U.S. FOOD & DRUG
ADMINISTRATION

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 22, 2020
9:00 – 11:00 AM

9:05 – 9:10 AM

WELCOME AND INTRODUCTION

Jay Tyler
Chief Financial Officer
Office of Finance, Budget and Acquisitions

Agenda

Topic	Presenter	Time
Begin Meeting	**Monica Ellerbe** Director, Business Management Services Office of Finance, Budget and Acquisitions	9:00 AM
Welcome and Introduction	**Jay Tyler** Chief Financial Officer Office of Finance, Budget and Acquisitions	9:05 – 9:10 AM
Update on 5-Year Financial Plans	**Robert Marcarelli** Supervisory Budget Analyst Office of Finance, Budget and Acquisitions	9:10 – 9:40 AM
Resource Capacity Planning (RCP) Implementation Updates	**Josh Barton** Director, Resource Capacity Planning Team Office of Program and Strategic Analysis | CDER	9:40 – 10:00 AM
Capacity Planning Adjustment Evaluation and Findings	**Athena Tang and Kendra Orjada** Booz Allen Hamilton	10:00 – 10:20 AM
Update on the FDA Action Plan in Response to Financial Management Evaluation	**Jay Tyler** Chief Financial Officer Office of Finance, Budget and Acquisitions	10:20 – 10:45 AM
Open Public Comment		10:45 – 11:00 AM

9:10 – 9:40 AM

UPDATE ON 5-YEAR FINANCIAL PLANS

Robert Marcarelli
Supervisor Budget Analyst
Office of Finance, Budget and Acquisitions

Overview of the PDUFA Financial Plan

Budgetary Resources	FY 2018	FY 2019		FY 2020	FY 2021	FY 2022
	Actual	Estimate	Actual	Estimate	Estimate	Estimate
Target Revenue	**$911,346,000**	**$1,010,322,000**	**$1,010,322,000**	**$1,074,714,000**	**$1,121,803,000**	**$1,168,054,000**
Cash Collections	$908,077,723	$1,010,322,000	$1,015,152,012	$1,074,714,000	$1,121,803,000	$1,168,054,000
Recoveries	$13,149,599	$10,000,000	$12,857,171	$9,000,000	$9,000,000	$9,000,000
Carryover Available for Use, Beginning of Year	$232,969,623	$125,372,943†	$125,372,943	$136,237,817†	$133,219,097	$128,916,297
Total Budgetary Resources	**$1,154,196,945**	**$1,145,694,943**	**$1,153,382,126**	**$1,219,951,817**	**$1,264,022,097**	**$1,305,970,297**

User Fee Obligations	FY 2018	FY 2019		FY 2020	FY 2021	FY 2022
	Actual	Estimate	Actual	Estimate	Estimate	Estimate
Payroll & Operating						
CBER	$129,543,398	$133,147,244	$132,847,629	$135,357,938	$140,880,201	$146,587,238
CDER	$688,935,477	$641,479,230	$632,811,258	$680,411,849	$717,861,387	$754,552,492
CDRH	$786,091	$2,630,174	$1,501,379	$4,051,811	$4,184,089	$4,321,933
ORA	$7,733,467	$8,498,654	$7,443,695	$8,628,940	$8,880,776	$9,143,184
HQ	$54,211,488	$58,486,768	$55,910,342	$56,102,552	$59,097,922	$55,178,077
Total Rent	$49,964,883	$65,278,320	$52,437,964	$65,931,103	$66,590,414	$67,256,319
Total Shared Services	$130,936,781	$133,751,844	$134,192,042	$136,248,526	$137,611,011	$138,987,121
Total Obligations	**$1,062,111,583**	**$1,043,272,234**	**$1,017,144,309**	**$1,086,732,719**	**$1,135,105,800**	**$1,176,026,364**

Carryover	FY 2018	FY 2019		FY 2020	FY 2021	FY 2022
	Actual	Estimate	Actual	Estimate	Estimate	Estimate
Total Carryover, End of Year	$209,223,938	$186,273,705	$220,088,812	$217,070,092	$212,767,292	$213,794,928
Carryover Unavailable for Use, End of Year	($83,850,995)	($83,850,995)	($83,850,995)	($83,850,995)	($83,850,995)	($83,850,995)
Carryover Available for Use, End of Year	**$125,372,943**	**$102,422,710**	**$136,237,817**	**$133,219,097**	**$128,916,297**	**$129,943,933**

**Numbers rounded to nearest whole dollar*
Target Revenue has been rounded to the nearest thousand dollars
†Indicates an actual amount

Carryover Balance

- Available carryover decreased from beginning of FY18 to end of FY20 (est.) by $99.8M
- Ending balance in FY22 accounts for roughly 9.5 weeks of operating reserves

Impact of Fee Structure Change

Increase in efficiency and stability

- Elimination of burdensome fees and additional “cleanup” billing
- In FY19 FDA collected 100.49% of the planned target revenue
- Through the first two years of PDUFA VI, FDA has collected 100.08% of the total planned target revenue

Overview of the BsUFA Financial Plan

Budgetary Resources	FY 2018	FY 2019		FY 2020	FY 2021	FY 2022
	Actual	Estimate	Actual	Estimate	Estimate	Estimate
Target Revenue	**$40,214,000**	**$38,847,000**	**$38,847,000**	**$41,923,000**	**$42,943,000**	**$43,988,000**
Cash Collections	$29,238,601	$38,847,000	$34,685,713	$41,923,000	$42,943,000	$43,988,000
Recoveries	$1,074,997	$500,000	$456,236	$400,000	$400,000	$400,000
Carryover Available for Use, Beginning of Year	$48,223,308	$38,257,343†	$38,257,343	$31,340,903†	$26,855,616	$22,338,762
Total Budgetary Resources	**$78,536,907**	**$77,604,343**	**$73,399,291**	**$73,663,903**	**$70,198,616**	**$66,726,762**

User Fee Obligations	FY 2018	FY 2019		FY 2020	FY 2021	FY 2022
	Actual	Estimate	Actual	Estimate	Estimate	Estimate
Payroll & Operating						
CBER	$-	$460,297	$-	$300,000	$307,302	$314,781
CDER	$31,113,433	$34,137,860	$33,004,440	$37,274,273	$38,181,492	$39,110,791
ORA	$1,128,256	$1,407,248	$676,738	$1,440,770	$1,475,837	$1,511,757
HQ	$2,293,521	$1,785,744	$1,529,197	$1,515,983	$1,555,190	$1,247,082
Total Rent	$1,104,785	$1,520,934	$1,382,811	$1,536,143	$1,551,504	$1,567,019
Total Shared Services	$4,639,568	$5,405,403	$5,465,202	$4,741,118	$4,788,529	$4,836,414
Total Obligations	**$40,279,564**	**$44,717,486**	**$42,058,388**	**$46,808,287**	**$47,859,854**	**$48,587,846**

Carryover	FY 2018	FY 2019		FY 2020	FY 2021	FY 2022
	Actual	Estimate	Actual	Estimate	Estimate	Estimate
Total Carryover, End of Year	$38,757,343	$33,386,857	$31,840,903	$27,355,616	$22,838,762	$18,638,917
Carryover Unavailable for Use, End of Year	($500,000)	($500,000)	($500,000)	($500,000)	($500,000)	($500,000)
Carryover Available for Use, End of Year	**$38,257,343**	**$32,886,857**	**$31,340,903**	**$26,855,616**	**$22,338,762**	**$18,138,917**

*Numbers rounded to nearest whole dollar
†Indicates an actual amount

Collection Shortfall

Collections were short of our revenue target in FY19 by 9%

- Fee paying applications were 22% lower than anticipated

Carryover Balance

FDA has decreased obligation estimates in future fiscal years to ensure that it can maintain a balance of roughly 21 weeks of operating by the end of FY22

- The volatility of the program requires the need to maintain a higher weekly balance than other programs

Impact of Spending Trigger

Spending Trigger Background

- FDA may not spend BsUFA fees in a fiscal year unless it allocates a minimum of $20,000,000 in appropriated funds (excluding user fees), multiplied by the adjustment factor applicable to that fiscal year, for the BsUFA program. The specified minimum level for FY19 is $22,038,420. The statute provides that this requirement is met if at least an amount that is 15% below the FY19 minimum level is spent.
- In FY19, FDA allocated and obligated $23,152,080 in appropriated funds (excluding user fees) for the BsUFA program. Since this was more than the specified minimum amount in FY19, the second legal condition was satisfied

Volatile workload impacts our ability to spend fees

- Results in conservative spending approach
- In FY19, FDA cleared the spending trigger by 5%
- This impact is limited by the 15% threshold granted by Statute
  - FDA cleared the 15% below threshold by $4.4M

Overview of the GDUFA Financial Plan

Budgetary Resources	FY 2018	FY 2019		FY 2020	FY 2021	FY 2022
	Actual	Estimate	Actual	Estimate	Estimate	Estimate
Target Revenue	**$493,600,000**	**$501,721,000**	**$501,721,000**	**$513,223,000**	**$525,714,000**	**$538,510,000**
Cash Collections	$493,655,974	$501,721,000	$496,503,494	$513,223,000	$525,714,000	$538,510,000
Recoveries	$4,920,184	$4,000,000	$8,544,957	$5,000,000	$5,000,000	$5,000,000
Carryover Available for Use, Beginning of Year	$137,412,048	158,715,667[†]	$158,715,667	$199,171,168[†]	$166,138,068	$137,560,699
Total Budgetary Resources	**$635,988,205**	**$664,436,667**	**$663,764,117**	**$717,394,168**	**$696,852,068**	**$681,070,699**

User Fee Obligations	FY 2018	FY 2019		FY 2020	FY 2021	FY 2022
	Actual	Estimate	Actual	Estimate	Estimate	Estimate
Payroll & Operating						
CBER	$49,462	$982,344	$23,658	$1,004,864	$1,029,321	$1,054,374
CDER	$323,591,582	$323,783,061	$316,437,772	$370,219,339	$379,203,830	$382,105,904
ORA	$46,518,651	$47,841,387	$40,694,363	$50,938,151	$50,129,256	$51,349,352
HQ	$27,801,624	$35,894,703	$27,565,531	$44,408,872	$43,397,237	$34,211,819
Total Rent	$22,019,962	$25,795,102	$24,962,969	$26,053,053	$26,313,583	$26,576,719
Total Shared Services	$57,291,257	$54,723,889	$54,908,657	$58,631,822	$59,218,140	$59,810,322
Total Obligations	**$477,272,539**	**$489,020,486**	**$464,592,949**	**$551,256,100**	**$559,291,369**	**$555,108,489**

Carryover	FY 2018	FY 2019		FY 2020	FY 2021	FY 2022
	Actual	Estimate	Actual	Estimate	Estimate	Estimate
Total Carryover, End of Year	$163,715,667	$180,416,181	$204,171,168	$171,138,068	$142,560,699	$130,962,210
Carryover Unavailable for Use, End of Year	($5,000,000)	($5,000,000)	($5,000,000)	($5,000,000)	($5,000,000)	($5,000,000)
Carryover Available for Use, End of Year	**$158,715,667**	**$175,416,181**	**$199,171,168**	**$166,138,068**	**$137,560,699**	**$125,962,210**

Numbers rounded to nearest whole dollar

Carryover Balance

- Expected to decrease significantly by the end of FY22
- Additional spending not expected to impact program going into FY23
- FDA is assessing opportunities to invest GDUFA resources to support the program. It continues to strive to hire scientific and regulatory staff, while also making targeted strategic investments to enhance productivity, support regulatory science and policy efforts, and ensure the availability of safe and effective generic drug products. FDA will continue working to ensure the financial resources available to the GDUFA program are being invested to support the long-term sustainability and productivity of the review program.

9:40 – 10:00 AM

RESOURCE CAPACITY PLANNING IMPLEMENTATION UPDATES

Josh Barton
Director, Resource Capacity Planning Team
Office of Program and Strategic Analysis | CDER

Agenda

#	Description
1	RCP Capability Update
2	Capacity Planning Adjustment Methodology

RCP Commitments

- As part of PDUFA VI, BsUFA II, and GDUFA II, FDA committed to:
  - Modernize its activity-based **time reporting**
  - Building a **resource planning capability (RCP)**

- The capabilities would provide FDA with the tools to better understand its **future resource needs** and adjust internal operations to meet the expected workload

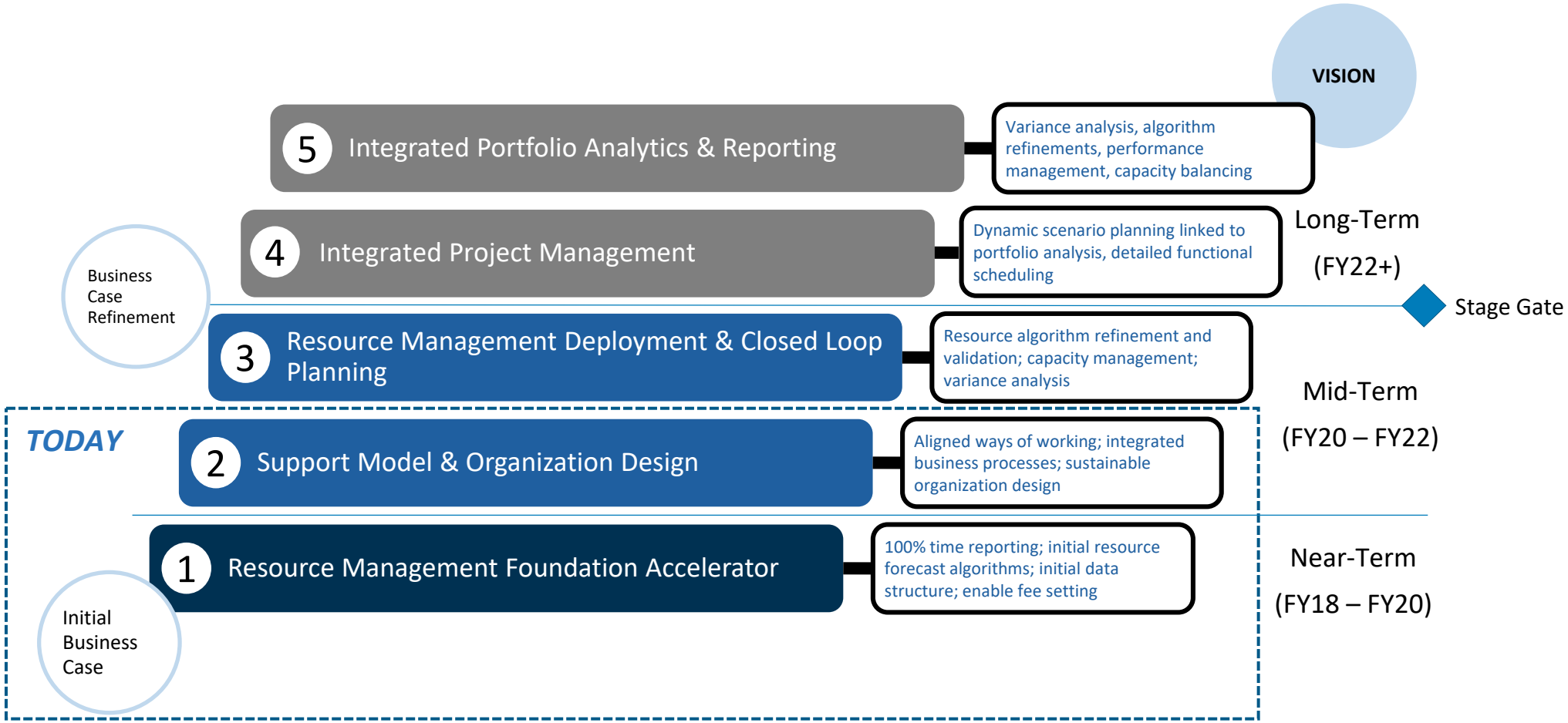
- There was a recognition that these two capabilities, when established, would provide FDA with the data to better inform a more optimal **Capacity Planning Adjustment (CPA)** for its user fee target revenue for **PDUFA and BsUFA**.

Progress towards Commitments

Commitment	Status
Publish an RCP/MTR implementation plan incorporating recommendations from a 3rd party by end of Q2 FY18	• Complete: https://www.fda.gov/media/112562/download
Staff an RCP team to implement and manage RCP system	• Team established in CDER to lead RCP implementation in collaboration with CBER • HQ team established to lead Insight Time Reporting
Conduct 3rd party assessment to recommend **new methodology to adjust fee revenue amounts based on resource needs**	• **PDUFA/BsUFA evaluation published; docket closed in May** • After public comment, **FDA may adopt new revenue adjustment method for PDUFA & BsUFA**

FDA's Journey to Excellence in Operations

FDA's vision will be achieved by first establishing a foundation and then building additional, more mature capabilities over time.



What is Resource Capacity Planning?

RCP allows FDA to identify the resources needed **before** they are needed

Modernized Time Reporting (MTR)

52-week time reporting to provide:

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

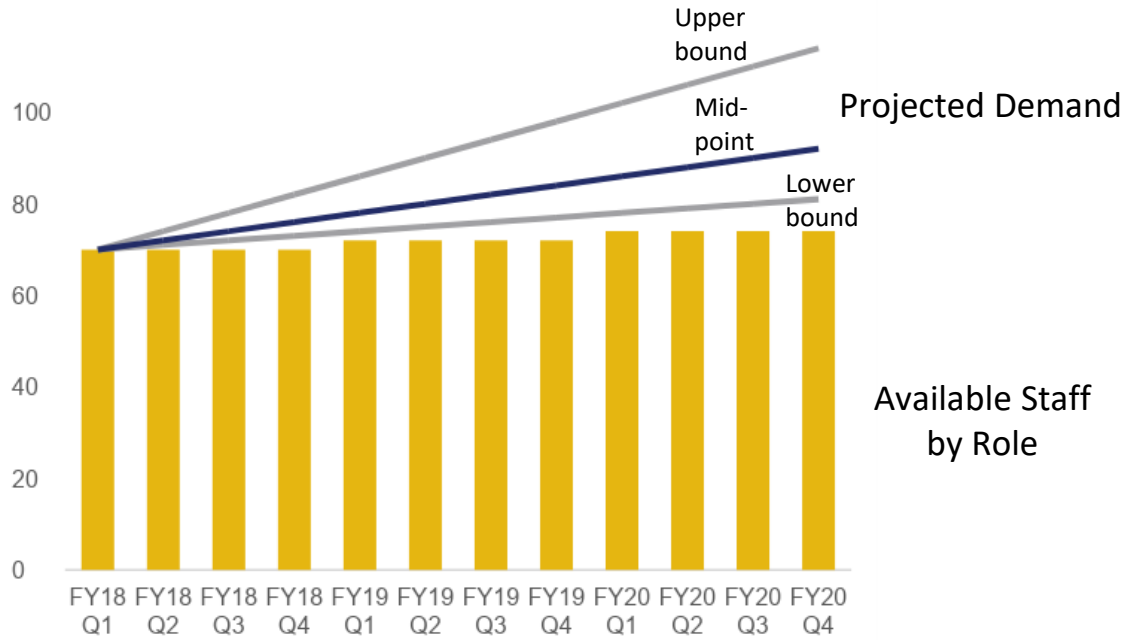
Workload Forecasting

Advanced analytics to forecast likely incoming work & productivity

Operational Data

HR Data (attrition, hiring times)
Financial Data

Resource Forecast



Applications of Resource Forecasts

Capacity Balancing
Identify ops to prioritize existing resources

Revenue Adjustment

Hiring Plans

Financial Forecasting

RCP near-term implementation timeline

Done

Build Foundational Capabilities

- Implement Time Reporting across CDER & CBER
- Develop the methodology for advanced resource capacity planning

Ongoing

Operationalize RCP Capabilities

- Ensure Time Reporting compliance & accuracy
- Operationalize predictive models and algorithm engines to produce resource forecasts

Next Steps

Develop Sustainable & Scalable IT & Support to Expand Capabilities

- Develop a technical infrastructure to enhance automation and replicability, of analysis and reporting
- Expand IT/RCP capabilities to other centers
- Build an enterprise-wide support model to sustain RCP capabilities

Program milestones to date

Established Time Reporting within CDER and CBER

- ~ 6,000 employees recording time year-round within CDER & CBER
- Achieved at least 95% center-wide compliance
- Created interactive dashboard visualizations to enable leadership decision-making

Designed predictive models for incoming regulatory submissions

- Developed models to predict upcoming future submissions (IND, NDA, BLA, supplements) and industry meetings across CDER and CBER
- Improved upon the previously used three-year average methodology

Developed future-looking resource forecasts

- Created continuous forecast resource algorithms which utilize time reporting and historical submission data
- Developed resource algorithms across both CDER and CBER offices

* CDRH and Oncology Center of Excellence have also recently implemented Insight Time Reporting

RCP capabilities will enhance the way FDA operates

Resource capacity planning is built on the data gathered through implementation of time reporting and sets the organization up for a more structured, data-driven approach to operational decisions.

Proactive Resource Planning

- Reprioritization of work and resources based on time reporting and utilization data
- Targeted hiring plans based on workload forecasts

Improved User Fee Setting Methodology

- Data driven target revenue adjustments based on predictive modeling of resources rather than historical averages of submission volume
- Ability to incorporate increases in submission complexity into the adjustment
- Future forecasts can provide foundational data for updating of the Five-year Financial Plan

Enhanced Management of Financial Resources

- Increased visibility into future resource needs to inform budget
- Tracking of forecasted financial needs versus actuals

Improved user fee setting methodology

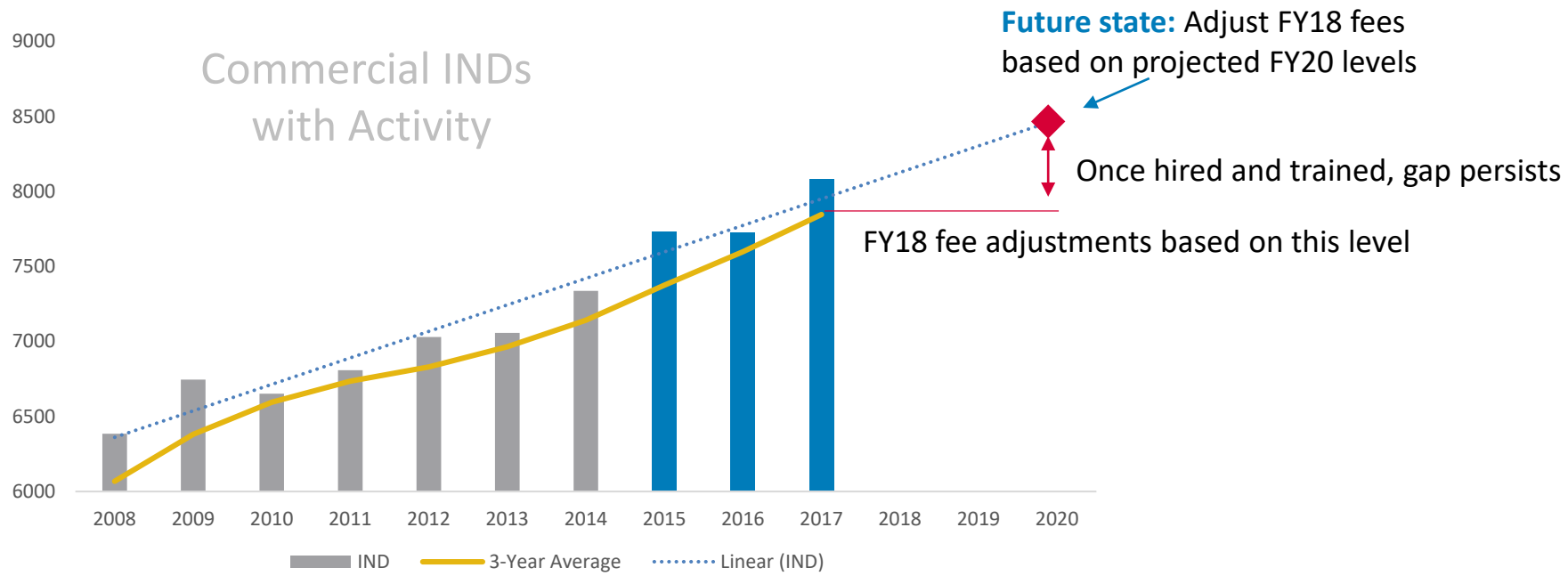
The new fee revenue setting methodology improves upon the interim CPA by developing a forward-looking approach.

PDUFA Current state adjustment:

- Lagging indicator using 3-year averages
- Compensates for increases occurring in the past
- Based on submission counts
- Timing compounded by hiring timeframes

Future state adjustment:

- Forward looking
- Compensates for likely increases
- Translates submission activity to likely resource demand
- Times resources to account for hiring and training timeframes



CPA adjustment approach

The adjustment accounts for expected direct review work – work driven directly by incoming volume of submissions.

1. Forecast Submission Volume

- Predictive models estimate the volume of direct review submissions

Includes:

- Commercial INDs/BPDs
- Original NDAs/BLAs
- Efficacy Supplements
- Labeling Supplements*
- Manufacturing Supplements
- Industry Meetings

2. Calculate Future Resource Forecast

- FTE forecast algorithms informed by time reporting data
- These algorithms forecast the required FTE demand for direct review effort

3. Assess Feasibility of Acquiring Needed Resources

- Compare the forecast against capacity and adjust the forecast to ensure that an adjustment is made only for what is needed and what can realistically be utilized.

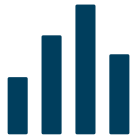
4. Convert Adjusted FTEs to Dollars

- Determined by FTE cost model
- The final feasible FTEs needed will be converted to a dollar amount and added to the inflation-adjusted annual target revenue

** New submission type included in adjustment*

Fully enabling RCP capabilities

The foundational RCP capabilities have been built, however development and identification of improvement opportunities continues.



Continually improve predictive models and resource algorithms

- Integrate additional data sources into the workload models for enhanced accuracy
- Ensure that time reporting compliance remains high and that activities are reported accurately
- Incorporate additional drivers of effort into resource forecasting algorithms

Build and maintain a technical environment to support RCP operationalization

- Create an environment to store foundational data in a centralized location
- Enable an advanced analytical capability to run predictive models and resource algorithms
- Provide visualization and reporting of RCP outputs to inform operational decision-making

Continue to incorporate RCP into FDA business processes and operations

- Integrate RCP outputs into FDA financial processes
- Hire required talent to support RCP capability at FDA
- Change its ways of working to support and maintain the RCP capability into the future

10:00 – 10:20 AM

CAPACITY PLANNING ADJUSTMENT EVALUATION AND FINDINGS

Booz Allen Hamilton

As part of the Prescription Drug User Fee Act (PDUFA) VI and Biosimilar User Fee Amendments (BsUFA) II commitments, FDA is developing a resource capacity planning function to enhance the management of user fee resources

Background

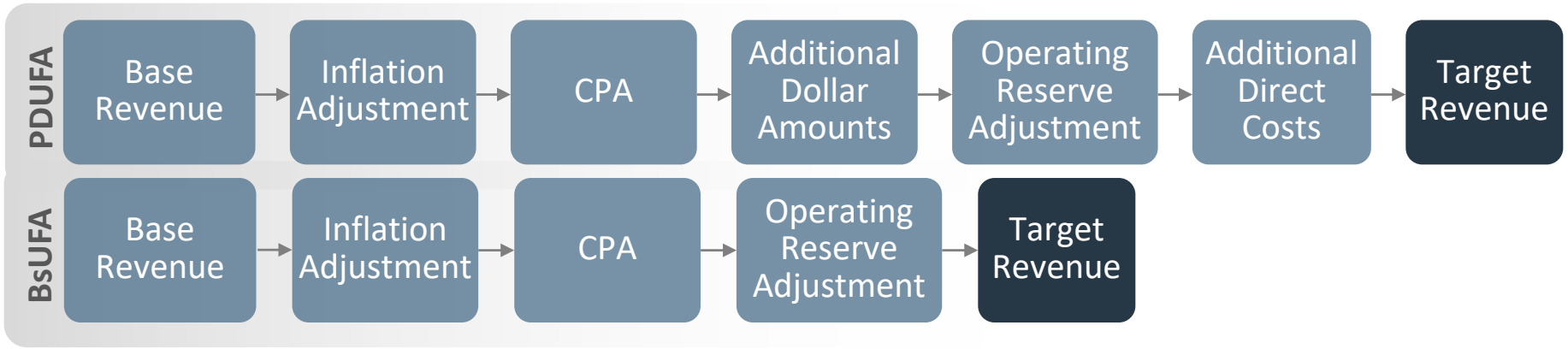
- The Food and Drug Administration (FDA) Reauthorization Act of 2017 (FDARA) requires FDA to develop a new capacity planning adjustment (CPA) methodology that accounts for sustained increases in workload for the human drug and biosimilar programs
- The proposed CPA methodology will adjust the annual base revenue to reflect changes in the resource capacity needs to review human drug, biologic, and biosimilar product submissions for the PDUFA and BsUFA programs
- FDA contracted Booz Allen to conduct an evaluation of the FDA's proposed CPA methodology for determining the resource needs of the PDUFA and BsUFA programs

Scope

- Evaluate FDA's proposed CPA methodology to assess the sustained workload and resource needs for the PDUFA and BsUFA user fee programs in comparison to the interim CPA methodology
- Provide recommendations and considerations that could feasibly improve the proposed CPA methodology

Currently, only PDUFA employs an interim CPA methodology. FDA is proposing to use a new, robust CPA methodology for both PDUFA and BsUFA that uses a four-step structured and data-driven process to determine the adjustment factor

PDUFA and BsUFA Target Revenue Methodologies



Booz Allen is also conducting a similar evaluation of the CPA methodology for the GDUFA program

The key objectives for the GDUFA evaluation are:

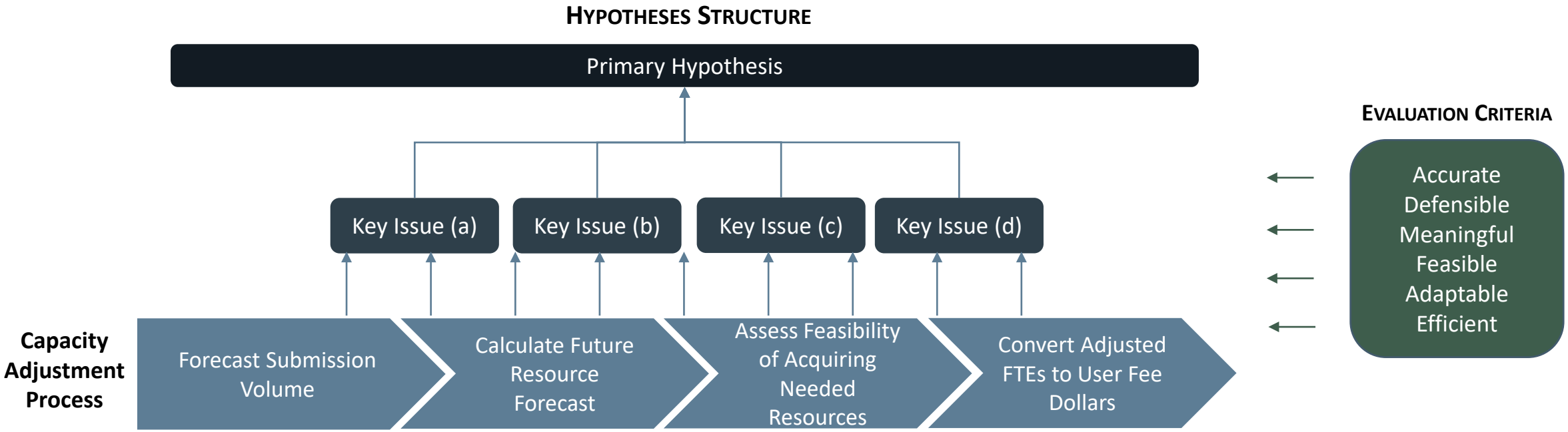
- Evaluate if the FDA's proposed methodology that assesses the workload level and resource needs of a user fee program could be applied.
- Determine if the FDA's proposed methodology could be used to monitor and report on resource needs.
- Provide recommendations and considerations that could feasibly improve the proposed methodology.

Overall, the GDUFA evaluation findings and recommendations align with the outcomes of the PDUFA and BsUFA evaluation:

- A similar approach can be applied to GDUFA, however, there are some program-specific differences reflected in how findings and recommendations are presented.
- The methodology outputs could meet the monitoring and reporting needs of the program. The methodology produces additional resource needs, in terms of FTEs, that would be required to support the direct review work. These resource needs could be communicated to industry stakeholders.

Booz Allen employed a hypothesis-driven approach to evaluate whether the proposed CPA methodology represents an improvement over the interim CPA methodology in assessing FDA's resource needs

The graphic below illustrates the bottom-up approach of the hypotheses structure that uses data and metrics to analyze: (1) the capacity adjustment process using distinct evaluation criteria, (2) key issues, and ultimately (3) answer the primary hypothesis.



An evaluation of key issues identified by FDA with interim CPA methodology was conducted to assess whether the proposed methodology represents an improvement over the interim methodology

An interim CPA methodology was employed for PDUFA while FDA developed and implemented a new and more robust methodology. FDA assessed this interim methodology to identify opportunities for improvement and was able to identify four key issues they intended to address within the proposed methodology.

Key Issues with PDUFA Interim CPA Methodology

Key Issue	Description
Interim CPA methodology is a lagging indicator	• The interim CPA methodology uses averages from previous years' workload submission volume. • Lagging indicators such as these give insights into the past however are not traditionally the best method to use for future workload.
Interim CPA methodology does not convert submission counts into resource demand	• The interim CPA methodology produced a cost percentage adjustment, which was added to the inflation-adjusted based revenue. • This does not accurately reflect resource capacity needs as there are no insights into how many FTEs FDA requires to meet workload demand.
Interim CPA methodology does not account for 'complexity'	• Complexity refers to the range of scientific and technical intricacies of human drugs, which can result in additional resource demand due to the novel regulatory issues and special considerations. • The interim CPA methodology does not include a way to measure this complexity.
Commitment to support 'organizational review components engaged in direct review work'	• The interim CPA methodology does not account for direct review submission type of labeling supplements. • FDA agreed that the organizations within FDA that execute the direct review work associated with the increased workload submission volume receive the funds generated from CPA.

Booz Allen also developed hypotheses based on six different evaluation criteria to drive our approach in assessing the potential effectiveness of the capacity adjustment process

Booz Allen selected criteria that were relevant and realistic ways of assessing the CPA, given the current phase of implementation. The development of definitions for each evaluation criteria accounted for a conceptual-level evaluation of the CPA.

Evaluation Criteria and Definitions

Criteria	Definition
Accurate	The methodology comprehensively includes workload submission types in a manner that will likely forecast resource demands close to real world figures (e.g., submission volume), and results will likely be reliable and unbiased.
Adaptable	The methodology can be scaled up as data and environment grow, expand, and change with new and evolving business needs.
Defensible	The objectives, inputs, mechanism, rationales, and expected outputs of the methodology are clearly defined. Methods and expected outputs are compatible with specified requirements.
Efficient	The methodology can be maintained in a manner that maximizes benefits, optimizes resources, and minimizes effort.
Feasible	The methodology can be implemented as planned and can be replicated and maintained in future years.
Meaningful	Expected methodology outputs are relevant and valid to the questions they are informing and are understood and accepted by decision-makers.

Booz Allen identified opportunities to strengthen the proposed CPA methodology and developed feasible recommendations to assist FDA in its further implementation based on analysis of data collected

Data collection and analysis occurred prior to implementation of the proposed methodology and focused on a conceptual analysis to ensure that the methodology employed by FDA would foreseeably provide accurate forecasts for resource needs.

Data Collection and Analysis Approach

Data Collection	Data Aggregation	Analysis	Recommendation Development
Collected information and data from the following sources: • Proposed CPA methodology documentation • Historical CPA documentation • Financial and resource documentation • Modernized Time Reporting (MTR) framework • FDA interviews and targeted discussions	• Developed central data repository • Added structure based on evaluation framework hypotheses and related questions • Tracked data and information collected across applicable evaluation framework components	• Validated hypotheses were fully addressed • Compared data and information collected against evaluation framework hypotheses • Identified themes based on analysis	• Developed implementation opportunity areas based on analysis • Outlined recommendations to address opportunities • Provided rationale for each recommendation

Booz Allen developed findings based on the proposed CPA's relationship to the definition of each evaluation criteria, which provides evidence that the proposed CPA methodology is an improvement from previous methodologies

There are distinct features in the proposed CPA methodology that address key issues identified by FDA in the interim CPA methodology:

Key Issues Findings

Key Issue	Finding
Interim CPA methodology is a lagging indicator	• The proposed CPA methodology is forward-looking by helping to estimate the likely submission volume and sustained resource demand required to support the direct review workload. • FDA will build predictive models through advanced analytical techniques using multiple data sources that can be a leading indicator to estimate submission volume.
Interim CPA methodology does not convert submission counts into resource demand	• The proposed CPA methodology uses time reporting data to convert estimated submission volume into resource needs measured by FTEs. • Historical data will be analyzed to understand the level of effort which helps convert the estimated submission forecasts into an estimated resource demand.
Interim CPA methodology does not account for 'complexity'	• The proposed CPA methodology analyzes the historical time reporting data which helps FDA capture a macro-level measure of complexity for each of the direct review workload submission types. • If the complexity on an average is increasing for any of the submission types, the time reporting data should reflect that increase in the average amount of time required per application.
Commitment to support 'organizational review components engaged in direct review work'	• The proposed CPA methodology will comprehensively consider all the direct review submission categories including the labeling supplements. • The interim CPA methodology excluded labeling supplements.

Booz Allen found that the CPA comprehensively includes workload submissions types that will likely forecast resource demand, can be scaled up as the data and environment grows, and meets specified requirements

Evaluation Criteria Findings

Accurate

- The workload forecast models will likely represent the amount of submissions FDA receives based on the approach used to predict submission volume.
- The proposed CPA methodology captures major types of direct review workload to measure the amount of resources needed.

Adaptable

- The proposed CPA methodology can account for new and expanded data sources through the use of open source software, which can read variety of data formats and operate within different technological environments.
- The managerial adjustment process can help FDA account for foreseeable future business needs that may impact resource demand.

Defensible

- The proposed CPA methodology aligns to requirements set in FDARA, and was developed using domain expertise.
- The overall CPA methodology and model development process are based on assumptions that are expected to remain true over time.

It was also found that the proposed CPA methodology optimizes resources, has the ability to be replicated and maintained, and the outputs expected to be relevant and valid for the purposes of forecasting resource needs

Evaluation Criteria Findings

Efficient

- FDA plans to create a technical infrastructure that can support components related to automation and operationalization of the model development process.
- FDA uses existing technology for forecasting and customizes to the unique challenges that are relevant in estimating the workload level and resource needs.

Feasible

- The overall paradigm of the proposed CPA methodology is fully documented and outlines the steps used to calculate the CPA factor for PDUFA and BsUFA.
- FDA has the tools and data sources available to begin the implementation of the proposed CPA methodology.

Meaningful

- The managerial adjustment process includes the following factors: 1) accuracy of previous years' forecasts, 2) if forecast resource needs are sustained over the next three years, 3) hiring and attrition rate trends, and 4) availability of other sources of funding.
- These potential decision factors were verified to be interpretable by the decision-makers and will likely give them relevant business insights to make informed decisions.

Booz Allen identified five potential actions to support the FDA's intent to continuously improve the CPA as data, tools, and processes mature throughout the implementation of the proposed CPA methodology

Summary of Recommendations

Prediction Interval	A prediction interval is a range with an upper and lower limit between which the expected resource needs to lie, based on a certain probability, which allows decision-makers the ability to assess the future uncertainty in the mean estimates and make relative adjustments.
Model Interpretability	Model interpretability is an exercise that can help FDA further understand why the models are estimating specific number of submissions and provide insights into how different values in variables from data sources play a role on the forecasts.
Related Direct Review Workload	FDA may want to explore expanding these models to reflect additional workload that may not tie directly to these major submission types, such as post-market safety and some subsets of policy and guidance development, but still be considered complex types of direct review work.
Managerial Adjustment Process	FDA may continue refining the managerial adjustment process with additional steps and data to help make informed decisions, such as evaluating managerial adjustment accuracy, developing business scenarios, and generating hiring metrics.
Methodology Documentation	FDA should consider including the overall methodology assumptions, rationales, and procedures in related documentation to help provide a baseline as the methodology evolves over time.

FDA may consider whether creating prediction intervals for the resource demand forecasts would add practical value for the decision-makers in the managerial adjustment process

Prediction Interval

- A prediction interval is a range with an upper and lower limit between which the expected resource needs lie, based on a certain probability.
- FDA may consider whether creating prediction intervals for the resource demand forecasts would add practical value for the decision-makers in the managerial adjustment process.

Benefits

- Decision-makers could use prediction intervals to assess the future uncertainty in the mean estimates produced by the resource demand forecast and make relative adjustments.
- If there is a high level of future uncertainty based on the prediction intervals, the managerial adjustment process may want to be conservative in the adjustments on the mean estimates of resource demand forecasts.
- This information would help supplement the other factors to consider in the managerial adjustment process.
- The prediction intervals may lead to additional accuracy in adjustments to resource demand forecasts by providing more insights into their uncertainty.
- This may also help provide further meaningful outputs to the decision-makers involved in the managerial adjustment process.

FDA may consider whether increasing interpretability within the complex models used in advanced analytical techniques for workload forecasting would help inform the managerial adjustment process

Model Interpretability

- Model interpretability is a data science exercise that can help FDA further understand why the models are estimating specific number of submissions.
- FDA may consider whether increasing interpretability within the complex models used in advanced analytical techniques for workload forecasting would help inform the managerial adjustment process.

Benefits

- Decision-makers may use the outputs of model interpretability exercise to understand the impact on workload and resource needs from various what-if business scenarios.
- Additionally, FDA could develop these business scenarios for the decision-makers, in collaboration with stakeholders, to produce only relevant qualitative factors.
- The model interpretability outputs and the application of what-if business scenarios may help provide additional meaningful outputs to the decision-makers involved in the managerial adjustment process.
- By adapting the methodology to include other types of direct review work, this may allow FDA to calculate any additional resource needs with further accuracy.

As the methodology continues to iterate yearly, FDA may want to perform data exploration that analyzes how to incorporate other, more complex types of direct review work into the workload and resource demand forecast models

Related Direct Review Workload

FDA may want to perform data exploration that analyzes how other, more complex types of direct review work, such as post-market safety and some subsets of policy and guidance development, could be incorporated into the methodology.

Benefits

- Currently, FDA includes all the major submission types in the workload forecast models; however, FDA may want to explore expanding these models to reflect additional workload that may not tie directly to these major submission types.
- Data exploration will help FDA identify how to incorporate these additional complex types of potential direct review work that the proposed CPA methodology does not capture currently.
- By adapting the methodology to include other types of direct review work, this may allow FDA to calculate any additional resource needs with further accuracy.

As the methodology matures, FDA may want to continue refining the managerial adjustment process to help make further informed decisions

Managerial Adjustment Process

FDA may continue refining the managerial adjustment process with additional steps and data to help make informed decisions by: 1) evaluating the accuracy of adjustments made in the previous fiscal years' managerial adjustment process, 2) exploring the development of business scenarios, and 3) generating hiring metrics.

Benefits

- FDA should consider evaluating the accuracy of adjustments made in the previous fiscal years' managerial adjustment process; if previous adjustments were too high or too low, FDA can evaluate the decisions made and identify the changes needed in the decision-making framework for continuous improvements.
- FDA should implement and validate rigorous decision frameworks to ensure objectivity and consistency for how to identify business scenarios associated with changes in program requirements, commitments, and priorities.
- FDA should consider generating hiring metrics that outline how long it takes on average to hire new FTEs by job role and discipline to help the decision-makers understand the feasibility and timing of onboarding the new FTEs identified to ensure FDA meets the resource needs of the user fee programs.
- These suggestions may help provide additional meaningful outputs to the decision-makers involved in the managerial adjustment process.
- This may enhance the accuracy of the adjustments to the resource demand forecasts during the process as well.

FDA should consider enhancing the documentation of the proposed CPA methodology to include overall methodology assumptions and model decision-making rationale

Methodology Documentation

FDA should consider including this overall methodology assumptions, rationale, and procedures in related documentation to help provide a baseline as the methodology evolves over time.

Benefits

- As the methodology matures, FDA should revise and enhance the assumptions for the overall process to reflect various iterations of the methodology. If the assumptions prove to be incorrect, this documentation will provide a baseline for the needed revisions to enable adaptability of the methodology over time.
- FDA may consider historical documentation of the rationale to support future analysis that enhances efficiency by providing a baseline for the needed revisions. To promote replicability and transparency, FDA may consider developing standard operating procedures.
- To promote replicability and transparency, FDA may consider developing standard operating procedures related to execution of the CPA process.
- By creating this documentation, the overall CPA methodology will be more defensible because there are clearly defined assumptions, rationales, and procedures.
- In addition, the documentation can create transparency and enhance communication with stakeholders.

10:20 – 10:45 AM

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

Jay Tyler
Chief Financial Officer
Office of Finance, Budget and Acquisitions

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.

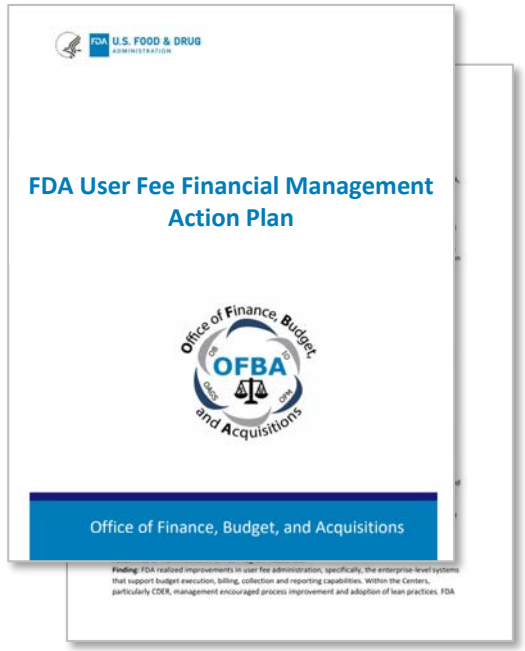
About: The Health FFRDC is the first **federally-funded research and development center** dedicated to protecting and promoting health and well-being. It is composed of an alliance of partners and members who are committed to providing conflict-free, objective expertise to HHS and its divisions.

FY2018 Financial Management Evaluation

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 Action Plan overview and progress in FY 2020

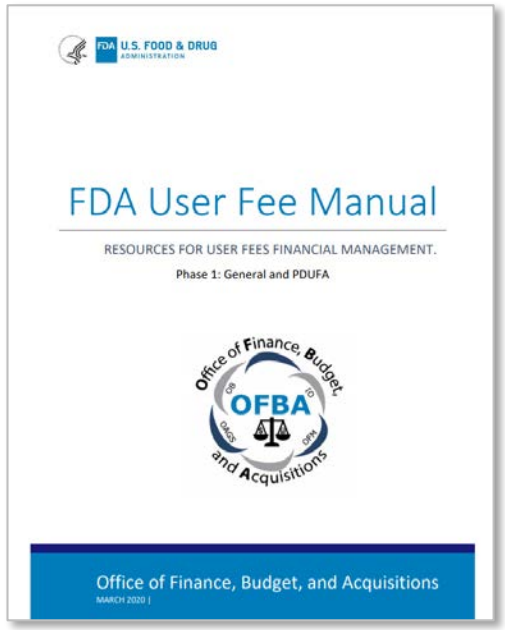
The FDA Action Plan is comprised of strategic and targeted measures that address the full scope of the evaluation's five focus areas. The FDA continues to track progress against the plan and is committed to continuous improvement.

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	On Track	Sept. 2020
	Develop and implement an online and classroom training module that covers user fee financial planning and administration.	On Track	Sept. 2020
	Require applicable FDA staffs to take the training and include this requirement in their performance plans for 2020	Completed	Sept. 2020
Focus Area 2: Administration of Fee Program Resources	Utilize specialized financial working group from the User Fee Financial Management Committee (UFFMC) to facilitate better financial analytics for user fee programs.	On Track	Sept. 2020
	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	On Track	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

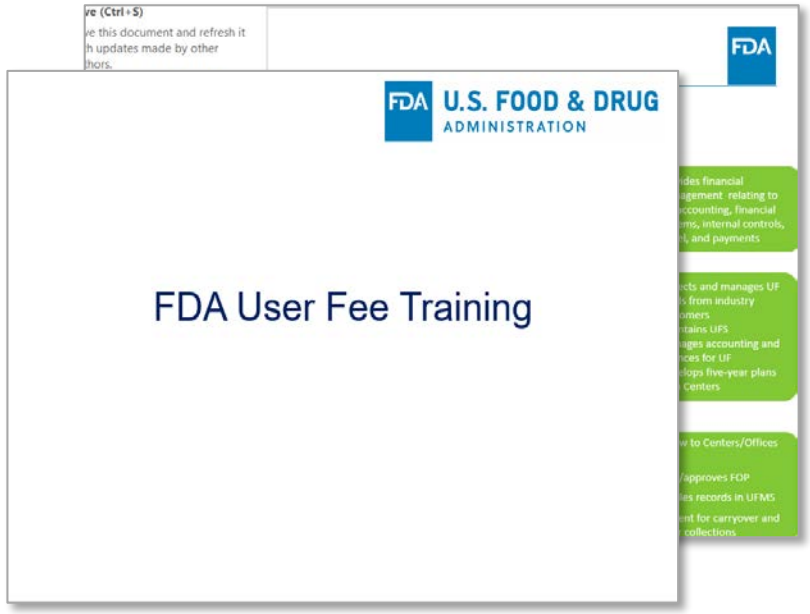
The FDA has taken a holistic approach to improve the financial management of human drug user fee programs. This includes developing new resources and integrating training on existing tools and reports to expand the knowledge base of FDA employees, better enabling them to keep up with the increasing complexity of the financial management of human drug user fee programs. The FDA is also in the process of developing an integrated Financial Management Manual, a “one-stop shop” for fiscal management resources that will be accessible to all FDA employees.

User Fee Manual



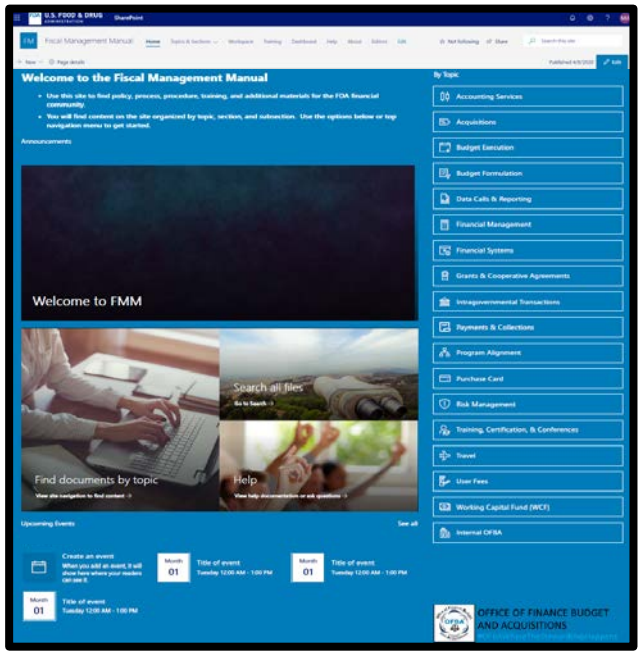
Launch: April 2020

Integrated Training Efforts



Launch: April 2020

Financial Management Manual



Expected Launch: June 2020

www.fda.gov

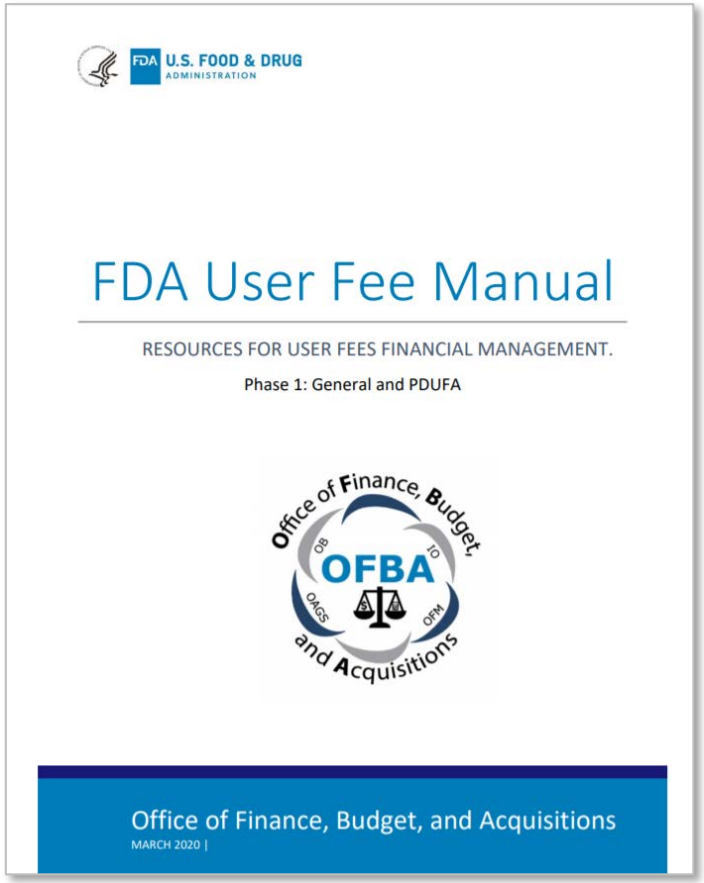
The FDA User Fee Manual

In response to the Health FFRDC's finding that there is an opportunity to increase the agency's knowledge base around understanding the financial management of user fee programs, the FDA developed the User Fee Manual to provide a centralized repository of user fee-specific financial management resources. Phase 1 of the User Fee Manual launched in April 2020 and Phase 2 is expected to launch in June 2020.

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 (expected to launch June 30, 2020)


U.S. FOOD & DRUG ADMINISTRATION

FDA User Fee Manual

RESOURCES FOR USER FEES FINANCIAL MANAGEMENT.

Phase 1: General and PDUFA

Office of Finance, Budget, and Acquisitions

MARCH 2020 |

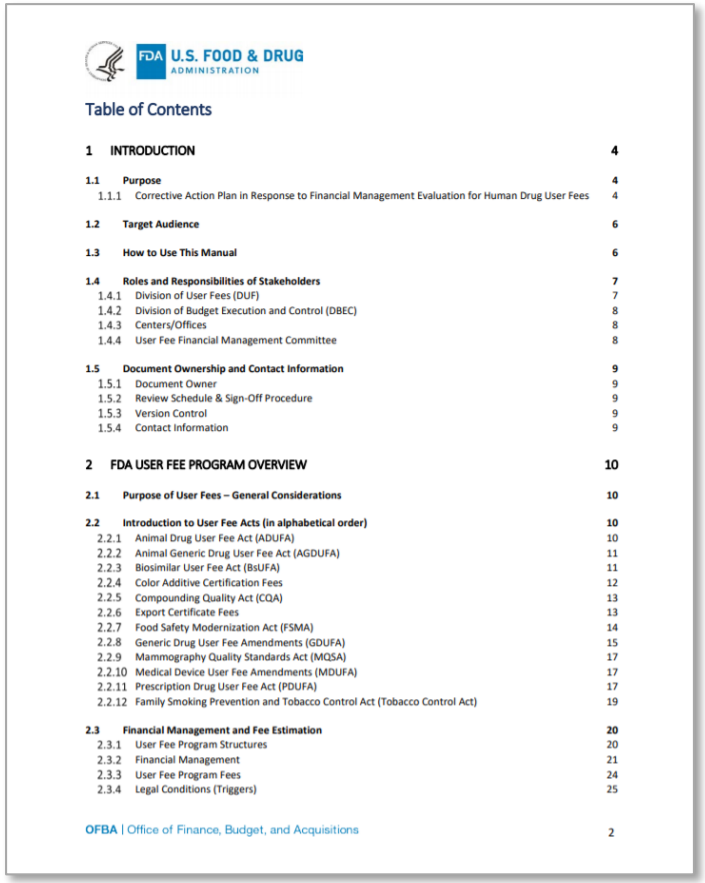

U.S. FOOD & DRUG ADMINISTRATION

Table of Contents

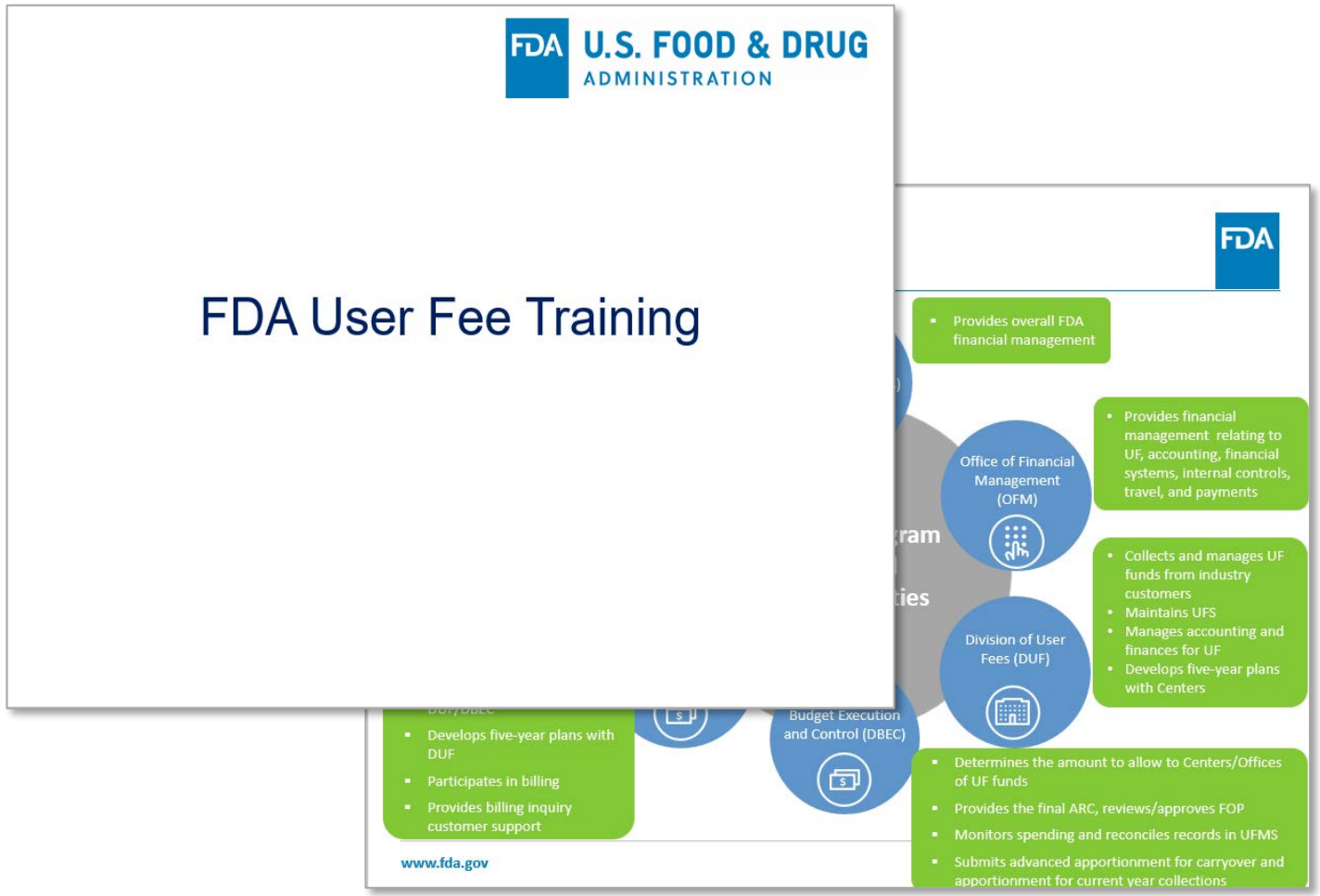
Integrated training efforts

In response to the Health FFRDC's finding that there is an opportunity to further increase technical understanding to better meet stakeholder needs, the FDA is integrating FDA-wide training on existing automated tools, systems and reports and has developed new trainings such as the FDA User Fee Training, which was launched in April 2020.

Training requirements on **existing automated tools** and **reports** have been incorporated into the 2020 **performance plans** of applicable FDA staff

This 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**

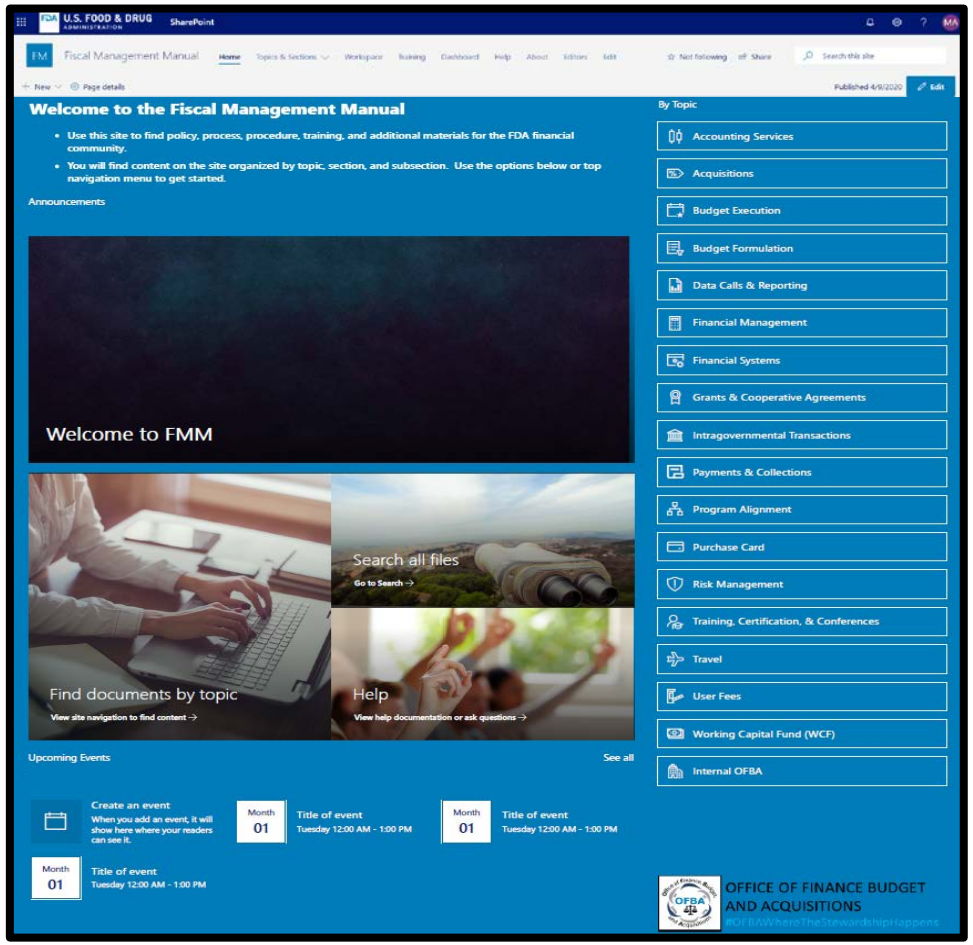


Looking ahead: Fiscal Management Manual

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 is in the process of developing a comprehensive fiscal manual, inclusive of sections on budget execution and user fee financial planning and administration. The manual is expected to launch in June 2020.

This Fiscal Management Manual will serve as a **"one-stop-shop"** for fiscal management resources and will be available FDA-wide

- **Easy access** to fiscal resources needed to perform job responsibilities
- **Improve** collaboration, productivity and learning **across FDA**
- **Increase consistency** to improve customer service



10:45 – 11:00 AM

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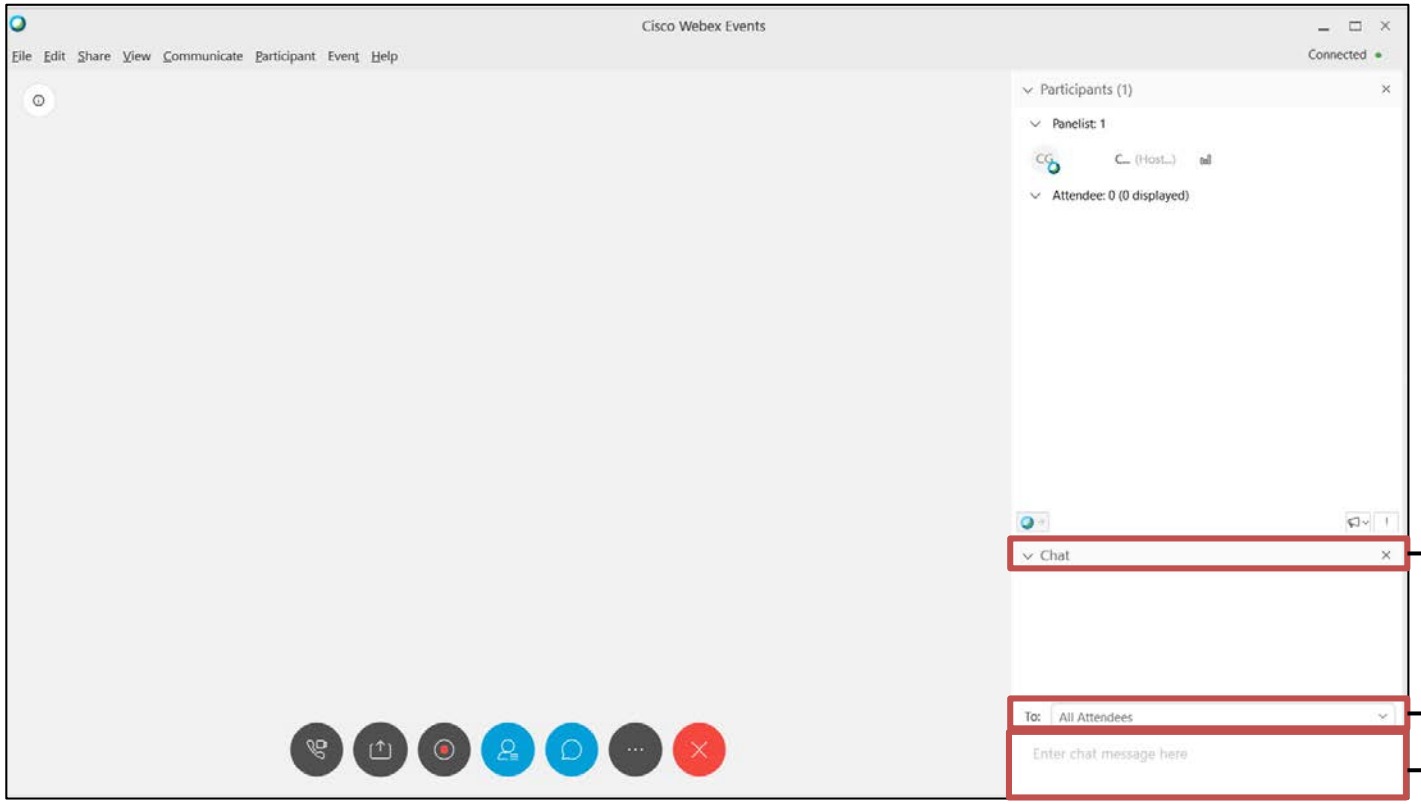

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