International Alliance for Biological Standardization

IABS 2nd Real World Evidence Workshop
"The Role of Alternative Approaches to Phase 3 Clinical Trials for Vaccine Efficacy and Licensure"

December 10-11, 2025
Montreal, Canada

Summary and insights from the EMA workshop (24-25 Nov 2025) on the use of animal models

The increase in global emergencies and the need to prepare for health threats—from emerging infectious diseases to bioterrorism, radiological, nuclear and chemical threats (CBRN)—advocates for efficient regulatory and scientific pathways for licensing medicinal products when human efficacy trials are not feasible because of absence of affected patients, or not ethical as humans cannot be challenged with threats for which there is no effective vaccine or treatment. In these scenarios, regulators traditionally have relied on non-clinical data (usually animal models) as key demonstration of efficacy for decision-making in the intended indication(s). In the two decades since the first medical countermeasures were approved based on non-clinical data, the scientific, regulatory, and societal contexts have evolved substantially, and there is now the possibility to discuss and critically review, based on concrete cases, the outcomes, translation, and methodology around non-clinical data as key evidence of efficacy for medical countermeasures.
The workshop brought together academics, regulators, developers and healthcare professionals to:

- Discuss the current regulatory frameworks for approval of medical countermeasures when no human efficacy studies can be conducted
- Review the translational outcomes of non-clinical data utilized in regulatory decisions as key evidence of efficacy
- Discuss how to: establish and choose non-clinical models that could reliably predict efficacy in humans; interpret and to bridge non-clinical results to expected clinical efficacy; identify success criteria for regulatory decision-making
- Review alternative approaches to the use of animal models and their potential for use in regulatory decision-making on medical countermeasures
- Consider options for confirmatory clinical studies during emergencies.