

## **RAMP Project Abstract: SOSHANGUVE, SOUTH AFRICA**

**Project Title:** Evaluation of a dual point-of-care test (POCT) for the diagnosis of syphilis infection in a high HIV and STIs prevalence setting, South Africa

**Project Type:** Short-term Project 8 weeks On-site

**Proposed Project Dates:** 8 weeks On-site between June 1, 2023 – August 31, 2023

**Project Site:** Setshaba Research Centre, Soshanguve, South Africa

### **Project Overview:**

After HIV and herpes, syphilis is the next commonest cause of sexually acquired diseases. Diagnosis of syphilis is based on a combination of clinical history, symptom presentation, and serologic test results. There are two types of diagnostic tests, treponemal and non-treponemal serological tests. The standard procedure is to use one diagnostic test and to confirm with the other if the test is positive. A dual treponemal and non-treponemal POCT (Chemio DPP<sup>R</sup> Syphilis Screen & Confirm) however, offers the ability to provide antibody detection of both tests. In high-prevalence settings, the combined test may reduce over-treatment. There is currently no published data evaluating the sensitivity, specificity, positive and negative predictive values of the dual POCT in a South African setting. Therefore, we aim to determine the performance of immunochromatographic POCT for the simultaneous detection of both non-treponemal and treponemal antibodies in the sera in a high-STI burden South African setting.

Setshaba Research Centre, based in Soshanguve, Tshwane, South Africa, conducts HIV vaccine and prevention trials under the HIV Vaccine Trials Network and HIV Prevention Trials Network. For this project, the scholar will work with a microbiologist/immunologist as the mentor, and will be supported by the community engagement and laboratory staff, other experienced researchers at our center, and a collaborating statistician at the South African Medical Research Council. The project will require two months at our center. The scholar will have the opportunity to interact with potential participants who are symptomatic for syphilis, obtain their consent, administer a questionnaire and manage specimens with the guidance and support of the community engagement team. She/he will learn to process the specimens and conduct three different methods to detect and quantify syphilis (comparing the POCT against the “gold standard” laboratory quantitative RPR test and the TPPA assay). Thereafter, the scholar will analyze the data with guidance from the mentor and statistician, and will prepare an oral/poster presentation and a manuscript for publication with assistance from the other investigators.

### **Project Summary:**

This study aims to determine the performance of immunochromatographic POCT for the simultaneous detection of both non-treponemal and treponemal antibodies (that acts as both a screening and confirmatory test) in the sera from patients with symptoms of STIs in a high-burden South African setting.

The objectives are:

1. To determine sensitivity, specificity, positive and negative predictive values of the dual POCT (The Chemio DPP<sup>R</sup> Syphilis Screen & Confirm) for the diagnosis of syphilis among HIV-infected and HIV-uninfected participants with symptoms of STIs presenting at various primary health care clinics and

HIV/STIs hotspots in Soshanguve and to compare it against the “gold standard” laboratory quantitative RPR test and the TPPA assay.

2. To determine the prevalence of syphilis infection amongst HIV-infected and HIV-uninfected study participants with symptoms of STIs presenting at various primary health care clinics and HIV/STIs hotspots in Soshanguve.

We aim to enroll 196 participants into the study. After written informed consent has been obtained from each study participant, a questionnaire will be used to collect socio-demographic and clinical data. Capillary whole blood will be collected and used immediately to perform the POCT. 3–5 ml of venous blood will be collected and transported on ice to the research laboratory for quantitative RPR and TPPA assays.

The following outcomes will be measured:

- Frequency of reported clinical symptoms and socio-demographics
- Prevalence of syphilis (Proportion of participants with suspected syphilis confirmed by POCT, RPR and TPPA assays)
- Sensitivity, specificity and positive and negative predictive values of the POCT by comparing the POCT results to the combination of RPR and the TPPA as the reference standards (“gold standard”).

*If COVID-19 restricts the scholar from working onsite, then all data collection, POCT, RPR and TPPA testing will be performed by site staff. The scholar will subsequently work with the statistician and other investigators to analyze and interpret the data, prepare a poster/oral presentation and write up the findings for a publication remotely.*

**Regulatory requirements for the project and plans for completing them:**

The proposal will be submitted to the University of Witwatersrand Human Research Ethics Committee in January 2023. Approval will be obtained before the project starts in May 2023 as it generally takes 3 months for approval. The scholar will be required to complete GCP training; virtual or online courses are available.

**Expected Deliverables:**

The scholar will receive training on all study and reporting procedures:

- Obtaining informed consent
- Collection of clinical and socio-demographic data
- Processing of samples and performing of POCT, RPR and TPPA assays
- Analysis of data and preparation of results
- Manuscript writing

A poster/oral presentation at an HVTN Full Group meeting (May 2024)

Publication in a peer-reviewed journal.

**Project Contact Person(s) (Name, Email):**

Dr Ayman Osman ([AOsman@setshaba.org.za](mailto:AOsman@setshaba.org.za)) - Mentor

Dr Athmanundh Dilraj ([ADilraj@setshaba.org.za](mailto:ADilraj@setshaba.org.za))

