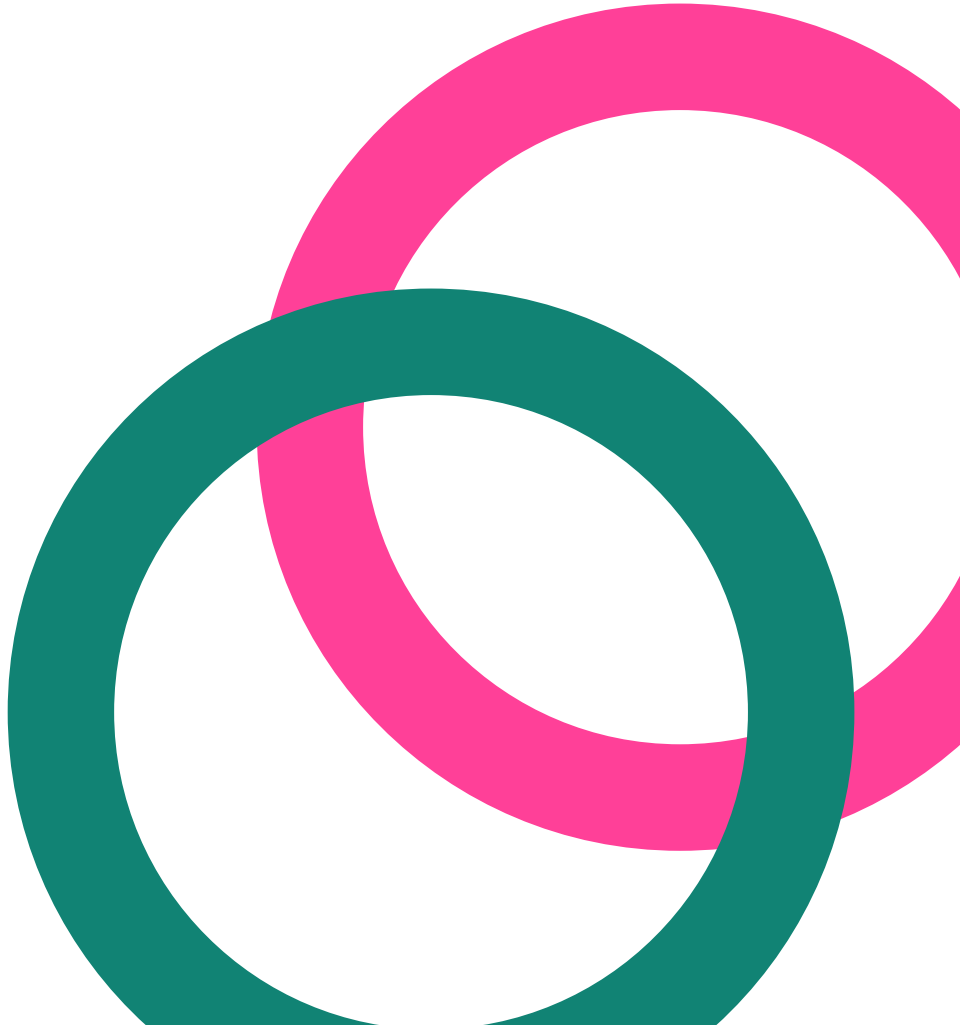




Pinnacle Community

14 – March 2024

Andrea Weber



TOPICS

- P21C Functionality
- Strength and Weak
- Q&A / Discussion



P21C Functionality

P21C Functionality

The screenshot displays the Pinnacle 21 Community web application. The interface includes a top navigation bar with a search field and a main menu on the left with options like Home, Validator, Define.xml, Converter, and ClinicalTrials.gov. The main content area features the Pinnacle 21 Community logo and tagline, followed by a 'Where would you like to begin?' section with four tool cards: Validator, Define.xml Generator, Data Converter, and ClinicalTrials.gov Miner. Below this is a 'Recent Updates' section listing five news items with dates ranging from 'a year ago' to '2 years ago'.

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

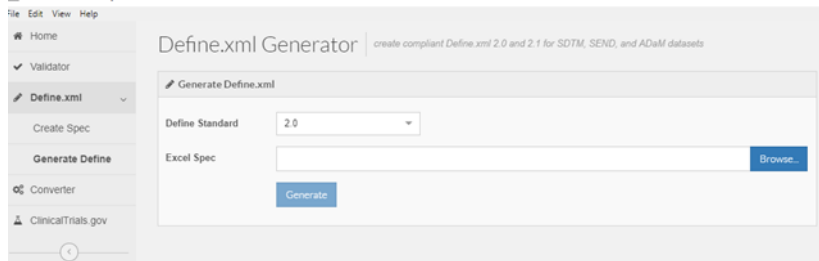
Where would you like to begin?

- Validator**
Check compliance with SDTM, SEND, ADaM, and Define.xml
- Define.xml Generator**
Create compliant Define.xml 2.0 and 2.1 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

- [PMDA engine 1511.6 to be decommissioned on March 27th, 2023](#) (a year ago)
- [Register for Webinar: PMDA's New Validation Rules 4.0 Explained](#) (a year ago)
- [Register for Webinar: Quality SDTM - the Bridge between Biostats and Medical Writing](#) (a year ago)
- [Exclusive Webinar: Validation Rule Updates in FDA Validator Version 1.6](#) (a year ago)
- [Register for Webinar: Explore the new P21 Community 4.0](#) (2 years ago)

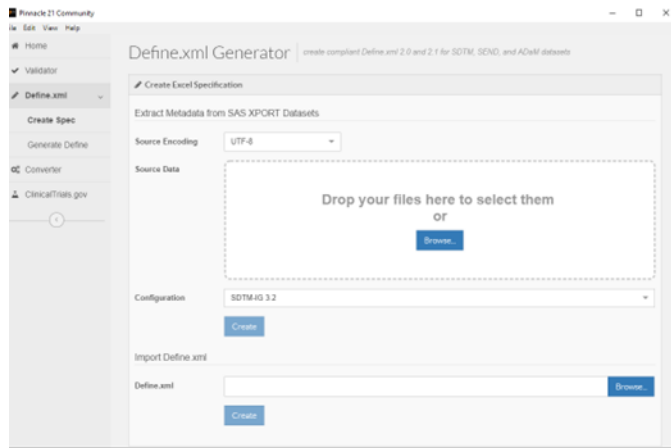
Generate Define



- needs excel sheets with Metadata
- generates define and stores it together with style sheets
- no need to create define programs themselves
- quick
- no message if excel sheet is not suitable, but creates an empty define

P21C Functionality

Creating Specification in excel format via xpt files or Define.xml file



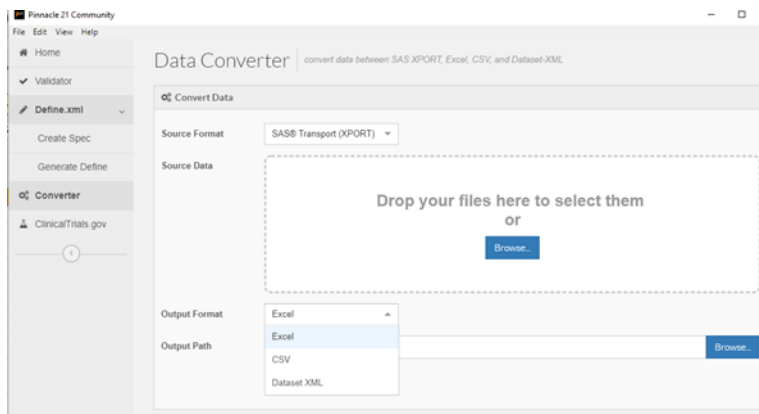
File explorer view showing a directory of XML files:

Name	Status	Date modified	Type	Size
ADaM-IG 1.0 (FDA).xml	🟢	16.05.2023 21:39	XML Document	272 KB
ADaM-IG 1.1 (FDA).xml	🟢	16.05.2023 21:39	XML Document	639 KB
ADaM-IG 1.1 (NMPA).xml	🟢	16.05.2023 21:39	XML Document	624 KB
Define.xml (FDA).xml	🟢	16.05.2023 21:39	XML Document	50 KB
Define.xml (NMPA).xml	🟢	16.05.2023 21:39	XML Document	47 KB
SDTM-IG 3.1.2 (FDA).xml	🟢	16.05.2023 21:39	XML Document	1.160 KB
SDTM-IG 3.1.3 (FDA).xml	🟢	16.05.2023 21:39	XML Document	1.478 KB
SDTM-IG 3.1.3 (NMPA).xml	🟢	16.05.2023 21:39	XML Document	1.366 KB
SDTM-IG 3.2 (FDA).xml	🟢	16.05.2023 21:39	XML Document	2.351 KB
SDTM-IG 3.2 (NMPA).xml	🟢	16.05.2023 21:39	XML Document	2.219 KB
SDTM-IG 3.3 (FDA).xml	🟢	16.05.2023 21:39	XML Document	3.164 KB
SEND-IG 3.0 (FDA).xml	🟢	16.05.2023 21:39	XML Document	1.106 KB
SEND-IG 3.1 (FDA).xml	🟢	16.05.2023 21:39	XML Document	1.407 KB
SEND-IG 3.1.1 (FDA).xml	🟢	16.05.2023 21:39	XML Document	1.409 KB
SEND-IG-AR 1.0 (FDA).xml	🟢	16.05.2023 21:39	XML Document	1.887 KB
SEND-IG-DART 1.1 (FDA).xml	🟢	16.05.2023 21:39	XML Document	1.744 KB

- Possibility to create a specification template via a xpt file or an existing define from another study to have the required specification format.
- Possibility to use configurations of P21C of the relevant data standard (e.g., SDFM 3.2 (FDA)).

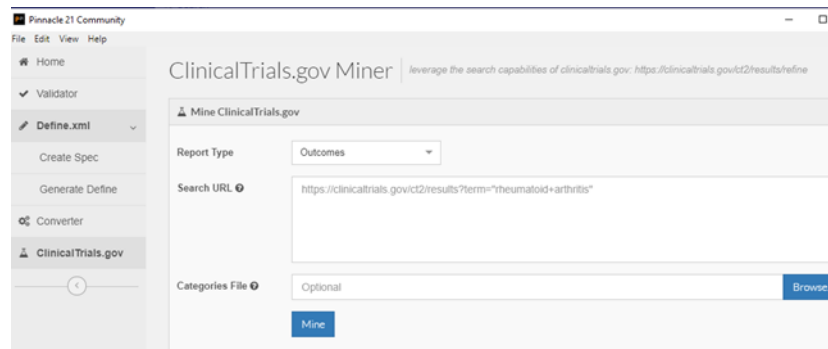
P21C Functionality

Data converter



- Possibility to convert xpt to excel, csv or xml file

ClinicalTrials.gov Miner



- aggregates clinical outcome measures/endpoints across trials and therapeutic areas

P21C Functionality

Validator

The screenshot shows the 'Validator' web application interface. The main heading is 'Validator' with a subtitle 'check compliance with SDTM, SEND, ADaM, and Define.xml'. Below this is a 'Validate Data' section with several dropdown menus and a 'Validate' button. The 'Engine' dropdown is set to 'FDA (2204.1)', the 'Standard' dropdown is set to 'Define-XML', and the 'Data Standard' dropdown is set to 'SDTM-IG 3.2 (FDA)'. The 'Define.xml' field contains the text 'Required' and has a 'Browse...' button next to it. The 'SDTM CT' dropdown is set to '2017-12-22'. A 'Validate' button is located at the bottom of the form.

- Validation of define.xml and /or data (xpt files) for the following standards
- SDTM, ADaM, SEND
- Results in excel format

P21C Functionality

Validation Summary

Pinnacle 21 Validator Report	
1	
2	
3	Configuration: C:\Users\leberandrea\OneDrive - ICON CLINICAL RESEARCH LTD - IRELAND\Documents\Pinnacle 21 Community\config\2204.1\SDTMK
4	Define.xml: C:\Users\leberandrea\OneDrive - ICON CLINICAL RESEARCH LTD - IRELAND\Documents\Pinnacle 21 Community\defines\define.xml
5	Generated: 2024-03-04T13:33:50+01:00
6	CDISC SDTM CT Version: 2017-12-22
7	MedDRA: 26.1
8	SNOMED: 2015-09-01
9	UMS: 2021-11-19
10	MED-RT: 2021-03-01
11	WHODD: GLOBALB3Sep23
12	Validation Engine Name: FDA 2204.1
13	Software Version: 4.0.2
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- Summary of Configuration: SDTM/or ADAM-IG version (FDA or PMDA), MedDRA, WHODD, SNOMED, MED-RT (Medication Reference Terminology), validation engine and software version

Dataset Summary

Pinnacle 21 Validator Report					
Processed Sources					
Domain	Label	Class	Source	Records	Rejects
GLOBAL	Global Metadata	--	--	0	0
AE	Adverse Events	EVENTS	ae.xpt	865	0
CE	Clinical Events	EVENTS	ce.xpt	224	0
CM	Concomitant Medications	INTERVENTIONS	cm.xpt	11986	0
DA	Drug Accountability	FINDINGS	da.xpt	385	0
DM	Demographics	SPECIAL PURPOSE	dm.xpt	339	0
SV	Subject Visits	SPECIAL PURPOSE	sv.xpt	2763	0
TA	Trial Arms	TRIAL DESIGN	ta.xpt	12	0
TE	Trial Elements	TRIAL DESIGN	te.xpt	6	0
TI	Trial Inclusion/Exclusion Criteria	TRIAL DESIGN	ti.xpt	54	0
TS	Trial Summary	TRIAL DESIGN	ts.xpt	76	0
TV	Trial Visits	TRIAL DESIGN	tv.xpt	12	0
VS	Vital Signs	FINDINGS	vs.xpt	12916	0
Total				322268	0
Unprocessed Sources					
Domain	Label	Class	Source	Records	Rejects
Total				0	0
Grand Total				322268	0

- List of datasets with class, number of records and number of rejections
- Overall summary of records and rejections

P21C Functionality

Issues Summary

Pinnacle 21 Validator Report			
Issue Summary			
Source	Pinnacle 21 ID	Message	Severity
AE	SD0021	Missing End Time-Point value	2
	SD1143	No Details info for AESMIE Adverse Event in SUPPAE domain	31
	SD1202	AESTDTC date is after RFPENDTC	4
	SD1204	AEENDTC date is after RFPENDTC	32
	SD1333	AEOUT = RECOVERED/RESOLVED, but an end date or collected duration is not provided	1
	SD1339	Missing EPOCH value, when a start or observation date is provided	5
CM	CT2002	CMDOSFRQ value not found in 'Frequency' extensible codelist	2003
	CT2002	CMDOSU value not found in 'Unit' extensible codelist	1500
	CT2002	CMROUTE value not found in 'Route of Administration Response' extensible codelist	1334
	SD0002	NULL value in CMTRT variable marked as Required	1
	SD0021	Missing End Time-Point value	16
	SD0022	Missing Start Time-Point value	446
	SD0031	Missing values for CMSTDTC, CMSTRF and CMSTRPT, when CMENDTC, CMENRF or CMENRPT is provided	438
	SD0035	Missing value for CMDOSU, when CMDOSE, CMDOSTX or CMDOSTOT is provided	8
	SD1202	CMSTDTC date is after RFPENDTC	10
	SD1204	CMENDTC date is after RFPENDTC	21
	SD1339	Missing EPOCH value, when a start or observation date is provided	485
DM	CT2002	RACE value not found in 'Race' extensible codelist	2
	SD0002	NULL value in ACTARM variable marked as Required	117
	SD0002	NULL value in ACTARMCD variable marked as Required	117
	SD0002	NULL value in ARM variable marked as Required	117
	SD0002	NULL value in ARMCD variable marked as Required	117
DS	CT2005	DSDECOD value not found in 'Completion/Reason for Non-Completion' extensible codelist when DSCAT == 'DISPOSITION EVENT'	2
	SD0022	Missing Start Time-Point value	10
	SD1118	Neither DSSTDTC, DSDTC nor DSSTDY are populated	10
	SD1274	DSTERM equals 'OTHER'	1

- List of issues per domain inclusive related rule and number of occurrences

Details

Domain	Record	Count	Variables	Values	Pinnacle 21 ID	Message	Category	Severity
AE	14		AENRTP	null, null	SD0021	Missing End Time-Point value	Consistency	
AE	17		AENRTP	null, null	SD0021	Missing End Time-Point value	Consistency	
AE	4		USUBJID, AESEQ, AESMIE	XXX-11002, 1, Y	SD1143	No Details info for AESMIE Adverse Event in SUPPAE domain	Presence	
AE	7		USUBJID, AESEQ, AESMIE	XXX-11005, 1, Y	SD1143	No Details info for AESMIE Adverse Event in SUPPAE domain	Presence	
AE	126		AESTDTC, SUB_RFPENDTC	2019-10-24T13:07, 2019-10-24T12:55	SD1202	AESTDTC date is after RFPENDTC	Limit	
AE	218		AESTDTC, SUB_RFPENDTC	2019-01-03T12:48, 2019-01-03T11:28	SD1202	AESTDTC date is after RFPENDTC	Limit	
CM		2003	CMDOSFRQ	OTHER	CT2002	CMDOSFRQ value not found in 'Frequency' extensible codelist	Terminology	
CM		1500	CMDOSU	OTHER	CT2002	CMDOSU value not found in 'Unit' extensible codelist	Terminology	
CM		1334	CMROUTE	OTHER	CT2002	Administration Response' extensible codelist	Terminology	
CM	283		CMENRTP	null, null	SD0021	Missing End Time-Point value	Consistency	
CM	4146		CMSTDTC	null	SD0022	Missing Start Time-Point value	Consistency	
CM	2652		CMSTDTC, CMENDTC, CMENRTP	null, 2018-10-09, null	SD0031	Missing values for CMSTDTC, CMSTRF and CMSTRPT, when CMENDTC, CMENRF or CMENRPT is provided	Consistency	
DM	121		ARMCD	null	SD0002	NULL value in ARMCD variable marked as Required	Presence	
DM	122		ACTARM	null	SD0002	NULL value in ACTARM variable marked as Required	Presence	
DM	122		ACTARMCD	null	SD0002	NULL value in ACTARMCD variable marked as Required	Presence	
DM	122		ARM	null	SD0002	NULL value in ARM variable marked as Required	Presence	
DM	122		ARMCD	null	SD0002	NULL value in ARMCD variable marked as Required	Presence	
DM	123		ACTARM	null	SD0002	NULL value in ACTARM variable marked as Required	Presence	
						NULL value in ACTARMCD variable		

- Details of issues

P21C Functionality

Validation Rules

	A	B	C	D	E	F
1	Pinnacle 21 ID	Publisher ID	Message	Description	Category	Severity
2	CT2001	CG0020, CG0085, CG0131,	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.	Terminology	
3	CT2002	FDAB917, CG0021	Variable value not found in extensible codelist	Variable should be populated with terms from its CDISC controlled terminology codelist. New terms can be added as long as they are not duplicates, synonyms or subsets of existing standard terms with the same Codelist Code value in CDISC control terminology. There is one-to-one relationship between paired variable values defined in CDISC control terminology by Codelist Code value.	Terminology	
4	CT2003	FDAB009, CG0021	Coded and Decoded values do not have the same Code in CDISC CT	Variable value not found in non-extensible codelist when value-level condition occurs	Terminology	
5	CT2004	CG0021	Variable value not found in extensible codelist when value-level condition occurs	Variable value not found in extensible codelist when value-level condition occurs	Terminology	
6	CT2005	CG0021	Variable value not found in extensible codelist when value-level condition occurs	Variable value not found in extensible codelist when value-level condition occurs	Terminology	
7	CT2006	FDAB009, CG0021	Coded and Decoded values do not have the same Code in CDISC CT when value-level condition occurs	Variable value not found in extensible codelist when value-level condition occurs	Terminology	
8	DD0101	eCTD 1736	Missing define.xml file	submissions must include a define.xml file for each study in Module 4 (nonclinical) and Module 5 (clinical). Note: Refer to the data standards catalog by the relevant Regulatory Agency for acceptance of standards and their versions.	Presence	Reject
9	SD0001	CG0408	No records in data source	Domain table should have at least one record.	Presence	
10	SD0002	CG0014, CG0208	NULL value in variable marked as Required	Required variables (where Core attribute is Req) cannot be NULL for any records.	Presence	
11	SD0003	CG0238	Invalid ISO 8601 value for variable	international standard.	Format	
12	SD0004	CG0413	Inconsistent value for DOMAIN	name of the dataset.	Consistency	
13	SD0005	CG0028	Duplicate value for --SEQ variable	The value of Sequence Number (--SEQ) variable must be unique for each record within a domain and within each Unique Subject Identifier (USUBJID) or Pool Identifier (POOLID) variables value when they are present in the domain. Exclusions are DO, DT, DU and DX domains in EG, LB, MB, MS, PC and VS domains, except for subjects who failed screening (ARMCD = 'SCREENFAIL') or were not fully assigned to an Arm (ARMCD = 'NOTASSGN') or were not treated (ACTARMCD = 'NOTTRT').	Consistency	
14	SD0006	TCG 4.1.4.1	No baseline flag record in Domain for subject	same Short Name of Measurement, Test or Examination (--TESTCD), Object of the Observation (--OB), Measurement, Test, or Examination Detail (--STDTL), Category (--CAT), Subcategory (--SCAT), Specimen Type (--SPEC) and Method of Test or Examination (--METHOD). Value for the Dictionary-Derived Term (--DECOD) variable must be	Presence	
15	SD0007	FDAB030	Inconsistent value for Standard Units	Value for the Dictionary-Derived Term (--DECOD) variable must be	Consistency	



Strength and Weak

Strength and Weak

Strength

- Desktop version, so no upload of data to clouds → data protection
- Clear arrangement of information
- Easy to handle
- No specific training required to get access
- Can be run isolated from previous runs so e.g., run on mock data without data being transferred to the next run.
- Can be run separately by unblinded teams

Strength and Weak

Weak

- Missing comparison between previous P21C run to
 - check for new issues
 - Check for change in number of issues
 - Copying over comments for persistent issues
- Output can not directly be copied to the Reviewer's guide without modification

At ICON

- Separate VBA tool for comparison
- Output still needs to be amended to copy to Reviewer's Guide



Q&A / Discussion

ICON



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