MATRIX-002 Acceptability and Safety Study of Two Prototype Vaginal Films

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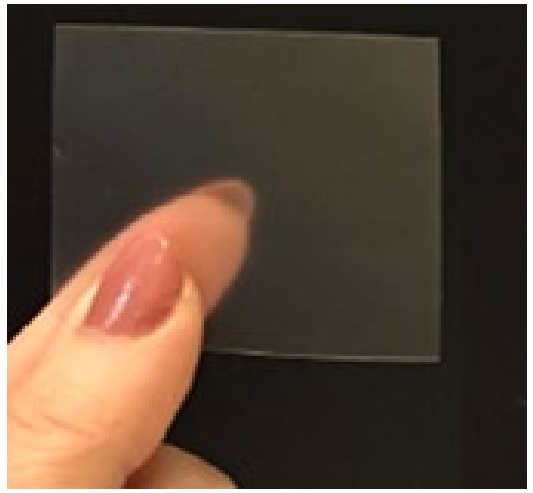
Advancing R&D of Innovative
HIV Prevention Products for Women

What is MATRIX-002?



- A study being designed to help inform next steps in the development of a vaginal film containing the ARV dapivirine to protect against HIV for one month
    - Once inserted in the vagina, the film begins to dissolve and in doing so, releases the drug until the film disappears
- Will assess the acceptability and safety of two prototype (placebo) vaginal films containing no active product
    - Will be the first study of a vaginal film that takes one month to dissolve
- Will enroll approximately 80 women at 5 trial sites in the US, Kenya, South Africa and Zimbabwe

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MATRIX-002 Trial Sites

In the US, MATRIX-002 will be conducted at the **University of Pittsburgh**, where the monthly dapivirine vaginal film is being developed

In Africa, MATRIX-002 will be conducted at:

- **Aurum Institute** (South Africa)
- **Wits RHI** (South Africa)
- Kenya Medical Research Institute - **KEMRI** (Kenya)
- **Harare Health and Research Consortium** (Zimbabwe)

Why MATRIX-002?

The concept of a vaginal film is unfamiliar to many women – perhaps especially, African women.

The idea of a monthly vaginal film is brand new

- **Quick-dissolve vaginal films** and a **7-day film** have been evaluated in US women
- In the QUATRO study, women in South Africa and Zimbabwe tried a **quick-dissolve placebo film**

Before evaluating the monthly dapivirine film in a first-in-human Phase 1 study:

- Researchers need to **know that women will be comfortable with the idea of using a monthly film** and are **able to insert it**
- They also want to be sure that **the "right" film is the one that moves forward**: which of the two films do women find easier to use? Which is safest?

Why MATRIX-002?

- MATRIX-002 will assess how well women are able to insert a vaginal film and seek women's feedback on two different prototype films
    - The vaginal film should feel "right" to the touch and be easy for women to insert – *all the way*. (It should feel smooth, not too sticky, and it should be pliable, not too stiff.)
    - The film must also remain in the vagina

How is MATRIX-002 designed?

- Women who enroll in the study will be randomly assigned to use one of two prototype vaginal films
- They will experience using their assigned film for two months
  - During the first month, they will be asked to abstain from vaginal sex
  - During the second month, they will be able to resume sexual activity
- Researchers will assess how well women in each group are able to insert the film, how comfortable they are with its use, and assess safety

What will women say about using the film?

Focus group discussions and/or in-depth interviews will be conducted to learn what participants have to say about:

- Insertion techniques
- Their experience with and awareness of the film
- Any problems with or concerns about the film coming out or leaking
- Their experience during sex and menses
- If they had disclosed participating in the study to their sexual partner, and if so, what did their opinion think about the film? Could it be felt during sex?
- What they viewed as the potential benefits, concerns or challenges with a film for HIV prevention
- Whether they would be willing to use a film for HIV prevention

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Who may enroll in the study?

To enroll in the study, women must:

- Be between the ages of 18-45 and assigned female at birth
- Be in general good health
- Be HIV-negative
- Not be pregnant or breastfeeding
- Use an effective form of contraceptive other than vaginal rings
- Agree to abstain from other intravaginal products (such as tampons and douches)
- Agree to be sexually abstinent for the first month of study product use
- Provide informed consent

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What's involved in being in the study?

- As currently designed, study participation will involve 5 visits to the clinic over the course of the 9-week study; telephone contact will be made with participants in between these times
- At the first study visit, participants will be randomized to one of the two films and will insert the first film -- guidance will be provided
- After using the film for 1 month:
  - Participants will return to the clinic and will be asked questions about their experience with the film and assessed for safety
  - The clinician will remove any visible film and the participant will insert a second film, which will be the same film type used in the previous month
- After using the second film for one month, participants will again come to the clinic for an acceptability and safety evaluation

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Current Status and Current Timelines

- The protocol is expected to be finalized before the end of the year (2022) and soon after, sites will seek regulatory and Institutional Review Board/Ethics Committee (IRB/EC) approvals to begin the study
- Pending approvals, the study is expected to start mid to late 2023 and be completed within 1 year, with results likely early 2025.

Acknowledgements

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