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Enterprise Modernization Action Plan (EMAP)

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The FDA's responsibilities to protect the public health are broad, complex, and necessary because the products we regulate are in every American home and used every day. Through the regulation of drugs, devices, human and animal food, cosmetics, and tobacco, the agency currently impacts 20 cents of every dollar spent in the United States.

The continuous technological advances being made in all industries along with the growing global market make these responsibilities increasingly complex in an interconnected environment. As clearly demonstrated during the COVID-19 public health emergency, the FDA plays a critical role in enabling rapid access to safe and effective vaccines and therapeutics and accurate diagnostic testing, monitoring and supporting the supply chains for critical components of these products, and continuing to ensure the safety of our food supply.

As the FDA's responsibilities expand and evolve, to continue to achieve our mission we must become more efficient in the way we work by creating optimized enterprise-wide processes that better support the people of the FDA and their work.

A comprehensive approach to process improvement will support the ongoing foundational technology and data modernization efforts already underway through the Technology Modernization Action Plan (TMAP) and the Data Modernization Action Plan (DMAP).

This Enterprise Modernization Action Plan (EMAP) describes our plans to shape FDA's future by delivering successful 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.

The three components of the EMAP are:

1. Create the infrastructure to support change
2. Develop a common operational approach
3. Ensure strategic alignment

The Case for Change

Historically, the FDA has taken a program or organizational unit-based approach to business process development and IT investments,

resulting in siloed solutions and a fragmented data environment. Similar business processes are developed independently and supported by different IT systems that are not optimally connected.

As a result, communication and shared regulatory activities between FDA organizations are often conducted via email or SharePoint, with stakeholders lacking access to timely, relevant information. Staff are required to engage in time-consuming data reconciliation and manual entry of information into multiple systems as there is no single source of truth system for information used by stakeholders across the agency.

This results in suboptimal access to data, inconsistent data definitions, and many redundant systems. Excessive reliance on custom solutions has resulted in legacy applications that are costly to implement and maintain. FDA organizations have initiated modernization efforts without sufficient coordination, which risks perpetuating this cycle.

To achieve important and needed efficiencies, the FDA is advancing an agency-wide enterprise business process, data, and IT management approach that will allow us to better leverage the vast amount of data that is the foundation of our work.

AGENCY-WIDE APPROACH

The impact of COVID-19 revealed opportunities for optimizing organizational and business processes for regulatory oversight activities. FDA published the [Resiliency Roadmap for FDA Inspectional Oversight](#) in May 2021, which reports on the scope of FDA inspections, alternative tools for oversight, and the substantial impact the COVID-19 pandemic had on these activities. An agency-wide process, data, and systems approach to inspectional activities would improve our ability to efficiently prioritize, conduct, and evaluate these critical oversight activities.

Desired State

The EMAP is the next fundamental installment of the FDA's foundational approach to modernization. We must modernize and optimize our business processes to develop the most effective IT systems and data management.

The EMAP is the backbone of the agency's [Technology Modernization Action Plan](#) (TMAP), launched in September 2019, and [Data Modernization Action Plan](#) (DMAP), released in March 2021; both are in action today. [Modernization in Action 2022](#), the TMAP and DMAP Anniversary Report, was released in March 2022.

The EMAP optimizes processes to support the people at the forefront of these efforts and more effectively achieve our public health mission. These efforts focus on common business problems affecting more than one FDA organization to best use our financial resources, improve operational efficiency, and improve use of our data.

These efforts will enhance decision-making by improving availability of information and knowledge across the FDA. This investment in our mission-driven staff, who are the collective stewards of our data, will enable us to meet increasing demands.

EMAP: Infrastructure, Operations, and Alignment

The three components of the Enterprise Modernization Action Plan are:

1. Create the Infrastructure to Support Change

The first step in the EMAP was the creation of the Enterprise Transformation Operation (ETO). The ETO is a team within the Office of the Commissioner that strategically reviews enterprise-wide challenges and implements optimized business processes.

The primary mission of the ETO is to improve operational efficiency and return on investments by implementing optimized enterprise business processes that solve cross-agency problems.

The ETO is governed by the ETO Steering Committee (SC). The SC is composed of members of the FDA Executive Committee, a governing council composed of the agency's senior leadership to prioritize the most pressing priorities and change opportunities. This reporting structure will ensure leadership support and alignment of ETO activities with FDA strategic planning and priorities.

The ETO is building a team of experienced process improvement personnel, analysts, and project managers to work with FDA organizations, including the Office of Digital Transformation (ODT), to analyze and implement high-priority enterprise business solutions.

2. Develop a Common Operational Approach

The ETO will employ a standardized approach to analyze, recommend, and implement agreed-upon enterprise business programs that solve shared, cross-agency issues by optimizing business processes and use of data across multiple Centers and Offices. This includes defining the problem to be solved, documenting the current state, recommending an optimized future state, and implementing agreed-upon changes.

The ETO maintains an FDA business capability model to provide a common understanding of core capabilities to support process governance, effective IT architecture, and investment management.

To effectively manage and implement these process changes, the ETO will establish project teams consisting of ETO project and program staff and Center/Office subject matter experts. The project teams will work together to optimize process changes and will coordinate with technology and data specialists in ODT to establish a comprehensive, harmonized approach to any required system changes or new implementations. As we work toward establishing a single source of truth for critical regulatory information focused on optimal use of data across FDA, we also work toward a single version of truth where we align on common approaches including definitions, analytics, and reporting.

3. Ensure Strategic Alignment

The third component of the EMAP is to improve alignment between agency-wide strategic objectives and program activities. Steps in this component include aligning on an FDA business capability model; assessing, in collaboration with ODT, FDA's current IT projects and priorities; and working with FDA organizations to prioritize modernization investments based on business needs.

This alignment will help us effectively manage funding to increase return on investment and improve operational and employee effectiveness and efficiency, while saving public dollars. These cost savings will be achieved, in part, through reduced duplication of efforts and increased sharing of resources and existing capabilities.



EMAP in Action

The ETO has been established in the Office of the Commissioner with a core team, standardized approaches are being developed, and several projects and initiatives are underway.

- **FDA Business Capability Model:** The team has completed work with FDA organizations and aligned on an FDA business capability model to provide a framework for current initiatives and future work.
- **Concept of Operations:** The team has developed a description of the model for engagement between the ETO team and Centers/Offices across FDA.
- **Inspections Process Optimization:** Extensive efforts have been initiated across the agency related to the modernization of our inspectional activities, and several ETO projects are designed to advance and coordinate these initiatives.
 - *Business process analysis and optimization:* Work is ongoing to document current inspection-related business processes in the Office of Regulatory Affairs (ORA) and the Centers; to analyze these processes and identify inefficiencies; and to propose business process changes that will streamline, standardize, and optimize the work and data sharing throughout the lifecycle of inspection processes.
 - *Enterprise inspection pilot:* A pilot of an optimized end-to-end workflow solution incorporating structured Inspection Protocols has been initiated to use a common system for workflow, data and information sharing, and reporting, from inspection assignment to regulatory classification. Lessons learned from this pilot will be used to create a “roadmap” for implementation to include all inspectional activities in this new process and data repository.
 - *Aligning on definitions:* To facilitate these efforts and allow for more effective metrics-driven reporting and improvements, the team is working across the agency to develop common definitions used in the inspections process and data dictionaries used in the IT systems to support these processes.

- **Firm Inventory Optimization:** A single, reliable, current, accessible inventory of FDA-regulated firms is essential for inspection work planning and risk-based inspection, oversight activities, sampling, and compliance actions. Current data integrity challenges include inaccurate, incomplete, and missing data and disparate data between systems. Recently, ORA and the Foods Program have undertaken major efforts to improve the existing firm inventory. The work of the ETO builds upon these efforts to optimize the data collection and maintenance of the Foods firm inventory while developing a model that can then be applied to all FDA-regulated products. This project started with human foods, animal foods, and cosmetics and has expanded to all FDA-regulated firms. This project will result in a single, reliable, and maintained dataset for firm inventory data in the Official Establishment Inventory (OEI), enabling efficient oversight activities.
- **FOIA Process Optimization:** With this initiative, the team is undertaking an assessment of agency-wide Freedom of Information Act (FOIA) activities to drive improvements in process and implement a common IT solution for tracking and managing FOIA requests that have increased exponentially during the COVID-19 pandemic.
- **IT Inventory and Business Process Landscape Analysis:** ETO and ODT are working together to assess the current IT inventory and analyze the agency's business process landscape to facilitate strategic planning and optimize FDA's IT portfolio and associated business processes.

Next Steps

Looking ahead, plans for the ETO include increasing staff, establishing an Office of Enterprise Transformation in the Office of the Commissioner, and continuing work across the agency to develop alignment and engagement in these critical activities. The result will be an environment where business process drives efficient IT development and use of data to optimize our critical and ever-expanding regulatory work.

Modernization at the FDA is an ongoing, continuous journey, which necessitates a comprehensive, flexible strategy, supported by a change mindset at all levels of the agency. It requires that we break down barriers and eliminate silos – both structural and behavioral. With the EMAP, TMAP, and DMAP, the FDA has a solid framework to drive the modernization that will improve business outcomes. This comprehensive and integrated approach ensures that we operate as a single agency, with our employees, technology, and budget all optimized to meet our public health mission.