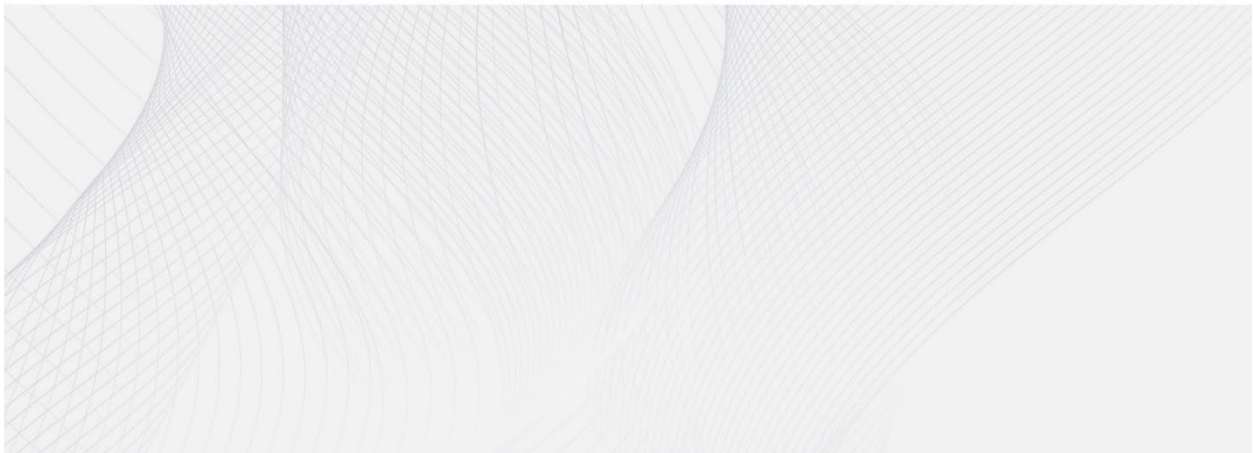


**FDA Information Technology
Strategy for Fiscal Years
2024 to 2027**



Message from the CIO



I am pleased to share our annual publication of the FDA IT Strategy for FY 2024 — FY 2027. This enterprise plan, shaped by the FDA's Centers and Offices and external stakeholders, will guide the FDA's Information Technology (IT) direction and investments through FY 2027. Over 250 stakeholders provided input into developing the first publication of our FDA IT Strategy through discovery sessions with IT and business leaders across the FDA, internal surveys, and Federal Register Requests for Information. We continue to elicit feedback during each refresh.

Our inclusive approach establishes a set of goals and objectives designed to drive public health outcomes while meeting the needs of the FDA's diverse stakeholders both nationally and globally.

I am incredibly proud of the significant advancements in the FDA's technology maturity. We will continue to revisit this strategy annually to build on our progress while adapting and aligning with internal and external changes.

Technology's role in promoting and protecting the health of the American people is only becoming more significant each year. The FDA's Centers and Offices, regulated industry, public health 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, the FDA IT team will transform how we align the FDA's technology with its business capabilities and needs while bolstering governance, modernizing critical systems, scaling IT solutions across the FDA's global 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 the 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 are building on the foundation we've established to lead the FDA through the next phase of the Agency's evolution. The FDA's IT Operating Plan, a companion to the IT strategy, defines an IT roadmap with initiatives we will execute to make measured progress against the IT goals and objectives within this strategy.

Vid Desai
Chief Information Officer
Office of Digital Transformation (ODT)



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



IT Strategy Executive Summary



Advancing Public Health Outcomes Enabled by Technology, Powered by Data

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



VISION

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



MISSION

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



FDA Strategic Goals, Objectives and Metrics

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

Objectives

<ul style="list-style-type: none"> Enhance Communication and Collaboration Promote Transparency Optimize Investments Strengthen Governance 	<ul style="list-style-type: none"> Provide Scalable and Efficient 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 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 Proactive 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
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Metrics

<ul style="list-style-type: none"> IT Strategy/ Operating Plan Updates & Progress Intake Process IT Budget Alignment Annual Business Reviews FDA Small Business Stakeholder Engagement External-facing Communications 	<ul style="list-style-type: none"> End-of-Life (Enol) Equipment Critical Services/ Applications Availability Electronic Submission Gateway (ESG) Availability Cloud Adoption Zero Trust Maturity Level Operations & Maintenance (O&M) Costs Network, Storage & Compute Spend 	<ul style="list-style-type: none"> IT Help Desk Customer Satisfaction Net Promoter Score Cyber Defense Modernization IT Development, Maintenance, & Enhancement (DME) vs. Operations & Maintenance (O&M) Spend Critical Services/ Applications Availability 	<ul style="list-style-type: none"> Data Sharing Assets and Partnerships Data Science Talent Third-party Data Services Costs 	<ul style="list-style-type: none"> Pending* 	<ul style="list-style-type: none"> IT Workforce Growth Rate GS to Title 21 Conversions Training Completion
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*Metric definition for Goal 5 is in progress.

FDA IT 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 and by ensuring the safety of our nation's food supply, cosmetics, and products that emit radiation. Our mission directly supports the HHS FY2022 – FY2026 Strategic Plan, the Office of Public Health Data, Surveillance, and Technology (ODHDST) Public Health Data Strategy, the FDA Center/Office-specific Strategic Plans and related strategies.

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. The FDA's aging infrastructure, systems, and equipment need help to keep up. Outdated data exchange practices, unstructured data submissions, disparate global standards and undue limitations on data sharing are just a few of the roadblocks to unlocking the value of data-driven insights. The FDA must accelerate its digital transformation to better support business, technology, and regulatory needs while proactively enhancing IT capabilities to advance its public health mission. As the FDA's IT transformation unfolds, stakeholders within the global public health ecosystem will benefit from efficient regulatory review, enhanced transparency and collaboration, dynamic data exchange for timely identification of public health needs, and effective management of emergent risks. The FDA will actively seek to increase engagement with international regulators to foster collaboration, share best practices and lessons learned, and ultimately promote global harmonization to realize these benefits.

IT Vision and Mission

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

FDA IT Vision

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

FDA IT Mission

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

To accomplish all of this, we will pursue six strategic goals to support the FDA's global mission needs.

Strategic Goals

1. Create a Shared OneFDA Ecosystem

Description:

Establish greater access to trusted data and shared resources across Centers, Offices, and external stakeholders¹. 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 the 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, Offices, and global public health partners.
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 the FDA to the overarching strategy through stronger financial fidelity, enhanced budget coordination, improved financial planning, and enterprise architecture. 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, alignment to global initiatives and standards where feasible, responsible procurement, streamlined processes, trustworthy AI, and more robust decision-making and accountability mechanisms.

¹External stakeholders include a broad range individuals, organizations, and entities that are not directly part of the FDA but have an interest or are affected by the FDA’s activities and decisions. This can include healthcare professionals, pharmaceutical companies, medical device manufacturers, patients and patient advocacy groups, consumer organizations, academic and research institutions, government agencies, regulatory bodies, and the general public.

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.



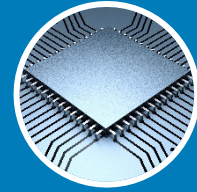
Objectives:

1. **Provide Scalable and Efficient Infrastructure Offerings:** Provide a marketplace with usage-based models for users to identify and implement cost-efficient 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, secure, and timely access to IT services through proactive, continuous monitoring of IT infrastructure service performance (e.g., Service Level Agreements, Operating Level Agreements) and feedback from the FDA users and global partners 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 the 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 benefits 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 the FDA's Business Capability Model and supporting business processes while optimizing alignment to global regulatory initiatives.
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) while providing flexibility for customization where relevant. Manage the life cycle 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, easing adoption, and considering regional-specific needs. Increase stakeholder engagement with the FDA's IT services by prioritizing external and internal feedback and establishing formal feedback loops.
5. **Modernize Cybersecurity Defenses:** Upgrade, enhance, and modernize the FDA's critical cyber defenses and practices (e.g., Zero Trust) to address the evolving threat landscape where risks to the 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 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. Advance adoption of global data standards to 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:** Make high-priority data assets widely available across the FDA and to its global public health partners in accordance with global regulatory policies and security controls.
4. **Enable Advanced Data Analytics:** Ensure experts can easily combine and analyze information from various FDA and non-FDA sources to gain comprehensive research insights to inform regulatory decision-making and actions.
5. **Enhance Secure Data Exchange:** Improve interoperable and secure data exchange and collaboration across the 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 the 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 and scientific impacts and effective risk response strategies. Establish appropriate guardrails where necessary including responsible AI principles for development, procurement and use of AI.
3. **Provide Proactive Thought Leadership:** Lead as a partner in creating novel use cases for emerging technologies through a deep understanding of business and research 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, global public health insights, and developing new capabilities. Apply a structured process to manage the innovation life cycle 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 the FDA’s regulated industries and technology. Develop holistic leaders equipped to lead through change and drive the 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, equity and inclusion, and talent development strategies. Drive improvements across the employee life cycle from recruitment to retirement. Expand pathways for students and early career professionals.
3. **Hire and Develop Resilient Leaders:** Strengthen leadership competencies required to drive holistic transformational IT initiatives in a dynamic environment successfully. Leverage career and succession planning to proactively identify, cultivate and retain a diverse cohort of future change leaders.
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



The FDA’s IT Strategy reflects a bold, ambitious set of goals that focuses on strengthening the FDA’s foundation while preparing for the future. By the end of 2027, the FDA’s IT Strategy aims to advance the FDA’s public health mission through enabling timely regulatory decisions, operational efficiencies in regulatory processes, increased public engagement and trust, and innovative and informed public health responses at enterprise scale. Culturally, this strategy is a paradigm shift from an ODT-only IT strategy to an enterprise IT strategy designed and driven in collaboration with the FDA’s Center, Office, and public health partners. Together, the FDA’s empowered IT leaders and teams from across the FDA will advance the continued transformation of the FDA’s IT capabilities, operations, and organization — continuing to build upon our progress achieved in the past year.

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

The FDA’s IT 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 our IT strategic goals. We will revisit this plan annually and refine it to maintain relevance.

Thank you to the 250+ stakeholders across HHS, the FDA, industry, vendors, and the public who continue to contribute to the FDA’s first-ever agency-wide IT Strategy.

Vid Desai
Chief Information Officer
Office of Digital Transformation