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I appreciate the opportunity to comment on FDA's proposal to establish a Quantitative Medicine Innovation Network (QMIN). I strongly support the overall goal of creating a cross-sector collaborative platform to advance quantitative approaches that improve drug development, regulatory decision-making, and patient care.

In my view, the most important determinant of QMIN's success will be whether it focuses on answering important public health and regulatory questions rather than on methodological development for its own sake. Quantitative methods should be viewed as tools for improving decisions. Accordingly, QMIN should prioritize use cases where quantitative approaches can demonstrably improve evidence generation, reduce uncertainty, increase efficiency, or improve patient outcomes.

The scope of QMIN should explicitly include not only pharmacometric and simulation approaches, but also real-world evidence, pharmacoepidemiology, causal inference methods, comparative effectiveness research, and postmarketing safety evaluation. Quantitative medicine is broader than predictive modeling alone and encompasses a wide range of methods used to support regulatory and clinical decisions.

Given finite resources, I recommend that QMIN pursue a limited number of high-impact demonstration projects rather than a broad portfolio. Potential examples include:

- Integration of randomized and real-world evidence for regulatory decision-making;
- Quantitative approaches to improve evidence generation in populations underrepresented in clinical trials;
- Methods to strengthen postmarketing safety surveillance and signal evaluation; and
- Approaches that improve comparative effectiveness assessments relevant to patients, clinicians, regulators, and payers.

QMIN should also emphasize transparency, reproducibility, and open science. The most valuable outputs may be shared datasets, validated methods, publicly available tools, and reproducible demonstration projects rather than consensus reports alone. Governance structures should ensure meaningful participation by FDA, academia, industry, healthcare providers, and patient representatives while maintaining scientific rigor and independence.

Finally, QMIN's success should be evaluated based on its impact on decision-making rather than its level of activity. Metrics such as improved decision confidence, more efficient evidence generation, enhanced regulatory consistency, better patient outcomes,

or more effective safety surveillance are likely to be more informative than counts of meetings, publications, or participating organizations.

In summary, I support establishment of the QMIN and encourage FDA to focus on high-priority use cases, rigorous evaluation, transparency, and the broad range of quantitative disciplines that contribute to regulatory and clinical decision-making. A successful QMIN could play an important role in advancing the generation and application of evidence that improves public health.