

GAIN Study Data Sources & Variables

Baseline Data		
	Gay City	Madison Clinic
Data Source (deidentified)	<ul style="list-style-type: none"> • Electronic Medical Record (EMR, or INSYNC database) • Phone calls (entered in INSYNC database) • PrEP Clinic database (Access) 	<ul style="list-style-type: none"> • EPIC (via ITHS) • University of Washington HIV Information System (UWHIS) • PrEP Patient Reported Outcomes (PRO)

Testing, PEP & PrEP: People with HIV status unknown going in to study visit		
	Gay City	Madison Clinic
Linking Survey (entered by RSC at study visit in REDCap)	<ul style="list-style-type: none"> • Name • Date of birth (DOB) • contact information • Study ID • EMR ID 	<ul style="list-style-type: none"> • Name • Date of birth (DOB) • contact information • Study ID • EPIC ID
GAIN Study Visit Survey (entered by RSC at study visit in REDCap)	<ul style="list-style-type: none"> • Study ID • Demographics (age, race/ethnicity, sex/gender identity, education, housing status, and insurance status) • Behavioral data (gender of sex partners and substance use) • Type of visit (HIV testing, PrEP start, PrEP persistence) • HIV status • History of PrEP/ART (current, previous, or never) • HIV test results (i.e. POC NAT, pooled or individual HIV RNA) • Date and method of receipt of POC NAT results (i.e. at clinic visit or by phone call) 	<ul style="list-style-type: none"> • Study ID • Demographics (age, race/ethnicity, sex/gender identity, education, housing status, and insurance status) • Behavioral data (gender of sex partners and substance use) • Type of visit (i.e. HIV testing, PEP, PrEP start, PrEP persistence) • HIV status • History of PrEP/ART (current, previous, or never) • HIV test results (i.e. POC NAT, pooled or individual HIV RNA) • Date and method of receipt of POC NAT results (i.e. at clinic visit or by phone call)
Test Results (ordered by study, clinic, or obtained via ROI results, entered in REDCap)	<ul style="list-style-type: none"> • POC NAT: SAMBA II Qual • INSTI if requested (clinic) • Ag/Ab combo (clinic) → Geenius if EIA+ (clinic) • Pooled NAT on serum ID by Study ID → individual RNA if EIA+ and/or Geenius + (clinic) 	<ul style="list-style-type: none"> • POC NAT: SAMBA II Qual • PEP: Ag/Ab combo (clinic), pooled RNA (study ID) • PrEP: Ag/Ab combo (clinic), pooled RNA (study ID) • HIV testing: INSTI (clinic), Ag/Ab combo (Clinic may order), RNA (Clinic or study if not ordered for clinic)
Study Forms	<ul style="list-style-type: none"> • Consent • HIPAA • ROI 	<ul style="list-style-type: none"> • Consent • HIPAA • ROI
Follow up	Data from INSYNC & f/u phone calls: <ul style="list-style-type: none"> • PrEP f/u: 3 mos, 6 mos call • To start PrEP: call based on priority score • If HIV+ test: 1, 3, 6 month calls 	Data from EPIC, PrEP PRO, and/or UWHIS: <ul style="list-style-type: none"> • Time to PrEP start • Number of persons initiating PrEP • Duration PrEP persistence • If HIV+ test: linkage to care, ART, VL via EPIC/UWHIS

Sample Storage	N/A	N/A
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People who are known to be HIV positive going in to study visit			
	Gay City HIV-positive	Madison Clinic: RCT	Madison Clinic: Multi-NAT group
Linking Survey (entered by RSC at study visit in REDCap)	<ul style="list-style-type: none"> Name DOB contact information Study ID EMR ID 	<ul style="list-style-type: none"> Name DOB contact information Study ID EPIC ID 	N/A
GAIN Study Visit Survey (entered by RSC at study visit in REDCap)	<ul style="list-style-type: none"> Study ID Demographics (age, race/ethnicity, sex/gender identity, education, housing status, and insurance status) Behavioral data (gender of sex partners and substance use) Type of visit (HIV testing, PrEP start, PrEP persistence, HIV-positive) HIV status History of ART (current, previous, never taken) HIV test results (i.e. POC NAT, pooled or individual HIV NAT) Date and method of receipt of POC NAT results 	<ul style="list-style-type: none"> Study ID Demographics (age, race/ethnicity, sex/gender identity, education, housing status, and insurance status) Behavioral data (gender of sex partners and substance use) Type of visit (i.e. HIV testing, PEP, PrEP start, PrEP persistence, HIV-positive) HIV status History of ART (current, previous, or never taken) HIV test results (i.e. POC NAT, pooled or individual HIV NAT) Date and method of receipt of POC NAT results 	<ul style="list-style-type: none"> Study ID Demographics (age, race/ethnicity, sex/gender identity, education, housing status, and insurance status) Behavioral data (gender of sex partners and substance use) Type of visit (i.e. HIV testing, PEP, PrEP start, PrEP persistence, HIV-positive) HIV status History of ART (current, previous, or never taken) HIV test results (i.e. POC NAT, pooled or individual HIV NAT) Date and method of receipt of POC NAT results
Test Results (ordered by study, clinic, or via ROI results, entered in Study Visit DB)	<ul style="list-style-type: none"> POC NAT: SAMBA II Semi-Q Indiv. RNA with study ID (study) 	<ul style="list-style-type: none"> POC NAT: SAMBA II Semi-Q Indiv. RNA (study will order if not ordered by clinic on the same day) with study ID 	<ul style="list-style-type: none"> POC NAT: SAMBA II Semi-Q Indiv. RNA with study ID (study)
Study Forms	<ul style="list-style-type: none"> Consent HIPAA ROI 	<ul style="list-style-type: none"> Consent HIPAA ROI 	<ul style="list-style-type: none"> Consent HIPAA ROI: Optional, for participants who wish to share result with their PCP
Follow up	<ul style="list-style-type: none"> follow up call entered into INSYNC 	<ul style="list-style-type: none"> Time to viral suppression via UWHIS or EPIC 	N/A
Sample Storage	N/A	N/A	<ul style="list-style-type: none"> From two 10 mL EDTA tubes: Plasma & cell pellet

Survey Group		
	Gay City	Madison Clinic
CASI Survey	<p>Will be a patient who has already participated in the study:</p> <ul style="list-style-type: none"> • 100 HIV negative (Testing & PrEP group) • 50 HIV positive (HIV-positive group) <p>Will link CASI survey to their study ID when submitted, then delete email from survey software.</p>	<p>Will be a patient who has already participated in the study:</p> <ul style="list-style-type: none"> • 100 HIV negative (Testing & PrEP group) • 50 HIV positive (from RCT group only) <p>Will link CASI survey to their study ID when submitted, then delete email from survey software.</p>
Qualitative Focus groups/interviews	<p>Will be a patient who has already participated in the study:</p> <ul style="list-style-type: none"> • 10 HIV negative (Testing & PrEP group) • 10 HIV positive (HIV-positive group) <p>Will record and transcribe, remove any identifiers, then delete the recording.</p>	<p>Will be a patient who has already participated in the study:</p> <ul style="list-style-type: none"> • 10 HIV negative (Testing & PrEP group) • 10 HIV positive (from RCT group only) <p>Will record and transcribe, remove any identifiers, then delete the recording.</p>