



MTN-042 Operational Guidance #03: End of Cohort 1 Accrual

This operational guidance document provides instruction to sites regarding the end of cohort 1 accrual.

Based on reported screening and enrollment numbers as of 30 March 2021, it is anticipated that MTN-042 cohort 1 accrual will reach the targeted N=150 participants as of **6 April 2021**.

- **Effective immediately, sites are instructed to discontinue conduct of any MTN-042 screening visits.**
 - If screening visits are scheduled on 31 March 2021, these may proceed per the discretion of the site IoR, but participants should be advised that the study is likely to complete accrual prior to their scheduled enrollment. Sites are asked to please notify FHI 360 of the scheduled enrollment dates for any screening visits completed on 31 March 2021.
 - All scheduled screening visits after 31 March 2021 should be canceled, and participants counseled accordingly (e.g., provided results of all screening labs, provided information about MTN-043, if interested).
- **Sites should proceed with all scheduled enrollments through 6 April 2021.** For enrollment visits scheduled *after* 6 April 2021, sites are asked to tentatively maintain these visits as backup—these visits will only proceed if the study has not met the cohort 1 accrual target of N=150 by 6 April 2021 and the site receives a specific request from FHI 360 to conduct an additional enrollment visit.
- Sites are asked to report daily to FHI 360 whether the enrollments scheduled for that day were successful.
- Sites should also report to FHI 360 if any enrollment visits are rescheduled to a different date.
- Sites will be notified via email when cohort 1 is confirmed to be fully enrolled.

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

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Ashley Mayo, Sr. Clinical Research Manager, FHI 360

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