

**SIG/Committee Name: Australia and New Zealand (ANZ) SIG**
**Date: 7 March 2024**
**Leadership: Melanie Hawkins, Jessica Roydhouse, Nadia Corsini, Imogen Ramsey**
**Board Liaison: Tolulope T. Sajobi**

**Mission:** This SIG fosters connections between local researchers in a geographically remote region of the world. We aim to support and prepare emerging researchers for international opportunities through collaborations, mentorships, and other projects year-round.

<b>Project/Working Group/ Initiative Title</b>	<b>Actions/Deliverables</b>	<b>Description</b>	<b>Project Chair(s)</b>	<b>Project Members</b>	<b>Date Executed/ Estimated Timeline</b>
1. Australian PROMs DownUnder 2025 conference	Proposal accepted by ISOQOL with some planning still to do.	A 2-day in person conference for Australian, New Zealand and Pacific region ISOQOL members to convene, connect, converse and collaborate.	Jessica Roydhouse	Melanie Hawkins, Nadia Corsini, Imogen Ramsey	In progress
2. Mentor / Mentee Program	Have assessed mentoring preferences for mentors and mentees.	This program aims to connect mentees with mentors in their field for ongoing conversations about topics of interest.	Jessica Roydhouse	Melanie Hawkins, Nadia Corsini, Imogen Ramsey	In progress
3. Bi-monthly webinars	Have gathered together suggestions for webinar topics and presenters.	Especially to encourage students and early/mid career researchers to present their work, these bi-monthly webinars aim to provide opportunity to practice presenting and to engage others in new investigator research.	Jessica Roydhouse	Melanie Hawkins, Nadia Corsini, Imogen Ramsey	In progress
4. Australia and New Zealand SIG, Canada-PRO SIG & Patient Engagement SIG: International Perspectives of Patient Engagement in Quality of Life Research	Presented at the ISOQOL 2023 conference in Calgary, Canada	The aim of this educational session was to explore patient engagement in quality of life research internationally. Presenters included clinicians, researchers, and patient research partners who shared their projects and perspectives on how patient engagement is carried out in quality of life research.	Sandra Zelinsky, University of Calgary, Canada  Sadia Ahmed, Master of Science, University of Calgary, Canada  Natasha Roberts, The University of Queensland, Australia	Leonie Young, John J Librett, Jessica Gentile, Maria J Santana, Sumedh Bele	Completed - October 2023
5. Core outcome set of PROMs in Cancer survivorship	This project aims to develop a core set in cancer survivorship based on COSMIN's recommended approach for the selection of measures.	Review of the literature and appraisal of 36 measures using the COSMIN criteria	Imogen Ramsey	Nadia Corsini, Jessica Roydhouse, Natasha Roberts, Ashika Maharaj	Publication in 2024



## 2024 ANNUAL REPORT

**Concerns/Questions/Comments:**

**SIG/Committee Name: Child Health SIG**
**Date: 26.02.2024**
**Leadership: Zephania Tyack, Sumedh Bele, Harpreet Chhina**
**Board Liaison: Roxanne E. Jensen**

**Mission:** This SIG unites professionals who share a common interest in the quality of life of children. We are open to new and interesting ideas that will foster improvements in child health and across the transition into early adulthood.

<b>Project/Working Group/ Initiative Title</b>	<b>Actions/Deliverables</b>	<b>Description</b>	<b>Project Chair(s)</b>	<b>Project Members</b>	<b>Date Executed/ Estimated Timeline</b>
1. Increase presence of CH-SIG and representation of methodological challenges/ issues associated with child health at ISOQOL Meetings	A joint <b>SIG workshop</b> with the Patient Engagement SIG (PE_SIG) for the 2024 ISOQOL Conference – Title: ‘Patient Engagement in Child Health Quality of Life Research’ has been submitted. With contributions from SIG members in UK and Canada.	Submitted ISOQOL workshop	Sumedh, Harpreet	Members of Child Health and patient engagement SIG	Deliver at annual conference Oct 2024 if accepted
2. Expanding membership & networking	Coordinated a <b>SIG Pre-Conference Dinner</b> at the annual conference in Calgary. A SIG Pre-Conference Meeting/Dinner is being organized for the 2024 conference in Cologne.	Consolidation of membership	Zephania, Holger (past chair)	19 attendees	Completed Oct 2023
3.	Chaired a <b>members meeting</b> at the annual conference in Calgary.	Consolidation of membership	Zephania, Sumedh, Harpreet	19 attendees	Completed Oct 2023
4.	Preparing a paper on <b>Patient Engagement in Child Health Quality of Life Research</b> .	Consolidation of membership	Sumedh, Zephania, Harpreet	Sumedh, Zephania, Harpreet, John, Holger, Sadia	Preparation ongoing
5. Further projects/activities	Conducted a <b>virtual mid-term members meeting</b>	Presented past, current and planned activities of the SIG and followed this by discussion	Zephania, Sumedh, Holger	Zephania, Sumedh, Holger, + 2 other SIG members	Completed May 2023
6.	Planning to conduct <b>virtual, structured members meetings</b> throughout the year (if supported by the SIG member survey)	To be determined by SIG member survey	Sumedh, Harpreet, Zephania	SIG members	March 2024 (Estimated)
7.	<b>Survey of member needs and interests</b> developed. To be sent out to members.	Survey of SIG member needs and interests	Sumedh, Harpreet, Zephania	To be distributed to all SIG members on Teamwork	By June 2024

**Concerns/Questions/Comments:**

1. Discussion at the annual conference SIG meeting indicated a strong preference for changing the time of the SIG meeting from the last day of conference and 7 am to lunch time and a different day
2. A suggestion made at the annual conference SIG meeting was that the SIG name be changed to Child-Youth SIG to capture the transition to early adulthood

**SIG/Committee Name: Chinese PRO SIG**
**Date:**
**Leadership: Qiuling Shi, Wenjie Duan**
**Board Liaison: Tolulope T. Sajobi**

**Mission:** This SIG focuses on promoting research and education of PROs for the Chinese population by connecting with international efforts related to research and application of PROs. We facilitate networking for Chinese researchers by supporting emerging researchers online, through collaborations, and at ISOQOL events.

<b>Project/Working Group/ Initiative Title</b>	<b>Actions/Deliverables</b>	<b>Description</b>	<b>Project Chair(s)</b>	<b>Project Members</b>	<b>Date Executed/ Estimated Timeline</b>
1. A Joint Conference by ISOQOL China SIG and China Anti-Cancer Association	1.Presentation sessions by renowned experts in the fields of quality of life research and cancer care 2.Interactive workshops focusing on innovative approaches to improve quality of life in cancer patients	The joint conference between the ISOQOL China SIG and the China Anti-Cancer Association (CACA) brings together two leading organizations dedicated to advancing quality of life outcomes in cancer care. This collaborative event will showcase the latest research and innovations in the field, offering attendees a unique opportunity to learn from experts, participate in hands-on workshops, and engage in discussions on the role of quality of life measures in cancer treatment and survivorship.	Qiuling Shi	Wenjie Duan, Daniel Fong, Jiqian Fang	Oct. 2024
2. An In-Depth Analysis of FDA' s New Guidance	A Comprehensive commentary article in Chinese discussing the implications and importance of the FDA' s new guidance on PRO	This activity aims to educate and inform the Chinese healthcare community about the significance of the FDA' s recent guidance on analyzing PRO data. Through in-depth commentary article, our team will delve into the nuances of the guidance, its potential impact on research and drug development, and best practices for incorporating PRO data into clinical trials.	Qiuling Shi	Jiqian Fang, Wenjie Duan, Daniel Fong, and the China SIG	Nov 2024
3. Training course for the use of PRO in Clinical trials	Development of training course for researchers and clinical coordinators in utilizing PRO tools in clinical trials	This project focuses on creating a series of courses tailored for researchers and clinical coordinators intending to integrate PROs into their clinical trials. The training will cover essential topics such as introducing commonly used PRO instruments in clinical trials, effective strategies for data collection using PRO tools through various mediums including paper-and-pencil, telephone, or web-based devices, as well as identifying and addressing potential pitfalls in PRO data collection.	Qiuling Shi	Jiqian Fang, Wenjie Duan, Daniel Fong, and the China SIG	July 2024

**Concerns/Questions/Comments:**

We have identified several concerns regarding the performance of ISOQOL communication:

1. The Teamwork platform used for global members is not commonly utilized by Chinese members.
2. The webinars for members are currently not accessible to non-members who are keen to utilize Patient-Reported Outcomes (PRO) tools but lack instructions on how to do so.
3. Collaboration between ISOQOL China SIG and local academic societies is impeded by the lengthy approval procedures required from both sides.

**SIG/Committee Name: Clinical Practice (CP) SIG**
**Date: March 1, 2024**
**Leadership: Angela Wolff (current), Amy Cizik (incoming chair), Elizabeth J. Austin (past chair)**
**Board Liaison: Tom Willgoss**

**Mission:** This SIG focuses on methodology and implementation initiatives to advance the effective use of PRO measures across different medical care settings. Our ultimate objective is to improve the management and treatment of individual patients, medical decision-making, and patient-centred care.

Project/Working Group/ Initiative Title	Actions/Deliverables	Description	Project Chair(s)	Project Members	Date Executed/ Estimated Timeline
a. <b>(Workgroup) Preparing clinicians / clinical teams for integration of PROMs (e.g., training, education, champions)</b>	<b>6 hr Workshop</b> 2023 ISOQOL conference: Making PROMs Work in Practice Settings: Practical Strategies to Support their Implementation by Healthcare Providers <ul style="list-style-type: none"> <li>• 36 attendees</li> <li>• Manuscript in development</li> </ul>		Angela Wolff	Elizabeth Austin; Kate Absolom; Maria Santana; Sara Ahmed; Angela Stover; Susan Bartlett	Publication Summer 2024
b. <b>(Workgroup) Preparing clinicians / clinical teams for integration of PROMs (e.g., training, education, champions)</b>	Meeting quarterly via Zoom for “work in progress sessions” (WIPs)  Attendance ranges 8-12 people per session	Focus on the needs of clinicians to adopt PROMs into practice (individual level), all professions and all settings. Sharing work allows for further networking	Angela Wolff	Amy Cizik, Maud Van Muilekon, Liz Siembida, Lauren Shapiro, Anna Maria Rodriuez, Gida Mody, Anna (Andra) Beurkens, Juliea Lai-Kwon, Carolin Terwee, Istvan Mucsi, Christine Blome, Yoldana Pardo	Ongoing with quarterly WIPs  2024 prioritizing <ul style="list-style-type: none"> <li>• Expert-led training / webinar</li> <li>• Workshop at 2024 conference</li> <li>• Small work-group</li> <li>• Library of recommended</li> </ul>

Project/Working Group/ Initiative Title	Actions/Deliverables	Description	Project Chair(s)	Project Members	Date Executed/ Estimated Timeline
					resources on teamwork
c. <b>(Workgroup) PROs in Telehealth, Delphi Study</b>	<ul style="list-style-type: none"> <li>• Three rounds of input completed Fall 2023</li> <li>• Data analysis in progress / near completion.</li> <li>• Publication writing in progress</li> </ul>	Topic: Delphi study on the use of PROs via telehealth	Elizabeth Unni	Lee Aiyegbusi Natasha Roberts Birgith E. Grove Liv Schougaard Elizabeth Austin Holger Muehlan Kedar Mate Klara Greffin	Ongoing  Publication Spring 2024  Abstract submission for ISOQOL 2024 Annual Conference
d. <b>(Workgroup) Engaging patients in PROM use (Collaboration with PE SIG)</b>	a. Scoping review search protocol finalized and completed. Currently in the analysis/synthesis phase. b. Symposium 5 (Oct 2023): Co-producing Better Health-Related Quality of Life: The Importance of Educating Patients and their Caregivers about the Use of Patient Reported Outcome Measures in Daily Clinical Care	Scoping Review to determine if patients are educated about PROs and if so, by whom and how. A call went out during 2022 ISOQOL annual meeting for those interested in the work	Elizabeth Unni	Olivia Biller, Cecilie Lindström, Egholm, Joanne Greenhalgh, A Groenewegen (Anouk), Andria Joseph, Maud van Muilekom, Elizabeth Unni,	Ongoing  Abstract submission for ISOQOL 2024 Annual Conference
e. <b>(Workgroup) Address disparities in cultural adaptation of PROs in clinical practice (Collaboration with Translation and</b>	Submitted proposal for Symposium entitled Promoting equitable PROM use in practice: Recommendations at the nexus of cross-cultural adaptation, implementation	Purpose of this workgroup was to submit symposium proposal.	Elizabeth Austin	Caroline Anfray; Benjamin Arnold; Emily Parks-Vernizzi; Anita Bradley-Gilbride; Lauren Shapiro; Megan Turner; Natasha Roberts	January 2023



Project/Working Group/ Initiative Title	Actions/Deliverables	Description	Project Chair(s)	Project Members	Date Executed/ Estimated Timeline
Cultural Adaptation SIG (TCA-SIG)	<p>science, and disparities research</p> <p>The proposal was not accepted and no further work is being done by this group.</p>				
<b>f. Using PROs for Screening</b>	<p>Workgroup created a glossary of screening-related definitions for standardized language / harmonized terminology.</p> <p>In Oct-Nov 2023 a survey was conducted to obtain feedback from ISOQOL members on the draft definitions for the glossary. N=88 respondents. For terms that required improvement input was provided by respondents. Initial data analysis is complete. Following revisions to complete a final draft, another review will be completed by 27 volunteers that have been obtained.</p>	<p>Goal is to create the ISOQOL Glossary or Dictionary of terms for the use of PROMs for screening.</p>	<p>Kathleen Yost and Theresa Coles</p>	<p>Minji Lee Angela Wolff Cindy Nowinski Natasha Roberts Others on distribution list lisa.wintner@tirol-kliniken.at; elizabeth.gibbons@evidera.com; obiller@its.jnj.com; shelly.sharma@bcm.edu; elizabeth.walkley@austin.org.au; jmacderm@uwo.ca; m.luijten@amsterdamumc.nl; j.greenhalgh@leeds.ac.uk; ana.a.popielnicki@gsk.com; marie-eve.poitras@usherbrooke.ca; smjones3@fredhutch.org; livschou@rm.dk; amy.cizik@hsc.utah.edu; mvance@santium.com; Brocha.stern@mountsinai.org; Ephln@nus.edu.sg; drkpavithran@hotmail.com; marie-eve.poitras@usherbrooke.ca; zach.hopkins@hsc.utah.edu; xswang@mdanderson.org; skye.barbic@ubc.ca; js-lai@northwestern.edu;</p>	<p>Ongoing</p> <p>Summer 2024 smaller group will revise and finalize the glossary.</p> <p>Possibly present at the 2024 ISOQOL Annual Meeting</p> <p>Endorsement by ISOQOL 2024 or 2025</p>

Project/Working Group/ Initiative Title	Actions/Deliverables	Description	Project Chair(s)	Project Members	Date Executed/ Estimated Timeline
				adesola_odole@yahoo.com; jmvalderas@nus.edu.sg; ShahR45@cardiff.ac.uk; imogen.ramsey@flinders.edu.au; natasha.hassija@mail.mcgill.ca; monika.sztankay@tirol-kliniken.at; bigcri@rm.dk; shlo@hkmu.edu.hk; smithan1@cardiff.ac.uk; Kedar Mate; istvan.mucsi@utoronto.ca; 'Elizabeth Austin; Birgith Engelst Grove; Michelle Ramirez; Jinxiang Hu	
g. <b>SIG Engagement: Prioritizing Activity for CP SIG</b>	<b>3 new CPSIG working groups?? Less focus on workgroups and more on just meeting quarterly</b>		Angela Wolff and Amy Cizik	Amy Cizik, Maud Van Muilekon, Liz Siembida, Lauren Shapiro, Anna Maria Rodriuez, Gida Mody, Anna (Andra) Beurkens, Juliea Lai-Kwon, Carolin Terwee, Istvan Mucsi, Christine Blome, Yoldana Pardo	Ongoing
h. <b>CPSIG Activities &amp; SIG Engagement</b>	<p><b>a. Networking activity</b> at 2023 Conference on Oct. 20, 2022, with 40-50 attendees.</p> <ul style="list-style-type: none"> <li>- We provided updates on CPSIG activities.</li> <li>- We held breakout groups (5) to allow members to brainstorm new topics for collaboration in 2024</li> </ul> <p><b>b. Quarterly “general” meetings</b> with entire CP SIG group – held meeting Nov 14, 2023</p>	b. follow up on prioritizing activity on Oct 20. Members would like to	Angela Wolff and Amy Cizik	Entire membership (n=285)	Ongoing  Quarterly general meetings (Apr, Aug, Oct, Dec)  Oct will be at the Annual conference  Tentative continue to have session about

Project/Working Group/ Initiative Title	Actions/Deliverables	Description	Project Chair(s)	Project Members	Date Executed/ Estimated Timeline
	<p>Adapted the Australia SIG template to follow a standard meeting agenda and recorded minutes.</p> <p>c. Held a session for the membership about submitting abstracts for symposiums and workshops.</p>	<p>meet quarterly as opposed to belonging to a workgroup</p> <p>c. assist members to better understand the process and differentiate between CP SIG sponsored and general</p>			submitting abstracts
<b>i. CPSIG Activities &amp; SIG Engagement</b>	<ul style="list-style-type: none"> <li>• Name change approved by ISOQOL board to be “Clinical Practice SIG”</li> <li>• Regular communication with Teamwork to communicate with members and advertise relevant CP activities/opportunities.</li> <li>• Communication via email to SIG membership list (for those not using teamwork)</li> </ul>	<p>General activities and engagement of the SIG members</p>	<p>Angela Wolff and Amy Cizik</p>	<p>Entire membership (n=285)</p>	<p>Ongoing</p> <p>Develop orientation for new SIG members (Fall 2024)</p>
<b>j. CP-SIG related presentations</b>	<p>Create a summary list of all CP-SIG related presentations of interest held at the Annual conference</p> <p>2 Workshops 1 SIG sponsored symposium</p>	<p>Allows ease for our members to attend presentations related to CP</p>		<p>Entire membership (n=285)</p>	<p>Create list again for 2024 conference.</p>

Project/Working Group/ Initiative Title	Actions/Deliverables	Description	Project Chair(s)	Project Members	Date Executed/ Estimated Timeline
	1 Symposium 1 Plenary 31 Poster sessions 14 Oral sessions 6 Oral brief sessions 1 Roundtable				

### Concerns/Questions/Comments:

- Overall use of Teamwork is sporadic, and many members may not be utilizing it for this SIG. We are wondering how the platform is working for other SIGs.
- Could ISOQOL staff assist with an orientation for new members to SIGs?
- Member are requesting opportunities to engage as a larger SIG rather than by workgroups. It is challenging to find leads for workgroups even though people are interested. As a result, we have suggested quarterly general meetings for the SIG. We have adopted an agenda template to structure the meetings and foster networking.
- We have great interest from the membership in the following key areas, but no one to lead the work. For example, we have interest from the membership in conducting a data visualization systematic review but no one to lead the work.
- Other work that needs someone to lead

#### Clinical applications of PROMs

- Work in Progress Session
- Small work-group
- Expert-led training / webinar

#### Introduction to implementation science

- Library of recommended resources on teamwork
- Expert-led training / webinar

#### Advancements in Implementation science

- Library of recommended resources on teamwork
- Expert-led training / webinar
- Work in Progress Session

Methodology in implementation research

- Expert-led training / webinar
- Workshop at 2024 conference

**SIG/Committee Name: Developing Nation SIG**
**Date:**
**Leadership: Liliane Lins Kusterer**
**Board Liaison: Elizabeth J. Unni**

**Mission:** This SIG identifies the social and economic issues and concerns that impact health and health related quality of life in developing countries to inform future research, practice, and policy recommendations. It also serves as a link between the members of this SIG and other SIGs to bring these social and economic issues and concerns to audiences where they may not otherwise be represented. We invite you to join us in addressing the challenges of measuring the quality of life in developing countries, considering language, and cultural barriers, the ethics of research in situations of poverty, and reduced autonomy.

<b>Project/Working Group/ Initiative Title</b>	<b>Actions/Deliverables</b>	<b>Description</b>	<b>Project Chair(s)</b>	<b>Project Members</b>	<b>Date Executed/ Estimated Timeline</b>
1. Knowledge dissemination	Organize on-line meetings on relevant topics, inviting members to present, sharing knowledge and skills. Prepare a regular member communication with updates. Member in the spotlight – we will invite SIG members to present results from their current work to disseminate information to other members and stimulate cooperation among SIG members.	Utilize online platforms like Zoom, Microsoft Teams, or Google Meet for webinars and workshops.  Create engaging content and promote it through the SIG TeamWork	Liliane Lins Kusterer	SIG members	Plan for 3 times a year
2. Collaboration	Arrange virtual meetups for members to connect.  Implement the use of tools such as Google Drive for project management and communication.	Encourage active participation and engagement among members.  Foster a culture of sharing ideas and resources through online platforms and regular communication.	Liliane Lins Kusterer	SIG members	Plan for 3 times a year

	<p>Initiate collaborative projects with other organizations or groups.</p> <p>Create the opportunity of allowing SIG members to submit ideas and proposals for collaborative projects at our quarterly meetings.</p>				
3. Membership Drive	<p>Launch campaigns to attract new members.</p> <p>Organize online events to recruit new members.</p> <p>Offer incentives for joining, such as access to exclusive content or discounts.</p> <p>Hosting of SIG members virtual meetings - To increase awareness about qualitative research and ISOQOL in our different regions so as to increase the membership in this SIG</p>	<p>Utilize social media platforms like Facebook, Twitter, and LinkedIn to reach a wider audience.</p> <p>Highlight the benefits of membership and make the joining process simple and straightforward.</p>	Liliane Lins Kusterer	SIG members	To be coordinated as part of sessions mentioned above, and during the year.

**Concerns/Questions/Comments:**

The Developing Nations SIG faced challenges in improving interaction and planning among co-chairs due to time zone differences. During a meeting, the co-chairs decided to conduct activities based on continents' time zones to facilitate alternating leadership in organizing SIG meetings. Unfortunately, the meetings did not take place.



**SIG/Committee Name: Digital Health and eCOA SIG**
**Date: 29 February 2024**
**Leadership: Alisa Heinzman, Megan Turner, Ana Popielnicki**
**Board Liaison: Tom Willgoss**

**Mission:** The Digital Health and eCOA SIG will broadly cover topics of interest related to the scientific rigor, development, validation, and implementation of PRO, ClinRO, PerfO, ObsRO, and Proxy measures in electronic modes of data collection as well as digital measures. The SIG promotes the visibility of digital measures and eCOA related to the development and use of COAs by facilitating collaborations between academia, industry, consultants, COA developers, and pharmaceutical sponsors.

<b>Project/Working Group/ Initiative Title</b>	<b>Actions/Deliverables</b>	<b>Description</b>	<b>Project Chair(s)</b>	<b>Project Members</b>	<b>Date Executed/ Estimated Timeline</b>
1. UX/UI Working Group	Manuscript to be submitted for publication in JPRO	Description (working manuscript title):  Lost in Translation: A systematic review of UI-UX practices applied in eCOA design.	Project chair: Anna Richards	Project members: Anna Richards Beatrice Tedeschi Jeanne Landgraf John Chaplin Justin Raymer Marlene Knupfer Megan Turner Vlad Zah	Manuscript development in progress. Target to submit for publication by October 2024
2. Digital Measures Definitions Resource (To be confirmed, not all will progress for 2024 production)	A glossary of terms for digital measures	Idea from Igor Matias, University of Geneva, QoL Lab	TBD	TBD	To be discussed in next SIG membership monthly meeting (18Mar24), request leads and members for each project.
3. Digital Health and eCOA Case Studies (To be confirmed, not all will progress for 2024 production)	TBD	SIG Members see evidence of Digital Health and eCOA in practice, but it isn't visible to the public.  Examples:  1. How are we using digital technology for patient-centric endpoints and to improve the patient experience?  2. Cognitive measures: there is no existing guidance. How do stakeholders build/handle them?	TBD	TBD	To be discussed in next SIG membership monthly meeting (18Mar24), request leads and members for each project.

4. Strategies to Speed Up eCOA Implementation (To be confirmed, not all will progress for 2024 production)	TBD	Investigate ways to handle eCOA Implementation more quickly. Examples:  1. eCOA Libraries 2. Item Banks	TBD	TBD	To be discussed in next SIG membership monthly meeting (18Mar24), request leads and members for each project.
5. Combining Operational and Human Factors for DHTs (To be confirmed, not all will progress for 2024 production)	TBD	Investigate the Human factors of Digital Health and eCOA through UX/UI and User Modeling.	TBD	TBD	To be discussed in next SIG membership monthly meeting (18Mar24), request leads and members for each project.
6. Use of Technology for PRO reporting: A Collaboration with Industry SIG (To be confirmed, not all will progress for 2024 production)	TBD	Collaborate with the Industry SIG to investigate uses of technology outside of common eCOA implementation such as:  1. Digital Bots 2. ConvoRos (COAs via chatbot) 3. SMS	TBD	TBD	To be discussed in next SIG membership monthly meeting (18Mar24), request leads and members for each project.
7. COA Measure Owners Forum (To be confirmed, not all will progress for 2024 production)	TBD	Collaboration with the eCOA and PRO Consortia. A forum whereby COA measure owners/developers, eCOA providers and sponsors could convene for mutual education opportunities in the context of eCOA licensing.	TBD	TBD	To be discussed in next SIG membership monthly meeting (18Mar24), request leads and members for each project.

### Concerns/Questions/Comments:

SIG Leadership conducted an informal survey among members to vote for each of the above-listed projects, which resulted from the inaugural meeting at the 2023 AC. Survey results will be discussed during the next monthly meeting (18Mar2024), and the selected topics will be distributed on a volunteer basis to subgroups with an assigned leader. We expect a subset of these initiatives to progress in 2024.

**SIG/Committee Name: German-speaking Countries SIG**
**Date: Feb 06, 2024**
**Leadership: Kathrin I. Fischer, Monika Sztankay, Klara Greffin**
**Board Liaison: Adesola Odole**

**Mission:** This SIG promotes communication, interaction, and collaboration between ISOQOL members from German-speaking countries. We create a platform that enables the exchange of information, promotes research and education of PROs, and facilitates networking and collaboration between researchers of all career stages, including clinicians, patients, colleagues from industry, government, regulatory agencies, not-for-profit institutions and all interested in advancing the science of quality of life (QOL) and related patient-centered outcomes (PCO) in German-speaking countries.

<b>Project/Working Group/ Initiative Title</b>	<b>Actions/Deliverables</b>	<b>Description</b>	<b>Project Chair(s)</b>	<b>Project Members</b>	<b>Date Executed/ Estimated Timeline</b>
1. 4 <sup>th</sup> SIG meeting during the annual conference in Calgary	<ul style="list-style-type: none"> <li>Inform members about the upcoming F2F meeting</li> <li>Prepare and host the meeting in Calgary</li> <li>Sent post-meeting summary</li> </ul>	The SIG meeting at the annual conference serves as an important touch point for the SIG to share information, facilitate networking and collaboration and to plan SIG activities for the upcoming year.	Kathrin Fischer	Klara Greffin, Monika Sztankay	Executed October 2023
2. SIG Symposium AC 2024	<ul style="list-style-type: none"> <li>Brainstorming of topics</li> <li>Drafting and submitting proposal</li> <li>Prepare presentations for symposium</li> <li>Deliver symposium at AC 2024</li> </ul>	The SIG symposium aims to present landmark initiatives in German-speaking countries.	Monika Sztankay, Klara Greffin	Felix Fischer, Viktoria Steinbeck, Holger Mühlen, Christine Blome, Sandra Nolte, Kathrin Fischer	Estimated Timeline December 2023 – October 2024
3. Local language workshop at the AC 2024 in Cologne	<ul style="list-style-type: none"> <li>Consult with ISOQOL office</li> <li>Draft and submit a workshop proposal</li> <li>Prepare content of workshop</li> <li>Deliver workshop at AC 2024</li> </ul>	The workshop will be addressed to the German-speaking community at the AC in Cologne/Germany. The workshop will be held in German.	Monika Sztankay, Klara Greffin, Kathrin Fischer	Felix Fischer, Sandra Nolte, Holger Mühlen, Viktoria Steinbeck, Niccole Bauch	Estimated Timeline December 2023 – October 2024
4. Continue to build the network of the SIG	<ul style="list-style-type: none"> <li>Inform SIG members about activities via Teamworks and LinkedIn</li> <li>Arrange virtual meetings throughout the year to stay connected</li> </ul>	The SIG aims to stay connected throughout the year; updates related to SIG activities, information related to quality of life research and patient-centered outcomes in German-speaking countries will be shared and virtual mid-year meeting will be planned	Monika Sztankay, Klara Greffin, Kathrin Fischer	All SIG Members	Timeline October 2023 – October 2024

**Concerns/Questions/Comments:**

**SIG/Committee Name: Health Preference Research SIG**
**Date: February 2024**
**Leadership: Donna Rowen, Julie A. Campbell, Ana Maria Rodriguez-Leboeuf**
**Board Liaison: Kathryn E. Flynn**

**Mission:** This SIG promotes educational activities and scientific research related to health-related preferences. We encourage our members to engage in organizational activities that support the growth and greater integration of health preference research.

<b>Project/Working Group/ Initiative Title</b>	<b>Actions/Deliverables</b>	<b>Description</b>	<b>Project Chair(s)</b>	<b>Project Members</b>	<b>Date Executed/ Estimated Timeline</b>
1. Annual SIG Meeting October 2023	During the meeting we discussed HPR SIG priorities over the next year.	Discussion during the meeting included a suggestion to meet during the year in between the conference, and organising this is in progress.	Donna Rowen	Julie Campbell Ana Maria Rodriguez-Leboeuf	October 2023
2. Change/Communicate structure/roles responsibilities of SIG chairs	We restructured our SIG chairs to the following roles: Past Chair - Donna Rowen Current Chair - Julie Campbell Chair – Elect – Ana Maria Rodriguez-Leboeuf	The current chair role will be responsible to set the SIGs agenda for the following year and submit the Annual Report. The current chair role will coach the chair-elect in the roles and co-lead where there are opportunities with the chair elect. They will lead the yearly activities of the SIG with the terms shifting from the Annual Meeting to the next Annual Meeting. The Past Chair can choose to remain engaged and be available to answer questions but will not be responsible to lead the SIG.	Donna Rowen	Julie Campbell Ana Maria Rodriguez-Leboeuf Heather Gelhorn (outgoing chair)	Completed October 2023
3. HPR pre-conference symposium, October 2023	A group of SIG members, led by Donna Rowen, submitted a SIG pre-conference symposium.	This was a truly collaborative effort with inclusion of members from several countries, members from academia and consultancy, and PhD students and early career researchers alongside established researchers. The event was well received and well attended.	Donna Rowen	Julie Campbell Ana Maria Rodriguez-Leboeuf Philip Powell Heather Gelhorn Ava Mehdipour Ana Moga Ahmed Osman Jiat Ling Poon Mehmet Inceer Sarah Knight	Completed October 2023, organised November 2022-October 2023

**Concerns/Questions/Comments:**



**2024 ANNUAL REPORT**





## 2024 ANNUAL REPORT

**SIG/Committee Name:** Industry SIG (I-SIG)

**Date:**

**Leadership:** Calvin N. Ho, Milena D. Anatchkova

**Board Liaison:** Tom Willgoss

**Mission:** This SIG connects individuals from academia with professionals representing the pharmaceutical, biotechnology, medical device and consulting industries who share a common interest in the application of health related QOL research. We are interested in innovative methods and research related to COAs, including PROs.

<b>Project/Working Group/ Initiative Title</b>	<b>Actions/Deliverables</b>	<b>Description</b>	<b>Project Chair(s)</b>	<b>Project Members</b>	<b>Date Executed/ Estimated Timeline</b>
1. SIG Symposium: An Industry Perspective: Best Practices for the Development of Conceptual Frameworks	Symposium proposal	Developed annual meeting SIG symposium actively engaging a wide range of SIG members from various parts of industry and various career stages.  Created survey to gather feedback from all SIG members, to be presented as part of the symposium.	Kathy Wyrwich	Natalie Aldhouse, Milena Anatchkova, Ana Maria Rodriguez, Michelle Carty, Tom Willgoss	October 2024
2. Regular symposium: The Value of Patient Experience Data Beyond the Label Claim	Symposium proposal	Developed annual meeting SIG symposium in partnership with R&HE SIG	Calvin Ho	Robyn Carson, Olivier Chassany, Lynda Doward	October 2024
3.					

**Concerns/Questions/Comments:**

--

**SIG/Committee Name: Japan**
**Date: 26 Jan. 24**
**Leadership: Yoshimi Suzukamo, Takuhiro Yamaguchi**
**Board Liaison: Tolulope T. Sajobi**
**Secretary: Rika Hayashida**

**Mission:** This SIG aims to increase opportunities for Japanese professionals in HRQL to communicate and exchange valuable information. We facilitate collaborations on high-quality studies, create opportunities for information exchange, and disseminate the results with the Japanese research community as well as with wider Asian Pacific and global audiences.

<b>Project/Working Group/ Initiative Title</b>	<b>Actions/Deliverables</b>	<b>Description</b>	<b>Project Chair(s)</b>	<b>Project Members</b>	<b>Date Executed/ Estimated Timeline</b>
1. SIG meeting in Calgary	Welcome/Introductions Activity reports Next activity plans Introduction of public funded research by our SIG members Change the co-chair	Eight members attended this meeting. We reported the annual activity, next activity plans, the public funded researches and several research introduced by members. We discussed about future tasks. We reported to change the Co-Chair and Secretary, too. The minutes of meeting were circulated through Teamwork.	Naito M Suzukamo Y		Complete at Oct. 20 <sup>th</sup> , 2023.
2. Developing of Japanese version of ISOQOL Dictionary	ISOQOL Dictionary (in Japanese)	We are reviewing the translated ISOQOL Dictionary into Japanese.	Suzukamo Y	Naito M, Shimosuma K, Miyazaki K, Saito S, Popielnicki A, and other members	In progress, by October 2024
3. 2018 Companion Guide to the ISOQOL 2015 User's Guide	2018 Companion Guide to the ISOQOL 2015 User's Guide		Suzukamo Y		In progress By March 2025
4. Regional conference with held jointly with the JSQolPro	JSQolPro research seminars and Annual Conferences	1) 10th Annual Conference of JSQolPro. Dec. 24, 2022 2) 18th JSQolPro research seminar. March 23, 2023 3) 19th JSQolPro research seminar. June 24, 2023 4) 11th Annual Conference of JSQolPro. Dec. 23, 2023 5) 20th JSQolPro research seminar. Feb. undecided, 2024 6) 21th JSQolPro research seminar. June undecided, 2024	1) Hayashida R 2) Murata T 3) Hikosaka M 4) Nishigori T 5) Iwatani T 6) Tanaka E	Members of Japan SIG and collaborators.	1)-4): Complete 5),6) under application

**Concerns/Questions/Comments:**

**SIG/Committee Name: Mixed Methods SIG**
**Date: 26 February 2024**
**Leadership: Rachel N. Cusatis, Bridget Gaglio, Amanda Barbeau**
**Board Liaison: Kathryn E. Flynn**

**Mission:** This SIG promotes the use of mixed methods research in the field of HRQL research by exploring the challenges and methodological solutions offered by this research paradigm, identifying opportunities for application of mixed methods research in the field, and defining good practice. Our ultimate aim is to share and learn best-practice methodologies that can be utilized to enhance the patient-centeredness of outcomes research.

<b>Project/Working Group/ Initiative Title</b>	<b>Actions/Deliverables</b>	<b>Description</b>	<b>Project Chair(s)</b>	<b>Project Members</b>	<b>Date Executed/ Estimated Timeline</b>
1. Longitudinal Qualitative Research Systematic Literature review (LQR SLR)	Original longitudinal review has been split into two reviews	Longitudinal Qualitative Research Methods Integrative Review. Data synthesis and manuscript drafting in process.  Scoping Review of Longitudinal Qualitative Research Methods in Clinical Trials. Full text review has been completed. Data extraction template is being finalized.	Brocha Stern Amanda Drury Vanessa Merker Carla Dias Barbosa	Team of 20 members from the SIG	Ongoing through 2024
2. Dissemination and SIG engagement	Annual in person SIG meeting  Ongoing SIG engagement	Successfully hosted a Mixed Methods SIG meeting at ISOQOL annual conference in Calgary.  Received feedback from members on interests and needs are planning to continue quarterly newsletters, webinars, and mid-year meeting. Starting to host monthly coffee chat for members to check in and connect.	Rachel Cusatis Bridget Gaglio	All SIG members who wish to take part.	October 2023; Ongoing through 2024.
3. Educational opportunities	Webinar and virtual mid-year SIG meeting	On 21 Jun 2023 the MM SIG hosted a webinar for SIG members. The session was on rapid qualitative analysis and was presented by Dr. Alison Hamilton. Webinars for the coming year will be based on member interests/requests.  On 10 May 2023 the MM SIG held a virtual mid-year meeting. Three presentations were mad: 1) digital biomarkers from PROs to TechROs; 2) collecting patient qualitative data during clinical trials to inform healthcare decision-making; and 3) ISOWOL Mixed Methods SIG special project: scoping reviews on longitudinal qualitative research methods. SIG updates were also presented by the SIG chairs. The SIG will host another virtual mid-year meeting in the spring/summer of 2024.	Rachel Cusatis Bridget Gaglio Amanda Barbeau	All SIG members who wish to take part.	Ongoing through 2024.



<p>4. Mixed Methods SIG Newsletters</p>	<p>Quarterly profile of members in a newsletter format to showcase our members.</p>	<p>Will curate articles including hot topics, article links, methodology, and ISOQOL specific information. Will also include announcements and updates on ongoing projects.</p> <p>The goal is to foster interrelationship and collaboration among members and to broaden knowledge of emerging topics and issues.</p>	<p>Rachel Cusatis Bridget Gaglio Amanda Barbeau</p>	<p>All SIG members who wish to take part.</p>	<p>Ongoing through 2024.</p>

**Concerns/Questions/Comments:**

None.

**SIG/Committee Name: New Investigators SIG**
**Date: Mar 1, 2024**
**Leadership: Jae-Yung Kwon, Lotte van der Weijst**
**Board Liaison:**
**Mission:**

This SIG provides professional development opportunities for:

- Graduate students
- Postdoctoral fellows who have completed their doctorate in the past five years
- Independent researchers who have recently transitioned to health related QOL research within the past five years

We provide early-career support to young professionals new to the field of HRQL research through a variety of online resources and in-person events.

<b>Project/Working Group/ Initiative Title</b>	<b>Actions/Deliverables</b>	<b>Description</b>	<b>Project Chair(s)</b>	<b>Project Members</b>	<b>Date Executed/ Estimated Timeline</b>
1. Tricks of the Trade: Looking back, trends, and advice	Session at ISOQOL Conference	Methods	Jae-Yung and Lotte	Jan (Editor of QLR) and Rasa (Editor of JPRO)	Submit to ISOQOL office by Apr 5th (Session in Oct 2024)
2. Commentary paper about citation patterns for ISOQOL New Investigators	Publish a commentary paper about ways to support publication for New Investigators at ISOQOL	Methods	Jae-Yung and Lotte	NI SIG Members	Session in Oct 2024
3. Online Webinar interview with Dagmara Kulis	Invite ISOQOL conference chair Dagmara Kulis to share with us tips on how to make the most of the conference in Cologne, Germany.	Application	Lotte and Jae-Yung	NI SIG Members	Beginning of September
4. ISOQOL Conference Happy Hour	Organize an informal meet-up for New Investigators on the first night of the annual conference (pending conference schedule). This will be an opportunity for members to meet and interact prior to the conference.	Application	Lotte and Jae-Yung	NI SIG Members	October 2024

**SIG/Committee Name: Patient Engagement SIG**
**Date: February 27, 2024**
**Leadership: Sadia Ahmed, Christel McMullan, Leonie Young**
**Board Liaison: Roxanne E. Jensen**

**Mission:** This SIG aims to ensure the patient voice is represented in ISOQOL activities through the advancement of patient engagement in HRQL research. Not only do we discuss ways to incorporate the patient voice in HRQL research, but we also are here to support ISOQOL's current and prospective Patient Research Partners (PRP).

<b>Project/Working Group/ Initiative Title</b>	<b>Actions/Deliverables</b>	<b>Description</b>	<b>Project Chair(s)</b>	<b>Project Members</b>	<b>Date Executed/ Estimated Timeline</b>
1. Patient Engagement in Quality of Life Research: International Perspectives	Formation of a working group with regional SIGs  Workshop at the ISOQOL 2023 meeting  Meetup in 2023	international perspectives of patient engagement in quality-of-life research and clinical practice. Patients as partners in research	PE SIG Co-Chairs (2023 Co-chairs: Sandra, Natasha, Sadia)	Sandra Zelinsky Leonie Young John Librett Natasha Roberts Sadia Ahmed Maria Santana Jessica Gentile Sumedh Bele	October 2023
2. Exploring patient engagement across the International Society for Quality of Life (ISOQOL): A Quality Improvement Project	Distribution of Survey to all SIG Chairs  Reporting back at the ISOQOL 2023 Meeting  Preparation of Report	Surveying SIG chairs to explore their understanding, needs and requirements with patient engagement within their SIGs	Natasha Roberts	Sandra Zelinsky Natasha Roberts Sadia Ahmed Christel McMullan Leonie Young	October 2023  Report: in progress
3. Scoping Review	Scoping Review	To explore patient engagement in Quality of Life Research	Natasha Roberts	Sandra Zelinsky Natasha Roberts Sadia Ahmed Christel McMullan Leonie Young	In Progress
4. Position Statement	Position Statement	Summarizing the work done by the PE SIG, definitions associated with patient	Natasha Roberts	Sandra Zelinsky Natasha Roberts Sadia Ahmed	In Progress

		engagement, and measuring what matters to patients and families		Christel McMullan Leonie Young	
5. Collaborative Partnerships	<p>Manuscript- Patient Adherence to Patient Reported Outcome Reporting in Clinical Practice</p> <p>Manuscript writing working group- Patient Engagement in Pediatric Research</p> <p>Submission for ISOQOL Workshop with Child Health SIG</p>	Partnerships with Child Health SIG	PE SIG Co-Chairs & Child Health SIG Co-Chairs	Sandra Zelinsky Sadia Ahmed Christel McMullan Leonie Young Sumedh Bele Harpreet Chhina John Chaplin Zephania Tyack	In Progress
6. Patient Partner Involvement in Research and in ISOQOL	Patient Partner Meet up – in development for 2024	Meetups for Patient partners and researchers interested in engaging with patient partners	Leonie Young	Sadia Ahmed Leonie Young Christel McMullan	In Progress
7. Advancing the Science of Patient Engagement	Patient Engagement Webinar Series – in development for 2024	Highlighting presentations from PE SIG Members on their PE projects and group discussions	PE SIG Co-Chairs (Sadia, Leonie, Christel)	Sadia Ahmed Leonie Young Christel McMullan  PE SIG members	In Progress

**Concerns/Questions/Comments:**

Development of strategies that support greater inclusion of patient partners/consumer representatives within the ISOQOL community and facilitated attendance at the ISOQOL meetings

**SIG/Committee Name: Regulatory and Health Technology Assessment Engagement (R&HE) SIG**
**Date: March 3, 2024**
**Leadership: Ashley F. Slagle, Robyn Carson, Wen-Hung Chen**
**Board Liaison: Tom Willgoss**

**Mission:** This SIG will routinely and actively engage with regulatory agencies and health technology assessment (HTA) bodies to address critical applied measurement issues raised by these entities or that emerge from their public communications (e.g., guidance documents, reflection papers, workshops). This collaboration embraces a broad measurement perspective and enables us to build scientifically-based patient-focused recommendations regarding the use of clinical outcome assessments (COAs) in the evaluation of therapeutic interventions aimed at advancing human health and well-being.

<b>Project/Working Group/ Initiative Title</b>	<b>Actions/Deliverables</b>	<b>Description</b>	<b>Project Chair(s)</b>	<b>Project Members</b>	<b>Date Executed/ Estimated Timeline</b>
1. Review & comment on regulatory and HTA publications/draft guidance	2023: Comments provided on FDA PFDD Guidance 4 (Complete)	Develop monitoring & dissemination process; Draft & submit comments to regulatory or HTA groups	TBD	Determined as needed aligned with expertise & availability	Ongoing throughout 2024
2. Understand current global regulators & reimbursement authorities' perspectives on methodological expectations & impact of PED	2024: Research Plan; Perspective Paper	Develop research plan & initiate research; Develop perspective paper on multi-stakeholder evidence requirements & core set of evidence to address in partnership with Industry SIG	TBD	TBD	<ul style="list-style-type: none"> <li>• Q224: Research Plan</li> <li>• Q324: Perspective Paper</li> </ul>
3. Facilitate Discussions with Representatives across Stakeholder Groups to Understand Value & Opportunities to Leverage PED Beyond the Label	2024: Symposium at 2024 Annual Meeting; Quarterly Discussions with RHE SIG	Partner with Industry SIG to foster discussion with external thought leaders representing industry, regulatory & reimbursement authorities to identify value & opportunity for PED beyond the label; Facilitate quarterly discussions with RHE SIG members to discuss timely topics & opportunities for application of PED beyond the label	TBD	TBD	Quarterly beginning in Q2; Symposium: October 2024 (pending acceptance)

**Concerns/Questions/Comments:**

**SIG/Committee Name: Statistics SIG**
**Date: 6<sup>th</sup> March 2024**
**Leadership: Antoine Regnault, Kim Cocks, Libby L. Floden**
**Board Liaison: Christopher Sidey-Gibbons**

**Mission:** This SIG connects statisticians working in the field of quality of life and provides a platform for communication, interaction and collaboration. Our aim is to identify and progress key areas for research and provide workshops and training for the wider ISOQOL membership.

<b>Project/Working Group/ Initiative Title</b>	<b>Actions/Deliverables</b>	<b>Description</b>	<b>Project Chair(s)</b>	<b>Project Members</b>	<b>Date Executed/ Estimated Timeline</b>
<ul style="list-style-type: none"> <li>Missing data workstream</li> </ul>	<ul style="list-style-type: none"> <li>Consider how best to make use of existing workshop materials</li> <li>Submit for 2024 conference workshop</li> </ul>	Workshop title: Analysis of longitudinal Patient-Reported Outcome (PRO) measures in randomized controlled trials with missing data. This was previously delivered in 2022 and after discussions between the authors was not deemed suitable for virtual delivery so aiming for another face to face workshop this year.	Kim Cocks	Bellinda King-Kallimanis Gina Mazza Andrew Trigg Gill Worthy	Submitted Jan 2024
<ul style="list-style-type: none"> <li>Data visualisation workstream</li> </ul>	<ul style="list-style-type: none"> <li>Create a group to work on a Statistics SIG data visualisation initiative</li> <li>Brainstorm ideas at 2023 conference</li> <li>Workshop/symposium submission for 2025 conference</li> </ul>	A high proportion of members at the meeting were interested in getting this workstream started. Members had the idea to create a very practical session (potentially virtual) consisting of participants being sent data to create a graphic on and then the meeting involving people presenting their different ideas.	Amylou Dueck Lisa Lix	Jane Johnson Ying Li Todd DeWees Brie Noble Oluwagbohunmi Awosoga Stella Ping Wang Jiabi Wen	Met October 2023, aiming for a 2025 conference submission
<ul style="list-style-type: none"> <li>Single item workstream</li> </ul>	<ul style="list-style-type: none"> <li>Create a group to work on this initiative</li> <li>Brainstorm ideas</li> <li>SIG symposium submission for 2024 conference</li> <li>Position paper</li> </ul>	Symposium title: Evaluating tolerability through a single item	John Devin Peipert Jessica Roydhouse Libby Floden	Jennifer Beaumont William Lenderking Antoine Regnault Kim Cocks	Met October 2023 SIG symposium submitted Jan 2024 and accepted
<ul style="list-style-type: none"> <li>Bayesian</li> </ul>	<ul style="list-style-type: none"> <li>Identify SIG-led activities for 2023/2024</li> </ul>	Bayesian analytics to address common issue in patient-reported outcome data presented by SIG members at 2023 conference. Potential workshop under discussion for 2025.	Katie Kunze  Yuelin Li	Rubina Shah  Fran Hu  Andrew Trigg	Symposium presented conference 2023

<ul style="list-style-type: none"> <li>Non-inferiority</li> </ul>	<ul style="list-style-type: none"> <li>Identify SIG-led activities for 2023/2024</li> </ul>	Abstract/paper under discussion	Stacie Hudgens	Gina Mazza Lene Kongsgaard Nielsen Tine Rosenberg	Met October 2023
<ul style="list-style-type: none"> <li>Estimands for PROs</li> </ul>	<ul style="list-style-type: none"> <li>Expand 2022 workshop into a webinar series</li> </ul>	Workshops on the estimand framework have been given at the 2020, 2021 and 2022 annual conferences. In an effort to reach a larger or different audience, this will be made into a series of webinars	Jessica Roydhouse  Libby Floden	Antoine Regnault Rachael Lawrance Corneel Coens	Expected to record April – June 2024

**Concerns/Questions/Comments:**

**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.

<b>Project/Working Group/ Initiative Title</b>	<b>Actions/Deliverables</b>	<b>Description</b>	<b>Project Chair(s)</b>	<b>Project Members</b>	<b>Date Executed/ Estimated Timeline</b>
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"> <li>- Literature reviews of existing guidelines/ practice</li> <li>- Survey on relevant areas following lit reviews</li> <li>- Evaluation of results</li> <li>- Identification specific aspects for guideline</li> </ul> <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>
--	--	--	--	--	--------------------------------------

## 2024 ANNUAL REPORT

### 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
<b>Artificial Intelligence (AI)</b>	To be determined, but potentially focused on: <ul style="list-style-type: none"> <li>• Definition(s) of AI as it applies to COAs</li> <li>• Literature search on current use of AI in translation of COAs</li> <li>• Early stage of AI: list caveats/concerns/shortcomings</li> <li>• Identify business cases</li> <li>• Deliverable: Reflection paper for AI usage in translation and linguistic validation</li> <li>• Could AI translate as well as people, and potentially faster to shorten translation timelines?</li> <li>• Could AI such as DeepL be used to produce versions as drafts for EC submissions?</li> <li>• Exploring how AI will impact translation and linguistic validation process for PROMs</li> <li>• Assessing the quality of AI applications (e.g., DeepL.com, ChatGPT) for translation of PROMs</li> </ul>	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
<b>Gender Inclusivity in Language Used on PRO/COA Measures</b>	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"> <li>• How gender inclusivity informs the translation and cultural adaptation process and usage of the measures in other cultures.</li> <li>• 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.</li> <li>• 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.</li> </ul>			Ester Villalonga Olives Jennifer Contreras Mrunmayee Pitkar Sonya Eremenco Jasmine Walker Tim Poepsel Melinda Johnson Barbara Brandt	
<b>Copyright Watch/Copyright Infringement for COAs and COA Translations</b>	<p>To be determined, but potentially focused on:</p> <ul style="list-style-type: none"> <li>• 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.</li> <li>• 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</li> </ul>	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"> <li>• 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.)</li> <li>• 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.</li> <li>• How to tackle copyright infringement</li> <li>• 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</li> </ul>				
<b>Assessing Readability of Languages</b>	<ul style="list-style-type: none"> <li>• Definition of readability</li> <li>• Review of existing guidelines and best practices.</li> <li>• Guidance/best practices on assessing readability</li> <li>• Development of a holistic method of readability, incorporating (converging) existing tools such as face validity, translatability assessment, usability testing</li> <li>• Review of the relevance and use of (automated) methods to test</li> </ul>	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"> <li>• No widely accepted method of assessing readability of translations exists</li> <li>• How do we assess readability across languages?</li> <li>• Does readability guarantee (or indicate) comprehensibility?</li> <li>• Is readability one component of a larger assessment?</li> <li>• Health literacy score- how does this differ from readability? Can this be used to assess readability?</li> <li>• Where does "cognitive linguistics" fit in?</li> <li>• How is readability different from comprehensibility or general understanding? Important to consider when defining readability.</li> <li>• How do we account for variations in readability expectations/standards across organizations/countries? For example, reaching the ideal age/grade level of the text.</li> </ul>				
--	--	--	--	--	--

**TCA SIG Leadership Team specific project**

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

**Concerns/Questions/Comments:**