

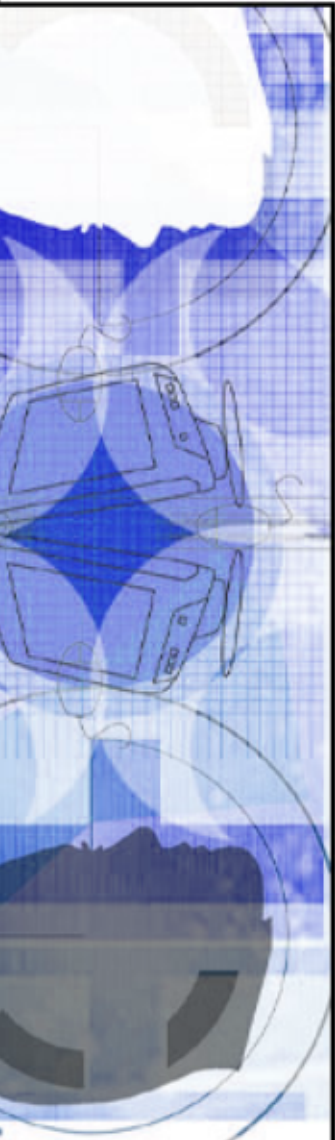


# The NIH Roadmap



Modified version of slides provided by Amy Patterson, NIH OD

# 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



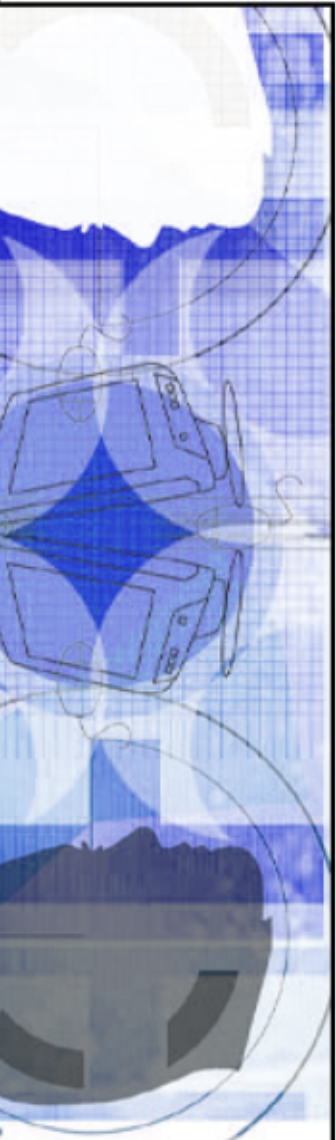
- **Broad consultation involving extramural scientists, NIH IC Directors, NIH program and intramural staff.**
- **In a series of meetings, including the NIH IC Director Leadership Forum, participants were asked:**
  - **Where do we need to go?**
  - **What are the scientific challenges?**
  - **What 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

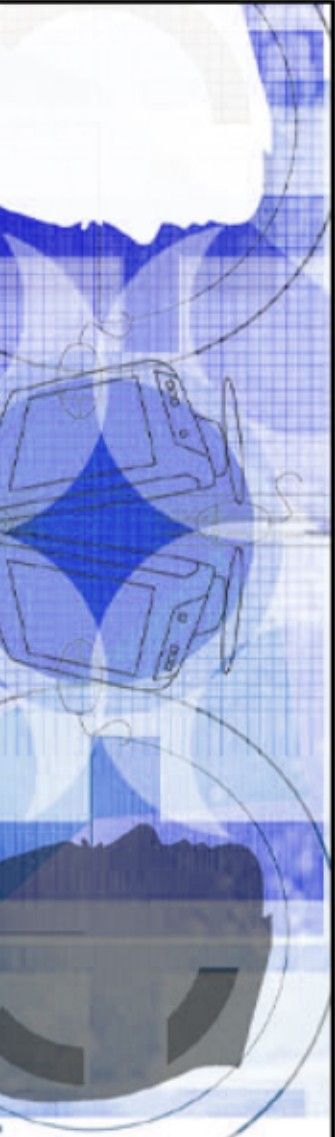


- **Facilitating patient-oriented and translational research, research innovations, and infrastructure/resources.**
- **Developing large-scale interoperable clinical research/clinical trial networks for epidemiology, clinical trials, natural history, and behavioral and outcomes research.**
- **Enhancing training and career pathways for the clinical research workforce.**

# Informatics – Critical for Success

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- **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**

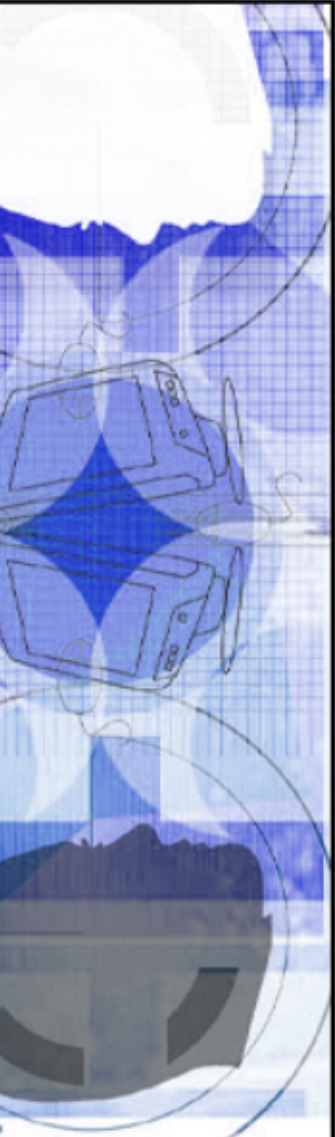


# SCCRI Working Groups

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



# Data Standards and Core Elements

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- **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



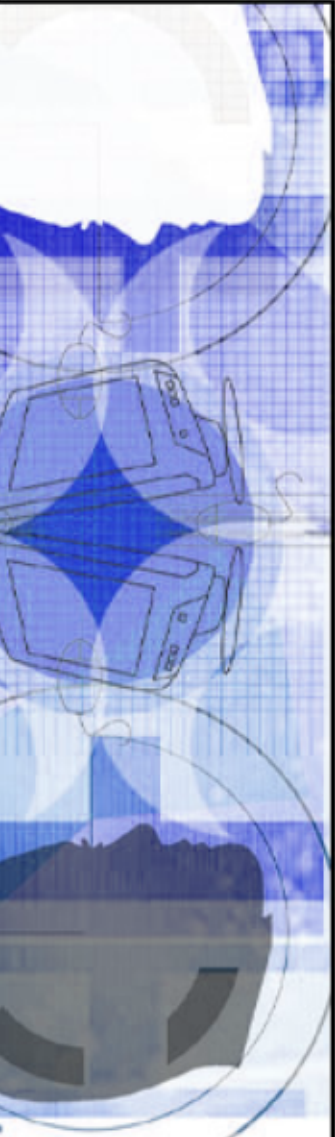
- **Identify existing useful informatics tools and software applications that enhance the design, conduct, development, and analysis of clinical trials**
- **Determine what (if any) additional tools and applications are needed**

# Model Systems and Practices

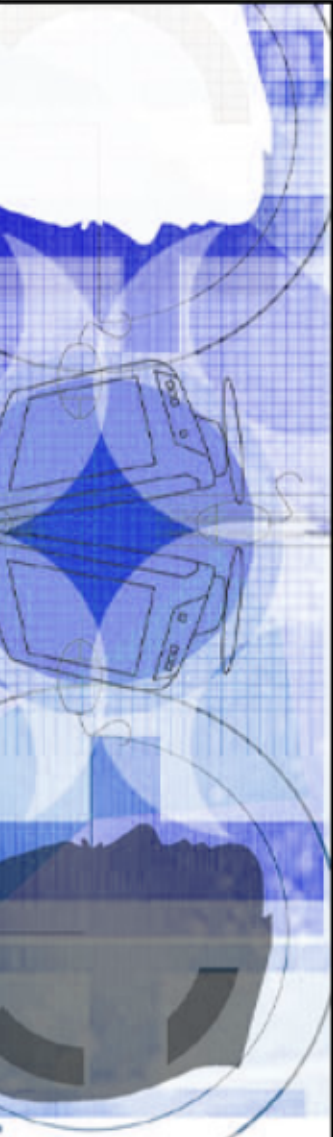


- **Analyze promising models/systems**
  - **Identify features of success, best practices, lessons learned**
- **Conduct needs assessment, gap analysis for achieving a national “network of networks” for clinical research**
- **Envision new models**
  - **may rely in part on existing systems**

# Inter-agency Coordination

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- **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

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- **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**