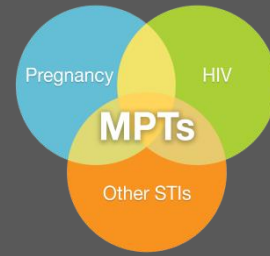




Comprehensive Sexual & Reproductive Health Prevention: The Promise of MPTs

Bethany Young Holt, PhD MPH
Director, Initiative for MPTs [IMPT]

Women's Sexual & Reproductive Health Risks are Interlinked



Unintended Pregnancy

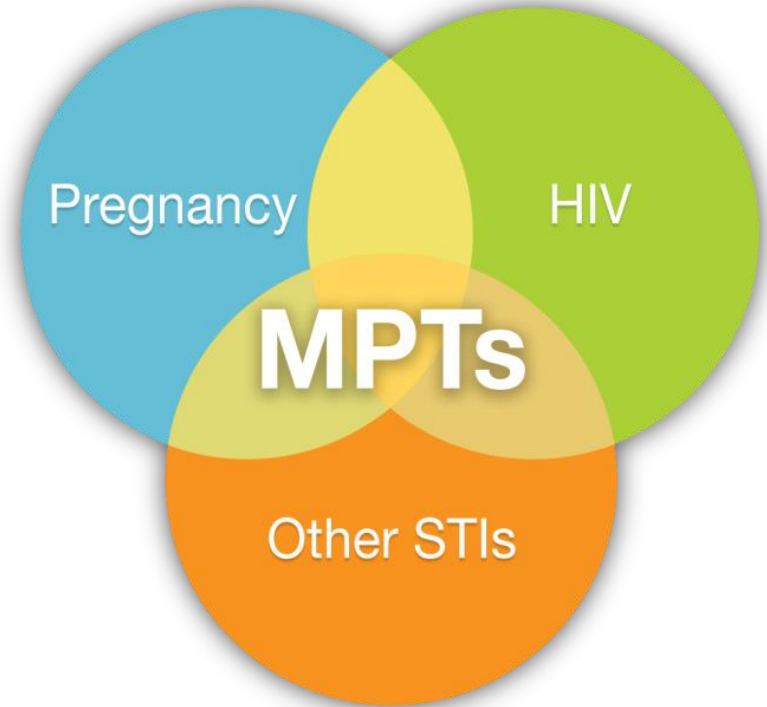
HIV

Other Sexually Transmitted Infections (STIs)

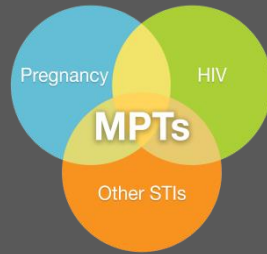
Multipurpose Prevention Technologies

MPTs combine protection against:

- **Unintended pregnancy**
- **HIV**
- **Other STIs**



Health & Social Impact of MPTs



**Women's
Health**



SDG 3 & 5



**Child & Family
Health**



SDG 3 & 5



**Educational
Attainment**



SDG 4 & 5

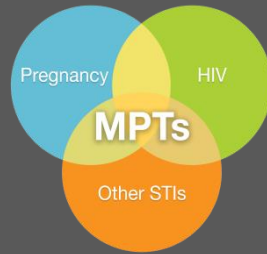


**Employment &
Economic Benefits**



SDG 1, 5 & 8

According to Market Research



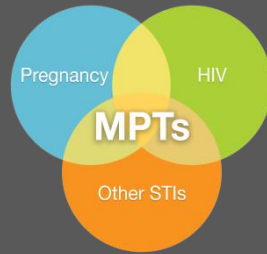
93%

of women want
an MPT



- 4% HIV only
- 2% Pregnancy only

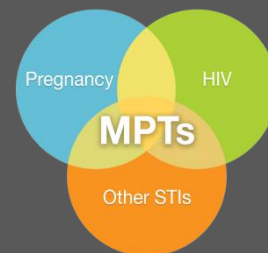
MPTs in the R&D Pipeline



- ❑ Vaginal rings
- ❑ Innovative vaginal delivery products
- ❑ New condom designs
- ❑ Injectables and implant technologies
- ❑ Other novel technologies and platforms



Options for MPTs



Co-formulated:



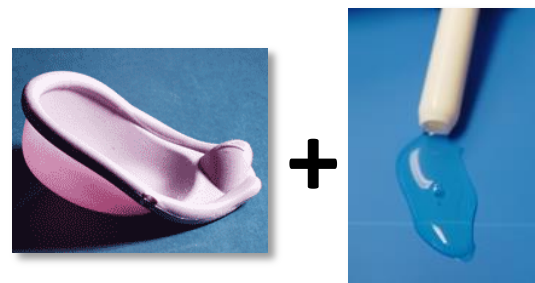
Multiple API formulated into a single dose



Co-administered:



Two independent products used together



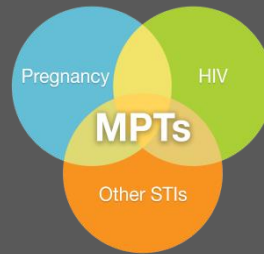
Co-packaged:



Two different doses packaged together in a single product for simultaneous co-use



A Suite of Products is Needed



Contraception
+ HIV & STI Prevention

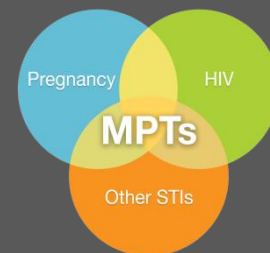
Contraception
+ HIV Prevention

Contraception
+ STI Prevention

HIV
+ STI Prevention



MPTs in Clinical Trials

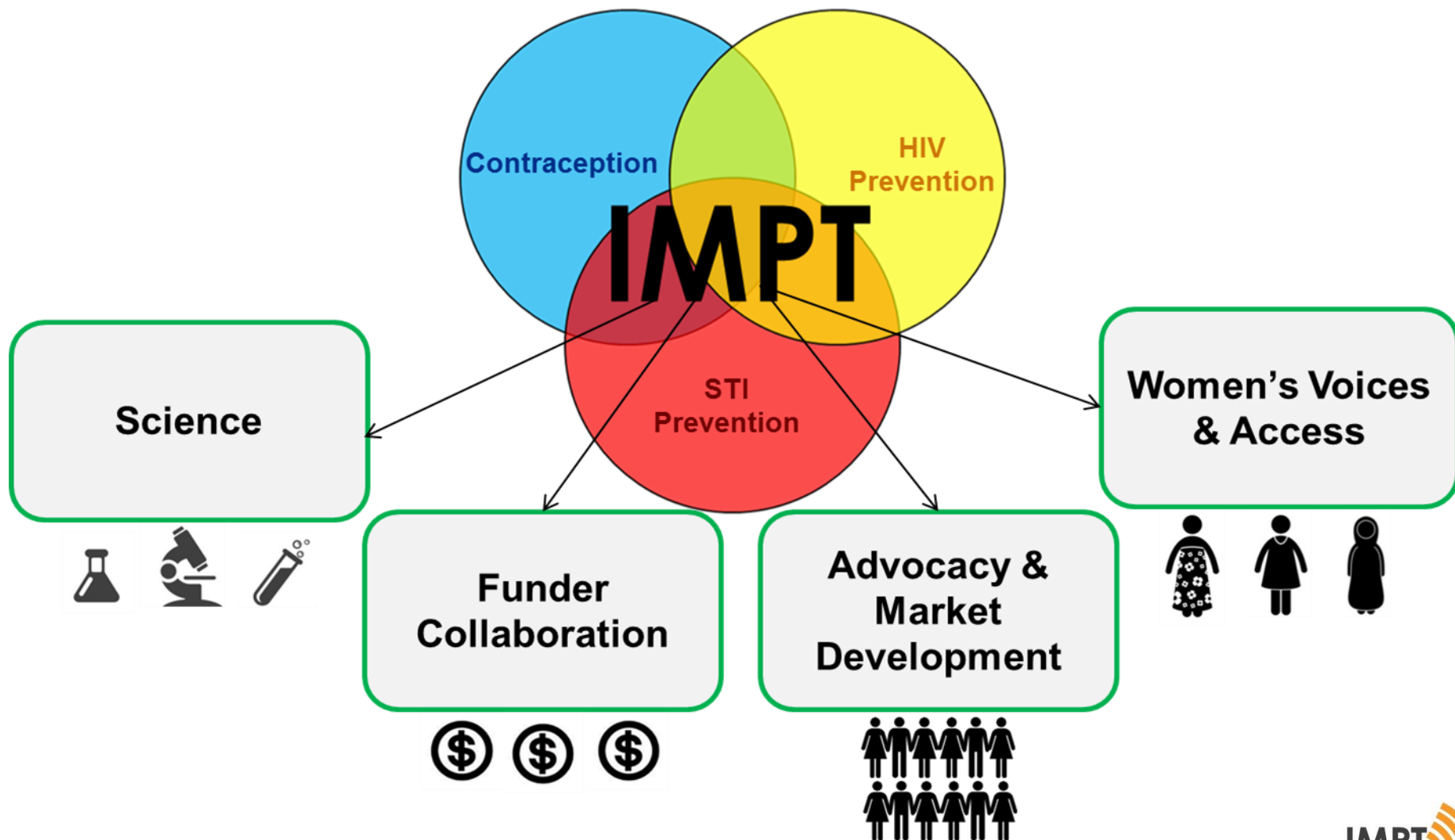
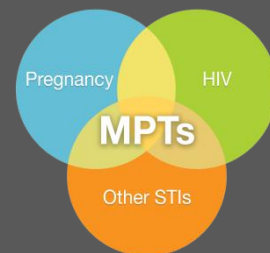


HIV + Other STIs	
1.0% Tenofovir Vaginal Gel	Phase III
mapp66 (mAb) Vaginal Film	Phase I
MIV-150 + Zinc acetate + Carrageenan Vaginal Gel	Phase I
Tenofovir + Acyclovir Intravaginal Ring	Phase I
Tenofovir Disoproxil Fumerate Intravaginal Ring	Phase I
Tenofovir Vaginal Film	Phase I
Tenofovir Intravaginal	Phase I
Tenofovir Vaginal Tablet	Phase I
TFV/FTC Vaginal Tablet	Phase I
Pregnancy, HIV & Other STIs	
Origami Female Condom	Phase III
Tenofovir + Levonorgestrel Intravaginal Ring	Phase I
Pregnancy & Non-HIV STIs	
Amphora Gel	Phase I

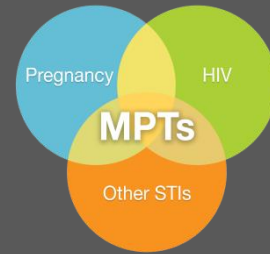
Plus products in preclinical development for:

- **HIV + Pregnancy**
- **HIV + Other STIs**
- **Pregnancy, HIV & Other STIs**
- **Pregnancy + Non-HIV STIs**

Initiative for MPTs



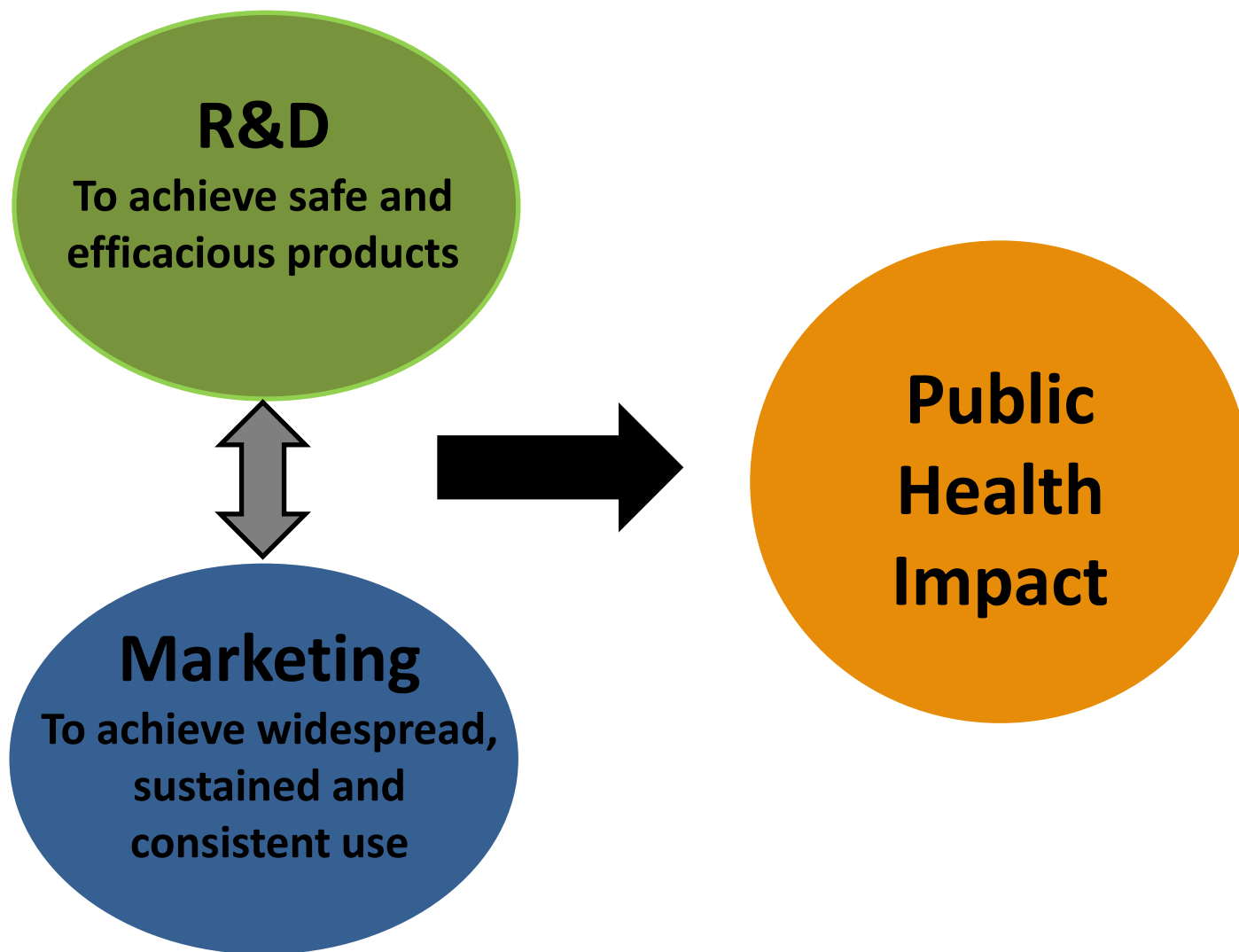
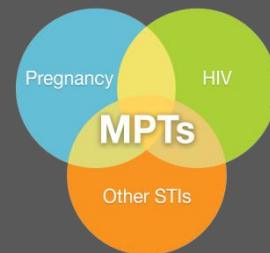
Leading the IMPT & Field



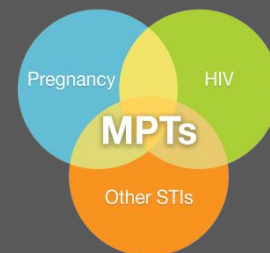
Steering Committee & MPT Supporting Agency Collaboration Committee

- ❑ Association for Reproductive Health Professionals
- ❑ Bill & Melinda Gates Foundation
- ❑ Department for International Development (DFID)
- ❑ Guttmacher Institute
- ❑ Indian Council for Medical Research
- ❑ Kenya Medical Research Institute
- ❑ Mary Wohlford Foundation
- ❑ Nanjing University
- ❑ National Institutes of Health
- ❑ PATH
- ❑ Population Council
- ❑ University of California, San Francisco
- ❑ U.S. Agency for International Development (USAID)
- ❑ The Wellcome Trust
- ❑ World Health Organization
- ❑ Wits Reproductive Health Institute

IMPT Strategic Approach: Market access in tandem with MPT R&D



IMPT builds the field



R&D: Science & Technical Aspects of MPT Development

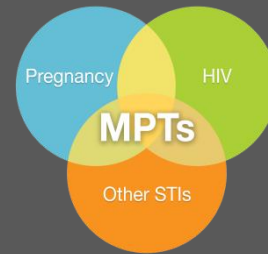
Scientific Feasibility
Product Prioritization & Gap Analysis
Dosage Form Specific TPPs
MPT Pipeline Database

Marketing: Social-behavioral & Market Access

Market Access Framework
Market Research
Impact Modeling
Communications and Advocacy among key stakeholder groups

Delivery & Distribution

MPT product strategies



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www.bjog.org

Commentary

The future of multipurpose prevention technology product strategies: understanding the market in parallel with product development

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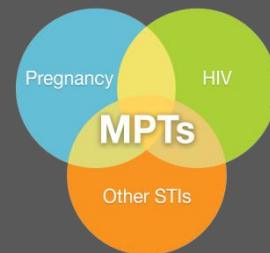
Accepted 26 March 2014.

Please cite this paper as: Romano JW, Van Damme L, Hillier S. The future of multipurpose prevention technology product strategies: understanding the market in parallel with product development. BJOG 2014; 121 (Suppl. 5): 15–18.

The development of multipurpose prevention technology (MPT) products for combined protection against sexually transmitted infections (STIs), including HIV, and unintended pregnancy is a priority. MPTs have a number of

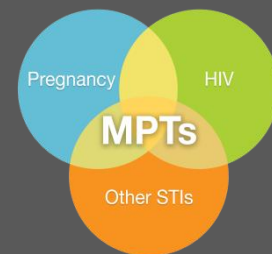
produce and deliver to the end user than separate products for each indication. Even with the risk of a higher cost of goods for an MPT relative to single-indication products, the cost benefit of an MPT could still be realised because

IMPT Priority Areas: R&D



- 1) Understand **hormonal contraceptive (HC)** knowledge gaps in the context of MPT development.
- 2) Assess challenges and other issues related to MPT **clinical trial design**.
- 3) Develop a process for achieving a more robust product development pathway for **non-HIV STI MPTs**.

R&D Moving Forward



Scientific meetings to address priority areas and gaps in the field

- Hormonal contraception and MPTs
- MPT Regulatory Challenges
- Manufacturing & CMC

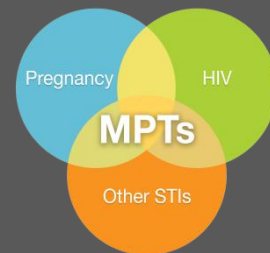


Implementation of task force activities



Strategic coordination of the MPT field

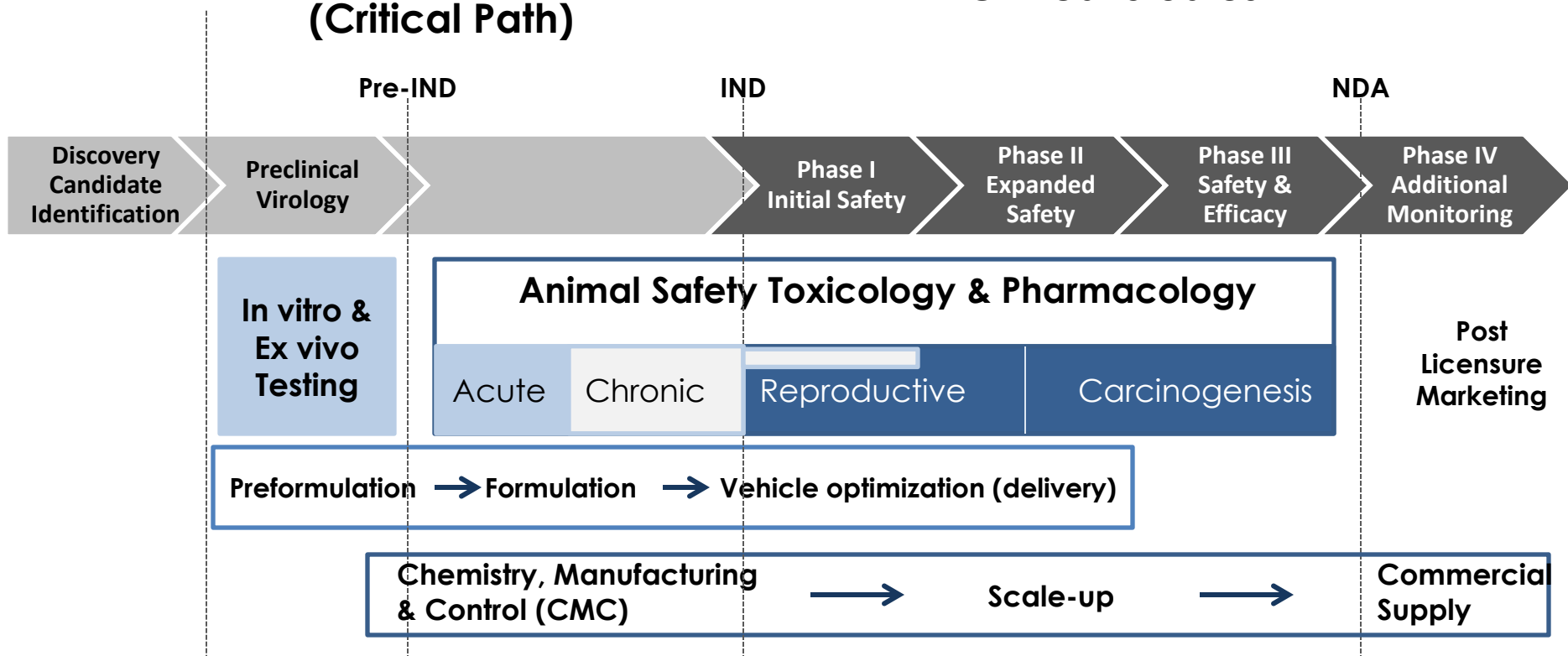
IMPT Priority Areas: Marketing



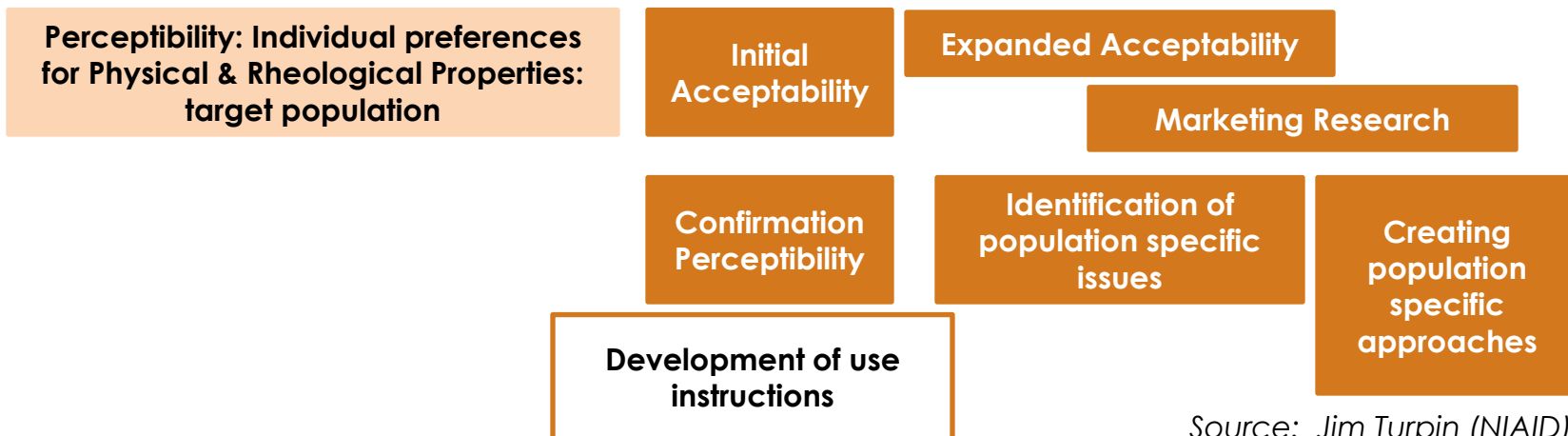
- 1) Assess the gaps in **social-behavioral knowledge for MPT development and MPT commercialization** potential.
- 2) Engage **modeling** efforts to robustly assess public health impact and cost effectiveness of MPT product options in specific target populations.

Preclinical Studies (Critical Path)

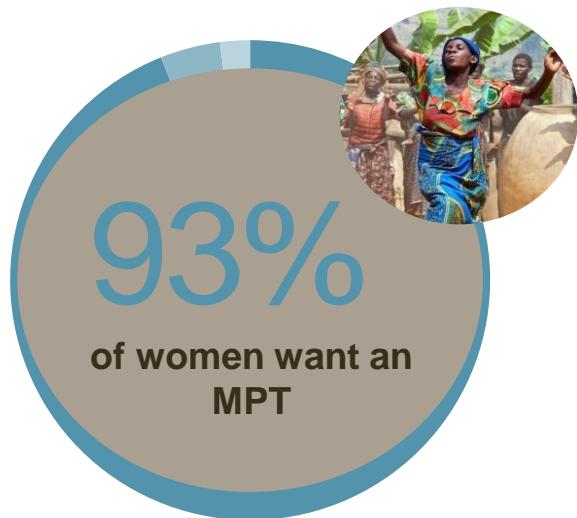
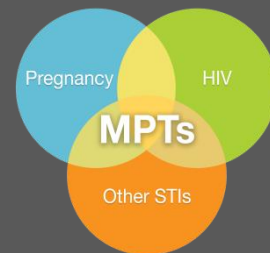
Clinical Studies



Market Factors

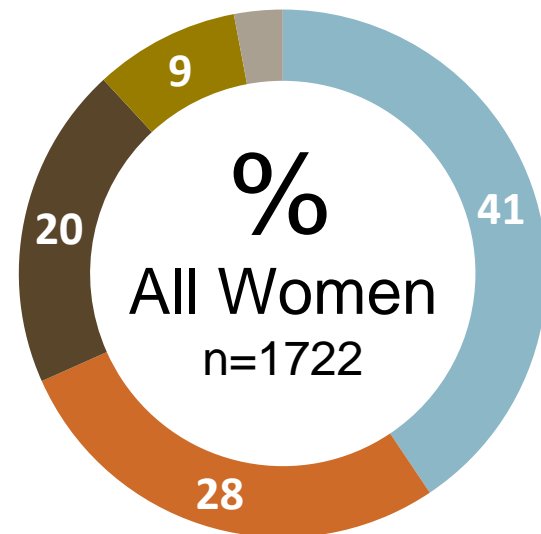
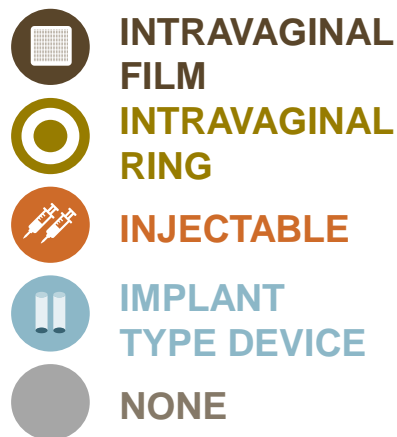


According to Market Research

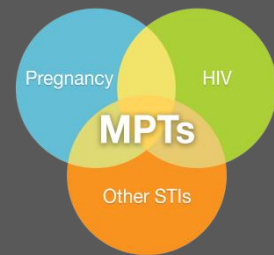


- 4% HIV only
- 2% Pregnancy only

What would women pick if all 4 MPTs were available to them today?



Marketing: Moving Forward



Assessment of end-user and provider preferences and acceptability issues in priority regions



Modeling public health impact of potential indication combinations among target populations

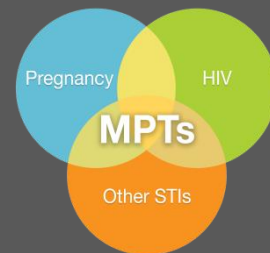


Addressing other critical market issues



Strategic coordination of the MPT field

Women need better prevention



- ❑ The promise of MPTs is great
- ❑ The IMPT has fortified the MPT field
- ❑ Continued field-wide guidance and collaboration will be necessary to see impactful MPT products



“

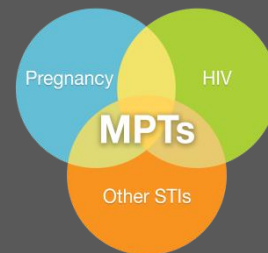
Against the backdrop of the Sustainable Development Goals, the need for improved, affordable and more ‘fit for purpose’ reproductive health technologies has been highlighted.

-- Helen Rees



Learn more at www.theMPT.org

Join the IMPT Network of Experts (NoE) at <http://mpts101.org/membership>





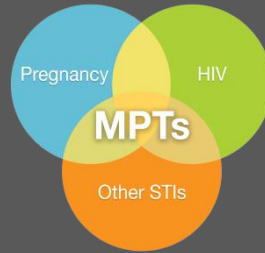
Thank You!



The Initiative for Multipurpose Prevention Technologies (IMPT) is a project of CAMI Health, an organization dedicated women's reproductive health and empowerment.



Co-packaging



Truvada



COC



Co-packaged
(mock example)

Development Requirements:

- 1) Demonstration of technical feasibility (stability)
- 2) End user informed packaging design and acceptability