ALTERNATIVES
RESEARCH & DEVELOPMENT
FOUNDATION

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Dr. Casey and ICCVAM co-chairs and members,

On behalf of the Alternatives Research & Development Foundation (ARDF) we appreciate the opportunity to provide comments, and we would like to commend the important work that the Interagency Coordinating Committee on the Validation of Alternative Methods (ICCVAM) has accomplished to advance the development, validation, and acceptance of alternative methods (also called new approach methods, NAMs). ARDF was established in 1993 to provide funding for researchers developing non-animal research methods with the potential to reduce or replace the use of animals in testing, biomedical research, and education, and we have watched with great enthusiasm the recent efforts at the National Institutes of Health (NIH), US Food and Drug Administration (FDA), and several other ICCVAM member agencies aimed at increasing support for the development and implementation of alternative methods.

We applaud the recent establishment of the Office of Research Innovation, Validation, and Application (ORIVA) in the Division of Program Coordination, Planning, and Strategic Initiatives (DPCPSI) at NIH. Locating these efforts in DPCPSI, in the NIH Office of the Director, underscores the importance that NIH places on driving advances in this space. Furthermore, Dr. Warren Casey's appointment as its director provides an experienced and highly respected leader, who can ensure ORIVA's success in coordinating trans-NIH and interagency efforts to advance human-based alternative methods.

The Complement-ARIE program's recently launched Validation and Qualification Network (VQN), coordinated by the Foundation for the NIH (FNIH), is a public-private partnership with significant potential to move some of the most promising alternative methods into regulatory use. Involving regulators in the earliest stages of the qualification process will help ensure that the methods being pursued for qualification meet regulatory and industry needs, and increase the likelihood of successfully moving these methods into widespread regulatory use.

We would also like to recognize the recent workshop on "*Advancing Research Infrastructure to Study Human Disease*" (June 8 and 12, 2026), organized by NIH's Office of Research Infrastructure Programs (ORIP). This event was an excellent example of bringing together stakeholders from government, academia, and industry to discuss both the opportunities and the practical challenges associated with advancing human-based research approaches. These conversations are critical for the widespread adoption of alternative methods, as successful implementation will require collaboration across sectors and a common understanding of the barriers that still need to be addressed.

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Although scientific progress in this area has been significant, ensuring that alternative methods are routinely considered and used in biomedical research and regulatory decision-making remains a tremendous challenge. Current funding structures, institutional practices, and peer reviewer experience and knowledge continue to influence model selection, rather than this decision being driven by science alone. However, this provides opportunities for additional focus by the ICCVAM member agencies to help accelerate the implementation of alternative methods.

Continued focus on transferability and implementation

It has been well demonstrated that scientific performance alone is not sufficient for broad adoption of new methods. Methods must also be accessible and practical to implement across laboratories and relevant sectors. Developers should be encouraged to give greater consideration early in the process of method development to factors such as transferability, accessibility, and sourcing of reagents and materials to ensure that resources are prioritized in support of approaches with the best potential for widespread implementation.

Strengthening regulatory capacity through training and coordination

As alternative methods continue to evolve, ensuring that regulatory reviewers have opportunities to maintain up-to-date knowledge on emerging technologies will be increasingly important. FDA reviewers make complex decisions across many scientific domains, and continued education is necessary to support consistent and scientifically appropriate consideration of human-relevant approaches. We encourage FDA to consider establishing recurring training opportunities related to alternative methods/NAMs for relevant review staff, accompanied by publicly available information on the courses offered, topics covered, and engagement across centers. Transparency around these efforts will help demonstrate continued institutional commitment to the adoption of these new technologies. Furthermore, because alternative methods/NAMs often have applications that extend across multiple regulatory areas, we encourage the establishment of a cross-center FDA coordinating body focused on implementation in the regulatory space. This entity could facilitate communication across centers, promote consistency in regulatory expectations, identify shared scientific challenges, and support alignment with international regulatory partners.

The alternatives research community has created a diverse portfolio of innovative human-based methods capable of modeling many aspects of human biology and disease. The challenge before us now is building the necessary confidence to ensure that these scientific advances are translated into meaningful public health benefits. We thank you for your consideration of these comments, and we look forward to celebrating continued progress on this front.

Thank you,

[redacted]

Angela N Hvitved, PhD
Director

[redacted]

Carolina Romero, PhD
Director of Science Policy