

Phase 3/4 Research, Including Demonstration Projects

Ongoing and Planned

- ◆ 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	20	13,210
Heterosexual Men & Women Serodiscordant Couples	18	16,940
Total	38	30,150

Phase 3/4 Research and Demonstration Projects

MSM

Study	N	Duration	Location
Ongoing Phase 3 Studies			
IPEGAY	1900	24 months	France, Canada
Demonstration Projects and Open-Label Extensions (planned and ongoing)			
DAIDS PrEP MSM Demo	557	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	180	12 months	U.S.
ALERT	400	12+ months	U.S.
Los Angeles PATH	300	48 weeks	U.S.
Hunter College PrEP (SPARK)	250	12 months	U.S.
NYC PrEP	200	12 months	U.S.
Brazilian PrEP	500	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

Continued...

*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

MSM (Continued)

Study	N	Duration	Location
Demonstration Projects and Open-Label Extensions (planned and ongoing)			
CHAMPS (33% men and 66% women)	50	12 months	South Africa
HVTN 505	1000	5 years	U.S.
CRUSH	170	48 weeks	U.S.
PrEP in STD Clinics***	68	18 months	U.S.
HPTN 080	600	12 months	U.S.
AMPrEP	250	Up to 39 months	Netherlands
TOTAL: 20	13,210		

*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)

***Includes MSM; serodiscordant couples and sex workers (men and women)

Phase 3 and 4 Research and Demonstration Projects

Heterosexual Women and Men

Study	N	Duration	Location
Demonstration Projects and Open-Label Extensions (planned and ongoing)			
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
UW Partners PrEP Demo (discordant couples)	1,000	24 months	Kenya, Uganda
CHAMPS (33% men and 66% women)	100	12 months	South Africa
CDC Bangkok OLE (IVDU)	1,000	12 months	Thailand
Senegal PrEP	1,500	48 weeks	Senegal
SAFER	80	24 months	Kenya
Zimbabwe PrEP	1,500	24 months	Zimbabwe
Benin PrEP/TasP	350	12-24 months	Benin
PrEP in Transgender Women	80	24 weeks	Peru
Continued...			

*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)

PrEP Corporate Grants Program

- Grants awarded to community organizations to education their constituents on the role of PrEP as part of a comprehensive HIV prevention package
- More than 50 grants awarded to date in key cities with high HIV prevalence
 - e.g., Atlanta, Baltimore, Chicago, Houston, New York, Oakland, and Washington, D.C.

Key areas of focus:

- Populations with higher HIV prevalence and risk of HIV infection
 - Young adult MSM of all races
 - Hispanic/Latino
 - African Americans
 - Transgender women
- Applications that clearly demonstrate:
 - How “underserved” populations will be reached through clearly defined goals and milestones
 - A strong community network with the ability implement a successful PrEP education program.
 - Educational concepts that could be replicated across the nation, specifically how the selected proposals could be taught, adapted, and launched by organizations in other communities