MTN 020 - A Study to Prevent Infection with a Ring for Extended Use (ASPIRE)
Data as of September 21, 2015

Screen-out Summary by Site - First 8 Sites

	All Sites	Malawi - Blantyre	Malawi - Lilongwe	SA - Cape Town	SA - CAPRISA eThekwini	SA - MRC/ Botha's Hill	SA - MRC/ Chatsworth	SA - MRC/ Isipingo	SA - MRC/ Tongaat
Participants Screened	5516	199	200	217	736	436	411	314	351
Participants Enrolled[1]	2629 (48%)	130 (65%)	142 (71%)	166 (76%)	244 (33%)	180 (41%)	150 (36%)	117 (37%)	103 (29%)
Participants not Enrolled	2887 (52%)	69 (35%)	58 (29%)	51 (24%)	492 (67%)	256 (59%)	261 (64%)	197 (63%)	248 (71%)
Participant did not complete all screening procedures	378 (7%)	0 (0%)	0 (0%)	16 (7%)	129 (18%)	0 (0%)	7 (2%)	10 (3%)	32 (9%)
Participant is eligible but declined enrollment	55 (1%)	0 (0%)	1 (1%)	1 (<1%)	2 (<1%)	1 (<1%)	4 (1%)	0 (0%)	2 (1%)
Reason participant not enrolled is missing	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Participant not eligible[2]	2454 (44%)	69 (35%)	57 (29%)	34 (16%)	361 (49%)	255 (58%)	250 (61%)	187 (60%)	214 (61%)
Participant < 18 or > 45 years old	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Plans for relocation/travel	68 (3%)	5 (7%)	3 (5%)	1 (3%)	20 (6%)	2 (1%)	2 (1%)	6 (3%)	0 (0%)
Participant is pregnant or planning to become pregnant	202 (8%)	5 (7%)	4 (7%)	0 (0%)	23 (6%)	10 (4%)	15 (6%)	10 (5%)	21 (10%)
Participant is breastfeeding	31 (1%)	3 (4%)	2 (4%)	0 (0%)	6 (2%)	1 (<1%)	7 (3%)	0 (0%)	0 (0%)
Participant has not had vaginal sex in the last 3 months	56 (2%)	2 (3%)	3 (5%)	6 (18%)	8 (2%)	1 (<1%)	3 (1%)	7 (4%)	0 (0%)
Participant has enrolled in another research study in the last 60 days	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Participant has participated in VOICE or other HIV prevention trial in the past 12 months	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
PEP exposure in the last 6 months	6 (<1%)	0 (0%)	2 (4%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (1%)	1 (<1%)
Participant is HIV-positive	854 (35%)	16 (23%)	3 (5%)	3 (9%)	5 (1%)	102 (40%)	79 (32%)	94 (50%)	139 (65%)
Participant declines effective method of contraception	27 (1%)	5 (7%)	0 (0%)	0 (0%)	6 (2%)	1 (<1%)	0 (0%)	4 (2%)	1 (<1%)
Participant has a grade 2 or higher pelvic exam finding	58 (2%)	3 (4%)	0 (0%)	2 (6%)	5 (1%)	10 (4%)	4 (2%)	6 (3%)	3 (1%)
Participant does not meet laboratory eligibility criteria	203 (8%)	2 (3%)	6 (11%)	8 (24%)	17 (5%)	21 (8%)	21 (8%)	14 (7%)	14 (7%)
Participant does not meet other clinical eligibility criteria	295 (12%)	1 (1%)	5 (9%)	1 (3%)	109 (30%)	6 (2%)	35 (14%)	15 (8%)	18 (8%)
Other reason, including investigator decision	754 (31%)	30 (43%)	30 (53%)	13 (38%)	184 (51%)	105 (41%)	89 (36%)	44 (24%)	22 (10%)

[1] Number of participants enrolled could differ from the accrual report since the data is taken from the ECI-1 CRF and not the ENR-1 CRF.
[2] Participants may be ineligible for more than one reason.

Source: SCHARP (janne) - /trials/mtn/p020/reporting/progress/code/t_screen_out_site.sas, SAS Version 9.4 (22SEP2015,9:43)

MTN 020 - A Study to Prevent Infection with a Ring for Extended Use (ASPIRE)
Data as of September 21, 2015

Screen-out Summary by Site - Last 7 Sites

	All Sites	SA - MRC/ Verulam	SA - MRC/ Umkomaas	SA - WRHI	Uganda - Kampala	Zimbabwe - Seke South	Zimbabwe - Spilhaus	Zimbabwe - Zengeza
Participants Screened	5516	346	259	401	408	434	403	401
Participants Enrolled[1]	2629 (48%)	150 (43%)	103 (40%)	213 (53%)	253 (62%)	224 (52%)	230 (57%)	224 (56%)
Participants not Enrolled	2887 (52%)	196 (57%)	156 (60%)	188 (47%)	155 (38%)	210 (48%)	173 (43%)	177 (44%)
Participant did not complete all screening procedures	378 (7%)	13 (4%)	2 (1%)	70 (17%)	31 (8%)	20 (5%)	42 (10%)	6 (1%)
Participant is eligible but declined enrollment	55 (1%)	7 (2%)	5 (2%)	13 (3%)	4 (1%)	6 (1%)	4 (1%)	5 (1%)
Reason participant not enrolled is missing	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Participant not eligible[2]	2454 (44%)	176 (51%)	149 (58%)	105 (26%)	120 (29%)	184 (42%)	127 (32%)	166 (41%)
Participant < 18 or > 45 years old	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Plans for relocation/travel	68 (3%)	1 (1%)	2 (1%)	3 (3%)	5 (4%)	7 (4%)	0 (0%)	11 (7%)
Participant is pregnant or planning to become pregnant	202 (8%)	6 (3%)	9 (6%)	14 (13%)	17 (14%)	22 (12%)	15 (12%)	31 (19%)
Participant is breastfeeding	31 (1%)	5 (3%)	2 (1%)	1 (1%)	2 (2%)	0 (0%)	0 (0%)	2 (1%)
Participant has not had vaginal sex in the last 3 months	56 (2%)	4 (2%)	9 (6%)	3 (3%)	3 (3%)	3 (2%)	1 (1%)	3 (2%)
Participant has enrolled in another research study in the last 60 days	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Participant has participated in VOICE or other HIV prevention trial in the past 12 months	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
PEP exposure in the last 6 months	6 (<1%)	2 (1%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Participant is HIV-positive	854 (35%)	92 (52%)	51 (34%)	25 (24%)	27 (23%)	113 (61%)	56 (44%)	49 (30%)
Participant declines effective method of contraception	27 (1%)	1 (1%)	2 (1%)	0 (0%)	6 (5%)	1 (1%)	0 (0%)	0 (0%)
Participant has a grade 2 or higher pelvic exam finding	58 (2%)	3 (2%)	2 (1%)	8 (8%)	2 (2%)	2 (1%)	1 (1%)	7 (4%)
Participant does not meet laboratory eligibility criteria	203 (8%)	35 (20%)	13 (9%)	16 (15%)	9 (8%)	9 (5%)	10 (8%)	8 (5%)
Participant does not meet other clinical eligibility criteria	295 (12%)	14 (8%)	17 (11%)	10 (10%)	6 (5%)	13 (7%)	26 (20%)	19 (11%)
Other reason, including investigator decision	754 (31%)	19 (11%)	49 (33%)	28 (27%)	52 (43%)	26 (14%)	23 (18%)	40 (24%)

[1] Number of participants enrolled could differ from the accrual report since the data is taken from the ECI-1 CRF and not the ENR-1 CRF.
[2] Participants may be ineligible for more than one reason.

Source: SCHARP (janne) - /trials/mtn/p020/reporting/progress/code/t_screen_out_site.sas, SAS Version 9.4 (22SEP2015,9:43)

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Listing of Other Reasons for Ineligibility by Site

Obs	Site	Reason
1	Malawi - Blantyre	has aortic valve disease
2		husband did not permit her to join the study
3		husband did not permit her to join the study
4		exceeded 28 days window period for enrollment.
5		husband has stopped her from participating in study
6		participant has exceeded the 28-day screening period.
7		has exceeded the 28-day screening period
8		participant not willing to provide adequate locator information
9		poor understanding of study
10		has a chest condition, for which she is being reviewed at QECH. condition may compromise study...
11		has exceeded the 28-days screening period.
12		she is out of window for screening.
13		not reliable
14		husband does not want her to participate in the study.
15		exceeded the 28 days screening period
16		she has exceeded the 28-days screening period
17		participant has exceeded the 28-day screening period
18		participant declined study participation
19		participant has exceeded the 28-day screening period
20		exceeded 28-day window period
21		Husband refused to let his wife participate in the study.
22		out of 28-day screening period
23		she has exceeded the 28 day window period
24		hiv discordant results
25		Husband does not allow participant to join ASPIRE
26		Participant exceeded the 28 day window period
27		Participant's nature of work does not allow her to freely participate in the study
28		husband has not given approval for client to be enrolled
29		Participant gave false locator information
30		raised bp at screening
31	Malawi - Lilongwe	enrollment window elapsed on 23 aug 13
32		enrolment window elapsed.
33		concerns with the amount of blood draws in the study
34		inadequeate locator information
35		out of window

Listing of Other Reasons for Ineligibility by Site

Obs	Site	Reason
36		enrollment window elapsed on 23aug13
37		inadequate locator information
38		allergic to latex
39		out of visit window
40		did not want any further blood draws.
41		enrollment window closed
42		Had issues with blood draw
43		out of window
44		allergic to latex
45		out of window
46		screening window elapsed
47		enrollment window elapsed on 22oct13
48		The findings on pelvic examination.
49		did not come for enrollment visit.
50		screening window elapsed
51		participant had CINII and was refered for management
52		no evidence of permanent or reliable contraceptive method
53		in doubt that participant is breast feeding.
54		enrollment window elapsed
55		enrollment window elapsed on 29aug13
56		out of enrollment window
57		out of screening and enrollment window
58		out of enrollment window
59		out of screening and enrollment window
60		Declined plasma sample collection.
61		13jul13 out of window
62	SA - CAPRISA eThekwini	ior decision : difficulty drawing blood
63		IOR decision: pt has galactorrhoea
64		IOR decision: concern over relocation
65		IOR decision: concern over social issues
66		ior decision: difficult bleed
67		IOR decision: pt has galactarrhoea
68		ICR cecision: studies may hamper participation in the study
69		ior decision: study and possible job opportunities will make it difficult for commitment to the s...
70		IOR decision: did not disclose important information with regards to pregnancy history
71		ior decision: participant lactating.

Listing of Other Reasons for Ineligibility by Site

Obs	Site	Reason
72		ior decision: high possibility she will be relocating.
73		ior decision: social circumstances not suitable for study
74		IOR decision: pt did not understand the comitment and time for the study
75		ior decision: inconsistent information regarding contraception use.
76		IOR decision participant is still in high school and may not have time for study visits
77		ior decision: participant is unlikely to be available for study visits
78		ior decision: participant lactating
79		ior decision: participant is scared of pelvic exams
80		IOR decision: unable to visualize cervix after two seperate attempts
81		ior decision: participant unlikely to be able to attend future visits
82		ior discretion: unreliable social circumstances
83		ior decision participant refused to conduct pelvic exam
84		ior decision : participant is likely to relocate in the future
85		IOR decision: ppt scared to conduct screening and future pelvic exams.
86		IOR decision: ppt is unlikely to be able to complete pelvic exams as unable to palpate and visual...
87		IOR decision: Galactorrhea
88		IOR decision: Travels a lot and may want to have child.
89		ior decision: pt lactating.
90		IOR decision - still in school, no time for visits.
91		IOR decision: Participant is scared to insert the ring due to her getting stomach cramps
92		ior decision - galactorrhea
93		IOR decision: Pt unlikely to be a good candidate based on unreliable information.
94		IOR decision - unwilling to complete pelvic exam
95		ior decision - galactorrhea
96		ior decision - refused to do procedures
97		IOR decision - balactorrhea
98		IOR discretion: galactorhaed
99		ior discretion: ongoing at 3 headache and no established cause.
100		ior decision: difficulty conducting pelvic exam.
101		IOR decision: participant has galactorrhoea
102		IOR decision: unable to commit to study as works irregular hours
103		participant still at school and will possibly leave the area
104		participant unsure of comitting to the study for 2 years. IoR decision
105		IOR deiscretion: doubt over contraception use and adherence.
106		less than 3 months from termination of pregnancy
107		IOR decision: unlikely to be adherant to contraception

Listing of Other Reasons for Ineligibility by Site

Obs	Site	Reason
108		ior decision: unlikely to be adherant to study visits due to studying commitments
109		IOR decision: limited time of participant makes clinic attendance difficult.
110		ior decision: participant did not want to be tracked at home.
111		icr decision: ongoing investigation with regards to cervical masses.
112		IOR decision: under investigation for a genital urinary problem and has allergic tendancy.
113		IOR decision: possible non-adherence to contraception.
114		IOR decision: study commitments make it difficult to attend study visits
115		IOR decision: study comittments will make it difficult to attend study visits.
116		discrepant information provided IOR decision.
117		IOR discretion: study + work commitments make clinic attendance difficult
118		IOR decision: study commitments makes it difficult for clinic attendence
119		IOR decision: possible unavailability for study visits.
120		IOR descretion: unable to visualize cervix
121		IOR decision: participant unlikely to stay in Durban for 2 years.
122		IOR decision: study commitments make clinic attendence difficult.
123		IOR discretion: uncertain of her plans in the next two years
124		IOR decision: work commitments make it difficult to attend clinic visits and a possible conflict ...
125		IOR discretion: possibility she may return to eastern cape as lack of social support in durban
126		participant refused to continue with pelvic exam
127		IOR decision: clinically significant uncontrolled medical condition
128		IOR decision: doubts on whether participant will honestly report symptoms
129		IOR decision: Strong possibility participant will be away from Durban for extended periods.
130		ior discretion: pt concerned with gynecelogical hygiene and washes her vagina frequently
131		IOR discretion: study commitments may interfere with her participating
132		IOR discretion: unlikely to commit to study due to work
133		IOR decision: past history of using traditional medication
134		IOR decision: non-disclosure of study participation may be a challenge to adherence
135		ior discretion: participant displays poor comprehension and discrepancy in answers.
136		IOR discretion: participant studying unlikely to adhere to visits
137		ior decision: partner + parents are not aware of her participating in the study and may dispprove.
138		IOR decision: dicciculty conducting pelvic exam, possible problems with future pelvic exams.
139		IOR decision: high possibly the participant may return to eastern cape
140		IOR decision: work commitments will make clinic attendance difficult
141		IOR discretion: possible relocation. possibly not consistant in terms of contraceptive use and in...
142		IOR decision: Participant lactating
143		IOR decision: participant lactating

Listing of Other Reasons for Ineligibility by Site

Obs	Site	Reason
144		ior decision: work commitments and use of traditional medications will present challenges in study.
145		IOR discretion: study commitments may struggle to adhere to visits.
146		ior decision: possibility of leaving area.
147		ior decision: difficult to visualise cervix and participant uncomfortable with speculum during pe...
148		ior decision: participant showed discomfort with regards to pelvic exam.
149		ior decision: poor insight of gynaelogical history
150		ior decision: participant lactating
151		ior decision: haematuria needs investigation
152		ior decision: participant lactating
153		ior decision: participant still at high school.
154		ior decision: participant lactating
155		ior decision: clinic attendance will be difficult due to schooling.
156		ior discretion: persistent elevation of creatinine
157		ior decision: participant lactating
158		IOR decision: Repeated discrepant information given
159		IOR decision: condyloma needs treatment due to its position in the vagina.
160		IOR decicsion: recurrent vaginal itching could possibly comprimise data.
161		IOR decision: recurrent vaginal itching would complicate interpretation of study data.
162		ior decision: participant did not take on 05aug13 up referral and appears to have written the ref...
163		ior decision: condyloma needing treatment before she is enrolled.
164		ior decision: backache with radiation to chest and associated dyspnoea. potential indicator of se...
165		ior decision: concerns whether she would adhere to oral contraception
166		IOR decision. pt has a hyper-allergic constitution
167		ior decision: details on contraception card unclear
168		ior decision: participant still lactating
169		ior decision: use of traditional medicyne and not seeking medical help with regards to her probl...
170		ior decision: participant unavailable to attend visits.
171		icr decision: participant still lactating
172		unable to give adequate locator information
173		ior decision likely to relocate out of the area.
174		ior decision: concern about availability for visits
175		ICR decision: unable to veiw or palpate the cervix
176		ior decision: unwilling to have home visits.
177		IOR decision: Discrepant information provided.
178		participant deliberately omitted/fabricated medical history.
179		IOR: decisions: beliefs and use of traditional medications make her unsuitable for the study

Listing of Other Reasons for Ineligibility by Site

Obs	Site	Reason
180		icr decision, participant lactating
181		ior decision: pt insight deemed poor.
182		unable to collect specimens
183		IOR discretion: study commitments may interfere with participant attending clinic
184		ior decision possibility of a social harm if enrolled.
185		ior decision: discrepant information provided.
186		ior: participant still lactating and inconsistent with information provided.
187		IOR decision: study commitments
188		IOR decision: concern about whether participant will be adherent
189		ior decision: likely relocation
190		ior decision: unreliable information provided and not certain she will be able to attend study v...
191		ior decision: unlikely to be able to attend study visits.
192		ior decision inconsistant information and not willing to undergo proper contraception counselling.
193		ior decision: inconsistant information provided about contraception use.
194		ior decision: ring use may result in a social harm
195		ior decision: participant smokes daggd for recreational use.
196		IOR decision; hypersensitive disposition may lead to allergic reaction to ring.
197		discordant HIV results
198		IOR discretion: unlikely to be adherent to study visits
199		IOR decision: unreliable information provided
200		IOR discrepant information provided
201		ior decision: unlikely to have time to commit to study visits
202		ior decision, unlikely to have the time to commit to the study.
203		IOR decision: unexplained menorrhagia needing further investigation.
204		IOR decision: Participant still lactating
205		ior decision: unlikely to be compliant to contraception.
206		IOR discretion: participant study and will possibly not available for visits
207		ior decision: unlikely to be available for clinic visits.
208		IOR decisions: participant still lactating.
209		IOR decision: work commitments make it difficult to attend study visits
210		ior decision: unlikely to be able to attend all clinic visits
211		study commitments will make it difficult to attend clinic visits IOR decision.
212		does not agree to not take part in any other studies.
213		ior decision: poor access to cervix.
214		ior decision: unlikely to be able to attend clinic visits due to schooling.
215		ior decision: history of emotional instability.

Listing of Other Reasons for Ineligibility by Site

Obs	Site	Reason
216		ior decision: unlikely to be able to attend clinic visits consistently
217		ior decision: investigation regarding grossly irregular menses needed participants referred to lo...
218		ior decision: allergic tendencies deem the participant unsuitable for the study.
219		IOR decision: unlikely to attend clinic visits due to study comittments.
220		IOR decision: participant unlikely to be able to attend clinic visits due to work comittments.
221		IOL decision: Study commitments may interfere with clinic visits.
222		IOR decision. sangoma training deemed unsuitable for study participation
223		ior decision: discrepant information provided.
224		ior decision study commitments may effect study visits.
225		icr decision: does not allow access for home visits for retention purposes.
226		icr decision: school commitments will hamper participation
227		IOR decision: lives in eastern cape and may not be able to attend all visits.
228		ior decision - unreliable participant
229		ior deciosn has work commitments
230		galactorrea-IOR decision
231		ior: unreliable and inconsistant information given.
232		plans to take part in other research studies involving vaginal products, medical devices or drugs.
233		risk of comfort breastfeeding: IOR decision
234		IOD discretion: displayed poor adherence to medication and no acknowledgement of it
235		ior decision: concerns that she may relocate.
236		IOT decision: Participant unlikely to meet time requirements of study.
237		IOR decision: travels far often and is unsure of using contraception
238		could not prove tubal ligation ior decision
239		inconsistent and unreliable information: IOR decision
240		falsification of documentation: ior decision
241		ior decision: galdetorhoea
242		discordant hiv rapid results
243		IOR decision study comitments difficult for aspire visits
244		unable to commit to study
245		Gr 3 elevated BP and reluctant to get reviewed at local clinic
246	SA - Cape Town	unable to perform venepuncture successfully
247		physical finding requiring specialist investigation
248		suspected of falsifying information
249		participant refused to wait
250		too anxious
251		polycythaemia

Listing of Other Reasons for Ineligibility by Site

Obs	Site	Reason
252		suicide attempt: nov 2012
253		unable to do study visits student
254		participat lost her phone using sister's phone
255		not a healthy participant bmi 50. raised blood pressure
256		participant very anxious at pelvic exam and dishonest.
257		emergency travel
258		Emergency travel therefore not able to enrol in 28 day window.
259	SA - MRC/Botha's Hill	Ppt does not understand study and reason for participation.
260		28 day screening window closed
261		Participant does not understand the informed consent.
262		Participant lacks commitment to the study and VR use.
263		28 day screening window closed
264		Participant's commitment to the study is questionable.
265		28 day screening window closed
266		28 day screening window closed
267		28 day during window closed
268		participant's bleeding patterns are concerning
269		PPt has lump in her breast that requires follow up at hospital
270		28 day screening window closed.
271		28 day screenign window closed
272		28 days screening window closed
273		28 day screening window closed
274		ppt is not a suitable candidate for the study - she plans to study further and possibly relocate
275		bleeding pattern yet to be established on oral contraception
276		28 day screening window closed
277		28 day screening window closed
278		28 day screening window closed.
279		ppt is obese - pelvic exam cannot be done, also hypertensive
280		28 day screening window closed
281		DIfficulty with pelvic exam
282		28 day screening window closed
283		28 day screening window closed
284		ppt has irregular prolonged bleeding patterns.
285		patner objects participant's study participation
286		ppt is a poor historian
287		Participant reported that she is no longer interested in the study

Listing of Other Reasons for Ineligibility by Site

Obs	Site	Reason
288		28 day scr/enr window closed
289		participant is relocated
290		Ppt is a learner and may not be able to honour study visits.
291		28 day screening window has closed
292		IOR discretion prolonged bleeding and unclear history
293		ior descretion
294		Clinical discretion
295		28 day screening/enrollment visit window has closed.
296		IOR discretion
297		28 day screening window closed
298		ppt disclosed that she is already aware of her hiv positive status.
299		28 day screening/enrollment visit window has closed.
300		28 day screening window closed
301		participant reported that she already knows her HIV positive status
302		28 day screening window closed
303		Ppt's bleeding patterns are of concern.
304		ppt refusing pelvic exams and refusing to wear VR.
305		28 day screening window closed
306		28 day screening window closed.
307		screening window for 28 days has closed
308		uncontrolled hypertension
309		clinical discretion
310		participant is obese
311		participant allergic to latex
312		28 day screening window closed
313		latex allergy
314		participant is working and can't get time to come for her study visits.
315		Participant declined enrollment
316		participant is lactating screened out at IOR discretion
317		28 day screening window closed.
318		28 day screening window closed
319		participant shows lack of commitment
320		Ppt is no longer interested in the study.
321		participant reported that she is no longer interested in the study
322		28 day screening window closed
323		Participant is not interested in the study

Listing of Other Reasons for Ineligibility by Site

Obs	Site	Reason
324		28 day screening window closed
325		28 day screening window window
326		28 day screening window closed
327		28 day screening window closed
328		ppt failed to truthfully disclose previous trial participation
329		ppt is still at school
330		28 day screening window closed.
331		Participant doesn't seem to be a good candidate for the study (IOR discretion)
332		28 day screening window closed
333		28 day screening window closed
334		latex allergy
335		ppt has renal disease.
336		haematological abnormality
337		28 day screening window closed
338		28 day screening window closed.
339		28 day screening window closed
340		28 days screening window closed
341		participant did not return for enrollment. screening/enrollment window closed.
342		participant did not return for enrollment. screening/enrollment window closed.
343		clinical discretion
344		Latex allergy
345		accrual reached
346		accrual reached
347		site reached accrual target
348		Participant gave discrepant information on several occassions
349		28 day screening windown closed.
350		lack of commitment.
351		accrual reached
352		Ppt is a poor historian and is unclear about her motives for joining the study - she is not a go...
353		28 day screening window closed
354		28 day screening window closed.
355		Ppt does not understand the IC
356		28 day screening window closed.
357		28 day screening window closed
358		accrual reached
359		28 day screening window closed

Listing of Other Reasons for Ineligibility by Site

Obs	Site	Reason
360		accrual reached
361		28 day screening window closed
362		28 day screening window closed
363		Ppt failed to understand the IC
364	SA - MRC/Chatsworth	screening window closed.
365		screening window closed
366		unlikely to attend future study visits
367		unlikely to adhere to study visits
368		Unlikely to comply with study procedures and visits
369		ppt is lactating
370		IOR discretion
371		not likely to comply with study requirements
372		ppt now working
373		participant will not be able to come for visits
374		ppt not willing to comply to study procedure
375		declines study procedures
376		screening window closed.
377		unable to attend study visits
378		screening pause and enrolment pause at site
379		enrolment paused at site
380		enrolment paused at site
381		Ppt was uncertain of using ring daily and not comfortable
382		pain and bleeding during condom use
383		family resides in eastern cape.
384		uncontrolled BP
385		uncontrolled BP
386		latex allergy
387		uncontrolled hypertension
388		uncomfortable with monthly blood draws
389		uncontrolled hypertension
390		ppt withdrew consent
391		uncontrolled hypertension
392		uncontrolled hypertension
393		IOR discretion
394		not willing to not use other investigational products
395		window closed

Listing of Other Reasons for Ineligibility by Site

Obs	Site	Reason
396		Ppt unreliable.
397		Ppt no longer interested in study.
398		ppt window closed
399		window closed
400		uncontrolled hypertension
401		ppt displays poor comprehension
402		inadequate locator
403		difficult blood draw
404		ongoing metrorrhagia
405		uncontrolled hypertension
406		unexplained intermittent pelvic pain
407		enrolment paused at site
408		due to participant unavailability
409		enrolment paused at site
410		enrolment paused at site
411		partner doesn't want her to be in the study
412		unexplained amenorrhoea.
413		unexplained heavy bleeding
414		enrolment paused at site
415		IOR discretion-unreliable ppt
416		unable to comply with study procedures
417		lactation - recently stopped breastfeeding
418		ppt is a difficult bleed for blood draw
419		window closed
420		IOR discretion
421		ppt is no longer sexually active and not interested in participation in study.
422		uncontrolled hypertension
423		ppt still in high school
424		window closed.
425		heavily bleeding
426		suicidal ideation, social stressors
427		uncontrolled BP
428		IOR discretion
429		window closed.
430		inadequate proof of identity
431		window closed

Listing of Other Reasons for Ineligibility by Site

Obs	Site	Reason
432		ppt window closed
433		uncontrolled diabetes mellitus
434		IOR discretion
435		ppt experiences anxiety during blood draws.
436		IOR discretion
437		window closed
438		ppt does not want to complete pelvic exam.
439		unlikely to have time to attend to clinic visits
440		window closed.
441		uncontrolled bp
442		vaginal pain due to condom use
443		pregnancy outcome 2 months ago
444		unexplained breast lumps and poor adherence to contraception
445		uncontrolled blood pressure/prefers tubal ligation
446		gynecologic procedure less than 90 days
447		window closed
448		ppt withdrew consent
449		ppt withdrew constent
450		ppt cannot come for visit due to personal comittments
451		window closed
452		referred for colposcopy. ASCUS. HGSIL not excluded
453	SA - MRC/Isipingo	difficult blood draw
454		unclear, unexplained menstrual history
455		? on reliable contraception
456		uncontrolled active asthma
457		uncontrolled elevated blood pressure
458		unexplained irregular menses
459		uncontrolled chronic condition (diabetus mellitus)
460		unable to attend the clinic
461		window closed
462		Unexplained amenorrhoea and intermittent pelvic pain
463		unexplained gynaecological finding
464		window closed
465		obese & chronic vaginal, cervical and adnexal pain & chronic constipation
466		screening window elapsed
467		window elapsed

Listing of Other Reasons for Ineligibility by Site

Obs	Site	Reason
468		window closed
469		participant employed - unable to attend clinic visits
470		Abnormal PAP findings
471		unable to attend clinic
472		lactating and likely to be breastfeeding
473		Window closed
474		uncontrolled chronic condition
475		window closed
476		window closed
477		window closed
478		window closed
479		window closed
480		window closed
481		window closed
482		window closed
483		screening window closed
484		side-effects experienced due to contraceptive use
485		using recreational drugs
486		window closed
487		window closed
488		participant scared of using ring
489		window closed
490		IOR discretion
491		bad obstetric history
492		screening window elapsed.
493		participant reported that she stopped breastfeeding only 10 days ago.
494		uncontrolled/chronic condition
495		screening window elapsed
496		dysfunctional uterine bleeding
497	SA - MRC/Tongaat	not sexually active
498		Ppt is a difficult phlebotomy
499		diagnosed with UTI
500		over 28 day of enrolment.
501		inconsistent menstrual history
502		over 28 days of enrolment.
503		over 28 days to enrol

Listing of Other Reasons for Ineligibility by Site

Obs	Site	Reason
504		over 28 days to enrol
505		due to morbid obesity and difficult phlebotomy
506		ppt referred for shortness of breath management
507		over 28 days to enrol
508		over 28 days to enrol
509		see comment
510		ppt had recent suicide attempt
511		ppt required repeat PAP in 4 weeks. will come for rescreening.
512		see comments
513		ppt refused to continue
514		enrollment window closed
515		visit window has closed
516		see comment below
517		ppt enrollment window has closed
518		visit window has closed
519	SA - MRC/Umkomaas	possible cancer remission
520		Unexplained amenoritoea
521		difficult pelvic exam-unable to obtain pap smear-cervix could not be visualised
522		difficult pelvic and participant unlikely to comply with study requirements
523		participant is afraid about how partner will react to her study participation
524		participant is afraid of her partner
525		participant not reliable. window closed.
526		enrollment hold
527		screening window closed. on 27may13
528		uncontrolled chronic condition - epilepsy
529		IOR discretion - ppt intentionally gave discrepant information
530		uncontrolled chronic condition
531		screening window closed
532		Underlying cardiovascular dx
533		uncontrolled elevated BP
534		unexplained amenorrhoea
535		screening window closed on 25feb13
536		latex allergy
537		Ppt chose not to proceed with the study
538		unable to attend clinic visits
539		window closed

Listing of Other Reasons for Ineligibility by Site

Obs	Site	Reason
540		unreliable participant
541		reqiures repeat pap.
542		unlikley to fulfill study requirements
543		participant was unable to complete screening visit within window.
544		participant unable to complete enrollment visit within window
545		uncontrolled hypertension
546		pregnancy outcome less than 90 days ago.
547		IOR discretion - unexplained irregular menses
548		no endocervical component on pap
549		unexplained irregular menstrual cycle
550		difficult pelvic exam, unable to visualise cervix
551		ppt unable to keep to scheduled visits
552		screening window closed on 23may13
553		ppt does not want to give blood. terrified of needles.
554		no endocervical component on pap
555		participant not reliable - did not return for completion of screening
556		Uncontrolled elevated blood pressure
557		participant had a total abdominal hysterectomy
558		Unable to conduct pelvic exam
559		ppt lactating
560		participant did not return for visit.
561		unable to contact participant
562		history of palpitations with chest pain
563		unexplained irregular bleeding patterns
564		severe uncontrolled arthritis
565		participant afraid of using ring.
566		Participant not reliable in adhering to scheduled visits
567		Participant not reliable in adhering to scheduled visits
568	SA - MRC/Verulam	enrollment halted due to poor adherence
569		grade 4 headache: further details required from participant as per IoR discretion
570		abdominal mass as per IoR discretion
571		uncontrolled condition - irregular menses as per IOR discretion
572		unintentional weight loss (6%)
573		ppt. not hiv-uninfected per appendix II, IoR/designee decision.
574		as per ICR/designee discretion
575		discordant results at enrollment

Listing of Other Reasons for Ineligibility by Site

Obs	Site	Reason
576		undiagnosed medical condition
577		unexplained amenorrhoea
578		lactating with engorged breasts
579		uncontrolled hypertension
580		lactating
581		discordant hiv results at screening
582		ppt is lactating
583		Discordant HIV results at screening
584		very irregular menstrual pattern.
585		discordant rapids at enrolment
586		difficulty to visualize cervix
587	SA - WRHI	retention concern
588		difficult blood draw-all attempts unsuccessful
589		History of uninvestigated dyspareunia
590		retention concern due to behavior with staff
591		window has closed for enrolment
592		participant allergic to latex
593		retention concern
594		participant has high blood pressure and refusing to use suitable contraceptive method.
595		Partner is HIV positive and participant reported burst condom incident the night before screening...
596		Participant has an uncontrolled thyroid condition
597		participant not keen on randomization
598		participant uncomfortable iwth pelvic exam and blood draws.
599		study product adherence concern
600		Participant not comfortable with blood draws
601		potential suicide concern
602		participant is afraid to insert the ring and is no longer interested in study participation
603		Does not want to use the vaginal ring
604		no longer interested due to parental influence
605		Retention concern as participant does not get regular leave and works from Monday to Friday.
606		prior trial participation (MDP)
607		gynaecological procedure (top) done less than three months ago.
608		known adverse reaction to latex
609		investigator decision
610		For discretion - Retention concerns
611		retention concerns

Listing of Other Reasons for Ineligibility by Site

Obs	Site	Reason
612		Participant does not want to have blood drawn from her again window for enrolment closed
613		retention concern on do not enrol
614		diagnosed with bipolar mood disorder
615	Uganda - Kampala	enrolment pause, screening window closed due to pause
616		Enrollment pause, screening window closed due to pause
617		enrollment pause, screening window closed due to pause
618		ongoing enrolment pause
619		Screening window closed before we could enroll her due to enrolment pause.
620		Participant may not adhere to study product as partner is suspicious of product when she disclose...
621		participant has a new job and may not adhere to study visits.
622		screening window closed before we could enrol her due to pause in enrolment
623		has uncontrolled chronic cardiovascular disease
624		ongoing enrolment pause
625		last pregnancy outcome < 90 days
626		participant fears use of study ring and would want to continue using herbs in the vagina.
627		partner refused participation to participate in the study.
628		Participant did not come for enrolment visit despite many attempts to contact her.
629		Participant did not return for enrolment, screening window closed.
630		emotionally unstable
631		has had treatment for candidasis 4 or more times.
632		participant's interest mainly iucd, not the study (aspire).
633		participant not likely to adhere to study visits
634		she is out of enrolment window
635		participant no longer interested in study
636		non-adherence to visits
637		partner refused participant to enrol/participate in study
638		husband refused her to participate in study
639		non-adherence to pre-enrollment visits.
640		out of window for enrolment
641		out of enrolment window
642		got a new job and will not adhere to study visits
643		participant plans to continue using oil based lubricant together with study ring if enrolled.
644		recurrent vaginal candidiasis
645		participant no onger intersted in participating in the study
646		chronic vaginal candidiasis

Listing of Other Reasons for Ineligibility by Site

Obs	Site	Reason
647		vaginal practices will complicate interpretation of study outcome data
648		participant not likely to be retainable
649		discordant rapid tests (HIV)
650		participant has lots of problems and feels she may not be able to participate well
651		Partner refused her to participate in study
652		indeterminate hiv rapid results
653		has adverse reaction to latex
654		Participant not likely to be retainable
655		Participant husband not supportive of her participation
656		enrolment pause, screening window closed due to pause
657		enrolment pause
658		pause in enrollment, screening window closed due to pause
659		participant does not have adequate locator information and may find it difficult ot adhere to stu...
660		participant not interested in ring use.
661		participant likely not to be retainable
662		she expects financial assistance from the study
663		participant not likely to be retainable
664		inadequate locator information
665		participant's boss refused her to participate in study
666		participant unlikely to adhere to study visits.
667	Zimbabwe - Seke South	participant refused enrollment.
668		exceeded 28 day window to enrol
669		referred to central hospital for pre-existing pv bleeding on implant inserted
670		participant is on treatment for mental illness
671		Per IOR's discretion
672		exceeded 28 day window to enroll.
673		investigator decision
674		allergic to latex
675		IOR's discretion
676		Ior discretion
677		investigator's discretion
678		participant not at high risk of contracting HIV
679		participant not high risk
680		uncontrolled hypertension
681		see comments below
682		IoR discretion

Listing of Other Reasons for Ineligibility by Site

Obs	Site	Reason
683		high number of preexisting conditions and poor understanding of study objectives
684		ior discretion - not deemed high risk
685		participant not enrolled due to irb approval lapse
686		IOR's discretion
687		Difficult pelvic exam
688		inadequate locator information
689		participant had indeterminate HIV rapid test results.
690		uncontrolled/chronic condition
691		exceeded 28 day window to enrol
692		exceeded 28 day window to enrol
693	Zimbabwe - Spilhaus	window closed
694		participant reported vaginal itchiness which has not been investigated. episodes are frequent.
695		unlikely to have good study packet adherence
696		screening window closed
697		HIV indeterminate result
698		awaiting biopsy results
699		participant deliberately misrepresented facts to study staff
700		poor comprehension -cannot give a consistent history
701		screening window closed
702		screening window closed
703		screening window closed
704		participant has other commitments
705		inadequate pap smear.
706		unlikely to adhere to visit schedule.
707		screening window closed
708		uncontrolled raised grade 2 blood pressure
709		hiv indeterminant
710		participant likely to have adherence and retention problems
711		screening window closed
712		Gyn/genitqal procedure within 90 days.
713		poor historian. information not consistent
714		immunological disorder
715		participant needs further evaluation.
716	Zimbabwe - Zengeza	28 day window closed before enrolment
717		28day window closed before enrolment
718		uncontrolled / chronic condition

Listing of Other Reasons for Ineligibility by Site

Obs	Site	Reason
719		28day window closed before enrolment
720		28 day window closed before enrollment
721		inadequate locator information
722		28 day window closed before enroment
723		Enrolment deferred, then window closed before participant enrolled.
724		day window closed before enrolment
725		partner denied participant to participart in the study
726		28 day window closed before enrolment
727		28 day window closed before enrolment.
728		28 day window closed before enrolment
729		28 day window closed before enrolment
730		28 day window closed before enrollment
731		inadequate locator
732		participant did not come for enrollment with 28 day window closed.
733		participant could not be enrolled within the window due to IRB approval lapse
734		participant could not be enrolled within the window due to an irb approval lapse.
735		28 day window closed before enrollment
736		item 3 of screening behavioural eligibility
737		28 day window closed before enrollment
738		chronic vaginal candidiasis
739		enlarged goitre. grade 1
740		uncontrolled hypertension grade 3
741		28 day window close before enrolment
742		chronic vaginal candidiasis
743		Uncontrolled grade 2 hypertension
744		last pregnancy outcome less than 90 days prior to enrolment
745		could not provide adequate locator details until visit window closed
746		no verifiable contraceptive documentation and inadequate location information until window closed.
747		allergic to latex
748		missed enrolment visit. was bleeding secondary to depo provera
749		chronic vaginal candidiasis
750		uncontrolled blood pressure
751		uncontrolled blood pressure
752		Grade 1 Migraine
753		raised blood pressure.

Listing of Other Reasons for Ineligibility by Site

Obs	Site	Reason
754		uncontrolled / chronic condition
755		hypertension is poorly controlled