The European Regulatory Issues on Quality of Life Assessment (ERIQA) Project

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Background: Summary

- FDA - EMEA guidance - Harmonization required not compatible
- Inconsistency within guidance recommen-dations - Clarifications required
- Important issues not mentioned at all - Guidance required

Draft guidance documents on health-related quality of life issues in clinical trials in CHF

	FDA (Oct 22, 1998)	EMEA (Feb 25, 1999)
HRQL domains:	Measure a few relevant HRQL domains	Measure a broad range of HRQL domains
HRQL questionnaire:	-	The Living with Heart Failure Questionnaire
Global Measure:	To be used	-
Psychometric Properties:	Not mentioned	Validation required
Duration of follow up:	Not mentioned	Not mentioned
Patients lost to follow up:	Not mentioned	Not mentioned
Other issues:	Standardized administration -	Standardized administration Training
Translations:	-	Validation required

Mission Statement

« establishing principles and practices for the integration of health-related quality of life outcomes in the regulatory process »

Target

- EMEA
  - Permanent Staff: Human Products Unit
  - CPMP Members: 30 people (2 per country)

  ==> Registration
- Country-Specific Agencies
  - Registration
  - Pricing, Reimbursement
  - Marketing

Objectives

- To provide European regulatory authorities (RA) with guidance on:
  - how to assess the quality of HRQL studies in clinical trials,
  - how to evaluate the validity of HRQL claims
- To inform purchasers and payors when and how HRQL studies might be relevant to decision-making or funding

Contributors

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Organisation: 2 Phases - 4 Steps

Phases/Steps	Deliverables
Phase I	**for Phase I**
step 1: Search and review of existing guidelines	1. Report
step 2: Production of a reference document	2. Reference document
step 3: Decide target areas and draft guidance : COPD/asthma, cancer as pilot areas	3. Draft guidance on COPD/asthma and cancer
step 4: Presentations to RA	**ALL 3 materials**
Phase II	**for Phase II**
Consensus meetings with all key players	consensus guidance on specific diseases

Report

- review and synthesis of the existing guidelines
- special focus on the EMEA documents
- to underscore areas to be improved or developed
- available June 1999

Reference Document

- basic guidance for RA to assess the quality of HRQL evaluation in RCTs and the validity of HRQL claims
  - 1. basic statements on HRQL issues
  - 2. checklist of key issues to be addressed
  - 3. examples taken from specific pathologies
- applicable to most of diseases
- available June 1999

Draft Specific Guidances

- pilots with two indications
  - cancer
  - COPD - asthma
- body of evidence important
- available Fall 1999

Links with Databases

- Need of references/evidence
- Importance of existing databases:
  - MOT
  - EORTC QoLQ
  - EUROQoL
  - IQOD
  - ....

Perspectives

- Collaboration with other initiatives:

==> mainly US/FDA (ISPOR, PhRMA)

==> to improve consistency between regulatory agencies (EMEA vs FDA)