ADEG	ECG Analysis Dataset	BOS	One record per subject per parameter, per time point.	Tabulations	STUDYID, USUBJID, PARAMCD, AVISITN, ADT, [ATPTN]	
ADEX	Exposure Analysis Dataset	OCCDS	One record per subject per exposure record	Analysis	STUDYID, USUBJID, EXTRT, EXSTDTC	
ADIE	Inclusion/Exclusion Analysis Dataset	FINDINGS	One record per subject per parameter	Analysis	STUDYID, USUBJID, PARCAT1, PARCAT2, PARAMCD	PARAMCD, PARAM, AVAL, AVALC, ADT, ASTDT, ASTDTM, CNSR
ADSL		SUBJECT LEVEL ANALYSIS DATASET	One record per subject	Analysis	STUDYID, USUBJID	

DefineXML and DefinePDF creation

PINNACLE²¹ ENTERPRISE

Malathi Hari Messages Logout

Home > Design Studies > Define.xml > SDTM-IG 3.2: Training study 1

Define: Training Project 1 > Training stu... + Import Export Copy Compare

Properties Datasets Variables Value Level Codelists Terms Methods Comments **Issues 158** History

Search Columns

Dataset	Description	Class	Structure	Purpose	Key Variables	Repeating	Reference	Comment
AE	Adverse Events	EVENTS	One record per adverse event per subject	Tabulation	STUDYID, USUBJID, AEDECOD, AESTDTC	Yes	No	
CM	Concomitant Medications	INTERVENTIONS	One record per recorded medication occurrence or constant-dosing interval per subject	Tabulation	STUDYID, USUBJID, CMTRT, CMSTDTC	Yes	No	
DA	Drug Accountability	FINDINGS	One record per drug accountability finding per subject	Tabulation	STUDYID, USUBJID, DATESTCD, DADTC	Yes	No	
DM	Demographics	SPECIAL PURPOSE	One record per subject	Tabulation	STUDYID, USUBJID	No	No	
DS	Disposition	EVENTS	One record per disposition status or protocol milestone per subject	Tabulation	STUDYID, USUBJID, DSDECOD, DSSTDTC	Yes	No	
EG	ECG Test Results	FINDINGS	One record per ECG observation per time point per visit per subject	Tabulation	STUDYID, USUBJID, EGTESTCD, VISITNUM	Yes	No	
EX	Exposure	INTERVENTIONS	One record per constant dosing interval per subject	Tabulation	STUDYID, USUBJID, EXTRT, EXSTDTC	Yes	No	
IE	Inclusion/Exclusion Criteria Not Met	FINDINGS	One record per inclusion/exclusion criterion not met per subject	Tabulation	STUDYID, USUBJID, IETESTCD	Yes	No	
LB	Laboratory Test Results	FINDINGS	One record per analyte per planned time point number per time point reference per visit per subject	Tabulation	STUDYID, USUBJID, LBTESTCD, LBSPEC, VISITNUM	Yes	No	

DefineXML Validation

Home > Design Studies > Define.xml > SDTM-IG 3.2: Training study 1

Define: Training Project 1 > Training stu... + Import Export Copy Compare

Properties Datasets Variables Value Level Codelists Terms Methods Comments **Issues 158** History

Q Search Print

RuleId	Variables	Values	Message	Description	Type
OD0080	Dataset Name, Variable Name, Variable DataType, CodeList ID, CodeList DataType	LB.LBORRES, LBORRES.LB.LBTESTCD.EQ.GLUC-02344fd5, text, LBORRES.LB.LBTESTCD.EQ.GLUC, integer	Codelist/Variable Data Type mismatch	Variable Data Type must match the Data Type of the referenced Codelist. Define-XML specification represents Variable as ItemDef.	Error
OD0080	Dataset Name, Variable Name, Variable DataType, CodeList ID, CodeList DataType	SUPPEX.QVAL, QVAL.SUPPEX.QNAM.EQ.SMNO-94a2ca5e, integer, QVAL.SUPPEX.QNAM.EQ.SMNO, float	Codelist/Variable Data Type mismatch	Variable Data Type must match the Data Type of the referenced Codelist. Define-XML specification represents Variable as ItemDef.	Error
OD0080	Dataset Name, Variable Name, Variable DataType, CodeList ID, CodeList DataType	VS.VSORRES, VSORRES.VS.VSTESTCD.EQ.HEIGHT-9064ed8b, float, VSORRES.VS.VSTESTCD.EQ.HEIGHT, integer	Codelist/Variable Data Type mismatch	Variable Data Type must match the Data Type of the referenced Codelist. Define-XML specification represents Variable as ItemDef.	Error
OD0080	Dataset Name, Variable Name, Variable DataType, CodeList ID, CodeList DataType	VS.VSORRES, VSORRES.VS.VSTESTCD.EQ.WEIGHT-f82b30fe, float, VSORRES.VS.VSTESTCD.EQ.WEIGHT, integer	Codelist/Variable Data Type mismatch	Variable Data Type must match the Data Type of the referenced Codelist. Define-XML specification represents Variable as ItemDef.	Error
DD0060	Variable, Define Label, Standard Label	EXTRT, Name of Actual Treatment, Name of Treatment	Define.xml/CDISC variable Label mismatch	Variable Label in standard domain must match the variable label described in corresponding CDISC implementation guide. When creating a new custom domain Variable Labels could be adjusted as appropriate to properly convey the meaning in the context of the data being submitted.	Warning

DefineXML Validation

Home > Design Studies > Define.xml > SDTM-IG 3.2: Training study 1

Define: Training Project 1 > Training stu...

+ Import Export Copy Compare

Properties Datasets Variables **Value Level** Codelists Terms Methods Comments Issues 158 History

Q Search Columns

Order	Dataset	Variable	Where Clause	Description	Type	Length	Digits	Mandatory	Codelist	Origin	Pages	Method
1	DA	DAORRES	DATESTCD EQ DISPAIT	Dispensed Amount	integer	2		Yes	DAORRES.DA.DAT	CRF	19	
5	DA	DAORRES	DATESTCD EQ RETAMT	Returned Amount	integer	2		Yes	DAORRES.DA.DAT	CRF	19	
1	EG	EGORRES	EGTESTCD EQ INTP	Interpretation	text	8		Yes	EGORRES.EG.EGT	CRF	12	
3	EG	EGORRES	EGTESTCD EQ PRMEAN	Summary (Mean) PR Duration	integer	3		Yes	EGORRES.EG.EGT	CRF	12	
7	EG	EGORRES	EGTESTCD EQ QRSDUR	Summary (Mean) QRS Duration	integer	3		Yes	EGORRES.EG.EGT	CRF	12	
15	EG	EGORRES	EGTESTCD EQ QTMEAN	Summary (Mean) QT Duration	integer	3		Yes	EGORRES.EG.EGT	CRF	12	
19	EG	EGORRES	EGTESTCD EQ VRMEAN	Summary (Mean) Ventricular Rate	integer	2		Yes	EGORRES.EG.EGT	CRF		
1	IE	IEORRES	IETESTCD EQ INCL03	Did not respond to a standard course of medication Abc	text	1		Yes	N			
1	LB	LBORRES	LBTESTCD EQ BILI	Bilirubin	float	2	1	Yes	LBORRES.LB.LBTE			
5	LB	LBORRES	LBTESTCD EQ BUN	Blood Urea Nitrogen	integer	2		Yes	LBORRES.LB.LBTE			
9	LB	LBORRES	LBTESTCD EQ GLUC	Glucose	text	8		Yes	LBORRES.LB.LBTE			

Value must be in CRF, Derived, Assigned, Protocol, eDT, Predecessor. If blank, the origin must exist on the source variable.

DefineXML - Export

Home > Design Studies > Define.xml > SDTM-IG 3.2: Training study 1

Define: Training Project 1 > Training stu...

[+ Import](#)
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[History](#)

Search

Dataset	Description	Class	Structure	Purpose	Key Variables	Yes	No	Comment
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Excel Spec
Define.xml
Define.pdf
Issue Report
Stylesheet

DefineXML Import

Home > Design Studies > Define.xml > SDTM-IG 3.2: Training study 1

Define: Training Project 1 > Training stu...

+ Import ▾

Export ▾

Copy ▾

Compare ▾

Validation Metadata

Excel Spec

Define.xml

Annotated CRF

Properties

Datasets

Variables

Value Level

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Search

Columns ▾

Dataset ▾	Description ▾	Class ▾	Structure ▾	Purpose ▾	Key Variables ▾	Repeating ▾	Reference ▾	Comment ▾
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Pre-populated Reviewer's guide

PINNACLE²¹ ENTERPRISE

Malathi Hari Messages Logout

- Home
- Configure
- Design Studies
- Define.xml
- Reviewer's Guide
- Manage Metadata
- Validate
- Report
- Administer

Home > Design > Reviewer's Guides

Reviewer's Guides

Search

Print

Study ^	Package ^	Project ^	Open Issues ^	Last Validated ^	Export Global Submission ^	Export FDA Submission ^	Export PMDA Submission ^
P21-OQ	SDTM	P21	26	2018-05-30 19:09:00	Export Global	Export FDA	Export PMDA
Training study 1	SDTM-IG 3.2	Training Project 1	168	2018-05-02 10:07:58	Export Global	Export FDA	Export PMDA
1194M12	SDTM-IG 3.1.3	Test	602	2017-09-28 10:40:27	Export Global	Export FDA	Export PMDA
Training study 1	ADaM-	4.2 Issues Summary					Export PMDA

Check ID	Diagnostic Message	Severity	Dataset	Count (Issue Rate)	Explanation
CT2002	CMDOSU value not found in 'Unit' extensible codelist	Warning	CM	60 (2.56%)	<Explanation>
CT2002	EGTESTCD value not found in 'ECG Test Code' extensible codelist	Warning	EG	1014 (15.28%)	<Explanation>
SD0087	RFSTDTC is not provided for a randomized subject	Warning	DM	3 (0.97%)	This issue is now closed. (Nils Luxhej, 10/4/2017 11:52 AM)
SD1044	No XCBLFL variable in custom Findings domain	Warning	XC	1 (100.00%)	<Explanation>
SD1076	Model permissible variable added into standard domain	Warning	AE	1 (5.26%)	This is a Trial needed variable (Malathi Hari, 10/5/2017 8:28 AM)



Microsoft Word
Document

This document is confidential

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Additional Reports

Home > Report > Training Project 1 > Training study 1

Training study 1: SDTM-IG 3.2

Filter: All Export Report

Dashboard Analysis Support Datasets Issues

Data Composition

Character Value Frequencies
 Test Variable Frequencies
 Suppqual Variable Frequencies
 Suppqual Character Values Frequencies
 Other Race Frequencies
 Unit Analysis
 Disposition Summary
 Screen Failures

Disposition Summary

Search

DSDECOD	DSCAT	DSSCAT	TREATA	TREATB	SCRNFIL	Total
ADVERSE EVENT	DISPOSITION EVENT		1			1
COMPLETED	DISPOSITION EVENT		124	122		246
CONTINUED	DISPOSITION EVENT		16	17		33
DEATH	DISPOSITION EVENT			1		1
LOST TO FOLLOW-UP	DISPOSITION EVENT		1	3		4
OTHER	DISPOSITION EVENT		1	5		6
PROTOCOL DEVIATION	DISPOSITION EVENT		2	1		3
WITHDRAWAL BY SUBJECT	DISPOSITION EVENT		12	5		17
INFORMED CONSENT OBTAINED	PROTOCOL MILESTONE		157	154	80	391
PHOTO CONSENT OBTAINED	PROTOCOL MILESTONE		149	147		296
RANDOMIZED	PROTOCOL MILESTONE		157	154		311
TREATMENT	PROTOCOL MILESTONE		157	153		310

LEFT KNEE PAIN WORSENING

Arthralgia

Screen Failures

Search

Domain Screen Failure Records

CM	3
DM	1
DS	2
IE	1
MH	4
SC	3
SE	2
SUPPCM	9
SUPPDM	2
SV	1

Quality

Events

CS

Match Details Score Number of Rows

Direct match to PT	100	2
Direct match to PT	100	1
Direct match to PT	100	1
Direct match to PT	100	1
Direct match to LLT	100	1
Direct match to LLT	100	1
Direct match to LLT	100	1
Direct match to LLT	100	1
Alternate spelling of LLT Vomited	98	2
Alternate spelling of LLT Palpitations aggravated	91	1
Alternate spelling of LLT Nausea aggravated	91	1
Could not match	0	1

Sample submission case

Background:

- Submission project scheduled for 2017
- Total 23 Trials
 - 12 major
 - 3 trials having Part 1 and Part 2
 - 4 trials having 2 interim analyses before final report
- A few older trials of deviating design
- 3 different SDTM versions
- 3 different MedDRA versions

Target and Strategy:

- **No pooling of SDTMs, SDTMs are submitted per trial**
 1. Recode and elevate trials to the same SDTM version
 2. Recode trials to the same MedDRA version
 3. Resolve Warnings and Errors
- **Submission readiness of SDTMs for all studies**
- **Redo ADaMs**
 - Re-run all ADaM programs on the reworked SDTMs
 - Resolve Warnings and Errors
- **Submission readiness of ADaMs for all studies**
- **Pooled ADaMs**

Sample submission case: Resolving Errors and warnings with Pinnacle 21 Community

Plan A:

- Run Pinnacle21 Community Edition in batch mode, producing CSVs for each trial
- Run a SAS program to collect all issues for all trials and produce an overview of issues across trials
- Estimate and fix each issue across all trials
- Fixing one issue at a time across trials vs fixing all issues in a trial

Initial estimates

- Solving all issues one-by-one for each trial - 1383 hours at 2.5 hours/issue
- Solving same issues across all trials
705 hours at 5 hours/issue
- Minimum 19 weeks net time for one person working 100% without breaks
- Translates to 1.3 years in calendar time
- 2 contractors hired

After 8 weeks, 65 unique issues outstanding (46%)

Process initiated to get Pinnacle21 Enterprise edition

Sample submission case: Pinnacle 21 Enterprise Edition

- Pinnacle21 Enterprise edition arrived
 - 3 weeks in Pinnacle21 Enterprise, most of the issues resolved
 - Small portion of issues remains to be documented in reviewers guide
 - Define.xml much faster compared to manual tools
 - SDRG is now a relatively minor task
- 470 message types for all trials, 141 unique issues across trials
- 1.371.463 messages in total
 - 1.016.466 messages fixed
 - 354.997 messages remaining
 - 99,9% of messages fixed
 - Messages with explanations => Reviewers Guide

Our Learnings!!

- Better estimate of solving an issues across (23) trials is 2.5 hours/issue
Roughly ½ hour/issue + 5 minutes per trial to copy the solution
- Pinnacle21 Enterprise edition is 2.6 times faster compared to Community edition due to added functionality

Few technical issues in early versions

- ❑ Closed issues re-open after running a validation
- ❑ Datatypes (and lengths) in Define vs. XPT files
- ❑ Codelists for continuous variables- Needed Refinement of which variables are up for codelists when creating first define from validation.
- ❑ Define.pdf has less information compared to Define.xml. Some data are missing (for example: Derivation/comment column for 'Predecessor' are missing
- ❑ Origin, Derivation /Comments are missing in Value level sheet
- ❑ Partial dates are handled in different ways in P21E and P21C

Conclusion

- ❑ Overall this is a smart tool that expedites the preparation for regulatory submission.
- ❑ Helps you to Foresee your data the same way the regulatory agencies do.
- ❑ Acts as Good collaboration and communication tool among teams, Sponsor/CROs.
- ❑ Save a lot of time in generating the needed submission documentation, such as define.xml and the reviewer guide

References

- <https://www.pinnacle21.com/>
- Pinnacle 21 Enterprise User Guide

Special Thanks to LEO Pharma team and my Larix colleagues who worked on this project

Thank you for your attention



Questions?