Evolution of a Clinical Research Informatics Group within a Service-oriented Clinical Trials Data Management Organization

B. McCourt, D. Fasteson-Harris, S. Chakraborty, C. Bova Hill

AMIA CRI Summit
San Francisco, March 2010

Topics

- Context
- Challenges
- Organizational Design Solution
- 2 Year Experience
- Now and next steps
DCRI Context

What is DCRI?

- DCRI is the largest academic clinical research organization (ARO) in the world
- A global coordinating center for multi-center clinical trials that integrates the medical expertise of Duke University Medical Center with the operational capabilities of a full-service CRO
DCRI Facts

- Founded in 1969 with the development of the Duke Databank for Cardiovascular Diseases
- 21 years of experience in coordinating multi-center trials in over 20 therapeutic areas
- 900+ staff and 120 clinical/statistical faculty
- Full-Service Capabilities
- 4,600 manuscripts in peer-reviewed journals
- More than 420 projects completed in 64 countries enrolling more than 579,900 patients

DCRI – Trials Experience by Phase and Size
CDM Challenges

History (1997 – 2007)

- History & Organizational Design
- Causal Issues
  - Capacity for change
  - Industry trends
- Environmental Issues
  - Organizational changes
  - Qualitative studies
Existing Org Structure (1997-2007)

- Clinical Data Integration
- Highly nested team units

- Clinical Data Managers
- Data Management Teams
- Quality Control
- Case Report Form Design
- Clinical Programming
- Duke Follow-up
- Medical Coding

10 Year Headcount Trend
Industry Trends  (2007)

- Increasing number of projects with increasing complexity and decreasing data processing

- Increased demand for EDC (vs. paper) and increased demand for CDI consulting with sponsor EDC tools & implementations

- Increasing infrastructure initiatives supporting DCRI, DTMI, NIH & Industry to develop and adopt innovative operational methods.
Industry Trends (cont)

- Increased reliance on standards and technology to meet increasing variety of CDM requirements
- Emerging industry recognition of increasing CDM scope and trends

Environmental Studies

- DCRI wide telephone survey
- Departmental web survey
- Horizontal focus groups
What did the studies tell us?

- **Opportunities for improvement:**
  - Inconsistent management decisions
  - Career progression
  - More effective communications
  - Trust
  - Collaboration

- **Mastery of administrative, technical, training and project management was difficult to achieve**

Organizational Design Solution
Impact of matrixed CDM teams

- **Administrative Reporting Relationships**
  - 90 of 138 Employees switching managers

- **Project Teams Intact**
  - 88 projects total
  - 69 have no changes to CDM Lead
  - 12 the new lead has been involved already and lead role being formalized
  - 4 leads will change after resources available
  - 2 new projects not yet assigned
  - 1 project transition is being scheduled
DCRI Research Informatics

- Support research data integration projects with complex research requirements.
- Evaluate and operationalize new ideas for data management tools and methods ('data management pipeline')
- Develop and implement clinical data standards

10 Year Headcount Trend
Emergence of CRI

Synergies and Distinctions Between Computational Disciplines in Biomedical Research: Perspectives from the Clinical and Translational Science Award Programs

Peter J. Embi, MD, MS, Philip B. O. Payne, PhD

Abstract

Clinical Research Informatics: Challenges, Opportunities and Definition for an Emerging Domain

Original Investigations

Clinical Research Informatics context
BioSignatures \ Biomarker Studies

High level overview of Biomarker Information

- 100% eSource
- Metadata heavy
- Sample management
- New workflow

2 Year Experience
T1 Challenges in CDM Services Context

- Evolving science causes evolving data requirements
  - Scope, pricing, workflow, bio and information science skills

- Discovery based work now within scope of FDA regs and pharma traditions
  - Mismatch of burden/benefit and common understanding of regulations

- Data Management systems are immature or don’t exist.
  - Bioinformatics tools lack data management workflow
  - IT -> Research IT\Computer Science

Decision support methodology: implementation on a clinical trial

![Diagram showing the flow of information and decision making in a clinical trial context.]
T2 Challenges in CDM Services Context

- **New risk profile of research tasks within patient care process.**

- **EHR’s -> Disease cohorts -> Trials -> EHR**
  - Complex governance
  - Consent; research vs quality improvement; future use; Identification.
  - Data collection design

- **Interoperability**
  - CDISC : HL7; WHO Drug : RxNorm; MedDRA : …; Metadata!
Key Issues

- Unanticipated acceleration of trends
  - CTSA, ARRA, Duke Center for Health Informatics, DCRI BioSignatures Program

- What is informatics?
  - Depends on who you ask
  - Functional bounds of interdisciplinary domain

- Field is still immature
  - Too few examples
  - Talent gap

- Cost constraints & allocation
  - Project vs infrastructure
Where Next?

- Practical need for CRI will meet vision (bottom up meets top down)
- Grow as research partner, beyond service provider
  - CRI Faculty
- Data Infrastructure
  - Adopt HL7 Development Framework as methodology
  - Heavily use & contribute to standards
  - Leadership, data governance

Conclusions

- The challenges discussed at this meeting have corresponding business challenges
- The research trends driving the growth of CRI exist
  - Not only as CTSA phenomena
  - Can be expected to impact services market
- CRI is not yet well defined or established
- Need to demonstrate value
Acknowledgements

- Connor Blakeney
- Robert Harrington, MD
- Meredith Nahm
- James Tcheng, MD
- Swati Chakraborty, M.Eng.
- Carol Hill, PhD
- Cindy Kluchar, MS
- James Topping, MS
- Becky Wilgus, RN, MSN

Evolution of a Clinical Research Informatics Group within a Service-oriented Clinical Trials Data Management Organization

B. McCourt, D. Fasteson-Harris, S. Chakraborty, C. Bova Hill

AMIA CRI Summit
San Francisco, March 2010