

Market Access Framework for Multipurpose Prevention Technology (MPT) Development and Introduction

The **Initiative for Multipurpose Prevention Technologies (IMPT)** is a global collaborative partnership to advance the development and introduction of products that simultaneously address multiple sexual and reproductive health needs, namely unintended pregnancy and sexually transmitted infections (STIs), including HIV. Established in 2009, the IMPT has engaged product developers, scientific researchers, health care providers, funders and community-based advocates in Africa, China, India, the United States and Western Europe behind this common agenda. Leveraging the multidisciplinary expertise of this diverse network, the IMPT works to advance the science to support the development of MPTs and to support their successful introduction into target populations with high unmet need.

Multipurpose prevention technologies (MPTs) for reproductive health are products that combine protection against unintended pregnancy and STIs, including HIV. The vision for **MPTs** is a suite of accessible products that are woman-initiated, efficient and easy to use. Safe and effective MPTs that are also acceptable, affordable, and made widely available would greatly improve the lives of women and their families and save resources across the globe.

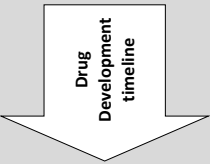
This framework document was prepared by Laura Dellplain (IMPT), Bethany Young Holt (IMPT), Anke Hemmerling (UCSF and IMPT Scientific Advisor), Joseph Romano (NWJ Group and IMPT Scientific Advisor), Ariane van der Straten (RTI International and IMPT Scientific Advisor), and Jim Turpin (NIAID). This work could not have been completed without the valuable insights and contributions from IMPT partner organization representatives. The IMPT Secretariat would like to thank Amy Lin and Janine Hum (USAID) in particular for their guidance and engagement during this process.

Support for this work was provided by the generous support of the American people through the United States Agency for International Development (USAID) under the terms of the HealthTech V Cooperative Agreement #AID-OAA-A-11-00051, managed by PATH. Support was also provided by the Mary Wohlford Foundation. The contents of this document are the responsibility of the IMPT and the Public Health Institute and do not necessarily reflect the views of USAID, the United States Government, or the other sponsors of this work.

For questions or comments, please contact: cami@cami-health.org. The IMPT Secretariat is a project of CAMI Health, an organization dedicated women's reproductive health and empowerment based in Folsom, CA, USA. The Public Health Institute is the fiscal agent of CAMI Health.

Multipurpose prevention technology (MPT) development is a complex process, and the success of such products having a meaningful public health impact will require the consideration of a range of factors from basic science and clinical trials, to market and access, to advocacy and funding. The Market Access Framework for MPT Development and Introduction is intended to serve as a resource to inform product development and investment decision-making that is focused specifically on market access components of MPT development and introduction—in other words, activities that are critical to ensuring that MPTs in development are not only efficacious in clinical trials, but also **desired, acceptable, and accessible to women and adolescent girls** once introduced and commercially available. Originally developed as a commercialization and social-behavioral research “overlay” to the traditional Target Product Profiles (TPPs), this framework document has been revised to align closely with the “[Idea to Impact](#)” guide by USAID’s Center for Accelerating Innovation and Impact and their ongoing work in the area of sexual health prevention products.ⁱ

The adapted IMPT Market Access framework is comprised of two parts: 1) a table outlining priority market access activities for MPTs to be initiated at particular points along the conventional drug development timeline, organized by four broad areas of focus for a team of implementers with diverse expertise (please note that these activities and their language have largely been pulled from the “Idea to Impact” guide for continuity), and 2) an Appendix containing more detailed descriptions of each priority activity (Appendix A).ⁱ Overall, the IMPT Market Access Framework is one component of a larger **IMPT ‘Toolkit’ for MPT Development and Introduction** comprised of a range of technical resources available on the IMPT Secretariat website, including [dosage-form specific MPT Target Product Profiles \(TPPs\)](#), an [MPT product prioritization technical brief](#), an [MPT product development database](#), and [regulatory issues for product development](#). The development of this framework continues to be an iterative process, and **any suggested revisions or changes are welcome**.

		Clinical and Regulatory	Policy and Advocacy	Manufacturing and Distribution	Market and End-User Understanding
Product Development	Discovery to Pre-Clinical	<ul style="list-style-type: none"> - Define the Target Product Profile (TPP) - Determine quantitative biomedical measures of adherence - 	<ul style="list-style-type: none"> - Conduct global policy assessment relevant to MPT development, manufacture, and distribution 	<ul style="list-style-type: none"> - Perform manufacturability assessment and landscape - Conduct intellectual property evaluation 	<ul style="list-style-type: none"> - Identify target end-user populations and settings based on epidemiologic assessment of need. - Conduct situation/market assessment - Evaluate attitudes of and develop value proposition for user, sexual partner, healthcare provider, policymaker, market, and other stakeholder audiences - Understand end-user needs and desires in the context of MPTs through market research and human-centered design - Develop trial participant recruitment strategies for various phases.
	Phases 1 & 2 (Earlier clinical)	<ul style="list-style-type: none"> - Develop and execute clinical plan with clearly defined endpoints - Conduct regulatory landscape assessment 	<ul style="list-style-type: none"> - Develop communications, advocacy, and key stakeholder engagement strategy - Conduct cost-effectiveness analysis of TPP 	<ul style="list-style-type: none"> - Develop manufacturing strategy - Develop distribution strategy - Identify partnership opportunities - Conduct cost of goods sold analysis - Conduct demand forecast - Develop business plan for partners (SROI and/or ROI) 	<ul style="list-style-type: none"> - Update situation assessment - Conduct supply and demand bottleneck analysis - Develop user segmentation - Update and strengthen understanding of end-user needs and desires, including acceptability of MPT product types, design and packaging, through market research and human-centered design
Product introduction	Phases 3 & 4 (Later clinical)	<ul style="list-style-type: none"> - Complete clinical trials - Obtain national regulatory authority approvals 	<ul style="list-style-type: none"> - Support inclusion in treatment guidelines and on country-level essential medicines lists - Execute communications, advocacy, and key stakeholder engagement strategy - Update cost-effectiveness analysis 	<ul style="list-style-type: none"> - Establish manufacturing strategy - Establish distribution strategy - Continue to identify partnership opportunities - Finalize product and packaging designs - Update cost of goods sold analysis - Update demand forecast - Update business plan for partners 	<ul style="list-style-type: none"> - Update situation assessment - Develop strategic launch plan with uptake targets - Update bottleneck analysis - Update end-user needs and acceptability assessments - Develop pricing strategy - Develop demand generation strategies and create marketing material
	Full commercialization	<ul style="list-style-type: none"> - Continue with national regulatory authority approval(s) for new markets - Conduct post-market surveillance 	<ul style="list-style-type: none"> - Continue to support inclusion in treatment guidelines and on country-level essential medicines lists for new markets - Validate impact and cost-effectiveness analysis - Develop appropriate advocacy strategy to minimize counterfeit and sub-standard MPT products. 	<ul style="list-style-type: none"> - Evaluate manufacturing and distribution footprint and adjust as necessary - Redesign and optimize product and/or packaging if necessary 	<ul style="list-style-type: none"> - Evaluate strategic launch plan progress and achievement of uptake targets - Evaluate progress against prioritized barriers and update bottleneck analysis - Introduce into new markets and to new user segments as appropriate - Expand demand generation campaigns for new markets and user segments

Appendix A: Priority Activities Detail

Discovery to Pre-clinical (3 – 7 years)

Clinical and Regulatory

- **Define the Target Product Profile (TPP).** The IMPT has developed dosage-form specific TPPs for intravaginal rings and injectables as well as a technical brief on TPPs for MPTs that may be used as guidance for the development of TPPs for specific products. In other words, a TPP for a particular product concept/dosage form can be used to help align investors and product developers around specific product attributes necessary for addressing unmet medical needs in targeted at risk populations. Product-specific TPPs for MPTs should be developed using market research and user-centered design research throughout, and will include information the product's indications, dosage, use-requirements, mechanism of action, target populations, efficacy, storage/shelf life, preclinical and clinical safety, pharmacokinetics, contraindications, costs/pricing, and relevant data pertaining to each of these attributes.
- **Determine quantitative biomedical measures of adherence.** This effort includes developing or adapting existing technology to measure drug release and drug load *in vivo*; more specifically, determining appropriate technology to measure over-time in vitro drug release that is equivalent to drug release in vivo, developing technology to measure residual drug load after product removal, assessing the reusability of a product (if applicable), and assessing the suitability of certain technologies as a proxy for direct measurement of the drug. Such measures should support an understanding of adherence beyond the binary of yes/no and include duration of use and possible coverage during exposure.

Policy and Advocacy

- **Conduct global policy assessment relevant to MPT development, manufacture, and distribution.** Such an assessment could entail the policy environment for women's health, family planning and sexual health, and/or HIV at local, national, and/or international levels.

Manufacturing and Distribution

- **Perform manufacturability assessment and landscape.** It is critical to examine the scale up potential of a product in development by examining the raw materials supply chain, procurement logistics for targeted settings, and potential suppliers and their manufacturing capacities and considering strategies to foster manufacturing efficiency.
- **Conduct intellectual property evaluation.** This process is necessary to evaluate patents, trademarks, copyrights, and other similar issues relevant to commercializing a developed MPT.

Market and End-User Understanding

- **Identify target end-user populations and settings based on epidemiologic assessment of need.** MPTs could have any number of indication combinations that may be best suited for one end-user population over another. All subsequent market access activities hinge on successfully identifying the user group and better understanding the needs and perceptions of this group.
- **Conduct situation/market assessment.** At this stage, this type of assessment identifies the need for a particular MPT, the competitor landscape, the size of the target market, cost considerations, exploration of how to develop a sustainable market, and other market considerations.
- **Evaluate attitudes of and develop value proposition for user, sexual partner, healthcare provider, policymaker, market, and other stakeholder audiences.** This is an assessment of the perception of relative added value or importance of a particular MPT for each stakeholder group.
- **Understand end-user needs and desires in the context of MPTs through market research and human-centered design.** A preliminary assessment of end-user needs and desires for a given MPT is critical to increase the likelihood of producing an acceptable product (e.g., what is being used now; how can this be improved; is there a role/need for a new product?). This early stage is more likely to identify products that shouldn't move forward and a wide range of products that could be acceptable. This effort should assess all relevant product characteristics and their relative importance, including MPT delivery form, usage requirements, effectiveness, duration of action, reversibility (i.e., return to fecundity for contraceptive products), residual effect after product use, effect on sexuality, physical or emotional impact on partner, effect on future fertility, suitability within sociocultural context, etc.
- **Develop trial participant recruitment strategies for various phases.** This includes the identification and evaluation of elements to define and select optimal trial participant population. Include the development of trial roll out messaging engaging naïve and comparator study populations. The recruitment strategy will vary considerably between the phases of clinical trials, since the type of participants

needed varies considerably throughout the clinical trial process. Early trials may target women at low risk, sometimes sexually abstinent, etc. The type of user understanding data needed from these participants is quite different from what is needed from participants in later stage trials, or as part of post-approval activities.

Phases 1 & 2 (Earlier Clinical) (2 - 4 years)

Clinical and Regulatory

- **Develop and execute clinical plan with clearly defined endpoints.** A clinical trial plan should outline what data are to be collected to answer particular questions with regard to efficacy and effectiveness, including adherence. Such a plan will help to guide clinical decision-making, including go/no-go decisions. For example, targets could be set for a product that achieves a certain level of efficacy, is used with a certain level of adherence, is delivered in to a population with a certain level of incidence, and achieves a certain level of “uptake.” If along the way, it appears that the targets cannot be met (e.g., efficacy is too low, “uptake” is too slow, adherence is too low), then the product development should be adjusted or halted because it will not reach the target impact level. Notably, understanding the causes suboptimal uptake and adherence targets could inform appropriate messaging or education that could improve these targets, and thus this context should be considered prior to abandoning development. Information sharing during these evaluations is critical to the advancement MPT field, with the large caveat that some products may have acceptable uptake in certain geographies, and need a longer trajectory in other geographies, requiring a shift of cultural norms (e.g., tampons took 20 years to be widely adopted by women of all ages). Specific clinical activities in early stage trials include:
 - Define preliminary release specs.
 - Develop/qualify release/stability tests.
 - Clinical dose investigation (dose ranging) for safety, PK, PD.
 - Define target exposure(s)/dose.
 - Formulation adjustments based on end-user feedback.
 - Device biocompatibility studies.
 - Definition of side effects/AEs.
 - Expanded clinical safety assessment.
 - Additional preclinical safety (as needed).
 - Male safety studies.
 - Final determination of side effects/AEs.
 - Address outstanding PK/PD.
 - DDI clinical studies.
 - Finalize formulation (drug load, configuration, etc.).
 - Determine final dose and dosing regimen.
 - Preliminary definition of contraindications.
 - Effects of non-adherence on product performance/integrity/drug load.

The clinical trial plan should also include the trial participant recruitment strategies developed in *Market and User Understanding* during discovery – preclinical.

- **Conduct regulatory landscape assessment.** Assessing the landscape of applicable regulations and their potential impact on MPT development and introduction is critical at this stage. There are unique regulatory considerations for MPTs given the complexity and diversity of products in development, and these need to be thoughtfully explored and addressed with regulators.

Policy and Advocacy

- **Develop communications, advocacy, and key stakeholder engagement strategy.** It is critical to inform and engage the necessary stakeholders about MPTs early on, but one must also work to avoid false expectations with regard to MPT development and introduction timeline projections. A communications and advocacy strategy must then include ways to attract diverse stakeholder groups to the promise of MPTs and also describe this timeline and development process so that it is understandable.
- **Conduct cost-effectiveness analysis of TPP.** For MPT funders/investors, for example, such cost-effectiveness modeling should be conducted in the context of other prevention options to see addition of public health value and thus investment worth.

Manufacturing and Distribution

- **Develop manufacturing strategy.** After assessing the manufacturability of a particular product, it will be critical to assess the manufacturing landscape and explore viable options to ensure high quality, consistency, efficiency, and low cost. Considerations should include the raw material supply chain, establishing an early phase manufacturing equipment plan for scalable production, and examining commercial scale manufacturing capacity with robust cost estimates.

- **Develop distribution strategy.** The exploration of possible distribution channels and partners is useful at this early stage, particularly given the cross-cutting nature of MPTs and the range of delivery setting options (e.g., HIV prevention setting, family planning setting, maternal and child health setting etc.). A critical consideration here is assessing and strategizing around the impact of the product on the proposed delivery system(s); for example, necessary level of healthcare worker expertise, follow up schedule, frequency/number of health care system visits, etc. The impact of presentation (e.g., packaging) and the environmental impact of packaging and waste on delivery and distribution strategies should also be assessed.
- **Identify partnership opportunities.** Having conducted assessments of manufacturing and delivery system capacities, it is important to build relationships at an early stage with stakeholders who can enhance the success of eventual product introduction. This could include manufacturers, distributors, ministries of health, healthcare provider groups, and civil society organizations.
- **Conduct cost of goods sold analysis.** This analysis will help to generate an initial determination of whether the product can meet the proposed price target for public and private sector markets.
- **Conduct demand forecast.** This assessment quantifies product purchase or uptake over a 15-25 year period using real data and modeling, projecting the profit potential and helping to inform the development of manufacturing and distribution strategies.
- **Develop business plan for partners (Social Return on Investment [SROI] and/or Return on Investment [ROI]).** Utilizing data and analysis from prior epidemiological and market assessments, begin to build a case for investment in advancing the development and eventual introduction of the product. Note that some funders may be more interested in social return arguments rather than financial return.

Market and End-User Understanding

- **Update situation/market assessment.** Product development and introduction planning should be an iterative process based on evolving conditions and increased data. Additional areas of assessment to include at this stage could be to evaluate the effect of social influences and community feedback related to the progression of MPT development and plans for introduction, including trial participation.
- **Conduct supply and demand bottleneck analysis.** This assessment enables planners to anticipate challenges with product uptake, identify possible challenge areas (e.g., in the manufacturing process, delivery channels, etc.), and strategize to address these challenges early on.
- **Develop user segmentation.** Having identified the target market, user segmentation can be useful to refine marketing and distribution strategies through the identification and assessment of population segments within the target market with unique characteristics. For example, strategies might be different when targeting older versus younger women within the larger target market.
- **Update and strengthen understanding of end-user needs and desires, including acceptability of MPT product types, design and packaging, through market research and human-centered design.** Updates could relate to end-user preference assessments for MPT delivery form, dosage, product attributes with placebo, and use-requirements (e.g., timing, continuous use, etc.). In terms of a specific MPT product, updates could include end-user acceptability of the active pharmaceutical ingredient (API) in terms of actual and perceived benefits and risks (e.g., side effects, efficacy, lack of perceived harm including social harm, and perceived barriers) or of the delivery form in terms of appearance, size, administration, ease of use, target dosing regimen, partner perceptions, concealability, willingness to pay, and/or other social and cultural norms. Updated end-user data should be incorporated into the MPT design process, and it could be helpful to establish dosage-form specific product design modification strategies for end-user acceptability/preference results. Another critical clinical application of this understanding will be in establishing agreed upon end-user acceptability and preference measure standards for the field, across studies and MPT product types. Outside of MPT product attributes, it will also be important to investigate user preferences for MPT delivery and delivery setting (e.g. HIV prevention setting, family planning setting, etc.), including assessing attitudes towards accessing the healthcare system, HIV testing and counseling, etc. At this early stage and using similar methodologies, it may be helpful to investigate provider attitudes and limitations in the context of product uptake and make product or packaging adjustments accordingly.

Phases 3 & 4 (Later Clinical) (3 – 5 years)

Clinical and Regulatory

- **Complete clinical trials.** Complete execution of the clinical plan, making adjustments as necessary, to demonstrate efficacy and safety of the product. Learnings from the updated understanding of end-user needs and desires in the Earlier Clinical period can be applied to improve adherence if necessary. Specific clinical activities during later stage trials include:
 - Finalization of all chemistry and manufacturing controls process and test validations.
 - Late stage preclinical safety (e.g., carcinogenicity study, Seg III reprotoxicity).
 - Large scale safety determination.
 - Clinical efficacy determination.
 - Determination of testing requirements (if any).
 - Final definition of contraindications.

- Conduct ongoing pharmacovigilance and long-term safety data.
- Establish surrogate measures of effectiveness.
- Bio-marker and self-report data on adherence.
- Open label trials in real life conditions.
- **Obtain national regulatory authority approvals.** The logistics of this process will be informed by the initial regulatory landscape analysis.

Policy and Advocacy

- **Support inclusion in treatment guidelines and on country-level essential medicines lists.** This will be required for some public sector markets.
- **Execute communications, advocacy, and key stakeholder engagement strategy.** The buy-in of policymakers, ministries of health, and healthcare providers will help to ensure the success of product introduction.
- **Update cost-effectiveness analysis.** Refine key variables with added manufacturing, distribution, and market assessment information. It is important to demonstrate the cost-effectiveness of a product at this stage to help make the case for investment.

Manufacturing and Distribution

- **Establish manufacturing strategy.** Manufacturing avenue(s) should be selected based on preliminary and updated assessments.
- **Establish distribution strategy.** Distribution channel(s) should be selected based on preliminary and updated assessments. It will be important to assess and strategize around the burden of large scale distribution on health care systems and in expanded populations and geographies.
- **Continue to identify partnership opportunities.** This process is ongoing and will enhance the likelihood of successful product manufacturing and introduction.
- **Finalize product and packaging designs.** Final designs should incorporate collected marketing and end-user data, and should be tested prior to launch.
- **Update cost of goods sold analysis.** This update should possible strategies to reduce cost of goods to maximizing affordability while maintaining quality.
- **Update demand forecast.** An updated demand forecast can include real use data from later stage trials to help build the case for investment and refine the manufacturing and distribution strategies.
- **Update business plan for partners.** This may include updated demand forecast data, cost of goods analysis, and pricing strategy. Social return on investment arguments should also be updated to include new data.

Market and End-User Understanding

- **Update situation assessment.** This process should be iterative based on other evolving plans and assessment activities related to MPT development and introduction.
- **Develop strategic launch plan with uptake targets.** This plan involves the activities and timelines for launch and scale up, and should consider public health need, key stakeholder and country readiness, and other strategic priorities. Innovative and culturally appropriate models to improve uptake or accelerate behavior change (e.g., leveraging social media, social franchising, or conditional cash transfers) should be considered. It will also be important to articulate requirements for provider and counselor's training and monitoring for particular MPT products. Uptake targets must be established to monitor and evaluate progress.
- **Update bottleneck analysis.** This analysis should incorporate information from other updated assessments and overall progress of the development and introduction effort. Barriers to product effectiveness in real life settings should be prioritized and minimized.
- **Update end-user needs and acceptability assessments.** The assessment may be updated and refined through clinical trial data, including the evaluation of all aspects of adherence (e.g., initiation, persistence or discontinuation, fatigue, and lack of good execution). More attention should be paid at this stage to assessing sexual partner, healthcare provider, and other "gatekeeper" acceptability of the product and other relevant aspects such as delivery setting. At this stage the assessments will be updated based on the constraints of the product (packaging vs. administration).
- **Develop pricing strategy.** This will be based on the updated situation assessment, market and end-user analysis, and user segmentation to refine prices based on delivery channel and user segment.
- **Develop demand generation strategies and create marketing material.** Such strategies involve developing and refining messaging for various target audiences (e.g., end-user, partner, community, religious leader, etc.), including messaging on biological effects of products, based on findings from formative work and updated end-user needs and acceptability assessments. Some of this work could begin earlier in this stage or even during Phases 1 & 2 as a strategy to enhance adherence during clinical trials.

Full Commercialization (at least 1 year)

Clinical and Regulatory

- **Continue with national regulatory authority approval(s) for new markets.** In anticipation of market expansion, this process should be ongoing.
- **Conduct post-market surveillance.** After clinical trials in a smaller sample size, post-market surveillance will continue to evaluate and refine the safety of the product once introduced to the general population

Policy and Advocacy

- **Continue to support inclusion in treatment guidelines and on country-level essential medicines lists for new markets.** In anticipation of market expansion, this process should be ongoing.
- **Validate impact and cost-effectiveness analysis.** These models can be validated with real data from distribution and use at scale.
- **Develop appropriate advocacy strategy to minimize counterfeit and sub-standard MPT products.** It will be important to strategize about ascertaining and problem solving around black market sales of MPTs.

Manufacturing and Distribution

- **Evaluate manufacturing and distribution footprint and adjust as necessary.** Strategies developed and implemented in earlier stages of product development may need to be modified depending the capacity of local manufacturers and distributors and markets expand.
- **Redesign and optimize product and/or packaging if necessary.** Although much work will have already been completed on packaging prior to this stage, optimization can only be completed once “real world” feedback can be obtained. Real world feedback can feed into a revamp of product and product packaging that can further enhance and optimize uptake and public health impact.

Market and End-User Understanding

- **Evaluate strategic launch plan progress and achievement of uptake targets.** Monitoring and evaluation systems should be in place to monitor uptake, awareness of the product, messaging resonance, health facility utilization and other healthcare system impacts. Routine monitoring will allow for real time adjustments to the strategy. This process should be very dynamic in the first year and allow for constant trial and error.
- **Evaluate progress against prioritized barriers and update bottleneck analysis.** Given the constant evolution of supply conditions and market demand, this process should continue after full commercialization of the product.
- **Introduce into new markets and to new user segments as appropriate.** After initial markets have manufacturing and distribution at scale, new markets and segments can be explored if appropriate. Updated cost-effectiveness analyses and other modeling will help to inform this strategy.
- **Expand demand generation campaigns for new markets and user segments.** As the market diversifies and increases through commercial expansion, these strategies should evolve to meet the needs of specific settings.

¹ USAID. (2015). Idea to Impact: A Guide to Introduction and Scale of Global Health Innovations. Retrieved from: <https://www.usaid.gov/cii/guide-introduction-and-scale>.