ISPOR Second Annual European Conference
Edinburgh - November 11-13, 1999

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

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ERIQA PROJECT: Overview

Members:
Academics
Ph. Industry
Reg. Authorities

To provide European regulatory authorities with guidance on:

- how to assess the quality of HRQL studies in clinical trials,
- how to evaluate the validity of HRQL claims

Phase I
step 1: review of existing guidelines
step 2: reference document (general guidance)
step 3: pilots guidance (COPD-asthma)
step 4: presentation to authorities

Phase II
development of consensus guidelines in specific diseases

Collaboration with FDA, PhRMA HOWG, ISPOR, ISOQOL

ORGANISATION

Advisors to coordination
Katrin Conway,
Bernard Jambon,
Dorothy Keininger
Mapi Research Institute

Coordination
Catherine Acquadro,
Mapi Research Institute

General Reviewers of each step

Harry Burns,
Greater Glasgow Health Board
Dominique Dubois,
Janssen, Belgium
Bernard Genesté,
RPR, France
Asha Hareendran,
Pfizer, UK
Jeff Kirsch,
SKB, UK
Caroline Miltenburger,
Schering AG, Germany
Margaret Rothman,
Janssen, USA

+ members of each Working Group

Literature Review Working Group
Phase I, Step 1
Giovanni Apolone, leader,
Mario Negri Institute, Italy
Ingela Wiklund,
AstraZeneca, Sweden
Gianfranco De Carli,
GlaxoWellcome, Italy

Reference Document Working Group
Phase I , Step 2
Olivier Chassany, leader,
French Medicines Agency
Neil Aaronson,
The Netherlands Cancer Institute
Steve Fullerton,
UCLA Dpt of Medicine, USA
Patrick Marquis,
Mapi Values, France
Pierre Sagnier,
Bayer UK

Pilots Working Group
Phase I, Step 3
Asthma / COPD WG
Marianne Sullivan, co-leader,
Gothenburg University, Sweden
Giovanni Apolone, co-leader,
Mario Negri Institute, Italy

Review/Comments
Selected members of European Regulatory Bodies

RESULTS

- Phase I
  - step 1: completed
  - step 2: on-going → 3rd draft
  - step 3: planned for year 2000
  - step 4: meetings with RA (Nov. 1999 + year 2000), on-going European Survey

PERSPECTIVES FOR THE FUTURE

Promote collaboration between all regulatory initiatives to improve consistency between future guidelines produced by EMEA/FDA

- Harmonisation conferences on HRQL Issues (Year 2000)