



MTN-032 Data Communiqué #2 – 08 July 2016

This is official study documentation for MTN- 032. Please circulate it among relevant staff for their review, print it, and place it in your MTN-032 SSP Manual in the Data Communiqués section. This document is considered part of the MTN-032 SSP manual.

CLARIFICATION

CRF Completion Clarification

1. Participant Status Form Phase 1, item 7

Mark this item based on the participant's drug detection level used for recruitment. This should match the level listed on the recruitment list. If a participant was recruited for an FGD and therefore does not have a drug detection level listed on the recruitment sheet, refer to that participant's visual tool and use the image for Month 3 blood plasma (as described in Operational Guidance #3). If the image is green then she is in the "high drug detection" group, if the image is white she is in the "low drug detection" group. If there is no blood plasma data for Month 3, use the next available blood plasma data to determine the drug detection level.

2. Participant Status Form Phase 1, item 8

Record all the participant's reaction(s) to receiving their individual drug level results. If the reaction is not listed or the response/reaction does not fit clearly into one of the provided options (e.g. "guilty"), do not try to fit into one of the provided options, instead mark "Other, specify" and write in the reaction on the specify line.