FDA's Technology Modernization Action Plan (TMAP)

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FDA

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Recent scientific and biomedical advances—from genomic sequencing to development of cell and gene therapies and nanotechnologies— have brought the promise of significant improvements to the health of many millions of Americans. To date, however, we have seen little of this promise in our day-to-day lives because a large and persistent gap separates important scientific advances and the technologies needed to translate those advances into new therapies for patients and new ways to protect the public health. The FDA's Technology Modernization Action Plan (TMAP), described in this document, is an important step FDA is taking to address and close this gap.

The plan describes important near-term actions that FDA is taking to modernize use of technology—computer hardware, software, data, and analytics—to advance FDA's public health mission. **TMAP has three elements: (1) modernization of FDA's technical infrastructure; (2) enhancing FDA's capabilities to develop technology products to support its regulatory mission; and (3) communication and collaboration with stakeholders to drive technological progress that is interoperable across the system and delivers value to consumers and patients.** The TMAP provides a sturdy technological foundation for development of FDA's ongoing strategy around **data** itself—a strategy for the stewardship, security, quality control, analysis, and real-time use of data—that will accelerate the path to better therapeutic and diagnostic options for patients and clinical care providers, and better tools to enhance and promote public health.

> FDA—and biomedicine as a whole—will be applying novel and rapidly evolving technologies at an increasing pace, demanding an approach that scales the work at FDA and across biomedicine. This will be a data-rich environment. To meet our public health mission, it is critical that FDA be prepared.
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> FDA is committed to pursuing its Technology Modernization Action Plan as a fundamental near-term step. Subsequent actions will focus on data and application of solutions unlocked by the TMAP.

I. WHY A TECHNOLOGY MODERNIZATION ACTION PLAN FOR FDA? WHY NOW?

Technology, broadly defined, is revolutionizing human and animal health. Scientific breakthroughs have enabled the development of new, more personalized therapeutic options and treatments, advanced manufacturing and information technologies, and state-of-the-art solutions such as blockchain, genomics, and real-time analytics. These new technologies feature increased biological complexity, complex data and software technology, and personalization and precision of interventions.

As a byproduct of the amount and variety of data that we generate, need and use is rapidly increasing. We are entering an era in which the data that is collected during the routine care of patients, coupled with traditional clinical trial evidence, will be used to generate steady improvements in future patient care. Other data types, such as genomics, toxicology data, and output from medical devices, are a part of the data ecosystem. Data-informed technologies, such as distributed ledger solutions like blockchain, will be critical to support FDA's track-and-trace priorities.

Near-term modernization in computer hardware and software technologies are the focus of FDA's Action Plan. Unlocking this potential will require infrastructure to securely receive, store, exchange, link, and analyze data; careful attention to data quality, integrity and security; analyses-at-scale including real-time dashboards, blockchain, appropriate strategies for both structured and unstructured data, and artificial intelligence; and a learning culture that continuously builds on prior knowledge. Information technology is not only a core utility but also the key infrastructure that facilitates seamless yet secure networking, data exchange and collaboration. Foundational requirements for a modern FDA technology infrastructure include virtual data storage ("the cloud"), problem-specific software development ("devops"), and solutions for efficiently exchanging data.

FDA is focusing on these areas to promote innovation not only in how FDA uses software and data in its work, but also across the biomedical ecosystem. FDA's role in regulating medical and animal products and food gives it a unique responsibility to drive this technological change—when FDA applies more advanced technologies to its work, stakeholders can explore new ways of developing FDA-regulated products and new methods of generating data to inform the regulation of those products. We must define our technical interfaces and data exchange protocols—this clarity from FDA will support broader efficiencies in communication and data exchange among the broader biomedical and health care community.

Ongoing modernization of FDA's core technology infrastructure complements cutting-edge FDA policies and actions. As one example, FDA is building the scientific and policy infrastructure to support increasing use of real-world evidence[1] to support regulatory decisions. The 21st Century Cures Act, enacted in 2016, highlighted the importance of real-world evidence in the context of drug development. Late in 2018, FDA issued the Framework for FDA's Real-World Evidence Program for drugs and biologics.[2] FDA has also issued guidance on considerations related to the use of real-world evidence in the context of regulatory decision-making for medical devices.[3] FDA is continuing to develop guidance to assist sponsors interested in using this emerging evidence source.

Real world evidence is only one area in which new technologies will shape future medical product development. Sophisticated data collection and analysis are also reshaping clinical trials, offering the ability to make clinical trial data more efficient to collect and more representative of diverse patient populations. Novel and rapidly evolving technologies also promise to enhance the generation of evidence where the size of a clinical trial is limited—for instance, in the context of a rare disease. These

[1] https://www.fda.gov/science-research/science-and-research-special-topics/real-world-evidence
[2] *Framework for FDA's Real-World Evidence Program*, available at https://www.fda.gov/media/120060/download.
[3] FDA Guidance for Industry and FDA Staff: *Use of Real-World Evidence to Support Regulatory Decision-Making for Medical Devices*, available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/use-real-world-evidence-support-regulatory-decision-making-medical-devices.

technologies will also give FDA sensitive new tools for detecting safety issues, allowing rapid and targeted response.

However, without modernized technical capabilities, FDA will not be able to help close the gap between the promise of these new technologies and policies, and the patients who stand to benefit from them. To realize this promise, FDA needs to have a technical infrastructure that can to accept, evaluate, and analyze novel sources of data (e.g., real-world data[4]) and apply that data to regulatory decision making. Building this infrastructure is a primary goal of the TMAP.

Ongoing technological advances will be needed to help FDA scale its capacity to meet a rapidly increasing regulatory review workload. The novel and rapidly evolving technologies and innovations described previously hold great promise for human and animal health; a corollary is the rapid expansion of the number of products undergoing regulatory review. Consider applications for medical products: FDA has seen applications and approvals/clearances for new medical products surge in recent years, and multiple trends suggest that review workload at the agency will increase at an accelerating pace. For example, of the 59 new molecular entities approved by FDA in 2018, 34 included orphan indications. In the same year, FDA approved 106 novel medical devices, the highest number in the 40-year history of the program. There are already 800 active cell-based or directly administered gene therapy Investigational New Drug Applications (INDs) currently on file and, by 2020, we anticipate at least 200 new INDs each year, representing a significant increase in workload.[5] Remarkable progress in FDA's generic drug and biosimilars programs in recent years has also resulted in substantial new review workload for FDA.

The complexity of FDA's review work is increasing as well. An estimated one-third of all medical products under development today are combination products that involve input from at least 2 FDA Centers; the number of combination product requests for assistance nearly doubled between 2016 to 2017 alone. Such rapid growth demands technological advances to help FDA meet the demands of increased review workload both in the premarket and post-market space, as well as tools that support and foster inter-Center coordination.

Advanced hardware, software and data technologies will allow FDA to deploy its resources more effectively and efficiently. FDA is already beginning to deploy advanced technological tools to help its scientific and medical reviewers collect the information they need to make regulatory decisions. New tools also allow FDA's investigators in the field to operate more efficiently—maximizing FDA's operational footprint in crucial areas like facility inspections and import operations. Yet, for these new technologies to achieve their full potential, we need to make sure that there is a modern technical infrastructure in place, coupled with a close eye on cybersecurity. Otherwise, the benefits enabled by new technologies will not be fully realized, and opportunities for consumers, patients, and the economy will be lost.

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[4] https://www.fda.gov/science-research/science-and-research-special-topics/real-world-evidence

[5] *Statement from FDA Commissioner Scott Gottlieb, M.D. and Peter Marks, M.D., Ph.D., Director of the Center for Biologics Evaluation and Research on new policies to advance development of safe and effective cell and gene therapies,* available at https://www.fda.gov/news-events/press-announcements/statement-fda-commissioner-scott-gottlieb-md-and-peter-marks-md-phd-director-center-biologics

In summary, FDA—and biomedicine as a whole—will be applying novel and rapidly evolving technologies at an increasing pace, demanding an approach that scales the work at FDA and across biomedicine. This will also be a data-rich environment. To meet our public health mission, it is critical that FDA is prepared.

FDA is committed to pursuing its Technology Modernization Action Plan as a fundamental near-term step. Subsequent actions will focus on data and application solutions unlocked by the TMAP.

II. HOW WILL FDA PURSUE TECHNOLOGY MODERNIZATION?

FDA's action plan has three elements: (1) modernization of FDA's technical infrastructure; (2) enhanced capabilities at FDA to develop technology products to support its regulatory mission; and (3) communication and collaboration between FDA and stakeholders, including the technology industry and other government agencies, to drive technological progress that is interoperable across the system and delivers value to consumers and patients.

Importantly, we view these to be the most critical components to be actioned in the next 12-24 months. These near-term actions are designed to be executed with minimal resources and lay the groundwork for future efficiencies. They prepare the landscape for a modern tech/data-forward FDA strategy, to be announced and actioned in approximately 18-36 months. The actions laid out in the TMAP will provide the operational experience needed to evaluate the resources needed to achieve future capabilities, including a modern data infrastructure for FDA and novel applications of artificial intelligence and other capabilities to FDA's regulatory mission.

A. BUILDING THE FOUNDATION: MODERNIZATION OF FDA's TECHNOLOGY INFRASTRUCTURE

Fortifying FDA's technical foundation is the top priority of FDA's Technology Modernization Plan. This includes making sure we have a robust infrastructure, cloud-forward plans, clear and efficient external data interfaces, and a focus on cybersecurity. FDA's technology infrastructure provides the backbone for ongoing improvements in the way: (1) FDA receives, generates, protects, and manages data; (2) analyzes data with advanced algorithms, including artificial intelligence (e.g. machine learning); and (3) makes the data available for use in regulatory decision making. This book of work includes traditional information technology (IT) operational capabilities like computer, storage and networking as well as modern technical strategies such as infrastructure-as-a-service, software-as-a-service, platform-as-a-service, data lakes and warehouses, and agile software development.

Modernization of FDA's technology infrastructure will involve dynamic, enterprise-wide collaboration among Agency programs. FDA's diverse regulatory programs require technology infrastructure that is scalable and flexible. FDA's enterprise-level technology organization, the Office of Information Management and Technology (OIMT), will have the responsibility for modernizing and maintaining the core technology platform and strategy for FDA. OIMT will collaborate with FDA's Centers and regulatory programs to assess business-specific needs and build a technology infrastructure that supports data- and computation-intensive regulatory tools.

ACTIONS

- **Enterprise-wide modernization of FDA technology infrastructure.** A multi-year strategic plan developed in collaboration with FDA Centers and external stakeholders will inform our plans. Example areas of focus include:
  - **Cloud strategy**
  - **Streamlined software development capabilities for business-specific needs ("devops")**
  - **Data stewardship, data management and data exchange including application programming interfaces (APIs), standards, and other exchange mechanisms and tools**
  - **Data clean-up and migration to cloud environments**
  - **Continued adoption of "as-a-service" models**
  - **Ongoing dedication to cybersecurity excellence**
  - **Integration of scientific computing into enterprise IT planning**
  - **Organizational alignment within the enterprise-level technical organization OIMT and across FDA**
  - **Operational excellence and multi-year technical planning**
  - **Cost containment and elimination of redundancy**
  - **Enterprise IT governance**
  - **Retiring legacy systems and software applications where appropriate**

B. DEMONSTRATING INNOVATION: DEVELOPMENT TARGETED TO TECHNOLOGY "USE CASES"

FDA will build technology "product" development capabilities to generate best-in-class technology solutions that will allow FDA to efficiently evaluate and catalyze new solutions to inform regulatory decision-making. Technology products developed by FDA will demonstrate and enable capabilities needed for the near- and mid-term FDA technology roadmap and will showcase what is possible with a modern FDA. This approach will incorporate a product development mindset including: focus on products that, by addressing key business and data requirements, may be adapted to different FDA program areas, reducing duplication; development of "minimum viable products" for testing; adoption of "devops" mindset and practices; willingness to "fail fast," iterate and pivot; focus on "product-market fit" for the FDA environment; collaborative culture; improved user experience, satisfaction and adoption; and, opportunities to showcase what is possible in the near- and medium- term.

FDA will develop a set of technology tools around specific regulatory "use cases": Development of novel technology products will be focused on a set of FDA "use cases" that will be used to identify and organize the requirements for each product. Use cases will highlight key areas in which new or enhanced technology solutions can bring the most tangible benefits. Use cases are, by design, narrow in scope. This helps ensure that a technology (e.g., software) product is feasible to design and develop on a reasonable timescale and with an efficient use of resources. However, a product developed around a targeted use case will be designed to be scaled up or adapted to an expanded set of problems to maximize FDA's return on technology investments. Use cases will be "regulatory" in the sense that they

will focus on topics important to conducting FDA's regulatory mission (e.g., medical product approvals, foodborne outbreaks, collaboration with other government agencies).

For some projects, FDA will perform the role of a traditional technology developer: seeking and taking a leading role in the technological modernization of our regulatory review system as well as the underlying infrastructure that supports it. Some products will be shepherded by a centralized FDA team while other products will be developed by a FDA team in one of the FDA Centers with support from the central team. Other solutions will be catalyzed by FDA but otherwise built within the larger biomedicine ecosystem, including through collaboration with other government agencies. FDA will also continue to review the overall technology marketplace for new fit-for-purpose off-the-shelf solutions that can be efficiently adopted into the FDA environment.

> **Example "use case": Artificial intelligence to inform seafood product inspections.** FDA is currently testing the efficacy of a machine learning solution using a seafood use case. This proof of concept will inform FDA's efforts to identify potentially violative seafood products. In this example, FDA's food regulatory program is responsible for building and testing the prototype, and, if viable, the centralized Agency product team will help to consider requirements for adapting the software tool to other areas of FDA's regulatory mission.

Expanded use case development will enable FDA to focus modernization efforts and investments on the right technology/problem combinations. Use cases will also provide examples of actionable steps that reduce the complexity of digital transformation and enable meaningful progress in areas related to FDA's mission, such as medical product development and food safety. Key goals include:

- Demonstrate what is possible with a modern FDA and in the next 5-20 years for biomedicine
- Provide a "how to" roadmap to address key tasks such as utilizing cloud technologies for FDA purposes, appropriate data sharing with FDA, and application of new technologies like blockchain to FDA challenges; and
- Highlight what is required from FDA and the biomedical ecosystem to leverage data and technology in service of a learning health system

ACTIONS

- **Build FDA's product development capabilities:** FDA will develop an enterprise-level function to collaboratively design, develop, test, and deploy new technologies. Multidisciplinary product development teams at FDA will integrate best-in-class solutions with organizational competency in areas like agile development, product management, user experience design, and engineering. This expertise will place user experience at the heart of efforts aimed at technology and business integration, unified data and processes, and expanded analytical abilities. FDA's augmented product development capabilities will empower the agency to deliver high product quality, improved customer satisfaction, reduced risks, and a higher return on investment. Parallel efforts will also include the development of an integrated change management plan and process to support organized agility.

- **Develop use cases:** FDA will start with small pilot use case projects to mature its product development abilities and expertise. These projects will link regulatory expertise with technology know-how by bringing FDA reviewers and technologists together to identify and refine use case concepts. The use cases will target compelling problems and opportunities that will strategically serve to advance modernization efforts. Once the goals and requirements have been refined, the project teams will experiment, innovate, and build rapid prototypes. Successful prototypes and pilots will be expanded as FDA develops new expertise in product development. This prototype and testing approach will accelerate learning while mitigating the risk of deploying new technologies. Use cases will fall into three categories:
    1. **Ongoing and/or near-term**: use cases already under development that demonstrate central solutions and enhancement of regulatory capabilities made possible by data/technology. These solutions highlight what is possible within FDA's current environment. Examples for consideration include PrecisionFDA, 7- and 15-day safety reporting for Investigational New Drug (IND) applications, and updating the PREDICT model with machine learning.
    2. **To be initiated**: new solutions to be initiated that resolve a critical challenge, highlight an emerging opportunity, or unlock new potentials. By demonstrating new capabilities to users, these solutions will unlock creative new ways to apply the technology to FDA's mission. Examples for consideration include real-time FDA operational management dashboards, a collaborative project with Office of the National Coordinator for Health Information Technology (ONC) on the "life of a data element", and technological solutions for FDA's import operations.
    3. **Aspirational:** solutions that may not be possible today but highlight where we want to go as FDA and society. For example, real-time, personalized medical product labels or real-time assessment of food safety at the point of purchase.

C. COLLABORATION TO ACHIEVE SCALE: *Collaboration between FDA, other government agencies, and stakeholders—including the data/technology sector—will catalyze more effective development of the technical tools needed for the future*

FDA's technology modernization will be informed by direct engagement with stakeholders. FDA will engage directly with the public to collect broad input on its approaches to technology modernization. Opportunities to engage a diversity of stakeholders include not only public meetings or workshops, but also online environments that can be used to demonstrate and test technology products with participants outside the agency. For example, FDA has used PrecisionFDA to provide a community platform for the evaluation of next-generation sequence data and regulatory exploration[6] and will continue to look for new ways of engaging through technology-enabled channels, in addition to more traditional means.

Clear technical interfaces for external stakeholders can increase predictability and catalyze innovation across the biomedical ecosystem. Clarity and transparency from FDA about its approach to novel and

[6] https://precision.fda.gov/docs/intro

rapidly evolving technologies is crucial because this provides the guideposts to industry, researchers, and other stakeholders who develop data for submission to, or otherwise interact with, FDA. Clear regulatory and technology guideposts from FDA can catalyze innovation and competition in the technology and biomedical sectors. As FDA builds out increasingly advanced technologies, FDA will work with external partners to build appropriate application programming interfaces (APIs) and other tools to allow for the efficient submission of high-quality data to FDA.

Collaboration with government partners to ensure regulatory consistency and efficiency. FDA's partnership with government partners is essential to achieving efficiency and interoperability across broad technological systems, like the modern health system. For example, FDA will continue to strengthen its collaborations with our sister agencies in the Department of Health and Human Services (HHS), including ONC and the Centers for Medicare & Medicaid Services (CMS).

> **Example collaboration: Partnering to shift to cloud securely.** FDA collaborated with vendors to conduct a FedRAMP security assessment for a new genomics platform. Lessons learned from this partnership will inform FDA's efforts to support regulatory efficiency and facilitate cloud adoption without compromising security or privacy.

Advance the dialogue with the technology sector. Technology innovators are developing the tools that are changing the way data is collected and used in health care, but FDA is only beginning to have a robust dialogue with stakeholders this sector. FDA will identify ways to enhance the transparent exchange of ideas with the technology sector.

ACTIONS

- **Engage directly with public stakeholders:** FDA will receive input on the implementation of the TMAP as well as subsequent plans related to data at FDA from stakeholders—including patients, academia, and industry—through public meetings or workshops. FDA will look for novel opportunities to engage with a broad spectrum of stakeholders and new, technology-enabled methods of engagement with the public, building on the success of collaborative efforts like PrecisionFDA.
- **Identify a suite of toolkits that foster data/tech innovator involvement in medical product development and foodborne outbreak response:** FDA will work together with data/tech stakeholders to identify and develop solutions to enable faster and smoother engagement with FDA as well as a clearer understanding of expectations of innovators in this space (both regulated and unregulated).
- **Collaborate with government agencies:** FDA will collaborate with other government agencies, including CMS and ONC, to explore how complementary efforts by each agency can promote greater efficiencies within government and for external stakeholders.

III. HOW WILL FDA MEASURE THE SUCCESS OF THE TECHNOLOGY MODERNIZATION ACTION PLAN?

FDA prioritizes transparency and accountability in the implementation of TMAP. Ongoing evaluation of our progress will enable iterative improvement of our modernization strategy.

- **Stakeholder engagement**: Stakeholders will be engaged at multiple points during this process, providing both proactive ideas and reactive feedback.
- **Regular updates:** FDA will provide public annual updates on TMAP-related activities, including accomplishments, challenges, and lessons learned.
  New tools for public transparency: FDA will evaluate new tools for sharing our progress on technology modernization with the public, including with online dashboards.

IV. WHAT COMES NEXT?

TMAP orients FDA in the direction of ongoing development of new technology tools and the successful application of these tools to FDA's regulatory mission. TMAP also provides a foundation for the development of FDA's strategy around **data itself**. In the coming months, FDA will engage with stakeholders to develop a strategy and understanding of common priorities for the Agency's approach to data. Issues to address in this context will include:

- How FDA will ensure that regulatory decisions at the Agency continue to be informed by **high-quality** data;
- How FDA will promote **efficient data use** and **data stewardship** across the Agency;
- How FDA will continue its ongoing commitment to a **highly secure data and IT environment**.