IEC and NRA Successful Collaboration in Approving Medical Device Clinical Trials: A Product Development Partnership

Annalene Nel, VP CMO IPM

DNDi, A Decade of R&D for Neglected Diseases in Africa
Nairobi, Kenya – 4 June 2013
Product Development Partnerships...

offer many advantages to global health R&D –

✓ True Partners
✓ Broad Disease Profile
✓ Implement Globally but Think Locally
✓ Focus on Good Study Participant Care
✓ Global Quality and Standards
✓ Collaboration with global & local IECs and NRAs for Regulatory Pathway
Preparing for Large Pivotal Phase III Trials

**Epidemiology studies**
- Understand epidemic
- GCP, GPP & GCLP

**Phase I – II clinical trials**
- Advance candidate
- Test in appropriate population

**Drug Development Plan consistent with Regulatory Pathway**
Clinical Safety & Efficacy Trials

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

- Product Development Plan
- Regulatory Pathway
- Protocol Development Process
- Regulatory and Ethics Submission & Approval Process
- Product Import License
- Data Dissemination Process
- Regulatory Dossier Submission Plan
- Access Plan
## Regulatory and Ethics

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Collaboration Activities

**Initiative:**
To understand & enhance the clinical protocol review process in the microbicide product development field in high HIV-incidence countries of Sub-Saharan Africa

**Countries:** Kenya, Malawi, Rwanda, South Africa, Tanzania, Uganda, Zambia, Zimbabwe

**Product:** Microbicides (Dapivirine Ring-004)

**PDP role:**
- Engagement of Sub-Saharan NRA & IEC members principal investigators & stakeholders
- Collaboration with EDCTP & WHO regulatory officers
- Convening Workshops & Meetings Platforms
- Knowledge sharing of Microbicide and HIV prevention research fields
- Coordination of Agenda & Minutes
- Funding pass-through to ensure EU compliance requirements were met
Collaboration Activities cont.

**Approach:**
- Establish a platform for open dialogue between Sub-Saharan NRAs & IECs
- Knowledge sharing of in-country regulations and processes
- HIV prevention clinical research perspective in context of community and stakeholder engagement
- Overview and Status of Microbicide clinical research
- Sharing of Product Development Plan

**Funding:**
- European Commission
- Standard Grant Application: Aid for poverty-related diseases (HIV/AIDS, malaria and tuberculosis) in developing countries

**Regulatory & Ethics Meetings:**
- October 2007, Cape Town, South Africa
- September 2008, Cape Town, South Africa
- March 2009, Dar Es Salaam, Tanzania
- September 2009, Nairobi, Kenya
- October 2010, Cape Town, South Africa
- June 2011, Cape Town, South Africa
## Regulatory and Ethics

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• Keep track of many regulatory evolutions  
• Process varies from country to country  
• Clinical Trial Application and lengthy approval processes  
• Language barriers  
• Lack of CMC expertise, even if excellent preclinical & clinical review staff  
• Differing approaches/view toward trial “insurance” | • Good understanding of local NRA and Ethics requirements  
• Time required for the CTA regulatory process and requirement for import and export licenses should be taken into consideration  
• Accurate completion of CTA and support documentation, reduces the potential for delays  
• Understanding of local culture and language is key  
• Establish a company-wide standard that can be applied across all African countries, based on the most stringent existing regulatory requirements |
The Outcome....

• Maximization of networking opportunity amongst NRAs and IECs

• Enhanced trust and efficient communication

• Open communication early in clinical development program

• Consultation of in-country investigators in protocol development

• Better understanding of processes and submission requirements, including proactive provision of background and supporting documentation

• NRA/IEC feedback aligned with protocol and indication science
Conclusion

• Proactive participation with continuous updates & open communication lines to date led to a more efficient CTA process with a shortened review & approval timeline of clinical protocols

It starts with a T-R-U-E Collaboration:

» T : Transparency
» R : Respect
» U : Understanding of Expectations
» E : Enthusiasm
Successful Collaboration to Make a Difference for Women

Acknowledgement

• Sub-Saharan Africa Country Regulators & Ethics Representatives
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• IPM colleagues
• Participants
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