September 2, 2025

Americans for Medical Progress Comments to SACATM September 2025 Meeting

Americans for Medical Progress appreciates the opportunity to provide comments to the Scientific Advisory Committee on Alternative Toxicological Methods (SACATM). As a nonprofit advocating for ethical biomedical research, we support the integration of validated New Approach Methodologies (NAMs), while recognizing the continued importance of animal models for many areas of science.

At this pivotal time in research and technology development, SACATM's expertise will be essential in helping agencies refine evolving standards and policies while also modeling balanced, science-driven decision-making. With both the Food and Drug Administration (FDA) and National Institutes of Health (NIH) signaling a larger role for the Interagency Coordinating Committee on the Validation of Alternative Methods (ICCVAM), this committee's deliberations carry heightened importance.

Recognizing ICCVAM and SACATM as trusted resources, it is important to note that each committee's scope is centered on toxicology, a field that represents only a limited part of biomedical research involving animals and NAMs. If these advisory bodies are to guide broader biomedical policy, expertise and resources must expand accordingly.

We encourage SACATM to consider the following recommendations:

1. **Establish a Standardized Definition of NAMs.** The term "NAMs" is used inconsistently across agencies and disciplines, leading to misinterpretations and conflicting policy expectations. SACATM is well-positioned to lead a formal effort to establish a standardized, cross-agency definition. Precise terminology will enhance interagency coordination, facilitate stakeholder input, and foster public trust. In doing so, the committee should weigh two key distinctions: defining NAMs narrowly as specific non-animal technologies (e.g., "Non-animal Models," "Novel Alternative Methods") or adopting the broader "New Approach Methodologies" framework that encompasses the 3Rs and reflects a more comprehensive research approach. We strongly encourage the latter, as it better captures the full scope of ongoing scientific and ethical commitments while avoiding oversimplification.

2. **Ensure ICCVAM's Expansion is Supported by Commensurate Expertise and Resources Necessary to Address Biomedical Research Broadly**. While ICCVAM's progress in toxicology—like developing validated alternatives for skin and eye irritation testing—has revolutionized the field, these advancements do not directly extend to other scientific areas such as neuroscience or infectious disease. These fields have distinct scientific and ethical considerations that demand tailored approaches. For ICCVAM to succeed in a broader biomedical role, we encourage SACATM to consider the following:
    a. Recognize that the role of NAMs and animal models differs across scientific disciplines.
    b. Broaden expertise and stakeholder engagement by including laboratory animal veterinarians, Institutional Animal Care and Use Committee (IACUC) professionals, and basic science and translational researchers.

c. Coordinate closely with the Office of Laboratory Animal Welfare (OLAW) to align oversight and animal welfare policies.
d. Reinforce the complementary, not competitive, relationship between NAMs and animal models.

3. **Provide Clear Communication and Set Realistic Expectations for NAMs**. As leaders in the research policy, SACATM has a crucial opportunity to offer a realistic, evidence-based perspective on the role of NAMs in biomedical research. It is important not to overpromise the current capabilities of NAMs. Clear communication with stakeholders and the public should emphasize:
    a. Where animals remain necessary for advancing science and safeguarding health.
    b. The current limitations of NAMs and areas where further development is needed.
    c. The practical implications of these realities for public health and biomedical progress.

Advancing scientific progress requires harnessing the complementary strengths of both NAMs and animal studies. SACATM is uniquely positioned to guide constructive dialogue towards this goal and ensure that future research policies and tools are designed to serve, rather than define the science.