

# HPTN 035

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Salim S Abdool Karim

On behalf of the HPTN 035 Protocol Team

MTN Annual Meeting

11 September 2008



# Primary Objectives

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- **To evaluate the safety of BufferGel and 0.5% PRO 2000/5 Gel (P) when applied intravaginally by women at risk for sexually-transmitted HIV infection**
- **To estimate the effectiveness of BufferGel and 0.5% PRO 2000/5 Gel (P) in preventing HIV infection**

# HPTN 035 To Date

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- **Accrual of 3099 participants began in February 2005 and was completed in July 2007**

# HPTN 035 To Date

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- **Over 64,000 follow-up visits have been completed to date, involving:**
  - **Performing more than 23,000 pelvic examinations**
  - **Dispensing of nearly 430,000 applicators of gel**
  - **Completion of over 411,000 case report forms**

# HPTN 035 To Date

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- **The last study exit visits will be completed this week**
- **Across sites, 94% of participants have been retained for exit visits**

# HPTN 035 Future Planning

## (Subject to Change)

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- **Completion of final laboratory testing and results reporting to SCHARP**
  - **HIV status**
  - **HSV-2 status**
  - **Bacterial vaginosis (gram stain)**
  - **Genital ulcer disease etiology**
- **By 31 October 2008**

# HPTN 035 Future Planning

## (Subject to Change)

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- **October and November 2008**
  - **Planning and preparation for results dissemination**
    - **Data cleaning and analysis**
    - **Preparatory communications with authorities and stakeholders**
    - **Development of planning scenarios with site and community involvement**

# HPTN 035 Future Planning

## (Subject to Change)

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- **December 2008**
  - **Continued planning and preparation for results dissemination**
  - **Unblinding and results interpretation by study investigators**
  - **Submission of late-breaker abstract to 16<sup>th</sup> Conference on Retroviruses and Opportunistic Infections (CROI)**



# **HPTN 035 Future Planning**

## **(Subject to Change)**

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- Late January / Early February 2009**
  - Public release of study results**
  - Presentation of results at CROI**
  - Finalization of scientific manuscript for publication**

# Acknowledgements

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