Stakeholder Feedback and Discussion

MATRIX and the Framework for HIV Prevention in Kenya

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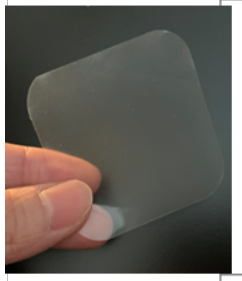
PEPFAR
U.S. President's Emergency Plan for AIDS Relief

USAID
FROM THE AMERICAN PEOPLE

MATRIX
Advancing R&D of Innovative HIV Prevention Products for Women

MATRIX current product pipeline

Product	Developer	Product Type	Active Ingredient(s)	How used	Protection Goal	Unique Features/ Additional Info	Development Status
 **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 time of sex)*	**At least 1 day**	TAF shows activity against HSV- may be added benefit. . Outside of MATRIX, CONRAD evaluating as rectal insert.	**MATRIX-001** – safety and acceptability Phase 1 study (US & African sites)..
 **Dapivirine vaginal film**	**Univ of Pittsburgh** (USA)	**Vaginal film**	**Dapivirine** *NNRTI (ARV)*	**Women insert themselves**	**1 month**	Film would slowly release drug as it dissolves. *Also being developed as dual-purpose*	**MATRIX-002** – safety, acceptability & usability of 2 placebo films (US & African sites) –informing film design for first-in-human trial of active product.
 **Dapivirine & levonorgestrel dual-purpose vaginal film**	**Univ of Pittsburgh** (USA)	**Vaginal film** ***(dual purpose)***	**Dapivirine** *NNRTI (ARV)* **Levonorgestrel** (LNG) *(hormonal contraceptive)*	**Women insert themselves**	**1 month**	Film would slowly release dapivirine and LNG as it dissolves	**Pre-clinical**
 **Non-ARV/ nonhormonal contraceptive dual-purpose vaginal ring**	**Oak Crest Inst of Science** (USA)	**Vaginal ring** ***(dual purpose)***	**Antiviral peptide** *(protein fragmen -non-ARV)* **soluble Adenylyl Cyclase (sAC) inhibitor** (*non-hormonal contraceptive*)	**Women insert themselves**	**1 month**	Antiviral shows activity against HSV & HPV- may be added benefit. sAC inhibitor affects sperm's ability to swim	**MATRIX-003 –** acceptability of 2 placebo rings (US & African sites) – deciding ring for first-in-human study of active product.

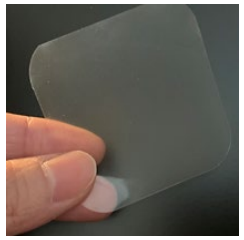
MATRIX studies at a glance

MATRIX-001

- **Phase 1 study** of safety, drug distribution and acceptability of **TAF/EVG fast-dissolving insert**
- First Phase 1 in African women
- 3 sites: **Kenya**, South Africa, US
- Enrollment of 60 participants near complete
- Results expected 2025

MATRIX-004

- Phase 1 trial in development

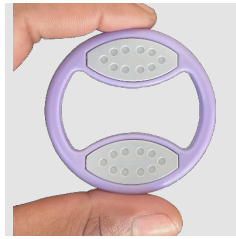


MATRIX-002

- **Placebo study** of 2 prototype monthly vaginal films for acceptability, usability and safety
- To inform film design for first-in-human trial of **monthly dapivirine film**
- 5 sites: **Kenya,** South Africa (2), US, Zimbabwe
- Enrollment of 100 participants near complete
- Results expected Q4 2024/Q1 2025

MATRIX-006

- To be developed



MATRIX-003

- **Placebo study** of 2 prototype rings for safety and acceptability.
- To inform ring design for Phase 1 trials related to **non-ARV / nonhormonal contraceptive monthly dual-purpose vaginal ring**
- 5 sites: South Africa (3), US, Zimbabwe
- To enroll 100 participants
- Results expected 2025

MATRIX-005

- Beginning to develop

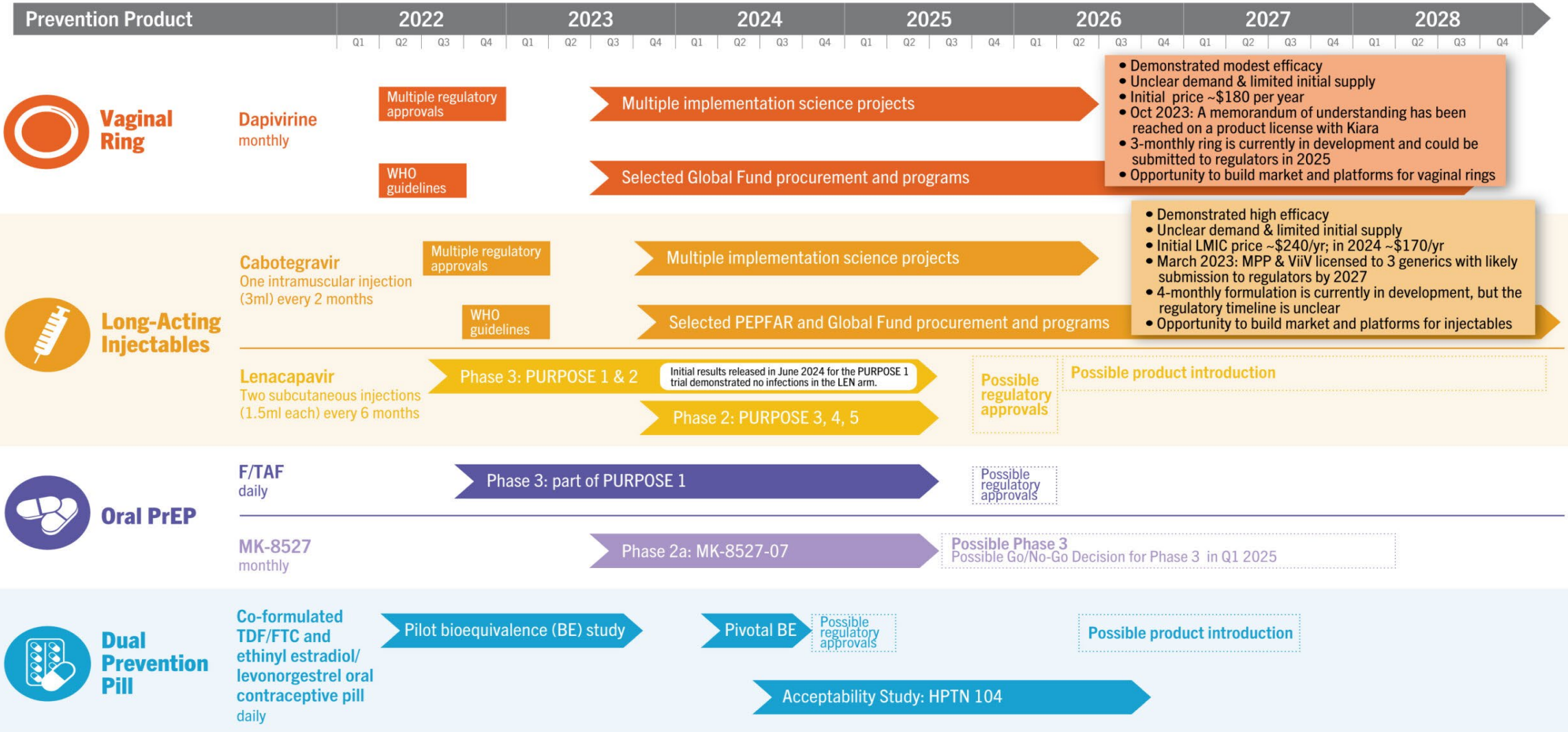
MATRIX-007 (CARE-PrEP) study

- Will enroll up to 800 participants in the CATALYST implementation study who become pregnant and opt to continue use of ARV-based prevention, as well as their infants
- **Aims to contribute quality data** on the **safety** of **CAB-LA**, **dapivirine ring and oral PrEP during pregnancy** – data on the use of CAB-LA is especially important
- To be conducted at sites in **Kenya**, **Lesotho** and **Zimbabwe**.
- Pending ethics and regulatory approvals, expect to begin screening and enrollment Oct 2024
- Study is expected to be completed 2026

MATRIX is collaborating with the USAID-funded MOSAIC collaborative, drawing on the experience and expertise in this specialized area of research of team members from both programs, most notably as part of the NIH-funded Microbicide Trials Network

Years Ahead in HIV Prevention Research

Time to Market



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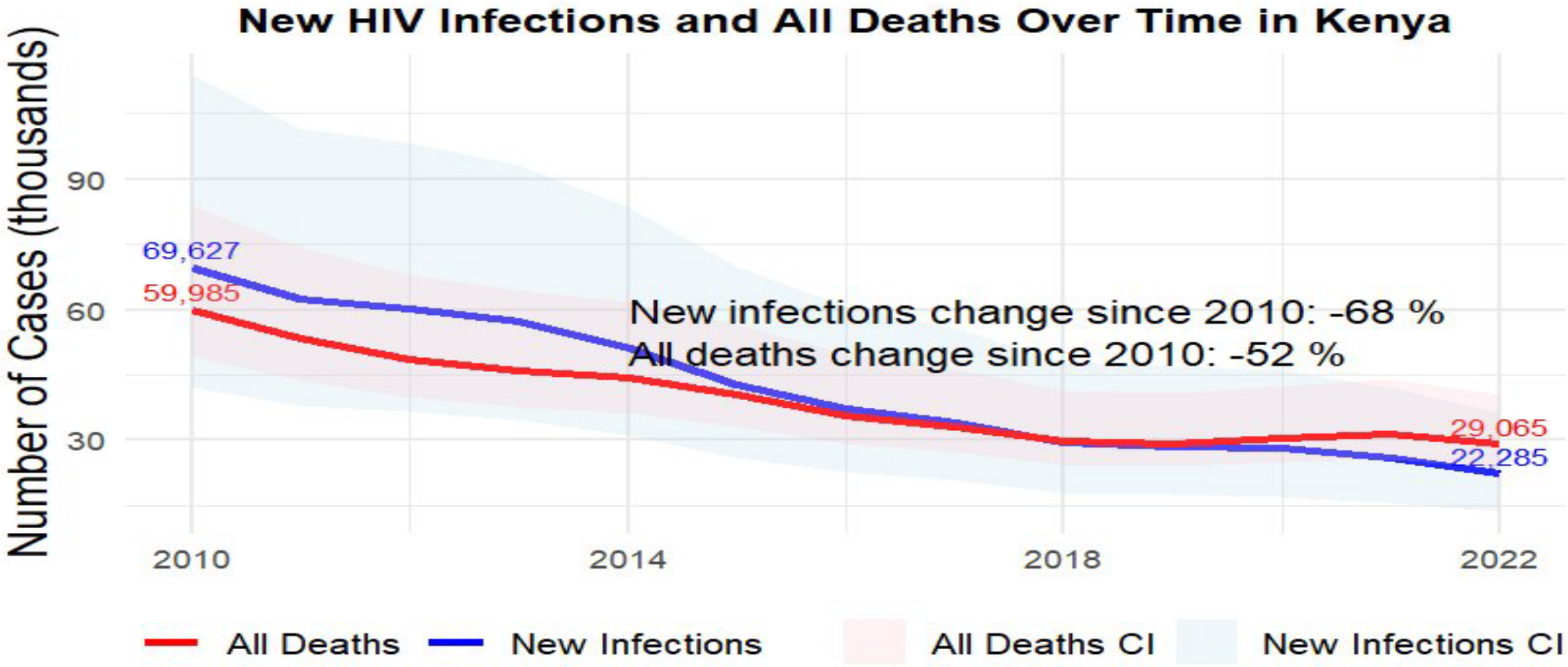
HIV Epidemiological Trends from 2010-2022



Source NASCOP Kenya

STRATEGY 5: Institute Mechanisms for Rapid Introduction of New HIV Prevention Technologies and Program innovations

Priority Actions Include:

- Conduct annual consultative forums involving all stakeholders to review research evidence and rally support for introduction of new technologies and approaches.
- Develop policy and guidance and seek regulatory approvals to introduce new and approved prevention technology, including supply and distribution
- Conduct assessment with priority populations to understand their needs and preferred delivery modalities for new prevention technology.

Discussion