

# OPTIONS

*Dapivirine Ring Common Agenda  
December 2019*





## Context

- The OPTIONS Consortium developed this common agenda in collaboration with the [International Partnership for Microbicides \(IPM\)](#).
- IPM is the developer of the dapivirine ring. IPM's mission is to develop HIV prevention products and other sexual and reproductive health technologies for women, and to make them available and accessible where they are urgently needed.
- [OPTIONS](#), funded by the U.S. Agency for International Development (USAID) in partnership with the U.S. President's Emergency Plan for AIDS Relief (PEPFAR), is working to accelerate and sustain access to antiretroviral-based HIV prevention products (collectively referred to as PrEP).
- With the Common Agenda, OPTIONS, IPM and USAID/PEPFAR seek to **engage and support coordination between partners** at the global and national levels in the planning and introduction process for the dapivirine ring, if it is approved by regulatory authorities.



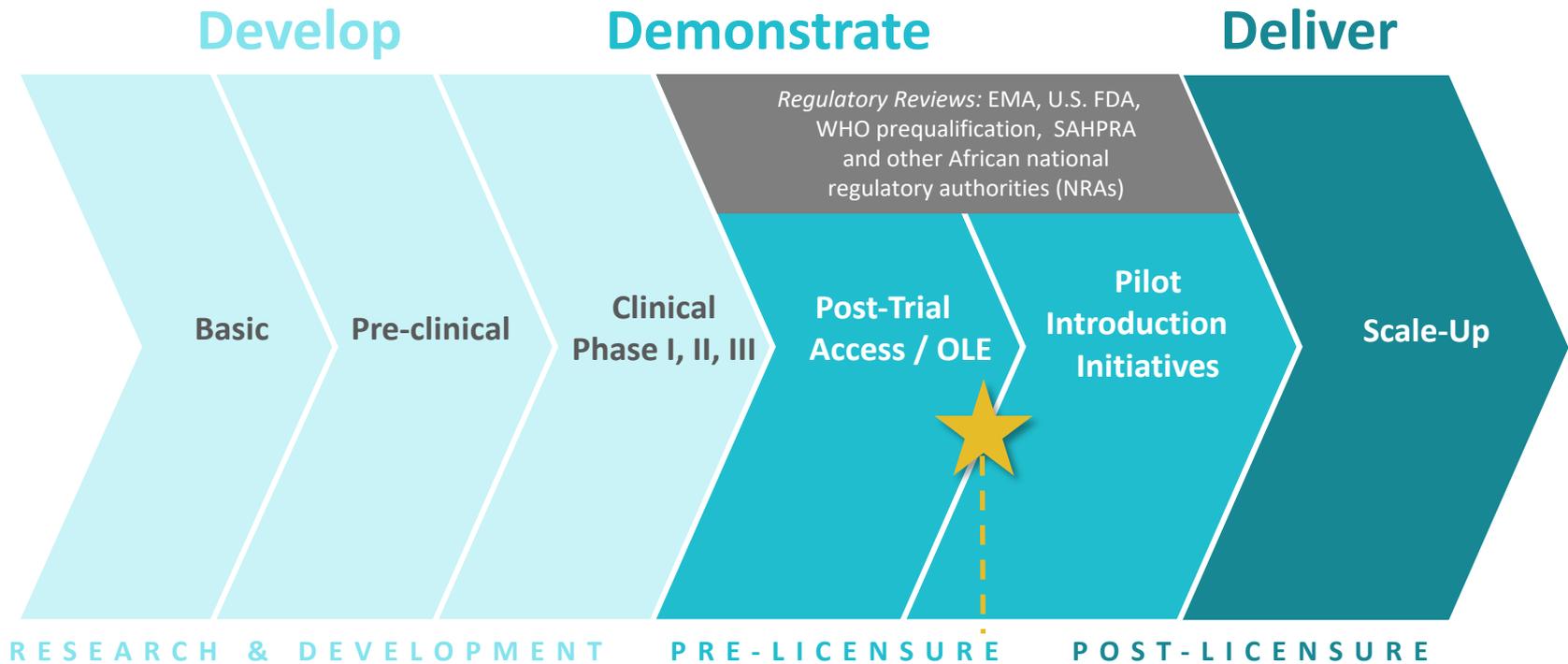
## Purpose of the Common Agenda

- Serve as a **shared guide** for stakeholders working on a wide array of activities required to accelerate potential introduction of the dapivirine vaginal ring, in line with key opportunities and considerations identified by national policymakers
- Keep stakeholders informed and engaged in a **coordinated, efficient and transparent** planning process for ring introduction and scale-up
- **Streamline and accelerate** collective efforts for ring introduction and scale-up



# Ring Introduction Process

## *Where we are today*



*As of December 2019:* Awaiting global regulatory opinions to proceed with implementation research and introduction initiatives



# Ring Introduction Process

## Common Agenda

### Develop

### Demonstrate

### Deliver



*The **Common Agenda** identifies nine areas of action that are critical to support introduction of the ring in the event of a positive EMA opinion or other regulatory approval.*

*Details on each area can be found on the following slides.*

#### Common Agenda Components

##### *Regulatory Approval & Policy*

1. Regulatory approvals
2. Clinical and policy guidelines
3. Advocacy for the ring

##### *Pilot Planning*

4. Introduction initiatives
5. Donor support

##### *End-User Insights & Engagement*

6. Market research
7. Demand generation strategies, messages, materials

##### *Supply Chain & Health Systems*

8. Supply chain development
9. Provider engagement and training



# Regulatory Approval & Policy

Components	Current Context	Next Steps	
<p><b>1</b> Regulatory approval</p>	<p>IPM is managing the regulatory process and provides regular updates on the status of filings to the EMA, FDA, WHO prequalification, SAHPRA, and other National Regulatory Authorities.</p> <p><a href="#">IPM</a>, <a href="#">Microbicide Trials Network (MTN)</a>, <a href="#">AVAC</a> and others have presented and published findings from the clinical trials and results from the most recent open label extension studies are available on their websites.</p>	<p><b>Next step</b></p>	<p><b>Status</b></p>
<p><b>2</b> Clinical &amp; policy guidelines</p>	<p>The availability of comprehensive policy and clinical guidance is critical for national regulatory approval and product introduction in countries.</p> <p>All product launch countries* cite WHO guidance as a critical trigger for national introduction of the ring.</p>	<p>Prepare submission to FDA, SAHPRA, other NRAs, and WHO PQT</p>	<p>Grey box</p>
<p><b>3</b> Advocacy for the ring</p>	<p>Advocates, particularly ring users, are powerful voices to move media, donors and implementers. IPM has a global advocacy program, AVAC has several programs to support advocates, and some countries have civil society organizations (CSOs) advocating for the introduction of the ring.</p> <p>However, this work lacks a dedicated funding stream to develop and implement a comprehensive advocacy effort.</p>	<p>Ensure regulatory opinions and current status are well known by global and national stakeholders, including PrEP technical working groups (TWGs)</p>	<p>Grey box</p>
		<p>Support WHO review and guideline development, including provision of necessary information for WHO Essential Medicines List submission</p>	<p>Grey box</p>
		<p>Support national policymakers to adapt WHO guidelines to local context</p>	<p>Diagonal lines pattern</p>
		<p>Identify donors interested in supporting advocacy</p>	<p>Green box</p>
		<p>Outline advocacy strategy to amplify voices calling for ring introduction within key countries</p>	<p>Green box</p>
		<p>Support coordination and alignment of key messages and engage supporters at both national and global levels</p>	<p>Green box</p>

-  Next step is underway and managed by IPM, OPTIONS, or WHO
-  Next step is currently awaiting progress elsewhere to begin
-  Next step urgently needs additional investment

\*The seven countries involved in ring clinical trials: Kenya, Malawi, Rwanda, South Africa, Tanzania, Uganda, Zimbabwe



# Pilot Planning

Components	Current Context	Next Steps	
		Next step	Status
<p><b>4</b> Introduction Initiatives</p>	<p>Following regulatory approval, policymakers, implementation partners, IPM, OPTIONS and others will explore best approaches for pilot introduction initiatives for the ring, building on lessons learned from oral PrEP introduction:</p> <ul style="list-style-type: none"> <li>- Pilots should address highest priority questions raised by national and global stakeholders</li> <li>- Pilots should be conducted at sufficient scale to demonstrate meaningful findings</li> <li>- Pilots should be directly linked to national plans for ring introduction and not operate as “stand alone” projects</li> <li>- Pilots should integrate ring delivery with combination HIV prevention and other services, e.g. family planning (FP), sexually transmitted infections (STI), perinatal care (PNC)</li> </ul>	<p>Identify project leads and develop pilot introduction initiatives (e.g., locations, protocols, outcomes) and share for input, ideas and coordination</p>	
		<p>Coordinate with policymakers regularly to ensure implementation studies align to support country adoption</p>	
		<p>Establish real-time learning mechanisms alongside early introduction initiatives to gather lessons learned to inform national rollout and scale-up of the ring</p>	
<p><b>5</b> Donor support</p>	<p>Current donors for the ring include: the Danish Ministry of Foreign Affairs, Flanders Department of Foreign Affairs, Irish Aid, the German Federal Ministry of Education and Research (BMBF) through the KfW Development Bank, the Ministry of Foreign Affairs of the Netherlands, UK aid from the British people, the American people through the United States Agency for International Development (USAID) in partnership with the US President’s Emergency Plan for AIDS Relief (PEPFAR), and the Bill &amp; Melinda Gates Foundation. IPM also receives in-kind support from Johnson &amp; Johnson Global Public Health.</p> <p>Funding has not yet been secured for rollout of ring.</p>	<p>Continue donor coordination and build momentum to secure funding for ring pilots and implementation</p>	
		<p>Engage and collaborate with advocates to drive political and financial support for the ring in product launch countries*</p>	

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# End-User Insights & Engagement

Components	Current Context	Next Steps	
<p><b>6</b> Market research</p>	<p>A wide array of end-user market research is currently underway for consumers and providers. The research includes human centered design and end-user segmentation. Additionally, the ring will be able to leverage end-user market research insights that were generated for oral PrEP and some family planning and reproductive health products.</p>	<p><b>Next step</b></p>	<p><b>Status</b></p>
		<p>Summarize existing end-user research findings for the ring and relevant oral PrEP research into digestible compendium</p>	<p>Grey box</p>
<p><b>7</b> Demand generation</p>	<p>Like all new product types, demand generation is critically important for the ring. Several aspects will be particularly important to consider: enabling informed choice across a portfolio of PrEP product options, building understanding about the level of protection offered by a partially efficacious product, and building comfort with a vaginally-inserted product.</p> <p>Informed by market research, IPM is leading the development of a demand creation strategy that encourages continued use, which can be adapted for country and population levels.</p>	<p>Widely disseminate market research to increase transparency and accessibility while minimizing duplication</p>	<p>Green box</p>
		<p>Consider lessons learned from family planning about building demand for a portfolio of product options</p>	<p>Green box</p>
		<p>Consider how other vaginally inserted products have developed community acceptability (including female condoms, tampons, menstrual cups)</p>	<p>Green box</p>
		<p>Leverage research and lessons learned to develop consistent messaging for providers and clients about use of a partially efficacious product and the related level of protection</p>	<p>Green box</p>
		<p>Translate existing knowledge and best practices into comprehensive demand generation strategies</p>	<p>Green box</p>

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# Supply Chain & Health System

Components	Current Context	Next Steps	
<p><b>8</b> Supply chain</p>	<p>IPM contracted Celsian Consulting (formerly a division within Imperial Logistics) to conduct a 7-country supply chain analysis, which was finalized September 2019.</p> <p>OPTIONS has developed an analysis of the potential to make the ring available via private sector healthcare channels (focus on South Africa, Kenya and Zimbabwe).</p>	<p><b>Next step</b></p>	<p><b>Status</b></p>
		<p>Based on Celsian’s analysis, identify partners to implement the supply chain</p>	
		<p>Plan supply chain needs for pilot studies, if different from long-term supply chain planning</p>	
<p><b>9</b> Provider engagement and training</p>	<p>As the ring would provide an additional choice in biomedical HIV prevention options, the knowledge, attitudes, and perceptions of providers is critically important to the delivery and uptake of the ring. Engaging providers to understand the differences between oral PrEP and the ring, and how to counsel clients to choose the best option for them, will be necessary.</p> <p>IPM is leading the development of an initial provider training curriculum based on insights from provider research in product launch countries*. This curriculum could then be adapted in each country where the ring is approved.</p>	<p>Learn from family planning training materials to consider lessons learned about presenting choices to clients</p>	
		<p>Collect training curricula and materials for oral PrEP; review and share assessment about what could be adapted for the ring</p>	
		<p>Develop provider training materials and curricula; share with implementation partners and national policymakers to prepare for broader introduction</p>	

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# Common Agenda Goals 2020 - 2021

	Component	2020 goal	2021 goal
<b>Regulatory Approval &amp; Policy</b>	1. Regulatory approvals	Obtain regulatory opinions from the EMA Submit applications to FDA, SAHPRA	Obtain national regulatory opinions/approvals (FDA, SAHPRA, national regulatory authorities) & WHO prequalification
	2. Clinical & policy guidelines	Develop WHO guidelines and submit EML application	Adapt WHO guidelines to local context
	3. Advocacy for the ring	Catalyze global and national advocates (e.g., with key information, messages)	Sustain advocacy for the ring, contributing to wide demand among end-user groups and national support
<b>Pilot Planning</b>	4. Pilot introduction initiatives	Identify the evidence that will need to be demonstrated in pilot studies by coordinating with national policymakers	Develop proposals and budgets to launch pilots/ demonstration projects in 2-3 countries; integrate the ring into ongoing combination HIV prevention and other services (e.g. FP, STI, PNC)
	5. Donor support	Catalyze donor support for 2-3 early pilots / demonstration projects	Catalyze and coordinate donor support for broader implementation / scale-up
<b>End-User Insights &amp; Engagement</b>	6. Market research	Gather, consolidate and widely disseminate existing market research	Develop market research necessary for broader introduction, informed by early pilots
	7. Demand generation strategies, messages, materials	Identify demand generation strategies and messages that can be leveraged from oral PrEP and family planning	Develop demand generation strategies, messages and materials for the ring, refine based on experience, share widely with implementers
<b>Supply Chain &amp; Health Systems</b>	8. Supply chain development	Lay out options for supply chain and procurement systems for pilots	Establish supply chain and procurement systems for broader introduction
	9. Provider engagement and training	Develop plan for provider training, catalogue lessons, gaps and challenges for broader introduction	Use strategies/tools in implementation studies, refine based on experience, share widely with implementers

## Appendix – Key Questions



# Questions for Early Implementation

- Over the course of 2018 and 2019, OPTIONS **interviewed over 160 stakeholders** from the seven African countries involved in ring trials to date (Kenya, Malawi, Rwanda, South Africa, Tanzania, Uganda, and Zimbabwe). Interviewees have included a range of national policy makers, key implementing partners, researchers, donors and civil society leaders.
- The next slide highlights **key questions raised in these interviews that may inform implementation decision-making**. The table on the next slide indicates whether each question has been answered, and if not, the proper setting and timeframe to address that question.
- Our collective goal is to **develop and widely share insights** on these questions through early pilot projects in 2019 and 2020.



# Questions for Early Implementation

## Questions raised by national policymakers and other key stakeholders

## Method and next steps

**Safety and efficacy:** Is the ring safe? In what scenarios is the ring most efficacious?

*Complete:* Answered via clinical trials

**Target populations:** For which populations is this product appropriate? How are these populations different from the target populations for oral PrEP?

*In process:* Answered via market research, will revisit post implementation research

**Impact of a long-acting product on adherence and continuation:** How does a long-acting product impact uptake, adherence, and continuation? In what ways will a long-acting product improve adherence and continuation for populations that have difficulty using oral PrEP consistently (e.g., AGYW)?

*In process:* REACH study examining choice and adherence with ring and oral PrEP among AGYW

**Health system implications:** What are the implications of adding the ring to HIV prevention services for the health system and health care workers? What guidelines, training, and resources are needed to support healthcare worker and end user decision-making between HIV prevention choices?

*In process:* IPM and partners leading the creation of provider materials.

**Demand generation & acceptability:** How can acceptability of the ring be increased among different age groups? What are effective demand generation messages and strategies for the ring? What messaging is appropriate for a partially efficacious product? How can messaging support informed end user choice?

*In process:* IPM and partners leading messaging and positioning for ring. Further market research is underway.

**Delivery channels:** Which channels are effective for delivery of the ring? How can delivery of the ring be integrated with family planning? How can the ring be effectively delivered in non-clinical settings? What healthcare worker cadres will be able to deliver the ring (e.g., nurse, pharmacist, community health worker)?

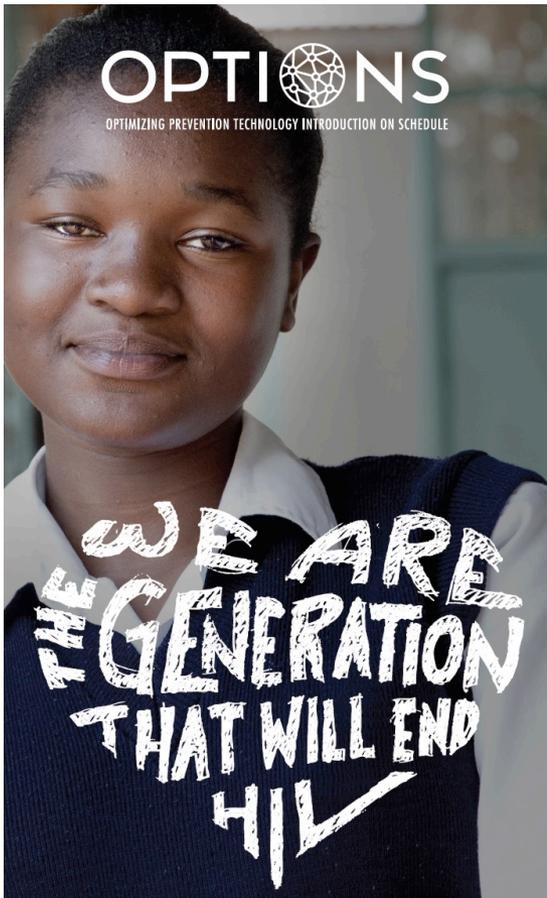
*Immediate need:* Implementation research will inform

**Impact and cost-effectiveness:** What is the impact of adding the ring to a comprehensive HIV prevention portfolio (e.g., alongside oral PrEP and condoms)? How many infections could be averted? How cost-effective is the ring, relative to other prevention options? What is the cost of introducing the ring alongside oral PrEP?

*Immediate consideration:* Implementation research and modeling will inform

**Introduction of a new product:** How will investment decisions be made between HIV prevention products and approaches across end user groups? What is the incremental budget required to add the ring to a comprehensive HIV prevention portfolio?

*Immediate consideration:* Implementation research and modeling will inform



# Thank you

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## OPTIONS Consortium Partners

