FDA CDISC Standards Planning meeting (8 Apr 2015):

Attendees:
FDA: Colleen (OSP CDISC Lead), TJ Chen(OSP), Jack Zhang (CBER standards lead) Doug Warfield & Lisa Lin (Informatics eData), Helena Sviglin (OCS, Stds. Dev)
Armando Oliva (OCS, Validation Rules CCB)
CDISC: Wayne Kubick (CDISC), Diane Wold (CDISC, SDS, TAs), Shannon Labout (CDISC Education, CDASH) Fred Wood (SDS, SEND, TAs), Sally Cassells (XML), Susan Kenny (ADaM)

Agenda Items:
Reviewed and explained the CDISC Technical Roadmap and Technical Plan

Discussion items:

- Jack: CDASH – CDASH has always lagged behind SDTM. Can CDISC put more work into CDASH?
- Wayne: Goal is to do that, and we're working now to incorporate CDASH domains in Therapeutic Areas, as well as catching up to SDTMIG versions in CDASH v2.
- Shannon: The CDISC Model will help; we can now create new domains much more rapidly than before.
- Jack: Terminology is far behind; missing many elements we want to see not there
- Wayne: We have many initiatives underway to improve the speed of terminology development, leveraging SHARE. But it would also help if FDA could provide feedback on the types of terminology they'd like to see that is missing.
- Jack: We've seen many validation issues with ADaM datasets identified by validator. Any idea why? Is this an OpenCDISC or CDISC issue?
- Susan: They may not be using Define-xml correctly – OpenCDISC doesn't seem to differentiate between all the different ADaM data structures.
- Wayne: Will have to check with Open-CDISC, but ADaM does publish its validation rules.
- Jack: It often seems like SDTM is moving too fast, which may causing confusion among sponsors. What can we do?
- Fred: Most sponsors that I work with are managing versions OK, but understand it can be confusing if they don't invest time to keep up.
- Wayne: This is a serious change management challenge, but we have these separate goals of trying to minimize custom, non-standard interpretations of CDISC while addressing new needs like therapeutic areas, so we need to make progress on this.
- Diane: We're committed to doing a better job on explaining what's different in new versions in the future, and SHARE will greatly help.
- Doug: Working on how to tie SDTM versions to User Guide examples. Can we accept a TA in some cases even if it doesn't conform to the latest version of SDTMIG?
- Wayne: Yes, you can – and the impact analysis Diane mentioned will help explain this better in the future. Perhaps we should have meetings with FDA each time we release a major new IG or UG version.
- Sally: Being able to specify use of multiple standards is a key feature of Define-XML v2.1
- Susan: Variations in Sponsor interpretation of the new standard is another issue,

Other items:

- Need additional time to explore some key issues, such as how to handle the topic of multiple physiology domains and making FDA more comfortable with the Collected Exposure domain.
- Try to schedule next meeting in May, specifically on SDTMIG v3.2 acceptance.