
2013 Annual Meeting

Rockville, MD

# Prioritization and Gap Analysis for Multipurpose Prevention Technologies

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# What is a multipurpose prevention technology (MPT)?

A single product, configured for at least two SRH prevention indications:

1. Pregnancy, STI, and/or HIV

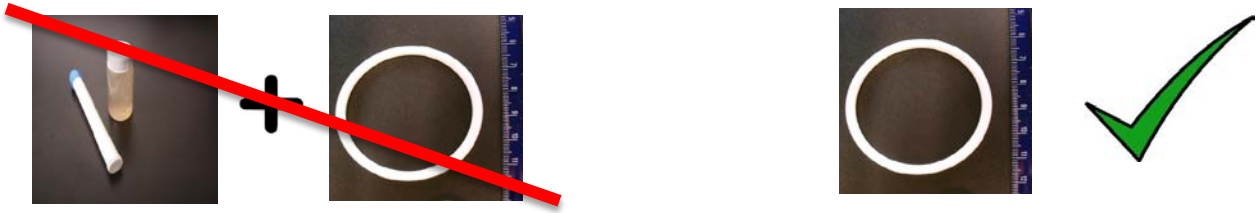


Alternative configurations:

1. Drug:Drug
2. Drug:Device
3. Vaccine

# Why Multipurpose Prevention Technologies?

- Greater efficiency in terms of cost, access and delivery of SRH prevention products



- Capitalize on the demand in populations using one product type to achieve uptake and use of a second "product"

Contraception

Contraception
HIV Prevention

# Some History of the MPT Movement

**The Players:**

1. **IMPT:** Initiative for Multipurpose Prevention Technologies
2. **CAMI:** Secretariat for the IMPT
3. **USAID:** Primary funder for the IMPT at CAMI
4. **SAWG:** Scientific Agenda Working Group of the IMPT

**The Activities:**

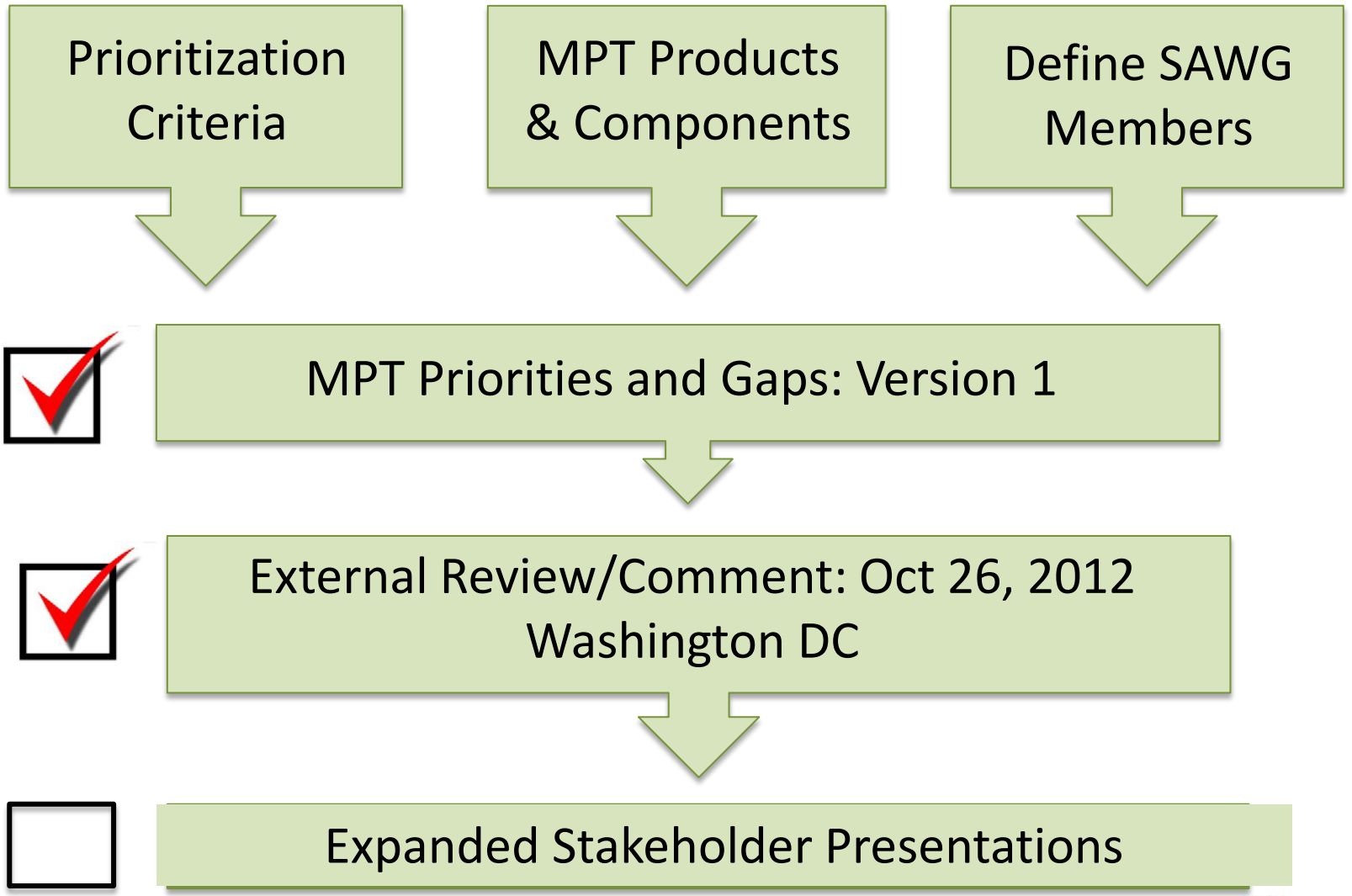
1. MPT Think Tank, Washington DC, May 2011
2. MPT TPP Exercise: Washington DC, Nov 2011
3. MPT TPP Review: London, UK, Jan 2012
4. MPT Pipeline Prioritization/Gap Analysis: Ongoing from mid 2012

# MPT Pipeline Prioritization and Gap Analysis (SAWG)

## Goal:

To provide an objective basis for coordinated donor investment and developer collaboration in the advancement of development of MPT products with the highest public health impact potential

# Prioritization and Gap Analysis Process






CAMI
COALITION ADVANCING MULTIPURPOSE INNOVATIONS

# SAWG Members

| Coordinating Committee | |
|---|---|
| J. Romano (Chair), NWJ Group | B. Young Holt, CAMI |
| A. Hemmerling, UCSF | P. Harrison, AVAC |

| Donor Representatives | Regional Representatives |
|---|---|
| D. Blithe, NICHD | N. Chandhiok, ICMR (India) |
| G. Brown, OAR | H. Rees, U. Wits (SA) |
| C. Deal, NIAID/DMID | A. Wu, Nanjing Univ. (China) |
| S. Kinn, DFID | |
| J. Manning, USAID | |
| J. Turpin, NIAID/DAIDS | |
| S. Ward, BMGF | |

# Prioritization Criteria: MPT TPP, Other

| Critical Attributes Considered: | |
|---|---|
| Indications | Target Population |
| Efficacy | Adherence |
| Route of Administration | Dosage Form & Schedule |
| Side Effects | Storage Conditions |
| Reversibility | Other Health Benefits |
| Contra-indications & precautions | Use by preg./lactating women |
| Product Provision (Rx vs. OTC vs. ?) | Acceptability Measures |
| Shelf Life | Medical Support |
| Time to Market | COG/Total Cost |
| Product Presentation | Packaging |
| IP Status | Disposal/Waste |
| R&D Costs | Development Entity |

## Priority Indications:

1. HIV and Pregnancy

1. HIV and STI
   - HSV, HPV, BV

2. STI and Pregnancy

# MPT Products/Components Identified During the Prioritization Exercise

| | | |
|---|---|---|
| 10 MPT IVR | 10 Single Indication IVR | 31 HIV Entry Inhibitors |
| 3 On-Demand MPT | 12 On-Demand HIV Only | 11 Enzyme Inhibitors |
| 2 Barrier MPT | 2 Injectable HIV Only | 7 Other HIV Inhibitors |
| 23 HC products | 2 Lacto-based Products | 29 non-HC products |

**Outside the SAWG Scope:**

- Study-section type review of specific MPT products or component products and technologies
- Recommendations on funding for specific products or technologies

# MPT Pipeline Prioritization and Gap Analysis Summary

# MPT Priorities and Gaps: API

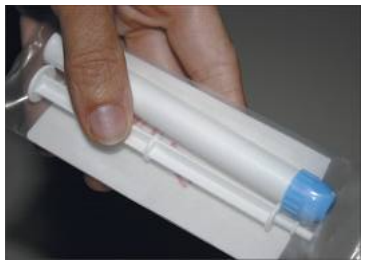
| Indication | Priority/Comments |
|---|---|
| HIV Prevention | **Small organic molecule ARV: Potency & Data**<br>-Approved drugs over earlier stage ARV<br>- Consideration of resistance potential<br>-Focus on alternatives to RTI (e.g., TNF) ***GAP***<br>-rProtein/peptides: many options; high cost & risk |
| Pregnancy | **Hormone Based: Proven efficacy, wide use**<br>-LNG lead (?); Others to be studied<br>-HC not prioritized for on demand use- Cycle Effects<br>-Potential risk of HIV with specific HC use ***GAP***<br>-non HC options very early stage ***GAP*** |
| STI Prevention | **Alternatives to broadly neutralizing API**<br>-Minimal number of viable options ***GAP***<br>-Rapid resistance selection with anti HSV drugs |

# MPT Priorities and Gaps: Dosage Forms

1. Sustained Release:
   – I.e., Vaginal Rings

2. Long Acting Injectable

3. On-Demand (pericoital)



**GOAL: An MPT of each type for each of the prioritized combination indications**

# Priority Dosage Forms: Comments & Issues

## IVR:

1. Multiple IVR with minor differences in development
   a. Priority: Achieve single P3 lead
   b. Priority: Mitigate risk of current focus on RTI
2. Insufficient data on IVR acceptability and demand
   a. Priority: Objectively quantify both
   b. Address IVR w/ HC use (menses)
3. Robustness and reliability of raw material supply chain
4. IVR polymer compatibility with API limitations
5. Limited number of CMO options

# Priority Dosage Forms: Comments & Issues

**Long Acting Injectable:**

1. Co-administration is an acceptable option
2. Equity in duration of effect required
3. Limited area of development: Additional ARV options required
4. Dosage form management:
    a. Necessity of oral run-in?
    b. Addressing long duration drug level "tail"

**On Demand:**

1. Multiple on demand formulations of same API combo not feasible
2. STI and contraception options limited (HC seen as problematic)
3. **Adherence**: Correct and consistent use? True acceptability?
4. Safety and effectiveness of intermittent ARV use

# Other MPT Priorities, Gaps and Comments

**Regulatory:**

1. Engage regulators early; Familiarity at local regulatory level
2. "Bridging" dosage forms via BE studies: Potential challenges

**Social/Behavior:**

1. Critical to study MPT in adolescent populations
2. MPT needs and issues will differ regionally

**Access and Delivery:**

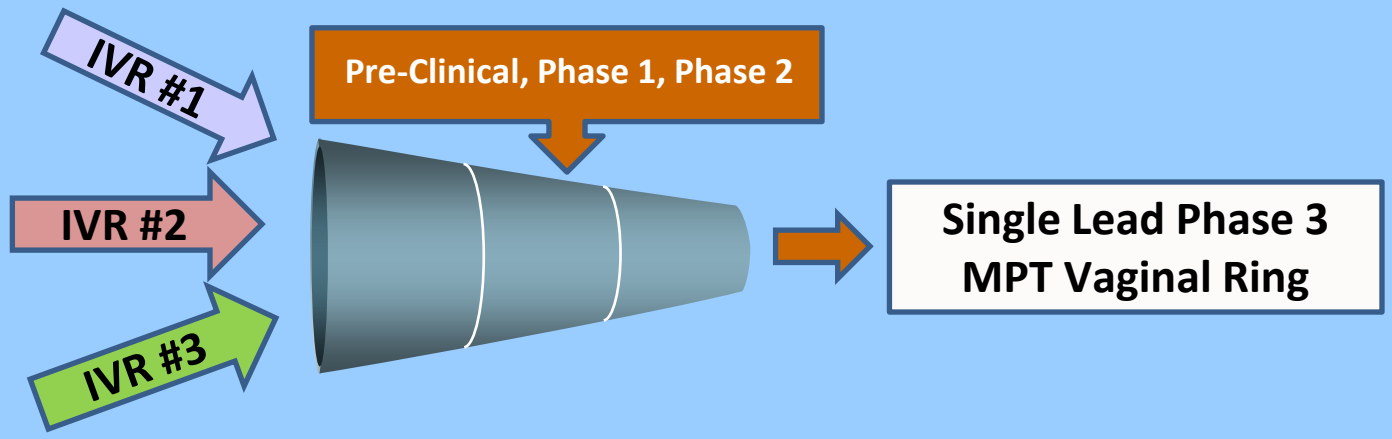
1. Proof of demand (**not need**) early in development
2. Accurate and relevant forecasting
3. Policies and practices of the procuring entity
4. Manufacturability and automation
5. Supply chain (raw materials, finished product)
6. Delivery channels (**last mile!**)
7. Partnering options

# Final Consensus Priorities and Thoughts:

1. Coordinated donor investment based on common priorities and objectives will be required

2. Single, best in class leads must be identified for P3

Example:




3. Pooling of capacity, capability, expertise, and other resources between viable development entities interested in MPT products

- *Needs of the MPT field supersede individual organizational needs*

# Thank You!

## 1:00-3:00 MPT Follow Up Discussion Session



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