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FDA Seeks Feedback on Proposed Quantitative Medicine Innovation Network

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The Food and Drug Administration (FDA) continued its efforts to modernize drug development and regulation with the recent publication of a notice in the *Federal Register* from the Center for Drug Evaluation and Research's (CDER) Quantitative Medicine Center of Excellence announcing a request for information (RFI) to inform the development of the Quantitative Medicine Innovation Network (QMIN). The agency is seeking to better understand current quantitative medicine capabilities, challenges, and opportunities and specific feedback on how it might shape the structure, priorities and activities of this proposed collaborative ecosystem to advance the science and application of quantitative medicine in furtherance of public health.

As outlined in the Notice published on August 5, 2026, quantitative medicine (QM) approaches integrate mathematical and computational models with biological, clinical and statistical data to inform drug development, regulatory and clinical decisions, and these approaches have the potential to improve the efficiency of drug development, optimize treatment strategies and ultimately improve patient outcomes. The agency's vision for the QMIN is to create a cross-sector collaboration that accelerates the translation of quantitative medicine approaches to transform drug development, regulatory science and clinical decision-making for patient benefit.

The RFI poses a series of questions specifically focused on the QMIN's scope, operating model and priority use cases. Some of the questions posed in the Notice include the agency asking what areas of quantitative medicine, such as disease modeling or New Approach Methodologies (NAMs), would most benefit from a coordinated, cross-sector network as well as feedback on the greatest gaps in tools, standards and infrastructure. The agency is also

seeking feedback on what activities are most appropriate for a precompetitive network versus those better addressed within individual development programs or regulatory submissions, what governance structures would best support such a multi-stakeholder network involving the agency, industry, academia and patient groups, and how to demonstrate value and measure impact, such as through reduced animal use and/or development time. The agency also asks questions about how to fund the collaborative, including what funding or resourcing models should be considered, and what criteria should be used to select and evaluate priority use cases.

This notice may be of particular interest to industry, academia, health care providers and patient groups that are interested in exploring collaborative demonstration projects or research on innovative approaches aimed at addressing high priority areas through the application of QM. While interested parties have until November 3, 2026, to submit comments to this RFI, the range of questions posed by it suggests that the agency intends to take an iterative approach to establishing and implementing a QMIN and the comments received will help inform related considerations and potential next steps. The proposed QMIN is also likely to be of interest to Congress, especially as it prepares to consider the upcoming Prescription Drug User Fee Act (PDUFA) reauthorization next year and continues to consider how to modernize drug development with the goal of improving patient and public health outcomes.

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