

# FROG-ICU - Cohort of Patients Admitted to Intensive Care for Serious Illnesses: Study on Mortality Risk Factors Up to One Year

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## General

### Identification

Detailed name Cohort of Patients Admitted to Intensive Care for Serious Illnesses: Study on Mortality Risk Factors Up to One Year

Sign or acronym FROG-ICU

CNIL registration number, number and date of CPP agreement, AFSSAPS (French Health Products Safety Agency) authorisation CCTIRS ref. 11134 on 10/03/11 CNIL authorisation 30/06/11 under no. 911169 CPP 15/03/11 under ref. 2011/05NI; Clinical Trials.gov NCT01367093. Biological collection declaration at the ministry 21/06/12.

### General Aspects

Medical area Anesthesiology ? Intensive care

Health determinants Healthcare system and access to health care services  
Iatrogenic  
Lifestyle and behavior

Keywords intensive care, SF36, serious illness, mortality, morbidity, quality of life

### Scientific investigator(s) (Contact)

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|----------------------|-------------------------------------|
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| Unit                 | Lariboisière Clinical Research Unit |
| Organization         | AP-HP                               |

## Collaborations

## Funding

|                |        |
|----------------|--------|
| Funding status | Public |
|----------------|--------|

Details AP-HP (Paris Public Hospitals)

## Governance of the database

Sponsor(s) or organisation(s) responsible Assistance Publique - Hôpitaux de Paris

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 institutions and services

Database recruitment is made on the basis of: Another treatment or procedure

Additional information regarding sample selection. 21 centres throughout France and Belgium.

## Database objective

Main objective This study aims to identify the risk factors of

mortality within a cohort of patients during the year following discharge from the intensive care unit.

|  |   |
|--|---|
| Inclusion criteria                           | Adult patients admitted to the ICU.<br>Patients must be intubated for at least 24 hrs or treated with an inotropic agent.                           |
| <b>Population type</b>                       |   |
| 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   |
| Gender                                       | Male<br>Woman   |
| Geography area                               | National  |
| Detail of the geography area                 | France and Belgium  |
| <b>Data collection</b>                       |   |
| <b>Dates</b>                                 |   |
| Date of first collection (YYYY or MM/YYYY)   | 2011  |
| <b>Size of the database</b>                  |   |
| Size of the database (number of individuals) | [1000-10 000[ individuals   |
| Details of the number of individuals         | 2,136   |
| <b>Data</b>                                  |   |
| Database activity                            | Data collection completed   |
| Type of data collected                       | Clinical data<br>Declarative data<br>Biological data  |
| Declarative data (detail)                    | Paper self-questionnaire<br>Face to face interview  |
| Details of collected declarative data        | Quality of life analysis (SF36)   |

|                            |  |
|----------------------------|--|
| Presence of a biobank      | Yes  |
| Details of biobank content | Yes; managed by the Lariboisière CRB (Centre de ressources biologiques [biological resource centre]) |

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|---------------------------|---|
| Health parameters studied | Health event/mortality<br>Quality of life/health perception |
|---------------------------|---|

## Procedures

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|------------------------|--|
| Data collection method | Data collected in an eCRF designed by the St. Louis DBIM (data and biostatistics unit), monitoring carried out by the Lariboisière Clinical Research unit; queries published and resolved. |
|------------------------|--|

|                        |     |
|------------------------|-----|
| Participant monitoring | Yes |
|------------------------|-----|

|                                       |                            |
|---------------------------------------|----------------------------|
| Details on monitoring of participants | Follow-up at 3/6/12 months |
|---------------------------------------|----------------------------|

|                                 |    |
|---------------------------------|----|
| Links to administrative sources | No |
|---------------------------------|----|

## Promotion and access

### Promotion

|                      |  |
|----------------------|--|
| Link to the document | <a href="#">Legrand M, Januzzi JL Jr, Mebazaa A. Critical research on biomarkers: what's new? Intensive Care Med. 2013 Oct;39(10):1824-8. doi: 10.1007/s00134-013-3008-7. Epub 2013 Jul 5.</a> |
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|                      |   |
|----------------------|---|
| Link to the document | <a href="http://tinyurl.com/PUBMED-FROG-ICU">http://tinyurl.com/PUBMED-FROG-ICU</a> |
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### Access

|   |   |
|---|---|
| Terms of data access (charter for data provision, format of data, availability delay) | Access to database through login and code for site users and coordinating team (DBIM, URC, Mebazaa team). |
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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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