

# Medical Research Funding and Regulation

Third Annual  
Medical Research Summit  
March 6, 2003

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National Institutes of Health



**NATIONAL INSTITUTES OF HEALTH**

**Total**

**Clinical Research - Extramural and Intramural**

**(dollars in millions)**

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

\* May not add due to rounding

# Current Research Challenges

- Acceleration in the pace of discoveries in the life sciences
- Need for rapid translational processes
- Urgent need for novel approaches

# Clinical Research

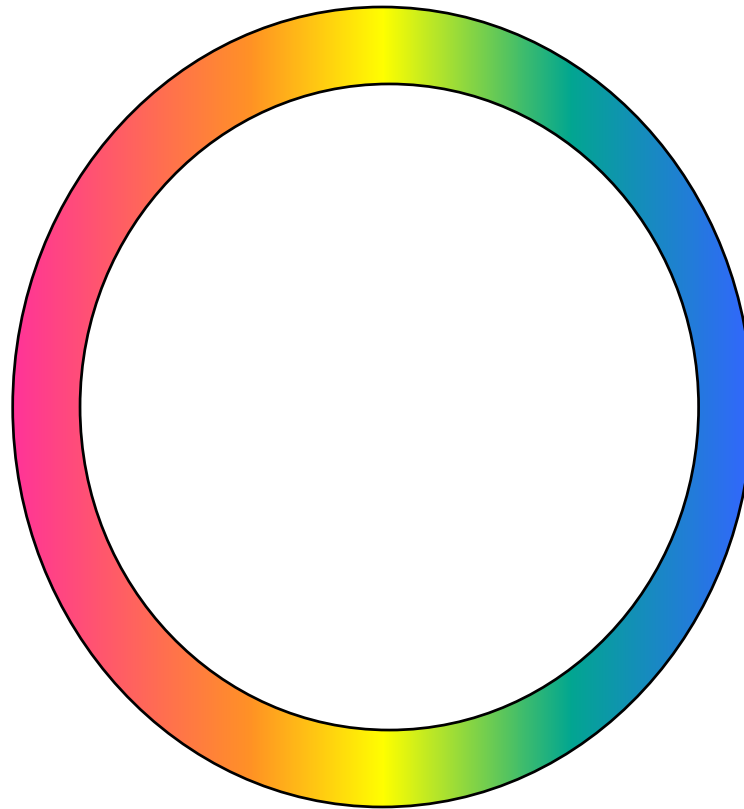
## The needs

- 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

# The Way it Should Work

**Laboratory  
Research**

**Clinical  
Research**



**Population Research**

# **The Clinical Research Enterprises Attributes of the System**

- Accountability
- Transparency
- Partnerships
- Integration
- Public trust

# **The Clinical Research Enterprise Opportunities and Challenges System-Wide**

- Patient safety
- Harmonization of reporting requirements
- Privacy and confidentiality
- Clinical research ethics education
- IRB functioning
- Public trust

# **The Clinical Research Enterprise Opportunities and Challenges Specific Initiatives**

- Human subjects enhancement RFA
- Clinical research ethics PA
- Increased participation of public representatives
- Clinical research re-engineering



# **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.

## Ultimate 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.