

REGATE - Longitudinal Study on Patients with Rheumatoid Arthritis and Study on Tolerance and Efficacy of Tocilizumab (REGistry-RoAcTEmra)

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General

Identification

Detailed name Longitudinal Study on Patients with Rheumatoid Arthritis and Study on Tolerance and Efficacy of Tocilizumab (REGistry-RoAcTEmra)

Sign or acronym REGATE

CNIL registration number, number and date of CPP agreement, AFSSAPS (French Health Products Safety Agency) authorisation CNIL REGistry-RoAcTEmra

General Aspects

Medical area Geriatrics
Rheumatology

Health determinants Medicine

Keywords RA, TCZ, tolerance, comorbidity, efficacy

Scientific investigator(s) (Contact)

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Unit	Service de rhumatologie, Centre national de références des maladies auto-immunes systémiqueshôpital de HautepierreCHU de Strasbourg
Organization	CHU de
Collaborations	
Funding	
Funding status	Private
Details	French Rheumatology Society
Governance of the database	
Sponsor(s) or organisation(s) responsible	Société Française de Rhumatologie
Organisation status	Private
Sponsor(s) or organisation(s) responsible	Club Rhumatiques et Inflammation
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 carried out as part of an interventional	No

study	
Database objective	
Main objective	The main objective of the REGATE study is to identify the tolerance and efficacy of Tocilizumab currently used for Rheumatoid Arthritis (RA).
Inclusion criteria	- aged 18 or over - patient with rheumatoid arthritis
Population type	
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	France
Data collection	
Dates	
Date of first collection (YYYY or MM/YYYY)	01/2011
Date of last collection (YYYY or MM/YYYY)	10/2012
Size of the database	
Size of the database (number of individuals)	[500-1000[individuals
Details of the number of individuals	1,500
Data	
Database activity	Data collection completed
Type of data collected	Clinical data Biological data

Clinical data (detail)	Direct physical measures Medical registration
Details of collected clinical data	History, drug intake, DAS28 score, comorbidities such as: Severe infection, cancer, infusion reactions, pregnancy, gastrointestinal perforation, cardiovascular events, cytopenia, cytolysis.
Biological data (detail)	Rheumatoid factor, ACPA
Presence of a biobank	No
Health parameters studied	Health event/morbidity Health care consumption and services
Care consumption (detail)	Medicines consumption
Procedures	
Participant monitoring	Yes
Details on monitoring of participants	at 3 and 6 months, then every 6 months for 5 years.
Links to administrative sources	No
Promotion and access	
Promotion	
Link to the document	http://www.ncbi.nlm.nih.gov/pubmed/?term=regate+AND+%28Morel[author]+OR+Sibilia[author]%29
Description	List of publications in Pubmed
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