

Meeting Objectives

Explore alternatives to Phase 3 trials and the role of real-world evidence



Review alternative approaches to Phase 3.



Evaluate evidence types that support licensure.



Clarify role of real-world evidence.



Understand stakeholder expectations.



Build principles and a working framework.

Context

- Traditional Phase 3 RCTs are not always feasible.
- Challenges: rare diseases, emerging pathogens, ethical or logistical limits.

Why This Matters

- Impact on public health, innovation access, and preparedness.
- Goal: Flexible but rigorous pathways for vaccines.

Meeting principles

- Open discussion.
- Align on principles.
- Define actionable recommendations.