Aligning Investments in R&D

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MPTs for HIV panel session
Women Deliver International Conference
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Why Develop MPTs?

1. To meet women’s multiple SRH needs in one product

2. To achieve efficiencies in cost of delivery of prevention products

3. To leverage existing delivery channels to achieve higher levels of prevention product uptake and demand
Complexity of developing MPTs

**INDICATION**
- Pregnancy
- HIV
- HSV
- HPV
- Gonorrhea
- Syphilis
- Chlamydia
- BV
- Candida
- Trichomonas

**MECHANISM OF ACTION**
- Barrier
- HC
- Non-HC
- Anti-Microbial
- Probiotic
- Anti-viral
- Anti-fungal

**DOSAGE & ADMINISTRATION**
- **Topical Per-coital**
- **Oral Per-coital**
- **Topical Daily**
- **Oral Daily**
- **Topical Sustained**
- **Systemic Sustained**

**FORMULATION & DELIVERY**
- Vaginal gel
- Vaginal film
- Vaginal tablet
- Vaginal ring
- Non-IVR device
- Oral pill
- Implant
- Injection
**Developing Target Product Profiles (TPPs) for MPTs**

- **Why a TPP?**
  - To identify key attributes/parameters for MPT products that would lead to the highest potential public health impact (i.e., prioritization)
  - To guide product development and donor investment strategies

**Initiative for MPTs (IMPT) TPP Working Group Process:**

- Solicited expert review from domestic and international SRH researchers on ideal and minimally acceptable thresholds of product attributes / parameters
- Surveyed US and African providers as to key priority attributes for MPTs:
  - 593 US providers who are members of the Association of Reproductive Health Professionals (U.S.-based)
  - 289 African providers attending the 2011 International Conference on Family Planning in Dakar, Senegal
  - 34 Indian providers attending the Regional Conference on MPTs in New Delhi, India (Dec 2012)
- Consolidated consensus views
# Key Attributes of MPTs:

- **Indications:**
  - HIV & Pregnancy
  - HIV & STI
    - HSV, HPV, BV
  - STI & Pregnancy

- **Dosage Forms:**
  - Sustained release
  - Topical over oral
  - On demand over daily

- **Product Related (e.g.):**
  - 40°C storage
  - 36 month shelf life
  - Concealable presentation

## Critical Attributes Considered:

<table>
<thead>
<tr>
<th>Attribute</th>
<th>Attribute</th>
</tr>
</thead>
<tbody>
<tr>
<td>Indications</td>
<td>Target Population</td>
</tr>
<tr>
<td>Efficacy</td>
<td>Adherence</td>
</tr>
<tr>
<td>Route of Administration</td>
<td>Dosage Form &amp; Schedule</td>
</tr>
<tr>
<td>Side Effects</td>
<td>Storage Conditions</td>
</tr>
<tr>
<td>Reversibility</td>
<td>Other Health Benefits</td>
</tr>
<tr>
<td>Contra-indications &amp; precautions</td>
<td>Use by preg./lactating women</td>
</tr>
<tr>
<td>Product Provision (Rx vs. OTC vs. ?)</td>
<td>Access Potential &amp; Restrictions (testing?)</td>
</tr>
<tr>
<td>IP Status</td>
<td>R&amp;D Costs</td>
</tr>
<tr>
<td>Time to Market</td>
<td>Product Cost</td>
</tr>
<tr>
<td>Product Presentation</td>
<td>Packaging</td>
</tr>
<tr>
<td>Shelf Life</td>
<td>Disposal/Waste</td>
</tr>
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</table>
TPP Input from Regional Providers

Priority Indications for MPTs

<table>
<thead>
<tr>
<th>Condition</th>
<th>Africa</th>
<th>US</th>
<th>India</th>
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</thead>
<tbody>
<tr>
<td>Preg. + HIV</td>
<td>60</td>
<td>20</td>
<td>40</td>
</tr>
<tr>
<td>Preg. + other STIs</td>
<td>40</td>
<td>40</td>
<td>20</td>
</tr>
<tr>
<td>HIV + other STIs</td>
<td>20</td>
<td>20</td>
<td>60</td>
</tr>
</tbody>
</table>

Priority STI (other than HIV)

<table>
<thead>
<tr>
<th>STI</th>
<th>Africa</th>
<th>US</th>
<th>India</th>
</tr>
</thead>
<tbody>
<tr>
<td>BV</td>
<td>80</td>
<td>20</td>
<td>10</td>
</tr>
<tr>
<td>HPV</td>
<td>60</td>
<td>40</td>
<td>20</td>
</tr>
<tr>
<td>HSV</td>
<td>40</td>
<td>60</td>
<td>10</td>
</tr>
</tbody>
</table>

Priority Dosage Form

<table>
<thead>
<tr>
<th>Dosage Form</th>
<th>Africa</th>
<th>US</th>
<th>India</th>
</tr>
</thead>
<tbody>
<tr>
<td>Topical</td>
<td>10</td>
<td>20</td>
<td>50</td>
</tr>
<tr>
<td>Oral</td>
<td>40</td>
<td>30</td>
<td>20</td>
</tr>
<tr>
<td>Injection</td>
<td>20</td>
<td>40</td>
<td>10</td>
</tr>
<tr>
<td>Implant</td>
<td>10</td>
<td>10</td>
<td>50</td>
</tr>
<tr>
<td>IUD</td>
<td>50</td>
<td>10</td>
<td>50</td>
</tr>
<tr>
<td>Sustained release device</td>
<td>10</td>
<td>30</td>
<td>50</td>
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## Summary of TPP Priorities

### Conclusions from the MPT TPP process:

*Although challenging, it is possible to identify general development priorities and product design targets for MPTs*

### SRH Researchers:

- **Priority Indications:**
  - Pregnancy + HIV
  - HIV + HSV

- **Dosage Forms:**
  Major determining factor is PRODUCT ADHERENCE, so highest development priority is Sustained Release

### US, Indian and African Providers:

- **Priority Indications:**
  - Pregnancy + HIV
  - Pregnancy + HPV

- **Dosage Forms:**
  - US preference for oral; Indian preference for sustained release; African preference across several dosage forms (which may help to foster greater acceptance / use)
Why prioritize product design targets for MPTs?

- Useful to funders in determining investment potential
- Useful to developers in focusing R&D efforts

The IMPT Scientific Agenda Working Group (SAWG) conducted a Product Development Prioritization and Gap Analysis

April – October, 2012

<table>
<thead>
<tr>
<th>SAWG Members</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Donor Representatives</strong></td>
</tr>
<tr>
<td>BMGF</td>
</tr>
<tr>
<td>NIH/NIAID</td>
</tr>
<tr>
<td>NIH/OAR</td>
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<table>
<thead>
<tr>
<th>Regional Representatives</th>
</tr>
</thead>
<tbody>
<tr>
<td>Africa</td>
</tr>
<tr>
<td>India</td>
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</tbody>
</table>

| IMPT Coord. Committee |
SAWG MPT Pipeline Prioritization Process

- Assemble comprehensive list of MPT-related products/components

<table>
<thead>
<tr>
<th>Category</th>
<th>Count</th>
</tr>
</thead>
<tbody>
<tr>
<td>10 MPT IVR</td>
<td>10 Single Indication IVR</td>
</tr>
<tr>
<td>3 On-Demand MPT</td>
<td>12 On-Demand HIV Only</td>
</tr>
<tr>
<td>2 Barrier MPT</td>
<td>2 Injectable HIV Only</td>
</tr>
<tr>
<td>23 HC products</td>
<td>2 Lacto-based Products</td>
</tr>
<tr>
<td>10 MPT IVR</td>
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<td>23 HC products</td>
<td>2 Lacto-based Products</td>
</tr>
<tr>
<td>31 HIV Entry Inhibitors</td>
<td></td>
</tr>
<tr>
<td>11 Enzyme Inhibitors</td>
<td></td>
</tr>
<tr>
<td>7 Other HIV Inhibitors</td>
<td></td>
</tr>
<tr>
<td>29 non-HC products</td>
<td></td>
</tr>
</tbody>
</table>

- Evaluate for development feasibility, and number per product types (MOA, chemical class, dosage form, etc.)
- Evaluate per general TPP findings
- Evaluate per other criteria
- Access expertise from contraceptive field

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
SAWG MPT Prioritization and Gap Analysis: General Summary

**Top Priorities**

- **Suite of product types:**
  - On-demand formulations
  - Vaginal rings
  - Long-acting injectables

- **Active Pharma. Ingredients (APIs):**
  - ARVs for HIV
  - Hormonal contraceptives
  - STI-specific APIs

**Long term R&D needs**

- STI-specific APIs
- Non-ARV based HIV prevention
- Lactobacillus-based products
- Non-hormonal contraceptives
- Novel on-demand product configurations

**Process Priorities**

- Consensus on development objectives across donors and developers
- ID single leads through common R&D pathways using TPPs specific to product types
- Coordinated investment and collaborative development
- Pooling of capacity, expertise, and other resources between MPT R&D partners
- Early and proactive engagement of regulatory authorities

Thank you!