Medicines Control Authority of Zimbabwe

# Clinical Trials Registry

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| **PUBLIC TITLE/ACRONYM** | The CATALYST Study |
| **Scientific Title** | Catalyzing access to new prevention products to stop HIV |

Primary Sponsor Details

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| **Sponsors** * | FHI 360 |

Secondary Sponsor Details

**Contact for Public Queries**

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|---|---|
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**Contact for Scientific Queries**

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| **Affiliation** | Pangaea Zimbabwe AIDS Trust (PZAT) |

**Countries of Recruitment ***

Kenya, Lesotho, South Africa, Uganda, and Zimbabwe

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| **Source of Funds** | U.S. President's Emergency Plan for AIDS Relief (PEPFAR) |
| **Health Condition(s) or Problem(s) Studied *** | HIV Pre-Exposure Prophylaxis |
| **Medicine Name *** | Dapivirine Vaginal Ring |
| **Quantity of medicine required *** | 7200 |

**7.0 PRINCIPAL INCLUSION CRITERIA ***

Eligibility criteria to enroll in the study cohort for Stages I and Stages II are:

1. Tested HIV-negative as determined by the national HIV testing algorithm at a CATALYST site on the same day as enrollment
2. Self-identify with at least one of the following populations:
    1. Adolescent girl or young women (AGYW) ages 15–24 years
    2. Female sex worker (FSW) ages 18 years and older
    3. Pregnant and breastfeeding populations (PBFP) ages 15 years and older
    4. Individuals assigned female at birth of any gender identity ages 15 years and older
    5. Individuals assigned male at birth who identify as women ages 15 years and older
    6. Other women ages 25 years and older
3. Interested in learning about HIV prevention
4. Willing to be contacted for follow-up by phone or other means (e.g., through a community health worker)
5. Willing and able to provide informed written consent for participation

**7.1 PRINCIPAL EXCLUSION CRITERIA ***

Participants will be excluded based on the following criteria:

1. For participants ages 15–17 years, potential participants under the age of 18 may be excluded from study participation based on country guidelines and the age of consent. This determination will vary by country, including countries' definitions of emancipated minors. Country-specific informed consent forms will outline the country-specific inclusion criteria related to age.
    - In ZImbabwe we are not planning on enrolling unemancipated minors, as per current country legislation. Only emancipated minors, according to the Zimbabwean legislation, will be enrolled in the study. These are individuals below the age of 18 but are:-
        - legally married
        - financially independent
        - in cases of child-headed families.

**7.2 PRIMARY END POINTS ***

The overall goal of the study is to characterize and assess the implementation of an enhanced service delivery package providing choice of PrEP products among women at PEPFAR/USAID delivery sites in Kenya, Lesotho, South Africa, Uganda, and Zimbabwe. For this study, the term "women" is inclusive of individuals assigned female at birth of any gender identity or individuals assigned male at birth who identify as women.

9.0 DESIGN OF THE TRIAL

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| **Type of trial *** | Opened |
| *If controlled* | |
| **Randomised** | |
| **Single Blind** | |
| **Double Blind** | |
| **Parallel group** | |
| **Cross over** | |
| **Other** | |
| **If yes to other, specify** | |
| **If controlled, specify the comparator** | |
| **Other medicinal product(s)** | |
| **Placebo** | |
| **Other** | |
| **If yes to other, specify** | |

**Other**

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| **Expected Number of participants in Zimbabwe *** | 2253 |
| **Total enrolment in each site: (if competitive enrolment, state minimum and maximum number per site.) *** | Enrollment in Stage I will continue until the target number of ring initiations is achieved (n=approximately 280 across the country), 12 months of recruitment in the country have elapsed, or cabotegravir is approved and enrollment in Stage II begins, whichever occurs sooner. Approximately 280 Oral PrEP users are expected to be enrolled in Stage I in the country. A total of 560 participants are expected to be enrolled during Stage I across all 6 Study sites in Zimbabwe, and enrolment is not competitive, therefore there will be no minimum or maximum number per site. Recruitment into Stage II will continue until the targeted number of cabotegravir initiations is achieved (n=approximately 845 per country) or until 12 months of recruitment have elapsed per country. Approximately 424 Oral PrEP, and 424 Ring users are expected to be enrolled in Stage II in the country. A total of 1693 participants are expected to be enrolled during Stage II across all 6 Study sites in Zimbabwe, and enrolment is not competitive, therefore there will be no minimum or maximum number per site. |
| **Total participants worldwide *** | 11265 |

**Time period for the trial *** March 2023 - September 2025