

# Study Monitoring Committee (SMC) Review Summary and Recommendations

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VOICE





# Summary

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- 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

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- 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

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- 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.