



One Vision, Many Interpretations?

Paper PDo2

Overview

- Understanding Vision and:
 - How it relates to standards and consistency within programming deliverables
- In the Information Age
- Examples
 - SDTM/Legacy Data Mapping
 - Define.xml
 - Patient Profiles

Vision (and Mission), Example



Strength Through Collaboration

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Mission & Principles

Mission Statement

CDISC is a global, open, multidisciplinary, non-profit organization that has established standards to support the acquisition, exchange, submission and archive of clinical research data and metadata. **The CDISC mission is to develop and support global, platform-independent data standards that enable information system interoperability to improve medical research and related areas of healthcare.** CDISC standards are vendor-neutral, platform-independent and freely available via the CDISC website.

Vision...

“... vision can vary tremendously from person to person or in different environments... Additional ... factors affecting the interpretation of vision include ... fatigue, personality, experience, novelty, complexity...” - J. Elton Moore and B.J. LeJeune

Vision, Before...



Vision, After...



Purpose

- One Vision, *Minimal* Interpretations
- Examples
 - Standards (CDISC SDTM)
 - Electronic Submissions (US)
 - Define.xml
 - Patient Profiles
- The myth of ‘exceptions’
 - ‘The reality Real Exceptions’?
- Recommendations

Standards within Social Context

Generations: Baby Boomers, Generations X, Y (Millennial)

- **Baby Boomers:** Born between 1946 and 1964
 - *“associated with a rejection or redefinition of traditional values; however, ... in 2004, the UK baby boomers held 80% of the UK's wealth and bought 80% of all top of the range cars, 80% of cruises and 50% of skincare products” – Wikipedia*
- **Generation X:** Born between 1965 to 1984
 - *A generation once labeled "slackers," detached and melancholic has grown up to find out that reality doesn't bite as much it seemed when they were younger – CNN*
- **Millennial Generation:** born from 1985 to the early 2000s
 - *“... a sense of entitlement and narcissism based on personality surveys that showed increasing narcissism among Millennials compared to preceding generations when they were teens and in their twenties...” – Jean Twenge, author of *Generation Me**

How Millennial Are You?

How Millennial Are You? Results

How your score compares with other Americans who took the test in our national telephone survey:



Source: Pew Research Center

<http://www.pewresearch.org/quiz/how-millennial-are-you/>

Theme?

- **Theme and Key Message**
 - Each generation, when in their youth, may have been defined similarly and, as they aged, may have gravitated toward similar attitudes.
 - Ensure that you know the material you are supposed to know, participate actively in discussions that will have an impact on you, and continue to seek new experiences in the pharmaceutical programming industry!

SDTM Mapping, Simple, right?

- Implementation Guide
- Organization's Interpretation of IG
- Working with vendors/partners
- Legacy Data?

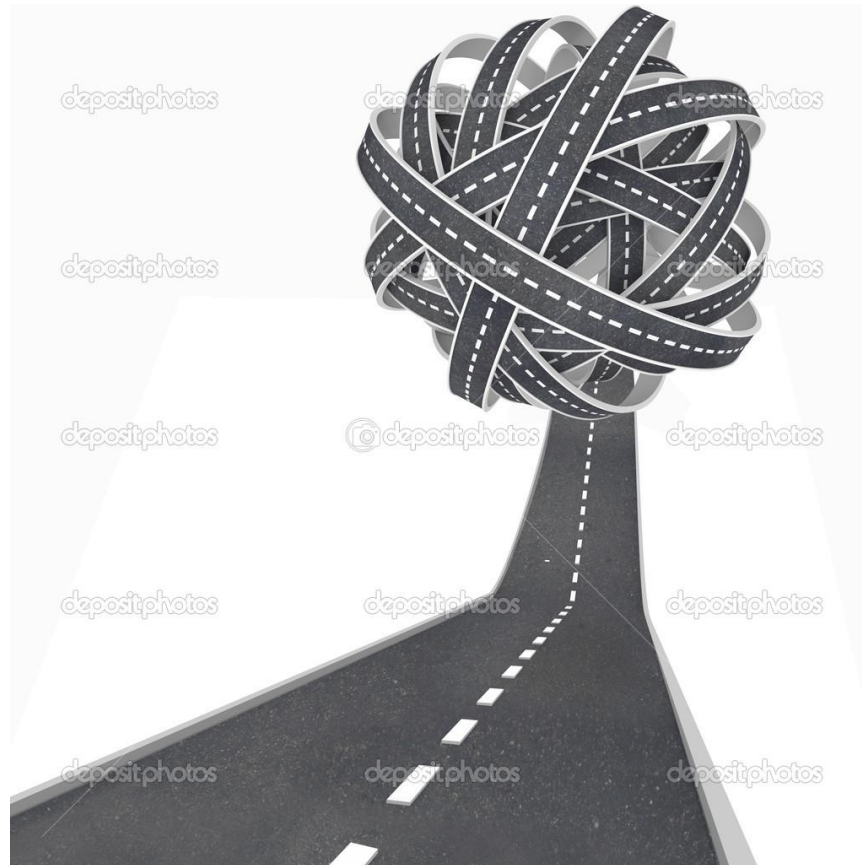
SDTM Mapping, cont'd.



Legacy Data Mapping

- Definition of Legacy Data
 - Inherited Studies
 - Investigator Sponsored Trials
 - Academic Data
- What are the benefits/disadvantages of mapping?
 - Pooling of data in the event it's necessary
 - Data is often very different if not mapped to SDTM
 - Not submitting/using the data
 - Bottom Line: Ensure the relevant parties are on the same page prior to moving forward with the decision

Legacy Data Mapping, cont'd.



Define.xml

- Standard has been well-defined (One Vision), but...
 - What about ‘Comments’ and ‘Computational Algorithms’?
 - Comments are not intended to replace a properly defined computational algorithm, which is expected for derived variables. – Define-XML-2-0-Specification.pdf

Define.xml Comment Definition

4.7. Comment Definitions

Define-XML allows the definition of Comments at both the dataset and the variable and value levels.

The mechanism allows referencing short comments self-contained in the Define-XML document or long comments referenced in external documents. For comments in external documents, the reference can include specific pages within the document.

Comments are not intended to replace a properly defined computational algorithm, which is expected for derived variables.

Define.xml Computational Method definition

4.6. Computational Method Definitions

The *MethodDef* element describes the algorithms used to generate values for variables defined as derived. See section 5.3.13 for details of the *MethodDef* element. The algorithm is linked to a variable or value using the *MethodOID* attribute in the corresponding *ItemRef* element (see section 5.3.8.1).

To enhance traceability users are encouraged to provide descriptions that include accurate and consistent references to source variables and derivations.

For cases where the algorithm description is longer than a few lines, the *MethodDef* can include a *def:DocumentRef* element to link to a section in a supplemental document containing the additional details. See section 5.3.6.1 for details of the *def:DocumentRef* element.

A *MethodDef* can also link to a text file that contains the specific programming code to be executed. However, the external location has to be agreed by sender and consumer.

Comment and Computational Algorithms Summary

- Recommendation is to have a seamless flow between SDTM/AdAM specifications and define.xml
- Using technology that is transparent and updates/modifies upstream data to be reflected in Define.xml

Patient Profiles

- Selection Criteria
 - Death
 - SAE
 - AE leading to study/drug discontinuation
- Presentation
 - How much detail?
 - Presenting data only surrounding the event(s)?
 - Only on treated patients?
 - What is relevant?
 - Adverse Events of Interest
 - Potential technical issues working with Adobe, etc.
- QC
 - Only selection criteria?
 - Everything?

The Myth of ‘Exceptions’

There are many reasons and ways that programming deliverables can be different, however:

- With all other constants (e.g., quality, cosmetic, ‘quirkiness’ of a particular disease area, etc.) remaining the same, the faster the deliverables are generated the faster the potential therapy gets to patients!

Conclusion

- One Interpretation' may sound stifling, unimaginative, uncreative
 - Not True!
- Vast array of different styles that programmers use (even within a single programming language)
- Each style has its own merits and limitations and there is no 'silver bullet' in terms of a specific programming technique
- Generations of programmers with different backgrounds, degrees and experiences as well as risk
- Examples of types of deliverables in which there is (or could be) much consistency across the industry – SDTMs, Patient Profiles, Safety analyses, etc.
- Many reasons and ways that programming deliverables can be different
- Consistent presentations will ultimately reap exponential rewards in terms of both quality and efficiency, and leave the more novel and exciting programming for the rest of us
 - Safety tables
 - Patient profiles
 - SDTMs (at least consistent mapping strategy conceptually)

The Future...



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