

# Symptom Based Questionnaires: development of a time-efficient procedure

EORTC Quality of Life Group

EORTC Soft Tissue and Bone Sarcoma Group

EORTC Breast Cancer Group

# Collaborators

- Colin Johnson, UK Breast, GIST
- Ellen Copson, UK Breast
- Fabio Efficace, Italy (+ collaborators) CML
- Mirjam Sprangers, NL
- Deb Fitzsimmons, UK Breast
- Andrew Bottomley, Belgium Breast
- Peter Hohenberger, Germany GIST
- Jean-Yves Blay, France GIST
- Joanna Kozaka, PL Breast
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- Peter Fayers, UK

# QLG develops PRO measures

- Well established procedures for development of reliable instruments
- Based on patient-derived data
- Core module (QLQ-C30) + modules
  
- Measure of QL and disease/treatment symptoms
- Huge resource of validated questions – Item Bank

## QLG Modules – disadvantages

- Long time to develop
- Come as a “package” – difficult to add new questions
- Biological treatments (Herceptin, Imatinib) have different side effects
- Changes in treatment may be rapid – how can we respond?
- Industry works to short deadlines in drug development

# Development survey

November 2010 all QLG members

17 replies, all modules

Delay or time required longest for

interviews

translations

ethics in multiple countries

# Symptom based questionnaires

- Clinical trials need PRO of symptoms/toxicity
- Drug development needs timely Q development
- Data from phase 1&2 clinical trials can inform PRO measure for Phase 3 clinical trial
- Module development procedures are not flexible/quick enough
- Change of practice and QLG modules: add symptom list or revise whole module?

# Research questions

- Can we devise short symptom lists? using
  - Modified procedures that retain patient input (FDA require this)
  - Item Bank of already validated questions
- Can this be done more quickly than for QL modules?
- Can we devise Guidance for future workers?

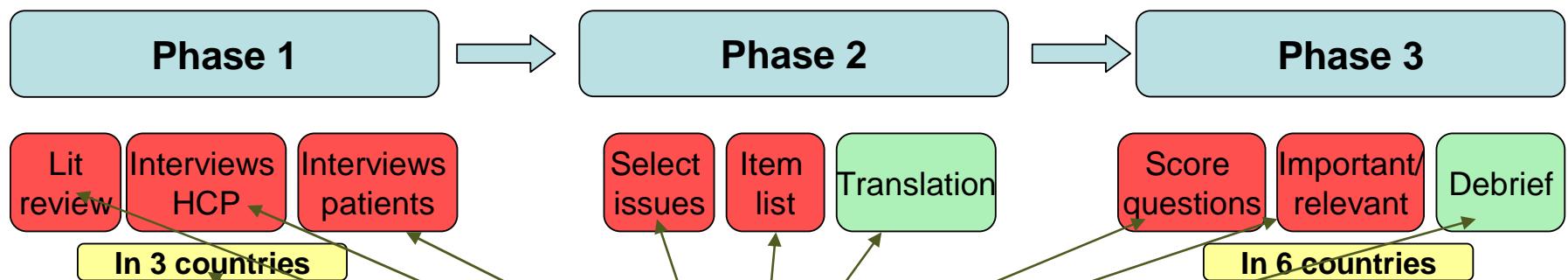
# Aims and design

To examine whether SBQs can be developed more rapidly and efficiently than current module development guidelines allow

- To develop SBQ for patients receiving biological treatment; in Breast cancer, CML, and GIST.
- ONE, maybe three SBQ, as data indicate
- To register time needed and information gained (=items) for each step and critical evaluation of each step's contribution to the whole process.
- Explore costs
- Formulation of SBQ Development Guidelines

# Plan of investigation

## Biologicals in 3 different tumour types follow module development guidelines



Collect data at each step:

Issues/items contributed; time taken;  
reasons for delays

# Progress so far

Grant awarded May 2011

Preliminary discussion of protocol

Ethics in UK September 2011

## Development of SBQ for biological therapy

- Follow existing module development guidelines
- Keep separate record of information gathered from each aspect (lit review, interviews etc) and evaluate in real time.
- Each centre to present separate lists of items generated from each aspect of each phase.
- Time spent will be logged for all Phases
- Expert clinical review after each phase; experts in the field/clinical group
- Delphi review of proposed guidelines

# Time frame

- September 2011: Ethics and appointment of staff
- January 2012: Phase 1 and establishing networks
- June 2012: Phase 2
- September 2012: Consensus questionnaires at QLG meeting
- March 2013: Phase 3
- September 2013: Analysis of Phase 3 data
- January 2013: Delphi study to create new guidelines
- March 2014: Finalise report and new guidelines

## Phase 1 interviews – open qualitative

- Not all interviews will be audio-taped; responses can be written down.
- Ask patients what they think the cause of their symptoms is: is it related to their treatment (rather than the cancer, for instance)?
- Include any symptoms that may be related to their treatment – physical or psychological symptoms:

# Focus groups

- This approach may simplify data gathering from patients
- Focus groups may not be feasible for rare cancers (GIST).
- Assess data by comparison:
  - focus group(s) vs interviews
  - one focus group or more countries?

# Costs

- In Southampton log costs/time spent in detail
- Use published cost data to value time of researchers
- Calculate and compare overall research costs
- No recording of direct costs for patients as that will not influence future guidelines.

# Symptom burden

- Do we need a question on symptom burden?

such as:

to what extent have the symptoms you describe affected your QOL?

- Should we include an open question?

such as:

have you had other symptoms not listed above?

# Time frame of items

- During the *last week/month*
  - Patients with daily treatment: during last week
  - Patients with treatment cycles: during last month

Explore this issue in phase 1

# Pilot testing

- Discussion: Do we really need to pilot test in more than 1 country?
- Should we record ethnicity? Country of birth?
- Treatment regimes may differ for countries

# Outcomes

- ?publish or register study protocol
- Conference presentations and publication describing the symptom list
- EORTC “Biological Treatment SBQ”
  - Possibly breast/bio, GIST/bio, CML/bio SBQs
- EORTC Guidance for creation of SBQ

# Other collaborators welcome!

Access to patients with GIST or breast cancer

(CML – collaboration with existing module development)

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