Rectal vs. Oral Use of On-demand PrEP

INFORMATIONAL WEBINAR

PrEP Your Booty:

Investigating the safety and acceptability of a **tenofovir-based rectal douche** for HIV prevention in cisgender men and transgender women who have sex with men.

Thursday, August 29
9:00 a.m. – 10:30 a.m. ET

WELCOME

HPTN
HIV Prevention Trials Network

THE CHOICE AGENDA
HIV prevention research - a new forum for advocacy on the latest

AVAC

Advocacy. Access. Equity.

THE CHOICE AGENDA

HIV prevention research – a new forum for advocacy on the latest

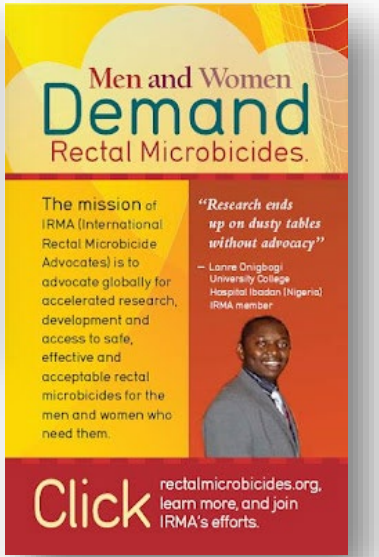
avac.org/project/choice-agenda

irma | international rectal microbicide advocates

2005 – 2020

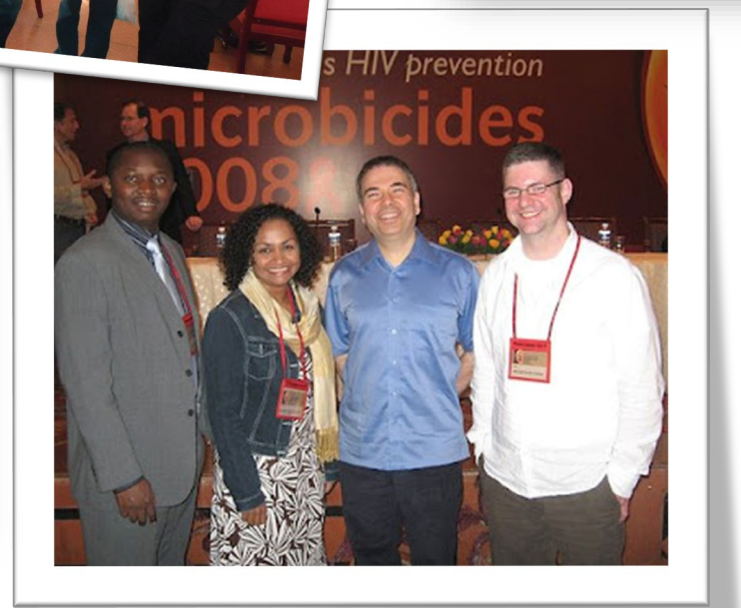
Rectal Microbicides

WE NEED LESS SILENCE AND MORE SCIENCE

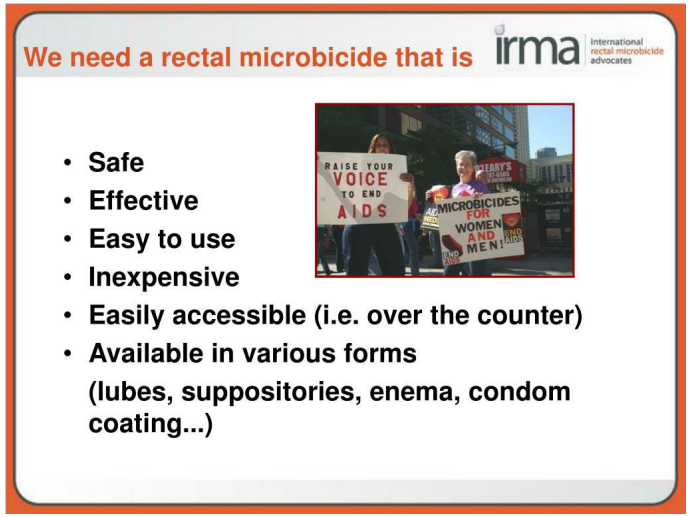


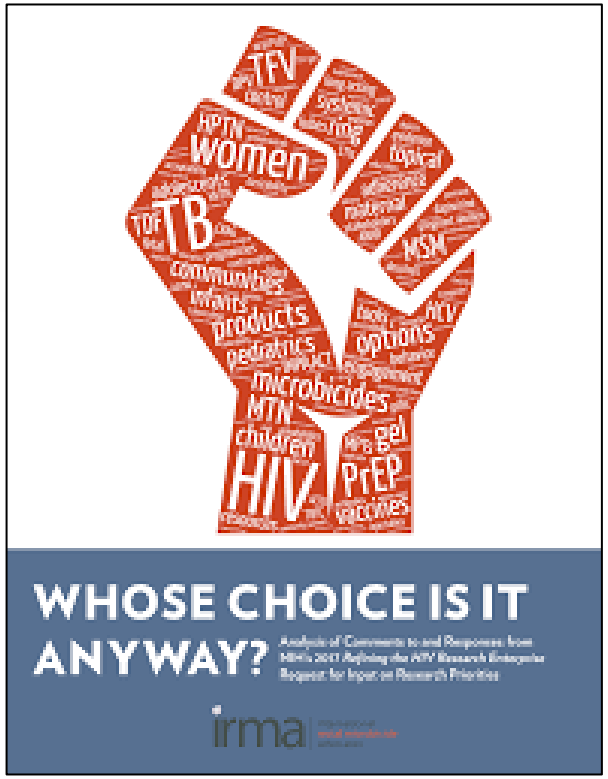
ReadyTalk

RECTAL DOUCHING AND ENEMA SURVEY

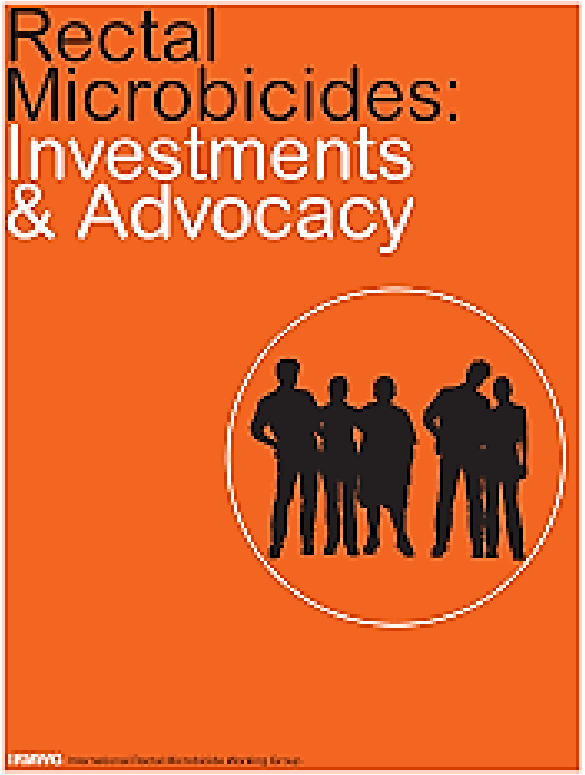


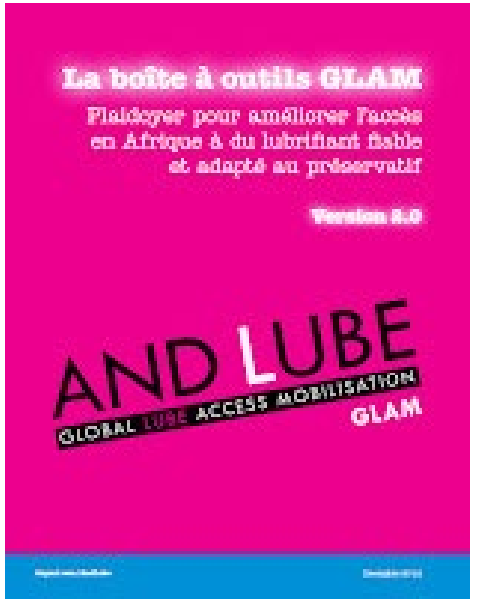

RECTAL PRIDE
WITH MICROBICIDES
VISIT IRMA
RECTALMICROBICIDES.ORG


We need a rectal microbicide that is
irma
international rectal microbicide advocates
Safe
Effective
Easy to use
Inexpensive
Easily accessible (i.e. over the counter)
Available in various forms
(lubes, suppositories, enema, condom coating...)
RAISE YOUR VOICE TO END AIDS
MICROBICIDES FOR WOMEN AND MEN!

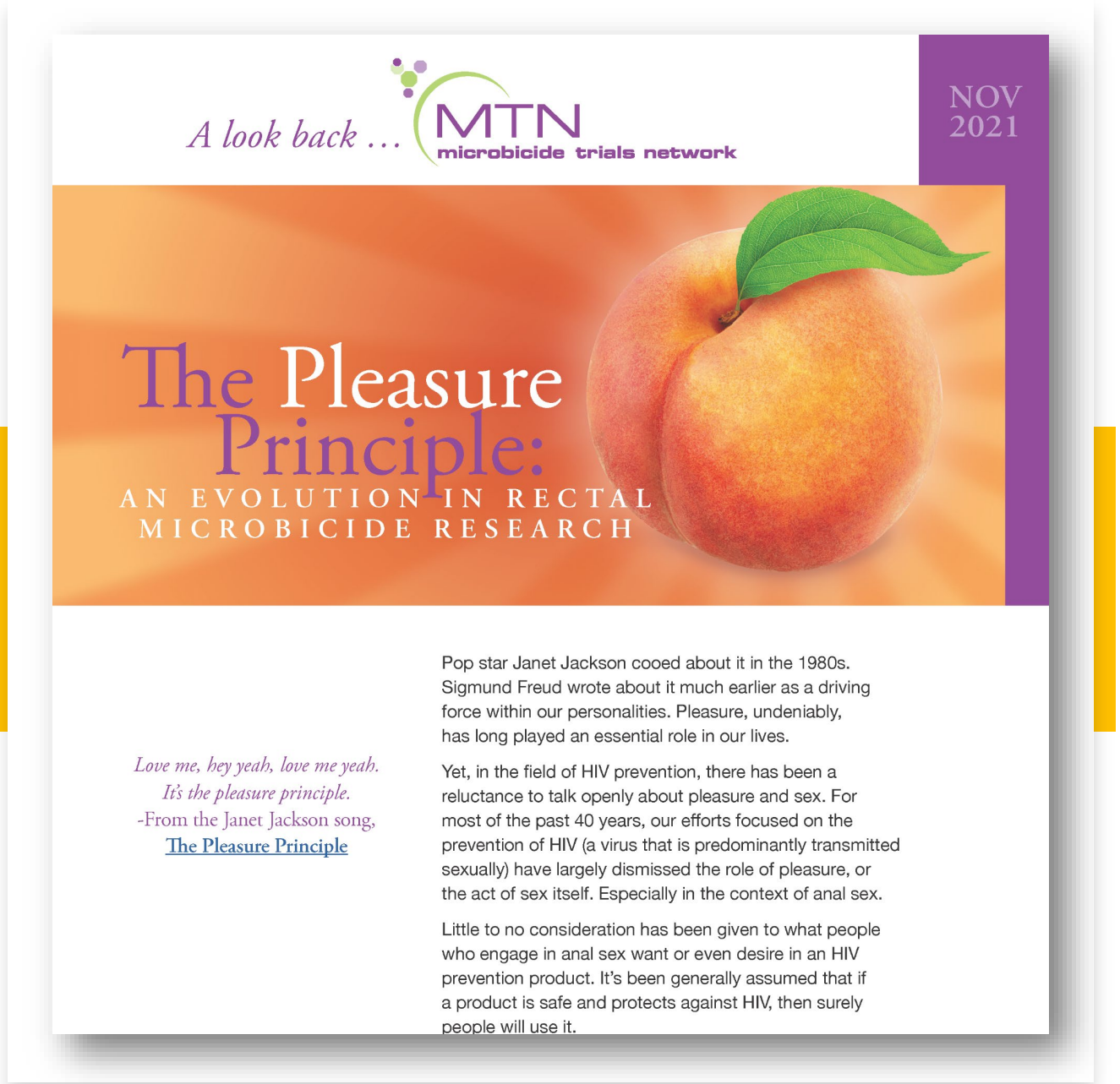

TFV
HPTN
women
TB
topical
MSM
communities
products
pediatrics
options
microbicides
MTN
children
HIV
gel
PrEP
vaccines
WHOSE CHOICE IS IT ANYWAY?
irma


THE RECTAL REVOLUTION IS HERE
NOW PLAYING


Rectal Microbicides: Investments & Advocacy


La boîte à outils GLAM
Plaidoyer pour améliorer l'accès en Afrique à du lubrifiant fiable et adapté au préservatif
Version 2.0
AND LUBE
GLOBAL LUBE ACCESS MOBILISATION
GLAM


AFRICA NEEDS RECTAL MICROBICIDES TOO
STRATEGIES TO ENSURE AFRICA IS ON THE RECTAL MICROBICIDE RESEARCH AND ADVOCACY MAP



A look back … MTN microbicide trials network

NOV 2021

The Pleasure Principle:

AN EVOLUTION IN RECTAL MICROBICIDE RESEARCH

Love me, hey yeah, love me yeah.
It's the pleasure principle.
-From the Janet Jackson song,
The Pleasure Principle

Pop star Janet Jackson cooed about it in the 1980s. Sigmund Freud wrote about it much earlier as a driving force within our personalities. Pleasure, undeniably, has long played an essential role in our lives.

Yet, in the field of HIV prevention, there has been a reluctance to talk openly about pleasure and sex. For most of the past 40 years, our efforts focused on the prevention of HIV (a virus that is predominantly transmitted sexually) have largely dismissed the role of pleasure, or the act of sex itself. Especially in the context of anal sex.

Little to no consideration has been given to what people who engage in anal sex want or even desire in an HIV prevention product. It's been generally assumed that if a product is safe and protects against HIV, then surely people will use it.

Read the story of rectal microbicide research.

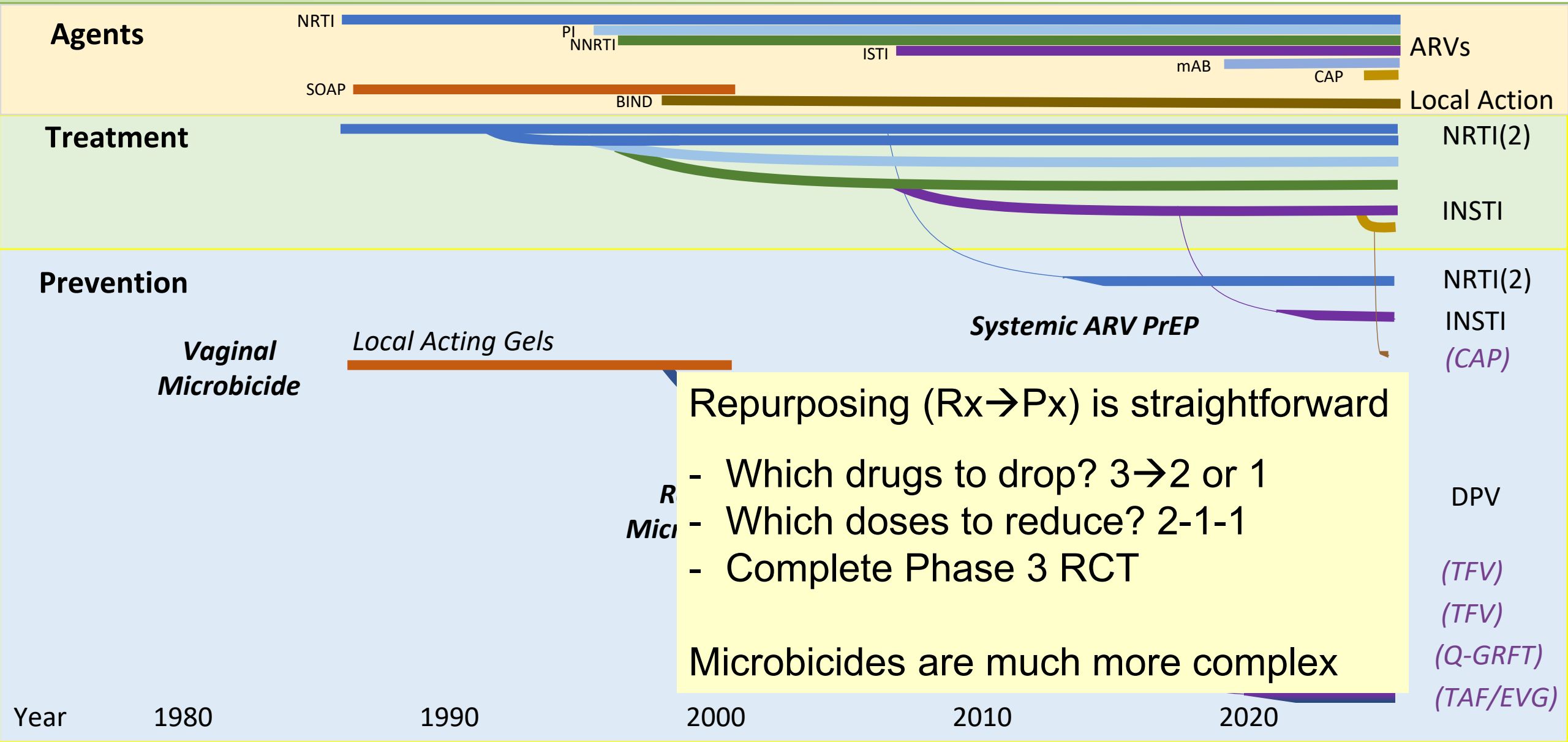
Ready to REV UP? …the road to HPTN 106!

Craig Hendrix
Johns Hopkins University

Disclosures

- Research grants
  - Gilead, Merck
- US Patents
  - 10,092,509; 10,646,434; Hypotonic microbicides
- Prionde Biopharma, LLC
  - Rectal microbicide product development
  - Founder, manager, no fiduciary or financial role
  - Conflicts managed by Johns Hopkins University

PrEP Development History



Repurposing (Rx→Px) is straightforward

- Which drugs to drop? 3→2 or 1
- Which doses to reduce? 2-1-1
- Complete Phase 3 RCT

Microbicides are much more complex

Key Microbicide Questions?

- *Is candidate drug product protective (antiviral)?*
- *Where is the anatomical target for drug action?*
- *What is drug concentration & duration at target?*
- *Do any behaviors or products alter drug distribution or effect?*
- *Are any drugs, vehicles, sex, or sex products toxic?*
- *If we develop it, will folks use it?*

Vaginal Microbicide Lessons

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Methods/Vehicle Development

- "HIV" surrogate distribution?
- Tissue pharmacology?
- Luminal distribution?
- Pre-clinical Challenge Models?
- Vaginal product optimization?
- End-User Product Experience?

Drug Product Development

Phase I ***Phase II*** ***Phase III***

No NDA

Vaginal Formulation (VF)
3,111 mOsm/kg
TFV 1%

HPTN 050
PK blood
AEs, culposcopy

HPTN 059
PK blood
AEs

CAPRISA 004 BAT 24 - 39% RRR (73% post hoc)
VOICE QD – NS (88% post hoc)
FACTS 001 BAT 24 - NS

- Only DPV vaginal ring even partly successful at licensure (*with many more clinical studies in the development path*)
- Failed to bring many products to regulatory review
- Development without many necessary tools (left)
- In parallel - richer set of behavioral & biomedical tools developed
- Rectal microbicide development has been a driver & beneficiary

Key Microbicide Questions?

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HIV Prevention Trials Network

- ✓ *Is candidate drug product protective (antiviral)?*
- *Where is the anatomical target for drug action?*
- *What is drug concentration & duration at target?*
- ✓ *Do any behaviors or products alter drug distribution or effect?*
- ✓ *Are any drugs, vehicles, sex, or sex products toxic?*
- ✓ *If we develop it, will folks use it?*

Rectal Microbicide Development

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Methods/Vehicle Development	*Drug Product Development*	*Phase I*	*Phase II*	*Phase III*
JHU "HIV" surrogate distribution				
JHU Tissue pharmacology				
CDC/NIH Luminal PK-D imaging				
NIH PD Surrogates: Explant, BLT, NHP				
MDP 2/2b RF vehicle development				
MDP 1 Enema vehicle development				
JHU Lube dosing feasibility				

Rectal Microbicide Development

HPTN HIV Prevention Trials Network

Methods/Vehicle Development

- **JHU** "HIV" surrogate distribution
- **JHU** Tissue pharmacology
- **CDC/NIH** Luminal PK-D imaging
- **NIH** PD Surrogates: Explant, BLT, NHP
- **MDP 2/2b** RF vehicle development
- **MDP 1** Enema vehicle development
- **JHU** Lube dosing feasibility

Drug Product Development

Phase I ***Phase II*** ***Phase III***

Vaginal Formulation (VF)
3,111 mOsm/kg
TFV 1%

RMP-02/MTN-006 → ***No Phase II •Safety/AEs***

Not well tolerated Rectal Toxicity

Rectal Microbicide Development

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Methods/Vehicle Development

- **JHU** "HIV" surrogate distribution
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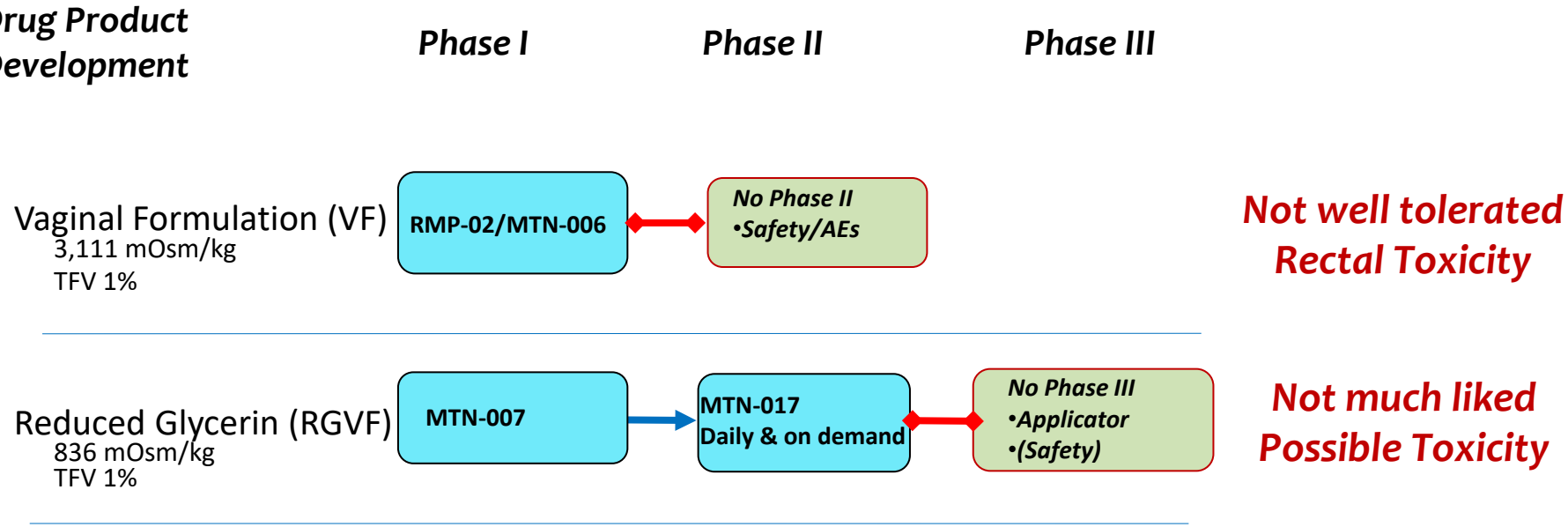

Rectal Microbicide Development

HPTN HIV Prevention Trials Network

Methods/Vehicle Development

- **JHU** — "HIV" surrogate distribution
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- **CDC/NIH** — Luminal PK-D imaging
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- **MDP 2/2b** — RF vehicle development
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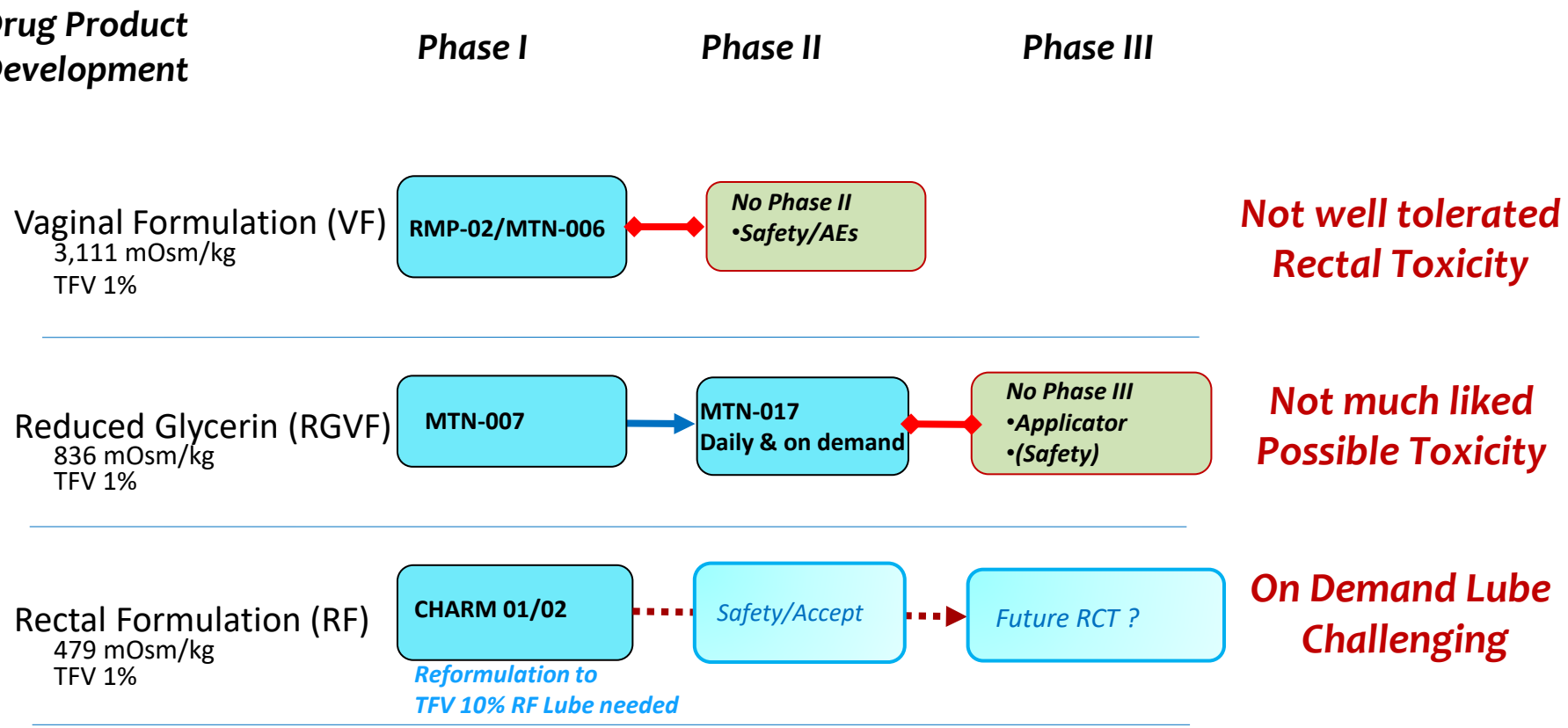

Rectal Microbicide Development

HPTN HIV Prevention Trials Network

Methods/Vehicle Development

- **JHU** "HIV" surrogate distribution
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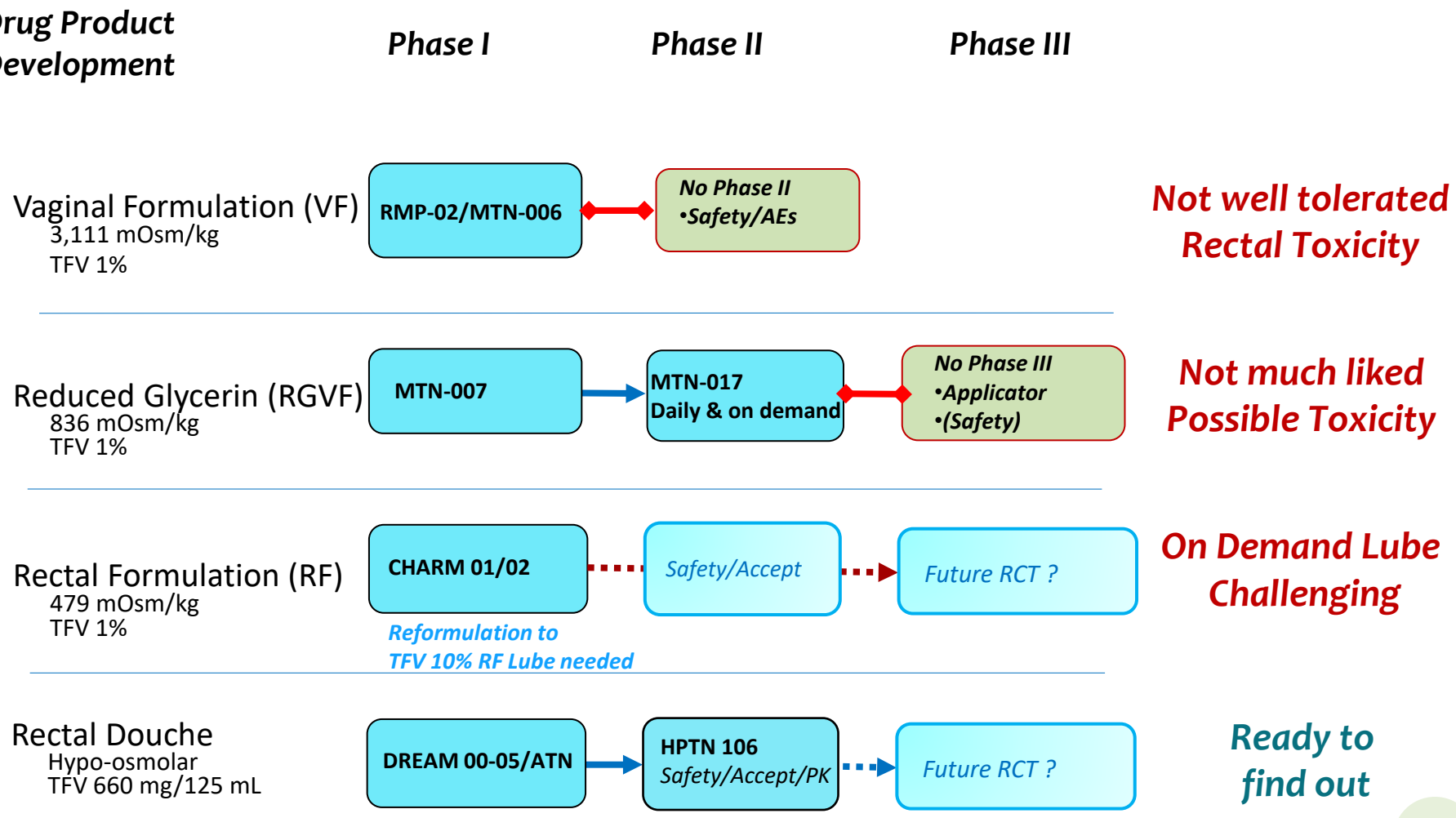

Rectal Microbicide Candidates?

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Drug	Formulation	NHP SHIV Challenge	Clinical PK	Ex Vivo HIV Challenge	Toxicity	Acceptability	BHVR-CONG	Status
TFV	VF gel	Rect/Vag	Sustained	0.5 log_{10}	AE's	Modest		End
TFV	RGVF gel	Rectal	Sustained	0.8 log_{10}	none	Modest		End
TFV	RF gel	-	Sustained	1.0 log_{10}	none	High	*lube*	**Phase 1**
TFV	**liquid**	**Rectal**	**Sustained**	**1.6 log_{10}**	**none**	**High**	**douche**	**Phase 2**
DPV	gel	-	Brief	1.0 log_{10}	none	High		End
DPV	gel	-	Brief	0.3 log_{10}	none	High	lube	End
PC-1005	gel	Rect/Vag	Brief	0.5 log_{10}	none	High		End
IQP-0528	gel	-	Brief	1.6 log_{10}	minor	High		End
MVC	gel	Rectal	Brief	NR	none	High		End
OB-002H	gel	Vaginal		ND	none	High		?
Q-GRFT	**liquid**	**(Vaginal)**	**Moderate**	**0.4 log**	**none**	**High**	**douche**	**Phase 1**
TAF/EVG	**insert**	**Rect/Vag**	**Sustained**	**2.0 log_{10}**	**none**	**High**		**Phase 1**

NR not relevant; ND not done

Vaginal Microbicide Douche?

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- Optimal product protects on demand vaginal & rectal sex
- 40% of HIV infection is women due to anal sex[1]
- Douching very common among FSW[2], not well studied
- Vaginal douching poses new product challenges
- Vaginal douche optimization under study

[1]O'Leary et al., AIDS Behav 2017; Elmes et al., Am J Repro Immunol 2020
[2]Pines et al., Int J STD AIDS 2019; Pines, et al., BMC Public Health 2018

Next Steps?

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Rectal vs. Oral Use of On-demand PrEP

Responding to the Demand for Rectal Microbicides

Mark Marzinke, PhD

Johns Hopkins University
School of Medicine

HPTN
HIV Prevention
Trials Network

HPTN 106
REV UP

Disclosures

- I have no relevant conflicts to disclose

The Need for Rectal Microbicide Products

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- Unprotected receptive anal intercourse (RAI) is the highest risk sexual activity of HIV transmission
- RAI is a very common human behavior. Humans of all genders and sexual identities practice RAI in both the developed and developing world.
- Most people use products in preparation for, or in conjunction with, RAI

What Is the Product Profile of a Rectal Microbicide?

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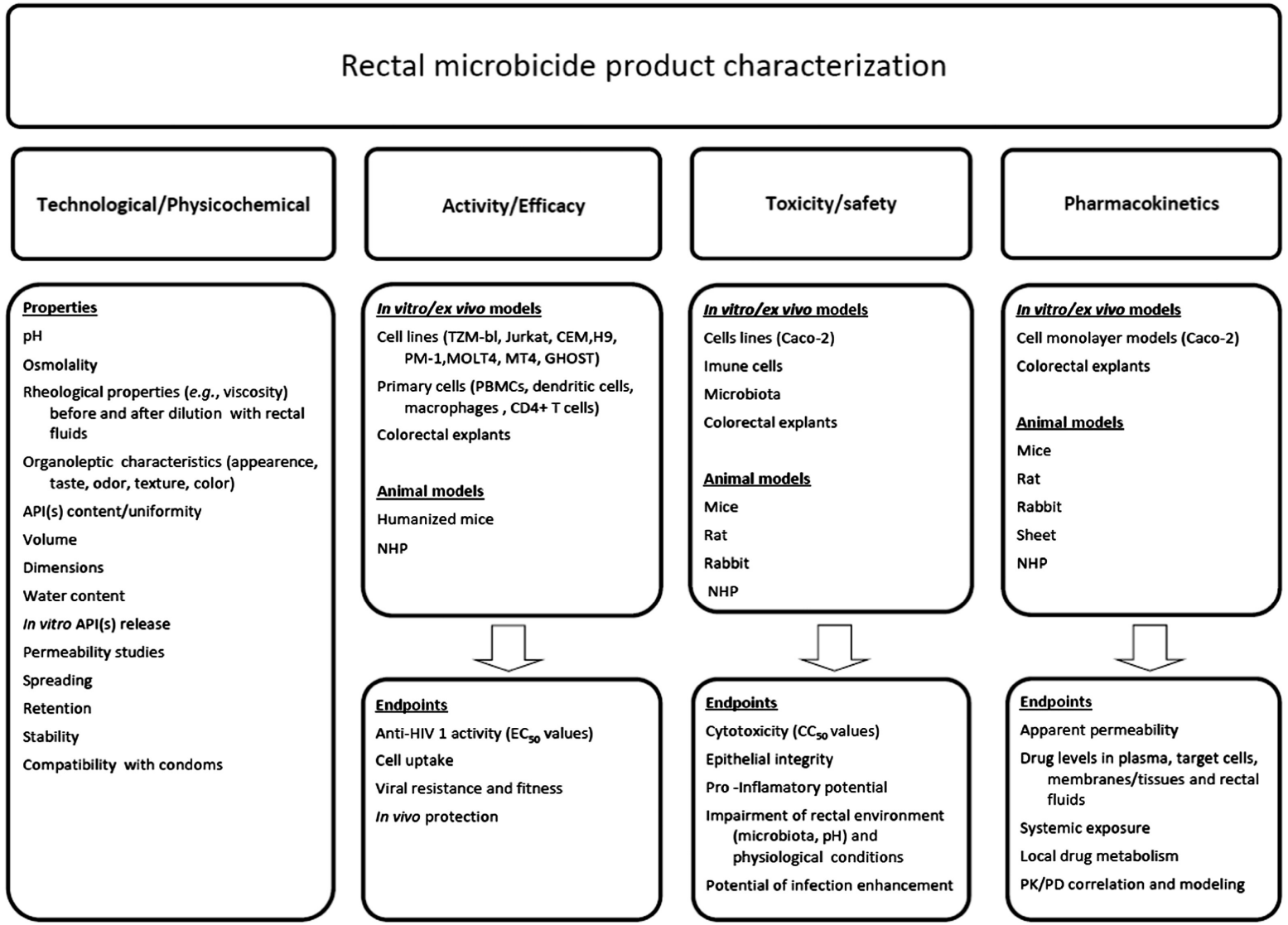
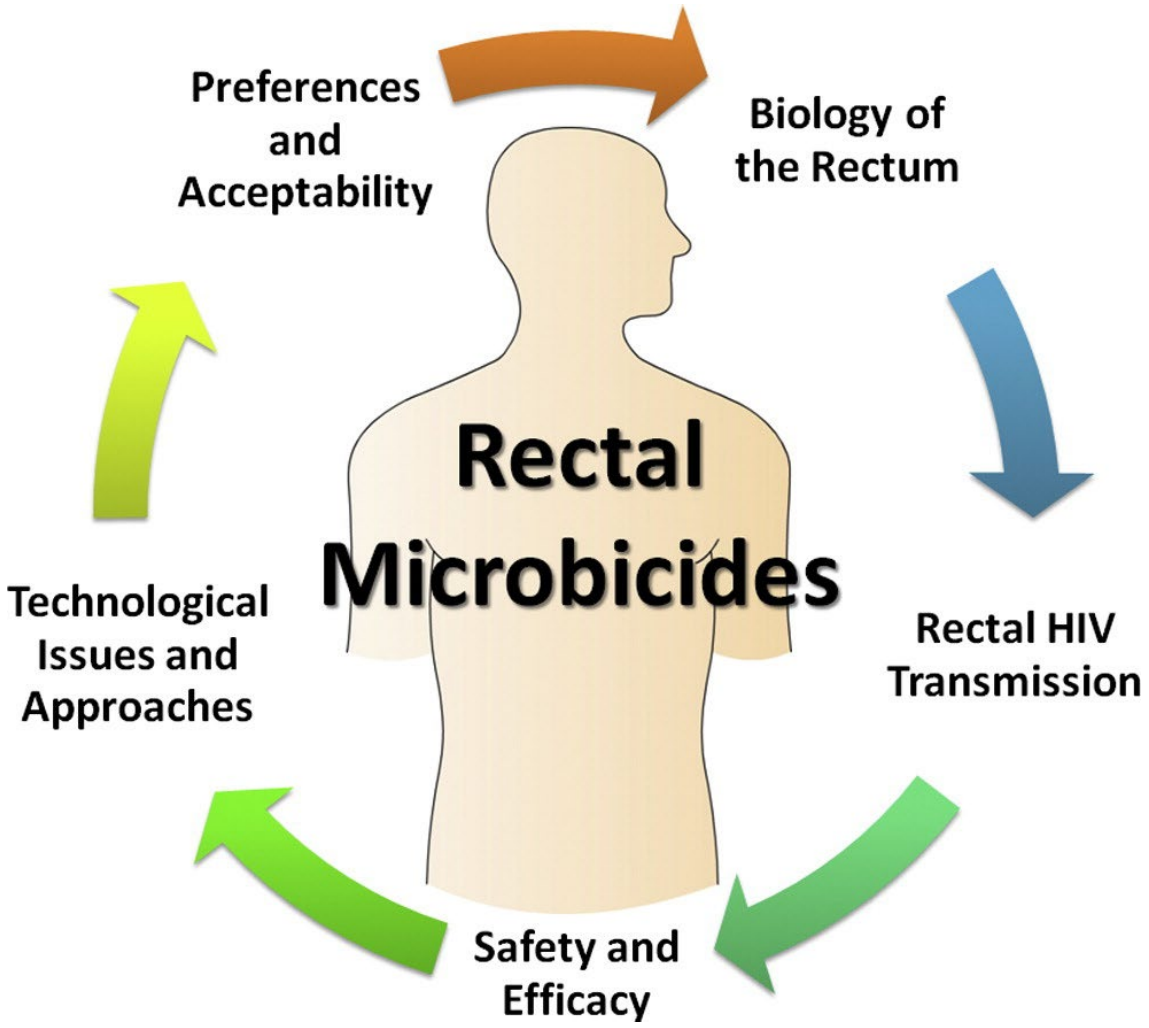


Nunes et al. J Contr Rel, 2014

What Is the Product Profile of a Rectal Microbicide?



Nunes et al. J Contr Rel, 2014

Considerations and Rationale for Rectal Microbicides

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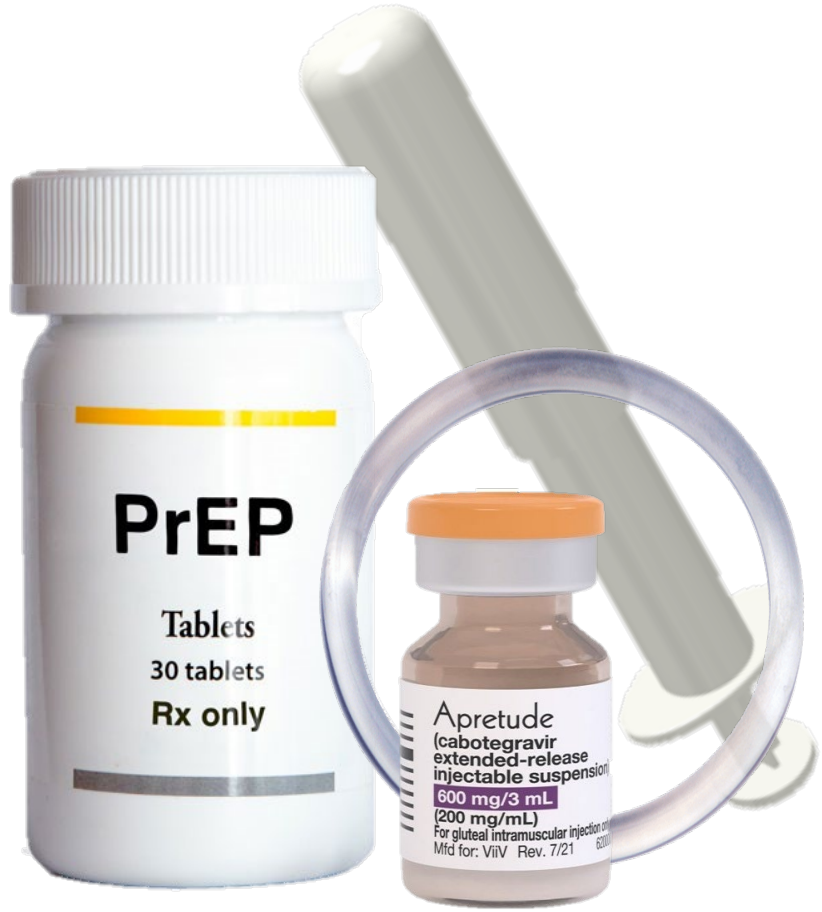
- Having a product that does not need a provider to administer (user-driven)
- Non-systemic exposure to drugs/microbicidal agents
- Not all people want to commit to a drug or modality continuously/long-term
- Efficacy is not the only product attribute that is important

Biological Rationale for Rectal Microbicides

- Single-agent drug administration has proven to be effective in the oral, topical, and long-acting spaces
  - Oral TDF
  - DPV IVR
  - Injectable CAB-LA and *LEN*
- On-Demand has proven efficacious
  - Oral F/TDF in persons assigned male sex at birth
  - TFV vaginal gel
- Topical products (DPV IVR, TFV vaginal gel) have proven efficacious with high adherence



Rectal Microbicide Development: PrEP Douche

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HIV Prevention Trials Network

PrEP Rectal Douche

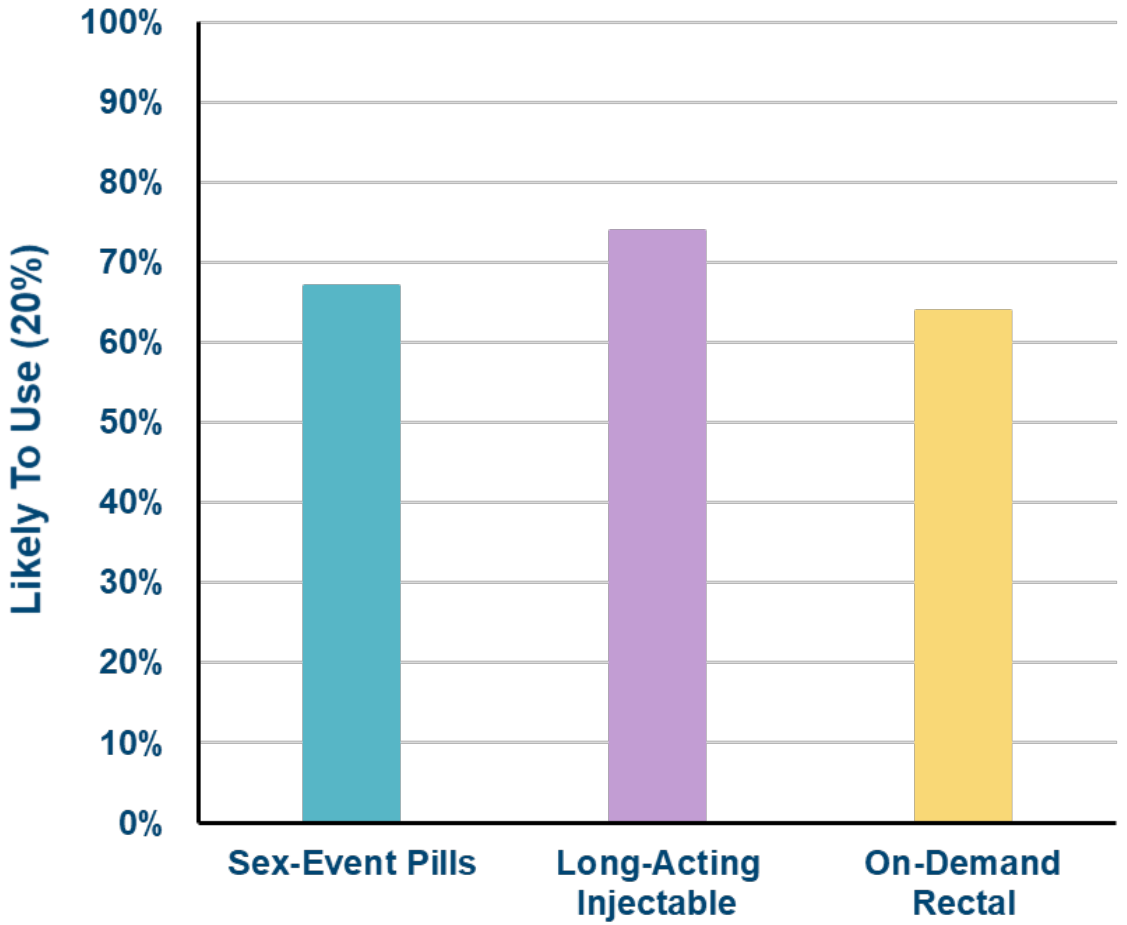
- On-demand, use only when needed
- Topical (locally active), not systemic
- Behaviorally Congruent

Opportunity for Rectal Microbicides: Behavioral Congruence

- Leverages an existing behavior that can be used as a dosing strategy to reduce the new behaviors needed for use
  - May lead to greater uptake and consistent product use
  - Relies on existing behaviors
  - Aligns with existing behaviors

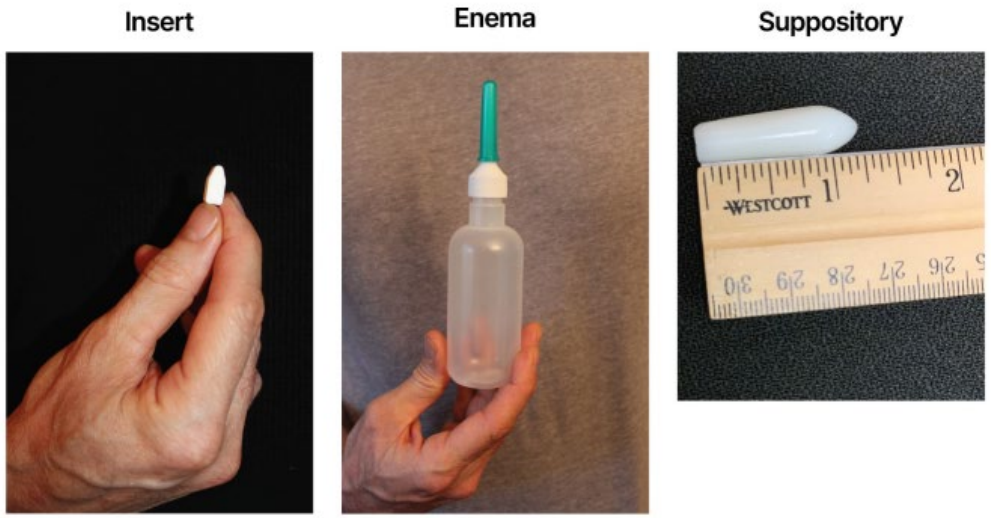
Opportunity for Rectal Microbicides: More Choice

- Survey among MSM (n=782) from three US cities (Atlanta, Detroit, New York City)
  - Most participants stated they were likely to use each formulation when available
  - Based on likelihood and preference assessments, two groups of potential product users were identified:
    - Sexual event-based products
      - More likely to be preferred by non-PrEP users
    - Non-sexual event-based products (daily pill, long-acting injectable)
      - More likely to be preferred by current PrEP users



Mansergh et al. JIAS, 2021

Rectal Microbicide Product Options: MTN-035 (DESIRE Study)

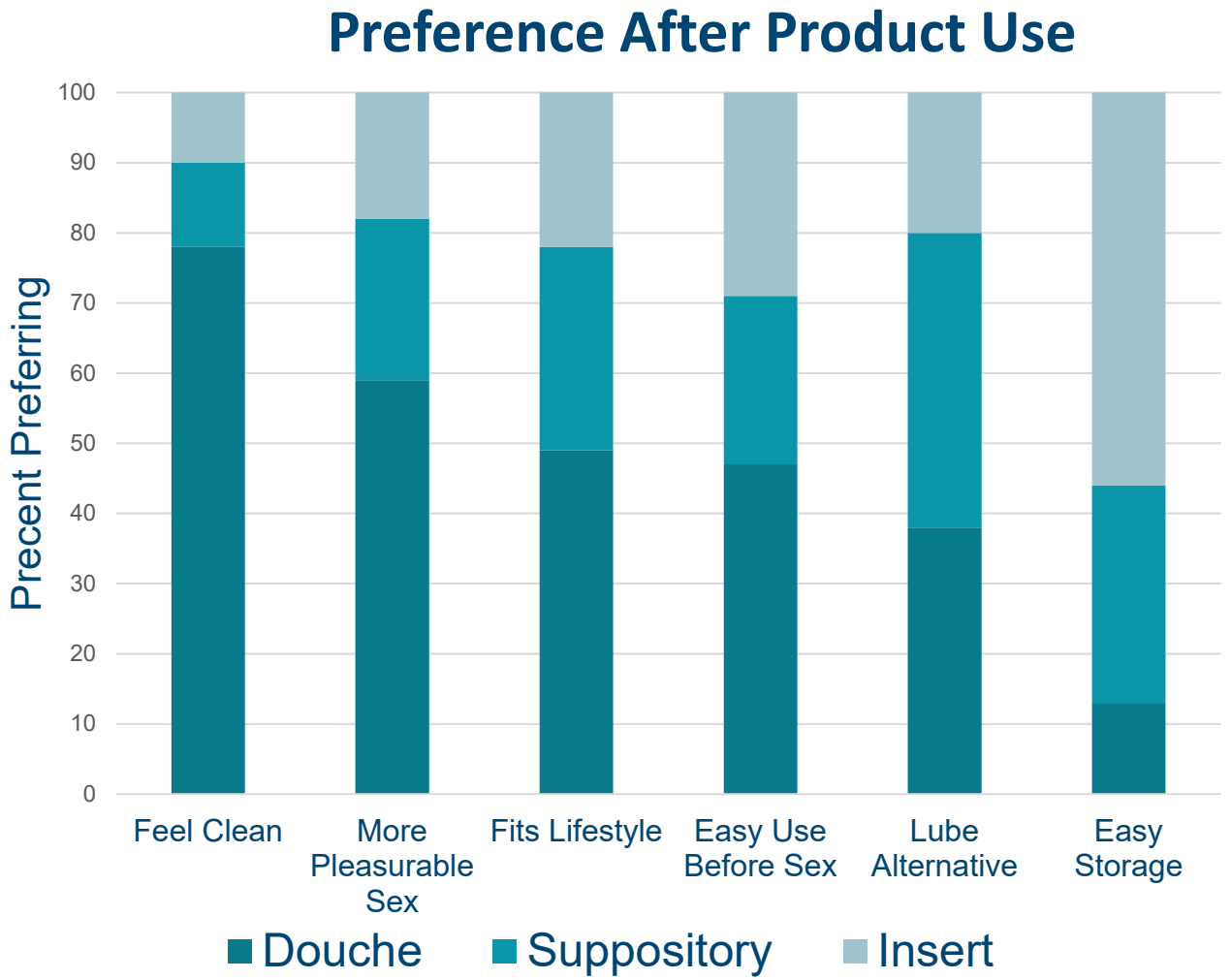


- Evaluated safety, acceptability, and adherence of three rectal microbicide placebo formulations
  - 217 Transgender men, transgender women, and cisgender men who have sex with men, aged 18-35 enrolled in study
  - Products used for 4 weeks, within 30 min-3 h prior to RAI, following usual RAI practices
  - United States, Malawi, Peru, Thailand, South Africa

Bauermeister et al. PLoS One, 2023

Rectal Microbicide Adherence and Acceptability: MTN-035

Product	Acceptability	Adherence
Douche	73%	83%
Insert	72%	75%
Suppository	66%	74%



Bauermeister et al. PLoS One, 2023
Bauermeister, et al. IAS 2021

Rectal Microbicide Adherence and Acceptability: MTN-035

- Based on computer-assisted self-interview (CASI) questionnaire completed by all participants:
  - Rectal douche most preferred product in the United States, Peru, and South Africa
  - Suppository most preferred by participants from Malawi
  - Inserts most preferred by participants from Thailand

- Qualitative interviews revealed following douche preferences attributed to:
  - Familiar
  - Easy to use
  - Best to use in conjunction with sex (behavioral congruence)
  - Dual function (cleanliness + protection)

Giguere et al. AIDS Behav, 2024

Road to REV UP (HPTN 106)

HPTN
HIV Prevention Trials Network

A Phase 2 Crossover Study of On-Demand Prep Formulations Comparing Rectal and Oral Tenofovir-Based Prep Evaluating Extended Safety, Acceptability, and Pharmacokinetics-Pharmacodynamics

Protocol Chair: Craig Hendrix, MD

Protocol Co-Chair: Mark Marzinke, PhD

Rectal vs. Oral Use of On-demand PrEP

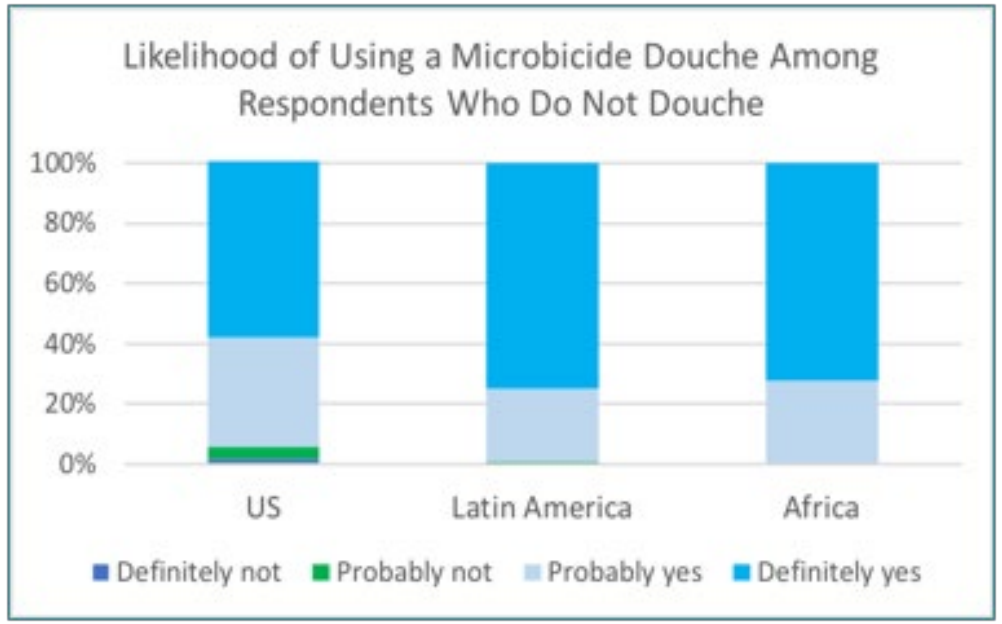
Road to REV UP: Development of a Rectal Enema as a Microbicide (DREAM) Program

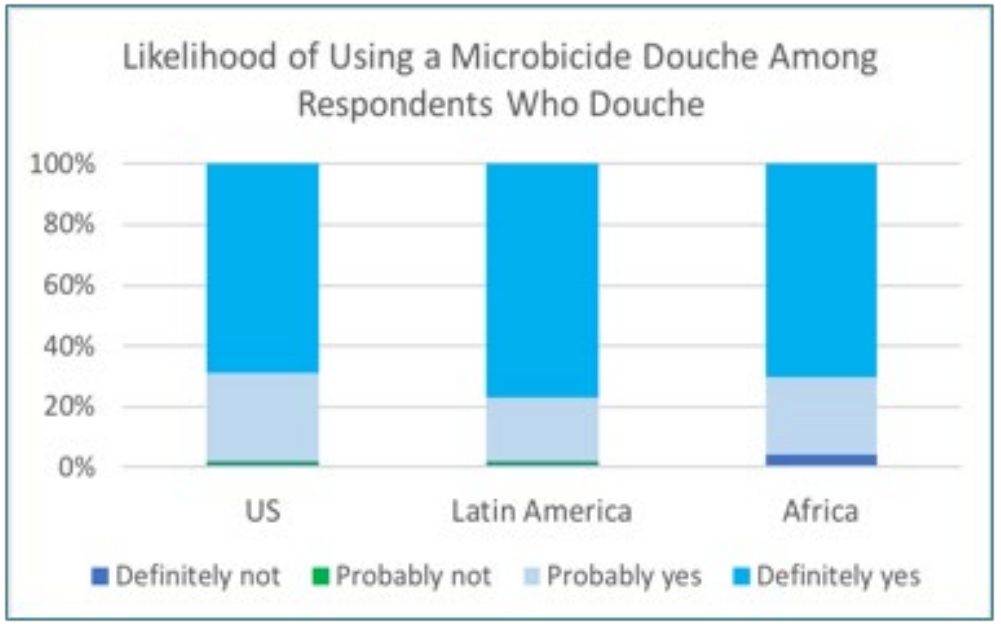
HPTN HIV Prevention Trials Network

- The DREAM Program Project Grant facilitated foundational work that evaluated multiple aspects of a medicated TFV douche
  - Behavioral
  - Safety
  - Pharmacological

Behavioral Survey of Potential User Preferences (DREAM-00)

- 5,127 respondents from 52 countries
  - 80% US, 63% Latin America, 73% Africa douche before RAI
  - >80% who douche, do so <1 hour before sex
  - >95% respondents likely to use medicated douche
  - 96% insertive partners support RAI partners using medicated douche





Giguere et al. CROI 2020 (Abstract 998)

Variability in Douche Delivery Options

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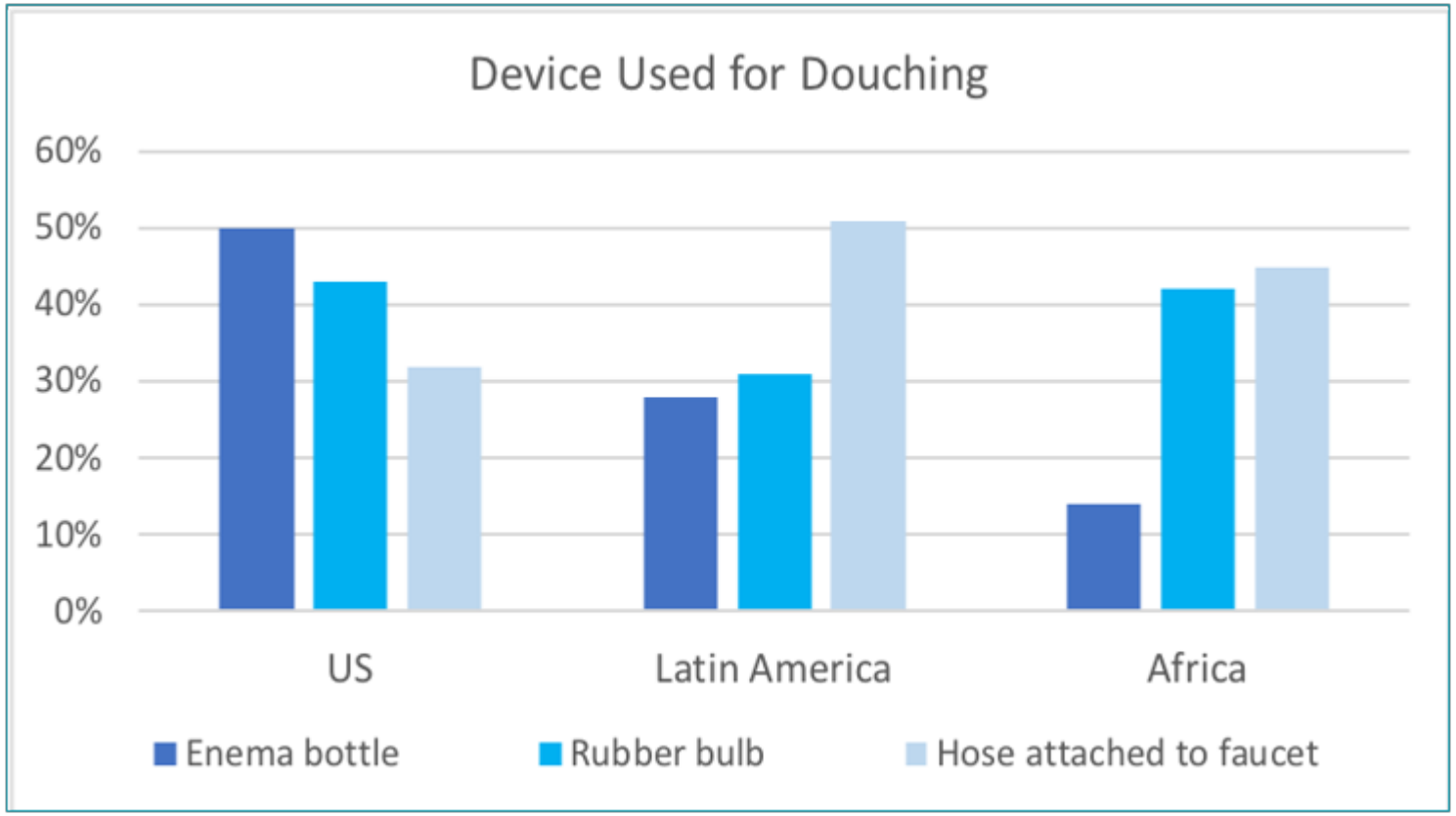
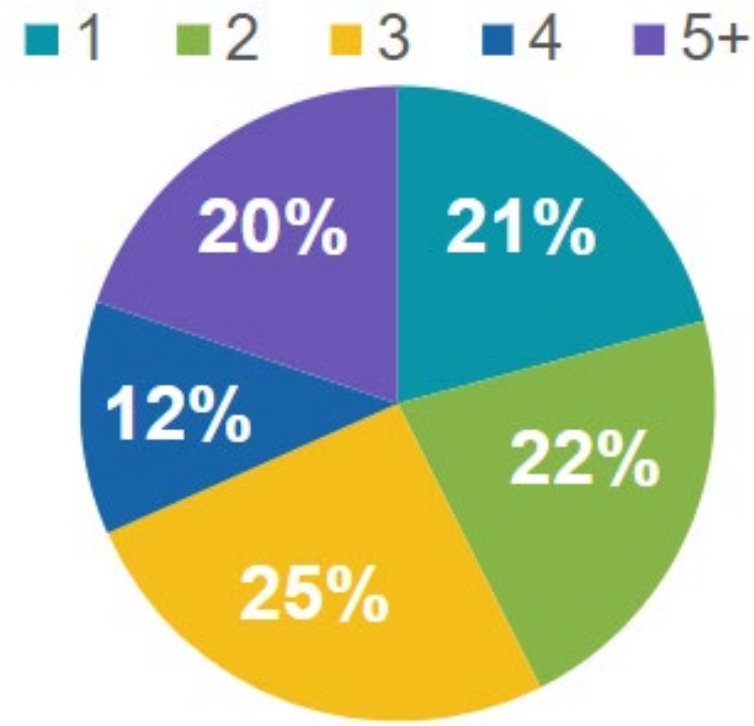
Douche Device



Number of Douches



Giguere et al. CROI 2020 (Abstract 998)

Variability in Douche Delivery Options

HPTN HIV Prevention Trials Network

Douche Device **Number of Douches**

HPTN 106 (REV UP) will evaluate the addition of a TFV sachet to an enema bottle

Giguere et al. CROI 2020

Safety of TFV Rectal Douche (DREAM Program)

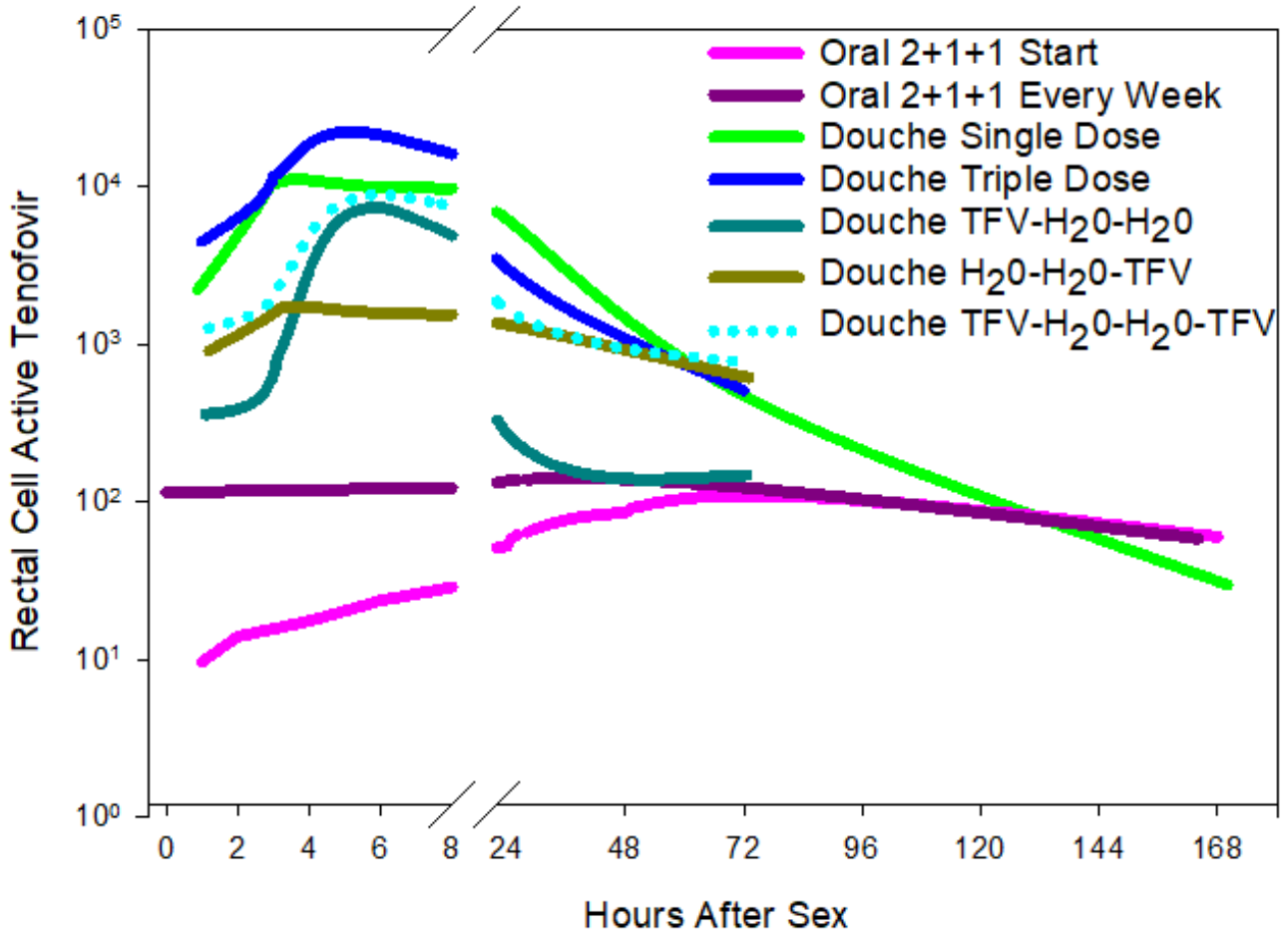
- Phase 1 Studies
  - 4 Studies, 42 Participants, 110 total doses
- Histology
  - No change from baseline: IBD scale, epithelial denudation, lamina propria hemorrhage

Study	Design	N	Grade 1	Grade 2	Grade 3	Attrib.	SAE
DREAM-01	hypo & iso, 3 doses	21	56	2	3	2	1
DREAM-02	hypo, + sex, 2 doses	9	5	6	0	1	0
DREAM-03	hypo, + H2O douches, 3 doses	6	27	12	0	2	0
DREAM-ATN	hypo, younger (18-24), 1 dose	8	2	4	0	0	0
Total		**42**	**90**	**24**	**3**	**5**	**1**

Attributable: all grade 1, reversible (2 pelvic discomfort; 1 rectal dryness, 1 blood tinged mucus h/o IBD; 1 bloating)

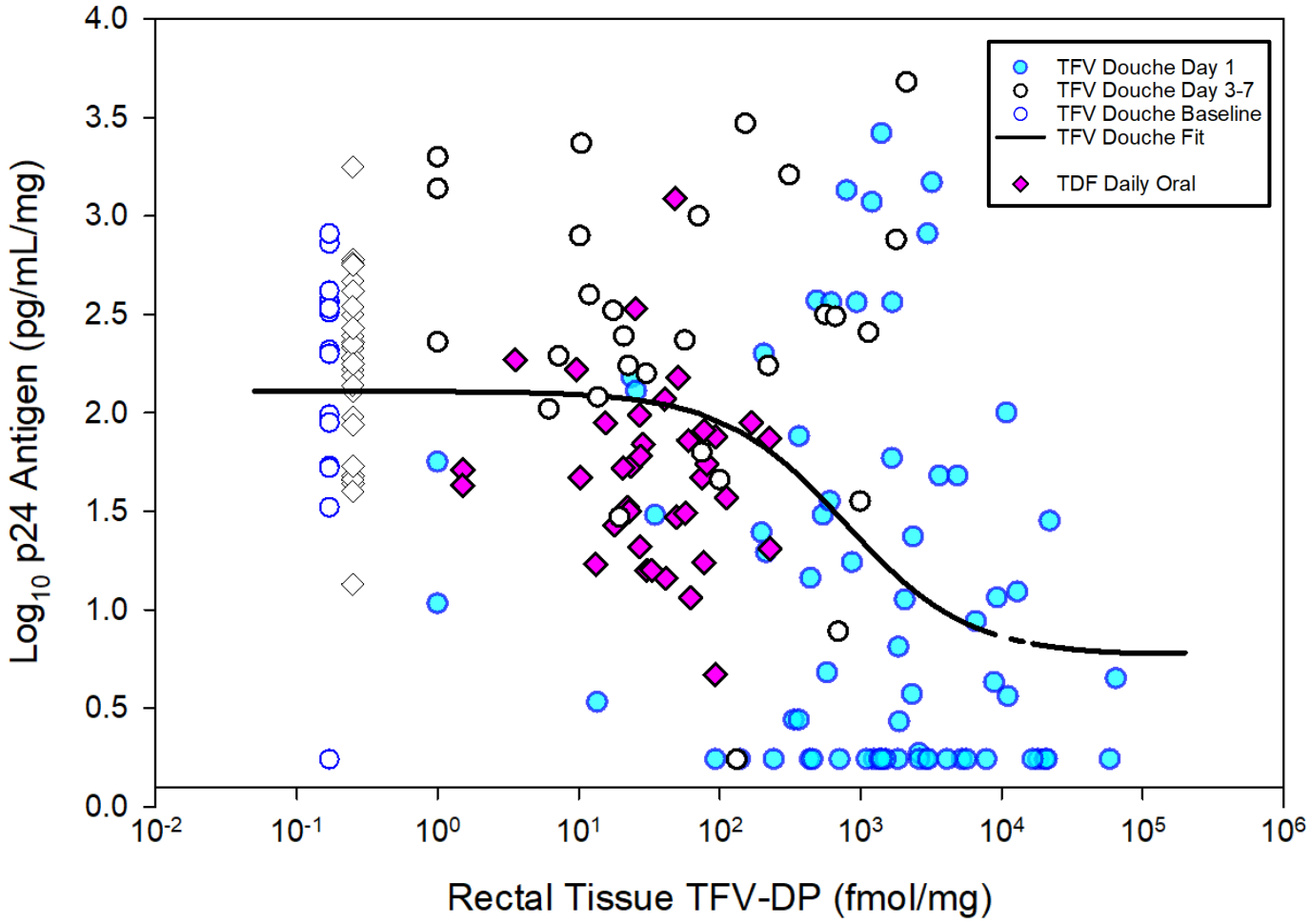
Pharmacokinetics of TFV Rectal Douche Exceeds Oral TFV in Target Rectal Cells

- Rectal mucosal mononuclear cell (MMC) tenofovir diphosphate (TFV-DP) concentrations were evaluated following different TFV douche sequences
  - TFV-TFV-TFV
  - TFV-H_2O-H_2O
  - H_2O-H_2O-TFV
- Water douches before or after a TFV douche lower TFV exposure
- Rectal MMC TFV-DP concentrations exceed rectal concentrations with on-demand oral F/TDF
- To maximize TFV exposure, TFV douches should be given at the beginning and end of a douche sequence (using simulations based upon these data)



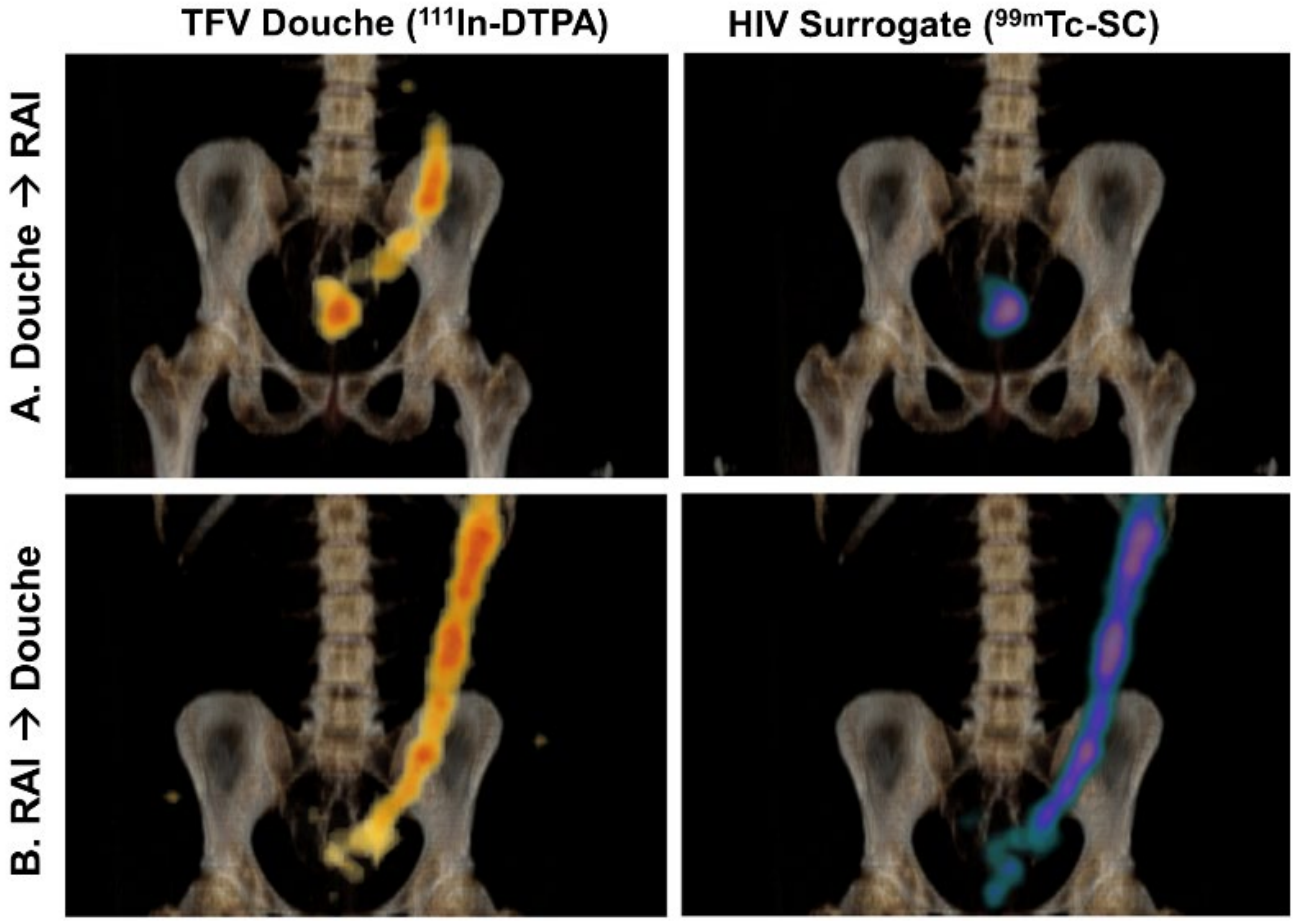
Rectal Tissue TFV-DP PK-PD Concentration-Effect Relationship

- Increased reduction in p24 viral antigen production post-TFV douche as compared to daily oral F/TDF



Additional Rationale for Douche Sequencing: DREAM-02

- Goal
  - Impact of douche-sex sequence
- Method
  - 5 healthy volunteers
  - Imaging surrogates
    - ^{99m}Tc-sulfur colloid “HIV” in autologous semen (sRAI)
    - ^{111}In-DTPA “TFV Douche”
  - SPECT/CT dual isotope imaging @ 1h after dosing
  - Two sequences
    - TFV Douche → sRAI
    - sRAI→ TFV Douche
- Results
  - Douching before sRAI
    - 5/5 “douche” ≥ “HIV”
  - Douching after sRAI
    - 1/5 “HIV” > “douche”
    - 5/5 ↑ “HIV” (vs. douching first)
- Impact
  - Counseling - TFV douche before RAI



SPECT/CT Images 1 hr after TFV douche (J205). A (TOP). TFV douche preceded simulated RAI. B (BOTTOM). Simulated RAI preceded TFV douche. LEFT TFV douche ^{111}In-DTPA; RIGHT HIV surrogate 99mTc-SC. Amber scale CT (spine, pelvis); color scale indicates isotope signal intensity.

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Rectal vs. Oral Use of On-demand PrEP

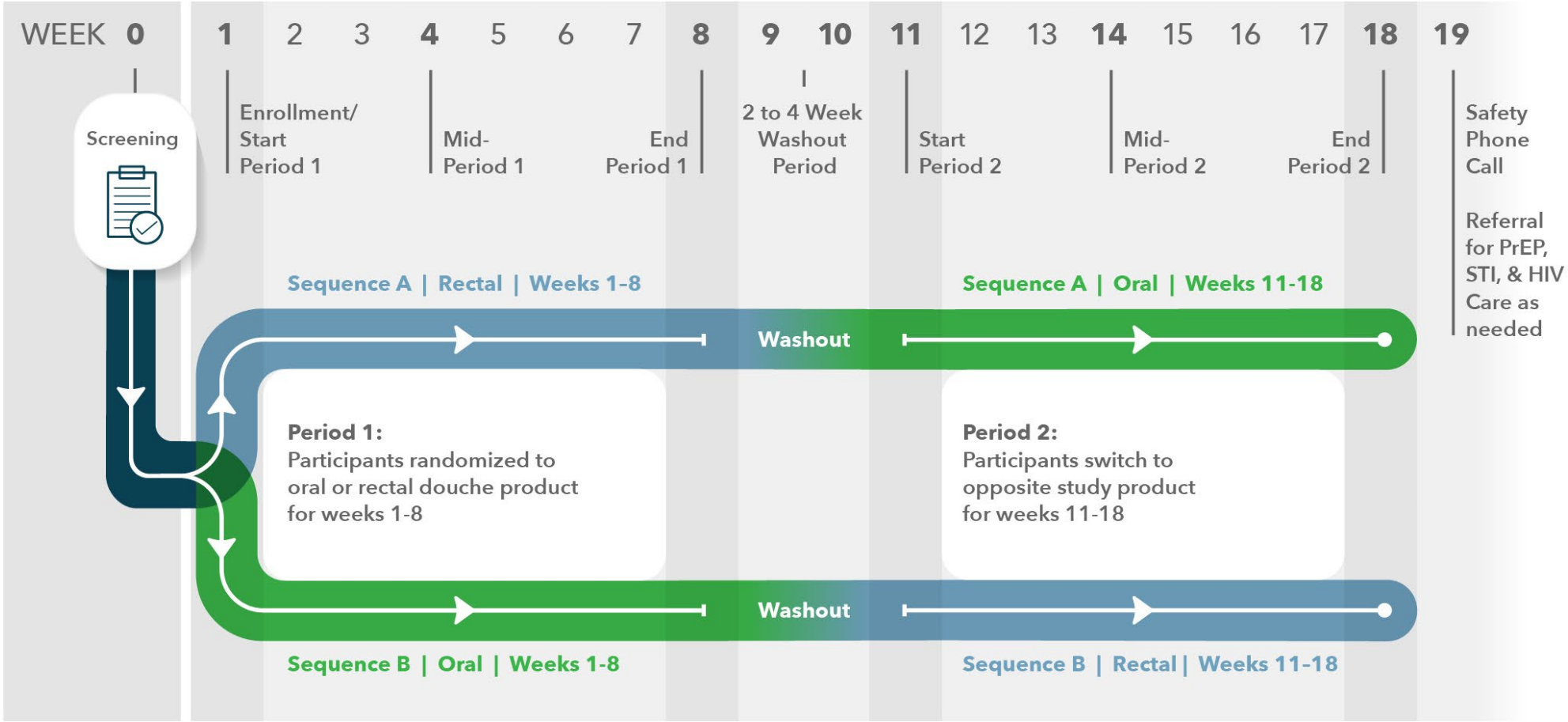
HPTN 106 Study Objectives

- Primary
  - To describe the safety of the on-demand rectal TFV douche and compare it to the safety of the on-demand oral F/TDF tablet
  - To describe the acceptability of the on-demand rectal TFV douche and compare it to the acceptability of the on-demand oral F/TDF tablet
- Secondary
  - To compare participant preference between the on-demand oral F/TDF tablet and on-demand rectal TFV douche after Period 2
  - To describe the adherence of the on-demand rectal TFV douche and compare it to the adherence of the on-demand oral F/TDF tablet
  - To describe the systemic and local pharmacokinetics (PK) of the on-demand rectal douche and compare it to the on-demand oral F/TDF tablet

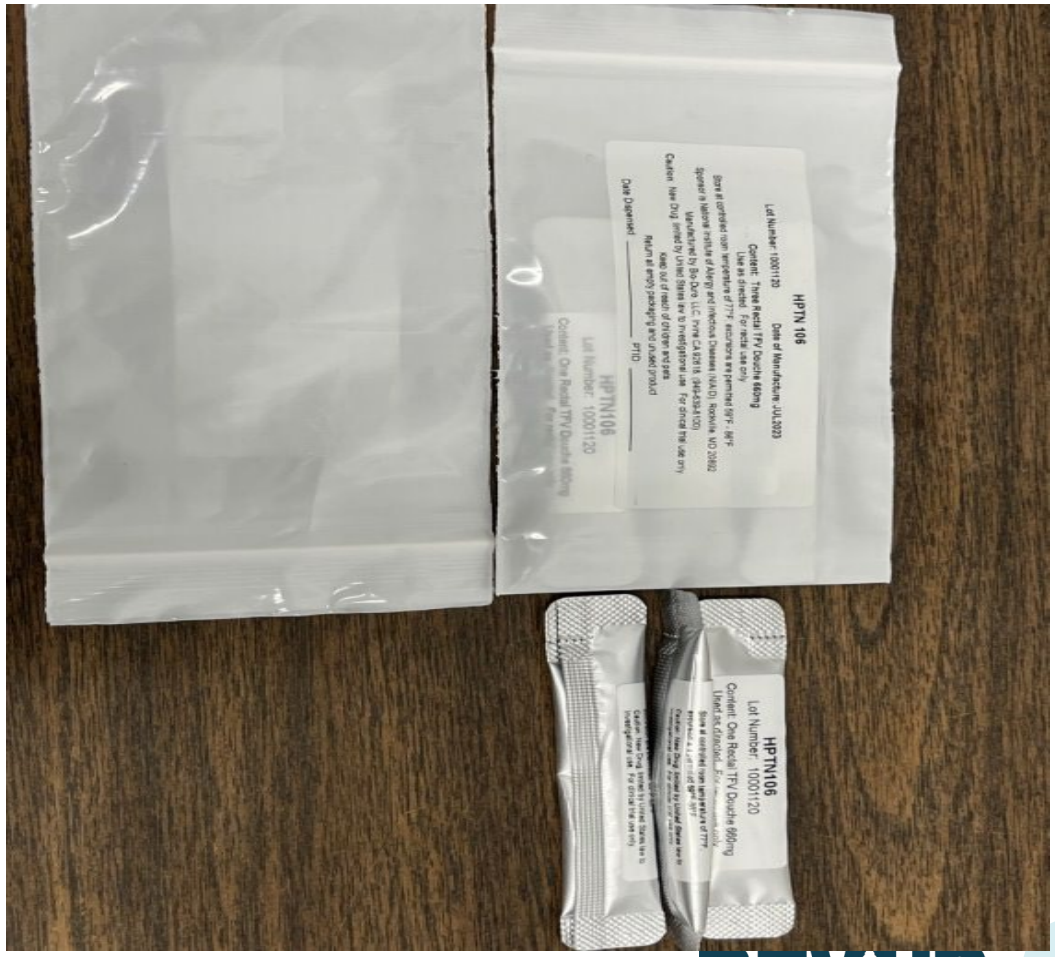
HPTN 106 (REV UP) Study Characteristics

Purpose	To establish the extended safety and acceptability of tenofovir (TFV) rectal microbicide douche to advance the product along the critical pathway for on-demand HIV pre-exposure prophylaxis (PrEP).
Design	Open label comparative randomized crossover
Population	Assigned male at birth, 18 years of age or older, not living with HIV, have receptive anal intercourse (RAI) at least five times in lifetime and at least once in the prior 3 months, and douche regularly (at least half the time) before RAI
Study Size	150 participants
Study Duration	Approximately 19 weeks per participant
Study Location	8 sites within the United States (US)
Study Regimen	Participants will be randomized 1:1 to either of two on-demand open label product sequences – TFV rectal microbicide douche(s) then oral emtricitabine/TFV disoproxil fumarate (F/TDF) or oral F/TDF then TFV rectal microbicide douche(s). Each product will be administered for 8 weeks with a 2 to 4-week washout period in between.

HPTN 106 (REV UP) Study Design

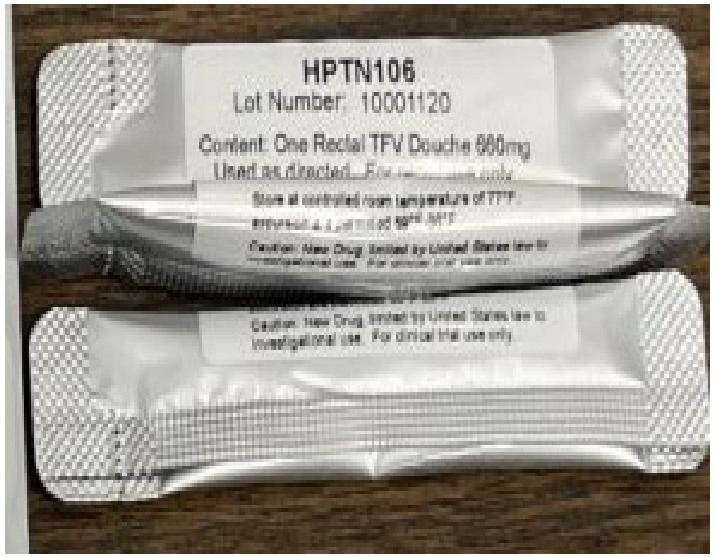


HPTN 106 Study Products



TFV Sachet

- Perforated sachet closure to facilitate easy tear-off
- Smaller opening to control transfer of materials to enema bottle
- Granule size increased for easier pouring
- Sachet dimensions for increased portability/discretion



HPTN 106 PK-PD Sub-Study Objectives

- Secondary:
  - Pharmacokinetics: To describe the systemic and local PK of the on-demand rectal TFV douche and compare it to the on-demand oral F/TDF tablet

- Exploratory:
  - Antiviral: To characterize ex vivo pharmacodynamic (PD) responses following oral and rectal study product dosing
  - PK/PD Modeling: To describe intercompartmental drug PK and the concentration-antiviral response relationship for each study drug
  - Histology: To characterize any changes in rectal tissue histology compared to baseline and up to one week after a single sequence of each study product
  - Microbiome: To characterize the rectal microbiome over the course of each oral and rectal study product dosing

Summary

- Development of rectal microbicides can facilitate expanded choice in PrEP options, may be used in a way that is acceptable to end-users, and provide protection when it is needed

- HPTN 106 (REV UP) will evaluate the safety, acceptability, user preferences, and pharmacology of a TFV douche as compared to on-demand oral F/TDF
  - This study is critical in the product development pipeline for an on-demand rectal product.

HPTN 106
Operations & Logistics

Marianne Gildea, RN, BSN, MS
Clinical Research Operations Manager

HPTN
HIV Prevention Trials Network

HPTN 106 REV UP

Leadership and Operations Center (LOC)

HPTN
HIV Prevention Trials Network

Located at FHI 360 in Durham, N.C.

- Clinical Research and Operations
- Communications
- Community Engagement
- Finance & Contracting
- Network Governance

HPTN 106 (REV UP) Sites

Alabama CRS

Chapel Hill CRS

Fenway Health CRS

Hope Clinic CRS

Johns Hopkins University CRS

UCLA CARE Center CRS

University of Pittsburgh CRS

Weill Cornell Chelsea CRS

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HPTN 106 REV UP

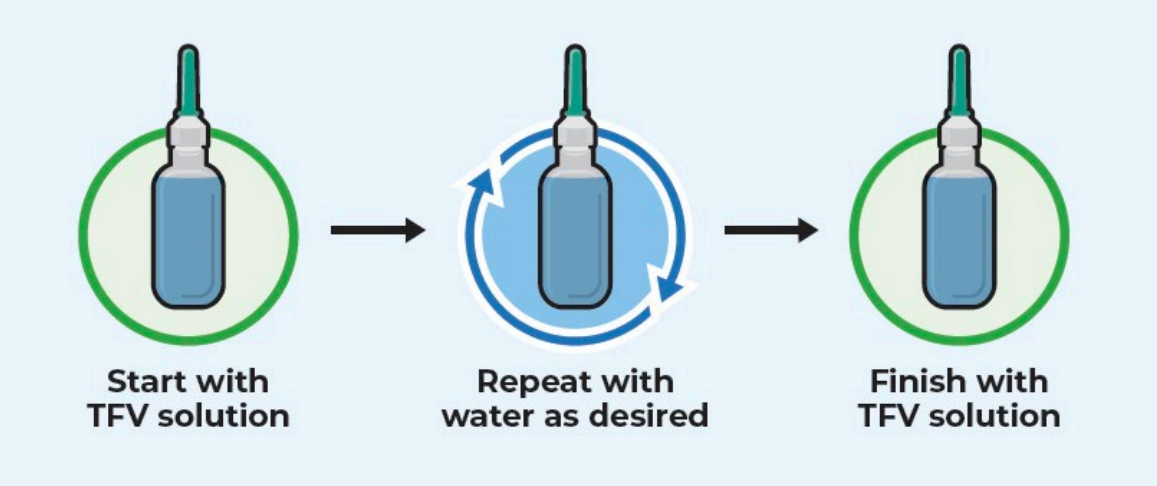
HPTN 106 (REV UP) Sites

Site/Academic Institution	Principal Investigator
Univ. of Alabama (Birmingham)	Craig Hoesley
University of North Carolina (Chapel Hill)	Christopher Hurt
The Fenway Institute (Boston)	Ken Mayer
The Hope Clinic (Emory)	Colleen Kelley
Johns Hopkins University (Baltimore)	Santiago Alvarez-Arango
UCLA Care Center	Raphael Landovitz
University of Pittsburgh	Ken Ho
Weill Cornell Chelsea (New York City)	Grant Ellsworth

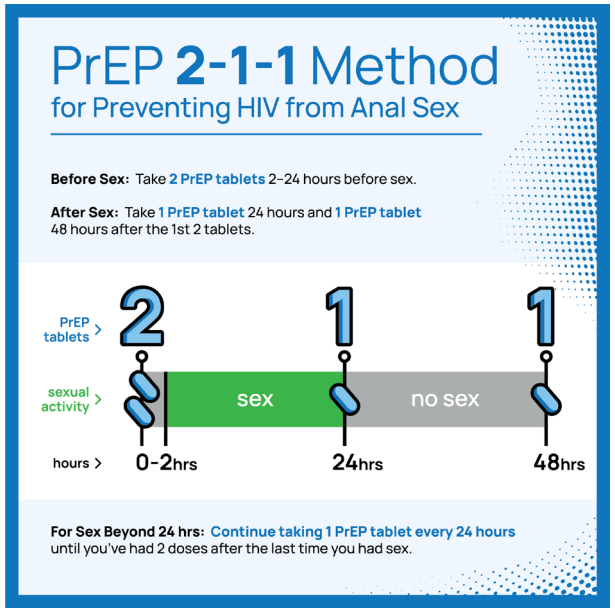
Community Engagement During Protocol Development

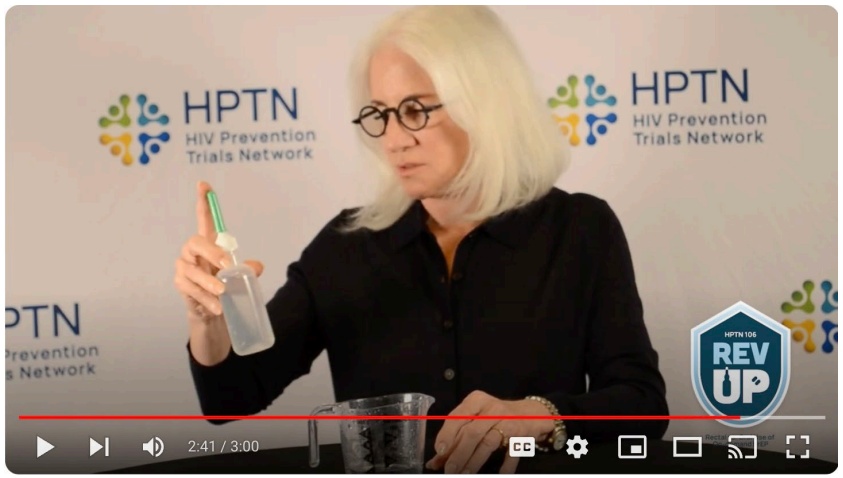
- Feedback on study protocol during protocol development
- Feedback on participant materials and behavioral questionnaires
- Dissemination of educational materials/webinars to engage community
- Assembled HPTN 106 (REV UP) Community Working Group

Tips and Tricks on How to Use Study Products



- **Materials for Participants**
  - 2-1-1 Oral Scenarios
  - Rectal Douche Scenarios
  - Short Video Instruction on Rectal douche prep





Supplies

Supplies


Good
Clean Love
ALMOST
naked
PERSONAL LUBRICANT
95% ORGANIC
WATER BASED WITH ALOE
DOCTOR RECOMMENDED
#O-MATCH
TECHNOLOGY
Good
clean love
95% ORGANIC
ALMOST NAKED
Personal Lubricant

Starting Timelines

2024 Timelines

DAIDS approved protocol v 1.0 & funding received

April

May

FDA clearance safe to proceed

Site Training & Regulatory Approvals

June-September

September

Open to Enrollment !!

Where to find out more?

HPTN 106 is Registered on ClinicalTrials.gov

HPTN
HIV Prevention Trials Network

The National Clinical Trial Number (NCT) is: **06560684**

NOT YET RECRUITING

CROSSOVER STUDY OF ON-DEMAND PREP FORMULATIONS COMPARING RECTAL AND ORAL TENOFOVIR

ClinicalTrials.gov ID NCT06560684

Sponsor National Institute of Allergy and Infectious Diseases (NIAID)

Information provided by National Institute of Allergy and Infectious Diseases (NIAID) (Responsible Party)

Last Update Posted 2024-08-19

https://clinicaltrials.gov/search?intr=NCT06560684

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HPTN
HIV Prevention Trials Network

Scan:

www.hptn.org/research/studies/hptn-106

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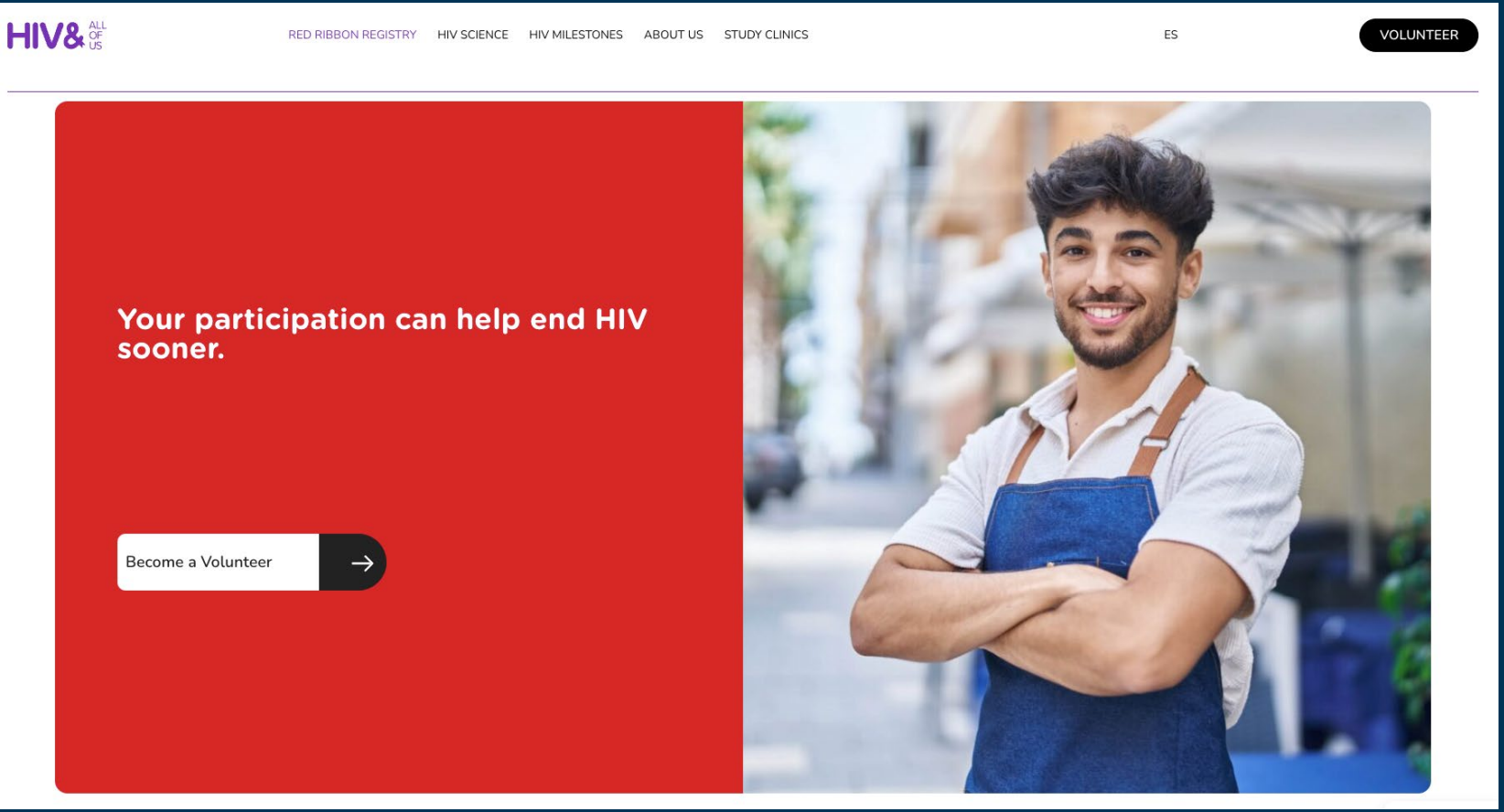
Red Ribbon Registry



https://www.helpendhiv.org/red-ribbon-registry/

Note: Not all research sites participating in HPTN 106 "REV UP" use the Red Ribbon Registry.

Acknowledgments

Overall support for the HIV Prevention Trials Network (HPTN) is provided by the National Institute of Allergy and Infectious Diseases (NIAID), Office of the Director (OD), National Institutes of Health (NIH), National Institute on Drug Abuse (NIDA), the National Institute of Mental Health (NIMH), and the Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD) under Award Numbers UM1AI068619 (HPTN Leadership and Operations Center), UM1AI068617 (HPTN Statistical and Data Management Center), and UM1AI068613 (HPTN Laboratory Center).

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