Clinical Trial Management Systems Workspace Teleconference

Date, Time & Location: June 22, 2004; 12:00-1:00 PM EDT; Teleconference

Attendees:

Center	Attendee
CARRA	Diane Paul
Case Western	Robert Lanese
City of Hope	Joyce Niland
Dartmouth	Donna Marlatt
Duke	Kim Johnson
First Genetic Trust	Aris Floratos
Georgetown	Jieping Li
OHSU	Lara Fournier
UCSF	Teri Melese
University of Iowa	Terry Braun Jill Kuennen
UC Irvine	Andrea Hwang
University of Minnesota	Barry Brown Don Connelly
University of Pittsburgh	Mike Becich Doug Fridsma
Vanderbilt	Sorena Nadaf
Yale	Charles Lu Cynthia Brandt
NCI	Sue Dubman Mary Jo Deering
Booz Allen Hamilton	Chalk Dawson Scott Finley Davis Bu

Introduce Scott Finley:

- Joining BAH to help with the Clinical Trials Workspace
- From Johns Hopkins Cancer Center
- Interest is in automating clinical and research activities
- Contact: finley_scott@bah.com

Contracts Update:

- Have made lots of progress in past few weeks
- BAH, NCI and GovWorks met yesterday, and identified issues where flexibility is possible in the GovWorks requirements
- Contracts should be finalized soon

CaBIG compatibility document:

- Released last June 18, 2004
- Encompasses initial views on how to meet compatibility with the caBIG initiative
- Will feed into caBIG compatibility SIG to create report card
- Allows for several levels of compatibility
- Living document that will evolve with feedback from the community, especially the Architecture and Vocabularies Working Groups
- Forward comments to Arumani Manisundaram, Architecture Workspace lead (manisundaram_arumani@bah.com)
- Will raise regulatory issues with both the Architecture group (Diane Paul) and the Strategic Planning group (Chalk Dawson)

SIG Reports:

- CaBIG compatibility
  - Setting up first meeting
  - Will work with compatibility document
- Structured Protocol Representation
  - June 15th
  - Discussed the scope and goals of SIG, and identify available resources
  - Focus on lifecycle of protocol setup and administration
  - Desiderata of protocol representation (computable, flexible, maintainable, build on CDE, standards)
  - Identify resources groups to include and interface with (external agencies, legacy systems)
  - Summary 4 might be a good place to start
  - Face to face meeting: define life cycle, look at summary 4, first pass at harmonizing with one or two institution
  - Next meeting: next week, look at use cases for the pilot
- Adverse event
  - Drafted a dimensions graph and functionality matrix, which will be distributed with the meeting notes
  - Brainstormed a broad sweep of functionality, that will then be prioritized
  - Next two meetings July 2, July 16 at 3pm EDT
  - Will draft a high level view of flow of information for adverse event reporting
  - Anticipate interaction with CTMS/CDUS Reporting SIG
  - Will analyze existing system, and explore how they could be leveraged
- CTMS/CDUS Reporting
  - Reviewed the current reporting environment
  - Discussed C3D reporting functionality as a model
  - Discussed opportunities to coordinate with CTEP
  - Will invite CTEP representatives to future meetings
  - Will work with Adverse Event Reporting SIG, and may leverage common information flow diagram
- Lab Interfaces
  - Reviewed systems in current use at Centers
  - Will create survey to distribute to the Centers that describe their environment (systems used that require an interface)
  - Discussed need for HL7v3 compatibility
  - Discussed need for additional HL7v3 training (possibly as face-to-face meeting agenda or webcast)
  - HHS has mandated that we move to HL7
  - Should coordinate with Architecture workspace
- CDE curation: will identify representatives and coordinate activities with the Vocabularies Working Group
- IRB SIG
  - Roll into Structured Protocols SIG
  - Coordinate demonstration of Western IRB/Vanderbilt system

caBIG cancer Biomedical Informatics Grid

Clinical Trial Management Systems Workspace Teleconference, June 28, 2004

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- Face to Face Meeting
  - Logistics
  - Two full days
  - Second day for SIG working day
  - Length of SIG each SIG breakout session: ~2 hours
  - First day: SIG progress report
  - Roadmap for Clinical Trial Management System Workspace, including timeline
  - Tutorials, CAMP

Action Items:

Name Responsible	Action Item	Date Due	Notes
Diane Paul	Raise regulatory issues with Architecture Working Group	7/13/2004	
Chalk Dawson	Raise regulatory issues with Strategic Working Group	7/13/2004	