

Working Guidelines of the OMERACT Ultrasound working group and sub groups

Introduction

The Outcome Measures in Rheumatology (OMERACT) Ultrasound Working Group (WG) belongs to the OMERACT topic called “Imaging & Biomarkers” and was founded in 2004 with the aim to validate outcome measurement instruments (scores) based on imaging (ultrasound) for use in clinical research to ensure valid and comparable results between trials and to benefit the clinical decision makers. The research plan within the WG should fulfill the requirements of the OMERACT filter 2.1. (1), and the validation of ultrasound as outcome measurement instrument, whatever the disease, should follow a structured approach according to the stepwise methodology recently published by the WG (2):

- Step 1: apply OFISA to the published literature to verify the evidence (systematic literature review);
- Step 2: in the absence of evidence produce consensual ultrasound definitions of the domain under study (Delphi consensus process with or without images);
- Step 3: test the consensus through web-based and patient-based reliability exercises to create the ultrasound score;
- Step 4: apply the score in multicentre studies on responsiveness, prediction, impact or other topics.

How does the OMERACT Ultrasound WG work?

1. Participation in the OMERACT Ultrasound WG and subgroups is open to every OMERACT member who is interested and willing to actively participate in the work of the group.

2. The structure of the OMERACT Ultrasound WG is open, transparent, and collaborative. Major decisions should be taken preferably on a consensus basis - in a meeting where a maximum number of members can be present. These meetings are open to every member and are announced on the OMERACT Ultrasound WG's website: OMERACT-us.org by the OMERACT Ultrasound co-chairs. This website has a webmaster who the current role is to upload material send to him only by the chairs.
3. The leadership of the OMERACT Ultrasound WG consists of 2 tiers. Currently, there are three co-chairs who supervise and coordinate the activities of the group. In addition, an overall WG mentor supports the group in his/her position of senior advisor. The three co-chairs (and the mentor), as responsible of the OMERACT spirit, are in every sense the engine of the WG group:
 - a. They are responsible for drawing the research agenda for the various subgroups, for which they act as "mentor" (only one mentor for each subgroup);
 - b. They take care of a balanced participation of interested members and members-experts in a certain field.
 - c. They are responsible for the agenda of the main WG meeting, the convocation, the preparation and the making of the minutes of the WG meetings that will be listed on the website;
 - d. They are also responsible for ensuring the website update in collaboration with the convenors of the subgroups. All the members of the OMERACT WG are invited to regularly email update to the three co-chairs and the mentor (all four should be addressed in the email).
4. The co-chairs are rotating in their position every 6 years (3 OMERACT meetings) and should represent the 3 main continents' groups: Australasia, Europe, and Americas (North, South and Central). Co-chairs acting as "mentor" for the projects initiated in a subgroup are responsible of the good progress during their co-chair time. Projects initiated but still not finished during this "6 years" period will still be mentored by the co-chair who initiated the project. However, after the term of the "6 years", the co-chair cannot act as "mentor" of new projects initiated by the subgroup after this term, neither be "mentor" of new subgroups initiated

after they step down. This will ensure that the incoming co-chair can actively participate and take responsibility of new projects.

5. OMERACT Ultrasound WG meetings are held annually both at the EULAR congress and ACR; biannually at the OMERACT Conference. The EULAR meeting is held on the Friday morning of the congress and the ACR meeting is held on the Sunday of the congress. The ACR meetings are longer compared to the EULAR meetings for ensuring in-depth discussion and progress.

OMERACT Ultrasound subgroups

1. Any member of the OMERACT US WG may suggest the creation of a new subgroup, but the subgroup can only be formed in agreement with the co-chairs and mentor. Subgroups are relevant in areas of unmet needs in relation to clinical trials where ultrasound may have a role as an outcome measurement instrument. Not all topics are relevant as an OMERACT Ultrasound subgroup.
2. Every subgroup consists of an accountable leadership, i.e., a core group with one or more convenors, responsible for progress of the work proposed by the particular subgroup. The members of each subgroup should work coordinated and actively for the progression of the topic. This work includes also the following: organizing research meetings, (including reliability exercises on patients), ensure solid financial funding and establish relationships with a statistician.
3. The participation in the subgroup meetings are open. However, to be involved into the practical work (i.e. so-called reliability exercises), participants must attend the meetings and should have a minimum requirement of ultrasound competency according to EULAR level 1 or a similar national certification.
4. Every subgroup has a website responsible person who updates the scientific progress of the subgroup in a standardized form that is sent to the co-chairs who then liaise with the webmaster for uploading the updated information onto the website.
5. Each subgroup update must contain information about the convenor, the list of members and co-chairs involved. Further, the web-responsible

subgroup member must be listed, and the group update must be indicated with the date of the update.

6. Meetings should be organized in full collaboration with the 3 co-chairs (one acting as mentor of the subgroup) and the overall WG mentor. The three co-chairs are invited to the meeting and at least one of them (if the mentor responsible of the subgroup is absent) should be present at the meeting. Immediately after the meeting, the data should be analysed by a statistician and the results should be distributed among the organizers of the meeting and the 3 co-chairs and the WG mentor. An update of the work should be posted in the website within 6 months after the meeting and ideally, according to the progress of the project, a draft manuscript should be ready within 12 months after the meeting. There should be clarity about the list and the rank of the authors in this manuscript, preferably since the beginning.
7. The authorship in the publication of the subgroups work should be homogeneous in all publications on behalf of the OMERACT WG group: the order of the authors should reflect the contribution of each author and, in case of equal contribution, alphabetic order may be used but should be addressed in the notes. The principal positions (that can vary, depending on the interest of the principal investigators) should be agreed among the principal investigators and the convenors. The three co-chairs and the WG mentor, in addition to participate in the meetings, are responsible for the work conducted, therefore should review and approve all publications on behalf of OMERACT, before sending this to the OMERACT Exec Committee, and they must be included in the authorship list (in the last part and according to the above mentioned indications based on the active participation). The mentor of the subgroup may have the last position when he/she has actively coordinated the work and participated to all steps, but this position is not automatically related to his/her mentoring activity.
8. Other OMERACT members not actively involved in the published work of the subgroups can be acknowledged in the manuscript.

OMERACT bi-annual meeting

Every other year the bi-annual OMERACT meeting is held. The meeting rotates between, Canada, North America, Europe and Australasia. Here the WG has the possibility to present the work done for validating ultrasound as an outcome measurement instrument as a SIG (Special Interest Group) session. Further, already validated ultrasound outcome instruments could be provided as a measurement instrument for other working groups.

1. The ultrasound WG has usually the option to produce up to 3 short papers representing the meeting to be published in J Rheumatol. These papers cannot be update papers but must be original papers.
2. The ultrasound WG has a group fund. The money is equally divided over 2 years to fund the catering of the annual WG meetings during EULAR and ACR as well as the funding of the publications related to the bi-annual OMERACT meeting.
3. For the biannual meeting the group may have one or more OMERACT fellows who are currently working within the OMERACT US WG. The fellow attends a special “fellows session” during the OMERACT meeting and will present the work done for the meeting both orally in during the WG SIG and orally or as poster during the dedicated fellows session.
4. The fellow may register to the bi-annual meeting to a lower price but the ultrasound WG has no funding for the fellow who must provide his/her own funding for the meeting and the travels.

***caveats**

Before the current update of the OMERACT SOPs, four ultrasound subgroups (previously called “sub task forces”) have had two mentors - since both mentors in these groups have been involved in the work from the beginning, they will act as subgroup mentors until the initiated subgroup work has been finalized. For future subgroups and for all other subgroups future activities, there will only be one mentor per subgroup.

In the future if a new area/task within a subgroup is initiated this will be listed under the current/future steps of the group and will not be an independent subgroup, but a project within.

Currently, the MDA group should not have been an independent subgroup but should have been listed under the RA synovitis subgroup as current steps as is the work on reduced joint count. As the subgroup has existed before the update of the SOPs and has had an independent fellow working on this, the subgroup will stay as an independent subgroup until the work has finished. Similarly, scoring of dactylitis is not an independent subgroup but under the dactylitis subgroup's current work.

References

1. Maxwell LJ, Beaton DE, Shea BJ, Wells GA, Boers M, Grosskleg S, et al. Core Domain Set Selection according to OMERACT Filter 2.1: The 'OMERACT Way'. J Rheumatol. 2019;46(8):1014-1020
2. Terslev L, Naredo E, Keen HI, Bruyn GAW, Iagnocco A, Wakefield RJ, Conaghan PG, Maxwell LJ, Beaton DE, Boers M, D'Agostino MA. The OMERACT Stepwise Approach to Select and Develop Imaging Outcome Measurement Instruments: The Musculoskeletal Ultrasound Example. J Rheumatol. 2019 Mar 15.