Midcourse Review of the

NIH-Wide Strategic Plan for Fiscal Years 2021–2025

Prepared by the Office of Evaluation, Performance, and Reporting (OEPR)

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How to Use this Report

The Midcourse Review of the *NIH-Wide Strategic Plan for Fiscal Years 2021-2025* includes 24 reports on representative activities selected to illustrate progress toward the Plan's nine Subobjectives, and 35 reports on progress towards each of the Plan's Bold Predictions from the launch of the Plan through the midpoint of the plan's lifecycle. This document is not intended to be read cover-to-cover, and sections are organized around the framework of the Plan. You can use the Table of Contents on page 3 to navigate to the section you are interested in. Reports on Progress begin on page 7 and Appendices begin on page 62.

Executive Summary

NIH-Wide Strategic Plan

As the foremost agency for funding biomedical[1] research in the U.S., NIH's 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. NIH accomplishes its mission through the work of 27 Institutes and Centers (ICs), and the NIH Office of the Director (OD); see Appendix A for a full list of NIH Institutes, Centers, and Offices (ICOs) and Appendix B for a list of other U.S. Government components mentioned throughout this report. To realize its mission and harmonize strategic planning across the entire agency, NIH developed the *NIH-Wide Strategic Plan for Fiscal Years 2021–2025* (hereafter referred to as the *NIH-Wide Strategic Plan* or the Plan). The Plan is designed to complement and harmonize strategic plans across the agency. It articulates the highest priorities of NIH overall, how these priorities align with the agency's mission and goals in an evolving research landscape, and how NIH might achieve those priorities. The Plan is not intended to be a comprehensive listing of the many important activities that NIH does and will do in the future.

From fiscal years 2019–2021 (FY19–FY21), the NIH Division of Program Coordination, Planning, and Strategic Initiatives (DPCPSI) within the OD, coordinated the development of the *NIH-Wide Strategic Plan* to cover FY21–FY25. The goal was to follow a process that was transparent, focused on science and good stewardship of research, guided by evidence, and informed by NIH's many communities. The Plan was developed by an internal working group, composed of staff from ICOs, representing the broad range of NIH's activities and research portfolios. It represents an update to the previous iteration of the Plan, which covered FY16–FY20, and highlights accomplishments made during that period.[1] To inform development of the Plan, the working group conducted an extensive information gathering process, inviting input from communities across and external to NIH. The Plan was published in July 2021, following final review by leadership across NIH and other operating divisions within HHS.

Framework of the Plan

The Plan is organized by a strategic Framework that identifies three Objectives—key areas of opportunity that align with NIH's goals and guide NIH in its support of the biomedical research enterprise. These three Objectives outline NIH's priorities in biomedical and behavioral research areas,

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[1] For the purposes of this review, the term biomedical is used broadly to include biological, behavioral, and social scientific perspectives.

research capacity, and research conduct. These Objectives are further divided into nine Subobjectives that describe specific areas of NIH effort toward each of the three Objectives. Across all these priorities, NIH emphasizes several Crosscutting Themes—approaches that are common to all Objectives of the Plan—improving minority health and reducing health disparities; enhancing women's health; addressing public health challenges across the lifespan; promoting collaborative science; and leveraging data science for biomedical discovery. The Plan also presents 35 Bold Predictions—short-term predictions that are considered aspirational goals for biomedical and behavioral research that are potentially within reach, but by no means guaranteed outcomes. The Bold Predictions are not an exhaustive list of all the potential avenues of success for NIH but are designed to illustrate some of the wide-ranging achievements that might be possible under NIH's stewardship by FY25.

Midcourse Review of the Plan

In FY23, as the Plan reached the mid-point of its five-year cycle, DPCPSI coordinated the development of a Midcourse Review of the Plan with the support of staff across NIH. The Midcourse Review articulates progress that has been made toward the Plan's strategic priorities over the course of the first half of the Plan's lifecycle and identifies specific steps that are being taken to further achieve these priorities over the second half of the Plan's lifecycle. This will help to identify gaps and opportunities for action over the upcoming 2.5 years, and support NIH's overall commitment to accountability and transparency. This review will also help to identify successes, challenges, gaps, and opportunities that will inform the next NIH strategic planning process, which will begin in early FY25.[2]

To conduct the Midcourse Review, DPCPSI staff tracked progress toward the Plan's priorities via two approaches—assessing progress toward each Subobjective of the Plan and toward the 35 Bold Predictions. Staff from ICOs were engaged throughout the process; see Appendix C and Appendix D for additional information on the process undertaken. This Midcourse Review includes 24 reports on representative activities, selected to illustrate progress toward the nine Subobjectives, and reports on progress towards each of the 35 Bold Predictions. This document is not intended to be read cover-to-cover, and sections are organized around specific NIH priorities of interest. The Midcourse Review was approved by DPCPSI leadership and shared with NIH leadership to inform the agency on the progress that has been made toward the *NIH-Wide Strategic Plan*.

Midcourse Review Conclusions

From FY21–FY23, NIH made great progress toward the Subobjectives and Bold Predictions outlined in the *NIH-Wide Strategic Plan*. The activities described in the Subobjectives section were selected by DPCPSI leadership based on their alignment with NIH's highest priorities as articulated by the nine Subobjectives of the Plan, and the exemplary progress that they have shown during this timeframe. There has also been significant progress toward achieving 34 of the 35 aspirational Bold Predictions, with many close to fully achieving their predicted outcomes. One Bold Prediction has not seen significant progress, as written, because the project did not proceed as initially anticipated due to staffing changes and shifting priorities.

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[2] For purpose of this report, the acronym CY is used when referring to calendar year and the acronym FY is used when referring to fiscal year.

Midcourse Review of the *NIH-Wide Strategic Plan for Fiscal Years 2021–2025*

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Reports on Progress

Objective 1: Advancing Biomedical and Behavioral Sciences

The NIH portfolio is designed with the breadth and flexibility to address public health needs and emerging areas of scientific opportunity. To do this—in alignment with priorities outlined in the *NIH-Wide Strategic Plan*—NIH is propelling cutting-edge biomedical and behavioral sciences forward on three interrelated fronts, by Driving Foundational Science, Preventing Disease and Promoting Health, and Developing and Optimizing Treatments, Interventions, and Cures.

1.1 Driving Foundational Science

Foundational science includes basic biological, behavioral, and social sciences research that generates the knowledge of how living systems work at the molecular, cellular, organismal, behavioral, and social levels. It provides the building blocks for future diagnostics, treatments, and cures across the entire spectrum of health. By investing in foundational science, NIH is laying the groundwork for important future advances that will improve the nation's health. The following describes progress that NIH has made over the last 2.5 years, as well as plans for the next 2.5 years, to enhance our understanding of human development, foundational neuroscience, and social determinants of health.

Human Development

NIH supports efforts to drive foundational science to better understand human development, including through large initiatives such as the Adolescent Brain Cognitive Development (ABCD) Study® and the INvestigation of Co-occurring conditions across the Lifespan to Understand Down syndromE (INCLUDE) Project. These initiatives are poised to dramatically improve our understanding of basic human development and how the environment and co-occurring conditions—conditions that are often present at the same time—impact development and health, ultimately informing real-world interventions to enhance health outcomes.

The ABCD Study® is the largest long-term study of child health and development ever conducted in the U.S.[2] With 21 sites across the country, this longitudinal study follows nearly 12,000 children and collects brain imaging data, biological materials, and cognitive, environmental, and survey data from participants to help understand how the experiences of adolescence shapes brain, cognitive, and social development over time. From FY21–FY23, the ABCD Study® made brain imaging data available to researchers on an ongoing basis, and all other data were released once per year to encourage secondary analysis by the broader scientific community. As a result, more than 700 scientific papers based on ABCD Study® data have been published on a range of topics—including mental health, screen time, neighborhood disadvantage, obesity/weight gain, genetics, and impacts of the COVID-19 pandemic—and their interactions with brain structure and function.[3] Over the next 2.5 years, the ABCD Study® will continue to collect and share data for follow-up visits. With three more planned release time-points of brain imaging data and six more time-points of behavioral data, researchers will continue to publish more papers, contributing immeasurably to our understanding of factors that influence diverse developmental trajectories.

The INCLUDE Project supports basic, translational, and clinical research on Down syndrome and aims to expand our knowledge about the condition.[4,5] INCLUDE researchers study conditions, such as dementias, celiac disease, congenital heart disease, sleep apnea, and other conditions that affect individuals with Down syndrome and the general population. For example, in a Phase 1 clinical trial of children with

Down syndrome and severe sleep apnea, researchers investigated how a sleep apnea therapy that is already FDA-approved for adults—called hypoglossal nerve stimulation—impacted these children.[6] They found that this therapy improved attention, school performance, and speech clarity in trial participants. If the Phase 2 trial is successful, it could mean immediate changes in the management of sleep apnea for children with Down syndrome. INCLUDE also aims to ensure that standard treatments for co-occurring conditions are appropriate for people with Down syndrome. Notably, INCLUDE helped scientists broaden clinical research participation by assembling a large registry of individuals with Down syndrome and their families who are interested in future research participation.[7] Reflecting INCLUDE's commitment to diversity, equity, inclusion, and accessibility among research participants and the scientific workforce, current funding initiatives and planned webinar series are focused on engaging diverse communities and their perspectives, reducing health disparities, and training the next generation of clinical Down syndrome researchers. Over the next 2.5 years results from these ongoing studies will continue to improve our foundational understanding of Down syndrome.

Together these studies, and the many other NIH investments in foundational human developmental research, will continue to substantially increase the efficacy of interventions and enhance health outcomes for all.

Foundational Neuroscience

In alignment with NIH's priority to advance cutting-edge biomedical and behavioral sciences by driving foundational science, NIH supports a variety of research activities focused on developing fundamental knowledge in neuroscience to inform diagnostics, treatments, and cures across the spectrum of health, diseases, and other conditions that impact the brain.

Consistent with this priority, NIH is committed to funding robust research to identify genetic variants— differences in an individual's DNA compared to other people—that increase an individual's likelihood of developing mental disorders. In FY22, NIH-supported researchers found approximately twice as many locations on the human genome—the complete set of human DNA—that are associated with bipolar disorder than were found in previous research.[8] These findings can help improve our understanding of the biological origins of bipolar disorder. In FY23, NIH-supported researchers identified variations in 10 genes that significantly raise the risk for schizophrenia.[9] Understanding the genetic correlates for these diseases can help identify new areas to target when developing treatments. In the coming years, NIH will continue to support research that generates relevant foundational knowledge on genetic factors and biological processes that contribute to mental disorders. This includes support for the Ancestral Populations Network (APN), an effort to accelerate genetic discovery for mental disorders in cohorts of non-European ancestry.[10] Diversity in genomic studies is key to obtaining more rigorous and comprehensive results that will allow the field to unravel the full set of underlying causes of complex disordered brain function.

As another example of NIH's investment in foundational neuroscience research, the NIH Brain Research Through Advancing Innovative Neurotechnologies® Initiative, or the BRAIN Initiative®, recently launched three large-scale transformative projects that promise to change the trajectory of foundational neuroscience research through understanding how the brain works at a cellular level.[11,12] One of these projects is the BRAIN Initiative® Cell Atlas Network (BICAN), a collaborative research network tasked with creating a comprehensive atlas of the cells in the brain across multiple species, with an emphasis on humans.[13] BICAN builds on the groundbreaking work of the BRAIN Initiative® Cell Census Network

(BICCN) that unveiled a comprehensive description of cell types in the region of the brain responsible for voluntary movement in mice, nonhuman primates, and humans.[14] The BICCN findings, published in FY22 and FY24, are described in 27 and 24 scientific papers, respectively.[15,16,17] The second transformative project is the BRAIN Initiative® Connectivity Across Scales (BRAIN CONNECTS) Network.[18] This project is designed to develop the resources needed to map the connections that brain cells use to communicate with each other. The third project is the Armamentarium for Precision Brain Cell Access, which aims to create powerful new tools to monitor and target the activity of specific cell types in the brain that support complex behaviors.[19] Combined, these projects promise to accelerate development of a comprehensive human brain cell atlas toward identifying the cell types and pathways affected in conditions including Alzheimer's disease and Parkinson's disease.[20]

By leveraging emerging technologies to improve understanding of the biology of the brain, and by expanding and disseminating tools that allow researchers to access and map individual brain cells, these efforts lay the foundation to support the development of therapies to treat devastating human brain disorders. NIH will continue to invest in and support these efforts over the next 2.5 years and beyond.

Social Determinants of Health

To build a strong foundation for biomedical science, researchers have worked to construct an overall picture of human health that incorporates physiological, behavioral, and social factors alone and in combination. Conditions in which an individual is born, lives, learns, works, and ages—referred to as the social determinants of health (SDOH)—combined with the behaviors that they engage in can affect a wide range of health outcomes.[21] Since the launch of the *NIH-Wide Strategic Plan*, NIH has made exceptional and coordinated progress in promoting research on SDOH.

In FY22, NIH established the NIH-wide Social Determinants of Health Research Coordinating Committee (SDOH RCC).[22] The overarching goal of the SDOH RCC is to accelerate NIH SDOH research across diseases and conditions, populations, stages of life, and SDOH domains—such as health care access and quality and economic stability—by facilitating information sharing, developing capacity and expertise for these research areas, and building community and collaboration within NIH.[23] The SDOH RCC focuses on effectively leveraging SDOH investments and innovations across NIH, with over 20 ICOs participating in the RCC. In FY23, the SDOH RCC developed a unified framework to guide NIH-wide coordination and strategic growth of SDOH research at NIH and to effectively advance methods for developing and testing interventions.[24]

In FY22, NIH invested nearly $4.1 billion in SDOH research, funding more than 8,200 SDOH-related research and training awards.[25] In addition, several NIH-wide initiatives were established to advance SDOH research. For example, the SDOH Collection available in the PhenX Toolkit—a resource that provides recommended standard data collection protocols for conducting biomedical research—expands data collection methods to measure individual and structural factors that shape behaviors and health outcomes.[26] These methods make it easier for researchers to design their studies in a way that allows them to compare, share, and combine data from different studies, building greater capacity for SDOH research. In FY23, the NIH PhenX SDOH working group expanded the toolkit, which now has 37 measurement protocols. The toolkit includes 23 individual protocols to facilitate collecting information from individuals about their built (physical) environment, sociocultural environment, or health care system, and it includes 14 structural protocols to collect data on factors at the societal or community level linked to a specific geographic area.

NIH supports SDOH research through the [NIH Rapid Acceleration of Diagnostics Underserved Populations (RADx®-UP) initiative](). Launched in FY21, this initiative sponsors a working group seeking to understand social determinants of COVID-19 testing and vaccination rates by better understanding access to COVID-19 testing and vaccines.[27] NIH also created the Science Collaborative for Health disparities and Artificial intelligence bias REduction (ScHARe), a cloud-based platform which allows researchers to access a wealth of SDOH and other social science data and collaborate with each other to reduce bias in AI and advance health disparity research.[28] These programs and other new initiatives will continue to expand, accelerate, and innovate SDOH research over the next 2.5 years.

1.2 Preventing Disease and Promoting Health

NIH research strengthens the evidence base on which national public health objectives and related disease prevention and health promotion strategies are built. Prevention research targets biological, social, and environmental factors, individual behaviors, and health services and informs health-related guidelines, policies, and regulations. NIH supports a broad portfolio of research that examines the best way to bring effective disease prevention and health promotion strategies into communities. The following describes specific examples of how NIH has advanced this objective over the last 2.5 years and will continue to do so over the next 2.5 years, through investments in vaccine development, precision nutrition, physical activity, postpartum health, and rural health.

mRNA Vaccine Technology

Decades of NIH-supported research on viruses, the immune system, and vaccines has led to the development of new vaccine approaches to prevent disease. Most vaccines contain a weakened or dead bacteria or virus. However, researchers have developed a new type of vaccine that uses a molecule called messenger RNA (mRNA) rather than part of an actual bacteria or virus.[29] mRNA vaccines work by introducing a piece of mRNA that corresponds to a viral protein. As part of a normal immune response, the immune system recognizes that the protein is foreign and produces antibodies against it. If a person is exposed to a virus after receiving mRNA vaccination for it, antibodies can quickly recognize it, attach to it, and mark it for destruction before it can cause serious illness. NIH's investments in this vaccine technology laid the groundwork for the rapid development of mRNA vaccines in the first 100 days of the COVID-19 pandemic.[30] The mRNA-1273 COVID-19 vaccine, co-developed by scientists at NIH and Moderna, received FDA approval for people ages 18 years and older at the beginning of CY22.[31] Later that year, it was authorized for use in children ages 6 months and older. As of March 2022, the U.S. COVID-19 vaccination program is estimated to have prevented 2 million deaths, 17 million hospitalizations, and 66 million infections.[32] Today, there are two COVID-19 mRNA vaccines approved by the FDA, and efforts are underway to develop a universal coronavirus vaccine, as reflected in [Bold Prediction 17](). The success of the COVID-19 mRNA vaccines has prompted renewed and re-prioritized research and development of mRNA vaccines to target other types of viruses since the publication of the *NIH-Wide Strategic Plan*.

To meet the ambitious goal of *Ending the HIV Epidemic* in the U.S. by CY30 as set by HHS, NIH-supported researchers are advancing the development of an mRNA vaccine for HIV.[33] NIH recently launched a Phase 1 clinical trial for three experimental mRNA HIV vaccines to be tested within the NIH HIV Vaccine Trials Network (HVTN).[34,35,36] These vaccine candidates are designed to train the immune system to target HIV—the virus that causes AIDS—with the goal of preventing individuals from becoming infected with HIV if they are exposed to the virus.

mRNA vaccines are also being investigated as a potential approach to developing a universal influenza (flu) vaccine, an effort that is described in detail in [Bold Prediction 16](). Currently, influenza vaccines require yearly updates based on the circulating flu strains. Ideally, a flu vaccine that provides robust, long-lasting protection against multiple subtypes of flu would eliminate the need for a yearly vaccination. NIH scientists recently launched a Phase 1 clinical trial on three vaccine candidates that leverage mRNA technology to target multiple subtypes of flu.[37] This early-stage trial is being conducted through the NIH Collaborative Influenza Vaccine Innovation Centers (CIVICs) program, which was created to support the development of broadly protective, longer lasting flu vaccines.[38]

In addition to HIV and influenza, in FY22, a Phase 1 clinical trial was launched to assess a candidate mRNA vaccine against Nipah virus.[39] Nipah virus can cause mild to severe disease, including swelling of the brain and death.[40] This was the first clinical trial launched for a vaccine that addresses a virus of concern that was identified using the methods outlined in the *NIAID Pandemic Preparedness Plan*.[41] This Plan, published in FY22, outlined a research strategy focused on identifying infectious agents of public health concern and the technologies required to manage them. It will continue to serve as a backbone resource for driving NIH's efforts to prevent disease and promote health.[42] Over the next 2.5 years, NIH will continue to leverage the research on mRNA vaccine technologies to address the COVID-19 pandemic, support research to improve current vaccine technologies, and develop novel strategies to apply to vaccine development for additional infectious diseases of public health concern.

Precision Health Research

Good nutrition is essential for healthy development and basic survival, but it is also integral to well-being and disease prevention. Health conditions linked to poor diet constitute the most frequent and preventable causes of death in the U.S., and are major drivers of health care costs, estimated in the hundreds of billions of dollars annually.[43] There is, however, no such thing as a perfect, one-size-fits-all diet that everyone can follow to stay healthy. To address this, precision nutrition aims to predict and account for differences in the way people respond to food based on a combination of genetic, environmental, and social factors to optimize their diets. Given the promise of precision nutrition to promote health and address diet-related chronic diseases, NIH has been coordinating nutrition research and has placed a high priority on precision nutrition initiatives to accelerate the development of this field of research.

The NIH Common Fund's *Nutrition for Precision Health, powered by the All of Us Research Program (NPH)*, launched in FY22, has a goal of describing and understanding variations in how different people respond to different diets, with the aim of developing computational models to predict individual responses to food and dietary patterns. [44] NPH is building on recent advances across various fields of biomedical science, including artificial intelligence and research on the microbiome—the collection of all microbes such as bacteria, fungi and viruses that live in and on our bodies—and is leveraging the infrastructure and the large and diverse participant group of the *All of Us* Research Program.[45] Together, these advances and infrastructure provide unprecedented opportunities to generate new data, providing insight into precision nutrition at a scale and within a diverse participant population unavailable to other nutrition studies. The study began enrolling participants in FY23 from 14 sites across the U.S., with the goal of engaging 8,000 participants with diverse backgrounds. Over the next few years through programs such as NPH, NIH will continue to conduct nutrition studies involving large numbers of diverse participants, perform analyses on biological responses to foods and dietary patterns,

develop computational models and algorithms, and share data with the research community, ultimately leading to more personalized nutrition guidance.

NIH Pathways to Prevention (P2P) Program

The NIH Pathways to Prevention (P2P) program is designed to identify research needs and gaps in important public health topics through convening scientific workshops.[46] Each workshop focuses on a disease prevention topic that has limited existing research, and the workshops are used to develop evidence-informed recommendations that will guide federal research priorities on that disease area and develop action plans to move the field forward by leveraging federal partnerships. The P2P program furthers the research objective toward preventing disease and promoting health in the *NIH-Wide Strategic Plan*—which highlights the role NIH research plays in strengthening the evidence base on which effective disease prevention and health promotion strategies are built—by facilitating NIH investment in underdeveloped areas of disease prevention.

From FY21–FY23, the P2P program convened four workshops on important public health topics: 1) Can Physical Activity Improve the Health of Wheelchair Users?, 2) Improving Rural Health Through Telehealth-Guided Provider-to-Provider Communication, 3) Nutrition as Prevention for Improved Cancer Health Outcomes, and 4) Identifying Risks and Interventions to Optimize Postpartum Health.[47,48,49,50] In the first workshop, experts considered that individuals who use wheeled mobility devices long-term have distinct health challenges, often experience poorer health outcomes, and may encounter barriers to accessing preventive health care compared to the general population.[51,52] Two of the resulting recommendations were to better measure what matters most to people who use mobility devices and to involve people with lived experience as wheelchair users in the research planning process. In the second workshop, experts considered how telehealth may help health care services reach rural communities. About one-fifth of people in the U.S. live in rural areas; people living in rural areas experience health care provider shortages and have a lower life expectancy than people who live in urban areas.[53] Research recommendations from this workshop included identifying which telehealth services can most effectively improve health and involving patients and clinicians in research. The third workshop focused on the fact that as many as 80% of people with cancer experience malnutrition. Studies have shown that interventions like medical nutrition therapy can help people with cancer keep a healthy body weight, maintain strength, respond to cancer treatment, and have a better quality of life.[54] Recommendations from this workshop highlighted the need for studies on nutritional interventions and studies on the mechanisms that might impact dietary approaches. Finally, the fourth workshop focused on the growing maternal health crisis in the U.S.[55] Many maternal deaths and severe pregnancy-related complications occur during the first year after pregnancy.[56,57] Research recommendations from the Postpartum Health workshop called for a collaborative approach to prevention research with a focus on the communities most affected; and increasing access to essential health services.[58]

NIH will continue to convene partners from across NIH and other federal agencies to collaboratively examine evidence, identify research needs and gaps, and address critical public health problems affecting people's lives.

1.3 Developing and Optimizing Treatments, Interventions, and Cures

Building on the solid foundation of fundamental discoveries in biology, health and disease, and behavior, as well as innovations in data science and emerging technologies, NIH-supported scientists continue to develop new and improved treatments and cures. The path to a new treatment often begins

in the laboratory, where basic researchers refine our understanding of disease and identify aspects of disease causation or progression that could be targeted therapeutically. Researchers use this information to design candidate treatment approaches using cell or tissue samples, animal models, or computer simulations. Over the last 2.5 years, NIH has invested in tools and approaches to develop and optimize interventions, such as tissue chips and precision medicine, and in interventions for specific public health needs, such as aging, cancer, and opioid use disorder.

Tissue/Organ Systems Chips for Drug Screening

Many promising medications have failed to be safe and effective in human clinical trials despite promising preclinical studies. NIH is at the forefront of innovation in biomedical research and drug development, seeking new ways to test and optimize treatments for human diseases using novel alternative methods—tools and methods to reduce and refine the future use of animals in some areas of research.[59] Tissue chips are one of the tools that has greatly improved our ability to effectively test treatments early in development. Tissue chips, or "organs-on-chips," are small devices that mimic human organs and tissues—such as the lung, liver, and heart—by supporting the growth and function of living cells. This novel technology has made notable advances over the last several years.

Collaborations and partnership are vital to the success of NIH's Tissue Chips for Drug Screening program, known as the Tissue Chips program. Through this program, NIH works closely with the pharmaceutical industry and FDA to support research using tissue chips to test new medications and predict whether they will be safe and effective in humans.[60,61] Around 85% of late-stage clinical trials of investigational drugs fail because of problems with drug safety or effectiveness, despite promising preclinical test results using conventional models. This program aims to improve those rates as well as increase researchers' ability to test therapeutics for rare disorders or pediatric conditions, which are not adequately represented in clinical trials, by leveraging tissue chip technology. In FY22, NIH-supported researchers created tissue chips that mimics the biology of two rare neuromuscular diseases and used preclinical data from these tissue chips to get FDA authorization for clinical testing in humans.[62] From FY20–FY23, NIH awarded 10 inaugural grants as a part of the Clinical Trials on a Chip program, an initiative under the Tissue Chips program, which supports researchers' efforts in creating tissue chips to inform clinical trial design for both common and rare diseases.[63,64] Several of these grants will be supported through FY25. This program also aims to use tissue chips to improve the rates of success of new therapeutics in development.

As part of the Tissue Chips program, tissue chips are being used to advance understanding of human health and aging through the Tissue Chips in Space program.[65] Since CY18, NIH has collaborated with the International Space Station U.S. National Laboratory (ISS-National Lab) and NASA to send different types of tissue chips to the ISS-National Lab to determine how human tissues behave in space when exposed to reduced gravity.[66] In order to send the tissue chip technology to space for astronauts to use, the complex technology was automated and miniaturized—from the size of a refrigerator to the size of a shoebox. Through this collaboration, researchers learned that within a few weeks of microgravity exposure, a variety of tissue chips—including skeletal muscle, immune cells, and heart cells—undergo molecular and physiological changes that are similar to aging. This allows researchers to study aging cells within weeks or months at the ISS-National Lab compared to the years or decades needed to study similar changes on Earth. Researchers hope to use these techniques to develop interventions to mitigate the effects of aging. In FY22, three tissue chips took their second flights to the ISS-National Lab to enable

further study of the blood-brain barrier, muscle wasting, and the impact of aging on the immune system.[67,68,69]

Over the next 2.5 years, NIH plans to expand the Tissue Chips program and build upon the successes and lessons learned to develop multi-organ integrated systems, referred to as a "body-on-a-chip." NIH will also support research to generate tissue chips using cells from diverse population groups and continue to advance individualized medicine approaches. Additionally, NIH is building on the recommendations of its Advisory Committee to the Director working group focused on novel alternative methods.[70] The working group built its recommendations based on public and scientific input, and NIH will continue implementing programs in the coming years. Further, NIH is collaborating with the FDA to establish centers that generate data on specific tissue chip platforms and whether those platforms can be used as tools for drug development and for regulatory acceptance by the FDA.[71]

Precision Medicine

Precision medicine is an innovative approach to tailoring treatments for diseases that considers differences in an individual's genes, environments, and lifestyles.[72] Precision medicine allows doctors and researchers to predict more accurately which treatment and prevention strategies will work best in an individual. It contrasts with how treatments are usually developed—using strategies developed for the average person. NIH is investing in precision medicine approaches to develop and optimize treatment across a variety of diseases and for all people. Over the last 2.5 years, NIH has provided and expanded support for resources and initiatives to bring genomic data and precision medicine into the clinic.

Historically, most genomic studies were performed in populations with European ancestry. To optimize precision medicine treatments for all, NIH is working to include people with more diverse ancestry in genomic studies. A critical part of this work is making the polygenic risk scores (PRS)—a number used to describe a person's risk of developing a disease—more applicable to non-European individuals. Since the release of the *NIH-Wide Strategic Plan*, NIH supported the creation of the Polygenic Risk Methods in Diverse Populations (PRIMED) Consortium, which is working to improve the techniques used to predict disease and health outcomes across diverse populations.[73] Multiple PRIMED sites are developing and evaluating methods used to calculate PRS for diseases, including cardiovascular disease, diabetes, and cancer, using datasets that include larger numbers of non-European individuals. To further understand how genomics contributes to a person's risk of developing a disease, NIH supports the Electronic Medical Records and Genomics (eMERGE) Network, which develops and applies approaches to research that combine genetic data with electronic medical record systems.[74] Using this network's resources, researchers have identified new potential treatments for diseases.[75] In the coming years, NIH will continue to support these efforts to ensure PRS are inclusive and generalizable, and researchers have access to medical records data that will improve precision medicine techniques.

From FY21–FY23, NIH supported clinical trial networks to better understand the effectiveness of precision medicine approaches in regular health care settings and in specific diseases. For example, NIH supported the Implementing Genomics in Practice (IGNITE) Pragmatic Clinical Trials Network (PTN) to conduct clinical trials of genomic medicine interventions in diverse populations at participants' regular health care settings. [76] To specifically study the effectiveness of precision medicine approaches to cancer, NIH supported the Molecular Analysis for Therapy Choice (MATCH) Trial.[77] Completed in FY23, MATCH enrolled almost 1,600 patients nationwide to receive a treatment that targeted a specific

genetic change in their tumor, regardless of cancer type. The trial has inspired additional trials furthering our understanding of individuals' tumors and how best to treat them, including for childhood cancers.[78,79]

NIH researchers have also used precision medicine approaches to develop new treatments for rare genetic diseases. In FY19, the first patient received gene therapy treatment at the NIH Clinical Center for a rare genetic disorder impacting the nervous system—GM1 gagliosidosi.[80,81] From FY19–FY23, ten more patients with GM1 gagliosidosi have undergone the treatment with positive results, providing promise for similar approaches to treat other genetic diseases. Into the future, NIH will continue to support the research and research infrastructure needed to bring precision medicine treatments to more patients in their regular health care settings.

NIH Helping to End Addiction Long-term® (HEAL) Initiative
Through the NIH Helping to End Addiction Long-term® Initiative, or NIH HEAL Initiative®, NIH works to accelerate scientific solutions to the opioid crisis, including developing and optimizing novel treatments and intervention strategies for pain, opioid use disorder (OUD), and overdose. Approximately half of NIH HEAL Initiative® funding is congressionally mandated to focus on safe and effective pain management, which is critical to preventing opioid misuse and related harms, including OUD.[82,83] This funding supports research to develop and test non-opioid pain medications, devices, and non-pharmacological therapies for a broad range of pain conditions. The NIH HEAL Initiative® was launched in FY18, and since the launch of the *NIH-Wide Strategic Plan* in FY21, many HEAL-supported programs have made significant advances.

From FY21–FY23, NIH supported clinical trials to test and determine the effectiveness of innovative therapies and pain management approaches in real world settings for multiple pain conditions.[84] For example, one NIH HEAL Initiative® program aims to personalize treatment for chronic low back pain by developing wearable devices to assess back pain and help in prevention and rehabilitation.[85] Toward this end, NIH supports a large, patient-centered, precision medicine clinical trial to learn what back pain treatments are most effective for people based on their unique traits. NIH HEAL Initiative®-supported researchers are also investigating how brain activity changes with chronic pain and are leveraging that knowledge to reduce pain through electrical stimulation of the brain.[86,87]

Additionally, NIH has substantially expanded the OUD therapeutics development pipeline. In CY23 alone, NIH HEAL Initiative® translational pain research supported five new applications to the FDA, seeking approval to test potential treatments for OUD and overdose in humans.[88] NIH has supported more than 36 such applications to FDA over the course of the NIH HEAL Initiative®.[89] While there are highly effective, FDA-approved medications to treat OUD and opioid overdose, these treatments are not effective for all patients, and the increasing potency and diversity of drugs found in the illicit market, including synthetic opioids like fentanyl, requires novel treatment options. NIH HEAL Initiative® OUD medication development research spans preclinical and clinical studies examining novel treatment approaches, including antibodies and vaccines that can target specific drugs in the bloodstream and help remove them from the body.[90,91] For example, NIH is supporting the first-in-human clinical studies of a treatment that targets fentanyl, addressing the urgent need for tools to prevent fentanyl overdose.[92] Other NIH-supported studies are developing and testing new longer-acting formulations of existing medications, which helps improve retention in treatment as fewer visits to the clinic are required.[93]

NIH is poised to expand on the efforts of the NIH HEAL Initiative® and its recent advances, including FDA-approval of Brixadi, a long-acting form of the medication buprenorphine to treat OUD that can help patients adhere to treatment.[94] As these many efforts progress, NIH will continue to develop and optimize strategies to treat pain, OUD, and overdose.

Objective 2: Developing, Maintaining, and Renewing Scientific Research Capacity

NIH also pursues its mission by ensuring that the biomedical research workforce is well trained and diverse and conducts its work within an infrastructure that enables groundbreaking results at a rapid pace. Since the launch of the *NIH-Wide Strategic Plan,* NIH has worked to enhance its support of research capacity to maximize the potential of the research that the agency sustains through Enhancing the Biomedical and Behavioral Research Workforce and Supporting Research Resources and Infrastructure.

2.1 Enhancing the Biomedical and Behavioral Research Workforce

NIH recognizes that its mission will be met only through the continued efforts of a talented and dedicated biomedical research workforce and its strength depends on the sustainability and diversity of the workforce. This is achieved by both maintaining an appropriate balance of researchers at different career stages and supporting research environments that encourage participation from a full and diverse range of talent. The following describes NIH's efforts to enhance workforce diversity and support early career researchers over the last 2.5 years and plans to further these efforts over the next 2.5 years.

Workforce Diversity

As prioritized by the *NIH-Wide Strategic Plan*, NIH is continuously developing and expanding efforts to enhance and support a broad, talented, and diverse biomedical research workforce that can help address pressing biomedical research questions by leveraging their diverse perspectives. To further illustrate the agency's commitment in this area, NIH recently released the *Fiscal Years 2023–2027 NIH-Wide Strategic Plan for Diversity, Equity, Inclusion, and Accessibility (DEIA),* which includes specific strategies toward implementing organizational practices to center and prioritize DEIA in the biomedical research workforce. [95]

An example of NIH's efforts to support a diverse research workforce, the Institutional Development Award (IDeA) Networks of Biomedical Research Excellence (INBRE) program aims to broaden the biomedical research workforce in states that receive low levels of NIH funding by supporting a network in each IDeA state. The networks are supported by a system in which one or more research-intensive institution coordinates the efforts of the primarily undergraduate institutions in the network. In FY23, an evaluation of the INBRE program showed that over half of Historically Black Colleges and Universities, Tribal Colleges and Universities, and Hispanic-Serving Institutions in IDeA states participate in INBRE networks, and that these networks have led to significant changes in institutional research culture, particularly at primarily undergraduate institutions.[96] In FY23, the INBRE program supported a diverse pool of over 1,450 undergraduate students through varied research experiences.

The NIH Common Fund's Faculty Institutional Recruitment for Sustainable Transformation (FIRST) program focuses on enhancing diversity and inclusion among biomedical faculty by providing funds to institutions to recruit cohorts of early-stage research faculty with demonstrated commitment to inclusive excellence, and by establishing inclusive environments within these institutions to help recruited faculty succeed.[97] As of FY23, the FIRST program funds 15 cohort awards to U.S. colleges and

universities. In FY21, NIH supported the establishment of a Coordination and Evaluation Center, which will analyze data provided by FIRST Cohort awardees to evaluate participating institutions' progress in culture change, diversity, and inclusion.[98]

The Maximizing Opportunities for Scientific and Academic Independent Careers (MOSAIC) program facilitates the transition of promising postdoctoral researchers from diverse backgrounds into independent, tenure-track (or equivalent) faculty positions at research-intensive universities.[99] To achieve this aim, MOSAIC combines individual postdoctoral career transition awards with a cohort-based program through which partner organizations—such as scientific professional societies—support and mentor researchers. This model has been successful in helping a diverse pool of researchers transition into faculty positions with funding for their first two years of independent research. As of FY23, over 130 individuals were funded through the first three years of this program—roughly 75% of whom were women and 70% individuals from underrepresented racial and ethnic groups. Additionally, over 42 individuals who participated in the program have already reached the goal of finding independent faculty positions.

NIH also established a working group of its Advisory Committee to the Director focused on re-envisioning NIH-supported postdoctoral training.[100] The goal of this working group was to better understand the challenges facing postdoctoral trainees and make recommendations to address those concerns—especially those that are due to issues with equity and inclusion. Over the next 2.5 years, NIH will continue efforts to enhance the breadth, diversity, and talent of the biomedical research workforce by supporting the above-mentioned programs, while continuing to develop new programs that align with the values and priorities outlined in the *NIH-Wide Strategic Plan* and the *NIH-Wide Strategic Plan for DEIA*.[101]

Early Stage Investigators

NIH is committed to enhancing the biomedical research workforce by expanding opportunities to support and prioritize early stage investigators (ESIs), and other researchers who are early in their careers. NIH's support for investigators across this career stage is critical because ESIs convey new insights, develop innovative ideas, and advance the translation of scientific research into improved health for all.

NIH launched the Next Generation Researchers Initiative (NGRI) in FY17 to address longstanding challenges faced by researchers trying to embark upon and sustain independent research careers.[102] Since its launch, NGRI has promoted the development of policies to increase opportunities for ESIs to receive funding and enhanced training and mentorship programs toward the goal of enhancing the diversity and sustainability of the biomedical research workforce across career stages.[103] One such policy has resulted in grant applications from ESIs being given special consideration during the review process and funding consideration. In FY22, NIH supported an all-time high of 1,609 new ESIs as first-time principal investigators on research project awards, a 6.3% increase over FY21.[104] Going forward, NIH will continue its focus on supporting ESIs, as well as analyzing NGRI policies to ensure that these efforts further career development for women, individuals from underrepresented backgrounds, and people with disabilities in biomedical research.

NIH has several other initiatives to enhance career progression and funding opportunities for ESIs.[105] Within the NIH Common Fund's High-Risk, High-Reward program, two awards are specifically targeted to ESIs.[106] The NIH Director's New Innovator Award supports exceptionally creative ESIs who propose

innovative, high-impact projects in the biomedical, behavioral, or social sciences within the NIH mission.[107] In FY21, 64 investigators were supported by this award and 72 were supported in FY22. Similarly, the NIH Director's Early Independence Award supports outstanding junior scientists with the intellect, scientific creativity, drive, and maturity to bypass the traditional postdoctoral training period to launch independent research careers.[108] In FY21 and FY22, this program supported 13 and 14 investigators, respectively. NIH also continues to fund the Maximizing Investigators' Research Award, the NIH Pathway to Independence Award, the Maximizing Opportunities for Scientific and Academic Independent Careers program,[3] and the Katz ESI Program, all of which contribute to supporting ESIs now and into the future.[109,110,111,112]

NIH is also working to create a better biomedical research ecosystem for ESIs by reframing how early career researchers are defined. For example, rather than focusing on a researcher's age when they receive their first grant, NIH will continue to shift the paradigm to a more holistic view of the time it takes to transition from obtaining a doctoral-level degree to becoming an independent investigator. Among other things, this helps account for differences in the age of matriculation, given that many more individuals may be starting a research career later in life. NIH will continue to develop new initiatives to meet the needs of this critical population within the biomedical research workforce.

2.2 Supporting Research Resources and Infrastructure

For the biomedical research workforce to succeed in moving discovery forward, it requires a scientific infrastructure that is expansive, durable, and capable of quickly integrating state-of-the-art resources that are available to all. To achieve this goal, NIH develops a number of programs and policies designed to provide the biomedical research workforce with stability and flexibility, broad access to innovations in tools and technologies, materials, and knowledge repositories necessary for the design of impactful research programs. The following describes how, over the last 2.5 years, NIH has invested in research networks to improve collaboration and resource sharing, research tools and technology to improve access to expensive and limited equipment, and biological atlases that can be leveraged to find new cures and treatments.

Research Networks

Moving biomedical discoveries forward requires the establishment and maintenance of strong scientific infrastructure that can bring together diverse expertise, integrate state-of-the-art resources, and ensure a well-trained biomedical research workforce. NIH maintains programs that provide broad access to tools and technologies, materials, knowledge repositories, and workforce development necessary for impactful research at local, regional, and national levels. Since the release of the *NIH-Wide Strategic Plan*, NIH-supported networks have been a critical part of the biomedical research infrastructure.

The NIH Common Fund's Undiagnosed Diseases Network (UDN), which transitioned to IC support in FY23, is a nationwide network of clinicians and researchers who leverage basic and clinical research to improve the level of diagnosis of rare and undiagnosed conditions and to uncover their underlying mechanisms.[113,114] Since its launch in FY13, the UDN has provided participants with more than 600 diagnoses and this number continues to grow, including new diseases and syndromes, and has identified hundreds of disease-linked genes and genomic variants.[115] In FY23, the UDN added new clinical sites to expand geographic coverage and reach more diverse participants through the network—including

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[3] For more information on this program, see the section on [Enhancing Workforce Diversity](#).

underserved and underinsured populations—and NIH established a Data Management and Coordinating Center, which will provide infrastructure and research support for this new network of clinical sites.[116,117]

Another NIH network providing critical multidisciplinary research infrastructure and coordination with community partners including government, academia, and industry, is the Center for Alzheimer's and Related Dementias (CARD).[118] In FY22, the NIH Roy Blunt Center for Alzheimer's Disease and Related Dementias Research opened as a home for CARD on the NIH campus.[119] Through CARD, NIH researchers are able to work closely with scientists from around the world to accelerate the translation of scientific findings into real-world applications. Among the many advances made, in FY23, CARD researchers contributed to the identification of a novel genetic cause of Parkinson's disease in some people of African ancestry.[120]

The NIH Clinical and Translational Science Awards (CTSA) Program is a nationwide network designed to speed the translation of research discoveries into improved care, and currently consists of over 60 biomedical research institutions and their partners.[121] To address health disparities, the CTSA Trial Innovation Network (TIN)**,** a national network for multi-site clinical trials, is testing new trial designs and remote technologies to increase the reach of clinical research into rural areas.[122] The CTSA TIN is also accelerating multi-site trials through the Streamlined, Multisite, Accelerated Resources for Trials (SMART) Institutional Review Board (IRB) platform. This platform provides a standardized IRB agreement that ensures appropriate protections for research participants while enabling multi-site studies to begin within weeks instead of months.[123] In FY22, the SMART IRB platform reached 1,000 participating sites making it one of the largest medical research study reliance agreements in the U.S.

Another NIH clinical trials network, the National Clinical Trials Network (NCTN), is a collection of organizations and clinicians that coordinate and support cancer clinical trials at more than 2,200 sites across the U.S., Canada, and internationally.[124] NCTN was instrumental in the FY22 FDA approval of new drug treatments for high-risk early breast cancer and the FY23 FDA approval of treatments for pediatric Hodgkin lymphoma.[125,126,127] Moving forward, NIH will continue to build research capacity and advance our knowledge of diseases and their treatments through these networks.

Research Tools and Technology
Robust and innovative technologies and state-of-the-art instruments are essential for advancing research and accelerating discoveries. NIH's efforts to develop critical resources include programs that provide broad access to state-of-the-art infrastructure for the biomedical research community. Since the launch of the *NIH-Wide Strategic Plan,* NIH has provided, and continues to provide, opportunities for researchers to leverage these resources, democratizing access and facilitating new discoveries that would otherwise be impossible.

Cryoelectron microscopy (cryoEM) and cryoelectron tomography (cryoET) are technologies that enable high-resolution, 3D data collection from biological samples on which prior tools could not collect such data.[128] The NIH Common Fund's Transformative High-Resolution Cryoelectron Microscopy Program (CryoEM Program) is broadening access to cryoEM and cryoET by creating national service centers and cultivating a skilled workforce through the development and implementation of training materials.[129] To facilitate equitable access to research resources, NIH—through the CryoEM Program—conducts targeted outreach to researchers in Institutional Development Award (IDeA)-eligible states that historically have low levels of NIH-funding.[130,131] Research institutions in these states often lack

infrastructure that could support cryoEM research. From FY21–FY23, NIH supported access to these tools by directly funding 15 CryoEM awards.[132] Increased access to these technologies due to the CryoEM Program have led to novel discoveries about proteins involved in neurodegenerative and neuropsychiatric diseases, COVID-19, and antibiotic resistance.[133,134,135,136] The CryoEM program will continue to be supported to continue catalyzing discoveries and accelerating the development of therapeutics.

NIH also supported cutting-edge supercomputing instruments that have transformed biomedical discovery in areas such as cancer, neurological diseases, infectious diseases, and drug discovery.[137,138] Supercomputing is a type of high-performance computing that uses multiple central processing units allowing researchers to perform numerous complex calculations simultaneously. In FY22, supercomputing enabled researchers to calculate the efficacy of mRNA COVID-19 vaccines.[139] Similarly, research published in FY23 used NIH-supported supercomputers to assess data on patients with persistent COVID-19 and found that these patients can spread new variants of the virus.[140] As NIH continues to increase access to supercomputing for biomedical science, more researchers will be able to leverage these resources toward lifesaving discoveries.

Atlases as Research Resources

In complex multicellular organisms, such as humans, the proper functioning of organs and tissues depends on the organization, specialization, and interaction of individual cells. Understanding the functions of, and relationships between, the estimated 37 trillion cells in the human body is a monumental undertaking that could provide key insights into health and disease. Since the release of the *NIH-Wide Strategic Plan*, NIH has invested in critical resources to advance this effort by supporting the development of "atlases" of individual cells in various tissues or organs. These atlases are designed to be open access, comprehensive, dynamic, and 3D and describe everything from what genes are expressed in a cell to where that cell exists spatially in an organ or tissue.

One such effort, the NIH Common Fund's Human BioMolecular Atlas Program (HuBMAP), has supported the development of a framework for mapping the human body at single cell resolution.[141] HuBMAP provides the platform to bring data from multiple sources into a single, widely available resource to allow researchers to access data across different projects. As of FY23, HuBMAP has generated over 2,000 datasets representing 31 human organs.[142] Scientists have used this resource to determine how molecular and organizational changes result in a range of conditions including chronic kidney disease and colon cancer.[143,144] The novel tools, technologies, and datasets developed through HuBMAP will continue to support future discoveries through the program's duration and after the planned program completion in FY25.

The Molecular Atlas of Lung Development Program (LungMAP) is building a molecular atlas of the human lung that is available to the research community.[145] To do this, the LungMAP Consortium, a group of researchers and experts in lung biology, have been working to synthesize current data into a comprehensive and practical atlas of the cells in the lung.[146] This flagship program enables better understanding of human lung development and facilitates development of novel treatments for lung diseases. In FY22, NIH-supported researchers published a comprehensive and practical cellular census of the lung, including different cell types delineated by function and other factors.[147] This resource is available for researchers in the LungMAP Consortium to continue to build upon in the coming years.

The Human Tumor Atlas Network (HTAN), supported by the Cancer Moonshot℠, is an initiative to construct atlases of the dynamic characteristics of human cancers as they evolve from cells that are likely to become cancerous (but have not yet become cancer cells) to advanced disease.[148] HTAN has five research centers focused on these precancerous cells and five focused on cancers.[149] As of FY23, researchers supported by this network have constructed 13 atlases across 51 cancer types. Additionally, in FY22, results from the HTAN Breast PreCancer Atlas study provided a deeper understanding of how abnormal cells within milk duct tissue can progress to invasive breast cancer—cancer that spreads from where it began in the breast into surrounding normal tissue.[150] These findings can help understand what drives relapses for invasive breast cancer and offers insights into potential ways that these cancers can be prevented.

Between FY21–FY23, NIH has supported many additional atlas projects as part of the Brain Research Through Advancing Innovative Neurotechnologies® Initiative or the BRAIN Initiative®, Kidney Precision Medicine Project, Accelerating Medicines Partnership®, and others.[151,152,153,154,155] Moving forward, NIH will continue to support and leverage these research resources and networks to make critical discoveries about human health and disease.

Objective 3: Exemplifying and Promoting the Highest Level of Scientific Integrity, Public Accountability, and Social Responsibility in the Conduct of Science

NIH has a responsibility to uphold public trust and confidence in the agency. In addition to supporting innovative research, NIH must endeavor to ensure that all its operations and the research it supports are conducted efficiently, responsibly, ethically, and with integrity. As prioritized in the *NIH-Wide Strategic Plan*, NIH maintains and strengthens the processes by which it governs the conduct of science by Fostering a Culture of Good Scientific Stewardship, Leveraging Partnerships, Ensuring Accountability and Confidence in Biomedical and Behavioral Sciences, and Optimizing Operations.

3.1 Fostering a Culture of Good Scientific Stewardship

NIH promotes policies and programs that foster and ensure a strong culture of good scientific stewardship. Over the last 2.5 years, NIH has cultivated good scientific stewardship by, among other efforts, developing and maintaining grant review processes that effectively identify impactful research, standardizing health data collection to enhance data sharing amongst researchers and building evaluation capacity within NIH to collect and use data for decision-making.

Grant Review Process

NIH demonstrates its commitment to effective scientific stewardship via its two-stage peer review process for funding applications. Through the peer review process, NIH seeks to ensure that applications for funding receive fair, independent, expert, and timely scientific reviews, so that NIH can support the most promising research. Since the publication of the *NIH-Wide Strategic Plan*, many actions have been taken to strengthen the peer review process at NIH.

NIH is updating and simplifying the criteria used to evaluate funding applications. Currently, reviewers—experts selected from the scientific community—score most applications across five criteria: Significance, Investigators, Innovation, Approach, and Environment.[156] However, for many years NIH has been aware of concerns about the complexity of the current process. With the Simplified Framework for NIH Peer Review, the five regulatory criteria are reorganized into three factors, which will allow reviewers to focus on three central questions: how important the proposed research is, how rigorous

and feasible are the methods, and whether the investigators and institution have the expertise and resources necessary to carry out the project.[157] The new review framework will be in place in FY25.

Actions have also been taken across NIH to enhance the diversity of who reviews funding applications. CSR handles the peer review of 94% of NIH research project grants. To ensure that NIH hears a range of expert scientific perspectives, NIH increased the diversity of its CSR-organized peer review committees in multiple dimensions, including scientific background, demographics, geographic, and career-stage.[158] For example, in FY18, only 35.5% of all reviewers were female, and that increased to 42.7% in FY23.

NIH has also taken steps to ensure that the peer review process proceeds without inappropriate influences. To address the most common biases observed in peer review, in FY21, NIH launched bias awareness training for reviewers.[159] By the end of FY23, the training had been completed by over 22,000 reviewers.[160] Of the surveyed reviewers, 91% found the training substantially increased their awareness of potential biases in review and 93% reported being substantially more comfortable intervening.[161] In FY22, NIH launched a new review integrity training module.[162] More than 90% of reviewers who took the training in the first month after its launch reported that the training increased their knowledge of tools to prevent and report integrity breaches.[163] As of FY24, both the review integrity and bias awareness trainings are required for all NIH reviewers.[164] As these efforts are realized over the next several years, peer review at NIH will become fairer and more inclusive, and better represent the needs and demographics of the scientific community.

Common Data Elements

NIH fosters a culture of good scientific stewardship by ensuring that research data collection is consistent with FAIR principles—that all data should be findable, accessible, interoperable, and reusable.[165] To reach this goal, NIH has actively promoted the adoption of research data standards in research projects and clinical trials. Of note, over the last 2.5 years NIH has expanded and improved the use of Common Data Elements (CDEs) in NIH-supported research. CDEs are standardized, well-defined questions, paired with a set of allowable responses that can be used systematically across different sites, studies, clinical trials, or clinical settings.[166] Using CDEs can help researchers collect data consistently within their own projects and across related projects, share and combine datasets, meet funding requirements, and save time.[167] Additionally, CDEs and other efforts to standardize research data collection have many benefits for open science—the principle and practice of making research products and processes available to all, while respecting diverse cultures, maintaining security and privacy, and fostering collaborations, reproducibility, and equity. By encouraging researchers and institutions to adopt these standards, NIH is enhancing the quality and reproducibility of research outcomes.

In FY20, the NIH Scientific Data Council charged a new NIH CDE Governance Committee with determining which CDEs submitted from across NIH meet the criteria for inclusion in the NIH CDE Repository.[168,169] As of FY23, the committee has reviewed hundreds of CDEs against their criteria for acceptability, reusability, and validity, and determined which should be made available in the CDE Repository. The committee also provided feedback to submitters to help them revise and resubmit their CDEs for inclusion in the Repository. To ensure that the Repository is user-friendly and accessible, the committee has also worked with users through continued user testing.[170]

The CDE Repository and use of CDEs also supports the *FY23 NIH Data Management and Sharing Policy*.[171] This policy is designed to promote sharing of scientific data and to accelerate biomedical

research discovery by enabling validation of research results, providing access to high-value datasets, and encouraging data reuse.[172] Biomedical research data are often collected in different ways for various research purposes, using different data models, which presents significant challenges for collaborative research, meta-analysis, and management/sharing of data. These challenges and opportunities led the NIH Scientific Data Council to launch an effort to better understand the use and development of CDEs in research and to inform appropriate NIH guidance and mechanisms.[173] The council is specifically aiming to lower the barriers to CDE use and improve the ability to aggregate and integrate CDE-based data. In FY24, a working group of this council published a request for information to seek public input, including from patient advocacy groups, on these and additional topics selected by the Scientific Data Council.[174] One such topic is which CDEs might be included in a core set of minimum CDEs to be adopted for all NIH translational or clinical studies.

In the future, improved standardization is expected to increase the adoption of CDEs in NIH-supported research, and the CDE Repository will be expanded to encompass a broader range of research domains and data types with resources to help researchers use CDEs in their studies.[175]

Evaluation Capacity Building

As part of its mission, and in response to Title 1 of the *Foundations for Evidence-Based Policymaking Act of 2018* (P.L. 115-435), NIH remains committed to strengthening organizational capacity to build and use high-quality data to measure the progress and effectiveness of its activities and to enhance decision-making.[176] Using data to inform decision-making is critical to fostering a culture of good scientific stewardship, and NIH has made significant progress by creating opportunities and resources for information sharing and effective evaluation practices.

In FY22, NIH launched the Evaluation and Analytics Community of Practice to create an inclusive and interactive community focused on improving the quality of NIH evaluations and analyses. The community of practice has members from many different functional areas at NIH, including staff who focus on evaluation and analysis, in addition to research programs, policy, agency budgets, and more. This community offers all members opportunities to share with each other the different strategies taken to analyze and evaluate NIH initiatives.

NIH has developed resources to support staff across the agency as they use data to inform decision-making. In FY22, NIH launched a web-based tool that NIH staff can use to collect and share resources for designing and conducting more robust evaluations and other assessments of research training programs.[177] In FY22, NIH also curated a list of over 90 opportunities for NIH staff seeking further training in evaluation, and NIH launched a pilot Coursera-based learning program. In FY23, NIH began creating a suite of resources, including evaluation tools, evaluation templates, and additional resources, to support NIH staff in acquiring contracted evaluation and/or analytic expertise. These efforts are ongoing.

Evaluations and other analyses of its policies, programs, and operations provides NIH with evidence that can inform decisions. For example, a recent evaluation of the Native American Research Centers for Health (NARCH) resulted in changes in the program's design.[178] NARCH is a capacity-building program that supports health-related research, research career enhancement, and research infrastructure enhancement activities within federally recognized American Indian/Alaska Native (AI/AN) tribal entities. The evaluation included an assessment of the program's effectiveness in addressing the health research, education, and training needs prioritized by AI/AN communities. The evaluation led to changes

in the NARCH program that streamlined the process for applicants, ensured that the majority of NARCH funds remain with AI/AN tribal entities rather than non-AI/AN partner organizations, and incorporated culturally appropriate language into review guidelines.[179] NIH will continue to support these evaluation capacity-building activities and its evaluation community to further strengthen its data-informed decision making.

3.2 Leveraging Partnerships

Advancing NIH's mission requires strategic partnerships with a range of organizations, including other federal agencies, international governments, the private sector, and the public. These partnerships bring enhanced coordination, critical expertise, pooled resources, and novel community connections to augment NIH efforts. Over the last 2.5 years, NIH has engaged in partnerships to combat the COVID-19 pandemic, built a program that leverages community partnerships to advance science for society, and supported existing public-private partnerships to further enhance our understanding of a range of diseases and conditions.

Partnerships to Combat the COVID-19 Pandemic

NIH's ability to respond to current and emerging public health needs relies on collaborations with partners in industry, academia, non-profits, communities, and U.S. and international government agencies. These partnerships bring enhanced coordination, critical expertise, pooled resources, and novel community connections, all of which improve the impact and effectiveness of NIH efforts. The value of these partnerships has been evident in the response to the COVID-19 pandemic over the past several years.

Coordinated by the Foundation for the National Institutes of Health, the Accelerating COVID-19 Therapeutic Interventions and Vaccines (ACTIV) public-private partnership enabled the open exchange of ideas and information among government, industry, and researchers.[180] From FY20–FY23, ACTIV successfully accelerated the development of COVID-19 vaccines, therapeutics, and diagnostics, including testing 37 potential therapeutic agents through six clinical trials at more than 620 clinical trial sites.[181] Additionally, NIH launched the NIH Community Engagement Alliance (CEAL) Against COVID-19 Disparities initiative to work directly with communities in multiple states that were disproportionately affected by COVID-19.[182] Through CEAL's and ACTIV's partnerships, researchers were able to reach out to and recruit more diverse clinical trial participants, including the populations who were most impacted by COVID-19 and bore the greatest burden of illness.[183]

In addition to ACTIV, NIH leveraged partnerships across the federal government—with BARDA, DARPA, FDA, and CDC—to develop the Rapid Acceleration of Diagnostics (RADx®) initiative to advance the development, commercialization, and implementation of technologies to detect the virus that causes COVID-19.[184] Two examples of RADx® programs that continue to leverage these partnerships to address COVID-19 are RADx® Tech and RADx® Underserved Populations (RADx®-UP).[185,186] Through RADx® Tech, NIH leverages partnerships to accelerate innovation in COVID-19 diagnostic tests.[187] Between April 2020 and March 2023, the program bolstered the national testing capacity, providing more than 8 billion COVID-19 tests and test products by supporting dozens of tests that received emergency use authorizations (EUAs) from FDA.. By FY22, the capacity developed through this program enabled more than 500 million COVID-19 tests to be produced each month, up from just 19 million produced each month at the beginning of FY21.[188]

Despite the paradigm shift to at-home testing, COVID-19 diagnostics bypassed significant populations including people with low or no vision, reduced dexterity or motor skills, and older adults. In FY22, NIH, through the RADx® Tech Accessibility Program, brought together key groups to focus on how to improve the design of diagnostic at-home COVID-19 tests for a range of accessibility challenges. In FY23, this resulted in an FDA authorization for a COVID-19 test that incorporates design principles for accessibility.[189,190] Similarly, RADx®-UP encourages collaboration with researchers and community members to assess and expand COVID-19 testing access for [populations most affected by COVID-19](#). Since the middle of FY20, RADx®-UP has supported more than 144 research projects and continues to build partnerships for community-directed research with the goal of informing multi-level public health policy decisions (local, state, federal).[191,192] It also seeks to support the implementation of effective strategies for reducing disparities in future pandemics and emerging infectious diseases.

The accomplishments of these programs over the last several years has advanced our pandemic preparedness both domestically and globally, and NIH will continue to leverage the collaborations, tools, and processes developed through these programs to help combat future emerging infectious diseases.

NIH Community Partnerships to Advance Science for Society (ComPASS) Program

The most pressing and complex challenges in biomedical research require people with different perspectives, experiences, and resources to come together in search of innovative and effective solutions. NIH has been investing in efforts that leverage partnerships with communities to address the pervasive and persistent issue of health disparities for racial and ethnic minorities and other disproportionately affected populations, and since the launch of the *NIH-Wide Strategic Plan,* NIH has supported new programs to advance these efforts. Health disparities is a biomedical research challenge that requires engaging partners from different sectors to effectively address the multi-level structural factors that contribute to health inequities.

As one component of the NIH response to this challenge, the NIH Common Fund's Community Partnerships to Advance Science for Society (ComPASS) program aims to 1) develop, implement, evaluate, and share community-led health equity structural interventions that leverage partnerships across multiple sectors to reduce health disparities, and 2) develop a new health equity research model for community-led, collaborative intervention research across NIH and other federal agencies.[193] In FY21, NIH sought input from external communities including representatives from academic institutions; nonprofit, community-based, and faith-based organizations; foundations, think tanks, and professional societies; and tribal communities and organizations through listening sessions.[194] The participants discussed research opportunities, challenges, and community needs for interventions that target social factors influencing health and health disparities. The results of these listening sessions informed the development of the ComPASS program, such as its emphasis on including the voices, talents, and lived experiences of community members in research studies conducted in their communities.

In FY22, the ComPASS program was launched, and in FY23, through ComPASS, NIH supported 25 awards to community organizations working with academic researchers and other partners to identify specific community health needs and develop approaches to address them.[195] These partnerships will enable organizations to develop, launch, and evaluate structural interventions addressing community concerns, such as economic development, neighborhood characteristics, health care access and quality, and nutrition and access to healthy food.

Through ComPASS, NIH is supporting communities and researchers to work collaboratively as equal partners in all phases of the research process to enhance the quality of interventions and advance health disparities research. These efforts will advance the program's goals of increasing diversity and inclusion in research by cultivating community trust and partnerships, building research capacity among the community and relevant partners, and enhancing community organization competitiveness for future funding. Into the future, NIH will continue to leverage these partnerships, gaining valuable experience and insight into how to support successful future community-led health research.

Accelerating Medicines Partnership® (AMP®)

NIH leverages partnerships to further expand fundamental knowledge of biological systems and explore ways of applying that knowledge. One such partnership is the Accelerating Medicines Partnership® (AMP®) program, which is a public-private partnership, managed by the Foundation for the National Institutes of Health, between NIH, FDA, and multiple life science, pharmaceutical, and non-profit partners.[196] AMP® aims to improve understanding of disease pathways and validate potential therapeutic targets for a wide range of diseases. To date, AMP® has successfully launched 10 programs including the AMP® Rheumatoid Arthritis and Systemic Lupus Erythematosus (RA/SLE) program, AMP® Autoimmune and Immune-Mediated Diseases (AIM) program, and AMP® Bespoke Gene Therapy Consortium (BGTC) program.

Autoimmune diseases, like RA/SLE, are the result of the immune system mistakenly attacking one's own body. These diseases have a lot of variability in symptoms and patients often respond differently to the same treatment.[197,198] Through AMP® RA/SLE, NIH has leveraged established partnerships to gain important insights into these diseases that would not have been possible without these collaborations. In FY23, AMP® RA/SLE, one of the original AMP® projects, formally closed as part of its planned lifecycle.[199] In FY23, NIH launched the Arthritis and Autoimmune and Related Diseases Knowledge (ARK) Portal to house the research data collected through AMP® RA/SLE.[200,201] The publicly available portal facilitates collaboration by accumulating and organizing a diverse portfolio of datasets generated by research teams focused on arthritis and autoimmune and related diseases. In FY21, NIH and its partners launched AMP® AIM as an expansion of AMP® RA/SLE.[202] The goal of AMP® AIM is to further advance the discovery of disease mechanisms and therapeutic targets for a variety of autoimmune and immune-mediated diseases. AMP® AIM also seeks to identify and define how different autoimmune diseases have similar or overlapping mechanisms driving them.

Developing gene therapies for rare genetic diseases is another area where the partnerships in AMP® are essential to making progress. The AMP® BGTC program aims to foster the development of gene therapies to treat rare genetic diseases, including those diseases too rare to be of commercial interest.[203] In FY23, AMP® BGTC announced the selection of eight rare diseases for its clinical trial portfolio.[204] The selected diseases are caused by a single gene mutation, and thus can potentially be treated by gene therapy. These clinical trials are designed to demonstrate ways to streamline the approval pathway for first-in-human clinical trials to develop novel gene therapies for rare diseases. If successful, these approaches are expected to be especially promising for other rare diseases caused by a single, known gene mutation. Over the coming years, NIH will leverage the results from these trials to increase efficiency in clinical trials for other gene therapies to help bring cutting-edge health interventions to more patients.

These are just a subset of the many programs that have benefitted from NIH leveraging partnerships to improve our understanding of human disease. NIH has similarly supported AMP® programs to drive research on Alzheimer's Disease, Schizophrenia, Heart Failure, and more.[205]

3.3 Ensuring Accountability and Confidence in Biomedical and Behavioral Sciences

To foster confidence in NIH-supported research, NIH must ensure that both its operations and its supported research are conducted efficiently, responsibly, ethically, and with integrity. NIH is taking steps to maintain and strengthen the processes by which it governs the conduct of science, continuing to be accountable for the public funds it invests in research. The following illustrates how NIH has ensured accountability and confidence through two avenues—prioritizing safe and respectful work environments within NIH and improving timely public access to data and research results.

Safe and Respectful Work Environments

As prioritized in the *NIH-Wide Strategic Plan*, NIH is committed to promoting safe, respectful, and healthful work environments conducive to high-quality research, by working to prevent harassment and mitigate its detrimental impacts within scientific environments and wherever NIH-supported research is conducted. This is critical to ensuring accountability and confidence in NIH research.

The NIH Civil Program provides the internal NIH community with reporting tools and a process to review all allegations of misconduct in an objective and consistent manner. This program works to identify inappropriate behaviors and refer findings to management so they may ensure that inappropriate behavior is curtailed and addressed via corrective action.[206] Since FY21, more than 1,400 allegations of inappropriate conduct have been reported to Civil, resulting in the identification of more than 300 violations of the *NIH Anti-Harassment Policy*—all of which resulted in corrective administrative actions.[4,207,208] These efforts help ensure safety and accountability for the more than 20,000 staff at NIH.[209]

To address harassment and discrimination within the extramural research community, over the past several years NIH has taken many substantive actions based on NIH's grant authorities. NIH expects recipient institutions to have policies and practices in place that foster an environment free from harassment—including sexual harassment, discrimination, and other forms of inappropriate conduct that can result in a hostile work environment.[210] Through regular outreach, notifications, and engagement with the research community, NIH communicates to institutions and researchers that such behaviors are not acceptable.[211,212] In FY23, NIH revised the NIH Grants Policy Statement setting the expectation that grant recipients establish codes of conduct, which define expectations of integrity and ethical values and include criteria of competence for personnel involved in the work supported by NIH grant funds. This includes assuring work environments are free of discriminatory harassment and are safe and conducive to high-quality work. In FY22, NIH published a notice informing recipients of their statutory obligation to notify NIH when an individual on an NIH award has been removed from their position or has been otherwise disciplined by the recipient institution due to concerns about harassment, bullying, retaliation, or hostile working conditions.[213,214] NIH is now much better positioned to prevent individuals found responsible for harassment from resigning and seeking new employment without notifying new employers of the misconduct.

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[4] Note, these violations do not include the more than 128 allegations that are currently active in the Civil process.

Allegations and notifications related to harassment, discrimination, and hostile work environments have increased substantially since NIH started tracking these in FY18.[215] This rise in numbers is likely due in part to the heightened awareness of harassment in the scientific workforce, as well as NIH's outreach efforts and strengthened recipient notification requirements.[216,217] NIH regularly updates the data publicly reported on harassment allegations and outcomes.[218] Moving forward, NIH will continue to record and respond to accounts of workplace harassment and hostility to promote accountability and confidence in the agency.

Public Access and Data Sharing

Ensuring timely public access to the products of NIH research—including data and scientific publications—fosters confidence in NIH-supported research and demonstrates good stewardship and accountability. NIH's investment in infrastructure and policies that support public access to research results is one part of ongoing efforts to ensure that NIH's operations and supported research are conducted efficiently, responsibly, ethically, and with integrity.

Since FY08, NIH has maintained the *NIH Public Access Policy*, which requires that all NIH-supported researchers submit an electronic version of any final, peer-reviewed manuscript to NIH's PubMed Central—the online platform where all NIH-supported research articles are publicly available.[219] In FY22, the White House OSTP published a memorandum on free, immediate, and equitable access to research, with several new directives for agencies to make articles and associated data available immediately following their publication.[220] Previous OSTP guidance allowed researchers up to 12-months after publication before requiring articles to be made publicly accessible. In FY23, NIH revised its *Public Access Policy* to address this new guidance and to outline NIH's policies for public access to research results. NIH sought public comment on its updated policy and will gather additional input through a workshop of the National Academies.[221,222,223] This will inform further revisions to the *NIH Public Access Policy*, expected by FY25.

Over the last 2.5 years, NIH has also substantially increased its efforts to support the sharing of data generated from NIH-supported research. In FY23, the *NIH Data Management and Sharing (DMS) Policy* took effect, which requires NIH-supported researchers to prospectively plan for maximizing scientific data sharing, while considering factors such as legal, ethical, or technical issues that may limit the extent of data sharing and preservation. NIH requires all applicants planning to generate scientific data to prepare a DMS Plan that describes how the scientific data will be managed and shared. As part of the policy launch process, NIH sought public input on implementation approaches and guidance materials, including resources on how to develop informed consent language, protect participant privacy, and develop appropriate DMS Plans when working with Tribes.[224,225,226,227] NIH provides a centralized resource with DMS guidance for researchers, including how to find data repositories, as well as educational materials, such as sample DMS Plans and recorded webinars.[228,229,230] As researchers start following NIH's guidance to comply with the DMS Policy, NIH will monitor compliance and continue ensuring that the expectations on researchers are clear. NIH also will continue to support opportunities for greater coordination and streamlining of existing data infrastructure to allow for improved implementation of these policies.[231,232] These efforts will allow the public to access NIH research products in a more efficient and accessible manner, improving NIH's stewardship of public funds to advance biomedical science.

3.4 Optimizing Operations

NIH seeks to continually optimize operations across an array of business, administrative, and scientific functions, as well as to improve its physical and technological infrastructures. Increasing coordination and engagement throughout the agency and managing risk while fostering innovation are critical to the stewardship of the nation's biomedical and behavioral research ecosystem. Over the past 2.5 years, NIH has invested in digital and other technologies that can improve the efficiency of operations as well as the physical infrastructure that allows NIH scientists to leverage these new technologies.

Digital Efficiencies

NIH works to optimize its operations by improving its digital capabilities, taking a strategic account of existing digital technologies, and prioritizing future investments. Advances in digital technology and data science are fundamentally changing the very nature of how biomedical scientists conduct research and how NIH operates. Digital technology has become an inseparable component of the scientific process, enabling innovation across the research spectrum at unprecedented scale. Since the release of the *NIH-Wide Strategic Plan*, NIH has been developing guidelines and tools to advance digital technology for research and operations.

Rapid innovation in digital technology is creating new demands for high-speed computation, scalable and cost-effective data storage, advanced analytics, and a broad range of technology-support functions. In early FY22, NIH leadership initiated NIH-wide planning efforts to identify the changes and capabilities needed to advance NIH's mission and guide NIH's technology investment strategies over the next five years. The strategies within the NIH-wide digital strategic plan—*Digital NIH: Innovation, Technology, and Computation for the Future of NIH for FY 2023–2028*—propose new approaches to manage and govern NIH technology investments; describe a framework to guide implementation of high-priority, high-value capabilities; and recommend a path for NIH to move forward.[233]

One example of how NIH is advancing the use of digital technology is through its transition to electronic records. NIH provides guidance and support across the agency to promote electronic recordkeeping through the NIH Records Management Help Desk, which provides office hours for NIH staff.[234] In addition to supporting the transition to electronic records, NIH provides support across the agency on the proper maintenance of existing physical records. In FY23, OMB and the National Archives and Records Administration issued a memorandum requiring that federal records be managed in a digital format by FY24.[235] NIH has been working to digitize its records over the past 2.5 years and will continue to invest in and improve these efforts over the coming years.

An example of how digital tools are improving operations is the integration of real-time dashboards into NIH's grant review process. In FY21, NIH launched three dashboards to better support scientific review staff in the management of their work. The Reviewer and Meeting Dashboards are used by NIH staff to monitor data such as critiques and scores from grant review panels, allowing NIH staff to track which applications have or have not yet been reviewed. The Video-Assisted Meetings (VAM) dashboard provides data and analytics support for virtual grant review meetings, and the Scientific Review Officer Workload Dashboard supports the peer review process and continuously tracks the workload of NIH staff in real-time, aiding in staff management.[236] These tools enable the identification and resolution of issues in real-time, replacing inefficient and ineffective manual tracking processes. As a result, NIH staff can spend more time on other critical aspects of peer-review oversight.

NIH Buildings and Facilities (B&F) Program Prioritization Model

The conduct of scientific discovery is enabled through safe and reliable facilities that can be adapted to support research to address current and emerging public health needs. Existing NIH facilities must be properly maintained, and new state-of-the-art facilities must be made available to provide access to innovative technologies, meet environmental needs, enhance sustainability, and achieve NIH's goals. In FY19, the National Academies published a consensus study report on *Managing the NIH Bethesda Campus Capital Assets for Success in a Highly Competitive Global Biomedical Research Environment*.[237] The report laid out 14 recommendations for NIH, including suggestions for how to prioritize building and facilities projects and that NIH should explicitly prioritize the initiatives specified within the *NIH-Wide Strategic Plan*.

Since the release of the *NIH-Wide Strategic Plan*, and in accordance with the recommendations made in this National Academies' report, NIH has enhanced its building and facilities project prioritization and selection process to better identify which renovation and new construction projects should be undertaken. Through the IC Buildings and Space Planning interview process, NIH has placed a greater emphasis on linking its strategic research goals and objectives to the reality of the age and condition of NIH facilities, the supporting infrastructure, the buildings and facilities program funding challenges, and congressional mandates.

To address the National Academies' recommendation to better align its priorities for research and facilities, NIH has made several advancements. In FY21, the site and building plans for the Surgery Radiology and Lab Medicine facility on the Bethesda campus were approved.[238] This facility will alleviate operational and building deficiencies and provide flexibility for the NIH Clinical Center to better support current and emerging medical research initiatives. In FY24, the Comparative Medicine Center on the Rocky Mountain Laboratories campus will be completed.[239] This new facility is critical to NIH's ability to respond to emerging infectious diseases that require more extensive biocontainment precautions, such as the viruses that cause COVID-19, MERS, and Ebola. In FY25, the Clinical and Computational Sciences Building on the Research Triangle Park campus will begin construction. This facility will be designed to advance team science and discovery by bringing together expertise in computational and data science, life sciences, and computer technologies.[240]

In the coming years, NIH will further enhance operating procedures to improve visibility of the critical relationship between the facilities planning process and NIH research priorities. Project programming, master planning, and corporate decision-making procedures will be fully documented and communicated to all parts of the NIH community. These efforts to improve and maintain NIH facilities will be critical in further optimizing operations to better support the NIH mission.

Bold Predictions

In the *NIH-Wide Strategic Plan*, NIH set out 35 ambitious goals—Bold Predictions—for the next five years. These short-term predictions are intended to be aspirational goals for biomedical research, outcomes that are potentially within reach but by no means guaranteed in the five-year cycle of the Plan. The Bold Predictions are not an exhaustive list of all the potential avenues of success for NIH but are designed to span the broad scope of NIH's priorities in research areas, research capacity, and research conduct. This is illustrated by Appendix E, which outlines how the 35 Bold Predictions align with the nine subobjectives of the Plan.

From FY21–FY23, NIH made significant progress toward almost all Bold Predictions, with one Bold Prediction demonstrating how challenges due to shifting priorities can profoundly affect the pace of scientific advancement.

1. The *All of Us* Research Program will reach its goal of one million diverse participants and will have gathered the most diverse collection of data (e.g., deep phenotypic, -omic, electronic health records, digital health technology) on one million or more participants of any research resource in the world.

The NIH *All of Us* Research Program is inviting one million people across the U.S. to help build one of the most diverse health databases in history, capable of informing thousands of studies on a variety of health conditions. Since its launch in FY18, *All of Us* has refined its efforts to meet the most pressing biomedical research needs and updated its goal to reach one million participants by the end of CY26. *All of Us* has built and nurtured a consortium of more than 100 awardee partners across the country. As of FY23, more than 695,000 participants have consented to join the program and more than 480,000 participants have completed the initial steps of the program.[241] Nearly 50% of participants who have completed these initial steps identify with a racial and ethnic minority group, and more than 80% of participants are from populations underrepresented in biomedical research including people over age 65, LGBTQ+ people, those who live in rural areas, people with low income or limited education, and people with disabilities.[242]

All of Us has begun sharing data with researchers to enable precision medicine discoveries. In FY23, *All of Us* expanded its dataset to include nearly a quarter million whole genome sequences for broad research use.[243] About 45% of this data was donated by people who self-identify with a racial or ethnic group that has been historically underrepresented in medical research. The data expansion provides registered researchers access to the world's largest and most diverse dataset of its kind, paving the way to help advance health equity and uncover health care approaches better tailored to people's genes, lifestyles, and environments. As of FY23, more than 6,400 researchers from over 550 institutions are registered to use the *All of Us* Researcher Workbench, with over 6,300 active research projects underway.

All of Us has collaborated across NIH to include data relevant to different research portfolios. This includes launching the NIH Common Fund's *[Nutrition for Precision Health, powered by the All of Us Research Program](link)*, which seeks to engage 8,000 participants from diverse backgrounds at 14 sites nationwide to learn more about how our bodies respond differently to food; releasing two new mental health and well-being surveys covering a range of behavioral and emotional health topics; and making plans to integrate environmental exposure data tied to the locations where participants live.[244,245,246]

Over the next 2.5 years, *All of Us* will continue to develop, test, and implement innovative approaches to grow its diverse participant community and make more data available to drive medical breakthroughs. New awards to support data linkages, participant and partner services, community engagement, and recruitment will further this work. These efforts will support the goal to recruit one million diverse participants by FY26 to generate the most diverse health databases in the world.

2. The regular use of genomic information will have transitioned from boutique to mainstream in all clinical settings, making genomic testing as routine as complete blood counts.

Over the last 2.5 years, NIH has prioritized integrating genomic testing into routine clinical care through various efforts, such as holding an online seminar with the public in FY21.[247] The general consensus across the biomedical community is that routine genomic testing in everyday clinical settings will require broader availability of trained clinicians with genetics expertise and a shift in genomic testing practice so that it is used to determine risk before a condition is diagnosed.

Toward this end, NIH supports multiple initiatives to expand genetics knowledge for all clinicians, including the Implementing Genomics in Practice (IGNITE) Pragmatic Clinical Trials Network.[248] This Network is currently conducting two trials, one comparing genotype-guided drug therapy versus standard approaches to drug therapy selection, and another looking at the effect of returning genetic risk information to patients of African ancestry with hypertension (high blood pressure) and their primary care providers. In a new phase of the Electronic Medical Records and Genomics (eMERGE) Network—a consortium that NIH has supported since FY07—the eMERGE Genomic Risk Assessment and Management Network focuses on understanding how to best validate and implement genome-informed risk assessments, which are defined as a combination of genomic, family history, and clinical risk factors used to estimate a patient's risk of developing disease. Supported from FY20–FY25, coinciding with the timeframe of the *NIH-Wide Strategic Plan*, the group is demonstrating how limits to the regular use of genomic information in clinical settings can be addressed.[249]

From FY21–FY23, NIH also supported research into specific applications of genetic testing in the clinical setting, such as to better target therapies to improve quality of life with aging and treat osteoporosis, and in clinical trials to study the effectiveness of targeting specific genetic changes in a person's tumor.[250,251] For example, NIH supports a series of [precision medicine](#) cancer treatment clinical trials building from infrastructure established for the Molecular Analysis for Therapy Choice (MATCH) and Pediatric MATCH clinical trials, which are winding down after completion of more than 30 studies.[252][253] In FY23, NIH launched three second generation precision medicine trials, including ComboMATCH to test combinations of different therapies, MyeloMATCH for patients with acute myeloid leukemia or myelodysplastic syndrome, and ImmunoMATCH to test immunotherapies.[254] Finally, NIH is continuing to advance essential tools for transformation of data to knowledge and the distillation of large amounts of information on genes and their resulting traits into actionable results, including interpretation for clinical use.

Through the Advancing Genomic Medicine Research program, NIH supports research designed to stimulate innovation and advance understanding of when, where, and how best to implement the use of genomic information and technologies in clinical care. Running through FY28, these grants are the next step in realizing NIH's Bold Prediction to integrate genomic testing into multiple real-world clinical settings.[255]

3. Human studies on type 1 diabetes will assess the long-term survival and function of encapsulated human islets, as well as their efficacy in preventing or delaying the onset of complications and increasing overall survival.

In people with type 1 diabetes, the body's immune system launches a misguided attack on islet cells—which produce the essential hormone insulin—in the pancreas. People with type 1 diabetes need to take insulin by injection to manage their blood glucose (sugar) levels. To relieve people of this burden and

prevent the eye, kidney, nerve, and heart complications that result from high blood glucose, scientists have been studying ways to replace damaged islets—regions of the pancreas that contain islet cells. Decades of NIH-supported research led to the landmark FDA approval in FY23 of an entirely new type of therapy for people with type 1 diabetes whose disease cannot be managed using current therapies: islet transplantation.[256] Similar to patients who receive organ transplants, islet transplant recipients must take long-term immunosuppressants to prevent the body from attacking the transplanted islets, and such medicines may cause serious side effects. NIH researchers are looking for ways to prevent islet transplant rejection without the need for long-term immunosuppressants. One promising strategy is using encapsulated human islets, which are coated with a material that protects them from attacks by the patient's immune system and promotes their healthy functioning. Assessing the survival and function of these encapsulated islets requires innovative multidisciplinary teams including cell biologists, immunologists, and bioengineers, as prioritized in the *NIH-Wide Strategic Plan*.

From FY22–FY23, significant progress has been made toward developing encapsulated human islets, such as the identification of hydrogels and microgels for coating the islets; the development of mouse and nonhuman primate models for studying their efficacy; and the development of different approaches like immunotherapy to transplant the islets.[257,258,259,260,261] In addition, computational modeling and machine learning are being used to predict and optimize different approaches to transplanting the encapsulated islets.[262] Taken together, these studies may aid the clinical translation of these therapies for type 1 diabetes and other diseases.

Over the next 2.5 years, NIH research will continue to build evidence to support testing encapsulated human islets in clinical trials. For example, building on encapsulated islet technology developed by NIH-supported research, pharmaceutical companies are now sponsoring clinical trials to test encapsulated islets in participants with type 1 diabetes.[263] It is expected that continued preclinical research supported by NIH will further identify, optimize, and test the best materials for coating the islets in parallel with research toward generating and preserving sufficient numbers of islets for implantation, yielding knowledge necessary to further develop this therapeutic approach and lay the foundation for future human clinical trials in patients with type 1 diabetes.

4. Incorporating novel genomics findings from clinical studies on congenital heart disease will help researchers move toward precision therapy and personalized counseling, leading to improved outcomes and longevity for affected children and adults.

Rapid genomic sequencing has the potential to diagnose heritable genetic diseases, such as congenital heart disease—the most common type of birth defect—in critically ill infants, allowing for timely diagnoses, changes in disease management, and more personalized interventions. With this increased access to genomic information, NIH researchers are exploring ways to care for children and adults with congenital heart disease using precision therapy and personalized counseling—innovative approaches that use an individual's genomic, environmental, and lifestyle information to guide medical decisions. This research requires ongoing exploration into the different genomic causes of congenital heart disease and the impact of genomics on clinical outcomes. To accomplish this, researchers will need to use multiple layers of molecular data combined with characteristic information from affected individuals, following up with them over time, to measure clinical outcomes including survival, heart function, comorbidities, neurocognitive function, mental health, and quality of life.

From FY21–FY23, NIH supported research to understand the full range of genomic causes of congenital heart disease. An estimated one-third of rare diseases remain unsolved at a genomic level, including many previously undiscovered causes of congenital heart disease. The NIH Common Fund Undiagnosed Diseases Network is an initiative that brings together clinical and research experts to solve the most challenging medical mysteries using advanced technologies.[264] NIH also supports the Genomics Research to Elucidate the Genetics of Rare Diseases (GREGoR) Consortium, and results from a Clinical and Translational Science Award hints at a genetic basis between one of the most common causes of heart failure and a rare form of pregnancy-linked heart failure.[265,266,267]

The NIH Pediatric Cardiac Genomics Consortium (PCGC) has enrolled over 13,000 individuals with congenital heart disease and many of their relatives, resulting in one of the largest cohorts for congenital heart disease genomic analysis that has improved our understanding of the genetic underpinnings of congenital heart disease.[268] Since FY21, NIH-supported researchers have used PCGC data to identify genetic links between congenital heart disease and comorbidities like neurodevelopmental disability and cancer, and to explore more common heritable genomic variants in congenital heart disease. [269,270] Currently, findings from the PCGC are being used to elucidate the impact of genomics on clinical outcomes, including neurodevelopmental disability.[271]

Over the next 2.5 years, NIH will expand on the success of the PCGC by sharing approaches and data with the NIH Pediatric Heart Network.[272] NIH will also continue to refine the PCGC's approach by harnessing data from electronic health records and other existing databases and registries, progressing toward incorporating genomic findings into clinical care for individuals with congenital heart disease.

5. The high burden of heart disease in communities of color and rural areas will be reduced, especially for major outcomes, such as maternal morbidity and mortality, hypertension, and heart failure.

Cardiovascular disease, a term for all diseases of the heart or blood vessels, remains the leading cause of death in the U.S., and its effects are particularly felt by communities of color and people who live in rural areas. The NIH-supported Multi-Ethnic Study of Atherosclerosis analyzed disparities in U.S. cardiovascular disease mortality across four racial and ethnic groups, with adjustments for socioeconomic status and other factors.[273] In FY22, the study found that despite decreases in heart attack mortality rates, persistent disparities continued to exist in these populations. Higher mortality rates were seen in Black people, men, people living in the South, and people living in rural counties.[274] Cardiovascular disease is also the leading cause of pregnancy-related deaths in the U.S., accounting for more than one-third of such deaths annually. Thus, the *NIH-Wide Strategic Plan* prioritizes efforts to reduce the burden of heart disease and improve the heart health of underserved populations, such as those identified above.

Toward this end, NIH is continuing to invest in established studies on cardiovascular disease in African American people, American Indian people, and people living in rural areas, while investing in new research opportunities and infrastructure.[275,276,277] From FY20–FY27, the first phase of the Disparities Elimination through Coordinated Interventions to Prevent and Control Heart and Lung Disease Risk (DECIPHeR) Alliance is exploring approaches to translate knowledge about social determinants of health into strategies to achieve health equity and bring evidence-based interventions into broader practice for cardiovascular disease.[278] In FY21, NIH initiated funding opportunities for the Early Intervention to Promote Cardiovascular Health of Mothers and Children (ENRICH) program to investigate whether

incorporating heart-healthy lifestyle interventions can reduce cardiovascular disease and its risk factors in mothers and their children (0–5 years old) living in low income households, in low-resource communities, or in U.S. regions with a high burden of cardiovascular disease.[279]

Launched in FY14, the Accelerating Medicines Partnership® (AMP®) program is a public-private partnership between NIH, FDA, multiple biopharmaceutical and life science companies, non-profit, and other organizations to transform the current model for developing new diagnostics and treatments.[280] In FY22, AMP® Heart Failure (AMP® HF) was launched to better understand and treat heart failure with preserved ejection fraction, one of the most common forms of heart failure in which the heart muscle is stiffer than normal, and which is responsible for roughly half of all heart failure cases.[281] Also in FY22, the NIH Technology Accelerator Challenge for Maternal Health awarded a total of $1 million to winning teams for designing and developing low-cost screening and diagnostic technologies to reduce maternal morbidity and mortality.[282] Finally, in FY23, NIH-supported researchers developed a fully wireless ultrasound patch, which can capture detailed medical information like heart rate and blood pressure and wirelessly transmit the data to a smart device.[283]

In the coming years, NIH will continue to focus on supporting research to reduce cardiovascular disease risk by engaging with those at high risk and supporting them where they live and work.

6. A gene therapy for muscular dystrophy will restore the function of the mutated gene and improve patient outcomes.

Muscular dystrophies are a group of genetic disorders that cause progressive weakness of skeletal muscles. The different forms of muscular dystrophy vary in their age of onset, severity, and pattern of muscles affected. Duchenne muscular dystrophy (DMD) results from mutations in the *dystrophin* gene. Since FY01, the NIH Paul D. Wellstone Muscular Dystrophy Specialized Centers have spurred research on muscular dystrophy to better understand its different forms and to develop gene therapies, approaches to treat genetic disorders by providing new DNA or correcting DNA within certain cells.[284] Gene therapies hold promise to treat many diseases, but the approaches are still new and may have risks, necessitating more research to ensure safety and effectiveness for patients, who for DMD are young children. From FY21–FY23, significant milestones have been met toward making available a gene therapy for DMD that restores function and improves patient outcomes.

Developing gene therapy for DMD is challenging because the *dystrophin* gene is the largest known human gene, making it three-times too large for traditional gene therapy packaging. Thus, NIH-supported researchers have spent years developing new ways to engineer and deliver gene therapy for patients with DMD.[285] In FY23, the FDA granted accelerated approval to a biopharmaceutical company for its gene therapy for DMD, which built upon decades of NIH-supported research to develop a smaller version of the *dystrophin* gene that could be delivered safely to human skeletal muscle.[286] This gene therapy encodes a gene for a protein called microdystrophin—which is much smaller than dystrophin— that partially reproduces the functionality of full-length dystrophin. As part of the FDA's accelerated approval pathway, the company is sponsoring a clinical trial to verify the predicted clinical benefit to patients with DMD.[287]

NIH continues to support research in animal models to engineer and deliver gene therapy that is safe, effective, and accessible, ultimately benefiting patients with muscular dystrophy and other genetic disorders. In FY21 and FY23, NIH-supported researchers published the results of work to develop and

optimize approaches to deliver gene therapy to different types of muscle in animal models using lower doses and reducing unwanted side effects, including approaches using microdystrophin and the full-length *dystrophin* gene.[288,289,290] Since microdystrophin only partially reproduces the functionality of full-length drystrophin, the hope is that developing a gene therapy approach that can deliver full-length dystrophin will improve patient outcomes. Also, in FY23, NIH-supported researchers explored gene therapy in aging and old animal models of DMD as a first step towards potentially expanding the patient population eligible for DMD gene therapy, as currently only 4- and 5-year-old boys are eligible.[291] In the coming years, NIH will continue to support research to treat muscular dystrophy, and these efforts to develop a new gene therapy approach for DMD may be applicable to other forms of genetic disorders, helping to improve the lives of many patients.

7. Gene-based therapies for sickle cell disease will be evaluated and refined in large-scale clinical trials, offering a cure to the approximately 100,000 people in the U.S. and 20 million globally who suffer severe pain and premature death from this condition.

Gene-based therapies for sickle cell disease (SCD)—an inherited blood disorder that can lead to chronic pain, organ failure, and premature death—have made significant progress over the last 10 years. Multiple small-scale clinical trials of gene-based therapies have resulted in the alleviation of SCD-associated pain, a reduction in hospital visits, and a slowing of disease progression. As conveyed in the *NIH-Wide Strategic Plan*, large-scale clinical trials are needed to demonstrate if gene-based therapies can cure SCD, and these trials must be conducted where a substantial population of individuals with SCD reside, such as Africa or India.

From FY21–FY23, NIH led and supported research on SCD in the U.S. and around the world, working to improve treatments and evidence-based clinical care for all individuals living with SCD. The NIH Cure Sickle Cell Initiative focuses on developing curative gene therapies while also considering the total effect of living with the disease on a patient, such as mental health and financial toxicity.[292] In FY22, as part of the Initiative and in collaboration with the Bill & Melinda Gates Foundation, NIH continued to support ongoing clinical trials and launched additional clinical trials testing potential curative therapies for SCD.[293,294] This research aims to move gene-based therapies for SCD away from an individualized approach to a more generalized approach in order to reach greater populations, including in low resource settings, and to fund the collection of data to demonstrate to the FDA the effects of these therapies—both beneficial and adverse. As much as gene therapy offers to patients in need of cures, it still has risks, including immune reactions or cell abnormalities that could lead to cancer. NIH works closely with researchers to enhance safety monitoring of trial participants to reduce those risks.

NIH also supports clinical research to improve the way that care is delivered to individuals living with SCD, taking lessons learned from treating individuals with HIV who also faced stigma and significant barriers to receiving care.[295,296] Managing the chronic pain caused by SCD is an important focus of NIH research efforts, and requires a diverse approach to pain management as leveraged by the [Helping to End Addiction Long-term® Initiative, or NIH HEAL Initiative®](#).[297] Research is currently focused on developing new strategies to relieve pain by using techniques such as ultrasound, and by testing complementary and integrative treatment approaches to ensure that they can be implemented in clinical practice under real-world conditions.[298,299,300] In addition, NIH recently launched the Democratizing Education for Sickle Cell Disease Gene Therapy Project, to provide educational materials for individuals living with SCD and their support networks to learn about the gene therapy clinical trial

process, its benefits and risks, mental health considerations, and the science behind different treatment options.[301]

Over the next 2.5 years, NIH-supported research will continue to focus on making gene therapies for SCD safer and more effective, including evaluating how long the treatment lasts and any observed side effects. These efforts will generate progress towards the goal of offering a cure to the approximately 100,000 people in the U.S. and 20 million globally who suffer severe pain and premature death from SCD.

8. First-in-human clinical trials will demonstrate the efficacy of induced pluripotent stem cell-derived products.

Induced pluripotent stem cells (iPSCs)—adult cells that have been genetically reprogrammed to an early developmental stage, such that they can be turned into any cell type in the body—offer hope as a new form of therapy for degenerative and aging diseases such as age-related macular degeneration (AMD), Alzheimer's disease, heart disease, cancers, and more. While stem cell therapies have shown a long history of successful transplantation, iPSC therapies are especially compelling for scientists because they start with a patient's own cells, resulting in reduced immune rejection and easier methods of collection. However, significant hurdles remain for these therapies to reach clinical care as manufacturing and quality-control of patient-specific therapies are time-intensive and costly. NIH prioritizes ensuring the quality, safety, and efficacy of cell-based therapies as these new therapies are delivered to patients.

NIH has taken important steps to capitalize on the development of stem cell technology for an advanced form of AMD, the leading cause of vision loss in older Americans. In FY20, NIH intramural researchers launched the first clinical trial in the U.S. to use patient-derived iPSCs to replace and repair dying cells in the patient's retina.[302] Following delays due to the COVID-19 pandemic, the first two patients received this therapy in FY22, marking the first successful transplantations of patient-derived iPSCs in the U.S.[303] Once safety of this therapy is confirmed, additional clinical trials will include more patients to assess effectiveness in preventing blindness and restoring vision in patients with AMD.

In FY22 and FY23, NIH-supported preclinical research using mouse models further demonstrated the exciting potential of iPSC therapies for defects in joint cartilage development, heart disease, Alzheimer's disease, and glaucoma—a leading cause of irreversible blindness.[304,305,306,307] Together, this research shows the potential for iPSCs to replace and repair cells throughout the body, including those that make up connective tissue like tendons and ligaments, organ tissues like the heart, and highly specialized cells like those found in the immune system and eye.

Over the next 2.5 years, NIH will continue to invest in preclinical and clinical research to demonstrate broad applicability of iPSC-derived products, as well as their safety and efficacy. As progress is made across these efforts, it will be imperative for NIH and its partners to ensure that manufacturing and quality control of iPSC-derived products is time- and cost-effective to realize the full therapeutic potential of iPSC-derived products.

9. Engineered biological cells and scaffolds will be successfully used to repair and replace tissue damaged by chronic wounds or such disorders as osteoarthritis.

Regenerative medicine is a broad field that includes research on the body's normal wound healing processes and on tissue engineering—the practice of combining scaffolds, cells, and biologically active molecules into functional tissues. By understanding how cells interact with their environment, respond

to signals, and organize into tissues and organs, researchers can help the body repair and replace damaged tissue. NIH supports a broad portfolio of research into engineering biological cells and scaffolds that can be used to aid the body with tissue regeneration, including for chronic wounds and disorders such as osteoarthritis. For example, NIH-supported researchers developed the first implant to stimulate the healing of torn anterior cruciate ligaments (ACL) in the knee, which received marketing authorization from the FDA in FY21.[308,309] Shortly thereafter, a clinical trial of the ACL implant was launched to compare long-term post-surgery outcomes with standard ACL reconstruction techniques.[310]

From FY21–FY23, NIH supported a broad range of preclinical research into cells and scaffolds for improving tissue repair after medical procedures like spinal surgery, root canal, and radiation; for treating birth defects like craniosynostosis by correcting skull shape and restoring brain function; and for treating diseases like osteoarthritis and inflammatory conditions such as rheumatoid arthritis.[311,312,313,314,315,316] NIH also supported research into creating patient-specific, 3D-printed scaffolds for repairing large defects in jaw bones after disease or trauma.[317] In addition, NIH-supported research to advance treatment of wounds enabled researchers to discover that fibroblasts—cells known to help rebuild skin after injury—also help to clear dead skin tissue before repair occurs.[318] Because this clearance was previously thought to be a role only of immune cells, this finding may lead to new targets to enhance wound healing.

NIH is currently supporting development and testing of many potential treatments for wounds and diseases using engineered cells, tissues, organs, and scaffolds at various stages in the research pipeline. These experimental treatments are showing great promise to improve patient outcomes as compared to the current standards of care, such as bone grafting. Over the next 2.5 years, researchers will continue to test these approaches in preclinical and clinical research to establish methodological standards, including source, preparation, delivery, and dosing of cells and scaffolds, and to demonstrate effectiveness and safety. Larger-scale clinical trials will also need to be conducted to demonstrate safety and efficacy as compared to current standard treatments.

10. Insight will be gained into the ultimate ability to regenerate human limbs, using emerging technologies to activate the body's own growth pathways and processes.

Each year, about 1 in every 1,900 babies in the U.S. are born with limb defects. Additionally, an estimated 2.1 million people are living in the U.S. with limb injury or disease-induced amputations, and the number is expected to double by CY50.[319] Together, these cases place a heavy load on the U.S. health care system. Regenerative medicine is a broad field that includes research on the body's normal wound healing processes and on tissue engineering—the practice of combining scaffolds, cells, and biologically active molecules into functional tissues. While lower order vertebrates such as salamanders and newts are capable of limb regeneration, humans and other higher order vertebrates are not. However, a review of recent research demonstrating various levels of success in stimulating tissue repair in non-regenerating vertebrate limbs suggests the potential for regeneration may exist in higher order vertebrates.[320] Advancing our understanding of how regeneration can be activated in higher order vertebrates has the potential to ultimately ameliorate pain and suffering due to limb loss or limb deficiency in humans.

Since the launch of the *NIH-Wide Strategic Plan*, NIH investment has encouraged development in the field of limb regeneration, awarding $874 million in FY21 and $934 million in FY22 for regenerative medicine research.[321] In FY22, NIH-supported research established that the patterns of gene expression

that underlie limb regeneration in salamanders are similar to those that underlie the initial development of their limbs.[322] Further, in FY23, other NIH-supported research outlined a key mechanism in the development of a blastema—a mass of cells capable of growth and regeneration in salamanders.[323] Together, these recent advances in salamanders will help researchers gain insights into the ability to regenerate human limbs and how to activate the body's own growth pathways.

In FY22, NIH released the *NIH Research Plan on Rehabilitation*, which describes NIH's efforts to support development of limb regeneration techniques through its focus on driving translational research.[324] This work is advanced through a partnership with the VA to develop specific technologies including tissue regeneration, and a cooperative agreement with the DoD, in part, to support regenerative medicine approaches to limb repair through the Armed Forces Institute of Regenerative Medicine.

In FY23, NIH released a funding opportunity, committing $3.2 million in FY24 to fund transformative basic research on limb regeneration using animal models.[325] This funding opportunity was released following a public call for information and a two-day symposium on the topic in FY21.[326,327] In addition, NIH helps to support the annual International Symposium on Regenerative Rehabilitation, which is the largest medical and scientific conference specific to regenerative rehabilitation in the world.[328]

11. Research on new approaches to cervical cancer screening will lead to the development of self-sampling for women, with the potential to substantially reduce the incidence and mortality of this disease.

Over half of new cervical cancer cases in the U.S. each year are among women who have never been screened or who are infrequently screened, reflecting barriers presented by socioeconomic disparities, geographic inaccessibility, and other factors.[329] Almost all these cases of cervical cancer are caused by human papillomavirus (HPV) infection, which can transform healthy cells of the cervix into pre-cancerous lesions and eventually cancer. While FDA-approved vaccines—which target up to 90% of cervical cancer-causing HPV types—have been available since CY06, thanks in part to seminal work from NIH intramural researchers, uptake has been slow. NIH is dedicated to eradicating cervical cancer through prevention such as vaccination and early detection through screening.

Over the course of the *NIH-Wide Strategic Plan*, NIH research will work to remove barriers to cervical cancer screening through the development of self-sampling to facilitate cervical cancer screening outside of a health care setting. Self-sampling for HPV testing is expected to broaden the settings in which cervical cancer screening can be performed and has significant potential to expand screening to never screened or under-screened women, tackling a pressing public health concern. To that end, the World Health Organization found that participants in 33 clinical studies were twice as likely to accept HPV screening if given the option to self-sample.[330]

While self-sampling has been implemented in other countries, at the time of this writing the FDA is currently reviewing the evidence to consider approval of self-sampling for use in the U.S. To provide additional evidence needed for approval, NIH launched a public-private partnership called the Cervical Cancer 'Last Mile' Initiative, to contribute evidence about the accuracy and clinical effectiveness of self-collection-based HPV testing for cervical cancer screening.[331] This trial will evaluate multiple self-sampling methods, implementation, and dissemination strategies in underserved and high-burden populations and will facilitate discussions on changes clinical practice. In FY22, NIH established a multi-year partnership with HRSA, and several other agencies, called the Federal Cervical Cancer

Collaborative—an offshoot of the Cancer Moonshot℠ effort to Accelerate Cervical Cancer Control—to address persistent disparities seen in cervical cancer through more equitable prevention, screening, and management strategies.[332]

In FY23, NIH launched the HIV/Cervical Cancer Prevention 'CASCADE' Clinical Trials Network focused on optimizing the cervical cancer screening, management, and precancer treatment cascade (or care continuum) for women living with HIV, which includes research to support self-sampling.[333] Women living with HIV have a five-to-six-fold higher risk for cervical cancer than women in the general population—thus, expanding access to screening by offering self-sampling could make a significant difference for these patients.

Clinical trials evaluating self-sampling for cervical cancer screening in the U.S. are advancing. Over the next 2.5 years, partnerships with other federal agencies will be imperative to realize the vision of offering self-sampling for cervical cancer screening in a way that is wide-spread and accessible, thus reduce the incidence and mortality for all women, including those who are most vulnerable.

12. At least one novel, non-hormonal pharmacologic treatment for endometriosis will be identified and moved to clinical trials.

Endometriosis is a disease in which tissue similar to the lining of the uterus grows in other places in the body. It is one of the most common gynecological diseases, affecting approximately 10% of women aged 15–44, and its primary symptoms include chronic pain and infertility. Diagnosis is often delayed by years as surgery is required to confirm its diagnosis, and effective treatments are limited. Current medical and surgical treatments carry substantial risks and side effects, and endometrial lesions and symptoms often return even after surgical removal. Treatment may involve drugs that suppress estrogen levels, however, these treatments may cause adverse effects, such as bone thinning or weakening, hot flashes, memory loss, and insomnia. The *NIH-Wide Strategic Plan* has prioritized efforts to seek less invasive, non-hormonal ways to diagnose and treat this debilitating disease.

In FY21, NIH established the Centers to Advance Research in Endometriosis (CARE) to support basic, translational, and clinical research projects to enhance our understanding of the origin, causes, and progression of endometriosis; and enable the development of more effective strategies for the diagnosis, management, and prevention of the disease.[334] Research is currently underway to develop methods for non-invasive detection and diagnosis, identify genomic signatures and mechanisms of disease development, identify therapeutic targets and treatments, and develop approaches for endometriosis education and outreach.

NIH research to identify novel, non-hormonal treatments for endometriosis is already underway in mouse models of the disease. In FY22, NIH-supported researchers tested an experimental therapy that uses heat to remove disease-causing tissues as a non-surgical method to treat endometriosis in a mouse model.[335] The technique appears safe and effective, but more work is needed before it can be used in people. In FY23, an NIH-supported study in mice and human cells found that oleuropein, a compound found in olive oil and olive leaves, may have the potential to treat endometriosis with fewer side effects than current treatments.[336] In mice with endometriosis, oleuropein suppressed endometriosis and improved the pregnancy rate, suggesting that oleuropein may be further explored as a non-hormonal option for human endometriosis treatment. Over the next years, NIH will continue to support research to treat endometriosis, including exploratory research initiatives aimed at better understanding chronic

conditions that have been understudied among women and/or that disproportionately affect populations of women.[337,338]

13. The number of maternal deaths per year in the U.S. will be significantly decreased, particularly among Black and American Indian or Alaska Native women, by implementing results of research studies focusing on links between social determinants and biological risk factors.
Compared to other high-income countries, the U.S. has a high rate of maternal deaths, with more than 1,200 such deaths occurring in CY21. Tens of thousands more Americans each year experience severe pregnancy-related complications, which can raise the risk of future health concerns, including high blood pressure, diabetes, and mental health conditions. There are stark disparities in maternal health outcomes by racial and ethnic group, age, education, socioeconomic status, and geographic region. According to the American College of Obstetricians and Gynecologists (ACOG), to optimize the health of women and infants, postpartum care should become an ongoing process of engagement with services and support tailored to an individual's needs, rather than a single encounter.[339] Identifying and implementing strategies to reduce maternal mortality has the potential to save over a thousand lives every year, reduce the number of mothers who experience severe pregnancy complications, and significantly reduce health care costs.

As prioritized in the *NIH-Wide Strategic Plan*, NIH has been strengthening and expanding its support for maternal health research. In FY23, NIH hosted a workshop, which brought together members of an independent panel to review the scientific evidence on postpartum risks and interventions and provide recommendations for optimizing postpartum health.[340] The two resulting reports have received public input and are being revised for publication. In addition, a commentary on the topic is in preparation.[341] Recommendations from this panel align with those from ACOG and recommend a focused research program to decrease maternal mortality rates, combined with synergistic action between health care systems, communities, and policymakers.

Also in FY23, NIH awarded $24 million in first-year funding to establish the Maternal Health Research Centers of Excellence.[342] Part of the Implementing a Maternal health and PRegnancy Outcomes Vision for Everyone (IMPROVE) initiative, the Centers will develop and evaluate innovative approaches to reduce pregnancy-related complications and deaths and promote maternal health equity.[343] Together, these Centers will support research to address the biological, behavioral, environmental, sociocultural, and structural factors that affect pregnancy-related complications and deaths. Through collaborations with community partners and other organizations, the Centers will generate critical scientific evidence to help guide clinical care and reduce health disparities during and after pregnancy. Leveraging a range of activities, NIH will continue working to reduce maternal morbidity and mortality and ensure that the specific priorities of diverse and disproportionately affected populations are addressed.

14. Following PRGLAC Task Force findings that almost no data exist on medications in pregnant and lactating women, label changes will be facilitated by results of clinical trials for at least three therapeutics specific to (1) pregnant women and lactating women and (2) children.
While more than 90% of people take at least one medication during pregnancy and lactation, less than 10% of medications have enough information to determine their safety during pregnancy.[344] Additionally, nearly two-thirds of medicines on the market are not approved for use in children, although physicians frequently prescribe these drugs "off label" for pediatric use. Many barriers have prevented pregnant people, lactating people, and children from being included in clinical research,

which has limited the availability of data to support the safety and appropriate dosing of therapeutics used during pregnancy and lactation and in pediatric care. To respond to this public health need, the *21ˢᵗ Century Cures Act (P.L. 114-255)* established the Task Force on Research Specific to Pregnant Women and Lactating Women (PRGLAC) to advise the HHS Secretary regarding gaps in knowledge and research on safe and effective therapies for pregnant women and lactating women.[345,346] From FY21–FY25, in alignment with the *NIH-Wide Strategic Plan* and PRGLAC's charge, NIH has prioritized efforts to ensure that pregnant people, lactating people, and children are appropriately included in research and clinical trials to inform approvals and label changes for therapeutics.

From FY21–FY23, NIH support of maternal and pediatric therapeutics research included capacity building efforts, such as the development of a research hub to conduct and foster therapeutics-focused research in obstetrics, lactation, and pediatrics while enhancing inclusion of people with disabilities; and clinical research to support the development of new treatments for people suffering from postpartum depression, and to improve the safety and efficacy of medicines for children.[347,348] In FY22, NIH gathered nominations for the *Best Pharmaceuticals for Children Act (BPCA)(P.L. 107–109)* Program's annual priority list of pediatric therapeutic needs.[349,350] NIH works closely with the FDA and scientific experts in pediatrics to identify off-patent drugs in need of further study in pediatric populations and sponsor clinical studies of prioritized drugs; any proposed label changes resulting from the research are reviewed and approved by the FDA. In FY22 and FY23, NIH BPCA research led to four label changes for diazepam, clindamycin, rifampin, and levetiracetam to improve the dosage, safety, and/or efficacy information of these therapeutics in children.[5,6,7,8,351,352,353,354] Three additional studies are currently pending final review, and clinical studies are under way to study anesthetics, pain medicines, and antipsychotics in children. A large-scale effort is also in progress to study commonly used prescription medicines in lactating people and breastfed infants.

NIH will continue supporting research to improve our knowledge on the safe use of specific therapeutics in children, pregnant people, and lactating people. A second iteration of PRGLAC will meet in FY24 to build off the first iteration's progress and report back to the HHS Secretary.

15. NIH-wide research will lead to new implementation strategies for pre-exposure prophylaxis that will significantly reduce the number of new HIV infections and to new long-acting therapies to improve viral load suppression among people with HIV to levels that prevent transmission. Antiretroviral therapy (ART)—a medication regimen for HIV—benefits both people living with HIV and those who are at high-risk for acquiring HIV, as it suppresses viral load to undetectable levels, preventing transmission of the virus to others, and slows progression of the disease, resulting in a near normal life expectancy. When ART is administered before exposure to HIV it is known as pre-exposure prophylaxis (PrEP), because it can protect individuals from acquiring HIV. As lifechanging as ART and PrEP are, further research is needed to address barriers impeding the adoption of these therapies across diverse communities and health care systems. From FY21–FY25, NIH will continue to support implementation

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[5] Diazepam is prescribed to treat life-threatening seizures.
[6] Clindamycin is prescribed to treat various infections in children, including lower respiratory tract infections, intra-abdominal infections, sepsis (infection in the blood), and bone and joint infections.
[7] Rifampin is used to treat tuberculosis.
[8] Levetiracetam is used to treat seizures.

research into alternative strategies for ART and PrEP, and research to develop new long-acting therapies to offer people with HIV more options to achieve viral suppression.

Decades of basic and clinical research sponsored by NIH have revolutionized strategies to treat and prevent transmission of HIV. From FY21–FY23, NIH continued to build upon those strategies by testing new ways to deliver medicine that could improve uptake in different populations. In FY21 and FY22, NIH published funding opportunities to develop multipurpose prevention technologies that would combine PrEP with other therapies to prevent other sexually transmitted infections and pregnancy.[355,356] In FY22, the FDA approved an injectable long-acting ART that an NIH HIV Prevention Trials Network study showed could be administered every few months, providing a more practical option than daily pills.[357,358] In addition, NIH supports efforts to evaluate interventions to prevent and treat HIV in infants, children, adolescents, and pregnant and postpartum people through clinical trials networks like the International Maternal Pediatric Adolescent AIDS Clinical Trials Network, Adolescent Medicine Trials Network for HIV/AIDS Interventions, and Microbicide Trials Network.[359,360,361] In FY23, interim results from two NIH-supported clinical studies suggested that a vaginal ring that slowly releases an HIV medicine was safe for pregnant and lactating people, and another NIH-supported study suggested that an antibody therapy may be a promising alternative for children with HIV to maintain viral suppression.[362,363,364]

Over the next 2.5 years, more progress is expected toward new implementation strategies for treating and preventing HIV in various community settings. For example, pharmacists and pharmacies have demonstrated exceptional reach and impact in the delivery of COVID-19 and influenza vaccines in recent years. NIH plans to support research to deliver HIV testing, prevention, and care services through pharmacists and pharmacies, and support training for pharmacies to effectively deliver HIV services to the communities they serve.[365] Recently, NIH expanded the Prevention And Treatment through a Comprehensive Care Continuum for HIV-affected Adolescents in Resource Constrained Settings (PATC3H) consortium to include an Implementation Science Network, which seeks to expand the reach of PATC3H to new geographic settings and adolescent populations.[366] Finally, in FY23, NIH launched the HIV and Women Signature Program to prioritize support for implementation research to increase PrEP access and uptake for affected communities of women.[367] Taken together, there are many promising new implementation strategies for PrEP in the pipeline that aim to reduce new infections and ease the burden on those taking the therapy.

16. At least one candidate universal influenza vaccine against groups 1 and 2 with 75% efficacy will be submitted to the FDA for consideration.

Each year in the U.S., seasonal influenza, or flu, makes millions of people sick and causes thousands of hospitalizations and flu-related deaths. From decades of NIH-supported research, scientists know that some types of flu have the potential to be dangerous and have been responsible for global outbreaks. A key focus of NIH-supported influenza research is developing a universal flu vaccine—one that could protect against multiple types of flu and eliminate the need for an annual seasonal flu vaccine. Thus, the *NIH-Wide Strategic Plan* has prioritized developing at least one candidate universal influenza vaccine that is at least 75% effective against symptomatic infection. Accomplishing this would provide the American people with a broadly protective vaccine that provides more effective and longer lasting influenza immunity, thereby reducing the risk of an influenza pandemic and eliminating the need for annual flu vaccines.

From FY21–FY23, NIH supported research and research infrastructure—such as the Vaccine Research Center (VRC) and the Collaborative Influenza Vaccine Innovation Centers (CIVICs)—to develop vaccines against newly emerging influenza viruses, improve seasonal flu vaccines, and create a universal flu vaccine.[368,369] Influenza vaccines train the immune system to recognize and respond to hemagglutinin (HA), a protein on the surface of the influenza virus. From FY21–FY23, NIH supported animal studies and clinical trials to develop and test experimental flu vaccines that recognize and target the HA protein from multiple flu virus strains—one experimental vaccine even targets all 20 known flu virus types—an approach that could be broadly protective.[370,371,372] While one portion of the HA protein, known as the head, tends to change as the flu virus spreads and evolves, a more stable portion, known as the stem, evolves very slowly and is very similar across many different types of the flu virus. Currently available flu vaccines target the HA head, so NIH-supported researchers hypothesized that designing vaccines to target the HA stem may induce longer term immunity against a broad range of flu viruses. In FY23, a Phase 1 clinical trial showed that an experimental influenza vaccine targeting the HA stem region was safe, well tolerated, and induced broad antibody responses.[373,374,375] A version of this vaccine developed using mRNA is currently being evaluated in a Phase 1 clinical trial.[376]

Another approach to vaccine design being tested involves using whole virus rather than specific viral proteins to train the immune system. In FY22, NIH-supported researchers evaluated a whole-virus influenza vaccine that uses four types of inactivated influenza virus in a Phase 1 clinical trial to determine its safety and effectiveness when given as an injection or a nasal spray, and a Phase 2 clinical trial is now in the planning stage.[377,378]

Over the next 2.5 years, NIH will continue to support research to develop new experimental influenza vaccines and rigorously test and validate the vaccine candidates already in clinical trials, with the goal to submit at least one to the FDA for consideration. For example, another clinical trial is planned for FY25 that will test a vaccine candidate designed by NIH researchers that targets the stem protein of multiple influenza viruses. By developing and testing a variety of different platforms for a universal flu vaccine, researchers are more likely to find one that is both safe and provides strong and broad immunity against a variety of types of influenza, including both seasonal and pandemic influenza viruses.

17. NIH-supported researchers will develop a universal coronavirus vaccine.

Over the last 20 years, outbreaks caused by several coronaviruses—severe acute respiratory syndrome coronavirus 1 (SARS-CoV-1), Middle Eastern respiratory syndrome coronavirus (MERS-CoV), and most recently, severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2)—highlighted the need for vaccines that are effective against multiple types of coronaviruses and their variants. To this end, NIH scientists outlined the features of an ideal universal coronavirus vaccine that would provide durable protection from most or all coronaviruses for individuals of all ages and communities at large. To achieve this goal, fundamental questions about the nature of coronavirus protective immunity must be addressed, including what vaccine approaches best elicit rapid immune responses, such as antibodies, and lasting immune memory responses that could defend against newly emergent coronaviruses.[379] From FY21–FY25, NIH continues to leverage research infrastructure established to combat COVID-19 (the disease caused by SARS-CoV-2)—such as the Accelerating COVID-19 Therapeutic Interventions and Vaccines (ACTIV) public-private partnership—and launch new large-scale research efforts to develop a universal coronavirus vaccine.

In FY21, NIH launched the Serological Sciences Network (SeroNet) to quickly increase the nation's antibody testing capacity and to understand the immune response to SARS-CoV-2 and COVID-19.[380] Also in FY21, NIH launched the ACTIV Tracking Resistance and Coronavirus Evolution (TRACE) initiative to identify emerging variants of SARS-CoV-2.[381] From FY21–FY23, researchers continued to advance these efforts, monitoring new viral variants and studying how the immune response to infections and vaccinations differs to learn how to design vaccines to better protect the body against future infection. For example, NIH released a funding opportunity to encourage researchers to explore multiple approaches to vaccine design, such as mRNA or DNA vaccines, to develop candidate universal coronavirus vaccines and determine which approaches are the best at limiting infection and transmission.[382] Because current COVID-19 vaccines are targeted to the virus's spike protein—which can change with mutations—antibodies resulting from vaccinations that target the spike protein may provide less immune protection against variants. Thus, researchers are looking at the virus's nucleocapsid protein—which is present on all coronaviruses and rarely mutates—as an option for future universal coronavirus vaccines to target.[383] In FY24, NIH plans to leverage existing research infrastructure and network sites to evaluate up to 10 next-generation COVID-19 vaccines in clinical trials as part of Project NextGen in order to accelerate and streamline the development of the next generation of vaccines and treatments for COVID-19.[384]

Over the next 2.5 years, these research activities, and the resulting body of knowledge on coronaviruses and vaccine design will contribute to the development of a universal coronavirus vaccine, which will be an important tool in preventing future pandemics. This will be of utmost importance as a growing body of scientific evidence strongly suggests that novel coronaviruses will continue to infect animals and potentially emerge to pose a pandemic threat to humans.

18. By actively engaging with underserved populations to reduce disparities for COVID-19, researchers will prevent and curb the spread of COVID-19 and save lives.

The COVID-19 pandemic highlighted the magnitude of disparities in health and health care across the U.S. among populations experiencing long-standing health inequities, including individuals from racial and ethnic minority groups and those living in underserved rural areas. For example, individuals from racial and ethnic minority populations consistently experienced higher rates of infection, hospital stays, and death caused by COVID-19 compared to White individuals. Factors such as housing, racism, discrimination, and living and working conditions exacerbated this impact, deepening these communities' mistrust in science and medicine, and underscoring how the spread of inaccurate information can hamper the effectiveness of population-level efforts to address public health emergencies. To reduce and redress the adverse effects of COVID-19 on underserved communities, as prioritized by the *NIH-Wide Strategic Plan*, NIH has actively engaged with underserved communities to ensure: 1) equitable access to and utilization of evidence-based health information; 2) enhanced understanding of COVID-19; 3) increased efforts to build community trust in science and medicine; and 4) increased COVID-19 testing and vaccination.

In late FY20 and FY21, NIH established two key initiatives—the NIH Community Engagement Alliance (CEAL) Against COVID-19 Disparities and the Rapid Acceleration of Diagnostics–Underserved Populations (RADx®-UP)—to coordinate agency-wide involvement in community engagement activities to promote trust in science, address misinformation, advance health communication, and promote COVID-19 testing and vaccination.[385,386] As of FY23, 21 CEAL research teams are working across 21 states, the District of

Columbia (D.C.), and Puerto Rico to collaborate with more than a thousand organizations including hundreds of community partners. CEAL research teams have held more than 6,800 events reaching over 780,000 participants, including vaccination events at which over 640,000 people received the COVID-19 vaccine and over 3,000 people signed up to participate in COVID-19-related clinical trials.[387] As of FY23, RADx®-UP is a consortium of 137 research projects across 50 states, 5 territories, and D.C., studying approaches and interventions to increase COVID-19 testing. RADx®-UP also collaborates with community partners, which led to the administration of more than 471,000 COVID-19 tests, 167 published articles, 210 community-engagement resources, and 86 projects sharing research data.[388] A RADx®-UP project, *Say Yes! COVID Test*, distributed more than four million free, rapid, at-home COVID-19 tests in CY21.[389] Another RADx®-UP project, the Safe Return to School Diagnostic Testing Initiative, showed that the COVID-19 testing program increased testing uptake by 34% and decreased missed days of school by 1.5 fewer days.[390]

From FY21–FY23, NIH established relationships with numerous communities through initiatives like CEAL and RADx®-UP to reduce health disparities from COVID-19 in underserved communities. Over the next 2.5 years, NIH will continue efforts to strengthen these community relationships to build trust in science and medicine. In addition, analyses of CEAL and RADx®-UP data will provide insights into how active engagement with underserved populations affected rates of COVID-19 diagnosis, treatment, and prevention.[391,392]

19. Artificial intelligence will reveal molecular signatures associated with the return to health after an acute illness (e.g., COVID-19).

Using artificial intelligence (AI) to identify biomarkers—biological markers that can be measured and used as indicators of health and disease—will enable scientists to better understand what causes some patients to return to health after an acute illness (one that lasts for a short time) and what causes other patients to progress to a chronic illness (one that is long lasting). This information in turn will enable clinicians to predict which patients will return to health or progress to chronic illness and identify better treatments for them. Many biomarkers come from simple measurements made during a routine doctor visit, like blood pressure or body weight, while other biomarkers are based on laboratory tests of blood, urine, or tissues. Some capture changes at the molecular and cellular level by looking at genes or proteins. By collecting information on multiple types of biomarkers and training AI to recognize patterns in this information, researchers will be able to generate standardized signatures down to the molecular level that illustrate what is going on during health and disease.

From FY21–FY23, NIH supported the development of AI models to identify risk factors for acute and chronic illnesses and provided data resources to help researchers conduct these types of studies. The NIH Researching COVID to Enhance Recovery (RECOVER) Initiative has significantly advanced our understanding of post-acute sequelae of SARS-CoV-2 infection (PASC) or Long COVID—the chronic illness associated with COVID-19—yielding valuable insights into its symptoms and impact across various demographic groups.[393] In FY22, using data from the National COVID Cohort Collaborative (N3C), RECOVER researchers developed and validated an AI model to identify patients who may have Long COVID.[394,395,396] Using the same AI model, RECOVER researchers identified molecular signatures associated with COVID-19 reinfection and the development of Long COVID.[397] Additionally, in FY23, NIH-supported researchers developed methods to predict COVID-19 status (positive or negative) and

severity using molecular signatures found in saliva, providing new clues to the development of this illness.[398]

Challenges remain in developing AI models that can identify molecular signatures associated with the return to health after an acute illness. Currently, molecular data is available only for select cohorts from clinical trials or postmortem studies. These data are not collected as part of routine care, and long-term molecular data from the same patient over time is rare. Furthermore, developing AI models that perform equitably across multiple populations requires training and testing across diverse datasets, including an understanding for when separate models are appropriate, such as in adult and pediatric studies.

Over the next 2.5 years, NIH expects to enhance the quality and diversity of data fueling research that uses AI. This includes increased efforts in establishing standard methods and common vocabularies for AI to use to generate reliable and accurate predictions. By FY26, the NIH *All of Us* Research Program expects to recruit one million diverse participants to generate the most diverse health database in the world, including genomic and other data types collected over time to add to the pool of molecular data that can be used to train and validate AI models.[399,400] Finally, N3C has been a landmark development in connecting clinical data from participants across studies and programs; it will be imperative that NIH continues to expand the scope of patient data while maintaining patient privacy.[401]

20. Biomarkers will guide the choice of the most effective therapy for each individual rheumatoid arthritis patient.

Rheumatoid arthritis (RA) is a chronic (long lasting) autoimmune disease that mostly affects joints. RA occurs when the immune system, which normally helps protect the body from infection and disease, attacks its own tissues. The disease causes pain, swelling, stiffness, and loss of function in joints. Studies show that a combination of factors—including genes, environment, and sex hormones—may lead to the disease. RA affects people differently, and each patient responds to treatment differently. If it is not treated or the treatments are not working, RA can worsen and affect more joints. Thus, it is essential to develop biomarkers—biological markers that can be measured and used as indicators of health and disease—to identify the most effective therapy for each individual RA patient. Further research into the mechanisms underlying RA will lead to the discovery and use of biomarkers in guiding individualized treatment plans, as prioritized in the *NIH-Wide Strategic Plan*.

Launched in FY14, the [Accelerating Medicines Partnership® (AMP®) program](#) is a public-private partnership between NIH, FDA, multiple biopharmaceutical and life science companies, non-profit, and other organizations to transform the current model for developing new diagnostics and treatments.[402] The AMP® Rheumatoid Arthritis and Systemic Lupus Erythematosus (AMP® RA/SLE) program has been working to uncover the biological pathways underlying RA.[403] In FY22, building on the success of AMP® RA/SLE, the AMP® Autoimmune and Immune-Mediated Diseases (AMP® AIM) program launched to focus on understanding how interactions among cells and pathways contribute to RA.[404] In FY24, AMP® RA/SLE-supported researchers analyzed and developed a profile of all the cells found in inflamed joint tissue in RA patients.[405] Further analysis of these cellular profiles has enabled researchers to identify subtypes (groups) of RA patients, which could inform better targeted treatments for RA.

In FY23, NIH-supported researchers also explored approaches to develop biomarkers for RA and other rheumatic (inflammatory) diseases. For example, NIH-supported researchers analyzed blood samples

from patients with elderly-onset RA and found differences that could be used to establish a blood biomarker profile to distinguish RA from another rheumatic disease called polymyalgia rheumatica.[406] In another study, NIH-supported researchers used blood protein signatures to stratify Native American patients with rheumatic diseases into distinct immune subtypes, which may facilitate earlier diagnoses and guide more personalized treatments.[407] Finally, an NIH-supported clinical trial was completed that used medical imaging to detect changes in inflammation in RA that lead to cardiovascular disease, a condition that commonly occurs in people with RA.[408,409] This approach is expected to help guide treatment for patients with RA and co-occurring conditions, and results are expected to be published in the next few years. In the coming years, research through AMP® and other NIH programs will continue to stratify RA patients into specific subtypes, enabling physicians to provide more individualized treatments based on these subtypes.

21. NIH-supported research will lead to the development of a clinically actionable biomarker for precision psychiatry, using neuroimaging and/or additional physiological and psychological biomarkers.

Practicing precision medicine involves using data about a patient to make precise treatment recommendations that apply to that patient's particular circumstance. For some illnesses—like some forms of cancer—precision medicine is already used in practice. For psychiatry and mental illness, precision medicine is still an aspirational goal. Researchers and health providers have several tools to collect information about how the brain is working, such as magnetic resonance imaging (MRI), electroencephalography (EEG), and behavioral tests, but it has been difficult to figure out how to use this information to develop reliable biomarkers—biological markers that can be measured and used as indicators of health and disease—that can answer clinically relevant questions. Such biomarkers could improve the ability to predict the likelihood that someone may develop a psychiatric disorder or respond to potential treatments and may reveal novel targets for therapeutics. From FY21–23, NIH supported research to develop biomarkers that could be used in clinical practice to inform treatment decisions for individuals with mental illnesses.

Launched in FY14, the Accelerating Medicines Partnership® (AMP®) program is a public-private partnership between NIH, FDA, multiple biopharmaceutical and life science companies, non-profit, and other organizations to transform the current model for developing new diagnostics and treatments.[410] In late FY20, NIH launched the AMP® Schizophrenia (AMP® SCZ) program to address the critical need for more effective treatments for people with schizophrenia, or those who are at high risk for the disorder. Over the past 2.5 years, AMP® SCZ-supported researchers across three research projects have worked to identify biomarkers that can help predict the likelihood that a person will develop schizophrenia, inform how well treatments work for different groups of people, and lead to the development of new treatments to reduce or even stop symptoms as early as possible.[411]

In FY23, NIH launched the Individually Measured Phenotypes to Advance Computational Translation in Mental Health (IMPACT-MH) initiative to advance research on precision psychiatry.[412] The initiative supports research that uses behavioral measures and computational methods to define novel clinical signatures, such as biomarkers, that can be used to inform disease prediction, diagnosis, and treatment decisions in mental disorders.[413,414] For example, there are many different options for treating people with depression, including psychotherapy, brain stimulation therapies, and several kinds of antidepressant medications. But not all treatments work for all people and selecting the most effective

treatment for a person often requires some trial and error, which means some people with depression could wait weeks or months before symptoms improve. Through this initiative, NIH is supporting clinical trials and other research to develop and validate accurate, fast, easy-to-use, and widely accessible biomarkers and tools that can inform treatment selection by predicting treatment response at the individual level.[415] In FY23, NIH-supported researchers also leveraged existing biomarkers to guide delivery of brain stimulation therapy for people with treatment-resistant depression.[416]

Starting in FY23, NIH supports research to identify and develop tracers (compounds used to label specific molecules or structures) that can be used to better study the structure and function of the brain and identify biomarkers for mental illness, with the potential to predict and monitor symptoms, and offer patients treatment options that are tailored to meet their individual needs.[417,418]

22. Comprehensive atlases of cell types in the mouse and human brain will provide a deeper understanding of the circuits underlying behavior and a foundation for understanding the circuits affected in complex human brain disorders, including depression.

The human brain, with its nearly 100 billion neurons and trillions of connections, is arguably the most complex organ in the known universe. A critical step toward unraveling this complexity is to catalogue how many and what types of cells make up the brain in comprehensive cell atlases, which can be thought of as maps of the brain. Launched in FY13, the NIH Brain Research Through Advancing Innovative Neurotechnologies® Initiative, or the BRAIN Initiative®, aims to produce a dynamic picture of the brain that shows how individual cells and complex neural circuits interact in both time and space.[419] From FY21–FY23, NIH supported large-scale research programs to transform neuroscience research, helping researchers to better understand the complex workings of the human brain in health and disease.[420]

In FY18, NIH established the BRAIN Initiative Cell Census Network (BICCN) to generate 3D brain cell atlases integrating molecular, anatomical, and functional data for cell types in mouse, human, and nonhuman primate brains.[421] In FY22, NIH-supported researchers as part of BICCN published a landmark series of 27 scientific papers with data from genetic analysis of 450,000 cells from a specific region of the brain—the motor cortex—in mice, nonhuman primates, and humans.[422,423] Building on this work, in FY24, BICCN researchers published another compendium of 24 scientific papers mapping the genetic, cellular, and structural makeup of the human brain and the nonhuman primate brain.[424,425] The data collected through this effort are available to researchers through the BICCN Data Inventory.[426] This information is already enabling significant advances in understanding the locations and functions of brain cell types, the differences and similarities among species, and the accuracy of the technologies used to acquire the data. Importantly, these resources are now being used to identify the human brain cell types affected in Alzheimer's disease and Parkinson's disease, enabling researchers to better understand the mechanisms of disease progression, which will be essential for devising strategies for cures and prevention.

In FY22, NIH launched the BRAIN Initiative Cell Atlas Network (BICAN), the Armamentarium for Precision Brain Cell Access, and the BRAIN Initiative Connectivity Across Scales (BRAIN CONNECTS) programs to transform our understanding of brain cells and their connections, and the precise tools needed to access them.[427,428] NIH-supported researchers, as part of BICAN, are working to generate an atlas of cell types in the human brain across the lifespan, which will detail the vast array of cells in the human brain and map cell interactions that underlie a wide range of brain disorders. NIH-supported researchers, as part

of the Armamentarium (toolkit) project, are leveraging these brain cell atlases to develop new approaches to target specific brain cells and circuits, laying a foundation for future precision gene therapies. Finally, NIH-supported researchers in the BRAIN CONNECTS program are working to generate wiring diagrams of how the different brain cells connect to form circuits that affect behavior and can cause brain disorders.

Together, over the next 2.5 years, these transformative projects will provide researchers with a deeper understanding of the circuits underlying behavior and a foundation for understanding the circuits affected in complex human brain disorders, such as depression, substance use disorders, dementia, and schizophrenia.

23. Invasive and noninvasive human brain recording and stimulation technologies will enable new paradigms for interventions in movement disorders and neuropsychiatric diseases, as well as the development of brain-machine interfaces for sensory and motor neural prostheses.

Disorders of the brain and nervous system, such as Parkinson's disease, and mental illnesses, such as depression, are taking a major toll on communities. In many cases, current treatments are ineffective, underscoring the need for new approaches and interventions.[429] The NIH Brain Research Through Advancing Innovative Neurotechnologies® Initiative, or the BRAIN Initiative®, funds the development of technologies to record and stimulate the human brain to grow our understanding of the connections in the brain and enable new approaches for interventions in movement disorders and neuropsychiatric diseases, in alignment with the *NIH-Wide Strategic Plan*.[430] From FY21–FY23, these efforts have led to new adaptations of existing therapies like deep brain stimulation (DBS) and breakthroughs in experimental therapies like brain-machine interfaces.

DBS involves surgically implanting a small device into a patient's brain, similar to how a pacemaker is implanted in the heart, to send targeted electrical impulses to a specific region. For decades, DBS has been used to alleviate the symptoms of Parkinson's disease with great success, because the disease site of Parkinson's disease is known and consistent across patients. Other brain disorders and mental illnesses often have disease sites and mechanisms that vary from person-to-person, so locating the right brain region for placement of DBS is critical. In FY21 and FY22, NIH-supported researchers used DBS as a therapy for patients with treatment-resistant opioid use disorder, obsessive compulsive disorder, and treatment-resistant depression, showing promising results.[431,432,433] In FY23, NIH-supported researchers conducted a first-in-human test of DBS in the cerebellum of patients after stroke, with early results indicating that DBS may help recovery of upper limb function.[434]

Through crosscutting, collaborative approaches, NIH has fueled the development of brain-machine interfaces to improve the lives of patients by restoring sensory and motor functions. In FY21, NIH-supported researchers successfully implanted a device into a patient's brain, and recorded brain activity from it, allowing a paralyzed, non-verbal, brainstem stroke survivor to communicate through a computer speech synthesizer.[435] This study marks the first-time that brain activity has been successfully decoded to form complete sentences. Also in FY21, NIH-supported researchers advanced development of a prosthetic limb that provides sensory feedback to the nervous system, allowing patients to sense the movement of the prosthetic and improve their motor control.[436] In FY23, NIH-supported researchers successfully used electrical stimulation of the spinal cord to restore arm and hand mobility in two stroke patients, enabling them to perform activities such as using a fork to eat a meal.[437]

Together these advances reflect a revolution in how researchers understand the human brain and its complexities. Armed with the right data and tools, NIH-supported researchers are developing innovative neurotechnologies that seemed like science-fiction just a decade ago.

24. Preventive approaches targeting vascular risk factors will reduce the risk for dementia and promote healthy brain aging.

Dementia is the loss of cognitive functioning—thinking, remembering, and reasoning—and behavioral abilities to an extent that it interferes with daily life and activities. Most individuals with dementia experience vascular (blood vessel) damage in the brain that seems to make the disease and its symptoms worse. In FY19, a landmark NIH-supported clinical trial, Systolic Blood Pressure Intervention Trial (SPRINT) Memory and Cognition in Decreased Hypertension (SPRINT-MIND), showed that lowering blood pressure to 120/80 mmHg decreased participants' risk for mild cognitive impairment by approximately 20%, and lessened vascular damage in the brain.[438,439] Moreover, uncontrolled blood pressure appears to play a major role in driving substantial racial and ethnic disparities in dementia prevalence. Fortunately, there are effective strategies to maintain or improve vascular health—including healthy diet, physical exercise, and hypertension medications.

From FY21–FY23, NIH supported research to identify individuals who may benefit most from preventive approaches targeting vascular risk factors, and to test implementation of different approaches, including those tailored to different populations. In FY21, NIH-supported researchers explored how a specific type of vascular-related damage in the brain contributes to cognitive impairment and dementia, and whether magnetic resonance imaging (MRI) can effectively identify individuals at higher risk for dementia.[440] In FY22, NIH-supported researchers reported that a telephone-based lifestyle intervention focused on the Dietary Approaches to Stop Hypertension (DASH) diet helped Black participants achieve better blood pressure control compared with usual care.[441] In FY23, an NIH-supported study showed that reductions in U.S. dementia prevalence over the last 25 years were linked to improved markers of brain vascular health, specifically reduced athero- and arteriosclerosis (plaque buildup) in the brain.[442] In addition, in FY23, NIH-supported research established the role of social determinants of health (SDOH) in determining risk for uncontrolled blood pressure, stroke, and poor cognitive outcomes.[443] Finally, NIH-supported researchers focused on identifying intervention strategies to inform the design of future studies testing interventions to target vascular risk factors in dementia in health disparity populations.[444]

NIH also supports public health campaigns to communicate the importance of vascular risk factor control for heart and brain health. From FY21–FY23, NIH developed new educational materials for the NIH Mind Your Risks® campaign, which raises awareness about the importance of controlling blood pressure among adult Black men ages 28 to 45; and The Heart Truth®, which raises awareness about heart disease and provides educational resources tailored to key audiences, including Asian American and Pacific Islander people, American Indian and Alaska Native people, African American people, Hispanic and Latino people, women, and pregnant people.[445,446,447]

Over the next 2.5 years, NIH expects to launch additional interventional trials to reduce vascular risk and mediate SDOH that contribute to dementia outcomes. With help from federal, non-federal, and community partners, NIH expects to increase the uptake of public health messaging and encourage more individuals to take steps to lower their risk of age-related cognitive impairment and dementia.

25. At least one promising lifestyle intervention to prevent Alzheimer's disease and related dementias will be rigorously demonstrated in the next 5 years.

Over six million Americans are currently living with Alzheimer's disease, and these numbers are expected to grow rapidly as members of the Baby Boomer generation reach older age. Alzheimer's disease is the most common cause of dementia among older adults, and it is a brain disorder that slowly destroys memory and thinking skills, and eventually, the ability to carry out the simplest tasks. Prevention or delay of onset of Alzheimer's disease and Alzheimer's disease-related dementias (AD/ADRD) remains a major priority for the scientific and medical communities. One NIH-supported research team estimated that delaying the onset of Alzheimer's disease for even five years would result in 41% lower prevalence and 40% lower cost of care for Alzheimer's disease in CY50.[448] With these estimates in mind, the *NIH-Wide Strategic Plan* prioritized supporting research to identify promising lifestyle interventions that may delay or prevent onset of AD/ADRD.

Many of the prevention and treatment studies in progress for AD/ADRD do not involve drug candidates that interfere with disease pathways. Instead, NIH-supported researchers are exploring lifestyle and behavioral interventions—such as eating a nutritious diet, physical activity, social engagement, and mentally stimulating activities—to help reduce the risk of cognitive decline and prevent or delay AD/ADRD. For example, in FY20, an NIH-supported study of more than 3000 research participants over age 65, showed that participants who adhered to four or five specific healthy behaviors—not smoking, light-to-moderate alcohol consumption, a high-quality diet, regular cognitive activities, and at least 150 minutes per week of moderate- to vigorous-intensity physical activity—had a 60% lower risk of Alzheimer's disease.[449]

Building on those results, recent clinical trials in FY23 have tested specific diets as a promising lifestyle intervention to prevent AD/ADRD. In FY23, an NIH-supported study of more than 2,200 participants showed that daily multivitamin and mineral supplementation for 3 years improved global cognition, episodic memory, and executive function in older adults.[450] Additionally, in FY23, the Mediterranean-DASH (Dietary Approaches to Stop Hypertension) Intervention for Neurodegenerative Delay (MIND) diet and the Mediterranean diet—both of which rely heavily on vegetables (particularly green leafy vegetables), berries, beans and other legumes, and fish; include olive oil and whole grains; and limit red meat—were shown to reduce signs of Alzheimer's disease pathology in the brain.[451] However, in a separate study of cognitively unimpaired, overweight individuals with a family history of dementia, changes in cognition and brain biomarkers did not differ significantly over three years between participants who followed the MIND diet and those who followed a control diet with mild caloric restriction.[452] Further research is needed to confirm the findings from these studies in more diverse cohorts of participants and to identify the mechanisms underlying the findings. Moving forward, NIH will continue to support new and ongoing clinical trials of promising lifestyle interventions to prevent AD/ADRD and will develop and test approaches to support sustained engagement in corresponding long-term lifestyle changes.[453]

26. The role of cellular senescence in aging and disease will be clarified and translated into interventions to improve health.

One cell dividing into two is a hallmark of development in living beings. However, as living beings age the tissues in a body accumulate a small number of cells that no longer divide. These cells are called senescent cells, and they play important roles in health and disease across the lifespan. Under certain

circumstances, such as aging, senescent cells accumulate and release a collection of molecules that can cause damage to nearby tissue. Under other conditions, such as cancer or wound healing, senescent cells can protect health by preventing tumor growth or releasing molecules that promote the growth of new tissue. Biomedical researchers still have many unanswered questions about how, when, why, and where senescent cells form, because their rarity and diversity make them difficult to identify and characterize in the body. Despite this challenge, cellular senescence is an attractive target for new therapeutics, with some already in development. From FY21–FY23, NIH supported research to understand the role of cellular senescence in aging and disease and develop interventions and therapies to delay or reverse the effects of senescent cells.

In FY21, NIH launched the NIH Common Fund Cellular Senescence Network (SenNet) program to identify and characterize the differences in senescent cells across the body, across various states of human health, and across the lifespan.[454] NIH-supported researchers, as part of SenNet, will develop innovative tools and technologies that leverage previous advances in single cell analysis to identify and characterize these rare cells. From FY21–FY23, seven NIH-supported tissue chip projects—small devices that mimic human organs and tissues by supporting the growth and function of living cells—were sent to the International Space Station U.S. National Laboratory (ISS National Lab) as a part of the [Tissue Chips in Space program](#).[455] This program is a partnership between NIH and the ISS National Lab to study physiological changes that happen to the body while in space, which resemble those changes observed during aging, such as impaired tissue healing, altered immune function, loss of muscle strength and mass, and loss of cardiovascular and neurological capacity—all areas that may be impacted by cellular senescence.[456]

In FY22 and FY23, NIH-supported researchers uncovered new and valuable insights into how senescent cells affect diseases of aging, such as Alzheimer's disease, cardiovascular disease, age-related bone loss and skeletal fragility, and aging diabetic kidney disease.[457] For example, in FY22, NIH-supported researchers showed in a pilot study that senolytic therapy—a therapy that selectively induces the removal of senescent cells—may reduce the brain pathology of Alzheimer's disease and improve cognition in patients, thereby delaying disease progression.[458] This finding suggests safety and feasibility of senolytic treatment and supports the development of full-scale clinical trials.[459] In addition, NIH-supported researchers demonstrated that senolytic therapy has the ability to delay, prevent, or treat multiple age-associated diseases in preclinical models.[460] Taken together, the potential to leverage senolytic therapy to treat multiple age-related conditions simultaneously is an exciting one that warrants further investigation.[461]

27. Infant survival will be optimized by synthesizing milk that captures all of the components and properties of human milk, even individualizing it to the characteristics of the infant's mother.

Breast milk provides essential nutrients that infants need for optimal growth, health, and development. It also offers protection against common childhood infections and promotes better survival during a baby's first year compared to formula. However, very little is known about human milk composition and not all infants have access to milk from a lactating parent. NIH has prioritized supporting research to better understand and synthesize human breast milk, as communicated in the *2020–2030 NIH Strategic Plan for Nutrition Research* and the *NIH-Wide Strategic Plan*.[462] Because breast milk is an enormously complex and personalized food, this research requires studying parent and infant factors influencing its composition, synthesis, and best use.

From FY21–FY23, NIH supported research to better understand the components and properties of human milk and its impact on infant health, awarding approximately $11.9 million in FY21 and $17.9 million in FY22 in total grants.[463] In FY21, NIH announced a funding opportunity to encourage research that expands our understanding of the factors influencing the composition and function of human milk.[464] This funding opportunity was released concurrently with a call to action by NIH scientists and other researchers for more research in this area.[465] Research is already starting to advance our understanding of breast milk, as in research papers released in FY21 and FY23,, NIH-supported researchers demonstrated that one component in human milk has antimicrobial properties, while another component supports the growth of beneficial bacteria in the infant gut.[466,467,468]

NIH recognizes that understanding and synthesizing human milk will require collaboration between researchers and regulators. In FY21, NIH, in collaboration with the FDA, sponsored a workshop to explore what is currently known about the biologically active components in human milk and their alternatives, and safety implications of their inclusion in infant formula.[469] As a result of the workshop, scientists identified several areas of research needed to inform regulatory and public health decisions on the use of ingredients in synthetic human milk. To communicate these results, in FY23, NIH published a funding opportunity inviting research applications to support regulatory science on infant formula, and NIH and FDA staff coauthored a paper summarizing commentary from the workshop.[470,471] Also in FY21, the Breastmilk Ecology: Genesis of Infant Nutrition (BEGIN) project hosted a webinar series to explore human milk as an active biological system and better understand the inputs of the lactating parent, the infant, and the environment to that system.[472,473] In FY23, the BEGIN project published a supplement outlining an agenda to inform future research and support the research community's efforts to ensure safe, efficacious, and context-specific infant feeding practices in the U.S., and globally.[474] Over the next few years, NIH will continue to build on these and other efforts to optimize infant health and survival through the synthesis of human breast milk, and to better understand the role of human breast milk in the developmental origins of health and disease.[475]

28. NIH research will discover how technology exposure and media use affect developmental trajectories, health and educational outcomes, and parent–child interactions in childhood in the post-COVID-19 era.

Social media and digital tools have become part of daily life for many children. While these platforms may offer a number of benefits, excessive screen time and digital media use among children have also been associated with adverse physical, developmental, and mental health outcomes. Children's screen time increased during the COVID-19 pandemic, making it more important than ever to understand the impact of technology and digital media on children's health and development. From FY21–FY25, NIH has prioritized characterizing how technology and social media affect child development, behavior, and health and education outcomes.

In FY21, NIH announced a funding opportunity to support research on how technology and digital media exposure and usage impact development and health outcomes in early childhood and adolescence.[476] Researchers will build on a growing body of research aimed at understanding the full impact of screen time and social media use during developmentally sensitive periods of childhood and adolescence. For example, in FY22, NIH-supported research suggested an association between postpartum depression, dysfunctional parent–child interactions, and problematic media use in young children and parents.[477] In FY23, NIH-supported researchers also showed that toddlers who spent more time on screens spent less

time playing with other children, increasing their risk of developmental delay.[478] In FY23, NIH released several funding opportunities for research on adolescent mental health, inviting applications to investigate the two-way relationship between social media use and mental health and to develop technology-based interventions for adolescent mental health treatment.[479,480,481]

From FY21–FY23, two major NIH programs, the Environmental influences on Child Health Outcomes (ECHO) Program and the Adolescent Brain Cognitive Development (ABCD) Study®, continued to collect information from thousands of children, including information about technology and media habits.[482,483] NIH-supported researchers, as a part of ECHO, found that during the pandemic, increases in children's screen time persisted for more than one year, were greatest for Hispanic or Black children, and were mitigated in families with flexible parent work schedules.[484,485,486] To build on this work, ECHO will incorporate additional data elements related to screen time and media use for children and adolescents into its program. As a part of the ABCD Study®, NIH-supported researchers showed that children's screen time is associated with development of mental and behavioral disorders and nearly 9% of young adolescents experience cyberbullying, leading to increased suicidal thoughts or attempts.[487,488,489,490]

Over the next 2.5 years, NIH will continue to support research to understand how exposure to technology and social media affects child development, health, and behavior. For example, some reports suggest that screen time increases have led to increased incidence of myopia (nearsightedness) in children. In response, NIH is incorporating wearable light sensors in its studies of myopia and other refractive errors—types of vision problem that makes it hard to see clearly—to measure exposure to ambient light and digital screens. Discovering the full effects of technology and social media on childhood development, health, and behavior, and how to leverage them for interventions, will be paramount as these tools continue to be a part of our daily lives.

29. NIH research will lead to optimized treatment for infants with neonatal opioid withdrawal syndrome.

Newborns exposed to opioids in the womb are at risk for a condition called neonatal opioid withdrawal syndrome (NOWS) or neonatal abstinence syndrome. Symptoms can include tremors, excessive crying and irritability, and problems with sleeping, feeding, and breathing. From CY10–CY17, the estimated rate of NOWS increased from 4.0 to 7.3 per 1,000 birth hospitalizations.[491] Little is known about the long-term effects of this condition, and few standard, evidence-based treatments exist for NOWS. The *NIH-Wide Strategic Plan* has prioritized research to optimize treatments and standardize clinical care for infants with NOWS.

In FY21, researchers from the Advancing Clinical Trials in Neonatal Opioid Withdrawal Syndrome (ACT NOW) Program—which is supported by the [NIH Helping to End Addiction Long-term® Initiative, or NIH HEAL Initiative®](#)—showed that considerable variations in care for NOWS exist in 30 research hospitals across the U.S.[492,493,494] The ACT NOW Program combines the efforts of two large NIH networks—the Neonatal Research Network and the Institutional Development Award (IDeA) States Pediatric Clinical Trials Network—to inform the clinical care of infants who are exposed to opioids in the womb. In FY23, an ACT NOW clinical trial showed that newborns with NOWS who were cared for with the Eat, Sleep, Console (ESC) care approach rather than the traditional Finnegan Neonatal Abstinence Scoring Tool (FNAST) were ready for release from the hospital almost one week earlier.[495] They were also less likely to require medication treatment with opioids to manage withdrawal symptoms. The study spanned

hospitals in rural and medically underserved communities, which have been particularly impacted by the opioid crisis. A two-year follow-up study is ongoing.

In FY22 and FY23, NIH supported researchers and their small businesses to develop therapeutic devices and treatments for infants with NOWS and pregnant people with opioid use disorder (OUD). For example, researchers, as a part of the NIH HEAL Initiative®, are testing new hospital bassinet pads and hearing aid-like devices to help ease newborns' withdrawal symptoms.[496,497] The hospital bassinet pad is undergoing an expedited FDA review process for novel medical devices that have no comparable devices approved on the market. Approval would make this product the first available medical device to treat newborns diagnosed with NOWS. In addition, optimizing treatment for pregnant people with OUD may also reduce the rate or severity of NOWS. Researchers supported by the NIH Clinical and Translational Science Awards program identified a new form of medication to treat OUD in pregnant people that may minimize formation of the harmful breakdown product that contributes to NOWS, while still treating opioid-dependence and preventing relapse in the parent.[498] To build on this work, the researchers formed a company to bring this agent through the drug development pipeline and have been successful in several business plan prize competitions across the U.S. and Canada.[499] In the coming years, NIH will continue to support research to optimize and standardize care for infants with NOWs, ensuring the safety and efficacy of treatments in geographically and racially diverse patient populations.

30. NIH research will identify one promising intervention to mitigate risks of altered brain development trajectories produced by exposure to alcohol and other drugs among adolescents.

Adolescent substance misuse has been linked to immediate and sometimes lasting changes in the brain. Alcohol consumption is known to affect brain function as well as increase the risk of alcohol use disorder and mental illnesses, such as anxiety and depression, throughout life. Research has also shown that heavy alcohol use alters the development of the adolescent brain, and weakens connections between brain areas that affect cognition, memory, and emotional regulation. More research is needed to clarify how substance use impacts adolescent brain development and to advance prevention and treatment of adolescent substance use. Developing interventions to mitigate these risks could prevent long-term harm to the brain caused by adolescent alcohol and drug use. In alignment with the *NIH-Wide Strategic Plan,* NIH supports a range of efforts to better understand the effects of alcohol and drugs on brain health and behavior.

NIH supports several large, long-term studies to investigate the impact of alcohol and substance use on the adolescent brain, including the National Consortium on Alcohol and Neurodevelopment in Adolescence–Adulthood (NCANDA-A), the Adolescent Brain Cognitive Development (ABCD) Study®, and the HEALthy Brain and Child Development (HBCD) Study.[500,501,502] Together, these studies will provide a comprehensive picture of brain development from adolescence to adulthood, how it is impacted by exposure to alcohol and other drugs, and potential strategies for interventions to mitigate those risks.

From FY21–FY23, a series of studies supported by NIH showed that escalating alcohol use in adolescence and young adulthood was associated with an elevated risk of opioid misuse in young adulthood. This research also demonstrated that the likelihood of substance misuse was reduced when teachers and parents in urban environments used intervention strategies to promote positive behaviors during the early elementary school years.[503,504,505,506] Over the next 2.5 years, researchers will continue to study these intervention strategies to determine their long-term effects and identify the best way to tailor strategies for specific populations.[507]

NIH also supports research through programs like the Neurobiology of Adolescent Drinking in Adulthood (NADIA) consortium, which uses animal models to examine the mechanisms by which adolescent drinking leads to changes in brain structure and function that persist into adulthood.[508] In FY22 and FY23, NIH-supported researchers tested different types of interventions, such as gene-editing techniques and therapeutics, to reverse changes observed in the adult rodent brain after adolescent alcohol exposure, which resulted in decreased anxiety and alcohol drinking, and less damage to nerve cells in the brain region that controls learning and memory.[509,510,511] Moving forward, NIH expects to identify targets that inform the development of interventions to prevent and mitigate the effects of adolescent substance use.

31. Increasing evidence of the effectiveness of nonpharmacologic treatments for pain will transform the way pain is managed and decrease the need for opioids and other medications.

Chronic pain is a common health problem in the U.S., affecting 1 in 5 adults.[512] New cases now outnumber those of other common chronic diseases or health conditions, such as diabetes, depression, and high blood pressure.[513] As such, chronic pain produces a significant national economic burden, affecting quality of life for millions. Over the last few decades, extensive use of prescription opioids for managing chronic pain has contributed to the current opioid crisis. In CY20, approximately 44 people died each day due to prescription opioid overdoses, totaling more than 16,000 deaths, and prescription opioids were involved in about 24% of all opioid overdose deaths.[514] Besides the risks that opioids can cause for patients, there is limited evidence supporting the efficacy of long-term opioid therapy for chronic pain. Thus, the *NIH-Wide Strategic Plan* has prioritized supporting research on nonpharmacologic treatments for pain to transform the way that pain is managed and decrease the need for opioids and other medications.

From FY21–FY23, NIH supported new and ongoing research efforts to address this issue in at-risk populations. In FY21 and FY22, NIH launched the Back Pain Consortium Research Program and the Restoring Joint Health and Function to Reduce Pain Consortium, which will use innovative methods to address the need for personalized nonpharmacological treatments for lower back and joint pain.[515,516] NIH continued to support the NIH-VA-DoD Pain Management Collaboratory, which studies nonpharmacological approaches for pain management in clinical settings serving military personnel, veterans, and their families; the Pain Management Effectiveness Research Network, which evaluates different pain therapies to guide clinical practice; and the Pragmatic and Implementation Studies for the Management of Pain to Reduce Opioid Prescribing (PRISM) program, which focuses on pain management interventions that can be applied in routine health care settings, such as acupuncture and guided relaxation.[517,518,519] Finally, in FY23, the [Pathways to Prevention (P2P) Program](#) hosted a workshop that identified risks and interventions to optimize postpartum health, including ways to improve care for substance use disorders during the postpartum period.[520]

From FY21–FY23, NIH also supported clinical trials testing new routes to pain management and care that leverage our increased access to digital health care since COVID-19. For example, one study is looking at the effects of a web-based pain coping skills program that will track medication use, the ability for patients to manage their own pain, quality of life, and other factors in cancer survivors.[521] A related study is examining the impact of web-guided meditation and mindfulness interventions on patients who had abdominal surgery for cancer.[522] Finally, another clinical trial is testing the effectiveness of

telehealth-based cognitive-behavioral therapy for chronic pain, an approach intended to address the needs of populations who have limited access to health care.[523]

Over the next 2.5 years, results from these projects are expected to provide new evidence-based pain therapies that will be translated into clinical care for the benefit of millions of Americans. This new knowledge will help reduce the burden of both pain and opioid use in the U.S., with a direct impact on health care costs, well-being, and productivity.

32. Effective screening based on a person's genetics, environmental exposures, and socio-behavioral factors will significantly decrease the 9 million lives lost each year to global air pollution by identifying those who are most vulnerable for early intervention.

Air pollution is a mix of hazardous substances from both human-made and natural sources. It is a major threat to health, responsible for approximately 9 million deaths globally each year.[524] Exposure to air pollution is associated with increased risk of certain cancers, cardiovascular disease, and respiratory diseases, among others. Genetics, environmental exposures, and social and behavioral factors can play a role in how people are affected by air pollution. Collaborative efforts across NIH are driving the development of innovative strategies to identify individuals most vulnerable to air pollution-related illnesses and public health interventions to save millions of lives.

The advancement of high-throughput technologies and data science have enabled the integration of multiple data types from different research areas—referred to as omics—to study different aspects of biological systems at the same time. From FY21–FY23, NIH supported research programs and workshops to leverage this approach to science to better understand who is most vulnerable to air pollution-related illnesses. For example, two research programs—the Trans-Omics for Precision Medicine (TOPMed) program and the SubPopulations and InteRmediate Outcome Measures in COPD Study (SPIROMICS)— support researchers to investigate the combined effects of genetics, environmental exposures, and social and behavioral factors on lung health and disease, including chronic obstructive pulmonary disease (COPD), with an aim toward developing targeted interventions.[525,526] In FY23, NIH hosted a workshop on integrating environmental exposure data with other omics in experimental models to inform strategies for cancer risk assessment.[527]

NIH also supported research to establish links between different factors—such as genetics, environmental exposures, and social and behavioral factors—and several health conditions—lung health and disease, neurodegenerative diseases, and cancer. In FY22, the Lung Health Cohort started enrolling 4,000 young adults to establish links between a variety of these factors and lung health.[528,529] Also in FY22, NIH-supported researchers identified a link between environmental exposure to ultrafine particles during pregnancy and an increased risk of asthma in offspring.[530] In FY23, NIH-supported researchers leveraged extensive environmental exposure data and health records to understand the connection between air pollution and Alzheimer's disease.[531] Additionally, NIH released a funding opportunity to support innovative research to better understand the effects of climate change across the cancer control continuum, from cancer etiology (causes) and cancer risks through survivorship, and ways to prevent or mitigate negative health effects.[532]

Over the next 2.5 years, NIH will continue to support research to identify how air pollution affects health and disease, and who is most affected.[533] For example, the TOPMed program plans to incorporate multi-omics data from approximately 270,000 biospecimens to advance our understanding of the biological

function of different genetic variants, gene-environment interactions, and to discover potential therapeutic biomarkers. Taken together, these studies should advance development of effective screening strategies to identify those most vulnerable to global air pollution, ultimately informing environmental policy and mitigation measures.

33. NIH and NASA will spearhead the development of a space-based platform that will monitor species diversity and predict geographic areas of climate concern.

Climate change plays an important role in species diversity around the world. Monitoring these changes may provide important information on the resilience of ecosystems and opportunities to mitigate and adapt to the effects of climate change. NASA has worldwide collaborations to monitor changes in biodiversity by linking satellite data to other measurements, and NIH and NASA have collaborated on research topics since the 1960s.[534] For example, the NIH–NASA Scientific Potential/Actual Collaborative Efforts (SPACE) group convenes quarterly with representation from NASA and 20 NIH ICs to explore and facilitate communication and collaboration in biomedical scientific research that fulfills the mandates of NIH and NASA.[535] In FY21, NIH prioritized working with NASA to spearhead the development of a space-based platform that will monitor species diversity and predict geographic areas of climate concern. However, due to staff changes and shifting priorities over the last 2.5 years, NIH has focused on other areas of climate change research.

In FY22, the NIH Climate Change and Health Initiative was revitalized with the aim to reduce health threats from climate change across the lifespan and build health resilience in individuals, communities, and nations around the world.[536] Efforts thus far have focused on identifying risks and optimizing benefits from actions to mitigate or adapt to climate change, developing the necessary research infrastructure and workforce, and leveraging partnerships with other scientific and social disciplines and organizations to achieve the most impactful results. Toward this end, in FY23, NIH supported the establishment of four sites of the Alliance for Community Engagement on Climate and Health, which will work to promote sustainable strategies that address the impacts of climate change on vulnerable communities, while emphasizing health equity.[537] In early FY24, NIH announced the inaugural class of the NIH Climate and Health Scholars Program, which will bring climate and health scientists from outside of the federal government to work with NIH staff to share knowledge and collaborate on a diverse array of activities.[538]

Over the next 2.5 years, NIH will continue to support research to reduce health threats from climate change across the lifespan and build health resilience, especially among individuals, communities, and nations in geographic areas of climate concern. As of FY22, NIH has available a number of funding opportunities for research projects to address the impact of climate change on health and well-being over the life course, including the health implications of climate change in the U.S. and globally.[539] In the future, NIH hopes that there may be additional opportunities for NIH and NASA to collaborate on monitoring the relationship between species diversity and climate change.

34. The number of NIH R01 awards that support principal investigators from underrepresented racial and ethnic groups will be increased by 50%, and the racial funding disparities gap for NIH R01 grants will be eliminated by FY25.

The Research Project Grant (R01) is the original and historically oldest grant mechanism used by NIH. The R01 provides support for health-related research and development based on the NIH mission. In FY11, NIH-supported researchers reported a significant racial gap in NIH R01 or equivalent grant

funding, illuminating the historical underrepresentation of individuals from diverse backgrounds among those receiving funding for biomedical and behavioral research.[540] In the *NIH-Wide Strategic Plan*, NIH committed to increasing the number of R01 awards that support [researchers from underrepresented groups](#) and erasing the racial and ethnic funding disparities gap by FY25. Achieving this will require a broad range of efforts from targeted funding programs to changes in policy. NIH recognizes that a fully engaged biomedical and behavioral research workforce is critical to accelerate the pace of innovative discoveries and impactful outcomes for human health.

From FY21–FY23, NIH bolstered its commitment to closing the funding gap, as demonstrated by several efforts. In FY22, NIH released a funding opportunity to invite R01 grant applications from new and at-risk investigators[9] from diverse backgrounds.[541] Since its original publication involving three ICs, seven more ICs have signed on to it. For more than three decades, NIH and the CDC have supported eligible individuals from diverse backgrounds, including those from groups that have been shown to be underrepresented in health-related research and researchers with disabilities, through administrative supplements—non-competing awards that provide additional funding to currently funded grants to meet unexpected costs.[542] In FY23, NIH renewed its support of these supplements and expanded eligibility to three new grant types.

In FY23, NIH released its first-ever *Fiscal Years 2023–2027 NIH-Wide Strategic Plan for Diversity, Equity, Inclusion, and Accessibility (DEIA)*.[543] This plan articulated NIH's commitment to strengthening and integrating DEIA across all NIH activities, including enhancing consideration of DEIA in the biomedical and behavioral research funding cycle. Strategies include improving access to NIH resources to ensure equity in the application process; improving representation and mitigating potential bias in the grant review process; advancing DEIA in research awards; and ensuring fair, consistent, and civil engagement throughout the pre- and post-award phases.

These illustrative activities embody NIH's commitment to erasing the R01 racial and ethnic funding gap. NIH continues to monitor funding rates, and the latest data suggests a trend towards narrowing the gap for R01-equivalent awards (98% of which are R01s), signaling NIH's ability to eliminate funding gaps across all NIH grant mechanisms; however, significant work remains.[544,545] Over the next 2.5 years**,** NIH will continue developing new interventions, and enhancing existing programs and policies to promote inclusive excellence, building upon demonstrated success.

35. New forms of scientific communications, such as preprints, will accelerate clinical research and shorten the evidence-to-practice cycle.

Standard practice for reporting scientific results follows that researchers submit scientific manuscripts to journals to undergo peer review prior to final publication. New forms of scientific communication are emerging rapidly, such as preprints, which are complete and public drafts of scientific documents not yet certified by peer review. While NIH has permitted the inclusion of preprints as evidence in grant proposals and progress reports since FY17, the COVID-19 pandemic highlighted the role that preprints could play in shortening the interval from research findings to publication and making the products of science available faster and to more people.[546] Thus, from FY21–FY23, NIH prioritized establishing

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[9] An investigator is considered a New Investigator if they have not competed successfully for substantial, NIH independent funding from NIH. An investigator is considered an At-Risk Investigator if they have had prior support as a Principal Investigator on a substantial independent research award and, unless successful in securing a substantial research grant award in the current FY, will have no substantial research grant funding in the following FY.

research infrastructure to support new forms of scientific communication and their potential role in accelerating the research evidence-to-practice cycle, while ensuring scientific integrity.

As part of NIH's response to the COVID-19 pandemic, in FY20, NIH launched the NIH Preprint Pilot to support accelerated discoverability of NIH-supported research on SARS-CoV-2 and COVID-19 being shared on public preprint servers.[547] From FY20–FY22, NIH added more than 3,300 preprint records reporting on the results of NIH-supported research on SARS-CoV-2 and COVID-19, with over three million views.[548] For preprints resulting in peer-reviewed articles published in journals included in PubMed as citations or PubMed Central as full text, the preprint appeared on average 100 days earlier than the peer-reviewed article, demonstrating that the NIH Preprint Pilot provided an avenue for discovery of NIH-supported research prior to journal publication during the ongoing public health emergency. Based on the pilot's success, in FY23, NIH expanded its scope to include access to preprints beyond COVID-19, to include all preprints reporting NIH-supported research and posted to an eligible preprint server in PubMed and PubMed Central.

From FY21–FY23, NIH enabled rapid scientific communication by expanding access to results of NIH-supported research through updates to overarching NIH policies—such as the *NIH Data Management and Sharing Policy, NIH Public Access Policy,* and *NIH Scientific Integrity Policy*—and more program-specific policies—such as the Cancer Moonshot℠ Public Access and Data Sharing Policy and the NIH Helping to End Addiction Long-term® (HEAL) Initiative Public Access and Data Sharing Policy.[549,550,551,552,553] In addition, NIH leveraged data to develop new forms of scientific communication. For example, in FY21, NIH held the LitCoin Natural Language Processing (NLP) Challenge to develop NLP systems with the ability to identify concepts from a biomedical publication and link them together to create knowledge graphs (or networks) for each publication.[554,555] Also in FY21, NIH collaborated with an ophthalmology journal to create a specific section and article type for data science to summarize and describe datasets or software libraries.[556]

Over the next 2.5 years, NIH will continue to build research infrastructure to support these new forms of scientific communication and track the impact of these approaches in accelerating discovery and shortening the evidence-to-practice cycle.

Appendices

Appendix A. List of NIH Institutes, Centers, and Offices

Acronym	Full Name
AoU	*All of Us* Research Program Office
CC	Clinical Center
COSWD	Chief Officer for Scientific Workforce Diversity
CSR	Center for Scientific Review
DPCPSI	Division of Program Coordination, Planning, and Strategic Initiatives
ECHO	Environmental influences on Child Health Outcomes Program Office
FIC	John E. Fogarty International Center
FNIH	Foundation for the National Institutes of Health
ICOs	Institutes, Centers, and Offices
ICs	Institutes and Centers
NCATS	National Center for Advancing Translational Sciences
NCCIH	National Center for Complementary and Integrative Health
NCI	National Cancer Institute
NEI	National Eye Institute
NHGRI	National Human Genome Research Institute
NHLBI	National Heart, Lung, and Blood Institute
NIA	National Institute on Aging
NIAAA	National Institute on Alcohol Abuse and Alcoholism
NIAID	National Institute of Allergy and Infectious Diseases
NIAMS	National Institute of Arthritis and Musculoskeletal and Skin Diseases
NIBIB	National Institute of Biomedical Imaging and Bioengineering
NICHD	*Eunice Kennedy Shriver* National Institute of Child Health and Human Development
NIDA	National Institute on Drug Abuse
NIDCD	National Institute on Deafness and Other Communication Disorders
NIDCR	National Institute of Dental and Craniofacial Research
NIDDK	National Institute of Diabetes and Digestive and Kidney Diseases
NIEHS	National Institute of Environmental Health Sciences
NIGMS	National Institute of General Medical Sciences
NIH	National Institutes of Health
NIMH	National Institute of Mental Health
NIMHD	National Institute on Minority Health and Health Disparities
NINDS	National Institute of Neurological Disorders and Stroke
NINR	National Institute of Nursing Research
NLM	National Library of Medicine
OAM	Office of Administrative Management
OAR	Office of AIDS Research
OBSSR	Office of Behavioral and Social Sciences Research
OCPL	Office of Communications and Public Liaison
OD	Office of the Director
ODP	Office of Disease Prevention
ODS	Office of Dietary Supplements

Acronym	Full Name
ODSS	Office of Data Science Strategy
OEPR	Office of Evaluation, Performance, and Reporting
OER	Office of Extramural Research
OHR	Office of Human Resources
OIR	Office of Intramural Research
OM	Office of Management
ONR	Office of Nutrition Research
OPA	Office of Portfolio Analysis
ORFDO	Office of Research Facilities Development and Operations
ORIP	Office of Research Infrastructure Programs
ORWH	Office of Research on Women's Health
OSC	Office of Strategic Coordination
SGMRO	Sexual and Gender Minority Research Office
THRO	Tribal Health Research Office

Appendix B. List of Other U.S. Government Agencies

Acronym	Full Name
AHRQ	Agency for Healthcare Research and Quality
BARDA	Biomedical Advanced Research and Development Authority
CDC	Centers for Disease Control and Prevention
CMS	Centers for Medicare and Medicaid Services
DOD	Department of Defense
EPA	Environmental Protection Agency
FDA	Food and Drug Administration
HHS	Department of Health and Human Services
HRSA	Health Resources and Services Administration
IHS	Indian Health Service
ISS National Lab	International Space Station U.S. National Laboratory
NARA	National Archives and Records Administration
NASA	National Aeronautics and Space Administration
NOAA	National Oceanic and Atmospheric Administration
NSF	National Science Foundation
OMB	Office of Management and Budget
OSTP	Office of Science and Technology Policy
PCORI	Patient-Centered Outcomes Research Institute
SAMHSA	Substance Abuse and Mental Health Services Administration
USDA	Department of Agriculture
VA	Department of Veterans Affairs

Appendix C. Approach to Assessing Progress Towards the Subobjectives

To assess progress toward the Subobjectives, staff from ICOs submitted up to two NIH activities that aligned with each Subobjective of the Plan. The staff then voted on which activities best represented progress toward each Subobjective. DPCPSI leadership used the results of those votes, as well as consideration of balance across different ICOs and portfolios, to finalize the shortlist of activities to include in the report. The activities were organized into 2-3 general themes per Subobjective. The lead ICO for each of these activities coordinated with contributing ICOs to prepare writeups on progress made over the last 2.5 years, as well as planned actions for the next 2.5 years.

Subobjective	Representative Activities Theme	ICOs (Lead ICOs are bolded)
1.1: Driving Foundational Science	Human Development	NCI, NHGRI, NHLBI, NIA, **NICHD**, **NIDA**, NIDCD,
1.1: Driving Foundational Science	Foundational Neuroscience	**NIMH, NINDS (including OBD)**
1.1: Driving Foundational Science	Social Determinants of Health	**NIMHD, OD/DPCPSI/OBSSR**
1.2: Preventing Disease and Promoting Health	mRNA Vaccine Technology	**NIAID**
1.2: Preventing Disease and Promoting Health	Precision Nutrition Research	OD/AoU, OD/DPCPSI/ONR, **OD/DPCPSI/OSC**
1.2: Preventing Disease and Promoting Health	NIH Pathways to Prevention (P2P) Program	NCATS, NCI, NHLBI, NIA, NICHD, NIMHD, NINDS, **OD/DPCPSI/ODP,** OD/DPCPSI/ODS, OD/DPCPSI/ONR, OD/DPCPSI/ORWH
1.3: Developing and Optimizing Treatments, Interventions, and Cures	Tissue/Organ Systems Chips for Drug Screening	**NCATS,** NCI, NHLBI, NIA, NIAID, NIAMS, NIBIB, NICHD, NIDA, NIDCR, NIDCD, NIDDK, NEI, NIEHS, NIMH, NINDS, OD/DPCPSI/ORWH
1.3: Developing and Optimizing Treatments, Interventions, and Cures	Precision Medicine	**NCI, NHGRI**
1.3: Developing and Optimizing Treatments, Interventions, and Cures	NIH Helping to End Addiction Long-term® (HEAL) Initiative	**NIDA, NINDS**
2.1: Enhancing the Biomedical and Behavioral Research Workforce	Workforce Diversity	**NIGMS**, OD/COSWD, OD/DPCPSI/OSC
2.1: Enhancing the Biomedical and Behavioral Research Workforce	Early Stage Investigators	OD/DPCPSI/OSC, **OD/OER**
2.2: Supporting Research Resources and Infrastructure	Research Networks	**NCATS**, NCI, NIA, NINDS, OD/DPCPSI/OSC

Subobjective	Representative Activities Theme	ICOs (Lead ICOs are bolded)
2.2: Supporting Research Resources and Infrastructure	Research Tools and Technology	**OD/DPCPSI/ORIP, OD/DPCPSI/OSC**
2.2: Supporting Research Resources and Infrastructure	Atlases as Research Resources	NCI, NHLBI, NIDDK, **OD/DPCPSI/OSC**
3.1: Fostering a Culture of Good Scientific Stewardship	Grant Review Process	**CSR**, NIMH, NINDS (including OBD)
3.1: Fostering a Culture of Good Scientific Stewardship	Common Data Elements	CIT, NEI, NIDDK, NINDS, **NLM**, OD/DPCPSI/ODSS
3.1: Fostering a Culture of Good Scientific Stewardship	Evaluation Capacity Building	NIGMS, **OD/DPCPSI/OEPR**
3.2: Leveraging Partnerships	Partnerships to Combat the COVID-19 Pandemic	NCATS, NIBIB, NIGMS, NIMHD, NLM, OD/DPCPSI/ODSS, **OD/IMOD**
3.2: Leveraging Partnerships	NIH Community Partnerships to Advance Science for Society (ComPASS) Program	**OD/DPCPSI/OSC**
3.2: Leveraging Partnerships	Accelerating Medicines Partnership® (AMP®)	NCATS, NIAID, NIAMS, OD/DPCPSI/ORWH, **OD/OSP**
3.3: Ensuring Accountability and Confidence in Biomedical and Behavioral Sciences	Safe and Respectful Work Environments	**OD/OER**, OD/OM/OHR
3.3: Ensuring Accountability and Confidence in Biomedical and Behavioral Sciences	Public Access and Data Sharing	NHGRI, NLM, OD/DPCPSI/ODSS, OD/OER, **OD/OSP**
3.4: Optimizing Operations	Digital Efficiencies	**CSR, NLM, OD/OM/OMA**
3.4: Optimizing Operations	NIH Buildings and Facilities (B&F) Program Prioritization Model	**OD/OM/ORFDO**

Appendix D. Approach to Assessing Progress Towards the Bold Predictions

During the strategic planning process from FY19–FY21, ICOs were asked to submit Bold Predictions for inclusion in the *NIH-Wide Strategic Plan*. The NIH Director selected from these submissions which Bold Predictions to include in the Plan.

To assess progress towards the Bold Predictions, the lead ICO that originally proposed the Bold Prediction coordinated with contributing ICOs to gather information on and develop reports describing the progress made over the last 2.5 years as well as planned actions for the next 2.5 years. All ICOs that participated in the process are listed below, with the lead ICO in bold. In a few Bold Predictions, there were two lead ICOs.

Bold Prediction	ICOs (Lead ICOs are bolded)
1. The All of Us Research Program will reach its goal of 1 million diverse participants and will have gathered the most diverse collection of data (e.g., deep phenotypic, -omic, EHR, digital health technology) on 1 million or more participants of any research resource in the world.	CC, CIT, NCATS, NCI, NEI, NHGRI, NHLBI, NIA, NIDCD, NIEHS, NIMH, NLM, **OD/AoU**, OD/DPCPSI/ONR, OD/DPCPSI/THRO
2. The regular use of genomic information will have transitioned from boutique to mainstream in all clinical settings, making genomic testing as routine as complete blood counts.	NCI, **NHGRI**, NIA, NIAMS, NLM
3. Human studies on type 1 diabetes will assess the long-term survival and function of encapsulated human islets, as well as their efficacy in preventing or delaying the onset of complications and increasing overall survival.	**NIDDK**
4. Incorporating novel genomics findings from clinical studies on congenital heart disease will help researchers move toward precision therapy and personalized counseling, leading to improved outcomes and longevity for affected children and adults.	NCATS, NHGRI, **NHLBI**
5. The high burden of heart disease in communities of color and rural areas will be reduced, especially for major outcomes, such as maternal morbidity and mortality, hypertension, and heart failure.	NCATS, **NHLBI**, NIA, NIBIB, NIEHS, NIMHD, OD/DPCPSI/ODP, OD/DPCPSI/ONR
6. A gene therapy for muscular dystrophy will restore the function of the mutated gene and improve patient outcomes.	**NIAMS**, NICHD, NINDS
7. Gene-based therapies for SCD will be evaluated and refined in large-scale clinical trials, offering a cure to the approximately 100,000 people in the U.S. and 20 million globally who suffer severe pain and premature death from this condition.	NHGRI, **NHLBI**
8. First-in-human clinical trials will demonstrate the efficacy of iPSC-derived products.	CC, **NEI**, NHGRI, NIA, NIAMS
9. Engineered biological cells and scaffolds will be successfully used to repair and replace tissue damaged by chronic wounds or such disorders as osteoarthritis.	NCATS, NEI, NIA, NIAMS, NIBIB, NIDCR

Bold Prediction	ICOs (Lead ICOs are bolded)
10. Insight will be gained into the ultimate ability to regenerate human limbs, using emerging technologies to activate the body's own growth pathways and processes.	NIAMS, NIBIB, **NICHD**
11. Research on new approaches to cervical cancer screening will lead to the development of self-sampling for women, with the potential to substantially reduce the incidence and mortality of this disease.	**NCI**, NLM, OD/DPCPSI/ORWH
12. At least one novel, non-hormonal pharmacologic treatment for endometriosis will be identified and moved to clinical trials.	NCI, **NICHD**
13. The number of maternal deaths per year in the U.S. will be significantly decreased, particularly among Black and American Indian or Alaska Native women, by implementing results of research studies focusing on links between social determinants and biological risk factors.	NHLBI, NIA, **NICHD**, NIDA, NIEHS, NIMH, NIMHD, OD/DPCPSI/OBSSR, OD/DPCPSI/ODP, OD/DPCPSI/ONR, OD/DPCPSI/ORWH
14. Following PRGLAC Task Force findings that almost no data exist on medications in pregnant and lactating women, label changes will be facilitated by results of clinical trials for at least three therapeutics specific to (1) pregnant women and lactating women and (2) children.	**NICHD**, NIMH, OD/DPCPSI/OBSSR, OD/DPCPSI/ORWH
15. NIH-wide research will lead to new implementation strategies for pre-exposure prophylaxis that will significantly reduce the number of new HIV infections and to new long-acting therapies to improve viral load suppression among people with HIV to levels that prevent transmission.	NIA, **NIAID**, NICHD, NIDA, NIMH, OD/DPCPSI/OAR, OD/DPCPSI/OBSSR, OD/DPCPSI/ORWH
16. At least one candidate universal influenza vaccine against groups 1 and 2 with 75 percent efficacy will be submitted to the FDA for consideration.	CC, **NIAID**
17. NIH-supported researchers will develop a universal coronavirus vaccine.	NCI, NIA, **NIAID**
18. By actively engaging with underserved populations to reduce disparities for COVID-19, researchers will prevent and curb the spread of COVID-19 and save lives.	FIC, NCATS, NHGRI, NHLBI, NIA, NIBIB, NICHD, NIEHS, NIGMS, NIMH, **NIMHD**, OD/DPCPSI/OBSSR, OD/DPCPSI/ORWH, OD/DPCPSI/THRO, OD/IMOD
19. Artificial intelligence (AI) will reveal molecular signatures associated with the return to health after an acute illness (e.g., COVID-19).	CIT, NCATS, NHLBI, NIAID, OD/AoU, **OD/DPCPSI/ODSS**
20. Biomarkers will guide the choice of the most effective therapy for each individual rheumatoid arthritis patient.	**NIAMS**
21. NIH-supported research will lead to the development of a clinically actionable biomarker for precision psychiatry, using neuroimaging and/or additional physiological and psychological biomarkers.	NHGRI, NIA, **NIMH**

Bold Prediction (continued)	ICOs (Lead ICOs are bolded)
22. Comprehensive atlases of cell types in the mouse and human brain will provide a deeper understanding of the circuits underlying behavior and a foundation for understanding the circuits affected in complex human brain disorders, including depression.	NHGRI, NIA, NIDA, **NIMH**, NINDS (including OBD), OD/DPCPSI/OBSSR
23. Invasive and noninvasive human brain recording and stimulation technologies will enable new paradigms for interventions in movement disorders and neuropsychiatric diseases, as well as the development of brain-machine interfaces for sensory and motor neural prostheses.	NICHD, NIBIB, NIDA, NIMH, **NINDS (including OBD)**
24. Preventive approaches targeting vascular risk factors will reduce the risk for dementia and promote healthy brain aging.	NHLBI, **NIA**, NIMH, **NINDS**
25. At least one promising lifestyle intervention to prevent Alzheimer's disease and related dementias will be rigorously demonstrated in the next 5 years.	**NIA**, NINDS, OD/DPCPSI/OBSSR
26. The role of cellular senescence in aging and disease will be clarified and translated into interventions to improve health.	NCATS, NCI, NEI, **NIA**, OD/DPCPSI/OSC
27. Infant survival will be optimized by synthesizing milk that captures all of the components and properties of human milk, even individualizing it to the characteristics of the infant's mother.	**NICHD**, OD/DPCPSI/OBSSR, OD/DPCPSI/ODS, OD/DPCPSI/ONR
28. NIH research will discover how technology exposure and media use affect developmental trajectories, health and educational outcomes, and parent–child interactions in childhood in the post-COVID-19 era.	NEI, **NICHD**, NIMH, OD/DPCPSI/OBSSR, OD/ECHO
29. NIH research will lead to optimized treatment for infants with Neonatal Opioid Withdrawal Syndrome.	NCATS, **NICHD**, NIDA, OD/DPCPSI/OBSSR, OD/ECHO, **OD/HEAL**[10]
30. NIH research will identify one promising intervention to mitigate risks of altered brain development trajectories produced by exposure to alcohol and other drugs among adolescents.	**NIAAA**, NIDA, **OD/HEAL**[11]
31. Increasing evidence of the effectiveness of nonpharmacologic treatments for pain will transform the way pain is managed and decrease the need for opioids and other medications.	NCATS, **NCCIH**, NCI, NIA, NIAMS, NICHD, NINDS, OD/DPCPSI/OBSSR, **OD/HEAL**[12]

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[10] At the time of preparation of this section of the report, HEAL was in the OD. Now it is in NIDA and NINDS.
[11] At the time of preparation of this section of the report, HEAL was in the OD. Now it is in NIDA and NINDS.
[12] At the time of preparation of this section of the report, HEAL was in the OD. Now it is in NIDA and NINDS.

Bold Prediction (continued)	ICOs (Lead ICOs are bolded)
32. Effective screening based on a person's genetics, environmental exposures, and socio-behavioral factors will significantly decrease the 9 million lives lost each year to global air pollution by identifying those who are most vulnerable for early intervention.	NCI, NHGRI, NHLBI, NIA, **NIEHS**
33. NIH and NASA will spearhead the development of a space-based platform that will monitor species diversity and predict geographic areas of climate concern.	CIT, **NIEHS**, OD/DPCPSI/OBSSR
34. The number of NIH R01 awards that support principal investigators from underrepresented racial and ethnic groups will be increased by 50 percent, and the racial funding disparities gap for NIH R01 grants will be eliminated by fiscal year 2025.	NCI, NEI, NHGRI, NHLBI, NIA, NIAMS, NIBIB, NIDA, NIDCD, NIDCR, NIEHS, NIGMS, NIMH, NIMHD, NLM, **OD/COSWD**, OD/DPCPSI/OBSSR, OD/DPCPSI/ODS, OD/IMOD, OD/OER
35. New forms of scientific communications, such as preprints, will accelerate clinical research and shorten the evidence-to-practice cycle.	CIT, NCATS, NCI, NEI, NHGRI, **NLM**, OD/DPCPSI/OBSSR, OD/OER, OD/OSP

Appendix E. Alignment of Bold Predictions with the Subobjectives

Subobjectives (columns)	1.1	1.2	1.3	2.1	2.2	3.1	3.2	3.3	3.4
Bold Predictions (rows)									
1		X			X			X	
2		X	X		X				
3	X		X						
4	X		X		X				
5		X	X				X		
6			X						
7			X				X	X	
8			X						
9	X		X						
10	X						X		
11		X					X		
12		X	X						
13		X					X	X	
14		X	X		X		X	X	
15		X	X		X			X	
16		X			X				
17	X	X			X		X		
18		X			X		X	X	
19	X	X			X			X	
20			X				X		
21			X				X		
22	X				X			X	
23			X						
24		X					X		
25		X							
26	X	X	X		X		X		
27	X	X					X		
28	X	X							
29			X						
30	X		X						
31		X	X		X		X		
32	X	X							
33		X		X	X		X		
34				X		X	X	X	
35					X	X		X	

[1] NIH-Wide Strategic Plan, Fiscal Years 2016–2020. https://www.nih.gov/about-nih/nih-wide-strategic-plan-fy-2016-2020

[2] Adolescent Brain Cognitive Development Study. https://www.addictionresearch.nih.gov/abcd-study

[3] ABCD Study Scientific Publications. https://abcdstudy.org/publications/

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