



INTERNATIONAL
PARTNERSHIP FOR
MICROBICIDES

Supporting Clinical Research Centres: A PDP Model

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Overview

- The PDP Model
- Product Development Process
- Research Centre Development
- Community Engagement and Mobilization
- Ethical Considerations
- Communication Process
- Planning for Success



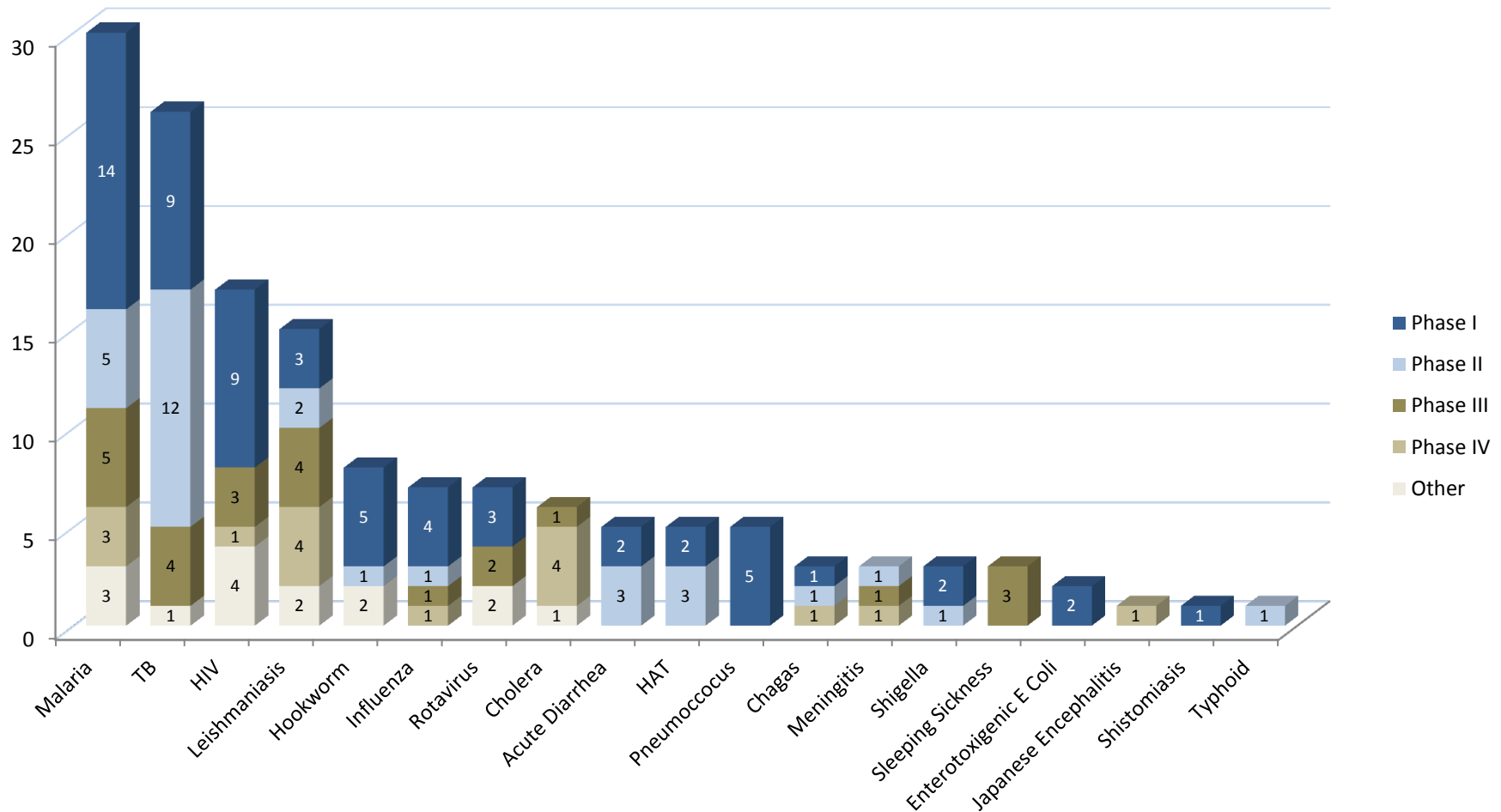
The PDP Model

- Harness expertise of nonprofit and private sectors
- Expedite development of new products to fight diseases with greatest global mortality/morbidity
- Facilitate collaboration for products that are not prioritized in developed countries
- PDPs have developed and licensed over 16 new products for 7 diseases including Malaria and TB



PDP Studies address 19 Disease Areas

Ongoing and planned studies



Source: Based on estimates last updated in the PDP Portal in January 2013 by 14 BMGF-funded PDPs that are part of the Global Clinical Health Consortium. Including ongoing and planned studies

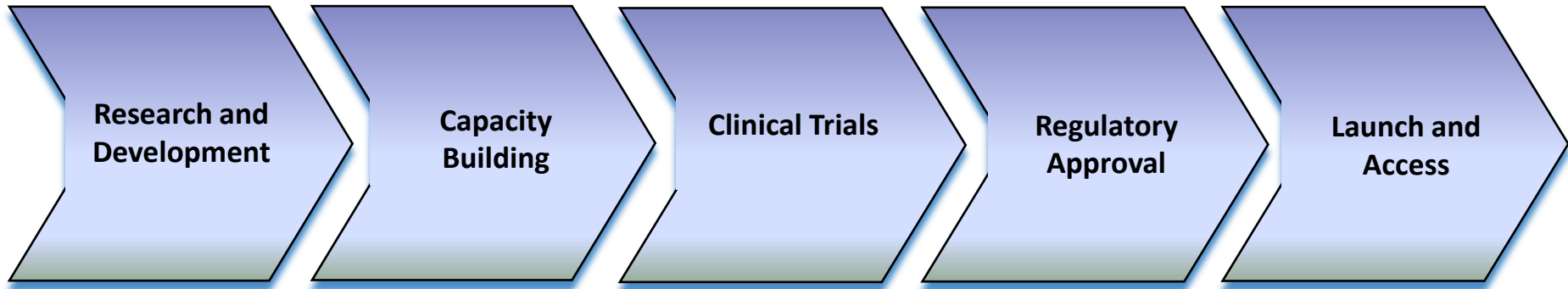
Product Development Partnerships...

offer many advantages to
global health R&D –

- ✓ True Partners
- ✓ Broad Disease Profile
- ✓ Diversity
- ✓ Implement Global but Think Local
- ✓ Experienced, Skilled Scientists and Researchers
- ✓ Focus on Good Study Participant Care
- ✓ Global Quality and Standard



Product Development Process



- Intellectual property rights
- Formulations
- Preclinical studies

- Research centre staff
- Infrastructure & Training
- Community engagement
- Epidemiology studies

- PK / PD
- Bioequivalence
- Safety
- Efficacy
- Acceptability

- Licensure
- Post-licensure studies

- Manufacturing
- Service delivery
- Availability

➤ Drug development approach consistent with Regulatory path

conducting Clinical Trials.....

Before the trial can start:

- Product Development Plan
- Protocol Development
- Regulatory and Ethics submissions
- Product Import License

DSMB (with “Local” representation)

Enrollment and vaccination(s)

- Primary Care Relationship and Letter of Intent
- General Standard of Care
- Follow-up: visits to clinic
- Centralized vs. local laboratories (Safety, Specialized, HIV testing)

Voluntary Counseling and Testing

- HIV prevention education
- Access to condoms

**Approvals
received**

**Clinical Trial
begins**

**Clinical Trial is
completed**



Clinical trial sites preparation

- Selection Process
- Development if required
- GCP and GCLP Assessment

Community engagement Volunteer recruitment

- Community Engagement and Outreach
- CABs
- Informed Consent
- Screening: eligibility
- Good Participatory Practices

Results / Data Dissemination:

- Data analysis
- Clinical Study Report
- Publications
- Communications Plan:
 - Regulatory
 - Government
 - Media
 - Research Center
 - Community

Preparing for Large Pivotal Phase III Trials

Epidemiology studies

- Understand epidemic
- Clinic and Lab skills

Phase I – II trials

- Advance candidate
- Test in appropriate population

Efficacy Studies

World Medical Association Declaration of Helsinki
International Conference on Harmonisation Good Clinical Practice
EU Directive on Clinical Trials
US Food and Drug Administration
Country Specific Regulatory Authority Guidelines & Regulations

Building Capacity to ensure Success

- Disease Prevalence & Incidence
- Community and Stakeholder Engagement
- Referral Networks for Medical Care, Treatment & Support
- Infrastructure and Equipment
- Staff Training and Development
- Communication Tools
- Financial Management Support



GCP Readiness Assessments: GCP-compliance

- Performed at all research centres:
 1. Management responsibilities
 2. Quality systems (including GCP)
 3. Facilities
 4. Equipment
 5. SOPs (including GPP)
 6. Computerization of system
 7. Document management
 8. Sample logistics (including GCLP)
 9. Vendor / Purchase / Subcontractor management
- Financial management and monitoring
- Identify action items
- Provide SOP examples and templates
- Conduct follow-up visits



Laboratory Assessments: **GCLP-compliance**

- Assessment tool:
 - GCLP readiness
 - Compliance, capacity, quality control systems for reliable results
- Assessments performed at:
 - Local/Central labs
 - Research Centres
 - BHCG testing, centrifugation, aliquoting, storage and shipment of samples, documentation
 - HIV Rapid Testing and HIV Algorithm
 - Records & reports
- Assist with SOPs
- Provide training where necessary
 - QC / QA



Capacity Building and Strengthening

Research Centre Development

- SOPs
- QA/QC systems
- GCP and GCLP

Laboratory Training

- Laboratory Project Management
- Rapid test

Community Engagement

- Informed Consent
- Community Liaison Officers
- Adherence Education
- Recruitment and Retention
- Community Advisory Boards

Clinical Safety

- Safety reporting
- Colposcopy
- Monitoring

Counseling

Toolkit for systematization of quality assurance processes in counseling & adherence, working with vulnerable populations

- Pre and Post-HIV testing
- Contraceptives
- STIs
- Behavioral questionnaires

Finance Management

- Financial Processes and Systems
- Monitoring



Community Engagement and Mobilization



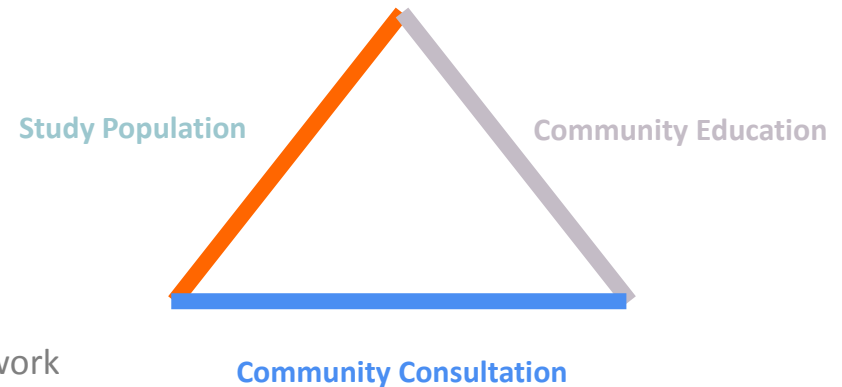
Community Engagement and Mobilization

- **Research Centres**

- Build capacity of community staff to educate and train others
- Annually revised community engagement plans:
 - Community Engagement & Mobilization Framework
 - Stakeholder and Community Mapping
 - Recruitment and Retention Plan
 - Communication Plan

- **Community Advisory Boards**

- Protocol Development
- Informed Consent Review process
- Constitution/Operating procedures
- CAB/CAG Country and Regional training sessions



Awareness of Cultural Differences

- Awareness of needs to involve local health care providers in early stages of protocol development
- Awareness on the use of local medical practices, especially traditional medicine
- Lack of translations for certain words, phrases, or concepts
- Continual use of clinical trial language that may be foreign concepts
- Local community view of biopsies, sample collection, and blood draws
- Implementation of informed consent

Unblinding – “Imfana”
direct Xhosa translation
the blind leading the blind
- No “unblinding” word

Ethical Considerations



Ethical Considerations for Clinical Trials

- General Standard of Care
- Informed consent process
- Risk reduction counseling
 - Provision of condoms
- STI screening and treatment
- Family planning
 - Management of pregnancy
- Counseling and referrals for treatment
 - If HIV-positive at screening
 - For participants who become HIV-positive during clinical trials
- Treatment / Referrals
 - For any medical condition that arises
- Post-trial access to products



Informed Consent

Good Participatory Practice

- Guidelines for biomedical HIV prevention trials
- www.unaids.org

Interaction with communities

- CAB Reviews



Culturally appropriate assessment of understanding

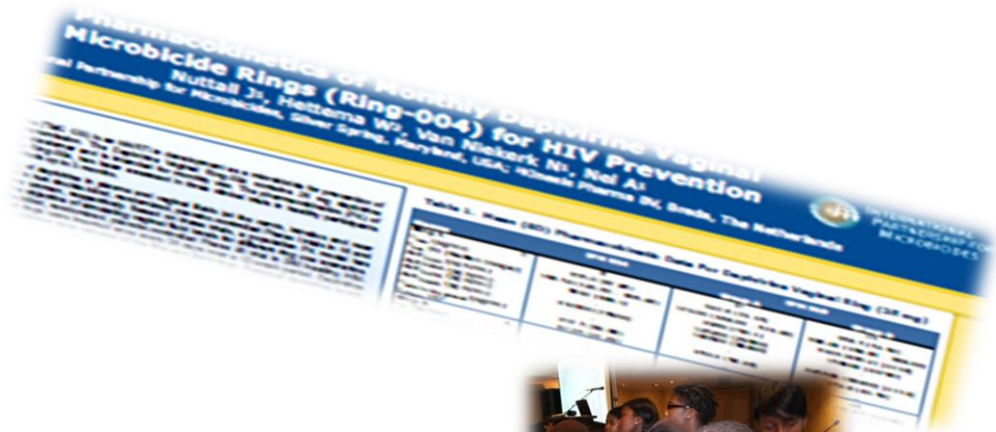
- Assessment of Understanding (AoU) Informed Consent or Informed Consent Comprehensive Assessment:
 - ✓ Enables counselors to effectively assess whether the volunteer is truly informed of the potential risks and benefits of participation.
 - ✓ Improves the volunteers' experience of participating in trials and ensures that volunteers are better informed of their role in the trial.

Communication Process



Communication Process

- Results
- Clinical Study Report
- Communication Plan:
 - Conferences
 - Publications
- Data Dissemination Process:
 - Regulatory
 - Government
 - Media
 - Research Centre
 - Community



ACCESS Principles: Planning for Success

Architecture

Availability

Acceptability

Affordability

Appropriate Use



Benefiting People, Communities, Countries

- Promote reproductive health and HIV awareness
- Empower communities through education and counselling
- Encourage HIV testing
- Improve delivery of and access to health services
- Engage communities, and support establishment of community advisory boards
- Provide employment and professional opportunities
- Build medical research capabilities in geographical areas of need



Success is....



Acknowledgements

- Donors
- PDP leadership
- All Research Centers Globally
- Participants



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