EHR Clinical Research Standards Harmonization

HITSP Board Update
9 February 2009

Rebecca Kush, PhD
President and CEO, CDISC

CDISC

Background of EHR Clinical Research Value Case

- July 2008 - EHR Clinical Research Value Case presented as a priority use case to AHIC

- Fall 2008 - AHIC acknowledged Clinical Research is an important area for harmonization of clinical research standards with healthcare/EHR standards and development of interoperability specifications

- But, Clinical Research did not make the AHIC prioritized list for 2009; however, HHS/ONC agreed that it could be advanced as a 'supplemental pathway' if additional funds could be raised to support this work, including private sector funds

EHR Clinical Research Value Case Workgroup

- With support/encouragement from HHS/ONC and others, ANSI convened an EHR Clinical Research Value Case Workgroup for prioritization of clinical research use/value cases
  - Workgroup co-chaired by Drs. Greg Downing of HHS and Rebecca Kush of the Clinical Data Interchange Standards Consortium (CDISC)
  - Members represent numerous organizations in EHR Clinical Research domain
  - Met in person 10 November; subsequent teleconferences every ~ 2-3 weeks
  - Vision and Value Case documents developed; accompanying use case document in progress (anticipated completion in April)
- ECO (Education, Outreach and Communication) and fundraising initiated fall 2008
- HHS identified federal funding for use case development (NIH NICHD and NCI and NCRR; Asst Sec of Planning and Evaluation; ONC and AAAS Science and Technology Policy Fellow)
- Targeting additional $250,000 to go to ANSI for HITSP process
  - as of 31 December ~ 20%
  - *as of 7 February ~ 70% from ~ 25 contributors, and still going…..*

EHR Clinical Research Priority Value Case

- Initial Prioritized Value Case: Identify a common set of information that can readily be exchanged between EHRs and clinical research systems
  - Anticipated to leverage existing standards and to provide a foundation for potential future use cases including:
    - Patient participation in research (subject recruitment)
    - Adverse event reporting
    - Pharmacogenomics and biomarkers

- ***Long-term objective:*** *create an infrastructure through which healthcare advances clinical research and in turn informs clinical care*

- Additional Information: **http://cdisc.org/publications/hitsp.html**