



# THE OMERACT HANDBOOK

FOR ESTABLISHING AND IMPLEMENTING CORE OUTCOMES IN  
CLINICAL TRIALS ACROSS THE SPECTRUM OF RHEUMATOLOGIC  
CONDITIONS

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Striving to improve endpoint outcome measurement through a data driven, iterative consensus process involving relevant stakeholder groups.

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## Chapter 2: OMERACT Working Groups

### Introduction

Working Groups are the hub of the activities at OMERACT. In fact, all of the work of OMERACT is facilitated by participants within various working groups who provide input on the development of OMERACT research agendas. OMERACT is a ‘bottom up’ organisation in which members select themselves by participating in its activities.

A foundational principle of OMERACT is the bringing together of multiple international stakeholders in collaborative research. For the purposes of OMERACT, stakeholders may be defined as: individuals or groups who are responsible for (or potentially affected by) an outcome measure and the healthcare decisions that would result from its implementation. The principle of stakeholder engagement implies a bi-directional relationship between researchers and stakeholders that will inform the development, prioritization, and/or use of the research project. Engagement requires the identification of the appropriate individuals, giving them a voice, and involving them in not only the decision-making, but also the overall research process.

Working Groups are made up of representatives from multiple continents, and from multiple stakeholder groups, including patients research partners. They report to the OMERACT Technical Advisory Group (TAG) and are accountable to the OMERACT Executive Committee. The role of the TAG is to critically appraise submitted documentation from OMERACT Working Groups for adherence to Filter 2.1 checklist requirements. TAG therefore focuses on the methods used, and that things were done and reported according to OMERACT guidance. This allows OMERACTers to focus on the results.

The following chapter is intended to serve as guide for Working Groups to assist them in following the OMERACT Way for Core Outcome Sets or OMERACT Methodology development while adhering to the Spirit of OMERACT.

## 1. Topic submitted and approved by OMERACT

Individuals interested in developing a core outcome set or OMERACT Methodology should first check on the OMERACT website ([www.omeract.org/working-groups/](http://www.omeract.org/working-groups/)) to ensure that their topic of interest is not part of a current OMERACT Working Group. If no overlap is identified, submit a brief outline of the proposed topic to the OMERACT Secretariat. The topic will be reviewed by the Technical Advisory Group, and if no overlap exists, approved and assigned to an OMERACT Senior Methodologist to work with the Working Group to develop the research program and help them complete the steps in the OMERACT Way.

Please follow this link to submit your topic of interest to the OMERACT Secretariat: <https://omeract.org/new-topic-submission/>

## 2. Forming the Working Group Team

The inclusion of multiple perspectives from the inception phases of research, as well as throughout the process, is critical to maximize the impact of research and facilitate research dissemination. Asking a question such as, “Who has the necessary expertise and content knowledge for our project?” can help identify an initial list. Asking “In what settings and populations are these outcomes intended to be used?” may provide additional stakeholder groups to consider. For instance, for an outcome intended only for use in a clinical trial, the groups would include those who perform clinical trials, methodologists, pharmaceutical companies, clinicians, regulatory groups, and patients. If a Working Group hoped their work would be adopted in longitudinal observational studies, it would be important to consider a wider range of stakeholders: comparative effectiveness researchers; more broad-based representation of direct health care providers; and health care systems representatives.

Early consultation with those who might have a very different view of outcome measurement in the area may be beneficial to better understand their concerns. This could also help identify potential barriers to implementation and feasibility. It helps to identify “blind spots” and unrecognized areas of controversy and identify opportunities for expansion of the research agenda.

Consider and define the specific role anticipated for a stakeholder group or individual, when their contribution would be most useful, and how they will participate. Over the lifespan of a given research project, the individuals and groups, as well as their roles, may vary considerably.

The stages for potential stakeholder engagement in developing a core outcome set include:

- Defining and refining the study question
- Identifying unmet needs and gaps
- Determining the appropriate population and settings of intended use
- Identifying other stakeholder groups and when to engage them
- Developing the overall research plan
- Participating in the conduct of the research such as the collection of data
- Serving as part of a Delphi Exercise or other consensus activities
- Reviewing results
- Serving as moderators and reporters at OMERACT meetings
- Developing plans for, and participating in dissemination to respective constituencies
- Implementing measures into specific settings to help with further refinement
- Helping with fundraising for research activities

For example, in the development of a PRO measure, the inclusion of patients would be quite critical during a phase of domain identification and prioritization, debriefing questions, and understanding impact. During a phase of psychometric analysis of the performance of items, there may not be as much patient involvement. However, in the phase of evaluating the results, patients would be critically needed to ensure that the results were in line with their experience in terms of establishing content and face validity. A situation could arise in which an aspect of disease was deemed to be highly relevant by patients, yet as existing measures were tested, there was not an

adequate instrument to address this. Patient engagement would be critical in addressing this discrepancy and in developing a research agenda to further evaluate this particular domain or sub-domain. As different research projects develop, evolve, and progress over time, there may be a need to engage new or different stakeholders.

Stakeholders vary between projects and may even change within a given project over time. Reasons for multiple stakeholder involvement include:

- increasing the number of ideas, perspectives, and depth of questions considered
- inclusion of all sectors affected
- establishing credibility and ensuring relevance and meaning to different groups
- enhancing quality
- increasing the face validity of final proposals
- identifying concerns, barriers, and controversies that would not have otherwise been considered
- increasing transparency
- increasing uptake and dissemination of the outcome measure or research product
- fostering relationships for future research efforts

OMERACT Working Group consists of a wide group of participants along with a smaller number of individuals who form the Co-Chairs and Steering Committee.

### Co-Chairs:

The role of the Co-Chairs of a working group is to drive the group's research agenda forward and ensure that the Working Group is adhering to the Spirit of OMERACT ([ref insert hyperlink](#)). The co-chairs provide leadership to the broader group members, while ensuring breadth of participation across different stakeholder groups. There is a minimum number of 3 co-chairs per working group representing a minimum of 3 continents.

### Steering Committee:

In addition to the co-chairs there needs to be a steering committee consisting of:

- Co-chairs
- 2 Patient Research Partners minimum [ideally at least 3 representing at least 3 different continents]
- 1 fellow and/or returning fellow minimum [ideally at least 3 representing at least 3 different continents]
- At least 2 other members with expertise or experience in the topic of the Working Group to provide input from the different stakeholder groups

The role of the Steering Committee of a working group is to move the goals of the group forward, while ensuring breadth of participation across different stakeholder groups. The Steering Committee is collaborative and inclusive - all members have an equal voice.

The responsibilities of the Steering Committee are fundamental to the success of the development of the Core Outcome Sets for the working group. These responsibilities include:

- Being guided by the Spirit of OMERACT principles
- Leading and facilitating the development of the working group Core Outcome Sets, through protocol development, research production, consensus development, voting and dissemination as described in the OMERACT Handbook
- Forming, maintaining, and regularly updating all members of working group
- Ensuring the completion and submission of the group Workbook to the OMERACT Technical Advisory Group in accordance with agreed timelines

- Identifying the needed resources and where needed, applying for supplementary sources of funding to support the development of the Core Outcome Sets

### **Working Group Members:**

A working group member is an individual interested in furthering the agenda of the Co-Chairs and Steering Group. As Working Groups are established, a brainstorming, or thought exercise, is recommended to identify potential stakeholders. An early statement from a nascent Working Group regarding the types of stakeholders considered, the rationale for their inclusion or exclusion, the proportional representation considered ideal, etc., is helpful in guiding the assembly of the larger Working Group, identifying potential gaps, and moving toward meaningful consensus. Discussions with other OMERACT Working Groups, mentors, and other organizations involved in consensus-based exercises, and a review of the evolving literature regarding stakeholder engagement, may also be helpful in identifying relevant groups.

Asking a question such as, “Who has the necessary expertise and content knowledge for our project?” can help identify an initial list. Asking “In what settings and populations are these outcomes intended to be used?” may provide additional stakeholders groups to consider. For instance, for an outcome intended only for use in a clinical trial, the groups would include those who perform clinical trials, methodologists, pharmaceutical companies, clinicians, regulatory groups, and patients. If a Working Group hoped their work would be adopted in longitudinal observational studies, it would be important to consider a wider range of stakeholders: comparative effectiveness researchers; more broad-based representation of direct health care providers; and health care systems representatives.

The responsibilities of the Working Group members include:

- Being guided by the Spirit of OMERACT principles
- Attending meetings of the Working Group
- Reviewing pre-read materials prior to meetings and come prepared for engaged discussion, active listening, and respectful dialogue
- Accepting responsibilities to share workload
- Accepting consensus-based decision making
- Supporting research and outreach between meetings as needed and agreed-upon authorship

### **Senior Methodologist & Technical Advisory Group (TAG) Members:**

A Senior Methodologist from OMERACT Central and a representative of the Technical Advisory Group (TAG) is allocated to join each of the working groups to support and mentor the work of the Working Group and to ensure they have the information they need for decision making.

For further information see the article from OMERACT 2016 by Tunis et al., “Engaging stakeholders and promoting uptake of OMERACT core outcome sets” available from <http://www.jrheum.org/content/44/10/1551.long>)

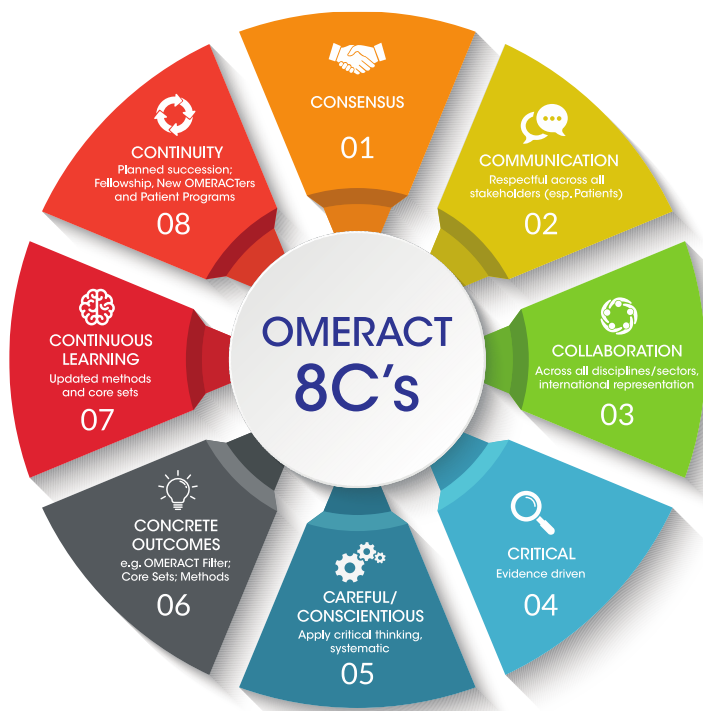
### **Working Group Membership Reporting:**

OMERACT has developed a template for keeping track of the various Working Group members. This form will be used to keep your Working Group website up to date and submitted along with your Domain or Instrument Selection Workbook.

<https://omeract.org/domain-selection/domains-downloadable-forms/>

## Ways of Working:

The approach of the Working Group should be one of shared learning and collaboration. Please remember the Spirit of OMERACT 8 C's. These values apply not only to those in leadership positions within OMERACT, but also to all OMERACT participants.



- To facilitate the responsibilities of the Working Group effectively, the Steering Committee is expected to host regular virtual meetings and openly share information with all members of the group. Meetings [with minutes circulated to all Working Group members] should be held bimonthly (every other month) during the year leading to the OMERACT conference, by Teleconference. Zoom conference details can be provided by the OMERACT Secretariat. Many groups find setting more regular meetings helps keep momentum going.
- Sharing of information and resources will be supported via OneDrive or simply via email at the agreement of the Steering Committee. Published resources developed by the group will be made available on the OMERACT website, administered by the OMERACT Secretariat.
- OMERACT has developed an online sign-up for all working groups, membership lists are posted on the individual working groups websites: <https://omeract.org/working-groups/>.
- Publication Dissemination of published materials is highly encouraged as an output of the working group. All Working Group members will be included as research paper authors, in accordance with publishing journal guidelines.

An important aspect of Working Group member engagement is providing some estimation of the level of commitment of time required, as well as an understanding of the specific role and expectations for participation. It is crucial that this is established at the beginning of the process. Communication with and between stakeholders is a key aspect of meaningful engagement and participation. It is also important for a Working Group to consider how and when communication will occur over the course of the project with the various group members and stakeholders.

Adequately engaging stakeholders may require additional education concerning a project, its goals, the methodologies, and vocabulary and terminologies. This might include; relevant background and reading, one-on-one pre-briefings and debriefings, and additional discussions to ensure that the stakeholders understand the work

and their roles. The OMERACT Glossary, originally developed for patients, is a useful resource to those new to the process. Furthermore, we anticipate that the Handbook will serve as an additional resource, as well as orientations for new OMERACTERS at meetings. For stakeholders that are new to the OMERACT process, there may be reluctance to speak up and participate. Group leaders should ensure that all participants are provided with opportunities and encouragement. If a particular stakeholder is not participating, it may be beneficial to discuss with them one-on-one to determine their reasons (e.g. not familiar with the process, not an expert with the content being discussed, not comfortable with voicing a contradictory position) so that any concerns may be addressed and reflected and assurance provided that their opinions are important.

## **Publication:**

**This guidance applies to manuscripts and not abstracts.**

1. We request that all OMERACT Working Groups publications use OMERACT in their publication title and to use OMERACT as a keyword.
2. Authorship must reflect the breadth of individuals who participated in a particular working group or collaboration, including patient members, in accordance with journal authorship guidelines.
3. For those groups submitting articles to Seminars in Arthritis and Rheumatism, for inclusion in the OMERACT collections, manuscripts must include substantive new content:
  - a. If you are including an 'update' paper with details of the projects, processes, outcomes and future research agenda of the working group it is expected to summarise substantial work and should include original research.
  - b. Additional publication(s) will be considered if they are original research and contain appropriate robust results. If there are no new findings, for example because results are being utilised in another manuscript, a manuscript will not be supported for publication. Decision on additional manuscripts will be based on abstracts submitted to the committee pre or post-OMERACT meeting that describe the content of all OMERACT proceedings manuscripts coming from that group.
4. We ask that OMERACT Working Groups wishing to publish OMERACT work outside Seminars making reference to OMERACT in the title or manuscript abstract, please send the manuscript to the OMERACT secretariat to ensure alignment with OMERACT principles before submission. The committee will ensure rapid turnaround of such manuscripts.

## **Accountability:**

The Steering Committee is accountable to the OMERACT Executive Committee.