A CRO perspective on implementation of SDTM across multiple sponsors

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Overview

- CROs are exposed to many different interpretations of SDTM by our clients
  - What are the challenges this creates?
  - What are the benefits it provides?
  - What lessons have we learned?
Key areas of interest

• Client level of expertise
  - What level do they consider themselves to be at?
  - How does that compare to the level of the CRO?

• Client interpretation
  - Expected differences across clients
  - Unexpected differences across clients
Client Level of Expertise

SDTM Naive
- No direct experience
- Told they need to use SDTM, but don’t really understand what this means
- No internal processes or governance related to SDTM

SDTM Experts
- Extensive internal processes and governance for SDTM mapping
- Involved in SDS team
- Very involved in how SDTM should be applied for their studies

- Minimal internal process or governance related to SDTM
- Just beginning to create internal SDTM process and governance
- May have outsourced SDTM creation to one or more CROs
Level of Client Expertise

- CRO needs to assess the client level of SDTM expertise early in the project
  - Through direct questions:
    - Are you familiar with SDTM?
    - How long has your company been using SDTM?
    - How long has this project team worked with SDTM?
    - Do you have any internal custom domains, controlled terminology, etc. that we need to be aware of?
    - Do you have examples of SDTM datasets from other studies?
  - Are they members of CDISC?
  - Are the actively involved in CDISC teams and/or Users Groups?
Set Expectations for Naïve Clients

- Have they seen/worked with SDTM before?
  - Try to avoid delivering SDTM and client deciding they would prefer not to have SDTM once they’ve seen it
  - Can CRO provide client example SDTM domains?

- Do they have other studies also using SDTM?
  - Often won’t realize that SDTM has many areas where mappings could differ
Lessons Learned for SDTM-Naïve Clients

- Be open to the possibility that SDTM might not be appropriate for a study
- CRO may need to provide some level of introduction/education on SDTM
- Be clear that CRO will follow their own guidelines for ambiguities in SDTM
Set Expectations for Non-naïve Clients

- How involved would the client like to be with mapping of custom domains?
  - Client owns mapping
  - CRO owns mapping
  - CRO collaborates with client, making suggestions for mapping

- If the client is not managing metadata, is there a way to see examples of existing domains created for other studies?
What to do when your experts disagree?

- How receptive is the client to discussion?
- Is there something in the IG that can support one of the opinions?
- How critical is the disagreement?
  - Could it cause WebSDM or JANUS checks to fail?
  - If so, should document the differing opinions, along with the rationale on which was followed
  - Helpful to have the historical information for reference later on
Training-related Challenges

• Distinguishing between
  - Items that are defined by SDTM and should not be different across clients
  - Items that are client-specific

• Staff dedicated to a single client often struggle when asked to assist on other client work
  - Confusion about what is “correct”
Training Lessons Learned

- Make sure CRO staff understand the differences between SDTM requirements and client-specified requirements
  - If staff have only worked with a single client for a long time, they may need “SDTM refresher” training when they work with another client
  - Example:
    - Client A has defined VISIT to 20 characters
    - Client B has defined VISIT to 40 characters
      - This is OK - staff should not tell either client that the length is incorrect

- Staff new to SDTM are at greater risk for confusing client rules with SDTM rules
Managing different “flavours”

- Central location on our network where all CDISC documentation is kept
- Hierarchical folder structure
  - SDTM at the top
  - Subfolders for each client-specific SDTM details
    - Client controlled terms
    - Process differences
  - Helps reinforce concept that client implementations are still based on standard SDTM
Other internal communication tools

- **Data Management forum on intranet**
  - SDTM topic area
  - SDTM for each client has its own topic area
  - Project teams can more easily share knowledge across many locations
  - Responses are monitored by internal SMEs to ensure no mis-information is being posted

- **DM WIKI**
  - For more detailed descriptions of client-specific implementations
  - Place to remind staff of the differences between each client
Some More Lessons Learned

• CRO should have default conventions for when clients do not have their own
  - Provides consistency across multiple studies
  - Gives CRO staff a starting point
  - Example: Do not include Study Day unless client specifies in order to avoid confusion over lack of “Day 0” in SDTM
Lessons Learned (again)

- Easy to identify SDTM-naïve clients
- More difficult to determine where non-naïve clients fall along the spectrum from novice to expert
Are there examples?

• If client has no internal conventions, another CRO may have already defined some in a different study

• To be consistent, and avoid additional work, try to find out if datasets from other studies can be referenced
  - Test codes for questionnaires
  - Categories for Medical History, Labs, etc.
• CROs have the ability to see many different examples of SDTM implementation
  - Similar to Users Group benefits, but on a smaller scale
  - Being able to review many variations on mappings allows CRO to optimise by taking the best parts from many examples
  - If you’ve only ever seen one way to do something, you may not even realize there is a better approach to take
Benefits

• Since SDTM is non-proprietary, a CRO can apply examples of mappings seen in any study
  - Compiling a mini-CDISC SHARE concept internally
  - References for project teams to see if an example custom domain already exists

• CRO can bring experience with a wider variety of situations than a client may be exposed to
Summary

• CROs can take advantage of a wide variety of examples across clients
• Clients can benefit from suggestions based on this wide variety
• Training and setting expectations can dramatically affect whether the experience is positive or negative
Questions?

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