

NIH



Re-engineering Clinical Research: Mapping the Road from Bench to Bedside

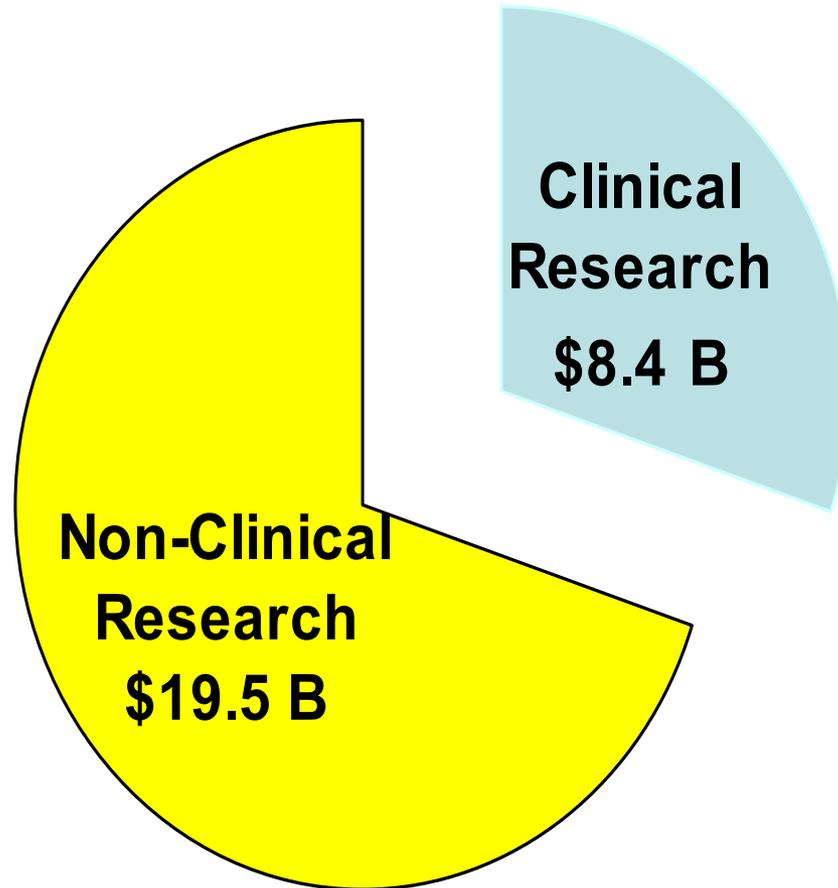
**Testimony of Elias Zerhouni, M.D.
Director, National Institutes of Health**

**Hearing Before the Subcommittee on Health
Committee on Energy and Commerce
March 25, 2004**

Clinical Research is the Key to Translating Discovery into Practice



FY 2004 NIH Budget



Evolving Public Health Challenges Require New Strategies of Research



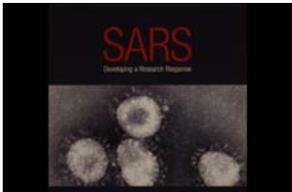
Acute to chronic conditions



Aging Population



Health Disparities

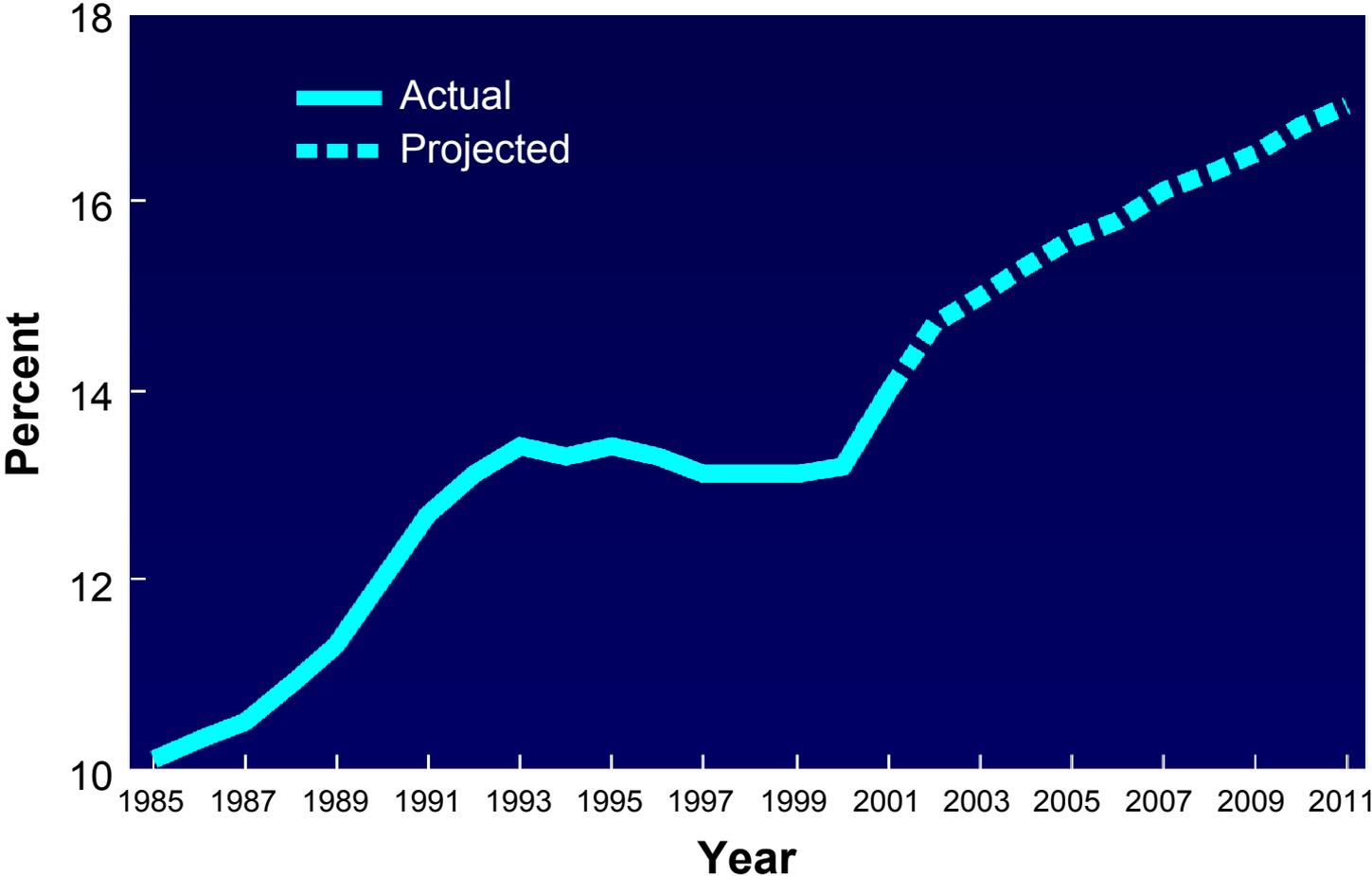


Emerging Diseases



Biodefense

U.S. Health Expenditures (Percentage of GDP)



NEED TO TRANSFORM MEDICAL RESEARCH IN THE 21st CENTURY

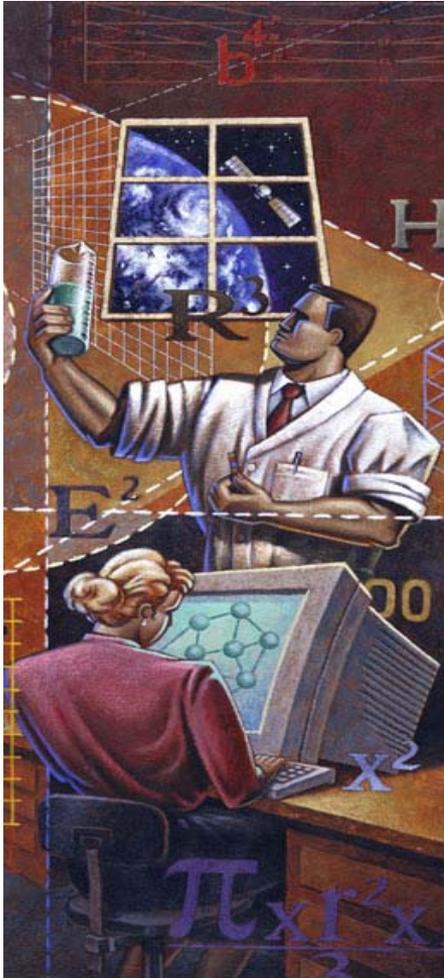
• 20th Century

- Treat disease when symptoms appear and normal function has been lost
- WHY: we did not understand the molecular and cellular events leading to disease
- Expensive in financial and disability costs

• 21st Century

- Intervene before symptoms appear and preserve normal function for as long as possible
- WHY: Better methods and understanding of disease process. Ability to detect patients at risk.
- Orders of magnitude more effective

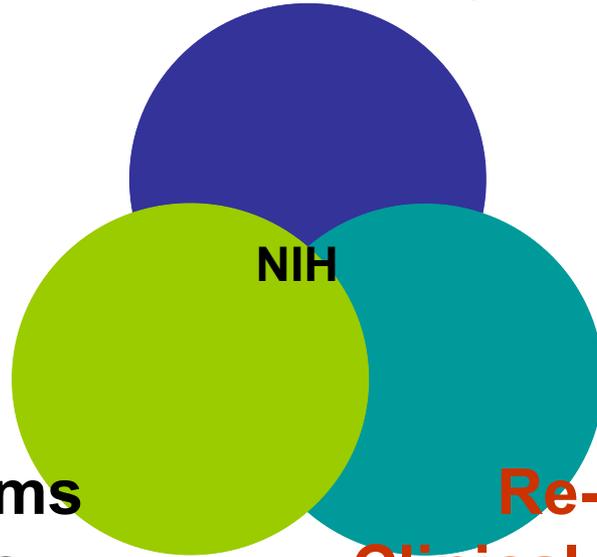
NIH Roadmap Goal



- Accelerate basic research discoveries and speed translation of those discoveries into clinical practice
- Explicitly address roadblocks that slow the pace of medical research in improving the health of the American people

Clinical Research is Key Component of the NIH Roadmap for Medical Research

**New Pathways
to Discovery**

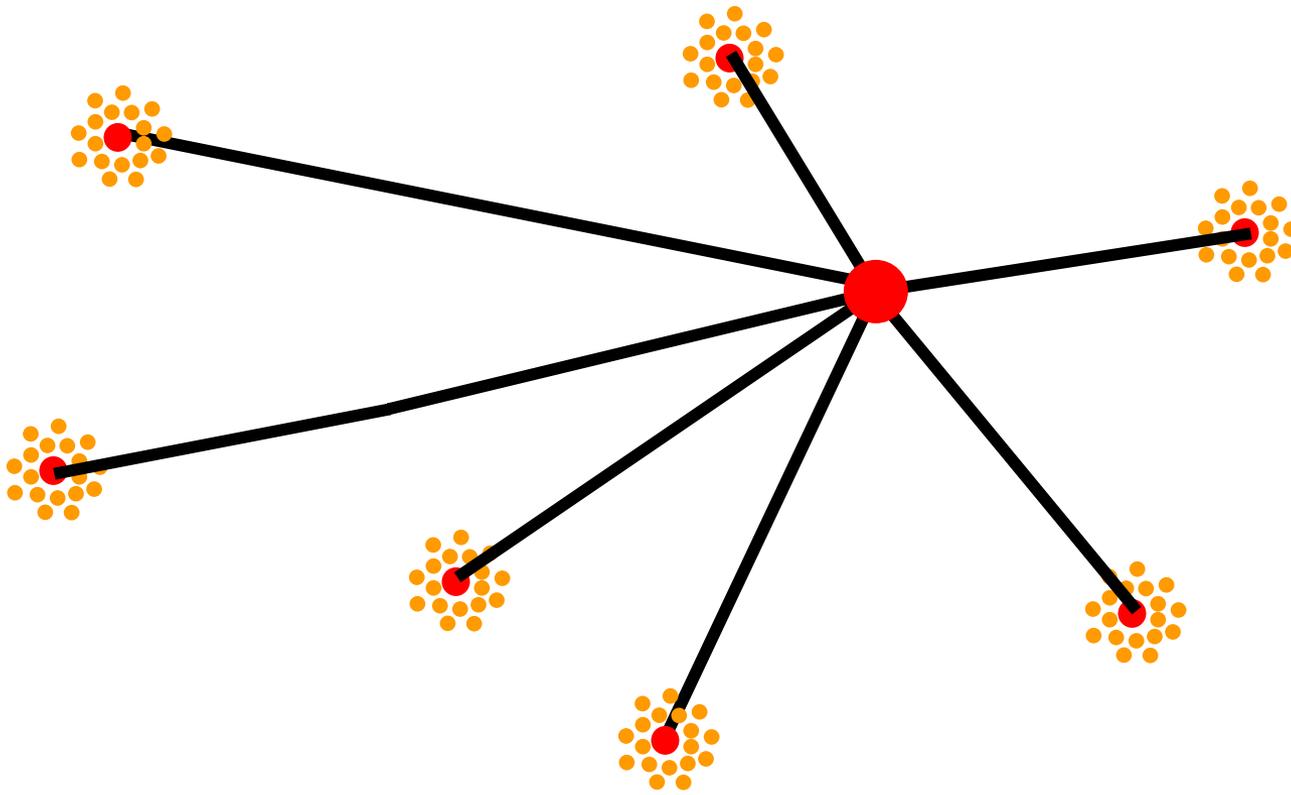


**Research Teams
of the Future**

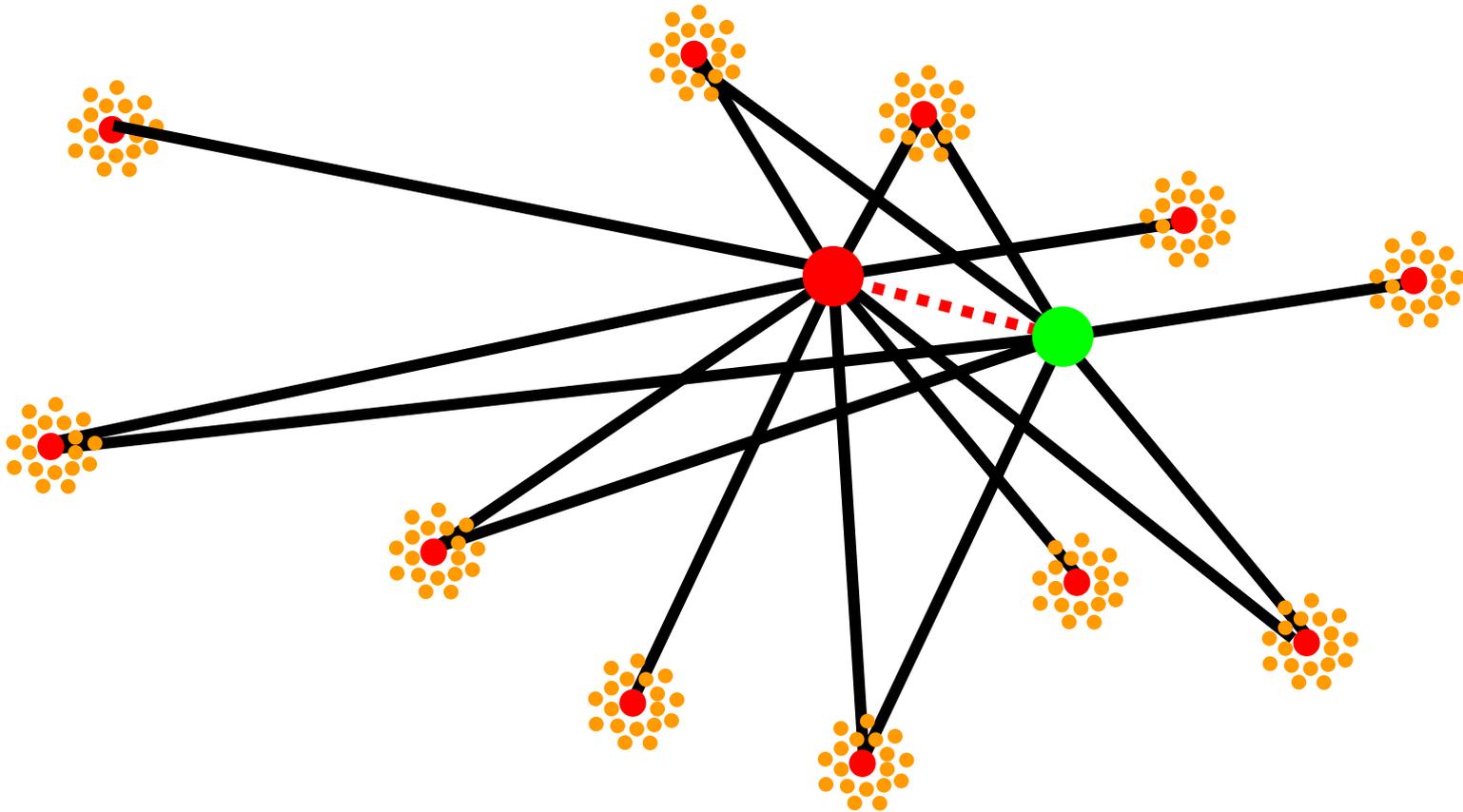
**Re-engineering the
Clinical Research Enterprise**

Typical NIH Network

Academic Health Center Sites and Data Coordinating Center



Interoperable Networks Share Sites and Data



Integration of Clinical Research Networks

- Create inter-operable '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 healthcare providers linked to regional academic centers
- Will enroll and follow their own patients
- Accelerate translation of results into practice
- Access to NIH-NECTAR information system at practice site

Steps:

- **Determine feasibility:** Inventory training methods, best practices
- Develop core competencies, certification

Clinical Research: Navigating the Roadway

- Clinical research impeded by duplicative federal requirements
 - Variability among and within agencies
 - Creates uncertainty about how to comply
 - Hampers safety and effectiveness



Engaging the Public in Clinical Research

**Engaging the public in clinical
research is a priority.**



Engaging the Public in Clinical Research

- **Priorities**

- Building trust and enhance needed partnership between patients and researchers
- On-going communication between research community & public
- Education and provide research access to patients in all communities

- **Benefits**

- Aid the translation of research findings into practice
- Accelerate the clinical research process
- Increase the efficiency of the research process
- Necessary to study chronic diseases and their prevention in their community context

Dynamic Assessment of Patient-Reported Chronic Disease Outcomes

- **Background:**

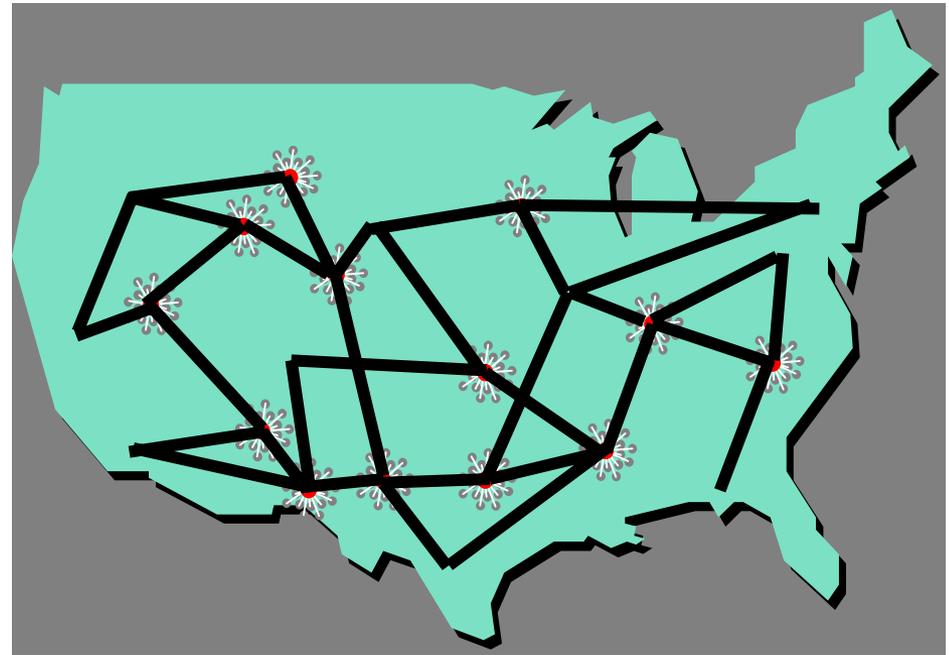
- Assessment of chronic diseases relies heavily on subjective reports of symptoms and health related quality of life items

PROMIS – Patient-Reported Outcomes Measurement Information System:

- A collaborative network of investigators charged to develop and implement a publicly available system of a large item bank and a Computerized Adaptive Tests for more sensitive and efficient testing of major chronic disease symptoms and functioning.

Integration of Clinical Research Networks and enhance Community based research

- Link existing networks so clinical studies and trials can be conducted more effectively
- Ensure that patients, physicians and scientists form true “Communities of Research”





NIH



Ideas
People
Resources
Leadership

