

**Public Private Partnerships (PPP) Key Function Committee (KFC)
October 28, 2009
DRAFT Meeting Summary**

3:00 PM – 4:30 PM ET

Participants

CTSA Representatives: Brad Castanho (Wash U.), Melissa Cornish (Duke) Kathleen Denis (Rockefeller), Terry Fadem (UPenn), Mike Hazard (Rochester), Clay Marsh (Ohio State), Kate Marusina (UCDavis), David McGee (UC, Davis); Becky Moen (Duke); Rick Neale (Scripps), Jane New (Ohio State); Lynn Rose (UWash), Chandan Sen (Ohio); David Schoenhaut (Einstein), Scott Steele (Rochester); Tim Stout (OHSU), Meng Tan (Michigan) Dave Winwood (UAB)

NIH/Government Representatives: Carmen Rosa (NIDA); Mark Scheideler (NINDS)

Committee Coordinators: Greg Evans (NCI), Lili Portilla (NCRR)

Booz Allen Hamilton Staff: Helen Lee

I. CTSA Consortium Updates

Dr. Holroyd provided an update on the feedback received from the PI Liaisons, Drs. Topol and Orwoll regarding discussions at the CTSA Consortium Steering Committee (CCSC). The interest in the Consortium around doing multi-center trials involving CTSA members has increased recently. A number of PIs have proposed studies that would be open to cross site collaboration.

The current status of this is that the PIs will confer more and will inform the PPP KFC about what will make sense.

II. CTSA Consortium Multicenter Trials Initiative

The group raised a number of issues that were of interest. These included:

- Trying to get broad principles for the management of conflict of interest;
- Seeing how multicenter projects are identified as they come from industry – What would the guidelines be for participating sites?
- Recommendations for central infrastructure that the CTSA's have for managing multicenter trials as well as for relationships with industry;
- How should CTSA sponsored trials be attributed to projects?

Dr. Evans indicated that Drs. Topol and Orwoll would take these matters to the CTSA Consortium Executive Committee (CCEC) for further discussion, and that some charges would be given to the various committees.

The group discussed whether the trials are initiated by the CTSA's or by industry. The general consensus was that the ideas for the trials often come from individual PIs within the Consortium, after having discussions with members of industry. However, there have also been cases where the idea came solely from CTSA members.

Members asked for contract templates for dealing with industry. Dr. Rose volunteered to post her template for contracts onto the CTSA Wiki.

III. Industry Workshop Planning Committee Meeting Outcomes

The Industry Workshop planning committee had a meeting in Philadelphia on September 24, 2009 that was a planning meeting for the February 17-18, 2010 CTSA Industry Forum. There were 10 members from industry, representation from 7 CTSA's represented and 5 individuals from the NIH. Dr. Fadem moderated the discussion at that meeting.

The representatives from industry were very supportive of having the joint meeting, as were the Consortium members. The February meeting is seen as the "first step" in making collaboration between the CTSA and industry more efficient. Helen Lee will send the summary from that meeting to the members of the PPP KFC.

Dr. Portilla noted that the 30 minutes scheduled for poster sessions the end of the first day is an error, and that at least one hour would be allotted for the poster session. We will be soliciting abstracts and posters, however the planning committee is requesting feedback on how the session can be designed and what topics to focus on.

The Food and Drug Administration (FDA) will be invited to the workshop, however its role has not yet been determined. It was suggested to use the FDA to assist in providing use cases to help understand the regulatory process.

The planning meetings will be held weekly, on Wednesdays, from 12:00 – 1:00 pm, ET. Industry members will remain involved in the planning, and will be invited to participate in as many of the planning calls as is possible.

There are also links to two polls included in the e-mail meeting announcement for this meeting. Please take a few moments to participate in each.

IV. Updated on IP Website

The Aggregating Resources workgroup is functioning as a testing group for the CTSA IP website. The current focus is on trying to develop a communication strategy, and then to develop a shared vision for future capabilities. There are currently 15 members on the website so far, 4 of which joined in the last two months.

In terms of the communication strategy, the group met with Cindy McConnell, the Communications Director at NCRR, to start a plan for disseminating information to industry about the website's creation and goals. Ms. McConnell put together a Q&A about the site, which is now being edited based on member feedback. A "roadshow" PowerPoint presentation has also been created to help explain what the website is

about, how to join and how to use it. Finally, the group has begun work on a vision statement. A draft has been distributed and is under review. Each of these items will eventually be distributed to the entire KFC for broader comments and feedback.

V. Next Meeting

The PPP KFC will have its next meeting on November 25, 2009, 3:00 – 4:30 pm ET.

VI. Action Items

#	Action Items	Owner	Due Date
1	Post the contract template to the CTSA Wiki	Dr. Rose	11/6/2009
2	Send the summary from the September 24 Industry Forum planning committee meeting to the entire KFC	Helen Lee	11/6/2009
3	Participate in the polls included in the October 27 e-mail from Helen Lee	All PPP members	11/13/2009