Statistical Center for
HIV/AIDS Research & Prevention
SCHARP

MEMORANDUM

To: MTN 005 Protocol Team

From: MTN 005 SDMC

RE: MTN 005 Visit Adherence and Procedure Completion Report

Purpose

To summarize site performance regarding study primary endpoint data collection, by site and overall, with particular attention given to: 1) Distribution of visits, as the number of days between target and actual visit dates, 2) the number of days between sequential visits; 3) Number and percentage for completing the required procedures - pelvic exams; pregnancy tests; colposcopic exams; ring adherence assessments; ACASI questionnaires; storage of plasma for resistance testing; storage of gram stain, vaginal and cervical swabs for evaluating the vaginal micro-environment; and HIV tests.

Expectations and Data Used in this Report

The measures above can only be accurately assessed if the relevant forms are expected to have been collected in the database, and have actually been received. For purposes of this report, forms are expected for visits for which the allowable window has passed. Participant visits are required and expected only if the participant presents herself at the site for a visit. Missed visits are not considered expected for purposes of this report.

Table Descriptions

Distribution of Visits: Number of Days Between Target and Actual Visit Dates

For each of the visits in follow-up, we subtract the actual visit date from the target visit date among visits that were expected and completed (missed visits are not considered). The table provides the following statistics which describe the distribution of time between target and actual visit dates: 1) “N”, which is the number of participant visits being summarized; 2) “Mean”, which is the average, a mean greater than 0 indicates the actual visit occurred after the target date, on average, and a mean less than 0 indicates the actual visit occurred before the target date, on average; “SD”, which is the standard deviation; 3) “Median”, which is the median, or middle value of the distribution; 4) “25th%tile”, which is the first quartile; “75th %tile”, which is the third quartile; and 5) “Min”, which is the minimum or the lowest value; “Max”, which is the maximum or the highest value.

Distribution of Visits: Number of Days Between Sequential Visits

For all participants, we summarize the table by subtracting the two visit dates of the visits that are consecutive to each other (the date of the current month and the date of the previous month), among

visits that were expected and completed (missed visits are not considered). The table provides the following statistics which describe the distribution of time between sequential monthly visits: 1) “N”, which is the number of participant-visits being summarized; 2) “Mean”, which is the average; “SD”, which is the standard deviation; 3) “Median”, which is the median, or middle value of the distribution; 4) “25th%tile”, which is the first quartile; “75th%tile”, which is the third quartile; and 5) “Min”, which is the minimum or the lowest value; “Max”, which is the maximum or the highest value;.

Completion of Procedures: (Pelvic exams; Pregnancy tests; colposcopic exams; ring adherence assessments; ACASI questionnaires; Storage of plasma for resistance testing; Storage of gram stain, vaginal and cervical swabs for evaluating the vaginal micro-environment and HIV tests)

Each of the measures in this table has separate requirements regarding the visits at which the procedures are required, and the data elements on the Case Report Form (CRF) that must be received in order for the procedure to be considered “completed.” This study has procedures that need to be completed at enrollment, 4 week follow-up visits, and termination visits.

Pelvic exams are required at all scheduled visits for all participants. A pelvic exam is considered “Completed” if “abnormal findings” or “no abnormal findings” box is marked for item 1 on the Pelvic Exam CRF.

Pregnancy tests are required of all participants at termination visit. A pregnancy test is considered “Completed” if the “negative” or “positive” box is marked for the “hCG for pregnancy” item on the Follow-up Visit CRF.

Colposcopic exams are required at week 12 and termination visits for all participants. A colpo exam is considered “Completed” if “abnormal findings” or “no abnormal findings” box is marked for item 7 on the Pelvic Exam CRF.

Ring adherence assessment data is collected on RA CRF and at all follow-up visits for IVR (Intravaginal Ring) cohort. This assessment collects information on product adherence. This is said to be completed if item 3 has a response on the RA CRF.

ACASI questionnaires are required at all scheduled visits for all participants based on which cohort they are assigned to. An ACASI questionnaire is considered “Completed” if there is a response recorded for item 6 on the Follow-up Visit CRF.

Plasma storage is a measure for resistance testing and is required only at the enrollment visit. This procedure is considered “Completed” if the response to item 1 on the Specimen Storage CRF is marked “stored”.

Storage of gram stain is a measure for vaginal micro-environment and is required at all scheduled visits. This procedure is considered “Completed” if the response to item 2 on the Specimen Storage CRF is marked “stored”.

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Storage of vaginal swabs (PCR and culture) is a measure for vaginal micro-environment and is required at all scheduled visits. This procedure is considered “Completed” if the responses to item 3 and item 4 on the Specimen Storage CRF are marked “stored”.

Storage of cervical swabs is a measure for vaginal micro-environment and is required at enrollment and termination visits. This procedure is considered “Completed” if the response to item 5 on the Specimen Storage CRF is marked “stored”.

HIV test is required of all participants at termination visit. An HIV test is considered completed if we receive a local laboratory results CRF with a marked response in item 5.

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