- PGRx : Lupus

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General

Identification

Detailed name	PGRx : Lupus
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)	Systemic and cutaneous lupus, Systemic lupus erythematosus (SLE)
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) responsible	LA-SER
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 lupus are recruited by a network of internal medicine, dermatology, rheumatology and pediatrics centers and the referenst by a network of GPs across France.

Database objective

Main objective	Surveillance and assessment of the risk of lupus 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 an incident lupus declared by the specialist, for which 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	- 98 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	methods for accessing the database are currently

for data provision, format of data, availability delay)	being defined
Access to aggregated data	Access on specific project only
Access to individual data	Access on specific project only