Progress Report

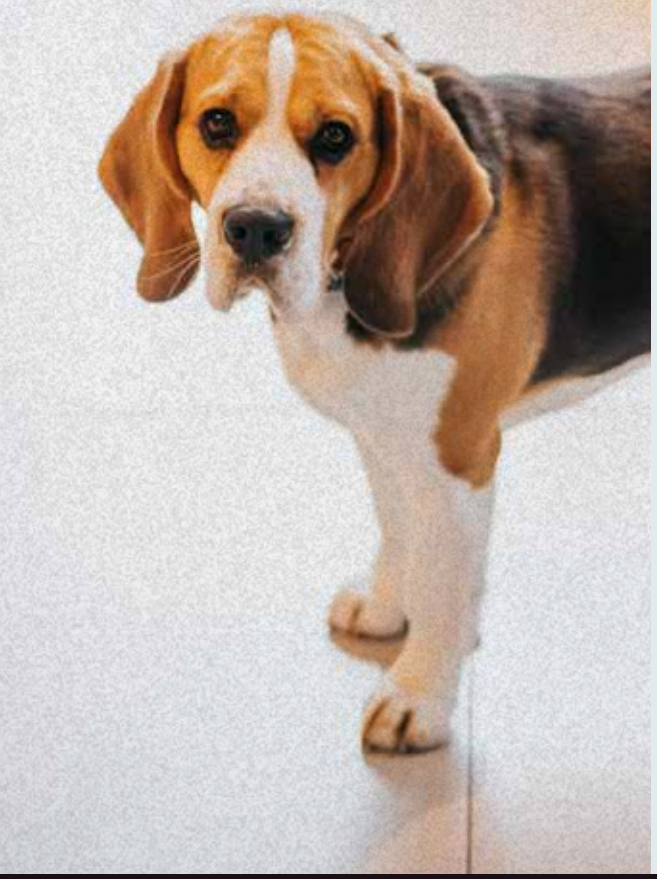
April 2025 - June 2026

Food and Drug Administration

CROSSROADS2029
THE SHIFT TO SCIENCE WITHOUT SUFFERING

Agency Pledge

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



4/10/25

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."

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.

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.

7/7/25

FDA-NIH workshop

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

7/31/25

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.

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10/8/25

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.

10/27/25

Cancer drug approval

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

12/2/25

Draft Guidance to reduce monkey testing

The FDA issued draft guidance outlining specific product types for which the FDA believes six-month non-human primate toxicity testing can be eliminated or reduced.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

3/18/26

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.

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April 2026

FDA launches NAMs Acceptability Database

FDA launched a searchable database identifying where NAMs are accepted in regulatory submissions. The resource is intended to improve transparency and make it easier for developers to incorporate validated non-animal methods into drug development.

May 2026

FDA encourages reduction of animal testing for certain cancer therapies

FDA released draft guidance recommending streamlined nonclinical safety studies for certain oncology biologics and conjugated products. The guidance encourages sponsors to use a weight-of-evidence approach to reduce or eliminate unnecessary animal studies when existing scientific data adequately characterizes safety, helping accelerate drug development while reducing animal use.

4/20/2026

FDA announces year one goals met

The FDA announced it has met its key first-year milestones under its Roadmap to Reduce Animal Testing in Preclinical Safety Studies. Notable achievements include releasing draft guidance to reduce or eliminate nonhuman primate (NHP) use in monoclonal antibody development, advancing guidance to transition away from horseshoe crab-derived endotoxin testing, and qualifying the first AI-based tool for drug development, among other steps.

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Where FDA Progress Falls Short

- The roadmap scope is narrow and conservative, limited to preclinical safety for drugs/biologics.
- There are no hard deadlines after which specific animal testing cannot be done.
- The goal is to make animals the "exception," not abolish their use completely.
- Transparency to measure progress is lacking.
- Roadmap relies on voluntary adoption by scientists and drug manufacturers.

How NAVS is Helping the FDA Fulfill its Pledge

- NAVS submitted comments to the FDA ahead of the 20th annual meeting of the International Cooperation on Cosmetics Regulation (ICCR), urging the agency to accelerate the transition to human-relevant, non-animal approaches for cosmetic safety assessment. The comments called for greater international acceptance of NAMs, expanded use of next-generation risk assessment, increased regulatory transparency, and a long-term commitment to replacing animal testing for cosmetics.
- NAVS submitted comments on the FDA's draft guidance for the use of NAMs in drug development, urging the agency to accelerate the transition from animal testing to human-relevant science. The comments called on FDA to recognize the scientific limitations of animal models, evaluate NAMs based on human relevance rather than their ability to replicate animal data, establish measurable timelines for replacing animal studies, and eliminate unnecessary duplicate animal testing.
- Driving policy change: NAVS supports legislative updates, including the FDA Modernization Act 3.0, to require the agency to phase out animal tests when qualified non-animal methods exist.
- Pushing for regulatory updates: NAVS submits targeted comments urging the FDA to revise guidance and remove animal-first expectations, replacing them with NAMs-first standards.
- Increasing accountability: Through this progress report, public comments, and information requests, NAVS tracks the FDA's actions and highlights gaps in transparency and implementation.
- Strengthening the scientific case for NAMs: NAVS funds and promotes human-relevant research, showcases the limits of animal models, and connects experts to accelerate acceptance of non-animal approaches.
- Mobilizing the public: Through education and action alerts, NAVS keeps supporters informed and engaged, increasing pressure on the FDA to meet and expand its commitments.

→ https://navs.org/crossroads-2029