Translating Clinical Trial Outcomes Measures

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An overview

SEEd

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Introduction

The purpose of this book is to provide a general overview of the translation and cultural adaptation process of clinical research survey instruments with a focus on the linguistic aspects of the process. Survey instruments here refer to any text, printed or electronic, prepared in order to collect information in a clinical research setting. This broad definition covers patient-reported, clinician-reported, and caregiver-reported outcomes measures, as well as patient diaries, indexes, scales, symptom checklists, etc. The target audience includes translation agencies that specialize in the translation of clinical research survey instruments, contract research organizations and their respective translation departments, regulators, industry, and academia.

The book is made up of two parts. The first part offers a brief introduction to selected linguistic aspects of translation. Its purpose is twofold: firstly, to provide definitions of key linguistic concepts that will be used in the following chapters, and secondly, to set a tentative theoretical framework for the translation and cultural adaptation process. The second part describes the main steps used in the translation process. It relies heavily on the *"Principles of Good Practice for the Translation and Cultural Adaptation Process for Patient-Reported Outcomes (PRO) Measures"* [Wild, 2005]. The original Principles of Good Practice (PGP) identified ten steps:

1. Preparation;
2. Forward Translation;
3. Reconciliation;
4. Back Translation;
5. Back Translation Review;

6. Harmonization;
7. Cognitive Debriefing;
8. Review of Cognitive Debriefing Results and Finalization;
9. Proofreading;
10. Final Report.

These steps have been rearranged and modified in order to optimize the presentation of material and also to reflect the most recent trends and developments in the area of translation and cultural adaptation. Since the book focuses almost exclusively on the linguistic aspects of translation, the irrelevant procedures have been removed from the discussion, and new, more relevant ones, have been added. Thus, the Preparation step now includes a new process that has recently received growing attention in Clinical Outcomes Assessment (COA) development and linguistic validation community, namely, Translatability Assessment. Forward Translation and Reconciliation are described in one chapter since the two steps are closely interconnected and interdependent. For the same reason, Back Translation, Back Translation Review and Harmonization are presented in one chapter. The Proofreading step has been extended to include Check, Revision and Review, in line with the new ISO 17100:2015 standards for translation services. The preparation of the Final Report has not been included in the discussion as it is not relevant for the description of linguistic aspects.

The discussion of each step includes the definition of its most important components, a list of key professionals involved in implementing the step, a detailed critical description of the processes involved in the implementation of the step, as well as a brief overview of areas where more research is needed. The latter component was added because we felt that the translation and cultural adaptation process should be based on sound empirical evidence drawn both from daily practice of language professionals as well as high quality research initiatives.

The final chapter covers the translation of electronic versions of clinical research survey instruments, with a brief discussion of the necessary modifications of each step in order to meet the needs of an electronic instrument translation.