

## ASPIRE and The Ring Study Results – A Snapshot

Study	The Ring Study (IPM 027) International Partnership for Microbicides	ASPIRE (MTN 020) Microbicide Trials Network
<b>Study design and enrollment</b>		
<b>Objectives</b>	Long term safety and effectiveness	Safety and effectiveness
<b>Study design</b>	Double blind randomized placebo controlled with 2:1 randomization (active: placebo)	Double blind randomized placebo controlled with 1:1 randomization (active: placebo)
<b>Enrollment</b>	Total: 1959 women, ages 18-45 Active arm: ~1300	Total: 2629 women, ages 18-45 Active arm: ~1325
<b>Regulatory requirement</b>	3000 women on dapivirine ring for at least 1 year follow-up 1500 women on dapivirine ring for 2 year follow-up	
<b>Participant follow-up</b>	2 years + 6 weeks following ring discontinuation	Minimum 1 year + 4 weeks following ring discontinuation
<b>Research sites</b>	7 IPM research center partners in South Africa and Uganda	15 MTN research centers in Malawi, South Africa, Uganda, Zimbabwe
<b>Results</b>		
<b>Overall results</b>	31% effective, confidence interval 1-51	27% effective, confidence interval 1-46
<b>Secondary analysis that excluded data from 2 sites with lower retention and adherence</b>		37% effective, confidence interval 12-56
<b>Results by age stratification (post hoc analysis)</b>		
<b>Women over 21 years of age</b>	37% effective, confidence interval 3.5-59	56% effective, confidence interval 31-71
<b>Women 18-21 years of age</b>	No statistically significant effect	No statistically significant effect
<b>HIV incidence</b>		
<b>Overall</b>	4.1% among women in active arm 6.1% among women in placebo arm	3.3% among women in active arm 4.5% among women in placebo arm