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Towards a framework for alternative approaches to Phase 3 Vaccine Efficacy Trials

Breakouts 1 & 2

2nd IABS REAL WORLD EVIDENCE WORKSHOP :

THE ROLE OF ALTERNATIVE APPROACHES TO PHASE 3 CLINICAL TRIALS FOR VACCINE EFFICACY AND LICENSURE

10-11 Dec 2025

Breakout Session Purpose

Identifying knowledge gaps, next steps, and priorities for future guidelines or research

Breakout 1: When are alternative approaches needed for vaccine licensure?

What have we heard so far?

- Alternate approaches are needed when randomized controlled trials:
  - Are not feasible – low symptomatic disease prevalence, disease occuring in low surveillance areas, lack of well qualified clinical sites
  - Are not ethical to conduct - placebo control (follow on products)
- Alternate approaches are available in most global regulatory systems, but pre- and post-approval requirements vary greatly
  - Benefit-risk capabilities across regions vary, especially in regard to immunologically-based benefit data
- Pre-licensure safety requirements are consistent across approval pathways

Let’s probe deeper…

1. What other scenarios could support alternate approaches for vaccine licensure?

   Small group discussion: 20 minutes
   Read-out: 5 minutes

2. What gaps exist that ‘block’ acceptance of alternative pathways?

   Small group discussion: 20 minutes
   Read-out: 5 minutes

Breakout 2: What are the alternative approaches and when are they acceptable?

What have we heard so far?

- Post-marketing data needs to be attainable, practical, financially and logistically feasible
- The totality of the data used to grant approval is important to determine post-marketing follow-up
- Observational studies will remain important in post-market surveillance setting
- Need to consider other ways to generate good evidence (e.g. pragmatic trials, targeted efficacy trials)

Let's probe deeper…

Small group discussion 30 minutes
Read-out: 20 minutes

1. Which study types and designs can support decision-making?
2. When generating RWD, what differences in data robustness might be acceptable depending on disease severity, location, and available infrastructure?
3. If applying pragmatic approaches, which are the key factors to support implementation vs. RWE approaches?

Scenario 1: Outbreak response using investigational products

Scenario 2: Roll-out under Emergency Use Authorizations

Scenario 3: Post-marketing commitments when alternate approaches were used for 1 or more population


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