

# Tenofovir Alafenamide / Elvitegravir Fast Dissolving Inserts

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# TAF/EVG Inserts in brief

For flexible on-demand use –  
either before or after sex

Inserted by user  
into the vagina or  
rectum



For users of  
all ages and  
genders



Prevents HIV  
and HSV  
(Herpes)  
acquired  
vaginally or  
rectally



Contain two  
drugs proven  
safe and  
effective  
against HIV



**MATRIX**

# Why TAF/EVG Inserts? What gaps does it fill?

**Value Add:** Provides HIV and Herpes (HSV) prevention option for end-users who:

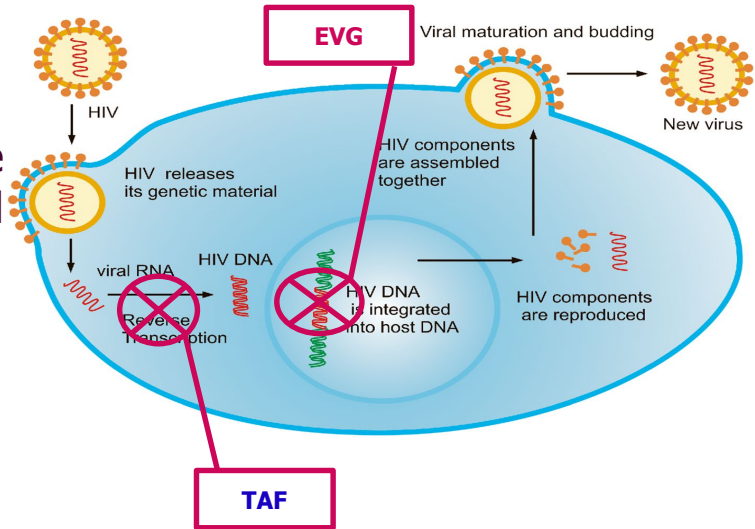
- ✓ Have infrequent or clustered sex, or
- ✓ Only want to use an anti-retroviral (ARV) product around the time of sex
- ✓ Don't want to take oral PrEP or other systemic or long-acting ARV medications

## Added Benefits

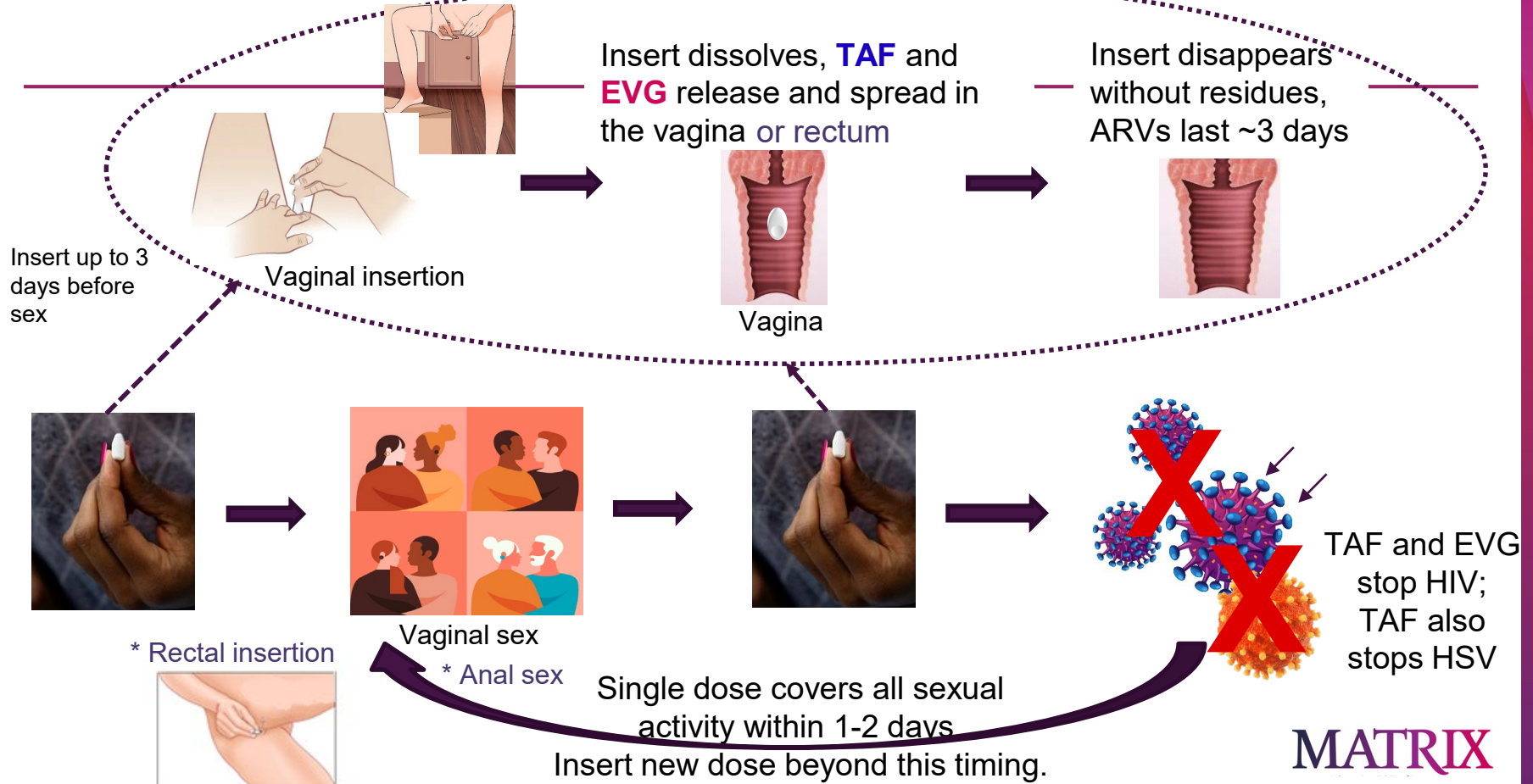
- + **Fast dissolving materials are generally recognized as safe (GRAS)**
- + **Stored at room temperature**, suitable for limited-resource clinics
- + **Easy to manufacture** at large scale and **low cost**
- + Release of ARVs where and when it's needed resulting in **local drug exposure** (not to the whole body)
- + **Easy and painless** to insert with a finger, and leaves no residue after quickly dissolving
- + **Pre- or Post-exposure protection** when you need it most

# How does it stop HIV?

- Each insert contains 2 ARVs that work together to stop HIV from establishing infection
  - If HIV enters a human cell, **TAF** blocks the HIV virus from replicating and making viral DNA copies
  - Should a viral DNA still get into the cell's nucleus, **EVG** prevents it from integrating into the DNA of the host cell
  - This **"one-two punch"** is why the TAF/EVG combination offers both **pre- and post-sex protection**



# How do the inserts work?



# Studies Conducted to Date and Key Takeaways



## Formulation Development

- Iterative design process



## Clinical Studies

- CONRAD 135 – placebo (US)
- CONRAD 146 – first-in-women, single dose (US)
- MTN 039 – rectal use, single/double dose (US)



## Preclinical Animal Testing

- Rat Studies
- Monkey Studies



## End User Research

- USAID EMOTION (SA)
- USAID QUATRO (SA, Zim)
- MTN 035 DESIRE (multinational)

Inserts were a preferred product in comparative vaginal product acceptability study in SA



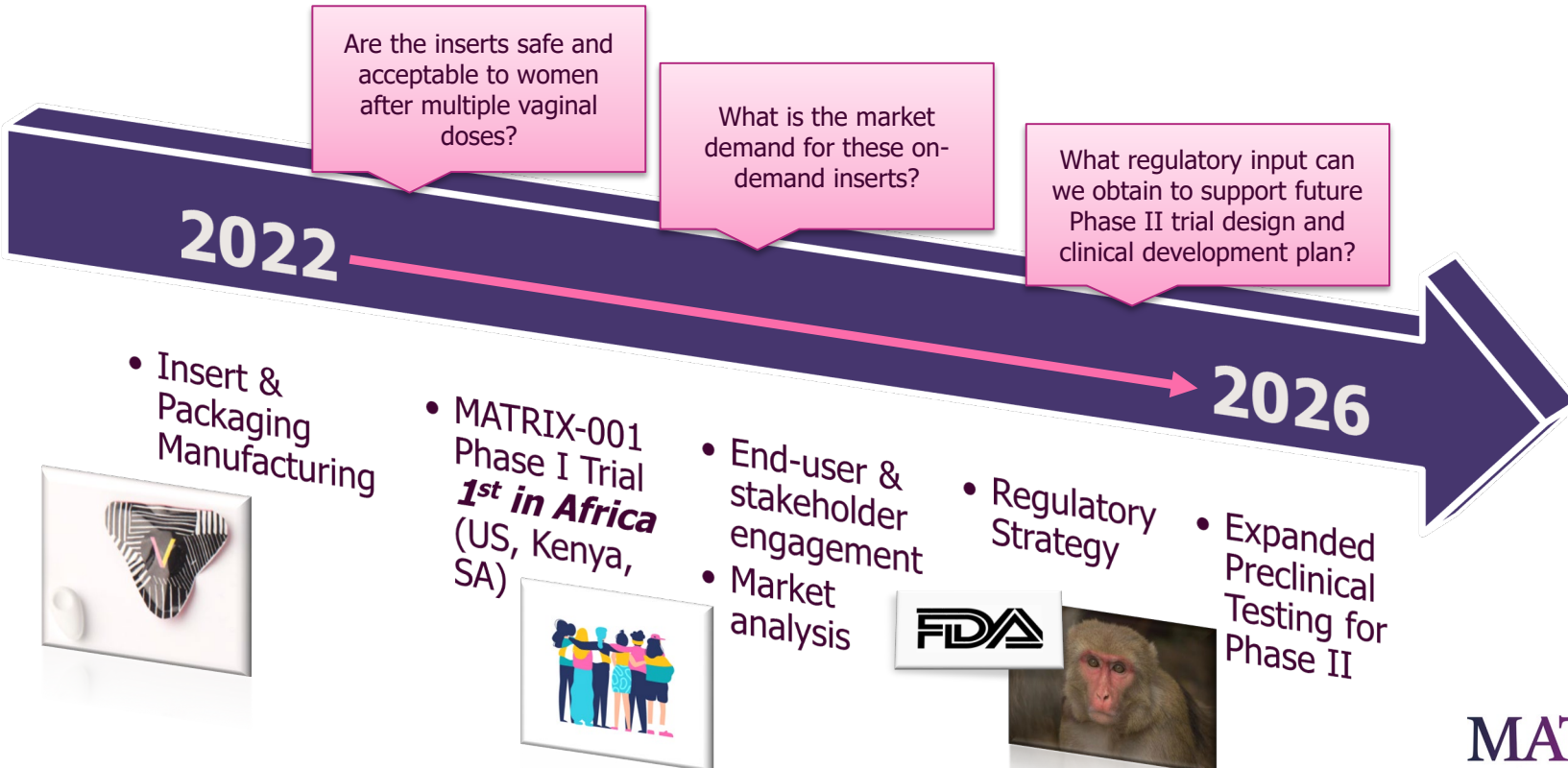
## Regulatory

- Investigational New Drug (IND) file with FDA

Inserts are effective when used before or after virus exposure, vaginally or rectally

Monkey and human Phase I clinical data support TAF/EVG inserts for HIV-1/HSV prevention

# Next steps and key questions to address



# Acknowledgements

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# Acknowledgements

