

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

**The European Regulatory
Issues on Quality of Life
Assessment (ERIQQA)
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

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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

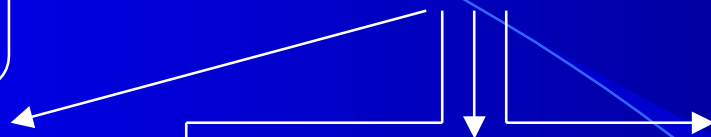
+ members of each Working Group

**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

1 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)