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US FDA's CDER Creates Quantitative Medicine Center Of Excellence; Job Includes AI Oversight

by Derrick Gingery

The group will coordinate quantitative medicine issues throughout the FDA's Center for Drug Evaluation and Research to help streamline drug development.

The US Food and Drug Administration established a center of excellence to coordinate quantitative medicine work due to its quick growth in the drug development space.

The Center for Drug Evaluation and Research will house the new Quantitative Medicine (QM) Center of Excellence, which will oversee application of exposure-based, biological, and quantitative modeling and simulation approaches created from nonclinical, clinical and real-world sources, according to a 25 March FDA announcement.

QM could inform development, regulatory decision-making and patient care and contribute to the understanding of drug benefits and risks, the FDA said.

The CDER-wide QM effort will include:

- Spearheading policy development and best practices to allow for consistent use of QM approaches during drug development and regulatory assessment
- Facilitating systematic outreach to scientific societies, patient advocates and other stakeholders
- Coordinating education and training efforts

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No QM Center of Excellence director has been announced. The FDA told the *Pink Sheet* that an executive board with leadership from the Office of New Drugs, Office of Generic Drugs, Office of Pharmaceutical Quality and Office of Translational Sciences also will help govern it, along with the executive board chair and board project manager.

More information on the QM Center of Excellence will be released during a *25 April public meeting* on streamlining drug development and improving public health through quantitative medicine. FDA officials will solicit public feedback on education, outreach and policy needs, as well as update participants on the center of excellence's goals and status.

The center of excellence builds on existing QM efforts, including the Model-Informed Drug Development (MIDD) and Complex Innovative Trial Design (CID) programs. Both allow participants to meet with FDA experts and receive advice on clinical trial designs. (Also see "*PDUFA VII Negotiations Completed, Commitment Letter Ratification Ongoing*" - Pink Sheet, 22 Mar, 2021.)

A Model-Integrated Evidence (MIE) pilot for generic drug sponsors also launched in late 2023. (Also see "*Generic Drug Pilot On Model-Informed Evidence Aims To Boost Review Efficiency*" - Pink Sheet, 21 Jan, 2024.)

QM Center Will Oversee AI Issues

Along with pharmacometrics, mechanistic modeling, biomarker-endpoint development, clinical trial simulations and in silico predictions, the QM Center of Excellence also will oversee machine learning and artificial intelligence approaches, the FDA said.

AI is a growing interest at the FDA, in part due to its potential applications to agency activities and drug development. The agency on 15 March published a paper with four high-level priorities for AI regulation in the medical product space that will align and streamline work in the agency's drug, device, and biologic centers, and Office of Combination Products.

More guidance and research is planned as the agency works with industry to understand and implement AI in health care. (Also see "*Artificial Intelligence: US FDA Plans Guidances On Algorithm Bias, Product Development*" - Pink Sheet, 15 Mar, 2024.)

Latest of Several Centers of Excellence

The QM Center of Excellence joins a growing number of topics that use the centers of excellence concept inside and outside the FDA.

The most recognizable is the Oncology Center of Excellence, which was created in 2016 as a stand-alone entity within the agency. OCE Director Richard Pazdur has used the organization to push reform to clinical trials, advisory committee meetings and other issues. (Also see "*Eye On*

ODAC: Former Members, FDA's Pazdur Talk Pre-Meeting Mindsets, Impact Of Sponsor's Experts" - Pink Sheet, 20 Mar, 2024.)

The FDA also established Centers of Excellence in Regulatory Science and Innovation at several universities to modernize and improve drug development. (Also see "*Good Neighbors Make Good Regulatory Science Centers, FDA Decides*" - Pink Sheet, 28 Nov, 2011.)

CDER officials have resisted calls for a Rare Disease Center of Excellence, saying a reorganization is not necessary to coordinate expertise and application review efforts in the space. (Also see "*Center Of Excellence Not Best Model For US FDA Rare Disease Program, Woodcock Says*" - Pink Sheet, 13 Sep, 2018.)

The QM Center of Excellence may more closely resemble the Accelerating Rare Disease Cures (ARC) program, which was created in 2022 to coordinate rare disease work throughout CDER and help speed drug development. (Also see "*Rare Disease Challenges At US FDA: CDER Director Says More Staff, Not Reorganization, Will Fix Issues*" - Pink Sheet, 6 Apr, 2022.)