

Ongoing and Planned PrEP Open Label, Demonstration and Implementation Projects, August 2018							AVAC Global Advocacy for HIV Prevention	
Trial/Project	Sponsor/Funder	Type/Category	Location	Population	Design/Key questions	Status	Status Details	
California Collaborative Treatment Group Consortium/ALERT (Active Linkage, Engagement and Retention to Reduce HIV)	California Collaborative Treatment Group	Demonstration Project	US	MSM	Plans to enroll 400 eligible high-risk MSM, for two years who will receive daily TDF/FTC-based PrEP, into a randomized study that evaluates whether a text messaging-based adherence intervention can improve adherence to the PrEP medication.	Completed	Completed; ended October 2015.	
East Bay Consortium/ CRUSH (Connecting Resources for Urban Sexual Health)	California HIV/AIDS Research Program of the University of California	Demonstration Project	US (East Bay, California)	Young MSM of color	Aims to test and link young MSM of color to sexual health services; enhance and evaluate engagement and retention strategies for HIV-positive young MSM of color; and engage and retain HIV-negative young MSM of color in sexual health services, including PrEP.	Ongoing	Ongoing; started in May 2013.	
LAC PATH PrEP Demo Project	University of California, Los Angeles	Demonstration Project	US	MSM, Transgender women	Plans to enroll 375 high-risk MSM and transgender women who will receive a customized prevention package that may include PrEP.	Completed	Completed.	
Linking Women to PrEP Care	Rhode Island Hospital	Clinical Trial	US	Women	Pre-exposure prophylaxis (PrEP) can be very effective at preventing HIV infection among women at high-risk for HIV but is underused in this population. Periods of incarceration represent an opportunity to identify women at risk and link them to PrEP care as they leave jail or prison. This study aims to improve linkage to community-based PrEP care to reduce HIV acquisition in a high-need, underserved community.	Ongoing	Ongoing; started October 2017.	
PrEP Adherence Enhancement Guided by iTAB and Drug Levels for Women (AEGIS)	California HIV Research Program	Demonstration Project	US (California)	FSW, Women aged 18+	The purpose of this study is to test a program that uses drug level monitoring, text messaging ("ITAB") and personalized counseling with HIV prevention services, including PrEP (medicine that can help prevent HIV infection when taken daily).	Ongoing	Recruitment started May 2016; expected end date is early 2018.	
PrEP Implementation with US HIV-Serodiscordant Couples: Couples PrEP Demo Project	University Of Rochester	Open Label Study	US	Serodiscordant Couples	A mixed-methods prospective open-label demonstration project of daily oral Truvada/PrEP among HIV-serodiscordant heterosexual couples in high-prevalence communities in New York City. The specific aims are to describe the temporal patterns and identify multilevel determinants of PrEP outcomes, including (a) uptake, acceptability and retention in care, (b) medication adherence, (c) safety and toxicity, (d) compliance with HIV testing and clinical monitoring, and (e) changes in sexual risk behavior. This research employs a biobehavioral multi-site longitudinal design to identify critical factors affecting PrEP implementation outcomes at the provider, dyadic, and individual level.	Ongoing	Ongoing; started July 2017.	
Project PrEPare	NICHHD	Clinical Trial	US	MSM	Designed to explore the safety, acceptability and feasibility of PrEP among young men who have sex with men (YMSM) who are at risk for HIV infection. This study will take place at clinical sites across the US with about 100 HIV-uninfected YMSM.	Completed	Completed; no longer providing PrEP to former participants.	
SPARK Project NYC	NIAAA	Implementation Project	US	MSM, Transgender women	SPARK is a PrEP demonstration-implementation hybrid designed to develop and test an intervention that integrates PrEP delivery and support into a comprehensive prevention package delivered in a "real world" community health center. The project is also designed to identify and examine social and behavioral factors associated with disparities in access to prevention and care services among gay, bisexual, and other men who have sex with men in NYC that might direct or impact PrEP implementation programs and policies.	Completed	Completed.	
Sustainable Healthcenter Implementation PrEP Pilot Study (SHIPP)	CDC; CDC Foundation; Gilead Sciences	Implementation pilot study	US	MSM and heterosexual women	Evaluates real-world PrEP use in MSM, heterosexual women and men and people who inject drugs in four federally qualified health centers and primary care services, in 1,200 participants.	Ongoing	Ongoing; started October 2014.	
The Stay Study: A Demonstration Project Advancing PrEP Delivery in the San Francisco Bay Area Transgender Community	Public Health Foundation Enterprises, Inc.	Demonstration Project	US (California)	Transgender Individuals	The Stay Study is a multi-site, open-label HIV pre-exposure prophylaxis (PrEP) demonstration project for advancing PrEP delivery in the San Francisco Bay Area Transgender Community. Approximately 188 HIV-uninfected participants will be enrolled at 4 sites in San Francisco and Fremont and will be provided Truvada to take orally once daily as PrEP.	Ongoing	Ongoing; started August 2017. Expected completion in March 2020.	