



International Alliance for
Biological Standardization

2nd IABS Workshop on Real World Evidence: Alternative Approaches to Phase 3 Clinical Trials for Vaccine Efficacy and Licensure: the role of Real World Evidence

**December 10-11, 2025
Montreal, Canada**

Title: Real world measurement of COVID-19 vaccine effectiveness through the pandemic and beyond

The COVID-19 pandemic provided, and continues to provide, unique opportunities to develop methods for the real world assessment of vaccine effectiveness. The rapid evolution of the SARS-CoV-2 virus, with the constant parade of variants, and the attendant production of vaccines attempting to keep up with this, requires a rapid and agile approach to evaluating vaccines.

Randomised controlled trials/ phase III trials will be too slow to keep up with campaigns that often are targeted to take place multiple times per year, with a virus whose dominant variant can change within a month; alternative methods and on-going evaluation of current vaccination campaigns are vital.

Public health policy relies on making use of real world evidence to inform future policy and vaccine strategy; and will encompass vaccine coverage and cost effectiveness, alongside side vaccine effectiveness. Methods such as test negative case control studies, cohort studies, and age-discontinuity studies can all supply this essential information.

