

## **Subject: FACTS 001 Study Announces Participant Enrolment**

Dear Colleagues and Friends,

We are writing to share some exciting news about the Follow-on African Consortium for Tenofovir Studies (FACTS). On Friday, 21 October 2011, we enrolled our first study participant in FACTS 001, a pivotal Phase III clinical trial of vaginal tenofovir gel, a microbicide for the prevention of HIV infection.

We are pleased to announce that five sites in Cape Town, Johannesburg, Soweto, Rustenburg and Pretoria have begun to screen women, and the Desmond Tutu HIV Centre has enrolled the first study participant. Initiating this study is an important milestone, as it brings us one step closer to knowing whether a vaginal gel containing the antiretroviral drug, tenofovir gel, can be used successfully by women to prevent HIV.

The study, called FACTS 001, is a large-scale, randomised placebo-controlled clinical study designed to test the safety and effectiveness of vaginal tenofovir gel used before and after sex to protect women against HIV infection and also against HSV-2, a virus that causes genital herpes. The study will enroll a minimum of 2,200 HIV-negative women aged 18-30 years at nine sites in South Africa.

The FACTS 001 study builds on the positive results seen in the CAPRISA 004 study, which showed that use of tenofovir gel reduced women's chance of HIV infection as well as HSV-2. FACTS 001 is designed as a confirmatory study of the safety and effectiveness of vaginal tenofovir gel using the same dosing as CAPRISA 004. If the FACTS 001 study, along with VOICE, which is testing the daily use of tenofovir gel as well as the daily use of oral Truvada tablets, confirm that tenofovir gel is safe and effective, these combined data could contribute to the licensure of the first vaginal microbicide product and subsequently provide women with a powerful new women-controlled HIV prevention method.

We want to take this opportunity to thank the FACTS CORE and site teams who have worked tirelessly this past year to get the study into the field into record time. Thank you also to our sponsor, donors, ACRO and all our partners and colleagues who have provided us with guidance and support these many months.

We have had hundreds of women coming to the clinics, eager to volunteer for FACTS 001. Our clinic doors are now open, and we are ready for the work ahead.

Sincerely,



Prof Helen Rees  
Protocol Chair, FACTS



Prof Glenda Gray  
Protocol Co-chair, FACTS

## **About FACTS**

FACTS is a South African-led research consortium established in 2010 to conduct clinical studies to determine whether tenofovir gel is safe and effective at protecting women from HIV and herpes simplex virus (HSV-2). The collaboration is coordinated by the Wits Reproductive Health and HIV Institute (WRHI) in Johannesburg, with data management coordinated by the Perinatal HIV Research Unit (PHRU) and biostatistics coordinated by the Medical Research Council.

The FACTS 001 study will include nine study sites at: the Aurum Institute in Rustenburg and Tembisa; the Desmond Tutu HIV Centre (DTHC) in Cape Town; Maternal, Adolescent and Child Health (MatCH) in Pietermaritzburg; the Medunsa Clinical Research Unit in Pretoria; Perinatal HIV Research Unit (PHRU) in Soweto; Qhakaza Mbokodo Research Clinic in Ladysmith; the Setshaba Research Centre (SRC) in Pretoria; and the Wits Reproductive Health and HIV Institute (WRHI) in Johannesburg.

FACTS 001 is sponsored by CONRAD and funded by the South African Department of Science and Technology, the U.S. Agency for International Development (USAID) and the South African Department of Health. CONRAD and Gilead Sciences, Inc. are providing the study products.

To learn more about the FACTS Consortium and the FACTS 001 study, please visit our website at:

[www.facts-consortium.co.za](http://www.facts-consortium.co.za)