

**Clinical Research Management Taskforce Session  
CTSA Consortium Oversight Committee Meeting  
January 15, 2008  
Attachment C**

The breakout session focused on the development of a concept for a Workshop and related deliverables. The Clinical Research Management Taskforce of the Regulatory Knowledge Workgroup will sponsor a Workshop titled "Improving Efficiency of Clinical Research Management". It will be held on June 23-24, 2008 in Bethesda, Maryland. The funds available to support the workshop limit the size of the audience. Hotel rooms are already reserved.

Approximately 100 people are expected to attend, composed largely of those interested in improving protocol processing at their CTSA sites. This workshop is intended to give people a forum to exchange ideas, especially the administrative staff (IRB Administrators, legal contracting, etc.). The goal of the workshop is stimulate a leader from each institution to come away from the meeting motivated to create change and equipped with the tools and resources to help in the process. Ultimately the Taskforce would like to develop and publish standard criteria for metrics for showing that the whole consortium has improved in process management and that each site has improved individually.

The group discussed a range of potential topics that it could list on the program including the following:

- The program will include a discussion of metrics for use by the CTSA Consortium and individual sites. The goal of the Consortium is to achieve standardization of metrics that it could use to show outside institutions that CTSA's can process protocols efficiently. The Consortium will start with the easiest metrics, such as those used for multi-center trials with NIH or corporate sponsors.
- The Workshop would be likely to feature local institutional stories about problem-solving in process management.
- Speakers will describe instances in which outside partners assisted in protocol processing as examples of ways of achieving efficiency. Examples of partners include contract research organizations (CROs), the NIH, and Industry.
- If they can agree, the participants at the Workshop might determine one or more best practice(s) for protocol processing such as measures that improve the processing of protocols by
  - IRBs
  - Contracts & Grants
  - Special committees (e.g. radiation safety)

Specialists will be invited to speak at the workshop. Examples include:

- Lawyers
- Investigators
- IRB members
- Clinical Research Managers/Research Nurses
- Business School/business process analysts

- Educators
- Informatics
- Administrators
- CTSA Finance/Budget department
- Cultural anthropologists
- NIH – What performance criteria do the extramural programs measure?
  - Time to enrollment
  - Rate of enrollment
  - Trial completion

Meeting Outcomes:

- Reduce mean protocol receipt – enrollment time
  - At each site
  - For entire consortium
- Develop best practices
- Examine role of prioritized processing of protocols
- Draft a document for a publication in a peer-reviewed journal

**Action Item**

The organizing meeting for the Workshop will be a teleconference held on January 23, 2008. It will include 10 participants with no more than one per CTSA site.