Data Standards and the National Cardiovascular Research Infrastructure (NCRI)

A partnership with Duke Clinical Research Institute (DCRI) and the American College of Cardiology Foundation (ACCF)

November 5, 2010
NCRI Mission

Integrate existing resources to efficiently execute large simple clinical research projects

- Site recruitment and education
- Randomization, Research Data Collection (DCRI)
- Quality Improvement Registry Data collection
- Data standards (CDISC, HL7)
- Guideline development (ACCF)

The Infrastructure and operations requirements go far beyond standards development and database programming
ACCF and NCDR

- National Cardiovascular Data Registry (NCDR) receives data from 2,300 + hospitals
  - CathPCI Registry has over 10 million encounters and accepts data from 1100 sites

- NCDR integral in hypothesis generation, guideline development, development of performance measures
NCDR and NCRI Mission

- Vision to have fully integrated platforms between the NCDR, clinical research and electronic health records

- To relate pre-marketing clinical data with post-marketing clinical data
Integrating Quality into the Cycle of Therapeutic Development

Domain Analysis Model (nomenclature, process)

NCRI & (CDISC CDASH & SDTM)

Figure 1. Model for the integration of quality into the therapeutic development cycle.
NCRI and Data Standards

- Utilize Clinical Data Acquisition & Standards Harmonization (CDASH) in the development of a set of consensus data standards

- Represent the data using SDTM and HL7 RIM Mappings

- Use NCRI infrastructure to conduct a randomized clinical trial as a demonstration of interoperability between healthcare and research
Patient

Data Standards
Single Source

Patient

Clinician

Multiple Uses

Data Uses

Patient care
Quality Improvement
Research
Reimbursement
Post Marketing Safety
Decision Support
Administration & Mgt.
Public Health Reporting

...
Data element: chest x-ray result
Background

- History of data oriented work by CV professional societies and by Duke.

- 2006-2008: NIH Roadmap contract, Duke, CDISC and HL7 to develop data standards for Tuberculosis & Cardiology

- May 2008: ACS project resulted in 21 standard data elements

- 2008-2010: New initiatives
  - ACC Informatics Committee ‘Top 100’
  - FDA Cardiovascular endpoints

- 2010: Opportunity to expand the content of these standards and stakeholder community
Project Overview

Cardiovascular Data

<table>
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<tr>
<th>Non-specialty data</th>
<th>Common cardiovascular clinical observations - Sub-specialty domains</th>
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<tbody>
<tr>
<td>CDISC BP</td>
<td>ACC/AHA/STS Registries</td>
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<td>Cardiac Imaging</td>
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Demographics
- Concomitant Medications
- Adverse Events
- Vital Signs
- 18 total domains and growing

ACS History & Symptoms
- Top 100 EHR data elements
- CV Outcomes
- Women's Presentation Sx
- Stroke

STEMI/NSTEMI (ACTION)
- Coronary Artery Stenting and Endarterectomy (CARE)
- Cardiac Cath and PCI
- Congenital Heart Conditions (IMPACT)
- Cardioverter defib procedures (ICD Registry)

Future
- Echocardiography
- Coronary CTA
- Exercise Electrocardiography
- SPECT MPI

*National Cardiovascular Research Infrastructure

CV Clinical
- Data Elements
- Event definitions
- Clinical terminology and data definitions

CDISC
- SDTM standard for FDA submission
- Controlled Terminology alignment
- CRF templates
- Stds adoption by researchers

HL7
- Mappings to HL7 RIM & EHR stds
- Adoption support for EHR’s
- CCHIT EHR Certification (future)
Collaborating Organizations

- American College of Cardiology Foundation (ACCF)
- Clinical Data Standards Interchange Consortium (CDISC)
- Duke Clinical Research Institute (DCRI)
- Duke Translational Medicine Institute (DTMI)
- US Food and Drug Administration (FDA)
- Health Level Seven (HL7)
- National Cancer Institute (NCI)
- National Cardiovascular Research Infrastructure (NCRI)

Partial funding provided by NHLBI Award 1RC2HL101512-01
Engaging Subject Matter Experts

- Formed a working group of subject matter experts to oversee the clinical content of consensus data standards
  - H. Vernon Anderson, MD, FACC
  - Mark Kremers, MD, FACC
  - Martha Radford, MD, FACC
  - Matthew Roe, MD, FACC
  - Richard Shaw, MD, FACC
  - James Tcheng, MD, FACC
  - William Weintraub, MD, FACC
Data Elements

- Out of scope
  - Insufficient value/use
  - Administrative: demographics, insurance etc.
  - Of CV value, but not within CV specialty domain (e.g. stroke details)

- Pending
  - Women’s Health Initiative
  - Death
  - FDA Endpoints

- SME Set Approved
  - Medical History (90)
  - Family History (2)
  - Adverse Events (12)
  - Procedures (92)
  - Medications
    - CDASH with 34 meds + 26 classes
  - Lab Results
    - CDASH with 19 labs
  - Physical Exam
    - CDASH
  - Discharge (58)

400 + expected...
Standardized Data Collection for Cardiovascular Trials Initiative

- Initiated by the FDA

- Composed of representatives from professional societies, academic centers and standards organizations

- Goal is to associate our data elements with the endpoints
Process of Building Standards

ACC Top 100

NCDR-STS Harmonized Data Elements

ACC-AHA Data Standards

NCDR Harmonized Data Elements
Domain Analysis Model

- Represents the domain of cardiology using both technical and non-technical language
  - Use Cases
  - Activity Diagrams
  - Story Boards
  - Information Model
- Data will be annotated with CDISC SDTM and HL7 RIM representations
- Is the medium through which requirements are communicated to technical experts
## Work Products

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<th>Research</th>
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And for patient care, this means improved:

- Efficiency of and Capacity for Evidence Synthesis
- Efficiency for Hypothesis Generation
- Efficient development and conduct of Clinical Research Initiatives
- Findings Dissemination
- Care Delivery Guideline Development
- Quality Monitoring
Challenges When Applying Standards

- Applying health care and clinical research standards to other use cases
  - Developing a process for creating therapeutic standards
  - Using CDASH conventions for secondary reporting data and the need for different levels of granularity
  - Trying to fit elements from quality improvement registries into SDTM domains
  - Governance and maintenance
Challenges When Applying CDASH/SDTM

- Elements in CDASH are designed to capture real-time clinical trials data
  - ex. Registries collect medications and labs in the context of a time period (Pre-procedure, Post-procedure)

- Concept of Intervention different for a registry and a clinical trial
  - ex. An “Intervention” to a registry is defined as a procedure in which a device is employed
**Impact**

Potential for economic efficiencies and reduced health care cost

Potential for quality improvement in patient care

Potential to develop CV EHR Profile via HL7 that can be used for CCHIT Certification and Meaningful Use
Thank You!

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