



## 2019 ANNUAL REPORT

**SIG/Committee Name:** Translation & Cultural Adaptation SIG

**Date:** February 15, 2019

**Co-Chairs:** Ana Popielnicki, Huda Shalhoub

**Secretary:** Dagmara Kuliś

**Board Liaison:** Josephine Norquist

**Mission:** The overall objectives of the TCA-SIG are to identify and advance research into practices and outcomes of translation and cultural adaptation of clinical outcome assessments (COAs); and to promote visibility of cross-cultural issues in development and use of COAs in ISOQOL.

**Number of SIG Members:** 189

| Project/Objective                                   | Actions/Deliverables  | Project Chair   | Project Members   | Timeline   |
|---|---|---|---|--|
| 1. Conduct SIG Annual Meeting                       | The 2018 Annual SIG meeting was held on 27 October 2018. The presentation by the team chairs included updates on work conducted by the TCA-SIG in the last year, the SIG structure and leadership model, and an interactive group activity. Ben Arnold said his farewell as outgoing chair and added that he was joining the Steering Committee. Huda Shalhoub was also introduced as chair-elect. The group activity consisted of separating the attendees into groups of 3 or 4. The participants went through introductions and discussed the guide questions, exploring challenges in their own organizations within the field of translation and cultural adaptation, ideas to advance the industry, and whether they were interested in getting involved in any workgroups or future efforts. | Benjamin Arnold, Ana Popielnicki, Huda Shalhoub (chair-elect), Dagmara Kuliś (secretary)  | Entire SIG was invited  | At the Dublin ISOQOL Annual Meeting – 27 October 2018  |
| 2. Non-PRO COA Translation Guidelines Working Group | The objectives of this working group are to address non-PRO COA translation challenges, and to prepare a good practices document suggesting additions/modifications to the generally accepted approaches for PRO translation.<br><br>There are four different groups working on different aspects of this project: a literature review group, and groups for ClinRO, ObsRO and PerFO measures. Since the last report, the sub-groups have combined their findings into one manuscript. Diane Wild has stepped down as the Literature Review chair and there is currently no replacement. The TCA-SIG leadership team is working on getting a replacement or next steps clarified. The last manuscript draft was circulated among all members at the beginning of January 2019.                      | Christelle Giroudet (overall project coordinator and PerFO), No current chair (Literature Review), Mona Martin (ClinRO), Shawn McKown (ObsRO) | Each group has approximately 6-8 volunteers from the SIG membership                             | After current review round by group contributors has been finalized, edits will be implemented. Target date for full SIG review is tentatively April 2019; and subsequent Board review and approval is likely June 2019, target journal for publication is JPRO. |
| 3. Publications                                     | Two manuscripts were published in 2018:<br><br><b>Translatability Assessment Paper: Emerging Good Practices for Translatability Assessment (TA) of Patient-Reported Outcome (PRO) Measures</b><br>Authors: Catherine Acquadro, Donald Patrick, Sonya Eremenco, Mona Martin, Helena Correia, Dagmara Kuliś, Katrin Conway <ul style="list-style-type: none"> <li>Published in <i>JPRO</i> February 2018</li> </ul>   | Caroline Anfray   | Benjamin Arnold, Mona Martin, Sonya Eremenco, Donald Patrick, Katrin Conway, Catherine Acquadro | N/A  |



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|   | <p><b>Copyright Paper: Reflection Paper on Copyright, Patient-Reported Outcome Instruments and their Translations</b><br/>         Authors: Caroline Anfray, Benjamin Arnold, Mona Martin, Sonya Eremenco, Donald Patrick, Katrin Conway, Catherine Acquadro<br/>         Status:</p> <ul style="list-style-type: none"> <li>• <a href="#">Published in Health and Quality of Life Outcomes December 2018</a></li> </ul>   |   |   |  |
| 4. Working Group: Principles of Good Practice for Translation of Electronic Clinical Outcome Assessment (eCOA) Measures         | <p>This work proposal was accepted in the summer of 2018 after the working group team submitted a proposal. The work initiated with a kick off call that took place in November 2018. This working group aims to create and outline a step-by-step descriptive approach of the methods to be used to translate non-instrument text needed for eCOA implementation; this need currently is not yet met in the field. The plan is to have a draft of a manuscript for publication consideration by end of the year (2019). To get there, the team is working on a literature review and a survey for dissemination between vendors to be able to collect data to write the manuscript recommendations.</p> | Megan Turner and Huda Shalhoub                  | 14 members total  | Dec 2019 submit manuscript draft   |
| 5. Working Group: Principles of Good Practice for Concept Definition Development for Clinical Outcome Assessment (COA) Measures | <p>The kick-off call for this working group was conducted on 27 September 2018. The methodology agreed upon after discussion is as follows: a) Literature review to gather information on concept definitions as pertains to COAs; b) Survey to groups who currently perform concept definition development to determine methods being used; and c) Produce a manuscript on principles of good practice for development of concept definitions.</p>  | Dana Weiss                                      | 14 members total  | TBC, but results of literature review should be circulated by beginning of March 2019. |
| 6. Translations Guidelines for ISOQOL Dictionary  | <p>Recommendations for the translation of the ISOQOL Dictionary were reviewed by the ISOQOL Board and approved.</p>  | Benjamin Arnold, Ana Popielnicki, Dagmara Kuliś | Benjamin Arnold, Ana Popielnicki, Dagmara Kuliś, SIG Steering Committee | N/A  |
| 7. Japanese Translation of the ISOQOL User's Guide  | <p>The Japanese QOL Society translated the ISOQOL User's Guide into Japanese. The TCA-SIG Japanese project team reviewed the back-translation and provided comments to the Japanese team. These comments were addressed and a table with responses/edits/rationale was provided by the Japanese team in November 2018. The BT review team has assessed the majority of the edits and we are pending a final section to be reviewed.</p> <p>Next steps are to request a revised clean file from the Japanese team and provide the finalized translation to the Executive Office for publication.</p>  | Ana Popielnicki                                 | Barbara Gandek, Shawn McKown, Ana Popielnicki, Dana Weiss               | TBC: Timeline is determined by the Japanese QOL Society team.                          |
| 8. Newsletter   | <p>The leadership team continues to regularly update the membership on the progress of various projects via a newsletter. Newsletters are prepared every 6-8 weeks and distributed through the Teamwork mailing list.</p>  | Ana Popielnicki, Huda Shalhoub, Dagmara Kuliś   | SIG membership  | Every 6-8 weeks  |



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| <p>9. Collaboration with Psychometrics SIG on Workshop in 2018</p> | <p>The TCA-SIG collaborated with the Psychometrics SIG and developed a workshop on cross-cultural measurement issues and challenges in pooling translation data for clinical trials. The workshop was held at the ISOQOL Annual Meeting in Dublin. Attendance was excellent with 20 people registered and 18 attending the workshop. Feedback from attendees was very positive. The same team has submitted the workshop for the 2019 Annual Meeting in San Diego, CA.</p> | <p>Antoine Regnault<br/>Stacie Hudgens,<br/>Lori McLeod, Sonya Eremenco, Mona Martin</p> | <p>(these 3 worked on organizing and presenting with Psych. SIG)</p> | <p>Workshop was held 24 October 2018<br/><br/>If accepted, workshop to be held in conjunction with 2019 Annual Meeting.</p> |
| <p>10. Teamwork portal</p>   | <p>Teamwork is in use by the full membership. Files are uploaded on a regular basis and it serves as a place to consult any SIG-related documents.</p>   | <p>Dagmara Kuliś</p>   | <p>SIG membership and Working Group Chairs</p>                       | <p>Ongoing use</p>  |