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

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## General

### Identification

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|---|---|
| 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

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|---|---|
| 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)



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|---|---|
| Name of the director | BLIN |
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|---|---|
| Unit | Bordeaux PharmacoEpi - Université de Bordeaux - Service de Pharmacologie médicale - CIC Bordeaux CIC 1401 |
| Organization | Université de Bordeaux |

## Collaborations

## Funding

| | |
|---|---|
| Funding status | Private |
| Details | Aptalis Pharma |

## Governance of the database

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|---|---|
| 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

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|---|---|
| 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 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 |

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| | 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<br>- 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<br><br>Exclusion criteria :<br>- Women who are pregnant or nursing<br>- 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)<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 |
| Pathology | B98 - Other specified infectious agents as the cause of diseases classified to other chapters |
| Gender | Male<br>Woman |
| Geography area | National |
| Detail of the geography area | France |
| **Data collection** | |
| **Dates** | |

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| Date of first collection (YYYY or MM/YYYY) | 2014 |
| Date of last collection (YYYY or MM/YYYY) | 2016 |
| **Size of the database** | |
| Size of the database (number of individuals) | < 500 individuals |
| Details of the number of individuals | 200 subjects |
| **Data** | |
| Database activity | Current data collection |
| Type of data collected | Clinical data<br>Declarative data<br>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 Pyelra® treatment and upon completion of the 10-day treatment with Pylera® |
| Presence of a biobank | Yes |
| Contents of biobank | Whole blood<br>Plasma |
| Details of biobank content | Whole blood and plasma sample |
| Health parameters studied | Health event/morbidity<br>Health event/mortality<br>Health care consumption and services<br>Others |
| Care consumption (detail) | Medicines consumption |

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|---|---|
| Other (detail) | Whole blood and plasma concentration of bismuth |
| **Procedures** | |
| Data collection method | Paper Case Report Form completed by investigator at each follow-up visit. |
| Classifications used | MedDRA coding for neurological and non neurological adverse event (SOC and PT); ATC code |
| Participant monitoring | Yes |
| 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. |
| Links to administrative sources | No |
| **Promotion and access** | |
| **Promotion** | |
| **Access** | |
| Presence of document that lists variables and coding procedures | Yes |
| Terms of data access (charter for data provision, format of data, availability delay) | A confidentiel 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. |
| Access to aggregated data | Access on specific project only |
| Access to individual data | Access on specific project only |