IMPLEMENTATION AND DELIVERY OF LENACAPAVIR FOR PREP IN A COMMUNITY PHARMACY SETTING (L4P in Pharm)

Protocol Number: 002

National Clinical Trial (NCT) Identified Number: TBD

Principal Investigator*: Elyse Tung, PharmD, BCACP

Sponsor: Kelley-Ross Pharmacy Group

Grant Title: INCLUSION: Implementation of Twice-yearly Lenacapavir to Address Unmet Needs in HIV Prevention)

Grant Number: IN-US-974-7746

Funded by: Gilead Sciences, Inc.

28 July 2025

Statement of Compliance

The study will be carried out in accordance with Good Clinical Practice (GCP) as required by 21 CFR Part 50 Protection of Human Subjects (Informed Consent), 21 CFR Part 54 Financial Disclosure by Clinical Investigators, and 21 CRF Part 56 Institutional Review Boards.

SIGNATURE PAGE

The signature below constitutes the approval of this protocol and the attachments and provides the necessary assurances that this trial will be conducted according to all stipulations of the protocol, including all statements regarding confidentiality, and according to local legal and regulatory requirements and applicable US federal regulations and ICH guidelines.

Site Investigator:

Signed: _____ Date: _____

Elyse Tung, PharmD, BCACP
Director of Clinical Services
Kelley-Ross Pharmacy Group

Table of Contents

page

Contents

Table of Contents - *continued*

List of Abbreviations

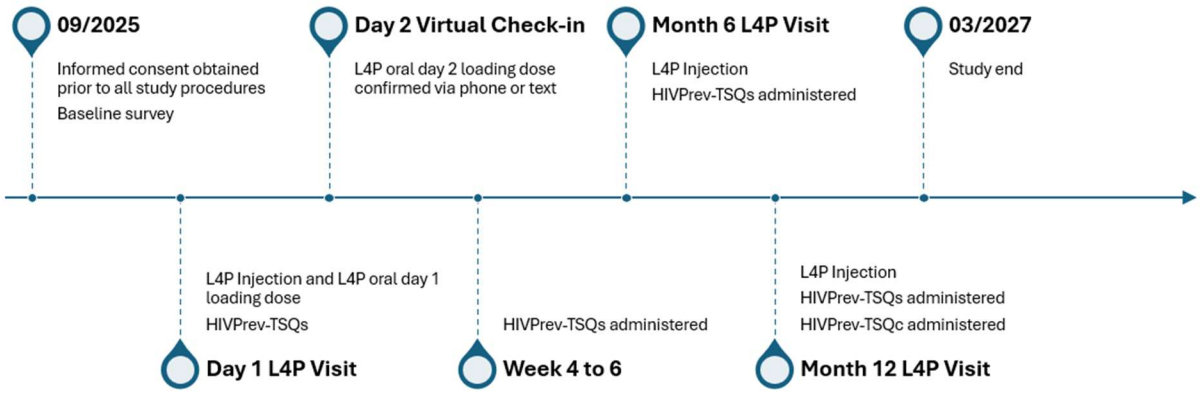
AE	Adverse event
AFAB	Assigned female at birth
AMAB	Assigned male at birth
APR	Antiretroviral Pregnancy Registry
CAB-LA	Long-acting cabotegravir
CDC	Centers for Disease Control
CFR	Code of Federal Regulation
CDTA	Collaborative drug therapy agreement
CPA	Collaborative practice agreement
DSMB	Data and Safety Monitoring Board
ESD	Early Study Discontinuation
FDA	Food and Drug Administration
FWA	Federal-Wide Assurance
GCP	Good Clinical Practice
HIV	Human Immunodeficiency Virus
ICF	Informed Consent Form
ICH	International Conference on Harmonisation
IEC	Independent or Institutional Ethics Committee
IRB	Institutional Review Board
L4P	Lenacapavir for PrEP
MSM	Men who have sex with men
N	Number (typically refers to subjects)
NIH	National Institutes of Health
PI	Principal Investigator
POC	Point of care
PrEP	Pre-exposure prophylaxis
SAE	Serious Adverse Event
SMC	Safety Monitoring Committee
SOP	Standard Operating Procedure
STI	Sexually transmitted infection
TAF/FTC	Tenofovir alafenamide/emtricitabine
TDF/FTC	Tenofovir disoproxil fumarate/emtricitabine
TGW	Transgender women
WHO	World Health Organization

IMPLEMENTATION AND DELIVERY OF LENACAPAVIR FOR PREP IN A COMMUNITY PHARMACY SETTING (IDLinC)

Title	Implementation and Delivery of Lenacapavir for PrEP in a Community Pharmacy Setting (IDLinC)
Funder	Gilead Sciences, Inc.
Study Design	Prospective, longitudinal, observational, mixed methods study with a retrospective matched cohort study
Study Population	HIV uninfected people at risk of acquiring HIV infection, age 18 and older, living in Washington State
Study Size	75 participants
Study Duration	Approximately 1 year
Study Site(s)	Kelley-Ross Pharmacy at the Polyclinic Kelley-Ross Capitol Hill Pharmacy
Intervention Description	This is an open-label, single center study to evaluate implementation of a pharmacist-managed delivery of L4P in a community pharmacy setting and the impact of twice-yearly vs. quarterly PrEP visits on STI rates.
Study Aim	Aim 1: Evaluate the implementation of a pharmacist-managed L4P service in a community pharmacy setting. Aim 2: Compare the impact of twice-yearly vs quarterly PrEP visits.
Primary Objective	Aim 1: Evaluate the feasibility of a pharmacist-managed L4P service in a community pharmacy setting. Aim 2: Evaluate the effect of 6-month versus 3-month PrEP monitoring visits.
Secondary Objective	Aim 1: Evaluate the acceptability and effectiveness of a pharmacist managed L4P service. Aim 2: Compare visit frequency and STI positivity rates between people receiving PrEP visits every 3 months versus every 6 months

1 STUDY SCHEMA

1.1 Subject Schema



1.2 Pharmacist Subject Schema

2 KEY ROLES

Elyse Tung, PharmD, BCACP
Director of Clinical Services
Kelley-Ross Capitol Hill Pharmacy
400 E Pine St Suite 100B Seattle, WA 98122
Phone # 206-641-7766
Fax # 206-641-7767
Email: etung@kelley-ross.com

Peter Shalit, MD, PhD, FACP, AAHIVS
Medical Director
901 Boren Ave Suite 850 Seattle, WA 98104
Phone # 206-624-0688
Fax # 206-624-2432
Email: peter@tribalmed.com

Alexi Duenas, PharmD
Clinical Pharmacist
Kelley-Ross Capitol Hill Pharmacy
400 E Pine St Suite 100B Seattle, WA 98122
Phone # 206-641-7766
Fax # 206-641-7767
Email: aduenas@kelley-ross.com

Jolene Pfulmann
Pharmacy Technician and Medical Billing Specialist
Kelley-Ross Capitol Hill Pharmacy
400 E Pine St Suite 100B Seattle, WA 98122
Phone # 206-641-7766
Fax # 206-641-7767
Email: jpfulmann@kelley-ross.com

Francis Slaughter
Data Scientist
Seattle's LGBTQ+ Center
400 E Pine St Suite 100 Seattle, WA 98122
Phone # 206-860-6969
Email: francis@gaycity.org

3 BACKGROUND INFORMATION AND SCIENTIFIC RATIONALE

3.1 Background Information

HIV pre-exposure prophylaxis (PrEP) is a comprehensive prevention strategy that utilizes antiretroviral medications in combination with behavioral risk reduction techniques to reduce the risk of acquiring HIV in high-risk individuals. For years, pharmacists have demonstrated success in managing PrEP through clinic-based protocols called collaborative practice agreements (CPAs) or collaborative drug therapy agreements (CDTAs). CPAs and CDTAs are formal practice relationships between a pharmacist and a prescriber that allow the pharmacist to perform certain functions that are beyond the typical scope of practice but are delegable under specified circumstances and allow the pharmacist to perform all functions necessary to manage medication therapy. Such functions include ordering and interpreting laboratory tests, initiating, managing, and administering medication therapy. CPAs are now legal in 48 states.

Kelley-Ross Pharmacy in Seattle has managed the U.S.'s first pharmacist-run PrEP clinic for 10 years. We have initiated over 5,000 patients on PrEP and currently have over 1,600 active patients. In 2023, KR became the first pharmacy to offer LA-CAB for PrEP, and we presented our results in 2024. Since then, we have initiated 214 people with over 170 people still active on LA-CAB. The success and scalability of this program has led multiple pharmacies nationwide to replicate the service and inspired legislative changes in 10 states. With the upcoming approval of L4P, data on the management of the medication in community pharmacies will be needed, particularly the comparison between 3-month versus 6-month PrEP monitoring visits. Patients may find quarterly STI screenings burdensome, leading to discontinuation.

3.2 Scientific Rationale

Until recently, only oral formulations of PrEP were available. With the availability of long-acting PrEP injectables, new strategies will need to be developed to deliver this new treatment option. Current data shows that the management of oral PrEP in community pharmacy settings is feasible and acceptable. The availability of L4P offers an opportunity to expand PrEP access outside traditional healthcare settings. However, data on the feasibility and acceptability of L4P in community pharmacies is lacking. Community pharmacies are ideal for L4P due to their accessibility and the ability to utilize both pharmacy and medical billing for reimbursement of medication and clinical services, unlike traditional healthcare settings. Pharmacists are one of the most highly accessible healthcare professionals in the community. There are over 60,000 community pharmacies across the U.S. The study will evaluate implementation outcomes (feasibility, acceptability), real-world effectiveness, and whether L4P can be used for same day starts or treatment switches. If successful, this model could expand L4P nationwide, reducing visit burden and increasing PrEP access.

4 OBJECTIVES

4.1 Study Goal

- We aim to operate a demonstration project to evaluate the feasibility and acceptability of a pharmacist-managed L4P program in a community pharmacy setting. The study is divided into 2 aims.

4.2 Aim 1

4.2.1 Primary Objective

- The primary objective is to evaluate the feasibility of a pharmacist-managed L4P service in a community pharmacy setting.

4.2.1.1 Feasibility Outcomes

Feasibility outcomes include retention, adherence, and persistence rates.

- Retention rate will be calculated by dividing the number of participants present in the study at 1 year by the number of individuals enrolled.
- Adherence rate will be collected as the proportion of injections that are successfully administered during each target injection window period over 1 year.
- Persistence will be measured as the length of time a person remains on L4P for over 1 year.
- Sample characteristics will include baseline demographics (age, gender, race), housing status, HIV risk factors, PCP, and insurance status.

4.2.2 Secondary Objective

- The secondary objective of Aim 1 is to evaluate the acceptability and effectiveness of a pharmacist managed L4P service.

4.2.2.1 Acceptability Outcomes

- Patient Acceptability: Measured by the HIV-PrevTSQs questionnaire at baseline (for those already on an FDA approved PrEP regimen within 3 months from enrollment), 4-6 weeks and 1 year and HIV-PrevTSQc at 1 year.
- Pharmacist Acceptability: Assessed using the FIM, AIM, and IAM surveys at baseline and 1 year.

4.2.2.2 Effectiveness Outcomes

- L4P Initiations: Number of L4P starts by end of 1 year
- Time to first injection
- HIV Seroconversions: Rate at the end of 1 year
- STI Rates: Rate at the end of 1 year
- Reasons for early discontinuation
- Adverse Reactions: Rates, including injection site reactions at 1 year.

4.3 Aim 2

4.3.1 Primary Objective

- The primary objective is to evaluate the effect of 6-month versus 3-month PrEP monitoring visits.

4.3.1.1 Primary Outcome

- Retention rate will be calculated by dividing the number of participants present in the study at 1 year by the number of individuals enrolled.

4.3.2 Secondary Objective

- The secondary objective is to compare visit frequency and STI positivity rates between people receiving PrEP visits every 3 months versus every 6 months.

4.3.3 Secondary Outcome

- Visit frequency will be measured as the overall number of PrEP visits and in-between STI visits per person year.
- STI positivity rate will be measured as the number of chlamydia, gonorrhea, or syphilis diagnosed per 100 visits.

5 STUDY DESIGN

5.1 Study Design

We aim to conduct a prospective observational study enrolling 75 subjects into the cohort to report on the feasibility and acceptability of a pharmacist-managed L4P in a community pharmacy setting. This will be done as a longitudinal, observational, mixed methods study of our experiences of operating this service for 1 year using our existing pharmacy clinic models and infrastructure. We will also conduct a retrospective cohort study to assess the impact on PrEP visits every 3 months vs. every 6 months. All subjects must meet all eligibility criteria to participate in the study. Subjects will have the opportunity to start or switch to commercially available L4P. PrEP start will be defined as subjects starting PrEP who have not taken PrEP for the previous 3 months. All forms of FDA approved PrEP products indicated for each person will be offered, and each patient will have an opportunity to participate in the study. Patients interested in initiating will be offered the opportunity to enroll and provide informed consent. Initiation of L4P will be based on medical, laboratory, and coverage qualifications.

Patients on L4P will be managed by a pharmacist provider utilizing a CDTA based on the DHHS Guidelines for the Use of Antiretroviral Agents in Adults and Adolescents with HIV and FDA approved label for lenacapavir. It will be administered on Day 1, Day 2 (oral loading dose only), and every six months thereafter. Subjects will be followed for 12 months, and electronic health record data will be collected retrospectively throughout the study duration. Subjects will be given a survey 4 to 6 weeks after initiation and at study end. Subjects will have the option to discontinue at any time for any reason and standards of care for discontinuation will be followed. Any participants who do not meet criteria for management under the CDTA (positive HIV screening, pregnancy, or other complicated health conditions) will be referred to their existing primary care provider or the clinic medical director for further management. Referral for substance abuse, mental health, and primary care services will also be provided. At the end of the study, each patient will complete a survey and be offered the option to continue commercially available L4P.

L4P will be administered by the pharmacist provider. A pharmacist training program will be created by the study team and completed by all pharmacists providing L4P services. Pharmacies are health care settings, and as such, all safety measures will be followed for the administration of L4P. These include informed consent and counseling on risks versus benefits, post-injection observation, policies, and procedures in place for emergency services and allergic reactions. Access to epinephrine and diphenhydramine will be onsite. All pharmacist providers will have CPR and blood-borne pathogen training. Pharmacists who choose to enroll in the study and provide informed consent will be given at survey at study start and end. The pharmacist surveys will be validated psychometric assessments measuring implementation outcomes that often considered “leading indicators” of implementation success: Acceptability of Intervention (AIM), Intervention Appropriateness Measure (IAM), and Feasibility Intervention Measure (FIM). Pharmacists will be reimbursed $100 for completing surveys.

A pharmacy technician will assist with administrative tasks such as scheduling, billing, prior authorizations, benefit verification, and patient assistance programs. Specific attention will be given to overcoming billing barriers. Commercial drug product will be utilized in this study. To

create a sustainable program after funding ceases, real world reimbursement programs, such as insurance and patient assistance programs, will be used to reimburse pharmacist time for performing these clinical services and for the reimbursement of commercial drug product. Uninsured patients will have an opportunity to participate. The pharmacy technician will assist patients in enrolling in state and commercial drug assistance programs to cover service and medication costs.

The study intervention is divided into 2 aims. For aim 1, we aim to conduct a prospective observational study enrolling 75 subjects into the cohort to report on the feasibility and acceptability of a pharmacist-managed L4P in a community pharmacy setting. This will be done as a longitudinal, observational, mixed methods study of our experiences of operating this service for 1 year. The primary objective is feasibility as measured by retention. Additional feasibility outcomes include adherence, persistence and seroconversion collected through EHR review. Secondary outcomes include acceptability (as determined by subject and provider subject surveys), STI rates, HIV seroconversions, reason for discontinuation, and pharmacist providers and patient perspectives on barriers and facilitators. In aim 2, subjects enrolled in the L4P cohort will have the option of conducting STI testing every 6 months versus every 3 months. We will conduct a retrospective matched cohort study to assess the differences in retention and STI positivity rates between groups. All participants will be able to get tested in between monitoring visits. Primary outcome measure will be adherence to PrEP medication as measured by the proportion of people who successfully attend their PrEP monitoring visits over 12 months. Secondary outcomes include visit frequency and STI positivity rate. Visit frequency will be measured as the overall number of PrEP visits and in-between STI visits per person year.

6 Study Population

6.1 Inclusion Criteria

Patients who meet all the following criteria are eligible for inclusion in this study:

- 18 years of age or older at the time of screening
- Weight ≥ 35 kg
- HIV-negative status
- Willing to provide informed consent and undergo all required study procedures

6.2 Exclusion Criteria

Participants who meet any of the following criteria will be excluded from this study:

- Unknown or positive HIV status
- Coadministration of drugs that significantly decrease lenacapavir concentrations according to the FDA package insert.
- Any participants that do not meet criteria for management under CDTA

6.2.1 Additional Cohort Matching Exclusion Criteria

- Any subjects on 2-1-1 TDF/FTC PrEP regimen
- Any subjects on CAB-LA for PrEP regimen

6.3 Study Sample

- Aim 1: 75 subjects who meet all the inclusion criteria, none of the exclusion criteria, and provide informed consent will be enrolled as study participants
- Aim 2: Up to 300 subjects who meet all the inclusion criteria and none of the exclusion criteria will be selected as cohort matches

6.4 Recruitment

- Participants will be recruited through our existing panel of patients, as well as obtaining referrals from other PrEP providers. If insufficient recruitment exists, a multimedia outreach program of new patients from our local geographical area will be utilized. The recruitment strategies are designed to ensure broad awareness of the study while minimizing the risk of coercion and respecting participant autonomy.
- The cohort will be matched with our existing panel of PrEP patients as detailed in Section 8.3.2.

6.4.1 Multimedia Outreach

- We will use platforms such as Google, Meta (Instagram), and Tik Tok to share IRB-approved advertisements about the study. Posts will include brief study description, eligibility criteria and contact information for interested individuals. All content will be reviewed and approved by the IRB prior to dissemination. We will not use direct messaging to contact potential participants.
- In-person recruitment will occur at the pharmacy and partner organization sites where our target population is likely to be present.

Trained study staff will provide brief, IRB-approved information about the study and offer flyers. Staff will respect all refusals to engage. As part of routine clinical care, all patients receiving HIV prevention services will be offered general information about a new PrEP option, lenecapavir. If a patient expresses interest in learning more about lenacapavir, study staff will provide additional clinical information. At that point, staff will also inform the patient about this optional research study. Interested individuals will be screened for eligibility and invited to participate in the study. Participation in the study is voluntary, and declining will not affect access to lenacapvir or services. Study staff will follow a standardized, IRB-approved recruitment script and consent process to minimize the risk of undue influence.

- Telephone recruitment of potential participants will be made with people who have previously consented to be contacted by the pharmacy. Call will be made by trained study staff using standardized, IRB-approved script. No cold-calling or unsolicited outreach will be conducted. Voicemails will only be left if the participant has previously consented to being contact by phone.

7 STUDY PROCEDURES/EVALUATIONS

7.1 Study Procedures

Study Procedures							
Procedure	Preenrollment	Screening	Day 1 Initiation	Day 2	Follow Up L4P	Early D/C	End of study
Pharmacist							
Informed Consent		X					
Pharmacist training	X						
FIM, AIM, IAM Survey	X						X
Subject							
Study Interventions							
Informed Consent	X						
Patient baseline demographics survey		X					
HIVPrev-TSQs			X		X		X
HIVPrev-TSQc						X	X
Electronic health record data collection		X	X	X	X	X	X
Standard of Care per CDC Guidelines							
Medical history collection		X					
Review of concomitant medications, medical conditions, and allergies		X	X		X	X	X
Patient interview for sexual history and recent risk events		X	X		X	X	X
Screening for STI symptoms		X	X		X	X	X
STI site testing		X	X		X	X	X
Assessment for acute signs and symptoms of HIV		X	X		X	X	X
Patient education on acute signs and symptoms of HIV			X		X		
Rapid HIV- 1/2 Ag/Ab			X		X	X	X
4th generation Ag/Ab laboratory test			X		X	X	X
HIV-1 RNA qualitative laboratory test			X				
hCG pregnancy test			X		X	X	X
PrEP choice counseling			X		X	X	X
Risk reduction counseling			X		X	X	X
Review of AEs and SAEs			X		X	X	X
Adherence to target injection window period counseling			X		X	X	X
In-depth discussion of L4P, patient counseling and education			X				

Patient attestation of counseling intervention			X				
Drug dispensation and/or administration			X	X	X		X
Recording and documentation of all SAEs			X	X	X	X	X

7.2 Screening and Enrollment

- Screening will occur by pharmacist providers for all patients who request HIV PrEP consultation at Kelley-Ross One-Step PrEP™ clinic. This study will be open to patients both newly starting PrEP therapy and those who decide to switch from another PrEP regimen to L4P.
- Informed consent will be obtained for every study participant before any study procedures are initiated.
- All standard of care procedures as recommended by CDC PrEP guidelines and FDA approved labeling instructions for the medication will be followed.
- It is the responsibility of the PI to ensure that the subject is eligible for the study. Once eligibility has been confirmed, each subject will be assigned a unique subject number. Once a subject number has been assigned to a subject, it will not be reassigned to any other subject.
- The study will conclude after 1 year of operation from full study enrollment. The retrospective cohort study will be conducted after this 1 year of operations.
- Patients who choose L4P but decline to participate in the study will be able to access L4P through Kelley-Ross One-Step PrEP™. Declining to be in the study will not preclude the individual from receiving care are Kelley-Ross Pharmacy.

7.2.1 Screening Visit

- Written informed consent completed prior to any other assessments.
- Medical history taking including information about alcohol use in the past year, self-reported sexual risk events, medications used by the participant, allergies, recent sexual risk events, interest in using PrEP, self-identification of gender identity, sexual orientation, sex assigned at birth, education and employment status, housing status, use of tobacco and controlled substances, immunization status, height, and weight.
- Standard of care procedures for STI site testing, intervals, and symptom presentation will be conducted according to the CDC guideline.
    - Site specific testing will be provided based on patient's needs: rectal swab, pharyngeal swab, vaginal swab, or urine sample for gonorrhea and chlamydia on a schedule in accordance with FDA labeling.
    - Syphilis testing: Blood sample collection for laboratory analysis. If screening is positive, confirmatory testing will be performed by laboratory.

- Subjects who test positive for any STI will be treated in accordance with local STI guidelines.

- All standard of care procedures as recommended by CDC PrEP guidelines and FDA approved labeling instructions for commercially available L4P will be followed and include:
  - Rapid HIV-1/2 Ag/Ab test (or optimal test approved, per local standard).
  - Laboratory HIV- 1/2 4th generation Ag/Ab confirmatory test
  - HIV-1 RNA testing
  - Any subject with a positive HIV rapid test, laboratory 4th generation HIV test, or HIV-1 RNA result will receive counseling and be referred for appropriate care per procedures listed in the preliminary positive HIV tests (section 7.4).
  - Assessment for acute signs/symptoms of HIV.
  - Pregnancy testing for patients with the ability to conceive.
  - Patient interview for sexual history and recent events
    - Patients who are not currently receiving PrEP who seek care within 72 hours after an isolated sexual or injection related HIV exposure will be evaluated and offered nPEP.
  - Risk reduction counseling, including provision of condoms.
  - Subjects will be educated on the signs and symptoms of acute HIV infection and will be instructed to call and/or present to the site immediately for evaluation and HIV testing.
- PrEP Choice Counseling
  - The pharmacist provider will determine the appropriate HIV prevention indication per CDC guidelines. The pharmacist provider will discuss all FDA-approved oral and injectable options for PrEP therapy deemed clinically indicated for the individual.
  - Pharmacist providers will use patient education materials as approved by the FDA and according to package labeling. Patients will be given an opportunity to ask questions to their satisfaction before choosing their preferred therapy.
  - Patients will have the opportunity to choose the PrEP medication best for them.
  - All patients will be provided with risk reduction counseling including provision of condoms as per standard of care.

- Patients who choose L4P will then be offered study enrollment. L4P initiation visits may or may not occur on the date of study enrollment, pending benefits investigation and enrollment in patient assistance programs.

7.3 Positive STI testing

- Subjects who test positive for any STI will be treated in accordance with local STI guidelines.

7.4 Preliminary Positive HIV Test

- Any individuals with a reactive/positive POC HIV test at screening will not be eligible for this study and will promptly receive counseling and referred for appropriate medical care.
- Subjects who present to clinic with signs/symptoms of acute HIV, regardless of HIV test result, will not be eligible for enrollment until HIV has been ruled out with appropriate laboratory testing.
- Any subject with a positive HIV rapid test, laboratory 4th generation HIV test, or HIV-1 RNA result will receive counseling and be referred for appropriate care.
    - The subject will immediately discontinue the study, receive counseling, and be referred for appropriate care.
    - Counseling will consist of explanation of test results, emotional support, emphasis on the importance of HIV medical care and decrease in risk behaviors, and referral to one of the following for appropriate care:
        - Patient's designated primary care provider or provider of their choice
        - Medical Director, Peter Shalit, MD
        - Public Health- Seattle & King County (PHSKC) Sexual Health Clinic
        - For newly reactive HIV tests, patients may also be referred to the PHSKC One-on-One program.

7.5 Initiation L4P Visit (Day 1 Visit)

- Commercially available FDA approved L4P drug product will be used.
- The Day 1 (Initiation) visit will occur after screening and payment coverage for commercially available drug product has been confirmed. This can be through medical insurance, pharmacy insurance, patient assistance programs, or patient payment.
- Baseline demographics survey will be administered.
- HIV-PrevTSQs survey will be administered to all subjects switching from another PrEP regimen to L4P. Subjects that have not had any PrEP medication within the last 3 months will be considered PrEP naïve and are not eligible to take the HIV-PrevTSQs at the Day 1 initiation visit.

- Standard of care procedures for STI site testing, intervals, and symptom presentation will be conducted according to CDC guidelines.
    - Site specific testing will be provided based on subject's needs: rectal swab, pharyngeal swab, vaginal swab, or urine sample for gonorrhea and chlamydia.
    - Syphilis testing: blood sample collection for laboratory analysis. If screening is positive, confirmatory testing will be performed by laboratory.
    - Subjects who test positive for any STI will be treated in accordance with local STI guidelines.
- All standard of care procedures as recommended by CDC PrEP guidelines and FDA approved labeling instructions for commercially available L4P will be followed and include:
    - HIV virologic testing:
        - Rapid HIV- 1/2 Ag/Ab test (or optimal test approved, per local standard).
        - Laboratory HIV -1/2 4th generation Ag/Ab confirmatory test
        - HIV-1 RNA testing
            - Any subject with a positive HIV rapid test, laboratory 4th generation HIV test, or HIV-1 RNA result will receive counseling and be referred for appropriate care per procedures listed in preliminary positive HIV tests (section 6.4). The subject will no longer be permitted to participate in the study.
    - Assessment for acute signs/symptoms of HIV
    - Pregnancy testing for subjects with the ability to conceive
    - Risk reduction counseling, including provision of condoms
    - Review of changes in concomitant medications, medical conditions, and allergies since last visit
    - Review of AEs and SAEs
    - Subject interview for sexual history and recent risk events
        - Subjects not receiving PrEP who seek care within 72 hours after an isolated sexual or injection related HIV exposure will be evaluated and offered nPEP
    - Adherence to target injection window period counseling
    - Subjects will be educated on the signs and symptoms of acute HIV infection and will be instructed to call and/or present to the site immediately for evaluation and HIV testing
    - Counseling will include an in-depth discussion of FDA approved patient information handout from package insert for L4P.

- Subjects will be given an opportunity to ask questions to their satisfaction. Pharmacist provider will obtain subject attestation of counseling intervention prior to initiation.
- Drug dispensation and administration
  - L4P injections will be administered according to the FDA approved labeling instructions
  - L4P oral loading dose will be administered according to the FDA approved labeling instructions. Day 1 600 mg L4P oral loading dose administration will be directly observed by the pharmacist provider at the L4P initiation visit.
  - Day 2 600 mg L4P oral loading dose will be dispensed. Counseling on administration will be provided.
- Serious Adverse Events:
  - From the time of obtaining informed consent through the first administration of L4P, investigators will record all SAEs on FDA Form 3500. All other untoward medical occurrences observed during the screening period, including exacerbation or changes in medical history, are to be captured in the electronic health record. See section 7 Safety Monitoring and Adverse Event reporting for additional details.

7.6 L4P Day 2 Oral Loading Dose

- Day 2 600 mg oral L4P dose will be dispensed at the L4P initiation visit.
- Pharmacist providers will contact all study subjects to confirm successful administration of 600 mg oral L4P the day after L4P initiation visit. Confirmation will be recorded in the EHR.

7.7 Follow Up L4P Visits

- Commercially available L4P drug product will be used.
- Administration of commercially available L4P must take place within 24 to 28 weeks after the last injection of L4P.
- Follow-up visits will occur once payment coverage for commercially available drug product has been confirmed. This can be through medical insurance, pharmacy insurance, patient insurance programs, or patient payment.
- Standard of care procedures for STI site testing, intervals, and symptom presentation will be conducted according to the CDC guidelines.
  - Site specific testing will be provided based on subject's needs: rectal swab, pharyngeal swab, vaginal swab, or urine sample for gonorrhea and chlamydia on a schedule that is in accordance with CDC guidelines.

- Syphilis testing: Blood sample collection for laboratory analysis. If screening is positive, confirmatory testing will be performed by the laboratory.
- Subjects who test positive for any STI will be treated in accordance with local STI guidelines.

- All standard of care procedures as recommended by CDC PrEP guidelines and FDA approved labeling instructions for commercially available CAB-LA for PrEP will be followed and include:
  - HIV virologic testing:
    - Rapid HIV-1/2 Ag/Ab test (or optimal test approved, per local standard).
    - Laboratory HIV- 1/2 4th generation Ab/Ag confirmatory test
    - Any subject with a positive HIV- 1/2 4th generation Ab/Ag result will receive counseling and be referred for appropriate care per procedures listed in preliminary positive HIV tests (section 6.4). The subject will no longer be permitted to participate in the study.
  - Assessment for acute signs/symptoms of HIV
  - Pregnancy testing for subjects with the ability to conceive
  - Risk reduction counseling, including provision of condoms
  - Changes in concomitant medications, medical conditions, and allergies since the last visit
  - Review of AEs and SAEs
  - Subject interval for sexual history and recent risk events
  - Adherence to target injection window period counseling
  - Subjects will be given an opportunity to ask questions to their satisfaction.
  - Drug dispensation and administration
    - L4P will be administered according to FDA approved labeling instructions.
  - Serious Adverse Events:
    - From the time of obtaining informed consent through the first administration of L4P, investigators will record all SAEs on the Gilead form. All other untoward medical occurrences observed during the screening period, including exacerbation or changes in medical history, are to be captured in the electronic health record. See section 7 Safety Monitoring and Adverse Event reporting for additional details.

7.8 Missed Injection Visits

- Study participants who miss their injection visit will be contacted on the same day of the missed appointment and rescheduled for another visit within their target injection

window. Study participants will be contacted three times per standard of care clinic procedures to reschedule an injection visit. Any participant who does not respond will be considered lost to follow up and is no longer eligible for the study.

- If a subject cannot make an appointment within the injection window but can reschedule an injection visit outside the injection window, drug will be dispensed and administered as indicated by FDA labeling for missed injections. This includes continuing injections, bridging with oral L4P, or transitioning to oral PrEP therapy as approved by the FDA and detailed in product labeling.
- Subjects will be counseled on
    - How to safely continue or restart L4P
    - Need for daily oral PrEP or other effective HIV prevention methods if ongoing risk of HIV exposure is anticipated

7.9 L4P Discontinuation

7.9.1 Early study discontinuation assessment

- Participants may voluntarily discontinue participation in the study at any time for any reason.
- Investigators will discontinue individual participation in the study for the following reasons:
    - L4P product-related toxicity requiring discontinuation per FDA labeling
    - Request by study participant to discontinue therapy
    - HIV acquisition
    - Initiation of medication contraindicated with L4P, as stated by FDA labeling
- Counseling will include an in-depth discussion of the following warning and precautions, as detailed in FDA labeling, prior to discontinuation:
    - How to safely discontinue or restart L4P
    - Need for daily oral PrEP or other effective HIV prevention methods if ongoing risk of HIV exposure is anticipated
        - If study participants elect to transition to daily oral PrEP, the pharmacist provider will offer to retain subject within Kelley-Ross One-Step PrEP™ or transition PrEP care to a provider of the participants choosing.

7.9.2 Study discontinuation visits

- Study discontinuation visits will occur 12 months from subject enrollment.

- HIV-PrevTSQs and HIV-PrevTSQc will be administered.
- At this visit, the subject will choose to continue with commercially available L4P, transition to another PrEP regimen, or counseled on how to safely discontinue L4P.
- Subjects who wish to discontinue L4P should be counseled about:
    - How to safely discontinue or restart L4P for PrEP
    - Need for daily oral PrEP or other effective HIV prevention methods if ongoing risk of HIV exposure is anticipated
- Standard of care procedures for STI site testing, intervals, and symptom presentation will be conducted according to the CDC guideline.
    - Site specific testing will be provided based on subject's needs: rectal swab, pharyngeal swab, vaginal swab, or urine sample for gonorrhea and chlamydia on a schedule that is in accordance with CDC guidelines.
    - Syphilis testing: Blood sample collection for laboratory analysis. If screening is positive, confirmatory testing will be performed by the laboratory.
    - Subjects who test positive for any STI will be treated in accordance with local STI guidelines.
- All standard of care procedures as recommended by CDC PrEP guidelines and FDA approved labeling instructions for commercially available CAB-LA for PrEP will be followed and include:
    - HIV virologic testing:
        - Rapid HIV-1/2 Ag/Ab test (or optimal test approved, per local standard).
        - Laboratory HIV- 1/2 4th generation Ab/Ag confirmatory test
        - HIV-1 RNA testing
        - Any subject with a positive HIV-1 RNA result will receive counseling and be referred for appropriate care per procedures listed in preliminary positive HIV tests (section 6.4). The subject will no longer be permitted to participate in the study.
    - Assessment for acute signs/symptoms of HIV
    - Pregnancy testing for subjects with the ability to conceive
    - Risk reduction counseling, including provision of condoms
    - Changes in concomitant medications, medical conditions, and allergies since the last visit
    - Review of AEs and SAEs

- Subject interval for sexual history and recent risk events
- Adherence to target injection window period counseling
- Subjects will be given an opportunity to ask questions to their satisfaction.
- Drug dispensation and administration
    - L4P will be administered according to FDA approved labeling instructions.
- Serious Adverse Events:
    - From the time of obtaining informed consent through the first administration of L4P, investigators will record all SAEs on FDA form 3500. All other untoward medical occurrences observed during the screening period, including exacerbation or changes in medical history, are to be captured in the electronic health record. See section 7 Safety Monitoring and Adverse Event reporting for additional details.

7.10 Adherence Strategies

- Subject adherence to target injection date will be monitored through our electronic health record.
- If an injection is missed, an alert to staff will be made by the EHR and procedures for missed injections (Section 6.8) will be followed.

7.11 Interventions

7.11.1 Aim 1:

7.11.1.1 Pharmacist provider surveys

- Investigators will administer FIM, AIM, and IAM surveys to pharmacist providers prior to training and 1 year after service implementation of L4P. Surveys are detailed in the appendix (Section 14.4)

7.11.1.2 Study Participant Surveys

- Study participant surveys will be administered according to the following schedule
    - At L4P initiation visit: All study subjects will complete the baseline demographics survey. The HIV-PrevTSQs will be administered to patients on a PrEP regimen within the last 90 days prior to enrollment. Any subjects who have not had PrEP in the last 90 days will not be eligible for this survey.

- Four to six weeks after first L4P injection: HIV-PrevTSQs for all participants remaining in the study
- 12 months after study enrollment: HIV-PrevTSQs and HIV-PrevTSQc for all participants remaining in the study

- Surveys are detailed in the appendix (Section 14)

7.11.2 Aim 2:

7.11.2.1 Retrospective Case Control Matched Cohort

- The 75 subjects who provided informed consent will be retrospectively case control matched to a cohort of people for age, gender identity, insurance status, postal code, predictors of STI risk, number of partners, genders of partners, condomless sex, receptive anal sex. Adjustments will be made to matching ratio if all matches are not found.
- Data collected through retrospective chart review of the case control matched cohort will include visit frequency and outcome of bacterial STI acquisition. Bacterial STI acquisition includes acquiring one or more of the following STI's gonorrhea, chlamydia, syphilis.
- This aim involves a retrospective chart review of matched control subjects. Access to protected health information (PHI) is necessary to identify eligible cases and appropriate matched controls, and to extract relevant clinical variables. This research poses no more than minimal risk to privacy since PHI will be accessed only by study personnel, stored securely, and will be de-identified or destroyed at the earliest opportunity consistent with the research aims. Therefore, a waiver of written HIPAA authorization for the matched cohort is needed.
- If, for any reason, a subject's record is flagged as restricted or if the IRB or requires exclusion, those records will not be included in the research dataset, and no PHI from those individuals will be retained or used. All other records will be handled according to the study's HIPAA protections and de-identification procedures.

8 STATISTICAL ANALYSIS

8.1 Study Endpoints

- Primary Endpoints
    - Aim 1
        - Retention rate will be calculated by dividing the number of participants present in the study at 1 year by the number of individuals enrolled.
        - Adherence rate will be collected as the proportion of injections that are successfully administered during each target injection window period over 1 year.
        - Persistence will be measured as the length of time a person remains on L4P for over 1 year.
    - Aim 2
        - Retention rate will be calculated by dividing the number of participants present in the study at 1 year by the number of individuals enrolled.
- Secondary Endpoints
    - Aim 1
        - Patient Acceptability: Measured by the HIV-PrevTSQs questionnaire at baseline (for those already on an FDA approved PrEP regimen within 3 months from enrollment), 4-6 weeks and 1 year and HIV-PrevTSQc at 1 year.
        - Pharmacist Acceptability: Assessed using the FIM, AIM, and IAM surveys at 1 year.
        - L4P Initiations: Number of L4P starts by end of 1 year
        - HIV Seroconversions: Incidence of HIV seroconversions as defined by HIV RNA by PCR
        - STI Rates: Rate at the end of 1 year
        - Reasons for early discontinuation
    - Aim 2
        - Visit frequency will be measured as the overall number of PrEP visits and in-between STI visits per person year.
        - STI positivity rate will be measured as the number of chlamydia, gonorrhea, or syphilis diagnosed per 100 visits.

8.2 Sample Size Considerations

- We aim to enroll 75 patient participants into this program during the first year. We hypothesize that at least 50% of participants will remain on L4P at 12 months. Using a 95% confidence interval (CI) with a critical value of 1.96, our standard error is 0.0577, resulting in an estimated CI range of 0.387 to 0.613. If retention falls below 50%, we will reassess the feasibility of scaling the intervention.

- For the retrospective cohort analysis, we will compare the L4P group to patients on a different PrEP formulation during the same 18-month period as detailed by section 6.2.1. We will perform a matched cohort study and then further confirm our findings using propensity score matching.

8.3 Analysis Plan

8.3.1 Aim 1

- Statistical analyses will be conducted using both descriptive and comparative methods to assess the study's primary and secondary outcomes. Descriptive statistics will be used to summarize baseline and outcome variables. Categorical variables, including demographics, HIV risk factors, housing status, retention, and adherence will be summarized using frequencies, medians, and modes to describe central tendencies. Proportions will be presented with corresponding confidence intervals. Ordinal variables, such as Likert-scale survey responses, will be assessed using medians and interquartile ranges to evaluate distributions. Continuous variables, such as age, will be analyzed using measures of central tendency and variability, including the mean, median, standard deviation, and range.

- Comparative analyses will be performed to evaluate differences between subgroups. Differences in retention and adherence will be assessed using Chi-squared or Fishers exact tests for categorical variables, as appropriate. Ordinal and continuous variables, such as Likert scale responses, will be compared using non-parametric methods, including the Mann-Whitney U test or Kruskal-Wallis test, depending on the number of comparison groups.

8.3.2 Aim 2

- We will attempt to match our cohort on 1:4 6-month follow-up to 3-month follow-up. We will match on covariates chosen a priori based on previous studies. Covariates will include the following: age, gender identity, insurance status, postal code, predictors of STI risk, number of partners, genders of partners, condomless sex, receptive anal sex. Adjustments will be made to matching ratio if all matches are not found.

- To provide more robust results, we will use propensity score matching to approximate the effect of randomization by balancing observed covariates between study groups. As done in the matched retrospective cohort we will select a group of comparison patients who had 3-month follow up who are most like our participants who had 6-month follow up. Following the methods laid out by Montaño et. al., we will include all collected variables in our propensity score model, related to PrEP eligibility, sexual behavior, STI risk, recent STI diagnoses, and demographic characteristics. We will then match on propensity score. The period for patients in the 3-month follow up group who will be matched on propensity score will be those who were enrolled in the center at time of study initiation to its conclusion.

- We will initially analyze results using conditional logistic regression using the binary outcome of bacterial STI acquired or not. We will compare those in the 6-month follow-up group to those in the 3-month follow-up group with the outcome of bacterial STI acquisition at any point during the study period. Bacterial STI acquisition includes acquiring one or more of the following STI's gonorrhea, chlamydia, syphilis. We will exclude 6-month follow up participants who left the study prematurely and their corresponding matches. This analysis will be done for both retrospective cohort 1:M match as well as propensity score.

- As a secondary analysis we use Poisson regression to compare incidence of bacterial STI acquisition between 6-month follow-up group to those in the 3-month follow-up group. This analysis will be done on time to event and thus will not exclude those who dropped out of study prematurely and instead include them as person time.

- Data cleaning, matching and analyses will be conducted using R statistical software (version 4.4.0 or later)

9 SAFETY MONITORING AND ADVERSE EVENT REPORTING

9.1 Safety Monitoring

- Close cooperation between study team members will be necessary to monitor participant safety and to respond to safety events in a timely manner. The team will have regularly scheduled conference calls during the study and additional ad hoc calls will be convened if required.
- All pharmacist providers are responsible for continuous close monitoring and management of AEs. Sites will have detailed SOPs describing methods for AE reporting to ensure that AEs are reported and managed in accordance with the protocol. In the case of drug-related toxicities, pharmacy providers will follow the FDA package insert and CDC PrEP guidelines. Information on the identified and potential risks with L4P and the recognized adverse events can be found in the FDA package insert for L4P.
- All safety measures will be followed for the administration of L4P. These include informed consent, counseling on risks versus benefits, patient observation for 10 minutes post-injection, policies and procedures in place for emergency services, and allergic reactions. Access to epinephrine and diphenhydramine will be onsite. All pharmacist providers will have CPR and blood-borne pathogen training.

9.2 Adverse Event Reporting

9.2.1 Definition of Adverse Events

- An adverse event (AE) is defined as any untoward medical occurrence in a patient or clinical investigation participant, temporally associated with the use of a medicinal product, whether or not considered related to the medicinal product. An AE can therefore be any unfavorable and unintended sign, symptom, or disease temporally associated with the use of a medicinal product.
- A serious adverse event (SAE) is defined as any untoward medical occurrence that, at any dose, results in death, is life threatening, requires hospitalization or prolongation of existing hospitalization, results in disability/incapacity, is a congenital abnormality/birth defect, or other situations. Medical or scientific judgment should be exercised in deciding whether reporting is appropriate in other situations, such as important medical events that may not be immediately life-threatening or result in death or hospitalization but may jeopardize the subject or may require medical or surgical intervention to prevent one of the other outcomes listed in the above definition. These should also be considered serious.

- All persons with study involvement are responsible for detecting, documenting, and reporting events that meet the definition of AE or SAE and are responsible for following up with AEs that are considered serious, considered related to the study intervention or the study, or cause the participant to discontinue.

9.2.2 Time Period and Frequency for Reporting AE and SAE Information

- All AE information will be collected from the first injection visit (Day 1) until either patient discontinuation or study end; whichever comes first at all specified timepoints (see Table 1).

- All SAE information will be collected from signing of informed consent form until either patient discontinuation or study end, whichever comes first at all specified timepoints (see Table 1).

- Medical occurrences that begin after obtaining informed consent and prior to the first injection visit (Day 1) will be recorded within the patient's electronic health record.

- All SAEs considered related to L4P will be recorded and reported to the sponsor within 24 hours of notification. Any updated information about the SAE will be submitted to the sponsor within 24 hours of it being available. Email is the preferred method for communication of SAEs. If email is not available, communication will be submitted by facsimile.

- Investigators are not obligated to actively seek AE or SAE data after the study conclusion; however, if the investigator learns of any SAE, including a death, at any time after the participant is no longer enrolled in the study, and they consider the event to be reasonably related to the study intervention or participation, the investigator must notify the sponsor.

9.2.3 Method of Detecting AEs and SAEs

- AEs and SAEs will be detected through patient interview at all specified time points (Table 1). Care will be taken not to introduce bias when detecting AE and/or SAE with open-ended and non-leading verbal questioning as the preferred method.

9.2.4 Follow-up of AEs and SAEs

- After the initial AE/SAE report, the investigator is required to proactively follow each participant at subsequent visits/contacts. All SAEs will be

followed until the event is resolved, stabilized, or otherwise explained, or the participant is lost to follow-up.

9.2.5 Pregnancy

- Women of childbearing potential must have a negative pregnancy test at the initiation visit. Pregnancy testing will also be conducted as described in the Study Procedures (Table 1) and at any time during the study when pregnancy is suspected. If a pregnancy is reported, the investigator will inform Gilead within 7 days of learning of the pregnancy and the participant will no longer be eligible to participate in the study. Pregnancies will be reported to the Antiretroviral Pregnancy Registry (APR).

- Upon confirmation of a pregnancy, the pharmacist provider will consult with the medical director for referral for comprehensive prenatal care and transition of PrEP.

10 SUBJECT CONFIDENTIALITY

10.1 Informed Consent

- Written informed consent will be obtained from every study participant prior to any study procedures. See Informed Consent document in Appendix (Sections 14.1 and 14.2). Discussion of risks and possible benefits of participants in this study will be provided to study participants. Consent forms describing the study procedures and risks are given to the participant and written documentation of informed consent is required prior to study enrollment. Consent forms will be IRB approved, and the participant will be asked to read and review the document. The investigator will then explain the research study to the participant and answer any questions. The participant will have the opportunity to think about enrollment in the study prior to agreeing to participate. Study participants may withdraw their consent at any time during the study for any reason. A copy of the informed consent document will be given to participants for their records. The rights and welfare of the subjects will be protected by emphasizing to them that the quality of their medical care will not be adversely affected if they decline to participate in this study.

10.2 Incentives

- Pending IRB approval, participants will be compensated for their time and effort in this study. Reimbursement amounts will be specified in the study informed consent forms.

10.3 Confidentiality

- The investigator will ensure that subjects' anonymity will be strictly maintained and that their identities are protected from unauthorized parties.
- Each study subject will be assigned a unique subject number by the investigator. Once a subject number has been assigned to a subject, it will not be reassigned to any other subject. A master linking file (linking identifiers to study codes) will be stored separately in a locked cabinet or encrypted file accessible only to the study personnel. No identifiable data will be transmitted via unsecured email or cloud storage. The master linking file will be destroyed as soon as they are no longer needed for data verification or study follow-up, but no later than 2 years after data collection is complete. The electronic files will be securely deleted using institution-approved secure deletion software to ensure they cannot be recovered Any printed PHI or paper linking documents will be securely destroyed. After destruction, only the de-identified dataset will be retained for analysis and publication purposes
- Only the subject initials, date of birth or subject number will be recorded on any form, survey or study data forms.

- Access to identifiable PHI will be restricted to study personnel listed on the IRB-approved protocol who have completed HIPAA and human subjects research training. PHI will not be shared with any unauthorized individuals.
- Paper records: Any PHI printed or abstracted will be stored in a locked file cabinet in a secure office accessible only to study personnel.
- All study-related information will be stored on a secure and encrypted HIPAA-compliant Microsoft Teams software channel. Microsoft Teams is a password protected and uses multi-factor authentication. Only study staff will have access to this secure channel and therefore have access to study-related information. and all devices will have automatic screen-lock and secure password policies.
- All records that contain names or other personal identifiers, such as locator forms and informed consent forms, will be stored separately from study records identified by subject number. All local databases will be secured with password-protected access systems and multifactor authentication.
- Study information will not be released without the written permission of the participant, except as necessary for monitoring by US FDA, OHRP, other government and regulatory authorities, and/or site IRBs.
- All data used in presentations, publications, or reports will be de-identified, with direct identifiers removed. Only aggregate data or coded study IDs will be reported. No individual patient names, dates of birth, medical record numbers, or other identifying information will be included. Any tables, figures, or case examples will be carefully reviewed by the study team to ensure that individuals cannot be indirectly identified.
- Study Files and Retention of Records will be maintained until at least 2 years after completion or discontinuation of study or according to local laws, whichever is longer.
    - Investigator Study File will contain the following:
        - Protocol/amendments
        - IRB and governmental approval with correspondence
        - Informed consent
        - Staff curriculum vitae and authorization forms
        - Case report forms
    - Subject Clinical Source Data files will include the following for each subject
        - Subject identification (name, date of birth, gender)
        - Documentation that subject meets eligibility criteria
        - Documentation of the reason a consented individual is not enrolled
        - Participation in study (including study number)
        - Study discussed and date of informed consent
        - Dates of all visits
        - Documentation that protocol-specific procedures were performed
        - Record of all adverse events and other safety parameters (start and end date, and including causality and severity)

- Concomitant medication
- Date of study completion and reason for early discontinuation if it occurs

10.4 Communicable Disease Reporting Requirements

- Study staff will comply with all applicable local requirements to report communicable diseases identified among study participants to local health authorities. Participants will be made aware of all reporting requirements during the study informed consent process. In Washington state, health care professionals are legally required to notify public health authorities at their local health jurisdiction of suspected or confirmed cases of selected diseases or conditions. These are referred to as notifiable conditions.

10.5 Study Discontinuation

- The study also may be discontinued at any time by the investigators, other government, or regulatory authorities (OHRP), or site IRBs.

- Discontinuation procedures will be arranged, and the appropriate regulatory authorities will be notified.

11 TIMELINES

Milestone	
IRB approval, Survey creation, protocol on clinicaltrials.gov	09/01/2025
Marketing plan initiated	09/15/2025
Pharmacist Training	09/15/2025
Study start	09/30/2025
50% participant enrollment	11/15/2025
100% participant enrollment	01/31/2025
Study End	09/30/2026
Data collection and analysis	10/30/2026
Submission of 48-week abstract/post/oral presentation	12/31/2026
Manuscript Submitted	03/01/2027

12 PRESENTATION AND PUBLICATION PLANS

The results of this study may be published or presented at scientific meetings. If this is foreseen, the investigator agrees to submit all manuscripts or abstracts to Gilead Sciences before submission. This allows Gilead Sciences to protect proprietary information and provide comments.

13 LITERATURE REFERENCES

Austin PC. An Introduction to Propensity Score Methods for Reducing the Effects of Confounding in Observational Studies. *Multivariate Behav Res*. 2011;46(3):399-424. doi:10.1080/00273171.2011.568786

Bell-Mandla N, Wilson E, Sharma D, et al. Predictors of participant retention in a community-based HIV prevention cohort: perspectives from the HPTN 071 (PopART) study. Trials. 2023;24(1):434. Published 2023 Jun 27. doi:10.1186/s13063-023-07404-y

Centers for Disease Control and Prevention. Advancing team based care through collaborative practice agreements: a resource and implementation guide for adding pharmacists to the care team. Atlanta, GA, USA: Centers for Disease Control and Prevention, U.S. Department of Health and Human Services; 2017. Available online at: https://www.cdc.gov/cardiovascular-resources/media/cpa-team-based-care.pdf [verified 28 July 2025].

Centers for Disease Control and Prevention. PREEXPOSURE PROPHYLAXIS FOR THE PREVENTION OF HIV INFECTION IN THE UNITED STATES – 2021 UPDATE. Atlanta, GA, USA: Centers for Disease Control and Prevention, U.S. Department of Health and Human Services; 2021. Available online at https://stacks.cdc.gov/view/cdc/112360 [verified 28 July 2025].

Garcia MR, Leslie SW, Wray AA. Sexually Transmitted Infections. [Updated 2024 Apr 20]. In: StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; 2025 Jan-. Available from: https://www.ncbi.nlm.nih.gov/books/NBK560808/http://cdc.gov/sti/prevention/index.html

Gilead Sciences, Inc. (n.d.). Yetztugo™ (lenacapavir) tablets for oral use: Prescribing information. https://www.gilead.com/-/media/files/pdfs/medicines/hiv/yeztugo/yeztugo_pi.pdf

Glasgow RE, Vogt TM, Boles SM. Evaluating the public health impact of health promotion interventions: the RE-AIM framework. *Am J Public Health*. 1999;89(9):1322-1327. doi:10.2105/ajph.89.9.1322

Groot Bruinderink ML, Boyd A, Coyer L, et al. Online-Mediated HIV Pre-exposure Prophylaxis Care and Reduced Monitoring Frequency for Men Who Have Sex With Men: Protocol for a Randomized Controlled Noninferiority Trial (EZI-PrEP Study). *JMIR Res Protoc*. 2023;12:e51023. Published 2023 Nov 8. doi:10.2196/51023

Iwagami M, Shinozaki T. Introduction to Matching in Case-Control and Cohort Studies. Ann Clin Epidemiol. 2022;4(2):33-40. Published 2022 Apr 4. doi:10.37737/ace.22005
Lopez MI, Cocohoba J, Cohen SE, et al. Implementation of pre-exposure prophylaxis at a community pharmacy through a collaborative practice agreement with San Francisco Department of Public Health. JAPhA, 2020:60:138-144.

Jourdain H, de Gage SB, Desplas D, Dray-Spira R. Real-world effectiveness of pre-exposure prophylaxis in men at high risk of HIV infection in France: a nested case-control study. Lancet Public Health. 2022;7(6):e529-e536. doi:10.1016/S2468-2667(22)00106-2

Lopez MI, Grant RM, Dong BJ. Community pharmacy delivered PrEP to STOP HIV

transmission: An opportunity NOT to miss! JAPhA, 2020: 60; e18-e24.

Montaño MA, Dombrowski JC, Dasgupta S, et al. Differences in sexually transmitted infection risk comparing preexposure prophylaxis users and propensity score matched historical controls in a clinic setting. *AIDS*. 2019;33(11):1773-1780. doi:10.1097/QAD.0000000000002281

Nair AS, Diwan S. Propensity Score Matching with Retrospective and Observational Data in Palliative Care. *Indian J Palliat Care*. 2020;26(1):149-150. doi:10.4103/IJPC.IJPC_100_19

Qato DM, Zenk S, Wilder J, Harrington R, Gaskin D, Alexander GC. The availability of pharmacies in the United States: 2007e2015. PLoS One. 2017;12(8). e0183172.

Rogers BG, Sosnowy C, Zanowick-Marr A, et al. Facilitators for retaining men who have sex with men in pre-exposure prophylaxis care in real world clinic settings within the United States. BMC Infect Dis. 2022;22(1):673. Published 2022 Aug 5. doi:10.1186/s12879-022-07658-y

Tung E, Thomas A, Eichner A, et al. Implementation of a community pharmacy-based preexposure prophylaxis services: a novel model for pre-exposure prophylaxis care. Sexual Health. 2018;15:556-561.

Wagner GA, Wu KS, Anderson C, Burgi A, Little SJ. Predictors of Human Immunodeficiency Virus Pre-Exposure Prophylaxis (PrEP) Uptake in a Sexual Health Clinic With Rapid PrEP Initiation. Open Forum Infect Dis. 2023;10(3):ofad060. Published 2023 Feb 8. doi:10.1093/ofid/ofad060

Zucker J, Carnevale C, Richards P, et al. Predictors of Disengagement in Care for Individuals Receiving Pre-exposure Prophylaxis (PrEP). J Acquir Immune Defic Syndr. 2019;81(4):e104-e108. doi:10.1097/QAI.0000000000002054

14 APPENDICES

14.1 Study Subject Informed Consent

14.2 Pharmacist Provider Informed Consent

14.3 Study Participant Surveys

14.3.1 Baseline Survey

Please enter your study ID number [free text box]

These questions ask about your background

1. How old are you today in years? (Mark one answer)
    a. 18 to 24
    b. 25 to 29
    c. 30 to 39
    d. 40 to 49
    e. 50 to 59
    f. 60 or over
    g. Prefer not to answer
2. What is your race? (Mark one answer)
    a. American Indian or Alaska Native
    b. Asian
    c. Black or African American
    d. Native Hawaiian or Pacific Islander
    e. White
    f. Different race not listed (please specify)
    g. Prefer not to answer
3. What is your Ethnicity? (Mark one answer)
    a. Hispanic or La tinx
    b. Not Hispanic or Latinx
    c. Prefer not to answer
4. How do you describe yourself? (Mark one answer)
    a. Male
    b. Female
    c. Trans Male/Trans Man
    d. Trans Female/Trans Woman
    e. Genderqueer/Gender nonconforming
    f. Different identity (please specify)
    g. Prefer not to answer
5. What sex were you assigned at birth, such as on the original birth certificate? (Mark one answer)
    a. Male
    b. Female
    c. Prefer not to answer

6. What do you consider your sexual orientation to be?
    a. Heterosexual or straight
    b. Gay
    c. Lesbian
    d. Bisexual
    e. Pansexual
    f. Different sexual orientation not listed
    g. Prefer not to answer
7. What is your marital status? (Mark one answer)
    a. Married (civil union or legal partnership)
    b. Not married, but living with primary or main partner
    c. Have a primary or main partner, not living together
    d. Single
    e. Divorced
    f. Widowed
    g. Prefer not to answer
8. What is your level of education? (Mark one answer)
    a. Less than high school
    b. High school graduate
    c. Some college
    d. Bachelor's degree or higher
    e. Prefer not to answer
9. What is your current employment status? (Mark one answer)
    a. Employed, Full time working
    b. Employed, Part time working
    c. Unemployed, Seeking opportunities currently
    d. Unemployed, not seeking opportunities (on leave, disability, etc.)
    e. Retired
    f. Prefer not to answer
10. What is your annual income? (Mark one answer)
    a. Less than $18,000
    b. $18,000 to $50,000
    c. $51,000 to $74,999
    d. Over $75,000
    e. Prefer not to answer
11. What is your living situation today? (Mark one answer)
    a. I have a steady place to live
    b. I have a place to live today, but I am worried about losing it in the future
    c. I do not have a steady place to live (I am temporarily staying with others, in a shelter, hotel, living outside or in a car)
    d. Prefer not to answer

These questions ask about your sexual activity

12. What do you think the chances are that you will ever get HIV? (Mark one answer)
    a. Very high
    b. Somewhat high
    c. Neutral

d. Low
e. Very low

13. Which kind of sex do you engage in? (Select all that apply)
    a. Solo masturbation
    b. Mutual masturbation (two people stimulating each other at the same time, hand job)
    c. Receiving oral sex
    d. Giving oral sex
    e. Receiving vaginal (front hole) sex
    f. Insertive vaginal (front hole) sex
    g. Receiving anal (back hole) sex
    h. Insertive anal (back hole) sex
    i. Different type of sex not listed (please specify)
14. Are you in an ongoing sexual relationship with a partner who is living with HIV?
    a. Yes
    b. I am unsure of my partner(s) HIV status
    c. No
15. Have you had anal sex without a condom in the last 6 months?
    a. Yes
    b. No
16. Have you been diagnosed with an STI (Example: chlamydia, gonorrhea, or syphilis) in the last 6 months?
    a. Yes
    b. No
17. Have you injected drugs that were not prescribed for you in the last 6 months?
    a. Yes
    b. No
18. Have you used HIV post-exposure prophylaxis, also known as PEP (used in emergencies by someone without HIV within 72 hours of HIV exposure), in the last 12 months?
    a. Yes
    b. No
19. What are you doing to prevent pregnancy?
    a. Rhythm or calendar method
    b. Birth control pills
    c. Birth control patches
    d. Vaginal ring (Nuvaring®)
    e. Injection (Depo-Provera®)
    f. Diaphragm
    g. IUD
    h. Condoms
    i. Vasectomy (surgery to cut the tube that supplies sperm to your semen near the testicles)
    j. Hysterectomy (removal of uterus)
    k. Oophorectomy (removal of ovaries)
    l. I do not have sex with people with reproductive organs that are different than mine
    m. Different method not listed (Please specify:_____)

n. I am not actively trying to prevent pregnancy

These questions ask about PrEP

20. Have you ever used PrEP before? (Mark one answer)
    a. Never (skip to question 24)
    b. I am currently on PrEP
    c. I have previously been on PrEP, but stopped within the last 90 days (3 months)
    d. I have previously been on PrEP, but stopped over 90 days (3 months) ago
21. What PrEP options have you used in the past? (Select all that apply)
    a. Truvada® (emtricitabine/tenofovir disoproxil fumarate) one pill daily
    b. Truvada® (emtricitabine/tenofovir disoproxil fumarate) On Demand, or 2-1-1
    c. Descovy® (emtricitabine/tenofovir alafenamide) one pill daily
    d. Apretude® (cabotegravir) one injection every month for 2 months followed by 1 injection every 2 months
22. If you have stopped PrEP in the past for more than 2 weeks, why? (Select all that apply)
    a. Insurance or financial problems
    b. Clinic or pharmacy problems (long wait times, limited hours, delays in refills, miscommunication with pharmacy providers, difficulty getting patient assistance programs)
    c. Scheduling barriers (getting to clinic for appointments)
    d. Moved and needed to find a new provider
    e. PrEP medication side effects
    f. Drug interactions with PrEP medicine
    g. Disease or problems with organs (example: kidney or liver) with PrEP
    h. Trouble with remembering to take the medication
    i. Medication beliefs (do not want to take medicine every day, act of taking a pill makes you feel old or sick)
    j. Decreased risk (changes in relationship status, becoming monogamous, or decreasing sexual activity)
    l. I cannot remember a time where I stopped PrEP in the past for more than 2 weeks
    k. Different reasons not listed (Please specify: _____)

14.3.2 HIVPrev-TSQs

HIV-Prevention Treatment Satisfaction Questionnaire (HIV-PrevTSQs)

The following questions are concerned with your medical treatment for the prevention of HIV and your experience over the past few weeks. Please answer each question by circling a number on each of the scales.

1. How satisfied are you with your current treatment to prevent HIV?
   very satisfied 6 5 4 3 2 1 0 very dissatisfied

2. How effective do you feel the treatment is in protecting you against HIV?
   very effective 6 5 4 3 2 1 0 very ineffective

3. How satisfied are you with any side effects of your present treatment?
   very satisfied 6 5 4 3 2 1 0 very dissatisfied

4. How satisfied are you with the demands made by your current treatment?
   very satisfied 6 5 4 3 2 1 0 very dissatisfied

5. How convenient have you been finding your treatment to be recently?
   very convenient 6 5 4 3 2 1 0 very inconvenient

6. How flexible have you been finding your treatment to be recently?
   very flexible 6 5 4 3 2 1 0 very inflexible

7. How satisfied are you with your understanding of your current treatment to prevent HIV?
   very satisfied 6 5 4 3 2 1 0 very dissatisfied

8. How satisfied are you with the extent to which the treatment fits in with your life-style?
   very satisfied 6 5 4 3 2 1 0 very dissatisfied

9. Would you recommend your present treatment to someone else who is being offered this treatment for prevention of HIV?
   Yes, I would definitely recommend the treatment 6 5 4 3 2 1 0 No, I would definitely not recommend the treatment

10. How satisfied would you be to continue with your present form of treatment?

very satisfied	6	5	4	3	2	1	0	very dissatisfied

11. How easy or difficult have you been finding your treatment to be recently?

very easy	6	5	4	3	2	1	0	very difficult

12. How satisfied are you with the amount of discomfort or pain involved with your present form of treatment?

very satisfied	6	5	4	3	2	1	0	very dissatisfied

Please make sure that you have circled one number on each of the scales.

13. Are there any other aspects of the treatment to prevent HIV, causing either satisfaction or dissatisfaction, that have not been covered by the questionnaire?

yes ☐ no ☐

If yes, please describe below.

Thank you for taking the time to complete this questionnaire.

14.3.3 HIVPrev-TSQc

HIV-Prevention Treatment Satisfaction Questionnaire (change): (HIV-PrevTSQc)

For the past 12 months you have been taking part in a study of treatment to prevent HIV. At the start of the study you may have had a change of treatment. Today we would like to know how your experience of your current treatment has changed from your experience of treatment before the study began. Please answer each question by circling a number on each of the scales to indicate the extent to which you have experienced changes. If you have experienced no change, please circle '0'.

1. How satisfied are you with your current treatment to prevent HIV?

much more satisfied now	3	2	1	0	-1	-2	-3	much less satisfied now

2. How effective do you feel the treatment is in protecting you against HIV?

much more effective now	3	2	1	0	-1	-2	-3	much less effective now

3. How satisfied are you with any side effects of your present treatment?

much more satisfied now	3	2	1	0	-1	-2	-3	much less satisfied now

4. How satisfied are you with the demands made by your current treatment?

much more satisfied now	3	2	1	0	-1	-2	-3	much less satisfied now

5. How convenient have you been finding your treatment to be recently?

much more convenient now	3	2	1	0	-1	-2	-3	much less convenient now

6. How flexible have you been finding your treatment to be recently?

much more flexible now	3	2	1	0	-1	-2	-3	much less flexible now

7. How satisfied are you with your understanding of your current treatment to prevent HIV?

much more satisfied now	3	2	1	0	-1	-2	-3	much less satisfied now

8. How satisfied are you with the extent to which the treatment fits in with your life-style?

much more satisfied now	3	2	1	0	-1	-2	-3	much less satisfied now

9. How likely would you be to recommend your present treatment to someone else who is being offered this treatment for prevention of HIV?

much more likely to recommend the treatment now	3	2	1	0	-1	-2	-3	much less likely to recommend the treatment now

English for USA 7.2.24 (from GB-HIV-PrevTSQc rev. 31.8.23)

www.healthpsychologyresearch.com

10. How satisfied would you be to continue with your present form of treatment?

much more satisfied now	3	2	1	0	-1	-2	-3	much less satisfied now

11. How easy or difficult have you been finding your treatment to be recently?

much easier now	3	2	1	0	-1	-2	-3	much less easy now

12. How satisfied are you with the amount of discomfort or pain involved with your present form of treatment?

much more satisfied now	3	2	1	0	-1	-2	-3	much less satisfied now

Please make sure that you have circled one number on each of the scales.
Thank you for taking the time to complete this questionnaire.

14.3.4 HIVPrev-TSQ (early discontinuation)

HIV-Prevention Treatment Satisfaction Questionnaire (change): (HIV-PrevTSQc)

For the past few weeks/months you have been taking part in a study of treatment to prevent HIV. At the start of the study you may have had a change of treatment. Today we would like to know how your experience of your current treatment has changed from your experience of treatment before the study began. Please answer each question by circling a number on each of the scales to indicate the extent to which you have experienced changes. If you have experienced no change, please circle '0'.

1. How satisfied are you with your current treatment to prevent HIV?

much more satisfied now	3	2	1	0	-1	-2	-3	much less satisfied now

2. How effective do you feel the treatment is in protecting you against HIV?

much more effective now	3	2	1	0	-1	-2	-3	much less effective now

3. How satisfied are you with any side effects of your present treatment?

much more satisfied now	3	2	1	0	-1	-2	-3	much less satisfied now

4. How satisfied are you with the demands made by your current treatment?

much more satisfied now	3	2	1	0	-1	-2	-3	much less satisfied now

5. How convenient have you been finding your treatment to be recently?

much more convenient now	3	2	1	0	-1	-2	-3	much less convenient now

6. How flexible have you been finding your treatment to be recently?

much more flexible now	3	2	1	0	-1	-2	-3	much less flexible now

7. How satisfied are you with your understanding of your current treatment to prevent HIV?

much more satisfied now	3	2	1	0	-1	-2	-3	much less satisfied now

8. How satisfied are you with the extent to which the treatment fits in with your life-style?

much more satisfied now	3	2	1	0	-1	-2	-3	much less satisfied now

9. How likely would you be to recommend your present treatment to someone else who is being offered this treatment for prevention of HIV?

much more likely to recommend the treatment now	3	2	1	0	-1	-2	-3	much less likely to recommend the treatment now

10. How satisfied would you be to continue with your present form of treatment?

much more satisfied now	3	2	1	0	-1	-2	-3	much less satisfied now

11. How easy or difficult have you been finding your treatment to be recently?

much easier now	3	2	1	0	-1	-2	-3	much less easy now

12. How satisfied are you with the amount of discomfort or pain involved with your present form of treatment?

much more satisfied now	3	2	1	0	-1	-2	-3	much less satisfied now

Please make sure that you have circled one number on each of the scales.
Thank you for taking the time to complete this questionnaire.

14.4 Pharmacist Provider Survey

Acceptability of Intervention Measure (AIM)

	Completely disagree	Disagree	Neither agree nor disagree	Agree	Completely agree
1. Lenacapavir for PrEP in a Community Pharmacy Setting meets my approval.	○	○	○	○	○
2. Lenacapavir for PrEP in a Community Pharmacy Setting is appealing to me.	○	○	○	○	○
3. I like Lenacapavir for PrEP in a Community Pharmacy Setting.	○	○	○	○	○
4. I welcome Lenacapavir for PrEP in a Community Pharmacy Setting.	○	○	○	○	○

Intervention Appropriateness Measure (IAM)

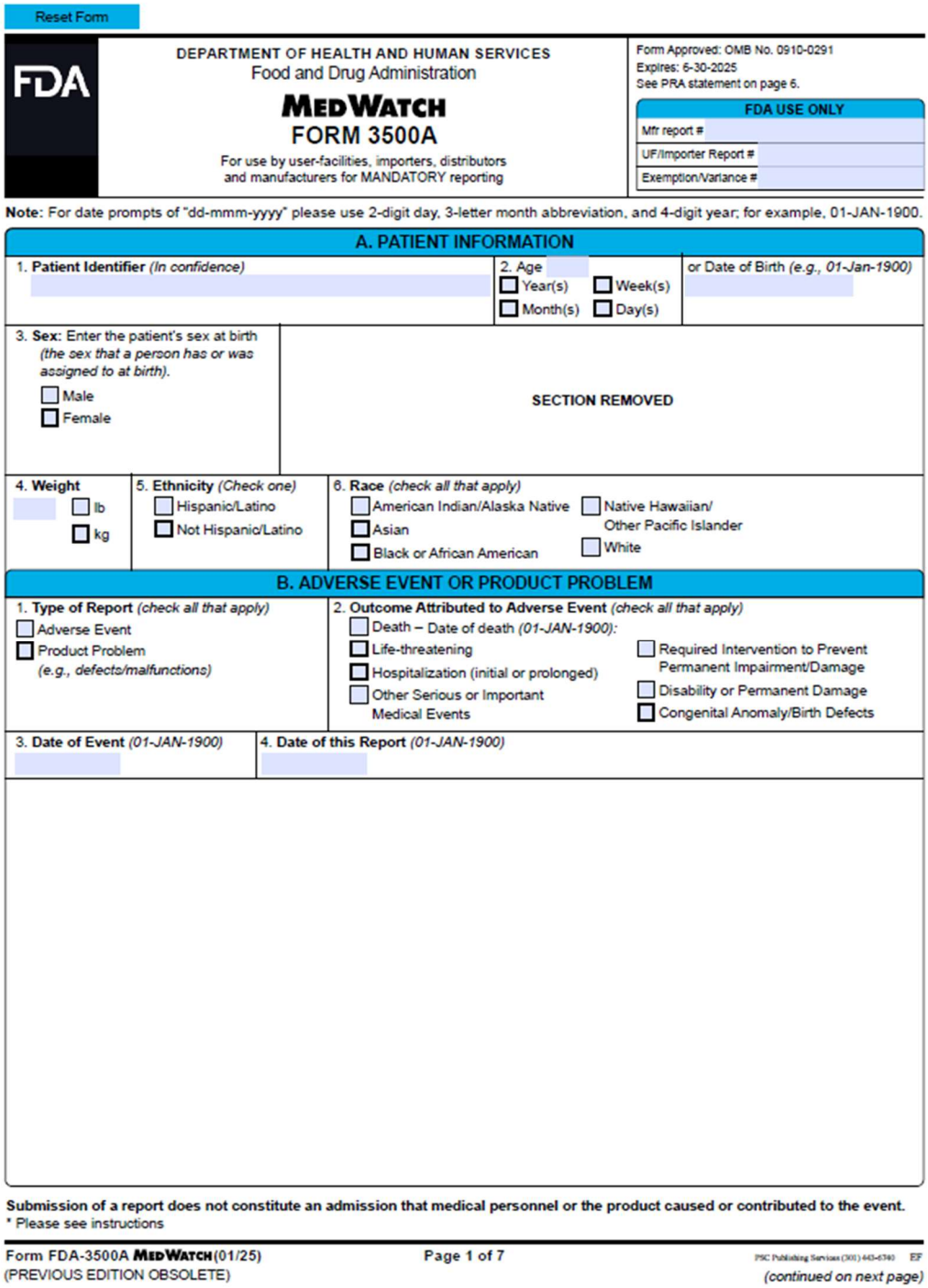
	Completely disagree	Disagree	Neither agree nor disagree	Agree	Completely agree
1. Lenacapavir for PrEP in a Community Pharmacy Setting seems fitting.	○	○	○	○	○
2. Lenacapavir for PrEP in a Community Pharmacy Setting seems suitable.	○	○	○	○	○
3. Lenacapavir for PrEP in a Community Pharmacy Setting seems applicable.	○	○	○	○	○
4. Lenacapavir for PrEP in a Community Pharmacy Setting seems like a good match.	○	○	○	○	○

Feasibility of Intervention Measure (FIM)

	Completely disagree	Disagree	Neither agree nor disagree	Agree	Completely agree
1. Lenacapavir for PrEP in a Community Pharmacy Setting seems implementable.	○	○	○	○	○
2. Lenacapavir for PrEP in a Community Pharmacy Setting seems possible.	○	○	○	○	○
3. Lenacapavir for PrEP in a Community Pharmacy Setting seems doable.	○	○	○	○	○
4. Lenacapavir for PrEP in a Community Pharmacy Setting seems easy to use.	○	○	○	○	○

14.5 Forms for Safety Data Reporting

14.5.1 FDA Form 3500A



Reset Form

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

MEDWATCH
FORM 3500A

For use by user-facilities, importers, distributors and manufacturers for MANDATORY reporting

Form Approved: OMB No. 0910-0291
Expires: 6-30-2025
See PRA statement on page 6.

FDA USE ONLY
Mfr report #
UF/Importer Report #
Exemption/Variance #

Note: For date prompts of "dd-mmm-yyyy" please use 2-digit day, 3-letter month abbreviation, and 4-digit year; for example, 01-JAN-1900.

A. PATIENT INFORMATION

1. **Patient Identifier** *(In confidence)*
2. Age ☐ Year(s) ☐ Week(s) ☐ Month(s) ☐ Day(s)
or Date of Birth *(e.g., 01-Jan-1900)*

3. **Sex:** Enter the patient's sex at birth *(the sex that a person has or was assigned to at birth).*
☐ Male
☐ Female

SECTION REMOVED

4. **Weight** ☐ lb ☐ kg
5. **Ethnicity** *(Check one)*
☐ Hispanic/Latino
☐ Not Hispanic/Latino
6. **Race** *(check all that apply)*
☐ American Indian/Alaska Native
☐ Asian
☐ Black or African American
☐ Native Hawaiian/ Other Pacific Islander
☐ White

B. ADVERSE EVENT OR PRODUCT PROBLEM

1. **Type of Report** *(check all that apply)*
☐ Adverse Event
☐ Product Problem *(e.g., defects/malfunctions)*
2. **Outcome Attributed to Adverse Event** *(check all that apply)*
☐ Death – Date of death *(01-JAN-1900)*:
☐ Life-threatening
☐ Hospitalization (initial or prolonged)
☐ Other Serious or Important Medical Events
☐ Required Intervention to Prevent Permanent Impairment/Damage
☐ Disability or Permanent Damage
☐ Congenital Anomaly/Birth Defects

3. **Date of Event** *(01-JAN-1900)*
4. **Date of this Report** *(01-JAN-1900)*

Submission of a report does not constitute an admission that medical personnel or the product caused or contributed to the event.
* Please see instructions

Form FDA-3500A MEDWATCH (01/25)
(PREVIOUS EDITION OBSOLETE)
Page 1 of 7
PSC Publishing Services (301) 443-6740 EF
(continued on next page)

5. **Describe Event or Problem**

6. **Relevant Test/Laboratory Data**	**Date** *(01-JAN-1900)*	**Relevant Test/Laboratory Data**	**Date** *(01-JAN-1900)*

Additional comments

7. **Other Relevant History, Including Preexisting Medical Conditions** *(e.g., allergies, pregnancy, tobacco product use, alcohol use, and liver/kidney problems, etc.)*

C. SUSPECT PRODUCTS

SUSPECT PRODUCT #1

1. **Name, Strength, Manufacturer/Compounder**

Product Name	Strength	Unit
		--

NDC # or Unique ID	Manufacturer/Compounder Name	Lot #

2. **List Medical Product and Treatment Given at the Same Time of the Event and Date** *(Do not include treatment for initial event)*

3. **Dose or Amount**	**Frequency**	**Route**
Unit --	**Other Frequency**	**Other Route**

4. **Treament Dates/Therapy Dates** *(give best estimate of length of treatment (start/stop) or date of dose reduction.)*

Therapy started on *(e.g., 01-Jan-1900)*	Therapy stopped on *(e.g., 01-Jan-1900)*	Dose Reduced *(e.g., 01-Jan-1900)* **OR**	Duration	Unit
				--

5. **Diagnosis for use** *(indication)*	6. **Product Type** *(check all that apply)*	7. **Expiration Date** *(e.g., 01-Jan-1900)*
	☐ OTC ☐ Generic ☐ Compounded ☐ Biosimilar	

8. **Event Abated after use Stopped or Dose Reduced?**	9. **Event Reappeared after Reintroduction?**
☐ Yes ☐ No ☐ Doesn't apply	☐ Yes ☐ No ☐ Doesn't apply

SUSPECT PRODUCT #2

1. **Name, Strength, Manufacturer/Compounder**

Product Name	Strength	Unit
		--

NDC # or Unique ID	Manufacturer/Compounder Name	Lot #

2. **List Medical Product and Treatment Given at the Same Time of the Event and Date** *(Do not include treatment for initial event)*

3. **Dose or Amount**	**Frequency**	**Route**
Unit --	**Other Frequency**	**Other Route**

4. **Treament Dates/Therapy Dates** *(give best estimate of length of treatment (start/stop) or date of dose reduction.)*

Therapy started on *(e.g., 01-Jan-1900)*	Therapy stopped on *(e.g., 01-Jan-1900)*	Dose Reduced *(e.g., 01-Jan-1900)* **OR**	Duration	Unit
				--

5. **Diagnosis for use** *(indication)*	6. **Product Type** *(check all that apply)*	7. **Expiration Date** *(e.g., 01-Jan-1900)*
	☐ OTC ☐ Generic ☐ Compounded ☐ Biosimilar	

8. **Event Abated after use Stopped or Dose Reduced?**	9. **Event Reappeared after Reintroduction?**
☐ Yes ☐ No ☐ Doesn't apply	☐ Yes ☐ No ☐ Doesn't apply

D. SUSPECT MEDICAL DEVICE

1. **Brand Name**	2a. **Common Device Name**	2b. **Procode**

3. **Manufacurer Name, City and State**		

4. **Model #**	**Lot #**	**Catalog #**

Expiration Date *(01-JAN-1900)*	**Serial #**

Unique Device Identifier *(UDI)* **#**

5. **Operator of Device**	6a. **If Implanted, Give Date** *(01-JAN-1900)*	6b. **If Explanted, Give Date** *(01-JAN-1900)*
☐ Health Professional ☐ Patient/Consumer ☐ Other		

7a. **Is this a single-use device that was reprocessed and reused on a patient?** ☐ Yes ☐ No	7b. **If yes, enter the name and address of the reprocessor**
8. **Was this device ever serviced by a third-party servicer?** ☐ Yes ☐ No ☐ Unknown	9. **Is this Device Available for Evaluation?** *(Do not send to FDA)* ☐ Yes ☐ No ☐ Returned to manufacturer on *(01-JAN-1900)*

10. **Concomitant Medical Products and Therapy Dates** *(Exclude treatment of event)*

	Product Name	Therapy Start Date *(01-JAN-1900)*	Therapy End Date *(01-JAN-1900)*
1.			
2.			
3.			
4.			
5.			
6.			
7.			
8.			
9.			
10.			

E. INITIAL REPORTER

1. **Name and Address**

Last Name	First Name

Address

City	State/Province/Region	ZIP/Postal Code	Country
			--

Phone #	Email

2. **Health Professional?**	3. **Occupation** *(Select from list)*	4. *Initial reporter also sent report to FDA*
☐ Yes ☐ No	--	☐ Yes ☐ No ☐ Unknown

F. FOR USE BY USER FACILITY/IMPORTER *(Devices Only)*

1. **Check One**
☐ User Facility ☐ Importer

2. **User Facility/Importer Report Number**

3. **User Facility or Importer Name/Address**

4. **Contact Person**

5. **Phone Number**

6. **Date User Facility or Importer Became Aware of Event** *(01-JAN-1900)*

7. **Type of Report**

8. **Date of This Report** *(01-JAN-1900)*

9. **Approximate Age of Device**

10. **Adverse Event Problem** *(Refer to coding manual)*

Health Effect – Clinical Code	Health Effect – Impact Code	Medical Device Problem Code	Component Code

11. **Report Sent to FDA?**
(If Yes, enter date (01-JAN-1900))
☐ Yes ☐ No

12. **Location Where Event Occurred**
☐ Ambulatory Surgical Facility ☐ Outpatient Treatment Facility ☐ Other *(Specify)*
☐ Home ☐ Outpatient Diagnostic Facility
☐ Hospital ☐ Nursing Home

13. **Report Sent to Manufacturer?**
(If Yes, enter date (01-JAN-1900))
☐ Yes
☐ No

14. **Manufacturer Name/Address**

G. ALL MANUFACTURERS

1. **Contact Office** *(and Manufacturing Site for Devices)* **or Compounding Outsourcing Facility**

Name	Email Address	Phone Number

Address

Compounding Outsourcing Facility 503B?
☐ Check box if applicable

Outsourcing Facility

2. **Report Source** *(check all that apply)*
☐ Foreign ☐ Literature ☐ Health Professional ☐ Company Representative
☐ Study ☐ Consumer ☐ Use Facilty ☐ Distributor/Importer ☐ Other *(Please list)*

3. **Date Received by Manufacturer** *(01-JAN-1900)*

4. **NDA #**	**ANDA #**	**IND #**	**BLA #**	**PMA/510***(k)* **#**

Check all that apply:
☐ Combination product ☐ Pre-ANDA ☐ Pre-1938 ☐ OTC ☐ Compounded Product

5. **If IND/Pre-ANDA, Give Protocol #**

6. **Type of Report** *(Check all that apply)*
☐ 5-day ☐ 15-day ☐ Periodic ☐ Follow-up #
☐ 7-day ☐ 30-day ☐ Initial

7. **Adverse Event Term***(s)*

8. **Manufacturer Report Number**

H. DEVICE MANUFACTURERS ONLY

1. Type of Reportable Event *(check all that apply.)*

- ☐ Death
- ☐ Malfunction
- ☐ Serious Injury
- ☐ Summary Report

No. of events summarized

2. If Follow-up, What Type?

- ☐ Correction
- ☐ Additional Information
- ☐ Response to FDA Request
- ☐ Device Evaluation

3. Device Evaluated by Manufacturer?

- ☐ Yes
- ☐ No

4. Device Manufacture Date *(01-JAN-1900)*

5. Labeled for Single Use?

- ☐ Yes
- ☐ No

6. Adverse Event Problem *(Refer to coding manual)*

Health Effect – Clinical Code	Health Effect – Impact Code	Medical Device Problem Code	Component Code

Type of Investigation	Investigation Findings	Investigation Conclusions

7. If Remedial Action Initiated, Check Type

- ☐ Recall
- ☐ Relabeling
- ☐ Patient Monitoring
- ☐ Repair
- ☐ Notification
- ☐ Modification/Adjustment
- ☐ Replace
- ☐ Inspection
- ☐ Other:

8. Usage of Device

- ☐ Initial Use of Device
- ☐ Reuse
- ☐ Unknown

9. If action reported to FDA under 21 USC 360i(g), list correction/ removal reporting number:

10. Related Report Number

11. Additional Manufacturer Narrative

This section applies only to requirements of the Paperwork Reduction Act of 1995. This section applies only to requirements of the Paperwork Reduction Act of 1995. The public reporting burden for this collection of information has been estimated to average 73 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

Please DO NOT RETURN this form to the above PRA Staff email address.

OMB Statement: *"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number."*