Leadership Modernization Action Plan (LMAP)

Background

The Leadership Modernization Action Plan (LMAP) is the approach by which the FDA’s Office of Digital Transformation (ODT) seeks to evolve the role of the CIO and technology leaders into empowered business leaders by developing and operationalizing modern leadership and management principles necessary to drive innovation and change in support of the FDA’s critical public health mission.

FDA began its digital modernization journey in September 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 highest potential without alignment with business and organization priorities, the FDA developed an Enterprise Modernization Action Plan (EMAP) in May 2022 to guide business transformation in parallel with IT and Data modernization efforts. More recently, we released the Cybersecurity Modernization Action Plan (CMAP) in November 2022 to recognize the continued importance of integrating cybersecurity.

As we reflected on the success factors for modernization, one critical element was salient: the leaders driving the work forward. The Leadership Modernization Action Plan (LMAP) describes our intent to shape the FDA’s future by developing immediate and long-term strategies to grow and modernize leadership capacity within ODT and across the FDA technology and data ecosystem. We must modernize our leadership capabilities to operate at the accelerating pace of the agency. In the next decade, FDA will see a significant rise in regulatory review activities and increasing complexity of scientific decision-making and reliance on primary data sources. In addition to leading and managing technology services, leaders need the skills and experience to govern and align activities across the FDA. They must be fiscally responsible and able to articulate business cases and needs internally and externally so that the vital agency activities get the support needed without wasting taxpayer dollars. This new focus on business-driven leadership competencies extends the aperture of IT leaders outside of technical domains. It requires that we develop capable career leaders within the FDA with the experience and skills to lead strategy, planning, and decision-making at all levels. Leaders can no longer succeed with strengths in only one area. Aptitude across all leadership abilities and competencies is required.

"IT leaders need to shift their perception of being IT solution providers to business solution providers."

- Vid Desai, CIO

ODT leadership must modernize to rise to the mission. It is vital to build leadership competencies and ensure consistency with leadership practices. Shaping successful outcomes require aligning leaders with a shared understanding of business goals and creating a management structure that supports effective execution. 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 and build a more resilient organization.

It is also important to recognize that leaders and change agents exist at all levels of the organization. Every employee is empowered and expected to demonstrate leadership. When everyone leads in every moment, the speed of change accelerates. Culture change requires a shared vision, commitment, and high levels of leadership and employee engagement.

The fundamental element of this new ecosystem is trust: building trust and building trusting teams. Trust enables leaders at all levels to create a workplace that is engaged, collaborative, safe and accountable for individual and organizational success. It builds a stable foundation for employees and teams to adapt, and thrive in times of change and transition. The LMAP aims to develop and expand the skills and tools that are fundamental to building trust, including empathy, authenticity, communication, and diversity, equity, and inclusion. By investing in leadership development that emphasizes trust, ODT can increase alignment and organizational effectiveness.
Collectively, these efforts will enhance our leadership capabilities while strengthening the alignment between agency-wide strategic objectives, outcomes, and impacts.

The three elements of the LMAP are:
1. Create an environment where business and IT programs are aligned and collaborate to achieve business priorities and leverage IT opportunities to enhance outcomes.
2. Develop and operationalize an IT strategy that is reflective of business needs.
3. Develop a leadership pipeline that can maintain strategic continuity through leadership and organizational change.

The Case for Change

The FDA has historically taken a decentralized approach to IT strategic planning, investments, and program oversight. This program-based model has resulted in a legacy, fragmented environment with siloed solutions and unsustainable IT costs. The current approach inhibits the agency’s ability to keep up with rapidly changing technology and business priorities. The lack of thought leadership, collaborative planning, and governance has resulted in redundant systems, suboptimal access to data, and unsatisfactory user experiences. Similarly, FDA has historically outsourced IT strategy, planning, and decision-making to external consultants rather than driving this work internally. This approach has created alignment and competency gaps that have hindered our modernization efforts. We need to cultivate these critical organizational and leadership capabilities within our own organization. We are addressing these challenges as part of our ongoing change journey and Blueprint for Good IT work. This will strengthen the agenda and better enable us to respond to dynamic changes in the broader environment. The industries the FDA regulates are rapidly changing, as is the technology landscape. IT shares the responsibility to keep pace with the scientific, regulatory, and legal changes; while ensuring that public health decision makers have access to the data they need to make the most informed decisions. The COVID-19 pandemic required rapid adaptation and innovation to ensure the continuity of operations during a time of increased workloads and elevated cybersecurity risk. The FDA rose to this challenge but identified many areas of opportunity for growth and increased resiliency.

The shift to hybrid work during the pandemic highlighted the value of enterprise IT, with IT leadership more critical than ever in enabling the continuity of operations. The industry standard is increasing for IT organizations to function as strategic business partners. Historically, IT leaders have worked closely with senior executives but have had challenges leading IT strategy or enacting rapid change. The pandemic underscored the need to bring IT leaders and teams into the heart of the organization. It also highlighted the importance of leadership competencies and strategic vision for leading technology modernization.

Digital transformation is a continuous journey that touches every part of an organization. ODT is moving away from standard service provisioning to partnering with Centers to use technology and data for better business outcomes. While technology was previously a secondary function, it is now a driver of operational effectiveness and workforce performance. It is not enough to build or buy the latest tools and technologies – you must have the management infrastructure and people to implement, secure, and maintain them. As we progress, the FDA must have strong leaders at the helm of ODT and Center programs. Our organization must also have a pipeline of strategic thinkers and future leaders operating in a continuous learning mindset to design, innovate and adapt to ever-increasing demand and complexity.

A Vision for the Future

The LMAP is the next milestone in the FDA’s modernization journey. We must strengthen our leadership capabilities to effectively drive change at the business, technology, data, and cybersecurity levels. The LMAP is the final piece of the agency’s modernization framework: Technology Modernization Action Plan (TMAP), Data Modernization Action Plan (DMAP), Enterprise Modernization Action Plan (EMAP), and newly released Cybersecurity Modernization Action Plan (CMAP). All four five strategic frameworks are in action today, and the LMAP puts people, and leaders, at the forefront of these efforts. This investment in developing our mission-driven staff will enable us to successfully actualize our bold transformation vision.
As a concept, leadership modernization is grounded in the processes for managing change and centers on how leaders must lead in more contemporary ways, now and in the future. Our leaders must be able to adapt to constant change because a strategy that worked yesterday, may not work today, and may not be the right approach for tomorrow. Our strategy focuses on shifting outdated paradigms and perspectives of business practices, human behaviors, and the meaning of organizational success. This approach to leadership modernization is a new beginning to leading organizational change and achieving business results while at the same time retaining leadership practices and techniques that are proven to be effective and produce results.

Leadership modernization aims to grow leadership capacity at an organizational level in line with digital transformation and IT modernization objectives. It is a strategic approach to enable and empower leaders to manage a modern workforce and successfully drive innovation and change. Leadership Modernization requires leaders to embrace new practices and mindsets to become capable and comfortable with managing modern technologies and projects of increasing complexity while creating a positive and productive environment for their teams that will attract and retain top talent.

The future vision is an evolution of the CIO and technology leaders into empowered business leaders, first and foremost. In today’s digital world, all business activities are dependent on IT services. Engaged IT leaders can understand business operations from a unique vantage point. As change accelerates and data, security, and business agility become more salient, so does the role of technological leadership. Aligning IT strategy with business objectives ensures that our limited IT resources are focused on the right organizational priorities. The FDA’s IT leaders are strategic partners in tackling the agency’s most complex problems. They must now rise to the challenge of strengthening business value, shaping the FDA’s future, and driving lasting strategic impact.

The Leadership Modernization Action Plan

The three components of the Leadership Modernization Action Plan (LMAP) will build a sustainable environment for IT leadership to thrive within ODT and across FDA.

1. Create an environment where business and IT programs are aligned and collaborate to achieve business priorities and leverage IT opportunities to enhance outcomes.

The Agency established the Office of Digital Transformation in September 2021 and directly elevated the CIO reporting structure to the FDA Commissioner to address these challenges. The FDA is now advancing an enterprise IT, data, cybersecurity, and business process management approach that will allow us to better leverage and secure FDA data. Planning, governance, financial management, and workforce mobilization are at the core of these organizational changes. Senior executives are now engaging the FDA CIO and ODT’s Executive Leadership Team for more strategic discussions. It is imperative that ODT leaders continue to actively engage at the FDA’s Executive Committee level to ensure synergies with business leaders. As these relationships evolve, ODT leaders will translate business priorities and needs into IT requirements, and help ensure alignment with Center-level IT programs.
The FDA Technology Council will serve as the governing body for effective distributed leadership across the organization’s IT and business ecosystem. The Technology Council will lay the foundation for establishing an IT Working Capital Fund for shared decision-making and resource investments. ODT will scale its Technology Business Management (TBM) framework agency-wide to bridge the gap between organizational strategy and technology investments. These changes will strengthen the FDA’s alignment with industry standards like Information Technology Infrastructure Library governance structures and processes. Together with our center partners, ODT will create the framework for inclusive leadership and transparent decision-making.

2. Develop and operationalize an IT strategy that is reflective of business needs.

ODT will adapt its structure and functions to enable more effective enterprise IT strategic planning, collaborative governance, and decision-making. We will elevate the Office of Enterprise Portfolio Management within ODT and create a Chief Enterprise Portfolio Officer role to shepherd the creation of an agency-wide IT Strategic Plan. This effort will map ODT’s Strategic Plan with Center-level plans to incorporate User Fee Program commitments. We will also align with the U.S. Department of Health and Human Services Strategic Plan and federal mandates governing IT investments like the Federal Information Technology Acquisition Reform Act (FITARA).

FITARA enhanced the role of federal CIOs to ensure CIOs have oversight of all agency IT resources and programs. FITARA requires agencies to improve governance processes to provide products and services that align with business needs. It also requires the agency to develop and adopt a robust IT strategic planning process. ODT is shepherding an enterprise-wide IT Strategic Plan as part of the Prescription Drug User Fee (PDUFA) VII Reauthorization to be released in Fiscal Year 2023. Through this framework, ODT will utilize collaborative governance and decision-making practices at the FDA Technology Council to work with center stakeholders and focus on their understanding of center IT priorities and strategies.

3. Develop a leadership pipeline that can maintain strategic continuity through leadership and organizational change.

Change is a continual and iterative process much like the product development lifecycle. Our leadership and workforce must be adaptable and ready to shift their focus to align with change. People are the foundation for the success or failure of digital transformation initiatives- and leadership is the great enabler and differentiator. Change leadership is about inspiring vision, action, and enabling the full potential in others.

Our increased focus on people and organizational culture in the context of modernization efforts will foster an environment that attracts and retains top talent. We will also work to cultivate leaders and change agents at every level of the organization. Empowered leaders and employees are a force multiplier- when everyone leads in every moment, the speed of change accelerates. We will start with small pilots to test innovative talent and leadership development strategies. We will continue to invest in ourselves and build a high performing workforce and leadership pipeline to sustain and advance the FDA's modernization journey.

The LMAP in Action

The projects highlighted below represent the first steps toward a coordinated, strategic investment in organizational excellence aligned with our leadership modernization framework. These projects cut across all ODT strategic priorities and will enable ODT to build the internal capacity and resiliency necessary to meet FDA’s toughest challenges now and into the future.

Organizational Design and Culture Change: ODT established a service and team within the Immediate Office focused on fundamentally changing how we work. This function will continuously reimagine and reshape our organizational structure and internal culture. Plans are underway to incrementally shift to a matrixed structure of cross-functional teams to increase ODT agility and performance.
Enterprise Technology Business Management (TBM): ODT is driving agency-wide adoption of the TBM Taxonomy. TBM aligns cost to IT services to improve delivery and efficiency. TBM empowers the CIO and agency leaders to understand and better communicate IT spending to senior executives, mission support offices, and program managers. Expanding TBM knowledge and adoption will improve leadership decision-making and business acumen.

IT Working Capital Fund: The FDA Working Capital Fund (WCF) has funded enterprise IT since its inception in 2019. IT is one of several Enterprise Services financed by the WCF. Other services financed by the WCF include Human Resources, Finance, Procurement, Legal, Freedom of Information Act (FOIA), and Communications. ODT is working to establish a dedicated IT WCF to advance IT Strategic Planning and enterprise TBM implementation. A dedicated fund will help IT leaders manage and reduce costs while better targeting FDA's IT investments.

Blueprint for Good IT: The team established an internal consulting service to advance technology modernization and adopt industry standards. ODT staff partner with Center leaders to develop a common framework of the FDA's best practices, enterprise technology standards, resource management, and technology solutioning. This service creates a new partnership model for higher-value IT services and strengthens the IT ecosystem.

Project Elixir: The team has completed work to develop a new hiring and compensation strategy for ODT. We are shifting 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.

Project UpTech: Project UpTech bridges the gap between FDA's new technology capabilities and FDA employees’ digital literacy skills. This technology upskilling and reskilling initiative improves ODT’s current training offerings to build the technology workforce of the future. In July 2022, ODT announced the release of FDA Academy, an enterprise instance of LinkedIn Learning. Work is underway to expand ODT’s training program to include IT certifications, “smart skills” training, applied learning, and immersive rotations.

Strategic Leaders Program: ODT is launching a Strategic Leaders Program for new and rising leaders that sets a solid foundation for instilling ODT’s core values and building competencies through targeted learning sessions, 360 assessment, coaching, and independent learning activities. The goal is to prepare ODT leaders to be successful in their role and is an essential first initiative as part of ODT’s succession planning leadership strategy. The pilot cohort will focus on the newest senior leaders and will serve as the baseline for expanding our leadership development opportunities.

Summary

ODT is developing the next generation of brave leaders who will contribute to business strategy, offer their technical expertise, and exemplify leadership, communication, engagement, and collaboration principles. These leaders embody ODT’s values of accountability, empowerment, and effective execution. The ‘Future CIO’ is a change agent who translates technology potential into business strategy and weight and demonstrates creativity, empathy, and resiliency. By rethinking the traditional leadership paradigm, we are cultivating an organization that trains government leaders equipped to lead modernization and innovation under a unified, sustainable strategy.

We refer to these leaders as “changemakers,” who understand how to shift roles and focus, upskill themselves and their colleagues, take measured risks, and improve our organizational outcomes. This new elevated, business-oriented role will help guide our agency through increasingly complex regulatory environment mandates as we implement change and modernize our services. Our people-centered and integrated approach will create an organizational environment where budget informs action and change is enduring. Modernization at the FDA is a continuous, long-term journey requiring adept change leaders at all levels. Organizational change and development are also incremental. Investing in leadership as a critical component of technology and business transformation will better prepare us to tackle the Agency’s most complex challenges. The leaders that will drive this work forward must be leaders who can break down barriers and eliminate silos – both structural and behavioral. With the TMAP, DMAP, EMAP, CMAP, and now LMAP, the FDA has a well-grounded framework to drive the modernization that will advance FDA’s public health mission.