



## MTN-041 Data Communiqué #1 – 26 June 2018

This is official study documentation for MTN-041. Please circulate it among relevant staff for their review, print it, and file it in the Data Communiqués section of the MTN-041 SSP. This document is considered part of the MTN-041 SSP manual.

### CRF CLARIFICATIONS

#### CRF Completion Clarifications

1. Participant Status Form (PSF), has been updated to version 1.2, dated 26 Jun 2018. The updates include addition of item 7:

7.	FGD Number:	41 – F <input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> N/A
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Complete this item using the number of the FGD the participant has participated in (see SSP section 3.7). If the participant was not an FGD participant, mark “N/A”. If a participant does not complete an FGD for any reason, mark “N/A”.

For participants that have already completed their FGD (i.e. who have already had a PSF completed), no retrospective form updates are required.

Sites should follow all local IRB requirements for submission and approval of CRFs. If IRBs require approval of updated CRFs prior to implementation, sites should continue to use version 1.1 (05 Mar 2018) of this CRF in the interim and not delay any study activities while this approval is pending. Please notify the management team regarding any IRB approval requirements, and the date of implementation of this updated CRF.

Julia Ryan, RTI International  
Printed Name

DocuSigned by:  
*Julia Ryan*  
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Signature

6/26/2018  
Date