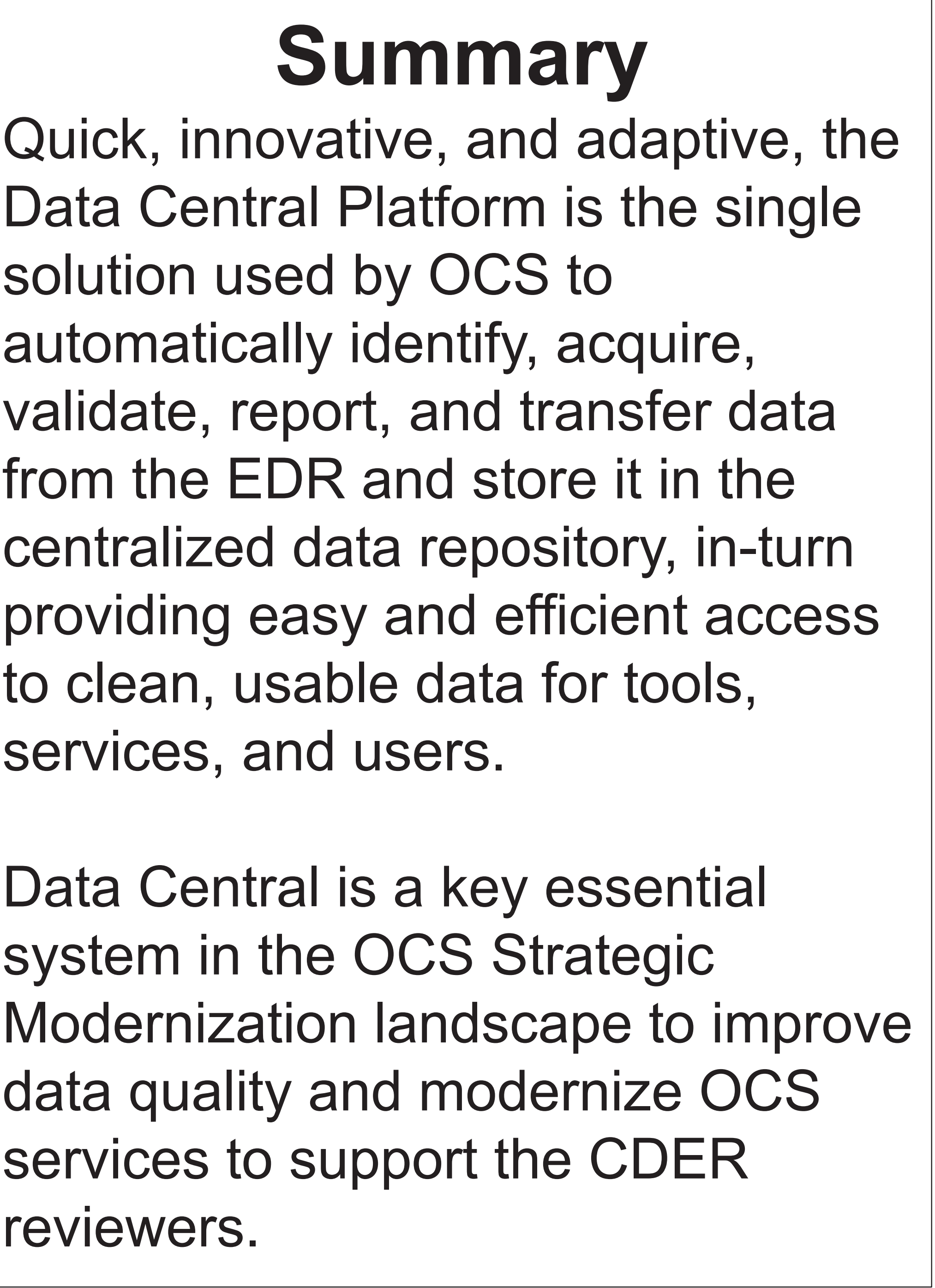


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Quick, innovative, and adaptive, the Data Central Platform is the single solution used by OCS to automatically identify, acquire, validate, report, and transfer data from the EDR and store it in the centralized data repository, in-turn providing easy and efficient access to clean, usable data for tools, services, and users.

Results

Data Central has enabled OCS to provide more services and support to CDER Reviewers than ever before. Compared to the previous manual processes, Data Central has increased data throughput from source (EDR) to tool/service 20-fold.

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Built on a Hybrid Cloud environment, developed using Microservices Architecture and following Agile Methodology, Data Central is designed to be flexible and capable of keeping up with the rapid pace and hyper-dynamic needs of users.

[illegible]

<h3>Data Management Microservices</h3>  <p>OCS Data Central includes key Data Management Microservices that automate Data Management process in pre-scheduled and ad hoc manner</p>	<h3>Database & Repository</h3>  <p>Establish a centralized repository and database to store the identified OCS specific study data as well as metadata</p>
<h3>Workflow Automation</h3>  <p>OCS Data Central provides full workflow automation including automatic notifications, and scheduled execution of DM Microservices</p>	<h3>Web-based Application</h3>  <p>The web application provides a UI for internal OCS users and potentially a larger user community the ability to use DM Microservices individually or jointly for various business needs</p>

 Locate Locate any data in EDR or OCS Data Central Repository	 Migrate Migrate data to and from any location in seconds	 Convert Convert the data from XPT to other useful data formats
 Visualize Visualize the quantity of data acquired during any time range to determine trends	 Watchlist Enter an application and the Watchlist will watch for new or updated data and notify you	 Report Generate a report of all new and updated data that has come in over a selected time period

The diagram illustrates the deployment schedule for the OCS Data Central Environment. A central blue arrow points from left to right, labeled "OCS Data Central Environment Schedule". Above and below the arrow, milestones are listed with corresponding colored boxes indicating their status: dark blue for completed, medium blue for current, and light blue for future. A yellow star highlights the "Sept. 2020: Go-Live" milestone.

Date	Environment	Status
June 2019	Deploy to TEST	Completed
March 2020	TEST Integrated with Applan	Completed
April 2020	PRE-PROD Integrated with Applan	Completed
June 2020	PROD Integrated with Applan	Completed
June 2019	Deploy to DEV	Completed
March 2020	DEV Integrated with Applan	Completed
May 2020	Deploy to PRE-PROD	Current
June 2020	Deploy to PROD	Current
Sept. 2020	Go-Live	Future

Legend:

- Dark Blue Box = Completed
- Medium Blue Box = Current
- Light Blue Box = Future

- JumpStart
- KickStart
- Janus Clinical
- Janus Nonclinical
- Site Selection Tool
- CoreDF Clinical Original

- IND Smart Template
- CoreDF OCP
- CoreDF OOD
- Line Listing Tool

Total Studies Handled
FY20 has Already Surpassed FY19

With an ever-increasing amount of data coming into the Agency, the advent of the Data Central system is timely and critical. For Scientific Computing, Data Central is developed to optimize the Data Management and Data Quality components needed to solve computationally demanding problems and improve the regulatory drug review process. And Data Central fits in perfectly with the SDC 2020 theme as the primary goal of Data Central is Lower Barriers to Data that comes into FDA and the ability to scale to handle large volumes of data such as Real World Evidence data.