CFAST Therapeutic Area Program Steering Committee
2012 Meeting Minutes

6 Sept. 2012 Minutes

Attending: Mary Ann Slack, Ron Fitzmartin (FDA)
Sue Dubman, Diane Wold (TBI)
Enrique Aviles (C-Path)
Wayne Kubick (CDISC)

Regrets: Bron Kisler (CDISC), Jon Neville (C-Path)

Agenda Items:

1. Review ground rules, operating principles, roles and responsibilities.
   We reviewed Slide 6 from the CFAST_Structure_v2 Powerpoint deck which describes high level responsibilities of the CFAST Therapeutic Area Standards Program Steering Committee (PSC). We then reviewed the current operating principles listed in the draft charter document. We need more clarity in the role of the scientific advisory committee for CFAST.
   ACTION: All Attendees agreed to send in specific comments/change requests on the charter to Wayne by end of next week so they could be reviewed next call.

2. Regular Meeting Schedule
   We agreed to meet biweekly at the same time for the foreseeable future. Meeting schedule may be modified as necessary over time by PSC agreement.
   ACTION: Wayne to schedule.

3. Discuss Election of Chair
   We agreed that participation would be limited to one vote for each of the 4 sponsoring organizations: FDA, TBI, C-Path, CDISC. We agreed that the Chair would be empowered to cast a tie-breaking vote in the event of a lack of consensus (Wayne to add to Charter). The PSC agreed unanimously that Wayne will serve as interim Chair until the Charter is finalized and a formal election can be scheduled.

4. Identify initial topics for SC review and approval
   In addition to finalizing the Charter and electing a Chair, the PSC will need to define and approve a set of guiding principles that will apply to the entire program, and be used to support prioritization and decision-making by the
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PSC. These should include principles such as:

a. Avoiding redundancy -- using best efforts to adopt and reuse applicable prior work when available; develop new only when needed
b. Defining a finite scope for projects that prioritizes what's needed to facilitate regulatory review and analysis
c. In balancing decisions among the quality/time/cost triangle, try to adjust scope to minimize extensive time delays, which may mean finding ways to increase resources
d. Establishing clarity in boundaries between TA standards and foundational standards.

ACTION: Wayne will compile a list for discussion at next meeting, based on principles drafted for the SHARE meeting, today's discussion, and suggestions sent by Sue and others.

We also discussed the need to identify potential scenarios which might require deferring to the CFAST Board, or the Scientific Advisory Committee, or one of the organizations. For example, what does the PSC do if a project is in conflict with a CDISC governance policy on standards development?

ACTION: All to try to identify potential scenarios which may need conflict resolution and submit to Wayne prior to next meeting.

5. Discuss requirements for selecting initial pilot project for November kickoff.

We discussed the list of tier 1 priority projects that had been identified at the July Hever/TBI meeting. We agreed it's important to document a set of criteria to choose a priority, or to approve a charter or project to proceed after a go/no go review. These criteria should be incorporated into checklists that project teams complete so that review by the PSC can be streamlined. Among the criteria for choosing a pilot project are:

a. Well defined, manageable scope, capable of being a quick win
b. Availability of sufficient prior work to minimize the need to conduct extensive preparatory analysis (must be able to start quickly)
c. Limited complexity -- any large-scale area like Oncology must be able to be broken down into a manageable chunk

ACTION: All participants to review, discuss with their organization colleagues, and add any other potential decision-making criteria to help with prioritization -- especially selection of first pilot.

We agreed that of the previously discussed projects, Oncology was too big to start with and QT Studies were probably too small. Schizophrenia was eliminated since work by the CIC is still in progress and going to be reballeted in January -- we should defer starting until that is resolved. This narrows down the potential list to Asthma and Diabetes, if the latter can be broken down into a
clearly defined, manageable chunk.
ACTION: All participants to explore these two with internal experts and be prepared to make a decision in one of next 2 meetings.

We discussed the need to use messaging effectively to manage expectations as we perform these projects with a limited scope so the broader community understands we can't do it all the first time around.

6. Next meeting and any other business.
Sept. 20 at 11am EDT. Wayne to schedule and confirm.

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Attending: Ron, Enrique, Diane, Wayne, Jon, Mary Ann, Sue
Regrets: Bron (in transit)

1. Acceptance of Minutes - accepted unanimously with no comments.

2. Steering Committee Charter and Prioritization Principles
We reviewed comments sent in by C-Path and FDA. Wayne had created a custom charter for the TA Standards Program Steering Committee (TAPSC) based on the general CFAST charter. This included some wording changes previously suggested by Diane.
There was some discussion about the program goals, which specified at least 55 TA projects. C-Path noted that there may be other CFAST projects that are funded externally by foundations or patient advocates for development even if not prioritized by FDA and TransCelerate. It was agreed to revise the goal statement to remove reference to a specific number. It was also agreed that any CFAST projects must conform to the same standards development process, and should be communicated openly and transparently, so that the TAPSC could feel comfortable that they do not detract CFAST focus from the TAPSC projects.

The question of whether TAPSC members should have defined terms; instead, we agreed to insert a clause stating that membership must be reaffirmed by sponsoring organizations every 2 years. Additional changes to the draft charter were interactively applied to a new draft and attached to these minutes.

ACTION: All -- please return comments on revised draft (attached) to Wayne.

3. Selection of Pilot Project
Both Mary Ann and Sue feel that it is possible to define a corner of diabetes to meet our "manageable scope" and "quick win" criteria, but a definite scope has not yet been proposed. FDA will be submitting recommendations based on
defined endpoints; Sue will also continue to check with Transcelerate companies. Both C-Path and CDISC are currently more comfortable with Asthma.

ACTION: All members are asked to solicit remaining input from their organizations so a decision can be made at the next meeting, based on the stated guiding principles and prioritization criteria.

4. Prioritizing list of other Tier 1 projects
We discussed the top list that had been recommended at the July Hever meeting, and agreed that the TAPSC would need to reaffirm the next set of projects after the pilot was chosen. We’ll continue this discussion at next meeting.

5. Any other business
Mary Ann Slack noted that an FR Notice will announce that the therapeutic area projects are now proceeding under FDAA and PDUFA V, that the priority list is posted on the FDA website, and input from the public will be welcomed on this.

We briefly discussed the importance of communication about the projects -- how do we describe the scope so that expectations are kept reasonable and external parties are encouraged to participate? We’ll continue that discussion later.

An action from the last meeting was to identify potential scenarios which might require conflict resolution. C-Path did provide a list of these, which should be discussed at a future meeting:

1. A TAPSC project needs to deviate from the current CDISC process for TA standards development (reduction in deliverables, request for shortened review cycles, etc)
2. A TA project from a different PSC creates a resource conflict or scheduling conflict with TAPSC TA projects (to make it more interesting, say the non-TAPSC project is a contractual obligation…)
3. A TAPSC project is dependent on a foundational standards update which gets delayed, impacting a TAPSC project completion target (this could be important when we have multiple projects allocated to the working team, so a downstream ripple delay effect occurs)
4. The CFAST scientific advisory board recommends a change of scope or halting of an existing TAPSC project

6. Plans for next meeting.
We’ll extend the next meeting to at least 90 minutes (Wayne will reserve 2 hours to allow for overrun). We will plan to choose the pilot, but may still encourage teams to continue to collect inputs on both of the top two priority therapeutic areas, so the runner up will be ready to become project 2.
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Attending:  Sue Dubman, Diane Wold (TransCelerate)
            Jon Neville (C-Path)
            Wayne Kubick, Bron Kisler (CDISC)

Regrets:   Mary Ann Slack, Ron Fitzmartin (FDA), Enrique Aviles (C-Path)

Guest:     Salah Benyamina (TransCelerate)

Due to unforeseen circumstances, neither FDA representative was able to participate. Another FDA representative had been invited by Mary Ann but did not attend. While Jon was available to represent C-Path, he had not attended prior meetings or had the opportunity to connect with Enrique before the meeting. Since our proposed Charter says that we need one representative from each voting organization to meet quorum, we were unable to make any decisions at this meeting. We did discuss all agenda items briefly, and identified a few that decisions can possibly be made with email input from FDA or Enrique, listed as actions below.

The draft agenda had somehow neglected to include the key issue on pilot project selection, which was inserted as item 3A.

1. Acceptance of prior meeting minutes. These were acceptable to members who were present, and had been approved by FDA; however we did not have an explicit approval from C-Path.
   ACTION: Jon to check with Enrique and send Wayne C-Path approval or requested changes. Postscript: Approved by C-Path.

2. Charter - final discussion and approval (attached again -- Indicated as acceptable by Diane, Mary Ann, Enrique without further changes) We had received explicit agreement from Mary Ann, Ron and Enrique, however, due to lack of quorum, we were unable to formerly approve. TransCelerate and CDISC agreed to approve so we could make the charter publicly available -- we agreed we could always amend later as needed.
   ACTION: FDA and C-Path to send votes for/against approval to Wayne by COB Friday. Copy attached again. Postscript: Approved by FDA and C-Path.

3A. Selection of Therapeutic Area for Pilot Project.
As of last meeting, both TransCelerate and FDA were to consult with their diabetes SMEs to try to propose a constrained scope for an initial project that would explore a manageable subset of the diabetes therapeutic area. Salah Benyamina, a clinical SME invited by Sue, reported that their research was still in process, and we had not received any input yet from FDA. Salah felt that he
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would be able to have enough information to make some recommendations by next week, but nobody has yet proposed a manageable scope for diabetes. Since we were unable to make a decision at this meeting, concerns were raised that we would not be able to kickoff in November unless a decision could be made very soon. Some members felt we should already begin to solicit inputs on asthma, even if these are used in a later project. There was general agreement that asthma should be chosen unless a realistic, manageable diabetes option could be defined and selected by the next meeting.

ACTION: Make final proposal for diabetes scope by next meeting so it can be weighed by TAPSC against asthma.

3B. Review of next set of priority areas.
We recognized that we should re-assess the pipeline for 2013 to aid in budget planning. Diane recovered the list of first core set of priority projects identified at the July Hever meeting (attached): these include QT studies, schizophrenia and oncology in addition to asthma and diabetes. In addition to that list, there are plans for a new release of Alzheimer’s (partial funding under an FDA grant to C-Path), Schizophrenia and Cardiovascular imaging (partial funding through an FDA grant to CDISC), an updated release of TB including more elements and CDASH forms (potentially partially funded through a Bill & Melinda Gates foundation grant), and possibly others through third party foundation grants. Some of these will not necessarily align with top FDA and TransCelerate priorities (TB is on the FDA list, but not the TransCelerate list). It was recognized that these additional projects may also compete for CDISC and C-Path resources, and that their timing may not coincide with the plans to finalized and pilot the new process (since some of those may need to start concurrent with the initial pilot).

For the FDA/TransCelerate list, the sequence of project priorities in the pipeline are proposed to be:
1. Asthma or Diabetes
2. QT Studies (which seems well defined and relatively easy to implement as a project after the pilot)
3. Diabetes or Asthma (whichever wasn't chosen earlier)
4. Schizophrenia (though CDISC project will likely need to begin sooner)
5. Oncology (once an initial manageable scope can be defined -- Scott Getzin was assigned to convene a group to try to identify this).

4. Communication of project priorities: We could begin communicating the need to do Asthma as soon as we're ready -- whether it's project 1 or 3. We can't communicate diabetes until we can narrow down the scope to describe how we will be approaching it.
5. Conflict resolution scenarios: we briefly reviewed the list that was included in the prior meeting minutes. All were felt to be relevant, but it was premature to address them until we can get going on the first project. We'll leave these in the parking lot for now.

6. Broadening participation in TA standards development or TAPSC: we talked about how other, smaller pharma companies might be able to participate -- either by joining TransCelerate or via CDISC. Diane was not aware of whether TransCelerate would accept additional members. CDISC is always willing to involve other volunteers, though it will be challenging to depend on volunteers given these project timelines unless they can be committed in the same way as TBI participants. We also had some discussion about the role of the scientific advisory committee, which has yet to be formed. CDISC will request that NCI have a participant on that committee since they are such an important partner of CDISC on the development of controlled terminology.

ACTION: Diane/Sue to investigate how other companies may participate in the TA standards program through TransCelerate.

7. Any other business - None raised.

8. Plans for next meeting.
Our next scheduled meeting is Oct. 18. Wayne will attempt to find a meeting time next week if all parties are available. Otherwise, the decision will need to be postponed until Oct. 18.

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Attending:
Sue Dubman, Diane Wold (TransCelerate)
Enrique Aviles, Jon Neville (C-Path)
Wayne Kubick, Bron Kisler (CDISC)
Mary Ann Slack (partial), Ron FitzMartin (FDA)

Agenda:

1. Acceptance of prior meeting minutes.
The minutes were accepted with no comments or changes.

2. Action item and status updates.
Diane has confirmed that it will be possible for other companies to join TransCelerate. However, CDISC member companies will also be encouraged to participate as team members through the CDISC volunteer system, even if their companies are not members of TransCelerate. This will be necessary, since
TransCelerate does not expect to be able to staff all of the projects anyway.

3. Selection of pilot Therapeutic Area.
We reviewed the background of the pilot selection process, pointing out that while Asthma is relatively narrowly defined, diabetes is much more complex and needs to be broken down into smaller chunks. Sue has been working to do this, but has determined that more time is needed to consult with clinical experts and get FDA input before we can get narrow down a way to approach diabetes as a series of versioned projects. FDA has been consulting with internal diabetes experts but has not had time to identify clinical experts for Asthma yet, and, given the usual end of year rush of submissions that are expected, FDA is concerned that they may not be able to get sufficient involvement until early next year. Based on current projections, it's likely that the rest of this year will be primarily spent on the initiation and scoping portion of the process, with detailed work on the information concepts and modeling beginning in January, when FDA active involvement would be most critical. C-Path has been working with some FDA experts on asthma through a PRO consortium, and will send this list of names to FDA. While FDA also wants to be involved in the initiation and scoping, FDA participants agreed that the need to identify FDA asthma experts should not be a limitation to the selection of asthma for the pilot.

Motion by Sue Dubman to move forward with Asthma as the proof of concept/pilot project, while simultaneously beginning work to define, plan, scope and collect inputs for other areas, beginning with diabetes, so they will be ready to be initiated as early as possible.
Seconded by Enrique Aviles.
Vote 4-0 in favor; motion passed unanimously.

4. Review of next set of priority areas.
We reviewed the rest of the list of 5 priority projects that had been discussed at the July meeting with Hever members, FDA, CDISC and C-Path representatives hosted by Accenture. This list had been determined from the FDA priority list, an industry survey conducted by Critical Path Institute, and a survey of TransCelerate companies. CDISC is soon to publish another TA standard on Polycystic Kidney Disease for Comment, and Parkinson's Disease and Devices are expected to be released for provisional use shortly. Both PKD and Virology should be posted for provisional use by end of year. CDISC is also still working on completing a project for cardiovascular data elements that will likely be released for comment early next year. Other projects due to begin soon include CDISC projects for Schizophrenia and Cardiovascular Imaging (funded partly by an FDA grant) and a funded C-Path project for an updated version of Alzheimer's. Cardiovascular is another complex disease area, so it will be necessary to identify what else needs to be done in that area after the first User
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Guide is published.

FDA has initiated an internal project to define requirements for 9 therapeutic areas as a model, which needs to be coordinated with the CFAST projects. The Process Team, meanwhile, has drafted a form to be used to solicit information on concepts and inputs for the modeling process. This will be beta tested on the Asthma pilot, and then used on the other TAs after refinement.

The SC in general agreed with an approach of prioritizing a set or package of therapeutic areas at a time, so that it would be possible to begin planning and input gathering well in advance of project kickoffs. Motion by Wayne Kubick that the other 3 projects previously identified -- QT studies, Schizophrenia and Oncology -- be approved as priorities for 2013, in addition to Asthma and Diabetes.
Seconded by Sue Dubman.
Vote 4-0 in favor; motion passed unanimously.

5. Communication of project priorities and input gathering
Now that we have an approved list of 5, we can begin to identify participants, stakeholders and input providers. According to Ron, it is not necessary that each individual TA project be communicated in the Federal Register. Under PDUFA V, FDA is required to publish a project plan for TA Standards development by June 2013. FDA must also publish when it has accepted a published standard for use. So CFAST can communicate directly when it's ready to receive inputs for new areas.
Question raised about whether FDA had accepted previously published standards for TB and Pain for use yet.
ACTION: Ron to investigate.
FDA is also publishing a Federal Register notice soliciting input on priorities for therapeutic area standards due to be released within a few weeks. This input will be used to help select the next group of priority areas.

6. Any other business
ACTION: Wayne will post the Steering Committee Charter and minutes of past meetings on the CDISC website.

7. Plans for next meeting.
Those SC members who are attending the CDISC interchange will try to meet for lunch on Thursday for an ad hoc meeting.
Now that we have resolved the most critical issues, it may be possible for us to cancel the next meeting, making our next formal meeting Nov. 16. Among topics to discuss in future meetings are:
1. General review of CFAST/TBI projects
2. Governance process for handling multiple projects
3. Understanding process for FDA acceptance of therapeutic area standards for use.
4. Review and approval of Asthma charter and plan.

Notes from 25 October lunch encounter:

We had a brief meeting during lunch at the CFAST Interchange on Oct. 25. Bron captured a few notes which I've edited and included below for the record, but, unless anyone objects, I won't include these in the formal cumulative meeting minutes now posted (along with the charter) on the CDISC website.

Attending: Enrique, Jon, Sue, Diane, Ron, Bron, Wayne.

Discussed known Therapeutic Area project opportunities in the next year and resourcing:

TransCelerate -- will also provide technical resources for 3 projects:

- Asthma
- Diabetes
- One more from the initial list of five (QT Studies, Oncology, Schizophrenia)

CDISC committed and partly funded projects under an FDA grant:
- Schizophrenia (also on TransCelerate list)
- Cardiovascular Imaging

Potential other CDISC projects:
- Traumatic Brain Injury (One Mind for Research; CDISC is currently scoping this project opportunity and discussing possible funding)

C-Path committed projects:
- Multiple Sclerosis (MS Society; funding secured)
- Alzheimer’s ver 1.1 (funding identified)

Potential C-Path projects:
- C-Path is also expecting to do work on a version 1.1 release of TB

We discussed again our prior plan to define a slate of projects to be initiated over a period of time -- in this case, this defines our expected list for 2013. It would be useful to communicate this initial slate to the broader community once we discuss
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at the SC.

We had discussed earlier that we would cancel the meeting for Nov. 2 (when several of us are not available). Our next formal meeting will be Nov. 16 -- I've asked Enrique and Bron to chair since I won't be available to participate. The SC will discuss these upcoming priorities for 2013, and continue discussions (minuted in prior meetings) about other potential SC issues.

Cumulative minutes and charter should be posted by tomorrow at http://www.cdisc.org/therapeutic.

Dec. 5 Meeting Minutes:

Attending: Enrique, Diane, Mary Ann, Wayne

Meeting attendance was limited due to rescheduling issues and technical difficulties. Nevertheless quorum was reached and the Board proceeded to meet.

1. Meeting minutes from past meetings were accepted without change.

2. Action items and status updates
Wayne has posted the Charter and past meeting minutes on the CDISC TA website.
Mary Ann verified that the recent Federal Register notice, published on Nov. 20, was intended to publish earlier in the year to raise awareness of the PDUFA V commitment.
Ron was unable to attend. The topic of FDA readiness to accept recently published TB and Pain standards was deferred until Ron can report on it. ACTION: Ron to update this action (from 10/18 meeting) at next meeting.

3. Asthma Pilot status
The pilot kickoff meeting was successfully conducted last week. The team is actively working on scoping, but clearly much work needs to be done to fill out and refine the process. All agreed on the importance of supporting this pilot project since it is intended as a baseline for future projects.
Several essential drivers for active and visible governance of the project were discussed:
1. The Steering Committee must show visible evidence internally and to observers of CFAST’s intent and ability to deliver using the new process.
2. The projects must demonstrate that they can engage both clinical research and healthcare communities, and key stakeholders in the project areas to identify common information concepts and move toward interoperability.

3. The Steering Committee must show intent to learn from mistakes and apply lessons effectively to future projects.

It was agreed that achieving full healthcare interoperability is challenging and long-term – our short-term goal should be to make sure we are involving clinicians outside of research, capitalizing on past work and existing terminology standards where possible, and making it clear that CFAST is not operating in a silo. Engaging healthcare experts and other relevant stakeholders is the key. Enrique pointed out that CDISC and C-Path have been engaging with such experts on past TA projects, for PKD, Parkinson’s and TB, for instance. CFAST needs to continue such outreach aggressively. The Board also has a core principle to reuse past work and not seek to reinvent, but in practice this is challenging. In some areas there are published ontologies, but these can be difficult to find and assess. The Board noted that each project will need assistance in tapping into the right areas and groups. Right now, NCI has been helping by searching the NCI semantic sources to look for relevant material for Asthma.

The FDA has identified a medical reviewer and statistical reviewer to liaise with the Asthma team. Their names will be sent to the Asthma project manager. Mary Ann noted that the FDA review division uses the National Asthma Guideline from NHLBI, which is already being used by the Asthma project team.

4. Plans for next priority areas

The Board discussed the need to queue up a set of projects that can be communicated widely so that participants can be engaged and prepare. The first step is to develop a clear initial plan that represents all of the projects currently identified and proposed for 2013 (from the CFAST queue and other projects of CDISC and C-Path).

**ACTION:** Wayne will prepare a chart of planned 2013 projects for discussion at next call.

The Board will review and approve the therapeutic areas projects on this chart and make it available as the 2013 plan through the CDISC website for therapeutic area standards. FDA plans to point to this site as well for TA project status.

The Board will review this list at least quarterly, adjust and amend it with new projects and status on an ongoing basis. Projects will be added as capacity becomes available, but right now, it seems as though the queue may need to be limited for 2013.

5. Communication of project priorities and input gathering
Given the need to engage outside experts and the desire of industry to know what’s in process, the Board needs to work actively to communicate. The original CFAST plan was to have dedicated communications assistance to help with this, but that’s not currently possible due to lack of funding. **ACTION:** Wayne to discuss at next TransCelerate meeting.

6. Guest participation of key partner stakeholders at future SC meetings. Other organizations have expressed desire to join the TAPSC, which is possible under the Board’s charter. While the current TAPSC is not ready to add new members yet, there was agreement that the NCI EVS group, a key partner for terminology, should be invited to attend as a guest to future meetings. A motion was made by Wayne to invite Margaret Haber to future meetings. The motion was seconded by Enrique. Passed unanimously, assuming that absent members are in agreement. **ACTION:** Absent members please indicate assent or comments to Wayne, who, assuming no objections, will invite Margaret to future meetings.

7. Understanding process for FDA acceptance of therapeutic areas for use. Mary Ann indicated that FDA has made progress on this and agreed to present progress at next meeting. **ACTION:** Mary Ann to present at Dec. 13 meeting.

FDA has also begun an internal project to engage review divisions in capturing requirements for TA review. The project’s objective is to develop small clinical models representing study data requirements in specific disease/therapeutic areas. The initial effort focuses on a small group of TAs to assess value and efficiency of the approach. The TAs proposed in this initial effort are:

- ACNE
- Overactive Bladder
- Lipid altering drug groups
- Hepatitis-C (must determine overlap with the recent CDISC Virology TA User Guide)
- Diabetes (next project on the CFAST list)

8. No other business was discussed.

9. Plans for next meeting.
Review the current draft technical plan of TAs due to start or deliver in 2013. Discuss governance of multiple projects. Mary Ann will present on process work for FDA acceptance of new standards. Continue discussions of the next group for the list.

**Dec. 13, 2012 Meeting:**
Attending: Mary Ann, Ron, Diane, Wayne, Jon

Agenda:

1. Acceptance of prior meeting minutes.
   Now that the minutes are being posted publicly, the TAPSC needs to review them more closely in advance. Members requested time until next meeting to review and send edits.
   ACTION: Members to send updates/corrections to 12/5 meeting minutes by Tuesday, Dec. 18 so corrected versions can be sent prior to next meeting.

2. Action item and status updates (from minutes).
   Ron's Action on FDA acceptance was deferred to topic 6; which in turn was also deferred due to lack of time.
   Wayne has prepared a draft pipeline for topic 3.
   Wayne has discussed the need for more communications resources with TransCelerate but no solutions found so far.
   One absent member wished to discuss further the plans to invite external guests before issuing invitations, so this will be tabled until next meeting.

3. Review First Draft 2013 CDISC Project Pipeline of Therapeutic Areas.
   Wayne presented a draft Gantt chart that represents the potential therapeutic area project pipeline for 2013 based on knowledge to date. We are still trying to publish the provisional Parkinson's guide in December, and PKD in January. The Cardiovascular standard should be posted for comment in Q1 2013. The chart also shows 12 additional projects that may initiate in 2013, in addition to Asthma which has recently kicked off. One of these is a potential "grass roots" effort that has been suggested -- but this would still need to be coordinated and managed through the process by CDISC.
   Only 5 of the projects have been discussed by the CFAST SC to date -- the ones involving TransCelerate. But other projects are being commenced through Duke Clinical research, C-Path, and CDISC, some of which have partial funding from outside sources. Members agreed that the list was challenging, since one of our goals was to ensure we could optimize the process before initiating too many new projects. There is also concern that the research community, as well as CDISC, may not be able to handle so many concurrent projects (potentially 11 at a time in Q2) in addition to participating in foundational standard activities. TAPSC would like to better understand what is a reasonable capacity that could be effectively managed without hurting quality.
   We agreed to continue this discussion at next meeting.

4. Discussion: Governance and coordination of multiple projects
The project list highlighted the need for transparent communications and effective governance for the full TA project portfolio. This discussion will be continued at next meeting.

5. Defining the next set for the project queue
We agreed that we need to carefully review and agree on the ordering of the next 9-11 projects, since the TAPSC has only discussed in detail Asthma and Diabetes as the first two.

6. FDA acceptance of new standards
Due to lack of time, this will be discussed at a future meeting.

7. Any other business
Mary Ann raised the need for the process to include high-level validation requirements as part of the standard. Wayne noted there is a place for this in the process, but the details on how to address this have not yet been worked out. We'll continue this discussion in future meetings as well.

8. Plans for next meeting.
We will try to plan a meeting for next week (potentially Dec. 20 at the same time) to continue discussions. We will adjourn after that until the new year.

Dec. 20 Meeting:

Attending: Wayne, Bron, Mary Ann, Ron, Jon, Enrique, Sue - Quorum achieved.

Proposed Agenda:

1. Review and approval of prior meeting minutes (see below): Dec. 5 and Dec. 13
   Revised minutes from 12/5 meeting were approved. We deferred approval of 12/13 minutes until next call. (12/13 minutes reattached at bottom of this message).

2. Action item and status updates (from minutes).
   Actions had been addressed previously, covered elsewhere in this meeting or deferred for future meetings (due to lack of time).

3. Accessibility of TAPSC minutes
   We had previously discussed posting meeting minutes to ensure committee actions were fully transparent to the research community. However, it was pointed out that posting full minutes might limit flexibility, and there was a risk that the press might misinterpret committee discussions. We considered whether we
should make minutes available in a less public place (such as for the CDISC CAB only). Motion made that in the future we log meeting notes for access by TAPSC members only and publish a quarterly update of highlights and key decisions which will continue to be placed on the CDISC website. Seconded and passed unanimously.

ACTION: Wayne will draft "highlights and key decisions" document for review and discussion at next meeting.

4. Participation of other organizations in CFAST TAPSC

At the Dec. 5 meeting we had proposed inviting Margaret Haber of NCI as a non-voting guest to future TAPSC meetings, since NCI is a major resource contributor to this program. We discussed whether to add another NIH guest representative (though Margaret is part of NIH), since they have put together ~26 Common Data Element models that are relevant to the TA Program. NLM is also defining standards for meaningful use with ONC that may also be relevant. However, finding a single individual to represent all of NIH may be challenging given its diversity. We agreed that we would not invite any new voting members on the TAPSC until the committee gets better established; however we felt we could accommodate up to 2 guests at a time (one of these being Margaret Haber); it might be disruptive with more than two.

However, we should also be careful that the TAPSC doesn't appear to be US-centric. While TransCelerate and CDISC are global organizations, we don't have any representatives from ex-USA governments. The European IMI partnership is also doing much work in TAs that is relevant.

ACTION: Wayne to invite Margaret for future meetings in 2013.

ACTION: Others to suggest potential candidates to be a NIH point of contact guest: Bron to contact Becky Kush; Enrique to contact Lynn Hudson; Sue to check with Doug Fridsma. We'll continue discussion at next meeting.

5. Continued discussion of 2013 TA Project pipeline and governance of multiple projects

Note: Ron reports that FDA will have 2 sets of models available in January 2013; 2 more in April 2013

We continued discussing the CDISC project list and the fact that there may already be more (14-19) projects in the pipeline than can be accommodated, especially since we wish to make sure the first projects go well and nurse the overall process toward improved productivity and timeliness. It was proposed that we separate a list of projects that are to be governed by the TAPSC from other CDISC projects and that we look at how to shorten the list, though this will be challenging. Ultimately, we have to separate high priority projects from others that may get less attention, and pare down projects that cannot be adequately resourced.
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6. Any other business
None raised.

7. Plans for next meeting.
We’ll reconvene on Jan. 3 at 11am ET and continue on a biweekly schedule after that. At future meetings we'll continue discussions on guest attendees, the project list, and discuss FDA acceptance of new standards.

CFAST Therapeutic Area Program Steering Committee
2012 Meeting Summaries
Nov-Dec 2012

Dec. 5, 2012 Meeting:

Attending: Enrique, Diane, Mary Ann, Wayne. Quorum achieved.

1. Meeting minutes from past meetings were accepted without change.

2. Action items and status updates
The TAPSC Charter and past meeting minutes have been posted on the CDISC TA website.
The recent Federal Register notice, published on Nov. 20, was originally intended to have been published earlier in the year to raise awareness of the PDUFA V commitment.

3. Asthma Pilot status
The pilot kickoff meeting was successfully conducted last week. The team is actively working on scoping, but clearly much work needs to be done to fill out and refine the process. All agreed on the importance of supporting this pilot project since it is intended as a baseline for future projects.
Several essential drivers for active and visible governance of the project were discussed:
4. The Steering Committee must show visible evidence internally and to observers of CFAST’s intent and ability to deliver using the new process.
5. The projects must demonstrate that they can engage key stakeholders in both the clinical research and healthcare communities who have an interest in these project areas to identify common information concepts and move toward interoperability.
6. The Steering Committee must show intent to learn from mistakes and apply lessons effectively to future projects.
It was agreed that achieving full healthcare interoperability is challenging and long-term – our short-term goal should be to make sure we are involving clinicians outside of research, capitalizing on past work and existing terminology standards where possible, and making it clear that CFAST is not operating in a silo. Engaging healthcare experts and other relevant stakeholders is the key. CDISC and C-Path have been engaging with such experts on past TA projects, for PKD, Parkinson’s and TB, for instance. CFAST needs to continue such outreach aggressively. The TAPSC also has a core principle to reuse past work and not seek to reinvent, but in practice this is challenging. In some areas there are published ontologies, but these can be difficult to find and assess. Each project will need assistance in tapping into the right areas and groups. Right now, NCI has been helping by searching the NCI semantic sources to look for relevant material for Asthma. The FDA has identified a medical reviewer and statistical reviewer to liaise with the Asthma team. Their names will be sent to the Asthma project manager. The FDA review division uses the National Asthma Guideline from NHLBI, which is already being used by the Asthma project team.

4. Plans for next priority areas
The TAPSC discussed the need to queue up a set of projects that can be communicated widely so that participants can be engaged and prepare. The first step is to develop a clear initial plan that represents all of the projects currently identified and proposed for 2013 (from the CFAST queue and other projects of CDISC and C-Path).

ACTION: Prepare a chart of proposed 2013 projects for discussion at next call. The TAPSC will review and approve the therapeutic areas projects on this chart and make it available as the 2013 CFAST plan through the CDISC website for therapeutic area standards. FDA plans to point to this site as well for CFAST TA project status. The TAPSC will review this list at least quarterly, adjust and amend it with new projects and status on an ongoing basis. Projects will be added as capacity becomes available, but right now, it seems as though the queue may need to be limited for 2013.

5. Communication of project priorities and input gathering
Given the need to engage outside experts and the desire of industry to know what’s in process, the CFAST TA Program needs to work actively to communicate. The original CFAST plan was to have dedicated communications assistance to help with this, but that’s not currently possible due to lack of funding.

ACTION: Discuss at next TransCelerate meeting.

6. Guest participation of key partner stakeholders at future SC meetings.
Other organizations have expressed desire to join the TAPSC, which is possible under the charter. While the current TAPSC is not ready to add new members yet, there was agreement that the NCI EVS group, a key partner providing substantial resources for terminology, should be invited to attend as a guest to future meetings. A motion was to invite Margaret Haber to future meetings was passed unanimously, pending agreement from absent members.

7. Understanding process for FDA acceptance of therapeutic areas for use. FDA has made progress on this and agreed to present progress at a future meeting.

FDA has also begun an internal project to engage review divisions in capturing requirements for TA review. The project’s objective is to develop small clinical models representing study data requirements in specific disease/therapeutic areas. The initial effort focuses on a small group of TAs to assess value and efficiency of the approach. These models should be of value to future TA efforts, and are an indication of interest among some FDA reviewers, standards projects in these areas would have to be prioritized in the same manner as other CFAST projects. The TAs proposed in this initial effort are:

- Acne
- Overactive Bladder
- Lipid altering drug groups
- Hepatitis-C (possible overlap with the recent CDISC Virology TA User Guide)
- Diabetes (next project on the CFAST/TCB list)

8. No other business was discussed.

**Dec. 13, 2012 Meeting:**

Attending: Mary Ann, Ron, Diane, Wayne, Jon

Agenda:

1. Acceptance of prior meeting minutes.
   Accepted

2. Action item and status updates (from minutes).
   Discussed in subsequent topics.

3. Review First Draft 2013 CDISC Project Pipeline of Therapeutic Areas.
Discussed a draft Gantt chart that represents the potential therapeutic area project pipeline for 2013 based on knowledge to date. CDISC plans to publish the Parkinson’s guide in December, and PKD in January. The Cardiovascular standard should be posted for comment in Q1 2013. The chart also shows 12 additional projects that have been proposed to initiate in 2013, in addition to Asthma, which has recently kicked off. One of these is a potential "grass roots" effort that has been suggested -- but this would still need to be coordinated and managed through the process by CDISC. Only 5 of the projects have been discussed by the CFAST SC to date -- the ones involving TransCelerate. But other projects are being commenced through Duke Clinical research, C-Path, and CDISC, some of which have partial funding from outside sources. TAPSC needs to better understand what is a reasonable capacity that could be effectively managed without hurting quality.

4. Discussion: Governance and coordination of multiple projects
The project list highlighted the need for transparent communications and effective governance for the full TA project portfolio.

5. Defining the next set for the project queue
TAPSC will continue prioritizing the next 9-11 projects, since the TAPSC has only discussed in detail Asthma and Diabetes as the first two.

6. Any other business
Need for the process to include high-level validation requirements as part of the standard. We'll continue this discussion in future meetings as well.

Dec. 20, 2012 Meeting:

Attending: Wayne, Bron, Mary Ann, Ron, Jon, Enrique, Sue - Quorum achieved.

Proposed Agenda:

1. Review and approval of prior meeting minutes (see below): Dec. 5 and Dec. 13
Revised minutes from 12/5 meeting were approved. We deferred approval of 12/13 minutes until next call.

2. Action item and status updates (from minutes).
Actions had been addressed previously, covered elsewhere in this meeting or deferred for future meetings.

3. Accessibility of TAPSC minutes
Motion made that in the future we publish a quarterly update of highlights and key decisions which will continue to be placed on the CDISC website. Seconded and passed unanimously.

4. Participation of other organizations in CFAST TAPSC
At the Dec. 5 meeting we had proposed inviting Margaret Haber of NCI as a non-voting guest to future TAPSC meetings, since NCI is a major resource contributor to this program. Proposal to add another NIH guest representative, since NIH has put together ~26 Common Data Element models that are relevant to the TA Program. NLM is also defining standards for meaningful use with ONC that may be relevant. TAPSC agreed to not invite any new voting members on the TAPSC until the committee gets better established; but will consider inviting other guests representing the global research community.

5. Continued discussion of 2013 TA Project pipeline and governance of multiple projects
FDA will have 2 sets of models available in the first quarter 2013; 2 more in the second quarter 2013
TAPSC continued discussing the CDISC project list, which already proposes to be accommodating 14-19) projects in the pipeline. It was proposed that we separate a list of projects that are to be governed by the TAPSC from other CDISC projects and that we look at how to shorten the list.