

KENYA

Stakeholder Consultation Summary and Key Comments

D2D Pillar 3
November 23, 2022



KENYA Consultation

- Took place in Nairobi, 8-9 November 2022
- Was attended by 69 participants, with 55 external stakeholders, including:
 - National Syndemic Diseases Control Council (NSDCC) CEO
 - Prominent researchers and clinical trialists
 - Pharmacists and pharmacologists
 - Service providers, community health volunteers and international health service organizations (e.g., CHAI, JHIPIEGO, AMPATH, Public Services International)
 - A member of the National Commission for Science, Technology & Innovation's (NACOSTI) National Scientific and Ethics Review Committee (NSERC)
 - Civil society, NGOs and advocacy organizations (e.g., IAVI, Kenya AIDS NGOs Consortium, LVCT Health)
 - Young women and advocates, including a member of the MOSAIC NextGen Squad
 - Former trial participants and Community Advisory Board members

Meeting Objectives

1. Introduce MATRIX and describe its rationale and approach for accelerating early research and development of innovative HIV prevention products for women.
2. Sensitize stakeholders regarding early phase trials, including first-in-human studies, being conducted in Eastern and sub-Saharan Africa and discuss ways to mitigate potential community concerns.
3. Seek stakeholders' feedback on the MATRIX product pipeline
4. Establish a foundation for ongoing, bi-directional engagement through the lifecycle of the project and the product development lifecycle.

A message for stakeholders

"MATRIX is all about improving the chances of success...a new way to do things by involving communities early... At the end of the day, we want products that are affordable, not just beautiful products sitting on shelves... we want products that are safe, easy to distribute, easy to use, comfortable to use..."

(Nelly Mugo)

"With MATRIX, we are putting the horse before the cart."

(Kenneth Nguire)

Agenda: Interactive Sessions and Deep Dives

- Overviews of the current HIV prevention landscape, MATRIX, the R&D process and what's involved in conducting early phase studies were followed by interactive sessions and deep dives
- Interactive sessions made use of polling software (Audience Response System – ARS) to seek views regarding:
 - The need for additional HIV prevention options (besides oral PrEP, dapivirine ring and CAB-LA)
 - Different product classes (e.g., on-demand, MPTs)
 - The overall MATRIX pipeline
 - The notion of conducting early phase studies in SSA
- Deeper dives into:
 - TAF-EVG fast-dissolving insert and MATRIX-001
 - Monthly dapivirine vaginal film and MATRIX-002
 - MPT vaginal ring (LAMP-IVR)

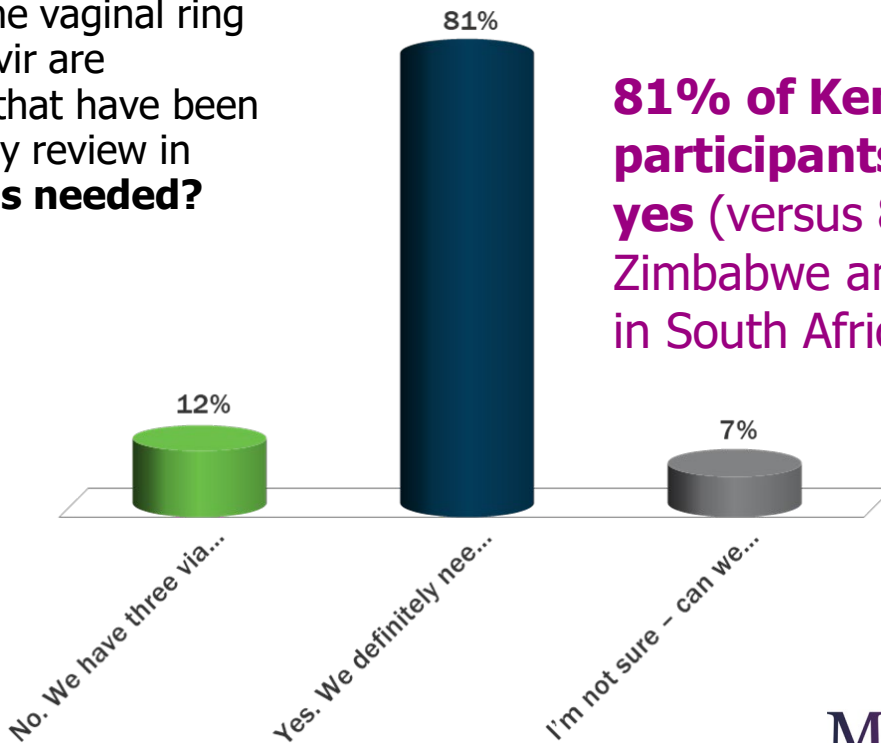
Is there a place for new methods and product formulations?

ARS results and comments during the meeting

Are other options needed?

Daily oral PrEP, the monthly dapivirine vaginal ring and long-acting injectable cabotegravir are biomedical HIV prevention methods that have been approved and/or are under regulatory review in several countries. **Are other options needed?**

- A. No. We have three viable options, and we should be focusing our efforts on seeing that they are made more widely available and ensuring counseling programs are in place to support their effective use.
- B. Yes. We definitely need more options. Women have different needs and preferences at different times in their lives.
- C. I'm not sure – can we talk about this some more?



81% of Kenya participants said yes (versus 87% in Zimbabwe and 69% in South Africa)

Are other options needed?

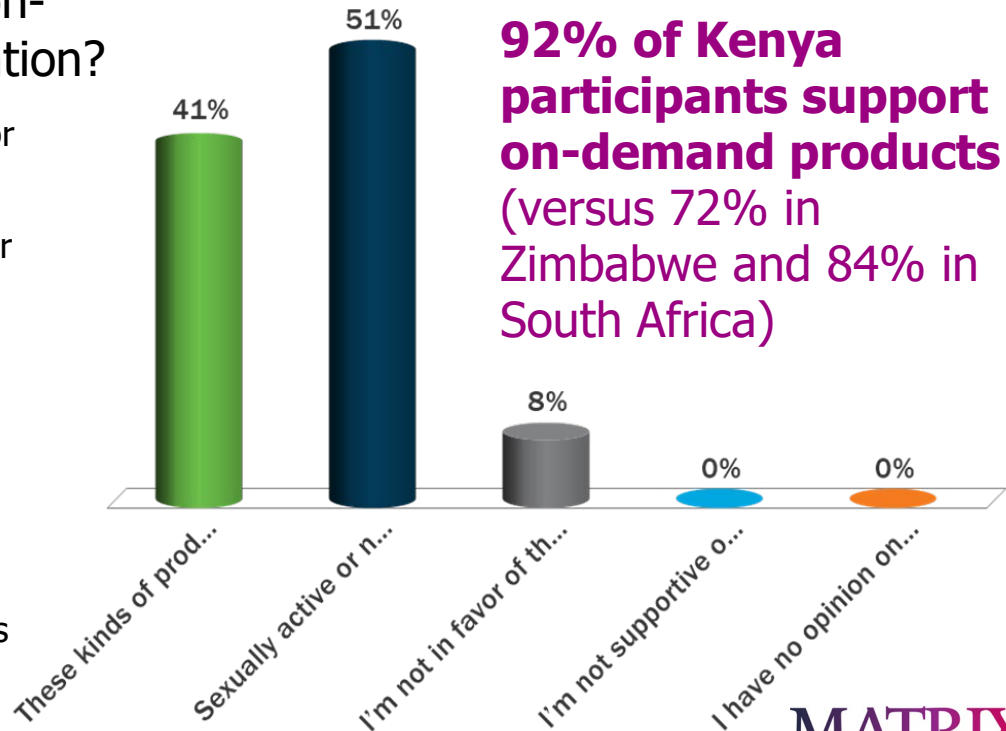
"For many years women have been robbed of the power to make choices... We want to see young women able to access products and they have power and choice over... having many options that are discreet, that are comfortable, that women can control, that are long-acting or short-term depending on what a woman would want – and most importantly that are available – will go a long way in ensuring that we reduce HIV prevalence infection in our countries."

(Young woman and reproductive health advocate)

What about on-demand products?

What are your views regarding on-demand products for HIV prevention?

- A. These kinds of products would be good for women who are only having sex occasionally and are likely to be preferred over a method needing to be used daily or that is long-acting.
- B. Sexually active or not, there will be women who prefer not to use a systemic method, so an on-demand product might be an appealing option.
- C. I'm not in favor of these so-called on-demand products because everyone should have protection all the time.
- D. I'm not supportive of on-demand products for other reasons.
- E. I have no opinion one way or another.



92% of Kenya participants support on-demand products (versus 72% in Zimbabwe and 84% in South Africa)

Views on on-demand products

"I believe everyone needs what works for them, and this will be good for those that don't want a continuous method."

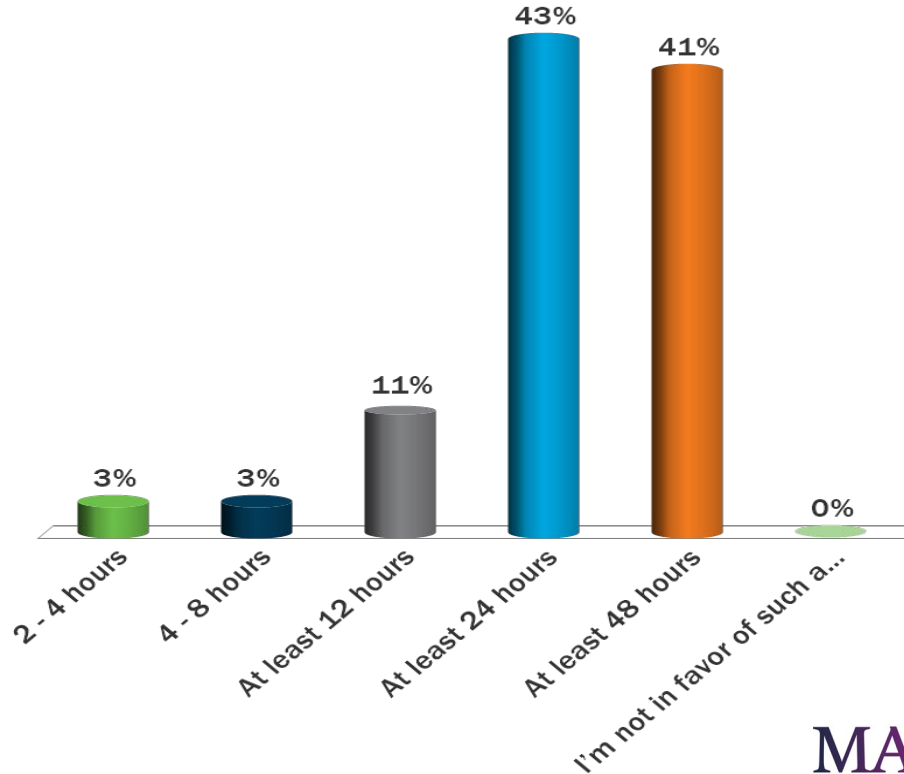
(meeting participant)

"We have an on-demand product for men, the condom, so women also need one for when they can't negotiate [use of protection]."

(meeting participant)

How long should an on-demand product provide protection against HIV?

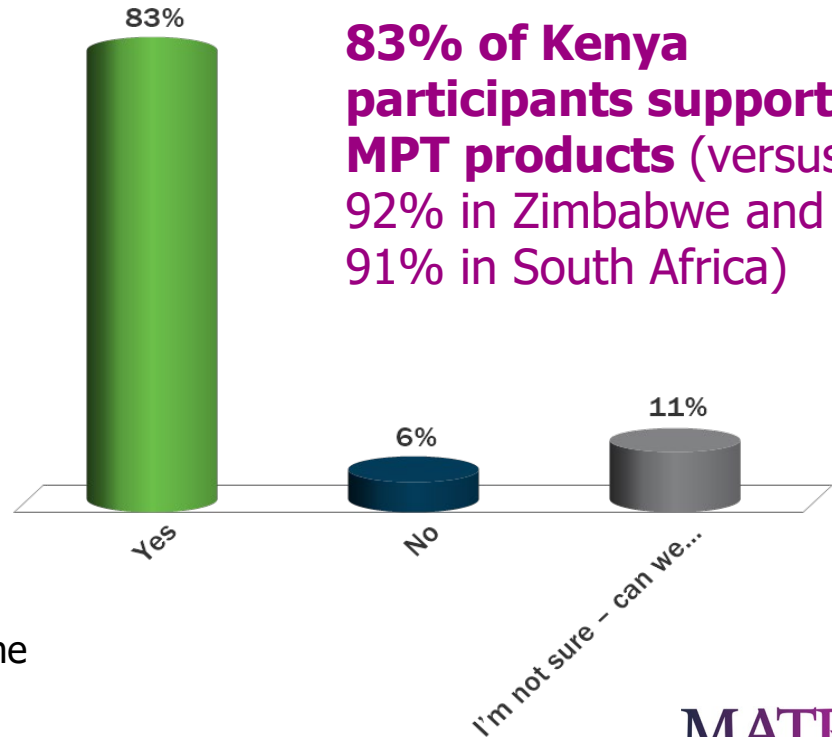
- A. 2 - 4 hours
- B. 4 - 8 hours
- C. At least 12 hours
- D. At least 24 hours
- E. At least 48 hours
- F. I'm not in favor of such a method



Should MPTs be a priority?

Six of the nine products in the MATRIX pipeline are being designed to not only protect against HIV but also against other sexually transmitted infections (herpes simplex virus – HSV; and/or human papillomavirus - HPV) and/or unwanted pregnancy – products often referred to as an MPT, short for multi-purpose technology. **What is your opinion about MPTs – should their development be a priority for the HIV prevention field?**

- A. Yes
- B. No
- C. I'm not sure – can we talk about this some more?



83% of Kenya participants support MPT products (versus 92% in Zimbabwe and 91% in South Africa)

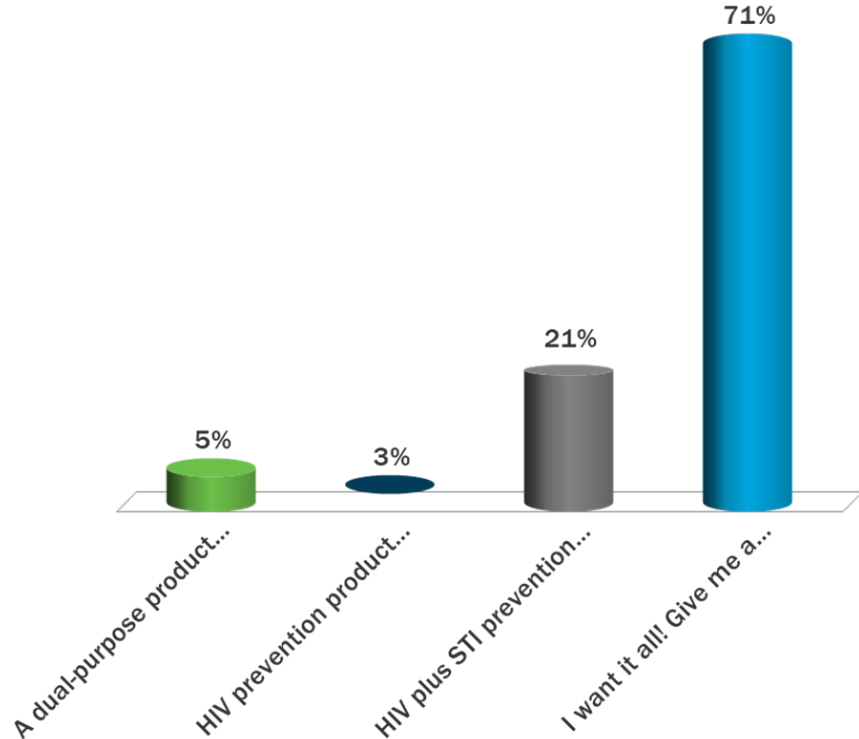
Views on the need for MPTs

"I am excited about these products being developed that can protect against HIV and so many diseases and pregnancy." (medical worker)

"... we will be killing two birds with one stone..." (several stakeholders)

What's more important: Having an HIV prevention product that includes contraception, an HIV prevention product that protects against other STIs or a product that is solely for HIV prevention?

- A. A dual-purpose product that protects against HIV and offers contraception would be a game-changer.
- B. HIV prevention product only – Women already have a number of contraceptive methods to choose from. Why can't they continue with what they're already using and just use something else for HIV?
- C. HIV plus STI prevention product – It's about time we did something to address the high incidence of STIs. I'm all for an HIV prevention method that would work against HPV and/or HSV as well.
- D. I want it all! Give me a single product that protects women against HIV, STIs and unwanted pregnancy!



Views on the need for MPTs

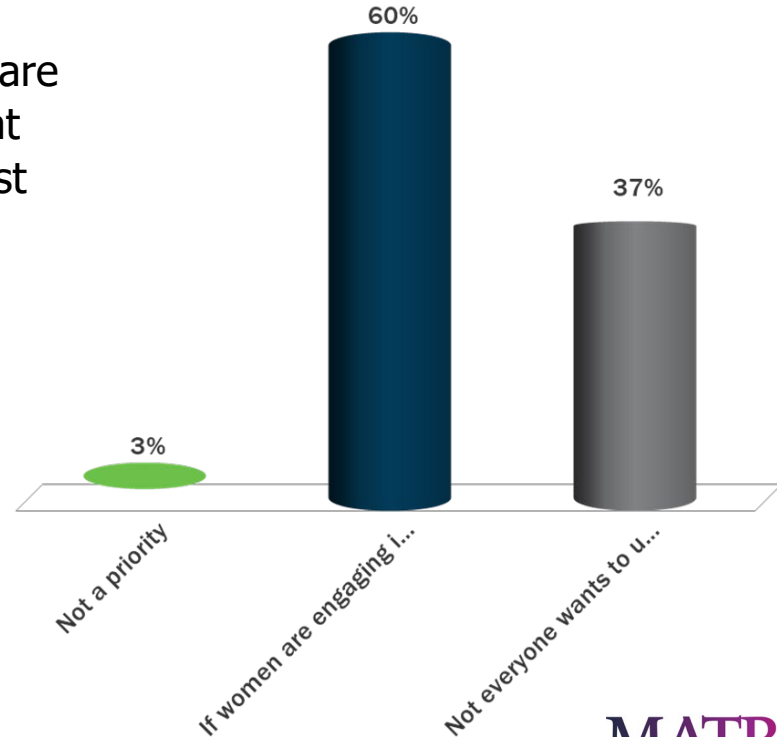
"These days we say in Kiswahili, 'mambo ni mengi, muda ni mchache' (too much to do, too little time). I want a one-stop shop that meets all my needs all under one roof"

(service provider)

Rectal microbicides for women?

The risk of acquiring HIV through anal sex is much greater than through vaginal sex. What are your thoughts about the need for products that women could use to protect themselves against HIV during anal sex?



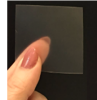



- A. Not a priority
- B. If women are engaging in both anal and vaginal sex they should be taking oral PrEP (or another systemic product like cabotegravir injectable PrEP)
- C. Not everyone wants to use a systemic method like oral PrEP or injectable cabotegravir, so I'd support having rectal products – in addition to vaginal products.



Overall MATRIX Product Pipeline

KENYA Stakeholders Views

MATRIX Product Pipeline Overview

Product	Developer	Product Type	Active ingredient	How used	How long protected?	MPT?	Unique features	Status
 TAF/EVG Fast-dissolving insert	CONRAD (USA)	Fast-dissolving insert	TAF/EVG tenofovir alafenamide & elvitegravir (NRTI and 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
 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
 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
 Non-ARV/nonhormonal contraceptive multipurpose vaginal ring	Oak Crest Inst of Science (USA)	Vaginal ring	2 Peptides (protein fragments) – one acts against HIV (& HSV/HPV), the other inhibits movement of sperm & ability to penetrate & fertilize egg	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
 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
 Cabotegravir dissolvable pellets	CONRAD (USA)	Pellet implant	Cabotegravir Integrase strand inhibitor	Implanted under skin	9-12 months		Slowly dissolves over course of a year (biodegrades) Can be removed after 1-2 mo if needed	Pre-clinical

	One month dapivirine vaginal film plus levonorgestrel (LNG)		Cabotegravir injectable depot plus LNG		Cabotegravir dissolvable pellets plus LNG
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Three products also to be developed as an MPT with the addition of a hormonal contraceptive

How products were presented

- All product videos were screened
 - Individual sessions were devoted to TAF-EVG fast-dissolving insert, the 30-day dapivirine vaginal film, and MPT ring (LAMP-IVR)
 - Griffithsin fast-dissolving insert and CAB dissolvable pellet implants and CAB injectable depot were featured in a session, “Looking further ahead”
- There were varied opinions on each of the products, as well as several questions. Some products attracted more questions than others. (NOTE: Specific feedback about each product will be shared with individual PDs)
- At the end of the meeting, stakeholders were asked to select the 3 products they were most excited about or felt were most needed

Views on the overall pipeline

"I think all these products are allowing women to have power to make autonomous decisions about their sexual lives and to take care of themselves."

(young woman and advocate)

"As a HIV advocate, I'm really excited that there's progress on MPTs that women can control, that there's a whole basket of choice for women. I'm proud that we may eventually be able to offer these products."

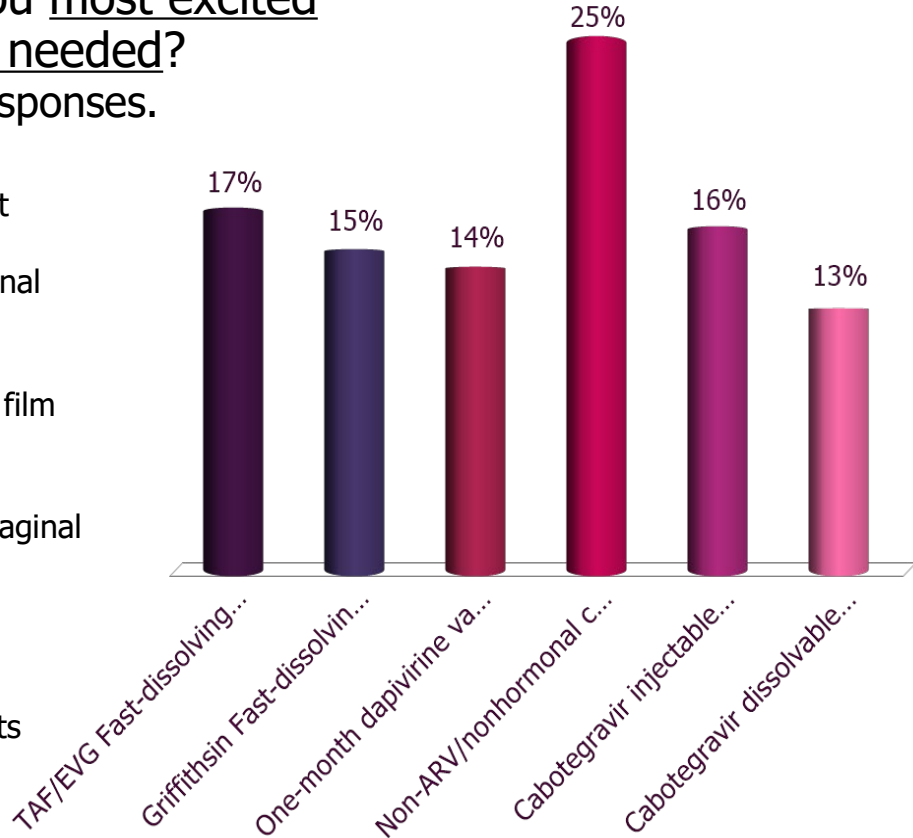
(civil society representative)

"These products give women the freedom, just the fact that there are products a woman can use without seeking men's permission."

(NGO representative)

Which 3 products in the MATRIX product pipeline are you most excited about or feel are most needed? Please rank order your responses.

- A. TAF/EVG Fast-dissolving insert
- B. Griffithsin Fast-dissolving vaginal insert
- C. One-month dapivirine vaginal film
- D. Non-ARV/nonhormonal contraceptive multi-purpose vaginal ring (LAMP-IVR)
- E. Cabotegravir injectable depot
- F. Cabotegravir dissolvable pellets



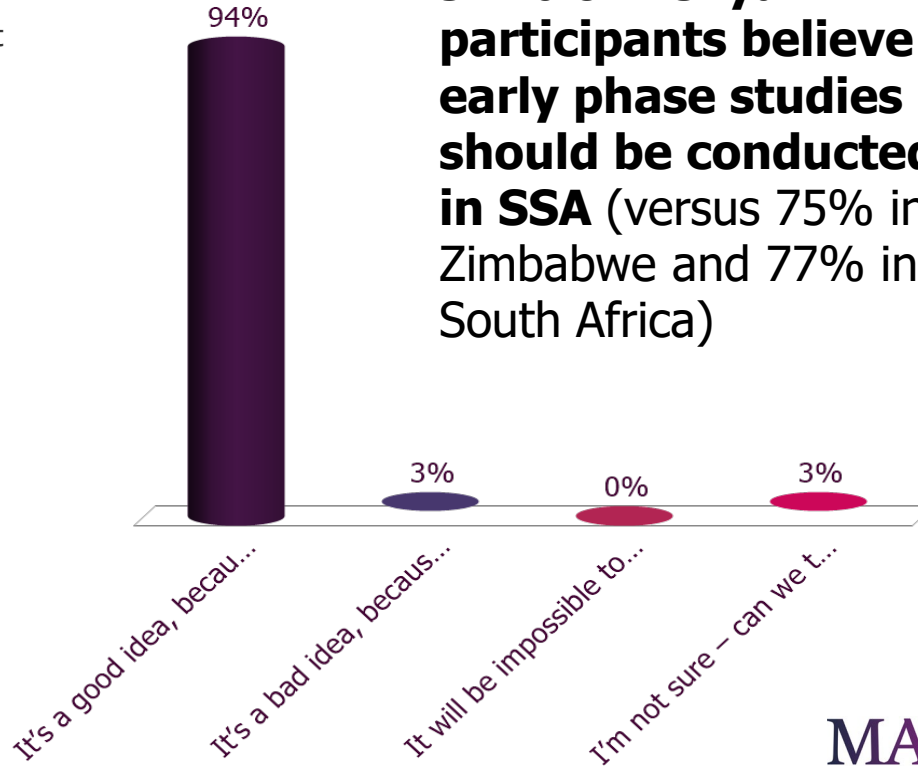
As with Zimbabwe and South Africa, the top-ranked product of Kenya stakeholders was the non-ARV/nonhormonal contraceptive MPT ring. The TAF-EVG fast-dissolving insert and cabotegravir injectable depot were one and two, respectively, though results also indicate interest in all of the products.

Views on conducting early phase clinical trials and placebo studies in SSA

Views about including African women in early phase studies

Most HIV prevention studies in Africa have been later phase studies (Phase 2 or 3) and conducted only after Phase 1 safety studies among women (at low risk of HIV) in the US or Europe indicated it be safe to do so. MATRIX intends to conduct early-phase studies here in Africa, in addition to the US. The MATRIX-001 Phase 1 study of the TAF/EVG fast-dissolving insert, for example, will enroll women at three trial sites – in the US, Kenya and South Africa. What are your views about including African women in early phase studies?

- A. It's a good idea, because early safety and acceptability data from African women will result in products that African women want.
- B. It's a bad idea, because safety should be assured in US women before the studies are done in African women.
- C. It will be impossible to do early safety studies in African women because the women in early phase studies have to be at very low risk of HIV.
- D. I'm not sure – can we talk about this some more?



Views about including African women in early phase studies

"It is important because it will give a sense of ownership of the final product by African women, having been part of the process from the beginning."

(program officer, international NGO/ service provider)

"It will help empower us to pass on information, from African women to other African women."

(research scientist)

"It is important because for the longest time, we never had opportunity to tailor-make interventions for us, we didn't contribute."

(meeting participant)

Views about MATRIX and its approach

"I want to congratulate this team because when you start like this [consulting end users], you really begin getting some of these end questions and I hope that we will move forward on that."

(National Syndemic Diseases Control Council CEO)

"... nobody raised their hand when asked if anybody has ever been called to this kind of a meeting before...I love the MATRIX approach, it is important that you are involving the end users early enough in the process ... this a great example of human-centred design."

National Commission for Science, Technology & Innovation's (NACOSTI)
National Scientific and Ethics Review Committee (NSERC) member

"[The female condom] fits so many of the things we think a woman-empowerment product should have, but at the beginning of it, did we ask women whether they'd use it? "

(Nelly Mugo)

"Normally we talk to users when the product is already in the market, and we have to deal with these issues at the end, and going back to manufacturers is quite difficult because they've passed the prototype stages and all that. So, sitting in this room I feel like this was a great and timely event, a great opportunity, to sit here and give feedback that will help refine both the products and the research protocols."

(project director, international NGO/service provider)

As a potential end user of these products, I'm leaving feeling empowered with a lot of information, and praying that these products will be successful in the trials so that we young women have many choices when it comes to protection. When I deal with adolescents and other young people at the facility, they complain about oral PrEP, about the pill burden, about having to take the pill every day ... now they will have a choice."

(Young woman and advocate)

"I'm so happy we are seated here because this is the beginning of the process ensuring that us as young women have a say and can help you design products and commodities that will be of use to us ... We want to be meaningfully engaged, and most importantly, consistently engaged... At the end of the day, the end users voice matters. Nothing for us without us."

(Young woman and reproductive health advocate)

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