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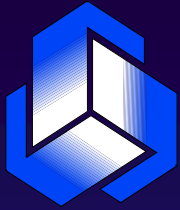
# **Report from Module Development Committee May 2006**

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

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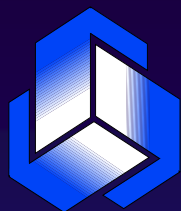
**Quality of Life Unit**

**EORTC**



## Summary of minutes Nov 2005

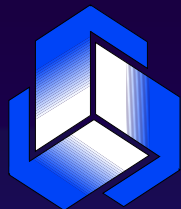
- 
- Module Development is progressing well.
  - More flexible methodology for development and validation of modules is being used. There is a need to formally describe the methodology.
  - Reviewers of module reports are to be acknowledged when the module is published.
  - Finished manuscripts are to be reviewed by Chair of the Module Developers within a 2-week time frame.
  - Policy on use of single items from the item bank - can be used provided that the researcher explains why they need single items and acknowledges EORTC Quality of Life group item bank.



## Validated modules

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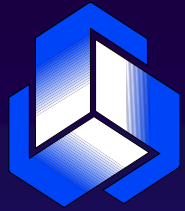
- Head and neck cancer
- Ovarian
- Breast cancer
- Lung
- Satisfaction with care - published
- Oesophageal
- Gastric cancer
- **Cervix – paper submitted**



## Modules in Phase IV

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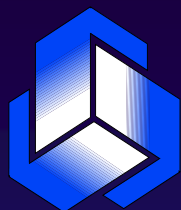
- Prostate cancer- analysis completed
  - Multiple myeloma – analysis completed (N=477) one manuscript submitted, 2<sup>nd</sup> – draft circulated
  - Liver metastases from colorectal cancer (LMC21) – cont. recruitment, analysis 2006
  - Pancreatic cancer
  - Brain tumours – awaiting analysis of data from clinical trial for validation
  - Peripheral Neuropathy –used in Phase 3 trial for validation
  - **Information module – publication Psycho-oncol, Ph4 started**
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## Completed Phase III (1)

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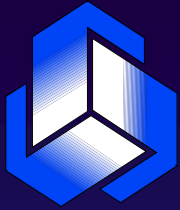
- **GI Neuro-endocrine tumours (GI NET 21)- protocol for Ph4**
- **EORTC QLQ-C15 PAL – SF for palliative care;**
- **Colorectal cancer – updated version, patient interviews**
- **High-dose chemotherapy- draft manuscript, EBMT trial**
- **Hepatocellular Carcinoma (HCC18) – protocol for Ph4**
- **Ophthalmic cancer**
- **Bladder cancer**
- **Chronic Lymphocytic Leukemia**



## In Phase III

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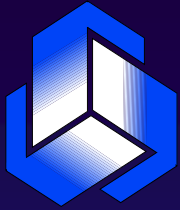
- Spiritual well-being
- Fatigue - Phase 3 protocol preparation
- **BUT no formal review**
- Radiation proctitis – Ph2 module developed in Australia, to be extended to Europe; 26 items
- Nasopharyngeal cancer NPC42 – must submit report for review; ? Translations



## In Phase III

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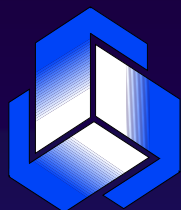
- **Different methodology**
- Oesophago-gastric module
- Update of colorectal cancer module
- Cholangiocarcinoma – combine LMC21 and PAN26, ?in phase 3, must submit report for Ph1 and Ph2



## In Phase 1

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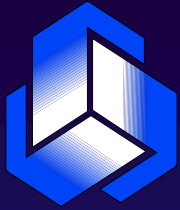
- Bone metastases module – funded in Canada, Interviews ongoing in Canada, European centres to join
- Breast reconstruction module – Ph1 interviews completed
- Testicular cancer
- Cancer in the elderly
- **New proposals**
- Endometrial cancer



## Publications since last meeting

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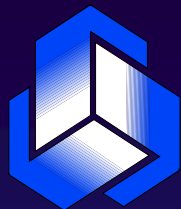
- **GI NET – Phase 3 paper EJC March 2006**
- **Info module – Phase 3 paper Psycho-oncology**
- **Myeloma module – methodology paper submitted to EJC**
- **Bone metastases – overview in Clin Oncol 2006**
- **In preparation**
  - **Cervix module**
  - **High-dose module**



# Procedures

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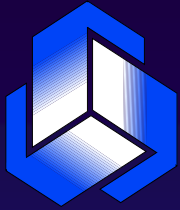
- **Procedures**
- Reminder for procedure for reviewing modules
  - MDC review **after Phase 2** and **Phase 3**
  - How to proceed if researchers do not submit formal Ph2 report
- Phase 3 report / manuscript
  - Aim to review module reports within 8-12 weeks of submission
  - 4 week deadlines for reviews; Guidelines
  - Acknowledge reviewers in publications
- Quick review of finished manuscripts – MDC and previous reviewers within 2 weeks
- Only **completed Ph3** modules to be distributed by QLU - Send approved Ph3 modules to Karen, QLU



# Methodology

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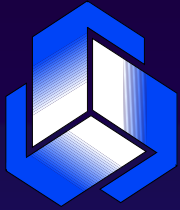
- Guidelines for translation of Phase 2 modules
- Methodology for revising validated modules (CR)
- Methodology for combining modules (oesophago-gastric Ca, cholangioCa)
- Update of manuals
- Phase 4 validation
  - Flexible validation (cervix)
  - Emphasis on clinical interpretation of scores and change over time
- Item Bank (Fabio)
  - policy on use of single items
  - adding and removing items



## Other Issues

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- **Authorship of manuscripts**
  - models
- **Evidence-Based Interpretation Guidelines of EORTC QLQ-C30**
  - Experts to review papers



## Many thanks to

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- To Sheila and Ken
- And to all reviewers
  - Eva
  - Teresa
  - Jane
  - David Osoba
  - Julia Brown
  - Kristin
  - Karin
  - Colin

