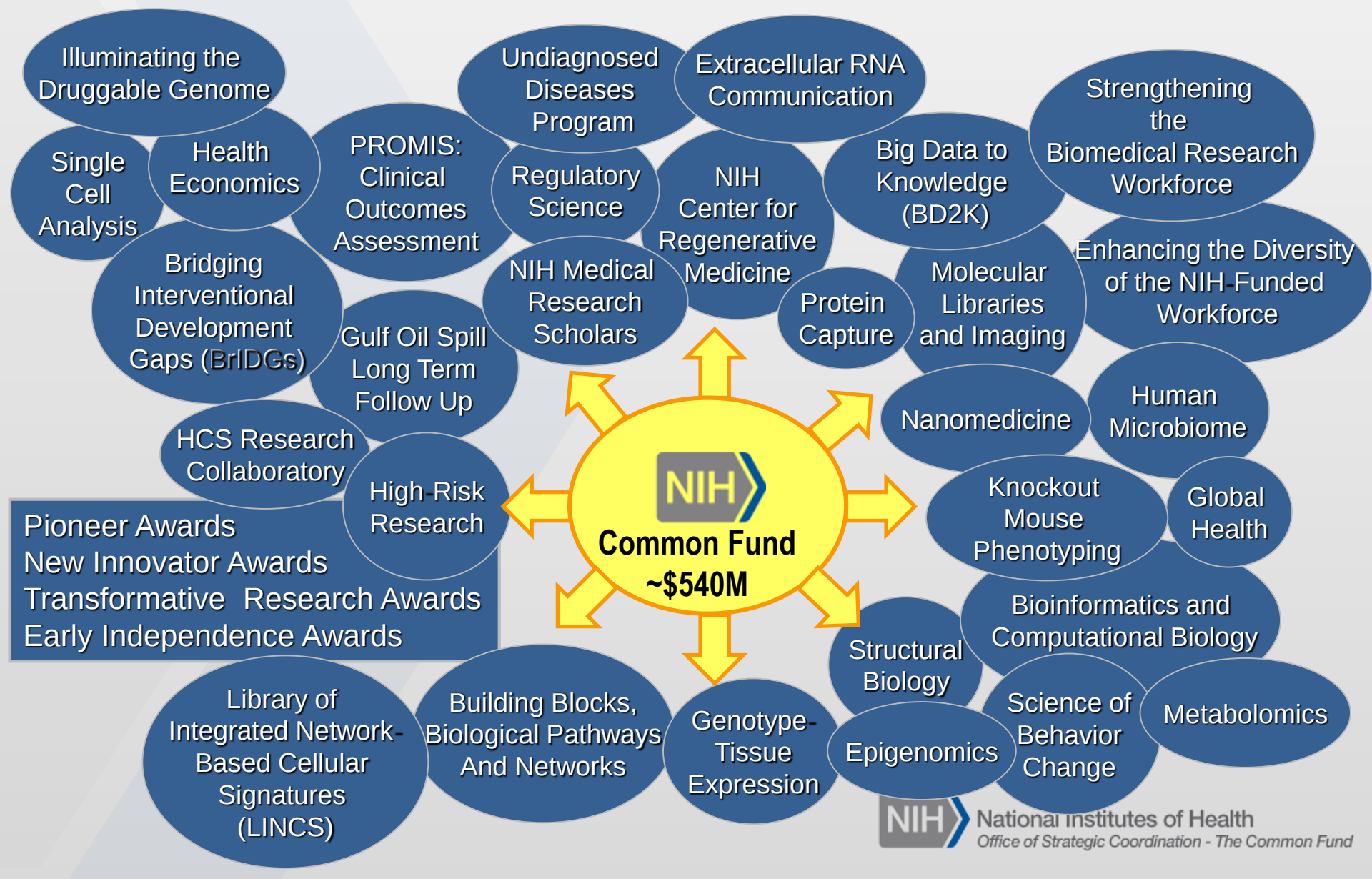
The Common Fund at 10 Years: How are we doing?

September, 2013
Council of Councils

Betsy Wilder
Director, Office of Strategic Coordination, DPCPSI

Current Common Fund Programs (2013)



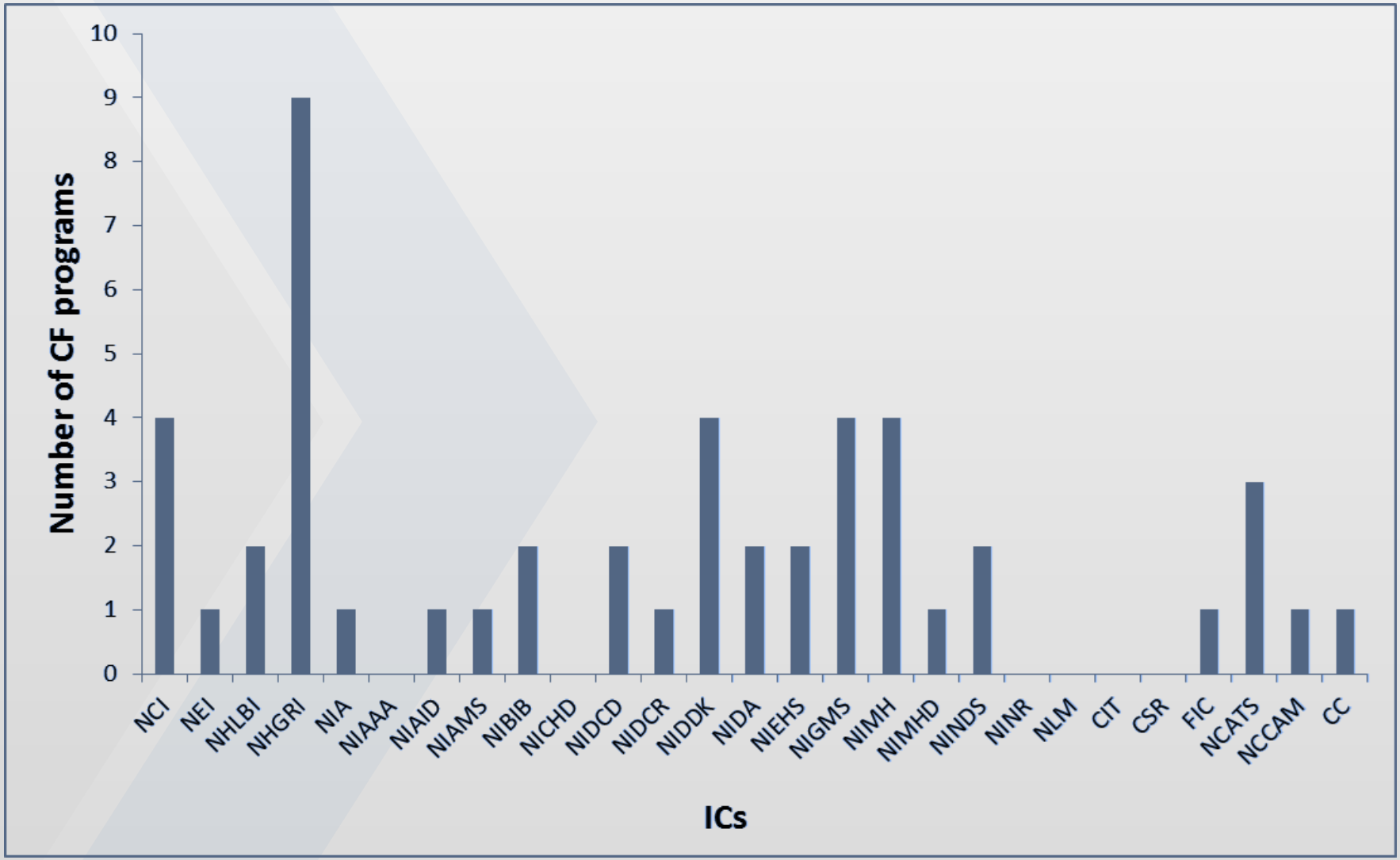
http://commonfund.nih.gov/

The CF represents a significant investment and a new way of managing science:

- Over $4 Billion expended since inception
  - ❖ FY 2013 budget of $513,475,595
  - ❖ Similar to mid-sized IC budgets

- Over 70 staff across the NIH contribute at least 50% effort to manage ~30 programs
  - ❖ Many more contribute between 10-50%

Many ICs lead Common Fund Programs



Lead ICs in Common Fund Programs

	BD2K	NCBC	BrIDGs	TCNP	EG	xRNA	GTEx	GH	GuLF	HC	HE	HMP	DV	MP	LINCS	ME	ML	NM	NIH CRM	CR6	PROMIS	PC	RS	SO	SC	BW	SB	UDN
NCI						X	X									X						X						
NEI																		X										
NHLBI													X		X													
NHGRI	X						X	X				X		X	X		X					X						X
NIA											X																	
NIAAA																												
NIAID												X																
NIAMS																			X		X							
NIBIB																								X	X			
NICHD																												
NIDCD																						X						
NIDCR												X																
NIDDK				X	X											X						X						
NIDA					X						X																	
NIEHS					X				X																			
NIGMS		X																				X				X	X	
NIMH							X										X							X	X			
NIMHD													X															
NINDS																						X				X		
NINR																												
NLM																												
CIT																												
CSR																												
FIC																												
NCATS			X			X																	X					
NCCAM										X																		
CC																				X								

Outline of today's presentation

- Review of the Common Fund's origins
  - ❖ Rationale
  - ❖ Original processes for planning and management
  - ❖ Changes brought by the 2006 Reform Act
- Review of Unusual Features of Common Fund Programs
  - ❖ Planning: Two phases
  - ❖ Ten Year Lifetime
  - ❖ Distributed Management: the OD and ICs as Partners
- Overview of Planning and Management for 3 Example CF Programs
- Discussion of the need for evaluation
  - ❖ What do we want to know?

Review of the Common Fund's Origins: Rationale

"Twenty-seven fingers without a palm is not a hand."

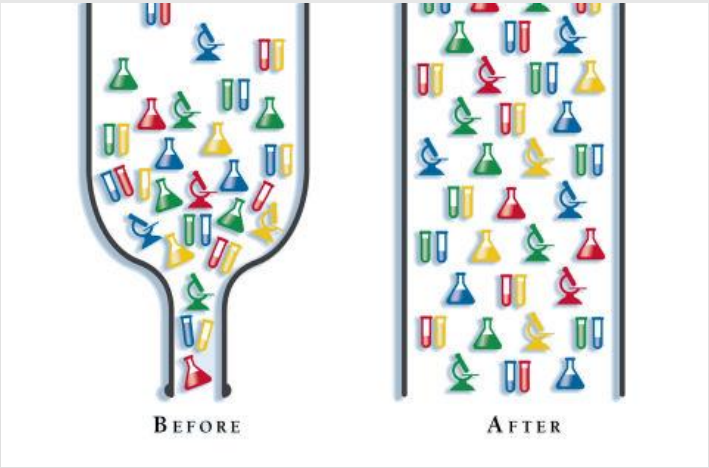
Elias Zerhouni, 2003

Organizational Challenges:

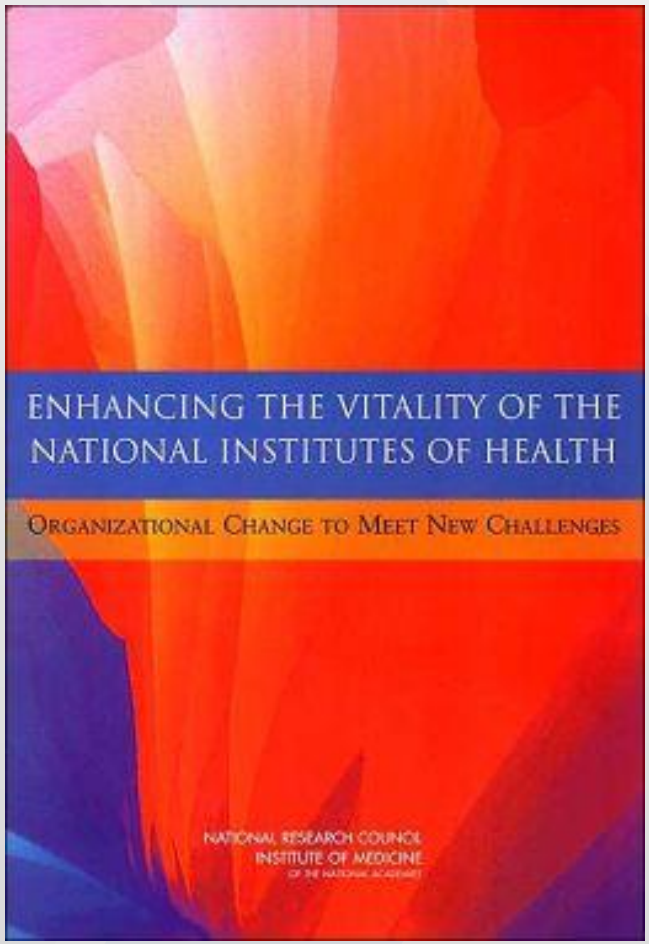
In 2002, there was no mechanism for the NIH as a whole to consider and address challenges and opportunities.

Scientific Challenges:

What are the most significant bottlenecks in biomedical research, and what needs to be done to address them?



The IOM came to similar conclusions



Recommendations included:

- Enhance and increase trans-NIH strategic planning and funding
  - "The committee recommends that the Director be given the responsibility and authority to develop and implement, with and through the ICs, a series of time limited trans-NIH initiatives that are identified through a broad-based strategic planning process open to participation by all internal and external stakeholders and transparent to the public."

Original processes for planning and management

NIH ROADMAP—THEMES, IMPLEMENTATION GROUPS, AND INITIATIVES*

New Pathways to Discovery

Building Blocks, Pathways, and Networks Implementation Group
- National Technology Centers for Networks and Pathways
- Metabolomics Technology Development
- Standards for Proteomics and Metabolomics/Assessment of Critical Reagents for Proteomics

Molecular Libraries and Imaging Implementation Group
- Creation of NIH Bioactive Small-Molecule Library and Screening Centers
- Cheminformatics
- Technology Development
- Development of High-Specificity/High-Sensitivity Probes to Improve Detection
- Comprehensive Trans-NIH Imaging Probe Database
- Core Synthesis Facility to Produce Imaging Probes

Structural Biology Implementation Group
- Membrane Protein Production Facilities

Bioinformatics and Computational Biology Implementation Group
- National Centers for Biomedical Computing

Nanomedicine Implementation Group
- Planning for Nanomedicine Centers

Research Teams of the Future

High-Risk Research Implementation Group
- NIH Director's Innovator Awards

Interdisciplinary Research Implementation Group
- Interdisciplinary Research (IR) Centers
- Interdisciplinary Research Training Initiative
- Innovations in Interdisciplinary Technology and Methods (Meetings)
- Removing Structural Barriers to Interdisciplinary Research.
- NIH Intramural Program as a Model for Interdisciplinary Research
- Interagency Conference on the Interface of Life Sciences and Physical Sciences

Public-Private Partnerships Implementation Group
- Designation of a Public-Private Sector Liaison
- High-Level Science-Driven Partnership Meetings

Reengineering the Clinical Research Enterprise

Clinical Research Implementation Group
- Harmonization of Clinical Research Regulatory Requirements
- Integration of Clinical Research Networks
- Enhance Clinical Research Workforce Training
- Clinical Research Informatics: National Electronic Clinical Trials and Research (NECTAR) Network
- Translational Research Core Services
- Regional Translational Research Centers
- Enabling Technologies for Improved Assessment of Clinical Outcomes

The original Roadmap planning process led to the development of 9 major programs, involving 28 initiatives.

How did we get there?

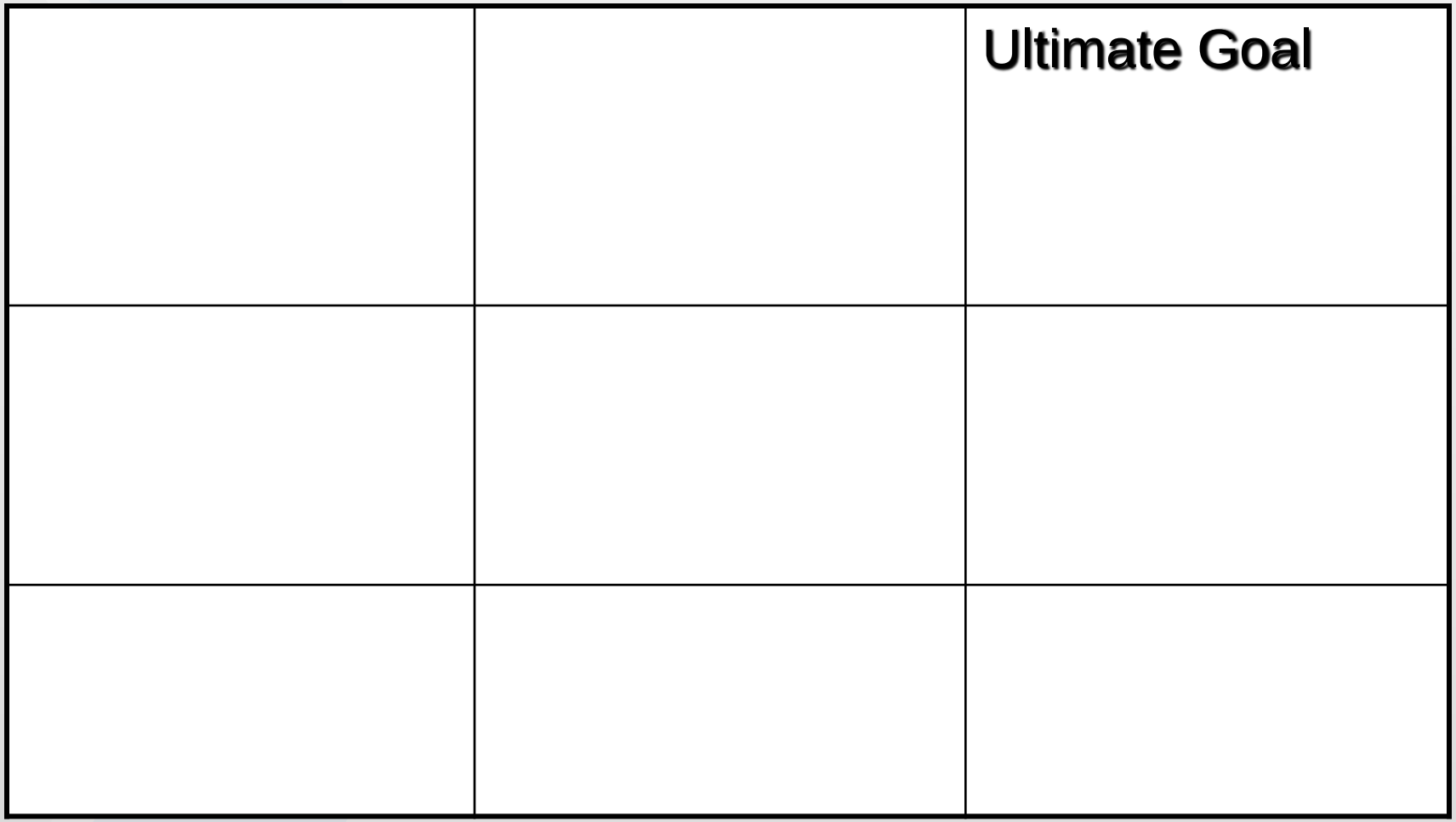
Roadmap Chronology

August 2002	Consultation with over 100 thought leaders
September 2002	IC Directors Leadership Forum
March 2003	Formation of 15 Roadmap Working Groups, involving over 300 experts
April 2003	Presentation to Council of Public Representatives (COPR)
May 2003	Working Groups Develop Proposed Roadmap Initiatives and Plans
June 20, 2003	IC Directors' Retreat
June 30, 2003	Presentation to the Advisory Committee to the Director (ACD)
2003 and beyond	Adaptive Implementation

Roadmap 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?

Sample Matrix -



Structural Biology Matrix

Increasing Level of Difficulty

1-3 years	4-7 years	8-10 years
Based on experimental and computational studies, link selected sequences and structures with biological function and disease etiology.	Study protein dynamics and flexibility through time resolved structural determinations Determine the structure of a substantial number of membrane proteins at high resolution for biological and medical applications	**Routinely determine the structures of most proteins at high resolution from their DNA sequences** **Routinely determine large macromolecular assemblies**
Determine the structure of post-translationally modified proteins at high resolution.	Determine the structure of stable, mid-sized macromolecular assemblies for functional and disease-related studies.	Complete the structural determination of representatives of 75% of all protein families, permitting structural coverage of most proteins in nature Engineer proteins for selected biological function
Develop infrastructure, methods/instruments, and bioinformatics/ computational tools for structural biology Enhance the automated structural genomics pipeline leading from DNA sequence to protein structure		Apply protein structural information to basic biological problems and medical applications.

Time

Roadmap Considerations

- **Is the initiative truly transforming -- will it dramatically change how or what biomedical research is conducted in the next decade?**
- **Would the outcomes from the initiative be used by and synergize the work of many ICs?**
- **Can the NIH afford NOT to do it?**
- **Will the initiative be compelling to our stakeholders, especially the public?**
- **Does the initiative position the NIH as unique -- doing something that no other entity can or will do?**

Common Fund Criteria

Transformative: Programs are expected to have exceptionally high and broadly applicable impact. They should be relevant to many diseases and many ICs. They should set new standards for research or clinical practice, create entirely new approaches to research or clinical care, or establish new biological paradigms.

Catalytic, Short Term and Goal-driven: Programs must achieve - not just work toward - a goal. They have deliverables - data sets, tools, technologies, approaches, or fundamental principles of biology, etc – that can be achieved within 5-10 years. If the deliverable is expected to have ongoing maintenance costs, a vision for transition and sustainment must be articulated.

Synergistic /Enabling: Programs should be valued-added to the ICs, with the output enabling the mission of multiple ICs.

Requires a high level of Trans-NIH Coordination: CF programs should address complex issues that require trans-NIH teams, insights and perspectives to design and manage. There must be a reason why strategic coordination is required.

Novel: Programs should provide new solutions to specific challenges. If similar efforts exist, the CF program should be tightly coordinated to prevent duplication of effort.

NIH ROADMAP—THEMES, IMPLEMENTATION GROUPS, AND INITIATIVES*

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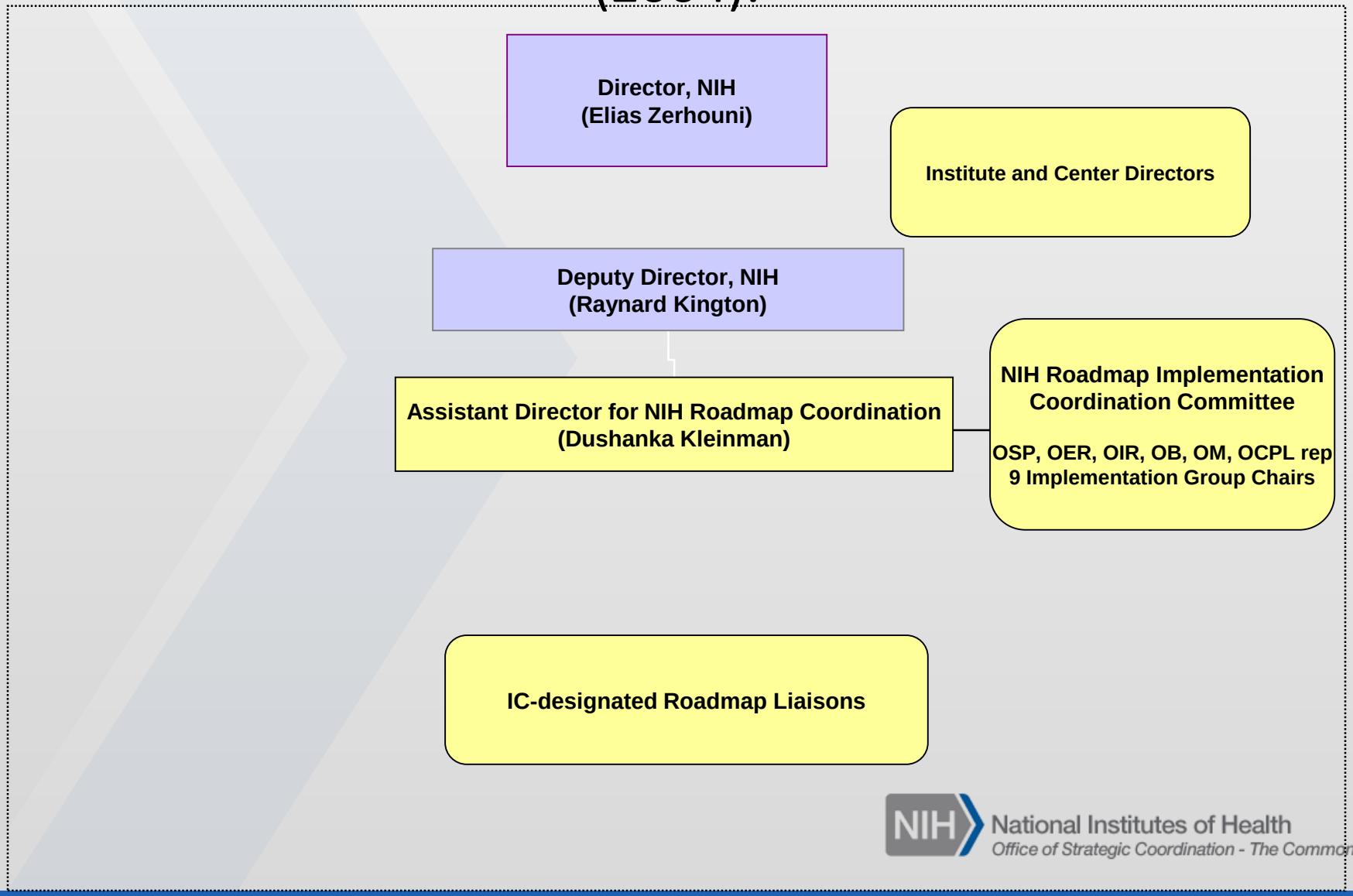
Roadmap coordination/implementation structure (2004):



Roadmap Implementation Coordination Committee (RICC)

- Provided governance for overall Roadmap
  - Set policy and oversight
  - Reviewed fiscal and human resources
- Facilitated coordination and communication among working groups
- Provided guidance for evaluation of overall Roadmap
- Worked within funding levels projected for FY04-FY09

Roadmap Working Groups

- 2-3 IC Director Co-Chairs
- 1-3 Program Coordinators
- Multiple Project Team Leaders – Program Officials responsible for individual initiatives
- Many Working Group Members – Program Officials representing their IC's interests
- 1 Budget Point of Contact

➢ Each group worked independently to:
  - Articulate goals
  - Establish consortium partnership practices
  - Develop processes to assess progress
  - Communicate about the programs to stakeholders
  - Manage the budget

Management Challenges

- Static, silo'ed budgets limited flexibility
  - Programs proposed budget envelopes that were approved and became fixed
  - No clear route to plan for future opportunities and challenges
- Information flow between OD and ICs was limited and inconsistent across groups
- The OD required evaluative information about the programs, but there was no structure to do this.
  - Each group conducted self-evaluations.
  - All evaluations were positive.

Challenges aside, many felt the RM was off to a good start…

"This has been a great experience – I would not have ordinarily had a chance to interact with many of the committee members and it was really eye-opening. The depth and breadth of the talent around NIH is really impressive……..

I suspect you are hearing similar things from other groups – this has been NIH at its finest!

Thanks for the opportunity to be involved in this."

108TH CONGRESS
HOUSE OF REPRESENTATIVES
OFFICE OF THE DIRECTOR

The Committee provides $45,000,000 within the Office of the Director for the Director*s Discretionary Fund (DDF), which is the same as the Administration request and $25,130,000 above the fiscal year 2003 comparable level. The Director is encouraged to maximize the use of the fund to implement the "roadmap" being developed by NIH to structure its future research portfolio. Within the "roadmap" research supported by the DDF, the Committee urges the Director to emphasize translational and clinical research designed to expedite delivery of new treatments with therapeutic promise and cures to patients with serious and degenerative illnesses. The Committee also encourages the Director to use the one percent transfer authority that is provided in the bill to allocate additional resources to clinical and translational research identified in the roadmap.

Changes Brought by the Reform Act

One Hundred Ninth Congress
of the
United States of America

AT THE SECOND SESSION

Begun and held at the City of Washington on Tuesday, the third day of January, two thousand and six

An Act

To amend title IV of the Public Health Service Act to revise and extend the authorities of the National Institutes of Health, and for other purposes.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the "National Institutes of Health Reform Act of 2006".

TITLE I—NIH REFORM

2004: NIH Roadmap is launched

December 9, 2006: Congress unanimously passes a reauthorization bill affirming importance of NIH and its vital role in advancing biomedical research to improve the health of the Nation

Establishes the Division of Program Coordination, Planning, and Strategic Initiatives (DPCPSI) within the Office of the Director and the NIH Common Fund to provide a dedicated source of funding to enable *trans*-NIH research

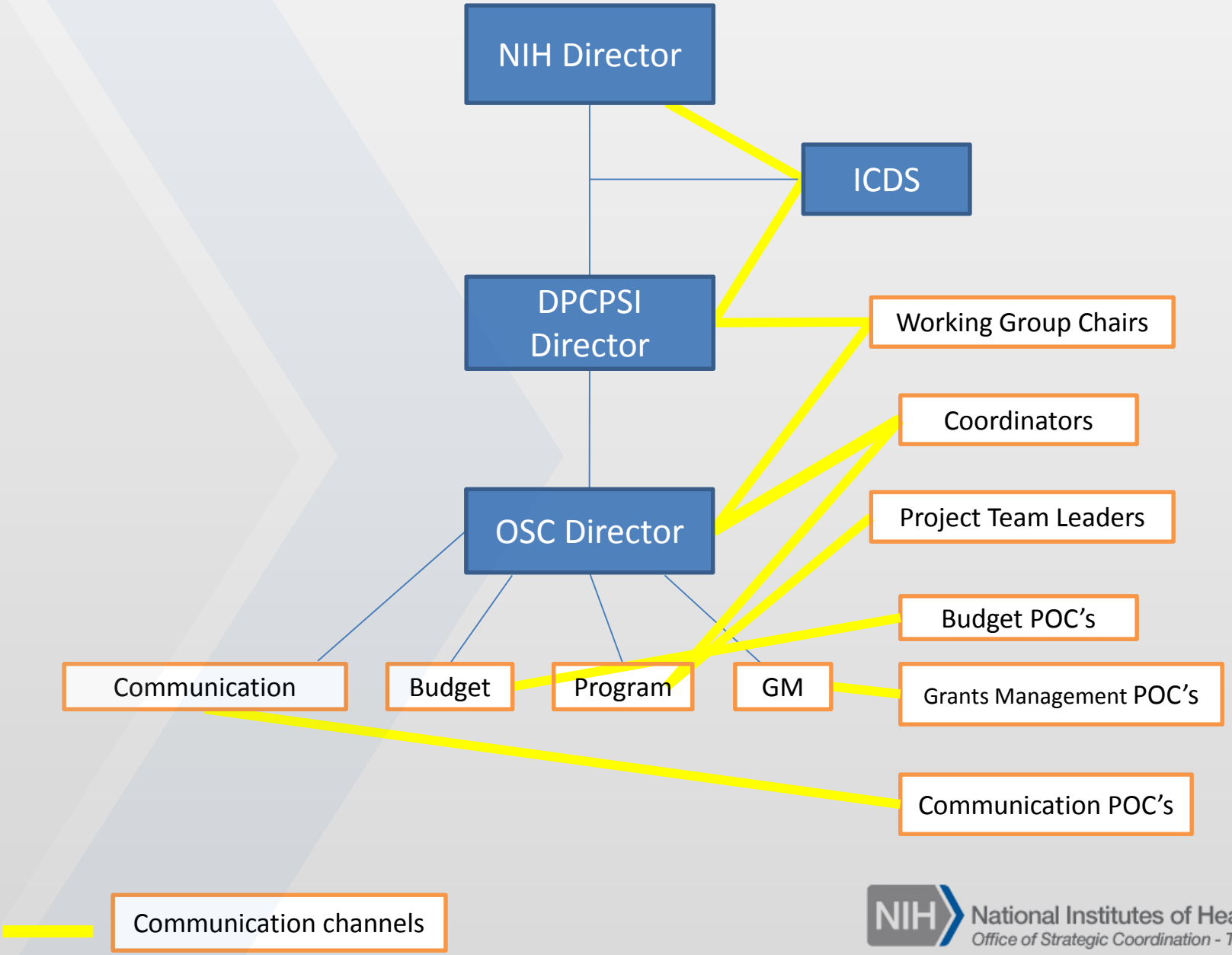
Impact of the Reform Act on the Roadmap

- The Common Fund
  - Appropriation of funds to the NIH Director strengthened the role of the Director in overseeing the funds.
  - The description of the CF perpetuated the goals of the RM to address strategic, trans-NIH needs.
- DPCPSI
  - The creation of DPCPSI provided the OD with the administrative structure to manage the CF.

The net effect is that management of the CF became a partnership between the ICs and the OD.

Impact of the Reform Act on the Roadmap

- Stronger ties between the OD and the ICs at all phases of CF programs
  - OD Leadership not only selects broad program topics, but also participates in articulation of specific goals and provides guidance at critical points.
  - DPCPSI/OSC works in partnership with IC teams to:
    - Develop management plans
    - Implement initiatives and track budgets
    - Oversee and assess progress
    - Make adjustments to address changes in field
    - Communicate about the programs
    - Plan for transition at end of CF support


NIH Director
ICDS
DPCPSI Director
Working Group Chairs
Coordinators
OSC Director
Project Team Leaders
Budget POC's
Communication
Budget
Program
GM
Grants Management POC's
Communication POC's
Communication channels

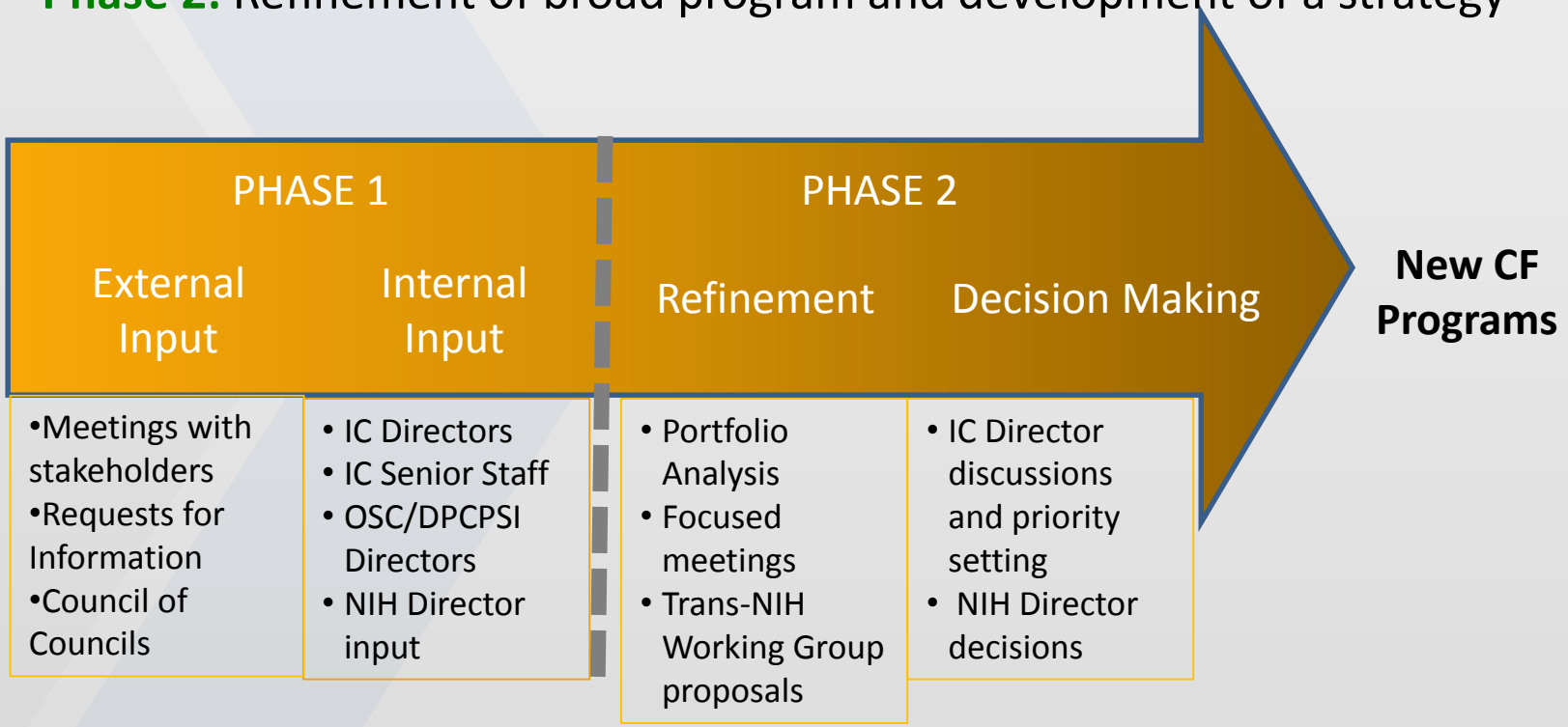
Review of Unusual Features of Common Fund Programs

National Institutes of Health
Office of Strategic Coordination - The Common Fund

Two Phase Strategic Planning

Phase 1: Identification of strategic needs and opportunities, with a "rough draft" proposal of initiatives that would be required

Phase 2: Refinement of broad program and development of a strategy



- A new round of Common Fund strategic planning is initiated annually
- The entire process (Phase 1 through Phase 2) lasts 18 months

Specific Goals -> Defined Lifetime -> Sustained Impact

- **Strategic Planning for the Common Fund involves definition of specific deliverables – goals for the program to achieve within a defined, 5-10 year period of time.**

- **IC Strategic Plans have a broader focus. The focus tends to be at the level of entire fields, with the IC in a position to lead: "where should this field go and how do we lead it there?"**

- **CF Programs ask "What specific deliverables can we provide that will transform the field and thereby have a sustained impact?"**

Articulating clear goals for a defined timeframe is the hardest part of CF Program Planning.

OD-IC-IC Partnership

- **All CF programs are managed by multi-IC teams.**
  - **Brings the most relevant NIH expertise to bear on the program and keeps the IC Directors engaged**
  - **Helps to ensure that the ICs benefit from the program – that the output of the program is maximally useful and widely disseminated**

- **OSC staff are part of each team and provide a bidirectional link between each team and OD Leadership.**
  - **Guidance from OD Leadership to groups**
  - **Information and recommendations about program to Leadership**

What types of programs are “Common Fundable”?

How do our planning and management practices influence them?

- Human Microbiome Project
- Patient Reported Outcomes Measurement Information System
- Metabolomics

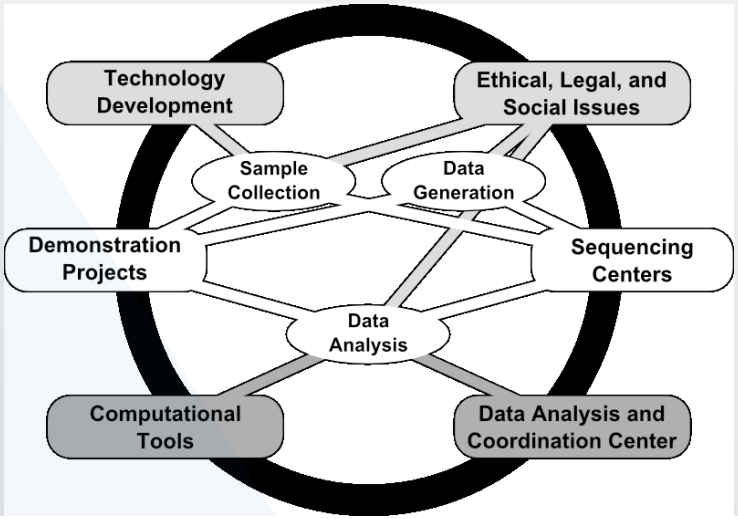
NIH Common Fund Human Microbiome Project

http://commonfund.nih.gov/hmp)

Community resources

Repositories:

- sequence data
  - microbiome
  - *human*
- strains
- clinical/phenotype data
- *nucleic acid extracts*
- *cell lines*



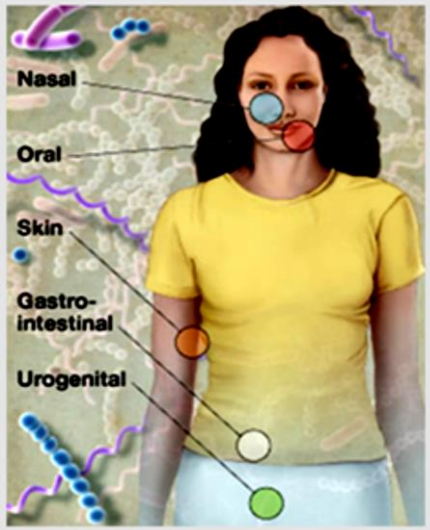
9 Initiatives in HMP

Interact through DACC and 400+ member consortium

IHMC founding member

www.hmpdacc.org

Healthy cohort study



Clinically healthy

300 male/female

18-40 y.o.

18 body sites

Up to 3 visits in 2 yrs

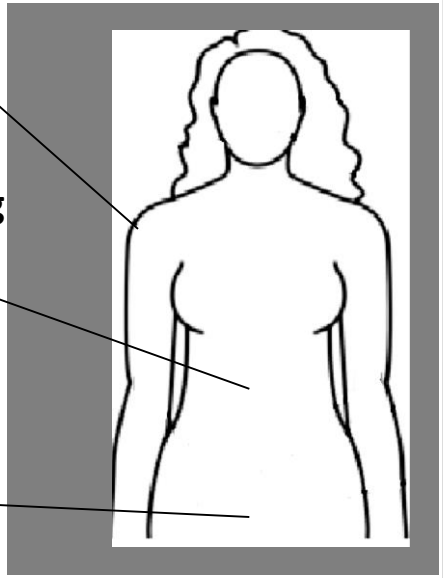
16S rDNA, WGS metagenomes

Demonstration Projects

Skin: eczema, psoriasis

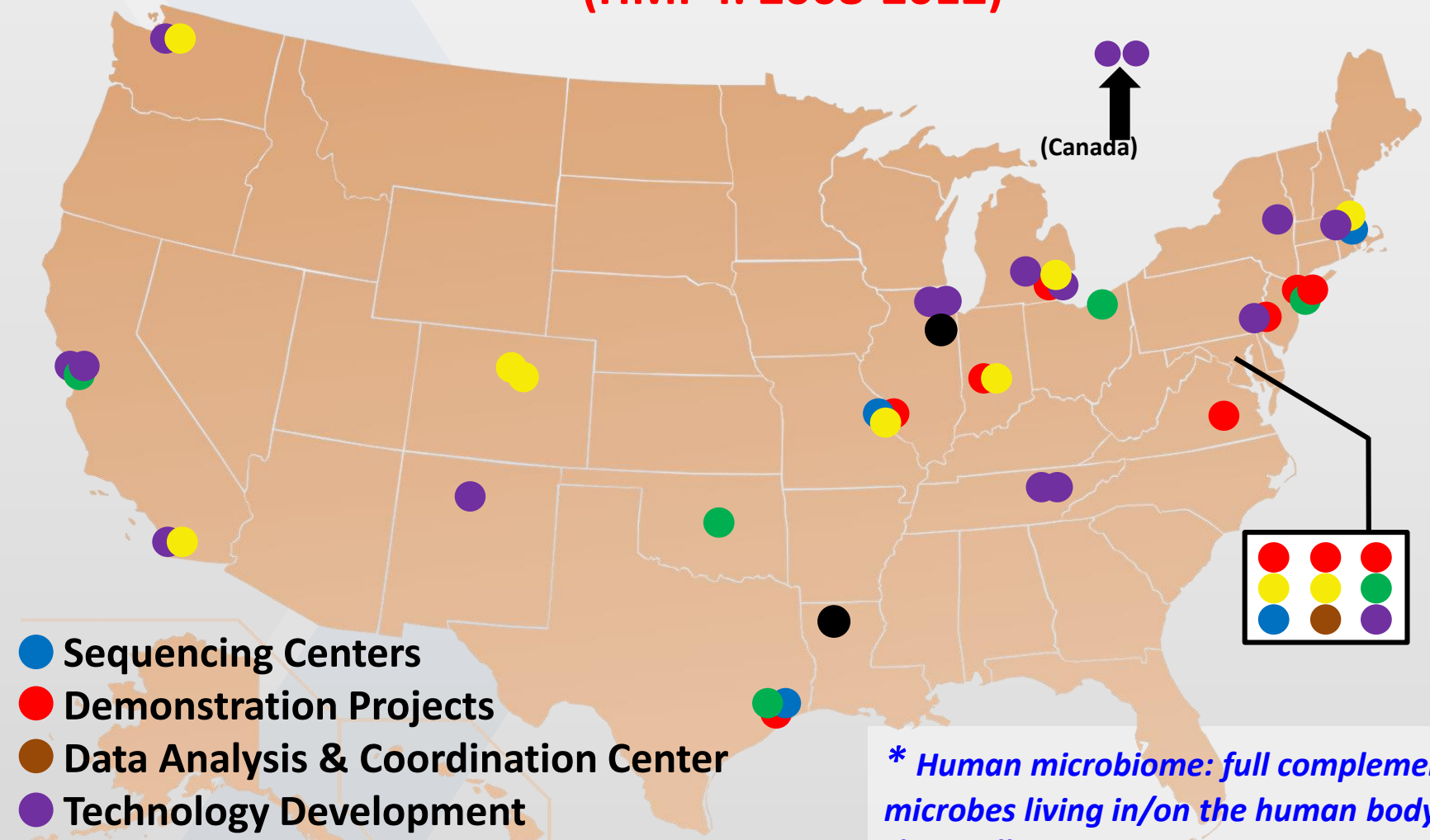
GI: Crohn's disease, esophageal adenocarcinoma, necrotizing enterocolitis, pediatric IBS, ulcerative colitis

Urogenital: bacterial vaginosis, circumcision, sexual histories



NIH Human Microbiome* Project

(HMP I: 2008-2012)



- Sequencing Centers
- Demonstration Projects
- Data Analysis & Coordination Center
- Technology Development
- Computational Tools
- ELSI
- Clinical labs

** Human microbiome: full complement of microbes living in/on the human body and their collective genes & genomes.*

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PROMIS

The Patient-Reported Outcomes Measurement Information System (PROMIS) aims to provide clinicians and researchers access to **efficient, precise, valid, and responsive** adult- and child-reported measures of health.

PROMIS uses measurement science to create an efficient **state-of-the-art assessment system** for self-reported health.

PROMIS®

Dynamic Tools to Measure Health Outcomes from the Patient Perspective

Sample Questions

See samples of actual questions taken from selected physical health, mental health, and social health short forms.

More ...

1 2 3 4 <-Prev Next->

Twitter

promisNIH PROMIS - NIH

Know yourself? PROMIS® Computer Adaptive Test instantly reports on up to 9 diff moods like anger, fatigue. http://t.co/v9LY4ANH

Oct 29 (2 days ago)

Reply Retweet Favorite

promisNIH PROMIS - NIH

#Researchers, #Clinicians..what is your preferred format to access research/pubs on Twitter? Presentation, PDF, or Video?

Oct 25 (6 days ago)

Reply Retweet Favorite

Researchers

Provides efficient, reliable, and valid assessments of adult and child (pediatric) self-reported health

- PROMIS Instruments Selected References
- PROMIS In Research

Clinicians

Provides data about the effect of therapy that cannot be found in traditional clinical measures

- PROMIS for Clinicians
- Select Publications
- Computer Adaptive Test (CAT) Demonstration

Patients

Measures what you are able to do and how you feel

- More on PROMIS
- What Patient Reported Outcomes (PROs) are
- PROMIS Measures

PROMIS OUTCOMES

Informatics: Assessment Center Supports >100 Studies

Tools: 40 Adult Measures, 20 Pediatric Measures

Translations: 11 Fatigue items in Spanish and 8 short forms into Chinese

Advancing Knowledge: >100 Peer-Reviewed Publications

Cooperative Group: 12 Research Sites, 3 Centers, 150+ Scientists

Outreach: ~140 users downloaded short-forms in the three week period following the availability to the public in September 2012 (http://www.nihpromis.org/default.aspx)

Integration into Healthcare: Selected short-forms Version 1.0 have been added to the Epic "Miscellaneous Assessment Tools Collection. Epic MyChart is the most widely used patient portal.

Epigenetics of Human Health and Disease

EPIGENETICS RESEARCH PORTFOLIO

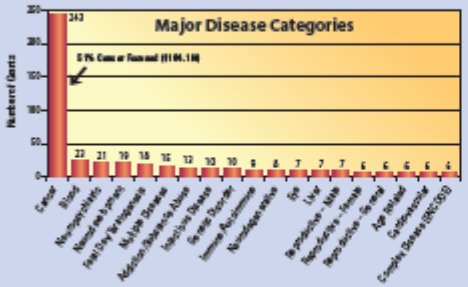
NIH RESEARCH

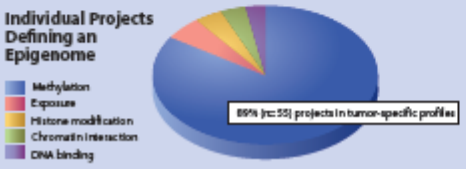
The NIH research portfolio in "epigenetics" was evaluated by IC staff to determine scientific strengths, areas of current investment, and research opportunities. Focus areas included: disease, organ, epigenetic mechanism, biological process, model system, technology development, bioinformatics, exposure type, and clinical research.

	Extramural	Intramural
Number of Awards	584	46
Total NIH Investment	$231M	

SUMMARY:

- Few large-scale, coordinated programs: 95% individual awards, 5% centers (ENCODE)
- Limited disease-focused research, except cancer (51%)
- Limited technology (14%) or bioinformatics tool development (4%)
- 1 grant addressing standardization (sample prep)
- Limited clinical research emphasis (33%)
- "Epigenomes" defined primarily as DNA methylation profiles in human tumors (89%); 3% (n=2) defined in ES cells
- No comprehensive epigenomes integrating multiple marks
- Similar trends for extramural and intramural portfolio





INTERNATIONAL RESEARCH

EUROPEAN UNION	€ 54.6M
• Human Epigenome Program (HEP)	2M
• High Throughput Epigenetic Regulatory Organization in Chromatin (HEROIC)	12M
• ESTOOLS – Advances with Human Embryonic Stems Cells	12M
• Epigenome Network of Excellence (NoE)	12.5M
• National Methylome Project for Chromosome 21 (NAME21)	1.7M
• Epigenetic Treatment of Neoplastic Disease (EPITRON)	10.9M
• Epigenetic Plasticity of the Mammalian Genome (GEN-AU)	3.5M
CANADA	**$16M**

RESEARCH EMPHASIS:

- Consortia of individual projects across multiple research groups
- Emphasis on mechanistic studies of chromatin regulation and DNA methylation
- Emphasis on comparative biology (human, mouse, Arabidopsis, Drosophila) in cell lines, stem cells, progenitor cells
- Limited focus on human disease, except cancer
- Small-scale efforts to establish reference epigenomes in human genes and tissues

OPPORTUNITIES FOR COLLABORATION:

- Establish international standards for epigenomic research (technology platforms, reagents, protocols)
- Develop reference epigenomic maps and computational infrastructure to enable researchers world-wide
- Accelerate our understanding of epigenetic mechanisms in human health and disease

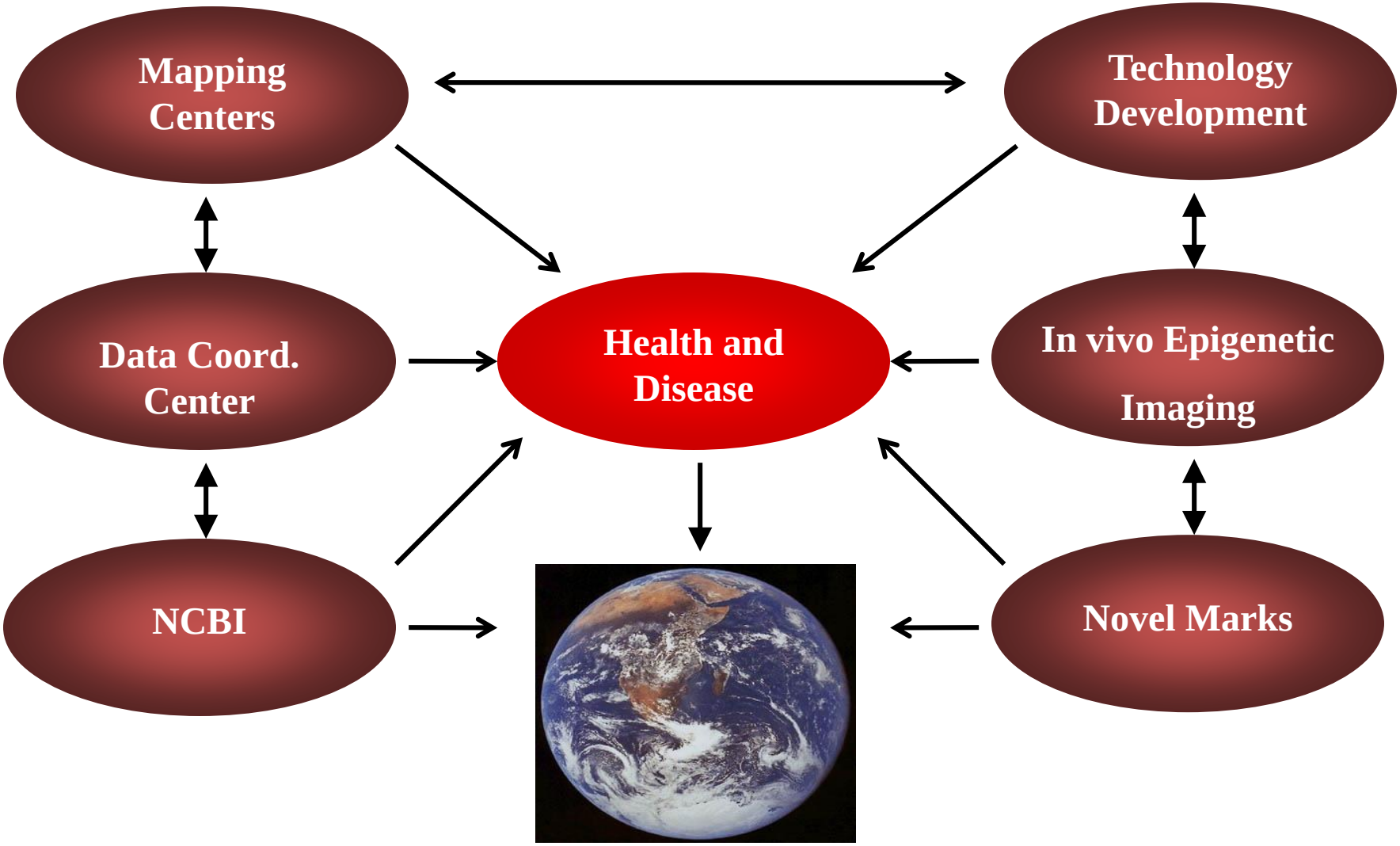
Epigenomics

The concept was proposed as "Epigenetics" with enthusiasm for exploration of epigenetic mechanisms underlying many diseases.

What was being done, and what were the challenges and opportunities?

NIH National Institutes of Health
Office of Strategic Coordination - The Common Fund

NIH Common Fund Epigenomics Program



NIH Epigenomics Working Group

Co-Chairs: Nora Volkow (NIDA), Linda Birnbaum (NIEHS), James Battey (NIDCD)

Co-Coordinators: John Satterlee (NIDA), Pat Mastin (NIEHS)

Christine Colvis	NCATS
Carol Pontzer	NCCAM
Grace Ault	NCI
Jennifer Couch	NCI
Paul Okano	NCI
Richard Piekarz	NCI
Sharon Ross	NCI
Mukesh Verma	NCI
Hemin Chin	NEI
Elise Feingold	NHGRI
Mike Pazin	NHGRI
Weiniu Gan	NHLBI
Susan Old	NHLBI
Pothur Srinivas	NHLBI
Anna McCormick	NIA
Suzana Petanceska	NIA
Conrad Malia	NIAID
Nasrin Nabavi	NIAID
Ashley Xia	NIAID
William Sharrock	NIAMS
Guoying Liu	NIBIB
Roderic Pettigrew	NIBIB
Carol Kasten-Sportes	NICHD
Lisa Freund	NICHD
Susan Taymans	NICHD
Mark Caulder	NIDA
Genevieve deAlmeida-Morris	NIDA
Donna Jones	NIDA
Jonathan Pollock	NIDA
Dena Procaccini	NIDA
Joni Rutter	NIDA
David Shurtleff	NIDA
Bracie Watson	NIDCD
Lillian Shum	NIDCR
Kristin Abraham	NIDDK
Olivier Blondel	NIDDK
Jessica Faupel-Badger	NIDDK
Philip Smith	NIDDK
Julie Wallace	NIDDK
Lisa Chadwick	NIEHS
Gwen Collman	NIEHS
Christie Drew	NIEHS
Astrid Haugen	NIEHS
Jerry Heindel	NIEHS
Laurie Johnson	NIEHS
Kimberly McAllister	NIEHS
Srikanth Nadadur	NIEHS
Kristi Pettibone	NIEHS
Fred Tyson	NIEHS
Leroy Worth	NIEHS
Anthony Carter	NIGMS
Andrea Beckel-Mitchener	NIMH
Michelle Freund	NIMH
Thomas Lehner	NIMH
Roger Little	NIMH
Aleksandra Vicentic	NIMH
Robert Riddle	NINDS
Randall Stewart	NINDS
Stephanie Courchesne	OSC
Patricia Labosky	OSC
Johanna Dwyer	ODS
Deborah Olster	OBSSR

The Need for Evaluation:
What do we want to know?

- **Are Common Fund processes working optimally to:**
  - **Identify programmatic areas where transformation is needed and possible?**
  - **Articulate specific goals and manage programs to ensure the goals are met?**
  - **Adapt to evolving scientific needs?**
  - **Assess program outcomes?**

- **Are OD-IC partnerships adequate to support program management?**
  - **Do Working Groups receive appropriate guidance from OD Leadership?**
  - **Do ICs have the resources they need to manage CF programs?**
  - **Is IC-DPCPSI/OSC communication fluid and effective?**
  - **Do Working Groups see OSC as part of the team, or as "them" versus "us"?**

Evaluation of CF Planning and Management

- **Consistent with the role of the Council of Councils to "advise the Director on matters related to the policies and activities of DPCPSI, including making recommendations with respect to the conduct and support of research [supported by the Common Fund]."**

Proposed Charge to the Council of Councils CF Planning and Management Working Group (CPMWG)

Assess and advise on the processes used to manage the CF, including those used to plan and implement/oversee programs.

1. Are planning processes optimal for identifying program areas that meet the CF criteria?
2. Are management/oversight processes optimal for achieving program goals?

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2. Are management/oversight processes optimal for achieving program goals?

Request a motion to approve creation of the Council of Councils Common Fund Planning and Management Working Group

Proposed Process for the CPMWG

Work Plan: review of materials prepared by OSC, interviews and surveys of stakeholders

Timeline:

Oct. 22, 2013 – Kick-off meeting to charge WG and review background materials and draft work plan

Jan. 31, 2014 – Present findings and recommendations for planning process (Question 1) to Council of Councils

Jun. 20, 2014 – Working group presents to Council of Councils findings and recommendations for CF oversight, and governance processes (Question 2)

Comments?