

RV144 in Detail

First trial to show any efficacy of an HIV vaccine candidate



THE TRIAL

A Phase IIb test-of-concept trial, based on the expected number of HIV infection endpoints, conducted by Thailand Ministry of Public Health

Co-primary endpoints: Prevention of HIV infection and ability to reduce viral load

Duration: Six years

- September 2003—screening starts
- October 2003—first vaccination
- July 2009—data analysis begins

Sponsor: US Army, Surgeon General

Trial Cost/Funders: US\$105 million; US National Institute of Allergy and Infectious Diseases (NIAID) (75%), US Army (25%)



THE VOLUNTEERS

16,402 Thai citizens (60% male, 40% female) enrolled, 16,395 received at least one dose of vaccine or placebo

Inclusion criteria:

- Male or female Thai citizen, 18-30 years of age
- Available for participation for 3.5 years
- Can understand study and give written informed consent
- Completed enrollment in screening protocol

Exclusion criteria:

- HIV infected, active tuberculosis, or chronic use of immune-modifying therapy
- History of anaphylaxis or other serious adverse reactions to vaccines



Trial sites:
Rayong Province
Chon Buri Province
HIV clade E predominant in these regions



THE VACCINE CANDIDATES

Prime

ALVAC-HIV (vCP1521)

A live, recombinant, non-replicating canarypox viral vector vaccine encoding clade B *gag/pro* and clade E *env*
(Vaccine Developer: Sanofi Pasteur)

Boost

AIDSVAX gp120 B/E

A genetically engineered version of HIV gp120 (*env*) from clade B and E (Vaccine Developer: Genentech; its spin-off, VaxGen, tested AIDSVAX previously; intellectual property rights now owned by Global Solutions for Infectious Diseases)

Dosing schedule



THE TEAM

Key collaborators:

- NIAID
- Sanofi Pasteur
- Global Solutions for Infectious Diseases
- US Military HIV Research Program, a branch of Walter Reed Army Institute of Research

Other collaborators:

- Mahidol University in Thailand
- Armed Forces Research Institute of Medical Science—US and Thai components

Principal investigator: Supachai Rerks-Ngarm, Thailand Ministry of Public Health