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
- Hybrid meeting -

Explanatory (i.e. conventional) randomized controlled trials (RCTs) have long been—and continue to be—the gold standard for 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 decision-making. However, they are not always feasible or appropriate, for example, where timelines, ethical considerations, rare outcomes, or unpredictable epidemiology limit their applicability.

Post-authorization observational studies typically complement RCTs by providing insights into real-world use, including evidence of effectiveness and safety in more diverse populations, as well as evidence of effects that extend beyond the initial indications. However, because treatment allocation is not randomized, observational studies are more susceptible to bias and confounding.

Pragmatic RCTs offer a powerful alternative by combining the methodological rigor of randomization with study conduct embedded in routine medical practice. This approach enables efficient, large-scale and patient-centered evidence generation that is representative of real-world populations and the actual use of medicinal products. Pragmatic RCTs can generate robust real-world evidence on vaccine effectiveness, safety, population-level impact, and value, particularly when conventional RCTs are not feasible and timely evidence is needed to inform public health decisions.

Given their promise, greater clarity and alignment are needed on how pragmatic RCTs can best be used to support regulatory decision-making for vaccines. Key scientific, ethical, operational, and regulatory considerations must be addressed to ensure their appropriate use.

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 key stakeholders to explore these considerations and build a shared understanding of the opportunities and challenges associated with leveraging pragmatic RCTs to advance regulatory decision-making for vaccines.

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 (remote)**, FDA
Phil **Krause**, Independent Consultant
Joshua **Nealon**, Sanofi
Christopher **Nelson**, Independent Consultant
Liz **Miller**, Independent Consultant
Camille **Roux**, Events Coordinator, IABS/MC'Com
Dean **Smith**, Health Canada
Sylvia **Taylor**, GSK

Regulators Panelists:

Marco **Cavaleri**, EMA
Phil **Krause**, Independant Consultant
Hector **Izurieta** (remote), FDA
Brenda **Gomes Valente,** Anvisa
Ariane **Alves de Oliveira**, Anvisa
Mikal **Ayiro**, Kenya PPB
Nele **Steens**, FAGG-AFMPS

Workshop Program

Day 1: Wednesday, November 18, 2026

8.30 am **Opening of the meeting – Welcome & Objectives**
Kaat **Bollaerts**, P95

Session I: Setting the scene
Session Chair: Phil **Krause**, independent consultant

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

8.50 am Let's hear from you: your experience with pragmatic vaccine RCTs
All participants

Session II: Perspectives from Regulators, Sponsors and Investigators
Session Chair: Liz **Miller**, independent consultant

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

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

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

9.30 am PHI perspective on value and role of pragmatic RCT
Nick **Andrews**, MHRA

9.40 am NITAG/Payer perspective on value and role of pragmatic RCT
Jaime Jesús **Perez**, Regional Ministry of Health of the Region Murcia

9.50 am Panel discussion
All Speakers

10.05 am ***Coffee Break***

Session III: Methodological Considerations
Session Chair: Joshua **Nealon**, Sanofi

10.25 am — Session Introduction
Joshua **Nealon**, Sanofi

10.35 am — Core design considerations
Arto **Palmu**, Finnish Vaccine Research

10.50 am — Outcome ascertainment and validity
Sima **Mohammadi**, University Medical Center Utrecht

11.05 am — Safety monitoring in pragmatic trials
Rachael **Williams**, Medicines and Healthcare products Regulatory Agency

11.20 am — Q&A Session

Session IV: Debate: Meaningful Evidence or Misleading Endpoint? The Relevance of All-Cause Outcomes in Regulatory Decision-Making

Session Chair: Phil **Krause**, Independent Consultant

11.55 am — Session Introduction
Phil **Krause**, Independent Consultant

12.00 pm — Is there a role for all-cause outcomes in regulatory processes?
Brad **Gessner**, Independent Consultant

12.10 pm — All cause outcomes: limitations and impediments to use as regulatory outcomes
Marco **Cavaleri,** EMA

12.20 pm — Panel discussion / Q&A
All Speakers

12.45 pm — ***Lunch***

Session V: Implementing pragmatic Vaccine RCTs: What Has Been Achieved, What Still Holds Us Back, and What Needs to Change
Session Chair: Kaat **Bollaerts**, P95

2.00 pm — Session Introduction
Kaat **Bollaerts**, P95

2.05 pm — Lessons Learned from Launching BronquiVal, the First Pragmatic Randomized Trial in the Valencian Community, Spain
Alex **Orrico Sanchez**, FISABIO

2.15 pm — Pragmatic Randomized Trials: the New Danish Take
Tor **Biering-Sorensen**, Copenhagen University Hospital

2.25 pm — Leveraging Integrated Healthcare Systems to Implement Large Pragmatic Randomized Vaccine Trials
Nicky **Klein,** Kaiser Permanente

2.35 pm	Challenges with post-licensure RCT trials in Africa: lessons from RSV-IMPACT Shabir **Madhi (remote)**, University of Witwatersrand
2.45 pm	Panel discussion All Speakers
3.00 pm	***Coffee Break***

Session VI: Observational studies versus Pragmatic RCT in Routine and Outbreak Settings
Session Chair: Danielle **Craig**, CEPI

3.25 pm	Session Introduction Danielle **Craig**, CEPI
3.30 pm	Pragmatic RCTs in Outbreaks: Design Options, Real-World Experience, and Regulatory Fit Amol **Chaudhari**, CEPI
3.50 pm	Real-World Evidence in Outbreaks: When Observational Studies Are the Faster Route to Regulatory Decisions Gabrielle **Breugelmans**, CEPI
4.10 pm	Panel discussion: Observational Studies or Pragmatic RCTs? Principles for Choosing the Right Evidence in Outbreaks All Speakers, Regulator panelists
4.50 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**
Phil **Krause**

Session VII: Vaccine Pragmatic Trials: Ethical Perspectives?
Session chair: Brad **Gessner**, Independent Consultant

8.40 am — Session Introduction
Brad **Gessner**, Independent Consultant

8.45 am — Ethical Considerations for Pragmatic Trials with Vaccines
Stephanie **Morain,** Johns Hopkins Berman Institute of Bioethics

9.10 am — Ethics at both ends of pRCTs: from ethics review to the use of results
Jean-Claude **Dupont**, Institut Pasteur

9.30 am — Panel discussion
All speakers & Regulators Panelists

Session VIII: Debate: As Traditional Vaccine Trials Reach Their Limits, Are Pragmatic RCTs Ready to Become Pivotal Evidence for Regulatory Decisions?
Session Chair: Saranya **Sridhar**, Sanofi

10.00 am — Session Introduction: Problem statement
Florence **Meunier**, Sanofi

10.10 am — Panel discussion
Regulator panelists &
Florence **Meunier -** Sanofi
Elizabeth **Begier -** Pfizer
Evan **Anderson –** Moderna

11.00 am — ***Coffee break***

Session IX: Breakout Groups – Defining Priorities and Next Steps
Session Chair: Sylvia Taylor, GSK

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

11.40 am — Break Out Groups

Session X: Report-back – Identifying Priority Areas
Session Chair: Sylvia Taylor, GSK

12.20 pm — Groups read-out
5 groups presenting for 7 minutes each

1.00 pm — ***Lunch***

Session XI: Towards a Shared Forward Agenda

Session Chair: Sylvia Taylor, GSK

2.15 pm	Moderated Plenary: Reflections and the Way Forward Liz **Miller**, Sylvia **Taylor**
3.15 pm	Key Takeaways and Closing Remarks Pieter **Neels**, IABS
3.30 pm	End of Day 2