# - PGRx: Acute Liver Damage

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## General

### Identification

| | |
|---|---|
| Detailed name | PGRx: Acute Liver Damage |
| CNIL registration number, number and date of CPP agreement, AFSSAPS (French Health Products Safety Agency) authorisation | 908.025 |

### General Aspects

| | |
|---|---|
| Others (details) | Acute liver damage |
| Keywords | Pharmacoepidemiology |

### Scientific investigator(s) (Contact)

| | |
|---|---|
| Name of the director | Grimaldi - Bensouda |
| Surname | Lamiae |
| Address | 10 place de Catalogne - 75014 Paris |
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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

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|---|---|
| Type of database | Study databases |
| Study databases (details) | Case control study |
| Database recruitment is carried out by an intermediary | A selection of health care professionals |
| Database recruitment is carried out as part of an interventional study | No |
| Additional information regarding sample selection. | Cases of acute liver damage are recruited by a network of hepatology or gastroenterology centres and by referrals from a network of general practitioners located throughout the territory. |

### Database objective

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|---|---|
| Main objective | Surveillance and assessment of the risk of liver damage from drug exposure during actual treatment. |
| Inclusion criteria | Case subjects: patients, men or women over 18 years old, with acute liver damage confirmed by a specialist and followed-up for a maximum of 6 months before recruitment. Case-controls: patients (men and women over 18 years old) who have consulted a general practitioner |

### Population type

| | |
|---|---|
| Age | Adulthood (19 to 24 years)<br>Adulthood (25 to 44 years)<br>Adulthood (45 to 64 years)<br>Elderly (65 to 79 years)<br>Great age (80 years and more) |
| Population covered | General population |
| Gender | Male<br>Woman |
| Geography area | International |
| Detail of the geography area | France, Germany |

## Data collection

| | |
|---|---|
| **Dates** | |
| Date of first collection (YYYY or MM/YYYY) | 2008 |
| **Size of the database** | |
| Size of the database (number of individuals) | [10 000-20 000[ individuals |
| Details of the number of individuals | - 60 cas/cases - 13000 témoins/controls |
| **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** | |
| Link to the document | http://www.em-consulte.com/en/article/211579 |
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| **Access** | |
| Terms of data access (charter for data provision, format of data, availability delay) | To be defined |

| | |
|---|---|
| Access to aggregated data | Access on specific project only |
| Access to individual data | Access on specific project only |