

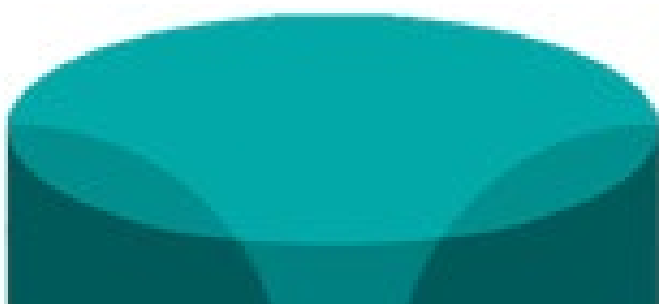
Data Central: Accelerating CDER's Regulatory Review Process with Quality Study Data at the Right Time, in the Right Place, in the Right Format

FDA CDER OTS Office of Computational Science

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PP24



All the Data you Want.
In One Place. Centralized.



Summary

Quick, innovative, and adaptive; Data Central is an automated solution used in CDER to acquire, process, and deliver reviewer-ready study data from FDA's Electronic Data Repository (EDR) to downstream systems and services, providing easy and efficient access to clean, usable study data.

Data Central accelerates CDER's regulatory review process by providing quality study data at the right time, in the right place, in the right format – empowering data consumers to focus on data analysis, not data wrangling.

Data Central At-A-Glance:

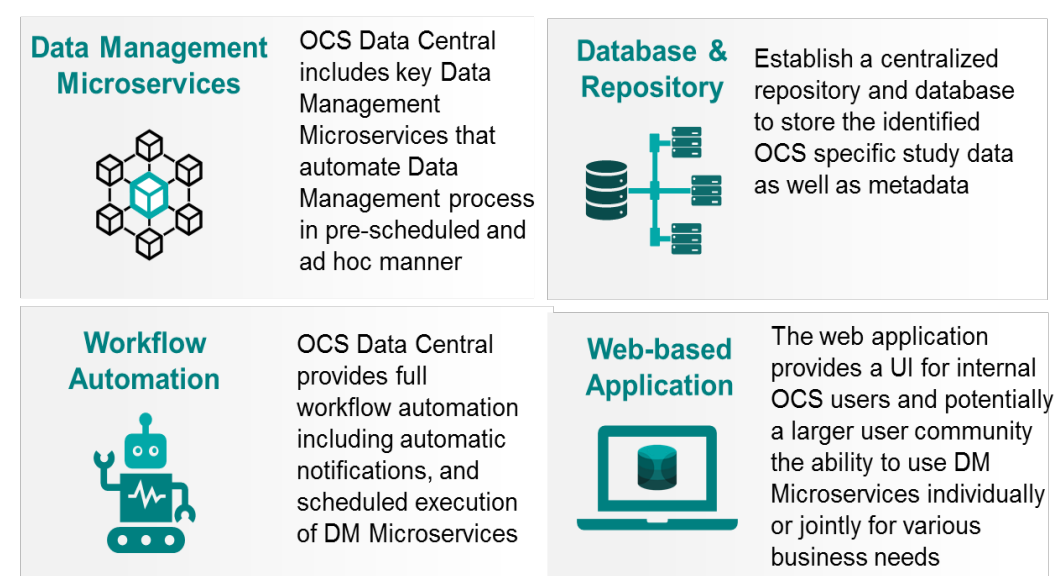
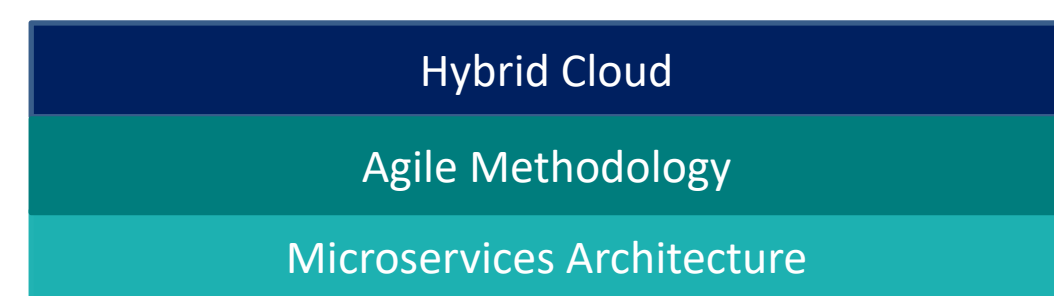
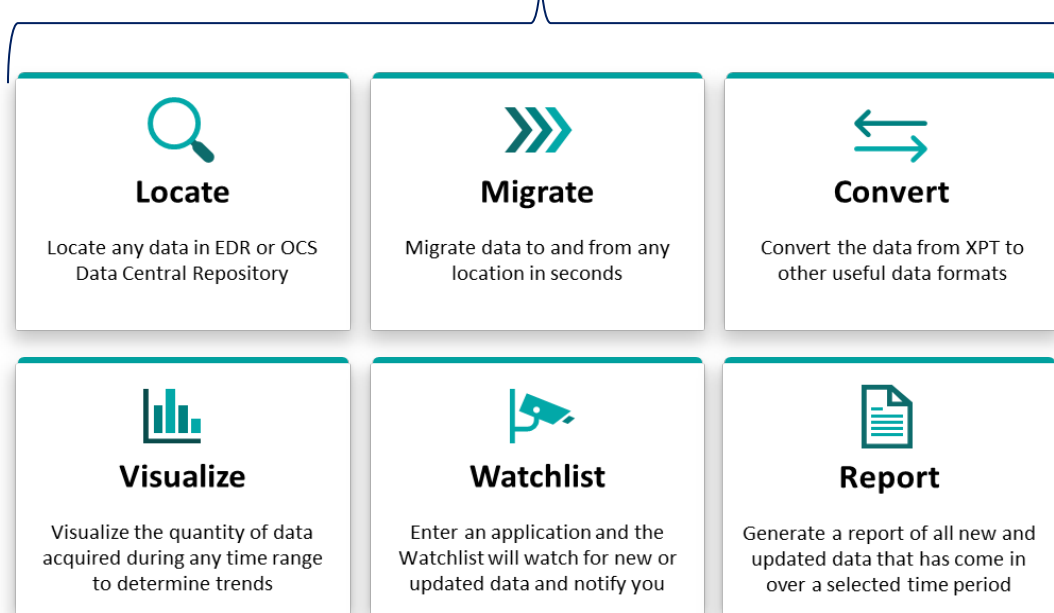
 Application Types INDs, NDAs, ANDAs, BLAs and ELiAs	 Modules M1, M2, M4, and M5	 Study Data Standards SDTM, ADaM, SEND, ISS, and BIMO
 Documents Types SDRGs, CSRs, NRS, ACRFs, Cover Letters, Labeling, etc.	 Domain Types All Domains/XPTs	 Converted File Formats .sas7bdat, .rds, and .csv
 Notifications Automated email notifications as study data is found in EDR	 Runtimes Daily at 12 AM, 1 AM, 2 AM, 3 AM, and 3 PM	 Submission Sequences All Sequences (since Go-Live in Sep 2020)
 Folder Structure Application ID, Sequence, Module, Study ID, Data Standard, File Type (e.g., Dataset, Labeling, Cover Letter, CSR, etc.)	Folder Structure Examples NDA123456_0004_m5_3256782_SDTM_DA NDA654321_0098_m5_bimo_BIMO_DA IND60267_0636_m4_h34523581_NR	

Technology & Design

Data Central is comprised of 4 key components:

1. Data Management & Data Quality Microservices
2. Workflow Automation
3. Data Repository & Database
4. Web-based Application

Built on a Hybrid Cloud environment, developed using Microservices Architecture and following Agile Methodology, Data Central is designed to be flexible and adaptive to business needs.

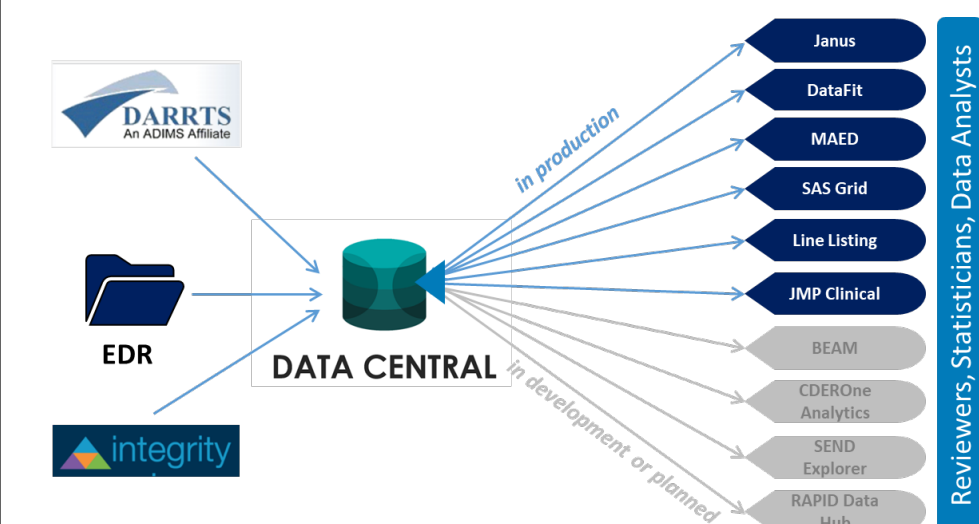


Recent Accomplishments

Since Go-Live in the fall of 2020, Data Central has expanded its automated connections, metadata offerings, and validation services.

1. Automated Connections

In FY2022, Data Central established new API connections with Janus, MAED, and DataFit while additional connections are currently underway.



2. Metadata Offerings

Data Central now generates daily metadata reports for CoreDF, OCS Nonclinical Services and the Site Selection teams that, for the first time, integrate metadata from EDR and DARRTS.

1	2	3	4	5	6	7	8
ORGANIZATION NAME	ORGANIZATION ACRONYM	SUBMISSION TYPE	SUBMISSION SUBTYPE	ORIGINAL	EFFICACY SUPPLEMENT	INITIAL SUBMIT	
Division of Oncology 1	CDER/ONC/ODD/DO1	Original Application	Application	Y	N	Y	
Division of Oncology 1	CDER/ONC/ODD/DO1	Original Application	Application	Y	N	Y	
Division of Oncology 1	CDER/ONC/ODD/DO1	Original Application	Application	Y	N	Y	
Division of Oncology 1	CDER/ONC/ODD/DO1	Original Application	Application	Y	N	Y	
Division of Oncology 1	CDER/ONC/ODD/DO1	Original Application	Application	Y	N	Y	
Division of Oncology 1	CDER/ONC/ODD/DO1	Original Application	Application	Y	N	Y	
Division of Oncology 1	CDER/ONC/ODD/DO1	Original Application	Application	Y	N	Y	

3. Validation Services (e.g., “Clinical Data Checks”)

Data Central now features clinical data checks performed on behalf of the OCS Clinical Services team.

Benefits to FDA's Center for Drug Evaluation and Research (CDER)

With its increasing number of automated system connections, Data Central's repository of quality study data is available to ever more users across CDER. Through its metadata offerings, Data Central enriches the analytical view of each incoming submission. By adding Clinical Data Checks, Data Central establishes a framework for additional validation services, and more importantly reliable study data. For more information about Data Central, please contact: OCSDataManagement@fda.hhs.gov