

SIG/Committee Name: Translation and Cultural Adaptation (TCA) SIG
Date: March 2024
Leadership: Caroline Anfray, Barbara Brandt, Anita Bradley-Gilbride
Board Liaison: Tom Willgoss

Mission: This SIG advances the research of clinical outcome assessment (COA) translation and cultural adaptation. We promote the visibility of cross-cultural issues related to the development and use of COAs by promoting collaborations between academia, industry, consultants and pharmaceutical companies.

Project/Working Group/ Initiative Title	Actions/Deliverables	Description	Project Chair(s)	Project Members	Date Executed/ Estimated Timeline
1. Working group: Best practice guideline for global UX/UI practices of COAs destined for electronic based studies	<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. Phase 2: Literature and full paper review complete. Submission as manuscript to JPRO [deliverable]</p>	Application	Anna Richards	Megan Turner, David Churchman, Justin Raymer, Jeanne Landgraf, Vladimir Zah, Marlene Knupfer, John Chaplin, Yoshimi Suzukamo, Ay-Woan Pan	This working group has moved to be within the newly established Digital Health and eCOA Special Interest Group, and the status will be included in their annual report.
1. Working group: Concept Definition Standards	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.	Methods	Benjamin Arnold, Emily Parks-Vernizzi	Dana Weiss, Benjamin Arnold, Ana Popielnicki, Barbara Brandt, Sonya Eremenco, Emily Parks-Vernizzi, Jussi	Submitted to JPRO in January 2024.

				Repo, John Chaplin, Alexandra Crane, Mark Wade, Teresa Williams, Miguel Ruiz, Holger Muhlan- Rehmer, Clayton Hamilton, Adelina Lear, Beatrice Tedeschi, Katrin Conway, Eli Yohe Moore	
2. 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	Submitted to JPRO in January 2024. Submitted abstract for consideration for SIG Symposium at ISOQOL 31st Annual Conference. Submitted with second abstract : Addressing the concerns of instrument developers and copyright holders regarding electronic implementation of their measures

<p>3. 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. 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. Subteams established in 2023 are: Licensing and Translations Communication and Education, Licensing Copyright Requirements and Processes, Libraries, Translations Author Requirements, Translation Implementation/Standardisation, Translations Regulatory IRB EC Requirements, and Migration.</p>	<p>Methods/Application</p>	<p>Scotti Kern, C-Path Project Liaison: Kate Zarzar (Genentech) Project Team Leaders: Piero Bindi (IQVIA) and Teresa Williams (Lilly) TCA-SIG representatives Sonya Eremenco Caroline Anfray Emily Parks-Vernizzi</p>	<p>TCA-SIG and C-PATH members: Caroline Anfray, Barbara Brandt, Sonya Eremenco, Megan Turner TCA-SIG members: 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>As of Q1 2024, 22 unique deliverables have been developed or are in process, with the last deliverables to be completed by Q3 2024. A call for an ISOQOL Task Force was sent out in February 2024.</p>
<p>4. 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. Clinical practice settings face unique challenges when selecting and implementing PROMs. For example,</p>	<p>Methods/Application</p>	<p>Elizabeth Austin, Co-Chair CP-SIG</p>	<p>TCA-SIG members: Megan Turner, Caroline Anfray, Benjamin Arnold, Emily Parks-Vernizzi,</p>	<p>SIG Symposium Abstract was submitted for consideration for the 2023 ISOQOL Annual Meeting and</p>

	<p>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>Anita Bradley-Gilbride</p> <p>CP-SIG members: N/A</p>	<p>rejected. Project closed out.</p>
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NEW WORKING GROUPS

Call for new Project Ideas launched on 24 July 2023 to TCA SIG members
 5 suggestions for new topics – discussed with TCA SIG Steering Committee
 4 topics retained, one rejected as out of scope of TCA SIG

Call for volunteers for new working groups launched during annual meeting in Calgary – 20 October 2024
 Follow up in December 2023 with additional Call for volunteers + identify priority projects

Project/Working Group/ Initiative Title	Actions/Deliverables	Description/	Project Chair(s)	Project Members	Date Executed/ Estimated Timeline
Artificial Intelligence (AI)	To be determined, but potentially focused on: <ul style="list-style-type: none"> • Definition(s) of AI as it applies to COAs • Literature search on current use of AI in translation of COAs • Early stage of AI: list caveats/concerns/shortcomings • Identify business cases • Deliverable: Reflection paper for AI usage in translation and linguistic validation • Could AI translate as well as people, and potentially faster to shorten translation timelines? • Could AI such as DeepL be used to produce versions as drafts for EC submissions? • Exploring how AI will impact translation and linguistic validation process for PROMs • Assessing the quality of AI applications (e.g., DeepL.com, ChatGPT) for translation of PROMs 	Application	Benjamin Arnold, Shawn McKown	Melinda Johnson, Alisa Heinzman, Mark Wade, Mark Aiello, Jacqueline Lewis, Manchandan Sandhu, Helena Correia, Jiyoung Son, John Chaplin, Piero Bindi, Sonya Eremenco, Abigail Boucher, Jennifer Contreras, Caroline Anfray	Expected to start Q1/Q2
Gender Inclusivity in Language Used on PRO/COA Measures	To be determined, but potentially focused on:	Methods/Application	Emily Parks-Vernizzi, Dagmara Kulis	Abigail Boucher, Karen Leyton, Adesola Odole, Lillian Savic	Expected to start Q1/Q2

	<ul style="list-style-type: none"> • How gender inclusivity informs the translation and cultural adaptation process and usage of the measures in other cultures. • Research could include a literature review of articles published on this topic in the linguistics and life science fields to understand what practices are currently in place to provide for inclusivity. • Collaboration with COA developers to understand what more is needed to provide inclusivity in the language used on their measures and how this affects their translation and cultural adaptation. 			Ester Villalonga Olives Jennifer Contreras Mrunmayee Pitkar Sonya Eremenco Jasmine Walker Tim Poepsel Melinda Johnson Barbara Brandt	
Copyright Watch/Copyright Infringement for COAs and COA Translations	<p>To be determined, but potentially focused on:</p> <ul style="list-style-type: none"> • x2 brief (ideally only a page each) Sector Good Practice Guidance notes (possibly under the general theme of “Respect the ©”): i) For COA Authors/Developers/Licensors/Managers and ii) For COA Users (Licensees). The above drawing upon TCA SIG 2018 Paper (Reflection on copyright) -- Could be presented as an extension of the Reflection paper. • Sector Good Practice Guidance notes on i) Recommendations to avoid copyright infringement, ii) Policing for / identifying copyright infringers and ii) How to effectively manage identified potential copyright infringement cases 	Methods/Application	Clare Bradley, Caroline Anfray	Megan Turner, David Churchman, Sonya Eremenco, Jasmine Walker, Megan Duff, Dagmara Kulis	Expected to start Q3/Q4

	<ul style="list-style-type: none"> • A case study review of European Union Clinical Trials Register (EU CTR) with short written report of case review, findings and suggested next steps. (Challenge: EU CTR wants copies of ‘patient facing documents’ including questionnaires and translations to be made public on their website along with protocols.) • Explore potential mechanism to easily identify the use of Official (authorised / licensed) versions (original and translations) of instruments. A written report on the challenge and suitable solution(s) with an appraisal of resource burden to administer such a mechanism. • How to tackle copyright infringement • How to prevent Users from posting copies of full questionnaires on websites and in journal publications leading to unauthorized translation and use of measures using substandard methodologies 				
Assessing Readability of Languages	<ul style="list-style-type: none"> • Definition of readability • Review of existing guidelines and best practices. • Guidance/best practices on assessing readability • Development of a holistic method of readability, incorporating (converging) existing tools such as face validity, translatability assessment, usability testing • Review of the relevance and use of (automated) methods to test 	Methods/Application	TBD	Rebecca Israel, Jasmine Walker, Hadeel Bakhsh, Holger Muehlan, Tim Poepsel, Barbara Brandt, Dagmara Kulis, Christian Apfelbacher, Katharina Piontek, Mark Aiello	To be launched in 2025

	<p>the comparability of linguistic complexity/simplicity and readability/understandability of translations (e.g., readability indices) in the context of COA.</p> <ul style="list-style-type: none"> • No widely accepted method of assessing readability of translations exists • How do we assess readability across languages? • Does readability guarantee (or indicate) comprehensibility? • Is readability one component of a larger assessment? • Health literacy score- how does this differ from readability? Can this be used to assess readability? • Where does "cognitive linguistics" fit in? • How is readability different from comprehensibility or general understanding? Important to consider when defining readability. • How do we account for variations in readability expectations/standards across organizations/countries? For example, reaching the ideal age/grade level of the text. 				
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TCA SIG Leadership Team specific project

Project/Working Group/ Initiative Title	• Actions/Deliverables	• Description/	Project Chair(s)	Project Members	Date Executed/ Estimated Timeline
Development of the Welcome Package for new members.	<ul style="list-style-type: none"> • Welcome Package/PowerPoint Presentation 	<ul style="list-style-type: none"> • Developing “Welcome package” – also available on Teamwork. Suggested content: • Introduction to TCA-SIG (Chairs, Steering Committee, history, past WG and deliverables, number of members, list of countries covered, etc.) • On-going WGs • How to join a WG • Minimum requirements/commitment (for permission from employer) • Role implications (WG leader, WG member) • Tips/ recommendations for deliverables (white paper / peer reviewed articles) • Templates for project management • Annual meetings at ISOQOL conference • Teamwork (Presentation, how to use) 	TCA-SIG Leadership team	TCA-SIG Leadership team	Expected delivery Q1/Q2

Concerns/Questions/Comments: