

**MTN 029 - Phase 1 Pharmacokinetic Study of the Dapivirine Vaginal Ring in Lactating Women
Data as of June 6, 2022**

Screen-out Summary by Site

	Pittsburgh	Birmingham	All Sites
Participants Screened	12	20	32
Participants Enrolled ¹	8 (67%)	8 (40%)	16 (50%)
Participants not Enrolled	4 (33%)	12 (60%)	16 (50%)
Participant did not complete all screening procedures	0 (0%)	0 (0%)	0 (0%)
Participant is eligible but declined enrollment	0 (0%)	2 (10%)	2 (6%)
Participant is eligible but accrual closed prior to enrollment	0 (0%)	1 (5%)	1 (3%)
Reason participant not enrolled is missing	0 (0%)	0 (0%)	0 (0%)
Participant not eligible ²	4 (33%)	9 (45%)	13 (41%)
< 18 years old	0 (0%)	0 (0%)	0 (0%)
< 6 weeks postpartum at Enrollment	0 (0%)	0 (0%)	0 (0%)
HIV infected at Screening or Enrollment	0 (0%)	0 (0%)	0 (0%)
Is still breastfeeding child at Enrollment	0 (0%)	2 (22%)	2 (15%)
Intends to provide expressed breast milk to her child(ren) or others for consumption after study product initiation	0 (0%)	0 (0%)	0 (0%)
Does not agree to use effective method of contraception during protocol-specified time period	0 (0%)	0 (0%)	0 (0%)
Unwilling/unable to express breast milk at least twice daily for the duration of study drug exposure	1 (25%)	1 (11%)	2 (15%)
Unable/unwilling to provide written informed consent	0 (0%)	0 (0%)	0 (0%)
Unwilling/unable to communicate in spoken and written English	0 (0%)	0 (0%)	0 (0%)
Does not agree to refrain from participation in other research studies for the duration of study participation	0 (0%)	0 (0%)	0 (0%)
Has significant or uncontrolled active or chronic disease, as defined in protocol	0 (0%)	1 (11%)	1 (8%)
Diagnosed with UTI, STI, and/or RTI at Screening or Enrollment, which has not resolved or undergone complete treatment	0 (0%)	0 (0%)	0 (0%)
Unwilling to refrain from use of vaginal products during study participation, as reported at Screening	0 (0%)	0 (0%)	0 (0%)
Has grade 2 or higher pelvic exam finding at Enrollment or incomplete postpartum involution of the uterus	0 (0%)	0 (0%)	0 (0%)
Unwilling to refrain from receptive sexual activity or insertion of nonstudy objects into vagina for 24 hours prior to each visit	0 (0%)	0 (0%)	0 (0%)
Milk supply < 1 ounce per expression, at Screening and Enrollment	2 (50%)	3 (33%)	5 (38%)
Use of oral and/or vaginal preparations of antibiotic or antifungal medications, within 5 days prior to Enrollment	0 (0%)	0 (0%)	0 (0%)
Unwilling/unable to provide adequate locator information	0 (0%)	0 (0%)	0 (0%)

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.

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No documented satisfactory Pap result, per protocol	0 (0%)	2 (22%)	2 (15%)
Participated in investigational drug/device trial within 30 days prior to enrollment	0 (0%)	0 (0%)	0 (0%)
Has Grade 2 or higher AST/ALT at Screening	0 (0%)	0 (0%)	0 (0%)
Other, including investigator decision	1 (25%)	1 (11%)	2 (15%)

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Listing of Other Reasons for Ineligibility by Site

Obs	Site	Reason
1	Birmingham	Infant weaning not complete before screening window closed.