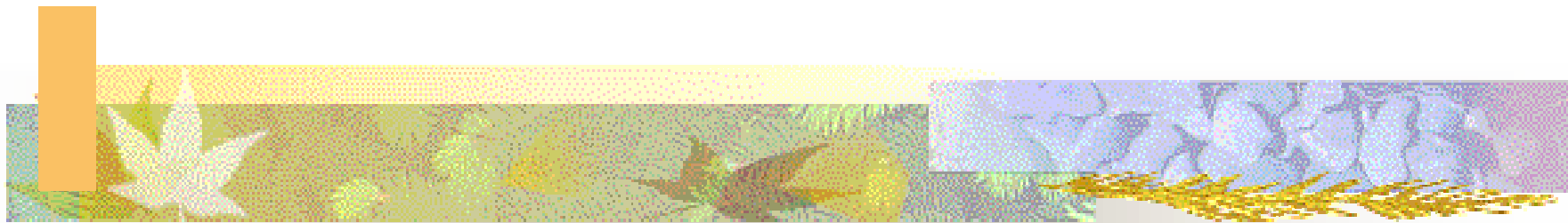


ERI QA recommendations for translation and cultural adaptation of HRQL Measures



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Background: Why? (1)

- European regulators concerned about the « International Validation of HRQL Questionnaires »*

(*meeting between ERI QA and representatives of the EMEA)



Background: How? (2)

Review of Existing Guidelines

- Lack of consensus regarding the terminology
- Differences in methodologies
- Only two papers explored in detail the key issue of equivalence of HRQL measures across countries and cultures
- Finally with only two articles comparing methodologies, the review could not determine the best method to apply



Objectives

- To develop a paper describing principles of good practice for use by regulators
 - Focus on Linguistic Validation (LV)
 - The document is developed in two parts:
 - Review of existing guidelines
 - Checklist to be used during regulatory review process
- To stress importance of LV report to track decision-making



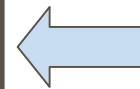
Structure of LV Checklist (1)

- Description of Steps
- Team involved
- Minimal Requirements
- Links to equivalence

Structure of LV Checklist (2)

11 Items (+1)

- Conceptual Definition (1)
- Forward translation (4)
- Back translation (3)
- Cognitive debriefing (2)
- Harmonisation (1)
- *Psychometric Evaluation (+1)*



**LV
Step**



What's next ?

- Disseminate and Publish Checklist
- Discuss applicability of Checklist on all types of PROs
- Collaborate with other groups for consensus
 - Discuss controversial points
 - Another Harmonization Project??