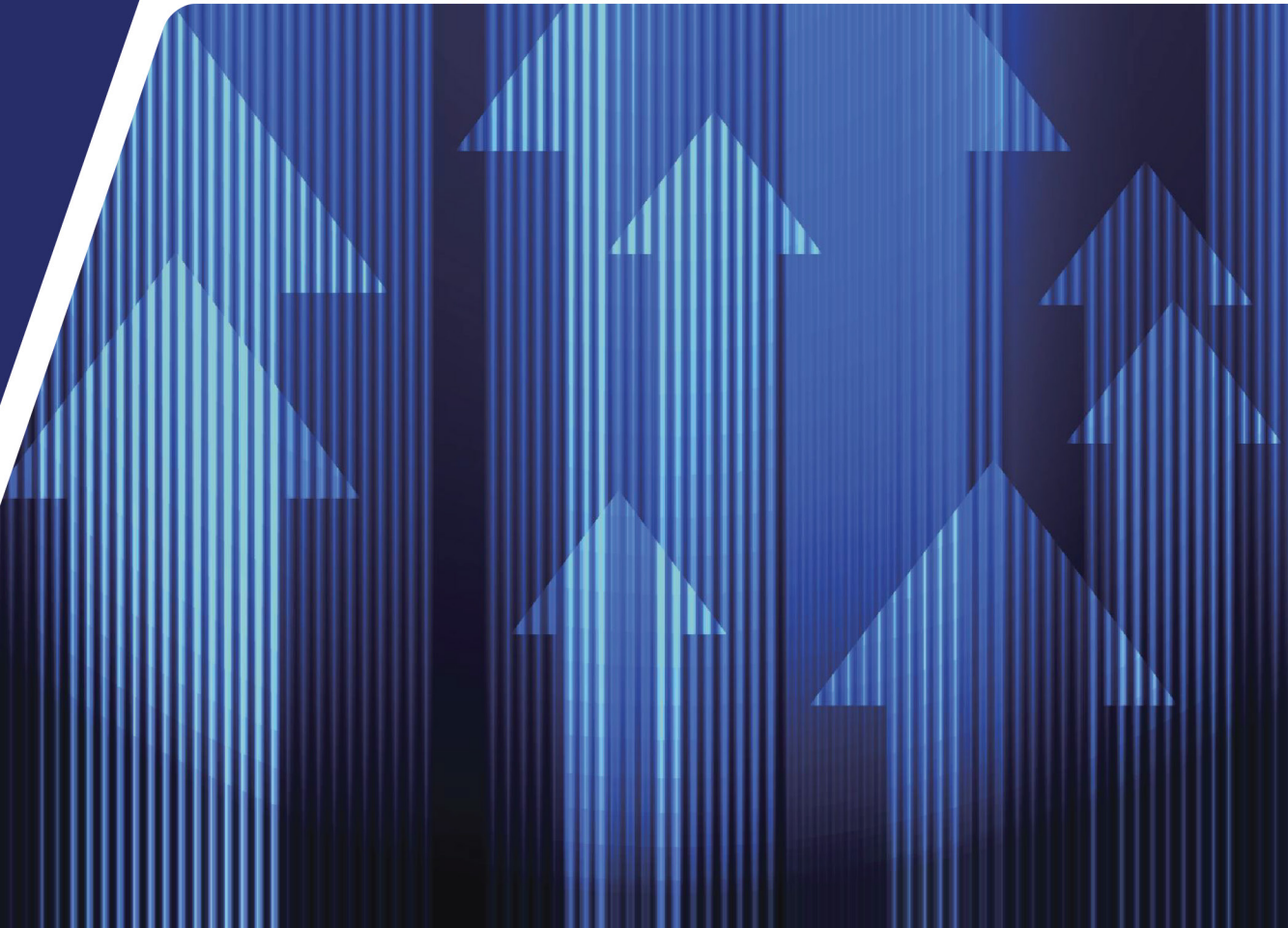




**U.S. FOOD & DRUG  
ADMINISTRATION**

OFFICE OF DIGITAL TRANSFORMATION

# 2023 Annual Report



# CONTENTS

<b>From Vid Desai, FDA Chief Information Officer (CIO)</b>	<b>3</b>
<b>FDA IT Strategic Goals and Objectives</b>	<b>4</b>
<b>ODT by the Numbers</b>	<b>5</b>
<b>2023 Achievements</b>	<b>6</b>
<b>Creating a Shared Ecosystem: OneFDA</b>	<b>6</b>
<b>Strengthening IT Infrastructure</b>	<b>8</b>
<b>Modernizing Enterprise Services and Capabilities</b>	<b>8</b>
<b>Sharing Data for Mission Outcomes</b>	<b>10</b>
<b>Cultivating Talent and Leadership</b>	<b>12</b>
<b>Looking Ahead</b>	<b>15</b>
<b>Publications</b>	<b>16</b>
<b>Awards</b>	<b>17</b>
<b>ODT in the Media</b>	<b>19</b>



## From Vid Desai

FDA Chief Information Officer (CIO)

This year, I want to recognize the continued progress of the Office of Digital Transformation toward maturing their operations and their service to the FDA's mission.

Our organization recently examined IT operations, goals, and spending across the entire agency by conferring with hundreds of stakeholders inside and outside the FDA. Through this IT Assessment, we produced the FDA Information Strategy, which asserts six broad strategic goals and the objectives that support them. We also finalized a draft of our IT Operating Plan, which will lay out the metrics and actions that will fulfill the goals of the FDA Information Strategy. We detail our progress toward those six goals in this report.

We also leveraged our research on the agency's projects, contracts, and finances to build a Technology Business Management (TBM) model that will align our IT spend with TBM categories. ODT will use this model to drive FDA toward better investments in our IT and mission capabilities. Further, our office chairs the FDA Technology Council, which ensures the FDA's investments in technology align with its priorities for the agency and the mission.

We committed to the concept of OneFDA in our strategic goals, to overcome the limits of a federated IT environment. ODT's partners and peers across the FDA's centers and offices were major contributors to our achievements in 2023. In our second annual Digital Transformation Symposium, we invited all FDA centers to share the podium with us and celebrate our collective wins in data, cybersecurity, and technology.

We're proud of where we stand today and how far we've come as an organization. I offer my thanks to all our employees, contractors, vendors, centers, customers, and stakeholders for partnering with us, driving this change at the FDA, and making the following achievements possible. I look forward to even more progress in our service to the FDA's mission in 2024.

Vid Desai

Chief Information Officer  
Office of Digital Transformation

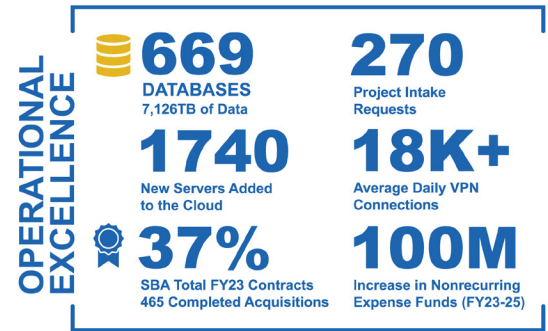
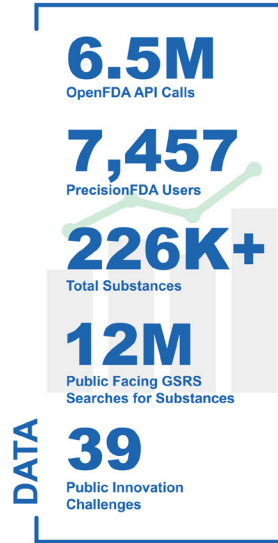
# IT STRATEGIC GOALS & OBJECTIVES

For FY 2024-2027

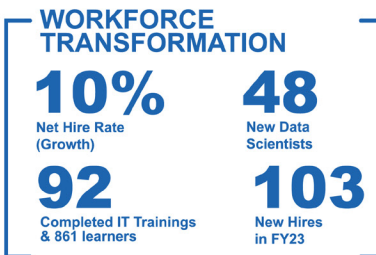
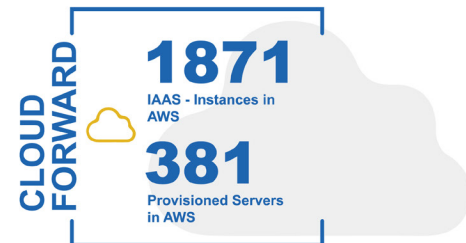
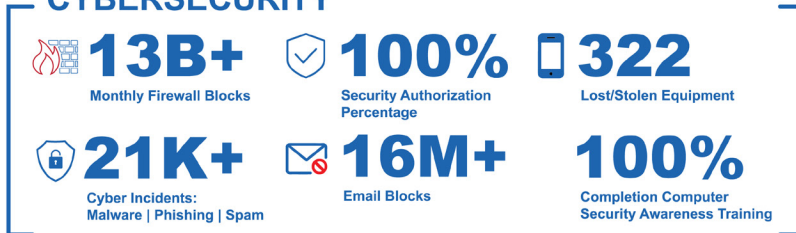
	<b>Create a Shared OneFDA Ecosystem</b>	<ul style="list-style-type: none"><li>▪ Enhance Communication and Collaboration</li><li>▪ Promote Transparency</li><li>▪ Optimize Investments</li><li>▪ Strengthen Governance</li></ul>	1
	<b>Strengthen IT Infrastructure</b>	<ul style="list-style-type: none"><li>▪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

# ODT BY THE NUMBERS

## ORGANIZATIONAL EXCELLENCE



## CYBERSECURITY



# 2 Year Anniversary

Office of Digital Transformation  
Year Two by the Numbers

# 2023 ACHIEVEMENTS

*The Office of Digital Transformation (ODT) is the central information technology office of the FDA. We provide the vision and leadership in information technology, data, and cybersecurity that advances the FDA's mission and strategic priorities. Our Chief Information Officer leads ODT and reports to the FDA Commissioner. This report highlights our achievements on behalf of the FDA in 2023.*

To learn more about our organization, visit [FDA.gov](https://www.fda.gov).

## Creating a Shared Ecosystem: OneFDA

Through ODT's efforts, the FDA started approaching technology and data as a unified agency:

- The FDA will be managing Freedom of Information Act (FOIA) requests across the entire agency through a harmonized process and new central technology platform supplied through Enterprise Transformation Operation (ETO) project activities.
- ODT introduced a Center of Excellence to start applying financial best practices from Technology Business Management (TBM) to all of the FDA's IT investments. ODT will continue to help FDA align its IT budgets and spending with the agency's strategic priorities. The FDA also benefits from a revised IT Enterprise Portfolio Lifecycle (EPLC) platform, which governs the project management of new IT applications across the agency. In 2023, ODT received requests for 270 projects, reviewed the progress of projects over 400 times, and consulted to our Center partners over 160 times.
- The FDA began unifying its approach to contracts that develop, deploy, and maintain IT applications (IT Acquisition Strategy.) We awarded 37% of total IT contracts to the Small Business Administration (SBA). FDA also pioneered a system to track contracts after they are awarded (eSTARS), kickstarted a Vendor Management Program, and organized and delivered 65 training sessions to Contracting Officer's Representatives.
- ODT established a Strategic Communications function to deliver clear and useful explanations, guidance, instructions, and references to the agency, our partners, and the public.

## Spotlight: Developing an IT Strategy

ODT assembled a specialty "tiger team" of specialists across the FDA to develop the agency's first comprehensive IT strategy. Two federal acts required this plan: the FDA's Prescription Drug User Fee Act and the Omnibus Reform Act. The FDA Technology Council directed the team. The team's specialists conferred with hundreds of stakeholders across the FDA, reached out to the public through a Federal Register Notice, held multiple workshops inside and outside the agency, listened to industry groups, and examined over 10,000 artifacts of information about the FDA's IT environment. As a result, ODT published the FDA Information Technology (IT) Strategy for Fiscal Years 2024-2027, which established the six goals that we pursued in our 2023 achievements. We will continue to review and update our strategy to keep pace with rapid changes in technology and healthcare.

## Spotlight: Engaging Stakeholders for Success

The 2023 FDA Digital Transformation Symposium was a significant milestone in aligning various stakeholders with the new FDA Information Technology (IT) Strategy. ODT's active thought leadership, support, and participation was central to the Symposium's remarkable success. With an impressive lineup of nearly 40 sessions, over 70 presenters, and 2,400 registrants, the Symposium facilitated a depth of discussions and presentations that was truly extraordinary. It fostered a collaborative environment to discuss strategy alignment and best practices.

One of the stand-out features of the Symposium was the introduction of Vendor Day, a platform for information exchange and discussion. This innovative program provided attendees with firsthand exposure to the latest technological solutions that hold the potential to advance the FDA's digital transformation goals. It showcased the FDA's commitment to forging new partnerships and strengthening existing ones, which are essential for the ongoing evolution of the FDA's digital landscape.

## Spotlight: Enhancing Inspection of Foreign Products

ODT used machine learning to translate foreign product information and aid inspections.

The FDA's presence at the U.S. Postal Service's International Mail Facilities (IMF) defends against products entering the U.S. market that are illegal, illicit, unapproved, counterfeit, and potentially dangerous.

The information for these products is often in a language that investigators can't read. The investigators must translate this information to properly examine these packages. The FDA also must translate documents that firms submit under the Foreign Supplier Verification Program to conduct its inspections. The FDA's human translators could only handle about 10-15 requests per day and were often handling languages outside their specialty.

ODT introduced a solution through Machine Learning as a Service (MLaaS) on a cloud-based platform. Over 80 field inspectors can now scan a product's information and the MLaaS solution will securely translate it for them in seconds. The inspectors can then easily share this translated information across other systems that support the FDA's inspections. The inspection process retains its quality and integrity at a faster pace.

## Strengthening IT Infrastructure

ODT supported a hybrid work model that includes over 18,000 teleworkers. The hybrid work model reduces the agency's carbon footprint and supports the Executive Order on Tackling the Climate Crisis at Home and Abroad (2021). ODT simplified how we deploy and manage computers to the FDA's staff, which reduced the annual costs across the agency's Centers by over \$2 million. For onsite workers, ODT enhanced our wi-fi network across the FDA's headquarters and its other sites, including 500 new wireless access points. We now carry data, voice, and video across a single converged network.

### Spotlight: Cloud-based Backup and Recovery

ODT moved its backup and recovery methods to the cloud, eliminating an archive of 48,000 physical tapes and a contract for storing them offsite. The new cloud-based backup and recovery method is more reliable, more secure, easier to manage and perform, and over 50% faster to restore service. ODT's use of cloud-based backups saves about \$200k per year in maintenance service, reduces the cost to power and cool our data center, and reduces the area used by equipment in our data center. This upgrade supports the FDA's continuity of operations (COOP) and the Data Center Optimization Initiative (DCOI). It also aligns with a second strategic goal: modernizing enterprise services and capabilities.

## Modernizing Enterprise Services and Capabilities

ODT continued to align the agency's technology with its mission:

- ODT collected and analyzed data from across the agency about its administrative, human resources, financial, and technology operations.
- ODT ensured that FDA users receive the newest tools/apps available on the latest computer operating systems through continuous, automatic updates. ODT enhanced their helpdesk support through a "live chat" feature that lets FDA staff reach a technician faster than through a phone call. This aligns our practices with standards in the support industry, and it helps teleworkers in our hybrid work model.
- ODT introduced Zoom (ZoomGov) to the FDA for large hybrid meetings. We securely opened Microsoft Teams and SharePoint so outside partners can collaborate with FDA on our main platforms.
- ODT upgraded wi-fi across most FDA campuses and expanded how staff and guests can securely use it. Staff can now make mobile phone calls over wi-fi to overcome limited cellphone signal, at a lower cost than augmenting the cellular network.
- ODT continued to support FDA 'Return to Facilities' and 'Workplace Thrives' programs. We implemented network infrastructure enhancements, maintained uptime of services, and supplied training and guidance to FDA staff on how to operate in a hybrid work model.
- ODT decommissioned hundreds of data center servers, applications, platforms, and devices that were at the end of their useful life. This reduced the agency's technical debt and our risks to the enterprise.



## Spotlight: Strengthening Cybersecurity

ODT introduced new cybersecurity capabilities to fortify how we protect the FDA's digital assets. Our ongoing Zero Trust implementation has boosted our threat protections, improved our access controls, and expanded our ability to monitor to detect and respond to suspicious patterns that suggest attacks, breaches, disruptions, and outages to our FDA networks, systems, and applications. We also developed a new scorecard method to assess our Zero Trust maturity across the FDA IT enterprise.

Our cybersecurity defenses prevented and protected against potential theft, unauthorized access, modification, and exploitation of sensitive data. We also elevated our threat level due to significant increases in phishing, social engineering, and exploitation attempts. Despite billions of attempts to access the agency's networks, the FDA had no major breaches or cyber incidents in 2023.

ODT successfully implemented key capabilities driven by Cybersecurity Modernization Action Plan and FDA Zero Trust Cybersecurity Network Defense Implementation Plan to reduce the overall risk to FDA's IT infrastructure and sensitive data as evidenced by our compliance with data security and privacy protection guidance as required by the Presidential Executive Order 14028, Improving the Nation's Cybersecurity, and Office of Management and Budget OMB M-22-09 Zero Trust Strategy.

The HHS Office of the Inspector General (OIG) praised and rated our FDA Cybersecurity, Counterintelligence, and Insider Threat Program at a Level 4 Maturity. FDA was the only HHS Operating Division rated at Level 4 following this year's FY23 FISMA Audit.

## Spotlight: Improving How We Collaborate Outside the FDA

ODT enhanced the FDA's ability to work with its partners by securely allowing them to use part of the agency's Microsoft SharePoint and Teams platforms where most FDA staff collaborate.

Before this upgrade, the FDA's partners usually shared files through email, which limited them to simple transactions. FDA staff can now invite their partners to securely engage in their workspace and work activities, including co-authoring documents, managing file versions, and informally chatting in a shared area.

We also surveyed the platform's users for their feedback so we could keep refining the service. We improved support for international users, reduced the number of administrative steps for outside users, and made sites quicker to setup. We now operate 270 sites that the FDA uses to collaborate with 300 of its partner organizations.

## Sharing Data for Mission Outcomes

### ODT continued to expand how we share data across the FDA:

- ODT established a unified inventory of about 1.5 million regulated firms and products, plus central catalogs of inspections and regulatory data. We expect this centralization to reduce operations costs by 30% and improve the quality and reliability of regulatory data.
- ODT released the second version of its Intelligent Data Lifecycle Ecosystem (FiDLE), which makes 90% of FDA's data science applications and tools easily available for multi-omics and data science users.
- ODT also expanded Precision.FDA.gov, our public portal of data research and expertise. Usage increased by 40%, with over 35,000 registered users and over 5,700 informative articles.
- The FDA's Global Substance Registration System now has over 1,200 active users and was searched 12 million times in 2023. The OpenFDA Application Programming Interface (API) had over 6.5 million calls.
- ODT and the Office of Regulatory Affairs (ORA) co-launched a pilot program to standardize inspection workflows.
- ODT fostered data literacy by offering training in data science, sharing knowledge in a central portal, publishing newsletters about genomic data, and hiring experts in data analytics who can quickly respond to FDA's unique regulatory challenges. We also completed 39 open innovation data challenges.
- ODT chaired the Data Modernization Steering Committee. We worked closely with our center partners and data experts, engaged FDA's stakeholders, gained their feedback, and improved the quality and delivery of data products that inform decision-making.
- ODT connected experts in real-world data (RWD) and real-world evidence (RWE) from across the agency, government, and academia. The RWD Multidisciplinary Analysis Group (RMAG) hosted the collaboration. The group covered topics including University of California, San Francisco, Centers of Excellence in Regulatory Science (CERSI); Pulse Oximetry Collaboration; lessons learned from the COVID-19 response.

### Spotlight: Adopting Artificial Intelligence (AI)

ODT developed the AI Playbook to help our partners in the agency use and understand AI, as outlined in FDA's Technology Modernization Action Plan. Five projects used the playbook to guide their use of AI in risk assessment, predictive analysis, and product recalls. In 2023, the AI Playbook was visited over 5,400 times this year. The videos on AI development were visited over 360 times in the last few months of 2023 alone.

ODT hired an Artificial Intelligence / Machine Learning Lead for a focused and coordinated response to FDA's AI/ML efforts, in support of the FDA Technology Modernization Action Plan.

ODT also partnered on an AI solution with the Office of Prescription Drug Promotion (OPDP) in the Center for Drug Evaluation and Research (CDER). The solution reduced the effort to complete each review of promotional drug materials by 8-16 hours.

## Spotlight: Establishing AI Governance

The new FDA Information Technology Strategy's "Adopting Artificial Intelligence (AI) and Innovations" goal set a clear direction for the agency's approach to AI. As an important next step, ODT introduced the FDA AI Governance and Advisory Board to guide the agency through the complexities of AI integration.

The board includes a diverse group of representatives from each agency center and specialists in legal, ethical, privacy, security, and diversity. Their collective expertise ensured a holistic understanding of AI technology's facets, and their work led to the first policy to outline the FDA's approach to Generative AI.

The board's first major contribution was position paper "The Rise of Generative Artificial Intelligence." The paper detailed the FDA's strategic plan for using generative AI technologies, especially Large Language Models (LLMs). It also offered a comprehensive strategy for embedding Generative AI into the FDA's operational framework. This strategy aligns the FDA with the expectations of both the new Executive Order on the Safe, Secure, and Trustworthy Development and Use of Artificial Intelligence (2023) and the Data Strategy of the Department of Health and Human Services. It also included guiding principles for the safe and effective use of Generative AI, representing the FDA's commitment to responsible and mission-driven AI.

The AI Governance and Advisory Board established itself through this paper as a key player in guiding the FDA toward the effective use of AI's transformative power. The formation of the Board and the publication of the position paper were milestones and a clear indication of ODT's dedication to embracing cutting-edge technology. This effort propels the FDA forward in an era of rapid technological advancement.

## Spotlight: Introducing Data Analytics as a Service (DAaaS)

Data Analytics as a Service (DAaaS) is a data science community that rapidly responds to urgent and complex data analytics efforts for stakeholders inside and outside the FDA. Our DAaaS community provides the FDA with a reliable method of collecting internal and external data and generating accurate insight from that data to inform decision-making. ODT designed DAaaS to directly support duties in the FDA's mission like recalls and supply chain monitoring.

Our service recently enhanced how we monitor trends in the infant formula supply chain and the analgesics supply chain. We now proactively and continually respond to the supply chain based on methodically analyzing accurate and consistent data. Our service also helps the US Department of Agriculture because their Women Infants and Children program is also considered with the infant formula supply chain.

Because of the value we supplied through DAaaS, the FDA saved \$1.5 million in 2023 and will continue to save \$2-3 million every year.

DAaaS aligns with our IT Strategy and Data Modernization Action Plan.

## Cultivating Talent and Leadership

**In 2023, ODT continued to respond to our employees' career interests, develop our employees' skillsets, foster skills among future workers, and attract seasoned professionals to our organization.**

- Each year, the FDA performs the Federal Employee Viewpoint Survey to gauge how satisfied employees are with their experiences at the FDA. In 2023, ODT's employees were more positive toward several aspects of leadership than employees of the average FDA office or center. Specifically, ODT employees agreed more often that:
  - management encourages innovation (+14.4%),
  - management makes effective changes to address challenges (+11%)
  - they can make decisions without getting permission first (+10.2%),
  - senior leaders generate high levels of motivation and commitment (+9.8%)
  - employees consistently look for ways to improve customer service (+9.6%).
- ODT completed its 'OneODT' initiative to further improve our employees' satisfaction. We hosted a total of seventy-eight (78) employee engagement events in FY2023 ranging from Knowledge Cafés to Open Houses. The ODT Virtual Water Cooler supported internal communication and employee engagement with 557 active users and 2,233 engagements.
- ODT established its Diversity, Equity, Inclusion, and Accessibility (DEIA) Action Plan. ODT committed to integrate DEIA as a key strategic mission and operation party. ODT hosted 22 DEIA events on DEIA, including the Women in Innovation Summit and Employee Resource Group Open House. As of 2023, 44% of our employees and 49% of our GS-15 staff are women. 29% of our employees are African American and 21% are Asian. 15% of our employees are veterans. 7% of our employees self-reported a disability. ODT also coordinates guidance on Accessibility for IT products and outputs (Section 508 of the Rehabilitation Act). Our DEIA Action Plan aligns with the FDA's Leadership Modernization Action Plan and its DEIA Strategic Plan
- The #ODTCares initiative delivered thirty gifts and cards to employees experiencing significant life events, including surgery or injury, deaths, and weather emergencies. This voluntary giving program sponsored by the Senior Leadership Team supports our culture of empathy and belonging.
- Digital Leadership Program (Pilot): ODT partnered with experts in leadership development to start a development program for ODT staff in leadership positions. The program intends to build a pipeline of capable leaders that can drive innovation and change at the agency. ODT and its partners based the program's content on the findings in our Leadership Modernization Action Plan (LMAP). For the program's 8-month pilot, ODT executives invited 18 senior leaders from across its office to learn from instructors, coaches, and executives, both in-person and virtually. The progress and feedback from the 18 senior leaders will inform the program's final design.
- Project Elixir: ODT developed hiring and compensation strategies under Title 21 to strengthen its technology workforce. We achieved a net hire growth rate of 10% and reduced our attrition to 5.8%, showcasing an increasingly robust talent acquisition strategy.
- Project UpTech: ODT supplies custom training for critical IT specialties that support ODT's strategic priorities and the FDA's mission. In 2023 the project's FDA Academy digital learning program attracted over 9,000 employees who completed nearly 7,000 courses and 220,000 hours of coursework.

- ODT organized 34 Brown Bag sessions for over 3,000 employees and delivered nearly 100 Microsoft application training courses to 1,000 employees who gave a satisfaction score of 92%.
- Summer Scholars: This program provides opportunities for diverse undergraduate and graduate students to work over the summer with ODT supervisors and mentors on projects that advance the FDA's mission. The program employed five students this year.
- ODT introduced a Recruitment and Outreach Team to enhance our appeal to new talent as a choice employer. We also participated in IT hiring events aimed at job candidates and Minority Serving Institutions.
- ODT's executive leaders continued to raise our profile among potential partners and recruits. Our executives delivered 9 keynote addresses at conferences, gave interviews to 2 media publishers, and hosted 2 listening sessions with leaders in industry and technology.
- ODT championed performance, accountability, and excellence by awarding \$1.4 million in performance awards, \$324k in incentive awards, and 469 FDA and Office of the Commissioner Honor Awards.
- ODT continued to transparently inform both the FDA and the public about our work. Internally, we produced news articles on over 100 topics for our FDA readership. Our public facing PrecisionFDA newsletter increased its readership to over 17,000 subscribers. We also published a range of plans to a public audience, including our Cybersecurity Modernization Action Plan, Leadership Modernization Action Plan, OneODT White Paper, ODT Annual Report, and ODT DEIA Action Plan.

## Spotlight: Developing New Data Scientists

ODT began upskilling FDA staff specifically in data-related skills and specialties. Our DataForward program gathered 10 mentors to teach data science practices to 40 employees in 2023.

We invited FDA staff with a range of roles, career levels, and experiences to our program. Some were new to the field and curious about the opportunity, while others had data expertise that they hadn't yet applied to their roles.

ODT brought the staff together on data science projects, taught them how to use our data tools, and supplied them with expert context and guidance. The program also introduced the staff to existing data science communities and experts and invited them to join this data science network. The staff returned to their centers with new skills to benefit the center's mission, and a circle of peers and mentors to assist them in their efforts.

Our new Data Scientists developed dashboards in our FiDLE data ecosystem and helped reduce the manual processing time for critical data pipelines. In addition, our "squad" model brings Data Scientists together for more complicated data science efforts. The squad's participants handled three projects across four offices and centers.

ODT also coordinated FDA's portion of the HHS CoLab. We reviewed and chose 21 participants and supplied them with extensive hands-on data science and technical support.

## Spotlight: Inspiring Future IT Professionals

ODT launched the aimHI Summer Incubator Program to cultivate interest in Information Technology career paths and academic paths among diverse, high-achieving high school students. ODT hosted 20 underrepresented students and immersed them in learning for IT, AI, Machine Learning, Data Science, and Cybersecurity.

We supplied this 5-week hybrid learning experience through our partnership with the Maryland's Montgomery County Public Schools. It featured interactive IT sessions, robust development modules, and special projects.

Students were grouped into project teams to develop Medical Mobile Applications and showcased their prototypes at a Code-A-Thon. They had hands-on machine learning and robotics using AWS DeepRacer, which we capped with a special Race Day. Students also toured the White House, learned leadership skills, and sampled our FDA and Tech Academy curriculum.

Our aimHI program advances our goal to cultivate talent and leadership, as outlined in the IT Strategy and ODT's Diversity, Equity, Inclusion, and Accessibility Action Plan. Some of its activities also align with ODT's broader Project UpTech upskilling and reskilling initiative.

# LOOKING AHEAD

**The Office of Digital Transformation (ODT)** is proud of our journey, and we are optimistic about what lies ahead. We have solidified our role as a cornerstone in the **FDA's** mission, and our progress is evident on every page of this report.

In 2023, we conducted a broad IT Assessment and responded with an **FDA** IT Strategy of six strategic goals. We are currently drafting an IT Operating Plan, and we will use it to meet the goals of our IT Strategy with clear metrics and actions.

The concept of **OneFDA** has unified our efforts and led to remarkable collaboration across the **FDA**. We will continue these partnerships in 2024 to drive change and advance our public health mission.

# PUBLICATIONS

## [When can real-world data generate real-world evidence?](#)

by Motiur Rahman, Gerald Dal Pan, Peter Stein, Mark Levenson, Stefanie Kraus, Aloka Chakravarty, Donna R. Rivera, Richard Forshee and John Concato

Pharmacoepidemiology and drug safety. Oct 19, 2023. [DOI](#); PMID 37855046

## [Empowering Efficient Literature Searching: An Overview of Biomedical Search Engines and Databases](#)

by Pitchai Balakumar, Joanne Berger, Gwendolyn Halford and Gowra Jagadeesh

The Quintessence of Basic and Clinical Research and Scientific Publishing, pp.619-644  
Springer Nature Singapore. Oct 1, 2023. [DOI](#)

## [Managing Cold-start in The Serverless Cloud with Temporal Convolutional Networks](#)

by Tam Nguyen

arXiv.org April 1, 2023. [DOI](#)

## [Considerations for defining medication exposure when analyzing real-world data](#)

by Alecia Clary, Nancy D Lin, Tamar Lasky, Matthew W Reynolds, Anand Chokkalingam and Carla Rodriguez-Watson

Pharmacoepidemiology and drug safety. March 16, 2023. PMID 36929112

## [Real-world utilization of SARS-CoV-2 serological testing in RNA positive patients across the United States](#)

by Carla V Rodriguez-Watson, Natalie E Sheils, Anthony M Louder, Elizabeth H Eldridge, Nancy D Lin, Benjamin D Pollock, Jennifer L Gatz, Shaun J Grannis, Rohit Vashisht, ... (32 authors)

PloS one, Vol.18(2), pp.e0281365-e0281365. Feb 10, 2023. [DOI](#); PMID 36763574



# AWARDS

**2023 Washington Executive Top Tech Leader to Watch in 2023** – Federal IT leaders who play a critical role in ensuring the wellbeing of the nation, along with their achievements, expertise, and vision for bringing their agencies into the future to better serve the people

*Awarded to Vid Desai*

**FedHealthIT 2023 Disruptive Tech Change Agent Award** – Federal IT and Consulting leaders who take calculated risks and positively disrupt the Federal market, while having a measurable impact on the culture and the critical missions of their organizations (Peer-nominated)

*Awarded to Jessica Berrellez, Mahesh Choksi, Sohail Chaudhry, Joshua Lehman, Joseph Montgomery*

**FORBES 2023 CIO Next List** – 50 top tech leaders who are leveraging technology to transform their companies and the role of the CIO

*Awarded to Vid Desai*

**FORBES CIO of the Year** – Top executives who are redefining the traditional role of IT in exciting ways and driving game-changing innovations

*Awarded to Vid Desai*

**Constellation's 2023-2024 Business Transformation 150** – Who's who of innovation CIO, CMOs, CDOs, and other digital leaders from around the globe

*Awarded to Vid Desai*

**FedHealthIT Lifetime Achievement Award** – 100 dynamic leaders who drive change and advancement within the Federal Tech Consulting Community

*Awarded to Vid Desai*

**2023 Service to the Citizen Award** – Public servants at all levels who deliver an outstanding experience to the public, impact the public's lives, and rebuild trust in the government

*Awarded to Joshua Lehman*

**FORUM (FederalHealthIT) 2023 Disruptive Tech Program Awards** – Federal IT and Consulting leaders who take calculated risks and positively disrupt the Federal market, while having a measurable impact on the organizations they serve (Peer nominated)

*Awarded to the program teams for CFSAN Product Tracing System, Microsoft Office 365 User Experience, OIMT Automation, ORA Automated Laboratory Information System, Technology Business Management (TBM) Taxonomy*

**2023 FORUM Health IT Innovation Award** – Programs that drive innovation and results across the Department of Veterans Affairs, the Military Health System, and the Department of Health and Human Services

*Awarded to Mohammad Hossain, Farhan Khan, Rajasekhar Raja, Quinn Ton, and Van Tran*

**2023 AFCEA Bethesda Chapter InnovateIT Award** – Workforce Innovation Leader of the Year  
*Awarded to Jessica Berrellez*

**2023 Leading Impact Award** – Women who create a positive impact and lead organizations and mission-focused strategic programs across the Federal Civilian, Federal Health, Military Health, Technology, and Consulting communities  
*Awarded to Jessica Berrellez, Amy El-Naggar, and Trudy Lilly*

**FedScoop 50 Awards 2023: Most Inspiring Up and Comer** – Early-career executives whose exceptional achievements over the past year have put them on a track to be next generation leaders in the Federal IT Community  
*Awarded to Jessica Berrellez*

**2024 Engage Federal Health Honorees** – Leaders who stand out from the crowd for their willingness to drive bold approaches and innovative engagement strategies while supporting a culture shift which values collaboration, open communication, transparency, and partnership (Peer-nominated)  
*Awarded to Vid Desai, Jessica Berrellez, Farhan Khan*

**FDA Commissioner’s Special Citation** – Outstanding leadership or significant achievement that contributed to the successful accomplishment of FDA’s mission and strategic priorities  
*Awarded to ODT’s Office of Information Security – Zero Trust Initiative, FDA Information Technology Strategy Team, FiDLE Integrated Project Team*

**FORUM Health IT 100 Winner Award** – Programs recognizing select group of dedicated individuals within the Federal health IT community who are making an impact, going above and beyond, and driving innovation and positive outcomes.  
*Awarded to Mohammed Sohail Chaudhry*

**2023 Pinnacle Awards** – Healthcare Executive of the Year  
*Awarded to Mohammed Sohail Chaudhry*

# ODT IN THE MEDIA

## **FDA's It Strategy Will Focus on Modernization**

Jeff Craven. Regulatory Focus, A RAPS Publication. September 2023.

## **FDA's Digital Transformation Efforts**

FCW Magazine. March 2023.

## **Top Government Tech Leaders to Watch in 2023: FDA's Vid Desai**

Washington Exec. April 24, 2023.

## **FDA Keep Tabs On 'Common Efforts' to Improve Public Health Through Master Data Management**

Jory Heckman, Federal News Network. January 26, 2023.

## **FDA's IT Strategy: Unlocking Potential, Leading Transformation**

Health IT Answers.net September 27, 2023.

## **'As-a-Service' IT Delivery Models Driving Modernization'**

GovCIO Media & Research. August 3, 2023.

## **Food and Drug Administration Seeks Input on Digital Transformation Plan**

John Hewitt Jones. Fedscoop.com. April 25, 2023

## **CX Exchange 2023: FDA's Josh Lehman on How Employees Come First**

Jason Miller. Federal News Network. April 2023.

## **Real-time Feedback is Central to FDA's Upcoming Goals for Customer Experience**

Drew Friedman, Federal News Network, September 2023.

## **FDA's Draft Plan Calls for AI, Other Emerging Tech in Modernization Efforts**

Alexandra Kelley. Nextgov. September 18, 2023.

## **FDA Starts Work on New Data and Technology Strategic Plan**

Aaron Boyd. NextGov.com. April 13, 2023

## **FDA Staffing: Retirements Account for More Than One-Third of FY 2023 Departures**

Sue Sutter. Pink Sheet, Citeline.com. June 6, 2023

## **FDA Charts Future of Zero Trust in New Cyber Plan**

Government CIO Media. December 13, 2023

## **Network Modernization Summit (defenseone.com)**

### **[On Demand recording Mohammed Chaudhry]**

GovExec 12:02 PM EDT Tuesday, October 19, 2023

## **Mohammed Chaudhry | 2023 WashingtonExec Pinnacle Awards**

WashingtonExec. September 20, 2023

## **FDA's IT Strategy Focuses on Developing Tech Talent**

Jayla Whitfield. GovCIO Media & Research. December 7, 2023