HPTN 091 − Integrating HIV Prevention, Gender−Affirmative Medical Care, and Peer Health Navigation for Transgender Women in the Americas: A Vanguard Study
Atlas Open Report − September 15, 2025
Visit Cutoff Date: September 15, 2025
Table O1 − Screening Summary by Site

	Overall	New York − Harlem Prevention	San Francisco	Houston AIDS Research Team CRS	Philadelphia	Rio de Janeiro − Manguinhos
Total Participants Screened	427	85	58	54	61	169
Missing	0/427 (0.0%)	0/85 (0.0%)	0/58 (0.0%)	0/54 (0.0%)	0/61 (0.0%)	0/169 (0.0%)
Eligible and Enrolled	304/427 (71.2%)	48/85 (56.5%)	45/58 (77.6%)	51/54 (94.4%)	50/61 (82.0%)	110/169 (65.1%)
Eligible/Not Enrolled	24/427 (5.6%)	1/85 (1.2%)	0/58 (0.0%)	0/54 (0.0%)	1/61 (1.6%)	22/169 (13.0%)
Ineligible	79/427 (18.5%)	32/85 (37.6%)	7/58 (12.1%)	2/54 (3.7%)	5/61 (8.2%)	33/169 (19.5%)
Incomplete Screening	17/427 (4.0%)	1/85 (1.2%)	6/58 (10.3%)	1/54 (1.9%)	5/61 (8.2%)	4/169 (2.4%)
Ineligible but Enrolled	3/427 (0.7%)	3/85 (3.5%)	0/58 (0.0%)	0/54 (0.0%)	0/61 (0.0%)	0/169 (0.0%)
Ineligible participants who failed to meet one or more of the inclusion criteria [1]						
Eighteen years or older at the time of screening	0/79 (0.0%)	0/32 (0.0%)	0/7 (0.0%)	0/2 (0.0%)	0/5 (0.0%)	0/33 (0.0%)
Willing and able to provide informed consent for the study	0/79 (0.0%)	0/32 (0.0%)	0/7 (0.0%)	0/2 (0.0%)	0/5 (0.0%)	0/33 (0.0%)
Interest in PrEP	2/79 (2.5%)	1/32 (3.1%)	1/7 (14.3%)	0/2 (0.0%)	0/5 (0.0%)	0/33 (0.0%)
Non−reactive HIV test results at screening and enrollment	2/79 (2.5%)	0/32 (0.0%)	0/7 (0.0%)	0/2 (0.0%)	2/5 (40.0%)	0/33 (0.0%)
Available to return for all study visits and within site catchment area	7/79 (8.9%)	4/32 (12.5%)	1/7 (14.3%)	1/2 (50.0%)	0/5 (0.0%)	1/33 (3.0%)
At risk for sexually acquiring HIV infection based on self−report:						
Sex with any HIV−unknown partner in the previous 3 months	5/79 (6.3%)	2/32 (6.3%)	0/7 (0.0%)	0/2 (0.0%)	0/5 (0.0%)	3/33 (9.1%)
Sex in exchange for money, etc. in the previous 3 months	2/79 (2.5%)	2/32 (6.3%)	0/7 (0.0%)	0/2 (0.0%)	0/5 (0.0%)	0/33 (0.0%)
History of STI(s) in the past 6 months	2/79 (2.5%)	2/32 (6.3%)	0/7 (0.0%)	0/2 (0.0%)	0/5 (0.0%)	0/33 (0.0%)
Willing to undergo all required study procedures	3/79 (3.8%)	2/32 (6.3%)	1/7 (14.3%)	0/2 (0.0%)	0/5 (0.0%)	0/33 (0.0%)
General good health, as evidenced by the following laboratory values:						
Calculated creatinine clearance > 60 mL/minute	1/79 (1.3%)	1/32 (3.1%)	0/7 (0.0%)	0/2 (0.0%)	0/5 (0.0%)	0/33 (0.0%)
ALT and AST < 2.5 times the upper limit of normal (ULN)	1/79 (1.3%)	0/32 (0.0%)	0/7 (0.0%)	0/2 (0.0%)	0/5 (0.0%)	1/33 (3.0%)
HBV surface antigen (HBsAg) negative	2/79 (2.5%)	2/32 (6.3%)	0/7 (0.0%)	0/2 (0.0%)	0/5 (0.0%)	0/33 (0.0%)
Ineligible participants who met one or more of the exclusion criteria [1]						
Any reactive or positive HIV test result at screening or enrollment	10/79 (12.7%)	4/32 (12.5%)	0/7 (0.0%)	1/2 (50.0%)	0/5 (0.0%)	5/33 (15.2%)
Plans to move away from the site area within the next 18 months	1/79 (1.3%)	1/32 (3.1%)	0/7 (0.0%)	0/2 (0.0%)	0/5 (0.0%)	0/33 (0.0%)
Co−enrollment in any other research study	0/79 (0.0%)	0/32 (0.0%)	0/7 (0.0%)	0/2 (0.0%)	0/5 (0.0%)	0/33 (0.0%)
Liver disease or hepatic or biliary abnormalities	7/79 (8.9%)	0/32 (0.0%)	2/7 (28.6%)	0/2 (0.0%)	0/5 (0.0%)	5/33 (15.2%)
History of deep vein thrombosis, pulmonary embolism, and/or clotting disorder	7/79 (8.9%)	1/32 (3.1%)	3/7 (42.9%)	0/2 (0.0%)	0/5 (0.0%)	3/33 (9.1%)
Use of medications with significant drug interactions	0/79 (0.0%)	0/32 (0.0%)	0/7 (0.0%)	0/2 (0.0%)	0/5 (0.0%)	0/33 (0.0%)
Any other condition	12/79 (15.2%)	3/32 (9.4%)	0/7 (0.0%)	0/2 (0.0%)	3/5 (60.0%)	6/33 (18.2%)

[1] Participants could have multiple reasons for not being enrolled.

Source: SCHARP (Haima) − /trials/hptn/p091/analysis/atlas/code/open/t_screening_summary.sas, SAS Version 9.4 (15SEP2025,8:15)