Clinical Trial Management Systems

Date, Time & Location: May 25, 2004; 12:00-1:00PM EDT; Teleconference

Attendees:

Center	Attendee
Case Western	Robert Lanese
City of Hope	Joyce Niland Hemant Shah
Duke	Larry Malin
Fox Chase Cancer Center	Michael Bookman
Georgetown	Jieping Li
Karmanos	Rick Pense
Mayo Clinic	Sharon Elcombe
Memorial Sloan-Kettering	John Speakman
OHSU	Lara Fournier
PAIR	Debra Collyar
Rosell Park	James Kepner
UCSF	Teri Melese Karen Kimura
University of Colorado	Jessica Bondy
University of Iowa	Jill Kuennen
UC Irvine	Andrea Hwang
University of Minnesota	Barry Brown Don Connelly
University of Penn	Lynn Schuchter
University of Pittsburgh	Mike Becich Doug Fridsma Valerie Monaco
University of Wisconsin	Rhoda Arzoomanian
Vanderbilt	Sorena Nadaf
Wake Forest	Bob Morrell Todd Thornburg
Yale	Charles Lu
NCI	Ken Buetow Sue Dubman Christo Andonyadis Leslie Derr Margaret Haber Anne Tompkins
Booz Allen Hamilton	Chalk Dawson Davis Bu

Update on Contracts:

- Contacted all 50 centers
- Held 80 teleconferences to discuss details
- One contract has been signed, and another is in the signature process
- Open dialogue has provided good input, which has produced a contract mechanism that would work for most cancer centers
- Although no deadline for signing the contracts has been established, delays in signing will delay issuance of task orders and funding
- Patient Representative offered to act as arbiter if negotiations get off track

Facts Sheet:

- At the last teleconference, a facts sheet was distributed that defines a vision for the workspace
- The target audience are the Cancer Centers
- Feedback since then was that the Facts Sheet was on target

	• One suggestion was to highlight Adverse Event reporting needs as the highest priority • Debra Collyar's comments have not yet been incorporated • Plan on posting later this week • Will forward the facts sheet to the communication group for distribution of the message to a larger audience
SIGs:	• Special Interest Groups are being formed • Participation in all groups is open to academic center members, but numbers will have to be balanced with manageability • Will send out compiled list this week of participants for the SIGs
CaBIG Compatibility SIG	• Goal is to evaluate existing academic and commercial software with regards to caBIG compatibility • First step is to collect a definition for caBIG compatibility • Need a digestible document regarding what it means to be caBIG compatible, which is under development • Develop a report card to see if solutions meet standards for caBIG compatibility • Would assist centers making decisions now to meet their need for clinical data management solutions in the caBIG context • Incorrect perception exists that NCI is endorsing Oracle Clinical; NCI is not endorsing Oracle Clinical • NCI has Oracle Clinical in place for internal, selected SPORES, and selected Cooperative Group use, and was able to extend a deal struck by the Department of Health and Human Services for the entire cancer research community, not just caBIG participants. • Goal is to have a rich collection of caBIG-compliant application modules so as to provide the community with greater choices • Compatibility would ultimately foster a competitive marketplace with victories based on merits of system • Key to success is partnership of academic and commercial groups working together within standards
IRB/Document Management	• IRB submission is problematic: very institution specific, difficult to standardize, not stable over time • Some movement toward centralization of IRB approval is occurring, for example, the centralized and electronic system used by Western IRB (IRIS?) • This system is used at Vanderbilt, and they are trying to integrate with the system internally • An IRB system ultimately has a high need for configurability • May 26 conference call at Fox Chase regarding document and record management

Clinical Trial Management Systems Teleconference, May 25, 2004

Face to Face Meeting

- Ground rules for face to face meetings:
  - Should last 1-1.5 days
  - Agenda items should benefit from face to face interaction
  - Agenda should be substantial and lead to agreement on key decisions
- Possible agenda items:
  - Report from SIGs on their findings
  - caBIG compatibility
  - CDE curation process
- Send proposals for agenda items to Davis Bu
- Volunteers to host include City of Hope, UCSF and Wake Forest
- Possible dates: early to mid July

Action Items:

Name Responsible	Action Item	Date Due	Notes
Sorena Nadaf	Send info on Western IRB system to Davis Bu	May 26, 2004	
John Speakman	Distribute details of FCCC Conference Call to Davis	May 25, 2004	
UCSF, City of Hope, Wake Forest	Investigate possibility of hosting next face to face meeting and report to Workspace	June 8, 2004	

Please list below and attach Meeting Materials and Agenda (if prepared separately):