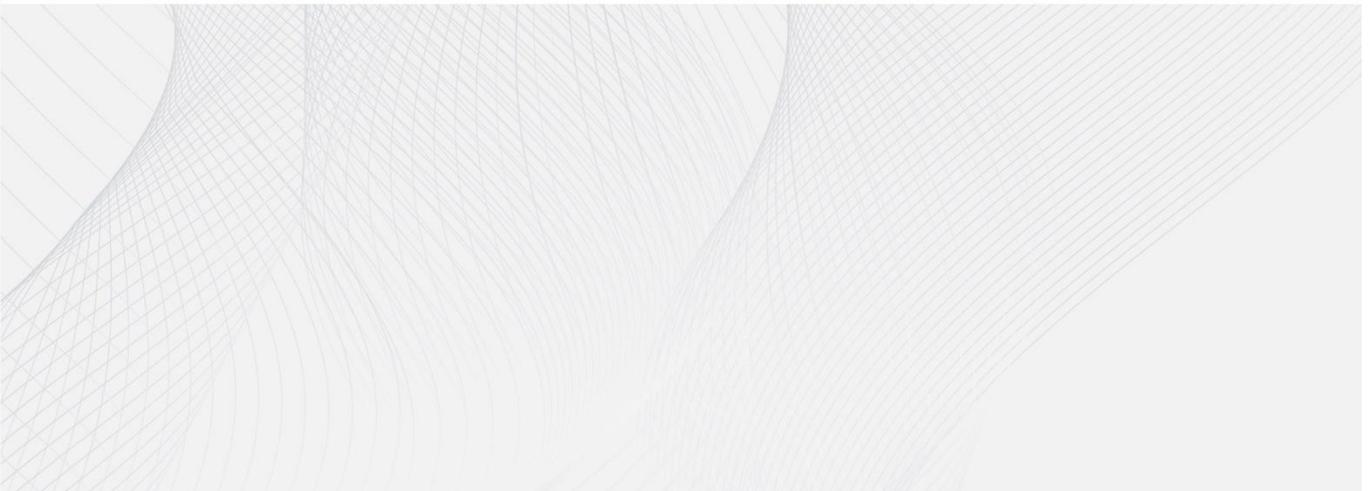


**FDA Information Technology
Strategy for Fiscal Years
2024 to 2027**



Message from the CIO



I am pleased to share the FDA IT Strategy for FY 2024 – FY 2027. This enterprise plan, shaped by FDA’s Centers and Offices and external stakeholders, will guide FDA’s Information Technology (IT) direction and investments for the next four years. Over 250 stakeholders provided input into developing the FDA IT Strategy through discovery sessions with IT and business leaders across the FDA, internal surveys, and a Federal Register request for information. FDA IT’s inclusive approach resulted in a set of goals and objectives designed to drive public health outcomes while meeting the needs of FDA’s diverse stakeholders. We plan to revisit this strategy annually to adapt and align with internal and external changes.

We are not beginning from a blank canvas – FDA IT’s [modernization framework](#) provides a strong foundation for what is to come. This framework takes a shared enterprise approach to drive business outcomes by focusing on action plans for technology, data, enterprise, cybersecurity, and leadership. I am incredibly proud of the significant advancements in FDA’s technology maturity during unprecedented challenges and change.

Technology’s role in promoting and protecting the health of the American people is only becoming more significant each year. The Centers and Offices within FDA, regulated industry partners, external collaborators, and others depend on the data and technology we provide to drive innovation, insights, and efficiency as they work to assure the safety, efficacy, and security of foods, drugs, and medical devices. As we reimagine the possible, FDA IT will transform how we align FDA’s technology with its business capabilities and needs while bolstering governance, modernizing critical systems, scaling IT solutions across the FDA enterprise, enabling data sharing, and leveraging emerging technologies.

The macro-environment we operate in is complex. We are responding to rapid advancements and changes in demand from FDA’s regulated industries, competing for scarce IT talent, understanding use cases for emerging technologies (such as artificial intelligence (AI)), enabling business process modernization, optimizing investment management, and continuing to break down barriers to data sharing and collaboration, all while protecting the assets, intellectual property, and personal information the public entrusts us with. We must enforce more robust governance, become more agile and think differently to narrow the gap between current IT capabilities and the rapid pace of innovation and technology advancements to continue protecting the American people.

With this strategic plan, we will build on the foundation established through FDA IT’s modernization framework to lead the FDA through the next phase of the Agency’s evolution. FDA IT’s Operating Plan will define an IT roadmap with a combination of projects already in progress and new projects. We will execute FDA’s IT roadmap in phases to make measured progress against the IT goals and objectives we define within this strategy.

Vid Desai
Chief Information Officer
Office of Digital Transformation



We need the ability to create systems that allow us to keep up with the complexities of the industries and products we regulate with immense consequences for the health of all Americans.

Robert M. Califf M.D., M.A.C.C.,
Commissioner of Food and Drugs for the
Food and Drug Administration



Executive Summary



Advancing Public Health Outcomes Enabled by Technology, Powered by Data

Food & Drug Administration (FDA) Information Technology (IT) Strategy



V I S I O N

Unleash FDA's technology and data potential to improve health for all.



M I S S I O N

Empower stakeholders to safeguard public health through high quality, secure technology, and data capabilities.

FDA IT Strategic Goals and Objectives

1. Create a Shared OneFDA Ecosystem	2. Strengthen IT Infrastructure	3. Modernize Enterprise Services and Capabilities	4. Share Data for Mission Outcomes	5. Adopt AI and Mission-Driven Innovations	6. Cultivate Talent and Leadership
 <ul style="list-style-type: none"> Enhance Communication and Collaboration Promote Transparency Optimize Investments Strengthen Governance 	 <ul style="list-style-type: none"> Provide Flexible Infrastructure Offerings Accelerate Cloud Adoption Ensure Service Availability Implement Zero Trust Approach 	 <ul style="list-style-type: none"> Increase Business Alignment Scale Operations Increase Digital Maturity Improve Customer Experience Modernize FDA Cybersecurity Defenses Reduce Technology Debt 	 <ul style="list-style-type: none"> Enhance Data Governance Foster OneFDA Data Literacy Improve Data Visibility and Accessibility Enable Advanced Data Analytics Enhance Secure Data Exchange 	 <ul style="list-style-type: none"> Balance Policy and Technology Value Ensure Responsible Use of Innovations Provide Thought Leadership Foster Innovation 	 <ul style="list-style-type: none"> Instill OneFDA Mindset Attract and Retain Talent Hire and Develop Resilient Leaders Develop Skills for the Future of Work

Strategic Direction



U.S. Department of Health and Human Services (HHS) agencies are enhancing the health and well-being of all Americans amidst an evolving public health landscape. The U.S. Food and Drug Administration (FDA), specifically, is focused on protecting public health by ensuring the safety, efficacy, and security of human and veterinary drugs, biological products, and medical devices. The FDA also safeguards the nation's food supply, cosmetics, and products that emit radiation.

A Case for Change

Across all these areas, science is evolving fast, technology and data environments are transforming rapidly, and regulations are changing to keep pace. FDA's aging infrastructure, systems, and equipment need help to keep up. Outdated data exchange practices, unstructured data submissions, and undue limitations on data sharing are just a few of the roadblocks to unlocking the value of data-driven insights. We must accelerate FDA's digital transformation journey to better support FDA's business, technology, and regulatory needs today while proactively enhancing and developing new IT capabilities to drive FDA's public health mission forward.

IT Vision and Mission

In alignment with HHS's IT strategy and FDA's mission, this IT strategy will leverage technology — powered by data — to drive public health outcomes as described in FDA IT's vision and mission.

FDA IT Vision

Unleash FDA's technology and data potential to improve health for all.

FDA IT Mission

Empower stakeholders to safeguard public health through high quality, secure technology, and data capabilities.

To accomplish all of this, we will pursue six strategic goals.

Strategic Goals

1 — Create a Shared OneFDA Ecosystem

Description:

Establish greater access to trusted data and shared resources across Centers, Offices, and external stakeholders. Encourage and facilitate cross-functional investment in technology to support enterprise business objectives for speed, scale, and value through robust Agency level governance processes, enhanced collaboration channels, and technology products and services. Shift FDA’s culture to make sharing across Centers and Offices and with external stakeholders (where relevant) the norm - where prioritizing Agency-level public health outcomes improves results for everyone.



Objectives:

1. **Enhance Communication and Collaboration:** Foster information and resource sharing with internal and external stakeholders to achieve both agency and specific stakeholder outcomes, using a variety of communication channels to reach broader audiences. Enable collaboration and develop strong partnerships across Centers and Offices through integrated technologies and platforms.
2. **Promote Transparency:** Actively involve impacted stakeholders in IT solution planning, development, and execution to drive expected outcomes.
3. **Optimize Investments:** Align the diverse needs across FDA to the overarching strategy through stronger financial fidelity, enhanced budget coordination, and improved financial planning. Ensure effective IT resource utilization, transparency in IT budget allocation, and measurement of results achieved.
4. **Strengthen Governance:** Ensure the effective and efficient use of IT in enabling the FDA to achieve mission outcomes through established standards, responsible procurement, and more robust decision-making and accountability mechanisms.

2 — Strengthen IT Infrastructure

Description:

Continue to modernize and secure the foundational IT infrastructure for all IT services and solutions. Proactively provide the ability to adapt to changes in workload demand, detect issues before they impact stakeholders, and quickly resolve technology issues to avoid disruptions to day-to-day operations.



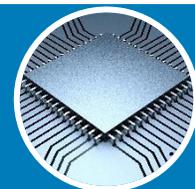
Objectives:

1. **Provide Flexible Infrastructure Offerings:** Provide a marketplace with usage-based models for users to identify and implement the infrastructure solutions based on their business requirements with an appropriate chargeback model.
2. **Accelerate Cloud Adoption:** Empower users with cloud offerings to meet their mission needs, e.g., scalability and agility. Provide best practice guidance on cloud models, e.g., hybrid and transition strategies based on the unique needs across Centers and Offices.
3. **Ensure Service Availability:** Provide stable access to IT services through proactive, continuous monitoring of IT infrastructure service performance (e.g., Service Level Agreements, Operating Level Agreements) and feedback from FDA users to identify potential problems and implement targeted improvements.
4. **Implement Zero Trust Approach:** Establish a comprehensive zero trust and risk-based approach to obtain optimal maturity level by upgrading, modernizing, and enhancing FDA's security and cyber defenses.

3 — Modernize Enterprise Services and Capabilities

Description:

Optimize the IT services portfolio to support everyday needs with cross-cutting, mission-critical offerings and benefit from economies of scale. Ensure enterprise IT services are stable, resilient, and adaptive, with opportunities for stakeholders to tailor solutions, where appropriate, and feedback loops to drive continuous improvement.



Objectives:

1. **Increase Business Alignment:** Lead with a business-first approach to modernizing enterprise services and capabilities to ensure technology enables the capabilities defined in FDA's Business Capability Model and supporting business processes.
2. **Scale Operations:** Develop and drive adoption of enterprise solutions for standard capabilities, e.g., Finance/Budget, Human Resources, Acquisitions, Inspections, Freedom of

Information Act requests, and Complaints Management with continuous user testing while providing flexibility for customization where relevant. Manage the lifecycle of applications within the enterprise portfolio.

3. **Increase Digital Maturity:** Maximize the use of technology (e.g., data, automation) in core business areas and enable processes to improve their ability to adapt to changes and scale.
4. **Improve Customer Experience:** Create customer-centric solutions that enhance satisfaction by improving accessibility to IT solutions, including external-facing systems (e.g., Electronic Submission Gateway Next Generation), streamlining processes, and easing adoption. Increase stakeholder engagement with FDA IT services by prioritizing customer and employee feedback and establishing formal feedback loops.
5. **Modernize FDA Cybersecurity Defenses:** Upgrade, enhance, and modernize FDA’s critical cyber defenses and practices to address the evolving threat landscape where risks to FDA’s critical assets, industry, and sensitive data exist.
6. **Reduce Technology Debt:** Decommission legacy systems, applications, and End-of-Life (EoL) devices and reinvest in enterprise solutions and business process improvements to minimize technical debt and enterprise risk.

4 — Share Data for Mission Outcomes

Description:

Identify common data assets critical to stakeholders across FDA and make them widely available and consumable to drive operational efficiencies and excellence. Leverage valuable data assets and insights to develop new capabilities and services and enable public health innovation.



Objectives:

1. **Enhance Data Governance:** Implement AI-powered best practices for governance and enterprise data management that improve data quality, security, and the speed and accuracy of insights and decisions.
2. **Foster OneFDA Data Literacy:** Educate the workforce on best practices and the benefits of consuming, analyzing, and making data-based decisions.
3. **Improve Data Visibility and Accessibility:** Prioritize which data assets to make widely available first based on value to the mission and the most significant number of stakeholders.
4. **Enable Advanced Data Analytics:** Ensure experts can easily combine and analyze information from various internal and external sources to gain comprehensive insights.
5. **Enhance Secure Data Exchange:** Improve interoperable and secure data exchange and collaboration across FDA and its public health partners.

5 — Adopt AI and Mission-Driven Innovations

Description:

Drive exploration and address impacts of emerging technologies and trends such as AI and virtual reality on the FDA’s IT portfolio and regulatory operations. Proactively identify opportunities and risks to FDA’s mission and inform responsible use of technology. Enhance partnerships with external experts to leverage these technologies and promptly respond to their impact.



Objectives:

1. **Balance Policy and Technology Value:** Develop ethical guidance for technology use while maximizing business value, such as guidance on AI strategy. Ensure responsible actions by conducting comprehensive research and analysis to fully understand technological advancements’ potential impacts and implications on society.
2. **Ensure Responsible Use of Innovations:** Deploy technological innovations, such as AI/Machine Learning (ML), responsibly with an understanding of regulatory impacts and effective risk response strategies. Establish appropriate guardrails where necessary.
3. **Provide Proactive Thought Leadership:** Lead as a partner in creating novel use cases for emerging technologies through a deep understanding of business processes, industry, and technology. Stay at the forefront of technological advancements by harnessing industry expertise and fostering collaboration.
4. **Foster Innovation:** Create an environment where innovative approaches are encouraged, identified, shared, and evaluated for use in driving operational efficiency and developing new capabilities. Apply a structured process to manage the innovation lifecycle from ideation to investment to adoption (or project shutdown) to produce usable innovations.

6 — Cultivate Talent and Leadership

Description:

Mature Agency-wide IT competencies to deepen technology expertise and keep pace with the accelerated rate of change in FDA’s regulated industries and technology. Develop holistic leaders equipped to lead through change and drive FDA’s digital transformation journey forward. Deliver enterprise IT services with an Agency-first mindset. Given the continued competition for talent, proactively build a robust talent pipeline for targeted roles leveraging a combination of recruitment, retention, and talent development strategies.



Objectives:

1. **Instill OneFDA Mindset:** Cultivate an Agency-first approach to IT so that decisions promote and protect the health of the American people first and foremost.
2. **Attract and Retain Talent:** Build a diverse talent pipeline through a compelling employee value proposition and total compensation approach, talent acquisition, employee engagement, and talent development strategies. Drive improvements across the employee lifecycle from recruitment to retirement.
3. **Hire and Develop Resilient Leaders:** Strengthen leadership competencies required to drive holistic transformational IT initiatives in a dynamic environment successfully.
4. **Develop Skills for the Future of Work:** Develop IT skills and competencies required to deliver current and future IT services through upskilling, reskilling, and continuous learning.

Looking Ahead



FDA IT's strategy reflects a bold, ambitious set of goals that focuses on strengthening the FDA's foundation while preparing for the future. Culturally, this strategy is a paradigm shift from an ODT-only IT strategy to an enterprise IT strategy designed and driven in collaboration with FDA's Center and Office partners. Together, FDA's empowered IT leaders and teams from across FDA will advance the continued transformation of the FDA's IT capabilities, operations, and organization – continuing to build upon the foundation established through FDA IT's modernization framework.

As we progress, FDA IT's strategy will underpin governance decisions on budget formulation, investments, and resource allocation to focus on the highest priority areas for FDA's public health mission. FDA's Technology Council with agency-wide decision makers, and recently formed Technology Business Management Center of Excellence, will play critical roles in aligning FDA's investments to this strategy and reporting on FDA's progress.

FDA IT's Operating Plan, a companion to this strategy, defines tactical guidance for governance and execution. It includes a roadmap of the in-progress and upcoming initiatives and metrics for each IT strategic goal. We will revisit this plan annually and refine it to maintain relevance.

Thank you to the 250+ stakeholders across HHS, FDA, industry, vendors, and the public who contributed to developing the FDA's first-ever Agency-wide IT Strategy.

Vid Desai
Chief Information Officer
Office of Digital Transformation