B009 - Follow-up study of patients treated with drotrecogin alfa (activated) (Xigris®) in France

Head :Laboratoire , Eli Lilly France

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General

Identification

Detailed name	Follow-up study of patients treated with drotrecogin alfa (activated) (Xigris®) in France
Sign or acronym	B009
CNIL registration number, number and date of CPP agreement, AFSSAPS (French Health Products Safety Agency) authorisation	CNIL N°908282

General Aspects

Medical area	Infectious diseases
Others (details)	severe sepsis
Keywords	Severe sepsis, drotrecogin alpha (activated), survival, conditions of use

Scientific investigator(s) (Contact)

Name of the director	Laboratoire
Email	Fr_mail_pharmacoepi@lilly.com
Unit	Eli Lilly France

Collaborations

Funding

Funding status	Private
Details	Eli Lilly and Company

Governance of the database

Sponsor(s) or organisation(s) responsible	Eli Lilly

Organisation status	Private

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 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.	All intensive care services in French hospitals which treated patients with drotrecogin alpha (activated) during the study period were eligible.

Database objective

Main objective	Primary objective: evaluate 1-month mortality (at 28 days and 31 days) of patients treated with drotrecogin alpha (activated) in intensive care forsevere sepsis and describe causes of death. Secondary objectives: characteristics of patients and conditions of use.
Inclusion criteria	All adult patients treated with drotrecogin alpha (activated) in France in the course of routine care in intensive care services.

Population type

Age	Adulthood (19 to 24 years) Adulthood (25 to 44 years) Adulthood (45 to 64 years) Elderly (65 to 79 years)
Population covered	Sick population
Gender	Male Woman
Geography area	National

Detail of the geography area	National
Data collection	
Dates	
Date of first collection (YYYY or MM/YYYY)	2008
Date of last collection (YYYY or MM/YYYY)	2009
Size of the database	
Size of the database (number of individuals)	[1000-10 000[individuals
Details of the number of individuals	1049
Data	
Database activity	Data collection completed
Type of data collected	Clinical data Biological data
Clinical data (detail)	Direct physical measures Medical registration
Biological data (detail)	hematology, biochemistry
Presence of a biobank	No
Health parameters studied	Health event/morbidity Health event/mortality
Procedures	
Data collection method	Study data collection form
Participant monitoring	Yes
Links to administrative sources	No
Promotion and access	
Promotion	
Access	
Terms of data access (charter	Reports and publications

for data provision, format of data, availability delay)	
Access to aggregated data	Access on specific project only
Access to individual data	Access on specific project only