CDER's IT Modernization Journey

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Learning Objectives

After this session, you should be able to

- List challenges that drive FDA's and CDER's modernization
- Understand the guiding principles for CDER's IT/Informatics modernization
- Identify key CDER initiatives and their primary roles in the IT/Informatics landscape

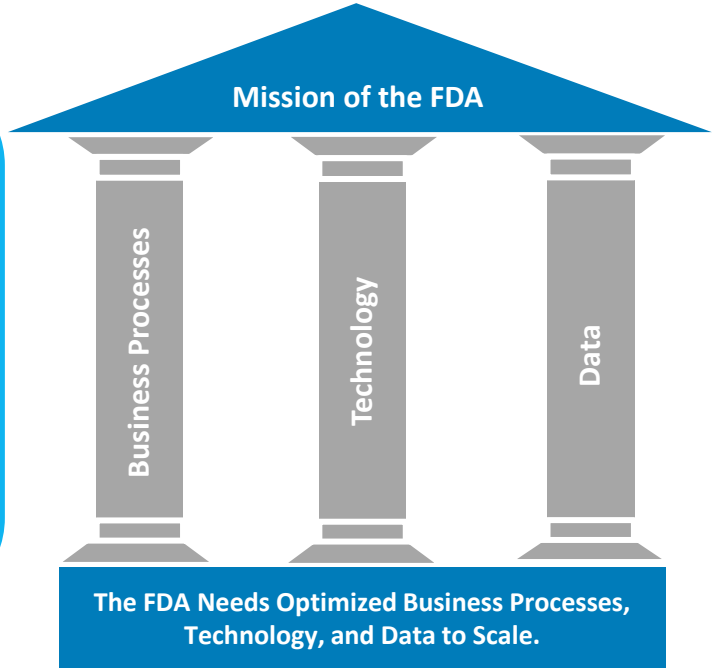
So What's Going On?

Landscape Forces At Play

FDA-regulated products account for **~20 cents of every dollar** spent by U.S. consumers ($2.8 Trillion).

The FDA Expects an Exponential Increase in Workload

- Regulates **78%** of U.S. Food Supply
- Approved **20,000+** Prescription Drugs
- Regulates **$2.5T** Imports and **$1.6T** Exports
- Oversees **270,000** Registered Facilities



The Science is Changing

From Chemistry to Genetics

From PDFs to Large Genetic and DNA Sequencing Data Sets

Personalized Care & Treatments

Regulations are Changing

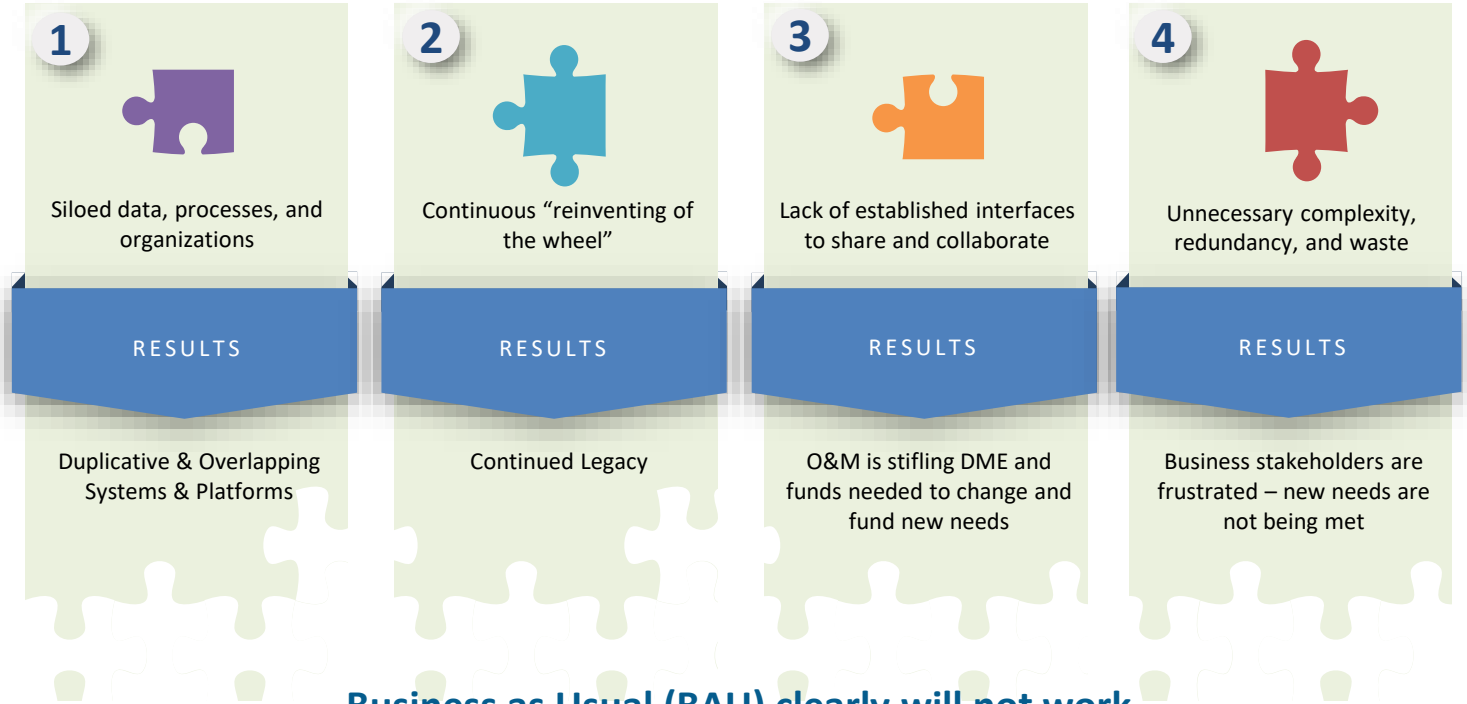
21st Century Cures Legislation

Real World Data / Evidence

Technology is Changing

Cybersecurity, Cloud, Big Data, Internet of Things (IoT), Artificial Intelligence

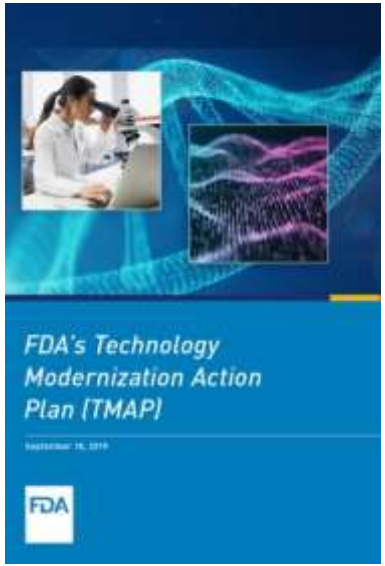
The “Old Way”



Business as Usual (BAU) clearly will not work

FDA's Modernization Framework

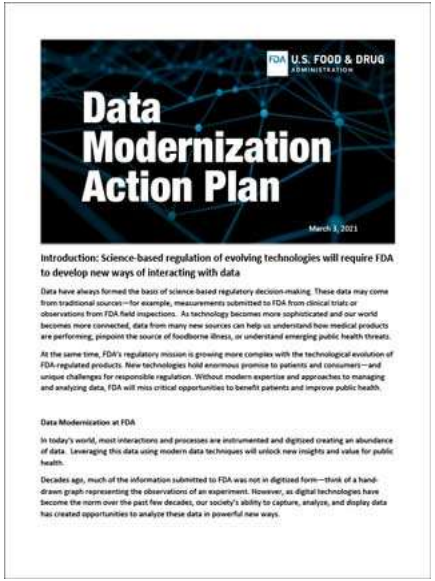
- Technology Modernization Action Plan (TMAP)



Released in September 2019, TMAP's three focus areas include:

- Modernizing the FDA's technical infrastructure and operations
- Enhancing the FDA's capabilities to develop technology products
- Communication and collaboration with external stakeholders

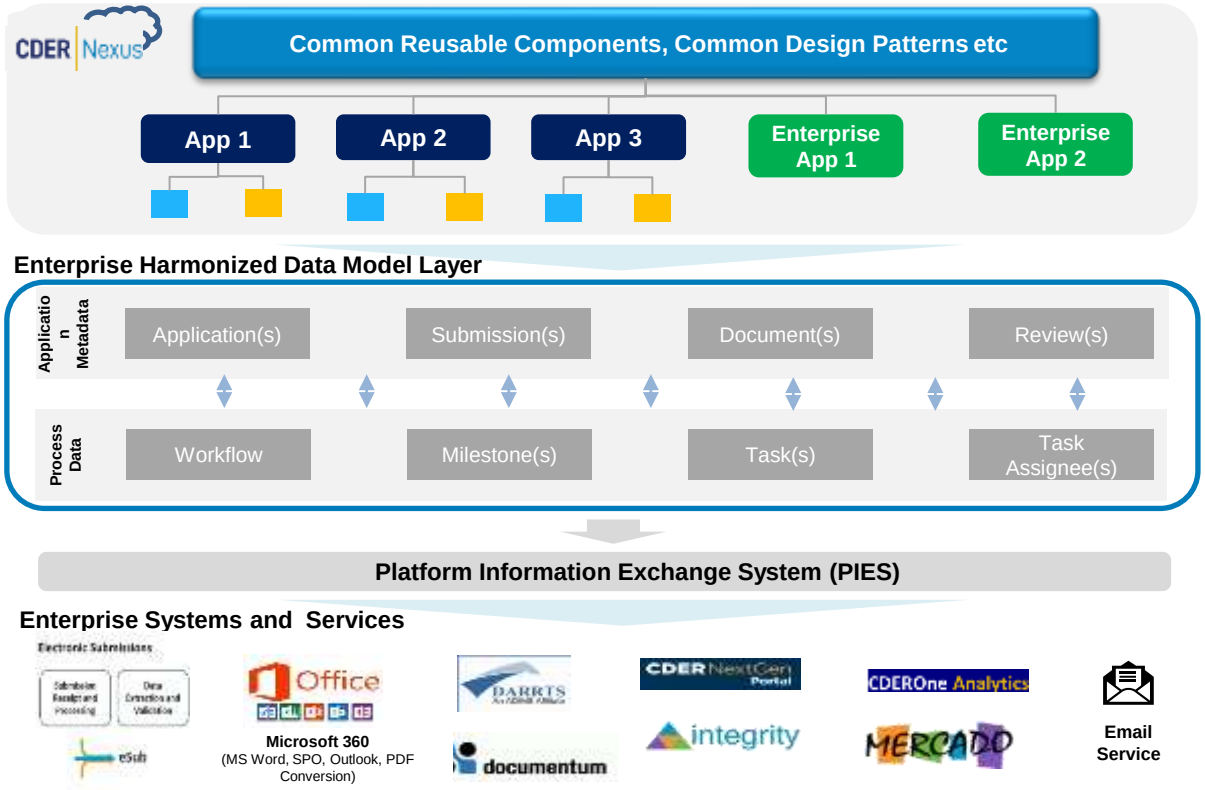
- Data Modernization Action Plan (DMAP)



Released in March 2021, DMAP's three focus areas include:

- Identifying and executing high-value driver projects Developing consistent and repeatable data practices
- Creating and sustaining a strong talent network

CDER's Future State Architecture



Key Features

- ✓ Reusable Common Components & Design Patterns
- ✓ Enterprise Solutions for Common Process
- ✓ Harmonized Data model
- ✓ Scalable Architecture
- ✓ Development Acceleration
- ✓ Unified Business Process
- ✓ Consistent User Experience

CDER's IT Guiding Principles

Cross-office collaboration to ensure solutions are useful and interoperable

Transparency around full life-cycle cost and organizational impact to enable CDER to prioritize work and leverage integrated roadmaps

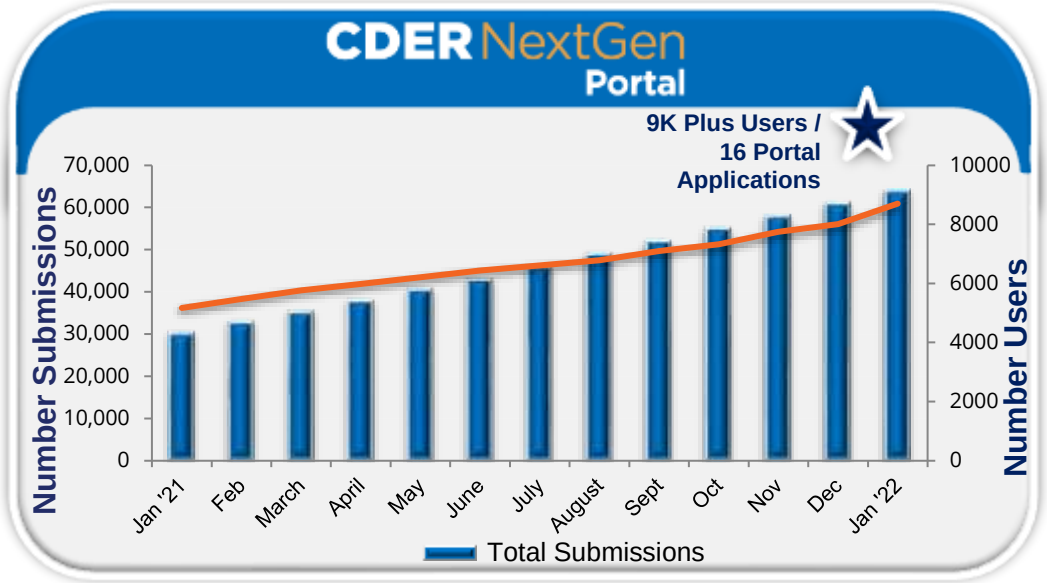
Clear, repeatable business processes to increase usability and decrease complexity for staff

Scalable enterprise solutions aligned to center priorities and corresponding reduction of legacy and office specific solutions

Minimal duplication of tools and capabilities to free up resource demand and complexity for users and technical staff

Data Intake: NextGen Portal

*An **industry facing submission portal** to report information to the FDA.*
The Portal provides an improved and efficient mechanism for industry to send submissions and communicate with the FDA.

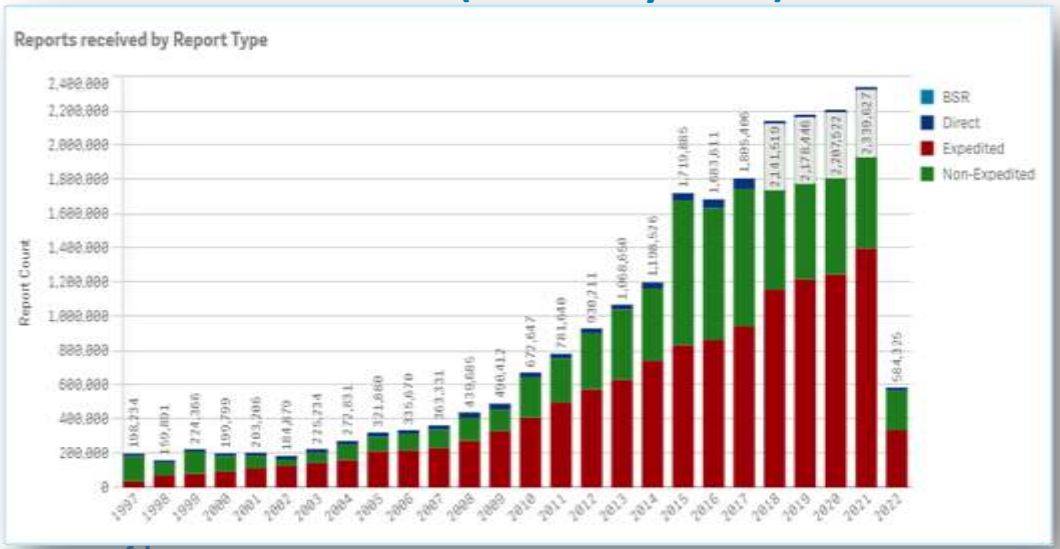


- Provides a streamlined solution for Industry stakeholders to submit certain information to FDA CDER and receive correspondences.
- Enables formerly manual data entry to occur automatically.
- Triggers automated workflows in CDER's workflow management system.

Information Management: FAERS II

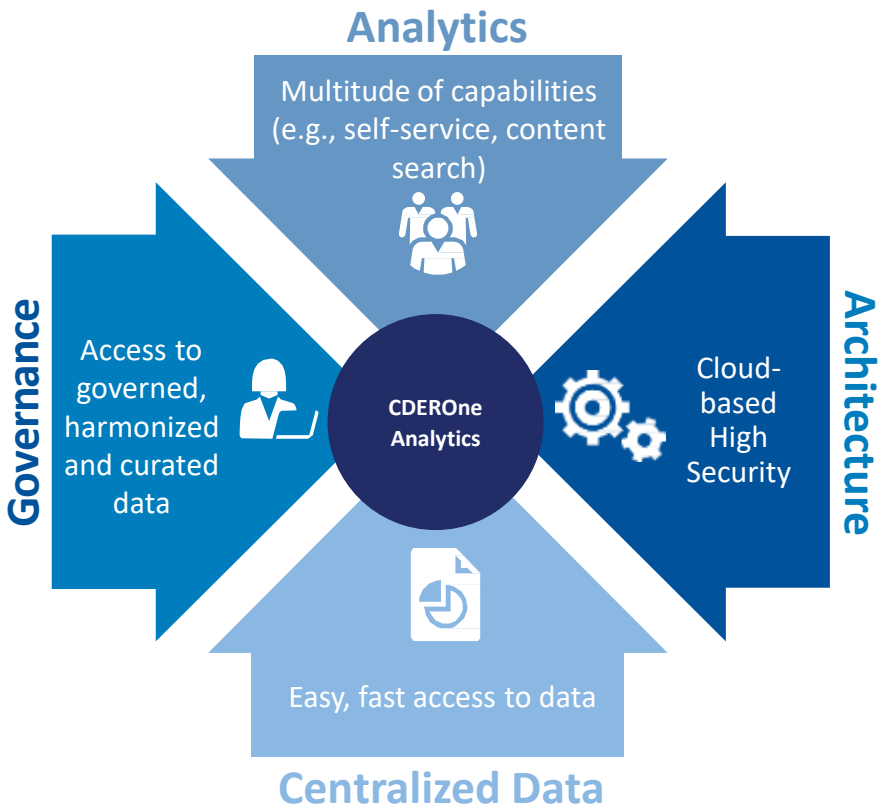
The FAERS II system includes more than 20 million adverse event reports. More than two million reports are submitted every year.

FAERS Publicly-Available Report Information (as of May 2022)



- FAERS II is FDA's next generation adverse event (AE) reporting system
- CDER uses FAERS II to capture and monitor AEs and other safety data to identify safety concerns that may require further investigation

Information Management: CDEROne Analytics



CDEROne provides "one-stop shop" access to multiple internal and external Data Sources and Analytical Capabilities

- FISMA High cloud platform
- Tailored solutions
- Self-Service capabilities
- Advanced analytics

Workflow Management: CDER Nexus

Description: *CDER Nexus, powered by Appian, is the enterprise workflow management solution that enables work processes, reduces redundancies, and enhances connections across stakeholders.*

CDER | Nexus

3,458 users (reviewers, RPMs, leadership)
35 applications in production
16 enhancements and O&M requests
8 new deployments in 2022
20 in development for 2022

2021/2022 Major Deployments:

- KASA
- PLAIR
- REMS
- Orange Book
- Labeling Review Tool

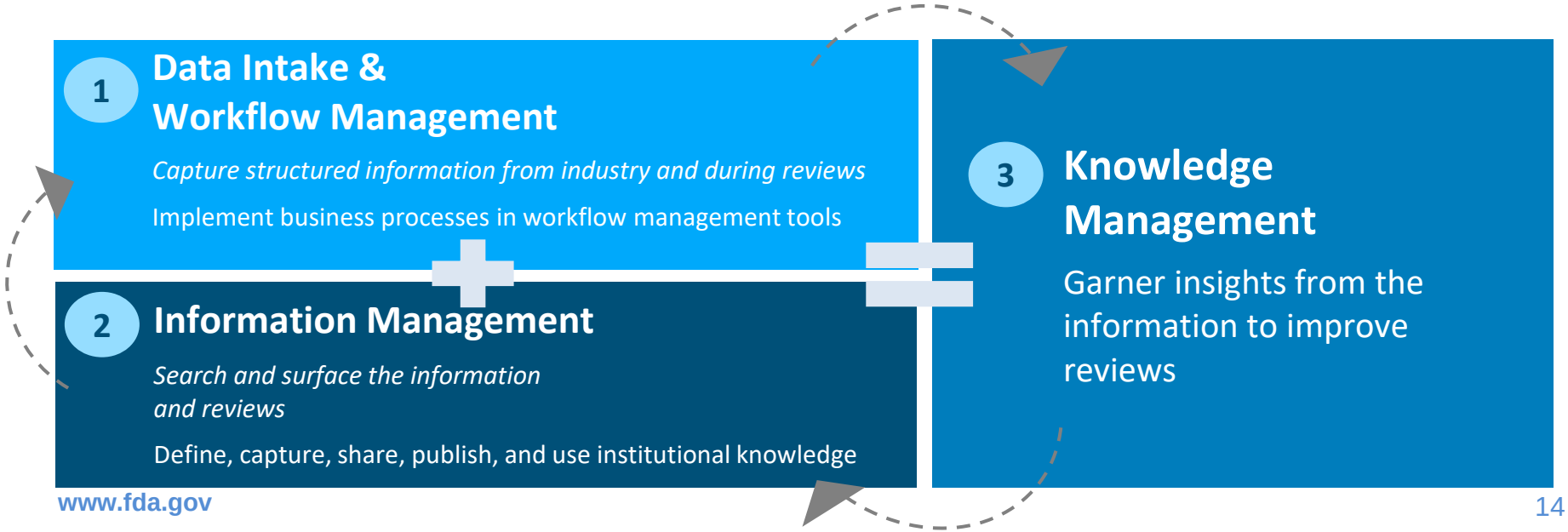
Workflow Management: KASA

The **Knowledge Aided Assessment and Structured Application** modernizes CDER's quality assessment of regulatory drug applications by capturing information about inherent risk and control approaches for product design, manufacturing, and facilities in a structured format, enabling computer-aided analyses of regulatory standards and quality risk across drug products and facilities.

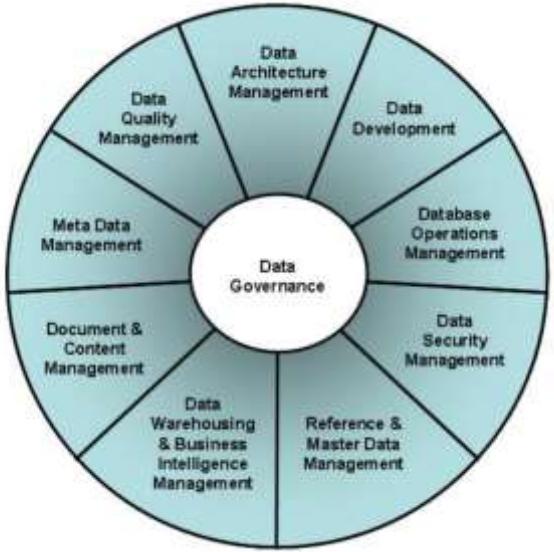
- Enables knowledge sharing and transparency across reviews
- Increased efficiency and consistency across reviews through structured design and data integrations with source systems
- Increased effectiveness in the identification of impurity risks through improved pathway capture and visualization

Knowledge Management Program

CDER's Knowledge Management (KM) program *addresses an enterprise need for improved governance, information sharing, and knowledge management systems. This enables CDER to* ***capture, organize, develop, share, and effectively use institutional knowledge to achieve Center objectives.***



CDER Enterprise Data Governance Overview



Key Components of Data Governance

- Defines Roles and Responsibilities
- Establishes Activities
- Supports Process

Enterprise Data Governance Program Goals

Streamline Operating Model

Enable Data Context, Quality and Trust

Treat data as an organizational asset

What Else is Coming?

PDUFA VII - Digital Health and Informatics

Digital Health Technologies (DHT)

- Establishes a DHT framework to guide the use of DHT-derived data in regulatory decision-making, and a newly established committee to support implementation.

- Focused efforts to expand capacity and enhance consistency in this area, including a series of public meetings, issue-focused demonstration projects, and new or updated guidances.

PDUFA VII - Digital Health and Informatics

Data/IT Modernization

- Activities to further enhance transparency of FDA IT activities and modernization plans, regular meetings between FDA and industry IT leadership, maintaining catalogs, standards, and plan updates published to the website.
- Establishes a Data and Technology Modernization Strategy that reflects the FDA's Technology and Data Modernization Action Plan.
- Transitions Electronic Submission Gateway (ESG) to a modernized, cloud-based ESG and IDAM.

PDUFA VII - Digital Health and Informatics

Data/IT Modernization

- Accelerates CBER's data and technology modernization to facilitate an efficient review process.
- Explores how cloud and cloud-based technologies could promote innovation in the drug development and regulatory review process through demonstration projects.
- Supports additional expertise, staff capacity, and IT resources to manage the substantial increase in the volume and diversity of bioinformatics and computation biology information and data in regulatory submissions.

Challenge Time

Challenge Question #1

Why is the CDEROne initiative so important to CDER?

A. It holds important data that isn't available anywhere else

B. It's a cloud-based platform

C. It reduces the need for many copies of the same data

D. It sounds cool

Challenge Question #2

Which of the following is NOT one of CDER's IT guiding principles?

A. Minimal duplication of tools and capabilities to free up resource demand and complexity

B. Transparency around full life-cycle cost and organizational impact

C. Clear, repeatable business processes

D. Cloud implementation wherever possible

Summary

- FDA and CDER are on a modernization journey that enables us to be more agile, transparent, efficient and effective in meeting the increasingly more sophisticated and evolving needs of our community.
- We've made enormous progress, with much more to come. The journey is underway.

U.S. FOOD & DRUG ADMINISTRATION

Thank You!

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