

## - 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)

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

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