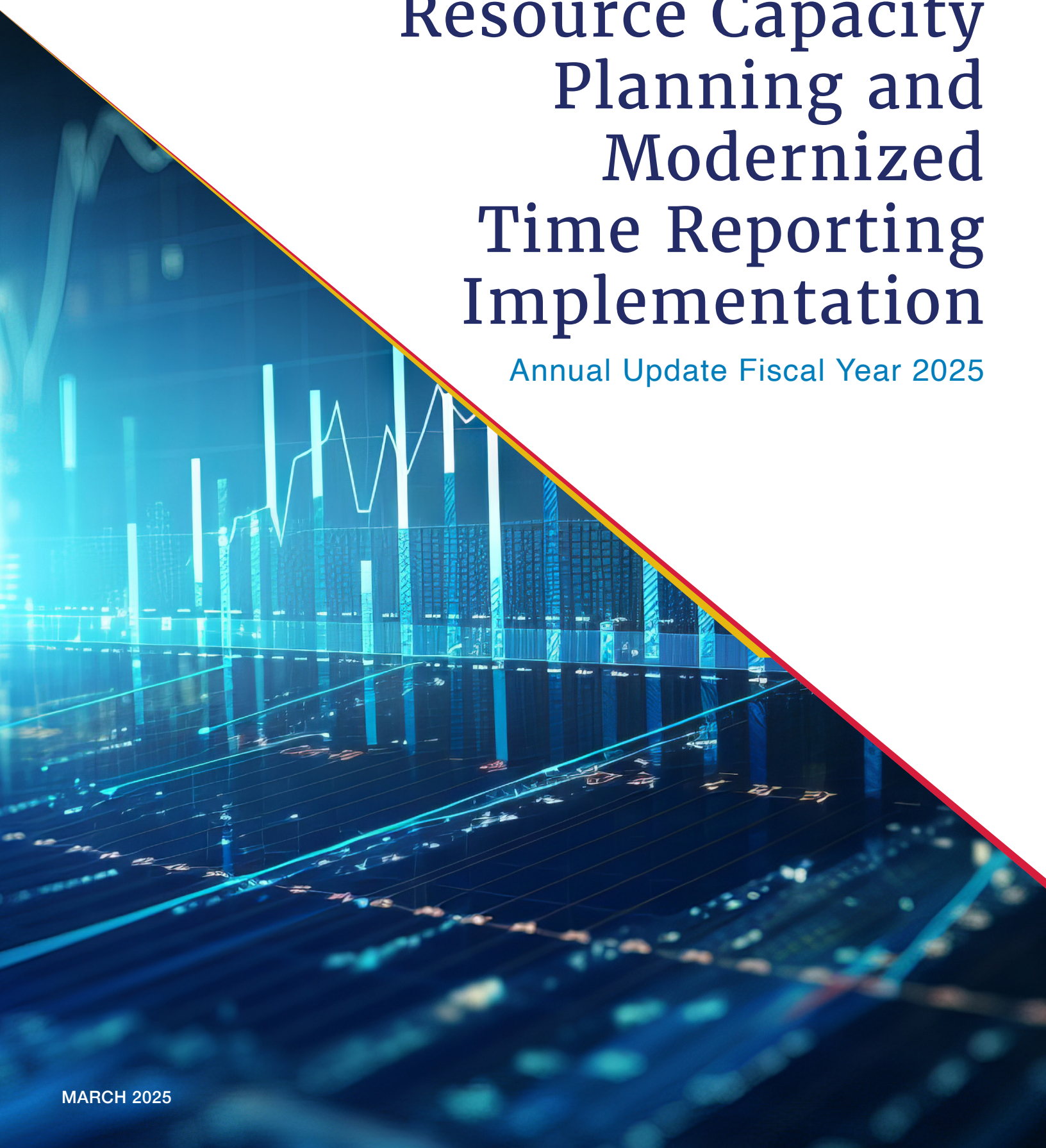
U.S. FOOD & DRUG ADMINISTRATION

Resource Capacity Planning and Modernized Time Reporting Implementation

Annual Update Fiscal Year 2025



MARCH 2025

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Purpose

The purpose of this annual update is to provide progress regarding the activities described in the March 2023 Resource Capacity Planning and Modernized Time Reporting Implementation Plan.

The publication of this annual update satisfies the following commitments for fiscal year (FY) 2025:

- PDUFA VII: "FDA will provide annual updates on the FDA website on the Agency's progress relative to activities detailed in (the March 2023) implementation plan by the end of the 2nd quarter of each subsequent fiscal year."[1]
- BsUFA III: "FDA will provide annual updates on the FDA website on the Agency's progress relative to the activities detailed in (the March 2023) implementation plan on or before the end of the 2nd quarter of each subsequent fiscal year."[2]
- GDUFA III: "FDA will provide annual updates on the FDA website on the Agency's progress relative to activities detailed in (the March 2023) implementation plan by the end of the second quarter of each subsequent fiscal year."[3]

An annual update will be published each subsequent fiscal year (FY) pursuant to the above commitments.

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

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

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

Background

In FY 2018 (the first year of PDUFA VI, BsUFA II, and GDUFA II), FDA formally initiated efforts to establish a Resource Capacity Planning (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 establish this capability was memorialized in the respective commitment letters for these programs.

The intent of RCP is 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.

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

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 FYs 2023–2027, accounting for PDUFA VII, BsUFA III, and GDUFA III). Those commitments included publishing a plan in FY 2023 describing how RCP and time reporting will continue to be implemented and utilized during PDUFA VII, BsUFA III, and GDUFA III.

FDA committed to provide annual updates 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 on the FDA website.

This document serves as the annual update for FY 2025. It describes progress to-date toward each item described in the implementation plan section of the March 2023 plan. Please reference section 3.2 of that plan.

Annual Update on Progress

The numbering in this section refers to the implementation plan section of the March 2023 plan.

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

In August 2023, FDA engaged a contractor to conduct a feasibility study of integrated project management, portfolio analytics and reporting (phases 4 &5)[4] with RCP. This study was intended to address the feasibility of this integration including an assessment of readiness, costs, pros, cons, gaps, and potential alternatives across the Center for Biologics Evaluation and Research (CBER), the Center for Drug Evaluation and Research, and the Office of Inspections and Investigations (OII).

The assessment found that CBER, CDER, and OII could benefit from the capabilities envisioned by phases 4 and 5 of the RCP implementation plan. Full implementation of these capabilities would solve for a number of operational challenges and pain points and would enable leaders to view and plan for work and resources at a variety of levels and timeframes.

The feasibility assessment established the following capabilities as needed to deliver on the vision of phases 4 and 5 of the original RCP implementation plan. These are:

- A workload management system aligned with a common data model. This is a fundamental component of the RCP future state vision as the full portfolio of work must be defined and tracked to fully enable resource analysis and the management of operations.

[4] See p. 13-14 of the March 2023 implementation plan for a description of phases 4 & 5

- Enhanced time reporting aligned with a common data model to support more granular and detailed workload forecasting and resource analysis.
- A technology platform to enable the development of necessary data pipelines, repeatable analytical processes, scenario planning, and visualization tools.

The assessment recognized that CBER, CDER, and OII are operating at a different level of feasibility and readiness for the future state of RCP. The assessment noted that each organization is currently making strides towards it.

- CDER is actively planning deployment of its workload management system with a common data model which will provide the foundational data for RCP. CDER has also begun collecting RCP requirements to incorporate into planning for its workload management system. It has also established the requisite technology platform to support RCP analytics.
- CBER is continuing to develop a common data model and a plan for a Center-wide workload management system. It is evaluating development of its technology platform to support RCP in collaboration with CDER.
- OII currently has plans to establish a resource planning system, which may align with the future state RCP vision.
- For all these organizations, enhanced time reporting was found to not be feasible at this time. Enhanced time reporting would require significant additional detail in time reporting data entry. This feasibility should be reassessed following the implementation of workload management systems when technologies such as artificial intelligence may be considered as a potential aid to this capability.

The assessment recommends that CBER, CDER and OII should maintain coordination and transparency on decisions impacting the future state of RCP to enable consistent methodological implementation.

FDA has incorporated relevant findings from this assessment into its system planning efforts. It has begun a process to align RCP requirements, where appropriate, into workload management system planning and to ensure alignment of common data model efforts with RCP current state needs. FDA will continue migrating its code, processes, and reporting into the technology platform, while developing any required toolsets. It will consider appropriate evaluation of tools and technologies to support potential future opportunities for enhanced time reporting. It will work to ensure continued coordination as appropriate across CBER, CDER, and OII. FDA notes that while RCP requirements are coming into alignment with broader technology planning and implementation efforts, due to many significant dependencies and complexity of successful design and implementation of the foundational tools, fully realizing the RCP vision as described in the 2018 implementation plan will be a long-term effort.

3.2.2 RCP Updated Concept of Operations

FDA refined the existing RCP support and operating model in FY 2024. This operating model will be adapted annually as needed as part of a continual improvement process.

3.2.3 Continual Improvement of Time Reporting

In FY 2024, program representatives established a cross-Center time reporting board to share best practices, enhance knowledge sharing, and align on priorities for enterprise-wide management of the Insight Time Reporting tool. This board has resulted in streamlined processes to identify operations and maintenance priorities and to collaboratively support adoption of best practices across Centers. The board has begun efforts to establish a common framework for the management of data quality to align practices as appropriate across Centers.

CBER completed one-year of use of Insight Time Reporting (ITR) following its successful transition and has averaged 99.1% compliance in FY 2024. Throughout FY 2024, CBER has pursued several initiatives to ensure user experience and data quality are continually improving within the system. These efforts include the development and launch of new activity codes aligned to user needs, deployment of a data quality program with checks every pay period to ensure accuracy of data, and feature development to facilitate ease of user experience.

CDER's time reporting operations remain stable.

In FY 2024, OII focused on better understanding how investigators were using the activity codes and logging their time into OII's Insight Time Reporting system by issuing surveys to all investigatory staff. The results of the surveys were used to develop clearer, more consistent reporting guidance. For example, the ITR program team developed additional training resources and reporting guidance focused on travel. More detailed guidance on reporting time spent trip planning, managing travel activities, and time spent in travel status was issued and communicated widely.

3.2.4 Continual Improvement of the CPA

Enhancements and continual improvements of the CPA and related processes have continued, including in technical, analytical, and process areas. Enhancements prescribed by statute were completed in the prior year.

FDA has made significant strides to implement a cloud-based technology platform to support RCP work. With this platform largely in place now, the RCP staff has worked to leverage pipelines and build the code infrastructure to strengthen repeatability, automation, and rapid hypothesis testing to guide model refinements. These advances make relevant data readily and consistently available, enable standardized approaches to ensure consistency across models and enable smooth transition of models across analysts as needed. These improvements are expected to enable a more effective modeling capability with increased efficiency. Once fully implemented, this would help further transition analyst time to focus on model refinement and improvement efforts and less time on model operations and maintenance.

FDA has also worked to enhance existing modeling efforts by including new multivariate and panel-based forecasting approaches to improve predictive power and explainability within models, where feasible.

Enhancements were also implemented to ensure consistent incorporation and alignment of time reporting data from CBER's legacy time reporting system through its transition to ITR. Additionally, the CPA code base for CDER was consolidated into one set of programs to streamline maintenance and increase efficiencies within the CPA refresh process.

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

RCP continues to engage in efforts to provide analytic support to further the efficiency and effectiveness of regulatory operations in CBER, CDER, and OII as appropriate. In addition, work has continued to harden processes connecting time reporting data to financial management on FDA programs. This includes processes to align time reporting data to inform relevant tables required for FDA's budget justification documents.

3.2.6 The Implementation of the GDUFA CPA

The GDUFA CPA was implemented for CDER for FY24 fee-setting.[5] CDER is now focused on continual improvement of the GDUFA CPA.

While thus far all ANDA supplements have been grouped together for the purposes of the GDUFA CPA, CDER is planning to implement distinct models for Prior Approval Supplements and Changes-Being-Effected supplements for the FY 2026 GDUFA CPA.

CDER continues to evaluate readiness to enable the distinction of complex original ANDAs from non-complex original ANDAs for the purposes of the GDUFA CPA. This enhancement, however, would not be implemented before the setting of FY 2027 fee amounts.

OII is aiming for implementation of its portion of the GDUFA CPA for FY 2027 fee-setting to ensure readiness of its data and methodology. To this end, OII has been working to address gaps in the workflow and improve documentation of processes.

5 Generic Drug User Fee Rates for Fiscal Year 2024: https://www.federalregister.gov/documents/2023/07/28/2023-16081/generic-drug-user-fee-rates-for-fiscal-year-2024

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