FDA’s Enterprise Data Modernization

July 20-21, 2021
Welcome & Overview | Day 1

Mark McClellan
Duke-Robert J. Margolis, MD, Center for Health Policy
## Meeting Agenda

### Day One
- Overview and Discussion of the Data Modernization Action Plan and Data Strategy
- **Session 1:** How the FDA Utilizes Non-Clinical Trial Data
- **Session 2:** Implementing Solutions to Modernize the Use of Non-Clinical Trial Data

### Day Two
- **Session 3:** Using Data to Monitor Supply Chains
- **Session 4:** Implementing Solutions to Address Challenges in Utilizing Supply Chain Data
- **Session 5:** Key Themes and Future Steps
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- Research & development plans
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- Strategies or plans to award business or remove business from a specific company, to participate or not participate in any particular business opportunity or type of business opportunity
- Status of negotiations with present or potential customers, suppliers, payers or healthcare providers
- Any other confidential business information that could be used to reduce competition
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• While, we’ll begin each session with prepared remarks, we hope that everyone will share their thoughts during each open discussion period.
Overview of the Data Modernization Action Plan and Data Strategy

Ram Iyer
U.S. Food and Drug Administration
Session 1: How the FDA Utilizes Non-Clinical Trial Data

Moderators: Mark McClellan & Rachele Hendricks-Sturrup
Duke-Robert J. Margolis, MD, Center for Health Policy
Charlie Yongpravat and Bakul Patel

U.S. Food and Drug Administration
Panelists

- 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
Discussion

• For each use case, what are the operational challenges facing FDA staff that need to use this data? Are there commonalities between the use cases?
• For each use case, what tools or knowledge does the FDA need to further modernization efforts?
• In developing an Enterprise scale service(s), we need to consider center specific regulations (both current and evolving) in designing the data infrastructure. What strategies should the agency adopt in building and maintaining RWD data infrastructure to meet these objectives?
Session 2: Implementing Solutions to Modernize the Use of Non-clinical Trial Data

Moderator: Mark McClellan
Duke-Robert J. Margolis, MD, Center for Health Policy
Panelists

• 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
Discussion

Focus Area 1: Using Non-clinical Trial Data

• Where can implementation of data standards improve FDA processes?
• Given that the FDA deals with a broad range of data types, what cross-center interoperability standards are needed to improve the agency’s capacity for surveillance and other public health data needs?
• In what areas, if any, does the FDA need direct access to large quantities of RWD or other non-clinical trial data?
• What database tools does the agency need to efficiently handle large influxes of data?
• What skillsets does the FDA need to develop to fully implement a modern infrastructure? How can the Agency be strategic in its strategic organization and talent acquisition?
Discussion

Focus Area 2: Data Quality

• What kind of information does FDA need to understand data lineage? Does FDA have the capability to ingest this type of metadata efficiently? What internal mechanisms does the FDA need to assess the reliability of submitted data?
• What kind of systems can FDA set up to ensure that reliability assessments are consistent across centers?
• What kind of processes can FDA setup to acknowledge and adapt for data collection algorithms that may change over time?

Focus Area 3: Projects

• What type of projects or initiatives would be well positioned to address the considerations discussed?
Day 1 Adjournment
FDA’s Enterprise Data Modernization

July 20-21, 2021
Welcome & Overview | Day 2

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Day 1 Overview

• Proper implementation of automated procedures may augment the capabilities of FDA, streamline repetitive and common tasks, and standardize certain assessments.
• Templates for common data elements will support the cataloging of data and ability to share key data characteristics.
• New infrastructure must be capable of handling a variety of data types, not just data from EHRs and claims.
• How can FDA design its infrastructure to address specific data use and processing needs? For example, how do the infrastructure needs vary for validating or extending submitted data vs. direct analysis of the data for real-time FDA surveillance
• How do we scale efforts to the enterprise level?
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## Day Two
- **Session 3:** Using Data to Monitor Supply Chains
- **Session 4:** Implementing Solutions to Address Challenges in Utilizing Supply Chain Data
- **Session 5:** Key Themes and Future Steps
Session 3: Using Data to Monitor Supply Chains

Moderators: Mark McClellan & Rachele Hendricks-Sturrup
Duke-Robert J. Margolis, MD, Center for Health Policy
Pamela Ogonowski
U.S. Food and Drug Administration
Grace Chai
U.S. Food and Drug Administration
Panelists

- **Eugene Reilly**, U.S. Food and Drug Administration
- **Heather Zenk**, AmerisourceBergen
- **Soumi Saha**, Premier Inc.
- **Eva Katcher**, MITRE Corporation
Discussion

• What is the breadth of use cases where FDA uses or could use supply chain information?
• How important is real-time access to high-quality data for the FDA?
• To what extent does the FDA face issues of access to sufficient data on supply chains or recalled products?
• What data or data tools does the FDA need to manage risks to medical product supply chains?
• Does the FDA need access to large quantities of raw data for supply chain surveillance?
• Are there ensemble methods that the agency can use instead of running models from raw data?
Session 4: Implementing Solutions to Address Challenges in Utilizing Supply Chain Data

Moderator: Mark McClellan
Duke-Robert J. Margolis, MD, Center for Health Policy
Panelists

- Tammy Beckham, U.S. Food and Drug Administration
- Stephen Schondelmeyer, University of Minnesota
- Troy Kirchenbauer, Vizient, Inc.
Discussion

**Focus Area 1: Using Supply Chain Data**

- Where can implementation of data standards improve FDA supply chain processes?
- Given that the FDA deals with a broad range of data types, what cross-center interoperability standards are needed to improve the agency’s capacity for supply chain surveillance and related data needs?
- What tools does the FDA need to develop to fully implement a modernized infrastructure for the discussed use cases (ex. AI or cloud-based solutions)?
- What skillsets does the FDA need to develop to fully implement a modern supply chain data infrastructure?
- What database tools does the agency need to efficiently handle an influx of real-time supply chain data?
Discussion

Focus Area 2: Data Quality

• How best can the FDA access high-quality, real-time supply chain data?
• What kind of information does FDA need to understand data lineage? Does FDA have the capability to ingest this type of metadata efficiently? What internal mechanisms does the FDA need to assess the reliability of submitted data?

Focus Area 3: Projects

• What type of projects or initiatives would be well positioned to address the considerations discussed?
Session 5: Key Themes and Next Steps

Moderator: Mark McClellan, Duke-Robert J. Margolis, MD, Center for Health Policy
Panelists

• 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
Discussion

• Are there other use cases that could be helpful to think about as the FDA works on updating the Agency’s data infrastructure?
• How can the challenges raised in this workshop be addressed during the implementation process?
• Based on the discussions at this workshop, what broad capabilities, tools, and skillsets does the FDA need to implement a modern data infrastructure?
• How can the FDA best align cross-Agency to ensure the strategy outlined in the DMAP benefits all centers? What steps can be taken to enable the FDA to efficiently answer questions that rely on data from multiple centers?
• How can we deliver incremental value while building a complex data infrastructure to address these and other driver projects and use cases?
• What type of driver projects would be well positioned to address the considerations discussed?
Closing Remarks & Meeting Adjournment

Moderator: Mark McClellan

Duke-Robert J. Margolis, MD, Center for Health Policy
Thank You!

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