



MEASURING WHAT MATTERS SYMPOSIUM

How should we be measuring functioning as
a marker of clinical benefit in clinical trials?

23-24 July 2018 • Washington, D.C., USA



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American Cancer Society



Vector Psychometric Group

Measuring What Matters Symposium

How should we be measuring functioning as a marker of clinical benefit in clinical trials?

Function is a multidimensional concept that is emerging as an important aspect of clinical benefit assessment across many therapy areas, as well as a concept that matters greatly for patients (and families), regulators, HTA groups, clinicians and payers when making treatment decisions.

Symposium Objectives

1. To develop a greater understanding of measurement concepts related to functioning, and how these may vary by therapeutic focus.
2. To identify fit-for-purpose approaches to measuring functioning in clinical trial and real-world settings.
3. To understand evidence needs from different stakeholders including regulators, payers, clinicians and patients

Table of Contents

About ISOQOL	2
Program Agenda	3
Venue Map	5
General Symposium Information	6
Speaker Biographies	8
Exhibitors	12
Meeting Glossary	13

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Sheraton Pentagon City Hotel

900 South Orme Street
Arlington, Virginia, USA 22204

Thank you to the planning committee for contributing to the creation of this Symposium:

Andrew E. Mulberg, MD, FAAP, CPI - Co-Chair
Jennifer A. Petersen, MPH - Co-Chair
Tom Willgoss, PhD - Co-Chair
Diana Rofail, PhD, CPsychol - Board Liaison



About ISOQOL

Dedicated to the promotion of excellence in the science of health-related quality of life.

International Society for Quality of Life Research (ISOQOL) established in 1993, is a non-profit society to advance the scientific study of health-related quality of life and other patient-centered outcomes to identify effective interventions, enhance the quality of health care and promote the health of populations. ISOQOL provides the premiere opportunity for those in the quality of life research field to connect and network.

Quality of life has become a prominent subject in philosophy, social science, clinical medicine, health services, and outcomes research. With over 720 members representing 47 countries, ISOQOL is an international society with activities focused on promotion of high quality research in the science of health-related quality of life (HRQOL) measurement and patient-reported outcomes (PRO).

Mission Statement

"The mission of the International Society for Quality of Life Research (ISOQOL) is to advance the science of quality of life and related patient-centered outcomes in health research, care and policy."

Vision Statement

"The International Society for Quality of Life Research (ISOQOL) will improve quality of life for people everywhere by creating a future in which their perspective is integral in health research, care and policy."

Patient Engagement Statement

"ISOQOL supports the patient voice in quality of life and patient-reported outcomes research. Patient engagement initiatives are intended to align ISOQOL's priorities and infrastructure with efforts to establish best practices in patient-engaged quality of life research and create educational efforts and model programs that promote best practices and fulfill ISOQOL's mission."

Education Programs

- Annual Conference
- Measuring What Matters Symposium
- Intro to Patient-Reported Outcomes (IPRO) Course – *Introduction to Quality of Life and Patient-Reported Outcomes: Theory, Measurement, and Applications*
- Intro to PCOR for Pharma (IPCOR-Pharma)- *Introduction to Patient-Centered Outcomes Research (PCOR) for the Pharma/Biotech Industry*
- Mentor/Mentee Program
- Webinars
- Special Interest Groups


Publications

- *Journal of Patient Reported Outcomes (JPRO)*
- *Quality of Life Research Journal (QLR)*
- *ISOQOL Dictionary of Quality of Life and Health Outcomes Measurement (English & Portuguese)*
- *User's Guide to Implementing Patient-Reported Outcomes Assessment in Clinical Practice (2015)*
- *Companion Guide to the ISOQOL User's Guide (2018)*
- *ISOQOL's comment on EMA draft reflection paper on the use of patient-reported outcome (PRO) measures in oncology studies (2015)*
- *ISOQOL Recommends Minimum Standards for Patient-Reported Outcome Measures Used in Patient-Centered Outcomes and Comparative Effectiveness Research (2013)*
- *Patient-Reported Outcomes in Randomized Clinical Trials (2012/2018)*
- *Using Patient-Reported Outcome Measures to Improve Clinical Practice (2012)*



Program Agenda

Monday, July 23, 2018

Time	Session	Room
1:00 pm - 1:15 pm	Welcome and Introductions	Cavalier ABC
1:15 pm - 2:25 pm	Session I: <i>What I talk about when I talk about functioning</i> Speakers: <ul style="list-style-type: none"> Bryce Reeve, PhD, <i>Duke University School of Medicine</i> Patty Spears, <i>Research Patient Advocate</i> Elektra Papadopoulos, MD, MPH, <i>U.S. Food and Drug Administration (FDA)</i> 	Cavalier ABC
2:25 pm - 3:55 pm	Workshop I: <i>Conceptualizing functioning</i> Facilitators: <ul style="list-style-type: none"> Andrew Mulberg, MD, <i>Amicus Therapeutics, Inc.</i> Jennifer Petersen, MPH, <i>Genentech</i> Tom Willgoss, PhD, <i>Roche Products Ltd</i> 	Cavalier ABC
3:55 pm - 4:25 pm	Interactive Coffee Session: <i>Featuring wearable devices and mobile apps</i> Exhibitors: <ul style="list-style-type: none"> ActiGraph Aparito chemoWave Elektra Labs 	Concourse
4:25 pm - 5:25 pm	Session II: <i>Incorporating measurement of functioning in clinical trials: Common pitfalls and lessons learned</i> Speakers: <ul style="list-style-type: none"> Bryce Reeve, PhD, <i>Duke University School of Medicine</i> Sonya Eremenco, MA, <i>Critical Path Institute</i> Katie Zarzar, <i>Genentech</i> 	Cavalier ABC
5:30 pm - 6:30 pm	Welcome Reception and Exhibits Open <i>Sponsored by: Vector Psychometric Group</i> 	Concourse

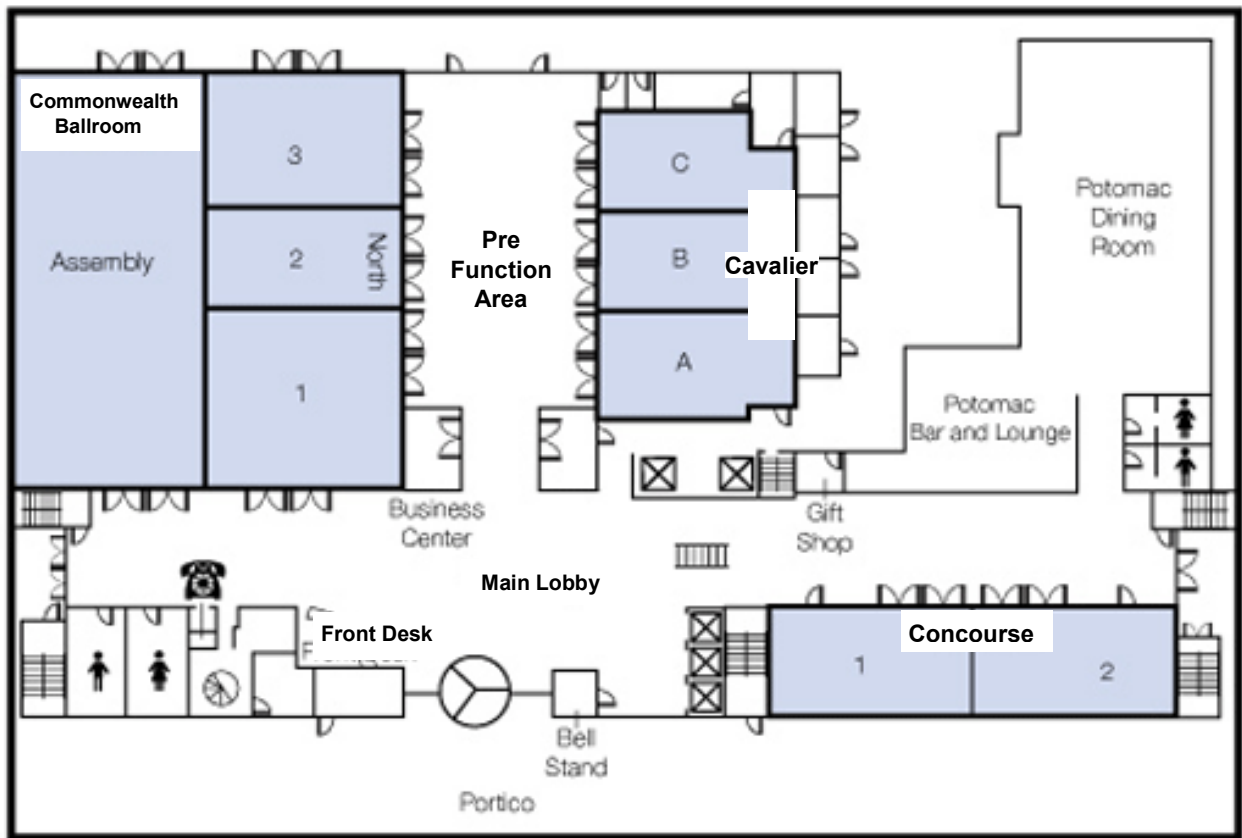


Tuesday, July 24, 2018		
Time	Session	Room
8:30 am - 9:00 am	Continental Breakfast	Concourse
9:00 am - 9:15 am	Reflection and Goals	Cavalier ABC
9:15 am - 10:45 am	Session III: <i>Generating meaningful evidence for key stakeholders</i> <u>Speakers:</u> <ul style="list-style-type: none"> Paul Kluetz, MD, <i>Oncology Center of Excellence, U.S. Food and Drug Administration (FDA)</i> Francis Pang, <i>Amicus Therapeutics, Inc.</i> Raquel Cabo, <i>Ovid Therapeutics</i> 	Cavalier ABC
10:45 am - 11:15 am	Interactive Coffee Break: <i>Featuring wearable devices and mobile apps</i> <u>Exhibitors:</u> <ul style="list-style-type: none"> ActiGraph Aparito chemoWave 	Concourse
11:15 am - 12:30 pm	Session IV: <i>Measuring functioning in the 21st century: State of the science</i> <u>Speakers:</u> <ul style="list-style-type: none"> Kipp Bradford, <i>The KippWorks</i> Antonia Bennett, PhD, <i>University of North Carolina at Chapel Hill</i> Matt Lashey, <i>chemoWave</i> <u>Joining Panel Discussion</u> <ul style="list-style-type: none"> Paul Kluetz, MD, <i>Oncology Center for Excellence, U.S. Food and Drug Administration (FDA)</i> 	Cavalier ABC
12:30 pm - 1:30 pm	Boxed Lunch Break and Exhibits Open	Concourse
1:30 pm - 2:30 pm	Workshop II: <i>Looking to the future</i> <u>Facilitators:</u> <ul style="list-style-type: none"> Bellinda King-Kallimanis, PhD, <i>Center for Drug Evaluation and Research, U.S. Food and Drug Administration (FDA)</i> Andrew Mulberg, MD, <i>Amicus Therapeutics, Inc.</i> Jennifer Petersen, MPH, <i>Genentech</i> Tom Willgoss, PhD, <i>Roche Products Ltd</i> 	Cavalier ABC
2:30 pm - 3:00 pm	Wrap-up & Close	Cavalier ABC



Sheraton Pentagon City Hotel

First Floor



General Information

Hotel Information

Sheraton Pentagon City Hotel
900 South Orme Street
Arlington, Virginia, USA 22204

Phone: +1 (703) 521-1900
Check-in: 3:00 pm
Check-out: 12:00 pm

<http://www.starwoodhotels.com/sheraton/property/overview/index.html?propertyID=829>

Session Location

All sessions at the Measuring What Matters Symposium will be held on the ground level of the Sheraton Pentagon City Hotel.

Registration Desk

ISOQOL accepts MasterCard, Visa, American Express and Discover credit cards. Payment by check is accepted so long as the check is in US dollars and drawn on a US bank account.

Hours

Monday, 23 July: 11:00 am – 5:00 pm
Tuesday, 24 July: 7:30 am – 3:00 pm

WiFi

Network name: Sheraton_meeting
Password: MWMS2018

Session Recording

Session content is copyright-protected by ISOQOL. Recording of any session without the consent of ISOQOL is prohibited. Any recording done with consent of ISOQOL is for personal use only and cannot be reproduced or distributed

Evaluation

Please take time to complete the Measuring What Matters evaluation that will be distributed electronically immediately following the conclusion of the symposium. Your input and comments are essential in planning future educational events.



Travel Information

Parking

For those driving to the conference hotel, the ISOQOL parking rate is \$12 per day. Once at the hotel, please stop by the ISOQOL registration desk for a parking voucher to receive this discount.

Arriving by Public Transport

By Bus

Pentagon City Metro Station: \$1.10 USD - \$3.25 USD

By Hotel Airport Shuttle

Washington National/Ronald Reagan International Airport: Transportation from Airport: The Sheraton Pentagon City offers a complimentary shuttle to/from Washington National/Ronald Reagan International Airport. The shuttle picks up from Terminal A outside Doors 5 & 9 at :15 and :45 past every hour.

By Hotel Metro Shuttle

Pentagon City Metro Station

from Metro to Hotel: Shuttle runs weekdays from 6:30 am and weekends starting 7:30 am until 11:30 pm. The shuttle leaves the metro station every 30 minutes on the hour and half hour. Last shuttle leaves the metro at 11:30 pm.

from Hotel to Metro: Shuttle runs weekdays from 6:15am and weekends starting at 7:15am, until 11:15 pm. The shuttle leaves the hotel at :15 and :45 past every hour. The last shuttle leaves the hotel at 11:15 pm.

If you require transportation assistance, or if you have any additional requests, contact the hotel at 1(703) 521-1900.

Cancellation Policy

ISOQOL reserves the right to cancel any event due to lack of enrollment or other factors. In the event of a cancellation, registered participants will be notified by e-mail and will have the option to exchange their ticket for an available alternative, or to receive a complete refund.

In the event that an attendee requests a refund, the requests must be submitted in writing to the ISOQOL office for review. Cancellations received after 30 days prior to the event will not be eligible for a refund. If granted, all refunds will be paid after the conclusion of the event. Special considerations will be given for health or family emergencies if requested in writing no later than 15 days after the last day of the event.

ISOQOL shall not be liable for reimbursing the cost of travel or accommodation arrangements made by individual delegates.



Organizer Biographies

Andrew E. Mulberg, MD, FAAP, CPI

Co-Chair

Amicus Therapeutics, Inc.
Cranbury, NJ, United States



Andrew is Head, Vice President, Global Regulatory Affairs of Amicus Therapeutics, Inc. which focuses on rare disease drug development. He is former

Division Deputy Director of Gastroenterology and Inborn Errors Products, U.S. Food and Drug Administration (FDA) since 2010. Before joining FDA, Andrew was Portfolio Leader in Established Products for providing worldwide leadership in support of GI and Internal Medicine products in Johnson and Johnson from 2000-2010. Andrew is a graduate of Columbia University and of the Mount Sinai School of Medicine. Andrew is Adjunct Professor of Pediatrics at the University of Maryland School of Medicine.

Jennifer A. Petersen, MPH

Co-Chair

Genentech
South San Francisco, CA, United States



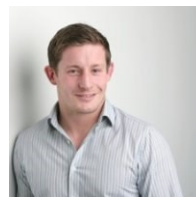
Jennifer (Jenny) Petersen is Associate Director in the Patient Centered Outcomes Research group at Genentech and leads the Breast and GI Oncology Franchise team. At

Genentech, Jenny and her team partner with patients to develop relevant and more rigorous endpoints to understand patients' experience on therapy. Over the past 10 years she has worked in the areas of development (drug, digital and diagnostics), measure and endpoint creation, and market access. Her research interests include treatment management, the use of technology to improve treatment outcomes, and the measurement of function from the patients' perspective. Jenny completed her masters in International Public Health at New York University, and earned her BS in Microbiology, cum laude, from Clemson University.

Tom Willgoss, PhD

Co-Chair

Roche Products Ltd.
Welwyn Garden City, United Kingdom



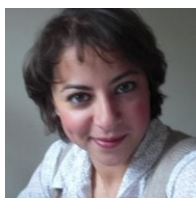
Tom is Associate Director in Patient-centered Outcomes Research, Neuroscience and Rare Disease at Roche. In his role, he develops patient-centric measurement

strategies for products in Roche's neuroscience portfolio to support regulatory approval and maximize patient access. Prior to joining Roche, Tom worked as a consultant in health outcomes and as a lecturer in research methods. Tom has a PhD in patient-reported outcome (PRO) measure development and an MSc in Physiotherapy. He is active within the ISOQOL community, serving as Co-Chair of both the Mixed Methods Special Interest Group (SIG) and the Webinar Committee.

Diana Rofail, PhD, CPsychol

Board Liaison

Roche Products Ltd.
Welwyn Garden City, United Kingdom



Diana is the Global Head of Patient-Centered Outcomes Research for Neuroscience and Rare Diseases at Roche. She formed and leads an international team of clinical

outcome assessment experts who focus on patient-relevant endpoints for label/promotion, registration and formulary access. Prior to Roche, Diana was a Director at various health outcomes agencies where she advised and provided strategic consultation to pharmaceutical companies. During her academic and clinical career, she worked at the world renowned Institute of Psychiatry, and the Maudsley Hospital, King's College London. She has a PhD in Treatment Satisfaction and Dissatisfaction in Chronic Low Back Pain from Brunel University, London, and is currently embarking on an Executive MBA from the University of Cambridge. Diana has served the ISOQOL board of directors since 2016 and is co-chair of the 2018 ISOQOL Annual Conference in Dublin, Ireland.



Speaker Biographies

Antonia Bennett, PhD

University of North Carolina
Chapel Hill, NC, United States



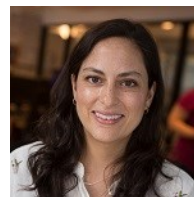
Dr. Antonia Bennett is a health services researcher and patient-reported outcomes methodologist at the University of North Carolina.

Her research focuses on new

methods for assessing patient-centered outcomes, primarily in oncology. Dr. Bennett is the Faculty Director of the UNC Patient-Reported Outcomes Core (PRO Core), and she provides consultation regarding the implementation of PRO and wearable device data capture in research and practice. In addition, she directs the Measurement Core of the Palliative Care Research Cooperative Group, and is a member of ISOQOL and the Alliance for Clinical Trials in Oncology.

Raquel Cabo, MSc

Ovid Therapeutics
New York, NY, United States



Raquel Cabo has over ten years of experience across a variety of healthcare industry sectors in the US and Europe. Prior to joining Ovid, Raquel was Director of

Global Market Access at GE Healthcare, based in London. In this role she led a global team responsible for market access and health economics for new product introductions from the company's imaging technology portfolio across all therapy areas. Raquel earned her MSc in International Health Policy and Health Economics from the London School of Economics and earned her BA in Psychology and French, cum laude, from the University of Pennsylvania.

Kipp Bradford

The Kippworks
Pawtucket, RI, United States



Kipp Bradford is an engineer working at the boundaries of emerging technology and industries. Most recently, he was a senior Research Scientist at the MIT Media

Lab, hired as a result of the "Professor of Other" faculty search for an interdisciplinary scientist. His research merges biology, ecology, and thermodynamics to develop new ways to manage climates at every scale—from personal thermal comfort up to global weather systems. His background spans biomechanical and electrical engineering, design, entrepreneurship, and thermodynamics. He's founded start-ups in the fields of HVAC+R, transportation, consumer products, and medical devices, and holds numerous patents for his inventions.

Sonya Eremenco, MA

Critical Path Institute
Tucson, AZ, United States



Sonya L. Eremenco is Associate Director of the Patient-Reported Outcome (PRO) Consortium at the Critical Path Institute. Sonya has over 20 years of

experience in PRO (and other clinical outcome assessment) instrument development, with a focus on multicultural development, linguistic validation, and electronic implementation. Prior to joining C-Path's PRO Consortium staff, Sonya was Director, ePRO New Products, at Evidera, Inc. She currently serves on the Steering Committee of ISOQOL's Translation and Cultural Adaptation Special Interest Group. Sonya holds a Bachelor of Arts in Cultural Anthropology from Duke University and a Master of Arts in Multicultural Communication from DePaul University.



Bellinda King-Kallimanis, PhD

U.S. Food and Drug Administration
Silver Spring, MD, United States



Bellinda King-Kallimanis received her PhD in psychometrics from the University of Amsterdam, the Netherlands. Since then she worked as a postdoctoral research fellow on the Longitudinal Study on Ageing at Trinity College Dublin, Ireland investigating the measurement of the frailty syndrome, and was Associate Director of Clinical Outcome Assessments (COAs) at Pharmerit International. She currently works at US FDA in the Office of Oncology and Hematology Products in the Office of New Drugs (OND) in the Center for Drug Evaluation and Research (CDER) working on the use of COAs to support patient focused drug development.

Paul Kluetz, MD

U.S. Food and Drug Administration
Silver Spring, MD, United States



Paul Kluetz is a medical oncologist and the Acting Associate Director of Patient Outcomes in the Oncology Center of Excellence at the U.S. FDA. His interests include defining clinical benefit in oncology trials, the use of expedited programs such as accelerated approval, and opportunities and challenges associated with patient reported outcomes (PRO) data, wearable technologies, and other methods to quantify the patient experience in the clinical trial and “real-world” settings. He is currently leading a team to develop regulatory science and policy initiatives to advance patient-focused drug development in cancer trials.

Matt Lashey, MBA

Treatment Technologies & Insights, LLC
El Segundo, CA, United States



Matt Lashey is CEO of Treatment Technologies & Insights, and the creator of chemoWave, a free app that equips chemotherapy patients with data-driven insights to better manage the physical and emotional rollercoaster of chemo, and also arms care providers with data to provide better and more efficient care. Lashey has served as a strategic research executive for Discovery Networks, A&E Networks and Lifetime Entertainment, and at Maddock Douglas where he spearheaded innovation engagements for clients such as Walmart, Nationwide, ACT, Transamerica, Penn Mutual and SwissR. Lashey received an MBA from Columbia Business School and a BFA from The Boston Conservatory.

Francis Pang, MBA

Amicus Therapeutics
Gerrards Cross, United Kingdom



Francis Pang is VP, Global Market Access at Amicus Therapeutics where he is responsible for global pricing, reimbursement and health economics. He was the inaugural Research Fellow in Pharmacoeconomics at the Centre for Health Economics, University of York, where his research was focused on the generalizability of health economic evaluations. Francis has served on the NICE HST Committee since 2013. Francis is a contributing author to the text: OUP ‘Economic Evaluation: Merging Theory with Practice’. Francis is a graduate of the University of York in Health Economics, attended Kyoto University as a Monbusho Scholar and has an MBA from INSEAD.



Elektra J. Papadopoulos, MD, MPH

U.S. Food and Drug Administration
Silver Spring, MD, United States



Elektra J. Papadopoulos, MD, MPH is the Associate Director for the Clinical Outcome Assessments (COA) Staff in the Office of New Drugs, Center for Drug Evaluation

and Research, FDA. The Staff contributes to the integration of the patient voice in drug development through COAs, including patient-reported outcomes, which are meaningful to patients, valid, reliable and sensitive to change. The Staff works collaboratively to provide consultation for COAs used across all stages of drug development, manages the COA Drug Development Tool Qualification Program to develop and qualify COAs, and provides education and outreach to advance the science of COAs.

Bryce Reeve, PhD

Duke University School of Medicine
Durham, NC, United States



Dr. Bryce Reeve is a Professor of Population Health Sciences serves as Director of the Center for Health Measurement. Trained in psychometric methods, Dr.

Reeve's work focuses on enhancing the application of patient-reported data in clinical research and practice to improve the quality of care for pediatric and adult patients with chronic diseases. This includes the development of patient-reported questionnaires using qualitative and quantitative methodologies and integration of patient-reported data in research and healthcare delivery to inform decision-making.

Patty Spears

UNC Lineberger Comprehensive Cancer Center
Raleigh, NC, United States



Patty Spears is an 18-year breast cancer survivor and cancer research advocate. She has extensive clinical trial advocacy experience and is currently serving as Chair of

the Patient Advocate Committee of the Alliance for Clinical Trials in Oncology. She is a Komen Scholar, serves as Vice Chair on the Komen Advocates in Science Steering Committee and is an FDA Patient Representative. She also has an interest in Patient Reported Outcomes (PROs) in drug development. Ms. Spears is currently working as a scientific research manager and patient advocate at UNC Lineberger Comprehensive Cancer Center.

Katherine Zarzar

Genentech, a member of the Roche Group
South San Francisco, CA, United States



Katherine Zarzar leads the Outcomes Measurement team within Genentech's Patient-Centered Outcomes Research (PCOR) group, focusing on improving the execution of

COA strategies to generate patient-relevant evidence. Katie's past experience includes supporting the development and delivery of PCOR strategies at Roche, and leading the design and oversight of linguistic validation programs for a variety of sponsors at TransPerfect. Past publication topics include linguistic validation methodology, development of measures in a global context, and improving translation and eCOA delivery in global trials. Katie is passionate about designing systems and exploring new methods to better capture and understand the patient experience.



Meet the Exhibitors

Meet the exhibitors during Interactive Coffee Sessions and at the Welcome Reception.



ActiGraph is a leading provider of wearable physical activity and sleep monitoring solutions for the global scientific community. Their mission is to provide leading pharmaceutical, research, and healthcare organizations with innovative activity and sleep monitoring hardware, software, and data analytics and management solutions to improve study efficiency, data quality, and patient outcomes.

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Aparito provides wearable devices and disease-specific mobile apps and wearable devices to provide remote patient monitoring outside of the hospital environment. This approach allows for clinical trials to be conducted anytime/anywhere in the world, and enhancing the value of patient generated data in the drug development process.

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chemoWave is a free mobile app designed to help patients navigate through their treatment journey. It tracks symptoms, mood, and activities – and then goes further to give personalized insights to help patients take control of their chemotherapy experience.

www.chemowave.com



elektralabs

Elektra Labs is a National Science Foundation I-Corps backed start-up building tools for digital medicine developers. Its first tool, an endpoint and biometric sensor search platform, is making it easier to find, select, and eventually develop new digital biomarkers. Visit their booth to learn more about their pre-competitive consortia.

www.elektralabs.com



Measuring What Matters Symposium Glossary

The term “function”/ “functioning” can have several different meanings, and definitions for it have varied in the literature. We acknowledge that there is no decisive way to define functioning and related terms and that a number of well-known models exist. The glossary below contains suggestions for how we might define these terms, but it is not exhaustive.

Please refer to the *ISOQOL Dictionary* as a comprehensive reference tool for terminology related to Quality of Life and Health Outcomes Measurement.

Function:

- Umbrella term encompassing all body functions, activities and participation; positive aspects of disability^{1,7}
- Dynamic interaction between a person’s health condition, environmental factors and personal factors⁷

Physical Function:

- Includes lifting and carrying objects, walking and moving, mobility (unspecified), and self-care³
- Ability to carry out various activities that require physical capability, ranging from self-care (basic activities of daily living (ADL)) to more-vigorous activities that require increasing degrees of mobility, strength, or endurance⁶
- An individual’s capacity to undertake everyday tasks¹¹

Cognitive Functioning: The intellectual activity that includes mental processes, such as, attention, processing speed, learning and memory, executive function, verbal fluency, and working memory⁸

Social functioning: An individual's interactions with their environment and the ability to fulfill their role within such environments as work, social activities, and relationships with partners and family⁹

Emotional Function: Awareness, expression, and regulation of emotions¹⁰

Clinical Outcome: An outcome that describes or reflects how an individual feels, functions or survives¹²

continued



Clinical Outcome Assessment (COA): Assessment of a clinical outcome can be made through report by a clinician, a patient, a non-clinician observer or through a performance-based assessment. There are four types of COAs¹²:

Clinician-Reported Outcome (ClinRO): A measurement based on a report that comes from a trained health-care professional after observation of a patient's health condition. ClinROs involve a clinical judgment or interpretation of the observable signs, behaviors, or other manifestations related to a disease or condition¹²

Patient-Reported Outcome (PRO): A measurement based on a report that comes directly from the patient (i.e., study subject) about the status of a patient's health condition without amendment or interpretation of the patient's response by a clinician or anyone else. A PRO can be measured by self-report or by interview provided that the interviewer records only the patient's response¹²

Performance Outcome (PerfO): A measurement based on standardized task(s) performed by a patient that is administered and evaluated by an appropriately trained individual or is independently completed.

Observer-reported Outcome (ObsRO): A measurement based on a report of observable signs, events or behaviors related to a patient's health condition by someone other than the patient or a health professional. ObsROs are reported by a parent, caregiver, or someone who observes the patient in daily life and are particularly useful for patients who cannot report for themselves (e.g., infants or individuals who are cognitively impaired)¹²

Sensor: A device, module, or subsystem whose purpose is to detect events or changes in its environment and send the information to other electronics⁴

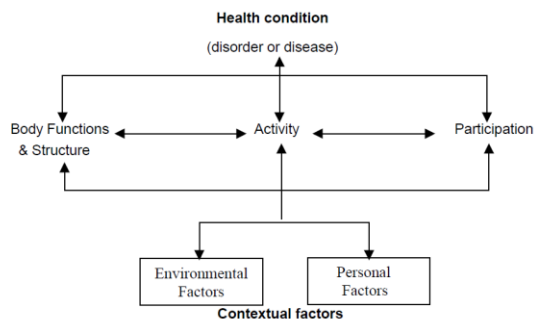
Active user data collection: When an end user deliberately provides information, typically through the use of web forms, text boxes, check boxes or radio buttons⁵

Passive data collection: Data collection in which information is gathered automatically, sometimes without the end user's knowledge⁵

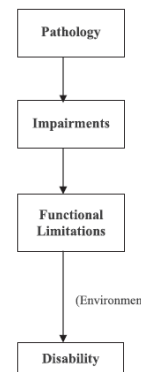


Shortlist of Frameworks

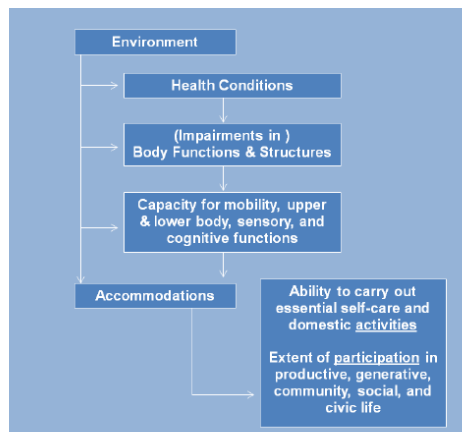
International Classification of Functioning, Disability and Health (ICF)-WHO functioning framework



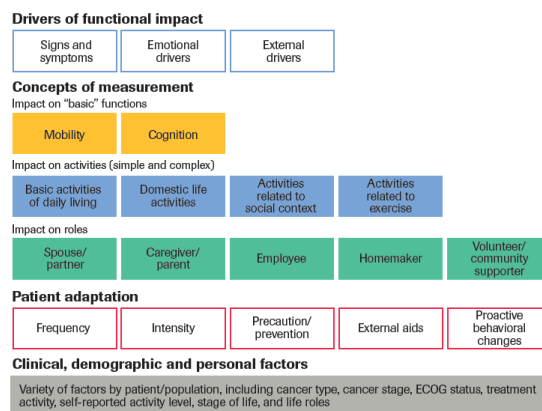
Nagi Model of Disablement^{14,15}



NHATS Disability Conceptual Framework^{13, 14}



Concept Model for assessment of the impact of cancer and its treatment on function²



References

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