

**HPTN 076 - Phase II Safety and Acceptability of an Investigational Injectable Product, TMC278 LA, for Pre Exposure Prophylaxis (PrEP)
Data as of 16JAN18**

Table 1 - Type of Protocol Deviations and Enrollment Violations by Site

| | Bronx CRS | New Jersey CRS | Emavundle ni CRS | Spilhaus CRS | Overall |
|--|-----------|-------------------|---------------------|-----------------|----------|
| Participants Enrolled | 19 | 17 | 48 | 52 | 136 |
| Number of Protocol Deviations and Enrollment Violations | 0 | 7 | 5 | 2 | 14 |
| Type of Protocol Deviations and Enrollment Violations | | | | | |
| Inappropriate enrollment | 0 (-%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Failure to follow trial randomization or blinding procedures | 0 (-%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Study product management deviation | 0 (-%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Study product dispensing error | 0 (-%) | 1 (14%) | 1 (20%) | 0 (0%) | 2 (14%) |
| Study product use/non-use deviation | 0 (-%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Study product sharing | 0 (-%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Study product not returned | 0 (-%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Conduct of non-protocol procedure | 0 (-%) | 0 (0%) | 1 (20%) | 0 (0%) | 1 (7%) |
| Improper AE/EAE follow-up | 0 (-%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Unreported AE | 0 (-%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Unreported EAE | 0 (-%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Breach of confidentiality | 0 (-%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Physical assessment deviation | 0 (-%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Lab assessment deviation | 0 (-%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Mishandled lab specimen | 0 (-%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Staff performing duties that they are not qualified to perform | 0 (-%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Questionnaire administration deviation | 0 (-%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Counseling deviation | 0 (-%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Use of non-IRB/EC-approved materials | 0 (-%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Use of excluded concomitant meds, devices, or non-study products | 0 (-%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Informed consent process deviation | 0 (-%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Visit completed outside of window | 0 (-%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Other | 0 (-%) | 6 (86%) | 3 (60%) | 2 (100%) | 11 (79%) |