ANRS CO8 APROCO-COPILOTE - Cohort of HIV-infected patients who began treatment with protease inhibitor in 1997-1999. Follow-up over 4 years on the long-term effects linked with adherence and tolerance (COPILOT).

Head :Leport Catherine, LABORATOIRE DE RECHERHE EN PATHOLOGIE INFECTIEUSE

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General	
Identification	
Detailed name	Cohort of HIV-infected patients who began treatment with protease inhibitor in 1997-1999. Follow-up over 4 years on the long-term effects linked with adherence and tolerance (COPILOT).
Sign or acronym	ANRS CO8 APROCO-COPILOTE
CNIL registration number, number and date of CPP agreement, AFSSAPS (French Health Products Safety Agency) authorisation	Accord CNIL
General Aspects	
Medical area	Infectious diseases
Health determinants	Genetic
Keywords	unexpected events, Observed health events, serious adverse events, cardiovascular risk factors
Scientific investigator(s) (Contact)	
Name of the director	Leport
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Unit	LABORATOIRE DE RECHERHE EN PATHOLOGIE INFECTIEUSE
Organization	ANRS
Collaborations	

Yes

networks and consortia	
Funding	
Funding status	Mixed
Details	ANRS, COLLEGE DES UNIVERSITAIRES DE MALADIES INFECTIEUSES ET TROPICALES (CMITT EX APPIT), SIDACTION ENSEMBLE CONTRE LE SIDA ABBOTT, BOEHRINGER-INGELHEIM, BRISTOL- MYERS SQUIBB, GILEAD, GLAXO-SMITHKLINE, PFIZER, ROCHE
Governance of the database	
Sponsor(s) or organisation(s) responsible	Agence Nationale de Recherches sur le Sida et les hépatites virales (ANRS)
Organisation status	Public
Additional contact	
Main features	
Type of database	
Type of database	Study databases
Study databases (details)	Cohort study
Database recruitment is carried out by an intermediary	A selection of health institutions and services
Database recruitment is carried out as part of an interventional study	No
Additional information regarding sample selection.	Prospective
Database objective	
Main objective	General objective: To investigate determinants for long-term effects of adherence and tolerance to highly active antiretroviral drugs, in relation to patients infected with HIV-1 who were treated for the first time under a protease inhibitor in 1997-99. Secondary objectives: - to determine the part that host genetic polymorphisms play in the progression of the infection and onset of serious adverse events - to investigate viral load and antiretroviral

	resistance in plasma cell compartments in relation to antiretroviral concentrations over time.
Inclusion criteria	Patients included in the APROCO cohort (adults infected with HIV-1 at first prescription of protease inhibitor in 1997-99), monitored for four years in APROCO after initial enrolment, monitored by voluntary services in order to participate in extended follow-up, having given their written consent.
Population type	
Age	Adulthood (19 to 24 years) Adulthood (25 to 44 years) Adulthood (45 to 64 years)
Population covered	Sick population
Gender	Male Woman
Geography area	National
Detail of the geography area	France
Data collection	
Dates	
Date of first collection (YYYY or MM/YYYY)	03/2003
Date of last collection (YYYY or MM/YYYY)	01/2009
Size of the database	
Size of the database (number of individuals)	[1000-10 000[individuals
Details of the number of individuals	717: Copilote 1281: Aproco
Data	
Database activity	Data collection completed
Type of data collected	Clinical data Declarative data Paraclinical data Biological data

Clinical data (detail)	Medical registration
Declarative data (detail)	Face to face interview
Paraclinical data (detail)	Anthropometric measurements
Biological data (detail)	Type of samples taken: Blood samples, samples at fasting and after gluose load
Presence of a biobank	Yes
Contents of biobank	Plasma Cell lines DNA
Details of biobank content	Plasma bank, DNA bank, cell bank
Health parameters studied	Health event/morbidity Health event/mortality Quality of life/health perception
Procedures	
Data collection method	Self-administered questionnaire: from a paper questionnaire (Manual input) with double data entry Interview: From paper questionnaire (Manual input) with double data entry Clinical Examinations: Handwritten (Manual input) and double data entry
Participant monitoring	Yes
Details on monitoring of participants	Follow-up duration: 10 years
Links to administrative sources	No
Promotion and access	
Promotion	
Link to the document	http://www.hal.inserm.fr/ANRSCO8
Description	List of publications in HAL
Link to the document	<u>http://www.ncbi.nlm.nih.gov/pubmed/?</u> <u>term=ANRS+C08+OR+Aproco+OR+%28cohere+</u> <u>AND+%28hiv+OR+AIDS%29%29</u>
Description	List of publications in Pubmed
Access	

Terms of data access (charter for data provision, format of data, availability delay)	Data may be used by academic teams Data may not be used by industrial teams
Access to aggregated data	Access on specific project only
Access to individual data	Access on specific project only