Study Monitoring Committee (SMC) Review Summary and Recommendations

VOICE
Summary

- The MTN SMC conducted its first review VOICE on 26 February 2010
- The SMC congratulated the team for initiating a complex study.
- Review of participant demographics raised no issues or concerns.
Summary

- Participant accrual rates are above target; and early retention data show high visit completion rates.
- Product use adherence rates appear to be high, although some inadequacies in reporting make this difficult to judge.
- At the time of the SMC review, there have been four pregnancies in the study; this early high pregnancy rate trend is concerning.
Recommendations

- Very early data on participant termination and pregnancy show higher numbers than expected, which the protocol team should address.

- The SMC strongly recommends revision of study processes to allow unbiased estimates of adherence from objective product count adherence measures.
  - Collection of empty bottles from participants on the oral arm.