

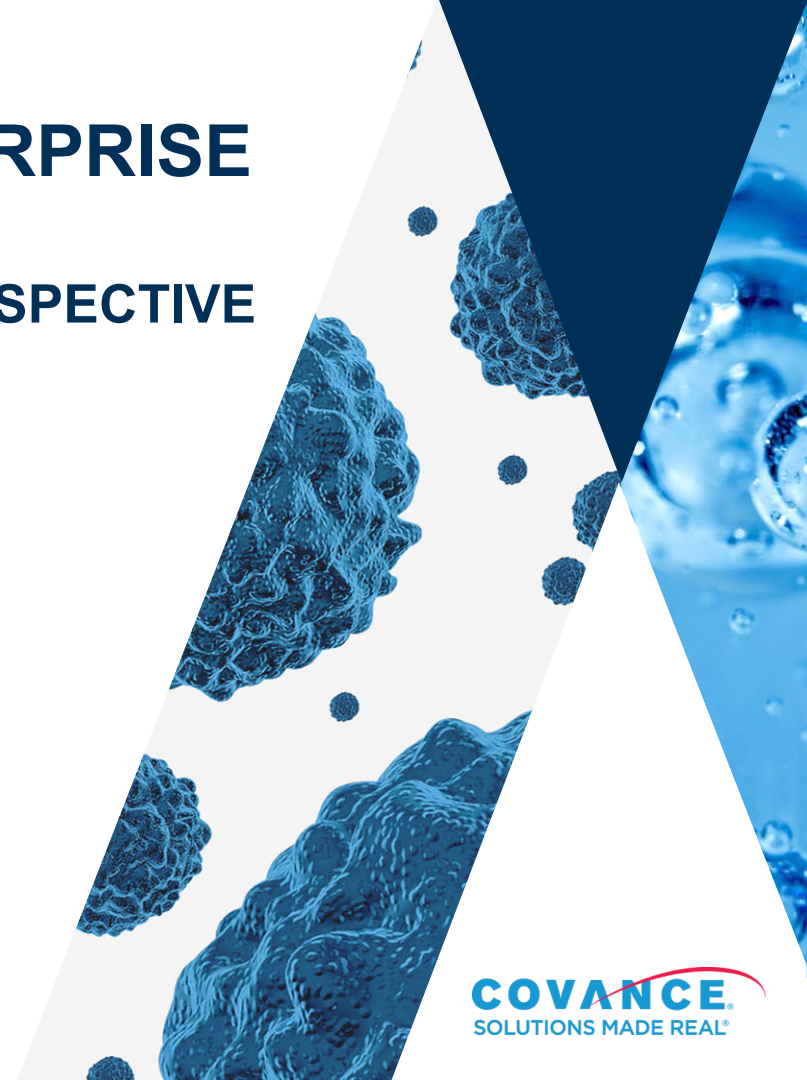
USING PINNACLE 21 ENTERPRISE FOR DEFINE.XML

TIPS AND TRICKS FROM A CRO PERSPECTIVE

February, 2019

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Public



COVANCE
SOLUTIONS MADE REAL®

Frank Menius

BIOGRAPHY

Frank Menius is a graduate of the University of North Carolina at Chapel Hill with a BA in International Studies, and was recently conferred a graduate certificate in Applied Statistics and Data Management at NC State University.

Mr. Menius is a former police officer, having served on the line for 12 years prior to fulfilling his lifelong dream of putting his uber computer-geek skills to good use. He is a SAS-certified programmer with extensive experience in data standards and define.xml creation.

Frank is currently an Associate Statistical Programmer at Covance, where his primary interests include training and process improvement. He has recently worked to develop processes and structures for the roll out of Pinnacle 21 Enterprise at Covance.

About Covance

Covance Inc., the drug development business of Laboratory Corporation of America Holdings (LabCorp), is the world's most comprehensive drug development company.

We are dedicated to advancing healthcare and delivering Solutions Made Real® by providing high quality nonclinical, clinical, commercialization and informatics services to pharmaceutical and biotechnology companies to help increase the speed, precision and effectiveness of drug development.

Covance is currently working on about half of all active clinical trials globally and has been involved in all top 50 best-selling drugs on the market.

How we use P21 Enterprise

At Covance P21 Enterprise is currently contracted with the client on a per study basis.

- P21E is used for submission based deliverables (validation checks, Data Fitness Score, define creation, compiling a Reviewer's Guide)
- Covance uses a modified P21 define template (spec) for specification writing

Creating a Define – Where to Start

The screenshot displays the PINNACLE 21 ENTERPRISE web interface. The top navigation bar includes the application name, user 'Frank Menius', messages, and a logout button. The left sidebar contains a menu with options: Home, Configure, Design Studies, Define.xml, Reviewer's Guide, Manage Metadata, Validate, Report, and Administer. The main content area shows a breadcrumb trail: Home > Design Studies > Define.xml > New Define.xml. Below this is a sub-header 'Create A New Define.xml' and a progress bar with four steps: Step 1: Create Option (active), Step 2: Data Package, Step 3: Select Details, and Step 4: Confirm. The central heading is 'Create Options' with the instruction 'Please select a method to create define.xml'. Six circular icons represent different creation methods: 'Start from Scratch' (document icon), 'Copy from Standard' (two document icons), 'Copy from Define' (document with square icon), 'Import Excel Specification' (document with 'X' icon), 'Import Define.xml' (document with code icon), and 'Create from a Validation' (checkmark icon). The 'Start from Scratch' option is highlighted with a red rectangular box.

Creating a Define – Where to Start

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Creating a Define – Where to Start

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Creating a Define – Where to Start

The screenshot displays the PINNACLE 21 ENTERPRISE web interface. The top navigation bar includes the application name, user 'Frank Menius', 'Messages', and 'Logout'. The left sidebar contains navigation links: Home, Configure, Design Studies, Define.xml, Reviewer's Guide, Manage Metadata, Validate, Report, and Administer. The main content area is titled 'Create A New Define.xml' and shows a four-step wizard: Step 1: Create Option (active), Step 2: Data Package, Step 3: Select Details, and Step 4: Confirm. Under 'Create Options', the instruction 'Please select a method to create define.xml' is followed by six options: Start from Scratch, Copy from Standard, Copy from Define, Import Excel Specification, Import Define.xml, and Create from a Validation. The 'Create from a Validation' option is highlighted with a red rectangular box.

Editing the Define – Properties

Define: P21 > P21-OQ > SDTM

+ Import Export Copy Compare

Properties Datasets Variables Value Level Codelists Terms Methods Comments Issues 301 History

Define Properties

Name P21-OQ

Description SAMPLE STUDY DEVELOPED TO DEMONSTRATE A SAMPLE SUBMISSION

Protocol

Standard SDTM-IG 3.2

SDTM CT 2017-06-30

Language English

Dictionaries

ID	Name	Data Type	Dictionary	Version
MedDRA	Adverse Event Dictionary	text	MedDRA	20.0
NDF-RT	Pharmacological Class Dictionary	text	NDF-RT	2017-06-14
SNOMED	Trial Indication Dictionary	text	SNOMED	2017-03-01
UNII	Treatment Dictionary	text	UNII	2017-04-28

Documents

ID	Title	Href
acrf	Annotated Case Report Form	acrf.pdf
reviewersguide	Study Data Reviewer's Guide	reviewersguide.pdf

Editing the Define – Properties

Define: P21 > P21-OQ > SDTM

+ Import Export Copy Compare

Properties Datasets Variables Value Level Codelists Terms Methods Comments Issues 301 History

Define Properties

Name: P21-OQ

Description: SAMPLE STUDY DEVELOPED TO DEMONSTRATE A SAMPLE SUBMISSION

Protocol: Protocol?

Standard: SDTM-IG 3.2

SDTM CT: 2017-06-30

Language: English

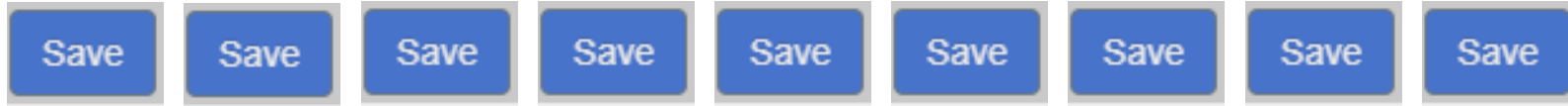
Dictionaries

ID	Name	Data Type	Dictionary	Version
MedDRA	Adverse Event Dictionary	text	MedDRA	20.0
NDF-RT	Pharmacological Class Dictionary	text	NDF-RT	2017-06-14
SNOMED	Trial Indication Dictionary	text	SNOMED	2017-03-01
WHODrug	Treatment Dictionary	text	WHODrug	2017-01-28

Documents

ID	Title	Href
reviewersguide	Study Data Reviewer's Guide	reviewersguide.pdf

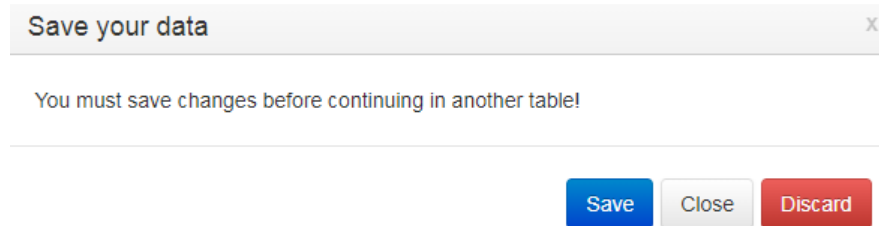
Editing the Define – PAUSE TO SAVE



Save before clicking on another tab. ALWAYS

Issue: You clicked on another tab without saving and now it won't let you.

Solution: Copy/Cut what you last typed into Excel. Then remove it from module. Then Save. Then Paste back into module. Then Save.

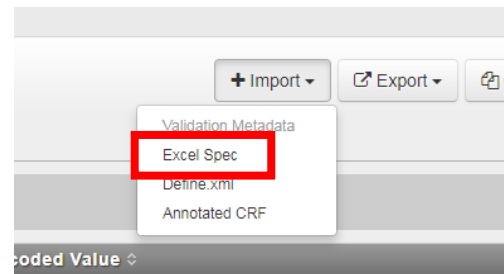
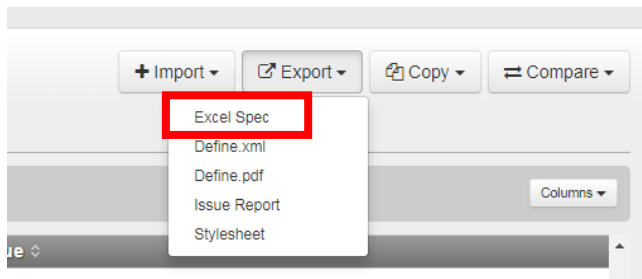


Editing the Define – PAUSE TO SAVE



Issue: You try to save and receive a message that says it can't save because the item has been recently changed by X user.

Solution: Export the define to Excel Spec. Immediately Import the Excel Spec. Make changes that were previously attempted. Saving should work now.



Editing the Define – Datasets

Define: P21 > P21-OQ > SDTM

+ Import ▾ ↗ Export ▾ 📄 Copy ▾

Properties **Datasets** Variables Value Level Codelists Terms Methods Comments Issues **301** History

🔍 Search

Dataset ▾	Description ▾	Class ▾	Structure ▾	Purpose ▾	Key Variables ▾
AE	Adverse Events	EVENTS	One record per adverse event per subject	Tabulation	STUDYID, USUBJID, AEDECOD,
CM	Concomitant Medications	INTERVENTIONS	One record per recorded medication occurrence or constant-dosing interval per subject	Tabulation	STUDYID, USUBJID, CMTRT, CM
DA	Drug Accountability	FINDINGS	One record per drug accountability finding per subject	Tabulation	STUDYID, USUBJID, DATESTCD
DM	Demographics	SPECIAL PURPOSE	One record per subject	Tabulation	STUDYID, USUBJID
DS	Disposition	EVENTS	One record per disposition status or protocol milestone per subject	Tabulation	STUDYID, USUBJID, DSDECOD,
EG	ECG Test Results	FINDINGS	One record per ECG observation per time point per visit per subject	Tabulation	STUDYID, USUBJID, EGTESTCD
EX	Exposure	INTERVENTIONS	One record per constant dosing interval per subject	Tabulation	STUDYID, USUBJID, EXTRT, EX
IE	Inclusion/Exclusion Criteria Not Met	FINDINGS	One record per inclusion/exclusion criterion not met per subject	Tabulation	STUDYID, USUBJID, IETESTCD
LB	Laboratory Test Results	FINDINGS	One record per analyte per planned	Tabulation	STUDYID, USUBJID, LBTESTCD

Editing the Define –

- Is this correct?
- Is this worded the way you want it?
- Is this consistent w/ other deliverables in you package?

Define: P21 > P21-OQ > SDTM

+ Import ▾ | Export ▾ | Copy ▾

Properties | Datasets | Variables | Value Level | Codelists | Terms | Methods | Comments | Issues 301 | History

Q Search

Dataset ▾	Description ▾	Class ▾	Structure ▾	Purpose ▾	Key Variables ▾
AE	Adverse Events	EVENTS	One record per adverse event per subject	Tabulation	STUDYID, USUBJID, AEDECOD,
CM	Concomitant Medications	INTERVENTIONS	One record per recorded medication occurrence or constant-dosing interval per subject	Tabulation	STUDYID, USUBJID, CMTRT, CM
DA	Drug Accountability	FINDINGS	One record per drug accountability finding per subject	Tabulation	STUDYID, USUBJID, DATESTCD
DM	Demographics	SPECIAL PURPOSE	One record per subject	Tabulation	STUDYID, USUBJID
DS	Disposition	EVENTS	One record per disposition status or protocol milestone per subject	Tabulation	STUDYID, USUBJID, DSDECOD,
EG	ECG Test Results	FINDINGS	One record per ECG observation per time point per visit per subject	Tabulation	STUDYID, USUBJID, EGTESTCD
EX	Exposure	INTERVENTIONS	One record per constant dosing interval per subject	Tabulation	STUDYID, USUBJID, EXTRT, EX
IE	Inclusion/Exclusion Criteria Not Met	FINDINGS	One record per inclusion/exclusion criterion not met per subject	Tabulation	STUDYID, USUBJID, IETESTCD
LB	Laboratory Test Results	FINDINGS	One record per analyte per planned	Tabulation	STUDYID, USUBJID, LBTESTCD

Editing the Define – Variables

Define: P21 > P21-OQ > SDTM

+ Import ▾ ↗ Export ▾ 📄 Copy ▾ ≡

Properties Datasets **Variables** Value Level Codelists Terms Methods Comments Issues **301** History

🔍 Search

Order ▾	Dataset ▾	Variable ▾	Label ▾	Type ▾	Length ▾	Digits ▾	Mandatory ▾	Codelist ▾	Origin ▾
1	AE	STUDYID	Study Identifier	text	7		Yes		Protocol
2	AE	DOMAIN	Domain Abbreviation	text	2		Yes		Assigned
3	AE	USUBJID	Unique Subject Identifier	text	14		Yes		Derived
4	AE	AESEQ	Sequence Number	integer	1		Yes		Derived
5	AE	AESPID	Sponsor-Defined Identifier	integer	1		Yes		
6	AE	AETERM	Reported Term for the Adverse Event	text	25		Yes		
7	AE	AEMODIFY	Modified Reported Term	text	9		No		Assigned
8	AE	AEDECOD	Dictionary-Derived Term	text	18		Yes	MedDRA	Assigned
9	AE	AEBODSYS	Body System or Organ Class	text	52		Yes	MedDRA	Assigned
10	AE	AESEV	Severity/Intensity	text	8		Yes	AESEV	

Editing the Define – Variables

Define: P21 > P21-OQ > SDTM

Start Here by Importing the aCRF

+ Import ▾ | Export ▾ | Copy ▾ | =

Validation Metadata
Excel Spec
Define.xml
Annotated CRF

Properties | Datasets | Variables | Value Level | Codelists | Terms | Methods | Comments | Issues 301 | History

Q Search

Order ▾	Dataset ▾	Variable ▾	Label ▾	Type ▾	Length ▾	Digits ▾	Mandatory ▾	Codelist ▾	Origin ▾
1	AE	STUDYID	Study Identifier	text	7		Yes		Protocol
2	AE	DOMAIN	Domain Abbreviation	text	2		Yes		Assigned
3	AE	USUBJID	Unique Subject Identifier	text	14		Yes		Derived
4	AE	AESQ	Sequence Number	integer	1		Yes		Derived
5	AE	AESPID	Sponsor-Defined Identifier	integer	1		Yes		
6	AE	AETERM	Reported Term for the Adverse Event	text	25		Yes		
7	AE	AEMODIFY	Modified Reported Term	text	9		No		Assigned
8	AE	AEDECOD	Dictionary-Derived Term	text	18		Yes	MedDRA	Assigned
9	AE	AEBODSYS	Body System or Organ Class	text	52		Yes	MedDRA	Assigned
10	AE	AESV	Severity/Intensity	text	8		Yes	AESV	

Editing the Define – Variables

Start Here by Importing the aCRF

Define: P21 Validation > P21 E - PQ > ...

+ Import Export

Properties Datasets Variables Value Level Codelists Terms Methods Comments Issues 171 History

Q Search

	Type	Length	Digits	Mandatory	Codelist	Origin	Pages
	text	8		Yes	AESEV		
	text	1		Yes	NY	CRF	84
eatment	text	16		Yes	AEACN	CRF	85
	text	16		Yes	AEREL	CRF	84
Event	text	10		Yes		CRF	84
Event	date			No		CRF	84
se Event	integer	3		Yes		Derived	
se Event	integer	3		No		Derived	

Editing the Define – Variables

Origins:

- All variables must be assigned an origin of **CRF, eDT, Assigned, Derived, Protocol or Predecessor**
- Variables can only be assigned 1 of the above
 - If there are multiple origins for a variable our solution is to pick one, and then make a comment for the remainder. If one is CRF then you want to use that in the origin box so that the hyperlinks populate
 - If variable has value level metadata that comes from more than one source then the variable origin is left blank and origin is assigned at the value level. There can not be conflict between Variable level and Value level

Editing the Define – Variables

Origins:

- If the variable has an origin of **Derived** P21E requires a method to be populated.
- If the variable has an origin of **Assigned** it is recommended that a comment be populated.

Codelist ▾	Origin ▾	Pages ▾	Method ▾	Predecessor ▾
	Derived			
	Derived			
STENRF				
	Protocol			
	Assigned			
	Derived			
	Derived			
	Assigned			
CMDECOD	Assigned			
CMCAT	Assigned			

Editing the Define – Variables

Comments and Methods:

- Creating comments and methods is done similarly on their respective tabs.
- The ID column is the link between the comment/method and the variable
- Comments and Methods can be used more than once if applicable

Editing the Define – Variables

Comments and Methods:

Properties Datasets Variables Value Level Codelists Terms Methods Comments Issues 301 History

Q Search

ID Description

THIS IS THE LINK This is the body of the comment.

Variables Value Level Codelists Terms Methods Comments Issues 301 History

Columns

Type	Length	Digits	Mandatory	Codelist	Origin	Pages	Method	Predecessor	Comment
text	10		Yes						
date			No						
integer	3		Yes		Derived				
integer	3		No		Derived				
text	5		No	STENRF					
text	7		Yes		Protocol				
text	2		Yes		Assigned				THIS IS THE LINK
text	14		Yes		Derived		THIS IS THE LINK2		
integer	2		Yes		Derived		THIS IS THE LINK2		
text	23		Yes						
text	23		No		Assigned				
text	26		Yes		Assigned				

Editing the Define – Variables

Comments and Methods:

Properties Datasets Variables Value Level Codelists Terms Methods Comments Issues 301 History

Search Columns

ID	Name	Type	Description	Expression Context	Expression Code
THIS IS THE LINK2	This is how it is displayed in Define		This is the body of the derivation	optional	optional

Computation
Imputation

Variables Value Level Codelists Terms Methods Comments Issues 301 History

Columns

Type	Length	Digits	Mandatory	Codelist	Origin	Pages	Method	Predecessor	Comment
text	10		Yes						
date			No						
integer	3		Yes		Derived				
integer	3		No		Derived				
text	5		No	STENRF					
text	7		Yes		Protocol				
text	2		Yes		Assigned				THIS IS THE LINK
text	14		Yes		Derived		THIS IS THE LINK2		
integer	2		Yes		Derived		THIS IS THE LINK2		
text	23		Yes						
text	23		No		Assigned				
text	26		Yes	CME500	Assigned				

Editing the Define – Value Level

Assigning Origins to Value Level works the exact same way as at the Variable.

Just note again - If variable has value level metadata that comes from more than one source then the variable origin is left blank and origin is assigned at the Value Level. There can not be conflict between Variable and Value Level

Editing the Define – Value Level

If you need to build more complex where clause statements P21E version 3.4 has a where clause builder accessible by hovering over window

Order ▾	Dataset ▾	Variable ▾	Where Clause ▾	Description ▾
31	QSCS	QSORRES	QSTESTCD EQ CSDD16	Suicide
33	QSCS	QS		
35	QSCS	QS		

Click to activate Where Clause Builder

Where Clause Builder

Variable: QSTESTCD Comparator: EQ Value: CSDD16 and

Where Clause
QSTESTCD EQ CSDD16

Submit Cancel

Editing the Define – Codelists

P21E will auto populate the codelists for you

- It may not be an exhaustive list – you will need to add

Properties

Datasets

Variables

Value Level

Codelists

Terms

Methods

Comments

Issues 301

History

Q Search

ID	Name	NCI Code	Type
EXTRT	Name of Treatment		text
IECAT	Category for Inclusion/Exclusion	C66797	text
IETEST	Inclusion/Exclusion Test Name		text
IETESTCD	Inclusion/Exclusion Test Code		text
LBCAT	Category for Lab Test		text
LBMETHOD	Method of Test or Examination in LB	C85492	text
LBNRIND	Reference Range Indicator in LB	C78736	text
LBORRES.LB.LBTESTCD.EQ.BILI	Bilirubin		float
LBORRES.LB.LBTESTCD.EQ.BUN	Blood Urea Nitrogen		integer
LBORRES.LB.LBTESTCD.EQ.GLUC	Glucose		text
LBORRES.LB.LBTESTCD.EQ.HCT	Hematocrit		float
LBORRES.LB.LBTESTCD.EQ.HGB	Hemoglobin		float
LBORRES.LB.LBTESTCD.EQ.LYM	Lymphocytes		float
LBORRES.LB.LBTESTCD.EQ.OCCBLD	Occult Blood		text
LBORRES.LB.LBTESTCD.EQ.PH	pH		float
LBORRES.LB.LBTESTCD.EQ.VITB12	Vitamin B12		integer
LBORRES.LB.LBTESTCD.EQ.VITB9	Vitamin B9		float

Editing the Define – Codelists

P21E will auto populate the codelists for you

- It may not be an exhaustive list – you will need to add
- You may need to delete some that are meaningless

The screenshot shows the 'Codelists' tab in the Covance Define software. The interface includes a search bar at the top. Below the search bar, there are two main sections. The left section is a list of variables, and the right section is a table of codelists.

Left Section: Variable List

ID	Name
EXTRT	Name of Treatment
IECAT	Category for Inclusion/Exclusion
IETEST	Inclusion/Exclusion Test Name
IETESTCD	Inclusion/Exclusion Test Code
LBCAT	Category for Lab Test
LBMETHOD	Method of Test or Examination in LB
LBNRIND	Reference Range Indicator in LB
LBORRES.LB.LBTESTCD.EQ.BILI	Bilirubin
LBORRES.LB.LBTESTCD.EQ.BUN	Blood Urea Nitrogen
LBORRES.LB.LBTESTCD.EQ.GLUC	Glucose
LBORRES.LB.LBTESTCD.EQ.HCT	Hematocrit
LBORRES.LB.LBTESTCD.EQ.HGB	Hemoglobin
LBORRES.LB.LBTESTCD.EQ.LYM	Lymphocytes
LBORRES.LB.LBTESTCD.EQ.OCCBLD	Occult Blood
LBORRES.LB.LBTESTCD.EQ.PH	pH
LBORRES.LB.LBTESTCD.EQ.VITB12	Vitamin B12
LBORRES.LB.LBTESTCD.EQ.VITB9	Vitamin B9

Right Section: Codelist Table

Order	Codelist	Term	NCI Code
2	LBNRIND	HIGH	C78800
2	LBNRIND	LOW	C78801
1	LBORRES.LB.LBTESTCD.EQ.BILI	0.4	
2	LBORRES.LB.LBTESTCD.EQ.BILI	0.3	
3	LBORRES.LB.LBTESTCD.EQ.BILI	0.2	
1	LBORRES.LB.LBTESTCD.EQ.BUN	26	
2	LBORRES.LB.LBTESTCD.EQ.BUN	18	
3	LBORRES.LB.LBTESTCD.EQ.BUN	16	
4	LBORRES.LB.LBTESTCD.EQ.BUN	14	
5	LBORRES.LB.LBTESTCD.EQ.BUN	12	
6	LBORRES.LB.LBTESTCD.EQ.BUN	15	
7	LBORRES.LB.LBTESTCD.EQ.BUN	13	
1	LBORRES.LB.LBTESTCD.EQ.GLUC	100	
2	LBORRES.LB.LBTESTCD.EQ.GLUC	87	

Editing the Define – Codelists

Codelists in P21E consist of 3 parts.

1. The Codelists Tab – ID, Name, NCI Code, and Type of codelists. Must be completed first
2. The Terms Tab – Order, Codelist (ID from Codelists Tab), Term, NCI Code, Decoded Value
3. The link in the Variable/Vaule Level Tab (ID Codelists Tab)

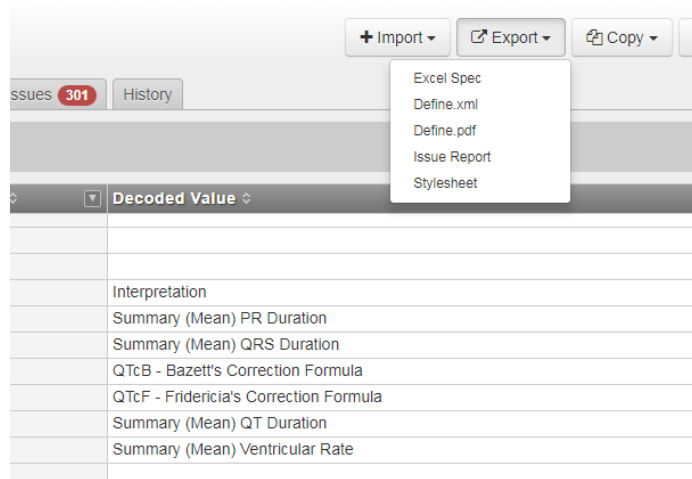
ID	Name	NCI Code	Type						
EGTESTCD	ECG Test Code	C71153	text						
ELEMENT	Description of Element		text						
EPOCH	Epoch	C00070	text						
Order	Codelist	Term	NCI Code	Decoded Value					
5	EGTEST	Q101 - Fridericia's Correction Formula							
6	EGTEST	Summary (Mean) QT Duration							
7	EGTEST	Summary (Mean) Ventricular Rate							
1	EGTESTCD	INTP	C41255	Interpretation					
2	EGTESTCD	PRMEAN		Summary (Mean) PR Duration					
3	EGTESTCD	QRS DUR		Summary (Mean) QRS Duration					
Order	Dataset	Variable	Label	Type	Length	Digits	Mandatory	Codelist	Origin
5	EG	EGSEQ	Sequence Number	integer	2		Yes		Derived
6	EG	EGSPID	Sponsor-Defined Identifier	text	6		Yes		
7	EG	EGTESTCD	ECG Test or Examination Short Name	text	6		Yes	EGTESTCD	Assigned
7	EG	EGTEST	ECG Test or Examination Name	text	38		Yes	EGTEST	Assigned
8	EG	EGPOS	ECG Position of Subject	text	6		Yes	EGPOS	
9	EG	EGORRES	Result or Finding in Original Units	text	8		No		
10	EG	EGORRESU	Original Units	text	9		No	EGORRESU	
11	EG	EGSTRESC	Character Result/Finding in Std Format	text	8		Yes		

Editing the Define – Codelists

Work Arounds:

Issue - Sometimes the NCI Code does not populate on the Terms Tab.

Solution – Export the define to Excel Spec and then reimport the define from Excel Spec



Editing the Define – Codelists

Work Arounds:

Issue – The Terms are sorted in random/illogical order

Solution – Copy and paste into Excel or even create the terms list in Excel, use the tools in Excel to sort appropriately, then copy and past into P21E

Properties	Datasets	Variables	Value Level	Codelists	Terms	Methods	Comments	Issues 301	History
Search									
Order	Codelist	Term	NCI Code	Decoded					
12	CMCLAS	PSYCHOANALEPTICS							
13	CMCLAS	VACCINES							
14	CMCLAS	COUGH AND COLD PREPARATIONS							
15	CMCLAS	ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS							
1	CMCLASCD	C08							
2	CMCLASCD	A10							
3	CMCLASCD	C09							
4	CMCLASCD	A12							
5	CMCLASCD	A11							
6	CMCLASCD	A02							
7	CMCLASCD	N02							
8	CMCLASCD	H03							
9	CMCLASCD	N05							
10	CMCLASCD	A04							
11	CMCLASCD	V03							

What if the Data Changes?

P21 has the ability to import the changed metadata after it has been validated and merge it with the define. HOWEVER, I strongly urge AGAINST this.

- P21 redoes the auto-population replacing the links/overwriting anything that was changed by the user from original version.

Links to codelists, comments, and methods will be affected.

Deleted codelists will return.

Expect to spend significant time fixing this.

What if the Data Changes?

Alternatives?

If changes are minor, get a change list and make updates manually.

If changes are large and you must merge in a new validation, use the history tab to compare The pre-import and after import versions. This report can be exported to excel and will show all differences between the versions allowing you to pinpoint your corrections.

Define: P21 > P21-OQ > SDTM

+ Import ▾ ↗ Export ▾ 📄 Copy ▾ ⚖ Compare ▾

Properties Datasets Variables Value Level Codelists Terms Methods Comments Issues **197** History

+ New Version ✓ Compare 🔍 Search

🖨 Print 📄 Copy 📄 Download

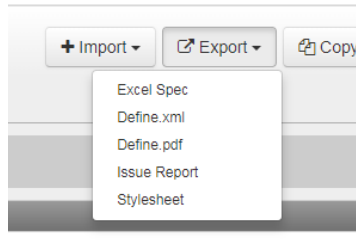
Version ▾	Revert	Reason	Created By	Creation Date	Last Modified By	Modification Date
✓ 5	Current Version	Import Excel	Frank Menius	2018-11-19 10:41:33	Frank Menius	2018-12-06 13:10:37
✓ 4	Revert to this version	Upload CRF	Frank Menius	2018-11-19 10:19:20	Frank Menius	2018-11-19 10:35:38

Define Completion and the P21 Report

When define is complete, export the define.xml and stylesheet to the location of the data.

Note: To properly view the define the define.xml, the stylesheet, and all linked documents must be in the same folder. Right click the define.xml file and open with browser.

Revalidate the study to produce the report with cross validation checks with the define.xml



Your Studies

Q Search

Study ^	Package ^	Project ^	Reports ^	Validate ^	Open Issues ^	Your Issues ^	Score ^
P21-OQ	SDTM	P21	View Reports	Validate Study	174	0	20

Questions?

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