



PEPFAR



USAID
FROM THE AMERICAN PEOPLE

USAID and MATRIX Investigator Meeting 2023

Presenters:

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United States Agency for International Development
Bureau for Global Health / Office of HIV and AIDS /
Research Division / Microbicide Branch

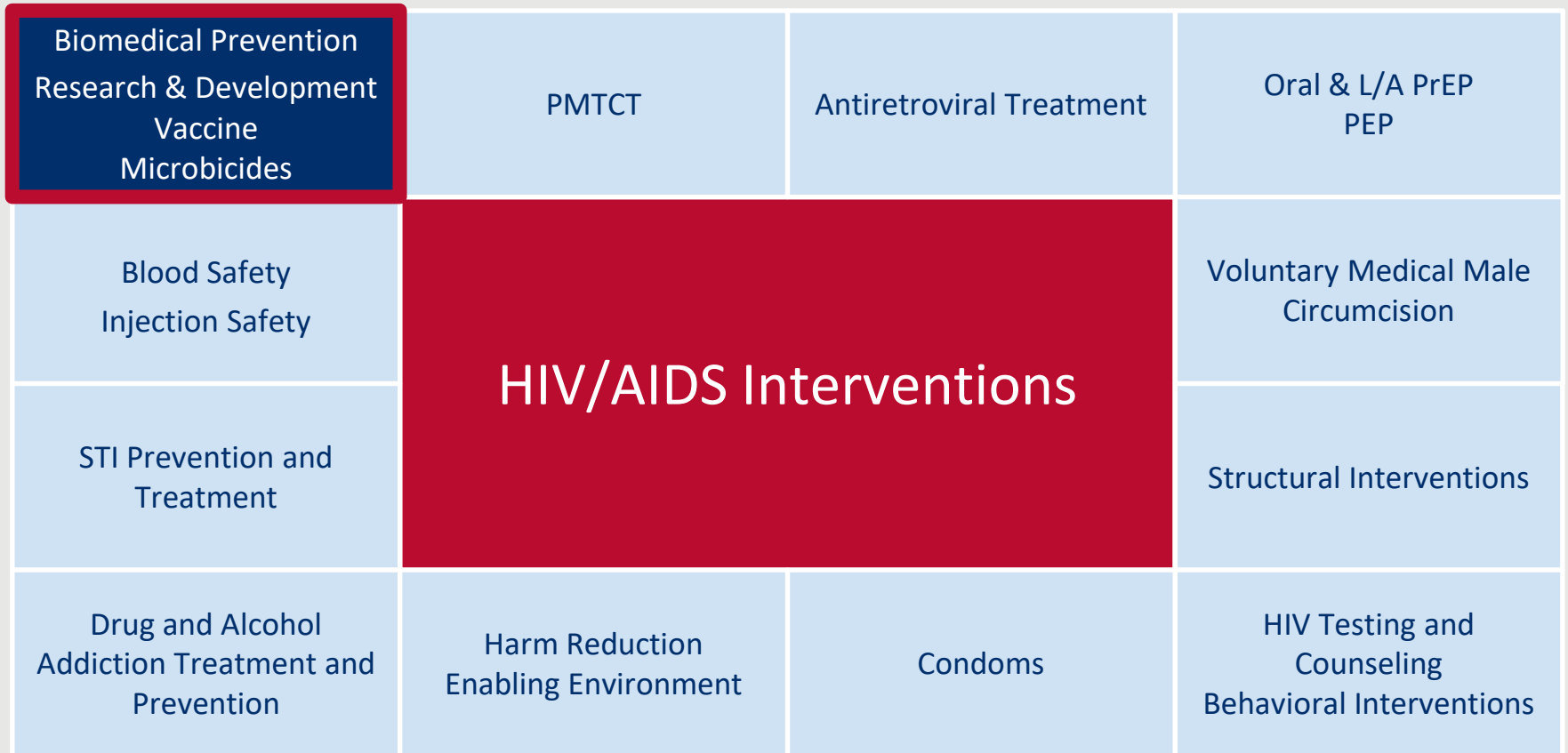


Where does MATRIX fit into larger HIV ecosystem?

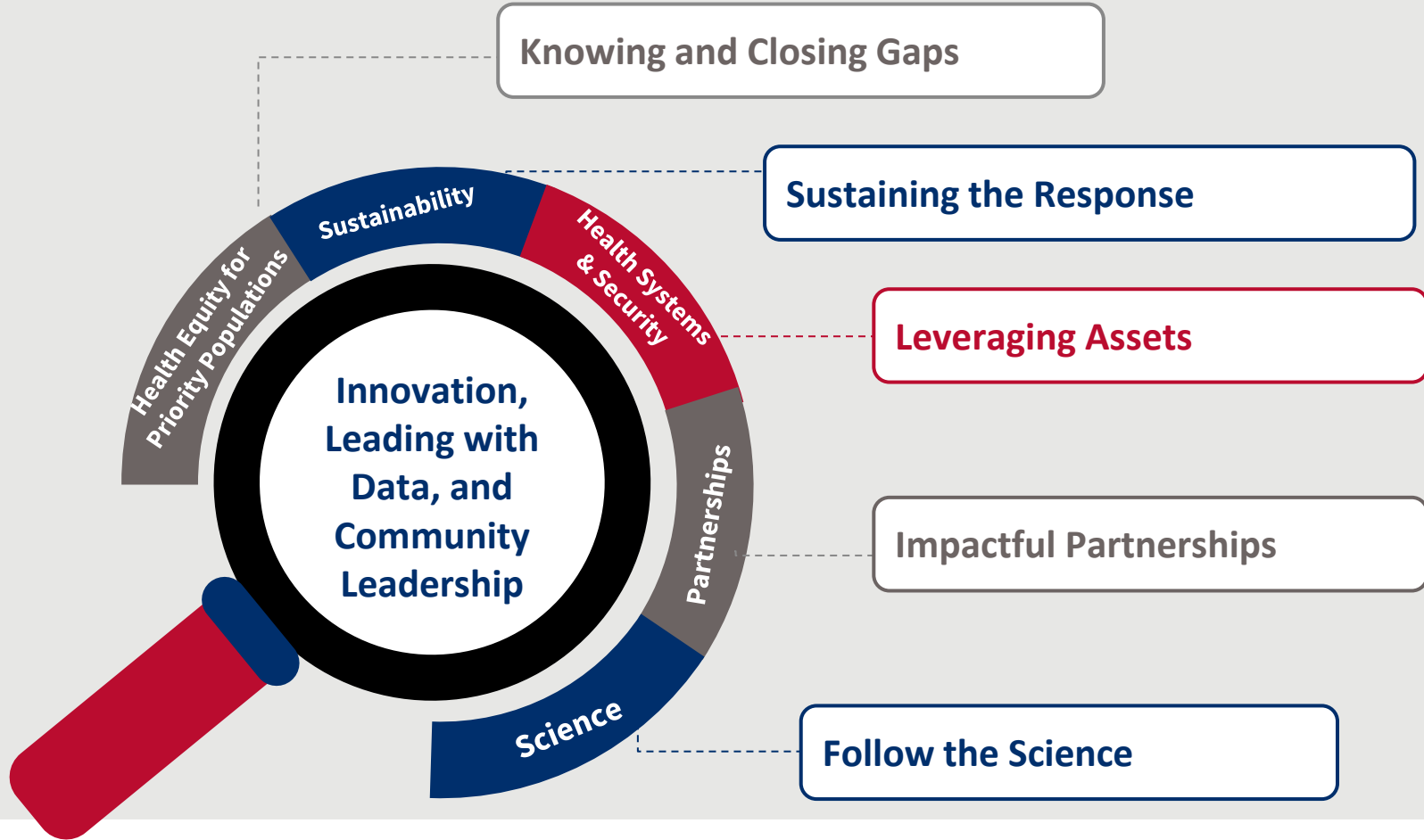
1. PEPFAR and MATRIX
2. USAID and MATRIX
3. Research Division and MATRIX
4. What have we accomplished so far and where are we going?

PEPFAR and MATRIX

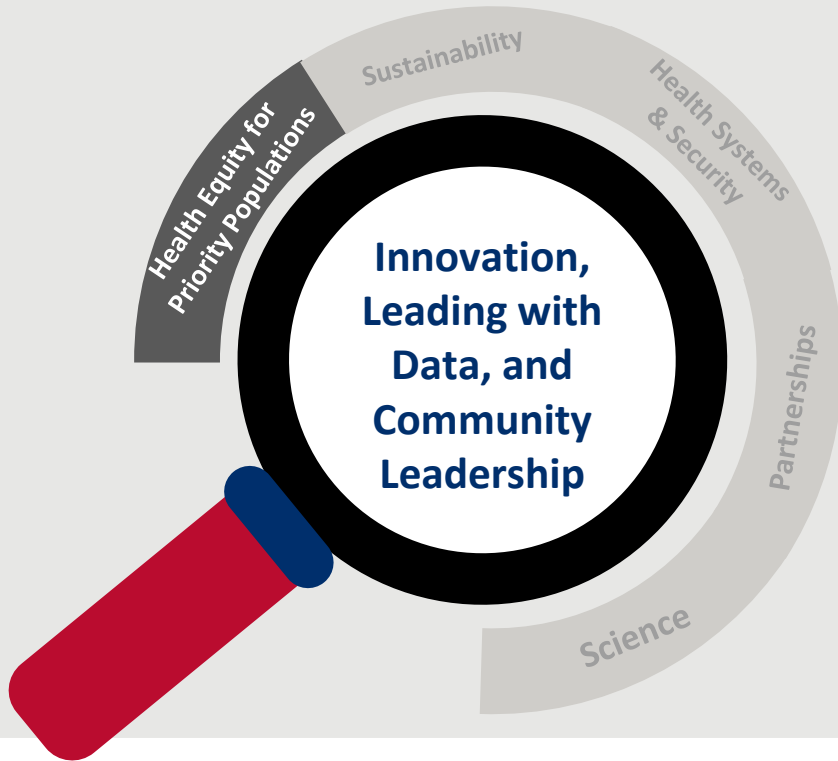
PEPFAR is Committed to Achieving Epidemic Control



PEPFAR Program Evolution



PEPFAR Program Evolution



Health Equity for Priority Populations

Reducing prevention and treatment gaps for AGYW and KP

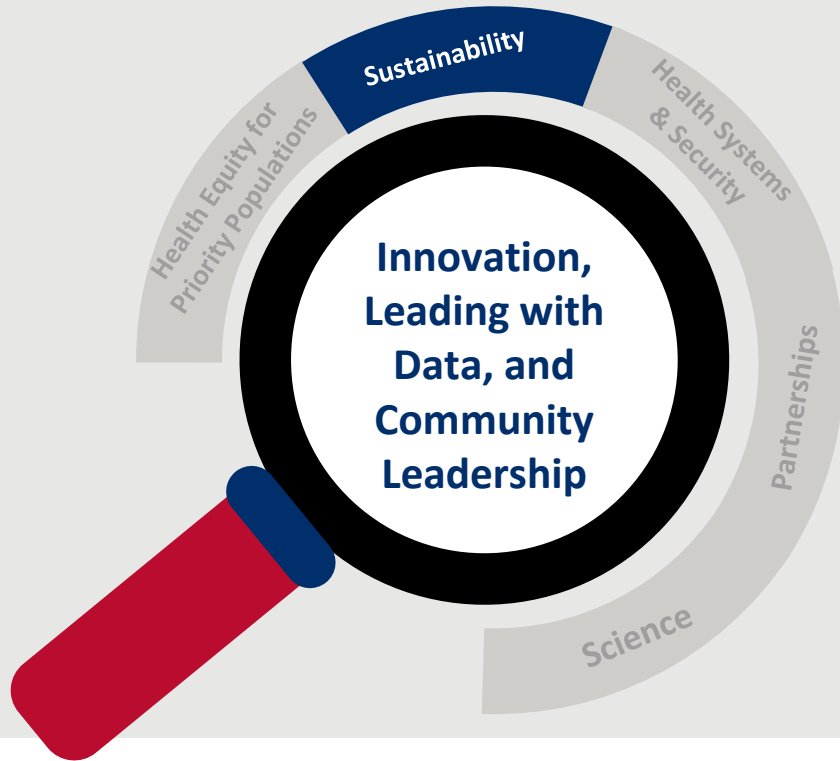
Key Focus Areas

- Adolescent girls and young women
- Children
- Key populations
- Barriers to health equity

MATRIX Contribution to: **Health Equity for Priority Populations**

- Addresses disproportionate number of new infections in AGYW
- Incorporates inputs from FSW, SMW, PBFW potential users
- Engages key decision-makers in the earliest stages of R&D to remove barriers

PEPFAR Program Evolution



Sustainability

**Strengthening leadership
within governments,
programs, and community**

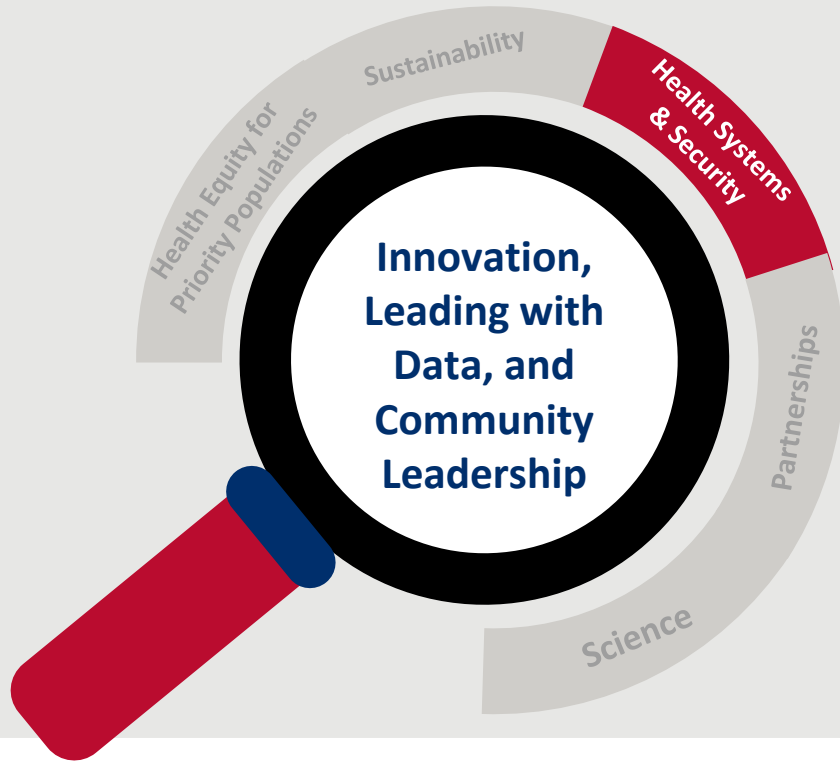
Key Focus Areas

- Sustainability roadmap
- Localization
- Integration
- Alignment

MATRIX Contributions to: Sustainability

- Includes Stakeholder buy in during early R&D
- End-user feedback influences product before it gets to pharmacies, “Nothing for us, without us”
- CaSE equips local investigators with skills and knowledge needed to drive continued progress in HIV prevention research and development within their countries.

PEPFAR Program Evolution



Health Systems and Security

Equip countries and strengthen capacity to enhance and sustain impact

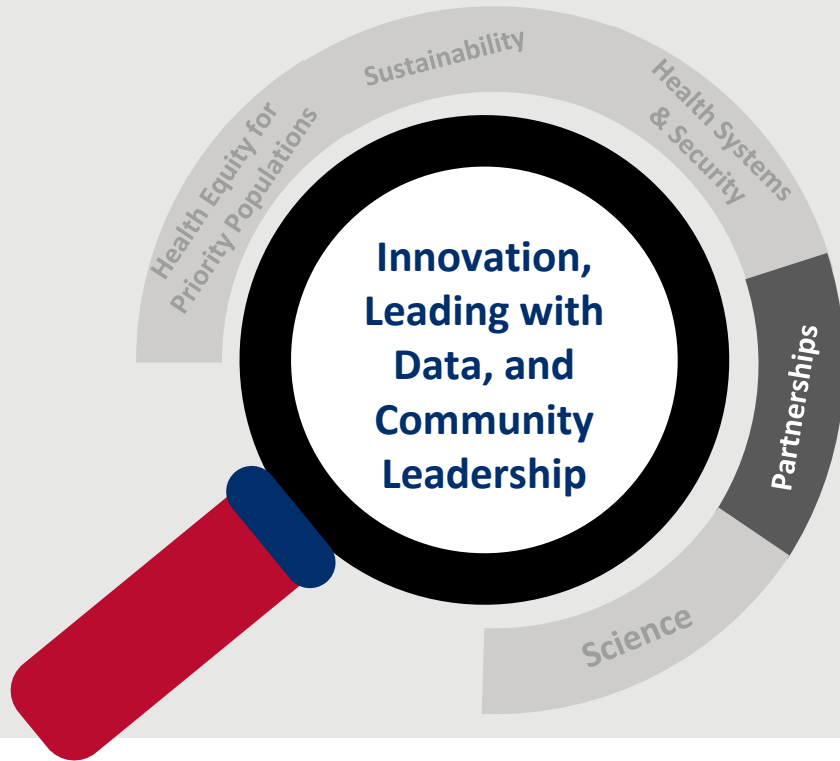
Key Focus Areas

- Regional and National Public Health Institutions
- Health Workforce
- Regional Manufacturing
- Supply Chain Public Health for PLHIV
- Leveraging PEPFAR Assets for Health Security

MATRIX Contributions to: Health Systems and Security

- Proof of concept research to manufacture APIs on the continent
- Encourage product developers to assess local manufacturing capabilities
- Utilizing the existing capacity of research institutions and researchers to build new products

PEPFAR Program Evolution



Partnerships

Designing new private/
public partnerships to
compliment existing
programs

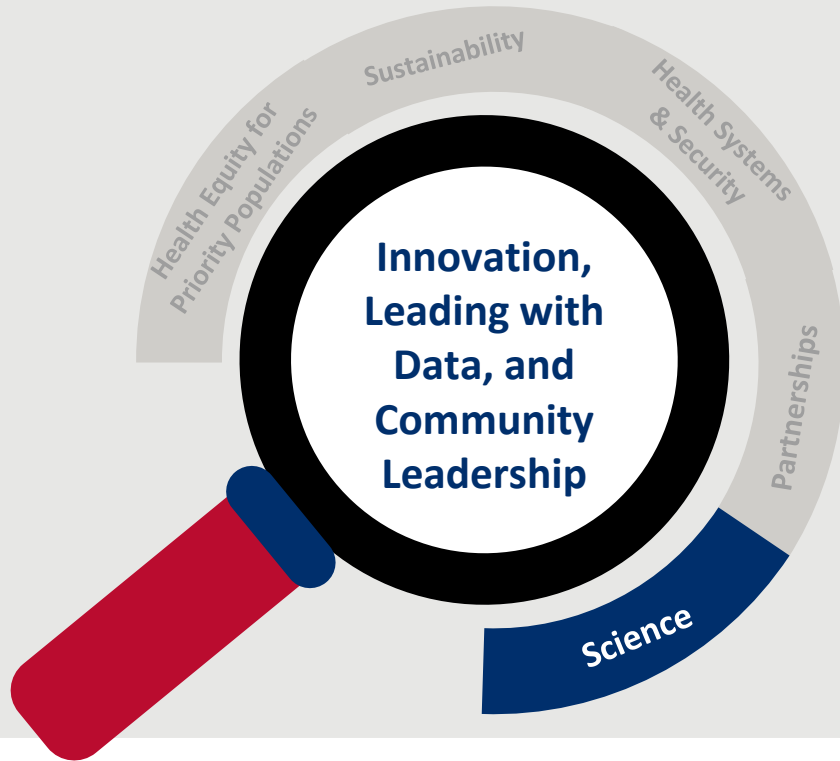
Key Focus Areas

- Multilateral Partners
- Philanthropies
- Private Sector
- American Institutions

MATRIX Contributions to: Partnerships

- External partner's call
- Relationship building with pharmaceutical companies (MERCK, GILEAD and ViiV)

PEPFAR Program Evolution



Science

Use science and data to
drive programming
decisions

Key Focus Areas

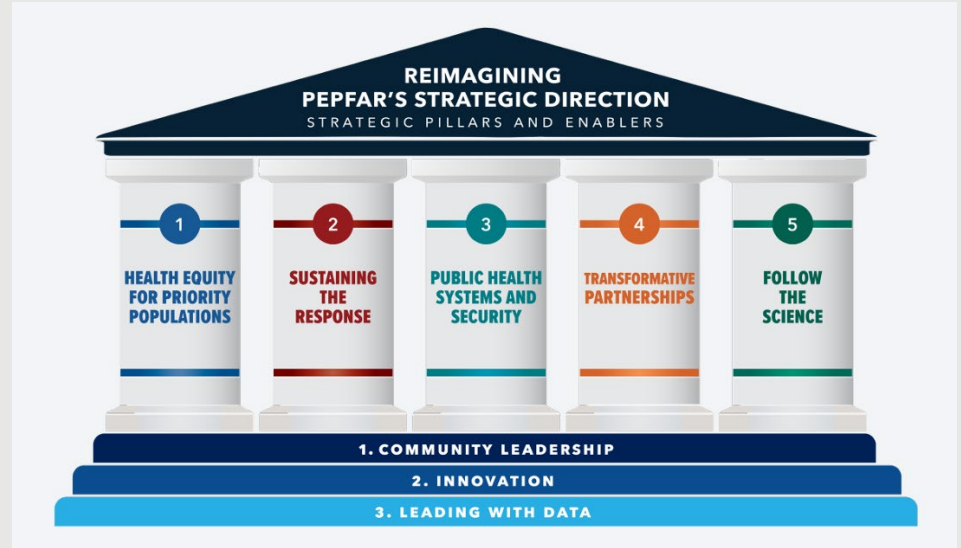
- Behavioral science
- Implementation science
- Market shaping
- HIV Testing services
- Applied epidemiology and surveillance

MATRIX Contributions to: Science

- Uses SBR to develop HIV prevention products that align with end-users' preferences and needs
- Shapes markets by fostering collaborations between public and private sectors, driving innovation and ultimately influencing global landscape of HIV prevention

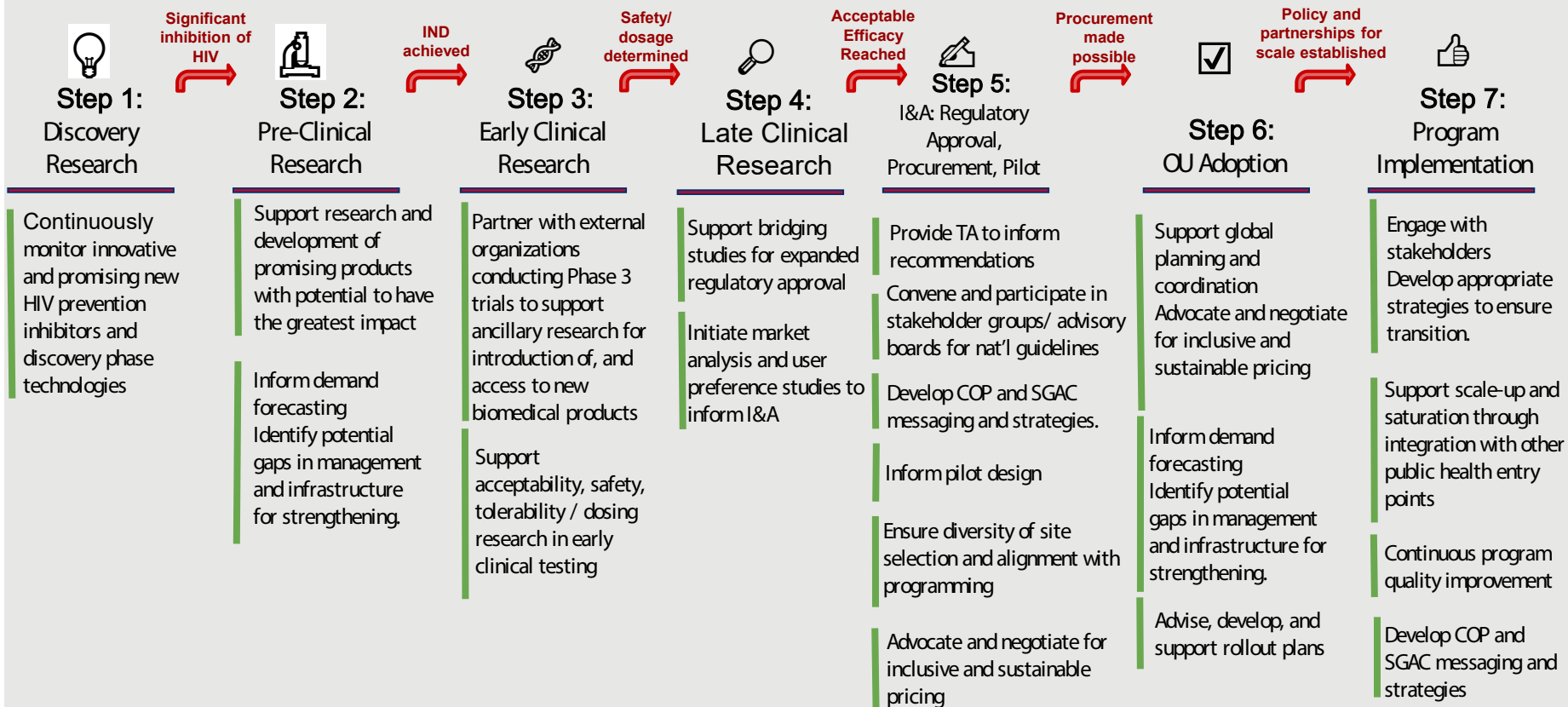
MATRIX and PEPFAR's 3x5 Vision

- **Community Leadership:**
 - Local communities, leadership
 - Direct, early stakeholder, user feedback and buy in
 - CaSE trains next PDs in SSA with tailored mentorship and training for local investigators
- **Innovation:**
 - 9 products in our portfolio
 - Addressing critical unmet need for women to have choice, options for PrEP
- **Leading with Data:**
 - Data-driven decision-making, research and programming choices informed by rigorous scientific insights from our clinical trials
 - Feedback from end-users and stakeholders from D2D

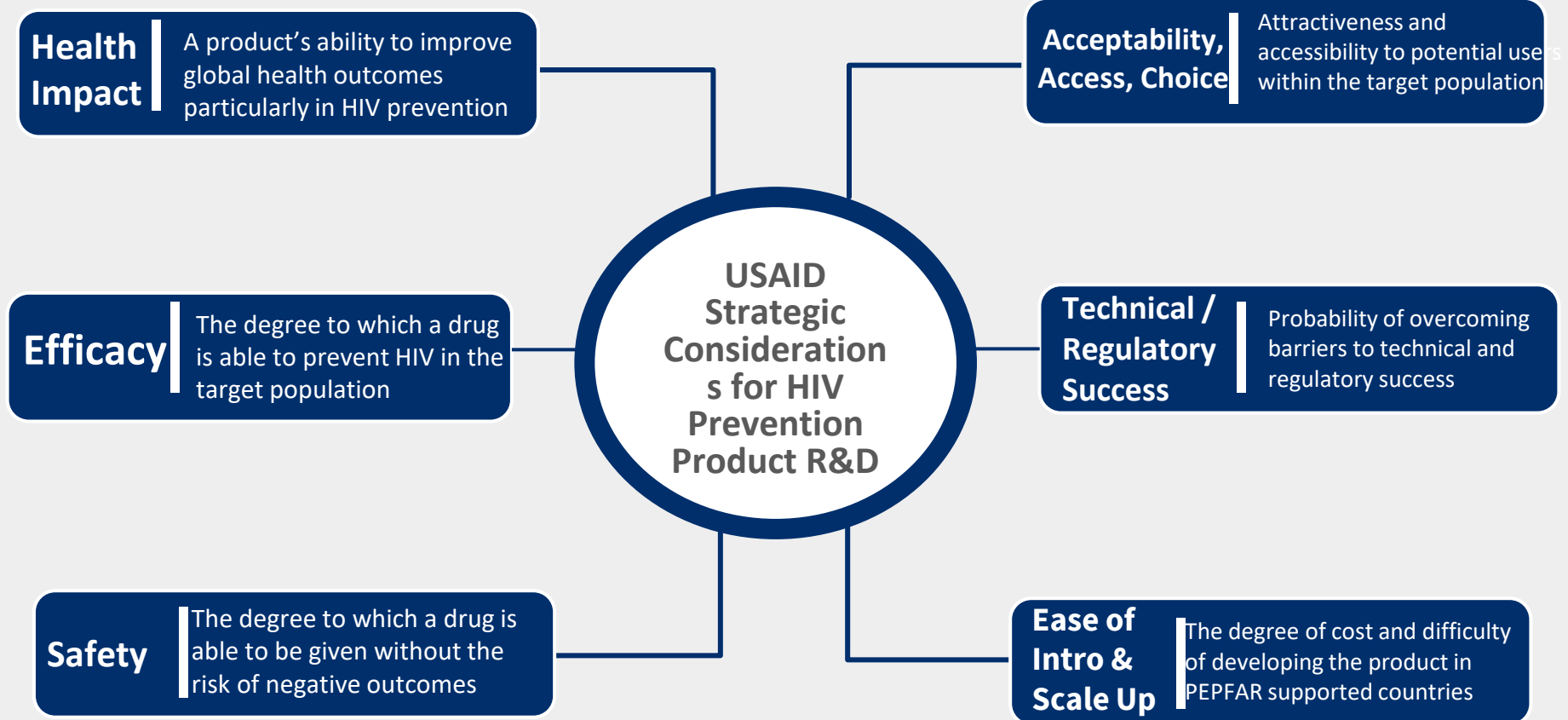


USAID and MATRIX

USAID Engages at Each Phase Along the Product Development Pathway



USAID Priorities for New Products



USAID MATRIX Project Management Team

1) Early-stage Product R&D

Lab scientists, GLP, Biomedical engineers, Formulation pharmaceuticals

6) Business Case for R&D

Market Demand, Cost effectiveness analysis, Business plans, Regulatory Strategies, Investor matching, Manufacturing & distribution plans

5) Local R&D Capacity Strengthening

Mentoring, Training, South-South Collaboration, Institutional Strengthening, Leadership roles

2) Late-stage Product R&D

Regulatory, Manufacturing (CMC, GMP), Bridging/Phase 3 Study Design, Safety, Efficacy, Epidemiology & Statistics

3) Clinical Trial Design for R&D

Clinical Expertise, Safety Monitoring, Protocol Design, Epidemiology & Statistics, Human Subjects Research Ethics

4) Participatory Research for Product R&D

Socio-behavioral research methods, Qualitative & Quantitative research methods, Survey design & implementation, Community engagement

Core Team

Shannon Allen, AOR
Chelsea Solmo, Alt-AOR
Simone Cho, AO
Mike Orquiza, Sr. TA
Antoinette Nelson, TA
Kristin Vahle, PA
Brandon Brown, Intern
Vacant, Intern

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Daniel Kiesa, OHA/SCH, Activity Manager

Elijah Kahn, GH/AA Consulted Advisor

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Megan Coleman, PPIR Consulted Advisor

Mary Latka, Chelsea Solmo, Kristin Vahle

Ashley Lima, OHA/RES Consulted

Addressing USAID Strategic Priorities Through MATRIX

- **Successes**

- ***Decision-making transparency*** with technical teams and OHA leadership
- ***Buy-in from*** program-based ***technical teams*** through ***active involvement*** in decision making
- Ensuring ***R&D is well-aligned*** with programing and PEPFAR/field priorities
- ***Shaping donor considerations*** around product development investments
- ***Identifying potential risks*** to product development and/or programmatic implementation/access

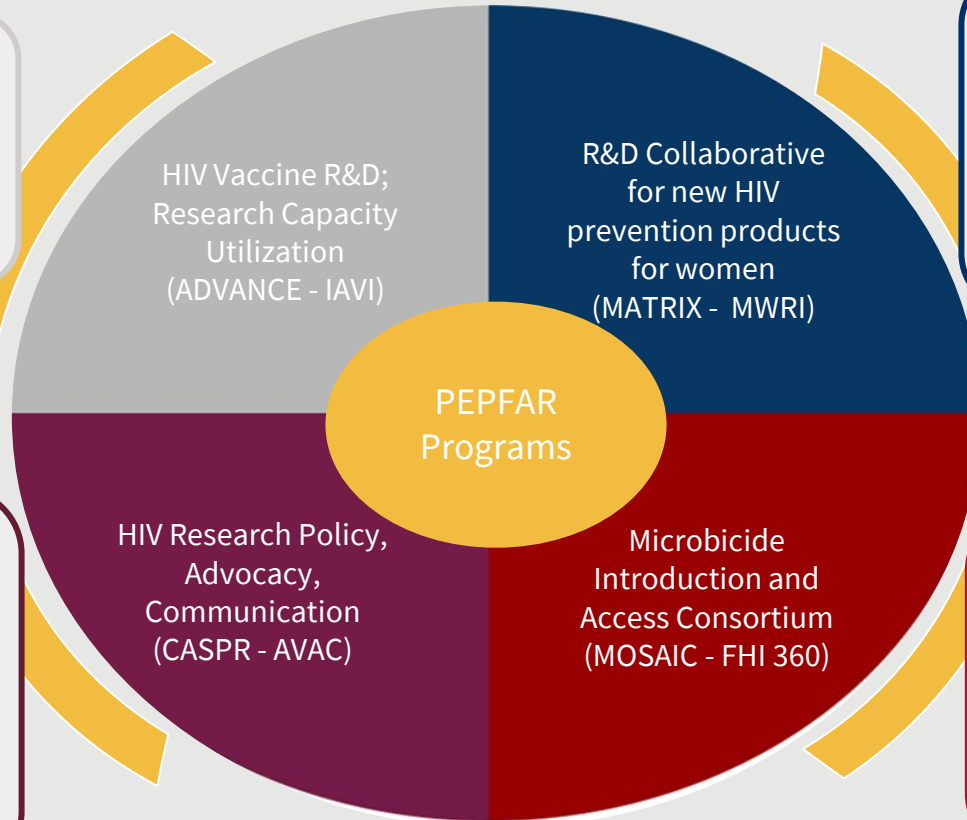
Research Division, Microbicide Program and MATRIX

USAID's Research Program to Develop New Products for HIV Prevention

Mission: To develop a safe, effective HIV vaccine and biomedical prevention products for global use.

Vaccine Program

Mission: To advocate for biomedical HIV interventions in the pipeline from research to rollout and to bring together experienced partners committed to a collaborative movement for responsive HIV prevention research.

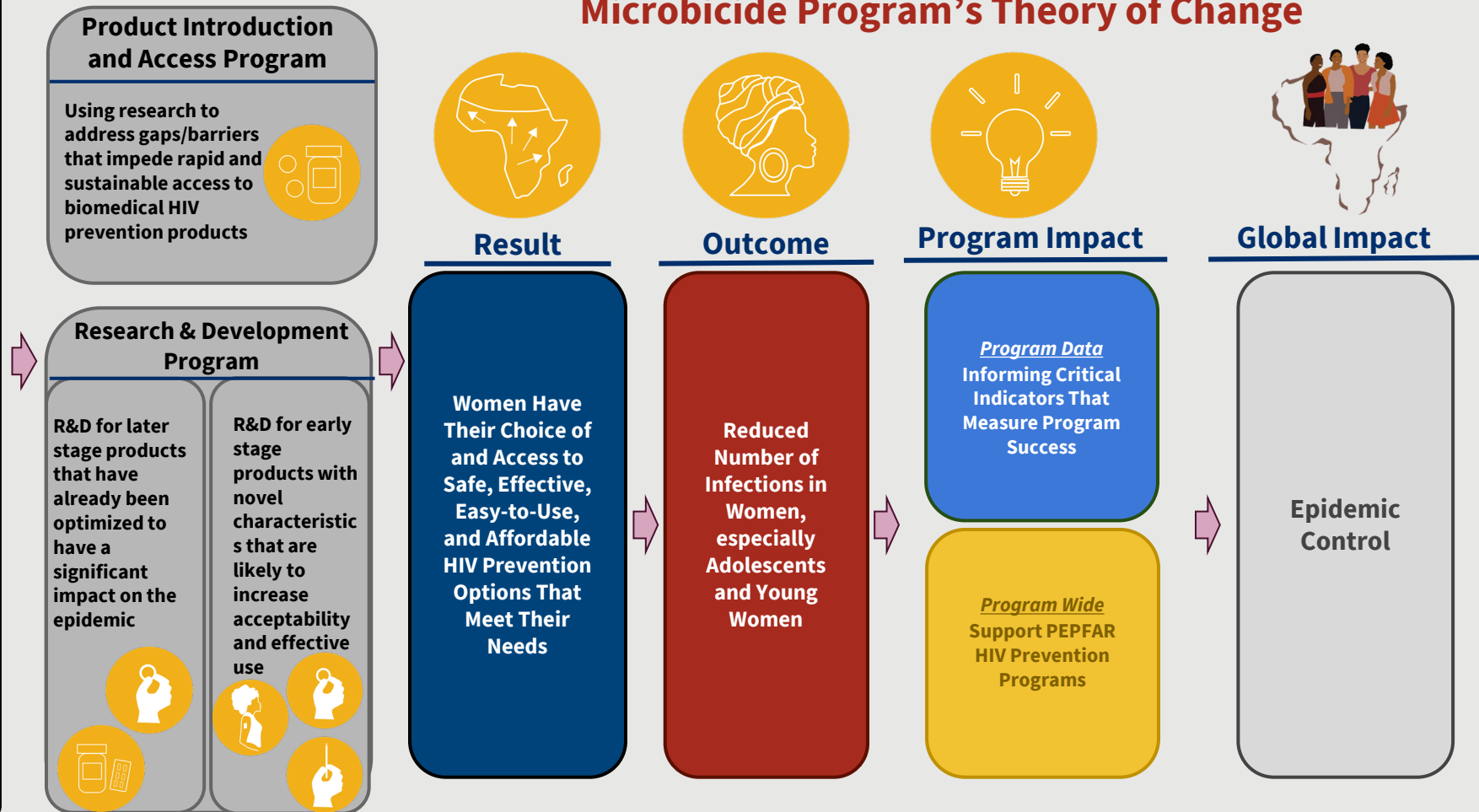


Mission: To develop a range of feasible (acceptable, effective, affordable, scalable, and deliverable) biomedical prevention technologies that meet the unmet needs of women, especially AGYW at substantial risk of HIV.

Microbicide Program

Mission: To target, optimize, and expedite the introduction and access of highly impactful HIV biomedical prevention products that best respond to the needs of women at substantial HIV risk.

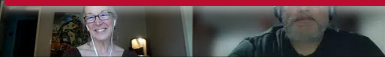
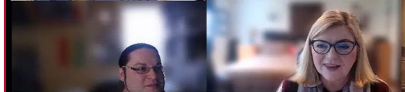
Microbicide Program's Theory of Change



MATRIX Success from a USAID Perspective



Our Shared Purpose: In collaboration with Magee-Womens Research Institute and 18 esteemed partners spanning Kenya, South Africa, Zimbabwe, and the U.S., MATRIX is propelling early-stage research and development in HIV. Our efforts resonate deeply with women at risk, echoing the unmet needs that inspire our mission.





Global Vision, Local Touch

Our influence spans across nations, touching lives in regions as diverse as our partnerships. The heart of our endeavor lies in empowering women's health through innovations that are not just scientifically groundbreaking, but also accessible and affordable.

Fueling Scientific Discovery and Progress:



The Technology Accelerator domain, encompassing both problem mitigation and innovation incubation, fuels the growth of new technologies.



Our Clinical Trials hub thrives on local engagement, generating evidence to inform safety and acceptability of emerging products.



The Design to Delivery hub empowers end-users and stakeholders to shape product development



Business, Market Dynamics, and Commercialization hub nurtures product strategies.



The Capacity Strengthening, Engagement, and Mentoring hub fosters mentorship and training opportunities, ensuring a strong legacy of expertise.

Progress and Milestones: TA 1 & 2

- Two rounds of RFAs were released to solicit potential seed projects through competitive process and scientific review panel
- 4th annual SAG convened August 15th
- 4th Landscaping Review submitted to USAID

1		TAF/EVG Fast-dissolving vaginal insert
2		Griffithsin Fast-dissolving vaginal insert
3		Dapivirine vaginal film
4		Cabotegravir hydrogel injectable
5		Cabotegravir dissolvable pellets
1		Non-ARV/ nonhormonal contraceptive dual- purpose vaginal ring
2		Dapivirine and levonorgestrel vaginal film
3		Cabotegravir/ levonorgestrel hydrogel injectable
4		Cabotegravir/ levonorgestrel dissolvable pellets

Clinical Trials: Pioneering Advances in Prevention

CONRADs Phase I safety/PK/PD study of TAF/EVG insert (MATRIX-001)

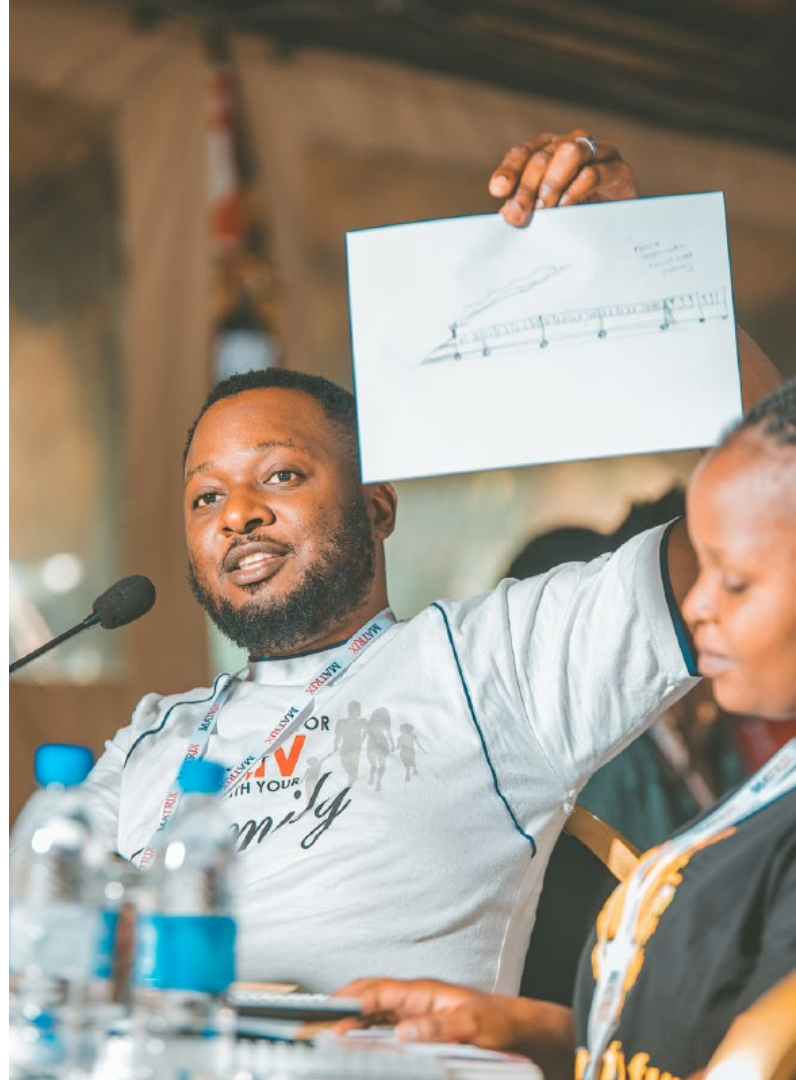
- US and SSA study activation expected in Oct 2023

UPitt placebo film study (MATRIX-002)

- US study activation expected Sept 2023
- SSA study activation expected Oct 2023

Oak Crest placebo IVR study (MATRIX-003)

- US study activation expected Oct 2023
- SSA study activation expected Dec 2023



CaSE: Fostering Local Partner Leaderships

- Track 1 e-learning courses: Courses will launch in parallel in August 2023 and end in December 2023
- Track 2 short-term placements of scholars with MATRIX Hubs: BACH Scholar
- Track 3 Sustainable technical skills and capacity development with 5 components
 - Continues to develop a sustainable capacity development program in early product development with 5 distinct components. Solicitation and selection of scholars are ongoing.



Progress and Milestones: D2D

- Promoting development of acceptable products through engagement with end-users and integration of SBR in clinical trials
- Providing feedback to product developers to inform product development with input from African stakeholders and to inform introduction, access, and uptake.
- Support and mentorship of CaSE D2D Scholars Wanzi Makoni from PZAT, Zimbabwe and Njeri Wairimu from KEMRI, Kenya.



Progress and Milestones: BACH

- Needs assessment completed with all PDs
- Convened two webinars with favorable participant responses
- Cost effectiveness analysis
- Development of a commercialization roadmap
- Manufacturing capability assessment
- Developing a COGs estimate and supply chain cost analysis
- Developing a methodology and framework for demand assessment





A Visionary Path Forward

Our ultimate goal for the future is to, through our research hubs, shepherd at least one of our pioneering products through to Phase 2 trials.

As we look ahead, these aspirations guide us toward a future where MATRIX continues to be a beacon of progress, innovation, and collaborative excellence in the realm of HIV prevention and the needs of AGYW.