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

Head :Laboratoire , Eli Lilly France

Last update : 01/01/2020 | Version : 1 | ID : 80

General

Identification

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

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

Scientific investigator(s) (Contact)

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

Collaborations

Funding

Funding status	Private
Details	Eli Lilly and Company

Governance of the database

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

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. Stratification by region and by zone (urban/town).
Database objective	
Main objective	Primary objective: evaluate the conditions for use of duloxetine in routine practice; 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) Adulthood (25 to 44 years) Adulthood (45 to 64 years) Elderly (65 to 79 years) Great age (80 years and more)
Population covered	Sick population
Gender	Male Woman

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

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