MTN-026 Data Communiqué #3 - June 28, 2018

This is official study documentation for MTN-026. Please circulate it among relevant staff for their review, print it, and place it in your MTN-026 SSP Manual in the Data Communiqués section. This document is considered part of the MTN-026 SSP Manual.

UPDATES

1. Updated Eligibility Criteria CRF
The field “Select inclusion and/or exclusion criteria that contributed to participant’s study ineligibility” has been updated to provide a 1:1 correlation with the inclusion/exclusion criteria specified per the MTN-026 protocol, Version 2.0, dated 21 July 2017. Specifically, the following criteria were added:

- Anticipated use of and/or unwillingness to abstain from the following medications during study participation:
  - Aspirin (greater than 81 mg)
  - Any other drugs that are associated with increased likelihood of bleeding

In addition, spelling errors were corrected, and a few minor wording updates were made for consistency.

If participants have screened out for any of the above criteria, sites should review and update the Eligibility Criteria CRF as appropriate.

An updated Medidata Rave eCRF output, Version 4.0, dated 28 June 2018, has been posted onto the MTN-026 Atlas webpage: https://atlas.scharp.org/cpas/project/MTN/026/begin.view?

2. CRF Completion Guidelines (CCGs)
The CRF Completion Guidelines have been updated to Version 1.3 (dated 28 June 2018) and are posted on the MTN-026 Atlas webpage (https://atlas.scharp.org/cpas/project/MTN/026/begin.view?) for download. A Summary of Changes summarizing the specific updates is included at the end of the CCGs document.

CLARIFICATIONS
No updates

REMINDERS
No updates