Ancillary Study Proposals

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VOICE Meeting, 27 March 2011

MTN
microbicide trials network

Objective measures of adherence

- Biomarkers
  - Hair, PBMC, plasma
    - Current assays depend on absorption of drug from site of administration, so may not be optimal for vaginal or rectal gel
  - Measure drug at site of administration
    - Vaginal swabs, rectal swabs
    - Good measure of drug when present, but may reflect very recent product use
    - Other options?

Objective measures of adherence

- Event Monitoring Systems (EMS):
  - Indirect objective measure of product use
  - Opening events are electronically recorded
    - Stored on a battery OR
    - Sent real life via a wireless phone system
  - MEMS or Wisepill (tablets); Wisebag (gel)

Wisebag™ (Wisepill Technologies, SA)

- Innovative Pill technology adapted for applicator count

- 2 small studies conducted so far:
  - 10 women for applicator count in CAP004 (1)
  - 50 infant/caregiver pairs for pediatric Rx, Uganda (2)

(1) T. Gengiah M2010 presentation; (2) J. Haberer, personal communication

Wisebag Pilot Study

Protocol chair: Ariane van der Straten, PhD, MPH
Site Investigator: Gonasagrie Nair, MBChB

- Feasibility, acceptability and performance Pilot study @ CAPRISA eThekwini site
- ~50 HIV(-) ♀ who screen out from VOICE
- 3 arm RCT (1:2:2) for daily opening of Wisebag
  - Placebo (dummy) Wisebag
  - Online device Wisebag (real time signal via wireless phone)
  - Offline device Wisebag (signal stored only on chip in bag)

Wisebag Pilot Study

- Primary Objectives:
  - Compare on-site technical performance of the “offline” and “online” functionalities of Wisebag
  - Assess success of attempted blinding of “dummy” vs. active (“online” or “offline”) Wisebag
  - Measure concordance between Wisebag opening-event data (both “online” and “offline”) and self-reported data
  - Explore feasibility and acceptability of Wisebag use by participants

Wisebag Pilot Study

- No study product; stickers used as substitute
- Participant asked to open Wisebag daily, peel off a sticker and place on a study diary card
- Duration: 2 weeks, 2 visits (enrollment & exit)
- Proposal currently under discussion
- Expect accrual to occur over 8 weeks
- Expected implementation timeline: June – Aug. 2011

PREMIS

Preventive Misconception in HIV Prevention Trials

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Kevin Weinfurt, PhD

NIH Grant R21 MH092253

Background

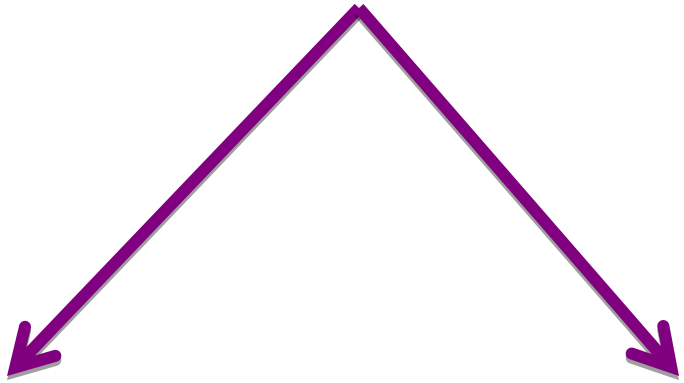
- Concern that some participants in HIV prevention trials might misunderstand nature of the trial
  - "*Preventive misconception*"
    - False belief that participation in prevention trial protects against HIV
- Significance
  - Opportunity to address informed consent issues
  - Preventive misconception might lead to engagement in more risk behaviors

Aims

1. Refine conceptual model of preventive misconception
2. Develop and evaluate a measure of preventive misconception
3. Explore whether scores on the measure are associated with risk behaviors among participants in HIV prevention studies

The success of PREMIS depends on collaboration with ongoing HIV primary prevention studies

2-Part Data Collection



Qualitative Interviews
(≤ 30 people across 1 or more sites)

Closed-ended Items in Parent Trial CRF
(≤ 10 items)

Qualitative Interviews

- Goal: To test understanding and appropriateness of PREMIS items
- Recruit up to 30 English-speaking participants from 1 or more trial sites
- One-on-one audio-recorded interview with each participant
  - Each interview lasts approximately 1 hour
  - Interviews conducted either by researchers from local trial sites or by interviewers from PREMIS team

Validation Study

- Goal: Evaluate how well PREMIS items perform and explore relationship between understanding and engagement in risk behaviors
- Use data from cognitive interviews to revise measure
- Final measure will likely include no more than 10 items
- Build measure into data collection procedure of parent trials
- Collect data from up to 250 participants