NAVS

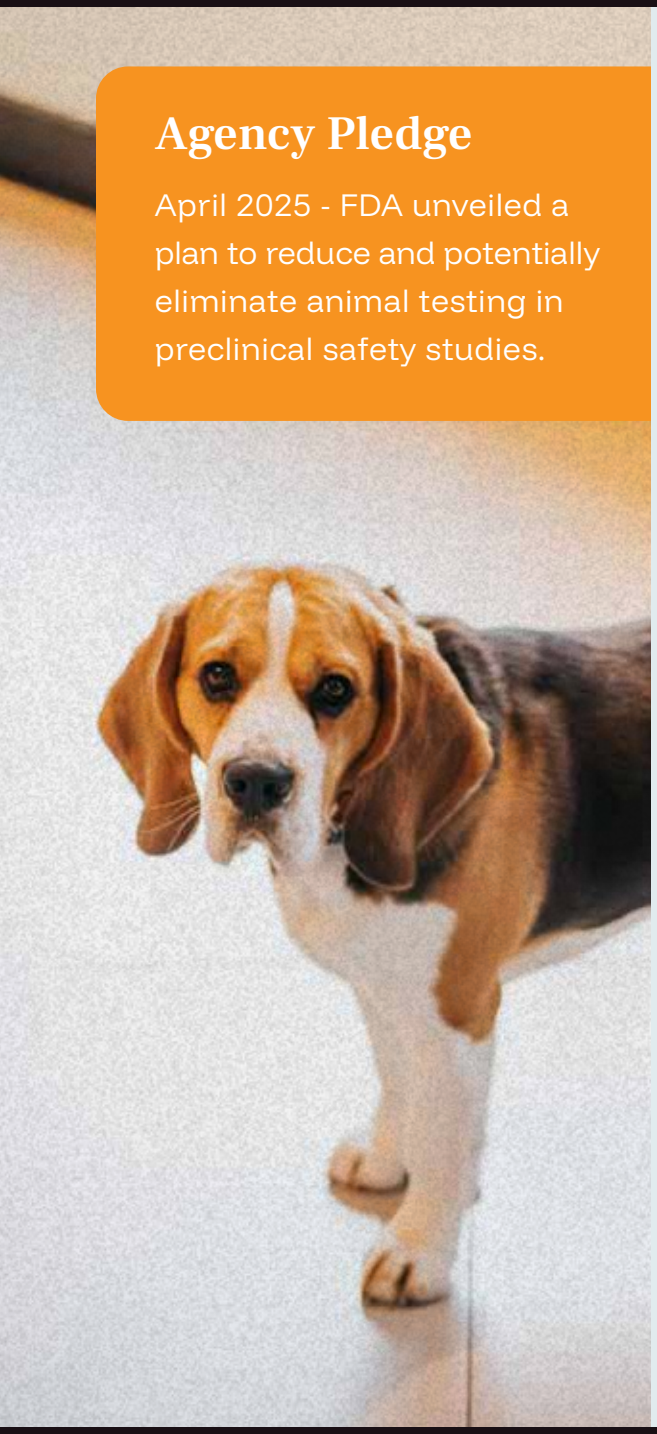
Progress Report

April 2025 - March 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 NAMs data for Investigational New Drug (IND) 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Draft Guidance to reduce monkey testing

The FDA issued draft guidance outlining specific product types for which the FDA believes six-month non-human primate toxicity testing can be eliminated or reduced.

3/18/26

Draft Guidance on NAMs Use

The FDA issued draft guidance intended to help drug developers validate new approach methodologies (NAMs) to be used instead of animal testing in drug development, and to bring safe,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.

Where FDA Progress Falls Short

- The roadmap scope is narrow and conservative, limited to pre-clinical 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

- Driving policy change: NAVS supports legislative updates—including 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