



INTERNATIONAL
PARTNERSHIP FOR
MICROBICIDES



“The Ring Study”: What have we learned?

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Developing HIV Prevention Products
for Women worldwide



Introduction

- The Ring study, a Phase III, multi-site, safety and efficacy dapivirine study is currently underway in four Research Centres in South Africa
- The fifth site is in Ruanda Africa and will commence screening soon
- All these sites were established by IPM as early as 2004/2006.
- The target for enrollment is 1650 and 624 participants already enrolled
- In the presentation we share lessons that have been learned by the RCs from the Ring Study





Research Centres involved in the Ring Study



Lessons Learned

Lessons learned	Description
<p>Infrastructure</p> 	<ul style="list-style-type: none"> • Expect demand for more space as the trial starts • Certain rooms like lab may need to be redone to meet the Phase III trial requirements • Better to get assistance from experts, they are creative and do jobs faster and efficiently
<p>Staffing</p> 	<ul style="list-style-type: none"> • Review staffing to meet all study needs and to avoid overstressing staff with multiple tasks • Always start with adequate staff as staff shortage may compromise the quality of work • Engaging new staff late may affect team functioning • Plan in advance for staff movement as it may destabilise the study activities • Recruitment of doctors very strenuous especially in rural areas and competitive salaries could be a big challenge

Lessons Learned (Cont)

Lesson Learned	Description
<p>Recruitment</p> 	<ul style="list-style-type: none"> • No single model of recruitment works, try others • Others include part-time community mobilizers- trained, but ownership of the trial could be a challenge • Every staff member to be kept on top of things by mapping up recruitment targets with data quality management • Be always prepared for unexpected natural and other events for example, rain, snow, worker strikes, taxi driver strikes as these could affect targets • Always have alternative plans in place, be flexible to change strategies, it's important to do so • In cases of myths and misconception, address media before media reports incorrect information • Recruitment is a responsibility of all study staff and requires regular monitoring so as to identify bottlenecks and align accordingly

Lessons Learned (cont)

Lesson Learned	Description
<p>Retention</p> 	<ul style="list-style-type: none"> • Retention should start as soon as the first participant is screened and enrolled • Participants appreciate understanding from researchers, react to community problems • Engage participants in activities that will keep them busy
<p>Acceptability of the ring</p>	<ul style="list-style-type: none"> • Dapivirine ring is acceptable to most women and their partners • Well tolerated by women

Lessons Learned (cont)

Lesson Learned	Description
Feedback	<ul style="list-style-type: none"> • It is important to have a continuous and prompt, feedback loop between the community, participants, site staff, monitors and sponsor so as to trouble shoot instantly • Effective and reliable communication methods should be used
Timelines	<ul style="list-style-type: none"> • These could be affected and changed by a variety of factors and thus flexibility and reaction to be prompt in such cases
Training	<ul style="list-style-type: none"> • Training never stops, new staff, retraining on protocol, GCP and includes community training for empowerment



Slide Title

Lessons learned	Description
Male Involvement	<ul style="list-style-type: none">• Strategies to be in place for involving and engaging men generally in the community as well as partners of participants• Men need health and HIV prevention information• Men have questions, they love and want to protect their women,• They need open answers and some can cause social harms if left ill informed- open / awareness days
Community Engagement	<ul style="list-style-type: none">• Very critical in microbicide trials• Should go beyond CAB• To be taken as partners and be informed of every development• Is a continuous process



Lessons Learned	Description
Team Work	<ul style="list-style-type: none">• Site success or failure depends on effectiveness of teams• Build team as early as is possible• Understanding of the study long-term goal very important• Skill building necessary for effectiveness and for the team to journey together• Constructive feed back needed
Data management	<ul style="list-style-type: none">• Source document templates to match with CRFs otherwise this could affect the quality of data collection• Monitoring system to start as soon as the trial starts to avoid backlog• Data management requires participation of the whole team• Data teams need clear guidance and training from the beginning from the sponsor to avoid errors.





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