

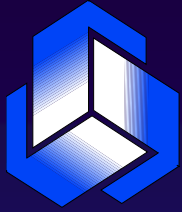
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# Revision of Module Development Guidelines

*summary of  
final document*

**Colin Johnson**

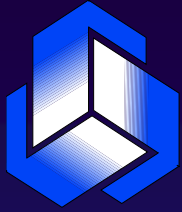
**Neil Aaronson, Jane M Blazebly, Andrew Bottomley, Peter  
Fayers, Michael Koller, Dagmara Kuliś, John Ramage,  
Mirjam Sprangers, Galina Velikova, Teresa Young**



# Module Development Guidelines

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- Working group shared the tasks
- Focus on:
  - Statistical requirements
  - Translation
  - Revision/update and module merging
  - Overall revision of text
- Main changes summarised



# Phase 1

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## Starting a new module

identification of research question and target population –  
approval by MDC  
language – English

## Phase 1: generation of QoL issues

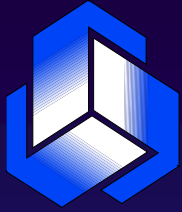
**Systematic review** of literature (including existing questionnaires),

**patients – by semistructured interviews – key element**

**Cross cultural: minimum Eng, N and S Europe**

health care professionals (HCPs; e.g., physicians, nurses, radiographers, dietitians etc) **with clinical expertise in the area of the module (complement patient data)**

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## Phase 1 Decision Rules for inclusion of issues

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**Be inclusive (even if many provisional items); all issues mentioned (>5% if n>30)**

**Qualitative data – review each issue**

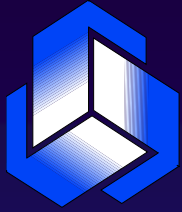
**Accept issues in scale context**

**Avoid overlap/duplication**

**Exclude if mean score <2 for relevance and importance (scores 1- 4)**

***Apply criteria for validity of patient derived data?***

***(include now or develop guidance for quality control?)***

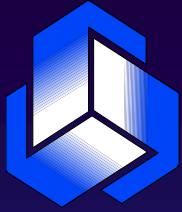


## Quality control

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**Brod, M., L. Tesler, et al. (2009). "Qualitative research and content validity: developing best practices based on science and experience." Qual Life Res 18(9): 1263-78.**

***Suggestions are offered for dealing with logistical issues regarding facilitator qualifications, ethics approval, sample recruitment, group logistics, taping and transcribing interviews, honoraria and documenting content validity.***

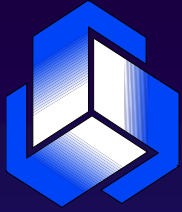


## Content validity

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**Rothman, M., L. Burke, et al. (2009). "Use of Existing Patient-Reported Outcome (PRO) Instruments and Their Modification: The ISPOR Good Research Practices for Evaluating and Documenting Content Validity for the Use of Existing Instruments and Their Modification PRO Task Force Report." Value Health.**

***Published evidence of the content validity of a PRO instrument for an intended application is often limited. Such evidence is, however, important to evaluating the adequacy of a PRO instrument for the intended application.***

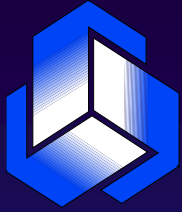


## Data saturation

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Kerr, C., A. Nixon, et al. (2010). "Assessing and demonstrating data saturation in qualitative inquiry supporting patient-reported outcomes research." Expert Rev Pharmacoecon Outcomes Res 10(3): 269-81.

*offer preliminary recommendations for future qualitative PRO studies for assessing and documenting saturation*

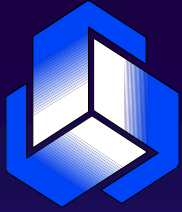


# Cognitive debriefing

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**Fortune-Greeley, A., K. Flynn, et al. (2009).  
"Using cognitive interviews to evaluate items  
for measuring sexual functioning across  
cancer populations: improvements and  
remaining challenges." Qual Life Res 18(8):  
1085-93**

***Cognitive interviews were critical for item  
refinement in the development ...***



## Phase 2

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### PHASE 2: Construction of the item list

#### Item construction

Follow standard wording, timeframe

Avoid double question (*...troubled by nausea or vomiting?*)

Avoid negative phrasing (*how much have you not been able...*)

What is the question? Symptom or interference?

#### Use the Quality of Life Group Item Bank

Avoids duplication and redundancy

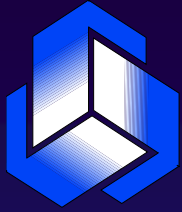
Translations already exist

#### Item list and debrief to a small number (<10) patients

Consultation of health care professionals – final approval

#### Translations for Phase 3

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## Phase 3 structure

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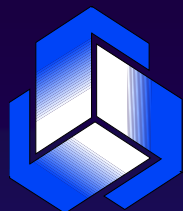
The aims of pre-testing are:

- to identify and solve **potential problems** (e.g., the phrasing of questions, the sequence of questions)
- to identify **missing or redundant issues**.

Preliminary psychometric testing and exploration of scales may be performed

Pre-testing consists of:

- International recruitment (at least 6 countries: Eng, N S E Europe and at least one non-European country)**
- Administering the core questionnaire and the provisional module to patients for **scoring, relevance and importance**
- Structured interviews with each patient after completion



## Phase 3 Sample and Analysis

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A sample matrix may include relevant treatments

**treatment stage**

**disease stage**

Each cell should contain at least 15 patients

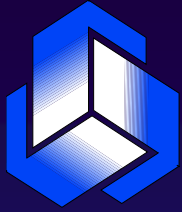
Retention/deletion of items

Difficulties in the wording upsetting or irrelevant

highlighted as important ranked to assess the most important/relevant

Clear decision rules **before** analysis

	Before Treatment	During Treatment	After Treatment	Palliativ Care
Localised Disease	15	15	15	-
Advanced Disease	15	15	15	-
Palliative Care	-	-	-	15



## Phase 3 Scale Structure

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**Preliminary testing of hypothesized scale structure**

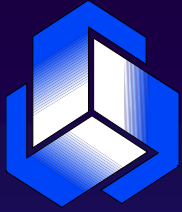
**In Phase 2, a number of scales will have been developed. (to be tested fully in phase 4)**

**Preliminary testing of hypothesized scales may include:**

**Reliability**

**Convergent validity**

**Exploratory factor analysis**



## Phase 4

### FIELD-TESTING

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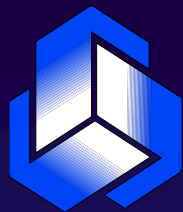
to determine reliability, validity, and cross-cultural applicability, scale structure and reliability

Will include assessment of:

*Dispersion of scores, internal consistency (Cronbach's alpha) of hypothesised scales Validity and Test-retest reliability*

**New section on statistical analysis including *item-response theory* and *differential item functioning* or item bias analysis**

**Need SOP suitable for electronic completion, and reliable data monitoring/GCP - ? New post in QLD? Refer to planned development**



## Update modules

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**Important changes and advances in treatment may affect QoL evaluation.**

**New chemotherapeutic drugs**

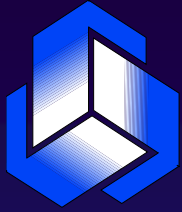
**Biological agents,**

**Radiotherapy protocols**

**Changes in surgical approach and extent**

**Questionnaires to assess PROs may become obsolete or require additional items**

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# Update Modules

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## Four phases:

- 1: generation of new issues related to the new treatments  
identification of problematic items and/or scales
- 2: create new item list  
change the wording of problematic items,
- 3: pre-testing the new module and
- 4: international validation field testing

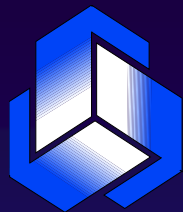
## Literature searches

- update the original literature review
- Identify issues associated with new treatments
- identify all studies that have used the EORTC module

## Interviews with patients and HCPs

## Phases 2, 3 and 4 follow standard guidance

- Create item list
  - pre-testing
  - validation of the updated module
-



# Merge modules

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**Approval of the MDC required.**  
demonstrate the need  
combined module appropriate

## *Phase 1*

literature search

existing modules combined into a single set of logical clinical groups (corresponding to scales)

new issues included from the literature search

**new issues converted to questions/items at this stage, if possible using items from the Item Bank**

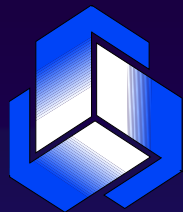
**Patient interviews to consider new item list for omissions etc**

## Phase 2

**Select provisional list of items using agreed rules**

Phases 3 and 4 as per Guidelines

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# Description of modules

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**In Phase 1 and 2.** Module has been approved by MDC. Developer demonstrated

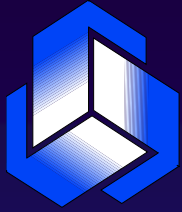
need for such a module,  
no overlap with existing modules

**Completed Phase 2.** has completed phases 1 and 2  
includes approval of a Report of phases 1 & 2

**Completed Phase 3.** has completed phase 3 as described in the  
Guidelines  
approval by the MDC

**Validated. Completed phase 4 successfully**  
approval by the MDC based on its cross-cultural, psychometric  
performance

A module which has completed phase 3 and is undergoing  
validation testing may be described as “*in phase 4 testing*”



# Availability

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**Modules that have completed Phase 3 are available for general use**

**tested for acceptability with patients,**

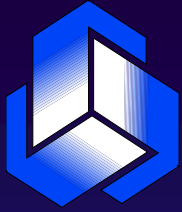
**have not undergone psychometric testing in a large international group of patients**

**scales for those modules are hypothetical and may change after psychometric analysis.**

**Validated modules have undergone formal psychometric testing in a large international group of patients**

**scale structure has been confirmed.**

**can be used in clinical trials and other studies without the need for extensive psychometric analysis.**



# Translation

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## **Full revision of Translation Guidelines 2009**

Summary of procedure in Mod Dev GL

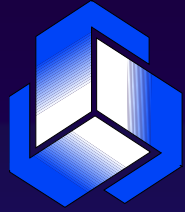
2x forwards – agree – 2 x back – agree

Repeat if necessary

Translate Phase 1 issues within group

**Phase 3 and 4 translations handled by QLD**

Document all stages – report to QLD

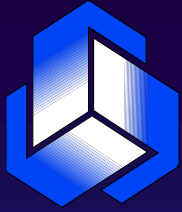


# Module Development Guidelines progress

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## Still to do:

- **Final document for approval (September 2010)**
- **Develop SOP and Quality Control procedures for all phases of development (? Refer to this as work in progress)**

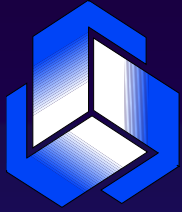


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# **Report from Module Development Committee September 2010**

**Colin Johnson,  
Ken Cornelissen, Sheila Sanderson,  
EORTC Quality of Life Group,  
EORTC Quality of Life Department**

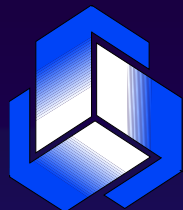
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## Module updates

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- Dr. Mariagrazia Mecoli - update CML module
- Julie Winstanley - Melanoma
- Wei-Chu Chie – HCC



## Publications since April 2010

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INFO25. Eur J Cancer. 2010 Jul 30. [Epub]

OUT-PATSAT35 RT. Validation study for Spanish patients.  
Psychooncology. 2010 Jun;19(6):657-64.

ELD15. Eur J Cancer. 2010 Aug;46(12):2242-52.

EN24 accepted EJC

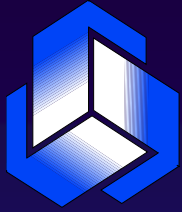
Cholangiocarcinoma submitted BJC

Mandarin version of the EORTC QLQ-OES18. Quality of Life  
Research 2010; online publication.

Taiwan Chinese version of the EORTC QLQ-PR25 Urological  
Science 2010; 21(3): 118-125.

Huang CH, et al. Quality of life in Taiwanese breast cancer survivors  
with breast-conserving therapy. JFMA 2010; 109(7):493-502.

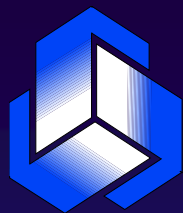
EORTC



## New modules

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- Vulva Phase 1&2 grant application
- Cachexia/Nutrition grant application
- Pleural effusion – **no news**
- **Children and adolescents interest group meeting**
- **Communication expression of interest**



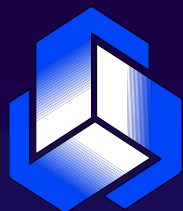
# Summary of modules in development

Updated Details will be posted on QLG website

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<b>New proposals</b>	<b>2</b>
<b>Phase 1 &amp; 2</b>	<b>7 + update H&amp;N</b>
<b>In phase 3</b>	<b>4 + update CLL</b>
<b>Completed phase 3</b>	<b>9</b>
<b>In phase 4</b>	<b>6</b>
<b>Validated modules</b>	<b>14</b>

**29 modules for use in clinical trials**



## Many thanks to

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- To Sheila, Ken, Galina
- *To the reviewers of modules:  
cholangiocarcinoma  
INFO25, fatigue*

Thank You!

