

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?

What is the Problem?

“...the bioinformatics equivalent of neighboring but isolated medieval nation states, each with different systems of weights and measures.”

Stein, L. (2002). Creating a bioinformatics nation. *Nature*, 417, 119-120.

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)

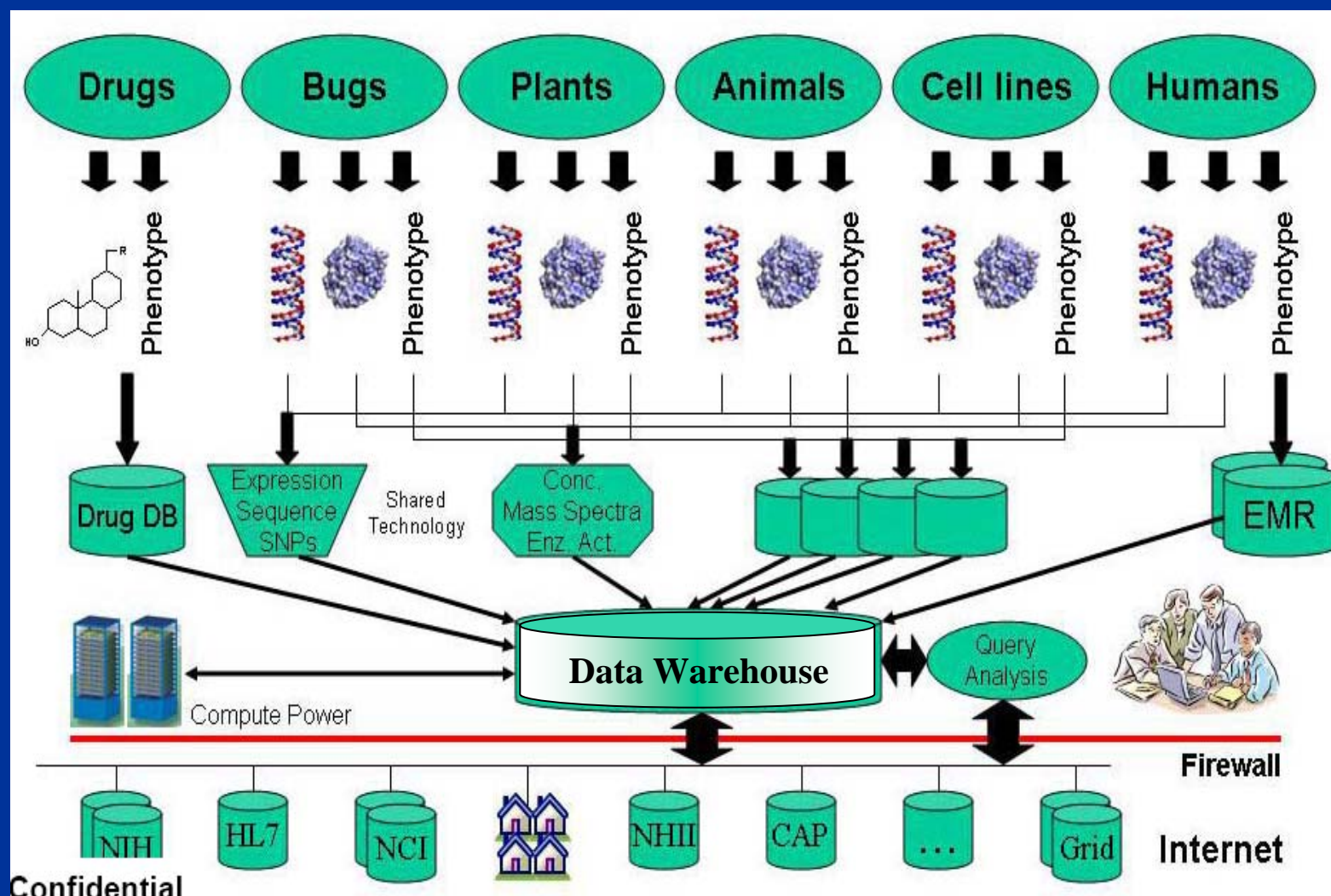
- Development Scope
 - Single study
- Data Storage Format
 - Database structure and fields reflect the content of the study

Entity	Weight	Height	Sex
1	150	62	F
2	210	72	M

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



Taking the next step

What is being done about
these problems?

National Cancer Institute (NCI)

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

National Cancer Institute (NCI)

caBIG

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.

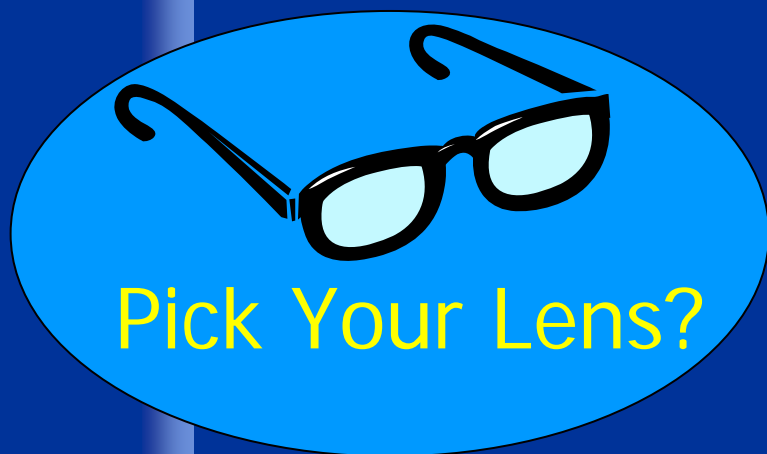
Clinical Trial Management Systems Workspace

- **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?



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?



Direct impact on
investigator time

Academic Research: Investigator Endpoints

- Grant
- Article
- Presentation
- Poster
- Practice Improvement

Taking the next step: Software Development

Example software tool for
clinical research

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Large-scale Software Development for Research

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")

*Galitz WO. The essential guide to user interface design: An introduction to GUI design principles and techniques. 2nd ed. New York, NY: John Wiley & Sons, Inc., 2002

Taking the next step: Software Development

