The Road Ahead For Drug Development In The US

By **Jacqueline Berman and Ariel Seeley** (April 3, 2026)

Jacqueline Berman

Ariel Seeley

Following its release of a road map for phasing out animal testing, on March 18, the U.S. Food and Drug Administration released a draft guidance on general considerations for the use of new approach methodologies in drug development.

This guidance signals a willingness by the FDA to consider the use of new technologies for drug development. Technology developers should pay special attention to this evolving and growing area of FDA opportunity and regulation, as it creates openings for new entrants into the drug development ecosystem, as well as new requirements.

The FDA's draft guidance comes at a time when drug development in the U.S. is approaching a crossroads. Due to regulatory challenges, the time it takes to initiate U.S. clinical trials and the overall cost, companies are looking to other countries for their initial development efforts, such as China and Australia, where early-stage development may proceed at a faster pace.

Recognizing this, the FDA has begun taking steps to facilitate and encourage domestic drug development activities, including proposals for the next reauthorization of the Prescription Drug User Fee Act to include both carrots and sticks to promote the conduct of Phase 1 clinical trials in the U.S.

Further, FDA Commissioner Marty Makary recently articulated the need for the FDA to shorten the time it takes for sponsors to move into Phase 1 trials, including through reforms to Institutional Review Board requirements. Accordingly, the FDA is likely to be receptive to industry innovation that makes U.S.-based drug development faster or less expensive.

Guidance for New Approach Methodologies

Against this backdrop, the FDA's draft guidance provides a validation framework for new approach methodologies, or NAMs, used in drug development to improve predictive toxicology in humans and move away from reliance on animal testing.

NAMs include a variety of testing methodologies, including in-vitro human-derived systems

(e.g., organ-on-chip), computer modeling and simulation techniques, and other innovative platforms.

Under the guidance, sponsors seeking to validate a NAM to enhance interpretability and reliability for use in support of regulatory decision-making should focus on four key factors: (1) the context of use, (2) human biological relevance, (3) technical characterization and (4) fit for purpose.

The guidance is less clear, however, on the actual need for NAM validation.

On one hand, it states that "validation is warranted to help determine the quality of the data produced and how the results should be interpreted for regulatory decision-making."

On the other hand, it also states "for a NAM to be considered for review in drug development, the test does not necessarily need to be validated … A fit-for-purpose NAM, even if not validated, may adequately address specific toxicological concerns."

NAMs for Medical Devices Remain Challenging

The NAM draft guidance is part of the FDA's deliberate and coordinated agencywide efforts to reduce development costs and reduce animal testing for all FDA-regulated product areas.

Outside of drugs, the FDA has also encouraged the use of NAMs in medical device testing and development, in particular for biocompatibility studies. Despite the FDA's overall enthusiasm for NAMs, in practice the use of NAMs in medical device clinical trials is more complex.

The FDA has cited regulatory science gaps and challenges, such as insufficient NAMs that are validated or qualified for biocompatibility assessment of medical devices, among other factors, as limiting the utility of NAMs for medical devices. And while the FDA issued a draft guidance in 2024 related to alternate approaches for medical device biocompatibility studies, it has yet to issue a guidance on the use of NAMs for medical devices.

The FDA's current expectations for biocompatibility studies continue to be a pain point for medical device companies. While only time will tell if the fit-for-purpose concept and other elements in the draft NAM guidance are helpful in expanding successful use of NAMs in drug clinical trials, medical device companies may want to advocate for the FDA to adopt a

similar concept as a least burdensome approach to medical device biocompatibility studies, in the hopes that the FDA's rhetoric around alternative methods will become a reality for medical device companies.

The Bigger Picture

Despite the questions raised by the NAM draft guidance and medical device biocompatibility draft guidance, these actions signal a growing trend within the FDA and the medical product development ecosystem to find new ways to leverage technology to decrease the cost and time required for product development in the U.S.

While NAMs focus on preclinical development, this openness to new methods will create new opportunities for technology companies throughout all stages of development.

Current and future uses for new technologies include the integration of artificial intelligence and machine learning into early-stage drug development, and target and compound selection, as well as in clinical trials, such as to facilitate enrollment, clinical trial design, detection of clinical trial issues and even to substitute for at least some subjects through the use of digital twins.

These innovations are being integrated into medical device development as well, such as through innovative testing approaches like 3D models that simulate human tissue responses to device materials; computer simulations and AI-driven modeling to assess device safety, biocompatibility and chemical risks; and the organ-on-chip microchips that replicate living human cells.

These technologies may also show potential to change the way that clinical trials are conducted, such as through the use of interconnected devices and software to further facilitate decentralized trials, decreasing the burden of trial conduct on patients.

However, it will be important for new technology company entrants to understand the highly regulated nature of the product development and clinical trial environment as technology companies may be used to operating under fewer requirements and restrictions.

For instance, companies will need to grapple with not only regulations that may be directly applicable to them, such as medical device and privacy requirements, but also requirements that will be applicable to their customers, e.g., clinical trial sponsors. These

will include requirements related to good clinical practices, research ethics and data integrity.

Technology companies will also have to consider how to handle and mitigate risk that is inherent in development, including through the implementation of policies and procedures, and contractual terms that meet the needs of both study sponsors and the technology companies.

Accordingly, technology companies that are taking up the call to reform FDA-regulated product development should ensure they are well acquainted with the FDA's requirements, and have the necessary processes and controls in place to ensure compliance.

Jacqueline R. Berman is a partner at Morgan Lewis & Bockius LLP.

Ariel Z. Seeley is of counsel at the firm. She previously served as associate director for regulatory documents and special projects at the Center for Devices and Radiological Health's Office of Policy within the U.S. Food and Drug Administration.