



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

DIGITAL TRANSFORMATION SYMPOSIUM

2023

Hosted by FDA's Office of Digital Transformation

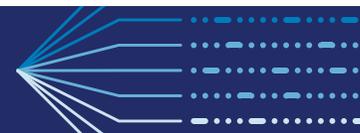




Enterprise Transformation Operation (ETO)

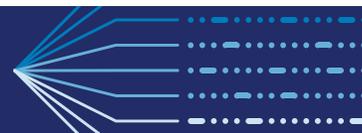
Jim Mulholland, Associate Director, Office of Digital Transformation (ODT)

Meredith Chuk, M.D., Director, Enterprise Transformation Operation (ETO), Office of the Commissioner (OC)



Enterprise Transformation Operation (ETO)

- ✓ ETO Overview
- ✓ Project: FOIA Optimization
- ✓ Project: Inspection Modernization





ETO Overview

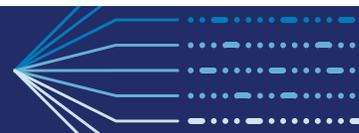
Process Optimization at FDA

Update on Enterprise Transformation

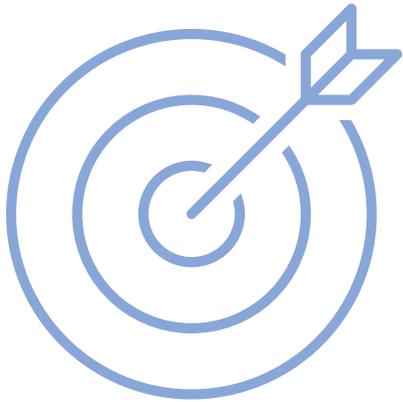


The FDA is advancing an **agency-wide enterprise approach** to business process, data, governance, and IT management improvement.

The **Enterprise Transformation Operation (ETO)**, within the Office of the Commissioner, is charged with implementing optimized business processes across the Agency.

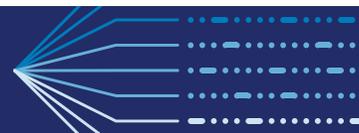


Purpose and Mission



ETO will serve as **cultural change champions** to ensure successful implementation of transformational enterprise projects and programs.

ETO will collaborate across FDA to drive **enterprise change within harmonized common business processes** that address cross-agency challenges and emerging opportunities to improve operational efficiency.





Freedom of Information Act (FOIA) Process Optimization

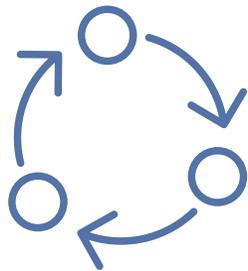
FOIA Process Optimization

ETO is continuing to advance the Agency’s goal of implementing an **efficient, governed, and standardized** Freedom of Information Act (FOIA) **business process** within an **enterprise technology platform**.



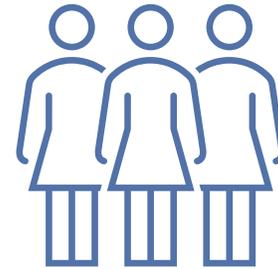
FOIA Optimization Approach

Process



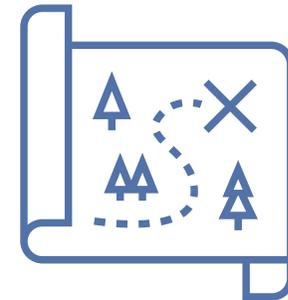
Assess current tools and Center/Office-based processes to co-create a harmonized business process

People



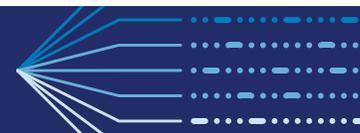
Charter FOIA Council as a decision-making body, with governance over harmonized process and platform

Platform*



Evaluate, select, and implement enterprise platform

*Current activity

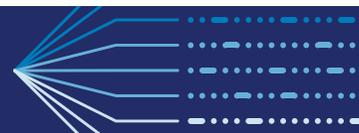




Inspection Modernization

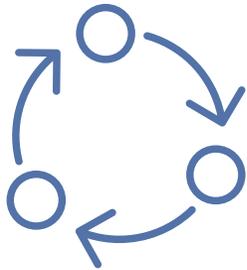
Goals

- Develop an Enterprise Inspection Platform, with the goal of implementing a **single system for end-to-end workflow** and an **enterprise data repository** for all inspectional activities
- Provide a governance structure to enable **key decision-making** and maintain a **coordinated approach** to the work
- **Support FDA staff** in the context of enterprise change



Inspection Modernization Approach

Process



Analyze and document current state and design future state inspection processes

People

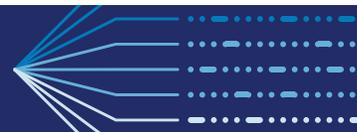


Use change management tools (e.g., communication, training) to support staff; establish effective governance to ensure success

Platform

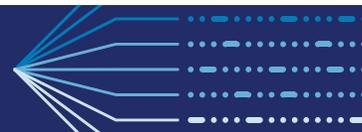


Collect business requirements for and develop the enterprise platform

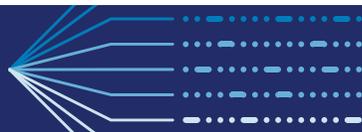
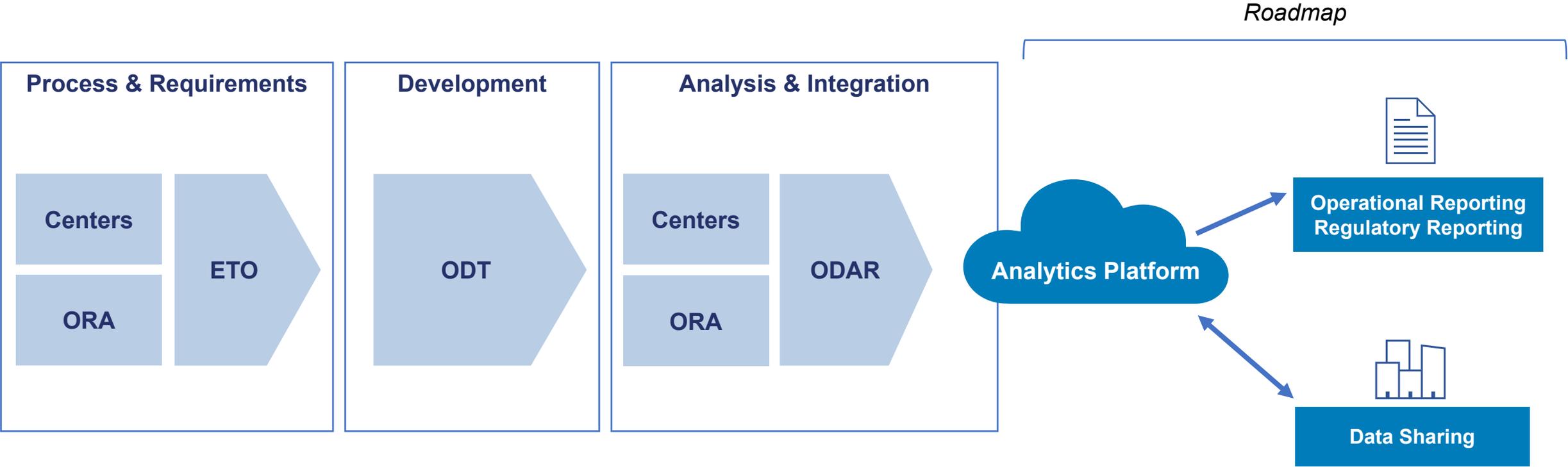


Inspection Modernization Updates

- ✓ Analyzed **current state inspection processes**
- ✓ Documented **challenges** and **opportunities**
- ✓ Developing **future state processes**
- ✓ Collecting **business requirements**
- ✓ Completed initial **proof-of-concept** for platform
- ✓ Expanding **platform development**
- ✓ Establishing **governance framework** to support project expansion



Collaborating on Platform Data





Q&A