

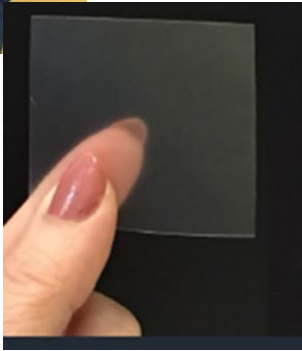
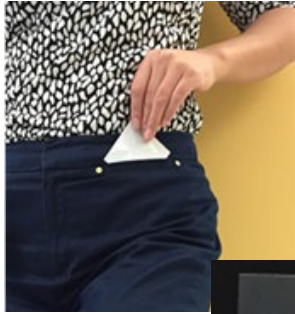
# One-Month Dapivirine Vaginal Film

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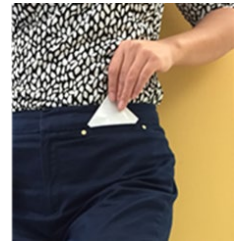
# One-month vaginal film for HIV prevention

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- Contains dapivirine, an anti-HIV drug
- Women can insert the film themselves
- Designed to provide protection from HIV for 1 month

# Why film?

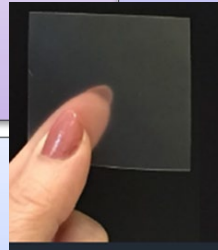


## **Ease of Use & Privacy:**

Women control use and insertion of film  
Can be used discreetly and inserted anytime  
in private  
Not expected to impact sex

## **Superior & Convenient Platform:**

Removal not required  
Complete drug release  
Small and portable



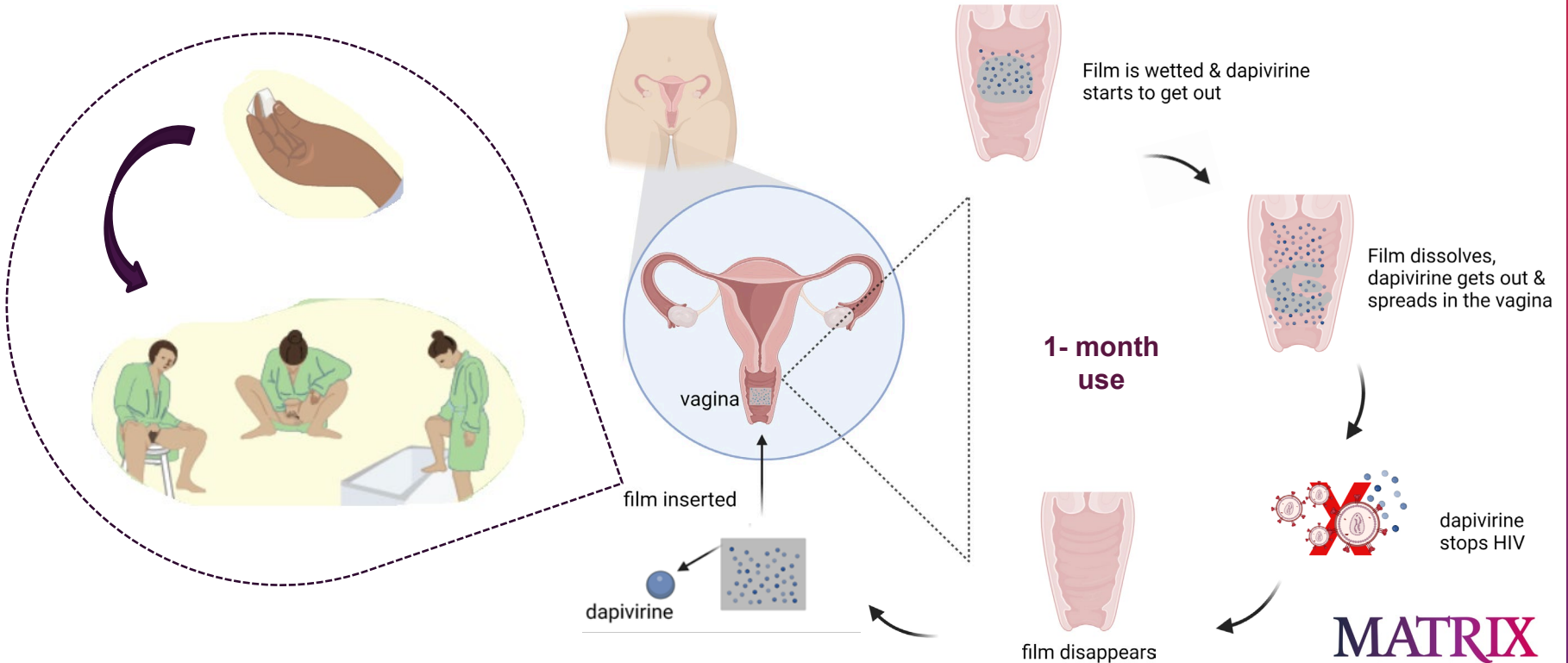
## **Low Cost:**

Inexpensive to manufacture  
No applicator required

## **Safe with No Messiness:**

Minimal impact on vaginal health  
Minimal to no additional vaginal discharge

# How does the dapivirine film work?



# What kind of studies have been conducted to date?

## Acceptability

- >2500 women
- ✓ USA, Burkina Faso, Tanzania, Zambia, South Africa and Zimbabwe

## Feasibility

- Dapivirine 1-day film (Two Phase 1 trials completed)
- ✓ Safety, acceptability, & drug release similar to gel
- ✓ Initial computer model developed
- Feasibility of 7 and 30-day films confirmed

## DPV 1 month film

- Initial prototype developed
- ✓ *in vitro* release studies confirm extended-release properties
- ✓ Currently being evaluated in macaque model
- ✓ Manufacturing activities initiated

# Key questions to address

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## **Is a 30-day vaginal film acceptable to women in Africa? What features in its design will be important?**

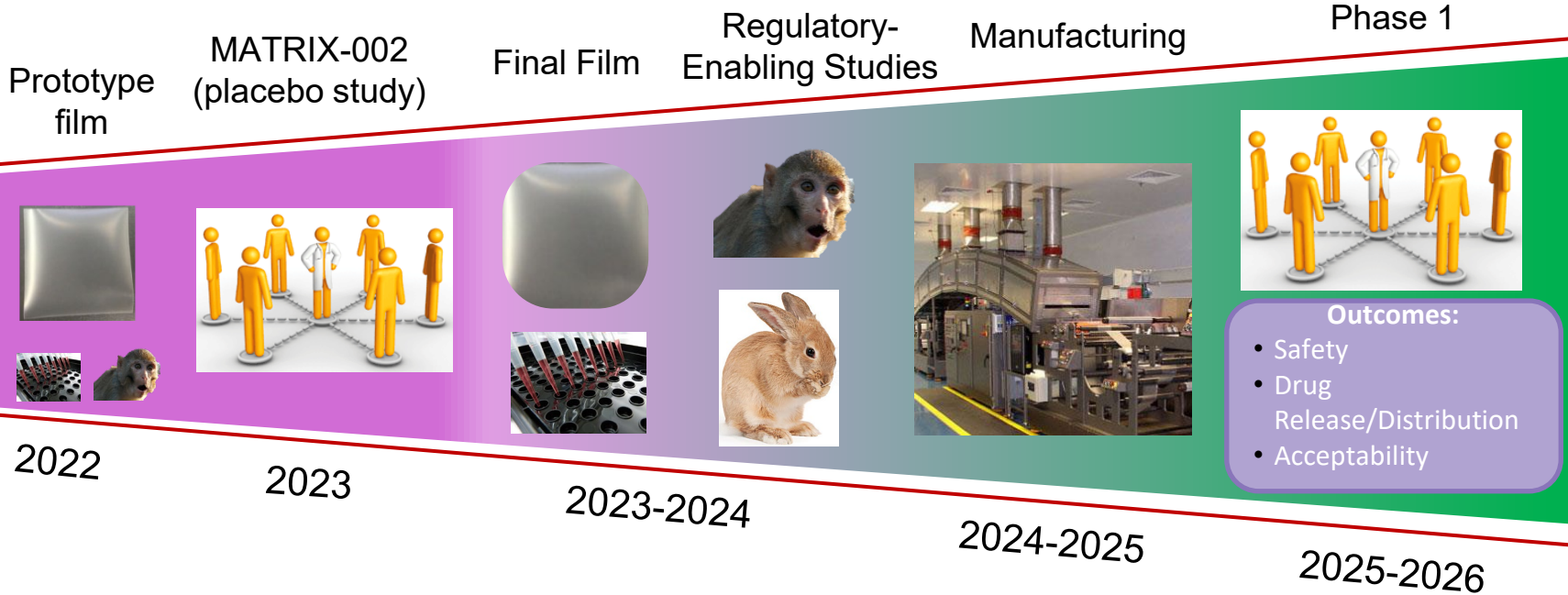
A placebo study will be conducted in US and Africa to understand film safety and what aspects of the film design lead to higher user acceptability

- When: 2023
- Where: Pittsburgh, Kenya, South Africa, Zimbabwe
- How many women: 80
- Feedback from users and stakeholders will inform final film design

## **Can and should the developed prototype film proceed into clinical trials?**

Studies in macaques will assess whether the film has the potential to provide effective drug levels in the vagina for HIV protection. If so, the first human studies of dapivirine film will evaluate the film's safety and drug levels in the body.

# Overall product development timeline (2022-2026)



# Acknowledgements

*This program was made possible by the generous support of the American people through the U.S. President's Emergency Plan for AIDS Relief (PEPFAR) and the U.S. Agency for International Development (USAID).*

*The contents in this presentation are those of the presenter and do not necessarily reflect the view of the U.S. President's Emergency Plan for AIDS Relief, the U.S. Agency for International Development or the U.S. Government.*





# Acknowledgements



## VALUE PROJECT TEAM

