

# SISTOLA - Observational usage and effectiveness of candesartan in heart failure treatment in France

Head :Thomas-Delcourt Florence, AstraZeneca

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## General

### Identification

Detailed name Observational usage and effectiveness of candesartan in heart failure treatment in France

Sign or acronym SISTOLA

CNIL registration number, number and date of CPP agreement, AFSSAPS (French Health Products Safety Agency) authorisation CNIL approval : 907230 - 27 November 2007

### General Aspects

Medical area Cardiology

Others (details) Congestive heart failure

Keywords candesartan

### Scientific investigator(s) (Contact)

Name of the director Thomas-Delcourt

Surname Florence

Phone +33 (1) 41 29 40 25

Email florence.thomas@astrazeneca.com

Unit AstraZeneca

### Collaborations

### Funding

Funding status Private

Details AstraZeneca / Takeda

### Governance of the database

Sponsor(s) or organisation(s) responsible	ASTRAZENECA / TAKEDA
Organisation status	Private
<b>Additional contact</b>	
<b>Main features</b>	
<b>Type of database</b>	
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
<b>Database objective</b>	
Main objective	To describe the way candesartan is used in heart failure treatment in France (treatment initiation and follow-up) treatment discontinuation occurrences and reasons why and patients clinical evolution
Inclusion criteria	Patients starting or who have recently started (less than 30 days) a treatment with candesartan for heart failure
<b>Population type</b>	
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
Gender	Male Woman
Geography area	National
Detail of the geography area	Consultation in cardiology

## Data collection

### Dates

Date of first collection (YYYY or MM/YYYY) 2008

Date of last collection (YYYY or MM/YYYY) 2010

### Size of the database

Size of the database (number of individuals) < 500 individuals

Details of the number of individuals 452

### Data

Database activity Data collection completed

Type of data collected  
Clinical data  
Declarative data  
Biological data

Clinical data (detail)  
Direct physical measures  
Medical registration

Declarative data (detail)  
Phone interview

Biological data (detail)  
ionogram, with blood potassium in particular,  
natremia and kidney function

Presence of a biobank No

Health parameters studied  
Health event/morbidity  
Health event/mortality

### Procedures

Participant monitoring Yes

Details on monitoring of participants 12 months

Links to administrative sources No

## Promotion and access

### Promotion

## Access

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

Methods for accessing the database are currently being defined

Access to aggregated data

Access on specific project only

Access to individual data

Access on specific project only