

# ANRS CO12 CIRVIR - Prospective cohort involving patients with viral cirrhosis B and C

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## General

### Identification

|                                                                                                                          |                                                                                              |
|--------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------|
| Detailed name                                                                                                            | Prospective cohort involving patients with viral cirrhosis B and C                           |
| Sign or acronym                                                                                                          | ANRS CO12 CIRVIR                                                                             |
| CNIL registration number, number and date of CPP agreement, AFSSAPS (French Health Products Safety Agency) authorisation | CPP : PC/AP 11-2005 (15.06.2012), CNIL : 90.54.63 (19.01.2006), CCTIRS : 05.394 (01.09.2005) |

### General Aspects

|                     |                                                                               |
|---------------------|-------------------------------------------------------------------------------|
| Medical area        | Gastroenterology et hepatology                                                |
| Health determinants | Lifestyle and behavior                                                        |
| Keywords            | Cirrhosis related HCV and/or HBV, HCC, predictive factors, prognostic factors |

### Scientific investigator(s) (Contact)

|                      |                                                                                                                                                                                                           |
|----------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Name of the director | Nahon                                                                                                                                                                                                     |
| Surname              | Pierre                                                                                                                                                                                                    |
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| Unit                 | Service d'Hépatologie, Hôpital Jean Verdier                                                                                                                                                               |
| Organization         | APHP-Inserm                                                                                                                                                                                               |

|                      |                                                                  |
|----------------------|------------------------------------------------------------------|
| Name of the director | Roudot-thoraval                                                  |
| Surname              | Françoise                                                        |
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| Unit                 | Service de santé publique, Hôpital Henri Mondor                  |
| Organization         | APHP                                                             |

### Collaborations

|                                                   |     |
|---------------------------------------------------|-----|
| Participation in projects, networks and consortia | Yes |
|---------------------------------------------------|-----|

### Funding

|                |        |
|----------------|--------|
| Funding status | Public |
|----------------|--------|

|         |                                                                                                         |
|---------|---------------------------------------------------------------------------------------------------------|
| Details | Agence Nationale de Recherche sur le Sida et les hépatites Virales (ANRS - agence autonome de l'Inserm) |
|---------|---------------------------------------------------------------------------------------------------------|

### Governance of the database

|                                           |                                                                                   |
|-------------------------------------------|-----------------------------------------------------------------------------------|
| Sponsor(s) or organisation(s) responsible | Agence Nationale de Recherches sur le SIDA et les Hépatites Virales (ANRS) Public |
|-------------------------------------------|-----------------------------------------------------------------------------------|

|                     |        |
|---------------------|--------|
| 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 - Closing date for inclusion not determined |
|----------------------------------------------------|---------------------------------------------------------|

## Database objective

Main objective Description of the natural history of HBV and/or HCV compensated cirrhosis.

Inclusion criteria

1. Presence of a histologically proven cirrhosis (metavir F4 or established cirrhosis)
2. No prior episode, not on the day of inclusion, decompensation or CHC
3. Presence of a laboratory evidence of infection with the hepatitis B and/or hepatitis C virus

Note: HIV coinfections are eligible.

## Population type

Age

Adulthood (19 to 24 years)  
Adulthood (25 to 44 years)  
Adulthood (45 to 64 years)  
Elderly (65 to 79 years)

Population covered Sick population

Gender

Male  
Woman

Geography area National

Detail of the geography area 38 centers in France

## Data collection

### Dates

Date of first collection (YYYY or MM/YYYY) 03/2006

### Size of the database

Size of the database (number of individuals) [1000-10 000[ individuals

Details of the number of individuals 2000

### Data

Database activity Current data collection

Type of data collected

Clinical data  
Paraclinical data  
Biological data

|                                                                                       |                                                                                                                                     |
|---------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------|
| Clinical data (detail)                                                                | Medical registration                                                                                                                |
| Biological data (detail)                                                              | CBC-platelets, TP, factor V, normal liver chemistry (ASAT, ALAT, PA, GGT), total bilirubin, albumin, alpha fetoprotein              |
| Presence of a biobank                                                                 | Yes                                                                                                                                 |
| Contents of biobank                                                                   | Serum<br>Plasma<br>DNA                                                                                                              |
| Details of biobank content                                                            | Serum bank, plasma bank, cell bank                                                                                                  |
| Health parameters studied                                                             | Health event/morbidity<br>Health event/mortality                                                                                    |
| <b>Procedures</b>                                                                     |                                                                                                                                     |
| Participant monitoring                                                                | Yes                                                                                                                                 |
| Details on monitoring of participants                                                 | Half-year follow-up (according to HAS recommendations) in terms of clinical examination, biological balance and imagery examination |
| Links to administrative sources                                                       | No                                                                                                                                  |
| <b>Promotion and access</b>                                                           |                                                                                                                                     |
| <b>Promotion</b>                                                                      |                                                                                                                                     |
| Link to the document                                                                  | <a href="http://www.hal.inserm.fr/CO12_CIRVIR">http://www.hal.inserm.fr/CO12_CIRVIR</a>                                             |
| Description                                                                           | List of publications in HAL                                                                                                         |
| Link to the document                                                                  | <a href="http://www.ncbi.nlm.nih.gov/pubmed/?term=CO12+Cirvir">http://www.ncbi.nlm.nih.gov/pubmed/?term=CO12+Cirvir</a>             |
| Description                                                                           | List of publications in Pubmed                                                                                                      |
| <b>Access</b>                                                                         |                                                                                                                                     |
| Terms of data access (charter for data provision, format of data, availability delay) | Methods of distribution: BEH<br>Request placed with the Investigator-coordinator                                                    |
| Access to aggregated data                                                             | Access on specific project only                                                                                                     |
| Access to individual data                                                             | Access on specific project only                                                                                                     |