



Medicines Control Authority of Zimbabwe

## Clinical Trials Registry

**PUBLIC TITLE/ACRONYM** ENGAGE

**Scientific Title** A Phase II Acceptability Study of Oral emtricitabine/tenofovir alafenamide (F/TAF) vs emtricitabine/tenofovir disoproxil fumarate (F/TDF) for the Prevention of HIV Acquisition in Adolescent Girls and Young Women (AGYW)

### Primary Sponsor Details

**Sponsors \*** CONRAD

### Secondary Sponsor Details

### Contact for Public Queries

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**Affiliation**

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**Affiliation**

### Countries of Recruitment \*

South Africa and Zimbabwe.

**Source of Funds** USAID and Gilead

**Health Condition(s) or Problem(s) Studied \*** HIV

**Medicine Name \*** emtricitabine/tenofovir disoproxil fumarate (F/TDF, Truvada®) and emtricitabine/tenofovir alafenamide (F/TAF, Descovy®)

**Quantity of medicine required \*** 330 bottles of Descovy and 330 bottles of Truvada

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## 7.0 PRINCIPAL INCLUSION CRITERIA \*

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1. Female, age 15 to 24 years (inclusive), ages 16-24 in Zimbabwe
  2. Literate, per local standards, to English and/or local language
  3. In general good health, per participant reported medical history and investigator judgement, without any clinically significant systemic disease including but not limited to: significant liver disease or hepatitis, gastrointestinal disease, kidney disease, osteoporosis or bone disease (e.g., pathologic bone fractures not related to trauma), autoimmune disorder, and diabetes.
  4. Willing to give voluntary informed consent and sign an informed consent form
  5. Women at potential risk of acquiring HIV
  6. Willing and able to comply with protocol requirements, including swallowing tablets
  7. Total body weight  $\geq 35$  kg
  8. eGFR or Creatinine Clearance of  $\geq 60$  mL/min according to the Cockcroft-Gault formula
  9. Have not used oral PrEP ever (PrEP naïve) or in the past 6 months
  10. If pregnant, must be considered a healthy, singleton pregnancy, considered low risk by local standard of obstetric practices
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## 7.1 PRINCIPAL EXCLUSION CRITERIA \*

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1. Positive test for HIV or HBsAg
  2. Signs or symptoms of acute HIV infection
  3. Use of ARV PrEP within the past 180 days
  4. History of sensitivity or allergy to any component of the study drug products
  5. Systemic use in the last two (2) weeks or anticipated use during the course of the study of any restricted products, as outlined in Section 8.2 of the protocol
  6. Known current drug or alcohol abuse which could impact study compliance
  7. Grade 2 or higher laboratory abnormality, per the Division of AIDS, National Institute of Allergy and Infectious Disease (DAIDS) Table for Grading the Severity of Adverse Events, or clinically significant laboratory abnormality as determined by the clinician or study PI
  8. Abnormal finding on laboratory or physical examination or a social or medical condition in the volunteer, which, in the opinion of the investigator, would make participation in the study unsafe or would complicate interpretation of data
  9. Participation in any other investigational trial with use of a drug/device within the last 30 days or planned participation in any other investigational trial with use of a drug/device during the study
  10. History of pathological bone fracture
  11. Pregnant <33 weeks gestation (must have received antenatal care); breastfeeding with infant >6 months old
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## 7.2 PRIMARY END POINTS \*

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Acceptability: Discontinuation rate; attendance at follow-up visits; responses to quantitative assessments collected through questionnaires, and qualitative data collected through in-depth interviews (IDIs) and focus group discussions (FGDs)

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## 9.0 DESIGN OF THE TRIAL

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**Type of trial \*** Controlled

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*If controlled*

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**Randomised** Yes

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**Single Blind** No

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**Double Blind** No

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**Parallel group** Yes

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**Cross over** No

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**Other** Yes

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**If yes to other, specify** This two-arm open label acceptability study will examine acceptability of, and adherence to, standard oral PrEP once daily dosing regimen of F/TDF and an investigational once daily dosing oral PrEP regimen of F/TAF under standard of care counselling.

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**If controlled, specify the comparator** Truvada (emtricitabine 200 mg and tenofovir disoproxil fumarate 300 mg)

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**Other medicinal product(s)** No

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**Placebo** No

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**Other** No

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**If yes to other, specify**

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**Other** Yes

<b>Expected Number of participants in Zimbabwe *</b>	110
<b>Total enrolment in each site: (if competitive enrolment, state minimum and maximum number per site.) *</b>	110
<b>Total participants worldwide *</b>	330

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**Time period for the trial \*** 1 year