

**MTN 023 - Study of Dapivirine Vaginal Ring (VR) in Adolescents**  
**Report - June 6, 2022**  
**Visit Cutoff Date: June 6, 2022**  
**. Screen-out Summary by Site**

	Birmingham, AL	Bronx, NY	Denver, CO	Fenway, MA	Memphis, TN	Pittsburgh, PA	All Sites
Participants Screened	10	22	30	12	29	25	128
Participants Enrolled <sup>1</sup>	9 (90%)	16 (73%)	23 (77%)	10 (83%)	18 (62%)	20 (80%)	96 (75%)
Participants not Enrolled	1 (10%)	6 (27%)	7 (23%)	2 (17%)	11 (38%)	5 (20%)	32 (25%)
Participant did not complete all screening procedures	0 (0%)	0 (0%)	1 (3%)	0 (0%)	0 (0%)	0 (0%)	1 (1%)
Participant is eligible but declined enrollment	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (3%)	1 (4%)	2 (2%)
Reason participant not enrolled is missing	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Participant not eligible <sup>2</sup>	1 (10%)	6 (27%)	6 (20%)	2 (17%)	10 (34%)	4 (16%)	29 (23%)
Participant < 15 or > 17 years old	1 (100%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (3%)
Participant not Tanner stage 4 or 5 at Screening	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Participant HIV infected at Screening or Enrollment	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Participant has no reported history of penile-vaginal intercourse at Screening	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Participant has positive pregnancy test at Screening or Enrollment	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (10%)	0 (0%)	1 (3%)
Participant does not agree to use effective method of contraception during protocol-specified time period	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Participant plans to become pregnant during the study participation period	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Participant plans to relocate from study site during study or plans to travel away from site for more than 4 consecutive weeks	0 (0%)	0 (0%)	0 (0%)	1 (50%)	0 (0%)	0 (0%)	1 (3%)
Participant diagnosed with urinary tract infection (UTI) and/or reproduction track infection (RTI) which has not resolved	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Participant diagnosed with pelvic inflammatory disease (PID) or STI within 60 days of enrollment	0 (0%)	0 (0%)	0 (0%)	0 (0%)	4 (40%)	1 (25%)	5 (17%)
Participant has a grade 2 or higher pelvic exam finding at Enrollment	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Participant report of 3 or more penile-vaginal sexual partners in the month prior	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Participant does not meet laboratory eligibility criteria	0 (0%)	2 (33%)	4 (67%)	0 (0%)	1 (10%)	1 (25%)	8 (28%)
Participant does not meet other clinical eligibility criteria	0 (0%)	2 (33%)	1 (17%)	0 (0%)	0 (0%)	0 (0%)	3 (10%)
Other reason, including investigator decision	0 (0%)	2 (33%)	1 (17%)	2 (100%)	4 (40%)	2 (50%)	11 (38%)

<sup>1</sup> 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.

<sup>2</sup> Participants may be ineligible for more than one reason.

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**. Listing of Other Reasons for Ineligibility by Site**

<b>Obs</b>	<b>Site</b>	<b>Reason</b>
1	Bronx, NY	Concerns that participant will not comply, lack of followup, unable to reconent parent and parti...
2		mother withdrawing consent.
3	Denver, CO	unable to comply with all study procedural requirements (unable to complete visits).
4	Fenway, MA	Pt. not currently on contraception. Will turn 18 years old in next 30 days
5		surgery pending 5/2015 for hydrocephaly complication
6	Memphis, TN	Ppt did not get refills for 30 day birth control and never returned for rescreening
7		unable to comply with study visit
8		unable to comply with study visits
9		Unable to confirm on birth control for 30 days and declined enrollment
10	Pittsburgh, PA	difficulty tolerating pelvic exam, concerns < compliance
11		inconsistent history