

# Defining a standardized core data set for pregnancy registers in rheumatic diseases - an European approach

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### Conclusions

The majority of the invited European experts participated in the first round of the Delphi process. A total of 77 data items reached the consensus-in status, meaning that ≥ 70% of the experts rated the item as critically important to be included in a core data set for pregnancy registers in rheumatology. However, results are only preliminary and final results are expected at the beginning of 2019.

### Background & Objectives

Robust data on the outcomes of pregnancy and influence of drug exposure in various inflammatory rheumatic diseases (IRD) are needed. Joint analyses of data from different sources could overcome the issue of small study sample sizes in single databases. A prerequisite for collaborative analyses would be a common data set, collected from each of the collaborators.

**Objective:** The objective was to develop a core data set for observational research to measure pregnancy course and outcomes of women with underlying IRD.

### Patients & Methods

The European Network of Pregnancy registers in rheumatology (EuNeP) consists of scientists who run pregnancy registers, namely EGR2 (France), RePreg (Switzerland), REVNATUS (Norway) and Rhekiss (Germany). During a face-to-face meeting involving all principal investigators of the mentioned registers, the scope and core areas of the core data set have been developed according to COS-STAD recommendations<sup>1</sup> by consensus. Consensus about the importance of each data item to be included in the final core data set is going to be reached by applying a 2-step Delphi survey. For each item, the importance must be rated on a numeric scale from 1 to 9. According to response rates, items were categorized into consensus-in, consensus-out and equivocal.

<sup>1</sup> Kirkham et al. PLoS medicine. 2017;14(11):e1002447.

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### Results

The initial list of data items within the 3 core areas (Maternal information, Pregnancy, Medication) possibly relevant for pregnancy registers included 143 items and was generated based on (I) data items already collected by registers participating in EuNeP, (II) a systematic literature search and (III) results of a survey amongst 3 patient representatives. Delphi round 1 has already been taken place. Of the invited 71 experts all-over Europe, 63 (89%) completed Delphi round 1. Characteristics are given in figure 1.

Figure 1: Characteristics of the participants of Delphi round 1

COUNTRY OF RESIDENCE			PROFESSION	WORK EXPERIENCE
Germany:	25%	Denmark:	5%	Rheumatologist: 71%
France:	13%	Italy:	5%	General internist: 10%
Norway:	11%	Netherlands:	5%	Other physician: 5%
United Kingdom:	10%	Spain:	5%	Obstetrician: 3%
Hungary:	6%	Czech Republic:	2%	Epidemiologist: 5%
Switzerland:	6%	Turkey:	2%	Midwife: 3%
Austria:	5%	Sweden:	2%	Patient representative: 3%
				GENDER
				Female: 70%
				Male: 30%

In Delphi round 1, 77 data items reached the consensus-in status (≥ 70% of participants rate the item as critical (scores 7-9)), no item reached the consensus-out status (≥ 70% of participants rate the item as not import (scores 1-3)) and 66 items were rated as equivocal (items that are neither in consensus-in nor in consensus-out). All items rated as consensus-in are presented in figure 2. Of note, these results are preliminary. For the final core data set, results of Delphi round 2 and - if necessary - of a further voting will be considered. Delphi round 2 will take place at the end of 2018.

Figure 2: Scope, core areas and answering scores of Delphi round 1 (only data items that reached consensus-in status are presented).

