DEVELOPING AND REFINING CORE OUTCOME SET METHODOLOGIES WORKPLAN

WORKING GROUP:

This work plan template is intended for OMERACT Methods Working Groups developing or refining methodology to support Core Outcome Set development. It draws from Chapter 6 of the OMERACT Handbook and should be used alongside the Checklist Supporting OMERACT Working Groups In Developing And Refining Core Outcome Set Methodologies. Completing this work plan will help align your efforts with OMERACT's standards and may support future publication or dissemination of your work. This template describes your work plan only; the outcomes of your work will be addressed in later sections of the Checklist Supporting OMERACT Working Groups In Developing And Refining Core Outcome Set Methodologies.

1. **TITLE.** PROPOSED TITLE OF THE METHODOLOGICAL WORK:

Provide a concise, descriptive title

2. **BRIEF SUMMARY OF OBJECTIVES.** SUMMARY OF OBJECTIVES AND INTENDED IMPACT ON CORE OUTCOME SET METHODOLOGY

Outline the primary objectives for developing or refining this methodology, including the specific goals, intended applications, and anticipated impact.

3. SCOPING REVIEW STRATEGY (IF APPLICABLE IF NOT SKIP TO NEXT ITEM)

Provide a detailed protocol for conducting a scoping review. 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 (IF APPLICABLE IF NOT SKIP TO NEXT ITEM)

Describe the protocol (plans) for conducting qualitative research.
*** 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: identify 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. ONLINE SURVEY PLANS (IF APPLICABLE IF NOT SKIP TO NEXT ITEM)

*If your working group plans to conduct an online survey please describe your methodology in detail below. This includes how you will design, distribute, and analyze your survey, ensuring methodological rigor and ethical standards are met. ** To enhance transparency and improve the quality of reporting, it is strongly recommended that your survey aligns with the Checklist for Reporting Results of Internet E-Surveys (CHERRIES). The table below was adapted from CHERRIES Checklist.*

Item & Description	Working Group Qualitative Work Plans
Target Population & Sampling: Describe the intended population and whether this is a convenience sample.	
Survey Design Summary: Describe the type of survey and its structure.	
IRB Approval: Will the study be reviewed and approved by an ethics board?	
Informed Consent: How will consent be obtained? Describe information given to participants (e.g., purpose, time, data storage).	
Data Protection: What mechanisms are in place to protect personal or sensitive information?	
Survey Development Process: Describe how items will be generated and reviewed.	
Usability/Functionality Testing: Will the survey be tested for usability or technical functionality before launch?	
Open vs. Closed Survey: Will the survey be public (open) or restricted to a defined group (closed)?	
Contact Mode: How will participants be invited (email, QR code, social media, etc.)?	
Survey Advertisement: How will the survey be promoted or announced? Include wording if available.	
Survey Mode: Web-based, email-based, app-based, etc.?	
Survey Context: Describe the host platform or site	
Incentives: Will any incentives beoffered? If so, describe.	
Timeframe: Provide the start and end dates for data collection.	
Item Randomization: Will any questions or responses be randomized?	
Adaptive Questioning: Will items be conditionally displayed based on responses?	

Items per Page: Number of questions shown per screen.	
Number of Pages: Over how many pages/screens will the survey be spread?	
Completeness Check: Will participants be prompted to complete all questions? Describe method.	
Review Option: Could participants review or change answers before submitting?	
Unique Visitor Definition: How will you define and track unique survey visitors?	
Cookies: Will cookies be used to track/respondents? If so, describe.	
IP Check: Will IP be used to identify or block repeat entries?	
Log File Analysis: Will logs be analyzed to detect multiple entries? Describe how.	
Registration Controls: For closed surveys, how will multiple submissions from the same user prevented?	
Handling Incomplete Data: Will partial responses be analyzed? If so, how?	

6. DELPHI STUDY PLANS (IF APPLICABLE IF NOT SKIP TO NEXT ITEM)

OMERACT has developed a standard protocol for conducting online Delphi surveys. Please indicate which approach your working group will take to plan the Delphi process:

Follow the OMERACT Delphi Protocol

○ The working group will follow the established OMERACT Delphi protocol. You can access the protocol HERE. Please ensure that all required ethics approvals are obtained before launching the survey, as delays in approvals may impact your timeline.

Propose an Alternative Delphi Approach

○ If your working group intends to use a different method from the OMERACT Delphi protocol, please provide a clear rationale and outline of your proposed Delphi methodology. This alternative plan must be submitted to the OMERACT Technical Advisory Group (TAG) for review and approval prior to implementation.

7. EXPERT PANEL (IF APPLICABLE IF NOT SKIP TO NEXT ITEM)

If your working group will use an expert panel as part of your methodology (e.g., to review findings, generate consensus, or validate items/domains), describe the process and structure.

Item & Description	Working Group Expert Panel Plans
Purpose of Expert Panel: Describe the intended purpose of involving an expert panel (e.g., item generation, face validity assessment, domain prioritization).	
Composition: Describe the composition of the panel, including the number and types of experts (e.g., methodologists, clinicians, patients, regulators). Ensure diversity across disciplines and geography.	
Selection Criteria: Describe how panelists will be identified and selected. Include criteria such as expertise, lived experience, previous involvement with COS development, etc.	
Engagement Process: Outline how the panel will be engaged (e.g., virtual meetings, surveys, modified Delphi). Specify how often they will meet and how input will be captured and synthesized.	
Decision-Making Process: Describe the consensus or decision-making methods (e.g., majority vote, consensus threshold, nominal group technique).	
Documentation and Transparency: Specify how decisions, feedback, and recommendations will be documented, shared with the working group, and reported in outputs.	

8. OTHER (PLEASE PROVIDE DETAILS BELOW) (IF APPLICABLE IF NOT SKIP TO NEXT ITEM)

Use this section to describe any other methods, strategies, or activities that do not fall under the prior categories but are essential to your methodological work.

Item & Description	Working Group Additional Methodological Components
Description of Other Activities: Provide a detailed description of any other relevant methodological work (e.g., co-design workshops, simulation studies, stakeholder dialogues, user testing, consensus conferences).	
Purpose and Relevance: Explain how these activities contribute to your overall objective. Why are they necessary or valuable for developing/refining COS methodology?	
Participants or Data Sources: Identify who will be involved (e.g., patients, researchers, clinicians) or what data will be used.	
Methodological Rigor: Describe how these activities will be conducted with rigor, including ethical considerations, documentation, and plans for evaluation or dissemination.	
Expected Outputs: List any expected products or deliverables that will result from this work (e.g., reports, validated tools, methodological recommendations).	

10. TIMELINE AND MILESTONES

Estimated timeline for key activities

Date of Submission: