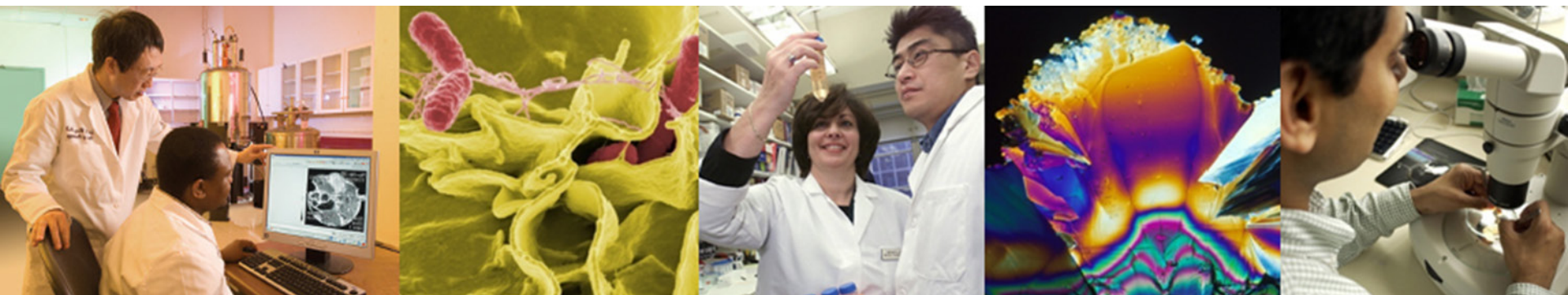


Developing the NIH-wide Strategic Plan

DPCPSI Council of Councils

September 1, 2015



Lawrence A. Tabak, DDS, PhD
Principal Deputy Director, NIH
Department of Health and Human Services



Background

CROmnibus H.R. 83 - 346 (enacted December 16, 2014)

- NIH shall submit to Congress an **NIH-wide 5-year scientific strategic plan** no later than 1 year after enactment

21st Century Cures Act, Section 1021 (pending)

- Within 270 days of enactment, develop and maintain a 5-year biomedical research strategic plan
- Use of Plan: Identify research opportunities and develop individual strategic plans with a common template for the research activities of each IC
- Contents: Plans shall identify **strategic focus areas** that consider **return on investment**. This includes overarching and trans-NIH strategic focus areas, known as **Mission Priority Focus Areas**
- Ensure that **rare and pediatric diseases** remain a priority
- Ensure that maintaining the **biomedical workforce** remains a priority

Goals of the NIH-Wide Strategic Plan

- Develop a “living document” that will help guide NIH in fulfilling its mission over the next 5 years
- Articulate approaches and opportunities that are forward-looking and inspirational in nature
- Identify major trans-NIH themes that will advance biomedical research

What the Strategic Plan Should and Should Not Be

- The strategic plan should clearly articulate the highest priorities of the NIH overall
- The strategic plan should describe how the NIH will achieve the highest priorities
- The strategic plan should be a living document that will require refinement throughout its lifecycle
- The strategic plan should not describe all the many important things that NIH does and will do in the future
- The strategic plan should not address priorities of the individual Institutes, Centers, and Offices (ICOs) since each of the ICOs has their own strategic plan (that will each be referenced in the executive summary of the NIH strategic plan)

Development of the Strategic Plan

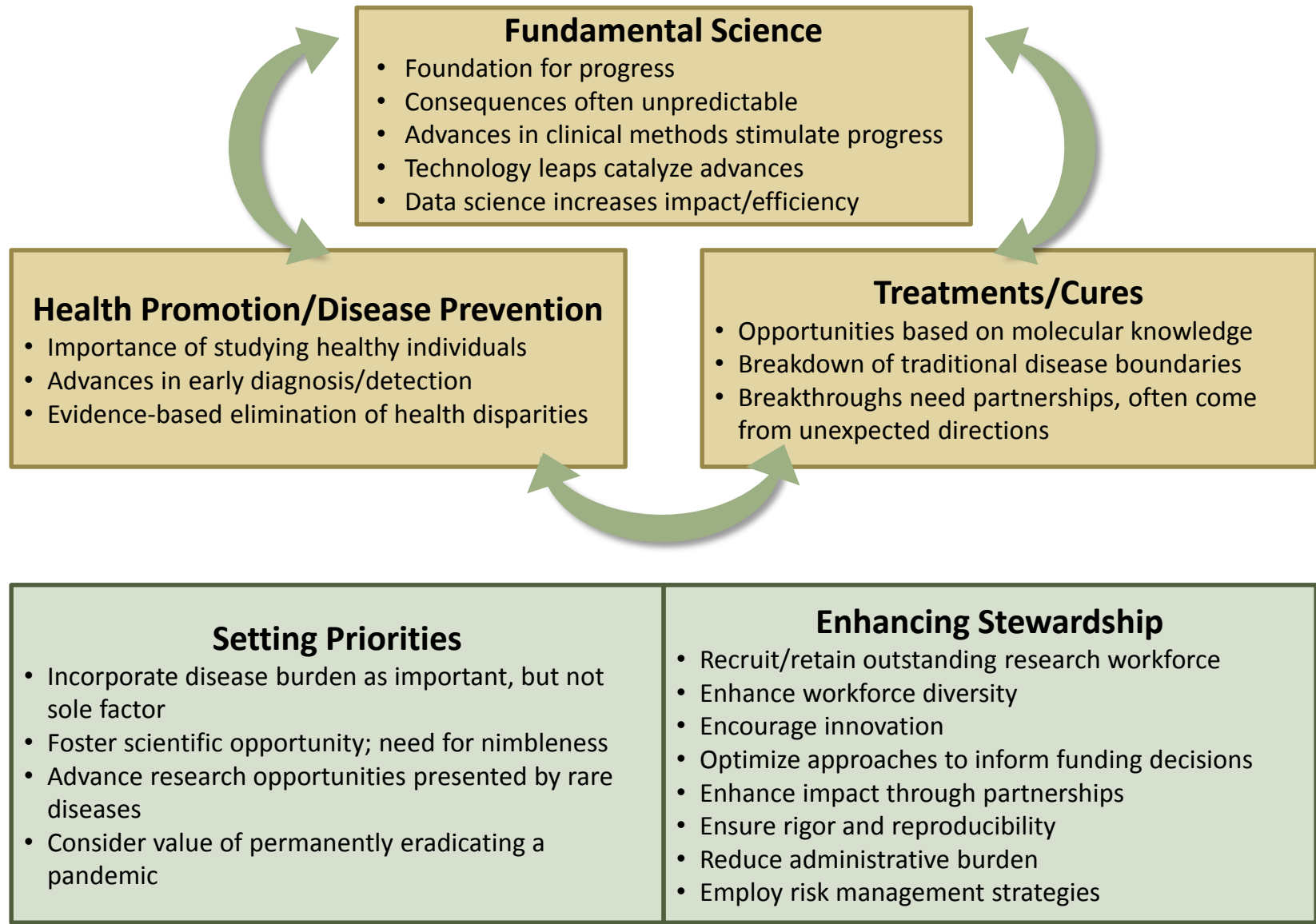
- Initial involvement by NIH senior leadership
- Involvement of ICOs – Working Group
 - Receive feedback from ICO representatives weekly
 - Five DPCPSI representatives on the working group
 - Critical in developing the contents and research examples
 - Over 80 “call-out” examples received

Development of the Strategic Plan (cont.)

- Review and input from the ACD
 - Have met twice to review overall plan and framework
 - Received positive comments on most recent framework
 - Advocated for additional emphasis on the interconnected nature of the research, and the inclusion of clinical methodologies, data science, and workforce retention
- The NIH Director is monitoring progress carefully and will oversee development of the final document

Overview

- Mission of NIH
- Unique moment of opportunity in biomedical research
- Current NIH-supported research landscape
- Constraints confronting the community in the face of lost purchasing power



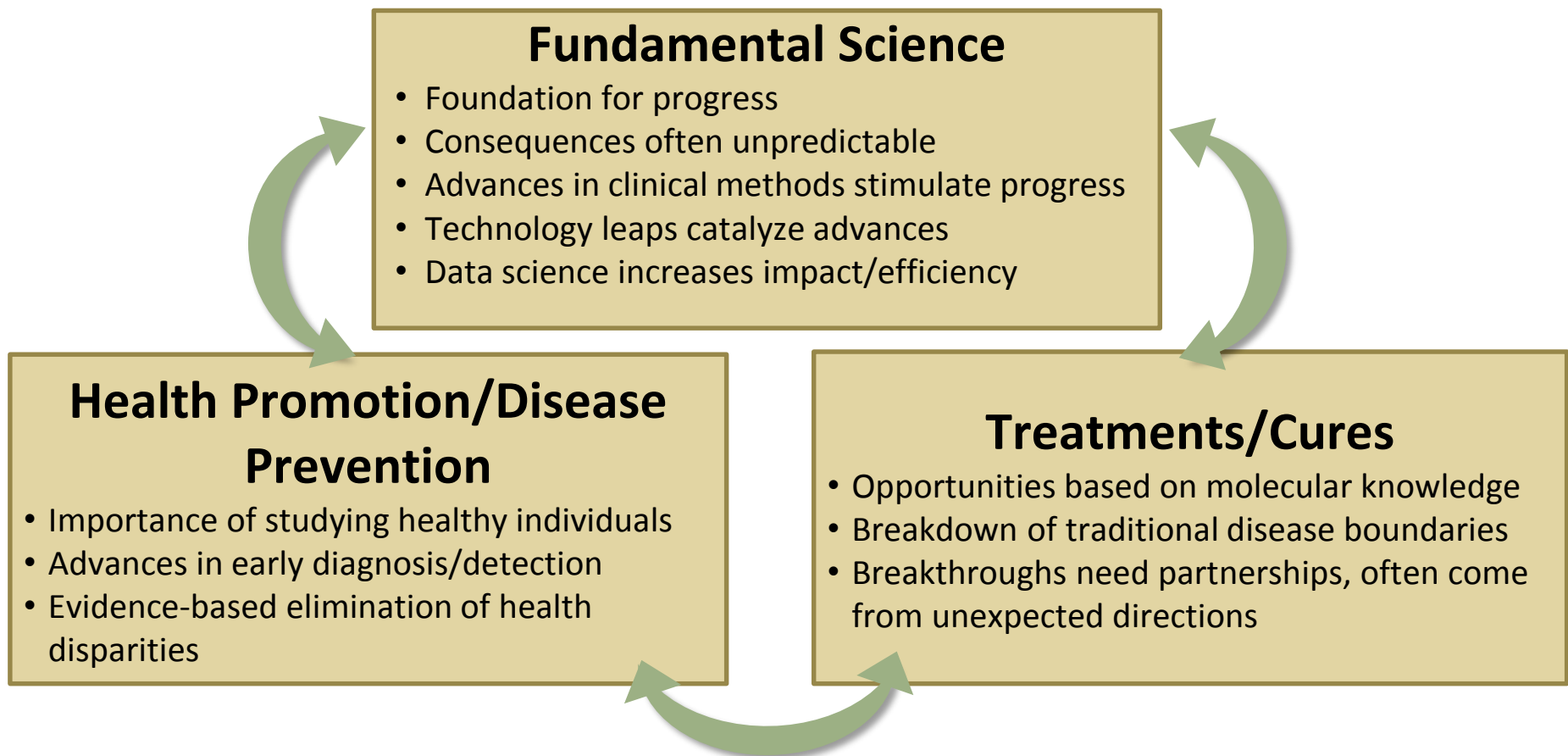
Draft Framework (cont'd)

Overview

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Draft Framework (cont'd)

■ Areas of Opportunity that Apply Across Biomedicine

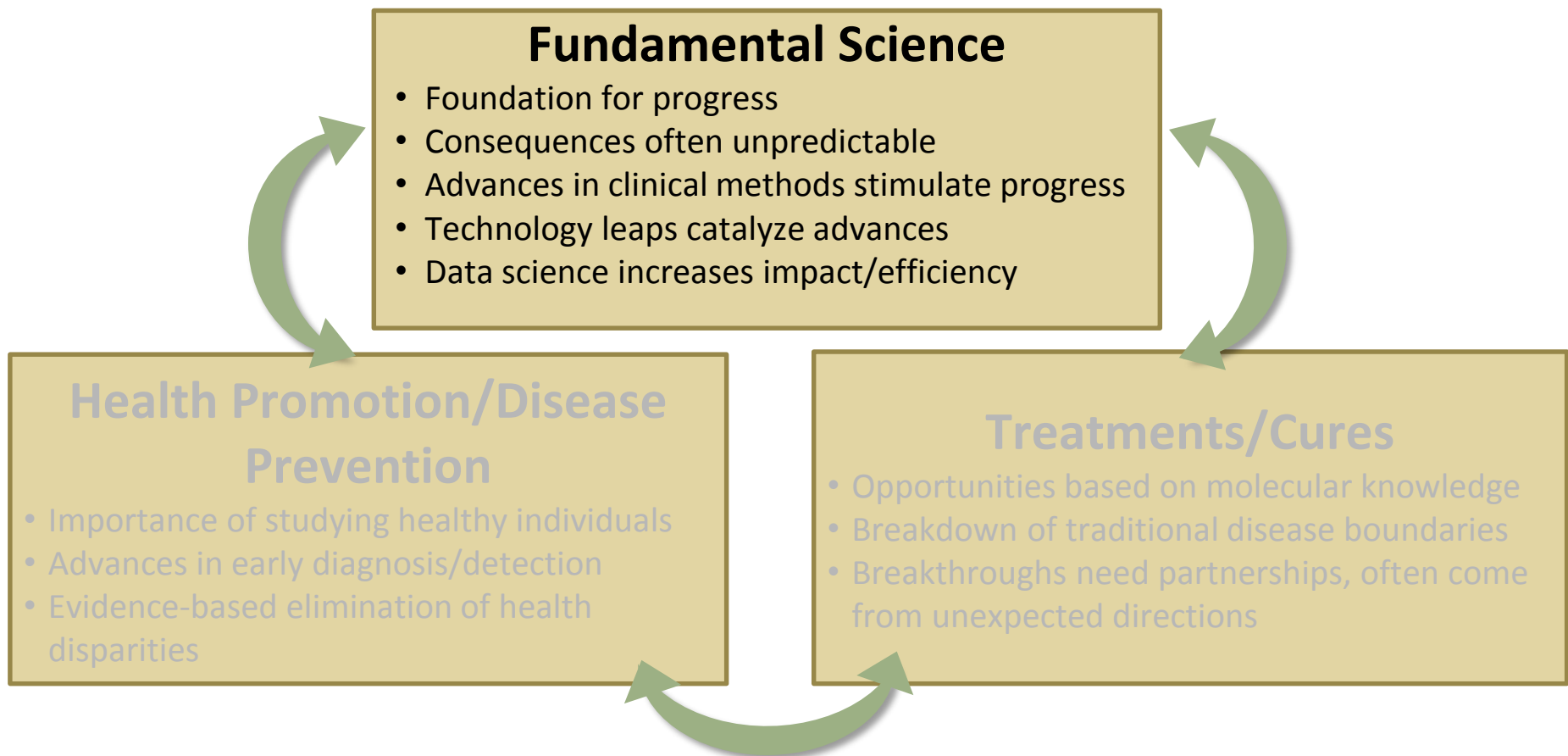


Draft Framework (cont'd)

- **For each of the Areas of Opportunity:**
 - We will have a succinct description of emergent opportunities (and what NIH needs to realize the opportunities)
 - We will also highlight specific examples of recent breakthroughs – “Research Call-Outs”

Draft Framework (cont'd)

■ Areas of Opportunity that Apply Across Biomedicine



Illustrative Examples: Fundamental Science

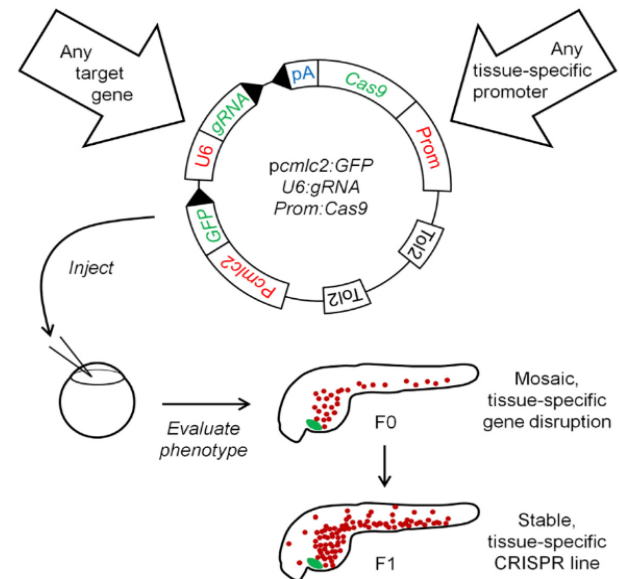
By studying fundamental questions about microbial diversity, scientists made unpredictable discoveries:



Human Metaorganism
Credit: National Cancer Institute

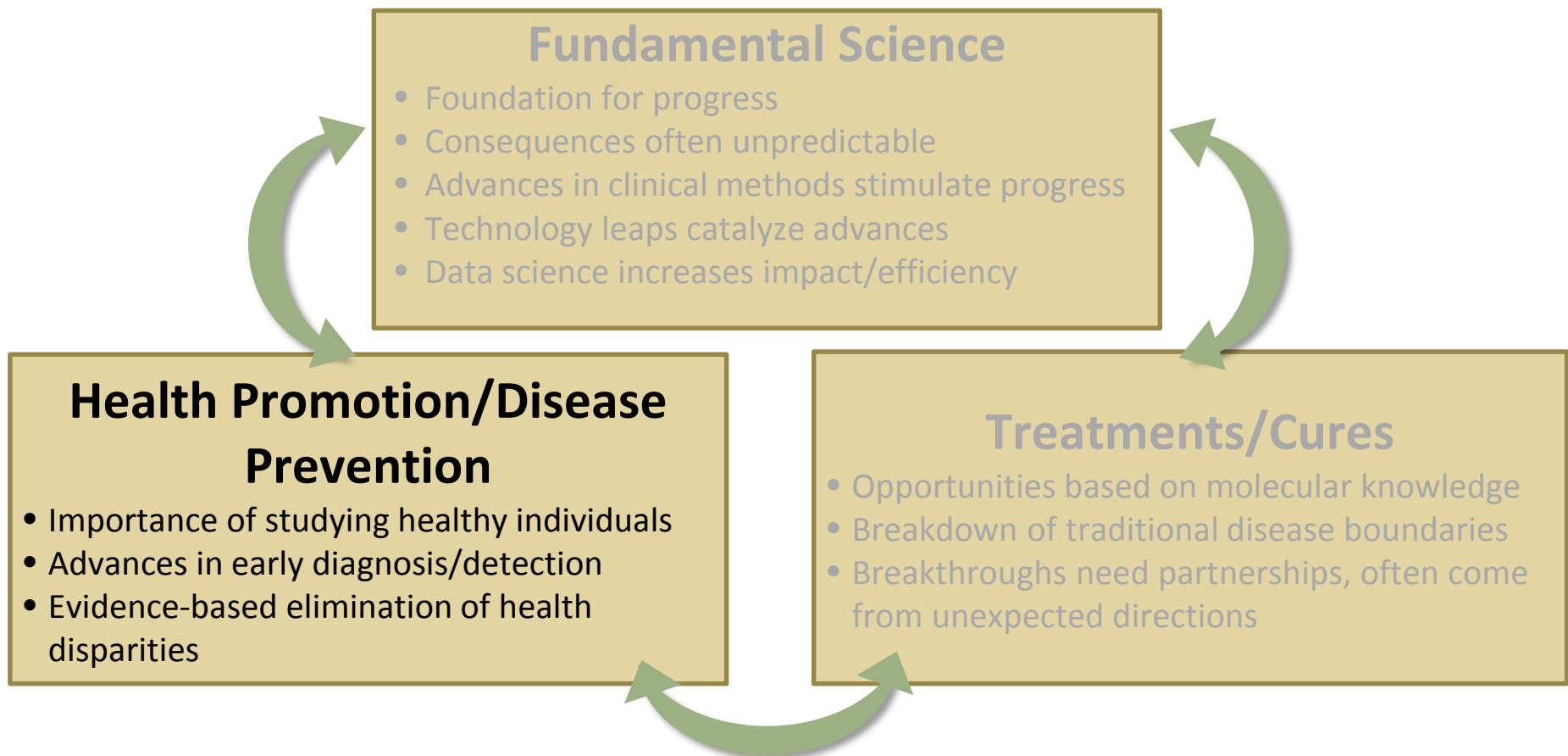
- The role of the gut **microbiome** in immune system development and disease

- Bacterial defense mechanisms that led to the new Clustered Regularly Interspaced Short Palindromic Repeats (**CRISPR**) genome editing technology



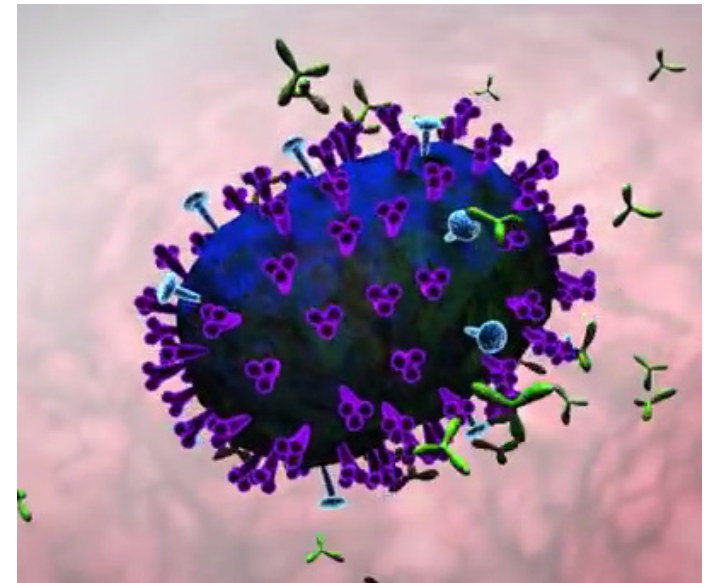
Draft Framework (cont'd)

■ Areas of Opportunity that Apply Across Biomedicine



Illustrative Examples: Health Promotion and Disease Prevention

- NIH is a global leader in vaccine design and development
- The **Vaccine Treatment and Evaluation Units** comprise a clinical trials network that evaluates promising vaccine candidates and can rapidly test vaccines designed to counteract emerging public health concerns

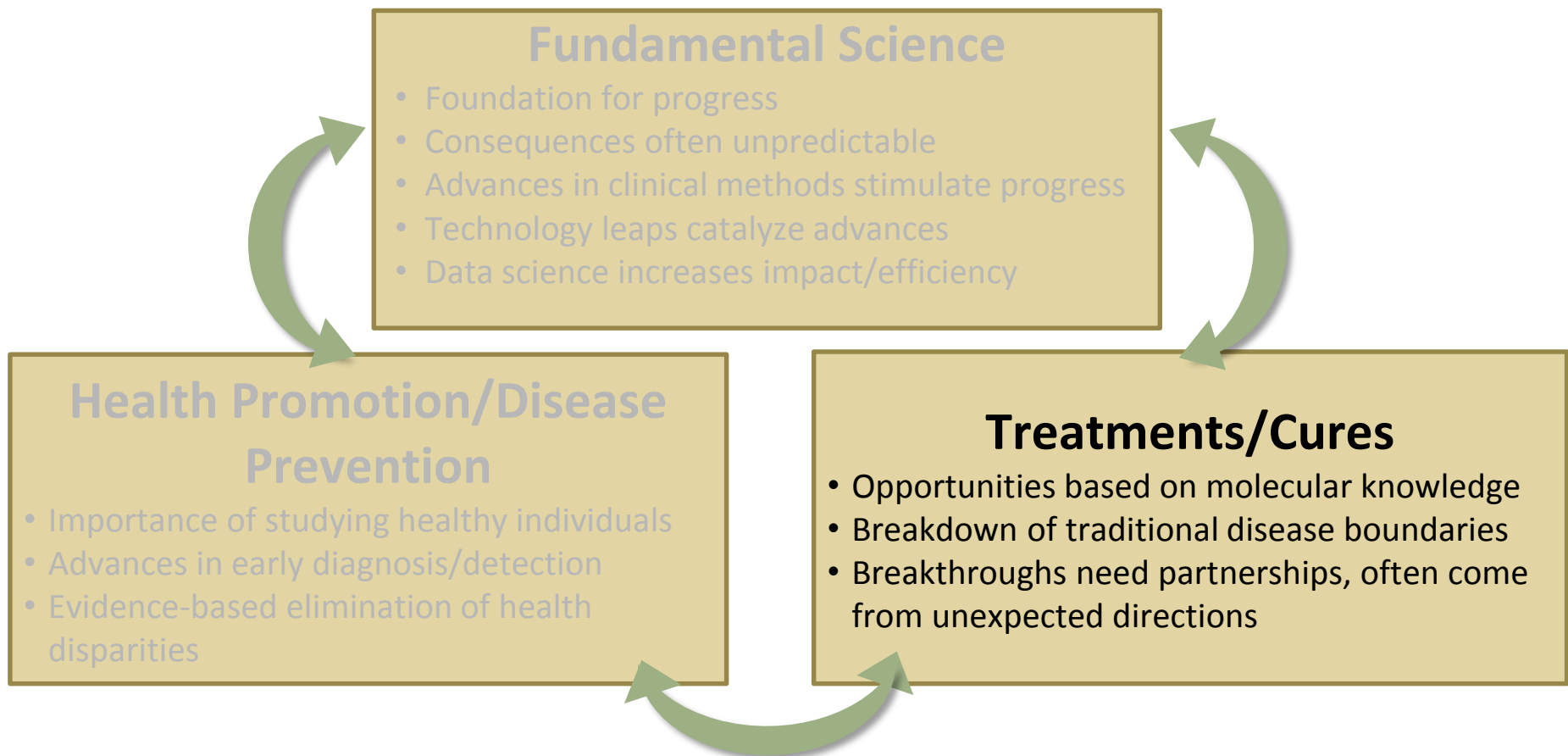


Influenza virus

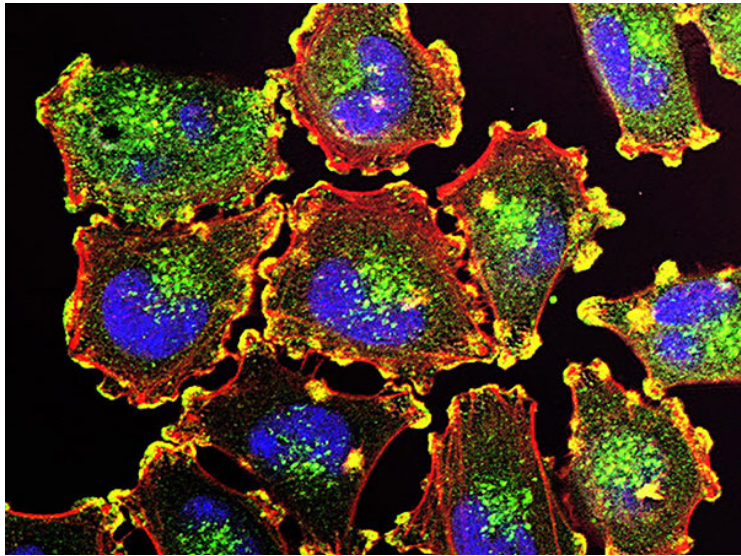
Credit: National Institute of Allergy and Infectious Diseases

Draft Framework (cont'd)

■ Areas of Opportunity that Apply Across Biomedicine



Illustrative Examples: Treatments and Cures



Metastatic melanoma cells
Credit: National Cancer Institute

Opportunities to discover new treatments and cures on the basis of molecular knowledge are tremendous:

- Cancer researchers have found commonalities in the pathways and processes that lead to abnormal tissue growth in various cancer types, resulting in breakthroughs in **cancer immunotherapy**

Draft Framework (cont'd)

■ Unifying Principles

Setting Priorities

- Incorporate disease burden as important, but not sole factor
- Foster scientific opportunity; need for nimbleness
- Advance research opportunities presented by rare diseases
- Consider value of permanently eradicating a pandemic

Enhancing Stewardship

- Recruit/retain outstanding research workforce
- Enhance workforce diversity
- Encourage innovation
- Optimize approaches to inform funding decisions
- Enhance impact through partnerships
- Ensure rigor and reproducibility
- Reduce administrative burden
- Employ risk management strategies

Draft Framework (cont'd)

- **For each of the Unifying Principles:**
 - We will have a description of the current status and/or emergent opportunities (and what NIH needs to realize the opportunities)
 - We will also highlight specific examples of recent breakthroughs – “Stewardship Call-Outs”

Draft Framework (cont'd)

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Illustrative Examples: Setting Priorities

Treatments and cures for diseases are invaluable even when the affected population size is small

- The NIH Clinical Center is an important hub for **rare disease research**
 - Facilitates intramural-extramural collaborations and accelerating new therapeutic discoveries
 - Supports the Undiagnosed Disease Program (UDP) which has recently been expanded to include several extramural sites

Draft Framework (cont'd)

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Illustrative Examples: Enhancing Stewardship

Enhancing impact through partnerships:

- The Accelerating Medicines Partnership (**AMP**) is a partnership among the NIH, FDA, 10 pharmaceutical companies, and nonprofit organizations to develop new diagnostics and treatments by identifying and validating promising biological targets



Outreach and Feedback: NIH Webpage



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Visitor Tours
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NIH Publications List

NIH Strategic Plan

Register for the NIH-wide Strategic Plan Webinars:

- Wednesday, August 5, 3:00pm-4:30pm ET
- Tuesday, August 11, 3:30pm-5:00pm ET
- Thursday, August 13, 4:00pm-5:30pm ET

RFI on Framework for the NIH-wide Strategic Plan

[NIH Strategic Plan Framework \(Printable PDF\)](#)  (PDF - 166KB)

In order to advance its mission and fulfill a request from Congress, NIH is developing a 5-year NIH-wide Strategic Plan to outline a vision for biomedical research that will pursue fundamental knowledge about the nature and behavior of living systems and apply that knowledge to extend healthy life and reduce illness and disability. NIH senior leadership and staff from all 27 Institutes, Centers, and Offices (ICOs), with input from the Advisory Committee to the Director of NIH, have developed a framework for the Strategic Plan.

The framework outlined below identifies areas of opportunity that apply across biomedicine and unifying principles to guide NIH in supporting the biomedical research enterprise. The aim is to exemplify the breadth of ICO priorities by identifying major cross-cutting themes. The myriad of important research opportunities for specific disease applications are covered in individual strategic plans from each ICO, and thus will not be the focus of this larger NIH-wide Strategic Plan. The NIH-wide Strategic Plan is due to the Congress in December 2015.

<http://www.nih.gov/about/strategic-plan>

Outreach and Feedback: RFI

- Closed on August 16, 2015; ~460 responses
 - Mostly positive comments on the framework
 - **Broad suggestions:** Emphasize implementation and interdisciplinary science
 - **Specific suggestions:** Promote use of big data, emphasize population health, change peer-review process
 - **Disease-specific comments:** Advocated for greater focus on mental illness and ME/CFS/SEID

Outreach and Feedback: Webinars

- ACD and Community Participation
 - August 5: Dr. Cori Bargmann; ~235 participants
 - August 11: Drs. Eric Goosby, Helen Hobbs, and Cato Laurencin; ~285 participants
 - August 13: Dr. Ian Lipkin; ~200 participants
- Feedback
 - We received questions/suggestions on workforce training, **patient partnerships**, peer review, more explicit inclusion of **behavioral and social sciences**, basic vs. applied research, **systems approaches**, **interdisciplinary research**, and the process for developing the plan

Timeline

Activity	Timeframe
Assemble a subgroup of IC Directors (7-8) to develop the plan, informed by available DPCPSI framework	April - May
Discuss draft plan with IC Directors	Early June 2015
Present planning process to the ACD, requesting input and their help engaging the public	June 11-12
Call with HHS	July 10th
Call with ACD members	July 20th
Public comment period (i.e., RFI)	July/August 2015
Publish RFI	July 20th
Webinars	Early to Mid-August
Analyze and incorporate RFI feedback	Mid-August to September
Share with National Advisory Councils and gather feedback	September
Brief DHHS (Draft submitted for clearance)	By October 15
Incorporate all feedback	October/November 2015
Brief key Hill staff/members	Fall 2015 (late Oct/early Nov)
Distribute plan to ACD members	By November 23
Present at December ACD meeting	December 10-11, 2015
Send to Congress	Mid-December 2015

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Questions for Discussion

- What are the benefits and drawbacks of the framework structure and content?
- Is the framework compatible with the broad scope of the NIH mission?
- Are there any trans-NIH themes that have not been captured?
- Are there future opportunities or emerging research needs that should be included?



NIH...

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Turning Discovery Into Health

