



INTERNATIONAL  
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# Dapivirine Ring Regulatory Process and timelines – Who might be able to use the ring?

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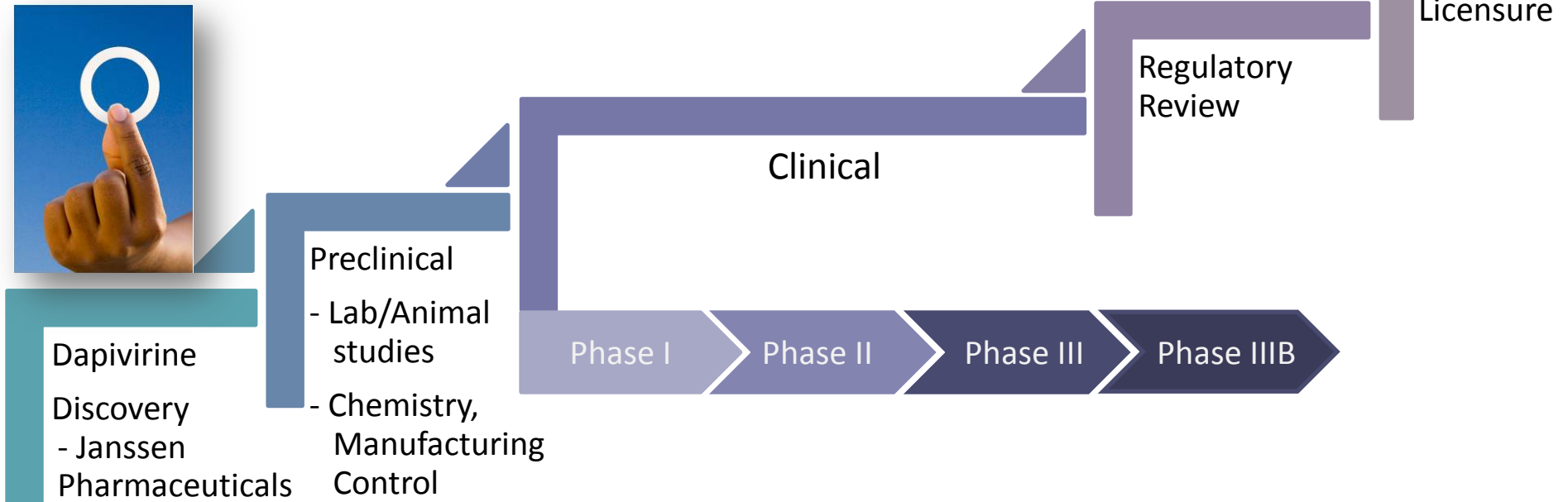
*Developing HIV Prevention Products  
for Women worldwide*

# Regulatory Objective

To obtain marketing authorizations in multiple African countries to make the dapivirine ring available as early as possible to women at significant risk of HIV-1 infection via vaginal intercourse.



# Dapivirine Ring-004 Development Path



- IPM Leadership: From Idea to Impact
- IPM regulatory sponsor
- IPM developed and manufactured Dapivirine Ring-004
- Women-initiated prevention technology
- Long-acting: monthly or longer
- **No preclinical, toxicology safety concerns**

# Regulatory Authority Consultations

Scientific and regulatory advice on Phase III trial design and requirements:

- US Food and Drug Administration (FDA)
- European Medicines Agency (EMA)

Country-specific requirements from national regulatory authorities (NRAs):



Kenya



Uganda



Malawi



Zambia



South Africa



Zimbabwe



Tanzania



# Dapivirine Ring-004 Development Path



Drug  
Discovery

Preclinical

Clinical

Regulatory  
Review

Post  
Licensure

Phase I

Phase II

Phase III

ASPIRE  
(MTN-020)



The Ring Study  
(IPM 027)



# Dapivirine Ring-004 Development Path

Post  
Licensure

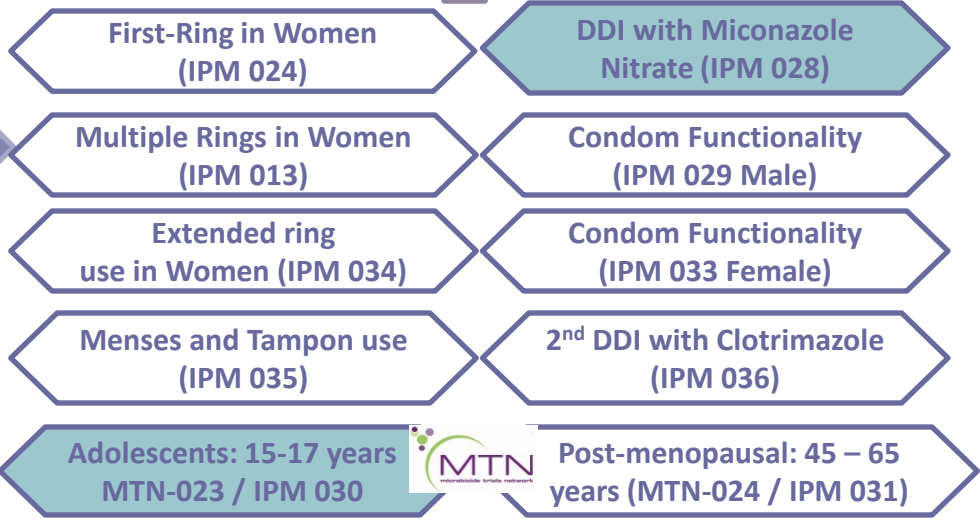
Regulatory  
Review

Clinical

Preclinical

Phase I/II

Drug  
Discovery



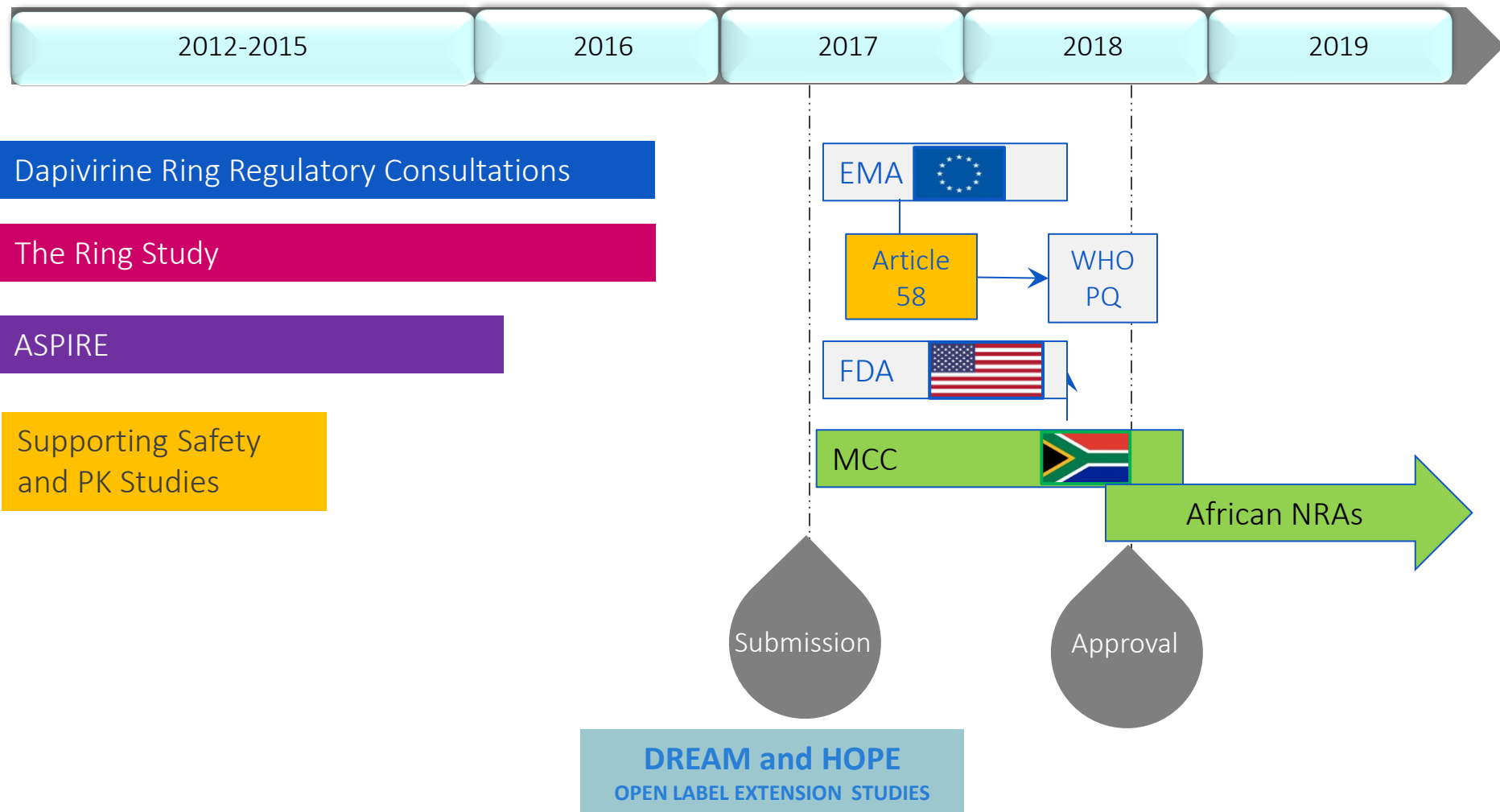
Safety, Pharmacokinetics, Acceptability and Adherence	
Double-blind, Placebo controlled, Randomized (3:1)	
96 Healthy, HIV-uninfected, sexually experienced pts	
6 consecutive rings	3 consecutive rings
6 sites active in US	3 sites active in US

Included in dossier

Ongoing - not included in first dossier submission



# Dapivirine Ring Licensure Program



# Between Efficacy/Safety and Regulatory Approval



- Demonstration of efficacy and safety in Phase III trial does not automatically translate into product licensure
- Phase III b Follow-on, Open-label studies will give former Phase III study participants access to the ring while under regulatory review
- Open-label studies not part of regulatory approval package





# Product Label

## Initial

Healthy HIV negative women  
18 – 65 years of age  
Not pregnant or breastfeeding

## Future

### Adolescents

- MTN-023:
  - US population
  - 6 months ring use
- MTN-034
  - African population
  - 6 months ring use

Breastfeeding (MTN-029)

Pregnant



# Acknowledgements

- Participants
- Research Centre Teams
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- MTN / NIH / DAIDS colleagues
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- IPM Colleagues
- IPM Board of Directors
- Donors

*It takes a village to raise the child: Dapivirine Ring-004*



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