3rd IABS Workshop on Real World Evidence:
Pragmatic Randomized Controlled Vaccine Trials: Toward Global Alignment on Regulatory Framework and Evidence Standards

November 18-19, 2026
Leiden, The Netherlands

Explanatory (i.e. traditional) randomized 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-authorization 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 randomization, blinding, and controlled comparisons, constraining their interpretability for regulatory and policy decision-making.

Pragmatic randomized controlled trials offer a powerful and increasingly relevant approach that bridges this gap. By combining the methodological strength of randomization 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 randomized controlled trials within evidence frameworks and on how they can best support regulatory 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)(Leuven, 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 randomized 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.

Scientific/Organizing Committee

Kaat **Bollaerts**, P95 (Co-Chair)
Pieter **Neels**, IABS (Co-Chair)
Frank **Vandendriessche**, IABS (Co-Chair)
Marco **Cavaleri**, EMA
Danielle **Craig**, CEPI
Madinina **Cox**, Events Manager, IABS/MC'Com
Brad **Gessner**, Independent Consultant
Hector **Izurieta**, FDA
Phil **Krause**, Independent Consultant
Liz **Miller**, Independent Consultant
Christopher **Nelson**, Independent Consultant
Liz **Miller**, Independent Consultant
Camille **Roux**, Events Coordinator, IABS/MC'Com
Dean **Smith**, IABS-North America (NA)
Sylvia **Taylor**, GSK

Workshop Preliminary Program

Day 1: Wednesday, November 18, 2026

8.30 am **Opening of the meeting – Welcome & Objectives**
Pieter **Neels**, IABS

Session I: Setting the scene
Session Chair: TBC

8.45 am Vaccine Pragmatic RCTs: Definitions, Existing Regulatory Guidance, and Framework for Discussion
Phil **Krause**, Consultant

Session II: Perspectives from Regulators, Sponsors and Investigators
Session Chair: Liz Miller, Independant Consultant

9.00 am Regulatory perspective on value and role of pRCT
Marco **Cavaleri**, EMA

9.10 am Industry perspective on value and role of pRCT
Sylvia **Taylor**, GSK

9.20 am CEPI perspective on value and role of pRCT
Danielle **Craig**, CEPI

9.30 am NITAG/Payer perspective on value and role of pRCT

9.40 am Panel discussion
All Speakers

10.10 am ***Coffee Break***

Session III: Methodological and Ethical Considerations
Session Chair: Brad Gessner, Independent Consultant

10.40 am	Session Introduction Brad **Gessner**, Independent Consultant
10.45 am	Ethical considerations and acceptability
10.55 am	Core design considerations
11.05 am	Outcome ascertainment and validity
11.15 am	Safety monitoring in pragmatic trials Rachael **Williams**, MHRA
11.25 am	Q&A Session

Session IV: Outcome selection including All-cause outcomes - Relevance, interpretation and use
Session Chair: Brad Gessner, Independent Consultant

11.55 am	Session Introduction Brad **Gessner**, Independent Consultant
12.00 pm	All cause outcomes Brad **Gessner**, Independent Consultant
12.10 pm	All cause outcomes
12.20 pm	Panel discussion / Q&A All Speakers
12.45 pm	***Lunch***

Session V: Experience and Case Examples of Conducting Pragmatic Trials
Session Chair: Kaat Bollaerts, P95

1.45 pm	Session Introduction Kaat **Bollaerts**, P95
1.50 pm	RWE
2.05 pm	RWE
2.20 pm	RWE

2.35 pm Panel discussion
All Speakers

3.05 pm ***Coffee Break***

Session VI: RWE vs Pragmatic RCT Across EUA and Outbreak Settings

Session Chair: TBC

3.25 pm Session Introduction

3.30 pm RWE in outbreaks

3.45 pm pRCT in outbreaks

4.00 pm Panel discussion
All Speakers

4.45 pm Day 1 – Synthesis and Key Takeaways

5.30 pm **End of Day 1**

Day 2: Thursday, November 19, 2026

8.30 am **Summary of Day 1 & Objectives of the day**
TBC

Session VII: Are we ready to consider pRCTs as pivotal evidence for primary indication approvals ?

Session Chair: Pieter Neels, IABS

8.45 am Session Introduction
Pieter **Neels**, IABS

8.50 am Advance towards use

9.05 am Approach with caution

9.20 am Panel discussion
All Speakers

Session VIII: Breakout Groups – Defining Priorities and Next Steps

Session Chair: Sylvia Taylor, GSK

9.50 am Introduction to the Break-Outs
Sylvia **Taylor**, GSK

9.55 am Break Out Groups

Session IX: Report-back – Identifying Priority Areas

Session Chair: Sylvia Taylor, GSK

11.10 am Group 1 read-out

11.25 am Group 2 read-out

11.40 am Group 3 read-out

11.55 am Group 4 read-out

12.10 pm Group 5 read-out

12.25 pm ***Lunch***

Session X: Towards a Shared Forward Agenda

Session Chair: Sylvia Taylor, GSK

1.15 pm Moderated plenary

Closing Session:

Session Chair: TBD

2.00 pm Reflection and a way forward - Moderated plenary
Kaat **Bollaerts**, P95

2.15 pm End of Day 2