**Evaluation 2016****Session: RTDE5 Evaluation as a Tool for Strategic Planning**

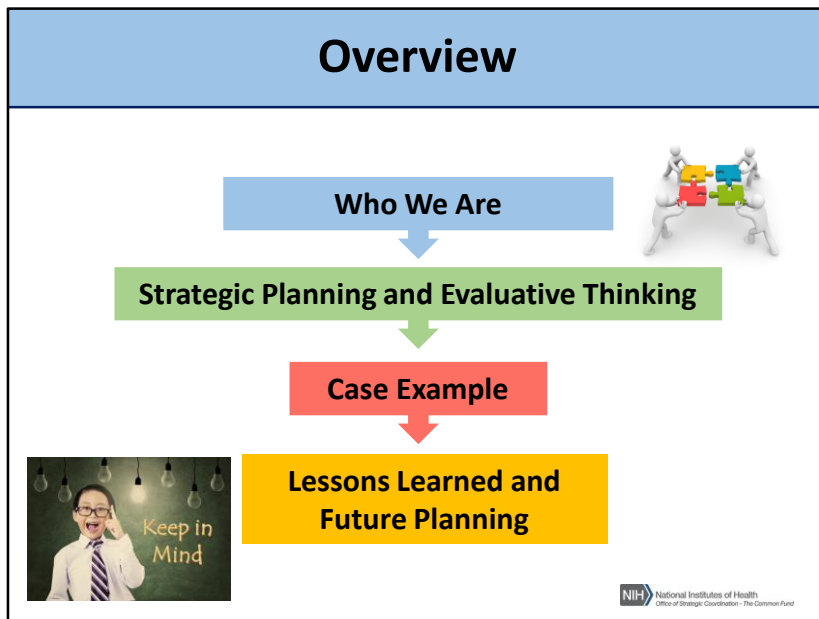
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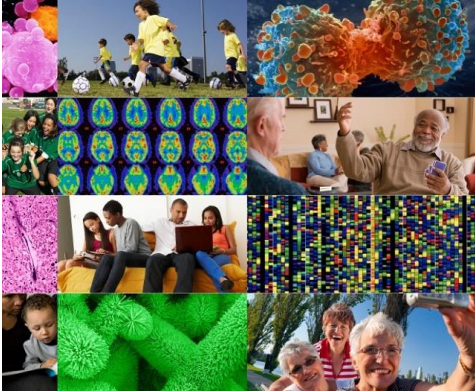
Presentation Abstract:

Biomedical research programs address questions vital to expanding knowledge and improving health, but are resource intensive. Therefore, careful consideration of the existing research environment during program planning is needed. We present how a combination of methods grounded in evaluation practice inform strategic planning for biomedical research programs managed by the National Institutes of Health (NIH) Common Fund. Frequently used methods include analysis of the NIH research portfolio, landscape scans to identify other funding entities in the research area, and review of the scientific literature. In addition, input from experts on the science topic is often elicited through workshops, webinars, and public Requests for Information. This iterative process includes strategies for working with and building consensus among key stakeholders so informed decisions about research direction, resources, and funding can be made. Evaluators looking to apply evaluation practice to program planning will benefit from the real-world experiences of the NIH Common Fund.




General Presentation Overview

National Institutes of Health (NIH)



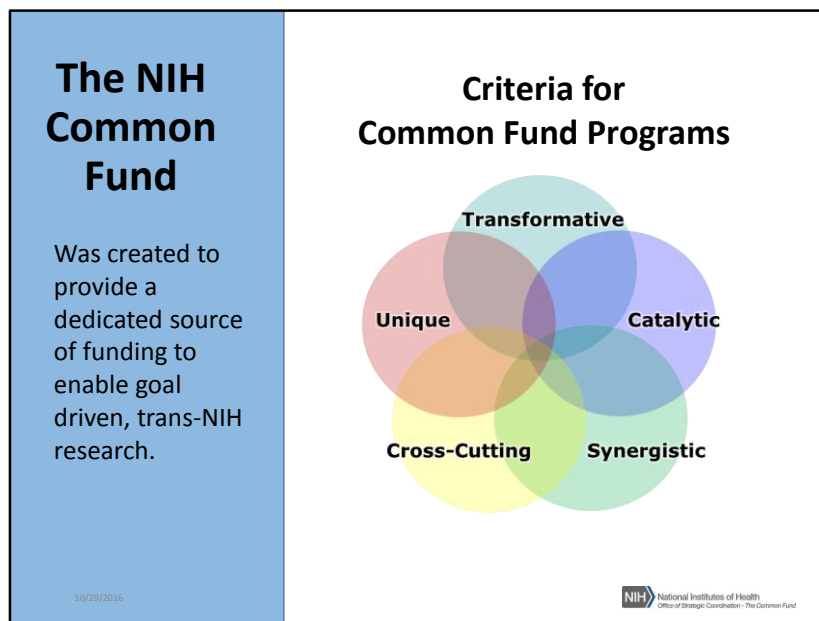
“Science in pursuit of **fundamental knowledge** about the nature and behavior of living systems....

and the **application of that knowledge** to extend healthy life and reduce the burdens of illness and disability.”

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There are 27 Institutes and Centers (ICs) at NIH. Some focus on a particular disease (e.g., National Cancer Institute). Some focus on organs (e.g., National Heart, Lung and Blood Institute; National Eye Institute). Others have a broad focus that crosses many diseases/organ systems (e.g., National Institute of General Medical Sciences, National Institute on Aging, National Human Genome Research Institute).

Most or all ICs develop forward-looking strategic plans, to define priorities and set research agendas.

**NIH Common Fund Overview:**

The intent of NIH Common Fund programs is to provide a strategic and nimble approach to address key roadblocks in biomedical research that impede basic scientific discovery and its translation into improved human health.

In addition, these programs capitalize on emerging opportunities to catalyze the rate of progress across multiple biomedical fields.

Common Fund programs are expected to transform the way a broad spectrum of health research is conducted. Initiatives that compose Common Fund programs are intended to be catalytic in nature by providing limited term investments in strategic areas to stimulate further research through IC-funded mechanisms.

Origins of the NIH Common Fund:

2004: NIH Roadmap was 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
- As part of NIH reauthorization bill, the NIH Common Fund (which evolved from the NIH Roadmap) was created within the Office of the Director to provide a dedicated source of funding to enable goal driven, trans-NIH research.

Criteria for Common Fund Programs: There are 5 criteria used to prioritize proposed programs.

- Transformative: Exceptionally high & broadly applicable impact
- Catalytic: Achieve a set of high impact goals within a defined period of time
- Synergistic: Value-added to the NIH Institutes and Centers
- Cross-Cutting: Address complex issues requiring management by trans-NIH teams
- Unique: Provide new solutions to specific challenges



The Common Fund has a process for strategically planning our research programs.

This involves:

- Vision
- Teams
- Targets/ goals
- Communication
- Timing

Why Use Strategic Planning for Research Programs?

- Make decisions about use of limited resources
- Identify emerging scientific opportunities
- Address pressing science challenges that can potentially have a transformative impact on public health
- Support science in the context of many related science programs



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Science program planning is used for:

- Decisions about use of limited resources
- Identify emerging scientific opportunities
- Address pressing science challenges that can potentially have a transformative impact on public health
- Need to manage for accountability, evidence, learning, reporting, impact and overall opportunities for improvement.

Why Involve Evaluators?

Involvement of evaluators in Program Planning can aid in:

- Asking and answering questions needed to make decisions
- Providing information about what is already known and not known about a science topic
- Recognizing gaps and needs where science findings can potentially transform public health



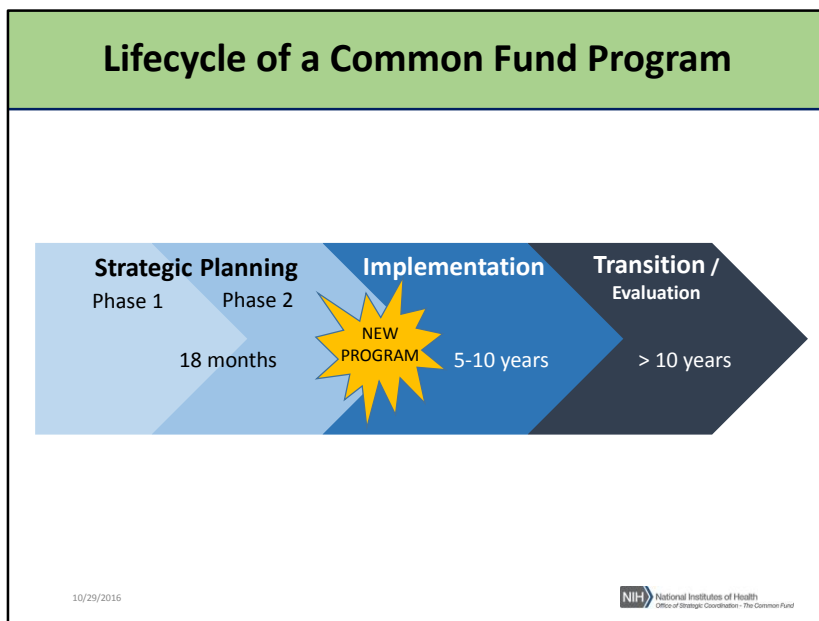
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In addition to formulating and answering questions, involvement of evaluators early can help with setting program goals, milestones, and metrics can aid program monitoring and outcome evaluation.



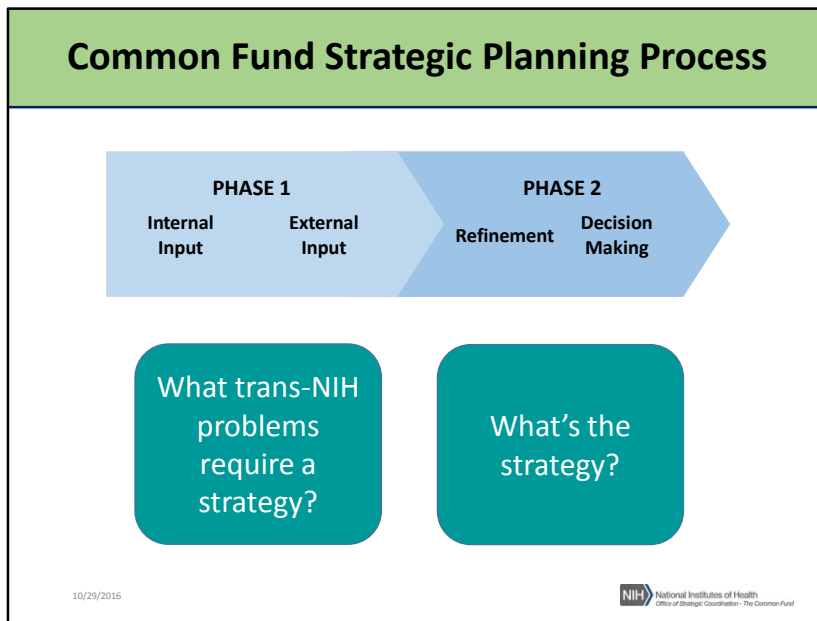
How is Strategic Planning conducted for NIH Common Fund programs?



As shown in this graph, our strategic planning process takes about 18 months and involves 2 phases.

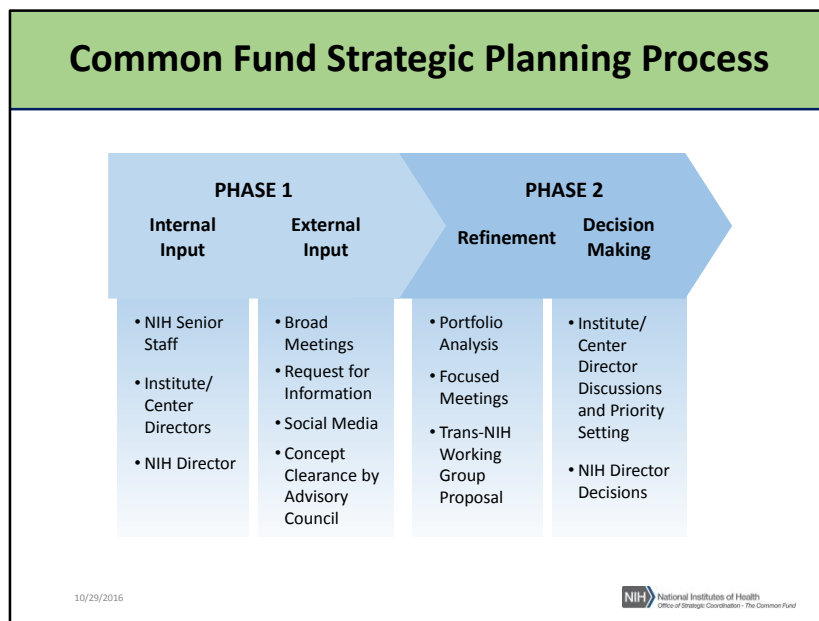
Once a program is approved, it is supported by the Common Fund for 5 to 10 years.

Toward the end of the program, plans are made for transitioning what has been learned and developed by the science program to the NIH ICs, NIH partners, and/or the biomedical industry.



As we focus on the strategic planning process of research programs, each phase is guided by overall questions.

- During Phase 1, “What trans-NIH science problems require a strategy?”
- During Phase 2, “What’s the strategy to deal with these problems?”



This graphic focuses on the various pieces of our strategic planning process for Common Fund programs.

Key principles underlying strategic planning:

- Input is sought from people representing the perspectives of all ICs
- The trans-NIH, national, and international research portfolios are reviewed to assess current level of support in potential program areas
- NIH Leadership is engaged in strategic planning, so that efforts are focused in areas of greatest enthusiasm and potential science impact

During Phase 1: Identification of broad topic areas that address the biggest challenges and greatest opportunities in biomedical research

During Phase 2: Refinement of broad areas into well-defined programs and initiatives.

During both phases, we seek input from a variety of people and sources.

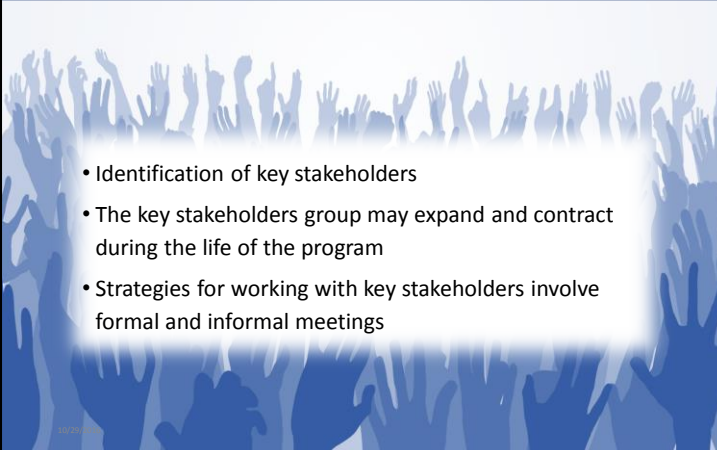
Methods to Answer Program Planning Questions						
	NIH Portfolio Analysis	Other Federal Agencies	Landscape Analysis	Pubs/ Review of Lit	Experts Input	Stakeholders
What is known about the science?				✓	✓	✓
Who is conducting the research?	✓	✓	✓	✓	✓	✓
Who is funding the research and for how much?	✓	✓	✓		✓	✓
What is the major obstacle/ challenge / opportunity that the Common Fund should address?	✓	✓	✓	✓	✓	✓
Why is now the right time to address this topic?	✓	✓	✓	✓	✓	✓
What would the goals of the program be?					✓	✓
What is the expected or potential outcome / impact of a program?					✓	✓

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This matrix shows the questions that we need to answer for strategic planning along with the evaluative methods we used.

Stakeholders and Experts are Key for Program Planning



- Identification of key stakeholders
- The key stakeholders group may expand and contract during the life of the program
- Strategies for working with key stakeholders involve formal and informal meetings

1) **As we identify key stakeholders, we consider the following:**

- Diverse perspectives/experiences/ Expertise
- Responsibility; decision authority; program implementers/ Influence / Interest /Support
- Users of program outcomes and resources developed

2) **Common Fund Program Key Stakeholders**

- Common Fund staff and Trans-NIH staff (including top IC administrators and science administrators)
- External scientists
- Industry – pharmaceuticals, devices, research tools/instruments/software
- Depending on the programmatic topic – policy advocates, clinicians, other govt agencies, NGOs, international groups

3) **Strategies for working with key stakeholders involve Formal and informal meetings of stakeholders.** We also consider: Time/ Budget/ Stakeholder location/ Stakeholder availability/ Tensions & values that may shape a program

The Program Evaluation Standards addresses “attention to stakeholders” as one of the standards for guiding evaluation. **Engaging Stakeholders:**

- PUTS MORE IDEAS on the TABLE
- Gains **buy-in and support** from all sectors
- **Strengthens your position if there’s opposition**
- **Contributes to the program logic** and framing of key evaluation questions
- **Facilitates quality data collection**
- Helps to **make sense of the data** that has been collected
- **Increases the utilization** of the findings (i.e., success) by building knowledge about and support for the planning process.

Other Resources:

- Bryson & Patton in Wholey et al, *Handbook of Practical Program Evaluation, 3rd edition* have a nice stakeholder engagement planning matrix that may be helpful to you.

“Using Evaluation Tools, Methods, and thinking in Planning NIH Common Fund Programs”

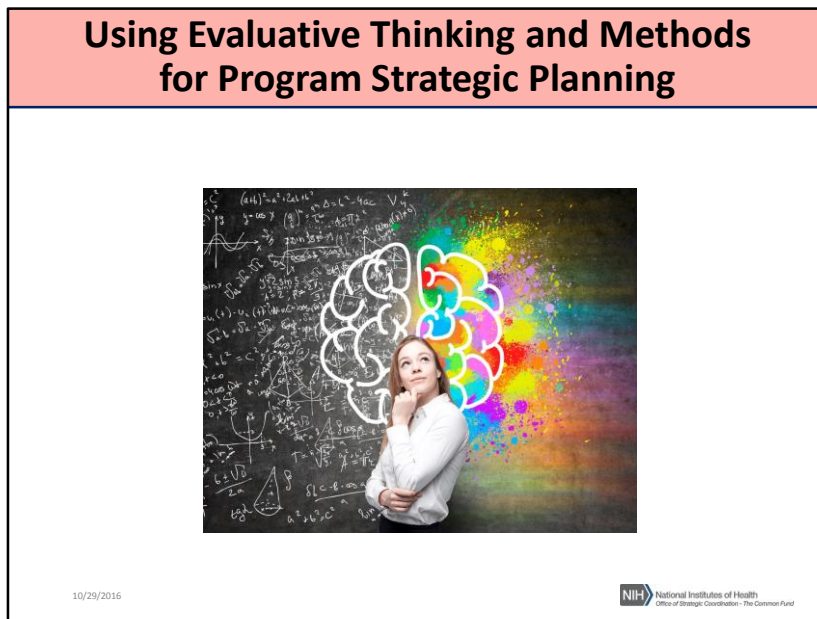
- Hallie Preskill & Nathalie Jones (2009) published *A Practical Guide for engaging stakeholders in developing evaluation questions*.



During the process of planning programs, we:

- Seek input from stakeholders and experts – internal and external – multiple times
- And at the same time, we collect information, refine data collection terms and boundaries based on findings, and refine data collection

So as shown in this picture, planning is an iterative process.



Now that you see how we conduct our strategic planning, we'll move on to the evaluative methods and thinking that we use.

As shown in this picture, we take a variety of information and using evaluative thinking help turn it into products of Strategic Planning like a program design, or assessment plan.

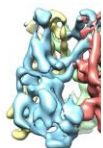
Case Example: Transformative High Resolution Cryo-Electron Microscopy Program

What is Cryo-Electron Microscopy (CryoEM)?



CryoEM technology dramatically improves our ability to see biological molecules at near atomic resolution.

Old Metho



New Methods



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What is CryoEM?

- A method for imaging biological samples at cryogenic (very cold) temperatures using transmission electron microscopy
- Allows the study of fine cellular structures, viruses and protein complexes at near atomic resolution
- Biological specimens remain in their native state without the need for dyes or fixatives, allowing the study of fine cellular structures, viruses and protein complexes (i.e., less alteration to specimen)
- Revolutionizing structural biology and overthrowing older methods such as x-ray crystallography, so that we can see how the essential machinery of the cell operates.

Case Example: Transformative High Resolution Cryo-Electron Microscopy Program

What is Cryo-Electron Microscopy (CryoEM)?



What is it used for?

Examples:

- Investigation of protein linked to Alzheimer's disease
- Imaging Ebola, Dengue, and Zika viruses for vaccine development

Need for a Common Fund Program

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What is CryoEM used for?

Use of CryoEM can reveal precisely how the essential machinery of the cell operates and how molecules involved in disease might be targeted with drugs

Some examples of early use include:

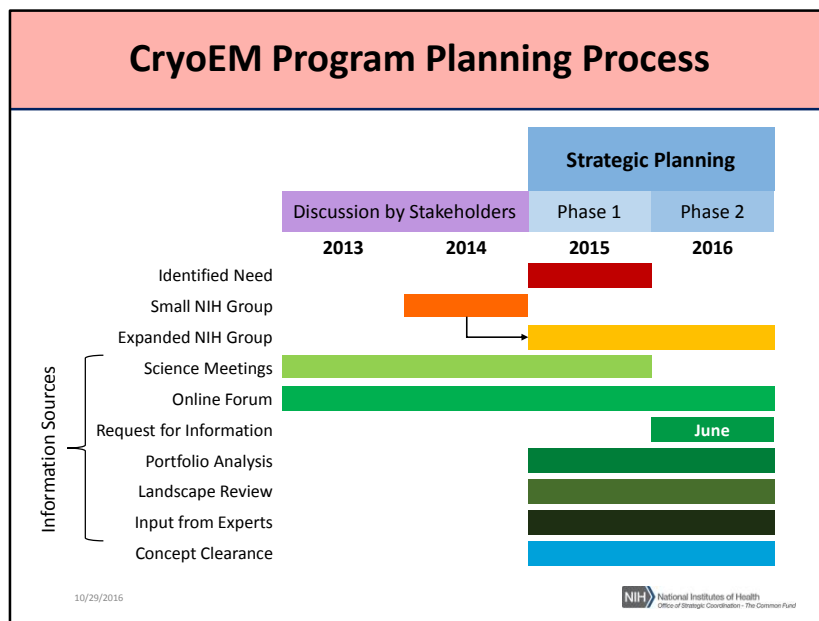
- Investigation of a protein linked to Alzheimer's disease-may aid drug development
- Imaging Ebola, Dengue, & Zika viruses to aid in vaccine development

Why is a Common Fund program for CryoEM needed now?

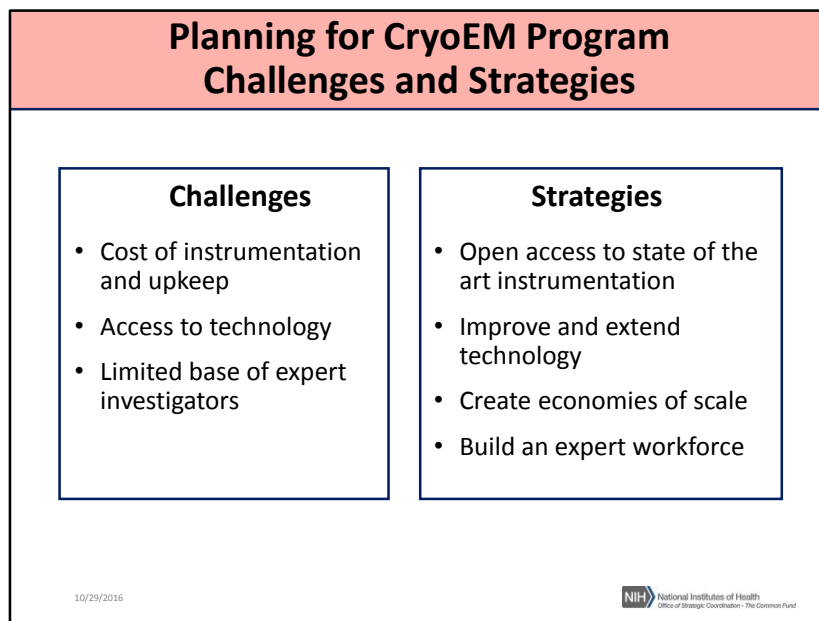
New improvements in technology and analysis has opened up/revolutionized this field and portends future rapid developments in understanding disease and preventing/treating disease—knowing the cellular structure allows us to develop prevention/treatment strategies

What is needed?

- Access to microscopes and trained personnel (cost prohibited)
- Training on scopes, sample preparation, and analysis
- Further development and refinement of technology and image analysis



- Strategic planning for CryoEM is iterative and ongoing...as indicated by the bars on this timeline.
- The idea for a CryoEM program supported by the Common fund emerge4d from NIH scientists and other experts, science meetings, and online discussions. This is reflected on this timeline in 2013-2014.
- Scientists at a couple of Institutes and Centers (ICs) were discussing how to advance the potential of CryoEM. In 2015, one of the ICs suggested that the Common Fund support a CryoEM program.
- A group of key stakeholders from 7 ICs plus staff from the Common Fund came together and continued to refine the program topic through Phase 1 .
- Additional information about the state of the science related to CryoEM was collected from experts, portfolio analysis, landscape reviews, etc.
- In June 2016. a public request for information (RFI) related to the use of CryoEM was released. NIH received 46 responses by close in Aug 2016. Theses were categorized by:
 - Need and Capacity
 - Training and Workforce
 - Technology Development

**As planning for this program has evolved, several challenges have been identified related to:**

- Cost of instrumentation and upkeep
- Access to high performance data collection
- Limited base of expert investigators

In an effort to address these challenges, our current plan for this program is to:

- Create open access centers
- Provide training
- Develop new technology & methods
- Work collaboratively with other agencies and organizations

These strategies are currently being refined prior to final decisions are made about launching this Common Fund program.



- The CryoEM planning example that we just discussed reflects the result of how strategic planning has evolved at the NIH Common Fund.
- Since the beginning of the Common Fund, the expansion of data collection for strategic planning has become more systematized while remaining flexible to new input and discoveries.
- There has been a shift over time in the approach and thinking about strategic planning. This includes embracing evaluative thinking and methods that can benefit this process.
- Evaluative thinking is important in the identification and development of program goals, milestones, and metrics.
- In the future, we hope to make Strategic Planning processes using evaluative thinking and methods more efficient and effective.
- The hope is that strategically planning Common fund programs more effectively will translate into intended outcomes and impact that ultimately enhance health, lengthen life, and reduce illness and disability.

Acknowledgements

NIH Common Fund Staff

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For more information about the NIH Common Fund

<https://commonfund.nih.gov>

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