

# Accurate Translations With Clinical-Focused PMTs



## Executive Summary

Complex global study requirements mandate that translation service companies specialize in the Life Sciences industry. Project Management Teams (PMTs) can assist in streamlining collaboration and delivery of an international study, helping control costs, manage risks and improve patient care.

Taking a quick survey of any pharmacy's inventory, you'll notice specific information provided in many languages. Side effects, dosages, and warnings are only a small portion of the critical communication provided in languages other than English. Milton Friedman's "The World is Flat" describes the real world in which we, as clinical players, operate on a daily basis. Ease of entry into Rest of World (RoW) countries is being expedited by technology, treaties, and global access to shipping at an unprecedented rate. Life Science companies are constantly breaking new ground as naive populations are made available and previously unreachable areas are uncovered. The translation of material into specific languages and dialects has moved to the forefront of the industry as a primary influencer on study timelines and increased risk, potentially resulting in increased costs.

English is often touted as the official language around the world. However, of the 5.5 billion people around the globe, only 375 million people speak it as their primary language and 500 million speak it as their second. Although English is, by international treaty, the official language for aerial and maritime communications, clinical studies require that native populations understand the information at a very personal level, most often, specific to their native dialect within the locality or village in which they reside. Many directives within the EU exist that make it mandatory that clinical and medical labels be translated into the native language in which they are tested (Medical Device Directive – MDD, In-Vitro Diagnostics Directive – IVDD, etc).

The FDA mandates that patient information is required to be in the language of the subject or representative. Informed Consent Forms, Diaries, Recruitment Brochures and Patient Study Guides, are examples of material that require the content to be conveyed in the local dialect in order to provide a thorough understanding at the basic level. Any ambiguity could result in a violation of FDA regulation, along with subsequent penalties. Translation service providers specializing in clinical study material development need to be aware of, and understand, these stringent requirements. An ideal translation process for a clinical study follows specific, independent steps designed to

convey consistent information. Study translations need to communicate the true intention of the study, accurate site direction, and precise understanding by the patient. Finding a company specializing in expediting the clinical study process and providing proven clinical translation experience can help create a seamless process where the overall negative impact on the timeline of multiple RoW languages and dialects is minimized.

It is essential that translation companies specializing in Clinical Research have established PMTs versed in global management of studies in order to provide their Life Sciences clients the efficiency and cost savings of a single-source provider. The PMT will either manage all aspects of the clinical translation project independently or in close collaboration with client teams, from translation and graphic design to print and distribution services, streamlining the process, improving already rushed timelines and reducing overall cost and risk. The responsibilities of the PMTs include: consultation, proposals, file management, project coordination, customer service and quality assurance. Having an array of integrated design and translation services offers support in the development of patient- and site-focused materials in any language, with the resources and expertise to produce and distribute the materials internationally.

Employing a Global Network of Experts specializing in Life Sciences is an absolute necessity for translation providers in the Clinical Research field. As any country within the global network can be optimized for the focus of any particular study, it is imperative that hundreds of professional linguists, graphic designers, project managers and medical experts be readily accessible all over the world. Strict selection criteria should be established and documented based on source and target language proficiency, educational and advanced training credentials, subject matter expertise, and a demonstrated history of success.

Health care and regulatory requirements demand that quality assurance documentation be provided to the IRBs and Ethics Committees. This is in addition to the translator and Life Sciences experience certifications. Clinical study translation companies need to be able to guarantee a standardized, multi-phase translation process for all languages, and be willing to provide a notarized translation certificate as verification. This process needs to include the PMT, and encompass translation, editing, proofreading and review. Teams of professional linguists for Life Sciences should be relegated to native speakers of the target language for translating, editing and proofreading wherever possible.

Whatever the clinical research study requirements, it is critical that limitations not be imposed on site and patient selection due to language availability. Partnering with a translating company capable of managing hundreds of translators, and with an established and documented process in close collaboration with experienced PMTs, will provide improved timelines, controlled costs and managed risks.

“Accurate Translations With Clinical-Focused PMTs”  
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