

The International Partnership for Microbicides



IPM's Goal

*To accelerate the discovery,
development and accessibility of
safe and effective microbicides ...*



IPM's Objectives

- **Expand the breadth and level of public and private sector funding for microbicides**
- **Identify critical gaps in microbicide research & development, access, and advocacy;**
- **Leverage partnerships with both new and existing public and private players;**
- **Help raise the awareness of microbicides globally**



MICROBICIDE INITIATIVE WORKING GROUPS

Advocacy

- To identify gaps in advocacy and resource mobilization and create a strategy to fill these gaps

Access

- To assess and plan for efforts required to ensure equitable access to microbicide products (prior to launch)

Pharmaco-economics

- To estimate the market potential, returns to investment and public benefits of microbicides

Scientific

- To survey the state of microbicide R&D, identify intellectual or resource gaps, and specify how to best fill these gaps

Public Health Benefit

- To measure the impact of a microbicide on the transmission of HIV, and determine the public health benefit

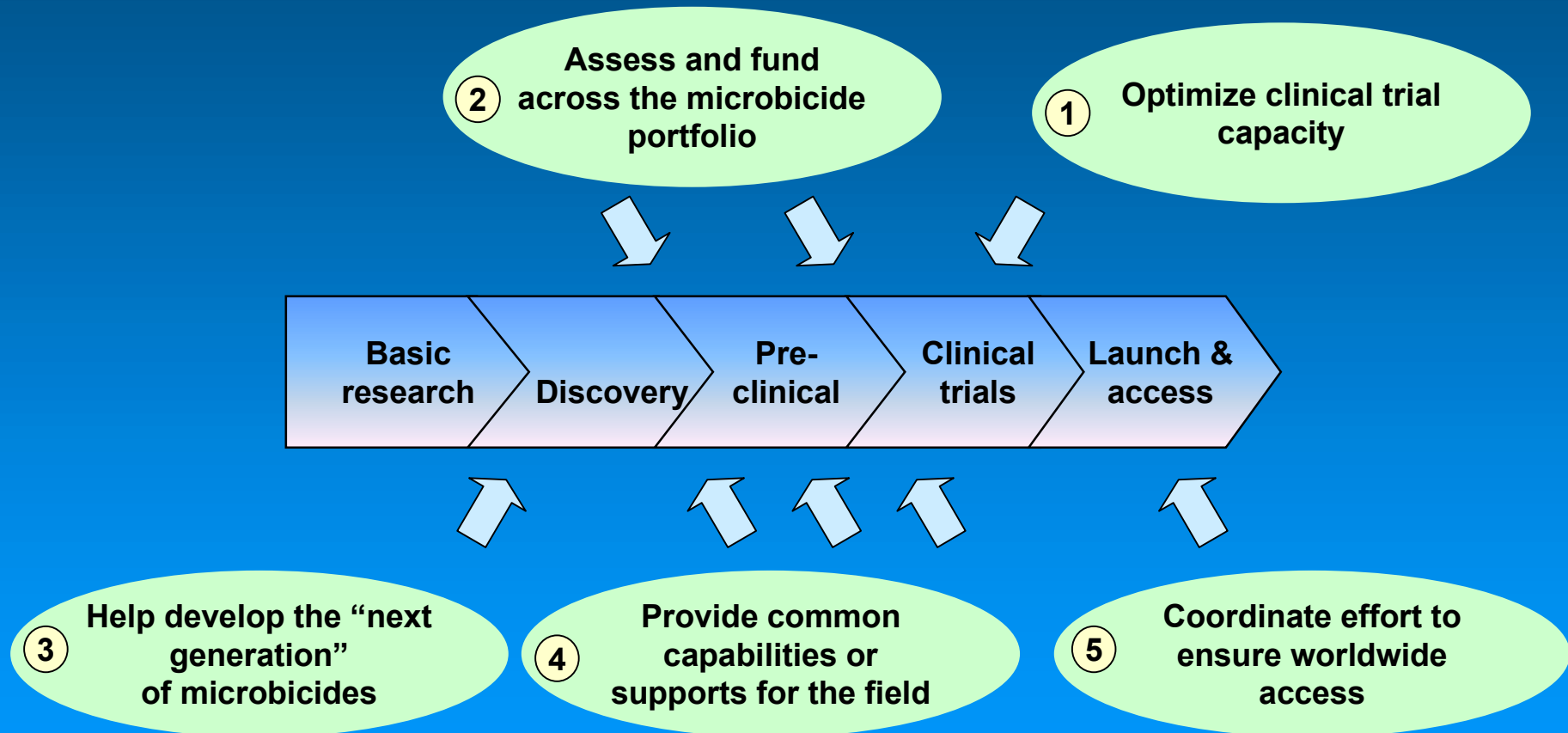


Why a New Initiative?

- ◆ Despite substantial progress, the existing institutions in the microbicide field do not have sufficient funding to most efficiently develop a microbicide
- ◆ No existing organization has the capacity to survey and assess all the products in the pipeline and implement a plan for rapid development of select leads



OPPORTUNITIES FOR ACTION



IPM Strategies

- **Develop and implement a strategic plan to identify the most promising leads for resource-poor countries**
 - Determine the obstacles to the most efficient development of current products
 - Work rapidly to overcome those obstacles by partnering with existing institutions in the field and/or actively seeking out new entities when needed
 - Apply a similar approach to select innovative microbicide leads that are not currently being pursued



IPM Strategies

- **Enhance capacity for the field through establishing shared resources in areas including:**
 - ▶ formulation research
 - ▶ animal model testing
 - ▶ manufacturing and packaging
 - ▶ clinical trial site development
 - ▶ regulatory document submission
 - ▶ management of intellectual property rights



IPM Strategies

- **Help to ensure that women worldwide will have access to a microbicide once effectiveness has been demonstrated**
 - work with existing organizations to develop a strategic agenda for access issues
 - ensure that access issues inform and are integrated into all aspects of the microbicide R&D process.



IPM Strategies

- **Raise resources for the microbicide field**
 - ▶ serve as a central coordinating mechanism to advocate for and receive needed financial resources for the field
 - ▶ support the most efficient strategies for R&D and Access through existing and new organizations
 - ▶ actively support individual organization's requests for support from other sources.



Initial Programme of Work

➤ **Research and Development**

- Progression of candidate products
- Enhancing clinical trial capacity
- Formulation research
- Manufacturing capability

➤ **Access**

- Regulatory approval strategies
- Country profiles
- Financing policies



Potential Partnerships

- ◆ Anticipate a variety of relationships with other organizations including non-profits, biotech and pharma companies, and academia
 - Funding for milestone-driven projects
 - Collaborative ventures
 - Joint strategic planning/consultation



Conclusion

Acceleration of product development

- Facilitate pipeline assessment; fund gaps in product development pathway
- Coordinate investment in common support platforms and infrastructure (e.g. clinical trial sites, manufacturing support, regulatory liaison)

Ensuring wide spread access and use

- Develop strategic agenda for access addressing such issues as regulatory approval and licensing, product distribution, and cost and financing
- Provide central reference point for broader audiences (e.g. global AIDS community, business community)

Increased donor support

- Aid donors with prioritization of their investments
- Provide a directed way to get involved in microbicide field
- Catalyze increased funding for entire field

Shorten product development and access timelines

Save scarce resources

Better decision making across the field

Coordinated mechanism for donor support

