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E2. Open science

Biospecimens from tuberculosis cases and controls in a healthy adult HIV vaccine trial cohort in South Africa

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Biospecimens before and after diagnosis of tuberculosis (TB) are a valuable resource for advancing our understanding of Mycobacterium tuberculosis (Mtb) infection, immunology, and disease. The HVTN 702 Phase 2b-3 trial (Uhambo) tested the efficacy of ALVAC-HIV plus gp120. The vaccine showed potent humoral and cellular responses that supported testing efficacy. The higher incidence and community prevalence of HIV predicted a higher rate of other infections such as Mtb. We describe the chronology of incident TB cases and sample availability for studies on MTB and TB disease.

In Uhambo, 5404 adults living without HIV-1 received vaccine or placebo. The primary efficacy outcome was HIV-1 infection through 24 months. Participant ages ranged from 18-45; diabetes, HIV, and active TB were exclusion criteria from the parent study. HIV-1 infection was diagnosed in 271 participants (138 vaccine; 133 placebo), demonstrating no vaccine efficacy. No protocol-specified TB testing was performed, but we reviewed adverse event and concomitant medication logs for evidence of incident TB during the study.

Twenty-six participants had TB diagnoses after enrolling, with a mean time to diagnosis from enrollment of 1.16 years and an incidence of 196.1 cases per 100,000 person years. Three participants were diagnosed with HIV prior to TB. Baseline and subsequent sample collection included cryopreserved PBMCs and serum. Sample collections were made prior to TB diagnosis (8 cases with only baseline sample; 18 had 1-5 additional pre-diagnosis samples. Six of the cases had no post-diagnosis samples, and the remaining 20 provided samples ranging from within days up to a year after diagnosis of TB. We also selected 104 controls that were matched by site, sex, and age with three sample timepoints each over the course of their 24 months in the study.

Thousands of samples are available from TB cases and matched controls for investigations into the microbiology and immunology of Mtb and TB disease.

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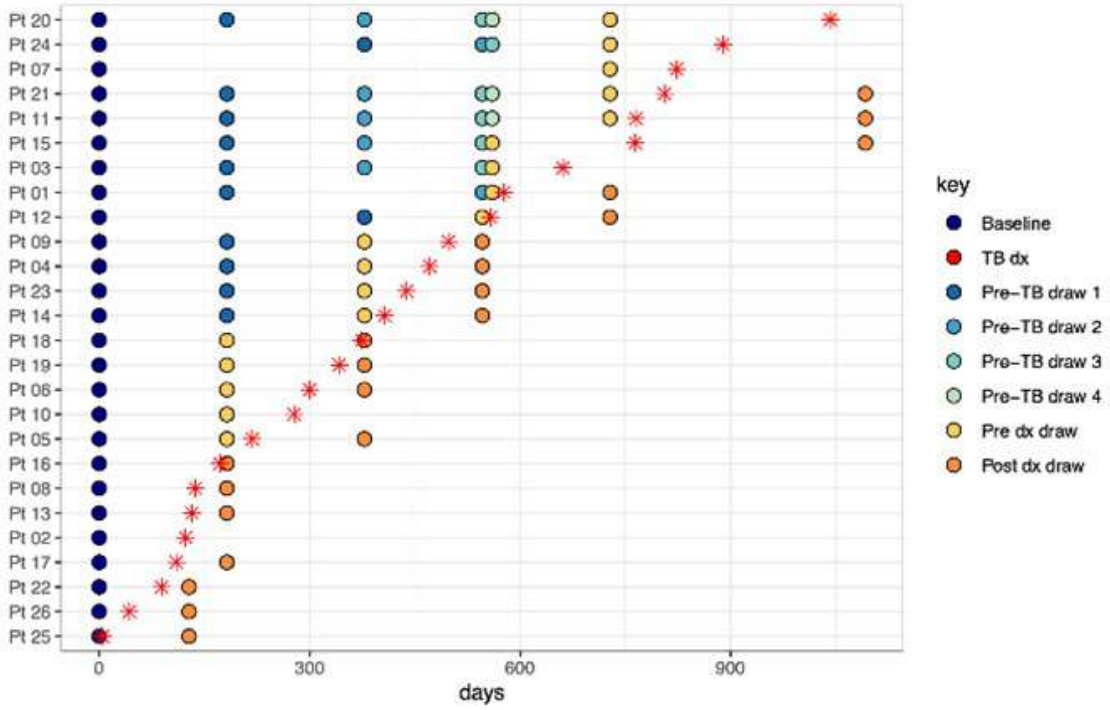
Conflicts of Interest

None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