BACKGROUND/AIMS
People with inflammatory/autoimmune rheumatic and musculoskeletal diseases (I-RMDs) were excluded from Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) vaccine clinical development programmes; therefore, concerns regarding the safety and effectiveness of SARS-CoV-2 vaccines in this population still exist. Previous studies in people with I-RMDs were small albeit reassuring in terms of the incidence of I-RMD flares and adverse events. Our aim was to describe the safety of vaccines against SARS-CoV-2 in people with I-RMD.

METHODS
Physician-reported registry of I-RMD and non-inflammatory RMD (NI-RMD) patients vaccinated against SARS-CoV-2. From 5/Feb/2021 to 27/Jul/2021, we collected data on demographics, vaccination, RMD diagnosis, disease activity, immunomodulatory/immunosuppressive treatments, flares, adverse events (AEs) and SARS-CoV-2 breakthrough infections. Data were analysed descriptively.

RESULTS
The study included 5121 participants from 30 countries, 90% with I-RMDs (n = 4604, 68% female, mean age 60.5 years) and 10% with NI-RMDs (n = 517, 77% female, mean age 71.4). Inflammatory joint diseases (58%), connective tissue diseases (18%) and vasculitis (12%) were the most frequent diagnostic groups; 54% received conventional synthetic disease-modifying anti-rheumatic drugs (DMARDs), 42% biologic DMARDs and 35% immunosuppressants. Most patients received the Pfizer/BioNTech vaccine (70%), 17% AstraZeneca/Oxford and 8% Moderna. In fully vaccinated cases, breakthrough infections were reported in 0.7% of I-RMD patients and 1.1% of NI-RMD patients. I-RMD flares were reported in 4.4% of cases (0.6% severe), 1.5% resulting in medication changes. AEs were reported in 37% of cases (37% I-RMD, 40% NI-RMD), serious AEs in 0.5% (0.4% I-RMD, 1.9% NI-RMD).

CONCLUSION
The safety profiles of SARS-CoV-2 vaccines in patients with I-RMD were reassuring, and comparable to patients with NI-RMDs. The majority of patients tolerated their vaccination well with rare reports of I-RMD flare and very rare reports of serious AEs. These findings should provide reassurance to rheumatologists and vaccine recipients, and promote confidence in SARS-CoV-2 vaccine safety in I-RMD patients.

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