

# - PGRx : Myositis

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## General

### Identification

Detailed name PGRx : Myositis

CNIL registration number,  
number and date of CPP  
agreement, AFSSAPS (French  
Health Products Safety Agency)  
authorisation CNIL : 907.309

### General Aspects

Medical area Internal medicine  
Rare diseases  
Rheumatology

Others (details) Incident cases of myositis and dermatomyositis

Keywords pharmaco-epidemiology

### Scientific investigator(s) (Contact)

Name of the director Grimaldi-Bensouda

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### Collaborations

### Funding

Funding status Private

Details LA-SER

### Governance of the database

Sponsor(s) or organisation(s) LA-SER

responsible

Organisation status

Private

Additional contact

Main features

Type of database

Type of database

Study databases

Study databases (details)

Case control study

Database recruitment is carried out by an intermediary

A selection of health institutions and services  
A population file

Database recruitment is carried out as part of an interventional study

No

Additional information regarding sample selection.

Cases of myositis and dermatomyositis are recruited by a network of internal medicine, dermatology, rheumatology and pediatrics centers and the referents by a network of GPs across the territory.

Database objective

Main objective

Surveillance and assessment of the risk of myositis and/or dermatomyositis associated with drug or vaccine use under real life situations.

Inclusion criteria

For cases: patient, man and woman aged from 0 to 79 years inclusive, with a clinico-biological presentation evocative of myositis/dermatomyositis declared by the specialist, for which the first symptoms of the episode began less than 12 months ago.  
For controls: patient, man and woman aged from 0 to 79 years, who have consulted a GP.

Population type

Age

Newborns (birth to 28 days)  
Infant (28 days to 2 years)  
Early childhood (2 to 5 years)  
Childhood (6 to 13 years)  
Adolescence (13 to 18 years)  
Adulthood (19 to 24 years)  
Adulthood (25 to 44 years)  
Adulthood (45 to 64 years)  
Elderly (65 to 79 years)

|  |  |
|--|--|
| Population covered                           | General population                           |
| Gender                                       | Male<br>Woman                                |
| Geography area                               | International                                |
| Detail of the geography area                 | France, Italy, Spain, United Kingdom, Canada |
| <b>Data collection</b>                       |  |
| <b>Dates</b>                                 |  |
| Date of first collection (YYYY or MM/YYYY)   | 04/2008                                      |
| <b>Size of the database</b>                  |  |
| Size of the database (number of individuals) | [10 000-20 000[ individuals                  |
| Details of the number of individuals         | - 57 cas/cases - 11125 référents/controls    |
| <b>Data</b>                                  |  |
| Database activity                            | Current data collection                      |
| Type of data collected                       | Clinical data<br>Declarative data            |
| Clinical data (detail)                       | Direct physical measures                     |
| Declarative data (detail)                    | Phone interview                              |
| Presence of a biobank                        | No   |
| Health parameters studied                    | Health event/morbidity                       |
| <b>Procedures</b>                            |  |
| Participant monitoring                       | No   |
| Links to administrative sources              | No   |
| <b>Promotion and access</b>                  |  |
| <b>Promotion</b>                             |  |
| <b>Access</b>                                |  |

Terms of data access (charter for data provision, format of data, availability delay)

methods for accessing the database are currently being defined

Access to aggregated data

Access on specific project only

Access to individual data

Access on specific project only