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# **PrEP Pipeline**

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# Topical PrEP

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- ◆ Studies done in partnership with CONRAD, IPM, USAID, BMGF, NIH (MTN), CDC, Einstein, Utah, Pitt, and others
- ◆ Tenofovir (TFV)
  - Rings
    - TFV
    - TFV/ hormonal contraceptive
  - Quick dissolve tablets
    - TFV/FTC
  - Films
- ◆ Tenofovir disoproxil fumarate (TDF)
  - Rings
- ◆ Tenofovir alafenamide fumarate (TAF GS-7340)
- ◆ Elvitegravir

# Oral PrEP

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- ◆ Preclinical and animal studies with CDC, NIH, and others
- ◆ Tenofovir alafenamide fumarate (TAF GS-7340)
- ◆ TAF/FTC
- ◆ Elvitegravir
  
- ◆ Other possible approaches
  - Capsid inhibitor?

# Refining TVD for PrEP

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- ◆ Can you identify individuals at high risk for HIV?
- ◆ Will these high risk individuals access HIV prevention services?
- ◆ Which high risk individuals are candidates for PrEP?
- ◆ Will they take PrEP?
- ◆ How will they take PrEP and for how long?
- ◆ Can PrEP be used as a tool to reduce high risk behavior and get off PrEP
- ◆ PrEP +/- condoms?

# Ongoing and Planned Phase 3/4 Research, Including Demonstration Projects

- ◆ Phase 3 studies are continuing to evaluate PrEP in various demographic groups
- ◆ Gilead is committed to post-marketing demonstration studies in the U.S. and globally
- ◆ Collaborators: ANRS, CDC, FHI, MRC, NIAID (DAIDS), NICHD (ATN), SFDPH, U. Washington, and Gilead Sciences

Population	Studies	Participants
MSM	17	13,920
Heterosexual Men & Women Serodiscordant Couples	10	14,630
<b>Total</b>	<b>27</b>	<b>28,550</b>

# Phase 3/4 Research and Demonstration Projects in MSM

Study	N	Duration	Location
<b>Ongoing Phase 3 Studies</b>			
IPERGAY	1900	24 months	France, Canada
<b>Demonstration Projects and Open-Label Extensions (planned and ongoing)</b>			
iPrEx OLE	1770	72 weeks	Americas, Thailand, S. Africa
DAIDS PrEP MSM Demo	500	12 months	U.S.
CDC PrEP Demo*	600	12 months	U.S.
PROUD	5000 (500 as pilot)	12 months on tx, 12 month follow-up	U.K.
Project PrEPare 110	200	48 weeks	U.S.
SFDPH EPIC PrEP	300	12 months	U.S.
ALERT	400	12 months+	U.S.
Los Angeles PATH	300	48 weeks	U.S.
Seattle PrEP	300	48 weeks	U.S.
NYC PrEP	200	12 months	U.S.
Brazilian PrEP	400	12 months	Brazil
Rio PrEP	65	12 months	Brazil
HPTN 073	225	12 months	U.S.
HPTN 069**	400	48 weeks	U.S.
HPTN 067**	360	34 weeks	U.S., Thailand, S. Africa
HVTN 505	1000	5 years	U.S.
<b>TOTAL: 17</b>	<b>13,920</b>		

\*CDC PrEP Demo includes both MSM and heterosexual men and women (1200 participants total)

\*\*Includes both MSM and heterosexual women (estimated 50% MSM, 50% heterosexual women)

# Phase 3/4 Research and Demonstration Projects in Heterosexual Women and Men

Study	N	Duration	Location
<b>Ongoing Phase 3 Studies</b>			
Partners PrEP (discordant couples)	4758 couples	12 month extension	Kenya, Uganda
CDC Bangkok TDF (IVDU)	2413	Endpoint driven	Thailand
MTN 003/VOICE (women)	5029	36 months	Uganda, South Africa, Zimbabwe
<b>Demonstration Projects and Open-Label Extensions (planned and ongoing)</b>			
CDC PrEP Demo* (men and women)	600	12 months	U.S.
HPTN 069**	200	48 weeks	U.S.
HPTN 067**	~180	34 weeks	U.S., Thailand, S. Africa
TDF2 Open-Label Extension (men and women)	900 (all rollover)	12 months	Botswana
CHAMPS (men and women)	150	12 months	South Africa
MTN 018/CHOICE (women)	4300 (4000 VOICE rollover)	12 months	Uganda, South Africa, Zimbabwe
UW Partners PrEP Demo (discordant couples)	1000	24 months	Kenya, Uganda
<b>TOTAL: 10</b>	<b>14,630+</b>		

\*CDC PrEP Demo includes both MSM and heterosexual men and women (1200 participants total)

\*\*Includes both MSM and heterosexual women (estimated 50% MSM, 50% heterosexual women)

+Excluding rollover participants