MATRIX Stakeholders Meeting Recap of Day One

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

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

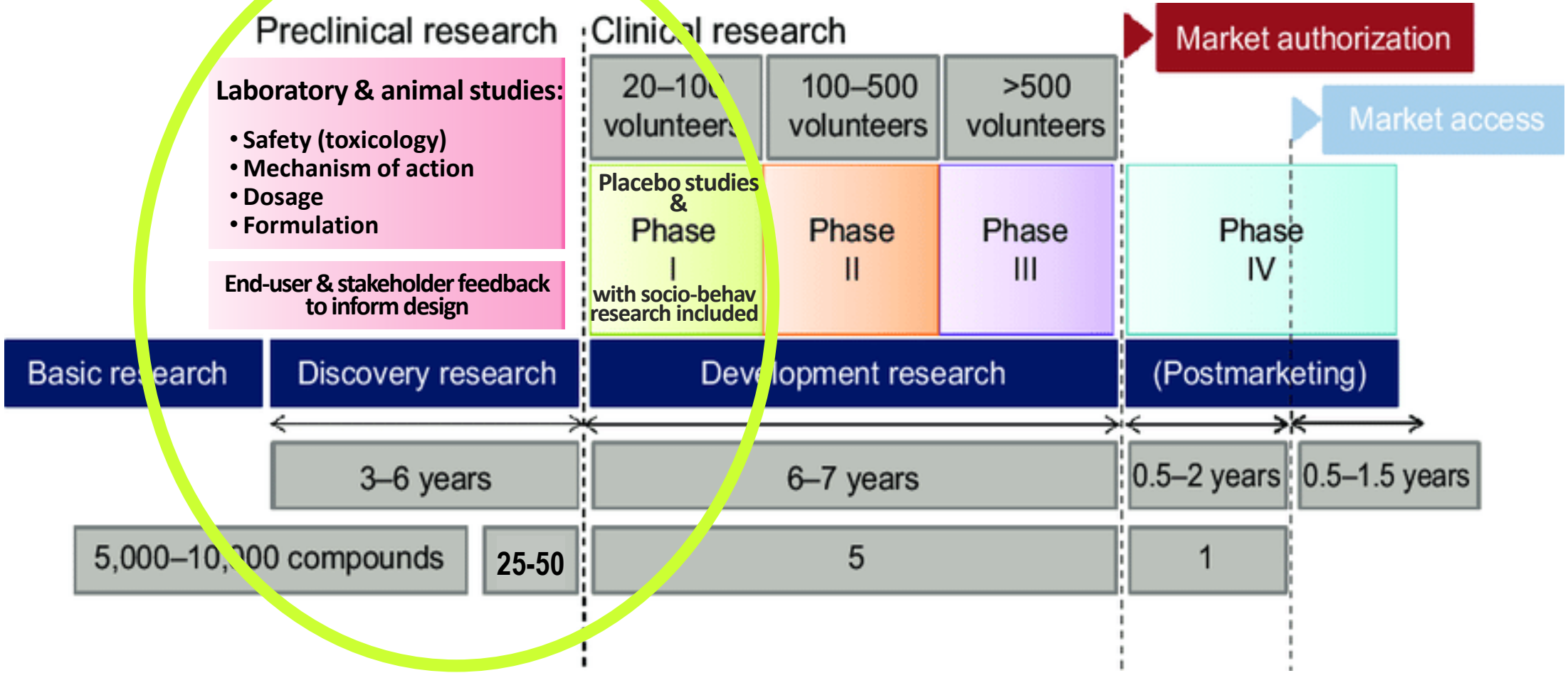
What is MATRIX?

- A USAID Project to Advance the Research and Development of Innovative HIV Prevention Products for Women – funded in Dec. 2021 for 5 years
- Brings together 19 partner organizations from Sub-Saharan Africa and North America, with expertise in product development, clinical trials, social and behavioral research and market and business case development

Mission:

To expedite the research and development of a range of HIV prevention products for women that will be safe and effective as well as **acceptable**, **affordable**, **scalable** and **deliverable** in settings where they are needed most.

All about early development



How is MATRIX unique?

- Will be seeking and **integrating feedback of end-users and stakeholders early in the product development process** to inform decisions about product design and overall research priorities
- **Placebo studies and early phase (Phase 1) clinical trials to be conducted in Africa – not just in the US** – to obtain important data on safety and acceptability of new products and how and where the active drug is taken up in the body in the populations of women that matter most
- Through its structure of balanced North-South partnerships, **aiming to recognize and strengthen the research and development capacity of African investigators to facilitate full and sustainable ownership of this work** into the future.

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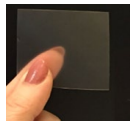
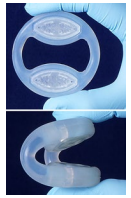
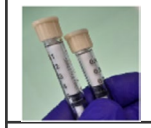
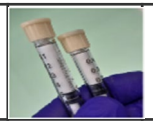
What does the MATRIX product portfolio include?

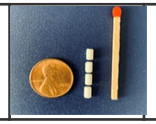
- A ***range*** of product types to ensure women have different options:
  - Long-acting implants or injectables (systemic products)
  - Long-acting and on-demand vaginal products
  - Multi-purpose products (MPTs) to protect against HIV plus other sexually transmitted infections and/or pregnancy
- Most are ***early-stage products*** that have not been tested in clinical trials yet

MATRIX Product Pipeline Overview

	Product		Developer	Product Type	Active ingredient	How used	How long protected?	MPT?	Unique features	Status
1		TAF/EVG Fast-dissolving insert	CONRAD (USA)	Fast-dissolving insert	TAF/EVG tenofovir alafenamide & elvitegravir (NRTI & integrase inhibitor)	On-demand (at the time of sex)	Up to 3 days	HIV *and* HSV	Could be used vaginally or rectally - as PrEP or PEP	US/North American studies conducted first Phase 1 study in African women planned for 2023
2		Griffithsin Fast-dissolving vaginal insert	Population Council (USA)	Fast-dissolving insert	A protein -Griffithsin Viral entry inhibitor	On-demand (at the time of sex)	4 hours	HIV *and* HPV HSV	Active ingredient derived from seaweed	Pre-clinical
3		One month dapivirine vaginal film	Univ of Pittsburgh (USA)	Vaginal film	Dapivirine NNRTI	Women insert themselves	1 month		Releases drug until film completely dissolves	Placebo study being planned for 2023
4		Non-ARV/ nonhormonal contraceptive multipurpose vaginal ring (LAMP-IVR)	Oak Crest Inst of Science (USA)	Vaginal ring	A peptide (protein fragment)- acts against HIV (& HSV/HPV) A small molecule Inhibits sperm's movement & ability to penetrate, fertilize eggs	Women insert themselves	1-3 months	HIV *and* HPV HSV pregnancy	Non-ARV and nonhormonal Could be used with or without contraceptive	Placebo trial being planned for 2023
5		Cabotegravir injectable depot	CONRAD (USA)	Injectable depot (storage bubble)	Cabotegravir Integrase strand inhibitor	Injection given under the skin	4-6 months		May be less burden on healthcare system and users	Pre-clinical
6		Cabotegravir dissolvable pellets	CONRAD (USA)	Pellet implant	Cabotegravir Integrase strand inhibitor	Implanted under skin	9-12 months		Slowly dissolves over course of a year; Can be removed after 1-2 months if needed	Pre-clinical

7  One month dapivirine vaginal film plus levonorgestrel (LNG)

8  Cabotegravir injectable depot plus LNG

9  Cabotegravir dissolvable pellets plus LNG

Three products also to be developed as an MPT with the addition of a hormonal contraceptive

The realities of early product development – and how we might improve the odds for success

- We can't expect the entire pipeline of products to make it all the way to regulatory approval – that's the reality of research and development
- However, we hope to improve the odds for success by ensuring only the most promising products advance from pre-clinical research to early phase testing.

Products that:

- Laboratory and animal studies suggest will be safe and effective in humans
- End-users indicate they are likely to use
- Could be manufactured and distributed locally and at low cost
- Are likely be easy to deliver, with minimal burden on healthcare systems
- Meet the needs of Ministries of Health and national HIV prevention programs

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Acknowledgements

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