
# 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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## PART 1 – WORKING WITH PATIENT RESEARCH PARTNERS

### A. INTRODUCTION

Capturing the patient perspective is an important part of research because the objective of OMERACT is to improve clinical outcomes for patients [1]. In order to effectively capture the patient perspective during the research phase, active collaboration between researchers and patients is essential. OMERACT has been involving patients in research as patient research partners (PRPs) since 2002, [2] to enable efficient inclusion of the patient perspective in the development of clinical outcome measures.

### B. PATIENT RESEARCH PARTNERS (PRPS)

Patient Research Partners (PRPs) are defined as "persons with a relevant disease who operate as active research team members on an equal basis with professional researchers, adding to benefit of their experiential knowledge to a research project" [3]. In health research, several terms describe the specific role of patients in the context of research, including patient stakeholders, health care consumers, or patient partners. OMERACT has chosen to use the term PRPs to distinguish the active role of patients as collaborative partners from the role of patients as participants in a trial, a focus group, an interview, or a survey.

Although PRPs may themselves participate as subjects in research projects, their specific role as a PRP is one that reflects inclusion within the OMERACT work on an "equal basis". This refers to equality in opportunities for full participation in the research process, to review all Working Group materials, and to vote in decision-making on the research process.

### C. OVERARCHING PRINCIPLES OF PATIENT INVOLVEMENT IN OMERACT

OMERACT has adopted 3 overarching principles and 8 recommendations regarding patient involvement in research throughout the OMERACT process. These were developed through consensus and accepted at OMERACT 2014 [4]. A brief history of patient research partner involvement in OMERACT is given in the second part of this chapter.

#### 1. OMERACT values the experiential knowledge of Patient Research Partners (PRPs)

The experiential knowledge of patients complements the evidence-based knowledge and clinical expertise of researchers and other stakeholders. Incorporating the patient perspective is an imperative for developing disease specific core-sets and patient reported outcomes. In such cases, patient participation is an unconditional requirement, independent of personal opinions or preferences.

### 2. Engaging patient research partners (PRPs) as integral stakeholders throughout the research process is a fundamental OMERACT principle.

Patients are an essential stakeholder in outcome research. Their involvement over the last decade has proven to add important values to the OMERACT research agenda and the conduct of outcome research. Patient participation has the advantage of aligning the focus of the scientific research with patient needs and priorities. The involvement of PRPs has also led to more empowered patients. They have taken co-ownership over research themes that are close to their own disease, or to their daily life. [5]

By recognising the important role of patients, those in leadership roles within OMERACT should enable patients to contribute to the research process by providing appropriate psychosocial and practical support.

The OMERACT Executive recognizes that the level of involvement may vary depending on the scope and type of a particular research project. For example, a statistical project might necessitate less patient involvement as explained in the recommendations below.

OMERACT participants subscribe to the OMERACT values. These values include trust, respect, transparency, partnership, communication, diversity, confidentiality, and co-learning, with respect to patient involvement. The general values apply not only to those in leadership positions within OMERACT, but also to all OMERACT participants. We recognize that patients share their personal experiences and require personal support in order to undertake their role.

## D. RECOMMENDATIONS FOR PUTTING THE OVERARCHING PRINCIPLES INTO PRACTICE

### 1. Working Group leadership and appropriate representation

While the Working Group leader should take primary responsibility, the entire research team has an active role in supporting patient involvement. The Working Group leader should take responsibility for the appropriate representation of the patient perspective in the research project. The Working Group leader may delegate a specific support role to one of the other Working Group members, who would organize, support and facilitate the involvement of PRPs in the research project.

PRP involvement throughout the entire research project is expected. However, patient roles and tasks within an individual project or Working Group may vary according to the stage or content of the research project. In general, full PRP involvement will be expected in:

a. All groups working on domain selection, identification or prioritization, including patient reported outcomes (PROs); alternative or composite uses of PROs; and construction of patient-reported scales;
b. All attempts to define ‘Core Sets’;
c. Groups considering the conceptual frameworks underpinning outcome measures;
d. Classification of outcomes to aid clinical decision-making;
e. Groups working on instruments or responsiveness.

Less direct PRP involvement may be appropriate in some circumstances:

a. Projects which focus on instruments and responsiveness for outcomes which are not patient-reported (such as imaging techniques, blood tests and biomarkers). For example, defining the smallest detectable difference for detecting an erosion for an MRI or ultrasound may not require high levels of patient input. However, determining a clinically relevant difference for

the measurement as related to its consequential validity would require full patient involvement.

b. Projects which focus on methodology. For example, a discussion of the use of item-response theory or Rasch analysis to develop an interval scale for assessment may not require high levels of patient input (depending on the expertise of the PRPs). However, if a core patient-identified domain was excluded on the basis of its failure to meet measurement concerns, then this would require patient input to determine the face validity of the instrument and consideration of whether this area should remain a critical feature of a research agenda.

For each project submitted to OMERACT, full PRP involvement is expected unless the OMERACT Executive has agreed otherwise. In order to receive an exception, Working Group leaders should discuss the issue with their Executive Mentor and the Executive Patient Stream leaders as soon as possible. Re-evaluation of the specific level of patient involvement should be considered over the life of a research project as needs and requirements may change.

All Working Groups will have PRPs attending their sessions during OMERACT conferences so that all groups will receive at least some PRP input.

Each group should involve at least 2 patient research partners. Two PRPs is the minimum number in each Working Group as recommended by other organisations [3]. An exception can may be made in the in some projects e.g. a statistical project where one PRP may be involved. Exception where only one PRP is recruited requires approval by the OMERACT Executive and relates to the examples given in recommendation1.

Not all PRPs involved in Working Groups will be able to attend OMERACT conference. Patient participation is limited to 10% of participants. The OMERACT Executive, working through the Patient Stream leaders, formally invites PRPs to attend the conference. Invitations consider the range of activities taking place at the conference and the overall financial situation.

Working Groups running a Workshop will usually be expected to nominate 2 PRPs and those running a SIG will usually be expected to nominate 1 PRP. This limit on the number of PRPs a work group can nominate to attend an OMERACT conference does not preclude a much wider PRP involvement in the research process outside of the conference.

PRPs attending an OMERACT conference, in the same way as other participants, will also participate in and contribute to sessions not related to the particular research area of their nominating Working Group.

The Working Group should support the cost of PRP participation, for example by seeking to provide traveling expenses to attend meetings or reimbursing other incidental expenses. In addition to Working Group funds, some financial support (e.g. part of the travel and OMERACT meeting registration) for PRPs will be provided and coordinated through the OMERACT Executive Patient Stream leaders. Patients are not expected to fund the cost of their participation in OMERACT conferences and related activities.

### 2. Patient research partners should be identified based on experiential knowledge and language skills, and personal interest

These required characteristics are based on existing recommendations and guidelines available in the literature of PRP involvement in research projects [7,7,8]. Diversity is an important principle of OMERACT. Recruitment and selection of PRPs should consider differences in geographic origin, socioeconomic and cultural contexts, gender, age, disease duration, disease severity and disease impact, and potentially other disease, personal, or external characteristics. An attitude based on critical yet constructive collaboration and a potential interest in research are important characteristics.

The involved PRPs in an OMERACT Working Group are not intended to represent inclusion of the entire patient perspective. The use of multiple, additional forms of data collection to capture the patient perspective, such as Delphi surveys, focus group interviews and surveys are likely to form part of the Working Group agenda, and should be performed appropriately.

Some participants may have overlapping roles as researchers and patients. This should be recognised so that roles can be appropriately defined. As with other OMERACT participants, potential conflict of interest needs to be disclosed, in particular financial interests that may be impacted by the person's involvement in the research project. Such financial interests may include: stocks; bonds; ownership or partnership; consulting arrangements; grants or contracts; employment; and copyright on a specific measure or questionnaire. [9]

### 3. Patient Research Partners and the Working Group leadership should discuss the goals of the project and mutual expectations.

Discussion of mutual goals and expectations before the start of the project, preferably during the first contact with a potential PRP, is good practice [10,11]. These expectations should be reviewed regularly throughout the process. Where possible, it is desirable to estimate the expected time PRPs are required to allocate for the project (e.g. 2 hours per month over 6 months) [11] with feasible timelines (e.g. feedback requested within 2 weeks).

### 4. Patient Research Partners should be given the opportunity to be involved throughout the research process.

PRPs should have the opportunity to be involved throughout the research process. [3,5,7,10,12,13,14] This includes the following stages: identifying the research question; reviewing and contributing to the study design; recruitment; data collection; analysis of findings; and dissemination of the results. PRPs should be consulted about and take part in decisions on implementation of the Working Group's research agenda. Whenever possible PRPs should attend meetings of the Working Group or be connected by teleconferences etc.

Some PRPs may not wish or may not be available to participate in all phases, but they should be given the opportunity to do so. The frequency of involvement may differ, depending on the stage of the project. For example, in core domain selection, frequent involvement may be required, whereas data mining for discrimination may require less. This decision of inclusion or exclusion on any area of the project should be discussed by the PRPs and the Working Group leader.

### 5. The Working Group leadership should provide PRPs with timely and tailored support and information.

PRPs are full members of the Working Group, and in order to contribute fully, will require appropriate information and support. There is a wide range of support which can be provided, as indicated in the next section.

### 6. The nature of Patient Research Partner involvement should be reported throughout the OMERACT process

This recommendation encourages Working Groups to report the expected level of involvement and the names of the proposed PRPs in the initial research proposal. This ensures PRPs are involved early on in the process. To allow OMERACT participants to understand the extent of PRP involvement, sufficient detail should be reported in OMERACT documents such as proposals and pre-reading materials.

### 7. Involvement of Patient Research Partners should be recognized appropriately including co-chairing, co-presenting and co-authorship if applicable

Appropriate recognition can be enhanced by having PRPs who are willing (and able to do so) involved in facilitating discussion groups and reporting back at OMERACT conferences, presenting of data, and review of manuscripts. Recognition can also be provided by additional support to PRPs, such as arranging access to literature and libraries, offering thanks at special occasions, or financial help to attend an educational symposium or international congress such as ACR and EULAR.

Acknowledgement of PRPs' contributions can take place through a text box at the end of the final research report or by offering co-authorship where the requirements of authorship are met. [3].

## E. METHODS OF SUPPORTING PRP INVOLVEMENT

### 1. Information

PRPs are full members of the Working Group. Each team member is responsible for ensuring equality of all members in order to work effectively together. Each is responsible for creating a safe environment of open and honest interactions, that are sensitive to differences in culture, training and education of each member [6,10]. PRPs should receive appropriate and relevant information. For example, lay summaries and explanation of relevant statistics, research terms and disease features.

Open communication is important to all members of the Working Group, including PRPs. [6,10] Involvement in email exchanges, conference calls and corridor meetings at OMERACT conferences and other international congresses should be encouraged. Emails to the research team should either include the PRPs or a specific patient email should be sent at a similar frequency. Even when tasks or phases of the project may need little patient involvement a specific email or newsletter addressed to PRPs should be sent to keep PRPs informed.

PRPs should be offered the choice whether they would like to receive all information or whether they would like to receive less information relevant for the Working Group.

## 2. Invitations to meetings

While Working Groups do not provide financial support to members to attend Working Group meetings held at international conferences such as ACR or EULAR, it may be appropriate to offer PRPs financial support if it is available. It will be the decision and efforts of each Working Group leadership to try to facilitate PRPs if their input is necessary. If PRPs are not present at the meeting, they should receive an update about what has been discussed at the meeting.

## 3. Support overall

Support refers to actions that encourage and promote PRPs to contribute with confidence throughout the research project by guaranteeing a positive and welcoming environment. Support includes tailored information, debriefings, and encouragement of PRPs to speak up during meetings or during the research process. [6,11,12,15]. (Here we are not referring to financial subsidies.)

## 4. Support during meetings and conferences

This refers to the provision of summaries of research in lay language ahead of the OMERACT meeting, as well as a list of abbreviations, terms and phrases relevant to the discussions and copies of appropriate outcome measures. It is also important to provide adequate time for PRPs to think about documents before responding. A rule of thumb is to allow at least one week, ideally 2, between distribution and feedback or subsequent teleconference. Moderation skills are important to enhance participation in group meetings. [12]

## 5. Support between meetings

While involvement of PRPs between OMERACT meetings in Working Groups may vary according to the specific work phase PRPs should be kept informed. For some Working Groups, a separate PRP group may be established with a designated PRP leader who is a member of the Working Group steering committee. PRPs can have additional meetings and telecalls with PRPs to provide non-technical updates to keep the group informed and to receive additional input. Such separate discussions can be beneficial before or after regular telecalls of the Working Group to provide introductions and debriefing to material, discussions and issues for discussion.

There may be occasions on which PRPs are less comfortable in participating. For example, when a conference call will be discussing methods of statistical analysis for a PRO, or outcome measure, in which PRPs are an essential part of the group. In this case PRPs may be less able to contribute to the specific discussions or decision making. The starting point is the principle of inviting participation from PRPs throughout the process, regardless of the topic. However, it is recognized that “getting everyone on the same page” or to the same level of understanding may be difficult with certain technical aspects.

With a PRP as part of a group steering committee working with the co-chairs and other members of the steering committee, there will be opportunities to discuss the aspects of the work in which more or less PRP involvement may be appropriate.

## 6. Support from the OMERACT Executive Committee

The OMERACT Executive committee provides "generic" education and implements patient-centered ways to prepare interested patients to become capable PRPs in order to optimize research and results. During the OMERACT conference, care is taken to maximize PRP participation within the overall constraints of the program. The patient stream leaders (designated by the OMERACT Executive) coordinate the patient group and patient involvement, working with the members of the Patient Board.

Examples of current initiatives include:

a. Patients arrive one day before the start of the formal conference
b. Summaries of research in lay language provided to patients ahead of the formal conference (prepared by Working Group leaders)
c. Addressing administration issues, special needs and concerns
d. A half-day PRP session at the beginning of the conference, including short education workshops to help understand some 'terms' and 'methods' of the research (e.g. explanation of statistics)
e. Daily sessions to explain each of the Working Group's projects
f. Patient mentoring/buddy system (an experienced patient mentors with a less experienced patient)
g. Planned individual timetables (Personalized Patient Program) to prevent overburdening by pacing of time and energy of patients
h. Provision of an "on-call" physician to serve to triage medical concerns that may arise during the meeting
i. Glossary of medical and research terms updated before each conference
j. Personalized arrangements with conference hotels.

## 7. List for Working Group leaders

| Working Group checklist for involvement of and support for patient research partners | | | |
|---|---|---|---|
| Paragraph | Text | Action | Check |
| 4.D.1 | The working group leadership should take responsibility for appropriate representation of the patient perspective in the research project. | 4.D.1.1 There is one person among the working group leadership nominated to take responsibility for coordination and support of PRPs in the research project. | ☐ |
| | | 4.D.1.2 Patient involvement is appropriate: patients are fully involved or the OMERACT Executive has given approval to a lower level of patient involvement. | ☐ |
| 4.D.2 | Each working group should involve at least 2 patient research partners. An exception may be some projects (e.g. a statistical project) where one patient research partner may be involved. | 4.D.2.1 The working group includes at least 2 PRPs or the OMERACT Executive has given approval to a reduced extent of patient involvement. | ☐ |
| 4.D.3 | Patient research partners should be identified based on experiential knowledge and language skills, taking into account their personal interest in the topic. | 4.D.3.1 The selected PRPs have good English language skills and have appropriate experiential knowledge | ☐ |
| | | 4.D.3.1 The PRPs fulfil the requirements set by the working group leadership | ☐ |
| 4.D.4 | Patient research partners and the working group leadership should discuss the goal of the project and mutual expectations. | 4.D.4.1 Goals and mutual expectations have been discussed with the PRPs prior to involvement. | ☐ |
| | | 4.D.4.1 Goals and mutual expectations have been discussed with the PRPs at least once during the project, before the OMERACT conference. | ☐ |
| | | 4.D.4.1 Goals and mutual expectations are discussed with the PRPs who are present at the OMERACT meeting, at the beginning of the OMERACT conference. | ☐ |
| 4.D.5 | Patient research partners should be given the opportunity to be involved throughout the research process. | 4.D.5.1 Oppotunity for PRPs to be involved in identifying the research question | ☐ |
| | | 4.D.5.1 Oppotunity for PRPs to be involved in identifying the reviewing and contributing to the study design | ☐ |
| | | 4.D.5.1 Oppotunity for PRPs to be involved in recruitment | ☐ |
| | | 4.D.5.1 Oppotunity for PRPs to be involved in data collection | ☐ |
| | | 4.D.5.1 Oppotunity for PRPs to be involved in analysis of findings | ☐ |
| | | 4.D.5.1 Oppotunity for PRPs to be involved in dissemination of results | ☐ |
| | | 4.D.5.1 Oppotunity for PRPs to be involved in decisions on implementation of the working | ☐ |
| | | 4.D.5.1 PRPs attend meetings of the working group or are connected by teleconferences etc. | ☐ |
| | | 4.D.5.2 Decisions about inclusion or exclusion of PRPs in any area of the project discussed by the PRPs and the working group leader | ☐ |
| 4.D.6 | The working group leadership should provide PRPs with timely and tailored support and information. | 4.E.1.1 PRPs should receive appropriate and relevant information: for example: lay summ | ☐ |
| | | 4.E.1.2 Involvement in email exchanges, conference calls and corridor meetings at OMERACT conferences and other international congresses | ☐ |
| | | 4.E.1.3 Discussion help with PRPs relating to methods of communication | ☐ |
| | | 4.E.2.1 Consideration of financial and other support to attend meetings | ☐ |
| | | 4.E.4.1 Working group contributes to PRP support during OMERACT conferences | ☐ |
| | | 4.E.5.1 & 4.E.5.2 Consideration of additional PRP support measures | ☐ |
| 4.D.7 | The nature of patient research partner involvement should be reported throughout the OMERACT process. | 4.D.7.1 PRP involvement is reported in the initial proposal. | ☐ |
| | | 4.D.7.1 PRP involvement is reported in OMERACT reports. | ☐ |
| 4.D.8 | Involvement of patient research partners should be recognized appropriately including co-chairing, co-presenting and co-authorship if applicable. | 4.D.8.1 PRP recognition is enhanced by specific workigngroup efforts | ☐ |
| | | 4.D.8.2 PRP contribution to publiccations acknowledged appropriately | ☐ |

## F. DURING THE OMERACT MEETING

### 1. Patients opening session

Patients arrive the day before the meeting. On the morning of the meeting, they attend a 2-hour session preceding the main meeting program. This includes information about the diseases or conditions that are included in the conference programme; history and outputs of OMERACT; in particular the history of patient involvement and its consequences; the role of patients as key participants in the meeting consensus process; information about opportunities for participation in the process for reaching consensus including pre-conference, conference and post-conference time periods; an opportunity to ask experienced OMERACT patient and professional participants about issues or concerns.

### 2. Patients daily session

The purpose of the patient's daily session is principally to prepare patients for the upcoming activities in the main programme. The first one takes place immediately after the patients opening session, and then each afternoon in preparation for the following day. In general, there are three workshop or module sessions requiring preparation. For 15 min each, the leader(s) of each session come and explain how the session came to be in the programme, what the main issues are, and where patient input would be particularly useful. They can also address any questions the patients may have in particular.

### 3. Patients final session

On the day before the final plenary session, there will also be time to explain to patients how this session works and how the OMERACT voting takes place. There is also usually time for the patient group to reflect on the overall conference programme and prepare feedback to the organisers.

## PART 2 – A BRIEF HISTORY OF OMERACT PATIENT RESEARCH PARTNERS

### 1. Introduction

One member of the first group of patients to attend an OMERACT conference subsequently decided to study in detail how patients came to be involved in OMERACT, how the organisation changed in response to this, the lessons learned, the successes achieved and the challenges that lie ahead. These were the subject of his PhD thesis and some of the publications that derived from it [16,17,18,19] which provide an in-depth understanding of the process and outcome of these developments. The following section is extracted from Maarten de Wit's thesis with minor modifications.

### 2. Initial decision to invite PRPs

During OMERACT 5 in 2000, participants discussed the concept of a Minimum Clinically Important Difference (MCID). Based on methodological arguments a growing interest in Patient Reported Outcomes (PROs) emerged, culminating in a spontaneous proposal at the final session to invite patients to the next conference. All participants voted in favor of this proposal [2]. The chair of the conference felt confident about the proposal because it had been discussed in the organizing committee before, although no decisions had been taken. Participants of the MCID module argued that patient perspectives should be explored further [20] and took responsibility for identifying 11 patients to join OMERACT 6 (2002) and to review the RA core set.

A document analysis revealed the unconditional positive reception of patient delegates at OMERACT conferences, and PRPs have confirmed during interviews that concerns regarding their involvement were misplaced [u]. They felt their reception was extremely welcoming [21]. Also, the organizers were excited and called the patient involvement "a tremendous success" [22].

## 3. Subsequent role of PRPs

Between 2002 and 2012, a total of 57 PRPs with different rheumatic diseases had participated as full delegates with equal voting rights [23]. Their role and contributions had developed over time. At OMERACT 2002 they formed a homogeneous group of people with RA with little or no experience in scientific research. The level of involvement in the conference was limited; support was not organized, and the number of sessions patients attended was restricted. Contributions centered on participation in workshop discussions about the severity of fatigue and the definition of low disease activity, although there was a PRP keynote speech at the opening ceremony [21]. In contrast, by OMERACT 2014, PRPs were a heterogeneous group with different rheumatic conditions and different levels of experience and cultural backgrounds. They received a pre-conference information pack and were actively supported by a pre-conference dinner, a glossary of used OMERACT research terms, training sessions, and a buddy system. They carried out a variety of tasks similar to that of professionals such as giving plenary presentations, co-chairing and reporting back from breakout sessions, and preparing consensus statements. Several PRPs became co-authors of peer-reviewed publications and have presented aspects of group work at other conferences.

## 4. Patient contributions to OMERACT meetings and outcome research

In interviews about the OMERACT 2010 meeting, participants reported a variety of contributions made by PRPs during the conference, where they were an integral part of the deliberative and consensus-building process [24].

## 5. Five categories of contribution

Five main categories for PRP participation have been identified:

1) Contributions to the research agenda;

2) The development of core sets;

3) The development of patient reported outcomes;

4) The culture of OMERACT; and

5) Consequences outside OMERACT.

For example, PRPs have made contributions to the research agenda from the very beginning as they had significant influence by participating in workshops and small group discussions. They identified new outcome domains that are relevant from their perspective, but not included in existing core sets [25]. The first Patient Perspective Workshop, attended by 11 patient participants and 41 professionals, focused on the development of "valid outcome instruments that incorporate the perspective of the patient and to prepare the evidence and arguments for their inclusion in the (RA) core set" [26]. The preconference paper pointed out the methodological and political challenges: How to elicit and incorporate preferences of patients in RCT's? [23] The workshop had been specifically arranged to support the PRP contributions including a pre- and post-workshop meeting. The workshop identified subjective experiences of RA, not encompassed in the RA core set but important aspects of the disease: a sense of well-being, fatigue, and disturbed sleep [26].

## 6. An added perspective

After the first conference attended by PRPs, it became apparent that perspectives of professionals and patients had differed, and more research was needed to articulate patients' priorities [27,28,29,30]. PRPs emphasized the need for a holistic approach to people with arthritis [21]. The acknowledgement of the discordance of perspectives initiated new studies looking into the preferences, opinions and experiences of people with rheumatic diseases [31,32,33] and developing patient-derived core sets [12]. This made all OMERACT participants more aware of the relevance and importance of inclusion of the patient perspective. New topics emerged: remission, pain, flares, and

foot problems. Contributions in the other areas identified are discussed in detail in a paper, whose first author was among the first OMERACT PRPs [24].

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