Public Meeting on Financial Transparency and Efficiency of the Prescription Drug User Fee Act, Biosimilar User Fee Act, and Generic Drug User Fee Amendments

Public Meeting

June 28, 2021

2:00 – 4:00 PM

www.fda.gov

2:05 – 2:10 PM

WELCOME AND INTRODUCTION

Sahra I. Torres-Rivera

Deputy Chief Financial Officer, Office of Financial Management Director

Office of Finance, Budget, Acquisitions and Planning

Agenda

FDA

Topic	Presenter	Time
Begin Meeting	**Monica Ellerbe** Director, Business Management Services Office of Finance, Budget, Acquisitions and Planning	2:00 PM
Welcome and Introduction	**Sahra I. Torres-Rivera** Deputy Chief Financial Officer, Director of Office of Financial Management Office of Finance, Budget, Acquisitions and Planning	2:05 – 2:10 PM
Update on 5-Year Financial Plans	**Robert Marcarelli** Director, Division of User Fees Office of Financial Management	OFBAP	2:10 – 2:30 PM
Resource Capacity Planning (RCP) Implementation Updates	**Josh Barton** Director, Resource Capacity Planning Staff Office of Program and Strategic Analysis	CDER	2:30 – 2:50 PM
Update on the FDA Action Plan in Response to Financial Management Evaluation	**Sahra I. Torres-Rivera** Deputy Chief Financial Officer, Director of Office of Financial Management Office of Finance, Budget, Acquisitions and Planning	2:50 – 3:20 PM
Wrap Up & Additional Information		3:20 – 4:00 PM

FDA

2:10 – 2:30 PM

UPDATE ON 5-YEAR FINANCIAL PLANS

Robert Marcarelli

Director, Division of User Fees

Office of Finance, Budget, Acquisitions and Planning

Overview of the PDUFA Financial Plan

Budgetary Resources	FY 2018 Actual	FY 2019 Actual	FY 2020 Estimate	FY 2020 Actual	FY 2021 Estimate	FY 2022 Estimate
Target Revenue	$911,346,000	$1,010,322,000	$1,074,714,000	$1,074,714,000	$1,107,199,000	$1,144,915,000
Cash Collections	$908,077,723	$1,015,152,012	$1,074,714,000	$1,020,229,037	1,107,199,000	$1,144,915,000
Recoveries	$13,149,599	$12,857,171	$9,000,000	$28,773,047	$12,000,000	$12,000,000
Carryover Available for Use, Beginning of Year	$271,257,205	$130,372,943	$136,237,817†	$141,237,817	$94,752,990†	$90,898,147
Total Budgetary Resources	$1,192,484,527	$1,158,382,126	$1,219,951,817	$1,190,239,900	$1,213,951,990	$1,247,813,147

User Fee Obligations	FY 2018 Actual	FY 2019 Actual	FY 2020 Estimate	FY 2020 Actual	FY 2021 Estimate	FY 2022 Estimate
Payroll & Operating						
CBER	$129,543,398	$132,847,629	$135,357,938	$136,614,045	$149,475,247	$161,477,428
CDER	$688,935,477	$632,811,258	$680,411,849	$685,618,671	$698,930,717	$721,276,326
CDRH	$786,091	$1,501,379	$4,051,811	$3,360,240	$4,122,893	$4,233,943
ORA	$7,733,467	$7,443,695	$8,628,940	$7,553,941	$8,753,009	$8,961,189
HQ	$54,211,488	$55,910,342	$56,102,552	$51,768,233	$59,746,750	$51,730,481
Total Rent	$49,964,883	$52,437,964	$65,931,103	$53,231,596	$66,590,414	$67,256,319
Total Shared Services	$130,936,781	$134,192,042	$136,248,526	$137,340,185	$135,434,813	$136,789,161
Total Obligations	$1,062,111,583	$1,017,144,309	$1,086,732,719	$1,075,486,910	$1,123,053,843	$1,151,724,846

Carryover	FY 2018 Actual	FY 2019 Actual	FY 2020 Estimate	FY 2020 Actual	FY 2021 Estimate	FY 2022 Estimate
Total Carryover, End of Year	$209,223,938	$220,088,812	$217,070,092	$193,603,985	$189,749,142	$194,939,296
Carryover Unavailable for Use, End of Year	($78,850,995)	($78,850,995)	($83,850,995)	($98,850,995)	($98,850,995)	($98,850,995)
Carryover Available for Use, End of Year	$130,372,943	$141,237,817	$133,219,097	$94,752,990	$90,898,147	$96,088,301

Target Revenue has been rounded to the nearest thousand dollars
All other numbers have been rounded to the nearest dollar
†Indicates an actual amount

Collection Shortfall

- Cohort year 2020 collections were short of the revenue target by 4%.

Carryover Balance

- Operations in FY 2020 resulted in a net decrease of the carryover balance due to a decrease in application fee collections and higher refunds than planned.

Overview of the BsUFA Financial Plan

Budgetary Resources	FY 2018 Actual	FY 2019 Actual	FY 2020 Estimate	FY 2020 Actual	FY 2021 Estimate	FY 2022 Estimate
Target Revenue	$40,214,000	$38,847,000	$41,923,000	$41,923,000	$42,493,000	$43,314,000
Cash Collections	$29,238,601	$34,685,713	$41,923,000	$37,971,967	$42,493,000	$43,314,000
Recoveries	$1,074,997	$456,236	$400,000	$535,834	$600,000	$600,000
Carryover Available for Use, Beginning of Year	$48,723,308	$38,757,343	$31,340,903†	$31,840,903	$35,475,695†	$36,369,722
Total Budgetary Resources	$79,036,907	$73,899,291	$73,663,903	$70,348,704	$78,568,695	$80,283,722

User Fee Obligations	FY 2018 Actual	FY 2019 Actual	FY 2020 Estimate	FY 2020 Actual	FY 2021 Estimate	FY 2022 Estimate
Payroll & Operating						
CBER	$-	$-	$300,000	$46,149	$304,080	$309,954
CDER	$31,113,433	$33,004,440	$37,274,273	$25,932,156	$32,781,241	$38,511,023
ORA	$1,128,256	$676,738	$1,440,770	$1,092,113	$1,460,366	$1,488,574
HQ	$2,293,521	$1,529,197	$1,515,983	$1,297,005	$1,627,682	$1,232,939
Total Rent	$1,104,785	$1,382,811	$1,536,143	$732,615	$1,551,504	$1,567,019
Total Shared Services	$4,639,568	$5,465,202	$4,741,118	$4,772,972	$4,474,100	$4,518,841
Total Obligations	$40,279,564	$42,058,388	$46,808,287	$33,873,010	$42,198,973	$47,628,351

Carryover	FY 2018 Actual	FY 2019 Actual	FY 2020 Estimate	FY 2020 Actual	FY 2021 Estimate	FY 2022 Estimate
Total Carryover, End of Year	$38,757,343	$31,840,903	$27,355,616	$36,475,695	$37,369,722	$33,655,371
Carryover Unavailable for Use, End of Year	$0	$0	($500,000)	($1,000,000)	($1,000,000)	($1,000,000)
Carryover Available for Use, End of Year	$38,757,343	$31,840,903	$26,855,616	$35,475,695	$36,369,722	$32,655,371

Collection Shortfall

- Cohort year 2020 collections were short of the revenue target by 9%.

Carryover Balance

- Operations in FY 2020 resulted in a net increase of the carryover balance. The primary driver of the increase is the impact of COVID-19-related efforts, as well as fewer-than-expected submissions, which caused a decrease in payroll spending.

Target Revenue has been rounded to the nearest thousand dollars
All other numbers have been rounded to the nearest dollar
†Indicates an actual amount

Overview of the GDUFA Financial Plan

Budgetary Resources	FY 2018	FY 2019	FY 2020		FY 2021	FY 2022
	Actual	Actual	Estimate	Actual	Estimate	Estimate
Target Revenue	$493,600,000	$501,721,000	$513,223,000	$513,223,000	$520,209,000	$530,544,000
Cash Collections	$493,655,974	$496,503,494	$513,223,000	$483,285,782	$520,209,000	$530,544,000
Recoveries	$4,920,184	$8,544,957	$5,000,000	$9,968,653	$7,000,000	$7,000,000
Carryover Available for Use, Beginning of Year	$142,412,048	$163,715,667	$199,171,168	$204,171,168	$152,731,582†	$118,846,058
Total Budgetary Resources	$640,988,205	$668,764,117	$717,394,168	$697,425,603	$679,940,582	$656,390,058

User Fee Obligations	FY 2018	FY 2019	FY 2020		FY 2021	FY 2022
	Actual	Actual	Estimate	Actual	Estimate	Estimate
Payroll & Operating						
CBER	$49,462	$23,658	$1,004,864	$131,615	$1,018,541	$1,038,776
CDER	$323,591,582	$316,437,772	$370,219,339	$378,276,891	$385,402,867	$395,125,900
ORA	$46,518,651	$40,694,363	$50,938,151	$48,355,675	$49,604,248	$50,589,736
HQ	$27,801,624	$27,565,531	$44,408,872	$35,022,863	$37,774,571	$33,812,690
Total Rent	$22,019,962	$24,962,969	$26,053,053	$19,802,082	$26,313,583	$26,576,719
Total Shared Services	$57,291,257	$54,908,657	$58,631,822	$59,104,896	$60,980,714	$61,590,521
Total Obligations	$477,272,539	$464,592,949	$551,256,100	$540,694,021	$561,094,525	$568,734,343

Carryover	FY 2018	FY 2019	FY 2020		FY 2021	FY 2022
	Actual	Actual	Estimate	Actual	Estimate	Estimate
Total Carryover, End of Year	$163,715,667	$204,171,168	$171,138,068	$156,731,582	$122,846,058	$91,655,715
Carryover Unavailable for Use, End of Year	$0	$0	($5,000,000)	($4,000,000)	($4,000,000)	($4,000,000)
Carryover Available for Use, End of Year	$163,715,667	$204,171,168	$166,138,068	$152,731,582	$118,846,058	$87,655,715

Collection Shortfall

- Cohort year 2020 collections were short of the revenue target by 6%.

Carryover Balance

- Operations in FY20 resulted in a net decrease of the carryover balance. The decrease was primarily driven by increased hiring for the program, lower than projected attrition rates, and actual collections being less than estimated.

Target Revenue has been rounded to the nearest thousand dollars
All other numbers have been rounded to the nearest dollar
†Indicates an actual amount

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2:30 – 2:50 PM

RESOURCE CAPACITY PLANNING IMPLEMENTATION UPDATES

Josh Barton

Director, Resource Capacity Planning Staff

Office of Program and Strategic Analysis | CDER

Recap: Our Vision for the Program is to…

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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)?

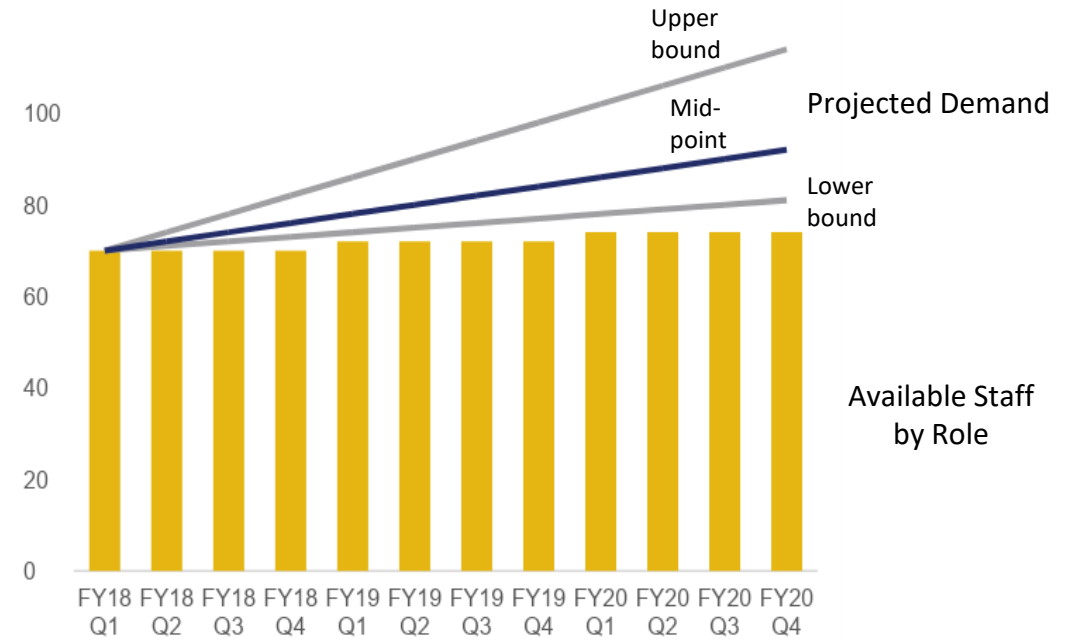FDA

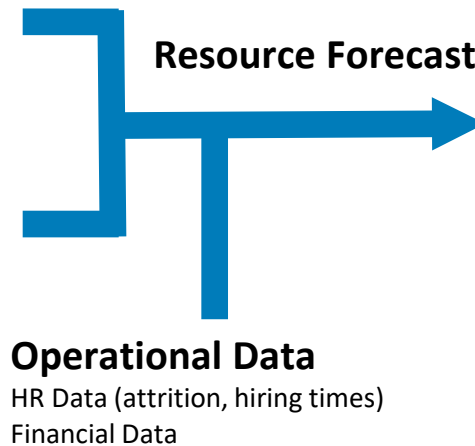Identifying the resources you need **before** you need them.

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

Resource Forecast

Operational Data
HR Data (attrition, hiring times)
Financial Data

Upper bound

Projected Demand

Mid-point

Lower bound

Available Staff by Role

(Chart axis values: 100, 80, 60, 40, 20, 0; x-axis: FY18 Q1, FY18 Q2, FY18 Q3, FY18 Q4, FY19 Q1, FY19 Q2, FY19 Q3, FY19 Q4, FY20 Q1, FY20 Q2, FY20 Q3, FY20 Q4)

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.

Predict Submission Volume × [Historical Time Reporting Data ÷ Historical Submission Volume = Resource Algorithms] = Resource Forecast

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

FDA

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

Modernized 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
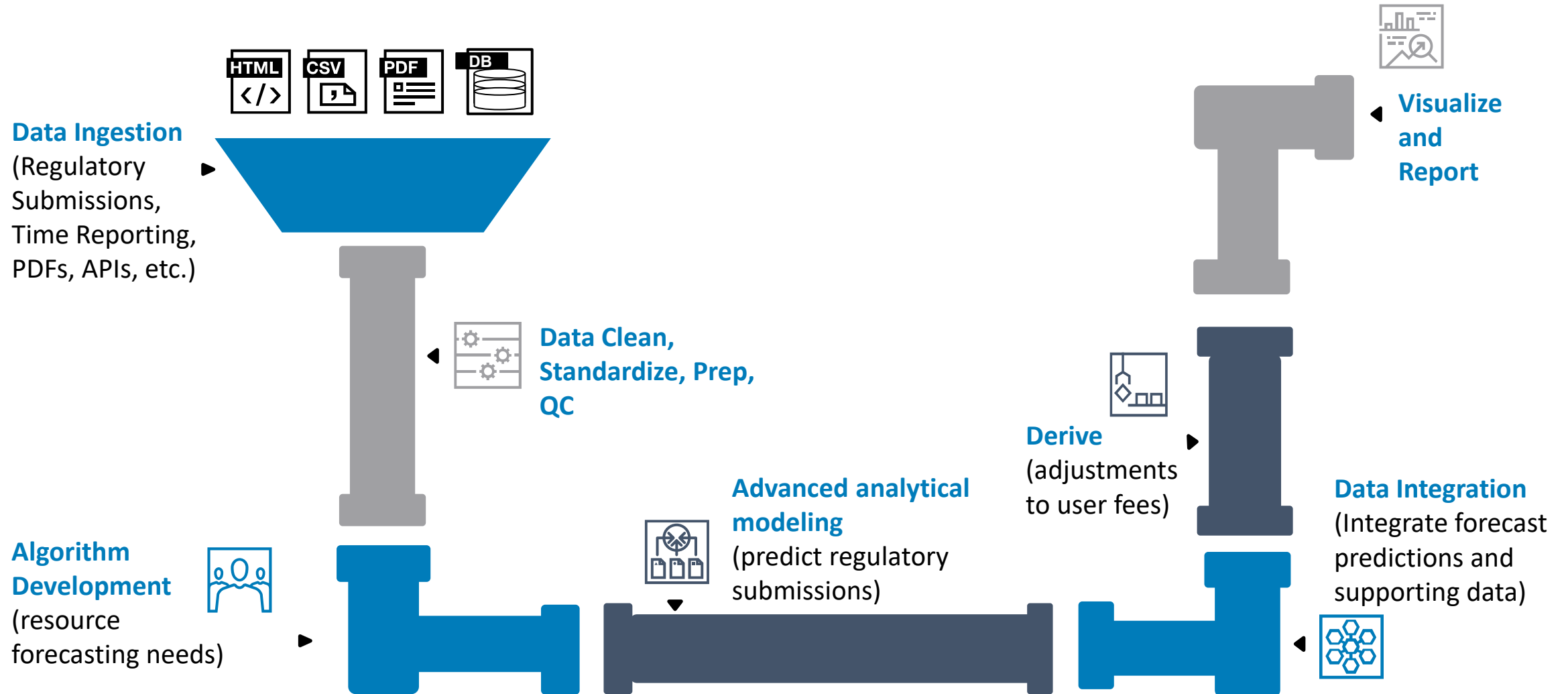
Informing Business Processes

Piloted use of resource forecasts to support resource needs and operations

Increased Automation & QC

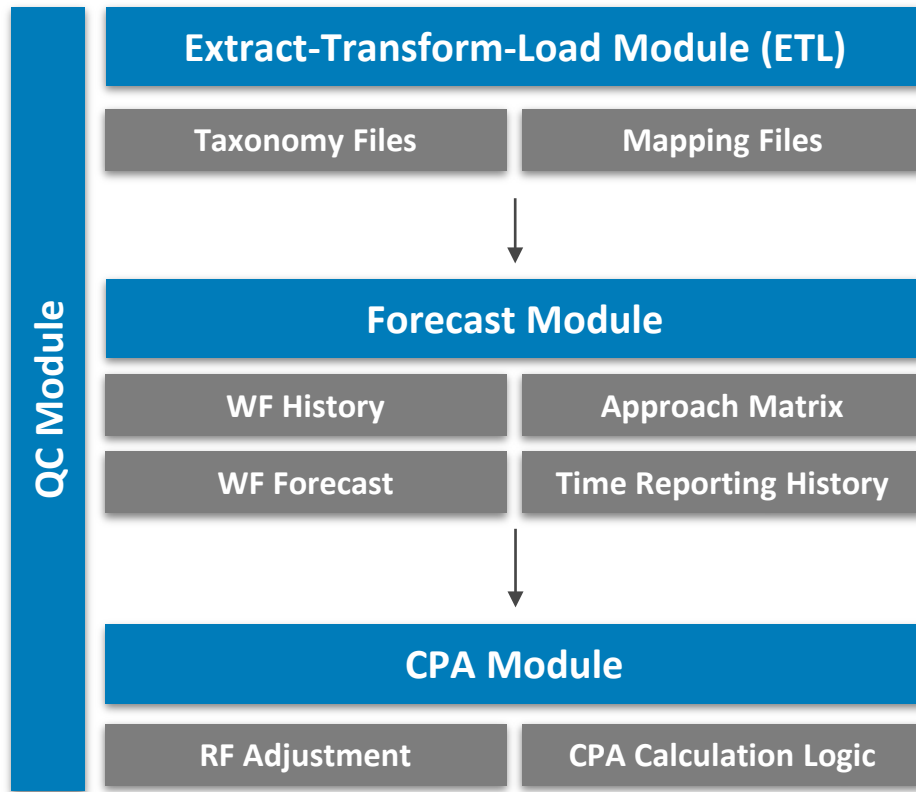Developed a code-based algorithm engine to generate resource forecasts and significantly reduce manual effort

Implementing & Operationalizing RCP

Data Ingestion
(Regulatory Submissions, Time Reporting, PDFs, APIs, etc.)

Data Clean, Standardize, Prep, QC

Algorithm Development
(resource forecasting needs)

Advanced analytical modeling
(predict regulatory submissions)

Derive
(adjustments to user fees)

Data Integration
(Integrate forecast predictions and supporting data)

Visualize and Report

HTML CSV PDF DB

Pipeline Automation: The Algorithm Engine

FDA

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

QC Module

Extract-Transform-Load Module (ETL)	
Taxonomy Files	Mapping Files

Forecast Module	
WF History	Approach Matrix
WF Forecast	Time Reporting History

CPA Module	
RF Adjustment	CPA Calculation Logic

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.

Resource Forecast for Direct Review Effort

Generate algorithm-based resource forecast for Direct Review Offices by User Fee allocation

Assess Feasibility of Acquiring Needed Resources

Adjust the forecast for internal operational factors i.e. sustainability of workload, hiring capacity, outstanding vacancies, financial considerations

Convert Adjusted FTEs to User Fee Dollars

The final feasible FTEs are converted to a dollar amount and added to the inflation-adjusted annual target revenue

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**
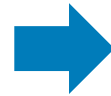
New Adjustment Methodology
(PDUFA & BsUFA)

- 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.

2:50 – 3:20 PM

UPDATE ON THE FDA ACTION PLAN IN RESPONSE TO FINANCIAL MANAGEMENT EVALUATION

Sahra I. Torres-Rivera

Deputy Chief Financial Officer, Office of Financial Management Director

Office of Finance, Budget, Acquisitions and Planning

Background on the FY 2018 Financial Management Evaluation

During FY 2018, the CMS Alliance to Modernize Healthcare (The Health FFRDC) was engaged to develop a comprehensive evaluation focused on five specific areas of FDA's financial management capability for PDUFA, BsUFA and GDUFA programs. In response, the FDA developed an Action Plan to address the recommendations.

About: The Health FFRDC is the first **federally-funded research and development center** dedicated to protecting and promoting health and well-being. It is composed of an alliance of partners and members who are committed to providing conflict-free, objective expertise to HHS and its divisions.

FY2018 Financial Management Evaluation

Fiscal Year 2018
Financial Management Evaluation for Human Drug User Fees

Presented by:
The MITRE Corporation & Grant Thornton, LLP
June 7, 2019

CMS Alliance to Modernize Healthcare (The Health FFRDC)

FA 4: Technical Capabilities — FDA is able to financially manage and administer human drug user fees.

FA 5: User Fee Estimating Methodology — In FY 2018, FDA was within 2% of target revenue across all human drug user fee programs, with some opportunities for improvement.

The Health FFRDC

Financial Management Evaluation Focus Areas

Focus Area 1: Resource Planning, Request and Allocation, and User Fee Administration

Focus Area 2: Administration of Fee Program Resources

Focus Area 3: Oversight and Governance

Focus Area 4: Technical Capabilities

Focus Area 5: User Fee Estimating Methodology

FDA Action Plan

FDA U.S. FOOD & DRUG ADMINISTRATION

FDA User Fee Financial Management Action Plan

OFBA
Office of Finance, Budget, and Acquisitions

Office of Finance, Budget, and Acquisitions

Finding: FDA realized improvements in user fee administration, specifically, the enterprise-level systems that support budget execution, billing, collection and reporting capabilities. Within the Centers, particularly CDER, management encouraged process improvement and adoption of lean practices. FDA

FDA Action Plan Overview and Progress in FY 2021

FDA

The FDA Action Plan is comprised of strategic and targeted measures that address the full scope of the evaluation's five focus areas. The FDA continues to track progress against the plan and is committed to continuous improvement.
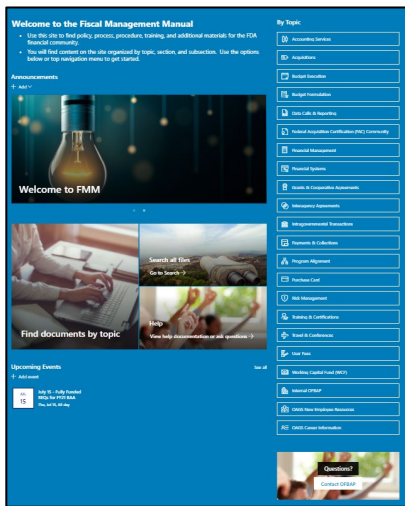
Focus Area	Action	Status	Date
Focus Area 1: Resource Planning, Request and Allocation, and User Fee Administration	Develop a comprehensive fiscal manual, inclusive of sections on budget execution and user fee financial planning and administration. • Phase 1: General aspects of user fee financial management and for the PDUFA program • Phase 2: BsUFA and GDUFA Programs • Phase 3: Other programs (ADUFA, AGDUFA, Color Cert, CQA, EREA, MDUFA, MQSA, PRV, TPA, VQIP, Tobacco, RR, and OMUFA)	Completed	Sept. 2020
	Develop and implement an online and classroom training module that covers user fee financial planning and administration.	Completed	Oct. 2020
	Require applicable FDA staffs to take the training and include this requirement in their performance plans for 2020	Completed	Dec. 2020
Focus Area 2: Administration of Fee Program Resources	Leverage corporate tools and ensure they are appropriately deployed into the FDA centers and offices.	On Track	Sept. 2021
	Utilize specialized financial working group from the User Fee Financial Management Committee (UFFMC) to facilitate better financial analytics for user fee programs.	Completed	Sept. 2021
	Train applicable FDA Center and Office staff on existing automated tools and reports. Require that completion be incorporated into 2020 performance plans of identified staffs. • Phase 1: Develop training for applicable FDA Center and Office staffs	Completed	Sept. 2020
	Include clearer information about roles and responsibilities relative to FDA user fee financial planning and administration in the fiscal manual. Leverage the UFFMC to enhance collaboration and increase knowledge base of user fee financial management processes across the agency.	Completed	June 2020
Focus Area 3: Oversight and Governance	Receive strategic policy direction from FDA's Executive Committee to be leveraged by UFFMC when making user fee resource allocation decisions.	Completed	Oct. 2019
	Formally document decisions from the UFFMC and review results relative to investment decisions at least once within one year after funds have been allocated.	Completed	Feb. 2020
	Utilize a specialized financial working group from the UFFMC to enhance business case templates and documentation required to provide more business analytics and robust financial analysis to facilitate user fee investment decisions.	Completed	Feb. 2020
Focus Area 5: User Fee Estimating Methodology	Develop new predictive models to enhance forecasts of fee-paying units in PDUFA, BsUFA and GDUFA as part of the resource capacity planning capability. Work to outline the new fee forecasting methodologies into the annual fee setting process, including making any changes to MAPPs, SOPs, and delegations of authority as needed.	Completed	May 2020

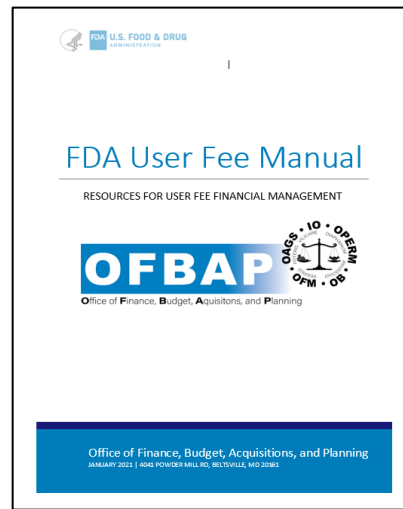# Highlights from the FDA Action Plan

The FDA has taken a holistic approach to improve the financial management of human drug user fee programs. This includes developing new resources and integrating training on existing tools and reports, better enabling FDA employees to keep up with the increasing complexity of the financial management of human drug user fee programs.
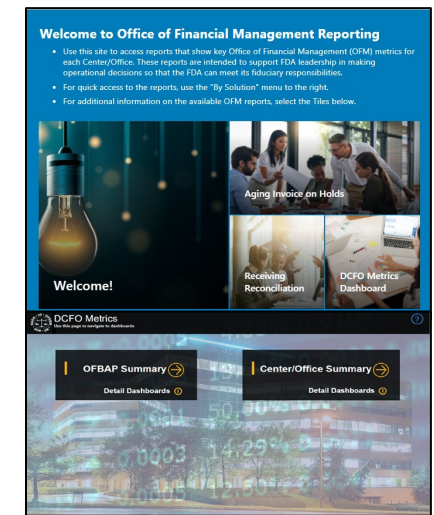
Financial Management Manual

User Fee Manual

User Fee & FBIS/IBAPS Reports Training

DCFO Metrics Dashboard
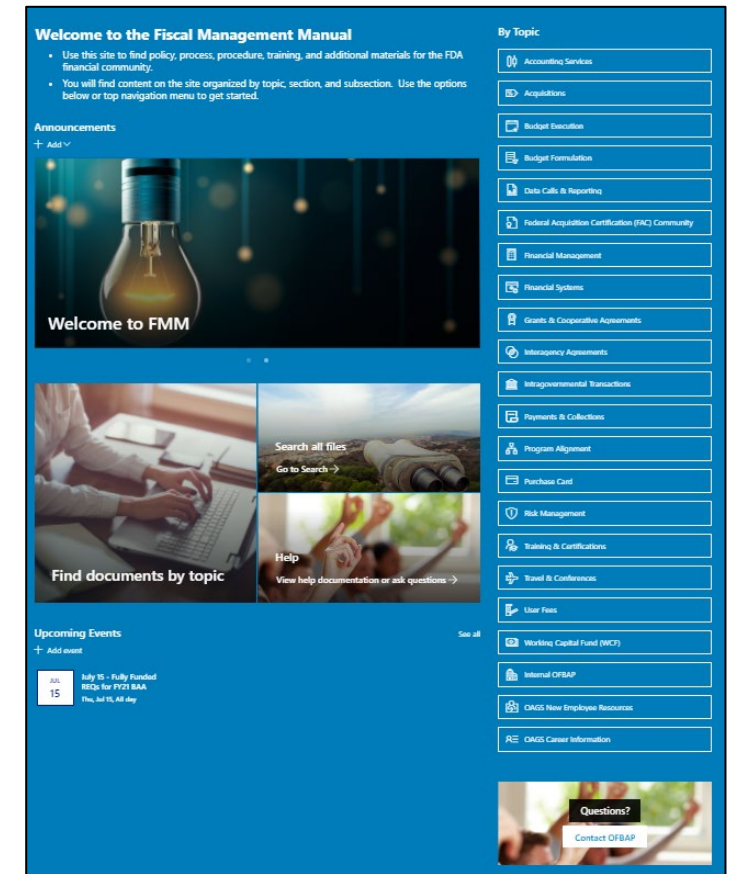
Fiscal Management Manual

As part of the FDA's response to the Health FFRDC's recommendation for a fully integrated user fee management policy and procedures framework, FDA developed a comprehensive fiscal manual, inclusive of sections on budget execution, user fee financial planning and administration.

The Fiscal Management Manual (FMM) serves as a **"one-stop-shop"** for fiscal management resources and is available FDA-wide. The FMM:

- Provides **easy access** to fiscal resources needed to perform job responsibilities

- Improves **collaboration**, **productivity and learning** across FDA

- Increases **consistency** to improve customer service

Impact

- Over 45 finance, budget, and acquisition SMEs collaborated to identify, update, and upload over **2,800 documents** into the FMM

- FDA staff has visited the FMM site over **56,000 times** since its launch in October 2020

FDA User Fee Manual

FDA developed the User Fee Manual (UFM) as part of FDA's Action Plan, which leverages opportunities and challenges identified in the fiscal year 2018 Financial Management Evaluation for Human Drug User Fees. The User Fee Manual provides a centralized repository of user fee-specific financial management resources.

This User Fee Manual **consolidates** high-level summaries of the FDA's user fee standard operating procedures (SOPs), manuals, job aids and templates in one location to expand **agency-wide awareness** and **understanding.**
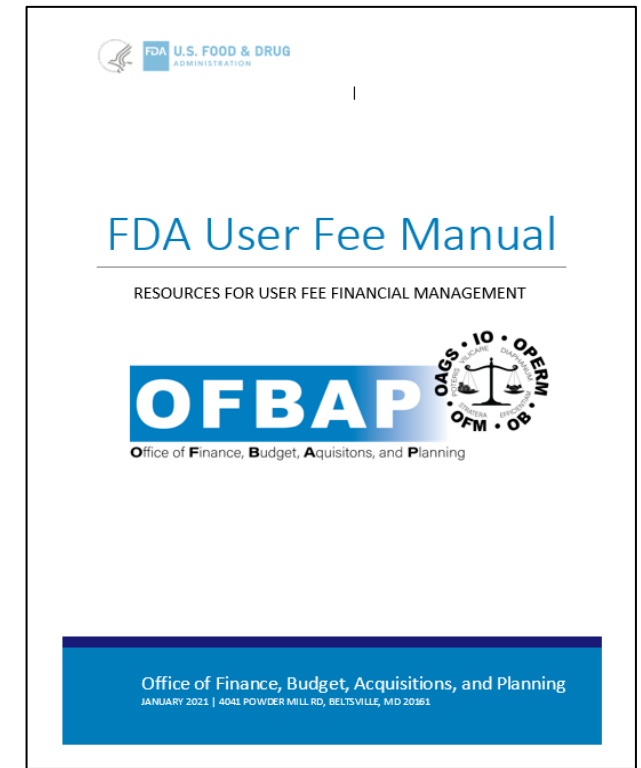
Phase 1: General Overview and PDUFA (launched April 1, 2020)

Phase 2: BsUFA and GDUFA (launched June 30, 2020)

Phase 3: Other Programs (launched January 13, 2021)

Impact

- OFBAP developed an automated solution in February 2021 to streamline the ongoing, manual, and time-intensive process of updating and validating the **150+ links** in the UFM

- Since November 2020, the UFM has been accessed **719 times by 157 unique users**, making the UFM the most accessed document on the FMM

U.S. FOOD & DRUG
ADMINISTRATION

FDA User Fee Manual

RESOURCES FOR USER FEE FINANCIAL MANAGEMENT

OFBAP

Office of Finance, Budget, Aquisitons, and Planning

Office of Finance, Budget, Acquisitions, and Planning
JANUARY 2021 | 4041 POWDER MILL RD, BELTSVILLE, MD 20161

User Fee Training

In response to the Health FFRDC's finding that there is an opportunity to further increase technical understanding to better meet stakeholder needs, FDA integrated FDA-wide training on existing automated tools, systems and reports.

The User Fee Training is an **instructor-led training** that educates FDA-wide learners on:

- **Purpose** of the user fee program
- Key **roles** and **responsibilities** involved in administering user fees
- User fee **billing** and **collections processes**
- User fee budget operations and key **budget activities**

Impact

- Since June 2020, FDA has conducted **12 FDA User Fee Training sessions** to **194 employees**, augmenting their understanding of billing, collections, and budgeting activities for their roles

FBIS/IBAPS Reports Training

In response to Action 3 of **Focus Area 2: Administration of Fee Program Resources** in the FDA Action Plan, FDA Center and Office staff have undergone training on existing automated tools and reports such as the FDA Adverse Event Reporting System (FAERS) Business Intelligence System (FBIS) and the Integrated Budget & Acquisition Planning System (IBAPS).

The FBIS/IBAPS Reports Training:

- Educates FDA-wide staff on **existing reporting capabilities** within IBAPS and FBIS

- Supports analyzing system-based End User Report usage to **create an inventory of reports**

- Incorporates requirements that **streamlines reporting systems** into user fees management systems and tools

Impact

- Action 3: Inventory of reports were shared, and the training was completed to all centers in FY 2020.

- In addition, as part of continuation of daily FBIS support for FY21, a total of **42 outreach/brown bag sessions** have been completed across 5 Centers and 1 Office for **235 attendees.**

#	Center	Planned	Completed FY 21 (Oct - May)	In Progress FY 21 (Jun-Sep)
1	All (Brown Bags)	8	5	3
2	CDRH	1	1	0
3	CBER	2	-	2
4	CDER	2	-	2
5	CVM	3	2	1
6	NCTR	2	2	0
7	OFBAP	35	32	3
	Total	**53**	**42**	**11**

DCFO Metrics Dashboard

FDA

In order to streamline the process of capturing Office of Financial Management (OFM) metrics, the FDA developed the Deputy Chief Financial Officer (DCFO) Metrics Dashboard.

The DCFO Metrics Dashboard enables FDA leadership to make **informed decisions** to improve the fiscal health of the FDA and to ensure FDA's resources are being allocated appropriately to **achieve its mission**. The dashboard contains 36 metrics across the following six areas:
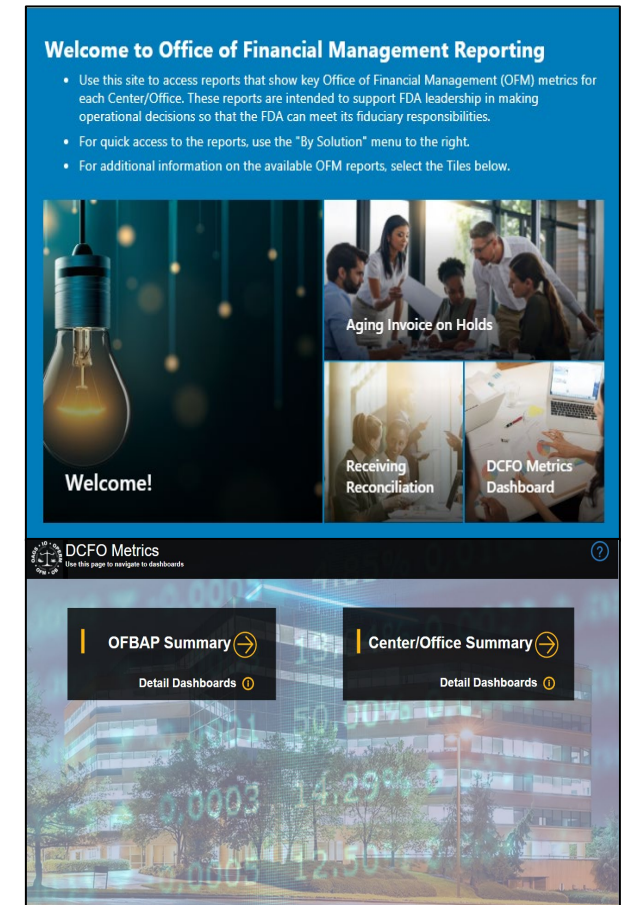
- Travel
- **User Fees**

- Accounting Transactions
- Invoices & Payments

- Reconciliations
- Administrative

User Fees Metrics

1. User Fees Net Collections by Program
2. Unearned Revenue
3. Balance and Aging of User Fee Accounts Receivable

------------------------------ **Impact** ------------------------------

- The Dashboard provides a centralized location for key finance-related metrics and uses automated workflows to consolidate **34 reports from 8 financial systems**

Welcome to Office of Financial Management Reporting
- Use this site to access reports that show key Office of Financial Management (OFM) metrics for each Center/Office. These reports are intended to support FDA leadership in making operational decisions so that the FDA can meet its fiduciary responsibilities.
- For quick access to the reports, use the "By Solution" menu to the right.
- For additional information on the available OFM reports, select the Tiles below.

Aging Invoice on Holds

Welcome!

Receiving Reconciliation

DCFO Metrics Dashboard

DCFO Metrics
Use this page to navigate to dashboards

OFBAP Summary →
Detail Dashboards

Center/Office Summary →
Detail Dashboards

3:20 – 4:00 PM

WRAP UP AND ADDITIONAL INFORMATION

To submit a public comment following this meeting, please follow these steps:

1. Go to Regulations.gov
2. Use Docket No. FDA-2021-N-0431 to locate this meeting
3. Submit your comment

You will have until **July 19th** to submit a comment.