ANRS 0146s NOVAA TEN – Information for Study Participants

Yellow fever vaccination in HIV-1-infected individuals:
Study of long-term immune responses

At a Glance	Principal Investigator: **Dr. Nathalie COLIN DE VERDIER**
	Organization/teams: **Center for Methodology and Management: Prof. Laurence MEYER /INSERM SC10-US19** **Investigating Centers:** • **Dr. Nathalie Colin de Verdière, *Infectious Diseases Department, Saint Louis Hospital, Paris*** • **Prof. Jade Ghosn, *Department of Infectious and Tropical Diseases, Bichat Claude Bernard Hospital, Paris*** • **Prof. Odile Launay, *Vaccinology Clinical Research Unit at Cochin Hospital, Paris***
	Start Date: **June 2025** Study End Date: **June 2025 + 6 months after the date of the last visit by the last participant**
	Number of participants: **60 participants: 40 people living with HIV and 20 controls**
	Study status: ***Currently recruiting***
	Condition: ***HIV-1***
	Sponsored by: **Inserm - ANRS MIE**
	Funded by: **NA**
The project	This is a non-randomized, multicenter study comparing two parallel groups initially consisting of 40 HIV-positive subjects and 20 HIV-negative subjects. After signing the informed consent form and verifying the inclusion criteria (participants in the ANRS EP46 NOVAA study), the subjects are included in the study: • 40 HIV-positive subjects enrolled in the Infectious Diseases Department • 20 HIV-negative subjects enrolled in the Travelers' Clinic Evaluation will take place at **M156 (+/- 18 months)**, i.e., more than 10 years after the vaccine injection.
Latest news	Study currently being monitored
Publication References	
Study type	Category 2, multicenter interventional study comparing two parallel groups of 40 HIV-positive and 20 HIV-negative subjects included in the ANRS EP46 NOVAA study.
Primary objectives	To determine vaccine responses by measuring neutralizing antibody titers using long-term PRNT neutralization tests in participants of the ANRS EP46 NOVAA study, PLHIV and vaccination-naive controls, 156 months after primary yellow fever vaccination
Secondary objectives	-To determine vaccine responses by measuring neutralizing antibody titers using AcN 400 pseudo-type neutralization tests. -Determine the clinical and biological factors predictive of a sustained vaccine response.
Optional: Link to the	

research website	

Summary

A – Overall research results

B – Secondary use of data and samples

A – Overall research findings

Summary of results: Ongoing study

Publication references: ANRS EP46 Novaa on 1- and 5-year follow-up:
Immunogenicity and safety of yellow fever vaccine in HIV-1-infected patients.
Colin de Verdiere N, Durier C, Samri A, Meiffredy V, Launay O, Matheron S, Mercier-Delarue S, Even S, Aboulker JP, Molina JM, Autran B, Simon F; ANRS EP46 NOVAA Group.
AIDS. 2018 Oct 23;32(16):2291-2299. doi: 10.1097/QAD.0000000000001963. PMID: 30096071
A 5-year neutralizing immune response to yellow fever vaccine in HIV-infected and HIV-uninfected adults
Christine Durier, Séverine Mercier-Delarue, Nathalie Colin De Verdière, Vincent Meiffrédy, Sophie Matheron, Assia Samri, Martine Resch, Lucie Marchand, Brigitte Autran, Odile Launay, François Simon; ANRS NOVAA EP46 study group
AIDS. 2022 Feb 1;36(2):319-321.doi: 10.1097/QAD.0000000000003114. PMID: 34934023

B – Secondary reuse of data and samples

This section applies to participants who have been included in the research and have consented to the reuse of their data and/or samples. Through its website and this document, the research sponsor informs you of projects related to the secondary reuse of your data and/or samples.

B1. For the uninitiated projects listed below only, you have the option to object to the secondary use of your samples and/or data. To do so, you must send an email to the following address**: dpo@inserm.fr**, specifying the name of the research and the title of the project for which you are refusing the reuse of your data and/or samples, no later than one week before the project's scheduled completion date. If you have not exercised your right to object before the project begins, please be aware that the processed data and/or samples cannot be deleted, as their deletion could make it impossible or compromise the achievement of the research objectives.

Projects not yet initiated: *Not Applicable*

Project Title	

Project Summary	
Estimated project start date	
Recipients of the data in France	
Recipients of data abroad	
Identity and data controller	
Transfer of data and/or samples	
Estimated retention period for data and/or samples for this project (from the project start date)	
Data category	

B2. For ongoing projects: ***Not applicable***

Project title	
Project summary	
Project start dates	
Project completion date	
Recipients of data in France	
Recipients of data abroad	
Identity and data controller	
Transfer of data and/or samples	
Retention period for data and/or samples for this project (from the project start date)	
Data category	

B2. For completed projects: ***Not applicable***

Project title	
Project summary	
Project start and end dates	
Data recipients in France	
Recipients of data abroad	
Identity and data controller	
Transfer of data and/or samples	

Retention period for data and/or samples for this project (from the project start date)	
Data category	
Overall project results	Publication or summary of results