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 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 BIE
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
Initial vaccination Weeks after vaccination
1 ALVAC-HIV 4 ALVAC-HIV 12 ALVAC-HIV AIDSVAX 24 ALVAC-HIV AIDSVAX

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

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