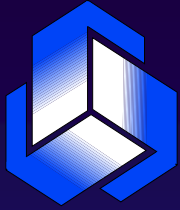


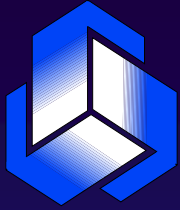
**Report from Module
Development
Committee
April 2008**

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



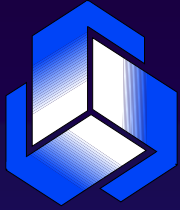
Agenda

- **Report from Chair**
 - update on Module Development
 - website: keeping module information up to date
 - ◆ Development and translations
 - ◆ Publications
- **Record keeping and data storage**
- **Presentations from Module Developers**
 - oral cancer Marianne Jensen
 - testicular cancer Bernhard Holzner
 - brain module Martin Taphoorn and Lily Claasens
- **Possible new modules**
- **Revision of module development and scoring guidelines**



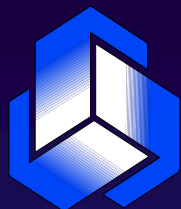
Review procedures

- 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 – ask Colin if names not known**
- Quick review of finished manuscripts – MDC chair and previous reviewers within 2 weeks
- Only completed Ph3 modules to be distributed by QLD/added to Item Bank
- send approved Ph3 modules to Ken / check module entry on QOL website



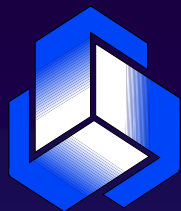
Validated modules

- **Head and neck cancer**
(proposal to update – Suzanne Singer)
 - **Ovarian**
 - **Breast cancer**
 - **Lung**
 - **modifications suggested, but no report to MDC**
 - **Satisfaction with care**
 - **Oesophageal**
 - **Gastric cancer**
 - **Cervix CX24**
 - **Multiple myeloma MY20**
-



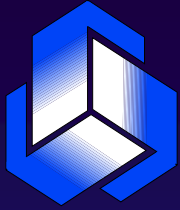
Modules in Phase IV

- Prostate cancer- Final version of MS ready (for EJC)
- Liver metastases from colorectal cancer (LMC21) – study closed, publication 2008?
- Pancreatic cancer - scaling analysis in progress, translations in 33 languages (complete 21)
- Brain tumours –analysis of data from clinical trial for validation presented – ASCO poster – awaiting final phase 4 report
- Peripheral Neuropathy –used in Phase 3 trial for validation, data now ready for analysis
- Information module – 467 patients 6 countries closing July 08
- GI NET module – open: >130 entered data returns for 86, 400 target 12 sites. End 2009
- Colorectal cancer CR29 OPEN (TARGET 350, recruiting well).
- Hepatocellular Carcinoma (HCC18) recruitment started



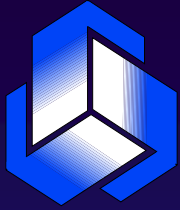
Completed Phase III

- **EORTC QLQ-C15 PAL – SF for palliative care; validation study has been completed but awaits analysis**
- **High-dose chemotherapy (HDC29) published. No plan for phase 4**
- **Ophthalmic cancer**
- **Bladder cancer**
- **Chronic Lymphocytic Leukemia – ready for publication**
- **Combined oesophago-gastric OG25 Phase 4 will be in use analysis.**



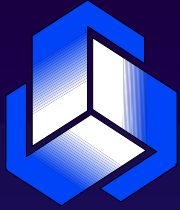
In Phase III

- **Spiritual well-being -57 patients in 6 countries**
- **Fatigue- 320 patients from 7 countries closed. report May 2008**
- **Radiation proctitis –PR21 translations (F, D, N, S) for Europe, Phase 3 aims to close during 2008. Phase 1,2 report in press**
- **Nasopharyngeal cancer NPC42 – report awaited**
- **Cholangiocarcinoma – combine LMC21 and PAN26, 21 patients entered, target 35 ?end 2008**
- **Bone metastases BM22 phase 3 135 entered, report submitted March 08. Proposal for short form**
- **Cancer in Elderly translations and ethics underway, recruitment started n = 41 from 3 countries**
- **Endometrial cancer – EN34 Phase3 recruitment almost complete 80+ pts**



In Phase II

- **Breast reconstruction –Ph2 report in preparation, expected September 08. More interviews needed. Translations in progress**
- **Testicular cancer Phase 2 report revised following review. For submission April 08**
- **Social Support – on hold**
- **Proposal to validate C15PAL + BN20 for brain mets. Protocol to be reviewed**

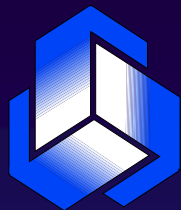


In Phase 1

New modules

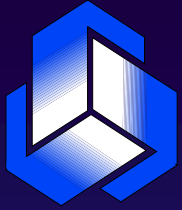
- Oral health (Marianne Hjermsstad)
 - Literature review done updated March 08 and list of issues finalised
 - Interviews professionals done
 - Patient interviews start May 2008 Norway Greece, Germany UK – more sites welcome

- Proposals for discussion
 - Nutrition status/symptoms – Sue Alves
 - Spinal cord compression – Martin Taphoorn
 - Biological agents – Suzanne Singer



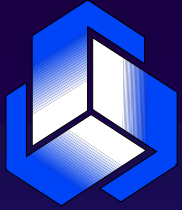
Publications since November 2007

- **Proctitis International Journal of Radiation Oncology, Biology and Physics. *In Press.***



Module Development Guidelines

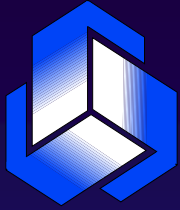
- **Revision now needed**
- **Working group to share the tasks**
- **Focus on:**
 - **Statistical requirements**
 - **Translation**
 - **Revision/update and module merging**
 - **Overall revision of text**



Other Issues discussed

- **website: keeping up to date**
 - **module information**
 - **publications**
- **Record keeping and data storage**

MODULE DEVELOPERS PLEASE NOTE



Many thanks to

- To Sheila and Ken
- To the reviewers of modules: BM22; EN34
- And to Galina, for continued help and advice

Colin

