CONTACT: Lisa Rossi
rossil@mwri.magee.edu
+1-412-916-3315

MATRIX

A USAID Project to Advance the Research and Development of Innovative HIV Prevention Products for Women

About MATRIX

- MATRIX is a five-year program funded by the U.S. Agency for International Development (USAID) in 2021 that is expediting the research and development of HIV prevention products for women – including products designed to protect against both HIV and pregnancy – that in addition to being safe and effective, will be ***acceptable***, ***affordable***, ***scalable*** and ***deliverable*** in the settings where they are needed most.

- MATRIX activities are focused on the *early* research and development of products, which involves both pre-clinical research – the laboratory and animal studies needed to support a product's evaluation in humans – and the first clinical trials of products. Through its North-South Partnerships, MATRIX is strengthening the research and development capacity of African investigators to facilitate full and sustainable ownership of this work.

- MATRIX is being implemented by Magee-Womens Research Institute (MWRI) in collaboration with partner organizations based in Kenya, South Africa, the United States and Zimbabwe. Leading the project is Sharon Hillier, Ph.D., of MWRI and the University of Pittsburgh, USA, with Thesla Palanee-Phillips, Ph.D., from the Wits Reproductive Health and HIV Institute (Wits RHI) and University of Witwatersrand, South Africa, serving as deputy director. Collectively, MATRIX partners have expertise across multiple fields, including drug formulation, drug delivery and product development; clinical trials design and implementation; human-centered design and socio-behavioral research; market strategy and business case development; capacity strengthening; and stakeholder engagement.

How is MATRIX unique?

- The research and development of new products begins with rigorous testing in the laboratory and then in animals that seek to demonstrate their safety and efficacy. These studies must be conducted, and other regulatory requirements be met, before a product can proceed to human clinical trials. The products being developed under MATRIX must also meet a second set of standards that considers what women want and are likely to use and whether the product will be practical and feasible to introduce in countries most affected by HIV. Indeed, a key feature of MATRIX is its focus on being responsive to end-user and stakeholder feedback during the earliest stages of product development to inform decisions about product design and MATRIX's overall research agenda.

- While early-phase clinical trials of new HIV prevention products have typically been conducted in the United States or Europe, MATRIX is also conducting these kinds of studies in sub-Saharan Africa in order to gain important insight into the safety and acceptability of new products in the populations that are most important.

The MATRIX Product Pipeline

- MATRIX's primary focus is on the development of HIV prevention products for women, including HIV prevention products that provide contraception. Of the nine products being developed under MATRIX, four are dual-purpose products for prevention of both HIV and pregnancy.

- Diversity is the hallmark of the MATRIX pipeline of products, which includes those designed to provide protection for six months to a year; on-demand vaginal products meant to be used around the time of sex; and vaginal products that would be used for a month at a time. Some products are new formulations of existing antiretroviral (ARV)-based methods, while others contain novel antiviral agents.

- Two clinical trials are expected to start in 2023. MATRIX-001 is a Phase 1 study that will evaluate the safety and acceptability of the TAF/EVG fast-dissolving insert in approximately 60 healthy, HIV-negative women at three sites in the U.S., Kenya and South Africa – the first study of the insert in African women. MATRIX-002, which will evaluate the acceptability and usability of two monthly placebo vaginal films (with no active drug), will be the first study of a film designed to dissolve over the course of a month. MATRIX-002, which will enroll 100 women at five clinical research sites in the U.S., Kenya, South Africa and Zimbabwe, will help determine which film should move forward into a first-in-human Phase 1 trial of the monthly dapivirine vaginal film. A third study, MATRIX-003, is being designed to evaluate the acceptability of two different vaginal ring prototypes as a precursor to a first-in-human study of the non-ARV/nonhormonal contraceptive dual-purpose monthly vaginal ring. MATRIX-003 is anticipated to begin early 2024.

		Product	Developer	Product Type	Active Ingredient(s)	How used	Protection Goal	Development Status
		Products for Prevention of HIV						
1		**TAF/EVG Fast-dissolving vaginal insert**	**CONRAD** (USA)	**Fast-dissolving insert**	**TAF/EVG** *tenofovir alafenamide & elvitegravir NRTI & integrase inhibitor (ARVs)*	**On-demand** *(women insert themselves at or around time of sex)*	**Up to 3 days**	**MATRIX-001** to evaluate the safety and acceptability of insert at 3 sites in Kenya, South Africa and US –the first Phase 1 study in African women. Expected start 2023.
2		**Griffithsin Fast-dissolving vaginal insert**	**Population Council** (USA)	**Fast-dissolving insert**	**Griffithsin antiviral protein (non-ARV)** *Viral entry inhibitor*	**On-demand** *(women insert themselves at time of sex)*	**4-8 hours**	**Pre-clinical**
3		**Dapivirine vaginal film**	**Univ of Pittsburgh** (USA)	**Vaginal film**	**Dapivirine** *NNRTI (ARV)*	**Women insert themselves**	**1 month**	**MATRIX-002** to evaluate acceptability and usability of 2 placebo films at 5 sites in Kenya, South Africa, Zimbabwe and US. Expected start 2023.
4		**Cabotegravir hydrogel injectable**	**CONRAD** (USA)	**Injectable depot**	**Cabotegravir** *Integrase strand inhibitor (ARV)*	**Injection given under the skin**	**4-6 months**	**Pre-clinical**
5		**Cabotegravir dissolvable pellets**	**CONRAD** (USA)	**Pellet implant**	**Cabotegravir** *Integrase strand inhibitor (ARV)*	**Inserted under skin**	**Up to 1 year**	**Pre-clinical**
		Products for Prevention of HIV and Pregnancy (Dual Purpose)						
1		**Non-ARV/ nonhormonal contraceptive dual-purpose vaginal ring**	**Oak Crest Inst of Science** (USA)	**Vaginal ring**	**Antiviral peptide (non-ARV)** *(protein fragment)* **Non-hormonal contraceptive** *A soluble Adenylate Cyclase (sAC) inhibitor; affects sperm's ability to move, fertilize eggs*	**Women insert themselves**	**1 month**	**MATRIX-003** to evaluate acceptability of 2 placebo vaginal rings at 5 sites in South Africa, Zimbabwe and the US. Expected start 2024.
2		**Dapivirine and levonorgestrel vaginal film**	**Univ of Pittsburgh** (USA)	**Vaginal film**	**Dapivirine** *NNRTI (ARV)* **Levonorgestrel** (LNG) *hormonal contraceptive*	**Women insert themselves**	**1 month**	**Pre-clinical**
3		**Cabotegravir/ levonorgestrel hydrogel injectable**	**CONRAD** (USA)	**Injectable depot**	**Cabotegravir** *Integrase strand inhibitor (ARV)* **Levonorgestrel** (LNG) *hormonal contraceptive*	**Injection given under the skin**	**4-6 months**	**Pre-clinical**
4		**Cabotegravir/ levonorgestrel dissolvable pellets**	**CONRAD** (USA)	**Pellet implant**	**Cabotegravir** *Integrase strand inhibitor (ARV)* **Levonorgestrel** (LNG) *hormonal contraceptive*	**Inserted under skin**	**Up to 1 year**	**Pre-clinical**

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