10 Year Update on the Common Fund

May 7, 2013
NACDA

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Director, Division of Program Coordination, Planning, and Strategic Initiatives
Current Common Fund Programs (FY14)

- Illuminating the Druggable Genome
- Single Cell Analysis
- Health Economics
- Bridging Interventional Development Gaps (BrIDGs)
- HCS Research Collaboratory
- Pioneer Awards
- New Innovator Awards
- Transformative Research Awards
- Early Independence Awards
- Library of Integrated Network-Based Cellular Signatures (LINCS)
- Building Blocks, Biological Pathways, and Networks
- Genotype-Tissue Expression
- Epigenomics
- Structural Biology
- Epigenomics
- Undiagnosed Diseases Program
- PROMIS: Clinical Outcomes Assessment
- Gulf Oil Spill Long Term Follow Up
- High-Risk Research
- NIH Medical Research Scholars
- Regulatory Science
- Extracellular RNA Communication
- Protein Capture
- Molecular Libraries and Imaging
- Nanomedicine
- Knockout Mouse Phenotyping
- Global Health
- Metabolomics
- Bioinformatics and Computational Biology
- Science of Behavior Change
- Metabolomics
- Human Microbiome
- Enhancing the Diversity of the NIH-Funded Workforce
- Strengthening the Biomedical Research Workforce
- Nanomedicine
- Regulatory Science
- Molecular Libraries and Imaging
- Structural Biology
- Epigenomics
- Undiagnosed Diseases Program
- Extracellular RNA Communication

Common Fund ~$540M

http://commonfund.nih.gov/
The CF represents a significant investment and a new way of managing science:

• Over $4 Billion expended since inception
  ❖ FY 2014 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%
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?
The Common Fund’s Origins: Rationale

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

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

“Twenty-seven fingers without a palm is not a hand.”
Elias Zerhouni, 2003
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.”
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?
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

Changes Brought by the Reform Act

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
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.
Some Unusual Features of Common Fund Programs
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

- **PHASE 1**
  - **External Input**
    - Meetings with stakeholders
    - Requests for Information
    - Council of Councils
  - **Internal Input**
    - IC Directors
    - IC Senior Staff
    - OSC/DPCPSI Directors
    - NIH Director input

- **PHASE 2**
  - **Refinement**
    - Portfolio Analysis
    - Focused meetings
    - Trans-NIH Working Group proposals
  - **Decision Making**
    - IC Director discussions and priority setting
    - NIH Director decisions

- 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

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

Skin: eczema, psoriasis
GI: Crohn’s disease, esophageal adenocarcinoma, necrotizing enterocolitis, pediatric IBS, ulcerative colitis
Urogenital: bacterial vaginosis, circumcision, sexual histories

9 Initiatives in HMP

Interact through DACC and 400+ member consortium
IHMC founding member
www.hmpdacc.org
NIH Human Microbiome* Project
(HMP I: 2008-2012)

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

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

More...
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.
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 Common Fund Epigenomics Program

Mapping Centers

Data Coord. Center

NCBI

Technology Development

In vivo Epigenetic Imaging

Novel Marks

Health and Disease
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Co-Chairs: Nora Volkow (NIDA), Linda Birnbaum (NIEHS), James Battey (NIDCD)
The Need for Evaluation:
What do we want to know?
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?

Report due on June 20, 2014
# Common Fund Evaluation Working Group Membership

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<tr>
<th>Name</th>
<th>Position/Role</th>
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<th>CF Program</th>
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Accelerating Translation of Glycoscience: Integration and Accessibility

New FY15 Common Fund Program
The primary roadblock: the limited availability of affordable and accessible tools and technologies that can be used by non-specialists

Objective: To develop accessible new tools and technologies that make glycoscience possible for any biomedical investigator.

- less complex
- easily available and affordable
- easy to understand and adapt to different systems
  - Training and education an important component
  - Integration with genome and proteome databases

Operationalizing “accessibility”:
- Applicants will need to provide rationale for how their proposals meet these definitions
- Cross-validation of projects
• How genomic information directs spatial- and temporal-specific gene expression programs in individual cell types and tissues remains to be elucidated, despite:
  – *completion of the human genome project*;
  – *extensive mapping of epigenomic marks on the nuclear genome*;
  – *mounting evidence from imaging and chromatin interaction data that mammalian genomes are non-randomly organized.*
• A better description of the 3D Nucleome could help:
  – identify regulatory sequences that contribute to disease;
  – extract more meaningful information from genetic data;
  – develop new diagnostic tools and tissue-specific therapeutics;
  – better understand individual disease risks, responses to medications, and biological impact of environmental factors.

• The “3D Nucleome” program will bring us closer to these goals by providing:
  – comprehensive reference maps of the 3D architecture of the interphase nucleus;
  – new and improved tools to explore the relationship between nuclear organization and gene expression in development and disease.
Leveraging and IntegraEng Knowledge and Resources

Library of Integrated Network-based Cellular Signatures (BD2K-LINCS)

Epigenomics Program and Reference Datasets

Encyclopedia Of DNA Elements (ENCODE)

Haplotype Map of the human Genome (HapMap)

Genotype – Tissue Expression (GTEx)

The Cancer Genome Atlas (TCGA)
3DN Co-Chairs

Dinah S. Singer, NCI
Phil Smith, NIDDK

Max Guo, NIA
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Thank you