

## JOINT THAI-US PHASE III TRIAL OF HIV PRIME-BOOST VACCINES

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**Purpose:** To describe the plan for initiating and implementing a community based, phase III efficacy trial of a prophylactic HIV candidate vaccine combination in Thailand.

**Methodology:** Trial Objectives: Determine whether this vaccine combination 1) reduces the HIV infection rate by at least 50%, and /or 2) results in decreased viral load and increased CD4 cell count in recipients who become infected with HIV, and 3) is safe and will be tolerated.

Vaccines: designed specifically for the predominant circulating HIV of Thailand (CRF01\_AE).

Prime - recombinant canarypox ALVAC-HIV containing subtype Gag/Pro and Env-TM, and subtype E Env (R5) gene insertions (vCP1521), Aventis Pasteur); Boost-monomeric gp120s B(X4) + E(R5) with alum (AIDSVAX B/eE, Vax Gen).

Study population: 16,000 20-30 year old. Thai citizens from the communities of Rayong and Chon Buri, Thailand.

Study design: Randomized (vaccine: placebo = 1:1, placebo- controlled, double-blind, 3.5 year duration).

Endpoints: Primary Efficacy- HIV infection based on serological and nucleic acid testing; Secondary Efficacy - HIV RNA and CD4 Quantitation; Safety - Adverse events and HIV risk-relevant behaviors.

Project start date: December 2002.

**Discussion:** Other than HIV vaccine candidates based on envelope subunit proteins, recombinant canarypox is the only candidate vaccine that has been assessed adequately to transition into phase III testing. Combining both strategies results in humoral and cellular immunity and increases the likelihood of vaccine protection. We describe the world's first efficacy trial of a HIV prime-boost vaccine combination. The predominance and relatively narrow diversity of HIV subtype E in Thailand provide an optimal setting for the test of this concept utilizing vaccines derived from Thai primary isolates. An update of this phase III plan will be shared with the international community.

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