U.S. FOOD & DRUG ADMINISTRATION

Resource Capacity Planning & Modernized Time Reporting Implementation Plan

Annual Update Fiscal Year 2024

March 2024

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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) 2024:

- 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 establishing this capability was memorialized in the respective commitment letters for these programs.

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.

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 first annual update. 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 back 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, Booz Allen Hamilton, to conduct a feasibility study of integrated project management, portfolio analytics and reporting (phases 4 &5)[4] with RCP. 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. The study is expected to continue through the end of 2024.

3.2.2 RCP Updated Concept of Operations

FDA is currently engaged in an effort to refine the existing RCP support and operating model. This refinement will begin to be implemented in FY 2024 and will be reviewed and adapted annually as part of a continual improvement process. Concurrently, refinements to the operating model for the Insight Time Reporting (ITR) program are being explored as it continues to be implemented throughout the Agency.

3.2.3 Continual Improvement of Time Reporting

The Center for Biologics Evaluation and Research (CBER) successfully transitioned its full-time reporting capability to the Insight Time Reporting (ITR) system in September 2023. ITR offers improved functionality and new features to

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

support CBER's continuing efforts to improve its time reporting. As its prior system was near the end of its functional life without significant upgrades, the transition to ITR mitigates operational risks and reduces operating costs.

In FY 2023, the Center for Drug Evaluation and Research (CDER) institutionalized an annual review process under its ITR Change Control Board to review opportunities to remove time reporting codes that are no longer needed, in order to minimize time reporting burden and ensure categories remain relevant.

In April 2023, the Office of Regulatory Affairs (ORA) celebrated the one-year anniversary of the full implementation of ITR to all offices. Throughout the past year, ORA has pursued several initiatives to improve compliance and expand data accessibility. As the program reaches maturity, ORA will continue to use a data-driven approach to make improvements to the code, guidance, and procedures to ensure ORA fully realizes the potential of ITR.

3.2.4 Continual Improvement of the CPA

Enhancements and continual improvements of the CPA and related process have continued, including in technical, analytical, process, and statutory areas.

Technical improvements include continued efforts toward establishing a cloud-based technology platform to support RCP in CDER. Several technical capabilities have been enabled in the past year to support data science work which is required to support RCP. CDER is working towards fully migrating RCP processes to this environment which, once completed, will enhance efficiencies of its data science work. CBER will also be leveraging this environment to support its RCP work. Additional technical improvements have included significant efforts to refactor and streamline the CPA code base, which will make it more efficient to operate and maintain.

Improvement processes have continued for all constituent analytical aspects of the CPAs, including all submission forecast models. This has included foundational work to explore feasibility of forecasting complex and non-complex ANDAs as distinct entities. Work will continue to further refine this foundational model, with potential implementation in the GDUFA CPA for FY 2026 fee-setting.

Process improvements have included advances to automate and formalize incorporation of an annual variance analysis process across the CPAs to enhance efficiency and to identifying opportunities for continued enhancements.

FDA has implemented additional elements in the CPAs as provided for in statute. PDUFA VII expanded the definition of the PDUFA program to include certain allergenics products. These products were incorporated into the CPA models used in FY 2024 fee-setting. However, given the low-volume of allergenics submissions, there has yet to be an impact on the overall CPA forecast.

In addition, as provided for in statute, annual reports, postmarketing commitments/ postmarketing requirements (PMR/PMCs), and active Risk Evaluation and Mitigation Strategies (REMs) were also incorporated into the CPAs, as relevant, for FY 2024 fee-setting. The impact of these additions has been minimal to-date.

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

While RCP work products are well-integrated into financial processes, work has continued to adapt approaches to support constituent offices in CDER and CBER. RCP is working to establish fit-for-purpose models to meet the needs of its offices. Model development efforts for internal uses are currently underway alongside an organizational needs assessment to help target opportunities moving forward. These efforts will help bridge internal analysis needs to optimize operations in the interim as the vision for future RCP integration (as developing within the Feasibility Assessment describes in section 3.2.1 above) comes into focus.

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. It is evaluating readiness to enable the distinction of complex original ANDAs from non-complex original ANDAs, as well as Prior Approval Supplements from Changes-Being-Effected supplements. These potential enhancements would not be implemented before the setting of FY26 fee amounts. The GDUFA CPA is also now engaged in the standard continual improvement process including annual variance analysis and identification of any opportunities for continued enhancements.

ORA is aiming for implementation of its portion of the GDUFA CPA for FY26 fee-setting to ensure readiness of its data and methodology.

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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