

# *How the Activity Hubs Support our Product Development...*

## TECH ACCELERATOR Domains 1 & 2

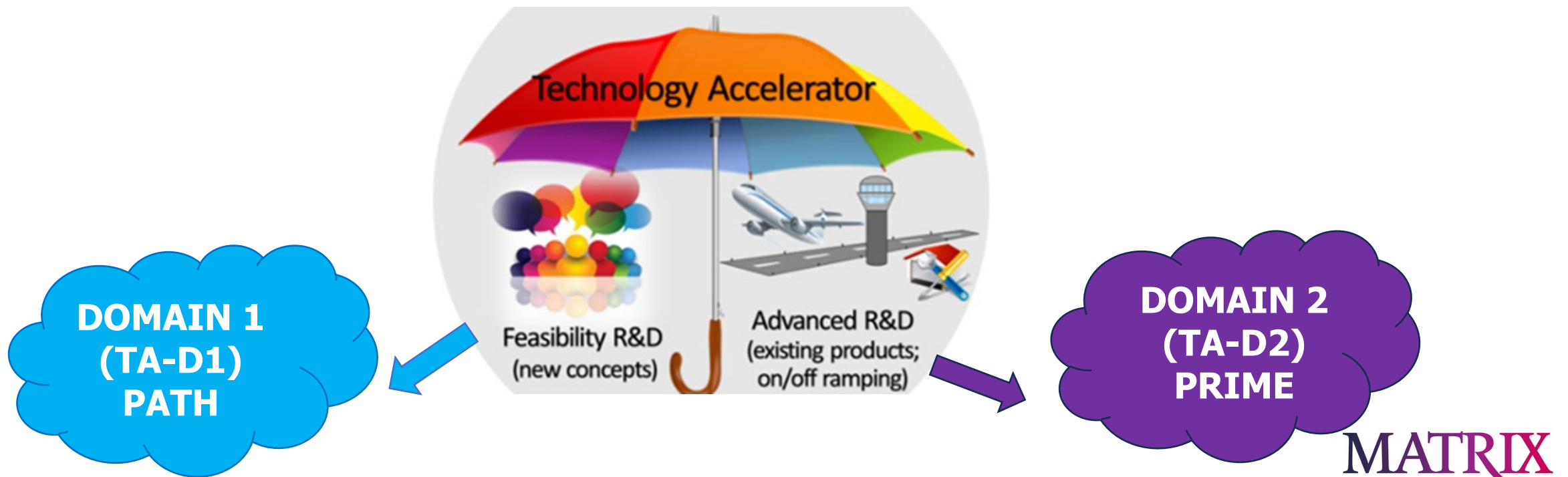
Davina  
Canagasabay,  
PATH

Ariane van der Straten,  
for PRIME



# The Technology Accelerator Hub

Umbrella under which new products or existing products with HIV prevention and MPT/Dual Purpose indications can accelerate R&D.



# MATRIX Scientific Operations

## A. Drug Development

### Critical Path Projects

Ongoing

New

Scientific Advisory Group (SAG)  
Biannual Evaluation

✓ Proceed

STOP

Off-ramp  
for  
mitigation

Approve?  
**YES/NO**

## B. Capacity Strengthening

TA-Domain  
1

RFAs

Review  
Panels

SEED  
Projects

Prevention  
Challenges

PATH monitors

Independent  
Special  
Projects

Invited  
application

Expert  
Review

PRIME  
monitors

## C. Prevention field Landscaping

Partners  
Calls  
with NIH,  
Pharma and  
Foundations

Literature/  
Desktop  
Review of  
non-vaccine  
prevention  
landscape

# Technology Accelerator-Domain 2

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## Domain 2:

- Allows for new products or technologies to come into MATRIX and for current products to be on-ramped or off-ramped from the main portfolio when appropriate
- Directed by Jim Turpin and Ariane van der Straten

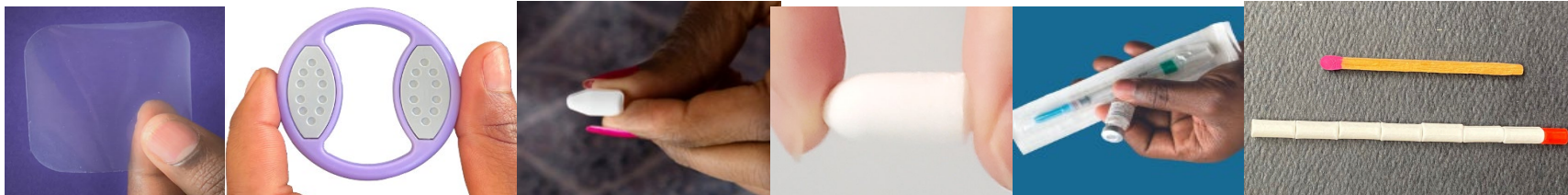


- ✓ Management of Scientific Advisory Group (SAG), biannual meetings & associated activities
- ✓ Management of Integrated Special Projects (ISP)
- ✓ Prevention field landscape activities

# A. Drug Development

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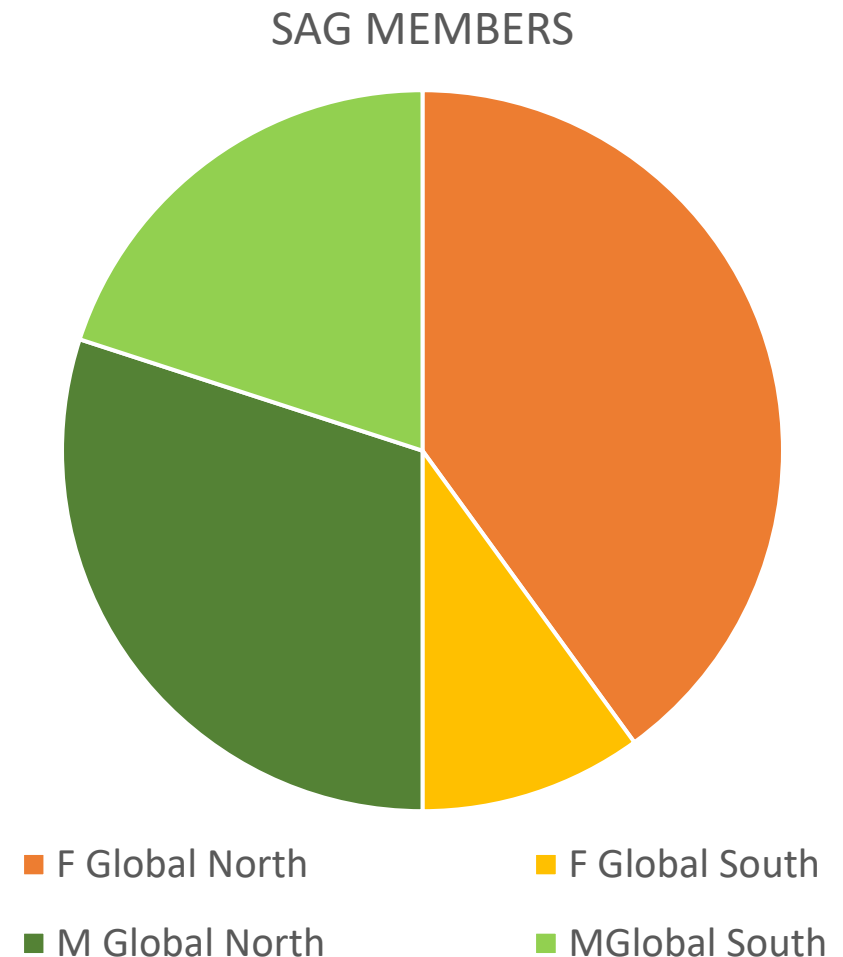
- 9 critical path projects (6 delivery forms): HIV prevention only (5) or Dual Purpose (4) indications



- New projects may also be considered to onboard on the critical path, if deemed of scientific priority to MATRIX.

# Scientific Advisory Group

- 10 SAG Members
  - 1/2 Females, 1/3 from the Global South (GS)
  - 8 members since inception/ 2 new members onboarded
  - Range of expertise: virology/ID, regulatory, CMC, preclinical & clinical research, pharmacology, socio-behavioral research, business/marketing.
- SAG meets 2x per year (Q1, Q3) to evaluate progress and advise PRIME and USAID on Critical Path projects
  - ✓ SAG makes recommendations
  - ✓ USAID concurs (or not) & implements decision



# SAG related activities

- Biannual meetings (4<sup>th</sup> conducted on 8/15-16, 2023)
- Evaluate/Review all 9 critical path projects
  - Supports PDs by identifying gaps and successes
  - Makes recommendations to optimize drug development path
- New projects: makes recommendations for onboarding (or not) based on scientific merit, regulatory considerations and value added for HIV prevention space & MATRIX portfolio of projects.





# SAG: Successes and Challenges

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## • **SUCCESSES** 😊

- Highly engaged team members/all participate
- Complementary expertise
- Support PDs and projects
  - Provide useful recommendations at meetings & on an ad-hoc basis
  - Ask hard questions
- Everyone learns through the process

## • **CHALLENGES** 😞

- PDs: Big lift (volume of materials) to generate every 6 months
- Big time commitment to all:
  - Hundreds of pages of materials to review for SAG members
  - 8h+ of meetings every 6 months
- Logistically challenging to organize & conduct



# Capacity Strengthening Technology Accelerator-Domain 1

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## Domain 1:

- Feasibility R&D provides small pilot funds for new technologies or products: SEED Projects and PREVENTION CHALLENGES
- Directed by Jessica Mistilis and Mutsumi Metzler / Davina Canagasabey



- All selected projects are also reviewed by PRIME and USAID for CONCURRENCE
- PATH and PRIME monitor progress

# MATRIX Seed Projects: Overview

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- Fund potentially game changer research in HIV prevention, with secondary aim of strengthening research capacity in sub-Saharan Africa.
- Projects solicited through a request for application (RFA) process; recipients selected by scientific review panel.
- Grants funded for 18 months; budget maximum of \$150,000 US dollars.

## Seed Project RFA Rounds

### Round 1

RFA process launched August 2022; one application received for evaluation. One seed project grant awarded in December 2022, and research started January 2023.

### Round 2

RFA process launched December 2022; seven applications received. Five were evaluated, with two selected for award in May 2023. Anticipate research starting by October 2023.

### Round 3

Planning for a third RFA process to be launched in late 2023, with grants targeted to start early summer 2024.

# MATRIX Seed Projects: Selected Concepts

Project Title	Organization	Principal Investigator (PI)
<b>Round 1</b>		
Develop the VagiTab as an intravaginal drug delivery system against HIV and sexually transmitted infections	University of Witswatersrand	Yahya Choonara

UPDATE: Activities progressing according to project plan—Pre-formulation studies have been completed, and currently moving forward with formulation evaluation and optimization activities for tablet systems.

<b>Round 2</b>		
Next Generation 3D Printed Intravaginal Ring for Prevention of HIV, herpes simplex virus, and Unintended Pregnancy	University of North Carolina at Chapel Hill	S. Rahima Benhabbour
Developing a Portable and Inexpensive Module for Quantifying Antiretroviral Drug Levels in Point-of-Care Settings	University of Washington	Ayokunle Olanrewaju

# MATRIX Prevention Challenges: Overview

- Funding to support development of solutions to specific challenges facing the field of HIV prevention.
- Projects solicited through RFA process, with recipients selected by scientific review panel.
- Three mechanisms to address Prevention Challenges (see table).

Challenge type	Duration (up to)	Award ceiling
<p><b>Think tank (TT)</b> Groups of experts convened to provide guidance to address the posed challenge and propose next steps</p>	1 year	\$100,000
<p><b>Best practices working group (BPWG)</b> Groups of researchers charged with identifying best practices to address challenge; perform limited proof-of-concept studies to support proposed best practice (if applicable)</p>	1.5 years	\$200,000
<p><b>Research challenges (RC)</b> Applicants propose and perform specific laboratory-based research to address the challenge</p>	2 years	\$350,000/year

# Prevention Challenges RFA: Status

**12** applications received; **8** with PIs/co-PIs from Kenya, South Africa, or Zimbabwe.

Successful recipients will be notified in September 2023, with work anticipated to begin in December 2023.

Prevention challenge	Applications received
<b>TT-1:</b> Determine the minimal acceptable efficacy threshold for a vaginal topical HIV prevention product.	1
<b>TT-2:</b> Develop a bridging structure to span the prevention drug development gap between MATRIX and MOSAIC.	1
<b>BPWG-2:</b> Optimize the collection of end-user perception feedback to inform prevention products.	5
<b>RC-1:</b> Identify changes in microbiota (bacterial, viral, fungal, and phage) that impact HIV acquisition and HIV prevention product efficacy and safety	1
<b>RC-2:</b> Identify new drugs that could be developed for HIV prevention or incorporated into a multipurpose prevention technology for HIV and unintended pregnancy	3
<b>RC-4:</b> Analyze vaginal pro-inflammatory cytokines from clinical trials in Kenya, South Africa, and Zimbabwe	1

# Technology Accelerator-Domain 1: Successes and Challenges

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## SUCCESSSES

- Increased interest (# of letters of intent) and higher number of submitted applications with each round.
- Increasing proportion of applications from PIs/co-PIs based in sub-Saharan Africa.
- Strong participation and dedication among application reviewers.



## CHALLENGES

- Applications received that were not aligned with MATRIX's technical scope and focus on HIV prevention.
- Applications received from PIs/co-PIs based outside MATRIX countries (Kenya, South Africa, Zimbabwe).

# ISP: Independent Special Project(s)

- **Main objectives:** support critical, **high interest/impact projects** designed to **strengthen HIV prevention research capacity in SSA** which address issues that may impede or block the delivery of new HIV prevention products / MPTs in SSA.
- Proposals by invitation for a technical area of special interest (combining capacity strengthening and scientific opportunity). Two years project.
- First ISP: Winks & Chibale (H3D, CPT)  
KinetiChem & OCIS: Capacity building for new method to synthesize ARVs in Africa (see Monday presentation)





# Prevention Field Landscaping: Partners Call

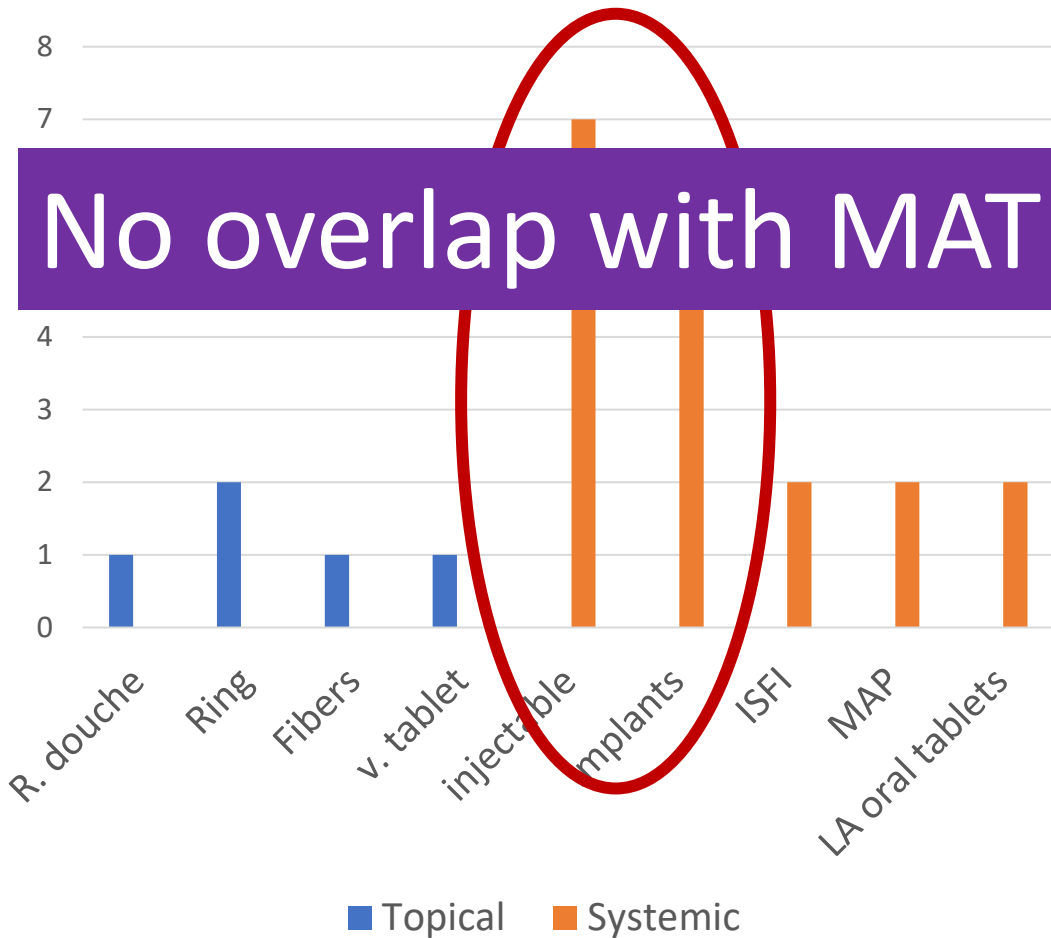
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MATRIX Prime required to monitor R&D activities in the HIV prevention and microbicide research space through partners calls and desktop reviews

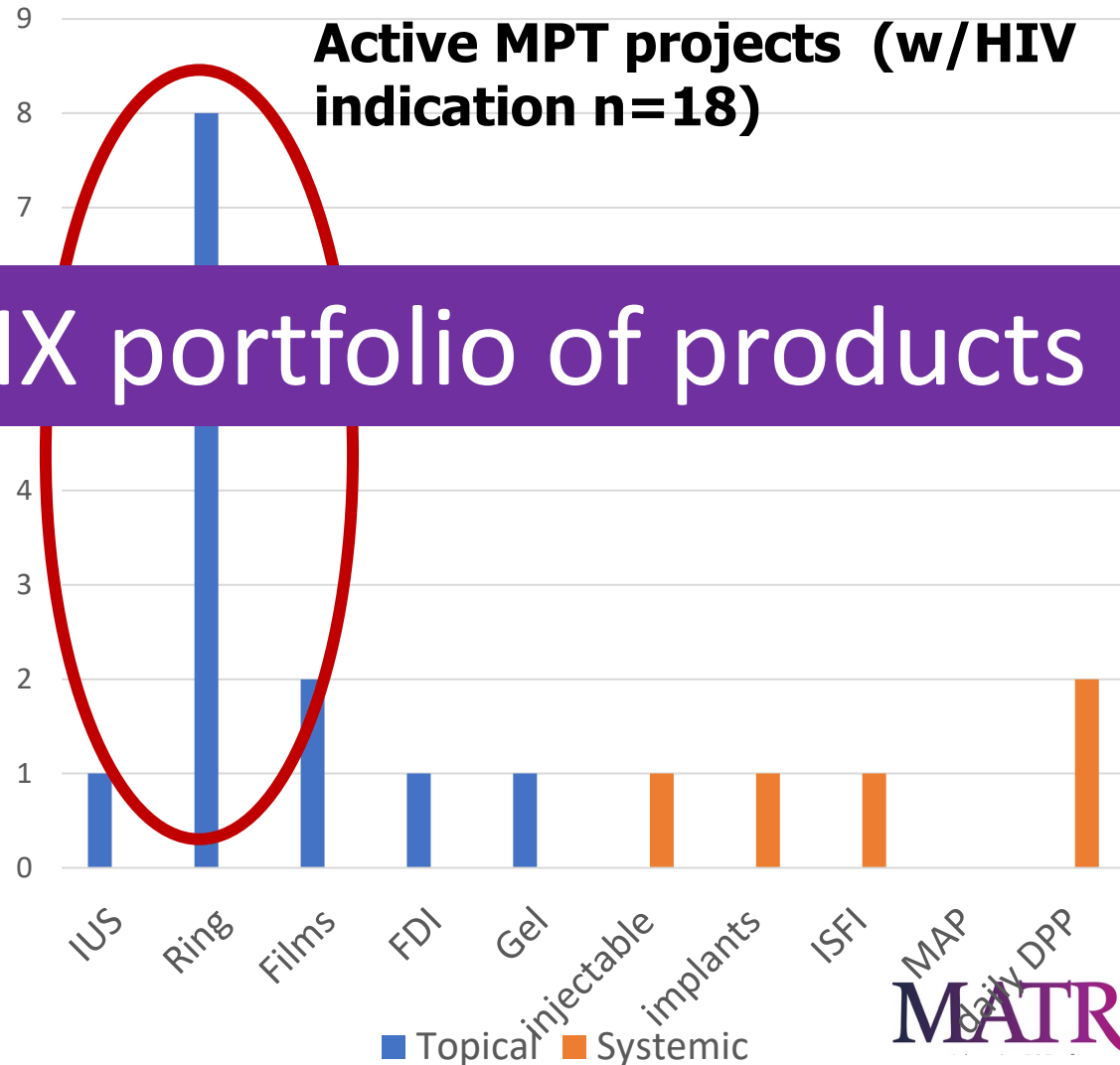
- 2 Partners calls conducted so far (Jan 2023 and August 2023)
  - Includes US government funders, Private foundations, Multilateral agencies, Pharma partners.
- ✓ Interactive meeting to listen and learn from each others.
- ✓ Ongoing work with partners and Forum For Collaborative Research to understand/map the **regulatory path for MPTs**/Dual Purpose Products.

# Prevention Field Landscaping: Biannual Desktop/Literature review

Active HIV Projects (n=23)

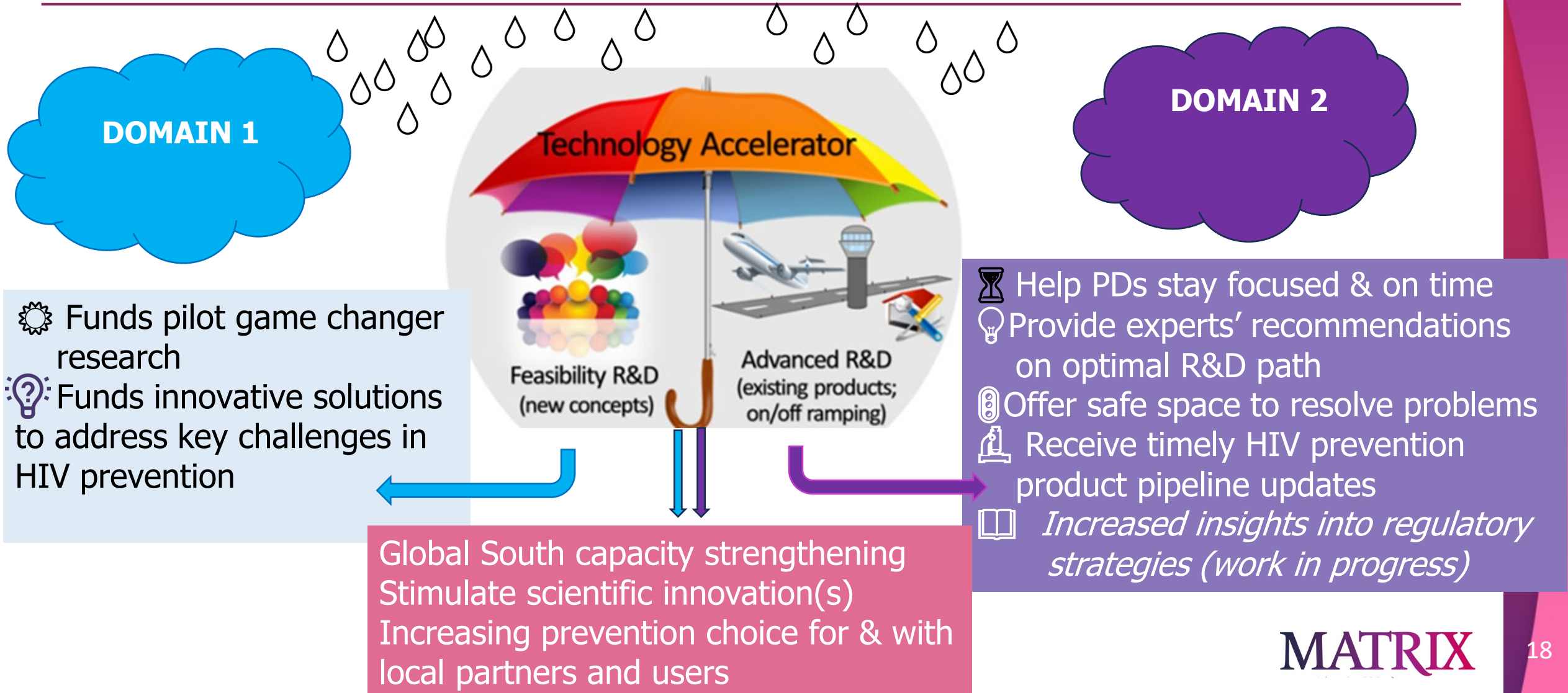


Active MPT projects (w/HIV indication n=18)



No overlap with MATRIX portfolio of products

# Summary: How Technology Accelerator (TA) Hub Supports Product Development ?



# 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.*

