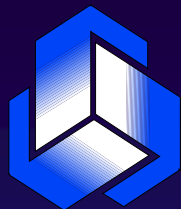


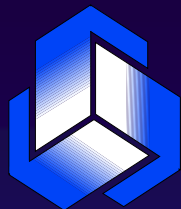
**Report from Module
Development
Committee
November 2006**

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



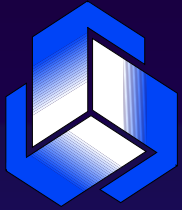
Outline

- **Key points and issues**
- **Update on modules**
 - **EBIG project – clinical significance**



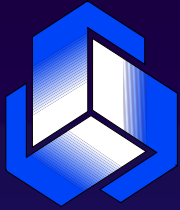
Key points

- **Module Development is very active**
- Need to update methodology for development and validation of modules. Using and combining existing modules.
 - Working group/ task force
- **Phase 4 protocol and studies – quality control, separate role from module development**
- **Important** - describe patient input in module development in publications
 - FDA guidance on PRO



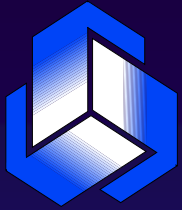
Key points -2

- Reviewers of module reports are to be acknowledged when the module is established.
- 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
- Authorship on manuscripts – group authorship is acceptable



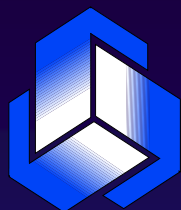
Review procedures

- MDC review **after Phase 2** and **Phase 3**
- Phase 3 report / manuscript
 - Aim to review module reports within 8 weeks of submission
 - 4 week deadlines for reviews;
 - 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 Linda, QLU



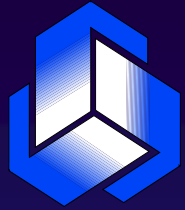
Validated modules

- Head and neck cancer
 - Ovarian
 - Breast cancer
 - Lung
 - modifications suggested, but no report to MDC
 - Satisfaction with care - published
 - Oesophageal
 - Gastric cancer
 - Cervix CX24– paper published in Cancer
 - Multiple myeloma MY20– sending for publication
-



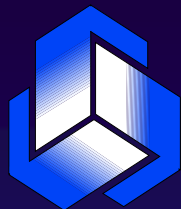
Modules in Phase IV

- Prostate cancer- analysis completed, draft manuscript
- Liver metastases from colorectal cancer (LMC21) – cont. recruitment, analysis 2006
- Pancreatic cancer – analysis now
- 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
- GI NET module – publication on Ph3 EJC



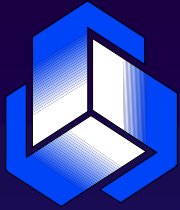
Completed Phase III

- EORTC QLQ-C15 PAL – SF for palliative care;
- Colorectal cancer – updated version
- High-dose chemotherapy- publication in EJC, EBMT trial
- Hepatocellular Carcinoma (HCC18) – protocol for Ph4
- Ophthalmic cancer
- Bladder cancer
- Chronic Lymphocytic Leukemia



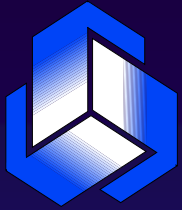
In Phase III

- **Spiritual well-being**
 - **Fatigue**
 - **Oesophago-gastric module**
 - **Radiation proctitis – Ph2 module developed in Australia, to be extended to Europe; 26 items**
 - **Nasopharyngeal cancer NPC42 – report to be reviewed**
 - **Cholangiocarcinoma – combine LMC21 and PAN26**
-



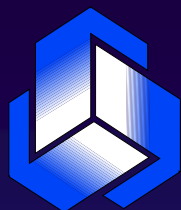
In Phase II

- **Bone metastases – funded in Canada, Interviews ongoing in Canada, European centres to join; Ph2 report to be reviewed**
- **Breast reconstruction – entering Ph2**
- **Testicular cancer**
- **Endometrial cancer – EN33 recently funded, different methodology (Cx24 and OV28)**
- **Social Support-on hold**



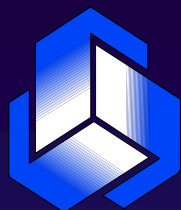
In Phase 1

- Cancer in the elderly
- **New modules**
- Oral health (Marianne Hjermsstad)



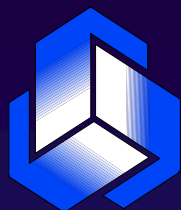
Publications in 2006

- **Pall care – Groenvold EJC, Petersen - JCE**
- **GI NET – Phase 3, EJC**
- **Info module – Arraras et al, Psycho-oncology, Phase 3**
- **Cervix module – Greimel et al, Cancer, Phase 4**
- **High-dose module – Velikova et al, EJC, Phase 3,**
- **Bone metastases – Chow et al, overview in Clin Oncol 2006**
- **Myeloma module – two manuscript for re-submission**



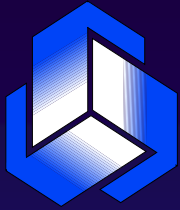
Evidence-based interpretation guidelines (EBIG) project

- Aims to use existing data from QLQ-C30 and familiarity with scores to develop interpretation guidelines
- Experts in QLQ-C30 and cancer review identified papers
- Meta-analysis will be used to estimate large, moderate and small differences



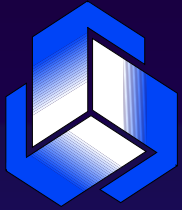
EBIG project progress

- Stage I complete – 377 papers identified.
- Stage II expert review in progress – 35 reviewers, 55 reviews completed so far.
- Stage II patient review – pilot study development in progress. Qualitative research to assess whether patients can also input into evidence-based interpretation guidelines.



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- **Thanks to the volunteers from the EORTC.**
 - **More experts still needed to review haematological papers, papers looking at weight loss/nutrition across different cancers, papers looking at psychological aspects of cancer.**
 - **Timelines**
 - **Reviews to be completed by August 2007**
 - **Analysis and write up by April 2008**
 - **If anyone is interested in hearing more about the project please contact Kim:**

k.cocks@leeds.ac.uk



Many thanks to

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

