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# Dapivirine Vaginal Ring: Path to Regulatory Approval

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Microbicide Trials Network Regional Meeting

Cape Town



# Path to Regulatory Approval

## IPM's role: Dapivirine ring's regulatory sponsor

- Holds worldwide rights to dapivirine
- Ensure all preclinical, clinical and pharmaceutical quality/chemistry, manufacturing and controls (CMC) data meet regulatory requirements
- Formally apply for dapivirine ring approval through European, US and African regulatory authorities



Approval pathway for new HIV prevention drug can be more complex than for a drug already approved for treatment (e.g., oral Truvada)

# Regulatory Submission Update

- Scientific opinion via Article 58, (EC Regulation 726/2004)
- Submission: 22 June '17; CTD currently under review
- D80: Assessment report 30 Sep '17
- D120: Questions 9 Nov '17

European Medicines Agency (EMA)

World Health Organization (WHO)

WHO Prequalification (PQ)

Observer Countries:

- Kenya
- South Africa
- Tanzania

Essential Drug List

Sub-Saharan NRAs

- Following WHO PQ, first tier of submissions to Kenya, Malawi, Rwanda, Tanzania, Uganda, Zambia and Zimbabwe

Medicines Control Council (MCC, SA)

- Target submission Q1/2 2018

US Food and Drug Administration (FDA)

- Target submission Q3/4 2018

# Why WHO Prequalification?



- **Process to evaluate whether a drug meets global standards**  
Quality, Safety, Efficacy
- **Many African regulatory agencies use WHO prequalification to determine which new products to approve, and review EMA decisions**

# But why does it take so long?

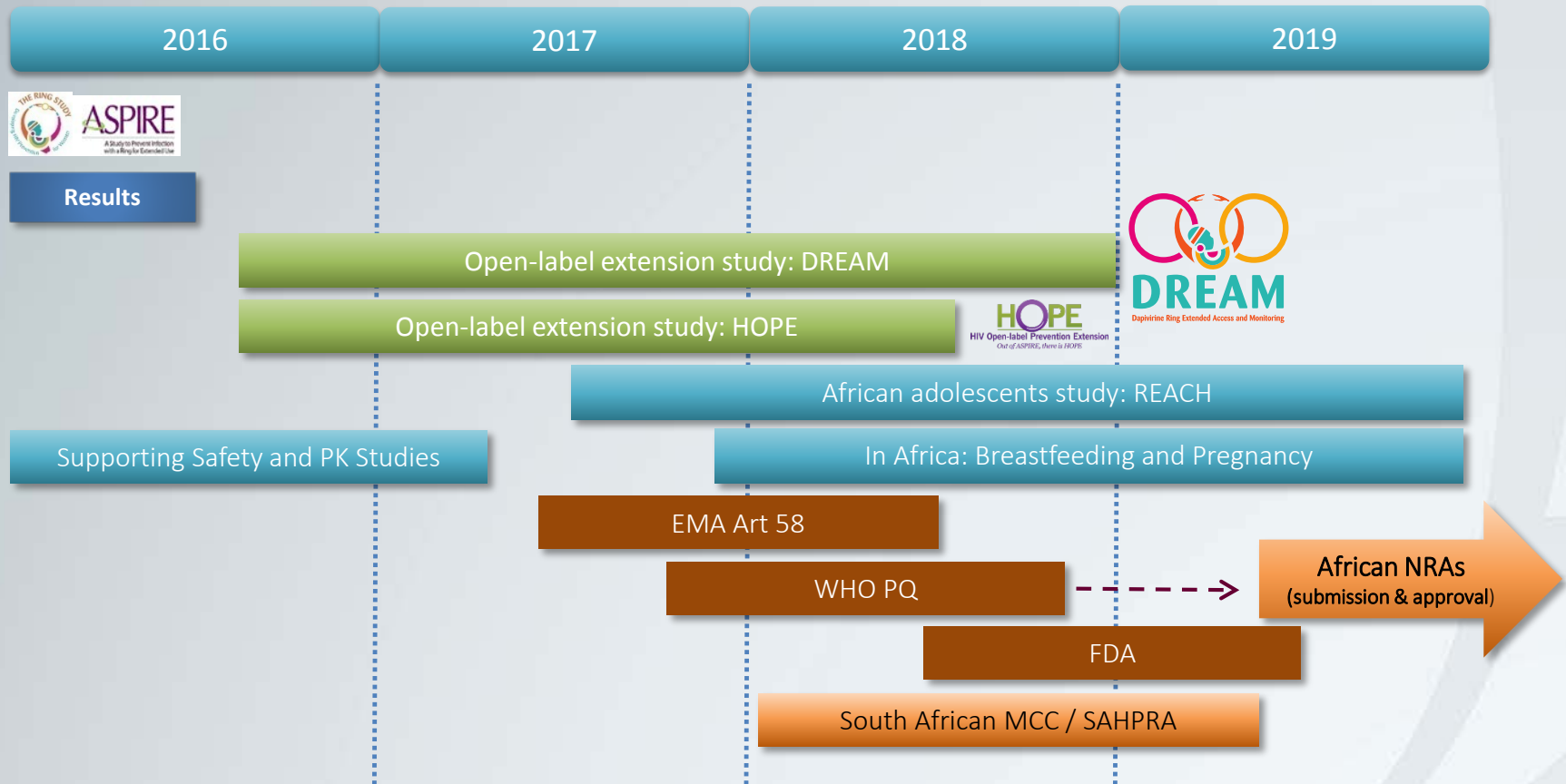
For the dapivirine ring, IPM has organised 13 years of data and findings from nearly 250 studies into each application

- 260000 pages
- 1200 files
- 69000 links
- >10 hour to upload



Submission done by eCTD

# Regulatory Timeline



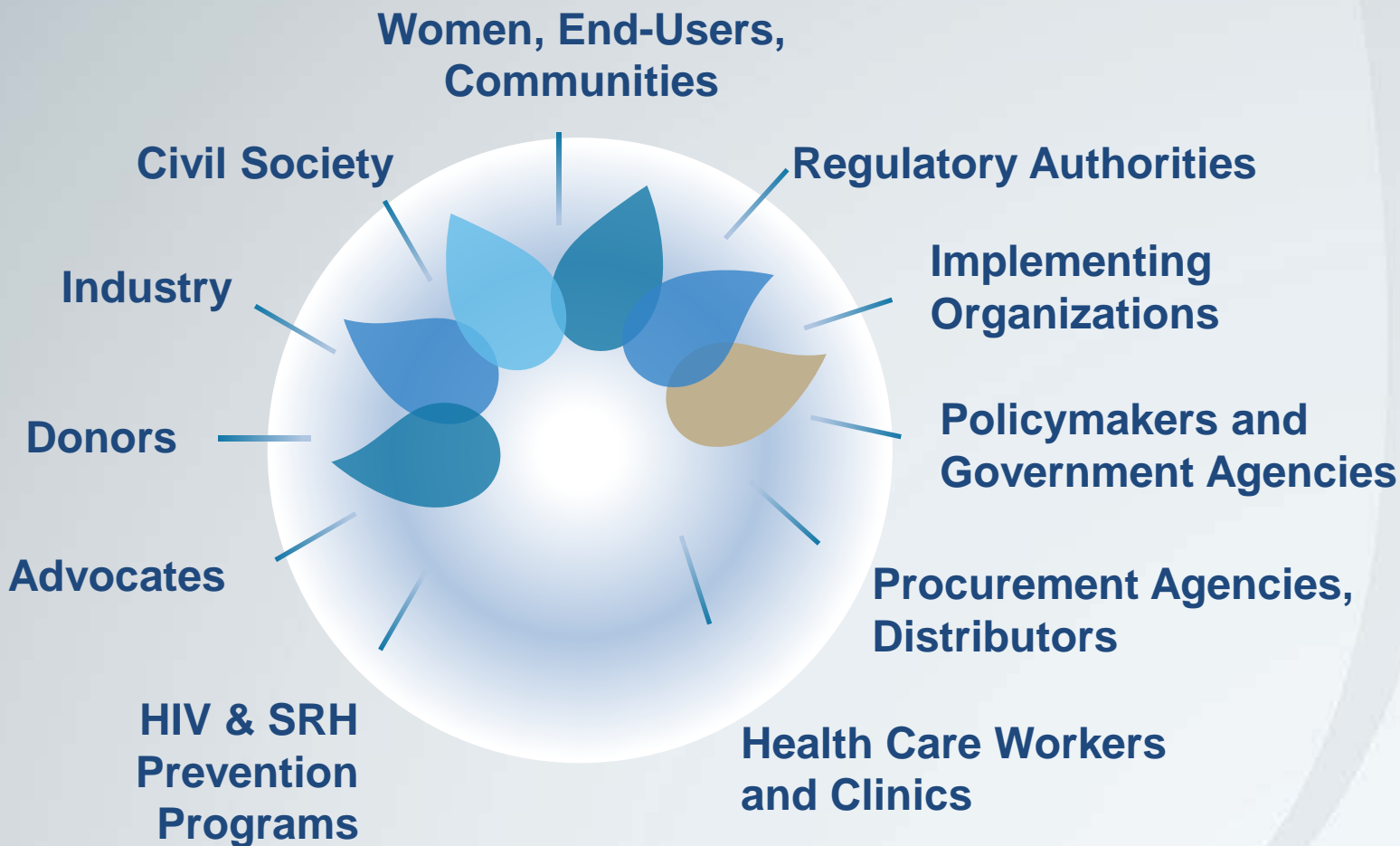


# Access



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# We need strong partnerships





# Questions



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