OMERACT CORE DOMAIN SET DEVELOPMENT WORK PLAN

WORKING GROUP:

OMERACT has created a work plan template for working groups to complete, ensuring alignment with OMERACT's guidance on developing a Core Domain Set (CDS). By completing this protocol, working groups have the opportunity to publish their work on platforms like Trials, Open Science or Seminars in Arthritis and Rheumatism. A successful example is the Foot & Ankle Working Group's publication, accessible here. This template also incorporates the key steps from the Core Outcome Set-STAndardised Protocol Items (COS-STAP), PRISMA Extension for Scoping Reviews (PRISMA-ScR), and the Standards for Reporting Qualitative research: a synthesis of Recommendations (SRQR) checklist. This template describes your work plan; the outcomes of your work will be addressed in later sections of the OMERACT CDS development checklist.

1. **Title**
   Provide a concise, descriptive title that identifies the condition, population, or clinical setting targeted by this CDS. This ensures that the intended scope and focus are immediately clear to readers, and potential collaborators.

2. **Brief Summary of CDS objectives**
   Outline the primary objectives for developing this CDS, including the specific goals, intended applications, and anticipated impact on clinical research or practice. This summary should provide context for why this CDS is necessary and how it will address unmet needs in outcome measurement within the specified domain.

3. **Scoping Review Strategy**
   Provide a detailed protocol for conducting a scoping review to identify existing domains. This should include databases, search terms, methods of selection and extraction, languages, study characteristics, and outcome characteristics. ** Note reporting standards for publishing scoping reviews PRISMA Extension for Scoping Reviews (PRISMA-ScR) may be asked for by journals. We recommend engaging a librarian or information specialist to help design the search strategy.

Item & Description	Working Group Scoping Literature Review Plans
Eligibility Criteria: Specify the characteristics of the sources of evidence (e.g., years considered, language, publication status) used as eligibility criteria. Provide a rationale for these criteria.	
Information Sources: Describe all sources of information used in the search (e.g., databases with date ranges of coverage, grey literature, contact with experts or authors to identify additional sources).	
Search Strategy: Present the complete electronic search strategy for at least one database. Include any limits or filters applied, ensuring that the search can be repeated by others.	
Selection of Sources of Evidence: Outline the process for selecting sources of evidence, including screening and eligibility criteria for inclusion in the scoping review. Specify how the selection will be conducted (e.g., independently or in duplicate).	
Data Charting Process: Describe methods for charting data from the included sources of evidence, including the use of calibrated forms or tested forms. Specify whether charting will be done independently or in duplicate, and explain verification methods.	
Data Items: List and define all variables for which data will be extracted. Include any assumptions or simplifications made in the process.	
Synthesis of Results: Detail methods for managing, handling, and summarizing the charted data, and explain how the data will be synthesized to inform conclusions.	

4. **Qualitative Research Plans**
   Describe the protocol (plans) for conducting qualitative research (e.g., focus groups, interviews, structured and moderated online discussion board, etc.) for generating candidate domains.
   ** Note reporting standards for publishing qualitative work Standards for Reporting Qualitative research: a synthesis of Recommendations (SRQR) (equivalent to CONSORT standards for RCTs) may be asked for by journals.

Item & Description	Working Group Qualitative Work Plans
Ethics: Describe any ethics approvals needed for qualitative work. Remember to plan as it does take time to get the necessary approvals.	
Facilitator Qualifications and Role: include details about the person conducting the focus group, specifying their role in the research. Provide information about their credentials, such as academic degrees (e.g., PhD, MD), and describe their current occupation or professional role at the time of the study. It is important to indicate the facilitator's gender to consider any potential influences on the group dynamic. Additionally, outline their relevant experience or training in conducting focus groups or qualitative research to ensure they have the necessary expertise in data collection.	
Relationship Between Facilitator and Participants: dentify if a relationship with participants will be established before the study. Describe what participants will know about the researcher, such as goals or reasons for the research, and note any relevant facilitator characteristics, including biases or interests.	
Theoretical framework: What methodological orientation will underpin the study? e.g. grounded theory, discourse analysis, ethnography, phenomenology, content analysis	

Participant Selection Process: describe how participants will be selected (e.g., purposive, convenience, snowball) and the method of approach (e.g., face-to-face, telephone, email). Indicate the planned sample size and how the group will track any non-participation, including the number of refusals or dropouts and their reasons. OMERACT recommends focus groups or interviews should aim to be as representative as possible of potential clinical trial participants with a minimum of 30 participants total with representation from at least 3 continents	
Setting: identify where the data will be collected (e.g., home, clinic, workplace) and whether anyone besides the participants and researchers will be present. Provide a description including key characteristics that will be asked such as demographic data and relevant dates.	
Data Collection: Describe how the data will be collected, including whether an interview guide with questions or prompts will be provided and if it will be pilot tested. Specify if repeat interviews will be conducted, and if so, how many. Indicate whether audio or visual recordings will be used, if field notes will be made during or after the sessions, the expected duration of interviews or focus groups, and how data saturation will be addressed. Lastly, clarify if transcripts will be returned to participants for feedback or correction.	
Domain Identification: provide a brief description of how domains will be identified and synthesized from the interviews/focus groups.	
Data Analysis Plan: identify how the data will be analyzed, including how many data coders will be involved. Specify whether a coding tree will be developed and described. Indicate whether themes will be identified in advance or derived from the data. Mention what software, if any, will be used to manage the data. Finally, clarify whether participants will be asked to provide feedback on the findings.	

5. **Binning & Winnowing**

After generating a list of domains, themes, or concepts from the scoping review and qualitative work, please select the working group approach for binning and winnowing domains.

○ **Follow OMERACT Methods**: use the Domain Development Tracker and follow the OMERACT methods for binning and winnowing, as outlined in the OMERACT Handbook.

○ **Propose Alternative Methods**: the working group plans to use a different approach. Please provide a detailed explanation of the proposed methods for binning and winnowing the generated domains, including the rationale for deviating from the OMERACT protocol. TAG Review

6. **Prioritizing Domains - Delphi Process**

OMERACT has developed a protocol for prioritizing domains through an online Delphi process. Please select the working group approach to prioritize the list of domains.

○ **Follow OMERACT Delphi Protocol**: Follow the established OMERACT Delphi protocol for prioritizing domains. To view the protocol, click HERE. Ensure that any necessary ethics approvals for your online Delphi surveys are obtained in advance, as this can take time and may cause delays if not appropriately planned.

○ **Propose Alternative Methods**: if the working group plans to deviate from the OMERACT Delphi protocol, explain the proposed methods for prioritizing domains through an online Delphi process for submission to the Technical Advisory Group (TAG) for review.

7. **Prioritizing Domains – OMERACT Onion**

Describe the plans for Working Group Consensus for selecting and placing domains into the OMERACT Onion.

Date of Submission: