



## MTN-043 Operational Guidance #02: Change to criteria for purposive IDI participant selection

This operational guidance document changes the current Qualitative SSP guidance on the purposive selection of participants for in-depth interviews (IDIs) in MTN-043 given the insufficient enrollment of participants with medium (10-13) and high (>13) EPDS scores at enrollment required in the original IDI selection plan (described below). This document describes how to select participants for the remaining IDIs at each site. Sites should implement this new plan immediately upon receipt.

### Original qualitative target sample:

The original qualitative target sample was 12 IDIs at each site, stratified by product assignment ratio (3:1) and three EPDS score ranges at enrollment (low [0-9], medium [10-13], and high [>13]). That is, four participants with low scores at enrollment, of which three are assigned to the ring and one assigned to pills; four participants with medium scores at enrollment, of which three are assigned to the ring and one assigned to pills; and four participants with high scores at enrollment, of which three are assigned to the ring and one assigned to pills.

### Modified qualitative target sample:

Moving forward, there will be only two EPDS score ranges to consider when selecting participants for qualitative interviews. The original EPDS score range for “medium” (10-13) has been consolidated into the high category with a goal of enrolling four participants at each site from this group, three participants assigned to the ring and one participant assigned to pills. The target number of participants to enroll for low scores has been doubled to eight, with six ring users and two participants assigned to pills. Sites are instructed to fill all newly available low EPDS score IDI slots with participants who either next enroll with an EPDS score below 10 or are currently enrolled with an EPDS score below 10. The slots for high EPDS scores may be filled by participants currently enrolled and/or next enrolled who have a score of 10 or above ( $\geq 10$ ). \*If targets for high scores are unmet by the last enrollment at each site, participants who scored 0-9 on the EPDS at enrollment may be invited to fill the available slots.


### New purposive IDI targets per site:

| <b>EPDS Score</b>   | <b>Ring</b> | <b>Pills</b> | <b>Total</b> |
|---------------------|-------------|--------------|--------------|
| Low (0-9)           | 6           | 2            | 8            |
| High* ( $\geq 10$ ) | 3           | 1            | 4            |
| <b>Total</b>        | <b>9</b>    | <b>3</b>     | <b>12</b>    |

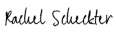
### Completing the QPL:

Sites are advised to cross out “medium” on the IDI slot list (rows 4-6 and 11) and write “low” next to/above it. Similarly, the word “medium” may be crossed out from the EPDS category title cell. The QPL should continue to be completed with the new guidance that any EPDS score of 10 or greater is categorized as a high score.

Please note that this Qualitative Operational Guidance is official study documentation and should be filed as part of Essential Documents.

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