Assessment of trajectories of high-risk drug users: incidence of abuse and impact on morbidity and mortality (METEOR)

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Administrative details

PURI

https://redirect.ema.europa.eu/resource/1000000248

EU PAS number

EUPAS1000000248

Study ID

1000000248

DARWIN EU® study

No

Study countries

France

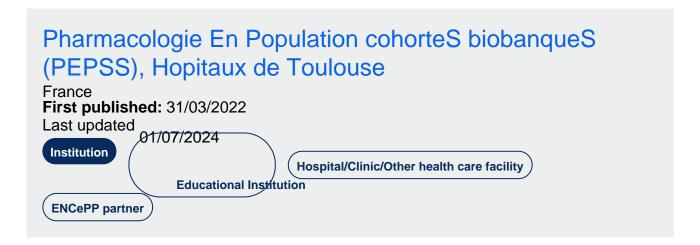
Study status

Planned

Research institution and networks

Institutions

Department of Clinical Pharmacology and Pharmacosurveillance, University Hospital of Marseille France First published: 12/12/2011 Last updated Institution Hospital/Clinic/Other health care facility Educational Institution ENCePP partner



Contact details

Study institution contact

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Study contact

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Primary lead investigator

Thomas Soeiro

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual:

20/12/2021

Study start date

Planned: 01/01/2022

Date of final study report

Planned: 31/12/2024

Sources of funding

National competent authority (NCAs)

More details on funding

EPI-PHARE/ANSM

Study protocol

MICALLEF projet METEOR - epi-phare document_scientifique_aap2021.pdf(1.13 MB)

Regulatory

Was the study required by a regulatory body? No

Is the study required by a Risk Management Plan (RMP)? Not applicable

Methodological aspects

Study type list

Study topic:

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Safety study (incl. comparative)

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Study drug International non-proprietary name (INN) or common name

BUPRENORPHINE

FENTANYL

GABAPENTIN

METHADONE

MORPHINE

OXYCODONE

PREGABALIN

TRAMADOL

Anatomical Therapeutic Chemical (ATC) code

(N01AH01) fentanyl

(N02AA01) morphine

(N02AA05) oxycodone

(N02AB03) fentanyl

(N02AE01) buprenorphine

(N02AX02) tramadol

(N02BF01) gabapentin

(N02BF02) pregabalin

(N03AX12) gabapentin

(N03AX16) pregabalin

(N07BC01) buprenorphine

(N07BC02) methadone

Data management

Data sources

Data source(s)

Système National des Données de Santé (French national health system main database)

Use of a Common Data Model (CDM)

CDM mapping

No

Data quality specifications

Check conformance

Yes

Check completeness

Yes

Check stability

Yes

Check logical consistency

Yes

Data characterisation

Data characterisation conducted

Yes