

Resource Capacity Planning

How CDER is Modernizing Resource Planning Capabilities

Small Business and Industry Assistance
Regulatory Education for Industry Conference 2021

Recap: Our vision for the program is to...

Develop a **unified & trusted resource management capability** to foster innovation and **maximize our operational performance**, facilitating a flow of products to **patients first in the world** in order to **protect & promote public health** and **meet our commitments to the American** public.



Recap: What is resource capacity planning (RCP)?

Identifying the resources you need **before** you need them

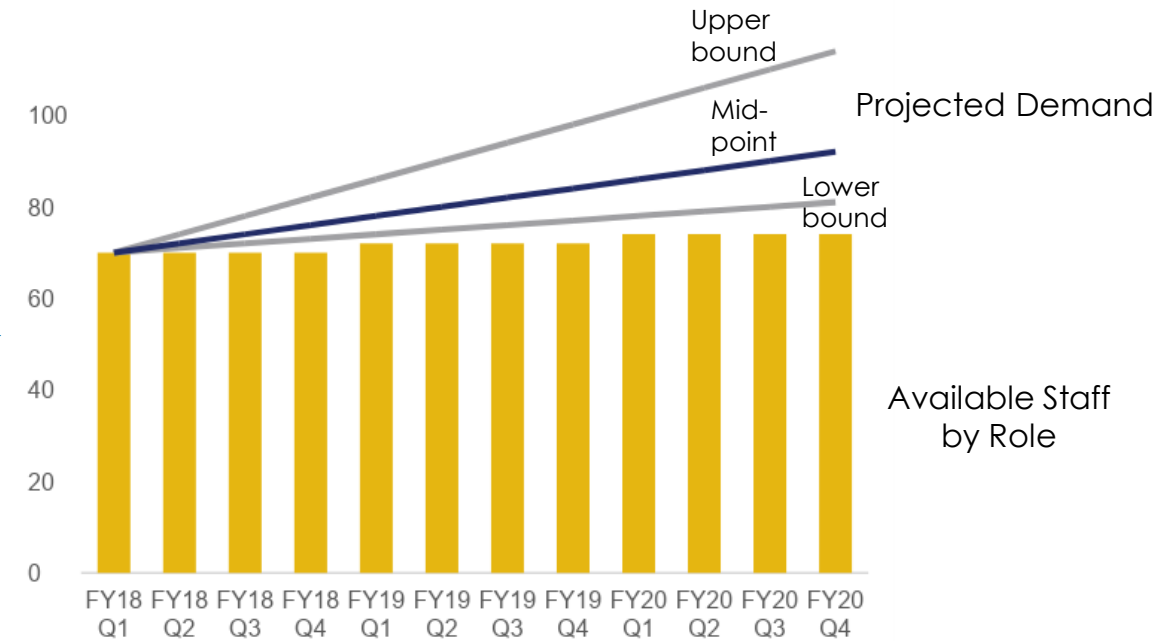
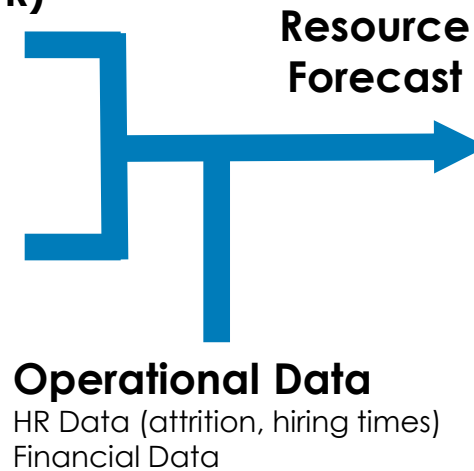
Modernized Time Reporting (MTR)

52-week time reporting to provide:

- Better measure of level of effort
- Better analysis of available hours

Workload Forecasting

Advanced analytics to forecast likely incoming work & productivity



Applications of Resource Forecasts

Capacity Balancing

Identify ops to prioritize existing resources

Revenue Adjustment

Hiring Plans

Financial Forecasting

Recap: RCP Methodology at FDA

FDA has developed a sequenced approach to sequencing the implementation of key resource capacity planning capabilities. Resource demand will be generated utilizing the following general methodology.



Forecast Workload

Utilize analytical techniques to develop predictive models to estimate the volume of direct submission categories i.e. NDA/BLAs, INDs, Supplements, Meetings

Develop Resource Algorithms

Continuous forecasting algorithms are calculated based on historical time reporting data. For direct review effort, unit effort algorithms are calculated by aligning historical time reporting data with historical volume data.

Generate Resource Forecasts

Algorithms are applied to estimated submission volumes to generate a demand forecast for offices.

Recent Key Achievements



Workload Forecasting



2nd Generation Workload Models

Identified and implemented improvements to the PDUFA and BsUFA workload models prior to last refresh cycle



GDUFA Planning

Continued refinement of predictive models for GDUFA submissions for internal planning purposes



Increased Automation & QC

Optimized source data integration, transformation and predictive model code to decrease manual effort while monitoring data quality

Insight Time Reporting



Continued to Support Accuracy & Compliance

Utilized targeted training & communications to provide guidance on how to report time accurately



Understanding Resource Utilization

Developed a set of operational dashboards to understand resource utilization & effort to organizational priorities



Enhanced Quality Control

Developed an automated code-based methodology to identify potential outliers in time reporting data based on historical information

Resource Forecasting



Improved Algorithm Design

Continued refinement of resource algorithms based on growing time reporting dataset



Informing Business Processes

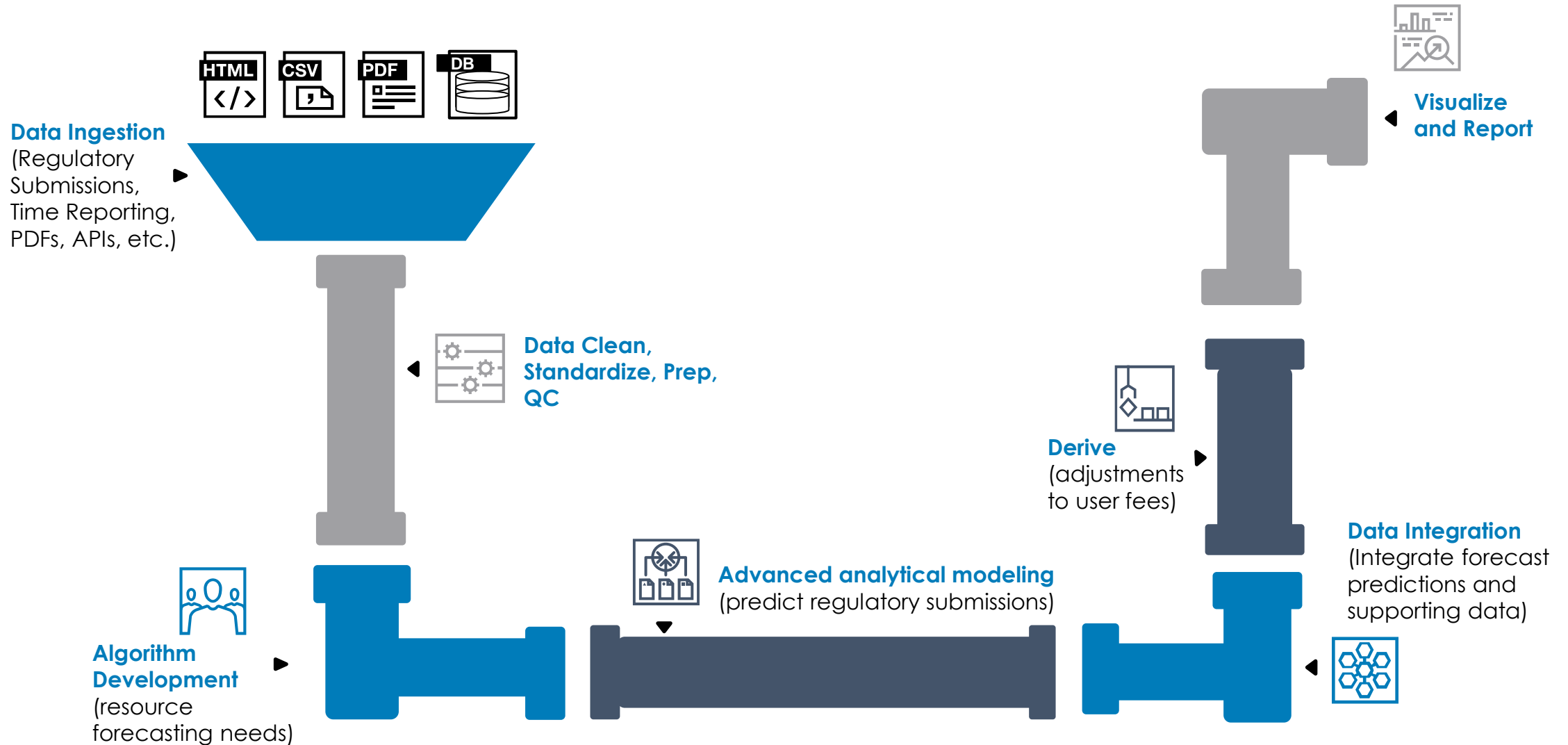
Piloted use of resource forecasts to support resource needs and operations



Increased Automation & QC

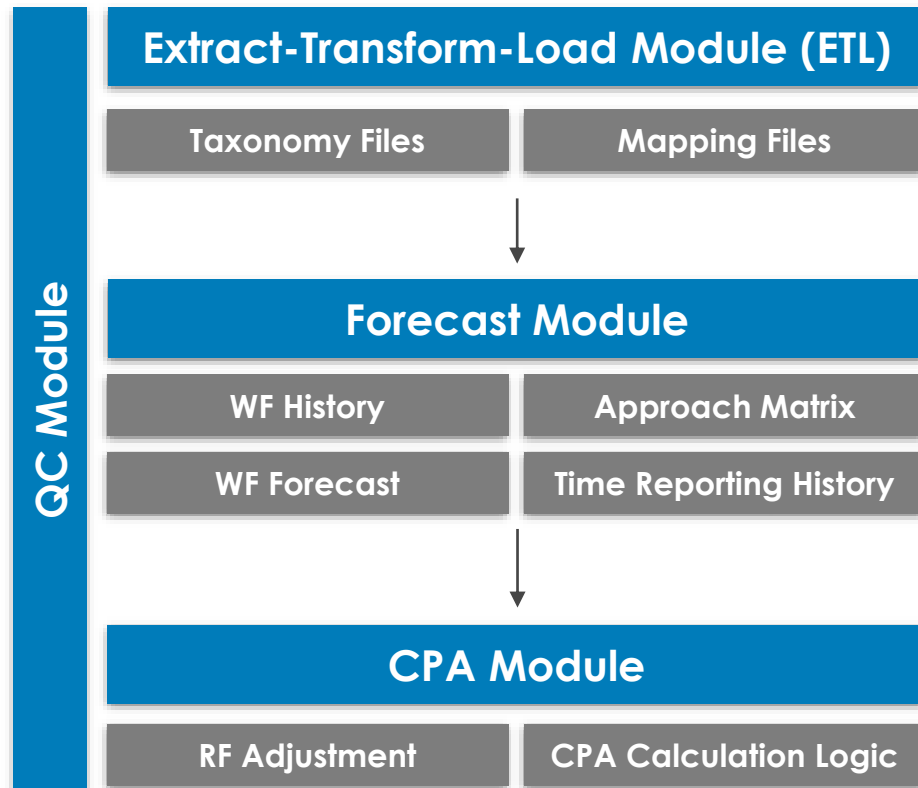
Developed a code-based algorithm engine to generate resource forecasts and significantly reduce manual effort

Implementing & Operationalizing RCP



Pipeline Automation: The Algorithm Engine

The Algorithm Engine streamlines Resource Forecast, Workload Forecast and Capacity Planning Adjustment while providing transparency of the models to the end user.

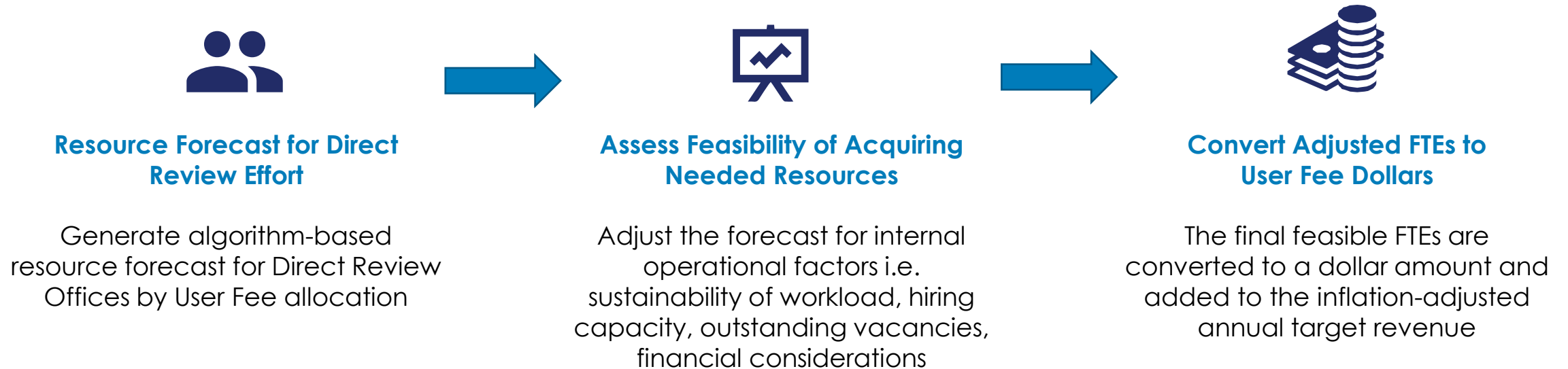


Module Descriptions

- The **ETL module** provides a standardized data extraction, cleaning, and mapping process to create common datasets that can be utilized by downstream modules
- The **Forecast module** integrates WF volume and resource forecast to provide an automated FTE forecast
- The **CPA module** converts CPA-specific resource forecast results and WF volume into CPA output for managerial decision
- The **QC module** is implemented throughout the algorithm engine to streamline QC process with automated logics and taxonomy files

Utilizing RCP in the Capacity Planning Adjustment

The adjustment methodology was reviewed by an independent third party prior to implementation last year and is currently in-progress for FY22.



Improving Upon Previous CPA Methodology

Utilizing the RCP capabilities in the CPA process enables FDA to address several challenges with the previous methodology employed for PDUFA.* FDA plans to continually improve the CPA methodology as additional data and insights become available.

Previous Adjustment Methodology

(PDUFA only)

- Utilized a **lagging** indicator of upcoming submission volumes through a moving **three-year retrospective average**
- Did not** translate volume into expected **resource demand**



New Adjustment Methodology

(PDUFA & BsUFA)

- Utilizes **forward-looking** advanced analytical models to predict future workload
- Incorporates **time reporting** and **submission data** to calculate **expected future effort**



* The previous adjustment methodology applied to PDUFA only. It was known as the Workload Adjuster prior to PDUFA VI and as the Interim Capacity Planning Adjustment from FY18 – FY20.

Looking to the Future: Enabling, Embedding & Utilizing RCP Capabilities in Operations



Models & Algorithms Enhancements

*Further advance
workload and resource
forecasting capabilities*



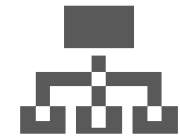
Operations Support Framework & Methodology

*Utilize RCP outputs to
inform existing operational
processes at FDA*



Business Process & Support Model

*Define processes &
related roles and
responsibilities to
maintain and utilize RCP
capabilities*



Technical Environment Design & Deployment

*Design and deploy RCP
capabilities on a scalable
technical environment to
enable flexibility and
efficiency.*