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. 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)
Marco **Cavaleri**, EMA
Danielle **Craig**, CEPI
Madinina **Cox**, Events Manager, IABS/MC'Com
Brad **Gessner**, Independent Consultant
Hector **Izurieta**, 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**, 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: Phil **Krause**, independent consultant

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

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

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

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

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

9.28 am NITAG/Payer perspective on value and role of pragmatic RCT
TBC

9.35 am Panel discussion
All Speakers

9.50 am *Coffee Break*

Session III: Methodological and Regulatory Considerations
Session Chair: Joshua **Nealon**

10.20 am Session Introduction
Marco **Cavaleri**, EMA

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

10.50 am Outcome ascertainment and validity
Miriam **Sturkenboom**, 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	All cause outcomes: rationale, successes, and failures Brad **Gessner**, Independent Consultant
12.10 pm	All cause outcomes: limitations and impediments to use as regulatory outcomes Marco **Cavaleri,** FDA
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

1.45 pm	Session Introduction Kaat **Bollaerts**, P95
1.50 pm	TBC Alex **Orrico Sanchez** , FISABIO
2.00 pm	TBC Tor **Biering-Sorensen**, Copenhagen University Hospital
2.10 pm	TBC TBC
2.20 pm	TBC Shabir **Madhi**, University of Witwatersrand
2.30 pm	Panel discussion All Speakers
3.05 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 TBD
3.30 pm	RWE in outbreaks TBD
3.45 pm	pRCT in outbreaks TBD
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: Vaccine Pragmatic Trials: Ethical Perspectives?
Session chair: TBC

	TBC
8.35am	Jean-Claude **Dupont**, Institut Pasteur
	TBC
8.50am	Stephanie **Mouran,** Johns Hopkins Berman Institute of Bioethics
	Panel discussion (speakers)
9.05am	

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

9.30 am	Session Introduction – problem statement TBC
9.40 am	Panel discussion Marco **Cavaleri,** EMA, Phil **Krause** & Hector **Izurieta**, FDA, Rachael **Williams**, MHRA, Brenda **Gomez,** ANVISA
10.25 am	***Coffee break***

Session IIX: Breakout Groups – Defining Priorities and Next Steps

Session Chair: Sylvia Taylor, GSK

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

10.55 am Break Out Groups

Session IX: Report-back – Identifying Priority Areas

Session Chair: Sylvia Taylor, GSK

11.25 am Group 1 read-out

11.40 am Group 2 read-out

11.55 am Group 3 read-out

12.10 pm Group 4 read-out

12.25 pm Group 5 read-out

12.40 pm ***Lunch***

Session X: Towards a Shared Forward Agenda

Session Chair: Sylvia Taylor, GSK

1.30 pm Moderated plenary
Sylvia **Taylor**, GSK

Closing Session

Session Chair: TBD

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

2.30 pm **End of Day 2**