

Govender, S. (2008). Can higher retention be achieved in mdp301 than implied by the preceding cohort studies? . Microbicides 2008. Delhi.

Background: MDP 301 is a randomised, blinded, placebo-controlled trial to assess PRO 2000/5 being conducted in 6 sites: 3 in South Africa; Tanzania; Uganda; and Zambia. Feasibility (cohort) studies preceding the trial (2002-2004) suggested that retention decreased with time, and this contributed to censoring the primary scientific analysis at wk40. The objective is to explore the hypothesis that experience from Feasibility and access to product helped increase retention rates in the trial. Method Data were extracted from the merge of 15/09/07. Each visit has a 2 week window beyond the date predicted by enrolment within which it should occur, except wk52 which can occur 6 weeks beyond scheduled visit. Expected attendance was calculated for visits where the 14 day window had passed, and where this fell before or on the 1st September 2007, to allow for data entry of the specimen collection CRF (= women seen). Women that have been withdrawn are not included post withdrawal visit. Results 124 (2%) of 6252 women enrolled have been withdrawn in this dataset; 2667 and 1511 were expected at wks 40 and 52 respectively. In five sites retention at wk40 was higher than Feasibility, with 86% (range 79-92%) of the cohort seen. Retention remained high at week 52, with 88% seen (range 80-94%). In one site, 50% of the participants were retained at wk40, and 3 (43%) of the 7 expected seen at wk52. These figures are lower than manual records from site, and maybe due to delays in CRF entering. Conclusions: In spite of the challenging setting, high (>85%) retention rates are achievable. Results do not support the hypothesis that retention falls between wks 40 and 52, it maybe appropriate to revisit the decision to censor at wk40. Other parameters like gel adherence, pregnancy and HIV incidence rates over time are considered.