Why a Roadmap?

• Acceleration in the pace of discoveries in the life sciences:
  – A national priority
  – A race against time

• More rapid translational processes.

• Urgent need for novel approaches:
  – Orders of magnitude more effective than current approaches, e.g., molecular prevention and behavioral modification research
The NIH Roadmap

• Broad consultation involving extramural scientists, NIH IC Directors, NIH program and intramural staff.

• In a series of meetings, including the NIH IC Director Leadership Forum, participants were asked:
  - Where do we need to go?
  - What are the scientific challenges?
  - What are the roadblocks to progress?
  - What can’t be accomplished by any single Institute, but is a responsibility of NIH as a whole?
The NIH Roadmap: Three Themes

- New Pathways to Discovery
- Multidisciplinary Research Teams of the Future
- Re-engineering the Clinical Research Enterprise
Re-engineering the Clinical Research Enterprise

• **1-3 years**
  - Plan and start demonstration networks
  - Simplify complex regulatory systems – demonstration projects
  - Standardize nomenclature, data standards, core data, forms for most major diseases
  - Inventory and evaluate existing public-private partnerships, networks, CR institutions, and regulatory systems
  - Streamline, harmonize, and establish standards w/OHRP, FDA, NIH
    - adverse event reporting
    - human subjects protection
    - GCRC- IRBs
  - Establish NIH criteria for minimum standards of consistent phenotypic and historic data required of all patients participating in NIH-funded studies

• **4-7 years**
  - Data standards shared across NIH institutes and with the extramural community
  - Public private partnership mechanisms in place
  - Funding mechanism to sustain national system through consensus of all constituents
  - Simplified regulatory system in place for networks
Clinical Research Roadmap: Three Themes

- Facilitating patient-oriented and translational research, research innovations, and infrastructure/resources.
- Developing large-scale interoperable clinical research/clinical trial networks for epidemiology, clinical trials, natural history, and behavioral and outcomes research.
- Enhancing training and career pathways for the clinical research workforce.
• The NIH clinical research informatics initiative objectives:
  – Develop/reiterate data standards
    • Clinical care records
    • Administrative/regulatory information
  – Implement software solutions for information exchange within/between agencies – between extramural organizations and NIH
  – Streamline interagency coordination and data sharing
  – Develop networks to share common data
  – Develop ways to conduct outreach/education of clinical research investigators and administrators
Steering Committee on Clinical Research Informatics (SCCRI)

- **Working groups**
  - Focus on informatics objectives
  - Develop goals/outputs
  - Establish broad membership

- **Consultation process**
  - Outside experts on workgroups
  - Briefings on relevant initiatives
  - Summit Meeting
SCCRI Working Groups

- Data Standards and Core Elements
- Toolbox: Smart Tools and Applications
- Model Systems and Practices
- Inter-Agency Coordination
Data Standards and Core Elements

- Identify and analyze:
  - existing health data standards
    - clinical care records
    - administrative information
  - any significant gaps in current standards development activities

- Recommend NIH actions that will:
  - promote immediate testing, use, and refinement of existing standards applicable to clinical research
  - increase participation in standards development activities to ensure needs of the clinical research community are met
Clinical Research Toolbox: Smart Tools and Applications

- Identify existing useful informatics tools and software applications that enhance the design, conduct, development, and analysis of clinical trials
- Determine what (if any) additional tools and applications are needed
Model Systems and Practices

- Analyze promising models/systems
  - Identify features of success, best practices, lessons learned

- Conduct needs assessment, gap analysis for achieving a national “network of networks” for clinical research

- Envision new models
  - may rely in part on existing systems
Inter-agency Coordination

- **Identify**
  - common business processes for coordination
  - common information requirements
  - extent of implementation efforts ongoing
  - means to ensure streamlined administration

- **Recommend NIH actions that will:**
  - promote coordination with other agencies to identify common standards and approaches
  - participate in development, testing, use, and refinement of shared tools
Roadmap Pilot Projects

- NIH internal funding of pilot projects to:
  - jumpstart roadmap efforts
  - expand ongoing roadmap relevant projects
  - support collaborative efforts
    - within NIH
    - between NIH and extramural community
    - between NIH and other agencies