ICCVAM Public Forum 2025

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Our Mission

To keep medical advances moving ahead.

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Who We Are

Americans for Medical Progress (AMP) is a team of subject-matter experts that fosters an environment where vital medical advancements can continue through companies and academic institutions within the research community.

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Recommendation 1: Establish a Standardized Definition of NAMs

The acronym "NAMs" has various definitions amongst stakeholders, including federal agencies, which complicates effective policy implementation and mutual understanding.

"Non-Animal Models"
"Novel Alternative Methods"
"New Alternative Methods"

Emphasis is more on the methodology itself

"New Approach Methods"
"New Approach Methodologies"

Emphasis is more on the broader research approach, which could include the 3Rs (Reduce, Refine, Replace)

A clarified definition of this term that all agencies can adopt would significantly benefit policy discussions and public messaging.

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Recommendation 2: Promote Understanding of Federal Policy Changes

Roadmap to Reducing Animal Testing in Preclinical Safety Studies

Executive Summary

This roadmap outlines a strategic, stepwise approach for FDA to reduce animal testing in preclinical safety studies with scientifically validated new approach methodologies (NAMs), such as organ-on-a-chip systems, computational modeling, and advanced *in vitro* assays. By partnering with federal agencies like NIH and VA through ICCVAM, FDA can accelerate the validation and adoption of these human-relevant methods, improving predictive accuracy while reducing animal use. This transition will enhance public health by streamlining drug development and ensuring safer therapies reach patients faster, while positioning FDA as a global leader in modern regulatory science and innovation.

Background

There is growing scientific recognition that animals do not provide adequate models of human health and disease.[1] Over 90% of drugs that appear safe and effective in animals do not go on to receive FDA approval in humans predominantly due to safety and/or efficacy issues (1). Animal-based data have been particularly poor predictors of drug success for multiple common diseases including cancer (2), Alzheimer's (3) and inflammatory diseases (4). Some medications which are generally recognized safe in humans, such as aspirin, may have never passed animal testing (5). Conversely, some compounds which have appeared safe in animal models have been lethal in human trials (5). These examples highlight basic physiologic differences between humans and other animal species.

Due to the limitations of animal testing as well as ethical concerns about animals testing, there has been increased focus within the scientific community on New Approach Methodologies (NAMs). NAMs encompass *in vitro* human-based systems, *in silico* modeling, and other innovative platforms that can collectively evaluate immunogenicity, toxicity, and pharmacodynamics in humans and provide an opportunity to improve the predictive relevance of preclinical drug testing while reducing or replacing animal use. NAMs also have enormous cost saving potential (6).

Recent legislative changes have signaled Congress is simultaneously open to regulatory innovation. In late 2022, Congress passed the FDA Modernization Act 2.0,[2] which explicitly authorized the use of non-animal alternatives (cell-based assays, computer models, etc.) to support an investigational new drug (IND) application and "remove[d] a requirement to use animal studies" for biosimilar biologics license application (BLA) (7). This landmark policy empowered FDA to accept NAMs in lieu of animal studies. Then in 2024, the Science Board to the FDA provided comprehensive recommendations on how the agency can spur adoption of scientifically validated NAMs.[3]

Public sentiment is also supportive of this transition with a recent survey finding that >85% of both Democratic and Republican-identifying adults felt that animal experiments should be phased out in favor of more modern methods.[4] Together, scientific advances and policy drivers create an opportune moment for the FDA to chart a roadmap to reduce animal testing while improving drug development.

[1] https://www.acd.od.nih.gov/documents/presentations/12142023_NAMs_Working_Group_Report.pdf
[2] H.R.2565 - 117th Congress (2021-2022): FDA Modernization Act of 2021 | Congress.gov | Library of Congress
[3] https://www.fda.gov/media/182478/download#:~:text=NAM%20Subcommittee%20Recommendations,all%20of%20FDA%20to%20use
[4] https://pcrm.widen.net/s/qzfxtfh7bw/animal-testing-survey

NIH Funding Announcements to Align with NIH Initiative to Prioritize Human-based Research

July 10, 2025

On April 29, NIH announced it is prioritizing human-focused research and reduc… animal use in research. To further this initiative, all new Notices of… that relate to animal model systems (NOFOs) m… approaches such as clinical trial… Examples of NAMs i… organs and precision… systems and organoi… combinations thereof.

Importantly, NIH will no… …pporting animal models or limit/specify the types o… …se used. The intent of this effort is to ensure investigators consider th… models most appropriate for understanding human states of health and disease and are not constrained by the NOFO. NIH Institutes, Centers and Program may issue NOFOs that exclude proposals for animal use entirely.

This new emphasis on human-based research will accelerate medical advances, save animals and help NIH achieve its crucial mission of improving human health.

Tuesday, April 29, 2025

NIH to prioritize human-based research technologies

New initiative aims to reduce use of animals in NIH-funded research.

How Does the NIH Initiative to Prioritize Human-Based Research Affect Research Proposing the Use of Laboratory Animals?

July 18, 2025

In July 2025, NIH announced it will no longer develop new funding opportunities focused exclusively on animal models of human disease. Rather, going forward, new funding opportunities will be …gned more broadly with language that also encourages various approaches be considered. This me… …hoose any model they deem appropriate – including a combination of approaches… …ubmitting applications seeking NIH support. This strategy is intended to… …bmitted in response to funding opportunities, not be…

…ants (like clinical trials), particular laboratory …nce, in silico approaches, other alternative …gh our fair and impartial review process, the merit of …and if it is best suited to answering the research question that …overy. Our overarching goal is to accelerate progress, encourage innovation, and …quality and validation of new approach methodologies.

We are also prioritizing human-based technologies and models, where scientifically valid and justified. Likewise, funding opportunities will indicate a special emphasis on human-based approaches.

These steps should encourage investigators to choose the best models for their research without constraints. To reiterate, NIH will continue to support grants that use laboratory animal models if scientifically appropriate, justifiable, and with appropriate animal welfare oversight. Moreover, if laboratory animals are proposed, scientists must still continue to clearly explain why they are necessary for their research, that the minimal number needed to ensure rigorous and reproducible studies will be used, and why the study cannot be done using another model or approach (see more here).

While traditional animal models continue to be important to advancing scientific knowledge, NIH recognizes that prioritizing new and emerging human-based technologies can offer unique strengths to expand the toolbox for researchers to answer previously difficult or unanswerable biomedical research questions. It also moves us toward our continued long-term goal of reducing, refining, and replacing the use of laboratory animals in NIH-supported research.

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Recommendation 2: Promote Understanding of Federal Policy Changes

- **Clarifying Policy Requirements**
  ICCVAM can play a vital educational role by helping stakeholders understand what federal policies do—and do not—require.

- **Providing Scientific Guidance**
  ICCVAM's expertise in establishing frameworks and criteria for scientific confidence will be especially valuable as new policy changes are implemented.

- **Promoting Balanced Understanding**
  It's important to acknowledge both the scientific promise and limitations of NAMs. While these tools are unlocking exciting new possibilities, animals remain essential for many areas of research.

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Recommendation 3: Proactively Engage with the Veterinary and IACUC Community

- **Essential Voices in Responsible Research**
  Veterinarians, animal care staff, and IACUC professionals are critical to advancing the 3Rs and ensuring the ethical, responsible use of animals in research

- **Bridge Policy with Practical Implementation**
  Their expertise in protocol design, literature search for alternatives/NAMs, and study refinements brings real-world insight to policy development.

- **Strengthen Credibility and Buy-In**
  Including these voices fosters transparency, trust, and broader acceptance of both animal and non-animal studies.

Goal:

Ensure we serve the science, not define it.