

## OVERVIEW

The Pox-Protein Public-Private Partnership (P5) was established in 2010 to build on results from the RV144 trials. The partnership seeks to advance and ultimately license HIV pox-protein vaccine candidates that have the potential to achieve a broad public health impact. The P5 assembled a collaborative team across four continents, including representation from academia, private industry, government agencies, the HIV Vaccine Trials Network (HVTN), and the Bill and Melinda Gates Foundation. The goal of this project is to expand the HVTN's clinical trials capacity in Africa to 18 active sites, through site identification, selection, development, and training. Specifically, the need existed to increase capacity to conduct HIV clinical trials in humans in the clade C region of southern Africa for the P5 program. The outcome of this investment is 11 new active sites to support three early phase and one efficacy study conducted concurrently. These sites will serve an estimated 5,996 participants. The specific studies/trials are as follows: 1) the Phase 1 HVTN 100 (n=240), which led to the Phase 3 development trial HVTN 702 (n=5,400); and 2) three phase 1 trials: HVTN 108 (n=132 at African sites), HVTN 111 (n=132), HVTN 120 (n=92 at African sites).

Site development to prepare for the capacity required to conduct the P5 program occurred in stages. The first round of site development prepared 4 new sites to conduct the smaller early phase trials. The second round prepared 7 additional sites. The clinical trials network in the clade C region for the P5 program consists of 18 sites: 3 sites active at the start of this award in the conduct of HVTN trials, 2 sites operated and funded by the U.S. Military HIV Research Program, 2 sites developed with funding from the US NIH, National Institute of Allergy and Infectious Diseases (NIAID), and 11 sites developed as a result of this request.

Development and training activities at each site included equipment acquisition; renovations for clinics, pharmacies, and laboratories; development of site management documentation (e.g. standard operating procedures and clinical quality management plans); and development of a small community engagement program. The HVTN has a structured process for site preparation, including standardized assessment checklists. These checklists were uniquely tailored to clinic facilities, site management, participant management, data management, community education, community advising, pharmacies, and laboratories. The pre-activation training period focused on capacity building: local institution training, Good Clinical Practices, human subject protection, HVTN core competencies, and protocol-specific guidelines. Laboratory training included specimen processing and Good Clinical Laboratory Practice guidance. Clinical site training incorporated skill-building for talking about HIV research with regulatory bodies, the media, and the community. Workshops ensured that site personnel (at all levels) were trained in the standards necessary to conduct HIV vaccine trials. These trainings were developed into online tools on clinical and non-clinical topics relevant to protocol implementation. The curriculum also included such topics as pregnancy prevention counseling, mucosal sample collection, and data management. These tools can be used for sites to orient and train new staff as turnover occurs.

## RESEARCH OBJECTIVES

- 1.) Completion of structured site preparation visits for selected sites.
- 2.) Completion of action items identified during the site preparation visits (unique to each site).
- 3.) NIAID approval to conduct HVTN trials at all newly-developed sites.
- 4.) Completion of clinic, pharmacy, and laboratory training by all site staff prior to the opening of each site's first trial.

## Grant at a Glance

### Principal Investigator

James  
Kublin, MD, MPH



### Grantee Institution

Fred Hutchinson  
Cancer Research Center,  
Seattle, USA

### Project Title

HIV Vaccine Trials Site Development  
for the P5 Program

### OPPID

1088039

### Grant Award

Up to \$7.1 Million, awarded in  
November 2013