Welcome to the educational program on HRQoL and PRO in RCTs and observational studies

December 1, 2006
CVZ, Diemen
The Netherlands

Agenda

- What is the ERIQA group
- Program today
- Who are the speakers
- Objective of the today

European Regulatory Issues on Quality of Life Assessment (ERIQA) Group

- Mapi Research Trust established in 1998 the ERIQA Group.
- ERIQA brings together HRQoL researchers, representatives from pharmaceutical companies, and healthcare authorities with the objective of establishing HRQoL as a credible criterion for evaluation in clinical trials.

ERIQA Project: Overview

www.eriqa-project.com

Members
Academics
Ph. Industry
Reg. Authorities

1. 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

2. To convince European Regulators that HRQL is a relevant key outcome, i.e. a credible criterion of evaluation of medicines

Contacts with regulators at each step

Phase I
1- Review of existing guidelines/Survey
2- Guidance document (general guidance)
3- Harmonization meetings
4- Training sessions for regulators

Phase II
Development of consensus guidelines in specific diseases

Collaboration with FDA, PhRMA HOC, ISOQOL, ISPOR

ERIQA Project: Mission Statement

« Establishing principles and practices for the integration of Health-Related Quality of Life outcomes in the regulatory process »

AGENDA

Time	Type of session	Content	Speakers
9:00 - 9:15	Presentation	**Welcome & Objectives of the day**	J. Van Loon
9:15 - 10:30	Presentation	**Various issues surrounding the assessment of HRQL (or PROs)**	N. Aaronson
10:30 – 10:45 Coffee Break			
10:45 - 12:30	Presentation	**Analysis & Interpretation of HRQL data included in clinical trials**	O. Chassany
12:30 – 13:30 Lunch			

AGENDA

Time	•Type of session	•Content	Speakers
13:30 - 15:00	Presentation	**Cost-effectiveness data from Observational studies**	J. Brazier
15:00 – 15:15 Coffee Break			
15:15 - 15:30	Presentation	**Q&A session on PRO/utilities**	All
15:30 - 16:45	Presentation	**Case studies** **Examples of observational studies requested by the French Transparency Commission**	H. Méchin
16:45 - 17:00	Presentation	**Concluding Remarks**	J. van Loon
17.00		**Drinks**	

Speakers today

Neil Aaronson, PhD

Head, Division of Psychosocial Research & Epidemiology, The Netherlands Cancer Institute (NKI), Amsterdam

Professor, Chair in Psychosocial Oncology, Faculty of Medicine, Vrije Universiteit, Amsterdam

Olivier Chassany, MD, PhD

Medical manager of R&D department of Assistance Publique - Hopitaux de Paris (institutional sponsor)

President of IRB (Comité de Protection des Personnes Ile de France n°4)

Member of and reviewer for several committees at French Drug Agency (AFSSAPS): gastroenterology, OTC, advertisement,

Clinical expert for EMEA

Writing of the EMEA reflection paper on HRQL with Dr Pavlovic (AFSSAPS)

Speakers today

John Brazier, PhD

John Brazier is Professor of Health Economics in the section of Health Economics and Decision Science at the School of Health and Related Research at the University of Sheffield. He has served on the NICE Appraisal Committee

Hubert Mechin, MD

Director Mapi Naxis

Naxis is specialized in epidemiological and pharmaco-epidemiological studies in France. Since 2003, Hubert is training students in pharmaco-epidemiology in both Lyon and Paris Universities.

Jeanni van Loon, MSc

Development Director-Europe, Mapi Values

Global company in the development and interpretation of HE and PRO arguments to facilitate access to the market and optimize medical intervention

Objective of the educational program

- **To help** reviewers, and investigators of clinical trials acquire the skills needed to assess PRO included in regulatory/reimbursement files and publications
- **To facilitate decisions** made by health authorities and health-care providers
- **To facilitate dialogue** between regulators, members of pharmaceutical companies, and health-care providers through the same training