

The nature and extent of data items collected across European pregnancy registers - first results of the European Network of Pregnancy Registers in Rheumatology (EuNeP)

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Conclusions
 Although the registers in this collaboration have similar designs, we found considerable differences in data items collected. In particular, the level of details of documented data and the information on disease-specific characteristics varied. Harmonization of data collected in pregnancy registers would facilitate collaborative analysis.

Background & Objectives
 There is a high unmet need of robust data on the outcomes of pregnancies and drug safety in various inflammatory rheumatic diseases (IRD). The aims of the European Network of Pregnancy Registers in Rheumatology (EuNeP, start: 09/2017) are to bring together experts who run pregnancy registers, to define a core data set and to perform concerted data analyses. The objective of this work was to describe data items collected in the registers participating in EuNeP.

Methods
 A comprehensive survey on details of the registers was performed. Information was given on:
 a) structure and design of registers e.g. inclusion criteria and which data items are collected (generally and disease specific), and
 b) status of patient enrolment, demographics and diagnoses.
 Beside structured options, free text answers were possible for all questions. Questionnaires were sent to the principle investigator(s) of the participating studies. Only data items collected during pregnancy are shown.

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Results
 The following registers are involved in the EuNeP collaboration:

- EGR2 (France, started in 2014)
- RePreg (Switzerland, started in 2017)
- REVNATUS (Norway, started in 2006)
- Rhekiss (Germany, started in 2015)

Current numbers of enrolled patients and pregnancies as well as patient age and disease duration are presented in the table.

Distribution of diagnoses in patients enrolled in the registers

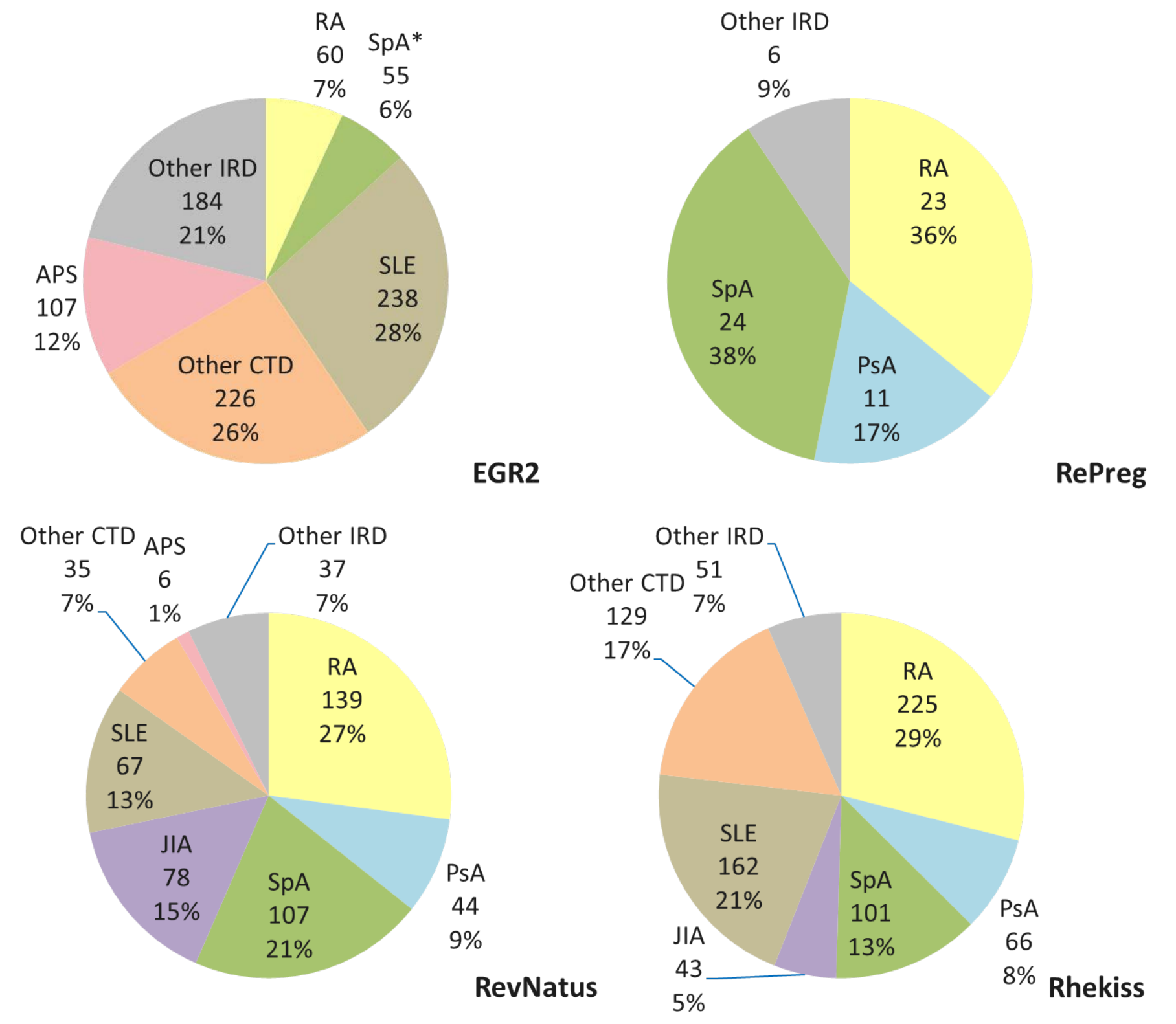


Figure 1: Distribution of diagnoses shown as number of patients and percentage. * PsA patients are included as peripheral SpA. Abbreviations: APS, primary antiphospholipid syndrome; JIA, juvenile idiopathic arthritis; PsA, psoriatic arthritis; RA, rheumatoid arthritis; Other CTD, other connective tissue diseases; SLE, systemic lupus erythematosus; SpA, spondyloarthritis.

Table: Characteristics of registers and patients enrolled.

	EGR2	RePreg	REVNATUS	Rhekiss
No. of participating units	66	16	13	91
No. of patients enrolled	879	64	513*	777
No. of pregnancies	780	32	287	595
No. of pregnancies with outcome	446	6	266	344
Mean (SD) patient age in years	32.1 (4.8)	33.6 (4.0)	30.8 (4.8)	32.4 (4.2)
Mean (SD) disease duration in years	7.3 (6.1)	11.0 (7.4)	6.5 (6.8)	11.2 (81.7)

*Only patients enrolled in the IT-System that started in 2016 are considered.

Data items collected in the registers

All registers collect data prospectively and nationwide. Patients can be included before pregnancy (child wish) or during pregnancy in all registers, and in RePreg also up to week 8 postpartal. Enrolment during pregnancy is possible until gestation week 12 or thereafter in some specific cases (EGR2), week 20 (Rhekiss) or during complete pregnancy (RePreg and REVNATUS). All registers capture data via IT-based systems, REVNATUS documented on paper until 2016. During pregnancy, data is reported once every trimester by physicians and patients.

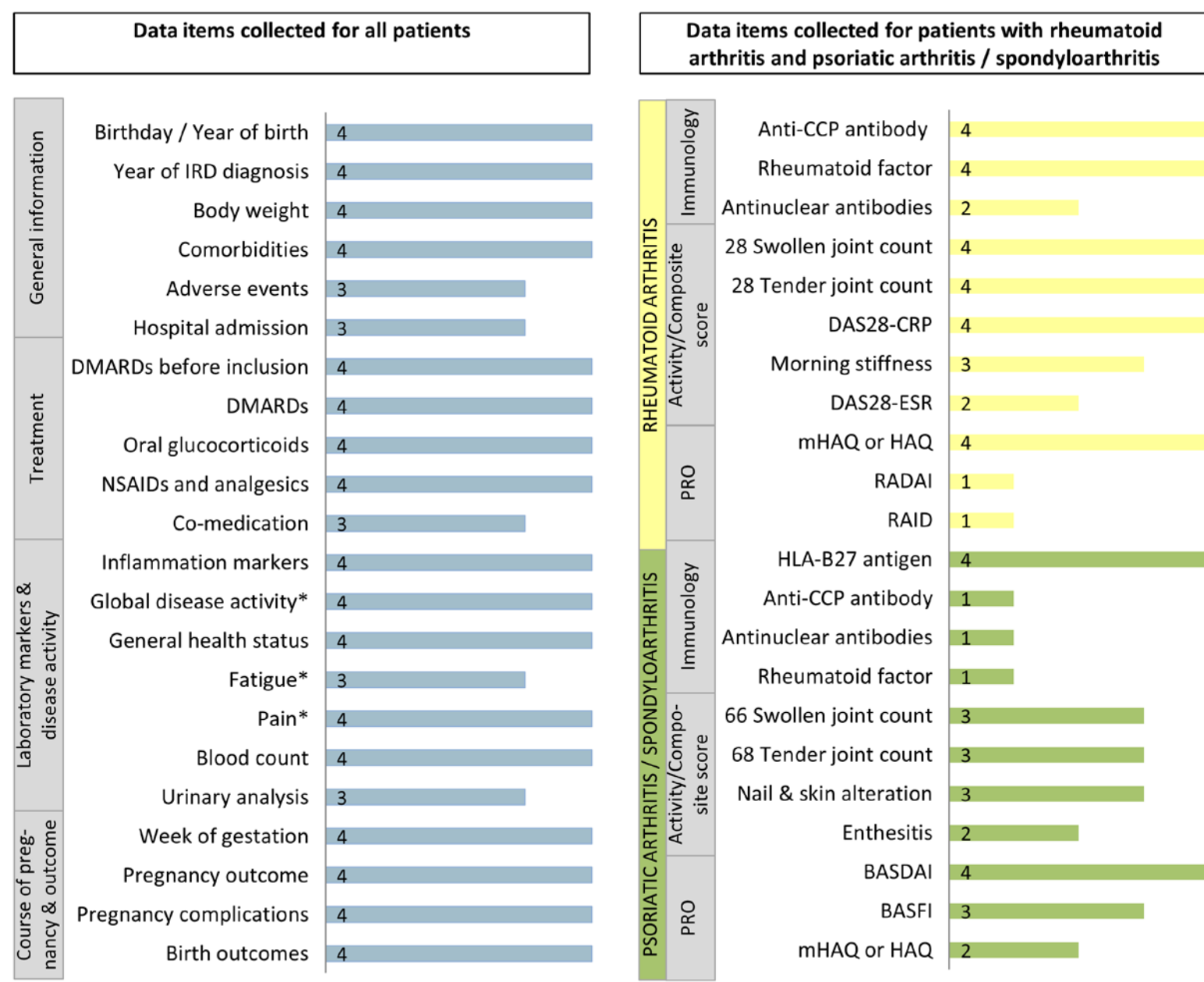


Figure 2: Left side: No. of registers collecting data items for all patients including patient characteristics, disease activity, treatment and pregnancy outcomes. Right side: No. of registers collecting disease specific data for patients with rheumatoid arthritis (yellow), and psoriatic arthritis /spondyloarthritis (green). *Only for selected diseases in one register. Abbreviations: (m)HAQ, (modified) Health Assessment Questionnaire; IRD, Inflammatory Rheumatic Disease; PRO, Patient Reported Outcomes.