

# IPM 027 Current Status

*Dr Annalene Nel, IPM CMO*

ASPIRE Team Meeting  
MTN Regional Meeting  
Westin Cape Town Hotel, Cape Town South Africa  
25 October 2014



**Microbicides**

Giving Women New Hope and Choice in HIV Prevention

# The Ring Study

IPM 027

Protocol Version 3.0 Amendment 1.0 Dated 12 September 2013

<b>Objectives</b>	Long-term Safety and Efficacy
<b>Study design</b>	Double-blind, Randomized (2:1), Placebo-controlled
<b>Investigational product</b>	Vaginal rings inserted every 4 weeks $\pm$ 7 days
<b>Endpoints</b>	Approx 96 endpoints; 2 year on IP
<b>Power</b>	81% power to detect 50% treatment effect
<b>Targeted enrollment</b>	1950 women, ages 18-45 1300 on Ring-004
<b>Sites in Africa</b>	7 IPM research center partners in 2 countries
<b>Participant follow-up</b>	2 years + 6 weeks following ring discontinuation



# Clinical Research Centres



## ***Madibeng Center for Research***

Brits, South Africa

First enrolled participant – 11 Apr '12



## ***Maternal, Adolescent and Child Health (MatCH)***

Edendale, South Africa

First enrolled participant – 26 Apr '12



## ***Prevention of HIV/AIDS Project (PHIVA)***

Pinetown, South Africa

First enrolled participant – 23 Apr '12



## ***Qhakaza Mbokodo***

Ladysmith, South Africa

First enrolled participant – 16 Apr '12



## ***Uganda Virus Research Institute (UVRI)***

Masaka, Uganda

First enrolled participant – 12 Sep '13

## ***Desmond Tutu HIV Foundation (DTHF)***

Masiphumelele, South Africa

First enrolled participant – 19 Feb '14



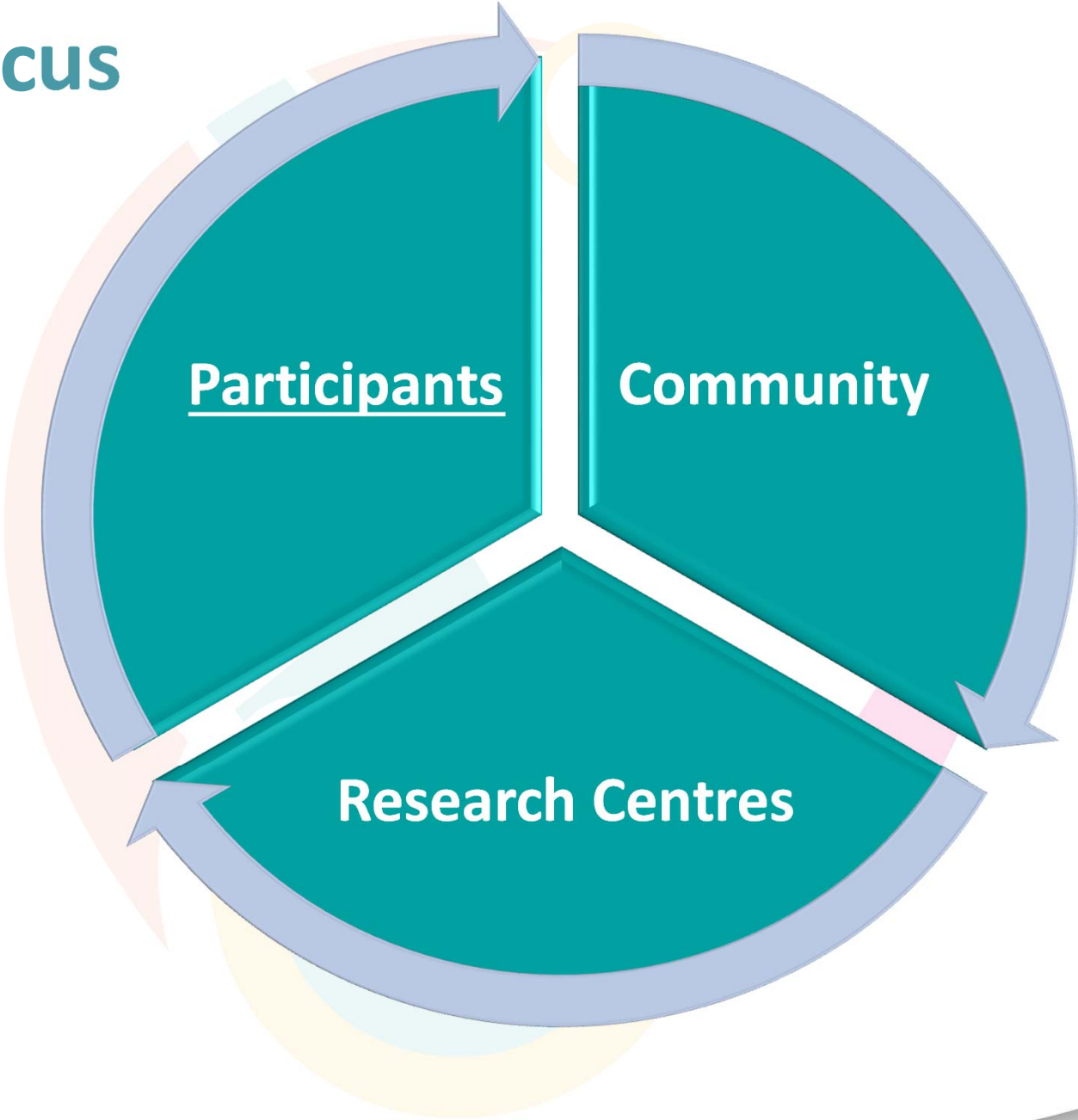
## ***Ndlovu Care Group***

Groblersdal, Limpopo, South Africa

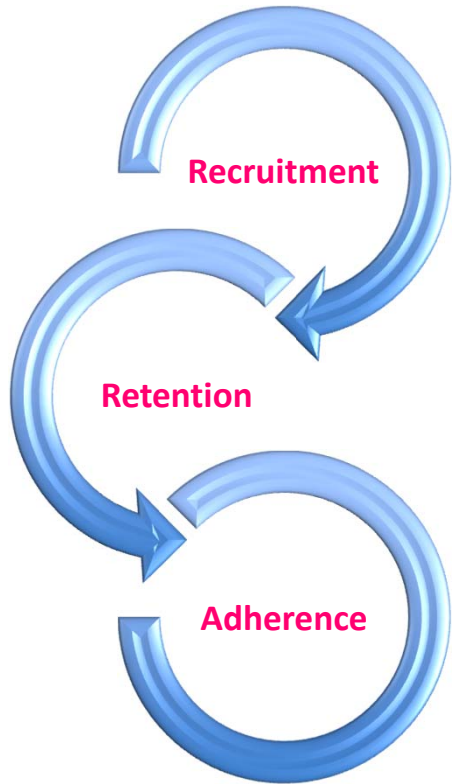
First enrolled participant – 20 Mar '14



# Key focus



# Key focus - Participants



## **Recruitment – *Screening stopped***

- Initiated 2 new Research Centres
- Regular calls to review recruitment plans & strategize

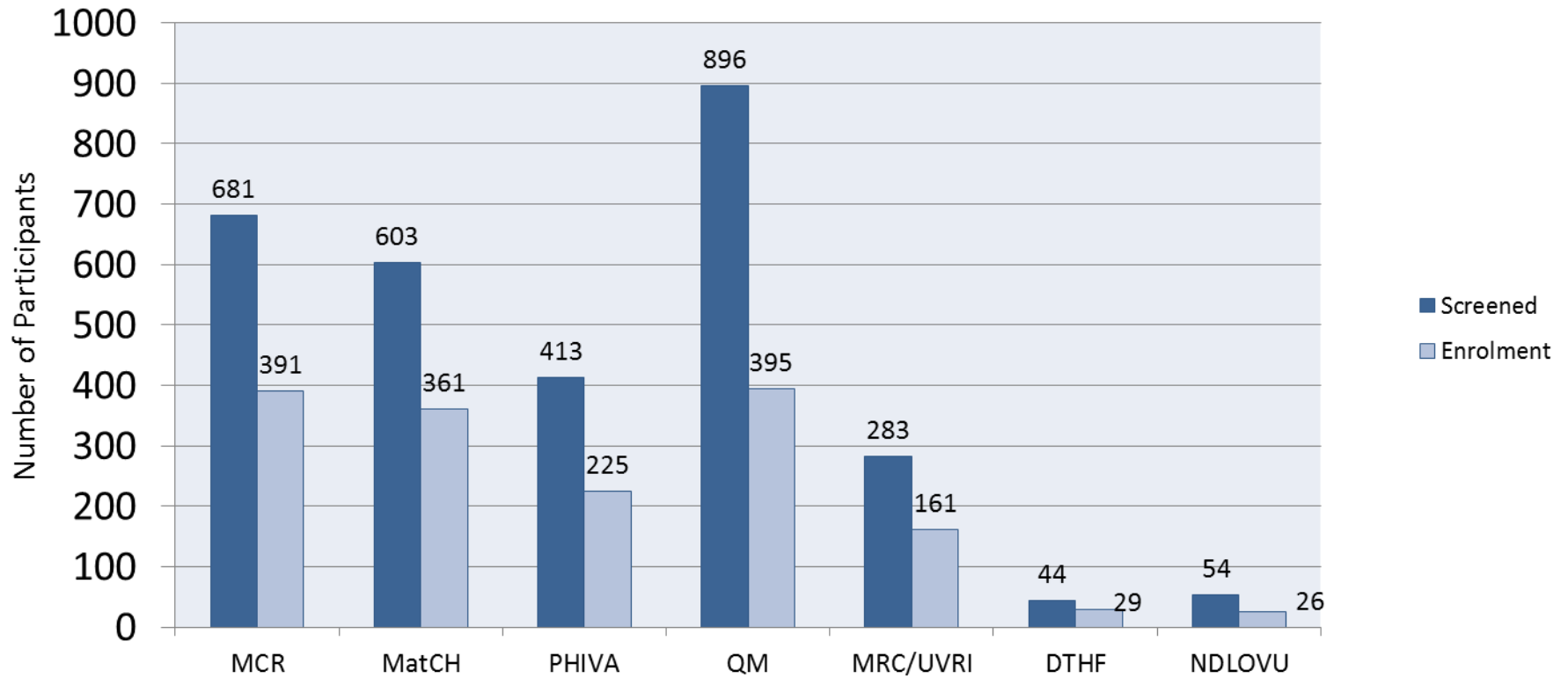
## **Retention – *Downward trend in discontinuation rate***

- Weekly notification of missed / late visits
- Regular calls to review discontinuations & strategize
- Additional rings dispensed



# Recruitment

400 Additional  
1919 enrolled  
31 to enroll  
57 in screening



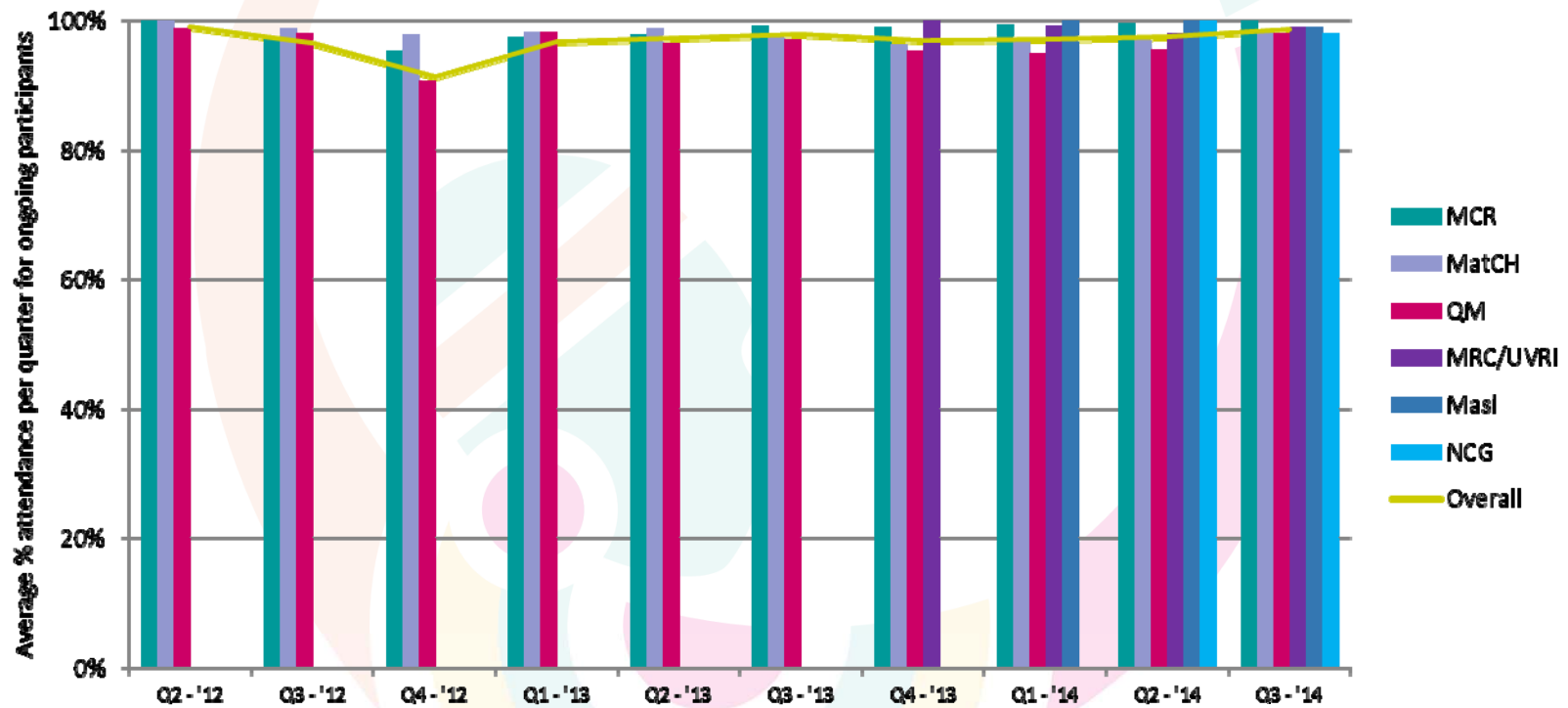
**Screened : Enrolled Ratio is 2:1**

Snapshot: 23 Oct '14

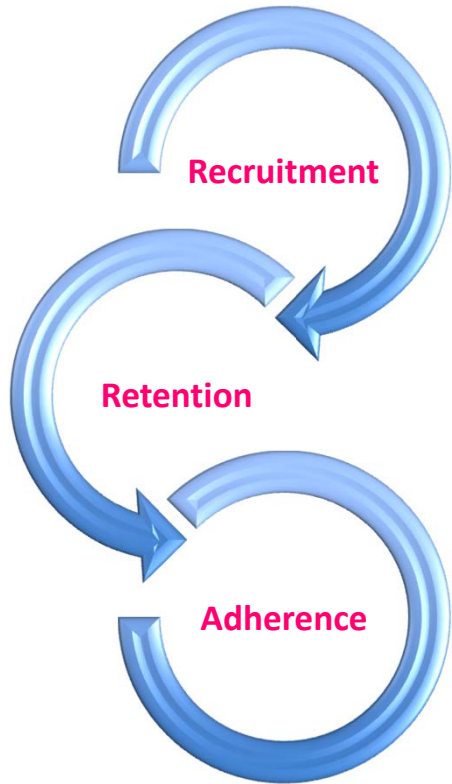


# Visit Adherence

IPM 027 average attendance per quarter for ongoing participants



# Key focus - Participants



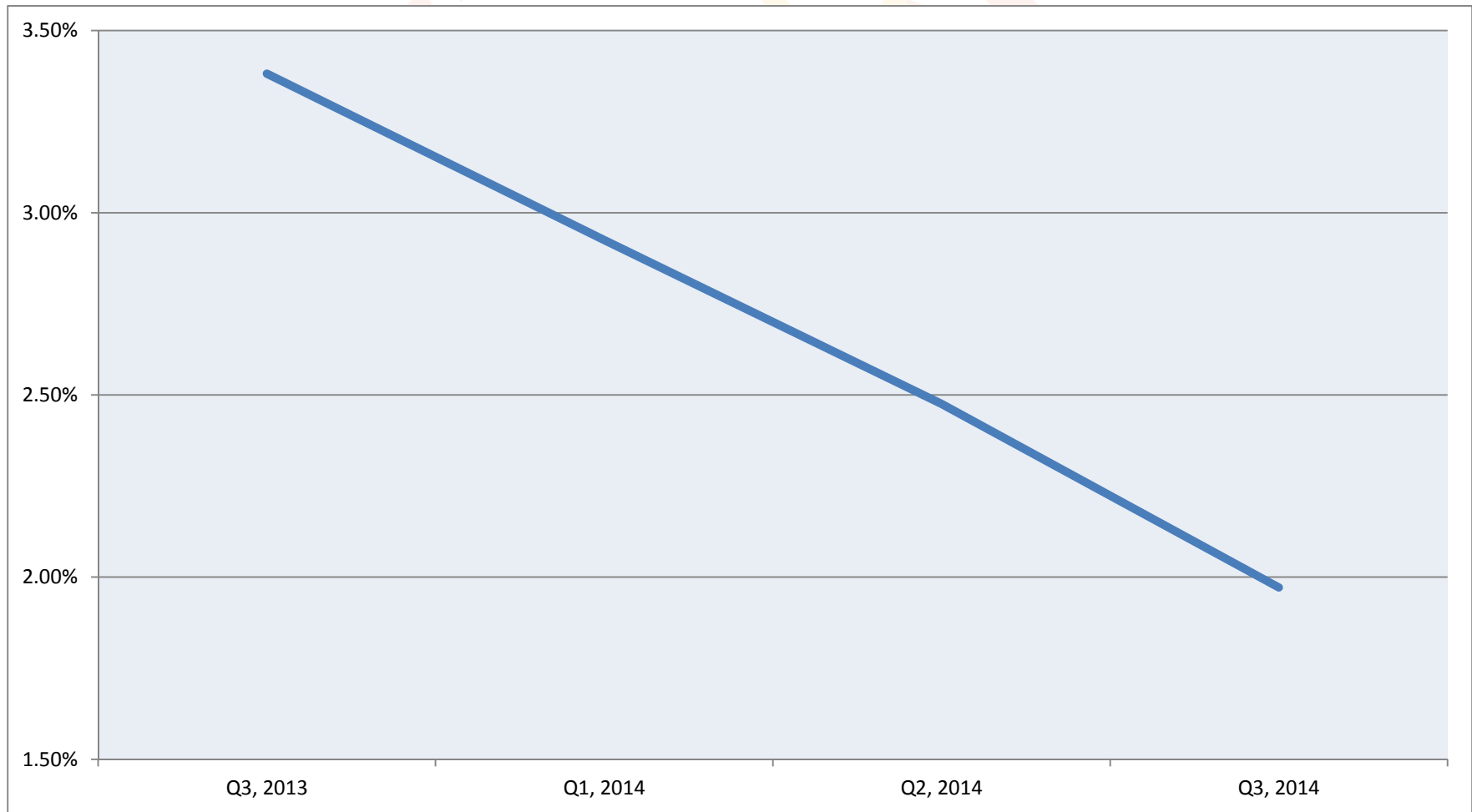
## ***Adherence - Positive trend in protocol adherence***

- Increase in no of additional rings dispensed
- Weekly notification of missed / late visits
- Monthly participant adherence events
- “Ring out” listings - targeted counselling & adherence events
- Targeted messages on ‘adherence is key’ (e.g. armbands, key rings, t-shirts)
- Blinded objective adherence data shared monthly
- Review counselling source documentation - feedback and training provided
- New face for research centre waiting areas
- Vision boards for communication with participants





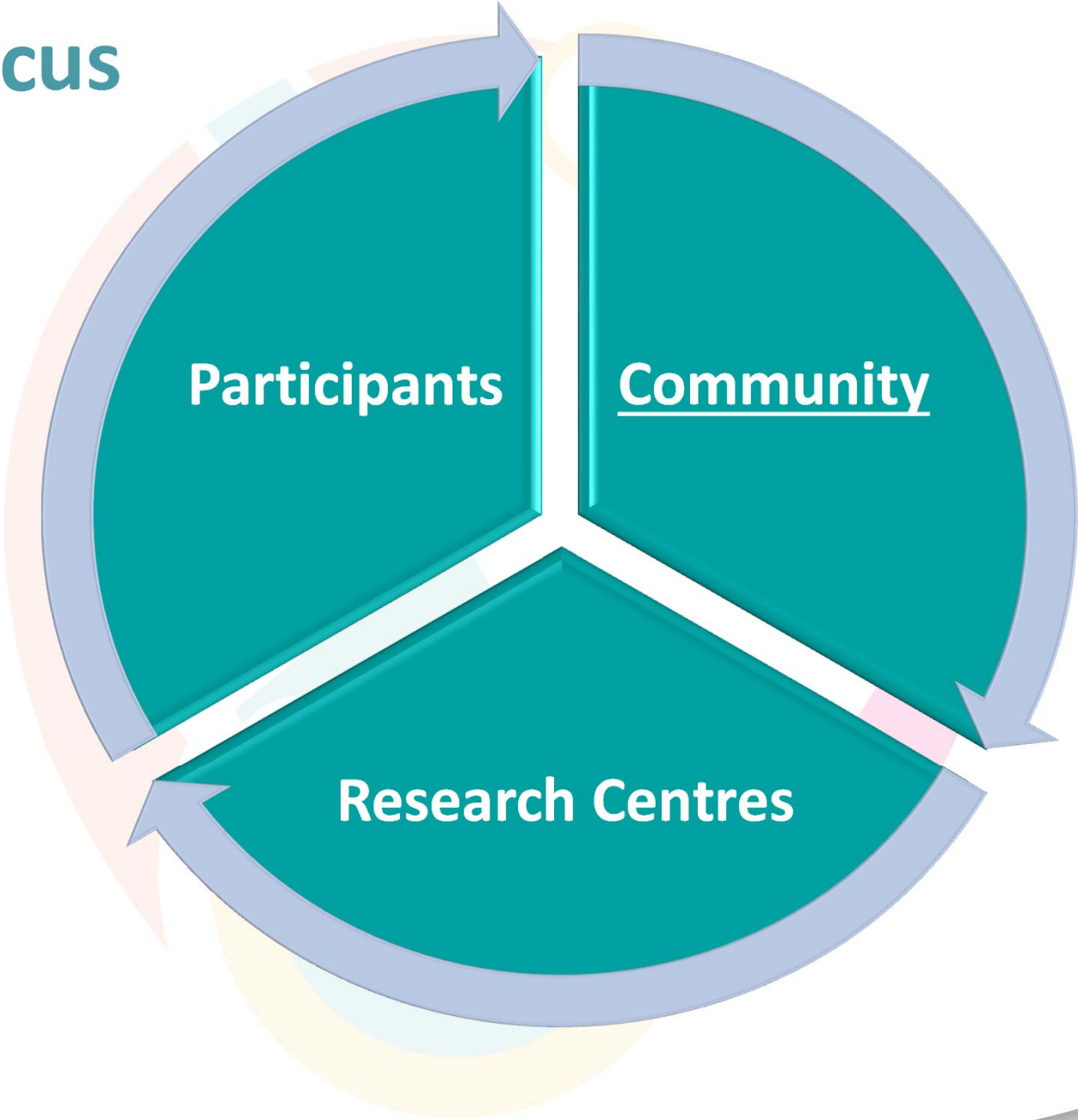
# % Missed Visits / Quarter



\*Note Missed Visits are calculated on retrospective data and may change as participants are discontinued or reach end of product dates.



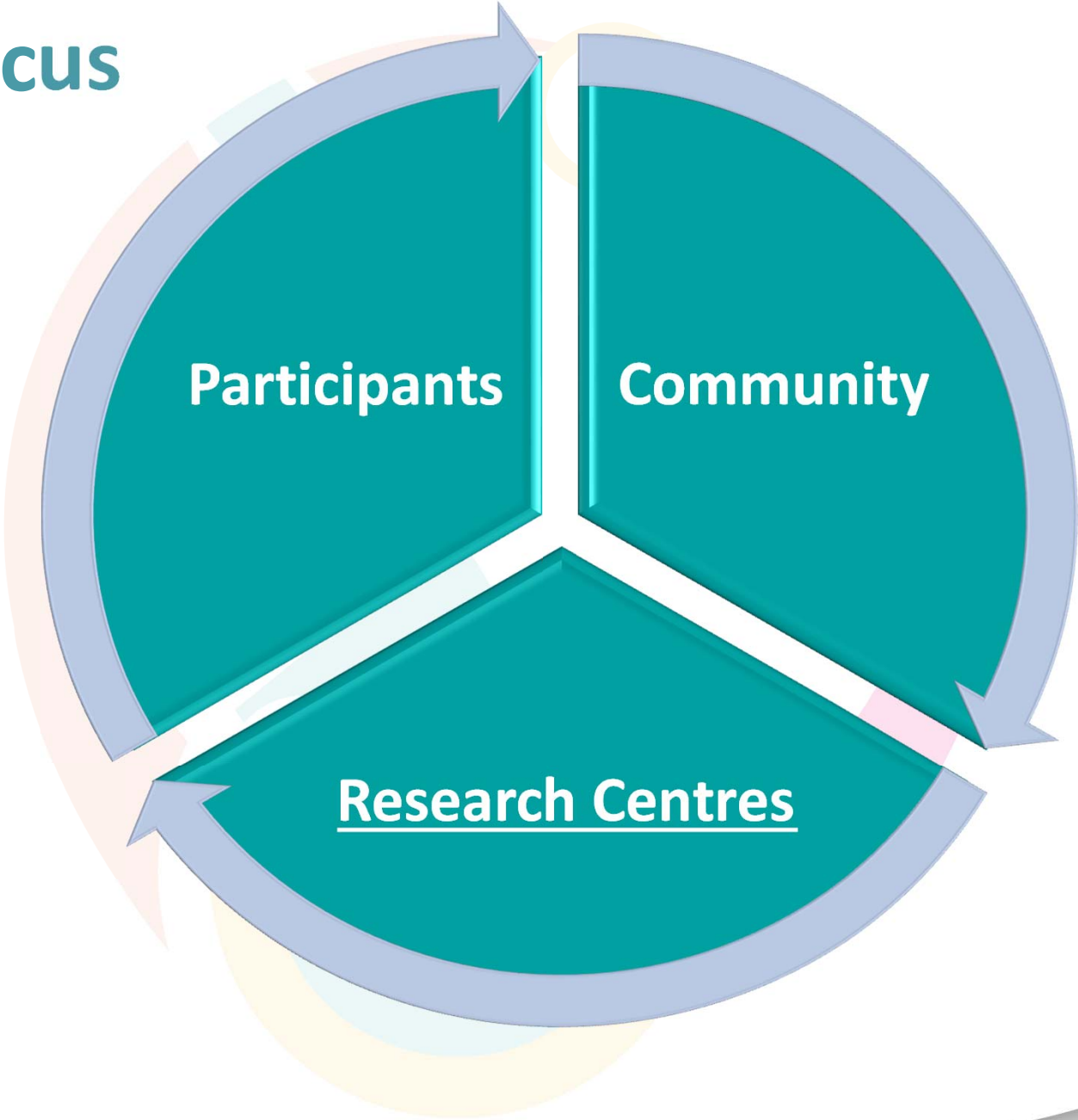
# Key focus



# Key focus – Community Engagement



# Key focus



# Key focus - Research Centres



## Next 12 months: Preparing for Success

Adherence – remains key focus

Complete enrolment

Planning for Dec / Jan holiday period

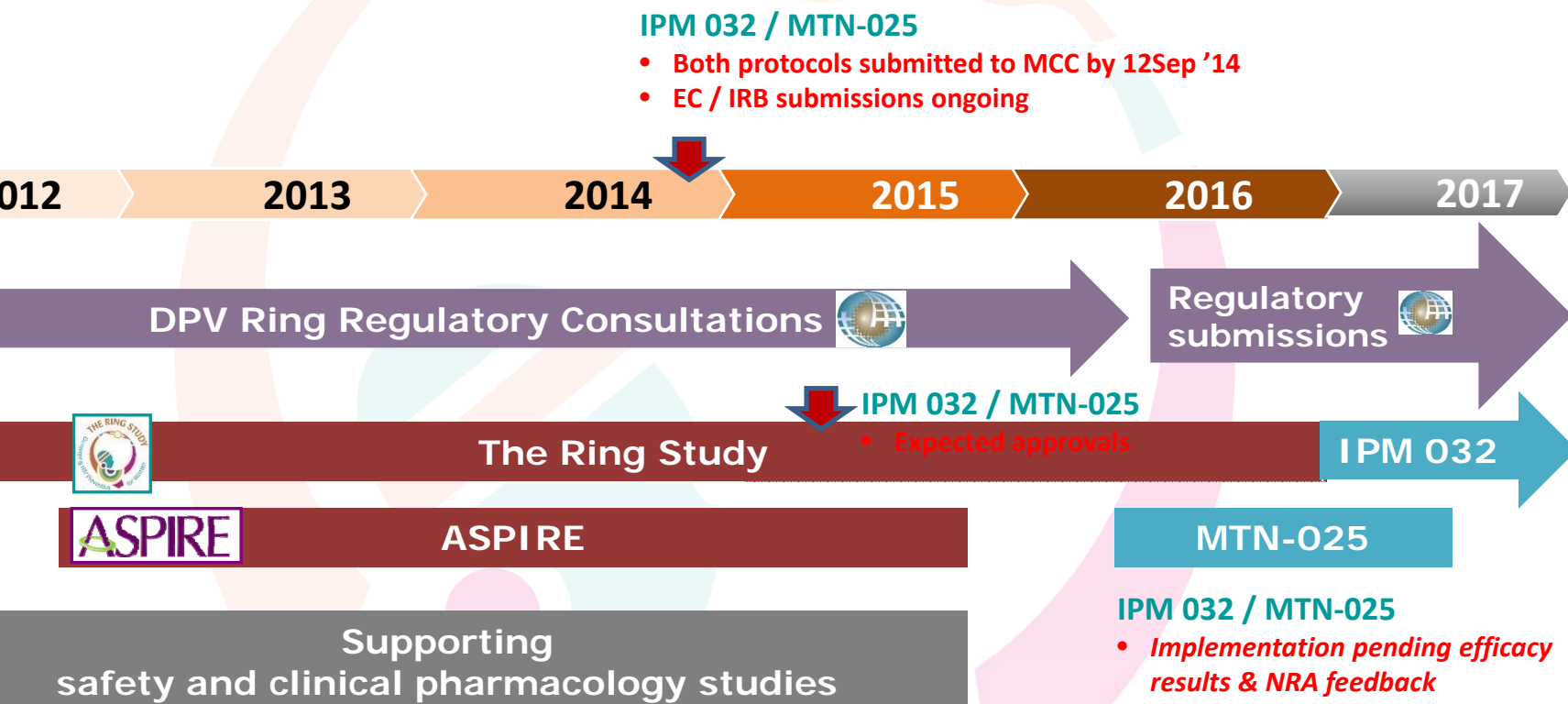
Retention → Women on product for 2 years

Keeping participants & teams passionate

Preparing for success – IPM 032

Inspection readiness

# Open-Label Timeline Scenarios



## IPM 032 / MTN-025

- Both protocols submitted to MCC by 12Sep '14
- EC / IRB submissions ongoing

2012

2013

2014

2015

2016

2017

DPV Ring Regulatory Consultations



Regulatory submissions



The Ring Study

## IPM 032 / MTN-025

- Expected approvals

IPM 032

ASPIRE

ASPIRE

MTN-025

Supporting safety and clinical pharmacology studies

## IPM 032 / MTN-025

- Implementation pending efficacy results & NRA feedback

Together Everyone Achieves More....







**ASPIRE**

A Study to Prevent Infection  
with a Ring for Extended Use

Thank you .....



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