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EULAR COVID-19 Vaccine (COVAX) Registry

The COVID-19 pandemic has severely influenced all aspects of life in 2020. This pandemic also affected patients with Rheumatic and Musculoskeletal diseases (RMDs) and impacted the care given to them. With the development of vaccines, the future is becoming brighter. However, the possibility of vaccination also raises questions, especially for patients with inflammatory RMDs and patients that are treated with drugs that may influence their immune system.

Please help EULAR address these questions by responding to the questionnaire below.

- **Please report all COVID-19 vaccinated RMD patients, with inflammatory or non-inflammatory conditions.**
- **Please report all COVID-19 vaccinated RMD patients, with or without vaccine-related adverse events.**
- **Please submit reports at least one month after the administration of the last dose of the vaccine.**
- **Please do NOT report adverse events that are definitely NOT related with the vaccine administration.**

For patients without adverse events the questionnaire should take 1-2 minutes to complete. For patients with adverse events the questionnaire should take less than 5 minutes to complete. Reporting the maximum number of cases, including cases without adverse events, is extremely important as this will allow us to understand better how common a certain adverse event is.

Thank you for your participation!

EULAR COVID-19 vaccine (COVAX) registry in patients with inflammatory and non-inflammatory rheumatic and musculoskeletal diseases (RMDs)

Provider information

Today's date
* must provide value

29-01-2021 Today D-M-Y

Family name/last name of reporting provider
* must provide value

Given name/first name of reporting provider
* must provide value

Email address (institutional email preferred)
* must provide value

Role of reporting provider

- ○ Physician
- ○ Nurse
- ○ Physiotherapist
- ○ Research assistant/coordinator
- ◉ Other

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Other role:

Specialty of reporting provider

- ☐ Rheumatology
- ☐ Internal Medicine
- ☐ Not applicable
- ☑ Other

Other specialty:

Hospital, clinic or private practice name

City of hospital/clinic

Country of hospital/clinic

* must provide value

Are you a member of any of the following organisations?

- ○ Yes, member of ERN ReCONNET (European Reference Network on Rare and Complex Connective Tissue and Musculoskeletal Diseases)
- ○ Yes, member of ERN RITA (European Reference Network on Rare Immunodeficiency, Autoinflammatory and Autoimmune Diseases Network)
- ○ No, I am not a member of these organisations

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Patient information

Patient age (years)

* must provide value

Patient sex at birth

* must provide value

- ○ Female
- ○ Male
- ○ Other or not known

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Was the patient ever diagnosed with COVID-19/SARS-CoV-2 infection BEFORE being vaccinated?

- ○ Yes
- ○ No
- ○ Not known

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Was the patient ever diagnosed with COVID-19/SARS-CoV-2 infection AFTER being vaccinated?

- ○ Yes
- ○ No
- ○ Not known

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Which COVID-19 vaccine did the patient receive?

* must provide value

How many doses of the COVID-19 vaccine did the patient receive?

* must provide value

- ○ One
- ◉ Two
- ○ Unknown

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First dose date

Today D-M-Y

Second dose date

Today D-M-Y

Main rheumatic disease diagnosis (please start typing if you would like to use the text search function; in case of concomitant inflammatory and non-inflmmatory disease, the main diagnosis should always be the inflammatory disease)

* must provide value

Secondary rheumatic disease diagnosis (please choose/type "Not applicable" if there is no secondary rheumatic disease diagnosis)

For inflammatory RMDs, please estimate (clinician's judgement) disease activity at the time of first dose of vaccine administration (please select not applicable for non-inflammatory RMDs)

Immunomodulatory/immunosuppressive treatments (including Glucocorticoids) within one month before vaccination (or for rituximab within the 12 months before vaccination):

* must provide value

- [ ] None
- [ ] Abatacept
- [ ] Alemtuzumab (Campath)
- [ ] Antifibrotics (pirfenidone, nintedinib)
- [ ] Antimalarials (including hydroxychloroquine, chloroquine)
- [ ] Apheresis
- [ ] Apremilast
- [ ] Azathioprine / 6-mercaptopurine (6-MP)
- [ ] Belimumab
- [x] Rituximab
- [ ] Cyclophosphamide (IV or oral)
- [ ] Cyclosporine
- [x] Glucocorticoids
- [ ] Human stem cell transplant
- [ ] IL-1 inhibitors (including anakinra, canakinumab, rilonacept)
- [ ] IL-6 inhibitors (including tocilizumab, sarilumab)
- [ ] IL-12/23 inhibitors (ustekinumab)
- [ ] IL-23 inhibitors (guselkumab, risankizumab, tildrakizumab)
- [ ] IL-17 inhibitors (including secukinumab, ixekizumab)
- [ ] Intravenous immunoglobulin (IVIG)
- [ ] JAK inhibitors (including tofacitinib, baricitinib, upadacitinib)
- [ ] Leflunomide
- [ ] Methotrexate
- [ ] Mycophenolate mofetil / mycophenolic acid
- [ ] Sulfasalazine
- [ ] Tacrolimus
- [ ] Thalidomide / lenalidomide
- [ ] TNF-inhibitors (including adalimumab, certolizumab, etanercept, golimumab, infliximab, and biosimilars)
- [ ] Unknown
- [ ] Other

Date of last Rituximab administration (if day of the month not known, please use "15"):

Today D-M-Y

Daily glucocorticoid dose (prednisone equivalent, in mg)

Rituximab - Was the original therapeutic regimen changed or stopped before or after COVID-19 vaccination?

- [ ] No
- [x] Yes, Medication stopped BEFORE vaccination
- [ ] Yes, Medication reduced BEFORE vaccination
- [ ] Yes, Medication stopped AFTER vaccination
- [ ] Yes, Medication reduced AFTER vaccination
- [ ] Do not Know

Rituximab - Date when the medication was stopped Today D-M-Y

Rituximab - Date when the medication was re-started Today D-M-Y

Glucocorticoids - Was the original therapeutic regimen changed or stopped before or after COVID-19 vaccination?

- [ ] No
- [ ] Yes, Medication stopped BEFORE vaccination
- [ ] Yes, Medication reduced BEFORE vaccination
- [ ] Yes, Medication stopped AFTER vaccination
- [ ] Yes, Medication reduced AFTER vaccination
- [ ] Do not Know

Was there a flare of the inflammatory RMD following any of the injections of the vaccine?

* must provide value

- (•) Yes
- ( ) No
- ( ) Do not know

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Date of first signs of flare Today D-M-Y

Type of flare

- [ ] Fever
- [ ] Weight loss
- [ ] Increase in fatigue
- [ ] Increase in dryness
- [ ] Enlarged lymph nodes
- [ ] Polyarthralgia
- [ ] Arthritis flare
- [ ] Cutaneous flare
- [ ] Pulmonary flare
- [ ] Renal flare
- [ ] Neurological flare
- [ ] Muscular flare
- [ ] Cardiac flare
- [ ] Gastro-intestinal flare
- [ ] Haematological flare
- [ ] Other

Severity of flare

- [ ] Mild/Minor
- [ ] Moderate
- [ ] Severe/Major without hospitalisation
- [ ] Severe/Major WITH hospitalisation
- [ ] Not known/Unable to determine

Was the medication changed or the dosage increased due to the flare?

- ( ) Yes
- ( ) No
- ( ) Unknown

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Apart from flare of the underlying RMD, did the patient experience any other probably/possibly vaccine-related adverse events? If definitively not related to the vaccine, please do not report.

* must provide value

- (•) Yes
- ( ) No
- ( ) Do not know

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Early adverse events within 7 days from vaccination?

- [x] Pain at the site of injection
- [ ] Redness at the site of injection
- [ ] Swelling at the site of injection
- [ ] Generalized muscle pain
- [ ] Generalized joint pain
- [ ] Headache
- [ ] Fever
- [ ] Chills
- [ ] Fatigue
- [ ] Vomiting
- [ ] Diarrhoea
- [ ] None of the above
- [ ] Unknown

Any other adverse event?

- [x] Immunologic - Anaphylaxis
- [ ] Immunologic - Vasculitides
- [ ] Immunologic - Arthritis
- [ ] Respiratory - Acute respiratory distress syndrome (ARDS)
- [ ] Cardiac - Microangiopathy
- [ ] Cardiac - Heart failure and cardiogenic shock
- [ ] Cardiac - Stress cardiomyopathy
- [ ] Cardiac - Coronary artery disease
- [ ] Cardiac - Arrhythmia
- [ ] Cardiac - Myocarditis, pericarditis
- [ ] Haematologic - Thrombocytopenia
- [ ] Haematologic - Deep vein thrombosis
- [ ] Haematologic - Pulmonary embolus
- [ ] Haematologic - Cerebrovascular stroke
- [ ] Haematologic - Limb ischemia
- [ ] Haematologic - Hemorrhagic disease
- [ ] Renal - Acute kidney injury
- [ ] Gastrointestinal - Liver injury
- [ ] Neurologic - Generalized convulsion
- [ ] Neurologic - Guillain-Barr Syndrome (GBS)
- [ ] Neurologic - Acute disseminated encephalomyelitis (ADEM)
- [ ] Neurologic - Aseptic meningitis
- [ ] Neurologic - Encephalitis / Encephalomyelitis / Meningoencephalitis
- [ ] Neurologic - Anosmia, ageusia
- [ ] Neurologic - Ageusia
- [ ] Neurologic - Bell's palsy
- [ ] Dermatologic - Chilblain-like lesions
- [ ] Dermatologic - Single organ cutaneous vasculitis
- [ ] Dermatologic - Erythema multiforme
- [ ] Other, please state

Immunologic - Anaphylaxis

Did the AE occur after the first, after the second, or after both doses of the COVID-19 vaccine?

- (•) After the first dose
- ( ) After the second dose
- ( ) After both doses

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Immunologic - Anaphylaxis - AE after the first dose

Date of onset of the AE after the first dose (if known): [ ] Today D-M-Y

Degree of confidence in the relationship between the AE and the COVID-19 vaccine after the first dose

- ( ) Possibly related
- ( ) Probably related

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Seriousness of the AE after the first dose (tick all that apply)

- [ ] Mild
- [ ] Moderate
- [ ] Severe - Important medical event
- [ ] Severe - Hospitalisation (or prolongation of existing hospitalisation; hospitalisation being defined as at least 24 hours in a hospital or an overnight stay)
- [ ] Severe - Life-threatening
- [ ] Severe - Resulted in persistent or significant disability/incapacity
- [ ] Severe - Resulted in death
- [ ] Severe - Congenital anomaly/birth defect

Outcome of the AE after the first dose

- ○ Ongoing/Continuing
- ○ Recovered/resolved without sequelae
- ○ Recovered/resolved with sequelae
- ○ Death
- ○ Unknown

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Comments

Would you like to make any other comments about this case?

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– or –

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