

PhysiciansCommittee

for Responsible Medicine

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Sent via email to guyr2@niehs.nih.gov

Dear NTP Board of Scientific Counselors:

The Physicians Committee for Responsible Medicine appreciates the opportunity to comment in support of ICCVAM's roadmap for implementation of new approaches for safety testing and on your work advising the National Toxicology Program.

NICEATM has done an excellent job coordinating the ICCVAM federal agencies to obtain consensus on a vision, mission and objectives that will play a key role in the safe, effective and timely implementation of human-based, predictive approaches for toxicity testing. We support the vision, mission and objectives, and look forward to opportunities to assist ICCVAM in implementation.

Over the past year, we have noticed an increase in interest by pharmaceutical and device companies to submit information from modern, human-focused approaches. However, traditional validation techniques can serve as a roadblock. We are pleased that exploring new approaches to validation is included as a roadmap objective. We look forward to collaborating on validation projects that incorporate known human data.

An over-arching theme throughout the roadmap objectives is enhanced communication. Clear language regarding agency testing requirements and acceptance of new approaches will help resolve inconsistencies in current written and stated policy. This communication, along with identified forums and case studies to discuss regulatory acceptance and examples of successful use of modern approaches, will help provide necessary industry and agency assurances regarding modern approaches.

As the roadmap objectives indicate, training will be a necessary component to advancing new approaches. Industry and regulators need confidence in each new approach and their own ability to use and understand the information provided. The Physicians Committee has extensive experience providing industry and agency training on modern approaches and will offer continued collaboration in this area.

We ask the Board of Scientific Counselors to continue to support NICEATM/ICCVAM's work on the roadmap, as it is an important step in advancing science and ensuring agencies are prepared to accept innovative, modern tools to obtain the best information possible.

In addition to supporting the roadmap, we want to express our appreciation for your work as members of the Board of Scientific Counselors to advise NTP in its efforts to protect human and environmental health. Recently, NTP conducted an impressive initiative to evaluate a modern skin sensitization approach that is now on a path to regulatory acceptance. We ask the Board to encourage NTP to build off this success by expanding work and resources allocated to advancing other modern, human-based tools, such as organ chips. We also suggest consideration of how NTP in vitro expertise—such as that within the Biomolecular Screening Branch—can impact current NTP toxicological testing projects.

Collaborations with additional government centers such as the National Center for Toxicological Research may be a strong option to explore when considering additional projects and resources.

Thank you for consideration of our comments.

Respectfully submitted,



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