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3rd IABS Workshop on Real World Evidence

Pragmatic Randomized Controlled Vaccine Trials: Toward Global Alignment on Regulatory Framework and Evidence Standards

Explanatory (i.e. traditional) randomised controlled trials (RCTs) have long been—and continue to be—the gold standard for rigorously evaluating the safety and efficacy of medicinal products, including vaccines. When well designed and rigorously conducted, they can provide the highest level of scientific evidence for regulatory submissions and decision-making, as part of an overall data package. However, they are not always feasible, appropriate, or fit-for-purpose in all settings—for example where timelines, ethical considerations, rare outcomes, or unpredictable epidemiology limit their applicability.

Post-authorisation observational studies typically complement RCTs by providing further insights into real-world use, including evidence of effectiveness and safety in broader real-world populations shaped by policy makers, as well as evidence of effects that extend beyond initial targets for an indication. However, observational designs are inherently limited due to their inability to incorporate randomisation, blinding, and controlled comparisons, constraining their interpretability for regulatory and policy decision-making.

Pragmatic randomised controlled trials offer a powerful and increasingly relevant approach that bridges this gap. By combining the methodological strength of randomisation with more streamlined execution and follow-up using real-world data sources, pragmatic trials can enable more efficient evidence generation at scale. Importantly, their design—often embedded within routine care and conducted in broad, more representative populations—creates opportunities to generate confirmatory evidence of observational findings. This includes a deeper understanding of vaccine effectiveness, safety, population-level impact, and overall value in real-world settings, particularly in situations where conventional trial designs are not feasible but timely evidence is critical for public health action.

Given their promise, greater clarity and alignment are needed on the use of pragmatic randomised controlled trials within evidence frameworks and on how they can best support regulatory and policy decision-making. This includes a discussion of important scientific, ethical, operational, and regulatory considerations. This workshop aims to convene key stakeholders to explore these considerations and to advance a shared understanding of the opportunities and challenges associated with pragmatic trial designs.

The International Alliance for Biological Standardization (IABS) has a strong track record of convening impactful workshops on real-world evidence (RWE) (Leuwen 2023 and Montreal 2025). Building on previous RWE workshops and discussions, the upcoming IABS workshop will bring together leading vaccine experts in study design and regulatory science across all stakeholders. Its objective is to develop consensus-based recommendations on the conduct of vaccine randomised controlled trials to strengthen the evidence base and support regulatory and policy decision-making. The outcomes are expected to improve global alignment and to develop methodological standards.

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