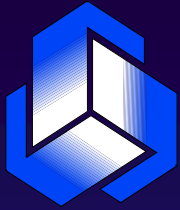


Report from Module Development Committee November 2005

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

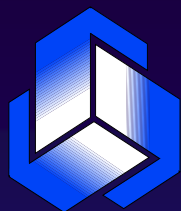
Quality of Life Unit

EORTC



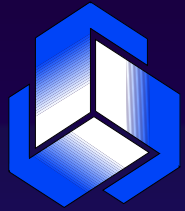
Validated modules

- **Head and neck cancer**
- **Ovarian**
- **Breast cancer**
 - no manuscript from Phase 4
- **Lung**
 - modifications suggested, but no report to MDC
- **Satisfaction with care - published**
- **Oesophageal**
- **Gastric cancer – Study now open combine in oesophago-gastric module**



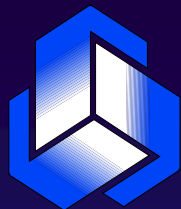
Modules in Phase IV

- **Prostate cancer- for analysis in 2006**
- **Multiple myeloma**
 - **N=477, analysis done, presentation this meeting, 2 draft manuscripts**
- **Liver metastases from colorectal cancer (LMC21)**
– n=200, analysis 2006
- **Pancreatic cancer**
- **Cervix – psychometric validation in Ph3 – 370 patients**



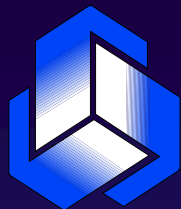
Completed Phase III (1)

- **Peripheral Neuropathy – publication EJC 2005, used in Phase 3 trial**
 - **Brain tumours – analysis of data from clinical trial for validation**
 - **Colorectal cancer – updated version, patient interviews**
 - **High-dose chemotherapy- draft manuscript, EBMT trial**
 - **EORTC QLQ-C15 PAL – SF for palliative care; 2 publications (EJC and JCE)**
 - **Hepatocellular Carcinoma (HCC18) - publication**
-



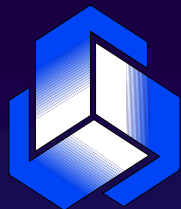
Completed Phase III (2)

- **Ophthalmic cancer**
- **Bladder cancer**
- **Chronic Lymphocytic Leukemia- publication submitted**
- **Information module – publication submitted
Psycho-oncol, grant application for Phase 4,
draft protocol;**
- **Carcinoid / GI Neuro-endocrine tumours (GI
NET 21)- report approved**



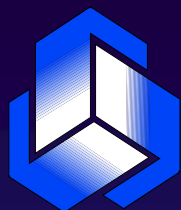
In Phase III

- **Spiritual well-being – ethics approval for UK**
- **Fatigue - grant for Phase 3**



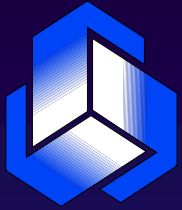
In Phase II

- **Cholangiocarcinoma – combine LMC21 and PAN26, ?in phase 3, must submit report for Ph1 and Ph2**
- **Radiation proctitis – Ph2 module developed in Australia, to be extended to Europe; 26 items**
- **Nasopharyngeal cancer NPC42 – must submit report for review; ? Translations**
- **Social Support-on hold**



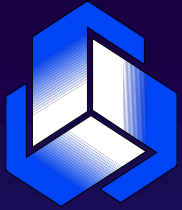
In Phase 1

- Bone metastases module – funded in Canada, Interviews ongoing in Canada, European centres to join
 - Breast reconstruction module
 - **New proposals**
 - ? Oral morbidity/oral health in cancer
 - Cancer in the elderly
 - Testicular cancer
 - Endometrial cancer
-



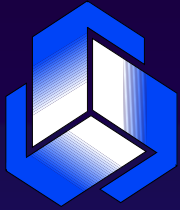
Publications since last meeting

- Posters and abstracts – spir, fa, sat, info, bone,
- Neil - Postma TJ et al, EJC 2005 neuropathy
- Mogens and Morten – PAL EJC 2005, JCE in press
- Juan – Phase 3 information module- in press Psycho-oncology
- Anne – SAT EJC 2005
- Pan26 Am J Gastroenterology 2005



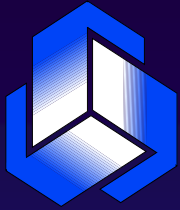
Issues for discussion (1)

- **Procedures**
 - **Reminder for procedure for reviewing modules**
 - MDC review **after Phase 2** and Phase 3
 - **Phase 3 report / manuscript**
 - **Reviewing process – is working!**
 - Aim to review module reports within 8-12 weeks of submission
 - 4 week deadlines for reviews; Guidelines
 - Acknowledge reviewers in publications
 - **Send approved Ph3 modules to Karen, QLU**
-



Issues for discussion (2)

- **Methodology**
- Guidelines for translation of Phase 2 modules
- Methodology for revising validated modules (CR)
- Methodology for combining modules (cholangioCa)
- Flexible validation of Phase 3 modules (cervix)
- Quick review of finished manuscripts – MDC and previous reviewers within 2 weeks
- Item Bank
 - policy on use of single items
 - adding and removing items



Many thanks to

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

