



Progress Report

April 2025 - September 2026

Food and Drug Administration



Agency Pledge

April 2025 - FDA unveiled a plan to reduce and potentially eliminate animal testing in preclinical safety studies.



4/10/2025

Released Roadmap

The FDA released their *Roadmap to Reducing Animal Testing in Preclinical Safety Studies*, outlining a 3–5 year plan where animal testing becomes the “exception, not the norm.”

Summer 2025

Acceptance of NAMs data for new drugs

The FDA started accepting data from New Approach Methods (NAMs) for Investigational New Drug applications and offered regulatory relief.

7/31/2025

ISTAND program

The agency announced that the Innovative Science and Technology Approaches for New Drugs (ISTAND) pilot program, created to support innovative drug development methods, is now a permanent part of the Drug Development Tool (DDT) Qualification Program.

Spring 2025

Pilot program launch

The agency launched a pilot program allowing monoclonal antibody developers to submit non-animal data in lieu of traditional animal tests.

7/7/2025

FDA-NIH workshop

FDA leadership participated in a joint FDA-NIH workshop to promote transition strategies and implementation pathways for reducing animal testing.

Progress Report

April 2025 – September 2026

Food and Drug Administration



10/8/2025

CDER updates website

The Center for Drug Evaluation and Research (CDER) updated its website to include inventory of methods that drug companies can use to reduce or eliminate animal tests.

10/27/2025

Cancer drug approval

For the first time, the FDA approved a new cancer drug for human clinical trials based solely on non-animal data.

12/2/2025

Draft guidance to reduce monkey testing

The FDA issued draft guidance outlining specific product types for which the FDA believes six-month non-human primate toxicity testing can be eliminated or reduced.

12/8/2025

AIM-NASH

The FDA qualified its first AI-based drug development tool, AIM-NASH, helping streamline and improve the consistency of liver disease assessments in clinical trials.

3/18/2026

Horseshoe crab reduction

The agency updated its endotoxin testing guidance to support replacing horseshoe crab-derived reagents with validated non-animal methods, marking a step toward reducing reliance on animal-derived materials.

3/18/2026

Draft guidance on NAMs use

The FDA issued draft guidance intended to help drug developers validate NAMs to be used instead of animal testing in drug development, and to bring safe, effective drugs to market sooner based on human-centric data.



Progress Report

April 2025 – September 2026

Food and Drug Administration



June 2026

Draft guidance on computer-modeled dosing

The FDA issued guidance on using quantitative systems pharmacology, a computer-modeling approach, to help select starting doses for first-in-human clinical trials.

6/3/2026

Acceptance of first AI tool for liver toxicity

The FDA accepted an AI-powered computer model into its drug development tool qualification program to predict drug-induced liver injury, a leading cause of drug failures that animal models do not reliably predict in humans.

7/28/2026

Workshop on NAMs in safety testing

The FDA co-hosted a workshop on integrating NAMs into safety pharmacology studies, laying framework to amend global safety pharmacology requirements using NAM data.

9/21/2026

Replacement of language favoring animal use

The FDA replaced “animal tests” and “animal studies” with “nonclinical tests” and “nonclinical studies” throughout its drug testing regulations, effectively removing terminology favoring animal studies.

9/21/2026

NAMs use case database

The agency launched a public collection of 25 real-world examples showing acceptable data submissions that did not use animal data.

9/21/2026

American Type Culture Collection

The FDA selected ATCC to advance organoid and organ-on-chip methods for infectious disease and cancer research.

Progress Report

April 2025 - September 2026

Food and Drug Administration



Where FDA Progress Falls Short

- The roadmap focuses primarily on drug and biologic safety testing. Although FDA has begun broader initiatives, it has not established a comprehensive replacement plan covering animal testing across all products it regulates.
- The FDA has not established enforceable dates after which specific animal tests must stop.
- Work to date aims to make animal studies the exception, rather than end them entirely. Its September 2026 regulatory update explicitly preserves animal testing as an acceptable option.
- The agency is opening pathways for non-animal methods but generally leaves manufacturers to decide whether to use them. The September rule clarifies that alternatives are permitted without requiring their use when suitable methods are available.
- Clearer expectations are needed to ensure human-based methods replace animal experiments rather than simply supplement them.



How NAVS is Helping the FDA Fulfill its Pledge

- Advocating for animal-free cosmetic safety testing: NAVS submitted comments ahead of the 20th International Cooperation on Cosmetics Regulation meeting, urging greater international acceptance of non-animal methods, more transparent regulatory decisions, and a commitment to replacing animal testing for cosmetics.
- Pushing for stronger drug-development standards: NAVS submitted comments on FDA's draft NAMs guidance, calling for human relevance to guide evaluation, measurable timelines for replacing animal studies, and an end to unnecessary duplicate animal testing. NAVS also urged FDA to acknowledge the scientific limitations of animal models.
- Pressing for replacement requirements: Through legislative advocacy and regulatory comments, NAVS urges FDA to move beyond permitting non-animal methods toward making them the expected approach when suitable methods are available.
- Tracking progress and building public pressure: NAVS evaluates FDA's commitments through these progress reports and keeps supporters informed through education and action alerts, highlighting where stronger requirements, transparency, and implementation are needed.

→ <https://navs.org/crossroads-2029>