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# **Report from Module Development Committee**

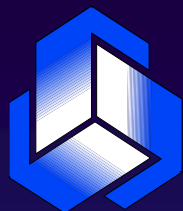
## **September 2009**

**Colin Johnson,**

**Ken Cornelissen, Sheila Sanderson,**

**EORTC Quality of Life Group and EORTC  
Quality of Life Unit**

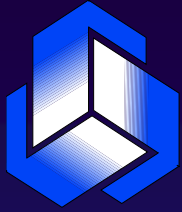
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# MDC Agenda September 2009

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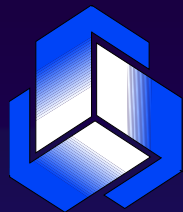
- **Report from Chair**
  - Publication of module text
  - update on Module Development
- **Presentations from Module Developers**
  - Spinal cord compression
  - Brain mets and Bone mets
  - Oral health
- **Possible new modules/revisions**
  - Lung module LC13 revision
  - Melanoma
  - Pleural effusion
  - CML



# Review procedures

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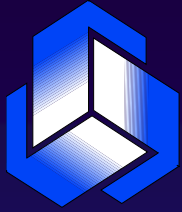
- **Phase 1&2 full report**
    - review module reports within 8 weeks of submission
  - Phase 3 report = manuscript plus appendices
  - Phase 4 report = manuscript plus appendices
    - 4 week deadlines for reviews
    - **Acknowledge reviewers in publications – ask Colin if names not known**
    - Quick review of revised 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
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## Publications since March 2009

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- Bone Metastases Phase 1-3 BM22: Eur J Cancer 2009 May;45(7):1146-52
- **Perceptions of patients and professionals of issues in bone metastases Eur J Cancer. 2009 Sep;45(14):2510-8**
- **OV28 in Taiwan. Wei-Chu Chie. Psycho-Oncology in press**
- **Revision of CR29 EJC in press**



# Publication of modules

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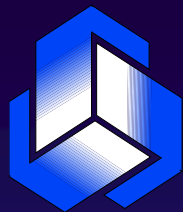
**2002 guidelines prohibit publication in phase 1-3**

Variations in content during development

Protection of intellectual property

**Developer may publish validated modules  
(Phase 4 completed)**

**Should the text of final module be published?**



## Publication of modules yes or no?

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**Dissemination of module,  
ease of access**

**Established practice**

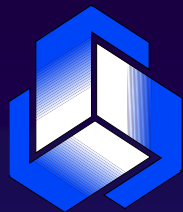
**Full format illustrates how  
module operates**

**Module may be used  
separately from C30**

**Use with C30 requires  
website registration  
anyway**

**Copyright must be retained  
by EORTC not Journal**

**Electronic dissemination  
makes copyright  
protection more difficult**



## Publication of modules yes or no?

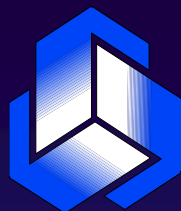
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**Consensus support for  
publication of validated  
modules**

**Published modules should  
be “watermarked” -  
copyright or specimen**

**Suggestion to  
avoid/restrict use of  
modules in phase 4**

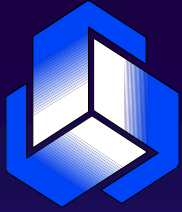
**Assert ownership of  
module – publish by  
permission of QLG**



# Validated modules

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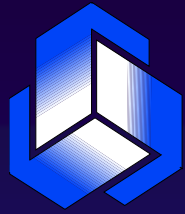
- Head and neck cancer HN35 - (update in progress – Suzanne Singer)
- Ovarian OV28
- Breast cancer
- Lung LC13 - modifications suggested, but no report to MDC
- Satisfaction with care
- Oesophageal
- Gastric cancer
- Cervix CX24
- Multiple myeloma MY20
- Prostate PR25
- Liver metastases from colorectal cancer LMC21
- **Brain tumours BN20**
- **Colorectal revision CR29**



## Modules in Phase IV

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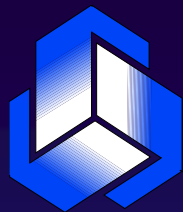
- Pancreatic cancer - scaling analysis in progress, translations in 33 languages (complete 21)
  - Peripheral Neuropathy –used in Phase 3 trial for validation, data now ready for analysis
  - Information module –**Ph4 closed, report end 2009. Presentation IPOS**
  - GI NET module – open: 227 entered, slow recruitment revised target 270 12 sites. End 2009
  - Hepatocellular Carcinoma (HCC18) recruited 201 pts (4 centres plus 2 new sites), aim for 250 ?November 2010
  - Bone metastases BM22 8 countries, 126 pts. New translations Arabic Turkish Hindi
  - Endometrial cancer – EN34 now closed. Report Jan 2010
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## Completed Phase III

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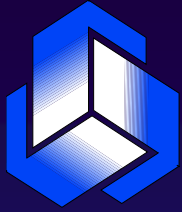
- EORTC QLQ-C15 PAL – SF for palliative care; validation study has been completed but awaits analysis
- High-dose chemotherapy (HDC29) published. No plan for phase 4
- Ophthalmic cancer
- Bladder cancer
- Chronic Lymphocytic Leukemia – ready for publication
- Combined oesophago-gastric OG25 PAPER PUBLISHED Phase 4 will be in use analysis. Translation x 8
- Radiation proctitis –PR21 Grant awarded for phase 4
- Fatigue



## In Phase III

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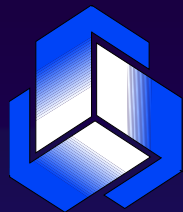
- **Spiritual well-being – closed. Report by end 2009**
- **Nasopharyngeal cancer NPC42 – report awaited**
- **Cholangiocarcinoma – combine LMC21 and PAN26, recruitment completed – report awaited presentation BASL**
- **Cancer in Elderly, recruitment complete. Report nearly ready for submission**
- **Validation of C15PAL + BN20+2 for brain mets. 6 countries, 36 patients (Step 1). 2 further translations**
- **Testicular cancer, recruitment in progress**



## In Phase II

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- **Breast reconstruction – Interviews completed. Report end 2009. Translations in progress**
- **Social Support – on hold**
- **Oral health phase 1-2 report end 2009**



## In Phase 1

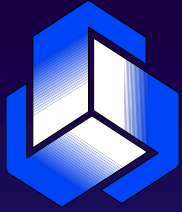
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### New modules

- Nutrition status/symptoms – no progress
- Spinal cord compression - Gunita
- Vulva – Gynae group progressing
- Melanoma : literature review. Group established. Proposed search item bank -Julie
- Pleural effusion
- CML - Fabio

### ● Update

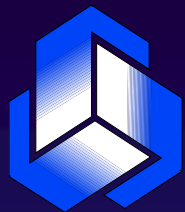
- H&N35 - grant awarded
- LC13 revision proposed



# Module Development Guidelines

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- Revision planned for some time
- Working group shared the tasks
- Focus on:
  - Statistical requirements
  - Translation
  - Revision/update and module merging
  - Overall revision of text
- Progress is slow (co-ordination)

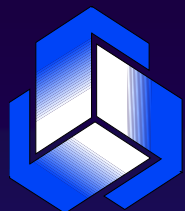


# Module Development Guidelines progress

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## Still to do:

- Collate all sections and circulate to revision group
- Final document for approval (?end 2009)

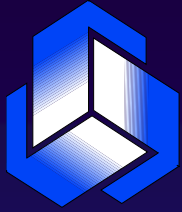


## Summary of modules in development

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New proposals	4
Phase 1	3
Phase 2	4
In phase 3	5
Completed phase 3	8
In phase 4	7
Validated modules	13

**24 modules for use in clinical trials**



# Many thanks to

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- To Sheila, Ken, Galina
- To the reviewers of modules: Fatigue, BN20, EN34

Thank You!

