



MTN 023/IPM 030

The US Adolescent Dapivirine Ring Study

Project iMatter

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On behalf of MTN 023/IPM 030 protocol team

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- Phase 2a safety study of a vaginal ring containing dapivirine in adolescent females
- Collaborative effort between the MTN and the Adolescent Medicine Trials Network for HIV/AIDS Interventions (ATN) funded by the *Eunice Kennedy Shriver* National Institute of Child Health and Human Development (NICHD)

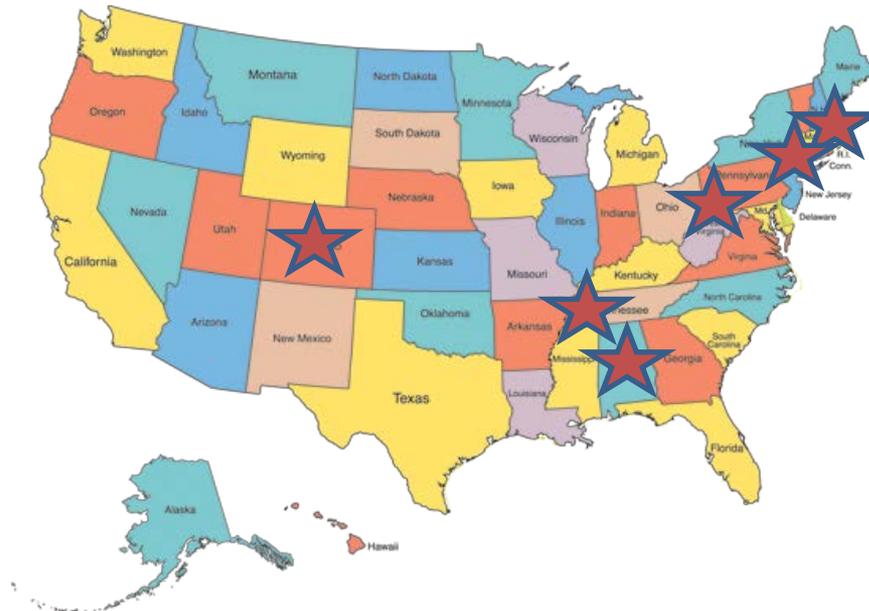
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STUDY SITES

- 4 sites initially (3 ATN, 1 MTN)
- 2 added* (1 ATN, 1 MTN)

ATN

Denver
Bronx
Boston
Memphis*



MTN

Birmingham
Pittsburgh*

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STUDY ELIGIBILITY

- 96 HIV-negative 15-17 year old teens
 - Non-pregnant and not breastfeeding
 - On an effective method of contraception x 30d
 - History of penile-vaginal intercourse at least once
 - Last pregnancy outcome > 90 days
 - Agree to use condoms during study
 - Excluded if STI/UTI at Screening/Enrollment
- Written parental consent required

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- Randomized 3:1 to DPV or placebo ring

GROUP	N	Group Description
A	72	Dapivirine VR, containing 25 mg dapivirine
B	24	Placebo VR

- Monthly ring use x 6 months

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PRIMARY OBJECTIVE:

- **Safety** To assess the safety of dapivirine (25 mg) administered via a silicone vaginal ring in HIV-uninfected adolescent females, when inserted once every 4 weeks during 24 weeks of study product use

PRIMARY ENDPOINT:

- **Grade 2 related and higher AEs**

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SECONDARY OBJECTIVES/ENDPOINTS:

- **Acceptability:** self report
- **Adherence:** self report
- **Pharmacokinetics:** DVP levels in plasma and VF

EXPLORATORY OBJECTIVES/ENDPOINTS

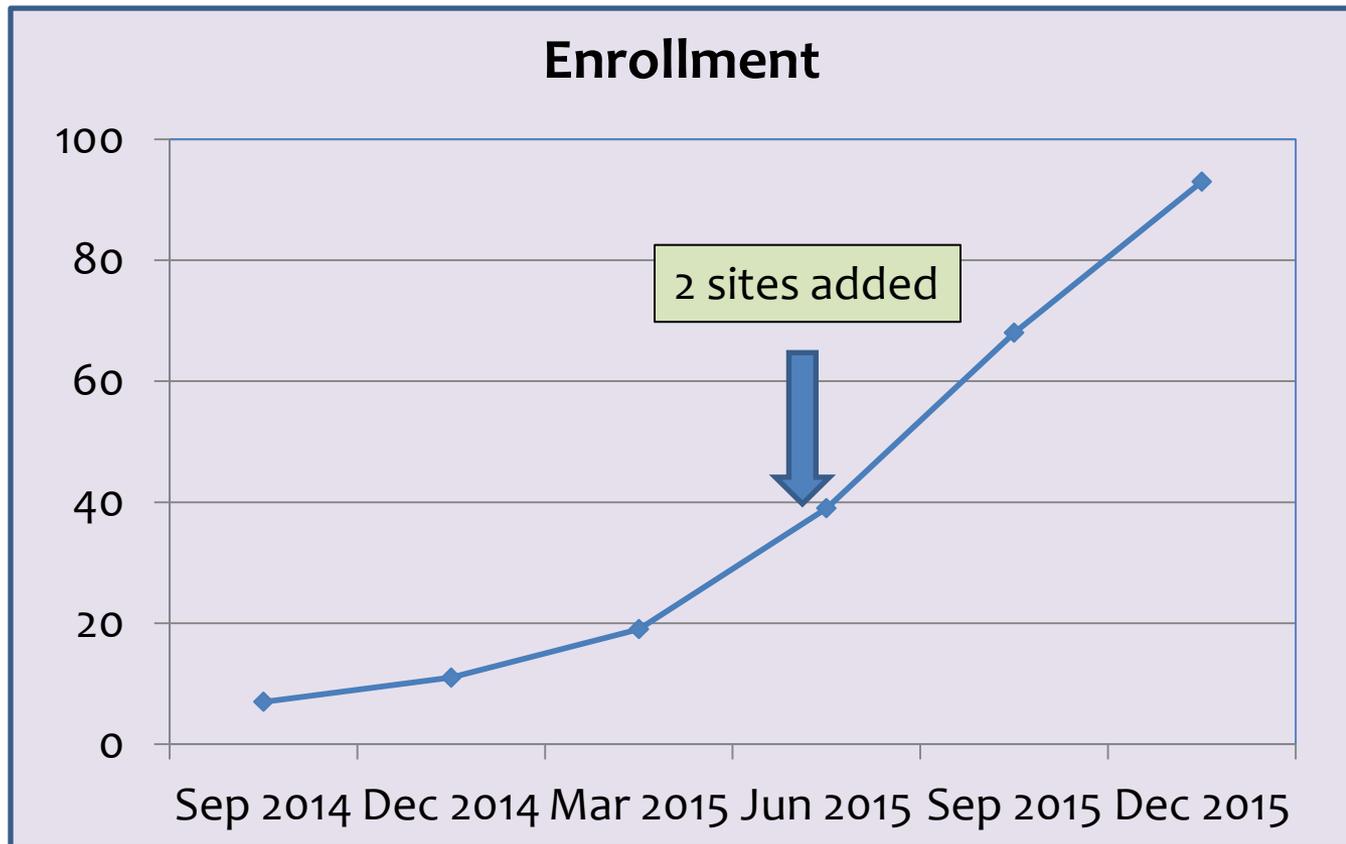
- **Acceptability:** correlation with DVP levels
- **Adherence:** correlation with DVP levels
- **Vaginal microenvironment:** changes in vaginal pH, microflora, and biomarkers

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	SCR	ENR	1 wk	2 wk	4 wk	8 wk	12 wk	16 wk	20 wk	24 wk	25 wk
Safety Labs	X									X	
Vaginal Ring		X			X	X	X	X	X		
PK				X	X		X			X	
Vaginal swabs	X	X			X		X			X	
Behavioral ?		X			X	X	X	X	X	X	

Challenging Enrollment

- Enrollment began June, 2014



- Completed January, 2016

Lessons Learned

Recruitment

Consent

Retention

Contraception

Recruitment Challenges

- Unable to access teens
 - Department of Health clinics
 - General health fairs
 - Most public and private schools
 - Youth after school programs
 - Friends of current participants
- “The study is not a good fit”
 - Concerns over promoting sex
 - Concerns over protecting teen confidentiality

Recruitment Lessons

- Traditional advertising had limited success
 - Emails, posters, fliers
 - Social medial: Facebook, Instagram



Condoms



Bus Ads



T-shirts

Recruitment Lessons

- Relying on referrals from a trusted source was most successful
 - Adolescent and Gynecology clinic staff, school nurses
 - Followed with face to face discussions with site staff
 - Reassurance about ring size
 - Reviewing consent form before parents
- Built/strengthened relationships with adolescent clinics, schools, after school programs, teen groups

Lesson #1

Find referral champions

Consent Challenges

- Parental consent and adolescent assent required
- Scheduling screening and consent was challenging
 - Off site consent visits
 - Extended clinic hours
- Ensuring participant assent was essential
 - Conducted separate interview with teens

Lesson #2

Maintain flexibility in scheduling

Retention

- 94% retention across sites
- Sites created a welcoming environment
- Teens felt valued and respected
- Site staff emphasized confidentiality
- Flexibility in scheduling was key
- Ensuring safe transport was essential
- Texting was the backbone of communication

Lesson #3

Value and respect teen participants

Contraception

- The vast majority of participants were on oral contraceptive pills or DMPA
- Sites not set up to provide long acting reversible contraception
- 3 pregnancies in a 6 month study
 - 1 termination
 - 1 miscarriage
 - 1 full term delivery

Lesson #4

Revamp contraceptive counseling with an emphasis on LARC

Other Lessons.....

- Study procedures were well tolerated
- Teens were comfortable inserting and removing the ring themselves
- The ring appeared to be well tolerated
- The teens appreciated the time and attention they received at the clinic

Summary

- Our biggest challenge was recruitment due to the inclusion criterion of a history of penile-vaginal intercourse
- Through perseverance and identifying champions in the community and adolescent clinics the team completed enrollment
- Lessons learned from Project iMatter may inform MTN-034

Acknowledgments

- Study participants and their guardians
- MTN023/IPM030 study staff
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