SCIENTIFIC MANAGEMENT REVIEW BOARD

REPORT ON APPROACHES TO ASSESS THE VALUE OF BIOMEDICAL RESEARCH SUPPORTED BY NIH

MARCH 2014

DEPARTMENT OF HEALTH & HUMAN SERVICES USA

NIH National Institutes of Health
Turning Discovery Into Health

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ACKNOWLEDGMENTS

Members of the Scientific Management Review Board (SMRB) would like to thank the following individuals for their assistance in developing this report:

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CONTENTS

EXECUTIVE SUMMARY

The Scientific Management Review Board (SMRB) was established under the National Institutes of Health (NIH) Reform Act of 2006 to advise the NIH Director and other appropriate officials on the use of certain organizational authorities reaffirmed under the same act. In July 2012, the SMRB was charged by NIH Director Francis Collins with helping to identify appropriate parameters and approaches for assessing and communicating the value of biomedical research supported by NIH. NIH is the steward of public investments in biomedical research and strives to uphold high standards of accountability, manage resources effectively, and convey important findings to the public. Improved assessments of the value of NIH-supported biomedical research will help NIH achieve these goals.

In response to the charge, the SMRB assembled the Working Group on Approaches to Assess the Value of Biomedical Research Supported by NIH. The Working Group conducted extensive consultations, were briefed on existing and planned assessment tools and databases, and reported their findings and recommendations to the full SMRB. SMRB members found that the breadth and complexity of the biomedical research enterprise makes the task of assessing its value very challenging. Assessment efforts must contend with lengthy timeframes and unpredictable paths from basic discoveries to tangible outcomes, as well as the many individuals, institutions, industries, and agencies that contribute to these outcomes. These challenges are present when assessing the value of a single area of research and are significantly compounded when assessing the broad range of biomedical research supported by NIH. Therefore, assessing the value of biomedical research supported by NIH requires a systematic, comprehensive, dynamic, and strategic approach.

The SMRB concluded that, at the present time, the essential tools, techniques, and data systems required for developing comprehensive measurements of value at an aggregate NIH level are in the early stages of development. Members identified several ways to improve NIH's assessment efforts, recommending the following:

1) NIH should intensify its efforts to assess systematically, comprehensively, dynamically, and strategically the value of biomedical research for the purposes of accountability, effective management, and public awareness. This will require a sustained investment in strengthening NIH's data infrastructure and a dedicated funding stream or mechanism to support assessment projects.

2) Assessments of the value of NIH-supported research should examine connections between the generation and communication of basic and clinical knowledge and the impact of this knowledge along differing translational pathways.

3) Credible, interpretable, and useful assessments of the value of NIH-supported research should, to the extent possible: (i) attribute outcomes to all contributors and (ii) adopt a timeframe that is long enough to include sufficient time for discoveries to be applied.

4) NIH's assessments and the development of assessment tools, techniques, and databases should be done in partnership with its many stakeholders. Given that the study of a process (including the metrics used for analysis) may alter the process itself, NIH should avoid assessment activities that could negatively influence the conduct of research.

5) NIH should establish a trans-NIH Committee on Assessments of the Value of Biomedical Research that will:

   a. Develop a strategy to support or conduct assessments of value, including through grants or contracts with external experts;

   b. Determine a process for strategically selecting study topics that map to a conceptual framework, including different translational pathways;

   c. Oversee (in conjunction with NIH's recently established "Big Data" committees) NIH efforts to strengthen data needed for assessing value, including:

      i. Identifying and gaining consensus on a core set of indicators to be included in its data infrastructure and

      ii. Creating better data linkages with NIH's partners and hand-off sectors;

   d. Adopt a systematic approach to designing case studies that can both illustrate the research process and illuminate the outcomes;

   e. Identify promising analytical approaches and develop an assessment approach guide that outlines the factors to consider and the mix of methodologies (e.g., retrospective, prospective, qualitative, quantitative) that should be employed in attempting to capture value; and

   f. Seek input from external experts in the development of methods and tools to improve assessments of the value of biomedical research.

6) Every assessment activity that NIH undertakes should begin with identifying the purpose of the study and its audiences. Assessment study designs should include diverse communication strategies to disseminate results in ways that will enhance awareness and understanding of the scientific research process among a variety of audiences.

The findings and recommendations of the SMRB are described in detail in the following report.

I. INTRODUCTION

The American public has entrusted the National Institutes of Health (NIH) with the Nation's largest investment in biomedical research. NIH's mission is to support scientific research aimed at enhancing health, lengthening life, and reducing illness and disability. Throughout its 120 years of existence, NIH has contributed to many of the scientific breakthroughs that have led to tangible improvements in the health of the public. Yet, systematically and comprehensively capturing these improvements in ways that clearly link them to the public's investment in NIH remains a significant challenge.

As a steward of public funds, NIH is responsible for using its resources effectively to address the many health challenges that face our Nation and the world. When reviewing proposed projects and setting research priorities, NIH uses a well-established, rigorous decision-making process that relies on scientific expertise and stakeholder input. As a Federal agency, NIH is obligated to demonstrate the effectiveness of its stewardship of public funds and to communicate the results of its efforts. Accurate and comprehensive assessments of which management or research approaches are most effective could also enhance NIH's priority-setting and decision-making processes and help NIH further increase the value it provides.

Today, because of increasing data sophistication and greater access to information, there are opportunities for NIH and similar agencies around the globe to improve their understanding of the full range of outcomes. In addition, NIH and other funding institutions must make difficult decisions about how to advance biomedical research with finite resources and face additional pressures during the current era of constrained budgets and economic challenges, thereby providing further incentive to understand which research activities tend to generate the greatest value.

The first steps in designing an assessment of the value of biomedical research are to establish guidelines and principles to ensure that the results are credible. For this reason, the NIH Director charged the NIH Scientific Management Review Board (SMRB) with helping to identify the best strategies and methods for assessing the value of NIH-supported research. Specifically, the SMRB is charged with:

- Undertaking a comprehensive analysis of the strategies and methods used in assessing the value of biomedical research;
- Defining the fundamental principles that should underpin any strategy used in assessing the value of investing in NIH; and
- Identifying strategies to be used in assessing the value of NIH-supported research that are scientifically sound and reflect the diverse outcomes related to this investment.

In undertaking this charge, the SMRB created the Working Group on Approaches to Assess the Value of Biomedical Research Supported by NIH to:

- Analyze studies assessing the value of biomedical research across nations and sectors to consider the strengths and weaknesses of different approaches;
- Define a range of diverse outcomes that are or may be attributable to NIH activities, including improvements in human health, advances in knowledge, technological innovations, economic benefits, etc.;
- Identify strategies for assessing the value of biomedical research and articulate the rationale for their selection;
- Seek input regarding assessment approaches from the general public and stakeholders in the biomedical research community, as well as from individuals with expertise in assessing health, scientific, technological, economic, and broader societal impacts of publicly funded research and development in the U.S. and abroad;
- Hold deliberations in conjunction with the full SMRB; and
- Report findings and conclusions to the full SMRB.

Over the course of its deliberations, members of the Working Group reviewed many studies that assess the value of the biomedical enterprise; considered the merits of models, tools, and databases currently used in value assessments; reviewed reports that survey commonly used methods in measuring research; and heard from a broad range of stakeholders and experts in scientific assessment, health, economics, international research, management, and information technology. The Working Group and the entire Board greatly appreciated the time and effort of those who made presentations to the SMRB (Appendix A). A comprehensive list of reports and studies reviewed by the Working Group can be found in Appendix B.

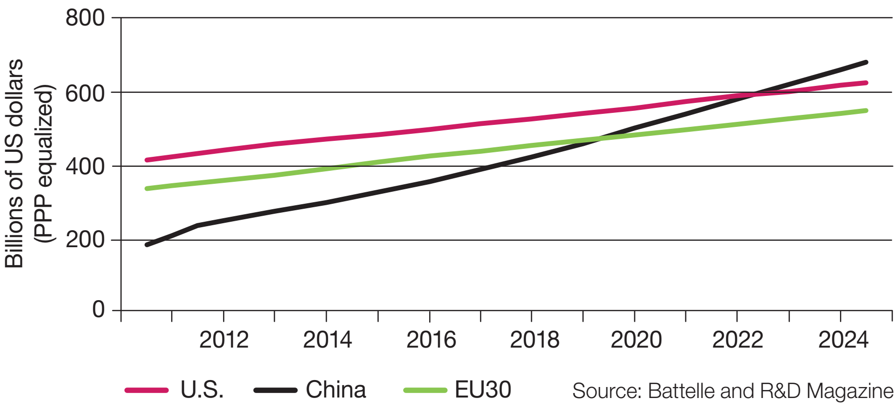
II. OVERVIEW: ASSESSING THE VALUE OF NIH-SUPPORTED RESEARCH

A. The biomedical research enterprise

Biomedical research includes basic research on biological processes and applied research to understand and alter the course of disease and disability. Many scientific fields contribute to biomedical research, working together to develop a greater understanding of human biology and the diseases and conditions that affect humans. The ultimate goal of biomedical research is to improve human health and longevity by providing a scientific knowledge base that is applied within the health ecosystem. Successful application of this knowledge base to human health is a long and often unpredictable process. The concept of a research continuum is helpful to understanding the significant time and effort it may take to move from discovery to health application. The continuum starts with basic research to identify fundamental biological and behavioral mechanisms and how they go awry. This understanding may then be translated into new approaches to identify and prevent or interrupt disease processes, leading to testing of diagnostic, therapeutic, and preventive approaches and exploring the means by which these new approaches may benefit the public. The length of time from an initial scientific discovery to health impact is substantial and can take many years or even decades.[1,2]

The biomedical research enterprise spans the globe and is supported by multiple sectors, including Federal and State Governments, academic institutions, biotechnology companies, industry, and philanthropic foundations. Each sector has a unique role and advances research, often through the hand-off of knowledge and intellectual property, synergy between experts in different fields, and leveraging of resources. Biomedical research is becoming increasingly global as many countries, recognizing the importance of biomedical research and development (R&D), increase the share of gross domestic product (GDP) spent on biomedical R&D.[3]

Figure 1. Projected R&D spending by the U.S., China, and the European Union (E.U.)



Given China's increasing investment in R&D and higher rate of economic growth, it is projected to surpass the E.U. and U.S. in total R&D spending in the coming decade.

[1] Balas EA, and Boren SA (2000). Managing clinical knowledge for health care improvement. In: Bemmel J, McCray AT, eds. *Yearbook of Medical Informatics 2000: Patient-Centered Systems,* 65–70.

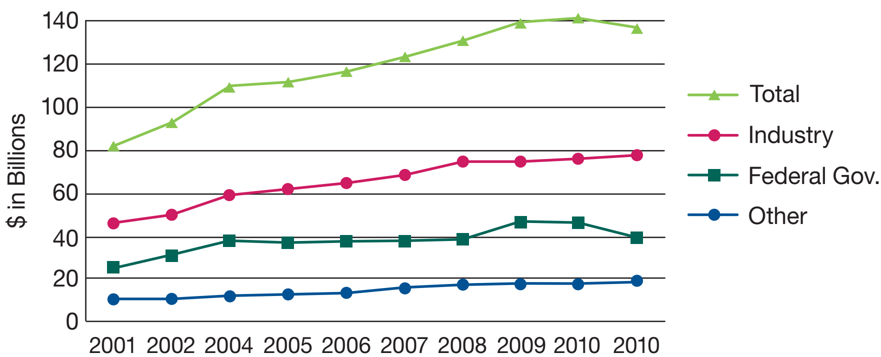
[2] Morris ZS, Wooding S, and Grant J (2011). The answer is 17 years, what is the question: understanding time lags in translational research. *Journal of the Royal Society of Medicine,* 104(12), 510–520.

[3] Chakma J, Sun GH, Steinberg JD, Sammut SM, and Jagsi R (2014). Asia's ascent—Global trends in biomedical R&D expenditures. *New England Journal of Medicine,* 370(1), 3–6.

Figure 1 demonstrates the projected increase in spending by the U.S., China, and the European Union (E.U.) on total R&D,[4] of which biomedical R&D is an important part. Greater international participation in this dynamic and interconnected system can advance research by encouraging collaboration and by pooling resources and risk. As a result, any one scientist may receive support from a growing number of sectors and funders involved in the biomedical research enterprise, and a particular research finding may advance through multiple sectors on what is often a necessarily complex path to health application.

The U.S. leads the world in biomedical research and development spending,[5] with over $130 billion total investments in 2011 (Figure 2). In 2011, the Federal Government provided approximately $40 billion in biomedical research funding, allocating approximately $30 billion of these funds to NIH. The remainder of Federal support for biomedical research is spread across more than a dozen other agencies, including the National Science Foundation (NSF), the Department of Defense, and the U.S. Department of Agriculture. Because the private sector has little incentive to conduct high-risk or early stage research that is decades away from becoming a profitable product, funding from NIH and other government agencies is essential for generating a steady stream of fundamental research discoveries. The government is uniquely positioned to invest in long-range research goals, such as

Figure 2. U.S. Health research investment by sector ($ in billions)[6]



Source: Research|America analysis

Total U.S. investment in health research recently declined due to cuts in federal budgets and slowed health research spending in industry and other sectors.

[4] Battelle and R&D Magazine (2013). *2014 global R&D funding forecast.* http://www.rdmag.com/sites/rdmag.com/files/gff-2014-5_7%20875x10_0.pdf.

[5] U.S. leadership in biomedical R&D is challenged by declining investment by the U.S. government and increased spending by some other countries. For more information, see http://www.unitedformedicalresearch.com/wp-content/uploads/2012/07/Leadership-in-Decline-Assessing-US-International-Competitiveness-in-Biomedical-Research.pdf.

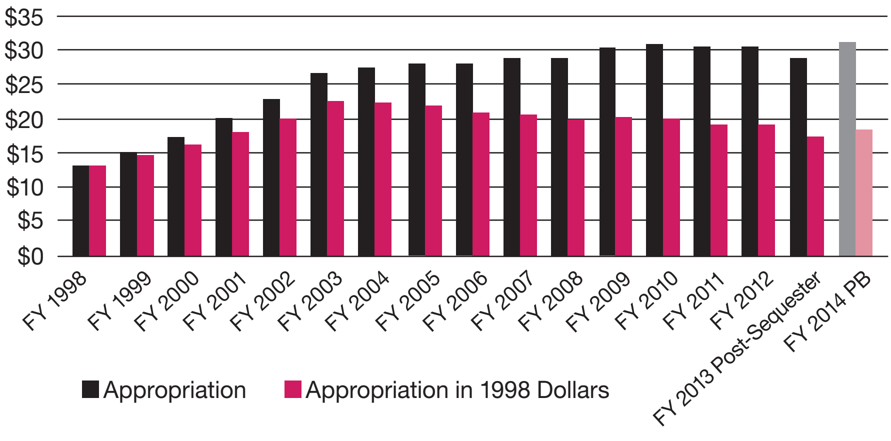
[6] For more information, see http://www.researchamerica.org/research_investment.

basic research and research that is not likely to lead to large profits, such as vaccine development or research that addresses rare conditions. Indeed, such research is likely to slow significantly or come to a halt without government support.

B. NIH's role in the biomedical research enterprise

With its origins as a single-room "laboratory of hygiene" created in 1887 within the Marine Hospital Service,[7] NIH today is the largest public funder of biomedical research in the world. A Federal agency with 27 Institutes and Centers, NIH's $30.86 billion budget in fiscal year 2012 supported approximately 50,000 competitive grants to more than 300,000 researchers at over 2,500 universities, medical schools, and other research institutions that are located in every State and around the world. NIH also supports intramural research projects, including approximately 1,200 principal investigators and 6,000 trainees ranging from high school students to postdoctoral and clinical fellows. Figure 3 portrays U.S. investment in NIH over 15 years.

Figure 3. NIH program level in appropriated dollars and constant 1998 dollars ($ in billions)



The actual buying power of the NIH budget has declined significantly in the past decade, as shown by inflation-adjusted budget appropriations in orange.

NIH's primary role is to support biomedical research through funding research projects, developing research infrastructure (e.g., facilities, databases, research equipment), and training the scientific workforce. NIH also conducts biomedical research within its own intramural research program. NIH's Clinical Center is a unique resource for advancing clinical research and, in particular, for patients with diseases of unknown etiologies. Furthermore, NIH is responsible for communicating

[7] For more information, see http://www.nih.gov/about/history.htm.

information about the research process and research results to both the research community and the broader public.

NIH's role in nurturing the biomedical and health research enterprise goes much further than direct support of the research itself; NIH's investment in training, infrastructure, and resources provides an essential platform for research and enduring value to the biomedical research system. Through its training and fellowship programs, NIH supports the development of biomedical researchers and future leaders in health care at every career stage. NIH conducts workshops, bringing together top scientists to address pressing biomedical issues, and establishes cooperative agreements and cross-Institute initiatives to accomplish research goals. NIH also plays a leadership role in advancing global health and training health policy experts, including in low- and middle-income countries. Scientific research is a global endeavor, and NIH supports the international activities necessary to develop solutions to global disease threats.

Furthermore, NIH support for developing and maintaining databases, information systems, analytic tools, and other resources ensures that all researchers can access and analyze data to corroborate or expand scientific studies. In addition, through its dissemination of resources, such as the National Library of Medicine's PubMed, NIH provides inexpensive and often free access to scientific literature in formats accessible to scientists and the public.

Beyond the role of supporting and advancing science through various mechanisms, NIH provides resources for patients and their family members who need reliable information on a particular disease or disorder. NIH also communicates breakthrough research findings that may affect health and helps increase public knowledge of health-related research.

NIH plays an important role in the biomedical research enterprise due to the public investment, its infrastructure, and its ability to convene key players from academia, industry, regulatory bodies, and around the world to address challenges and advance research. NIH can quickly leverage its resources and position to address public health emergencies, such as the HIV/AIDS crisis, severe acute respiratory syndrome (SARS), or the anthrax scare in 2001.

C. The NIH mission

NIH funds research with the goal of improving human health. Its mission is to,

> "…seek fundamental knowledge about the nature and behavior of living systems and the application of that knowledge to enhance health, lengthen life, and reduce illness and disability."

Achieving this mission first depends upon NIH's ability to catalyze the generation of fundamental scientific knowledge. To do this, NIH-supported scientists, through scientific inquiry, obtain data on the function and interactions of biological and behavioral systems and what happens when these systems go awry.

Achieving NIH's mission also requires that fundamental knowledge is applied to develop actionable interventions that are implemented to enhance health, lengthen life, and reduce illness and disability. While NIH's mission to improve human health can only be achieved through the implementation of biomedical research advances, it is not in NIH's purview to provide, monitor, or regulate health services and products. Instead, NIH must ensure that research findings are disseminated to the public and to those whose mission is to develop, provide, and regulate health services, products, and policy. To accomplish this, in addition to its own dissemination activities, NIH must partner with many other actors in the health ecosystem, including the private sector, health care providers, and NIH's sister agencies within the Department of Health and Human Services (HHS), such as the Centers for Disease Control and Prevention (CDC) and the Food and Drug Administration (FDA).

D. Capturing the value of NIH's achievements

From the Latin *valére*, which means "to be of worth" or "to be strong," the value of NIH-supported research is rooted in NIH's mission and role. NIH activities lead to new knowledge and improvements in health, which generate additional societal gains. For the purpose of this report, the value of NIH-supported research to society can be categorized as (i) the generation of scientific knowledge, (ii) the impact of scientific knowledge on the health of the public, and (iii) the broader effects of NIH-funded activities on other aspects of society.

The value of fundamental knowledge. Scientific knowledge is accumulated and evaluated through a cycle of discovery, validation by peers, and eventual consensus. The impact and value of any one finding is unpredictable and will change over time as the scientific enterprise evolves. Rather than simply valuing knowledge for knowledge's sake, much of the value of knowledge is realized when reproducible research findings are made accessible to others and can support or inform action within the biomedical research enterprise and the larger health ecosystem.

The value of health effects. The value of NIH-supported research to the public's health is derived from its ability to generate knowledge that has relevance and applicability to health challenges. This can also be viewed as a staged process: initial application to human health, implementation and uptake into medical and community health settings, and eventual downstream effects on individual and population health status. The process of translating research to practice is far from regular or linear, and the health impact of foundational scientific discoveries often takes years and even decades to be realized.

The value of broader societal impacts. These broader mission-related achievements can include economic benefits, international competitiveness, technological advancements, increased scientific literacy, international collaboration, as well as many other effects. Furthermore, when knowledge is applied to the improvement of the health of the public, additional spillover effects can be generated: a more health-literate population chooses healthier behaviors and informed care-seeking[8]; healthier populations lead to averted medical costs and increased productivity (ultimately increasing GDP)[9,10]; advances in the pharmaceutical and biotechnology industries create more effective drugs, research tools, or medical devices; and international health efforts can serve as cornerstones of diplomacy.[11,12]

E. The purpose of assessing the value of NIH-supported research

NIH has long engaged in activities to assess the value of the research it supports. The compelling reasons for undertaking these assessment activities can be considered under three general categories: accountability, management, and communication.

Accountability to the public. As a Federal agency, NIH is accountable to the public and its elected representatives. It is incumbent on the agency to demonstrate effective stewardship of the resources with which the public has entrusted it. Assessments done for the purpose of demonstrating accountability must be designed with an eye to the audiences most in need of the information, including HHS, the Administration, and Congress. Often these assessments are done in response to government-wide efforts to standardize accountability measures. For example, since the 1990s NIH has responded to the requirements of the Government Performance and Results Act (GPRA) by identifying specific scientific goals and providing yearly reporting on progress towards those goals.

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[8] Berkman ND, DeWalt DA, Pignone MP, Sheridan SL, Lohr KN, Lux L, Sutton SF, Swinson T, and Bonito AJ (2004). *Literacy and health outcomes* (AHRQ Publication No. 04-E007-2). Rockville, MD: Agency for Healthcare Research and Quality.

[9] Murphy KM, and Topel R (1999). *The Economic Value of Medical Research*. Chicago, IL: University of Chicago.

[10] Murphy KM, and Topel R (2006). *The value of health and longevity.* J Polit Econ, 114(5), 871–904.

[11] Daulaire N (2012). *The importance of the global health strategy.* Am J Trop Med Hyg, 87(3), 382–4.

[12] Glass RI (2013). What the United States has to gain from global health research. *JAMA*, 310(9), 903–4.

Management of NIH's portfolio and activities. Constant improvement in the management of NIH's research portfolio and its activities and processes is achieved through the continual assessment of program performance, including the measurement of outputs (i.e., products of research). A better understanding of all aspects of NIH's work leads to increased efficiency and effectiveness of that work. In addition, these assessments may provide insights regarding barriers to achieving research goals, such as the causes of non-reproducible findings and the slow adoption of some validated research advances by clinicians and patients.

NIH has created and continually refines a vast data infrastructure to manage its research funding. Analyses of outcomes based upon this data are used to inform NIH senior leadership and aid in their decision-making. In addition, in a climate of economic constraints, there is a recognized need to identify priority funding areas. While NIH faces difficult choices in resource allocation, challenges facing human health are seemingly more complex than ever. By better understanding the results of its activities, NIH leadership can make ever-more informed decisions with an eye toward enhancing the value of its activities to the American public.

Communicating results of assessments. NIH must be transparent and responsive to its many partners and stakeholders, including the public, patient and provider communities, and policy makers at all levels of government. NIH should be clear in its role, in its approach, and in explaining its contributions so that its partners and stakeholders can fully understand its functions and accomplishments. Better capturing the value of NIH's endeavors and communicating that value to the public and health care professionals is essential.

F. Challenges to accurately assessing value

It is a daunting task to assess the value of activities that produce such a broad range of effects: the generation of knowledge, the application of that knowledge to health, and the impacts of these pursuits on broader society. The challenges of assessing the value of such activities are described below.

Differing definitions of value. Value varies depending on differing viewpoints and perspectives over time. For example, is a finding that profoundly alters the life trajectory of a small number of individuals more valuable than a finding that has a lesser benefit for multitudes of people? Greater societal goals also influence value judgments, such as the value placed on scientific freedom, reducing health disparities, or balancing public health needs with individual rights (e.g., privacy).

Time considerations. To assess the value of NIH's investments adequately, one must take the long view. Realized benefits accumulate, meaning that today's discoveries can affect multiple generations. For example, research on surfactants to treat premature infant lung development not only saves the lives of babies today but also will allow those babies to grow to adulthood, contribute to society, and raise future generations. A discovery that seems to have little significance today may prove transformational in the future, and a single finding may have implications for numerous subsequent lines of inquiry. For example, the Nobel Prize–winning discovery of the polymerase chain reaction (PCR) has had implications, many of them difficult to predict, for innumerable fields of study over the course of decades of research. However, a protracted timeframe introduces many variables that are difficult to track and are often beyond the control of NIH.

Distinguishing NIH's contributions to the biomedical research and health enterprises. The diversity of research funders complicates efforts to assign credit for particular advances. As biomedical research becomes increasingly global, retracing the steps that led to a breakthrough and assigning attribution becomes even more difficult. Given that one scientist could be supported by multiple funders across the research enterprise, how can one apportion NIH's contribution to that particular scientist's accomplishments?

The issues of attribution to NIH are even more complex when considering its impact on health. These include the (i) multifactorial influences that affect human health (including social determinants); (ii) challenges associated with documenting health-related behavior, their relationship to health outcomes, and the influence of research findings on behavior; (iii) lag time between initial discoveries and their impact on human health; and (iv) data limitations in linking research results to changes in practice. For example, NIH has contributed to the noted decline in U.S. deaths due to heart disease. But how much credit may be given to NIH-supported research versus other developments in health? For example, what percentage of the decline in mortality rates is due to better medical intervention in the form of statins, aspirin, and beta-blockers versus changes in behavior like smoking less and eating a better diet? And for both advances in medical intervention and behavior change, what role did NIH play in bringing about these improvements?

Even more challenging is the issue of attribution of broader societal impacts to NIH. How can one begin to determine the contribution of NIH to overall economic gains or to changes in the U.S. population's scientific literacy?

Lack of agreement on metrics related to biomedical research outputs, outcomes, and impacts. There is no universally agreed-upon list of metrics for assessing the overarching value of biomedical research activities. Efforts to capture the outputs of biomedical research have looked at the quantity and quality of research patents, journal articles, Nobel Prizes, and other indicators, but the value of such outputs only constitutes a small piece of the overall value of research. A number of studies attempt to measure longer-term research outcomes, such as changes in the cost of medical care, life expectancy, and quality of life. However, there are many assumptions inherent to these measures and little consensus on their appropriate use. For example, what value should be assigned to an additional year of life?

III. FINDINGS AND RECOMMENDATIONS

A. Overarching findings and recommendations

Demonstrating the value of biomedical research in a systematic way is extremely challenging. While markers of progress measure some of what NIH produces, capturing the full impact of NIH's investments is a more complicated venture. Fortunately, there is growing worldwide interest in assessing the outcomes of scientific endeavors and in capitalizing on improvements in communication, data collection, and analysis. Furthermore, economic and budgetary uncertainty increases the need to capture the outcomes of scientific endeavors more definitively to inform the public and decision-makers.

> **Recommendation:** NIH should capitalize on the ongoing innovations in data collection and analysis by intensifying its efforts to assess systematically, comprehensively, dynamically, and strategically its value. Results of studies over the next several years can be used to demonstrate accountability, enhance management, and increase public awareness.

Such an effort requires a commitment by NIH leadership to carry out assessments of the value of NIH-supported research and requires significant resources to organize, develop, and support thorough, well-designed studies. To ensure the highest quality and validity of these assessments, NIH should couple internal efforts with engaging external experts in the planning and conduct of assessments of the value of NIH-supported research.

> **Recommendation:** NIH should establish dedicated and sustained resources to support the planning and conduct of assessments of the value of NIH research. These resources should be modest in comparison with the expenditure of funds for core NIH research.

B. Considerations for assessing and communicating the value of NIH-supported research

The value of NIH-supported biomedical research is derived from producing knowledge that can be applied to improve the public's health. The primary value of NIH-supported research lies in the knowledge it generates, and not just the immediate value of knowledge but also its "option value." Much like stock options, scientific knowledge is often exercised at a later date; both have inherent value before they are applied. In this analogy, NIH-funded research generates options that others in the health ecosystem might choose to exercise. For example, a private company may work to develop new medications based on NIH-funded research, or CDC may act on NIH research findings in its response to a public health emergency. Scientific knowledge can affect society through myriad pathways, ranging from medical practice to international relations. Tracing these pathways back to the initial point of knowledge generation presents an opportunity for NIH to define the value of that knowledge.

Given the well-appreciated time lag from discovery to application and the multitude of ways knowledge is applied, it is extremely difficult, if not impossible, to predict which scientific discoveries today will prove to be the most valuable in the future. It is also challenging to place an empirical value on knowledge. An essential role for NIH, therefore, is to create a diverse portfolio of viable knowledge-options both for further scientific discovery and its implementation. Value is derived from the generation of these options and the many ways in which they are exercised.

> **Recommendation:** Assessments of the value of NIH-supported research should attempt to trace NIH's contribution to the numerous translational pathways that exist and draw clear connections between the generation of knowledge and its application to health and broader societal impacts.

Many factors need to be considered in order to accurately determine NIH's contribution to a particular outcome. To be unbiased and effective, an assessment must be appropriately rigorous in determining attribution, but assigning attribution adds complexity to the assessment process. For example, NIH works with many partners to support research, training, and infrastructure development, and these partnerships must be appropriately acknowledged in any assessment. In addition, other actors in the health ecosystem are responsible for taking the knowledge generated by NIH and advancing it to affect health and other societal impacts. These other actors and the public itself will influence the range and depth of the value of NIH's contributions.

Other factors inherent in the scientific process also confound efforts to assign attribution. For example, a single discovery may have multiple applications, and a single application may be based upon multiple discoveries. In addition, the significant lag time that often occurs between a discovery and its application further complicates a timely and accurate assessment of the value of NIH-supported research.

Recommendation: Credible, interpretable, and useful assessments of the value of NIH-supported research should, when possible:

a. Acknowledge and determine the role of other players in the advancement and adoption of research findings or other outcomes of interest;

b. Attribute outcomes entirely to NIH only when this is proven to be the case; and

c. Establish a timeframe that is broad enough to include sufficient time for discovery to be applied.

NIH affects and is affected by many participants in the scientific and health ecosystems; therefore, many stakeholders must be considered in any attempt to assess and communicate the value of the research it supports. Thorough and accurate assessments of the value of NIH-supported research require concerted and continual effort, with input from numerous participants in the scientific and health ecosystems. Many of the diverse audiences for assessments of NIH-supported research overlap with the participants in the process, including NIH leadership and program staff who design and conduct the value assessments as well as researchers, research institutions, patients, practitioners, the general public, policy makers, other Federal agencies, and the private and nonprofit sectors.

Recommendation: NIH's assessment strategies should be informed by a broad range of stakeholders, and NIH should regularly seek input from stakeholders to inform its assessment activities and communicate its results.

Practitioners, patients, industry, and other Federal agencies often develop the knowledge generated by NIH research into its end use or product. Because NIH is often not directly involved in this aspect of the research enterprise, it will be necessary to engage these hand-off sectors in the collection, validation, and linkage of data about the scientific, health, and broader societal outcomes that are produced by biomedical research.

Recommendation: NIH should seek ways to partner with other entities in government, non-governmental organizations (NGOs), and the private sector in its attempt to develop tools, techniques, and databases to strengthen assessments of value.

It is especially important for NIH to take into account the effect assessments may have on researchers and research institutions when designing future assessment studies. For example, many metrics focus on the number of publications produced because data on this activity are readily available, but this focus can disincentivize the production of other valuable research outputs. Data collection and reporting for assessment purposes can be time consuming and may require specific knowledge or understanding. The time, effort, and resources researchers devote to these assessment-related activities are often at the expense of research efforts.

> **Recommendation:** NIH should give careful consideration to the consequences of its assessment efforts, ensuring that assessment measures do not negatively influence the conduct of research.

C. Components of scientifically rigorous assessment approaches

Numerous attempts to assess aspects of the value of NIH-supported research have been undertaken by NIH and by many of its stakeholders, but these efforts have not been comprehensive, systematic, or coordinated. NIH and its stakeholders engage in numerous activities to assess and communicate the outcomes of NIH activities, ranging from disseminating stories of discoveries to formal program evaluations. Each of the NIH Institutes, as well as the NIH Office of the Director, conducts studies to measure the outcomes of specific NIH programs and activities. Several external studies, samples of which are found in Appendix B, have also tried to assess outcomes of NIH activities. However, these studies vary in rigor and scope, and many authors are forced by the lack of available data to base their conclusions on a multitude of assumptions.

The complexities of the scientific process, the vast array of research areas addressed, and the numerous strategies NIH employs in pursuit of its mission make it nearly impossible to assess the overall value of NIH activities. Yet, with planning and cross-agency coordination, assessments could capture a better approximation of the value of the enterprise as a whole. A comprehensive strategy to address each aspect of study design, including deciding upon the specific study question, determining the data needed, designing an appropriate methodology for the collection and analysis of the data, and effectively communicating the results of the study, must be created through a concerted and sustained effort across the agency in partnership with its stakeholders.

1. Study topics

A comprehensive, systematic, and coordinated approach towards assessing the value of NIH-supported research begins with identifying a representative sample of NIH activities to study that will reflect the whole of NIH and the many avenues by which NIH influences any number of societal factors. Assessments of value should attempt to measure the impact of all NIH-supported activities, including research, workshops, conferences, training, public-private partnerships, infrastructure, database development and maintenance, and communication of health research and information in numerous scientific areas. Although analyses cannot be conducted on every research topic or activity in which NIH is engaged, capturing a representative sample of NIH investments and outcomes can help define the scope and range of the value of research funded by NIH.

In addition to the range of activities NIH undertakes to carry out its mission, the scientific knowledge it generates translates into varied outcomes via many pathways. The studies included in Appendix B attempt to measure outcomes along several of these translational pathways, including NIH's contributions to changes in health measures, its impact on pharmaceutical innovation, or its influence on the U.S. economy. A more systematic approach to capturing some of these outcomes is warranted.

> **Recommendation:** NIH should support internal and external assessment studies that are strategically and systematically selected to represent the full spectrum of NIH activities and processes, as well as the variety of translational pathways by which they affect individual health, the health of the public, and broader societal impacts.

NIH must also consider the attributes, elements, and components necessary for a rigorous assessment study. For example, the study must be feasible, with defined indicators and quality data sources in place. The purpose of the assessment and its audience should also be considered as study questions are formulated; the most appropriate study design may vary according to the different goals or purposes for gathering the information. How value is assessed may also vary for different modes of research (e.g., basic, translational, clinical).

Study topics should include both research successes and research "failures," since important lessons may be learned from each. "Failure" can have multiple meanings in the context of biomedical research. Research that is not well designed or well executed could be considered a true failure and a waste of resources. However, the failure to show safety or efficacy in a clinical trial may well generate critical knowledge and provide re-direction for research and development. In this case, the research yielded a valuable result. Additionally, well-planned, well-performed research studies with null or negative results are not "failures," and it is important to communicate to the public that the essence of science is the discovery of what will and will not work.

Study Topic Selection

During the course of their deliberations, members discussed a wide range of study topic suggestions (list not prioritized):

- Examination of changes in treatment for 25 diseases over several generations to examine the effects on and the outlook for patients
- Case studies on research areas lacking economic incentives for investigation
- Study of an alleged "failure" that still resulted in positive economic impact (e.g., unexpected applications, resources redirected to more promising research)
- Mapping NIH's investment and role in major biomedical breakthroughs (e.g., top 10 scientific breakthroughs as chosen by *Science* magazine, *Wall Street Journal* list)
- Contributions of NIH to research and/or researchers of note (e.g., Nobel Prize winners)
- Specific health and disease topic areas such as antibiotics, vaccines, polio, HIV/AIDS, cardiovascular disease, Alzheimer's disease, diabetes, premature births, behavioral therapies, etc.
- Prevention strategies and campaigns (e.g., smoking, obesity)
- The impact of funding by the American Recovery and Reinvestment Act
- The effect of doubling the NIH budget
- Studies that address critiques of NIH and the larger biomedical research system
- The effectiveness of NIH communication activities

The selection of representative study topics in a systematic way will require creating a framework that captures a concept of the whole of NIH in terms of its activities and the outcomes it aims to achieve. Developing such a framework will require a concerted, agency-wide effort and should be informed by outside experts.

Recommendation: An internal trans-NIH Committee on Assessments of the Value of Biomedical Research should be established to coordinate agency efforts in assessing its value, including devising a systematic approach for the selection of study topics. External experts should be consulted in the selection of study topics.

2. Data needs

There is insufficient data collection, storage, and linkage between data sets to conduct thorough assessments of value. Sound data, along with a rigorous and interconnected data infrastructure, is a prerequisite for valid assessments of value. This requires NIH to identify relevant and reliable sources of data, collect and store data in a routine and highly organized fashion, link multiple data sources together, and enable access to such data in formats amenable to analysis.

> **Recommendation:** The trans-NIH Committee on Assessments of the Value of Biomedical Research should coordinate efforts, including solicitation of nationally recognized experts, to improve NIH's data infrastructure for monitoring and assessing the value of NIH-supported research.

Recent NIH efforts in this arena are encouraging and have led to the development of data systems such as RePORTER, the Scientific Publication Information Retrieval and Evaluation System (SPIRES), the Electronic Scientific Portfolio Assistant (eSPA), and STAR METRICS.[13] These systems have greatly improved NIH's ability to identify, analyze, and report shorter-term scientific outputs of its research spending, in particular publications, citations, patents, job creation, and economic activity in the private sector. However, NIH's data infrastructure was built primarily to manage grants and contracts during their life cycle, not to track outcomes. As such, NIH's ability to examine medium- and long-term outputs, especially those related to health and broader societal impacts, is limited.

A number of data types and sources can be used to track research outputs. While not exhaustive, Table 1 lists dozens of research outputs mapped to the three value streams of scientific knowledge, health, and broader societal impacts that could be measured in short-, medium-, and long-term timeframes. Ultimately, these outputs are a means to an end, leading to the outcomes or end goals of biomedical research. Appendix C presents a chart that matches these outputs to their potential sources. In this chart, specific data gaps, limitations, and weaknesses that could hinder assessment are noted in red text. Some of these outputs are much easier to measure than others, and the tendency to measure what is easy has undoubtedly influenced the current use of certain outputs as indicators of progress. Although an active area of study, the identification and community acceptance of reliable and appropriate indicators of NIH's outcomes remains a challenge. There are differing opinions regarding which indicators are both feasible to collect and best reflect the

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[13] Callahan K, Onken J, Drew C, Evans F, Ghosh-das D, Ikeda R, Lockmuller J, Roberts L, Santangelo G, Sheehy P, Wagner R, Wright K, Wu C, and Zoha S (2012). *Assessing the Outcomes of NIH Research Spending: Toward a Better Approach.* Bethesda, MD: National Institutes of Health.

products and impacts of research spending. Moreover, even if perfect data existed for each of the indicators listed in Appendix C, comprehensively measuring and analyzing all of these indicators would be impractical.

Table 1. Biomedical research outputs and outcomes for science, health, and broader societal impacts

SCIENCE	
Outputs	
Discovery	Primary research articles • Conference abstracts/ presentations • Submissions to research databases and repositories (e.g., National Gene Vector Biorepository (NGVB), National Database for Autism Research (NDAR)) • Development of research resources and infrastructure • Non-peer–reviewed research findings and reports (e.g., self-publishing, data sharing)
Validation	Patents • Licenses • IP transfer agreements • Development and initial clinical testing of diagnosis, treatment, and prevention interventions (e.g., FDA applications; Phase I–III clinical trials) • Standardized research protocols • Validated data repositories (e.g., National Center for Biotechnology Information [NCBI's] GenBank)
Consensus	FDA approvals of New Drug Applications (NDAs) • Consensus Development Conferences and Bodies (e.g., National Toxicology Program) • Book chapters • Post-grad curriculum guidelines • Systematic reviews/meta-analyses • Knowledge transfer metrics (e.g., citations, Web hits)
Outcomes/Goals	
Fundamental scientific knowledge • Dissemination of knowledge • Improvements in the process of science	
HEALTH	
Outputs	
Application	Advanced testing of evidence-based diagnostics • Advanced testing of evidence-based therapeutic interventions • Advanced testing of evidence-based preventive interventions and strategies • Identification of major health issues and disease risk factors
Implementation	Drugs to market • Dissemination and implementation efforts, practice guidelines, etc. • Adoption of evidence-based diagnosis, treatment, and prognosis strategies • Public health campaigns
Health measures	Burden of disease • Quality of life • Disability • Longevity
Outcomes/Goals	
Lower levels of disease • Reduced disability • Improved quality of life • Longer lives	

BROADER SOCIETAL IMPACTS	
Outputs	
Proximal	Government, science, and technology jobs • Demand for R&D supplies • International collaboration • Support for academia • Reduced risk in pre-competitive space • Cross-sector collaboration
Intermediate	Private sector activity (e.g., Biotech, Pharma) • Enhanced STEM education • Communication and interpretation of findings across sectors and to the public • International S&T capacity building • Spurring the local economy
Distal	Uptake and spread of technological innovations • Workforce output (e.g., longevity, health) • Workforce development • Internationally competitive science and technology sectors • GDP • Emergence of new sectors and industries • Health care costs
Outcomes/Goals	
Scientifically literate public • Health care–related cost savings • Higher productivity • Greater capacity for innovation • Greater global R&D competitiveness • Diplomacy and stability through science	

NIH should prioritize a set of indicators that can better demonstrate the value of NIH-supported research and the diverse outcomes of NIH spending. Given NIH's stature in biomedical research, the agency could be a leader in establishing and refining indicators that could provide a richer account of the science-based outputs that affect society.

> **Recommendation:** NIH should identify and gain consensus on a core set of indicators to be included in its data infrastructure.

Establishing core indicators presents both a hazard and an opportunity because the indicators that NIH measures are likely to influence the behavior of scientists and their research outputs. Core indicators need to have strong credibility and acceptance across the biomedical research and practice communities, which will require a clear articulation of their limitations, predictive value, and how the agency will use such measures. The agency must take care that core indicators do not present a high risk of unproductive behavior change in the research community. On the other hand, NIH could introduce novel positive incentives related to a broad set of activities (e.g., training, mentorship, data sharing, collaboration, software development, community outreach, science communication).

Funding bodies and research organizations are enhancing and opening access to data as a means to better analyze scientific outputs and outcomes. NIH can partner with the many different science agencies that are also seeking better ways to measure their impact. Internationally, the Medical Research Council in the United Kingdom and the Canadian Institutes of Health Research, to cite two examples, have recently implemented advanced performance data collection and analysis systems to capture a wide range of possible research project outputs and outcomes. Universities are also increasingly engaged in finding ways to demonstrate the educational, scientific, commercial, and economic value of their research activities, especially at the regional and state level. In addition, many of NIH's partners in the health enterprise, both public and private, are also looking to better capture health outcomes. An excellent example is CDC's Data Linkage Program, which links together administrative data, such as the National Death Index and claims from the Centers for Medicare & Medicaid Services (CMS), with data from numerous population health surveys to uncover factors that influence health and health outcomes.

> **Recommendation:** NIH should link its own data infrastructure, as appropriate, with that of its many partners in the science and health ecosystems who are already tracking many outcomes of interest to NIH (e.g., CDC, U.S. Patent and Trademark Office [USPTO], FDA).

Once a core set of outcome and impact data has been established, the agency can focus on acquiring the data, analytic tools, and skill for measuring this set of indicators rigorously. The advent of "Big Data" is providing rapidly emerging capabilities only imagined a decade or two ago. There are unprecedented opportunities to improve the collection, quality, and linkages of vast amounts of data that will enable better assessments of the value and diverse outcomes of NIH-supported research. New and emerging capabilities will make the data infrastructure more useful to those assessing biomedical research.

> **Recommendation:** The trans-NIH Committee on Assessments of the Value of Biomedical Research should examine ways to capitalize on NIH's many efforts in "Big Data" by conferring with newly established NIH Big Data committees.

There are many opportunities to improve the quality of data and the way data are collected, linked, and made available for analysis. These include:

- ***Filling gaps:*** Existing NIH databases could be enhanced to provide more data on relevant inputs, outputs, and outcomes. For example, many of these systems were not designed to track individuals (e.g., investigators, trainees, research project staff), making it difficult for the agency to track job placement of NIH trainees and NIH-funded researchers.

Opportunities arising from NIH's new administrative data collection efforts

Three recent efforts led by the NIH's Office of Extramural Research are aimed at enriching NIH's administrative data on funded research projects and researchers. The **Research Performance Progress Report (RPPR)**, which was mandated by the Office of Management and Budget, will help address many existing data weaknesses. First, the RPPR will collect some performance data in a structured format. Second, all U.S. Government agencies that fund research will use the RPPR, so the RPPR essentially establishes a set of common, standardized data elements. Both of these features of the RPPR represent marked advances in project performance reporting that may greatly improve the ability of each research agency to link and integrate performance data. Moreover, there are emerging opportunities to integrate performance-measurement systems like the RPPR with other reporting and monitoring systems, allowing NIH to leverage data infrastructure improvements to reduce reporting burden from the research community while also enhancing the utility of outcomes data for the researchers themselves. For example, RPPR will link to another newly established NIH administrative data tool, the **Science Experts Network Curriculum Vitae or SciENcv**, which enables researchers to easily maintain and generate biosketches for Federal grant applications and progress reports. SciENcv also provides a mechanism (via the third-party organization, ORCID) for users to generate and associate a unique international ID to their profiles. Third, NIH is engaging in a large-scale data-sharing effort with several other major biomedical research funders internationally to build the **World RePORT** database. The system integrates detailed data on funded projects into an illustrative mapping system designed to enhance communication and coordination among research funders. Now in a beta version, World RePORT displays information on projects being funded in Sub-Saharan Africa by nearly a dozen public and private funders, including the Canadian Institutes of Health Research, the UK's Medical Research Council and Wellcome Trust, and the European Commission.

- ***Linking data systems:*** Linking data between existing NIH systems is currently difficult because no single data element or data field (such as project ID or investigator ID) exists within all relevant databases. For example, clinicaltrials.gov does not currently include investigator IDs. This is even more problematic when attempting to link between NIH and other government databases, whether they also support science (e.g., NSF, Department of Defense) or are implementing the NIH evidence base (e.g., FDA, USPTO, and Agency for Healthcare Research and Quality [AHRQ]). Even more complicated is linking to non-government data sources, such as those curated by research institutions and the private sector. This greatly hinders the ability to draw connections between short-term NIH outputs (e.g., publications, clinical trials, patents) and longer-term outputs (e.g., changes in health practice, industry startups, and FDA approvals).

- ***Improving quality:*** Many factors may drive inaccurate, inconsistent, and incomplete data, including the use of multiple systems for data entry, lack of data entry and reporting enforcement or incentives, and lack of validation.

- ***Improving utility through data standardization:*** The utility of data is often hampered by a lack of consensus on terminology and nomenclatures. Data elements may look similar across databases but may be defined somewhat differently. Addressing standardization issues will require building consensus on definitions or producing data thesauri so that data elements are comparable across databases.

- ***Collecting and storing data in structured formats:*** Usability of data can be greatly enhanced by collecting and storing data in more structured formats. For example, while recent progress has been made in identifying patent applications and licenses that are a direct off-shoot of research performed by NIH grantees, patent applications also contain citations to prior articles. However, these citations are not collected or stored in a structured format. Addressing this limitation could allow NIH a new avenue in understanding the role of biomedical research in establishing the evidence base for intellectual property.

- ***Opening access:*** Some databases are subject to limited access. By opening access to data, multiple user communities can also test the data, allowing for continual improvements in data quality.

Recommendation: NIH should improve the quality and integrity of core data and linkages through standardized data collection and established governance.

There is no single solution to strengthening data. Successfully addressing data considerations will require continual and highly coordinated effort and resources, but the payoff is worthwhile. For example, a major element of the attribution challenge includes identifying reliable links between shorter-term NIH-supported outputs and the myriad downstream effects that may also be part of the value equation. Well-designed, linked data systems can substantially ease the attribution challenge. In short, better data will promote better assessments and improve NIH's ability to optimize value.

3. Methodologies

A suite of rigorous and feasible methodologies is needed to better capture the value of NIH-supported research. Of the many assessments that have been undertaken, no single approach has proven entirely satisfactory. Strategies and methods for measuring the value and impact of biomedical research are quickly evolving, but no single assessment strategy can capture the full value of biomedical research. Thus, a multi-pronged approach to value assessment will be most effective.

A sample of recent assessment studies (Appendix B) includes a range of methodologies, both quantitative (e.g., bibliometrics, economic analyses) and qualitative (e.g., case studies). In addition, several reports in the last few years have attempted to survey assessment methodologies, including the National Research Council's 2011 workshop on measuring the impacts of Federal investments in research[14] and a 2012 National Academy of Science (NAS) report entitled *Best Practices in Assessment of Research and Development Organizations*.[15] Notable reports from international government funders and advisory councils also addressed methodologies in use or in development by other countries to measure research impact, including the UK, Australia, and Canada.[16,17,18] A study commissioned by the Association of American Medical Colleges and conducted by RAND Europe presented a useful summary of methodologies and tools used by large international science funders to assess research outputs and outcomes.[19] According to these reports, some common categories of assessment approaches include bibliometrics, Web-based metrics (e.g., altmetrics), case studies, economic

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[14] National Academy of Sciences (2011). *Measuring the Impacts of Federal Investments in Research: A Workshop Summary.* Washington, DC: National Academies Press.

[15] National Academy of Sciences (2012). *Best Practices in Assessment of Research and Development Organizations – Summary of a Workshop.* Washington, DC: National Academies Press.

[16] Panel on Return on Investment in Health Research (2009). *Making an Impact: A Preferred Framework and Indicators to Measure Returns on Investment in Health Research.* Ottawa, ON, Canada: Canadian Academy of Health Sciences.

[17] Rymer L (2011). *Measuring the Impact of Research: The Context for Metric Development, Go8 Backgrounder 23.* Turner, Australia: The Group of Eight.

[18] Research Excellence Framework (2014). *Decisions on Assessing Research Impact.* Bristol, UK: Higher Education Funding Council for England.

[19] Guthrie S, Wamae W, Diepeveen S, Wooding S, and Grant J (2013). *Measuring Research: A Guide to Research Evaluation Frameworks and Tools.* Santa Monica, CA: RAND Corporation. Available at http://www.rand.org/pubs/monographs/MG1217.

analyses, peer and expert review/opinion, algorithmic clustering and text classification, and network analysis.

Many of these reports also stressed the need to consider the purpose, audience, and context when choosing the most appropriate assessment approaches. The method selected for assessment, whether prospective or retrospective, qualitative or quantitative, must produce results that can be effectively communicated to all audiences.

Narratives constructed from well-designed case studies can be especially effective illustrations of the broad impacts of biomedical research. Carefully constructed retrospective case studies can demonstrate stewardship and capture value in a range of outcomes, including the impact of a basic finding on public health, or the economic return on investment for a specific research endeavor. However, case studies must by design be narrow in focus and therefore have limitations in scope and generalizability. To use case studies most effectively to capture value, the topics for these studies should be strategically chosen to best represent the full range of NIH activities and scientific areas. Information and stories for case studies can come from a variety of sources, including the publications and communications documents of research institutions in all sectors and from around the globe.

> **Recommendation:** NIH should adopt a systematic approach to designing case studies that can tell compelling and accurate stories of NIH's role in turning discovery into health.

Data and analysis can strengthen both case studies and more personal patient narratives by supporting the stories with details and context, thereby presenting a more comprehensive picture not only of the value of the research but of the obstacles to determining and attributing that value.

> **Recommendation:** Analytic approaches should balance numbers with narratives, illustrating the complexities of progress, such as the time-dependence of R&D and the pivotal roles of other actors in the biomedical sciences.

Important methodological considerations include:

- *Use complementary methods:* The combination of multiple assessment strategies and indicators can create a composite perspective on value and impact. Include quantitative and qualitative dimensions as well as both prospective and retrospective methods to assess value.
- *Choose appropriate timeframes:* Timeframes for assessment studies should allow for an appropriate period of time for the scientific process to unfold and for implementation to occur. Insufficient timeframes could seriously bias results.

- *Choose the appropriate unit of analysis:* Value and impact can be assessed at many levels: individuals, research groups, institutions, fields, and regions or countries. Many indicators are appropriate or reliable only at specific levels of analysis. For example, bibliometric analysis is generally more applicable at higher levels of aggregation, such as at the university level rather than at the level of evaluating individual scientists.
- *Identify a baseline or comparison group:* At best, assessments should establish a counterfactual (theoretical exercise to show what would happen without a particular scientific finding). If a counterfactual is not possible, a similar comparison group and/or baseline should be established.
- *Make use of expert interpretation and judgment:* Analyses should inform rather than replace expert judgment. Meaningful and appropriate interpretations require synthesis and judgment by experts with detailed contextual knowledge.
- *Avoid over-attribution:* Clear caveats describing data sources, methodologies, and thoughtful discussions of study limitations should always be presented.

Making the most of these tools and methods and ensuring that they are used appropriately will require not only the expertise of NIH program managers and analysts but also the expertise of economists, computer programmers, demographers, epidemiologists, mathematicians, statisticians, and trained evaluators. NIH should support and encourage the development of new and improved tools, both internally and in the extramural community, by expanding collaborations with academic and industry experts in research assessment and by funding researchers who can develop new analytic tools.

> **Recommendation:** The recommended trans-NIH Committee on Assessments of the Value of Biomedical Research should develop an assessment approach guide to help NIH ICs select appropriate and feasible methodological approaches based on a number of nested factors beginning with the kind and purpose of the evaluation. This guide should be updated at yearly intervals to reflect new tools or approaches. The Committee should engage external experts in the development of assessment approaches.

4. Communication

Effectively communicating the results of assessments of the value of NIH-supported research gives the agency the opportunity to increase public understanding of the scientific research process, NIH's mission, and the ways in which biomedical research affects daily life. The many audiences for the assessment of NIH-supported research include the general public, patient communities, domestic and international policy makers, the research community, and practitioners. Each of these groups may have different needs, value different aspects of NIH's activities, and respond to different types of assessments. Conveying information effectively to each of these audiences requires a variety of communication strategies, and all audiences could benefit from communication efforts that present the results of assessment studies against a backdrop of information about science research and the role that NIH plays in the science and health systems.

> **Recommendation:** NIH assessment efforts should begin with identifying the purpose of the study and its audiences. Any assessment study design needs to include a plan for communication of results that includes information about the scientific research process to increase awareness and understanding of NIH's role.

Both the general public and patient communities are the ultimate recipients of NIH efforts to improve human health. These groups tend to relate to narratives describing advances, treatments, and improvements that enhance quality of life. Policy makers are answerable to the public and patient communities, making them primarily concerned with NIH's contribution to improved health and good stewardship of the public's investment. They also respond to narratives but may seek more quantitative benchmarks to aid in decision-making. Research and practitioner communities tend to focus more on rigorous and evidence-based assessments. Results of NIH assessments may have important implications for the research community by influencing their own research directions. For practitioners, results of NIH assessments may affect their adoption of evidence-based practices and changes to clinical practice guidelines.

> **Recommendation:** NIH's strategies for communicating the results of assessments of its value should be diverse to reflect its many audiences.
>
> a. Stories are a particularly compelling communication tool. NIH should conduct studies that capture its impact in terms of human experiences (e.g., the impact of research for the patient), which are relatable to many audiences.
>
> b. Attempts to quantify NIH's impact are particularly useful for certain audiences, and these studies should be communicated with a mix of detailed analysis and contextual stories or information as well as transparency regarding the inherent limitations of quantification efforts.
>
> c. When using specific examples, note that they do not represent a general proof of the value of NIH-supported biomedical research.

IV. SUMMARY

SMRB members are encouraged by ongoing assessment activities and those currently under development within and outside NIH. However, NIH leadership and the many individuals throughout NIH who are responsible for accountability, management, and communication of research will benefit from the development of a more credible, systematic, and comprehensive assessment strategy. Table 2 summarizes the findings on approaches to assess the value of biomedical research supported by NIH and recommendations for strengthening those assessments.

Table 2. Summary of findings and recommendations

	FINDINGS	RECOMMENDATIONS
Assessing the value of research	Due to the complexity of the biomedical enterprise, it is extremely difficult to demonstrate empirically the value of biomedical research as a whole and even harder to ascertain NIH's specific contribution.	1. NIH should intensify its efforts to assess systematically, comprehensively, dynamically, and strategically the value of biomedical research for the purposes of accountability, effective management, and public awareness. This will require a sustained investment in strengthening NIH's data infrastructure and a dedicated funding stream or mechanism to support assessment projects.
Considerations for assessing and communicating the value of NIH research	NIH's value is derived from producing knowledge that can be applied to improve the public's health.	2. Assessments of the value of NIH-supported research should examine connections between the generation and communication of basic and clinical knowledge and the impact of this knowledge along differing translational pathways.
	Many factors need to be considered in order to determine accurately NIH's contribution to a particular outcome.	3. Credible, interpretable, and useful assessments of the value of NIH-supported research should, to the extent possible: (i) attribute outcomes to all contributors and (ii) adopt a timeframe that is long enough to include sufficient time for discovery to be applied.
	NIH affects and is affected by many participants in the scientific and public health ecosystems; therefore, many stakeholders must be considered in any attempt to assess and communicate its value.	4. NIH's assessments and the development of assessment tools, techniques, and databases should be done in partnership with its many stakeholders. Given that the study of a process (including the metrics used for analysis) may alter the process itself, NIH should avoid assessment activities that could negatively influence the conduct of research.

Table 2. Summary of findings and recommendations *(continued)*

	FINDINGS	RECOMMENDATIONS
Components of scientifically rigorous assessment approaches	Numerous attempts to assess aspects of NIH's value have been undertaken by NIH and by many of its stakeholders, but these efforts have not been comprehensive, systematic, or coordinated. There is insufficient data collection, storage, and linkage between data sets to conduct thorough assessments of value. A suite of rigorous and feasible methodologies is needed to improve assessments of the value of NIH-supported research. Of the many assessments that have been undertaken, no single approach has proven entirely satisfactory.	5. NIH should establish a trans-NIH Committee on Assessments of the Value of Biomedical Research that will: a. Develop a strategy to support or conduct assessments of value, including through grants or contracts with external experts; b. Determine a process for strategically selecting study topics that map to a conceptual framework, including different translational pathways; c. Oversee (in conjunction with NIH's recently established "Big Data" committees) NIH efforts to strengthen data needed for assessing value, including: i. Identifying and gaining consensus on a core set of indicators to be included in its data infrastructure and ii. Creating better data linkages with NIH's partners and hand-off sectors; d. Adopt a systematic approach to designing case studies that can both illustrate the research process and illuminate the outcomes; e. Identify promising analytical approaches and develop an assessment approach guide that outlines the factors to consider and the mix of methodologies (e.g., retrospective, prospective, qualitative, quantitative) that should be employed in attempting to capture value; and f. Seek input from external experts in the development of methods and tools to improve assessments of the value of biomedical research.
	Effectively communicating the results of assessments of the value of NIH-supported research gives the agency the opportunity to increase public understanding of the scientific research process, NIH's mission, and the ways in which biomedical research affects daily life.	6. Every assessment activity that NIH undertakes should begin with identifying the purpose of the study and its audiences. Assessment study designs should include diverse communication strategies to disseminate results in ways that will enhance awareness and understanding of the scientific research process among a variety of audiences.

V. STATEMENT ON FUTURE USE OF COMPREHENSIVE ASSESSMENTS

As noted previously, the ultimate goal of assessing the value of biomedical research supported by NIH is to use this information to enhance that value. Having a clear picture of value across the spectrum of biomedical research could enable decision-makers to better identify which research will have the greatest impact on health, the economy, and other aspects of society or to note impediments to producing value. However, assessments of biomedical research value are not yet comprehensive or systematic enough to provide a foundation for making management decisions regarding how to enhance that value. As comprehensive assessments of value become more rigorous, NIH should study how best to use the results of these assessments to enhance value.

VI. CONCLUSION

During an SMRB teleconference held December 18, 2013, SMRB members endorsed the findings and recommendations of this report (13 favored; 0 opposed). The findings and recommendations presented in this report address ways to strengthen NIH's ability to identify and assess the outcomes of its work so that NIH can more effectively determine the value of its activities; communicate the results of studies assessing value; ensure continued accountability; and, in the long term, further strengthen processes for setting priorities and allocating funds. The SMRB believes NIH can further improve assessments of value for biomedical research activities it supports by accepting and acting upon the recommendations set forth in this report.

APPENDIX A

Speakers and Dates

JANUARY 14, 2013

- William B. Rouse, Ph.D., Chair of Economics and Engineering, Stevens Institute of Technology
- Andrew A. Toole, Ph.D., Economist, Economic Research Service, U.S. Department of Agriculture
- Simon Tripp, Senior Director, Technology Partnership Practice, Battelle Memorial Institute

MARCH 13, 2013

- Richard A. Ikeda, Ph.D., Director, Office of Research Information Systems and Research, Condition, and Disease Categorization, Office of Extramural Research, Office of the Director, NIH

MARCH 19, 2013

- Mark L. Rohrbaugh, Ph.D., J.D., Director, Office of Technology Transfer, Office of the Director, National Institutes of Health
- George M. Santangelo, Ph.D., Director, Office of Portfolio Analysis, Division of Program Coordination, Planning, and Strategic Initiatives, Office of the Director, National Institutes of Health

JUNE 4, 2013

- James M. Anderson, M.D., Ph.D., Deputy Director for Program Coordination, Planning, and Strategic Initiatives, NIH
- Irma E. Arispe, Ph.D., Director, Office of Analysis and Epidemiology, National Center for Health Statistics, Office of Surveillance, Epidemiology, and Laboratory Services, Centers for Disease Control and Prevention
- James W. Curran, M.D., M.P.H., James W. Curran Dean of Public Health, Rollins School of Public Health, Emory University
- David M. Cutler, Ph.D., Otto Eckstein Professor of Applied Economics, Harvard University

- Barbara Entwisle, Ph.D., Vice Chancellor for Research and Kenan Distinguished Professor, University of North Carolina at Chapel Hill
- Laurel L. Haak, Ph.D., Executive Director, ORCID
- Della M. Hann, Ph.D., Deputy Director, Office of Extramural Research, NIH
- Mark B. McClellan, M.D., Ph.D., Director of the Engelberg Center for Health Care Reform and Leonard D. Schaeffer Chair in Health Policy Studies, Brookings Institution
- Robert H. Topel, Ph.D., Professor in Urban and Labor Economics, University of Chicago Booth School of Business
- Elias A. Zerhouni, M.D., President of Global R&D, Sanofi

JUNE 5, 2013

- David Baker, Founder and Executive Director, CASRAI, Canada
- Margaret E. Blume-Kohout, Ph.D., Senior Research Economist, New Mexico Consortium
- Jason Priem, Ph.D. Student, School of Information and Library Science, University of North Carolina–Chapel Hill

AUGUST 8, 2013

- Ann C. Bonham, Ph.D., Chief Scientific Officer, Association of American Medical Colleges
- Susan Guthrie, Ph.D., Senior Analyst, RAND Europe
- Anthony Mazzaschi, Senior Director, Scientific Affairs, Association of American Medical Colleges
- Steven Wooding, Ph.D., Research Leader, RAND Europe

AUGUST 13, 2013

- J. Michael McGinnis, M.D., M.P.P., IOM Senior Scholar and Executive Director of the IOM Roundtable on Value & Science-Driven Health Care
- Bhaven N. Sampat, Ph.D., Associate Professor, Department of Health Policy and Management, Mailman School of Public Health, Columbia University

AUGUST 22, 2013

- Julia I. Lane, Ph.D., Senior Managing Economist, American Institutes for Research

SEPTEMBER 26, 2013

- Pritty P. Joshi, Ph.D., Health Science Policy Analyst, Office of Extramural Research, National Institutes of Health
- Luci Roberts, Ph.D., Director of Planning and Evaluation, Office of Extramural Research, National Institutes of Health

OCTOBER 24, 2013

- Alan I. Leshner, Ph.D., CEO, American Association for the Advancement of Science
- Peter R. Orszag, Ph.D., Vice Chairman of Corporate and Investment Banking and Chairman of the Financial Strategy and Solutions Group, Citigroup
- Harvey V. Fineberg, M.D., Ph.D., President, Institute of Medicine
- Elaine K. Gallin, Ph.D., Partner, QE Philanthropic Advisors
- Kathryn N. Ahlport, M.S.P.H., Executive Director, Health Research Alliance
- Carl Rhodes, Ph.D., Senior Scientific Officer, Howard Hughes Medical Institute
- Marie Nierras, Ph.D., Assistant Vice President, International Partnerships, Juvenile Diabetes Research Foundation
- Mary Woolley, President, Research!America
- Antoinette Royster, Member, NIH Clinical Center Patient Advisory Board
- Jerry Sachs, Member, NIH Clinical Center Patient Advisory Board
- Ian Viney, Ph.D., Head of Evaluation, Medical Research Council, UK
- Philip Yeo, M.S., M.B.A., Chairman, SPRING Singapore

NOVEMBER 19, 2013

- John T. Burklow, Associate Director for Communications and Public Liaison, National Institutes of Health
- Sally J. Rockey, Ph.D., Deputy Director for Extramural Research, National Institutes of Health

DECEMBER 5, 2013

- M.R.C. Greenwood, Ph.D., President Emerita, University of Hawaii

APPENDIX B

Literature

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APPENDIX C

Biomedical Research Outputs and Outcomes with Measurement and Assessment Tools
(1) Scientific Impacts

	OUTPUTS
Discovery	• **Primary research articles** (Assessment tools: PubMed, Scopus, Thomson Reuters Web of Knowledge, eSPA, SPIRES, RePORTER, NIH RPPRs, etc.)
	• **Conference abstracts/presentations** (Assessment tools: RPPRs; additional tools needed)
	• **Submissions to research databases and repositories** (e.g., NGVB, NDAR) (Assessment tools: Individual metrics but no comprehensive tools)
	• **Development of research resources and infrastructure** (Assessment tools: Resource and infrastructure grants; RPPRs)
	• **Non-peer reviewed research findings and reports** (e.g., self-publishing, data sharing) (Assessment tools: RPPRs collect information on self-reported Web sites, protocols, software, etc.; altmetrics approaches are emerging)
Validation	• **Patents** (Assessment tools: U.S. Patent and Trademark Office [USPTO] database, eSPA, RePORTER, RPPRs, FDA Orange Book, iEdison)
	• **Licenses** (Assessment tools: USPTO database, FDA Orange Book, iEdison)
	• **IP transfer agreements** (Assessment tools: Individual University Admin. databases; no aggregate databases)
	• **Development and initial clinical testing of diagnosis, treatment, and prevention interventions** (e.g., FDA applications and Phase I–III clinical trials) (Assessment tools: Clinicaltrials.gov, RePORTER [projects linked to Clinicaltrials.gov], ExPORTER, RPPRs, new medical entity [NME] and investigational new drug [IND] applications in FDA Orange Book; comprehensive tool lacking)
	• **Standardized research protocols** (Assessment tools: Publications databases; comprehensive tools lacking)
	• **Validated data repositories** (e.g., NCBI's GenBank, Protein Data Bank) (Assessment tools: NCBI analytical tools, etc.; comprehensive tool lacking)
Consensus	• **FDA approvals of NDAs** (Assessment tools: FDA Orange Book)
	• **Consensus development conferences and bodies** (e.g., National Toxicology Program) (Assessment tools: comprehensive tools lacking)
	• **Book chapters** (Assessment tools: Publication databases; comprehensive tools lacking)
	• **Post-grad curriculum guidelines** (Assessment tools: Tools lacking)
	• **Systematic reviews/meta-analyses** (Assessment tools: PubMed, Cochrane database; no comprehensive tools)
	• **Knowledge transfer metrics** (e.g., citations, Web hits) (Assessment tools: SPIRES, eSPA [linking projects to citations], Thomson Reuters Web of Knowledge, ScienceWire, Elsevier's Scopus, Google Scholar, Journal Impact Factor, H-Index, "Altmetrics" [Web-driven computational approaches])

OUTCOMES/GOALS
Fundamental scientific knowledge • Dissemination of knowledge • Improvements in the process of science

Biomedical Research Outputs and Outcomes with Measurement and Assessment Tools (2) Health Impacts

	OUTPUTS
Application	• **Advanced testing of evidence-based diagnostics** (Assessment tools: RePORTER, ExPORTER, RPPRs, Patent applications [USPTO], IC-provided data, FDA, other HHS agencies; comprehensive tools lacking)
	• **Advanced testing of evidence-based therapeutic interventions** (Assessment tools: Clinicaltrials.gov [Phase IV trials], RePORTER [linking projects to Clinicaltrials.gov], ExPORTER, RPPRs, FDA Orange Book [approvals of NDAs]; comprehensive tools lacking)
	• **Advanced testing of evidence-based preventive interventions and strategies** (Assessment tools: Clinicaltrials.gov [Phase IV trials], RePORTER [linking projects to Clinicaltrials.gov], ExPORTER, RPPRs, FDA Orange Book [approvals of NDAs]; comprehensive tools lacking)
	• **Identification of major public health issues and disease risk factors** (Assessment tools: CDC [National Center for Health Statistics (NCHS)], World Health Organization [WHO])
Implementation	• **Dissemination and implementation efforts, practice guidelines, etc.** (Assessment tools: HHS dissemination and implementation activities, AHRQ's National Guideline Clearinghouse, public health agency recommendations, professional medical associations guidelines; tools needed to track research citations in policies/guidelines)
	• **Adoption of evidence-based diagnosis, treatment, and prognosis strategies** (Assessment tools: Health care claims data [e.g., Medicaid]; AHRQ, HHS evaluations; mHealth apps to monitor adherence; many other tools in development)
	• **Public health campaigns** (Assessment tools: HHS activities [e.g., CDC], NGO activities; comprehensive tracking tools lacking)
Health Measures	• **Burden of disease and quality of life** (Assessment tools: quality-adjusted life years, disability-adjusted life years, health-related quality of life, etc.; CDC [NCHS], WHO, survey data [NSHAP, NHANES, etc.])
	• **Disability** (Assessment tools: Activities of Daily Living [ADLs], Mini Mental State Exam, CDC [NCHS], WHO, survey data)
	• **Longevity** (Assessment tools: Life expectancy, CDC [NCHS], WHO, survey data)
	OUTCOMES/GOALS
	Lower levels of disease • Reduced disability • Improved quality of life • Longer lives

Biomedical Research Outputs and Outcomes with Measurement and Assessment Tools
(3) Broader Societal Impacts

	OUTPUTS
Proximal	• **Government, science, and technology jobs** (Assessment tools: NIH Budget Office, RPPRs, contract invoicing, STAR METRICS)
	• **Demand for R&D supplies** (Assessment tools: Purchase requests, RPPRs, STAR METRICS)
	• **International collaboration** (Assessment tools: NIH funding and cooperative agreements for international activities, RPPRs, Fogarty database)
	• **Support for academia** (Assessment tools: NIH funding, RePORTER, STAR METRICS, RPPRs)
	• **Reduced risk in pre-competitive space** (Assessment tools: R&D investment by pharma and biotech industries; comprehensive tools lacking)
	• **Cross-sector collaboration** (Assessment tools: Material Transfer Agreements; other tools needed)
Intermediate	• **Private sector activity** (e.g., Biotech, Pharma) (Assessment tools: FDA approvals, patents, industry reports [PhRMA], Bureau of Labor Statistics)
	• **Enhanced STEM education** (Assessment tools: NSF Report on Science and Engineering Indicators, NAS, Department of Education)
	• **Communication and interpretation of findings across sectors and to the public** (Assessment tools: IC-provided data, HHS Assistant Secretary for Planning and Evaluation and NIH evaluations, CDC [NCHS])
	• **International science and technology capacity building** (Assessment tools: Tools lacking)
	• **Spurring the local economy** (Assessment tools: Tools lacking)
Distal	• **Uptake and spread of technological innovations** (Assessment tools: Tools lacking)
	• **Workforce output** (e.g., longevity, health) (Assessment tools: CDC [NCHS], WHO)
	• **Workforce development** (Assessment tools: NSF Report on Science and Engineering Indicators)
	• **Internationally competitive science and technology sectors** (Assessment tools: NSF Report on Science and Engineering Indicators, Organisation for Economic Co-operation and Development [OECD])
	• **GDP** (Assessment tools: Data from Bureau of Labor Statistics, Department of Commerce)
	• **Emergence of new sectors and industries** (Assessment tools: Data from Bureau of Labor Statistics, Department of Commerce)
	• **Health care costs** (Assessment tools: Federal data sources, commercial data sources)
	OUTCOMES/GOALS
	Scientifically literate public • Health care–related cost savings • Higher Productivity • Greater capacity for innovation • Greater global R&D competitiveness • Diplomacy and stability through science