# - PGRx : Central demyelination

Head :Grimaldi - Bensouda Lamiae

Last update : 07/10/2012 | Version : 2 | ID : 2383

## General

### Identification

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|---|---|
| Detailed name | PGRx : Central demyelination |
| CNIL registration number, number and date of CPP agreement, AFSSAPS (French Health Products Safety Agency) authorisation | CNIL : 907.069 |

### General Aspects

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|---|---|
| Medical area | Neurology |
| Others (details) | First central demyelinating event, Demyelination, Multiple Sclerosis (MS) |
| Keywords | pharmaco-epidemiology |

### Scientific investigator(s) (Contact)

| | |
|---|---|
| Name of the director | Grimaldi - Bensouda |
| Surname | Lamiae |
| Address | 10 place de Catalogne, 75014 Paris |
| Phone | 01 55 42 53 00 |

### Collaborations

### Funding

| | |
|---|---|
| Funding status | Private |
| Details | LA-SER |

### Governance of the database

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|---|---|
| Sponsor(s) or organisation(s) responsible | LA-SER |
| Organisation status | Private |

## Additional contact

## Main features

### Type of database

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|---|---|
| Type of database | Study databases |
| Study databases (details) | Case control study |
| Database recruitment is carried out as part of an interventional study | No |
| Additional information regarding sample selection. | Cases of central demyelination are recruited by a network of neurology and pediatric centers and the referents by a network of general practitioners, distributed all across the territory. |

### Database objective

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|---|---|
| Main objective | Surveillance and assessment of the risk of central demyelination associated with drug or vaccine use in real life situations. |
| Inclusion criteria | For the cases: patients, males and females aged from 0 to 79 years, having a first central demyelinating event reported by the neurologist, for which the first symptoms of the episode occurred less than 12 months ago.<br>For the controls: patients, males and females aged from 0 to 79 years, having consulted a general practitioner. |

### Population type

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|---|---|
| Age | Newborns (birth to 28 days)<br>Infant (28 days to 2 years)<br>Early childhood (2 to 5 years)<br>Childhood (6 to 13 years)<br>Adolescence (13 to 18 years)<br>Adulthood (19 to 24 years)<br>Adulthood (25 to 44 years)<br>Adulthood (45 to 64 years)<br>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 |
| **Data collection** | |
| **Dates** | |
| Date of first collection (YYYY or MM/YYYY) | 2007 |
| **Size of the database** | |
| Size of the database (number of individuals) | [10 000-20 000[ individuals |
| Details of the number of individuals | 517 cas et 11125 référents |
| **Data** | |
| 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 |
| **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 |