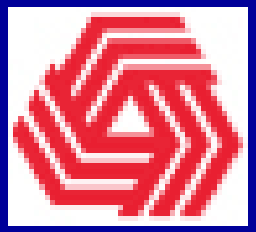


Research data and information: Perspectives from NIH

Elliot Siegel, PhD, National Library of Medicine
Greg Farber, PhD, National Center for Research Resources

National Academies Board on Research Data and Information
January 29, 2009, Washington, DC

National Library of Medicine

More than a Library

www.nlm.nih.gov

- World's largest medical library (>8 million artifacts)
- Intramural research laboratories
  - Lister Hill Nat'l Center for Biomed. Comms.
  - National Center for Biotechnology Information
- Extramural research and training
- Information services for various audiences
  - Medline – citations to published literature
  - PubMed Central – full text journal articles
  - MedlinePlus – consumer-oriented information
  - Special Populations - Arctic Health, Native American, Asian American, Seniors
  - Genbank – gene sequences
  - Genetics Home Reference
  - dbGaP – genome wide associations
  - PubChem – small molecules database
  - Hazardous Substances Database
  - ToxTown - for school children
  - ClinicalTrials.gov

NLM Long Range Plan 2006-2016: Overall Goals

1. Seamless, uninterupted access to expanding collections of biomedical data, medical knowledge, and health information
2. Trusted information services that promote health literacy and the reduction of health disparities worldwide
3. Integrated biomedical, clinical, and public health information systems that promote scientific discovery and speed the translation of research into practice
4. Strong and diverse workforce for biomedical informatics research, systems development, and innovative service delivery

National Center for Research Resources (NCRR)

Accelerating research from basic discovery to improved patient care

Community engagement

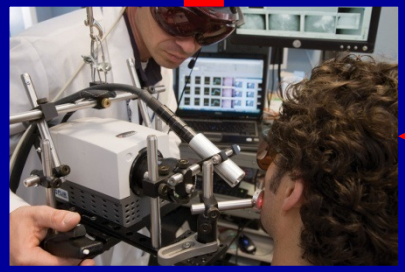
Animal model resources

Community

Improved patient care

Pre-clinical

Clinical research support



Clinical

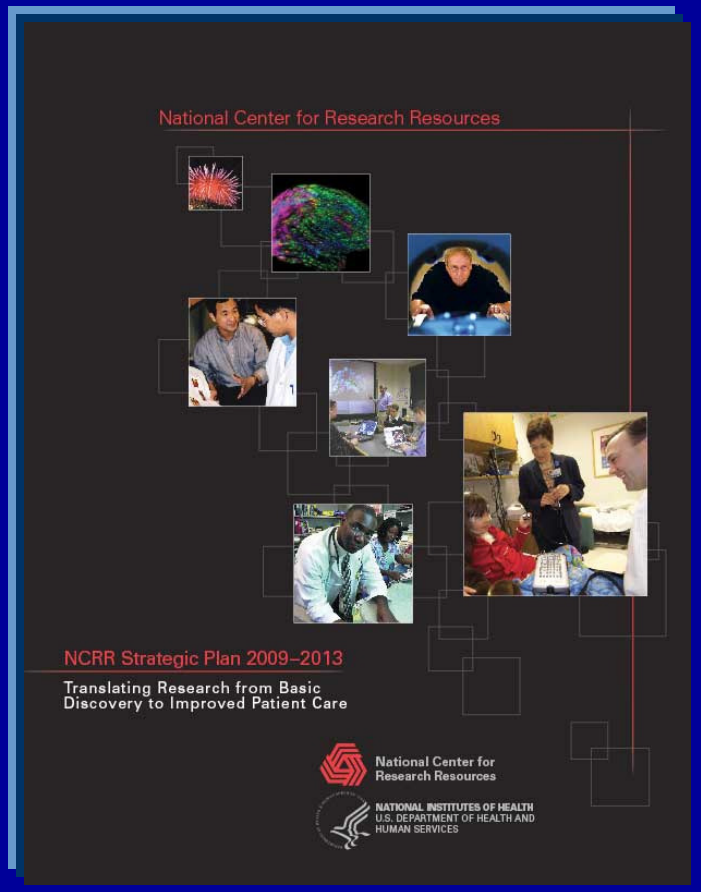
Technology & informatics advances

NCRR Strategic Plan: 2009- 2013

Translating Research from Basic Discovery to Improved Patient Care

Strategic Themes

- Build capacity
- Advance research through animal models
- Foster research through technologies
- Develop informatics approaches to support research
- Strengthen the research workforce
- Maximize partnerships



NIH efforts to promoting data sharing and access

- NIH Data Sharing Policy
  - Funded researchers who receive >USD 500,000 from NIH in a single year
  - Expected to include with their grant proposal a plan for making research data available to other researchers, or explain why not possible.
- NIH Public Access Policy
  - Applies to all NIH-funded investigators and NIH researchers
  - Required to submit peer reviewed manuscripts to PubMed Central upon acceptance for publication
  - Up to 12-month delay before manuscript is publicly available
- NIH Genome Wide Association Study (GWAS) Policy
  - Applies to funded investigators for GWAS
  - Submit de-identified genotypic and phenotypic data to NLM Database of Genotype and Phenotype (dbGaP).
  - Other investigators may request access to GWAS data sets for research purposes.
- Clinical Trials Registration and Results Reporting
  - FDA Amendments Act requires registration of applicable clinical trials of drugs, biological products, and devices, regardless of funding source
  - Reporting of results required for products that have been approved/cleared by FDA.
  - Penalties for noncompliance (withhold grant funds, monetary fines)

Interesting aspects of biomedical data/information

- Volume and complexity of biomedical information increasing rapidly
  - Explosion of genomic and proteomic information, in addition to other scientific information (e.g., biology, chemistry)
  - Collection of clinical information augmented by Electronic Patient Records and growing body of Clinical Trials
  - Information collected and used in context of care as well as research
    - Genomic information gathered during genetic tests, clinical trials – personalized medicine
    - Clinical information collected in clinical trials and care settings, used for treatment decisions, comparative effectiveness studies, etc.
  - Increased combination of clinical and scientific data/information in research
    - Genome-Wide Association Studies (GWAS) that associate genotypes with phenotypes
- Biomedical data/information accessed by wide range of users
  - Not just scientists and researchers, but also clinicians, patients and families, public health officials
  - Information contributes to decision-making, as well as research
  - Heightened need for trustworthy information in form tailored to different consumers
- Privacy & identifiability
  - Strong concerns about protecting privacy, esp. of clinical and genomic info
  - Biomedical data pushes the frontier on identifiability (e.g., genomic information)

Some Topics/Issues of Interest to NIH

- How to recognize and reward data sharing by researchers
  - Consideration in promotion and tenure decisions
  - Recognition by peers, funding agencies
  - E.g., metric to measure citations of electronically published data that could be used by tenure committees
- How to embed informatics/data sharing in training programs for scientists/ researchers
  - Current approach ad hoc, based on apprenticeship
  - Inclusion in training/education of principles of data collection, data curation, and sharing
  - Roles of institutional libraries and individual labs, departments
- Development of a research agenda for management of scientific data and information
  - Take advantage of ongoing trends in information and communications technology
  - Identify research areas in which investments by agencies such as NIH, NSF improve scientific data/info management
- Promotion of effective approaches for data sharing
  - Development of agency and institutional policies, scientific community practices
  - Strategies and good practices for encouraging data sharing among researchers
  - Identification of necessary resources and infrastructure (e.g., centralized repositories, distributed databases, registries, standards)

More information on data/ information sharing at NIH

NIH Data Sharing Policy
http://grants.nih.gov/grants/policy/data_sharing/

NIH Public Access Policy
http://publicaccess.nih.gov/

NIH GWAS Policy
http://grants.nih.gov/grants/gwas/

ClinicalTrials.gov
http://www.clinicaltrials.gov

National Library of Medicine
http://www.nlm.nih.gov

National Center for Research Resources
http://www.ncrr.nih.gov