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Healthcare Information Technology Standards Panel

Report from the EHR Clinical Research Tiger Team

June 1, 2009

Presented by: Walter Suarez, MD, MPH
Tiger Team Co-Chair

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Background

- Clinical research an important priority identified early by AHIC and ONC; in June, 2008 AHIC approved a recommendation to develop a clinical research use case
- In late 2008 ANSI convened an **EHR Clinical Research Value Case Workgroup**
- CCHIT added in January, 2009 clinical research to roadmap for EHR certification; HL7 EHR Clinical Research Profile passed ballot
- Value case anticipated to provide a foundation for future use cases:
  - Patient eligibility and recruitment
  - Pharmacogenomics and biomarkers
  - Safety reporting
  - Compliance reporting
- Long-term goal: create an infrastructure through which health care advances clinical research which, in turn, informs clinical care

Acknowledgement - EHR Clinical Research Workgroup Members

- Jonathan Andrus - SCDM
- Robert Annechiarico - Duke Comprehensive Cancer Center
- Kate Blenner – Faster Cures
- Kenneth Buetow – NCI
- Christopher Chute – Mayo Clinic, CTSA
- Perry Cohen - Parkinson Pipeline Project
- Elaine Collier – NCRR
- Kevin Coonan – Harvard, HL7, Dana Farber
- Timothy Cromwell - VA
- Jeffrey David - HIMSS
- Peggy Devine - Cancer Information and Support Network
- * **Gregory Downing - HHS**
- Paul Harris - Vanderbilt University, CTSA
- Steven Hirschfeld – NICHD
- Charles Jaffe – HL7
- Michael Kahn – AMIA, Colorado Children's
- Linda King – eClinical Forum, PhRMA, Eli Lilly
- Judith Kramer – Duke, CTTI
- * **Rebecca Kush - CDISC**
- David Leventhal – Pfizer, ASTER
- Nikolay Lipskiy - CDC
- Armando Oliva - FDA
- Rachel Richesson – USF
- John Speakman – NCI
- Gary Walker - ACRO

**Co-chairs*

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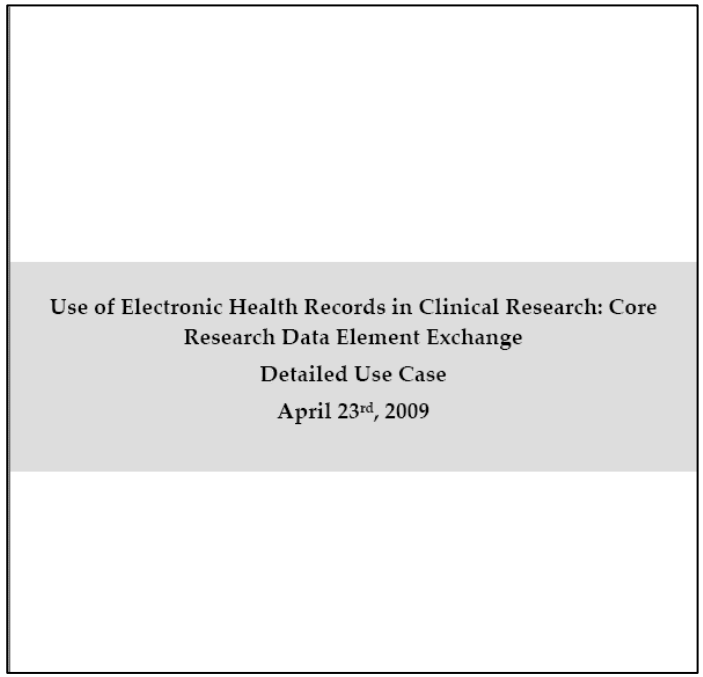
Value Case

- Workgroup developed initial draft detailed value case and extensions (Nov 2008 – Feb 2009)
- Draft value case posted for public comment in March 2009
- Detailed value case completed by end of April, 2009; value case submitted HITSP for development of interoperability specifications
- Document describes three value scenarios:
  - Scenario 1: Data exchange from EHR to clinical research sponsor for submission to regulatory, public health, and other agencies
  - Scenario 2: Exchange of information from EHR to registries or other databases
  - Scenario 3: Exchange of information from EHR in a distributed research network



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Value of Standards for Clinical Research

- Facilitate investigator/site participation in multicenter studies
- Study data in standard format readily populates reports, publications, registries
- Increase data quality
- Enable data integration into ‘knowledge warehouses’ to improve science, marketing and safety surveillance
- Improve communication among project teams
- Enable efficient exchange of information among a variety of tools and technologies
- Minimizes customization of EHRs to support research
- Site research data archive helps meet regulatory compliance
- Improve data exchange among partners (e.g. academic institutions, FDA, NLM, IRBs, DSMBs)
- Facilitates regulatory reviews

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TT Formation

- HITSP group convened as a ‘Tiger Team’ in early-May
- Intent is to start the HITSP work on the value case, while Technical Committees are on temporary hold during the ARRA realignment
- Focus of TT work: conduct requirements analysis through mid-July, 2009
- Outcome to be transferred to appropriate Technical Committee upon restart of regular HITSP work after mid-July

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TT Leadership, Members

- Leadership
  - Walter Suarez, MD, Institute for HIPAA/HIT Education & Research, Co-Chair
  - Gene Ginther, JBS International, Staff Co-chair
  - Landon Bain, CDISC, Technical Writer
- Membership
  - Rapid growth (87 members in 2 weeks)
  - Representatives from provider organizations, research institutions, federal and state public health government, national research associations and fora, vendors
  - Added a large number of new members to HITSP

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Terms of Reference

1. Review Use Case, provide feedback to requestor, evaluate scope of effort and develop statement of work for completion.

2. Perform high level design of Interoperability Specification and lower level constructs including requirements analysis and minimum data set identification.

3. Submit for public comment detailed Requirements Analysis and Design documentation

4. Identify Domain Committee(s) for construct development and provide high level design and statements of work.

5. Review and evaluate existing Interoperability Specifications for the selected standards, integrating relevant constructs.

6. Manage overall execution plan/schedule in collaboration with Domain Committees.

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Timeline (Through July 15, 2009)

Month	Week	Action	Dependencies
May	11-15	TT Orientation	
	18-22	Requirements Analysis	Table 2.2-1 drafted by writer
	25-29	Requirements Analysis	
June	1-5	Data Requirements Discussion	Table 2.2.2-1 and 2.2.2-2 drafted by writer
	9-11 F2F	Review EHR Lite scenarios to determine reuse possibilities	EHR Lite is available from Tiger Team
		Review CMHR and SPI constructs ID'd as reuse candidates	Domain TC reps avail to provide overview
		Define new construct needs and discuss with Domain TCs	Domain TC reps available
	15-19	Review 1st draft Sections 1 & 2	Writer has completed draft
	22-26	Section 3 Discussion (Assumptions, Pre/Post Conditions, Triggers, Constraints)	
July	29-3	Review Updated Draft (Sections 1, 2, & 3)	Writer has updated draft
	6-10	Approve final draft and submit to IRT and Production	Writer has completed draft doc
	13-17	Approve updated document (IRT and Production changes incorporated) for release for public comment	IRT and Productions changes are incorporated into doc

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Status

- Initial meeting held May 14
  - Overview of TT, Terms of Reference, HITSP Process, Value Case
- Requirements Analysis started
  - Review of value case scenarios
  - Started mapping of value case events, actions, exchange and data requirements
- Meeting schedule
  - Full TT meeting Thursdays from 1:00 pm to 3:00 pm eastern time