The NIH Roadmap

From clinical trials to community:
Jan 13 – Relationship to the Roadmap
Dr. Raynard Kington, Deputy Director
NIH

The Problem

Bench ⟷ **Bedside** ⟷ **Practice - {Includes the community}**

Translational Research is not new to NIH

- During the 1980's NIH including NCI and NHLBI suggest a sequence of research
  - Hypothesis generation to intervention methods development
  - Controlled intervention trials [RCT's]
  - Studies in defined populations
  - Demonstration research

Why a Roadmap?

- Accelerated pace of discoveries in the life sciences
- Need for their more rapid translation into practice
- Opportunities to build an integrated system that is far more effective than current approaches

Roadmap Chronology

August 2002	**Consultation with over 100 thought leaders**
September 2002	**IC Directors' Leadership Forum**
March 2003	**Formation of 15 Working Groups including over 300 outside experts**
April 2003	**Presentation to Council of Public Representatives (COPR)**
May 2003	**Working Groups propose initiatives**
June 2003	**IC Directors commit to initiatives**
June 2003	**Presentation to the Advisory Committee to the Director (ACD)**
September 2003	**Presentation to advocacy groups, press**
FY 2004-2013	**Staged implementation**

Criteria for Roadmap Initiatives

- Is it 'transforming' -- will it change how or what biomedical research is conducted in the next decades?
- Would its outcome enhance the ability of all ICs to achieve their own missions?
- Can the NIH afford to NOT attempt it?
- Will it be compelling to our stakeholders, especially the public?
- Is it something that no other entity can or will do?

Roadmap Implementation

- All Institutes and Centers committed to invest jointly in a pool of resources to support current and future Roadmap initiatives
- $128 M in FY 2004
- Over $2 B by FY 2009

Many of the initiatives are ***difficult*** – some may fail!

Three *Core* Themes

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

New Pathways to Discovery

Bench ⇔ **Bedside** ⇔ **Practice**

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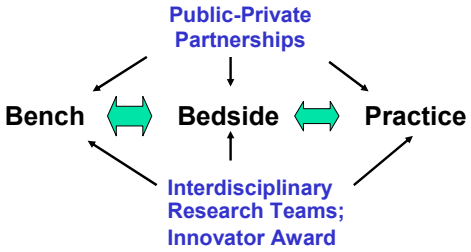
Building Blocks and Pathways
Molecular Libraries
Bioinformatics
Computational Biology
Nanomedicine

Research Teams of the Future



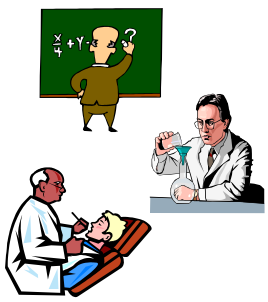
Research Teams of the Future

Scale and complexity of current science require novel team approaches

- Interdisciplinary Research Teams
- Public-Private Partnerships
- NIH Director's Innovator Award

Challenges to Interdisciplinary Research

- The current system of academic advancement favors the independent investigator
- Most institutions house scientists in discrete departments
- Interdisciplinary research teams take time to assemble and require unique resources



NIH Director's Innovator Award

- New program to support individuals with untested ideas that are potentially groundbreaking
- Encourages innovation, risk-taking
- Totally new application and peer review process
- Provides $500 K/year for 5 years
- Expected to be highly competitive

Translational Research

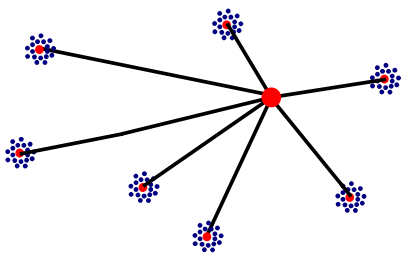
- Enhanced Translational Research Centers

Enabling technologies for improved assessment of clinical outcomes

Focuses on quality of life measures discussed at the conference

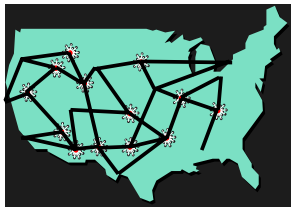
Typical NIH Network

Academic Health Center Sites & Data Coordinating Center

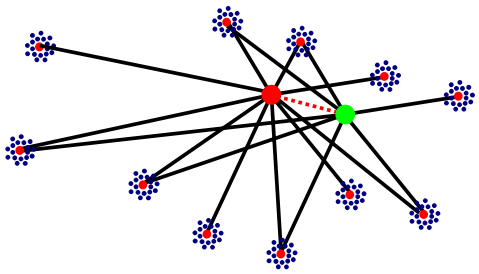


Integration of Clinical Research Networks

- Link existing networks so clinical studies and trials can be conducted more effectively
- Ensure that patients, physicians, and scientists form true "Communities of Research"
- **Includes translational research topics.**



Interoperable Networks Share Sites and Data



Integration of Clinical Research Networks

- Create interoperable 'Network of Networks'
  - National Electronic Clinical Trials/Research Network **(NECTAR)**
  - Common data standards, informatics
  - Software application tools for protocol preparation, IRB management, adverse event reports
- Use existing networks to rapidly address questions beyond their traditional scope

National Clinical Research Associates

Goal:

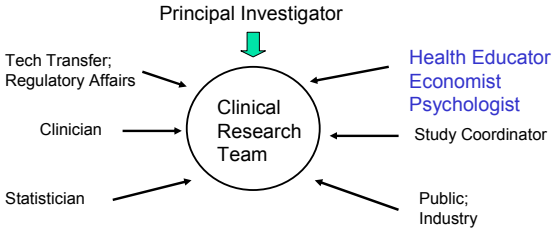
- Diverse national group of trained and certified community health care providers
- Will enroll and follow their own patients
- Accelerate translation of results into practice

Steps:

- **Determine feasibility:** Barriers? Communities? Incentives needed?
- Inventory training methods, best practices
- Develop core competencies, certification

Multidisciplinary Clinical Research Team

Members have unique skills and career paths



Question: How to make each path viable?

Trans-NIH Multidisciplinary K12 Career Development Program (RFA)

Goal:

- Promote development of investigators from a variety of disciplines (MD, PhD, RN, MPH, DC …)
- To be trained in multidisciplinary team settings

Features:

- Up to 5 years of training
- Core didactic courses, project-specific training
- Mentored research experience in team settings
- Faculty and mentor support to protect their time
- Tuition support
- Annual meetings
- Translational studies possible

Harmonization of Clinical Research Regulatory Processes

Goal: Harmonize and simplify requirements for clinical research in ways that enhance public trust

- Adverse event reporting
- Human subjects protection
  - DSMB-IRB interactions
  - Consent procedures
- Auditing and monitoring clinical trials
- HIPAA, privacy, conflict of interest policies
- Investigator registration, financial disclosure
- Standards for electronic data submission/reporting

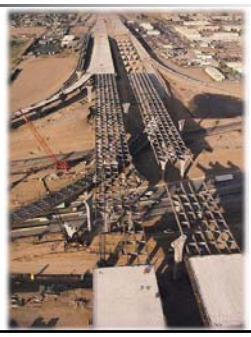
Consultation

- Participation, consultation, collaboration, and funding are needed from patients, health care providers, foundations, industry, academia, Federal partners …*all stakeholders* … to build vibrant communities of clinical research
- nihroadmap.nih.gov

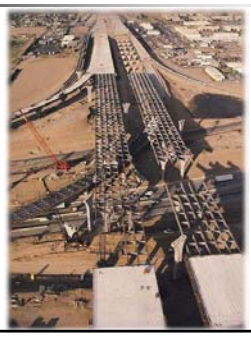
Roadmap and Translational Research

- One of the key goals of the Roadmap is to strengthen all types of clinical research
- Translational research includes from the bedside to practice and the community
- Strengthening the infrastructure of the clinicial networks should provide greater capability for translational research

The Roadmap:
A Work in Progress



The Roadmap:
Questions or comments?






NIH

Ideas
People
Resources