

# ESPRIT - Cross-Sectional Study on Primary Care for Adverse Events

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## General

### Identification

Detailed name	Cross-Sectional Study on Primary Care for Adverse Events
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Sign or acronym	ESPRIT
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CNIL registration number, number and date of CPP agreement, AFSSAPS (French Health Products Safety Agency) authorisation	CNIL
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### General Aspects

Medical area	General practice
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Health determinants	Healthcare system and access to health care services
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Keywords	risk management, frequency, adverse events
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### Scientific investigator(s) (Contact)

Name of the director	Michel
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Surname	Philippe
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Email	philippe.michel@chu-lyon.fr
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Organization	Comité de Coordination de l'Évaluation Clinique et de la Qualité en Aquitaine
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### Collaborations

Participation in projects, networks and consortia	Yes
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Details	Partnership with Open Rome <a href="http://esprit.openrome.org/documents/Rapport_ESPRIT_final.pdf">http://esprit.openrome.org/documents/Rapport_ESPRIT_final.pdf</a>
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Funding	
Funding status	Public
Details	Ministry of Health.
Governance of the database	
Sponsor(s) or organisation(s) responsible	Comité de Coordination de l'Évaluation Clinique et de la Qualité en Aquitaine (CCECQA)
Organisation status	Public
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 selection of health care professionals
Database recruitment is carried out as part of an interventional study	No
Additional information regarding sample selection.	All patients seen or contacted by 127 voluntary general practitioners from the Network of Regional Influenza Surveillance Groups (GROG).
Database objective	
Main objective	To estimate the incidence of avoidable treatment-related adverse effects in general medicine and to describe the typology.
Inclusion criteria	<ul style="list-style-type: none"> <li>- Male and female;</li> <li>- Patients seen or contacted by voluntary general practitioners from the study.</li> </ul>
Population type	
Age	Adulthood (19 to 24 years) Adulthood (25 to 44 years) Adulthood (45 to 64 years)
Population covered	General population

Gender	Male Woman
Geography area	National
Detail of the geography area	19 regions throughout metropolitan France.
Data collection	
Dates	
Date of first collection (YYYY or MM/YYYY)	01/2012
Date of last collection (YYYY or MM/YYYY)	12/2013
Size of the database	
Size of the database (number of individuals)	< 500 individuals
Details of the number of individuals	475
Data	
Database activity	Data collection completed
Type of data collected	Declarative data
Declarative data (detail)	Paper self-questionnaire
Details of collected declarative data	General practitioner profile questionnaire; procedure registry for the collection of completed procedures during the collection period; questionnaire on treatment-related adverse effects, consequences and causes.
Presence of a biobank	No
Health parameters studied	Health event/morbidity Quality of life/health perception
Procedures	
Data collection method	Collection will be carried out over a randomly selected week during the data collection period that is scheduled beforehand with all general practitioners, according to availability. All data is collected on a secure website hosted by Open Rome, except for general practitioners who choose

to send questionnaires in paper format to Open Rome, who are in charge of recording.

#### Quality procedure(s) used

Data completeness will be monitored: ? in real time, - when files arrive to Open Rome by post. If required, the organisation will contact to the physician again to adjust or supplement data collection. The quality of data recording and consistency will be checked by those in charge of the database in accordance with regular procedures

#### Participant monitoring

No

#### Links to administrative sources

No

### Promotion and access

#### Promotion

##### Link to the document

[http://www.invs.sante.fr/beh/2014/24-25/2014\\_24-25\\_1.html](http://www.invs.sante.fr/beh/2014/24-25/2014_24-25_1.html)

##### Link to the document

<http://www.ccecqa.asso.fr/sites/ccecqa.aquisante.piv/files/fiches-projets/Projets-PJ-ESPRIT-rapport-final.pdf>

##### Link to the document

[http://www.ncbi.nlm.nih.gov/pubmed/?term=ESPRIT+AND+Michel+P+\[Author\]](http://www.ncbi.nlm.nih.gov/pubmed/?term=ESPRIT+AND+Michel+P+[Author])

#### Access

Terms of data access (charter for data provision, format of data, availability delay)

Contact the scientist in charge.

##### Access to aggregated data

Access on specific project only

##### Access to individual data

Access on specific project only