HPTN 035

Salim S Abdool Karim
On behalf of the HPTN 035 Protocol Team
MTN Annual Meeting
11 September 2008
Primary Objectives

- 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
Accrual of 3099 participants began in February 2005 and was completed in July 2007
HPTN 035 To Date

- 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

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

- 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)

- December 2008
  - Continued planning and preparation for results dissemination
  - Unblinding and results interpretation by study investigators
  - Submission of late-breaker abstract to 16th Conference on Retroviruses and Opportunistic Infections (CROI)
HPTN 035 Future Planning
(Subject to Change)

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