



## MTN-042 Operational Guidance #08: End of Cohort 3 Accrual

This operational guidance document provides instruction to sites regarding the end of Cohort 3 accrual.

Based on reported screening and enrollment numbers as of 9 December 2022, it is anticipated that the study soon have enough participants in the pipeline to achieve the targeted N=250 participants enrolled.

- **Effective Friday, 16-Dec-2022, sites are instructed to stop recruitment/prescreening efforts. All remaining screening visits must be scheduled no later than Friday 23-Dec-2022.**
  - If participants are unable to attend screening visits prior to 23-Dec-2022, they should be counseled accordingly that they will be unable to screen for the study.
- **All participants who have completed screening visits as of 23-Dec-2022 will be allowed to proceed through to their scheduled enrollment visit.**
  - There is no cutoff date by which this enrollment visit must occur, but all participants who are enrolled must adhere to previously outlined guidance on the last allowable estimated delivery date (EDD) being on or before 15-May-2023 (see Operational Guidance #07).
- Please continue to send weekly reports of scheduled screening and enrollment visits to FHI 360 by COB each Friday until all participants in the pipeline have enrolled, at which point each site team should notify FHI 360 that cohort 3 enrollment has been completed.

All Operational Guidance documents must be printed and filed with study essential documents.

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