AVAC
Advocacy. Access. Equity.

Advocates' Guide to Multipurpose Prevention Technologies (MPTs)

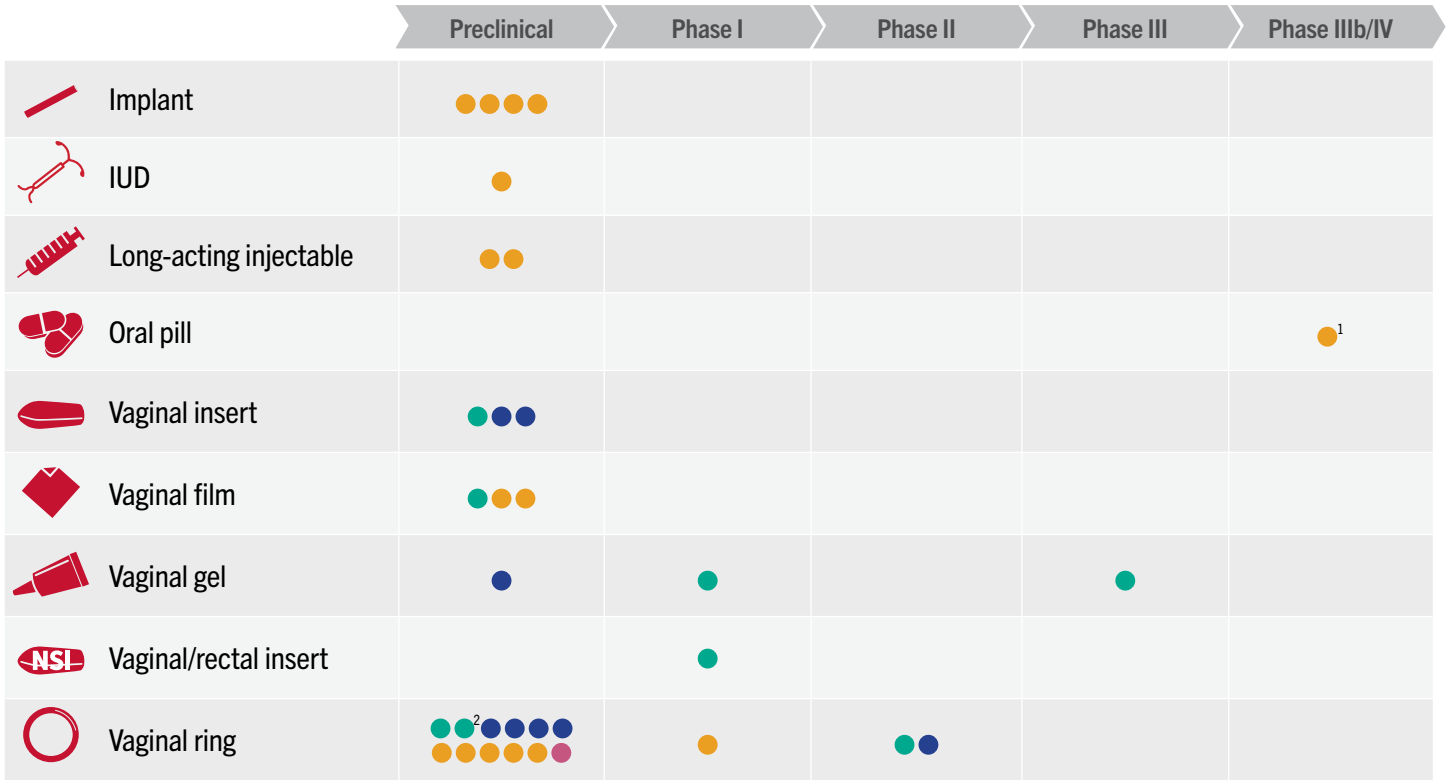
What are MPTs?

Multipurpose prevention technologies (MPTs) are products designed to simultaneously address more than one sexual and reproductive health (SRH) concern. Condoms—which protect against pregnancy, HIV and other sexually transmitted infections (STIs)—are the only MPTs currently available. Many others are in development, and there are several examples of products used for multiple purposes outside of SRH.

Several MPTs are being developed as co-formulations (multiple drugs combined into one product) or co-packaged products (two products administered together). MPT products in development include oral pills, vaginal rings, vaginal/rectal

AT A GLANCE: THE MPT R&D PIPELINE

Status of products in development



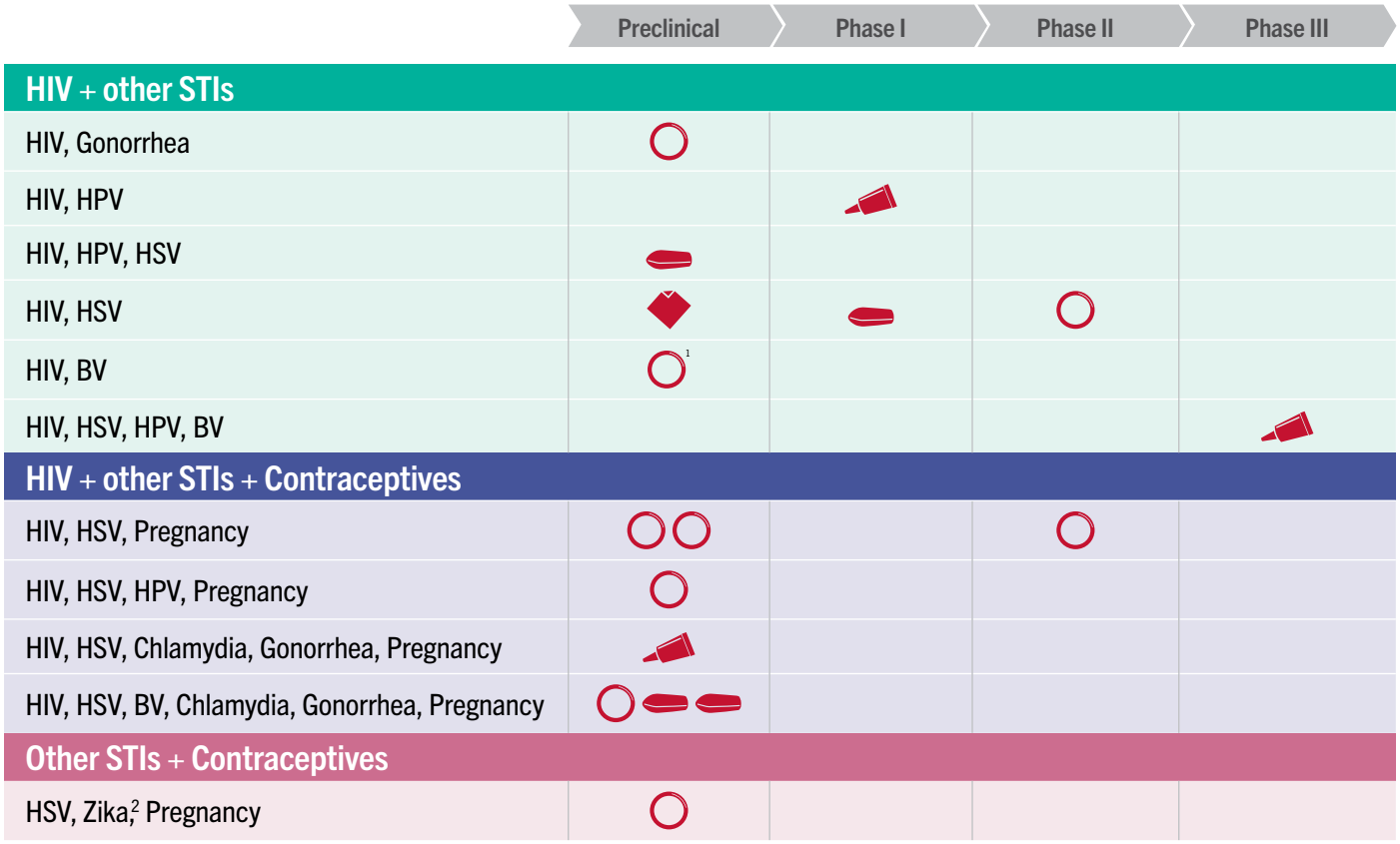
HIV + Contraception	HIV + other STIs	HIV + other STIs + Contraception	Contraception + other STIs
16	8	1	1

[1] The dual pill product is going through bioequivalence studies in lieu of clinical trials because the drug components are already approved separately, but not in combination. Therefore, it does not follow the traditional R&D pathway.

[2] This product addresses both HIV and Bacterial vaginosis (BV). BV is not sexually transmitted but can be linked to sexual activity. While BV is not an STI, it has been included here for simplicity.

Adapted from: *The Initiative for MPTs (IMPT) Product Development Database; Treatment Action Group (TAG) 2023 Pipeline Report; MATRIX R&D Landscape Review 2024.*

SPOTLIGHT ON MPTs ADDRESSING STIs



HIV + other STIs + Contraception	HIV + other STIs	Contraception + other STIs
8	8	1

[1] Bacterial vaginosis (BV) is not sexually transmitted but can be linked to sexual activity. While BV is not an STI, it has been included here for consistency.

[2] The Zika virus can be transmitted through sexual contact and lead to pregnancy complications and congenital defects. It is included here for its adverse effects on sexual and reproductive health.

For more information about STI trials, please visit stiwatch.org

Adapted from: *The Initiative for MPTs (IMPT) Product Development Database; Treatment Action Group (TAG) 2023 Pipeline Report; MATRIX R&D Landscape Review 2024.*

inserts, gels, films, implants, injectables and intrauterine devices (IUDs). MPT products in development are also addressing a diverse set of STIs—including gonorrhea, herpes simplex virus (HSV-1 and HSV-2), human papillomavirus (HPV), and chlamydia. While most MPTs use hormonal contraceptives, there are also non-hormonal MPTs in development in response to growing demand.

Moving products through product development is complex for MPTs; the process may differ depending on if the MPT is combining already approved drugs or developing new drugs. When developing new drugs, it can take 10 years to move from pre-clinical to Phase 3, and not all products will make it through the pipeline. While few options are currently in late-stage development, early-stage research and development still gives hope to future availability of diverse MPTs.

Why are MPTs needed?

MPTs have the potential to simplify service delivery and use of prevention products for all populations.

For decades, cisgender women, especially young cisgender women (under 25 years), have asked for discreet products they can control and that address multiple SRH needs, such as pregnancy and HIV prevention combined in a single product,

underscoring the urgency for women-centered options. Underrepresentation of cisgender women in clinical trials is well-documented, and only now are women learning from research on dosing regimens (recent and comprehensive research indicates 4-6 doses/week is protective) for oral pre-exposure prophylaxis (PrEP) despite the introduction of oral PrEP over a decade ago (Marrazzo et al, JAMA, 2024).

From the earliest days of microbicide research, women's health advocates have been the drivers of women-centered, SRH products. More recently, the African Women's HIV Prevention Community Accountability Board (AWPCAB)'s ***HIV Prevention Choice Manifesto***, demonstrates the power and impact of community-led leadership for choice. Advocacy groups such as the Coalition to Accelerate & Support Prevention Research (CASPR), Coalition to build Momentum, Power, Activism, Strategy & Solidarity (COMPASS) Africa, Dual Prevention Pill Civil Society Advisory Group and more are crucial to mobilize resources and broad support through all stages of R&D and to ensure access to products as they become available.

Gay, bisexual, and other men who have sex with men (GBMSM) and transgender individuals have also advocated for products that simultaneously prevent multiple STIs, including HIV. While the number of MPT products for cisgender women has increased, the same trend is not reflected for other populations. It remains critical for MPT R&D to be inclusive of all gender minorities so that no population is left behind. With many forms of ARV-based prevention (PrEP) now on the market, from pills to rings and injectables, there are new opportunities to develop MPTs in various forms. Effective, affordable and widely accessible MPTs would save lives and money, improving the health of communities around the globe and providing additional convenient options.

What should advocates be watching closely in the MPT space?

- **A Dual Prevention Pill is in advanced development.** As oral PrEP continues to scale up, a Dual Prevention Pill (DPP) that combines oral PrEP and combined oral contraception could be a familiar and desirable choice for women seeking an option that will meet multiple SRH needs. The DPP is the MPT closest to market and the first-ever with PrEP. It could be available by late 2025, pending regulatory approval (see *At a Glance* graphic above). Because the DPP combines two products previously approved by regulators and with no drug-drug interactions, regulators will rely on bioequivalence of this combined product, since safety and efficacy are already established, shortening the time from research to rollout.

  A *Market Preparation and Introduction Strategy* is guiding plans around how, where and to whom the DPP is introduced, with Kenya, South Africa, and Zimbabwe as initial focus countries. Advocacy must ensure that the rollout of the DPP focuses efforts where HIV incidence among cisgender women and unintended pregnancies are high. Importantly, lessons from the DPP will lay the groundwork for other MPTs in the pipeline. Using other licensed HIV prevention products to develop new MPTs will also be critical. For more information on the DPP, see https://www.prepwatch.org/products/dual-prevention-pill/.

- **What's next for the Dapivirine Vaginal Ring, and why it matters.** As of May 2024, national regulatory authorities in eleven African countries have approved the DVR, with other approvals pending. In 2022, the Population Council announced an agreement with the International Partnership for Microbicides (IPM), developer of the DVR, to purchase technology for the monthly DVR alongside two other rings in development—the three-month DVR and three-month dapivirine-levonorgestrel MPT ring. In 2023, Population Council signed a Memorandum of Understanding with South Africa-based Kiara Health to eventually manufacture the DVR with the goal of reducing cost and accelerating access.

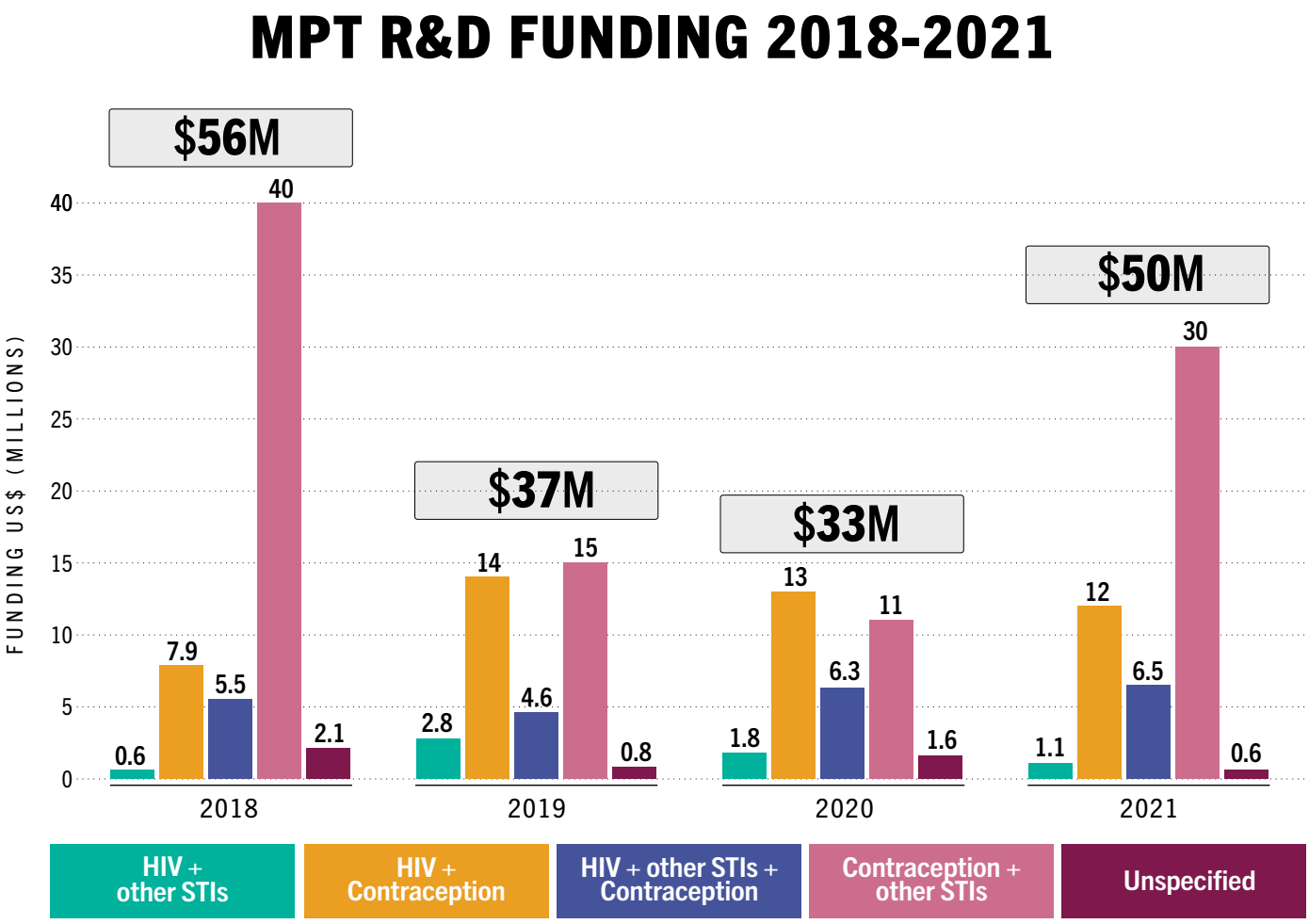
  Successful introduction of the DVR can pave the way for the three-month dapivirine-levonorgestrel ring and other ring-based MPTs to move forward. Implementation studies, such as the CATALYST study, are playing a pivotal role in introducing the ring, and women—especially young women and former trial participants—can influence rollout plans in implementation studies. At country level, advocates can apply pressure to secure resources and build political

commitment for the DVR. Successful advocacy campaigns, specifically in domestic financing, PEPFAR COPs and Global Fund proposals, can be adapted and leveraged to accelerate access to the ring and future ring-based MPTs.

- **The MATRIX project is investing in early-stage development of MPTs for cisgender women.** MATRIX is a USAID-funded project working to develop a portfolio of products for cisgender women at risk of HIV, including three MPTs. These include a monthly non-antiretroviral (ARV)/non-hormonal dual-purpose vaginal ring and a monthly dapivirine-levonorgestrel vaginal film—both for the prevention of HIV and pregnancy. The project is also developing a fast-dissolving insert containing tenofovir alafenamide and elvitegravir (TAF/EVG) for the prevention of HIV and herpes simplex virus (HSV) that can be used on-demand (at the time of sex) and inserted vaginally or rectally. All of these products are women-controlled and designed with input from early consultations with communities. It remains to be seen which of these, if any, will make it to market given they are still in early R&D, but dedicated funding for their development should signal that MPTs are a growing donor priority and demonstrates potential to expand the suite of MPT options for cisgender women. For additional detailed information on these and other products, refer to The Future of ARV-Based Prevention and More.

What is the status of MPT investment?

Based on data from the 2023 Policy Cures Research Sexual and Reproductive Health G-FINDER Report: *Beyond Spillovers*, global funding for MPT product development totaled $176 million over the last four years, with a significant recovery in 2021 to $50 million from a low of $33 million in 2020. The



Based on data provided by the 2023 Policy Cures Research Sexual and Reproductive Health G-FINDER Report: Beyond Spillovers

fluctuations in MPT funding have been largely driven by industry investments, particularly for MPTs that provide dual protection against pregnancy and non-HIV STIs. MPTs that offer dual protection against pregnancy and HIV received $47 million (27%) of the total funding. Contraceptive MPTs have consistently received the majority of MPT funding (90%). However, non-contraceptive MPTs designed to protect against both HIV and other STIs simultaneously received less than 5% of the funding, highlighting a significant disparity in investment.

What can advocates do to push for MPT development and introduction?

*A robust MPT R&D pipeline is crucial, as not all products will make it to later phase clinical trials. Advocates can influence the **research agenda**:*

1 Demand people-centered research agendas. MPTs are more likely to be utilized by the people who need them when their preferences, pleasure, environment, beliefs, needs, and motivations are solicited and incorporated into the product research and development phase. For example, input from women on product cost, shape, size, color and other attributes can increase uptake of future products. Pushing researchers to meaningfully engage communities at all stages of the R&D process will provide an opportunity for advocates to influence early-stage MPT research.

ACTION Ask researchers for detailed plans on how user perspectives are being included as part of the research process, and especially in the design. Researchers must make community engagement plans widely available and articulate how they are engaging at site-level, as well as with advocates and CSOs, even if products are in early phases of research. Social and behavioral research must be funded and conducted with equal importance to ensure that products are developed with individuals' behaviors and preferences in mind. Research literacy must be integrated into engagement processes to ensure stakeholders have a nuanced understanding of the research process.

2 Ensure a diverse pipeline of MPTs to meet diverse health needs. Often, MPTs are thought of as methods that prevent HIV and pregnancy for cisgender women. But there are also MPTs in the pipeline that can be used to prevent HIV and other STIs among people who engage in vaginal and/or anal sex but do not need or desire to prevent pregnancy, who are already pregnant, or are post-menopausal. These options are critical given the persistently high rates of HIV and other STIs observed in clinical trials across diverse settings and populations, including among cisgender women, GBMSM and transgender men and women. *No Data No More: Manifesto to Align HIV Prevention Research with Trans and Gender Diverse Realities* offers practical and essential considerations for the inclusion of transgender and gender diverse populations in MPT R&D, and R&D broadly.

ACTION Advocates should continue to press for resources to support a diverse pipeline of interventions—including vaginal and rectal products—that prevent HIV, other STIs and pregnancy to meet the needs of all individuals and that the communities for whom those products are for are included in the engagement process.

3 Push for research and implementation targets to support MPTs. In the HIV response, global targets have neglected research. Targets must promote diverse product choices and support the development and introduction of new MPT products. These targets should be specific and time-bound (e.g., one new dual-prevention product introduced in at least three countries within 12 months of licensure; 3% increase in MPT R&D investment by the largest FP, HIV and STI research institutions by 2025).

ACTION Urge the WHO, FP2030, UNFPA and UNAIDS to introduce targets for moving products through trials and into programs. Advocates can use these targets to hold national and local governments accountable. Advocates can utilize research engagement platforms such as NIAID's open calls or 'Requests for Information' to share community perspectives on MPT R&D and influence research targets.

*A pathway for MPT introduction requires integrated systems that will support **equitable access**:*

4 Integration of HIV and SRH services is essential for the delivery of MPTs in the future. MPTs that address contraception, HIV and other STIs will be delivered most effectively where services are integrated, allowing for a more person-centered and holistic approach when discussing prevention options, as integration will streamlininge care for people seeking multiple services. Providers can be trained in FP, HIV and STI counseling and service provision (including testing and initiation of new products) so that users understand the range of SRH options offered and make informed decisions about their method choice. Services can quickly incorporate MPTs when they become available.

The World Health Organization (WHO)/UNAIDS provide a policy brief that outlines approaches to integrating services and implementing MPTs. Implementers and advocates should prioritize approaches to integration that include behavioral and structural interventions (e.g., policy reform, community norms-changing, economic empowerment, addressing gender-based violence) to reach those with multiple prevention needs. Universal Health Coverage (UHC) policies and programs are currently being defined at the country level; these discussions provide a pivotal platform to elevate SRH integration within UHC. With the introduction of new MPTs on the horizon, the time to integrate services is now.

ACTION Advocate to scale up programs that integrate FP, HIV and other STI services, pushing Ministries of Health, funders and program implementers to prioritize and fund models of integration that will address the immediate needs of the population and support future MPT introduction and access. Engage with country-level mechanisms (like UHC planning and technical working groups) and donor funding processes (like the PEPFAR Country Operational Plan process and Global Fund funding requests) to demand sufficient funding to drive impact. The SRH Integration Advocacy Roadmap, released July 2024, provides a practical guide for advocates focused on SRH integration.

5 Health systems must adapt to provide a pathway for MPTs, starting with the DPP. Siloed HIV and SRH systems are a barrier to the swift introduction of MPTs. Donors may need to reconfigure funding streams and procurement agencies may need to update their supply chain processes to incorporate MPTs. Regulatory agencies will need to define the evidence requirements for approval of MPTs, which may be a new category of products as they cut across multiple health areas. While regulatory review of an MPT like the DPP may be more straightforward since it combines two approved products, MPTs using new drugs and/or delivery forms are likely to be more complicated and regulatory pathways for different MPT types will need to be defined. Addressing these health systems issues will be needed to roll out the DPP in the near-term. Once in place, they will offer a clear, accelerated path to rollout of future MPTs.

ACTION Convene consultations with funders, procurers and regulators to ensure they are working towards enacting changes that would facilitate and not slow down MPT introduction. Raise awareness on the imminent rollout of the DPP among these stakeholders to build support for adaptations to ease approval and launch of MPTs in the future. Ally with partners to navigate the complex regulatory environment and push for clear pathways for approval and rollout.

More information on MPTs is available at www.avac.org/mpt. For additional resources and background on the MPT pipeline, please refer to www.avac.org/mpt-factsheet and The Initiative for MPTs (IMPT) at theimpt.org.

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AVAC is a non-profit organization that uses education, policy analysis, advocacy and a network of global collaborations to accelerate the ethical development and global delivery of new HIV prevention options as part of a comprehensive response to the pandemic.