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; 80:49–56. 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)	

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