**GAIN Study Data Sources & Variables**

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| **Baseline Data** |
|  | **Gay City** | **Madison Clinic** |
| Data Source (deidentified) | * Electronic Medical Record (EMR, or INSYNC database)
* Phone calls (entered in INSYNC database)
* PrEP Clinic database (Access)
 | * EPIC (via ITHS)
* University of Washington HIV Information System (UWHIS)
* PrEP Patient Reported Outcomes (PRO)
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| **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) | * Name
* Date of birth (DOB)
* contact information
* Study ID
* EMR ID
 | * Name
* Date of birth (DOB)
* contact information
* Study ID
* EPIC ID
 |
| **GAIN Study Visit Survey** (entered by RSC at study visit in REDCap) | * 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)
 | * 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) | * 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) | * 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** | * Consent
* HIPAA
* ROI
 | * Consent
* HIPAA
* ROI
 |
| **Follow up**  | Data from INSYNC & f/u phone calls: * 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: * Time to PrEP start
* Number of persons initiating PrEP
* Duration PrEP persistence
* If HIV+ test: linkage to care, ART, VL via EPIC/UWHIS
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| **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) | * Name
* DOB
* contact information
* Study ID
* EMR ID
 | * Name
* DOB
* contact information
* Study ID
* EPIC ID
 | N/A |
| **GAIN Study Visit Survey** (entered by RSC at study visit in REDCap) | * 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
 | * 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
 | * 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) | * POC NAT: SAMBA II Semi-Q
* Indiv. RNA with study ID (study)
 | * POC NAT: SAMBA II Semi-Q
* Indiv. RNA (study will order if not ordered by clinic on the same day) with study ID
 | * POC NAT: SAMBA II Semi-Q
* Indiv. RNA with study ID (study)
 |
| **Study Forms** | * Consent
* HIPAA
* ROI
 | * Consent
* HIPAA
* ROI
 | * Consent
* HIPAA
* ROI: Optional, for participants who wish to share result with their PCP
 |
| **Follow up** | * follow up call entered into INSYNC
 | * Time to viral suppression via UWHIS or EPIC
 | N/A |
| **Sample Storage** | N/A | N/A | * From two 10 mL EDTA tubes: Plasma & cell pellet
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| **Survey Group** |
|  | **Gay City** | **Madison Clinic** |
| **CASI Survey** | Will be a patient who has already participated in the study: * 100 HIV negative (Testing & PrEP group)
* 50 HIV positive (HIV-positive group)

Will link CASI survey to their study ID when submitted, then delete email from survey software. | Will be a patient who has already participated in the study: * 100 HIV negative (Testing & PrEP group)
* 50 HIV positive (from RCT group only)

Will link CASI survey to their study ID when submitted, then delete email from survey software. |
| **Qualitative Focus groups/interviews** | Will be a patient who has already participated in the study: * 10 HIV negative (Testing & PrEP group)
* 10 HIV positive (HIV-positive group)

Will record and transcribe, remove any identifiers, then delete the recording. | Will be a patient who has already participated in the study: * 10 HIV negative (Testing & PrEP group)
* 10 HIV positive (from RCT group only)

Will record and transcribe, remove any identifiers, then delete the recording. |