U.S. FOOD & DRUG ADMINISTRATION

Resource Capacity Planning and Modernized Time Reporting Implementation Plan

March 2023

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1 Executive Summary

The Prescription Drug User Fee Act of 1992 (PDUFA), Biosimilar User Fee Act of 2012 (BsUFA), and Generic Drug User Fee Amendments of 2012 (GDUFA) authorize FDA to collect user fees from industry to support activities related to the review of certain human medical product submissions. These user fee programs have expanded in scope since their origination, and the growing volume and scientific complexity of product submissions has led to increased resource demands on the agency.

To address this need, FDA committed under PDUFA VI, BsUFA II, and GDUFA II to establish a *resource capacity planning* (RCP) capability and to modernize its time reporting to better anticipate and address resource demands in the user fee programs. RCP is a systematic approach to quantifying the number and type of resources needed to optimally address forecasted workload. Modernized time reporting was implemented in the Center for Biologics Evaluation and Research (CBER) in 2018, the Center for Drug Evaluation and Research (CDER) in 2019, and the Office of Regulatory Affairs (ORA) in 2021. The initial RCP capability was established in CDER and CBER in 2020.

RCP is a systematic approach to quantifying the number and type of resources needed to optimally address forecasted workload.

Together, the RCP and modernized time reporting capabilities enabled FDA to implement its *Capacity Planning Adjustment* (CPA) methodology, which adjusts user fee revenues to account for changes in resource needs. The CPA methodology uses forecasting to help FDA anticipate staffing needs in order to have resources in place to complete timely review of incoming submissions. The CPA was first implemented for adjusting FY 2021 fees for PDUFA and BsUFA. The authorization of GDUFA III includes a provision providing for a CPA for the GDUFA program beginning with the setting of FY 2024 fees. With this expansion of the CPA to GDUFA, these capabilities are being extended or established, as warranted, across CDER and ORA.

The purpose of this plan is to outline FDA's approach to maturing its RCP capability during PDUFA VII, BsUFA III, and GDUFA III (i.e., FY 2023–2027) per the commitments in each respective commitment letter (see section 2.1). The plan describes FDA's progress to date and the current state of its RCP capability, then describes FDA's areas of focus for further development of this capability over the next five years. This work will include the refinement of the Agency's operational support model for RCP; the implementation of the GDUFA CPA for setting FY 2024 fees; the continual improvement of the CPA for the PDUFA and BsUFA programs; the continual improvement of time reporting and its use in the CPA; and the continued integration of RCP analyses into the Agency's financial and operational decision-making processes.

By implementing the approach to RCP maturation outlined in this plan, FDA expects to help ensure optimal use of user fee resources and to enhance its ability to deliver on its commitments to the public.

2 Introduction

2.1 Purpose

The purpose of this implementation plan is to describe how FDA will continue to mature and utilize its resource capacity planning (RCP) and modernized time reporting capabilities during the PDUFA VII, BsUFA III, and GDUFA III authorization period (i.e., FY 2023–2027). The publication of this plan satisfies the following specific commitments:

- PDUFA VII: "By the end of the 2nd quarter of FY 2023, FDA will publish an implementation plan that will describe how resource capacity planning and time reporting will continue to be implemented during PDUFA VII."[1]
- BsUFA III: "On or before the end of the 2nd quarter of FY 2023, FDA will publish an implementation plan that will describe how resource capacity planning and time reporting will continue to be implemented during BsUFA III."[2]
- GDUFA III: "By the end of the 2nd quarter of FY 2023, FDA will publish an implementation plan that will describe how resource capacity planning and time reporting will continue to be utilized during GDUFA III."[3]

1 PDUFA Reauthorization Performance Goals and Procedures Fiscal Years 2023 through 2027, p. 57 (https://www.fda.gov/media/151712/download)

2 BsUFA Reauthorization Performance Goals and Procedures Fiscal Years 2023 through 2027, p. 32 (https://www.fda.gov/media/152279/download)

3 GDUFA Reauthorization Performance Goals and Program Enhancements Fiscal Years 2023 through 2027, pp. 38–39 (https://www.fda.gov/media/153631/download)

2.2 Background

In FY 2018 (the first year of PDUFA VI, BsUFA II, and GDUFA II), FDA formally initiated efforts to establish an RCP capability to support these user fee programs. The idea for an RCP capability emerged from the user fee reauthorization process, and the commitment to establishing this capability was memorialized in the respective commitment letters for these programs.[4,5,6]

The intent of RCP was to build more systematic, data-driven, and repeatable processes to understand and anticipate current and future resource demand in these user fee programs, thereby enabling the Agency to proactively ensure its organizational components are optimally and efficiently resourced. FDA defined the following as a working vision statement to help guide the development of its RCP 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.[7]

In addition to establishing RCP, FDA also committed to modernize its activity-based time reporting programs and to modernize the Capacity Planning Adjustment[8] (CPA) methodology.

To coordinate delivery of these commitments in both word and spirit across multiple medical product centers, FDA developed an RCP implementation plan. That plan defined a five-phase approach, as described in section 3.2 below.

During the FY 2018–2022 implementation period (accounting for PDUFA VI, BsUFA II, and GDUFA II), FDA delivered on its commitments, as evidenced by the following accomplishments. (Note: Table 1 states each commitment as described in the PDUFA VI commitment letter[9] as an example. These commitments were described similarly in the BsUFA II[10] and GDUFA II[11] commitment letters.)

4 PDUFA Reauthorization Performance Goals and Procedures Fiscal Years 2018 through 2022 (https://www.fda.gov/media/99140/download)

5 BsUFA Reauthorization Performance Goals and Procedures Fiscal Years 2018 through 2022 (https://www.fda.gov/media/100573/download)

6 GDUFA Reauthorization Performance Goals and Program Enhancements Fiscal Years 2018 through 2022 (https://www.fda.gov/media/101052/download)

7 Resource Capacity Planning and Modernized Time Reporting Implementation Plan (https://www.fda.gov/media/112562/download)

8 Note: The concept of the capacity planning adjustment evolved from the PDUFA workload adjuster. PDUFA VI provided for an interim capacity planning adjustment until the updated CPA was ready for implementation.

9 See footnote 4.

10 See footnote 5.

11 See footnote 6.

Table 1. FDA's RCP–Related Commitments and Accomplishments Under PDUFA VI, BsUFA II, and GDUFA II

Commitments	Related Accomplishments
Implementation Plan: "FDA will publish a PDUFA program resource capacity planning and modernized time reporting implementation plan no later than the 2nd quarter of FY 2018. FDA will continue to utilize information and recommendations from a third-party assessment of resource capacity planning, financial analytics, and modernized time reporting for PDUFA as part of the implementation plan."	• Through a competitive process, FDA hired PricewaterhouseCoopers (PwC) as the third-party to assess and advise on its approach to implementing resource capacity planning. • PwC's private-sector Pharmaceutical & Life Sciences R&D Advisory Services helped to fit their Integrated Operations and Business Planning (IOBP) framework to meet the needs of these UFA programs to enable RCP. • FDA worked to align on an approach to meet the commitments across the Agency's organizational components by adapting the IOBP to its operating paradigm. • FDA articulated its approach in the Resource Capacity Planning and Modernized Time Reporting Implementation Plan[12] published in March 2018.
RCP Team: "FDA will staff a resource capacity planning team that will implement and manage a capacity planning system across the PDUFA program in PDUFA VI."	• FDA established the Resource Capacity Planning Staff in CDER to serve as the lead on FDA RCP activities in collaboration with CBER. CBER also hired staff to support RCP. • FDA established an HQ team to support implementation, operations, and maintenance of the Insight Time Reporting application.

12 See footnote 7.

Table 1. (continued)

Commitments	Related Accomplishments
CPA Methodology: "FDA will obtain through a contract with an independent accounting or consulting firm an evaluation of options and recommendations for a new methodology to accurately assess changes in the resource and capacity needs of the human drug review program. The report will be published no later than end of FY 2020 for public comment. Upon review of the report and comments, FDA will implement robust methodologies for assessing resource needs of the program. This will include the adoption of a new resource capacity adjustment methodology, in place of the current PDUFA workload adjuster, that accounts for sustained increases in PDUFA workload."	• FDA commissioned Booz Allen Hamilton to conduct two evaluations: one of the PDUFA/BsUFA CPA methodology,[13] and a second of the GDUFA CPA methodology.[14] • FDA published both evaluation reports in FY 2020. Findings endorsed the methodology while providing considerations for future enhancements. • The proposed CPA methodology for PDUFA and BsUFA was implemented for setting FY 2021 fees. • The proposed CPA methodology for GDUFA was evaluated, but there was no statutory mechanism to implement the methodology for fee-setting during the FY 2018–2022 authorization period.
Allocation and Reporting of CPA Funds: "FDA recognizes that revenue generated by the workload adjuster and the resource capacity adjustment will be allocated to and used by organizational review components engaged in direct review work to enhance resources and expand staff capacity and capability. FDA will document in the annual financial report how the workload adjuster and resource capacity adjustment fee revenues are being utilized."	• FDA established processes to ensure that revenues generated by the CPA are allocated to review components in CDER and CBER. • FDA added documentation to annual financial reports on the distribution of these resources.

13 Independent Evaluation of the PDUFA and BsUFA Resource Capacity Planning Adjustment Methodology (https://www.fda.gov/media/136606/download)

14 Independent Evaluation of the GDUFA Resource Capacity Planning Adjustment Methodology (https://fda.report/media/140656/Independent+Evaluation+of+the+GDUFA+Resource+Capacity+Planning+Adjustment+Methodology_0.pdf)

Recognizing the continued value of RCP to support optimal resourcing and operations, additional RCP-related commitments were agreed upon through the most recent user fee reauthorization process (covering FY 2023–2027, accounting for PDUFA VII,[15] BsUFA III,[16] and GDUFA III).[17] Those commitments include publishing a plan by the end of the second quarter of FY 2023 describing how RCP and time reporting will continue to be implemented and utilized during PDUFA VII, BsUFA III, and GDUFA III. This implementation plan will address topics relevant to the maturation of resource capacity planning, including FDA's approach to the following areas:

- The continued maturation of its resource capacity planning capability, including:
  - » The continual improvement of the PDUFA and BsUFA CPA (section 3.2.4)
  - » The continual improvement of time reporting and its utilization in the CPA (section 3.2.3)
- The integration of resource capacity planning analyses in the Agency's resource and operational decision-making processes (section 3.2.5)
- The implementation of the GDUFA CPA, with a first year of adjustment for FY 2024 user fees (section 3.2.6)

In addition to the commitments above, FDA will provide annual updates on the FDA website on the Agency's progress relative to the activities detailed in this implementation plan by the end of the second quarter of each subsequent fiscal year.

This plan will describe the current state of resource capacity planning, outlining the progress to date against the initial journey map and identifying opportunities for continued enhancement. It will then discuss FDA's approach to the topics described above as well as additional opportunities to evolve RCP to fully deliver on FDA's vision.

15 See footnote 1.

16 See footnote 2.

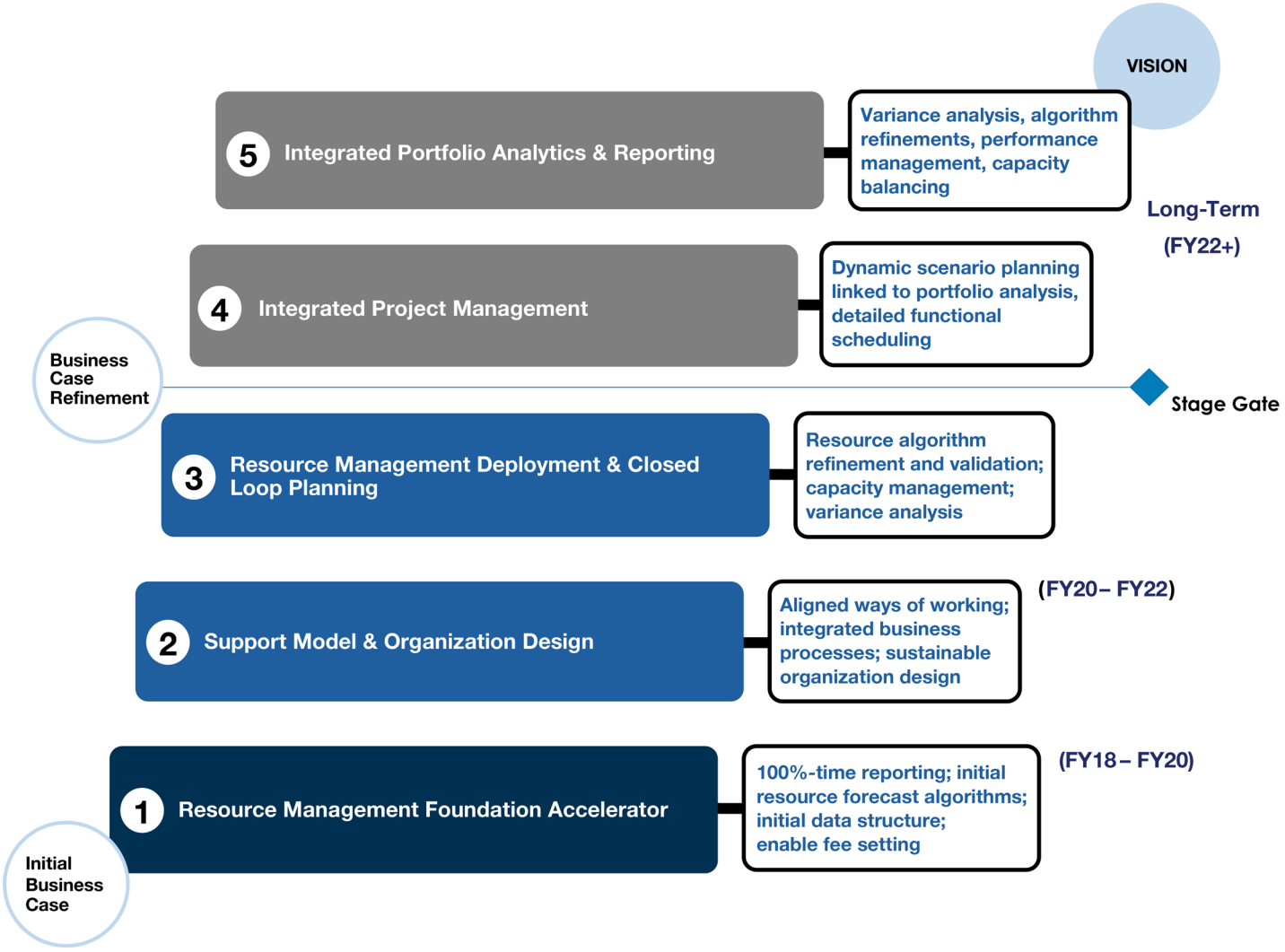
17 See footnote 3.

3 Resource Capacity Planning in FDA's Human Drug and Biologics Programs

3.1 FDA's RCP Capabilities

Guided by the vision statement above, FDA defined a tailored journey for RCP and time reporting in the original implementation plan published in 2018. This journey reflected near-, mid- and long-term capability development. Stage gates along the journey were included to provide for the evaluation of progress and next steps based on a business case. This approach, as articulated in the original public implementation plan, is summarized in Figure 1.[18]

Figure 1. FDA's Journey for the Development of Its RCP Capability.



18 See footnote 7.

Phase 1: Resource Management Foundation Accelerator

The first phase of the RCP journey focused on building a foundation for the RCP capability in CDER and CBER. It included implementing modernized time reporting, establishing a resource forecasting capability, and enabling the capacity planning adjustment.

Modernized time reporting was established in 2018 and 2019 in CBER and CDER respectively, such that all staff are now required to report time 52 weeks per year. CBER enhanced an existing tool to enable its modernized time reporting approach. CDER collaborated with Agency stakeholders to develop and implement the Insight Time Reporting application to enable its approach to modernized time reporting. Beyond CDER, Insight Time Reporting has provided the technical and programmatic infrastructure to support the modernization and consolidation of other time reporting applications in other parts of the Agency. These implementations included significant change management efforts that prepared and supported staff to ensure sustainment of the time reporting capability. CBER and CDER have both fully institutionalized the modernized time reporting paradigm, and both centers regularly experience compliance rates exceeding 95 percent.

The resource forecasting approach was established in CBER and CDER concurrently through a collaborative effort. This effort included the development and implementation of a program to model and forecast certain sponsor submissions that drive aspects of CBER's and CDER's workload, including, for example, applications, supplements, and sponsor meetings. This effort also included the implementation of a methodology to forecast the number of full-time equivalent employees needed to deliver on the forecasted workload. This methodology was built on a foundation of the modernized time reporting data.

The implementation of modernized time reporting and the development of the resource forecasting approach enabled the implementation of an updated approach to the CPA. The CPA is a mechanism utilized in the annual fee-setting process to adjust the annual revenue amount to account for projected workload volumes. The CPA has its conceptual roots in the PDUFA workload adjuster, which existed since PDUFA III. An interim CPA methodology for PDUFA, incorporating some updates to the PDUFA workload adjuster, was established by the legislation that authorized PDUFA VI. That statute also provided a process by which the PDUFA methodology could be updated and by which a BsUFA methodology could be first implemented. This process included commissioning a third-party study, publishing the study on the FDA website, and reviewing public comment on the study prior to implementing the updated methodology. After publication of the study[19] and review of the public comment,[20] FDA first implemented the new CPA methodology for PDUFA and BsUFA in the setting of fees for FY 2021.[21,22]

As described above, CBER and CDER have largely completed the foundational work described in phase 1 of the journey map. However, modifications to this foundation are needed to sustain the existing capabilities and extend them as required, particularly in relation to the GDUFA program.

While FDA had commitments in GDUFA II similar to PDUFA VI and BsUFA II, the GDUFA II statute did not provide for a CPA methodology. CDER established the foundation of a CPA for GDUFA as committed[23] but was not able to implement it within the fee-setting process. GDUFA III, however, does establish the CPA as a component of the annual GDUFA fee-setting process starting for FY 2024 fee-setting. GDUFA III also expanded the scope of workload to be included within the GDUFA CPA to include a number of workload drivers, including some inspections led by the Office of Regulatory Affairs (ORA). As such, while CDER has been working to update its methodology to provide for the expanded scope, ORA has been working to build the requisite foundation for its component of the GDUFA CPA. While ORA has long maintained systems to report time for inspections and laboratory work, it has recently implemented Insight Time Reporting to provide time reporting data for the full scope of its operations. In addition, ORA is working to establish a resource forecasting capability to enable forecasting algorithms to account for its in-scope GDUFA workload in the GDUFA CPA.

Over the next five years, in addition to expanding the foundation as described to provide for the GDUFA CPA, FDA will refine the PDUFA and BsUFA CPAs to incorporate allergenics and a set of post-approval activities as provided by statute.

19 See footnote 13.

20 Comment from Pharmaceutical Research and Manufacturers of America (PhRMA) Re: Docket No. FDA-2020-N-0989 (https://www.regulations.gov/comment/FDA-2020-N-0989-0002)

21 Prescription Drug User Fee Rates for Fiscal Year 2021 (https://www.federalregister.gov/documents/2020/08/03/2020-16833/prescription-drug-user-fee-rates-for-fiscal-year-2021)

22 Biosimilar User Fee Rates for Fiscal Year 2021 (https://www.federalregister.gov/documents/2020/08/04/2020-16858/biosimilar-user-fee-rates-for-fiscal-year-2021)

23 See footnote 14.

Phase 2: Support Model & Organizational Design

While phase 1 focused on establishing the foundational functions of the resource capacity planning capability, phase 2 focused on developing a support model and organizational design to sustain the capability.

Given the complex and multi-center nature of the user fee programs, a layered organizational approach was developed. For the core of the RCP capability, FDA took a center-led, collaborative approach to the development of RCP. CBER and CDER developed staffs to focus on the collaborative development, operations, and continued enhancement of the RCP capability and to serve as a resource for other centers across the Agency in the RCP space, as appropriate. With the expansion of the CPA to include GDUFA, ORA has recently been focused on building the capabilities and support model to support its specific needs.

The modernized time reporting support model has taken a different approach to meet the broader needs of that capability. FDA developed Insight Time Reporting, the first IT deployment at FDA to use agile development methods, to support the common, yet varied, time reporting needs of organizational components across FDA. ITR was first implemented to support CDER's time reporting needs and has since been implemented in the Center for Devices and Radiological Health (CDRH), ORA, and select components of the Office of the Commissioner (OC). While CBER adapted its existing time reporting tool to meet its immediate modernized time reporting needs in FY 2018, it is planning to transition to the ITR system.

In order to meet these modernized time reporting needs in an effective and efficient manner, FDA adopted a hybrid support model for ITR. This model included a team in OC that was established to serve as the ITR product owner, manage technical aspects of the application, and support implementation efforts. Concurrently, centers have established their internal ITR support teams. The center-specific teams focus on the functional aspects of the tool and work to ensure their specific center's time reporting requirements are being achieved.

This support model has functioned well during the first five-year authorization period to establish the foundation as the capability delivered on its initial core commitments. The resiliency during the initial shocks of the COVID public health emergency are a testament to the strength of this support model. With the continued expansion and growth of RCP, and the focus shifting from development to sustainment, FDA will continue to evolve the support model as needed to meet the moment. This work will include formalizing, sustaining, and continually improving the support model and business processes for RCP across the next authorization period while incorporating partner teams from ORA as appropriate. In addition, FDA will review governance functions to ensure consistency in processes and decisions across the expanding RCP capability.

Technology is an additional core component of the support model. The RCP staff have been collaborating with internal stakeholders to design and implement a modern, cloud-based, analytical infrastructure to support and maintain the technical aspects of the RCP program. This implementation would provide myriad benefits to RCP and its client stakeholders, including reduced manual effort in model operations and maintenance, greater computational power, increased automation and reproducibility of model runs, and enhanced automation of reporting capabilities within the organization, to name a few. The implementation of this technology environment is anticipated to be iterative over the next authorization period.

Phase 3: Resource Management Deployment and Closed Loop Planning

Phase 3 included resource management deployment and closed loop planning. Resource management deployment refers to enabling systematic and consistent resource capacity analyses across the organization and integrating those analyses with financial planning processes. The RCP capability has enabled this consistent analysis at the center-level, providing a streamlined ability to make data-informed

resource allocation decisions. Over the next authorization period, FDA will continue to integrate RCP analyses with operational and resource decision-making processes. FDA will work to assess and deliver on opportunities for fit-for-purpose RCP tools to support operational capabilities within the review programs.

The term “Closed loop planning” refers to a process of feedback loops. For example, when a forecast of a submission volume or FTEs needed is produced, the actuals are then tracked and compared to the forecasted values. Then, an analysis process assesses factors contributing to any significant variances, and learnings from that process inform modifications to the forecasting approach moving forward. This is a form of continuous learning or continuous improvement and is a best practice in any forecasting capability.

RCP was designed with these closed-loop continual improvement processes in mind from the start. The submission volume forecast modeling process has, from inception, involved an annual reassessment of data and appropriate modeling approaches to ensure that the forecasting models are adapting and utilizing the approaches that best fit actual values out of sample. There will always be some variance with any forecasting model, but the goals are to ensure minimal and unbiased variance across the full suite of models utilized.

Phase 4: Integrated Project Management & Phase 5: Integrated Portfolio Analytics and Reporting

Phases 4 and 5, as originally conceived, refer to the integration of the RCP capability with project management, portfolio analytics, and reporting capabilities. These phases were recognized in the original 2018 RCP implementation plan as a potential but optional part of the long-term vision, which would be dependent on an assessment process to evaluate the potential cost-benefit of such integrations and select the optimal path forward. This integrated capability could, in theory, modernize FDA’s regulatory work by enabling both granular and holistic understanding of FDA’s resource capacity needs in real time.

Phase 4 refers to integrating project management and RCP capabilities to enable data-driven management of regulatory operations. At a minimum, this integration would require aligning project management processes with the RCP capability through a common data model. It may also involve the implementation of an enterprise IT infrastructure that integrates RCP data and analyses with project management functions. Successful integration of project management and RCP capabilities could provide a single source of truth on project, resource, and cost information. Equipped with this information, front-line managers could develop staffing plans for projects that are informed by real-time resource forecasts and analysis of user fee program costs. Managers could proactively align resources to respond to shifts in workload demand.

Phase 5 refers to the implementation of portfolio analytics and reporting capabilities that augment the project management and RCP capabilities integrated in phase 4. Implementation of this phase could strengthen FDA's ability to understand its micro- and macro-level resource needs within one holistic book of work. Portfolio and resource capacity data could support strategic and operational decision-making across all levels of the organization. For example, real-time reporting and analysis could support prioritization of work, identification of constraints or bottlenecks that are impacting regulatory operations, and modeling of what-if scenarios. Increased visibility into regulatory operations would enable continuous improvement and optimization of regulatory processes.

The decision to implement an integrated project management, portfolio analytics and reporting ecosystem is complex and requires significant planning. Proceeding on this pathway would be a significant, multi-year investment requiring coordination across multiple complex centers and offices. It would impact operations across much of the human drug and biologics programs and would require significant change management efforts. It would require substantial efforts to standardize processes and data across organizations and require aligning of a complicated existing IT infrastructure that differs across organizations. It would likely change how most staff interact with technology and would likely entail significant changes to the management of regulatory operations. While the potential benefits to FDA's operations of this fully implemented capability could be significant, so too could be the costs, both in dollars and staff time. In addition, a flawed implementation could have significant risks and operational impacts. As such, deliberate and detailed planning are required to ensure an appropriate approach.

After considering the current state landscape, FDA maintains an aspiration to move towards an integrated operational capability similar to that described above. It also identified, however, that more information is needed to make an informed decision on the appropriate path forward and to better understand the feasibility, impact, costs, benefits, and risks of this integration, as well as any potential alternatives. Thus, FDA aligned on the need for a feasibility study to better understand the optimal path forward.

3.2 Implementation Plan

As RCP matures and FDA considers future integration options, we will continue to develop, manage, and optimize RCP's existing capabilities.

3.2.1 Feasibility Assessment of Integrated Project Management, Portfolio Analytics, and Reporting

In FY 2024, FDA will engage a contractor to conduct a feasibility study of integrated project management, portfolio analytics and reporting (phases 4 and 5). This study is intended to address the feasibility of this integration and include assessment of readiness, costs, pros, cons, gaps, and potential alternatives. Based on the findings of the feasibility study, FDA will consider how best to proceed.

3.2.2 Updated RCP Concept of Operations

As noted above, the first authorization period with RCP commitments (FY 2018 – 2022) focused on the development of the foundational RCP capability through a collaborative approach across CDER and CBER. With this foundation now established, FDA will focus on sustaining, refining, and expanding the RCP capability over the next five years of the current authorization period. This effort will include a review of the existing support and operating model and subsequent updates to the cross-center governance as needed to align ORA.

3.2.3 Continual Improvement of Time Reporting

As noted above, CDER and CBER established modernized time reporting in the previous authorization cycle. CDER collaborated on the development of Insight Time Reporting (ITR), while CBER updated its existing time reporting system to enable reporting 52 weeks a year. ITR has also now been implemented in other parts of FDA, including ORA.

Prior to the implementation of ITR, ORA conducted partial time reporting utilizing other ORA systems, and only investigative and laboratory staff reported time. This led to gaps in the time reporting data needed to describe ORA's full workload and to support its operations. The full, modernized time reporting approach enabled by ITR will help ORA to quantify and forecast its GDUFA workload while supporting the management and operations of its GDUFA resources.

CBER is planning to transition its time reporting to ITR during the current authorization period while maintaining the existing data structure with its current program to ensure longitudinal stability of its data. As both CBER and ORA adapt to ITR, the RCP function will look to enhance opportunities to support, facilitate, and strengthen ITR-related knowledge sharing, best practices, and data alignment across the organizations. This cross-center collaboration may include areas such as change management, category alignment, reporting, and technical features of the ITR application.

FDA will work to ensure that the categories included in ITR remain consistent with evolving program needs while balancing the time burden on employees to enter their time. For example, in FY 2022 CDER and CBER collaborated on ITR category updates to ensure that the category structure appropriately reflects new priorities and programs in the new authorization period for PDUFA, BsUFA, and GDUFA. In addition, CDER and CBER formalized processes to ensure annual review of ITR categories to identify and make updates, including the removal of categories no longer needed. This annual review process will help to manage the costs of entering time across thousands of employees while supporting use of the collected data for resource management and operational insights.

3.2.4 Continual Improvement of the CPA

In the previous authorization period, FDA developed a CPA methodology for PDUFA, BsUFA, and GDUFA and implemented this methodology for PDUFA and BsUFA fee-setting. Over the current authorization period, FDA will implement the CPA methodology for GDUFA fee-setting and continually improve the technical, analytical, and organizational processes as needed to support the PDUFA, BsUFA, and GDUFA CPAs.

Opportunities for technical improvements include items such as streamlining and refactoring existing model code to increase efficiency, maintenance, and interpretability and migrating to a cloud-based analytics environment.

Opportunities for analytical improvements include ongoing continual improvement of all models based on the latest data. Additionally, refinements to models may be introduced to account for program dynamics, as appropriate and feasible. For example, FDA plans to work toward adapting its Abbreviated New Drug Application (ANDA) forecasting model to differentiate between complex and non-complex ANDAs once requisite data is available and models are validated.

Opportunities for process improvements include continual improvement, formalization, and automation of annual variance analysis procedures; formalization of processes to align decision-making and governance across organizations; and other administrative procedures relating to the CPAs.

As appropriate, FDA will work to implement additional elements in the CPAs over the current authorization period as provided for in statute. For PDUFA and BsUFA, these elements include:

- Incorporation of allergenics
- Incorporation of post-approval activities relating to annual reports
- Implementation of post-market requirements and commitments
- Review of risk evaluation and mitigation strategies

3.2.5 Integrating RCP Analyses into Financial and Operational Decision-Making Processes

Over the current authorization period, FDA will leverage the RCP foundation by adapting existing financial and resource management processes to utilize RCP data and analyses. By integrating RCP analyses into these processes, FDA will enable more proactive management of user fee funding and resources.

FDA will coordinate with internal stakeholders to plan and prioritize opportunities to integrate RCP analyses into existing financial and resource management processes. Such opportunities include engaging financial and operational leaders to identify opportunities to leverage RCP data to help address their specific needs and challenges, then delivering or enhancing RCP reporting tools or fit-for-purpose analyses to address these needs. FDA will engage its internal budget community to identify opportunities to enhance financial management through the use and application of RCP data. FDA will consider opportunities such as building a resource management community of practice to serve as a forum for sharing knowledge and best practices about resource planning and analytics across centers.

FDA will explore enhancing its scenario planning capability to enable dynamic use of resource models by an extended set of internal stakeholders, as technology allows. Such a capability could provide program leaders the ability to model workload scenarios to understand implications on resource demands. This capability could support modeling of what-if scenarios and empower program leaders to proactively balance capacity so that user fee funds and resources are used optimally.

3.2.6 The Implementation of the GDUFA CPA

Per the framework agreed to and reauthorized as GDUFA III in the FDA User Fee Reauthorization Act of 2022,[24] FDA shall establish a CPA methodology for GDUFA beginning with the setting of fees for FY 2024. The CPA methodology to be implemented for GDUFA is to be derived from the methodology described in the evaluation report,[25] to "incorporate approaches and attributes determined appropriate," and to be limited to the workload categories described in the GDUFA III commitment letter.[26]

As noted, FDA established a conceptual model for the GDUFA CPA during the GDUFA II authorization period. This model was evaluated and described in the FY20 evaluation published on FDA's website. As the GDUFA III commitment letter describes a broader set of workload drivers than those included in the conceptual model, FDA has been working to refine the models for the existing workload drivers while also preparing models for the additional workload drivers.

24 Division F of Public Law 117-180 (https://www.congress.gov/117/plaws/publ180/PLAW-117publ180.pdf)

25 See footnote 14.

26 See footnote 3.

The existing conceptual model for the GDUFA CPA included ANDA originals and their resubmissions and amendments; ANDA supplements and their resubmissions and amendments; controlled correspondences; and meetings. These models have undergone a review to prepare for implementation of the GDUFA CPA for FY 2024 fee-setting. This review has included an assessment of time reporting category design to ensure currency, as well as review of any new programmatic requirements, data sources, or other pertinent details relevant to these workload drivers.

Model preparation for additional workload drivers has focused on suitability petitions, post-market safety activities, and surveillance inspections. FDA has established a model for suitability petitions that follows the conceptual framework established for the existing workload drivers. For post-market safety activities, model development was coordinated across PDUFA and BsUFA to ensure consistency in approaches.

ORA has been working to develop methods to account for surveillance inspections and other field work required by the GDUFA CPA workload drivers. Given the relative recency of ORA's ITR implementation, FDA will aim to incorporate ORA's GDUFA workload into the GDUFA CPA beginning with the setting of FY 2025 fees.

After implementation, FDA will work to continually improve the GDUFA CPA each year. This will include engaging the same process established for PDUFA and BsUFA to evaluate and refine models each year based on the latest data. Additionally, FDA will adjust approaches where additional details or granularity may provide value for forecasting outputs. For example, FDA intends to work towards implementing models to forecast complex and non-complex ANDAs. Towards this end, time reporting categories have been structured and implemented to support these models. Once sufficient data is collected, FDA will assess the feasibility and utility of implementing ANDA models at this level of detail.

4 Moving Forward

Over the course of the last few years, RCP has grown into a capability that has provided modernized tools to assess and inform resource needs. While the foundation has been put into place, there are continued opportunities for RCP to grow toward optimizing resource allocation and operations in support of regulatory review and the public health goals of FDA's human drug and biologics programs.

FDA remains committed to ensuring the sustainability of user fee program resources and to enhancing its operational agility, as demonstrated by its continued investment in sustaining, refining, and expanding its RCP capabilities.

FDA will continue to meet its commitments to report out on progress of the maturation of RCP, the use of CPA funds, and to the evaluation of RCP. See section 4.1 for an accounting of these commitments.

4.1 Assessment and Reporting

Table 2 provides details regarding the assessment and reporting requirements for PDUFA VII, BsUFA III, and GDUFA III as stated in the respective commitment letters for these programs.[27,28,29]

Table 2. FDA's RCP-Related Assessment and Reporting Requirements Under PDUFA VII, BsUFA III, and GDUFA III

Requirement	Description
Annual Updates on the RCP Implementation Plan	"FDA will provide annual updates on the FDA website on the Agency's progress relative to activities detailed in this implementation plan by the end of the 2nd quarter of each subsequent fiscal year."
Annual PDUFA Financial Report	"FDA will document in the annual PDUFA Financial Report how the CPA fee revenues are being utilized."
Annual BsUFA Financial Report	"FDA will document in the annual BsUFA Financial Report how the CPA fee revenues are being utilized."
Annual GDUFA Financial Report	"FDA will document in the annual GDUFA Financial Report how the CPA fee revenues are being utilized."

27 See footnote 1.

28 See footnote 2.

29 See footnote 3.

Table 2. (continued)

Requirement	Description
RCP Assessment	"By the end of FY 2025, an independent contractor will complete and publish an evaluation of the resource capacity planning capability. This will include an assessment of the following topics: a. The ability of the CPA to forecast resource needs for the [BsUFA, GDUFA, and PDUFA programs], including an assessment of the scope of the workload drivers in the CPA and their ability to represent the overall workload of the [BsUFA, GDUFA, and PDUFA programs]; b. Opportunities for the enhancement of time reporting toward informing resource needs; and c. The integration and utilization of resource capacity planning information within resource and operational decision-making processes of the [BsUFA, GDUFA, and PDUFA programs]. The contractor will provide options and recommendations in the evaluation regarding the continued enhancement of the above topics as warranted. The evaluation findings and any related recommendations will be discussed at the FY 2026 [BsUFA, GDUFA, and PDUFA] 5-year financial plan public meetings. After review of the findings and recommendations of the evaluation, FDA will, as appropriate, continue improving the resource capacity planning capability and the CPA."
Annual PDUFA Financial Public Meeting	"FDA will convene a public meeting no later than the end of the 3rd quarter of each fiscal year to discuss the PDUFA 5-year financial plan and the Agency's progress in implementing resource capacity planning, including the continual improvement of the CPA and time reporting, and the integration of resource capacity planning in resource and operational decision-making processes."
Annual BsUFA Financial Public Meeting	"FDA will convene a public meeting on or before the end of the 3rd quarter of each fiscal year to discuss the BsUFA 5-year financial plan and the Agency's progress in implementing resource capacity planning, including the continual improvement of the CPA and time reporting, and the integration of resource capacity planning in resource and operational decision-making processes."
Annual GDUFA Financial Public Meeting	"FDA will convene a public meeting no later than the third quarter of each fiscal year starting in FY 2024 to discuss the GDUFA 5-year financial plan, along with the Agency's progress in implementing modernized time reporting and resource management planning."

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