

What is Cognitive Debriefing?

Cognitive debriefing is a language test of a linguistically validated questionnaire of healthy volunteers or patients with a specific disease to prove that the translation is indeed clear, easy to understand, relevant and culturally adapted to future users.

1. Purpose

The purpose of each interview is to assess the clarity of the translation of the patient's questionnaire, its relevance to a specific culture, and whether it is appropriate for the target audience.

Note: The purpose of the interview is NOT to gather information on whether the patient is in good or bad health.

A language expert reviews the patient's responses and assesses whether the translation needs to be revised. The language expert makes the final decisions on whether further changes to the translation need to be made to ensure that any patient can understand each translated question. The revised translation is usually used in much larger future studies.

It is important for the interviewer to keep in mind that the sole purpose of the interview is to confirm that the patient's questionnaire is clear and appropriate for the language and country in which it is being tested.

The cognitive debriefing form provided should be used as a tool for interviewing respondents.

2. Interviews

The purpose of each interview is to identify the questions and the possible answers in the patient's questionnaire that are problematic, to determine why, and to record the suggestions given by the respondents.

The interviewer encourages respondents to focus on how the questions are expressed, rather than the order or structure of the possible answers.

Each interview consists of three parts:

1. Introductory part, in which the interviewer provides information about the interview to the respondent;
2. Filling in the questionnaire by the respondent independently;
3. Discussion of the point's statement between the respondent and the interviewer.

Presentation of the interview to the respondent

- The interviewer explains that the purpose of the interview is to discuss the translation of the questionnaire in order to understand whether the way of expression is clear and easy to understand before distributing it to future respondents.
- The interviewer emphasizes that the information provided by the respondent will remain anonymous (i.e. his/her name will

not be recorded and will not be linked to what he/she says) and confidential (i.e. it will not be disclosed out of context of the translation project and will only be used to improve the translation).

- The interviewer reminds the respondent that his/her participation is voluntary, that he/she may refuse to participate or terminate his/her participation in the interview at any time and is free to refuse to answer some of the questions.
- The interviewer explains what will happen during the interview and what the expected duration of the interview is.

Completion of the patient questionnaire by the respondent

- The interviewer gives the questionnaire to the respondent and asks them to complete it independently. If the respondent asks for help, the interviewer should encourage them to answer as best as they can, but the interviewer does not help them understand the question. At the same time, the interviewer does not force the respondent to answer every question.
- The interviewer reminds the respondent that their main interest is not to answer each question, but it is their opinion and suggestion regarding the expression of the question (because it is translated from English). The interviewer reminds the respondent that their opinion and suggestion will be used to improve the translation.
- The interviewer notes the time each respondent takes to complete the questionnaire and writes it down in minutes.

Discussion of issues

- General impression: the interviewer asks about the general impression of the respondent from the questionnaire: - is it clear and easy to understand?
- Is it easy to answer the questions, i.e. did he have difficulty choosing the possible answers ("No", "Yes, to some extent", "Yes, to some extent")
- Is it too long?
- Is it suitable for the condition?
- Are the instructions clear?
- Review of the questions one by one: the interviewer goes through the whole questionnaire question by question and checks:
- Was the question difficult to understand and if so, why? Are there words that are difficult to understand, or is the meaning of the question unclear?
- How does the respondent interpret the question? The interviewer encourages them to explain what they think the question means, and what it refers to in their daily life or experience.
- Would the respondent express this question in any other way and how?
- Are the possible answers clear, are they sufficiently different from each other and are they compatible with the question?
- The client sends the project for cognitive debriefing stating the following requirements:
- Number of healthy volunteers or patients with a specific disease to be tested on the questionnaire (usually 5, in very rare cases 10)
- Age groups (usually 18 to 80 years old; sometimes children are included who need to be interviewed with their caregivers and/

- or parents)
- Education (people with both secondary and higher education should be involved)
- Male to female ratio (2: 3 or 3: 2)

The Provider makes an offer for the service by e-mail and upon approval of the Client the Provider contacts its doctor-consultant for the recruitment of patients with the respective disease and/or posts an ad on the internet. Once the Provider recruits the required number of patients according to the Client's requirements, he fills in the recruitment report stating the number of patients, the type of disease, the date of diagnosis, demographic data such as age, education and occupation and the name of the drugs that patients take currently (if any). Neither the Provider nor the Client collects personal data from patients such as names, address, personal identification number, medical records, etc. During the selection, the participant is informed that the interview would be recorded on audio media.

The client then approves the recruited patients and sends the translated files ready for testing by the Provider. The provider contacts the recruited patients and arranges dates for the interviews, which take place at a convenient day and time for the participants. Prior to the interview, the participant fills in a Declaration of Confidentiality and Non-Disclosure of Personal Data, as well as the clinical questionnaire itself. During the interview, the interviewer asks questions about whether the text is clear and easy to understand, whether it corresponds to the patient's condition, how he can express the sentence in his own words and whether the questions and answers correspond to what has been said. After the interview, the Provider prepares and submits the following documents to the client:

- Completed questionnaire from each interview (to be filled in by the patient);
- Declaration of confidentiality and non-disclosure of personal data (to be filled in by the patient);
- Completed cognitive debriefing form for each interview (to be filled in by the interviewer);
- A report on the recruited patients (although incomplete, it is submitted before the start of the interviews so that the client can approve the participants). At the end of the project, the provider submits the same report in its final version;
- Analysis of the results (the interviewer writes down the patient's remarks and makes suggestions for improvements in the translation);
- Audio recording of the interview (the patient is informed in advance that what he/she says will be recorded on audio media);
- Reconciliation report (it includes recording the patient's remarks, the interviewer's opinion regarding the patient's remarks and suggestions and making improvements in the direct and reverse translation);
- Updated translation of the clinical questionnaire in the target file.

Personal data is stored in a manner that ensures confidentiality, protection against loss, theft or destruction.

In case it is necessary to use property belonging to external providers, the conditions for its management are determined in the contract/order for assignment of the implementation of the process.

In cases where the property of a client or an external provider has been lost, damaged or otherwise found to be unusable, the manager shall inform the client or the external provider and store documented information about the incident.



Nataliya Nedkova



Nataliya Nedkova is a translation company owner of NN Translations EOOD with a focus on medical and pharmaceutical translations for the Balkan languages and a well-established English-Bulgarian translator, proofreader, cognitive debriefer and linguistic validation consultant with 16 years of experience in the medical, pharmaceutical, law, technical, marketing and business industries as well as the fashion, cosmetics and tourism sectors. Nataliya Nedkova is passionate about the English language and in 2005 she also obtained a Bachelor's Degree in English Language and Literature from the St. Cyril and St. Methodius University of Veliko Tarnovo, Bulgaria, and a Master's Degree in Translation Studies from the same university. In 2011 she became a member of the Chartered Institute of Linguists, UK and in 2012 she became a Proz Certified Pro member. In 2013 Nataliya also joined the International Association of Professional Translators and Interpreters (IAPTI).