



10<sup>th</sup> International Cochrane Colloquium,  
Stavanger , Norway

**Workshop:**

**Advanced Programme on Health-Related  
Quality of Life for Reviewers of Clinical Trials**

*Saturday 3<sup>rd</sup> August, 2002*

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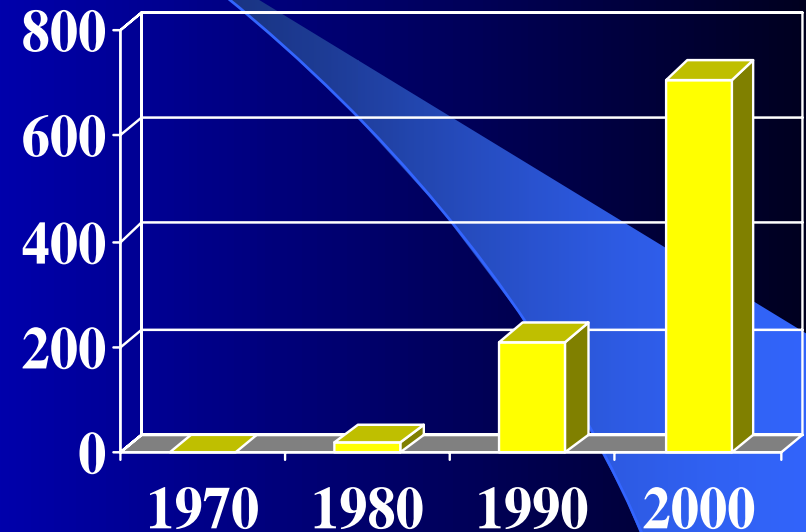
# Evolution of HRQL assessment in Clinical Trials since 1966

## ★ Literature search (Medline)

“Quality of Life” Matched with  
“Clinical Trials”:

Results: number of references

- ★ 1966 to 1970: 0
- ★ 1966 to 1980: 20
- ★ 1966 to 1990: 210
- ★ 1966 to 2000: 708



Considerable increase  
of HRQL assessment  
in Clinical Trials

# Cochrane Health-Related Quality of Life Methods Group

## Objective:

- To advise Cochrane reviewers about when and how to incorporate HRQL data into systematic reviews of health care interventions

- **Convenors: Catherine Acquadro, MD**

  - Prof. Dick Joyce, PhD, FBPSS**

  - Prof. Donald L. Patrick, MSPH, PhD**

- **Coordinator: Lucile Lapalus ([llapalus@mapi.fr](mailto:llapalus@mapi.fr))**

- **Active members : 37 from 12 countries**

# Objectives

- To help reviewers of clinical trials to acquire the skills needed to assess HRQL outcomes included in regulatory files and publications
- To facilitate decisions made by Health Authorities and health care providers

# Presentation of the Workmats (1/2)

- **Workmats :**

- large worksheets
- contain concise information: background
- present various assignments

- **Workbook :**

- reference source
- additional information on HRQL

# Presentation of the Workmats (2/2)

- **Interactive learning method**
- **Participants**
  - Small group discussions and interactions
  - To understand the new information
  - To complete the assignments through group discussions (writing material)
  - Group answers have to be discussed by all the groups to reach a consensus

# Content

<b>Workmats</b>	<b>Content</b>
1	How do disease and treatment affect Health-Related Quality of Life (HRQL)?
2	<b>Deciding which domains to include in a HRQL instrument</b>
3	How is a new HRQL questionnaire developed? 1 <sup>st</sup> steps
4	<b>Choosing an appropriate existing HRQL measure</b>
5	Analysis of HRQL data
6	<b>Presentation and interpretation of HRQL outcomes included in clinical trials?</b>

# **WORKMAT 5**

**Analysis of HRQL data**



# **WORKMAT 5 : (14:30 – 14:45)**

- **Learning objectives**

- To identify the issues and potential problems in designing a statistical analysis plan for HRQL data
- To understand the different methods of treating missing data
- To gain the knowledge and skills needed to analyse differences in HRQL outcomes between two or more treatments

# WORKMAT 5

- Learning points

- To pre-specify hypotheses and to establish a rigorous analysis plan with a special focus on multiple test and missing data
- The type of missing data should be specified (missing items / missing questionnaires)

# **WORKMAT 6**

**Presentation and interpretation of HRQL  
outcomes included in clinical trials**

# **WORKMAT 6 : (15:45 – 16:15)**

- **Learning objective**

- To critically evaluate published literature describing HRQL surveys
- To interpret HRQL data that are reported in the published literature

# WORKMAT 6

- Learning points

- There are several ways to interpret, all have advantages and disadvantages : Effect Size (ES), Minimal Important Difference (MID), Number of Patients to Treat (NNT)
- As the experience of interpreting HRQL outcomes is minor, raw HRQL scores may be difficult to interpret at the moment
- Attempts to interpret in different ways HRQL scores in a file are recommended
- The evaluating techniques for HRQL data analysis are still in development but are valuable techniques