2nd IABS Real World Evidence Workshop :

The Role of Alternative Approaches to Phase 3 Clinical Trials for Vaccine Efficacy and Licensure

PROGRAM

IABS
International Alliance for Biological Standardization

December 10-11, 2025

Montréal, CANADA

E-Book

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for their support for this meeting

Rules for remote participants & Q&A

Make sure your camera and microphone are off during talks.

Questions will be discussed after the series of presentations. Apologies if all questions cannot be answered due to lack of time

For any questions or comments, please use the Chat Box

This meeting is recorded

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Agenda - **Day 1**

Wednesday, December 10, 2025

8.30 AM *Registration & Welcome Coffee*

9.00 AM Opening of the meeting – Welcome – Pieter NEELS, IABS

Session I – Vaccine approval in the absence of RCT efficacy data, challenges and overview

Session Chair: Laurence de Moerlooze, P95

9.05 AM Introduction to the meeting objectives
Laurence DE MOERLOOZE, P95

9.10 AM Developing a Group B Streptococcus vaccine for maternal immunization: challenges for clinical development in a low-incidence, high impact infectious disease setting
Lidia OOSTVOGELS, Minervax

9.20 AM Review of vaccines licensed in absence of a Phase 3 randomized controlled efficacy trial
Danielle CRAIG, CEPI

Session II – Alternative approaches to RCT efficacy data to demonstrate vaccine benefit for initial approval

Session Chair: Laurence de Moerlooze, P95

9.40 AM *Summary and insights from the EMA workshop (24-25 Nov 2025) on the use of animal models*
Marco CAVALERI, EMA

10.10 AM Evidence on vaccine benefit from Human Infection Models: insights and considerations
Robert READ, University of Southampton

10.40 AM *Coffee Break*

11.10 AM Evidence on vaccine benefit based on Correlates of Protection: insights and considerations
Phil KRAUSE, Independent Consultant

11.40 PM Panel discussion: Dealing with uncertainty in vaccine benefit at initial approval and its consequences for post-marketing activities
All Speakers and **Dean SMITH**, Health Canada, **Hector IZURIETA**, FDA and **Brenda GOMES VALENTE**, ANVISA

12.10 PM *Lunch*

Session III – RWE to confirm vaccine benefit

Session Chair: Laurence de Moerlooze, P95

1.10 PM Real-World Evidence from observational studies to pragmatic trials, supporting initial licensure to label expansion
Kaatje BOLLAERTS, P95

1.20 PM Real-World Evidence to confirm vaccine benefit: Mpox Vaccine
Victoria JENKINS, Bavarian Nordic

1.40 PM Real-World Evidence to confirm vaccine benefit: Meningococcal B vaccine
Ilaria BARTALESI, GSK

2.00 PM Real-World Evidence to confirm vaccine benefit: Ebola vaccines
Phil KRAUSE, Independent Consultant

2.20 PM Real-World Evidence to confirm vaccine benefit: Chikungunya vaccine
Victoria JENKINS, Bavarian Nordic

2.40 PM *Coffee Break*

3.10 PM Progress of the Post-Approval Effectiveness Study (DEN-401) of TAK-003 Against Hospitalized, Virologically Confirmed Dengue in Pediatric and Adolescent Populations
Suely TUBOI, Takeda

3.30 PM Real-World Evidence to confirm vaccine benefit: Next generation pneumococcal vaccines
Brad GESSNER, Independent Consultant

3.50 PM Real world measurement of COVID-19 vaccine effectiveness through the pandemic and beyond
Alexander ALLEN, UKHSA

4.10 PM Real-World Evidence to confirm vaccine benefit: Updating COVID-19 vaccines
Kyla HAYFORD, Pfizer

4.30 PM *End of Day 1*

Agenda - **Day 2**

Thursday, December 11, 2025

9.00 AM Objectives of the day
Laurence DE MOERLOOZE, P95

Session IV – Pragmatic Randomized Controlled Trials for vaccine effectiveness

Session Chair: Laurence de Moerlooze, P95

9.10 AM Lessons from the pragmatic randomized trials of high-dose vs. standard-dose influenza vaccine against severe clinical outcomes (FLUNITY-HD)
Joshua NEALON, Sanofi

9.30 AM Lessons from the pragmatic randomized trial to evaluate RSV vaccine effectiveness against hospitalizations
Brad GESSNER, Independent Consultant

9.50 AM Cracking the Code: Identifying RSV Correlates of Protection in a South African Vaccine Effectiveness Trial
Alane IZU, Wits VIDA

10.10 AM Pragmatic RCTs and the power of vaccine probe analysis: The experience from Finland
Arto PALMU, FVR

10.30 AM *Coffee Break*

11.00 AM *Panel discussion: Barriers to and requirements for the use of pragmatic trials*
Marco CAVALERI, Robert READ, Dean SMITH, Hector IZURIETA, Brenda GOMES VALENTE

Session V – Break Out Session

Session Chair: Laurence de Moerlooze, P95

11.30 AM Introduction Break-Out (1): Towards a framework for alternative approaches to Phase 3 Vaccine Efficacy Trials
Danielle CRAIG, CEPI

11.40 AM Break Out (1): When are alternative approaches needed for vaccine licensure?

12.30 PM *Lunch*

1.30 PM Introduction Break Out (2): Towards a framework for alternative approaches to Phase 3 Vaccine Efficacy Trials
Danielle CRAIG, CEPI

1.40 PM Break Out (2): What are the alternative approaches and when are they acceptable?

2.30 PM *Coffee break*

3.00 PM Group discussion: Next steps towards alternative approaches to Phase 3 Vaccine Efficacy Trials
Laurence DE MOERLOOZE, P95

3.50 PM *End of Day 2*

UPCOMING IABS EVENTS

International Alliance for Biological Standardization

Advances in Analytical Technologies for Biopharmaceutical Products

June 2026
Virtual Meeting

Assessing Consequences on Maternal Immunization on Fœtal Outcomes

June 2026
Switzerland

Bovine Serum: Challenges and opportunities in the research and development and manufacture of vaccines and other biological products

September 2026
Budapest, Hungary

Analytics in Cell Therapy: Ensuring Quality in Flow Cytometry – Established Guidelines for Flow Cytometry and QC Needs in Cell Therapy

Autumn 2026
Lisbon, Portugal

More information on www.iabs.org

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