

# PEPS - PharmacoEpidemiological study of the imPact of RoActemra® treatment on fatigue in rheumatoid arthritis patientS in a real life setting

Head :Roche Medical Data Center

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## General

### Identification

Detailed name	PharmacoEpidemiological study of the imPact of RoActemra® treatment on fatigue in rheumatoid arthritis patientS in a real life setting
Sign or acronym	PEPS
CNIL registration number, number and date of CPP agreement, AFSSAPS (French Health Products Safety Agency) authorisation	ML22457

### General Aspects

Medical area	Rheumatology
Study in connection with Covid-19	No
Pathology (details)	Rheumatoid arthritis
Health determinants	Iatrogenic Medicine
Keywords	Tocilizumab

### Scientific investigator(s) (Contact)

Name of the director	Roche Medical Data Center
Address	4 cours de l'Île Seguin - 92650 BOULOGNE-BILLANCOURT
Email	data_sharing_france@roche.com
Organization	Roche SAS

### Collaborations

Participation in projects, networks and consortia No

## Funding

Funding status Private

## Governance of the database

Sponsor(s) or organisation(s) responsible Roche SAS

Organisation status Private

Presence of scientific or steering committees Yes

## Additional contact

Name of the contact <https://www.roche.fr/fr/innovation-recherche-medicale/data-sharing-portail-d-information-partage-des-donnees.html>

## 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: Medication(s) taken

Database recruitment is carried out as part of an interventional study No

## Database objective

Main objective Primary objective: To describe in a real life setting the evolution of fatigue in patients with moderate to severe RA during the first 4 months of RoActemra® treatment, as well as to search for predictive factors of an improvement in this symptom.

Secondary objectives:  
- To describe patient baseline characteristics and level of fatigue experienced at inclusion by the

- patient population treated with RoActemra®;
- To evaluate the correlation between the evolutions of fatigue as assessed by FACIT-Fatigue questionnaire and VAS fatigue during the first 4 months of RoActemra® treatment;
  - To evaluate the time of onset of RoActemra® effect on fatigue in a real life setting;
  - To assess the correlation between evolution of fatigue and disease activity during 4 months of RoActemra® treatment;
  - To evaluate the PASS of the fatigue scales (FACIT-Fatigue, VAS fatigue, SF36 vitality) after 4 months of RoActemra® treatment;
  - To evaluate the correlation between evolution of fatigue and other patient reported outcomes (PROs): pain, quality of sleep, disability, SF36 vitality, anxiety, depression;
  - To describe the management of RA patients treated with RoActemra®;
  - To describe all adverse events occurring during the study.

#### Inclusion criteria

##### Inclusion criteria:

- Male or woman aged over 18 years.
- Patients presenting with moderate to severe rheumatoid arthritis and for which treatment with RoActemra(R) was planned by the investigator;
- Patients willing and able to complete, during consultations and at home, the study questionnaires aimed at evaluating the impact of their disease and treatment;
- Patients who received complete written and oral information about the study, and who gave their consent for future automated processing of the data generated during the study.

##### Exclusion criteria:

- Patient with known hypersensitivity to RoActemra®, or to any constituent of the study medication;
- Patient presenting with an active concomitant infection;
- Patient currently participating in a clinical trial aimed at evaluating another treatment in 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
Pathology	M05-M14 - Inflammatory polyarthropathies
Gender	Male Woman
Geography area	National
<b>Data collection</b>	
<b>Dates</b>	
Date of first collection (YYYY or MM/YYYY)	2010
Date of last collection (YYYY or MM/YYYY)	2011
<b>Size of the database</b>	
Size of the database (number of individuals)	[500-1000[ individuals
Details of the number of individuals	721
<b>Data</b>	
Database activity	Data collection completed
Type of data collected	Clinical data
Clinical data (detail)	Medical registration
Details of collected clinical data	Patient demographic characteristics - History of rheumatoid arthritis - Concomitant treatments - Tender and swollen joint counts - Biological parameters - Management of rheumatoid arthritis - Adverse events - FACIT-Fatigue - VAS fatigue - VAS pain - VAS disease activity - VAS quality of sleep - HAQ-DI - SF36 vitality - HADS - PASS Fatigue.
Presence of a biobank	No
Health parameters studied	Health event/morbidity Health care consumption and services Quality of life/health perception
Care consumption (detail)	Medicines consumption
<b>Procedures</b>	

Classifications used	CDISC
Quality procedure(s) used	GCP/GVP
Participant monitoring	Yes
Monitoring procedures	Monitoring by contact with the referring doctor
Links to administrative sources	No
<b>Promotion and access</b>	
<b>Promotion</b>	
<b>Access</b>	
Dedicated website	<a href="https://www.roche.fr/fr/innovation-recherche-medicale/data-sharing-portail-d-information-partage-des-donnees.html">https://www.roche.fr/fr/innovation-recherche-medicale/data-sharing-portail-d-information-partage-des-donnees.html</a>
Presence of document that lists variables and coding procedures	Yes
Access to aggregated data	Access on specific project only
Access to individual data	Access on specific project only