

MTN-037 Data Communiqué #1 - June 27, 2018

This is official study documentation for MTN-037. Please circulate it among relevant staff for their review, print it, and place it in your MTN-037 SSP Manual in the Data Communiqués section. This document is considered part of the MTN-037 SSP manual.

UPDATES

Eligibility Criteria CRF:

The field “Select inclusion and/or exclusion criteria that contributed to participant’s study ineligibility” was updated to provide a 1:1 correlation with the inclusion/exclusion criteria specified per the MTN-037 protocol, Version 1.0, dated 09 NOV 2017.

In addition, the inclusion/exclusion criterion numbers were added next to each inclusion/exclusion criterion per protocol, some spelling errors were corrected, and a few minor wording updates were made to accommodate for character length restrictions.

The updated Eligibility Criteria CRF, Version 2.0, dated 27 June 2018 is located on the MTN-037 Atlas webpage:

<https://atlas.scharp.org/cpas/project/MTN/037/begin.view?>

CLARIFICATIONS - None

REMINDERS - None