

**ONLINE SUPPLEMENTARY DATA**

*Supplementary Table 1.* Results of the survey on work done previously on CFs within OMERACT WGs.

<b>Definition of contextual factors</b>					
	<b>Question 1: How do you define a contextual factor (CF) for your PRO's?</b>		<b>Question 2: Did patient research partners (PRPs) play a role in developing the definition?</b>		
Ankylosing Spondylitis (ASAS)	ICF definition [, and therefore all CF relevant for functioning and health (only environmental factors)		Patients involved in development of ICF core set and further reduction of factors in development of ASAS HI		
Equity group (EG)	No formal definition reported		Yes PRPs involved in description of CFs		
Hand Osteoarthritis (H-OA)	OMERACT handbook (Boers M. et al. 2014) . Possible CF for all outcome domains		No		
Health Literacy (HL)	" ..a factor / variable that may modify the level or importance of the PRO measured."		No		
Rheumatoid Arthritis Flare (RA-F)	OMERACT handbook (Boers M. et al. 2014) and ICF definition (environmental and personal factors)		No		
Shared Decision-Making (SDM)	OMERACT handbook (Boers M. et al. 2014)		No		
Vasculitis (VA)	OMERACT handbook (Boers M. et al. 2014) and ICF definition (environmental and personal factors)		No		
Worker Productivity (WP)	ICF definition (environmental and personal factors) and CF definition of Badly in relation to work outcomes		Yes PRPs involved in specification of CF definition		
<b>Identification of contextual factors</b>					
	<b>Question 3: How did you identify CFs?</b>	<b>Question 4: How did you gain further input about your specific CFs?</b>	<b>Question 5: Did you classify / categorize CF's in different groups or sets?</b>	<b>Question 6: Was an effort undertaken to identify CFs that are more relevant than others?</b>	<b>Question 7: Have you identified CFs that may be confounders or covariates?</b>
Ankylosing Spondylitis	During the development	Debriefing of ASAS-HI	Grouping based on ICF	Yes	Environmental Set of

(ASAS)	of the ICF core set for AS . Further item reduction by correlation with ASAS HI		chapters	Correlation with outcome Prospective testing of predictive validity, confounding, effect modification is ongoing	ASAS-HI No formal analysis done
Equity group (EG)	Concerns of PRPs	Development of tool to assess health literacy	No	Yes Expert discussion at OM 12	Patients ability to accurately respond PROM No formal analysis done
Hand Osteoarthritis (H-OA)	Discussion of H-OA experts, Pat-focus group, OMERACT participants, ICF core set for hand condition	Delphi survey with H-OA experts and PRPs	Grouping into Mandatory / Non mandatory CFs	No	Age, gender, hand OA subset, BMI, hand symptoms duration No formal analysis done
Health Literacy (HL)	Literature, Interviews, Focus group, Delphi survey, Experts, patients	Semi-structured interviews, Expert committee: examining proposed items for PROM	In well-known categories, as demographics, socioeconomics, Guided by ICF	Yes Reduction of CF by data analysis	ongoing
Rheumatoid Arthritis Flare (RA-F)	Literature research, Expert and PRPs expertise, (Breakout session at OMERACT 12)	projects in preparation	Categorization into 8 groups	Yes Expert discussion at OM 12	Self- management
Shared Decision-Making (SDM)	Literature research, Discussion of SIG participants	Planned Delphi exercise and OM work shop on consensus of CFs to be included in SDM set	Grouping identified by SIG participants Modified nominal group , Literature review	Yes Voting of SIG participants	No
Vasculitis (VA)	ICF core set, Development of PRO for AAV	Semi-structured patient interviews, Patient questionnaires	Environmental factors: ICF classification, Personal factors: Geyh et al. Classification	Yes Patient questionnaire Expert Delphi	ongoing
Worker Productivity (WP)	Literature and nominal group technique including stake holders. Classification based on /	Brainstorming WP-SIG, Dot voting on CFs, Literature review	Environmental & Personal factors and further into one of 15 broad domains	Yes	No

Item reduction further by statistical evidence from literature

<b>Measurement and analysis of contextual factors</b>			
	<b>Question 8: How are the CF's measured?</b>	<b>Question 9: How do you anticipate analysis of statistical influence/ impact of CFs?</b>	<b>Question 10: Have PRPs provided input to assess the impact of CF'</b>
Ankylosing Spondylitis (ASAS)	The new ASAS-HI contains a CF item set of 9 potential CF	Prospective study; data collection ongoing	Yes Interpretation of results
Equity group (EG)	ELF-Q	None	Yes Development and testing of tool to assess PROMs
Hand Osteoarthritis (H-OA)	Standard variables (e.g. age)	CFs treated as confounders in multi regression analysis or Used to stratify patient populations for sub-analysis	No projects are planned
Health Literacy (HL)	No measure CFs are measured in most usual approach	IRT approach to test for interaction, Testing for difference or measurement level between relevant groups, Determine Minimal Clinical Important Difference for developing PRO	Yes Conceptualization, input on content and items of PRO. Interviews, focus groups, scientific committee discussions.
Rheumatoid Arthritis Flare (RA-F)	Flare questionnaire	Not clarified yet	Yes ongoing
Shared Decision-Making (SDM)	No measure	Not discussed yet	No Delphi survey planned Work shop at OM 14 planned
Vasculitis (VA)	Questionnaire based on semi-structured interviews	None Include CF's in final data analysis models	Yes In all stages of research
Worker Productivity (WP)	No measure	Not discussed yet	No Not at current stage of project

*Data Supplement 1. SIG – CONTEXTUAL FACTORS – Questionnaire.*

Name:

Subgroup Leader:

E-Mail address:

(Health)Professional , please specify:

Patient

Industry

OMERACT Working Group you working with:

How many OMERACT congresses have you already attended?

**PART 1:**

Please indicate three contextual factors (CF) that, from your perspective, are important to be assessed alongside with a primary outcome in a clinical trial in order to understand the results.

(Please don't choose established sociodemographic factors, such as gender and age etc.)

Please discuss your findings with your subgroup members.

a) Write down your chosen CF:

b) How did you select these factors ?

Personal opinion /experience

Expert consensus

Research evidence (e.g. Literature review, Delphi survey, patient interviews)

c) Do you feel it is worthwhile to group/categorize these factors ?

d) After the discussion with your SIG- group members, do you think your chosen CF are as important that they should be measured and further investigated in different settings because of their potential impact?

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**PART 2:**

a) Do you think that your chosen CFs will have potential to get core CF and why ?

(please use the other side to explain your opinion)