International Alliance for Biological Standardization

IABS 2nd Real World Evidence Workshop
"The Role of Alternative Approaches to Phase 3 Clinical Trials for Vaccine Efficacy and Licensure"

December 10-11, 2025
Montreal, Canada

Bridging Pre-Licensure and Post-Marketing Evidence: The CHIKV VLP Vaccine Journey - Victoria Jenkins

VIMKUNYA® (CHIKV VLP, Bavarian Nordic) is the first recombinant virus-like particle (VLP) vaccine approved for the prevention of chikungunya virus (CHIKV) infection in individuals aged 12 years and older. Licensed in early 2025 under accelerated pathways in the United States, European Union, and United Kingdom, VIMKUNYA's approval was supported by immunogenicity endpoints derived from serum neutralising antibody (SNA) titres, validated through passive transfer studies in non-human primates.

Phase 3 clinical trials demonstrated a rapid and robust seroresponse, with 97.8% of participants achieving protective antibody levels by Day 21, and a favourable safety profile with no treatment-related serious adverse events. As part of post-marketing commitments, Bavarian Nordic has initiated a Phase 3b efficacy study designed to confirm clinical benefit in real-world settings. The study's implementation is contingent on outbreak occurrence in endemic regions such as Thailand and the Philippines, and leverages simulation modelling and seroepidemiological assessments to optimise trial design and site selection.

A key learning from the VIMKUNYA programme has been the importance of early and sustained regulatory engagement, as well as harmonised global licensure strategies to facilitate rapid access and uptake. This presentation will explore how post-marking evidence complements pre-licensure clinical trial data, and the role it plays in confirming vaccine benefit.