Dhookie, J. (2008). Participant adherence to gel use instructions regarding timing for gel insertion and for vaginal cleansing in the mdp 301 microbicides trial in johannesburg Microbicides 2008. Delhi.

Background: PRO 2000/5, currently in a Phase III trial is delivered vaginally via an applicator which must be inserted within one hour before a sex act. Vaginal cleansing should occur at least one hour after the sex act. As adherence to rigid timelines may be problematic and therefore impact on the long term success of the product.
Methods: To determine ability to adhere to gel use instructions for timing of insertion before a sex act (<1 hour) and timing of vaginal cleansing after a sex act (? 1 hour)and reported sex acts where gel was used at Johannesburg were assessed. Information collected on case record forms at specified time points was used to determine the factors that influenced gel use. Results were analysed using STATA.
Results: Of 13829 reported sex acts protected by gel, timing for insertion was mostly correct, 96.94%, CI (95.16-96.19). Vaginal cleansing was reported for 52.57% (51.74-53.40) of sex acts where gel was used; of these timing was correct for 78.65% (77.69-79.59) of observations. Analysis at each time point showed a trend for increasing correct gel use (p value < 0.001). Soweto based participants reported a higher percentage of correct use compared with Orange Farm for both timing for insertion (97.94%; (97.60 - 98.25) vs 95.70% (95.16 - 96.19) and vaginal cleansing (87.10%; CI 85.84-88.29 vs 72.83%;CI 71.47-74.15). There were significant differences between sites for mean age (p < 0.001) and level of education (p<0.001)
Conclusion: Participants are able to adhere to gel use instructions. Correct use increases with increasing trial participation and may be attributed to ongoing counseling during participation. Orange Farm reporting a higher percentage of incorrect use which may be attributed to an older population who have lower levels of education and therefore were less adept at correctly assimilating information.