



Global Solutions from the World's Largest Data-Focused CRO

Know Your Data About Data

www.quanticate.com

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Agenda

- Metadata?
- Why Metadata?
- Work Flow using Metadata
- Types of Metadata
- Pinnacle 21

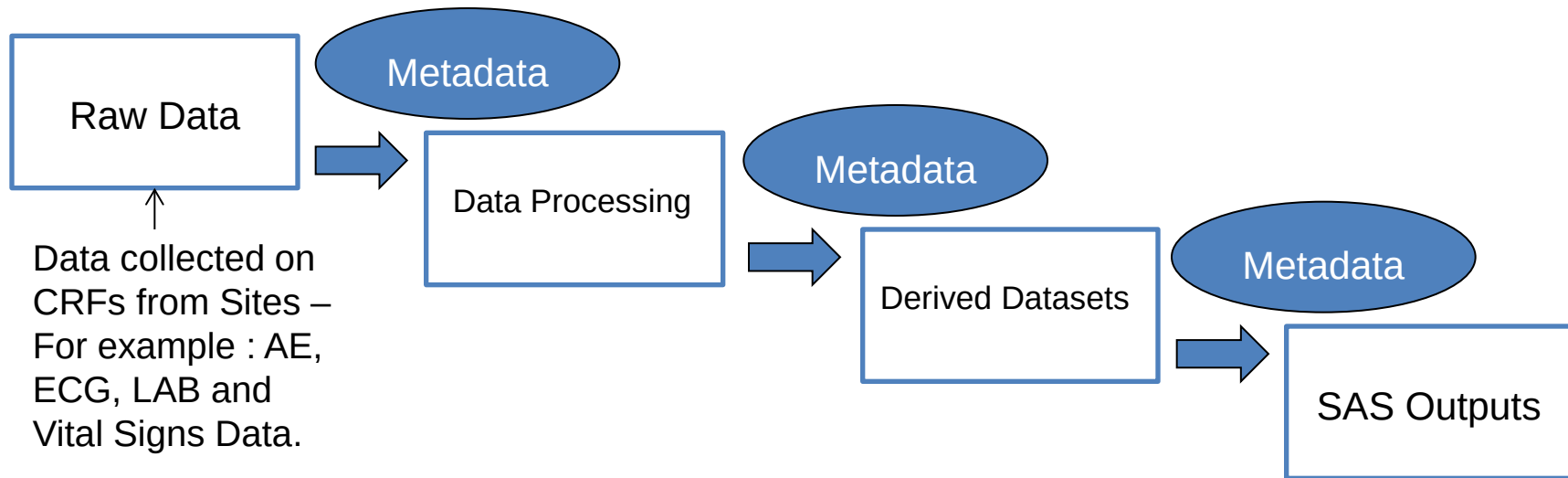
Metadata?

- It is 'Data about Data', explains the contents of data
- Gives descriptive information about an object or resource, whether it is physical or electronic
- Provides additional information to regulatory authorities about the production of datasets in the form of define.xml

Why Metadata?

- Efficiently manage large quantity of information
- Effective and efficient metadata strategy to prevent suffering from the chaotic situation associated with proliferation of mass amounts of information
- Vastly increase work efficiency and reduce the mistakes in drug development
- CDER Technical Conformance Guide says that *“The data definition file describes the metadata of the submitted electronic datasets, and is considered arguably the most important part of the electronic dataset submission for regulatory review ”*

Work Flow Using Metadata



Types of Metadata

- SDTM Metadata
 - *Dataset Definition Metadata*
 - *Variable Level Metadata*
 - *Value Level Metadata*
- ADaM Metadata
 - *Dataset Definition Metadata*
 - *Variable Level Metadata*
 - *Analysis Parameter Level Metadata*
 - *Analysis Results / Display Level Metadata*

Dataset Definition Metadata

- Dataset Name
- Dataset Description/Label
- Dataset Class
- Dataset Structure
- Dataset Purpose
- Keys

Dataset	Description	Class	Structure	Purpose	Keys*	Location
DM	Demographics	Special Purpose Domains	One record per subject	Tabulation	STUDYID, USUBJID	dm.xpt

Variable Level Metadata

- As per SDTM, there are 7 attributes defined they are:
 - Variable name
 - Variable label
 - Variable source / origin
 - Variable type
 - Controlled terms
 - Role
 - Derivation/comments

Variable Name	Variable Label	Type	Controlled Terms, Codelist or Format	Role
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Variable Level Metadata Cont...

- In addition to these metadata attributes, the CDISC domain models include three other shaded columns that are not sent to the FDA
- These columns assist sponsors in preparing their datasets:
 - CDISC Notes
 - Core
 - References

Variable Name	Variable Label	Type	Controlled Terms, Codelist or Format	Role	CDISC Notes	Core	References
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Analysis Parameter Level Metadata

- Parameter Identifier is required in variable-level metadata for Basic Data Structure (BDS) analysis dataset

Analysis Variable Metadata Field	Description
PARAMETER IDENTIFIER	Contains either 1) the value of PARAMCD that identifies the analysis parameter to which the variable metadata applies; or 2) controlled terminology to indicate groupings of analysis parameters: *ALL* - Used when the variable metadata applies to all analysis parameters in the dataset. *DEFAULT* - Used when the variable metadata applies to all analysis parameters in the dataset except for those specifically listed within the metadata.

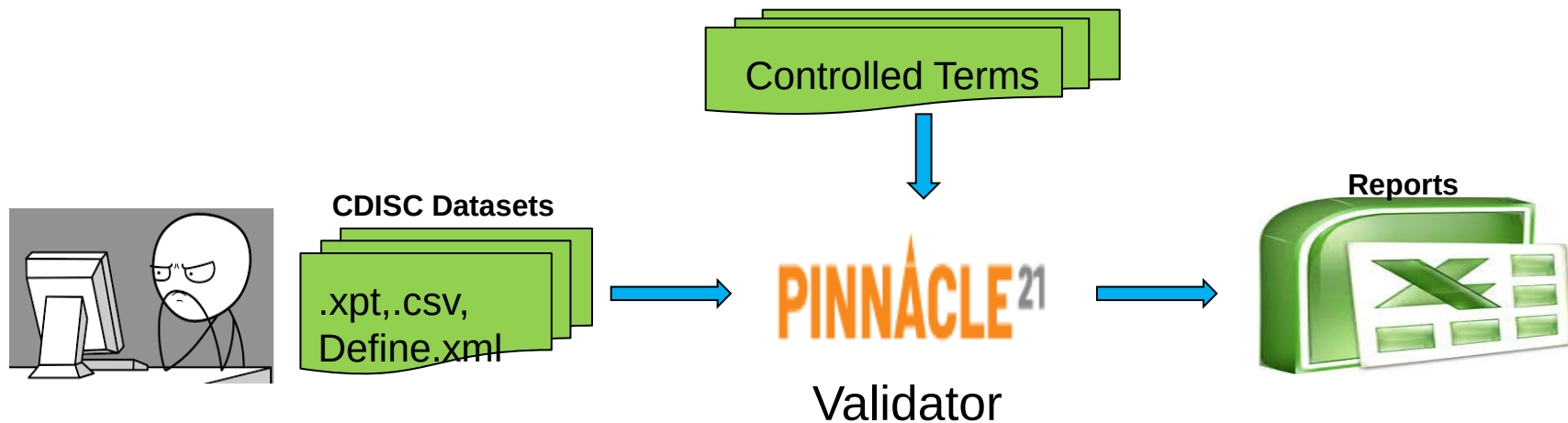
Analysis Results / Display Level Metadata

- Display Identifier
- Display Name
- Result Identifier
- Param
- Paramcd
- Analysis Variable
- Reason
- Dataset
- Selection Criteria
- Documentation
- Programming Statement

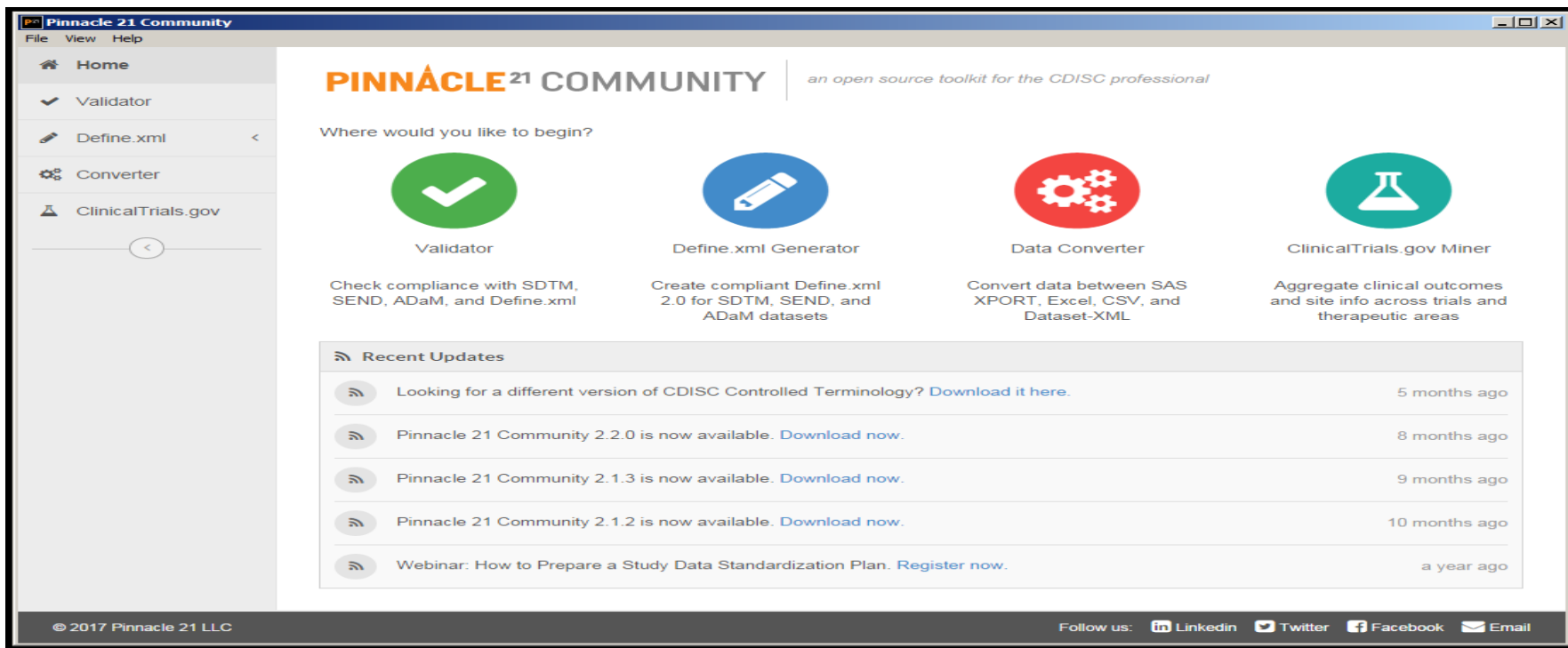
Pinnacle 21

- Pinnacle 21 Community is a free and easy to use toolset, which is useful for clinical programmers who work with CDISC standards
- Pinnacle 21 has been used to validate Metadata and Datasets (SDTM and ADaM)

Pinnacle 21 Validator Architecture



Pinnacle 21



The screenshot shows the Pinnacle 21 Community web application. The interface includes a sidebar with navigation links: Home, Validator, Define.xml, Converter, and ClinicalTrials.gov. The main content area features the title "PINNACLE²¹ COMMUNITY" and the tagline "an open source toolkit for the CDISC professional". Below this, a section titled "Where would you like to begin?" offers four options, each with a colored circular icon and a brief description:

- Validator** (Green checkmark icon): Check compliance with SDTM, SEND, ADaM, and Define.xml
- Define.xml Generator** (Blue pencil icon): Create compliant Define.xml 2.0 for SDTM, SEND, and ADaM datasets
- Data Converter** (Red gears icon): Convert data between SAS XPORT, Excel, CSV, and Dataset-XML
- ClinicalTrials.gov Miner** (Teal flask icon): Aggregate clinical outcomes and site info across trials and therapeutic areas

Below these options is a "Recent Updates" section with a list of announcements, each preceded by a RSS icon and followed by a timestamp:

- Looking for a different version of CDISC Controlled Terminology? [Download it here.](#) 5 months ago
- Pinnacle 21 Community 2.2.0 is now available. [Download now.](#) 8 months ago
- Pinnacle 21 Community 2.1.3 is now available. [Download now.](#) 9 months ago
- Pinnacle 21 Community 2.1.2 is now available. [Download now.](#) 10 months ago
- Webinar: How to Prepare a Study Data Standardization Plan. [Register now.](#) a year ago

The footer of the application displays "© 2017 Pinnacle 21 LLC" on the left and social media links for LinkedIn, Twitter, Facebook, and Email on the right.

Validator

Pinnacle 21 Community File View Help

Home
✓ Validator
Define.xml <
Converter
ClinicalTrials.gov

Validator

check compliance with SDTM, SEND, ADaM, and Define.xml

✓ Validate Data

Standard Define.xml Configuration Define (PMDA)
Report Format Excel ⚙

Define.xml Browse...

CT Standard SDTM CDISC CT 2016-06-24

Validate

OpenCDISC Validator Report

Configuration: <Path>Define.xml 1.0.xml				
Define.xml: <Path>Define.xml				
Generated: 2017-03-24T09:39:17				
Engine Version: 2.0.1				
Issue Summary				
Source	OpenCDISC ID	Publisher ID	Message	Severity
DEFINE				Found
	OD0079		Duplicate 'CodedValue'	Error 1

	A	B	C	D	E	F	G	H
1	xpath	Variables	Values	OpenCDISC ID	Publisher ID	Message	Category	Severity
2	//ItemDef[@OID=ValueList.LBTESTCD.WBC]	@OID	ValueList.LBTESTCD.WBC	OD0031		Duplicate 'ItemDef' element	Consistency	Error
3	//ItemDef[@OID=ValueList.LBTESTCD.PROT]	@OID	ValueList.LBTESTCD.PROT	OD0031		Duplicate 'ItemDef' element	Consistency	Error
4	//ItemDef[@OID=ValueList.LBTESTCD.GLUC]	@OID	ValueList.LBTESTCD.GLUC	OD0031		Duplicate 'ItemDef' element	Consistency	Error
5	//ItemDef[@OID=ValueList.LBTESTCD.COMM]	@OID	ValueList.LBTESTCD.COMM	OD0031		Duplicate 'ItemDef' element	Consistency	Error
6	//def.ValueListDef[@OID=ValueList.LBTESTCD]/ItemRef[@ItemOID=ValueList.LBTESTCD.WBC]	@ItemOID	ValueList.LBTESTCD.WBC	OD0041		Duplicate 'ItemRef' element	Consistency	Error
7	//def.ValueListDef[@OID=ValueList.LBTESTCD]/ItemRef[@ItemOID=ValueList.LBTESTCD.PROT]	@ItemOID	ValueList.LBTESTCD.PROT	OD0041		Duplicate 'ItemRef' element	Consistency	Error
8	//def.ValueListDef[@OID=ValueList.LBTESTCD]/ItemRef[@ItemOID=ValueList.LBTESTCD.GLUC]	@ItemOID	ValueList.LBTESTCD.GLUC	OD0041		Duplicate 'ItemRef' element	Consistency	Error
9	//def.ValueListDef[@OID=ValueList.LBTESTCD]/ItemRef[@ItemOID=ValueList.LBTESTCD.COMM]	@ItemOID	ValueList.LBTESTCD.COMM	OD0041		Duplicate 'ItemRef' element	Consistency	Error
10	//CodeList[@OID=UNIT]/CodeListItem[93]	@CodedValue	MILL/MCL	OD0079		Duplicate 'CodedValue'	Consistency	Error

Contact Information



Pradeep Kumar
Programming Technical Expert



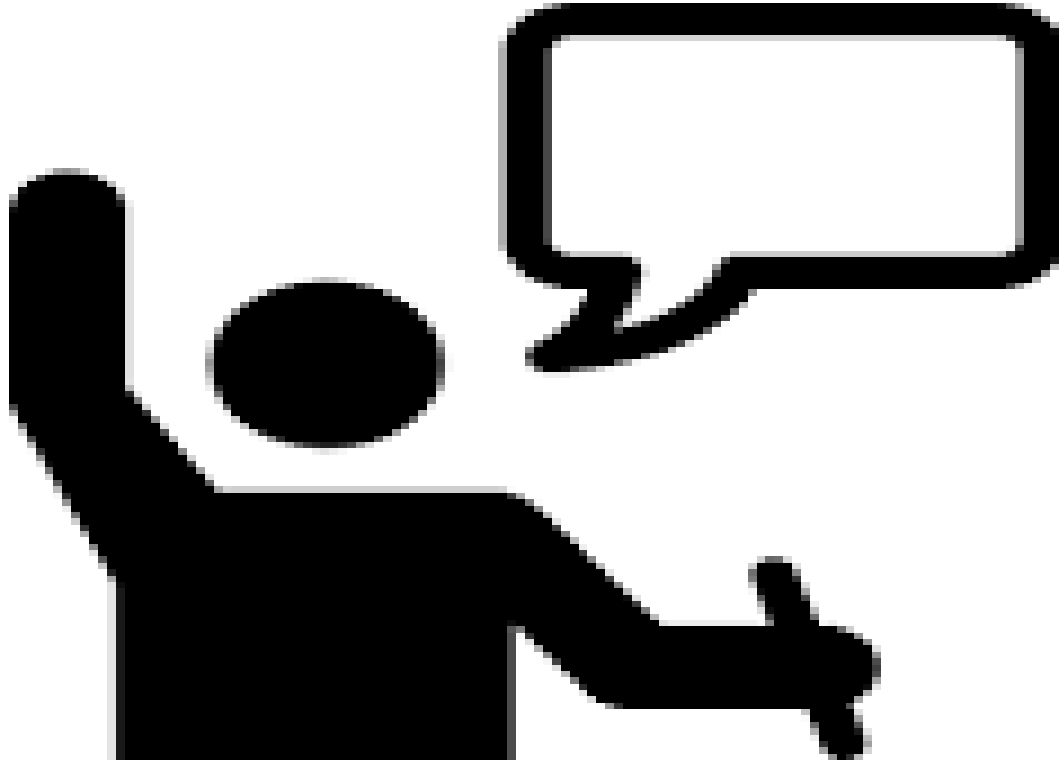
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Thank you