Introducing & Rollout Out PrEP: Hot Issues

Agenda (60 mins)

1. Interactive Issue Identification: Challenges and opportunities (10 mins)
2. Product Introduction Process (8 mins)
3. Global PrEP Status (12 mins)
4. Discussion: What keeps us up at night? (30 mins)
Oral PrEP: Challenges & opportunities

Write down 2-3 challenges and opportunities that you think relate to oral PrEP and put them on the boards.
Product Introduction Process: Research to rollout

**Develop**
- Basic
- Preclinical
- Clinical (Phase I, II, III)

**Demonstrate**
- Post-Trial Access/OLE
- Implementation Research/Demonstration Projects

**Deliver**
- Introduction Initiatives
- Scale-Up
# Product Introduction Process: Moving a product to the “real world”

<table>
<thead>
<tr>
<th>Component</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Post-trial access</td>
<td>After trial ends, intervention provided to participants, and sometimes their communities.</td>
</tr>
<tr>
<td>Open label extensions (OLE)</td>
<td>Follow-on study, intervention available for specific time to participants from randomized controlled trial who know they are receiving active intervention/potential benefit.</td>
</tr>
<tr>
<td>Implementation research</td>
<td>Research protocol enrolling new participants (not previously in trials/OLE), aiming to assess intervention in a more “real world” setting.</td>
</tr>
<tr>
<td>Demonstration projects</td>
<td>“Road tests” use of new intervention in real-world settings, can address delivery infrastructure needs and ways individuals integrate it into daily activities &amp; decision making.</td>
</tr>
<tr>
<td>Introduction initiatives</td>
<td>Large-scale provision of an intervention, sometimes part of country rollout, aiming to learn and apply lessons from introducing an intervention at scale.</td>
</tr>
<tr>
<td>Scale-up</td>
<td>Complex process of making new intervention widely available, includes mobilization of sufficient resources for procurement, distribution, delivery, worker training, etc.</td>
</tr>
</tbody>
</table>

**Demonstrate**
- Implementation Research / Demonstration Projects

**Deliver**
- Introduction Initiatives
- Scale-Up

Framework for Scaling Up Oral PrEP

- Policies, Plans, & Budgets
- Supply Chain Management
- Delivery Considerations & Best Practices
- Promoting Demand & Uptake
- Monitoring & Evaluation
Total Oral PrEP Initiations Globally: 189,170

- North America: 140K+
- Europe: 4K+
- Asia: 5K+
- EMEA: 300+
- South America: 300+
- sub-Saharan Africa: 24K+
- Oceania: 13K+
Global Oral PrEP Status: Regulatory Status of Truvada

**Truvada approved for prevention**

- Australia
- Belgium
- Canada
- England
- France
- Greece
- Israel
- Scotland
- South Africa
- Slovenia
- Swaziland*
- Taiwan
- Tanzania
- Thailand
- United States
- Zambia
- Zimbabwe

**Regulatory application submitted for a prevention indication for Truvada**

- Brazil
- Chile
- Hong Kong
- Nigeria
- South Korea
- Ukraine

*Approved via import license from South Africa.

1. India, SA and Kenya have generic PrEP approval.
2. The European Commission granted Gilead marketing authorization for Truvada as PrEP in Q3 2016. This should encourage countries within the EU to make PrEP available within their national health systems, based on cost factors and individual country regulatory requirements.
<table>
<thead>
<tr>
<th>Country</th>
<th>FY18 PREP_NEW (DSD) Targets</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cote d'Ivoire*</td>
<td>1</td>
</tr>
<tr>
<td>Mozambique*</td>
<td>5</td>
</tr>
<tr>
<td>Dominican Republic</td>
<td>150</td>
</tr>
<tr>
<td>Ukraine</td>
<td>500</td>
</tr>
<tr>
<td>DRC</td>
<td>530</td>
</tr>
<tr>
<td>Botswana</td>
<td>1,000</td>
</tr>
<tr>
<td>Swaziland</td>
<td>1,300</td>
</tr>
<tr>
<td>Namibia</td>
<td>1,550</td>
</tr>
<tr>
<td>Asia Regional Program</td>
<td>1,680</td>
</tr>
<tr>
<td>Vietnam</td>
<td>1,700</td>
</tr>
<tr>
<td>Zambia</td>
<td>1,700</td>
</tr>
<tr>
<td>Zimbabwe</td>
<td>2,769</td>
</tr>
<tr>
<td>Kenya</td>
<td>4,496</td>
</tr>
<tr>
<td>Uganda</td>
<td>11,757</td>
</tr>
<tr>
<td>Tanzania</td>
<td>12,815</td>
</tr>
<tr>
<td>South Africa</td>
<td>16,150</td>
</tr>
<tr>
<td>Lesotho</td>
<td>23,993</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>82,096</strong></td>
</tr>
</tbody>
</table>

* - Possible data entry errors
Discussion: What’s keeping us up at night?
• Researcher obligation to provide PrEP in trials where national rollout occurring
• Population specific access (different types of rollout)
• PrEP in pregnancy
• PrEP in women
• How/where to reach AGYW
• SOP
• Demand creation/social media