

# SPARE-1 - Description in real life of glucocorticoid-sparing in patients treated with Roactemra® for moderate to severe rheumatoid arthritis

Head :Roche Medical Data Center

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## General

### Identification

Detailed name	Description in real life of glucocorticoid-sparing in patients treated with Roactemra® for moderate to severe rheumatoid arthritis
Sign or acronym	SPARE-1
CNIL registration number, number and date of CPP agreement, AFSSAPS (French Health Products Safety Agency) authorisation	ML25634

### General Aspects

Medical area	Rheumatology
Study in connection with Covid-19	No
Pathology (details)	Moderate to severe rheumatoid arthritis
Health determinants	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,	No
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## 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 real life the glucocorticoid-sparing effect after 12 months of treatment with RoActemra® in patients with moderate to severe RA and to determine predictive factors.

Secondary objectives:

1. to describe the characteristics of the population at baseline;
2. to evaluate efficacy of RoActemra® (EULAR response and/or glucocorticoid dosage) in real life;

3. to describe therapeutic management of RA [glucocorticoids and/or conventional Disease-Modifying Anti-Rheumatic Drug(s) (DMARDs) in combination with RoActemra®];
4. to describe change in functional capacity of patients and impact of the disease on the patient over time during follow-up (HAQ-DI and RAID self-report questionnaires);
5. to assess safety of RoActemra®.

#### Inclusion criteria

##### Inclusion criteria:

- Patients aged 18 years and older;
- Patients with moderate to severe rheumatoid arthritis;
- Patients for whom the rheumatologist decided to initiate treatment with RoActemra®;
- Patients taking oral glucocorticoids >5 mg/day of prednisone or equivalent for at least 3 months;
- Patients having received oral and written information about the study and having raised no objections to the collection and computer processing of his/her personal data.

##### Exclusion criteria:

- Patients participating in a clinical trial on rheumatoid arthritis at time of inclusion could not participate to the study.

#### 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

#### Data collection

##### Dates

Date of first collection (YYYY or MM/YYYY)

2011

Date of last collection (YYYY or

2013

MM/YYYY)

## Size of the database

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

Details of the number of individuals 321

## Data

Database activity Data collection completed

Type of data collected Clinical data  
Biological data

Clinical data (detail) Medical registration

Details of collected clinical data Validation of inclusion and exclusion criteria - Sociodemographic data - Medical history and concomitant diseases - RA history, previous and/or ongoing RA treatments - Most recent clinical and biological data - Physician global assessment of RA activity (asymptomatic to very severe) - RA treatments and reason for discontinuation where applicable - Treatment with RoActemra® - Adverse events - Reason for early study discontinuation - HAQ-DI, RAID scale.

Presence of a biobank No

Health parameters studied Health event/morbidity  
Health event/mortality  
Health care consumption and services  
Quality of life/health perception

Care consumption (detail) Medicines consumption

## Procedures

Data collection method paper

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

## Promotion and access

### Promotion

### Access

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>
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Presence of document that lists variables and coding procedures	Yes
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Access to aggregated data	Access on specific project only
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Access to individual data	Access on specific project only
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