



# Update of the Bone Metastases Module and Proposed Shortening of the EORTC QLQ-BM22

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# Bone Metastases Module

- There is an absence of well-developed quality of life instruments specifically for bone metastases patients

## **Objective:**

*To develop a set of robust items and scales for assessing quality of life issues not sufficiently covered by the EORTC QLQ-C30 core questionnaire and considered to be relevant for cancer patients with bone metastases in clinical trials*



# Bone Metastases Module

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- This module will assess QOL in patients with bone metastases.
- Administered with the EORTC QLQ-C30.



# Bone Metastases Module

- Why did we develop this questionnaire?
- Prior to the development of the Bone Metastases Module, there was no QOL questionnaire specifically for pts with bone metastases.
- Routinely used questionnaires did not accurately assess treatment-related and disease-specific issues for bone metastases pts.



# Bone Metastases Module

- The Bone Metastases Module (after international validation) will enable uniform assessment of treatment impacts on QOL.
- QOL outcomes will be compared between trials and effective treatments will be more readily identified.
- Clinicians will be better able to follow the QOL of their pts over time.



# Methods

- The actual module development process consists of four phases:

Phase I: Generation of relevant QOL issues

Phase II: Operationalization of the QOL issue into a set of items

Phase III: Pre-testing the module questionnaire

Phase IV: Large-scale international field testing



# Phase I

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- Patient and health care professional interviews and a literature search produced a list of 61 relevant items for pts with bone metastases.
- These items were administered as a questionnaire to determine which were the most important and should be included in the final module.



## Phase II

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- After interviewing 413 bone metastases pts and 152 HCPs in five cancer centres in Canada, Australia and Germany, the 22 items were finalized by Edward Chow and the EORTC coordinators.



# EORTC QLQ-BM22



## EORTC QLQ – BM22

Patients sometimes report that they have the following symptoms or problems. Please indicate the extent to which you have experienced these symptoms or problems during the **past week**. Please answer by circling the number that best applies to you.

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<b>During the <u>past week</u> have you had <u>pain</u> in any of the following parts of your body?</b>	<b>Not at All</b>	<b>A Little</b>	<b>Quite a Bit</b>	<b>Very Much</b>
1. in your back?	1	2	3	4
2. in your leg(s) or hip(s)?	1	2	3	4
3. in your arm(s) or shoulder(s)?	1	2	3	4
4. in your chest or rib(s)?	1	2	3	4
5. in your buttock(s)?	1	2	3	4
<b>During the <u>past week</u>:</b>				
6. Have you had constant pain?	1	2	3	4
7. Have you had intermittent pain?	1	2	3	4
8. Have you had pain not relieved by pain medications?	1	2	3	4



# EORTC QLQ-BM22

9. Have you had pain while sitting or lying down?	1	2	3	4
10. Have you had pain when trying to stand up?	1	2	3	4
11. Have you had pain while walking?	1	2	3	4
12. Have you had pain with activities such as bending or climbing stairs?	1	2	3	4
13. Have you had pain with strenuous activity (e.g. exercise, lifting)?	1	2	3	4
14. Has pain interfered with your sleeping at night?	1	2	3	4
15. Have you had to modify your daily activities because of your illness?	1	2	3	4
16. Have you felt isolated from those close to you (e.g. family, friends)?	1	2	3	4
17. Have you been thinking about your illness?	1	2	3	4
18. Have you worried about loss of mobility because of your illness?	1	2	3	4
19. Have you worried about becoming dependent on others because of your illness?	1	2	3	4
20. Have you worried about your health in the future?	1	2	3	4
21. Have you felt hopeful your pain will get better?	1	2	3	4
22. Have you felt positive about your health?	1	2	3	4



## Phase III

- Module pre-testing and international validation
- Countries involved:
  - Argentina
  - Australia
  - Austria
  - Canada
  - China
  - Germany
  - Greece
  - India
  - Israel
  - Italy
  - Japan
  - The Netherlands
  - Nigeria
  - Norway
  - Spain
  - Sri Lanka
  - Uganda
  - United Kingdom
  - United States



# Phase III

- BM22 Translations (*EORTC approved*):
  - Chinese
  - Danish (formal and informal)
  - Dutch
  - French
  - German
  - Greek
  - Italian
  - Japanese
  - Norwegian
  - Spanish (South American and European)
  - Swedish
  - Turkish



# Current Status

## Countries in the **translation** process:

- Sri Lanka
- India
- Nigeria
- Uganda
- Israel

## Countries in **Stage I: Pre-testing** (*Non-English Speaking*)

- Austria
- Japan
- France
- Norway
- Italy
- Spain

## Countries in **Stage II: Content Validation**

- Argentina
- Greece
- Australia
- The UK
- Germany
- The Netherlands
- Hong Kong
- USA
- Canada



# Completed Phase III: Stage I

*(Non-English Speaking)*

- Argentina (n=14)
- Hong Kong (China) (n=10)
- Germany (n=10)
- Greece (n=13)
- The Netherlands (n=12)



## Completed Phase III: Stage II

- Canada (n=35)
- Australia (n=16)
- Germany (n=10)
- Greece (n=16)
- United Kingdom (n=4) *ongoing*



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*If you are interested in joining, please contact:*

**Edward Chow**

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# **Our Proposal...**

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**Shortening of the European Organization  
for Research and Treatment of Cancer  
Bone Metastases Module  
(EORTC QLQ-BM22)**



## Rationale

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- The EORTC QLQ-C15-PAL was successfully developed from the C30 to assess QOL in palliative cancer pts.
- Shortening the BM22 for clinical use alongside the PAL15 will make it easier for pts of low performance status to complete the QOL assessment.



# Methods

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- We will employ the same methodology to shorten the BM22 as was used to shorten the C30:
  - Differential Function Analysis (DIF)
  - Item Response Theory (IRT)



# Differential Function Analysis (DIF)

- DIF means that the items in the scale function differently in different subgroups:
  - Age, gender, cancer site, and stage.
- If there is DIF, the shortened scale's ability to predict may vary from subgroup to subgroup; the shortened scale might not be an appropriate measure to use in all subgroups of palliative care pts.



# Item Response Theory (IRT)

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- IRT-based method is used for the selection of items for the shortened scales and for the prediction of scale scores.



# Categorizing the BM22

	<b>During the past week have you had pain in any of the following parts of your body?</b>
<b>1. Painful sites</b>	1. in your back?
	2. in your leg(s) or hip(s)?
	3. in your arm(s) or shoulder(s)?
	4. in your chest or rib(s)?
	5. in your buttock(s)?
<b>2. Pain characteristics</b>	<b>During the past week:</b>
	6. Have you had constant pain?
	7. Have you had intermittent pain?
<b>3. Functional interference</b>	8. Have you had pain not relieved by pain medications?
	9. Have you had pain while sitting or lying down?
	10. Have you had pain when trying to stand up?
	11. Have you had pain while walking?
	12. Have you had pain with activities such as bending or climbing stairs?
	13. Have you had pain with strenuous activity (e.g. exercise, lifting)?
	14. Has pain interfered with your sleeping at night?
<b>4. Psychosocial aspects</b>	15. Have you had to modify your daily activities because of your illness?
	16. Have you felt isolated from those close to you (e.g. family, friends)?
	17. Have you been thinking about your illness?
	18. Have you worried about loss of mobility because of your illness?
	19. Have you worried about becoming dependent on others because of your illness?
	20. Have you worried about your health in the future?
	21. Have you felt hopeful your pain will get better?
	22. Have you felt positive about your health?



# Implications

- Clinicians will be able to follow their pts as their disease progresses.
- Ease pt burden in clinical trial assessments.
- Identify clinically beneficial treatments.
- Enable QOL scores for pts completing the original BM22 (those of higher performance status) to be compared to those completing the shortened BM22 (those of lower performance status).



# Methods

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- This project will require pre-testing and international validation.
- We welcome any interested parties to contact the investigators.



# Interested Centres So Far

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**Odette Cancer Centre**

Toronto, Ontario

**Princess Margaret Hospital**

Toronto, Ontario

**Tom Baker Cancer Centre**

Calgary, Alberta

**Universitätsklinikum Charité**

Berlin, Germany



# Thank-you!

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Comments or suggestions?

*Please contact us if you are interested in participating*

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