FDA's Enterprise Data Modernization

2-Day Private Virtual Meeting
July 20-21, 2021

Overview:
On July 6th 2021, the U.S. Food and Drug Administration reinforced its commitment to modernizing the FDA's data and technology infrastructure [FDA's Budget: Data Modernization and Enhanced Technologies | FDA](), as mentioned in the following announcement:

> *"The U.S. Food and Drug Administration's mission to protect and promote the public health impacts the life of every American, every day. Our work encompasses an ever-widening array of foods, additives, cosmetics, medicines, and medical devices as the FDA regulates approximately 20 cents of every dollar spent annually by American consumers. The industries we regulate are constantly innovating, attracting skilled professionals, and upgrading their technological capabilities. The FDA must keep pace."*

> *"Scientific breakthroughs have enabled the development of new, more personalized therapeutic treatments, advanced manufacturing, and modern data solutions such as blockchain, genomic information, and real-time analytics. As a byproduct of these exciting advancements, the amount and variety of data that the FDA generates, needs, and uses is rapidly increasing. But we are often hampered by antiquated methods…"*

The FDA's Data Modernization Action Plan (DMAP) [Data Modernization Action Plan (fda.gov)](), which launched in March 2021, is a key foundational framework to guide the FDA's data modernization efforts and to help the FDA "keep pace". Fundamental to modernizing data at the FDA is understanding how the Agency can develop new approaches to ingesting, analyzing, maintaining, and interfacing with data that drive regulatory, policy, and operational decision-making across the Agency. As mentioned in the DMAP:

> *"Although FDA's legacy technology and data systems allow the Agency to meet its regulatory responsibilities, FDA urgently needs new, robust, and flexible capabilities to avoid losing future opportunities."*

The DMAP recognizes that change does not happen overnight rather through iterative improvement. The DMAP will be implemented through 3 pillars – Driver Projects, Data Practices and Talent Development.

The FDA's Chief Data Officer team is focused on driving improvement by creating enterprise level solutions to help resolve Center level challenges. The team actively partners with Centers to identify common data issues and to co-create solutions.

Meeting Objective:
The goal of this two-day workshop is to address the data infrastructure needs for two critical FDA driver initiatives: Non-clinical Trial Data, such as real-world data (RWD), and Supply Chain. The focus of the meeting is to identify challenges and opportunities, translate those insights into needs, and recommend potential data solutions. While policy is important and critical to the FDA's success, this is not a policy focused discussion. This is a discussion on the data infrastructure to support these key initiatives. The objective of this meeting is to leverage specific use cases from FDA Centers to identify key challenges ingesting data, addressing supply chain issues affecting public health, and to propose solutions (short and long-term) to improve the FDA's data infrastructure, processes and systems. This includes the full lifecycle of data from identifying, acquiring, ingesting to governance, security, and appropriate use for generating actionable insights.

Day 1 Agenda

2pm – 5:00pm ET

2:00 pm   **Welcome and Overview** *(5 min)*

- **Mark McClellan**, Duke-Robert J. Margolis, MD, Center for Health Policy

2:05 pm   **Overview of the Data Modernization Action Plan and Data Strategy** *(15 min)*

- **Ram Iyer,** U.S. Food and Drug Administration

2:20 pm   **Discussion of the Data Modernization Action Plan and Data Strategy** *(20 min)*
Moderator: Mark McClellan

- **Robert Califf,** Verily Life Sciences
- **Ram Iyer,** U.S. Food and Drug Administration

2:40 pm   **Session 1: How the FDA Utilizes Non-Clinical Trial Data** *(75 min)*
Moderator: Mark McClellan
Objective:
The goal of this session is to leverage use cases to highlight the challenges Centers experience when analyzing and ingesting non-clinical trial data during the regulatory process. The presentations will focus on data issues within the medical space including digital health and oncology. The session will explore specific data challenges when ingesting, processing and interpreting data with a focus on RWD. While the examples may highlight common RWD issues, this is not a standard RWD discussion. The goal is to leverage the use cases to go beyond the traditional RWD conversation to include action-oriented data infrastructure or process solutions.

Presentations (30 min):
- **Opportunities for FDA Infrastructure to Meet Current and Future Regulations**
  - Example: **Current Use of RWD for Market Authorization**
  - Presenter: **Charlie Yongpravat**, U.S. Food and Drug Administration
  - Presenter**: Bakul Patel,** U.S. Food and Drug Administration
- **Real-World Data for Oncology Drug Approvals**
  - Presenter: **Laleh Amiri-Kordestani**, U.S. Food and Drug Administration

Reactant Remarks (25 min):
- **Aloka Chakravarty**, U.S. Food and Drug Administration
- **Cathy Critchlow,** Amgen, Inc.
- **Atul Butte**, University of California San Francisco
- **Vera Mucaj,** Datavant
- **Jennifer Goldsack,** Digital Medicine Society

Open Discussion (20 min)

3:55 pm   **Break** *(10 min)*

4:05 pm   **Session 2: Implementing Solutions to Modernize the Use of Non-clinical Trial Data** *(60 min)*
Moderator: Mark McClellan
Objective: Building on Session 1, this session will discuss opportunities to address the challenges of utilizing non-clinical trial data. Panelists will highlight potential solutions and approaches the Agency can take to modernize the FDA's data infrastructure and data processes. The discussion will focus on opportunities to implement iterative as well as transformational solutions at the enterprise level.

Panel Discussion (25 min):
- **Donna Rivera,** U.S. Food and Drug Administration
- **Laura Roe,** U.S. Food and Drug Administration
- **Jeremy Rassen,** Aetion, Inc.
- **Patrick Ryan,** Observational Health Data Sciences and Informatics
- **William Crown,** Brandeis University

Open Discussion (35 min)

5:05 pm   **Day 1 Closing Remarks and Adjournment** *(5 min)*

Day 2 Agenda

FDA's Enterprise Data Modernization
2-Day Private Virtual Meeting
July 20-21, 2021
2pm – 5:35pm ET

2:00 pm   **Welcome and Overview of Day 1**

- **Mark McClellan**, Duke-Robert J. Margolis, MD, Center for Health Policy

2:10 pm   **Session 3: Using Data to Monitor Supply Chains** *(70 min)*
Moderator: Mark McClellan
Objective: In this session, presenters will highlight use cases to discuss how the Agency's ability to track potential supply chain disruptions, product shortages, and recalls may be improved through data modernization efforts. Three use cases will be presented that explore challenges faced by the FDA related to 1) processing medical product recall data; and 2) tracking medical projects including devices and drugs used during the COVID-19 pandemic. Panelists will discuss data and technical challenges facing current supply chain modernization efforts.

Presentations (30 min):
- **Respirator Supply Chain Challenges During COVID-19**
  - Presenter: **Linda Ricci,** U.S. Food and Drug Administration
- **Leveraging Recall Data to Protect the Public**
  - Presenter: **Pamela Ogonowski**, U.S. Food and Drug Administration
- **Modernizing FDA Drug Supply Chain Data Infrastructure**
  - Presenter: **Grace Chai,** U.S. Food and Drug Administration

Reactant Remarks (20 min):
- **Eugene Reilly,** U.S. Food and Drug Administration
- **Heather Zenk,** AmerisourceBergen
- **Soumi Saha,** Premier Inc.
- **Eva Katcher,** MITRE Corporation

Open Discussion (20 min)

3:20 pm   **Break** *(10 min)*

3:30 pm   **Session 4: Implementing Solutions to Address Challenges in Utilizing Supply Chain Data** *(55 min)*
Moderator: Mark McClellan
Objective: Building on Session 3, panelists will highlight potential iterative and transformational solutions the FDA can implement to advance supply chain data efforts at the Center and enterprise level.

Panel Discussion (20 min):
- **Tammy Beckham,** U.S. Food and Drug Administration
- **Stephen Schondelmeyer**, University of Minnesota
- **Troy Kirchenbauer,** Vizient, Inc.

Open Discussion (35 min)

4:25 pm   **Break** *(10 min)*

4:35 pm   **Session 5: Key Themes and Future Steps** *(55 min)*
Moderator: Mark McClellan
Objective: Panelists will react to the conversations from both days of the workshop and explore short- and long-term next steps for the FDA as a whole. Participants will discuss challenges faced across the FDA and consider potential projects for implementing the DMAP in the context of the discussed use cases.

Panel Discussion (20 min):
- **Vid Desai,** U.S. Food and Drug Administration
- **Mary Ann Slack,** U.S. Food and Drug Administration
- **Eric Perakslis,** Duke University
- **David Shaywitz,** Astounding HealthTech

Open Discussion (30 min)

5:30 pm   **Day 2 Closing Remarks and Adjournment** *(5 min)*

"By modernizing how we use data, we will be in a better position to meet our public health mission because we can't use outdated technology when the rest of the world is moving ahead of us"
Dr. Janet Woodcock – Acting FDA Commissioner