

## Case Study: Expedited Reporting via DAERS

The participant is a 25 year old, HIV uninfected, Black male, who enrolled in the HVTN 702 study in the Republic of South Africa on January 18, 2016.

On January 15, 2016, during the screening visit, the participant's HIV test was negative. All other laboratory tests and the physical examination were normal.

On January 18, 2016, the participant was enrolled in the study. On the same day, the participant received the first administration of the study vaccine, ALVAC-HIV (vCP2438) OR Placebo for ALVAC-HIV (vCP2438), 1 mL intramuscularly (IM) in the left deltoid. All other laboratory tests and the physical examination were normal.

On February 15, 2016, at the month 1 study visit, the participant received the second administration of the study vaccine, ALVAC-HIV (vCP2438) OR Placebo for ALVAC-HIV (vCP2438), 1 mL IM in the left deltoid. All other laboratory tests and the physical examination were normal.

On April 19, 2016, at the month 3 study visit, the participant received the third administration of the study vaccine, ALVAC-HIV (vCP2438) OR Placebo for ALVAC-HIV (vCP2438), 1 mL IM in the left deltoid. The participant received the first administration of the study vaccine, Bivalent Subtype C gp120/MF59 OR Placebo for Bivalent Subtype C gp120/MF59, 0.5 mL IM in the right deltoid. All other laboratory tests and the physical examination were normal.

On June 24, 2016, the participant went to the study clinic with complaints of abdominal pain, diarrhea, vomiting, and nausea, all of which had started on June 20, 2016. The study physician assessed the symptoms as grade 3. The study physician suspected gastroenteritis and referred the participant to the hospital for further management. Upon admission to the hospital, he was given IV fluids for rehydration and ondansetron (Zofran) for nausea. Blood was taken for a complete blood count and serum electrolytes.

Later on June 24, 2016, an abdominal ultrasound was performed and the results were normal. His complete blood count showed a white blood cell count of  $11.18 \times 10^3 /\mu\text{L}$  (normal range: 4.00-10.00), and the rest of the parameters were within normal ranges. His serum electrolytes revealed a sodium of 129 mmol/L (normal range: 136-145), potassium of 3.1 mmol/L (normal range: 3.3-5.3), and chloride of 94 mmol/L (normal range: 99-113). A stool sample was collected and the results are pending. The participant started to improve on the treatment. The study vaccine regimen will be continued without change.

On June 27, 2016, the participant's condition improved and he was discharged with a diagnosis of presumed gastroenteritis that was assessed as grade 3. At discharge, he had residual abdominal pain for which he was prescribed paracetamol 500 mg orally as needed.

The site Principal Investigator has assessed the event of presumed gastroenteritis as not related to the study vaccines, ALVAC-HIV (vCP2438) OR Placebo for ALVAC-HIV (vCP2438) and Bivalent Subtype C gp120/MF59 OR Placebo for Bivalent Subtype C gp120/MF59.

Past medical/surgical history: The participant is HIV-uninfected with no significant past medical history. No history of trauma or illness.

Social history: The participant smokes one pack of cigarettes a day, occasionally consumes alcohol and is sexually active.

Concomitant medications: Ibuprofen as needed for pain for the past ten years. Multivitamin as a daily supplement for the past ten years.

### **UPDATE**

On July 17, 2016, the study physician evaluated the participant in the clinic during a follow-up visit. The participant reported that the abdominal pain had resolved. He had no complaints and the physical examination was normal. The participant provided a copy of the discharge summary.