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FDA Reports Meeting Year One Goals for Reducing Animal Drug Testing

On May 29, 2026, the Food and Drug Administration (FDA) released its latest guidance related to FDA's intent to reduce unnecessary animal testing for nonclinical safety assessments, Oncology Pharmaceuticals: Streamlined Nonclinical Safety Studies for Biologics and Conjugated Products. The guidance is intended to help reduce unnecessary animal testing by incorporating an integrated knowledge-based risk assessment with a focus on three-month toxicology studies for certain oncology pharmaceuticals.

Sponsors may propose alternative approaches for a three-month general toxicology study for product classes not described in the guidance, provided such approaches are sufficient to address product safety. Such approaches for a three-month general toxicology study may include a non-sacrificial toxicology study, an alternative study design to reduce animal numbers, or a weight of evidence (WoE) risk assessment for products with well-understood targets to replace animal studies. These approaches could be supplemented with new approach methodologies (NAMs), as appropriate.

FDA's recommendations cover general toxicology and WoE Assessment. For general toxicology, FDA stated that animal toxicology studies should use pharmacologically relevant species or WoE risk assessment in its absence. FDA stated that if pharmacological activity is similar to humans in both rodent and non-rodent species, then general toxicology may be conducted in a single rodent species and supplemented with WoE risk assessment as appropriate.

A WoE risk assessment may include multiple factors. The factors include nonclinical and clinical data generated with the investigational product (e.g., pharmacology,

safety, and pharmacokinetics), a literature-based assessment of potential toxicities with the molecular target, toxicity findings in animals and humans associated with the same class of pharmaceuticals, and other data. The Center for Drug Evaluation and Research's (CDER) oncology review divisions will determine when the WoE risk assessment is sufficient to address the safety risks based on the totality of evidence.

This guidance builds upon FDA's initial Roadmap to Reducing Animal Testing in Preclinical Safety Studies (April 2025) to provide a strategic, stepwise approach using NAMs, such as organ-on-a-chip systems, computational modeling, and advanced *in vitro* assays (e.g., organoids and microphysiological systems). The principles come from a growing scientific recognition that animals are inadequate models of human health, i.e., over 90% of drugs that appear safe and effective in animals do not go on to receive approval in humans. In addition, the time and cost of long-term animal studies delay therapies reaching patients, e.g., developing a monoclonal antibody costs $600-750 million and may take up to nine years, with typical programs using 144 non-human primates at costs reaching $50,000 per animal.

FDA's one-year progress report, Reducing Animal Testing in Nonclinical Studies Year One Progress and the Path Forward (April 2026) declared that the necessary foundations or goals had been met or exceeded, resulting in additional guidance. Some of those goals included:

- On July 31, 2025, FDA made the Innovative Science and Technology Approaches for New Drugs pilot program permanent. The program employs the Drug Development Tool Qualification regulatory framework, providing a clear, predictable pathway for developers to gain formal FDA acceptance of NAMs.
- In August 2025, FDA and the National Institutes of Health formalized a partnership in a Memorandum of Understanding to accelerate the standardization, qualification, and adoption of human-relevant alternative methods.
- In October 2025, the CDER / Office of New Drugs Streamlined Nonclinical Studies and Acceptable New Approach Methodologies database went live, providing a searchable, regularly updated inventory of specific drug development contexts where streamlined nonclinical programs are acceptable.
- In November 2025, FDA researchers from the National Center for Toxicological Research and CDER, collaborating with Emulate Inc. and the University of North

Carolina at Chapel Hill, published challenges and solutions in measuring commonly used biomarkers for drug-induced liver injury in a liver-on-a-chip platform.

- On December 2, 2025, FDA released draft guidance, Monoclonal Antibodies: Streamlined Nonclinical Safety Studies.
- On December 8, 2025, FDA crossed a technological threshold by qualifying the AI-Based Histologic Measurement of NASH its first AI-based drug development tool for use in metabolic dysfunction-associated steatohepatitis clinical trials.
- On March 18, 2026, FDA published a draft guidance document: General Considerations for the Use of New Approach Methodologies that established four core validation principles to transform the abstract question of "When is an alternative acceptable?" into concrete, actionable requirements. On the same date, FDA's Level 2 update to "Pyrogen and Endotoxins Testing: Questions and Answers" guidance provided the flexibility for manufacturers to transition from Limulus Amoebocyte Lysate (LAL) reagents for bacterial endotoxin testing to transition from harvesting horseshoe crabs for production of LAL reagent to recombinant agents.

We will continue to monitor FDA's continuing implantation of a framework to reduce animal testing in nonclinical studies.

This blog was drafted by Brian Malkin, a Spencer Fane attorney on the FDA Pharmaceutical and Biologics Market Team. For more information, visit spencerfane.com.

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