

To: MTN 016 Protocol Team
From: MTN 016 SCHARP Team
RE: MTN 016 Retention Report

Table Description

While the study is ongoing, retention is evaluated with respect to scheduled visits. For each scheduled visit, a participant is expected to have returned to the site clinic within a protocol- specified visit window. We evaluate retention only for scheduled visits that are expected; that is, visits for which the allowable window has passed. The proportion retained at a scheduled visit is obtained by dividing the number of participants who have completed the visit by the number of participants expected for that visit.

The follow-up visit schedule differs between women and infants enrolled in MTN-016. Therefore, the retention data for the two cohorts is provided in separate reports. In determining which visits are "expected" it is important to note that follow-up is dependent on the time of enrollment. Women can enroll anytime during pregnancy and up to within one year after the pregnancy outcome, and follow-up visits are to take place from enrollment until the pregnancy outcome. The number of expected follow-up visits is dependent on how much time remains in the pregnancy. For example, a woman who enrolls in MTN-016 after her pregnancy outcome will not have any expected follow-up visits. Similarly, infants can be enrolled anytime from birth up to one year after birth. Again, depending on the infant's age at the time of enrollment determines how many follow-up visits will be expected.

For this report, retention has been calculated for the visits which are expected through the date of this report.

Thank you.