NIH Roadmap for Medical Research and Common Fund

> Update on Recent Changes

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### Roadmap/Common Fund: Trans-NIH Research Program

- NIH Roadmap for Medical Research initiated by NIH Director in 2003
  - To address fundamental knowledge gaps
  - > To develop transformative tools and technologies
  - > To foster innovative approaches to complex problems
  - To provide flexibility to respond to emerging challenges and new opportunities
- Supports programs for limited period of 5 10 years after which initiatives transfer to an IC or end

#### Roadmap/Common Fund Budget

- FY 2004 FY 2006: Roadmap Funded by a tap on NIH Institutes and Centers
  - FY 2004: \$128 M (.34% IC tap)
  - FY 2005: \$240 M (.63% IC tap)
  - FY 2006 \$329 M (.89% IC tap)
- FY 2007: Common Fund became line item in NIH budget
  - Fiscal Year 2007: \$483 M
  - Fiscal Year 2008: \$496 M
  - Fiscal Year 2009: \$534 M (request)
    - Represents 1.8% of NIH Budget
- ~\$30 \$50 M uncommitted each year for new initiatives

# Scientific Programs

### Roadmap/Common Fund Programs Cohort 1: Initiated in 2004

- Building Blocks, Biological Pathways, and Networks
- Molecular Libraries and Imaging
- Structural Biology
- Bioinformatics and Computational Biology
- Nanomedicine
- Interdisciplinary Research

- NIH Pioneer Awards
- NIH Director's New Innovator Awards
- Interdisciplinary Research
- Clinical Research Networks
- Clinical Outcomes Research
- Clinical Research Training
- Translational Research--Clinical Translational Science Awards (CTSAs)

#### Roadmap/Common Fund Programs Cohort 2

• Human Microbiome Project (Initiated in FY 2008)

• Epigenomics (Initiated in FY 2008 and FY 2009)

### Cohort 2: Human Microbiome Program (HMP)

Purpose: To generate resources to enable the comprehensive characterization of the human microbiota and analysis of its role in human health and disease. The HMP aims to lay the foundation for further studies of human associated microbial communities.

#### Broad Goals:

- Determine whether individuals share a core human microbiome
- Understand whether changes in the human microbiome can be correlated with changes in human health
- Develop the new technological and bioinformatic tools needed to support
  these goals
- Address the ethical, legal and social implications raised by human microbiome research

For information on specific initiatives see: <u>http://nihroadmap.nih.gov/hmp/grants.asp</u>

#### **Cohort 2: Epigenomics Program**

Purpose: To examine the role of epigenetic regulation in the origins of health and disease susceptibility. The program focuses on the epigenetic mechanisms that control stem cell differentiation and organogenesis and contribute to responses to external and endogenous stimuli.

Broad Goals:

- Develop comprehensive reference epigenome maps
- Develop new technologies for comprehensive epigenomic analysis

For information on specific initiatives see: <u>http://nihroadmap.nih.gov/epigenomics/grants.asp</u>

### <u>New</u> Transformative RO1Program

#### New Transformative Research Program

Convergence of recurring themes across three NIH Working Groups :

- High-Risk, High-Reward Implementation Working Group
  - Foster scientific creativity through support of high-impact cutting edge research
- NIH 2007-2008 Peer Review Working Group
  - Develop mechanisms that encourage innovative research proposals
- NIH Roadmap/Common Fund Leadership Meetings
  - Success of Pioneer and New Innovator Awards

#### NIH Roadmap Transformative RO1 Program

- FOA will invite innovative, paradigm "disrupting/creating" ideas
- FOA will use RO1 mechanism; essay format of 5-8 pages
- FOA will include special focus areas identified recently as RM proposals:
  - Development of New Protein Capture Technologies
  - Science of Behavior Change
  - Functional Variation in Mitochondrial Disease
  - 3-D Tissue Models
  - Enabling Pharmacogenomics "My Meds"
  - Acute to Chronic Pain Transition
- Pilot Program of \$25 M per year over 5 years from the Common Fund

# Governance



#### NIH Roadmap/Common Fund Governance



## Selection and Implementation of Roadmap Concepts

#### Generation and Selection of Roadmap Concepts



#### Current Roadmap/Common Fund Implementation



**Reviews** 

Program Transition to IC

or terminate

#### NCI Participation in the Roadmap

#### NCI Leadership/Coordination Team

- NIH IC Directors-- provide scientific leadership
  - > Dr. John Niederhuber
- OPASI Working Group-- provides advice on processes and policies
  - ➢ Dr. Robert Croyle
- IC Senior Program Staff Committee (ICSPS)-- provides initial triage of ideas submitted to NIH as possible RM/Common Fund programs
  - > Dr. Dinah Singer
- IC Roadmap/Common Fund Liaisons—coordinate NCI participation
  - ➢ Dr. Dinah Singer
  - ➢ Ms. Anne Tatem
  - ➢ Dr. Margaret Ames
- ~ 40 NCI staff participate in Roadmap/Common Fund program implementation working groups

#### Challenges

- How do we define truly transformative areas of science?
- What are the best approaches for identifying Roadmap/Common Fund topic areas?
- How specific should the RM be in identifying research areas or problems and/or solutions?
- What types of opportunities are we missing through the current RM process?