

SIG/Committee Name: Translation & Cultural Adaptation SIG

Date: April 2023

Co-Chairs: Emily Parks-Vernizzi, Caroline Anfray and Anita Bradley-Gilbride (secretary)

Board Liaison: Richard Skolasky

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

Project/Objective	Actions/Deliverables	Methods, Theory or Application	Project Chair	Project Members	Timeline
<p>1. Working group: Best practice guideline for global UX/UI practices of COAs destined for electronic based studies</p> <p>NOTE: Potential for this working group to be coordinated within the newly established Digital Health Special Interest Group chaired by Megan Turner.</p>	<p>Aim of this working group is to create a guideline of best practices for visual aspects of UI/UX for the instrument developers within digital based studies, for use in initial measure development and with an emphasis on the visual and functional capabilities.</p> <ul style="list-style-type: none"> - Literature reviews of existing guidelines/practice - Survey on relevant areas following lit reviews - Evaluation of results - Identification specific aspects for guideline <p>Phase 1: Topics, keywords, roles, and timelines have been defined.</p> <p>Phase 2: Literature and full paper review complete.</p> <p>Submission as manuscript to JPRO [deliverable]</p>	Application	Anna Richards	<p>Megan Turner, David Churchman, Justin Raymer, Jeanne Landgraf, Vladimir Zah, Marlene Knupfer, John Chaplin, Yoshimi Suzukamo, Ay-Woan Pan</p>	<p>Current Status:</p> <p>Phase 3: Synthesis of research followed by first draft of manuscript- ongoing.</p> <p>We are in phase 3 at the moment.</p> <p>We have completed the last phase of full extraction with 56 papers identified for manuscript write up and another 70 papers to be additionally potentially included.</p> <p>Now we are in a research synthesis phase (preparatory manuscript phase), before embarking on manuscript draft phase (which is set to begin end of February /beginning of March 2023 and is anticipated to take 6-8 weeks).</p> <p>Submission: TBD</p>
<p>2. Working group: Concept Definition Standards</p>	<p>The objective of this working group is to prepare a good practices document for the development of concept definitions as part of the translation and cultural adaptation of COAs.</p>	Methods	<p>Benjamin Arnold, Emily Parks-Vernizzi</p>	<p>Dana Weiss, Benjamin Arnold, Ana Popielnicki, Barbara Brandt, Sonya Eremenco, Emily Parks-Vernizzi,</p>	<p>Submission to JPRO is anticipated in (late) Summer 2023.</p>

	As of February 2023, a draft version of the manuscript is ready and review cycles will be starting (1. Working Group, 2. TCA-SIG Steering Committee, 3. ISOQOL Executive Committee).			Jussi Repo, John Chaplin, Alexandra Crane, Mark Wade, Teresa Williams, Miguel Ruiz, Holger Muehlan-Rehmer, Clayton Hamilton, Adelina Lear, Beatrice Tedeschi, Katrin Conway	
3. Identify and advance research into cognitive debriefing (CD) methods in pediatric and adolescent populations during translation and adaptation processes	ISOQOL Oral Session 302: Qualitative methods in the development and application of PROs, “A Paediatric Case Study: Cognitive Debriefing with Trans-Adapted Neurocognitive Assessments.”	Methods/ Application	Monika Vance, Jeanne Landgraf	John Chaplin, Holger Muehlan-Rehmer, Sonya Eremenco, Jeanne Landgraf, Monika Vance, Ligia Chavez, Ana Popielnicki, Beatrice Tedeschi, Rita A., Ahmed Osman	Project completed. Monika will consult with the group co-chair, Jeanne Landgraf about next steps. There is a possibility of generating posters on pediatric CD and transadaptation/usability of cognitive and maladaptive behaviour batteries.
4. Working group: Principles of Good Practice for Translation of Electronic Clinical Outcome Assessment (eCOA) Measures	This work proposal was accepted in the summer of 2018 after the working group team submitted a conceptual proposal. This working group aims to: (1) identify any existing translation approaches utilized in eCOA development; (2) review the currently used methodologies and summarize all steps, identifying similarities and differences between approaches, and lastly, (3) define and outline a minimal set of mandatory and optional steps as principles of good practice for eCOA translation. In order to prepare a manuscript, the team did a literature review and conducted a survey for eCOA and translation providers to be able to collect data. A second survey with copyright holders/developers was conducted during the autumn of 2021.	Methods/ Application	Huda Shalhoub, Megan Turner	Anita Bradley-Gilbride, Ben Arnold, Caroline Anfray, Dagmara Kuliś, Emily Parks-Vernizzi, Holger Muehlan-Rehmer, Jason Bredle, John Chaplin, Mark Wade, Sonya Eremenco, Jussi Repo	Submission to JPRO expected by Fall 2023.

	<p>Results of the 2nd survey were analysed; the results and the discussion sections were written. Second round of manuscript review by co-authors completed at end of January 2023.</p> <p>Next step: Review by writing team by end of March 2023.</p> <p>The ISOQOL Board and TCA-SIG reviews will take place prior to submission.</p>				
<p>5. 'Getting Better Together Initiative (GBTI): "eCOA Translations and Licensing Management Project"</p>	<p>Project launched in Quarter 3 2022. Goal: to optimize eCOA implementation in clinical trials.</p> <p>Summary: This project intends to educate and inform the clinical trial community of the implications of the business practices/processes around obtaining licenses and translations for electronic formats of PRO measures as part of the clinical trial study start-up process. The purpose of the project is to identify specific pain points in the translations and licensing process and collaborate on development of educational materials to illustrate where all stakeholders can improve their respective processes to support on-time clinical trial initiation.</p>	<p>Methods/ Application</p>	<p>Scotti Kern, C-Path</p> <p>Project Liaison: Kate Zarzar (Genentech)</p> <p>Project Team Leaders: Piero Bindi (IQVIA) and Teresa Williams (Lilly)</p> <p>TCA-SIG representatives</p> <p>Sonya Eremenco</p> <p>Caroline Anfray</p> <p>Emily Parks-Vernizzi</p>	<p><u>TCA-SIG and C-PATH members:</u></p> <p>Caroline Anfray, Sonya Eremenco, Megan Turner</p> <p><u>TCA-SIG members:</u> Benjamin Arnold, Maria Arnott, Dipika Bansal, David Churchman, Marlene Knupfer, Dagmara Kuliś, Shawn McKown, Sandra Mitchell, Ahmed M.Y. Osman, Emily Parks-Vernizzi, Ana Popielnicki, Jussi Repo, Anna Richards, Ana María Rodríguez Leboeuf, Lillian Savic, Anita Bradley-Gilbride, Dana Weiss</p>	<p>Kick-off meeting held on September 28, 2022.</p> <p>October 25, 2022, a survey distributed to allow volunteers to indicate preferences for subtopic areas of interest and expertise.</p> <p>November 11, 2022, draft charter and project sub-topics distributed to all volunteers to review and provide feedback; responses were requested by November 18, 2022, for review by the Project Team Leadership. The Project Team Leadership made selections for sub-topic leaders and all volunteers have been notified of the group they are part of; all sub-topics teams will target launch in February.</p>

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<p>6. CP-SIG/TCA-SIG Collaboration</p>	<p>Aim: develop guidance to support clinical practice settings in navigating PROM use when the availability of translations and/or cultural adaptation are limited.</p> <p>Clinical practice settings face unique challenges when selecting and implementing PROMs. For example, payers or other governing bodies may require specific PROMs to be used to support reimbursement, healthcare providers may have preferences for certain PROMs based on their clinical utility, or electronic health records systems may incentivize or deter use of a particular PROM. Furthermore, clinical practice settings often have limited knowledge and/or access to psychometric expertise and language support resources. These challenges limit the agency clinical practice settings have to prioritize PROMs based on the availability of the language and cultural translations, and may subsequently contribute to disparities in PROM use.</p>	<p>Methods/ Application</p>	<p>Elizabeth Austin, Co-Chair CP-SIG</p>	<p><u>TCA-SIG members:</u> Megan Turner, Caroline Anfray, Benjamin Arnold, Emily Parks-Vernizzi, Anita Bradley-Gilbride</p> <p><u>CP-SIG members:</u> TBA</p>	<p>SIG Symposium Abstract was submitted for consideration for the 2023 ISOQOL Annual Meeting.</p> <p>Awaiting decision – announcement of SIG symposium approval expected in March 2023.</p>
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Issues Requiring Board Attention:

A new SIG focused on Digital Health has been established, with Megan Turner as one of the Co-Chairs. There is a possibility that the 'Best Practices for Global UX/UI practices for COAs destined for electronic based studies' (led by Anna Richards and Vladimir Zah) will be moved to the new DH-SIG.