



**Summary of translation method used by MAPI Research Institute, 27 rue de la Villette, 69003 Lyon, France.**

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The aim of a linguistic validation process is to obtain a translation of an original instrument in a target language that is both conceptually equivalent to the original and easily understood by the people to whom the translated questionnaire is administered.

This is achieved using an internationally accepted translation methodology recommended by Mapi Research Institute which is outlined below. This describes the general approach taken by Mapi to translations. For local reasons, the translation process may differ in minor respects for some languages. This translation of the RMDQ was carried out in collaboration with Professor Martin Roland, Director of the National Primary Care Research and Development Centre, at the University of Manchester.

### 1.1. Standard linguistic validation process

The standard linguistic validation process recommended by Mapi Research Institute comprises the following steps:

Conceptual analysis of the original instrument in collaboration with the developer to define the notions investigated through each item.

The developer is also involved throughout the linguistic validation process whenever further clarification is needed.

1.1.2. Recruitment and briefing of a consultant in each target country as project manager and supervisor of the translation process.

#### 1.1.3. Forward translation step

a. Production of two independent forward translations of the original questionnaire by two professional translators, native speakers of the target language and fluent in the source language.

b. Production of a reconciled language version on the basis of the two forward translations and of a report in English explaining translation decisions.

c. Review of the report by Mapi Research Institute and discussion with the consultant.

#### 1.1.4. Backward translation step

a. Production of a backward translation of the reconciled language version into the source language by one professional translator, native speaker of the source language and fluent in the target language.

b. Comparison of the backward translation and the original, analysis of

the discrepancies encountered, resulting, if necessary, in changes in the reconciled translation in the target language, and subsequent production of a second language version.

c. Production of a report in English explaining translation decisions.

d. Review of the backward translation and report by Mapi Research Institute and discussion with the consultant.

#### 1.1.5. Pilot testing

##### 1.1.5.1. Clinician's review

a. Review of the second language version by a clinician appointed by the sponsor in the target country to get feedback from experts in the relevant medical field.

##### 1.1.5.2. Cognitive Debriefing

a. Test of the second language version on a small sample of individuals representative of the target population and native target language speakers, in order to assess the clarity, appropriateness of wording and acceptability of the translated questionnaire.

b. Production of the third language version based on the results of the clinician's review and respondents' feedback, followed by a report in English explaining translation decisions made.

c. Review of the report by Mapi Research Institute and discussion with the consultant, resulting in the third language version.

#### 1.1.6. International harmonisation

a.. When more than one language is involved, comparison of all translations with one another and with the original, during a meeting with translators representing each target language in order to ensure conceptual equivalence in all versions.

b. Discussion of suggestions made during international harmonization with the consultant, resulting in the fourth language version.

#### 1.1.7. Proof-reading

a. Proof-reading of the fourth language version by the consultant and by one translator, native speaker of the target language.

b. Discussion of proof-reading results with the consultant, resulting in the final language version.

#### 1.2. Adjusted linguistic validation process

For some languages that are close to one another (e.g. British English and American English), the complete standard linguistic validation process with forward and backward

translation steps may not be appropriate. For such cases, an adjusted linguistic validation process has been established.

The forward and backward translation steps are replaced by an adaptation step, where the work is based on a version considered as the "mother language" version.

The subsequent steps are identical to those used in the standard linguistic validation process.

This adjusted process is as follows:

#### 1.2.1. Conceptual analysis

See 1.1.1.

1.2.2. Recruitment and briefing of a consultant in each target country as project manager and supervisor of the translation process.

#### 1.2.3. Adaptation step

a.. Review of the "mother language" version by the consultant to check its suitability for the linguistic and cultural context of the target country, leading to the establishment of a first country-specific version.

b.. Production of a report in English explaining the decisions made.

c.. Review of the report by Mapi Research Institute and discussion with the consultant.

#### 1.2.4. Pilot testing

##### 1.2.4.1. Clinician's review

See 1.1.5.1.

##### 1.2.4.2. Cognitive Debriefing

See 1.1.5.2..

#### 1.2.5. International harmonisation

See 1.1.6.

#### 1.2.6. Proof-reading

See 1.1.7.