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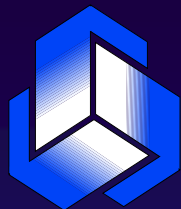
# **Report from Module Development Committee April 2005**

**Galina Velikova, Ken Cornelissen, Sheila  
Sanderson,  
EORTC Quality of Life Group and EORTC**

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**Quality of Life Unit**

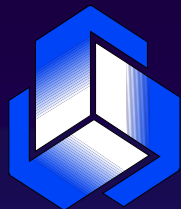
**EORTC**



## **EORTC Quality of Life Group**

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- **Modular approach to Quality of Life measurement in clinical trials**
  - **Core questionnaire – EORTC QLQ-C30**
  - **Disease- and treatment specific modules – Breast cancer module - EORTC Br-23**
- **Guidelines for Module Development – Mirjam Sprangers, Ann Cull, Neil Aaronson**
- **Translation Guidelines**

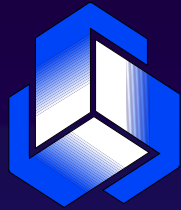


## **EORTC Quality of Life Group**

### **Guidelines on development of disease / treatment specific modules**

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- State the **aims** of the module development
- Phase I      Generation of QOL issues
  - **Literature search**
  - **Semi-structured interviews with specialists**
  - **Semi-structured interviews with patients**
- Phase II      Construction of issues into a provisional questionnaire
  - **The items are worded to be compatible with the EORTC QLQ- C30 response categories**
  - **Review by professionals and 3-5 patients**
  - **Translations**

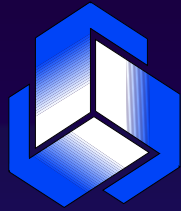


## **EORTC Quality of Life Group**

### **Guidelines on development of disease/treatment specific modules**

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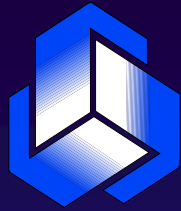
- **Phase III** Testing of the module for acceptability and relevance
    - **Patients complete the module and are interviewed**
    - **Results are analysed according to response prevalence and variance**
    - **Report is approved by Module Development Committee**
  - **Phase IV** Field testing in an international group of patients
    - **The module is tested for reliability, validity and cross-cultural application**
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## Validated modules      Modules in Phase IV

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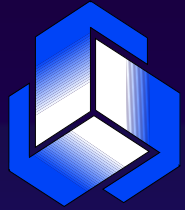
- Breast cancer
  - Lung
  - Head and neck cancer
  - Oesophageal
  - Ovarian
  - Gastric cancer
  - Satisfaction with care
- Prostate cancer-completed recruitment
  - Multiple myeloma-completed recruitment
  - Colorectal Liver metastases module



## Completed Phase III

## In Phase III

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- Brain tumours
  - Hepatocellular Carcinoma
  - Peripheral Neuropathy
  - High-dose chemotherapy
  - Colorectal cancer
  - Ophthalmic cancer
  - Bladder cancer
  - Pancreatic cancer
  - Short form – Palliative care
  - Information module
- Cervix
  - Carcinoid / Neuroendocrine tumours
  - Chronic Lymphocytic Leukemia
  - All above under review at present
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# Completed Phase II      Phase I Modules

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- Fatigue
- Spiritual well-being
- Revision of Colorectal cancer module
- **New proposals**
  - Bone metastases module
  - Oral morbidity/oral health in cancer
  - QOL in elderly cancer patients
- Cholangiocarcinoma
- Radiation proctitis
- Nasopharyngeal cancer