PP26 The "CDISC Stupidario" (the CDISC Nonsense)

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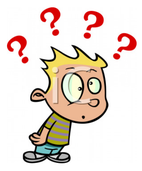
Abstract

In the last 5-10 years I have been exposed to several studies requiring the use of the CDISC standards, either as programmer study lead or as CDISC SME reviewing both internal (Cytel) or external packages (delivered by Pharma or other CROs), where I also regularly provide answers to questions/doubts.

With this presentation I would like to go through the main CDISC "Nonsense" from my experience. This can range from "nonsense" question to a complete misunderstanding of the CDISC Ig(s); some of this "nonsense" has also emerged from the CDISC packages I have reviewed including CDISC documentation such as the reviewer guide. The main focus of the presentation will be the SDTM and ADaM standards.



Challenge yourself or **Discuss with the author** or **Wait for the paper to be published**

If you want to challenge yourself try to answer below and fill the red gaps

1. TOO LAZY TO CORRECT _ _ _ _ _ _

What's wrong with the following conformance section of a cSDRG?

DEFINE	Define.xml/CDISC dataset Description mismatch	Warning	LB, IE, QS, FA label is incorrect in XPT (programmatic error)
QS	Variable is n wrong order within domain	Warning	QSCAT and QSSCAT are incorrectly placed

2. WHERE IS MY _ _ _ _ _ _ _ _ _ _ _ _ _?

My concern: "*In ADEG you did derive a record with the average of the triplicates; I recommend keeping also original SDTM records from which you created the mean*"

What's wrong with this answer "*The original records were not retained in ADEG because they are in SDTM EG*"?

3. MY _ _ _ _ _ SHOULD be ENOUGH!

My concern: "*Why you did create AVALU in your ADaM dataset*"

What's wrong with the answer "*To store the unit of my parameter*"?

4. ADaM "SUPERFLUO" SUBMISSION

How many ADaM datasets do I need to create?

What ADaM datasets are required for a submission?

Should there be an ADaM dataset for every SDTM domain?

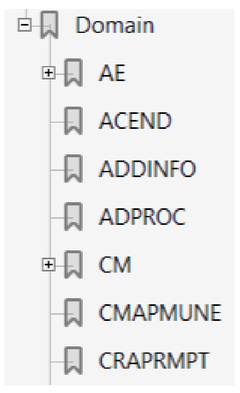
What is for ADIE – ADaM for Inclusion / Exclusion Criteria?

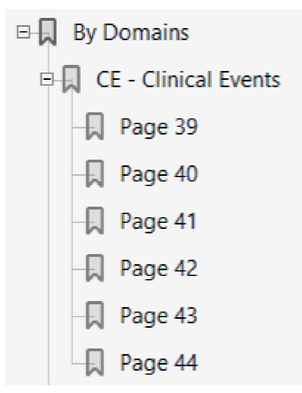
5. SOMETHING WRONG WITH MY TERMINOLOGY

My concern (in 2018): "*Fine with me your standard system is based on SDTM Ig 3.1.3, but could you please update your CDISC CT to a more recent version?*"

What's wrong with the answer "*This is XXX Inc. standard, the development of SDTM Ig 3.1.3 has been done in 2013*"?

6. SOMETHNG WRONG WITH MY ACRF BOOKMARKS





7. WHAT STANDARD IS CDISC FOR?

My Stats friend: "*Angelo can you please let me know what is the CDISC standard for representing summary of demographics in output table?.*"

What should I answer?

Where she could find the CDISC standards for output templates in the CDISC website?

8. I'M YOUR REVIEWER, CAN YOU PLEASE SAY SOMETHING MORE IN THE DATA _ _ _ _ _ _ _ _ _ _ _ SUMMARY SECTION OF THE C _ _ _ _

Conformance Issue (P21 Message)	Justification provided in the CSDRG
1. Missing FADY variable, when FADTC variable is present	Variable not used
2. Invalid value for --TEST variable	Many instances of --TEST >40 characters. --TEST values are directly assigned from the labels taken from the Case Report Form to have clear understanding of the test code and therefore text was not changed
3. NULL value in SEX variable marked as Required	Data Issue: Sex is collected in the raw data
4. NULL value in AEDECOD variable marked as Required	Terms were not coded in the database
5. Inconsistent value for Standard Units	Data Issue: We have not been able to convert these to standard units

Conclusions and Recommendations

- The efficacy and safety of your drug are of course what matter, but **lack of traceability**, **poor or insufficient documentation** might **trigger questions and concerns from the reviewer**
- You may think these are minor issues because they do not ultimately impact any results. However, **you are risking your credibility with the FDA reviewer**, who may conclude that your package is not of good quality
- **The Sponsor "own" the data** and they should not simply rely on partners expertise (more surveillance)