Data Central

Accelerating CDER's regulatory review process by providing quality study data at the right time, in the right place, in the right format

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Introduction

The regulatory review process is a critical component of ensuring the safety and efficacy of medical products. However, data wrangling and inefficient data access can hinder the analysis and decision-making capabilities of regulatory reviewers. Data Central aims to address these challenges by providing quality study data at the right time, in the right place, and in the right format, enabling data consumers to focus on analysis rather than data wrangling.

Methods

Data Central deems to improve access to quality to data by developing offerings for existing tools and services, as well as future integrations, to improve touch points throughout the reviewer process:

Data Selection
Automatic, nightly scan of EDR to identify new, incoming submissions

Validations
Runs folder and file-level validation checks on submissions

Conversions
Enables automatic format conversions from .xpt into .sas7bdat, csv, and .rds

Automated Connections
Provides automated, seamless connection to downstream tools, services, and Quality Assessments through API

Metadata Reporting
Features metadata-powered reporting and filtering on submissions and study data

Notifications
Email notification with links to file locations

Leveraging a Hybrid Cloud environment, Data Central has been developed using Microservices Architecture and follows Agile Methodology to ensure flexibility and adaptability to evolving business needs.

Results

Data Central Supported Systems & Services

Systems
Analysis Studio
CDEROne Analytics
DataFit
IND Smart Template
Janus Nonclinical
JMP Clinical
Line Listing Tool
MAED
OCP iPortal
RAPID
SARGE
SEND Explorer
Site Selection Tool Clinical Investigator (SST-CI)
Study Data Platform

Services
CoreDF
OCS Clinical Service
OCS Nonclinical Services

Figure 1. *Established integrations for source data and onboarded downstream systems.*

Applications Acquired by Data Central from 08-08-2020 to 07-07-2023

Application Type	ADaM	SEND	SDTM	BIMO
BLA	2864	283	1096	251
NDA	7271	1575	3558	425
ANDA	4773	139	3198	0
IND	1467	12703	1032	1
EUA	58	11	34	6
Total	**16433**	**14711**	**8918**	**683**

Figure 2. *Number of Applications Acquired by Data Central from 08-08-2020 to 07-07-2023*

Applications Acquired by Data Central from 08-08-2020 to 07-07-2023

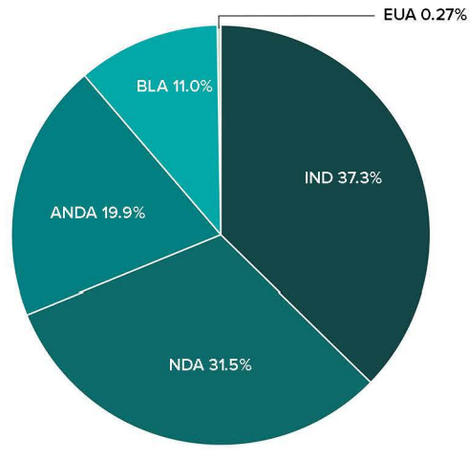

Figure 3. *Percentage of Studies Acquired by Application Type from 08-08-2020 to 07-07-2023.*

Findings

Since its implementation in 2020, Data Central has made significant progress in expanding its automation capabilities, validation services, and metadata offerings.

This includes the integration of additional Application Programming Interfaces (APIs) (6+) and increased connectivity to downstream systems and service teams (16+) ***(Figure 1)*** to support regulatory review.

Notably, Data Central now offers enhanced clinical data checks, further ensuring the reliability and accuracy of the study data.

Data Central's process to identify and acquire application studies has provided the Office of Computational Sciences visibility to the sheer number of application data that is disseminated to projects and tools ***(Figure 2, Figure 3)***.

Conclusion

Data Central has proven to be a quick, innovative, and adaptive solution in the Center for Drug Evaluation and Research (CDER). By seamlessly acquiring, processing, and delivering reviewer-ready study data from the FDA's Electronic Data Repository (EDR) to downstream systems and services, Data Central provides efficient and easy access to clean, usable data.

This automated approach significantly streamlines the regulatory review process, enabling regulatory reviewers to focus on critical data analysis tasks. Data Central's impact on accelerating CDER's regulatory review process is invaluable, facilitating better-informed decision-making and ultimately benefiting public health.