

# Toward a Roadmap for Biomedical HIV Prevention Investment Standards: *Strategic Insights from Key Industry Stakeholders*

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## Introduction

Sub-Saharan Africa accounts for over 70% of the global burden of HIV infection.<sup>1</sup> Three out of every four new HIV infections in the region occur among adolescent girls and young women, who are twice as likely to be living with HIV than men.<sup>2</sup> Biomedical HIV prevention is an important strategy in combating the HIV epidemic among women, but such approaches have demonstrated lower efficacy among younger women in clinical trials.<sup>3-5</sup> Developing a product women can identify with, access, and value has been elusive.<sup>6-10</sup> In clinical trials, women cite low desirability and cultural factors as key barriers to use— noting that some existing product formulations do not fit well into their lives as they are difficult to use.<sup>11-15</sup>

Incorporating end-user research early and throughout biomedical HIV product development has become increasingly recognized as a critical part of the product development process, as evidenced by a growing body of research in this area.<sup>6-16</sup> Biomedical HIV prevention product development requires significant investment; and amalgams of funding from public and private sectors, including for- and non-profit entities, are used to bring HIV prevention products with the greatest potential global public health impact to market. Guidance on what type of user and market data to incorporate at which stage, from product R&D to launch, may promote product adoption and success among those in the highest risk populations. However, standards for comparing and evaluating development and investment decisions for such products from the user perspective are complex and not consistently applied across stakeholders. While some industry and philanthropic entities and non-governmental organizations (NGOs) have internal standards that incorporate end-user perspectives in their product development and investment decisions, these standards do not exist for public sector funders.

The United States Agency for International Development (USAID) is a major funder of biomedical HIV prevention product development. In response to USAID's desire for standards to help guide decisions for prioritizing investments and integrating user perspectives at various stages of product development, the Initiative for MPTs (IMPT) provided technical assistance to USAID's Office of HIV/AIDS (OHA) to develop a Biomedical HIV Prevention Product Investment Framework. The purpose of this framework is to provide high-level guidance for USAID on biomedical HIV prevention investment decisions that integrate user perspectives at various stages of product development, namely from the pre-clinical/discovery to regulatory phases. Critical to the development of this framework were consultations with experts representing global pharmaceutical organizations, smaller biotechnology companies, non-profit product developers, academia, and supporting agencies.

Traditionally, product development and investment standards for USAID have been guided by Target Product Profiles (TPPs). These include information on product indications, dosage, mechanism of action, target populations, efficacy, storage/shelf life, pre-clinical and clinical safety, pharmacokinetics, and contraindications.<sup>17-19</sup> Lessons learned from the HIV prevention and treatment field have shown that efficacy and availability do not always predict product uptake nor consistent use, and product modification resulting from later stage end-user research can be extremely difficult and expensive.<sup>12,13,16,20-24</sup>

Multipurpose prevention technologies (MPTs) are an emerging prevention option for women at high risk of HIV infection and illustrate the benefits of a framework to guide investment decisions incorporating end-user perspectives. As the MPT development pipeline has expanded over the past decade, women have continually articulated willingness to consider use of and acceptability around the MPT concept, with many women citing preference for an MPT over a single-indication prevention product.<sup>25-30</sup> Of the 31 MPTs in development, all but two products aim to deliver HIV prevention combined with either

contraception or prevention of other sexually transmitted infections (STIs), the majority of which are in pre-clinical or early-stage development.<sup>25</sup> The vast majority of MPT investment comes from the United States government, namely USAID and the National Institutes of Health (NIH). Given the high cost of research and development (R&D), including clinical trials, and limited resources, rigorous standards to guide investment decisions with end-user perspectives can help ensure product success.

The development of the Biomedical HIV Prevention Product Investment Framework consisted of two key components: 1) a landscape review of published and grey literature on existing standards and approaches, and 2) key informant interviews (KIIs) and virtual convenings with experts from the pharmaceutical and biotechnology industries, public and private sector funders, and public-private partnerships to understand what standards and frameworks currently exist in industry and elsewhere that could help inform a framework for USAID ([Table 1](#), Appendix). This report captures critical insights from the technical consultations that inform the resulting framework. In addition to serving as a tool for USAID, the iterative and collaborative process involved in developing this framework aims to optimize coordination and collaboration amongst the diverse stakeholders who are essential for successful biomedical HIV prevention product development.

## Methodology

Key informant interviews and virtual convenings with experts were instrumental in guiding the development of the Biomedical HIV Prevention Product Investment Framework. Experts consulted represented global pharmaceutical organizations with experience in standard R&D and public-private partnerships, smaller biotechnology companies, non-profit product developers, academia, and public and private sector funding entities. Technical consultations with key stakeholders resulted in a guiding framework and commitment to future coordination and collaboration.

### *Key Informant Interviews*

Nineteen KIIs were conducted with informants identified by USAID and the IMPT from existing relationships and represented experts working on a range of biomedical products, including contraceptives, HIV prevention products, and products designed to improve maternal and child health ([Table 2](#), Appendix).

Prior to beginning the KIIs, a semi-structured interview guide was developed, consisting of open-ended questions that addressed the key elements of the biomedical product development process ([Table 3](#), Appendix). All interviews were conducted by phone in English by the USAID/IMPT team between March and July 2018, and each lasted between 45-60 minutes. The interviews were transcribed, coded, and analyzed by two members of the USAID/IMPT team to identify overarching themes, as well as dissonance between informants.<sup>31</sup>

### *Virtual technical convenings*

Two virtual convenings were held with 20 technical experts in February 2019 to probe more deeply into key themes identified in the interviews; nine experts who participated in the KIIs also participated in a virtual convening. Each virtual convening was facilitated by two members of the USAID/IMPT team using a PowerPoint presentation and open-ended questions to guide the discussion. Detailed notes of each convening were recorded, and key themes were used to inform the final framework.

## Findings

Critical insights and recommendations from the KIIs and virtual convenings are summarized below and were used to develop the resulting framework.

There was consensus that standards for comparing and evaluating development and investment decisions for global health products from the user perspective are very complex, particularly for products that rely on an amalgam of funding, such as biomedical HIV prevention products. No 'gold standard' approach currently exists, and methods for collecting and interpreting these data varied across organizations.

All KII and technical convening participants emphasized the importance of **incorporating end-user and market data** into product R&D decision-making early and throughout to inform product development and launch.

**Key recommendation:** *Integrate end-user research into R&D at product conceptualization.*

*Incorporating end-user input into product R&D decision-making is essential for informing decisions around product features, preferences, cost, product access, and understanding customer journeys. This input should be considered from the beginning and throughout the product development process.*

**Benefit:** *Ensures that product development decisions benefit the user and have end-stage considerations in mind.*

**Challenge:** *No standard framework.*

The approaches for the universal recommendation to integrate end-user research into R&D at product conceptualization vary by target market (low-, middle-, or high-income countries) and funding source (public/private; for-profit/non-profit). Several participants noted that smaller biotechnology companies may not have the funding capacity or internal expertise to integrate end-user research early into decision-making. Rather, the technology itself and lessons learned from related fields are relied upon to inform their decision-making. Among larger pharmaceutical companies, each product in development typically has a project team, and several models of integrating end-user and behavioral elements into product R&D decision-making were described.

While some companies have a standardized tool, similar to or included in a TPP, to ensure integration of end-user input, others tap into the expertise of commercialization staff and/or outside consultants from social science, marketing, and clinical research to integrate these data and perspectives throughout the R&D process; still others may rely wholly on the team lead to request and consider end-user data.<sup>27</sup>

**Identification and characterization of the primary target population** for a product is a critical first step in the end-user research process, first using epidemiological data, followed by consideration of socio-cultural, demographic, and geographic factors. As participants noted, this can help inform if and how products in early stages of development can have impact and success. Approaches used to characterize the target populations include the collection of qualitative data through in-depth interviews and focus groups within the target populations, followed by quantitative assessments, including conjoint analysis and discrete choice experiments. Mathematical models are also useful tools, but accurate correlations between demand forecasting and future product performance, for example, directly correlate with the quality and accuracy of data used to generate the models.<sup>32</sup>

**Key recommendation:** Identification and characterization of the primary target population.

*Using epidemiological data followed by consideration of socio-cultural, demographic, and geographic factors is an important first step.*

**Benefit:** *Informs if and how products in early stages of development can have impact and success.*

**Challenges:** *The ability to identify the target market varies by low-, middle-, and high-income target country and resources available to the developer.*

This early-stage end-user research can allow researchers and developers to gain insight into end-user lifestyles, drivers, and barriers to HIV prevention products, and preferred product attributes. This research can also inform the feasibility of the product in development, with regard to usability, acceptability, and product characteristic preferences, with the end result of informing product development decisions, such as the selection of molecules, polymers, delivery devices, and so on. It is important to gather this information from both end-users and their influencers, including providers and family and community members, as these groups may all have an impact on the end-user's decision-making process.

The importance of **assessing market access and sustainability early** was also a key recommendation. As noted by several virtual convening participants, a basic tenant of pre-clinical product development is to 'think with the end in mind.' A challenge, however, is the interpretation of such end-stage data to realistically guide and inform choices (i.e., molecules, polymers, delivery devices, etc.) from which basic scientists can select for pre-clinical drug development.

Approaches for integrating market data into early-stage decision-making varied. Market size estimation, through the identification and characterization of the primary target population, is often done early in product development with existing epidemiologic data. Market segmentation, demand forecasts, comparative advantage, and cost-effectiveness analyses are then conducted as feasible product characteristics become apparent and cost of goods can be estimated.

**Key recommendation:** *Assess market access and sustainability early.*

*The ability of the market to sustain a new product must be considered early and fully integrated with the product strategy.*

**Benefit:** *Maximize a product's market potential and validate the investment opportunity.*

**Challenge:** *Traditional business models are not well equipped for gaining access to low- and middle-income markets.*

Another recommendation was to facilitate **ongoing engagement with internal and external stakeholders** to leverage resources, incorporate varied perspectives throughout the process of product design, and help ensure product success. Of particular note is the engagement of payers and policymakers during development (e.g., insurance companies, Ministries of Health, and global health product procurers). These key gatekeepers should be mapped in each setting, and their support and interest must be cultivated, and concerns addressed, if a product is to have successful market introduction.

The formation of a ‘disciplined’ donor collaboration platform, by which donors can collaborate, leverage resources, avoid duplication of efforts, and define priorities for go/no go decision-making, was also recommended. Convening a group of multiple funders can be challenging, given varying funder mandates. However, similar platforms do exist for related biomedical areas. Examples include:

- The [European & Developing Countries Clinical Trials Partnership \(EDCTP\)](#) was created as a European response to the global health crisis related to poverty-related infectious diseases, namely HIV/AIDS, tuberculosis, malaria, and other poverty-related infectious diseases prevalent in sub-Saharan Africa.
- The [Global HIV Vaccine Enterprise](#) is an alliance of organizations formed to accelerate the search for an HIV vaccine.
- The [Coalition for Epidemic Preparedness Innovations \(CEPI\)](#) is an alliance which aims to finance and coordinate the development of new vaccines to prevent and contain infectious disease epidemics.

**Key recommendation:** *Ongoing engagement with stakeholders.*

*Key stakeholders from across the development and funding landscape must be collaboratively engaged throughout the process of product design.*

**Benefit:** *Leverage stakeholder resources and expertise throughout the process of product design to help ensure product success and avoid duplication of efforts.*

**Challenge:** *Facilitation of collaboration amongst multidisciplinary stakeholders with varied missions/mandates.*

Creating a **stage gate between Phase 1 and Phase 2 clinical trials** was recommended by about half of the participants. Some companies have formal guidance documents for decision-making, while others were driven by individual project managers. Some examples of required evidence for decision-making included: user tolerance; interactions with other drugs likely to be taken with the candidate drug; safety; and efficacy. Product category, whether drug, device, or biological, also influences the approach. Behavioral and perceptibility data are important considerations for companies developing prevention products, as opposed to treatments. Less evidence would be collected for products offering an incremental improvement over existing products as opposed to a new category or dosage form, under the assumption that it will require only education and marketing within existing channels upon approval. Approaches for developing biomedical prevention products are quite different for developed versus low- and middle-income markets for a variety of reasons, including the paucity of market-level data as well as supply chain and storage issues in developing markets. For example, developing markets often

require new data collection, while developed markets may have industry databases and previous work to learn from and build upon. Informants reported challenges with obtaining quality commercialization and market input into their R&D processes for developing markets.

### **Biomedical HIV Prevention Product Investment Framework**

The below framework is divided into five columns, representing the process by which an HIV biomedical prevention product is developed. The Discovery/Pre-clinical phase is when many key decisions around product characteristics are made. This is thus where end-user research should be initiated in order to incorporate these findings into product development as early in the process as possible. The next three phases represent the phases of a clinical trial. Phase 4 trials were excluded for the purpose of this framework. The final phase in the framework is Regulatory, when developers are preparing a product to go to market following clinical trials.

On the left side of the framework are items to consider when making funding decisions, divided into five categories: End-user Considerations, Market Considerations, Product/R&D, Stakeholder Engagement, and Resource Considerations. Note within the framework that the End-user Considerations, while conducted at the very first stages, encompass all components of the process. This is in order to convey the key finding that end-user research is a critical component which should inform decisions made at each step in the process of biomedical HIV prevention product development and investment. Also note that these activities, each represented by a horizontal bar, start at different points within each phase, representing approximate points to initiate each activity. The dots within the framework, all at the end of Phase 2 (2a/2b), represent a point at which that item should be re-evaluated. This timing is derived from the importance of critically assessing each component of a product and the research done up until that point, prior to commencing the expensive and time-consuming process of undergoing phase 3 trials.

Links within individual framework items direct the reader to further resources on that topic. The full citations for these items can be found in [Table 4](#) within the Appendix.

### **Conclusion**

As highlighted in this report, future efforts in the HIV prevention field must include targeted end-user insights from the very first stages of product development in order to create an effective product which is acceptable to the end-user. Guidance on what type of user and market data to incorporate at which stage, from R&D to launch, would increase the potential success of new biomedical HIV prevention products in the highest risk populations.

This framework aims to incorporate findings from the technical consultations with industry stakeholders and funders described in this report for use by USAID's Office of HIV/AIDS. The iterative and collaborative process involved in developing this framework also aimed to optimize buy-in for future coordination and collaboration amongst the diverse stakeholders who are essential for successful biomedical HIV prevention product development.

## Biomedical HIV Prevention Product Investment Framework

		Discovery/ Preclinical	Phase 1	Phase 2 (2a/2b)	Phase 3	Regulatory	
<b>End-user Considerations</b>	Identify and characterize target population(s)	■			●		
	Conduct qualitative and quantitative end-user assessments	■			●		
	Assess social and technical barriers to using the product within the target population	■			●		
	<b>Strategic Evaluation Framework</b>						
	<b>Market Considerations</b>	Develop Target Market Profile	■			●	
		Develop Target Product Profile	■	■		●	
		Develop Strategic Target Profile	■	■		●	
		Assess value added to market	■			●	
		Assess feasibility of introducing into new markets	■			●	
		Define market segmentation	■			●	
		Conduct budget impact analysis	■			●	
		Develop a business case	■	■		●	
		Estimate market size	■	■		●	
		Forecast demand	■	■		●	
		Predict effectiveness and efficacy	■			●	
		Evaluate effectiveness and efficacy				■	
		Develop marketing strategy				■	■
	<b>Product/ R&amp;D</b>	Develop Integrated Product Development Plan	■			●	
		Assess product R&D feasibility	■			●	
		Assess manufacturing and scale-up considerations	■	■		●	
<b>Stakeholder Engagement</b>	Create / engage with multidisciplinary working group	■	■	■	■	■	
	Create / engage with donor collaboration platform	■	■	■	■	■	
	Conduct stakeholder mapping	■	■		●		
	Identify commercialization partners	■	■		●		
	Develop commercialization plan	■	■	■	●		
<b>Resource Considerations</b>	Review any available country implementation plans	■		■			
	Consider health care provider perspectives to inform end-user and resource needs	■			●		
	Assess storage capacity, transportation and cold chain considerations	■			●		
	Assess clinic and other distribution considerations	■			●		
	Identify opportunities/leverage resources	■	■	■	■	■	
Assess provider training needs	■	■		●			

● Signifies that this item should be revisited at this point and findings re-evaluated before moving forward.

[Click here to view full text of embedded links](#)

## Appendix

<b>Table 1: Framework Development Process</b>	
Phase I	Landscape review of published and grey literature on existing standards and approaches, covering pre-IND through Phase III development (aligned with the USAID funding space).
Phase II	<ol style="list-style-type: none"> <li>1. KIIs summarized in this report. These interviews with experts from the pharmaceutical and biotechnology industries as well as public-private partnerships build upon phase I by reviewing standards in practice.</li> <li>2. Virtual convenings with key stakeholders resulted in a guiding framework and buy-in for future coordination and collaboration.</li> </ol>

<b>Table 2: Characteristics of KII and Virtual Convening Participants *</b>	
<b>Product Development Model</b>	<b>Participants (n)</b>
Global Pharmaceutical Company	9
Public-Private Partnership	8
Academia	3
Funder	11
Biotechnology Company	2
Non-profit Product Developer	8

\*Some experts had multiple areas of expertise

**Table 3: Key Informant Interview Details**

Interviews were conducted via teleconference call between March and July 2018

Interview Questions Included:

- What is the general organizational structure for product development research and marketing/commercialization activities? Is there integration of expertise or specific positions that facilitate communication and collaboration?
- Is evidence required early on in the R&D process with regard to end-user preferences, market assessment or demand forecast, commercialization, manufacturing, or supply chain? What type of evidence is required? Who gathers and analyzes this evidence?
- Is end-user/market research conducted and incorporated into development as a way to mitigate risk of on-going investment in a product candidate or at go / no-go decision points? If it is incorporated, what methods are used, at which points in R&D, and who is involved?
- Are there different methodologies or considerations used for products that may have immediate benefit to users compared with a longer outlook (is there a specific time threshold)? Are there different methodologies for treatment versus prevention? Where are these differences most pronounced? Are there differences in methodologies or considerations for products where a significant portion of users would be anticipated to be 15-24 years old?
- Is there a threshold of any kind used to justify advancing a product candidate forward? At which stage of development? What is the strength of the evidence considered and how does this change as a product progresses in the pipeline?
- Are there existing guidelines, best practices, or timelines for implementation that can be shared?
- Are there specific definitions/formulas, tools, templates, or methodologies that can be shared?
- Could you recommend someone else that would be able to speak with me further about these issues, particularly as related to products for prevention and/or adolescents?

**Table 4: Additional Resources in Framework**

Identify and characterize target population(s) [page 3](#)  
Conduct qualitative and quantitative end-user assessments [page 3](#)  
Strategic Evaluation Framework [21](#)  
Develop Target Market Profile [17](#)  
Develop Target Product Profile [18](#)  
Develop Strategic Target Profile [23](#)  
Develop a business case [33](#)  
Create/engage with multidisciplinary working group [page 5](#)  
Create/engage with donor collaboration platform [page 5](#)  
Develop Commercialization Plan [34](#)

## References

- 1 Kharsany, A. B., & Karim, Q. A. (2016). HIV infection and AIDS in Sub-Saharan Africa: Current status, challenges and opportunities. *The Open AIDS Journal*, 10, 34–48. [doi:10.2174/1874613601610010034](https://doi.org/10.2174/1874613601610010034)
- 2 UNAIDS. (2019). Global HIV & AIDS statistics — 2019 fact sheet. Retrieved from <https://www.unaids.org/en/resources/fact-sheet>
- 3 Palanee-Phillips, T., Schwartz, K., Brown, E.R., Govender, V., Mgodhi, N., Kiweewa, F.M., ...Baeten, J. (2015). Characteristics of women enrolled into a randomized clinical trial of dapivirine vaginal ring for HIV-1 prevention. *PLoS ONE*, 10(6), e0128857. [doi.org/10.1371/journal.pone.0128857](https://doi.org/10.1371/journal.pone.0128857)
- 4 Cutrell, A., Donnell, D., Dunn, D.T., Glidden, D.V., Grobler, A., Hanscom, B., ...Cuffe, R.L. (2017). HIV prevention trial design in an era of effective pre-exposure prophylaxis. *HIV Clinical Trials*, 18(5), 177-188. [doi.org/10.1080/15284336.2017.1379676](https://doi.org/10.1080/15284336.2017.1379676)
- 5 Atujuna, M., Newman, P.A, Wallace, M., Eluhu, M., Rubincam, C., Brown, B., & Bekker, L.G. (2018). Contexts of vulnerability and the acceptability of new biomedical HIV prevention technologies among key populations in South Africa: A qualitative study. *PLoS ONE*, 13(2), e0191251. [doi.org/10.1371/journal.pone.0191251](https://doi.org/10.1371/journal.pone.0191251)
- 6 Ipsos. (2014). Summary booklet: Assessing the potential of MPTs in South Africa, Uganda and Nigeria [PDF document]. Retrieved from <http://www.theimpt.org/documents/BMGF-AssessingMPTSolutions-Booklet.pdf>
- 7 Van der Straten, A., Agot, K., Ahmed, K., Weinrib, R., Browne, E.N., Manenzhe, K., ..., Minnis, A. (2018). The tablets, ring, injections as options (TRIO) study: What young African women chose and used for future HIV and pregnancy prevention. *Journal of the International AIDS Society*, 21(3), e25094. <https://doi.org/10.1002/jia2.25094>
- 8 Mensch, B.S., Richardson, B.A., Husnik, M., Brown, E.R., Kiweewa, F.M., Mayo, A.J., ...van der Straten, A. (2018). Vaginal ring use in a phase 3 microbicide trial: A comparison of objective measures and self-reports of non-adherence in ASPIRE. *AIDS and Behavior*. [doi: 10.1007/s10461-018-2261-8](https://doi.org/10.1007/s10461-018-2261-8)
- 9 Jacot, T.A., Clark, M.R., Adedipe, O.E., Godbout, S., Peele, A.G., Ju, S., ...Doncel, G.F. (2018). Development and clinical assessment of new objective adherence markers for four microbicide delivery systems used in HIV prevention studies. *Clinical and Translational Medicine*, 7(1), 37. [doi: 10.1186/s40169-018-0213-6](https://doi.org/10.1186/s40169-018-0213-6)
- 10 Desai, M., Field, N., Grant, R., & McCormack, S. (2018). State of the art review: Recent advances in PrEP for HIV. *British Medical Journal*, 359, j5011. [doi: https://doi.org/10.1136/bmj.j5011](https://doi.org/10.1136/bmj.j5011)
- 11 Woodson, C., MacQueen, K., Amico, K.R., Friedland, B., Gafos, M., Mansoor, L., ...McCormack, S. (2013). Microbicide clinical trial adherence: Insights for introduction. *Journal of the International AIDS Society*, 16(1), 18505. [doi: 10.7448/IAS.16.1.18505](https://doi.org/10.7448/IAS.16.1.18505)
- 12 Gengiah, T.N., Moosa, A., Naidoo, A., & Mansoor, L.E. (2014). Adherence challenges with drugs for pre-exposure prophylaxis to prevent HIV infection. *International Journal of Clinical Pharmacy*, 36(1):70-85. [doi: 10.1007/s11096-013-9861-1](https://doi.org/10.1007/s11096-013-9861-1)

- 13 Morrow, K., Rosen, R., Richter, L., Emans, A., Forbes, A., Day, J., ... Mayer, K. H. (2003). The acceptability of an investigational vaginal microbicide, PRO 2000 Gel, among women in a phase I clinical trial. *Journal of Women's Health*, 12(7), 655–666. <https://doi.org/10.1089/154099903322404302>
- 14 Holt, B. Y., Morwitz, V. G., Ngo, L., Harrison, P. F., Whaley, K. J., Pettifor, A., & Nguyen, A.-H. (2006). Microbicide preference among young women in California. *Journal of Women's Health*, 15(3), 281–294. <https://doi.org/10.1089/jwh.2006.15.281>
- 15 Shapley-Quinn, M. K., Manenzhe, K., Agot, K., Minnis, A. M., & van der Straten, A. (2019). “We are not the same”: African women’s view of multipurpose prevention products in the TRIO clinical study. *International Journal of Women's Health*, 11, 97–107. <https://doi.org/10.2147/IJWH.S185712>
- 16 AVAC. (2018). Understanding effective HIV prevention among adolescent girls and young women in South Africa [Webinar]. Retrieved from <https://www.avac.org/event/breaking-cycle-transmission-effective-hiv-prevention-among-AGYW>
- 17 Tebbey, P. W., & Rink, C. (2009). Target Product Profile: A Renaissance for its Definition and Use. *Journal of Medical Marketing: Device, Diagnostic and Pharmaceutical Marketing*, 1(9), 301–7. [/doi.org/10.1057/jmm.2009.34](https://doi.org/10.1057/jmm.2009.34)
- 18 Food and Drug Administration. (2007). Guidance for industry and review staff target product profile--a strategic development process tool [PDF document]. Retrieved from [www.fda.gov/media/72566/download](http://www.fda.gov/media/72566/download)
- 19 Initiative for MPTs. (2014). MPT dosage-form specific target product profiles (TPPs). Retrieved from <https://www.theimpt.org/resource-results/51-technical-brief/504-mpt-product-prioritization-and-gap-analysis-2014-summary-2>
- 20 Delany-Moretlwe, S., Lombard, C., Baron, D., Bekker, L.G., Nkala, B., Ahmed, K., ... Rees, H. (2018). Tenofovir 1% vaginal gel for prevention of HIV-1 infection in women in South Africa (FACTS-001): a phase 3, randomised, double-blind, placebo-controlled trial. *The Lancet Infectious Diseases*, 18(11):1241-1250
- 21 Initiative for MPTs. (2017). Strategic evaluation framework (SEF) for MPTs: Strategic target profile context summaries [PDF document]. Retrieved from [http://www.theimpt.org/documents/reports/SEF-NextSteps-Report\\_FY17.pdf](http://www.theimpt.org/documents/reports/SEF-NextSteps-Report_FY17.pdf)
- 22 Mensch, B.S., Richardson, B.A., Husnik, M., Brown, E.R., Kiweewa, F.M., Mayo, A.J., ...van der Straten, A. (2018). Vaginal ring use in a phase 3 microbicide trial: A comparison of objective measures and self-reports of non-adherence in ASPIRE. *AIDS and Behavior*. doi: 10.1007/s10461-018-2261-8
- 23 Microbicide Trials Network. (2016). Dapivirine vaginal ring helped protect women against HIV in ASPIRE Phase III trial. Retrieved from <https://www.sciencedaily.com/releases/2016/02/160222155635.htm>
- 24 Schulze, U. & Ringel, M. (2013). What matters most in biopharma commercial success? Retrieved from <https://www.bcg.com/en-us/publications/2013/innovation-what-matters-most-biopharma-commercial-success.aspx>
- 25 Initiative for MPTs. (2019). MPT product development database. Retrieved from <http://mpts101.org/mpt-database>

- 26 Tolley, E.E. (2017). Traditional socio-behavioral research and human-centered design: Similarities, Unique Contributions and Synergies [PDF document]. Retrieved from <https://www.theimpt.org/documents/reports/Report-HCD-BSS-Research.pdf>
- 27 Dellplain, L., Thomas, V., Russell, E., Young Holt, B., El-Sahn, M., & Lucas, J. (2017). Laying the groundwork for a strategic evaluation framework (SEF) for HIV prevention and MPT product development [PDF document]. Retrieved from [https://www.theimpt.org/documents/breif/IMPT\\_Activity1Report\\_Final122116.pdf](https://www.theimpt.org/documents/breif/IMPT_Activity1Report_Final122116.pdf)
- 28 Quaife, M., Terris-Prestholt, F., Eakle, R., Escobar, M. A. C., Kilbourne-Brook, M., Mvundura, M., ... Vickerman, P. (2018). The cost-effectiveness of multi-purpose HIV and pregnancy prevention technologies in South Africa. *Journal of the International AIDS Society*, 21(3), e25064. [doi.org/10.1002/jia2.25064](https://doi.org/10.1002/jia2.25064)
- 29 van der Straten, A., Agot, K., Ahmed, K., Weinrib, R., Browne, E. N., Manenzhe, K., ... on behalf of the TRIO Study Team. (2018). The Tablets, Ring, Injections as Options (TRIO) study: What young African women chose and used for future HIV and pregnancy prevention. *Journal of the International AIDS Society*, 21(3), e25094. [doi.org/10.1002/jia2.25094](https://doi.org/10.1002/jia2.25094)
- 30 Woodsong, C., Musara, P., Chandipwisa, A., Montgomery, E., Alleman, P., Chirenje, M., ... Hoffman, I. (2014). Interest in multipurpose prevention of HIV and pregnancy: Perspectives of women, men, health professionals and community stakeholders in two vaginal gel studies in southern Africa. *BJOG: An International Journal of Obstetrics and Gynaecology*, 121 Suppl 5, 45–52. <https://doi.org/10.1111/1471-0528.12875>
- 31 Dedoose Version 8.0.35 [Computer software]. (2018). Los Angeles, CA: SocioCultural Research Consultants, LLC.31 USAID. (2019). Center for innovation and impact (CII). Retrieved from <https://www.usaid.gov/cii>
- 32 Initiative for MPTs. (2017). Status of modelling efforts in the field of multipurpose prevention technologies: Summary report [PDF document]. Retrieved from [http://www.theimpt.org/documents/reports/MPTModellingSummaryReport\\_0217.pdf](http://www.theimpt.org/documents/reports/MPTModellingSummaryReport_0217.pdf)
- 33 USAID. (2019). Center for innovation and impact (CII). Retrieved from <https://www.usaid.gov/cii>
- 34 NIH. Writing a good commercialization plan. (2019). [Word document]. Retrieved from [https://sbir.nih.gov/sites/default/files/ic\\_nida/Commercialization-Plan\\_clean.docx](https://sbir.nih.gov/sites/default/files/ic_nida/Commercialization-Plan_clean.docx)

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