

# QLQ-ELD 15 Phase 4

An International Field Study of the Reliability and Validity of an EORTC Older Person-Specific Quality of Life (QOL) Questionnaire Module (the EORTC QLQ-ELD15) and EORTC QLQ-C30 in assessing the QOL of cancer patients aged 70 years and above.

# Phase 1-3 Development

2007-9 following module development guidelines

Adapted in Phase 1 and Phase 3 to allow **comparison with younger patients** – age specific issues

Important considerations

Are there **age-related differences in the concerns** of older and younger patients?

Are the EORTC QLQ-C30+ DSM's adequate to assess HRQOL concerns of relevance &

**PBRG** importance to older people?

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# Recruitment in Phase 3

	Age 50-69	Age >70
Local <i>Treated for cure</i>	34	35
Advanced <i>Unlikely to cure</i>	34	46
Metastatic	17	16

# The EORTC QLQ-ELD15

Conceptual scale	Issues
Mobility	Difficulty with steps or stairs Joint stiffness/pain Gait Help with household chores
Family support	Closeness of your family Being able to talk to family about illness
Worries about future	Worries about family coping Worries about the future of others Worries about future health Feeling uncertain about the future Worried about what happens at end of life
Autonomy and maintaining purpose	Having a positive outlook Feeling motivated to continue with normal life
Burden of illness	Burden of illness Burden of treatment

Report of Development Phases 1-3 *in press Eur J Cancer*

# Study Design – Phase 4

Prospective longitudinal study

Collect QOL data, socio-demographic and clinical data, and standard outcomes

Patients will complete the QLQ-C30, QLQ-ELD15 and debriefing questionnaire at **one assessment point during treatment and follow-up**

A sub-sample of patients will complete one test-retest analysis.

## Primary study objective

The primary study objective is to test the scale structure, reliability and validity of the EORTC QLQ-ELD15 in conjunction with the EORTC QLQ-C30 in people diagnosed with cancer aged 70 years or above who are at different stages of disease and treatment, and receiving different treatment modalities

# Cross-cultural sampling

**No detailed psychometric analysis**

**Sample includes 5 main groups of countries:**

- a) English-speaking: UK, Australia
- b) Northern European: Belgium, Holland, Germany and Sweden
- c) Southern European: Spain, France and Italy
- d) Eastern European: Turkey
- e) Asia: Taiwan

# Patient Selection

Consecutive series of cancer patients aged 70 years and above.

Patients will be stratified by age (70-79 years and 80+ years).

Two main groups based on treatment intention

Curative

Palliative

Treatments will reflect spectrum of active and palliative/supportive care interventions for older people with cancer.

# Patient groups

## Group C (potentially curative)

**C1** Patients who undergo potentially curative surgery (alone or with adjuvant treatment(s))

**C2** Patients who receive chemotherapy and/or radiotherapy and/or endocrine therapies as first line treatment (including patients who have received a primary excision/ biopsy to confirm disease).

## Group P (palliative)

**P1** Patients who receive palliative surgery, chemotherapy or radiotherapy either alone or in combination (e.g. radiotherapy with chemotherapy).

**P2** Patients who receive supportive interventions alone to control pain and cancer-related symptoms.

# Eligibility criteria

## Inclusion criteria for all groups

- a) Patients aged 70 years or above with a clinical, **radiological or histological** diagnosis of cancer
- b) Any solid tumour site
- c) Patients with haematological malignancies – **after phase 3 study**
- d) Any tumour stage
- e) No previous primary tumour
- f) Ability to give informed written consent in accordance with ICH GCP and national/local regulations and procedures.
- g) Ability to understand the language of the QOL questionnaires

## Exclusion criteria

- a) Patients participating in other QOL investigations that might interfere with this study.

# Sample size considerations

The primary endpoint of the study is to evaluate the hypothesised scale structure

Sample size is determined by the number of items  
15 items, the accepted 'rule of thumb' that 10-15 responses per item are needed

required sample will be  $15 \times 15 = 225$  patients.

We propose to collect this number in each of group C and P,

Test retest in 100 (50 in each group)

# Study management

Co-ordinator appointed April 2010

Ethics in progress

Start date June 2010

# Summary

**Standard Phase 4 study**

**Start date June 2010**

**2 year time line**

**Collaborators welcome**