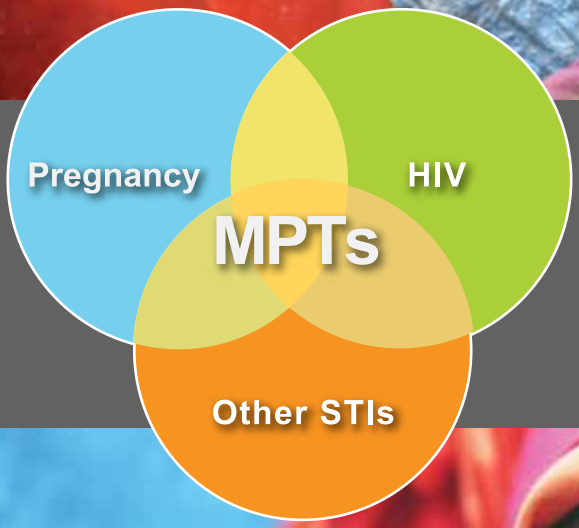

Clinical Trial Evaluation Workshop for MPTs: Strategic Steps to Ensure Success

Washington, D.C., USA

13-14 September 2016

IMPT for Reproductive Health

The **Initiative for Multipurpose Prevention Technologies (IMPT)** is a product neutral, global collaboration that advances the development of MPTs to address the interlinked risks of unintended pregnancy and sexually transmitted infections (STIs), including HIV. Comprised of members from across disciplines and more than 15 countries, the IMPT is the central body that researchers, product developers, funders, policymakers, and advocates rely on for objective technical guidance and strategic planning related to MPTs.

Multipurpose prevention technologies (MPTs) are an innovative class of products that deliver varied combinations of HIV prevention, other STI prevention, and contraception and will improve the lives of women and families worldwide. The vision for **MPTs** is an array 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 health and save resources across the globe.

This report was prepared by Carolyn Elizabeth McGrory (IMPT Rapporteur), Bethany Young Holt (IMPT), Laura Dellplain (IMPT), Joseph Romano (NWJ Group and IMPT Senior Scientific Advisor), and Anke Hemmerling (UCSF and IMPT Scientific Advisor). This work could not have been completed without the valuable contributions of the meeting presenters and participants.

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For questions or comments, please contact: IMPT@cami-health.org.

The Initiative for Multipurpose Prevention Technologies (IMPT) is a project of CAMI Health, an organization dedicated to women's reproductive health and empowerment. CAMI Health is housed at the Public Health Institute (PHI).

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IMPT for Reproductive Health

Workshop Background

With support from the United States Agency for International Development (USAID), the *Eunice Kennedy Shriver* National Institute of Child Health and Human Development (NICHD), and the Bill & Melinda Gates Foundation, the Initiative for MPTs (IMPT) convened a technical workshop on priority considerations for the clinical evaluation of multipurpose prevention technologies (MPTs). Recognizing the inherent and growing complexities of developing, testing, and delivering MPTs to populations at risk, this technical workshop was designed to inform an overall strategy for the identification and successful clinical evaluation of MPTs that can reduce the risk of HIV and unintended pregnancies among at-risk adolescent girls and young women (AGYW). These efforts are especially urgent in the context of the evolving HIV prevention field. Competition with other HIV interventions for funding and clinical trial capacity, as well as the availability of pre-exposure prophylaxis (PrEP), may limit opportunities for the progression of MPTs through full development to commercialization. The workshop objectives were to:

1. Define appropriate clinical and market-level data necessary to support the selection of optimal MPT products to advance into Phase 3 trials and commercialization.
    a. Identify the potential challenges and risks associated with these studies, and
    b. Outline strategies for successfully addressing these challenges and risks.
2. Identify critical market issues that can be addressed through clinical evaluations of MPTs, or through the study of the intended target populations.

Through presentations and lively discussions, the diverse experts at the workshop reviewed and debated a range of complex issues related to assessing the potential market impact and clinical evaluation of candidate MPT products. This document outlines a summary of key themes identified during the workshop and proposes priority next steps to move the field forward. Key themes are organized under several general categories: funding approaches; market and social-behavioral assessment; commercialization; active pharmaceutical ingredients (APIs); clinical evaluation focused on markers for efficacy; and clinical trial design. Given the range and complexity of topics addressed, time constraints did not allow for addressing all workshop objectives. However, workshop participants identified and agreed on a set of activities to continue to drive this work forward in key areas. Many of the points and next steps outlined here echoed key issues raised during the preceding IMPT Technical Meeting on Hormonal Contraception (HC) in MPTs, as well as during a follow-up strategy meeting among U.S. Government (USG) funders involved with the IMPT's Supporting Agency Collaboration Committee (SACC).

Although many product approaches and indications were discussed at the workshop, reviewing products early in development was not a primary focus. The agenda focused on clinical trials, so the presentations and discussions necessarily emphasized the candidate products furthest along in the pipeline. MPT pipeline options for the next three to five years can be categorized into three product strategies: 1) co-formulated; 2) co-packaged; and 3) co-administered (see Figure 1). Co-formulated refers to having multiple APIs formulated into a single dose; co-packaged refers to having two independent products

used together; and co-administered refers to having two different doses packaged together in a single product for simultaneous co-use. While co-packaged and co-administered strategies were addressed, the focus of the workshop was on the co-formulated strategy, and namely intravaginal rings (IVRs) that contain an antiretroviral (ARV) component for HIV prevention (one with tenofovir and the other with dapivirine) and levonorgestrel (LNG) for contraception.

Workshop Context

This document's summary of key themes and proposed priority next steps must be understood within the current biomedical HIV prevention landscape, as well as the opportunities and limitations of funding mechanisms across the sexual and reproductive health fields. Several critical points are outlined below to provide this context:

- AGYW will likely benefit most from MPTs. Adherence in HIV prevention trials for women, particularly among younger women, is a significant concern that has raised questions about the market potential of MPTs, including uptake and use of any product that is proven effective. Low adherence in studies can also hamper researchers' ability to adequately assess product safety and efficacy, especially among AGYW.

- The HIV prevention landscape is increasingly crowded and complex, with approval of Truvada for oral PrEP; potential licensure of the dapivirine ring; and ongoing clinical testing of long-acting injectables, broadly neutralizing antibodies, and vaccines. MPT development is moving slowly relative to these other interventions.

- At the same time, budgets in key funding agencies that support MPTs, notably the National Institutes of Health (NIH) and USAID, are static, with increased demands on flat or sometimes declining budgets.

- Robust standards that are rooted in evidence must be identified and agreed on for technical and market performance, including a product's potential for impact and successful commercialization. Developing these standards may necessitate bringing in additional expertise.

- Market considerations should include: identifying and quantifying priority target populations; forecasting need, demand, and potential impact; determining preferences for product characteristics among target populations; understanding of/strategizing around the full picture of life circumstances that impact product value and uptake; assessing the potential cost and impact that marketing and support for introduction and use could have on product uptake; and potential for commercialization (see further discussion below).

- Funders need to develop and agree on mechanisms to ensure a thorough and collaborative vetting process through which developers and funders alike are held accountable to these future technical and market standards, including product down-selection.

Funding Approaches

Key Points

- Along with overall funding constraints, the current grant-based funding models that provide the primary support for MPT development include strict and sometimes inflexible deliverables that can be incompatible with the pivoting and down selection practiced in the pharmaceutical industry.

- Most of the funding agencies that support MPT development are primarily concerned with a specific single indication such as HIV prevention, contraception, or preventing other diverse sexually transmitted infections (STIs). In light of these specific mandates, some agency representatives noted that it will be difficult to justify support for MPTs that may be less efficacious than existing products for the indication on which they focus, or for products outside the purview of a particular agency. For example, it would be difficult for agencies that support contraceptive development to support an MPT product that offers additional HIV protection, but is less effective for pregnancy prevention than currently available single-indication contraceptives.

- Funders should assess the extent to which there are alternative approaches to MPT development funding that are realistic and can be implemented.

- Funders should closely examine how existing funds are being spent in all phases of MPT development and determine if there are ways to redirect any of these funds to support projects identified as priorities for the MPT field. Given the relevance and urgency of addressing market questions, this assessment should include 1) determining an overall strategy and corresponding budget to be committed to fill gaps in social-behavioral and market research, 2) what each funder will contribute, and 3) the type(s) of work each funder will support (see section below). This activity has commenced following a USG funder meeting convened by the IMPT in November 2016 (described further below).

- At the same time, funders and advocates should urgently develop action plans to identify and access new funding sources for those projects identified as priority.

Next Steps

- Build on the SACC's ongoing joint work to strengthen collaboration and communication among MPT funders. Examine the feasibility of implementing new funding mechanisms to better support priority work to advance MPTs, and specify what is needed to move forward such a process.

- Funders to analyze, in detail, how existing funds are being spent across the phases of MPT development, in order to assess how flexible these mechanisms are, and to determine how best to use existing or new resources for priority projects, focused especially on market questions.

Market and Social-Behavioral Assessment

Key Points

- The first MPT product will likely not be acceptable or "right" for all populations, including all AGYW. Once the priority target population(s) are identified, MPTs that will have highest potential impact for this population should be advanced.

- It is critical that end-user research be integrated into MPT development strategies early in the product development process to maximize public health impact. End-user data should inform product design, messaging, and marketing; clinical trial design; and MPT service delivery approaches.

- There is a range of existing evidence from social-behavioral research, clinical trials of contraception, PrEP, and microbicides, and experience with product introduction and delivery that can offer important insights for MPTs. Once priority market questions have been identified, a critical analysis of existing information and how it can be applied to these questions can help pinpoint true gaps to be filled with new research.

    - Other relevant resources include: established frameworks for adolescent psychological development and behavioral drivers; ecological models; market segmentation and prioritization; defining rewards associated with product use; and other topics.

- Social-behavioral and market research approaches have both been implemented in the context of MPT and microbicide development. To address the outstanding market questions for MPTs, it will be important to better understand how and when these different end-user research modalities may be best harmonized. More specifically, it is important to understand where there may be overlap in social-behavioral and market research approaches, and where there may be unique and necessary contributions.

- Specific market questions that need to be further addressed through an assessment of existing evidence or conducting new research include:

    - Agreeing upon the priority target population(s), which is a critical underpinning to determining and prioritizing the market and clinical assessments for MPTs.

    - Assessing and characterizing the priority target population, understanding their needs, preferences, and potential drivers of MPT use.

- Target population acceptability of specific product characteristics, especially those related to LNG-containing IVRs: the tolerability of irregular menstrual bleeding, spotting, and amenorrhea; whether it is important that products can be concealed; and the ideal and acceptable duration of using one ring before switching to a new ring.

- Research on user preferences, cost effectiveness, and marketing and delivery must consider that MPTs will likely require initial and/or frequent HIV testing and may create additional burden on health systems.

Next Steps

- Identify and characterize the **priority target populations** in which an MPT with HIV and contraceptive indications could achieve appropriate impact. This analysis should draw on epidemiological HIV incidence data and contraceptive needs in these populations. Modeling data can inform MPT impact potential in these populations.

- **Assess the optimal MPT product attributes** for the priority target population(s) based on population needs and desires. This will involve: assessment of what is known to date based upon existing data; monitoring of ongoing research that may be informative over the next 12-18 months; and identification and implementation of research that that can inform current knowledge gaps in the prioritized target populations.

- Conduct **review of social-behavioral and market research methods** in the context of MPT development and suggest strategies for complementarity. This project has **recently been undertaken** by FHI 360 through the IMPT, with support from USAID's Office of HIV/AIDS.

Active Pharmaceutical Ingredients (APIs)

1. Contraception *[For more details, see the report from the Technical Meeting on HC in MPTs]*

Key Points

- The two products most advanced in the MPT pipeline both incorporate the progestin LNG as the active HC agent. Experts continue to debate whether 1) LNG or an alternative progestin is the most feasible and optimal contraceptive agent, or 2) a combination of progestin and estrogen would have a more desirable side effect profile. Finally, several ongoing concerns about LNG need to be addressed:

    - Is the characteristic of LNG to frequently cause intermittent bleeding acceptable to MPT target populations, or will this common side effect be an impediment to adherence, uptake, and sustained use?

    - What is the justification behind the dose determination for the MPTs in development?

- What are the implications of rising body mass index (BMI) in many women in target populations, and could the LNG dose levels in the MPTs being tested be too low to achieve sufficiently high plasma levels to ensure contraceptive efficacy?

Next Steps

- Develop **technical standards** around **hormonal dose determination** and justification for MPT products.

2. HIV/STI Prevention

Key Points

- The current lead products employ the antiretroviral agents dapivirine and tenofovir as the APIs for HIV prevention. Dapivirine is not yet licensed and consequently, there is relatively little data available on its use. Dapivirine vaginal rings have undergone clinical evaluation and regulatory dossiers are currently being compiled. Tenofovir has been widely used to treat HIV, and has been tested for HIV prevention with relatively extensive data available on oral use in diverse populations and on use as a vaginal gel in clinical trials (CAPRISA 004, VOICE, and FACTS 001 studies). One trial also demonstrated partial efficacy of a gel formulation in reducing the risk of HIV and herpes simplex virus (HSV) acquisition (CAPRISA 004).

- Co-packaging and co-administering contraceptive and HIV prevention products (oral or possibly injectable) will likely be the fastest route to providing joint protection from HIV and pregnancy. Given the complexity and timeframe to developing and delivering a new, co-formulated MPT product, such co-packaging should be actively pursued.

Next Steps

- Working closely with product developers, funders should develop **rigorous criteria** for assessing the potential trade-offs of dapivirine and tenofovir in vaginal rings, including:

    - The drug load and target release in vaginal rings;

    - Commercialization, including manufacturing for clinical trials and for scale up;

    - Acceptability in target populations;

    - Anticipated time to market;

    - Cost of goods and delivery; and

    - Commercial potential with an additional or prioritized HSV-2 indication.

- The outcomes of these assessments can continue to be adjusted and informed as development continues and additional data become available.

- Continue to explore possibilities for **co-packaging and co-administering** HIV prevention and contraceptive products, including identifying the regulatory pathway, key knowledge gaps, and a strategy for filling those gaps.

Clinical Evaluation

1. Markers for Efficacy

Key Points

- Surrogate markers for effectiveness that can inform product prioritization and dose selection are weak for both HIV prevention and contraception. This presents considerable risk for moving products forward and challenges for establishing product selection technical standards. Experience with HC and HIV prevention products, including other IVRs, may suggest such markers and their target minimum dose levels for effectiveness.

- Bioavailability and bioequivalence (BE) generally need to be determined within quite specific parameters. Typically, regulatory authorities require strict margins in BE assessments; percentages that are too low relative to the comparator product risk efficacy outcomes; percentages that are too high relative to comparator risk safety outcomes. Achieving these tight margins around the comparator target are generally quite difficult, and may be especially challenging for topically administered MPTs given complexities of inter-person variability of measurements and vaginal absorption, the burst effects of initially high drug release, and the limited pharmacological forgiveness (sustained drug levels sufficient for HIV protection during temporary device removal) associated with IVRs. Given this, it may not be feasible to rely on bioavailability and BE data of other approved products for regulatory review of new MPTs.

Next Steps

- Development strategies for dose and efficacy must be made in the context of limited surrogate markers for efficacy for both contraception and HIV prevention, as well as the current lack of improved models predicative of *in vivo* outcomes.

2. Clinical Trial Design

Key Points

A range of complex issues need to be addressed with respect to clinical trial design, especially for Phase 3 trials. These include control groups, standards of care, outcome measures, study sequencing, identifying trial populations that can best represent priority users, ethical issues, etc.

- The general approach and design for Phase 1 and Phase 2 trials are fairly well characterized. However, more attention is needed on what outcomes would inform decisions about whether to advance a candidate MPT product following each clinical trial phase.

- Many specific aspects of Phase 3 trial design will depend on the specific product being tested, including whether any component of the product has been previously approved by a stringent regulatory authority.

- Given the roll out of oral PrEP for HIV prevention and the potential for approval of the dapivirine IVR, any future HIV prevention trials may need to include active controls instead of placebo, requiring much larger sample sizes to prove effectiveness of an MPT.

- Current standard of care will need to be determined for HIV prevention, with potentially significant impacts on trial design, including sample size. Programs to provide oral PrEP are being planned and implemented in many settings and some include or target AGYW. Therefore, MPT trials may be required to offer oral PrEP to trial participants. Similarly, women in HIV prevention trials are required to use reliable contraception; it is unclear whether women in MPT trials would be required to use a second form of contraception in addition to the MPT being tested. Stakeholders, including researchers, ethical review committees, and community advisory boards, will need to grapple with standard of care and other issues to inform protocol development and technical standards such as studies of additional drug-drug interactions.

- Given challenges with product adherence, stakeholders need to aggressively assess approaches to maximizing and measuring adherence. For example, a run-in period could help identify women most likely to adhere to product use. However, such approaches have trade-offs. Women likely to adhere during clinical trials may differ from those at highest risk or who would benefit most from MPTs. This may require additional safety, bridging, post-marketing, or other studies to assess safety and efficacy among different user groups.

- Outcome measures for contraceptive effectiveness need to be specified, taking into account the large number of tested cycles required by regulatory agencies (i.e., 10,000-20,000). “Pearl creep,” a phenomenon describing a rising Pearl Index and decreasing efficacy in existing contraceptives over the past decade, may be due to increasing BMI.

- Integration of marketing expertise into aspects of trial design such as recruitment, materials, packaging, and product presentation should be considered.

Next Steps

- Convene a small working group of HIV, contraceptive, and clinical experts to examine the feasibility of current MPT candidate products to meet **Investigational New Drug (IND) Application requirements supporting an MPT phase 2b/3 protocol application** in 2020.

- Determine and prioritize how best to move forward on **key aspects of Phase 3 trial design for MPTs.** Follow up with calls, commissioned reports, smaller expert consultations, or other approaches as appropriate.

- Explore leveraging resources from across different publicly funded clinical trial networks to assess MPTs.

Commercialization

Key Points

- Any product tested in a Phase 3 study will be the final product for commercialization. Given the considerable challenges that can arise throughout this process, developers should have clear plans for the multiple complex elements of commercialization such as manufacturing capacity; scalability; pharmaceutical quality [chemistry, manufacturing, and controls (CMC)]; cost of goods; fully burdened costs; marketing; commercial partners; and so forth. Confirming that these processes are feasible and on track should be a key driver of funders' decisions about investing in a Phase 3 trial.

- Forecasting is needed to begin to estimate the size and contours of the market. This forecasting can build on epidemiologic information as well as prior research conducted for family planning programs to identify priority populations of AGYW for PrEP implementation and in anticipation of microbicide introduction.

- Critical determinants of overall MPT product costs should include cost of goods, delivery costs, clinical management, necessary testing, and other costs associated with use and delivery of these products. Cost will also be informed by forecasting product demand, which will be relevant to determining economies of scale.

- While MPTs to date have focused on HIV and contraception, indications for STIs, such as HSV, that are more prevalent in high and middle income country populations may be more attractive than the HIV indication from a market perspective. Higher resource markets could contribute to overall commercial viability and may help attract partner organizations or companies with capacity to commercialize MPTs.

- Identifying commercial partners will be a key element of this process. Appropriate and interested commercial partners may exist outside the U.S. pharmaceutical industry.

Next Steps

- Commission independent **forecasting and other analyses** for use by developers, funders, and other interested parties to estimate the size and contours of the market for MPTs, drawing on epidemiologic information, existing research on family planning, PrEP for AGYW, microbicide

introduction, and actual consumer demand data. This process should include cost scenarios for products, delivery approaches, and scale.

- Develop **standards for market assessment and commercialization** against which products will be evaluated. The IMPT will manage this process, including engaging outside expertise.

- Based on these standards, funders will access third party expertise to **evaluate the commercialization plans** of MPT developers. This would include the assessment of manufacturing, scalability, CMC, cost of goods, marketing, and commercial partners against these standards. The feasibility of these plans should be a key factor in selecting a product to move into Phase 3.

Data Requirements for Regulatory Approval and World Health Organization (WHO) Processes

Key Points

- MPT product development needs to be consistent with the regulatory guidance of a stringent regulatory authority such as the U.S. Food and Drug Administration or the European Medicines Agency to achieve regulatory licensure.

- The MPT regulatory strategy should also be consistent with the requirements for WHO prequalification.

Next Steps

- Top-line **data requirements** for **regulatory approval and WHO review processes** for MPTs should be identified to help inform product development criteria.

Prioritized Next Steps and Conclusions

The IMPT's Clinical Trial Evaluation Workshop underscored that while MPTs are an important opportunity to leverage younger women's need for contraception with prevention of HIV, there are a myriad of complexities that need to be addressed for their successful clinical evaluation. Critical next steps to advance the field were identified throughout the meeting, many of which were also identified during the Technical Meeting on Hormonal Contraception (HC) in MPTs and during a follow-up strategy meeting among USG funders involved with the IMPT's SACC.

During this follow-up meeting in November 2016, the IMPT Secretariat **convened USG SACC members** to discuss outcomes of the HC in MPTs meeting and Clinical Trial Evaluation Workshop and prioritize field-wide next steps. The following were agreed upon as prioritized next steps, which will be managed by the IMPT Secretariat over the next nine months:

- Convene a small working group of HIV, contraceptive, and clinical experts to examine the feasibility of current MPT candidate products to meet **IND Application requirements supporting an MPT phase 2b/3 protocol application** in 2020.

- Identify and characterize the **priority target populations** in which an MPT with HIV and contraceptive indications could achieve appropriate impact. This analysis should draw on epidemiological HIV incidence data and contraceptive needs in these populations. Modeling data can inform MPT impact potential in these populations.

- **Assess the optimal MPT product attributes** for the priority target population(s) based on population needs and desires. This will involve: assessment of what is known to date based upon existing data; monitoring of ongoing research that may be informative over the next 12-18 months; and identification and implementation of research that that can inform current knowledge gaps in the prioritized target populations.

- Conduct a **review of social-behavioral and market research methods** in the context of MPT development and suggest strategies for complementarity.

    - This project has **recently been undertaken** by FHI 360 through the IMPT, with support from USAID's Office of HIV/AIDS.

- **Reconcile feasibility of MPT candidate products** to meet Phase 2b/3 **IND requirements** in 2020 with the optimal MPT **product attributes** of the target population(s).

As described throughout this report, other clinical and market priority actions were identified during the workshop as well as in follow-up discussions among IMPT staff, funders, and outside experts. These included:

- Funders will **analyze, in detail, how existing funds are being spent** across the phases of MPT development, in order to assess how flexible these mechanisms are, and to **determine how best to use existing or new resources** for priority projects, focused especially on market questions.

- **Identify research gaps and appropriate funders and implementers** for future studies to fill gaps, and assess how to best manage and support this process.

- Determine and prioritize how best to move forward on **key aspects of Phase 3 trial design** for MPTs.

- Identify top-line **data requirements** for **regulatory approval and WHO review processes** for MPTs to help inform product development criteria.

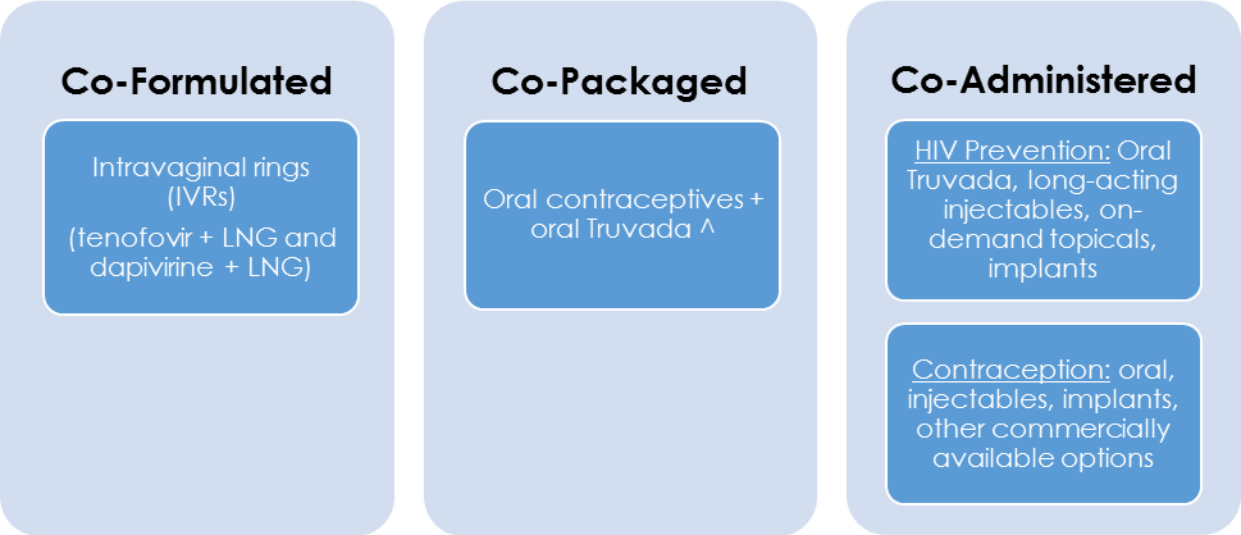
- Develop **technical standards** and justification for MPTs, including hormonal dose determination, drug load and target release in vaginal rings, market assessment, commercialization, etc.

- Continue to explore possibilities for **co-packaging and co-administering** HIV prevention and contraceptive products (e.g., oral contraceptive pills + Oral Truvada).

- Commission independent **forecasting and other analyses** for use by developers, funders, and other interested parties to estimate the size and contours of the market for MPTs.

Follow up on these actions may involve a range of activities, including: in-person meetings, small expert working groups convened virtually, commissioned reviews, and technical consultations. The IMPT Secretariat will work with partners to determine the most strategic division of labor so that these activities progress. These next steps are necessarily iterative and will require collaboration among the diverse array of stakeholders in the MPT field. In particular, given the landscape of limited resources and other HIV prevention, funder collaboration is essential. The selection and advancement of MPT products that will have the greatest public health impact relies on investment decisions made based on robust technical and market criteria. This funder commitment will enable the capacity to realize the full impact potential of the MPT concept.

Figure 1: Three-to-Five-Year HIV Prevention + Contraception MPT Pipeline Landscape, by Product Strategy



^ Product concept that is not currently funded.

List of Participants

**via teleconference*

Sharon Achilles*
University of Pittsburgh

Jared Baeten
University of Washington

Diana Blithe
NICHD

Martha Brady
Population Council

Gina Brown
NIH OAR

Alyssa Bruhn
USAID

Cal Bruns
Matchboxology

Anne Burke*
Johns Hopkins Medical Institute

Beatrice Chen*
University of Pittsburgh

Mike Chirenje
University of Zimbabwe

Lee Claypool
USAID

Craig Cohen*
University of California, San Francisco

Jessica Cohen
PATH

George Creasy
Population Council

Mitchell Creinin
University of California, Davis

Íde Cremin
Imperial College

Clint Dart
Health Decisions

Carolyn Deal
NIAID, DAIDS

Laura Dellplain
IMPT

Charles DiLiberti
Montclair Bioequivalence Services, LLC

Emily de Lacy Donaldson
AVAC

Gustavo Doncel
CONRAD

Laneta Dorflinger
FHI 360

Moushira El-Sahn
Routes2Results

David Friend
Evofem

Barbara Friedland*
Population Council

List of Participants continued…

**via teleconference*

Sarah Godfrey
Health Decisions

Peter Godfrey-Faussett
UNAIDS

Alexandra Graham
USAID

Rena Greifinger
PSI

Cynthia Harper
University of California, San Francisco

Anke Hemmerling
IMPT / University of California, San Francisco

Craig Hendrix
Johns Hopkins

Sharon Hillier
University of Pittsburgh

Jonathon Holt
IPM

Daniel Johnston
NICHD

Gregory Kopf
FHI 360

Amy Lin
USAID

Jeffrey Lucas
Routes2Results

Judy Manning
USAID

Carolyn Elizabeth McGrory
IMPT

Ruth Merkatz
Population Council

Tom Moench
Mapp Biopharmaceutical, Inc.

Charu Mullick
FDA

Clemensia Nakabiito
Uganda MTN

Kavita Nanda*
FHI 360

Annalene Nel*
IPM

Everlyne Ombati
IMPT / Kenya Medical Research Institute

Thesla Palanee
Wits Reproductive Health and HIV Institute

Kevin Peine
USAID

Jeanna Piper
NIAID

Chelsea Polis
Guttmacher Institute

List of Participants continued…

**via teleconference*

Dianne Rausch
NIMH

Barbra Richardson
University of Washington

Wilberto Robles
WomanCare Global

Joseph Romano
IMPT

Susan Rosenthal
Columbia University

Elizabeth Russell
USAID

Tanya Scharton-Kersten
Population Council

Hans Spiegel
NIAID

Petrus Steyn*
World Health Organization

Doug Taylor
FHI 360

Vanetta Thomas
IMPT

Andrea Thurman
CONRAD

Betsey Tolley
FHI 360

Jim Turpin
NIAID

Ariane van der Straten
RTI International

Kirsten Vogelsong*
The Bill & Melinda Gates Foundation

Mitchell Warren
AVAC

Mary Weitzel
Yaso Biotechnology, Inc.

Rich Weitzel
Yaso Biotechnology, Inc.

Kevin Whaley
Mapp Biopharmaceutical, Inc.

Bethany Young Holt
IMPT

Sheryl Zwerski
NIAID

Tom Zydowsky
Population Council

List of Acronyms & Abbreviations

AGYW – Adolescent Girls and Young Women
API – Active Pharmaceutical Ingredient
ARV – Antiretroviral
BE – Bioequivalence
BMI – Body Mass Index
CMC – Chemistry, Manufacturing, and Controls
DAIDS – National Institutes of Health – National Institute of Allergy and Infectious Diseases, Division of AIDS
FDA – U.S. Food and Drug Administration
HC – Hormonal Contraceptives / Hormonal Contraception
HIV – Human Immunodeficiency Virus
HSV – Herpes Simplex Virus
IMPT – Initiative for Multipurpose Prevention Technologies
IND – Investigational New Drug
IPM – International Partnership for Microbicides
IVR – Intravaginal Ring
LNG – Levonorgestrel
MPTs – Multipurpose Prevention Technologies
MTN – Microbicide Trials Network
NIAID – National Institutes of Health – National Institute of Allergy and Infectious Diseases
NICHD – *Eunice Kennedy Shriver* National Institute for Child Health & Human Development
NIH – National Institutes of Health
NIH OAR – National Institutes of Health – Office of AIDS Research
NIMH – National Institutes of Health – National Institute of Mental Health
PrEP – Pre-Exposure Prophylaxis
SACC – Supporting Agency Collaboration Committee
STI – Sexually Transmitted Infection
USAID – United States Agency for International Development
USG – U.S. Government
WHO – World Health Organization