National Institutes of Health

Digital NIH: Innovation, Technology, and Computation for the Future of NIH

FY2023 – FY2028

About This Document

The strategy and recommendations in this document are provided for internal NIH review and consideration.

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Introductory Message

Lawrence A. Tabak, D.D.S., Ph.D.

As the nation's premier biomedical research agency, the National Institutes of Health (NIH) plays a critical role in advancing basic, translational, and clinical research aimed at improving human health and contributes to the foundation of the nation's economic well-being.

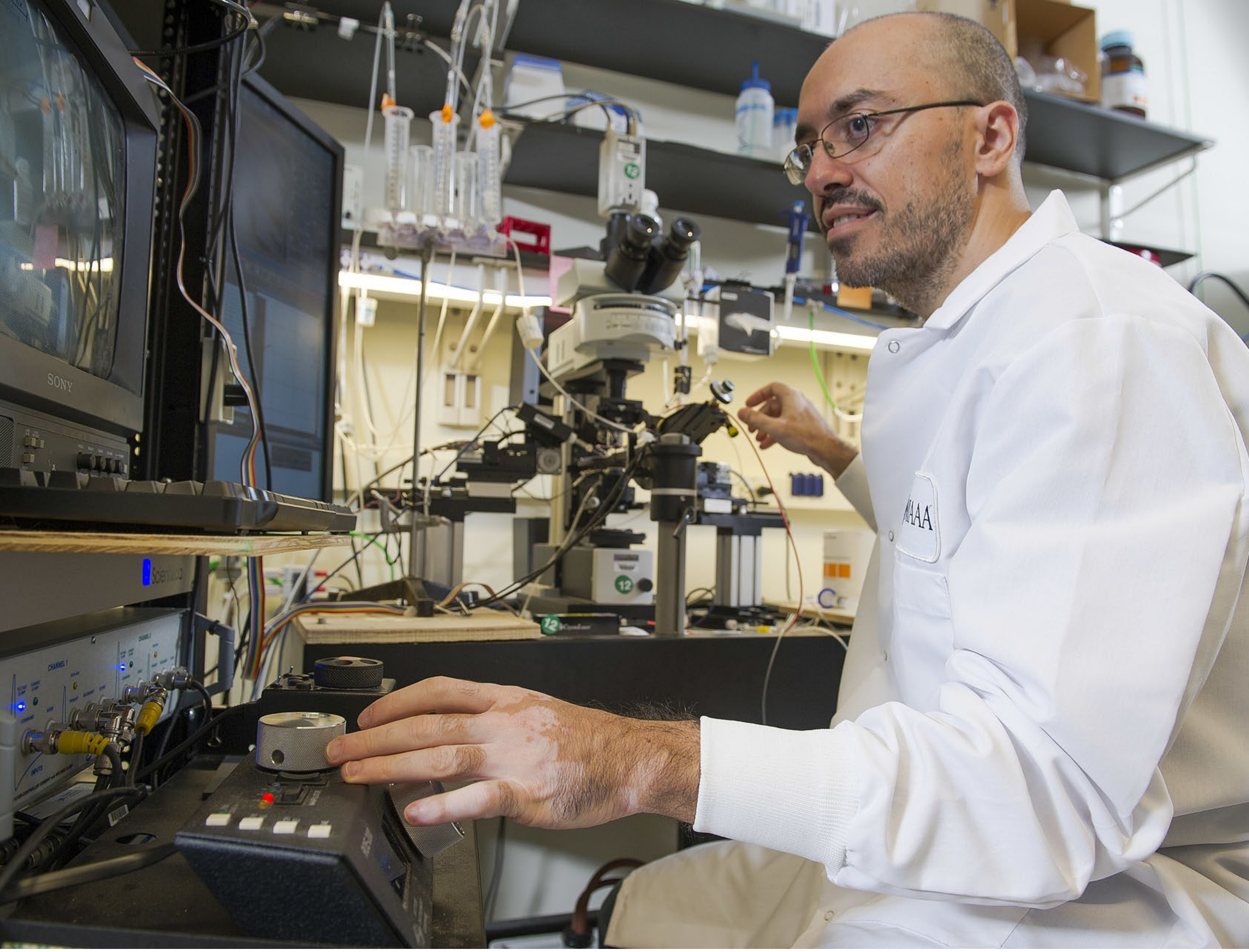
Some of the most exciting discoveries in biomedical research are being realized at the intersection of science and technology. In addition, technology, including information systems at various scales and sizes, has become integral to how NIH conducts science and administers and oversees the extramural biomedical research enterprise. In turn, this requires the adoption of new approaches and business models to support high impact, cutting edge approaches that foster scientific creativity and minimize administrative burden. With so much opportunity, NIH must be strategic and focused on evaluating the critical role that technology plays.

The strategy outlined in this document proposes a new and more synergistic approach for technology decision-making at NIH and describes a cohesive framework to guide how NIH prioritizes, selects, and delivers high-priority, high-value capabilities over the next five years. Most importantly, it recommends new ways of working together to ensure that NIH has the capabilities necessary to advance discoveries in the years ahead. This effort reflects information collected from hundreds of individuals across NIH, key subject matter experts, and many public and private sector organizations – an effort led by the Strategic Planning Committee for *Digital NIH*. I greatly appreciate the efforts of the Committee and its Co-Chairs, Ms. Andrea Norris, Director of the Center for Information Technology and NIH Chief Information Officer, and Dr. Patricia Flatley Brennan, Director of the National Library of Medicine, for their leadership in developing this strategy.

NIH is much stronger and more effective when we work together on matters of common interest. I look forward to working with NIH Institutes, Centers, and Offices, along with our stakeholders and partners, to ensure that technology continues to enable the enhancement of the health and well-being of all Americans.

Sincerely,

Lawrence A. Tabak, D.D.S., Ph.D.
Performing the Duties of the NIH Director



Section 1: Context and Overview

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NIH used mRNA technology to enable the development and deployment of an effective COVID-19 vaccine in less than a year. Photo: Chia-Chi Charlie Chang

NIH's use of innovative research methods and technologies are advancing effective treatments and cures for some of the most challenging public health issues and diseases. Most recently, innovative approaches contributed significantly to the development, approval, and deployment of COVID-19 diagnostics, vaccines, and therapeutics, reducing the impact of infection, and mitigating the risk of death for millions of individuals across the world. The mainstream use of electronic health records in health care has opened new avenues to use human health data for important areas of biomedical research. Advances in imaging and gene-editing technologies, such as CryoEM and CRISPR[1] provide exciting insights into the function of the human body and offer enormous promise of new ways to treat and heal patients. These are just a few examples where technology is enabling NIH to detect, visualize, and treat illness and disease in ways unimagined just a few short years ago.

"We are seeing a new approach to science in which technologies have become an inseparable component of the scientific process."
– NIH Researcher

In fact, advances in digital technology and data science are fundamentally changing the very nature of how biomedical scientists conduct research. Digital technology has become an inseparable component of the scientific process, enabling innovation across the research spectrum at unprecedented scale. This is creating new demands for high-speed computation, scalable and cost-effective data storage, advanced analytics, and a broad range of technology-support functions. For example, continued innovations in scientific instrumentation, methodologies, and techniques will necessitate a greater capacity to process and store petabyte-scale data. Broader adoption of machine learning and artificial intelligence will require a robust infrastructure that provides researchers with easy, secure access to data and technology resources, and equips them with significantly greater computing power. The 2023 NIH Data Management and Sharing Policy will create new expectations for innovative digital infrastructures to host and track scientific data products related to NIH-funded research. NIH

[1] Note: Please see the Glossary for definitions of terms and acronyms related to technologies and NIH systems.

Institutes, Centers, and Offices will also need new, integrated solutions, including those to manage the extramural research portfolio, issue and oversee grants and other types of awards, and perform a broad range of administrative management functions as the volume, scale, and complexity of research programs grow. NIH is simultaneously undergoing seminal transformations in when, where, and how the workforce operates. Beyond changes in biomedical research and data science, NIH anticipates a future of work quite different than the past, requiring technology-rich workplaces and laboratories to support hybrid, in-person, and remote work options.

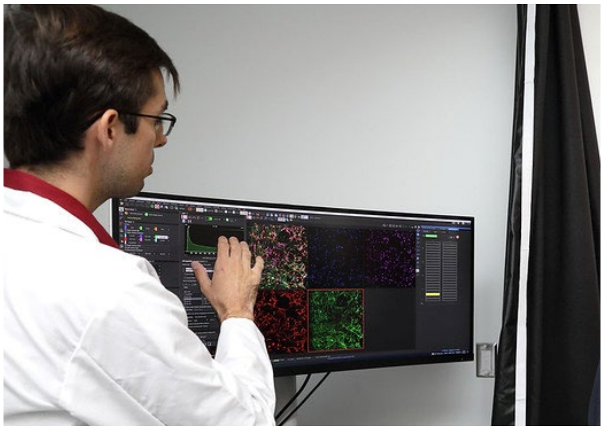
Recognizing these opportunities and challenges, in late 2021, NIH leadership initiated an NIH-wide planning initiative to identify the changes and capabilities needed to advance NIH's mission and guide NIH's technology investment strategies (inclusive of computational and information technologies) over the next five years. This document, *Digital NIH: Innovation, Technology, and Computation for the Future of NIH* (herein referred to as "*Digital NIH*") reflects the culmination of the efforts of approximately 50 NIH leaders and subject matter experts on the Strategic Planning Committee for *Digital NIH* (here in referred to as "the Committee"), over 400 NIH staff members, and experts from 19 leading public and private sector organizations.

The strategy within *Digital NIH* proposes new approaches to manage and govern NIH technology investments; describes a framework to guide implementation of high-priority, high-value capabilities; and recommends a path for NIH to move forward. Detailed descriptions of these important elements can be found in sections two through four of this document, with supplementary information provided in the appendices. Highlights of each section are described below.

New Approaches to Manage and Govern NIH Technology Investments

If NIH is to achieve the goals outlined in the NIH Strategic Plan and meet innovation expectations for 21st century science and research management, it must fundamentally change how it thinks about, plans, makes decisions for, invests in, and manages technology resources.

Traditionally, Institutes and Centers (ICs) have invested in and implemented their own specific systems, platforms, and information resources consistent with their IC-specific budgets, research priorities, and Institute needs. Individual IC technology investment levels range from $2 million to $200 million annually, and there is significant variance in quality and robustness of IC capabilities. Some larger ICs have more comprehensive technology solutions, but most lack modern, end-to-end digital solutions to support critical extramural research management, basic and clinical intramural research, and administrative and management functions.



With tools like robotic high-powered microscopes now common in labs, research increasingly relies on dense data and robust computational analysis. Photo: Chia-Chi Charlie Chang

Current approaches to manage and govern technology investments are no longer adequate to meet today's computationally intensive research requirements or those that are anticipated in the future. Very few ICs will have sufficient resources to keep pace with the rapid changes in science and technology or to meet increased demands for modern, end-to-end solutions that improve staff productivity and organizational effectiveness. In the future, NIH must be more focused and strategic in its treatment of technology as a critical resource, adopting new collaborative approaches and agile business models that deliver faster, better, more cost-effective capabilities that benefit all.

In the future, NIH leadership will play a critical role in advancing these new digital strategies by actively engaging in critical technology matters; prioritizing the capabilities needed; and involving the right individuals in technology planning, decision-making, and oversight processes. Technology considerations will be included as new programs, management initiatives, or policies are planned so that technology-related requirements can be proactively addressed. New holistic and collaborative planning and prioritization approaches will assure IC and NIH-level investments complement one another. Priority should be given to innovative, shared solutions that meet common needs and align with a robust technology architecture, which will establish data, software, and interoperability standards, and promote the use of common platforms. Funding decisions will be enriched by a more comprehensive and realistic understanding of the value and impact of new investments. This does not suggest a transition to monolithic, centrally managed systems or capabilities; nor should it limit an IC's ability to meet IC-unique technology needs that should continue to be managed and delivered locally. Success will be more likely if NIH adopts a more systematic approach to identify where ICs have been successful in implementing solutions that provide considerable benefit and to then leverage these solutions for the broader NIH. ICs interested in sponsoring an NIH-wide effort may want to serve as the lead or "center of excellence" for specific capabilities.

NIH should also implement a variety of flexible and integrated governance structures that align decision-making processes with the purpose, scope, complexity, and value of the investment, allowing NIH to be nimble in both planning and execution. New funding mechanisms that foster innovation and enable agile and timely decision-making will incentivize ICs to collaborate on technology initiatives of common interest, accelerate implementation of high-priority, high-value shared solutions, and encourage organizational units to experiment with strategies that could provide value to the broader NIH. NIH will provide ongoing funding to operate and maintain existing or new investments at healthy levels over the life of the solution or system.

Responsible governance will require new ways of working together to optimize current practices and deploy flexible technical solutions to meet common needs wherever practical. This requires a culture change that may not be easy but is critical to success moving forward. By working together in new, more intentional ways, NIH can more effectively and efficiently provide high-priority, high-value capabilities for all.

A Framework to Guide Implementation of High-Priority, High-Value Capabilities

In addition to adopting new approaches to manage and govern technology investments, NIH must define and implement new, high-priority, high-value capabilities (i.e., competencies, skills, and activities) necessary to meet current and future mission needs. Throughout the strategy planning effort, NIH staff consistently shared a need for modern, integrated, intuitive, efficient, secure, and data-driven technologies to perform their work, irrespective of their role or the organization they supported. They articulated a future state for NIH and identified a broad range of capabilities needed to support the work requirements of four functional areas common to all ICs:

- **Extramural Research Management** - The future will include cutting-edge, integrated digital platforms to enable robust application and portfolio administration and management. ICs should align on common solutions that effectively advance the management of funded research, ensure better compliance, reduce researcher and staff burden, and streamline planning and tracking across the award lifecycle.

- **Intramural Basic Research** - The future will be supported through access to holistic information on NIH's research portfolio and a suite of tools, applications, and software – such as electronic lab notebooks and data analytics packages. Automation of laboratory processes, along with an increase in computing resources, will enable state-of-the-art research approaches.

- **Intramural Clinical Research** - The future will be enabled through integrated, end-to-end platforms for clinical trial management, which allow investigators to design, conduct, and manage studies easily and securely. Integrated tools better support data sharing and management, as well as streamlined regulatory compliance and reporting.

- **Administration and Management** - The future will be facilitated through optimized business processes and common platforms that can be tailored to specific IC and Office of the Director (OD) needs. Automation and digitization will reduce manual administrative workflows and processes.

Examples of future capabilities identified for each functional area can be found in Section 3: A Framework to Guide Implementation of High-Priority, High-Value Capabilities. The Committee also identified a suite of cross-cutting capabilities that are necessary to deliver and sustain a cohesive suite of modern, integrated, intuitive, efficient, secure, and data-driven technologies. These capabilities are foundational in nature and support the high-priority, high-value capabilities needed by the four functional areas. The five cross-cutting capabilities are:

- A common architecture with well-defined standards to enable integration
- Innovative, cutting-edge storage, analytics, and computational infrastructure
- Increased technical competency of the workforce at all levels
- Technology to support an anywhere, anytime workplace of the future
- Risk-based, embedded cybersecurity protections

The functional areas and cross-cutting capabilities, when viewed together, serve as a framework to guide NIH implementation efforts. This framework complements the well-established IC orientation of NIH and reflects the shared nature of NIH's mission, while preserving the unique ways that this mission is carried out within individual ICs.

Path Forward

Key to the success of this strategy is the recognition that NIH requires new ways of doing business and, most importantly, new approaches to sustaining a scientific enterprise that is driven and empowered through technology. As with any significant organizational change effort, it is paramount that NIH senior leadership endorse and commit to the principles and recommendations described in *Digital NIH*. The NIH Steering Committee, NIH's highest governance body, should consistently and actively engage in the necessary efforts to supplant legacy operational models; functions, processes, and outcomes; and governance and decision-making. It is important that the NIH Steering Committee serve as both a champion for these efforts and a resource for IC leadership. It will be critical to maintain open and regular communication with many levels of NIH leadership, including a small group of advisors to specifically comment on the process.

The first stage of implementation planning requires a collaborative effort with broad representation across NIH. Three initial activities are essential for success in the first year:

1) **Adopt a New, More Strategic Approach to Technology Funding and Governance:** NIH must be more intentional as it balances the needs of IC autonomy and NIH-wide coordinated action. This includes devising new ways to make decisions about technology investments in a manner that is more accountable across NIH, avoids unnecessary redundancies, and is much less cumbersome and time-consuming than present approaches. As a high priority, NIH needs to change the current multi-committee, year-long decision-making processes, which address only a small part of NIH's technology portfolio. Instead, NIH leaders should champion a new, more enterprise-savvy approach to technology governance and decision-making that reflects holistic, integrated planning across NIH. Part of this effort should begin with the consideration of a new Innovation Fund, which will allow NIH to expeditiously fund investments to deliver the high-priority, high-value capabilities identified by the functional area and cross-cutting implementation planning teams (see item two below).

In addition, NIH may use a portion of funding to experiment with different approaches to incentivize adoption of an NIH-wide, coordinated approach to technology investments.

2) **Establish Implementation Planning Teams:** Further work is needed to identify the portfolio of capabilities needed, define their relative priority, and propose a sequence of delivery in a comprehensive NIH-wide implementation roadmap. To accomplish this, NIH will establish implementation planning teams for each of the four functional areas and one for overall cross-cutting capabilities. The teams will be responsible for defining and prioritizing high-value capabilities and developing a five-year implementation roadmap for each functional area and the cross-cutting capabilities, within the framework and principles detailed in *Digital NIH*. Within six months, each team should submit a business case and funding request for the first high-priority capability in their portfolio, with anticipation that successful requests will be funded as part of the FY2024 budget cycle, potentially through a new Innovation Fund. Implementation planning teams will work in parallel under the guidance of the Enterprise IT Council (EIT), which serves as NIH's highest-level governance group for technology and information technology strategic matters. The EIT will coordinate implementation activities and will report to NIH leadership through the NIH Steering Committee.

3) **Act on Immediate Cross-Cutting Priorities:** Concurrent with the activities described above, there are two additional areas that require immediate effort to establish high-priority cross-cutting capabilities needed to support all of NIH. Implementation efforts will initially focus on building the foundation of a **common architecture and standards** that can be used across NIH and on establishing **workforce development strategies** to equip NIH's entire workforce with the digital skills necessary to accomplish NIH's mission.

NIH must be bold and leverage the full synergy of all facets of the enterprise, ensuring that the agency is prepared to usher in this new era of science and technology. Implementation of this strategy will position NIH for long-term success and better address current and future technology opportunities and challenges. With an ambitious timeline, stakeholder engagement will be key, and NIH's readiness and willingness to adapt will determine the success of the opportunities presented.

Section 2: New Approaches to Manage and Govern NIH Technology Investments

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If NIH is to achieve the goals outlined in the NIH Strategic Plan and meet optimization and innovation expectations for 21st century science and research management, it must fundamentally change how it thinks about, makes decisions, plans for, invests in, and manages technology resources.

Opportunities to Optimize Technology Investments and Provide More Value

Traditionally, NIH ICs have invested in and implemented their own specific systems, platforms, and information resources consistent with their IC-specific budget, research priorities, and institutional needs. In FY2022, NIH invested approximately $1.7 billion in technology with individual IC investments ranging from $2 million to $200 million annually. The quality and robustness of capabilities within each of the 27 ICs varies widely and encompasses intramural research, extramural research management, and administrative management functions. Some larger ICs have been able to invest in more comprehensive solutions, but most lack modern, end-to-end digital solutions to support critical extramural research management, basic and clinical intramural research, and administrative and management functions.

NIH also supports a relatively small number of cross-NIH technology solutions to supplement ICs' efforts. These include enterprise systems, shared use research and scientific management resources, and NIH-wide computational infrastructure:

- **Shared use research and scientific management data and computational platforms and related services**. Examples include NIH's enterprise cloud platform services (i.e., STRIDES); the high-performance computational center (i.e., Biowulf); the repository of clinical research data (i.e., BTRIS); and high-impact data repositories and information resources supported by the NLM.

- **Administrative or institutional management systems** designed to support common transactional processes and management information and reporting needs. Examples include NIH's financial management and accounting system (i.e., NBS) and the eRA system used to manage extramural research programs.

- **Computational infrastructure and utility services** that benefit NIH through economies of scale. Examples include the NIH Network and commercial collaboration and communication platforms.

These resources are enterprise in nature and are generally governed through NIH-wide management processes. While they provide important support for all ICs, they represent a modest portion of NIH's technology portfolio, and sometimes ICs create similar but redundant solutions to address similar needs. For example, NIH has several enterprise systems to support commonly performed extramural program and administrative management functions. In addition, ICs collectively invest more than $250 million each year on IC-specific systems to address the same types of functions.

Fundamentally New Ways to Prioritize, Fund, and Manage Technology Investments

These traditional approaches are no longer adequate to meet today's computationally intensive research requirements or those that are anticipated in the future. Very few ICs will have sufficient resources to keep pace with the rapid changes in science and technology, and IC-specific solutions will never meet demands for modern, end-to-end solutions that improve staff productivity and organizational effectiveness. Current management processes often create artificial barriers between NIH-wide technology decisions and those at the IC level. This results in significant gaps, overlaps, and redundancies in technological solutions across NIH. In the future, NIH will need to be more focused and strategic in its treatment of technology as a critical resource, adopting new collaborative approaches and agile business models that deliver faster, better, more cost-effective capabilities that benefit all.

Principles to guide new management and governance approaches include:

- **Leadership will play a critical role in advancing new digital strategies** and promoting the important need to manage technology as a mission-critical resource. Given technology's strategic importance to the scientific process and effective institutional management, IC leadership should actively engage in critical technology matters, prioritizing the capabilities needed and engaging the right individuals in technology planning, decision-making, implementation, and oversight processes.

- **New holistic and collaborative planning and prioritization approaches** will assure IC and NIH-level investments complement one another. Priority will be given to innovative, shared solutions that meet common needs, wherever possible. Implementing processes that evaluate shared need will increase utilization of technologies that could benefit multiple ICs. Successful initiatives will align with a robust technology architecture, which will establish data, software, and interoperability standards and promote the use of common platforms. Governance bodies should consider technology investments, including local investments, in terms of the overall value and impact to NIH, while still recognizing and appreciating ICs' unique needs.

- **Technology considerations will be addressed early in the planning** of new programs or management initiatives and the introduction of new or significantly revised policies. NIH invests significant effort to assess and plan for the scientific aspects of a new program, policy, or management initiative. Technology considerations are often an afterthought, placing ICs in a reactive mode as they to struggle to meet new requirements. NIH will be more intentional about how to best use technology at the earliest stages of planning new programs or new initiatives and how it will be sustained over its useful lifecycle.

- **Funding decisions will be enriched by a more comprehensive and realistic understanding of value.** Governance processes will determine that adequate funding is provided for investments that provide broad value and minimize overall institutional risk, even if it is difficult to associate costs or benefits with a specific function or organization (e.g., technology infrastructure). Further, as research has become more computationally intensive, technology investments demand a greater share of research program costs. NIH's current means of understanding, accounting for, and reporting create a false dichotomy between science and technology (i.e., an increase in technology funding is perceived as occurring at the expense of funding for science and research programs). Investment processes will acknowledge and account for technology's role and the value it provides in enabling scientific priorities.

- **A variety of flexible and integrated governance structures will align decision-making processes with the purpose, scope, complexity, and value of the investment**, allowing NIH to be nimble in both planning and execution. For example, funding to deploy new capabilities that affect only one IC or organization should remain under the purview of the IC leadership but are still expected to align with NIH's common architecture and standards. Investments that could bring value to multiple ICs will require more collaborative planning and decision-making and more extensive oversight throughout their lifecycle. In this way, investments with similar characteristics will be evaluated together in a coordinated manner, with a focus on overall value and collective efficiencies.

- **New funding mechanisms will foster innovation and enable agile and timely decision-making.** New funding and new funding mechanisms will incentivize ICs to collaborate on technology initiatives of common interest, accelerate implementation of high-priority, high-value shared solutions, and encourage organizational units to experiment with strategies that could provide value to the broader NIH. For example, NIH may benefit from a digital technology innovation fund, a best practice of organizations that have been successful in digital transformation efforts. Flexible decision-making and funding timelines will be necessary to foster innovation and agility.

- **Adequate funding will address the costs to operate and maintain existing or new investments at healthy levels.** Provision of adequate funding will ensure investments are secure, up-to-date, and continue to meet NIH's needs. Modern approaches to fund and account for predictable capital costs (e.g., replacement of end-of-life equipment, ongoing operation of eRA) will minimize institutional risk and avoid unnecessary delays. Funding decisions regarding routine operations and maintenance activities to support current capabilities will become straight-forward and impose less oversight burden.

- **Responsible governance will continue NIH's commitment to stewardship,** applying the appropriate level of accountability and oversight, given the size and scale of the investment. Governance bodies should identify and take appropriate action to prevent system redundancies and organizational or functional silos, creating a more efficient and mission-driven technology investment strategy.

This strategy requires new ways of working together to optimize current practices and deploy flexible technical solutions to meet common needs, wherever possible. This does not suggest a transition to monolithic, centrally managed systems or capabilities; nor should it limit an IC's ability to meet IC-unique technology needs that should continue to be managed and delivered locally. Success will be more likely if NIH adopts a more systematic approach to identify where ICs have been successful in implementing solutions that provide considerable benefit and then leverage these for the broader NIH. ICs interested in sponsoring a broader NIH-wide effort may want to serve as the lead or "center of excellence" for specific capabilities. Standards for connecting, sharing information, and coordinating actions across platforms will make it easier for staff to work efficiently. This again requires a culture change that may not be easy but is critical to success moving forward. By working together in new, more intentional ways, NIH can be effective and efficient in providing high-priority, high-value capabilities for all.

Section 3: A Framework to Guide Implementation of High-Priority, High-Value Capabilities

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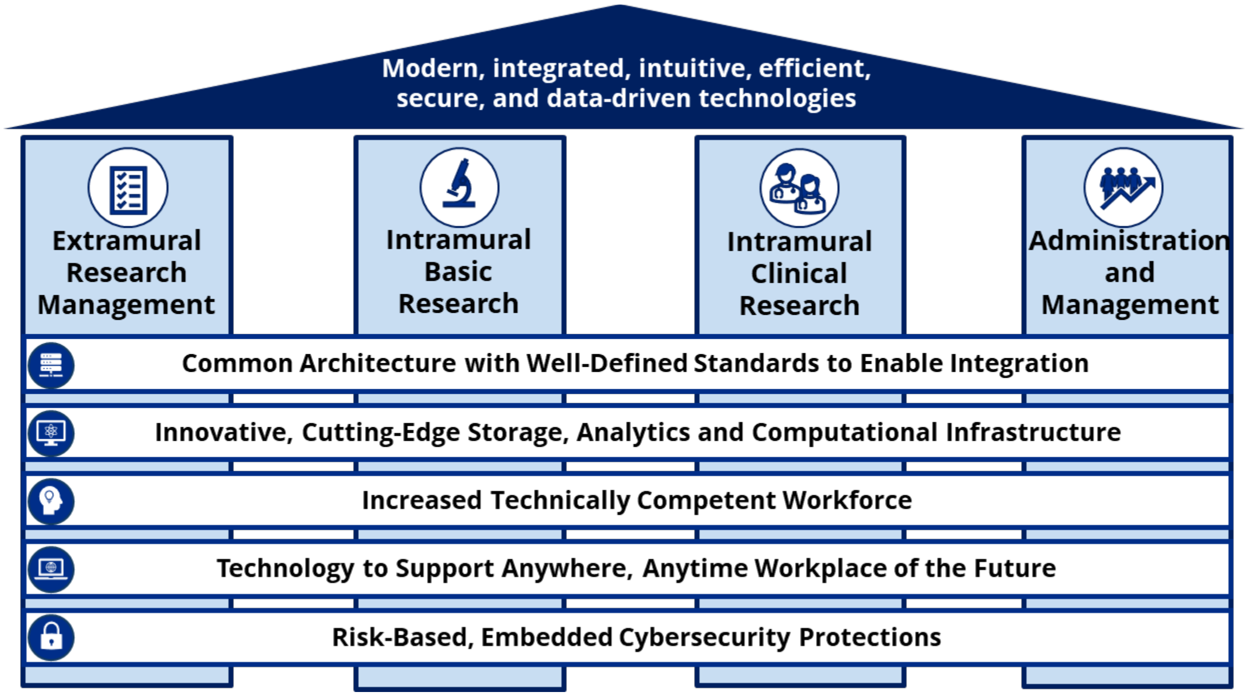
In addition to adopting new approaches to manage and govern technology investments, NIH must define and implement new high-priority, high-value capabilities (i.e., competencies, skills, and activities) necessary to meet current and future mission needs. Over the course of six months, the Committee engaged with more than 400 individuals to identify the capabilities NIH needs over the next five years. Throughout discussions and interviews, NIH staff consistently shared the need for more modern, integrated, intuitive, efficient, secure, and data-driven technologies to support their work, irrespective of the organization or role they represented. They also articulated a future state for NIH and described a broad range of capabilities needed to support the work requirements for four functional areas common to all ICs: Extramural Research Management; Intramural Basic Research; Intramural Clinical Research; and Administration and Management.

The Committee also identified a suite of critical cross-cutting capabilities, which are the foundational resources needed to support all four NIH functional areas and Institutes, Centers, and Offices. For example, NIH will need innovative, cutting-edge storage, analytics, and computational infrastructure that can be used by any entity, and a workforce that has the digital skills necessary to take advantage of more modern technical solutions. Cross-cutting capabilities support the broad needs of the entire NIH and are not unique to a given functional area or individual IC.

The following figure depicts the four functional areas that were the focus of this planning effort, the cross-cutting capabilities, and the interdependence of the two. Further work is needed from NIH experts that are well-versed in each functional area and in the cross-cutting capabilities to refine the information gathered through the strategy development effort. Specifically, NIH experts will need to identify and prioritize the portfolio of specific capabilities needed over the next five years, propose a sequence of delivery, and outline a comprehensive NIH-wide implementation roadmap. This framework can be used to guide the next stage of planning as well as implementation activities for the high-priority, high-value capabilities that are defined in the roadmap. More specific details of the path forward are provided in Section 4: Path Forward.



A Framework to Guide Implementation Planning

Details on each of the functional areas and the cross-cutting capabilities are provided in the following sub-sections.

Functional Areas

The framework is centered around four functional areas that comprise distinct groups of NIH staff with unique technology needs to optimize their work activities in science and research management:

- **Extramural Research Management:** Internal functions to administer, steward, and maintain accountability for NIH's funded research

- **Intramural Basic Research:** Efforts in the Intramural Research Program (IRP) focused on understanding the fundamental biology and molecular mechanisms that characterize life

- **Intramural Clinical Research:** Component of the IRP that includes observational studies and clinical trials involving human subjects

- **Administration and Management:** Functions within NIH that include, but are not limited to, acquisitions, budget and financial management, human resource and workforce management, property inventory, facility management, information technology, risk management, and travel

Extramural Research Management

Extramural research programs today are larger in scale, scope, and complexity than ever before, and the volume of grant applications continues to increase each year. More than 80 percent of NIH's funding is distributed to researchers and research institutions that make up the extramural research community through a rigorous, competitive process that includes more than 25,000 external reviewers. In 2021, NIH received more than 85,000 applications and funded approximately 56,000 new and continuing grants.[2] These grants support more than 300,000 researchers and support staff at all career stages, including more than 43,000 principal investigators at more than 2,500 universities, medical schools, and other research institutions in every state of the United States and around the world.[3] This extramural research enterprise is managed by NIH staff who facilitate and administer scientific programs, consult with scientific experts to inform priority setting, and act as agency experts for specific scientific areas.

The future of the Extramural Research Program at NIH will include cutting-edge, integrated digital platforms to enable portfolio management. ICs should align on common solutions that effectively advance the management of funded research, ensure better compliance, reduce researcher and staff burden, and streamline planning and tracking across the grant lifecycle.

NIH has been a long-standing leader in technology-enabled systems and information resources to support extramural research and grants management activities. eRA processes more than 50 percent of all grant applications submitted to Grants.gov and is used by all ICs as well as other federal agencies, including the Agency for Healthcare Research and Quality (AHRQ), the Centers for Disease Control and Prevention (CDC), the Food and Drug Administration (FDA), the Substance Abuse and Mental Health Services Administration (SAMHSA), Veteran Affairs (VA), and the U.S. Department of Defense (DoD). The Office of Extramural Research sponsors eRA and other technical solutions to provide extramural researchers and NIH extramural staff with the tools they need to administer research. The eRA model has succeeded in providing a common platform to address shared needs, nonetheless some requirements remain unaddressed through eRA. As a result, many ICs have developed IC-specific solutions that address particular needs that have not yet been resolved by eRA. These IC solutions have evolved over time, and processes are often overly complex and use technology platforms that are not extensible or sharable. Investment is

"Our success is dependent on having robust, cutting-edge, modern, evolving, and platforms that enable interactions with internal and external stakeholders, include analytics, and allow for retrievals of information efficiently and quickly."
– Listening Session Participant

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[2] https://nexus.od.nih.gov/all/2022/03/07/fy-2021-by-the-numbers-extramural-grant-investments-in-research/
[3] https://www.nih.gov/about-nih/what-we-do/budget

needed to adequately continue to support eRA so that it can easily meet new IC-driven requirements when they arise and to extend high-value IC-created technical solutions to other ICs. NIH can build on what has worked with eRA, working to improve it to reduce the need for one-off solutions.

The Committee also heard opportunities to improve the management activities to plan and oversee NIH's extramural research program throughout the lifecycle, from program concept development through project close out. Based on this insight, the Committee identified the following examples of future capabilities for the Extramural Research Management functional area that could be implemented under this strategy:

- **Robust, cutting-edge, modern, integrated platforms** allow for comprehensive and holistic portfolio views of applications, peer review, and funded research, making it easy to analyze performance, potential scientific gaps and overlaps across funded research.
- **Technology resources support the implementation of critical policies** such as the Data Management and Sharing Policy, Clinical Trial Registration and Reporting, Peer Review Simplification, Enhanced Public Access, Use of Digital Persistent Identifiers, and Enhanced Oversight of Other Support and Conflicts of Interest / Research Security that enable sharing scientific data and promote data reuse for future research studies.
- **Digital tools support NIH's stewardship responsibilities across a variety of funding mechanisms** that are submitted and received through different systems (e.g., ASSIST, system-to-system). These tools allow NIH to manage and track the award lifecycle, interface with financial systems, assure compliance with applicable laws, regulations, and policies, and share information as appropriate with internal and external stakeholders.
- **Embedded Artificial Intelligence (AI) and Machine Learning (ML) algorithms in systems trigger alerts** on key items such as grant progress, compliance tracking, and assignment of proposals to reviewers. Further, extensive use of robotic process automation (RPA) reduces staff effort on repetitive, structured tasks, increasing quality and productivity.
- **Advanced technologies improve the efficiencies and effectiveness of peer-reviewed processes,** attract a diverse pool of reviewers, and establish a flexible environment that meets the needs of the reviewers.
- **Technical solutions can easily accommodate new needs when they emerge, thus reducing the burden for local development**. Sustained base funding can maintain technology currency and agility to respond to new requirements. This will be critical in an ever-changing technological landscape.

Intramural Basic Research

> **The future of Basic Intramural Research** at NIH will be enabled through access to holistic information on NIH's research portfolio and a suite of tools, applications, and software – such as electronic lab notebooks and data analytics packages. Automation of laboratory processes, along with an increase in computing capabilities, will enable state-of-the-art research approaches.

The pace and scope of NIH's progress in improving health are made possible by decades of NIH-funded basic research within NIH's first-class IRP. The majority of NIH's 1,200 principal investigators, 1,800 staff clinicians and staff scientists, and over 4,000 postdoctoral fellows work to address questions on fundamental biology and the biochemical and electrophysical basis of systems. The majority of NIH ICs have an intramural research effort focused on conducting distinctive laboratory research in their respective health domains.

The IRP's basic research programs generate and rely on large amounts of data that require flexible, scalable storage technologies and are best understood using advanced analytics and computational strategies. Intramural research laboratories are highly dependent on NIH's on-premises and cloud-based computational resources. More than 70 percent of all IRP research groups currently use NIH's general-purpose High-Performance Computing resource, Biowulf, to analyze their research data. However, this important resource was modernized more than five years ago and will require significant investment to sustain over time. Many IRP researchers are using cloud-based computational resources through NIH's STRIDES initiative, and more are expected to transition to the cloud over the next several years.

> ***"NIH labs are now generating data from many of their own instruments. They are collaborating with other labs. They are performing an ever increasing number of genomic sequencing runs. The ability to coordinate, understand, and share all of this information requires a high level of computational power and knowledge."***
> ***– NIH Staff Member***

In the future, image-based data from optical microscopy, functional Magnetic Resonance Imaging, and CryoEM experiments, among others, will require new types of technological support, as NIH manages and unites internet-connected instrumentation. These devices also bring an increased requirement to process petabyte-scale data sets. Further, research projects in machine learning, artificial intelligence, neuroimaging, natural language processing, and long-timescale molecular dynamics are driving a significant need for increased CPU and hybrid GPU/CPU computing power. Both on-premises and cloud-based computational resources are now an integral part of the basic research process.

Investments to support today's computationally intensive science in more cohesive ways will accelerate scientific discovery, better-align government-funded research with private industry investment, foster NIH-wide collaboration, and support public trust in the research findings coming out of the IRP.

During the development of this strategy, the following key areas of opportunity were identified that would advance research performed across the basic intramural research space and enable new areas of scientific inquiry:

- **A portal allows researchers and staff from across Intramural and Extramural programs to easily identify information about current and historical research projects and related data assets, enabling collaboration**, use of high-value data sets, and connection with potential collaborators.
- **Secure electronic lab notebooks optimize laboratory workflows and enable the replication of scientific findings**, capture data from scientific instruments, and enable and facilitate data sharing.
- **Digital lab technologies automate lab workflows**, allow staff to integrate and monitor scientific instrumentation, experiments, and samples remotely and on-premises, and provide common storage and access to lab data.
- **Robust computational resources enable researchers and staff to analyze and efficiently store the massive datasets generated by** technologies like CryoEM, three-dimensional Nuclear Magnetic Resonance, super-resolution light microscopy, and advanced diagnostic imaging, with a particular emphasis on the ability to store and perform advanced analytics on Personally Identifiable Information/Protected Health Information data.
- **A cadre of individuals who have expertise in data science, information technology, cybersecurity, engineering, and related areas** support and guide researchers as they adopt and deploy new lab technologies (e.g., Internet of Things lab devices). Robust educational opportunities are available to all IRP trainees, allowing them to leverage new computational approaches.
- **IRP-wide site licenses for commonly used scientific software** allow researchers to utilize these software packages for free or at discounted rates, something that is especially important for researchers who only have an occasional need for specific software suites.

Intramural Clinical Research

An essential component of the IRP is the Clinical Research Program at NIH. Clinical research is intended to produce knowledge that will advance understanding of human disease, thereby preventing and treating illness and promoting human health. 24 of NIH's 27 ICs conduct intramural clinical research that falls into two broad categories: observational studies and clinical trials. Most

The future of Intramural Clinical Research at NIH will be enabled through integrated, end-to-end platforms for clinical trial management which allow investigators to design, conduct, and manage studies easily and securely. Integrated tools support data sharing and management, as well as streamlined regulatory compliance and reporting.

of this work is conducted at the NIH Clinical Center, the world's largest hospital entirely devoted to clinical research.

About 1,600 IC-supported clinical research studies are in progress at the NIH Clinical Center at any given time. NIH clinical researchers and support staff use the NIH Clinical Center's suite of systems; these include the electronic medical record system (i.e., CRIS), and an NIH-wide clinical data warehouse (i.e., BTRIS). A significant number of ICs have IC-specific systems and tools to support clinical research activities. Currently, over 130 systems and applications support intramural clinical research at NIH. Further, clinical research is highly regulated and has significant oversight and reporting requirements.

The NIH Office of Intramural Research recently initiated an NIH-wide clinical research technology planning effort – the Clinical Research Informatics Strategic Planning Initiative (CRISPI). In collaboration with the CRISPI initiative, the Committee identified additional capabilities unique to the clinical research program and will address existing technological gaps in the clinical research and data management lifecycles:

- **A portal or central site that provides access to a robust set of information resources, tools, and job aides** (i.e., that allow tracking of research documents and work processes) to guide and support clinicians, fellows, trainees, and staff throughout the clinical research lifecycle, thereby facilitating comprehensive data management, regulatory compliance and reporting, and workflow management.
- **Common platforms and a suite of technologies allow for integrated end-to-end clinical trial management.** These technologies help clinicians track, manage, and report on participant enrollment, manage clinical trials, support research administration, communicate clinical trial status, meet regulatory compliance and reporting requirements – and, most importantly, share information across the Clinical Center, between ICs, and with external stakeholders. Dashboards allow clinicians to easily manage and track key metadata and relevant status information on all protocols in their research portfolio. Clinicians can easily locate and access data related to current and historical clinical trials conducted by all ICs to help generate new hypotheses, refine protocol planning, and assist in patient enrollment.
- **Increased computing power and improved data storage infrastructure support the collection, integration, and analysis of complex clinical data sets**, such as participant-reported data and dense imaging and sequencing data. Any such system also facilitates the linking of internal and external data collected through major electronic health record systems. Common platforms and tools supporting data collection and workflows related to participant informed consent processes are accessible to all programs, with appropriate privacy and security protections and controls. Common approaches and digital technologies are available to support the de-identification and curation of electronic health record and controlled access data.
- **A common, easy-to-customize clinical research information system supports FHIR®-compliant data harmonization, data sharing, and participant identity management** in a manner that affords project-specific flexibilities while reducing the demand for IC-

specific data repositories. Standard protocols and interoperable application programming interfaces (APIs) allow streamlined submission and access to program- or IC-specific data.

- **Implementation of innovative communication technologies allow researchers to connect with study subjects no matter where they reside** through secure channels and telehealth platforms for virtual engagement. Researchers can collect clinical data remotely and in real time, including via wearables and virtually connected vitals.
- **Patient-focused tools and platforms reflect patient voice and outcomes and enhance patient diversity** to ensure patient-reported needs and outcomes are represented at the core of clinical research work at NIH.

Administration and Management

The future of Administration and Management at NIH will be enabled through common platforms that can be tailored to specific IC and OD needs and optimize business processes. Automation and digitization will reduce manual administrative workflows and processes.

NIH administrative and management functions include but are not limited to acquisitions, budget and financial management, human resources and workforce management, property inventory and facility management, information technology, risk management, and travel. These functions are subject to extensive legislative mandates, government-wide guidance, the U.S. Department of Health and Human Services policies, and significant oversight and reporting requirements. NIH has invested in several NIH-wide systems to support aspects of these functions over the years, the most significant being NIH's financial system. However, many operations are supported by smaller, legacy applications that were highly tailored to automate paper-based processes.

ICs invest significantly in automated technologies to support their local administrative and management functions but there is considerable disparity across the ICs in terms of the types of technologies they can access, and efforts to share or extend technologies are typically ad hoc. Programs across NIH should be supported in their efforts to innovate in a manner that enables integration of their solutions with NIH-wide investments at the appropriate time. There are many opportunities to improve administration and management functions for all ICs by working collaboratively to optimize workflows and information needs, and adopt standard technologies and tools to meet common process and information needs. An example of a successful implementation is the ECM program, which is based on a standard commercial technology platform, with an NIH-wide product license discount and a dedicated team to deploy high priority documents and workflow management solutions for all ICs. While noting the success, opportunities exist to continue improving solutions for the administration and management functions.

Moving forward, NIH must invest in data-rich, integrated, easy-to-use systems, applications, and tools to help staff efficiently administer science and conduct enabling functions that advance NIH's mission. Modernizing tools and technologies for administrative and management processes will reduce burden and manual processes, generate efficiencies, and provide consistent platforms for common administrative actions, which benefits the entire enterprise.

The Committee identified key capabilities to support digital transformation for administration and management at NIH, including:

- **Common management platforms are available for NIH-wide use and are tailorable** if ICs have unique needs. This includes scaling best-in-class solutions currently in use in individual ICs. Additionally, a wide-spread deployment of Internet-of-Things services that automate building and laboratory management functions support ICs' efforts to monitor processes such as inventory management, air filtration, and safety and building security, among others.
- **A common suite of analytic, reporting, and visualization tools, software, and applications provides easier access to the data and better means to interpret them,** informing data-driven decision-making on mission-critical topics.
- **Routine optimization of business processes for administrative functions** supports efficiency and integration into NIH-wide administrative interfaces. The efficient operation of business requires automation be applied to an optimized business process.
- **Greater automation and digitization enhance the accuracy and efficiency of administrative workflows.** Where possible, robotic process automation, AI, and digitization reduce manual and paper-based administrative and management functions.
- **NIH-wide information platforms and IC-specific platforms are supported by well-defined, common data architecture and access to updated information**. Standard protocols to submit or access data are widely used to reduce data duplication and inconsistencies across administrative and management systems.
- **Embedded learning in NIH-wide administrative systems and tools refreshes knowledge for users** who have not accessed the platform in a while. Guidance, tool tips, and reminders help users reacclimate to platforms or tools that require infrequent interaction.

"Local development is important, and there is a need to incorporate [those solutions] into the enterprise, but we don't know what's out there. It would be helpful to know what everyone is working on, so we don't have to re-invent the wheel."
– Listening Session Participant

Cross-Cutting Capabilities

The Committee synthesized needs and themes from the functional areas and identified five cross-cutting capabilities to enable the digital efforts within the functional areas while reducing redundancy. These capabilities are foundational resources designed to enable functional area capabilities. They set standards for system interoperability and build core, modern technical solutions for all of NIH and enhance NIH's capacity to leverage new types of technology and tools to support agile and flexible collaboration to meet the needs of emerging issues.

The cross-cutting capabilities enumerated below emerged both from common needs shared in NIH Stakeholder Sessions and from the practices of leading organizations. The Committee conducted benchmarking sessions with technology experts and organizational leaders across a variety of industries and sectors. They heard many leading organizations are investing in 1) integration and reusability of technology, 2) hybrid (cloud and on-premises) computational infrastructure, 3) workforce skill development, 4) technologies for greater collaboration—in-person and virtually, and 5) cybersecurity protections.

Solutions afforded by cross-cutting capabilities can be implemented at a laboratory, an IC, by two or more ICs, or at the NIH-wide level. The capabilities defined in this framework are NIH-wide in nature, meaning they are available for all NIH ICs and OD.

Common Architecture with Well-Defined Standards to Enable Integration

An NIH common architecture and parsimonious standards will provide guidance for how technology is built or acquired and will outline how different technologies interact, connect, or expand upon each other. This common foundation will support modular technical solutions, allowing ICs to easily scale and connect systems to accelerate information integration, data sharing, and efficient business and scientific practices. Governance processes will assure that new investments adopt and align with NIH's common architecture and standards, enabling ICs to acquire and build technology solutions that are sharable, interoperable, and sustainable.

> **Common Architecture and Standards** will be guided by an agreed upon set of uniform rules, platforms, technologies that will be adopted and used in a consistent way across NIH when ICs or the enterprise makes decisions on technology infrastructure. This will support efficiency and enable sharing and cross-IC adoption of technologies.

During the development of this strategy, common architecture and standards were defined to include the following examples:

- **A set of commonly identified platforms and tools along with defined software application standards** guide and align NIH-wide and IC-specific technology decisions on resources that can interact, integrate, and build upon each other.
- **Data design principles and best practices** on data models, metadata standards, and application methods and standards make it easier to access and exchange data (e.g., APIs and microservices).

- **Minimum operating standards for networks, hardware, identity management, operating systems, and end-user devices and tools** support greater compatibility and reduce the need for workarounds and exceptions.
- **Protocols and standards for database infrastructure enable the secure transit of research and operational data**, complementing the NIH Strategic Plan for Data Science.
- **Standardized principles establish parameters for technology platforms** that address common scientific or management needs (e.g., advanced AI/ML, content management, workflows).**A common approach for securing Personally Identifiable Information (PII)** that reduces the administrative burden on staff and provides a level of trust and transparency for those whose information we collect.

Innovative, Cutting-Edge Storage, Analytics, and Computational Infrastructure

Over the past five years, NIH has made significant advances in data acquisition and preservation, now housing the Sequence Read Archive—the largest federal data set freely available to the public through commercial cloud operations. Managing and exploiting these types of valuable biomedical data stores requires embracing innovative and cutting-edge analytics and computational infrastructure. The existing model common across NIH requires downloading large data sets to local compute environments, but this approach does not scale to the scope of data now available for discovery. Current scientific exploration that leverages large datasets, such as those from population-based studies and increasing resolution in structural biology require more facile data access, analysis, and sharing.

> **Computational Infrastructure** will include state-of-the-market computational infrastructure, including on-premises and cloud computational resources, along with a wide breadth of robust digital and analytical capabilities. Staff will be able to access the right computational tools – including storage, analytics, and processing power – for their needs while ensuring interoperability.

With the implementation of a robust computational infrastructure, investigators will have easy access to relevant data and data services to support research. Smart, intuitive interfaces will guide investigators to ML and AI analytic tools that enable them to interrogate complex data sets for new scientific insights.

During the development of this strategy, this capability was defined to include the following examples:

- **Investigator-inspired, human-centered design strategies display easy-to-access analytical tools,** with in-the-moment guidance that translates investigators' questions into trustable analytical models.
- **NIH-wide digital infrastructure is accessible, driven by data standards and shared data models across the enterprise that allow local tailoring to securely present data for specific research needs.** Researchers can link NIH data sets to external data sets, extract

the full value out of research data through NIH-wide platforms, and use robust tools for advanced analytics and visualization. The NIH network is robust and flexible to meet high performance requirements associated with petabyte-scale data resources.

- **Democratized access to state-of-the-market computational infrastructure allows NIH researchers to select and use the compute, storage, and analytical services that best meet their needs.** This includes both on-premises high-performance computing, including Biowulf, and growing cloud computing with efforts like the STRIDES initiative. Maintenance and modernization occur over time and as scientific methods and approaches evolve, technologies mature, and technology business models change.
- **Critical technologies and middleware applications support secure, role-based authentication and authorization.** Investigators whose programs transcend two or more ICs have seamless, secure pathways for transferring data from one IC to another.
- **Engagement with industry and academic partners promotes NIH access to emerging trends and cutting-edge technologies** relevant to NIH research needs. There is support for continuous learning and experimentation in next generation technologies (e.g., quantum computing).

Increased Technically Competent Workforce

From facilities staff using automated systems to monitor space utilization to researchers needing the competencies to process dense data sets, all members of NIH's workforce need greater digital proficiency. Current modes of training and support which include efforts from the Office of Data Science Strategy and the NIH Library should be augmented with new approaches that also ensure reach to every part of the NIH and diversification of the technical competent workforce. A technically competent workforce means all NIH staff have the digital skills and technology support required to conduct their assigned duties. NIH must also invest in recruiting and retaining internal experts who are well-equipped to scan the environment for technological innovations that will benefit NIH and are adept at using those innovations to advance NIH. Without a workforce composed of specialized talent—attracted and retained by creative hiring and management approaches—NIH will be in a constant state of "catch up".

> **A Technically Competent Workforce** will mean all staff have the necessary technical skills to efficiently accomplish their day-to-day work. NIH will take advantage of the right number of specialized staff with technical expertise, optimizing recruiting and retainment practices across the enterprise.

During the development of this strategy, the capability was defined to include the following examples:

- **All staff members have a baseline level of technical skills needed for their role and the type of work they perform.** All staff have opportunities to continually refresh and advance their digital competencies to keep up with the market and grow within the organization as new technology emerges.

- **A cadre of skilled technologists (e.g., a technology consultancy with highly adept technologists) is available** for consultation on IC-specific and NIH-wide projects that require special skillsets. The intention of this cadre is to not only provide support, but to engage the technical staff that have a desire to share their expertise more broadly.
- **Access to just-in-time coaching and training** for investigators, scientists, research support staff, and trainees provides tailored guidance and supports work as research processes become intertwined with cyber infrastructure.
- **Hiring processes fully leverage flexibilities to grow NIH's specialized IT workforce.** NIH increases the number of staff with expertise in cybersecurity, cloud architecture, data engineering, system integration, automation, network management, and scientific computing, to design, build, and utilize a modernized infrastructure.
- **Recruitment, training, and retention efforts exist to sustain a Digital Services-certified acquisition workforce.** This enables NIH to contract for needed technology expertise. Developing NIH staff with specialized technology acquisition skills and knowledge is critical since technology acquisition is heavily regulated.

Technology to Support Anywhere, Anytime Workplace of the Future

Technologies to Support the Workplace of the Future will allow for a flexible working environment that meets the needs of NIH staff wherever they are working and will include a robust and secure network infrastructure, access and authentication processes, and best-in-class remote collaboration and instrumentation tools.

The COVID-19 pandemic demonstrated that many NIH operations could be conducted remotely, although it also highlighted the need for better technologies to support virtual collaboration. NIH anticipates a transformed future of work, with the need to blend remote and in-person work. Supporting the workplace of the future means NIH provides all staff with secure access to information, data, tools, and platforms to support working productively from anywhere. The future NIH will be boundary-less, with mobile devices and computers using robust, secure information networks allowing staff to reach back into NIH's campus, connect with colleagues, or access relevant data sources. NIH will be able to leverage new types of technology and effective tools for supporting collaboration across the enterprise to advance its mission in an agile, flexible manner.

During the development of this strategy, this capability was defined to include the following examples:

- **Secure remote access to systems and information**, with improvements to authentication capabilities and enhancements to network bandwidth, allows staff to connect from multiple locations. To support the increasing demands for remote work, NIH continuously evaluates corresponding needs in network infrastructure, electricity, and facilities.

- **Continuous evaluation and judicious adoption of best-in-class solutions leveraging domestic and global solutions enable blended in-person and remote work environments** through a suite of solutions for hybrid meetings and collaboration. Accompanying guidance on the applications and use cases for these technologies educate staff on how to work together effectively, regardless of where they are located.
- **Digital tools available to all NIH staff are aligned with end-user needs,** account for the different abilities of all members of NIH's community and are based on usability assessments which incorporate consideration of Diversity, Equity, Inclusion, and Accessibility concerns.
- **Tools supporting virtual labs and remote science meet the needs of researchers** and advance the ability to track progress in on-premises environments while being off-site. Tools for remote monitoring and automated information collection integrate with existing applications to help staff continue operations securely, even from locations outside of NIH's campus.

NIH held more than 4.1 million virtual meetings with more than 17 million participants in FY21 and FY22, relying on NIH-wide digital meeting platforms.
– Center for Information Technology Data

Risk-Based, Embedded Cybersecurity Protections

Cybersecurity Protections will assure the integrity and quality of research data is upheld. Through common architecture and standards, NIH's innovative technologies and significant investments are optimized to be more effective in protecting resources in an increasingly sophisticated threat landscape.

NIH is committed to protecting high-value data and information resources and has made cybersecurity a high priority across the ICs. Cyberattacks have become common across the government and the health care system at large, amplifying the need for cybersecurity systems and practices to combat threats. NIH needs a proactive, risk-based approach where embedded cybersecurity protections are balanced to the level of protection needed given the nature of the asset or information. NIH should implement a security by design approach that inserts security in all technology products, services, processes (e.g., predictive analytics and ML for threat detection), and staff behaviors (e.g., training). As new technologies become integrated into the research infrastructure at NIH, security expands from a perimeter-protection process to an essential function of every device, computer, and imaging machine. Innovative technologies designed to anticipate, prevent, and address cybersecurity issues will be critical to protect the integrity of biomedical and health research and comply with regulations. By adopting more enterprise-level approaches and common security architecture and standards, NIH can optimize significant investments and be more effective in protecting resources in an increasingly sophisticated threat landscape.

During the development of this strategy, this capability was defined to include the following examples:

- **Modernized and innovative technologies, systems, and platforms learn from and stay ahead of cybersecurity challenges and attacks** with ML and AI integrated to provide early alert of security risks.
- **NIH efficiently generates clear guidance on how to apply externally-mandated security standards** through policy interpretation, making it easy for ICs to understand what controls they need to apply.
- **Risk-based cybersecurity practices are in place to minimize operational burdens,** and they are balanced with the associated level of risk, applying the right level of protection for each situation.
- **Security systems do not interfere with the process of work.** NIH staff have easy-to-use approval processes that support effective and timely requests, and cybersecurity personnel review and adjudicate quickly.
- **A continuous quality improvement model guides NIH security approaches.** Continuous exploration of new technology solutions and approaches (e.g., Supply Chain Security, Zero Trust Architecture) keep NIH at the forefront of cybersecurity in both industry and federal landscapes.

Section 4: Path Forward

Section 4: Path Forward

This document represents NIH's composite ambition for the future of NIH with a five-year time horizon. Key to the success of this strategy is the recognition that NIH requires new ways of doing business and, most importantly, new approaches to sustaining a scientific enterprise that is driven and empowered through technology. This requires a culture change that may not be easy but will be critical to success moving forward.

As with any significant organizational change effort, it is paramount that NIH senior leadership endorse and commit to the principles and recommendations described in *Digital NIH*. The NIH Steering Committee, NIH's highest governance body, must consistently and actively engage in the necessary efforts to enhance legacy operational models; functions, processes, and outcomes; and governance and decision-making. It is important that the NIH Steering Committee serve as both a champion for these efforts as well as a resource for IC leadership. It will be critical to maintain open and regular communication with many levels of NIH leadership including a small group of advisors to specifically comment on the process.

In addition, three initial activities must be accomplished during the **first year of implementation** of this strategy:

1) **Adopt a New, More Strategic Approach to Technology Funding and Governance.** NIH leaders will endorse and champion a new, more enterprise-savvy approach to technology governance and decision-making, including considering the creation of a new Innovation Fund to facilitate implementation and adoption of modern, high-priority, high-value capabilities in a way that maximizes benefit to all of NIH.

2) **Establish Implementation Planning Teams.** Further work is needed from NIH experts to identify the portfolio of capabilities needed, define their relative priority, and propose a sequence of delivery in a comprehensive NIH-wide implementation roadmap. Implementation planning teams will be responsible for defining and prioritizing high-priority capabilities and developing an implementation roadmap for each functional area and for the cross-cutting capabilities needed to support all of NIH.

3) **Act on Immediate Cross-Cutting Priorities.** Implementation efforts will initially focus on building the foundation of a common architecture and standards that can be used across NIH and on establishing workforce development strategies to assure NIH's entire workforce has the digital skills necessary to accomplish NIH's mission.

More detail on these activities is provided in the following paragraphs.

Adopt a New, More Strategic Approach to Technology Funding and Governance

NIH leadership must capitalize on the readiness for change that was echoed loudly and consistently by NIH staff and NIH leadership throughout this planning effort and at the agency leadership retreat. The scientific, technical, and administrative staff across NIH expressed an urgency for collaborative planning and rationalized investments where the totality of technological expenditures benefits the institution as a whole and advances NIH's mission. In response, and to enable the implementation of this strategy it is imperative that NIH leadership endorse the recommendations from *Digital NIH* with their own IC leadership teams and staff.

To be successful, NIH must be more intentional as it balances IC autonomy with NIH-wide coordinated action. This includes devising new ways to make decisions about technology investments in a manner that is equitable across the ICs, avoids unnecessary redundancies, is more nimble and adaptable, and is much less cumbersome and time-consuming than present approaches. NIH needs an approach that addresses all technology investments, including those that are centrally funded, and does away with the current requirement for each request to be reviewed by up to seven separate NIH-level governance groups, following processes that take up to a year for decision-making. NIH is initiating a review of the overall processes for the centrally funded activities and services, the results of which will help inform and shape activities moving forward.

NIH must recognize the imminent need to change from the current multi-committee, year-long process, which addresses only a small part of the technology expenditures, to one that encompasses coordination of all significant technology investments, including those of the ICs. This will require better ways to share information about existing capabilities across NIH and greater transparency and insight into IC - and NIH-level plans for new technology investments. As a result, funding decisions will be enriched by a more comprehensive understanding of the value and impact of new investments for individual ICs as well as for NIH. The level of review and deliberation should align with the purpose, scope, value, and risk of the investments. Additional consideration must be given to assure that proper governance committee(s) employ a light-weight scheme of checks and balances on investments made by individual ICs to ensure accountability towards NIH-wide benefit and goals. As noted earlier, this does not suggest a transition to monolithic, centrally managed systems or technologies; nor should it limit an IC's ability to meet IC-unique technology needs that should continue to be managed and delivered locally.

To experiment with and facilitate adoption and use of these new approaches, NIH should consider creating a multi-year Innovation Fund, which will allow NIH to expeditiously fund investments to deliver high-priority, high-value capabilities identified by the functional area and cross-cutting implementation planning teams. In addition, NIH may use a portion of funding to experiment with different approaches to incentivize adoption of a NIH-wide, coordinated approach to technology investments. This dedicated fund will initially be proposed for a five-year life. Preference would be given to investments that support innovations that could be shared across multiple ICs, or to provide funds to support the generalization of an IC-specific solution to the entire NIH.

Establish Implementation Planning Teams

In addition to adopting new approaches to manage and govern technology investments, NIH must define and implement new high-priority, high-value capabilities (i.e., competencies, skills, and activities) necessary to meet current and future mission needs. Throughout the planning effort, NIH staff consistently identified a need for modern, integrated, intuitive, efficient, secure, and data-driven technologies to perform their work, irrespective of their role or the organization they supported. They articulated a future state for NIH and identified a broad range of capabilities needed to support the work requirements of four functional areas common to all ICs. The next stage of implementation planning requires a collaborative effort with broad representation across NIH.

As a first priority, implementation planning teams comprised of NIH leaders and experts from the ICs and Office of the Director must be established. Implementation planning teams will work in parallel under the guidance of the EIT, which serves as NIH's highest-level governance group for technology and information technology strategic matters. These teams will be tasked with defining and prioritizing the specific capabilities needed over the next five years and developing a roadmap for implementation for their respective areas. Initially, the five implementation planning teams will be:

1) Extramural Research Management Implementation Team
2) Intramural Basic Research Implementation Team
3) Intramural Clinical Research Implementation Team
4) Administration and Management Implementation Team
5) Cross-Cutting Capabilities Implementation Team

Team members must have relevant knowledge and experience to define and prioritize the high-value capabilities needed over the next five years, within the framework and principles detailed in *Digital NIH*. Team members will also serve as strategy change agents within their organizations and across their functional areas, and promote the ethical applications of the selected technical solutions throughout the organization. The EIT will coordinate implementation, report annually to NIH leadership through the NIH Steering Committee, and provide briefings, as relevant, to the Office of Data Science and Strategy, the Scientific Data Council, and the Data Science Policy Council.

Each implementation planning team will be tasked with completing the following activities:

- **First 120 days:** Define the portfolio of high-priority capabilities needed to support NIH over the next five years. Team members will need to assess the current state of their respective area, identify current significant technology solutions and/or gaps that necessitate new acquisition or development activities, and define the purpose, scope, and value of new capabilities. Teams should place a priority on identifying IC-specific or NIH-wide technologies that, with modifications, could benefit all or the majority of NIH. Teams should also align activities and recommendations of other ongoing planning efforts relevant to this work (e.g., CRISPI and the NIH Strategic Plan for Data Science).

- **First 180 days:** Develop a cohesive implementation plan and roadmap that includes an overview of capabilities, recommended implementation timeframes, identification of pre-requisite activities or dependencies with other efforts, and rough order of magnitude cost analysis for full implementation. Implementation plans must also address the change management necessary for adoption and use across NIH.

- **First six months:** Submit a business case and funding request for the first high-priority capability in their portfolio, with anticipation that successful requests will be funded in FY 2024, potentially through the new Innovation Fund.

- **Over the next five years:** Iteratively refine and deliver capabilities, adjusting the roadmap based on shifts in NIH priorities and advances in technologies.

Act on Immediate Cross-Cutting Priorities

In addition to the actions described above, there are two areas that require immediate effort to establish high priority cross-cutting capabilities needed to support all of NIH. The Cross-Cutting Capabilities Implementation Team should work with relevant offices to act on the following:

- **Define Standards and a Common Architecture:** To improve NIH-wide interoperability and collaboration, primary efforts will focus on developing common architecture and standards for NIH to guide the functionality, organization, implementation of technological infrastructure.

- **Establish Workforce Technology Competency:** To support enhancement to workforce competency, the team will identify digital competency gaps for both general NIH staff and specialized technology staff and develop training curricula.

Implementation of this strategy will position NIH for long-term success and help the enterprise better address current and future IT challenges and opportunities. With an ambitious timeline, stakeholder engagement will be key, and the enterprise's readiness and willingness to adapt will determine the success of the opportunities presented. By working together in new, more intentional ways, NIH can be more effective and efficient in providing high-priority, high-value capabilities for all.

Appendices

Appendix A: Acknowledgements

NIH would like to acknowledge the outstanding work of the Committee Members and Subject-Matter Experts (SMEs) who led the development of this strategy (listed below) and the over 400 NIH staff members and experts from 19 leading public and private sector organizations who contributed their insights and expertise throughout this planning effort (see details on the groups in Appendix E).

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*Former NIH employee

Appendix B: Overview of NIH

NIH is an operating division of HHS and is responsible for carrying out the Department's goal of advancing scientific knowledge and innovation. NIH is the foremost agency for funding biomedical research in the United States, with a mission to seek fundamental knowledge about the nature and behavior of living systems and to use that knowledge to enhance health, lengthen life, and reduce illness and disability. To fulfill this mission, NIH supports innovative research with a long-term goal of protecting and improving human health; trains the biomedical research workforce and develops scientific infrastructure; contributes to the nation's economic growth by expanding the biomedical knowledge base; and promotes integrity, public accountability, and societal responsibility in scientific research.

NIH is made up of 27 ICs and OD. Each IC has its own mission and research priorities focused on specific diseases, body systems, life stages, or fields of science. More than 80 percent of annual funding, appropriated by the U.S. Congress, is passed on to researchers and research institutions across the country—the extramural research community—through a rigorous, competitive process, while the remaining 20 percent facilitates the intramural research mission—research conducted by scientists in NIH's own laboratories. Housed within the intramural programs of the ICs, and subject to an equally rigorous review, are resources that provide essential scientific support services to NIH; many of these are broadly used nationally and internationally, including the Vaccine Research Center, the Clinical Center, the Biowulf computation platform, and the scientific data resources of the NLM, including PubMed, PubMed Central, GenBank, the Sequence Read Archive and the ClinicialTrials.gov repository.

Appendix C: NIH's Current Technology Landscape

NIH has a significant technology landscape in place to support its broad mission, reflecting many years of continuous investment in the equipment, systems, and platforms needed to support research across more than 100 labs and a broad range of science and institutional management functions. In FY22, NIH invested $1.7 billion in computational infrastructure, systems, platforms, and tools to support the mission across extramural research management, intramural research – both basic and clinical – and administrative and management functions.

The majority of NIH's technology resources and assets are planned, acquired, managed, and operated by the ICs. A relatively small portion are enterprise-wide systems, capabilities, and enabling technology infrastructure, and typically managed and operated by OD or the Center for Information Technology (CIT). NIH supports its research mission with a technology portfolio that enables mission support areas and a distributed, computational infrastructure; examples of the technologies in place include the following:

- **Extramural Research Management Technologies.** Support the strategic planning of NIH's extramural scientific research agenda; support the pre-award application and peer review process; support and enable the analysis and reporting of NIH's research portfolio, typically by coding or otherwise identifying biomedical areas of research; and manage the allocation and tracking of funds. eRA is the largest system in this area.

- **Intramural Research Management Technologies.** Support the overall administration, management, and oversight of IRP; systems that manage high-level information about the IRP, its scientists, and resources allocated to supporting the program; systems that support the operations of an NIH lab; and investments in systems that support the care and management of non-human research subjects. This also includes clinical trials and management systems and the systems within the NIH Clinical Center that capture, store, and process clinical data and interface with medical instruments.

- **Administration and Management Technologies.** Support general administrative and institutional management functions such as human resources, acquisitions, logistics and operations management, financial management, and property management. One example is NIH's Facility Network Services (FACnet), which provides protected network connectivity for utilities monitoring, physical security, and environmental systems support. Some examples of FACnet end systems include monitoring refrigeration for scientific labs and providing tracking and approval support for facilities badge access.

- **Cross-Functional Technologies.** Support the above functional areas with systems and tools that enable service delivery, collaboration, and data sharing and analysis. These represent a diverse range of investments focused on collecting, curating, analyzing, and sharing data, including biomedical research data. These technologies also include tools that provide data analysis capabilities and support knowledge dissemination, including research publication.

Appendix D: Glossary of NIH-Wide Systems and Technical Terms

Term	Definition
AI	Artificial Intelligence: The power of a machine to copy intelligent human behavior.
ASSIST	Application Submission System and Interface for Submission Tracking: NIH's online system for the preparation, submission and tracking of grant applications through Grants.gov to NIH.
Biowulf	NIH's general-purpose high-performance computing resource (i.e., supercomputer), used exclusively by IRP staff to meet computationally intensive research needs spanning all ICs and research domains. Biowulf is an example of how NIH decided to invest and provide NIH-wide high-performance computing across the IRP, rather than each IC operating their own clusters. Two-thirds of 1,200 Principal Investigators' research programs actively use Biowulf to advance their research studies. Biowulf is the

Term	Definition
	largest supercomputer in the world solely dedicated to advancing biomedical research.
BTRIS	Biomedical Translational Research Information System: A resource available to the NIH intramural community that brings together clinical research data from the Clinical Center and other NIH institutes and centers. BTRIS provides clinical investigators with access to identifiable data for subjects on their own active protocols, while providing all NIH investigators with access to data without personal identifiers across all protocols.
CPU	Central Processing Unit: The processing component of a computer system that performs the system's basic operations (such as processing data), exchanges data with the system's memory and peripherals, and manages the system's components. Most modern CPUs run on integrated circuit microprocessors, with one or more CPUs on a single chip.
CRIS	Clinical Research Information System: The electronic medical record system for patients of the NIH Clinical Center. It supports clinical care, collects data for research, and supports hospital operations.
CRISPR	Clustered regularly interspaced short palindromic repeats: A technology used by research scientists to selectively modify DNA.
CryoEM	Cryo-electron Microscopy: A cryomicroscopy technique applied on samples cooled to cryogenic temperatures. CryoEM is used to study the 3D structure of cells, viruses, and protein assemblies at molecular resolution.
ECM	Enterprise Content Management Program: A program established to help automate and standardize common business and administrative needs across NIH and serves over 18,000 NIH staff. In partnering with NIAID, the program leveraged the OpenText Content Suite to establish a Software-as-a-Service (SaaS) approach to efficiently roll out workflow solutions that support nearly every employee at NIH. ECM is an example of NIH leveraging an IC-specific investment to establish an NIH-wide common platform for content management/workflow needs. ECM provides an easy way to extend applications that have been

Term	Definition
	developed to meet common business and administrative needs that all ICs can use.
eRA	Electronic Research Administration System: The largest federal grants management system, accounting for over 50 percent of the federal grant applications received by Grants.gov. It manages $39.6 billion in research and non-research grants awarded annually, efficiently awarding and managing grants with a secure suite of systems. eRA is an example of a strategic decision by NIH to develop a shared set of digital capabilities to meet common IC needs, delivering far more advanced capabilities than any single IC could provide and ensuring greater efficiencies and cost savings. Additionally, eRA is recognized as an experienced service provider, supporting NIH and various other agencies, including AHRQ, CDC, FDA, SAMHSA, VA, and DoD. eRA is considered one of HHS's High-Value IT Assets and is aligning itself with the goals of HHS's Quality Services Management Office (QSMO) of improving grants management.
FHIR®	Fast Healthcare Interoperability Resources: A standard that defines how health care information can be exchanged between different computer systems regardless of how it is stored in those systems.
GPU	Graphics Processing Unit: A specialized computer processing component designed for rapid and powerful graphics and image processing, including 3D images, animation, and video.
Grants.gov	A portal website to an associated information system that allows users to find and apply for federal grants.
ML	Machine Learning: A field of computer science that gives computers the ability to learn without being explicitly programmed by humans.
Robotic Process Automation (RPA)	Robotic Process Automation (RPA): Term used for software tools that partially or fully automate human activities that are manual, rule-based, and repetitive.
STRIDES	Science and Technology Research Infrastructure for Discovery, Experimentation, and Sustainability: An initiative to develop innovative partnerships with commercial cloud platform providers, allowing deep discounts to both NIH-funded

Term	Definition
	extramural research institutions and researchers and NIH intramural researchers. These partnerships are enabling NIH to make high-value datasets more accessible to researchers, which helps to optimize technology-intensive research and lower the technical, administrative, and economic barriers for researchers. To date, more than 1,000 research institutions and research programs have moved more than 200 petabytes of research data to the cloud; researchers have used more than 200 million hours of computational cycles; and more than 4,000 researchers have been trained in the use of cloud to support their research. STRIDES is an example of how NIH leveraged new partnerships and innovative approaches to reduce the barriers for adopting the cloud for all researchers; it would not have been possible without NIH-wide effort and collaboration.

Appendix E: Methodology for Developing this Strategy

To develop this strategy, NIH conducted a series of data gathering and analysis activities to better understand the institution's current state, define its future capabilities, and assess gaps and opportunities. A broad array of NIH stakeholder groups was engaged to inform the current state and define future priorities through discussions categorized as Listening or Foundational sessions. External organizations were interviewed by conducting Benchmarking sessions to discern best practices and high-priority technology capabilities to inform NIH's focus in the coming years. The data collected across all three types of sessions were synthesized to identify drivers and challenges in the current and future state of NIH and its IT landscape, and to develop a preliminary list of capabilities. The Co-Chairs, Committee members, and other SMEs across NIH reviewed the list and provided input, which helped categorize the capabilities by high-level themes.

This approach included a highly collaborative, iterative process, inclusive of groups and stakeholders across the NIH community. The Committee was formed to help identify technology capabilities and is composed of 48 leaders and SMEs from across the enterprise. Through 46 internal and external information-gathering sessions, NIH shared insights and identified key drivers that affect NIH's technology needs, desired capabilities, and associated governance considerations.

Monthly Committee Meetings

The Co-Chairs and Committee met monthly throughout the duration of the initiative to provide feedback on the strategy development process, discuss data from the data gathering activities, share unique perspectives, and act on next steps relating to the development of this strategy.

Through a total of eight meetings, Committee Co-Chairs reviewed progress and guided the Committee to complete key action items.

NIH-Wide Stakeholder Listening Sessions

The Co-Chairs conducted 18 30-minute Stakeholder Listening Sessions with key NIH-wide stakeholder groups that represented a specific community or function at NIH to extract perspectives on currently used technologies and needed future capabilities. The Listening Sessions offered the opportunity for different stakeholders across NIH to provide honest feedback on this strategy and technology considerations that impact their day-to-day work. Insights were summarized into executive summaries, which were provided to the Committee to review and leverage when developing the list of capabilities for this strategy. A total of 15 groups participated, with about 10-20 participants in each group, with some overlap across membership. Two groups met more than once to hold a follow-up discussion. For most Listening Sessions, existing meetings at NIH were leveraged by the Committee to discuss pre-identified questions and obtained specialized perspectives on the broader strategy initiative.

List of NIH Stakeholder Groups Involved in Listening Sessions
• IC Directors • Deputy IC Director’s Group • Executive Officer’s Group • OD Deputy Sr. Staff • Scientific and Clinical Director’s Group (SD/CD) • Strategic Administrative Management Advisory Committee (SAMAC) • Office of Management Managers (OMM) • IT Management Council (ITMC) • IT Budget Advisory Council (ITBAC) • Management and Budget Working Group (MBWG) • Facilities Working Group • Research Services Working Group (RSWG) • Extramural Activities Working Group (EAWG) • Scientific Data Council (SDC) • Tenure-Track Investigators

Foundational Sessions

NIH conducted nine 60 to 90-minute Foundational Sessions to establish a shared understanding of NIH’s current state across cross-cutting functions like the Intramural Program, Extramural Program, Administration and Management Functions, Data Science Program, as well as other topic areas critical for this strategy, such as clinical data; High-Performance Computing / STRIDES; and data program assets and infrastructure. Approximately 10 leaders and experts from across NIH met with the Committee to provide an overview of the current state of their functional area, to identify major drivers affecting their functional area over the next five years, and to discuss where technology was needed to meet critical requirements or could be used to optimize or transform processes and approaches. Some of these leaders and experts who presented on these topics were part of the Committee. They included the Deputy Director for Extramural Research, Deputy Director for Management and Chief Financial Officer, and Deputy Director for Intramural Research. The Foundational Sessions outlined challenges and opportunities for NIH—serving as a foundation to guide the development of this strategy. The Committee members participated in the meetings, as their schedules allowed, and they had time during the sessions to ask specific questions to better understand and identify opportunities and challenges relating to NIH technology capabilities.

List of Foundational Sessions
• Office of Extramural Research Program • Administration and Management • Office of Intramural Research Program • Facility Management Program • Office of Data Science Program • NIH IT Environment • Clinical Data Future State • High-Performance Computing/STRIDES • NIH Data Assets Panel Discussion

Benchmarking Sessions

NIH conducted 19 60 to 90-minute Benchmarking Sessions with external stakeholders representing organizations in academia, clinical research, government, research, and technology sectors and industries to gather insights on leading practices, approaches, trends, and challenges relating to technology capabilities. Sub-groups of the Committee led discussions for specific stakeholder groups, gathered and analyzed the discussion information, and synthesized outputs about best practices across other organizations into meaningful insights for this strategy. These insights were taken and distributed to the Committee to review, analyze, and leverage when finalizing the capabilities in this strategy.

NIH initially identified a list of 30 organizations to benchmark across a variety of sectors and industries. The list was refined based on input from the Committee about their priority areas of interest, 22 organizations were selected for outreach and a point-of-contact for each organization was identified; ultimately, 19 responded and agreed to a meeting. Tailored questions were developed for each organization ahead of the interviews.

List of Benchmarking Teams and Organizations Interviewed		
Benchmarking Team	**Committee Member/SME**	**Organizations**
Academia	• Rebecca Rosen • Alastair Thomson • Nick Weber • Michael Chiang • Nina Schor	• University of California San Diego (UCSD) • University of Chicago • Howard University
Clinical Research	• Gregory Farber • Jon McKeeby • Ben Solomon • Janice Lee	• City of Hope • University of Colorado • Mount Sinai (New York) • Kaiser Permanente
Federal Government	• Miles Fabian • Darla Hayes • Dave Heller • Brett Hodgkins • Colleen McGowan • Steve Sherry • Keith Martin	• Centers for Disease Control and Prevention (CDC) • Oak Ridge National Laboratory (ORNL) • Defense Advanced Research Projects Agency (DARPA) • National Aeronautics and Space Administration (NASA)
Research	• Jill Barnholtz-Sloan • Greg Germino • Tony Kerlavage • Elaine Ostrander • Valentina Di Francesco • Larry Reed	• Fred Hutchinson Cancer Research Center (Fred Hutch) • The Broad Institute • Chan Zuckerberg Initiative (CZI)
Technology	• Jacob Chang • Ivor D'Souza • Inna Faenson • Susan Gregurick • Dyung Le • Chris Lunt • Uday Metpally • Sam Michael • Jeff Shilling • Jennifer Freese	• NVIDIA • Internet2 • Google/Verily • Microsoft • Amazon Web Services (AWS)

Development Team Sessions

The Strategy Development Team was a sub-group of 12 members formed from the Committee to contribute to the development of the strategy outline and provide expertise to facilitate development of the key components of the final Plan. The Development Team met on a biweekly basis, four times in total, with additional weekly meetings with Development Team Co-Chairs, to finalize the list of capabilities and share input for the different key sections of the written document.

Development Team Members
• Stacie Alboum • Andy Baxevanis • Raymond Dillon • David Fargo • Shalini Kapur • Jim Matala • Kate O'Sullivan • Taunton Paine • Dennis Papula • Kim Pruitt • Xavier Soosai • Mike Tartakovsky

Funding and Governance Considerations

The Co-Chairs used a "Discover", "Analyze", and "Develop" approach to inform funding and governance considerations for integration into the draft this strategy. This approach captured the current state of the IT governance of funding structure at NIH and led to an assessment of challenges and accompanying recommendations and/or considerations to be included in this strategy.

Within the "Discover" phase, relevant insights were pulled from listening sessions and select benchmarking sessions to gather insights about the IT governance of funding. Research was conducted from existing materials and presentations around the current NIH IT governance and funding structures in addition to hosting several conversations with NIH-wide SMEs.

As part of the "Analyze" phase, research and information from the "Discover" phase were synthesized to identify key considerations and recommendations to include in this strategy. Challenges to the existing structures were identified, helping propose potential solutions to those challenges, including policy, process, and technology changes.

During the “Develop” phase, outputs from the “Discover” and “Analyze” phase were used to draft the language to be included in this strategy. Many stakeholders were involved in the “Develop” phase as both writers and reviewers of this document.

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