

Training regulatory agencies in PRO evaluation: the Workmats experience

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Background

The need to assess a patient's perception on the impact of disease and treatment in clinical trials has gained importance in the pharmaceutical industry.

At the same time, the **Food and Drug Administration (FDA)** has become increasingly concerned about the use of PRO and data yielded by its assessment in both labelling and promotional claims.

Similarly, the **European Agency for the Evaluation of Medicinal Products (EMA)** emphasizes key issues to be addressed, such as the added value of HRQL/PRO, psychometric properties of validated instruments and analysis/ interpretation of PRO data.

To meet the needs of clinical trials reviewers, Mapi Research Institute has developed the **PRO WORKMATS**, an **Educational Program on PRO assessment**, in collaboration with the **Cochrane Health-Related Quality of Life Methods Group** and the **ERIQA group**.

This educational program provides practical information on instruments for health outcomes assessment, utilization of the instruments in clinical trials, and interpretation of the results.

This training focuses on the understanding, problem-solving, and follow-up discussion of seven key aspects relating to PRO and HRQL (see one example below).

Participants are guided through each Workmat exercise under the direction of one or two session facilitators, each an expert in the PRO field.

In 2002 and 2003, regulators were trained in France (AFSSAPS, ANAES), in Belgium (INAMI) and in the US (FDA).

Members of the Cochrane Collaboration were also trained during the Stavanger (2002) and Barcelona (2003) colloquia.

Objectives

The main objective of this study is to assess the relevance and the impact of the Workmats training from the regulators perspective.

Methods

Following each Workmat session the facilitators distributed a questionnaire designed to evaluate the quality of the session and the level of satisfaction of the audience (see questionnaire below).

Question 5 was specifically designed for the sessions involving regulators.

Table 1: Quality/Satisfaction Questionnaire

1. How did you like the material?

a. the «Workmats»

1. the form:

Very satisfactory ; Satisfactory
Rather satisfactory ; Unsatisfactory

2. the content :

Very satisfactory ; Satisfactory
Rather satisfactory ; Unsatisfactory

b. the additional documents (Workbook, ERIQA guidance document, ...) : did they help you ? Yes No

2. Did you learn some useful information ? Yes No

3. Did the workshop come up to your expectations ? Yes No

4. Please let us know your comments on the organisation of that training session day?

a. Speakers :

Very satisfactory ; Satisfactory
Rather satisfactory ; Unsatisfactory

b. The programme (working timeline, discussions...)

Very satisfactory ; Satisfactory
Rather satisfactory ; Unsatisfactory

5. Will this training modify your way of evaluating files? Yes Maybe No

6. Would you recommend this workshop to your colleagues ? Yes No

Results

80 persons were trained: 32 members of the Cochrane Collaboration and 48 regulators.

To Question 2: Did you learn some useful information? 97.5% answered Yes.

To Question 3: Did the workshop come up to your expectations? 91.3% answered Yes, 6.2% No and 2.5% did not answer.

To Question 5: will this training change your way of evaluating files? 52% of the regulators said Yes, 35.5% say maybe, 6.25% said No and 6.25% did not answer.

To Question 6: Would you recommend this workshop to your colleagues? 68.75% said yes, 21.25% said maybe, 3.75% said No and 6.25% did not answer.

Questions	Answers (n - %)			
	Yes	Maybe	No	No Answer
Q2, n=80	78 - 97.5%		2 - 2.5%	
Q3, n=80	73 - 91.25%		5 - 6.25%	2 - 2.5%
Q5, n=48	25 - 52%	17 - 35.5%	3 - 6.25%	3 - 6.25%
Q6, n=80	55 - 68.75%	17 - 21.25%	3 - 3.75%	5 - 6.25%

Results from Q1 and Q4, specific to the organisation of the session and the material used are shown in Tables 3 and 4.

Questions	Answers (n - %)				
	Very satisfactory	Satisfactory	Rather Satisfactory	Unsatisfactory	No answer
Q1a1, n=48	14 - 29%	22 - 46%	10 - 21%	2 - 4%	
Q1a2, n=48	14 - 29%	23 - 48%	9 - 19%	1 - 2%	1 - 2%
Q4a, n=48	32 - 67%	15 - 31%	1 - 2%		
Q4b, n=48	16 - 33%	24 - 50%	8 - 17%		

Questions	Answers (n - %)		
	Yes	No	No Answer
Q1b, n=48	38 - 79%	4 - 8.5%	6 - 12.5%

Conclusion

Workmats have proved to be a useful training tool by providing basic information on PROs and enabling regulators to better understand the field. The fact that 87.5% of the regulators said that this training might change their way of reviewing files and 90% of all attendees might recommend the session to colleagues encouraged us to plan sessions in 2004 in other European countries and the US.