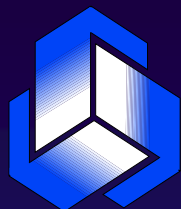


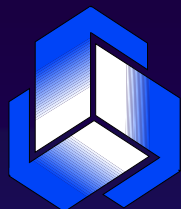
Report from Module Development Committee March 2007

**New Chair - Colin Johnson,
Ken Cornelissen, Galina Velikova,
EORTC Quality of Life Group and EORTC
Quality of Life Unit**



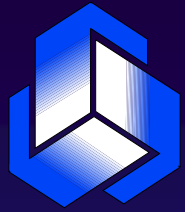
Validated modules

- Head and neck cancer
 - Ovarian
 - Breast cancer
 - Lung
 - modifications suggested, but no report to MDC
 - Satisfaction with care
 - Oesophageal
 - Gastric cancer – Study now open combine in oesophago-gastric module
 - **Cervix CX24**
 - **Multiple myeloma MY20– sending for publication**
-



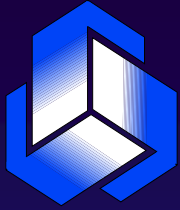
Modules in Phase IV

- **Prostate cancer- further analysis required**
- **Liver metastases from colorectal cancer (LMC21) – cont. recruitment, analysis 2007**
- **Pancreatic cancer - scaling analysis in progress**
- **Brain tumours – awaiting analysis of data from clinical trial for validation**
- **Peripheral Neuropathy –used in Phase 3 trial for validation, complex negotiations to access data**
- **Information module –Ph4 started 215 patients 6 countries**
- **GI NET module – open**
- **Colorectal cancer CR29**



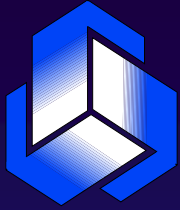
Completed Phase III

- EORTC QLQ-C15 PAL – SF for palliative care;
- High-dose chemotherapy (HDC29)
- Hepatocellular Carcinoma (HCC18) – protocol for Ph4
- Ophthalmic cancer
- Bladder cancer
- Chronic Lymphocytic Leukemia



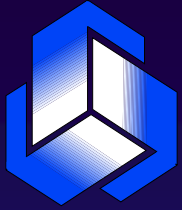
In Phase III

- **Spiritual well-being -57 patients in 6 countries**
- **Fatigue- 190 patients from 7 countries**
- **Oesophago-gastric module**
- **Radiation proctitis – Ph2 module PR21 developed in Australia report submitted, translations in progress for Europe, some Phase iii data collected**
- **Nasopharyngeal cancer NPC42 – report to be reviewed – where is this?**
- **Cholangiocarcinoma – combine LMC21 and PAN26**



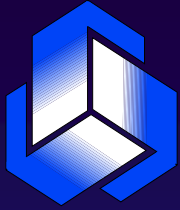
In Phase II

- **Bone metastases** – funded in Canada, Ph2 report reviewed and revised; Ph3 protocol for international clinical trial (Lit rev published *Journal of Cancer Pain & Symptom Palliation*).
- **Breast reconstruction** – entering Ph2
- **Testicular cancer**
- **Endometrial cancer** – EN33 report almost ready
- **Cancer in Elderly Ph1** completed draft module and report in preparation
- **Social Support-on hold**



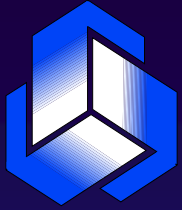
In Phase 1

- **New modules**
- Oral health (Marianne Hjermsstad)
- Literature review done, interviews start May 2007



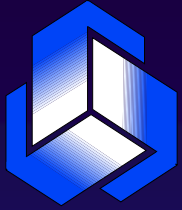
Review procedures

- MDC review **after Phase 2** and Phase 3
- Phase 3 report / manuscript
 - Aim to review module reports within 8-12 weeks of submission
 - 4 week deadlines for reviews;
 - Acknowledge reviewers in publications
- Quick review of finished manuscripts – MDC and previous reviewers within 2 weeks



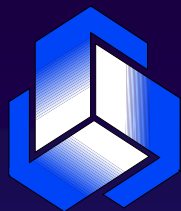
Discussion-1

- Module Development is very active
- Need to update methodology for development and validation of modules. Using and combining existing modules
 - Volunteers for writing group/task force- Galina, Jane, John R, Peter F; Colin will co-ordinate in April 2007
- Only completed Ph3 modules to be distributed by QLU or added to Item Bank,
- Send approved Ph3 modules to Ken / Sheila
- ? Pro-actively check modules on QOL website;



Discussion-2

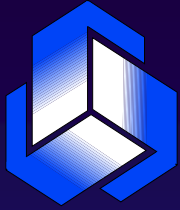
- Describe patient input in module development in publications (FDA guidance on PRO)
- ? Symptom modules



Publications since Nov 2006

- High-dose module – Ph 3, EJC 2007, 43: 87-94
- Myeloma module submitted
- Proctitis submitted

- EBIG project



Many thanks to

- To Sheila and Ken
- To the reviewers of the BM module
- And to Galina, for filling my place at the meetings

Colin

