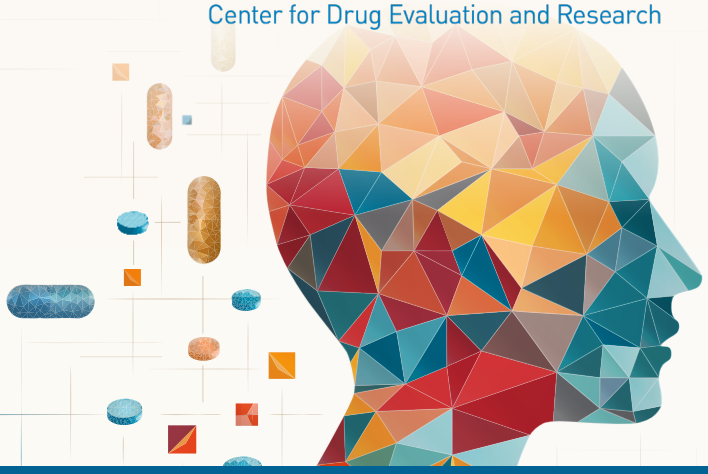
U.S. FOOD & DRUG ADMINISTRATION

Center for Drug Evaluation and Research

Quantitative Medicine
Center of Excellence

Leveraging Data to Advance Drug Development & Improve Patient Care



PROGRESS & PRIORITIES UPDATE

Director's Message

In this era of unprecedented scientific and technological advances which converge data, analytics and medicine, Quantitative Medicine (QM) approaches are primed to play a transformative role in advancing medical product development and informing regulatory evaluation. Recognizing this potential, the Center for Drug Evaluation and Research (CDER) took the proactive step to bring together interdisciplinary experts to establish the Quantitative Medicine Center of Excellence (QM CoE).

As we reflect on the past 16 months, we are pleased to share this Progress and Priorities Update — a snapshot of the work undertaken, the capabilities built, and the direction charted for the years ahead. Our efforts have centered on laying a strong operational and scientific foundation to not only fulfill our mission, but also to create the conditions for sustained, meaningful impact. Our foundational work has concentrated on three key areas: **Enterprise Planning and Coordination**, **Applied Regulatory Science**, and **Education and Ecosystem Development**. In this update, we share with you highlights of key areas of progress and evolving priorities. We are excited to share our focus and plan for the coming years guided by our vision, mission, and values.

We are deeply grateful for the continued partnership, trust, and collaboration across the scientific, regulatory, and drug development communities. We look forward to an exciting chapter as we move forward with clarity, commitment, and momentum.

Raj Madabushi
Director, CDER QM CoE

Connect with us! CDERQuantMed@fda.hhs.gov

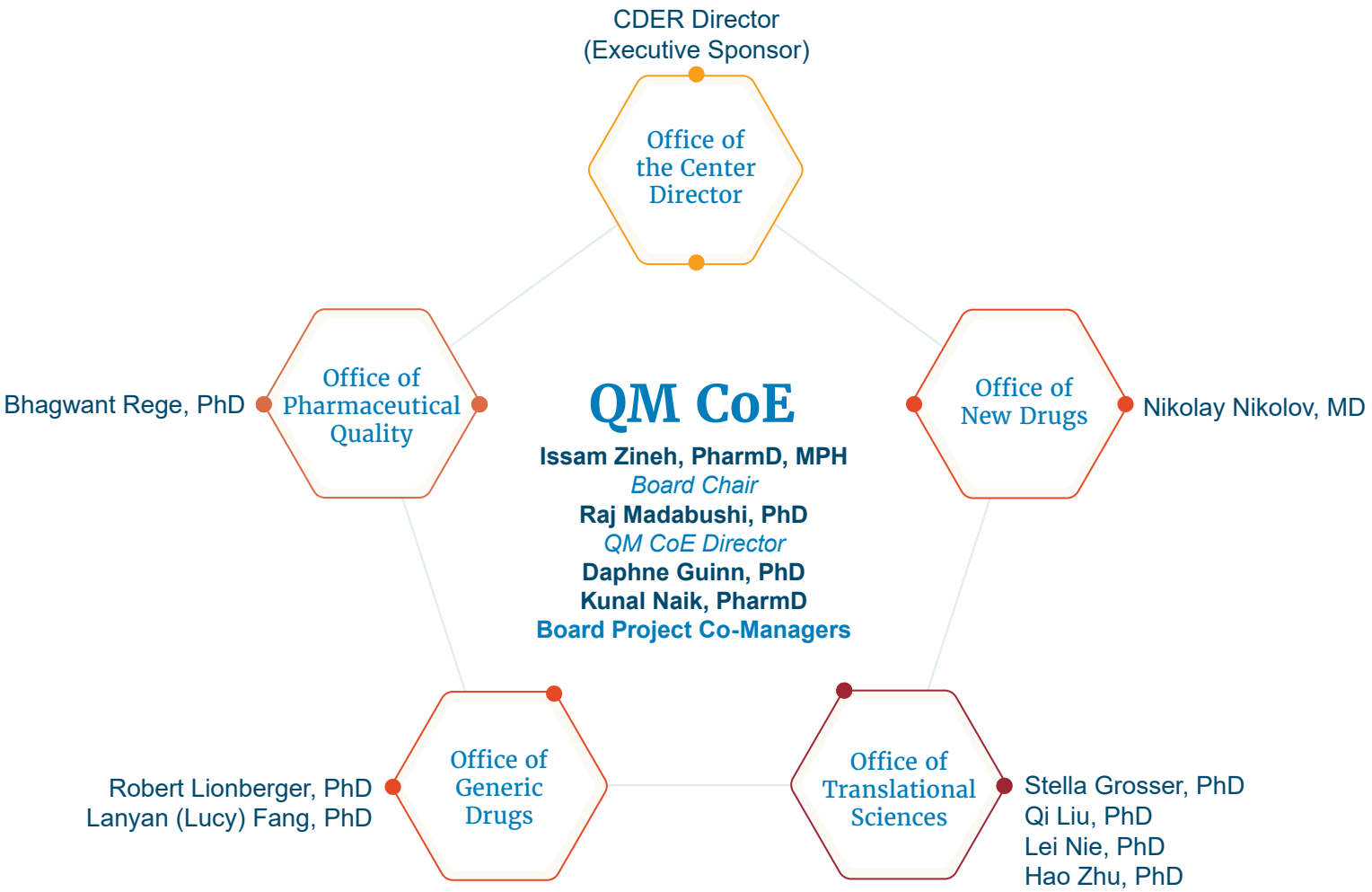
About the CDER Quantitative Medicine Center of Excellence

The QM CoE is a CDER-wide enterprise functioning as a cooperative, coordinating body to spur innovation and foster integration of QM approaches to advance therapeutic medical product development, inform regulatory decision-making, and promote public health.

QM, as defined by this effort, encompasses the development and application of exposure-based, biological, and quantitative modeling and simulation approaches derived from nonclinical, clinical, and real-world sources to inform drug development, regulatory decision-making, and patient care.

The CDER Director serves as the Executive Sponsor and the CoE is governed by a Director, an Executive Board Chair, and an Executive Board composed of staff from CDER offices that engage in QM. This report highlights the progress and accomplishments in the key areas across CDER.

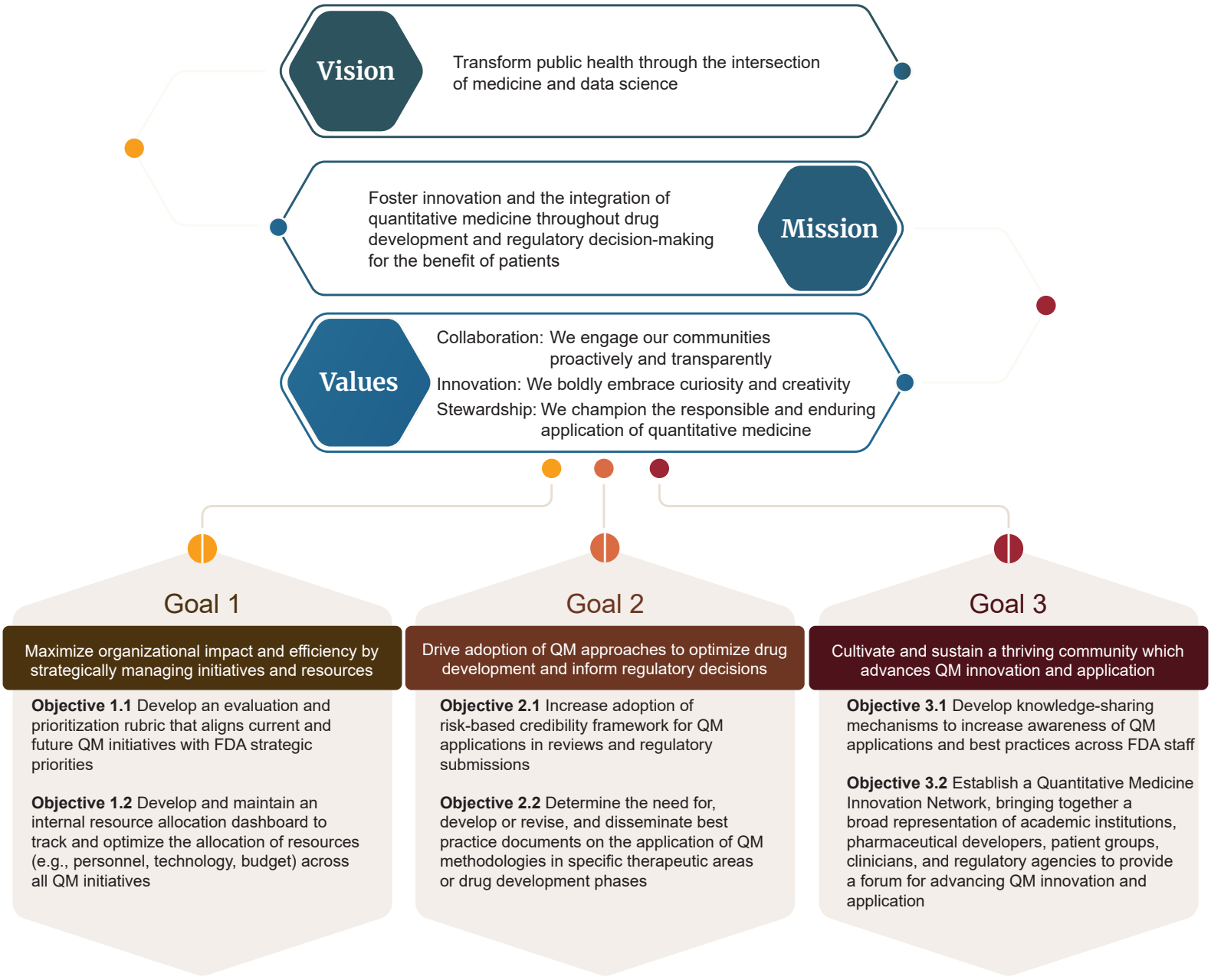
Figure 1 | QM CoE Organization



Enterprise Planning and Coordination

The QM CoE has developed and ratified a charter, establishing the purpose, scope, governance, and key activities. As part of long-term planning, we engaged internal and external parties to brainstorm, develop, and refine the strategic focus and priorities which were endorsed by the CoE Executive Board and CDER Center Director.

Figure 2 | QM CoE Charter Overview



Collaboration

As part of the coordination function, the CoE leadership is actively involved in identifying opportunities for collaboration with other center-wide initiatives including the **Accelerating Rare disease Cures (ARC)** program and the **Center for Clinical Trial Initiation (C3TI)** (Figure 3).

One such activity is the collaboration with ARC's **Translational Science Team (TST)** activities. The TST is a multidisciplinary group that includes staff from QM CoE member offices and works in collaboration with review teams to provide detailed evaluation on key regulatory drug development decisions that include translational science issues in the rare disease space. The QM CoE provides quantitative analysis support and is a resource for teams to address critical questions around biomarker endpoint translation in INDs, NDAs, and BLAs.

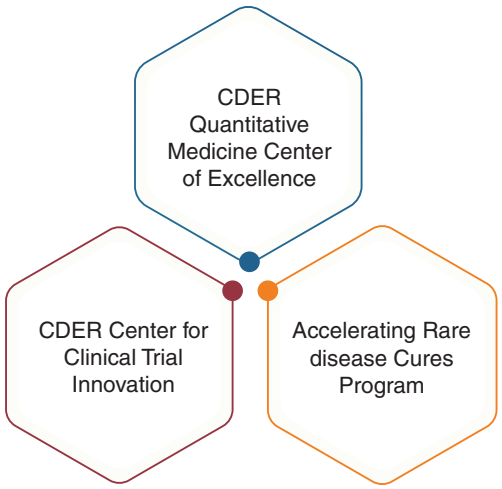


Figure 3 | Collaboration between CDER QM CoE and other center-wide initatives

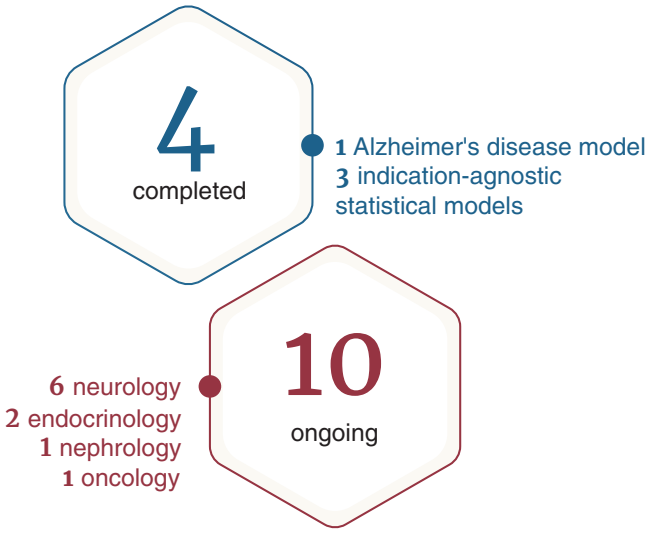


Figure 4 | Fit-For-Purpose by the numbers

Another instance of collaboration is the **Fit-For-Purpose Initiative (FFP)** which provides a pathway for regulatory acceptance of dynamic tools and novel frameworks for use in drug development programs. This initiative is coordinated by the QM CoE member offices, the Office of Clinical Pharmacology and the Office of Biostatistics. To date, 14 proposals for drug development tools have been accepted for review; four have been completed and nine are ongoing (Figure 3). Additionally, the FFP initiative has conducted 14 meetings with submitters and issued 24 communications. In 2025, one proposal for a new drug development tool was accepted for review.

Applied Regulatory Science

Within this focus area, the QM CoE aims to develop knowledge management resources to catalog past and current QM related regulatory interactions to support the development of evidence-based best practices. The QM CoE has met with key stakeholders to identify needs and gaps and has initiated efforts to develop best practices. Some of these collaborative activities are highlighted below.

Identifying priority focus areas for future development and engagement with interested parties in model-informed drug development

CDER and Center for Biologics Evaluation and Research (CBER) announced a request for information (RFI) for advancing model-informed drug development (MIDD). The purpose of RFI was to obtain feedback on how to increase application of established MIDD approaches in regulatory decision making, to identify how emerging MIDD approaches are being incorporated within drug product development, and to establish opportunities to enhance interactions with FDA when discussing MIDD approaches. Some of the topics identified included context of use for quantitative approaches, including appropriate methods and populations, improved understanding of regulatory precedence with examples, and increasing engagement with the Agency. The QM CoE intends to use these external comments to continue to determine areas for education, best practice development, and scientific engagement.

Draft Guideline: M15 General Principles for Model-Informed Drug Development

Developed under the auspices of the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH), this draft guideline discusses the multidisciplinary principles of MIDD and provides recommendations on MIDD planning, model evaluation, and evidence documentation.This draft guideline is intended to facilitate multidisciplinary understanding, appropriate use, and harmonized assessment of MIDD and its associated evidence. The QM CoE provided regulatory and subject matter expertise as well as led the effort to gather Agency feedback and facilitate FDA clearance through presentations and discussions.

Model Master Files

Model Master Files (MMF) is a framework similar to Drug Master Files (DMFs) aimed at model-sharing and model-reusability. The QM CoE facilitated a collaboration between three QM CoE member offices, the Office of Generic Drugs, the Office of Clinical Pharmacology, and the Office of Pharmaceutical Quality to support concept development, including participating in webinar preparation and providing input on communication documents. The concept and the regulatory path for MMF have been highlighted in a January 2024 Federal Register Notice as well as workshops in May 2024 and March 2025.

Education and Ecosystem Development

The QM CoE has prioritized activities related to educational enrichment and community engagement, both internally and externally. A key educational achievement was the public release of the FDA/ Critical Path Institute (C-Path) Model-Informed Drug Development Training Course. The CDER QM CoE, in collaboration with CDER's Office of Translational Sciences and C-Path, released free, web-based training modules with 29 presentations and more than 10 hours of content on a variety of MIDD topics. Resource suggestions are welcome to be shared by reaching out to the QM CoE at CDERQuantMed@fda.hhs.gov.

Community Engagement

Since inception, the QM CoE has engaged with various QM community members across FDA, academia, consortia, and industry. In April 2024, the QM CoE hosted its inaugural event to introduce the QM CoE, providing an overview of the scope, goals, and current state, while gaining feedback from the public on needs and opportunities in education, outreach, and policy.

QM CoE leadership and member offices contributed to various communications, workshops, presentations, and publications highlighting the regulatory importance of QM applications across the drug development lifecycle (see Figure 4). Representative publications can be found on the QM CoE website.

Figure 4 | QM CoE presentation highlights