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.

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REAL-WORLD EVIDENCE CONFIRMING THE VACCINE BENEFIT OF THE THIRD-GENERATION MPOX VACCINE MVA-BN (JYNNEOS/IMVANEX/IMVAMUNE)

Background: Randomized controlled trials for mpox prevention are not feasible due to ethical and epidemiologic constraints. Real-world evidence (RWE) therefore plays a pivotal role in establishing the effectiveness and safety of the third-generation, non-replicating Modified Vaccinia Ankara–Bavarian Nordic (MVA-BN) vaccine, developed to protect against orthopoxvirus infections with an improved safety profile compared to earlier smallpox vaccines.

Methods and Findings:
Twelve independent RWE studies from Israel, the United States, the United Kingdom, Canada, Spain, and Germany (2022–2025) consistently demonstrate high vaccine effectiveness (VE) and favorable outcomes. Single-dose VE ranged from 58–86%, while two-dose VE reached 75–88%. Protection was maintained regardless of administration route (label approved subcutaneous SC or off-label intradermal ID) and in people living with HIV. Vaccinated individuals had markedly lower rates of hospitalization, disease severity, and breakthrough infection (<1%), which were generally mild. Two systematic reviews (Mason 2024; Pischel 2024) corroborate these findings.

Discussion: Correlates of protection for mpox remain undefined due to limited case numbers, lack of standardized neutralization assays, and the multifaceted nature of immune responses (humoral, cellular, mucosal). Consequently, RWE serves as the most pragmatic and ethically appropriate framework to assess real-world vaccine performance.