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VOLUME 19 ISSUE 2 Newsletter for ISOQOL Members SPRING 2013



Bryce B. Reeve, PhD



Dear ISOQOL Friends.

I hope your quality of life is somewhere between very good and excellent, 90 to 100, very

cool to awesome, or whatever rating scale you prefer. However, my guess is that you, like me, find yourself burdened with a very long "to do" list and unanswered emails from weeks to months ago. It is here that I am supposed to provide some sage advice that your life will not be measured by the number of emails you answered, but I would ignore this advice as well. If it helps, we are all facing challenging deadlines and unending requests for our time (perhaps this letter is now turning to the "misery loves company" speech).

However, please know that ISOQOL provides an environment to connect with fellow researchers interested in similar research questions and methods, and I encourage you to reach out to them for comradery and

sharing of ideas (how do you like this transition sentence?). ISOQOL's Special Interest Groups (SIGs) gather researchers with similar interests: Child Health, Psychometrics, QOL in Clinical Practice, Response Shift, and Translation & Cultural Adaptation. We also have SIGs for specific geographic regions such as the Ibero-American SIG and Asian-Chinese SIG, and look to establish SIGs in new areas. The ISOQOL New Investigator SIG is our largest and very active; this is wonderful as the new investigators bring energy and new ideas (now I feel old).

I am very excited to announce that a new SIG is being established, the Patient Engagement SIG. I am thankful to Sam Salek and Rick Sawatzky for helping to create it. This SIG will serve a critical role to include patients as influential voices within ISOQOL and to engage patient advocacy organizations to partner with ISOOOL. As I have mentioned on previous messages, the healthcare field is becoming more patient-centered. For close to 20 years, ISOQOL has concentrated on how to better capture the experiences Continued on page 2.



The ISOQOL Newsletter is published four times a year by the International Society for Quality of Life Research.

Newsletter Editor

Ana Popielnicki, BA, USASend articles with subject line addressed "Newsletter Submission" to: **info@isoqol.org**

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and perspectives of patients and their caregivers. The Patient Engagement SIG will help to find better ways to connect with patient advocacy groups so they can learn of our work and we can learn of their needs.

Patients and survivors have access to a form of knowledge that others lack. In an interview conducted by anthropologist Linda Garro as part of a project on chronic pain, a woman given the pseudonym of Gail expressed, "And all these people in pain... We walk in different dimensions. We have access to different knowledges... I'm convinced only sick people know what health is. And they know it by its very loss."* This experiential knowledge can help to inform research priorities for ISOQOL. A better understanding of the impact of disease and its treatments on the lives of patients and their caregivers will identify critical knowledge gaps for HRQOL researchers and clinical investigators.

In addition, it will be the patient advocacy groups' voices that will influence policy makers and funding agencies. The extent that ISOQOL may serve as an advisor to the advocacy groups on better ways to enhance patient participation in research and to improve the measurement of HRQOL, the better the healthcare field can enhance the care it provides to patients.

An example of recent collaboration is between ISOQOL and the Stupid Cancer organization (http://stupid-cancer.org/), which is a non-profit organization that empowers young adults affected by cancer through innovative and award-winning programs and services. In the coming months, ISOQOL representatives will participate in an internet talk show to discuss the mission of ISOQOL

and answer questions from young adult cancer survivors as it relates to HRQOL issues. We are also in discussion with Matthew Zachary, CEO of Stupid Cancer and 17-year cancer survivor, on other future collaborations between our organizations.

It is my hope that ISOQOL's network of partner patient advocacy organizations grows rapidly over the next few years with the help of the Patient Engagement SIG. The future of our organizations is forever linked as we try to find better ways to tell the story of the experiences of patients, with the goal to identify effective interventions to enhance their lives.

Thus, I end this message with the hope that your quality of life is good despite the fact you are putting in long hours to manage the work load in front of you. For the work you are doing, the lessons you are learning, the problems you are solving will enhance someone's life. ISOQOL serves as the vehicle to share your results, to learn from others, and to create a better future for all.

Sincerely,
Byce B Reere III

Bryce

*Quoted in Garro L. "Chronic Illness and the Construction of Narratives." In Good M-J D, Brodwin PE, Good BJ, Kleinman A. (eds.) Pain as Human Experience. Berkeley and Los Angeles University of California Press, 1992, p. 129.

Frank AW, "Survivorship: In Every Expression a Crack." In Dresser R (ed.) Malignant: Medical Ethicists Confront Cancer. Oxford University Press, 2012.

FROM THE EDITOR'S DESK

By: Ana Popielnicki

Dear ISOQOLers:

I am pleased to present to you our Spring 2013 issue (or Fall, if you happen to be in, say, Southern Australia). As those of us in the Northeast US are finally starting to thaw (I think I saw a robin in my backyard), I am happy to report that, judging from the excellent articles in this issue, our global community is busy with exciting projects, task forces, and specialty group activities.

Our fearless leader Dr. Reeve brings us his traditional President Message, focusing on the enriching and supportive environment of our Society, particularly with the growth and activities of our SIGs. Dr. Reeve emphasizes the (coming soon to a theater near you!) new Patient Engagement SIG, which will facilitate ISOQOL's involvement with patient advocacy organizations and the patients themselves.

We caught up with Drs. Bottomley and Groenvold, from EORTC – check out their article updating us on EORTC recent activities, especially their 3rd QoL Conference on Cancer Clinical Trials. Other news on recent trials and developments are also shared with our members in this issue.

Our friends from the Ibero American SIG, with the collaboration of Drs. Ahmed and Snyder, bring us their notes and experiences on the 6th Ibero American Quality of Life Meeting, which was held this past November/December in Brazil – this was a wonderfully organized and enriching conference – both scientifically and culturally. I hear Sara and Claire are considering moving to Goiás (or at the very least arranging for shipments of corn ice cream from our colleagues in Brazil!).

Many thanks to Barb Brandt and Matt Talbert from CTi! They discuss the importance of adapting physical activities to achieve cultural applicability, while accurately conveying conceptual equivalence with the source document, when translating Clinical Outcome Assessments. This is essential in order to gather valid data across and within languages in multi-center trials.

A Calendar of Events for the 2nd Quarter is included. Take a look to find many educational and networking opportunities in the April – June Calendar. We welcome any suggestions for the upcoming quarters – please send us an email with your events for inclusion in future issues.

Also in this issue, please find news on the CONSORT PRO Extension recently published in JAMA, brought to you by your friendly ISOQOL Reporting Guidelines Taskforce. A link to more information about the Taskforce and the publication can be found in the article.

There are additional exciting opportunities for engagement in ISOQOL. Consider participating in the upcoming webinar, or nominate yourself or someone else for the Board of Directors or for an ISOQOL Award.

Your Communications Committee wants to hear from you! Please send your questions, suggestions, submissions, and comments to info@isoqol. org with "Newsletter" on your subject line.

Wishing you all a wonderful season, until our next issue, happy reading!

Ana Popielnicki Editor

(Allet)





Validated translations of PRO instruments equal validated results.

Corporate Translations' state-of-the-art linguistic validation process is modeled after the FDA guidance document and the ISPOR Good Practice Guidelines for the translation and validation of PRO instruments. As pioneers in linguistic validation, we have developed an array of support services designed to help our clients utilize PRO instruments in their global clinical trials. Corporate Translations has completed over 10,000 PRO instrument translations in a wide range of languages and therapeutic areas. That's why we are the preferred supplier of ISO 9001:2008 translation and linguistic validation solutions to the world's leading life science companies.

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RECENT OOL NEWS FROM THE EORTC

Dr. Andrew Bottomley, Assistant Director, Head of the EORTC Quality of Life Dept, EORTC; Dr. Mogens Groenvold, Professor, Chair of the EORTC Quality of Life Group.

We were honoured to be invited to write for the ISOQOL newsletter, and will take the opportunity to focus on our 3rd QOL Conference on Cancer Clinical Trials. We will also highlight some recent key trials and developments within our group.

We're proud to have successfully organized our 3rd QOL and Clinical Trials and Symptom conference five months ago. In the past, these conferences have included many close and dear friends as faculty, many of whom are also longstanding ISOQOL members. It's always a pleasure to invite our friends to come to give talks and discuss the challenges we face for the coming decade. In 2012, we had more than 40 presentations given over a 3-day period, hosted on 17-20 October at the European Parliament, in Brussels. The conference succeeded in getting speakers and policy makers together to debate on all the key issues in cancer clinical trials, design and reporting, including future policy and regulatory concerns. This meeting set the stage for future research and policy meetings to give greater visibility to quality of life as an outcome in clinical trials within the world of EU legislators.

Maria Matias, MEP, discussed the European Commission's Horizon 2020 research programme, which will replace the existing Framework Programmes for projects running from 2014 to 2020. Health is central to the societal challenges in Horizon 2020, and Ms. Matias said that negotiations were ongoing to make the budget of the programme as large as possible, with the largest share going to biomedical research. All the presentations from the conference are online and free to access,

and ISOQOL members are more than welcome to download them from the EORTC. A great measure of the success of this conference is the fact that the European Parliament is hosting us again in Spring 2014 for our 4th International QOL and Clinical Trials Conference, a rare gesture of support these days from our politicians, and we are grateful for the continued support of Ms. Matias and the European Parliament in pushing QOL into the limelight of the political agenda. ISOQOL members can register via http://groups.eortc.be/probe/

Many other events are taking place at the EORTC, and the EORTC Quality of Life Group keeps flourishing with new and established members, who continue to publish excellent papers and innovative new modules. Excellent progress is being made on the EORTC IRT project, as well as progress with field studies of modules such as the Fatigue module or the Bone Metastases module. All these and many more studies can be seen on our new-look website (http://groups.eortc.be/qol/). A newsletter is due out in mid-April and can be downloaded from the EORTC website free of charge or mailed to you on request.

The past six months have seen several major clinical trials published by the EORTC. For example, we have looked at therapy for patients with brain tumour metastases, which often includes removal of the stable solid metastases followed by whole-brain radiotherapy (WBRT), a treatment that has been the subject of much discussion. Arguments in favour of WBRT include the desire to limit the deleterious effects of disease progression on cognitive functioning, while argu-

ments against using WBRT include the risk of long-term neurotoxicity. The discussion is further complicated because many patients with brain metastases are under palliative care, and health-related quality of life (HRQOL) is a very important consideration. A phase III RCT (EORTC trial 22952-26001) with 359 patients published in JCO in December (http://jco.ascopubs.org/content/31/1/65.abstract) concluded that WBRT following surgical or radio-surgical removal of brain metastases reduces relapses and neurologic deaths, but does not improve how long patients remain functionally independent or their overall survival. Now, HRQOL results from this same EORTC trial show that adjuvant WBRT after surgery or radiosurgery of a limited number of brain metastases from solid tumours may negatively impact on some aspects of HRQOL, even if these effects are transitory. Several excellent editorials and podcasts (http://jco.ascopubs. org/site/podcasts/archive/2012/ oct-dec2012.xhtml) have debated the impact and importance of this study, leading to recommendations for clinical practice.

The EORTC is looking to the future and we are busy planning our strategy for clinical trials until 2020 (http://www.eortc.org/egam2013/programs/). It is for certain, even in the middle of a global financial crisis, that QOL and PRO assessment will be an increasingly important part of all our future research portfolio and within clinical trials, and that new measures will be developed to fit the needs of our researchers and investigators in order to make the most of our role in patients' QOL.

NEW CONSORT PRO EXTENSION PUBLISHED

THE NEW CONSORT PRO EXTENSION IS NOW FREELY AVAILABLE IN JAMA

Reporting of Patient Reported
Outcomes in Randomised Trials:
the CONSORT PRO Extension. JAMA
2013; 309 (8) 814-822 http://
jama.jamanetwork.com/article.
aspx?articleid=1656259, Calvert M,
Blazeby J, Altman D, Revicki D, Moher
D, Brundage, M for the CONSORT PRO
Group.

Clinical trials provide us with the best evidence to guide patient treatment and inform health policy. Yet, crucial information on PROs such as quality of life is often left out or poorly reported in clinical trial publications. This may be viewed as unethical and wasteful of limited resources. The new guidance informed by international stakeholders aims to facilitate the transparent reporting of PRO data from trials to inform patient care and health policy.

The development of this new guidance was led by the ISOQOL Reporting Guidelines Taskforce, in collaboration with the MRC Midland and ConDuCT Hubs for Trials Methodology Research, UK and the CONSORT Executive.

We'd like to take this opportunity to thank ISOQOL members and particularly the Reporting Guidelines Task Force for their valuable input to this successful initiative and hope that ISOQOL Members will endorse the new guidance. ISOQOL continues to prioritise work on best practice for PROs in clinical trials.

Further details on the ISOQOL Reporting Guidelines Task Force work that informed the CONSORT PRO Extension can be found here: Patient-reported outcomes in randomized clinical trials: development of ISOQOL reporting standards Quality of Life Research, Quality of Life Research Brundage M, Blazeby J, Revicki D, Bass B, de Vet H, Duffy H, Efficace F, King M, Lam CKL, Moher D, Scott J, Sloan J, Snyder C, Yount S, Calvert M.

http://link.springer.com/article/10.10 07%2Fs11136-012-0252-1

Mel Calvert Jane Blazeby Dennis Revicki Mike Brundage

on behalf of the ISOQOL Task Force and CONSORT PRO Exec.

This work was funded by the Medical Research council, UK and the Canadian Institutes of Health Research.

ISOQOL

ABSTRACT SUBMISSION DEADLINE EXTENDED

The abstract submission deadline for Oral and Poster Presentation Submissions has been extended through Friday, April 19. Abstract submission will close on Friday, April 19 at 11:59 pm CT.

Information on submitting abstracts, including abstract guidelines and step-by-step instructions, can be found on the Abstract Submission page on the ISOQOL website.

Abstracts should be organized into four sections: Aims, Methods, Results, and Conclusions. These four sections should total no more than 350 words.

Submit an Oral or Poster Presentation Abstract

ISOQOL has made substantial updates to the abstract submission site, so be sure to read the information provided on the Oral and Poster Presentation page for instructions and troubleshooting tips. Each abstract's submitting author will have the opportunity to edit submissions as often as necessary up to the new deadline of April 19.

Please note that the abstract submission site only permits up to ten (10) authors to be submitted at this stage. If your abstract has more than ten authors, please submit the first ten authors into the submission site, and e-mail Heather Vitale at info@isoqol.org with the name of your abstract and a complete list of authors.

ADAPTATION OF ACTIVITIES IN COAS: ACHIEVING SOURCE EQUIVALENCE WHILE MAINTAINING CULTURAL APPLICABILITY

Barbara A. Brandt, M.A., Matthew Talbert, M.A., Corporate Translations, Inc.

Clinical Outcomes Assessments (COAs) frequently include questions asking patients, observers, or clinicians to assess the patient's ability to perform a particular activity. Activities may include indoor or outdoor games and sports, household chores, and personal hygiene tasks. When translating a COA, some activities may not have a direct equivalent in the target language, necessitating adaptation. When adaptation is needed, a tendency exists to substitute an activity in the same category (i.e. a sport or game) which is equally recognizable and popular with native speakers of the target language, without considering the movement involved. The movement and exertion required, as well as cultural appropriateness, should be considered. Failure to do so can impede data pooling across languages in multinational trials. In some cases, developers elect to remove the activity altogether, also hindering data pooling and risking problems with missing data.

Corporate Translations recently looked at linguistic validation studies where cognitive debriefing subjects identified activities as inapplicable to their language and culture, and other activities as difficult to understand. Languages observed were Eastern European, Indian, Middle Eastern, Asian, and Southeast Asian, all of which presented difficulties in adapting "Western" activities.

Alternative equivalent activities were recommended by subjects and linguists. For example, in Arabic for Egypt, the game "bocce" was found to be inapplicable to the culture. The game "billiards" was suggested as an alternative. This is suitable, as both activities are light in nature, require standing and similar movements, and a similar amount of exertion. In addition, "billiards" is widely recognized by Arabic speakers in Egypt. "Bocce" also posed difficulties for Indian languages. The initial alternative was "cricket," which was not suitable, as it requires more bodily movement and running. A suitable alternative was "playing marbles," as the Indian version of the game "marbles" requires standing, light movement and no running. Another activity that proved problematic in Indian and Middle Eastern languages was "shoveling snow." Finding an activity with similar movement and exertion was not challenging, but finding one routinely performed within the target country proved difficult. "Gardening" was a popular alternative suggested by linguists; however, this can involve a wide range of exertion levels, from digging a shallow trench with a trowel while seated or on one's knees to standing while digging with a large shovel. A suitable replacement was "shoveling dirt in the garden," which reflects the appropriate amount of exertion and movement, and is familiar to respondents.

Questionnaires assessing respondent mobility often evaluate one's ability to carry out personal hygiene tasks, such as "getting in and out of a bathtub" and "getting on or off the toilet." In Indian languages, cognitive debriefing subjects did not understand "bathtub," and linguists noted that a majority do not have "bathtubs" in the home. A suitable alternative was "To sit on and get up from a small stool or a small seat in order to take a bath with a tumbler." In this way, source movement and exertion are replicated, and the activity is culturally appropriate. The concept of "toilet" was understood; however, because the source is referring to a Western style toilet, the movement required is different from toilets commonly found in India, which are on the ground and require much more bending of the knee. The suggested alternative, to achieve equivalence with the source movement, was "getting on or off a chair."

Adaptation of Western activities in COAs requires consideration of the movement and exertion involved in the source, as well as maintaining cultural appropriateness and familiarity to the respondent. This is an essential element when creating a localized questionnaire that will yield sound data both within and across languages.



May 8-10, 2013 Ritz-Carlton | Palm Beach, FL

visit the event newsletter



This is a small conference with high quality speakers and high quality participants from the industry. I don't always go to Summits, but when I do, I prefer **marcus evans**!"

Vice President, Clinical Operations, Biomarin Pharmaceutical Inc.

distinguished speakers include:

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Kenneth Getz, Director, Sponsored Research and Associate Professor, **Tufts CSDD, Tufts University School of Medicine**

Dr Tunde Otulana, Vice President, Clinical Development & Medical Affairs, Respiratory, **Boehringer Ingelheim**

Jorge Rodriguez-Larrain, Head, Global Site Management, Alcon Laboratories, **Alcon Laboratories**

Thomas Krohn, RPh, MBA, Director of Clinical Open Innovation, **Eli Lilly and Company**

Behzad Khosrovi, MA, PhD, Senior Vice President, Product Development, **NovaBay Pharmaceuticals, Inc.**

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CALENDAR OF EVENTS—APRIL

• Apr 15-17

CMC Workshop: Translating Science into Successful **Regulatory Submissions**

Washington D.C., USA http://staging.diahome.org/en-US/ Meetings-and-Training/Find-Meetingsand-Training/Meeting-Details. aspx?ProductID=30354

• Apr 15-17

National Healthcare CFO Summit Spring 2013

Palm Beach, FL, USA http://www.me-uk.com/summit/intro. asp?eventid=19250

• Apr 16-18

Regression Methods for Health Economic Evaluation

York, UK

http://www.york.ac.uk/che/courses/ short/regression-methods/

• Apr 17-18

Pharmaceutical Portfolio & Lifecycle Management

London, UK

http://www.smi-online.co.uk/ pharmaceuticals/uk/pharmaceuticalportfolio-product-life-cycle-management

• Apr 22-23

Network Meta-Analysis of Direct, Indirect, and Mixed Treatment **Evidence**

New York, NY, USA

http://www.iconplc.com/_uuid/ce3ca23b-9d09-47c5-8c02-654fa5c4fa35/index.xml

• Apr 24-25

World Drug Safety Congress Americas 2013

Boston, MA, USA

http://www.clocate.com/conference/ World-Drug-Safety-Congress-Americas-2013/24302/

• April 25-28

OMG 2013 Cancer Summit for Young Adults

Las Vegas, NV USA http://omgsummit.org/2013/index2.html

Apr 28-May 1

DIA/FDA Statistics Forum 2013: PDUFA V Statistical **Topics and Emerging New** Issues

North Bethesda, MD, USA http://www.diahome.org/Tools/Content. aspx?type=eopdf&file=%2Fproductfiles% 2F30457%2Fluncheon+roundtable.pdf

• Apr 29-30

12th Annual Patient Adherence and Support Summit

Philadelphia, PA, USA http://www.thehealthbridgesolution. com/event/cbi-12th-annual-patientadherence-and-support-summit

Apr 30–May 13

Oncology USA

Boston, MA, USA http://www.eyeforpharma.com/ oncologyusa/

CALENDAR OF EVENTS—MAY

• May 2-3

Mobile Engagement of Healthcare Professionals Conference

Chicago, IL, USA http://www.q1productions.com/ conferencepost/mobile-engagement-ofhealthcare-professionals-conference/

• May 2-5

Third Annual Association for Value-Based Cancer Care Conference

Hollywood, FL, USA http://www.avbcconline. org/?q=conference/2013

May 6−7

CBI's 10th Forum on Patient Reported Outcomes (PRO)

Philadelphia, PA, USA http://www.cbinet.com/conference/ pc13141#.UQrB8mfhewc

• May 6−8

PharmAccess Leaders Forum

Vienna, Austria http://springpharmaccess2013. nextlevelpharma.com

May 7–11

36th Annual European Medical Writers Association Conference 2013

Manchester, UK http://www.emwa.org/conferences/ Manchester-May-2013.html

May 7–10

Armada Specialty Pharmacy Summit

Las Vegas, NV, USA http://www.armadasummit.com/

CALENDAR OF EVENTS—MAY

• May 8-9

Oncology Market Access & Marketing Summit 2013

Boston, MA, USA http://www.conferencealerts.com/showevent?id=114464

• May 8-10

Evolution Summit

Palm Beach, FL, USA Contact: David Drey, 312-540-3000 x6583, d.drey@marcusevansch.com http://www.evolutionsummit.com/ evolution_isq

May 9

Understanding Searching Techniques to Inform HTA, Systematic Reviews and Guideline Development

York, UK

http://www.cochrane.org/news/tags/authors/understanding-searching-techniques-inform-hta-systematic-reviews-and-guideline-dev

• May 14–16

15th Annual Medicaid and GP Congress

Lake Buena Vista, FL, USA http://www.drugchannels. net/2013/03/15th-annual-medicaid-and-government.html

• May 14-15

Drug & R&D Portfolio Valuation Forum

Brussels, Belgium http://www.nextlevelpharma.com/ events/view/drug_r_d_portfolio_ valuation_forum

May 14–15

2013 NICE Annual Conference

Birmingham, UK http://www.niceconference.org.uk/

• May 14–15

UK Causal Inference Meeting

Manchester, England https://sites.google.com/site/ ukcausalinferencemeeting/

• May 16-17

Thought Leader Engagement, the Role of Medical Affairs and Medical Science Liaisons in the Era of Healthcare Concerns

Philadelphia, PA, USA World Congress Summit on Thought Leader Engagement, the Role of Medical Affairs and Medical Science Liaisons

• May 18-22

ISPOR 18th Annual International Meeting

New Orleans, LA, USA http://www.ispor.org/meetings/ NewOrleans0513/ SymposiumOpportunities.asp

• May 20-22

2013 Medicaid Managed Care Congress

Baltimore, MD, USA http://www.iirusa.com/mmcc/home.xml

May 20–21

3rd Annual U.S.-CHINA PHARMA Boston, MA, USA

http://www.chinarndpartnership.com/

• May 20-22

4th World Congress on Bioavailability and Bioequivalence

Beijing, China http://omicsgroup.com/conferences/ bioequivalence-bioavailability-2013/

• May 22-23

International Pharmaceutical/ Biotech Accounting and Reporting Congress

London, UK

http://www.biztradeshows.com/ conferences/internationalpharmaceutical-biotech/

• May 27-30

Committee for Medicinal Products for Human Use

London, UK

http://www.ema.europa.eu/ema/index. jsp?curl=pages/news_and_events/ events/2012/07/event_detail_000648. jsp&mid=WC0b01ac058004d5c3

• May 28-29

Health Economics for Non-Health-Economists

Brussels, Belgium http://www.celforpharma.com/pharmamanagement/training/pharma-healtheconomics-course.html?linkid=minimenu_ dates#dates

• May 31-June 2

Modelling the Impact of Diseases in the Economy

Darmstadt, Germany http://www.inomics.com/economics/ conferences/2012/11/11/economicsdisease-modelling-impact-diseaseseconomy-darmstadt-germa

CALENDAR OF EVENTS—JUNE

• June 1-2

Real World Evidence USA

Bethesda, MD, USA

http://www.eyeforpharma.com/real-world-data-and-health-outcomes/index.php

• June 3-9

CINCH Academy - Essen Summer School in Health Economics

Essen, Germany http://www.inomics.com/

• June 4-6

Pricing & Profit Optimization Forum - Life Sciences

Montreux, Switzerland http://www.pricingplatform.eu/ professionaldevelopment/forums/ forums-industryfocused/seminars-eventdetails.html

• June 5-6

Global ABAC - Third Party Diligence, Audit and Oversight

Washington, D.C., USA http://www.cbinet.com/conference/ agenda/pc13241

• June 5-7

Pharmaceutical Pricing, Reimbursement and Market Access South-east Europe & Turkey

Opatija, Croatia http://pharma-market-access.farmavitar. com/en/

• *Iune 5-6*

Real World Data: Partnerships & Health Outcomes

London, UK

http://www.eyeforpharma.com/ rwd/?utm_source=healtheconomics&utm_ medium=listing&utm_campaign=seo

• June 6-9

4-Day Certified Course in Introduction to Health Technology Assessment

Hall i.T., Austria http://2011.aspher.org/pg/event_calendar/view/8229

• June 11-12

The Strategies and Tactics of Pricing

Stockholm, Sweden http://www.pricingplatform.eu/ professionaldevelopment/trainings/ eppcertifiedopentrainingprogram/cetifiedtraining-program-event-detail/icalrepeat. detail/2013/06/11/265/36/the-strategiesand-tactics-of-pricing.html

• June 17–19

Global Health Metrics & Evaluation

Seattle, WA, USA

https://www.healtheconomics.org/conferences/5676-global-health-metrics-evaluation-2/

• June 18–19

Principles of Pharma Market Access in Europe

London, UK

http://www.celforpharma.com/pharma-management/training/pharma-market-access-course.html?linkid=minimenu_dates

• *Iune* 19–20

CBI's 6th Annual Bio/ Pharmaceutical Summit on Managed Care Marketing

Philadelphia, PA, USA http://www.cbinet.com/managedcare#. UQrFO2fhewc

• June 19-20

The Strategies and Tactics of Pricing

Amsterdam, The Netherlands http://www.pricingplatform.eu/professionaldevelopment/trainings/eppcertifiedopentrainingprogram/cetified-training-program-event-detail/icalrepeat. detail/2013/06/19/259/36/the-strategies-and-tactics-of-pricing.html

• June 20-21

Essentials of Pharmaceutical Pricing, 2-day course with Gary Johnson

London, UK

http://www.celforpharma.com/pharma-management/training/pharma-pricing-course.html?utm_source=Healtheconomics.com&utm_medium=ad2013&utm_campaign=PRI

• June 23-27

DIA 2013 49th Annual Meeting: Advancing Therapeutic Innovation and Regulatory Science

Boston, MA, USA http://www.diahome.org/en-US/ Flagship-Meetings/DIA2013.aspx

• Iune 24-27

12th Annual International Conference on Health Economics, Management & Policy

Athens, Greece http://www.atiner.gr/2013Conferences. htm

• June 24-27

Connected Health Asia 2013

Singapore, Singapore http://www.connectedhealthasia.com/

• June 24-27

Health Insurance Asia 2013

Singapore, Singapore http://www.healthinsurance-asia.com/

• Iune 24-27

Committee for Medicinal Products for Human Use

London, UK

http://www.ema.europa.eu/ema/index. jsp?curl=pages/news_and_events/ events/2012/07/event_detail_000649. jsp&mid=WC0b01ac058004d5c3

ISOQOL AWARDS

By: Rebecca Brandt, CAE; Executive Director, ISOQOL

EMERGING LEADER AWARD IN HONOR OF DONNA LAMPING, PHD

With the passing of Past President Donna Lamping, PhD in 2011, the Board of Directors agreed to establish an award for emerging leaders within ISOQOL and the field of health-related quality of life research. Donna spent much of her career mentoring young researchers and, by creating this award, ISOQOL hopes to honor her legacy. Special recognition goes to Neil Aaronson and Madeleine King for leading the process of designing this award.

The award nominee must be a current member of ISOQOL and have been active on an ISOQOL committee, SIG or working group for at least 2 years, having shown exceptional leadership skills and potential. Individuals must be within 10 years of completing a PhD (or equivalent), MD or Masters Degree. Current and past ISOQOL board members are

ineligible. Self-nominations are accepted. Full information regarding the application process can be found on www.isoqol.org.

PRESIDENT'S AWARD

The goal of this award is to recognize outstanding contributions (by an individual or group) to the advancement of the quality of life field in one or more of the following areas: "education of professionals, patients or lay individuals about the value of quality of life assessment as related to health"; "promotion or execution of quality of life research or other scholarly activities"; and "facilitating or furthering policy initiatives that impact upon health-related quality of life." The winner may be given the opportunity to give a 20-minute plenary during the Annual Meeting.

Please submit your nomination package consisting of a letter from the nominator specifying the nominee's

contributions, the curriculum vitae of the nominee, and an external support letter.

The award will be selected by the ISOQOL Executive Committee and approved by the Board of Directors. The award will consist of a plaque, a \$1,000 US honorarium and up to \$1,000 US in travel expenses if the recipient plans to attend the Annual Conference.

Make sure to read the full description and criteria for the awards at www. isoqol.org by clicking on "awards" on the left side of the homepage.

Please send your nomination package for either award to:

President's Award/Emerging Leader Award ISOQOL Executive Office 555 E. Wells Street, Suite 1100 Milwaukee, WI 53202 USA Fax: (414) 276-3349 (OR e-mail info@isoqol.org)

ISOQOL

ISOQOL WEBINAR: LESSONS LEARNED FROM PROS IN FDA & EMA LABEL CLAIMS

The Industry Advisory Committee, chaired by Josephine Norquist, MS, is presenting a webinar titled, Lessons Learned from PROs in FDA and EMA Label Claims, on Thursday, May 2 at 11 AM ET/3:00 PM GMT.

This intermediate-level webinar will include presentations from Incyte (ruxolitinib [Jakafi®]), Shire (icatibant [Firazyr®]) and their partners, OxfordOutcomes and Adelphi Values, who had recent FDA and EMA approvals including data from PRO measures in their labeling claims. A review of the PRO measures included in these approvals, lessons learned from interactions with the regulatory agencies and similarities/differences between FDA and EMA will be shared. Specifically, the webinar will address how to conduct a gap analysis, how to adapt or modify existing measures, and best practices for successfully including data from PRO measures in labeling claims through the use of the above mentioned case studies.

Registration is now available on the ISOQOL website (isoqol.org) under Research & Education.

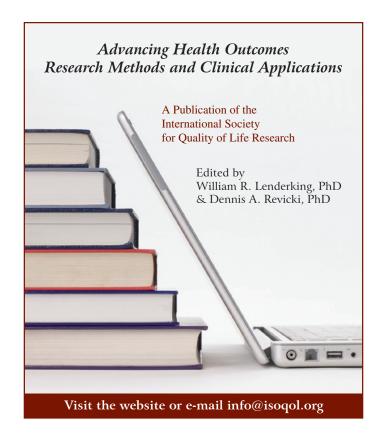


The ISOQOL Nominating Committee, chaired by President-elect Galina Velikova, is accepting nominations for the following ISOQOL leadership positions:

Member, Board of Directors 2013-2016 (Two open positions, three-year term) *Position begins at the 2013 Annual Conference and concludes at the 2016 Annual Conference.*

Self-nominations are accepted and encouraged. The ISOQOL Nominating Committee is committed to encouraging a strong diversity on the Board of Directors regarding geographic representation as well as representation from all aspects of health-related quality of life research.

An e-mail with full position descriptions will be e-mailed to all members. If you are interested in learning more about being nominated for a position, please contact Becky Brandt, ISOQOL Executive Director at rbrandt@isogol.org.



ORGANIZING AN IBERO-AMERICAN ISOQOL EVENT: A SUCCESSFUL EXPERIENCE

Maria Alves Barbosa; Virginia Visconde Brasil; Lizete Malagoni de Almeida Cavalcante Oliveira; Neuma Chaveiro; Claire Snyder; Sara Ahmed

There are times in our lives when we are challenged to do something unexpected. When this challenge involves organizing a meeting to discuss enhancing the quality of life of people we care for, it is easy to do whatever is necessary to take on the challenge. At the end of 2011, Brazil assumed the responsibility of hosting the 6th Ibero American Quality of Life Meeting, which was held November 29 through December 1, 2012, in Goiânia, the capital of a midwest state. While bringing health professionals from different countries together for an ISOQOL event is a big effort, working together we successfully convened a meeting with the central theme of "Implementing measures of quality of life in clinical practice". The conference was organized so that we could share our results, as well as the challenges we face in conducting quality of life research.

Leading the effort to organize the meeting was a young Multidisciplinary Study Group on Quality of Life at the Federal University of Goiás, and Brazilian researchers from São Paulo and Rio Grande do Sul. We also had the help of a group of enthusiastic Latin American fellows who volunteered hours of time and effort. Of course, we benefited greatly from the support

and resources shared with us by the ISOQOL management team.

The final result was a three-day meeting with 110 participants and 77 oral presentations. With speakers from Uruguay, the United States, Spain, Portugal, Colombia, Chile, Canada and Brazil, the meeting included a diverse range of experiences. The varied backgrounds and perspectives presented led to interesting discussions among the attendees about the stateof-the-art of quality-of-life assessment in clinical practice and factors that affect the intervention's success. Children and adolescents, persons with disabilities, workers, and cancer patients were populations of particular focus.

On the opening night, Claire Snyder presented to the group on the ISOQOL User's Guide for Implementing Patient-Reported Outcomes Assessment in Clinical Practice. This presentation went through each of the steps covered by the User's Guide and provided practical examples from her own research. Friday morning, Sara Ahmed presented on Factors that Interfere with Quality of Life Evaluation in Clinical Practice. Then Sara and Claire participated in a round-table discussion where they each presented on how patient-reported outcomes are

being used and tested in their own institutions. Other presenters described Latin American experiences. Everyone considers quality-of-life as not only the responsibility of authorities and experts, but as a permanent objective to be continuously improved by managers, leaders, and also by the general population.

Both as part of and outside of the meeting, participants had the opportunity to enjoy Goiânia. The opening session entertainment included a fabulous guitar duo and a samba demonstration. Claire and Sara loved the delicious corn ice cream – a real Brazilian experience! There were also opportunities for attendees to meet and network. The lobby and meeting rooms were full of participants exchanging knowledge, establishing new relationships, and exploring opportunities to work together.

We are grateful to everyone who helped organize and plan the meeting for their hard work. The key now is to take the knowledge gained from the conference and share it across institutions.

10th Patient Reported Outcomes

Technological and Strategic Advances in Data Collection and Analytics

May 6-7, 2013 • DoubleTree by Hilton • Philadelphia, PA

Leading Perspectives From:

Almac Clinical Technologies Applied Health Economics and Outcomes Research

AstraZeneca Pharmaceuticals LP Children's Hospital of Philadelphia

Daiichi Sankyo DATATRAK International, Inc. Duke Clinical Research Institute

Forest Research Institute GlaxoSmithKline Health Research Associates

Incyte Corporation PatientsLikeMe Pfizer

Pharmerit International National Cancer Institute Novartis Pharmaceuticals

Shire Pharmaceuticals Vector Psychometric Group, LLC

Co-Chairs:



Steven Blum,
Director of Health Economics,
Forest Research Institute (FRI)



Linda Deal,
Director of COA Center of Excellence,
Shire Pharmaceuticals

Benefit from Discussions on:

- The impact of the Affordable Care Act on PROs
- Patient utilization of social media as an outlet to report their symptoms
- The process of incorporating PROs on labels
- ePRO, mobile and sensor assessment technologies
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PLUS!

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- The Value of Psychometrics
- Labeling Claims
- Pivotal Trial Design
- Industry Challenges

Look inside for more details!

Register now at <u>www.cbinet.com/pro</u> or contact Mike Berube at 339-298-2185 for more information.

CALL FOR ABSTRACT REVIEWERS - ORAL AND POSTER PRESENTATIONS

Abstract Reviewers serve a vital role in the scientific program planning by ensuring the quality of the educational content presented at the Annual Conference. Serving as an Abstract Reviewer provides an excellent way to support ISOQOL. Time commitment is low, but the impact is high!

Abstract review will take place from late April through May 17, 2013. Abstract review is 100% electronic and all rankings will be submitted online. Contact the ISOQOL Executive Office at info@isoqol.org for more information or to volunteer to serve.

ANNUAL CONFERENCE TRAVEL SCHOLARSHIPS – DEVELOPING COUNTRIES SCHOLARSHIP

ISOQOL is pleased to announce that scholarships up to \$3,000 USD will be awarded to selected applicants to help defray costs associated with travel to the Annual Conference. Eligible applicants must be current ISOQOL members whose primary citizenship is held in one of the eligible emerging and developing economies. List of Eligible Countries

The ISOQOL scholarship program has been developed to provide access to the educational content of the Annual Conference, and to increase the opportunity for members from developing countries to meet with their peers and establish research contacts. Applications must be received by **Friday, May 31**, and notifications will be sent by the end of June.

Scholarship Application



2013 ANNUAL CONFERENCE PLENARY SESSIONS

The Scientific Program Committee for the 20th Annual Conference is pleased to announce the 2013 plenary sessions. Visit the Plenary page of the website for more information.

NEW HORIZONS IN QUALITY OF LIFE RESEARCH

The conference will open with the *New Horizons in Quality of Life Research* plenary on Thursday morning. Featured speakers, **Christopher B. Forrest, MD PhD**; **Carolyn E. Schwartz, ScD**; and **Kirsi Tirri, PhD MTh**, will discuss life course science, cognitive reserve, and multiple intelligences, and apply these emerging concepts and methodologies to health-related quality of life research.







Speaker bios and complete session details can be found on the New Horizons in Quality of Life Research page.

ACCENTUATE THE POSITIVE: THE SUNNY SIDE OF QUALITY OF LIFE

Friday morning will feature a discussion on positive psychology and its application to well-being and quality of life. **Mihaly Csikszentmihalyi, PhD**, championed for the highly influential, *Flow: The Psychology of Optimal Experience*; will join **Crystal Park, PhD**, who has done extensive research on post-traumatic growth and post-cancer psychological adjustment.





Speaker bios and complete session details can be found on the Accentuate the Positive: The Sunny Side of Quality of Life page.

CUTTING EDGE RESEARCH IN QUALITY OF LIFE

The 2013 Scientific Program Committee has introduced a new plenary session format to showcase some of ISOQOL's "best science" by selecting a few of the most highly-rated abstracts from open submission, and feature them as presentations in the Cutting Edge Research plenary. Speakers will be announced following abstract selection in June.

TWENTY YEARS OF ISOQOL - A CELEBRATION

The 20th Annual Conference will close with a celebration of the past, present, and future of ISOQOL and health-related quality of life research. ISOQOL Past Presidents will be invited to participate in a "Question and Answer" session. Questions and discussion topics will come from ISOQOL members and conference attendees. **Madeleine T. King, PhD**, and **Dennis Revicki, PhD**, will moderate this lively and interactive Celebration of ISOQOL.

Are you interested in sharing your ISOQOL experiences and memories? We are currently collecting photos and memories from the last twenty years of ISOQOL. Please send any photos or favorite memories to the ISOQOL Executive Office at info@isoqol.org.