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The key role of the translation of clinical trial protocols in the university training of medical translators

Alicia Bolaños-Medina, Universidad de Las Palmas de Gran Canaria (Spain)

ABSTRACT

Clinical trials conducted over the last three centuries have made advances in pharmacological knowledge and medical treatments possible. Although the consequences of an inaccurate translation of clinical trial protocols (CTPs) can be very serious in terms of human lives, credibility and economic revenues, translation is rarely given the attention that it requires. An updated insight into the translation of CTPs is offered with special stress on regulatory constraints, cultural aspects, quality assurance, the implementation of technology, the requirements for specialised biomedical translators and the localisation process itself. Finally, several pedagogical features of its instructional potential are presented, particularly those which make the translation of CTPs most suitable to be included in the University training programs of scientific and technical translators, both as an end in itself and as a key methodological step towards the mastery of the translation of other specialised genres.

KEYWORDS

Biomedical translation, clinical trial protocol, translation process, specialised translation, scientific and technical translation, translation teaching, translation training

1. Introduction

Advances in pharmacological knowledge and medical care have been possible thanks to clinical experiments conducted over the last three centuries. A clinical trial is still the most definitive method of assessing whether an intervention has the postulated effect (Friedman et al. 1985: 3); and can be defined as a scheduled experiment intended to assess the efficacy of a treatment in humans by comparing the outcomes in a group of patients treated with the test regimen with those found in an equivalent group receiving a control regimen (Meynert 1986: 3), all participants in both groups being enrolled, treated, and followed over the same period.

The middle third of the 20th century witnessed a blossoming of pharmaceutical discoveries, with breakthroughs in the production of synthetic vitamins, antibiotics and even hormones. Pharmaceutical firms in the United States, Europe, and Japan expanded rapidly after the Second World War with robust investments in research, development, and marketing. In the second half of the twentieth century, joint efforts involving more than one independent centre were needed, both so that a larger number of patients could be recruited, and in order to achieve clinical investigations of the highest quality. For instance, in the Aspirin Myocardial Infarction Study, initiated in 1975,

30 centres enrolled the necessary 4200 patients in one year [...] The largest of these centres enrolled slightly over 200 subjects over the initial three years, [...]

then the single largest centre would have required 21 years to complete the study (Friedman et al. 1985: 286).

These multi-centre trials soon became international and required professional and specialised translation services. Not only did they account for a more representative sample of the study population as far as race, geography, socioeconomic status and even lifestyle were concerned, but they also promoted enriching collaborative work among researchers from different backgrounds on a particular common problem.

Whereas it was common to speak of an American, German, French, or British drug company as recently as fifteen years ago, mergers and substantial cross-national investments in research and development have since rendered such demarcation somewhat irrelevant. Between 1985 and 2005, nearly 40 major mergers produced firms of an unprecedented size and scope in the pharmaceutical industry. Nowadays, following the consolidation of such important multinational pharmaceutical companies, there is a trend towards delocalising clinical trials in emerging countries, which represent a growing and prosperous market (Muddyman 2008). In a recent study published in the *New England Journal of Medicine*, Glickman *et al.* (2009) reviewed 300 articles reporting results of clinical studies in major scientific publications in 1995 and 2005, only to find that around one third of the clinical trials were conducted solely outside the United States. Results show that the largest proportion of study sites are also abroad and include developing countries; similarly they show how the percentage of studies conducted in the United States and Western Europe has decreased. The main reason for this delocalisation process is related to the reduction of costs and the enrolment of more willing participants with varied diseases. Other factors involved in the decision to situate a study outside Western Europe are “investigator availability, regulatory objectives, commercial planning, the sponsor’s previous experience in developing countries and timing” (Wade and Nowell 2007: 38). It is foreseeable that there will be an increasing need for global trials—and, presumably, clinical trial translation services—in the years to come, as less common medical conditions, and diseases that have reasonably effective standard therapies, are targeted (*ibid*).

Every pharmaceutical product demands a particular preparation and trial process before being ready for human use and it has been stated that pharmaceutical companies can spend more than ten years getting ready to launch a new drug on the market, and that the process can cost over 500 million dollars (Global Translation 2010). Although the consequences of an inaccurate translation can be extremely serious in terms of human lives, credibility and economic revenues, translation is often the last step in the planning of an international clinical trial, and it is rarely given the attention that it requires (Maeda-Nye 2009). Faulty translations may entail the “failure of the participant to act as instructed, disparities in prescription and administration of the study preparation and reduced

likelihood for appropriate follow-up and treatment of the underlying conditions and/or of side effects of the trial” (Eldar and Wexler 2009: 15), not to mention physical or emotional damage, misconduct of the experiment, time and money (*op.cit.*: 32).

Moreover, regulations regarding the obligation to translate all documents involved in a clinical trial differ from country to country, which leads to some trials being conducted without being completely translated, sometimes even as a way to shorten the time before approval (Shashok 2008) and reduce costs, to the detriment of the quality of the whole clinical procedure (Wager 2008). Since translation needs to be involved at many stages, from clinical research and regulatory submission and review to production and marketing, improving the quality of the translation services can actually reduce timelines and even save money. The role of translation in affecting the likelihood of lawsuits or rejection by regulators and in the safety and efficiency of the final product should not be underrated either.

The aim of this article is to offer an updated insight into the translation of clinical trial protocols (CTPs) as well as to reflect on its suitability as a specialised genre to be included in the University training programs of scientific and technical translators. After considering the translation of research trial protocol in context, we will proceed to a brief introduction to the CTP as a textual genre which needs to be translated. Subsequently, some key aspects related to this specialised type of translation will be reviewed, after which several pedagogical features of its instructional potential are presented.

2. Translating clinical trial protocols: an updated insight

2.1. Clinical trial protocols as a textual genre

Every well-designed clinical trial requires a protocol, which assists communication among all the people working in the trial and can be regarded as a “written agreement between the investigator, the subject, and the scientific community” (Friedman et al. 1985: 7). Each protocol describes the objectives, design, methods, statistical aspects and organisation of a trial (Clinical Trials European Directive, 2001: 36). Clinical trial protocols (CTP) as a whole constitute a textual genre, as defined by Swales (1990), that is a class of communicative event that takes place in a given communicative situation with a particular purpose and which presents a characteristic pattern of textual conventions in terms of schematic structure, style, content and intended audience. This particular genre presents two main focuses: an exhortative contextual focus, according to Gamero-Pérez’s classification (2001) following Hatim and Mason (1990), who define its aim as the formation of future behaviours through the regulation of action and thought with instructions; and an expositive focus (e.g. technical description). Although both focuses

are present here to some extent, they seem to alternate in importance and can be considered as being of a primary or secondary nature depending on which particular section we analyse. As for the agents involved in communication, while multicentre CTPs can be written by a chief researcher, or by a principal researcher when they are carried out in a single centre (Montalt-Resurreció and González-Davies 2007: 81), among the target readers of a clinical protocol there are ethics committees, researchers, monitors, pharmacists and the research team (Hurtado-González 2009).

Clinical trial protocols are written, formal documents of a very specialised nature which show a high degree of technical complexity and require a clear, concise and accurate style so that any ambiguity can be prevented (Hurtado-González 2009). The language used in CTPs is becoming more and more differentiated, as it blends medical, administrative and technical jargons (for instance, statistical terms) and it involves many traits which are not seen in other medical documents (Mugüerza-Pecker 2010). Thus, terminology from any field of medicine mingles with that from laboratory practice and from the Medical Dictionary of Drug Regulatory Activities or MeDRA (Maintenance and Support Services Organisation, 2011) and is very often unique to every individual trial (Wade 2006: 17).

However, not all documents related to clinical trials involve a highly technical content and the recipients of the translation must be taken into account. Clinical trial documentation producers and translators must be aware of the fact that each participant is supposed to have a different level of understanding of the development and use procedures of clinical trial-related documentation, which is best illustrated if we compare that of participants and the specific site researchers. For instance, in order to standardise the conduct of the trial and to facilitate communication between all the individuals involved, several types of instructions, which may be placed in an appendix, in the data collection forms, or not included in the protocol, can be created. They can also be added in a 'manual of procedures' together with other information. Spilker (1984: 205) distinguishes instructions to be given to patients; to be read to and discussed with patients and investigators; those prepared for investigators explaining how to perform specific tests; or for investigators and research coordinators, designed for the completion of each page of data collection forms; instructions on how to obtain and manage biological samples; those intended for pharmacists or for nurses or other specialists on their role in the study, or any other which may involve other topics related to the study.

In addition, Informed Consent Forms record dated and signed decisions to take part in a clinical trial, which are freely undertaken by individuals once they have been informed of its nature and risks; these documents must be easily understood by study participants and written in "lay terms." Dodsworth and Roe's (2009: 22) definition of this concept is illustrative:

By 'lay terms' we mean that the document should be written in simple English for a reading age of an 8-10 year old or at a level the average "Sun" reader can understand. Institutional Review Boards (IRBs) in the USA set an arbitrary grade level of the 6th-8th grade. The Flesch Reading Ease Score describes materials at 6th-8th grade reading level to have 14-17 words per sentence and 139-147 syllables per 100 words.

It has also been recommended that these documents should be kept as short as possible (Stiffler 2003) given their complex nature, both for the purposes of translation and back translation to check meaning.

Spilker (1984: 88) assumes that, even in different areas of medicine, protocol development tends to be carried out according to a given series of steps. Thus, protocols are conventional documents with a relatively patterned structure, although there may be slight variations among different authors. Those protocol format, content and administrative elements that may be relatively standardised according to Spilker (1984: 155), who refers to them as "boilerplate" sections, as they are similar from protocol to protocol, are shown in table 1.

A. Protocol format

1. Title page
2. Table of contents
3. List of abbreviations
4. References and appendices

B. Protocol content

1. Patient enrolment and duration of the study
2. Location of study site
3. Factors to control within or outside the study environment
4. Shipping of drugs to and from the study site
5. Obtaining, handling, and shipping biological samples
6. Defining the time of patient entry and completion
7. Eliciting and categorizing adverse reactions
8. Missed appointments
9. Patient lost to follow-up
10. Patient discontinuation
11. Early study discontinuation
12. Medical emergencies

C. Administrative elements

1. Administrative responsibilities of the investigator
2. Informed consent
3. Institutional approval
4. Confidentiality of data
5. Collection and processing of data
6. Publishing of data
7. Monitoring of the study
8. Protocol amendments

Table 1: Standardised elements in a clinical protocol (after Spilker 1984: 155).

Moreover, when writing or translating a clinical protocol, it is often assumed that it is a "self-contained document" (Spilker 1984: 88) that

does not need to refer to other protocols or texts for content, and should be regarded as such for translation purposes.

2.2. Regulatory constraints

The obligation to translate clinical-trial related documents varies from country to country. In the United States, all documentation for all participants and investigators must be in the local language (Wade and Nowell, 2007). In other countries, it is often taken for granted that most researchers are able to read and write English and this is one of the reasons why it is not compulsory to translate the texts specifically addressed to them, even though most regulatory bodies and ethics committees still require local language documents to be submitted for review and approval (*op. cit.*). For instance, in Spain, the current law has modified earlier legislation and it is no longer mandatory to translate clinical protocols. Nevertheless, it has been reported that translators and medical writers who work with Spanish researchers often conclude that sometimes “the latter may overestimate their English reading comprehension skills and misunderstand texts as a result” (Shashok 2008: 1).

It has also been stated that for national regulatory bodies of European Union countries it could be more convenient to accept English versions of the clinical protocols submitted for approval, since every member state has to record every trial conducted within their boundaries in the EudraCT Database in that particular language (Gómez-Polledo 2008: 72).

Before May 2004, there was no legislation at European Union level concerning clinical trials¹. Until that moment, Member States’ current practices diverged considerably, not only in terms of the rules on commencement and conduct of the trials but also with respect to the requirements for carrying them out, which resulted in delays and difficulties detrimental to the efficacious conduct of such studies. Then, the Commission Directive 2005/28/EC of 8th April 2005 came into force, which sets out the principles and detailed guidelines for good clinical practice as regards investigational medicinal products for human use, as well as the requirements for authorisation of the manufacture or importation of such products.

Nowadays all clinical trials worldwide are to be carried out in accordance with the ethical principles of the Declaration of Helsinki, which are consistent with Good Clinical Practice (GCP). By taking into consideration the current GCP of the European Union, Japan, the United States, Australia, Canada, the Nordic countries and the World Health Organisation (WHO), the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) aims to provide clinical trials with a unified standard while maintaining safeguards on quality, safety, efficacy, and regulatory obligations to protect public health.

2.3. Localising clinical trial protocols

Nowadays, pharmaceutical companies need more and more services that go beyond simple translation and enter the realm of localisation, that is, the modification of a product or a service to account for differences in different countries, markets or locales. Outsourcing to localisation and globalisation service providers has been a strategic decision so that they could remain focused on their core businesses. Involving as it does not only linguistic transfer but also content, cultural and technical issues, localisation accounts for changes in information, functionality, instrument design and all necessary aspects in an organised manner, thus facilitating quality assurance and control (LISA, 2003). This is particularly the case when it comes to trials being conducted in emerging and culturally distant countries in Asia, Africa, Eastern Europe or Latin America.

More recently, companies have begun to contract language service providers for all language and globalisation needs in the form of consulting services with reference to regional regulatory requirements, interpreting services, asking experts as technology advisors, etc. (Byrne and Ridgway, 2009). In this context, if translation is taken into consideration from the beginning of a study, it is more likely that all resources will be more efficiently assigned, delays will be more easily avoided and the documentation provided will be more “culturally and linguistically-appropriate” (Ecker and Peters 2007: 95). The moment immediately after deciding questions such as the countries in which the trial is to be conducted, the languages into which the documents need to be translated (for instance, Israel requires informed consents in Hebrew, Arabic and sometimes in Russian) and even while all documents are still under development, would seem to be the right time to fit translation in the planning process (Wade 2006).

2.4. Quality assurance

When conducting global clinical trials, the assumed risk increases dramatically due to the complexity added to their design by the question of language, which becomes “as critical as patient screening or any other trial preparatory component” (Wade and Nowell 2007: 39).

It has been stated that the quality of the translation of clinical trial-related documentation is rather poor nowadays; this is perhaps the case because of the relatively short timeframe given to translators in which they must complete their work (Mugüerza-Pecker 2010). It may also be due to the fact that the rare combination of professional translation skills and biomedical knowledge is not very common among professional translators (Eldar and Wexler 2009), or alternatively because the needs of the target reader of the translated document are not sufficiently taken into

consideration. Some cases of unsatisfactory translations in which the meaning had been considerably altered have been documented, and often led to the consultation of the English original version as the main binding document in the trial (Shashok 2008).

Among the factors that may jeopardise the safety of patients participating in clinical trials because of faulty translation, are: inconsistencies between the original text and the translated, inaccuracy, use of high language and omission of text. A sound review process once the translation is complete can take as long as 7 to 15 weeks, while providing reviewers with online tools or even outsourcing the review to an independent third party could improve this situation (Wade 2006).

The lack of consistency in the terminology and the methodology of different sets of quality guidelines available for translation and cultural adaptation is at the origin of the efforts made by a group of specialists working on Patient Reported Outcomes (PRO). The translation of PROs, a type of questionnaire designed to collect information directly from patients or subjects about their life, health condition, and treatment, illustrates the complex methodology put into practice so that quality and conceptual equivalence is assured. Considering the ten steps regulated by the principles of good practice reported by the International Society for Pharmacoeconomics and Outcomes Research, illustrates the efforts to safeguard quality assurance in this specialised type of translation: preparation, forward translation, reconciliation, back translation, back translation review, harmonisation, cognitive debriefing, review of cognitive debriefing results and finalisation, proofreading and final report (Wild et al. 2005).

2.5. Cultural aspects

Cultural differences between the countries involved in an international or global trial must be clearly understood and taken into consideration as they can negatively affect clinical research and even jeopardise the safety of a clinical trial. Indeed, some notions, ranging from the meaning of “research” itself to the ethics protecting the participants in the study, can be difficult to understand or may not exist in other languages or cultures. Cultural values and behaviour can present benefits and challenges for the sponsors of multinational clinical trials, in terms of internal and external management of relationships with subjects, investigators, and regulatory bodies (Stober 2003). As for the benefits, some cultures such as Japan and Russia are “cultures of compliance” and participants belonging to them tend to follow doctors’ instructions to the letter. However, that very same trait can become a problem when they do not easily complain or report adverse events.

The following cultural factors (Wade and Nowell 2007:39) must be taken into account if a global trial is to be successfully completed: differences in

the practice trends of physicians in the community involved (for example, when scheduling subject visits in Latin America, for many physicians work in hospitals only in the morning and spend the afternoons in private clinics); in standard therapies available for the condition being investigated; in referral patterns to the sites; in a patient's acceptance of 'experimental' therapies; in a patient's and family's attitudes to mental illness; in sensitivity toward questions regarding topics such as sex and in attitudes when responding to the limited efficacy of some therapies. Finally, the investigator's approach in presenting the study to the participants, and the degree of education of the site population, must also be borne in mind.

In order to overcome these cultural barriers, various measures have been suggested, such as enlisting the help of 'cultural experts' (Stiffler 2003) and implementing training programs for the medical personnel of the foreign sites participating in the study (Adams et al., 2005). Undeniably, accurate translation of study documents by native speakers from each country or locale plays an important role in the success of trials in any particular region (Politis-Virk 2009).

2.6. Technology, translation and clinical trials

As clinical trials and the pharmaceutical industry become more international and thus involve multiple sites in a wide range of countries with truly global virtual teams, communicating and accessing data efficiently from various sources worldwide is a crucial challenge.

The rapid implementation of Information Technology (IT) in recent years is intended to enhance data accessibility, assist data processing, promote flexible workflow and improve strong regulatory compliance, thus generating data of a higher quality. This is the case of software for electronic data capture (EDC) and data mining, involving the use of electronic Case Report Form (eCRF), electronic Patient reported outcomes (ePRO), interactive voice response (IVR) systems, Web portal technology for communication among clinical partners and regulators and mobile devices. Likewise, robust document management applications are necessary to handle new standard document formats defined by regulatory bodies (Beyster, Hardison and Lubin, 2005: 6) such as the International Conference of Harmonisation (ICH), like Structured Product Labelling (SPL) or the Electronic Common Technical Document (eCTD).

Each of the many electronic modalities of data collection which apply to clinical trials, such as hand-held devices, digital pens, tablets, touch-screen, etc. (Wade, 2008a) implies particular issues when considering their adaptation for all geographies in a given study. When the personnel involved in the trial feel more at ease in their native language, all software graphic user interfaces, documentation, and even eLearning materials should be localised in order to enhance compliance and the quality of

clinical data (Smyth 2010: 3) and “to ensure device effectiveness in patient reporting” (Wade, 2008a: 54). For instance, in the case of China, Smyth (2010) has even suggested that this localisation process should apply to the many relevant Chinese dialects.

The emergence of adaptive designs can be seen as an example of the impact of IT on overall clinical trial planning. In this way, ongoing clinical trials can implement changes in their initial plan, based on the data being observed and registered via EDC, and thus become more flexible. This trend is currently receiving increased attention as a way of improving the safety of a study and of reducing timelines (Wade and Nowell 2007). At the same time it could lead to an increased demand for translation of amendments in official protocol documentation.

The correct choice of the computer-assisted translation tools which best suit a particular assignment’s needs is fundamental both for the pharmaceutical industry’s interests and for those of the localisation provider company. Besides translation memory tools, the wide variety of business activities in and around the translation workflow can be better dealt with by using a translation management system, which acts as a sort of cooperative work environment which helps to centralise the language function, increases security and provides an audit and accountability during the process (Byrne and Ridgway 2009). Similarly, sign-off tools that help ensure compliance to regulations have also been devised (*ibid*). Other tools are translation review and terminology management software, although those products which include all the above mentioned features are, in general, in highest demand.

Most vendors provide a secure web portal within their work flow system, which allows clients to track a project from scratch and where clients can get quotations, upload files, check assignment updates and follow the progress of a project (Ribeiro 2010). Finally, the use of web-based collaborative technologies, which make the completion of forms by site personnel easier and the access to trial information more secure, has proven to be time-saving and particularly indicated for global trials (Smyth 2010).

2.7. Requirements for biomedical translators of clinical trial-related documentation

It has been suggested that, in an ideal situation, requirements for biomedical translators of clinical trial-related documentation should include (Ribeiro 2010; Byrne and Ridgway 2009; Eldar and Wexler, 2009; Gómez-Polledo 2008; Wade 2006; Dodsworth and Roe 2009):

- a high level of linguistic and translation competence;
- specific subject matter experience, degrees and certifications;

- a thorough and updated knowledge of the pharmaceutical industry, particularly of the relevant local and international legal framework in which the clinical study in question is being conducted;
- knowing when and how to seek the assistance of dictionaries and specialists;
- computer-assisted translation tools skills;
- workgroup skills, since effective collaborative teamwork is a key factor in the process;
- a professional medical background;
- years of translation experience.

Some companies specialised in clinical research protocols globalisation go even further when demanding not only experience in the relevant scientific field in a country in which the target language is the medium of communication, but also in a country in which the source language is the official language (Ric International 2010). Other companies even state that the fulfilment of all these prerequisites is not enough, and they test and re-certify each translator, all of whom are under constant evaluation on a regular basis to be sure they are able to deliver the highest quality translations (Wade 2007; Ribeiro 2010).

Even if some of these requirements cannot be acquired in the University classroom exclusively, it is quite clear that a specific and quality training is necessary so that a thorough understanding of the tasks, underlying concepts and methodologies involved in this type of translation can be deeply rooted.

3. Clinical trial protocol as a particularly suitable genre for medical translators training programmes

The genre-based approach to teaching and understanding translation has been widely accepted as suitable for scientific and technical translator training, particularly in a professional-oriented context (Gamero-Pérez 2001; Bolaños-Medina 2002; Montalt-Resurrecció 2005; Montalt-Resurrecció and González-Davies 2007). Genres are semiotic categories which facilitate the identification and understanding of certain communicative acts by our cognitive systems (Bhatia 1993; Beghtol 2000), which, in turn, anticipate a series of expectations regarding participants, rhetorical purpose, social function, general communicative situation, sociocultural context and text conventions. If genre conventions are not taken into account when translating a scientific or technical text, the target text will turn into a merely “understandable” document which does not fulfil the addressee’s expectations and which does not function as it should in the target culture (Gamero 2001).

Following Montalt-Resurrecció and García-Davies (2007: 59), medical translators are particularly interested in genres because they are one of the four factors which translation strategies, procedures and decisions

may depend on, together with comprehension, translation process and interlinguistic differences. On the one hand, being conversant with the conventions of the source text genre is an important precondition in order to fully understand it, and having a clear picture in mind of the structure of different genres helps us expect the key information when reading the source text and drafting the target text. On the other hand, there are usually various differences in the way a same genre is instantiated in different cultures; and, finally, medical translators can be asked to draft heterofunctional translations, that is, producing a target text that does not necessarily belong to the same genre as the source text. Furthermore, difficulties in the translation of medical phraseology have also been related to text genre (Lee-Jahnke 2001: 148).

CTPs represent a genre medical translation students are not cognitively or communicatively familiar with, in contrast with others such as patient information leaflets or newspaper articles, and socialising with genres with which translators are not conversant is fundamental for the competent comprehension of specialised texts (Montalt-Resurrecció and García-Davies 2007: 60). Given the limited number of hours and credits university training courses of scientific and technical translation are allocated, the selection of those textual genres which seem more appropriate so as to achieve the objectives devised in the syllabus constitutes a fundamental step towards success. In this context, the inclusion of CTP translation in this type of courses can bring students several benefits as far as widening their range and level of competencies is concerned, both as an end in itself and as a key methodological step towards the mastery of the translation of other specialised genres, as will be demonstrated in the following paragraphs.

In a course of scientific and technical translation, work on CTP analysis and translation constitutes an adequate bridge between both main content units, since it gathers not only several distinctive traits from scientific language, but also from technical genres. As we have seen, CTPs present an exhortative contextual focus which aims at the formation of future behaviours through the regulation of action and thought with instructions; just like many other instructional technical textual genres, they give directions on how something should be done through a series of sequenced steps. The following example illustrates the way carefully sequenced steps are used to explain how to perform the global assessment of the patient in a particular clinical trial, with future passive forms functioning as imperative verbs:

Adverse event monitoring will be performed.
Sitting blood pressure and heart rate measurements will be obtained.
Physical findings and symptoms of CHF will be evaluated.
Resting 12-lead ECG will be performed.

Another extract from the study design section of the same clinical protocol features a typical trait of scientific language, a complex nominal group containing strings of premodifiers, each providing greater specificity:

This is a randomized, double-blind, placebo-controlled, parallel design trial in patients with severe (NYHA Class III/IV) congestive heart failure.

Furthermore, the translation of CTP in the scientific and technical classroom is a more than adequate introduction to the study of other scientific textual genres for several reasons. First, it can help improve a chronological understanding of the way scientific research is crafted into textual genres in the timeline, since CTPs represent the first stage of human research, which necessarily takes place before research articles, patient information leaflets or specialised advertisements in medical journals. Secondly, it naturally precedes training in research article translation quite appropriately, given that clinical trial contents are commonly brought together and summarised in the “Materials and Methods” section of IMRD articles.

On the whole, CTP translation implies apprehending key concepts of scientific experimental methodology that are fundamental to building a solid specialised medical knowledge, and an early understanding of these will prove useful when approaching other medical genres and documents. Very often, they are assimilated through confrontation with their so-called opposite notions (in both languages) and acquiring these *conceptual cores* (Vandaele 2001) in a pedagogical setting should establish a cognitive basis on which “allowing translators to design logical search strategies and to replace, over time, uncertainty with an ever-increasing wealth of knowledge” (*op. cit.*: 16).

Translating this specialised genre in the University classroom is also particularly indicated to comprehend the importance of what Nord called the “extralinguistic restraints controlling text production” (2000: 32), such as legal norms -which in this case vary from country to country- and other recommendations from professional bodies. As a way of illustration, we can refer back to the principles of good practice reported by the International Society for Pharmacoeconomics and Outcomes Research for the translation of Patient Reported Outcomes (PRO). Likewise, in some cases the assignment initiators demand an organisation-specific use of language, which gives the translator more restraints when making decisions while problem solving. In these cases, trainees gain more insight into the need for agreements to be reached by the client and the translator as to which sources of documentation are to be provided by the former and as to whether the translator, on completion of the translation contract, is to return to the client all documents made available for the translation project (DIN 2345: 5).

Becoming familiar with medical ethics, particularly confidentiality, is an essential value in medical translation practice (Montalt-Resurrecció and García-Davies 2007). If safeguarding the confidentiality of documents is important in other fields, in the pharmaceutical industry it becomes a fundamental prerequisite, for competition-related reasons. Accordingly, by analysing a given CTP translation assignment in a pedagogical setting, students realise they are obliged to ensure confidentiality themselves and to prevent confidential material becoming accessible to unauthorised third parties, very often by signing an agreement submitted by the client.

Guided objective-based run-in comprehension activities, such as identification of the boilerplate sections and their fundamental content units can help pave the way for translation-related ones. CTPs lend themselves to schematic translations, for instance, when specialised recipients need an overview of the original text so as to decide if there is a clear need to translate it completely or not. Thus, these new offers of information, according to a different skopos, can lead to several activities, such as retrieving all numerical information explained or the main features (i.e., objectives, independent variable, dependent variable, patient groups, etc.) in the target language. Another way is to ask students to fill in a chart with the key data—without paying particular attention to form—of every study phase, such as its type, duration, drug titration and supervision measures. These activities are also thought to improve the “ability to simplify the text,” which Eldar and Wexler (2009: 33) consider to be of great importance in research protocol translators.

The fact that clinical research protocols, as we have seen, involve documents designed for addressees with different levels of specialised knowledge (for instance, informed consent requires the use of lay terms and language), helps reinforce the students’ notion of text as means of communication used for specific purposes and recipients and the need for translators to adapt to them. Moreover, inscribing every translation assignment in the wider context of a localisation project with culturally distant locales, together with guided research activities on the relevant local and international sociocultural and legal framework in which the clinical study in question is being conducted, will highlight the importance of cultural and world knowledge for translation.

As we have previously seen, the language of clinical protocols involves many traits which are not observed in other medical documents. Classroom assignments involving the compilation of terminology for the client or aimed at creating separate glossaries of medical, administrative and technical jargons (for instance, statistical terms) can help to understand the blurred barriers of LSP terminology and documentation sources. It is important that these can be accessed with collaborative CAT tools so that multiple contributors can achieve the utmost level of consistency in the target text.

Finally, inter-genre contrastive methodology can prove useful, for instance, among CTPs and methodology sections in research articles in terms of similarities and differences of the key factors of standardised communicative situations. A genre shift translation which abides by target genre conventions has been found to promote reflection and a deeper insight into particular forms of scientific communication.

4. Conclusions

At a time when the pharmaceutical industry is still gathering momentum, global clinical trials constitute a cornerstone in the development of new drugs. Following the statement that safety is all-important and that full understanding of the clinical protocol documentation is essential, it is clearly highly desirable that all recipients should be able to access all the relevant information in a language they feel at ease in, which is not always the case with the protocol source language. In order to overcome the cultural and linguistic barriers imposed by the multiplicity of countries involved, globalisation and localisation techniques must be applied in a systematic manner, and together with translation itself, should be considered from the early stages of strategy planning.

Even though technology plays a key role in the management and translation of clinical trial documentation nowadays, the human factor must not be underrated, in terms of the need for specialised knowledge, multicultural teamwork skills, high linguistic and translation competences, experience in the biomedical field and even knowledge of relevant local and international regulations and procedures. Although some of these requirements cannot be acquired in the university classroom exclusively, it is quite clear that training which is both specific and of high quality is fundamental so that a thorough understanding of the tasks, underlying concepts and methodologies involved in this type of translation can be deeply rooted. As the inclusion of CTP translation in University training programmes of scientific and technical translators can help widen students' range and level of competencies in various ways, both as an end in itself and as a key methodological step towards the mastery of the translation of other specialised genres, the development of a more specifically honed methodology, so as to exploit its instructional potential, should be the focus of thorough research in the future.

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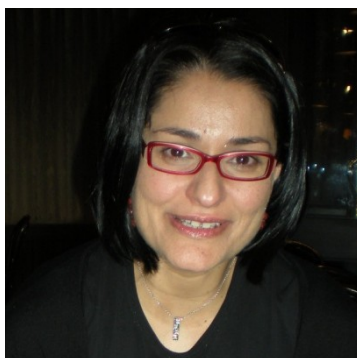
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Biography

Alicia Bolaños-Medina is a Doctor in Translation and a psychologist. She is also a professional translator and a Lecturer in Scientific and Technical Translation at the University of Las Palmas de Gran Canaria since 1996. Her main research interests include teaching methodology of scientific and technical translation, web site localisation and process-oriented studies in Translatology. She is currently a member of the research group *Expertise and Environment in Translation* (PETRA).



abolanos@dfm.ulpgc.es

¹ The provisions of the Clinical Trials Directive 2001/20/EC, on the approximation of the laws, regulations and administrative provisions of the member states, relating to the implementations of good clinical practice in the conduct of clinical trials of medicinal products for human use, only became effective and binding on 1st May 2004 (Wright and Nauwelaerts 2010).