# NIH and the Clinical Research Enterprise

Third Annual
Medical Research Summit
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**NATIONAL INSTITUTES OF HEALTH**

**Total**

**Clinical Research - Extramural and Intramural**

**(dollars in millions)**

| | 1997 Actual | 1998 Actual | 1999 Actual | 2000 Actual | 2001 Actual | 2002 Estimate | 2003 Estimate |
|---|---|---|---|---|---|---|---|
| Extramural | $3,508.4 | $3,769.4 | $4,260.1 | $4,984.5 | $5,619.6 | $6,320.4 | $7,039.8 |
| Intramural | 490.4 | 552.0 | 660.4 | 732.8 | 813.6 | 915.3 | 997.5 |
| Total | 3,998.8 | 4,321.4 | 4,920.5 | 5,717.3 | 6,433.3 | 7,235.7 | 8,037.3 |

* May not add due to rounding

# The Current Research Challenges

- Acceleration in the pace of discoveries in the life sciences.
- Need for rapid translational processes.
- Urgent need for novel approaches:
  - Orders of magnitude more effective than current approaches

# Why a NIH Roadmap Initiative

Identify overarching areas of scientific opportunity that can't be addressed by any single NIH Institute, but are a responsibility of NIH as a whole.

# The NIH Roadmap
# Initial Meetings

- Participants were asked:
  - What are today's scientific challenges?
  - What are the roadblocks to progress?
  - What do we need to do to overcome roadblocks?
  - What can't be accomplished by any single Institute – but is the responsibility of NIH as a whole?

# NIH Roadmap: three themes emerged

- New Pathways to Discovery
  - Approaches
    - A comprehensive set of building blocks for biology
    - Biological pathways and networks
    - Regenerative medicine
  - Technologies
    - Structural biology
    - Bioinformatics and computational biology
    - Molecular libraries
    - Nanotechnology
    - Molecular imaging
- Research Teams of the Future
  - Multidisciplinary teams
  - Private-public partnerships
  - High risk research
- Re-engineering the Clinical Research Enterprise

# Demands on Clinical Research

- Rate of growth of health care needs and expenditures requires accelerated discoveries and clinical validation.
- New clinical approaches will have to be an order of magnitude more efficient than current ones.
- Public support and participation are essential.

# Re-engineering the Clinical Research Enterprise Roadmap Meeting Jan 30-31, 2003

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

"Management is doing things right; Leadership is doing the right things."

*Peter Drucker*

NIH is seeking your best ideas about "doing the right things" to improve the nation's clinical research enterprise.

# Other Parts of the Clinical Research Roadmap

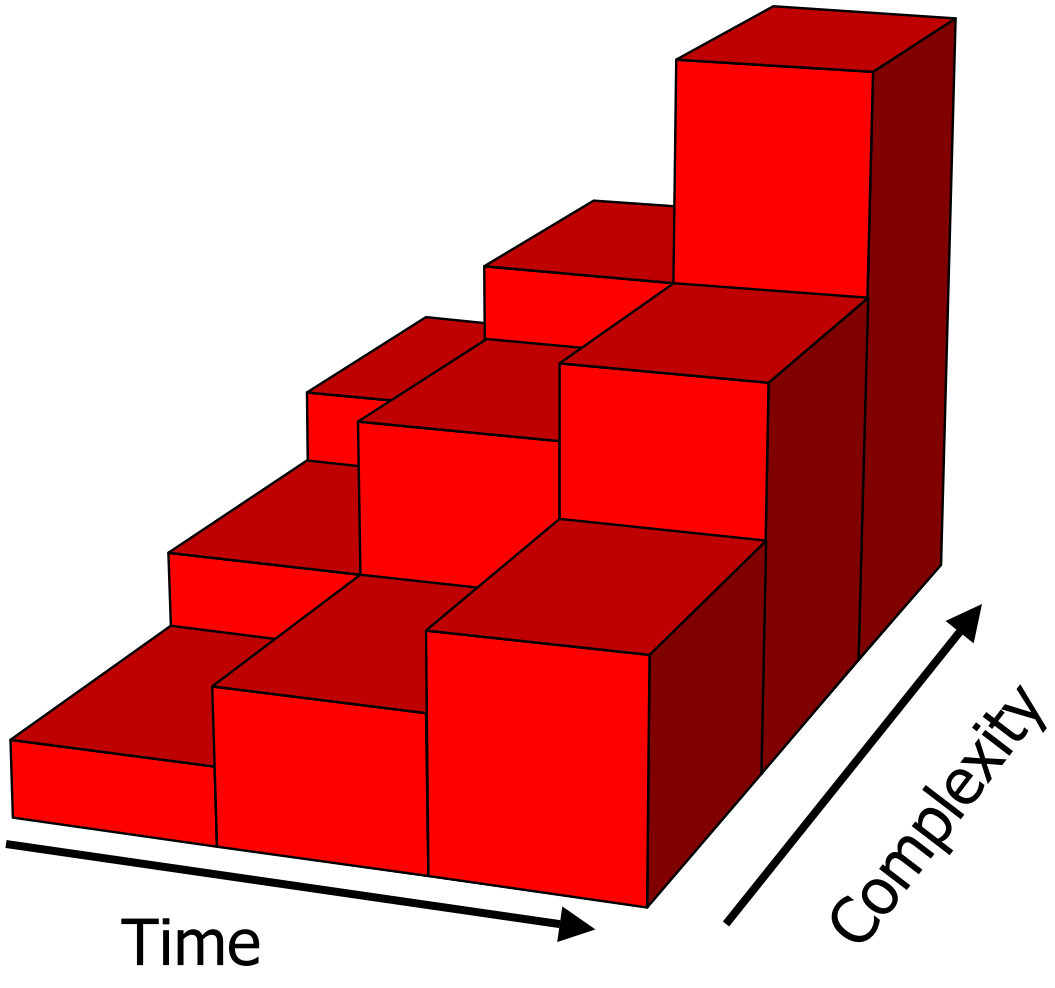
Public Trust

Patient safety, informed consent, patient recruitment, HIPAA

Clinical Research Informatics

Interoperable infrastructure, standards, and vocabularies, harmonized regulations

# Sequential action items reduce the activation energy of the ultimate goal



# Matrix Goals

- National, clinical research networks which develop research results, that can be rapidly disseminated into the community AND, in return, yield data on outcomes and quality of care; a sustained efficient infrastructure to rapidly initiate large clinical trials and to provide information to patients, families, advocacy groups.

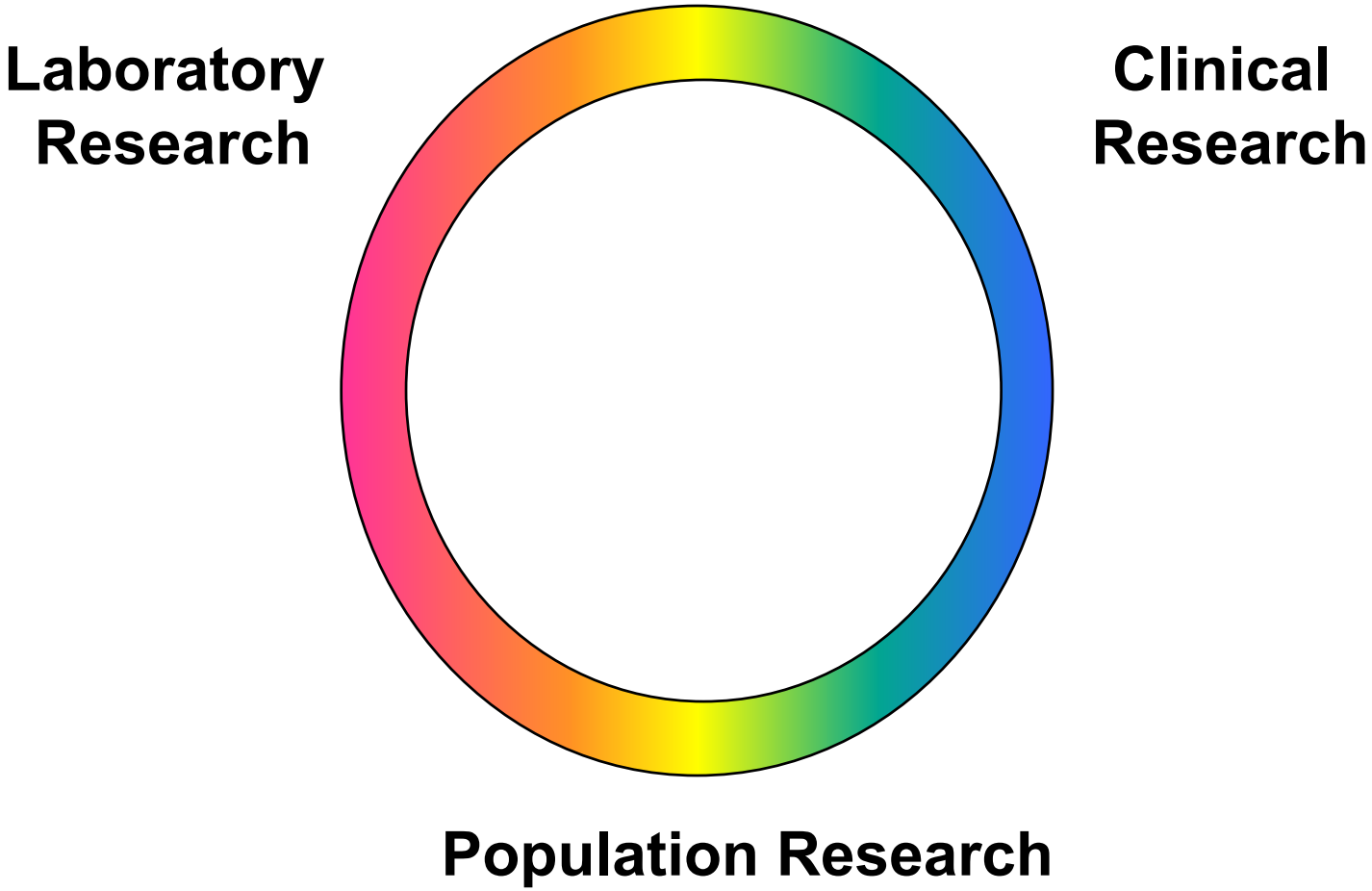
- A translational research infrastructure which facilitates the integrated, smooth, safe, and efficient transition from bench to bedside -- and back.

- An integrated, multidisciplinary, and diverse workforce that can meet current and future clinical research needs; a robust academic clinical research discipline.

# Converging Themes

- Harmonize complex regulatory systems
- Standardize nomenclature, data standards, core data
- Create interoperable networks with common infrastructure
- Create tissue/samples banks with related clinical data
- Create a National Clinical Research Corps
- Create a safe haven for clinical research data
- Inventory trial structures, identify best practices, and explore innovations in trial design
- Create clinical research infrastructure (incubator) cores
- Increase collaboration
- Change culture
- Improve review

# The Way it Should Work



# Mutual Obligations of Society, AHCs, and NIH

## NIH

- Continuously monitor scientific opportunity and public health need and recalibrate programs as warranted
- Obtain scientific community and public participation in the strategic planning of, conduct of, and evaluation of its science
- Actively disseminate new knowledge to end users – health care providers and the public

# In Sum

- Clinical Research has evolved haphazardly
  - Started as cottage industry and select centers
  - Now has more complex requirements: regulation, technology, speed, efficiency

- Need transformation to move into the 21st Century
  - Individual apprenticeship → discipline of clinical research
  - Uniform gauge → harmonize rules, build infrastructure and create networks
  - Focus on mentoring → multidisciplinary teams

- Working with the IC Directors to map out next steps