

Case Western Reserve University  
University Hospitals Case Medical Center  
Clinical Trials Unit

Lessons Learned  
MTN Annual Meeting  
4/22/09



# Working with a new clinical research network involved bigger cultural change than anticipated

- Terminology/procedures are different
- Questions from Unit to Protocol Team handled differently
- Enrollment/Outreach reporting requirements more frequent in MTN
- MTN more supportive/interested in community input
- Working knowledge of SSP content required
  - Unit Response: Routine review of various sections of SSP

Working with a new clinical research network involved bigger cultural change than anticipated

- Learning curve with data management system:
  - CRF completion
  - Faxing/re-faxing forms
- Knowing when to contact PSRT
  - Unit Response: Staff reviewed procedures, e.g. need to contact PSRT if participant fails to return study product, questions about eligibility or toxicity

# Outreach/Recruitment

- More difficult than anticipated
- Overestimated the number of initial contacts/enrollment ratio
- Need for stronger OB/GYN interactions for referrals
- Number of women who contact us for study information, but do not follow through with the education and screening process

# Enrollees

- Not a problem using the Special Immunology Unit (HIV Clinic) as the MTN clinic; no obvious stigma
- Vaginal biopsies not a major issue for enrollees
- Number of women who enrolled but subsequently did not start or discontinued using study product
  - Unit Response: Prior to signing enrollment consent form, a different research nurse than the screening nurse reviews study requirements with potential enrollee to give enrollee another opportunity to express any concerns about her participation in the study.

# Enrollees

- Venous access in some otherwise healthy young women
  - Unit Response: During pre-screening process, assess participants venous access; query potential participants about past difficulties with blood draws
- Validation that participants need a high level of commitment to complete the study requirements
- Participants do not seem bothered by the sexually explicit information asked in questionnaires and interviews