

M. Sue Marty, PhD, MPH

Chair, Scientific Advisory Committee on Alternative Toxicological Methods (SACATM)

Warren Casey, PhD

Executive Director, Interagency Coordinating Committee on the Validation of Alternative Methods (ICCVAM)

Director, NIH Office of Research Innovation, Validation, and Application (ORIVA)

Re: Written Comments for SACATM November 4-5, 2026 Meeting

Dear Dr. Marty, Dr. Casey, and Members of SACATM:

Americans for Medical Progress (AMP) appreciates the opportunity to provide comments to the Scientific Advisory Committee on Alternative Toxicological Methods (SACATM) for its November 4-5 meeting. As a national nonprofit dedicated to fostering public understanding of biomedical research and the tools necessary to advance it, AMP supports the rigorous development, evaluation, and scientifically appropriate adoption of New Approach Methodologies (NAMs). As these technologies advance, scientific decisions and public expectations must reflect their current capabilities and limitations, including where NAMs can reliably replace animal studies, where they can complement existing approaches, and where significant scientific gaps remain that require further research and investment before animal studies can be safely and effectively replaced.

Recognizing the growing disconnect between public expectations of NAMs and their current scientific capabilities, AMP believes SACATM has an important opportunity to help bridge this gap by promoting a more accurate and balanced understanding of where the science stands. With this in mind, AMP offers two recommendations for SACATM's consideration.

1. Develop a U.S. roadmap that reflects NAMs' scientific readiness and advances all three Rs

AMP encourages SACATM to recommend the development of a U.S. roadmap aligned with the EFPIA and UK three-baskets approach, with all three Rs—Replacement, Reduction, and Refinement—at its core. This effort would build on SACATM's ongoing work to harmonize validation approaches and technical guidance with international partners while helping establish a shared understanding of NAMs' scientific readiness and current capabilities.

The three-baskets approach advanced by the European Federation of Pharmaceutical Industries and Associations (EFPIA)¹ and the United Kingdom's 2025 national strategy² offers a practical, evidence-based framework to guide these efforts. It recognizes that NAMs exist along a continuum of scientific readiness, helping distinguish where animal studies can be replaced today, where NAMs can complement existing approaches but require further validation, and where significant scientific challenges remain that require longer-term research and

¹European Federation of Pharmaceutical Industries and Associations (EFPIA), Recommendations on Phasing Out Animal Testing for Chemical Safety Assessments (June 2025), <https://efpia.eu/media/meef32ki/efpia-recommendations-on-phasing-out-animal-testing-for-chemical-safety-assessments.pdf>.

²UK Government, Replacing Animals in Science: A Strategy to Support the Development, Validation and Uptake of Alternative Methods (November 2025), <https://www.gov.uk/government/publications/replacing-animals-in-science-strategy>.

investment. Rather than introducing another validation standard or assuming that every animal study has a direct non-animal substitute, this framework provides researchers and regulators with a common reference point to assess progress and prioritize future efforts. The European Commission's 2026 roadmap similarly recognizes the need to distinguish between near- and longer-term priorities, reinforcing the value of a coordinated, phased approach to advancing NAMs.

Equally important, the U.S. roadmap should recognize progress across all three Rs, rather than measuring success solely by the replacement of animal studies. Where complete replacement is not yet feasible, NAMs can still improve experimental design, reduce animal use, refine procedures, and provide valuable evidence alongside existing research approaches. Recognizing these contributions as meaningful scientific advances would help ensure that reduction and refinement remain priorities while research continues toward longer-term replacement goals. This broader approach would support continued progress in both science and animal welfare.

AMP's recommendation also builds on a recurring theme heard from U.S. and international colleagues at the recent October 20-21 NIH/ORIVA workshop on Alternative Methodologies in Pharmaceutical Development,³ where discussions reinforced the need for greater clarity and a shared understanding of NAMs' current capabilities, remaining scientific gaps, and how different research approaches can work together. A comparable U.S. roadmap would offer a practical way to build on these conversations and help translate that shared understanding into coordinated priorities.

To achieve this, it will be important to draw on the expertise and perspectives of the broader research community, including NAM developers, biomedical and translational researchers, institutions conducting animal studies, veterinary and animal welfare professionals, industry, and regulators. This collaborative approach can help ensure the roadmap reflects real-world research needs, identifies scientific and regulatory priorities, and provides a practical way to assess progress as the science evolves.

2. Make accurate public communication an explicit part of harmonization

International harmonization should also extend to how scientific progress is communicated and understood beyond the research and regulatory communities. Researchers and NAM developers recognize that no single method can answer every scientific question and that understanding complex disease processes or interactions across an entire living system may still require animal studies. Yet public announcements about advances in NAMs can create expectations that exceed their current capabilities, particularly when they do not clearly distinguish between methods under development, those undergoing validation, those accepted for specific regulatory uses, and those ready for routine application.

The disconnect between scientific understanding and public expectations can have significant consequences for policymaking and the research community. Public perceptions help shape discussions with Congress, federal agencies, and institutional leadership, and expectations that outpace the science can create uncertainty around research requirements, access to necessary animal models and expertise, and the future of important biomedical research programs. These pressures can also contribute to an increasingly challenging environment for scientists, veterinarians, and other personnel who conduct and support this work. None of this diminishes the importance of

³National Institutes of Health, Alternative Methodologies in Pharmaceutical Development: Workshop Agenda (October 20–21, 2026), https://ntp.niehs.nih.gov/sites/default/files/2026-10/AMPD_Agenda_Final_V2_16Oct2026_508.pdf.

advancing NAMs or investing in their continued development. Rather, it reinforces why that investment must be accompanied by equally responsible communication about their capabilities, limitations, and where the science stands today.

A public-facing version of the three-baskets roadmap offers a practical way to help bridge this gap. By clearly distinguishing where NAMs can already replace specific animal studies, where they offer valuable information alongside existing approaches but require further validation, and where significant scientific challenges remain, the framework could help federal agencies communicate progress more consistently and accurately. It could also provide useful context for agency announcements, helping the public understand not only what a new method can accomplish, but also its limitations, intended applications, and what additional evidence may still be needed.

By communicating these advances within their appropriate scientific context, federal agencies can help build public confidence in NAMs without creating unrealistic expectations about their capabilities or the pace at which animal studies can be replaced. Such transparency can also support more informed policy discussions and provide research institutions with greater clarity and predictability as they navigate an evolving scientific and regulatory landscape.

AMP appreciates SACATM's continued leadership in advancing the development, validation, and responsible adoption of NAMs. We believe a coordinated U.S. roadmap, informed by international efforts, grounded in all three Rs, and accompanied by clear, science-based public communication would be a meaningful step toward ensuring that scientific progress is both accurately understood and appropriately supported. AMP welcomes opportunities to contribute to these efforts alongside federal agencies and the broader research community as we work toward our shared goals of advancing science, improving animal welfare, and creating a healthier future for people and animals.

Sincerely,



Paula Clifford, MLA, RLATG, CVT
Executive Director

