

Poster presentation

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## PI4-13. Long-term follow-up of study participants in HIV prophylactic vaccine clinical trials in Africa

C Schmidt<sup>\*1,5</sup>, W Jaoko<sup>2</sup>, P Kaleebu<sup>3</sup>, E Karita<sup>4</sup>, Lehrman<sup>5</sup>, S Allen<sup>6</sup>, L Dally<sup>7</sup>, C Smith<sup>7</sup> and PE Fast<sup>5</sup>

Address: <sup>1</sup>International AIDS Vaccine Initiative, New York, USA, <sup>2</sup>Kenya AIDS Vaccine Initiative, University of Nairobi, Nairobi, Kenya, <sup>3</sup>UVRI-IAVI HIV Vaccine Program, Entebbe, Uganda, <sup>4</sup>Project San Francisco, Kigali, Rwanda, <sup>5</sup>International AIDS Vaccine Initiative, New York, USA, <sup>6</sup>Emory University, Atlanta, GA, USA and <sup>7</sup>The EMMES Corporation, Rockville, MD, USA

\* Corresponding author

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### Background

The International AIDS Vaccine Initiative (IAVI) has conducted phase I and IIA HIV vaccine clinical trials in healthy HIV-uninfected African adults. Different recombinant DNA and vector-based vaccines encoding HIV-1 genes from subtypes A, B and C were tested. Between 2001 and 2006, 391 volunteers were enrolled in 5 countries at 8 collaborating centers. All vaccines tested were found to be generally safe and well-tolerated, with no vaccine-related serious adverse events reported. This study is designed to monitor any late health effects in prior study participants.

### Methods

At the end of the clinical trial, enrollment into a long-term follow-up study is offered. Visits are scheduled 6-monthly. Follow-up is at least 5 years after the last vaccination. A health questionnaire is administered investigating any health problems, hospitalizations, new diagnoses of chronic disease, medications prescribed for more than 4 weeks, problems in the vaccinated arm(s), pregnancies and outcomes, and social harm. HIV testing is performed to detect incident HIV infection and/or to monitor persistence of vaccine-induced antibodies in HIV-uninfected volunteers testing HIV positive at final study visit.

### Results

So far, 242 individuals have been enrolled in long-term follow-up. To date, follow up is 301.2 person years. New

diseases lasting over 4 weeks include dermatological (fungal infections), gastrointestinal and musculoskeletal conditions. Seventeen 17 pregnancies, 12 hospitalizations (mostly pregnancy-related) and 1 new HIV infection have been reported; 9 volunteers experienced some social harm. There were no congenital abnormalities. Vaccine induced antibodies were detected until 2 years and longer after final study visit.

### Conclusion

No significant medical problems have been detected through long-term follow-up of HIV vaccine study participants. Overall, more than 92% of study participants report to be in good health at any visit. These data contribute to the long-term safety profile of HIV vaccines tested in healthy, HIV-negative African adults.