

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

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PP05



Data Central

All The Study Data
You Want. In One
Place. Centralized.

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 & efficient access to clean, usable study data**.

Application Types
INDs, NDAs, ANDAs, BLAs and EUAs

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
BLA123456_0004_m5_864248_SDtm_DA
NDA654321_0098_m5_bimo_BIMO_DA
IND102468_0531_m4_gH5432123_NR

Data Central provides 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.

Technology and Design

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.

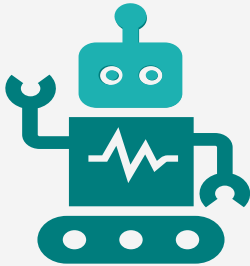
Data Management & Quality Microservices



Database & Repository



Workflow Automation



Web-based Application



Hybrid Cloud

Agile Methodology

Microservices Architecture

Adoption Through Collaboration

Since inception, Data Central has continued to experience increased adoption of its study data offerings across systems and services within CDER.

Systems

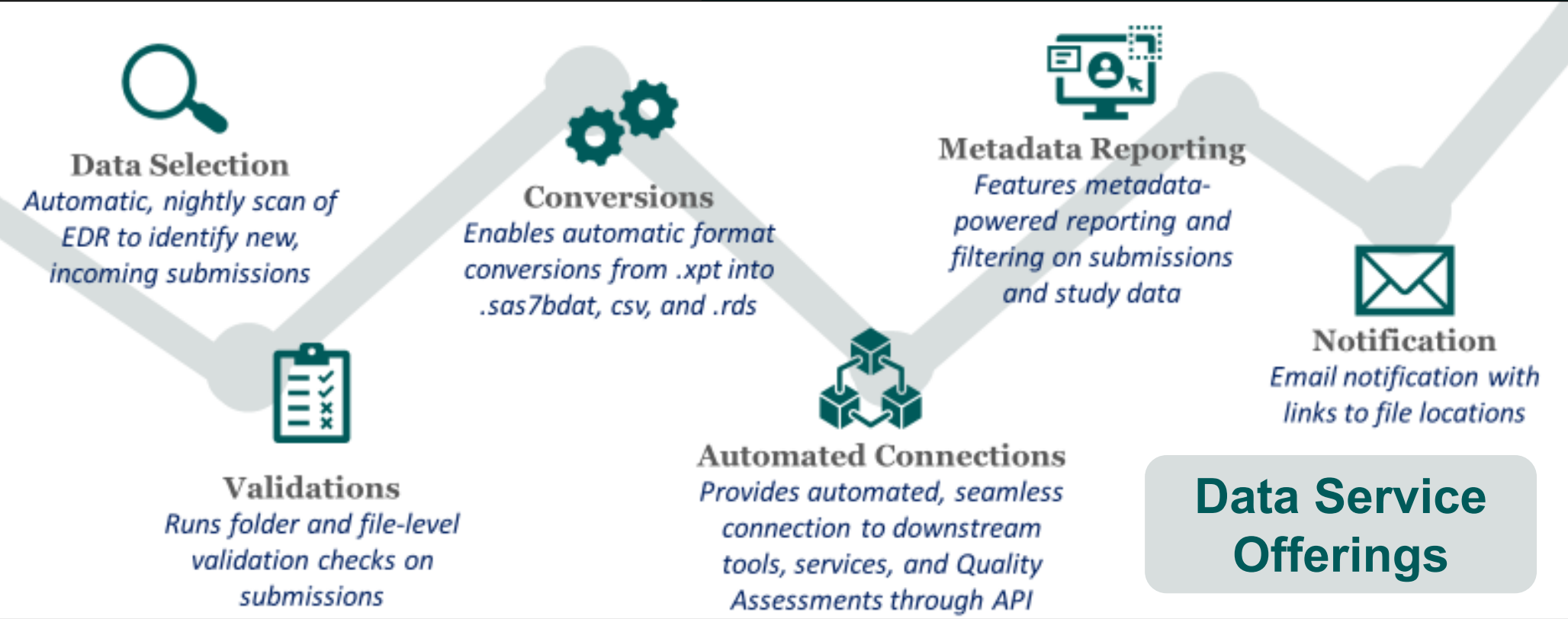
- Analysis Toolbox
- CDEROne Analytics
- DataFit
- IND Smart Template
- Janus Nonclinical
- JMP Clinical
- Line Listing Tool
- MAED
- iPortal
- RAPID
- SARGE
- SEND Explorer
- Site Selection Tool (SST-CI)
- Study Data Platform

Supported Systems & Services

- CoreDF Services
- OCS Clinical Services
- OCS Nonclinical Services

Automated Connections

Data Central's is now comprised of 6 APIs and 8 direct system connections, providing automated access to ADaM, SDTM, SEND, and BIMO datasets as well as forms, reports, and .XML files.



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 reaching more CDER users than ever. Through its multiple data service offerings – data selection, validations, conversions, metadata reporting, automated connections, and notifications – Data Central is expanding access to clean, usable study data across CDER.

For more information, please contact: OCSDDataManagement@fda.hhs.gov