
# 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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## INTRODUCTION

Working Groups at OMERACT are often oriented around core domain sets or core outcome measurement sets for a particular disease. There are situations when work is also done to advance outcome measurement with new methods that would cross diseases. Working Groups with this more methods-oriented focus are called Methodological Working Groups. Working in a similar process as the disease groups, Methodological Working Groups will use a SIG to generate interest and input, and as their goal advances, they will move to workshops to present their suggestions to the OMERACT community. Often consensus related to Methodological Working Groups will be around acceptance of a certain approach, or certain methods within all OMERACT Working Groups.

At present, there are several methodologically focused groups at OMERACT.

**Examples of working groups focused on methods:**

- Composite Outcomes
- Contextual Factors
- Equity
- Immune Related Adverse Events
- Patient preferences to value health outcomes for RCT's
- Remission in RA-patient perspective
- Safety
- Serum Urate - Surrogate Marker

## OMERACT MASTER CHECKLIST FOR DEVELOPING OMERACT METHODOLOGY

The OMERACT Master Checklist for Developing OMERACT Methodologies is a tool for OMERACT Working Groups to use as they move through the process of gaining consensus on a proposed OMERACT Methodology

| # | OMERACT Core Domain Set Checklist Item | Mark when complete |
|---|---|---|
| **Core Domain Set selection** | | |
| **Assembly of Working Group** | | |
| 1 | Assemble working group | ☐ |
| **Develop Methods Protocol** | | |
| 2 | Describe the methodological issue being addressed and relevance to OMERACT | ☐ |
| 3 | Scoping review of the field | ☐ |
| 4 | Categorize working group efforts | ☐ |
| 5 | **Deliverable:** Submission of protocol to Technical Advisory Group | ☐ |
| 6 | Review and approval of protocol for Core Domain selection by Technical Advisory Group | ☐ |
| **Implementation** | | |
| 7 | Implement the work from the protocol | ☐ |
| 8 | Working Group Progress Update | ☐ |
| 9 | **Deliverable:** Final report of the working group is submitted to TAG | ☐ |

An OMERACT Methodology Workbook is available by download here:. The workbook has been developed to help Working Groups keep track of their progress as they move through the Filter 2.2 process. Using the workbook will make it easier for Working Groups to report on their progress to the OMERACT Executive and OMERACT Technical Advisory Group and ensure that all necessary steps are fulfilled.

## ASSEMBLY OF WORKING GROUP

### 1. Assemble Working Group

OMERACT has established a philosophy around the communication and engagement of members entitled the 'Spirit of OMERACT'. This is outlined in detail in Chapter 1 of this Handbook. Working Groups are expected to foster the Spirit of OMERACT (e.g., collaboration, consensus) in all their work.

Following the guidelines for establishing a working group found in Chapter 2: OMERACT Working Groups, ensure your working group has all the required elements:

1. **International Representation – co-chairs from a minimum of three continents.**
2. **Stakeholder Engagement – particularly ensuring you have patient research partners (PRP), fellows, and other key stakeholders.**
3. **Topic Redundancy – a group that can represent all aspects your topic/disease area well.**

Working group will be asked to complete an online form in the early stages of formation more details on assembly on a Working Group can be found in Chapter 2.

## DEVELOP METHODS PROTOCOL

### 2. Describe the methodological issue being addressed and relevance to OMERACT

New Methods Working Groups need to provide a rationale for the relevance of this methods focus to OMERACT.

Groups should articulate how this method could be used and how it could impact the selection or interpretation of outcomes for OMERACT.

### 3. Scoping Review of the Field

One of the first tasks this group is expected to take on is a scoping or systematic review of the literature of the method, specifically, for how it is applied in the field of rheumatology (target conditions). Sensitive search strategies should be used to ensure capture of content that might be tapping this but not yet labeled as that specific methodology. The group will be encouraged to reach into literature from other areas – education, psychology, other clinical areas, statistics, to fully understand methods that are used in this field.

If a field has perfected this new method, it should be considered seriously and tested in the field of arthritis. Evidence of the methodology in arthritis, and of its ability to achieve the stated aim is still required, but there is no reason to recreate methods that are available in another discipline. If all the previous work has failed to demonstrate a proven approach, which was the case for patient-acceptable symptom states for Tubach (Tubach et al., 2005a), the Working Group will present this summary and a program of work that should be done to advance the field.

### 4. Categorize working group efforts:

Decide on status of the group – is it new, adapting or updating a field.

### 5. Deliverable: Submission of protocol to Technical Advisory Group

Once the Working Group has developed the protocol (checklist items 1, 2 & 3) they are ready to submit this for review by the Technical Advisory Group. This group will review the proposed methods. The protocol must adequately describe how they will conduct literature searches and articulate how this method could be used and

how it could impact the selection or interpretation of outcomes for OMERACT. The role of the Technical Advisory Group is to critically appraise submitted documentation from OMERACT Working Groups for adherence to Filter 2.2 checklist requirements. Specifically, their role is to verify that the recommended steps and methods are being followed and to identify any potential challenges (i.e., not enough continents involved).

### 6. Review and approval of protocol for Core Domain Set work by Technical Advisory Group

The Technical Advisory Group (TAG) will review and provide written comments on the methods described in the protocol to the co-chairs of the Working Group. At this stage the TAG will be looking at whether you have engaged a broad enough representation in your group, whether your planned methods are appropriate, and whether you have identified ways of sharing your work that will facilitate communication. Once the Technical Advisory Group has approved the protocol in writing, the Working Group can start work on the steps below. This may take a couple of iterations back and forth between TAG and the working group. The result will be a strong protocol.

## IMPLEMENTATION

### 7. Implement the Work from the Protocol

The Working Group has now established a program of work to move this methodology or its application to OMERACT targets forward. The work is now conducted. Methods groups are welcome to seek the collaboration of other groups to share data collection or datasets. Methods groups often just need a few items added to a survey to do some additional methods work.

SIG's can be held to support this ongoing work as necessary. Eventually the work should result in a workshop with solid recommendations for the OMERACT community as to the breadth of the methods, and the approach that should be taken by OMERACT based on the groups work.

#### *7.1 Scoping review or literature review?*

| TIP: Make use of a librarian or information specialist when developing your literature search strategy |
|---|

A review of the literature to see what method, specifically, for how it is applied in the field of rheumatology (target conditions). have been used in the past is often a good first step. It is up to the working group to decide who will lead this review, but many working groups have found this is a good project for an OMERACT Fellow and it has often led to a publication.

A librarian or information specialist should be consulted when developing the search strategy.

OMERACT recommends that this review is at the level of a scoping or systematic review rather than a narrative or descriptive literature review. As described below a scoping review is characterized by a comprehensive literature review with explicit methods of how articles were selected. Critical appraisal, which is a pillar of a "systematic" review, is not needed for a scoping review. As the name denotes, a scoping review is aiming to get a broad sweep of a field, rather than a very specific meta-analysis that could be the goal of a systematic review.

| | Literature Reviews | Scoping Reviews | Systematic review |
|---|---|---|---|
| QUESTION | Broad | Focused | Focused |
| SOURCES | Usually, unspecified.<br>possibly biased/ | Comprehensive.<br>explicit | Comprehensive, explicit |
| SELECTION | Unspecified.<br>possibly biased/ All study types/Developed post hoc at study selection stage | Criterion-based.<br>Uniformly applied | Criterion-based; uniformly applied |
| APPRAISAL | Not needed | Not needed | Quality appraisal of the methods used in the study is conducted |
| SYNTHESIS | Usually qualitative/ "Charts" data according to key issues, themes, etc. | Generally, not a quantitative meta-analysis conducted | Often is a formal synthesis such as a meta-analysis. |
| INFERFENCE | Generally, not evidence based | Usually, evidence based | Usually evidence-based |

**Table 1** Comparison of Literature, Scoping and Systematic Review

### *7.2 Conduct qualitative work*

> TIP: Remember that qualitative work must have representation from each relevant stakeholder group and from at least 3 continents with a suggested minimum of 30 participants' **total**

Formal qualitative research is an excellent way of obtaining the experiences of patients, family, and health care providers with the goal to explore the nature and the spectrum of the methodology

Rigorous qualitative methods must be used with the collaboration of a qualitative methodological expert. This is to ensure scientific rigor in study design (theoretical underpinning; patient selection; conduct, recording and transcribing of interviews; data analysis and interpretation). Having an informal discussion with a few patients can be a useful precursor but is not qualitative research. There are guidelines for well conducted inductive research technique to elicit new concepts. These include recent documents from the FDA on qualitative research to identify key domains, and the ISPOR work on concept elicitation. Both emphasize the conduct of solid qualitative work, engaging the correct stakeholder points of view, and a thorough exploration of each concept or domain. In

qualitative terms this is often called continuing your work until you hit “saturation” which means that no new ideas are being identified after a series of interviews, and there is a clear understanding of the breadth and depth of the idea that was discussed. Qualitative research is an entire field of research, too broad for this handbook. However, these two guidelines provide a focused approach to qualitative work aiming specifically at domain elicitation and definition.

Because we are an international organization and trials are often conducted or interpreted internationally, OMERACT recommends the qualitative work (individual interviews or focus groups) should aim to be as representative as possible of potential clinical trial participants with a minimum of 30 participants with a relevant stage and experience of disease, and with representation from at least 3 continents (11).

Publication of the results of qualitative work is strongly encouraged. Also having qualitative methodological expertise on the team will ensure this is to Consolidated criteria for reporting qualitative research (COREQ) standards (equivalent to CONSORT standards for RCTs) (http://www.equator-network.org/reporting-guidelines/coreq). Working Groups are encouraged to review this checklist for interviews and focus groups prior to starting qualitative work to ensure that all key items can be addressed in the reporting of their results. Any required ethics approvals and consent issues should be identified during the project plan discussions.

### 8. Working Group Progress Update

When preparing for the biennial conference Working Group progress updates are an important checkpoint with the conference planning committee. Written concisely, they offer high-level information about the status of the project, rather than every detail.

Doing progress updates is important because they help you keep all stakeholders in the loop and aligned on how your project is progressing. You’ll get considerably fewer questions about project status because you’re already ahead of the game. They show and tell that you’re on track, making you (and everyone else) feel confident.

And if your project isn’t on track, your status report will let others know what the delay is and what you’re doing to resolve any blockers, allowing you to show off your proactive approach to getting things back to where they should be.

### 9. Deliverable: Final report of the working group is submitted to TAG

Before presentation at the OMERACT Conference, the body of evidence for the methods should be presented to the TAG in the form of a written report summarizing:

- The issue being addressed
- The relevance to OMERACT
- The review of the literature on this method (include search, PRISMA summary along with synthesized results, append search strategy used)
- The additional work that has been assembled or conducted
- The recommendation for the OMERACT constituency.

Much of this information will be needed for the Technical Advisory Group to review the methods group for a OMERACT endorsement.

## FUTURE PLANS

**Future updates**. Working Groups should set a date when they plan to revisit the method and update their recommendations based on any new advances in the field.

**Dissemination plan** The Working Group should decide on an effective Knowledge Transfer and Dissemination plan that extends beyond the OMERACT papers. This could include using OMERACT SIGs to engage OMERACTers in the topic. It would also be in the approach used at the OMERACT Workshop to ensure all participants understand and can engage in an informed discussion and decision on the results of the work. At the end of the project, strategies might be in place to ensure uptake of the recommended methods by different disease Working Groups and groups outside of OMERACT.

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