

## GAIN Study Data Sources & Variables

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

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

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



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