



## MTN-042 Operational Guidance #07: Cohort 3 Accrual Plan Updates

This operational guidance document provides instruction to sites regarding updates to the Cohort 3 accrual plans. This guidance supersedes the Cohort 3 accrual plan outlined in SSP section 3.2.2. This information will be incorporated into the next version of the SSP, if it is updated.

The latest allowable estimated delivery date (EDD) for Cohort 3 is being updated from 15-Sep-2023 to **15-May-2023**. This is based on a number of factors, including that (1) early gestational age targets are nearly complete, (2) funding considerations which require completion of as much infant follow-up as possible prior to the end of November 2023, with limited follow-up extending into 2024, and (3) a need for primary safety data from Cohort 3 to be available *as soon as possible* to inform national guidelines in development regarding dapivirine ring use during pregnancy.

As of the date of this operational guidance document, all participants currently in screening can continue through to enrollment regardless of their EDD, as long as they meet protocol-specified Cohort 3 gestational age limits (i.e., between 12 0/7 weeks-29 6/7 weeks EGA at enrollment). Sites are asked to please notify FHI 360 of the EDDs for all participants currently in the screening pipeline.

**Moving forward, participants that are screened for the study must have an EDD by best available estimate (see SSP section 7.8) on or before 15-May-2023 to be considered for enrollment.**

Furthermore, the early gestational age target of 20% of all Cohort 3 participants will be considered an overall target (collectively across sites) vs. a site-specific target. The study will aim to enroll at least 50 participants overall in Cohort 3 (i.e., 20% of 250 total) in the gestational age range between **12-0/7 to 19 6/7 weeks**. Sites will no longer be monitored against previously set site-specific targets for the early GA group as per the risk mitigation plan. All sites are encouraged to continue to enroll participants in this early gestational age range as long as they have an EDD on or before 15-May-2023.

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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