Facility-based orientation
Project fieldworkers use a pictorial Flipchart and demonstration props (e.g. speculum, venepuncture equipment) to introduce trial objectives and key study procedures to potential participants

Those interested in attending a Screening Visit are given a scheduled appointment date and a Clinic Attendance Slip. Women who have not participated in a facility-based meeting are not eligible to attend for screening.

Screening Visit informed consent procedures
Clinic Registrar discusses the PIS with each subject and uses a laminated Key Messages List (Screening) to ensure all salient points are covered, prompting for questions at each stage. The Comprehension Checklist is then used to assess understanding and key message retention. Once the Registrar is satisfied that the subject has a sound comprehension and can make an informed decision regarding participation in the trial, written informed consent is obtained and a copy of the completed Screening ICF given to the subject to take home, with a copy of the PIS.

Subjects complete Screening Visit procedures and are invited to attend for enrolment visit if eligible to participate in the main trial

Enrolment Visit informed consent procedures
Clinic Registrar reviews the PIS with subject and uses a laminated Key Messages List (Enrolment) to ensure all salient points are covered, prompting for questions at each stage. The Comprehension Checklist is then used to assess understanding and key message retention. Once the Registrar is satisfied that the subject has a sound understanding and can make an informed decision regarding further participation in the trial, written informed consent is obtained and a copy of the completed Enrolment ICF given to the subject to take home.

Randomisation
Gel Coordinator provides detailed advice on gel use and assesses subjects’ understanding prior to randomisation at the end of the Enrolment Visit. Each subject is given a copy of the pictorial Gel Use Instructions and asked to listen to a pre-recorded 20-minute FAQ audio tape. Subjects are asked to carry out a directly observed first gel application in the clinic, after which they discuss any problems using the applicator or inserting the gel before being given a supply of study product, a copy of the Gel Use Instructions and a written transcript of the FAQ tape.

Participants return to clinic every 4 wks for clinical review visits at 4, 12, 24, 40 and 52 wks and shorter gel collection visits as other times

Follow-up informed consent procedures
Clinic Registrar reviews Comprehension Checklist with all subjects at 12, 24, 40 and 52 wk Visits. Subjects are advised that they can listen to the FAQ tape and/or discuss any trial-related concerns they may have at any point during follow-up.