

CASE STUDY: CLINICAL TRIALS

Brief

Our client in the pharmaceutical sector was looking to launch a clinical trial to test out a new drug for the treatment of Alzheimer's disease. For such projects, there is always a lot of documentation that needs to be prepared to be given out to participants and to be made generally available.

As this was a global clinical trial operating across a number of countries, it was very important that all relevant materials were translated in order to ensure a complete understanding by participants of what was required and to be expected. Comms was selected to translate the materials into 18 languages for distribution to patients and healthcare professionals.

Documents Required

The range of documentation that we translated for our client included:

- Invitations to potential participants
- Handouts
- Posters
- Patient information leaflets
- Appointment reminder cards
- Visit booklets
- Thank you cards





Translation and Localisation

We started out by translating the documents into the languages required for each trial. After that, everything was independently proofread by a second linguist, as per the ISO standard for translation services.

The teams selected for this project were hand-picked from our database of over 3,000 translators on the basis of their expertise in the translation of this type of material. They were qualified and experienced translators who had demonstrated previous work in the life sciences area.

For this particular project, our client did not require back translation of the translated text as a further review was to be carried out by their own internal native-speakers, although this step is a standard process that we would usually include for such materials.

Once the initial version of the translations had been finalised by our teams, we sent the documents off to our client for review and regulatory approval. As usual, the translations came back with very few changes and suggestions, and we then proceeded to the final stage of the project: multilingual typesetting.

DTP / Typesetting

As much of the documentation we had translated was given or shown to the patients as part of their involvement with the drug's trials, they had been designed to be visually appealing, and were created using standard graphic design software; in this case, QuarkXPress.

In many of the languages, our client's English-speaking DTP operators were not able to typeset the text themselves due to the complex nature of the scripts, so we were asked to produce translated artwork in each of the languages. In some cases, this also involved localising colours and images to better reflect local customs, whilst in others we simply needed to ensure the text was inserted into the template correctly and the language-specific line breaks and hyphenation rules applied properly. Once this was complete, we sent PDFs back to our client for their approval and final review before printing.

Result

Since the initial project, Comms has been asked to localise, adapt and translate a range of similar material for other trials in more languages. In several cases, we were also asked to provide supplementary cognitive debriefing support to their local partners to assist in the linguistic validation process.