



MANAGING THE TRANSLATION OF CLINICAL TRIAL DOCUMENTATION

There is a spate of global clinical trials during the current decade. The need to conduct trials on a larger population as demanded by the regulatory authorities, as well as conducting trials over a longer period is making pharmaceutical companies and clinical research organizations (CROs) go global.

Among the popular destinations for conducting clinical trials are the South Asian countries like Pakistan, Bangladesh, Sri Lanka and especially India. A large population which has resulted in easier recruitment of subjects, lower costs of running the trials and availability of trained manpower/organizations to conduct the trials has resulted in almost a 100% growth in the number of clinical trials conducted in India over the past two years.

However, conducting clinical trials in a linguistically diverse country like India comes with its share of problems. Though the costs are lower, the aspect of communicating with the subjects in a country with so many languages gains tremendous importance. All patients facing clinical trial documentation may need to be translated into the target languages of the trial population, for patients who are not familiar at all with medical terms. The documentation is replete with industry specific technical and medical terms. When it is translated, it has to be understood by the most naïve of the patients. So simply having a language translator is not enough, the translators of clinical research documentation need to have expertise to explain medical terms in a layman's language and access to subject matter experts for clarifying any new terminology he comes across.

The team involved in the clinical research has to understand the importance of translation during planning stage of the trial. The documents which are normally translated in a clinical research are the Investigator's Brochure, Clinical Study Protocol, Subject Information and Informed Consent Form (ICF). The quality of translation assumes significance as a bad translation can result in adverse patient reactions but more commonly a significant delay in the trial process. Delay in the translation process can delay the entire project. Also a bad translation found in the implementation stage can result in significant reworking. This ultimately results in a delay in getting the drug to market and in some cases losing competitive edge.

Linguistics is not a core competency of the pharmaceutical companies and clinical research organizations (CROs). In multilingual translation as is the case in clinical trials



in India, there are many aspects which need to be managed to ensure accuracy, lucidity and delivery in time. So project management of translations assumes significance here.

THE TRANSLATION PROCESS FOR CLINICAL TRIAL DOCUMENTS

1. The process begins with a preparatory step, to assess the documents to be translated. For this the documents are analyzed and anything that may not be entirely comprehensible is identified. In this step, concepts requiring clarification are identified and confirmed with the CRO.
2. The second stage is forward translation and proofreading. These two are done by two different linguists. The translation produced by the forward translator is verified against the original by the proofreader to ensure it captures the message of the original document. The proofread document is sent to the original translator who considers each suggestion and implements them on the original translation
3. Next is the stage of back translation. A third independent linguist translated the translated document back into source. This helps to evaluate the level of understanding of the patients of subject language of the documentation provided to them.
4. In reconciliation, any difference between the source document & back translation is reconciled. Discrepancies are analyzed. If necessary, portions of the forward translation is amended if it is felt that it will provide a better understanding to the subjects of the trials.
5. Though many CROs ignore this step, an importance step to ensure a successful translation is cognitive debriefing, where the documentation is tested with about 5 members of the target populations with similar demographical characteristics to the subjects of the clinical trials. A questionnaire accompanies the translation, and the response is analyzed by the project team to identify areas which may still be unclear or misunderstood. The results of the debriefing process are used to further refine the translation.

As the process is significantly complex and needs expertise, it is important to choose an appropriate Language Services Provider (LSP) who is able to handle the entire process. The LSP needs to have firm grip on managing the language as well as the processes at each stage.

If a trial is ready to begin, but the translation is not ready, the delay can cost millions to the sponsor. So the focus is to ensure that the translation is delivered at the right time



using resources having the right skills. The resource base needs to be refined and enlarged constantly to suit the needs of a fast growing industry. Only a suitably experienced Language Services Provider (LSP) can achieve this.

ABOUT INFORAYS

Inforays is a leading Language Services Provider (LSP) in India . Inforays has long-term partnerships with pharmaceutical companies and CROs all over the world for their requirements of translation of clinical research documentation into Indian languages.

Inforays handles the entire process of translation of clinical research documentation as per the requirements of clients

Inforays translation service handles all Indian languages which include

Hindi
Bengali (Both India & Bangladesh)
Urdu
Tamil
Marathi
Telugu
Malayalam
Kannada
Gujarati
Oriya
Assamese

Inforays' talented pool of translators and subject matter experts ensures quality translation at an economic cost right within your deadline. Also we have expertise in Indic font issues which are a concern for many clients.

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