ANRS 0788s MULTIVIR2025 - Information for Study Participants

Title: **STUDY OF THE PREVALENCE OF HIV-1 STRAINS RESISTANT TO ONE OR MORE FAMILIES OF ANTIRETROVIRAL DRUGS IN PATIENTS WHO HAVE FAILED VIRAL SUPPRESSION THERAPY.**

In brief	**Principal Investigator:** **Prof. Jade Ghosn:** *Department of Infectious and Tropical Diseases, Bichat-Claude Bernard Hospital, AP-HP Nord* *IAME - UMR 1137 INSERM, University of Paris* *46 rue Henri Huchard, 75018 Paris* **Scientific leaders:** **Prof. Constance Delaugerre**: *Department of Virology, Saint-Louis Hospital, AP-HP Nord 1 avenue Claude Vellefaux, 75010 Paris* **Dr. Quentin Le Hingrat:** *Department of Virology, Bichat-Claude Bernard Hospital, AP-HP.Nord, 46 rue Henri Huchard, 75018 Paris*
	Structure/teams: **Methodological coordination:** **Dr. Lambert ASSOUMOU**, *IPLESP, INSERM & Sorbonne University,* *Unit 1136, 56 Bd V Auriol, CS 81393, 75625 Paris Cedex 13*
	Start date: **March 2026** Research end date: estimated date: **February 2027**
	Expected number of participants: 800
	Research status: In progress
	Condition: HIV
	Sponsor: Inserm - ANRS MIE
The project	To monitor the evolution of resistance to antiretrovirals, we are conducting a cross-sectional, national, and multicenter study among people living with HIV who are receiving antiretroviral therapy to detect the presence or absence of mutations associated with resistance to antiretroviral treatment. The goal of this "MULTIVIR 2025" study is to assess the frequency and profile of these resistances in France, which will allow for better adaptation of first-line treatments and treatments in the event of treatment failure. This study is organized by the Virology and Clinical Pharmacology Network of the French National Agency for Research on HIV/AIDS, Viral Hepatitis, Tuberculosis, Sexually Transmitted Infections, and Emerging Infectious Diseases (ANRS MIE). The study is open to all virology laboratories that participated in the most recent quality control round for resistance genotyping conducted by the ANRS MIE Virology Laboratory Network, whose clinical centers have agreed to participate in this study (n = 49).
Latest News	Study currently being set up
Publication References	
Study type	Multivir2025 is a Category 3 human research study, non-interventional, in accordance with the Jardé Law.

	It is a cross-sectional, national, multicenter study involving retrospective and prospective data collection from all patients treated with antiretrovirals who have two consecutive viral loads (spaced at least two weeks and no more than twelve months apart) greater than 50 copies/ml. The second viral load must be measured during the inclusion period. An analysis of the virus's resistance to antiretrovirals will be performed using a blood sample already collected during a viral load test conducted at a follow-up visit. As part of this study, the results of this test will be used, and certain data will be collected.
Primary Objectives	The primary objective of the study is to determine, in a population of people living with HIV (PLHIV) experiencing virologic failure, the proportion of participants carrying a virus that is resistant or possibly resistant to at least one antiretroviral drug from four different therapeutic classes: nucleos(t)ide reverse transcriptase inhibitors (NRTIs), non-nucleoside reverse transcriptase inhibitors (NNRTIs), protease inhibitors (PIs), and integrase inhibitors (INIs).
Secondary objectives	To determine the proportion of participants harboring a virus resistant or possibly resistant to at least one antiretroviral drug from a single therapeutic class (NRTIs, NNRTIs, PIs, INIs), - Determine the proportion of participants with a virus that is resistant or possibly resistant to at least two drugs within a therapeutic class (INTI, NNRTI, PI, INSTI), - Determine the proportion of participants with a virus that is resistant or possibly resistant to all drugs in a therapeutic class (NRTIs, NNRTIs, PIs, N-acyl-tubulin inhibitors), - Determine the proportion of participants with a virus that is resistant or possibly resistant to at least 2 drugs from 3 different therapeutic classes, - Determine the proportion of participants with a virus that is resistant or possibly resistant to all drugs in 0, 1, 2, 3, or 4 therapeutic classes, - Assess the proportion of participants with a virus resistant or possibly resistant to antiretrovirals based on viral load at treatment failure, - Describe the rate of genotypic resistance testing, according to viral load level, - Describe the mutations associated with virologic failure, - Determine the factors associated with the selection of resistance mutations at treatment failure (virus resistant or possibly resistant to at least one antiretroviral), - Determine the proportion of participants with a virus carrying resistance mutations in the capsid, nucleocapsid, gp41, or gp120, - Compare trends in ARV resistance mutation selection rates between this study and two previous studies conducted in 2009 and 2014.
Optional: Link to the research website	