OPEN ACCESS

EULAR recommendations for a core data set for pregnancy registries in rheumatology

Yvette Meissner ,[1] Rebecca Fischer-Betz,[2] Laura Andreoli ,[3,4] Nathalie Costedoat-Chalumeau ,[5,6] Diederik De Cock,[7] Radboud J E M Dolhain,[8] Frauke Forger,[9] Doreen Goll,[10] Anna Molto ,[11,12] Catherine Nelson-Piercy,[13,14] Rebecca Özdemir,[15] Luigi Raio,[16] Sebastian Cruz Rodríguez-García ,[17] Savino Sciascia ,[18] Marianne Wallenius,[19,20] Astrid Zbinden,[9] Angela Zink,[1] Anja Strangfeld [1]

Handling editor Josef S Smolen

► Additional material is published online only. To view please visit the journal online (http://dx.doi.org/10.1136/annrheumdis-2020-218356).

For numbered affiliations see end of article.

Correspondence to
Ms Yvette Meissner, Epidemiology and Health Care Research, German Rheumatism Research Center Berlin, Berlin, Berlin, Germany; y.meissner@drfz.de

YM and RF-B are joint first authors.

Part of this work was presented at the EULAR Annual Conference 2019 (Meissner et al, Ann Rheum Dis. 2019; 78 (Suppl 2): 246–246).

Received 18 June 2020
Revised 1 September 2020
Accepted 7 September 2020
Published Online First
14 October 2020

To cite: Meissner Y, Fischer-Betz R, Andreoli L, *et al*. *Ann Rheum Dis* 2021;**80**:49–56.

ABSTRACT

Background and objective There is an urgent need for robust data on the trajectories and outcomes of pregnancies in women with inflammatory rheumatic diseases (IRD). In particular when rare outcomes or rare diseases are to be investigated, collaborative approaches are required. However, joint data analyses are often limited by the heterogeneity of the different data sources. To facilitate future research collaboration, a European League Against Rheumatism (EULAR) Task Force defined a core data set with a minimum of items to be collected by pregnancy registries in rheumatology covering the period of pregnancy and the 28-day neonatal phase in women with any underlying IRD.

Methods A stepwise process included a two-round Delphi survey and a face-to-face meeting to achieve consensus about relevant items.

Results A total of 64 multidisciplinary stakeholders from 14 different countries participated in the two rounds of the Delphi process. During the following face-to-face meeting of the EULAR Task Force, consensus was reached on 51 main items covering 'maternal information', 'pregnancy' and 'treatment'. Generic instruments for assessment are recommended for every item. Furthermore, for the five most frequent IRDs rheumatoid arthritis, spondyloarthritis, juvenile idiopathic arthritis, systemic lupus erythematosus and other connective tissue diseases, disease-specific laboratory markers and disease activity measurements are proposed.

Conclusion This is the first consensus-based core data set for prospective pregnancy registries in rheumatology. Its purpose is to stimulate and facilitate multinational collaborations that aim to increase the knowledge about pregnancy course and safety of treatment in women with IRDs during pregnancy.

INTRODUCTION

In recent years, several European pregnancy registries have been established in rheumatology to prospectively collect and analyse data on pregnant women with different inflammatory rheumatic diseases (IRD). However, certain research issues, for example, studying the pregnancy course in rare diseases, require even larger study populations, often exceeding the number of patients available in each registry, making collaborative analyses desirable. The European League Against Rheumatism (EULAR) Task Force on antirheumatic drugs during pregnancy and lactation[1] also highlighted the need for collaboration to collate data on newer medications.

Combined analysis of data from different sources requires a certain degree of homogeneity among the data collected. A recent comprehensive survey of four registries working together in the European Network of Pregnancy Registries in Rheumatology (EuNeP) showed similar study designs in terms of prospective data collection, inclusion of patients with IRD before or during early pregnancy, and reporting of data in each trimester of pregnancy.[2] However, major differences were found in the details of data collection, for example, in the instruments used to measure disease activity. As highlighted by other initiatives in rheumatology, harmonising and standardising items and their measurement across studies is critical to facilitate collaborative research.[3–6]

A EULAR Task Force was therefore convened to define a core data set for registries and observational studies that prospectively collect information about pregnant women with IRD including the neonatal phase (four weeks post partum). The core set was developed to encompass a minimum of standardised items to be collected paving the way for multinational collaborations.

METHODS

An iterative process according to EULAR standardised operating procedures was applied to develop the core set.[7] The Task Force comprised a convenor (AS) and coconvenor (RFB), a methodologist (AZi), a fellow (YM), eight Task Force members (LA, NC-C, RJEMD, FF, AM, CN-P, LR, MW), three EMEUNET members (DDC, SCRG, SS), two patient research partners (DG, RÖ) and one health professional (AZb). The scope and core areas of the core set according to the Core Outcome Set-STAndards for Development recommendations were defined by consensus.[8] A study protocol was developed and circulated among the Task Force. The flow chart gives an overview of all steps taken during the project (figure 1).

Generation of items

Items estimated relevant to be included in the core set were compiled (1) by a systematic literature

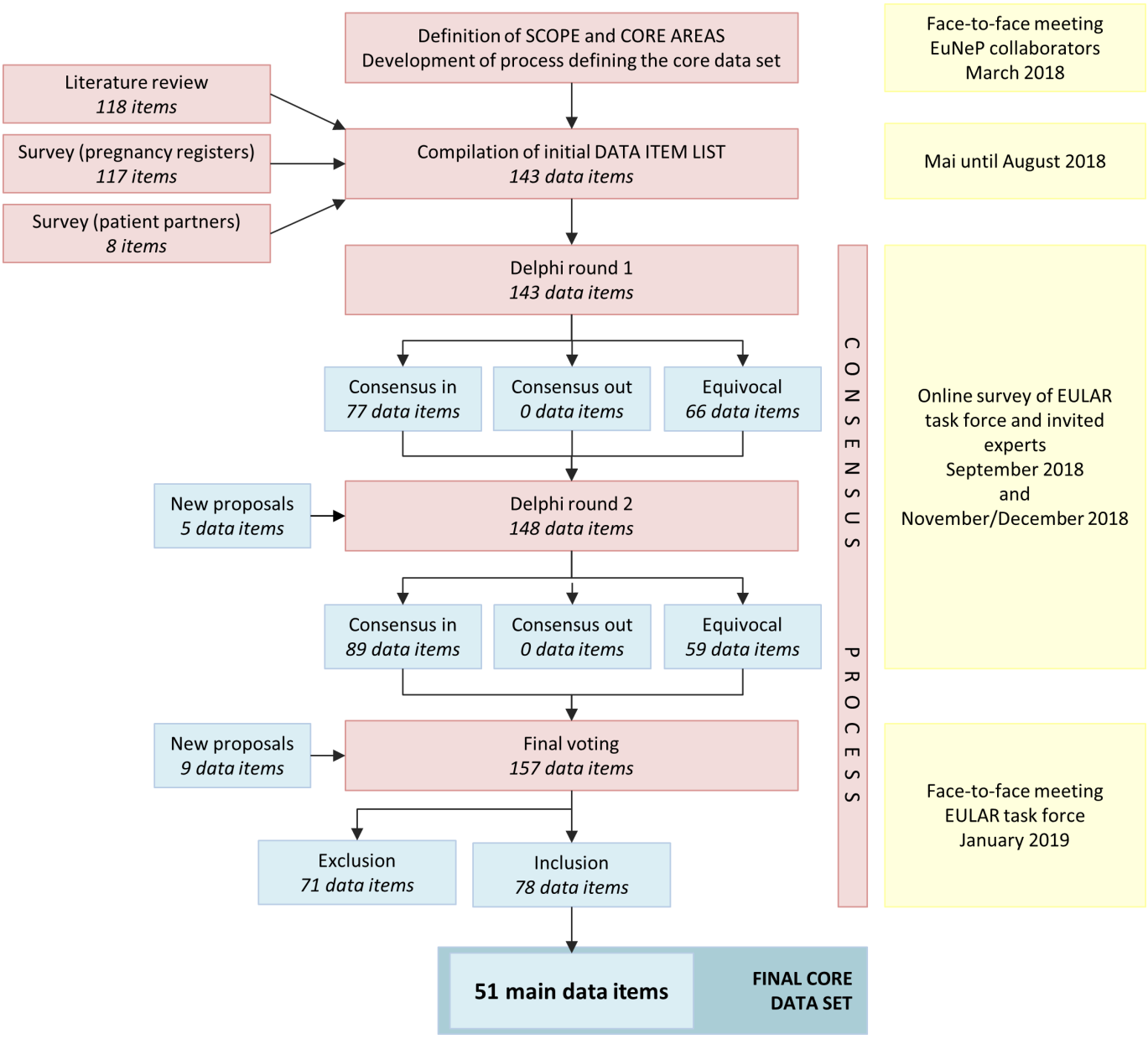

Figure 1 Flow chart of the development and consensus process for the core data set. EULAR, European League Against Rheumatism; EuNeP, European Network of Pregnancy Registries in Rheumatology

search (see online supplemental for details) and underpinned (2) by an inventory of items collected by registries participating in EuNeP[2] and (3) from results of a survey among three EuNeP patient representatives regarding their needs during pregnancy. An initial list of items was created by deleting duplicates, grouping similar items and refinement. Consequently, every item on the list was assigned to its respective core area.

Consensus process, outcome scoring and consensus definition

The importance of each item for the final core set was judged by a stepwise consensus process encompassing a two-round Delphi survey and a final vote. In addition to the members of the EULAR Task Force (except the fellow), additional experts in the field of pregnancy and rheumatology from different European countries were invited to participate during the Delphi votes. In particular, up to five clinicians involved in each of the four registries of the EuNeP collaboration, as well as clinical researchers and experts in the areas of rheumatology, epidemiology, obstetrics, gynaecology, internal medicine as well as other health professionals were directly invited by email. The Delphi process was performed using the online tool 'Delphi Manager' (http://www.comet-initiative.org/delphimanager/). This tool ensures the anonymity of all participants and adherence to the single steps of the Delphi process.

Participants were asked to rate the importance of each item to be included in a core set for pregnancy registries in rheumatology using the Grading of Recommendations, Assessment, Development and Evaluations scale[9] from 1 to 9 (1–3=not important, 4–6=important but not critical, 7–9=critical/very important). The participants had the option to indicate an item as 'unable to score' if necessary and could give comments on each item. Additionally, adding comments at the end of the survey was also possible. The scores of every participant were anonymous throughout the survey. Finally, participants were asked to suggest additional items that were not listed in the initial item list. All suggested, additional items were thoroughly reviewed by nine

Table 1 Consensus definitions

Decision	Definition	Explanation
Delphi round 1/2		
Consensus in	≥70% of the participants rated the item as critically important for the core data set (scores 7–9)	Item will be included into the final core data set
Consensus out	≥70% of the participants rated the item as not important for the core data set (scores 1–3)	Item will be excluded from the final core data set
Equivocal	All items that are neither in the consensus-in nor in the consensus-out group	No consensus was reached for the respective item. Final decision at the consensus meeting
Face-to-face consensus meeting		
Consensus in	Simple majority (>50% of votes)	Item will be included into the final core data set
Consensus out	Simple majority (>50% of votes)	Item will be excluded from the final core data set

members of the Task Force, and eligible items were added in Delphi round 2.

Every participant of Delphi round 1 was invited to rescore the items in round 2 taking total scoring results (given as percentages of all participants scoring 1–9) and their own scores of round 1 into account. Each Delphi round had to be completed within 3 weeks. After completion of both Delphi rounds, scores of round 2 were summarised and assigned to one of the three pre-specified consensus definitions comprising 'consensus in', 'consensus out' and 'equivocal' (table 1) according to OMERACT recommendations.[10]

All items that neither reached 'consensus in' nor 'consensus out' were defined as equivocal and needed a final voting. The final voting took place at a face-to-face consensus meeting of the EULAR Task Force. During this meeting the items were discussed and finally voted on. The voting was conducted via a mobile phone based electronic voting system (www.tedme.com). Items that reached a majority of votes were included into the core set, those with a majority of negative votes were excluded. Furthermore, the Task Force refined the core set and discussed all items with 'consensus-in' status regarding their applicability in a core set and usefulness for research purposes. Of note, the way of assessment of each item and their exact definition was not subject of the Delphi voting.

Since the core set is supposed to cover items important for a variety of IRDs, it was strengthened during the Task Force meeting to also define additional, disease-specific items covering laboratory markers as well as disease activity and damage measurements. All relevant items were summarised by the Task Force and the importance of each item for the respective disease was rated in a written non-anonymous voting. Each Task Force member made her/his decisions according to her/his expertise in the field. Items that reached a majority of positive votes were included in the additional item list. The additional items were defined for the most prevalent IRDs in women of reproductive age: rheumatoid arthritis, spondyloarthritis, juvenile idiopathic arthritis, systemic lupus erythematosus and other connective tissue diseases. Other connective tissue diseases include Sjögren's syndrome, undifferentiated connective tissue disease, scleroderma, myositis and mixed connective tissue diseases.

Data analysis

For both Delphi rounds, mean and SD, median, minimum and maximum as well as the distribution of scores within the three consensus categories were calculated using SAS software V.9.4.

RESULTS

Stakeholders

In total, 73 experts received an email invitation to participate in the Delphi vote, including 17 members of the EULAR Task Force. Of all experts invited, 65 (89%) participated in round 1 and 64 (88%) in round 2. About two-thirds of the experts (69%) participating in both Delphi rounds were women. The majority of participants (81%) had 10 years or more work experience, 14% were working for at least 5 and up to 10 years, and 5% indicated 5 years or less work experience. A total of 84% were rheumatologists, 5% each were obstetricians and epidemiologists, 3% each patients and midwives. Experts from 14 different European countries were represented (online supplemental table 1 shows country distribution).

Definition of core areas

Three core areas were defined as 'maternal information', 'pregnancy' and 'treatment' (figure 2). 'Maternal information' includes the core domains demographics and risk behaviours, disease characteristics of the underlying IRD and prevalent comorbidities. The core area 'pregnancy' encompasses information on obstetrical history, the course, outcomes and delivery of the current pregnancy and outcomes of the neonate. In the core area 'treatment', medical treatment within 12 months prior to conception, the treatment of the IRD during pregnancy and post partum as well as the use of other treatments during pregnancy are subsumed.

Results of the consensus process for non-disease specific items

A total of 143 items were up for voting in Delphi round 1. Of those, 77 items were voted as critically important by at least 70% of the participants. Another 69 new items were suggested to be added to the following Delphi round. All of them were thoroughly reviewed by eight members of the Task Force, and five items were considered as new and relevant for the item list (online supplemental table 2). They encompass gestational age at birth in previous pregnancies, number of previous miscarriages, neonatal infections, the use of non-steroidal anti-inflammatory drugs (NSAIDs) and start and stop dates of NSAID treatment.

With the newly suggested items of round 1, Delphi round 2 included a total of 148 items. Of those, 89 items reached consensus in during the vote, none of the items reached consensus out and 59 items were rated as equivocal and were therefore neither in nor excluded (figure 1, online supplemental table 3).

At a face to face meeting of the Task Force members (n=12), all equivocal items were voted on. Task Force members who were unable to attend the meeting (n=5) received the voting list in advance and their votes were incorporated into the decision process. Additionally, participants of the meeting discussed and evaluated all items of the final core set with respect to the importance of the item for research purposes and redundancy. All decisions are explained in detail in online supplemental table 3. In order to make the extensive list of the resulting 78 included items more comprehensible for the user, the items were consequently defined as either main item (n=51) or operationalizing item (n=27). Items of the final core set are presented in table 2. Furthermore, the way of assessment/operationalisation for each

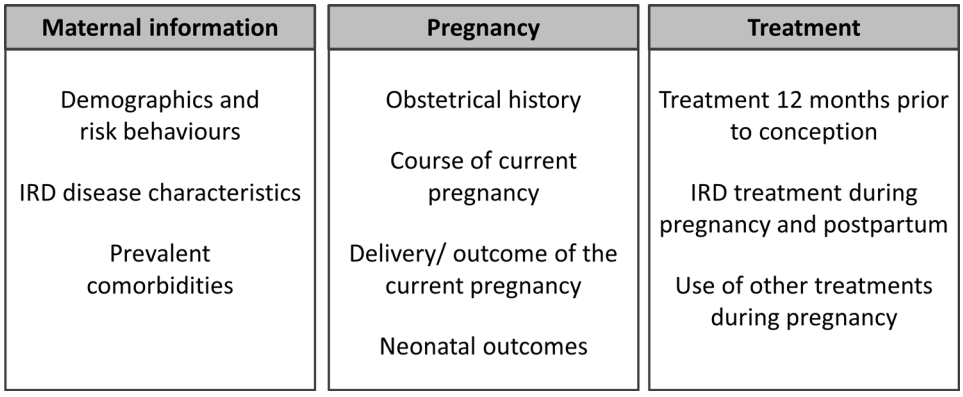

Figure 2 Core areas for the core data set for pregnancy registries in rheumatology. IRD, inflammatory rheumatic disease.

main item including instruments and categories where appropriate was defined and summarised in the online supplemental table 4.

Recommendations for disease-specific items

The recommended laboratory markers and disease activity measurements found to be relevant by the Task Force for the five IRDs rheumatoid arthritis, spondyloarthritis, juvenile idiopathic arthritis, systemic lupus erythematosus and other connective tissue diseases are presented in table 3. It is recommended for registers to collect the single components of a summary score rather than only the score, for example, C reactive protein (CRP), 28 swollen and tender joint count (SJC, TJC) rather than collecting only the disease activity score Disease Activity Score based on 28 tender and swollen joints and C reactive protein.

Methodological considerations

Pregnancy registries are prospective observational cohort studies that collect essential clinical information related to pregnancy in order to improve the safety of mother and child. The items defined with this core set refer to women with IRD and cover the pregnancy and the neonatal phase. The Task Force recommends that patients should be enrolled at the earliest possible point in time during pregnancy. Data should ideally be collected once every trimester and during the neonatal phase (within 28 days after birth). Besides the collection of items and their operationalisation, the visit date of every documented encounter between patient and physician should be reported. In addition, each registry must define, prior to its start, those diagnoses that shall be covered by the study.

DISCUSSION

We present the first consensus-based core data set for pregnancy registries in rheumatology. The comprehensive list of 51 main items should be uniformly collected by all pregnancy registries in rheumatology to ensure homogeneity and comparability of data and to enable joint utilisation of different data sources.

To date, no such recommendations for pregnancy registries in rheumatology are available even though the need has been highlighted previously.[1 11] In the absence of common standards, published pregnancy studies in rheumatology are highly heterogeneous, leading to partly controversial results[12] or non-comparable information.[13] In 2008, Schaefer *et al* summarised the objectives of pregnancy studies based on data of Teratology Information Services (TIS) and explained how they document and evaluate drug effects on pregnancy.[14] Although most of the variables are also essential for pregnancy registries in rheumatology, TIS are not tailored to patients with IRD. Since the chronic disease itself can affect the pregnancy and its outcomes,[15] it is essential to collect specific information on the disease course of IRD by registries and observational cohorts.

Recently, Vinet *et al* compiled basic lists with variables to be collected by rheumatic pregnancy registries focusing on the most important information needed to answer questions about disease activity, medication use and pregnancy outcome.[16] Many variables correspond to the herein proposed core set. However, this core set goes beyond the list of desirable information and makes recommendations on how and in what way the information should be collected in order to harmonise different data sources. In addition, the Task Force has summarised disease-specific parameters that are essential for assessing the course and severity of the IRD. Further differences can be found in methodological aspects. Vinet and colleagues followed an individual approach representing their (North American) views, while the core set is based on a structured consensus process following the methodology for EULAR recommendations. A variety of European experts in the field as well as patient representatives were involved. Registry holders and users were able to incorporate their experience into the different steps of the voting process, and the Task Force has taken the feasibility of implementing the core set in everyday clinical practice in different countries into account. International acceptance therefore can be expected to be high.

This EULAR endorsed core set represents clinically relevant and feasible parameters that are critical for scientific research, especially with a focus on multinational collaborations. The challenge of the stepwise consensus process was to select the most relevant items regarding maternal information and the rheumatic disease as well as pregnancy and neonatal outcomes. This explains the inclusion of 51 items, which is—in comparison to other core sets in rheumatology[3–5] or core sets with relation to maternal and new-born's health[17]—quite an extensive list.

The core set is a compromise between scientific purposes and research interests on the one hand and the feasibility for rheumatologists and other physicians or study nurses that document data from daily care on the other hand. We are for example aware of the importance of recording intrauterine growth restriction (IUGR) to differentiate between infants born small for gestational age (SGA) into those with a steady foetal development in rather lower percentiles of the growth curves versus those foetuses that first develop normally and then experience a sudden growth disturbance. However, we presume that information on IUGR may either be not available for many pregnancies or—since IUGR and SGA are often used interchangeably—their

Table 2 Main items of the final core data set for pregnancy registries in rheumatology and their operationalisation and instruments for assessment

No.	Main items	Operationalisation/instruments for assessment
Maternal information		
Demographics and risk behaviours		
1	Age	Date of birth or month/year of birth
2	Height	cm
3	Weight before (or in early) pregnancy	kg
4	Educational level	Highest educational level according to national standards or/total years of completed education
5	Alcohol consumption during pregnancy	Categorisation: yes/no
6	Smoking during pregnancy	Categorisation: yes/no
IRD disease characteristics		
7	IRD diagnosis	Physician reported clinical diagnosis*
8	Classification criteria	Indication, which criteria are fulfilled
9	Disease duration	Month/year or year of diagnosis
10	Physician reported IRD severity	NRS or VAS
11	Auto-antibodies†	See additional recommendations (table 3)
12	Physician reported flares	Assessment of (1) yes/no; (2) number of flares
13	Physician reported disease activity	NRS or VAS
14	Disease activity by score†	See additional recommendations (table 3)
15	C reactive protein	eg, mg/L
16	Patient reported disease activity	NRS or VAS
17	Patient reported global health	NRS or VAS
Prevalent comorbidities		
18	Selected prevalent comorbidities	Yes/no assessment of: (1) antiphospholipid syndrome, (2) diabetes mellitus, (3) arterial hypertension, (4) renal disease, (5) previous thromboembolic events
Pregnancy		
Obstetrical history		
19	Gravidity	Number
20	Parity	Number
21	Outcome of previous pregnancy(ies)	Categorised into foetal death (including pregnancy loss and stillbirths)/live birth; assessment of (1) number of foetal deaths and live births; (2) gestational age
22	Preterm birth(s)	Number
23	Neonatal death(s)	Number
24	Congenital malformations	Free text
25	Hypertensive pregnancy disorders	Yes/no assessment of: pre-eclampsia, eclampsia, HELLP syndrome
Course of current pregnancy		
26	Planned pregnancy	Yes/No
27	Assisted reproduction	Yes/No
28	Estimated date of conception	Day/Month/Year
29	Singleton/*-/multiple pregnancy	Number of foetuses
30	Adverse events of interest	(1) Yes/no assessment of non-serious and serious events of: (a) gestational hypertension, (b) pre-eclampsia, eclampsia, HELLP syndrome, (c) gestational diabetes, (d) thromboembolic events; (2) date of the beginning of the event; (3) indication if the event has led to hospitalisation or death‡
31	Other serious adverse events	Assessment of (1) the kind of event as free text; (2) date of the beginning of the event; (3) indication if the event has led to hospitalisation or death‡
Delivery/outcome of the current pregnancy		
32	Elective termination	Assessment of (1) yes/no; (2) gestational age; (3) reasons for termination categorised into (a) termination due to malformation, (b) termination due to other reasons
33	Foetal death	Including pregnancy loss and stillbirths; assessment of (1) yes/no; (2) gestational age (weeks) at diagnosis
34	Live birth	Yes/No
35	Gestational age at delivery	In weeks and days
36	Preterm premature rupture of membranes	Yes/No
37	Mode of delivery	(1) Categorised into spontaneous vaginal delivery/operative vaginal delivery/caesarean section (CS)/mode of delivery not specified, and in case of CS (2) reasons categorised into: elective CS/foetal reasons/maternal reasons/ combined foetal and maternal reasons/ unknown reasons
Neonatal outcomes		
38	Birth weight	In kilogram with two decimal digits or gram
39	Gender	Categorisation: female/male/other
40	Breast feeding	Categorisation: yes, for at least 4 weeks after birth/no
41	Congenital heart block	Yes/No
42	Congenital malformations	Free text
43	Neonatal serious adverse events during the first 28 days of live	Assessment of (1) the kind of event as free text; (2) date of the beginning of the event; (3) indication if the event has led to hospitalisation or death‡
Treatment		
Treatment 12 months prior to conception		
44	DMARD use	Assessment of (I) yes/no; (2) name§; (3) start/stop dates
45	Oral glucocorticoid use	Yes/No
46	Use of potentially teratogenic medication	Free text
IRD treatment during pregnancy and post partum		
47	DMARD use	Assessment of (1) yes/no; (2) name§; (3) dose; (4) application intervals; (5) start/stop dates; (6) reasons for discontinuation

Table 2 Continued

No.	Main items	Operationalisation/instruments for assessment
48	Oral glucocorticoid use	Assessment of (1) yes/no; (2) dose; (3) application intervals; (4) start/stop dates
49	Intraarticular glucocorticoid use	Assessment of (1) yes/no; (2) date of application
50	NSAID use	Assessment of (1) yes/no; (2) name; (3) start/stop dates
Use of other treatments during pregnancy		
51	Use of selected treatments	Yes/no assessment of use of (1) antihypertensive drugs, (2) aspirin, (3) folic acid and (4) heparin/other anticoagulants

Explanations of the main items are given in online supplemental table 4.
*Which diagnoses are covered by the registry, must defined in advance by every registry.
†Variables differ according to IRD diagnosis and are further defined in table 3.
‡This recommendation is based on the ICH E2A guideline.[25]
§For biological or targeted synthetic disease modifying antirheumatic drugs it is recommended to record the trade name.
DMARD, disease modifying anti-rheumatic drug; HELLP, complication of pregnancy characterised by haemolysis, elevated liver enzymes and a low platelet count; IRD, inflammatory rheumatic disease; NRS, Numeric Rating Scale; NSAID, non-steroidal anti-inflammatory drug; VAS, Visual Analogue Scale.

different meaning may not always be clear. We therefore decided to exclude IUGR from the core set.

The supplemental material contains descriptions and definitions for all main items as far as this is possible. Even though it would be desirable to have uniform definitions for all items, this is not feasible for various reasons. Registries can only collect data within the framework of the health system and regulatory requirements of their country of origin and therefore, country-specific differences cannot be avoided.[18 19] For a number of items, the reporting health professional has to rely on information that is provided by obstetricians, for example, the event of pre-eclampsia. Definition and classification systems however vary and can result in discrepancies of incidence rates.[20 21]

The period we were focused on for these recommendations was the time of pregnancy and the 28-day postpartum period (neonatal phase). The targeted patient population are patients with IRD. Since these recommendations shall be applicable to all IRDs, the final core set encompasses non-disease specific, generic items. Furthermore, for the five most prevalent IRDs, important laboratory markers and instruments to measure disease activity and damage have been defined. Of note, the core data set encompasses only the minimum items that have been classified as essential by experts in the field. It is up to each individual registry to add further items, to ask more details for an item and/or to use additional instruments or categories beyond those that are proposed within this core set.

Our proposed core set is on one side intended to serve as a basis for evolving registries to prioritise and facilitate data collection. On the other side, the core set can be used by existing observational studies and registries to focus their data quality management on those outcomes that were found to be of high importance to facilitate collaborative analyses with other registries. This will enable the growing number of (pregnancy) registries in Europe to perform joint analyses, allowing to explore relevant aspects in more detail and with robust data.

Collecting data in different countries by applying an internationally standardised protocol offers the chance to create the world's largest source of information of pregnancies in women with IRD including drug safety. Encouraging and recruiting pregnant patients and collecting reliable data is the basis to fill current knowledge gaps and to guide IRD patients with the wish to have children in the future. Such a database can also serve as an information source for regulatory authorities and can help

Table 3 Additional items for selected diseases

Disease	Autoantibodies/laboratory markers	Disease activity/ damage scores
Rheumatoid arthritis	► Anti-citrullinated protein antibody (ACPA) ► Rheumatoid factor (RF)	► 28 SJC ► 28 TJC ► DAS28-CRP3
Spondyloarthritis	► HLA-B27	► ASDAS ► BASDAI
Juvenile idiopathic arthritis	► Anti-citrullinated protein antibody (ACPA) ► Rheumatoid factor (RF) ► Antinuclear antibodies (ANA)	► 28 SJC ► 28 TJC ► DAS28-CRP3
Systemic lupus erythematosus	► Antiphospholipid antibodies (aPL), in particular: anti-cardiolipin (aCL) antibodies, anti-beta-2-glycoprotein-I-antibodies, lupus anticoagulant (LA) ► Antinuclear antibodies (ANA) ► Anti-double-stranded DNA antibodies ► Extractable nuclear antigen (ENA) antibodies, in particular: anti-La/SSB antibodies, anti-Ro/SSA antibodies, anti-Sm antibodies, anti-U1-ribonucleoprotein (RNP) antibodies ► Serum C3/C4	► SLEPDAI (SLEDAI*) ► SLICC/ACR damage index
Other connective tissue diseases	► Antiphospholipid antibodies (aPL), in particular: anti-cardiolipin (aCL) antibodies, anti-beta-2-glycoprotein-I-antibodies, lupus anticoagulant (LA) ► Extractable nuclear antigen (ENA) antibodies, in particular: anti-La/SSB antibodies, anti-Ro/SSA antibodies, anti-U1-ribonucleoprotein (RNP) antibodies ► Antinuclear antibodies (ANA) ► Serum C3/C4	

*SLEDAI instead of SLEPDAI for postpartum disease activity.
ASDAS, Ankylosing Spondylitis Disease Activity Score; BASDAI, Bath Ankylosing Spondylitis Disease Activity Index; DAS28-CRP3, Disease Activity Score based on 28 tender and swollen joints and C reactive protein; SLICC/ACR Damage Index, Systemic Lupus International Collaborating Clinics/American College of Rheumatology Damage Index; SJC, swollen joint count; SLEDAI, Systemic Lupus Erythematosus Disease Activity Index; SLEPDAI, Systemic Lupus Erythematosus in Pregnancy Disease Activity Index; TJC, tender joint count.

to establish research guidelines. With this core set, we hope to encourage other scientist to set up pregnancy registries and to collaborate in joint projects.

Strengths and limitations

The methodological strength of developing this core set is the application of robust methods with a stepwise consensus-based process[7 8 22 23] involving multi-stakeholder groups, for example, experienced rheumatologists, epidemiologists, obstetricians, healthcare professionals and patients. The Delphi process is an established method for achieving consensus[24] and has the advantage of maintaining the anonymity of participants. We had a low attrition rate with only one participant who did not complete both rounds. In all consensus steps, the participants were reminded that only those items that are both essentially important for joint research and feasible in daily clinical care, should be selected.

This core data set focuses on data collection during pregnancy including the outcome of pregnancy. This decision was made in order to achieve a minimal data set for the most important time period. However, information about the time before pregnancy and further observation of women and children after delivery is highly desirable in order to answer research questions like, for example, the time to pregnancy, early abortion/miscarriage rates or the development of the child beyond 4 weeks of age. We therefore recommend to extend the observation of the child beyond the time frame addressed here in order to assess long-term outcomes concerning child development. This is a gap in the current literature and should be the focus of future collaborative studies with paediatricians.

CONCLUSION

This EULAR Task Force proposes a core data set with a minimum of items to be collected by pregnancy registries in rheumatology. Our aim was to facilitate collaborative research and joint data analyses. As the design of registries may vary considerably between countries and will be influenced by the different healthcare systems, this common data set was deliberately kept short and simple, concentrating on the most important information that is needed for meaningful joint analyses. We hope that this proposal will be useful when establishing new registries and also increase the willingness of rheumatologists, other healthcare professionals and patients to contribute to the registries and provide the necessary data.

Author affiliations
[1]Epidemiology and Health Care Research, German Rheumatism Research Center Berlin, Berlin, Germany
[2]Department for Rheumatology and Hiller Research Institute, Heinrich Heine University Düsseldorf, Dusseldorf, Germany
[3]Department of Clinical and Experimental Sciences, University of Brescia, Brescia, Italy
[4]Unit of Rheumatology and Clinical Immunology, ASST Spedali Civili di Brescia, Brescia, Italy
[5]Internal Medicine Department, Referral Center for Rare Autoimmune and Systemic Diseases, Hospital Cochin, Paris, France
[6]CRESS, INSERM, INRA, Université de Paris, Paris, France
[7]Department of Development and Regeneration KU, KU Leuven, Leuven, Belgium
[8]Medical Centre, Department of Rheumatology, Erasmus University Rotterdam, Rotterdam, Netherlands
[9]Department of Rheumatology, Immunology and Allergology, Inselspital University Hospital Bern, Bern, Switzerland
[10]Patient research partner, Berlin, Germany
[11]Rheumatology Department, Hospital Cochin, Paris, France
[12]U-1153, INSERM, University of Paris, Paris, France
[13]Obstetric Medicine Service, Queen Charlotte's and Chelsea Hospital, London, UK
[14]Department of Women and Children's Health, Guy's and St Thomas' NHS Foundation Trust, London, UK
[15]Patient research partner, Duisburg, Germany
[16]Department of Obstetrics and Gynaecology, Inselspital University Hospital Bern, Bern, Switzerland
[17]Rheumatology Department, Hospital Universitario de la Princesa, Madrid, Spain
[18]Dipartimento di Malattie Rare, Immunologiche, Ematologiche ed Immunoematologiche. Centro di Ricerche di Immunopatologia e Documentazione su Malattie Rare (CMID). Struttura Complessa a Direzione Universitaria di Immunologia Clinica, Ospedale Torino Nord Emergenza San G. Bosco ed Università di Torino, Torino, Italy
[19]Institute of Neuromedicine and Movement Science, Faculty of Medicine and Health Sciences, NTNU, Norwegian University of Science and Technology, Trondheim, Norway
[20]Norwegian National Advisory Unit on Pregnancy and Rheumatic Diseases, Dept of Rheumatology, St Olavs Hospital University Hospital in Trondheim, Trondheim, Norway

Correction notice This article has been corrected since it published Online First. The first author statement has been added.

Twitter Laura Andreoli @lauraandreoli80, Diederik De Cock @DiederikDeCock, Anna Molto @annamolto, Catherine Nelson-Piercy @nelson_piercy and Sebastian Cruz Rodríguez-García @sdlcrodriguez

Acknowledgements The authors would like to thank all contributing experts who participated in the Delphi online survey: Peer Aries; Sebnem Ataman; Irene Bultink; Marion Couderc; Diana Dan; David d'Cruz; Jip de Vries; Thomas Dörner; Lene Dreyer; Aline Frazier; Ruth Fritsch-Stork; James Galloway; Ian Giles; Cornelia Glaser; Gaelle Guettrot-Imbert; Isabell Haase; Karin Hellgren; Jörg Henes; Merete Hetland; Kimme Hyrich; Synøve Kalstad; Emese Kiss; Estibaliz Lazaro; Véronique le Guern; Hanns-Martin Lorenz; Juan Antonio Martínez López; Monika Oestensen; Øyvind Palm; Jose Maria Pego-Reigosa; Antonia Puchner; Klara Rosta; Guillermo Ruiz-Irastorza; Christof Schaefer; Matthias Schneider; Carina Skorpen; Susanna Späthling-Mestekemper; Christof Specker; Tone Størseth Moksnes; Bjørg Tilde Svanes Fevang; Antonio Szanto; Gabriella Szucs; Tunde Tarr; Angela Tincani; Ines von Mühlenen; Anne Voss; Corinna Weber-Schoendorfer; Jakub Zavada.

Collaborators Peer Aries; Sebnem Ataman; Irene Bultink; Marion Couderc; Diana Dan; David d'Cruz; Jip de Vries; Thomas Dörner; Lene Dreyer;Aline Frazier; Ruth Fritsch-Stork; James Galloway; Ian Giles; Cornelia Glaser; Gaelle Guettrot-Imbert; Isabell Haase; Karin Hellgren; Jörg Henes; Merete Hetland; Kimme Hyrich; Synøve Kalstad; Emese Kiss; Estibaliz Lazaro; Véronique le Guern; Hanns-Martin Lorenz; Juan Antonio Martínez López; Monika Oestensen; Øyvind Palm; Jose Maria Pego-Reigosa; Antonia Puchner; Klara Rosta; Guillermo Ruiz-Irastorza; Christof Schaefer; Matthias Schneider; Carina Skorpen; Susanna Späthling -Mestekemper; Christof Specker; Tone Størseth Moksnes; Bjørg Tilde Svanes Fevang; Antonio Szanto; Gabriella Szucs; Tunde Tarr; Angela Tincani; Ines von Mühlenen; Anne Voss; Corinna Weber-Schoendorfer; Jakub Zavada.

Contributors All authors listed fulfil authorship criteria. They have contributed to the task force and have been engaged in the design of the work, attended meetings, were involved in drafting the manuscript and approved the final version.

Funding This work was supported by EULAR and received a research grant from FOREUM Foundation in Rheumatology.

Competing interests AM: speaker/consultant fees: Abbvie, BMS, MSD, Novartis, Pfizer, UCB; unrestricted grants: Pfizer and UCBAS: speaker fees: AbbVie, BMS, MSD, Novartis, Pfizer, Roche, Sanofi Aventis, UCBA Zbinden: none. AZink: speaker fees from AbbVie, Janssen, Pfizer, Roche and Sanofi-Aventis. CN-P: consultancy fees from UCB and Alliance Pharma. Speaker fees from UCB, Alliance Pharma, Alexion, Sanofi, Falk, Janssen. DDC: none. DG: none. FF: consultant for UCB, GSK, Roche. Speakers bureau: UCB, GSK. Research grants from UCBLA: speaker/consultant fees: GSK, Novartis, UCB, Eli Lilly, INOVA Diagnostics/Werfen Group. LR: none. MW: none. NC-C: no personal fees. Research grants from UCBRD: received an unrestricted research grant form UCB Pharma BV and from the Dutch Arthritis Association a non-commercial fund raising organisation. RFB: speaker/consultant fees: Abbvie, Biogen, BMS, Celgene, Chugai, GSK, Janssen, Lilly, Medac, MSD, Novartis, Roche, UCBRÖ: None. SCR-G: speaker fees from Sanofi, MSD, UCB, Novartis and Janssen. SS: none. YM: lecture honoraria from Pfizer.

Patient and public involvement Patients and/or the public were involved in the design, or conduct, or reporting, or dissemination plans of this research. Refer to the Methods section for further details.

Patient consent for publication Not required.

Ethics approval Full information about the study was given when inviting potential participants via email as well as on the website of the Delphi survey. Prerequisite for participation in the survey was a registration in the Delphi Manager system, which was considered to imply consent.

Provenance and peer review Not commissioned; externally peer reviewed.

ORCID iDs
Yvette Meissner http://orcid.org/0000-0003-0147-4112
Laura Andreoli http://orcid.org/0000-0002-9107-3218
Nathalie Costedoat-Chalumeau http://orcid.org/0000-0002-1555-9021
Anna Molto http://orcid.org/0000-0003-2246-1986
Sebastian Cruz Rodríguez-García http://orcid.org/0000-0002-7773-151X
Savino Sciascia http://orcid.org/0000-0003-1266-9441
Anja Strangfeld http://orcid.org/0000-0002-6233-022X

REFERENCES

1 Götestam Skorpen C, Hoeltzenbein M, Tincani A, *et al*. The EULAR points to consider for use of antirheumatic drugs before pregnancy, and during pregnancy and lactation. *Ann Rheum Dis* 2016;75:795–810.
2 Meissner Y, Strangfeld A, Costedoat-Chalumeau N, *et al*. European Network of Pregnancy Registers in Rheumatology (EuNeP)—an overview of procedures and data collection. *Arthritis Res Ther* 2019;21:241.
3 Radner H, Chatzidionysiou K, Nikiphorou E, *et al*. 2017 EULAR recommendations for a core data set to support observational research and clinical care in rheumatoid arthritis. *Ann Rheum Dis* 2018;77:476–9.
4 McCann LJ, Pilkington CA, Huber AM, *et al*. Development of a consensus core dataset in juvenile dermatomyositis for clinical use to inform research. *Ann Rheum Dis* 2018;77:241–50.
5 Ehlers L, Askling J, Bijlsma HW, *et al*. 2018 EULAR recommendations for a core data set to support observational research and clinical care in giant cell arteritis. *Ann Rheum Dis* 2019;78:1160–6.
6 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.
7 van der Heijde D, Aletaha D, Carmona L, *et al*. 2014 update of the EULAR standardised operating procedures for EULAR-endorsed recommendations. *Ann Rheum Dis* 2015;74:8–13.
8 Kirkham JJ, Davis K, Altman DG, *et al*. Core outcome Set-STAndards for development: the COS-STAD recommendations. *PLoS Med* 2017;14:e1002447.
9 Guyatt GH, Oxman AD, Vist GE, *et al*. Grade: an emerging consensus on rating quality of evidence and strength of recommendations. *BMJ* 2008;336:924–6.
10 Boers M, Kirwan JR, Tugwell P, *et al*. *The OMERACT Handbook*, 2018.
11 Task Force on Research Specific to Pregnant Women and Lactating Women (PRGLAC). Report to Secretary, health and human services Congress, 2018. Available: https://www.nichd.nih.gov/sites/default/files/2018-09/PRGLAC_Report.pdf [Accessed 16/11/18].
12 Giovannopoulou E, Gkasdaris G, Kapetanakis S, *et al*. And pregnancy: a literature review. *Curr Rheumatol Rev* 2017;13:162–9.
13 Andreoli L, Gerardi MC, Fernandes M, *et al*. Disease activity assessment of rheumatic diseases during pregnancy: a comprehensive review of indices used in clinical studies. *Autoimmun Rev* 2019;18:164–76.
14 Schaefer C, Ornoy A, Clementi M, *et al*. Using observational cohort data for studying drug effects on pregnancy outcome--methodological considerations. *Reprod Toxicol* 2008;26:36–41.
15 Østensen M, Andreoli L, Brucato A, *et al*. State of the art: reproduction and pregnancy in rheumatic diseases. *Autoimmun Rev* 2015;14:376–86.
16 Vinet E, Chakravarty EF, Clowse MEB. Power in numbers. *Rheumatology* 2018;57:v40–7.
17 Duffy J, Rolph R, Gale C, *et al*. Core outcome sets in women's and newborn health: a systematic review. *BJOG* 2017;124:1481–9.
18 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.
19 Putrik P, Ramiro S, Kvien TK, *et al*. Inequities in access to biologic and synthetic DMARDs across 46 European countries. *Ann Rheum Dis* 2014;73:198–206.
20 Phipps E, Prasanna D, Brima W, *et al*. Preeclampsia: updates in pathogenesis, definitions, and guidelines. *Clin J Am Soc Nephrol* 2016;11:1102–13.
21 Abalos E, Cuesta C, Grosso AL, *et al*. Global and regional estimates of preeclampsia and eclampsia: a systematic review. *Eur J Obstet Gynecol Reprod Biol* 2013;170:1–7.
22 Chiarotto A, Ostelo RW, Turk DC, *et al*. Core outcome sets for research and clinical practice. *Braz J Phys Ther* 2017;21:77–84.
23 Williamson PR, Altman DG, Blazeby JM, *et al*. Developing core outcome sets for clinical trials: issues to consider. *Trials* 2012;13:132.
24 Sinha IP, Smyth RL, Williamson PR. Using the Delphi technique to determine which outcomes to measure in clinical trials: recommendations for the future based on a systematic review of existing studies. *PLoS Med* 2011;8:e1000393.
25 ICH Guideline. Clinical safety data management: definitions and standards for expedited reporting E2A, 2020. Available: https://database.ich.org/sites/default/files/E2A_Guideline.pdf [Accessed 11/08/2020].

Supplement

Systematic literature review

The literature review in Pubmed focused on

(I) published literature on pregnancy and rheumatic diseases and

(II) on already published core data sets focussing on pregnancy and related issues.

Search terms for literature review (I):

#8,"Search ((((((((((((pregnan[Title]) OR birth[Title]) OR preterm[Title]) OR premature[Title]) OR foetal[Title]) OR matern*[Title]) OR labour[Title]) OR partum*[Title]) OR natal*[Title]) OR prepregnan*[Title])))) AND ((((((((((((((((((rheumatism[Title]) OR rheumatoid[Title]) OR rheumatic[Title]) OR arthritis[Title]) OR ankylosing[Title]) OR spondyloarthritis[Title]) OR lupus[Title]) OR sle[Title]) OR connective tissue[Title]) OR antiphospholipid[Title]) OR sjogren[Title]) OR myositis[Title]) OR scleroderma[Title]) OR vasculitis[Title]) OR behcet[Title]) OR polymyositis[Title]) OR dermatomyositis[Title])))) AND (((((((((observational[Title/Abstract]) OR prospective[Title/Abstract])))) AND cohort[Title/Abstract])) OR (((register[Title/Abstract]) OR registry[Title/Abstract])))",82,08:27:47*

#7,"Search (((((((observational[Title/Abstract]) OR prospective[Title/Abstract])))) AND cohort[Title/Abstract])) OR (((register[Title/Abstract]) OR registry[Title/Abstract]))",236495,08:27:34

#6,"Search (((((observational[Title/Abstract]) OR prospective[Title/Abstract])))) AND cohort[Title/Abstract]",104397,08:27:24

#5,"Search cohort[Title/Abstract]",424366,08:27:12

#4,"Search (((observational[Title/Abstract]) OR prospective[Title/Abstract])",589828,08:27:00

#3,"Search ((register[Title/Abstract]) OR registry[Title/Abstract])",137346,08:26:31

#2,"Search ((((((((((((((((((rheumatism[Title]) OR rheumatoid[Title]) OR rheumatic[Title]) OR arthritis[Title]) OR ankylosing[Title]) OR spondyloarthritis[Title]) OR lupus[Title]) OR sle[Title]) OR connective tissue[Title]) OR antiphospholipid[Title]) OR sjogren[Title]) OR myositis[Title]) OR scleroderma[Title]) OR vasculitis[Title]) OR behcet[Title]) OR polymyositis[Title]) OR dermatomyositis[Title])",232042,08:26:09

#1,"Search ((((((((((pregnan[Title]) OR birth[Title]) OR preterm[Title]) OR premature[Title]) OR foetal[Title]) OR matern*[Title]) OR labour[Title]) OR partum*[Title]) OR natal*[Title]) OR prepregnan*[Title])",455429,08:20:50*

We considered multicentric observational cohort or register studies reporting on pregnancy outcomes in women with inflammatory rheumatic diseases. Out of the 82 search results, data from 21 publications have been extracted.

Search terms for literature review (II):

#3,"Search (((((((((core data[Title]) OR core set[Title]) OR core outcome[Title]) OR core domain[Title]) OR minimal data[Title]) OR minimum data[Title]) OR template[Title])))) AND ((((((((((pregnan[Title]) OR birth[Title]) OR preterm[Title]) OR premature[Title]) OR foetal[Title]) OR matern*[Title]) OR labour[Title]) OR partum*[Title]) OR natal*[Title]) OR prepregnan*[Title]))",32,07:59:27*

#2,"Search ((((((((((pregnan[Title]) OR birth[Title]) OR preterm[Title]) OR premature[Title]) OR foetal[Title]) OR matern*[Title]) OR labour[Title]) OR partum*[Title]) OR natal*[Title]) OR prepregnan*[Title])",455429,07:59:18*

#1,"Search (((((((core data[Title]) OR core set[Title]) OR core outcome[Title]) OR core domain[Title]) OR minimal data[Title]) OR minimum data[Title]) OR template[Title])",9058,07:59:04

Recommended data items of 8 published core data sets (out of 32 search results) have been extracted.

Table 1: Countries of residence for participants completing round 1 and 2 of the Delphi survey.

Country of residence	Number of participants	Proportion
Germany	16	25%
France	7	11%
Norway	7	11%
UK	6	9%
Switzerland	5	8%
Hungary	4	6%
Spain	4	6%
Austria	3	5%
Denmark	3	5%
Italy	3	5%
The Netherlands	3	5%
Czech Republic	1	2%
Sweden	1	2%
Turkey	1	2%

Meissner Y, *et al. Ann Rheum Dis* 2020;0:1–8. doi: 10.1136/annrheumdis-2020-218356

Table 2: Suggestions of new data items by participants of Delphi round 1 sorted by core area.

No.	Suggested additional items by Delphi participants (Number of data item suggestion is given in bracket; (F)=item was suggested in a comment/as feedback)	Results of the discussion with selected task force members	Inclusion in Delphi round 2	Name of added item
	MATERNAL INFORMATION: Demographics			
1	Advice country instead of county and postcode (refers to data item 2, Area of maternal residence) (F)	This suggestion focuses on how to collect a data item, which is not the purpose of this Delphi round.	No	
2	Drug use by patient (F)	The recording of drug use by patients might be too unreliable.	No	
3	For mixed ethnicities need to homogenize the definitions (refers to data item 3, Maternal race) (F)	This suggestion focuses on how to collect a data item, which is not the purpose of this Delphi round.	No	
4	Work before; during and after pregnancy should be scored very precisely with start and stop and changes in work (39)	This is beyond the purpose of this core data set. Core data set focuses on data collection during pregnancy, not before or thereafter.	No	
	MATERNAL INFORMATION: Disease characteristics of the inflammatory rheumatic disease (IRD)			
5	Date of symptom onset (F)	Date of diagnosis (item 16) was thought to be sufficient	No	
6	Duration of flares during the first year postpartum and change of medication are of interest for future counselling (41)	The core data set focuses on data collection during pregnancy including the outcome of pregnancy, not before or postpartum.	No	
7	Flares in the year before the pregnancy; during and after pregnancy during the first 3 months; 3-6 months; 6-12 months (40)	The core data set focuses on data collection during pregnancy including the outcome of pregnancy, not before or postpartum.	No	
	MATERNAL INFORMATION: Patient reported outcomes			
8	Impact of IRD on working life (F)	This is beyond the purpose of this core data set.	No	
9	Use a more concrete definition of particular aspects of mental health that can be assessed with specific instruments. / what time point? at conception/during pregnancy? / please explore more easy reproducable question e.g depression scale 0-10; anxiety for RA and pregnancy score 0-10 etc (F)	This is beyond the purpose of this core data set.	No	
	MATERNAL INFORMATION: Serologic profile			

10	Positivity for ENA profile (7), Anti-Ro/SS-A (14), anti-SSA/SSB (F)	See item 31, going into detail is difficult as this is supposed to be a core data set for several IRDs	No	
11	SS-A or SS-B antibodies (30)	See item 31, going into detail is difficult as this is supposed to be a core data set for several IRDs	No	
12	Thrombophilia other than aPL antibodies (17)	See item 31, going into detail is difficult as this is supposed to be a core data set for several IRDs	No	
13	Use of pregnancy specific disease activity score where available (23)	This suggestion focuses on how to collect a data item, which is not the purpose of this Delphi round.	No	
	MATERNAL INFORMATION: Comorbidities, adverse events and death			
14	Comorbidity: Coeliac disease (F)	This is beyond the purpose of this core data set.	No	
15	Comorbidity: Secondary Sjogren's syndrome (F)	This is beyond the purpose of this core data set.	No	
16	Data item 58 / Comorbidity: Thrombosis - Add: during oral anticontraceptives (yes/no), after trauma etc. (F)	This is beyond the purpose of this core data set.	No	
17	Data item 59 / Comorbidity: Documentation of any other comorbidity - Add: gynecologic comorbidities (e.g. myoma; cervical insufficiency) / history of cancer; cardiovascular disease (MI; pulmonary arterial hypertension); lung disease (fibrosis). (F)	This is beyond the purpose of this core data set.	No	
18	Maternal inherited disorder (15)	This is beyond the purpose of this core data set.	No	
19	Results of renal biopsy (44)	This is beyond the purpose of this core data set.	No	
	PREGNANCY: Information about previous pregnancies			
20	Cause of previous neonatal death(s) (F)	This is beyond the purpose of this core data set.	No	
21	Gestational age at birth (F)	Item will be added to Delphi round 2	Yes	Gestational age birth(s)
22	Reasons for induced abortion(s) (F)	This is beyond the purpose of this core data set.	No	
23	Number of spontaneous abortions (F)	Item will be added to Delphi round 2	Yes	Number of spontaneous abortions

	PREGNANCY: Information about the current pregnancy			
24	A question about the year of counselling; what the general conclusion was of the counselling; change in medication needed?; information of influence of RA on pregnancy complications and pregnancy on RA during and after pregnancy understood; low threshold to inform complications of RA and pregnancy during this period and no waiting until next appointment; breastfeeding in combination with the prescribed medication; summarizing can we describe what items we discuss during prepregnancy counselling;(38)	Information about dates (e.g. year) should generally be available and included when collecting data prospectively. Consequences of the counselling were thought not to be important for this common core data set.	No	
25	Discussion of breastfeeding in pregnancy (25)	There will be differences in countries and cultures, and results would not be reliable.	No	
26	Fetal ultrasound with Doppler velocimetry of uterine arteries and umbilical arteries (normal vs abnormal) (20)	This is too complicated for a common core data set.	No	
27	History of vaccination during pregnancy (2)	This is beyond the purpose of this core data set.	No	
28	Method of assisted reproduction (F)		No	
29	Mother preeclampsia; Eclampsia; HELLP syndrome (34)	This is beyond the purpose of this core data set.	No	
30	Pre-pregnancy counselling by a rheumatologist and/or a gynaecologist (29)	The core data set focuses on the rheumatologic perspective.	No	
31	Pre-pregnancy counselling by obstetrician (F)	The core data set focuses on the rheumatologic perspective.	No	
32	Result of assisted reproduction (18)	As this core data set focuses on pregnant women, the result of the reproduction is known.	No	
33	sFlt-1/PLGF ratio (46)	This is beyond the purpose of this core data set.	No	
34	Sister preeclampsia; eclampsia; HELLP syndrome (35)	This is beyond the purpose of this core data set.	No	
35	Term date of current pregnancy as estimated by ultrasound during the first trimester of pregnancy (at 10-13 weeks) (36)	To our opinion the gestational age of the patient is important irrespective of the method used for calculation.	No	
	PREGNANCY: Delivery			
36	Administration of pain relief medication (F)	This is beyond the purpose of this core data set.	No	
37	In case of labour induction: Indication for labour induction (F)	This is beyond the purpose of this core data set.	No	

38	Placental weight (delivery ward) (45)	This is beyond the purpose of this core data set.	No	
	PREGNANCY: Infant outcomes			
39	Counselling on breastfeeding by obstetrician/ lactation expert (F)	This is beyond the purpose of this core data set.	No	
40	Duration of infant hospital admission (F)	This is beyond the purpose of this core data set.	No	
41	Infections of neonates (31)	The item will be added.	Yes	Serious infection of neonate
42	Neonatal lupus (apart from CHB); eg skin rash (19)	To our opinion difficult to obtain as the core data set focuses on data collection during pregnancy including the outcome of pregnancy, not before or postpartum.	No	
43	Occurrence of neonatal lupus (25)	In our opinion difficult to obtain as the core data set focuses on data collection during pregnancy including the outcome of pregnancy, not before or postpartum.	No	
44	There is nothing on the child (1)	Infant outcomes are addressed by items 103 to 116.	No	
	TREATMENT: DMARD treatment during pregnancy			
45	Increase of DMARD therapy during pregnancy (F)	If dose and application interval are reported at several time points, it will be possible to calculate a DMARD increase	No	
	MEDICATION: Treatment with oral glucocorticoids during pregnancy			
46	Increase of oral glucocorticoid therapy during pregnancy (F)	If dose and application interval are reported at several time points, it will be possible to calculate a glucocorticoid increase	No	
	MEDICATION: Treatment with intraarticular glucocorticoids during pregnancy			
47	Date or gestational age intraarticular glucocorticoid administration (F)	In case of prospective data collection, a date should be recorded.	No	
	MEDICATION: Treatment of other health conditions during pregnancy			

48	(Inadvertent) use of a teratogen or major fetotoxicant (e.g. RAS-I after GW 20) during pregnancy (5)	Item is of high interest, but will not be added as additional item to the core data set voting. Background: It is difficult to add this item when no list is provided that explicitly defines the names of teratogens/fetotoxic medication. However, one of the data items in the Delphi list is called 'Treatment with any prescription medicine'. That gives the possibility to indicate substances except the ones requested by names (e.g. DMARDs)	No	
49	Frequency / dosage and trimester or gestational weeks (GW) of NSAID usage (4)	NSAID usage, start and stop dates will be added, but not dosage.	(Yes)	Start and stop dates of NSAID treatment
50	Prophylactic or therapeutic treatment with folic acid (F)	This is beyond the purpose of this core data set.	No	
51	Start and stop dates of aspirin (F)	This is beyond the purpose of this core data set.	No	
52	Start and stop dates of folic acid (F)	This is beyond the purpose of this core data set.	No	
53	Use of NSAID during pregnancy (3)	The item will be added, and additionaly start and stop dates.	Yes	Use of NSAID
54	Which antihypertensive drug; moment of starting; augmenting one drug or more drugs (F)		No	
	OTHERS			
55	Breastfeeding post-partum (26)	The core data set focuses on data collection during pregnancy including the outcome of pregnancy, not before or postpartum.	No	
56	Children's follow-up at least in the first year of life with special attention on vaccinations; severe illnesses requiring hospitalization (23)	The core data set focuses on data collection during pregnancy including the outcome of pregnancy, not before or postpartum.	No	
57	Development of the newborn in the first two (or better 10) years of life (42)	The core data set focuses on data collection during pregnancy including the outcome of pregnancy, not before or postpartum.	No	
58	Discussion of subsequent contraception (28)	The core data set focuses on data collection during pregnancy including the outcome of pregnancy, not before or postpartum.	No	

59	Paternal age (9) + (12)	This is beyond the purpose of this core data set.	No	
60	Paternal inherited disorder (16)	This is beyond the purpose of this core data set.	No	
61	Paternal medication (8) +(11)	This is beyond the purpose of this core data set.	No	
62	Paternal use of antirheumatic drugs 12 months before and at conception (43)	This is beyond the purpose of this core data set.	No	
63	Postpartum disease activity over 3-12 months (21)	The core data set focuses on data collection during pregnancy including the outcome of pregnancy, not before or postpartum.	No	
64	Postpartum flare of disease (32)	The core data set focuses on data collection during pregnancy including the outcome of pregnancy, not before or postpartum.	No	
65	Postpartum medical treatment (33)	The core data set focuses on data collection during pregnancy including the outcome of pregnancy, not before or postpartum.	No	
66	Presence of Combined Outpatients Clinic (obstetrician+rheumatologist) (6)	This is beyond the purpose of this core data set.	No	
67	Rheumatologist and obstetrical team; in 1 clinic with regular contact; in more than 1 clinic and regular contact; in 1/2 clinics with no regular contact; something like this to evaluate whether close collaboration is useful; if this is applicable in this population of doctors who are going to gather these data; if they are only collaborators in 1 clinic with regular contacts it is superfluous (37)	This is beyond the purpose of this core data set.	No	
68	Use of medications in breastfeeding (27)	The core data set focuses on data collection during pregnancy including the outcome of pregnancy, not before or postpartum.	No	
69	Visit to the rheumatologist at least once each trimester? (10) + (13)	The core data set focuses on data collection during pregnancy including the outcome of pregnancy, not before or postpartum.	No	

Table 3: Results of Delphi votings round 1 and 2, of the F2F task force meeting, of their decisions and of the categorisation as well as comments/ explanations of the task force.

Data item		Results of Delphi round 1				Results of Delphi round 2				Results of F2F voting		Decisions of Delphi round 2	Decisions of F2F voting	Final core data set	Decisions of the task force
No.	Name	Score 1 to 3 (%)	Score 4 to 6 (%)	Score 7 to 9 (%)	*Unable to score (No. of experts)*	Score 1 to 3 (%)	Score 4 to 6 (%)	Score 7 to 9 (%)	*Unable to score (No. of experts)*	Yes/ Voting into the Core Data Set (No. of experts)	No / Voting out of the Core Data Set (No. of experts)				
MATERNAL INFORMATION: Demographics															
1	Maternal age at conception	0	5	95	*1*	0	2	98	*0*	-	-	**IN**	**IN**	**M [1]**	Renamed to "Age"
2	Area of actual maternal residence	32	54	14	*0*	41	58	2	*0*	0	16	**EQUIV.**	**OUT**	-	
3	Maternal race / ethnicity	6	46	48	*0*	6	55	39	*0*	6	10	**EQUIV.**	**OUT**	-	
4	Maternal body height	8	30	62	*0*	9	22	69	*0*	14	2	**EQUIV.**	**IN**	**M [2]**	Renamed to "Height"
5	Maternal body weight	2	27	71	*0*	2	13	86	*0*	-	-	**IN**	**IN**	**M [3]**	Renamed to "Weight"
6	Maternal marital / family status	32	62	6	*0*	44	55	2	*0*	0	16	**EQUIV.**	**OUT**	-	
7	Household income	32	63	5	*0*	48	48	3	*0*	1	15	**EQUIV.**	**OUT**	-	
8	Educational level of the patient	10	62	29	*0*	13	73	14	*0*	12	4	**EQUIV.**	**IN**	**M [4]**	Renamed to "Educational level"
9	Professional training of the patient	38	46	16	*0*	61	38	2	*0*	2	14	**EQUIV.**	**OUT**	-	
10	Maternal employment / work situation	19	60	21	*0*	27	64	9	*0*	4	12	**EQUIV.**	**OUT**	-	
11	Maternal sick leave	29	52	19	*0*	45	48	6	*0*	2	14	**EQUIV.**	**OUT**	-	
12	Alcohol consumption during pregnancy	2	17	81	*0*	0	9	91	*0*	-	-	**IN**	**IN**	**M [5]**	
13	Smoking during pregnancy	0	6	94	*0*	0	3	97	*0*	-	-	**IN**	**IN**	**M [6]**	
MATERNAL INFORMATION: Disease characteristics of the inflammatory rheumatic disease (IRD)															
14	Diagnosis of the inflammatory rheumatic disease	0	0	100	*1*	0	0	100	*1*	-	-	**IN**	**IN**	**M [7]**	Renamed to "IRD diagnosis"

15	Indication of the individual fulfilled classification criteria of the inflammatory rheumatic disease	0	37	63	*1*	0	24	76	*1*	-	-	**IN**	**IN**	**M [8]**	Renamed to "Classification criteria"
16	Date of diagnosis of the inflammatory rheumatic disease	3	15	82	*1*	0	13	87	*2*	-	-	**IN**	**IN**	**M [9]**	Renamed to "Disease duration"
17	Prior important manifestations of the inflammatory rheumatic disease	2	33	65	*0*	0	29	71	*1*	-	-	**IN**	**OUT**	-	Exclusion of item. Reason: Manifestations must be defined per IRD. Since severity (No. 18) and comorbidities are covered (No. 153), manifestations are not of that great importance.
18	Severity of the inflammatory rheumatic disease reported by the physician	3	15	82	*1*	2	6	92	*2*	-	-	**IN**	**IN**	**M [10]**	Renamed to "Physician reported IRD severity"
19	Flares of the inflammatory rheumatic disease during pregnancy	0	5	95	*0*	0	3	97	*1*	-	-	**IN**	**IN**	**M [12]**	Renamed to "Physician reported flares"
20	Disease activity of the inflammatory rheumatic disease reported by the physician	3	10	87	*0*	2	6	92	*1*	-	-	**IN**	**IN**	**M [13]**	Renamed to "Physician reported disease activity"
21	Disease activity estimated with appropriate score	0	8	92	*1*	0	5	95	*1*	-	-	**IN**	**IN**	**M [14]**	Renamed to "Disease activity by score"
Patient reported outcomes															
22	Disease activity of the inflammatory rheumatic disease	2	18	81	*1*	0	14	86	*1*	-	-	**IN**	**IN**	**M [16]**	Renamed to "Patient reported disease activity"
23	Fatigue	11	54	35	*0*	19	67	14	*1*	0	16	**EQUIV.**	**OUT**	-	
24	Global health	5	44	52	*1*	8	56	37	*1*	13	3	**EQUIV.**	**IN**	**M [17]**	Renamed to "Patient reported global health"
25	Health related quality of life	2	48	51	*0*	9	45	45	*0*	4	12	**EQUIV.**	**OUT**	-	
26	Impact of the inflammatory rheumatic disease on family life	19	53	27	*1*	27	66	8	*0*	0	16	**EQUIV.**	**OUT**	-	
27	Mental health	10	59	32	*0*	11	70	19	*0*	0	16	**EQUIV.**	**OUT**	-	
28	Pain	8	32	60	*0*	8	23	69	*0*	2	14	**EQUIV.**	**OUT**	-	
29	Physical function	6	35	59	*0*	8	27	65	*1*	4	12	**EQUIV.**	**OUT**	-	

30	Severity of the inflammatory rheumatic disease	10	31	60	*1*	8	18	74	*2*	-	-	**IN**	**OUT**	-	Exclusion of item. Reason: The task force decided that IRD severity should be judged by the physician. Furthermore, it might have been difficult for some Delphi participants to differentiate between physician and patient reported severity.
Serologic profile															
31	Disease-specific auto-antibodies of the inflammatory rheumatic disease	0	5	95	*1*	0	2	98	*2*	-	-	**IN**	**IN**	**M [11]**	Renamed to "Auto-antibodies"
32	Antiphospholipid antibodies	2	5	94	*1*	2	0	98	*1*	-	-	**IN**	**OUT**	-	This item is disease-specific and was part of a 3rd voting including all task force members.
Laboratory markers															
33	Alanine aminotransferase (ALAT)	17	40	43	*3*	20	51	30	*3*	1	15	**EQUIV.**	**OUT**	-	
34	Alkaline phosphatase (ALP)	20	48	32	*3*	30	52	18	*3*	0	16	**EQUIV.**	**OUT**	-	
35	Blood glucose	18	35	47	*3*	18	39	43	*3*	1	15	**EQUIV.**	**OUT**	-	
36	Complement components	3	20	76	*4*	3	15	82	*4*	-	-	**IN**	**OUT**	-	This item is disease-specific and was part of a 3rd voting including all task force members.
37	C-reactive protein (CRP)	7	13	80	*2*	5	11	84	*2*	-	-	**IN**	**IN**	**M [15]**	
38	Creatinine	7	20	73	*3*	5	15	80	*3*	-	-	**IN**	**OUT**	-	Exclusion of item. Reason: Renal diseases will be covered as comorbidity. It is not expected that creatinine levels will provide additional information for research purposes.
39	dsDNA antibodies	3	22	74	*5*	2	12	86	*5*	-	-	**IN**	**OUT**	-	This item is disease-specific and was part of a 3rd voting including all task force members.

40	Erythrocyte sedimentation rate (ESR)	28	31	41	*5*	39	25	36	*5*	0	16	**EQUIV.**	**OUT**	-	
41	Glomerular filtration rate (GFR)	8	32	59	*4*	10	30	61	*3*	1	15	**EQUIV.**	**OUT**	-	
42	Haemoglobin	7	27	67	*3*	3	26	70	*3*	-	-	**IN**	**OUT**	-	Exclusion of item. Reason: Haemoglobin levels are important for the individual pregnancy, but the task force does not expect additional benefit regarding research questions.
43	HbA1c (Glycated haemoglobin)	8	58	33	*3*	13	64	23	*3*	1	15	**EQUIV.**	**OUT**	-	
44	Leucocytes	12	33	55	*3*	13	34	52	*3*	0	16	**EQUIV.**	**OUT**	-	
45	Lymphocytes	15	48	37	*3*	21	48	31	*3*	2	14	**EQUIV.**	**OUT**	-	
46	Results of a clinical urinalysis	8	23	68	*3*	7	15	79	*3*	-	-	**IN**	**OUT**	-	Exclusion of item. Reason: Urinalysis is important for the individual pregnancy, but additional benefit regarding research questions is not expected.
47	Thrombocytes	7	32	62	*3*	7	28	66	*3*	3	13	**EQUIV.**	**OUT**	-	
48	Transaminase	14	39	47	*4*	15	41	44	*3*	1	15	**EQUIV.**	**OUT**	-	
49	Uric acid	20	50	30	*3*	23	59	18	*3*	0	16	**EQUIV.**	**OUT**	-	
MATERNAL INFORMATION: Prevalent comorbidities															
50	Comorbidity: Antiphospholipid syndrome	0	2	98	*1*	0	0	100	*1*	-	-	**IN**	**IN**	**O**	Summary to main item No. 153 “Selected prevalent comorbidities”.
51	Comorbidity: Depression and mood disorder	3	38	59	*0*	2	45	53	*0*	4	12	**EQUIV.**	**OUT**	-	
52	Comorbidity: Diabetes mellitus	0	6	94	*1*	0	5	95	*1*	-	-	**IN**	**IN**	**O**	Summary to main item No. 153 “Selected prevalent comorbidities”.
53	Comorbidity: Arterial hypertension	0	13	87	*1*	0	3	97	*1*	-	-	**IN**	**IN**	**O**	Summary to main item No. 153 “Selected prevalent comorbidities”.
54	Comorbidity: Hypothyroidism	2	38	61	*2*	2	34	65	*2*	3	13	**EQUIV.**	**OUT**	-	
55	Comorbidity: Hyperthyroidism	2	36	62	*2*	0	35	65	*2*	4	12	**EQUIV.**	**OUT**	-	

56	Comorbidity: Other autoimmune diseases	0	30	70	*2*	0	21	79	*2*	-	-	**IN**	**OUT**	**-**	Exclusion of item. Reasons: From a research point of view, overlap syndromes would be of interest. Since this concerns only a small number of patients, it is not expected to get enough data for joint analysis. Still, it is recommended that individual registers collect information of other autoimmune comorbidities.
57	Comorbidity: Renal disease	0	8	92	*1*	0	3	97	*1*	-	-	**IN**	**IN**	**O**	Summary to main item No. 153 "Selected prevalent comorbidities".
58	Comorbidity: Previous thromboembolic events	0	10	90	*1*	0	5	95	*1*	-	-	**IN**	**IN**	**O**	Summary to main item No. 153 "Selected prevalent comorbidities".
59	Comorbidity: Documentation of any other comorbidity	5	42	53	*1*	5	38	57	*1*	0	16	**EQUIV.**	**OUT**	**-**	
153	Selected prevalent comorbidities	*Item was introduced as a main item*								-	-	-	**IN (New)**	**M [18]**	New main item as a summary of items No. 50, 52, 53, 57, 58.
PREGNANCY: Obstetrical history															
66	Number of previous pregnancies (gravidity)	0	17	83	*0*	0	19	81	*0*	-	-	**IN**	**IN**	**M [19]**	Renamed to "Gravidity"
67	Parity	2	14	84	*0*	0	13	88	*0*	-	-	**IN**	**IN**	**M [20]**	
68	Year(s) of conception of previous pregnancy(ies)	13	47	40	*1*	11	62	27	*1*	1	15	**EQUIV.**	**OUT**	**-**	
69	Previous Cesarean section(s)	6	48	46	*0*	3	55	42	*0*	7	9	**EQUIV.**	**OUT**	**-**	
70	Previous stillbirth(s)	0	8	92	*0*	0	0	100	*0*	-	-	**IN**	**IN**	**O**	Summary to main item No. 149 "Outcome of previous pregnancy(ies)"
149	Outcome of previous pregnancy(ies)	*Item was added at the face-to-face meeting*								-	-	-	**IN (New)**	**M [21]**	New main item as a summary of items No. 70, 78 and 79.

71	Previous induced abortion / elective termination of pregnancy(ies)	11	38	51	*0*	13	42	45	*0*	4	12	**EQUIV.**	**OUT**	**-**	
72	Previous neonatal death(s)	2	5	94	*0*	0	0	100	*0*	-	-	**IN**	**IN**	**M [23]**	Renamed to "Neonatal death(s)"
73	Previous pre-eclampsia , eclampsia or HELLP syndrome	0	13	87	*0*	0	2	98	*0*	-	-	**IN**	**IN**	**M [25]**	Renamed to "Hypertensive pregnancy disorders"
74	Previous preterm birth(s)	0	14	86	*0*	2	8	91	*0*	-	-	**IN**	**IN**	**M [22]**	Renamed to "Preterm birth(s)"
75	Gender of the child(ren)	29	45	26	*1*	35	43	22	*1*	0	16	**EQUIV.**	**OUT**	**-**	
76	Birth weight(s) of previous live birth(s)	13	32	56	*0*	9	38	53	*0*	5	11	**EQUIV.**	**OUT**	**-**	
77	Congenital anomalies of previous born infant(s)	2	27	71	*0*	0	20	80	*0*	-	-	**IN**	**IN**	**M [24]**	
78	Gestational age at birth	*Item was added to round 2*				5	23	72	*0*	-	-	**IN**	**IN**	**O**	Summary to main item No. 149 "Outcome of previous pregnancy(ies)"
79	Number of spontaneous abortions of previous pregnancies	*Item was added to round 2*				0	16	84	*0*	-	-	**IN**	**IN**	**O**	Summary to main item No. 149 "Outcome of previous pregnancy(ies)"
PREGNANCY: Course of current pregnancy															
80	Planned pregnancy	11	33	56	*0*	11	25	64	*0*	10	6	**EQUIV.**	**IN**	**M [26]**	
81	Preconception counselling by rheumatologist	8	41	51	*0*	9	45	45	*0*	7	9	**EQUIV.**	**OUT**	**-**	
82	Assisted reproduction	5	27	68	*0*	0	20	80	*0*	-	-	**IN**	**IN**	**M [27]**	
83	Estimated date of conception	5	24	71	*1*	8	17	75	*1*	-	-	**IN**	**IN**	**M [28]**	
84	Indication of singleton or multiple pregnancy	3	15	82	*1*	2	8	90	*1*	-	-	**IN**	**IN**	**M [29]**	
85	Arterial hypertension	2	10	89	*1*	2	0	98	*1*	-	-	**IN**	**IN**	**O**	Summary to main item No. 154 "Adverse events of interest"
86	Gestational diabetes	0	15	85	*1*	0	2	98	*1*	-	-	**IN**	**IN**	**O**	Summary to main item No. 154 "Adverse events of interest"
87	HELLP syndrome	0	5	95	*1*	0	0	100	*1*	-	-	**IN**	**IN**	**O**	Summary to main item No. 154 "Adverse events of interest"

88	Infections	0	15	85	*1*	0	10	90	*2*	-	-	**IN**	**OUT**	-	Exclusion of item. Reason: Only serious infections are of interest, which will be covered by item No. 61.
89	Intrauterine growth restriction (IUGR)	0	8	92	*1*	0	2	98	*1*	-	-	**IN**	**OUT**	-	Exclusion of item. Reason: The Task Force expects confusion with small for gestational age since this core set addresses primarily rheumatologists.
90	Pre-eclampsia or eclampsia	0	3	97	*1*	0	0	100	*1*	-	-	**IN**	**IN**	**O**	Summary to main item No. 154 "Adverse events of interest"
91	Premature contractions / premature labour	2	18	80	*2*	3	13	84	*2*	-	-	**IN**	**OUT**	-	Exclusion of item. Reason: Premature contractions do also occur in women without IRD and it is not expected to gain additional information from this item.
92	Thromboembolic events	0	3	97	*1*	0	2	98	*1*	-	-	**IN**	**IN**	**O**	Summary to main item No. 154 "Adverse events of interest"
154	Adverse events of interest	*Item was introduced as a main item*								-	-	-	**IN (New)**	**M [30]**	New main item as a summary of items No. 85, 86, 87, 90, 92
60	Maternal non-serious adverse event(s)	13	39	48	*2*	15	45	40	*2*	0	16	**EQUIV.**	**OUT**	-	
61	Maternal serious adverse event(s)	0	13	87	*1*	0	3	97	*1*	-	-	**IN**	**IN**	**M [31]**	Renamed to "Other serious adverse events"
62	Maternal admission to hospital	5	21	74	*2*	5	14	81	*1*	-	-	**IN**	**IN**	**O**	Operationalisation for main item No. 61
63	Maternal death	0	0	100	*0*	0	0	100	*0*	-	-	**IN**	**IN**	**O**	Operationalisation for main item No. 61
64	In case of maternal death: Date of death	2	8	90	*0*	2	2	97	*0*	-	-	**IN**	**OUT**	-	Exclusion of item. Reason: Information will be covered by item No. 61 "Other serious adverse

															events".
65	In case of maternal death: Cause of death	0	3	97	*0*	0	0	100	*0*	-	-	**IN**	**OUT**	**-**	Exclusion of item. Reason: Information will be covered by item No. 61 "Other serious adverse events".
PREGNANCY: Delivery / Outcome of the current pregnancy															
93	Live birth	0	3	97	*0*	0	0	100	*0*	-	-	**IN**	**IN**	**M [34]**	
94	Induced abortion / elective termination of pregnancy	2	8	90	*0*	2	0	98	*0*	-	-	**IN**	**IN**	**M [32]**	Renamed to "Elective termination"
95	In case of induced abortion/ elective termination: Reasons for termination of pregnancy	6	11	83	*0*	3	8	89	*0*	-	-	**IN**	**IN**	**O**	Operationalisation for main item No. 94
96	In case of induced abortion/ elective termination: Gestational age	6	16	78	*0*	3	14	83	*0*	-	-	**IN**	**IN**	**O**	Operationalisation for main item No. 94
97	Pregnancy loss	0	3	97	*0*	0	0	100	*1*	-	-	**IN**	**IN**	**M [33]**	Renamed to "Foetal death"
98	In case of pregnancy loss: Gestational age	3	3	94	*0*	0	2	98	*1*	-	-	**IN**	**IN**	**O**	Operationalisation for main item No. 97
99	Gestational age at birth	0	5	95	*0*	0	0	100	*0*	-	-	**IN**	**IN**	**M [35]**	
100	Mode of delivery	5	21	75	*0*	3	13	84	*0*	-	-	**IN**	**IN**	**M [37]**	
101	In case of Cesarean section: Reasons for the Cesarean section	6	27	67	*0*	6	17	77	*0*	-	-	**IN**	**IN**	**O**	Operationalisation for main item No. 100
102	Labour induction	14	38	48	*0*	9	48	42	*0*	3	13	**EQUIV.**	**OUT**	**-**	
103	Preterm premature rupture of membranes (PPROM)	6	40	54	*0*	6	42	52	*0*	12	4	**EQUIV.**	**IN**	**M [36]**	
104	Administration of epidural analgesia during childbirth	29	44	27	*0*	39	58	3	*0*	2	14	**EQUIV.**	**OUT**	**-**	
PREGNANCY: Neonatal outcomes															
105	Birth weight	0	6	94	*0*	0	3	97	*0*	-	-	**IN**	**IN**	**M [38]**	
106	Body height/length of the neonate at birth	13	18	69	*1*	11	20	69	*0*	2	14	**EQUIV.**	**OUT**	**-**	
107	Gender of the neonate	18	27	55	*1*	13	32	56	*1*	11	5	**EQUIV.**	**IN**	**M [39]**	
108	Apgar score	3	31	66	*1*	3	30	67	*0*	4	12	**EQUIV.**	**OUT**	**-**	
109	Breastfeeding of the neonate	3	33	63	*0*	5	30	66	*0*	15	1	**EQUIV.**	**IN**	**M [40]**	

110	Chromosome abnormalities	3	13	84	*2*	0	6	94	*0*	-	-	**IN**	**OUT**	-	Summary to main item No. 150 ”Congenital malformations”.
111	Congenital heart block	0	6	94	*0*	0	0	100	*0*	-	-	**IN**	**IN**	**M [41]**	
112	Hospital admission of the neonate	3	18	79	*1*	2	13	86	*1*	-	-	**IN**	**IN**	**O**	Operationalisation for main item No. 152
113	Major congenital malformations	0	5	95	*0*	0	0	100	*0*	-	-	**IN**	**OUT**	-	Summary to main item No. 150 ”Congenital malformations”.
114	Medical treatment of the neonate	3	27	69	*1*	3	17	79	*1*	-	-	**IN**	**OUT**	-	Exclusion of item. Reason: No additional benefit is expected for research purposes.
115	Minor congenital malformations	6	22	71	*0*	3	16	81	*0*	-	-	**IN**	**OUT**	-	Summary to main item No. 150 ”Congenital malformations”.
150	Congenital malformations	*Item was added at the face-to-face meeting*								-	-	-	**IN (New)**	**M [42]**	New main item as a summary of items No. 110, 113 and 115.
116	Neonatal death	0	3	97	*0*	0	0	100	*0*	-	-	**IN**	**IN**	**O**	Operationalisation for main item No. 152
117	In case of neonatal death: Date of death	3	8	89	*0*	2	9	89	*0*	-	-	**IN**	**OUT**	-	Exclusion of item. Reason: It will be covered by item No. 152 “Neonatal serious adverse events”.
118	In case of neonatal death: Cause of death	3	2	95	*0*	0	2	98	*0*	-	-	**IN**	**OUT**	-	Exclusion of item. Reason: It will be covered by item No. 152 “Neonatal serious adverse events”.
119	Serious infection of neonate	*Item was added to round 2*				0	6	94	*0*	-	-	**IN**	**OUT**	-	Exclusion of item. Reason: It will be covered by item No. 152 “Neonatal serious adverse events”.
152	Neonatal serious adverse events during the first 28 days of live	*Item was added at the face-to-face meeting*								-	-	-	**IN (New)**	**M [43]**	New main item as a summary of items No. 116-119.
MEDICATION: Treatment 12 months prior to conception															
120	Name(s) of DMARD(s)	0	10	90	*0*	0	2	98	*1*	-	-	**IN**	**IN**	**O**	Operationalisation for main item No. 155

121	Dose(s) and application interval(s) of DMARD(s)	6	37	57	*0*	6	40	54	*1*	2	14	**EQUIV.**	**OUT**	-	
122	Start and stop dates of DMARD(s)	2	27	71	*0*	0	22	78	*1*	-	-	**IN**	**IN**	**O**	Operationalisation for main item No. 155
155	DMARD use	*Item was introduced as a main item*								-	-	-	**IN (New)**	**M [44]**	New main item as a summary of items No. 120 and 121
123	Use of oral glucocorticoid(s)	0	16	84	*0*	0	11	89	*1*	-	-	**IN**	**IN**	**M [45]**	
124	Dose(s) and application interval(s) of oral glucocorticoid(s)	5	32	63	*0*	3	33	63	*1*	2	14	**EQUIV.**	**OUT**	-	
125	Use of potentially teratogenic medication	3	3	94	*0*	0	3	97	*1*	-	-	**IN**	**IN**	**M [46]**	
MEDICATION: IRD treatment during pregnancy															
Treatment with disease modifying anti-rheumatic drugs (DMARD)															
126	Name(s) of DMARD(s)	0	2	98	*0*	0	0	100	*1*	-	-	**IN**	**IN**	**O**	Operationalisation for main item No. 156
127	Dose(s) and application interval(s) of DMARD(s)	2	11	87	*0*	2	8	90	*1*	-	-	**IN**	**IN**	**O**	Operationalisation for main item No. 156
128	Route of administration of DMARD(s)	6	37	57	*0*	8	38	54	*1*	2	14	**EQUIV.**	**OUT**	-	
129	Start and stop dates of DMARD(s)	0	10	90	*0*	0	2	98	*1*	-	-	**IN**	**IN**	**O**	Operationalisation for main item No. 156
130	Reasons for ending a DMARD therapy	5	19	76	*1*	2	17	81	*1*	-	-	**IN**	**IN**	**O**	Operationalisation for main item No. 156
156	DMARD use	*Item was introduced as a main item*								-	-	-	**IN (New)**	**M [47]**	New main item as a summary of items No. 126, 127, 129 and 130
Treatment with oral glucocorticoids (GC)															
131	Use of oral GCs	0	2	98	*0*	0	0	100	*0*	-	-	**IN**	**IN**	**M [48]**	Renamed to "Oral glucocorticoid use"
132	Dose(s) and application interval(s) of oral GCs	0	16	84	*0*	2	5	94	*0*	-	-	**IN**	**IN**	**O**	Operationalisation for main item No. 131
133	Start and stop dates of oral GC treatment	2	10	89	*0*	2	3	95	*0*	-	-	**IN**	**IN**	**O**	Operationalisation for main item No. 131
Treatment with intraarticular glucocorticoids (GC)															
151	Intraarticular GC	*Item was added at the face-to-face meeting*								15	1	-	**IN (New)**	**M [49]**	New main item.
134	Dosage of intraarticular GC	7	33	61	*2*	10	36	54	*3*	2	14	**EQUIV.**	**OUT**	-	

135	Administration date of intraarticular GC	3	40	56	*1*	6	37	56	*2*	10	6	**EQUIV.**	**IN**	**O**	Operationalisation for main item No. 151
Treatment with non-steroidal anti-rheumatic drugs (NSAID)															
136	Use of NSAIDs	*Item was added to round 2*				3	23	73	*0*	-	-	**IN**	**IN**	**M [50]**	Renamed to "NSAID use"
137	Start and stop dates of NSAID treatment	*Item was added to round 2*				13	34	53	*0*	11	5	**EQUIV.**	**IN**	**O**	Operationalisation for main item No. 136
MEDICATION: Treatment of other health conditions during pregnancy															
138	Treatment with analgesics other than non-steroidal anti-inflammatory drugs or opioids	3	41	56	*0*	2	44	55	*0*	3	13	**EQUIV.**	**OUT**	-	
139	Treatment with antibiotics	2	45	53	*1*	2	49	49	*1*	2	14	**EQUIV.**	**OUT**	-	
140	Treatment with antihypertensive drugs	0	24	76	*1*	0	17	83	*0*	-	-	**IN**	**IN**	**O**	Operationalisation for main item No. 157
141	Treatment with aspirin	0	11	89	*0*	0	3	97	*0*	-	-	**IN**	**IN**	**O**	Operationalisation for main item No. 157
142	Treatment with folic acid	0	25	75	*0*	0	16	84	*0*	-	-	**IN**	**IN**	**O**	Operationalisation for main item No. 157
143	Treatment with heparin or other anticoagulants	0	11	89	*0*	0	5	95	*0*	-	-	**IN**	**IN**	**O**	Operationalisation for main item No. 157
144	Treatment with opioids	2	35	63	*1*	3	37	60	*1*	4	12	**EQUIV.**	**OUT**	-	
145	Treatment with Vitamin D	8	48	44	*1*	5	52	43	*1*	1	15	**EQUIV.**	**OUT**	-	
146	Treatment with any other over-the-counter medicine	21	53	26	*1*	24	60	16	*1*	0	16	**EQUIV.**	**OUT**	-	
147	Treatment with any prescription medicine	8	52	40	*1*	16	48	37	*1*	5	11	**EQUIV.**	**OUT**	-	
148	Treatment with any supplements	26	53	21	*1*	33	57	10	*1*	2	14	**EQUIV.**	**OUT**	-	
157	Use of selected treatments	*Item was introduced as a main item*							-	-	-	-	**IN (New)**	**M [51]**	New main item as a summary of items No. 126, 127, 140 - 143

Data items that have been subject to the Delphi votings and F2F voting by task force members are categorized by domains and – especially for the Delphi votings, sub-categories have been introduced. Changing of decisions, e.g. inclusion of an item in Delphi round 2 and exclusion at the F2F meeting are highlighted in blue.

Abbreviations: EQUIV., equivocal; F2F, Face-to-face; M, Main data item; O, operational data item; TF, task force;

Table 4: Definition of data items of the final core data set and their recommended way of assessment.

New No.	Original No.	Name of the data item	Description/ Definition/ Explanation	Recommended way of assessment (categories / instruments)
MATERNAL INFORMATION: Demographics				
1	1	Age	Age of the mother at the time of conception.	Assessment of date of birth or month/year of birth
2	4	Height	Body height and weight are necessary to calculate body mass index.	Assessment in centimeters (cm)
3	5	Weight	Body height and weight are necessary to calculate body mass index. Body weight is needed to calculate weight gain during pregnancy.	Assessment in kilogram (kg)
4	8	Educational level	Highest educational level according to national standards is recommended to be reported (e.g. total years of completed education including years in school, college and university), or highest degree reached.	Assessment of highest educational level according to national standards or total years of completed education
5	12	Alcohol consumption during pregnancy	Alcohol consumption should encompass occasional and regular drinking of alcoholic beverages during pregnancy.	Assessment of yes/ no
6	13	Smoking during pregnancy	Smoking should compass occasional and regular smoking during pregnancy.	Assessment of yes/ no
MATERNAL INFORMATION: Disease characteristics of the inflammatory rheumatic disease (IRD)				
7	14	IRD diagnosis	As the core data set should serve for several IRDs, diagnosis would include those diseases covered by the individual register or study. The diagnoses should be determined prior to setting up the register.	Physician reported clinical diagnosis
8	15	Classification criteria	According to the underlying IRD it should be questioned if standardized classification criteria are fulfilled (e.g. does the patient with psoriatic arthritis fulfil the CASPAR criteria).	Indication, which criteria are fulfilled
9	16	Disease duration	Defines the time when the IRD was first diagnosed by a physician.	Assessment of month/ year or year of diagnosis
10	18	Physician reported IRD severity	Estimation of the severity of the IRD by the reporting physician on a pre-defined instrument.	Instrument: NRS or VAS
11	31	Auto-antibodies	Disease-specific auto-antibodies of the IRD	Instrument: See additional recommendation for selected IRDs in table 3
12	19	Physician reported flares	A flare is a clinically important worsening of the IRD.	Assessment of (I) Yes/ No; (II) Number of flares
13	20	Physician reported disease activity	How active is the disease at the moment?	Instrument: NRS or VAS
14	21	Disease activity by score	Measurement of the activity usig a disease-specific score.	Instrument: See additional recommendation for selected IRDs in table 3
15	37	C-reactive protein	C-reactive protein (CRP) is an inflammation marker. The appropriate unit should be indicated.	Assessment of in mg/l or md/dl
16	22	Patient reported disease activity	How active is the disease at the moment?	Instrument: NRS or VAS

17	24	Patient reported global health	How would the patient rate his/her global health at the moment?	Instrument: NRS or VAS
MATERNAL INFORMATION: Prevalent comorbidities				
18	153	Selected prevalent comorbidities		Yes/ No assessment of: (I) Antiphospholipid syndrome, (II) Diabetes mellitus, (III) Arterial hypertension, (IV) Renal disease, (V) Previous thromboembolic events
PREGNANCY: Obstetrical history				
19	66	Gravidity	Gravidity is the number of times a woman has been pregnant regardless of pregnancy outcome (1).	Assessment of number of previous pregnancies
20	67	Parity	Parity is the number of pregnancies reaching 20 weeks and 0 days of gestation or beyond, regardless of the number of foetuses or outcomes (1).	Assessment of parity number
21	149	Outcome of previous pregnancy(ies)	This item encompasses any foetal death (including pregnancy loss(es) (also named spontaneous abortions/ miscarriages) and stillbirth(s) as well as live birth(s) of previous pregnancy(ies).	Categorization into Foetal death / Live birth; Assessment of (I) Number of foetal deaths and live births; (II) Gestational age
22	74	Preterm birth(s)	Preterm born infants of previous pregnancies. According to the WHO, preterm birth is defined as birth before 37 completed weeks of gestation.	Assessment of number of preterm birth(s) in previous pregnancies
23	72	Neonatal death(s)	Neonatal death(s) of previous born infants. Neonatal death is defined as the death of a live born infant, regardless of gestational age at birth, within the first 28 completed days of life.	Assessment of number of neonatal death(s)
24	77	Congenital malformations	Indication of congenital anomalies of previous born infants. According to the WHO, congenital anomalies are also known as birth defects, congenital disorders or congenital malformations (2). Congenital anomalies can be defined as structural or functional anomalies that occur during intrauterine life and can be identified prenatally, at birth, or sometimes may only be detected later in infancy. For coding anomalies, it is referred to the EUROCAT Malformation Coding Guides (3). It is not recommended to restrict the reporting of anomalies to a selection of anomalies since the definition of groups etc. maybe subject of changes during time.	Reporting as free text
25	73	Hypertensive pregnancy disorders	Hypertensive pregnancy disorders in previous pregnanciy(ies) encompasses the events of pre-eclampsia , eclampsia or HELLP syndrome. Pre-eclampsia: Disorder of pregnancy with persistent hypertension (diastolic blood pressure ≥ 90 mm Hg) and substantial proteinuria (> 0.3 g/24 hours) (4). Eclampsia: Generalized seizures, generally in addition to pre-eclampsia criteria (4). HELLP syndrome: Complication of pre-eclampsia (H = Haemolysis, EL = Elevated Liver enzymes, LP = Low Platelets)(4). Definitions may vary according to national standards.	Assessment of yes/ no
PREGNANCY: Course of the current pregnancy				
26	80	Planned pregnancy	Did the patient plan to become pregnant?	Assessment of yes/ no
27	82	Assisted reproduction	Did the patient plan to become pregnant using assisted reproductive technology (ART)? ART are all treatments or procedures that include the in vitro handling of both human oocytes and sperm or of embryos for the purpose of establishing a pregnancy. It does not include assisted insemination (5).	Assessment of yes/ no

28	83	Estimated date of conception	Date of conception is important to calculate gestational age during the complete pregnancy and the estimated due date (estimated date of delivery). Both dates are essential for analysis of pregnancy course and outcome, e.g. determination of preterm delivery, exact times of drug exposure during pregnancy, etc. Date of conception should be defined using appropriate method, e.g. last menstrual period and/or ultrasound.	Assessment of day/month/year
29	84	Singleton/ multiple pregnancy	Indication if the current pregnancy is a pregnancy with one foetus or more than one foetus.	Assessment of number of foetuses
30		Adverse events of interest	Indication, if the patient has experienced a non-serious or serious adverse event of interest, which encompasses Gestational hypertension, Pre-eclampsia, eclampsia, HELLP syndrome, Gestational diabetes, Thromboembolic events (deep venous thrombosis or pulmonary embolisms). Definitions for these conditions may vary according to national standards. In accordance with the International Conference on Harmonisation E2A guideline (6), a serious adverse event or reaction is any untoward medical occurrence observed in a patient that results in death, is life-threatening, requires inpatient hospitalisation or results in prolongation of existing hospitalisation, results in persistent or significant disability/incapacity or is a congenital anomaly/birth defect.	Assessment (I) if the event has occurred as yes or no; (II) of the date of the beginning of the event; (III) if the event has led to hospitalization or death
31	61	Other serious adverse events	Besides the events of interest, other serious adverse interest should be reported. In accordance with the International Conference on Harmonisation E2A guideline (6), a serious adverse event or reaction is any untoward medical occurrence observed in a patient that results in death, is life-threatening, requires inpatient hospitalisation or results in prolongation of existing hospitalisation, results in persistent or significant disability/incapacity or is a congenital anomaly/birth defect.	Assessment (I) of the kind of event as free text; (II) of the date of the beginning of the event; (III) if the event has led to hospitalization or death
PREGNANCY: Delivery and outcome of the current pregnancy				
32	94	Elective termination	Termination of a clinical pregnancy using a therapeutic process (e.g. surgical abortion or medical abortion using the "abortion pill").	Assessment of (I) Yes/ No; (II) Gestational age; (III) Reasons for termination categorized into (a) Termination due to malformation, (b) Termination due to other reasons
33	97	Foetal death	Foetal deathencompasses any loss of pregnancy regardless of cause and time of loss (5). The embryo(s) or foetus(es) is/are nonviable). Pregnancy loss encompasses e.g. missed abortion, spontaneous abortion/ miscarriage, stillbirth.	Assessment of (I) Yes/ No; (II) Gestational age
34	93	Live birth	The complete expulsion or extraction from its mother of a product of conception, irrespective of the duration of the pregnancy, which, after such separation, breathes or shows any other evidence of life, such as beating of the heart, pulsation of the umbilical cord, or definite movement of voluntary muscles, whether or not the umbilical cord has been cut or the placenta is attached; each product of such a birth is considered liveborn (WHO definition, (7)).	Assessment of yes/ no
35	99	Gestational age at birth	Indication of gestational age when giving birth.	Gestational age in weeks and days
36	103	Preterm premature rupture of membranes	PPROM is a pregnancy complication when the foetal membranes rupture prior to 37 weeks of gestation (8).	Assessment of yes/ no

		(PPROM)		
37	100	Mode of delivery	Mode of delivery indicates the way the child is born. In case of a Caesarean section, assessment why it was performed (9).	(I) Categorization into spontaneous vaginal delivery/ operative vaginal delivery/ caesarean section/ Mode of delivery not specified; (II) Reasons for Caesarean section: Emergency reasons/ Obstetrical indication/ Caesarean section in previous pregnancies/ Unknown reason
PREGNANCY: Neonatal outcomes				
38	105	Birth weight	Indication of the weight at birth.	Assessment in kilogram with 2 decimal digits or in gram
39	107	Gender	Determination of the infant's gender at birth (gender/sex assignment).	Categorization into female/ male/ other
40	109	Breastfeeding	Did the mother breastfeed the neonate within the first 28 days after birth?	Categorization into Yes, for at least 4 weeks after birth/ No
41	111	Congenital heart block	Congenital heart block is a rare disorder and is characterized by interference with the transfer of the electrical nerve impulses (conduction) that regulate the normal, rhythmic, pumping action of the heart muscle (heart block) (Link: https://rarediseases.org/rare-diseases/heart-block-congenital/).	Assessment of yes/ no
42	150	Congenital malformations	Indication of congenital anomalies of previous born infants. According to the WHO, congenital anomalies are also known as birth defects, congenital disorders or congenital malformations. Congenital anomalies can be defined as structural or functional anomalies that occur during intrauterine life and can be identified prenatally, at birth, or sometimes may only be detected later in infancy. Also chromosome anomalies are encompassed by congenital anomalies. For coding anomalies, it is referred to the EUROCAT Malformation Coding Guides (3). It is not recommended to restrict the reporting of anomalies to a selection of anomalies since the definition of groups etc. maybe subject of changes during time.	Reporting as free text
43	152	Neonatal serious adverse events during the first 28 days of live	Especially hospital admissions and neonatal death are of interest. In accordance with the International Conference on Harmonisation E2A guideline (6), a serious adverse event or reaction is any untoward medical occurrence observed in a patient that results in death, is life-threatening, requires inpatient hospitalisation or results in prolongation of existing hospitalisation, results in persistent or significant disability/incapacity or is a congenital anomaly/birth defect.	Assessment of (I) The kind of event as free text; (II) The date of the beginning of the event; (III) Indication if the event has led to hospitalization or death
MEDICATION: Treatment 12 months prior to conception				
44	120	DMARD use	Indication of all disease modifying anti-rheumatic drugs (DMARDs) the patient received in the past 12 months prior to conception. DMARDs encompass conventional synthetic (cs)DMARDs, e.g. methotrexate, sulfasalazine, hydroxychloroquine etc., biologic (b)DMARDs, e.g. adalimumab, certolizumab, tocilizumab, abatacept etc., and targeted synthetic (ts)DMARDs like apremilast, baricitinib, etc.	Assessment of (I) Yes/ No; (II) Name*; (III) Start/ stop dates [*For b/tsDMARDs it is recommended to record the trade name]
45	123	Oral glucocorticoid use	Indication if oral glucocorticoids have been used in the past 12 months prior to conception.	Indication as yes or no
46	125	Use of potentially teratogenic medication	Indication if potentially teratogenic treatments have been used in the past 12 months prior to conception. Since there is no official list available for teratogenic medication, and such a list would be	Reporting as free text

			prone to continuous updates, we recommend the assessment as free text.	
MEDICATION: Treatment of the inflammatory rheumatic disease during pregnancy and postpartum				
47	126	DMARD use	Indication of all disease modifying anti-rheumatic drugs (DMARDs) the patient is currently receiving and has been received since conception or the last visit whatever is appropriate. DMARDs encompass conventional synthetic (cs)DMARDs, e.g. methotrexate, sulfasalazine, hydroxychloroquine etc., biologic (b)DMARDs, e.g. adalimumab, certolizumab, tocilizumab, abatacept etc., and targeted synthetic (ts)DMARDs like apremilast, baricitinib, etc.	Assessment of (I) Yes/ No; (II) Name*; (III) Dose; (IV) Application intervals; (V) Start/ stop dates; (VI) Reasons for discontinuation [*For b/tsDMARDs it is recommended to record the trade name]
48	131	Oral glucocorticoid use	Indication if the patient has used oral glucocorticoid since conception or the last visit whatever is appropriate.	Assessment of (I) Yes/ No; (II) Dose; (III) Application intervals; (IV) Start/ stop dates
49	151	Intraarticular glucocorticoid use	Indication if the patient has received intraarticular glucocorticoid since conception or the last visit whatever is appropriate.	Assessment of (I) Yes/ No; (II) Date of application
50	136	NSAID use	Indication if the patient has used NSAIDs since conception or the last visit whatever is appropriate.	Assessment of (I) Yes/ No; (III) Name; (III) Start/ stop dates
MEDICATION: Treatment of other health conditions during pregnancy				
51	157	Use of selected treatments	Indication if the patient has used one of the selected treatments since conception or the last visit whatever is appropriate. Selected treatments are: antihypertensive drugs, aspirin, folic acid and heparin/ other anticoagulants.	Yes/ No assessment of use of (I) Antihypertensive drugs, (II) Aspirin, (III) Folic acid and (IV) Heparin/ other anticoagulants

Abbreviations: IRD, Inflammatory rheumatic disease; DMARD, disease modifying anti-rheumatic drugs; NSAID, non-steroidal anti-inflammatory drugs.

Table 5: Results of additional item voting.

	Rheumatoid arthritis	Spondylo-arthritis (PsA + axSpA)	Juvenile idiopathic arthritis	Systemic lupus erythematosus	Other connective tissue diseases
Autoantibodies / Laboratory markers					
Anti-cardiolipin antibodies	Y/N/Miss: 2/7/8	Y/N/Miss: 1/7/9	Y/N/Miss: 1/7/9	Y/N/Miss: 9/1/7	Y/N/Miss: 7/2/8
Anticitrullinated protein antibody (ACPA)	Y/N/Miss: 9/0/8	Y/N/Miss: 1/7/9	Y/N/Miss: 5/3/9	Y/N/Miss: 0/9/8	Y/N/Miss: 0/8/9
Anti-double-stranded DNA antibodies	Y/N/Miss: 0/9/8	Y/N/Miss: 0/8/9	Y/N/Miss: 0/8/9	Y/N/Miss: 8/1/8	Y/N/Miss: 2/6/9
Anti-La/SSB antibodies	Y/N/Miss: 1/8/8	Y/N/Miss: 0/8/9	Y/N/Miss: 0/8/9	Y/N/Miss: 6/3/8	Y/N/Miss: 6/3/8
Antinuclear antibodies (ANA)	Y/N/Miss: 0/9/8	Y/N/Miss: 0/8/9	Y/N/Miss: 5/3/9	Y/N/Miss: 6/3/8	Y/N/Miss: 6/3/8
Anti-Ro/SSA antibodies	Y/N/Miss: 1/8/8	Y/N/Miss: 1/7/9	Y/N/Miss: 1/7/9	Y/N/Miss: 9/0/8	Y/N/Miss: 7/2/8
Anti-Sm antibodies	Y/N/Miss: 0/9/8	Y/N/Miss: 0/8/9	Y/N/Miss: 0/8/9	Y/N/Miss: 7/2/8	Y/N/Miss: 3/6/8
Anti-U1-ribonucleoprotein (RNP) antibodies	Y/N/Miss: 0/9/8	Y/N/Miss: 0/8/9	Y/N/Miss: 0/8/9	Y/N/Miss: 6/3/8	Y/N/Miss: 6/2/9
Beta-2-Glycoprotein-I-antibodies	Y/N/Miss: 1/8/8	Y/N/Miss: 0/8/9	Y/N/Miss: 0/8/9	Y/N/Miss: 8/1/8	Y/N/Miss: 6/3/8
HLA-B27	Y/N/Miss: 0/9/8	Y/N/Miss: 9/0/8	Y/N/Miss: 2/6/9	Y/N/Miss: 0/9/8	Y/N/Miss: 1/8/8
Lupus anticoagulant	Y/N/Miss: 1/8/8	Y/N/Miss: 0/8/9	Y/N/Miss: 0/8/9	Y/N/Miss: 9/0/8	Y/N/Miss: 6/3/8
Rheumatoid factor	Y/N/Miss: 8/1/8	Y/N/Miss: 1/7/9	Y/N/Miss: 5/3/9	Y/N/Miss: 0/9/8	Y/N/Miss: 1/8/8
Serum C3 / C4	Y/N/Miss: 0/9/8	Y/N/Miss: 0/8/9	Y/N/Miss: 0/8/9	Y/N/Miss: 9/1/7	Y/N/Miss: 6/4/7
Disease Activity /Severity					
28 SJC	Y/N/Miss: 6/2/9	Y/N/Miss: 2/5/10	Y/N/Miss: 5/2/10	Y/N/Miss: 1/6/10	Y/N/Miss: 1/6/10
28 TJC	Y/N/Miss: 6/2/9	Y/N/Miss: 2/5/10	Y/N/Miss: 5/2/10	Y/N/Miss: 1/6/10	Y/N/Miss: 1/6/10
66 SJC	Y/N/Miss: 1/7/9	Y/N/Miss: 3/4/10	Y/N/Miss: 1/6/10	Y/N/Miss: 0/7/10	Y/N/Miss: 0/7/10
68 TJC	Y/N/Miss: 1/7/9	Y/N/Miss: 2/5/10	Y/N/Miss: 1/6/10	Y/N/Miss: 0/7/10	Y/N/Miss: 0/7/10
ASDAS	Y/N/Miss: 0/8/9	Y/N/Miss: 6/1/10	Y/N/Miss: 1/6/10	Y/N/Miss: 0/7/10	Y/N/Miss: 0/7/10
BASDAI	Y/N/Miss: 0/8/9	Y/N/Miss: 6/1/10	Y/N/Miss: 1/6/10	Y/N/Miss: 0/7/10	Y/N/Miss: 0/7/10
BASFI	Y/N/Miss: 0/8/9	Y/N/Miss: 0/7/10	Y/N/Miss: 0/7/10	Y/N/Miss: 0/7/10	Y/N/Miss: 0/7/10
BILAG-2004P	Y/N/Miss: 0/8/9	Y/N/Miss: 0/7/10	Y/N/Miss: 0/7/10	Y/N/Miss: 1/6/10	Y/N/Miss: 0/7/10
CDAI	Y/N/Miss: 2/6/9	Y/N/Miss: 0/7/10	Y/N/Miss: 1/6/10	Y/N/Miss: 0/7/10	Y/N/Miss: 0/7/10
DAPSA	Y/N/Miss: 0/8/9	Y/N/Miss: 3/4/10	Y/N/Miss: 0/7/10	Y/N/Miss: 0/7/10	Y/N/Miss: 0/7/10
DAS28-CRP3	Y/N/Miss: 6/2/9	Y/N/Miss: 3/4/10	Y/N/Miss: 4/3/10	Y/N/Miss: 0/7/10	Y/N/Miss: 0/7/10
DAS28-CRP	Y/N/Miss: 2/6/9	Y/N/Miss: 1/6/10	Y/N/Miss: 1/6/10	Y/N/Miss: 0/7/10	Y/N/Miss: 0/7/10

DAS28-ESR	Y/N/Miss: 1/7/9	Y/N/Miss: 1/6/10	Y/N/Miss: 0/7/10	Y/N/Miss: 0/7/10	Y/N/Miss: 0/7/10
ECLAM	Y/N/Miss: 0/8/9	Y/N/Miss: 0/7/10	Y/N/Miss: 0/7/10	Y/N/Miss: 0/7/10	Y/N/Miss: 0/7/10
Enthesitis	Y/N/Miss: 0/8/9	Y/N/Miss: 2/5/10	Y/N/Miss: 0/7/10	Y/N/Miss: 0/7/10	Y/N/Miss: 0/7/10
Global Antiphopholipid Syndrome Score (GAPSS)	Y/N/Miss: 0/8/9	Y/N/Miss: 0/7/10	Y/N/Miss: 0/7/10	Y/N/Miss: 2/5/10	Y/N/Miss: 2/5/10
Generic RAID	Y/N/Miss: 1/7/9	Y/N/Miss: 1/6/10	Y/N/Miss: 1/6/10	Y/N/Miss: 1/7/9	Y/N/Miss: 1/7/9
Involvement of nails/skin	Y/N/Miss: 0/8/9	Y/N/Miss: 3/4/10	Y/N/Miss: 0/7/10	Y/N/Miss: 0/7/10	Y/N/Miss: 0/7/10
LAI	Y/N/Miss: 0/8/9	Y/N/Miss: 0/7/10	Y/N/Miss: 0/7/10	Y/N/Miss: 0/7/10	Y/N/Miss: 0/7/10
LAI-P	Y/N/Miss: 0/8/9	Y/N/Miss: 0/7/10	Y/N/Miss: 0/7/10	Y/N/Miss: 3/4/10	Y/N/Miss: 0/7/10
m-ECLAM	Y/N/Miss: 0/8/9	Y/N/Miss: 0/7/10	Y/N/Miss: 0/7/10	Y/N/Miss: 1/6/10	Y/N/Miss: 0/7/10
m-LAI	Y/N/Miss: 0/8/9	Y/N/Miss: 0/7/10	Y/N/Miss: 0/7/10	Y/N/Miss: 0/7/10	Y/N/Miss: 0/7/10
Morning stiffness	Y/N/Miss: 1/7/9	Y/N/Miss: 1/6/10	Y/N/Miss: 1/6/10	Y/N/Miss: 0/7/10	Y/N/Miss: 0/7/10
m-SLAM	Y/N/Miss: 0/8/9	Y/N/Miss: 0/7/10	Y/N/Miss: 0/7/10	Y/N/Miss: 1/6/10	Y/N/Miss: 0/7/10
PASI	Y/N/Miss: 0/8/9	Y/N/Miss: 2/5/10	Y/N/Miss: 0/7/10	Y/N/Miss: 0/7/10	Y/N/Miss: 0/7/10
RADAI	Y/N/Miss: 1/7/9	Y/N/Miss: 0/7/10	Y/N/Miss: 0/7/10	Y/N/Miss: 0/7/10	Y/N/Miss: 0/7/10
RAID	Y/N/Miss: 0/8/9	Y/N/Miss: 0/7/10	Y/N/Miss: 0/7/10	Y/N/Miss: 0/7/10	Y/N/Miss: 0/7/10
SDAI	Y/N/Miss: 0/8/9	Y/N/Miss: 0/7/10	Y/N/Miss: 1/6/10	Y/N/Miss: 0/7/10	Y/N/Miss: 0/7/10
SELENA SLEDAI	Y/N/Miss: 0/8/9	Y/N/Miss: 0/7/10	Y/N/Miss: 0/7/10	Y/N/Miss: 3/4/10	Y/N/Miss: 0/7/10
SLAM	Y/N/Miss: 0/8/9	Y/N/Miss: 0/7/10	Y/N/Miss: 0/7/10	Y/N/Miss: 0/7/10	Y/N/Miss: 0/7/10
SLEDAI	Y/N/Miss: 0/8/9	Y/N/Miss: 0/7/10	Y/N/Miss: 0/7/10	Y/N/Miss: 4/3/10	Y/N/Miss: 0/7/10
SLEPDAI	Y/N/Miss: 0/8/9	Y/N/Miss: 0/7/10	Y/N/Miss: 0/7/10	Y/N/Miss: 5/3/9	Y/N/Miss: 0/8/9
SLICC ACR Damage	Y/N/Miss: 0/8/9	Y/N/Miss: 0/7/10	Y/N/Miss: 0/7/10	Y/N/Miss: 5/2/10	Y/N/Miss: 1/6/10
Dermatologic manifestations	Y/N/Miss: 0/8/9	Y/N/Miss: 3/4/10	Y/N/Miss: 1/6/10	Y/N/Miss: 3/4/10	Y/N/Miss: 2/5/10
Erosions	Y/N/Miss: 3/5/9	Y/N/Miss: 3/4/10	Y/N/Miss: 3/4/10	Y/N/Miss: 0/7/10	Y/N/Miss: 0/7/10
Surgery for the articular disease	Y/N/Miss: 3/5/9	Y/N/Miss: 3/4/10	Y/N/Miss: 3/4/10	Y/N/Miss: 1/6/10	Y/N/Miss: 0/7/10
Uveitis	Y/N/Miss: 0/8/9	Y/N/Miss: 3/4/10	Y/N/Miss: 2/6/9	Y/N/Miss: 0/7/10	Y/N/Miss: 0/7/10

Results highlighted in red are added to the additional item list. Y/N/Miss: Y= Number of members voting Yes for inclusion / N= Number of members voting No for inclusion / Miss=Number of members not voting for the item according to their expertise.

Table 6: Definitions of obstetric terminology.

Term	Definition	Reference
Perinatal period	Commences at 22 completed weeks (154 days) of gestation and ends seven completed days after birth.	WHO: Neonatal and Perinatal Mortality (7)
Neonatal period	Begins with birth and ends 28 complete days after birth.	WHO: Neonatal and Perinatal Mortality (7)
Elective termination	Termination of pregnancy (induced abortion, elective abortion): Artificial interruption of pregnancy for any reason.	EMA GVP Guideline: Pregnant and breastfeeding women (10)
Foetal death	Death prior to complete expulsion or extraction from the mother of a foetus, irrespective of the duration of pregnancy. Also referred to as intrauterine death or in utero death.	EMA GVP Guideline: Pregnant and breastfeeding women (10)
Miscarriage	Spontaneous abortion and molar pregnancy. A miscarriage is the loss of pregnancy from natural causes before the 20th week of pregnancy.	EMA GVP Guideline: Pregnant and breastfeeding women (10) ICD-10 O03
Stillbirth	Death prior to the complete expulsion or extraction from its mother of a product of conception, irrespective of the duration of pregnancy; the death is indicated by the fact that after such separation the foetus does not breathe or show any other evidence of life.	WHO: Neonatal and Perinatal Mortality (7) ICD-10 P95
Live birth	The complete expulsion or extraction from its mother of a product of conception, irrespective of the duration of the pregnancy, which, after such separation, breathes or shows any other evidence of life.	WHO: Neonatal and Perinatal Mortality (7)
Preterm infants / preterm birth	28 completed weeks or more but less than 37 completed weeks (196 completed days but less than 259 completed days) of gestation.	ICD-10 P07.3
Extreme immaturity	Less than 28 completed weeks (less than 196 completed days) of gestation.	ICD-10 P07.2
Gestational age, gestational week, week of gestation	Measure of the age of a pregnancy calculated from the first day of a woman's last menstrual period or as estimated by a more accurate method such as ultrasound. Gestational age is indicated in weeks and days, eg. 39 weeks and 0 days. Calculation using the best obstetrical estimated due date (EDD) is based on the following formula: Gestational Age = (280 - (EDD - Reference Date))/ 7 (Reference Date: Date on which you are trying to determine gestational age)	EMA GVP Guidline: Pregnant and breastfeeding women (10) American College of Obstetricians and Gynecologists - Obstetric Data Definitions (1)
EDD / Estimated due date	The Estimated Due Date is determined by: Last menstrual period if confirmed by early ultrasound or no ultrasound performed, or early ultrasound if no known last menstrual period or the ultrasound is not consistent with last menstrual period, or	American College of Obstetricians and Gynecologists - Obstetric Data Definitions (1)

	known date of fertilization (eg, assisted reproductive technology)	

References

1. American College of Obstetricians and Gynecologists: Obstetric Data Definitions. Access day: 11/08/2020 [Available from: https://www.acog.org/practice-management/health-it-and-clinical-informatics/revitalize-obstetrics-data-definitions.
2. World Health Organization. Birth defects surveillance: A mannual for programme managers. ISBN 9789241548724. 2014.
3. EUROCAT Network Access day: 11/08/2020 [Available from: http://www.eurocat-network.eu/.
4. World Health Organiszation. WHO Recommendations for prevention and treatment of pre-eclampsia and eclampsia. ISBN: 9789241548335 2011 [
5. Zegers-Hochschild F, Adamson GD, de Mouzon J, Ishihara O, Mansour R, Nygren K, Sullivan E, Vanderpoel S, International Committee for Monitoring Assisted Reproductive T, World Health O. International Committee for Monitoring Assisted Reproductive Technology (ICMART) and the World Health Organization (WHO) revised glossary of ART terminology, 2009. Fertil Steril. 2009;92(5):1520-4.
6. ICH Guideline. Clinical safety data management: Definitions and standards for expedited reporting E2A Access day: 11/08/2020 [Available from: https://database.ich.org/sites/default/files/E2A_Guideline.pdf.
7. World Health Organization. Neonatal and Perinatal Mortality: Country, Regional and Global Estimates. ISBN 9789241563208. 2006.
8. Caughey AB, Robinson JN, Norwitz ER. Contemporary diagnosis and management of preterm premature rupture of membranes. Rev Obstet Gynecol. 2008;1(1):11-22.
9. Torloni MR, Betran AP, Souza JP, Widmer M, Allen T, Gulmezoglu M, Merialdi M. Classifications for cesarean section: a systematic review. PLoS One. 2011;6(1):e14566.
10. European Medicines Agency. Guideline on good pharmacovigilance practices (GVP) Product- or Population-Specific Considerations III: Pregnant and breastfeeding women. (EMA/653036/2019 DRAFT FOR PUBLIC CONSULTATION). 4.12.2019.

Supplement

Systematic literature review

The literature review in Pubmed focused on

(I) published literature on pregnancy and rheumatic diseases and

(II) on already published core data sets focussing on pregnancy and related issues.

Search terms for literature review (I):

#8,"Search ((((((((((((pregnan[Title]) OR birth[Title]) OR preterm[Title]) OR premature[Title]) OR foetal[Title]) OR matern*[Title]) OR labour[Title]) OR partum*[Title]) OR natal*[Title]) OR prepregnan*[Title])))) AND ((((((((((((((((((rheumatism[Title]) OR rheumatoid[Title]) OR rheumatic[Title]) OR arthritis[Title]) OR ankylosing[Title]) OR spondyloarthritis[Title]) OR lupus[Title]) OR sle[Title]) OR connective tissue[Title]) OR antiphospholipid[Title]) OR sjogren[Title]) OR myositis[Title]) OR scleroderma[Title]) OR vasculitis[Title]) OR behcet[Title]) OR polymyositis[Title]) OR dermatomyositis[Title])))) AND (((((((((observational[Title/Abstract]) OR prospective[Title/Abstract])))) AND cohort[Title/Abstract])) OR (((register[Title/Abstract]) OR registry[Title/Abstract])))",82,08:27:47*

#7,"Search (((((((observational[Title/Abstract]) OR prospective[Title/Abstract])))) AND cohort[Title/Abstract])) OR (((register[Title/Abstract]) OR registry[Title/Abstract]))",236495,08:27:34

#6,"Search (((((observational[Title/Abstract]) OR prospective[Title/Abstract])))) AND cohort[Title/Abstract]",104397,08:27:24

#5,"Search cohort[Title/Abstract]",424366,08:27:12

#4,"Search (((observational[Title/Abstract]) OR prospective[Title/Abstract])",589828,08:27:00

#3,"Search ((register[Title/Abstract]) OR registry[Title/Abstract])",137346,08:26:31

#2,"Search ((((((((((((((((((rheumatism[Title]) OR rheumatoid[Title]) OR rheumatic[Title]) OR arthritis[Title]) OR ankylosing[Title]) OR spondyloarthritis[Title]) OR lupus[Title]) OR sle[Title]) OR connective tissue[Title]) OR antiphospholipid[Title]) OR sjogren[Title]) OR myositis[Title]) OR scleroderma[Title]) OR vasculitis[Title]) OR behcet[Title]) OR polymyositis[Title]) OR dermatomyositis[Title])",232042,08:26:09

#1,"Search ((((((((((pregnan[Title]) OR birth[Title]) OR preterm[Title]) OR premature[Title]) OR foetal[Title]) OR matern*[Title]) OR labour[Title]) OR partum*[Title]) OR natal*[Title]) OR prepregnan*[Title])",455429,08:20:50*

We considered multicentric observational cohort or register studies reporting on pregnancy outcomes in women with inflammatory rheumatic diseases. Out of the 82 search results, data from 21 publications have been extracted.

Search terms for literature review (II):

#3,"Search (((((((((core data[Title]) OR core set[Title]) OR core outcome[Title]) OR core domain[Title]) OR minimal data[Title]) OR minimum data[Title]) OR template[Title])))) AND ((((((((((pregnan[Title]) OR birth[Title]) OR preterm[Title]) OR premature[Title]) OR foetal[Title]) OR matern*[Title]) OR labour[Title]) OR partum*[Title]) OR natal*[Title]) OR prepregnan*[Title]))",32,07:59:27*

#2,"Search ((((((((((pregnan[Title]) OR birth[Title]) OR preterm[Title]) OR premature[Title]) OR foetal[Title]) OR matern*[Title]) OR labour[Title]) OR partum*[Title]) OR natal*[Title]) OR prepregnan*[Title])",455429,07:59:18*

#1,"Search (((((((core data[Title]) OR core set[Title]) OR core outcome[Title]) OR core domain[Title]) OR minimal data[Title]) OR minimum data[Title]) OR template[Title])",9058,07:59:04

Recommended data items of 8 published core data sets (out of 32 search results) have been extracted.

Table 1: Countries of residence for participants completing round 1 and 2 of the Delphi survey.

Country of residence	Number of participants	Proportion
Germany	16	25%
France	7	11%
Norway	7	11%
UK	6	9%
Switzerland	5	8%
Hungary	4	6%
Spain	4	6%
Austria	3	5%
Denmark	3	5%
Italy	3	5%
The Netherlands	3	5%
Czech Republic	1	2%
Sweden	1	2%
Turkey	1	2%

Meissner Y, *et al. Ann Rheum Dis* 2020;0:1–8. doi: 10.1136/annrheumdis-2020-218356

Table 2: Suggestions of new data items by participants of Delphi round 1 sorted by core area.

No.	Suggested additional items by Delphi participants (Number of data item suggestion is given in bracket; (F)=item was suggested in a comment/as feedback)	Results of the discussion with selected task force members	Inclusion in Delphi round 2	Name of added item
	MATERNAL INFORMATION: Demographics			
1	Advice country instead of county and postcode (refers to data item 2, Area of maternal residence) (F)	This suggestion focuses on how to collect a data item, which is not the purpose of this Delphi round.	No	
2	Drug use by patient (F)	The recording of drug use by patients might be too unreliable.	No	
3	For mixed ethnicities need to homogenize the definitions (refers to data item 3, Maternal race) (F)	This suggestion focuses on how to collect a data item, which is not the purpose of this Delphi round.	No	
4	Work before; during and after pregnancy should be scored very precisely with start and stop and changes in work (39)	This is beyond the purpose of this core data set. Core data set focuses on data collection during pregnancy, not before or thereafter.	No	
	MATERNAL INFORMATION: Disease characteristics of the inflammatory rheumatic disease (IRD)			
5	Date of symptom onset (F)	Date of diagnosis (item 16) was thought to be sufficient	No	
6	Duration of flares during the first year postpartum and change of medication are of interest for future counselling (41)	The core data set focuses on data collection during pregnancy including the outcome of pregnancy, not before or postpartum.	No	
7	Flares in the year before the pregnancy; during and after pregnancy during the first 3 months; 3-6 months; 6-12 months (40)	The core data set focuses on data collection during pregnancy including the outcome of pregnancy, not before or postpartum.	No	
	MATERNAL INFORMATION: Patient reported outcomes			
8	Impact of IRD on working life (F)	This is beyond the purpose of this core data set.	No	
9	Use a more concrete definition of particular aspects of mental health that can be assessed with specific instruments. / what time point? at conception/during pregnancy? / please explore more easy reproducable question e.g depression scale 0-10; anxiety for RA and pregnancy score 0-10 etc (F)	This is beyond the purpose of this core data set.	No	
	MATERNAL INFORMATION: Serologic profile			

10	Positivity for ENA profile (7), Anti-Ro/SS-A (14), anti-SSA/SSB (F)	See item 31, going into detail is difficult as this is supposed to be a core data set for several IRDs	No	
11	SS-A or SS-B antibodies (30)	See item 31, going into detail is difficult as this is supposed to be a core data set for several IRDs	No	
12	Thrombophilia other than aPL antibodies (17)	See item 31, going into detail is difficult as this is supposed to be a core data set for several IRDs	No	
13	Use of pregnancy specific disease activity score where available (23)	This suggestion focuses on how to collect a data item, which is not the purpose of this Delphi round.	No	
	MATERNAL INFORMATION: Comorbidities, adverse events and death			
14	Comorbidity: Coeliac disease (F)	This is beyond the purpose of this core data set.	No	
15	Comorbidity: Secondary Sjogren's syndrome (F)	This is beyond the purpose of this core data set.	No	
16	Data item 58 / Comorbidity: Thrombosis - Add: during oral anticontraceptives (yes/no), after trauma etc. (F)	This is beyond the purpose of this core data set.	No	
17	Data item 59 / Comorbidity: Documentation of any other comorbidity - Add: gynecologic comorbidities (e.g. myoma; cervical insufficiency) / history of cancer; cardiovascular disease (MI; pulmonary arterial hypertension); lung disease (fibrosis). (F)	This is beyond the purpose of this core data set.	No	
18	Maternal inherited disorder (15)	This is beyond the purpose of this core data set.	No	
19	Results of renal biopsy (44)	This is beyond the purpose of this core data set.	No	
	PREGNANCY: Information about previous pregnancies			
20	Cause of previous neonatal death(s) (F)	This is beyond the purpose of this core data set.	No	
21	Gestational age at birth (F)	Item will be added to Delphi round 2	Yes	Gestational age birth(s)
22	Reasons for induced abortion(s) (F)	This is beyond the purpose of this core data set.	No	
23	Number of spontaneous abortions (F)	Item will be added to Delphi round 2	Yes	Number of spontaneous abortions

	PREGNANCY: Information about the current pregnancy			
24	A question about the year of counselling; what the general conclusion was of the counselling; change in medication needed?; information of influence of RA on pregnancy complications and pregnancy on RA during and after pregnancy understood; low threshold to inform complications of RA and pregnancy during this period and no waiting until next appointment; breastfeeding in combination with the prescribed medication; summarizing can we describe what items we discuss during prepregnancy counselling;(38)	Information about dates (e.g. year) should generally be available and included when collecting data prospectively. Consequences of the counselling were thought not to be important for this common core data set.	No	
25	Discussion of breastfeeding in pregnancy (25)	There will be differences in countries and cultures, and results would not be reliable.	No	
26	Fetal ultrasound with Doppler velocimetry of uterine arteries and umbilical arteries (normal vs abnormal) (20)	This is too complicated for a common core data set.	No	
27	History of vaccination during pregnancy (2)	This is beyond the purpose of this core data set.	No	
28	Method of assisted reproduction (F)		No	
29	Mother preeclampsia; Eclampsia; HELLP syndrome (34)	This is beyond the purpose of this core data set.	No	
30	Pre-pregnancy counselling by a rheumatologist and/or a gynaecologist (29)	The core data set focuses on the rheumatologic perspective.	No	
31	Pre-pregnancy counselling by obstetrician (F)	The core data set focuses on the rheumatologic perspective.	No	
32	Result of assisted reproduction (18)	As this core data set focuses on pregnant women, the result of the reproduction is known.	No	
33	sFlt-1/PLGF ratio (46)	This is beyond the purpose of this core data set.	No	
34	Sister preeclampsia; eclampsia; HELLP syndrome (35)	This is beyond the purpose of this core data set.	No	
35	Term date of current pregnancy as estimated by ultrasound during the first trimester of pregnancy (at 10-13 weeks) (36)	To our opinion the gestational age of the patient is important irrespective of the method used for calculation.	No	
	PREGNANCY: Delivery			
36	Administration of pain relief medication (F)	This is beyond the purpose of this core data set.	No	
37	In case of labour induction: Indication for labour induction (F)	This is beyond the purpose of this core data set.	No	

38	Placental weight (delivery ward) (45)	This is beyond the purpose of this core data set.	No	
	PREGNANCY: Infant outcomes			
39	Counselling on breastfeeding by obstetrician/ lactation expert (F)	This is beyond the purpose of this core data set.	No	
40	Duration of infant hospital admission (F)	This is beyond the purpose of this core data set.	No	
41	Infections of neonates (31)	The item will be added.	Yes	Serious infection of neonate
42	Neonatal lupus (apart from CHB); eg skin rash (19)	To our opinion difficult to obtain as the core data set focuses on data collection during pregnancy including the outcome of pregnancy, not before or postpartum.	No	
43	Occurrence of neonatal lupus (25)	In our opinion difficult to obtain as the core data set focuses on data collection during pregnancy including the outcome of pregnancy, not before or postpartum.	No	
44	There is nothing on the child (1)	Infant outcomes are addressed by items 103 to 116.	No	
	TREATMENT: DMARD treatment during pregnancy			
45	Increase of DMARD therapy during pregnancy (F)	If dose and application interval are reported at several time points, it will be possible to calculate a DMARD increase	No	
	MEDICATION: Treatment with oral glucocorticoids during pregnancy			
46	Increase of oral glucocorticoid therapy during pregnancy (F)	If dose and application interval are reported at several time points, it will be possible to calculate a glucocorticoid increase	No	
	MEDICATION: Treatment with intraarticular glucocorticoids during pregnancy			
47	Date or gestational age intraarticular glucocorticoid administration (F)	In case of prospective data collection, a date should be recorded.	No	
	MEDICATION: Treatment of other health conditions during pregnancy			

48	(Inadvertent) use of a teratogen or major fetotoxicant (e.g. RAS-I after GW 20) during pregnancy (5)	Item is of high interest, but will not be added as additional item to the core data set voting. Background: It is difficult to add this item when no list is provided that explicitly defines the names of teratogens/fetotoxic medication. However, one of the data items in the Delphi list is called 'Treatment with any prescription medicine'. That gives the possibility to indicate substances except the ones requested by names (e.g. DMARDs)	No	
49	Frequency / dosage and trimester or gestational weeks (GW) of NSAID usage (4)	NSAID usage, start and stop dates will be added, but not dosage.	(Yes)	Start and stop dates of NSAID treatment
50	Prophylactic or therapeutic treatment with folic acid (F)	This is beyond the purpose of this core data set.	No	
51	Start and stop dates of aspirin (F)	This is beyond the purpose of this core data set.	No	
52	Start and stop dates of folic acid (F)	This is beyond the purpose of this core data set.	No	
53	Use of NSAID during pregnancy (3)	The item will be added, and additionaly start and stop dates.	Yes	Use of NSAID
54	Which antihypertensive drug; moment of starting; augmenting one drug or more drugs (F)		No	
	OTHERS			
55	Breastfeeding post-partum (26)	The core data set focuses on data collection during pregnancy including the outcome of pregnancy, not before or postpartum.	No	
56	Children's follow-up at least in the first year of life with special attention on vaccinations; severe illnesses requiring hospitalization (23)	The core data set focuses on data collection during pregnancy including the outcome of pregnancy, not before or postpartum.	No	
57	Development of the newborn in the first two (or better 10) years of life (42)	The core data set focuses on data collection during pregnancy including the outcome of pregnancy, not before or postpartum.	No	
58	Discussion of subsequent contraception (28)	The core data set focuses on data collection during pregnancy including the outcome of pregnancy, not before or postpartum.	No	

59	Paternal age (9) + (12)	This is beyond the purpose of this core data set.	No	
60	Paternal inherited disorder (16)	This is beyond the purpose of this core data set.	No	
61	Paternal medication (8) +(11)	This is beyond the purpose of this core data set.	No	
62	Paternal use of antirheumatic drugs 12 months before and at conception (43)	This is beyond the purpose of this core data set.	No	
63	Postpartum disease activity over 3-12 months (21)	The core data set focuses on data collection during pregnancy including the outcome of pregnancy, not before or postpartum.	No	
64	Postpartum flare of disease (32)	The core data set focuses on data collection during pregnancy including the outcome of pregnancy, not before or postpartum.	No	
65	Postpartum medical treatment (33)	The core data set focuses on data collection during pregnancy including the outcome of pregnancy, not before or postpartum.	No	
66	Presence of Combined Outpatients Clinic (obstetrician+rheumatologist) (6)	This is beyond the purpose of this core data set.	No	
67	Rheumatologist and obstetrical team; in 1 clinic with regular contact; in more than 1 clinic and regular contact; in 1/2 clinics with no regular contact; something like this to evaluate whether close collaboration is useful; if this is applicable in this population of doctors who are going to gather these data; if they are only collaborators in 1 clinic with regular contacts it is superfluous (37)	This is beyond the purpose of this core data set.	No	
68	Use of medications in breastfeeding (27)	The core data set focuses on data collection during pregnancy including the outcome of pregnancy, not before or postpartum.	No	
69	Visit to the rheumatologist at least once each trimester? (10) + (13)	The core data set focuses on data collection during pregnancy including the outcome of pregnancy, not before or postpartum.	No	

Table 3: Results of Delphi votings round 1 and 2, of the F2F task force meeting, of their decisions and of the categorisation as well as comments/ explanations of the task force.

Data item		Results of Delphi round 1				Results of Delphi round 2				Results of F2F voting		Decisions of Delphi round 2	Decisions of F2F voting	Final core data set	Decisions of the task force
No.	Name	Score 1 to 3 (%)	Score 4 to 6 (%)	Score 7 to 9 (%)	*Unable to score (No. of experts)*	Score 1 to 3 (%)	Score 4 to 6 (%)	Score 7 to 9 (%)	*Unable to score (No. of experts)*	Yes/ Voting into the Core Data Set (No. of experts)	No / Voting out of the Core Data Set (No. of experts)				
MATERNAL INFORMATION: Demographics															
1	Maternal age at conception	0	5	95	*1*	0	2	98	*0*	-	-	**IN**	**IN**	**M [1]**	Renamed to "Age"
2	Area of actual maternal residence	32	54	14	*0*	41	58	2	*0*	0	16	**EQUIV.**	**OUT**	-	
3	Maternal race / ethnicity	6	46	48	*0*	6	55	39	*0*	6	10	**EQUIV.**	**OUT**	-	
4	Maternal body height	8	30	62	*0*	9	22	69	*0*	14	2	**EQUIV.**	**IN**	**M [2]**	Renamed to "Height"
5	Maternal body weight	2	27	71	*0*	2	13	86	*0*	-	-	**IN**	**IN**	**M [3]**	Renamed to "Weight"
6	Maternal marital / family status	32	62	6	*0*	44	55	2	*0*	0	16	**EQUIV.**	**OUT**	-	
7	Household income	32	63	5	*0*	48	48	3	*0*	1	15	**EQUIV.**	**OUT**	-	
8	Educational level of the patient	10	62	29	*0*	13	73	14	*0*	12	4	**EQUIV.**	**IN**	**M [4]**	Renamed to "Educational level"
9	Professional training of the patient	38	46	16	*0*	61	38	2	*0*	2	14	**EQUIV.**	**OUT**	-	
10	Maternal employment / work situation	19	60	21	*0*	27	64	9	*0*	4	12	**EQUIV.**	**OUT**	-	
11	Maternal sick leave	29	52	19	*0*	45	48	6	*0*	2	14	**EQUIV.**	**OUT**	-	
12	Alcohol consumption during pregnancy	2	17	81	*0*	0	9	91	*0*	-	-	**IN**	**IN**	**M [5]**	
13	Smoking during pregnancy	0	6	94	*0*	0	3	97	*0*	-	-	**IN**	**IN**	**M [6]**	
MATERNAL INFORMATION: Disease characteristics of the inflammatory rheumatic disease (IRD)															
14	Diagnosis of the inflammatory rheumatic disease	0	0	100	*1*	0	0	100	*1*	-	-	**IN**	**IN**	**M [7]**	Renamed to "IRD diagnosis"

15	Indication of the individual fulfilled classification criteria of the inflammatory rheumatic disease	0	37	63	*1*	0	24	76	*1*	-	-	**IN**	**IN**	**M [8]**	Renamed to "Classification criteria"
16	Date of diagnosis of the inflammatory rheumatic disease	3	15	82	*1*	0	13	87	*2*	-	-	**IN**	**IN**	**M [9]**	Renamed to "Disease duration"
17	Prior important manifestations of the inflammatory rheumatic disease	2	33	65	*0*	0	29	71	*1*	-	-	**IN**	**OUT**	-	Exclusion of item. Reason: Manifestations must be defined per IRD. Since severity (No. 18) and comorbidities are covered (No. 153), manifestations are not of that great importance.
18	Severity of the inflammatory rheumatic disease reported by the physician	3	15	82	*1*	2	6	92	*2*	-	-	**IN**	**IN**	**M [10]**	Renamed to "Physician reported IRD severity"
19	Flares of the inflammatory rheumatic disease during pregnancy	0	5	95	*0*	0	3	97	*1*	-	-	**IN**	**IN**	**M [12]**	Renamed to "Physician reported flares"
20	Disease activity of the inflammatory rheumatic disease reported by the physician	3	10	87	*0*	2	6	92	*1*	-	-	**IN**	**IN**	**M [13]**	Renamed to "Physician reported disease activity"
21	Disease activity estimated with appropriate score	0	8	92	*1*	0	5	95	*1*	-	-	**IN**	**IN**	**M [14]**	Renamed to "Disease activity by score"
Patient reported outcomes															
22	Disease activity of the inflammatory rheumatic disease	2	18	81	*1*	0	14	86	*1*	-	-	**IN**	**IN**	**M [16]**	Renamed to "Patient reported disease activity"
23	Fatigue	11	54	35	*0*	19	67	14	*1*	0	16	**EQUIV.**	**OUT**	-	
24	Global health	5	44	52	*1*	8	56	37	*1*	13	3	**EQUIV.**	**IN**	**M [17]**	Renamed to "Patient reported global health"
25	Health related quality of life	2	48	51	*0*	9	45	45	*0*	4	12	**EQUIV.**	**OUT**	-	
26	Impact of the inflammatory rheumatic disease on family life	19	53	27	*1*	27	66	8	*0*	0	16	**EQUIV.**	**OUT**	-	
27	Mental health	10	59	32	*0*	11	70	19	*0*	0	16	**EQUIV.**	**OUT**	-	
28	Pain	8	32	60	*0*	8	23	69	*0*	2	14	**EQUIV.**	**OUT**	-	
29	Physical function	6	35	59	*0*	8	27	65	*1*	4	12	**EQUIV.**	**OUT**	-	

30	Severity of the inflammatory rheumatic disease	10	31	60	*1*	8	18	74	*2*	-	-	**IN**	**OUT**	-	Exclusion of item. Reason: The task force decided that IRD severity should be judged by the physician. Furthermore, it might have been difficult for some Delphi participants to differentiate between physician and patient reported severity.
Serologic profile															
31	Disease-specific auto-antibodies of the inflammatory rheumatic disease	0	5	95	*1*	0	2	98	*2*	-	-	**IN**	**IN**	**M [11]**	Renamed to "Auto-antibodies"
32	Antiphospholipid antibodies	2	5	94	*1*	2	0	98	*1*	-	-	**IN**	**OUT**	-	This item is disease-specific and was part of a 3rd voting including all task force members.
Laboratory markers															
33	Alanine aminotransferase (ALAT)	17	40	43	*3*	20	51	30	*3*	1	15	**EQUIV.**	**OUT**	-	
34	Alkaline phosphatase (ALP)	20	48	32	*3*	30	52	18	*3*	0	16	**EQUIV.**	**OUT**	-	
35	Blood glucose	18	35	47	*3*	18	39	43	*3*	1	15	**EQUIV.**	**OUT**	-	
36	Complement components	3	20	76	*4*	3	15	82	*4*	-	-	**IN**	**OUT**	-	This item is disease-specific and was part of a 3rd voting including all task force members.
37	C-reactive protein (CRP)	7	13	80	*2*	5	11	84	*2*	-	-	**IN**	**IN**	**M [15]**	
38	Creatinine	7	20	73	*3*	5	15	80	*3*	-	-	**IN**	**OUT**	-	Exclusion of item. Reason: Renal diseases will be covered as comorbidity. It is not expected that creatinine levels will provide additional information for research purposes.
39	dsDNA antibodies	3	22	74	*5*	2	12	86	*5*	-	-	**IN**	**OUT**	-	This item is disease-specific and was part of a 3rd voting including all task force members.

40	Erythrocyte sedimentation rate (ESR)	28	31	41	*5*	39	25	36	*5*	0	16	**EQUIV.**	**OUT**	-	
41	Glomerular filtration rate (GFR)	8	32	59	*4*	10	30	61	*3*	1	15	**EQUIV.**	**OUT**	-	
42	Haemoglobin	7	27	67	*3*	3	26	70	*3*	-	-	**IN**	**OUT**	-	Exclusion of item. Reason: Haemoglobin levels are important for the individual pregnancy, but the task force does not expect additional benefit regarding research questions.
43	HbA1c (Glycated haemoglobin)	8	58	33	*3*	13	64	23	*3*	1	15	**EQUIV.**	**OUT**	-	
44	Leucocytes	12	33	55	*3*	13	34	52	*3*	0	16	**EQUIV.**	**OUT**	-	
45	Lymphocytes	15	48	37	*3*	21	48	31	*3*	2	14	**EQUIV.**	**OUT**	-	
46	Results of a clinical urinalysis	8	23	68	*3*	7	15	79	*3*	-	-	**IN**	**OUT**	-	Exclusion of item. Reason: Urinalysis is important for the individual pregnancy, but additional benefit regarding research questions is not expected.
47	Thrombocytes	7	32	62	*3*	7	28	66	*3*	3	13	**EQUIV.**	**OUT**	-	
48	Transaminase	14	39	47	*4*	15	41	44	*3*	1	15	**EQUIV.**	**OUT**	-	
49	Uric acid	20	50	30	*3*	23	59	18	*3*	0	16	**EQUIV.**	**OUT**	-	
MATERNAL INFORMATION: Prevalent comorbidities															
50	Comorbidity: Antiphospholipid syndrome	0	2	98	*1*	0	0	100	*1*	-	-	**IN**	**IN**	**O**	Summary to main item No. 153 “Selected prevalent comorbidities”.
51	Comorbidity: Depression and mood disorder	3	38	59	*0*	2	45	53	*0*	4	12	**EQUIV.**	**OUT**	-	
52	Comorbidity: Diabetes mellitus	0	6	94	*1*	0	5	95	*1*	-	-	**IN**	**IN**	**O**	Summary to main item No. 153 “Selected prevalent comorbidities”.
53	Comorbidity: Arterial hypertension	0	13	87	*1*	0	3	97	*1*	-	-	**IN**	**IN**	**O**	Summary to main item No. 153 “Selected prevalent comorbidities”.
54	Comorbidity: Hypothyroidism	2	38	61	*2*	2	34	65	*2*	3	13	**EQUIV.**	**OUT**	-	
55	Comorbidity: Hyperthyroidism	2	36	62	*2*	0	35	65	*2*	4	12	**EQUIV.**	**OUT**	-	

56	Comorbidity: Other autoimmune diseases	0	30	70	*2*	0	21	79	*2*	-	-	**IN**	**OUT**	**-**	Exclusion of item. Reasons: From a research point of view, overlap syndromes would be of interest. Since this concerns only a small number of patients, it is not expected to get enough data for joint analysis. Still, it is recommended that individual registers collect information of other autoimmune comorbidities.
57	Comorbidity: Renal disease	0	8	92	*1*	0	3	97	*1*	-	-	**IN**	**IN**	**O**	Summary to main item No. 153 "Selected prevalent comorbidities".
58	Comorbidity: Previous thromboembolic events	0	10	90	*1*	0	5	95	*1*	-	-	**IN**	**IN**	**O**	Summary to main item No. 153 "Selected prevalent comorbidities".
59	Comorbidity: Documentation of any other comorbidity	5	42	53	*1*	5	38	57	*1*	0	16	**EQUIV.**	**OUT**	**-**	
153	Selected prevalent comorbidities	*Item was introduced as a main item*								-	-	-	**IN (New)**	**M [18]**	New main item as a summary of items No. 50, 52, 53, 57, 58.
PREGNANCY: Obstetrical history															
66	Number of previous pregnancies (gravidity)	0	17	83	*0*	0	19	81	*0*	-	-	**IN**	**IN**	**M [19]**	Renamed to "Gravidity"
67	Parity	2	14	84	*0*	0	13	88	*0*	-	-	**IN**	**IN**	**M [20]**	
68	Year(s) of conception of previous pregnancy(ies)	13	47	40	*1*	11	62	27	*1*	1	15	**EQUIV.**	**OUT**	**-**	
69	Previous Cesarean section(s)	6	48	46	*0*	3	55	42	*0*	7	9	**EQUIV.**	**OUT**	**-**	
70	Previous stillbirth(s)	0	8	92	*0*	0	0	100	*0*	-	-	**IN**	**IN**	**O**	Summary to main item No. 149 "Outcome of previous pregnancy(ies)"
149	Outcome of previous pregnancy(ies)	*Item was added at the face-to-face meeting*								-	-	-	**IN (New)**	**M [21]**	New main item as a summary of items No. 70, 78 and 79.

71	Previous induced abortion / elective termination of pregnancy(ies)	11	38	51	*0*	13	42	45	*0*	4	12	**EQUIV.**	**OUT**	**-**	
72	Previous neonatal death(s)	2	5	94	*0*	0	0	100	*0*	-	-	**IN**	**IN**	**M [23]**	Renamed to "Neonatal death(s)"
73	Previous pre-eclampsia , eclampsia or HELLP syndrome	0	13	87	*0*	0	2	98	*0*	-	-	**IN**	**IN**	**M [25]**	Renamed to "Hypertensive pregnancy disorders"
74	Previous preterm birth(s)	0	14	86	*0*	2	8	91	*0*	-	-	**IN**	**IN**	**M [22]**	Renamed to "Preterm birth(s)"
75	Gender of the child(ren)	29	45	26	*1*	35	43	22	*1*	0	16	**EQUIV.**	**OUT**	**-**	
76	Birth weight(s) of previous live birth(s)	13	32	56	*0*	9	38	53	*0*	5	11	**EQUIV.**	**OUT**	**-**	
77	Congenital anomalies of previous born infant(s)	2	27	71	*0*	0	20	80	*0*	-	-	**IN**	**IN**	**M [24]**	
78	Gestational age at birth	*Item was added to round 2*				5	23	72	*0*	-	-	**IN**	**IN**	**O**	Summary to main item No. 149 "Outcome of previous pregnancy(ies)"
79	Number of spontaneous abortions of previous pregnancies	*Item was added to round 2*				0	16	84	*0*	-	-	**IN**	**IN**	**O**	Summary to main item No. 149 "Outcome of previous pregnancy(ies)"
PREGNANCY: Course of current pregnancy															
80	Planned pregnancy	11	33	56	*0*	11	25	64	*0*	10	6	**EQUIV.**	**IN**	**M [26]**	
81	Preconception counselling by rheumatologist	8	41	51	*0*	9	45	45	*0*	7	9	**EQUIV.**	**OUT**	**-**	
82	Assisted reproduction	5	27	68	*0*	0	20	80	*0*	-	-	**IN**	**IN**	**M [27]**	
83	Estimated date of conception	5	24	71	*1*	8	17	75	*1*	-	-	**IN**	**IN**	**M [28]**	
84	Indication of singleton or multiple pregnancy	3	15	82	*1*	2	8	90	*1*	-	-	**IN**	**IN**	**M [29]**	
85	Arterial hypertension	2	10	89	*1*	2	0	98	*1*	-	-	**IN**	**IN**	**O**	Summary to main item No. 154 "Adverse events of interest"
86	Gestational diabetes	0	15	85	*1*	0	2	98	*1*	-	-	**IN**	**IN**	**O**	Summary to main item No. 154 "Adverse events of interest"
87	HELLP syndrome	0	5	95	*1*	0	0	100	*1*	-	-	**IN**	**IN**	**O**	Summary to main item No. 154 "Adverse events of interest"

88	Infections	0	15	85	*1*	0	10	90	*2*	-	-	**IN**	**OUT**	-	Exclusion of item. Reason: Only serious infections are of interest, which will be covered by item No. 61.
89	Intrauterine growth restriction (IUGR)	0	8	92	*1*	0	2	98	*1*	-	-	**IN**	**OUT**	-	Exclusion of item. Reason: The Task Force expects confusion with small for gestational age since this core set addresses primarily rheumatologists.
90	Pre-eclampsia or eclampsia	0	3	97	*1*	0	0	100	*1*	-	-	**IN**	**IN**	**O**	Summary to main item No. 154 "Adverse events of interest"
91	Premature contractions / premature labour	2	18	80	*2*	3	13	84	*2*	-	-	**IN**	**OUT**	-	Exclusion of item. Reason: Premature contractions do also occur in women without IRD and it is not expected to gain additional information from this item.
92	Thromboembolic events	0	3	97	*1*	0	2	98	*1*	-	-	**IN**	**IN**	**O**	Summary to main item No. 154 "Adverse events of interest"
154	Adverse events of interest	*Item was introduced as a main item*								-	-	-	**IN (New)**	**M [30]**	New main item as a summary of items No. 85, 86, 87, 90, 92
60	Maternal non-serious adverse event(s)	13	39	48	*2*	15	45	40	*2*	0	16	**EQUIV.**	**OUT**	-	
61	Maternal serious adverse event(s)	0	13	87	*1*	0	3	97	*1*	-	-	**IN**	**IN**	**M [31]**	Renamed to "Other serious adverse events"
62	Maternal admission to hospital	5	21	74	*2*	5	14	81	*1*	-	-	**IN**	**IN**	**O**	Operationalisation for main item No. 61
63	Maternal death	0	0	100	*0*	0	0	100	*0*	-	-	**IN**	**IN**	**O**	Operationalisation for main item No. 61
64	In case of maternal death: Date of death	2	8	90	*0*	2	2	97	*0*	-	-	**IN**	**OUT**	-	Exclusion of item. Reason: Information will be covered by item No. 61 "Other serious adverse

															events".
65	In case of maternal death: Cause of death	0	3	97	*0*	0	0	100	*0*	-	-	**IN**	**OUT**	**-**	Exclusion of item. Reason: Information will be covered by item No. 61 "Other serious adverse events".
PREGNANCY: Delivery / Outcome of the current pregnancy															
93	Live birth	0	3	97	*0*	0	0	100	*0*	-	-	**IN**	**IN**	**M [34]**	
94	Induced abortion / elective termination of pregnancy	2	8	90	*0*	2	0	98	*0*	-	-	**IN**	**IN**	**M [32]**	Renamed to "Elective termination"
95	In case of induced abortion/ elective termination: Reasons for termination of pregnancy	6	11	83	*0*	3	8	89	*0*	-	-	**IN**	**IN**	**O**	Operationalisation for main item No. 94
96	In case of induced abortion/ elective termination: Gestational age	6	16	78	*0*	3	14	83	*0*	-	-	**IN**	**IN**	**O**	Operationalisation for main item No. 94
97	Pregnancy loss	0	3	97	*0*	0	0	100	*1*	-	-	**IN**	**IN**	**M [33]**	Renamed to "Foetal death"
98	In case of pregnancy loss: Gestational age	3	3	94	*0*	0	2	98	*1*	-	-	**IN**	**IN**	**O**	Operationalisation for main item No. 97
99	Gestational age at birth	0	5	95	*0*	0	0	100	*0*	-	-	**IN**	**IN**	**M [35]**	
100	Mode of delivery	5	21	75	*0*	3	13	84	*0*	-	-	**IN**	**IN**	**M [37]**	
101	In case of Cesarean section: Reasons for the Cesarean section	6	27	67	*0*	6	17	77	*0*	-	-	**IN**	**IN**	**O**	Operationalisation for main item No. 100
102	Labour induction	14	38	48	*0*	9	48	42	*0*	3	13	**EQUIV.**	**OUT**	**-**	
103	Preterm premature rupture of membranes (PPROM)	6	40	54	*0*	6	42	52	*0*	12	4	**EQUIV.**	**IN**	**M [36]**	
104	Administration of epidural analgesia during childbirth	29	44	27	*0*	39	58	3	*0*	2	14	**EQUIV.**	**OUT**	**-**	
PREGNANCY: Neonatal outcomes															
105	Birth weight	0	6	94	*0*	0	3	97	*0*	-	-	**IN**	**IN**	**M [38]**	
106	Body height/length of the neonate at birth	13	18	69	*1*	11	20	69	*0*	2	14	**EQUIV.**	**OUT**	**-**	
107	Gender of the neonate	18	27	55	*1*	13	32	56	*1*	11	5	**EQUIV.**	**IN**	**M [39]**	
108	Apgar score	3	31	66	*1*	3	30	67	*0*	4	12	**EQUIV.**	**OUT**	**-**	
109	Breastfeeding of the neonate	3	33	63	*0*	5	30	66	*0*	15	1	**EQUIV.**	**IN**	**M [40]**	

110	Chromosome abnormalities	3	13	84	*2*	0	6	94	*0*	-	-	**IN**	**OUT**	-	Summary to main item No. 150 ”Congenital malformations”.
111	Congenital heart block	0	6	94	*0*	0	0	100	*0*	-	-	**IN**	**IN**	**M [41]**	
112	Hospital admission of the neonate	3	18	79	*1*	2	13	86	*1*	-	-	**IN**	**IN**	**O**	Operationalisation for main item No. 152
113	Major congenital malformations	0	5	95	*0*	0	0	100	*0*	-	-	**IN**	**OUT**	-	Summary to main item No. 150 ”Congenital malformations”.
114	Medical treatment of the neonate	3	27	69	*1*	3	17	79	*1*	-	-	**IN**	**OUT**	-	Exclusion of item. Reason: No additional benefit is expected for research purposes.
115	Minor congenital malformations	6	22	71	*0*	3	16	81	*0*	-	-	**IN**	**OUT**	-	Summary to main item No. 150 ”Congenital malformations”.
150	Congenital malformations	*Item was added at the face-to-face meeting*								-	-	-	**IN (New)**	**M [42]**	New main item as a summary of items No. 110, 113 and 115.
116	Neonatal death	0	3	97	*0*	0	0	100	*0*	-	-	**IN**	**IN**	**O**	Operationalisation for main item No. 152
117	In case of neonatal death: Date of death	3	8	89	*0*	2	9	89	*0*	-	-	**IN**	**OUT**	-	Exclusion of item. Reason: It will be covered by item No. 152 “Neonatal serious adverse events”.
118	In case of neonatal death: Cause of death	3	2	95	*0*	0	2	98	*0*	-	-	**IN**	**OUT**	-	Exclusion of item. Reason: It will be covered by item No. 152 “Neonatal serious adverse events”.
119	Serious infection of neonate	*Item was added to round 2*				0	6	94	*0*	-	-	**IN**	**OUT**	-	Exclusion of item. Reason: It will be covered by item No. 152 “Neonatal serious adverse events”.
152	Neonatal serious adverse events during the first 28 days of live	*Item was added at the face-to-face meeting*								-	-	-	**IN (New)**	**M [43]**	New main item as a summary of items No. 116-119.
MEDICATION: Treatment 12 months prior to conception															
120	Name(s) of DMARD(s)	0	10	90	*0*	0	2	98	*1*	-	-	**IN**	**IN**	**O**	Operationalisation for main item No. 155

121	Dose(s) and application interval(s) of DMARD(s)	6	37	57	*0*	6	40	54	*1*	2	14	**EQUIV.**	**OUT**	-	
122	Start and stop dates of DMARD(s)	2	27	71	*0*	0	22	78	*1*	-	-	**IN**	**IN**	**O**	Operationalisation for main item No. 155
155	DMARD use	*Item was introduced as a main item*								-	-	-	**IN (New)**	**M [44]**	New main item as a summary of items No. 120 and 121
123	Use of oral glucocorticoid(s)	0	16	84	*0*	0	11	89	*1*	-	-	**IN**	**IN**	**M [45]**	
124	Dose(s) and application interval(s) of oral glucocorticoid(s)	5	32	63	*0*	3	33	63	*1*	2	14	**EQUIV.**	**OUT**	-	
125	Use of potentially teratogenic medication	3	3	94	*0*	0	3	97	*1*	-	-	**IN**	**IN**	**M [46]**	
MEDICATION: IRD treatment during pregnancy															
Treatment with disease modifying anti-rheumatic drugs (DMARD)															
126	Name(s) of DMARD(s)	0	2	98	*0*	0	0	100	*1*	-	-	**IN**	**IN**	**O**	Operationalisation for main item No. 156
127	Dose(s) and application interval(s) of DMARD(s)	2	11	87	*0*	2	8	90	*1*	-	-	**IN**	**IN**	**O**	Operationalisation for main item No. 156
128	Route of administration of DMARD(s)	6	37	57	*0*	8	38	54	*1*	2	14	**EQUIV.**	**OUT**	-	
129	Start and stop dates of DMARD(s)	0	10	90	*0*	0	2	98	*1*	-	-	**IN**	**IN**	**O**	Operationalisation for main item No. 156
130	Reasons for ending a DMARD therapy	5	19	76	*1*	2	17	81	*1*	-	-	**IN**	**IN**	**O**	Operationalisation for main item No. 156
156	DMARD use	*Item was introduced as a main item*								-	-	-	**IN (New)**	**M [47]**	New main item as a summary of items No. 126, 127, 129 and 130
Treatment with oral glucocorticoids (GC)															
131	Use of oral GCs	0	2	98	*0*	0	0	100	*0*	-	-	**IN**	**IN**	**M [48]**	Renamed to "Oral glucocorticoid use"
132	Dose(s) and application interval(s) of oral GCs	0	16	84	*0*	2	5	94	*0*	-	-	**IN**	**IN**	**O**	Operationalisation for main item No. 131
133	Start and stop dates of oral GC treatment	2	10	89	*0*	2	3	95	*0*	-	-	**IN**	**IN**	**O**	Operationalisation for main item No. 131
Treatment with intraarticular glucocorticoids (GC)															
151	Intraarticular GC	*Item was added at the face-to-face meeting*								15	1	-	**IN (New)**	**M [49]**	New main item.
134	Dosage of intraarticular GC	7	33	61	*2*	10	36	54	*3*	2	14	**EQUIV.**	**OUT**	-	

135	Administration date of intraarticular GC	3	40	56	*1*	6	37	56	*2*	10	6	**EQUIV.**	**IN**	**O**	Operationalisation for main item No. 151
Treatment with non-steroidal anti-rheumatic drugs (NSAID)															
136	Use of NSAIDs	*Item was added to round 2*				3	23	73	*0*	-	-	**IN**	**IN**	**M [50]**	Renamed to "NSAID use"
137	Start and stop dates of NSAID treatment	*Item was added to round 2*				13	34	53	*0*	11	5	**EQUIV.**	**IN**	**O**	Operationalisation for main item No. 136
MEDICATION: Treatment of other health conditions during pregnancy															
138	Treatment with analgesics other than non-steroidal anti-inflammatory drugs or opioids	3	41	56	*0*	2	44	55	*0*	3	13	**EQUIV.**	**OUT**	-	
139	Treatment with antibiotics	2	45	53	*1*	2	49	49	*1*	2	14	**EQUIV.**	**OUT**	-	
140	Treatment with antihypertensive drugs	0	24	76	*1*	0	17	83	*0*	-	-	**IN**	**IN**	**O**	Operationalisation for main item No. 157
141	Treatment with aspirin	0	11	89	*0*	0	3	97	*0*	-	-	**IN**	**IN**	**O**	Operationalisation for main item No. 157
142	Treatment with folic acid	0	25	75	*0*	0	16	84	*0*	-	-	**IN**	**IN**	**O**	Operationalisation for main item No. 157
143	Treatment with heparin or other anticoagulants	0	11	89	*0*	0	5	95	*0*	-	-	**IN**	**IN**	**O**	Operationalisation for main item No. 157
144	Treatment with opioids	2	35	63	*1*	3	37	60	*1*	4	12	**EQUIV.**	**OUT**	-	
145	Treatment with Vitamin D	8	48	44	*1*	5	52	43	*1*	1	15	**EQUIV.**	**OUT**	-	
146	Treatment with any other over-the-counter medicine	21	53	26	*1*	24	60	16	*1*	0	16	**EQUIV.**	**OUT**	-	
147	Treatment with any prescription medicine	8	52	40	*1*	16	48	37	*1*	5	11	**EQUIV.**	**OUT**	-	
148	Treatment with any supplements	26	53	21	*1*	33	57	10	*1*	2	14	**EQUIV.**	**OUT**	-	
157	Use of selected treatments	*Item was introduced as a main item*							-	-	-	-	**IN (New)**	**M [51]**	New main item as a summary of items No. 126, 127, 140 - 143

Data items that have been subject to the Delphi votings and F2F voting by task force members are categorized by domains and – especially for the Delphi votings, sub-categories have been introduced. Changing of decisions, e.g. inclusion of an item in Delphi round 2 and exclusion at the F2F meeting are highlighted in blue.

Abbreviations: EQUIV., equivocal; F2F, Face-to-face; M, Main data item; O, operational data item; TF, task force;

Table 4: Definition of data items of the final core data set and their recommended way of assessment.

New No.	Original No.	Name of the data item	Description/ Definition/ Explanation	Recommended way of assessment (categories / instruments)
MATERNAL INFORMATION: Demographics				
1	1	Age	Age of the mother at the time of conception.	Assessment of date of birth or month/year of birth
2	4	Height	Body height and weight are necessary to calculate body mass index.	Assessment in centimeters (cm)
3	5	Weight	Body height and weight are necessary to calculate body mass index. Body weight is needed to calculate weight gain during pregnancy.	Assessment in kilogram (kg)
4	8	Educational level	Highest educational level according to national standards is recommended to be reported (e.g. total years of completed education including years in school, college and university), or highest degree reached.	Assessment of highest educational level according to national standards or total years of completed education
5	12	Alcohol consumption during pregnancy	Alcohol consumption should encompass occasional and regular drinking of alcoholic beverages during pregnancy.	Assessment of yes/ no
6	13	Smoking during pregnancy	Smoking should compass occasional and regular smoking during pregnancy.	Assessment of yes/ no
MATERNAL INFORMATION: Disease characteristics of the inflammatory rheumatic disease (IRD)				
7	14	IRD diagnosis	As the core data set should serve for several IRDs, diagnosis would include those diseases covered by the individual register or study. The diagnoses should be determined prior to setting up the register.	Physician reported clinical diagnosis
8	15	Classification criteria	According to the underlying IRD it should be questioned if standardized classification criteria are fulfilled (e.g. does the patient with psoriatic arthritis fulfil the CASPAR criteria).	Indication, which criteria are fulfilled
9	16	Disease duration	Defines the time when the IRD was first diagnosed by a physician.	Assessment of month/ year or year of diagnosis
10	18	Physician reported IRD severity	Estimation of the severity of the IRD by the reporting physician on a pre-defined instrument.	Instrument: NRS or VAS
11	31	Auto-antibodies	Disease-specific auto-antibodies of the IRD	Instrument: See additional recommendation for selected IRDs in table 3
12	19	Physician reported flares	A flare is a clinically important worsening of the IRD.	Assessment of (I) Yes/ No; (II) Number of flares
13	20	Physician reported disease activity	How active is the disease at the moment?	Instrument: NRS or VAS
14	21	Disease activity by score	Measurement of the activity usig a disease-specific score.	Instrument: See additional recommendation for selected IRDs in table 3
15	37	C-reactive protein	C-reactive protein (CRP) is an inflammation marker. The appropriate unit should be indicated.	Assessment of in mg/l or md/dl
16	22	Patient reported disease activity	How active is the disease at the moment?	Instrument: NRS or VAS

17	24	Patient reported global health	How would the patient rate his/her global health at the moment?	Instrument: NRS or VAS
MATERNAL INFORMATION: Prevalent comorbidities				
18	153	Selected prevalent comorbidities		Yes/ No assessment of: (I) Antiphospholipid syndrome, (II) Diabetes mellitus, (III) Arterial hypertension, (IV) Renal disease, (V) Previous thromboembolic events
PREGNANCY: Obstetrical history				
19	66	Gravidity	Gravidity is the number of times a woman has been pregnant regardless of pregnancy outcome (1).	Assessment of number of previous pregnancies
20	67	Parity	Parity is the number of pregnancies reaching 20 weeks and 0 days of gestation or beyond, regardless of the number of foetuses or outcomes (1).	Assessment of parity number
21	149	Outcome of previous pregnancy(ies)	This item encompasses any foetal death (including pregnancy loss(es) (also named spontaneous abortions/ miscarriages) and stillbirth(s) as well as live birth(s) of previous pregnancy(ies).	Categorization into Foetal death / Live birth; Assessment of (I) Number of foetal deaths and live births; (II) Gestational age
22	74	Preterm birth(s)	Preterm born infants of previous pregnancies. According to the WHO, preterm birth is defined as birth before 37 completed weeks of gestation.	Assessment of number of preterm birth(s) in previous pregnancies
23	72	Neonatal death(s)	Neonatal death(s) of previous born infants. Neonatal death is defined as the death of a live born infant, regardless of gestational age at birth, within the first 28 completed days of life.	Assessment of number of neonatal death(s)
24	77	Congenital malformations	Indication of congenital anomalies of previous born infants. According to the WHO, congenital anomalies are also known as birth defects, congenital disorders or congenital malformations (2). Congenital anomalies can be defined as structural or functional anomalies that occur during intrauterine life and can be identified prenatally, at birth, or sometimes may only be detected later in infancy. For coding anomalies, it is referred to the EUROCAT Malformation Coding Guides (3). It is not recommended to restrict the reporting of anomalies to a selection of anomalies since the definition of groups etc. maybe subject of changes during time.	Reporting as free text
25	73	Hypertensive pregnancy disorders	Hypertensive pregnancy disorders in previous pregnanciy(ies) encompasses the events of pre-eclampsia , eclampsia or HELLP syndrome. Pre-eclampsia: Disorder of pregnancy with persistent hypertension (diastolic blood pressure ≥ 90 mm Hg) and substantial proteinuria (> 0.3 g/24 hours) (4). Eclampsia: Generalized seizures, generally in addition to pre-eclampsia criteria (4). HELLP syndrome: Complication of pre-eclampsia (H = Haemolysis, EL = Elevated Liver enzymes, LP = Low Platelets)(4). Definitions may vary according to national standards.	Assessment of yes/ no
PREGNANCY: Course of the current pregnancy				
26	80	Planned pregnancy	Did the patient plan to become pregnant?	Assessment of yes/ no
27	82	Assisted reproduction	Did the patient plan to become pregnant using assisted reproductive technology (ART)? ART are all treatments or procedures that include the in vitro handling of both human oocytes and sperm or of embryos for the purpose of establishing a pregnancy. It does not include assisted insemination (5).	Assessment of yes/ no

28	83	Estimated date of conception	Date of conception is important to calculate gestational age during the complete pregnancy and the estimated due date (estimated date of delivery). Both dates are essential for analysis of pregnancy course and outcome, e.g. determination of preterm delivery, exact times of drug exposure during pregnancy, etc. Date of conception should be defined using appropriate method, e.g. last menstrual period and/or ultrasound.	Assessment of day/month/year
29	84	Singleton/ multiple pregnancy	Indication if the current pregnancy is a pregnancy with one foetus or more than one foetus.	Assessment of number of foetuses
30		Adverse events of interest	Indication, if the patient has experienced a non-serious or serious adverse event of interest, which encompasses Gestational hypertension, Pre-eclampsia, eclampsia, HELLP syndrome, Gestational diabetes, Thromboembolic events (deep venous thrombosis or pulmonary embolisms). Definitions for these conditions may vary according to national standards. In accordance with the International Conference on Harmonisation E2A guideline (6), a serious adverse event or reaction is any untoward medical occurrence observed in a patient that results in death, is life-threatening, requires inpatient hospitalisation or results in prolongation of existing hospitalisation, results in persistent or significant disability/incapacity or is a congenital anomaly/birth defect.	Assessment (I) if the event has occurred as yes or no; (II) of the date of the beginning of the event; (III) if the event has led to hospitalization or death
31	61	Other serious adverse events	Besides the events of interest, other serious adverse interest should be reported. In accordance with the International Conference on Harmonisation E2A guideline (6), a serious adverse event or reaction is any untoward medical occurrence observed in a patient that results in death, is life-threatening, requires inpatient hospitalisation or results in prolongation of existing hospitalisation, results in persistent or significant disability/incapacity or is a congenital anomaly/birth defect.	Assessment (I) of the kind of event as free text; (II) of the date of the beginning of the event; (III) if the event has led to hospitalization or death
PREGNANCY: Delivery and outcome of the current pregnancy				
32	94	Elective termination	Termination of a clinical pregnancy using a therapeutic process (e.g. surgical abortion or medical abortion using the "abortion pill").	Assessment of (I) Yes/ No; (II) Gestational age; (III) Reasons for termination categorized into (a) Termination due to malformation, (b) Termination due to other reasons
33	97	Foetal death	Foetal deathencompasses any loss of pregnancy regardless of cause and time of loss (5). The embryo(s) or foetus(es) is/are nonviable). Pregnancy loss encompasses e.g. missed abortion, spontaneous abortion/ miscarriage, stillbirth.	Assessment of (I) Yes/ No; (II) Gestational age
34	93	Live birth	The complete expulsion or extraction from its mother of a product of conception, irrespective of the duration of the pregnancy, which, after such separation, breathes or shows any other evidence of life, such as beating of the heart, pulsation of the umbilical cord, or definite movement of voluntary muscles, whether or not the umbilical cord has been cut or the placenta is attached; each product of such a birth is considered liveborn (WHO definition, (7)).	Assessment of yes/ no
35	99	Gestational age at birth	Indication of gestational age when giving birth.	Gestational age in weeks and days
36	103	Preterm premature rupture of membranes	PPROM is a pregnancy complication when the foetal membranes rupture prior to 37 weeks of gestation (8).	Assessment of yes/ no

		(PPROM)		
37	100	Mode of delivery	Mode of delivery indicates the way the child is born. In case of a Caesarean section, assessment why it was performed (9).	(I) Categorization into spontaneous vaginal delivery/ operative vaginal delivery/ caesarean section/ Mode of delivery not specified; (II) Reasons for Caesarean section: Emergency reasons/ Obstetrical indication/ Caesarean section in previous pregnancies/ Unknown reason
PREGNANCY: Neonatal outcomes				
38	105	Birth weight	Indication of the weight at birth.	Assessment in kilogram with 2 decimal digits or in gram
39	107	Gender	Determination of the infant's gender at birth (gender/sex assignment).	Categorization into female/ male/ other
40	109	Breastfeeding	Did the mother breastfeed the neonate within the first 28 days after birth?	Categorization into Yes, for at least 4 weeks after birth/ No
41	111	Congenital heart block	Congenital heart block is a rare disorder and is characterized by interference with the transfer of the electrical nerve impulses (conduction) that regulate the normal, rhythmic, pumping action of the heart muscle (heart block) (Link: https://rarediseases.org/rare-diseases/heart-block-congenital/).	Assessment of yes/ no
42	150	Congenital malformations	Indication of congenital anomalies of previous born infants. According to the WHO, congenital anomalies are also known as birth defects, congenital disorders or congenital malformations. Congenital anomalies can be defined as structural or functional anomalies that occur during intrauterine life and can be identified prenatally, at birth, or sometimes may only be detected later in infancy. Also chromosome anomalies are encompassed by congenital anomalies. For coding anomalies, it is referred to the EUROCAT Malformation Coding Guides (3). It is not recommended to restrict the reporting of anomalies to a selection of anomalies since the definition of groups etc. maybe subject of changes during time.	Reporting as free text
43	152	Neonatal serious adverse events during the first 28 days of live	Especially hospital admissions and neonatal death are of interest. In accordance with the International Conference on Harmonisation E2A guideline (6), a serious adverse event or reaction is any untoward medical occurrence observed in a patient that results in death, is life-threatening, requires inpatient hospitalisation or results in prolongation of existing hospitalisation, results in persistent or significant disability/incapacity or is a congenital anomaly/birth defect.	Assessment of (I) The kind of event as free text; (II) The date of the beginning of the event; (III) Indication if the event has led to hospitalization or death
MEDICATION: Treatment 12 months prior to conception				
44	120	DMARD use	Indication of all disease modifying anti-rheumatic drugs (DMARDs) the patient received in the past 12 months prior to conception. DMARDs encompass conventional synthetic (cs)DMARDs, e.g. methotrexate, sulfasalazine, hydroxychloroquine etc., biologic (b)DMARDs, e.g. adalimumab, certolizumab, tocilizumab, abatacept etc., and targeted synthetic (ts)DMARDs like apremilast, baricitinib, etc.	Assessment of (I) Yes/ No; (II) Name*; (III) Start/ stop dates [*For b/tsDMARDs it is recommended to record the trade name]
45	123	Oral glucocorticoid use	Indication if oral glucocorticoids have been used in the past 12 months prior to conception.	Indication as yes or no
46	125	Use of potentially teratogenic medication	Indication if potentially teratogenic treatments have been used in the past 12 months prior to conception. Since there is no official list available for teratogenic medication, and such a list would be	Reporting as free text

			prone to continuous updates, we recommend the assessment as free text.	
MEDICATION: Treatment of the inflammatory rheumatic disease during pregnancy and postpartum				
47	126	DMARD use	Indication of all disease modifying anti-rheumatic drugs (DMARDs) the patient is currently receiving and has been received since conception or the last visit whatever is appropriate. DMARDs encompass conventional synthetic (cs)DMARDs, e.g. methotrexate, sulfasalazine, hydroxychloroquine etc., biologic (b)DMARDs, e.g. adalimumab, certolizumab, tocilizumab, abatacept etc., and targeted synthetic (ts)DMARDs like apremilast, baricitinib, etc.	Assessment of (I) Yes/ No; (II) Name*; (III) Dose; (IV) Application intervals; (V) Start/ stop dates; (VI) Reasons for discontinuation [*For b/tsDMARDs it is recommended to record the trade name]
48	131	Oral glucocorticoid use	Indication if the patient has used oral glucocorticoid since conception or the last visit whatever is appropriate.	Assessment of (I) Yes/ No; (II) Dose; (III) Application intervals; (IV) Start/ stop dates
49	151	Intraarticular glucocorticoid use	Indication if the patient has received intraarticular glucocorticoid since conception or the last visit whatever is appropriate.	Assessment of (I) Yes/ No; (II) Date of application
50	136	NSAID use	Indication if the patient has used NSAIDs since conception or the last visit whatever is appropriate.	Assessment of (I) Yes/ No; (III) Name; (III) Start/ stop dates
MEDICATION: Treatment of other health conditions during pregnancy				
51	157	Use of selected treatments	Indication if the patient has used one of the selected treatments since conception or the last visit whatever is appropriate. Selected treatments are: antihypertensive drugs, aspirin, folic acid and heparin/ other anticoagulants.	Yes/ No assessment of use of (I) Antihypertensive drugs, (II) Aspirin, (III) Folic acid and (IV) Heparin/ other anticoagulants

Abbreviations: IRD, Inflammatory rheumatic disease; DMARD, disease modifying anti-rheumatic drugs; NSAID, non-steroidal anti-inflammatory drugs.

Table 5: Results of additional item voting.

	Rheumatoid arthritis	Spondylo-arthritis (PsA + axSpA)	Juvenile idiopathic arthritis	Systemic lupus erythematosus	Other connective tissue diseases
Autoantibodies / Laboratory markers					
Anti-cardiolipin antibodies	Y/N/Miss: 2/7/8	Y/N/Miss: 1/7/9	Y/N/Miss: 1/7/9	Y/N/Miss: 9/1/7	Y/N/Miss: 7/2/8
Anticitrullinated protein antibody (ACPA)	Y/N/Miss: 9/0/8	Y/N/Miss: 1/7/9	Y/N/Miss: 5/3/9	Y/N/Miss: 0/9/8	Y/N/Miss: 0/8/9
Anti-double-stranded DNA antibodies	Y/N/Miss: 0/9/8	Y/N/Miss: 0/8/9	Y/N/Miss: 0/8/9	Y/N/Miss: 8/1/8	Y/N/Miss: 2/6/9
Anti-La/SSB antibodies	Y/N/Miss: 1/8/8	Y/N/Miss: 0/8/9	Y/N/Miss: 0/8/9	Y/N/Miss: 6/3/8	Y/N/Miss: 6/3/8
Antinuclear antibodies (ANA)	Y/N/Miss: 0/9/8	Y/N/Miss: 0/8/9	Y/N/Miss: 5/3/9	Y/N/Miss: 6/3/8	Y/N/Miss: 6/3/8
Anti-Ro/SSA antibodies	Y/N/Miss: 1/8/8	Y/N/Miss: 1/7/9	Y/N/Miss: 1/7/9	Y/N/Miss: 9/0/8	Y/N/Miss: 7/2/8
Anti-Sm antibodies	Y/N/Miss: 0/9/8	Y/N/Miss: 0/8/9	Y/N/Miss: 0/8/9	Y/N/Miss: 7/2/8	Y/N/Miss: 3/6/8
Anti-U1-ribonucleoprotein (RNP) antibodies	Y/N/Miss: 0/9/8	Y/N/Miss: 0/8/9	Y/N/Miss: 0/8/9	Y/N/Miss: 6/3/8	Y/N/Miss: 6/2/9
Beta-2-Glycoprotein-I-antibodies	Y/N/Miss: 1/8/8	Y/N/Miss: 0/8/9	Y/N/Miss: 0/8/9	Y/N/Miss: 8/1/8	Y/N/Miss: 6/3/8
HLA-B27	Y/N/Miss: 0/9/8	Y/N/Miss: 9/0/8	Y/N/Miss: 2/6/9	Y/N/Miss: 0/9/8	Y/N/Miss: 1/8/8
Lupus anticoagulant	Y/N/Miss: 1/8/8	Y/N/Miss: 0/8/9	Y/N/Miss: 0/8/9	Y/N/Miss: 9/0/8	Y/N/Miss: 6/3/8
Rheumatoid factor	Y/N/Miss: 8/1/8	Y/N/Miss: 1/7/9	Y/N/Miss: 5/3/9	Y/N/Miss: 0/9/8	Y/N/Miss: 1/8/8
Serum C3 / C4	Y/N/Miss: 0/9/8	Y/N/Miss: 0/8/9	Y/N/Miss: 0/8/9	Y/N/Miss: 9/1/7	Y/N/Miss: 6/4/7
Disease Activity /Severity					
28 SJC	Y/N/Miss: 6/2/9	Y/N/Miss: 2/5/10	Y/N/Miss: 5/2/10	Y/N/Miss: 1/6/10	Y/N/Miss: 1/6/10
28 TJC	Y/N/Miss: 6/2/9	Y/N/Miss: 2/5/10	Y/N/Miss: 5/2/10	Y/N/Miss: 1/6/10	Y/N/Miss: 1/6/10
66 SJC	Y/N/Miss: 1/7/9	Y/N/Miss: 3/4/10	Y/N/Miss: 1/6/10	Y/N/Miss: 0/7/10	Y/N/Miss: 0/7/10
68 TJC	Y/N/Miss: 1/7/9	Y/N/Miss: 2/5/10	Y/N/Miss: 1/6/10	Y/N/Miss: 0/7/10	Y/N/Miss: 0/7/10
ASDAS	Y/N/Miss: 0/8/9	Y/N/Miss: 6/1/10	Y/N/Miss: 1/6/10	Y/N/Miss: 0/7/10	Y/N/Miss: 0/7/10
BASDAI	Y/N/Miss: 0/8/9	Y/N/Miss: 6/1/10	Y/N/Miss: 1/6/10	Y/N/Miss: 0/7/10	Y/N/Miss: 0/7/10
BASFI	Y/N/Miss: 0/8/9	Y/N/Miss: 0/7/10	Y/N/Miss: 0/7/10	Y/N/Miss: 0/7/10	Y/N/Miss: 0/7/10
BILAG-2004P	Y/N/Miss: 0/8/9	Y/N/Miss: 0/7/10	Y/N/Miss: 0/7/10	Y/N/Miss: 1/6/10	Y/N/Miss: 0/7/10
CDAI	Y/N/Miss: 2/6/9	Y/N/Miss: 0/7/10	Y/N/Miss: 1/6/10	Y/N/Miss: 0/7/10	Y/N/Miss: 0/7/10
DAPSA	Y/N/Miss: 0/8/9	Y/N/Miss: 3/4/10	Y/N/Miss: 0/7/10	Y/N/Miss: 0/7/10	Y/N/Miss: 0/7/10
DAS28-CRP3	Y/N/Miss: 6/2/9	Y/N/Miss: 3/4/10	Y/N/Miss: 4/3/10	Y/N/Miss: 0/7/10	Y/N/Miss: 0/7/10
DAS28-CRP	Y/N/Miss: 2/6/9	Y/N/Miss: 1/6/10	Y/N/Miss: 1/6/10	Y/N/Miss: 0/7/10	Y/N/Miss: 0/7/10

DAS28-ESR	Y/N/Miss: 1/7/9	Y/N/Miss: 1/6/10	Y/N/Miss: 0/7/10	Y/N/Miss: 0/7/10	Y/N/Miss: 0/7/10
ECLAM	Y/N/Miss: 0/8/9	Y/N/Miss: 0/7/10	Y/N/Miss: 0/7/10	Y/N/Miss: 0/7/10	Y/N/Miss: 0/7/10
Enthesitis	Y/N/Miss: 0/8/9	Y/N/Miss: 2/5/10	Y/N/Miss: 0/7/10	Y/N/Miss: 0/7/10	Y/N/Miss: 0/7/10
Global Antiphopholipid Syndrome Score (GAPSS)	Y/N/Miss: 0/8/9	Y/N/Miss: 0/7/10	Y/N/Miss: 0/7/10	Y/N/Miss: 2/5/10	Y/N/Miss: 2/5/10
Generic RAID	Y/N/Miss: 1/7/9	Y/N/Miss: 1/6/10	Y/N/Miss: 1/6/10	Y/N/Miss: 1/7/9	Y/N/Miss: 1/7/9
Involvement of nails/skin	Y/N/Miss: 0/8/9	Y/N/Miss: 3/4/10	Y/N/Miss: 0/7/10	Y/N/Miss: 0/7/10	Y/N/Miss: 0/7/10
LAI	Y/N/Miss: 0/8/9	Y/N/Miss: 0/7/10	Y/N/Miss: 0/7/10	Y/N/Miss: 0/7/10	Y/N/Miss: 0/7/10
LAI-P	Y/N/Miss: 0/8/9	Y/N/Miss: 0/7/10	Y/N/Miss: 0/7/10	Y/N/Miss: 3/4/10	Y/N/Miss: 0/7/10
m-ECLAM	Y/N/Miss: 0/8/9	Y/N/Miss: 0/7/10	Y/N/Miss: 0/7/10	Y/N/Miss: 1/6/10	Y/N/Miss: 0/7/10
m-LAI	Y/N/Miss: 0/8/9	Y/N/Miss: 0/7/10	Y/N/Miss: 0/7/10	Y/N/Miss: 0/7/10	Y/N/Miss: 0/7/10
Morning stiffness	Y/N/Miss: 1/7/9	Y/N/Miss: 1/6/10	Y/N/Miss: 1/6/10	Y/N/Miss: 0/7/10	Y/N/Miss: 0/7/10
m-SLAM	Y/N/Miss: 0/8/9	Y/N/Miss: 0/7/10	Y/N/Miss: 0/7/10	Y/N/Miss: 1/6/10	Y/N/Miss: 0/7/10
PASI	Y/N/Miss: 0/8/9	Y/N/Miss: 2/5/10	Y/N/Miss: 0/7/10	Y/N/Miss: 0/7/10	Y/N/Miss: 0/7/10
RADAI	Y/N/Miss: 1/7/9	Y/N/Miss: 0/7/10	Y/N/Miss: 0/7/10	Y/N/Miss: 0/7/10	Y/N/Miss: 0/7/10
RAID	Y/N/Miss: 0/8/9	Y/N/Miss: 0/7/10	Y/N/Miss: 0/7/10	Y/N/Miss: 0/7/10	Y/N/Miss: 0/7/10
SDAI	Y/N/Miss: 0/8/9	Y/N/Miss: 0/7/10	Y/N/Miss: 1/6/10	Y/N/Miss: 0/7/10	Y/N/Miss: 0/7/10
SELENA SLEDAI	Y/N/Miss: 0/8/9	Y/N/Miss: 0/7/10	Y/N/Miss: 0/7/10	Y/N/Miss: 3/4/10	Y/N/Miss: 0/7/10
SLAM	Y/N/Miss: 0/8/9	Y/N/Miss: 0/7/10	Y/N/Miss: 0/7/10	Y/N/Miss: 0/7/10	Y/N/Miss: 0/7/10
SLEDAI	Y/N/Miss: 0/8/9	Y/N/Miss: 0/7/10	Y/N/Miss: 0/7/10	Y/N/Miss: 4/3/10	Y/N/Miss: 0/7/10
SLEPDAI	Y/N/Miss: 0/8/9	Y/N/Miss: 0/7/10	Y/N/Miss: 0/7/10	Y/N/Miss: 5/3/9	Y/N/Miss: 0/8/9
SLICC ACR Damage	Y/N/Miss: 0/8/9	Y/N/Miss: 0/7/10	Y/N/Miss: 0/7/10	Y/N/Miss: 5/2/10	Y/N/Miss: 1/6/10
Dermatologic manifestations	Y/N/Miss: 0/8/9	Y/N/Miss: 3/4/10	Y/N/Miss: 1/6/10	Y/N/Miss: 3/4/10	Y/N/Miss: 2/5/10
Erosions	Y/N/Miss: 3/5/9	Y/N/Miss: 3/4/10	Y/N/Miss: 3/4/10	Y/N/Miss: 0/7/10	Y/N/Miss: 0/7/10
Surgery for the articular disease	Y/N/Miss: 3/5/9	Y/N/Miss: 3/4/10	Y/N/Miss: 3/4/10	Y/N/Miss: 1/6/10	Y/N/Miss: 0/7/10
Uveitis	Y/N/Miss: 0/8/9	Y/N/Miss: 3/4/10	Y/N/Miss: 2/6/9	Y/N/Miss: 0/7/10	Y/N/Miss: 0/7/10

Results highlighted in red are added to the additional item list. Y/N/Miss: Y= Number of members voting Yes for inclusion / N= Number of members voting No for inclusion / Miss=Number of members not voting for the item according to their expertise.

Table 6: Definitions of obstetric terminology.

Term	Definition	Reference
Perinatal period	Commences at 22 completed weeks (154 days) of gestation and ends seven completed days after birth.	WHO: Neonatal and Perinatal Mortality (7)
Neonatal period	Begins with birth and ends 28 complete days after birth.	WHO: Neonatal and Perinatal Mortality (7)
Elective termination	Termination of pregnancy (induced abortion, elective abortion): Artificial interruption of pregnancy for any reason.	EMA GVP Guideline: Pregnant and breastfeeding women (10)
Foetal death	Death prior to complete expulsion or extraction from the mother of a foetus, irrespective of the duration of pregnancy. Also referred to as intrauterine death or in utero death.	EMA GVP Guideline: Pregnant and breastfeeding women (10)
Miscarriage	Spontaneous abortion and molar pregnancy. A miscarriage is the loss of pregnancy from natural causes before the 20th week of pregnancy.	EMA GVP Guideline: Pregnant and breastfeeding women (10) ICD-10 O03
Stillbirth	Death prior to the complete expulsion or extraction from its mother of a product of conception, irrespective of the duration of pregnancy; the death is indicated by the fact that after such separation the foetus does not breathe or show any other evidence of life.	WHO: Neonatal and Perinatal Mortality (7) ICD-10 P95
Live birth	The complete expulsion or extraction from its mother of a product of conception, irrespective of the duration of the pregnancy, which, after such separation, breathes or shows any other evidence of life.	WHO: Neonatal and Perinatal Mortality (7)
Preterm infants / preterm birth	28 completed weeks or more but less than 37 completed weeks (196 completed days but less than 259 completed days) of gestation.	ICD-10 P07.3
Extreme immaturity	Less than 28 completed weeks (less than 196 completed days) of gestation.	ICD-10 P07.2
Gestational age, gestational week, week of gestation	Measure of the age of a pregnancy calculated from the first day of a woman's last menstrual period or as estimated by a more accurate method such as ultrasound. Gestational age is indicated in weeks and days, eg. 39 weeks and 0 days. Calculation using the best obstetrical estimated due date (EDD) is based on the following formula: Gestational Age = (280 - (EDD - Reference Date))/ 7 (Reference Date: Date on which you are trying to determine gestational age)	EMA GVP Guidline: Pregnant and breastfeeding women (10) American College of Obstetricians and Gynecologists - Obstetric Data Definitions (1)
EDD / Estimated due date	The Estimated Due Date is determined by: Last menstrual period if confirmed by early ultrasound or no ultrasound performed, or early ultrasound if no known last menstrual period or the ultrasound is not consistent with last menstrual period, or	American College of Obstetricians and Gynecologists - Obstetric Data Definitions (1)

	known date of fertilization (eg, assisted reproductive technology)	

References

1. American College of Obstetricians and Gynecologists: Obstetric Data Definitions. Access day: 11/08/2020 [Available from: https://www.acog.org/practice-management/health-it-and-clinical-informatics/revitalize-obstetrics-data-definitions.
2. World Health Organization. Birth defects surveillance: A mannual for programme managers. ISBN 9789241548724. 2014.
3. EUROCAT Network Access day: 11/08/2020 [Available from: http://www.eurocat-network.eu/.
4. World Health Organiszation. WHO Recommendations for prevention and treatment of pre-eclampsia and eclampsia. ISBN: 9789241548335 2011 [
5. Zegers-Hochschild F, Adamson GD, de Mouzon J, Ishihara O, Mansour R, Nygren K, Sullivan E, Vanderpoel S, International Committee for Monitoring Assisted Reproductive T, World Health O. International Committee for Monitoring Assisted Reproductive Technology (ICMART) and the World Health Organization (WHO) revised glossary of ART terminology, 2009. Fertil Steril. 2009;92(5):1520-4.
6. ICH Guideline. Clinical safety data management: Definitions and standards for expedited reporting E2A Access day: 11/08/2020 [Available from: https://database.ich.org/sites/default/files/E2A_Guideline.pdf.
7. World Health Organization. Neonatal and Perinatal Mortality: Country, Regional and Global Estimates. ISBN 9789241563208. 2006.
8. Caughey AB, Robinson JN, Norwitz ER. Contemporary diagnosis and management of preterm premature rupture of membranes. Rev Obstet Gynecol. 2008;1(1):11-22.
9. Torloni MR, Betran AP, Souza JP, Widmer M, Allen T, Gulmezoglu M, Merialdi M. Classifications for cesarean section: a systematic review. PLoS One. 2011;6(1):e14566.
10. European Medicines Agency. Guideline on good pharmacovigilance practices (GVP) Product- or Population-Specific Considerations III: Pregnant and breastfeeding women. (EMA/653036/2019 DRAFT FOR PUBLIC CONSULTATION). 4.12.2019.