Clinical Research Informatics: Challenges And Trends

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Clinical Research Informatics

Outline

- What is the problem?
- National efforts to organize and coordinate basic science and clinical research
- Clinical research systems: What’s your Lens?
“...the bioinformatics equivalent of neighboring but isolated medieval nation states, each with different systems of weights and measures.”

What is the Problem?

The Scientific Method:
- Research is proposed and conducted in a sequential manner, moving from one scientific question to the next.

The Result:
- The sequential nature of research narrows the informatics scope to the most current study, typically resulting in a unique, ‘one-off’ solution.
Traditional ‘Content’ Oriented Approach

Typical Data Management Solution
(e.g., spreadsheet, database)

- Development Scope
  - Single study

- Data Storage Format
  - Database structure and fields reflect the content of the study

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Traditional ‘Content’ Oriented Approach

- Costs, Inefficiencies, and Limitations:
  - Redundant development costs
  - Learning curve re-encountered with each study
  - Little or no coordination, standardization, or interoperability between databases
  - Re-engineering costs
  - Complicated, time consuming data analytical process
  - Substantial amount of researcher’s time spent focused on data management issues
  - Poor incentive to develop reusable data management methods
Traditional ‘Content’ Oriented Approach
What is being done about these problems?
Themes of Restructuring Effort

- **Coordination**
  - Coordinate clinical trials research through data sharing and providing incentives for collaboration

- **Prioritization/Scientific Quality**
  - Involve all stakeholders in design and prioritization of clinical trials that address the most important questions, using the tools of modern cancer biology

- **Standardization**
  - Standardize IT infrastructure and clinical research tools

- **Operational Efficiency**
  - Use resources most efficiently through improved cost-effectiveness and accrual rates, and more rapid trial initiation

- **Integrated Management**
  - Restructure extramural and intramural oversight of NCI clinical trials
The cancer Biomedical Informatics Grid (caBIG) is a voluntary network or grid connecting individuals and institutions to enable the sharing of data and tools, creating a World Wide Web of cancer research.
Scope of caBIG

- **Workspaces**
  - **Clinical Trial Management Systems**
    - **Purpose**: Deploy and develop caBIG™ compliant tools to support data capture/analysis and management of clinical trials.
  - **Integrative Cancer Research**
    - **Purpose**: Assemble data, tools, and infrastructure that facilitate the cross silo use of cancer biology information.
  - **Tissue Banks and Pathology Tools**
    - **Purpose**: Develop a set of tools to inventory, track, mine, and visualize tissue samples and related information.
  - **Vocabularies and Common Data Elements**
    - **Purpose**: Create and maintain software systems for content development and content delivery; provide assessment of, and recommendations on vocabularies and common data elements.
Clinical Trial Management Systems Workspace

- **Standardization and Infrastructure Subcommittee**
  - Improve efficiency, reduce duplication of effort, and achieve cost savings
  - Facilitate innovation and promote integration across trials
  - Facilitate data interpretation and data comparison across trials
  - Allow for closer integration of biological measurements and clinical trial findings
Clinical Trial Management Systems Workspace

- Standardization and Infrastructure Subcommittee
  - Establish standards for the essential data to be collected in clinical trials and the format in which it is collected
    - Define core data elements
    - Define standardized Case Report Forms
    - Develop the caBIG standard infrastructure necessary to support clinical trials and interface caBIG with other databases utilizing standard elements
How to do research better?

Pick Your Lens?

Methodological Answer

- **Subjects**
  - Participation
- **Study Coordinator**
  - Study execution
- **Administrative Staff**
  - Oversight and security
- **Technical Staff**
  - System integration & data standards
- **Biostatisticians**
  - Transformation of data into information

Applied Answer

**Investigators**
- Traditionally left out
How to do research better?

Academic Research: Investigator Endpoints

- Grant
- Article
- Presentation
- Poster
- Practice Improvement

Pick Your Lens?

Direct impact on investigator time
Taking the next step: Software Development

Example software tool for clinical research
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Human Computer-Interaction

- User-interface design principles*
  
  - Reduce the visual, intellectual, memory, and motor related work of the user
  
  - Emphasize consistency and WYSIWYN ("What You See Is What You Need")

Taking the next step: Software Development