U.S. FOOD & DRUG ADMINISTRATION

Office of the Commissioner
Office of Digital Transformation

IT OPERATING PLAN

Food and Drug Administration

January 17, 2025

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Message from the CIO

I am excited to share our refreshed 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 the 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 are revisiting both our IT Strategy and our IT Operating Plan on a regular cadence. In the past year, we successfully leveraged our annual Capital Planning and Investment Control (CPIC) Select process to identify and prioritize new IT projects aligned to our IT Strategy and made progress on several of our strategic initiatives (See IT Roadmap for highlights).

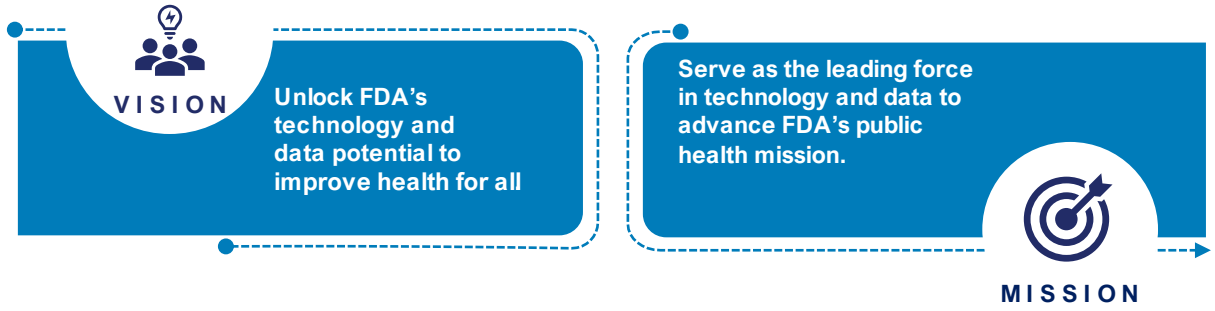
I am extremely proud of our progress and filled with anticipation for what we will continue to accomplish together. I extend my sincere gratitude for your unwavering support and commitment to our mission.

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. The plan is a blueprint designed to guide our organization's technological growth and development in accordance with the 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.

Figure 1. 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, the FDA's 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. The FDA's IT governance model establishes the framework for decision-making and accountability across the Agency's complex portfolio of enterprise and Center-specific IT investments. Using the Technology Council as a focal point, it ensures the 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 of the FDA.

Governance Model

Agency

"Final Authority"

Senior executive leadership who serve as the final decision makers, provide oversight and protect taxpayer value.

- Executive Committee[1]

Primary

"Enterprise Decision Makers"

Executives across the enterprise who establish strategies, fund portfolio, allocate resources, increase accountability and oversee benefit realization from investments and IT risk management.

- Technology Council
- Working Capital Fund Council (WCFC)[2]

Secondary

"Empowered Decision Makers"

- Make the majority of governance decisions across IT domains
- Cascade strategic direction and guardrails to relevant stakeholders for adherence, execution and delivery
- Review initiatives/projects for compliance
- Escalate decisions and makes recommendations to the Technology Council when required

AI

- AI Governance & Advisory Board

Architecture & Technology

- FDA Enterprise Architecture Technology Advisory Board (FEATAB)
- Applications & Platform Work Group
- Infrastructure & Operations Work Group

Cyber

- Cyber and Data Security Advisory Committee

Data

- Data Modernization Steering Committee

Investment

- Portfolio Review Board

Science (IT-related)

- Scientific Computing Board

[1] Guided by Executive Committee, the Enterprise Transformation Office executes Agency-wide high complexity and high priority projects.

[2] Makes investment decisions related to IT WCFC funds.

IT Strategy & Roadmap

Our 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. We 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.

We also defined a targeted set of metrics to assess the effectiveness of our IT Strategy in delivering value to stakeholders. In combination with existing and planned measures, we will use these metrics to evaluate progress on IT strategic goals, identify opportunities for improvement and make informed decisions on resource allocation, adjustments to strategy and other critical areas as needed.

Table 1. IT Strategy Goals, Objectives, Initiatives, Metrics and Risk

Goals	Objectives	Initiatives[1]	Metrics[2]	Risk[3] if not implemented
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	▪ Annual Update to IT Strategy ▪ Annual Update to IT Operating Plan ▪ IT Projects through Intake Process ▪ Annual Business Reviews Conducted ▪ FDA Small Business ▪ Stakeholder Engagement ▪ External-facing Communications	High

[1] See IT Roadmap section for additional details on strategic initiatives.

[2] See Performance Measurement & Monitoring for additional details on metrics.

[3] See IT Roadmap section for additional details on risks.

Goals	Objectives	Initiatives[1]	Metrics[2]	Risk[3] if not implemented
Strengthen IT Infrastructure	▪ Provide Scalable & Efficient Infrastructure Offerings ▪ Accelerate Cloud Adoption ▪ Ensure Service Availability ▪ Implement Zero Trust Approach	2.1 Stabilization/ End-of-Life (EoL)/ End-of-Service (EoS) 2.2 Cloud Transformation 2.3 Zero Trust	▪ EoL Equipment — Network, Storage, Compute Towers ▪ Critical Services/ Applications Availability ▪ Cloud Adoption — New Applications and Systems ▪ Zero Trust Maturity Level ▪ Operations and Maintenance Costs ▪ Network, Storage and Compute Spend	High
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 (User Experience (UX)/Customer Experience (CX)) 3.2 System Modernization 3.3 Electronic Submission	▪ IT Help Desk Customer Satisfaction ▪ Cyber Defense Modernization ▪ IT Spending across Development, Maintenance & Enhancement (DME) vs. Operations & Maintenance (O&M) ▪ Critical Services/ Applications Availability ▪ Electronic Submission Gateway (ESG) Availability	Medium
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 — Reduce Internal Data Use Agreement ▪ Number of Assets and Partnerships to Share Data ▪ Data Science Talent ▪ Third-party Data Services Costs	Medium

Goals	Objectives	Initiatives[1]	Metrics[2]	Risk[3] if not implemented
Adopt Artificial Intelligence (AI) 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	▪ Pending[1]	Medium
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 ▪ General Schedule (GS) to Title 21 Conversions ▪ Training Completion	Medium

[1] Metric for Goal 5 is in progress.

Challenges

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

Table 2. Challenges, Goal Alignment and Mitigation

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 the FDA's 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 3, 4, 5	Strategic Initiatives 3.3, 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, 3.2, 3.3

> 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

Progress

Progress against our strategic goals and objectives is marked by significant achievements and ongoing efforts to align with the FDA's vision of creating a unified OneFDA ecosystem, strengthening IT infrastructure, modernizing enterprise services, sharing data for mission outcomes, adopting AI and mission-driven innovations and developing its workforce. Selected accomplishments include:

Goal 1: Create a Shared OneFDA Ecosystem

We have made significant progress in unifying our approach to technology and data by strengthening governance, enhancing acquisitions and vendor management, and introducing agency-wide solutions. A notable achievement includes establishing a comprehensive view of IT spending across our $1 billion portfolio, earning recognition [1] as one of the most mature TBM environments in the U.S. Government. Additionally, the FDA has improved internal and external communications through initiatives like the FDA Tech Insights newsletter with over 27,000 FDA users (internal edition) and 14,000+ subscribers (external edition), fostering collaboration across Centers, Offices and stakeholders. Through focused efforts on acquisitions improvements and optimizations, the FDA has consolidated and optimized 30% of enterprise IT acquisitions while surpassing FDA Small Business usage per HHS's goals.

Goal 2: Strengthen IT Infrastructure

We are implementing key zero trust tools, cyber defenses and capabilities that will further protect and safeguard our critical assets and sustain our reputation as a world leader in public health and steward of industry information. Additionally, the transition to software-defined networking is enhancing infrastructure flexibility and scalability, ensuring cost savings and performance improvements.

Goal 3: Modernize Enterprise Services and Capabilities

We are streamlining the submission process by developing the enterprise Electronic Submissions Gateway Next Generation (ESG NextGen). This includes supporting capabilities such as the Electronic Document Repository (EDR)/Automated Submission Receipt (ASR) system with ESG NextGen launch anticipated in Q2 2025. We are also enhancing customer experience starting with the development of a comprehensive Customer Experience (CX) strategy. Notable progress on modernization efforts includes showcasing our interactive oneCVM concept, supporting Food Safety Modernization Act (FSMA) business processes changes in the FDA Unified Registration and Listing Systems (FURLS) IT modules for Laboratory Accreditation for Analysis of Foods (LAAF) Program, Voluntary Qualified Importer Program (VQIP) and Accredited Third-Party Certification Program (TPP) and the expansion of agency-wide support for HR processes. These initiatives are essential in meeting growing regulatory responsibilities and promoting global health.

Goal 4: Share Data for Mission Outcomes

We are advancing our data capabilities by delivering enterprise data analytics services and providing a single, governed version of truth across all Centers. This includes expanding the firm inventory to 5.6 million regulated companies and improving data accessibility and decision-making

[1] Recognized by the HHS CIO, GSA Office of Government-wide Policy, and OMB Office of Federal CIO.

through an agency-wide enterprise data catalog. These efforts enhance the FDA's ability to respond rapidly to public health concerns and streamline IT decision-making such as product recalls and supply chain monitoring.

Goal 5: Adopt AI and Mission-Driven Innovations

We are progressing in AI adoption by working through an agency-wide AI governance advisory body to pilot AI/ML use cases, such as AskFDALabel to enhance drug labeling document searches. Efforts are also focused on educating and licensing key staff for AI integration and productivity tools, ensuring responsible use of technology. We are at the beginning, or our AI journey and these initiatives position the FDA to capitalize on technological advancements.

Goal 6: Cultivate Talent and Leadership

Building on the 2023 skills assessment and training inventory, the TechTalent Workforce Development project has delivered training to over 1,000 FDA employees, covering essential technical skills, certifications and curated learning paths for the top 20 IT roles across the FDA. Through the precisionFDA Community Building and Challenge Program, we are fostering collaboration and innovation, exemplified by the precisionFDA Automated Machine Learning (AutoML) App-a-thon. In this App-a-thon, teams used AutoML tools on biomedical datasets to help assess whether AutoML can match or improve the performance of previously developed traditional ML models. These efforts are crucial in developing internal capacity and encouraging regulatory science advancements.

Looking Ahead

With technology playing a pivotal role in food, drug and medical devices' safety, this plan describes how the 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. We anticipate future iterations of the IT Operating Plan will become even more robust as data quality improves for the IT Roadmap.

We 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.

1.0 IT STRATEGY

VISION AND MISSION

IT STRATEGY GOALS AND OBJECTIVES

Table 3. Advancing Public Health Outcomes Enabled by Technology, Powered by Data

 Create a Shared OneFDA Ecosystem	▪ Enhance Communication and Collaboration ▪ Promote Transparency ▪ Optimize Investments ▪ Strengthen Governance
 Strengthen IT Infrastructure	▪ Provide Scalable and Efficient Infrastructure Offerings ▪ Accelerate Cloud Adoption ▪ Ensure Service Availability ▪ Implement Zero Trust Approach
 Modernize Enterprise Services and Capabilities	▪ Increase Business Alignment ▪ Scale Operations ▪ Increase Digital Maturity ▪ Improve Customer Experience ▪ Modernize FDA Cybersecurity Defenses ▪ Reduce Technology Debt
 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
 Adopt AI and Mission-Driven Innovations	▪ Balance Policy and Technology Value ▪ Ensure Responsible Use of Innovations ▪ Provide Proactive Thought Leadership ▪ Foster Innovation
 Cultivate Talent and Leadership	▪ Instill OneFDA Mindset ▪ Attract and Retain Talent ▪ Hire and Develop Resilient Leaders ▪ Develop Skills for the Future of Work

KEY CHALLENGES

Table 4. Key Challenges

	**Rapidly Changing Environment:** We are 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 we do 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 the 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 our 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, the 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, we 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, 3.2, 3.3)
	**Data Sharing:** There is a need to expand data sharing internally within the FDA and externally with industry, accelerate access to advanced technologies such as artificial intelligence, and strategically reuse data to enable new insights. If we cannot meet this need, we 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 3, 4, 5; Mitigated by Strategic Initiatives 3.3, 4.1, 5.1, 5.2)
	**Siloed Culture:** We continue 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)

2.0 IT ORGANIZATION

IT ORGANIZATION

The IT Strategy is executed by a central IT organization, the Office of Digital Transformation (ODT), headed by the CIO, in partnership with 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 vary 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 "The FDA IT" within this plan. View this organization chart to see all Centers/Offices across the FDA.

To achieve its mission, the 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, the FDA IT will focus on business enablement, proactively identifying opportunities for optimization and promoting customer experience across the IT portfolio. Through efficient resource sharing and management across the Agency, the FDA IT will supply the necessary infrastructure, systems, and tools to deliver core, enabling and strategic business capabilities.

Current IT Role

Agency-wide Technology Hub

- Provide foundational, enterprise IT services and solutions efficiently.
- Be the agency-wide technology "hub" delivering a comprehensive portfolio of enterprise IT services and solutions with self-service options.

Future IT Role

Optimize Shared Enterprise Resources

- Optimize enterprise IT services and enterprise business capabilities to empower staff to drive OneFDA and Center/Office-specific missions.

The 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 the 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 supporting the delivery of enterprise services/capabilities and operating as a vital component of the FDA IT, guided by the CIO.
- Through the Technology Council[1] ODT will provide governance for enterprise IT services delivered by Centers/Offices e.g., Office of Inspections and Investigations (OII), Office of Operations (OO) to promote consistency, limit duplication of effort and investments and provide subject matter expertise. All Centers/Offices adhere to this enterprise IT governance framework to ensure their activities are aligned with the FDA's mission and the established IT strategic goals.

Our 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 13833 Enhancing the Effectiveness of Agency Chief Information Officers. 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 categorizes essential skills and competencies for a technology workforce and identified gaps.

[1] The Technology Council is an executive level board that sets IT direction, makes investment decisions, and aligns IT to strategic direction.

3.0 IT GOVERNANCE & BUDGET

IT GOVERNANCE

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

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

The 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 IT strategic planning and execution as we shift 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

Table 5. IT Governance Framework

Agency

"Final Authority"

Senior executive leadership who serve as the final decision makers, provide oversight, and protect taxpayer value.

- Executive Committee[1]

Primary

"Enterprise Decision Makers"

Executives across the enterprise who establish strategies, fund the portfolio, allocate resources, increase accountability and oversee benefit realization from IT investments and risk management.

- Technology Council
- Working Capital Fund Council (WCFC)[2]

Secondary

"Empowered Decision Makers"

- Make the majority of governance decisions across IT domains
- Cascade strategic direction and guardrails to relevant stakeholders for adherence, execution, and delivery
- Review initiatives/projects for compliance
- Escalate decisions and make recommendations to the Technology Council when required

AI

- AI Governance & Advisory Board

Architecture & Technology

- FDA Enterprise Architecture Technology Advisory Board (FEATAB)
- Applications & Platform Work Group
- Infrastructure & Operations Work Group

Cyber

- Cyber and Data Security Advisory Committee

Data

- Data Modernization Steering Committee

Investment

- Portfolio Review Board

Science (IT-related)

- Scientific Computing Board

[1]Guided by Executive Committee, the Enterprise Transformation Office executes Agency-wide high complexity and high priority projects.

[2] Makes investment decisions related to IT WCFC funds.

Governance Processes/Frameworks

Key governance processes and frameworks that are followed to ensure efficiency, transparency, risk mitigation, and alignment to business value.

FITARA

- Technology Business Management (TBM)
- Capital Planning and Investment Control (CPIC)
- Enterprise Performance Life Cycle (EPLC)/Project Management
- Acquisitions

FISMA

- Authority to Operate (ATO)
- Audit

ITIL

- IT Service Delivery Process

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 the 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.
- The **Enterprise Transformation Office (ETO)** is an Agency-wide body driving strategic decision making for business process changes that need to be standardized across FDA Centers and Offices. The ETO focuses exclusively on executing high complexity and high-priority projects that require cross-Center/Office coordination and align with Agency strategic priorities and enterprise risk areas, many of which have a significant IT component. As a result, ETO participates in the Technology Council as a non-voting member. The Executive Committee governs project selection, oversight, and funding allocation for ETO.

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 decisions to the IT Strategy. 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 Tech Council is chaired by the CIO or his/her designee. The Council has the following responsibilities:
  - Establish IT vision and drive IT strategy
  - Make decisions on IT projects between $10-$30M or high impact/priority investments below $10M
  - Ensure Center/Office IT strategies are aligned with the FDA's IT goals and objectives
  - Resolve escalations when consensus is not achieved in secondary governance tier
  - Improve agency-wide IT communications
  - Establish (and delegate decisions to) 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 the 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, high-performance scientific computing, digitization, and open data.

Secondary Governance Tier

The Secondary tier primarily serve 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, Science (IT-related), and IT Investments. The Technology Council may choose to delegate decision authority to these governing bodies.

- 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 the legal, ethics, privacy, and security domains to provide balanced recommendations on AI use.
- 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 is comprised of the Chief Technology Officer (CTO) as chair, a rotating Center representative as Co-Chair, and technically and financially astute representatives from each Center. The Applications & Platform Work Group and Infrastructure & Operations Work Group provide inputs and recommendations on their respective areas 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 and membership is comprised of representatives at the Executive Officer (EO) and Associate Deputy CIO (ADCIO) levels from each Center/Office.
- Data: The Data Modernization Steering Committee provides the strategic framework for proper oversight and decision-making over the 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 is inclusive of 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.
- Science (IT-related only): The Scientific Computing Board (SCB) promotes collaboration and integration of scientific information technology needs and requirements to advance the Agency's regulatory science mission. The SCB informs scientific IT priorities and monitors the scientific computing community to ensure that scientific computing capabilities and cutting-edge technologies are made available to meet the FDA's regulatory and research activities. SCB is led by two co-chairs from different Centers. Voting members include representatives from each Center chosen to cover laboratory, review science and/or science management as well a representative from the Office of the Chief Scientist.

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 the 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, and governing bodies who are not integral to decision making for the 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 PROCESS 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.

Table 6. Governance Process and Framework Descriptions

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. As the "front door" for IT project requests, the process supports alignment to IT strategy, reduction in duplication of IT projects and promotes internal coordination.
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 take 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.
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, we identify and prioritize investments required to deliver on the FDA's mission and IT's strategic goals. We 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 FY25 and forward budget considerations for the 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. The Technology Council and Portfolio Review Board will evaluate and determine funding for IT projects based on impact to IT strategic goals and the FDA mission.
- **Enterprise Business Outcomes:** ODT will implement the 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.

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

Table 7. Future Proposed FDA IT Budget Execution Process

1	2	3	4	5
OFBAP and ODT Coordination	CPIC Pre-Select	Governance Review	Initiatives Funded	Initiative Projects begin EPLC Intake
ODT vets all eligible IT Initiatives from funding request. Funding decisions will be coordinated with Office of Finance, Budget, Acquisition and Planning (OFBAP).	Initiatives must complete the Capital Planning and Investment Control (CPIC) Pre-Select Process and participate in reviews.	FDA Technology Council and Portfolio Review Board (PRB) will vet initiatives.	Initiatives which are approved by the FDA Technology Council will receive funds in alignment with FDA's final FY budget.	Initiatives which have received funding through the FDA Strategic IT Fund must complete IT Project Intake. SMG** will require all IT projects regardless of investment type to report IT spend.

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

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

4.0 IT ROADMAP

IT ROADMAP

To advance the FDA's public health mission, this roadmap describes a comprehensive set of IT initiatives with transformative impact for the FDA. It serves as a guide to the strategic planning and implementation of IT's strategic initiatives across the FDA. For each IT strategic initiative, the roadmap identifies the primary IT strategic goal and objective alignment, underlying programs/projects, metrics, risks and an executive sponsor.

Center/Office stakeholders collaborated to identify initiatives and underlying programs/projects for inclusion in the IT Roadmap. These were 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.

We recognize there are opportunities to strengthen future iterations of the IT roadmap with additional information. There are 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 in a central location. As a result, Strategic Initiative 1.1, Strategy & Governance, was expanded to include collection and validation of additional project data. This year, our IT operating plan introduces a structured approach to monitoring progress for a selected subset of projects and programs. See appendix for more information on project progress.

Strategic Initiative Overview

The following table defines our IT strategic initiatives. The projects included in these initiatives are dependent on the availability and allocation of the IT budget. See subsequent tables in this section for an overview of each initiative and the appendix for additional details such as project/program description, business capability mapping and sponsoring Center/Office for each initiative.

Table 8. Strategic Initiative Overview

Goal	Strategic Initiatives
Goal 1: Create a Shared OneFDA Ecosystem	1.1 Strategy & Governance Drive ongoing strategic planning, and mature the FDA's IT governance framework and processes to include increased project oversight, 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 the FDA's IT Strategy with internal and external stakeholders and implement solutions enabling internal coordination, collaboration, and knowledge sharing.

Goal	Strategic 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[1]. **2.2 Cloud Transformation** Migrate, implement, and transform enterprise IT services by utilizing cloud-based capabilities and platforms. **2.3 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 the FDA's internal and external stakeholders. **3.3 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.
Goal 4: Share Data for Mission Outcomes	**4.1 Enterprise Data Services** Improve the 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 the FDA-specific AI guidelines and implement targeted use cases in accordance with the October 2023 Executive Order 14110 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 the FDA's mission.

[1] 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

Table 9. 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 Objectives	▪ Optimize Investments ▪ Strengthen Governance
Overview	Drive ongoing strategic planning and mature the 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.
Contributing Centers/Offices	CBER, CDER, CDRH, CTP, CVM, HFP, NCTR, OC, ODT, OII
Metrics	▪ IT Projects through Intake Process ▪ Annual Update to IT Strategy ▪ Annual Update to IT Operating Plan
Programs/Projects	▪ CDRH Acquisition & Administrative Planning System (CAAPS) — Completed ▪ Enterprise CPIC Select (Program) ▪ FDA IT Strategy & Operating Plan (Program) ▪ Freedom of Information Act (FOIA) Process Optimization ▪ IT Automation Process Factory and Service Catalog ▪ TBM Center of Excellence Implementation (Program) ▪ Budget System
Risks	▪ If IT spend continues in siloes without the ability to prioritize initiatives/projects with greatest impact to mission, the FDA may have challenges accelerating the advancement of business capabilities with effective IT solutions and services. ▪ If IT strategic and operational planning stagnates, the FDA's IT investments may not support mission needs leading to a lack of focus, inefficiency, wasted resources, and missed opportunities.

Table 10. 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 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.
Contributing Centers/Offices	ODT, OO
Metrics	▪ Annual Business Reviews Conducted ▪ FDA Small Business
Programs/Projects	▪ Acquisition Optimization: Enterprise Licensing Model Optimization (Program) ▪ Acquisition Optimization: Governance[1] (Program) ▪ Contract Optimization and Rationalization (Program) ▪ Vendor Management Program (Program)
Risks	If IT acquisitions are not governed effectively, the FDA may have: ▪ Overspending on duplicative IT goods and services ▪ Limited economies of scales in cost savings opportunities ▪ Challenges holding vendors accountable for delivering to agreed upon contract terms

[1] We recently published our IT Acquisition Strategy to streamline how the FDA acquires IT solutions across the organization, focusing on enhancing enterprise capabilities and solidifying a OneFDA approach.

Table 11. 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 Objective	▪ Enhance Communication and Collaboration ▪ Improve Customer Experience
Overview	Drive ongoing communications and change management in support of the FDA's IT Strategy with internal and external stakeholders and implement solutions enabling internal coordination, collaboration and knowledge sharing.
Contributing Centers/Offices	CBER, CDER, CDRH, CTP, CVM, HFP, NCTR, OC, ODT, OII
Metrics	▪ External-facing Communications ▪ Stakeholder Engagement
Programs/Projects	▪ Communications Planning & Execution (Program) ▪ Enterprise Consumer Complaints Management System (Program) ▪ Product Review & Approval (PRA) Formal Meetings Management (FMM) ▪ FDA Scientific Computing and Digital Transformation Symposium (Program) ▪ Hybrid Meeting Room Experience (Program) ▪ Guest Collaboration Experience (Program)
Risks	▪ If the FDA does not provide transparency into its key activities, the FDA may have: – Continuation of the siloed culture internal to the FDA – Loss of trust from key stakeholders including the public in the FDA's ability to protect public health – Increase in misinformation in the absence of providing facts – Stalled adoption of necessary changes ▪ If communication channels and platforms are misaligned with target audiences, then the FDA may experience misinformation, low stakeholder engagement, poor flow of information, and hindered internal coordination, collaboration, and knowledge sharing.

GOAL 2 STRATEGIC INITIATIVE SUMMARY

Strengthen IT Infrastructure

Table 12. 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 Objective	Ensure Service Availability
Overview	Decommission legacy systems, applications, and devices to stabilize enterprise IT services and reduce technical debt.
Contributing Centers/Offices	CTP, OC, ODT
Metrics	▪ End of Life (EoL) Equipment — Network, Storage, Compute Towers ▪ Critical Services/Applications Availability ▪ Operations and Maintenance Costs ▪ Network, Storage, and Compute Spend
Programs/Projects	▪ Network Infrastructure Modernization ▪ Storage & Backup Modernization ▪ RCI Tobacco Inspection Management Program (TIMP) (Program) ▪ CCW Collaboration and Document Management (Program) ▪ CCW Collaboration and Document Management FY23 (Program — Completed) ▪ Operating System (In Place Upgrade) ▪ Operating System (Image) (Completed)
Risks	If systems and equipment are not proactively upgraded prior to their EoL, the FDA may have: ▪ 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

Table 13. Strategic Initiative 2.2: Cloud Transformation[1]

Executive Sponsor	**Center/Office:** ODT **POC:** Mohammed Sohail Chaudhry
Primary IT Goal	Goal 2: Strengthen IT Infrastructure
Primary Objective	Accelerate Cloud Adoption
Overview	Migrate, implement and transform enterprise IT services by utilizing cloud-based capabilities and platforms.
Contributing Centers/Offices	CBER, CDER, CDRH, CTP, CVM, HFP, NCTR, OC, OII, ODT
Metrics	▪ Cloud Adoption — New Applications and Systems
Programs/Projects	▪ Backup Tape Modernization (Completed) ▪ Enterprise Inspections Platform ▪ Event Data Management 8.0 (Alternative eSub) (NextGen Portal) ▪ Information Governance — eDiscovery Technology Transition Implementation (Completed) ▪ Regulatory Submission Receipt and Analysis (RSRA) TRLM NextGen (Program)
Risks	If cloud adoption is not accelerated (where it makes sense), the FDA may have: ▪ Challenges quickly scaling to meet business needs ▪ Challenges combatting obsolescence due to longer cycles needed to update on-premises solutions ▪ Higher support costs associated with on-premises models, and lack of high availability

[1] FDA's technology guidance informs our use of cloud technologies: Electronic Systems, Electronic Records, and Electronic Signatures in Clinical Investigations: Questions and Answers | FDA

Table 14. Strategic Initiative
2.3 Zero Trust

Executive Sponsor	**Center/Office:** ODT **POC:** Craig Taylor
Primary IT Goal	Goal 2: Strengthen IT Infrastructure
Primary 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.
Contributing Centers/Offices	ODT
Metrics	▪ FDA Zero Trust Maturity Level
Programs/Projects	▪ Cybersecurity Zero Trust (ZTA) (Program) ▪ Endpoint Detection and Response (EDR) (Program) ▪ Endpoint Firewalls (Completed) ▪ Multi-Factor Authentication (MFA) and Encryption Ecosystem ▪ Software Defined Networking (SDN) Service Integrations
Risks	If a Zero Trust approach is not adopted, the 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

Table 15. 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 Objective	▪ Improve Customer Experience ▪ Promote Transparency ▪ Increase Business Alignment
Overview	Create and enhance solutions to increase customer satisfaction by improving accessibility to IT solutions, including external-facing systems, streamlining processes, and easing adoption.
Contributing Centers/Offices	CTP, CDER, CDRH, HFP, OC, ODT, CVM
Metrics	▪ IT Help Desk Customer Satisfaction
Programs/Projects	▪ Automated Call Distribution (ACD) Modernization ▪ Document Management Solution Expansion (Program) ▪ Email Modernization ▪ Phone System Modernization (Voice Over Internet Protocol) ▪ Wi-Fi Modernization ▪ CCW LTPS Database (Program) ▪ RSRA Advanced Information Retrieval Research System (AIRRS) (Program) ▪ Customer Experience Strategy (Program) ▪ RSRA Software Modeling of Physiological Parameters and Electronic Cigarette Constituents To Inform Risk Evaluation (SPECTRE)
Risks	If stakeholders have a poor customer experience, the FDA may have: ▪ Loss of trust and credibility (a key goal in HHS strategy) ▪ Decreased engagement in the FDA's public-facing services

Table 16. 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 Objective	▪ Increase Business Alignment ▪ 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 the FDA's internal and external stakeholders.
Contributing Centers/Offices	CBER, CDER, CTP, HFP, OC, ODT, OII
Metrics	▪ IT Help Desk Customer Satisfaction ▪ Critical Services/Applications Availability ▪ IT Spending across DME and O&M ▪ Cyber Defense Modernization
Programs/Projects	▪ Acquisition Lifecycle Platform (ALP) (Program) ▪ CBER Modernization ▪ CVM Data and Technology Modernization (Program) ▪ Enterprise Content Management Assessment (ECMA) ▪ FSMA Food Traceability/Product Tracing System (PTS) ▪ FSMA Food Safety Modernization Act (FSMA) FDA Unified Registration and Listing Systems (FURLS) (Program — Completed) ▪ Human Resources IT (HRIT) eSuite (Program) ▪ Implementation Initiative and Support (Workflow) (Nexus) ▪ Information Governance — Electronic Records Retention Project — Phase 2 (Program) ▪ Integrated Budget and Acquisition Planning System (IBAPS) Modernization (Program) ▪ Knowledge-Aided Assessment and Structure Application (KASA) (Program) ▪ CDER Bioresearch Monitoring (BIMO) Information Tracking Environment (CBITE) III — Implementation/Enhancements (Program) ▪ Quality Management Information System (QMiS) (Program) ▪ Research Management System Application Modernization and Maintenance ▪ Safety Reporting Portal ▪ Transition for precisionFDA ▪ User Fee System (Completed) ▪ Adverse Event Management System (CAEMS) (Program) ▪ OO Tobacco User Fee Application (TUFA) FY23 (Program) ▪ OO CTP Budget and Acquisition System (CBAS) FY23 (Program) ▪ RSRA Rhapsody (Program)
Risks	If the 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.

Table 17. Strategic Initiative 3.3: Electronic Submission

Executive Sponsor	**Center/Office:** ODT **POC:** Mohammed Sohail Chaudhry
Primary IT Goal	Goal 3: Modernize Enterprise Services and Capabilities
Primary Objective	▪ Increase Digital Maturity ▪ Improve Customer Experience
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.
Contributing Centers/Offices	CBER, CDER, CDRH, CTP, CVM, HFP, NCTR, OC, ODT, OII
Metrics	▪ ESG Availability
Programs/Projects	▪ Customer Collaboration Portal (CCP) ▪ Food Applications Regulatory Management (FARM) (Program) ▪ NextGen ESG (Program) ▪ Electronic Document Repository (EDR)/Automated Submission Receipt (ASR) ▪ RSRA eSubmissions Modernization (Program) ▪ RSRA eSubmissions FY23 (Program — Completed) ▪ RSRA eSubmissions FY2024 (Program)
Risks	If the FDA does not enhance electronic submission platforms, the FDA may have: ▪ Low adoption and conformance to the FDA standards ▪ Decreased time and capacity to review submissions in a timely manner ▪ Difficult access to the FDA resources for guidance on industry applications

GOAL 4 STRATEGIC INITIATIVE SUMMARY

Share Data for Mission Outcomes

Table 18. 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 Objective	▪ Improve Data Visibility and Accessibility ▪ Enhance Data Governance ▪ Enhance Secure Data Exchange ▪ Enable Advanced Data Analytics
Overview	Improve the 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.
Contributing Centers/Offices	OII, CBER, CTP, HFP, OC, CDER, ODT
Metrics	▪ Data sharing — Reduce Internal FDA Data Use Agreements ▪ Number of Assets and Partnerships to Share Data ▪ Data Science Talent ▪ Third-Party Data Services Costs
Programs/Projects	▪ CDEROne Intelligent Data Lake (iDL) (Program) ▪ Data Management System (DMS) — Data Intelligence Platform Implementation (CEDh) (Program) ▪ HFP (formerly CFSAN) Data Warehouse (CDW) (Program) ▪ Data Analytics as a Service (DAaaS) — (Program) ▪ Data Marketplace (Inspections Analytics) (Program — Completed) ▪ Pediatric Information Management System (PIMS) (Program — Completed) ▪ eMDM Data Services — Completed ▪ FDA Adverse Event Reporting System II (FAERS) (Drug Safety Platform) (Program) ▪ FDA Intelligent Data Lifecycle Ecosystem (FiDLE) (Program) ▪ Evaluation of precisionFDA Modernization (Completed) ▪ Global Substance Registration System (GSRS) (Program) ▪ OpenFDA (Program) ▪ precisionFDA Regulatory Information Service Module (PRISM) Proof of Concept ▪ RSRA Data Services FY23 (Program — Completed) ▪ RSRA Data Services FY2024 (Program) ▪ RSRA Tobacco Cost Model FY2024 (Program)
Risks	If the 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

Table 19. 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 Objective	▪ Foster Innovation ▪ Ensure Responsible Use of Innovations ▪ Balance Policy and Technology Value
Overview	Develop/refine the FDA-specific AI guidelines and implement targeted use cases in accordance with the October 2023 Executive Order 14110 on the Safe, Secure, and Trustworthy Development and Use of Artificial Intelligence.
Contributing Centers/Offices	CBER, CDER, CDRH, CTP, CVM, HFP, NCTR, OC, OII
Metrics	None at this time
Programs/Projects	▪ Artificial Intelligence Implementation (Program) ▪ Assessment of Large Language Models for FDA Business Activities (Program) ▪ AI Assessment for Medical Supply Chain Hardening (Program) (Completed)
Risks	If AI use cases are not aligned and governed in accordance with the EO, the 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.

Table 20. Strategic Initiative 5.2: AI Emerging Technologies

Executive Sponsor	**Center/Office:** ODT **POC:** Ram Iyer
Primary IT Goal	Goal 5: Adopt Artificial Intelligence (AI) and Mission-Driven Innovations
Primary Objective	Provide Proactive Thought Leadership
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.
Contributing Centers/Offices	CDER, NCTR, OII
Metrics	▪ None at this time
Programs/Projects	▪ AI Productivity Tools (Program) ▪ AskFDALabel ▪ Real-World Application for Innovation and Development (RAPID) V.1 Program III (Program)
Risks	If innovation, culture, and processes cannot be cultivated, the 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

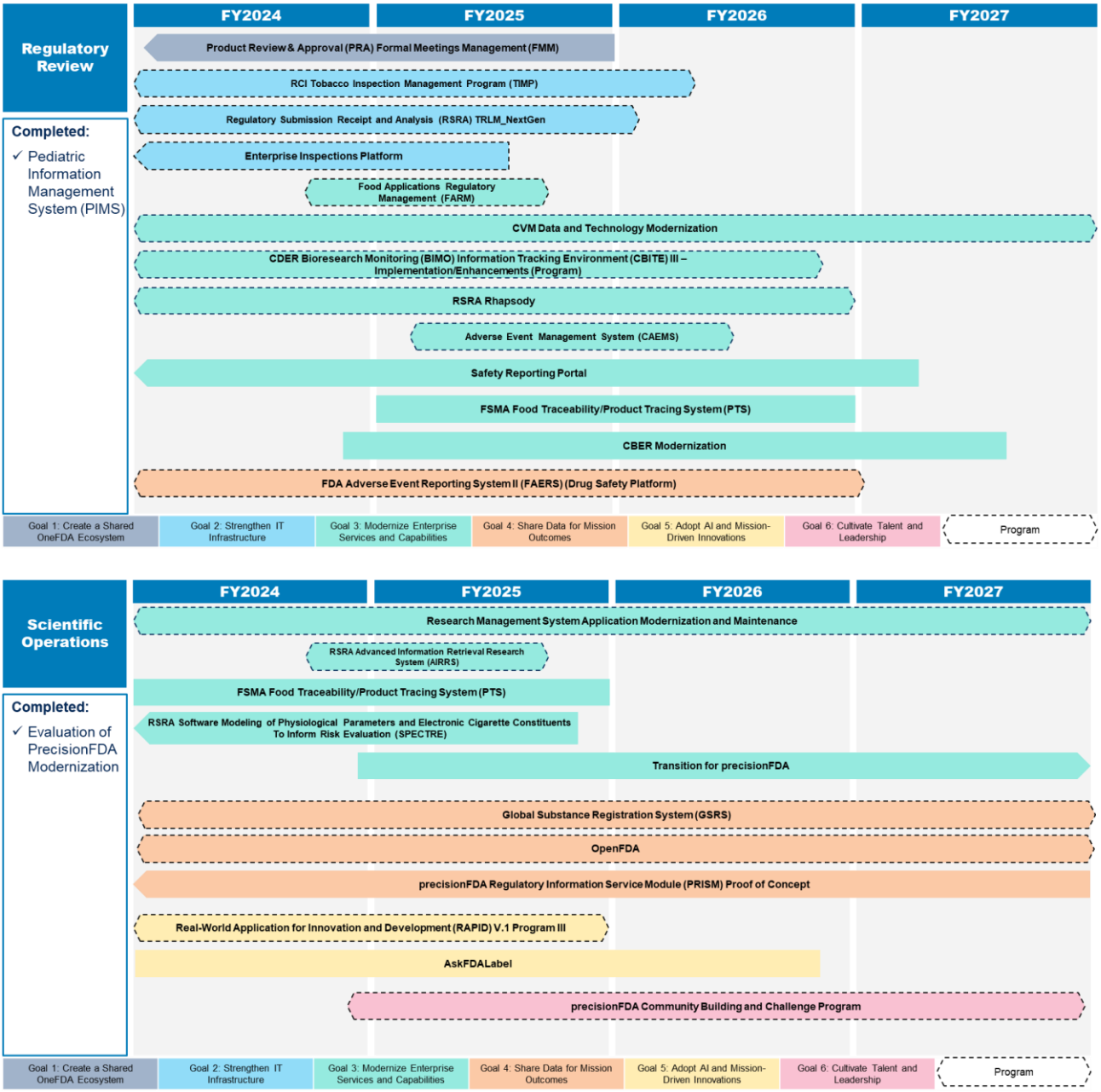
Table 21. Strategic Initiative
6.1: Workforce Modernization

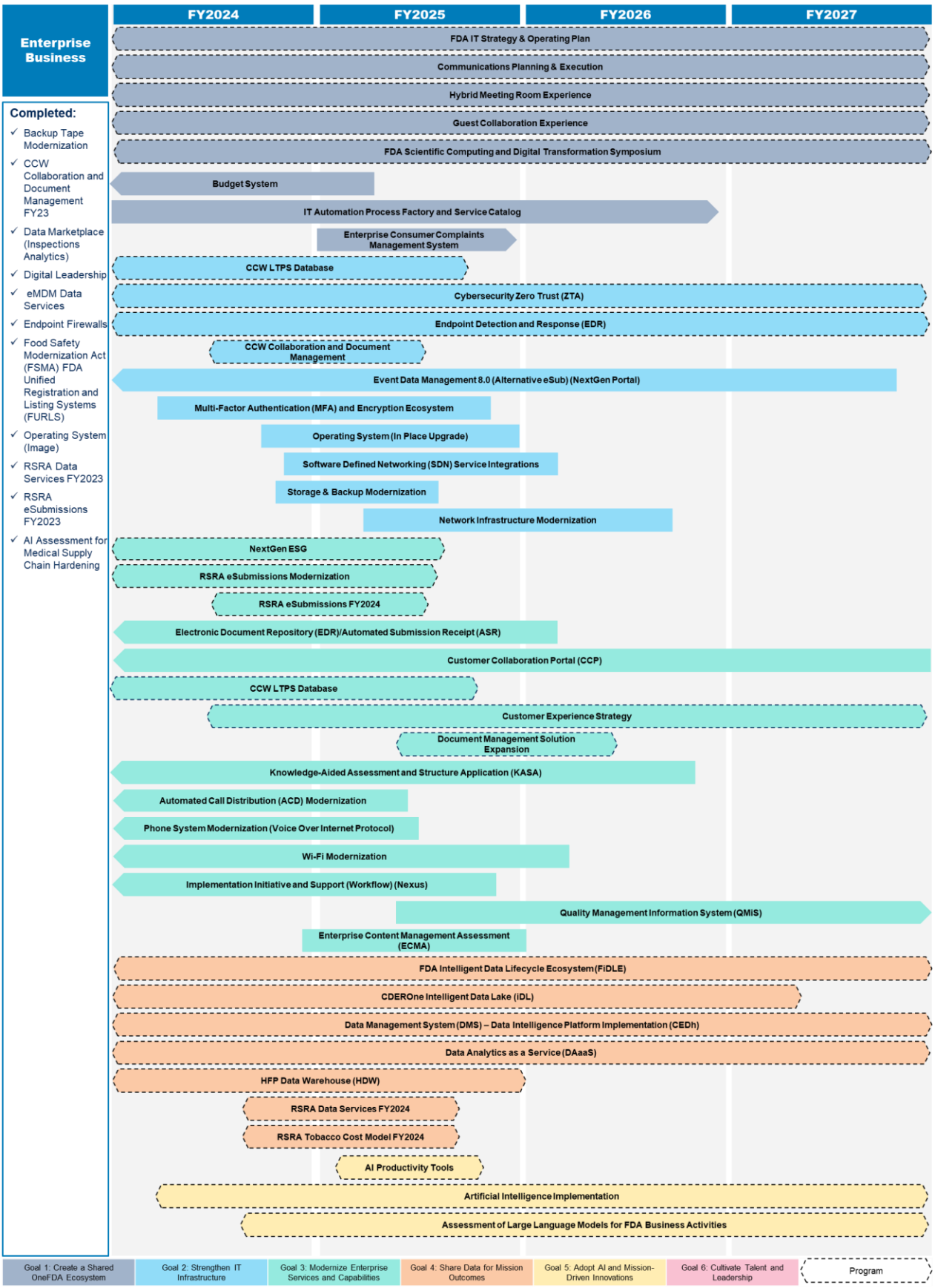
Executive Sponsor	**Center/Office:** ODT **POC:** Jess Berrellez
Primary IT Goal	Goal 6: Cultivate Talent and Leadership
Primary Objective	▪ Instill OneFDA Mindset ▪ Attract and Retain Talent ▪ Develop Skills for the Future of Work
Overview	Implement tactics and tools to attract, recruit, develop, and retain leaders and staff with the business and technical expertise needed to advance the FDA's mission.
Contributing Centers/Offices	OC, ODT
Metrics	▪ IT Workforce Growth Rate ▪ General Schedule (GS) to Title 21 Conversions ▪ Total Training Completion
Programs/Projects	▪ Candidate Relationship Management Module Tool (CRMT) (Program) ▪ DataForward — Applied Learning Tracks (Program) ▪ Digital Leadership (Program — Completed) ▪ Knowledge and Expertise Sharing ▪ precisionFDA Community Building and Challenge Program ▪ Project Elixir (Program) ▪ TechTalent Workforce Development (aka Project UpTech) (Program)
Risks	If the FDA does not address skill gaps and capacity constraints within the IT workforce, the 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

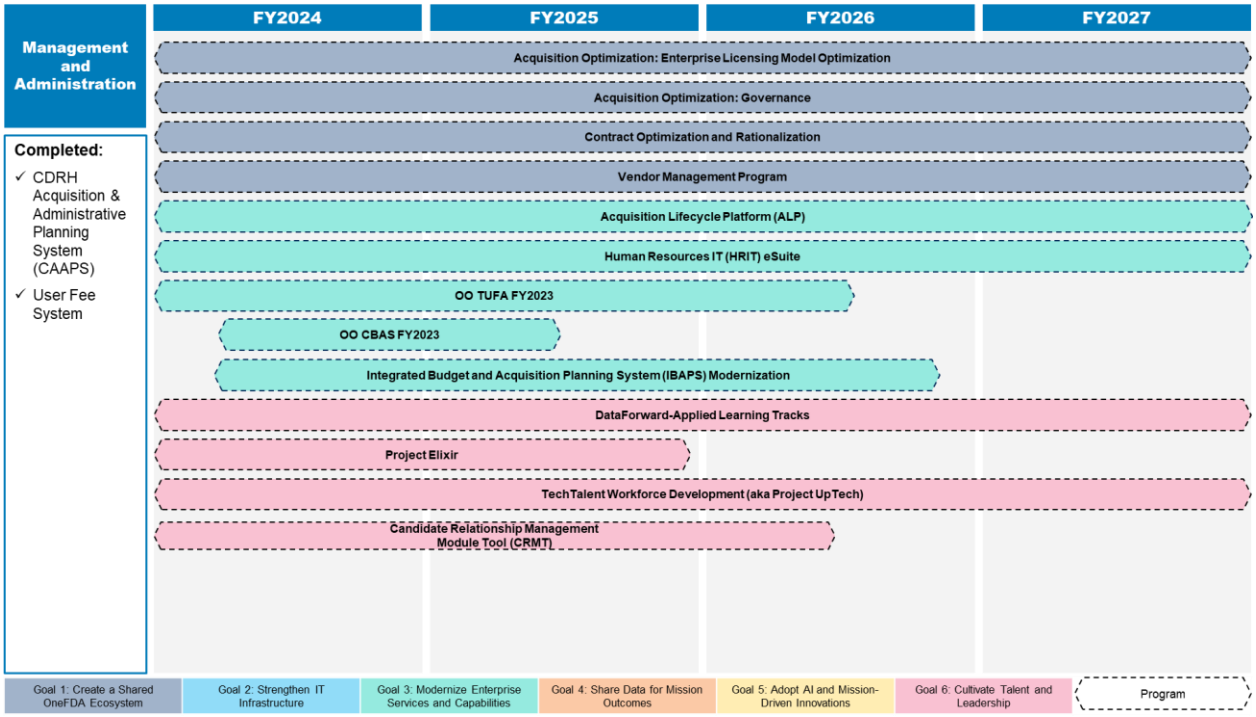
Strategic Projects Timeline

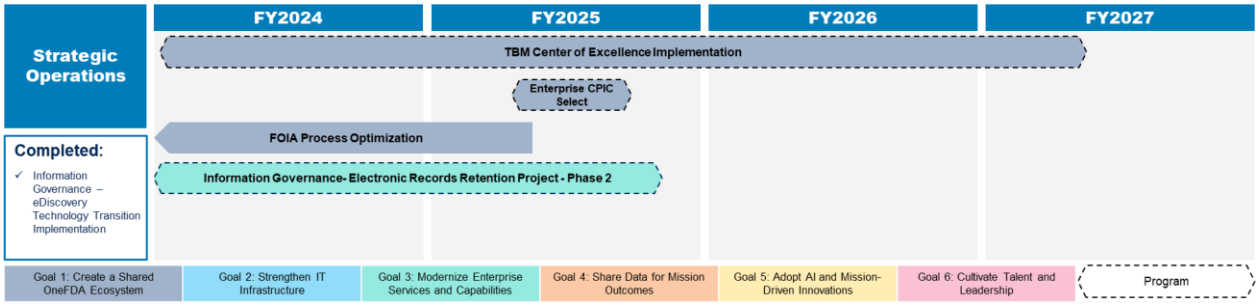
The charts below depict the timeline of strategic programs and projects within each strategic initiative above grouped by the business capability they enable. The business capabilities include Regulatory Review, Scientific Operations, Enterprise Business, Management and Administration and Strategic Operations.

Figure 2. Strategic Projects Timeline




Enterprise Business
FY2024
FY2025
FY2026
FY2027
FDA IT Strategy & Operating Plan
Communications Planning & Execution
Hybrid Meeting Room Experience
Guest Collaboration Experience
FDA Scientific Computing and Digital Transformation Symposium
Budget System
IT Automation Process Factory and Service Catalog
Enterprise Consumer Complaints Management System
CCW LTPS Database
Cybersecurity Zero Trust (ZTA)
Endpoint Detection and Response (EDR)
CCW Collaboration and Document Management
Event Data Management 8.0 (Alternative eSub) (NextGen Portal)
Multi-Factor Authentication (MFA) and Encryption Ecosystem
Operating System (In Place Upgrade)
Software Defined Networking (SDN) Service Integrations
Storage & Backup Modernization
Network Infrastructure Modernization
NextGen ESG
RSRA eSubmissions Modernization
RSRA eSubmissions FY2024
Electronic Document Repository (EDR)/Automated Submission Receipt (ASR)
Customer Collaboration Portal (CCP)
CCW LTPS Database
Customer Experience Strategy
Document Management Solution Expansion
Knowledge-Aided Assessment and Structure Application (KASA)
Automated Call Distribution (ACD) Modernization
Phone System Modernization (Voice Over Internet Protocol)
Wi-Fi Modernization
Implementation Initiative and Support (Workflow) (Nexus)
Quality Management Information System (QMiS)
Enterprise Content Management Assessment (ECMA)
FDA Intelligent Data Lifecycle Ecosystem (FiDLE)
CDEROne Intelligent Data Lake (iDL)
Data Management System (DMS) – Data Intelligence Platform Implementation (CEDh)
Data Analytics as a Service (DAaaS)
HFP Data Warehouse (HDW)
RSRA Data Services FY2024
RSRA Tobacco Cost Model FY2024
AI Productivity Tools
Artificial Intelligence Implementation
Assessment of Large Language Models for FDA Business Activities
Completed:
✓ Backup Tape Modernization
✓ CCW Collaboration and Document Management FY23
✓ Data Marketplace (Inspections Analytics)
✓ Digital Leadership
✓ eMDM Data Services
✓ Endpoint Firewalls
✓ Food Safety Modernization Act (FSMA) FDA Unified Registration and Listing Systems (FURLS)
✓ Operating System (Image)
✓ RSRA Data Services FY2023
✓ RSRA eSubmissions FY2023
✓ AI Assessment for Medical Supply Chain Hardening
Goal 1: Create a Shared OneFDA Ecosystem
Goal 2: Strengthen IT Infrastructure
Goal 3: Modernize Enterprise Services and Capabilities
Goal 4: Share Data for Mission Outcomes
Goal 5: Adopt AI and Mission-Driven Innovations
Goal 6: Cultivate Talent and Leadership
Program


Management and Administration
FY2024
FY2025
FY2026
FY2027
Completed:
✓ CDRH Acquisition & Administrative Planning System (CAAPS)
✓ User Fee System
Acquisition Optimization: Enterprise Licensing Model Optimization
Acquisition Optimization: Governance
Contract Optimization and Rationalization
Vendor Management Program
Acquisition Lifecycle Platform (ALP)
Human Resources IT (HRIT) eSuite
OO TUFA FY2023
OO CBAS FY2023
Integrated Budget and Acquisition Planning System (IBAPS) Modernization
DataForward-Applied Learning Tracks
Project Elixir
TechTalent Workforce Development (aka Project UpTech)
Candidate Relationship Management Module Tool (CRMT)
Goal 1: Create a Shared OneFDA Ecosystem
Goal 2: Strengthen IT Infrastructure
Goal 3: Modernize Enterprise Services and Capabilities
Goal 4: Share Data for Mission Outcomes
Goal 5: Adopt AI and Mission-Driven Innovations
Goal 6: Cultivate Talent and Leadership
Program


Strategic Operations
FY2024
FY2025
FY2026
FY2027
Completed:
✓ Information Governance – eDiscovery Technology Transition Implementation
TBM Center of Excellence Implementation
Enterprise CPIC Select
FOIA Process Optimization
Information Governance- Electronic Records Retention Project - Phase 2
Goal 1: Create a Shared OneFDA Ecosystem
Goal 2: Strengthen IT Infrastructure
Goal 3: Modernize Enterprise Services and Capabilities
Goal 4: Share Data for Mission Outcomes
Goal 5: Adopt AI and Mission-Driven Innovations
Goal 6: Cultivate Talent and Leadership
Program

5.0 PERFORMANCE MEASURING & MONITORING

PERFORMANCE MEASURING & MONITORING

The FDA's multi-layered IT performance measurement and monitoring process encompasses IT Strategy, IT Programs/Projects and IT Operations/Service Delivery. Specific to the IT Strategy, the 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 the FDA's public health mission. Our performance measurement process will continue to be refined and enhanced. We are committed to ongoing improvements to track and report impactful performance metrics to assess our strategy's effectiveness accurately, improve our ability to support our IT goals and demonstrate the strategy's value to stakeholders. We appreciate your patience and collaboration as we iteratively optimize this process.

During regular performance reviews with the Technology Council, the 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. The 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 the 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 the FDA's agency-wide performance management system that monitors the 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
	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
	Annual Business Reviews Conducted	Number of Annual Business Reviews Conducted/18
	FDA Small Business	Percentage of Small Businesses awarded FDA contracts
	Stakeholder Engagement	Number of impressions of communications content by channel
	External-facing Communications	Number of external-facing FDA events completed
2	EoL Equipment — Network, Storage, Compute Towers	FY23 Baseline – (End of Life Equipment/Total Equipment)
	Critical Services/Applications Availability	(Total number of hours – Total number of hours with Priority 1 Outages)/Total number of hours
	Cloud Adoption — New Applications and Systems	Percent of FDA's applications and services hosted in cloud environments
	FDA Zero Trust Maturity Level	FDA will measure progress and level of maturity (Traditional, Initial, Advanced, and Optimal) based on criteria defined in the CISA Zero Trust Maturity Model
	Operations & Maintenance (O&M) Costs	Percent change in O&M costs
	Network, Storage & Compute Spend	Network, Storage, and Compute Spend as percentage of Total IT Spending
3	IT Help Desk Customer Satisfaction	Positive responses/Total responses in the ODT customer satisfaction 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
	ESG Availability	(Total number of hours – Unplanned downtime)/Total number of hours
	Cyber Defense Modernization	Completion of 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

Goal	Metric	Calculation
4	Data Sharing — Reduce Internal Data Use Agreement	(Prior Year (PY) – Current Year (CY) Number of new Internal Data Use Agreements Requiring Adjudication)/CY Number of new Internal Data Use Agreements Requiring Adjudication
	Number of Assets and Partnerships to Share Data	(CY – PY Number of partnerships to share internal and external stakeholders)/(PY Number of partnerships to share internal and external stakeholders)
	Data Science Talent	(CY – PY Number of cross-trained data engineers, analysts, and scientists)/PY Number of cross-trained data engineers, analysts, and scientists
	Third-party Data Services Costs	(FY23 Baseline Costs – CY Costs of related licenses)/FY23 Baseline Costs
5	Pending	Metric definition for Goal 5 is in progress.
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
	General Schedule (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.)

6.0 COMMUNICATIONS & OUTREACH

COMMUNICATIONS & OUTREACH

The purpose of our communications and outreach is to build awareness and support execution of our IT Strategy and Operating Plan while increasing transparency and collaboration. Specifically, we will:

- Provide stakeholders with strategic context
- Promote opportunities for dialogue
- Proactively streamline internal coordination, and
- Provide more visibility into decision-making

Managed by staff dedicated to IT Communications, the communications strategy delves into the critical aspects of communicating to internal (e.g., FDA Executives, FDA Centers/Offices) and external stakeholders to advance our IT strategy. To ensure seamless execution, this strategy is complemented by project-specific communications and change management plans tailored to specific project needs.

Internal Stakeholders

Internal stakeholder engagement and outreach ensures collaboration across the FDA to establish and execute our IT strategic goals. Examples of communication channels include those mentioned below:

- 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 27,000 internal readers.
- Townhalls/Summits: We are committed to fostering a more connected FDA IT community through regular Town Hall Meetings, enhancing dialogue and information exchange. In FY 2025, we plan to hold our inaugural FDA-wide IT Townhall.
- 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. By actively involving diverse perspectives, we foster a collaborative environment that enhances transparency, trust, and the relevance of IT initiatives. We employ various communication channels to build awareness, facilitate valuable interaction and gather feedback such as those listed below:

- Monthly Newsletter: Includes updates on IT Strategy as well as events and activities open to the public e.g., Summits, Federal Register Notices, Innovation Challenges. Currently distributed to over 14,000 external readers.

- Publications/Social Media: Includes a variety of messages on IT Strategy to continue building awareness of our IT goals and objectives, highlight relevant IT projects, promote upcoming events/activities and more on platforms like LinkedIn, X, and others.
- Conferences/Summits/Listening Sessions: Interactive forums used to facilitate valuable interaction and feedback on IT strategic goals, IT projects and other topics related to the IT strategy e.g., listening sessions, public meetings, the FDA Digital Transformation Symposium, and Reverse Vendor Day. Additionally, 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.

We are committed to prioritizing stakeholder input and welcome suggestions for engagement with the FDA IT community. This initiative is pivotal for aligning our efforts with the needs and expectations of all constituents, ultimately enhancing the effectiveness of IT strategies and investments.

COMMUNICATION STRATEGY FOR INTERNAL STAKEHOLDERS

The following tables describe the strategies and protocols the 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.

Table 22. FDA IT Strategies and Protocols — Internal Stakeholders

Target Audience	Communication Champions	Desired Outcomes	Key Messages	Key Channels
Executive Leadership	CIO	▪ Executive approval of IT Strategy and related budget requests ▪ Cross-FDA collaboration ▪ Address challenges/risks ▪ Allocation of funding	▪ Alignment to HHS, FDA and Center/Office's mission and strategic priorities ▪ Budget requests will be aligned with IT strategy goals and objectives ▪ Commitment to success of IT Strategy ▪ Celebrate outcomes achieved/Reinforce FDA benefits ▪ Support needed to address challenges/risks	▪ Executive Committee ▪ Budget Formulation process
ODT	**ODT Executive Leadership Team (ELT)**	▪ Staff commitment ▪ Empower change champions ▪ Drive awareness ▪ Address challenges/risks	▪ Alignment to HHS, FDA and Center/Office's mission and strategic priorities ▪ Commitment to success of IT Strategy ▪ Act as change drivers to increase adoption and engagement with peers ▪ Celebrate outcomes achieved/Reinforce FDA benefits ▪ Address challenges/risks	▪ Monthly Newsletter/Blog ▪ Governance Councils ▪ Organization Change Management (OCM) Workshops/ Forums ▪ Strategy Progress Reporting ▪ Training as needed

Target Audience	Communication Champions	Desired Outcomes	Key Messages	Key Channels
Centers & Offices	Technology Council/ ADCIOs	▪ Stakeholder commitment ▪ Empower change champions ▪ Cross-FDA Collaboration ▪ Drive awareness ▪ Address challenges/risks	▪ Alignment to HHS, FDA and Center/Office's mission and strategic priorities ▪ Commitment to success of IT Strategy ▪ Act as change drivers to increase adoption and collaboration across Centers/Offices ▪ Celebrate outcomes achieved/Reinforce FDA benefits ▪ Address challenges/risks ▪ Promote relevant training opportunities ▪ Share your feedback	▪ Monthly Newsletter/Blog ▪ Governance Councils ▪ Quarterly Meetings ▪ Roadshows e.g., FDA-wide IT Townhall ▪ OCM Workshops/ Forums ▪ Strategy Progress Reporting ▪ Training as needed

COMMUNICATION STRATEGY FOR EXTERNAL STAKEHOLDERS

Table 23. FDA IT Strategies and Protocols — External Stakeholders

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

CLOSING MESSAGE FROM THE CIO

The implementation of the FDA's IT Strategy through this IT Operating Plan is of paramount importance at this juncture. 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 each year, we will include additional details on projects/milestones within the IT Roadmap. 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 (ODT)

END

7.0 APPENDIX

IT Strategic Goal Alignment
IT Skills Assessment Summary
IT Strategic Initiative Progress
IT Strategic Initiative Details

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 the FDA's business capabilities and priorities.

Table 24. 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			
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			

Table 25. FDA IT Strategic Projects Aligned to PDUFA and BsUFA Goals

Goal	IT Projects	Enhance Transparency	Develop Data and Technology Modernization Strategy	Promote Convergence	Accelerate CBER Modernization	Monitor and Modernize Electronic Submission Gateway (ESG)	Leverage Cloud Technologies to Progress Regulatory Digital Transformation	Provide Bioinformatics IT Support	Expanding and Enhancing Bioinformatics Support	Enhancing Use of Digital Health Technologies to Support Drug Development and Review	Develop Data and Technology Modernization Strategy	Monitor and Modernize Electronic Submission Gateway (ESG)
1	Product Review & Approval (PRA) Formal Meetings Management (FMM) — COMPLETED (CBER)				X							
1	FDA IT Strategy & Operating Plan		X								X	
1	FDA Scientific Computing and Digital Transformation Symposium	X										
1	Enterprise CPIC Select	X										
1	Guest Collaboration Experience	X										
2	Event Data Management 8.0 (Alternative eSub) (NextGen Portal) (CDER)			X			X					
2	Enterprise Inspections Platform						X					
3	NextGen ESG					X	X					X
3	CDER BIMO Information Tracking Environment (CBITE) III — Implementation/Enhancements (CDER)			X								
3	Implementation Initiative and Support (Workflow) (Nexus) (CDER)			X			X			X		
3	Knowledge-Aided Assessment and Structure Application (KASA) (CDER)			X			X					
3	Quality Management Information System (QMiS)				X							
3	Customer Experience Strategy					X						
3	Information Governance- Electronic Records Retention Project — Phase 2			X								
3	Transition for precisionFDA							X	X			
4	CDEROne Intelligent Data Lake (iDL) (CDER)			X			X			X		
4	FDA Adverse Event Reporting System II (FAERS) (Drug Safety Platform) (CDER)			X								
4	Data Marketplace (Inspections Analytics)			X			X					
4	FDA Intelligent Data Lifecycle Ecosystem (FiDLE)											
4	precisionFDA Regulatory Information Service Module (PRISM) Proof of Concept						X	X	X			
4	Evaluation of precisionFDA Modernization							X	X			
5	Real-World Application for Innovation and Development (RAPID) V.1 Program III (CDER)			X			X					
6	precisionFDA Community Building and Challenge Program							X	X			
6	Candidate Relationship Management Module Tool (CRMT)								X			

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

Table 26. 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

Table 27. 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		

IT SKILLS ASSESSMENT SUMMARY

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.

The 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 the 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, the FDA is committed to investing in upskilling, reskilling and new skilling our existing workforce. However, to truly excel in the FDA’s IT endeavors and advance the new strategy, the FDA must also strengthen its capability to attract and hire top-tier talent.

To this end, the 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 the 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 the FDA’s IT strategies. By balancing internal

development with strategic external hiring, the 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 eight-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.

IT STRATEGIC INITIATIVE PROGRESS

This fiscal year, our IT operating plan introduces a structured approach to monitoring progress for a selected subset of projects within the IT roadmap. This initial selection is based on enterprise impact and external commitments, ensuring that our focus aligns with strategic priorities and stakeholder expectations. As we refine our processes, this monitoring framework will gradually expand to encompass all projects within the IT roadmap. Beginning in FY25, these selected projects will provide quarterly updates on their progress, which will be evaluated by the Portfolio Review Board. To ensure project momentum is maintained and goals are achieved, the Tech Council will engage on an exception basis to support project execution. This approach underscores our commitment to strengthening governance and continuous improvement in our IT operations.

Strategic Initiative 1.1

Table 29. Progress on FDA IT Strategy & Operating Plan

Description	Develop an agency-wide IT Strategy and IT Operating Plan in collaboration with internal and external stakeholders. ▪ Refine our agency-wide IT governance model to support strategy execution ▪ Define a process to measure IT strategy performance ▪ Monitor the FDA's progress against IT strategic goals ▪ Refresh the IT Strategy and IT Operating Plan on an annual basis at minimum
Milestones	▪ 2023 03 — Start ▪ 2023 09 — Published initial IT Strategy ▪ 2024 02 — Published initial IT Operating Plan ▪ 2024 09 — Published IT Strategy annual refresh ▪ 2024 12 — Publish IT Operating Plan annual refresh ▪ 2025 09 — Publish IT Strategy annual refresh ▪ 2025 12 — Publish IT Operating Plan annual refresh ▪ 2026 09 — Publish IT Strategy annual refresh ▪ 2026 12 — Publish IT Operating Plan annual refresh ▪ 2027 09 — End
Accomplishments (Prior Fiscal Year)	▪ Leveraged collaborative, inclusive approach to develop and publish annual IT strategy refresh in Sept. 2024 ▪ Developed process to assess performance of strategic IT projects ▪ Developed recommendations to strengthen enterprise IT governance
Planned Activities	▪ Launch performance measurement process with a subset of strategic IT programs and projects ▪ Report FY2024 IT strategic metrics (available on FDA TRACK) ▪ Gather input from stakeholders through Federal Register and other channels ▪ Refresh IT Strategy and IT Operating Plan
Risks	▪ If IT strategic planning is not responsive to broader industry signals, forces and trends (e.g., technology, political, economical, social/cultural, trust/ethics, regulatory/legal and environmental), then the FDA may have challenges rapidly shifting its priorities in order to accelerate the advancement of business capabilities. Mitigate — Leverage strategic planning process to assess and respond to signals, forces and trends as high impact areas emerge (at minimum annually).

Table 30. Progress on FOIA Process Optimization

Description	Establish process, governance and technology to support the Freedom of Information Act (FOIA) enterprise workflow across FDA Centers.
Milestones	▪ 2023 10 — Start ▪ 2024 03 — Server environments provisioned ▪ 2024 11 — User acceptance testing completed ▪ 2025 02 — Go live
Accomplishments (Prior Fiscal Year)	▪ Provisioned all server environments ▪ Completed workflow discovery and harmonization ▪ Established FDA FOIA Council for ownership and decision-making ▪ Deployed fully functional software platform to testing environment ▪ Completed user acceptance testing (round 1)
Planned Activities	▪ Launch application in February 2025 – Replaces AIMS FOIA capability for FOIA response management including triage, Center handoff, reporting, and billing – Replaces Center-specific FOIA response activity, including processing, redaction, de-duplication, review and delivery – Eliminates redundant tools ▪ Manage application hypercare period and turnover to ODT March 2025 — April 2025
Risks	▪ If O&M to DAS is delayed, then go-live could be delayed. Mitigate — Foster ongoing, detailed understanding of O&M RACI assignments.

Strategic Initiative 1.3

Table 31. Progress on Enterprise Consumer Complaints Management System

Description	Reform how consumers report a problem to the Agency by developing a single, front-end interface and back-end data integrations to streamline complaints processing, improve customer interactions with the Agency and act on vital information more quickly to better serve the FDA's mission to protect the health of the public.
Milestones	▪ 2024 10 — IAA with U.S. Digital Services (USDS)[1] and contract vehicles established for Agency Front-End (underway) ▪ 2025 01 — Universal Intake Tool Demos begin (every 6 weeks) ▪ 2025 10 — Anticipated Product Launch for Universal Intake Tool ▪ 2024 08 — Front-end project launch with US Digital Services (USDS) Discovery Sprint ▪ 2024 10 — Interagency Agreement (IAA) with USDS and contract vehicles established for Agency Front-End (underway) ▪ 2025 01 — Universal Intake Tool Demos begin (every 6 weeks) ▪ 2025 10 — Anticipated Product Launch for Universal Intake Tool
Accomplishments (Prior Fiscal Year)	▪ Defined USDS Discovery Sprint Recommendations (July-August 2024) ▪ Began design sessions with FDA Centers/Offices/Programs
Planned Activities	▪ Conduct design sessions with key stakeholders ▪ Complete project charter ▪ Launch steering committee ▪ Onboard project manager and complete staffing/contracting ▪ Conduct ~ five (5) sprints to develop product ending Q4 FY25
Risks	▪ If Centers cannot align around an Agency front end, then they may generate entry points that skirt the effort. Mitigate — Build governance to decide where alignment cannot be achieved and require participation from all Centers. ▪ If additional funds are not obtained from the FY26 NEF or FY26 budget, then work may be incomplete. Mitigate — Phase the work so wherever possible a functional product with a narrower scope, not just an MVP, can be executed with existing funds. ▪ If clarity cannot be obtained on the long-run AI plan, then ongoing investments in D&M for current chatbots, which may not be compatible with long-term plan, may continue. Mitigate — Have leadership decide when/if to pause DM&E.

[1] USDS is an IT consulting unit of the Office of the President.

Strategic Initiative 2.1: Stabilization/End of Life/End of Service (EOL/EOS)

Table 32. Progress on Network Infrastructure Modernization

Description	Transition from end-of-life network gear to software-defined networking to enhance infrastructure flexibility, scalability and management, while ensuring cost savings and performance improvements.
Milestones	▪ 2024 01 — Start ▪ Ongoing — Deliverables vary each FY based on funding levels to modernize oldest equipment. This includes Data Centers and all field office locations. ▪ 2026 06 — End
Accomplishments (Prior Fiscal Year)	▪ Completed WODC SDN Migrations ▪ Completed White Oak Wi-Fi Modernization Phase 2
Planned Activities	▪ Complete modernization of Wi-Fi services at all HQ area facilities to provide high bandwidth and comprehensive coverage ▪ Complete migrations of ADC devices into new SDN fabric to increase reliability and eliminate EOL switches ▪ Refresh EOL LAN closet switches to ensure operational reliability and supportability
Risks	▪ If inadequate resources for implementation, then services will not be modernized. Mitigate — Leverage external labor contracts.

Strategic Initiative 2.2: Cloud Transformation

Table 33. Progress on Enterprise Inspections Platform

Description	Develop an enterprise end-to-end platform for all inspection types that accommodates diverse program needs. Scope for Release 1.0 is surveillance inspection for foods and pharmaceuticals (New Inspection Protocol Project (NIPP) and Preventive Controls for Human Food (PCHF)).
Milestones	▪ 2023 04 — Start ▪ 2024 01 — Desk inspection testing ▪ 2025 Q3/Q4 — Release 1 ▪ 2025 06 — End
Accomplishments (Prior Fiscal Year)	▪ Conducted discovery, business process mapping, and recommendations across all inspections ▪ Designed new shared business processes for the future state ▪ Gathered business requirements across all program areas ▪ Collaborated on technical proof-of-concept of new IT platform ▪ Finalized integration discovery plan ▪ Deployed 8 releases for iterative testing
Planned Activities	▪ Complete Release 1 development ▪ Complete desk and field user acceptance testing ▪ Complete user training ▪ Deploy Release 1
Risks	▪ If preliminary development estimates for EIP Release 1.0 need to be revised once user stories are complete and clarity is provided from SME review sessions; then there will be a delay in finalizing the schedule which may also impact budget. Mitigate — Develop and execute a comprehensive change management plan with sponsors at all levels within the organization. ▪ If there is limited sponsorship within stakeholder groups, then it could contribute to low adoption of process and technology. Mitigate — ETO to support consistent, deliberate engagement with sponsors at all levels of the organization to effectively communicate, ensure business needs are met, and solicit their help in advocating for the EIP, mitigating resistance and supporting communication. ▪ If there isn't enough funding to purchase iPads at the rate initially projected when project started, then the goal of providing a mobile field application will not be met and a modified development or rollout plan is required. Mitigate — Preferred approach (least technology risk) is to spread out the purchase of iPads given available yearly budget; for example, if it is determined that it would take 4 years to purchase the necessary iPads to support complete rollout, allocate those funds accordingly over those years; in this way, the timing of EIP sun-up and eNSpect sunset can be accurately forecasted and thus, prepared for; Additionally, selecting the iPad Air model would cost 50% less than previous iPad Pro estimations.

Strategic Initiative 2.3: Zero Trust

Table 34. Progress on Cybersecurity Zero Trust (ZTA)

Description	A centralized architecture or framework of various capabilities and policies to facilitate and provide secure access to FDA resources, such as applications, data, servers, devices, etc. Zero Trust Is a Shift in Our Approach to Cybersecurity from a network-centric to a data-centric approach to security.
Milestones	▪ 2021 01 — Zero Trust Initiative start ▪ 2022 10 — Advanced Level Zero Trust Maturity achieved ▪ 2023 09 — Endpoint Detection and Response (EDR) in production ▪ 2024 09 — Secure Access Service Edge (SASE) in production ▪ 2025 09 — Zero Trust enhancements beyond Advanced Maturity Level ▪ 2026 09 — Optimal Level Zero Trust Maturity ▪ Zero Trust is a framework, philosophy, and program that does not end.
Accomplishments (Prior Fiscal Year)	▪ Enhanced FDA's cybersecurity program through strategic procurement actions: Secure Access Service Edge (SASE), identity management, non-phishable MFA, firewall modernization and direct cloud-to-cloud connectivity. ▪ Implemented key zero trust tools, cyber defenses and capabilities to protect and safeguard our critical assets and sustain our reputation as a world leader in public health and steward of industry information. ▪ Effectively led the establishment and integration of counterintelligence (CI) and insider risk principles, as well as the CI Cyber RECON Hunt Team and Cyber AI Defense Team, within the Zero Trust framework to align with U.S. National Counterintelligence Strategy to protect against threat actors. ▪ Obtained Level 4 Maturity by the HHS Office of the Inspector General on FDA's Cybersecurity, Counterintelligence and Insider Threat Program.
Planned Activities[1]	▪ Implement Zero Trust enhancements beyond Advanced Maturity Level ▪ Achieve Optimal Level Zero Trust Maturity
Risks	▪ If increased funding and/or appropriate level of base budget to support the FDA Cybersecurity Program and related Zero Trust Initiative is not achieved for FY25 and FY26 then the FDA's ability to effectively acquire cyber defenses and services to protect against emerging and sophisticated global threats may be compromised as well as the related legal, reputational, business, operational, technical and compliance risks and the congressional and industry scrutiny. Mitigate — Strategically fund to enhance FDA's cybersecurity defenses and ensure sensitive data and information remains protected from sophisticated cyber threats including nation states and transnational criminal organizations.

[1] Details are on file in the FDA Cybersecurity Counterintelligence and Insider Threat Program Office.

Strategic Initiative 3.2: System Modernization

Table 35. Progress on CBER Modernization

Description	Modernize CBER capabilities across business, data and technology. Modernization integrates data and innovative technology that facilitate business solutions to maximize productivity, collaboration and connectivity for all CBER staff.
Milestones	▪ 2024 09 — Commence form-based applications/systems modernization ▪ 2025 09 — Complete modernization of at least two (2) form-based applications ▪ 2025 10 — Complete CBER Content Management Services (CCMS) implementation of Digital Signature process ▪ 2027 03 — Commence low code-based application/system modernization ▪ 2027 FY — Implement AI/ML-driven submission processing, data capture, and text summarization
Accomplishments (Prior Fiscal Year)	▪ Launched Automated Electronic Submission Processing (ESP) – Auto detection and rejection of non-conformant submissions – Reduced manual processing of submissions by over >50% – Decommissioned previous, outdated system ▪ Implemented a cloud-based business intelligence platform – Leveraged CDER One as a tenant space – Supports analysis of Resource Capacity Planning data – Supports reporting for Formal Meetings Management ▪ Consolidated Formal Meetings Management (FMM) – Moved capabilities from five (5) systems into CBER Connect – Decommissioned one system previously used to partially manage meetings ▪ Completed Black Box Analysis for forms-based applications ▪ Acquired digital signature software for CCMS
Planned Activities	▪ Enhance Formal Meetings Management to support remaining meeting types and add functionality ▪ Enhance Review Management by consolidating data entry for non-status changing communications – Enhance Automated Persons System to: – Improve access and control processes for legacy systems – Fold capabilities into modernized Identity and Access Management (IAM) – Decommission APS ▪ Develop requirements for: – Enterprise Content Management — Improve ability to manage regulatory and relevant non-regulatory content through entire life cycle – Research Central — Research Management including Veterinary Services – Records Management — Improve electronic record keeping and document accountability and tracking ▪ Conduct White Box Analysis for High Priority forms-based applications ▪ Conduct Black Box Analysis for low code and web-based applications ▪ Commence Modernization of Oracle Forms Applications ▪ Continue the Proof of Concepts (POCs) for CCMS Digital Signature solution

Risks	▪ If the 12 applications based on Oracle Forms technology (APS, BER, BLT, HCTERS, VAERS, LDD, BIRAMS, LRS, CRMTS, DATS, RMS-BLA) are not modernized by December 2027, which is the end of extended support then the applications will be running on unsupported/End of Life (EOL) technology. Mitigate — Work with ORO Management to include these applications on our IT Roadmap for Modernization, if not already included.

Table 36. Progress on CVM Data and Technology Modernization

Description	CVM is taking a holistic, data-first approach to how we collect, handle, and use data. CVM's data-first approach is the core concept of our modernization initiative that we call the OneCVM system. This OneCVM system will build a strong data foundation and will organize all CVM-collected data in a consistently retrievable format. Starting with modeling the animal drug lifecycle and data flow, then building a solid technical foundation on support of information receipt and retrieval, meeting our growing regulatory responsibilities to provide real-time, comprehensive, situational awareness to predict, protect and promote global human and animal health. The OneCVM system is the prototype of the larger OneFDA community.
Milestones	▪ 2023 09 — Start ▪ 2024 09 — Interactive oneCVM concept showcase to the Modernization Committee ▪ 2024 12 — New data access, infrastructure, and analytics into production for historical data deployment ▪ 2025 09 — Reporting capabilities expansion (integrate and refactor remaining CDP data schemas; integrate and refactor content management data) ▪ 2025 09 — Release CVM search for animal drugs ("Hey Wolfie")
Accomplishments (Prior Fiscal Year)	▪ Leveraged data-first vision including objectives (win-themes) and, business capabilities to illustrate OneCVM system potential ▪ Conducted industry drug lifecycle data catalog mapping ▪ Developed and showcased oneCVM concept ▪ Enhanced data access, infrastructure, and analytics by leveraging existing legacy data for our new data-first system
Planned Activities	▪ Expand reporting capabilities (integrate and refactor remaining CDP data schemas; integrate and refactor content management data) ▪ Release CVM search for animal drugs ("Hey Wolfie")
Risks	▪ If CVM is unable to leverage existing ODT IT contracts, then CVM will need to solicit support from OAGS to develop a new contract to support modernization activities. Mitigate — Continue to explore contracting opportunities with ODT ▪ If CVM resists the new data-first system or lacks enthusiasm in acquiring new data skills needed to support CVM's business programs, then CVM's adoption of the new data-first system will be impeded as will upgrading and migrating from the legacy platforms. Mitigate — Continue to develop and implement a change management program to inform CVM stakeholders, building their buy-in and assist them in transitioning to the new data-first system as the project develops.

Table 37. Progress on Enterprise Content Management Assessment (ECMA)

Description	The objectives of this project are to conduct a full technical assessment of FDA's Enterprise Content Services (ECS) including CDER's Electronic Document Room (CDER EDR) and evaluate the feasibility of migrating CDER EDR, Enterprise Document & Records Management Platform (EDRMP) and other on-prem applications to an Enterprise based Cloud Content Services Platform (ECSP).
Milestones	▪ 2024 09 — Start ▪ 2024 09 — Contract Award ▪ 2025 09 — End
Accomplishments (Prior Fiscal Year)	▪ Awarded ECMA contract ▪ Initiated survey for Insight into enterprise content services ▪ Developed stakeholder engagement list
Planned Activities	▪ Conduct technical assessment and review of CDER EDR ▪ Conduct technical assessment of EDRMP ▪ Conduct gap analysis of the current as-is EDRMP/Documentum-based ECM services, systems, business requirements ▪ Conduct Cloud based ECSP assessment, covering alignment to industry trends ▪ Develop ECSP strategy and roadmap ▪ Develop Level of Effort (LOE) and plan for converging content and document stores, to a unified cloud-based content services platform providing a consolidated ECM system for the enterprise ▪ Finalize Assessment Report
Risks	▪ If the ECM Program Governance Board (ECM PGB) is not formed as an ongoing parallel effort, then the ECMA team will have challenges engaging stakeholders in the enterprise-wide assessment. Mitigate — Identify existing governance boards with enterprise-wide representation that may be leveraged while the ECM PGB is being formed.

Table 38. Progress on Human Resources IT (HRIT) eSuite

Description	Provide a fully compliant, comprehensive, automated suite of applications to standardize HR processes and reduce manual entry and errors. Includes HRIT infrastructure, robust, data-driven, analytic tools, real-time reporting.
Milestones	▪ 2017 01 — Start ▪ 2024 08 — Update eClass to include new HFP organizations ▪ 2024 09 — Launch Title 21 eClass to add the ability to create/update SODs ▪ 2024 10 — Update ePMAP to accommodate HFP Org updates ▪ 2024 11 — Launch eIncentive module ▪ 2024 11 — Launch Title 21 COLA, WIGI, QSI, Zone Increase module ▪ End — Ongoing
Accomplishments (Prior Fiscal Year)	▪ Launched ePMAP to reduce the manual processing by 100% and meet OPM compliance standards ▪ Launched eClass to reduce the manual processing by 100% and meet OPM compliance standards ▪ Developed eFlex to create/track/maintain telework agreements ▪ Developed OneHR, a stop-shop of HR resources and provide a self-service portal for employee information ▪ Launched Title 21 SOD capability in eClass module ▪ Launched Title 21 COLA, WIGI, QSI, Zone Salary Increase Tool ▪ Updated ePMAP, eClass to accommodate HFP Reorg efforts
Planned Activities	▪ Continue to automate frequently used pdf forms and processes to improve tracking and efficiency ▪ Update eClass front-end framework utilizing Bootstrap ▪ Launch ePMAP for Executives/Title 21
Risks	▪ If the HRIT eSuite doesn't secure the required budget, then the agency runs the risk of failing to comply with OPM standards. Avoid — Ensure the budget request and obligation is confirmed no later than Nov 1st of each fiscal year.

Table 39. Progress on Integrated Budget and Acquisition Planning System (IBAPS) Modernization

Description	Enterprise-Wide application supporting key budget functions such as budget formulation, acquisition planning, payroll planning including payroll projections/forecast, purchase card and travel planning, budget execution and business intelligence/reporting.
Milestones	▪ 2024 01 — Start ▪ 2024 10 — Enterprise IBAPS Release 1.0 in support of FY25 Execution ▪ 2025 03 — Enterprise IBAPS Release 2.1 in support of FY26 Planning ▪ 2025 10 — Enterprise IBAPS Release 2.2: FDA Wide adoption for Planning and Execution ▪ 2026 06 — Enterprise IBAPS Release 2.3: Updates ▪ 2026 07 — End
Accomplishments (Prior Fiscal Year)	▪ Defined roadmap focused on consolidating Center budget systems into an enterprise-wide offering with target to deliver all current state functionality in two (2) phases and three (3) major releases. ▪ Began system integration testing for Core functions in support of FY25 Budget Execution with Acquisition, Travel, P-Card, Payroll and Project Tracking capabilities. ▪ Readied core FDA wide capabilities for Acquisition, Travel, P-Card, Miscellaneous and Payroll planning, and executions for Phase 1 deployment. ▪ Defined solution with ability to better integrate programs with their budgets through implementation of Projects Module which supports FDA Center's unique needs.
Planned Activities	▪ Engage stakeholders in Phase 2 requirements ▪ Implement Phase 2
Risks	▪ IF the wide group of users are not effectively able to participate in training efforts, THEN limited training attendance will impact the successful adoption of the application. Mitigate — Kick off training early, involve change champions, include self-paced training content, track training attendance and schedule catch-up training sessions for post-go-live.

Strategic Initiative 3.3: Electronic Submissions

Table 40. Progress on NextGen ESG

Description	Implement a modern Enterprise Electronic Submissions Gateway Next Generation (ESG NextGen) to replace legacy Electronic Submission Gateway (ESG) and align with the FDA Strategic Vision and Modernization to establish ESG NextGen as the sole enterprise electronic submission gateway for all FDA submissions which will: ▪ Provide Industry a better user experience ▪ Enable collaboration, cost sharing and reusability across the FDA ▪ Promote "OneFDA" ▪ Create a highly scalable, available and disaster resilient application able to support the changing business needs to fulfill the FDA's mission ▪ Meet PDUFA/BsUFA Commitments by the end of FY25 which includes Cloud based architecture; Identity, Credentialing, and Access Management (ICAM); and Increased submission bandwidth and storage.
Milestones	▪ 2023 10 — Start, Release I Kickoff ▪ 2023 12 — Planning Phase Complete ▪ 2024 10 — Completed UAT Wave I & Wave II ▪ 2024 11 — Complete Appian and ESG NextGen ATO ▪ 2025 02 — Release I Go-Live ▪ 2025 03 — End
Accomplishments (Prior Fiscal Year)	▪ Completed Core functionality development ▪ Completed ICAM integration ▪ Worked with Digital Service Partners (DSP) to standup Appian High pre-prod and prod environments ▪ Submitted Appian environment Authority to Operate (ATO) for review ▪ Conducted user acceptance testing with industries and Centers including drop-in question-and-answer sessions ▪ (Ongoing) Engage FDA Centers, international partners and industry representatives to provide requirements and participate in quarterly demonstrations and feedback sessions
Planned Activities	▪ Implement Release 1 and Release 2, known as the Minimum viable product (MVP) ▪ Replace and retire legacy ESG system ▪ Provide submission bandwidth greater than 1 TB (Release 2)
Risks	▪ If ESG NextGen does not go-live by beginning of FY25 Q2 there will not be funding or contract vehicles available to continue to support Legacy ESG until ESG NextGen is stable in production. Mitigate — Program is working on a 3 month task order extension through March 2025 with two, one-month option periods. Vendor was notified they would receive thirty days' notice (February 2025) if the FDA does not plan to renew licenses. ▪ If the ESG Program's budget for FY25 is reduced by 5% then Legacy ESG will not have the necessary funding to continue to support the application until ESG NextGen go-live and ESG NextGen will not have the necessary funding for licenses and O&M support necessary for go-live.

Mitigate — Program is working with DAS Leadership to provide justification for not reducing ESG Program's FY25 budget.

Table 41. Progress on Electronic Document Repository (EDR)/Automated Submission Receipt (ASR)

Description	The ASR system processes electronic submissions (e-submissions) submitted via the Electronic Submission Gateway (ESG). Submissions received in the electronic Common Technical Document (eCTD) format are validated before further processing. Processed submissions are forwarded to the EDR Shares and to CDER's Submission Tracking system (DARRTS). Provide Industry a better user experience.
Milestones	▪ 2023 11 — Start ▪ 2024 02 — EDR/ASR 5.1 Release ▪ 2024 04 — EDR/ASR 5.2 Release, Functionality is added to process eCTD v4 submissions ▪ 2024 05 — Support of CDER Universal Parser Integration ▪ 2024 06 — EDR/ASR 5.3 Release, Rejection of DocuSign Forms, Notification for forms 3988, 3989 and 3938 in ASR notifications and P4 interface ▪ 2024 09 — Increased EDR Repository storage ▪ 2025 09 — End
Accomplishments (Prior Fiscal Year)	▪ Updated ASR for compatibility with Rest Interface ▪ Upgraded product version ▪ Added support for eCTD v4 submissions. ▪ Completed interface updates for CDER Intermediary Messaging System (CIMS)/ Platform Information Exchange Services (PIES) ▪ Added additional 30 TB to the EDR Repository to continue support of incoming submissions from industry
Planned Activities	▪ Conduct pilot testing of the ability to process forward compatibility of eCTD submissions ▪ Release ASR 5.4 to add notification to CDER BOTS for marketing 2253 submissions. ▪ Upgrade to address EOL support ▪ Upgrade to address forward compatibility of eCTD submissions ▪ Release ASR 5.5 to add interface between CDER OneNexus ▪ Increase EDR Repository storage
Risks	▪ If data center patching schedule conflicts with target release date, then the release date may need to change. Accept — The CDER stakeholders have communicated about the possibility of moving the production release date to an alternate date to avoid conflicts with patching. ▪ If issues are identified with forward compatibility pilot testing, then it might impact the timely acceptance of the release. Mitigate — Communicate to the vendor about issues identified and address the issue in without any delays. Accept — If delays are inevitable, work with CDER/CBER stakeholders to plan for a minor release as a follow up. ▪ If the current architecture of EDR Repository does not support continued growth of incoming submissions from industry, then an alternate solution to address the growth will be needed. Mitigate — Work with the Center to continue assessment/analysis of alternatives to

modernize EDR Repository to an architecture that meets continue growth of incoming submissions from industry and then implement a solution that best meets the needs of the Center.

Strategic Initiative 4.1: Enterprise Data Services

Table 42. Progress on CDEROne Intelligent Data Lake (iDL)

Description	Enable critical data analytics use cases through streamlined and broader access to data. Facilitates consolidation of existing enterprise systems and solutions to reduce long-term operating spend and free budget for priority use cases. Quickly fulfill users' new, increasingly complex data analytics needs by making development process easier and allowing multiple development teams to be working in parallel. Advances CDER Cloud strategy by beginning to address key decisions and transitioning data.
Milestones	▪ 2019 09 — Start ▪ 2020 01 — Established FISMA high cloud platform ▪ 2021 09 — Established Tenant Framework ▪ 2023 05 — Migrated Search 360 from On Premise to CDEROne ▪ 2023 08 — Establish Generative AI Framework within CDEROne ▪ FY24-FY25 — Platform Transition ▪ 2027 01 — End
Accomplishments (Prior Fiscal Year)	▪ Delivered eight use cases to support legacy system transition ▪ Saved ~$500K in annual platform costs through annual purchases and optimizations ▪ Installed two (2) new commercial off the shelf products ▪ Onboarded three (3) new tenants ▪ Saved 3000+ hours using automated deployments ▪ Conducted 200+ user trainings/demos ▪ Saved ~$1.5M in infrastructure and licensing costs through technology optimization ▪ Installed cybersecurity technologies to support zero trust security model
Planned Activities	▪ Develop full-text search and analytics on compliance documents and data ▪ Launch health metrics dashboards for OQS ▪ Develop dashboard and search capabilities for over-the-counter (OTC) drugs and OMOR applications ▪ Support user fee acts for generic and prescription drugs ▪ Support workflow system migration to OneNexus ▪ Implement AI use cases that meet PDUFA VII requirement ▪ Scale-out AI-powered policy chatbot to support OPPQ staff on policy analysis ▪ Enhance searching and reporting capabilities for drug submissions
Risks	▪ If infrastructure resource projections and procurement processes are not completed in a timely or accurate manner, then the CDEROne platform may not have the resources to support its growing catalog of use cases and tenants. Mitigate — Proactively manage and monitor procurement process to ensure timely submission of information and escalate any signs of delays to leadership team/governance board for quick action. ▪ If stakeholder buy-in is not secured and maintained throughout the implementation of CDEROne's projects, then necessary resources (e.g., personnel, budget, infrastructure) may not be allocated, leading to project

timeline delays or multiple iterations and rework.
Mitigate — Leverage existing governance bodies that include key stakeholders to validate direction, check for continued support and share updates.

Table 43. Progress on Data Management System (DMS) — Data Intelligence Platform Implementation (CDRH Enterprise Datahub (CEDh))

Description	Improve ability to accept and analyze data and make higher quality data more available to staff for data science and MDUFA requirements.
Milestones	▪ 2023 01 — Start ▪ 2023 11 — Installation of and integration of Databricks platform into AWS Gov-Cloud ▪ 2024 03 — Installation of and integration of Pyramid Analytics platform into AWS Gov-Cloud and connected to Databricks infrastructure ▪ 2024 08 — Completion of first iteration of all data assets into the DataLake Warehouse infrastructure ▪ 2025 and Beyond — Ongoing (the datastore will be ongoing, as data are constantly accruing, changing and being added)
Accomplishments (Prior Fiscal Year)	▪ Included over 16 large-scale system datasets into the CDRH Enterprise Datahub (CEDh) ▪ Pipelines, Automation, Modeling, integration and dissemination of those system datasets into a Silver Layer (“warehouse construct” for users) ▪ Installation, training and deployment of Pyramid Analytics to users ▪ Start of creation of “Gold Layer” (data mart) for analyst users to create reports
Planned Activities	▪ Continue to evaluate additional options within the data infrastructure and may contemplate alternative infrastructures in the future. ▪ Continue to include data assets to ensure that our data are continuing to be collected, cleansed and usable for analyses. ▪ Include additional AI/ML technologies for data cataloging and data efficiency to ensure the relevance and usefulness of the data being collected.
Risks	▪ If funding continues to be reduced, then progress will slow to a crawl. This may result in slower response times and data will not be included as rapidly. Accept — Set expectations accordingly.

Table 44. Progress on Data Analytics as a Service (DAaaS)

Description	Enterprise data analytics service designed to provide ability to rapidly respond to urgent, complex data analytics efforts in support of FDA's mission such as product recalls and supply chain monitoring.
Milestones	▪ 2023 10 — Start ▪ 2023 10 — Began replicating analytic reports for the Infant Formula supply chain monitoring ▪ 2023 12 — Two additional use cases for the Chief Medical Officer and the USDA ▪ 2024 11 — DAaaS provides 16 customized data analytic reports each week to internal and external stakeholders
Accomplishments (Prior Fiscal Year)	▪ Continue to save $2-3 million every year for the Human Foods Program ▪ Transferred multiple years of data and metadata to precisionFDA ▪ Led the data analytics for the Human Foods Program to assess the impact of the Canadian Rail strike and the East Coast Port strike on public health commodities ▪ (Ongoing) Producing reports/dashboards on a regular cadence across several critical areas including infant formula, analgesics, HPAI (Avian Flu), state WIC for USDA
Planned Activities	▪ Develop a DAaaS playbook ▪ Receive funding via MOUs from existing customers
Risks	▪ If we do not have FDA-employee data scientist capacity, then we will have to continue to rely on contract support. Mitigate — Hire additional data scientist. ▪ If we do not move to a pay per service program, ODAR will increase vendor dependency and cost. Mitigate — Determine chargeback model for reimbursable work.

Table 45. Progress on eMDM Data Services

Description	Provide a single, governed version of truth across all Centers to empower faster and more accurate information processing required to protect public health. This effort: ▪ expands the firm inventory to include affiliated firms and corporate lineage for analytics, track/traceability shortages, etc. ▪ reduces agency spend on siloed data services by consolidating efforts and IT into an enterprise API catalog, and ▪ includes the agency's first enterprise data catalog to improve discoverability and speed to accessing data to respond to public health concerns and improve IT decision-making.
Milestones	▪ 2023 12 — Start ▪ 2024 01 — Launched FDAddressbook (firms inventory) ▪ 2024 03 — Launched FDA Data Marketplace — one-stop shop for FDA to access Dun and Bradstreet Data Catalog and Data Dictionary ▪ 2024 09 — Launched enterprise API services that exposes the data across the agency ▪ 2024 09 — End
Accomplishments (Prior Fiscal Year)	▪ FDAddress Book — First agency inventory to include company lineage (over 5.6M records including regulated and affiliated firms which provides a better understanding of supply chains and track and traceability). ▪ FDA Data Marketplace — Enterprise Data Catalog providing data asset inventory and access to third-party data services (i.e., Dun and Bradstreet). ▪ Published six (6) eMDM application programming interfaces (API) for the use of external and internal data validation and verification around firm address information.
Planned Activities	▪ Implement new data curation tools (AI/ML) of inspection forms and to expand the Firms inventory from 1.2M firms to over 6M related firms. ▪ Implement data governance tools to facilitate data sharing across CTP, HFP and more with 60% or more inventoried. ▪ Implement additional data security and data encryption methods to safeguard sensitive firm-related data. ▪ Reduce manual clean-up by 50% to ensure FDA has high-quality Firms data to support the needs and self-service capabilities of Centers and Offices.
Risks	▪ If project does not receive sustained base funding for operations and maintenance, then unforeseen technical problems with critical activities such as FDAddress Book and Enterprise Data Catalog (i.e., DUNS Data Repository) may not be addressed, which would adversely impact Centers' regulatory operations and harm the trust and relationship with ODT. Mitigate — Reprioritize funding within ODAR, if available. Identify baseline funding and leverage MOUs for Center usage of data services in exchange for funding.

Table 46. Progress on Global Substance Registration System (GSRS)

Project	GSRS is an agency-wide resource that provides foundational substance Unique Ingredient Identifiers (UNIIs) for regulated products. UNIIs are linked to their scientific definitions and other relevant information such as adverse events, clinical trials, manufacturers, conditions, applications (INDs, NDAs, BLAs), etc. GSRS has both a public-facing implementation with publicly available information for industry and regulators worldwide and an internal-facing implementation supporting FDA's internal regulatory processes. Substance data within GSRS serves as master data supporting FDA's regulatory mission.
Milestones	▪ 2023 11 — Critical GSRS software release ▪ 2024 09 — Nitrosamine Impurity Limit publication list updates ▪ 2024 09 — Critical GSRS software release ▪ 2024 09 — Integration of Nitrosamine CPCA predictive tool into GSRS production web application ▪ 2024 09 — In Vitro Pharmacology Module launched ▪ Ongoing — Daily updates to public UNII validation list
Accomplishments (Prior Fiscal Year)	▪ Submitted and processed approximately 20,000 electronic chemical structures into GSRS from Structured Data files (SD files) previously submitted only as images ▪ Integrated Nitrosamine CPCA predictive tool into GSRS production web application ▪ Delivered numerous chemical structure and prediction reports on critical supply chain and safety risks associated with drug substances and impurities used by CDER ▪ Captured 234,000+ substances so far (70% chemicals) ▪ Processed over 15 million queries from UNII Search public site in 2024 ▪ Integrated with CDER's application review tool (KASA): – Compare new regulated products to all substance data (impurities, manufacturing materials, etc.) – Compare to prior-approved products that use the same substances – Monitor the supply chain of manufacturing materials, research potential toxic impurities across all applications and all products ▪ Designed and launched open-Source In Vitro Pharmacology Module with help from international community
Risks	▪ If the GSRS system became unavailable or was not maintained for any significant length of time, then the consequences for the agency's long-term public health mission would be extreme. – Reviewers would be required to manually draw over 10,000 error-prone chemical structures to meet the need for predictive evaluations. – Safety and supply chain monitoring experts would now be required to search through hundreds of thousands of documents manually and inconsistently for scientific information rather than having it structured and available within minutes. – Newly approved medicinal products would not be marketable due to listing requirements and would also not be eligible for reimbursement through Center for Medicare and Medicaid Services (CMS). Mitigate — Ensure GSRS remains available and continues to update both software and data. ▪ If the amount of data curation and informatics support required by stakeholders exceeds the resources available to the program THEN the accuracy, responsiveness, and critical functions of GSRS would be severely impacted. Mitigate — Ensure GSRS resources can expand to meet the needs and employ automation where possible to reduce burnout.

Strategic Initiative 5.1: AI Executive Order (E.O.) Implementation & Governance

Table 47. Progress on AI Productivity Tools

Description	Educate, prepare, and license key staff responsible for supporting agency-wide AI integration for AI productivity tools. Includes compliance readiness process for comprehensive set of tools to meet a wide range of federal regulatory requirements such as identification and classification of data, data leak and loss prevention, continuous monitoring and reporting, and others.
Milestones	▪ 2024 11 — Start ▪ 2025 05 — End
Accomplishments (Prior Fiscal Year)	▪ Prepared for implementation by conducting multiple meetings with vendor ▪ Started addressing vendor recommendations for implementation ▪ Provisioned licensing to allow for implementation ▪ Initiated Center permissions review ▪ Confirmed completion of required baseline configurations
Planned Activities	▪ Complete initial sensitivity label analysis and recommendations. Sensitivity labels are utilized to ensure data is only consumed by desired audiences ▪ Conduct sensitivity label testing ▪ Implement solution
Risks	▪ If product is not available in the government cloud instance (GCC), then FDA will be unable to enable the solution. Accept — FDA has no control over this. ▪ If permissions and data are not updated per vendor recommendations and best practices, data could be consumed and utilized for unintended audiences. Mitigate — Continue to work with vendor to gather recommendations/best practices and working to implement.

Table 48. Progress on AskFDALabel

Description	AskFDALabel is a specific framework developed as a research tool to enhance the utilization of Large Language Models (LLMs) at FDA. The prototype of this framework is demonstrated on FDA labeling documents, and thus the first application is likely for drug labeling. Besides taking the advantages of latest LLM, AskFDALabel framework was further optimized by incorporating Retrieval Augmented Generation (RAG), database-based and sematic information retrieval, and customizable templates for common regulatory review tasks.
Milestones	▪ 2023 10 — Start ▪ 2024 06 — Publish a research manuscript ▪ 2024 09 — Update the LLM and start testing in FiDLE ▪ 2025 09 — Update the tool based on feedback and start testing in RAPID ▪ 2026 03 — Complete the testing phrase ▪ 2026 09 — Pilot Project End
Accomplishments (Prior Fiscal Year)	▪ Published the AskFDALabel manuscript in May 2024 ▪ Updated the LLM and submitted the second manuscript in Sept 2024 ▪ Started testing in FiDLE in Sept 2024
Planned Activities	▪ Complete testing in FiDLE to collect feedback from the reviewers ▪ Update AskFDALabel based on the user feedback and newly collected use cases ▪ Conduct the second round of testing in RAPID ▪ Make a decision on next steps based on pilot results
Risks	▪ If budget resources are limited, then it may take an extended timeline to complete updates. Accept — pending budget clarification and adjust the timelines. ▪ If the testing environment and development process are not flexible, then agile updates may not be allowed, leading to a longer period of testing and potential loss of testing experience and knowledge from the reviewers. Mitigate — Work with all stakeholders to increase flexibility and agility of development and testing environments. Inform the reviewers and collect their inputs thoroughly after testing.

Strategic Initiative 6.1: Workforce Modernization

Table 49. Progress on precisionFDA Community Building and Challenge Program

Description	Encourage experts inside and outside FDA to solve common problems and inform regulatory science. Community Building provides a cadre of engaged internal and external experts in evolving science dedicated to solving common problems to inform the regulatory mission.
Milestones	▪ 2024 09 — Start ▪ 2024 11 — Conduct Phase 2 of the DEFoGD Challenge (September to November 2024, anticipated) ▪ 2025 03 — Run the Generative AI Challenge Expert Blogs ▪ 2025 03 — Develop and post three additional Expert Blogs ▪ 2028 09 — End
Accomplishments (Prior Fiscal Year)	FY24 Challenges: ▪ Conducted Phase 2 of Veterans Cardiac Health and AI Model Predictions (V-CHAMPS) Challenge from August to December 2023, in which nine teams' artificial intelligence/machine learning (AI/ML) models were validated on real-world Veterans health data within the Veterans Health Administration (VHA). ▪ Conducted the precisionFDA Automated Machine Learning (AutoML) App-a-thon from February to April 2024, in which twelve submitting teams (total of 42 participants) used AutoML tools on biomedical datasets to help assess whether AutoML can match or improve the performance of previously developed traditional ML models. ▪ Supported the Brain Tumor Segmentation (BraTS) Challenge on Relevant Augmentation Techniques that occurred from April to August 2024, in which potential participants were asked to develop computational methods to augment a dataset of medical images such that a baseline AI/ML model, when retrained, will show improved performance and robustness on sequestered independent test data. ▪ Conducted Phase 1 of the Digitally-Derived Endpoints for Freezing-of-Gait Detection (DEFoGD) Challenge from May to August 2024, in which seven submitting teams (total of 15 participants) developed AI/ML models for creating digitally derived endpoints for freezing-of-gait in Parkinson's patients. FY24 Manuscripts: ▪ Published "Synthetic Health Data Can Augment Community Research Efforts to Better Inform the Public During Emerging Pandemics" in medRxiv in December 2023, describing how synthetic Electronic Health Record (EHR) data can have practical value to Veterans' health research community. ▪ Published "Towards accurate indel calling for oncopanel sequencing through an international pipeline competition at precisionFDA" in Scientific Reports in April 2024, highlighting how the NCTR Indel Calling from Oncopanel Sequencing Data Challenge helped to evaluate the performance of indel calling pipelines.

Accomplishments (Prior Fiscal Year) (Continuted)	FY24 Expert Blogs: ▪ Developed and posted the Democratizing and Demystifying AI Expert Blog, highlighting how the upcoming AI Challenge series and AutoML App-a-thon would further explore and illustrate how AI can support FDA's mission. ▪ Developed and posted the Understanding Risk and Protective Factors in the Veteran Population Expert Blog, describing work to improve outcomes for heart failure patients in the Veteran population. ▪ Developed and posted the Exploring Generative Artificial Intelligence (GenAI) Expert Blog, highlighting key considerations for generative AI applications and potential FDA use cases. FY24 Other Communications: ▪ Presented accepted poster at the 2023 and 2024 FDA Omics Days in October 2023 and September 2024, highlighting the impact of the precisionFDA Truth Challenge V2 and how precisionFDA is a sandbox for innovative omics advancement. ▪ Posted items to the News portion of the precisionFDA site and social media sites to enhance awareness of precisionFDA Challenges and App-a-thons and improve engagement and potential impact of submitted solutions.
Planned Activities	▪ Host an AI challenge on PrecisionFDA concerning predicting liver toxicity in animals based on synthetic data which mirrors data FDA reviewers use for their own assessments. If a suitable AI technique is found, it may be used to inform the reviewers. ▪ Launch a challenge on PrecisionFDA which utilizes the compute platform directly to a challenge question. This will help evaluate if the challenge program can be extended to processing offline data with submitted tools. If successful, this may accelerate adoption of useful AI tools within the agency. ▪ Update the challenge web pages to have more visibility for expert discussions and community feedback.
Risks	▪ If FY25 full funding is not received, then precisionFDA will not be able develop solutions via crowdsourcing Challenges and App-a-thons or help coordinate DSAB activities. Mitigate — Confirm funding for precisionFDA. ▪ If precisionFDA Challenges are not widely publicized, then engagement in Challenges will be low and the opportunity to develop impact solutions is decreased. Mitigate — Leverage various channels for approved communications, in collaboration with Challenge partners, and identifying impactful incentives. ▪ If components of the precisionFDA website are not functioning as anticipated, then delays in timeliness of Challenges/App-a-thons may impact reputation of the program and future engagement of participants. Mitigate — Communicate site bugs with the COR and technical support, identifying impact to deliverable schedule and providing updates to impacted parties.

Table 50. Progress on TechTalent Workforce Development

Description	UpTech is a cross-functional initiative to understand and address the IT training and recruiting needs of FDA. UpTech seeks to build internal capacity, ensure equitable access to career development opportunities and enable a high-performing workforce that is ready and able to lead FDA into the future.
Milestones	▪ 2022 02 — Start ▪ 2023 — Conducted skills assessment and training inventory ▪ 2024 11 — Offered technical certification courses (based on skills assessment findings) ▪ 2024 — Awarded Technical Training BPA with four (4) option years ▪ 2024 — Update skills inventory assessment ▪ 2028 07 — End
Accomplishments (Prior Fiscal Year)	▪ Conducted 2024 Deep Racer AI Learning Event ▪ Delivered 11 professional certification classes for 195 ODT FTEs ▪ Delivered 85 End User Classes to 783 FDA FTEs ▪ Conducted 2024 Student Outreach — AimHi (25 students) and Summer Scholars (Pathways — 12 students) ▪ Created FDA Tech Academy Learning Paths for the top 20 IT Roles in the Agency ▪ Awarded a $5M BPA for Technical and End-user training that will encompass and expand on many of the successful offerings and events that ODT has already orchestrated for FDA staff
Planned Activities	▪ Expand Technical Training for FDA and ODT staff to include higher-level technical courses and certifications courses ▪ Create additional FDA Tech Academy learning paths for IT Roles in the FDA ▪ Coordinate AI and machine learning events such as DeepRacer Day and “AI for Everyone” series ▪ Promote the next generation of FDA Technology Talent with our Summer Scholar and AimHi programs which give high school and undergrad students hands-on experience collaborating on cutting-edge technology while learning about FDA’s public health mission
Risks	▪ If equitable and continued investment in training and career development opportunities are not possible, then FDA’s employees' skills will not keep pace with what’s needed, and FDA may experience increased attrition. Mitigate — Based on funding level, determine impact to skill development and prioritize areas of focus that support critical needs. ▪ If FDA staff does not participate in the Skills assessment Survey, then the quality of training and learning opportunities that ODT provides may not align to the FDA’s needs, since the program is being led by customer involvement and requests. Mitigate — Proactively monitor survey response rates and leverage techniques to drive completion e.g., communications on value to employees, executive sponsors, reminders, etc.

IT STRATEGIC INITIATIVE DETAILS

For each IT strategic initiative, this section details the list of IT projects/milestones with key information including a project/milestone description, mapping to the FDA's Business Capability Model layer 3 level 1 and layer 3 level 2, and which Center/Office is the project owner.

1.1 Strategy & Governance

1.1.1 | CDRH Acquisition and Administrative Planning System (CAAPS) — Completed

The CDRH Acquisition and Administrative Planning System Phase III goal is to deliver enhancements that will provide integrated system functionality to manage the Budget Execution, Payroll Planning, Advanced Acquisitions, HR Position Based Management.

BCM L1	BCM L2	Lead Center/Office
Human Resource Management	Human Capital and Workforce Planning	CDRH/OM

1.1.2 | Enterprise CPIC Select

Implement agency-wide IT investment vetting business process. CPIC Select will enable the FDA to optimize our IT portfolio by leveraging the decision-making authorities granted to the FDA's Tech Council and Portfolio Review Board (PRB) while leveraging TBM and the FDA's BCM.

BCM L1	BCM L2	Lead Center/Office
Strategic Planning	Program Planning and Management	ODT/OEPM

1.1.3 | FDA IT Strategy & Operating Plan

Develop/update and publish the FDA IT Strategy annually in collaboration with internal and external stakeholders. Refinement the FDA's IT Governance Model and define a performance measurement process. Monitor and track the FDA's progress in advancing the IT Strategy.

BCM L1	BCM L2	Lead Center/Office
Information Tech Management	Delivery Services	ODT/OEPM

1.1.4 | Freedom of Information Act (FOIA) Process Optimization — Completed

Develop a unified approach to the FDA FOIA business process and governance while implementing a harmonized enterprise-wide technology solution called the FOIA Workflow Application (FWA).

BCM L1	BCM L2	Lead Center/Office
Stakeholder Relationship Management	Inquiry and Response Management	OC/ETO

1.1.5 | IT Automation Process Factory and Service Catalog

Develop Process Factory to standardize and automate manual processes to boost operational efficiency. Create Infrastructure and Application Services catalog using ServiceNow.

BCM L1	BCM L2	Lead Center/Office
Information Tech Management	Delivery Services	ODT/OTD

1.1.6 | Technology Business Management (TBM) Center of Excellence Implementation

Drive agency-wide adoption of TBM, implementation of a Single Source of Truth, Agency-level key performance indicators (KPIs).

BCM L1	BCM L2	Lead Center/Office
Strategic Planning	Program Planning and Management	ODT/OEPM

1.1.7 | Budget System

Implement a budget system that supports development of the ODT Spend Plan and alignment to TBM for budget line items.

BCM L1	BCM L2	Lead Center/Office
Information Tech Management	Delivery Services	ODT

1.2 Acquisitions & Vendor Management

1.2.1 | Acquisition Optimization: Enterprise Licensing Model Optimization

Analyze and review enterprise licensing models using industrial benchmark from entitlements/usage/compliance perspectives to bring efficiencies and cost reductions. Conduct analysis of major software implementation which resulted in $807K annual savings through disposal of unused licenses and reduction of unit costs. Conduct similar analysis for targeted enterprise licenses in future.

BCM L1	BCM L2	Lead Center/Office
Finance, Budget & Acquisitions Management	Acquisitions Management	ODT/OEPM

1.2.2 | Acquisition Optimization: Governance

Provide governance and oversight across Enterprise IT Acquisitions. Implemented the FDA CIO IT Acquisition Review (ITAR) process.

BCM L1	BCM L2	Lead Center/Office
Finance, Budget & Acquisitions Management	Acquisitions Management	ODT/OEPM

1.2.3 | Contract Optimization and Rationalization

Consolidation and rationalization of contracts resulting in cost savings, common processes, executive reporting. Set up a centralized database for all ODT contracts.

BCM L1	BCM L2	Lead Center/Office
Finance, Budget & Acquisitions Management	Acquisitions Management	ODT/OEPM

1.2.4 | Vendor Management Program

Set up Vendor Management at the FDA account level with Quarterly Business Review meetings for top strategic vendors, vendor performance evaluation and ratings, automated vendor management portal, and Improved efficiencies.

BCM L1	BCM L2	Lead Center/Office
Finance, Budget & Acquisitions Management	Acquisitions Management	ODT/OEPM

1.3 Internal/External Communications

1.3.1 | Communications Planning & Execution

Communication and event support services to advance the FDA IT Strategy implementation and ODT engagement and advocacy goals for internal and external stakeholders.

BCM L1	BCM L2	Lead Center/Office
Information Tech Management	Shared Services	ODT/IO

1.3.2 | Enterprise Consumer Complaints Management System

Reform how consumers report a problem to the Agency by developing a single, front-end interface and back-end data integrations to streamline complaints processing, improve customer interactions with the Agency, and act on vital information more quickly to better serve the FDA's mission to protect the health of the public.

BCM L1	BCM L2	Lead Center/Office
Information Tech Management	Delivery Services	ODT/OEPM

1.3.3 | Product Review & Approval (PRA) Formal Meetings Management (FMM)

Core build of a modernized Formal Meetings Management solution in support of the long-term goal to replace the current meeting management systems (CRMTS, BITS-PTS, and BLT). By the end of this project, high-priority requirements should be implemented such that common review tasks, including data entry, data viewing, and review process automation, can be demonstrated within the context of one or more chosen application and submission types (e.g., Pre-IND Meeting Request) in a production environment.

BCM L1	BCM L2	Lead Center/Office
Product Review & Approval	Product Evaluation and Assessment Management	CBER

1.3.4 | Hybrid Meeting Room Experience (Program)

The project is to implement Teams Rooms within FDA. Teams Rooms run software that's built on top of the Teams platform and designed for use on Teams Rooms devices and shared hybrid meeting scenarios. The Teams Rooms app delivers inclusive and easy-to-use meeting experiences that take both in-room and remote attendees into consideration. As of 8/16/2024, 92 Teams Rooms have been implemented.

BCM L1	BCM L2	Lead Center/Office
Information Tech Management	End User Services	ODT

1.3.5 | Guest Collaboration Experience (Program)

The Guest Collaboration Experience (GCE) leverages specially created GCE SharePoint Online sites, and GCE Microsoft Teams that satisfy FDA requirements, as well as, FDA Privacy office guidelines, allowing FDA staff to collaborate with external partners and industry. The Guest Collaboration Experience does not apply to existing team snor SPO sites. The initial version of GCE went live in September 2021. FDA continues to make improvements to the feature.

BCM L1	BCM L2	Lead Center/Office
Information Tech Management	End User Services	ODT

1.3.6 | FDA Scientific Computing and Digital Transformation Symposium (Program)

The symposium, co-hosted by the FDA Scientific Computing Board (SCB) and the Office of Digital Transformation (ODT), advances our strategic goal to 'Create a Shared OneFDA Ecosystem' and facilitates stakeholder engagement and knowledge sharing.

BCM L1	BCM L2	Lead Center/Office
Information Tech Management	End User Services	ODT

2.1 Stabilization/EOL/EOS

2.1.1 | Network Infrastructure Modernization

Transition from end-of-life network gear to software-defined networking to enhance infrastructure flexibility, scalability, and management while ensuring cost savings and performance improvements.

BCM L1	BCM L2	Lead Center/Office
Information Tech Management	Infrastructure Services	OTD

2.1.2 | Storage & Backup Modernization

Modernize and standardize the FDA's storage and backup systems to ensure robust data protection and rapid recovery to safeguard our critical business operations in case of unforeseen events. It will also support scalability and agility directly contributing to the FDA's resilience and long-term operational stability.

BCM L1	BCM L2	Lead Center/Office
Information Tech Management	Infrastructure Services	OTD

2.1.3 | RCI Tobacco Inspection Management Program (TIMP) (Program)

The Tobacco Inspection Management Program (TIMP) is intended to cover IT Services associated with the following task areas: Project Management, Architecture Support Services, Systems Engineering & Integration Services, Data Migration & Management Support Services, Training, Operations & Maintenance (O&M), Development Modernization & Enhancements (DME) (For TIMS, VIA, FAC, CCMS).

BCM L1	BCM L2	Lead Center/Office
Compliance & Enforcement	Compliance Activity Management	CTP

2.1.4 | CCW Collaboration and Document Management (Program)

Provide Development, Modernization and Enhancements (DME) and Operations & Maintenance (O&M) to all CTP sites in SharePoint Online (SPO).

BCM L1	BCM L2	Lead Center/Office
Information Tech Management	End User Services	CTP

2.1.5 | CCW Collaboration and Document Management FY23 (Program) — Completed

Support and oversee all of CTP SharePoint Online Environment.

BCM L1	BCM L2	Lead Center/Office
Information Tech Management	End User Services	CTP

2.1.6 | Operating System (In Place Upgrade)

Rollout the latest operating system to the Agency that offers new features and better performance.

BCM L1	BCM L2	Lead Center/Office
Information Tech Management	End User Services	ODT

2.1.7 | Operating System (Image) — Completed

The purpose of the project is to ensure FDA users have access to modern operating systems by implementing updated versions of Windows.

BCM L1	BCM L2	Lead Center/Office
Information Tech Management	End User Services	ODT

2.2 Cloud Transformation

2.2.1 | Backup Tape Modernization — Completed

Modernize our backup infrastructure with cloud-based solutions for improved management, reduced costs and support digital transformation.

BCM L1	BCM L2	Lead Center/Office
Information Tech Management	Infrastructure Services	OTD

2.2.2 | Enterprise Inspections Platform — Completed

Develop an enterprise end-to-end platform for all inspection types that accommodates diverse program needs. This will extend beyond FY25.

BCM L1	BCM L2	Lead Center/Office
Compliance & Enforcement	Compliance Activity Management	OC/ETO

2.2.3 | Event Data Management 8.0 (Alternative eSub) (NextGen Portal)

Industry-facing solution that enables industry users to have options and leverage an alternative electronic submission to submit Research INDs, Type III Drug Master Files (DMFs), Emergency Use Authorization (EUA), and exempted human drug applications to the FDA. It supports CDER's mission by improving efficiency and decision-making capabilities. The solution reduces regulatory overhead for sponsors, academia, research institutes, medical doctors and small businesses. In addition, the solution substantially reduces the amount of paper submissions and improves overall operational efficiency.

BCM L1	BCM L2	Lead Center/Office
Submission Management	Submission Resource Management	CDER

2.2.4 | Information Governance — eDiscovery Technology Transition Implementation - Completed

Leverage existing ODT expertise and support as well as internal and third-party Cloud services to optimize the FDA investments in IT and eDiscovery. As eDiscovery services grow in scope and demand, infrastructure management will become more complex and expensive to maintain internally. Thus, eDiscovery leveraged ODT shared services infrastructure support and the FDA Cloud Forward initiatives to improve services and make progress in agency information governance, compliance and risk management.

BCM L1	BCM L2	Lead Center/Office
Stakeholder Relationship Management	Inquiry and Response Management	OO/OEMS/DIG

2.2.5 | Regulatory Submission Receipt and Analysis (RSRA) Tobacco Registration & Listing Module NextGen (TRLM NG) (Program)

Tobacco Registration & Listing Module Next Generation (TRLM NG) is a cloud-based application conducting standard operation and system maintenance to include OIMT and other infrastructure upgrades and maintenance.

BCM L1	BCM L2	Lead Center/Office
Registration & Listing	Product Listing Information Management	CTP

2.3 Zero Trust

2.3.1 | Endpoint Detection and Response (EDR)

A security service that protects devices such as laptops, desktop, mobile and server computers. EDR is part of the Department of Homeland Security (DHS)/Cybersecurity and Infrastructure Security Agency's (CISA's) Continuous Diagnostic and Mitigation (CDM) program.

BCM L1	BCM L2	Lead Center/Office
Information Tech Management	Delivery Services	ODT/OIS

2.3.2 | Cybersecurity Zero Trust (ZTA)

The FDA has traditionally described Zero Trust as a set of principles, strategy or an approach that ensures that the right people have the right access to the right resources at the right time. Zero Trust is not one tool, but comprised of a centralized architecture or framework of various capabilities and policies to facilitate and provide secure access to the FDA resources, such as applications, data, servers, devices, etc.

Zero Trust Is a Shift in Our Approach to Cybersecurity from a network-centric to identity and data-centric approach to security.

BCM L1	BCM L2	Lead Center/Office
Information Tech Management	Delivery Services	ODT/OIS

2.3.3 | Endpoint Firewalls

Migrate the FDA endpoints to a next-generation firewall solution that offers enhanced security and cost savings while upholding the principles of data integrity, confidentiality and availability.

BCM L1	BCM L2	Lead Center/Office
Information Tech Management	Delivery Services	OIS/OBCA

2.3.4 | Multi-Factor Authentication and Encryption Ecosystem

Implement government-wide mandates to strengthen cybersecurity posture, protect sensitive data and ensure the FDA's integrity and operational effectiveness.

BCM L1	BCM L2	Lead Center/Office
Information Tech Management	Delivery Services	OIS/OTD

2.3.5 | Software Defined Network (SDN) Service Integrations

Modernize infrastructure through software-defined best practices to ensure efficient management.

BCM L1	BCM L2	Lead Center/Office
Information Tech Management	Delivery Services	ODT/OTD

3.1 Total Experience (UX/CX)

3.1.1 | Automated Call Distribution (ACD) Modernization

Implement Automated Call Distribution ecosystem aimed at reducing wait time and mis-routed calls.

BCM L1	BCM L2	Lead Center/Office
Information Tech Management	End User Services	ODT/OTD

3.1.2 | Document Management Solution Expansion

Enhance the FDA's document management through additional Open Text expansion to improve secure storage, retrieval of regulatory documents and compliance, providing public health data integrity and protection

BCM L1	BCM L2	Lead Center/Office
Information Tech Management	Platform Services	ODT/OTD

3.1.3 | Email Modernization

Modernize our email to have Microsoft Service fully manage email through the cloud service, decreasing the support complexity while improving the reliability of this critical service.

BCM L1	BCM L2	Lead Center/Office
Information Tech Management	End User Services	OBCA

3.1.4 | Phone System Modernization (Voice Over Internet Protocol (VoIP))

The FDA is migrating 18,500+ users to Microsoft Phone System Teams VoIP. Users migrations have started and will are expected to be completed by the end of September 2024.

BCM L1	BCM L2	Lead Center/Office
Information Tech Management	Infrastructure Services	ODT

3.1.5 | Wi-Fi Modernization

Modernize Wi-Fi connectivity across the FDA HQ and field locations, enhancing work flexibility and productivity via offering an enhanced operational infrastructure.

BCM L1	BCM L2	Lead Center/Office
Information Tech Management	Infrastructure Services	ODT

3.1.6 | CCW LTPS Database (Program)

Provide CTP's many stakeholders (the tobacco industry, public health organizations, retailers, the media, Congress, etc.), with an easy-to-use searchable database that provides the relevant categories, information and documents associated with the 20,000 identified tobacco products.

BCM L1	BCM L2	Lead Center/Office
Information Tech Management	End User Services	CTP

3.1.7 | RSRA Advanced Information Retrieval Research System (AIRRS) (Program)

The Advanced Information Retrieval Research System is a suite of applications serving the internal information and retrieval needs of members of the Office of Science (OS) within the Center of Tobacco Products (CTP). AIRRS supports domain-specific scientific and business analyses associated with CTP's regulatory and research mission.

BCM L1	BCM L2	Lead Center/Office
Regulatory Science	Scientific Computing and Research Management	CTP

3.1.8 | Customer Experience Strategy (Program)

Enterprise plan introducing the Agency's customer experience framework.

BCM L1	BCM L2	Lead Center/Office
Information Tech Management	Delivery Services	ODT

3.1.9 | RSRA SPECTRE

Software Modeling of Physiological Parameters and Electronic Cigarette Constituents To inform Risk Evaluation (SPECTRE) Development of a quantitative risk assessment platform for inhaled tobacco products that supports CTP's workflows and regulatory decisions.

BCM L1	BCM L2	Lead Center/Office
Regulatory Science	Scientific Computing and Research Management	CTP

3.2 System Modernization

3.2.1 | Acquisition Lifecycle Platform (ALP)

Allow Office of Acquisitions and Grants Services (OAGS) to review, assign, track and award acquisitions to improve efficiency, transparency, scalability, compliance and automated communication.

BCM L1	BCM L2	Lead Center/Office
Finance, Budget & Acquisitions Management	Financial Information Management	OO

3.2.2 | CBER Modernization (Program)

Modernize CBER capabilities across business, data and technology. Modernization integrates data and innovative technology that facilitate business solutions to maximize productivity, collaboration and connectivity for all CBER staff.

BCM L1	BCM L2	Lead Center/Office
Product Review & Approval	Product Evaluation and Assessment Management	CBER

3.2.3 | CVM Data and Technology Modernization (Program)

Identify critical IT gaps and rebuild IT service delivery and product portfolio to support digital transformation, increase operational efficiency, improve customer service and better support changing business demands for customers while managing IT cost and risk.

BCM L1	BCM L2	Lead Center/Office
Product Review & Approval	Product Evaluation and Assessment Management	CVM & ODT

3.2.4 | Food Safety Modernization Act (FSMA) Food Traceability/Product Tracing System (PTS)

Meet the requirements stated in the Food Traceability Rule Section 204(d), which requires establishment of a product tracing system 'to receive information that improves the capacity of the Secretary to effectively and rapidly track and trace food that is in the United States or offered for import into the United States.

BCM L1	BCM L2	Lead Center/Office
Product Review & Approval	Product Evaluation and Assessment Management	HFP

3.2.5 | FSMA FDA Unified Registration and Listing Systems (FURLS)

Support the following programs that require major new and/or enhanced Food Safety Modernization Act (FSMA) business processes to build a new or enhance existing the FDA Unified Registration and Listing Systems (FURLS) IT modules.

- Laboratory Accreditation for Analysis of Foods (LAAF) Program
- Voluntary Qualified Importer Program (VQIP)
- Accredited Third-Party Certification Program (TPP)

BCM L1	BCM L2	Lead Center/Office
Information Tech Management	Business Services: Health and Well-Being	HFP

3.2.6 | Human Resources IT (HRIT) eSuite

Provide a fully compliant, comprehensive, automated suite of applications to standardize HR processes and reduce manual entry and errors. Includes HRIT infrastructure, robust, data-driven, analytic tools, real-time reporting.

BCM L1	BCM L2	Lead Center/Office
Human Resource Management	Human Capital and Workforce Planning	OO/OHCM

3.2.7 | Implementation Initiative and Support (Workflow) (Nexus)

Modernize CDER's workflow management informatics solutions that support key mission activities related to regulatory drug review processes. Previously, the drug application review processes were segregated or siloed, across new drugs, generic drugs and biologics and separate offices used separate applications. This project improves information sharing, facilitates collecting regulatory metrics and Congressional reporting, reduces redundant data and processes, and mitigates the need for costly modifications on legacy systems.

BCM L1	BCM L2	Lead Center/Office
Information Tech Management	Platform Services	CDER

3.2.8 | Information Governance- Electronic Records Retention Project — Phase 2 (Program)

Create an Electronic Records Keeping System for the FDA Centers which will allow users to declare records from network and shared drives and move them into a central repository.

BCM L1	BCM L2	Lead Center/Office
Stakeholder Relationship Management	Inquiry and Response Management	OO/OEMS/DIG

3.2.9 | Integrated Budget and Acquisition Planning System (IBAPS) Modernization

Enterprise-Wide application supporting key functions such as purchase card solutions, travel tracking, budget formulation, acquisition planning, payroll projections, project management, data modeling, and reporting.

BCM L1	BCM L2	Lead Center/Office
Enabling Capabilities	Management and Administration	OO/OFBAP

3.2.10 | Knowledge — Aided Assessment and Structure Application (KASA)

Develop and maintain tools for drug quality assessors; making the application review process more structured and efficient for knowledge management across the Center; provide pre-populated assessment templates, algorithms for risk identifications, mitigation and communications all in a structured format, while minimizing the text-based narratives, administrative tasks and summaries of information; leverage structure data for data analytics to support assessors to make informed decisions during the review process. This project is a key part of the efforts focused on conducting reviews in a structured format, other projects include OGD's Label Review Tool (LRT) and Bioequivalance Evaluation (BE).

BCM L1	BCM L2	Lead Center/Office
Submission Management	Submission Resource Management	CDER

3.2.11 | CDER Bioresearch Monitoring (BIMO) Information Tracking Environment (CBITE) III — Implementation/Enhancements (Program)

Verify the integrity of efficacy and safety data submitted to the FDA in support of new drug applications via the CDER BIMO Information Tracking Environment (CBITE) that is a CDER OTS and OC modern information tracking environment for efficient bioresearch monitoring/inspection planning. The output will create an efficient and effective mechanism to support the Bioresearch Monitoring (BIMO) Program based programs through automation and streamlining affected processes. Office of Translational Sciences (OTS) and OC need the capability to integrate data between internal and external systems and to maintain and migrate data.

BCM L1	BCM L2	Lead Center/Office
Compliance & Enforcement	Compliance Activity Management	CDER

3.2.12 | Quality Management Information System (QMiS)

Recompete the current on-prem contract and look for cloud-based software for OII's Quality Management Information System (QMiS) in FY24. QMiS is needed by the labs to maintain their certification and OII is currently using MasterControl software on-prem that is ending this year. CBER also uses this contract for O&M and licenses and may need it for future DME work with some interest from other Centers as well.

BCM L1	BCM L2	Lead Center/Office
Collaboration Management	Information Sharing	OII

3.2.13 | Research Management System Application Modernization and Maintenance

Support and maintain the Research Management Support system (RMS) components and adjust as needed to meet stakeholder needs. The RMS enables NCTR leadership to marshal resources efficiently and effectively to plan, manage and report on research. It also enables stakeholders to perform business tasks in a timely manner and provides the flexibility to adapt to dynamic, external requirements.

BCM L1	BCM L2	Lead Center/Office
Regulatory Science	Scientific Computing and Research Management	NCTR

3.2.14 | Safety Reporting Portal

Create a reporting mechanism for food traceability data to comply with new regulations under the Food Modernization & Safety Act (FMSA). Assign, record and share traceability lot codes for Food Traceability List (FTL) foods, as well as link these lot codes to other information identifying the foods as they move through the supply chain. Enhance the use of the UPC Scanner to accurately capture product information from either a mobile or desktop user's device. Develop novel frameworks and data ingestion mechanisms to assist with the Agency's response to signal detection regarding product problems, adverse events and components of the suspect product.

BCM L1	BCM L2	Lead Center/Office
Post-Market Safety & Surveillance	Adverse Event/Complaint and Signal Management	HFP

3.2.15 | Transition for precisionFDA

Enable migration to a new platform when needed. Reduces dependency on current contractor.

BCM L1	BCM L2	Lead Center/Office
Regulatory Science	Scientific Computing and Research Management	OC

3.2.16 | User Fee System (Program — Completed)

Bill and collect fees from industry using the Order to Cash modules through the self-service web application and standardize business processes to gain efficiency after the automation of 5 Year Plan, Financial Reports and FR Notices.

BCM L1	BCM L2	Lead Center/Office
Finance, Budget & Acquisitions Management	Financial Information Management	OC-OO

3.2.17 | OO Tobacco User Fee Application FY23 (Program)

FDA assesses and collects user fees from manufacturers and importers of cigarettes, snuff, chewing tobacco, roll-your-own tobacco, cigar and pipe tobacco under Section 919 of the Family Smoking Prevention and Tobacco Control Act (FSPTCA). The Tobacco User Fee Application (TUFA) is a powerful data reconciliation tool created in order to support CTP's Division of Financial Management (DFM) Tobacco User Fee Team. TUFA captures, tracks, audits and reports all tobacco manufacturing and importing activities in order to better assess market shares and eventual User Fee allocation.

BCM L1	BCM L2	Lead Center/Office
Finance, Budget & Acquisitions Management	User Fee Management	CTP

3.2.18 | Adverse Event Management System (CAEMS) (Program)

CAEMS is a workflow application and database that supports HFP receipt, review, storage and provision of adverse event and product complaint report data.

BCM L1	BCM L2	Lead Center/Office
Post-Market Safety & Surveillance	Adverse Event/Complaint and Signal Management	HFP

3.2.19 | OO CTP Budget and Acquisition System (CBAS) FY23 (Program)

CBAS is a centralized solution used by CTP's Acquisition (AAT), Division of Financial Management (DFM), and Human Capital (HC) teams to standardize, track, and manage CTP's acquisitions, financial, and headcount data. These objectives are accomplished through the use of 4 applications (CBAS, CBASPAY, UFMSACT, and CBASHC), with an Oracle Hyperion back-end and 2 custom user interfaces that support 120+ CTP users. CBAS was developed as a highly configurable solution to cover CTP's unique business process needs such as Budget Formulation, Spend Plan Data Call, FOP, Spend Plan Execution, Payroll, Acquisition Planning, and end-to-end CTP Human Capital staffing/hiring. To further accommodate the Center's needs, CBAS is integrated with external applications such as Integrated Budget & Acquisition Planning System (IBAPS), Unified Financial Management System (UFMS), Procurement Information System for Management (PRISM), Enterprise Human Capital Management (EHCM), and Human Resources Processing System (HREPS)/Applicant Tracking Lifecycle and Analysis Solution (ATLAS). The CBAS project uses Agile/Scrum approach in addition to industry standard practices to incorporate new business processes and data enhancements for each feature.

BCM L1	BCM L2	Lead Center/Office
Finance, Budget & Acquisitions Management	Acquisitions Management	CTP

3.2.20 | RSRA Rhapsody (Program)

Rhapsody is a platform application that supports the Center for Tobacco Products (CTP) for their internal regulatory review management process for the CTP RHPMs, scientific discipline reviewers, leadership and compliance staff. It meets the needs of CTP's regulatory review processes for PMTA, EX, SE, GF/PX, MRTP submissions, TC-Meeting Requests, TC-General Correspondence, as well as PTVR complaints. Also within CTP, Rhapsody also supports the Office of Compliance and Enforcement (OCE) on several of their workflow processes which include; OCE Grandfather Review process, OCE Compliance Review Memo process, OCE Substantial Equivalent and Exemption Predicate Review Memo process and also Rhapsody integrates with two internal OCE systems; the Potential Tobacco Violation Reporting (PTVR) and the Tobacco Registry & Listing Module (TRLM) that send data to Rhapsody that initiates a review process workflow for OCE.

BCM L1	BCM L2	Lead Center/Office
Product Review & Approval	Product Evaluation and Assessment Management	CTP

3.2.21 | Enterprise Content Management Assessment (ECMA)

The objectives of this project are to conduct a full technical assessment of FDA's Enterprise Content Services (ECS) including CDER's Electronic Document Room (CDER EDR) and evaluate the feasibility of migrating CDER EDR, Enterprise Document & Records Management Platform (EDRMP), and other on-prem applications to an Enterprise based Cloud Content Services Platform (ECSP).

BCM L1	BCM L2	Lead Center/Office
Information Tech Management	End User Services	ODT

3.3 Electronic Submission

3.3.1 | Customer Collaboration Portal (CCP)

Enhancements to Customer Collaboration Portal (CCP), an external-facing platform for industry to submit pre-market submissions (Pega platform). This portal replaces manual submission and increases structured data ingestion and extract.

BCM L1	BCM L2	Lead Center/Office
Submission Management	Submitter Information Management	CDRH/OST

3.3.2 | Food Applications Regulatory Management (FARM) (Program)

Supports HFP's OFAS, ODSP, and ONFL in their review of a wide variety of submissions and petitions submitted by regulated industry, and also supports correspondence, Electronic Freedom of Information (EFOI) requests and archiving HFP historical files. FARM is the primary system available to HFP reviewers to access and review industry submissions and conduct analysis with regards to chemical, toxicological, environmental analysis and other issues, regarding specific ingredients (the basis for the regulatory safety decisions). In addition, FARM supports CVM's Ingredient Safety Team, Division of Animal Feeds.

BCM L1	BCM L2	Lead Center/Office
Product Review & Approval	Product Evaluation and Assessment Management	HFP

3.3.3 | NextGen ESG (Program)

Implement a modern Enterprise Electronic Submissions Gateway Next Generation (ESG NextGen) to replace legacy Electronic Submission Gateway (ESG) and align with the FDA Strategic Vision and Modernization to establish ESG NextGen as the sole enterprise electronic submission gateway for all FDA submissions which will:

- Provide Industry a better user experience
- Enable collaboration, cost sharing and reusability across the FDA
- Promote "OneFDA"
- Create a highly scalable, available and disaster-resilient application able to support the changing business needs to fulfill the FDA's mission
- Meet PDUFA/BsUFA Commitments by the end of FY25 which includes Cloud-based architecture; Identity, Credentialing, and Access Management (ICAM); and Increased submission bandwidth and storage.

BCM L1	BCM L2	Lead Center/Office
Submission Management	Submission Resource Management	ODT/OTD

3.3.4 | Electronic Document Repository (EDR)/Automated Submission Receipt (ASR)

The ASR system processes electronic submissions (e-submissions) submitted via the Electronic Submission Gateway (ESG). Submissions received in the electronic Common Technical Document (eCTD) format are validated before further processing. Processed submissions are forwarded to the EDR Shares and to CDER's Submission Tracking system (DARRTS).

BCM L1	BCM L2	Lead Center/Office
Submission Management	Submission Resource Management	CDER

3.3.5 | RSRA eSubmissions Modernization (Program)

The overarching goal of the eSubmissions Modernization project is to enhance and streamline the ingest processes for how CTP receives electronic submissions through the FDA enterprise electronic submission gateway (ESG), utilizing various business-specific IT systems. This comprehensive initiative aims to facilitate electronic submissions, account creation, and verification, alongside robust communication with submitters. It will establish an integrated system that eliminates operational silos and optimizes the submission process.

BCM L1	BCM L2	Lead Center/Office
Submission Management	Submission Resource Management	CTP

3.3.6 | RSRA eSubmissions FY23 (Program — Completed)

eSubmission processes support the collection, logging, storing, tracking, retrieval and analysis of tobacco industry-provided submissions. The CTP BPA eSubmissions project covers DME and O&M activities for the eSubmissions suite of applications that support the regulatory submission of Industry or publicly reported data to the Center for Tobacco Products (CTP). Specifically, there are 6 existing applications under DME, as well as ad-hoc DME for eSubmitter templates and VBA templates. All other eSubmissions applications are covered under O&M.

BCM L1	BCM L2	Lead Center/Office
Submission Management	Submission Resource Management	CTP

3.3.7 | RSRA eSubmissions FY2024 (Program)

eSubmission processes support the collection, logging, storing, tracking, retrieval and analysis of tobacco industry-provided submissions. The CTP BPA eSubmissions project covers DME and O&M activities for the eSubmissions suite of applications that support the regulatory submission of Industry or publicly reported data to the Center for Tobacco Products (CTP). Specifically, there are 6 existing applications under DME, as well as ad-hoc DME for eSubmitter templates and VBA templates. All other eSubmissions applications are covered under O&M.

BCM L1	BCM L2	Lead Center/Office
Submission Management	Submission Resource Management	CTP

4.1 Enterprise Data Services

4.1.1 | CDEROne Intelligent Data Lake (iDL)

Enable critical data analytics use cases through streamlined and broader access to data. Facilitates consolidation of existing enterprise systems and solutions to reduce long-term operating spend and free budget for priority use cases. Quickly fulfill users' new, increasingly complex data analytics needs by making development process easier and allowing multiple development teams to be working in parallel. Advances CDER Cloud strategy by beginning to address key decisions and transitioning data.

BCM L1	BCM L2	Lead Center/Office
Information Tech Management	Platform Services	CDER

4.1.2 | Data Management System (DMS) — Data Intelligence Platform Implementation (CEDh)

Improve ability to accept and analyze data and make higher-quality data more available to staff for data science and MDUFA requirements.

BCM L1	BCM L2	Lead Center/Office
Information Tech Management	Platform Services	CDRH/OST

4.1.3 | HFP (formerly CFSAN) Data Warehouse (CDW) (Program)

Leverage data to protect public health and foster data-driven decision-making by improving methods to store, organize, govern and analyze data. CDW is a centralized repository for the data used to execute the mission of the Human Foods Program including transactional or operational, systems and data assets from OII and external partners, including the CDC.

BCM L1	BCM L2	Lead Center/Office
Information Tech Management	Platform Services	HFP

4.1.4 | Data Analytics as a Service (DAaaS) — Completed

Establish a pre-production and development DAaaS to stay aligned with best practices, including buying KNIME licenses for each environment; 300 annual FIDLE Workbench licenses for use by ALT and Data Squad members; projected support for continuous supply chain monitoring.

BCM L1	BCM L2	Lead Center/Office
Information Tech Management	Platform Services	ODAR

4.1.5 | Data Marketplace (Inspections Analytics) (Program — Completed)

The FDA Data Marketplace (FDM) to provide agency-wide inspections data service with new data sources and streamlined access to inspections-related data (over 27 target systems identified). FDM the data hub that enables connectivity across enterprise systems and processes to deliver harmonized workflows and actionable data supporting the FDA's public mission and support the Human foods and OII modernization efforts.

BCM L1	BCM L2	Lead Center/Office
Information Tech Management	Platform Services	OC

4.1.6 | Pediatric Information Management System (PIMS) (Program — Completed)

Enable OCPP/OPT to capture post-market labeling and safety data in an Appian database. CDER Division of Pediatric and Maternal Health (DPMH) also uses the system to capture pre-market data. Pediatric labeling and study descriptor information from this system is posted on fda.gov.

BCM L1	BCM L2	Lead Center/Office
Product Review & Approval	Product Evaluation and Assessment Management	OC

4.1.7 | eMDM Data Services — Completed

ODT's Enterprise Master Data Management (eMDM) program provides a single governed version of truth to addresses to empower the faster and more accurate information processing required to protect public health. (1) This inventory expands the OII OEI (Inspections) inventory to include affiliated firms & corporate lineage for analytics, track/traceability shortages, etc. (2) eMDM also reduces agency spend on siloed data services by consolidating efforts and IT into an enterprise API catalog. (3) eMDM includes the agency's first enterprise data catalog to improve discoverability and speed to accessing data to respond to public health concerns and improve IT decision making.

BCM L1	BCM L2	Lead Center/Office
Information Tech Management	Platform Services	ODAR

4.1.8 | FDA Adverse Event Reporting System II (FAERS) (Drug Safety Platform) (Program)

Reduce the overall IT footprint, lowering redundant infrastructure costs and long-term maintenance costs. This also supports meeting CDER's published guidance requiring industry to submit R3. R3 extends the adverse event data model to allow for more effective analysis, improving the quality of CDER's pharmacovigilence program.

BCM L1	BCM L2	Lead Center/Office
Post-Market Safety & Surveillance	Adverse Event/Complaint and Signal Management	CDER

4.1.9 | FDA Intelligent Data Lifecycle Ecosystem (FiDLE) (Program)

Designed to meet cross-Center data management, advanced data science and analytics platform needs. It will address challenges associated with interoperability, scalability and machine learning availability by building up capabilities within several Enterprise Product Lines

BCM L1	BCM L2	Lead Center/Office
Information Tech Management	Platform Services	ODT

4.1.10 | Evaluation of PrecisionFDA Modernization — Completed

Support future of regulatory review and data collection of industry confidential data from outside of FDA and collaboration with trusted partners through evaluation of options including cost impacts. Note: Evaluation is complete, and research continues.

BCM L1	BCM L2	Lead Center/Office
Regulatory Science	Scientific Computing and Research Management	OC

4.1.11 | Global Substance Registration System (GSRS)

Global Substance Registration System (GSRS) is an agency-wide resource that provides foundational substance Unique Ingredient Identifiers (UNIIs) for regulated products. UNIIs are linked to their scientific definitions and other relevant information such as adverse events, clinical trials, manufacturers, conditions, applications (INDs, NDAs, BLAs), etc. GSRS has both a public facing implementation with publicly available information for industry and regulators worldwide and an internal facing implementation supporting the FDA's internal regulatory processes. Substance data within GSRS serves as master data supporting the FDA's regulatory mission.

BCM L1	BCM L2	Lead Center/Office
Regulatory Science	Scientific Computing and Research Management	ODAR

4.1.12 | OpenFDA (Program)

In response to the 2019 “Open, Public, Electronic, and Necessary, (OPEN) Government Data Act,” OpenFDA provides high-value, high priority and scalable datasets publicly available in an open machine readable format. openFDA lowers the barrier of entry for external and internal researchers, scientists, healthcare system developers, and others who want to access the FDA’s publicly available data via application programming interfaces (APIs) or downloads. OpenFDA is hosted in cloud, is open source and has had over 640 million API data requests since launched in 2015.

OpenFDA is a program. In FY 2024, Reagan-Udall conducted an assessment of the information on both www.fda.gov and open.fda.gov including interviewing a variety of stakeholder groups. Results for open.fda.gov were enthusiastic about what can be accessed for use. In 2024, a query was created for non-data scientists/programmers to access Animal Drug Product Listings and Adverse Events.

BCM L1	BCM L2	Lead Center/Office
Regulatory Science	Scientific Computing and Research Management	ODAR

4.1.13 | precisionFDA Regulatory Information Service Module (PRISM) Proof of Concept

Expand collaborative regulatory review use cases with industry, CDER and CBER creating efficiencies in regulatory processes to incorporate cross-cutting capabilities. OCE and CTP are working on research collaboration agreements to be part of Phase II.

BCM L1	BCM L2	Lead Center/Office
Regulatory Science	Scientific Computing and Research Management	ODAR

4.1.14 | RSRA Data Services FY23 (Program — Completed)

CTP seeks to improve its ability to manage data as a long-term strategic asset because data plays a significant role in the implementation of the regulatory and scientific processes of the Family Smoking Prevention and Tobacco Control Act (FSPTCA). The Data Modernization Project's DME efforts focus on enhancement and maintenance of Product Management Services (PMS), and implementation of a modernized platform to facilitate development of new data services in the form of packaged business capabilities.

BCM L1	BCM L2	Lead Center/Office
Information Tech Management	Platform Services	CTP

4.1.15 | RSRA Data Services FY2024 (Program)

CTP seeks to improve its ability to manage data as a long-term strategic asset because data plays a significant role in the implementation of the regulatory and scientific processes of the Family Smoking Prevention and Tobacco Control Act (FSPTCA). The Data Modernization Project's DME efforts focus on enhancement and maintenance of Product Management Services (PMS), and implementation of a modernized platform to facilitate development of new data services in the form of packaged business capabilities.

BCM L1	BCM L2	Lead Center/Office
Information Tech Management	Platform Services	CTP

4.1.16 | RSRA Tobacco Cost Model FY2024 (Program)

CTP contractor supported project to create a tobacco-specific cost model tailored to the tobacco industry's production and labeling processes. The Tobacco Cost Model (TCM) uses data inputs specific to the manufacturing of tobacco products to estimate costs based on a wide range of tobacco products characteristics and potential changes.

BCM L1	BCM L2	Lead Center/Office
Submission Management	Submission Resource Management	CTP

5.1 AI EO Implementation & Governance

5.1.1 | Artificial Intelligence Implementation (Program)

Drive innovation and collaborative knowledge sharing while also enhancing security measures in AI applications by focusing on delivering: Plug-and-Play Deployment solutions to reduce the technical burden for centers and partners; Shortening time to production accelerating AI project timelines with proper guidance and prepackaged tooling; Standardized, responsible AI principles to ensure consistency in adherence to governance, guidelines and policy; Enhanced User Experience: Focus on user-centric design for AI solutions.

BCM L1	BCM L2	Lead Center/Office
Information Tech Management	Delivery Services	ODT

5.1.2 | Assessment of Large Language Models for FDA Business Activities (Program)

Form a Governance and Advisory Board to understand opportunities and risks. Work closely with HHS and other stakeholders to develop a roadmap for internal operations and learn from policy initiatives. Identify use cases to demonstrate capability and improve organizational learnings. Identify skill development needs, make recommendations to develop new programs and/or modify existing programs.

BCM L1	BCM L2	Lead Center/Office
Information Tech Management	Delivery Services	ODT

5.1.3 | AI Assessment for Medical Supply Chain Hardening - Completed

Assess the feasibility and effectiveness of AI techniques in:

- Developing new strategies for predictive management of supply chain logistics.
- Enhancing the prediction of medical supply chain challenges.
- Identifying innovative and non-traditional participants in the supply chain.
- Improving the accuracy of forecasts related to shortages, bottlenecks, and choke points in supply chains.

BCM L1	BCM L2	Lead Center/Office
Information Tech Management	Delivery Services	ODAR

5.2 Emerging Technologies

5.2.1 | AI Productivity Tools

Educate, prepare, and license key staff responsible for supporting agency-wide AI integration for Microsoft productivity tools, using CoPilot. Includes compliance readiness process for comprehensive set of tools to meet a wide range of federal regulatory requirements such as identification and classification of data, data leak and loss prevention, continuous monitoring and reporting, and others.

BCM L1	BCM L2	Lead Center/Office
Information Tech Management	Delivery Services	ODT

5.2.2 | Real-World Application for Innovation and Development (RAPID) V.1 Program III (Program)

As the FDA's first dedicated cloud space to offer Innovation as a Service (IaaS), RAPID provides both an experimentation sandbox and a production environment in the AWS cloud space that is designed to explore datasets, develop and test new analytics. It minimizes the barriers to designing analytic solutions by bringing together data, infrastructure, development support, and knowledge gained through experimentation.

BCM L1	BCM L2	Lead Center/Office
Regulatory Science	Scientific Computing and Research Management	CDER

5.2.3 | AskFDALabel

AskFDALabel is a specific framework developed as a research tool to enhance the utilization of LLMs at FDA. The prototype of this framework is demonstrated on FDA labeling documents, and thus the first application is likely for drug labeling. Besides taking the advantages of latest LLM, AskFDALabel framework was further optimized by incorporating Retrieval Augmented Generation (RAG), database-based and sematic information retrieval, and customizable templates for common regulatory review tasks.

BCM L1	BCM L2	Lead Center/Office
Regulatory Science	Scientific Computing and Research Management	NCTR

6.1 Workforce Modernization

6.1.1 | Candidate Relationship Management Module Tool (CRMT)

Source and recruit candidates in highly specialized fields such as biostatistics, genetics, and health informatics through more proactive and technically advanced solutions enhancing the quality of its applicant pool and improving the overall candidate experience.

BCM L1	BCM L2	Lead Center/Office
Human Resource Management	Human Capital and Workforce Planning	OC

6.1.2 | DataForward — Applied Learning Tracks

Establish new Applied Learning Track Teams; New ALT Program Type (ALT Springboard); Develop and Deploy DataForward Squads; Acquisition of licenses for unified sandbox and platforms.

BCM L1	BCM L2	Lead Center/Office
Human Resource Management	Learning and Development	ODAR

6.1.3 | Digital Leadership

Hire and develop change adept leaders through the Digital Leadership Program and develop skills for the future of work through TechTalent Workforce Development 2.0. Advance the FDA IT Strategy and IT Operating Plan implementation by streamlining and improving the FDA IT Data Call process.

BCM L1	BCM L2	Lead Center/Office
Information Tech Management	Delivery Services	ODT-IO

6.1.4 | Knowledge and Expertise Sharing

Capture the content of all the FDA Commissioners, 22 Current FDA Leadership members, and top 1,000 current FDA authors to automatically populate the Portal as well as the FDA staff who co-authored the same publication. Expands and enhances the Expertise & Research Portal content and supports OSTP compliance.

BCM L1	BCM L2	Lead Center/Office
Collaboration Management	Information Sharing	ODT

6.1.5 | precisionFDA Community Building and Challenge Program

Encourage experts inside and outside FDA to solve common problems and inform regulatory science. Community Building provides a cadre of engaged internal and external experts in evolving science dedicated to solving common problems to inform the regulatory mission.

BCM L1	BCM L2	Lead Center/Office
Regulatory Science	Scientific Computing and Research Management	ODAR

6.1.6 | Project Elixir

Provide day-to-day operational support to meet critical hiring needs and implement process improvements.

BCM L1	BCM L2	Lead Center/Office
Human Resource Management	Human Capital and Workforce Planning	ODT-IO

6.1.7 | TechTalent Workforce Development (aka Project UpTech)

TechTalent Workforce Development (aka Project UpTech) is a cross-functional initiative to understand and address the IT training and recruiting needs of the FDA. UpTech seeks to build internal capacity, ensure equitable access to career development opportunities, and enable a high-performing workforce that is ready and able to lead the FDA into the future.

BCM L1	BCM L2	Lead Center/Office
Human Resource Management	Learning and Development	ODT-IO