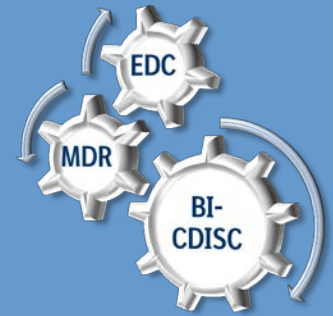


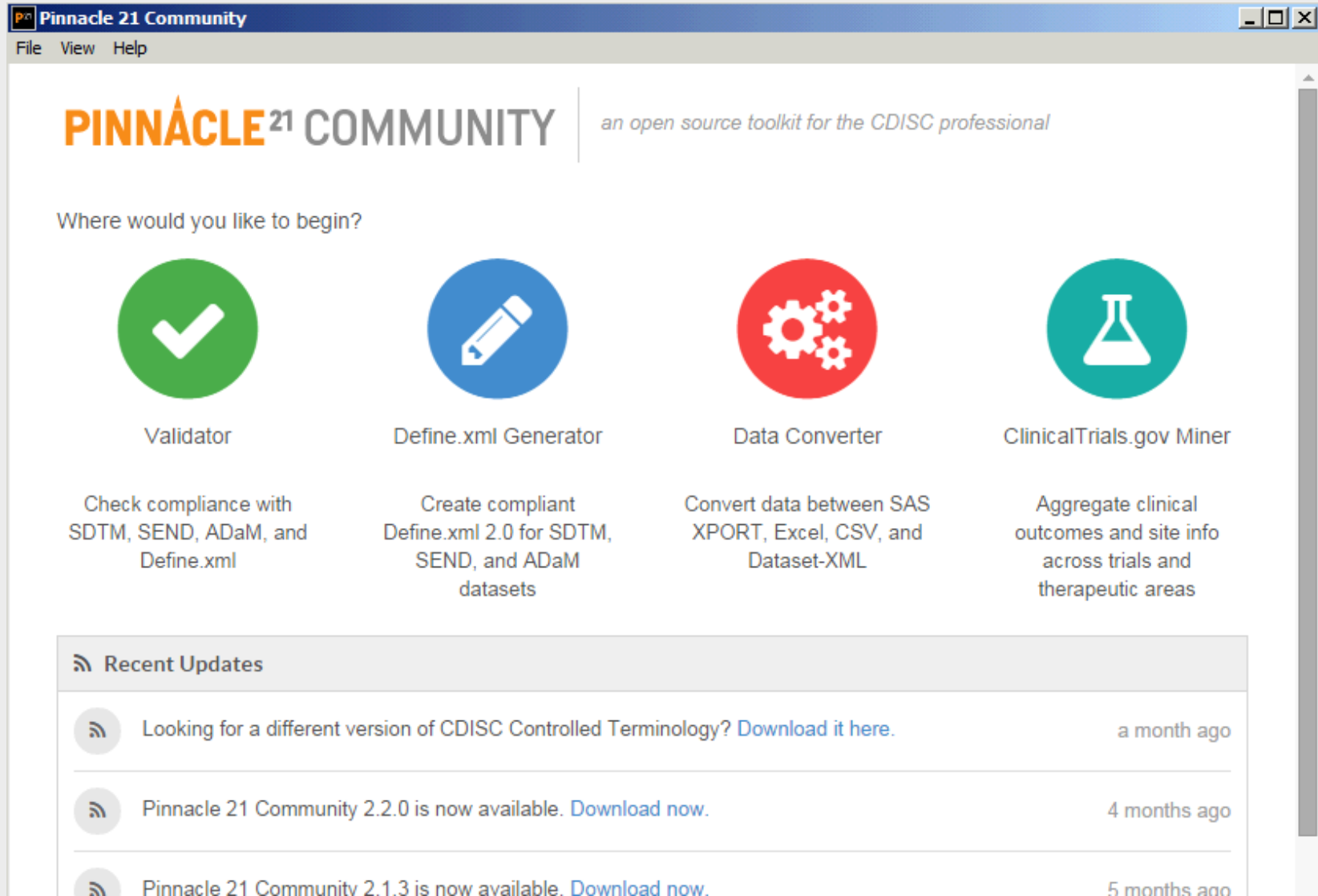
CDISC GS User Group Meeting

Pinnacle21: basic version
versus enterprise version



14 February 2017

Basic Version – Community Tool Interactive version



Pinnacle 21 Community *an open source toolkit for the CDISC professional*

Where would you like to begin?

- Validator**
Check compliance with SDTM, SEND, ADaM, and Define.xml
- Define.xml Generator**
Create compliant Define.xml 2.0 for SDTM, SEND, and ADaM datasets
- Data Converter**
Convert data between SAS XPORT, Excel, CSV, and Dataset-XML
- ClinicalTrials.gov Miner**
Aggregate clinical outcomes and site info across trials and therapeutic areas


Recent Updates

- Looking for a different version of CDISC Controlled Terminology? [Download it here.](#) a month ago
- Pinnacle 21 Community 2.2.0 is now available. [Download now.](#) 4 months ago
- Pinnacle 21 Community 2.1.3 is now available. [Download now.](#) 5 months ago

Basic Version – Community Tool SAS Macro

```
%INCLUDE ".....\gmlopenCDISC.sas";

%GMLOPENCDISC (
/* optionally the following parameters can be used */
/* otherwise always the latest version will be used*/
/*          VERSION      = 2.2|.0*/
/*          , CT          =          */
/*          , STANDARD    = SDTM    */
/*          , CONFIG      =          */
);
```

A	B	C	D	E	F	G	H	I
Pinnacle 21 Validator Report								
Configuration: D:\apps\OpenCDISC\pinnacle21-community_2_2_0\components\config\SDTM 3.2.xml								
Define.xml: Not provided								
Generated: 2017-02-01T01:44:35								
CDISC CT Version: 2016-06-24								
Software Version: 2.1.2								
Processed Sources								
Domain	Label	Class	Source	Records	Rejects	Errors	Warnings	Notices
▶ ▶ Dataset Summary ◀ Issue Summary ◀ Details ◀ Rules ◀ 								

Enterprise – Main Features 1

DATA VALIDATION FEATURES	COMMUNITY	ENTERPRISE
Validate SDTM, SEND, ADaM, and Define.xml	✓	✓
Metadata driven and configurable	✓	✓
Data composition and quality reports		✓
FDA Data Fitness assessment scorecards		✓
Manage issues throughout the study lifecycle		✓
Communicate and collaborate with partners		✓
Monitor data quality improvement over time		✓
Track changes across validations		✓
Customize specs for SDTM+ or sponsor formats		✓
Design rules for projects, studies, and partners		✓
DEFINE.XML FEATURES		
Create Define.xml 2.0 for SDTM, SEND and ADaM	✓	✓
Convert Define.xml 1.0 files into Define.xml 2.0	✓	✓
Extract metadata from SAS datasets	✓	✓
Extract origin page numbers from annotated CRFs		✓
Merge metadata from external specifications		✓
Generate Define.pdf		✓
Validate Define.xml content in real-time		✓
Compare content with standards and other studies		✓
Track changes between versions		✓
OTHER FEATURES		
Deployment Options	Desktop	Web Hosted
Automated software and rule updates	✓	✓
Central configuration and management		✓
Sandbox environment for training and testing		✓
Increased scalability		✓
Software license	Open Source	Subscription

- **Data Validation** per FDA and PMDA requirements incl.
 - **Issue Tracking and Management:**
Add comments, keep through the validation runs, see improvement
 - Change History
 - **Scorecards:**
Data **Quality** and **Fitness** towards FDA/PMDA **standard analysis** methods
 - Support of SDTM, SEND, ADaM, Define.xml and company standards
- **Define.xml** creation
- **Reviewer's Guide** creation: based on Phuse template

ALL701: SDTM

[Export Repo](#)

Dashboard Analysis Support Datasets Issues History More Reports Comparison ✕

Change Type ▾

Print Copy Download

Dataset	Rule	Message	Severity	Rate	Δ	Risk	Status
New (11 Issues)							
DV	SD1076	Model permissible variable added into standard domain	Warning	2.7% ⓘ	-		Open
PC	SD1117	Duplicate records	Warning	49.8% ⓘ	-		Open
PC	SD0005	Duplicate value for PCSEQ variable	Error	49.8% ⓘ	-		Open
PC	SD1095	Invalid dataset name for split domain	Error	100% ⓘ	-		Open
PC	SD2239	Inconsistent value for PCTPT	Error	1% ⓘ	-		Open
SUPPAE	SD2006	Unexpected MedDRA coding in the SUPPQUAL domain	Error	53.3% ⓘ	-		Open
SUPPMH	SD2006	Unexpected MedDRA coding in the SUPPQUAL domain	Error	57% ⓘ	-		Open
SUPPPC	SD0086	SUPPQUAL duplicate records	Error	47.4% ⓘ	-		Open
XD	CT2002	DOMAIN value not found in 'SDTM Domain Abbreviation' extensible codelist	Warning	100% ⓘ	-		Open
XD	SD1117	Duplicate records	Warning	18.5% ⓘ	-		Open
XD	SD1124	Missing value for XDREASND, when XDSTAT is 'NOT DONE'	Warning	54.7% ⓘ	-		Open
Resolved (101 Issues)							
AE	SD1141	No Treatment Emergent info for Adverse Event	Warning	-	-		Resolved
AE	SD1201	Duplicate USUBJID/--DECOD/--STDTC record	Warning	-	-		Resolved
AE	SD0002	NULL value in AEDECOD variable marked as Required	Error	-	-		Resolved
AE	SD0080	AE start date is after the latest Disposition date	Error	-	-		Resolved

MP0001: SDTM

[Export Report](#)

Dashboard Analysis Support Datasets Issues History More Reports

Data Fitness Scorecard



240 Issues
7.7% Issue Rate



Key Metrics

138 Subjects

28 Total Datasets

164493 Total Records

1 Custom Datasets

5 Support Datasets

Standards & Dictionaries

Standard Used
SDTM-IG 3.1.2

Dictionaries Used
MedDRA 17.1, SDTM-CT 2015-06-26, QRS-CT 2015-06-28

Important Links

[Trial Summary](#)
[Define.xml](#)
[Reviewers' Guide](#)
[Annotated CRF](#)

Severe Issues

Severity	Dataset	Issue
Reject	Define.xml	Missing required 'FileOID' value for 'ODM'.
Reject	Define.xml	Missing required 'TranslatedText' value.
Reject	DM	SDTM Required variable SEX not found
Reject	DM	NULL value in SITEID variable marked as Required
Error	Define.xml	Invalid Mandatory value.

Impacted Analysis

Impact	Analysis
Condition	JReview AE Incident Percentages Table with Verbatim Term
Condition	JReview AE Incident Percentages Table with Verbatim Term with SOC Selection
Condition	JReview AE Incident Rates by Arm
Condition	JReview AE SOC Incident Percentages by Arm
Condition	JReview Baseline vs Max Scatter Plots

Validation Spec	Score	Pass/Fail	Domains	Issues	Failures	Errors	Warnings
General Data Quality (3 Profiles)							
CDER Common Data Standards Issues	0	Fail	41	570	570	236	211
SDTM v3.1.2 General Data Quality	92	Pass	41	81	345,552	3,258	342,294
SDTM v3.1.3 General Data Quality	95	Pass	41	47	345,549	3,258	342,291
Laboratory Findings Analysis (6 Profiles)							
JReview Labs Baseline vs Max/Min Scatter Plots	0	Fail	3	2	784	392	392
JReview Hy's Law Patient Listing	0	Fail	3	2	784	392	392
JReview Hy's Law Plots	0	Fail	3	2	784	392	392
JReview Liver Function Baseline Box Whiskers	0	Fail	3	2	784	392	392
eDISH	96	Pass	6	7	17,993	0	17,601
Liver Function Analysis Panel	97	Pass	3	7	17,283	29	17,254
Overall Survival Analysis (1 Profiles)							
Overall Survival Analysis Panel	97	Pass	7	3	349	0	349
Standards Compliance (3 Profiles)							
SDTM v3.1.3 Compliance	77	Pass	41	185	175,996	408	175,444
SDTM Controlled Terminology	88	Pass	41	30	208,466	19,166	0
SDTM v3.1.2 Compliance	90	Pass	41	165	66,485	411	65,939
Subject Disposition Analysis (1 Profiles)							
Disposition Analysis Panel	59	Pass	4	2	629	392	237

Enterprise version: helps you prepare for a submission, not just looking through a list of issues.

Scorecard used to determine if your Data is 'fit for use',
eg. will your data support the FDA efficacy and safety review: SDTM compliance (Community version) is just one of the levers of an overall data scorecard.

Data fitness is an important FDA initiative.

Enterprise is an holistic approach to data quality and assures your data is fit for submission and helps to ensure rapid FDA review time.

- Pinnacle 21 provides the system as SaaS hosted in the US
- For a productive usage following options could be used:
 - On premise installation (expensive)
 - SaaS solution hosted in European/German data centers