
**OMERACT 11: International Consensus Conference on Outcome Measures in Rheumatology**

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# OMERACT 11 — International Consensus Conference on Outcome Measures in Rheumatology Clinical Trials

The biennial OMERACT 11 meeting was held in Pinehurst, North Carolina, USA, from May 12 to 17, 2012, with participants from North America, Europe, Asia, and Australia. One hundred ninety-eight attendees enjoyed the rural but manicured ambience of this famous golf retreat; however, as usual, given the grueling daily dawn-to-late-night scheduled meetings for discussions, few attendees were able to experience the famous golf courses. OMERACT participants came from a range of backgrounds and expertise, with clinical outcome methodologists who work in academic environments, regulatory agencies, pharmaceutical and biotech companies or clinical research organizations; clinicians with an interest in outcomes research; fellows; trainees; and patients.

As has been the case for the last 10 years, patients played an integral part in each aspect of the meeting, as well as spending time engaged in detailed discussions in their own dedicated sessions. Patient participation has proven to be extraordinarily informative in the development of OMERACT because we are attempting to develop outcome measures that are clinically relevant — and patient input is at the core of determining what might or might not be clinically relevant. At this meeting, 18 people living with rheumatic diseases being addressed by the working parties were an important constituency, providing unique perspectives that continually helped to reorient the larger audience concerning disease effects.

In addition to a commitment to patient participants in all aspects of our work, we are committed to further developing the field of outcome measure research by requiring each working group to provide a leadership role for their identified fellow. We collaborated with the European League Against Rheumatism and the American College of Rheumatology, who provided support for 5 fellows each. Twenty-two fellows participated within the meeting, with additional separate sessions including presentation of their abstracts of work within each OMERACT working group, which were critiqued by senior investigators involved in OMERACT and in outcomes research. Additionally, patients and fellows each had a separate daily discussion "track" including introductions to sessions for the following day. This provided a more personalized experience, to foster further development of patient research partners and to encourage young investigators to engage in outcomes research.

The traditional format was divided between 1 module, 5 workshops, and 10 special interest groups (SIG), with the resultant discussions summarized in 21 articles published in consecutive issues of *The Journal*. The meeting also introduced 2 changes within the structure of OMERACT. Prior to this meeting, the executive leadership expanded its membership from 5 to 14; and OMERACT work was divided into 4 streams: patients, methods, diseases, and imaging/biomarkers. This format allowed for more effective mentoring, monitoring, and management of working groups within each stream.

Five separate sessions were dedicated to reevaluating the current OMERACT filter of truth, discrimination, and feasibility, evaluating the need for revision or expansion, and providing a better framework for groups interested in developing core sets and improving outcome measures in randomized controlled trials (RCT) and other research settings. An important first step for RCT is to define a core set of domains that reflect clinically relevant outcomes for inclusion within such trials. Validated instruments are then needed to assess each domain, and a core set of outcome measures must then be consistently measured in RCT within the designated disease state. The original OMERACT filter (Filter 1.0) states that any outcome measure should meet criteria for being truthful, be discriminative between groups and responsive to the intended intervention, and be feasible to perform.

Given that initial development of the filter took place more than 20 years ago, it was recognized that some aspects required updating. To address those issues, about one-half of the OMERACT 11 meeting was dedicated to daily discussions regarding the filter in the context of updated general domains of health status. The original OMERACT filter was predicated on considering a simpler domain construct of the 4 "Ds": discomfort, disability, dollar cost, and death. It was recognized that broadening these original 4 Ds into a more global conceptual framework for outcome measurement across health conditions was needed (Filter 2.0), offering an opportunity to define a more explicit process to develop core measurement sets. The first step was to modify the original 4 D framework to comprise 3 core "areas:" death, life impact, and pathophysiologic manifestations. Following further discussion, it was recognized that adding resource use as a domain of measurement was desirable.

Individual sessions regarding Filter 2.0 included Session 1: Truth (1) Domains and How to Define Them; Session 2: Truth (2) Instruments and How to Validate Them; Session 3: Discrimination, Including Responsiveness & Feasibility; Session 4: Putting It All Together; The Example of Patient Reported Outcomes; and Session 5: Putting It All Together; The Example of Imaging and Biomarkers.

The entire meeting was integrated around the Filter 2.0 sessions. Specific disease or topic groups were invited to participate and present "case studies" for each of the Filter 2.0 discussions. Thus, practical issues (pros and cons) related to utilization, and examples of implementation, informed further evolution of the filter.

As with other OMERACT meetings, sessions were structured as (1) SIG to present data and obtain feedback for ongoing work streams and to aid in evaluation of their research agendas; (2) workshops, in which a group provided data and subsequent breakout groups for topic refinement or more intensive discussion followed by a plenary vote seeking endorsement; and (3) modules, with longer breakout sessions during which groups sought endorsement for finalization of a core set of outcome measures or a responder index. SIG presented at this year's meeting included connective tissue disease–interstitial lung disease; equity; hand osteoarthritis; Patient Reported Outcomes Medical Information System (PROMIS); Rasch analysis; magnetic resonance imaging (MRI) in hip osteoarthritis; MRI in inflammatory arthritis; MRI in juvenile idiopathic arthritis; myositis; and polymyalgia rheumatica. Workshops included acute gout; vasculitis; flare in rheumatoid arthritis; ultrasound: responsiveness in rheumatoid arthritis; and worker productivity; and there was a single module on psoriatic arthritis.

A special meeting was held immediately preceding the larger OMERACT meeting to discuss different approaches to data analysis, specifically addressing similarities and differences between item response theory (IRT) and Rasch approaches — both potentially applicable to a number of working groups in their development of outcome measures. Examples were presented of the IRT-developed PROMIS developed by the US National Institutes of Health, and for development of measures using the Rasch approach. Discussions of these topics were followed up in individual Rasch and PROMIS SIG held within the formal meeting.

The biennial meeting continues to be the highlight of the OMERACT process, which now covers an increasingly diverse range of rheumatic conditions. This meeting experience brings together diverse stakeholders, including patients, to ensure that decisions and discussions are relevant and applicable. The updating of the OMERACT Filter 2.0 to be more broadly applicable was a major focus of this meeting to provide a more explicit framework for the OMERACT process. A formative research agenda was developed for a number of groups that will provide considerable opportunities for ongoing collaborative research leading to the next meeting. Without a doubt, the products of OMERACT 11 will engender further debate and discussion that will be continued at the OMERACT meeting to be held in Budapest, Hungary, in 2014.

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**ACKNOWLEDGMENT**

Financial support for OMERACT 11 was provided by the following pharmaceutical companies and their subsidiaries: Amgen, USA; Astra Zeneca, UK; Bioberica, Spain; Bristol Myers Squibb, USA; Celgene, USA; Eli Lilly, USA; Forest, USA; Genentech/Roche, USA; Genzyme, USA; Horizon Pharma Inc., USA; Novartis, Switzerland; Pfizer, USA; Quintiles, Netherlands; Regeneron, USA; Savient, USA; Takeda, USA; UCB, USA.

The Organizing Committees thank the European League Against Rheumatism and the American College of Rheumatology for bursaries provided to young researchers to participate in the OMERACT program. The OMERACT conferences are possible only through the ongoing commitment of the (co-)chairs and their subgroups of the modules, workshops, and special interest groups, who provide the science. A special thank you goes to ICG (Innovations Consulting Group) for organizing the logistics of this conference. A very special thank you goes to the OMERACT Secretariat, and especially to its organizational head, Shawna Grosskleg, who has provided terrific support throughout the years.

J Rheumatol 2014;41:145–9; doi:10.3899/jrheum.130937

Papers presented at the OMERACT 11 Conference, Pinehurst, North Carolina, USA, May 12-17, 2012:

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| Part 1 | Methods |
| Part 2 | Imaging and Other Biomarkers |
| Part 3 | Disease-specific Outcomes I |
| Part 4 | Disease-specific Outcomes II |
| Part 5 | The OMERACT Filter 2.0 |

Part 2 will appear in the February issue.