U.S. FOOD & DRUG ADMINISTRATION

Office of Digital Transformation

IT Operating Plan

Prepared for Food and Drug Administration

February 12, 2024

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INTRODUCTION

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Introduction

Message from the CIO

I am excited to share our Information Technology (IT) Operating Plan, a key pillar supporting our FDA Information Technology Strategy for Fiscal Years (FY) 2024 to 2027. This plan is more than a roadmap for our technological endeavors. It is a blueprint to execute and monitor our progress against our IT strategic goals to enhance our service to the public. It outlines the proactive role we play in leading IT, defines a set of transformative strategic initiatives and describes our approach to increasing transparency, collaboration, and accountability.

Successful execution of our IT Strategy and Operating Plan hinges on our collective efforts. Our IT organizations across FDA are joining forces to dismantle long-standing silos and lead the charge in leveraging technology and data to propel public health forward. While the path ahead is challenging; the potential to generate value for our internal and external stakeholders is immense and far outweighs any hurdles we will face.

Given the rapid changes in our environment from product innovations to technology advancements, we will re-visit both our IT Strategy and our IT Operating Plan on a regular cadence. We have the most clarity for our FY24 – FY25 IT Roadmap now; however, I anticipate rapid changes for FY26 – FY27 as we go through our annual Capital Planning and Investment Control (CPIC) Select processes to identify and prioritize IT projects. It is also important to note, additional refinements to FY24 - FY25 will be necessary following approval of the federal budget.

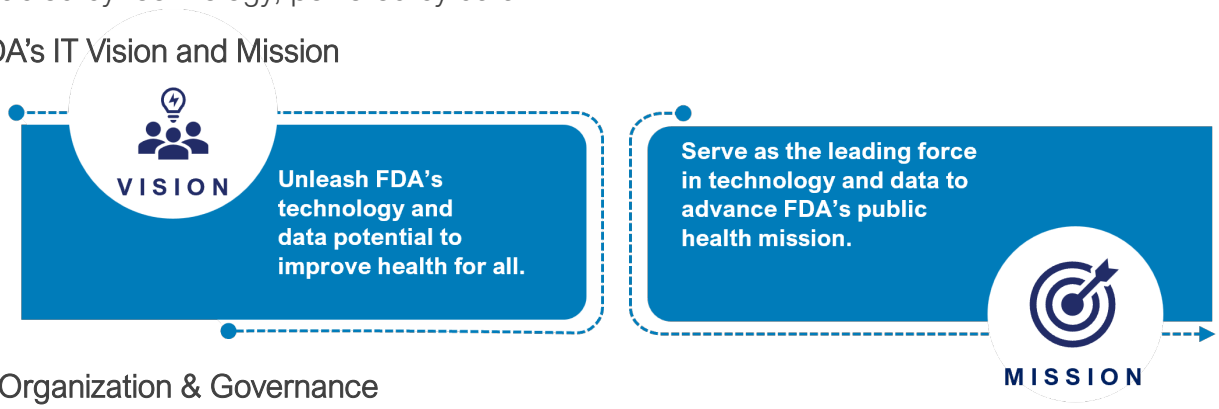
I am extremely proud of the progress we continue to make on our journey and filled with anticipation for what we will accomplish together over the next four (4) years. I extend my heartfelt gratitude for your unwavering support and commitment to our mission.

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

Executive Summary

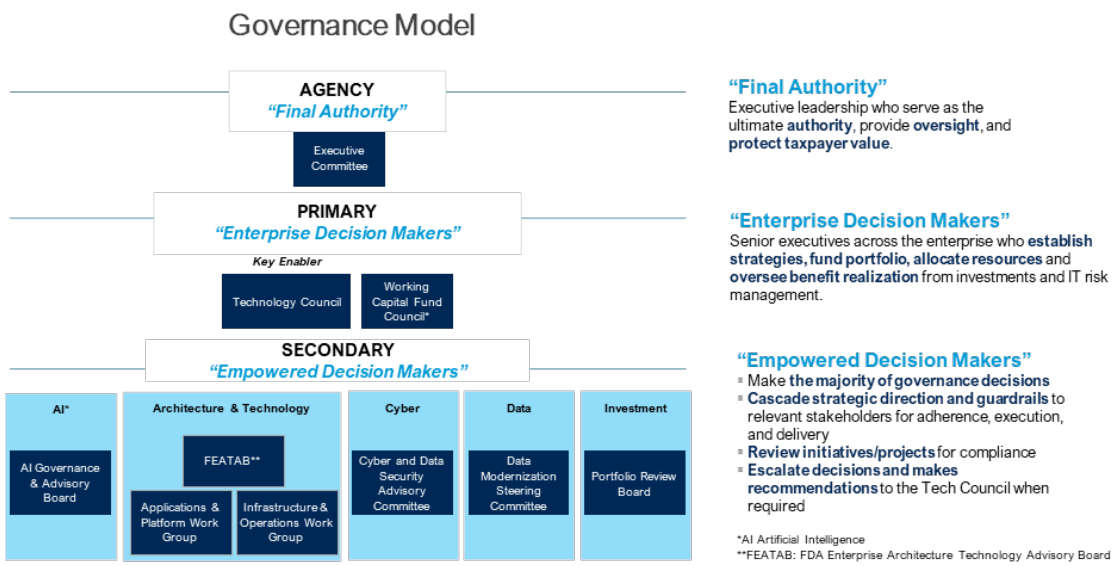
This Information Technology (IT) Operating Plan is a companion to the Food and Drug Administration (FDA) IT Strategy, published in September 2023. This plan is a blueprint designed to guide our organization's technological growth and development in accordance with FDA's IT strategic goals. It encompasses an IT strategic roadmap, governance and organization construct as well as a performance measurement process designed to advance public health outcomes - enabled by technology, powered by data.

FDA's IT Vision and Mission



IT Organization & Governance

With a bold vision and mission, IT's role is evolving from a technology hub providing basic services to a value-added business partner and service provider. Operating under a federated model, FDA IT is executed by the Office of Digital Transformation (ODT), headed by the Chief Information Officer (CIO), along with nine (9) distributed Center/Office IT organizations. FDA's IT governance model establishes the framework for decision-making and accountability across the Agency's complex portfolio of both enterprise and Center-specific IT investments. Using the Technology Council as a focal point, it ensures FDA's technology investments are aligned with its strategic objectives. The CIO serves as the Technology Council Chair and is a member of the Executive Committee, the seniormost governing body across all of FDA.



Executive Summary

IT Strategy & Roadmap

- FDA's IT Strategy identified six (6) strategic goals and associated objectives. This plan builds upon those goals with a comprehensive set of 13 strategic IT initiatives designed to have a transformative impact. Led by an Executive Sponsor, each initiative contains multiple projects with varying durations across the FY24 – FY27 planning horizon. While some projects are funded and underway, other mission critical projects are pending funding. FDA will use the Capital Planning and Investment Control (CPIC) Select process to secure funding for high priority projects driving outcomes aligned to IT's strategic goals.
- FDA also defined a targeted set of metrics to assess the effectiveness of its IT Strategy in delivering value to stakeholders. In combination with existing measures, FDA will use these metrics to evaluate progress against IT strategic goals, identify opportunities for improvement and make informed decisions on resource allocation, adjustments to strategy and other critical areas as needed.

	Goals	Objectives	Initiatives*	Metrics**	*Risk* if Not Implemented*
1	**Create a Shared OneFDA Ecosystem**	▪ Enhance Communication and Collaboration ▪ Promote Transparency ▪ Optimize Investments ▪ Strengthen Governance	1.1 Strategy & Governance 1.2 Acquisitions & Vendor Management 1.3 Internal/External Communications	▪ IT Strategy / Operating Plan Updates & Progress ▪ Intake Process ▪ IT Budget Alignment ▪ Annual Business Reviews ▪ FDA Small Business ▪ Stakeholder Engagement ▪ External-facing Communications	High
2	**Strengthen IT Infrastructure**	▪ Provide Flexible & Scalable Infrastructure Offerings ▪ Accelerate Cloud Adoption ▪ Ensure Service Availability ▪ Implement Zero Trust Approach	2.1 Stabilization/EoL/EoS 2.2 Cloud Transformation 2.3 Electronic Submission 2.4 Zero Trust	▪ End-of-Life (EoL) Equipment ▪ Critical Services/ Applications Availability ▪ ESG Availability ▪ Cloud Adoption ▪ Zero Trust Maturity Level ▪ O&M Costs ▪ Network, Storage & Compute Spend	High
3	**Modernize Enterprise Services and Capabilities**	▪ Increase Business Alignment ▪ Scale Operations ▪ Increase Digital Maturity ▪ Improve Customer Experience ▪ Modernize FDA Cybersecurity Defenses ▪ Reduce Technology Debt	3.1 Total Experience Enhancements (UX/CX) 3.2 System Modernization	▪ User Satisfaction with Enterprise/Center Services ▪ Net Promoter Score ▪ Cyber Defense Modernization ▪ IT Development, Maintenance & Enhancement (DME) vs. Operations & Maintenance (O&M) Spend	Medium
4	**Share Data for Mission Outcomes**	▪ Enhance Data Governance ▪ Foster OneFDA Data Literacy ▪ Improve Data Visibility and Accessibility ▪ Enable Advanced Data Analytics ▪ Enhance Secure Data Exchange	4.1 Enterprise Data Services	▪ Data Sharing ▪ Assets and Partnerships ▪ Data Science Talent ▪ Third-party Data Services Costs	Medium
5	**Adopt Artificial Intelligence and Mission-Driven Innovations**	▪ Balance Policy and Technology Value ▪ Ensure Responsible Use of Innovations ▪ Provide Proactive Thought Leadership ▪ Foster Innovation	5.1 Artificial Intelligence Executive Order Implementation & Governance 5.2 Emerging Technologies	▪ Investment in Innovation *Note: AI is in its early days. As FDA expands its understanding and use of AI, it will revisit AI-specific metrics for this goal.*	Low
6	**Cultivate Talent and Leadership**	▪ Instill OneFDA Mindset ▪ Attract and Retain Talent ▪ Hire and Develop Resilient Leaders ▪ Develop Skills for the Future of Work	6.1 Workforce Modernization	▪ IT Workforce Growth Rate ▪ GS to Title 21 Conversions ▪ Training Completion	High

*See IT Roadmap section for additional details on strategic initiatives and risks.
**See Performance Measurement & Monitoring for additional details on metrics

Executive Summary *(Continued)*

Challenges

The macro-environment FDA operates in presents several challenges. Successful execution of the IT Roadmap will significantly reduce the impact of these challenges.

Challenge	Goal Alignment	Mitigation
▪ Rapidly respond to changes e.g., technology advancements, changes in demand from its regulated industries	Goals 1, 3, 5	Strategic Initiatives* 1.3, 3.2, 5.1, 5.2
▪ Transform to a OneFDA IT culture where knowledge, resources and expertise are shared to advance FDAs public health mission and reduce duplication of effort and fragmentation	Goal 1, 6	Strategic Initiatives 1.1, 1.3, 6.1
▪ Break down barriers to data sharing and collaboration	Goal 2, 4, 5	Strategic Initiatives 2.4, 4.1, 5.1, 5.2
▪ Overcome budget constraints	Goal 1, 6	Strategic Initiatives 1.1, 1.2, 1.3, 6.1
▪ Compete for scarce IT talent	Goal 6	Strategic Initiative 6.1
▪ Modernize aging processes, systems and equipment	Goal 2, 3	Strategic Initiatives 2.1, 2.2, 2.3, 2.4, 3.2

> It's not just process improvement. You do have to replace boxes and you have to update processes, but what you really need to change is the culture. And that is the part that is hard to do.
>
> *Vid Desai, Chief Information Officer, Office of Digital Transformation*

FDA identified challenges with project-level data availability and quality due to lack of compliance with enterprise IT governance programs. Specifically, limited project milestone, risk and metric data exists. As a result, Strategic initiative 1.1 was expanded to include collection and validation of additional project data.

Looking Ahead

- With technology playing a pivotal role in food, drug, and medical devices' safety, this plan describes how FDA will execute on its vision for excellence. Developed in collaboration with Centers/Offices and reflecting input from external stakeholders, this is a monumental next step in evolving the technological landscape. FDA anticipates future iterations of the IT Operating Plan will become more robust as data quality improves for the IT Roadmap.
- FDA will refresh this plan on an annual basis, at a minimum, using a structured process to assess the impact of changes in the macro-environment, leverage input from internal and external stakeholders and prioritize IT Roadmap initiatives and projects through the Technology Council.

*See prior page for Goals and Strategic Initiatives

Section I

IT Strategy

Vision and Mission

VISION

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

Serve as the leading force in technology and data to advance FDA's public health mission.

MISSION

IT Strategy Goals and Objectives

Advancing Public Health Outcomes
Enabled by Technology, Powered by Data

Key Challenges

Rapidly Changing Environment

FDA is functioning in an increasingly fast paced environment where evolving product innovations coupled with rising threats to security, privacy, and data are expected, but not predictable. With archaic business processes in some areas, the benefits technology alone can provide are limited. If FDA does not quickly scale to address rapid growth in submission volumes, proactively understand emerging trends and modernize business processes, it could delay timely response to and public communication on threats. (Aligned to Goal 1, 3, 5; Mitigated by Strategic Initiatives 1.3, 3.2, 5.1, 5.2)

Budget and Costs

While FDA has a unified mission of protecting public health, Centers/Offices are tackling the challenge from diverse perspectives. Funds are often allocated with a Center/Office-specific purpose, which creates hurdles to funding cross-cutting Agency initiatives. This is compounded by persistently high inflation which has led to higher costs for vendor support, IT hardware, and software and other nonlabor costs - increasing internal financial risk. (Aligned to Goal 1, 6; Mitigated by Strategic Initiatives 1.1, 1.2, 1.3, 6.1)

Talent

In a tight labor market, funding constraints have cascading effects on attracting and retaining talent with high demand IT skills who require competitive compensation. The resulting labor shortages and talent gaps can, in turn, lead to overreliance on contractors, increased knowledge attrition, disruptions in quality IT service delivery and ultimately inhibit FDA's ability to perform the core functions of regulatory review and scientific operations. (Aligned to Goal 6; Mitigated by Strategic Initiative 6.1)

Aging Systems and Equipment

Due to individual and duplicative Center/Office investments, FDA has many legacy systems and equipment reaching end of life/end of service across the agency that require modernization or even replacement. Without scalable solutions/services and proactive replacement of end of life/end of service components to address this technical debt, FDA will struggle to adapt to emerging trends and inform regulatory action on advanced technologies in an agile manner, on top of a high risk of cybersecurity breaches. (Aligned to Goal 2, 3; Mitigated by Strategic Initiatives 2.1, 2.2, 2.3, 2.4, 3.2)

Data Sharing

There is a need to expand data sharing internally within FDA and externally with industry, accelerate access to advanced technologies such as artificial intelligence, and strategically reuse data to enable new insights. If FDA cannot meet this need, it will be at a disadvantage in predicting and pre-emptively acting on public health crises and enabling scientific advancements; putting citizens lives at risk. Further, these opportunities must be balanced with security and risk, otherwise unauthorized transmission of sensitive data can have negative impacts on public trust. (Aligned to Goal 2, 4, 5; Mitigated by Strategic Initiatives 2.4, 4.1, 5.1, 5.2)

Siloed Culture

FDA continues to make progress establishing a OneFDA culture. However, there are still siloes in some cases. These silos impede cross-FDA collaboration, sharing, and governance of IT resources in line with strategic goals. (Aligned to Goal 1, 6; Mitigated by Strategic Initiatives 1.1, 1.3, 6.1)

Section II

IT Organization

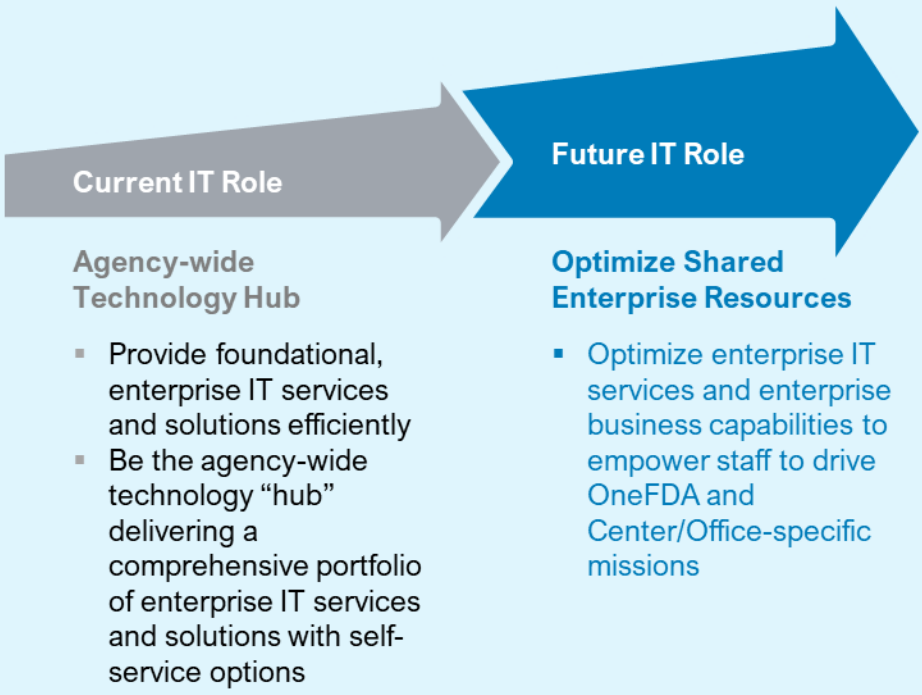
IT Organization

Execution of the IT Strategy is delivered through a central IT organization, the ODT, headed by the CIO, along with nine (9) distributed Center/Office IT organizations.

- ODT is comprised of the Office of Information Management and Technology (OIMT), Office of Data, Analytics, and Research (ODAR), and the Office of Information Security (OIS), under the direction of the Chief Technology Officer (CTO), Chief Data Officer (CDO), and Chief Information Security Officer (CISO) respectively.
- The Center/Office IT organizations are typically led by an Associate Deputy CIO (ADCIO). The scope, size and maturity of these IT organizations varies greatly based on the need for mission-specific IT solutions and funding.

The broader combination of ODT and Center/Office IT organizations are referred to as "FDA IT" within this plan. View this organization chart to see all Centers/Offices across FDA.

To achieve its mission, FDA IT is continuing to expand its role from a technology hub providing basic services, to a value-added business partner and service provider optimizing IT services and enterprise business capabilities across the Agency. Collectively, FDA IT will focus on business enablement, proactively identify opportunities for optimization, and promote customer experience across the IT portfolio. Through efficient resource sharing and management across the Agency, FDA IT will supply the necessary infrastructure, systems, and tools to deliver core, enabling and strategic business capabilities.



IT Organization
Federated Structure

FDA IT is steadily transitioning from a decentralized model to a federated model. In the federated model, Centers/Offices operate under a unified enterprise IT governance framework with standardized policies and guidance. See below for ODT and Center/Office responsibilities:

- ODT directs and coordinates enterprise strategic planning, policy, and resource management to ensure technology, data, and cybersecurity investments and activities provide maximum value to FDA. As an initial step forward on creating a OneFDA Shared Ecosystem (Goal #1), ODT will place an increasing focus on centralizing enterprise IT services and solutions and improving core enterprise business capabilities to include Human Resources (HR), Finance, Centralized Submissions Portals, Inspections, Imports, and Food Services
- Each Center/Office-specific IT organization focuses on the unique mission of their respective Center or Office, led by their ADCIO, while also operating as a vital component of FDA IT, guided by the CIO.
- ODT, through the Technology Council, will provide governance for enterprise IT services delivered by Centers/Offices e.g., Office of Regulatory Affairs' (ORA), Office of Operations (OO) to promote consistency, limit duplication of effort and provide subject matter expert support. All Centers/Offices adhere to this enterprise IT governance framework to ensure their activities are aligned with FDA's mission and the recently established IT strategic goals.

The CIO and ADCIOs work together to ensure seamless information flow and strategic alignment across the Agency through the Technology Council and other channels. The CIO has final authority over the IT portfolio as described in the Chief Information Officer Delegation of Authorities and Communication of Responsibilities to Operating Division memo from the HHS CIO dated March 2023. This delegated authority includes responsibilities reflected in Federal Information Technology Acquisition Reform Act (FITARA) and Executive Order Number 138332. The ADCIOs support development and execution of the enterprise IT strategy and design and execute Center-specific IT strategies aligned to the enterprise vision.

See appendix for details on ODT's IT Skills Assessment which categorized essential skills and competencies for a technology workforce and identified gaps.

Section III

IT Governance & Budget

IT Governance

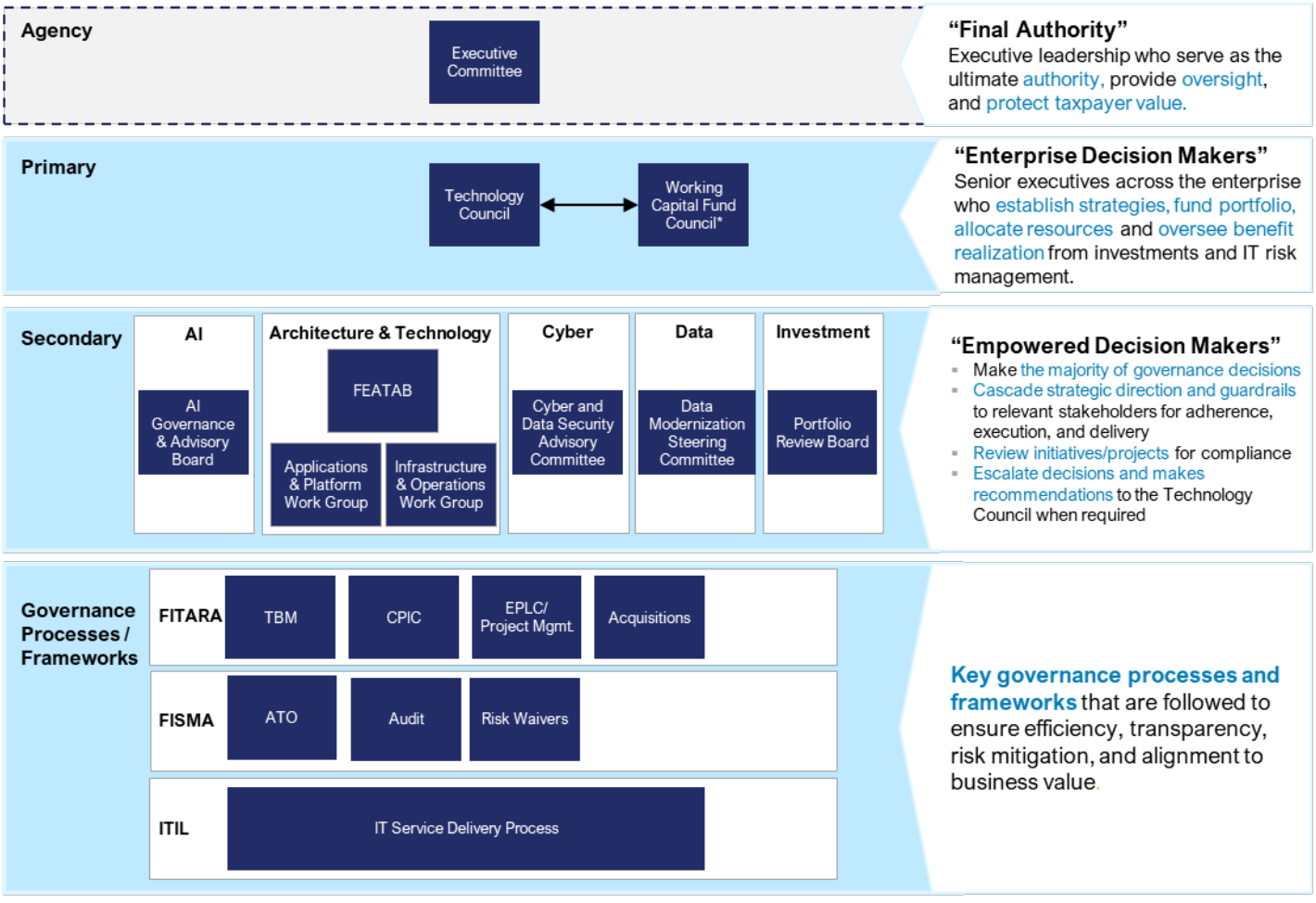
FDA's agency-wide IT governance framework defines the IT decision-making processes for its complex portfolio of both enterprise and Center-specific IT investments. This governance framework describes the "what" and "how" of IT decision-making within FDA. The IT governance framework is driven by three (3) key objectives:

- Align IT investments with strategic goals and the Technology Business Management (TBM) framework to actualize business value
- Ensure the effective use of IT resources
- Manage risks effectively

FDA IT's governance bodies are organized into tiers which address different IT domains to streamline decision making, assign decisions to the bodies with the relevant subject matter expertise and authority and optimize information exchange with the Centers/Offices (e.g., data calls). The framework highlights the governing bodies most critical to the IT strategic planning and execution as FDA IT shifts to a OneFDA shared ecosystem. Central to the framework is the Technology Council, which has an agency-wide scope. See "Primary & Secondary Governance Tiers" in this section for additional details.

The IT Roadmap includes Strategic initiative 1.1 Strategy & Governance to address known challenges in the existing governance framework.

IT Governance Framework



**Makes investment decisions related to IT WCF funds*

Agency Governance Tier

The Agency tier serves as a final authority for governance decisions.

- The Executive Committee provides oversight and direction on cross-cutting operational issues, strategic challenges, and scientific and policy issues for FDA. It also makes investment decisions for IT investments over $30 million. Its membership consists of senior executive leadership across the agency including the Commissioner, CIO, Center Directors, Office Leaders, and other executive level staff.

Primary & Secondary Governance Tiers

Primary Governance Tier

The Primary tier serves as the key decision makers for IT strategic direction and investments.

- The **Technology Council** is an executive level board that sets IT direction, makes investment decisions, and aligns IT to strategic direction. It includes representatives across Centers/Offices (typically ADCIOs and/or Executive Officers), and the Scientific Computing Board as voting members to promote an enterprise perspective. The CIO or his/her designee chairs the Technology Council. The Council has the following responsibilities:
  - Establish IT vision and drive IT strategy
  - Make decisions on IT investments between $5-$29M or high impact/priority investments below $5M
  - Ensure Center/Office IT strategies are aligned with FDA's IT goals and objectives
  - Resolve escalations when consensus is not achieved in lower governance bodies
  - Improve agency-wide IT communications
  - Establish subcommittees and working groups as needed
- The **Working Capital Fund Council (WCFC)** is an executive-level board, with a broader remit than IT. It plays a pivotal role in determining the level of funding for IT working capital funds. Its membership includes the Chief Operating Officer (COO), Chief Financial Officer (CFO), Deputy Chief Financial Officer (DCFO), CIO, a Center Co-Chair, and Center Directors. As part of its IT remit, it provides IT funding for a wide array of centrally administered services across FDA's programs that can reduce redundancy, achieve economies of scale, and incorporate consumption-based services tracked by usage and cost data. Key technology-based innovation needs are addressed by the WCFC including big data and analytics, cloud and high-performance scientific computing, mobility, digitization, and open data.

Secondary Governance Tier

The Secondary tier primarily serves as advisors in their subject matter expertise by making recommendations, decisions, and developing technology standards for the organization to follow across key IT domains: Artificial Intelligence (AI), Architecture and Technology, Cybersecurity, Data, and IT Investments.

- **AI**: The **AI Governance & Advisory Board** serves to advance the safe, ethical, and effective deployment of Artificial Intelligence (AI) at the FDA to further its public health mission. The voting membership of the board consists of representatives across Centers/Offices who are subject matter experts in AI. Non-voting members include advisors and experts in legal, ethics, privacy, security, and Diversity, Equity, and Inclusion (DEI) domains to provide balanced recommendations on AI use that follow legal and regulatory requirements.

Secondary Governance Tier

- Architecture and Technology: The FDA Enterprise Architecture Technology Advisory Board (FEATAB) serves as the enterprise-level advisory body on architecture and technology recommendations e.g., architecture reviews and standards. Its voting membership comprises of technically and financially astute representatives from each Center along with the Chief Technology Officer (CTO) as chair and a rotating Center representative as Co-Chair. The Applications & Platform Work Group and Infrastructure & Operations Work Group provide inputs and recommendations for FEATAB consideration.
- Cybersecurity: The Cyber and Data Security Advisory Committee assists the FDA Cybersecurity, Counterintelligence, and Insider Threat Program in a collaborative forum to support cybersecurity priorities established by the FDA CIO and Chief Information Security Officer (CISO) and the enterprise response to global, national, industry, and agency-level cyber related incidents. The FDA CISO serves as the Chair. Membership is comprised of representatives at the Executive Officer and Associate Deputy CIO levels from each Center/Office.
- Data: The Data Modernization Steering Committee provides the strategic framework for proper oversight and decision making over FDA's critical data assets related to data stewardship, security, quality control, analysis, and real-time use. The Chief Data Officer serves as its Chair. Voting members include two representatives from each Center/Office.
- Investment: The Portfolio Review Board (PRB) monitors the performance of the FDA IT Portfolio by ensuring it aligns to business and program objectives. It compels an enterprise-wide approach that considers the requirements of each Center. The PRB ensures compliance with FITARA, CPIC, and other IT investment management regulations. The Chair is designated by the CIO and CTO and the Co-Chair is selected by the Chair. Voting members are comprised of representatives across Centers/Offices.

In addition to the agency-wide governing bodies described, Centers/Offices may have governing bodies such as Information Technology Investment Review Boards (ITIRBs) or IT Advisory Councils that make recommendations and decisions on Center-specific investments and strategically manage Center/Office project.

Governance Scope

There are several other governing bodies across FDA involved in IT decisions not reflected in the framework for various reasons such as agency-wide governing bodies with IT as a relatively small component of their remit, Center/Office specific governing bodies without an agency-wide remit, governing bodies who are not integral to decision making for FDA's IT strategy. For example:

- Enterprise Risk Management (ERM) Council presides over agency-wide risk management at the FDA and facilitates leadership decisions across program areas and business operations.
- Center/Office-specific governing bodies who play a crucial role in providing IT investment governance and oversight of their specific investments as well as ensuring cross-agency collaboration to increase efficiencies and reduce silos.
- Non-decisional committees and temporary work groups supporting IT governance bodies by providing subject matter expert guidance on specific technology topics or in support of specific strategic initiatives.

Governance Processes and Frameworks

The Governance Processes / Frameworks tier highlights critical governance processes and frameworks related to strategic planning and execution and is intended to promote transparency, mitigate risks, and align to mission.

Process/ Framework	Description
Technology Business Management (TBM)	▪ Facilitates investment decisions in the Technology Council and other governing bodies by providing inputs needed to determine if the Agency is investing in the right areas to achieve the desired outcomes and track and monitor performance of IT spend.
Capital Planning and Investment Control (CPIC)	▪ Facilitates investment decisions by systematically gathering the inputs and requirements from Centers/Offices needed to make decisions on IT investments during budget formulation and execution. Decisions are made by the Portfolio Review Board and Technology Council depending on investment threshold.
Enterprise Performance Life Cycle (EPLC) / Project Management	▪ A structured, repeatable approach for managing IT projects from initiation to closure to achieve desired performance and outcomes. Projects are reviewed by the Portfolio Review Board with interventions and/or escalations occurring as needed.
Acquisitions	▪ A structured, repeatable approach for procuring goods and services from identifying the initial business need to contract award and ultimately vendor management. CIO signature is obtained for all IT Acquisition Plans (AP) with a total funding level greater than $5M and for all IT Brand Name Justifications (BNJs).
Authority to Operate (ATO)	▪ Manage the level of risk in the portfolio of systems through independent, comprehensive reviews of system controls to ensure they meet the necessary standards based on the system categorization.
Audit	▪ Assess compliance to the cybersecurity program through a comprehensive evaluation of adherence to Federal Information Security Modernization Act (FISMA) standards and takes appropriate action to manage risks based on the results. Results and recommended actions are reviewed by the Cyber and Data Security Advisory Committee as needed.
Risk Waivers	▪ After a thorough assessment and only where warranted (benefits outweigh risks), accept potential risks associated with an IT system when said system cannot meet certain security requirements due to technical or operational constraints. Decision is made by CISO with input from Cybersecurity Risk Management and Compliance as needed.
IT Service Delivery Processes	▪ Standardized, best-practice Information Technology Infrastructure Library (ITIL) processes to drive consistency and repeatability.

Budget Formulation & Execution

Through the budget formulation process, FDA IT identifies and prioritizes investments required to deliver on FDA's mission and IT's strategic goals. While budget formulation is complete for FY24 – FY25 of the IT Strategy planning horizon, FDA IT proposed an updated budget formulation process (see graphic below) for future IT strategic initiatives. A summary of proposed changes to the process is described below.

Key FY25and Forward Budget Considerations for FDA Staff:

- **Earlier Inclusion of IT Priorities/Governance Oversight:** ODT will engage the Technology Council at the beginning of the budget formulation process to create an enterprise view of prioritized IT budget requests. Starting with the FY26 budget formulation process, the Technology Council and Portfolio Review Board will evaluate and determine funding for IT projects based on impact to IT strategic goals and FDA mission.
- **Enterprise Business Outcomes:** ODT will implement FDA's first ever agency-wide business process for vetting and prioritizing all future IT investments.
- **Integration of TBM:** ODT will leverage the TBM framework to streamline IT resources, improve cost transparency, and enhance decision-making.

Future Proposed FDA IT Budget Execution Process

Source: Adapted from "FY25 HHSJ Commissioners Decision and Scenarios"

All FY26 IT projects to be vetted and governed by ODT and the Tech Council

The funded projects from the budget process will be integrated into the IT Roadmap on an annual basis.

*Office of Finance Budget Acquisitions and Planning (OFBAP)
**Staff Manual Guide (SMG)

Section IV

IT Roadmap

IT Roadmap

To advance FDA's public health mission, this roadmap describes a comprehensive set of IT initiatives with high, transformative impact for FDA. It serves as a guide to the strategic planning and implementation of IT's strategic initiatives across FDA. For each IT strategic initiative, the roadmap identifies the primary IT strategic goal and objective alignment, underlying projects/milestones, metrics, risks and an executive sponsor. FDA recognizes there are opportunities to strengthen future iterations of the IT roadmap with additional information, particularly on milestones and plans to address these challenges through strategic initiative 1.1 Strategy & Governance.

Similar to the IT Strategy, this roadmap takes an agency-wide view of strategic IT initiatives. Center/Office stakeholders collaborated to identify initiatives and underlying projects/milestones for inclusion in the IT Roadmap. These were then reviewed by the Technology Council with final approval from the CIO. As described in the IT Governance section, the Technology Council is the central IT decision-making governing body with an agency-wide scope.

The following table defines FDA's IT strategic initiatives. See subsequent tables in this section for an overview of each initiative.

Goal	Strategic Initiatives
Goal 1: Create a Shared OneFDA Ecosystem	**1.1 Strategy & Governance** Drive ongoing strategic planning and mature FDA's IT governance framework and processes to include increased project oversight and performance monitoring and enhancements to IT Strategy execution, Freedom of Information Act (FOIA), Capital Planning and Investment Control (CPIC) Select, and Technology Business Management (TBM) adoption. **1.2 Acquisitions & Vendor Management** Improve acquisitions and vendor management capabilities and processes to enable faster, more responsible procurement cycles while creating efficiencies, stronger partnerships, and improved contract terms that realize consolidation, rationalization, and new cost saving opportunities. **1.3 Internal/External Communications** Drive ongoing communications and change management in support of FDA's IT Strategy with internal and external stakeholders and implement solutions enabling internal coordination, collaboration and knowledge sharing.

IT Roadmap *(Continued)*

Goal	Initiatives
Goal 2: Strengthen IT Infrastructure	**2.1 Stabilization/End of Life/End of Service (EOL/EOS)** Decommission legacy systems, applications, and devices to stabilize enterprise IT services and reduce technical debt*. **2.2 Cloud Transformation** Migrate, implement and transform enterprise IT services by utilizing cloud-based capabilities and platforms. **2.3 Electronic Submission** Monitor and improve usability of the Electronic Submission Gateway (ESG) and other industry submission platforms by streamlining processes, increasing structured data ingestion, and addressing Enterprise Identity, Credential, and Access Management (ICAM). The ultimate goal is to move to a central submissions platform in support of regulatory activities. **2.4 Zero Trust** Adopt a Zero Trust approach to serve as an added layer of protection to the FDA's digital environment and create opportunities for enhancements across the enterprise.
Goal 3: Modernize Enterprise Services and Capabilities	**3.1 Total Experience (User Experience (UX)/Customer Experience (CX))** Create and enhance solutions to increase customer satisfaction by improving accessibility to IT solutions, including external-facing systems, streamlining processes, and easing adoption. **3.2 System Modernization** Transform or upgrade IT systems/solutions by implementing new technologies, streamlining processes and/or enhancing user interfaces to meet the evolving needs of FDA's internal and external stakeholders.
Goal 4: Share Data for Mission Outcomes	**4.1 Enterprise Data Services** Improve FDA's ability to collect and analyze data for regulatory review processes and to support emerging legislation, enable advanced analytics use cases using modern, cloud-based technologies, and improve collaboration and secure data sharing.
Goal 5: Adopt AI and Mission-Driven Innovations	**5.1 AI Executive Order (E.O.) Implementation & Governance** Develop/refine FDA-specific AI guidelines and implement targeted use cases in accordance with the October 2023 Executive Order on the Safe, Secure, and Trustworthy Development and Use of Artificial Intelligence. **5.2 Emerging Technologies** Experiment with current and emerging technologies to develop and test new analytics that can inform policies and drive innovation in regulatory processes and responding to public health threats.
Goal 6: Cultivate Talent and Leadership	**6.1 Workforce Modernization** Implement tactics and tools to attract, recruit, develop, and retain leaders and staff with the business and technical expertise needed to advance FDA's mission.

*Technical Debt: future liabilities and risks derived from a deviation of a system from any of its own nonfunctional requirements

Goal 1 Strategic Initiative Summary
Create a Shared OneFDA Ecosystem

Strategic Initiative 1.1 Strategy & Governance				
Executive Sponsor	**Center / Office**	ODT	**POC**	Joe Montgomery
Primary IT Goal	Goal 1: Create a Shared OneFDA Ecosystem			
Primary IT Objective	▪ Optimize Investments ▪ Strengthen Governance			
Overview	Drive ongoing strategic planning and mature FDA's IT governance framework and processes to include increased project oversight and performance monitoring and enhancements to IT Strategy execution, Freedom of Information Act (FOIA), Capital Planning and Investment Control (CPIC) Select, and Technology Business Management (TBM) adoption.			
Metrics	▪ IT projects through intake process ▪ IT budget aligned to IT Strategic Plan ▪ Annual update to IT Strategy and IT Operating Plan ▪ Quarterly progress on IT Strategy			
Project/Milestone(s)	▪ CDRH Acquisition & Administrative Planning System (CAAPS) ▪ Enterprise CPIC Select ▪ FDA IT Strategy & Operating Plan		▪ FOIA Process Optimization ▪ IT Automation Process Factory and Service Catalog ▪ TBM Center of Excellence Implementation	
Risks	If IT strategy spend continues in siloes without the ability to prioritize initiatives/projects with greatest impact to mission, FDA may have challenges accelerating the advancement of business capabilities with effective IT solutions and services. If IT strategic and operational planning stagnates, FDA's IT investments may not support mission needs leading to a lack of focus, inefficiency, wasted resources, and missed opportunities.			

Goal 1 Strategic Initiative Summary
Create a Shared OneFDA Ecosystem

Strategic Initiative 1.2 Acquisitions & Vendor Management				
Executive Sponsor	**Center / Office**	ODT	**POC**	Joe Montgomery
Primary IT Goal	Goal 1: Create a Shared OneFDA Ecosystem			
Primary IT Objective	Optimize Investments			
Overview	Improve acquisitions and vendor management capabilities and processes to enable faster, more responsible procurement cycles while creating efficiencies, stronger partnerships, and improved contract terms that realize consolidation, rationalization, and new cost saving opportunities.			
Metrics	▪ Annual Business Reviews Conducted ▪ FDA Small Business			
Project/Milestone(s)	▪ Acquisition Optimization: Enterprise Licensing Model Optimization ▪ Acquisition Optimization: Governance		▪ Contract Optimization and Rationalization ▪ Vendor Management Program	
Risks	If IT acquisitions are not governed effectively, FDA may have: ▪ Overspending on duplicative IT goods and services ▪ Limited economies of scales cost savings opportunities ▪ Challenges holding vendors accountable for delivering to agreed upon contract terms			

Strategic Initiative 1.3 Internal/External Communications				
Executive Sponsor	**Center / Office**	ODT	**POC**	Jess Berrellez
Primary IT Goal	Goal 1: Create a Shared OneFDA Ecosystem			
Primary IT Objective	▪ Enhance Communication and Collaboration ▪ Promote Transparency			
Overview	Drive ongoing communications and change management in support of FDA's IT Strategy with internal and external stakeholders and implement solutions enabling internal coordination, collaboration and knowledge sharing.			
Metrics	▪ External-facing Communications ▪ Stakeholder Engagement			
Project/Milestone(s)	▪ Communications Planning & Execution ▪ Complaints Management System		▪ Product Review & Approval (PRA) Formal Meetings Management (FMM)	
Risks	If FDA does not provide transparency into its key activities, FDA may have: ▪ Continuation of the siloed culture internal to FDA ▪ Loss of trust from key stakeholders including the public in FDAs ability to protect public health ▪ Increase in misinformation in the absence of providing facts ▪ Stalled adoption of necessary changes			

Goal 2 Strategic Initiative Summary
Strengthen IT Infrastructure

Strategic Initiative 2.1 Stabilization/End of Life/End of Service (EOL/EOS)				
Executive Sponsor	**Center / Office**	ODT	**POC**	Mohammed Sohail Chaudhry
Primary IT Goal	Goal 2: Strengthen IT Infrastructure			
Primary IT Objective	Ensure Service Availability			
Overview	Decommission legacy systems, applications, and devices to stabilize enterprise IT services and reduce technical debt.			
Metrics	▪ EoL Equipment – Network, Storage, Compute Towers ▪ Critical Services/Applications Availability ▪ Operations & Maintenance Costs ▪ Network, Storage, and Compute Spend			
Project/Milestone(s)	▪ Network Modernization (Switches, Routers, Wi-Fi)		▪ Storage & Backup Modernization	
Risks	If systems and equipment are not proactively upgraded prior to their EoL, FDA may have: ▪ Potential cyber attacks due to outdated security updates and patches ▪ Increased maintenance costs and/or limited support from vendors ▪ Increased system/equipment failures leading to disruption in business processes, loss of productivity and/or loss of data ▪ Challenges modernizing systems due to incompatibility issues with EoL systems/equipment			

Strategic Initiative 2.2 Cloud Transformation				
Executive Sponsor	**Center / Office**	ODT	**POC**	Mohammed Sohail Chaudhry
Primary IT Goal	Goal 2: Strengthen IT Infrastructure			
Primary IT Objective	Accelerate Cloud Adoption			
Overview	Migrate, implement and transform enterprise IT services by utilizing cloud-based capabilities and platforms.			
Metrics	▪ Cloud Adoption – New Applications and Systems ▪ Cloud Adoption – Legacy – Applications and Systems			
Project/Milestone(s)	▪ Backup Tape Modernization ▪ Enterprise Inspections Platform		▪ Event Data Management 8.0 (Alternative eSub) (NextGen Portal) ▪ Information Governance – eDiscovery Technology Transition Implementation	
Risks	If cloud adoption is not accelerated (where it makes sense), FDA may have: ▪ Challenges quickly scaling to meet business needs ▪ Challenges combatting obsolescence due to longer cycles needed to update on premise solutions ▪ Higher support costs associated with on premise models, and lack of high availability			

Goal 2 Strategic Initiative Summary
Strengthen IT Infrastructure

Strategic Initiative 2.3 Electronic Submission				
Executive Sponsor	**Center / Office**	ODT	**POC**	Mohammed Sohail Chaudhry
Primary IT Goal	Goal 2: Strengthen IT Infrastructure			
Primary IT Objective	▪ Accelerate Cloud Adoption ▪ Ensure Service Availability			
Overview	Monitor and improve usability of the Electronic Submission Gateway (ESG) and other industry submission platforms by streamlining processes, increasing structured data ingestion, and addressing Enterprise Identity, Credential, and Access Management (ICAM). The ultimate goal is to move to a central submissions platform in support of regulatory activities.			
Metrics	▪ ESG Availability			
Project/Milestone(s)	▪ Electronic Submission ▪ Food Applications Regulatory Management (FARM)		▪ NextGen ESG ▪ RSRA eSubmissions Modernization	
Risks	If FDA does not enhance electronic submission platforms, FDA may have: ▪ Low adoption and conformance to FDA standards ▪ Decreased time and capacity to review submissions in a timely manner ▪ Difficult access to FDA resources for guidance on industry applications			

Strategic Initiative 2.4 Zero Trust				
Executive Sponsor	**Center / Office**	ODT	**POC**	Craig Taylor
Primary IT Goal	Goal 2: Strengthen IT Infrastructure			
Primary IT Objective	Implement Zero Trust Approach			
Overview	Adopt a Zero Trust approach to serve as an added layer of protection to the FDA's digital environment and create opportunities for enhancements across the enterprise.			
Metrics	FDA Zero Trust Maturity Level			
Project/Milestone(s)	▪ CrowdStrike ▪ Cybersecurity Zero Trust (ZTA) ▪ G5 - Defender for Firewalls (Endpoint)		▪ Multi-Factor Authentication and Encryption Ecosystem ▪ Software Defined Security (NextGen Firewalls)	
Risks	If a Zero Trust approach is not adopted, FDA may have: ▪ Increased vulnerability to sophisticated cyber threats and attacks more traditional models often fail to protect against ▪ Increased unauthorized access and data breaches due to traditional reliance on perimeter defenses ▪ Disruptions in ability to carry out mission in the case of a successful attack			

Goal 3 Strategic Initiative Summary
Modernize Enterprise Services and Capabilities

Strategic Initiative 3.1 Total Experience (UX/CX)		
Executive Sponsor	**Center / Office** ODT	**POC** Josh Lehman
Primary IT Goal	Goal 3: Modernize Enterprise Services and Capabilities	
Primary IT Objective	Improve Customer Experience	
Overview	Create and enhance solutions to increase customer satisfaction by improving accessibility to IT solutions, including external-facing systems, streamlining processes, and easing adoption.	
Metrics	▪ FDA's Customer Experience with the public (Net Promoter Score)	
Project/Milestone(s)	▪ Automated Call Distribution (ACD) Modernization ▪ Document Management Solution Expansion ▪ G5 - End Node Management Modernization	▪ Phone System Modernization (Teams Voice Over Internet Protocol) ▪ Wi-Fi Modernization
Risks	If stakeholders have a poor customer experience, FDA may have: ▪ Loss of trust and credibility (a key goal in HHS strategy) ▪ Decreased engagement in FDA's public-facing services	

Goal 3 Strategic Initiative Summary
Modernize Enterprise Services and Capabilities

Strategic Initiative 3.2 System Modernization					
Executive Sponsor	**Center / Office**	ODT		**POC**	Farhan Khan
Primary IT Goal	Goal 3: Modernize Enterprise Services and Capabilities				
Primary IT Objective	▪ Increase Business Alignment ▪ Scale Operations ▪ Increase Digital Maturity				
Overview	Transform or upgrade IT systems/solutions by implementing new technologies, streamlining processes and/or enhancing user interfaces to meet the evolving needs of FDA's internal and external stakeholders.				
Metrics	▪ User Satisfaction with Enterprise Services and Center-Specific Services ▪ Critical Services/Applications Availability ▪ IT Spending across DME and O&M ▪ Cyber Defense Modernization				
Project/Milestone(s)	▪ Acquisition Lifecycle Platform (ALP) ▪ CVM IT Modernization ▪ FSMA Food Traceability/Product Tracing System (PTS) ▪ FSMA FURLS ▪ Human Resources IT (HRIT) eSuite ▪ Implementation Initiative and Support (Workflow) (Nexus) ▪ Information Governance- Electronic Records Retention Project - Phase 2 ▪ Integrated Budget and Acquisition Planning System (IBAPS) Modernization		▪ Knowledge-Aided Assessment and Structure Application (KASA) ▪ OTS PR&A CBITE III - Implementation/Enhancements (BIMO Program) ▪ Quality Management Information System (QMiS) ▪ Research Management System Application Modernization and Maintenance ▪ Safety Reporting Portal ▪ Transition for precisionFDA ▪ User Fee System		
Risks	If FDA is unable to provide the financial and human resources needed to stabilize and modernize the agency's Information Technology (IT) infrastructure, then Office of Digital Transformation (ODT) may not be able to provide highly available, secure, and efficient IT solutions that enable the FDA to promote and protect public health.				

Goal 4 Strategic Initiative Summary
Share Data for Mission Outcomes

Strategic Initiative 4.1 Enterprise Data Services				
Executive Sponsor	**Center / Office**	ODT	**POC**	Ram Iyer
Primary IT Goal	Goal 4: Share Data for Mission Outcomes			
Primary IT Objective	▪ Improve Data Visibility and Accessibility ▪ Enhance Data Governance			
Overview	Improve FDA's ability to collect and analyze data for regulatory review processes and to support emerging legislation, enable advanced analytics use cases using modern, cloud-based technologies, and improve collaboration and secure data sharing.			
Metrics	▪ Data sharing – Reduce Internal FDA Data Use Agreements ▪ Number of Assets and Partnerships to Share Data ▪ Data Science Talent ▪ Streamline Use of Third-Party Data Services and Reduce Costs and Maintenance			
Project/Milestone(s)	▪ CDEROne Intelligent Data Lake (iDL) ▪ CDRH Data Modernization (CDM) ▪ CFSAN Data Warehouse (CDW) ▪ Data Analytics as a Service (DAaaS) ▪ Data Marketplace (Inspections Analytics) ▪ DSC Appian Pediatric Information Management System (PIMS) ▪ eMDM Data Services ▪ FDA Adverse Event Reporting System II (FAERS) (Drug Safety Platform)		▪ FDA Intelligent Data Lifecycle Ecosystem (FiDLE) ▪ FedRamp High Evaluation for precisionFDA ▪ Global Substance Registration System (GSRS) ▪ OpenFDA ▪ precisionFDA Regulatory Information Service Module (PRISM)	
Risks	If FDA does not modernize its data infrastructure and expertise, then the Agency's ability to advance the "real-time" use of internal data, and our access to relevant external data to improve and protect public health, will be severely impacted and result in delayed action, inaction or actions based upon limited or incomplete information.			

Goal 5 Strategic Initiative Summary
Adopt AI and Mission-Driven Innovations

Strategic Initiative 5.1 AI Executive Order (E.O.) Implementation & Governance				
Executive Sponsor	**Center / Office**	ODT	**POC**	Ram Iyer
Primary IT Goal	Goal 5: Adopt Artificial Intelligence (AI) and Mission-Driven Innovations			
Primary IT Objective	▪ Foster innovation ▪ Ensure responsible use of innovations			
Overview	Develop/refine FDA-specific AI guidelines and implement targeted use cases in accordance with the October 2023 Executive Order on the Safe, Secure, and Trustworthy Development and Use of Artificial Intelligence.			
Metrics	▪ None at this time			
Project/Milestone(s)	▪ Artificial Intelligence Implementation ▪ Assessment of Large Language Models for FDA Business Activities		▪ Congressional AI Assessment for Supply Chain Hardening	
Risks	If AI use cases are not aligned and governed in accordance with the EO, FDA may have significant challenges with ethical decisions, legal ramifications if laws or regulations are violated, financial losses, vulnerabilities that may manipulate AI output, and/or loss of trust from public, regulated industries, staff and others.			

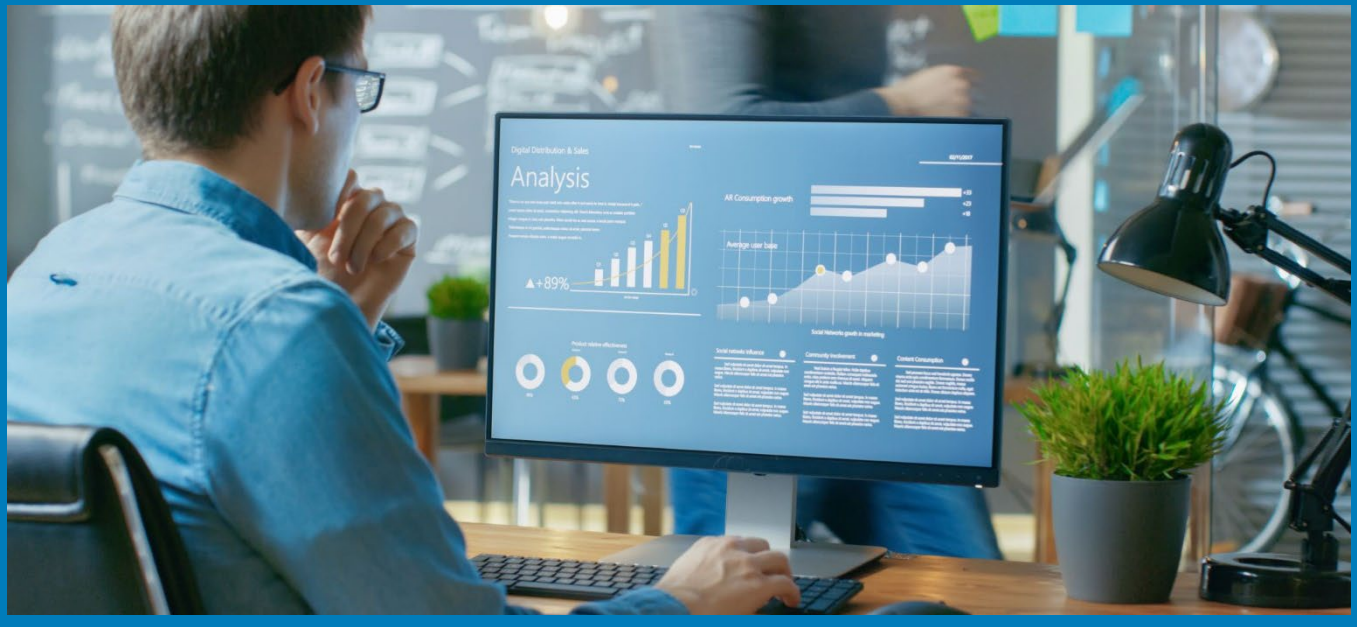
Strategic Initiative 5.2 Emerging Technologies				
Executive Sponsor	**Center / Office**	ODT	**POC**	Ram Iyer
Primary IT Goal	Goal 5: Adopt Artificial Intelligence (AI) and Mission-Driven Innovations			
Primary IT Objective	▪ Provide Proactive Thought Leadership ▪ Balance Policy and Technology Value			
Overview	Experiment with current and emerging technologies to develop and test new analytics that can inform policies and drive innovation in regulatory processes and responding to public health threats.			
Metrics	▪ Investment in Innovation			
Project/Milestone(s)	▪ Co-Pilot – Phase 1 ▪ Real-World Application for Innovation and Development (RAPID) V.1 Program III			
Risks	If innovation, culture, and processes cannot be cultivated, FDA may experience: ▪ Inadequate understanding and preparation for impacts of new technologies ▪ Harmful misuse of emerging technologies ▪ Lower opportunities to benefit from novel uses of upcoming technologies in public health			

Goal 6 Strategic Initiative Summary
Cultivate Talent and Leadership

Strategic Initiative 6.1 Workforce Modernization				
Executive Sponsor	**Center / Office**	ODT	**POC**	Jess Berrellez
Primary IT Goal	Goal 6: Cultivate Talent and Leadership			
Primary IT Objective	▪ Instill OneFDA mindset ▪ Attract and retain talent ▪ Hire and develop resilient leaders ▪ Develop skills for the future of work			
Overview	Implement tactics and tools to attract, recruit, develop, and retain leaders and staff with the business and technical expertise needed to advance FDA's mission.			
Metrics	▪ IT Workforce Growth Rate ▪ GS to Title 21 Conversions ▪ Total Training Completion			
Project/Milestone(s)	▪ Candidate Relationship Management Module Tool (CRMT) ▪ DataForward ▪ Digital Leadership ▪ Knowledge and Expertise Sharing		▪ precisionFDA Community Building and Challenge Program ▪ Project Elixir ▪ Project UpTech	
Risks	If the FDA does not address skill gaps and capacity constraints within the IT workforce, FDA IT may have: ▪ Increased attrition due to low employee satisfaction e.g., burnout ▪ Increased gap between current and necessary skills to deliver against IT commitments ▪ Challenges attracting talent			

Section V

Performance Measuring & Monitoring



Performance Measuring & Monitoring *(Continued)*

FDA's multi-layered IT performance measurement and monitoring system encompasses IT Strategy, IT Projects and IT Operations/Service Delivery. Specific to the IT Strategy, FDA defined a targeted set of metrics to assess its effectiveness in achieving the intended results. Each metric, aligned to at least one of the six IT strategic goals, provides perspective on a key aspect of strategic IT capabilities required to advance FDA's public health mission. FDA is currently defining the data collection requirements and process for each of the IT strategic metrics as part of strategic initiative 1.1 Strategy & Governance.

During regular performance reviews with the Technology Council, FDA will use these metrics to evaluate progress against IT strategic goals, identify opportunities for improvement and make informed decisions on resource allocation, adjustments to strategy and other critical areas as needed. FDA will also leverage existing performance measurements reported through the Enterprise Performance Life Cycle (EPLC), operational Service Level Agreements (SLAs) and other mechanisms to supplement the strategic metrics as needed. Strategic initiative 1.1 Strategy & Governance includes improving quality of project milestone data to strengthen FDA's ability to monitor project performance and develop a more detailed IT Roadmap.

To promote transparency, ODT will publish IT strategic metrics on FDA TRACK for stakeholders to monitor progress. FDA-TRACK is FDA's agency-wide performance management system that monitors FDA Centers/Offices through key performance measures and projects.

The following table summarizes the strategic IT metrics, providing a comprehensive evaluation of progress against the IT Strategy.

IT Strategic Metrics

Goal	Metric	Calculation
1	IT projects through intake process	(Number of IT Projects submitted through EPLC Intake) / (Total Number of IT Projects)
	IT budget aligned to IT Strategic Plan	(Number of IT Budget submitted through CPIC Select and TBM Center of Excellence data calls) / (Total Number of IT Budget Items submitted)
	Annual update to IT Strategy	(Number of completed annual IT Strategy updates) / 1
	Annual update to IT Operating Plan	(Number of completed annual IT Operating Plan updates) / 1
	Quarterly progress on IT Strategy	(Number of completed IT Strategy Progress Reports) / 3
	Annual Business Reviews Conducted	Number of Annual Business Reviews Conducted as a percentage / 18
	FDA Small Business	Number of Small Business awarded FDA contracts
	Stakeholder engagement	Number of impressions of communications content by channel
	External-facing communications	Number of external-facing FDA events

IT Strategic Metrics

Goal	Metric	Calculation
2	EoL Equipment – Network, Storage, Compute Towers	Reduction in the ratio of ODT equipment beyond operational life for the Network, Storage and Compute TBM IT Towers
	Critical Services/Applications Availability*	Percent of time Critical Services / Applications have been up without any unplanned downtime or Priority 1 outages (Total number of hours –Total number of hours with Priority 1 Outages) / Total number of hours
	ESG Availability	Percentage of time the ESG application is available without unplanned outages
	Cloud Adoption – New Applications and Systems	Percent of FDA's applications and services hosted in cloud environments
	Cloud Adoption – Legacy – Applications and Systems	Percent of legacy FDA's applications and services hosted in cloud environments
	FDA Zero Trust Maturity Level	Department of Homeland Security (DHS)/Cybersecurity & Infrastructure Security Agency (CISA) Zero Trust Model - Optimal Level 4.1 – 5.0
	Operations & Maintenance (O&M) Costs	Percentage change in O&M costs
	Network, Storage & Compute Spend	Network, Storage, and Compute Spend as % of Total IT Spending
3	User Satisfaction with Enterprise and Center-Specific Services	Customer satisfaction with help desk task/ticket resolution. A score of 4 or 5 (out of 5) is considered a satisfied customer
	FDA's Customer Experience with the public (Net Promoter Score)	Number of surveys presented to users on FDA.gov positivity survey
	Critical Services/Applications Availability*	Percent of time Critical Services / Applications have been up without any unplanned downtime or Priority 1 outages (Total number of hours –Total number of hours with Priority 1 Outages) / Total number of hours
	Cyber Defense Modernization	Completion of Presidential Executive Order (EO) 14028, Improving the Nation's Cybersecurity, DHS/CISA Continuous Diagnostic and Mitigation (CDM) and other federal mandates to modernize their cybersecurity/network capabilities, threat detection, vulnerability management, and other cyber defense capabilities.
	IT Spending across DME and O&M	Percentage DME vs Percentage O&M of Total IT Spend

*Critical Services/Applications are: Microsoft Internet Information Server (IIS), .NET Server (.NET), Atlassian Subversion, JIRA, Greenhopper, Apache Tomcat, Oracle Application Server (OAS), Forms and Reports Server, Weblogic, Exalogic, Business Objects.

IT Strategic Metrics *(Continued)*

Goal	Metric	Calculation
4	Data Sharing – Reduce Data Use Agreement	(Number of Internal Data Use Agreements Requiring Adjudication / Total Number of Internal Data Use Agreements Requiring Adjudication)
	Number of Assets and Partnerships to Share Data	FY23 Baseline + (Number of partnerships to share internal and external stakeholders) / (Total Number of Partnerships)
	Data Science Talent	FY23 Baseline - (Number of cross trained data engineers, analysts, and scientists) / (Total Trained)
	Third-party Data Services Costs	FY23 Baseline + (spend of related licenses and costs) / (Total spend of related licenses and costs)
5	Investment in Innovation	Innovation Spend as % of Total IT Spending
6	IT Workforce Growth Rate	((Number of IT FTEs at end of period - Number of IT FTEs at start of period) / Number of IT FTEs at start of period)*100
	GS to Title 21 Conversions	Number of ODT IT positions converted from GS positions to Title 21 Recruitments and Conversions.
	Training Completion	Total number of FDA employees that have taken at least one training (FDA Academy, ODT offered Training) or attended a conference in the fiscal year. Does not include FDA Mandatory Administrative Trainings (e.g., Ethics, Records Management, etc.).

Section VI

Communications & Outreach

Communications & Outreach

FDA IT will provide stakeholders with strategic context, promote opportunities for dialogue, proactively streamline internal coordination and provide more visibility into decision-making to establish an environment of increased collaboration and transparency. FDA has multiple stakeholder groups with differing priorities and its aim is to drive a cohesive ecosystem. The communications strategy delves into the critical aspects of communication for internal (e.g., FDA Executives, FDA Centers/Offices) and external stakeholders.

Internal Stakeholders

To enhance internal communication and ensure the successful implementation of the FDA IT Operating Plan, ODT is establishing a dedicated IT Communications team. This team will play a pivotal role in aligning FDA IT's efforts and keeping everyone informed. The IT Communications team will manage internal and external communication and stakeholder engagement such as those mentioned below:

- ODT Monthly Newsletter: Includes updates on the IT strategy and Operating Plan as well as highlights from the Technology Council and subcommittees, to ensure key discussion points and action items are widely shared. Currently distributed to 26,000 internal readers, this newsletter will be expanded for an external audience for transparency and reach.
- ODT Townhalls: ODT is committed to fostering a more connected FDA IT community through regular Town Hall Meetings, enhancing dialogue and information exchange.
- ODT Knowledge Café and Relevant Events: The recurring ODT Knowledge Cafés and other events, now extended to the entire FDA IT community, along with the expanded use of internal communication channels, will significantly improve current awareness, alignment, and coordination across the organization.

External Stakeholders

External stakeholder engagement and outreach is a core component to advancing the IT Strategy and Operating Plan, ensuring the inclusion of diverse perspectives and fostering a collaborative environment for successful strategy implementation. Such engagement is key to enhancing transparency, trust, and the relevance of IT initiatives, with activities like stakeholder listening sessions, public meetings, the FDA Digital Transformation Symposium, and Reverse Vendor Day facilitating valuable interaction and feedback. Conference presentations and institutional collaborations, as part of knowledge sharing efforts, along with expanded engagement to Capitol Hill and legislative advocacy, will ensure relevant strategies. To reinforce this commitment, the new ODT Communications team, will emphasize the importance of stakeholder input and welcome suggestions for engagement with the FDA IT community. This initiative is pivotal for aligning efforts with the needs and expectations of all constituents, enhancing the effectiveness of IT strategies and investments.

Communication Strategy for Internal Stakeholders

The following tables describe the strategies and protocols FDA IT will employ to ensure effective, transparent, and timely communication among all stakeholders. For each target audience, a communication champion, key outcomes, primary messages and communication channels to create a two-way dialogue are defined.

Target Audience	Communication Champion	Desired Outcomes	Key Message	Key Channels
Executive Leadership	**CIO**	▪ Executive Approval of IT Strategy and related budget requests ▪ Cross-FDA collaboration ▪ Address concerns ▪ Allocation of funding	▪ Alignment to FDA and Center/Office's mission and strategic priorities ▪ Future budget requests will be aligned with IT strategy goals and objectives ▪ Commitment to success of IT Strategy ▪ Reinforce FDA benefits and identify how to mitigate risks	▪ Executive Committee ▪ Budget Formulation process
ODT	**ODT Executive Leadership Team (ELT)**	▪ Staff commitment ▪ Empower Change Champions ▪ Drive awareness ▪ Address concerns	▪ Impact of IT Strategy on ODT and reinforcement of ODT support through changes ▪ Act as change drivers to increase adoption and engagement with peers ▪ Reinforce IT benefits and identify how to mitigate risks	▪ Monthly Newsletter/Blog ▪ Monthly Townhalls ▪ OCM Workshops/Forums ▪ Strategy Progress Reporting ▪ Training as needed
Centers & Offices	**Technology Council / ADCIOs**	▪ Stakeholder Commitment ▪ Empower Change Champions ▪ Cross-FDA Collaboration ▪ Drive awareness ▪ Address concerns	▪ Alignment to FDA and Center/Office's mission and strategic priorities ▪ Commitment to success of IT Strategy ▪ Act as change drivers and increase adoption and collaboration across Centers/Offices ▪ Reinforce FDA benefits and identify how to mitigate risks	▪ Monthly Newsletter ▪ Governance Councils ▪ Quarterly Meetings ▪ Roadshows ▪ OCM Workshops/Forums ▪ Strategy Progress Reporting

FDA Executives FDA Centers/Offices External Stakeholders

Communication Strategy for External Stakeholders *(Continued)*

Target Audience	Communication Champion	Desired Outcomes	Key Message	Key Channels
Accreditation Bodies	**Centers/ Offices**	▪ Acknowledge any improvements in communications/collaboration with FDA from implementation of IT strategy ▪ Provide feedback on any IT related FDA issues that impact their operations	▪ Implementation of IT strategy will increase efficiency of review and decision on accreditation body recognition ▪ Implementation of IT strategy will ease collaboration and information sharing with accreditation bodies	▪ Accreditation Program Communications
Government – Federal	**ODT / Office of External Affairs (OEA)**	▪ Positive GAO Audit Outcome ▪ Sufficient Funding ▪ Acknowledgement of FDAs IT contribution to HHS Agency goals	▪ Alignment to HHS mission and strategic priorities ▪ Alignment to FDA and Center/Office's mission and strategic priorities ▪ Acknowledgement of previous GAO Audit findings and progress made in line with findings ▪ Business case for continued funding	▪ Annual Budget Formulation Process ▪ GAO Audit ▪ Hill Briefings ▪ Strategy Progress Reporting
Government – International	**Office of External Affairs (OEA)**	▪ Increased engagement on regulatory standards, requirements, and topics ▪ Enhanced partnership via International Agreements ▪ Acknowledge any improvements in communications/collaboration with FDA from implementation of IT strategy	▪ Implementation of IT strategy will ease collaboration and information sharing with international governments/organizations leading to increased regulatory harmonization and partnerships	▪ Relevant Councils, Programs, and Groups e.g., International Council for Harmonisation (ICH) ▪ Clusters

Target Audience	Communication Champion	Desired Outcomes	Key Message	Key Channels
Industry	**User Fee Council / Centers & Offices**	▪ Acceptance of goals and UFA progress ▪ Sufficient funding ▪ Understanding of benefits from IT Strategy ▪ Strengthened partnership	▪ Alignment and commitment to UFAs ▪ Business case for continued funding ▪ Importance of industry relationship and dedication to more frequent communication cadence	▪ UFA Progress Reporting ▪ Quarterly Meetings ▪ FDA IT Symposium ▪ Federal Register
Industry – Other	**Office of External Affairs (OEA) / ODT**	▪ (Industry Consortium/Research Partners) Expand collaboration on regulatory science research ▪ (Vendor/Contractor) Deliver targeted proposals and deliverables aligned with fulfillment of IT goals ▪ (Industry Lobby Groups) Acknowledge progress in IT strategy ▪ (Academic Institutions) Expand engagement and motivation for innovation related initiatives	▪ (Industry Consortium/Research Partners) IT Strategy will ease collaboration to enhance regulatory science ▪ (Vendor/Contractor) Align current and future projects and support to IT Strategy goals and objectives ▪ (Industry Lobby Groups) IT Strategy will drive efficiencies in regulatory review ▪ (Academic Institutions) IT Strategy includes a targeted goal on innovation potentially increasing opportunities for collaborative innovation in the future e.g., AI	▪ Consortiums e.g., Critical Path Initiative ▪ Public Private Partnerships (PPP) ▪ Federal Register ▪ FDA IT Symposium ▪ Office of Acquisition & Grants Services (OAGS) ▪ Academic MOU Communications
Public	**Centers/Offices**	▪ Increased trust in FDA ▪ Understanding of benefits from IT Strategy	▪ Strengthened commitment to public health mission and protection of public enabled by IT Strategy ▪ Continued encouragement of public engagement to express concerns or questions	▪ Newsletters ▪ Federal Register ▪ Public Forums/Webinars ▪ Social Media Posts ▪ Public Performance Dashboard

FDA Executives | FDA Centers/Offices | External Stakeholders

Communications & Outreach

Closing Message from the CIO

The implementation of FDA's IT Strategy through this IT Operating Plan is of paramount importance at this juncture. This inaugural release of our IT Operating Plan focuses on our IT Roadmap, processes we will use to govern execution, how we will work together across the broad FDA IT organization, and ways we will measure and monitor progress. Following the CPIC Select prioritization and budgeting process, a subsequent release, will include additional details on projects/milestones within the IT Roadmap through FY26. We will continue to adjust each year as we go through our planning and budgeting cycles.

As we progress, our strategic planning process will serve as a compass, guiding us to answer key questions and make necessary adjustments:

- Are our actions aligned with our strategy?
- Are we delivering against our commitments?
- Are we generating the desired impact?

The rapidly evolving digital landscape necessitates a proactive, iterative approach to ensure the FDA's IT capabilities can meet the demands of the future. Our IT Strategy and Operating Plan will be updated annually, at minimum, to keep pace with the changes in our internal and external environment.

Vid Desai
Chief Information Officer
Office of Digital Transformation

END

Appendix

IT Strategic Goal Alignment
IT Skills Assessment Summary

Appendix

IT Strategic Goal Alignment

IT Strategic Goal Alignment

There are several strategic initiatives/projects supporting PDUFA and BsUFA user fee commitments, submissions review and management processes in alignment with FDA's business capabilities and priorities.

	FDA IT Strategic Goals					
	1. Create a Shared OneFDA Ecosystem	2. Strengthen IT Infrastructure	3. Modernization Enterprise Services and Capabilities	4. Share Data for Mission Outcomes	5. Adopt AI and Mission-Driven Innovations	6. Cultivate Talent and Leadership
PDUFA Information Technology and Bioinformatics Goals						
Enhance Transparency and Leveraging Modern Technology	X	X	X	X	X	X
Enhance Transparency	X					
Develop Data and Technology Modernization Strategy	X	X	X	X	X	X
Promote Convergence	X			X		
Accelerate CBER Modernization	X				X	
Monitor and Modernize Electronic Submission Gateway (ESG)	X	X	X			
Leverage Cloud Technologies to Progress Regulatory Digital Transformation		X		X		
Provide Bioinformatics IT Support						
Expanding and Enhancing Bioinformatics Support	X			X		X
Enhancing Use of Digital Health Technologies to Support Drug Development and Review		X		X	X	
BsUFA Information Technology Goals						
Develop Data and Technology Modernization Strategy	X	X	X	X	X	X
Monitor and Modernize Electronic Submission Gateway (ESG)	X	X	X			

IT Strategic Goal Alignment *(Continued)*

FDA's IT goals are in alignment with HHS's overall strategy and IT strategic goals.

	FDA IT Strategic Goals					
	1. Create a Shared OneFDA Ecosystem	2. Strengthen IT Infrastructure	3. Modernization Enterprise Services and Capabilities	4. Share Data for Mission Outcomes	5. Adopt AI and Mission-Driven Innovations	6. Cultivate Talent and Leadership
HHS Agency Strategic Goals						
1. Protect and Strengthen Equitable Access to High Quality and Affordable Healthcare			X	X		
2. Safeguard and Improve National and Global Health Conditions and Outcomes			X	X	X	
3. Strengthen Social Well-Being, Equity, and Economic Resilience			X	X	X	
4. Restore Trust and Accelerate Advancements in Science and Research for All	X		X	X	X	X
5. Advance Strategic Management to Build Trust, Transparency, and Accountability	X	X	X	X	X	X

	FDA IT Strategic Goals					
	1. Create a Shared OneFDA Ecosystem	2. Strengthen IT Infrastructure	3. Modernization Enterprise Services and Capabilities	4. Share Data for Mission Outcomes	5. Adopt AI and Mission-Driven Innovations	6. Cultivate Talent and Leadership
HHS IT Strategic Goals						
1. Optimize the IT Organization	X		X	X	X	X
.2 Accelerate Technology Modernization & Innovation	X	X	X	X	X	
3. Enhance Data & Interoperability	X		X	X	X	
4. Improve IT Management & Governance	X	X	X	X		
5. Strengthen Cybersecurity		X	X	X		

Appendix

IT Skills Assessment Summary

IT Skills Assessment

The ODT at the FDA is spearheading an initiative to align the FDA's technological capabilities with the digital literacy of its workforce. This initiative is a major component of the Leadership Modernization Action Plan (LMAP) released by ODT last year and is crucial in an era of rapid technological advancement. ODT began with a detailed IT Skills Assessment and Inventory. The objective was to categorize essential skills and competencies for a 21st-century technology workforce into four key areas: foundational, technical, data, and leadership. The ODT's strategy focused on leveraging these competencies to drive learning and development programs.

An extensive training inventory and skills self-assessment, guided by an industry best practice, Role-based Skills and Competencies Framework, was central to this initiative. The assessment comprised an agency-wide survey involving over two hundred and fifty IT-related personnel from the FDA, providing valuable insights into the current skill levels and training desires. The survey collected data on approximately two hundred thirty IT skills across the top twenty roles, with participants rating their proficiency and expressing their learning aspirations. This comprehensive approach helped identify a notable skills gap for technical positions.

Based on these findings, the ODT developed a series of tailored recommendations. These included expanding the agency's IT training portfolio, offering more intermediate and advanced IT certifications and courses, emphasizing applied learning opportunities, prioritizing technology leadership development, expanding cross-functional training, and reducing outsourcing to develop internal skills. Additional strategies proposed were regular skill audits, promoting a culture of continuous learning, fostering mentoring and coaching, better utilizing learning technologies, and offering personalized learning and career pathways.

FDA will take a multi-pronged approach to filling our critical skills gaps and preparing for the future of work. To address knowledge and expertise gaps effectively, the FDA will combine workforce development with increased efforts to fill critical hiring needs. This approach directly addresses existing skill shortages within the FDA by developing existing employees while strategically hiring for specific competencies. This integrated approach will ensure the FDA remains dynamic, competitive, and prepared for current and future challenges. Key focus areas include streamlined hiring processes, recruitment and outreach enhancement, expanded educational outreach, and modernizing hiring and pay strategies. It is important to emphasize that additional funding is needed to enable a surge in IT talent.

Presently, there is an urgent need to enhance FDA's IT team with specialized professionals, including data scientists, artificial intelligence specialists, cybersecurity experts, business analysts, and project managers. Recognizing the rapid evolution of technology, FDA is committed to investing in upskilling, reskilling, and new skilling our existing workforce. However, to truly excel in FDA's IT endeavors and advance the new strategy, FDA must also strengthen its capability to attract and hire top-tier talent.

IT Skills Assessment *(Continued)*

To this end, FDA IT will increasingly utilize the Title 21 Hiring Authority, which allows for more direct and swift recruitment of technical and professional experts. This approach will enable FDA to efficiently address immediate skill gaps and remain agile in a fast-paced technological landscape. However, as previously mentioned, successfully implementing this strategy requires adequate funding. Securing the necessary resources to hire these pivotal positions is critical, as the workforce is the cornerstone of effectively advancing FDA's IT strategies. By balancing internal development with strategic external hiring, FDA IT positions itself at the forefront of technological innovation and regulatory excellence.

The FDA is poised to take significant strides in further enhancing its training portfolio. Recognizing the evolving demands of the technology landscape, ODT will introduce a broader range of agency-wide intermediate and advanced training options, catering to the growing complexity and sophistication of IT skills required by the workforce. In October we launched an 8-month Digital Leadership Program Pilot with a cohort of 18 leaders from across ODT to develop and enhance the effectiveness of internal leadership practices with a focus on fostering a high-performance culture, driving digital innovation and managing change across the organization.

Other steps include expanding availability of IT certification opportunities, introducing micro-certifications, as well as offering more specialized and targeted learning opportunities for employees at all levels. ODT is committed to integrating more applied learning experiences, including action learning projects and immersive rotational assignments. This approach will bolster skill development and foster greater internal career mobility. Additionally, there is a planned expansion in data workforce and Artificial Intelligence (AI) literacy programs, aiming to equip the FDA staff with the necessary tools and knowledge to navigate and leverage the potentials of data science and AI.

The IT Skills Inventory at the FDA marks a transformative approach toward enhancing the organization's technological prowess. By analyzing the current skill sets and training needs of the FDA's IT workforce, the agency has laid a solid foundation for developing a technologically adept and future-oriented organization. The parallel focus on modernizing hiring pathways and compensation strategies is a promising blueprint for a robust, skill-rich future.