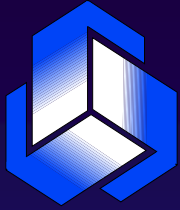


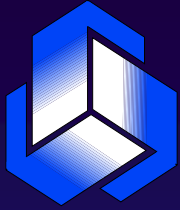
**Report from Module
Development
Committee
November 2007**

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



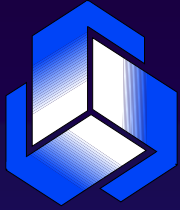
Agenda

- **Minutes from previous meeting**
- **Update on modules**
- **Issues for discussion**
 - **Patient involvement**
 - **Development guidelines revision**
 - **PROQOLID**
 - **Symptom scores – stand alone?**



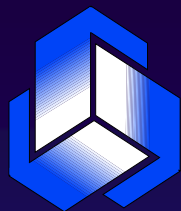
Review procedures

- 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 modules on QOL website, QLD



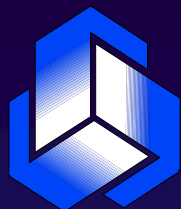
Validated modules

- Head and neck cancer
- Ovarian
- Breast cancer
- Lung
 - modifications suggested, but no report to MDC
- Satisfaction with care
- Oesophageal new transIn x2
- Gastric cancer Mexican, Hungary, Farsi, Tamil
- **Cervix CX24**
- **Multiple myeloma MY20– published**



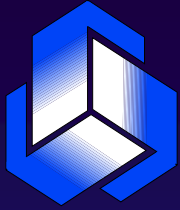
Modules in Phase IV

- **Prostate cancer- Final revision of MS (for EJC)**
- **Liver metastases from colorectal cancer (LMC21) – study closed, publication 2008? New transl Bulgaria**
- **Pancreatic cancer - scaling analysis in progress, translations in 33 languages (complete 21)**
- **Brain tumours – awaiting analysis of data from clinical trial for validation – planned for Stockholm**
- **Peripheral Neuropathy –used in Phase 3 trial for validation, data now received**
- **Information module –Ph4 started 387 patients 6 countries**
- **GI NET module – open: 111 entered, 400 target 12 sites**
- **Colorectal cancer CR29 OPEN (TARGET 350, 50 ENTERED). Paper published. Transl x 8**
- **Hepatocellular Carcinoma (HCC18) –Ph4 funded (Weichu) starts 2008 new transl x3**



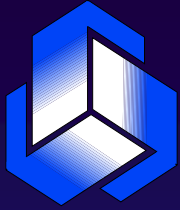
Completed Phase III

- EORTC QLQ-C15 PAL – SF for palliative care;
- High-dose chemotherapy (HDC29) published. No plan for phase 4
- Ophthalmic cancer
- Bladder cancer
- Chronic Lymphocytic Leukemia – ready for publication
- Combined oesophago-gastric OG25 PAPER PUBLISHED Phase 4 will be in use analysis. Translation x 8



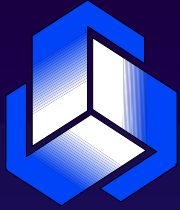
In Phase III

- **Spiritual well-being -57 patients in 6 countries**
 - **Fatigue- 320 patients from 7 countries closed. report Feb 2008**
 - **Radiation proctitis –PR21 translations (F, D, N, S) for Europe, Phase 3 aims to close early 2008. Phase 1,2 report submitted for publication**
 - **Nasopharyngeal cancer NPC42 – report awaited**
 - **Cholangiocarcinoma – combine LMC21 and PAN26 Phase 2 report approved Oct 07; 12 patients entered**
 - **Bone metastases BM22 phase 3 135 entered, report in preparation. Proposal for short form**
-



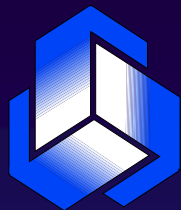
In Phase II

- **Breast reconstruction –Ph2 report in preparation, expected March 08. More interviews needed**
- **Testicular cancer Phase 2 report ready**
- **Endometrial cancer – EN34 report submitted (Phase3 funded and ready to start) transln x 8**
- **Cancer in Elderly Ph1,2 report submitted, translations and ethics for phase 3 underway**
- **Social Support-on hold**
- **Proposal to validate C15PAL + BN20 for brain mets. Protocol to be reviewed**



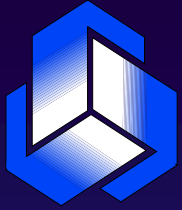
In Phase 1

- **New modules**
- **Oral health (Marianne Hjermsstad)**
 - Literature review done, interviews start May 2007
- **Proposals for discussion**
 - Survivorship
 - Nutrition status/symptoms
 - Lymphoma/elderly/prognostics



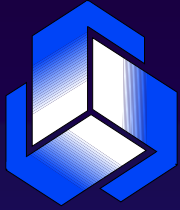
Publications since March 2007

- **Myeloma MY20 EJC 43:1670**
- **Proctitis submitted**
- **Fatigue FA-R15 ISOQOL abstr EJC Suppl A106**
- **CR29 EJC 43:1564**
- **OG25 EJC 43: 2066**



Issues discussed

- Important to describe patient input in module development in publications (FDA guidance on PRO)
- PROQOLID access for researchers within the group may be useful in Phase 1/2
- Symptom scales – should we do more?



Many thanks to

- To Sheila and Ken
- To the reviewers of modules: CR29, OG25, EN34, ELD, cholangio
- And to Galina, for continued help and advice



Colin