

# Common Agenda for the Dapivirine Vaginal Ring

## December 2018

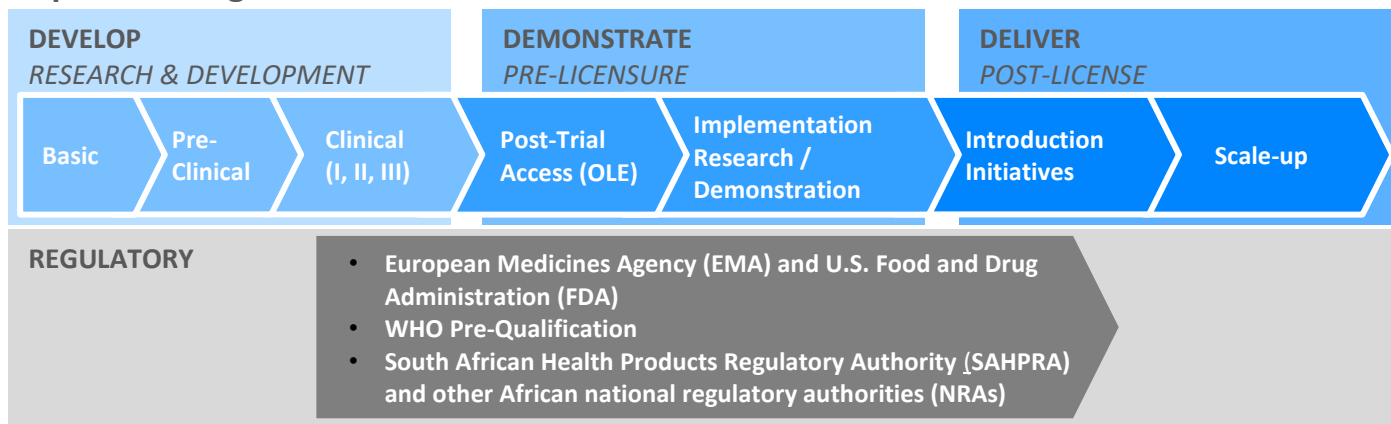
**Purpose:** The purpose of the common agenda is to serve as a shared guide for stakeholders working on a wide array of components required for introduction of the [dapivirine vaginal ring \(DVR\)](#). The common agenda aims to keep stakeholders informed and engaged in a coordinated, efficient and transparent planning process for ring introduction leading to scale-up with the goal of streamlining and accelerating collective efforts.

**Approach:** The OPTIONS Consortium developed this common agenda in collaboration with the [International Partnership for Microbicides \(IPM\)](#), the developer of the dapivirine ring. [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). OPTIONS aims to help countries move from PrEP potential to PrEP impact, so adolescent girls and young women have HIV prevention options that meet their needs. OPTIONS and IPM received feedback on an initial draft of this common agenda from stakeholders at the 2018 HIV Research for Prevention meeting. The document will likely change as progress is made.

**Contents:** This document includes a summary of **key components necessary for ring introduction**, an initial list of ongoing or planned efforts, and proposed next steps.

**Key Components for Ring Introduction:** The components outlined in this common agenda focus on the pre-licensure “demonstrate” phase of product introduction (see framework below).

### Dapivirine Ring Introduction Process: Research to Rollout



**Clinical Trials & Regulatory Approvals:** [The International Partnership for Microbicides \(IPM\)](#), [Microbicide Trials Network \(MTN\)](#), [AVAC](#) and others have made clinical trial findings and plans for upcoming studies widely available on their websites. IPM regularly provides updates on the status of the regulatory filings.

➤ **Potential Next Steps:** Ensure findings and status are well-known by key stakeholders at the global and national levels.

**Market Research:** A wide array of end user market research is currently underway, including both consumers and providers. The research includes human centered design, end user segmentation and assessment of health care workers' knowledge, attitudes, and drivers. OPTIONS aims to summarize these findings along with relevant oral PrEP research into a compendium to create an efficient way for implementers to understand the research to date and minimize duplication. IPM and OPTIONS are conducting additional market research on supply chain, private sector delivery, and willingness to pay.

- *Potential Next Steps:* Develop ways to increase transparency and accessibility of market research.

**Global & Country Stakeholder Perspectives:** A critical factor for successful transition from research to demonstration and on to wide-scale implementation is addressing post-approval questions hindering country adoption. OPTIONS initiated an analysis of questions from policymakers in select countries<sup>1</sup> and global stakeholders, which are detailed in the annex to this document.

- *Potential Next Steps:* Survey donors, WHO, and other globally influential policymakers to determine outstanding questions and devise ways to answer them. Gather questions from additional countries.

**Plans for Next Phases of Introduction:** IPM and others are designing studies to move the ring to introduction. A critical issue is to what extent we need further data on clinical efficacy, acceptability, adherence, feasibility and/or challenges and opportunities for implementation. Another factor is whether these studies will be at sufficient scale to demonstrate meaningful findings and whether they address the questions that key stakeholders have at country and global levels. Finally, these studies must be integrated into national plans for ring introduction, not operate independently. Much can be learned from the demonstration studies of oral PrEP.

- *Potential Next Steps:* Share potential demonstration study plans, locations, costs and outcomes for input, ideas and coordination. Identify potential implementers and funders.

**Clinical Practice & Policy Guidance:** The availability of adequate policy and clinical guidance plays a major role in determining the timing of product introduction in countries. Aligning the planning process for demonstration projects with the development of WHO guidance will be critical to ensure early implementation experiences can further inform WHO guidance.

- *Potential Next Steps:* Understand WHO's timeline for review and the information needed before and after initial guidance.

**Advocacy:** IPM has a global advocacy program, AVAC has several programs to support advocates including an Advocacy Fellows Program and some countries have civil society organizations advocating for the introduction of the ring. However, this work lacks a funding stream to develop and implement a comprehensive advocacy effort.

- *Potential Next Steps:* Outline how to amplify voices calling for ring introduction. Consider how to develop better coordination and alignment of key messages as well as an expansion of supporters at both country and global level.

**Communications & Training:** Informed by market research, IPM is leading the development of materials that can be adapted for use at country and population level. These include a training curriculum, end user messages targeted for specific populations, a demand creation strategy and IEC materials to encourage initiation and consistent ring use.

- *Potential Next Steps:* Review the status of the development of these materials, identify gaps and fill them, and disseminate the materials widely to decrease likelihood of duplication.

**Funding:** To date, the dapivirine ring's regulatory and market introduction planning activities were funded by a portfolio of donors including: USAID, the U.K. Department for International Development (DFID), the Ministry of Foreign Affairs of the Netherlands, Danida of the Ministry of Foreign Affairs of Denmark, Irish Aid, the Government of Flanders, the Bill and Melinda Gates Foundation (BMGF) and the Germany Ministry of Research and Development (BMBF). IPM also receives significant in kind support from Johnson and Johnson Global Public Health.

- *Potential Next Steps:* Continue donor coordination and build momentum to secure additional sources of funding from former and new donors. Develop key messages that advocates can use to tailor their messages to secure political and financial support for the ring.

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<sup>1</sup> Includes Kenya, Malawi, Rwanda, South Africa, Tanzania, Uganda and Zimbabwe - where ring clinical research took place

## Annex: Comprehensive Set of Questions & Potential Means to Answer Them

Questions <i>Implementation in blue / Clinical in gray</i>	Answered	Source	Further study?
What would be the <b>impact</b> of the ring? How many infections would be averted?	Yes	OPTIONS Modeling Case	Maybe
How does the ring <b>fit into a comprehensive package</b> of prevention?	partial	REACH, OPTIONS to develop Ring Planning Matrix	?
What are <b>adherence to and uptake of</b> the ring in the real-world? <sup>2</sup>	No		Yes
What <b>impacts</b> adherence (e.g., clinical setting, socio-economic status)? What <b>factors contribute</b> to low adherence among AGYW?	Partial	Phase 3, OLE, REACH Studies	Yes
What will be the <b>cost of investing</b> in the ring?	Not yet	OPTIONS to support countries to develop demonstration project budgets	Yes
How <b>feasible is the delivery</b> of the ring?	No	OPTIONS to support countries to develop demonstration project plans	Yes
Which <b>populations</b> are recommended for the ring?	No	IPM to conduct segmentation study	No
What are the implications for the <b>health system and health care workers</b> ? What additional demands will the ring place on the health system?	Partial	OPTIONS to develop Ring Planning Matrix  IPM conducting KAP survey of providers	Yes
Will the ring be <b>affordable</b> for end users where applicable (e.g. private sector)?	Partial	OPTIONS to conduct private sector and willingness to pay analysis for ring  J&J to conduct supply chain analysis	?
Should ring <b>clinical guidelines</b> be the same as those for oral PrEP (e.g., risk assessment, STI/HIV testing frequency)?	Partial	Phase 3, OLE and REACH Studies  WHO to develop guidelines	?
How <b>acceptable</b> is the ring among AGYW? How can <b>acceptability</b> be increased among <b>different age groups</b> (e.g., young women) and how does <b>behavior change</b> vary across age groups?	Partial	OPTIONS to develop a compendium of end user, provider insights and OPTIONS/CHARISMA to conduct a rigorous review of acceptability and preferences around ring as a product delivery	Yes

<sup>2</sup> Both a clinical and implementation question

		formulation across age groups and geographies  IPM/Dalberg Research  IPM/Thinkplace Research WHO to commission a systematic review of ring acceptability and preferences	
Has the ring been proven to be <b>safe</b> ?	Yes	Phase 3, REACH and OLE Studies	No
To what extent does the <b>effectiveness of the ring differ</b> among various populations? Is the ring <b>effective among AGYW</b> ?	Partial	Phase 3 and OLE Studies	?
What does behavioral data demonstrate about the impact of the ring on <b>condom use and other reproductive health practices</b> ?	Partial	Phase 3, REACH and OLE Studies	Yes
What is the <b>effectiveness of the ring in the real-world</b> ?	No		Yes
What are <b>adherence to and uptake of</b> the ring in the real-world? <sup>1</sup>	No		Yes
Can ring be used safely by pregnant women?	Not yet	MTN 042	No
What is the rate of <b>seroconversion</b> ?	Partial	Phase 3, REACH and OLE Studies	Yes
Is there risk of <b>resistance</b> ?	Yes	MTN analysis 2018, IPM medical safety data, virology reports	?