Where we are with the DELIVER and B-PROTECTED studies

3 things you need to know

In this time of COVID-19, the safety of study participants and site staff has and will always come first. Despite COVID-related delays and difficulties, both studies have made tremendous progress.

Background and Context

The Need
- Pregnant and breastfeeding women need HIV prevention methods they know are safe for both themselves and their babies.
- Both Truvada as daily oral PrEP and the monthly dapivirine vaginal ring have been found to be safe and effective, but more information about their safety during pregnancy and breastfeeding is needed, particularly for the ring.

The dapivirine ring is the first biomedical HIV prevention product specifically for women, and the WHO recommends it as an additional choice. The ring is under regulatory review in several African countries — the first approval was in Zimbabwe in July 2021.

DELIVER and B-PROTECTED aim to provide the kind of information national programs, health care providers and women themselves need to make informed decisions about the use of oral PrEP and the dapivirine ring during pregnancy and breastfeeding.

DELIVER and B-PROTECTED are:
- Designed to learn about the safety of the ring and oral PrEP in the safest, most efficient way possible.
- Phase IIIb open-label studies — participants use either oral PrEP or the ring, with more women using the ring.

How is safety being assessed in DELIVER?

Researchers closely monitor participants, taking note of certain complications that can occur during pregnancy: whether the baby was full-term, premature or stillborn; the type of delivery and birth weight. After each cohort, the IRP looks at whether these outcomes occurred with similar frequency to what is expected for women locally, using data from a special sub-study (MTN-042B) that involved reviewing more than 10,000 medical records at the same facilities where DELIVER participants give birth. Finding them similar would suggest the ring and PrEP are safe.

DELIVER has completed Cohort 1, and finding no safety concerns, is proceeding with the second group of women who are slightly earlier in pregnancy.

- February 2020 — Study launched
- May 2021 — Cohort 1 enrollment completed (150 women 8-9 months pregnant)
- June 2021 — IRP review of Cohort 1 safety data
- Early 2022 — Expected completion of Cohort 2 (150 women 7-8 months pregnant)

Knowing about the ring’s safety during pregnancy is more urgent than ever. Researchers have modified DELIVER’s design so the study can be completed earlier and its data made available sooner.

- DELIVER was to enrol 750 women across 4 groups. In May 2021, researchers modified the study to instead enrol 550 women across 3 groups.
- Cohort 3 could begin Q2 2022 and the study be completed mid-2023.

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B-PROTECTED has completed enrollment, with 197 breastfeeding mothers and their babies in the study.

- August 2020 — Study launched
- July 2021 — Enrollment completed — women and their infants are in the study for 3 months
- November 2021 — Study will be completed
- Mid-2022 — Results likely to be available

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