

**Clinical Research Forum
Information Technology Roundtable Meeting
Washington, DC
April 9, 2008**

Information Technology (IT) Roundtable Co-Chair Stephanie Reel, CIO and Vice Provost for Information Technologies at Johns Hopkins University, welcomed participants to the meeting.

Update from the American Medical Informatics Association (AMIA)

Dr. Don Detmer, President and CEO of AMIA, characterized this meeting as the formal start of an ongoing conversation and collaboration between AMIA and the Clinical Research Forum. AMIA's vision is to transform health care through informatics and to transform informatics from a serious avocation to a formally recognized health profession.

AMIA defines informatics as the use of computers for change management, human-computer interactions, communications, risk management, organizational behavior, workflow redesign, productivity improvement, organizational culture, safety, quality, etc. In contrast, the group defines information technology (IT) as hardware and software.

Strong synergies exist between the Forum and AMIA, such as their shared interest in improving training, public awareness, and funding for clinical research. AMIA and the Forum are considering creating joint sessions during their annual meetings.

Successful Implementation of Electronic Institutional Review Boards (eIRBs)

Ms. Mary Alice Annecharico, CIO of the University of Pennsylvania School of Medicine, chaired the session.

Diane Keogh, Corporate Director for Research Computing at Partners HealthCare Systems, Inc., explained that Partners HealthCare developed its own eIRB prototype in 2005 because the vendor market was not mature enough to support the organization's volume of protocols. Through this experience, Partners learned that governance is essential, institutions must allocate full-time IRB staff to the eIRB system, and the system must be flexible enough to generate a variety of easy-to-use forms.

Dr. Jim McNamee, Associate Dean for Information Services and CIO at the University of Maryland School of Medicine, reported that his institution purchased the Biomedical Research and Assurance Network (BRAAN), originally developed by Baylor College of Medicine, to streamline IRB operations. Over time, the university outgrew BRAAN because it needed more customization, better documentation, and simpler, more flexible reporting. The university chose eResearch Portal from Click Commerce, which will go live in May 2008.

John McIlwain, President and Co-Founder of Velos, Inc., explained that Velos is launching its eIRB product in July 2008. The system can be implemented (including conception, form and

workflow configuration, and pilot testing) within a few months and can be integrated into existing administrative systems.

CIOs: Challenges of Supporting the Research Community

Stephanie Reel served as chair for this session.

Jennifer Jarriel, Vice President and CIO of Baylor College of Medicine, reported that Baylor developed BRAIN, which became BRAAN when a commercial vendor purchased the system. Ms. Jarriel's department provides backup services, a deidentified repository for electronic medical records, a system to upload large files to a URL, and endpoint security for portable electronic equipment.

Dr. Richard Mendola, Vice President of IT and CIO at Emory University, explained that Emory created a new research IT division a year ago using seed funding. The division now has 13 FTEs and 42 active projects. It has leveraged new grants, established a Clinical and Translational Science Award (CTSA) biomedical informatics program, and launched a 1024 core high-performance computer cluster. The center also offers low-cost, high-capacity network attached storage (NAS) and a predictive health data system.

Rick Miller, Vice President and CIO at the University of Texas Health Science Center at Houston, reported that the challenges at his institution include:

- The need for ongoing funding to replace IT technology every 3-5 years.
- Security requirements inconsistent with open access and collaboration needs.
- Transmission and manipulation of enormous files.
- Users who do not follow procedures established by IT governance.
- Senior investigators in charge who do not always understand technology.

Dr. Jonathan Silverstein, Associate Director of the Computation Institute at the University of Chicago and Argonne National Laboratory, reported that his institution is converging budgets and operational processes from the biomedical side with those of the research and clinical sides. The University of Chicago organizes its IT systems into three groups: basic IT and administrative informatics needs, informatics needs related to patient and research subject data, and other CTSA informatics needs.

Clinical Trials Management and Data Collection

Fran Turisco, Research Expert at Computer Sciences Corporation, served as chair of this session.

Diana Gumas, Director of Clinical and Clinical Research Information Systems at Johns Hopkins University, explained that Hopkins purchased an enterprise-wide clinical research information system from a vendor in 2005. In 2007, an assessment showed that the project faced some substantial challenges, so Hopkins implemented its own Clinical Research Management System. The system includes a study and participant registry and an interface to the electronic patient record and eIRB. It offers help desk support, well-supported servers, and a formal specification process.

Dr. Andrew Cucchiara, Associate Director of Information Resources at the University of Pennsylvania (Penn) School of Medicine, reported that Penn purchased a clinical research management system from Oracle. However, after the two parties signed a contract, the company was reorganized and it stopped supporting one of the three products purchased by Penn. Even though the collapse of a more meaningful collaboration with Oracle had adverse effects on timelines for implementing various aspects of Penn's strategic plan for clinical research informatics, Penn learned a great deal that will help it better collaborate with other IT vendors.

Summary and Next Steps

Centralized systems allow all investigators' data to be used for additional research, increasing the return on investment. As with compliance responsibilities, investigators should not be able to opt out of using centralized research administration systems. Alternatively, frivolous requests to develop new systems for individual studies can be prevented by establishing a list of requirements (related to privacy, security, disaster recovery, and other issues) for such systems.

The scope of elements listed by the CTSA informatics consortium far exceeds the capacity of CTSA awards. Deans and administrators need to understand that the CTSA has challenged the field without providing the funding needed to achieve everything that the National Center for Research Resources (NCRR) has requested. The Forum could help CTSA institutions leverage all components within their organizations to meet the challenge provided by the CTSA.

Roundtable members discussed the justification for distinguishing between IT and informatics. Several argued against the distinction, noting that separating the fields promotes and endorses silos without yielding benefits. Others noted that the academic discipline of informatics is a science in its own right that goes beyond the provision of service.

Investigators must help their IT colleagues understand their needs. A cultural change is needed to move from an investigator-centric environment to an enterprise-enabling mode that values partnerships.

Deans constantly receive proposals for great ideas that need investment. Deans understand that their institutions require an IT and informatics infrastructure, so the Roundtable's message must go beyond a request for additional funding. Deans want to hear about concrete changes that can be made within their fiscal reality.

Concrete projects that the Roundtable could address are:

- Define information standards for research.
- Identify best practices for workflows.
- Identify a single, standardized clinical research architecture model.
- Identify barriers to intra- and inter-institutional collaboration and develop model policies to overcome these barriers.