

# REFLEX - Longitudinal Study on Aortic Regurgitation in Patients Treated with Benfluorex

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:- Épidémiologie respiratoire: de l'étiologie de l'asthme et de la BPCO au pronostic de la transplantation pulmonaire

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## General

### Identification

Detailed name Longitudinal Study on Aortic Regurgitation in Patients Treated with Benfluorex

Sign or acronym REFLEX

CNIL registration number, number and date of CPP agreement, AFSSAPS (French Health Products Safety Agency) authorisation CNIL no. 1286925

### General Aspects

Medical area Cardiology

Health determinants Medicine

Keywords Benfluorex, marketing authorisation, MA, research, side effects, post, adverse events, study

### Scientific investigator(s) (Contact)

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Unit U1152 Physiopathologie et épidémiologie des maladies respiratoiresÉquipe/activité :-  
Épidémiologie respiratoire: de l'étiologie de l'asthme et de la BPCO au pronostic de la transplantation pulmonaire

Organization

Institut national de la santé et de la recherche  
médicale -

## Collaborations

## Funding

Funding status

Public

Details

Ministry of Health.

## Governance of the database

Sponsor(s) or organisation(s)  
responsible

Institut national de la santé et de la recherche  
médicale - Inserm

Organisation status

Public

## Additional contact

## Main features

## Type of database

Type of database

Study databases

Study databases (details)

Longitudinal study (except cohorts)

Database recruitment is carried  
out by an intermediary

A selection of health institutions and services

Database recruitment is made  
on the basis of:

Medication(s) taken

Database recruitment is carried  
out as part of an interventional  
study

No

Additional information regarding  
sample selection.

Patients that meet the inclusion criteria are  
consecutively and systematically enrolled for one  
year.

## Database objective

Main objective

Echocardiography-based study on the development  
of valvular disease (decrease, stable, increase) in  
patients treated with benfluorex.

To compare the development of valvular diseases  
potentially linked to benfluorex and diseases not  
linked to benfluorex.  
- All patients and patients with valvular disease

potentially linked to benfluorex; assessment of development with regards to:

- Indication(s), duration of exposure to benfluorex and duration since stopping medication.
- Age and sex;
- diabetes and associated medical treatment.
- Presence of cardiac and non-cardiac diseases;
- current treatments and treatments that were undergone simultaneously with benfluorex.

#### Inclusion criteria

- Male and female;
- Adult;
- Patient treated with benfluorex from 2006-2009 with aortic/mitral grade regurgitation.

### Population type

Age

Adulthood (19 to 24 years)  
Adulthood (25 to 44 years)  
Adulthood (45 to 64 years)

Population covered

Sick population

Gender

Male  
Woman

Geography area

National

Detail of the geography area

60 cardiology centres throughout France.

### Data collection

#### Dates

Date of first collection (YYYY or MM/YYYY)

2011

#### Size of the database

Size of the database (number of individuals)

[500-1000] individuals

Details of the number of individuals

1,000

### Data

Database activity

Current data collection

Type of data collected

Clinical data  
Paraclinical data

Clinical data (detail)

Direct physical measures

Details of collected clinical data	---
Paraclinical data (detail)	Echocardiography.
Presence of a biobank	No
Health parameters studied	Health event/morbidity
<b>Procedures</b>	
Data collection method	Clinical and echocardiography data will be recorded at enrolment and follow-up visits.
Participant monitoring	Yes
Details on monitoring of participants	Additional visits will be provided if necessary, as part of regular patient monitoring.
Links to administrative sources	No
<b>Promotion and access</b>	
<b>Promotion</b>	
<b>Access</b>	
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