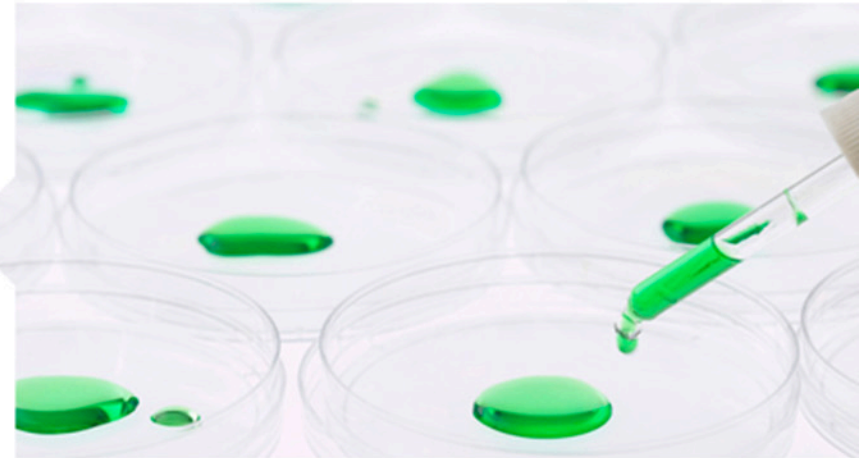




Considerations for CSR output production from ADaM datasets



Andrew Noller, 17th October 2012



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Agenda



- Introduction
- BDS Influence
- Listing Data Manipulation
- Precision Difference between table and listing
- Improved table summary production
- Conclusions

- When we are asked to implement CDISC standards on particular study data what are our immediate concerns?
 - > suitability of the CRF and database to provide SDTM friendly data
 - > unusual study designs or data domains
 - > number of ADaM datasets needed to allow sensible output production from dataset to table, listing or figure
- How much attention is given to the need for effective and efficient CSR output production?
- The ADaM IG v1.0 is clear in its purpose to ‘support efficient generation, replication and review of analysis results’
 - > a beneficial standardization of analysis variables and a basic data structure that encourages a repeatable approach to output programming
 - > prioritization of the statistical analysis element of outputs that support the key endpoints of a study

- The Basic Data Structure available to us in the ADaM IG is a structure that is well suited to Findings class SDTM datasets focussing on the parameter and results nature of these types of dataset
- **ADLB Unit Example**
 - > a study requires the lab data to be reported in both Conventional and SI units
 - > 2 different tables required to analyse each type of unit
 - > both in the same listing in 2 separate columns
 - > PARAM variable must include the units after the test details
 - > If we are to analyse the same parameter but with two unit options then two records will be required in the dataset to describe each subject, parameter, visit

BDS Influence

ADLB Unit Example



USUBJID	PARAM	PARAMCD
ABC-123-456	ALBUMIN (g/L), SI	SIALB
ABC-123-456	BLOOD UREA NITROGEN (mmol/L), SI	SIBUN
ABC-123-456	CALCIUM (mmol/L), SI	SICA
ABC-123-456	SERUM CREATININE (umol/L), SI	SICREAT
ABC-123-456	GAMMA-GT (U/L), SI	SIGGT
ABC-123-456	GLUCOSE (mmol/L), SI	SIGLUC
ABC-123-456	ALBUMIN (g/dL), US	USALB
ABC-123-456	BLOOD UREA NITROGEN (mg/dL), US	USBUN
ABC-123-456	CALCIUM (mg/dL), US	USCA
ABC-123-456	SERUM CREATININE (mg/dL), US	USCREAT
ABC-123-456	GAMMA-GT (U/L), US	USGGT
ABC-123-456	GLUCOSE (mg/dL), US	USGLUC

BDS Influence



ADLB Unit Example

- To produce the listing from this dataset we are asked to put both sets of results in the same listing
- Typically when creating a listing from a BDS dataset it could require a simple transpose of the data
- Listing column headers:

Subject Number | Lab Test | Visit | Result in SI Units | Unit | Result in Conventional Units | Unit

- The SDTM variables for lab test, standard units and original units (LBTEST, LBSTRESU and LBORRESU) are added to ADLB
- LBTEST instrumental in a successful transpose :

[SUBJID] [LBTEST] [VISIT] [AVAL, transposed] [LBSTRESU] [AVAL, transposed] [LBORRESU]
Subject Number | Lab Test | Visit | Result in SI Units | Unit | Result in Conventional Units | Unit

- Could this have been dealt with by listing directly from the SDTM dataset?

Listing only Example

- Sometimes an ADaM dataset needs to be produced to create only a single listing where the SDTM would have been sufficient
- Create ADPE on a BDS structure for 1 listing alone?
- Reasons for an ADaM dataset here:
 - > Requires merging of treatment and populations from your ADSL dataset in your listing program.
 - > If data does not fit the SDTM PE domain then this would go into the supplemental dataset SUPPPE
- Can we create analysis datasets for the purpose of only listing data that are not ADaM compliant datasets?

Listing Data Manipulation



- It is possible that the data that is entered into some listings may require some manipulation from the way it is recorded in the CRF
- Take Norfolk Quality of Life for Diabetic Neuropathy, one part of this asks patients if they have had symptoms in any of the following areas; feet, legs, hands, arms or none
- There are seven different symptom types (e.g. Numbness) and they can select one or more of these options

Listing Data Manipulation

Listing X.X.X
Norfolk Quality of Life - Diabetic Neuropathy – Part 1
(Randomized Subjects)

Treatment Group: <insert treatment group>								
Subject ID	Visit/ Date of Assessment	Numbness	Tingling, Pins and Needles	Electric Shocks	Other Unusual Sensations	Superficial Pain	Deep Pain	Weakness
xxxxxxxx	xxxx/ YYYY-MM-DD	Feet/ Legs	None	Feet/ Hands	Feet/ Legs/ Hands/ Arms	Arms	Feet/ Legs	Feet/ Legs
	xxxx/ YYYY-MM-DD	Feet/ Legs	Feet/ Legs	Feet/ Legs	Feet/ Legs	Feet/ Legs	Feet/ Legs	Feet/ Legs
	xxxx/ YYYY-MM-DD	Feet/ Legs	Feet/ Legs	Feet/ Legs	Feet/ Legs	Feet/ Legs	Feet/ Legs	Feet/ Legs
	xxxx/ YYYY-MM-DD	Feet/ Legs	Feet/ Legs	Feet/ Legs	Feet/ Legs	Feet/ Legs	Feet/ Legs	Feet/ Legs
	xxxx/ YYYY-MM-DD	Feet/ Legs	Feet/ Legs	Feet/ Legs	Feet/ Legs	Feet/ Legs	Feet/ Legs	Feet/ Legs
	xxxx/ YYYY-MM-DD	Feet/ Legs	Feet/ Legs	Feet/ Legs	Feet/ Legs	Feet/ Legs	Feet/ Legs	Feet/ Legs
	xxxx/ YYYY-MM-DD	Feet/ Legs	Feet/ Legs	Feet/ Legs	Feet/ Legs	Feet/ Legs	Feet/ Legs	Feet/ Legs
	xxxx/ YYYY-MM-DD	Feet/ Legs	Feet/ Legs	Feet/ Legs	Feet/ Legs	Feet/ Legs	Feet/ Legs	Feet/ Legs
	xxxx/ YYYY-MM-DD	Feet/ Legs	Feet/ Legs	Feet/ Legs	Feet/ Legs	Feet/ Legs	Feet/ Legs	Feet/ Legs

□

Listing Data Manipulation



PARAMCD	PARAM	PARAMN	AVAL	AVALC
SYMNUMBF	NUMBNESS - FEET	1.1	1	Y
SYMNUMBL	NUMBNESS - LEGS	1.2		
SYMNUMBH	NUMBNESS - HANDS	1.3	1	Y
SYMNUMBA	NUMBNESS - ARMS	1.4		
SYMNUMBN	NUMBNESS - NONE	1.5		
SYMTINGF	TINGLING, PINS AND NEEDLES - FEET	2.1		
SYMTINGL	TINGLING, PINS AND NEEDLES - LEGS	2.2	1	Y
SYMTINGH	TINGLING, PINS AND NEEDLES - HANDS	2.3		
SYMTINGA	TINGLING, PINS AND NEEDLES - ARMS	2.4		
SYMTINGN	TINGLING, PINS AND NEEDLES - NONE	2.5		

Listing Data Manipulation

PARAMCD	PARAM	PARAMN	AVAL	AVALC
SYMNUMBF	NUMBNESS - FEET	1.1	1	Y
SYMNUMBL	NUMBNESS - LEGS	1.2		
SYMNUMBH	NUMBNESS - HANDS	1.3	1	Y
SYMNUMBA	NUMBNESS - ARMS	1.4		
SYMNUMBN	NUMBNESS - NONE	1.5		
SYMNUMB	NUMBNESS	1.6		Feet/ Hands
SYMTINGF	TINGLING, PINS AND NEEDLES - FEET	2.1		
SYMTINGL	TINGLING, PINS AND NEEDLES - LEGS	2.2	1	Y
SYMTINGH	TINGLING, PINS AND NEEDLES - HANDS	2.3		
SYMTINGA	TINGLING, PINS AND NEEDLES - ARMS	2.4		
SYMTINGN	TINGLING, PINS AND NEEDLES - NONE	2.5		
SYMTING	TINGLING, PINS AND NEEDLES	2.6		Legs

Precision Difference Between Table and Listing



- In some analysis datasets a new statistic may be derived to create a result that was not one that could be captured on the CRF
- This could end up being one whose precision is captured to many decimal places
- The number that we use within our summary or statistical table would usually be the most accurate version held by SAS
- If this derived number is presented in a listing it is usually illustrated as a more rounded set of digits to a specific decimal place selection

Precision Difference Between Table and Listing



PARAM	PARAMCD	PARAMN	AVAL	AVALC
Number of Bleeds	NBLEED	1	1	1
Number of Bleeds Category	NBLEEDC	2	1	1
Number of Spontaneous Bleeds	NBLSPON	17	0	0
Number of Spontaneous Bleeds Category	NBLSPONC	18	0	0
Number of Traumatic Bleeds	NBLTRAU	19	1	1
Number of Traumatic Bleeds Category	NBLTRAUC	20	1	1
Average Time to First Injection	TMAVFINJ	3	2	2.00
Difference from estimated prior bleeds	DIFF	55	-33.3245412844037	-33.32
Internal	INTERNAL	31	1.67545871559633	1.68
Joint	JOINT	29	0	0.00
Muscle	MUSCLE	30	0	0.00
Overall	OVERALL	23	1.67545871559633	1.68

Precision Difference Between Table and Listing



- A compliant method would have been to create the listing result as a new row in the data with '(Listing)' text after what exists for the original PARAM with a new PARAMCD and PARAMN
- Another option is for AVALC to be 1-to-1 mapped but a formatting variable, AVALFMT/PARAMFMT, is added to contain the desired format for the listing to display (e.g. 7.2).
- This precision issue is something that does not frequently occur but could be easily remedied in the ADaM IG by the addition of an extra BDS variable

Improved Table Summary production

- Various types of standard safety tables that follow BDS closely can be produced quickly thanks to the standardized variable naming conventions for BDS structure datasets
 - > PARAM, AVAL, CHG, etc.
- If design of summary table shells such as change from baseline or shift types are consistent for your CSRs then it is possible to have much more generic and straightforward programs in place
- For statistical analysis tables, the ADaM document 'Examples in Commonly Used Statistical Analysis Methods' gives helpful instruction for the steps taken to construct an 'analysis-ready' dataset

- Implementing ADaM standards
 - > will mean output production will become more streamlined
 - > time saved in analysis dataset production and table/figure production will more than offset time spent on listing production
- Solutions to listing difficulties
 - > Bending ADaM standards by including one or two extra variables not defined in the standards
 - > Creating listings direct from SDTM by merging ADSL
 - > Creating non-ADaM analysis datasets that are used only for the listings
 - > Sticking to ADaM vertical rules by adding any extra rows if derivation is required for listing alone

Conclusions



- Long term improvement to time spent in CSR output production could be the reduction of listings in general and a move towards either automated SDTM generated listings or use of data review tools
- ADaM reduces the number of variables we use and standardises the naming convention for many variables allows for an efficient process to be put in place from ADaM dataset construction through to CSR output production

Questions?