

# SAPHARY - A Safety and Pharmacokinetic study in Real-life practice of Pylera® in France: The SAPHARY study

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## General

### Identification

Detailed name A Safety and Pharmacokinetic study in Real-life practice of Pylera® in France: The SAPHARY study

Sign or acronym SAPHARY

CNIL registration number, number and date of CPP agreement, AFSSAPS (French Health Products Safety Agency) authorisation CPP: 2012/76, 31/10/2012; EudraCT: 2012-004364-22; CCTIRS: n° 13.427; CNIL: n° 913386

### General Aspects

Medical area Gastroenterology et hepatology

Pathology (details) Helicobacter Pylori infection

Health determinants Others (specify)

Others (details) Medicinal product

Keywords Bismuth, neurological adverse event, Pylera, Helicobacter Pylori infection, Bordeaux PharmacoEpi, Service de Pharmacologie médicale

### Scientific investigator(s) (Contact)

Name of the director BLIN

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Unit  
Bordeaux PharmacoEpi - Université de Bordeaux -  
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Organization  
Université de Bordeaux

## Collaborations

## Funding

Funding status  
Private

Details  
Aptalis Pharma

## Governance of the database

Sponsor(s) or organisation(s)  
responsible  
Bordeaux PharmacoEpi - Université de Bordeaux -  
Service de Pharmacologie médicale - CIC Bordeaux  
CIC 1401

Organisation status  
Public

Presence of scientific or  
steering committees  
Yes

## Additional contact

## Main features

## Type of database

Type of database  
Study databases

Study databases (details)  
Cohort study

Database recruitment is carried  
out by an intermediary  
A selection of health care professionals

Database recruitment is made  
on the basis of:  
Medication(s) taken

Database recruitment is carried  
out as part of an interventional  
study  
Yes

Details  
Performed at individual level

Additional information regarding  
sample selection.  
The study is a single-arm, open label trial in 200  
presumed Helicobacter Pylori-positive subjects and  
is restricted to centers in France. Following  
identification of participating general practice and  
specialist study centers, subjects deemed eligible

for study will be identified. Subject inclusion in the study will be considered after the decision to treat with Pylera® has been made by investigator. The inclusion visit will be initiated following signature of Informed Consent. The study has an anticipated recruitment period of 24 months. Eligible subjects will stay in study for approximately 6 weeks.

## Database objective

### Main objective

The primary objective of the study is to verify the absence of accumulation of bismuth in subjects prescribed Pylera®, a pharmacokinetic approach in a real-life setting.

### Inclusion criteria

- Men and women 18 years of age and older who have received a prescription for Pylera® therapy from the Investigator
- Mental and legal ability to give written Informed Consent and judged by the Investigator to be capable of following the procedures outlined within the protocol

#### Exclusion criteria :

- Women who are pregnant or nursing
- Any concern by the Investigator regarding the safe participating of the subject in the study or for any other reason the Investigator considers the subject inappropriate for participating in the study

## 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

### Pathology

B98 - Other specified infectious agents as the cause of diseases classified to other chapters

### Gender

Male  
Woman

### Geography area

National

### Detail of the geography area

France

## Data collection

## Dates

Date of first collection (YYYY or MM/YYYY)	2014
Date of last collection (YYYY or MM/YYYY)	2016
<b>Size of the database</b>	
Size of the database (number of individuals)	< 500 individuals
Details of the number of individuals	200 subjects
<b>Data</b>	
Database activity	Current data collection
Type of data collected	Clinical data Declarative data Biological data
Clinical data (detail)	Direct physical measures
Details of collected clinical data	Medical charts, clinic charts, nurses' notes, medical correspondence regarding the human subject, subject progress notes, pathology reports, laboratory reports, study worksheets, electronic hospital reporting system
Declarative data (detail)	Face to face interview
Details of collected declarative data	Advers event
Biological data (detail)	Whole blood and plasma concentration of bismuth provided prior to start Pylera® treatment and upon completion of the 10-day treatment with Pylera®
Presence of a biobank	Yes
Contents of biobank	Whole blood Plasma
Details of biobank content	Whole blood and plasma sample
Health parameters studied	Health event/morbidity Health event/mortality Health care consumption and services Others
Care consumption (detail)	Medicines consumption

Other (detail)	Whole blood and plasma concentration of bismuth
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## Procedures

Data collection method	Paper Case Report Form completed by investigator at each follow-up visit.
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Classifications used	MedDRA coding for neurological and non neurological adverse event (SOC and PT); ATC code
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Participant monitoring	Yes
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Details on monitoring of participants	Eligible subjects will stay in the study for approximately 6 weeks with 2 follow-up visits: the end of treatment visit performed after the 10-day treatment with Pylera®, and the end of study visit performed 28 days post-treatment.
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Links to administrative sources	No
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## Promotion and access

### Promotion

### Access

Presence of document that lists variables and coding procedures	Yes
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Terms of data access (charter for data provision, format of data, availability delay)	A confidential study final report has be performed. The ownership of data is defined in a Master Agreement established between the Sponsor, the University of Bordeaux and ADERA (a non-profit making association). The terms of access to the database are to be defined for any third party.
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Access to aggregated data	Access on specific project only
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Access to individual data	Access on specific project only
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