

# ASSESS - Assessment of Systemic Involvement and Progression for Patients with Primary Sjogren's Syndrome

Head :Gottenberg Jacques-Eric, U1109 Immuno-rhumatologie moléculaire

Last update : 01/01/2019 | Version : 2 | ID : 6873

## General

### Identification

Detailed name Assessment of Systemic Involvement and Progression for Patients with Primary Sjogren's Syndrome

Sign or acronym ASSESS

CNIL registration number, number and date of CPP agreement, AFSSAPS (French Health Products Safety Agency) authorisation CPP 26/01/2007 N° 0711468

### General Aspects

Medical area Immunology

Keywords Prevalence, risk factor

### Scientific investigator(s) (Contact)

Name of the director Gottenberg

Surname Jacques-Eric

Address 1 Place de l'Hôpital 67000 STRASBOURG

Phone +33 (0)3 68 85 33 76

Email jacques-eric.gottenberg@chru-strasbourg.fr

Unit U1109 Immuno-rhumatologie moléculaire

Organization CHU

### Collaborations

### Funding

Funding status Public

|  |  |
|--|--|
| Details  | Ministère de la santé (Programme Hospitalier de Recherche Clinique 2005 P060228)   |
| <b>Governance of the database</b>                                      |  |
| Sponsor(s) or organisation(s) responsible                              | CHU Strasbourg   |
| Organisation status  | Public   |
| <b>Additional contact</b>  |  |
| <b>Main features</b>   |  |
| <b>Type of database</b>  |  |
| Type of database   | Study databases  |
| Study databases (details)  | Longitudinal study (except cohorts)  |
| 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   |
| <b>Database objective</b>  |  |
| Main objective   | To prospectively determine for the first time the prevalence and risk factors for systemic complications and lymphoma in primary Sjögren's syndrome. |
| Inclusion criteria   | - Men or women - adults - patients in tertiary centres for autoimmune diseases   |
| <b>Population type</b>   |  |
| Age  | Adulthood (45 to 64 years)<br>Elderly (65 to 79 years)   |
| Population covered   | Sick population  |
| Gender   | Male<br>Woman  |
| Geography area   | National   |
| Detail of the geography area   | France (15 Centres)  |
| <b>Data collection</b>   |  |

## Dates

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

Date of last collection (YYYY or MM/YYYY) 2009

## Size of the database

Size of the database (number of individuals) < 500 individuals

Details of the number of individuals 395

## Data

Database activity Data collection completed

Type of data collected Clinical data

Clinical data (detail) Direct physical measures

Presence of a biobank Yes

Contents of biobank Serum  
DNA  
DNAC/RNAm

Details of biobank content -----

Health parameters studied Health event/morbidity  
Health care consumption and services

Care consumption (detail) Hospitalization  
Medical/paramedical consultation  
Medicines consumption

## Procedures

Data collection method Paper case report form (CRF) completed by the investigator or co-investigator. CRFs are then sent to a data manager for input.

Participant monitoring Yes

Details on monitoring of participants Follow-up for serious adverse events.

Links to administrative sources No

## Promotion and access

### Promotion

Link to the document <http://tinyurl.com/Hal-ASSESS>

Description List of publications in HAL

Link to the document <http://tinyurl.com/Pubmed-ASSESS>

Description List of publications in Pubmed

### Access

Terms of data access (charter for data provision, format of data, availability delay) Data unavailable to other researchers, except for authorisation requests for IP data mining to the coordinating investigator

Access to aggregated data Access on specific project only

Access to individual data Access on specific project only