The FACTS 001 Study

Prof Helen Rees, Protocol Chair
Prof Glenda Gray, Protocol Co-Chair
CAPRISA 004 Results

- CAPRISA 004 showed that 1% tenofovir gel reduced the risk of vaginally transmitted HIV by 39% when used before and after sex (BAT24)
- Also demonstrated a reduction in the risk of Herpes Simplex Virus 2 (HSV2) by 51%.
BAT 24 regimen used in FACTS 001

Within 12 hours

ASAP and within 12 hours

Women should not use more than two gel applicators in a 24-hour period no matter how many times they have sex in a day.
### Rationale for confirmatory study

<table>
<thead>
<tr>
<th>Safety</th>
<th>• Safety of tenofovir gel when used as BAT 24 regimen.</th>
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<tbody>
<tr>
<td>Repeatability</td>
<td>• Effectiveness in diverse populations with different epidemics</td>
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<td>HIV Protection</td>
<td>• Confirm CAPRISA 004 results</td>
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<td>Generalizability</td>
<td>• CAPRISA 004 included 899 women in high incidence area of KZN.</td>
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<td>HSV-2</td>
<td>• Confirm data on effectiveness for prevention of HSV-2</td>
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Primary objective

• Evaluate effectiveness and safety of 1% tenofovir gel in preventing sexual transmission of HIV-1 infection in young women
Secondary objectives

• Effectiveness against HSV-2
• Impact on pregnancy outcomes
• Effectiveness of gel according to levels of condom use
• In women that become HIV infected during trial:
  • Effect of tenofovir gel on viral load set point
  • Tenofovir resistance
Study design of FACTS

2200 sexually active HIV uninfected women age 18-30 years

Tenofovir gel

Placebo gel

Enrolled over 10 months & followed up for 24 months
Retention
Adherence to gel
Behaviour
HIV risk reduction

Number of HIV infections in each study arm
Endpoint driven: 88
**FACTS 001 Sites in SA**

**Site Investigators**
- Khatija Ahmed, SRC
- Linda-Gail Bekker, DTHF
- Sinead Delany-Moretlwe, WRHI
- Busi Nkala, PHRU
- Matsontso Peter Mathebula, Medunsa
- Kedinnetse Sarah Mogotse, AURUM
- Tembisa, AURUM
- Zonke Mabude, MATCH, Pietermaritzburg
- Sydney Sibiya, QM, Ladysmith

**Locations**
- Medunsa
- Setshaba
- Aurum, Rustenberg
- PHRU, Soweto
- WRHI, Yeoville
- Aurum, Tembisa
- QM, Ladysmith
- MATCH, PMB
- DTHF, Cape Town
CAPRISA 002

• Safety and acceptability of use of 1% tenofovir gel in 16 and 17 year old girls in South Africa
• Submitted to MCC, S Africa
• Ongoing design considerations
  – How often to expose young girls noting this is BAT-24 regimen?
  – Daily versus BAT 24 ?
  – Combination of both?