# B030 - Observational study: Conditions of use of duloxetine in France

Head :Laboratoire , Eli Lilly France

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## General

### Identification

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|---|---|
| Detailed name | Observational study: Conditions of use of duloxetine in France |
| Sign or acronym | B030 |
| CNIL registration number, number and date of CPP agreement, AFSSAPS (French Health Products Safety Agency) authorisation | CNIL N°909021 |

### General Aspects

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| Medical area | Psychology and psychiatry |
| Others (details) | Depression |
| Keywords | Pharmacy, appropriate use, duloxetine, conditions of use |

### Scientific investigator(s) (Contact)

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|---|---|
| Name of the director | Laboratoire |
| Email | fr_mail_pharmacoepi@lilly.com |
| Unit | Eli Lilly France |

### Collaborations

### Funding

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| Funding status | Private |
| Details | Eli Lilly and Company |

### Governance of the database

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| Sponsor(s) or organisation(s) responsible | Eli Lilly |

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| Organisation status | Private |
| **Additional contact** | |
| **Main features** | |
| **Type of database** | |
| Type of database | Study databases |
| Study databases (details) | Not-repeated cross-sectional studies (except case control studies) |
| Database recruitment is carried out by an intermediary | A population file |
| Database recruitment is is made on the basis of: | Medication(s) taken |
| Database recruitment is carried out as part of an interventional study | No |
| Additional information regarding sample selection. | Patients recruited by pharmacies. Random selection of pharmacies using professional listing.<br>Stratification by region and by zone (urban/town). |
| **Database objective** | |
| Main objective | Primary objective: evaluate the conditions for use of duloxetine in routine practice;<br>Secondary objectives: characteristics of the patients treated by duloxetine, profiles of duloxetine prescribers, characteristics of treatment. |
| Inclusion criteria | Patient receiving duloxetine in a pharmacy regardless of the indication, whether treatment initiation or renewal |
| **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 | Sick population |
| Gender | Male<br>Woman |

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| Geography area | National |
| Detail of the geography area | National |
| **Data collection** | |
| **Dates** | |
| Date of first collection (YYYY or MM/YYYY) | 2009 |
| Date of last collection (YYYY or MM/YYYY) | 2010 |
| **Size of the database** | |
| Size of the database (number of individuals) | < 500 individuals |
| Details of the number of individuals | 294 |
| **Data** | |
| Database activity | Data collection completed |
| Type of data collected | Clinical data |
| Clinical data (detail) | Direct physical measures |
| Presence of a biobank | No |
| Health parameters studied | Health event/morbidity |
| **Procedures** | |
| Data collection method | Study data collection form |
| 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) | Report and publications |

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