HPTN096 Pilot Cross-sectional Assessment Study- Public Use Dataset ReadMe

Introduction

The protocol and data specifications are in the accompanying PDF Adobe Acrobat PDF (HPTN 096 Protocol FINAL V2.0 2March2022) and excel (HPTN096_Pilot_Cross sectional_Assessment_Study_Dictionary_PUD.xlsx) files.

The data is provided in two file types, one csv (comma-delimited text file) file that is unformatted, and one .csv file that contains the formatted data. The data file is fully described in the HPTN096_Pilot_Cross-sectional_Assessment_Study_Dictionary_PUD.xlsx mentioned above.

Privacy Information Disclosure

Fred Hutchinson Cancer Center and by extension the Statistical Center for HIV/AIDS Research and Prevention (SCHARP) is a covered entity regarding HIPAA Privacy Rule requirements, SCHARP uses the HIPAA Privacy Rule Safe Harbor model when publishing public use datasets. This De-identified Dataset is used for public health and research purposes only. No personal identifying information, such as site information (which is a city level information) and enrollment dates are included in the Datasets. This Dataset uses its own unique identifiers that cannot be used to identify the research participants (i.e., the Dataset identifiers are not participant IDs used in the research). SCHARP staff is trained on and sign an agreement to follow SCHARP's privacy and confidentiality policy.

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These procedures comply with relevant models required in FDA regulations such as Title 21 CFR Parts 20, 21, 803, Title 45 CFR Part 164.514(e)(3)(i), and as recommended in Good Clinical Data Management Practices (GCDMP) defined by the Society of Data Quality Management.

Acknowledgment

We thank Willie McFarlen and Henry Fisher Raymond for their help with the starfish sampling methodology. We also thank Michael Stirratt for continued support and guidance for study design and implementation. Finally, we thank Dawn Smith (1949 – 2022) for her support and data provision for the study, as well as her significant contributions to the fight against HIV, particularly in her work with underrepresented communities. She will be remembered as a respected and well-loved colleague, a mentor to many fellows and younger staff, and a shining example of scientific integrity, intellectual rigor, and dedication to social justice and public health.

Funding Statement

Overall support for the HIV Prevention Trials Network (HPTN) is provided by the National Institute of Allergy and Infectious Diseases (NIAID), Office of the Director (OD), National Institutes of Health

(NIH), National Institute on Drug Abuse (NIDA), the National Institute of Mental Health (NIMH), and the Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD) under Award Numbers UM1AI068619 (HPTN Leadership and Operations Center), UM1AI068617 (HPTN Statistical and Data Management Center), and UM1AI068613 (HPTN Laboratory Center).

ClinicalTrials.gov identifier: NCT05075967.

Data Content

Enrollment

Source variable:

- RECRUITMETHOD

Short Survey Questionnaire

Source and derived variables:

- AGE
- age_cat
- age_cat1
- ethnic_1
- ethnic_2
- ethnic_3
- Orient_1
- Orient_2
- Orient_3
- Orient_4
- Orient_5
- HIVYN
- HIVTEST
- LASTTEST
- PREPYN
- Drug
- HIVPROVIDER

Long Survey Questionnaire

Source and derived variables:

- Education
- Student
- Employment
- Income
- enough_money
- health_insurance_1
- health_insurance_2

- martial_status
- long_PrEP
- long_PrEP1
- long_PrEP2
- long_PrEP3
- long_HIV
- long_HIV1
- long_HIV2
- long_HIV3
- long_HIV4
- long_HIV5
- long_HIV6

Laboratory

The following are the source and derived variables:

- HIV_finaln
- HIV_status
- sup_statusn
- TFVDP
- Quant
- Dose