

**MTN 024 - Study of Dapivirine Vaginal Ring (VR) in a Postmenopausal Female Population
Data as of December 7, 2015**

Screen-out Summary by Site

| | Birmingham, AL | Cleveland, OH | Pittsburgh, PA | All Sites |
|--|----------------|---------------|----------------|-----------|
| Participants Screened | 61 | 76 | 63 | 200 |
| Participants Enrolled ¹ | 32 (52%) | 32 (42%) | 32 (51%) | 96 (48%) |
| Participants not Enrolled | 29 (48%) | 44 (58%) | 31 (49%) | 104 (52%) |
| Participant did not return (refused or lost contact) | 1 (2%) | 1 (1%) | 0 (0%) | 2 (1%) |
| Participant is eligible but declined enrollment | 3 (5%) | 1 (1%) | 0 (0%) | 4 (2%) |
| Reason participant not enrolled is missing | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Participant not eligible ² | 25 (41%) | 42 (55%) | 31 (49%) | 98 (49%) |
| Participant <45 or >65 years old | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Participant not post-menopausal, as described in the protocol | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Participant FSH level <40 ml u/ml | 11 (44%) | 21 (50%) | 2 (6%) | 34 (35%) |
| Participant not able to provide adequate locator information | 1 (4%) | 2 (5%) | 0 (0%) | 3 (3%) |
| Participant not able or willing to provide written informed consent | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Participant pregnant at screening | 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%) | 0 (0%) |
| Participant diagnosed with urinary tract infection (UTI) which has not resolved | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Participant diagnosed with pelvic inflammatory disease, and STI or reproductive tract infection (RTI), which has not resolved | 1 (4%) | 0 (0%) | 0 (0%) | 1 (1%) |
| Participant has grade 2 or higher pelvic exam finding | 1 (4%) | 2 (5%) | 0 (0%) | 3 (3%) |
| Participant does not meet laboratory eligibility criteria | 9 (36%) | 6 (14%) | 2 (6%) | 17 (17%) |
| Participant HIV-positive at screening or enrollment | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Participant does not meet other clinical eligibility criteria | 3 (12%) | 8 (19%) | 9 (29%) | 20 (20%) |
| Other reason, including investigator decision | 6 (24%) | 7 (17%) | 22 (71%) | 35 (36%) |

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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Listing of Other Reasons for Ineligibility by Site

| Obs | Site | Reason |
|------------|----------------|--|
| 1 | Birmingham, AL | has used hormone replacement therapy in last 6 months. |
| 2 | | uncontrolled hypertension |
| 3 | | ppt extremely anxious regarding study product and procedures |
| 4 | | Ppt. unable to complete all visits |
| 5 | | abnormal PAP |
| 6 | | grade 3 hypertension |
| 7 | Cleveland, OH | condition that would complicate the interpretation of study outcome data |
| 8 | | pap test abnormal. subject is to have calposcopy. |
| 9 | | site's enrollment target was met |
| 10 | | not in general good health as determined by ior. |
| 11 | | subject is poor historian which will complicate the interpretation of the study outcome data & in... |
| 12 | | lor believes subject's study participation would be unsafe + would complicate the interpretation ... |
| 13 | | site's enrollment target was met |
| 14 | Pittsburgh, PA | Current neurologic problems which are not thoroughly evaluated at this time |
| 15 | | Sites enrollment target met. |
| 16 | | not in general good health due to multiple medical problems |
| 17 | | not in general good health. uncontrolled hypertension. |
| 18 | | not in general good health |
| 19 | | Not in general good health |
| 20 | | not in general good health |
| 21 | | not in general good health |
| 22 | | difficulty performing pelvic exam |
| 23 | | not in general good health |
| 24 | | uncontrolled unmonitored hypertension. |
| 25 | | untreated hypertension noted at screening |
| 26 | | uncontrolled hypertension |
| 27 | | hostile and verbally abusive to staff |
| 28 | | could not tolerate speculum exam |
| 29 | | hypertension, uncontrolled and unmonitored. |
| 30 | | not in good general health |
| 31 | | not good general health |
| 32 | | not good general health |
| 33 | | not in good general health |
| 34 | | Not in general good health |
| 35 | | vulvar changes/findings and fissure makes her ineligible per P.I. decision |