

RV144: A Brief History

Selected key dates for the RV144 trial and its candidate vaccines

1992-2003	Approximately 20 studies evaluate safety, immunogenicity and dosing strategies of ALVAC HIV vaccine candidates in humans
1998	Two Phase III trials of AIDSVAX launch following safety testing
2001-2002	Thai and US collaborators develop and seek approval for RV144 protocol
	The two AIDSVAX Phase III trials show no evidence of benefit
	September: RV144 protocol approved by Thai and US regulatory bodies; volunteer screening begins
2003	September: Three AIDS NGOs receive a grant from Thai Ministry of Public Health for community engagement in study provinces
	October: First vaccination
	January: 18 AIDS researchers sign letter in <i>Science</i> magazine expressing concerns about scientific rationale for RV144
2004	July: Additional letters from scientists and advocates about RV144 published in <i>Science</i>
	Viral load added to protocol as a co-primary endpoint
	February: Low retention rates trigger US and Thai trial team overhaul of community engagement, recruitment and retention strategies
2005	December: Participant enrollment complete
	May: First Community Advisory Board meeting
	June: WHO-UNAIDS HIV Vaccine Advisory Committee external review of ethical and community-related aspects of the trial
2006	July: Vaccinations complete
2008-2009	Development and presentation of “road map” for potential trial outcomes
	June: Final protocol-specified study visit for participants
	September: Trial team announces initial findings that vaccine recipients had lower risk of HIV compared to placebo recipients
2009	October: Full data analysis published in <i>New England Journal of Medicine</i> and presented at AIDS Vaccine 2009 Conference in Paris
	October: Scientific working groups formed by trial team to develop follow-up research agenda
2010	March: Multi-stakeholder meeting in Bangkok to discuss ethical, regulatory, scientific and access issues of RV144 results for Thailand
	(Planned/anticipated): Announcement of next steps based on RV144 result