PHIA 2 Drug Resistance Data Use Manual

Reference Guide for Using Antiretroviral Drug Resistance Genotyping Data from the Population-based HIV Impact Assessments

PHIA Collaborating Institutions

ICAP at Columbia University
CIHEB at University of Maryland, Baltimore
The United States Centers for Disease Control and Prevention (CDC)
Westat
ICF

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Access this Manual Online

The PHIA Project at ICAP – http://phia-data.icap.columbia.edu
RESPONSE at – http://ciheb.org/PHIA/

Contact Information

ICAP at Columbia University
722 West 168th Street
New York, NY 10032
Website: icap.columbia.edu
Email: icap-communications@columbia.edu

CIHEB at University of Maryland, Baltimore
725. W. Lombard Street
Baltimore, MD 21201
Website: ciheb.org
Email: ciheb@ihv.umaryland.edu

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List of Abbreviations

AIDS	Acquired Immunodeficiency Syndrome
ART	Antiretroviral Therapy
ARV	Antiretroviral
CDC	US Centers for Disease Control and Prevention
CD4	CD4+ T Cell
CSV	Comma Separated Values
DBS	Dried Blood Spot
DTS	Dried Tube Specimens
DNA	Deoxyribonucleic Acid
EA	Enumeration Area
HIV	Human Immunodeficiency Virus
HIVDR	Human Immunodeficiency Virus Drug Resistance
ID	Identification Number
ILB	International Laboratory Branch, CDC
INSTI	Integrase Strand Transfer Inhibitor
LAg ODn	Limiting-Antigen Avidity (normalized) Optical Density
MDRI	Mean Duration of Recent Infection
mL	Milliliter
µL	Microliter
NNRTIS	Non-Nucleoside Reverse Transcriptase Inhibitors
NRTI	Nucleoside Reverse Transcriptase Inhibitors
PCR	Polymerase Chain Reaction
PEPFAR	U.S. President’s Emergency Plan for AIDS Relief
PHIA	Population-based HIV Impact Assessment
PI	Protease inhibitor
PII	Personally Identifying Information
RNA	Ribonucleic acid
QA	Quality Assurance
QC	Quality Control
TNA	Total Nucleic Acid
VL	Viral Load
VLS	Viral Load Suppression

1. Background

The purpose of the Population-based HIV Impact Assessment (PHIA) Project is to collect nationally representative data regarding the status of the HIV epidemic in the United States President's Emergency Plan for AIDS Relief (PEPFAR) priority countries, including HIV prevalence, HIV incidence, and viral load suppression (VLS) among persons living with HIV, alongside social, geographic, and economic data.

2. Methods

2.1 Study population

Refer to the PHIA-specific ***Data Manual Supplement*** for the PHIA survey design characteristics and survey target population.

HIV drug resistance (HIVDR) was assessed in specimens from all HIV-positive participants whose viral load (VL) is greater than 200 copies/mL using plasma or dried blood spots (DBS) specimens. Refer to Section 3.3 "Weights and Analysis" for details regarding the weighted population and analysis considerations.

2.2 Laboratory Methods

Stored plasma samples with a detectable viral load (> 200 copies / ml) were HIV-1 genotyped at an in-country reference lab. Protease and reverse transcriptase regions of the HIV-1 pol gene were genotyped using the Thermo Fisher HIV-1 Genotyping Kit (Life Technologies). HIVDR-relevant mutations targeted by the assay were selected based on the Stanford HIVDR database. Quality checks and confirmation of genotype findings and classification was provided by the HIVDR laboratory and the International Laboratory Branch (ILB), Division of Global HIV and TB at CDC, Atlanta, GA, USA.

3. Using Drug Resistance Data

3.1 How to Access Drug Resistance Data

Researchers who are approved to use a country's drug resistance data will be provided with the data as CSV, STATA (.dta), and SAS (.sas7bdat) files via a link where they can download the approved data. Please see the country-specific Data Manual Supplement for instructions for requesting and accessing the datasets, including the drug resistance data.

3.2 Merging Drug Resistance Data with Survey Data

Once downloaded, the drug resistance data can be merged with its corresponding household questionnaire, individual questionnaire, and biomarker data using the variables *householdid* or *personid* as noted in the PHIA data use manual.

The drug resistance data contain one observation per participant with a blood specimen for drug resistance testing. In addition to the unique identifiers, the drug resistance data contains an indicator of whether the genotyping was successful (*genotypingflagprrt & genotypingflagint*), the HIV subtype (*prrtsubtype & intsubtype*), and indicators for each detected drug resistance mutation. In some cases, the value of TNP (*genotypingflagprrt & genotypingflagint)* corresponds to test not performed, for example in cases for which the amount of sample was insufficient.

3.3 Weights and Analysis

When conducting analyses with drug resistance data, the user should carefully consider the aims of their analysis in determining an analytic plan. The survey weights associated with the PHIA survey data (for example, biomarker weights) are not recommended for use in drug resistance analyses. Drug resistance weights are available for analyses of HIV-positive participants whose VL is 1000 copies/mL or greater. Drug resistance data for participants with VL greater than 200 copies/mL but less than 1000 copies/mL are included in the dataset but are unweighted because they have low rates of successful amplification.

See the PHIA-specific **Drug Resistance Data Use Appendix** (hereafter, "**Appendix**") for additional details in the weighting process, the type of weights available by assay type, and how to use the weights.

3.4 Dataset Specifications

See the **Appendix** for the dataset specifications, such as the filename, number of variables, and number of observations. The datasets are available as SAS, Stata, and CSV files.

4. Data Confidentiality

To protect participant confidentiality, all participant IDs are scrambled to ensure that participants cannot be identified from the data. Specifically, *householdid* variables are randomly generated and cannot be linked to the participant. All other identifying information such as participant names, addresses, phone numbers, as well as identifying information provided in free-text fields have been excluded from all PHIA datasets.

The protection of participant privacy and confidentiality was maintained at each phase of PHIA data collection and processing. To ensure the protection of participant privacy and confidentiality, PHIA survey data processing encompasses various methods to reduce the risk of disclosure in the public use data. The mitigation of potential risk disclosure occurs at the household-level and individual-level and addresses both direct and indirect identifiers in the public use data.

Refer to the ***PHIA Data Manual*** *(Section 5: Data confidentiality processes)* and PHIA-specific ***Data Manual Supplement*** *(Section 5: Data confidentiality)* for additional details.

5. References

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6. Appendix

PHIA Drug Resistance Data Use Appendix