CFAST Therapeutic Area Program Steering Committee
2013 Meeting Summaries (January-August)

Participant full names and titles:
Wayne: Wayne Kubick, Chief Technology Officer, CDISC (Chair)
Becky: Rebecca Kush, President, CDISC
Bron: Bron Kisler, Vice President, Strategic Initiatives, CDISC
Enrique: Enrique Avilés, Chief Technology Officer, Director, Data Stds & Mgmt, Critical Path Institute,
Jon: Jon Neville, Assistant Director, Data Standards and Management, Critical Path Institute,
Mary Ann: Mary Ann Slack, Deputy Director, Office of Strategic Programs, FDA CDER
Ron: Ron Fitzmartin, Senior Advisor, Office of Strategic Programs, FDA CDER
Sue: Sue Dubman, Senior Director, Global Sanofi R&D IS, Sanofi-Aventis, TCB
Diane: Diane Wold, Director Data Standards, GSK, TCB
Dave: David Jordan, Project Leader, Abbvie, TCB
Margaret: Margaret Haber, Associate Director, NCI EVS

Notes from 1/3/2013 TAPSC Meeting:

Attending: Enrique, Jon, Sue, Diane, Mary Ann, Ron, Bron, Wayne, Margaret.
Welcome to Margaret now joining as a regular attendee representing NCI Terminology Services.

Agenda Topics:

1. Review and approval of prior meeting minutes: Dec. 13 and Dec. 20
   Minutes reviewed and accepted for both meetings with 2 corrections:
   Dec. 13: Change item 5 to "FDA Acceptance of new standards"
   Dec. 20: Change item 5, line 1 to "Note: Ron reports that FDA plans to have 2 sets of models available in Q1 2013; 2 more in Q2 2013"
   Corrected meeting notes inserted below.

2. Action item and status updates (from minutes).
   Addressed in subsequent items below.

3. TAPSC Highlights and Decisions Document
   General level of detail was acceptable to all attendees.
   ACTION ALL: Respond to Wayne with any specific change requests by next meeting (1/10).
   ACTION WAYNE: Create 2012 Highlights and Decisions document consistent with this approach from prior meeting minutes for formal approval and later posting.

4. Participation of other organizations in CFAST TAPSC
   Mary Ann is planning to discuss CFAST participation with Betsy Humphreys (NLM) and Doug Fridsma (ONC). Sue also is waiting to hear back from Doug. Enrique has had feedback from Lynn Hudson on possible NIH contacts.
   Margaret pointed out that her primary role was to gain insight into planning of NCI resources to support terminology services for CFAST therapeutic area projects, rather than to represent NIH needs or activities. NCI is collaborating with ONC and NLM, who are interested in NCI's LexEVS terminology services and metadata repository capabilities. NCI and NLM are collaborating on the technologies for NLM's planned value set repository, which has not yet been created. This would serve as a venue to publish out NIH and other standards (not a development environment). Wayne noted that CFAST is
planning to create a scientific advisory committee, which might be a more appropriate place for NIH, NLM and/or ONC to participate.

Mary Ann is concerned that Steering Committee participation may be needed because NIH/NLM/ONC are working in parallel on overlapping activities to create CDEs and models, and that is important to align projects and schedules, which would fit within the TAPSC charter. Wayne pointed out that CDISC experience with prior projects such as PKD and Parkinson’s indicated that the CDEs being created for NIH provided important background and were very useful but additional work was needed to fully develop into therapeutic area standards suitable to support regulatory review and analysis. CDISC has and will continue to use these as key inputs on TA projects in any event.

Identifying a point of contact and role for NIH/NLM/ONC remains an open action item as several TAPSC members continue to gather information, and will continue to be discussed at future meetings.

ACTION WAYNE: Circulate draft CFAST Scientific Advisory Committee Charter when ready for review.


The project Gantt chart was reviewed again. Wayne will prepare a separate version with TA projects only. It was agreed that once a chart is published expectations will have to be met, so it’s important to come up with an achievable program plan for TA development projects. While clearly projects that come with funding and resources should be prioritized, other projects that come with an available bolus of information inputs or prior modeling should also be take into account in prioritization as capacity permits.

ACTION ENRIQUE: Compare current top 15 draft project list with FDA roadmap and prior list of TransCelerate industry priorities and report back.

ACTION WAYNE: prepare TA only project list.

6. Any other business and plans for next meeting.

We will hold a regular meeting on 1/10 and continue with our regular biweekly schedule after that.

Notes from 1/10 TAPSC Meeting:

Attending: Ron, Enrique, Bron, Margaret, Jon, Diane, Wayne. Quorum achieved.

Regrets: Mary Ann

Agenda Topics:

1. Jan. 3 meeting minutes approved.

2. Action item and status updates (from minutes). CFAST Scientific Advisory Charter still being developed -- Wayne will circulate as soon as a stable draft is ready. Enrique distributed the comparison between FDA and TCB priorities for review next meeting. Wayne included a TA project list for discussion in item 5.

3. TAPSC Highlights and Decisions - Wayne has received comments from Diane to date. Draft did not apply change relevant to readiness date for FDA models (should be by quarter, not month). TAPSC agreed to the following:
   a. Leave detailed minutes from Sept-October posted on website (these have been posted for nearly 3 months already).

ACTION: Wayne to compose a brief paragraph describing TAPSC meeting frequency and future approach to posting meeting summaries once per quarter
ACTION: TAPSC submit final comments on draft decision document prior to next meeting so this can be approved and posted to catch up through end of 2012.

4. Review and discussion of Asthma project charter Under the new CDISC process, TAPSC would like to receive draft charters for approval 30 days after project kickoff. The charter is meant to be a ~2-page document that identifies the what, who, when and how of each project so that the TAPSC can make a go/no go decision on whether prioritized projects should proceed to implementation and so we can communicate the project definition and scope to the wider research community (these will be posted to the CDISC website after approval). The draft asthma charter was reviewed section by section in detail to try to identify what sections were most important for TAPSC review to provide feedback on the charter template in general and comments to the asthma team in particular.


The revised chart listing TA projects was reviewed. It was agreed that the number of projects needs to be reduced to a more manageable list of 2013 projects. The current pipeline and level of expectations will be difficult to meet, and even when resources are in place to drive the project, other dependent resources from NCI, the CDISC SRC or other CDISC project teams may not be available to support project completion.

ACTION: Wayne to reorder list according to 4 relative priority categories:
1. Projects already underway
2. Projects with funding/resources identified which have not yet begun (timing for these may be able to be pushed back in some cases)
3. Projects that are viewed as high priority needs, but lack sufficient funding or resources
4. All remaining potential TA projects in the queue. It was noted that the work on FDA models might fit into category 3 or 4, but indicate a high level of interest and potential availability of FDA reviewers to support a TA, which is a desirable success criterion.

6. Participation of other organizations in CFAST TAPSC Deferred; will be repeated at next meeting.

7. Any other business
FDA has requested periodic updates from Project Managers in future meetings. Wayne will provide status updates for now, but will invite individual PMs to answer questions when requested by TAPSC.

Notes from 1/24 TAPSC Meeting:
Attending: Ron, Enrique, Jon, Sue, Diane, Wayne, Mary Ann - Quorum Achieved
Regrets: Margaret, Bron

Agenda Topics:

1. Review and approval of prior internal meeting minutes: Jan.10
These had not been reviewed in detail by all parties and no objections were raised. Since these are not being posted, approval can be deferred; however, unless objections are raised by COB tomorrow, Wayne will assume acceptance and begin to compile a running document of these which will be amended once minutes are approved. Wayne will also amend the "Meeting Highlights" document after each meeting so review/approval can be done section by section.
Action - All: Please send any remaining comments to Wayne by 1/25.
Action - Wayne/Enrique: Identify a TAPSC portal for storing working documents, including the highlights, approved charters, etc.
2. Action item and status updates (from minutes).
Wayne will prepare a brief statement for the website (once the "Highlights" document is approved) that the TAPSCC meets every 2 weeks and will publish highlights of meetings once per quarter. A reordered priority list has been prepared to support discussion of item 7.

3. Approval of TAPSCC Highlights and Decisions document 2012
Comments received from Diane, Ron and Sue will be applied by Wayne. One additional change to Dec. 20 notes regarding decision to publish meeting highlights approved at meeting. ACTION: Barring receipt of any other change requests by COB Jan 25, Wayne will finalize and post document next week.

4. Review/approval discussion of revised Asthma project charter
The revised charter was reviewed in detail and found to be much improved. Discussion about the need to engage more stakeholders and the challenge of doing so – what is the best approach to reach the right groups? Ron noted that the FDA docket on TA standards received 5 responses, which can be reviewed at http://www.regulations.gov/#!docketBrowser;rpp%:po=dct=252BFR%252BPR%252BO:D?A-2012-N-0974. It was discussed that in the future it may be best to decouple the outreach, scoping and charter preparation in Stage 0 from Stages 1-3, when the details of the standard are developed. This will allow more time to reach out and communicate externally, and develop a backlog of projects ready to start when resources become available.
Enrique moved that the charter be approved, subject to completion of these changes. Seconded by Sue. Motion carried unanimously.

5. Review/discussion of Alzheimer's v1.1 project charter
Jon Neville guided discussion of this charter. Changes discussed for Asthma charter also need to be applied in this case.

Enrique moved that the charter be approved, subject to completion of these changes. Seconded by Mary Ann. Motion carried unanimously.

6. FDA Process of acceptance of new data standards
This was deferred for a future meeting.

7. Continued discussion of 2013 TA Project priority queue/pipeline (reordered TA chart attached) - process and commitments to date
The revised Gantt chart was noted as an improvement to help with prioritization decisions. It was noted that TB V2 should be moved to the "Potential" list -- corrected version attached (which also changed the order of some of the projects to be more chronologically aligned within the categories). It would also be helpful to represent FDA and C-Path priority scores.
The FDA Models include both UML and tabular models of key endpoints and relationships that reviewers see for given therapeutic areas, and these should be very helpful for scoping and concept development. The first of these should be completed shortly and made available for review.
Mary Ann noted that it's important to align the various ways that such requirements are collected via CDEs, CRFs, HL7 DAMs, CDISC and other groups to make it easier to review and interpret these. This will likely take some time to harmonize these very different modeling approaches, but should be a goal over time.
It's important to consider several guiding principles in prioritizing projects:
• Availability of sufficient resources
• Availability of enthusiastically engaged FDA reviewers -- reviewer input can be difficult to secure
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otherwise

- Availability of prior work to simplify the standards development process.
8. Participation of other organizations in CFAST TAPSC (see attached draft CFAST SAC Charter)
   This was deferred due to lack of time. However, it was pointed out that another interpretation of the SAC is that it would be parallel to the TAPSC as a decision-making body to help ensure project success.
Action - Wayne/Enrique to schedule separate call to discuss SAC charter and function.

Notes from 2/7 TAPSC Meeting:

Attending: Enrique, Jon, Ron, Diane, Sue, Margaret, Wayne - Quorum Achieved
Regrets: Mary Ann, Bron

Agenda Topics:

1. Review and approval of prior internal meeting minutes: Jan.24
   No comments or changes suggested to the minutes (other than one typo noted). Alzheimer's and Asthma final charters (after TAPSC requested updates) are attached and will be posted (ACTION: Wayne).

2. Action item and status updates (from minutes) 2012 Highlights and Decisions document (with explanatory text) now posted on CDISC website.
   Portal site still TBD. Draft Q1 Highlights and decisions doc for 2013 still pending. The role of the CFAST SAC has been discussed in a separate phone call and in the CFAST Executive Committee meeting. A revised charter will be circulated for comment shortly.

3. Decision on first set of 2013 CFAST TA Projects
   The full pipeline of proposed projects for 2013 was reviewed one by one, and recommendations to reduce the list to a more manageable and achievable length were discussed. The TAPSC objective was to identify a short list of acceptable standards projects that will clearly begin in the first half (or maybe first 9 months) of 2013 so that industry and FDA can begin to prepare to review and implement these. The messaging should ideally be synchronized with FDA communications through the Federal Register, and FDA would like to see validation requirements defined, so that FDA can announce when they'll be ready to officially "open shop" for new therapeutic area standards that are "available, supported, required."

   The pipeline includes 2 legacy projects (CV and PKD), which are continuing from prior years. Asthma and the Alzheimer's update were the first new projects approved by the TAPSC previously. A CDISC goal was to try to limit the number of new TA projects to 7 or 8 for 2013, to allow time to refine the process and get training, tools, etc. together so it can become possible to start up one project per month beginning in 2014. This allows room to schedule 6 more for this year (though perhaps more can be added in Q4 if things progress well in the meantime). However, the current pipeline is already listing 5 funded projects and another 6 underfunded projects, not including the 4 FDA models (in other words, 15 more and counting).

   The TAPSC expressed interest in learning about the FDA models, and Ron indicated that Boris can set up a Webex to review these (perhaps with both TAPSC and TCB attendees).
   ACTION: Ron.

   Of the funded projects, the C-Path Multiple Sclerosis and CDISC Traumatic Brain Injury projects have
sufficient funding and support to proceed, and should not be inhibited by TAPSC (since commitments to funding foundations have been made and resources are lined up).

Similarly, work on 2 DCRI projects (CV Imaging and Schizophrenia) is at least partly funded by FDA R24 grants to CDISC. Both of these are compatible with TCB priorities.

Diabetes is a high priority that had been pre-approved by the TAPSC last October, benefits from experience on the FDA's legacy conversion project, and will be resourced by TCB, which would like to begin work this spring.

Of the potential projects, the QT studies project was a high priority of FDA and also supported by TCB. FDA also has strong reviewer support from the Cardio-Renal division, and the project was viewed as having broad impact on multiple TAs and also relatively constrained in scope (and thus would be a great test of the new process). However, this is one of 4 CV-related projects currently in the pipeline, a heavy commitment in one specific area. The resource-balancing problem is compounded by 2 other CV related projects driven by DCRI (CV Imaging and CV Endpoints), the latter of which is not sufficiently funded to proceed anyway. As a result, the TAPSC considered whether CV should be treated as an ongoing program, and that related CV projects should be done more in sequence rather than in parallel, which would allow subsequent CV projects to build on prior experience and also be less demanding on the review community.

**ACTION:** Ron agreed to contact FDA reviewers to discuss how to potentially sequence the CV programs, possibly leading with QT studies before proceeding to Endpoints and CV Imaging. This would reserve a Cardiovascular track in our portfolio on an ongoing basis.

Diabetes is expected to occupy a similar track over several years, since the first version needs to be scoped as a constrained subset of this vast disease area. This approach was also discussed earlier to apply to Oncology, so that various aspects of Oncology could be approached in a logical sequence (which is already being explored with the help of a TCB lead).

It was concluded that projects need to be engaged this year in each of these major areas: CV, Diabetes, Oncology.

The eighth logical project was Schizophrenia, for which DCRI is already defining CDEs. This was also high on the FDA and TCB priority list, with CDISC funding under an FDA R24 grant.

This group of projects, with projected start dates is listed on the revised CFAST2013Planv1 document. Many of these projects also seemed to correspond well with NCI EVS plans, since they have been already involved in DCRI work or supporting other research in these areas.

A separate pipeline (which includes both the planned projects and other potentials) is also attached. Other potential opportunities will be added to this list and it will be reviewed periodically. One project that has been added is a proposed Vaccine project, which a grassroots team from pharma companies wishes to pursue this year as well. TAPSC obviously wants to encourage some activities yet needs to be careful of not exceeding our capabilities to succeed. We'll need to discuss how to handle such projects at future meetings. Some projects (like TB) may be able to secure funding, but ideally can be deferred until we make progress on achieving the current priority list.

4. Participation of other organizations in CFAST TAPSC - discussion of issues needing SAC input - continued

5. FDA Process of acceptance of new data standards (deferred again)No discussion on this topic.
Notes from 2/28 TAPSC Meeting:

Attending: Wayne, Bron, Margaret, Diane, Jon, Mary Ann
Regrets: Ron, Sue

This was a brief update meeting due to the unavailability of several key members. It was agreed to extend next week's meeting to 2 hours and seek to finalize the first list of ~8 new TAs to address in 2013 at that time.

Agenda Topics:

1. Approval of minutes was postponed to next call.

2. Action and status updates:

   The results of the last meeting (3 weeks ago) were reviewed which sought to distill the pipeline of ~20 proposed projects to a more manageable list of ~8 to start in 2013. The list of 8 allows for the possibility of adding 1 or 2 more in Q4 if we continue to make progress.

   One of the legacy projects, PKD is expected to be posted today. The draft User Guide for another legacy project, for Cardiovascular, was recently reviewed by the CDISC Standards Review Council, which recommended that it should not be released for comment in its current form. This UG stems from a project started 3 years ago with Duke Clinical Research and the American College of Cardiology, and in its present form was trying to map a disparate set of 400 cardiovascular data elements commonly used when treating cardiovascular patients to SDTM without a clearly defined scope and research focus -- most of these were relevant primarily to cath lab registration. Since TAPSC had discussed addressing cardiovascular as a single stream of sequential projects, it makes more sense to combine this work with something that has clear applicability to research, such as CV Imaging or endpoints, rather than releasing it by itself in its present form. TAPSC still needs input from FDA on how best to tackle the cardiovascular stream as a sequence of projects.

   Rebecca Kush is working on a revised charter for the Scientific Advisory Committee (SAC), which should be available for review and discussion next month. Becky and Wayne believe the new proposal, if accepted, can be implemented relatively soon.

   Wayne still has to post charters to the CDISC website and set up a TAPSC portal site.

   TAPSC still needs to be briefed on the current FDA models so they can be taken into account in the future priority queue.

3. Review of proposed list of first 8 priority areas:

   The current proposed list of 8 projects was reviewed and all parties were reminded of the need to approve and communicate these, which is planned for next meeting.

4. Identifying next set of priority areas:

   Once the initial list is posted, discussions can begin on defining the next set (using inputs from the FDA tiered roadmap, the C-Path survey and others) and the plan can be revisited periodically (every quarter or so). By defining packages of proposed projects to begin over a time horizon of 9-18
months, reviewers, sponsors and participants will be better able to plan for which projects are likely to impact them directly and encourage broader involvement. The TAPSC will be challenged to come up with a balanced, manageable portfolio of projects that are sufficiently resourced/funded and address major areas of need. At full capacity, it is anticipated that that 10-12 projects at a time can be managed. The workload management problem is complex because so many projects will have follow-on versions, such as Alzheimer’s v1.1 currently in development, and successive projects broadening the scope and reach within the Oncology, Diabetes and Cardiovascular disease areas. It was pointed out that the FDA model for Hepatitis C should likely build on the existing Virology TA User Guide, and that other FDA models (such as lipid-lowering drugs which might fit within the Cardiovascular track) are also likely to fit within current project streams. It’s logical to prioritize projects that can move more quickly by building on the progress of prior work.

So being able to balance these ongoing programs of projects within one area while still starting up new therapeutic area projects will be a continuing challenge. The TAPSC will seek to identify a model for maintaining this balance, hopefully in conjunction with the proposed CFAST SAC.

5. Other business:
Diane believes that progress is being made on defining initial scope of proposed Diabetes project -- should be ready for TAPSC review within next month.
Bron will be attending an IMI meeting on TB, which may spur a new version of the current TB TA standard, not currently in the 2013 queue.

Notes from 3/7 TAPSC Meeting:

Attending: Diane, Wayne, Jon, Ron, Sue, Margaret, Mary Ann, Enrique
Regrets: Bron

Agenda:

1. Review and approval of prior internal meeting minutes (inserted below): Feb. 7 and Feb. 28.
Wayne briefly reviewed the TAPSC CDISC portal site, which will be used as a document repository for the TAPSC (an open action item). Next the (internal) minutes of the past two meetings were reviewed, discussing the rationale for reducing the current pipeline of ~16 projects to a more manageable list of ~8. The list should be balanced across multiple disease areas, and generally favor projects that are adequately funded or resourced (and thus more likely to succeed). Some of the funding may come from external foundations (with grants to CDISC or C-Path). All agreed that it was important to agree on an initial list of priorities for 2013 so the research community could begin to prepare to contribute to and use the new standards.

2. Action item and status updates (from minutes - postings, temporary portal, FDA models, SAC, CV program)Ron has contacted Boris to see when a demonstration of one of the FDA models can be arranged for TAPSC. Ron will target an overview of the Overactive Bladder model at the April 4 TAPSC meeting.

In other areas, a proposal for establishing a CFAST Scientific Advisory Committee (SAC) composed of a single member from CDISC, C-Path, FDA and TCB plus invited experts is nearly readiness, and hopefully will get engaged with the Diabetes scope discussions now ongoing. The SAC role will be to see that project descriptions and scopes are scientifically valid and to provide input on scientific issues relevant to projects; the TAPSC role is to verify that they are realistically achievable within our planned 10 month project completion horizon, and to prioritize and manage the overall project portfolio.
The challenge of keeping up with so many standards related activities was discussed. NCI is working on a standards portal that may serve as a resource to identify what other related initiatives may be in progress around the world.

ACTION: Margaret to share details of new NCI portal as they become available.

Mary Ann briefly discussed how FDA's CSC is ramping up to provide training, support and mentoring (similar to that provided for eCTDs) for SDTM and ADaM. As part of their acceptance process for new TA standards, FDA will need to test each TA (perhaps asking sponsors to send sample data from previous submissions) and be ready to validate data for conformance with structural and content business rules associated with a TA standard. Reviewers are already discussing some of these content/business rules. Wayne stated that conformance requirements will be a part of the standards package but the CDISC teams have not yet worked out the details for this.

3. Review and determine steps need for approval of proposed short list of priority areas for 2013 Plan

The two Gantt charts were reviewed-- one with a short list of 8 proposed projects for the initial plan, and one showing a larger pipeline of known potential projects with some current activity.

Of the planned projects, Asthma and Alzheimer's v1.1 are approved and underway. A C-Path project for Multiple Sclerosis is funded and ready to start shortly. Another project funded by One Mind for Research through CDISC should start later this Spring. ACTION: Enrique and Wayne to proposal preliminary scope definitions to TAPSC by next meeting. This should proceed formal scoping and modeling and charter preparation activities.

TCB volunteers are working with CDISC to prepare for diabetes, and are also working on defining a proposed scope for the first increment of what will be a long term, complex project with many components. TCB is also working to define an initial target scope for the first part of Oncology, likely to start in Q3 if agreement on the first chunk can be found. FDA already has guidance in two areas for Oncology (Objective Tumor Response (already partly in SDTM) and Time to Efficacy (partly in ADaM) which should inform the scope definition process.

Schizophrenia, using data elements collected and defined by DCRI, is also resourced by an FDA R24 grant and potential TCB and other industry volunteers, but will start in Q3 or later depending on when the DCRI elements are ready to be transferred to CDISC. While these projects are dependent on Duke completing their modeling and vetting through HL7, it is anticipated that the CDISC part of the process should move more quickly since Duke will have completed the equivalent of Stage 1 of the CDISC process. However, the HL7 process so far has taken much longer (typically a year or more) than the entire timeframe we have allocated for a full Stage 0-4 standards project, so it's unclear how that can be accommodated on most projects if we hope to meet our timeline objectives.

One challenging area is Cardiovascular, which has multiple projects in the pipeline. One legacy project to map CV data elements for acute coronary care with DCRI dates back several years and was scheduled to be released for comment early this year. However, upon initial review the CDISC Standards Review Council saw that the project lacked a research focus, and seemed to only address mapping of disparate data elements to SDTM (but no clear study applicability). In addition there is a DCRI CV Endpoints project (current unfunded, and thus should probably be pushed out) and a DCRI/CDISC CV Imaging project, which is funded under an FDA R24 grant to CDISC but not yet ready to begin due to work in progress on CDEs by DCRI. Whichever of these is ready to go first can be combined with the work already done on the legacy CV Elements/Acute Care project that The QT study project is also related to CV, and potentially the FDA lipid-lowering drugs model.

ACTION: Wayne and Ron to meet with FDA Cardiovascular review division to discuss how to prepare
an orderly, more sequential plan for addressing CV needs over several years and combine at least some of these into a single project track.

**ACTION:** Diane and Sue to discuss CV needs with TCB community and potential identify resource availability.

To capitalize on the motivation and interest of FDA reviewers who have been contributing to FDA models, TAPSC felt it would be good to add one of the FDA models to the group. TAPSC voted to add Hepatitis-C to the initial list after Oncology, since it could build on the existing CDISC Virology User Guide, and was of high interest to both FDA and TCB. It was discussed that virology and vaccines might become another long-term project stream similar to Oncology, CV and Diabetes. Adding this to the list later this year will allow time to potentially identify resources. **ACTION:** Sue and Diane to contact TCB about identifying resources and interest in Hepatitis-C.

It was noted that additional work needs to be done to drill down the long-term plans for sequencing versions of CV, Oncology and Diabetes (and other such projects) once they are slotted in the overall queue. This will be addressed in future versions of the plan. **ACTION:** Wayne to update CFAST 2013 Plan Gantt Chart to accommodate these decisions. The attached version removes the sponsors from the list (for simplification, since, once approved, they are CFAST projects and the key sponsors can be found in the charter), adds an annotation describing the meaning of the bars and which projects need to be scoped incrementally in phases, adds Hepatitis-C, and makes adjustments to timing and sequence of projects. **ACTION:** TAPSC to review and send comments back by COB March 13.

4. Identifying the next set of priority areas

Work should begin immediately to start identifying candidate projects to comprise the next set for development. While these won’t begin for more than 8 months, TAPSC would like to eventually have a planning horizon of projects starting up over a floating 18 month window so everyone can plan, prepare, align. **ACTION:** TAPSC members to identify other candidates to add to the pipeline document for the 9-18 month horizon. The attached revised Pipeline removes completed projects, approved projects underway and the legacy CV elements project which will be merged with other CV projects, and adjusts some timelines. **ACTION:** TAPSC to review prior to next meeting.

5. Participation of other organizations in CFAST TAPSC

This topic had been deferred the past 2 meetings. The question is whether additional members should be added to TAPSC, what criteria should be involved, and (if so) who to add when. FDA has already discussed possibly inviting additional representation from NIH.

Some members expressed belief that new members should only be added if they are actively contributing to the CFAST program with resources and a commitment to harmonize (as NCI’s EVS/CaDSR group is already doing). CFAST is already committed to building on prior work wherever it can, but there’s a different between contributors or observers who may have some work that CFAST can build on, and those actively advancing the CFAST mission with direct commitment of resources. While CFAST may benefit from representation from NIH, IMI in Europe or other groups, we should be clear what the criteria are and consider how that will impact our ability to decide. It was agreed to continue this discussion after FDA meets with NIH representatives later this month and gathers more information. In the meantime, TAPSC members should continue to think about criteria and whether other voting members or observers should be considered.

6. FDA Process of acceptance of new data standards
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This will be scheduled for next meeting. Mary Ann has two slides to present on FDA’s current thinking.

7. Any other business
Enrique discussed the recent leadership changes at C-Path.

Notes from 3/21 TAPSC Meeting:

Attending: Wayne, Enrique, Diane, Margaret, Mary Ann, Ron, Sue.

1. Review and approval of prior internal meeting minutes (inserted below): Feb. 28 and Mar. 7
Most attendees had skimmed notes and had no comments. This will be considered final unless there are any change requests for edits by COB Tuesday, March 26.

2. Action item and status updates
Boris will give a 15-20 minute demo of FDA models at April 4 meeting. Wayne noted that the CFAST SAC was beginning to get engaged -- Mary Ann asked if a final charter was available.
ACTION: Wayne to contact Becky about distributing revised charter.

3. FDA Process of acceptance of new data standards
Mary Ann presented 3 slides discussing the FDA general process for assessing readiness and ability to accept and support new standards. The process would apply to any FDA standards activity, for example, between FDA and CDISC on CFAST projects. Essentially, FDA has to test and verify readiness for each new type of standard and version of a standard, and support for this must be included in the standards development. Wayne pointed out that for CFAST standards, the syntactical checks should be based on the base model (SDTM, ADaM, Define) and most of the TA-specific content checks should be based on appropriate use of value sets from controlled terminology codelists. Margaret noted how much terminology was already in place, but quite a queue was being assembled already. It would be essential to synch up the terminology process as early as possible during standards development (which is already a stated goal of the process). In order for this process to succeed with each new standard version, it will be necessary to find a way for check logic to be fairly stable and based on metadata-driven parameters. Perhaps one option would be to create a small sample SDTM, ADaM and Define test set with each new TA to drive the FDA readiness assessment.

Enrique raised two questions -- is this process being followed today for existing standards? And is it possible to "grandfather" existing TA standards (such as TB) so that companies already planning to use them do not find themselves in an unexpected non-compliance situation? It is important to encourage sponsors to begin using these standards.

Wayne asked whether FDA could describe how many different areas they were planning to use standards -- essentially, at what levels of granularity was this acceptance process being applied. Mary Ann said that a portfolio of areas should be published within the next weeks.

Mary Ann described an example of a content check that might verify that DM data for a pediatric study showed all patients under age 16. Wayne expressed caution that while a simple rule like this might be parameter-driven and applied to any TA, it would be easy to quickly get enmeshed in very complex rules, which could drag our timeline goals out.
ACTION: Wayne/Enrique/Ron to discuss scheduling a workshop to explore FDA validation/conformance expectations in greater detail.

4. Review description of Diabetes and MS TA
We reviewed the proposed Diabetes scope. The SAC is also in the process of reviewing the current draft scope. FDA is beginning a new requirements modeling session with the Diabetes division. Wayne noted that the Diabetes team was ready to proceed with input collection and scoping,
so that it would be necessary for FDA to provide their input before the scoping (and final charter) could be completed. In the meantime, all TAPSC members agreed that the input collection and scoping should proceed as planned, though there is a risk the scope may need to be adjusted depending on what FDA comes up with during their modeling process.

The proposed MS description was reviewed, which will use NINDS CDEs (like Parkinson's). Brief discussion on how, based on past experience, NIH CDEs are useful, but not sufficient as research standards. It was noted that the project was described more as general background without a specified research focus. However, it was noted that MS was likely to be of a manageable scope -- more like Asthma than diabetes, so this was not felt to be a great risk. But Enrique was asked to see if the description could be revised to emphasize the research focus more.

We also recapped the state of CV.
ACTION: Wayne and Ron will meet with FDA reviewers to determine how to proceed.

Notes from 4/9 Meeting

Attending: Mary Ann, Ron, Sue, Diane, Enrique, Jon, Bron, Wayne, Margaret

Agenda Topics:

1. Discussion of FDA Models Presentation from April 4.
A concern was raised whether the FDA modeling activities might delay the Diabetes project, but Mary Ann stressed there is no desire to delay this. The primary goal is to capture the top priorities of the review division. But there needs to be a way to ensure these activities are synchronized with CFAST plans.
Another concern was raised that the described approach was not consistent and might at times overlap with the CFAST process. Some of the slides seemed to be more about modeling SDTM rather than the details of Acne (again, this was not the intent) and attendees did not fully understand where the UML models would fit in. On the other hand, the list of primary endpoints identified by reviewers is extremely important to the process -- it's important to coordinate those inputs with project schedules.
A third concern was asking about where FDA's plans to define CRFs fits in, since CDASH CRFs were already included under the CDISC process for CFAST projects.
ACTION: Ron to follow-up with Boris and possibly invite him to a future meeting to discuss further (but we need not involve other modelers or process participants to this discussion).

2. Review and approval of prior internal meeting minutes (inserted below): Mar. 21 and Apr. 4 Minutes were accepted without comment.

3. Action item and status updates
Feedback on the SAC Charter should be directed to Rebecca Kush, who chairs the SAC. Other members include Lynn Hudson from C-Path, Chuck Cooper of FDA, and David Jordan of TransCelerate. Since the SAC is meant to be a CFAST organizational level entity (not limited to just the CFAST TA Data Standards Program) final approval of the SAC charter probably needs to come from the CFAST founding partners, CDISC and C-Path.

4. Vaccine Grass roots effort and CFAST
While CFAST has identified 9 projects for the 2013 priority list, there is a possibility that other groups may want to work on other projects that they'd like to include under the CFast umbrella. A proposal (from members of a group of pharma companies) to develop a vaccine standard has been recently submitted to Wayne. While CFAST wants to encourage any effort that can truly advance the
availability of therapeutic area standards, care must be taken to make sure project capacity is not overloaded and that there is a balanced portfolio. Thus by inserting additional projects, it may be necessary to push others back a bit.

Vaccines were not in the FDA roadmap or TransCelerate list, but it’s recognized that SDTM does not currently explicitly describe how to represent vaccine data, and there is certainly a public health impact. The question was raised as to whether this might be more properly a CDISC foundational standard as an SDTM implementation guide rather than a therapeutic area user guide, similar to SEND, Devices and Pharmacogenomics. Questions were raised as to whether this was a pure volunteer spare time effort, or whether the existing resources had dedicated company time to see it through. Mary Ann noted that there may be an opportunity to identify funding for an influenza project that might fit well with this if we could move quickly.

**ACTIONS:** Wayne to contact SAC for opinion on Vaccine as a TA and contact Vaccine team to determine their degree of resource commitment.

5. **TAPSC Participation and Coordination with SAC**

CDISC has proposed replacing Bron with Rebecca Kush as CDISC alternate TAPSC member, assuming her schedule can accommodate it. It will be necessary to set up a communication plan to share minutes and outputs, and possibly set joint meetings occasionally.

With regard to inviting other members to TAPSC, it was again clarified that TAPSC participation should be limited to organizations that are directly contributing resources to CFAST projects. NIH has expressed interest in joining, but is not currently involved directly in CFAST projects. Others whose role is primarily to inform and advise might be better suited to participate on the SAC.

**ACTION:** Any potential new members for the TAPSC should be formally nominated by an existing TAPSC participant together with an explanation of what they will contribute to CFAST and a rationale for their nomination. These will be reviewed by the TAPSC at future meetings as they are proposed.

6. **Identifying the next set of priority areas**

Under the new process, a project proposal with a draft description should be reviewed before priorities are set. In the effort to get started quickly, descriptions have not yet been created for projects other than Asthma, Alzheimer's, Diabetes and MS. Proposed definitions for all projects in the pipeline need to be drafted in a timely manner. This is especially important for broad multi-stage projects like Oncology. Once a clear definition is in place, it will be possible to begin preliminary efforts on gathering inputs for scoping. These should clarify the availability of resources as well and who is sponsoring the project.

**ACTION:** Wayne to work with CDISC, C-Path and TCB staff to draft project descriptions for the remaining projects on the 2013 priority list.

7. **Any other business**

Enrique asked for more detail about the FDA process for acceptance, particularly how it applied to previously approved TA standards. It's important that companies who are already adopting the published standards be comfortable that this will not risk acceptance by FDA. Mary Ann noted that the FDA process is not in place yet, so the answer is not yet clear. This topic will be discussed further at a future meeting.

**Notes from 4/18 Meeting:**

**Attending:** Jon, Enrique, Wayne, Bron, Diane, Ron

**Regrets:** Margaret, Sue, Mary Ann

**Agenda Topics:**
1. Review and approval of prior internal meeting minutes: Apr. 9
Minutes were accepted without comment and approved.

2. Action item and status updates
Attendees were reminded to send comments on the SAC charter to Rebecca Kush.
ACTION: Ron will look into scheduling an all-day workshop meeting at White Oak to discuss the topic of conformance requirements for therapeutic standards and how to ensure new standards can be efficiently tested and adopted at FDA. (See further discussion below under item 5).
CDISC and FDA have each been exploring CV, and CDISC has begun to assess and scope the list of CV Endpoint data elements prepared by Duke, which FDA agrees should be a top priority.
Wayne has followed up with the leader of the vaccines grassroots effort, and it was agreed that the work on vaccines should probably be a CDISC SDTM Implementation Guide foundational standard, which would provide the base structures for future CFAST projects in Hepatitis-C, Influenza and other viral therapeutic areas. But the vaccine project itself will not be a CFAST project.

3. Identifying the next set of priority areas - Definitions for current list; Process for submitting proposals.
Members were reminded of the need to draft brief statements of project intent as initial descriptions for all projects on the current priority list and for all additional projects proposed for prioritization. C-Path will prepare an updated statement along with a Charter for MS -- possibly by next meeting. CDISC will work on descriptions for TBI, CV and Schizophrenia. The SAC is expected to be looking at Oncology.

The project pipeline was reviewed-- the original list of known projects that were used to prepare the current prioritized plan. Each remaining project in this list must also be briefly described before TAPSC can discuss prioritization. Influenza was discussed as one opportunity -- it appears in the TCB Tier 1 list and some funding may be available to work on it. Diane will discuss TCB needs at the Monday TCB meeting. FDA must also revisit the plans for its work in process on TA models to see which ones can be described and considered for prioritization in the next set.
ACTION: All parties should work to prepare initial descriptions of planned and pipeline TAs by the May 16 TAPSC meeting. Specifically, C-Path will do MS, CDISC will do CV, TBI and Schizophrenia, TCB and the SAC should work on Oncology. (Alzheimer's Asthma and Diabetes are already covered). Any new candidates to be added to the pipeline must also be defined in advance moving forward. Also, please let Wayne know of any changes to make to the existing pipeline (attached).

4. TAPSC Participation and Coordination with SAC - communications plan
The expectation is that each member of either the TAPSC or SAC would communicate meeting results within their respective organizations, but it's not clear that's actually happening in all cases.
ACTION: Wayne to contact Becky to set up a joint TAPSC/SAC meeting to discuss relative roles of each group and how best to ensure smooth interactions, communication and coordination of activities.

5. Update on FDA models and standards acceptance process
FDA has invited CDISC to attend a call to discuss modeling approaches to therapeutic areas; apparently there have been previous meetings within FDA on this topic which have not included any of the other CFAST participants up until now, so it should be helpful to coordinate these FDA modeling activities more closely with CFAST.
With regard to Boris's modeling efforts at FDA, members are requested to submit any remaining questions in writing to Ron, who will invite Boris to attend a future meeting to respond, if necessary.

The workshop will address requirements related to FDA's acceptance process. A smooth and efficient acceptance process is critical to the agency, so there is a need to clearly specify what is expected of
the CFAST teams to support this activity. May 15 was suggested as a possible date for this meeting, though Ron will try to identify a few more dates after that. All agreed that the meeting should be held as soon as possible.

6. Updates on adding new members to TAPSC
As stated last meeting, any current member organization can nominate a new organization to join by submitting a nomination with a rationale explaining what contributions they will bring to CFAST. The nomination can then be discussed and voted upon at a future meeting.

**Corrected Notes from 5/16 Meeting**

Attending: Enrique, Jon, Mary Ann, Ron, Diane, Dave Jordan, Rebecca, Wayne - quorum achieved.

Agenda Topics:

1. Membership representation update (TCB and CDISC).
   Dave Jordan will sit in for Sue Dubman of TCB, who is anticipated to be on leave until mid-June. Rebecca Kush will replace Bron Kisler as CDISC alternate. Becky’s presence will also help improve interactions between TAPSC and the SAC.

2. Review and approval of prior internal meeting minutes: Apr. 18
   Approved with no comments. The May 3 meeting was cancelled due to unavailability of FDA. In future, meetings will be held if only 3 of the 4 voting members can attend, but any topics requiring votes will be deferred.

3. Action item and status updates
   Monday, June 3 at 2pm ET was proposed for a SAC/TAPSC meeting. This meeting will discuss the relative roles and responsibilities of the two groups to ensure communication is flowing smoothly and they work interact optimally with minimal overlap.
   The CV project is now beginning with CV Endpoints, building on prior work by Duke Clinical Research Institute. A small group is preparing a draft SDTM Implementation Guide for Vaccines. While this will be a resource for future TA projects such as Hep-C and Influenza, the Vaccines IG will be developed as a CDISC foundational standard and not a CFAST project.

4. FDA Workshop June 14 on Conformance Requirements for TA Standards (Attendees, Agenda, Goals)
   The purpose of the workshop is to determine what is necessary to support FDA user acceptance testing of new TA standards (or other CDISC submission-oriented standards such as SDTM, SEND, ADaM and Define). What does FDA need to determine when a standard is ready to be accepted by FDA for new submissions? FDA may need to include others involved in validation rule development (such as Open CDISC), but the meeting should be kept to a relatively small set of active participants (perhaps 8-10).

   **ACTION:** Ron/Mary Ann to try to reschedule this for later in June and identify other necessary participants who support FDA in this.

5. Review and approval of project summaries: CV Endpoints and Alzheimer’s
   The exact requirements for a project summary still need to be defined, so there has been some variation in the samples produced to date. Essentially, the summary (which should be written before scoping) is intended to explain what aspects of the therapeutic area the team intends to explore during
the scoping phase. It's understood that the description may change after scoping is completed, since a project is scoped to be doable within our target 10-12 month project period.

6. Review and approval of MS Project Charter
   We also reviewed the draft MS Project Charter. Under item 3, C-Path was requested to clarify which members were already committed to the project, and which were desirable, such as by adding a "Notes" column to explain this. C-Path was also requested to add a separate line for "EVS".
   ACTION: Wayne/Ron to forward to Karen for her review and comment.
   ACTION: Ron to update Charter.

7. Identifying list of candidate projects for the next set of priority areas
   FDA will be releasing their project plan shortly, but it won't address a specific list of priority areas -- these will continue to determined through TAPSC. FDA has worked with their previously published roadmap and the C-Path survey to identify a candidate list for the next 15 projects, which they are currently reviewing with OND leadership to line up support from the Review divisions. After this is completed, FDA will work with CFAST to formally approve and schedule the next list so it can be published. There may be a need to again reconvene a joint SAC/TAPSC meeting to review this list when it is available. The summary should provide sufficient detail so that people understand how we intend to approach the project and to guide the scoping team. Later the Charter will explain the scope in detail along with a rationale of why that particular scope was selected.

   After this introductory discussion, the Alzheimer's summary was approved (though somewhat tardily, since the Charter had been approved previously). The CV Charter also seemed adequate, but FDA wants to ensure that Karen Hicks agrees before approving.

   The draft MS Charter was also reviewed. Under item 3, C-Path was requested to clarify which members were already committed to the project, and which were desirable, such as by adding a "Notes" column to explain this. C-Path was also requested to add a separate line for "EVS".
   ACTION: Wayne/Ron to forward CV Endpoints Summary to Karen for her review and comment.
   ACTION: Jon to update MS Charter.

Notes from 5/30 Meeting:

Attending: Enrique, Margaret, Ron, Mary Ann, Diane, Dave, Becky, Wayne

Agenda Topics:

1. Review and approval of prior internal meeting minutes: May 16
   Minutes (including corrections provided by FDA) were approved. Corrected version included below.

2. Action item and status updates
   2a SAC-TAPSC Joint meeting:
   It appears the best time for those on the call will be Monday, June 17 between noon and 2pm ET. Some participants are only available for part of that period. Ideally a one hour meeting will be scheduled to discuss relative roles, responsibilities and relationship of the two committees, with a second hour reserved to discuss the FDA list of 15 new candidate projects -- if the list is available for review by that time. FDA is in the process of scheduling meetings with OND leadership to review and finalize candidate list.

   2b. FDA TA Standards Conformance meeting:
   The meeting, which will define what FDA requires from CDISC standards to support their
standards testing & acceptance process, has now been rescheduled for July 19. Wayne will be meeting with Ron, Boris and Ta-Jen Chen of FDA to plan agenda on June 10.

2c. CV Endpoints Summary
An updated charter with comments from Karen Hicks was circulated shortly before the call. Discussion ensued about the inclusion of PCI and PVI, which are interventions rather than endpoints, but apparently are associated with specific endpoints. Afterwards, the CDISC project manager, Amy Palmer, met with Karen and they agreed on the following revised summary which will be voted upon next call:

CV ENDPOINTS:

Version 1.0 of the Cardiovascular Therapeutic-area Data Standard and User Guide (CV-UG) will incorporate cardiovascular and stroke endpoint event definitions developed by subject matter experts at the U.S. Food and Drug Administration (FDA), academicians, professional societies, Clinical Data Interchange Standards Consortium (CDISC), Health Level 7, Clinical Trials Transformation Initiative (CTTI), and pharmaceutical and cardiovascular device manufacturers. The data elements to support these end point definitions were developed by Duke Clinical Research Institute (DCRI) with grant support from FDA.

The standardization of the cardiovascular endpoints is focused on the following: percutaneous coronary intervention (PCI), peripheral vascular intervention (PVI), heart failure, myocardial infarction (MI), stent thrombosis, transient ischemic attack (TIA), stroke, hospitalization for unstable angina, cardiovascular death, non-cardiovascular death, and undetermined cause of death. Additional data elements are included for CV anatomical locations, severity and symptoms of the events, as well as complications of the interventions. There are roughly 220 data elements currently under development for cardiovascular and stroke endpoints. This UG will also incorporate additional CDEs relevant to acute coronary care, which may be commonly collected during cardiovascular trials. Future versions of the CV-UG will include additional CV data standards, such as CV Imaging, when developed. The target completion date for the v1 CV data standard and UG is the end of the first quarter 2014.

3. Review of Hepatitis-C project summary:
This was reviewed and appeared satisfactory. However, FDA will ensure that the appropriate FDA SME reviews and provides input, as needed.

4. Review and approval of updated MS Project Charter
FDA added some revised description for their role on the project to the v2 provided by Jon. Changed version was approved unanimously and attached. The use of Stage 4 in the charter to identify future areas for enhancement after approval (additional terminology or new features) was identified as a useful approach to apply on other charters.

5. Review current project portfolio (attached) and Identify list of candidate projects for the next set of priority areas.
The CDISC Traumatic Brain Injury project, which is a collaborative project with NINDS, the OneMind Foundation, and a European research group, has begun an initiative to identify potential CDEs. Funding for the CFAST project is now projected to be available in September 2013, and the project has been moved back in the schedule accordingly. This has created an opportunity to promote another existing project or insert a new one. After evaluating alternatives, TAPSC voted to insert QT Studies, a project which was on the original top 6 priority list and which has FDA reviewer support.
ACTION: TCB (Dave, Diane) will draft a project description and identify a project manager for QT

5 September 2013
6. Discussion: Drug Induced Liver Injury (DILI)

The question was raised whether this should be addressed by CFAST as a separate project (which would create a reusable DILI component), or perhaps included in the scope of a specific TA project. DILI does raise some challenging data collection issues, and was thus explored as a potential CDASH project (but not completed). No consensus was achieved -- FDA will discuss internally and CDISC may add to the list of issues for its forthcoming team Intra-change in July. TAPSC will continue discussion at a future meeting.

7. Any other business

The SAC is exploring Oncology to define an initial scope for CFAST, and is talking with 5 expert groups (including NCI, ASCO and others). It was pointed out that TCB had already touched base with many of the same groups and had discussions and recommendations late last year under Scott Getzin. It was suggested that it might be good for all these groups to meet together with SAC, since each might learn from the others. Oncology is currently slated for an August start, so TAPSC will need a project description by July to make that date.

ACTION: Becky Kush to contact Scott Getzin to incorporate his findings.

8. Plans for next meeting

The next meeting will likely be combined with the SAC to review roles and responsibilities and possibly the next candidate list of 15. We'll continue discussions on project summaries, charters and DILI.

Notes from 6/17 TAPSC/SAC Joint Meeting

Attending: CDISC: Becky Kush, Wayne Kubick; C-Path: Enrique Aviles, Lynn Hudson, Jon Neville; TCB: Diane Wold, Dave Jordan; FDA: Ron Fitzmartin, Mary Ann Slack; NCI: Margaret Haber.

Regrets: Chuck Cooper

Agenda:

1. Status Updates
   • FDA list of next candidate areas for prioritization is still undergoing internal review
   • Diabetes package was sent out to TAPSC for approval of proposed scope, plan and Charter; TCB, CDISC and C-Path have responded positively. A meeting will be scheduled to discuss only if necessary after FDA completes its review.
   • A draft Project Proposal for QTc studies was attached for discussion later in call; TCB has already identified a PM.
   • SAC has scheduled calls with Oncology experts, including leader for SDS Oncology team (Barrie Nelson). FDA is also recapping experience to date with formal projects. Goal is to propose initial target scope by August.

2. Review of TAPSC and SAC Roles and Responsibilities in CFAST

The primary purpose of this joint meeting was to review relative roles and responsibilities of the CDISC TAPSC and SAC. The background of the CFAST joint initiative between CDISC and C-Path, and how the Therapeutic Area Standards Program was the first and only CFAST program established to date was reviewed. A slide depicting the current governance structure that had been adapted by Becky was reviewed and some input was provided, which Becky applied in an updated version. The slide shows different participant groups, including external volunteers who contribute to the individual projects.
The respective charters for the two groups were reviewed. The SAC charter was modified slightly to clarify that it focuses on scientific rather than business relationships and scientific resources. The committee goals section was modified to clarify the SAC role with respect to all of CFAST as compared to its specific role on the TA Program at this time. Feedback to clarify some bullet text was applied directly by Becky in an updated version of the SAC Charter attached to these minutes.

In general, all parties were in agreement that the SAC provides scientific and therapeutic advice and review while the TAPSC focuses on prioritization, approval of project proposals, scope and charter, and oversight of active projects. These roles were clarified in the diagram updated by Becky.

**ACTION:** Please provide any final feedback to Becky and Wayne on the proposed revised governance chart and SAC charter prior to next meeting (of your respective group).

3. Discussion of coordination between two groups and needs for future joint meetings.
   - Share agendas and minutes (so the other committee members can ask to join a meeting when appropriate)
   - Add a standing agenda item to each meeting to provide a status update on the corresponding committee
   - Set up a regular joint meeting, perhaps quarterly, and attach to one of the standing meeting schedules (for either SAC or TAPSC). Other ad hoc joint meetings can be requested when necessary to address a particular topic.

At the prior TAPSC meeting it was agreed to initiate a new project for QTc studies, which had been a priority of both FDA and TCB (this was possible because the timing of another project had slipped back a few months). The project proposal was briefly reviewed and found acceptable to attendees (though it was subsequently modified after later input from a subject matter expert – final version is available on CDISC website. FDA agreed to ask Dr. Stockbridge to review, with feedback received that the project should proceed. This will be formally approved by vote at next TAPSC, but the project is cleared to proceed into collecting inputs and scoping.

**QTc Project Summary:**

**QTc Studies for Evaluation of potential drug impact on QTc in multiple therapeutic areas [e.g., for Non-Antiarrrhythmic Drugs]**

CFAST is proposing development of the CDISC QTc Therapeutic-area Data Standard. This standard would build on the existing CDISC ECG [EG] standards, and related CDASH standards, to facilitate the collection and use of data specifically expected to be collected during so called ‘thorough QTc studies’ [Guidance for Industry E14 Clinical Evaluation of QT/QTc Interval Prolongation and Proarrhythmic Potential for Non-Antiarrrhythmic Drugs].

The workgroup proposes developing a CDISC therapeutic area User Guide, including concept maps, metadata, examples and controlled terminology. The standardization effort is expected to focus on the following areas of specific interest to QTc studies: ECG-related variables [e.g., morphology, intervals] whether from Standard 12-Lead ECGs or Ambulatory ECG Monitoring, AEs, dosing, pharmacokinetics & relevant pharmacogenomics data.

The project is planned to begin in July 2013, with target completion of the v1 QTc data standard and UG in Q2 2014.

Note: in particular, this project is not intended to cover cardiovascular endpoints, cardiovascular imaging which are being covered via other data standards development projects, but will be developed...
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in a manner consistent with the forthcoming CDISC CV [cardiovascular] Therapeutic Area data standard.

5. Any other business.
The question was raised as to whether NIH was supposed to join the SAC. This is still pending.
ACTION: Becky and Mary Ann to reach out separately to NIH contacts to follow up.
Dave Jordan reported that TCB is in the process of drafting project proposals for other projects, including depression, rheumatoid arthritis, and psoriasis for later review after prioritization.

Minutes of 6/27 Call

Attending: Enrique, Mary Ann, Dave, Margaret, Jon, Wayne (Eloise Sepeda also attended to assist with notes). Quorum achieved.

Agenda:

1. Review and approval of prior internal meeting minutes: May 30
Minutes approved unanimously.

2. Action item and status updates (from minutes - SAC-TAPSC Joint meeting, QTc studies, Oncology, Diabetes, Next candidate list)
Minutes from the Joint SAC-TAPSC meeting held last week have been distributed (with corrections from Dave) and both groups are now being cc’d on agendas and minutes. The QTc Studies project is now commencing, with a PM on board and approval of the project summary. This project was intended as a stress test of the new process and is expected to complete rapidly. It’s also a good project to use to build up interest and introduce outsiders to the TA standards, since most drugs need to do some QTc testing. It is important for QTc to also be taken expeditiously through the FDA acceptance process. Enrique suggested inclusion of Klaus Romero (C-Path PI) and Raymond Woosley as clinical expert reviewers.

CFAST-SAC is conducting meetings with Oncology experts to help define initial scope for v1. The Diabetes Charter and scoping package is awaiting approval pending feedback from FDA -- it has been found acceptable with minor edits by all other parties. The team is proceeding into the next stage in the meantime.

FDA candidate list still under internal review.

The award of a contract for SHARE has been announced with information provided on the website. ACTION: Wayne and Becky will meet with FDA on July 18 for a SHARE briefing. Wayne to meet separately with Margaret.

3. Project status update reporting to TAPSC.
CDISC is working on a dashboard status report on CFAST projects for TAPSC which ideally will be posted for the public as well. The first prototype was reviewed showing completion stage of each project. TAPSC reception was positive, with some comments:
- Include (or link to) info for completed legacy projects
- Add "Traffic light" icon to show whether project is on target, at risk, or in trouble
- Add brief summary of gating issues for each project that is slipping
- List projected month for completion of next stage (but only show one step ahead).
An updated version will be distributed after changes are applied and status info is verified.
Dave indicated that TCB may be able to provide resources to support the future Schizophrenia (which
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has a CDISC PM thanks to FDA grant support) and Hep-C projects. Schizophrenia is planned for October, assuming Duke CRI completes a Sept. HL7 ballot on time.

4. Review of project summaries Major Depressive Disorder (MDD) and Rheumatoid Arthritis (RA) These are included below to facilitate review by TAPSC. While FDA sometimes has challenges getting prompt response from review divisions, it's anticipated that they will be able to quickly review project summaries in the future within a 2-3 week target review period. Once these are approved, they should be posted publicly for access by the research community. There are still a few missing project summaries for the current list of prioritized projects that must be completed. The summaries for MDD and RA should thus be circulated for review by each CFAST organization, with a goal of approving at next call. Mary Ann noted that MDD is in progress as a Duke CRI project, with data elements expected to be balloted in Jan. 2014. Wayne reminded attendees that the DCRI process does add significant time beyond the 10-12 months targeted by CFAST.

ACTION: Mary Ann to follow up on Diabetes scoping package review by FDA.

5. Any other business
Dave asked whether the prior project summaries had been formally approved. The CV Endpoints summary, which had been updated after dialogue with Karen Hicks of FDA, was unanimously approved. Hepatitis-C (sent previous meeting) still needs FDA review and, along with those covered above will be targeted for approval votes at next meeting. ACTION: Mary Ann to follow up on Hep-C project summary with FDA Reviewer.

Notes from 7/11 TAPSC meeting:

Attending: Mary Ann, Ron, Enrique, Jon, Diane, Dave, Margaret, Wayne, Becky. Quorum achieved.
Guest for item 3: Rhonda

Agenda:

1. Review and approval of prior internal meeting minutes: June 27
Minutes approved without change.

2. Action item and status updates
FDA has approved the Diabetes Charter (which was acceptable to all other parties at prior meeting). Diabetes team was already proceeding at risk.
SAC is reviewing Oncology -- Scott Getzin will recap TBI work from 2012 for Becky. SAC hoping to propose scope by end of August.
The FDA's proposed next set of candidate projects was provided right before the meeting for discussion under item 6.

3. Project status update reporting to TAPSC (see attachment - Rhonda invited for this topic at approximately 11:15am ET)
Rhonda joined for this topic. TAPSC members were pleased with the report format. Some minor comments to clarify review stages as 3a, 3b, 3c and present dates for "in progress" light blue stages in italics (since they are projected). Clarified that months listed represent end of stage not beginning. Diane noted that there has been some blurriness between stages 1 and 2 -- these are often proceeding as overlapping parallel steps in practice. There was discussion on whether terminology should have its own stage, but it was agreed it was part of each stage, and any terminology issues or delays should be reported under comments. The final version will include links to project proposal summaries. TAPSC approved this for posting once final corrections are
completed. Updated version is attached.

4. Approval vote for project summaries Hep-C, MDD and RA (See below)
FDA had verified that the Hep-C project summary was acceptable. Hep-C approved unanimously (motion Diane; second Enrique). TCB will lead and support this project. MDD and RA is still awaiting review by FDA review divisions. MDD was approved to include reference to prior work underway by DCRI. See some updates below.

New proposals were briefly discussed. COPD is a logical follow-up to Asthma, since it shares many of the same concepts. According to previously defined process, the plan is to seek approval of these in one of the next 2 meetings, once each group has had time to review sufficiently. Minor mods to Schizophrenia after the call for more consistency with format of other proposals. Updates below.

6. Any other business (send agenda items in advance, if possible)
The FDA's proposed next set of candidate projects was reviewed (attached), which was provided right before the meeting. This list represents new areas for which FDA divisions will begin to collect internal requirements over the next year. The projects extend over all 3 tiers, and represent areas where review divisions have available time. Actual timing will depend on workload and other issues. The list is not meant for publication, but only as an input to be discussed and prioritized as projects by TAPSC. It was noted that some previous projects which had requirements collected by FDA earlier (acne, overactive bladder, lipid lowering drugs) also should be added to the list, as well as projects being defined by TBI, such as psoriasis. Each member group is requested to also submit other projects which either may have available funding or resources or should be prioritized for other reasons and add to the candidate list prior to our prioritization discussion. We will publish the next set of proposed projects after they are defined (in a proposal) and prioritized.

Ideally there will be a common table representing these, based on past info (including the Scott Getzin prototype and our new dashboard status report). ACTION: Wayne and Rhonda to make recommendations.

Enrique reports that C-Path has been invited to submit a grant proposal to FDA for influenza as a joint project with CDISC, which is now in progress. If funded, this will become a CFAST project.

Diane commented that we should try to standardize the proposal boiler plate moving forward, and that some of the recent contents (such as medical history, meds, etc.) should be omitted unless there are specific scoping details that can be shared. All TAs have some info in these areas -- we should only list what's different and unique. We agreed on the general 3 paragraph structure what it is, what it includes, when do we plan to begin. These changes were applied to some of the current proposals.

Ref. 4: Prior Project Proposals for Approval:

4A. TA Project Proposal for Virology V2: Hepatitis C (Approved)
CFAST is proposing development of the CDISC Hepatitis C Therapeutic-area Data Standard. This standard would build on the existing CDISC Virology TA standards to facilitate the collection and use of data relevant to Hepatitis C clinical trials.

The workgroup proposes developing a CDISC therapeutic area User Guide, including concept maps, metadata, examples and controlled terminology. The standardization effort is expected to focus on the following areas of specific interest to Hepatitis C: relevant medical history conditions, health care
resource utilization, patient reported outcomes, cirrhosis, progression of liver disease, AEs of special interest, CMs of special interest, HCV viral load testing, as well as the influence of HCV genotype / subtype on virological response.

The project is planned to begin in September 2013, with target completion of the v1 HepC data standard and UG in Q3 2014.

For more information on Hep-C, see: [http://www.who.int/mediacentre/factsheets/fs164/en/](http://www.who.int/mediacentre/factsheets/fs164/en/)

**Notes from 7/25 TAPSC meeting:**

Attending: Diane, Dave, Enrique, Jon, Mary Ann, Ron, Margaret, Becky, Wayne. Quorum achieved.

Agenda Topics:

1. Review and approval of prior internal meeting minutes: July 11
   Minutes approved without comment.

2. Action item and status updates
   The final version of the status report was reviewed (one minor change to list lead PM organization first). This will be posted on the website, with links to available project proposals and charters. SAC has continued to make progress with Oncology, and was impressed with SDTM work already completed. Should be on target to make recommendations within 2 months. The SAC has approved a position for ACRO (Association of CROs) on the SAC. They have volunteered to contribute a PM to a future project (and possibly other resources).

3. Plans for assembling list of potential next candidates (See attached presentation with new page added. Additions from C-Path, TCB, CDISC)

   At the last meeting a joint TAPSC/SAC 2-hour meeting to review next set of candidate TAs for prioritization was targeted for the 8/8 TAPSC call. Since Chuck Cooper is unavailable at that time, the meeting is planned for the afternoon of 8/12 instead, beginning at 1 or 2 pm ET. If this works, the 8/8 TAPSC call will be cancelled.

   The intent for that meeting will be to select a next set of 8-12 candidates to target for 2014 (though one may conceivably start in Nov. 2013). The order of these new projects will need to be scheduled as a separate step, once proposals for all candidates have been prepared and resource availability has been examined.

   Note that some of the projects may need to be new versions of previous projects. For example, do the Parkinson's, TB, and PKD projects -- all Tier 1 on TCB list -- need version 2 updates like Alzheimer's? Moreover, large scale complex disease areas like Oncology, Cardiovascular, Diabetes -- which are being broken down into manageable smaller chunks -- may need to be retained as ongoing streams and included in the mix as well and take some of the available slots (~10 for 2014). These enhancements/maintenance updates need to be factored in with new TAs.

   The FDA list (introduced last meeting) represented the next set of TAs where FDA review divisions would begin to identify requirements based on availability. The intent was to get many divisions involved where they were able, and thus the list contains some Tier 2 and 3 as well as 1's. Not all of these will make the next priority set. FDA does not expect the currently published FDA priority tiers to
change very much, though this is being reviewed. A new list was begun adding previous FDA requirements projects (like Acne) and other DCRI projects (MDD, CV Imaging). Similarly other organizations may have others to add. CDISC, for example, may be funded for work on HIV and Post Traumatic Stress Disorder, while C-Path (with CDISC) is working on an FDA funded proposal for influenza. TCB may want to revisit their priorities and compare to what's on the FDA list.

ACTION: Dave will take a cut at a comparison.

ACTION: All TAPSC members to submit additional candidate projects to propose for TAPSC consideration by COB August 8.

4. Approval vote for project summaries: MDD, Schizophrenia, RA

During discussion it was noted that some of the descriptions referenced CDASH. This reference refers to building on existing CDASH structures and not a commitment to create new ones (though that may be needed) and it was agreed it should be added to the template. It was also helpful to see FDA updates in blue text.

Individual motions to approve each of the project proposals in order -- MDD, Schizophrenia, RA -- by Diane, seconded by Mary Ann. All approved unanimously. Schizophrenia approved based on inclusion of standard statement regarding SDTM and CDASH used in others. This statement should be considered part of the template. See reference 4 below for final versions.

5. Status and additional discussion of new proposals: TBI and COPD

FDA is still seeking reviewer input on COPD. TBI is a new area submitted by CDISC. Diane had reviewed in advance, and expressed concern that this project, which uses pre-existing CDEs, might not align well with research applications based on some prior project experience (such as a project that was primarily seeking to validate a new surrogate marker rather than support research studies; similarly the CV endpoints projects seems to be largely about clinical decision criteria and adjudication, which is raising some modeling challenges). While this should not affect the approval of the proposal, the team will need to work closely during the scoping and input stage to make sure it fits the submission research model for the CFAST community. Becky noted that 2 large-scale studies are already in progress -- these would be a great source of inputs for the scoping phase.

ACTION: Becky to look into getting details of ongoing TBI studies.

6. Communication of TAPSC Decisions

CDISC is working on updating the website and catching up on posting past minutes. It is critical that we make new summaries and current charters available promptly to all participants.

7. Any other business (send agenda items in advance, if possible)

TAPSC agreed to move Hep-C up as the next project -- TCB will identify resources. Oncology will begin after that.

Ref. 4: Approved Project Proposals:

4A. TA Project Proposal for Major Depressive Disorder (MDD)

CFAST is proposing development of v1.0 of the CDISC MDD (Adult and Pediatric) Therapeutic-area Data Standard. This standard will build on the existing SDTM and related CDASH standards to facilitate the collection and use of data relevant to MDD clinical trials.

The workgroup proposes developing a CDISC therapeutic area User Guide, including concept maps, metadata, examples, and controlled terminology. The standardization effort is expected to focus on the
following areas of specific interest to MDD: data to substantiate diagnosis, medical history (psychiatric and neurologic, including course of illness), symptom rating scales, patient reported outcomes, suicidality, treatment history (drug and non-drug), medication side effects, and health care resource utilization, including psychiatric hospitalizations and emergency visits.

The project is planned to begin in Q1 2014, with target completion of the MDD data standard and User Guide in Q4 2014.

4B. TA Project Proposal for Schizophrenia

CFAST is proposing development of v1.0 of the CDISC Schizophrenia Therapeutic-area Data Standard, building on existing SDTM and related CDASH standards to facilitate the collection and use of data relevant to this disease area.

Schizophrenia is a mental disorder characterized by delusions, hallucinations, and disorganized speech, with the onset of symptoms usually appearing in young adulthood. The Clinical Data Elements (CDEs) to be used in developing v1.0 of the standard are being defined and developed by Duke Clinical Research Institute (DCRI) through HL7 with input from subject matter experts in government, academia, and industry under grant support from the FDA.

The Schizophrenia CDEs focus on the following data categories or domains areas: diagnosis, course of illness, family psychiatric history, psychiatric hospitalizations, AEs of special interest (e.g., tardive dyskinesia, akathisia, and hyperprolactinemia), and rating scales/questionnaires measuring multiple areas, including psychotic symptoms, functionality, neurocognition, and quality of life. This User Guide (UG) will be based on approximately 75 CDEs and will also include examples from several of the 135 applicable questionnaires.

The project will be managed by CDISC; the target completion date for the v1 Schizophrenia data standard and UG is third quarter 2014.

4C. TA Project Proposal for Rheumatoid Arthritis (RA)

CFAST is proposing development of the CDISC RA Therapeutic-area Data Standard. This standard will build on the existing SDTM and related CDASH standards to facilitate the collection and use of data specifically expected to be collected during adult and juvenile RA studies.

The workgroup proposes developing a CDISC therapeutic area User Guide, including concept maps, metadata, examples and controlled terminology. The standardization effort is expected to focus on the following areas of specific interest to rheumatoid arthritis (RA): medical history, duration of RA disease, past and baseline medication use for RA, screening procedures (such as screening for tuberculosis), clinical assessments (such as joint assessments), patient reported outcomes, radiographic assessments, health care resource utilization (such as ER visits, in-home health care visits), concomitant medication for RA, surgical procedures for RA, AEs of special interest (such as infections, including serious and opportunistic infections and tuberculosis, malignancies, including lymphoproliferative disorders, injection site reactions, systemic hypersensitivity reactions, including anaphylaxis, drug-induced liver injury), laboratory tests of special interest, device malfunction (for drug-device combination products).

The project is planned to begin in Q1 2014, with target completion of the RA data standard and User Guide in Q4 2014.

Notes from 8/12 Joint TAPSC/SAC Meeting
This was a joint meeting to make progress on prioritizing next set of potential TAs. Our intent was to select a next set of 6-12 candidates to target for 2014 (though one may conceivably start in Nov. 2013). The order of these will be scheduled as a separate step, once proposals for all candidates have been prepared and resource availability examined.

Attending: Mary Ann, Ron (FDA); Diane, Dave (TCB); Enrique, Jon, Lynn (C-Path); Becky, Bron Kisler, Wayne, Eloise (CDISC); Margaret (NCI).

**Agenda:**

1. Review and approval of prior TAPSC internal meeting minutes: July 25
   Minutes approved with no comments.

2. Action item and status updates
   - SAC review of Oncology continues - 2 calls last week. Will distribute minutes within a week. Targeting early September for a recommendation.
   - TBI project summary approval is on hold until more details can be learned from protocols about the interventional nature of 2 large-scale studies currently underway. (Action: Becky).
   - Funding agreement from OneMind received by CDISC.
   - SDTM 3.1.4 (with several new domains relevant to TAs) currently scheduled for release in September/October
   - TCB is looking to engage a contract PM for Hep-C. Becky noted that ACRO has promised a PM resource from Quintiles.
   - Action: Becky/Wayne to check with Quintiles.
   - Action: Ron/Mary Ann to identify FDA Oncology contact.
   - Action: Enrique will set up a meeting to discuss feedback on QT studies.

3. Plans for assembling list of potential next candidates (See attached spreadsheet updated during meeting; selected candidates are highlighted in green)

   The objective again was to come up with a next set of candidate projects, so draft proposals can be developed and potential resources identified. Scheduling/prioritization within the list will be addressed separately by TAPSC. It was noted that C-Path did not establish tiers on their project survey – the top 15 areas were selected according to a numeric score of expressed preference among respondents.

Current and past projects were reviewed to see whether any new versions are necessary for existing standards (as was the case with Alzheimer's). Key points:

- How should pediatric treatments within a TA be handled-- should these be considered as separate projects? Not at this time. The FDA list has not addressed pediatrics separately to date, and NCI is going to begin exploring next year. C-Path will also be exploring inclusion of pediatrics as a potential next version for the TB TA later this year. Action: TAPSC requested SAC to make a recommendation on how to handle pediatric treatments for TAs, perhaps beginning with diabetes.
- It was agreed that further work on Diabetes should wait after v1 is published, before proceeding to a second version (that may involve pediatrics).
- Major Depressive Disorder should be a candidate, given work in progress by DCRI; proposal has been approved.
- CV Imaging is complex and moving slowly -- should be considered later after CV endpoints assuming enough progress by Duke in 2014. There's a need to address different imaging modalities and identify an approach to addressing them. Action: SAC
- Influenza proposal (which will build on Virology and Hep-C) has been submitted to FDA by C-
Path; is also being worked in Europe through IMI; should be a candidate assuming funding comes through.

- COPD should be on candidate list -- TCB proposal submitted; logical follow-up to Asthma.
- Psoriasis and Rheumatoid arthritis should be on candidate list -- TCB proposals submitted
- Lipid-lowering drugs should be on candidate list -- FDA model completed.
- One of the 3 anti-infective proposals (urinary, skin, pneumonia) on FDA model list should be included as a candidate. Action: FDA and TCB to seek advice.
- Post-menopausal osteoporosis, solid organ transplant and at least one additional chunk of oncology should be candidates.
- May also need to consider another CV project for acute coronary syndrome treatment or prevention, depending on what is covered in the CV Endpoints TA User Guide.
- May consider HIV prevention or treatment depending on funding and review pipeline as an alternate later.
- Acne should be deferred; also defer post-traumatic stress disorder (may be reconsidered late in 2014 as a follow-on to TBI).

The discussion resulted in a candidate list of 10 projects marked in green in the attached spreadsheet.
Action: CFAST members requested to discuss these with their internal groups to assess interest, resourcing, potential submissions affected, etc. prior to next TAPSC meeting and to look at preparing draft project proposals.

4. Pending project summaries: COPD and TBI (See below Ref. 4)
FDA had no comments on COPD. Motion to approve (Diane); seconded (Mary Ann). Approved unanimously.

5. New proposals: Psoriasis (See below Ref. 5) and Breast Cancer CRFs
Psoriasis was reviewed briefly. It was agreed that while the additional details in this proposal summary were useful, they were actually providing detail more suited for the scoping and input phase. An abridged summary is included below for approval vote at a future meeting.
It was agreed that the proposal prepared by NCI for Breast Cancer CRFs should be treated as an input to the scoping and input phase of the Oncology project rather than approved as a separate project.

Ref. 4: Approved Project Proposals:

4A. TA Project Proposal for COPD  (approved)

CFAST is proposing development of v1.0 of the CDISC COPD Therapeutic-area Data Standard. This standard would build on the existing SDTM Asthma TA standards, Cardiovascular TA standards, and related CDASH standards to facilitate the collection and use of data relevant to COPD clinical trials. The workgroup proposes developing a CDISC therapeutic area User Guide, including concept maps, metadata, examples and controlled terminology. The standardization effort is expected to focus on the following areas of specific interest to COPD: data to substantiate diagnosis, medical history of special interest, pulmonary function tests, symptom assessment, COPD exacerbations, AEs of special interest (e.g. MACE), CMs of special interest (e.g. rescue medication), patient reported outcomes (e.g. Saint George's Respiratory Questionnaire (SGRQ), Transition Dyspnea Index (TDI)), and health care resource utilization including hospitalization, intensive care, and emergency visits.

The project is planned to begin in Q1 2014, with target completion of the COPD data standard and User Guide in Q4 2014.
Version 1.0 of the CDISC TBI Therapeutic Area Data Standard User Guide will be based on a set of Clinical Data Elements (CDEs) developed by National Institute of Neurological Disorders and Stroke (NINDS) with input from subject matter experts in government and academia.

The NINDS TBI CDEs focus on the following data categories or domain areas:

- History of trauma
- TBI injury characteristics
- Lab tests and biomarkers
- Questionnaires/scales
- Physical and neurological assessment examination elements (functional assessments, performance test (peg test))
- Imaging observations (results and characterization of device used (e.g. CT/MRI, etc.)
- Other quantitative endpoints (need to determine)

The proposed scope of the v1.0 TBI TA Standard will be based on approximately 120 CDEs, and will also include examples from 23 applicable questionnaires and approximately 50 core imaging CDEs. The project will be managed by CDISC; the target completion date for the v1.0 TBI Standard data standard and UG is third quarter 2014 from project initiation.

5B. TA Project Proposal for Plaque Psoriasis [Ps] (pending - abridged version below)

CFAST is proposing development of the CDISC Psoriasis Therapeutic-area Data Standard. This standard would build on the existing SDTM standards and related CDASH standards to facilitate the collection and use of data specifically expected to be collected during studies of plaque psoriasis.

The workgroup proposes developing a CDISC therapeutic area User Guide, including concept maps, metadata, examples and controlled terminology. The standardization effort is expected to focus on the following areas of specific interest to Psoriasis (Ps): medical history, including duration of Ps and specific areas of psoriatic involvement; past and baseline and concomitant medication use for Ps (including topical steroids), clinical assessments (such as PASI, sPGA, NAPSI, PSSI, PPASI), patient reported outcomes* (such as Itch NRS, DLQI, WPAI-PSO, PatGA, Skin Pain VAS, PSAB), health care resource utilization (hospitalizations, ER visits) and AEs of special interest (such as infections, including serious and opportunistic infections and tuberculosis; malignancies, including lymphoproliferative disorders; injection site reactions, systemic hypersensitivity reactions, including anaphylaxis; drug-induced liver injury), laboratory tests of special interest, device malfunction (for drug-device combination products).

This is intended to guide the organization, structure, and format of standard psoriasis clinical trial tabulation datasets submitted to a regulatory authority. The project is planned to begin in Q2 2014, with target completion of the Ps data standard and User Guide in Q4 2014.

Notes from 8/22 TAPSC call

Attending: Enrique, Jon, Diane, Dave, Ron, Mary Ann, Margaret, Wayne.
Regrets: Becky.

Agenda:

1. Review and approval of prior joint TAPSC/SAC internal meeting minutes: Aug. 12
Due to an undiagnosed technical problem, minutes from Aug. 12 were truncated from the agenda email received by many members. These minutes are repeated below and included as a separate
Word document, together with the 8/22 minutes. While no objections were raised toward approving the Aug. 12 minutes, formal approval will be repeated at the next call.

2. Action item and status updates
- SAC holding 90-minute Oncology discussion on 8/26. Still seeking FDA liaison. Scope should avoid surgical interventions and academic studies that don't lead to marketed products. Margaret has connected FDA with NCI I-Spy project contacts. FDA is interested in using I-Spy 3 with new standards, with a focus on incorporating standards from the start in protocol and CDASH CRFs, which would suggest to SAC to begin Oncology program with breast cancer.
- TBI summary still pending; Rhonda will meet with OneMind clinical experts to understand interventions being studied in current TBI projects and adjust summary as necessary prior to approval.
- A meeting was held to decide how to respond to some SME feedback on QT Studies. It appears his concerns can be addressed with minor changes to the summary FDA reports that while there is agreement with this additional feedback, the project should not be delayed.
  Actions: Enrique to follow up with SME; Dave to contact John Owen to update description.
- Dave reports TCB is close to engaging a PM for Hep-C.
- Ron Fitzmartin is now participating as interim SAC rep for FDA while a replacement for Chuck Cooper, who is no longer with FDA, is sought.

3. Review and feedback on list of next candidates -- are any ready to be prioritized in the next group? Feedback on anti-infective project choice? (See spreadsheet attached to 8/12 minutes - no new changes applied)
  TCB is working on project summaries for Lipid-lowering drugs, Osteoporosis and organ Transplants.
  We agreed that certain of the candidate projects were obvious candidates for the first set to be prioritized -- either because work was in progress (such as by DCRI), resources identified, or summaries already in place. These include: MDD, COPD, RA and Influenza. One of the Anti-Infectives should also be added once one of the 3 alternatives can be chosen and a project summary made available.

4. Understanding FDA review of TA project documents - MS project example
  FDA raised a question of what to expect for scoping and input review on the MS project. "Fast-Track" Projects like MS (as well as Schizophrenia and CV Endpoints) are essentially handed off to CDISC or C-Path after initial work is completed on defining common data elements and/or modeling -- essentially these are starting partway into Stage 1 rather than at Stage 0 under the process, since scope and data element content are already pre-defined (by NINDS for MS, Duke for Schizophrenia and CV). Such Fast-Track projects thus won't involve the same degree of scoping assessment and research as projects like Asthma, which begin from scratch at Stage 0. MS was started in March from a list of NINDS CDEs, and did not submit a specific scoping document for FDA review at that time. It was agreed that minimum requirements should be defined for scoping and assessment information to include with Charters for such projects so that FDA has sufficient information to conduct their review.
  ACTION: Jon Neville to explore MS scoping info that can be shared with FDA.
  ACTION: Wayne to discuss with Rhonda ensuring minimum details to accompany Charter for Fast-Track projects in future.

5. Pending project summaries: TBI and Psoriasis (See below Ref. 4 under 8/12 minutes)
  Shorter version of Psoriasis (sent with 8/12 minutes) had not been thoroughly reviewed due to an agenda problem. Will be tabled until next call along with final TBI summary.

6. Charter for review: CV Endpoints
  A preliminary draft of the CV Endpoints Charter was circulated for review. Final version will need to be accompanied with project plan and additional scoping details (which involve CDEs identified by DCRI...
in this case). Ron is circulating to Karen Hicks for FDA input. Will be slated for further discussion at next meeting with attachments.

7. Any other business
A preliminary internal review copy of Diabetes had been circulated for review. Input from FDA reviewers will be reflected in an updated version. FDA reviewers were surprised to learn that their previous input on the scope was not reflected in this copy. C-Path also noticed some inconsistent wording about CFAST in the package. We need to be respectful of requests for review and make sure that reviewers are clearly informed in advance.
ACTION: Wayne to discuss with Rhonda and Rachael Zirkle to ensure that requests for preliminary reviews are properly communicated, and that prior input from key stakeholders is addressed prior to seeking further review in the future for all projects.
CDISC has scheduled a CFAST F2F meeting for Nov. 8 after CDISC Interchange to review the first year of CFAST, discuss experience to date and review plans for 2014.

8. Plans for next meeting.
Next TAPSC meeting will be held on 9/5. Discussion of CV Endpoints, TBI and Psoriasis will continue plus review of any new summaries available. The proposed short list of next projects will also be reviewed.