4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2026-N-7605]

Establishment of a Quantitative Medicine Innovation Network: Scope, Feasibility, and Opportunities; Request for Information

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; request for information.

SUMMARY: The Center for Drug Evaluation and Research (CDER) within the Food and Drug Administration (FDA or Agency), through its Quantitative Medicine Center of Excellence (QM CoE), is announcing a request for information to inform the development of a Quantitative Medicine Innovation Network (QMIN). The vision for the QMIN is to create a cross-sector collaborative platform that accelerates the translation of quantitative medicine approaches to transform drug development, regulatory science, and clinical decision-making for patient benefit. The purpose of this request is to obtain feedback from industry, academia, healthcare providers, patient groups, and other interested parties on identifying critical community needs and establishing mechanisms for continuous engagement, supporting collaborative demonstration projects or research on innovative approaches aimed at addressing high priority areas through the application of QM approaches, and exploring mechanisms to leverage community expertise and capacity to promote QM innovation and adoption. Information submitted in response to this request will be considered in shaping the structure, priorities, and activities of the QMIN.

DATES: Either electronic or written comments on the notice must be submitted by [INSERT DATE 90 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. The https://www.regulations.gov electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of [INSERT DATE 90 DAYS

AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: https://www.regulations.gov. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to https://www.regulations.gov will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on https://www.regulations.gov.
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA-2026-N-7605 for "Establishment of a Quantitative Medicine Innovation Network: Scope, Feasibility, and Opportunities; Request for Information." Received comments, those filed in a timely manner (see ADDRESSES), will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at https://www.regulations.gov or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240-402-7500.

- Confidential Submissions--To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on https://www.regulations.gov. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to https://www.regulations.gov and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the

prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240-402-7500.

FOR FURTHER INFORMATION CONTACT: Daphne Guinn, Office of Clinical Pharmacology, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Silver Spring, MD 20993-0002, 301-837-7122, Daphne.Guinn@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing a request for information titled "Establishment of a Quantitative Medicine Innovation Network: Scope, Feasibility, and Opportunities." Information submitted in response to this notice will be used by CDER's Quantitative Medicine Center of Excellence (QM CoE) to inform the development and implementation of a cross-sector innovation network.

The proposed mission for the QMIN is to connect FDA scientists, academia, industry, healthcare providers, patient groups, and other regulatory partners in driving the development and application of quantitative medicine to tackle critical unmet needs of the community by fundamentally transforming drug development and clinical care.

Quantitative medicine approaches integrate mathematical and computational models with biological, clinical, and statistical data to inform drug development, regulatory, and clinical decisions. These approaches have the potential to improve the efficiency of drug development, optimize treatment strategies, and ultimately improve patient outcomes.

The QM CoE seeks to establish a collaborative ecosystem that brings together diverse stakeholders to advance the science and application of quantitative medicine toward transformative capabilities. The QMIN is envisioned as a multi-stakeholder network to accelerate the translation of quantitative approaches across the drug discovery, development, regulation, and utilization continuum, fundamentally transforming how safe and effective

therapies reach patients. This request for information is designed to gather input on how best to structure and implement the QMIN to maximize its impact on public health.

II. Request for Information

FDA is interested in detailed comments on the topics listed in this section to inform the establishment of the QMIN. The topics identified in this section are not meant to be exhaustive. FDA is also interested in any other pertinent information that interested parties would like to share related to advancing quantitative medicine through collaborative networks. The Agency encourages interested parties to provide specific rationale and basis for their comments, including any available supporting data and information.

The QM CoE seeks to understand the current landscape of quantitative medicine capabilities, challenges, and opportunities across different stakeholder groups. We are interested in establishing mechanisms for problem-solving that leverage community expertise and collaborative capacity.

Specific areas of interest include the following:

A. Scope

1. Priority Domains
   - What areas of quantitative medicine (e.g., disease modeling, trial simulation, New Approach Methodologies (NAMs) integration) would most benefit from a coordinated, cross-sector network?
   - Where currently are the greatest gaps in tools, standards, or infrastructure?
2. Depth vs. Breadth
   - Should the QMIN prioritize a limited number of high-impact domains (e.g., therapeutic area specific needs, methodology development) for deep investment, or a broader set of activities (e.g., improved adoption and integration of QM approaches across therapeutic areas)?
3. Boundaries of Activity

- What activities are most appropriate for a precompetitive network versus those better addressed within individual development programs or regulatory submissions?
- How should the QMIN define its role relative to existing efforts, including those led by FDA and external stakeholders?

B. Operating Model

1. Structure and Governance
   - What governance structures would best support a multi-stakeholder network involving FDA, industry, academia, and patient groups?
   - What roles should different stakeholders play in setting priorities, developing outputs, and ensuring scientific rigor?
2. Modes of Collaboration
   - What mechanisms (e.g., working groups, pilot projects, public workshops, shared platforms) would most effectively support the QMIN's objectives?
   - How should collaboration be structured to enable both innovation and broad participation?
3. Sustainability and Incentives
   - What incentives would encourage sustained participation from stakeholders?
   - What funding or resourcing models (e.g., public-private partnerships) should be considered?

C. Priority Use Cases

1. Selection of Use Cases
   - What types of use cases are most appropriate for initial QMIN focus?
   - What criteria should be used to select and evaluate use cases?
2. Demonstration of Value
   - How should the QMIN's use cases be designed to demonstrate clear impact?
   - What metrics (e.g., reduced development time, improved decision confidence, reduced animal use) are most appropriate?

(Authority: 21 U.S.C. 355)

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

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