

Clinical Outcome Assessments (COA) Qualification Program
DDT COA #000121: European Organization for Research and Treatment of
Cancer Quality of Life Core Questionnaire Physical Functioning (EORTC
QLQ-C30 PF)
Letter of Intent

Administrative Structure:

Description of the submitter including, but not limited to, principal investigator(s), working group member(s), institutions, and contact information not contained within the cover letter.

Working Group Members

Andrew Bottomley, PhD
Assistant Director – Head Quality of Life
Department
EORTC

andrew.bottomley@eortc.org

Anne-Sophie Darlington, PhD
Chair of the Quality of Life Department
EORTC

A.Darlington@soton.ac.uk

Mogens Groenvold, MD, PhD, DSci
Professor of Palliative Care and Quality of Life
Assessment

University of Copenhagen and Bispebjerg
Hospital

Mogens.Groenvold@regionh.dk

Dagmara Kuliś, MA
Translation Team Leader
EORTC

dagmara.kulis@eortc.org

Dennis Revicki, PhD Sr. Vice President, Patient-
Centered Research Evidera

dennis.revicki@evidera.com

Paul Swinburn, MRes
EU Director, Staff and Senior Research Scientist
Evidera

Paul.swinburn@evidera.com

Rebecca Speck, PhD, MPH
Research Scientist, Patient-Centered Research
Evidera

Rebecca.speck@evidera.com

Jennifer N. Hill, MA
Senior Research Associate, Patient-Centered
Research
Evidera

Jennifer.Hill@evidera.com

Development Program Manager

Rebecca Speck
Evidera
7101 Wisconsin Avenue, Suite 1400
Bethesda, Maryland 20814
Phone: 301-266-1439

Email: rebecca.speck@evidera.com

Address all correspondence to:

Dennis Revicki
Evidera
7101 Wisconsin Avenue, Suite 1400

Bethesda, Maryland 20814
Phone: 301-654-9729
Email: dennis.revicki@evidera.com

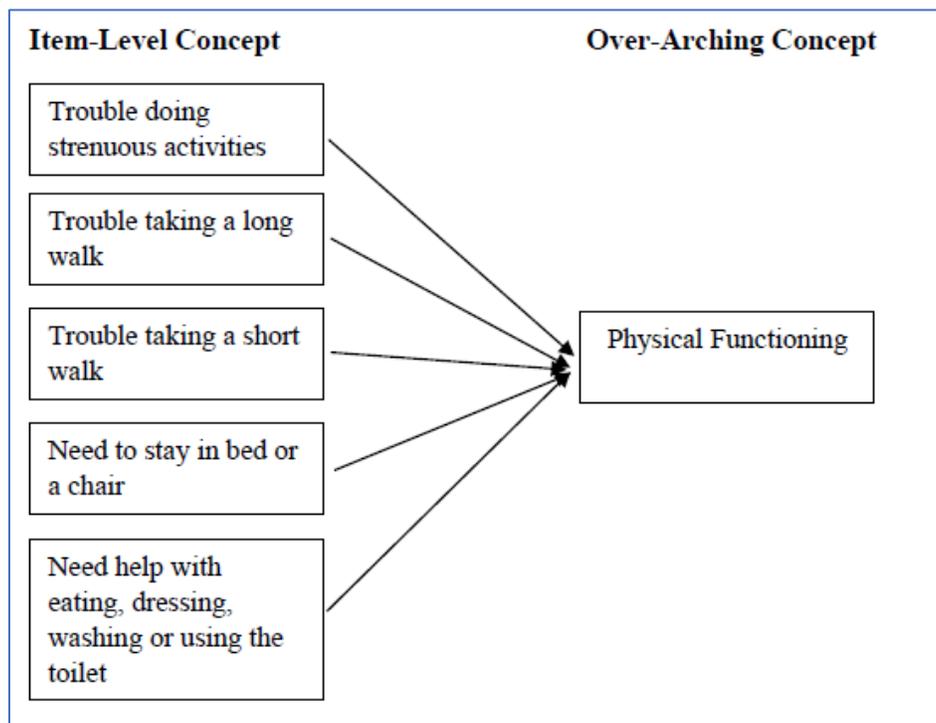
Concept(s) of Interest (COI) for Meaningful Treatment Benefit:

A description of the meaningful aspect of patient experience that will represent the intended benefit of treatment (e.g., presence/severity of symptoms, limitations in performance of daily activities).

The COA described in this LOI will be used to collect data to quantify the effects of treatment on patient-reported physical functioning. The COA of interest is the EORTC QLQ-C30 PF scale.

Provide a conceptual framework for the COA(s)

The conceptual framework for the PF scale is shown in Figure 1.



Context of Use for COA Qualification:

Targeted study population including a definition of the disease and selection criteria for clinical trials (e.g., baseline symptom severity, patient demographics, comorbidities, language/culture groups).

The target population of interest is cancer in adults (≥ 18 years and older) - all tumor types, locations, and stage of disease.

Targeted study design and statistical analysis plan (includes the role of the planned COA in future drug development clinical trials, including the planned set of primary and secondary endpoints with hierarchy, if appropriate).

The targeted study design is in the context of phase 2 and 3 clinical trials. The EORTC QLQ-C30 PF scale version 3 would be a primary or key secondary endpoint. The primary analysis of interest would be the proportion of responders within treatment arm.

Applicable study settings for future clinical trials

- ***Geographic location with language/culture groups***
- ***Other study setting specifics (e.g., inpatient versus outpatient)***

The EORTC QLQ-C30 is translated in over 100 languages and is used in thousands of studies each year world-wide. The applicable setting for future clinical trials will be multi-site, international studies that are investigating a variety of cancer treatment modalities.

COA Type: PRO