

Resource Capacity Planning & Modernized Time Reporting Implementation Plan



Table of Contents

Table of Contents.....	1
Executive Summary.....	3
Introduction	5
Purpose	6
Acknowledgements.....	7
Explanation of Key Terms	7
Resource Capacity Planning.....	7
Modernized Time Reporting	7
Capacity Planning Adjustment.....	7
A Framework for Resource Capacity Planning in FDA’s Human Medical Products Programs.....	9
Integrated Operations and Business Planning.....	9
Project Management	9
Resource Management.....	9
Financial Management.....	9
Portfolio Management.....	9
Operating Model.....	10
The Current State of Resource Capacity Planning in FDA’s Human Medical Products Programs	11
Organizational Background.....	11
Current State of FDA’s IOBP Capabilities	12
Project Management	12
Resource Management.....	12
Financial Management.....	13
Portfolio Management.....	13
FDA-Specific Challenges	14
No Systematic View into Likely Regulatory Review Workload Demand.....	14
Hiring and Training Time Frames	14
Defining the FDA’s Journey for Resource Capacity Planning and Modernized Time Reporting.....	15
FDA’s Resource Capacity Planning Vision	15
FDA’s Journey Defined	15

Benefits	17
1. Resource Management Foundation Accelerator	18
2. Support Model & Organizational Design	21
3. Resource Management Deployment and Closed Loop Planning	22
Stage Gate Review and Business Case Refinement	24
4. Integrated Project Management (pending stage gate review decision)	24
5. Integrated Portfolio Analytics and Reporting (pending stage gate review decision)	26
Critical Factors to Ensure Delivery of the Program Vision	28
Enabling Change	28
Enhancing Information Technology Infrastructure (IT)	29
Harmonizing Data Model and Processes	29
Building Internal Capability (Staffing)	30
Moving Forward	31
Public Engagement	31

Executive Summary

The U.S. Food and Drug Administration (FDA) performs an essential public health function by ensuring that safe and effective human medical products are available to improve the health of the American people. It receives user fee funding to help support activities related to the oversight and review of certain human medical product applications. These user fee programs include 1) the Prescription Drug User Fee Act (PDUFA), which provides support for activities related to new drug and biological products; 2) the Biosimilar User Fee Act (BsUFA), which provides support for activities related to biosimilar biological products; and 3) the Generic Drug User Fee Amendments (GDUFA), which provides support for activities related to generic drug products.

As the science of product development and regulation has grown increasingly complex, the FDA's user fee programs have also grown both in the scope of activities and the volume and complexity of submissions. Taken together, this growth has increased the operational demands on the agency. To help ensure that the agency is making optimal use of its financial resources to maximize its ability to efficiently and effectively deliver on its commitments to the public, the agency has committed to developing a resource capacity planning capability and to modernizing its time reporting approach. Through the development of these capabilities, FDA will build more systematic, data-driven, and repeatable processes to better understand and anticipate its current and future resource demands. This will enable the agency to more proactively ensure its organizational components are optimally resourced.

The purpose of this plan is to outline an approach for implementing these capabilities within the FDA's human medical product programs. FDA engaged PricewaterhouseCoopers LLP (PwC) to support the development of this implementation plan and to use the firm's Integrated Operations and Business Planning (IOBP[®]) framework to inform the design of this plan. FDA, in consultation with PwC, tailored this framework to fit FDA's current state and operational challenges.

This tailored plan focuses first on modernizing FDA's time reporting approach while also beginning development of its resource forecasting capability. It then includes designing the organization and support model for these capabilities, including the underlying business processes. Once the support model and initial time reporting and resource forecasting capabilities are in place, FDA will be able to begin comparing actual resource utilization to the forecasted resource utilization. This will enable FDA to improve its resource forecasts, prioritize its existing resources, and develop proactive plans to acquire the roles and skills it will likely require. The information will also help develop financial forecasts to better predict use of financial resources to support the user fee programs.

At this point, the requisite capabilities would be in place to enable the development of a new revenue adjustment methodology for PDUFA and BsUFA. FDA would engage in the process, as provided for in statute, for an independent accounting or consulting firm to develop recommendations for a new revenue adjustment methodology and for the public to provide comment on these recommendations before it may adopt the new methodology.

Once the foundational resource capacity planning and modernized time reporting capabilities are in place, FDA will engage in a “stage gate” review. This review will assess how well the capabilities have delivered on the expected benefits and will consider next steps. The review will also consider whether and how to proceed towards integrating the resource capacity planning and modernized time reporting capabilities with project management and portfolio reporting capabilities. FDA’s human medical product centers and their field and headquarters components have existing but distinct project and workload management systems, and developing an integrated project and resource management capability across the human medical product programs will require a significant investment. This investment would, however, also represent a significant opportunity for FDA’s human medical product programs to transform their operational capabilities.

To enable success in the development of these opportunities, FDA recognizes it must consider a number of significant factors. Foremost among these is aligning the organization around the program vision and managing change to ensure successful adoption of the new capabilities. It will also necessitate the acquisition of new information technology, as well as the harmonization of data models and business processes. FDA will also need to acquire and develop the staff necessary to build and manage these new capabilities.

FDA has also committed to hosting annual public meetings, beginning in 2019, to engage the public in discussions regarding its progress in the development of its resource capacity planning and modernized time reporting capabilities. The FDA will welcome public comment regarding its approach and progress at these meetings.

Introduction

The U.S. Food and Drug Administration (FDA) performs an essential public health function by ensuring that safe and effective human medical products are available to improve the health of the American people. FDA does this through a complex array of responsibilities, including overseeing clinical development, reviewing marketing applications, monitoring post-market safety, issuing policy and guidance, and many other related activities.

In the 1980s, the financial resources available to the FDA were being outpaced by the demands and expectations placed on the agency. In 1987, the median approval time for a new drug application was 29 months,¹ and many new products first became available in other countries. To help ensure that safe and effective new drug products became available to the American people more quickly, Congress, the regulated industry, and the FDA agreed to a framework whereby drug sponsors would pay certain fees to supplement existing public funding appropriated by Congress to improve staffing levels and systems that support new drug review. In return, FDA would commit to certain timeframes to complete review of marketing applications, as well as other enhancements that would support the new drug review program. This agreement, which would be known as the Prescription Drug User Fee Act (PDUFA), was signed into law in 1992. By fiscal year 1997, the last year of the initial authorization period, the median approval time for new drug applications had been reduced to 12 months and FDA was meeting all its review performance goals.^{2,3}

PDUFA would be reauthorized every five years, with each reauthorization providing an opportunity for stakeholders to assess the evolving demands on the program. In addition to enhancing predictability of review processes and reducing review times, the PDUFA program would expand to enhance consultation with sponsors during clinical development, to fund post-market safety and surveillance activities, to support guidance development, to improve internal systems, and to support regulatory science initiatives.

Along the way, the PDUFA program would serve as a model for other user fee programs at FDA. In 2002, Congress passed the Medical Device User Fee and Modernization Act, followed by the Animal Drug User Fee Act in 2003, the Animal Generic Drug User Fee Act in 2008, and the Biosimilar User Fee Act and the Generic Drug User Fee Amendments (BsUFA and GDUFA respectively) in 2012. Each of these programs are tailored to the needs of the respective regulatory paradigms, but they all share a few common

¹ <https://wayback.archive-it.org/7993/20170406002629/https://www.fda.gov/AboutFDA/ReportsManualsForms/Reports/UserFeeReports/PerformanceReports/ucm117257.htm> ; accessed 11/2/2017

² <https://wayback.archive-it.org/7993/20170406002557/https://www.fda.gov/AboutFDA/ReportsManualsForms/Reports/UserFeeReports/PerformanceReports/ucm117122.htm>; accessed 12/1/2017.

³ <https://wayback.archive-it.org/7993/20170406002524/https://www.fda.gov/AboutFDA/ReportsManualsForms/Reports/UserFeeReports/PerformanceReports/ucm116200.htm>; accessed 12/1/2017

elements, including the establishment of review timelines and performance goals and ensuring industry user fee funding supplement existing public funding.

As the number of programs increased and the scope of the programs broadened, so too did the scientific complexity of the products the FDA regulates. Concurrently, additional regulatory programs including, for example, the breakthrough therapy program, fast track designation, and accelerated approval, have been developed to provide FDA additional flexibilities and tools to keep pace with an increasingly innovative environment.

FDA’s recognizes the need to ensure that the functionally diverse organizational components that oversee human medical products have the appropriate resources at the right time to be able to meet public health and user fee commitments. To be able to get the resources at the right time, FDA needs to understand its future workload demand. This will require enhanced tools and systems to support program operations and to advance methods to identify emerging needs resulting from innovation and changes in human medical product development.

To this end, FDA committed to establishing a resource capacity planning capability supported through a modernization of its time reporting approach as part of the PDUFA VI, BsUFA II, and GDUFA II agreements.

Through the establishment of these capabilities, FDA will build more systematic, data-driven, and repeatable processes to better understand and anticipate its current and future resource demand. This will enable the agency to more proactively ensure its organizational components are optimally and efficiently resourced. As a result, FDA will enhance its agility and confidence in its ability to deliver on its myriad and critical commitments to the health of the American public.

Purpose

The purpose of this implementation plan is to outline a roadmap for the FDA’s resource capacity planning (RCP) and modernized time reporting (MTR) capabilities pursuant to the agency’s commitments under PDUFA VI, BsUFA II, and GDUFA II.

This implementation plan describes FDA’s human medical product programs’ current state, including the significant issues and challenges they face. It discusses FDA’s tailored approach to implementing these capabilities over the near- (1 to 2 years), mid- (3 to 5 years) and long-term (5+ years) planning horizons.

The publication of this plan satisfies the following specific commitments:

PDUFA VI p. 37	FDA will publish a PDUFA program resource capacity planning and modernized time reporting implementation plan no later than the 2nd quarter of FY 2018.
BsUFA II p. 27	FDA will publish a resource capacity planning and modernized time reporting implementation plan that includes BsUFA no later than the 2nd quarter of FY 2018.
GDUFA II p. 21	FDA will ... [publish] a GDUFA program resource management planning and modernized time reporting implementation plan no later than fourth quarter FY 2018.

As part of the 2017 reauthorization of the Medical Device User Fee Amendments (MDUFA), the MDUFA Commitment Letter states that “FDA will implement complete time reporting by the end of MDUFA IV such that data from time reporting can be used to conduct workload analysis and capacity planning.” FDA is incorporating the MDUFA time reporting requirements into its overall approach; however, this plan focuses primarily on the commitments made under PDUFA, BsUFA, and GDUFA.

Acknowledgements

The FDA engaged PricewaterhouseCoopers LLP (PwC) to support the development of this implementation plan and to use the firm’s Integrated Operations and Business Planning (IOBP®) framework to inform the design of this plan.

Explanation of Key Terms

Resource Capacity Planning

Resource capacity planning, as used in this plan, refers to a systematic approach for determining how many people with specified skills will be needed to meet performance goals given the projected workload within each program area. Thus, resource capacity planning includes workload forecasting and analysis of the types and amounts of technical and support resources needed to accomplish the forecasted work in accordance with specified performance standards.

Modernized Time Reporting

Modernized time reporting refers to the enhancement of FDA’s activity-based time utilization data collection, i.e., staff reporting data on how they spend their time on certain activities. FDA’s human medical product centers have long reported their time spent on activities over a sample of eight weeks each year to support the appropriate attribution of costs to user fee programs. Modernization entails moving from the eight-week sampling approach to year-round reporting, while also enhancing the tools, processes, and the support model for the modernized time reporting capability to better provide operational data to management across the organization.

This modernized time reporting will serve as a critical input into resource capacity planning by providing authoritative level-of-effort data across roles and work processes. It will serve as a sound basis for comparing actual level of effort to resource forecasts, and provide benchmarking information to model what-if scenarios for new programs, processes, or other work requirements.

Capacity Planning Adjustment

Following the authorization of PDUFA III that covered the FY2003 – FY2007 period, a workload adjustment mechanism was incorporated into the annual PDUFA fee setting process (*the PDUFA Workload Adjuster*). In response to significant growth in the workload of the PDUFA program, this provided a mechanism for adjusting the annual fee revenue amount based on changes in the counts of certain submission types. Over subsequent PDUFA authorizations various changes were made to the adjustment methodology. In addition, studies of the adjustment methodology were conducted in 2013⁴ and 2015⁵. Study results suggested some modest changes, and generally concluded that although the

⁴ <https://www.fda.gov/downloads/ForIndustry/UserFees/PrescriptionDrugUserFee/UCM350567>

⁵ <https://www.fda.gov/downloads/ForIndustry/UserFees/PrescriptionDrugUserFee/UCM464878.pdf>

methodology was not optimal, it was still likely the best methodology available given the state of FDA's data and systems at that time.

Modernization of time reporting and the development of a resource capacity planning capability provide the opportunity to address these shortcomings and enable the development of a robust adjustment methodology. For this reason, the FDA's commitment to develop these capabilities is linked to the ability to adopt a new methodology for adjusting PDUFA fee revenue amounts and for implementing a similar methodology for adjusting BsUFA fee revenue amounts.

A Framework for Resource Capacity Planning in FDA's Human Medical Products Programs

To guide and accelerate the development of its resource capacity planning capability, the FDA engaged PricewaterhouseCoopers LLP (PwC) in the development of this plan. PwC provided support by educating FDA on industry leading practices relevant to resource capacity planning, developing high-level requirements, and supporting the development of this long-term implementation plan.

Integrated Operations and Business Planning

FDA selected PwC's Integrated Operations and Business Planning (IOBP[®]) as a framework to guide the development of its resource capacity planning capability. The IOBP framework integrates four key capabilities necessary for resource capacity planning with an underlying operating model comprised of project management, financial management, resource management, and portfolio management. Each of these capabilities, as generally applied by industry, are described below in the order in which they are typically prioritized:

Project Management

Establishing the project management capability involves creating an integrated work breakdown structure to standardize project plans, activities, and milestones. The work breakdown structure sets the backbone for the data structure and establishes the multi-level aggregations to support scenario planning and reporting, thereby providing the ability to view project priorities, execute the agreed-upon project plan and meet timelines and budgets.

Resource Management

Establishing the resource management capability involves translating the project details into resource demand. This resource demand will then be used to calculate the numbers and types of human and other resources needed to execute a project. This capability will also support reporting and scenario analysis for future resource needs.

Financial Management

The financial management capability applies cost to the work and the resources enabling creation of a project cost forecast. This establishes an aggregated baseline budget and supports project reporting and analysis. This will support modelling of project scenarios to understand implications on revenues and costs to maximize value. In the private sector, this would enable dynamic net present value calculations based on marketing forecast inputs and forecasts of resources. In the public sector, this would help support the financial aspect of cost-benefit and trade-off analysis of different decisions.

Portfolio Management

With integrated schedules, resource demand and cost forecast now available, the portfolio management capability provides the ability to visualise the portfolio, analyse pipeline gaps and develop remediation strategies. It also enables analysis and modelling of relative risk and value options and strategies to optimize the portfolio. Overall, this capability facilitates the use of portfolio data to inform strategic business decisions and to provide senior management with the "big picture."

Operating Model

The operating model is the method by which the four capabilities defined above (project management, resource management, financial management, and portfolio management) integrate. The operating model defines the business processes, roles and responsibilities, and the organizational design of the resource capacity planning capability. It defines the interactions, and inputs/outputs for both the operating model and supporting tools. It provides the foundation that drives the adoption of the desired behavioural change by building into the operating model review timelines, metrics, process interactions, and system touch-points.

Organizations tend to have these capabilities at various levels of maturity, as well as their own particular business priorities and challenges, so they may customize the approach and sequence of implementing and integrating each capability. The next section describes the current state of these capabilities, as well as the pressing operational challenges, within the FDA's medical products programs. The section after next will address FDA's tailored approach to implementing the capabilities given its current state and operational challenges.

The Current State of Resource Capacity Planning in FDA's Human Medical Products Programs

Organizational Background

FDA's human medical product functions are organized primarily into centers:

- The Center for Drug Evaluation and Research (CDER) regulates human drugs and therapeutic biologics.
- The Center for Biologics Evaluation and Research (CBER) regulates biological products including vaccines, blood and blood products; and cells, tissues, and gene therapies for the prevention, diagnosis, and treatment of human diseases, conditions, or injuries.
- The Center for Devices and Radiological Health (CDRH) regulates medical devices and radiation-emitting products.

These human medical product centers are supported in their mission by the Office of Regulatory Affairs (ORA), which leads most field activities for the agency. This includes inspection of regulated products and manufacturers, conducting sample analyses of regulated products, and reviewing products imported into the United States.

The centers are also supported by the Office of the Commissioner (OC), which provides centralized program direction and management services to support effective administration.

There are broad similarities in the major functions of each of the product centers (for example, each center has product development oversight, pre-market review, post-marketing surveillance, and policy development responsibilities), but each center also has its own scientific and regulatory paradigms within which it operates as a result of the nature of the products and industries it oversees. Over the years, each center, as well as ORA and OC functions, have developed their own systems and processes to support and execute their work. This includes, to various degrees, administrative functions like budget execution and formulation, as well as regulatory review functions.

While this decentralization of systems and processes has enabled the centers to meet their specific operational needs, it has also created additional challenges for work that crosses centers, including integration with ORA's field inspections components and processes like combination product review that may require coordinated review activities in two centers as part of one marketing application review.

In the resource realm, each center and ORA has its own activity-based time reporting program, each utilizing its own technology and its own data models. Inconsistencies in data models inhibit the ability to compare level-of-effort on similar work activities (for example, the review of labeling supplements for approved biologics license applications in CDER and CBER). It also hampers efforts to consistently track activities that cross organizational boundaries.

Current State of FDA's IOBP Capabilities

Project Management

Within the human medical product centers, project management exists as an established and dedicated discipline to coordinate and manage the diverse and sometimes complex regulatory processes. Each center has developed its own systems and tools to manage, track, and report on the delivery of regulatory work products that are tailored to their specific needs and the performance commitments of each user fee program. These project management systems are not integrated across medical product centers, but they are well-established and functioning capabilities.

Resource Management

Time Reporting

For many years, FDA's human medical product centers have been required to report time expended on certain activities to support the allocation of payroll and other expenses to the proper revenue source. Each user fee program has defined in statute specific activities that the respective user fee funds can support. Because user fee funds directly support certain activities rather than specific employees or offices, FDA needed a methodology to determine the amount of time being spent on user fee-allowable activities versus activities that are not allowed to be supported by user fee funds. For example, a medical product reviewer in CDER's Office of New Drugs could theoretically within the same day review a new drug application (PDUFA allowable), attend a biosimilar biological product development meeting (BsUFA allowable), respond to a consultation request on a generic drug application (GDUFA allowable), and consult on an over-the-counter monograph review (not allowable on any current user fee program). To appropriately account for the time invested in allowable activities, FDA developed an activity-based time reporting capability.

Currently, CDER and CDRH conduct an activity-based time survey over the course of eight weeks each fiscal year. At the beginning of fiscal year 2018, CBER switched from an eight-week per year survey sample to a 52-week per year time reporting survey. The centers each independently manage their time reporting surveys with their own software tools and support functions. ORA currently captures activity-based time for its field-based work, but technical and administrative support functions do not report their time. OC has some small-scale local time reporting efforts, but lacks a comprehensive capability. This time reporting has provided an adequate sample to support the appropriate allocation of costs to each revenue source, but it does not provide the detail necessary to understand the resource demands required for the review of certain regulatory submissions, for example. FDA recognizes a need for a more comprehensive activity-based time reporting capability to better inform its operations and resource needs.

Resource Planning

Generally, FDA's human medical product programs' resource planning capabilities are reactive, localized, and ad hoc. The capability is *reactive* because the need to adjust resourcing levels often becomes apparent after workload demand has already shifted, providing few timely options. It is *localized* because no central standardized approach exists. Hence, individual offices within the centers

tend to develop their own analysis of their need. It is *ad hoc* because no systematic and repeatable processes exist to consider the holistic organizational needs and to balance trade-off decisions and set priorities among competing resource demands.

FDA's human medical product programs would benefit from improved data, methods, and business processes that enable more systemic, data-driven, and repeatable processes to plan for likely workload levels.

Financial Management

FDA operates in a different financial management paradigm from the industry it regulates. FDA is chiefly concerned with ensuring it can manage its finances to enable its operating components to meet their public health mission and user fee commitments in a financially sustainable manner.

FDA's financial management paradigm also differs from that of the typical government agency. The fees FDA collects are legally defined as *no-year funds*, meaning that once collected, the fees are available for obligation without any time-limiting restrictions. This contrasts with FDA's non-user fee funds, which are subject to the annual budget process and must be returned to the Treasury if they are not obligated by the end of the fiscal year for which they were appropriated. Each user fee program has a defined minimum amount of non-user fee funds that legally must be contributed to each program each year. This ensures that the user fee funds supplement a certain level of public funding for each program. The minimum level of non-user fee dollars that must be spent towards a user fee program is sometimes referred to as *trigger*.

Because of the activity-based definition of each user fee program, FDA employees are not funded by any specific user fee program. Rather, their activities must be tracked in order to attribute costs across user fee programs. This process supports FDA's ability to allocate and expend payroll resources according to the appropriate source of funds.

FDA lacks a systematic approach to forecast what is in industry's product development pipeline and how that pipeline may translate into future demand on FDA's resources. Therefore, financial planning efforts typically considers how to best use anticipated resources, rather than projecting the optimal level of resources that FDA would need to best deliver in its public health mission and user fee commitments.

Portfolio Management

FDA's centers have their own systems for tracking and managing their regulatory review and related work. While these systems can provide data and visibility into aspects of the total work portfolio, they are not integrated with resource data or forecasting capabilities. As such, FDA's current portfolio management capabilities are not able to provide views on the current and expected resource needs demanded by various activities.

FDA-Specific Challenges

No Systematic View into Likely Regulatory Review Workload Demand

One significant resource management challenge that FDA faces is that it has limited control over its workload. In contrast, the companies it regulates have more leeway to make informed choices about their projects and the impact on their workload.

FDA has commitments to review many types of regulatory submissions within defined time frames. Therefore, for FDA to be able to proactively ensure it has adequate resources to meet the workload created by the incoming regulatory submissions, it must develop capabilities to reasonably forecast, in a defined and structured manner, the types and mix of submissions it is likely to receive and the related work across the lifecycle of the products it regulates. To allow it to move beyond forecasts based only on historical trends, which are inadequate for predicting shifts in regulated industry, FDA needs to identify leading indicators of incoming regulatory submissions.

An improved workload forecasting capability would better enable FDA to proactively take steps to ensure its organizational components are optimally staffed when the work arrives. When a significant likelihood of a resource gap is identified, FDA may have a variety of options to consider in order to address the gap. This could include shifting existing resources where feasible, hiring additional resources, and/or re-prioritizing work.

Hiring and Training Time Frames

FDA has constraints that limit how quickly it can respond to changes in workload demands. The FDA's core regulatory functions are considered *inherently governmental* functions, which means that the hiring of contract labor to supplement this work would not be permissible. Recruiting the highly skilled and highly marketable scientific and technical labor force needed for regulatory review work generally takes an extended amount of time and involves a limited pool of candidates. For example, FDA requires Ph.D.-level biostatisticians to assess the clinical data within regulatory submissions, a need that is particularly acute with increasing interest and emphasis on the development of novel clinical trial designs. Despite this pressing need, only 167 biostatisticians earned Ph.D.s in 2014 from U.S. institutions,⁶ and FDA may not be able to compete for this limited labor supply based on compensation.

In addition, it takes time to train new staff in the regulations, policies, and procedures involved with review work, and to become experienced in review and other regulatory work.

Given these realities, a resource capacity planning capability that can indicate likely changes in various types of work with a reasonable level of confidence over an approximately two-year planning horizon is necessary to ensure that staff can be hired and trained in advance of any sustained changes in workload demand.

⁶ <http://www.ams.org/profession/data/annual-survey/2014Survey-NewDoctorates-Report.pdf>; accessed 12/1/2017

Defining the FDA’s Journey for Resource Capacity Planning and Modernized Time Reporting

In consultation with PwC, and guided by the IOBP framework and the current state of its IOBP-relevant capabilities and challenges, FDA developed a vision and a tailored long-term approach to sequencing implementation of key constituent resource capacity planning capabilities. This section describes the planned FDA-tailored journey to establishing and maturing its resource capacity planning capability.

FDA’s Resource Capacity Planning Vision

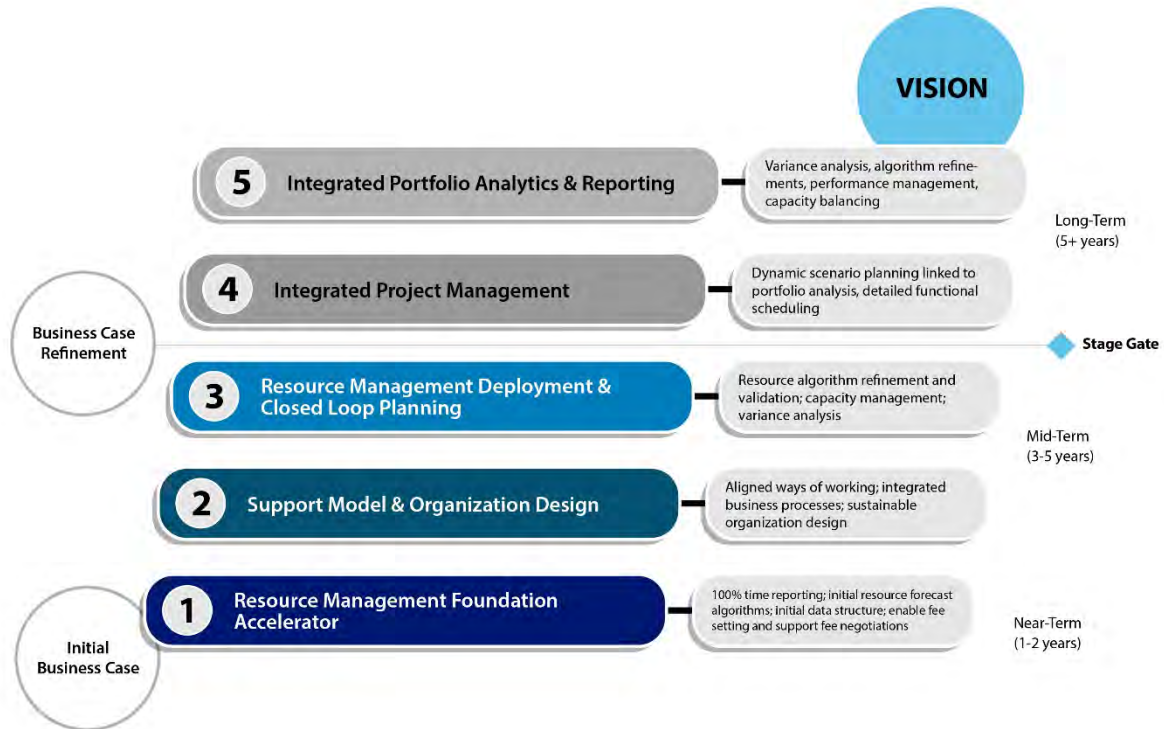
FDA defined the following as a working vision statement to help guide the development for its resource capacity planning capability:

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.

“Unified” recognizes the need for a systematic and coordinated approach actively supported and delivered across the relevant organizational components. “Trusted” recognizes that success requires broad buy-in and active management utilization of the capacity planning data across the organization. “Maximizing operational performance” recognizes the outcome of supporting an efficient regulatory review function by ensuring that resources are optimally distributed. “Fostering innovation and ... 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” connects the resource capacity planning function to the mission of the FDA. Thus, by building a robust resource capacity planning capability, FDA will enhance its ability to proactively identify the resources it needs to effectively and efficiently deliver on its public health mission and to its user fee commitments in a cost-effective manner.

FDA’s Journey Defined

With this vision in mind, FDA defined a tailored journey for the development of its resource capacity planning capability. This journey reflects an incremental and iterative development and integration of capabilities over near-, mid- and long-term planning horizons. Stage gates along the journey allow for the evaluation of progress and to identify any necessary adjustments to the plan.



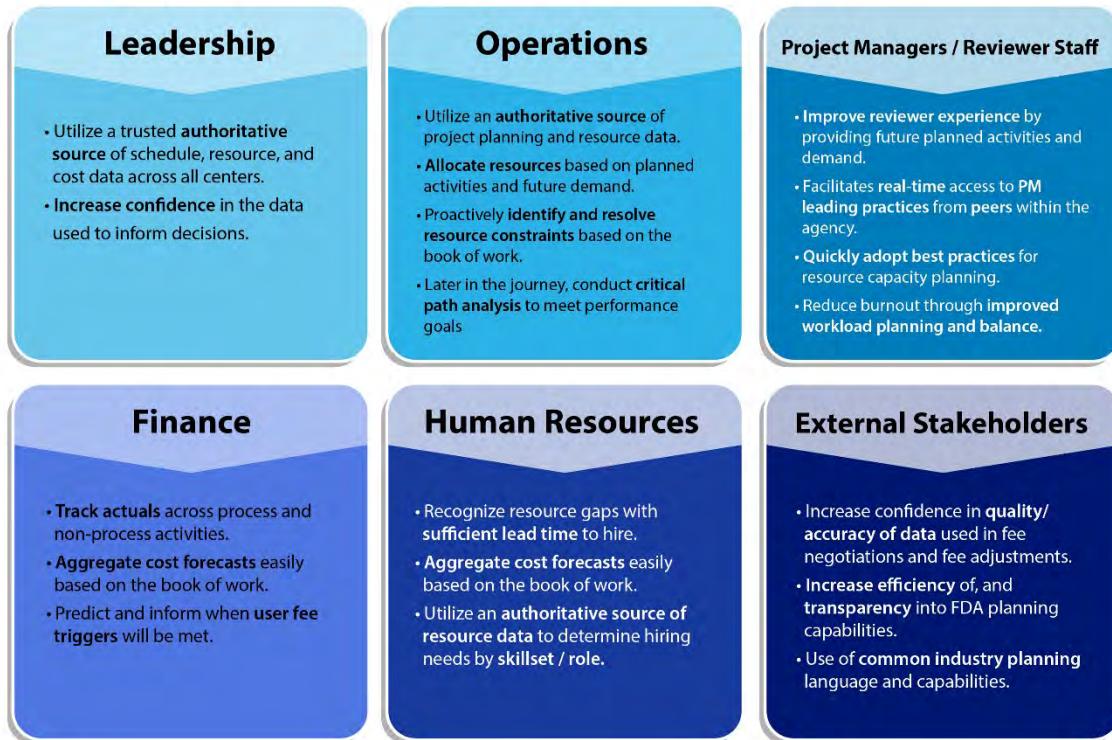
The journey is sequenced to focus first on the capabilities which will have the greatest impact relative to the time and investment required. These are the modernized time reporting approach and the development of the workload forecasting capability. Because integrating project management capabilities would require a significant investment in both money and time, and center-specific capabilities already exist, the integration of this capability will be considered after the development of the modernized time reporting and workload forecasting capabilities.

Benefits

Informed in part by PwC’s experience developing similar capabilities in the private sector, the table below summarizes some of the key benefits that would be expected to be realized by the organization in each phase in the journey.

Phase	Anticipated Benefits
1	Improved resource utilization data
1	Organizational alignment on analytical priorities for resource capacity planning
1	Foundational ability to track actual data against forecast to refine and expand algorithms
2	Ability to support and continually improve resource capacity planning capability
2	Improved business processes enabling more proactive financial and resource management and planning
2	Clear resource decision-making and accountability
3	Emerging pro-active ability to identify resource gaps and develop tactics to address gaps
3	Emerging holistic and comprehensive view of resource needs
3	Capability to establish trusted Capacity Planning Adjustment methodology to pro-actively adjust PDUFA and BsUFA annual fee revenue targets aligned with anticipated resource needs
4	Ability to proactively mitigate future bottlenecks
4	Authoritative source of planning data to enable sharing of best practices across organizations
4	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
5	Robust and flexible portfolio reporting capability based on one holistic book of work
5	Improved tools to support operational strategies and prioritization of work
5	Ability to deliver authoritative portfolio and resource capacity data as needed across all levels of the organization to support strategic and operational decision making

These organizational benefits would be experienced differently by different roles in the organization. The table below summarizes some of the benefits that would be expected at full-maturity (phase 5) by a selection of key roles in the user fee programs:



1. Resource Management Foundation Accelerator

This first phase focuses on building the foundation for the resource capacity planning capability in a manner that prioritizes FDA’s key resource planning challenges. It includes implementation of 52-week time reporting. This will include selection of a new time reporting system and the updating of a harmonized data model to reflect the new resource capacity planning requirements.

This phase will also include significant communication, change management and training efforts leading up to and through the initial implementation of the modernized time reporting program to prepare FDA staff and facilitate adoption of the time reporting changes.

It includes initial work to develop an approach to build resource forecasting algorithms. This will include identifying and conforming relevant internal and external data, considering approaches to collecting input on submission plans from industry, identifying analytical approaches and techniques, including the applicability of text mining, machine learning, and artificial intelligence, identifying any data gaps, and developing and executing an analytical work plan. The intended deliverable from this phase will be the establishment of an analytical capability based on real-time data. It will include an initial set of forecasting algorithms for the most significant areas of regulatory review work in the PDUFA, BsUFA, and GDUFA programs.

Modernize Time Reporting: This phase will initiate the change towards establishing 100% time reporting for all organizational components receiving PDUFA, BsUFA, and GDUFA funding. To manage and mitigate risks involved with the implementation of modernized time reporting, implementations will be scheduled in stages. This approach will help ensure that the implementation teams and support functions can focus on delivering the necessary functionality, managing the change to facilitate organizational adoption, and applying any lessons learned to subsequent implementations. Because CBER has already established its 100% time reporting program, the next focus will be to implement modernized time reporting in CDER as the home of the largest concentration of regulatory review work for PDUFA, BsUFA, and GDUFA. The initial focus on CBER and CDER will also enable the development of a new capacity planning adjustment methodology to account for the core regulatory review work driving PDUFA and BsUFA.

The planned timeline for implementing the modernized time reporting capability across the organization is depicted below:

Modernized time reporting anticipated implementation timeframe by major organizational component:



Major decisions in this phase will include selection, configuration, and implementation of a scalable new time reporting software solution. It will include significant change management and communication efforts to educate staff on the need, impacts, and benefits of the changes.

FDA organizational components will work to harmonize the data structure across their respective programs. While each organization will retain the flexibility within the data structure to be able to meet their own operational needs, FDA will also need to ensure that it can compare major common activities across its organizations to be able to support consistent application of resource capacity planning.

Initial resource forecasting algorithms: This phase will also focus on building the foundations for the requisite analytical capabilities. It will include developing a strategic analytical plan to establish priorities and outline the sequence of activities necessary to build the analytical capability. This planning stage will assess available internal and external data and work to clean and conform the data as necessary to prepare it for analysis. Outputs from this stage will be an initial set of algorithms focused on core regulatory review work for the PDUFA, BsUFA, and GDUFA programs.

Significant achievements in this phase:

- Modernized time reporting initiated through successive implementations
- Strategic analytical plan established
- Initial set of resource forecasting algorithms established

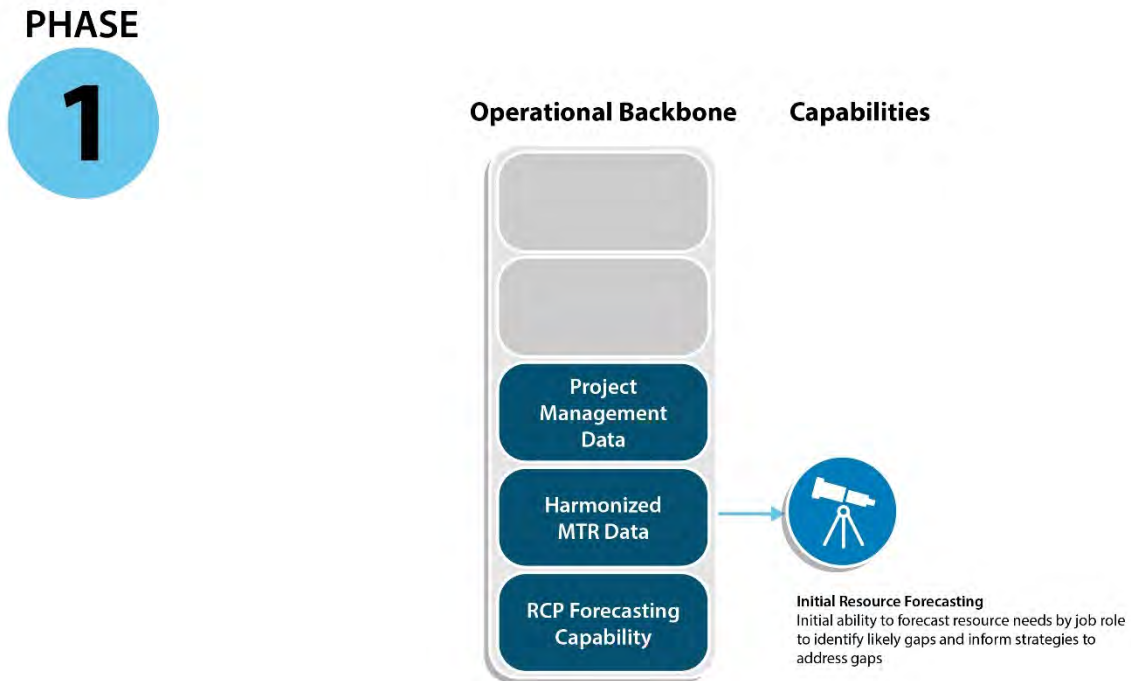
Anticipated benefits in this phase:

- Improved resource utilization data
- Organizational alignment on analytical priorities
- Foundational ability to track actual data against forecasts to refine and expand algorithms

By the end of FY 2019, FDA anticipates having active full-time reporting programs in both CDER and CBER that would be integrated through a harmonized data model. FDA also anticipates having completed the development of an initial core set of resource forecasting algorithms. At this stage, the initial forecasting capability would be expected to provide some insight into future resource demand. However, these algorithms would not yet be validated based on actual experience. Such validation would begin in phase 3.

Concurrently, FDA plans to be actively engaged in extending the modernized time reporting program to other organizational components (CDRH, ORA, OC).

Capability depiction at the completion of phase 1:



2. Support Model & Organizational Design

This phase runs concurrently with phase 1 and continues past the completion of phase 1. This phase focuses on building the organizational and business infrastructure to support the capacity planning and modernized time reporting capabilities while also aligning the analytical outputs of these capabilities into existing financial and resource management processes.

FDA will work to implement an organizational model to manage the resource capacity planning and modernized time reporting capabilities. As the PDUFA, BsUFA, and GDUFA programs are supported through multiple product centers, ORA, and HQ, these capabilities will benefit from centralized coordinating functions. This centralized support will manage the relevant enterprise software tools, establish common analytical methods and reporting standards, and manage and coordinate common services including change management, communications, and training support.

Each center or other major organizational component may also staff its own teams as needed. These center-specific teams will coordinate with and represent their organization's interest to the centralized support function; ensure their organization's key needs are being addressed; translate local business requirements; and tailor communications, training, and other services to ensure they are meeting the needs of their organization. These localized teams will develop internal networks of support within the constituent parts of their organizational component to drive implementation, adoption, and sustainability of the capabilities.

This phase will also include the establishment of an operating model to support resource capacity planning, and it will adapt existing resource management processes as necessary to utilize the resource capacity planning data in resource decision-making.

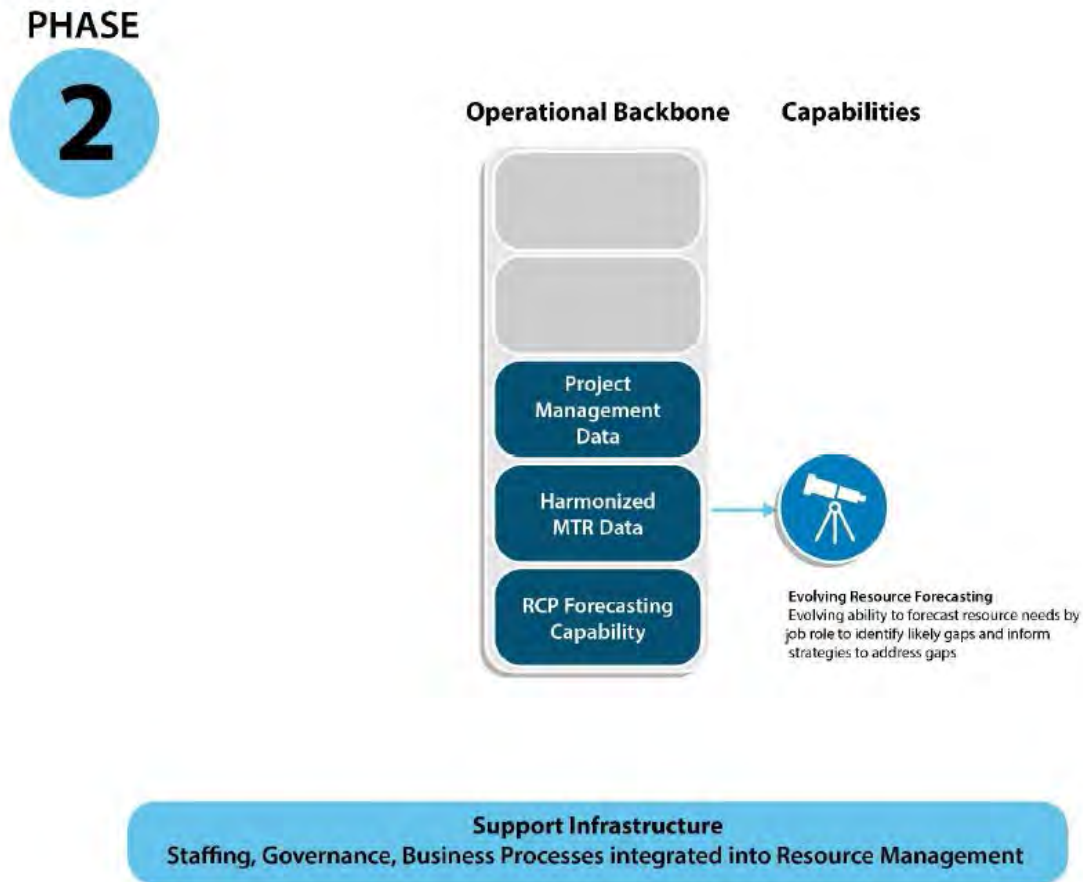
Significant achievements in this phase:

- Sustainable organizational design established
- Financial and resource management business processes incorporating resource capacity planning
- Resource capacity planning operating model established

Anticipated benefits in this phase:

- Ability to support and continually improve resource capacity planning capability
- Improved business processes enabling more proactive financial and resource management and planning
- Clear resource decision-making and accountability

Capability depiction at the completion of phase 2:



3. Resource Management Deployment and Closed Loop Planning

Once the initial capabilities are implemented and the building of the support model is progressing, phase 3 will focus on utilizing the collected time reporting data and comparing the actual submissions and effort expended to the forecasted submissions and forecasted effort. This will begin a process of continual improvement of the resource forecasting capability. As new data become available and are incorporated, the forecasting algorithms will be refined and the accuracy of the resource forecasts should improve. This phase will also entail development of additional workload forecasting algorithms beyond the initial algorithm set developed in phase 1.

This improving resource forecasting capability will then enable progressive analysis of options to balance capacity needs by re-allocating resources where practicable, to support more effective resource trade-off decisions, and to enable the development of proactive hiring plans that address anticipated demand.

Significant achievements in this phase:

- Ability to track actual effort versus forecasted effort and continually refine forecasts
- Systematic and consistent resource capacity analysis across the organization

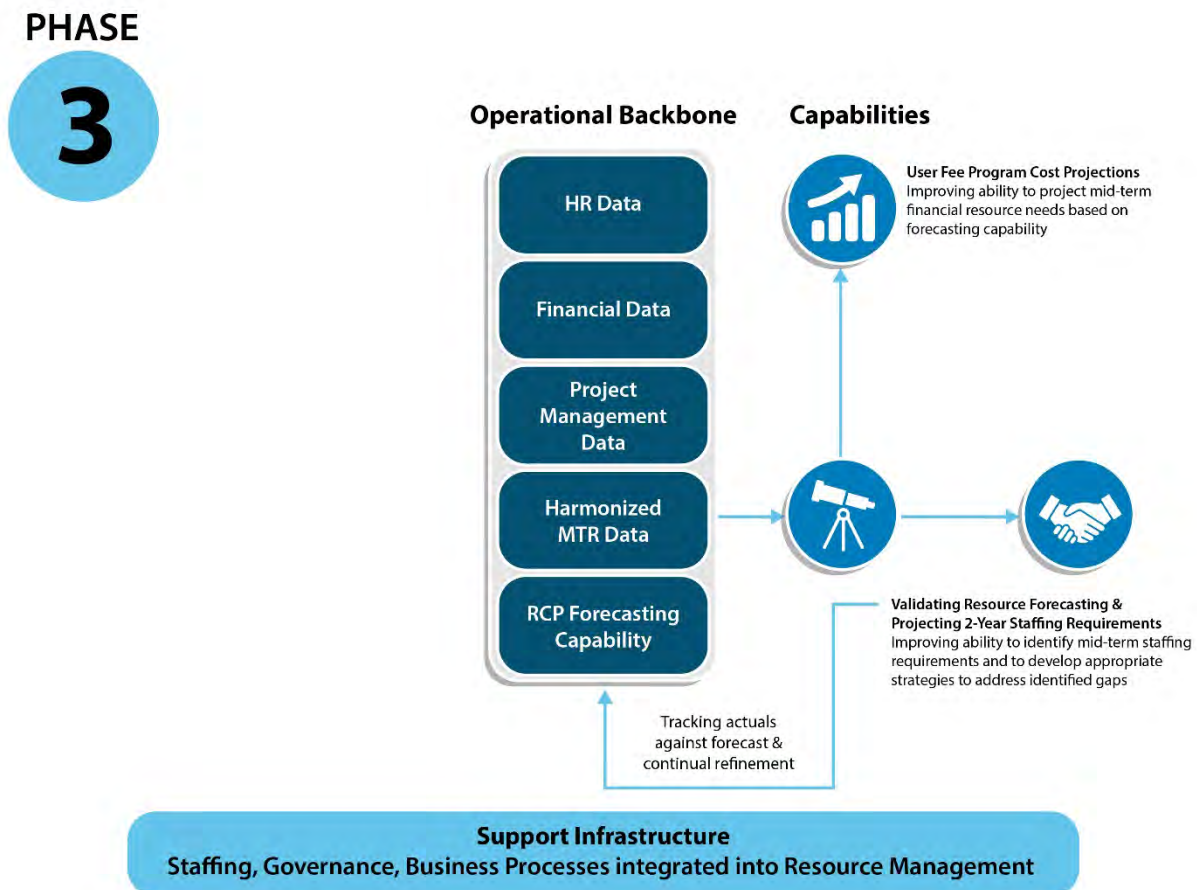
- Resource forecasts integrated with financial planning processes

Anticipated benefits in this phase:

- Emerging pro-active ability to identify resource gaps and develop tactics to address gaps
- Emerging holistic and comprehensive view of resource needs
- Capability to establish robust Capacity Planning Adjustment forecasting methodology to pro-actively adjust PDUFA and BsUFA annual fee revenue targets for anticipate resource needs

Capacity Planning Adjustment: At this point, FDA will bring in an independent accounting or consulting firm to conduct an evaluation that would provide options and recommendations for a new methodology to accurately assess changes in the resource and capacity needs of the PDUFA and BsUFA programs. After the evaluation is published, FDA will review public comments and would then be able to implement a new, forward-looking methodology to account for likely sustained changes in the resource need for these programs. This new method would replace the current interim capacity planning adjustment used in the setting of the PDUFA annual fee revenue amount. It would be a new adjustment mechanism for the setting of the BsUFA annual fee revenue amount.

Capability depiction at the completion of phase 3:



Stage Gate Review and Business Case Refinement

Following phase 3, FDA anticipates conducting a stage gate review to assess progress towards achieving the anticipated benefits of its modernized time reporting and resource capacity planning efforts. This review will consider how well the current implementation is realizing the program vision and identify any adjustments that may be necessary to fully realize the intended benefits.

This review will also consider the potential next steps towards further enhancing the operational capabilities. This may include integrating project management capabilities as well as portfolio analytics with the established resource capacity planning capabilities.

When successfully implemented, these integrated capabilities could potentially transform the FDA's operational ability to comprehensively assess its resource needs and work processes with real-time data. This integrated capability would enable a much more granular and real-time understanding of the resource capacity needs of the organization. It would improve FDA's ability to identify and react to process bottlenecks, identify opportunities to improve the efficiency of regulatory processes, and improve the agility at which FDA can ensure optimal deployment of its resources. This integrated capability could serve as a significant tool towards the operational modernization of FDA's regulatory work.

As part of this decision process, FDA may need to assess 1) the capabilities of its existing project management IT tools and systems, 2) how well existing tools and systems may integrate with the resource capacity planning and modernized time reporting capabilities, 3) whether integrating with existing systems would enable the desired end-state, and 4) the costs and benefits of available options. Depending upon the desired end-state and the results of analysis of alternative approaches, the integration of project management capabilities could represent a significant investment in long-term change that would have direct impacts on day-to-day regulatory review work across the organization. This change may require significant planning, requirements development, system configuration, training, and change management activities over a significant time-horizon to efficiently and effectively realize the desired end-state.

The business case review will weigh the expected costs and benefits of different options, as well as the organizational readiness and key factors that would enable successful implementation of the desired end-state. This review will result in an FDA decision on whether and how to best proceed.

4. Integrated Project Management (*pending stage gate review decision*)

Integrating project management capabilities with the resource capacity planning capabilities would provide a foundation for enabling the data-driven management of regulatory operations in real-time. This data-driven operational capability could significantly transform the way FDA manages its regulatory review resources, workload, and processes. It holds the promise of enabling the ability to pro-actively anticipate process bottlenecks and to more efficiently deploy resources when and where they are needed. It would enhance the ability to effectively and efficiently maintain performance on user fee performance goals while also maximizing the resources available for other critical regulatory and public health responsibilities.

At a minimum, these capabilities would need to ensure that project management and regulatory review processes are aligned through a common data model with the resource capacity planning capability. It could also involve deploying an enterprise information technology infrastructure for project management. Effectively integrating these capabilities would require significant support from agency leadership and investment in both dollars and staff time. It would require considerable planning, management, governance, and training to be effectively deployed. The implementation would also present significant risks that would need to be managed and mitigated, because it would impact daily operations.

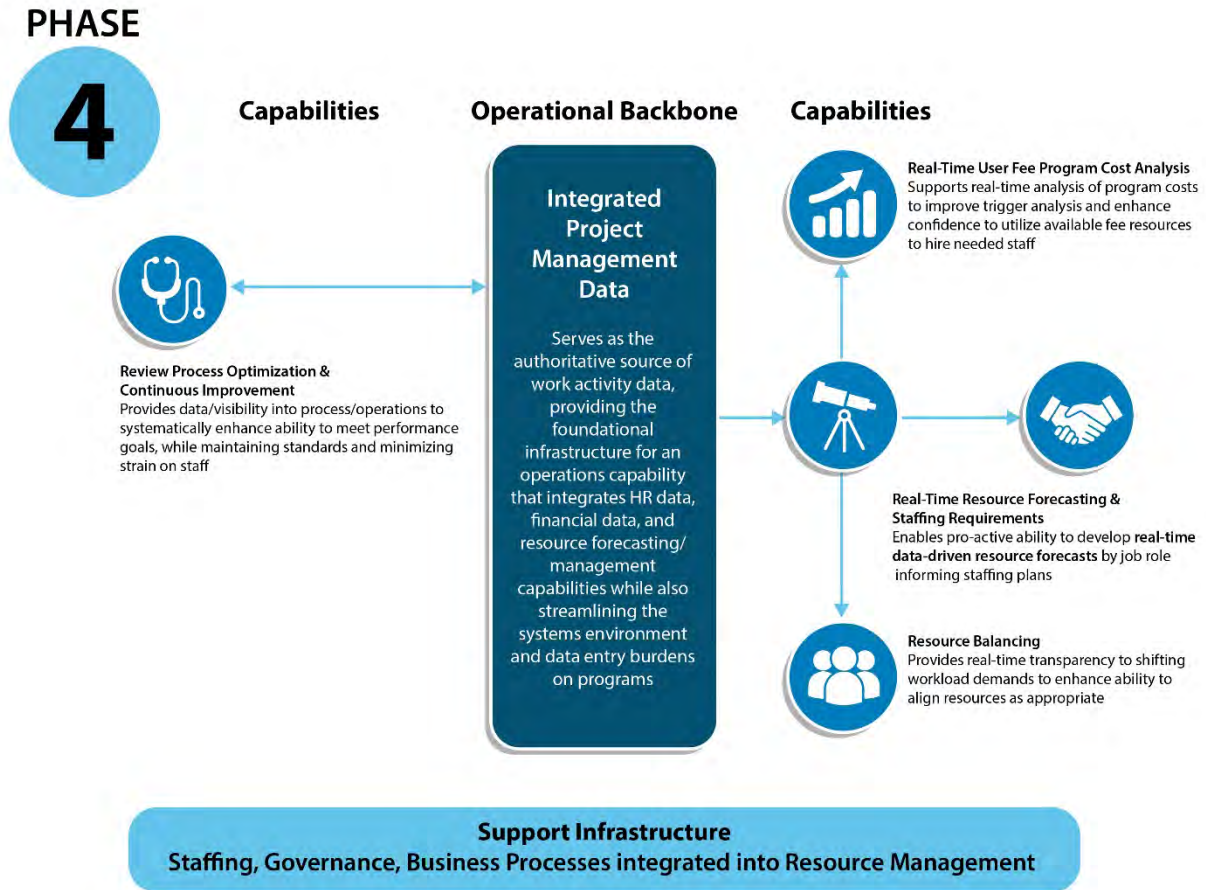
Significant achievements in this phase:

- Integrated IT infrastructure
- New ways of managing regulatory operations

Anticipated benefits in this phase:

- Authoritative source of planning data to enable sharing of best practices across organizations
- Ability to proactively mitigate future bottlenecks
- 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

Capability depiction at the completion of phase 4:



5. Integrated Portfolio Analytics and Reporting (*pending stage gate review decision*)

With the integration of both the resource capacity planning and project management capabilities, FDA will realize opportunities to vastly improve analysis and visualization of its operations and its work portfolio. In addition to further enhancing the integrated resource capacity planning and project management capabilities, implementation of this phase would enable strategic business decision-making with authoritative operational data not easily or efficiently available today. This would strengthen the ability of the organization across its many layers to understand its resource needs, identify bottlenecks, model what-if scenarios, and ensure appropriate capacity balancing through proactive processes.

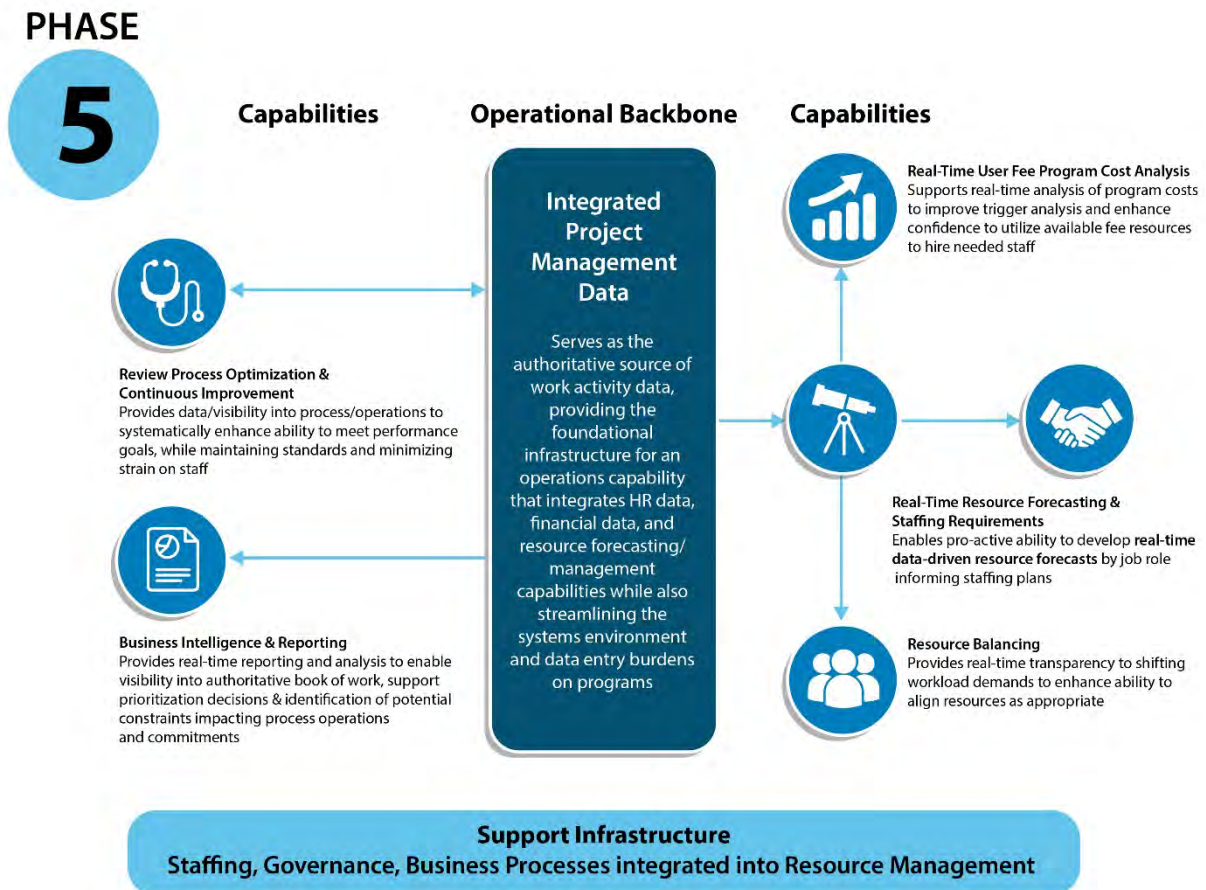
Significant achievements in this phase:

- Implementation of robust reporting and analytics capabilities that augment the integrated project management and resource capacity planning capabilities

Anticipated benefits in this phase:

- 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

Capability depiction at the completion of phase 5:



Critical Factors to Ensure Delivery of the Program Vision

This section identifies some of the major risks presented by the resource capacity planning implementation and how FDA will plan to mitigate these risks.

Enabling Change

FDA recognizes that success in the pursuit of a mature resource capacity planning capability will depend in large part on the ability of the FDA to align staff across the organization with the vision for the program. A successful program will need to cultivate buy-in and support of affected staff. This will require an active and evolving approach to managing the change.

The first change that will be most evident to staff will be the adoption of the 52-week modernized time reporting program. FDA will initiate a coordinated communication plan across the affected organizational components to share key details describing the program vision, the expected changes that will affect staff, and the benefits the changes will enable in the organization. This campaign will be built around a set of clear, consistent messages that are tailored to the specific needs and interests of different types of internal stakeholders. It will include messaging through different media, as well as meetings, focus groups, and listening sessions across the organization. It will also focus on ensuring that all levels of management have the information and tools to address questions and concerns they may receive from their direct reports.

Training will be necessary to enable successful change to the modernized time reporting paradigm. FDA will ensure that appropriate just-in-time technical training is available to support staff adoption of new time reporting software. In addition, FDA will build local support capabilities to address questions of a more operational nature (for example, “What time reporting category should I report X activity to?”). A knowledge management capability will support the ability to provide consistent answers to these questions, while also identifying any category gaps that may need to be addressed.

Recognizing the extent of the organizational change required in the initial implementation of the modernized time reporting approach, FDA is striving to keep the initial reporting demands as simple as possible to minimize the challenge of incorporating modernized time reporting into the normal course of business. Once this initial adoption phase succeeds, FDA will begin considering adding additional levels of detail to the modernized time reporting categories where it sees strategic value. This approach will provide a path to evolving the category structure while also balancing the need for organizational buy-in, and managing the costs and benefits of the modernized time reporting approach.

A second major area requiring change enablement will be among FDA’s levels of management. Managers will benefit from training and support to effectively begin utilizing the collected data and the delivered reports to help support the management of the operations within their organizations. FDA will develop training approaches to ensure management has the requisite financial and managerial ability to utilize the data and reports. The project team will engage in regular cadence across the levels of management to assess reporting needs and continually refine the data it provides to management.

A third major area requiring change enablement will be on the administrative support layer that supports and delivers resource planning. New business processes will need to be developed and continually improved to enable the agency to systematically deliver repeatable, data-driven, and efficient business processes that support a more agile resourcing capability in a dynamic environment.

Enhancing Information Technology Infrastructure (IT)

FDA will have to address several IT needs to realize the program vision. These include: new time reporting software; data warehousing capabilities; flexible reporting tools to provide standardized and ad hoc reporting services; analytical capabilities to understand activity costs, including support activities; capabilities to model “what-if” scenarios of various levels of workload demand and staffing models; and advanced predictive analytic capabilities to forecast likely regulatory submissions and other changes in workload demand. To support the longer-term vision, FDA may also need to consider how best to integrate the resource capacity planning capability tools with its project management systems, human capital data, and financial data.

To meet these needs, FDA will consider software tools that provide the maximum flexibility, while balancing lifecycle cost considerations. This may include cloud-enabled, platform-as-a-service capabilities to support systems flexibility and integration opportunities across the phases of the journey.

Harmonizing Data Model and Processes

In the near-term, FDA will need to invest in developing a data model for the modernized time reporting categories that aligns activities common to multiple centers and activities that cut across centers, while also providing for a degree of flexibility to provide the data needed within centers. This common data model will be necessary to support the updated resource capacity planning adjustment methodology, which will need to be able to balance programmatic resources needs across centers and other organizational components.

Select representative examples include:

- Review activities in CBER and CDER— both CDER and CBER review many types of applications, including BLAs, INDs, NDAs, etc. The common data model needs to ensure that, at an appropriate level, both Centers report common review activities in a consistent fashion so as to support analysis of resources needs between the centers.
- Combination product review – can involve more than one center in the review of a single application. The common data model needs to enable appropriate and consistent tracking of these cross-center workflows.
- Inspections – Pre-approval inspections may be conducted by ORA to support the review of marketing applications led by the centers. The common data model needs to enable appropriate and consistent tracking of these center-ORA workflows.

The harmonized data model will require ongoing management and the establishment of change control procedures to ensure it can continually evolve and improve in a strategic and controlled manner.

In addition to harmonization of the data model for the modernized time reporting categories, the move to integrated project management would necessitate consideration of the appropriate level for the harmonization of work processes that are common across centers or other major organizational components.

Building Internal Capability (Staffing)

Achieving the program vision will require a significant dedicated effort and a wide variety of skill sets, including project management, program management, contract management, financial management and analysis, resource management and planning, predictive analytics, business analysis and process improvement, change management, communications, training, and IT management, as well as domain-specific knowledge regarding FDA's regulatory paradigm and review processes.

FDA intends to build out the requisite support functions through a combination of leveraging existing internal staff and the targeted hiring of new staff to supplement skills needs. FDA will utilize contract resources to provide services that are either needed on a temporary basis, or where critical support is needed faster than hiring processes can accommodate.

Moving Forward

FDA is committed to establishing a resource capacity planning capability and to modernizing its time reporting approach for its human medical product programs. The implementation approach outlined in this plan, developed in consultation with leading thinkers in the field of R&D operations, aims to develop the resource capacity planning capability while providing for longer-term opportunities to further enhance the agency's operational capabilities through project management and portfolio analytics capabilities. FDA recognizes that it is at the beginning of a journey that will take many years to reach full maturity. However, it will realize progressive operational benefits across each phase of the journey. FDA believes that each successive phase of maturity will help enhance its ability to more effectively and efficiently deliver on its commitments to the public.

Public Engagement

Recognizing the interest of public stakeholders in the development of these capabilities, FDA has committed to convening public meetings each year to provide, in part, an update on progress towards the implementation of its resource capacity planning and modernized time reporting capabilities. These meetings will be held in the third quarter of FDA's fiscal year (April – June) each year beginning in FY 2019. The FDA will welcome public comment regarding its approach and progress at these meetings.