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 7, 2019
9:00 – 11:30 AM

Agenda

Topic	Presenter	Time
Welcome and Introduction	**Patrizia Cavazzoni, M.D.** Deputy Director for Operations Office of the Center Director | CDER	9:05 – 9:10 AM
General Overview of 5-Year Financial Plans	**David Miller** Director, Division of User Fees Office of Finance, Budget and Acquisitions	9:10 – 9:40 AM
Resource Capacity Planning (RCP) and Modernized Time Reporting (MTR) Implementation Progress	**Andrew Kish** Director Office of Program and Strategic Analysis | CDER **Josh Barton** Director, Resource Capacity Planning Team Office of Program and Strategic Analysis | CDER	9:40 – 10:20 AM
Break		10:20 – 10:30 AM
Financial Management Evaluation for Human Drug User Fees	**Jim Taylor** Grant Thornton, LLP | Health FFRDC	10:30 – 10:50 AM
FDA Response to Financial Management Evaluation	**Jay Tyler** Chief Financial Officer Office of Finance, Budget and Acquisitions	10:50 – 11:10 AM
Open Public Comment		11:10 – 11:30 AM

9:05 – 9:10 AM

WELCOME AND INTRODUCTION

Patrizia Cavazzoni, M.D.
Deputy Director for Operations
Office of the Center Director | CDER

9:10 – 9:40 AM

GENERAL OVERVIEW OF 5-YEAR FINANCIAL PLANS

David Miller
Director, Division of User Fees
Office of Finance, Budget and Acquisitions

Overview of the PDUFA Financial Plan

Prescription drug program target revenue for FY 2018 through FY 2022

Target Revenue	FY 2018 Actual	FY 2019 Actual	FY 2020 Estimate	FY 2021 Estimate	FY 2022 Estimate
Statutory Base	$878,590,000	$935,903,507	$1,001,480,000	$1,050,763,000	$1,092,005,000
Inflation Adjustment	$14,820,056	$16,572,979	$23,999,467	$27,060,562	$28,122,678
Capacity Planning Adjustment	$22,415,658	$27,685,634	$8,329,713	$8,754,891	$9,098,517
Additional Dollar Amounts	$20,077,793	$21,317,472	$16,953,329	$5,426,896	$2,769,609
Operating Reserve Adjustment	($33,287,582)	$0	$0	$0	$0
Additional Direct Costs Adjustment	$8,730,000	$8,842,303	$9,022,587	$9,213,173	$9,406,204
Target Revenue Total	**$911,346,000**	**$1,010,322,000**	**$1,059,786,000**	**$1,101,218,000**	**$1,141,402,000**

**Target revenue rounded to the nearest thousand dollars*

- Base amount is set in statute
- The inflation adjustment adjusts the base amount to maintain the purchasing power of fee funds in consideration of inflation.
- The capacity planning adjustment is intended to adjust the PDUFA target revenue for changes in the workload, or capacity needs of the program. The method will be established through a process outlined in statute.
- The additional dollar amounts are enhancement funds, negotiated with Industry, that are added to the base each fiscal year.
- The operating reserve adjustment was established in statute to provide a mechanism to support the management of a reasonable amount of fee funds carried over from year to year. FDA has committed to keeping the carryover balance below 14 weeks of operating.
- The additional direct costs adjustment were directly negotiated with Industry and is added as a one time amount through statute yearly.

Overview of the PDUFA Financial Plan

Budgetary Resources	FY 2018		FY 2019	FY 2020	FY 2021	FY 2022
	Estimate	Actual	Estimate	Estimate	Estimate	Estimate
Target Revenue	**$911,346,000**	**$911,346,000**	**$1,010,322,000**	**$1,059,786,000**	**$1,101,218,000**	**$1,141,402,000**
Cash Collections	$911,346,000	$908,077,723	$1,010,322,000	$1,059,786,000	$1,101,218,000	$1,141,402,000
Recoveries	$0	$13,149,599	$10,000,000	$10,000,000	$10,000,000	$10,000,000
Carryover Available for Use, Beginning of Year	$232,969,623	$232,969,623	$125,372,944	$102,422,710	$103,888,514	$103,440,188
Total Budgetary Resources	**$1,144,315,623**	**$1,154,196,945**	**$1,145,694,944**	**$1,172,208,710**	**$1,215,106,514**	**$1,254,842,188**

User Fee Obligations	FY 2018		FY 2019	FY 2020	FY 2021	FY 2022
	Estimate	Actual	Estimate	Estimate	Estimate	Estimate
Payroll & Operating						
CBER	$134,345,871	$129,543,398	$133,147,243	$136,234,641	$141,237,332	$146,379,543
CDER	$655,258,274	$688,935,477	$641,479,230	$670,583,126	$702,933,383	$734,170,189
CDRH	$1,292,304	$786,091	$2,630,174	$3,990,769	$4,125,016	$4,264,200
ORA	$8,307,191	$7,733,467	$8,498,654	$8,630,125	$8,895,537	$9,170,525
HQ	$60,309,328	$54,211,488	$58,348,569	$47,861,070	$51,444,387	$51,046,563
Total Rent	$64,632,000	$49,964,883	$65,278,320	$65,931,103	$66,590,414	$67,256,319
Total Shared Services	$126,189,050	$130,936,781	$133,751,844	$135,089,362	$136,440,256	$137,804,659
Total Obligations	**$1,050,334,019**	**$1,062,111,583**	**$1,043,133,935**	**$1,068,320,196**	**$1,111,666,325**	**$1,150,190,996**

Carryover	FY 2018		FY 2019	FY 2020	FY 2021	FY 2022
	Estimate	Actual	Estimate	Estimate	Estimate	Estimate
Total Carryover, End of Year	$211,120,182	$209,223,939	$186,273,705	$187,739,509	$187,291,183	$188,601,187
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	**$127,269,187**	**$125,372,944**	**$102,422,710**	**$103,888,514**	**$103,440,188**	**$104,750,192**

**Numbers rounded to nearest whole dollar*

Carryover Balance

- Decreased from beginning of FY18 to end of FY19 (est.) by $46.7M
- Projected to stabilize from FY19 through FY22
- Ending balance in FY22 accounts for roughly 8.5 weeks of operating reserves

Impact of fee change structure

Increase in efficiency and stability

- Elimination of burdensome fees and additional billing
- In FY18 FDA collected 99% of the planned target revenue

Overview of the BsUFA Financial Plan

Biosimilar program target revenue for FY2018 through FY2022

Target Revenue	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	Actual	Actual	Estimate	Estimate	Estimate
Base Amount	$45,000,000	$40,214,000	$40,947,000	$41,922,000	$42,997,000
Inflation Adjustment	$ -	$733,463	$975,398	$1,075,132	$1,102,701
Capacity Planning Adjustment	N/A	N/A	TBD	TBD	TBD
Operating Reserve Adjustment	N/A	($2,100,000)	TBD	TBD	TBD
FY 2018 Adjustment	($4,786,000)	N/A	N/A	N/A	N/A
Target Revenue Total	**$40,214,000**	**$38,847,000**	**$41,922,000**	**$42,997,000**	**$44,100,000**

**Target revenue rounded to the nearest thousand dollars*

- Base amount is set in statute
- The inflation adjustment adjusts the base amount to maintain the purchasing power of fee funds in consideration of inflation.
- The capacity planning adjustment is intended to adjust the BsUFA target revenue for changes in the workload, or capacity needs of the program. The method will be established through a process outlined in statute. This will include a third-party assessment of methodological options to be published for public comment.
- The operating reserve adjustment was established in statute to provide a mechanism to support the management of a reasonable amount of fee funds carried over from year to year. FDA has committed to keeping the carryover balance below 21 weeks of operating by FY22.

Overview of the BsUFA Financial Plan

Budgetary Resources	FY 2018		FY 2019	FY 2020	FY 2021	FY 2022
	Estimate	Actual	Estimate	Estimate	Estimate	Estimate
Target Revenue	**$40,214,000**	**$40,214,000**	**$38,847,000**	**$41,922,000**	**$42,997,000**	**$44,100,000**
Cash Collections	$40,214,000	$29,238,601	$38,847,000	$41,922,000	$42,997,000	$44,100,000
Recoveries	$0	$1,074,997	$500,000	$500,000	$500,000	$500,000
Carryover Available for Use, Beginning of Year	$48,223,308	$48,223,308	$38,257,343	$32,886,857	$27,739,865	$22,496,879
Total Budgetary Resources	**$88,437,308**	**$78,536,907**	**$77,604,343**	**$75,308,857**	**$71,236,865**	**$67,096,879**

User Fee Obligations	FY 2018		FY 2019	FY 2020	FY 2021	FY 2022
	Estimate	Actual	Estimate	Estimate	Estimate	Estimate
Payroll & Operating						
CBER	$208,018	$0	$460,297	$724,717	$743,303	$762,366
CDER	$31,055,273	$31,113,433	$34,137,860	$37,269,555	$38,225,370	$39,205,698
ORA	$1,382,041	$1,128,256	$1,407,248	$1,440,770	$1,477,720	$1,515,618
HQ	$2,544,981	$2,293,521	$1,785,744	$1,138,350	$1,228,037	$1,197,418
Total Rent	$1,505,875	$1,104,785	$1,520,934	$1,536,143	$1,551,504	$1,567,019
Total Shared Services	$3,769,100	$4,639,568	$5,405,403	$5,459,457	$5,514,052	$5,569,192
Total Obligations	**$40,465,297**	**$40,279,564**	**$44,717,486**	**$47,568,992**	**$48,739,986**	**$49,817,311**

Carryover	FY 2018		FY 2019	FY 2020	FY 2021	FY 2022
	Estimate	Actual	Estimate	Estimate	Estimate	Estimate
Total Carryover, End of Year	$48,472,011	$38,757,343	$33,386,857	$28,239,865	$22,996,879	$17,779,568
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	**$47,972,011**	**$38,257,343**	**$32,886,857**	**$27,739,865**	**$22,496,879**	**$17,279,568**

Collection Shortfall

Collections were short of our revenue target in FY18 by $11M

- Fee paying applications were 56% lower than anticipated

Carryover Balance

Estimated to decrease each year until the end of the cycle

FDA anticipates maintaining a balance close to 21 weeks by the end of FY22

- The volatility of the program requires the need to maintain a higher 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 FY18 is $21,711,380. The statute provides that this requirement is met if at least an amount that is 15% below the FY18 minimum level is spent.
- In FY18, FDA allocated and obligated $22,324,558 in appropriated funds (excluding user fees) for the BsUFA program. Since this was more than the specified minimum amount in FY18, the second legal condition was satisfied

Volatile workload impacts our ability to spend fees

- Results in conservative spending approach
- In FY18, FDA cleared the spending trigger by just 3%, or $600K
- This impact is limited by the 15% threshold granted by Statute
    - FDA cleared the 15% below threshold by 21%, or $3.9M

Overview of the GDUFA Financial Plan

Generic drug program target revenue for FY 2018 through FY 2022

Target Revenue	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	Actual	Actual	Estimate	Estimate	Estimate
Base Amount	$493,600,000	$493,600,000	$501,721,000	$513,223,000	$526,039,000
Inflation Adjustment	$0	$8,121,201	$11,501,954	$12,816,205	$13,136,246
Target Revenue Total	**$493,600,000**	**$501,721,000**	**$513,223,000**	**$526,039,000**	**$539,175,000**

Target revenue rounded to the nearest thousand dollars

- Base amount is set in statute
- The inflation adjustment adjusts the base amount to maintain the purchasing power of fee funds in consideration of inflation.

Overview of the GDUFA Financial Plan

Budgetary Resources	FY 2018		FY 2019	FY 2020	FY 2021	FY 2022
	Estimate	Actual	Estimate	Estimate	Estimate	Estimate
Target Revenue	**$493,600,000**	**$493,600,000**	**$501,721,000**	**$513,223,000**	**$526,039,000**	**$539,175,000**
Cash Collections	$493,600,000	$493,655,974	$501,721,000	$513,223,000	$526,039,000	$539,175,000
Recoveries	$0	$4,920,184	$4,000,000	$4,000,000	$4,000,000	$4,000,000
Carryover Available for Use, Beginning of Year	$137,412,048	$137,412,048	158,715,667	$175,416,181	$160,160,337	$145,671,792
Total Budgetary Resources	**$631,012,048**	**$635,988,205**	**$664,436,667**	**$692,639,181**	**$690,199,337**	**$688,846,792**

User Fee Obligations	FY 2018		FY 2019	FY 2020	FY 2021	FY 2022
	Estimate	Actual	Estimate	Estimate	Estimate	Estimate
Payroll & Operating						
CBER	$966,443	$49,462	$982,344	$1,004,864	$1,029,957	$1,055,677
CDER	$317,087,240	$323,591,582	$323,783,061	$370,153,071	$379,366,423	$382,508,683
ORA	$47,066,994	$46,518,651	$47,841,387	$48,938,151	$50,160,234	$51,412,836
HQ	$45,610,178	$27,801,624	$35,894,703	$31,058,578	$31,833,508	$32,627,789
Total Rent	$25,539,705	$22,019,962	$25,795,102	$26,053,053	$26,313,583	$26,576,719
Total Shared Services	$45,508,063	$57,291,257	$54,723,889	$55,271,128	$55,823,839	$56,382,078
Total Obligations	**$481,778,623**	**$477,272,539**	**$489,020,486**	**$532,478,844**	**$544,527,545**	**$550,563,781**

Carryover	FY 2018		FY 2019	FY 2020	FY 2021	FY 2022
	Estimate	Actual	Estimate	Estimate	Estimate	Estimate
Total Carryover, End of Year	$154,233,425	$163,715,667	$180,416,181	$165,160,337	$150,671,792	$143,283,011
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	**$149,233,425**	**$158,715,667**	**$175,416,181**	**$160,160,337**	**$145,671,792**	**$138,283,011**

**Numbers rounded to nearest whole dollar*

Carryover Balance

- Estimated to increase in FY19 due to hiring challenges
  - Expected to decrease significantly by the end of FY22
  - Additional spending not expected to impact program going into FY23

9:40 – 10:20 AM

RESOURCE CAPACITY PLANNING AND MODERNIZED TIME REPORTING IMPLEMENTATION PROGRESS

Andrew Kish
Director
Office of Program and Strategic Analysis | CDER

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

Commitments

Under PDUFA VI, BsUFA II, and GDUFA II, FDA committed to developing a resource capacity planning function and modernizing its time reporting approach.

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 • HQ team established
Conduct 3rd party assessment to recommend new methodology to adjust fee revenue amounts based on capacity needs	• Evaluation to be conducted in FY20 • After public comment, FDA may adopt new revenue adjustment method for FY21

What is Resource Capacity Planning?

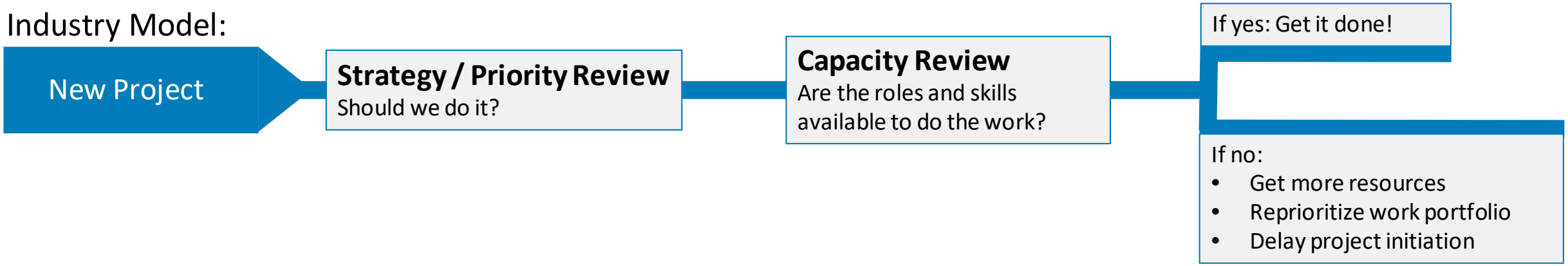
Long-term vision: **maximize operations to deliver on mission**

Develop a **unified and 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 and promote public health** and **meet our commitments** to the American public.

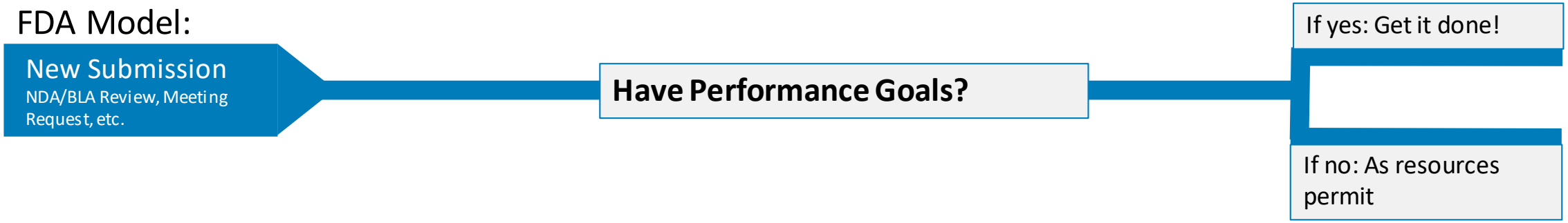
What is Resource Capacity Planning?

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

Industry Model:



FDA Model:



FDA needs to understand its likely resource demands with enough lead time to adjust staff levels

What is Resource Capacity Planning?

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

Insight Time Reporting

52-week time reporting to provide:

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

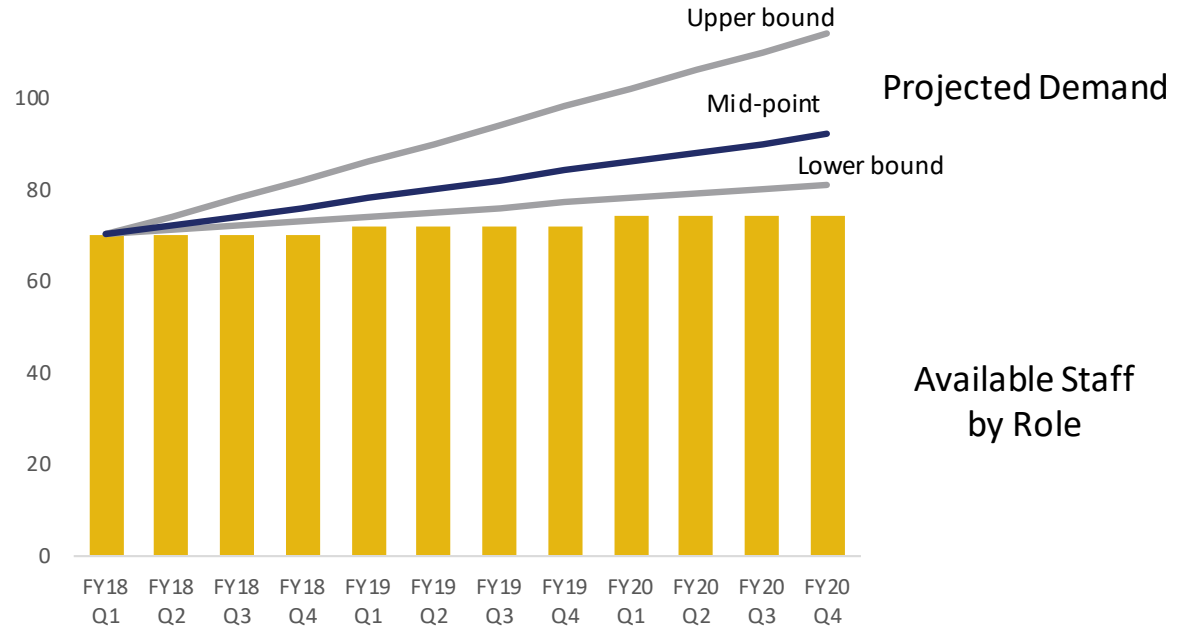
Workload Forecasting

Advanced analytics to forecast likely incoming work & productivity

Operational Data

HR Data (attrition, hiring times)
Financial Data

Resource Forecast



Outputs

Capacity Balancing
Identify ops to prioritize existing resources

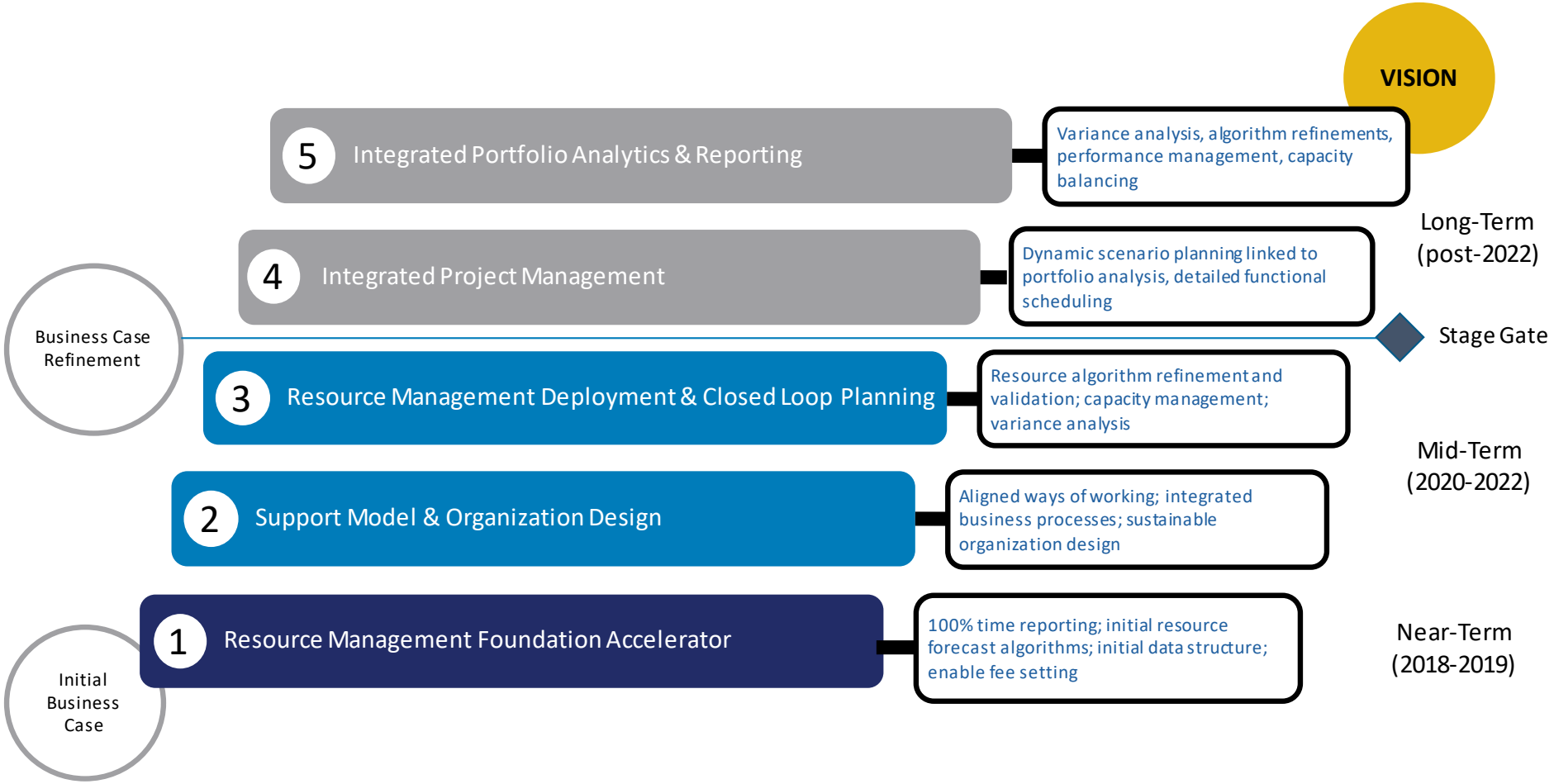
Revenue Adjustment
PDUFA & BsUFA

Hiring Plans

Financial Forecasting
e.g. Improve ability to manage BA

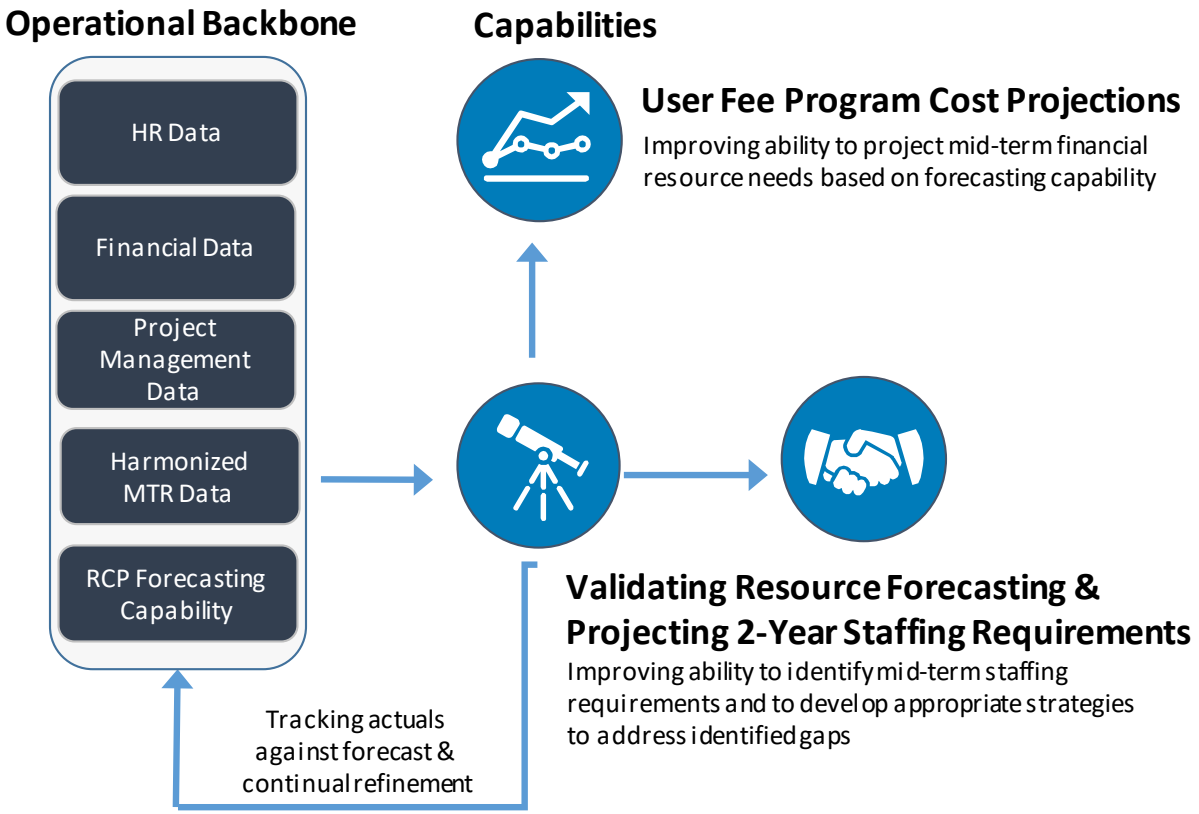
How Are We Going to Get There?

Full maturation requires progressive capability development over many years



How Are We Going to Get There?

3 Resource Management Deployment & Closed Loop Planning



Benefits at the completion of Phase 3:

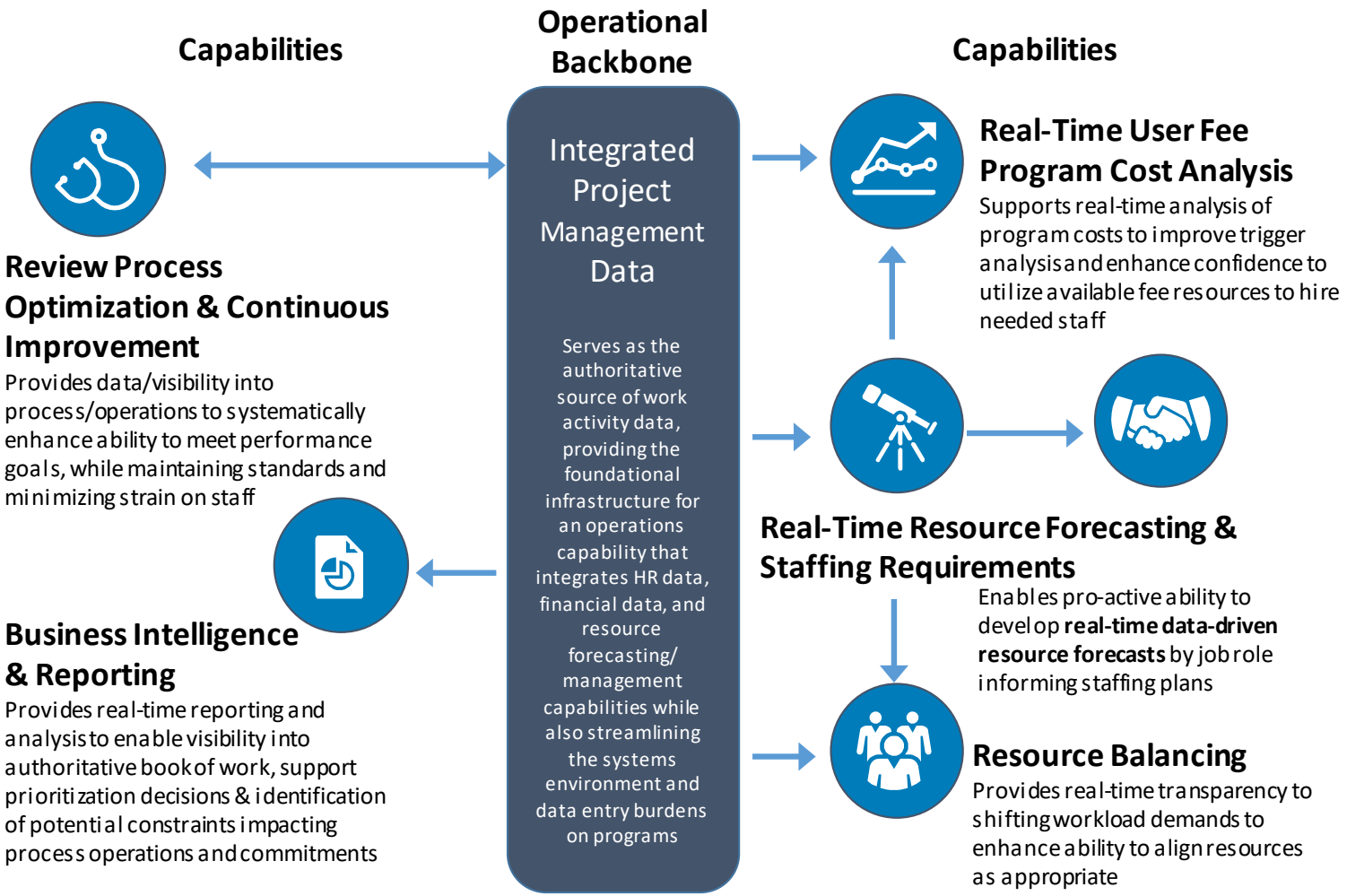
- Ability to track actual effort versus forecasted effort and continually refine forecasts
- Systematic and consistent resource capacity analysis across the organization
- Resource forecasts integrated with financial planning processes
- Emerging pro-active ability to identify resource gaps and develop tactics to address gaps
- Emerging holistic and comprehensive view of resource needs

Support Infrastructure

Staffing, Governance, Business Processes integrated into Resource Management

How Are We Going to Get There?

5 Integrated Portfolio Analytics & Reporting



Support Infrastructure

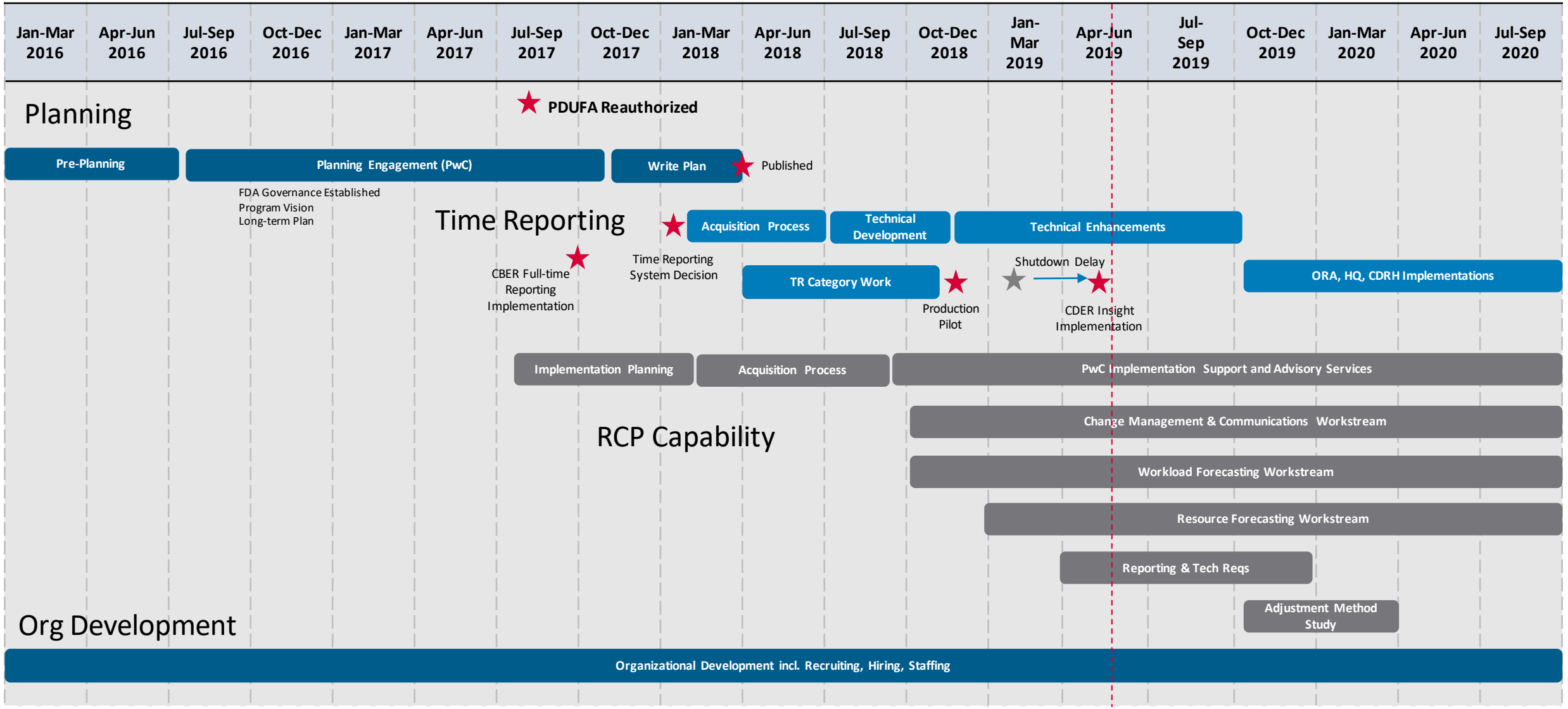
Staffing, Governance, Business Processes integrated into Resource Management

Benefits at the completion of Phase 5:

- Authoritative source of planning data to enable sharing of best practices across organizations
- Ability to provide key tactical resource capacity information to front-line management and to inform proactive user fee trigger analysis and the annual budget process
- Robust and flexible portfolio reporting capability based on one holistic book of work
- Improved tools to support operational strategies and prioritization of work
- Ability to deliver authoritative portfolio and resource capacity data as needed across all levels of the organization to support strategic and operational decision making

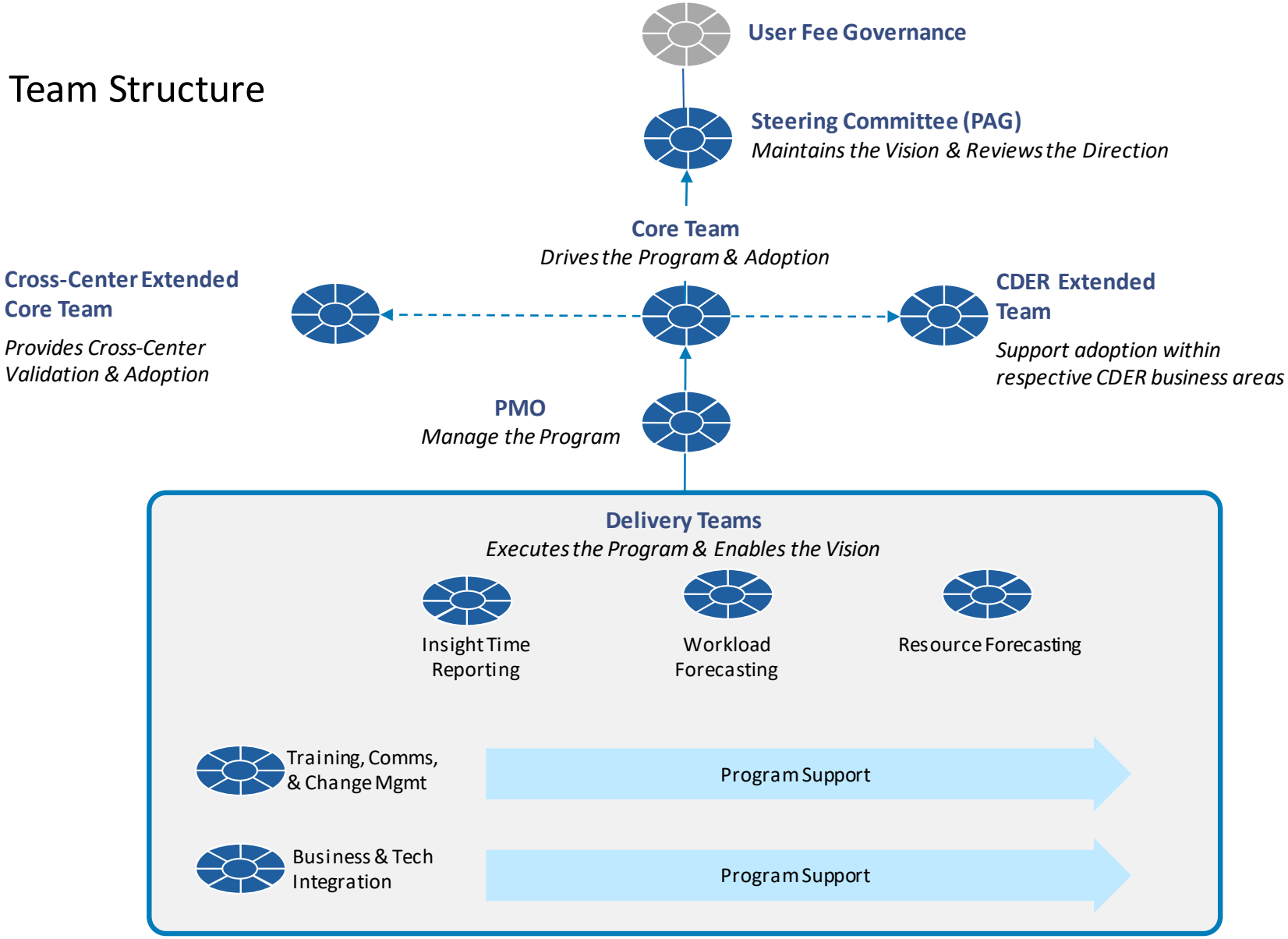
Status Update

Program Timeline



Program Governance

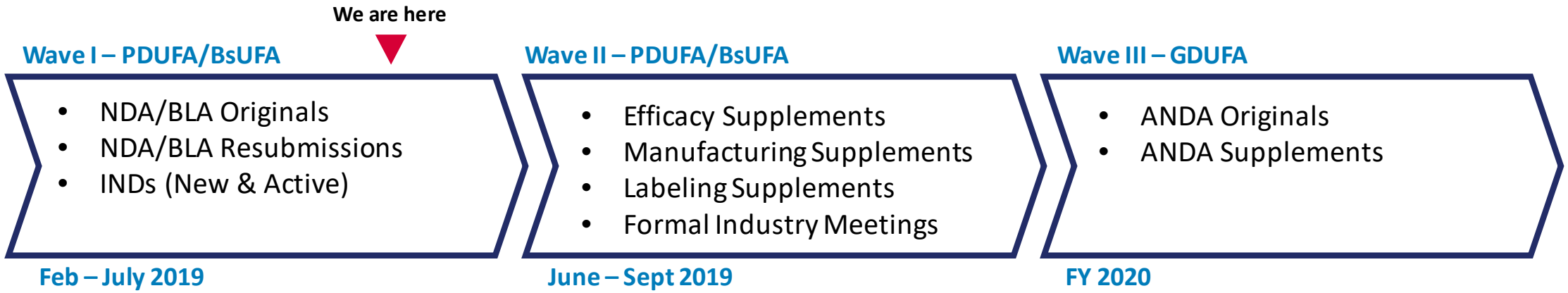
RCP Program Team Structure



Workload Forecasting

Objective: Predict regulatory submissions to inform likely sustained workload levels

Timeframes for initial model development:



We are in essence working towards **predicting activity for a large portion of the pharmaceutical industry**

Workload Forecasting

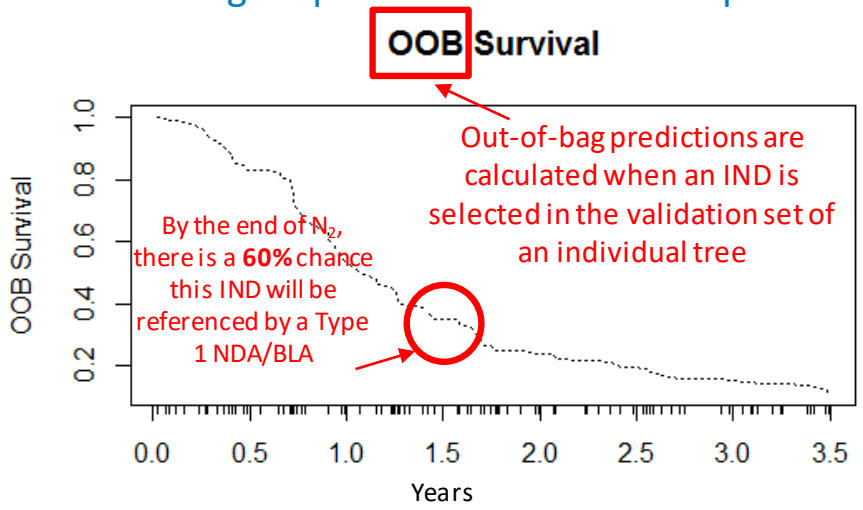
Example: IND-phase activity can predict NDA/BLA submission

PRELIMINARY ANALYSIS – For discussion purposes only

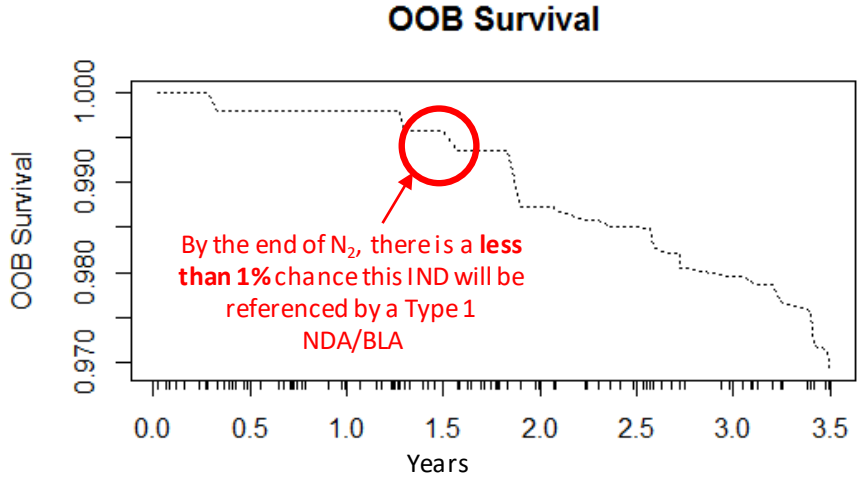
The Survival Random Forest output for individual INDs shows drastic differences in NDA/BLA submission rates for out-of-bag survival rates.

This is a promising result in being able to predict the timing of a marketing application submission.

End of P2 Meeting: 3-4 years prior
Proprietary Name Doc: 6-12 months prior
Meeting Request Doc: 6-12 months prior



End of P2 Meeting : None
Proprietary Name Doc: None
Meeting Request Doc: None



Adjustment Methodology

Statute outlines **public process** for implementing new fee adjustment mechanism

Sec 736(c)(2)(C):

CAPACITY PLANNING METHODOLOGY.—

(i) DEVELOPMENT; EVALUATION AND REPORT.—The Secretary **shall obtain, through a contract** with an independent accounting or consulting firm, a **report evaluating options and recommendations for a new methodology to accurately assess changes in the resource and capacity needs of the process for the review of human drug applications**. The capacity planning methodological options and recommendations presented in **such report shall utilize and be informed by personnel time reporting data as an input**. The report shall be **published for public comment no later than the end of fiscal year 2020**.

(ii) ESTABLISHMENT AND IMPLEMENTATION.—**After review of the report described in clause (i) and any public comments thereon, the Secretary shall establish a capacity planning methodology** for purposes of this paragraph, which shall—

(I) replace the interim methodology under subparagraph (B);
(II) incorporate such approaches and attributes as the Secretary determines appropriate; and
(III) be effective beginning with the first fiscal year for which fees are set after such capacity planning methodology is established.

← **3rd party evaluation** *(Nov'19 – Feb '20)*

← **Published for public comment** *(Mar '20)*

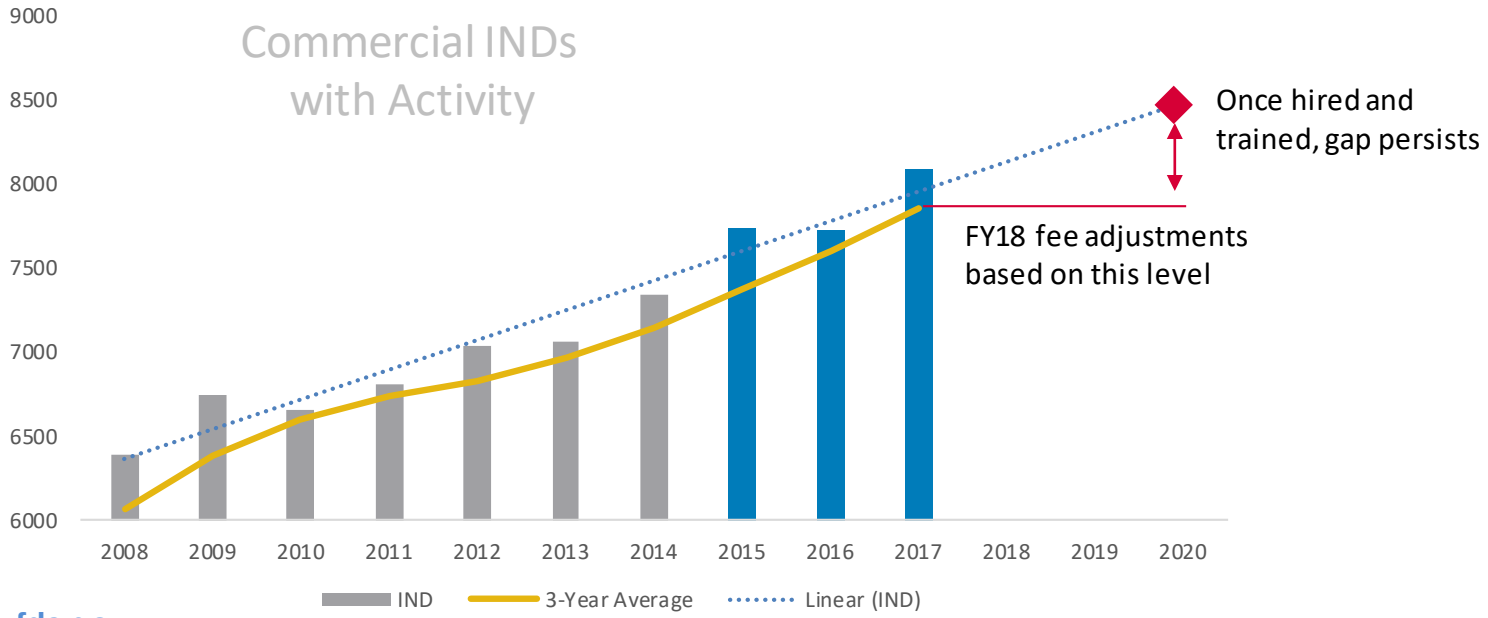
← **New adjustment**

Adjustment Methodology

Current fee adjustment presents structural issues

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

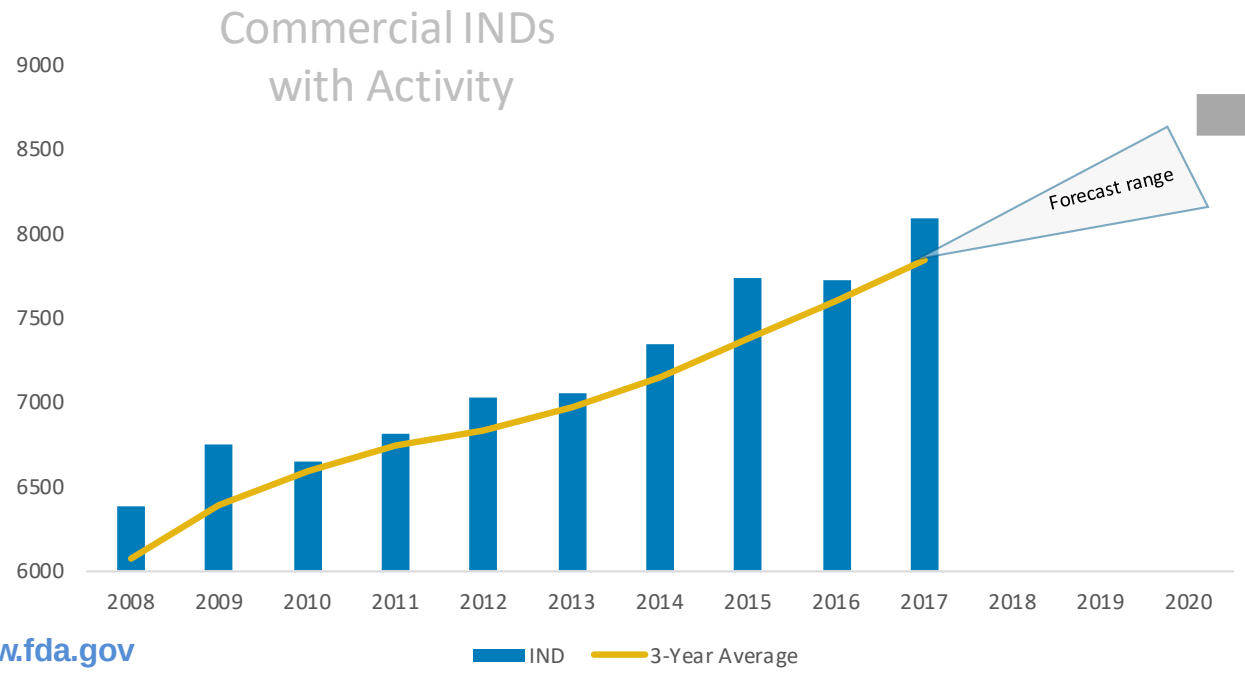


Adjustment Methodology

Opportunity to develop a **forward-looking** fee revenue setting methodology

Future state adjustment:

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

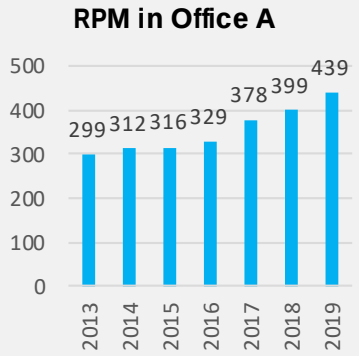


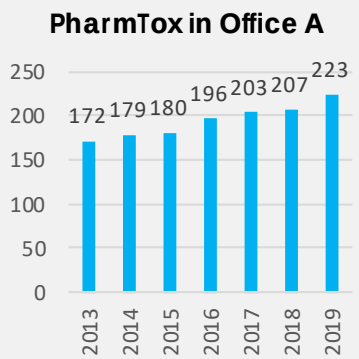
For Illustration Purposes

Example: 2 Year Resource Forecast

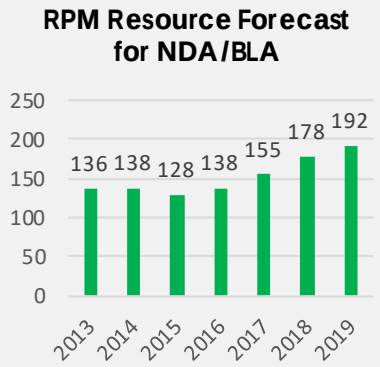
Sustained workload at this level, all other things being equal, translates to a need for additional resources to maintain performance:

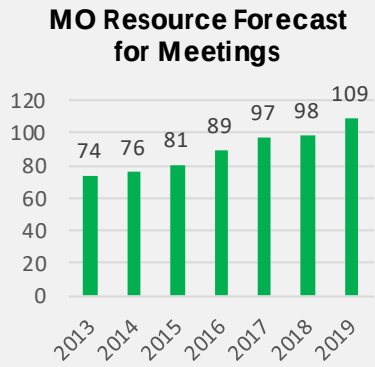
Forecast by Job Role





Forecast by Submission Category





10:20 – 10:30 AM

BREAK

10:30 – 10:50 AM

FINANCIAL MANAGEMENT EVALUATION FOR HUMAN DRUG USER FEES

Jim Taylor
Grant Thornton, LLP – Health FFRDC

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)

MITRE

About The Health FFRDC

The **CMS Alliance to Modernize Healthcare (The Health FFRDC)** is the first federally-funded research and development center (FFRDC) dedicated to protecting and promoting health and well-being.

The Health FFRDC is sponsored by the Centers for Medicare & Medicaid Services (CMS) and all divisions of the Department of Health and Human Services (HHS). MITRE, an objective not-for-profit organization, operates the Health FFRDC in partnership with CMS and all HHS agencies to implement innovative ideas to solve our nation's toughest health problems.

The Health FFRDC is composed of an alliance of partners and members who are committed to providing conflict-free, objective expertise to HHS and its divisions.

Background & Purpose

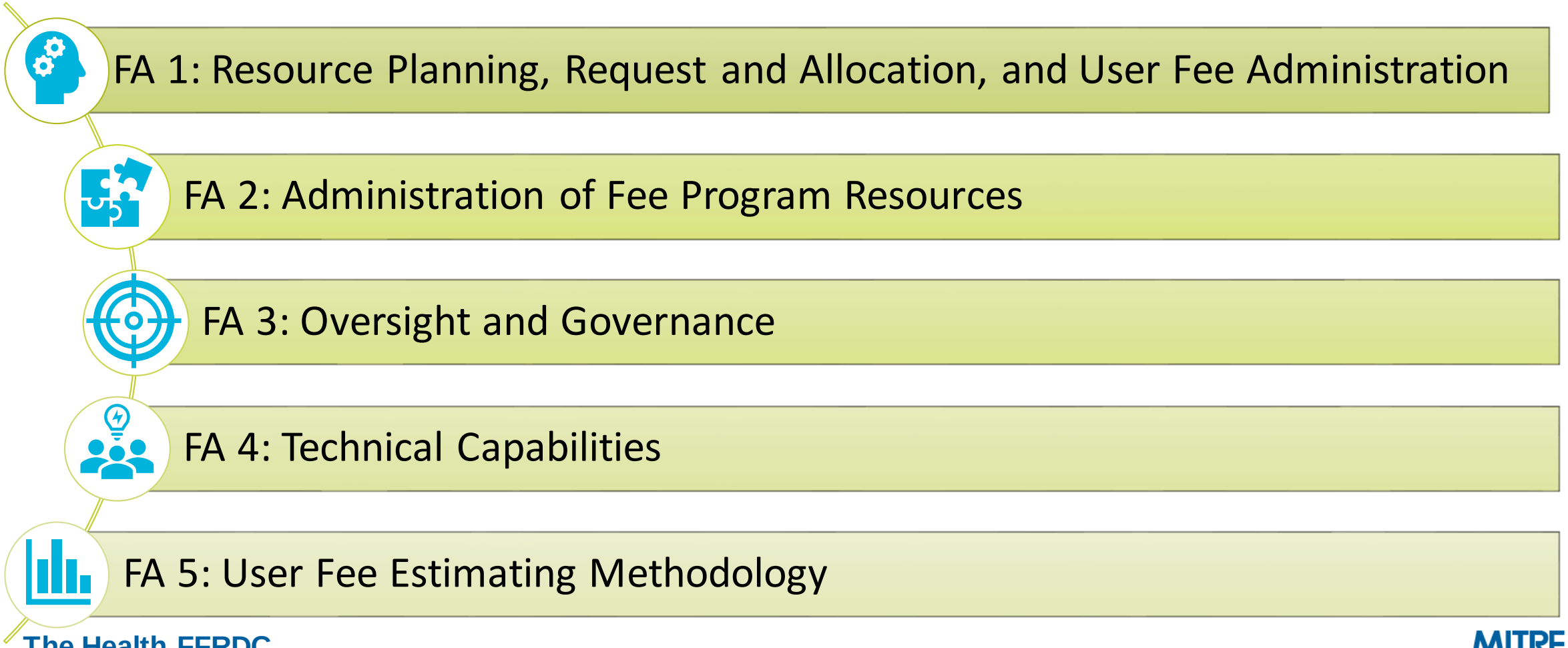
- FDA collects over $1.4 billion in human drug user fees annually.
- New user fee programs, including Generic Drug User Fee Act (GDUFA) and Biosimilar User Fee Act (BsUFA), have increased financial management complexity.
- Reauthorization agreements for Prescription Drug User Fee Act (PDUFA), GDUFA and BsUFA included FDA commitments to *engage an independent third party* to conduct an evaluation of its financial management practices.

PURPOSE

- Develop a *comprehensive evaluation focused on five specific areas of* FDA's financial management capability for PDUFA, BsUFA, and GDUFA programs during FY 2018.
- Provide *recommendations* based on *best practices* to help ensure that FDA's user fee financial management capability is consistent with best practices in the federal government.

Scope and Focus Areas

The Health FFRDC conducted an assessment that includes five focus areas (FA):



What did we find?

FA 1: Resource Planning, Request and Allocation, and User Fee Administration	Financial management practices fully comply with current financial management requirements.
FA 2: Administration of Fee Program Resources	FDA realized improvements in user fee administration: enterprise-level systems at the Agency-level support budget execution, billing and collections; provides robust reporting capabilities.
FA 3: Oversight and Governance	User fee governance structure is mature with some opportunities for improvement.
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.

Conclusion

- FDA's financial management maturity is appropriate for the governance, management, and oversight of its current human drug user fee programs
- FDA is fully compliant with financial management requirements
- FDA was within 2% of target revenue across all human drug user fee programs, with no over-collection of user fees
- FDA is on a path to improve its policies, processes, and procedures – and its technology systems – to meet the increasing complexity within the human drug user fee programs

Key Findings by Report Focus Area

FA 1: Resource Planning, Request and Allocation, and User Fee Administration

FDA's financial management practices fully comply with current financial management requirements.

Key Takeaways:

- FDA **meets Agency-level** user fee financial management requirements using HHS and FDA financial systems for routine tracking and reporting of user fee program funds.
- FDA is **developing enhanced system** capabilities (e.g., implementation of Full Time Reporting (FTR) for staff hours).
- The PDUFA, BsUFA, and GDUFA **billing and collection functions and processes are well executed**, and the process teams are continually exploring ways to innovate and automate processes.

Opportunities*

- FDA lacks a fully integrated User Fee Management policy and procedures framework resulting in localized processes; the resulting variation in practices leads to a lack of standardization.
- Centers and Offices rely on distributed tools and systems that require manual reconciliation and validation, which can lead to process inefficiency. (FDA plans to extend the central system to the Centers and Offices.)

*refer to Assessment report for full list of opportunities

FA 2: Administration of Fee Program Resources

FDA has realized improvements in user fee administration particularly at the Agency-level where enterprise-level systems support budget execution, billing and collections, and provide robust reporting capabilities.

Key Takeaways:

- Within the Centers, particularly CDER, management has encouraged process improvement and adoption of lean practices.
- Staffing changes over the last few years were deemed positive as new perspectives were introduced and levels more aligned with workload.

Opportunities:*

- Further efficiency gains can be realized through center-level automation:
  - electronic billing for PDUFA and BsUFA, *and*
  - use of automated-workflow tools to streamline waiver and exemption processing.
- Efforts are already underway to leverage existing FDA customer service technologies to streamline customer service and request processing for PDUFA, GDUFA, and BsUFA.

*refer to Assessment report for full list of opportunities

FA 3: Oversight and Governance

FDA's user fee governance structure is mature with some opportunities for improvement.

Key Takeaways:

- The decision-making structure for user fees is understood and working efficiently, decision authority is respected, executive leadership is engaged, and oversight bodies are actively seeking improvement.
- FDA is continuously improving its decision-making process.
- The CDER Financial Council (CDER FC) in particular has led the way in better management of their user fee portfolio of investments, basing decisions on available evidence, and following up to see if established outcomes have been accomplished.

Opportunities:*

- FDA would benefit from the creation of higher-level strategic objectives that cut across all user fee programs and describe the plans to achieve the negotiated, individual program performance commitments.

  Doing this would help user fee oversight bodies align their investments to projects that achieve optimal long-term outcomes and performance.

*refer to Assessment report for full list of opportunities

FA 4: Technical Capabilities

The assessment results indicate FDA is able to financially manage and administer human drug user fees.

Key Takeaways:

- 62% of employees are at or above their supervisors' desired proficiency level in the financial management skills required to manage user fee resources.
- This assessment indicates FDA staff meet expectations for program knowledge and have the skills to meet legal and regulatory requirements.
- Financial management has been able to hire and retain staff with all but one of the desired technical competencies.

Opportunities:*

- Based on supervisors' desired proficiency, the FDA and financial management staff should:
  - Increase proficiency in decision support, problem solving and analytical skills.
  - Improve training in financial and related systems.
  - Enhance organizational structure knowledge.

*refer to Assessment report for full list of opportunities

FA 5: User Fee Estimating Methodology

In FY 2018, FDA was within 2% of target revenue across all user fee programs.

Key Takeaways:

- FDA drug user fee programs annually assess and collect user fees to meet revenue targets 1, as authorized by the United States Federal Food, Drug, and Cosmetic (FD&C) Act.
- The programs' forecasting methodologies evolved over time to meet changing internal and external circumstances, including market dynamics, trends and fee structures.
- Despite these challenges, as well as those posed by unforeseen one-time policy changes, FDA was within 2% of target revenue across all user fee programs in Fiscal Year 2018 (FY 2018).

*Opportunities:**

- While the portfolio performed well in FY 2018 overall, the FDA could:
  - Improve the forecasting accuracy of individual fee units based on Federal best practices for predictive modeling.
  - Research alternate methodologies, quality data and policies with the help of stakeholders.
  - Apply methodological approaches that leverage industry inputs, external market data and subject matter expert opinion.

*refer to Assessment report for full list of opportunities

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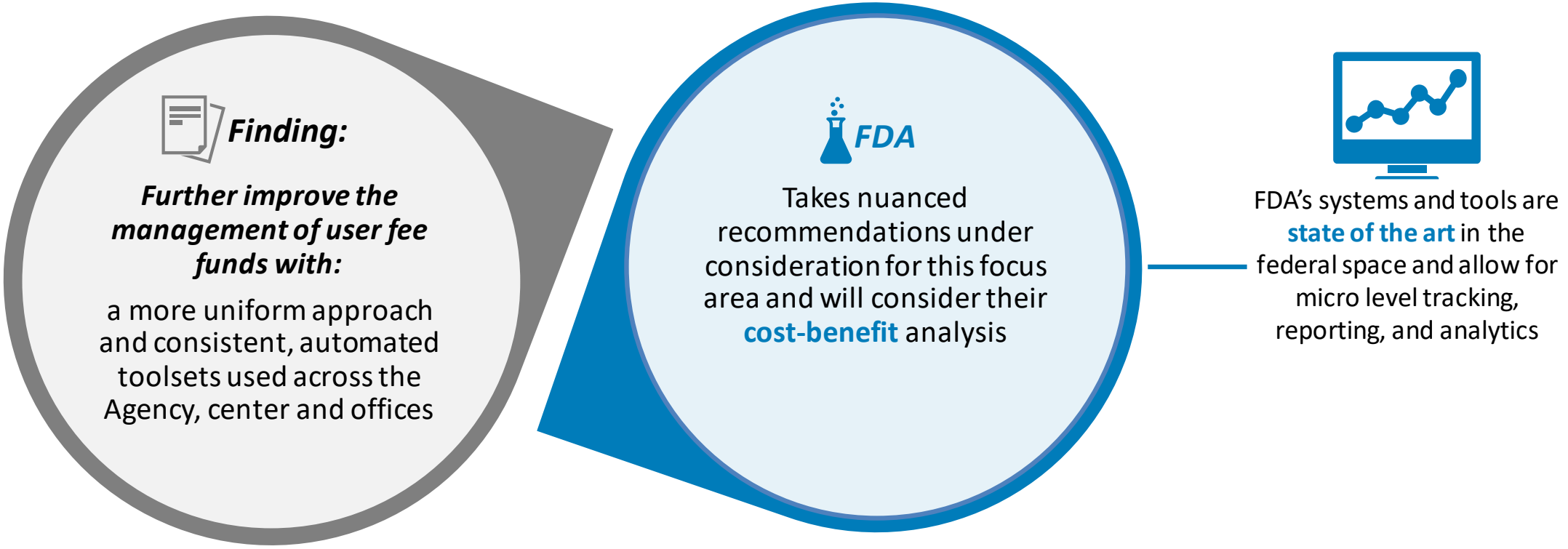
10:50 – 11:10 AM

FDA RESPONSE TO FINANCIAL MANAGEMENT EVALUATION

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

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

Health FFRDC finds that an **integrated** user fee management policy and procedures framework will lead to process **standardization** and **efficiency**.

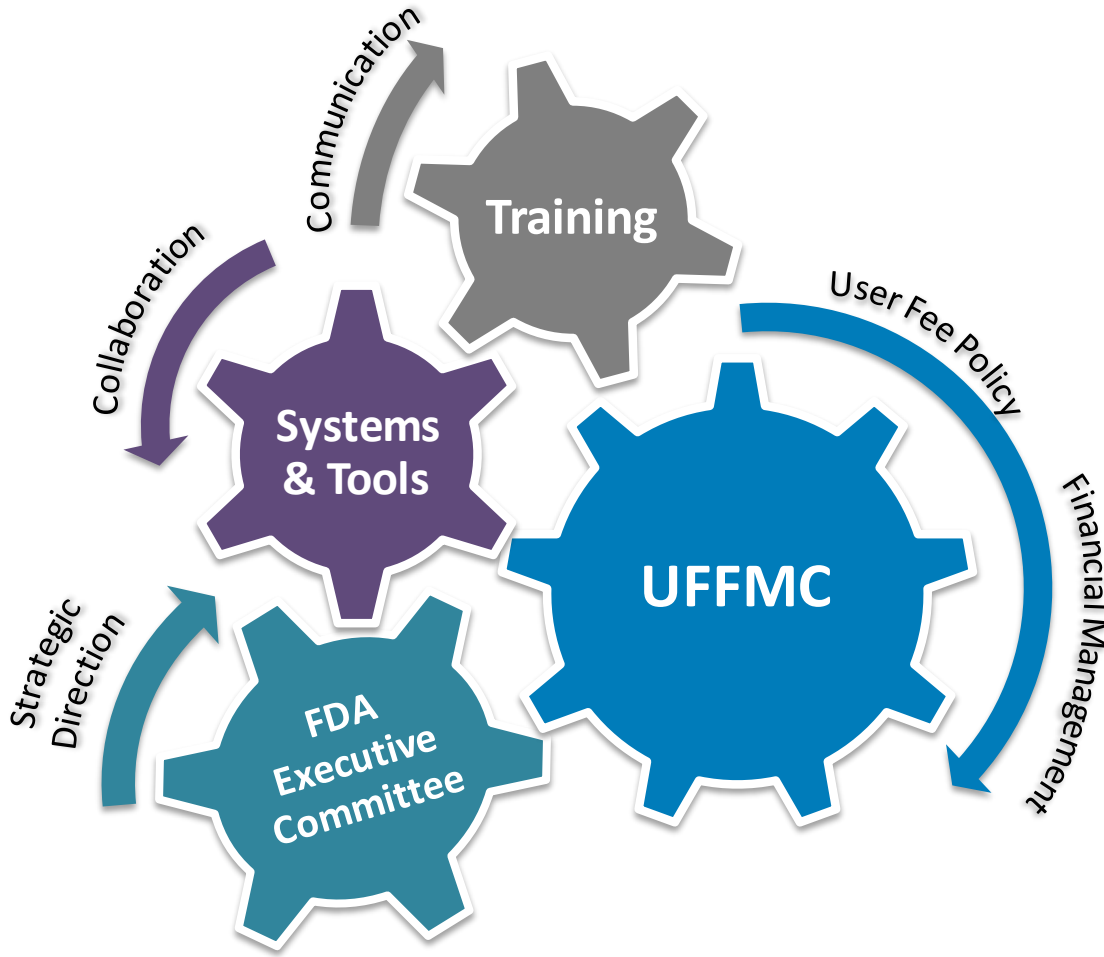


Focus Area 2: Administration of Fee Program Resources

Health FFRDC finds that **cross-collaboration** and **communication** supports the objective of meeting customer and stakeholder needs.

Finding:

Centers and offices can better integrate with and utilize the Agency level systems and tools; clarify roles and responsibilities, and increase analytic support



FDA

Broaden **training opportunities** on the use of the Agency level tools and systems and leverage newly reconstructed **User Fee Financial Management Committee (UFFMC)** and the **FDA Executive Committee** to facilitate clear direction on user fee policy, strategic direction and financial management

Focus Area 3: Oversight and Governance

Health FFRDC finds that aligning investments to projects that achieve **long term outcomes** and **performance** requires **strategic objectives** that cut across **all user fee programs**.

Finding:

Creation of higher-level strategic objectives that link to program performance commitments would help user fee oversight bodies make evidence-based decisions and align investments to strategy

FDA

Appreciates the need for return on investment (ROI) data to inform user fee investment decisions

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Takes advice on the utility of ROI under advisement but have no plans to mandate that quantifiable ROI data inform all user fee investment decisions as it is recognized that ROI information is not readily quantifiable, and is more often qualitative in the federal government

User Fee Financial Management Committee

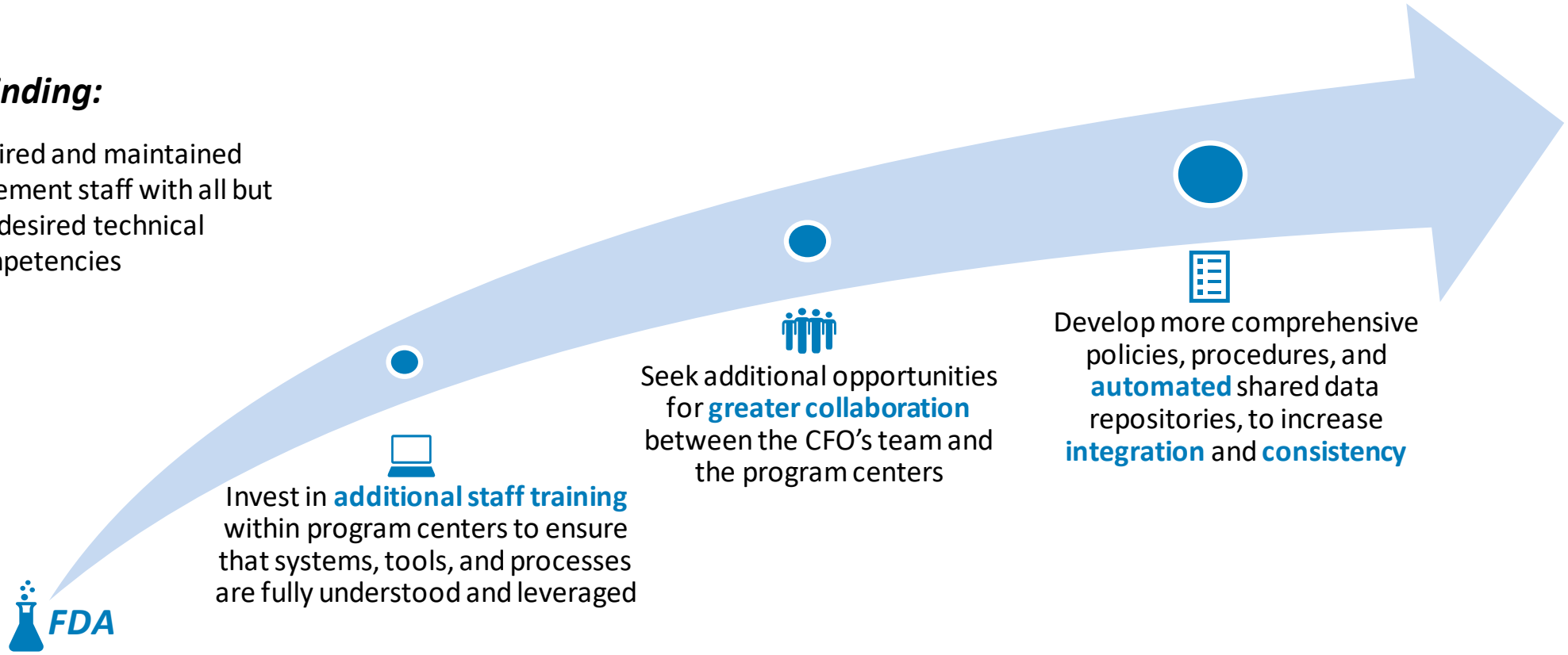
The newly restructured UFFMC will work to ensure **strategic alignment** of investment decisions and policy direction, with direct feedback from **FDA's Executive Committee**.

Focus Area 4: Technical Capabilities

Health FFRDC finds that financial management and administration of human drug user fees requires **knowledgeable** and **skilled staff** that can meet the **legal** and **regulatory requirements**.

Finding:

Successfully hired and maintained financial management staff with all but one of the desired technical competencies

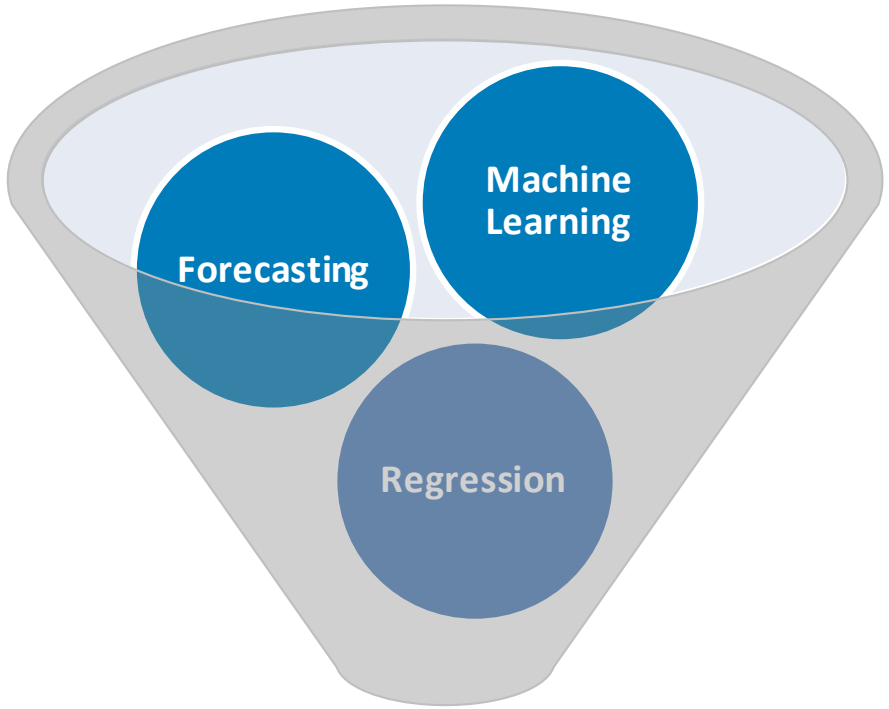


Focus Area 5: User Fee Estimating Technology

Health FFRDC finds that predictive modeling requires an **ongoing multi-pronged approach** to achieve improvements in **forecasting accuracy** as well as estimating confidence.

Finding:

Broadening of the methodologies applied would improve fee forecasting accuracy, help balance FDA's inherent strengths and weaknesses, as well as provide programs with a more comprehensive understanding of fee unit behavior



FDA

Several fees associated with GDUFA and BsUFA are new, which can cause a higher deviation early in the programs and the relatively small size of the BsUFA program inherently contributes to forecasting uncertainty for that program

Advanced Predictive Analytics

FDA is developing **advanced predictive analytics** to forecast regulatory submissions as part of its **Resource Capacity Planning initiative**. FDA expects this new capability will improve the number of fee-paying submissions

11:10 – 11:30 AM

OPEN PUBLIC COMMENT