Rheumatology Advances in Practice, 2024, **8(4)**, rkae135
https://doi.org/10.1093/rap/rkae135
Advance access publication 5 November 2024
Original Article

Clinical science

Recording of non-musculoskeletal manifestations, comorbidities and safety outcomes in European spondyloarthritis registries: a survey

Zohra F. Ahmadzay [1,2,*], Jette Heberg [1], Jacob B. Jørgensen [1], Lykke M. Ørnbjerg [1], Mikkel Østergaard [1,2], Signe Møller-Bisgaard [1,3], Brigitte Michelsen [1,4,5], Anne Gitte Loft [6,7], Gareth T. Jones [8], Pasoon Hellamand [9,10], Almut Scherer [11], Michael J. Nissen [12], Karel Pavelka [13,14], Jakub Závada [13,14], Karin Laas[15], Sigrid Vorobjov[16], Dan Nordström [17], Tuulikki Sokka-Isler[18], Anne C. Regierer [19], Andreas Reich [19], Bjorn Gudbjornsson [20,21], Katrin Thorarinsdottir [20,21], Florenzo Iannone [22], Ennio Giulio Favalli [23,24], Marleen van de Sande [10,25], Sella Aarrestad Provan [4,26], Tore K. Kvien[4], Ana Maria Rodrigues [27,28,29], Cátia F. Gonçalves [27], Catalin Codreanu [30], Corina Mogosan [30], Ziga Rotar [31,32], Katja Perdan Prikmajer [31,32], Isabel Castrejon [33,34], Lucía Otero-Varela [35], Daniela Di Giuseppe [36], Johan K. Wallman [37], Adrian Ciurea [38], Burkhard Möller [39], Gökçe Kenar-Artın [40], Tuba Demirci Yıldırım [40], Gary J. Macfarlane [8], Ovidiu Rotariu [8], Bente Glintborg [2,41,‡], Merete Lund Hetland [1,2,‡]

[1]Copenhagen Center for Arthritis Research (COPECARE), Center for Rheumatology and Spine Diseases, Rigshospitalet, Glostrup, Denmark
[2]Department of Clinical Medicine, University of Copenhagen, Copenhagen, Denmark
[3]Department of Rheumatology, Slagelse Hospital, Slagelse, Denmark
[4]Center for Treatment of Rheumatic and Musculoskeletal Diseases (REMEDY), Diakonhjemmet Hospital, Oslo, Norway
[5]Research Unit, Sørlandet Hospital, Kristiansand, Norway
[6]Department of Rheumatology, Aarhus University Hospital, Aarhus, Denmark
[7]Department of Clinical Medicine, Aarhus University, Aarhus, Denmark
[8]Aberdeen Centre for Arthritis and Musculoskeletal Health (Epidemiology Group), University of Aberdeen, Aberdeen, UK
[9]Department of Rheumatology and Clinical Immunology, Amsterdam University Medical Centers, Amsterdam, The Netherlands
[10]Amsterdam Rheumatology Immunology Center (ARC), Amsterdam UMC, Amsterdam, The Netherlands
[11]Swiss Clinical Quality Management Foundation, Statistics Group, Zurich, Switzerland
[12]Department of Rheumatology, Geneva University Hospital, Geneva, Switzerland
[13]Institute of Rheumatology, Prague, Czech Republic
[14]Department of Rheumatology, First Faculty of Medicine, Charles University, Prague, Czech Republic
[15]Department of Rheumatology, East-Tallinn Central Hospital, Tallinn, Estonia
[16]National Institute for Health Development, Tallinn, Estonia
[17]Departments of Medicine and Rheumatology, Helsinki University Hospital, Helsinki, Finland
[18]University of Eastern Finland and Hospital Nova Jyväskylä, Jyväskylä, Finland
[19]Deutsches Rheuma-Forschungszentrum Berlin, Epidemiologie, Berlin, Germany
[20]Centre for Rheumatology Research, Landspitali University Hospital, Reykjavik, Iceland
[21]Faculty of Medicine, University of Iceland, Reykjavik, Iceland
[22]Rheumatology Unit, Dipartimento di Medicina di Precisione e Rigenerativa e Area Jonica, University of Bari, Bari, Italy
[23]Department of Clinical Sciences and Community Health, University of Milan, Milan, Italy
[24]Department of Rheumatology and Medical Sciences, ASST Gaetanoi Pini-CTO, Milan, Italy
[25]Department of Rheumatology & Clinical Immunology and Department of Experimental Immunology, Amsterdam Institute for Infection and Immunity, Amsterdam, The Netherlands
[26]Public Health Section, Inland Norway University of Applied Sciences, Elverum, Norway
[27]Reuma.pt, Sociedade Portuguesa de Reumatologia, Lisbon, Portugal
[28]Nova Medical School, EpiDoC unit, CEDOC, Lisbon, Portugal
[29]Rheumatology Unit, Hospital dos Lusíadas, Lisbon, Portugal
[30]Center for Rheumatic Diseases, University of Medicine and Pharmacy, Bucharest, Romania

Received: 3 July 2024. **Accepted:** 25 September 2024

[31]Department of Rheumatology, University Medical Centre Ljubljana, Ljubljana, Slovenia
[32]Faculty of Medicine, University of Ljubljana, Ljubljana, Slovenia
[33]Department of Rheumatology. Hospital General, Universitario Gregorio Marañón, Madrid, Spain
[34]Faculty of Medicine, Complutense University of Madrid, Madrid, Spain
[35]Research Unit, Spanish Society of Rheumatology, Madrid, Spain
[36]Clinical Epidemiology Division, Department of Medicine Solna, Karolinska Institutet, Stockholm, Sweden
[37]Department of Clinical Sciences Lund, Rheumatology, Skåne University Hospital, Lund University, Lund, Sweden
[38]Department of Rheumatology, University Hospital Zurich, University of Zurich, Zurich, Switzerland
[39]Department Rheumatology and Immunology, Inselspital – University Hospital Bern, Switzerland
[40]Department of Internal Medicine, Division of Rheumatology, Dokuz Eylul School of Medicine, Izmir, Turkey
[41]DANBIO and Copenhagen Center for Arthritis Research (COPECARE), Center for Rheumatology and Spine Diseases, Rigshospitalet, Glostrup, Denmark

*Correspondence to: Zohra Faizy Ahmadzay, Copenhagen Center for Arthritis Research, COPECARE, Center for Rheumatology and Spine Diseases, Rigshospitalet, Glostrup, Valdemar Hansens Vej 17, Entrance 5, ground floor, DK-2600 Glostrup, Denmark. E-mail: zohra.faizy.ahmadzay@regionh.dk

‡B.G. and M.L.H. contributed equally.

Abstract

Objectives: Real-world evidence is needed to inform treatment strategies for patients with PsA and axial SpA (axSpA) who have non-musculoskeletal manifestations (NMMs), various risk factors and comorbidities. International collaboration is required to ensure statistical power and to enhance generalizability. The first step forward is identifying which data are currently being collected. Across 17 registries participating in the European Spondyloarthritis Research Collaboration (EuroSpA), we aimed to map recording practices for NMMs, comorbidities and safety outcomes in patients with PsA and axSpA.

Methods: Through a survey with 4,420 questionnaire items, we explored the recording practices of 58 pre-defined conditions (i.e. NMMs, comorbidities and safety outcomes) covering 10 disease areas. In all registries we mapped for each condition whether it was recorded, the recording procedure and the potential to identify it through linkage to other national registries.

Results: Conditions were generally recorded at entry into the registry and clinical follow-up visits using a pre-specified list or a coding system. Most registries recorded conditions within the following disease areas: NMMs (number of registries, $n = 15$–16), cardiovascular diseases ($n = 10$–14), gastrointestinal diseases ($n = 12$–13), infections ($n = 10$–13) and death ($n = 14$). Nordic countries had the potential for data linkage and generally had limited recording of conditions in their registry, while other countries had comprehensive recording practices.

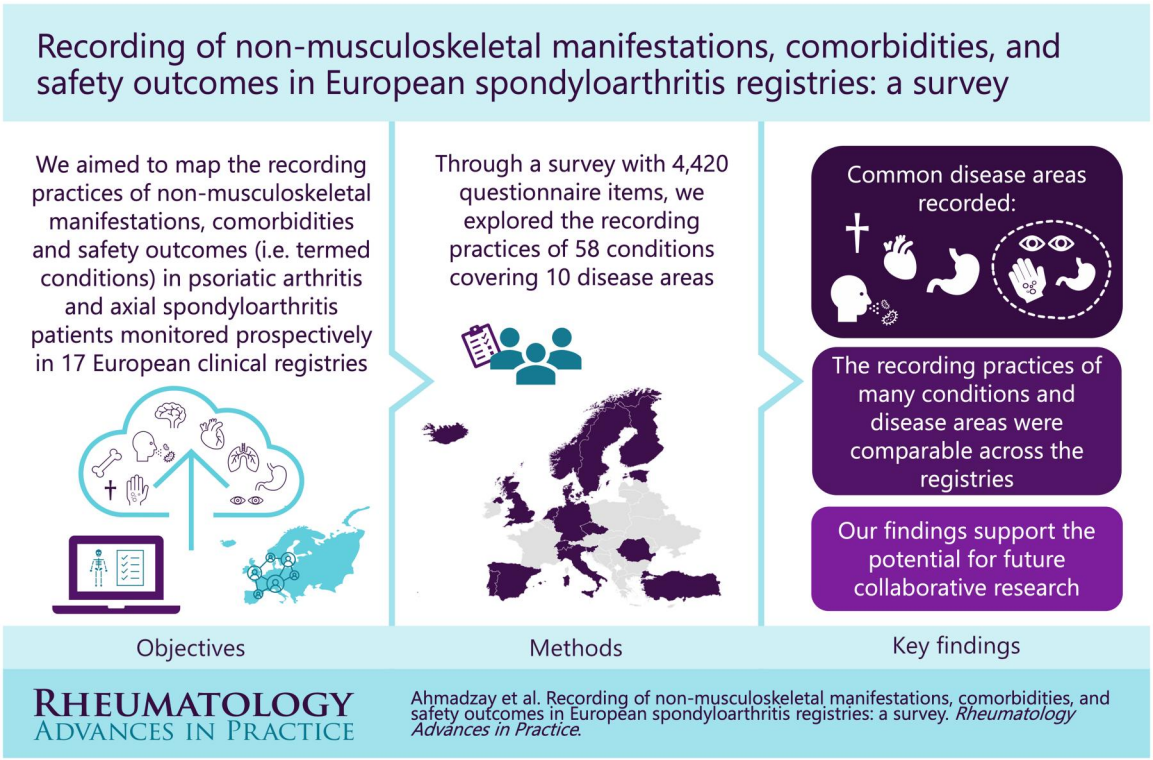
Conclusion: A wide range of conditions were consistently recorded across the registries. The recording practices of many conditions and disease areas were comparable across the registries. Our findings support the potential for future collaborative research.

Lay Summary

What does this mean for patients?

People with psoriatic arthritis (PsA) and axial spondyloarthritis (axSpA) often have many other health issues. These issues may affect their arthritis treatment, but we do not know how. To study this, we first need to know what data there are. Are these health issues being recorded in the clinics? This might be in local or national registries. We also need to know if different registries record data in similar ways. If they do, researchers can gather more information on the same health issues from many registries. We surveyed 17 registries in Europe to determine this. We asked if, and how, they record data on 58 health issues. We found that heart disease, gut disease, infections, psoriasis and uveitis are regularly recorded. Many registries used similar methods to record data. Our findings can help to pave the way for future research, leading to better treatment strategies for people with PsA and axSpA.

Graphical abstract



Keywords: spondyloarthritis, biological therapies, DMARDs, JAK inhibitors, comorbidity, multimorbidity, routinely collected data.

Key messages

- European clinical spondyloarthritis registries record with variations non-musculoskeletal manifestations, comorbidities and safety outcomes.
- The recording practices of many conditions and disease areas were comparable across the registries.
- Our findings support the potential for future collaborative research.

Introduction

PsA and axial SpA (axSpA) are disease entities within the broader SpA spectrum. Disease manifestations include arthritis, enthesitis, dactylitis, axial inflammation and non-musculoskeletal manifestations (NMMs) such as uveitis, inflammatory bowel disease and psoriasis [1–3]. PsA and axSpA are associated with various comorbidities. In PsA the prevalence of cardiovascular disease is reported to be 19.4% and for depression 11.9%, while in axSpA the prevalences are reported to be 12% and 10.9%, respectively [4, 5].

Effective management of PsA and axSpA often requires treatment with biologic and targeted synthetic (b/tsDMARDs) when initial therapy with NSAIDs or conventional DMARDs has failed [6, 7]. The effectiveness and safety of b/tsDMARDs should be considered when treating patients with NMMs and comorbidities [6–10]. This has been highlighted in the EULAR treatment recommendations for PsA from 2023, which added a new overarching principle: 'The choice of treatment should take account of safety considerations regarding individual modes of action to optimise the benefit–risk profile' [7]. Thus, to optimize treatment strategies, the impact of NMMs and comorbidities on the effectiveness and safety of b/tsDMARDs needs to be further investigated [6]. In that context, real-world studies are essential since they include a more diverse patient population compared with those eligible for inclusion in randomized clinical trials and have a broader generalizability [11–13]. Furthermore, with increasing b/tsDMARD treatment options available, collaboration between SpA registries is necessary to ensure sufficient statistical power to identify patient profiles that benefit from specific treatments. Initiating these collaborative studies requires insights into the recording practices of key NMMs, comorbidities and safety outcomes across various SpA registries. Currently, such knowledge is unavailable to researchers and stakeholders.

The European Spondyloarthritis Research Collaboration Network (EuroSpA) comprises clinical registries in 17 European countries that monitor the effectiveness of b/tsDMARDs in real-world patients with PsA and axSpA [14–16]. Through a detailed survey, this study aimed to map

the recording practices of NMMs, comorbidities and safety outcomes (here termed 'conditions') in European registries participating in EuroSpA.

Methods

The following registries participate in EuroSpA and monitor routine care patients with PsA and axSpA: ATTRA (Czech Republic), DANBIO (Denmark), ERSBTR (Estonia), ROB-FIN (Finland), RABBIT-SpA (Germany), ICEBIO (Iceland), GISEA (Italy), AmSpA (The Netherlands), NOR-DMARD (Norway), Reuma.pt (Portugal), RRBR (Romania), biorx.si (Slovenia), BIOBADASER (Spain), SRQ (Sweden), SCQM (Switzerland), TURKBIO (Turkey) and BSRBR-AS (UK, axSpA only). All registries record treatments with b/tsDMARDs and, aside from the Netherlands, concomitant conventional synthetic DMARDs (csDMARDs). The setup and detailed information, including funding, of each registry has been reported elsewhere [16–18] and in Supplementary Table S1, available at *Rheumatology Advances in Practice* online.

To map data collection practices on different conditions across registries, we constructed a survey with 4,420 different items (number of possible responses) using the online survey application Research Electronic Data Capture (REDCap) [19, 20]. For each respondent, some items were dynamic, e.g. if the registry responded that it was unable to use data linkage, then questions regarding data linkage were filtered out. To ensure the quality and relevance of the survey content, qualitative interviews were conducted during the development phase (using Microsoft Teams; Microsoft, Redmond, WA, USA) with representatives of a subset of the registries (in Denmark, Spain, Switzerland and the UK), who also provided screenshots of their registry user interface. The survey was pilot tested in 16 registries (all except Germany, who joined EuroSpA after finalizing the development of the survey) to ensure that the phrasing of questions was meaningful across registries.

The term 'condition' was used throughout to collectively refer to NMMs, comorbidities and safety outcomes. The survey addressed a total of 58 conditions covering the following 10 disease areas: NMMs, cardiovascular, endocrine, gastrointestinal, respiratory, psychiatric, cancer, infection, other conditions and death (see the complete list of conditions in Fig. 1). It was possible to record more or less granularity for some conditions (e.g. differentiated: type 1 diabetes mellitus and type 2 diabetes mellitus *vs* undifferentiated: diabetes). For each condition, we mapped the following: whether recording was possible in the registry; the recording procedure, including the system used for recording, the time points and frequency for recording, the dates that were related to the recorded condition and the persons who recorded the conditions; and the potential for linkage to other national registries to identify the condition. Furthermore, we investigated how the conditions were categorized in the registries (i.e. as a comorbidity and/or as a safety outcome) and their estimated data coverage. For the full survey, see Supplementary Data S1, available at *Rheumatology Advances in Practice* online.

Each registry assigned one or more representatives (typically a registry lead or researcher) with comprehensive insights into the registry to complete the survey. If a response gave rise to uncertainty, the respondents were contacted for clarification by one of the survey leaders. Interviews with local data managers were held when needed for a better understanding of their registry platform. The survey was conducted from 9 December 2022 to 1 February 2023. Respondents representing RABBIT-SpA (Germany) filled out the survey in November 2023, when they joined EuroSpA.

The results were processed and analysed using Microsoft Excel version 2208 and R version 2022.02.2 (R Foundation for Statistical Computing, Vienna, Austria) [21]. We used descriptive analyses, including counts, to summarize the recording practices of conditions across the registries. A colour-coded figure was created to show the total number of registries following specific procedures for recording a condition, categorized into thirds, i.e. based on the 33rd and 66th percentiles: yellow (number of registries, $n \leq 6$), light green ($n = 7$–10) and dark green ($n \geq 11$), respectively. Maps of the European countries were constructed in Microsoft Excel.

Results

All registries participating in EuroSpA ($n = 17$) completed the survey and, overall, 28 registry representatives contributed.

Recording possibilities of conditions in the registries

The number of conditions that potentially could be recorded in the registries ranged from 1 (Iceland) to 58 (Portugal, Slovenia and Turkey) (Fig. 1). Three registries (Denmark, Iceland and Sweden) recorded <15 conditions. The disease areas with the most frequently covered conditions were the NMMs (number of registries, $n = 15$–16), cardiovascular diseases ($n = 10$–15), gastrointestinal diseases ($n = 12$–13), infection ($n = 11$–13) and death ($n = 14$). The following conditions were recorded by >10 registries: obesity ($n = 16$), diabetes ($n = 15$), cancer ($n = 15$), pregnancy ($n = 12$), bone marrow depression ($n = 12$), injection site reactions ($n = 13$), systemic lupus erythematosus ($n = 12$) and Sjögren's syndrome ($n = 11$). It was more often possible to record undifferentiated conditions than differentiated conditions, e.g. uveitis ($n = 16$) *vs* specified (type of) uveitis ($n = 8$), diabetes ($n = 15$) *vs* type 1 or type 2 diabetes ($n = 10$), stroke ($n = 14$) *vs* ischaemic or haemorrhagic stroke ($n = 11$) and cancer ($n = 15$) *vs* specific site/type of cancer ($n = 10$) (Fig. 1).

Procedures for recording conditions in the registries

Fig. 2 shows an overview of different aspects of the recording procedures for the conditions.

System

Depending on the condition, the registries used one or several different recording systems: most of the registries reported using pre-specified lists of conditions ($n = 12$), free-text options ($n = 9$), the Medical Dictionary for Regulatory Activities (MedDRA) system ($n = 7$) or the International Classification of Diseases 9th or 10th Revision (ICD9 or 10) system ($n = 4$) (Fig. 2).

Time points

The most common time points for recording current and previous conditions were at the time of entry into the registry ($n = 16$), when adverse events occurred ($n = 15$) and at clinical follow-up visits ($n = 12$). At entry into the registry, >10 registries had the possibility of recording the following

Disease area	Condition \ Country	Czech	Denmark	Estonia	Finland	Germany	Iceland	Italy	Netherlands	Norway	Portugal	Romania	Slovenia	Spain	Sweden	Switzerland	Turkey	United	N, registries
NMM	Psoriasis	✓	✓	✓	✓	✓		✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	16
	Inflammatory bowel disease	✓		✓	✓	✓		✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	15
	Uveitis	✓	✓	✓	✓	✓		✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	16
	Specified uveitis							✓	✓	✓	✓		✓	✓		✓	✓		8
Cardiovascular	Cardiovascular disease	✓		✓	✓	✓		✓	✓	✓	✓	✓	✓	✓	✓	✓	✓		14
	Cardiac arrest	✓		✓		✓			✓	✓	✓		✓	✓		✓	✓	✓	11
	Stroke	✓		✓	✓	✓		✓	✓	✓	✓	✓	✓	✓		✓	✓	✓	14
	Ischemic stroke	✓				✓			✓	✓	✓	✓	✓	✓		✓	✓	✓	11
	Haemorrhagic stroke	✓				✓			✓	✓	✓	✓	✓	✓		✓	✓	✓	11
	Hypertension	✓		✓	✓	✓		✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	15
	Hypercholesterolemia	✓		✓		✓		✓	✓		✓	✓	✓	✓	✓	✓	✓	✓	13
	Ischemic heart disease	✓		✓	✓	✓		✓	✓	✓	✓	✓	✓	✓		✓	✓	✓	14
	Myocardial infarction	✓		✓	✓	✓		✓	✓	✓	✓	✓	✓	✓		✓	✓	✓	14
	Arteriosclerosis	✓		✓		✓		✓		✓	✓		✓	✓		✓	✓		10
	Deep venous thromboembolism	✓		✓	✓	✓		✓		✓	✓	✓	✓	✓		✓	✓	✓	13
	Pulmonary embolism	✓		✓	✓	✓		✓		✓	✓	✓	✓	✓		✓	✓	✓	13
Endocrine	Obesity	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓		16
	Diabetes	✓		✓	✓	✓		✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	15
	Type 1 diabetes mellitus	✓				✓		✓	✓	✓	✓		✓	✓		✓	✓		10
	Type 2 diabetes mellitus	✓				✓		✓	✓	✓	✓		✓	✓		✓	✓		10
	Osteoporosis	✓		✓		✓		✓		✓	✓	✓	✓	✓		✓	✓		11
	Thyroid gland disorders					✓				✓	✓	✓	✓	✓	✓	✓	✓		9
	Autoimmune thyroiditis					✓		✓		✓	✓		✓	✓		✓	✓		8
GI	GI ulceration	✓		✓		✓		✓	✓	✓	✓	✓	✓	✓		✓	✓	✓	13
	Diverticulitis	✓		✓		✓		✓		✓	✓	✓	✓	✓		✓	✓	✓	12
Resp.	Interstitial lung disease			✓	✓	✓		✓		✓	✓	✓	✓	✓		✓	✓		11
	Asthma	✓			✓	✓		✓		✓	✓	✓	✓	✓		✓	✓	✓	12
	Chronic obstructive pulmonary disease	✓			✓	✓		✓		✓	✓	✓	✓	✓		✓	✓	✓	12
Psychiatric	Psychiatric disorder					✓		✓		✓	✓	✓	✓	✓	✓	✓	✓		10
	Anxiety		✓			✓		✓		✓	✓		✓	✓		✓	✓	✓	10
	Depression	✓				✓		✓		✓	✓		✓	✓		✓	✓	✓	10
	Other affective disorder					✓		✓		✓	✓		✓	✓		✓	✓		8
	Schizophrenia					✓		✓		✓	✓		✓	✓		✓	✓		8
	Substance abuse					✓				✓	✓		✓				✓		5
Cancer	Cancer	✓		✓	✓	✓		✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	15
	Digestive organ/tract			✓		✓		✓		✓	✓		✓	✓		✓	✓	✓	10
	Respiratory system			✓		✓		✓		✓	✓		✓	✓		✓	✓	✓	10
	Skin			✓		✓		✓		✓	✓		✓	✓		✓	✓	✓	10
	Malignant melanoma	✓				✓		✓		✓	✓		✓	✓		✓	✓	✓	10
	Non-melanoma skin cancer	✓				✓		✓		✓	✓		✓	✓		✓	✓	✓	10
	Endo/neuroendocrine			✓		✓		✓		✓	✓		✓	✓		✓	✓	✓	10
	Urinary organ/tract			✓		✓		✓		✓	✓		✓	✓		✓	✓	✓	10
	Breast			✓		✓		✓		✓	✓		✓	✓		✓	✓	✓	10
	Reproductive/genital organ			✓		✓		✓		✓	✓		✓	✓		✓	✓	✓	10
Infection	Infection			✓		✓		✓	✓	✓	✓	✓	✓	✓		✓	✓	✓	12
	Tuberculosis	✓		✓	✓	✓		✓		✓	✓	✓	✓	✓		✓	✓	✓	13
	Opportunistic infection			✓		✓		✓	✓	✓	✓	✓	✓	✓		✓	✓		11
	Infection requiring hospitalisation			✓	✓	✓			✓	✓	✓		✓	✓		✓	✓	✓	11
	Infection site			✓		✓			✓	✓	✓	✓	✓	✓		✓	✓	✓	11
Other conditions	Pregnancy	✓		✓		✓		✓		✓	✓	✓	✓	✓		✓	✓	✓	12
	Birth defect in offspring					✓		✓		✓	✓		✓	✓		✓	✓	✓	8
	Bone marrow depression			✓		✓		✓	✓	✓	✓	✓	✓	✓		✓	✓	✓	12
	Injection site reactions			✓	✓	✓		✓	✓	✓	✓	✓	✓	✓		✓	✓		13
	Multiple sclerosis	✓		✓		✓		✓		✓	✓		✓	✓		✓	✓		10
	Systemic lupus erythematosus			✓	✓	✓		✓		✓	✓		✓	✓	✓	✓	✓	✓	12
	Sjögren's syndrome			✓	✓	✓		✓		✓	✓		✓	✓	✓	✓	✓		11
Death	Death	✓	✓	✓		✓		✓		✓	✓	✓	✓	✓	✓	✓	✓	✓	14
	Cause of death	✓		✓		✓		✓		✓	✓	✓	✓	✓		✓	✓	✓	12
N, conditions		33	5	40	21	57	1	51	25	57	58	33	58	57	14	57	58	40	

Figure 1. Conditions possible to record in each registry, sorted by disease area. Whether it is possible to record a condition, yes: ✓, no: empty. The total number of registries recording the condition is shown in the right column, ranging from yellow (number of registries, $n \leq 6$) to light green ($n = 7$–10) to dark green ($n \geq 11$). The total number of conditions recorded in each registry is shown at the bottom of the figure. resp: respiratory

Disease area	Condition	A. System				B. Time points							C. Dates			D. Recorded by			
		ICD-9 or -10	MedDRA	Pre-specified list of condition	Free text	Entry into the registry	Start of first b/tsDMARD	At change of b/tsDMARD	At clinical follow-up visits	At adverse event	Ad hoc	When lost to follow-up	Symptom or event	Diagnosis	Recording of condition	Physician	Nurse	Research staff	Patient
NMM	Psoriasis	3	7	11	6	16	9	9	12	14	9	4	10	5	13	15	13	7	2
	Inflammatory bowel disease	3	7	9	6	15	9	9	12	15	9	4	10	4	12	15	13	7	1
	Uveitis	3	7	11	6	16	9	9	12	15	10	4	10	5	13	16	13	7	2
	Specified uveitis	1	4	5	3	7	5	6	7	8	4	3	7	3	8	8	6	4	0
Cardiovascular	Cardiovascular disease	3	6	11	5	14	8	7	11	12	7	4	9	4	12	14	12	7	1
	Cardiac arrest	0	7	3	4	7	6	6	6	10	7	2	10	2	8	11	9	4	0
	Stroke	3	7	10	6	13	8	7	11	13	8	3	11	4	11	14	12	6	1
	Ischemic stroke	1	7	4	5	9	6	6	8	10	6	2	9	2	9	11	9	4	1
	Haemorrhagic stroke	0	7	3	5	8	6	6	7	10	6	2	9	2	9	11	9	4	1
	Hypertension	3	7	12	6	15	9	8	12	13	9	4	9	4	12	15	13	7	1
	Hypercholesterolemia	2	6	10	5	12	8	7	10	11	8	4	8	3	10	13	11	6	1
	Ischemic heart disease	3	7	9	5	14	8	7	11	12	7	3	9	4	11	14	12	6	1
	Myocardial infarction	2	7	10	5	11	8	7	9	13	8	3	11	4	11	14	12	6	1
	Arteriosclerosis	1	6	4	5	9	5	5	7	9	6	3	8	2	8	10	9	4	1
	Deep vein thromboembolism	2	7	8	5	9	6	6	8	13	8	3	11	3	10	13	11	5	1
	Pulmonary embolism	2	7	6	6	9	6	6	8	13	8	3	11	3	10	13	11	5	1
Endocrine	Obesity	2	6	6	9	14	8	6	11	11	10	4	9	4	13	15	12	7	
	Diabetes	3	7	12	6	15	9	8	12	13	8	4	9	4	12	15	13	7	1
	Type 1 diabetes mellitus	2	6	5	3	9	6	6	8	9	6	3	8	3	9	10	9	5	1
	Type 2 diabetes mellitus	2	6	5	3	9	6	6	8	9	6	3	8	3	9	10	9	5	1
	Osteoporosis	2	6	7	5	10	6	5	7	10	6	3	9	2	9	11	9	4	1
	Thyroid gland disorders	0	5	4	5	7	5	4	6	9	5	3	7	1	9	9	7	4	1
	Autoimmune thyroiditis	1	5	2	5	6	4	4	7	8	5	3	7	2	8	8	7	4	1
GI	GI ulceration	2	7	9	5	10	6	6	9	13	8	3	11	4	11	13	11	5	1
	Diverticulitis	1	7	5	7	8	6	6	8	12	8	3	9	3	10	12	10	4	1
Respiratory	Interstitial lung disease	3	5	6	7	9	4	4	8	10	5	3	8	3	10	11	9	5	0
	Asthma	3	7	6	5	11	6	6	9	12	7	3	9	3	10	12	10	5	1
	Chronic obstructive pulmonary disease	3	7	6	5	11	6	6	9	12	7	3	10	3	10	12	10	5	1
Psychiatric	Psychiatric disorder	1	5	7	5	9	5	5	9	10	6	4	8	2	10	10	8	5	1
	Anxiety	1	5	4	5	7	5	5	6	9	7	3	7	2	9	9	8	4	2
	Depression	2	7	5	3	10	7	6	7	10	7	3	9	2	8	10	9	4	2
	Other affective disorder	1	5	2	5	6	4	4	5	8	5	3	7	2	8	8	7	4	0
	Schizophrenia	1	5	2	5	6	4	4	5	8	5	3	7	2	8	8	7	4	0
	Substance abuse	0	4	2	4	3	1	2	3	5	3	1	4	1	5	5	4	1	0
Cancer	Cancer	2	7	11	6	14	9	9	12	14	9	4	10	6	13	15	13	7	1
	Digestive organ/tract	1	6	5	5	9	6	6	8	10	7	3	8	4	9	10	9	4	1
	Respiratory system	1	6	5	5	9	6	6	8	10	7	3	8	4	9	10	9	4	1
	Skin	1	6	5	5	9	6	6	8	10	7	3	8	4	9	10	9	4	1
	Malignant melanoma	1	7	4	5	10	7	7	8	10	7	3	9	3	8	10	9	4	1
	Non-melanoma skin cancer	1	7	4	5	10	7	7	8	10	7	3	9	3	8	10	9	4	1
	Endo/neuroendocrine	1	6	4	6	9	6	6	8	10	7	3	8	4	9	10	9	4	1
	Urinary organ/tract	1	6	4	6	9	6	6	8	10	7	3	8	4	9	10	9	4	1
	Breast	1	6	5	5	9	6	6	8	10	7	3	8	4	9	10	9	4	1
	Reproductive/genital organ	1	6	4	6	9	6	6	8	10	7	3	8	4	9	10	9	4	1
Infection	Infection	2	6	9	5	10	6	7	10	11	7	3	9	4	11	12	10	5	1
	Tuberculosis	3	7	9	5	12	7	7	10	13	8	3	10	4	11	13	11	5	1
	Opportunistic Infection	1	5	6	5	5	4	5	6	11	6	3	8	4	11	11	9	5	0
	Infection requiring hospitalisation	1	6	4	4	6	4	5	7	11	6	2	7	4	10	11	9	5	0
	Infection site	0	6	5	5	5	4	4	6	11	6	2	9	3	10	11	8	4	0
Other conditions	Pregnancy	1	6	7	5	7	7	7	6	11	8	3	9	3	10	12	10	4	1
	Birth defect in offspring	1	6	3	3	6	5	6	6	9	6	3	8	2	8	9	8	4	1
	Bone marrow depression	1	6	6	6	6	5	5	8	12	7	3	10	4	11	12	10	5	0
	Injection site reactions	2	6	6	5	6	4	5	7	12	6	3	8	5	12	12	10	6	1
	Multiple sclerosis	2	6	6	4	10	5	5	7	10	7	3	8	2	8	10	9	4	1
	Systemic lupus erythematosus	3	6	5	6	10	6	6	10	12	8	4	9	5	9	12	11	6	1
	Sjögren's syndrome	4	5	6	5	9	5	5	9	10	6	4	8	5	9	11	10	6	1
Death	Death	1	7	7	4	8	7	7	7	14	9	8	13	2	10	14	10	5	0
	Cause of death	1	6	5	5	7	6	6	6	12	8	6	11	2	9	12	9	4	0

Figure 2. Different aspects of the recording procedures for the conditions. Colour-coded figure ranging from yellow (number of registries, $n \leq 6$) to light green ($n = 7$–10) to dark green ($n \geq 11$) with the total number of registries for the type of recording system used, the time points and frequency for recording, the dates related to the recorded condition and who recorded the condition. The exact numbers for each registry can be found in Supplementary Figs S2–S4, available at *Rheumatology Advances in Practice* online

15 conditions: psoriasis, inflammatory bowel disease, uveitis, cardiovascular disease, stroke, hypertension, hypercholesterolaemia, ischaemic heart disease, myocardial infarction, obesity, diabetes, asthma, chronic obstructive pulmonary disease, cancer and tuberculosis. During follow-up, the majority of conditions could be recorded as adverse events (Fig. 2).

Dates

The date recorded by most registries was the date of event or symptom onset ($n = 13$) and the date when the recording of a condition took place ($n = 13$); it was less common to provide the date of diagnosis ($n = 6$) (Fig. 2).

Recorded by

Most conditions were recorded by healthcare professionals, such as physicians ($n = 16$) or nurses ($n = 13$), while recordings by research staff ($n = 7$) or patients themselves ($n = 2$) were less common (Fig. 2).

Categorization of conditions as comorbidities or safety outcomes

The categorization of a condition as either a comorbidity or a safety outcome was for many registries dependent on whether the condition emerged before or after the initiation of a b/tsDMARD treatment. Ten registries (Czech Republic, Estonia, Germany, Italy, Norway, Romania, Slovenia, Spain, Turkey and the UK) recorded conditions according to a prespecified list of conditions filled out at the patient's entry into the registry. These initially recorded conditions were considered comorbidities. Generally, for these 10 registries, conditions that emerged during b/tsDMARD treatment were considered safety outcomes and were mostly recorded with the MedDRA coding system ($n = 7$). In seven of the registries (Czech Republic, Germany, Italy, Norway, Romania, Turkey and the UK), the prespecified list of comorbidities could be updated with new information during the follow-up visits at the physician's discretion. In the other three registries (Estonia, Slovenia and Spain), any new information on conditions was generally recorded as safety outcomes.

In the Netherlands, Portugal, Sweden, Switzerland and 7 of 10 sites in Finland, the conditions could be recorded at any time. It was the treating physician's decision whether a condition was a comorbidity or a safety outcome. Denmark had limited recordings of conditions, which were performed annually by the patients and were considered comorbidities.

All 17 registries could report serious adverse events in their registries, whereas 5 could also obtain information through linkage to other national registries (Fig. 3).

Estimated data coverage

In Spain and Turkey, conditions were overall carefully recorded and the data coverage was estimated to be high by respondents. Germany and Italy estimated higher data coverage on conditions classified as comorbidities than as safety outcomes. Registries from the Czech Republic, Finland (in 7 of 10 sites), Norway, Slovenia and the UK prioritized the recording of conditions that could be classified as comorbidities or serious adverse events. Denmark, Iceland and Sweden reported having limited data coverage for all conditions in their registries (apart from death in Denmark and Sweden). For research purposes on comorbidities and safety issues, these registries mainly captured data by linkage to other national registries. In the Netherlands, despite the implementation of electronic recording systems alongside existing paper documentation, a substantial volume of records before 2021 remained in paper format, as they had not been digitized due to practical and financial constraints.

Estonia, Germany, Italy, Slovenia, Spain and Turkey had mandatory recording of NMMs and comorbidities at the patient's entry into the registry. In Estonia, Slovenia, Spain and Turkey, registration was also mandatory before initiation of the first b/tsDMARD treatment. For adverse and serious adverse events, it was mandatory to record them at any time in Estonia, Germany, Slovenia, Spain and Turkey, while for Denmark and Finland it was mandatory only for serious adverse events.

While many registries relied solely on manual recording of conditions, Finland captured recorded conditions automatically from electronic medical records directly into their registry in 3 of 10 sites. Spain cross-checked or obtained detailed information on conditions through inspection of patients' medical records. Turkey and the UK also reported this procedure being used when necessary. For the Danish, Finnish (until the end of 2018), Norwegian and Swedish registries, information on death was automatically obtained from other national registries.

Registries with the potential to link to other national registries

Linkage to other national registries, which had records of any conditions as diagnoses/contact reasons for hospitalization/hospital contacts, was mainly possible in Denmark, Finland, Iceland, Norway and Sweden (Fig. 4). Finland had access to the national patient registry until the end of 2018 (with an ongoing process regarding an update). Estonia was able to link a limited number of conditions in disease-specific national registries. Slovenia had the same potential with health insurance databases (Supplementary Fig. S1 and Table S2, available at *Rheumatology Advances in Practice* online).

For the remaining registries, such data linkage was not possible. Switzerland reported that although linkage was theoretically possible following ethical approval, it was not feasible due to bureaucratic obstacles. In the UK, linkage was not feasible due to the time, effort and expense required to obtain the data. In the Czech Republic and Italy, concerns regarding the General Data Protection Regulation prevented linkage.

Discussion

In this survey of 17 European rheumatology registries, we mapped the recording practices for NMMs, comorbidities and safety outcomes in patients with PsA and axSpA treated with b/tsDMARDs in routine care. For each registry we obtained detailed insights and a comprehensive overview of the recording possibilities and practices of 58 conditions covering 10 disease areas. There were more similarities than differences in recordings of conditions and disease areas across the registries. A wide range of conditions was consistently recorded at the patient's entry into the registry and during follow-up. To our knowledge, a multinational study on the recording practices of conditions in patients with PsA and axSpA has not been performed previously. This comprehensive overview paves the way for designing and conducting future collaborative research among rheumatology registries to investigate the impact of NMMs, comorbidities and safety

Serious adverse event	Country																	N, registries
	Czech Republic	Denmark	Estonia	Finland	Germany	Iceland	Italy	Netherlands	Norway	Portugal	Romania	Slovenia	Spain	Sweden	Switzerland	Turkey	United Kingdom	
Death	✓	✓	✓		✓	✓	✓	✓	✓	✓	✓	✓	✓		✓	✓	✓	15
Life-threatening event	✓	✓	✓	✓	✓		✓		✓	✓	✓	✓	✓		✓	✓	✓	14
Required or prolonged hospitalisation	✓	✓	✓	✓	✓			✓	✓	✓	✓	✓	✓		✓	✓	✓	14
Persistent impairment or disability	✓	✓			✓		✓	✓	✓	✓	✓	✓	✓		✓	✓	✓	13
Birth defects in offspring	✓	✓			✓		✓		✓	✓		✓	✓			✓	✓	10
Leads to intravenous anti-biotic/viral drug administration	✓			✓	✓				✓			✓	✓					6
Other pre-specified events								✓	✓	✓						✓		4
Events described in free-text				✓					✓				✓	✓	✓			5
Identified through linkage to other national registries		✓		✓		✓			✓					✓				5

Figure 3. Potentially recorded serious adverse events in each registry

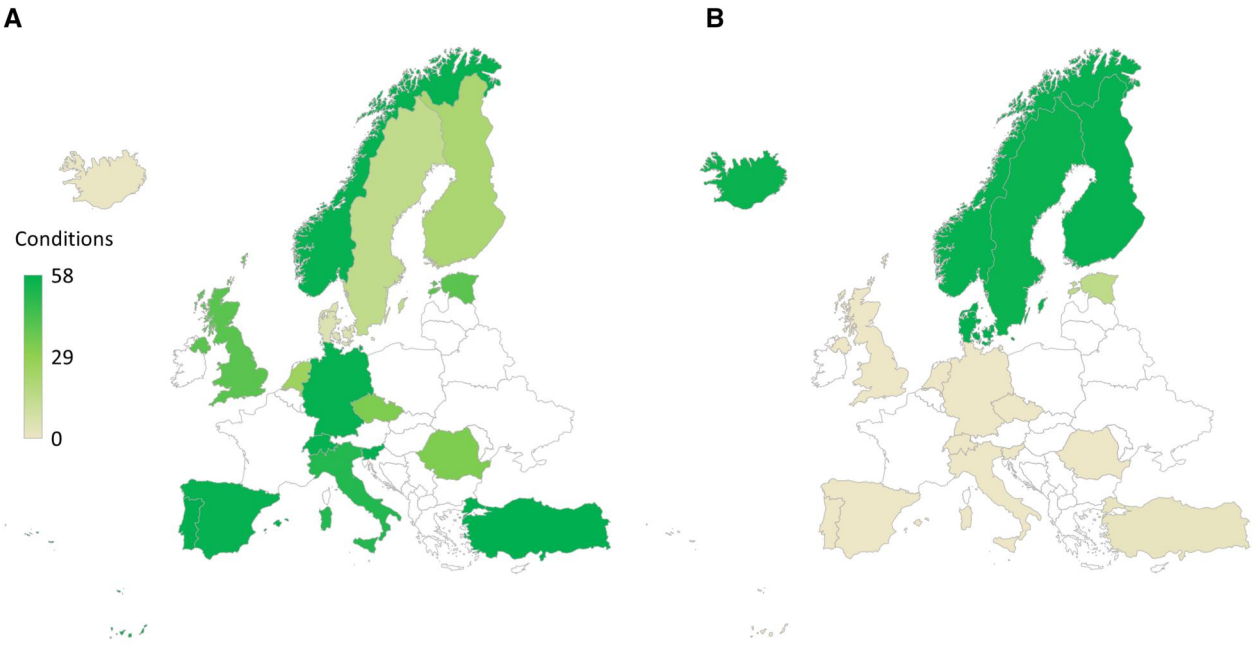


Figure 4. European maps of the total number of conditions recorded or obtained through linkage to other national registries. **(A)** The number of the 58 conditions that could be directly recorded in each European SpA registry. **(B)** The number of conditions that could be obtained through linkage to other national registries after relevant legal and/or ethical permits. The exact numbers for each registry/country can be found in Fig. 1 and Supplementary Fig. S1, available at *Rheumatology Advances in Practice* online

profiles of specific b/tsDMARDs on prescription patterns, treatment effectiveness and multiple other outcomes.

Surveys and data extraction have previously been undertaken to map SpA and RA registries, thus investigating consistencies and differences between countries [16, 22–24]. Even though these studies showed differences in definitions of data items and demographics of included patients, commonalities between the registries were also found. Most of the registries participating in our study had their primary focus on monitoring disease activity and treatment outcomes.

Thus conditions were generally recorded at the patient's entry into the registry or during clinical follow-up if they were on a prespecified list of conditions, such as NMMs and comorbidities. Other conditions were mostly recorded if they could be categorized as serious adverse events. In contrast, in registries with a primary focus on the safety of b/tsDMARDs in rheumatic diseases, e.g. the BIOBADASER in Spain [25], any conditions or events emerging during b/tsDMARD treatment were considered and recorded as safety outcomes.

In our survey, we accommodated some of the differences in the use of terminology by collectively referring to NMMs, comorbidities and safety outcomes as conditions. In research, it is generally sufficient to know the presence or absence of a specific condition during a defined time period. In EuroSpA it is feasible to link recorded conditions to specific therapies due to their near-complete data on b/tsDMARD treatment start and stop dates and on concomitant csDMARD use [16]. Thus, depending on the research question, any conditions recorded before the initiation of a particular b/tsDMARD could be considered comorbidities, while those occurring after treatment start could be considered potential safety outcomes.

We addressed the data quality of the recorded conditions in our survey. Inherently, in registries that recorded conditions at the discretion of physicians and nurses, there was a risk of potential underreporting of events. This result is in line with a previous study of 27 European RA registries [22]. Importantly, however, the registries estimated higher coverage of conditions that were considered major or serious. In some countries additional information could be obtained through linkage to administrative registries with high coverage of a wide range of conditions (Denmark, Finland, Iceland, Norway and Sweden [26, 27]) or for specific conditions (Estonia, Slovenia [28, 29]). Nevertheless, in all countries the linkage process was not seamless and could pose a hindrance for research.

Our results indicated a potential for future collaborative studies between existing European SpA registries investigating the impact of NMMs and selected comorbidities on b/tsDMARD effectiveness by using longitudinal data on treatment outcomes and data on NMMs and comorbidities. Safety studies on conditions defined as serious adverse events could also be considered.

Ideally, data collection should be harmonized to ensure comparability and facilitate data pooling [30, 31]. A EULAR initiative suggested a standardized core set of six comorbidity domains for chronic inflammatory rheumatic diseases (RA, SpA, CTDs and crystal arthropathies): cardiovascular diseases, malignancies, infections, peptic ulcers, osteoporosis and depression [32]. In our survey, we found that most of the registries recorded cardiovascular disease, malignancies and infections, whereas information regarding peptic ulcers, osteoporosis and depression was more limited. Prospective data harmonization is not a simple task, since each registry is well established and maintained independently. Rather, one may consider harmonizing existing data. Different methods have been applied to address, for example, heterogeneity in collaborative research between inherently different groups of patients and registries [33, 34]. Some studies used advanced statistical methods while others retrospectively harmonized data [14, 36–38].

Our study has several strengths. We developed a detailed survey and obtained complete participation from all 17 invited registries. Furthermore, through pilot testing of the survey, we ensured the face and content validity of the questions. We included multiple responders from each registry to reduce the potential impact of subjective estimation. Engaging in dialogue with the respondents ensured a valid interpretation of survey results. Limitations included the challenges of capturing the complexities of registration practices related to certain conditions. However, we addressed this limitation by consulting three of the registries during the development of the survey, encouraging free-text comments and follow-up dialogues with all registries. The inability of the survey to capture changes in recording practices since registry start was also a limitation.

Based on the survey results, an important next step would be to investigate the impact of NMMs, comorbidities and safety outcomes on treatment effectiveness in patients with PsA and axSpA in routine care across the 17 European registries.

In conclusion, this is the first multinational study to provide a comprehensive overview of the recording practices of multiple NMMs, comorbidities and safety outcomes covering 10 disease areas across 17 European SpA registries. The most common conditions covered were NMMs, cardiovascular diseases, gastrointestinal diseases, infections and death. The overlap in recording practices enables future collaborative research projects inspired by EULAR's recent recommendations [7] on how the choice of treatment should take safety considerations regarding individual modes of action into account.

Supplementary material

Supplementary material is available at *Rheumatology Advances in Practice* online.

Authors' contributions

The study was conceptualised by Z.F.A., J.H., L.M.Ø., M.Ø., B.M., A.G.L., G.T.J., P.H., A.S., M.J.N., B.Glintborg, and M.L.H.. The study analysis was performed by Z.F.A. and J.B.J.. Authours who contributed by completing the REDCap survey and/or participating in the follow-up interviews were B.M., A.G.L., G.T.J., P.H., A.S., J.Z., K.L., D.N., A.C.R., A.R., B.Glintborg, F.I., M.v.d.S., S.A.P., A.M.R., C. F.G., C.C., Z.R., I.C., L.O.V., D.D.G., J.K.W., G.K.A., T.D. Y., O.R., and B.Gudbjornsson. The manuscript was drafted by Z.F.A., B.Glintborg and M.L.H., and the final version of the manuscript was revised and approved by all authors, who also approved the submission. For further details, see CRediT (Contributor Roles Taxonomy) statement in Supplementary

Funding

This work was supported by Novartis Pharma AG. EuroSpA was financially supported by Novartis. Novartis had no influence on the data collection, statistical analyses, manuscript preparation or decision to submit the manuscript.

Data availability

All data are incorporated into the article and its online supplementary material.

Disclosure statement: Z.F.A. received a research grant from Novartis (paid to the employer). J.H. received a research

grant from Novartis (paid to the employer). J.B.J. received a research grant from Novartis (paid to the employer). L.M.Ø. received a research grant from Novartis (paid to the employer). M.Ø. received research grants from AbbVie, BMS, Merck, Celgene and Novartis and speaker and/or consultancy fees from AbbVie, BMS, Boehringer Ingelheim, Celgene, Eli Lilly, Hospira, Janssen, Merck, Novartis, Novo Nordisk, Orion, Pfizer, Regeneron, Roche, Sandoz, Sanofi and UCB. S.M.-B. received a research grant from AbbVie. B. M. received a research grant from Novartis (paid to the employer) and speaker fees from Novartis. The Centre for Treatment of Rheumatic and Musculoskeletal Diseases (REMEDY) is funded as a Centre for Clinical Treatment Research by the Research Council of Norway (project 328657). A.G.L. received a research grant from Novartis and speaker and/or consultancy fees from AbbVie, Janssen, Novartis, Pfizer and UCB. G.T.J. received research grants from AbbVie, Pfizer, UCB, Amgen and GSK and speaker fees from Janssen. P.H. received a research grant from Novartis (paid to the employer). A.S. was employed by BMS in 2007–2008. M.J.N. received speaker and consulting fees from AbbVie, Amgen, Eli Lilly, Janssens, Novartis, Pfizer and UCB and research grants from Novartis and Pfizer. K.P. received consulting fees from AbbVie, UCB, Pfizer, Eli Lilly, Celltrion, MSD and Novartis and speaker fees from AbbVie, Amgen, Pfizer, Eli Lilly, Viatris, Fresenius and Novartis. J.Z. received speaker fees from AbbVie, Eli Lilly, Sandoz, Novartis, Egis, UCB, Sanofi, AstraZeneca and Sobi. K.L. received speaker fees from AbbVie, Johnson & Johnson, Novartis and Pfizer. D.N. received consultant fees from BMS, Eli Lilly, MSD, Novartis, Pfizer and UCB; speaker fees from Pfizer and UCB and grants from MSD. T.S.-I. received grants from Amgen. A.C.R. received speaker fees from Amgen, BMS, Novartis, Pfizer and Roche. RABBIT-SpA is supported by a joint, unconditional grant from AbbVie, Amgen, Biogen, Celltrion, Hexal, Janssen-Cilag, Eli Lilly, MSD, Novartis, Pfizer, UCB and Viatris. F.I. received consulting and/or speaking fees from AbbVie, Amgen, AstraZeneca, Galapagos, Janssen, Eli Lilly, MSD, Novartis, Pfizer and UCB and research grants from BMS, Galapagos and Pfizer. E.G.F. received speaker and consultation fees from Eli Lilly, MSD, Novartis and Janssen. M.v.d.S. received consultant fees from Novartis, AbbVie, Janssen and UCB; speaker fees from Novartis, UCB and Janssen and grant/research support from UCB, Janssen, Novartis and Eli Lilly. S.A.P. received consultant fees and grants from Boehringer Ingelheim. T.K.K. received consultant fees from AbbVie, Amgen, Celltrion, Gilead, Novartis, Pfizer, Sandoz and UCB; speaker fees from Grünenthal, Sandoz and UCB and grants from AbbVie, Amgen, BMS, Galapagos, Novartis, Pfizer and UCB (to the institution). A.M.R. received consulting and/or speaking fees from AbbVie and Amgen and research grants from Novartis, Pfizer and Amgen. C.C. received speaker and consultancy fees from AbbVie, Amgen, Boehringer Ingelheim, Ewopharma, Eli Lilly, Novartis, Pfizer and Sandoz. C.M. received speaker fees from AbbVie, Boehringer Ingelheim, Ewopharma, Eli Lilly, Novartis and Pfizer. Z.R. received consultant fees from AbbVie, Novartis, Eli Lilly, Pfizer, Janssen, SOBI, Swixx BioPharma and AstraZeneca and speaker fees from AbbVie, Amgen, Novartis, MSD, Medis, Biogen, Eli Lilly, Pfizer, Sanofi, Lek, Janssen. K.P.P. received consultant fees from AbbVie, Novartis, Medis, Eli Lilly, Pfizer and Boehringer Ingelheim and speaker fees from AbbVie, Novartis, MSD, Medis, Eli Lilly, Pfizer, Lek and Janssen. I.C. received speaker and/or consultancy fees from BMS, Eli Lilly, Galapagos, Gilead, Janssen, Novartis, MSD, Pfizer and GSK. J.K.W. received research support from AbbVie, Amgen, Eli Lilly, Novartis and Pfizer and speaker fees from AbbVie and Amgen. B.M. received speaker fees from Eli Lilly, Janssen, Novartis and Pfizer and grants from Amgen. B.G. received research grants (paid to institution) from Pfizer, AbbVie and BMS. M.L.H. received research grants from AbbVie, Biogen, BMS, Celltrion, Eli Lilly, Janssen Biologics B.V, Lundbeck Fonden, MSD, Medac, Pfizer, Roche, Samsung Bioepis, Sandoz and Novartis. The remaining authors have declared no conflicts of interest.

Acknowledgements

We thank Novartis Pharma AG for supporting EuroSpA.

References

1. Ashrafi M, Ermann J, Weisman MH. Spondyloarthritis evolution: what is in your history? Curr Opin Rheumatol 2020;32:321–9.
2. Rudwaleit M, van der Heijde D, Landewé R *et al.* The Assessment of SpondyloArthritis international Society classification criteria for peripheral spondyloarthritis and for spondyloarthritis in general. Ann Rheum Dis 2011;70:25–31.
3. Bengtsson K, Forsblad-d'Elia H, Deminger A *et al.* Incidence of extra-articular manifestations in ankylosing spondylitis, psoriatic arthritis and undifferentiated spondyloarthritis: results from a national register-based cohort study. Rheumatology (Oxford) 2021; 60:2725–34.
4. Gupta S, Syrimi Z, Hughes DM, Zhao SS. Comorbidities in psoriatic arthritis: a systematic review and meta-analysis. Rheumatol Int 2021;41:275–84.
5. Zhao SS, Robertson S, Reich T *et al.* Prevalence and impact of comorbidities in axial spondyloarthritis: systematic review and meta-analysis. Rheumatology (Oxford) 2020;59(Suppl 4):iv47–57.
6. Ramiro S, Nikiphorou E, Sepriano A *et al.* ASAS-EULAR recommendations for the management of axial spondyloarthritis: 2022 update. Ann Rheum Dis 2023;82:19–34.
7. Gossec L, Baraliakos X, Kerschbaumer A *et al.* EULAR recommendations for the management of psoriatic arthritis with pharmacological therapies: 2023 update. Ann Rheum Dis 2020; 79:700–12.
8. Ward MM, Deodhar A, Gensler LS *et al.* 2019 update of the American College of Rheumatology/Spondylitis Association of America/Spondyloarthritis Research and Treatment Network recommendations for the treatment of ankylosing spondylitis and nonradiographic axial spondyloarthritis. Arthritis Care Res (Hoboken) 2019;71:1285–99.
9. Singh JA, Guyatt G, Ogdie A *et al.* 2018 American College of Rheumatology/National Psoriasis Foundation guideline for the treatment of psoriatic arthritis. 2019;71:5–32.
10. Coates LC, Corp N, van der Windt DA *et al.* GRAPPA treatment recommendations: 2021 update. J Rheumatol 2022;49:52–4.
11. Sheffield KM, Dreyer NA, Murray JF, Faries DE, Klopchin MN. Replication of randomized clinical trial results using real-world data: paving the way for effectiveness decisions. J Comp Eff Res 2020;9:1043–50.
12. Nordon C, Karcher H, Groenwold RHH *et al.* The "efficacy–effectiveness gap": historical background and current conceptualization. Value Health 2016;19:75–81.
13. Jones GT, Dean LE, Pathan E, Hollick RJ, MacFarlane GJ. Real-world evidence of TNF inhibition in axial spondyloarthritis: can we generalise the results from clinical trials? Ann Rheum Dis 2020;79:914–9.

14. Brahe CH, Ørnbjerg LM, Jacobsson L *et al.* Retention and response rates in 14 261 PsA patients starting TNF inhibitor treatment-results from 12 countries in EuroSpA. Rheumatology (Oxford) 2020;59:1640–50.
15. Michelsen B, Lindström U, Codreanu C *et al.* Drug retention, inactive disease and response rates in 1860 patients with axial spondyloarthritis initiating secukinumab treatment: routine care data from 13 registries in the EuroSpA collaboration. RMD Open 2020;6:1–12.
16. Linde L, Ørnbjerg LM, Rasmussen SH *et al.* Commonalities and differences in set-up and data collection across European spondyloarthritis registries–results from the EuroSpA collaboration. Arthritis Res Ther 2023;25:205.
17. Regierer AC, Weiß A, Baraliakos X *et al.* [RABBIT-SpA: a new disease register for axial spondyloarthritis and psoriatic arthritis]. Z Rheumatol 2020;79:135–42.
18. Önen F, Can G, Çapar S *et al.* A real-life analysis of patients with rheumatologic diseases on biological treatments: data from TURKBIO Registry. Eur J Rheumatol 2022;9:82–7.
19. Harris PA, Taylor R, Minor BL *et al.* The REDCap consortium: Building an international community of software platform partners. J Biomed Inform 2019;95:103208.
20. Harris PA, Taylor R, Thielke R *et al.* Research electronic data capture (REDCap)—a metadata-driven methodology and workflow process for providing translational research informatics support. J Biomed Inform 2009;42:377–81.
21. Hornik K; R Core Team. R FAQ. 2023. https://cran.r-project.org/doc/FAQ/R-FAQ.html (29 January 2024, date last accessed).
22. Radner H, Dixon W, Hyrich K, Askling J. Consistency and utility of data items across European rheumatoid arthritis clinical cohorts and registers. Arthritis Care Res (Hoboken) 2015;67:1219–29.
23. Kearsley-Fleet L, Závada J, Hetland ML *et al.* The EULAR Study Group for Registers and Observational Drug Studies: comparability of the patient case mix in the European biologic disease modifying anti-rheumatic drug registers. Rheumatology (Oxford) 2015;54:1074–9.
24. Curtis JR, Jain A, Askling J *et al.* A comparison of patient characteristics and outcomes in selected European and U.S. rheumatoid arthritis registries. Semin Arthritis Rheum 2010;40:2–14.e1.
25. Carmona L, Gómez-Reino J, González-González R. Spanish registry of adverse events of biological therapies in rheumatic diseases (BIOBADASER): report as of January 14, 2005. Reumatol Clin 2005;1:95–111.
26. Chatzidionysiou K, Hetland ML, Frisell T *et al.* Opportunities and challenges for Real-World studies on chronic inflammatory joint diseases through data enrichment and collaboration between national registers: the Nordic example. RMD Open 2018;4:e000655.
27. Furu K, Wettermark B, Andersen M *et al.* The Nordic countries as a cohort for pharmacoepidemiological research. Basic Clin Pharmacol Toxicol 2010;106:86–94.
28. Laas K, Teär CM, Pehme L *et al.* Reumatoidartriidi patsientide haigestumus tuberkuloosi enne ja pärast bioloogilise ravi kasutusele- võttu Eestis: kahe perioodi võrdlus. Eesti Arst 2019;98:555–60.
29. Rotar Z, Svetina P, Tomsic M, Hočevar A, Prapotnik S. Tuberculosis among patients treated with TNF inhibitors for rheumatoid arthritis, ankylosing spondylitis and psoriatic arthritis in Slovenia: a cohort study. BMJ Open 2020;10:e034356.
30. Dixon WG, Carmona L, Finckh A *et al.* EULAR points to consider when establishing, analysing and reporting safety data of biologics registers in rheumatology. Ann Rheum Dis 2010;69:1596–602.
31. Courvoisier DS, Lauper K, Kedra J *et al.* EULAR points to consider when analysing and reporting comparative effectiveness research using observational data in rheumatology. Ann Rheum Dis 2022;81:780–5.
32. Baillet A, Gossec L, Carmona L *et al.* Points to consider for reporting, screening for and preventing selected comorbidities in chronic inflammatory rheumatic diseases in daily practice: a EULAR initiative. Ann Rheum Dis 2016;75:965–73.
33. Verstappen SMM, Askling J, Berglind N *et al.* Methodological challenges when comparing demographic and clinical characteristics of international observational registries. Arthritis Care Res (Hoboken) 2015;67:1637–45.
34. Lesko CR, Jacobson LP, Althoff KN *et al.* Collaborative, pooled and harmonized study designs for epidemiologic research: challenges and opportunities. Int J Epidemiol 2018;47:654–68.
35. Lindström U, Di Giuseppe D, Delcoigne B *et al.* Effectiveness and treatment retention of TNF inhibitors when used as monotherapy versus comedication with csDMARDs in 15 332 patients with psoriatic arthritis. Data from the EuroSpA collaboration. Ann Rheum Dis 2021;80:1410–8.
36. Ørnbjerg LM, Brahe CH, Askling J *et al.* Treatment response and drug retention rates in 24 195 biologic-naïve patients with axial spondyloarthritis initiating TNFi treatment: routine care data from 12 registries in the EuroSpA collaboration. Ann Rheum Dis 2019;78:1536–44.
37. Aymon R, Mongin D, Bergstra SA *et al.* Evaluation of discontinuation for adverse events of JAK inhibitors and bDMARDs in an international collaboration of rheumatoid arthritis registers (the 'JAK-pot' study). Ann Rheum Dis 2024;83:421–8.
38. Nyberg F, Askling J, Berglind N *et al.* Using epidemiological registry data to provide background rates as context for adverse events in a rheumatoid arthritis drug development program: a coordinated approach. Pharmacoepidemiol Drug Saf 2015;24:1121–32.

Rheumatology Advances in Practice, 2024, 8, 1–11
https://doi.org/10.1093/rap/rkae135
Original Article