

Center for Drug Evaluation and Research

Quantitative Medicine Center of Excellence

Leveraging Data to Advance Drug Development & Improve Patient Care



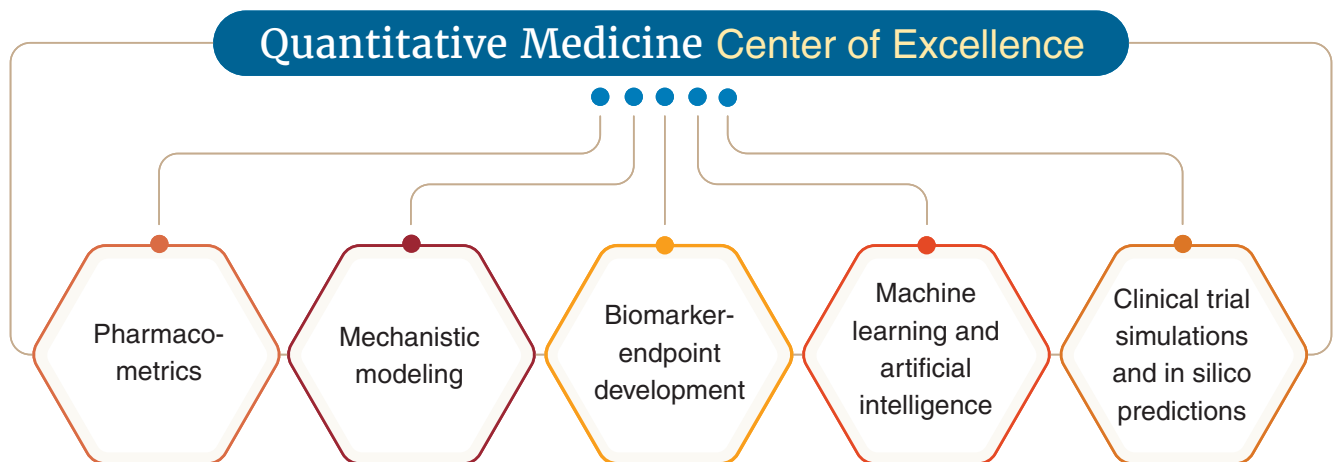
OVERVIEW FACT SHEET

The Center for Drug Evaluation and Research (CDER) Quantitative Medicine (QM) Center of Excellence (CoE) is established to facilitate and coordinate the continuous evolution and consistent application of QM for drug development and regulatory decision-making across CDER.

For decades, CDER offices have been at the forefront of advancing QM approaches to inform premarket product review and post-market product assessment. Given the tremendous growth in QM, we see many opportunities to maximize synergies across CDER by centrally coordinating efforts through strategic planning and execution. The QM CoE seeks to strengthen collaborations in outreach, education, scientific and regulatory initiatives, as well as policy development and implementation. The QM CoE will be a CDER-wide enterprise that will function as a cooperative, coordinating body that spurs innovation and fosters integration of QM approaches to advance therapeutic medical product development, inform regulatory decision-making, and promote public health.

What is QM?

QM includes 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.



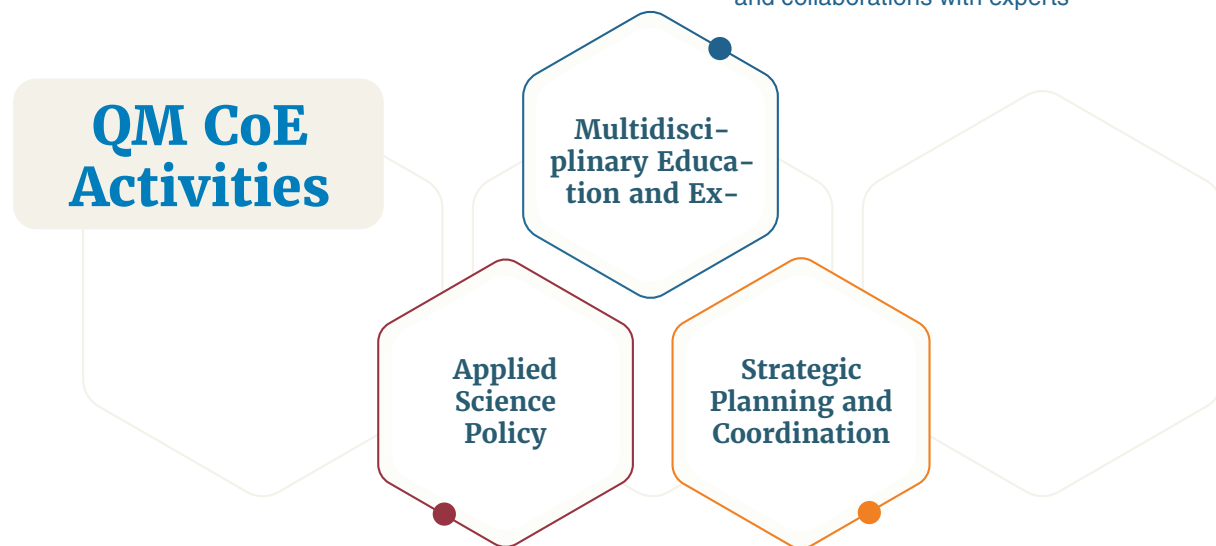
Who are the participants and key stakeholders of the CDER QM CoE?

A core value of the QM CoE is collaboration, and the primary CoE membership includes interdisciplinary experts that work in CDER. To ensure the CoE is equipped to carry out its mission, the CoE will be governed by leadership from the Office of Generic Drugs, Office of New Drugs, Office of Pharmaceutical Quality, and Office of Translational Sciences. Staff from other FDA Centers will be key stakeholders in all activities of the CoE, including but not limited to, development of best practices, trainings, and outreach.

What activities will the CDER QM CoE perform?

The CoE will introduce new activities and coordinate existing activities in three main areas: Strategic Planning & Coordination, Multidisciplinary Education and Exchange, and Applied Science Policy. See the Figure below for more information.

- **Educational Enrichment:** Provide applied regulatory science educational opportunities and resources internally and externally to promote the implementation and uptake of QM techniques
- **Community Engagement:** Convene and engage key external stakeholders through outreach activities and collaborations with experts



- **Knowledge Management:** Warehouse and promote best practices and standards related to QM; document and disseminate outcomes of QM applications

- **Policy Development:** Facilitate scientific exchange and lead the development and implementation of evidence-based scientific guidances, policies and best practices

- **Strategic Planning:** Identify and prioritize gaps in knowledge and determine areas of further research and development in CDER

- **Coordination:** Coordinate and elevate existing QM-related scientific and regulatory initiatives and outreach and educational activities within CDER