OFFICE OF DIGITAL TRANSFORMATION

One Year Later

2022
Annual Report

__The Office of Digital Transformation (ODT)__ provides the vision and leadership in information technology (IT), data, and cybersecurity needed to advance the Food and Drug Administration's (FDA's) mission and strategic priorities. This Annual Report highlights ODT's 2022 results and accomplishments.

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ODT 2022: CIO Review

Dear Colleagues,

In September 2021, we announced the creation the Office of Digital Transformation (ODT) to better align our organization to drive change. This December, as we prepare to close out our first full year, I'd like to recognize the significant progress we have made in our transformation journey, and the incredible teams who work tirelessly to enable our FDA and ODT mission. Together we are bringing this vision to life – and we have a lot to be proud of.

We've recently published two additional components of our strategy — the Enterprise Modernization Action Plan (EMAP) and the Cybersecurity Modernization Action Plan (CMAP). Together, these plans represent the continued evolution of our modernization efforts by driving change through business transformation initiatives and ensuring we are ever vigilant about prioritizing cybersecurity interests in the protection and promotion of public health.

While continuing to develop and implement our FDA Modernization Framework (TMAP, DMAP, EMAP and CMAP), we have been laser-focused on a multitude of initiatives aligned to our seven Strategic Priorities. Some of these projects were shared during our 2022 ODT Summit, along with an open discussion of the significant challenges the FDA is looking to ODT to address. We have also invited our government and industry partners to engage in this conversation during our first annual FDA Digital Transformation Symposium. This event will be the first of many efforts to increase collaboration across all sectors to ensure that FDA has the resources, information, and technology to meet its critical public health mission, now and into the future.

This 2022 ODT Annual Report highlights our significant achievements and the flourishing, proactive efforts of our organization – none of which would be possible without the relentless efforts and commitment of our employees. We are building this organization person-to-person, process-by-process, capability-by-capability, and bit-by-bit. I couldn't be prouder of our shared success and look forward to our continued progress in service to the FDA's mission.

Vid Desai

Chief Information Officer
Office of Digital Transformation

Overview of Organizational Structure

The Office of Digital Transformation (ODT) provides the vision and leadership in information technology (IT), data, and cybersecurity needed to advance FDA's mission and strategic priorities. ODT is led by the Chief Information Officer and reports to the FDA Commissioner. ODT directs and coordinates enterprise strategic planning, policy, and resource management to ensure that Agency IT, data, and cybersecurity investments and activities provide maximum value to FDA. 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).

ODT is committed to delivering trusted technology and data solutions that enable FDA to reimagine the possible. Watch this video to learn more about our organization and how we are striving to make an impact at FDA.

OneODT Campaign

Since the establishment of ODT, our organization prioritized addressing significant challenges in areas of communication, stakeholder partnerships, IT governance, staff recruitment and retention, and other institutional silos that inhibited our ability to collaborate on our strategic priorities. Internally, ODT has sought to build better team morale, improve communication, align our collaborative efforts under one clear direction toward achieving ODT's strategic priorities and fulfilling our organization's vision. The success of ODT's growth and development depended on a strategic theme that could unify all staff toward our shared vision and goals.

In 2022, ODT established the strategic theme of OneODT and implemented an organization-wide campaign to:

- Build camaraderie across ODT offices and divisions,
- Highlight staff and leaders who exhibit ODT's core values and strategic priorities,
- Learn from each other about our expertise and experience, and
- Connect communication and engagement opportunities with the FDA and ODT mission, vision, values, and priorities to recognize the value our work brings to the Agency.

The OneODT theme unified disparate organizations and teams by creating a shared identity and defining our organizational culture. Over the course of the year, OneODT inspired innovation resulting in high-impact outcomes including increased knowledge sharing and learning opportunities, leadership coaching, improved performance management, and other advancements in services that greatly benefit ODT staff.

NEXT STEPS

Organizational change, growth, and development are filled with new challenges and – eventually – inspiring opportunities. The reorganization of offices, overhauling of process and procedures, and realignment of priorities can cause a sense of whiplash across an organization and may impact team morale. What ODT has learned over the last year is that when you focus on a common purpose you can overcome the challenges, build a high performing team culture, and greatly benefit from the efforts of a strategically aligned workforce.

OneODT has been a rallying cry to establish our organizational identity. As we embark on 2023, we are expanding this theme to bring in our partners across the Agency. All FDA will build on the success of OneODT and ensure that our colleagues are part of our modernization journey as we not only transform the industry technically, but as we build the top technology, data, and cybersecurity organization in government with the best IT workforce and workplace in government.

NEW MODERNIZATION ACTION PLANS

Throughout the Annual Report all projects share the demand to provide enterprise-wide benefits that support the FDA's responsibility to protect public health by ensuring the safety, efficacy, and security of human and veterinary drugs, biological products, and medical devices; and by ensuring the safety of our nation's food supply, cosmetics, and products that emit radiation.

FDA began its digital modernization journey in 2019 with the release of the Technology Modernization Action Plan (TMAP). Early efforts uncovered the need for enhanced data governance and infrastructure to support the increasing complexity of data collection and stewardship. In September 2021, the agency released the Data Modernization Action Plan (DMAP) and established the new Data, Analytics, and Research (ODAR) office to oversee its implementation. Recognizing that technology and data cannot perform to their fullest potential without alignment with business, organization priorities and strong leadership, the FDA developed the Enterprise Modernization Action Plan (EMAP) in May 2022, Cybersecurity Modernization Action Plan (CMAP), and Leadership Modernization Action Plan (LMAP) in November 2022.

The Enterprise Modernization Action Plan (EMAP) describes ODT's plans to shape FDA's future by delivering cross-agency efforts that optimize common and essential business processes. These efforts will improve operational efficiency and use of our data, while strengthening the alignment between agency-wide strategic objectives and investments.

EMAP will:
- Create the Infrastructure to Support Change
- Develop a Common Operational Approach
- Ensure Strategic Alignment

The Cybersecurity Modernization Action Plan (CMAP) was released to strengthen our ability to protect sensitive information, modernize cybersecurity capabilities, and improve situational awareness to decrease overall security risks to the Agency. ODT in alignment with Presidential Executive Order (EO) 14028, Improving the Nation's Cybersecurity, will upgrade, enhance, and modernize FDA's critical cyber defenses to address the evolving threat landscape where risks to our critical assets, industry, and sensitive data remain moderately high. Compared to pre-pandemic, FDA has experienced a 457% increase in reconnaissance activities, denial of service, attempted exploitation, and other cyber incidents against the IT infrastructure.

CMAP will:
- Establish a comprehensive Zero Trust approach to facilitate new digital services and modernization efforts
- Promote software assurance best practices to include security measures at every stage of the development lifecycle
- Enhance interoperable and secure data exchange and collaboration across FDA and its public health partners
- Leverage Artificial Intelligence/Machine Learning (AI/ML) technologies to enhance cyber detection and response capabilities
- Integrate counterintelligence and insider risk principles with the Zero Trust model to enable an intelligence driven approach
- Prioritize and invest in FDA's cybersecurity workforce

The Leadership Modernization Action Plan (LMAP) is the next milestone in the FDA's modernization journey. The LMAP will shape the FDA's future by developing immediate and long-term strategies to grow and modernize leadership capacity within ODT and across the FDA. This new focus on leadership transformation will foster an environment and culture that attracts and retains top talent. It will establish a pipeline of strategic change leaders to drive digital transformation. Ultimately, these efforts will enhance FDA leadership capabilities, while strengthening the alignment between agency-wide strategic objectives, outcomes, and impacts.

LMAP will:
- Create an environment where the business and IT are aligned and collaborate to achieve business priorities and leverage IT opportunities to enhance outcomes.
- Develop and Operationalize an IT strategy that is reflective of business needs.
- Develop a leadership pipeline that can maintain strategic continuity through leadership and organizational change.

ODT STRATEGIC PRIORITIES

The FDA's Modernization Framework (TMAP, DMAP, EMAP, CMAP, and LMAP) is the foundation for ODT's strategic direction and define its seven key priorities:

1. **Cloud Forward:** Implement repeatable processes, provide packaged cloud offerings, and ensure the infrastructure supports agile migration and use of the cloud.

2. **Data:** Develop a responsible strategy for putting data to use and to allow the FDA to manage and analyze data to include driver projects, data practices, and talent.

3. **Organizational Excellence:** Continue improving our culture by enhanced talent acquisition, employee retention and engagement, and strengthening an emerging workforce.

4. **Governance:** Provide a framework aimed at improving the overall selection and management of IT systems and applications to enable FDA to manage IT risks, invest in the right priorities, ensure compliance, and measure performance.

5. **User Experience:** Market and communicate IT offerings and strategies and develop standards and best practices to deliver intuitive services to customers.

6. **Operational Excellence:** Help achieve the FDA's strategy by strengthening IT infrastructure and management operations to increase efficiency, effectiveness, and service levels.

7. **Cybersecurity:** Ensure the appropriate security measures and protections are in place to maintain the public's trust and the FDA's reputation as a global public health leader.

MISSION

To provide high quality, secure, and efficient technology, data, and cybersecurity solutions that enable the FDA to promote and protect the public health.

VISION

Collaborating as partners to enable data and technology to improve health for all Americans.

PRIORITIES

1 Cloud Forward

1.1 Network infrastructure optimization
1.2 Hybrid cloud environment
1.3 IT Shared Services
1.4 Enterprise IT architecture and application

2 Data

2.1 Data talent development
2.2 Data and analytics ecosystem
2.3 Data-driven processes
2.4 Artificial Intelligence

3 Organizational Excellence

3.1 Industry leadership
3.2 Knowledge management
3.3 High performance culture
3.4 Recruitment and retention

4 Governance

4.1 Technology Business Management
4.2 Procurement process
4.3 Vendor management program
4.4 Optimize IT Spend

5 User Experience

5.1 Collaboration experience
5.2 Remote and virtual technologies
5.3 Asset management process
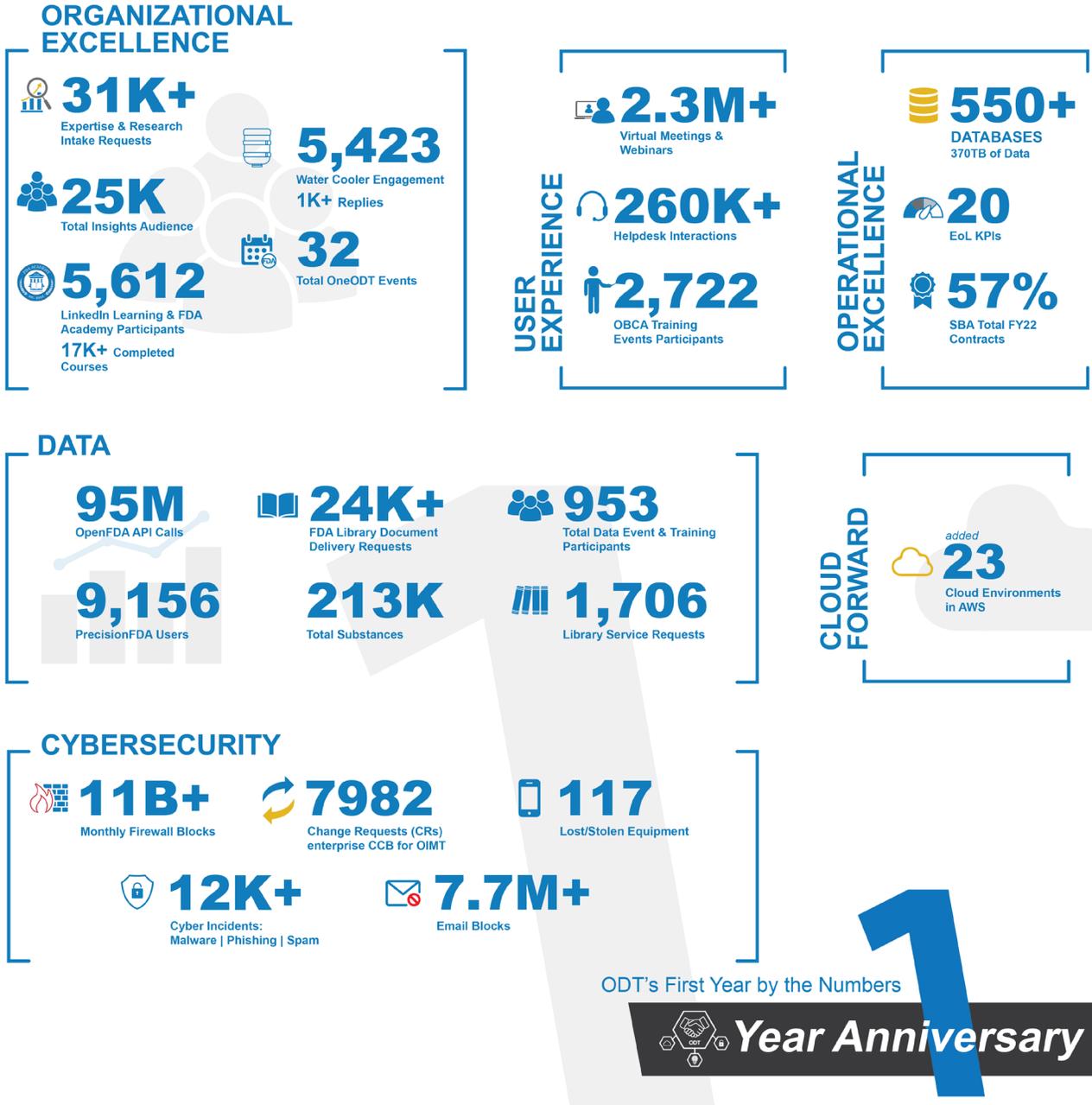5.4 FDA Hardware

6 Operational Excellence

6.1 Zero priority 1 incidents
6.2 Service modernization
6.3 Enterprise solutions
6.4 Application Portfolio
6.5 Unified Communications as a Service (UCaaS)

7 Cybersecurity

7.1 Protect FDA information
7.2 FDA Zero Trust
7.3 Modernized Cybersecurity Platform
7.4 Authorization process
7.5 Customer engagement
7.6 Intelligence driven threat mitigation

First Year by the Numbers

ODT faced ongoing changes in 2022 as it advanced enterprise modernization goals and an ambitious setof strategic priorities, while establishing a new organization. Amid this transformation, ODT maintained its core technology, cybersecurity, data, and business operations while also managing pandemic-related projects and initiatives. This was a significant undertaking given the breadth and complexity of the agency and a global pandemic, and it is underscored through selected highlights.

ORGANIZATIONAL EXCELLENCE

31K+
Expertise & Research Intake Requests

25K
Total Insights Audience

5,612
LinkedIn Learning & FDA Academy Participants
17K+ Completed Courses

5,423
Water Cooler Engagement
1K+ Replies

32
Total OneODT Events

USER EXPERIENCE

2.3M+
Virtual Meetings & Webinars

260K+
Helpdesk Interactions

2,722
OBCA Training Events Participants

OPERATIONAL EXCELLENCE

550+
DATABASES
370TB of Data

20
EoL KPIs

57%
SBA Total FY22 Contracts

DATA

95M
OpenFDA API Calls

9,156
PrecisionFDA Users

24K+
FDA Library Document Delivery Requests

213K
Total Substances

953
Total Data Event & Training Participants

1,706
Library Service Requests

CLOUD FORWARD

added
23
Cloud Environments in AWS

CYBERSECURITY

11B+
Monthly Firewall Blocks

12K+
Cyber Incidents:
Malware | Phishing | Spam

7982
Change Requests (CRs) enterprise CCB for OIMT

7.7M+
Email Blocks

117
Lost/Stolen Equipment

ODT's First Year by the Numbers

Year Anniversary

STRATEGIC PRIORITY 1: CLOUD FORWARD

The cloud forward initiative is moving the FDA towards a modernized model that utilizes cloud technology to implement repeatable processes, provide packaged cloud offerings, and ensure the infrastructure supports agile migration. Historically, the FDA hosted applications for internal and external users on multiple on-premises data centers. These solutions are often standalone applications for specific business processes and do not provide repeatable solutions across the FDA. These IT solutions also demand regular maintenance that creates excessive overhead in labor costs. The App Cloud Migration Plan was implemented to leverage the cloud to provide superior services to the end user while creating cost effective and repeatable solutions across the FDA.

With the advent of cloud technology, the cost and time to provide computing resources is reduced by utilizing services that are available through cloud service providers. At the same time, new IT advances can be quickly and easily deployed to the virtual environment and made available to the consumers for utilization. The App Cloud Migration Plan has introduced multiple blueprints in how it plans to achieve modernization by easing the on-boarding of developers, reducing infrastructure configuration, and achieving cost transparency. Over the past year the App Cloud Migration teams have greatly reduced the on-prem footprint by migrating numerous solutions to the cloud.

To further assist with the cloud forward initiative, ODT established the Digital Services Center (DSC) capability. The DSC provides solutions with Platform-as-a-Service (PaaS) and Software-as-a-service (SaaS) and a variety of development and security tools to quickly provide IT solutions through enterprise standards such as Appian and Salesforce. ODT also stood up an enterprise API (eAPI) service capability in support of enterprise integration, and others such as Microsoft Power Platform, ServiceNow, AWS/Azure Cloud IaaS, and OpenText for Agency support services.

A Closer Look: Cloud Forward Initiatives in Action

The Unified Communications as a Service (UCaaS) project began migrating FDA users (~20,000) from Cisco Unified Communications Manager to Microsoft Teams Phone System. Microsoft will be the sole communications platform used across FDA.

The Software Defined Networking (SDN) project is another cloud forward effort initiated to modernize end-of-life Data Center networking infrastructure, aligning with Zero Trust Architecture (ZTA), and supporting Hybrid Cloud automation. The SDN implementation provides a cloud forward solution that automates network configurations and security policy deployment into the core Data Center Design and associated tools providing end-to-end seamless network management.

STRATEGIC PRIORITY 2: DATA

ODT continues to drive and expand the agency's capabilities to meet the ever-changing data and analytics landscape. After developing a strategy for putting data to use, building a strong network of senior leaders and data practitioners, ODT led efforts allowing FDA to implement driver projects, talent acquisition strategies, and high-impact data practices.

ODAR is leading the Enterprise MDM (eMDM) program with an eMDM team responsible for building the foundation of an enterprise data platform that can be applied agency wide starting with the Firms Master Data. The team has begun provisioning the agency's first cloud-based comprehensive eMDM platform, including all aspects of data governance, stewardship, quality assessment, and metrics.

To accelerate the development of internal Data Science capabilities, ODT's Office of Data, Analytics, and Research (ODAR) developed applied learning and training. The DataForward learning program offers an experiential model to create a network of well-trained data scientists and analysts. Throughout 2022, ODT hosted Data Science and Data Visualization courses with 1500 trainees. Leveraging an agency use case as the learning project, the pilot resulted in a class of successful graduates the inaugural Applied Learning Track.

ODT established the Enterprise Artificial Intelligence (AI) Strategic Plan to outline our current state, vision, and strategies to leverage AI to support agency mission. The AI Playbook offers best practices and provides a framework to avoid common AI risks and improve the probability of AI project success. ODT is currently applying Playbook methodologies to pilot projects with and plans to expand the project more broadly in 2023.

Additionally, ODT has developed foundational Real-World Data (RWD) capabilities including the RWD Catalog and RWD Glossary. The RWD Team published the first agency-wide Real World Data Glossary to standardize the definition of 47 critical research and analysis terms across the agency.

ODT's Health Informatics continued its important role in managing 250,000 substances used in regulated products, leverage the Precision FDA for collaboration with 6500 users in 54 countries and OpenFDA which serviced over 144 million API calls for data.

A Closer Look – Leveraging FiDLE for Compliance Monitoring

ODT/ODAR launched FDA's Intelligent Data Lifecycle Ecosystem first release (FiDLE 1.0) in March 2022. It included foundational capabilities such as secure data storage, simplified licensing cost, AWS FISMA high environment and tools such as R and Business Objects.

In addition, FiDLE 1.0 includes successful launch of artificial intelligent/ machine learning solution for CDER's Office of Prescription Drug Promotion (OPDP). OPDP regulates advertising and promotion of all prescription drug products. 150,000 unique promotional materials were submitted in last 12 months and these submissions increase 5% each year. Version 1.0 of this solution is estimated to save over 1000 hours of reviewer per user annually.   It also allows for training new users on the best practices based on knowledge of experienced colleagues.

STRATEGIC PRIORITY 3: ORGANIZATIONAL EXCELLENCE

As ODT strives to become the best place to work in federal government, we have focused on organizational excellence by enhancing our culture through talent acquisition, employee retention, engagement, and capacity building.

ODT created the Executive Officer (EO) role, ODT's first-ever Executive Leadership Team position focused on people, culture, communications, organizational development, and performance. The newly established ODT Communications Team developed several new products and channels. We also established a stakeholder engagement capability and held Congressional and Senate briefings and tours.

We developed a new hiring and compensation strategy through an initiative titled Project Elixir. This project lays out an incremental approach to shift our IT, data, and cybersecurity workforce to the Title 21 Hiring Authority as part of the 21st Century Cures Act. This new model will enable FDA to recruit and retain the top talent needed to drive change.

As part of investing in ourselves, ODT launched a workforce development effort titled Project UpTech. This project provides FDA employees customized trainings for critical organizational roles in IT fields that aligns to ODT's strategic priorities and the FDA mission. An IT Skills Assessment was sent to employees across FDA Centers and Offices to identify skills gaps and collect requests for training topics. Plans are underway to expand ODT's training portfolio to include advanced topics and cutting-edge IT certifications. We also improved our rewards and recognition program to elevate our workforce by creating the ODT Challenge and ODT Collaborator Coin awards.

ODT continues to accentuate their support of workforce and leadership development with the release of the Leadership Modernization Action Plan (LMAP) and the Diversity, Equity, Inclusion, and Accessibility (DEIA) Action Plan.

A Closer Look – Workforce Development

ODT piloted the FDA Academy leveraging LinkedIn Learning to provide unlimited, on-demand access to over 16,000 expert-led courses. The enterprise-wide license is available to all FDA employees. As of September 2022, over 6,000 licenses were activated, over 80,000 videos completed, and 28,000 courses were viewed.

ODT sponsored opportunities for Diversity, Equity, Inclusion and Accessibility (DEIA) activities. This included content in the Virtual Water Cooler, events to focus on DEIA topics (e.g., Male Ally at Work, Deaf Culture, LGBTQ Happy Hour, Juneteenth Poetry Slam, and Water Cooler Pop Ups) where employees were able to share aspects of their cultures.

ODT also hosted over 40 OneODT events to foster collaboration, share expertise, and build relationships. This included Knowledge Café presentations on topics such as Artificial Intelligence (average 122 attendees), Open Houses to learn about each office and division (average 228 attendees), and team building events such as speed networking.

STRATEGIC PRIORITY 4: GOVERNANCE

The FDA Technology Council ("Tech Council") has been the enterprise governing authority for information technology (IT) operations since November 21, 2019. The Tech Council operates by a Charter that consists of the CIO and senior-level representatives across FDA's Centers and Offices. This charter was created to prioritize and provide governance decisions on key strategic IT initiatives that impact the wider enterprise.

The structure of the Tech Council provides a holistic view into the breadth of IT investments before they reach a stage where significant resources and funding are spent. They also help identify duplicative or unnecessary investments in business capabilities that may already have been addressed elsewhere. This is especially critical as the IT budget has not increased at a rate that matches the increase in demand.

ODT initiated an IT Assessment Initiative to optimize FDA's nearly $1B IT portfolio, eliminating redundancies and inefficiencies that have accumulated over time. The initiative is aimed at eliminating duplicative investments in technology, strengthening alignment of IT spend to agency priorities and promoting governance, transparency, and strategic planning at the agency level. In FY22, the IT Assessment resulted in a reprioritization of $15M from low priority investments into high priority strategic investments which address enterprise challenges.

To enable FDA to provide transparency across Cost, Consumption and Performance FDA has implemented enterprise-wide adoption of TBM. This work is providing FDA leadership an unprecedented view of the IT spending has enabled strategic decisions that are enabling FDA to improve quality, performance, and value. This work has been completed in the Enterprise IT portfolio and is rolled out to the business IT portfolio.

ODT Acquisitions program has successfully implemented multiple improvements that resulted in FDA receiving FY22 STAR of the Year Award for supporting outstanding results for the small business vendor community.   This work has also improved CPARS compliance and delivered 15 agile IT acquisition Catalogs that dramatically reduce time to award. ODT has also implement two enterprise -wide acquisitions tools that improve contract oversight, improves quality and reduces overhead for contract development.

A Closer Look – FDA Technology Council

In 2022, four enterprise-level project intakes have been reviewed and approved by the Tech Council - 1.) Microsoft Teams Phone System (VoIP); 2.) Center of Tabaco Products (CTP) Budget and Acquisitions System (CBAS); 3.) Center for Biologics Evaluation and Research (CBER) Common Technology Foundation Project (CTF); 4.) 2022 End-of-Life (EoL) Technology Initiatives.

Technology Business Management (TBM) Taxonomy was utilized to align data (i.e., Services, Towers, and Cost Pools) enhance transparency, understanding, and visibility in analyzing ODT's budget and identified opportunities to redeploy funding towards critical operational needs as well as strategic priorities.

The IT Vendor Management (ITVM) team was established to manage vendor relationships, relationships, and risks. The ITVM predicative-based approach to managing vendors with standardized, repeatable processes for collection, analysis, and review of vendor performance data to expose critical risks.

A Closer Look – Maturing Collaboration Capabilities

The need to provide modern collaboration capabilities between FDA and industry partners enhances and expedites FDA's ability to ensure Centers continue meeting the FDA mission. Providing guest access to Microsoft Office365 including Teams and SharePoint Online has provided collaboration tools with partners to support mission critical projects.

This collaboration provided direct support for mission critical, cross-agency response to the infant formula crisis. Adoption of this capability has grown to include 82 SharePoint Sites, 386 FDA Users, and 299 Guests.

STRATEGIC PRIORITY 5: USER EXPERIENCE

As technology evolves, the User Experience (UX) must stay at the forefront of ODT's work. Over the past year, ODT has matured its collaboration capabilities and improved endpoint management capability. The UX Program was incorporated into all ODT enterprise project rollouts particularly supporting remote worker's daily IT experience. The program is continuing to expand through partnerships with the Enterprise Performance Life Cycle (EPLC), briefings during UX Center Meetings, and the development of a UX Checklist for project managers to reference throughout the project lifecycle.

ODT utilized Microsoft Teams and SharePoint online as FDA's collaboration tools to support partnerships and work on mission critical cross-agency efforts. This involved moving all FDA users to Microsoft Teams to provide a unified solution that fulfills meeting needs across all Centers and Offices. The focus on improving our employee experience has enhanced capabilities for support through Chat. We have also achieved a significant improvement in boot speed for all PCs due to optimization efforts. ODT coupled this support with expanded access to self-service kiosks to facilitate immediate access to support services.

	Before	After	
VPN	1:30 mins	:30 secs	**Domestic**
FDA On-site		:15–:20 secs	
China	10 mins	3:30 mins	**International**
India	5 mins	2:30 mins	
Chile	1–2 mins	:30 secs	

Personal cloud storage with OneDrive and Edge Browser Sync is providing a foundation for rapid computer deployments. The UX Team is in the process of a executing a touchless remote PC Deployment Project that will reduce downtime for users. Once completed, this project will enable users to more easily logon and access resources and programs to complete their work from any machine.

STRATEGIC PRIORITY 6: OPERATIONAL EXCELLENCE

Operational Excellence provides a set of checks and balances to identify the right priorities, evaluate risks, ensure compliance, and measure performance to achieve FDA's strategy. ODT's Office of Information Management & Technology (OIMT) published the Operational Strategy for 2022-2024 to provide a clear vision, objectives, and prioritization to guide, Service Modernization and IT modernization.

Service Modernization focuses on how services are defined, acquired, and made available to the Agency's internal and external users to deliver capabilities and services. The Operational Strategy focuses on providing easier access to data, transforming the products that we manage through innovation, and improving the communication and decision-making processes. This is accomplished by increasing awareness of existing ODT enterprise shared service contracts and improving the efficiency of the contract review process.

IT Modernization is enhancing and augmenting the Agency's IT infrastructure, systems, cloud capabilities, and processes through rationalization, consolidation, innovation and applying emerging technologies where appropriate to make our IT more efficient today and increase the Agency's readiness for future needs. At the core of this strategy is providing enterprise solutions to provide value for the entire Agency and offer greater standardization and consistency in quality. This will expand the use of Agency-wide, reusable enterprise services, including enterprise services, in acquisitions and procurement, financial management, email, collaboration solutions, back-office, and IT services.

A Closer Look – Procurement Optimization

ODT released FDA wide tools for agile acquisition (Acquisition Submission Accelerator) and post-award contract execution (Enterprise Status Tracking and Reporting System). The team conducted 48 training sessions through Contracting Officers Representatives (CORs) Focused Fridays and simplified the Agile IT Software Acquisition Process. This work led to a reduction in paperwork from 10 forms to 3 and decreased the required time to complete the package from 40 hours to 10 hours.

These efforts also improved the Contractor Performance Assessment Reporting System (CPARS) compliance from 75% to 88% and led to awards for 15 catalogs and multiple Blanket Purchase Agreements (BPA).

ODT redirected $15M from low priority to high priority investments after conducting an IT assessment to optimize the FDA's nearly $1B billion investment portfolio to examine opportunities for portfolio optimization, identify shadow and fragmented IT projects, and deployed IT Assessment Tiger Teams to support Centers and Offices with high-priority findings.

STRATEGIC PRIORITY 7: CYBERSECURITY

Cyber threat actors have increasingly sophisticated techniques and capabilities at their disposal. They employ new and evolving ways to target U.S. government entities, global allies, academia, private industry, and the healthcare sector. ODT's Office of Information Security (OIS) ensure appropriate security measures and protections are in place to maintain the public's trust and the FDA's reputation as a global public health leader. ODT's Cybersecurity, Counterintelligence, and Insider Threat Program is comprised of highly skilled cyber professionals who actively identified and thwart cyber threats, vulnerabilities, and risks to FDA's IT Enterprise, including over 25,000 end users, 15 High-Value Assets, and 400 plus systems and applications. OIS is implementing a Zero Trust Model to upgrade, enhance, and modernize our cyber defenses to address the evolving threat landscape.

OIS prioritized cyber workforce development this year with the understanding that employees play a significant role in preventing cyber incidents. Hosted a successful Senior Leaders IT/Cybersecurity Incident Workshop and Exercise utilizing a real-world scenario to assess the effectiveness of the current incident response, recovery plans, and procedures.

OIS collaborated with FDA and federal law enforcement stakeholders to mitigate the serious risks associated with the extraordinary volume of threatening messages sent to FDA officials and Advisory Committee members due to the FDA's role in regulating vaccines and other medical products. OIS also established the FDA Cyber and Data Security Advisory Committee and Subcommittee to serve as an advisory body and the principal forum for identifying and recommending strategic and enterprise cybersecurity initiatives to support the FDA's cybersecurity and data protection needs. Under FedRAMP requirements, OIS authorized 29 cloud service providers that support 100 FDA production systems and applications.

A Closer Look – Cybersecurity Success Across the FDA

Globally, theft of intellectual property, trade secret, and other sensitive information is on the rise. During this COVID-19 pandemic, we have seen a significant increase in phishing, social engineering, and other nefarious activities by cybercriminals and nation-state actors targeting individuals, private industry, and government entities. Compared to pre-pandemic, FDA has experienced a 457% increase in reconnaissance activities, denial of service, attempted exploitation, and other cyber incidents against the IT infrastructure.

OIS developed the Cybersecurity Modernization Action Plan (CMAP) and the FDA Zero Trust Cybersecurity Network Defense Implementation Plan to strengthen FDA's ability to conduct highly effective incident response, enable operational situational awareness, and decrease the overall security risks to our sensitive data and information while providing the agility and balance to meet our public health objectives.

As a result of these efforts, FDA has not experienced a major cybersecurity-related breach or incident. We have also significantly reduced system and application outages and have maintained the reliability of FDA business systems.

Looking to the Future

ODT's 2022 resulted in many accomplishments that we should all be proud of while also highlighting opportunities for more success as we continue our path forward. The TMAP, DMAP, EMAP, CMAP, and LMAP will jointly serve as the foundation for FDA's modernization roadmap and ensure strategic alignment as we enhance the agency's ability to optimize all aspects of IT operations.

With our enhanced capability to focus and prioritize, ODT will lead the FDA's enterprise-wide approach to improving business processes and ensure the agency functions not as a collection of Centers but as an integrated organization getting the most from its investments.

The projects and successes listed through this report detail the efforts ODT has taken as we remain focused on delivering the safest and very best technology and data services while maximizing our resources and achieving our strategic goals. ODT is proud of its progress over the past year and looks forward to continuing its modernization journey.

ODT Awards

Awards	Award Criteria	Recipient(s)
FedHealthIT 100 Award	This award honors individuals who are making an impact, going above and beyond, driving innovation and positive outcomes, challenging conventional wisdom, and giving back to the larger community.	Vid Desai, Craig Taylor, Jessica Berrellez, Ram Iyer, and Sohail Chaudhry
G2X Change Agent Award	The G2X Change Agent Award recognizes Federal IT and Consulting leaders from industry and Government who are working every day to take calculated risks and positively disrupt the Federal market, while having a measurable impact on the culture and the critical missions of the organizations they serve.	Ram Iyer and Sohail Chaudhry
STAR OSDBU award of the HHS OSDBU Small Business	This department award recognizes any Office of Acquisitions employee who has demonstrated unity, team upward morale and inspired others with positive team productivity in moving forward the agency's mission, vision, values, and priorities.	ODT-Acquisition Strategies and Partnership (ASAP) Team
FDA FY22 Honor Awards - FDA Commissioner's Special Citation	For outstanding leadership or significant achievement that contributed to the successful accomplishment of FDA's mission and strategic priorities identified by the Commissioner.	Cybersecurity, Counterintelligence, and Insider Threat Program Leadership Team
ODT Collaborator Coin	Highest ODT recognition honor, is awarded to colleagues outside ODT to recognize their excellent leadership, partnership, and innovation across the agency.	Dr. Janet Woodcock, Janelle Barth, James (Jay) Tyler, Andrew Jernell, Dr. Steve Solomon, Dr. Mark Walderhaug, and Lionel Carter
ODT Challenge Coin	Awarded monthly to recognize and highlight the noteworthy efforts of ODT employees.	Mahesh Choksi, Tarsha White, Lew Harvey, Adrian Diaz, David Sharpe, Beau Brooks, Christine Foster, Josh Lehman, Bin Tah, Mia Mercer, and Dave Draley

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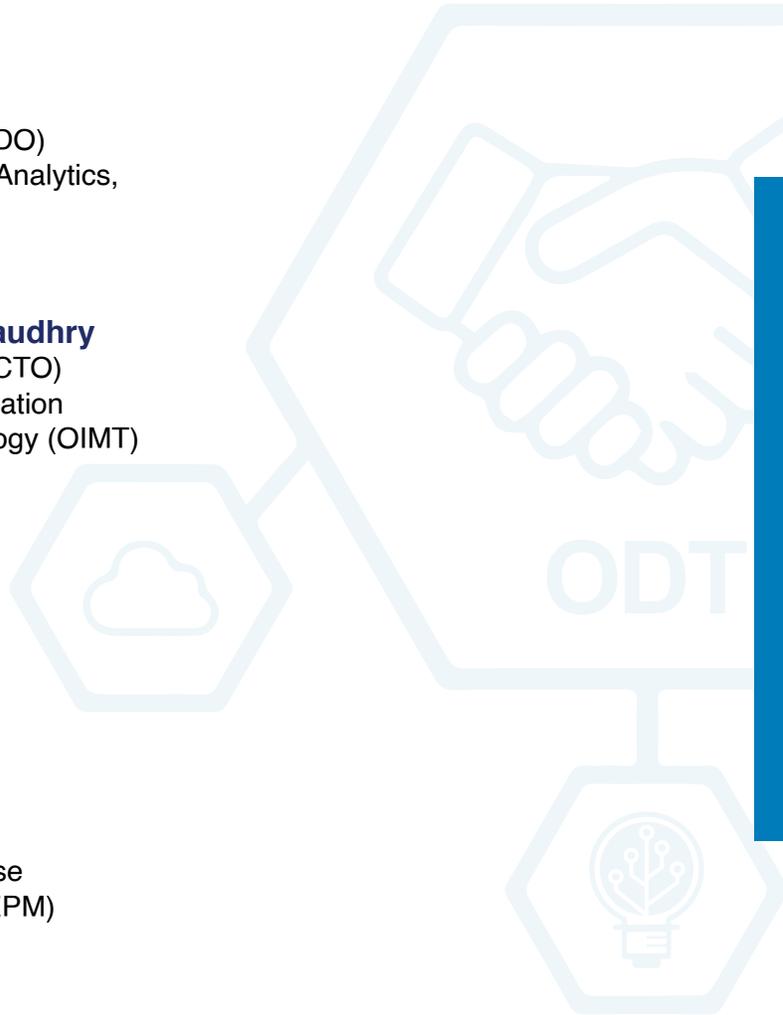
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