

A HOW-TO GUIDE FOR EXTENDING CONTROLLED TERMINOLOGY USING SAS CLINICAL DATA INTEGRATION

MELISSA R. MARTINEZ



AGENDA

- What is Controlled Terminology?
- Adding a New CDISC Controlled Terminology Version
- Extending CDISC Controlled Terminology Codelists
- Customizing Controlled Terminology for a Study
- External Data Dictionaries

WHAT IS CONTROLLED TERMINOLOGY?

CDISC definition: Set of standard value lists that are used throughout the clinical research process

Code	Codelist Code	Codelist Extensible (Yes/No)	Codelist Name	CDISC Submission Value
C66767		No	Action Taken with Study Treatment	ACN
C49503	C66767		Action Taken with Study Treatment	DOSE INCREASED
C49504	C66767		Action Taken with Study Treatment	DOSE NOT CHANGED
C49505	C66767		Action Taken with Study Treatment	DOSE REDUCED
C49501	C66767		Action Taken with Study Treatment	DRUG INTERRUPTED
C49502	C66767		Action Taken with Study Treatment	DRUG WITHDRAWN
C48660	C66767		Action Taken with Study Treatment	NOT APPLICABLE
C17998	C66767		Action Taken with Study Treatment	UNKNOWN

WHAT IS CONTROLLED TERMINOLOGY?

Set of *possible*
values for your study
within a codelist

Codelist Name ▼	CDISC Submission Value ▼	CDISC Synonym(s) ▼
Country	COUNTRY	Country
Country	ABW	ARUBA
Country	AFG	AFGHANISTAN
Country	AGO	ANGOLA
Country	AIA	ANGUILLA
Country	ALA	ALAND ISLANDS
Country	ALB	ALBANIA
Country	ZAF	SOUTH AFRICA
Country	ZMB	ZAMBIA
Country	ZWE	ZIMBABWE

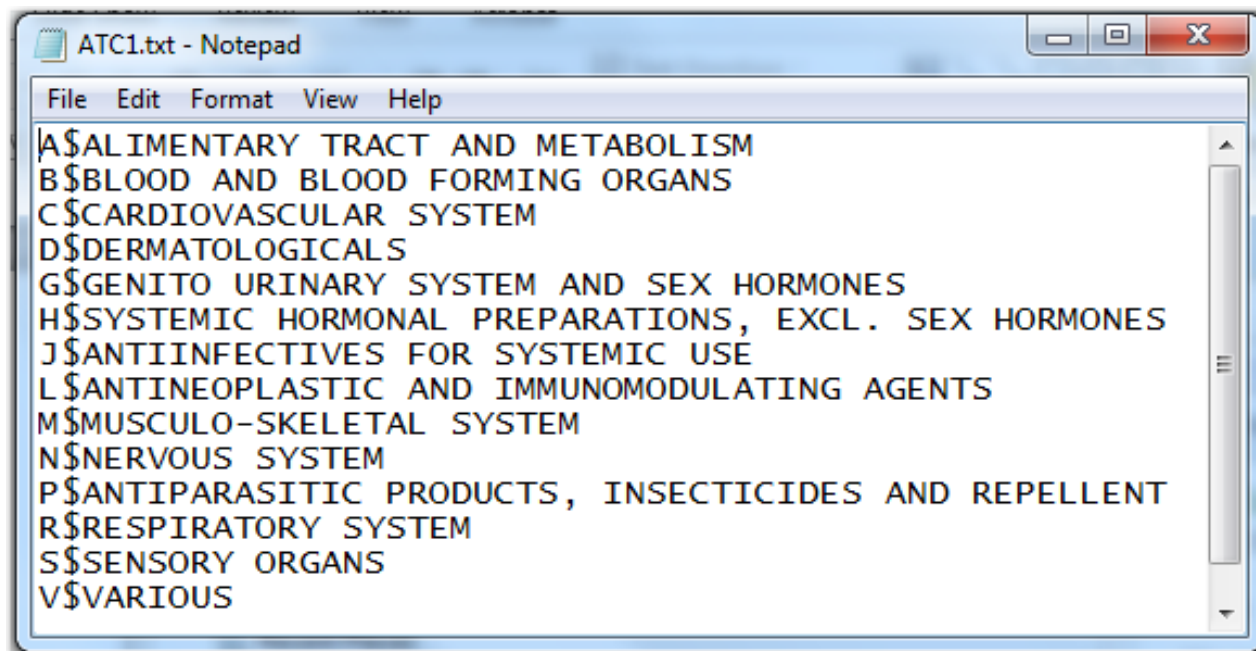
WHAT IS CONTROLLED TERMINOLOGY?

Set of *possible*
values for your study
within a codelist

Codelist Name ▼	CDISC Submission Value ▼	CDISC Synonym(s) ▼
Country	COUNTRY	Country
Country	CAN	CANADA
Country	MEX	MEXICO
Country	USA	UNITED STATES

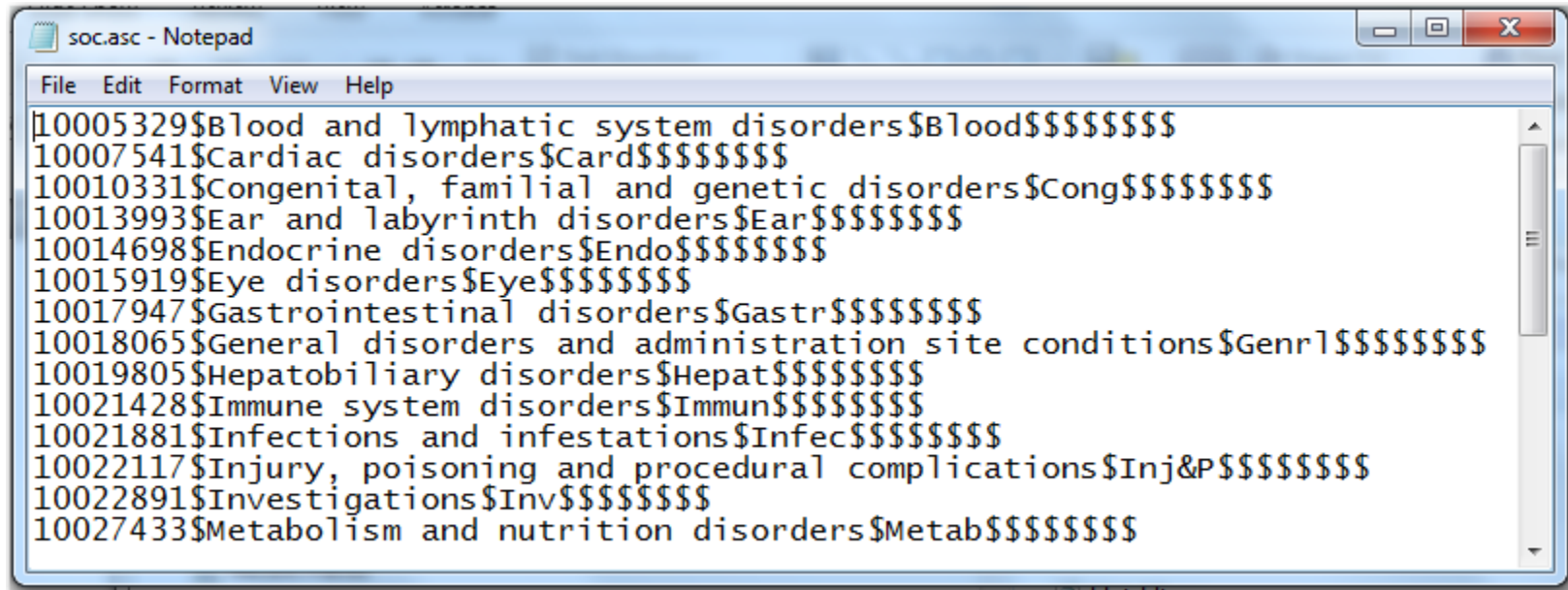
WHAT IS CONTROLLED TERMINOLOGY?

WHO Drug Dictionary – Dictionary of medicinal product information



WHAT IS CONTROLLED TERMINOLOGY?

MedDRA - Validated medical terminology



```
soc.asc - Notepad
File Edit Format View Help
10005329$Blood and lymphatic system disorders$Blood$$$$$$$$$
10007541$Cardiac disorders$Card$$$$$$$$$
10010331$Congenital, familial and genetic disorders$Cong$$$$$$$$$
10013993$Ear and labyrinth disorders$Ear$$$$$$$$$
10014698$Endocrine disorders$Endo$$$$$$$$$
10015919$Eye disorders$Eye$$$$$$$$$
10017947$Gastrointestinal disorders$Gastr$$$$$$$$$
10018065$General disorders and administration site conditions$Genr1$$$$$$$$$
10019805$Hepatobiliary disorders$Hepat$$$$$$$$$
10021428$Immune system disorders$Immun$$$$$$$$$
10021881$Infections and infestations$Infec$$$$$$$$$
10022117$Injury, poisoning and procedural complications$Inj&P$$$$$$$$$
10022891$Investigations$Inv$$$$$$$$$
10027433$Metabolism and nutrition disorders$Metab$$$$$$$$$
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A NOTE BEFORE PROCEEDING

DISCLAIMER ALERT



Please read full paper for complete details,
available in the conference proceedings.

A NOTE BEFORE PROCEEDING

DISCLAIMER ALERT



Please read my full paper for complete details,
available in the conference proceedings.

This paper was
developed for

SAS[®]
Clinical Data Integration 2.3

FOUR WAYS OF EXTENDING CONTROLLED TERMINOLOGY



ADDING A NEW CDISC CONTROLLED TERMINOLOGY VERSION

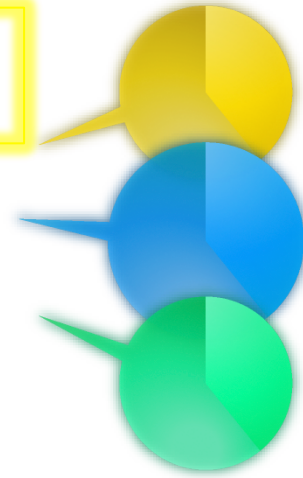


ADDING A NEW CDISC CONTROLLED TERMINOLOGY VERSION



WHY?

CDISC releases new versions frequently



ADDING A NEW CDISC CONTROLLED TERMINOLOGY VERSION



WHY?

CDISC releases new versions frequently

Too long until planned CDI upgrade



ADDING A NEW CDISC CONTROLLED TERMINOLOGY VERSION

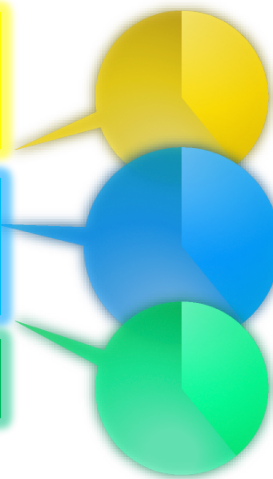


WHY?

CDISC releases new versions frequently

Too long until planned CDI upgrade

Take advantage of new terms



ADDING A NEW CDISC CONTROLLED TERMINOLOGY VERSION



RAW CDISC CONTROLLED TERMINOLOGY FILE

Code	Codelist Code	Codelist Extensible (Yes/No)	Codelist Name	CDISC Submission Value	CDISC Synonym(s)	CDISC Definition	NCI Preferred Term
C66767		No	Action Taken with Study Treatment	ACN	Action Taken with Study Treatment	Action Taken with Study Treatment	CDISC SDTM Action Taken with Study Treatment Terminology
C49503	C66767		Action Taken with Study Treatment	DOSE INCREASED		An indication that a medication schedule was modified by addition; either by changing the frequency, strength or amount. (NCI)	Dose Increased
C49504	C66767		Action Taken with Study Treatment	DOSE NOT CHANGED		An indication that a medication schedule was maintained. (NCI)	Dose Not Changed
C49505	C66767		Action Taken with Study Treatment	DOSE REDUCED		An indication that a medication schedule was modified by subtraction, either by changing the frequency, strength or amount. (NCI)	Dose Reduced
C49501	C66767		Action Taken with Study Treatment	DRUG INTERRUPTED		An indication that a medication schedule was modified by temporarily terminating a prescribed regimen of medication. (NCI)	Drug Interrupted
C49502	C66767		Action Taken with Study Treatment	DRUG WITHDRAWN		An indication that a medication schedule was modified through termination of a prescribed regimen of medication. (NCI)	Drug Withdrawn
C48660	C66767		Action Taken with Study Treatment	NOT APPLICABLE	NA	Determination of a value is not relevant in the current context. (NCI)	Not Applicable
C17998	C66767		Action Taken with Study Treatment	UNKNOWN	U; Unknown	Not known, not observed, not recorded, or refused. (NCI)	Unknown

ADDING A NEW CDISC CONTROLLED TERMINOLOGY VERSION



RAW CDISC CONTROLLED TERMINOLOGY FILE

Code	Codelist Code	Codelist Extensible (Yes/No)	Codelist Name	CDISC Submission Value	CDISC Synonym(s)	CDISC Definition	NCI Preferred Term
C66767		No	Action Taken with Study Treatment	ACN	Action Taken with Study Treatment	Action Taken with Study Treatment	CDISC SDTM Action Taken with Study Treatment Terminology
C49503	C66767		Action Taken with Study Treatment	DOSE INCREASED		An indication that a medication schedule was modified by addition; either by changing the frequency, strength or amount. (NCI)	Dose Increased
C49504	C66767		Action Taken with Study Treatment	DOSE NOT CHANGED		An indication that a medication schedule was maintained. (NCI)	Dose Not Changed
C49505	C66767		Action Taken with Study Treatment	DOSE REDUCED		An indication that a medication schedule was modified by subtraction, either by changing the frequency, strength or amount. (NCI)	Dose Reduced
C49501	C66767		Action Taken with Study Treatment	DRUG INTERRUPTED		An indication that a medication schedule was modified by temporarily terminating a prescribed regimen of medication. (NCI)	Drug Interrupted
C49502	C66767		Action Taken with Study Treatment	DRUG WITHDRAWN		An indication that a medication schedule was modified through termination of a prescribed regimen of medication. (NCI)	Drug Withdrawn
C48660	C66767		Action Taken with Study Treatment	NOT APPLICABLE	NA	Determination of a value is not relevant in the current context. (NCI)	Not Applicable
C17998	C66767		Action Taken with Study Treatment	UNKNOWN	U; Unknown	Not known, not observed, not recorded, or refused. (NCI)	Unknown

ADDING A NEW CDISC CONTROLLED TERMINOLOGY VERSION



RAW CDISC CONTROLLED TERMINOLOGY FILE

CDISC Submission Value					codelist	
Code	Codeli Code	CDISC Submission Value	Definition	NCI Preferred Term	ACN	ACN
C66767		ACN	Taken with Study Treatment	CDISC SDTM Action Taken with Study Treatment Terminology	ACN	
C49503	C66767	Action Taken with Study Treatment	DOSE INCREASED	Dose Increased	ACN	
C49504	C66767	Action Taken with Study Treatment	DOSE NOT CHANGED	Dose Not Changed	ACN	
C49505	C66767	Action Taken with Study Treatment	DOSE REDUCED	Dose Reduced	ACN	
C49501	C66767	Action Taken with Study Treatment	DRUG INTERRUPTED	Drug Interrupted	ACN	
C49502	C66767	Action Taken with Study Treatment	DRUG WITHDRAWN	Drug Withdrawn	ACN	
C48660	C66767	Action Taken with Study Treatment	NOT APPLICABLE	Not Applicable	ACN	
C17998	C66767	Action Taken with Study Treatment	UNKNOWN	Unknown	ACN	
					ACN	
					ACN	

A 3D pie chart is shown against a blue background. The chart consists of a large blue slice and a smaller green slice. The green slice is separated from the blue slice, suggesting it represents a distinct category or a specific data point. The chart has a slight 3D effect with shadows.

Code	Code	Codelist Intensible es/No)	Codelist Name	CDISC Submission Value	CDISC Synonym(s)	CDISC Definition	NCI Preferred Term
C6676	C66767		Action Taken with Study Treatment	ACN	Action Taken with Study Treatment	Action Taken with Study Treatment	CDISC SDTM Action Taken with Study Treatment Terminology
C4950	C49503		Action Taken with Study Treatment	DOSE INCREASED		An indication that a medication schedule was modified by addition; either by changing the frequency, strength or amount. (NCI)	Dose Increased
C4950	C49504		Action Taken with Study Treatment	DOSE NOT CHANGED		An indication that a medication schedule was maintained. (NCI)	Dose Not Changed
C4950	C49505		Action Taken with Study Treatment	DOSE REDUCED		An indication that a medication schedule was modified by subtraction, either by changing the frequency, strength or amount. (NCI)	Dose Reduced
C4950	C49501		Action Taken with Study Treatment	DRUG INTERRUPTED		An indication that a medication schedule was modified by temporarily terminating a prescribed regimen of medication. (NCI)	Drug Interrupted
C4950			Action Taken with Study Treatment	DRUG WITHDRAWN		An indication that a medication schedule was modified through termination of a prescribed regimen of medication. (NCI)	Drug Withdrawn
C4866	C49502		Action Taken with Study Treatment	NOT APPLICABLE	NA	Determination of a value is not relevant in the current context. (NCI)	Not Applicable
C1799			Action Taken with Study Treatment	UNKNOWN	U; Unknown	Not known, not observed, not recorded, or refused. (NCI)	Unknown
	C48660						
	C17998						

ADDING A NEW CDISC CONTROLLED TERMINOLOGY VERSION



RAW CDISC CONTROLLED TERMINOLOGY FILE

Code	Codelist (Intensible Names/No)	Codelist Name	CDISC S	code	CDISC Synonym(s)	CDISC Definition	NCI Preferred Term
C66767				C49503			
C6676		Action Taken with Study Treatment	ACN	C49504			CDISC SDTM Action Taken with Study Treatment Terminology
C4950		Action Taken with Study Treatment	DOSE IN	C49505		An indication that a medication schedule was modified by addition; either by changing the frequency, strength or amount. (NCI)	Dose Increased
C4950		Action Taken with Study Treatment	DOSE NI	C49501		An indication that a medication schedule was maintained. (NCI)	Dose Not Changed
C4950			DOSE RI	C49502		An indication that a medication schedule was modified by subtraction; either by changing the frequency, strength or amount. (NCI)	Dose Reduced
C4950		Action Taken with Study Treatment	DRUG IN	C49502	NA	Determination of a value is not relevant in the current context. (NCI)	Drug Interrupted
C4950		Action Taken with Study Treatment	DRUG W	C49502	U; Unknown	Not known, not observed, not recorded, or refused. (NCI)	Drug Withdrawn
C4866		Action Taken with Study Treatment	NOT API	C48660			Not Applicable
C1799		Action Taken with Study Treatment	UNKNO	C17998			Unknown

ADDING A NEW CDISC CONTROLLED TERMINOLOGY VERSION



RAW CDISC CONTROLLED TERMINOLOGY FILE

Code		Codelist Code		Codelist Name	CDISC Submission Value	CDISC Synonym(s)	CDISC Definition	NCI Preferred Term
C66767		C66767		Action Taken with Study Treatment	ACN	Action Taken with Study Treatment	Action Taken with Study Treatment	CDISC SDTM Action Taken with Study Treatment Terminology
C49503	C66767			Action Taken with Study Treatment	DOSE INCREASED		An indication that a medication schedule was modified by addition; either by changing the frequency, strength or amount. (NCI)	Dose Increased
C49504	C66767	C66767		Action Taken with Study Treatment	DOSE NOT CHANGED		An indication that a medication schedule was maintained. (NCI)	Dose Not Changed
C49505	C66767	C66767		Action Taken with Study Treatment	DOSE REDUCED		An indication that a medication schedule was modified by subtraction, either by changing the frequency, strength or amount. (NCI)	Dose Reduced
C49501	C66767	C66767		Action Taken with Study Treatment	DRUG INTERRUPTED		An indication that a medication schedule was modified by temporarily terminating a prescribed regimen of medication. (NCI)	Drug Interrupted
C49502	C66767	C66767		Action Taken with Study Treatment	DRUG WITHDRAWN		An indication that a medication schedule was modified through termination of a prescribed regimen of medication. (NCI)	Drug Withdrawn
C48660	C66767	C66767		Action Taken with Study Treatment	NOT APPLICABLE	NA	Determination of a value is not relevant in the current context. (NCI)	Not Applicable
C17998	C66767	C66767		Action Taken with Study Treatment	UNKNOWN	U; Unknown	Not known, not observed, not recorded, or refused. (NCI)	Unknown
		C66767						
		C66767						

ADDING A NEW CDISC CONTROLLED TERMINOLOGY VERSION



RAW CDISC CONTROLLED TERMINOLOGY FILE

Code	Codelist Code	Codelist Name	CDISC Submission Value	codelist_code	CDISC Definition	NCI Preferred Term
C66767		Action Taken with Study Treatment	ACN	C66767	Action Taken with Study Treatment	CDISC SDTM Action Taken with Study Treatment Terminology
C49503	C66767	Action Taken with Study Treatment	DOSE INCREASED	C66767	An indication that a medication schedule was modified by addition; either by changing the frequency, strength or amount. (NCI)	Dose Increased
C49504	C66767	Action Taken with Study Treatment	DOSE NOT CHANGED	C66767	An indication that a medication schedule was maintained. (NCI)	Dose Not Changed
C49505	C66767	Action Taken with Study Treatment	DOSE REDUCED	C66767	An indication that a medication schedule was modified by subtraction, either by changing the frequency, strength or amount. (NCI)	Dose Reduced
C49501	C66767	Action Taken with Study Treatment	DRUG INTERRUPTED	C66767	An indication that a medication schedule was modified by temporarily terminating a prescribed regimen of medication. (NCI)	Drug Interrupted
C49502	C66767	Action Taken with Study Treatment	DRUG WITHDRAWN	C66767	An indication that a medication schedule was modified through termination of a prescribed regimen of medication. (NCI)	Drug Withdrawn
C48660	C66767	Action Taken with Study Treatment	NOT APPLICABLE	C66767	Determination of a value is not relevant in the current context. (NCI)	Not Applicable
C17998	C66767	Action Taken with Study Treatment	UNKNOWN	C66767	Not known, not observed, not recorded, or refused. (NCI)	Unknown
	C66767			C66767		
	C66767			C66767		

ADDING A NEW CDISC CONTROLLED TERMINOLOGY VERSION



RAW CDISC CONTROLLED TERMINOLOGY FILE

Codelist Extensible (Yes/No)			Codelist Extensible (Yes/No)				
Code	Codlist Code	Codlist Extensit (Yes/No)	No				
C66767		No	Study	ACN	Action Taken with Study Treatment	Action Taken with Study Treatment	CDISC SDTM Action Taken with Study Treatment Terminology
C49503	C66767		Study	DOSE INCREASED		An indication that a medication schedule was modified by addition; either by changing the frequency, strength or amount. (NCI)	Dose Increased
C49504	C66767		Study	DOSE NOT CHANGED		An indication that a medication schedule was maintained. (NCI)	Dose Not Changed
C49505	C66767		Study	DOSE REDUCED		An indication that a medication schedule was modified by subtraction, either by changing the frequency, strength or amount. (NCI)	Dose Reduced
C49501	C66767		Study	DRUG INTERRUPTED		An indication that a medication schedule was modified by temporarily terminating a prescribed regimen of medication. (NCI)	Drug Interrupted
C49502	C66767		Study	DRUG WITHDRAWN		An indication that a medication schedule was modified through termination of a prescribed regimen of medication. (NCI)	Drug Withdrawn
C48660	C66767		Study	NOT APPLICABLE	NA	Determination of a value is not relevant in the current context. (NCI)	Not Applicable
C17998	C66767		Study	UNKNOWN	U; Unknown	Not known, not observed, not recorded, or refused. (NCI)	Unknown

ADDING A NEW CDISC CONTROLLED TERMINOLOGY VERSION

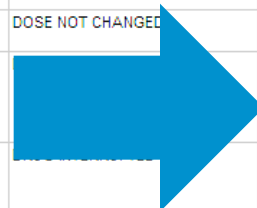


RAW CDISC CONTROLLED TERMINOLOGY FILE

Code	Codelist Code	Codelist Extensibility (Yes/No)	CDISC Submission Value	CDISC Synonym	NCI Preferred Term
C66767		No	Study ACN	Action Taken with Study Treatment	CDISC SDTM Action Taken with Study Treatment Terminology
C49503	C66767		Study DOSE INCREASED		Dose Increased
C49504	C66767		Study DOSE NOT CHANGED		Dose Not Changed
C49505	C66767		Study		Dose Reduced
C49501	C66767		Study		Drug Interrupted
C49502	C66767		Study DRUG WITHDRAWN		Drug Withdrawn
C48660	C66767		Study NOT APPLICABLE	NA	Not Applicable
C17998	C66767		Study UNKNOWN	U; Unknown	Unknown

Codelist Extensible (Yes/No)

No



codelist_extensible

No

No

No

No

No

No

No

A 3D pie chart is shown against a blue background. The chart is divided into two segments: a large blue segment and a smaller green segment. The green segment is positioned at the top right, and the blue segment occupies the rest of the chart. The chart has a slight 3D effect with a shadow.

Code	Codelist Code	Codelist Extensible (Yes/No)
C66767		No
C49503	C66767	
C49504	C66767	
C49505	C66767	
C49501	C66767	
C49502	C66767	
C48860	C66767	
C17998	C66767	

	CDISC Submission Value	CDISC Synonym
study	ACN	Action Taken on Study Treatment
study	DOSE INCREASED	
study	DOSE NOT CHANGED	
study		
study		
study	DRUG WITHDRAWN	
study	NOT APPLICABLE	NA
study	UNKNOWN	U; Unknown

	NCI Preferred Term
treatment	CDISC SDTM Action Taken with Study Treatment Terminology
on addition; efficacy,	Dose Increased
on (NCI)	Dose Not Changed
on	Dose Reduced
ing the int. (NCI)	
on temporarily imen of	Drug Interrupted
on ough regimen of	Drug Withdrawn
ot xt. (NCI)	Not Applicable
ot	Unknown

Codelist Extensible (Yes/No)

No

codelist_extensible

No

No

No

No

No

No

No

No

No

Codelist Extensible (Yes/No)

No

codelist_extensible

No

No

No

No

No

No

No

No

No

THE POWER
TO KNOW.

ADDING A NEW CDISC CONTROLLED TERMINOLOGY VERSION



RAW CDISC CONTROLLED TERMINOLOGY FILE

Code	Codelist Code	Codelist Extensible (Yes/No)	Codelist Name
C66767		No	Action Taker Treatment
C49503	C66767		Action Taker Treatment
C49504	C66767		Action Taker Treatment
C49505	C66767		Action Taker Treatment
C49501	C66767		Action Taker Treatment
C49502	C66767		Action Taker Treatment
C48660	C66767		Action Taker Treatment
C17998	C66767		Action Taker Treatment

CDISC Synonym(s)	CDISC Definition	NCI Preferred Term
Action Taken with Study Treatment	Action Taken with Study Treatment	CDISC SDTM Action Taken with Study Treatment Terminology
	An indication that a medication schedule was modified by addition; either by changing the frequency, strength or amount. (NCI)	Dose Increased
	An indication that a medication schedule was maintained. (NCI)	Dose Not Changed
	An indication that a medication schedule was modified by subtraction, either by changing the frequency, strength or amount. (NCI)	Dose Reduced
	An indication that a medication schedule was modified by temporarily terminating a prescribed regimen of medication. (NCI)	Drug Interrupted
	An indication that a medication schedule was modified through termination of a prescribed regimen of medication. (NCI)	Drug Withdrawn
NA	Determination of a value is not relevant in the current context. (NCI)	Not Applicable
U; Unknown	Not known, not observed, not recorded, or refused. (NCI)	Unknown

ADDING A NEW CDISC CONTROLLED TERMINOLOGY VERSION



RAW CDISC CONTROLLED TERMINOLOGY FILE

Code	Codelist Code	Codelist Extensible (Yes/No)	Codelist Name	CDISC Synonym(s)
C66767		No	Action Taker Treatment	Action Taken with Study Treatment
C49503	C66767		Action Taker Treatment	Action Taken with Study Treatment
C49504	C66767		Action Taker Treatment	Action Taken with Study Treatment
C49505	C66767		Action Taker Treatment	Action Taken with Study Treatment
C49501	C66767		Action Taker Treatment	Action Taken with Study Treatment
C49502	C66767		Action Taker Treatment	Action Taken with Study Treatment
C48660	C66767		Action Taker Treatment	NA
C17998	C66767		Action Taker Treatment	U; Unknown

codelist_name
Action Taken with Study Treatment
Action Taken with Study Treatment
Action Taken with Study Treatment
Action Taken with Study Treatment
Action Taken with Study Treatment
Action Taken with Study Treatment
Action Taken with Study Treatment
Action Taken with Study Treatment
Action Taken with Study Treatment

ADDING A NEW CDISC CONTROLLED TERMINOLOGY VERSION



RAW CDISC CONTROLLED TERMINOLOGY FILE

Code	Codelist Code	Codelist Extensible (Yes/No)	Codelist Name	CDISC Submission Value	CDISC Submission Value	CDISC Submission Value
C66767		No	Action Taken with Study Treatment	ACN	ACN	ACN
C49503	C66767		Action Taken with Study Treatment	DOSE INCREASED	DOSE INCREASED	DOSE INCREASED
C49504	C66767		Action Taken with Study Treatment	DOSE NOT CHANGED	DOSE NOT CHANGED	DOSE NOT CHANGED
C49505	C66767		Action Taken with Study Treatment	DOSE REDUCED	DOSE REDUCED	DOSE REDUCED
C49501	C66767		Action Taken with Study Treatment	DRUG INTERRUPTED	DRUG INTERRUPTED	DRUG INTERRUPTED
C49502	C66767		Action Taken with Study Treatment	DRUG WITHDRAWN	DRUG WITHDRAWN	DRUG WITHDRAWN
C48660	C66767		Action Taken with Study Treatment	NOT APPLICABLE	NOT APPLICABLE	NOT APPLICABLE
C17998	C66767		Action Taken with Study Treatment	UNKNOWN	UNKNOWN	UNKNOWN

ADDING A NEW CDISC CONTROLLED TERMINOLOGY VERSION



RAW CDISC CONTROLLED TERMINOLOGY FILE

cdisc_submission_value		CDISC Submission Value	
DOSE INCREASED		ACN	
DOSE NOT CHANGED		DOSE INCREASED	
DOSE REDUCED		DOSE NOT CHANGED	
DRUG INTERRUPTED		DOSE REDUCED	
DRUG WITHDRAWN		DRUG INTERRUPTED	
NOT APPLICABLE		DRUG WITHDRAWN	
UNKNOWN		NOT APPLICABLE	
		UNKNOWN	

tion	NCI Preferred Term
with Study Treatment	CDISC SDTM Action Taken with Study Treatment Terminology
hat a medication .modified by addition; ging the frequency, ount. (NCI)	Dose Increased
hat a medication .maintained. (NCI)	Dose Not Changed
hat a medication .modified by ther by changing the length or amount. (NCI)	Dose Reduced
hat a medication .modified by temporarily rescribed regimen of CI)	Drug Interrupted
hat a medication .modified through a prescribed regimen of CI)	Drug Withdrawn
of a value is not current context. (NCI)	Not Applicable
it observed, not efused. (NCI)	Unknown

ADDING A NEW CDISC CONTROLLED TERMINOLOGY VERSION



RAW CDISC CONTROLLED TERMINOLOGY FILE

Code	Codelist Code	Codelist Extensible (Yes/No)	Codelist Name	CDISC Submission Value	CDISC Syno	CDISC Synonym(s)		NCI Preferred Term
C66767		No	Action Taken with Study Treatment	ACN	Action Taken Study Treatm	Action Taken with Study Treatment	atment	CDISC SDTM Action Taken with Study Treatment Terminology
C49503	C66767		Action Taken with Study Treatment	DOSE INCREASED			on addition; ency,	Dose Increased
C49504	C66767		Action Taken with Study Treatment	DOSE NOT CHANGED			on (NCI)	Dose Not Changed
C49505	C66767		Action Taken with Study Treatment	DOSE REDUCED			on	Dose Reduced
C49501	C66767		Action Taken with Study Treatment	DRUG INTERRUPTED			ing the int. (NCI)	Drug Interrupted
C49502	C66767		Action Taken with Study Treatment	DRUG WITHDRAWN			on temporarily imen of	Drug Withdrawn
C48660	C66767		Action Taken with Study Treatment	NOT APPLICABLE	NA		on enough regimen of	Not Applicable
C17998	C66767		Action Taken with Study Treatment	UNKNOWN	U; Unknown		ot xt. (NCI)	Unknown
						NA		
						U; Unknown		

ADDING A NEW CDISC CONTROLLED TERMINOLOGY VERSION



RAW CDISC CONTROLLED TERMINOLOGY FILE

Code		Codelist Code		CDISC Submission Value		CDISC Syno		CDISC Synonym(s)		NCI Preferred Term	
C66767				ACN		Action Taken	Study Treatm	Action Taken with Study Treatment		atment	CDISC SDTM Action Taken with Study Treatment Terminology
C49503	C66767			DOSE INCREASED						on addition; ency,	Dose Increased
C49504	C66767			DOSE NOT CHA						on (NCI)	Dose Not Changed
C49505	C66767			DOSE RED						on	Dose Reduced
C49501	C66767			DRUG INTERRUPT						ing the int. (NCI)	Drug Interrupted
C49502	C66767			DRUG WITHDRAWN						on temporarily imen of	Drug Withdrawn
C48660	C66767			NOT APPLICABLE	NA					on enough regimen of	Not Applicable
C17998	C66767			UNKNOWN	U; Unknown					ot xt. (NCI)	Unknown
NA								NA			
U; Unknown								U; Unknown			

ADDING A NEW CDISC CONTROLLED TERMINOLOGY VERSION



RAW CDISC CONTROLLED TERMINOLOGY FILE

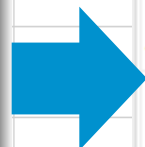
				CDISC Definition			
Code	Codelist Code	Codelist Extensible (Yes/No)	Codelist Name	Action Taken with Study Treatment	Term(s)	CDISC Definition	NCI Preferred Term
C66767		No	Action Taken w Treatment	An indication that a medication schedule was modified by addition; either by changing the frequency, strength or amount. (NCI)	with nt	Action Taken with Study Treatment	CDISC SDTM Action Taken with Study Treatment Terminology
C49503	C66767		Action Taken w Treatment	An indication that a medication schedule was maintained. (NCI)		An indication that a medication schedule was modified by addition; either by changing the frequency, strength or amount. (NCI)	Dose Increased
C49504	C66767		Action Taken w Treatment	An indication that a medication schedule was modified by subtraction, either by changing the frequency, strength or amount. (NCI)		An indication that a medication schedule was maintained. (NCI)	Dose Not Changed
C49505	C66767		Action Taken w Treatment	An indication that a medication schedule was modified by temporarily terminating a prescribed regimen of medication. (NCI)		An indication that a medication schedule was modified by subtraction, either by changing the frequency, strength or amount. (NCI)	Dose Reduced
C49501	C66767		Action Taken w Treatment	An indication that a medication schedule was modified through termination of a prescribed regimen of medication. (NCI)		An indication that a medication schedule was modified by temporarily terminating a prescribed regimen of medication. (NCI)	Drug Interrupted
C49502	C66767		Action Taken w Treatment	Determination of a value is not relevant in the current context. (NCI)		An indication that a medication schedule was modified through termination of a prescribed regimen of medication. (NCI)	Drug Withdrawn
C48660	C66767		Action Taken w Treatment	Not known, not observed, not recorded, or refused. (NCI)		Determination of a value is not relevant in the current context. (NCI)	Not Applicable
C17998	C66767		Action Taken w Treatment			Not known, not observed, not recorded, or refused. (NCI)	Unknown

ADDING A NEW CDISC CONTROLLED TERMINOLOGY VERSION



RAW CDISC CONTROLLED TERMINOLOGY FILE

Code	Codelist Code	Codelist Extensible (Yes/No)	CDISC Definition	CDISC Synonym
C66767		No	Action Taken with Study Treatment	
C49503	C66767		An indication that a medication schedule was modified by addition; either by changing the frequency, strength or amount. (NCI)	
C49504	C66767		An indication that a medication schedule was maintained. (NCI)	
C49505	C66767		An indication that a medication schedule was modified by subtraction, either by changing the frequency, strength or amount. (NCI)	
C49501	C66767		An indication that a medication schedule was modified by temporarily terminating a prescribed regimen of medication. (NCI)	
C49502	C66767		An indication that a medication schedule was modified through termination of a prescribed regimen of medication. (NCI)	
C48660	C66767		Determination of a value is not relevant in the current context. (NCI)	NA
C17998	C66767		Not known, not observed, not recorded, or refused. (NCI)	U; Unknown



ADDING A NEW CDISC CONTROLLED TERMINOLOGY VERSION



RAW CDISC CONTROLLED TERMINOLOGY FILE

Code	Codelist Code	Codelist Extensible (Yes/No)	Codelist Name	CDISC Submission Value	CDISC Submission Value
C66767		No	Action Taken with Study Treatment	ACN	Action Study
C49503	C66767		Action Taken with Study Treatment	DOSE INCREASED	
C49504	C66767		Action Taken with Study Treatment	DOSE NOT CHANGED	
C49505	C66767		Action Taken with Study Treatment	DOSE REDUCED	
C49501	C66767		Action Taken with Study Treatment	DRUG INTERRUPTED	
C49502	C66767		Action Taken with Study Treatment	DRUG WITHDRAWN	
C48660	C66767		Action Taken with Study Treatment	NOT APPLICABLE	NA
C17998	C66767		Action Taken with Study Treatment	UNKNOWN	U; Un

NCI Preferred Term
CDISC SDTM Action Taken with Study Treatment Terminology
Dose Increased
Dose Not Changed
Dose Reduced
Drug Interrupted
Drug Withdrawn
Not Applicable
Unknown

NCI Preferred Term
Treatment
CDISC SDTM Action Taken with Study Treatment Terminology
Dose Increased
Dose Not Changed
Dose Reduced
Drug Interrupted
Drug Withdrawn
Not Applicable
Unknown

ADDING A NEW CDISC CONTROLLED TERMINOLOGY VERSION



RAW CDISC CONTROLLED TERMINOLOGY FILE

nci_preferred_term		DISC Submission Value		CDISC	NCI Preferred Term	NCI Preferred Term	
Code	Codelist Code				CDISC SDTM Action Taken with Study Treatment Terminology	Treatment	CDISC SDTM Action Taken with Study Treatment Terminology
C66767		Dose Increased		CN	Dose Increased		Dose Increased
C49503	C66767	Dose Not Changed		DSE INCREASED		ation y addition; quency,	Dose Increased
C49504	C66767	Dose Reduced		DSE NOT CHANGED	Dose Not Changed	ation , (NCI)	Dose Not Changed
C49505	C66767	Dose Reduced		DSE REDUCED	Dose Reduced	ation y ng the ount. (NCI)	Dose Reduced
C49501	C66767	Drug Interrupted		DRUG INTERRUPTED	Drug Interrupted	ation y temporarily egimen of	Drug Interrupted
C49502	C66767	Drug Interrupted		DRUG WITHDRAWN	Drug Interrupted	ation rough d regimen of	Drug Withdrawn
C48660	C66767	Drug Withdrawn		OT APPLICABLE	Drug Withdrawn	s not ntext. (NCI)	Not Applicable
C17998	C66767	Not Applicable		UNKNOWN	Unknown	, not 'd)	Unknown
		Unknown			Not Applicable		
					Unknown		



ADDING A NEW CDISC CONTROLLED TERMINOLOGY VERSION



RESTRUCTURED CDISC CONTROLLED TERMINOLOGY

codelist	codelist_code	cdisc_submission_value	codelist_extensible	code
ACN	C66767	DOSE INCREASED	No	C49503
ACN	C66767	DOSE NOT CHANGED	No	C49501
ACN	C66767	DOSE REDUCED	No	C49502
ACN	C66767	DRUG INTERRUPTED	No	C49504
ACN	C66767	DRUG WITHDRAWN	No	C49502
ACN	C66767	NOT APPLICABLE	No	C48660
ACN	C66767	UNKNOWN	No	C17998

ADDING A NEW CDISC CONTROLLED TERMINOLOGY VERSION



RESTRUCTURED CDISC CONTROLLED TERMINOLOGY

	codelist_name	cdisc_synonym_s_	cdisc_definition	nci_preferred_term
	Action Taken with Study Treatment		An indication that a medication schedule was modified by addition; either by changing the frequency, strength or amount. (NCI)	Dose Increased
	Action Taken with Study Treatment		An indication that a medication schedule was maintained. (NCI)	Dose Not Changed
	Action Taken with Study Treatment		An indication that a medication schedule was modified by subtraction, either by changing the frequency, strength or amount. (NCI)	Dose Reduced
1	Action Taken with Study Treatment		An indication that a medication schedule was modified by temporarily terminating a prescribed regimen of medication. (NCI)	Drug Interrupted
2	Action Taken with Study Treatment		An indication that a medication schedule was modified through termination of a prescribed regimen of medication. (NCI)	Drug Withdrawn
0	Action Taken with Study Treatment	NA	Determination of a value is not relevant in the current context. (NCI)	Not Applicable
	Action Taken with Study Treatment	U; Unknown	Not known, not observed, not recorded, or refused. (NCI)	Unknown

ADDING A NEW CDISC CONTROLLED TERMINOLOGY VERSION



REGISTER AND IMPORT NEW CONTROLLED TERMINOLOGY VERSION

- Update standardsubtypes data set

ADDING A NEW CDISC CONTROLLED TERMINOLOGY VERSION



REGISTER AND IMPORT NEW CONTROLLED TERMINOLOGY VERSION

- Update standardsubtypes data set

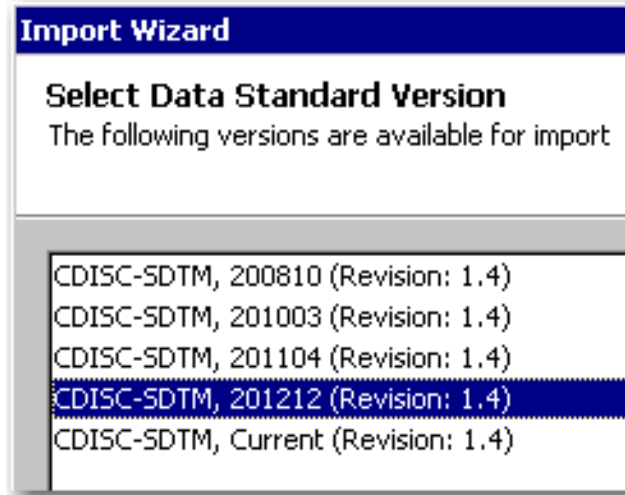
See Paper!

ADDING A NEW CDISC CONTROLLED TERMINOLOGY VERSION

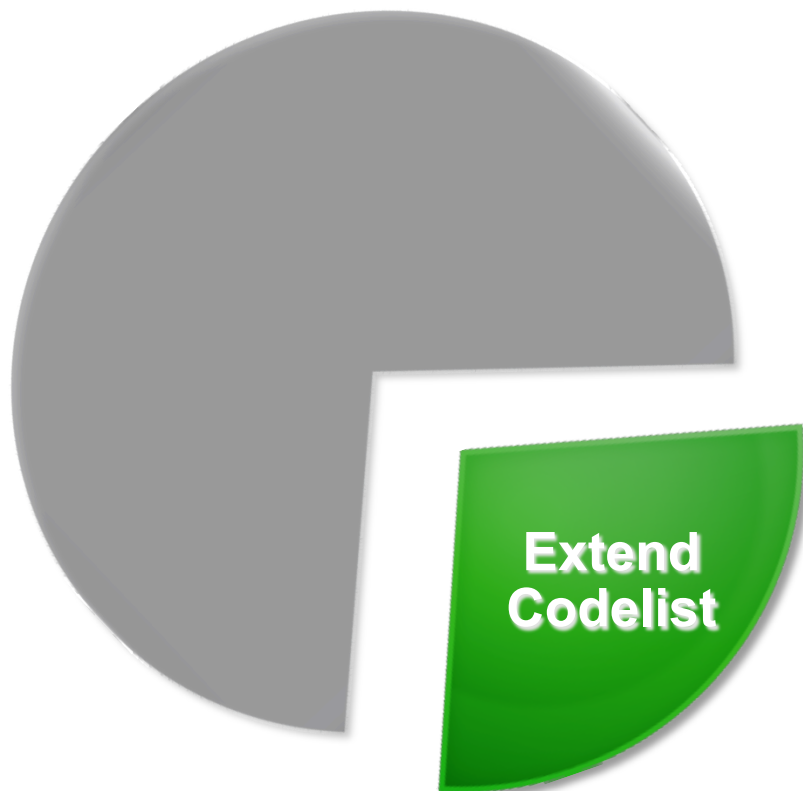


REGISTER AND IMPORT NEW CONTROLLED TERMINOLOGY VERSION

- Update standardsubtypes data set
- New CDISC Controlled Terminology version available in the Data Standards Import Wizard



EXTENDING CDISC CONTROLLED TERMINOLOGY CODELISTS

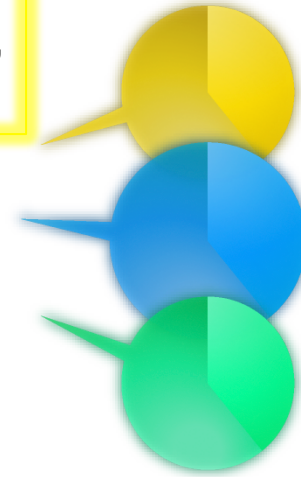


EXTENDING CDISC CONTROLLED TERMINOLOGY CODELISTS



WHY?

Some codelists are extensible
so that sponsors may add new,
non-duplicate values



EXTENDING CDISC CONTROLLED TERMINOLOGY CODELISTS



WHY?

Some codelists are extensible
so that sponsors may add new,
non-duplicate values

Add custom terms needed for
a study



EXTENDING CDISC CONTROLLED TERMINOLOGY CODELISTS



WHY?

Some codelists are extensible
so that sponsors may add new,
non-duplicate values

Add custom terms needed for
a study

Incorporate standard terms
from a newer CDISC
terminology release



EXTENDING CDISC CONTROLLED TERMINOLOGY CODELISTS



EXAMPLE: FRM CODELIST

- Pharmaceutical Dosage Form
- Study Drug is a Caplet

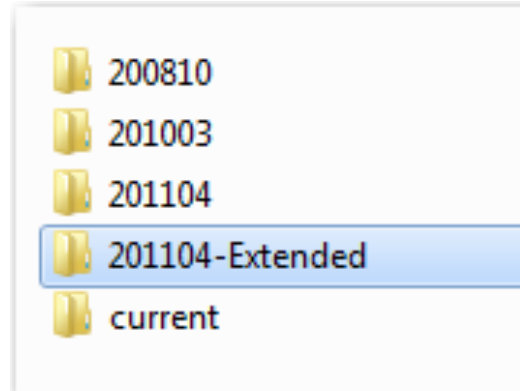
codelist	codelist_code	cdisc_submission_value	codelist_extensible
FRM	C66726	BEAD, IMPLANT, EXTENDED RELEASE	Yes
FRM	C66726	BLOCK	Yes
FRM	C66726	CAPSULE	Yes
FRM	C66726	CAPSULE, COATED	Yes
FRM	C66726	CAPSULE, COATED PELLETS	Yes
FRM	C66726	CAPSULE, COATED, EXTENDED RELEASE	Yes

EXTENDING CDISC CONTROLLED TERMINOLOGY CODELISTS



HOW-TO

- Make a new folder for the extended controlled terminology data set



EXTENDING CDISC CONTROLLED TERMINOLOGY CODELISTS



HOW-TO

- Make a new folder for the extended controlled terminology data set
- Insert new terms using data step programming

```
libname term2011 'C:\cstlibrarypath\201104\formats';  
libname termext 'C:\cstlibrarypath\201104-Extended\formats';
```

```
data newterms;  
    ...  
run;
```

```
data combinedterms;  
    set term2011.terms newterms;  
run;
```

```
proc sort data=combinedterms out=termext.terms;  
    by codelist code;  
run;
```

EXTENDING CDISC CONTROLLED TERMINOLOGY CODELISTS



HOW-TO

- Make a new folder for the extended controlled terminology data set
- Insert new terms using data step programming
- Register the new controlled terminology data set in standardsubtypes dataset

EXTENDING CDISC CONTROLLED TERMINOLOGY CODELISTS



HOW-TO

- Make a new folder for the extended controlled terminology data set
- Insert new terms using data step programming
- Register the new controlled terminology data set in standardsubtypes dataset

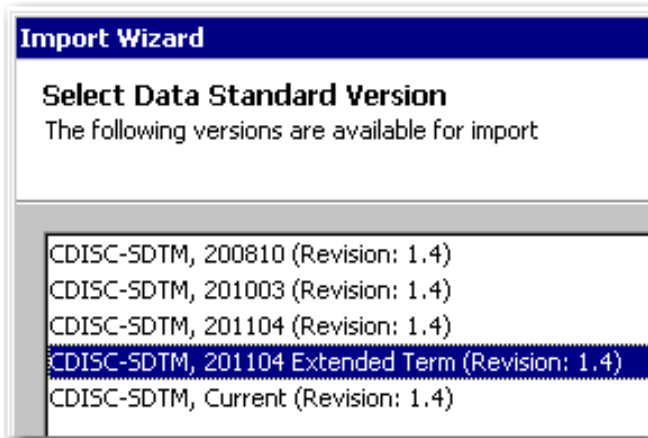
See Paper!

EXTENDING CDISC CONTROLLED TERMINOLOGY CODELISTS

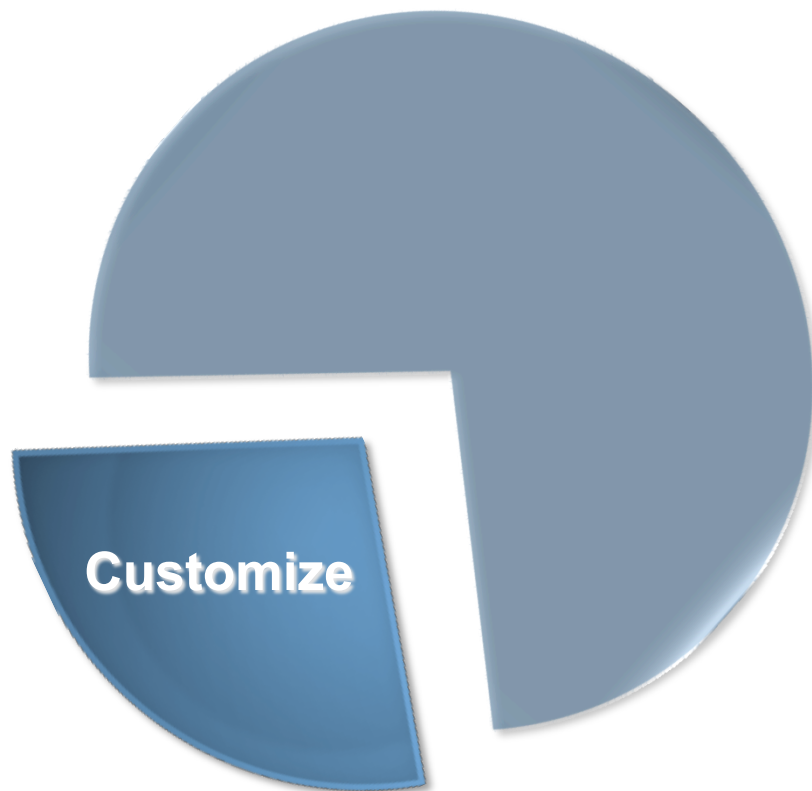


HOW-TO

- Make a new folder for the extended controlled terminology data set
- Insert new terms using data step programming
- Register the new controlled terminology data set in standardsubtypes dataset
- Import controlled terminology into CDI



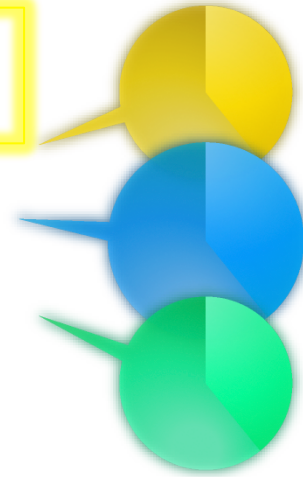
CUSTOMIZING CONTROLLED TERMINOLOGY FOR A STUDY



CUSTOMIZING CONTROLLED TERMINOLOGY FOR A STUDY

WHY?

Codelists should contain only
possible values for a study



CUSTOMIZING CONTROLLED TERMINOLOGY FOR A STUDY

WHY?

Codelists should contain only
possible values for a study

Catch invalid values accurately
with compliance checks



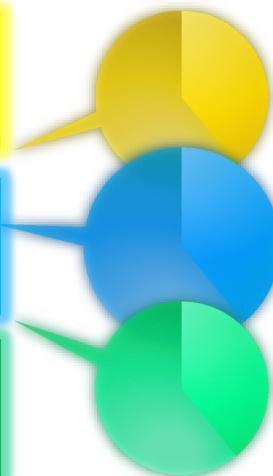
CUSTOMIZING CONTROLLED TERMINOLOGY FOR A STUDY

WHY?

Codelists should contain only *possible* values for a study

Catch invalid values accurately with compliance checks

Create a better, more accurate define.xml



CUSTOMIZING CONTROLLED TERMINOLOGY FOR A STUDY

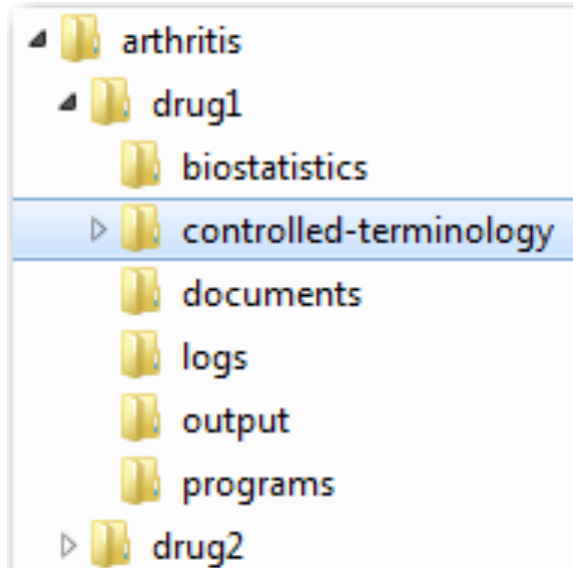
EXAMPLE: COUNTRY CODELIST

Codelist Name ▼	CDISC Submission Value ▼	CDISC Synonym(s) ▼
Country	COUNTRY	Country
Country	ABW	ARUBA
Country	AFG	AFGHANISTAN
Country	AGO	ANGOLA
Country	AIA	ANGUILLA
Country	ALA	ALAND ISLANDS
Country	ALB	ALBANIA
Country	ZAF	SOUTH AFRICA
Country	ZMB	ZAMBIA
Country	ZWE	ZIMBABWE

CUSTOMIZING CONTROLLED TERMINOLOGY FOR A STUDY

HOW-TO

- Make a new folder for the study-specific controlled terminology data set



CUSTOMIZING CONTROLLED TERMINOLOGY FOR A STUDY

HOW-TO

- Make a new folder for the study-specific controlled terminology data set
- Remove unneeded terms using data step programming

```
libname term2011 'C:\cstlibrarypath\201104\formats';  
libname locterm 'C:\arthritis\drug1\controlled-terminology\formats';  
  
data locterm.cterms;  
  set term2011.cterms;  
  if codelist_code="C66786" and code not in ("C16850","C17234") then delete;  
run;
```

CUSTOMIZING CONTROLLED TERMINOLOGY FOR A STUDY

HOW-TO

- Make a new folder for the study-specific controlled terminology data set
- Remove unneeded terms using data step programming
- Register the study-specific controlled terminology data set in standardsubtypes dataset



CUSTOMIZING CONTROLLED TERMINOLOGY FOR A STUDY



HOW-TO

- Make a new folder for the study-specific controlled terminology data set
- Remove unneeded terms using data step programming
- Register the study-specific controlled terminology data set in standardsubtypes dataset

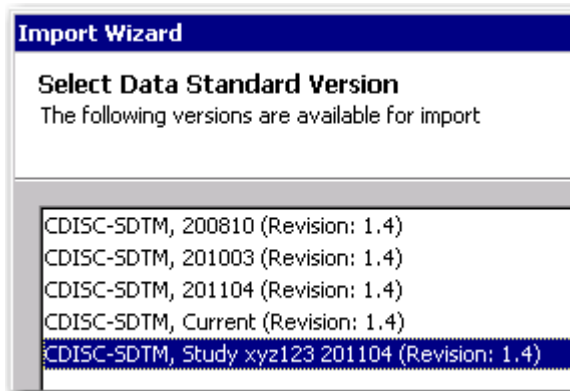
See Paper!

CUSTOMIZING CONTROLLED TERMINOLOGY FOR A STUDY



HOW-TO

- Make a new folder for the study-specific controlled terminology data set
- Remove unneeded terms using data step programming
- Register the study-specific controlled terminology data set in standardsubtypes dataset
- Import controlled terminology into CDI



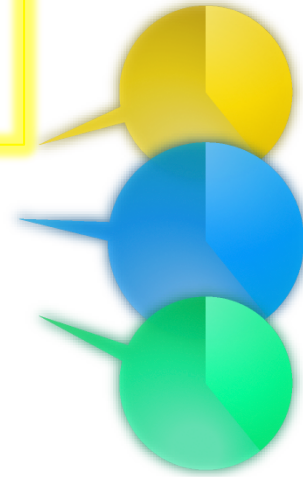
EXTERNAL DATA DICTIONARIES



EXTERNAL DATA DICTIONARIES

WHY?

Perform one more quality
check on data values through
compliance checks

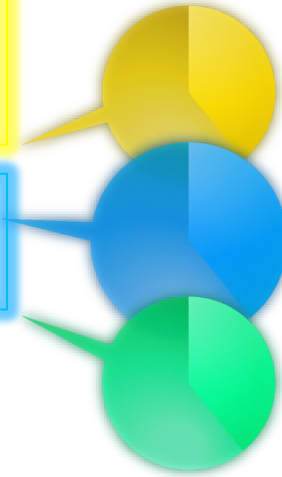


EXTERNAL DATA DICTIONARIES

WHY?

Perform one more quality
check on data values through
compliance checks

Ability to use several different
data dictionaries



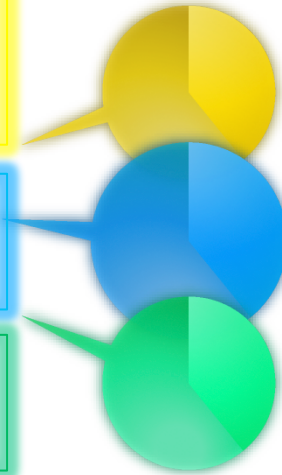
EXTERNAL DATA DICTIONARIES

WHY?

Perform one more quality
check on data values through
compliance checks

Ability to use several different
data dictionaries

Ability to use several versions
of a dictionary



EXTERNAL DATA DICTIONARIES

EXAMPLE: MEDDRA



```
soc.asc - Notepad
File Edit Format View Help
10005329$Blood and lymphatic system disorders$Blood$$$$$$$
10007541$Cardiac disorders$Card$$$$$$$
10010331$Congenital, familial and genetic disorders$Cong$$$$$$$
10013993$Ear and labyrinth disorders$Ear$$$$$$$
10014698$Endocrine disorders$Endo$$$$$$$
10015919$Eye disorders$Eye$$$$$$$
10017947$Gastrointestinal disorders$Gastr$$$$$$$
10018065$General disorders and administration site conditions$Genrl$$$$$$$
10019805$Hepatobiliary disorders$Hepat$$$$$$$
10021428$Immune system disorders$Immun$$$$$$$
10021881$Infections and infestations$Infec$$$$$$$
10022117$Injury, poisoning and procedural complications$Inj&P$$$$$$$
10022891$Investigations$Inv$$$$$$$
10027433$Metabolism and nutrition disorders$Metab$$$$$$$
```

HOW-TO

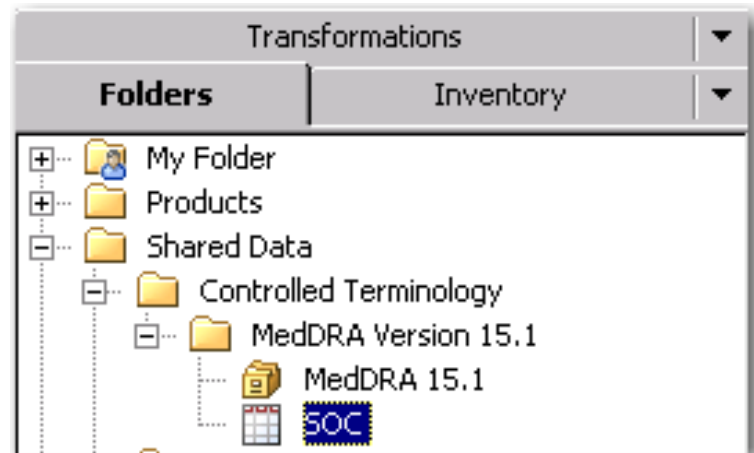
- Convert raw data file to SAS data set



soc_code	soc_name	soc_abbrev
10005329	Blood and lymphatic system disorders	Blood
10007541	Cardiac disorders	Card
10010331	Congenital, familial and genetic disorders	Cong
10013993	Ear and labyrinth disorders	Ear
10014698	Endocrine disorders	Endo
10015919	Eye disorders	Eye
10017947	Gastrointestinal disorders	Gastr
10018065	General disorders and administration site conditions	Genrl
10019805	Hepatobiliary disorders	Hepat
10021428	Immune system disorders	Immun
10021881	Infections and infestations	Infec

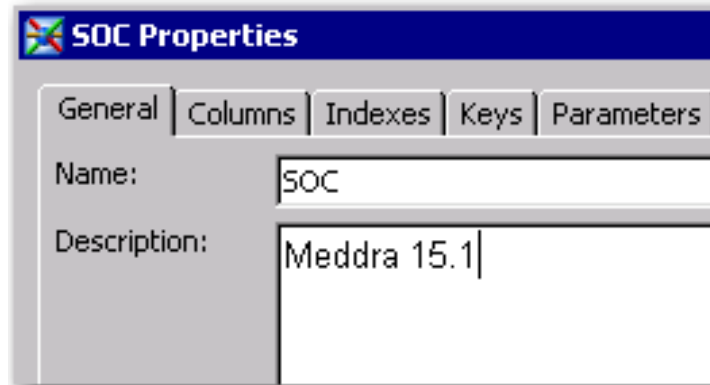
HOW-TO

- Convert raw data file to SAS data set
- Register table in CDI



HOW-TO

- Convert raw data file to SAS data set
- Register table in CDI



The image shows a dialog box titled "SOC Properties". It has a tabbed interface with tabs for "General", "Columns", "Indexes", "Keys", and "Parameters". The "General" tab is selected. Inside the "General" tab, there are two text input fields: "Name:" with the value "SOC" and "Description:" with the value "Meddra 15.1".

EXTERNAL DATA DICTIONARIES

HOW-TO

- Convert raw data file to SAS data set
- Register table in CDI
- Add to a terminology package



New Terminology Package

Terminology Sets
Specify the terminology datasets for the new Terminology Package

Selected datasets:

Name	Source Library	Description
SOC	MedDRA 15.1	Meddra 15.1

CONCLUSION



CONCLUSION

- Increase data quality in submission data sets
- Make define.xml file more complete and accurate
- Please read full paper for complete details, available in the conference proceedings

MELISSA R. MARTINEZ
SAS INSTITUTE, INC.

MELISSA.MARTINEZ@SAS.COM



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POWER
TO KNOW®**