

**CLINICAL RESEARCH FORUM**  
**IT Roundtable Meeting**  
**Washington, DC**  
**April 15, 2009**

Stephanie Reel, MBA, Vice Provost for Information Technology and Chief Information Officer, Johns Hopkins University, Co-Chair, CRF IT Roundtable, opened the meeting with her perspective of the current state of clinical research and the challenges and opportunities for clinical research IT regarding the \$2 billion stimulus package for healthcare IT.

**2009 IT Healthcare IT Stimulus Package - What Does It Mean for Clinical Research IT?**

Daniel E. Ford, MD, MPH, Vice Dean for Clinical Investigation, Johns Hopkins School of Medicine chaired this session. Dr. Ford suggested that the clinical research IT community move what has been learned from clinical IT to clinical research IT, noting that the federal stimulus package has changed the discussion from 'where will funding come from' to the question of 'how to make the most effective use of newly available funding'. The challenge for the clinical research IT community is to figure out priorities using clinical IT to inform clinical research IT initiatives.

Gregory J. Downing, DO, PhD, Project Director, Personalized Healthcare Initiative, Office of the Secretary, Department of Health and Human Services, presented on behalf of Robert Kolodner, MD, National Coordinator, Office of the National Coordinator for Health Information Technology. Dr. Downing began by acknowledging the role of the Forum in driving CRIT and health informatics. He stressed that patient privacy concerns are integral to both clinical care and clinical research, and suggested that clinical research IT professionals start with a review of the Federal Health IT Strategic Plan; American Recovery and Reinvestment Act (ARRA); and interoperability standards, and recent related federal government activities in the area of privacy in relation to health care reform. Key points included:

- The need for a strong clinical research IT infrastructure to inform quality standards and help manage costs and privacy issues
- In the next few years, EHR (Electronic Health Records) will be a priority, however, the pace at which hospitals are acquiring EMR (Electronic Medical Records) is increasing but still remarkably slow. Large institutions lead in implementing EMR but there is a problem with smaller hospitals. A real concern is that money will be spent on computer systems that will be unused or not useful.
- The total amount of funding available will not allow 100% EMR implementation; funds can start system acquisitions but will not be able to sustain and support the systems, with state and municipal government lacking funds to support local hospitals. Actual deployment of EMR infrastructure is a major issue, and cost savings are a long way off.

The Office of the National Coordinator's Coordinated IT Plan is the backbone for milestones as follows:

- Individual and population health and wellbeing includes health care transformation (quality, efficiency and patient-focused health care, which depends on the use of IT technology) and population health (public health, *e.g.*; state programs and the CDC. Public health includes emergency preparedness and population-driven data).
- The Health Information Technology Act (HITECH) addresses employment, provides career development and employment measures. The ONC will implement the HITECH Act.
- Interoperability, standards and certification--two federal advisory committees, the Health IT Policy Committee and the Health IT Standards Committee, will recommend standards to the ONC, with standard adoption to take effect not later than Dec 31, 2009.
- Nationwide networks where secure transmittal of medical information for clinical studies. NHIN involves 20 groups; NHIN Phase 1 completed in 2007; Phase 2 completed in 2008; Phase 3 started in 2009 (Path to Production). The Social Security Administration is involved in a project which demonstrates the feasibility of exchanging summary records (DOD military implementation) and support for consumers to see value of transferring health information.
- Privacy- A major change is that HIPAA penalty provisions are being extended to the business associates. The sale of health information will be prohibited.

Kevin Hutchinson, Vice Chair, Board of Directors for the National eHealth Collaborative (NeHC), provided an overview of NeHC, which is a public/private partnership aligning health IT and clinical research IT, and its goals. NeHC brings together stakeholders in nearly every area of health to accelerate development of the health IT systems, infrastructure, standards, protections, participation, and education needed to create a secure, interoperable, nationwide electronic health information system. Its goals are to:

- Accelerate adoption of breakthrough technologies, learn from each other, focus on what does not work as well as best practices, collaborate with private industry, bring constituents into the discussion.
- Develop effective implementation strategies (model processes and best practices).
- Build connections to government to assure an informed group understanding of on-the-ground experiences.

### **Clinical Research Value Case (AHIC Project)**

Rebecca Kush, PhD, President and CEO, CDISC (Clinical Data Interchange Standards Consortium), discussed how to get more involved in clinical IT standards and how to get clinical research IT on the national agenda. The CDISC has developed a clinical research workgroup which is prioritizing what needs to be done, and is starting with identifying common core elements for research data to be exchanged with EHRs. It will then build on patient eligibility - pharmacogenomics. Funding has been raised to get the CDISC on ANSI.

Gregory J. Downing DO, PhD, Project Director, Personalized Healthcare Initiative, Office of the Secretary, Department of Health and Human Services, discussed his work in personalized health care and his concerns about integrating clinical research into health IT. He recommended that AHCs increase their responses to federal notices and public comment periods.

## **eMerge Project – Extracting Phenotype Data Out of EHRs**

Dan Masys, PhD, Chair, Department of Biomedical Informatics, Vanderbilt University School of Medicine, chaired this session and provided an over view of eMERGE. The Electronic Medical Records and Genomics (eMERGE) Network brings together researchers with a wide range of expertise in genomics, statistics, ethics, informatics, and clinical medicine from leading medical research institutions across the country. Each center participating in the consortium, organized by the National Human Genome Research Institute with additional funding from the National Institute of General Medical Sciences, has proposed studying the relationship between genetic variation and a common human trait, using the technique of genome-wide association analysis. The consortium members include: Group Health of Puget Sound; Marshfield Clinic; Mayo Clinic; Northwestern University, and Vanderbilt University.

Justin B. Starren, MD, PhD, Director, Biomedical Informatics Research Center, Marshfield Clinic Research Foundation, discussed effective EHR phenotyping strategies. Key issues include: clinical treatment may not contribute to genetics or research study aims; EHR uses single data entry (not double), erroneous data can be entered; there is often missing/sparse data, duplication or disagreement of facts; and all data in not computable. The tool using the Cataract Project was demonstrated.

Christopher G. Chute, MD, PhD, Professor of Medical Informatics, Division of Biomedical Informatics, Mayo Clinic, commented on the need for community engagement, research on patient attitudes, and to have all data deposited into a quasi-public repository. His presentation focused on the forty-year heart disease surveillance in Olmstead County, Minnesota.

Dr. Masys presented on overview of data privacy issues arising from the combination of genomic and clinical data identified with the Bio VU project at Vanderbilt, which is a biobank intended to support a broad view of biology. It currently contains de-identified DNA extracted from leftover blood after clinically-indicated testing of Vanderbilt patients who have not opted out.

Informatics issues that have been identified in eMERGE include:

- Determination of comparability of patient populations across institutions
- Data exchange standards for phenotype data
- Representation of ‘clinical uncertainty’ for EMR-derived observations (definite—probable—possible for assertion and negation)
- Re-identification potential of pooled samples

It was noted that the eMerge project shows the value of clinical databases in clinical research IT, and the need for cost savings to be brought into the equation. Further discussion should focus on what clinical research databases can do, and their value. One approach is to focus on IT as enabling new types of research, which are IT-dependent. Currently, too many IT resources are being used to meet regulatory requirements.

The effect of HIPAA on moving clinical research data is a barrier. At present patients do not understand how IT improves their care. Patient groups need to be informed about how IT and sharing data can help achieve a successful health outcome. There is too much focus on protection issues yet failure to inform the public about how locking down data does not help patients and can hinder their care. Complete privacy and advances in healthcare are incompatible. To persuade Congress, it is important to link clinical research IT to healthcare reform and better health for the public, and the IT Roundtable should compile a list of clear-cut successes where IT has improved clinical care and health.

### **Summary - Where Do We Go From Here?**

Stephanie Reel summarized the meeting with the comment that it was not too long ago that CIOs complained about the absence of standards, yet now are complaining about the existence of standards. There were complaints about lack of funding and investments in clinical research IT, yet now \$2 billion in funding is available. She noted that there is a need to get involved in CDISC and with other groups, and that the key question is what the IT Roundtable can do to make a difference.

Where do we go from here? Projects for consideration include:

- Prepare a list of clear cut approaches that demonstrate improved health. IT RT compile this list; proof of concept.
- Show the value of clinical research databases; exploit investments in eMERGE, i2b2, etc.
- Demonstrate cost savings and increased productivity with IT
- Show how IT is enabling new types of research
- Demonstrate how IT is being used to overcome barriers
- Data scrubbing to EMRs
- Provide input on the specifics of new regs in HIPAA (III)
- Articulate the value of data sharing for clinical research and patient care; demonstrate the value to patients
- List the successes where IT improved clinical research