

# DUO - Descriptive epidemiological study of therapeutic decision-making during management of rheumatoid arthritis: physicians' criteria and patients' opinions

Head :Roche Medical Data Center

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## General

### Identification

Detailed name	Descriptive epidemiological study of therapeutic decision-making during management of rheumatoid arthritis: physicians' criteria and patients' opinions
Sign or acronym	DUO
CNIL registration number, number and date of CPP agreement, AFSSAPS (French Health Products Safety Agency) authorisation	ML22021

### 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
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## Funding

Funding status	Private
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## Governance of the database

Sponsor(s) or organisation(s) responsible	Roche SAS
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Organisation status	Private
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Presence of scientific or steering committees	Yes
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## Additional contact

Name of the contact	<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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## Main features

### Type of database

Type of database	Study databases
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Study databases (details)	Cohort study
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Database recruitment is carried out by an intermediary	A selection of health institutions and services
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Database recruitment is made on the basis of:	Medication(s) taken
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Database recruitment is carried out as part of an interventional study	No
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## Database objective

Main objective	<p>Primary objectives: To describe the criteria used for therapeutic decision-making for RA patients:</p> <ul style="list-style-type: none"><li>- clinical, biological and radiological data, impact of RA on patients' life according to physicians;</li><li>- impact of RA on patients' life according to patients;</li><li>- physicians' characteristics.</li></ul> <p>Secondary objectives:</p> <ul style="list-style-type: none"><li>- To describe the characteristics of the included patient population depending on treatment</li></ul>
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modifications after the inclusion visit.

## Inclusion criteria

Inclusion criteria:

- Adult (aged  $\geq 18$  years);
- Treated for RA;
- Willing and able to complete the self-questionnaire in French on the impact of RA during the visit;
- Having been informed about the study orally and in writing and not objecting to their data being processed.

Exclusion criteria:

- Patients participating in another clinical study assessing RA treatment at the time of inclusion.

## 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)

2009

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

1115

## Data

Database activity	Data collection completed
Type of data collected	Clinical data Biological data
Clinical data (detail)	Medical registration
Details of collected clinical data	Date of inclusion visit - Patient information about the study - General data: age, sex, weight, height - Date of initial diagnosis - Disease characteristics - Ongoing symptomatic treatment or corticosteroids (dose) - Past and current DMARDs: names of compounds (methotrexate, hydroxychloroquine, sulfasalazine, gold salts, leflunomide, D-penicillamine, azathioprine, cyclosporine, infliximab, etanercept, adalimumab, abatacept, rituximab, anakinra, others), ongoing therapeutic regimens, route of administration and date of implementation of methotrexate (if applicable), date of last infusion of rituximab (if applicable) - Safety: any adverse reactions or discomfort experienced by the patient, according to the physician - Patient interview: global RA activity (VAS), degree of asthenia, intensity of pain, duration of morning stiffness, nocturnal waking related to RA - Clinical examination: localisation of tender joints and swollen joints (out of 28) - Biological examination (last available for 2009): dates and values of ESR (1st hour), CRP and hemoglobin concentration - DAS 28 (if calculated), with ESR or CRP for the calculation - Treatment prescribed at the end of the visit (whether treatment modified or not) - Conditions under which the patient self-questionnaire was completed: before the visit/during the visit but before the therapeutic decision was made, other (to precise).
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>	
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
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Links to administrative sources	No
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## 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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