**ISOQOL Satellite Meeting**
**HRQL evaluation and Regulatory Issues**
**Barcelona - November 3rd, 1999**

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

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# Background

Exploratory meetings on Health-related Quality of Life and Regulatory Issues

- Vienna, November 4-5th, 1997:

  *Mapi Research Institute*

- Milano, October 1997:

  *Mario Negri Institute, GlaxoWellcome*

# Background (cont'd)

- Need to rationalise the field of HRQL and to make it credible as a criterion of evaluation to the regulatory authorities.
- Issue to be only resolved through a better collaborative effort between key players: regulatory authorities, HRQL researchers and pharmaceutical companies.

➔ **Creation of the ERIQA Group**

# Mission Statement

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

# Main Objective

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

for appropriate decision-making...

# Target

- EMEA
  - CPMP Members: 30 people (2 per country)

  ➔ Registration
- Country-Specific Agencies (15 countries)
  - Registration
  - Pricing, Reimbursement
  - Promotion

# Contributors

| | | |
|---|---|---|
| Neil Aaronson<br>The Netherlands Cancer Institute | Catherine Acquadro<br>Mapi Research Institute, France | Giovanni Apolone<br>Mario Negri Institute, Italy |
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# Sponsors

- Mapi Research Institute, Lyon, France
- AstraZeneca, Mölndal, Sweden
- Bayer, Slough, UK
- GlaxoWellcome, Verona, Italy
- Janssen Research Foundation, NJ, USA
- Pfizer, Sandwich, UK
- Rhône Poulenc Rorer, Antony, France
- Schering AG, Berlin, Germany

# Organisation: 2 Phases

| 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**: Draft pilot guidance : COPD/asthma | 3. Draft guidance on COPD/asthma |
| **step 4**: Presentations to RA | ALL 3 materials |
| **Phase II** | **for Phase II** |
| Consensus meetings with all key players to design consensus guidance in specific diseaeses | Consensus guidance on specific diseases |

# Ph.I - St. 1: Report

- review and synthesis of existing guidance
- special focus on the EMEA documents
- final version October 1999
  - to be distributed to EMEA CPMP members
  - submitted to publication (review of EMEA doc)

# Ph.I - St. 2: Reference Document (RD)

- basic guidance for RA to evaluate the quality of HRQL evaluation in RCTs and the validity of HRQL claims
- applicable to all areas
- 3rd draft available November 1999

# Ph.I - St. 3: Specific Pilot Guidance

- pilot with one indication
  - COPD - asthma
- body of evidence important
- to start when RD available

# Ph.I - St. 4: Presentation to Regulatory Authorities

- **Contact with Prof. J.M. Alexandre,**
  CPMP Chairman (EMEA), Head of Medicines Evaluation Dpt, French Medicines Agency:
  - Meeting scheduled on Nov. 29th, 1999 (Paris - French Medicines Agency)with members of French Agency
- **Contacts with European agencies**
  *(European survey follow up)*

# Phase II

- development of consensus guidance for specific diseases

- using:
  - reference document developed in phase I
  - experience from pilot
  - consensus meetings

# Other ERIQA activities

- Production of a document comparing all initiatives in the field of HRQL and Regulatory Issues (Europe / USA)

- European regulatory survey:
  15 countries, 60 regulators
  (among them 30 CPMP members)

# Conclusion

Promote collaboration between all initiatives:

- to improve consistency between regulatory agencies (EMEA / FDA)