ADaM Lessons Learned: A Sponsor's Perspective

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Note: The opinions in this presentation are those of the presenter and may not necessarily reflect the views of Eli Lilly and Company, PhUSE, or CDISC.

Some History as a Sponsor

- Began developing an ADaM strategy in 2011-2012
- Some prior experience with SDTM
- Little to no prior ADaM Experience before 2011
- Many years of legacy proprietary analysis “standards”

Some Lessons Learned…

- The following are some lessons learned and what to do/not do as learned since 2011 in the following areas:
  - Developing ADaM Expertise
  - Understanding impact of ADaM on Clinical Data Flows
  - Linkages to SDTM
  - Standards Development/Governance
  - Other Considerations

ADaM Expertise: What to Do

- Manage relationships with ADaM external partners to align on expectations with regards to ADaM expertise being provided
- Look for strong external ADaM experts to partner with to provide external influence on your organization
- Provide opportunities for internal “hands on work” to learn ADaM – Remember ADaM is a model and can also sometimes be an “art”

ADaM Expertise: What NOT to Do

- Losing sight of developing expertise among statisticians/statistical programming staff or expecting them to learn it all “on their own”
- Having programmed ADaM (or ADaM-like) datasets is enough to be considered an ADaM expert.

Clinical Data Flow – What to Do

- Be mindful that you may need to include ADaM in multiple data flows.
  - i.e. strategic needs to submit ADaM for earlier legacy trials
  - Multiple standards libraries (CDISC and Legacy)
  - Recognize technologies, lifecycles, and limitations in implementing ADaM in a data flow.
- Ensure strong ADaM support models are in place regardless of data flow

Linking to SDTM – What to do

- Ensure handoffs between SDTM/ADaM are clearly understood.
- Consider strong project management of handoffs between SDTM/ADaM
- Consider single point of accountability for SDTM and ADaM delivery.

Linking to SDTM – What NOT to do

- Operating SDTM and ADaM teams in “silos”
- Failing to involve statisticians/statistical programmers in SDTM reviews/SDTM development
- Bottom Line: A clear alignment between SDTM and ADaM will lead to surfacing and correcting issues sooner in the Data Flow before they become a problem in ADaM or TFLs

Standards Development – to Do

- Have a clear standards governance team or strategy that includes expertise participating on External influence teams
  - Ensure there is a clear escalation path to resolve standards governance issues
- Promote the creation of standards based on re-use as opposed to “if used once in study then it’s a standard”
- Accelerate internal therapeutic area standards development (in partnership with CDISC TA development)

Standards Development – NOT do

- Not getting ADaM SMEs involved enough in external working groups (PhUSE, CDISC, etc. to be able to provide industry influence on internal standards development)
- Not involving ADaM SME enough in external working groups to accelerate ADaM Standards development to minimize later re-work, especially outcomes from Therapeutic Area Working Groups

Misc. – What to Do

- Continue to stress that TFL Shell development (or at least a strong understanding of the analyses being performed) needs to happen sooner in the end-to-end process.

Misc. – What NOT to Do

- Don’t just “copy” legacy proprietary standards when creating ADaM
  - ADaM-like datasets <> ADaM datasets
  - Just because you added columns in the past doesn’t ensure BDS compliance
  - Starting from scratch with a clear understanding of the analysis being performed will better ensure ADaM compliance.

Questions?

- Thankyou PhUSE for the opportunity to present at the 2015 Chicago SDE!