



International Alliance for  
Biological Standardization

## IABS 2<sup>nd</sup> 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

### **Title: Progress of the Post-Approval Effectiveness Study (DEN-401) of TAK-003 Against Hospitalized, Virologically Confirmed Dengue in Pediatric and Adolescent Populations**

#### **Abstract**

**Background:** TAK-003 is a live-attenuated tetravalent dengue vaccine, approved in over 40 countries and available in more than 25. The DEN-401 study (EUPAS1000000218, NCT06843226), a post-approval effectiveness regulatory commitment, is designed to complement DEN-301 (NCT02747927) by providing data on hospitalization and severe dengue, particularly in baseline seronegative individuals and for dengue virus serotypes DENV-3 and DENV-4.

**Methods:** Conducted in collaboration with health authorities and academic institutions, this multi-country, nested case-control study is embedded within a community-based cohort of 70,000 participants aged 6–12 years, with primary data collection. TAK-003 will be provided through vaccination programs following WHO/SAGE recommendations. Three years of hospital-based active surveillance will identify hospitalized and severe dengue cases among both vaccinated and unvaccinated participants. Seven catchment areas have been identified: three in Thailand (35,000 participants, 7–10 years), three in Indonesia (30,000, 6–10 years), and one in Malaysia (5,000, 7–12 years).

**Results:** Cohort enrolment and vaccination programs are scheduled for completion by Q1 2026. The programs are community-based in Thailand (Ministry of Public Health), school-based in Indonesia (provincial health offices), and part of a community-based health promotion and dengue prevention program in Malaysia. Final results will be reported in 2029 following the completion of data collection and analysis.

**Conclusion:** Innovative solutions supporting this complex real-world project include feasibility assessments, novel frameworks for collaboration with Ministries of Health, local authorities, and academia, collection of cohort data and biological samples, and adapted site and laboratory monitoring. Key lessons learned will be presented.

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#### **Keywords (max 5):**

Dengue, Vaccination, Clinical Research, Effectiveness, Real-world evidence

