

Controlling Controlled Terminology

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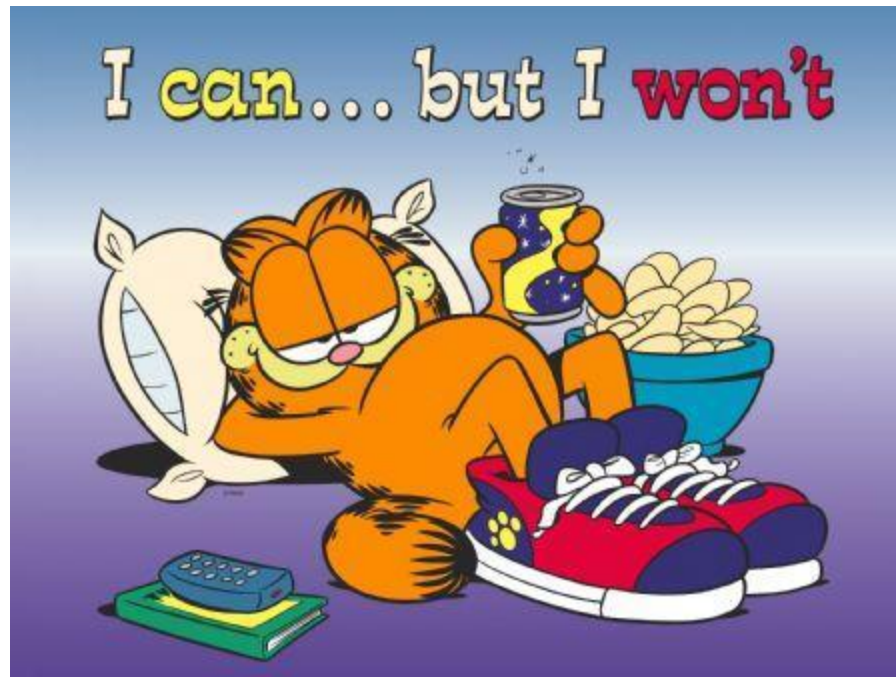
NEVER HAVE I FELT SO
CLOSE TO ANOTHER SOUL
AND YET SO HELPLESSLY ALONE
AS WHEN I GOOGLE AN ERROR
AND THERE'S ONE RESULT
A THREAD BY SOMEONE
WITH THE SAME PROBLEM
AND NO ANSWER
LAST POSTED TO IN 2003



Metadata

- Extra work
- Required
- Trendy buzzword
- Useful

Laziness, Alias Efficiency



Keys to Laziness

- Do it right
- Automate
- Do it once
- Use tools
- Copy and steal

The Old Ways

So I called this meeting today because the developers say they need our marketing data for their software. Unfortunately, all the data is stuck in an Access database, and I don't know how to use Access, so we have to figure something out. Any ideas?



Access?! If they wanted a database, then why didn't they just use Word?



You idiot! Word is a spreadsheet program. Obviously, we need to somehow get this data into Excel.



I know! I know!
We could cut and paste!
I know how to cut and paste. We could do that!



No! No cutting!
Remember what happened last time?
Look at my stump!



Ooooooh! I know!
We could print out the data, scan it in, and then paste the image into Excel!



The Old Ways' Problems

- Not reliably machine-readable
- Sharing is difficult
- Changes are painful and hard to track
- Easy to lose standards and keep bad habits
- Redundancy

Rho Metaspecer

- Oracle database
- Access user interface
- Assigns variable attributes, prints specifications, and creates define files
- Links to standards
- Sharing between studies
- Prompts, lists, and shortcuts

Metaspecer Interface

Rho [®] SDTM Variable Definitions for End To End Study															Menu
															Print Domains
Edit Value-Level															Domain: All
☐ = Required or Expected in SDTM-IG 3.1.2															
id	varName	sc	Label	SubmitDB	ODMType	Core	Tyr	Len	CRFloc	Origin	Role	CT	ProgDef	FDAdef	LastEditDateTime
AE	AELOC	15	Location of Event	☐	text	Perm	Char			CRF or Derived	Record Qualifier	(LOC)			3/23/2011 4:59:08 PM
AE	AESEV	16	Severity/Intensity	☒	text	Perm	Char	40	Adverse Events_200	CRF	Record Qualifier	(AESEV)	=RAW.AE.AESEV = UNKNOWN if RAW.AE.AESEV=UNKNOWN or UK		4/19/2012 5:48:10 PM
AE	AESEV	17	Serious Event	☒	text	Exp	Char	1	Adverse Events_200	CRF	Record Qualifier	(NY)	=RAW.AE.AESER		1/11/2012 7:52:15 PM
AE	AEACN	18	Action Taken with Study Treatment	☒	text	Exp	Char	40	Adverse Events_200	CRF	Record Qualifier	(ACN)	Recode RAW.AE.AEACN as follows: NONE = DOSE NOT CHANGED STUDY DRUG DISCONTINUED = DRUG WITHDRAWN		3/13/2012 1:47:54 PM
AE	AEACNOTH	19	Other Action Taken	☐	text	Perm	Char			CRF	Record Qualifier				
AE	AEREL	20	Causality	☒	text	Exp	Char	40	Adverse Events_200	CRF	Record Qualifier	(REL)	=RAW.AE.AEREL Recode 'UK' to 'UNKNOWN'.		3/23/2012 11:21:13 AM
AE	AERELNST	21	Relationship to Non-Study Treatment	☐	text	Perm	Char			CRF	Record Qualifier				
AE	AEPATT	22	Pattern of Adverse Event	☐	text	Perm	Char			CRF	Record Qualifier	*			
AE	AEOUT	23	Outcome of Adverse Event	☒	text	Perm	Char	40	Adverse Events_200	CRF	Record Qualifier	(OUT)	Recode RAW.AE.AEOUT as follows: RECOVERED = RECOVERED/RESOLVED ADVERSE EVENT STILL PRESENT = NOT RECOVERED/NOT RESOLVED		3/13/2012 1:48:12 PM
AE	AESCAN	24	Involves Cancer	☐	text	Perm	Char	1		CRF	Record	(NY)			3/23/2011 5:04:22 PM

Record: 1 of 1014

No Filter

Search

Metaspecer Database

Studies

IDSTUDY	STUDYTITLE	PROTOCOL	COMPOUND	PROJROOTDIR	FIELDSUSED-VARIABLESTABLE	FIELDSUSED-DATASETSTABLE	STUDYCREATION DATETIME	STUDYCREATED BY	RELSTUDS	SDTMVERSION NUMBER	LBLVARS_CUSTOM_TXT1	LBLDSNS_CUSTOM_TXT1
1412	End To End	9999-ABC-999	ETOE	Q\ETOE	VARNAME, IDDOMAIN, FDADEFINITION, CUSTOM_TXT1,...	DOMAIN, PURPOSE, STRUCTURE, KEYS, CLASS, CUSTOM_TXT1,...	6/6/2012 4:44:40 PM	r70818		3.1.2	SAPRef	CRFPages

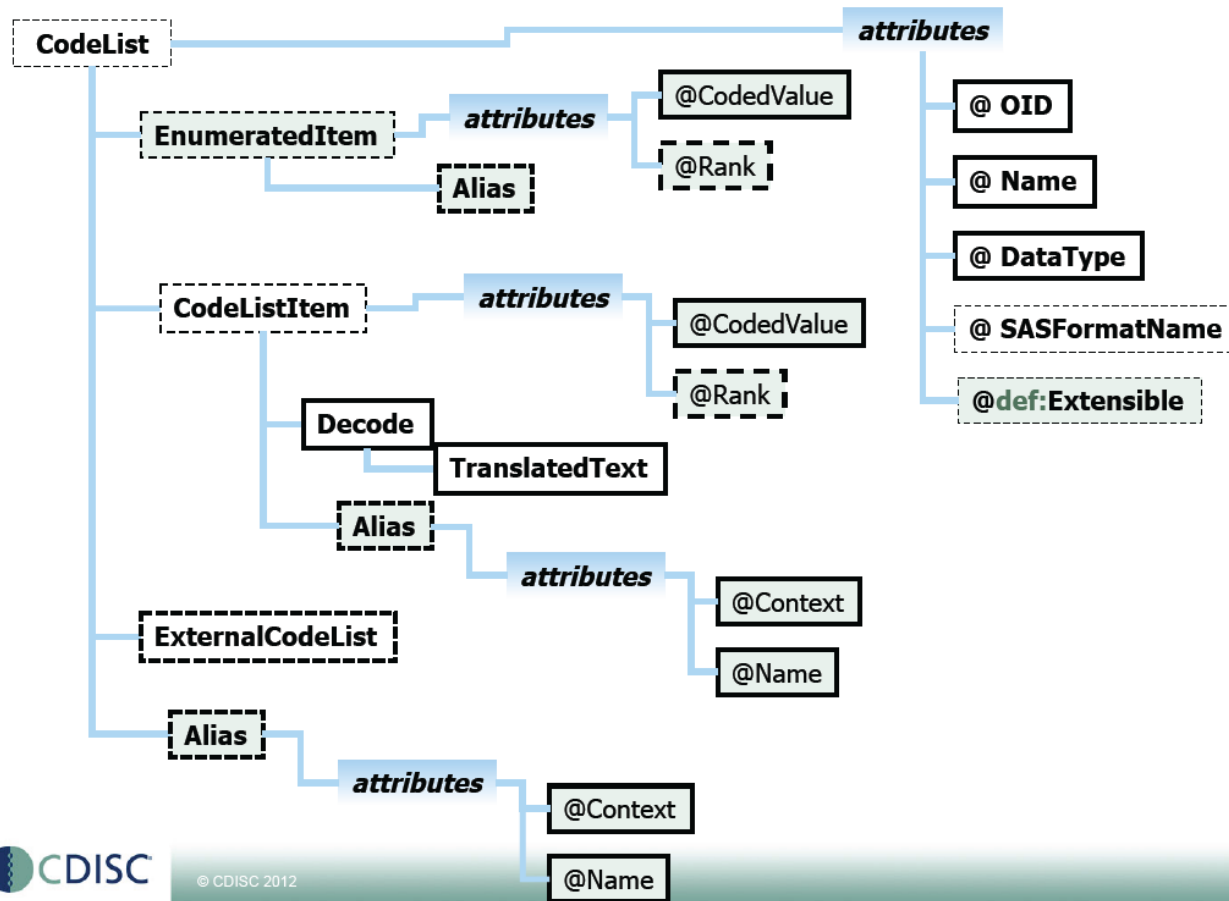
Datasets

idDomain	Domain	submitDB	Purpose	Structure	Keys	class	Description	input_notes	output_notes	CRFPages	lastEditDateTime	lastEditedBy
122705	AE	Yes	Tabulation	One record per adverse event per subject	STUDYID, USUBJID, AETERM, AESTDTC	Events	Adverse Events	Input dataset is RAW.AE. Subset where RAW.AE.AETERM is not missing.	Keep only subjects present in DM where ARMCD ne 'SCRNFIL'.		9/6/2012 12:53:02 PM	r70818

Variables

idVariables	idDomain	varName	sortOrder	label	submitDB	Core	ODMType	type	length	Origin	Role	CT	progDef	FDAdef	SAPRef
5673926	122705	AELOC	15	Location of Event	No	Perm	text	Char		CRF or Derived	Record Qualifier	24			
5673941	122705	AESEV	16	Severity/Intensity	Yes	Perm	text	Char	40	CRF	Record Qualifier	4	=RAW.AE.AESEV = UNKNOWN if RAW.AE.AESEV=UNKNOWN or UK		
5673913	122705	AEACN	18	Action Taken with Study Treatment	Yes	Exp	text	Char	40	CRF	Record Qualifier	51	Recode RAW.AE.AEACN as follows: NONE = DOSE NOT CHANGED STUDY DRUG DISCONTINUED = DRUG WITHDRAWN STUDY DRUG INTERRUPTED = DRUG INTERRUPTED UNKNOWN or UK = UNKNOWN		
5673914	122705	AEACNOTH	19	Other Action Taken	No	Perm	text	Char		CRF	Record Qualifier				
5673932	122705	AEREL	20	Causality	Yes	Exp	text	Char	40	CRF	Record Qualifier	71	=RAW.AE.AEREL Recode 'UK' to 'UNKNOWN'.		
5673933	122705	AERELNST	21	Relationship to Non-Study Treatment	No	Perm	text	Char		CRF	Record Qualifier				

Controlled Terminology



Controlled Terminology

- Enumerated items
- Coded lists
- External codelists
- Attributes
- No study or variable information

CT Interface

 **Controlled Terminology Selection** [Close](#)

CT: AESEV (A scale that defines the degree or state of disease existing in a patient as a result of the occurrence of an adverse event. (NCI)) [Edit Description](#)

UseValue	SubmissionValue	OKtoChange	Name	Sort Order	Input Code
☒	MILD	N	AESEV	1	
☒	MODERATE	N	AESEV	2	
☒	SEVERE	N	AESEV	3	

Record: 1 of 3 [No Filter](#)

CT Database

Lists

IDCTNAMES	LISTNAME	NCILIST CODE	LISTDESCRIPTION	EXTENSIBLE	LISTCUSTOM	LISTSYNONYM	LISTVERSION	NCITYPE	LISTNCIPREFTERM	LISTPREFTERM	FMTNAME
4	AESEV	C66769	A scale that defines the degree or state of disease existing in a patient as a result of the occurrence of an adverse event. (NCI)	N		Severity/Intensity Scale for Adverse Events			CDISC SDTM Severity Intensity Scale for Adverse Event Terminology	AESEV	\$AESEV
71	REL		Relationship	Y	1						

CT Database Values

IDCTVALUES	IDCTNAMES	CVALVALUE	CVALCODE	CVAL SORTORDER	CVAL CUSTOM	NCICODE	CVALDEFINITION	CVAL NCIPREFTERM	CVAL PREFTERM
21	4	SEVERE		3	0	C41340	A type of adverse event that interrupts usual activities of daily living, or significantly affects clinical status, or may require intensive therapeutic intervention.	Severe Adverse Event	SEVERE
20	4	MODERATE		2	0	C41339	A type of adverse event that is usually alleviated with additional specific therapeutic intervention. The event interferes with usual activities of daily living, causing discomfort but poses no significant or permanent risk of harm to the research participant.	Moderate Adverse Event	MODERATE
19	4	MILD		1	0	C41338	A type of adverse event that is usually transient and may require only minimal treatment or therapeutic intervention. The event does not generally interfere with usual activities of daily living.	Mild Adverse Event	MILD
18	71	UNKNOWN		6	1				
17	71	DEFINITE		5	1				
16	71	PROBABLE		4	1				
15	71	POSSIBLE		3	1				
14	71	UNLIKELY		2	1				
7	71	NOT RELATED		1	1				

Metaspecer Interface

CT Used

Rho® SDTM Variable Definitions for End To End Study

[Edit Value-Level](#) ☐ = Required or Expected in SDTM-IG 3.1.2

idD	varName	sc	Label	SubmitDB	ODMTType	Core	Typ	Len	CRFloc	Origin	Role	CT	ProgDef
AE	AELOC	15	Location of Event		text	Perm	Char			CRF or Derived	Record Qualifier	(LOC)	
AE	AESEV									RF	Record Qualifier	(AESEV)	=RAW.AE.AESEV = UNKNOWN if RAW.AE.AESEV=UK
AE	AESEV									RF	Record Qualifier	(NY)	=RAW.AE.AESER
AE	AEACN									RF	Record Qualifier	(ACN)	Recode RAW.AE.AEACN as foll NONE = DOSE NOT CHANGED STUDY DRUG DISCONTINUED = I WITHDRAWN
AE	AEACNOTH									RF	Record Qualifier		
AE	AEREL									RF	Record Qualifier	(REL)	=RAW.AE.AEREL Recode 'UK' to 'UNKNOWN'.
AE	AERELNST									RF	Record Qualifier		

Rho® Controlled Terminology Selection [Close](#)

CT: AESEV (A scale that defines the degree or state of disease existing in a patient as a result of the occurrence of an adverse event. (NCI)) [Edit Description](#)

UseValue	SubmissionValue	OKtoChange	Name	Sort Order	Input Code
☒	MILD	N	AESEV		1
☒	MODERATE	N	AESEV		2
☒	SEVERE	N	AESEV		3

Record: 1 of 3 [No Filter](#)

CT Database Used

IDCTUSED	IDSTUDY	IDCTVALUES	USEDPCODE	USEDSORT
32	941	21		
31	941	20		
28	941	19		
30	941	18	99	0
33	941	17	4	
34	941	16	3	
35	941	15	2	
29	941	14	1	
27	941	7	0	

CT Database Stitched Together

IDSTUDY	IDCTUSED	LISTNAME	CVALVALUE	CVALCODE	CVALSORTORDER	USEDSCODE	USEDSORT	IDCTNAMES	IDCTVALUES	NCILISTCODE	LISTVERSION	LISTCUSTOM	LISTDESCRIPTION	NCITYPE	EXTENSIBLE	LISTNCIPREFTERM	LISTPREFTERM	LISTSYNONYM	FMNAME	NCICODE	CVALCUSTOM	CVALDEFINITION	CVALNCIPREFTERM	CVALPREFTERM
941	32	AESEV	SEVERE	3				4	21	C66769			A scale that defines the degree or state of disease existing....	N		CDISC SDTM Severity Intensity Scale for Adverse Event Terminology	AESEV	Severity/Intensity Scale for Adverse Events	\$AESEV	C41340	0	A type of adverse event that interrupts usual activities....	Severe Adverse Event	SEVERE
941	31	AESEV	MODERATE	2				4	20	C66769			A scale that defines the degree or state of disease....	N		CDISC SDTM Severity Intensity Scale for Adverse Event Terminology	AESEV	Severity/Intensity Scale for Adverse Events	\$AESEV	C41339	0	A type of adverse event that is usually alleviated with additional specific....	Moderate Adverse Event	MODERATE
941	28	AESEV	MILD	1				4	19	C66769			A scale that defines the degree or state of disease existing....	N		CDISC SDTM Severity Intensity Scale for Adverse Event Terminology	AESEV	Severity/Intensity Scale for Adverse Events	\$AESEV	C41338	0	A type of adverse event that is usually transient and may....	Mild Adverse Event	MILD
941	30	REL	UNKNOWN	6	99	0	71	18				1	Relationship	Y							1			
941	33	REL	DEFINITE	5	4	5	71	17				1	Relationship	Y							1			
941	34	REL	PROBABLE	4	3	4	71	16				1	Relationship	Y							1			
941	35	REL	POSSIBLE	3	2	3	71	15				1	Relationship	Y							1			
941	29	REL	UNLIKELY	2	1	2	71	14				1	Relationship	Y							1			

Coconuts



Coconuts



Coconuts



Coconuts



Thank you for attending.

Send questions or comments to:

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