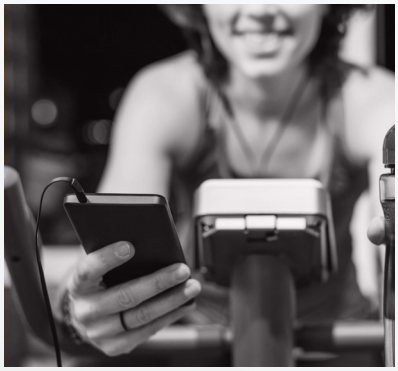
Modernization in Action 2022



Technology Modernization Action Plan (TMAP) and Data Modernization Action Plan (DMAP) Anniversary Report

FDA U.S. FOOD & DRUG ADMINISTRATION

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MODERNIZATION IN ACTION

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Introduction and Modernization Drivers

In September 2019 the FDA released the agency's Technology Modernization Action Plan (TMAP), followed in March 2021 by the release of the Data Modernization Action Plan (DMAP), (the "Plans"). The Plans shared the FDA's vision for technology and data modernization to advance the agency's mission. As we mark the one-year anniversary of DMAP, and nearly three years since launching TMAP, this update provides a review of the Plans, progress against the Plans' objectives with specific examples, and thoughts about the future.

The FDA Modernization Framework

TMAP

The Technology Modernization Action Plan (TMAP) outlined agency-wide technology modernization, including computer hardware, software, data, and analytics

TECHNOLOGY INFRASTRUCTURE
Modernizing the FDA's technical infrastructure, with a focus on cloud computing, data interfaces, and cybersecurity

TECHNOLOGY PRODUCTS
Enhancing the FDA's capabilities to develop solutions using standardized technology products to support its regulatory mission

STAKEHOLDER COLLABORATION
Communicating and collaborating with stakeholders to drive technological progress that is interoperable across the IT enterprise and delivers value to consumers and patients

DMAP

The Data Modernization Action Plan (DMAP) proposed a framework and actionable recommendations for the FDA's data strategy

HIGH-VALUE DRIVER PROJECTS
Identifying and executing high-value, scalable driver projects for individual centers and for the agency

DATA PRACTICES
Developing consistent and repeatable data practices across the agency

TALENT NETWORK
Creating and sustaining a strong talent network combining internal strengths with key external partnerships

The Plans include tangible steps the FDA is taking to address the gaps between important scientific advances and the data and technologies needed to translate these advances into new therapies for patients and to further protect public health. In early 2020, not long after the TMAP launch, the world was hit by the COVID-19 global pandemic, which helped drive the acceleration of the FDA's modernization of information technology (IT) infrastructure, analytic services, talent, and tools, supporting the agency's work at national and international levels.

Importantly, in September 2021, the FDA completed a strategic reorganization to form the Office of Digital Transformation (ODT). Reporting directly to the FDA Commissioner, ODT directs and coordinates enterprise strategic planning, policy, and resource management to ensure that IT, data, and cybersecurity investments and activities provide maximum value to FDA. ODT brings together the Offices of Information Management and Technology (OIMT); Data, Analytics, and Research (ODAR); and Information Security (OIS), to provide high quality, secure, and efficient IT and data solutions that enable the FDA to promote and protect public health. Building on TMAP and DMAP, ODT will lead with enterprise modernization, break down barriers, and eliminate silos, ensuring we get the most from talent, technology, and budget. Quite quickly, ODT has become #OneODT.

What's Driving Modernization?

The list is long, diverse, and dynamic – and for FDA it is a combination of ongoing operations, emergency and unplanned operations, and new initiatives.

The 21st Century Cures Act enacted in 2016 accelerates medical product development and brings new innovations to patients who need them faster and more efficiently and uses technology to rapidly advance science. This includes continued development in technologies like Artificial Intelligence (AI), Big Data, Analytics, Robotic Process Automation, Internet of Things, and more. The 2020 Executive Order (EO) on Promoting the Use of Trustworthy Artificial Intelligence in the Federal Government encouraged the ongoing acceptance and adoption of AI and the promise of AI to increase mission effectiveness, just as the demands on people, systems, and infrastructure continue to increase.

The COVID-19 pandemic impacted every area of American life – including how we work, eat, and shop, and think about health. The pandemic accelerated the need for modernization to account for these changes, which will continue to evolve as we emerge from the pandemic and apply the lessons it has brought. This includes the need to continue to support remote work from both an operations and User Experience (UX) perspective. As the future of remote work evolves, the FDA will accelerate its cloud adoption and shift to a Software Defined Network to support distributed workloads. This aligns with ongoing Federal IT Acquisition Reform Act (FITARA) data center consolidation and optimization initiatives.

COVID-19 also put a spotlight on the importance of collaboration, innovation, and internal and external UX, which is underscored in the upcoming Prescription Drug User Fee Act (PDUFA VII) reauthorization for fiscal years 2023-2027. The PDUFA VII performance goals include the increased use of cloud-based platforms, new data management tools and technologies, and continued modernization of the FDA's IT capacity and capabilities. Feedback from FDA stakeholders includes the need for software and tools to match and optimize FDA workflows and to optimize resource investments.

> If science is the brain of the agency, data is its circulatory system, and the technology is the musculoskeletal system.
>
> – FDA 2021 Year in Review

TMAP: Driving Technology Modernization Across the FDA

Infrastructure and Operations Modernization

TMAP outlined fortifying FDA's technical foundation as a top priority, specifically ensuring a robust infrastructure, cloud-forward plans, clear and efficient external data interfaces, and a focus on cybersecurity. The FDA delivers this in several ways, including examples shared here.

The Global Pandemic Presented New Challenges, in Addition to Business-as-Usual Demands

With the FDA's diverse staff needing to work primarily from home, beginning in March 2020, the agency quickly increased support for devices, systems, and data to support staff workflow in addition to the new and vast demands necessary to respond to the pandemic.

From hosting more than 429,000 virtual meetings annually, to managing more than 2,400 applications and databases, to managing a 457% increase in cyber-attacks compared to pre-pandemic levels, FDA met these challenges within budget as a result of modernization efforts.

The agency's abrupt shift to a teleworking mode during the pandemic to support 25,000 users – without missing a beat – demonstrated the stability of the FDA's IT environment and leadership approach. The FDA remains focused on strengthening and scaling IT infrastructure to meet both expected and unexpected technology changes ahead.

Cybersecurity: Adopting a Zero Trust Model

Cybersecurity is among the FDA's top priorities and is critical to protecting public health in today's environment of constant cybersecurity risks. The agency has implemented policies, processes, procedures, and tools to enhance our prevention, detection, and response to incidents. Globally, theft of intellectual property, trade secrets, and other sensitive information are on the rise. During the COVID-19 pandemic, we have seen a significant increase in phishing, social engineering, and other nefarious activities by cybercriminals and nation state actors that have targeted individuals, private industry, and government entities, and notable breaches. As a steward of industry and public health information, the FDA has taken a collective and shared approach to ensure that appropriate security measures and protections are in place to protect the public and the vast amounts of data we work with every day.

The FDA employs risk-based strategies to strengthen the agency's ability to protect sensitive information. To decrease overall security risk, we have implemented capabilities that facilitate highly effective incident response, insider threat detection, and improved operational situational awareness. To further ensure that sensitive information is appropriately protected against disclosure, access, or misuse, we have established key cybersecurity objectives that have led to strict user guidelines on processing, storing, and transmitting sensitive information. Presidential EO 14028, Improving the Nation's Cybersecurity, issued May 2021, directs agencies to modernize their cybersecurity capabilities. The FDA is modernizing security and cyber defenses to address the evolving cyber threat landscape through the implementation of Zero Trust, secure cloud computing, multi-factor authentication, encryption, threat detection, vulnerability management, and other cyber

defense capabilities. These initiatives align with the strategic priorities of the FDA Cybersecurity Strategic Plan and support TMAP and DMAP and will serve as our roadmap to effectively transition to a Zero Trust.

Cloud First Journey Continues

The FDA continues to meet significant milestones in our move to the cloud, concurrent with End-of-Life (EoL) modernization initiatives. With 35% of FDA systems using cloud components, the agency is focused on accelerating its cloud journey, reducing investments in physical equipment, rack space, power, and cooling. Importantly, cloud-based solutions offer innovative, efficient, and secure services across locations and devices. The agency consolidated Data Center utilization through 7.1% reduction in rack space, and a savings of $1.7 million through decommissioning equipment. Through EoL modernization, the FDA eliminated more than 240 servers, reduced data center footprint by 4%, and minimized block storage power and cooling by 90%. A plan has also been established to migrate most of the agency's Wiley Data Center to the cloud.

Next Generation Data Centers

ODT is transforming its IT infrastructure to the Next Generation (NextGen) Data Centers – a cloud-forward, operational support model employing software-defined technologies and support for continuous improvement – adding the agility needed to meet business requirements. With operational costs increasing and data center resources underutilized, this cloud-forward model places emphasis on achieving innovative IT solutions, performance improvements, cost reduction, and an overall simplification of the environment to improve operations towards agility and scalability. By re-evaluating our current operational support model, we have incorporated continuous improvement and modernization into NextGen efforts and anticipate a positive shift in infrastructure, applications, and security support concluding with a private cloud environment. With transition to a more agile workforce, this effort will drive down costs and reinvest into modernization efforts. Agile teams, automation, and repeatable processes are expected to reduce resourcing by 25%, with deployment times improved as a result of increased operational support and software-defined environments.

Operations as Foundational

As technology plays an increased role in executing strategic organizational initiatives, TMAP provides direction on aligning operations with impact and outcomes.

ODT's new Budget 2.0 strategic planning process aligns IT budget and funding needs, now tracked via the Technology Business Management (TBM) dashboard. Improved analytics drove cost savings and avoidance and redeployment of 7.5% of the FY22 budget.

The agency's Acquisition-as-a-Service model for IT acquisition is now used across FDA to identify cost reduction and cost avoidance opportunities, while managing vendor partnerships to reduce costs and improve efficiencies. Through the negotiation and close monitoring of select acquisitions, the Acquisition Strategies and Partnership (ASAP) division saved the FDA $6.9M in 2021. The FDA is now leveraging best management practices to manage the $800 million IT portfolio and has maintained an overall A on the Health and Human Services (HHS) FITARA Scorecard.

Governing Together

Enhanced governance has also played a part in the FDA's progress, with new processes and new and strengthened governing bodies. For example, all IT projects and investment decisions across the agency now follow a consistent intake process to ensure technology investments are efficient, effective, and aligned with the FDA's mission and priorities. The recently formed FDA Enterprise Architecture Technology Advisory Board (FEATAB) provides a collaborative framework with Center partners for determining when and how to make changes to FDA IT Standards. In short, the FEATAB is focused on ensuring our efficient use of technology and funding through strategic resource and project management. The agency-wide Technology Council includes technology leaders from across FDA with a charter to make strategic decisions on agency-wide IT operations, funding, infrastructure, enterprise architecture, priorities and investments. This work is laying the foundation for creating an FDA Enterprise Strategic Plan and planning process in alignment with PDUFA VII performance goals, ultimately assisting with the reduction of the agency's technical debt.

Agile and Product Culture

User Experience (UX) Front and Center – Anywhere, Anytime

The FDA's vision for better UX includes a modern platform for internal and external collaboration, modern mobile devices, and modern tools to leverage and display data in a meaningful way – supporting an empowered and productive workforce. The global pandemic drove an increased focus on enhancing the UX in a dynamic, mobile, and unpredictable work environment. ODT's Office of Business and Customer Assurance (OBCA) works across functional areas to make the vision of a modern user experience more of a reality. This collaboration has produced strong results that impact all FDA users, including redesigning the FDA intranet and offering mobile access to Microsoft apps like OneDrive, Teams, and Office 365 to support remote work. FDA users now have the same IT experience on their laptops and mobile devices. The migration to a new mobile device management platform and the rollout of Office 365 apps has increased productivity in the office and on the go. Users have the flexibility to check email, edit documents, and attend video conferences, regardless of device.

Also on the mobile front, the FDA upgraded 7,000 devices, while decommissioning 1,500, to a new mobile device management solution, improving both functionality and security. Mobility enhancements also include Virtual Private Network (VPN) improvements focused on data transmission reliability and security, with improved UX. Efforts are also in progress to increase the use of single sign-on for a more seamless experience. FDA-issued mobile devices also received Hotspot capability on all phones, providing backup network capabilities if a user's primary network goes down, providing the capability to continue critically important work.

FDA customer support was adjusted to deliver stronger remote support capabilities, and direct shipment options for hardware replacement for employees. ODT is also actively working to implement repeatable processes, provide packaged and self-service cloud offerings, and ensure infrastructure supports agile migration of FDA applications to the cloud. Overall, TMAP ensures a holistic, integrated UX approach to align efforts, streamline communications, and accelerate the availability of services for FDA technology users.

People and Culture Driving Impact

People are foundational to our modernization framework and by elevating ODT within the FDA, we are strengthening agency-wide collaboration and amplifying our expertise. As part of forming ODT and the #OneODT culture, FDA established a twelve-person team, Division of Management Services (DMS), focused on improving talent acquisition, increasing employee retention and engagement, and strengthening an emerging workforce within ODT. Thus far, the team has led a 9.6% hiring increase over the prior year, supported a 17% improvement in management communication scores, and delivered myriad communications, coaching, and training resources. Importantly, DMS is collaborating with senior leaders across ODT to define and prioritize staffing activities to ensure alignment with the FDA's priorities.

Stakeholder Collaboration

As outlined in TMAP, collaboration between the FDA, other government agencies, and stakeholders—including the data/technology sector—will catalyze more effective development of the scalable, technical tools needed for the future. Now more than ever, true collaboration is an imperative to delivering successful technology projects.

Guest Collaboration Experience

The Guest Collaboration Experience (GCE) in Microsoft Teams and SharePoint Online allows the FDA staff to communicate and collaborate with external entities. Additional oversight and review provide for a secure environment. GCE provides a secure environment for FDA users to co-author documents and participate in chats with external users on their FDA-issued laptop and mobile devices. Its availability allows the FDA to have instantaneous, direct access to external partners when time is of the essence while working on solutions to address public health issues.

The Evidence Accelerator Advances COVID-19 Response

In partnership with the Reagan-Udall Foundation, the FDA and the Friends of Cancer Research launched the Evidence Accelerator (EA) to advance the use of Real-World Data (RWD) to inform the COVID-19 response. The EA includes three workstreams: therapeutics, vaccines, and diagnostics. Nearly 120 external organizations have participated in the therapeutics meetings, including vaccines, and more than 150 organizations have participated in the Diagnostics Evidence Accelerator. The COVID-19 EA is helping answer critical research questions using RWD and modern, rigorous analytical methods. The effort has also created a roadmap for advancing RWD at the FDA.

precisionFDA Food Safety Challenge Expansion

In collaboration, ODT and the FDA's Office of Food Policy and Response hosted the FDA New Era of Smarter Food Safety Low- or No-Cost Tech-Enabled Traceability Challenge. FDA received 90 submissions from around the world to encourage the development of tech-enabled food traceability solutions that are low- or no-cost to the user. This work advanced the Food Safety Challenge by enabling operations of all sizes to implement traceability systems that make the human and animal food supply chain safer.

Stakeholder Engagement

ODT established a Strategic Communication and Outreach capability in 2021 to increase stakeholder communication and engagement. This emerging work will foster connections, trust, and support for ODT's key initiatives while ensuring they are proactively meeting the needs of our stakeholder constituents. Preliminary efforts include establishing Communications-as-a-Service and Events-as-a-Service capabilities and developing four enterprise communication products. This builds on User Fee Program involvement to engage sponsors and will expand to planned Vendor Engagement Days. ODT will also increase external communication in the upcoming year.

DMAP: Driving Data Modernization across the FDA

The DMAP was launched one year ago and provides a solid data roadmap for the FDA and ODT. With the formation of the Office of Data Analytics Research (ODAR), the FDA will continue to drive and expand DMAP to meet the ever-changing data landscape. ODAR has built a strong network of senior leaders and data practitioners across the agency to advise and implement DMAP using high-value and tangible driver projects and data practices. The Federal Chief Data Officer (CDO) Council Playbook mentions the FDA as examples for two out of four best practice plays in its 2022 document, a testament to the strategic thinking at the FDA. As part of the value realization of DMAP, ODAR is developing a detailed implementation plan to be executed in an agile and collaborative manner.

High-Value Driver Projects

As defined in DMAP, "driver projects" help generate value while building critical capabilities. Driver projects are initiatives with measurable value that help multiple stakeholders envision what is possible, allow technical and data experts to identify solutions, and develop foundational capabilities in the agency. This strategy was an intentional departure from collecting data first and, subsequently, defining the questions the data can answer. The initial driver projects have delivered high-value and significant learning for the FDA.

FiDLE: A Data Concierge

The FDA Intelligent Data Lifecycle Ecosystem (FiDLE) is an FDA cloud-based data and analytics platform and service, launching in April 2022. FiDLE is an example of a driver project developed in alignment with TMAP, DMAP, and FDA Information Security, to support the agency's long-term data modernization strategy. The FiDLE product support model includes a one-stop service for translating business needs in a scalable, accessible environment. Project teams and data scientists from across FDA will access enterprise-wide data and analytics tools, saving time, costs, and duplication of effort.

Improving Inspections

ODAR delivered data-driven dashboards to support planning and execution of surveillance inspections in an agile manner. Leveraging people and data assets from the FDA and other federal agencies, the team delivered a usable tool that was implemented in fewer than six weeks without additional costs or new tools. The dashboard was used by the FDA's Office of Regulatory Affairs (ORA) in its planning of surveillance inspections and was an integral component to balance its public health mission and the safety of inspectors. The output from the dashboard was also used by the FDA's Center for Drug Evaluation Research (CDER) as part of its risk model for conducting inspections. The integration into the CDER risk model was achieved through Application Programming Interface calls and automation.

How the RWD Research Lab Enhances Critical Data Practices

The Real-World Data (RWD) Research Lab, created in 2021, uses iterative, rapid-cycle approaches with internal and external partners to inform the agency's approach to the COVID-19 pandemic.

ODAR partnered with internal and external stakeholders to better understand the COVID-19 patient experience. The lab is designed to address data complexity by using real-world data and modern analytical methods to answer critical questions and gain key insights into diagnostics and therapeutics. The launch of the RWD Research Lab also established a RWD data catalog and glossary. This work is ongoing and helps increase accessibility, usability, and consistency in leveraging RWD for evidence generation.

A Modern Global Substance Registration System

In collaboration with the National Institutes of Health National Center for Advancing Translational Services (NIH/NCATS), the FDA modernized the Global Substance Registration System (GSRS) using a microservice architecture. This new approach arranges an application as a collection of services to improve flexibility and user experience. The new architecture supports more than 200 FDA users in managing information for substances. GSRS also established an international vaccine harmonization effort to support regulatory review during the COVID-19 pandemic. The new architecture enables GSRS's global footprint and collaboration with industry, foreign regulatory agencies, academia, and other stakeholders.

Data Practices

ODAR, initially in startup mode with a nimble team, is fully aligned with all things DMAP. Data practices include data lifecycle management from acquisition to insights, including data quality, access, model, and algorithm development. Specifically, data practices help simplify data acquisition and reduce cycle time, enable better governance, and provide security and scalability for enterprise use of data to ensure FDA has access to high-quality, well governed data for use in public health decision making.

FDA Data Modernization Steering Committee

The FDA Data Modernization Steering Committee (DMSC) was formed in 2021 with a mission to provide the strategic framework for proper oversight and decision making over FDA's critical data assets. As defined in DMAP, the DMSC will guide the implementation of the DMAP to "focus on the stewardship, security, quality control, analysis, and real-time use of data to accelerate the path to better therapeutic and diagnostic options for people and animals, better secure the food supply chain, and provide state-of-the-art tools to enhance and promote public health."

Fully aligned with DMAP, DMSC will facilitate transformation through:

- Driver Projects: Identify and prioritize high-value and pragmatic driver projects for Centers and the agency.
- Data Practices: Develop consistent and repeatable data practices across the agency.
- Talent Development: Create and sustain a strong talent network combining internal strengths with key external partnerships.
- Stakeholder Engagement: Develop and pilot a comprehensive change management and communications plan with internal and external stakeholders.

Pandemic Data + Analysis

In reaction to the pandemic, the FDA created the COVID-19 Multidisciplinary Analysis Group (CMAG), an agency-wide collaboration of subject matter experts to discuss a diverse array of issues relevant to the agency's response to the pandemic. This included the studies conducted with the support of the RWD Research Lab, focusing on the categorization of race and ethnicity data in real world evidence sources, and the use of genomics data in RWD sources.

Artificial Intelligence (AI) Playbook

The AI Playbook was developed to help FDA project managers and business leaders who are responsible for governing, leading, or guiding AI projects, with tools to map opportunities with a user lens, quickly assess potential ideas, bring in the right team members, manage execution and maintenance, while avoiding or mitigating risks. This work highlights, enables, and builds on work done by the Centers and best practices from industry. It is part of a broader effort to build a pathway for executing projects that leverage automation, machine learning, rule-based systems, and other elements of AI at the FDA.

Talent Network

The DMAP includes a strong focus on talent and elastic talent networks to drive innovation, efficiencies, and collaboration.

Enterprise-wide Data Science Training

Through ODAR, FDA increased agency-wide awareness and delivered education opportunities by launching the "What Can Data Do for You?" lecture series with 800 attendees and the Data Forward Data Science training course, welcoming more than 1,400 participants. Through DMAP, additional training for both specialists and business partners will ensure understanding of the role data plays in the FDA's mission and success.

Using Artificial Intelligence (AI) to Find and Share Expertise

In January 2022, the FDA Library in ODAR announced the release of the FDA Expertise and Research Portal. With the help of AI, this new Portal is a centralized, automated tool for finding FDA experts and linking to research data.

Results to date include creating over 8,000 FDA researcher profiles, harvesting over 33,000 research articles, and identifying over 59,000 FDA external co-authors.

The tool strengthens FDA's data talent network by making experts and their research more accessible and discoverable to support knowledge sharing and collaboration.

Calling all Data Scientists

The U.S. Office of Personnel Management (OPM), in collaboration with the Office of Management and Budget (OMB), the Chief Information Officer (CIO) Council, and other key stakeholders, has explored data scientist work in the Federal Government. OPM has identified key data scientist work roles, knowledge areas, skills, and competencies and developed a new Data Scientist series, 1560, within the Mathematical Sciences Group, 1500. ODAR is working with the Office of Talent Solution (OTS) to develop standardized position descriptions which will enable FDA to better hire, recruit, and develop data scientists in alignment with the DMAP talent network pillar.

Technology and Data Modernization Catalyzing Business Transformation at the FDA

Enterprise Transformation Operation

The TMAP and DMAP created the vision for technology and data modernization and the ODT reorganization established enhanced governance. The Enterprise Transformation Operation (ETO) is a newly created organization in the Office of the Commissioner that provides the executive engagement and business process alignment and optimization necessary to drive enterprise business modernization. With this next step, FDA has empowered the ETO team to strategically and thoughtfully look at enterprise-wide challenges and opportunities to improve collaboration and business outcomes. We'll take this initial work and learning opportunity to build the Enterprise Modernization Plan, or EMAP, with the goals of delivering scalable frameworks to drive process optimization, better use of our data, and more efficient IT development to support these optimized processes. With this focus and collaborative prioritization, we will look at business processes across the agency and ensure we function not as a collection of Centers, but as an integrated agency, getting the most from our talent, technology, and budget.

Blueprint for Good IT

The FDA's ODT remains relentlessly focused on delivering optimized information technology (IT) for the entire agency with the "Blueprint for Good IT." This internal consulting and engagement model service effort is designed to advance technology modernization and adopt industry standards. We have designed the Blueprint to create a rising tide to lift all boats – agency-wide across all teams and Centers. ODT staff partner with Centers to understand business needs, conduct a systematic evaluation, and develop actionable recommendations to establish a common framework with best practices, enterprise technology standards, resource management, and technology solutioning. Services include partnering and participating with Centers on enterprise councils, review boards, and working groups, within the areas of program and IT finance management, enterprise architecture, service management, and data management. This approach is designed to eliminate siloed data, processes, and organizations that cause unnecessary complexity, redundancy, and waste. The Blueprint for Good IT works by leveraging the Information Technology Infrastructure Library (ITIL) framework of best practices – coupled with strategic partnerships – to help transform strategy into tangible, measurable outcomes.

An early Good IT pilot included the Center for Veterinary Medicine (CVM) teaming with ODT to refine and actualize their IT modernization vision by means of a "blueprint" of advisory support, high-touch engagement, dedicated liaisons, and Good IT workshops to provide insight into best practices that can be customized for CVM.

The benefits of a Blueprint for Good IT and working together resulted in a long-term modernization strategy with an achievable short-term tactical plan that is estimated to save approximately $16M during FY22.

Importantly, the Blueprint for Good IT strengthens customer relationships and enables more effective resource management. Success relies on effective communication, collaboration, coordination, and the development of a shared common language based on senior leadership commitment, supportive resources, and dynamic teamwork.

Reimagining Strategic Planning

In 2021, ODT reimagined Strategic Planning and ensured optimal deployment of resources without creating redundant and overly complex processes for stakeholders. The ODT Executive Leadership Team (ELT) approved and prioritized the optimal list of FY22 initiatives/projects given ODT's limited resources and competing priorities, while optimizing planning processes managed by multiple offices.

The ELT partnered with the Office of the Enterprise Portfolio Management (OEPM) Cost Allocation and Budget Teams to develop a streamlined strategic planning and budget process. Using a newly developed planning tool and cost model with real-time data, the ELT reviewed 78 proposed new initiatives and projects for strategic alignment, interrelationships, and resource duplication. The outcome was a prioritized list of 45 selected initiatives and projects to advance ODT's Strategic Priorities in FY22. The success of these efforts will ultimately improve efficiency and customer service while also aligning with TMAP. ODT will leverage the work from the budgeting 2.0 initiative, TBM maturity, and strategic planning efforts to develop an agency-wide strategic planning process that will not only build the enterprise IT strategic plan but also inform the President's annual budget process.

Looking Ahead

TMAP and DMAP have provided important frameworks for the FDA's modernization over the past three years, the global pandemic notwithstanding. The agency has made meaningful progress in its digital transformation efforts during an era of unprecedented challenge and change. Our continued journey to the cloud and to a Zero Trust model, along TMAP's other objectives, will strengthen our technology infrastructure. DMAP, including the upcoming Enterprise Data Implementation Roadmap and the FDA AI strategy, will enhance our data posture. And as we continue to execute on the Plans, we will soon expand with EMAP, rounding out our robust modernization agenda. Through a focus on strategy and execution, the contributions of more than 500 ODT employees, and strong partnerships across the 18,000-strong FDA workforce and a diverse list of stakeholders, the FDA is proud of its progress and anticipates continued positive momentum. With an emphasis on collaborating as partners, through TMAP and DMAP – and soon EMAP – the FDA and ODT remain focused on delivering the safest and very best technology and data services to help the FDA advance its mission to protect public health.