Health IT and Standards to Support Clinical Research: Combining clinical and genomics data

Secretary’s Advisory Committee on Genetics, Health and Society

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Overview

- Health care and clinical research
- The ability of health IT to support clinical research
- A set of core clinical research elements
- Combining clinical data and genomics data
Medical Research

• Approximately $100B spent annually on medical research in the U.S.

• Data requirements for clinical research overlap substantially with clinical quality, safety and efficacy use cases.

• Health care and clinical research need to have consistent standards.
The Current State of Clinical Information

• Healthcare information is found in:
  – paper medical records
  – disparate databases
  – hospital-based information systems

• Clinical research data exists in:
  – additional databases
  – research notebooks

• Clinical trial data collection;
  – 3-part NCR forms in ~60% of trials
  – multitude of electronic data capture applications
    • sites average 3 different applications
Shared Information

Insurance Claims

Basic Clinical Research
- Investigator-Sponsored Data Acquisition, Analysis

Healthcare Delivery
- Patient Information

Protocol-driven Clinical Trials
- Government-Sponsored Pharmaceutical Data Acquisition, Analysis

Publications

Regulatory Reviews
ANSI has convened an EHR Clinical Research Workgroup for prioritization of clinical research use cases (the Workgroup is co-chaired by HHS and CDISC)

Should leverage existing clinical/medical research standards

Initial Prioritized Value Case: Identify a common set of data elements that can readily be exchanged between EHRs and clinical research systems
  - Anticipated to provide a foundation for potential future use cases including:
    - Patient participation in research (subject recruitment)
    - Pharmacovigilance
    - Clinical genomics and biomarkers

**Long-term objective:** create an infrastructure through which healthcare advances clinical research and in turn informs clinical care
Patient Value: Quality of Healthcare, Safety

Research informs healthcare more effectively and efficiently
Build quality into process at beginning

Research Site
(Healthcare Location, Investigator, Site Personnel)

Study Sponsor
(e.g. ARO, CRO, Vendor, Principal Investigator)

Reviewers
(e.g. Research Partner, Sponsor, Registry, Regulator, IRB, DSMB)

EHR

De-identified Data

Std. Common Research Dataset (+)

Research Results, eSubmission Standard Formats

Scientific Publication

Public Registries, IRB, DSMBs

Regulatory Authority

Site Research Archive
Core Research Data Elements

- Reporting Requirements
  - Language
  - Informed Consents
  - Eligibility Verification
- Subject Demographics
- Prior and Concomitant Medications
- Medical History

- Physical Examination
- Substance Use (e.g. Habits)
- Vital Signs
- Laboratory Data
- Untoward Clinical Events (i.e., Adverse Events)
Data Standards for Clinical Genomics

- **Workgroup**
  - Core Federal Workgroup Agencies: FDA, NCI
  - Expanding to both public and private stakeholders

- **Standardized terminology and messages to record/report all phases of the production of genomics data**

Genomics Data Information Flow

- **Biospecimen**
- **Sample Processing**
- **Data**
  - Analysis
  - Storage
  - Exchange

- **Collection**
- **Hybridization**
- **Format**
- **Normalisation**

- **Handling**
- **Representation**
- **Ontology**
- **Statistical Analysis**
- **Biological Analysis**
Status of Clinical Genomics Standards

• HL7 current status of clinical genomics
  ▪ Genetic Variation and Family History Models are available
  ▪ Gene Expression under development
  ▪ Genetic Testing Reports project proposal approved for development

• Innovative use in healthcare
  ▪ Tailor screening based on familial risk factors
  ▪ Customize treatment based on genetic profiling

• Innovative use in clinical research
  ▪ Cohort identification for study trials
  ▪ Drug metabolism
  ▪ Initial use for bio-marker discovery

• Standards development
  ▪ Joint effort by healthcare and research (CDISC and HL7)
  ▪ Development of ontologies to support standardization of data exchange (e.g. HL7 messages)
Current Barriers

• Research Barriers:
  ▪ Lack of clear regulatory mandate for genomics data in studies
  ▪ Lack of clearly defined process for bio-marker validation
  ▪ Lack of global standard to facilitate data exchange.
    ▪ Common standard needed to enable use of medical data in research.
    ▪ Maintenance of multiple standards not sustainable
    ▪ Many standards requires creation of cross-references
  ▪ **Cost-effective** data management requires global standards that enable data use for multiple purposes (healthcare, research, epidemiology/public health, health-access policy).

• Healthcare Barriers:
  ▪ Slow movement towards adoption of electronic healthcare records
  ▪ Ontologies points above also apply to healthcare

*Note: Standards comments include both clinical genomics and medical data*
Harmonized Information Exchange Standards for Clinical Research and Healthcare

Harmonization essential:

- To aggregate information across stakeholders so that research findings lead to informed healthcare decisions
- For timely global safety surveillance
- To link biomarkers (including an individual’s genetic markers) to population characteristics and outcomes
- To facilitate research for clinicians concurrent with clinical care

Net Impact: Reduce time and costs of research and improve quality and effectiveness of healthcare
Information and Contacts

EHR Clinical Research Value Case and Use Case
http://publicaa.ansi.org/sites/apdl/EHR%20Clinical%20Research/Forms/AllItems.aspx.

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Contributors to HITSP EHR Clinical Research Initiative

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- Biogen Idec
- Boehringer Ingelheim Pharmaceuticals, Inc.
- Cleveland Clinical and Translational Science Collaborative at Case Western Reserve University
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