How to Handle Increasing Volume of Data Coming into the FDA? Turn up the Automation & Continuously Improve Processes

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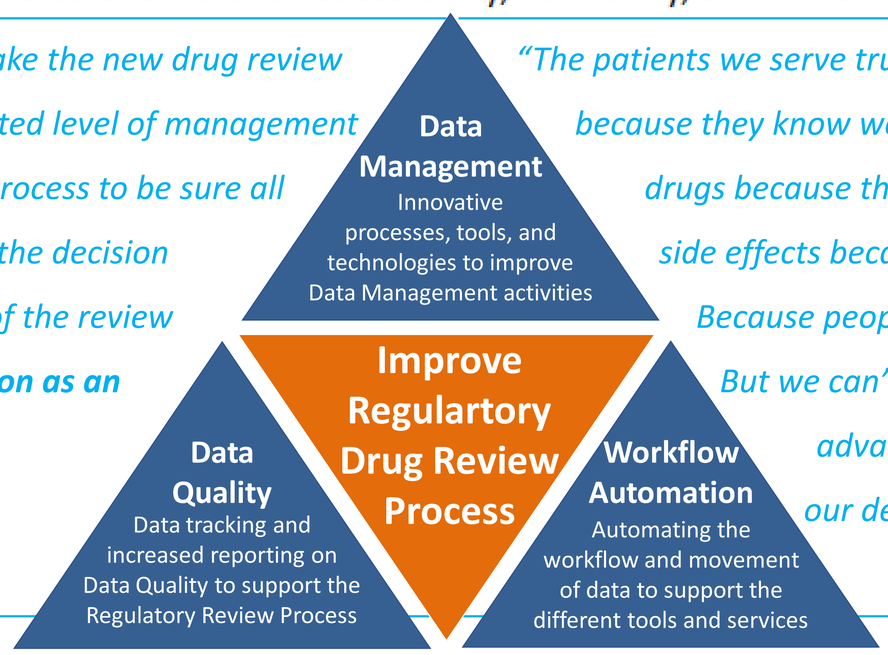
The **OCS Data Management** activities support all OCS tools and services to conduct safety assessments. Functions include validating and processing required data to ensure the accessibility, reliability, and timeliness of the study data for reviewers.

*"The goal of the 21st Century Review is to make the new drug review process more organized, with a more integrated level of management that allows sufficient time at the end of the process to be sure all concerns have been heard and addressed by the decision makers. To help achieve this goal, members of the review team should plan to **begin their review as soon as an application comes in the door**."*

Janet Woodcock, M.D.
Director, Center for Drug Evaluation and Research (CDER)



*"The patients we serve trust us to do our job. They enroll in clinical trials because they know we are watching over them. They take approved drugs because they know they meet our standards. They report side effects because they know we will seriously explore them. Because people trust us, we're asked to do more and more. But we can't just work harder to keep up. To maintain and advance our global leadership – and better support our deeply committed staff – **we need to modernize the New Drug Regulatory Program**."*

Janet Woodcock, M.D.
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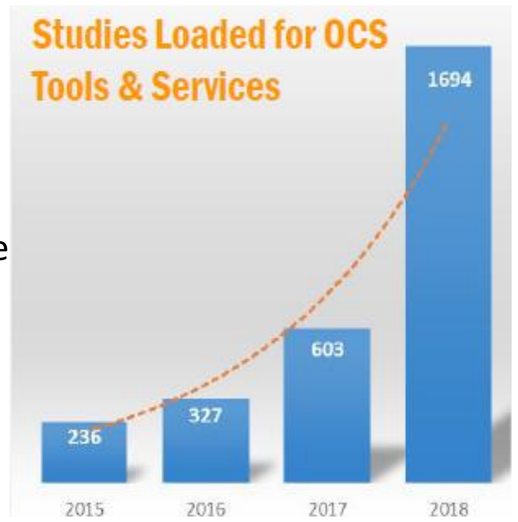
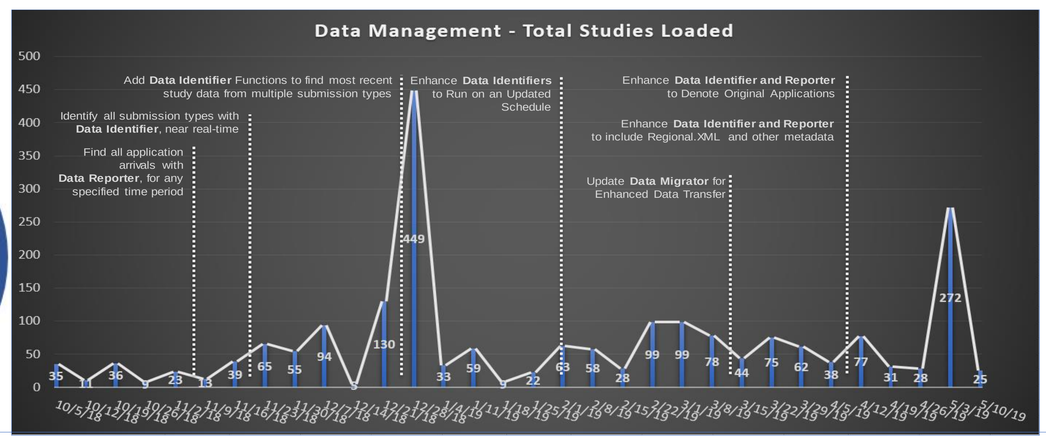
Key Accomplishments for 2018

- Instated **Agile** using JIRA to guide development of tools and documentation deliverables (**DocOps**)
- Conducted a **Current State assessment** and developed a **Data Management & Data Quality Strategy**
- Developed **Workflow Automation and Data Management Tools** for increased data processing efficiency
  - **SEND IND Identifier** locates INDs with SEND within 1 hour of arrival to EDR to support Kickstart service
  - **Data Identifiers** locates all new/updated data in EDR over the past 24 hours (INDs, NDAs, BLAs)
  - **Data Locator** opens most recent dataset files in EDR instantly based on user search inputs
  - **Data Migrator** copies data of any size from EDR to any location in seconds
  - **Data Reporter** finds all new/original submissions within a date range to support Core DataFit service
  - **Data Notifier** searches for known incoming applications by expected receipt date range



What We Are Doing in 2019

- Develop the **OCS Data Central System** to include Workflow Automation and an OCS Data Central Repository
- Develop **Data Quality Reporting System** using SAP.HANA to ingest data from multiple sources and generate reports using Business Objects
- Stand up a **Data Governance Framework and Committee** to develop data-related policies and procedures across OCS
- Turning up the automation and continuously improving **Data Management Processes** to handle the increasing volume of data coming into the FDA!