CLINICALINGUA CASE STUDY

PARTNERING WITH CROs IN THE DELIVERY OF INTEGRATED LINGUISTIC SERVICES FOR GLOBAL CLINICAL TRIALS

GOAL

To support a leading CRO in its management of a multiple sclerosis clinical trial by providing copyright and translation assessment for Patient-Reported Outcomes instruments in 30+ languages

SITUATION

As a full-service translation provider, ClinicaLingua manages the translation and linguistic validation of Patient-Reported Outcomes instruments in accordance with principles of good practice established by the International Society for Pharmacoeconomics and Outcomes Research (ISPOR). We skillfully adapt this process to meet our clients' unique project needs and our methodologies are accepted by regulatory agencies. In this case scenario, a CRO providing site initiation services for an international MS trial sought ClinicaLingua's assistance in confirming the copyright status and licensing requirements for the Multiple Sclerosis Quality of Life-54 (MSQOL-54), Beck Depression Inventory II (BDI-II), Multiple Sclerosis Functional Composite (MSFC), and the Columbia Suicide Severity Rating Scale (C-SSRS).

As one among multiple vendors the CRO had subcontracted to provide project support, ClinicaLingua's sister company Imperial Graphics was originally relegated to printing and distribution, while another vendor was contracted for translation services. However, expansion of our role revealed additional client needs and created a platform to deploy our capabilities as a Functional Service Provider (FSP) offering integrated start-to-finish clinical trial support. Imperial's FSP model includes patient recruitment, translation and materials development and distribution. Though this client was beyond the patient recruitment phase, Imperial leveraged FSP by fully utilizing the latter three components of the model.

During preliminary work on this project, ClinicaLingua determined that it could manage all of the translation and linguistic validation work required for the study within a 10- to 12-week timeframe, in addition to assisting with research and instrument procurement activities, saving the CRO time and money. It is at this point that Imperial's FSP model began to unfold.

Our research revealed that some of the PRO instruments had previously been translated into many of the languages while others had not. For example, the MSQOL-54 had limited translations; however, its QOL-related base – the Short-Form 36-Item Health Survey (SF-36 v1) – was already available in most of the languages. It would have cost our client upwards of $100,000 to purchase rights from the copyright holder, so we focused our efforts on finding an efficient, cost-effective way to develop the MSQOL-54. The options were to buy rights to the MSQOL-54 from the copyright holder and translate the 18 additional questions from the MSQOL-54 that are specific to multiple sclerosis, or use the RAND Corporation's SF-36 version — which is free to use in the public domain — then translate and validate the MSQOL-54 from scratch. ClinicaLingua opted to translate and validate the MSQOL-54 from scratch and use the original scoring methodology of MSQOL-54 developer, Dr. B.G. Vickrey. That decision saved considerable time and money for the CRO and the clinical trial sponsor.

Over the next several weeks, as the CRO came to rely more heavily on ClinicaLingua's expertise, the project scope broadened from the access points of copyright and translation assessment to include translation and linguistic validation, sourcing, formatting, printing, and global distribution.

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SOLUTIONS

- Copyright and translation assessment
  - (MSQOL-54, BDI-II, MSFC and C-SSRS)
- Translation and linguistic validation
  - (MSQOL-54)
- Translation and back translation
  - (BDI-II and MSFC)
- Expert review
  - (BDI-II)
- Sourcing PROs
  - (Existing MSFC , BDI-II and C-SSRS translations)

- Sourcing ancillary supplies
  - (MSFC-related items)
- Design/formatting
  - (BDI-II)
- Print
  - (BDI-II)
- Distribution
  - (BDI-II and MSFC-related ancillary items)
- Project management

LOCALES

- Belgium
- Bulgaria
- Canada
- Croatia
- Czech Republic

- Finland
- Germany
- Hungary
- Italy
- Latvia

- Lithuania
- Poland
- Russia
- Serbia
- Spain

- Switzerland
- Turkey
- Ukraine
- United Kingdom

DELIVERABLES

- Copyright/translation assessment report
- Validated MSQOL-54 translations and certificates for 28 languages/locales; final report detailing the linguistic validation process
- BDI-II translations, back translations and certificates for 25 languages/locales
- MSFC versions obtained from Mapi
- Translations, back translations and certificates for 12 additional language versions of the MSFC
- C-SSRS translations for 25 languages/locales obtained from Dr. Posner/Columbia University
- Formatted, print-ready PDFs of the BDI-II for 26 languages/locales
- Ancillary supplies for MSFC (stop watch, retractable measuring tape, 9-hole peg test, Dycem non-slip mat, PASAT audio CD)
- 666 printed copies of BDI-IIs in local languages

ACHIEVEMENTS

ClinicaLingua delivered synergistic solutions that off-loaded the CRO's project management support time significantly. All materials requiring translation and validation were streamlined and fast-tracked through our integrated design, translation, print, and fulfillment service package. Further, the efficiency of our FSP model yielded significant cost savings.

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COMPANY HIGHLIGHTS

Exclusive focus in the life sciences

Global network of in-country linguists

Experienced, multilingual project management team

ISO 9001:2008 certification

Support for 100+ languages & locales

INTEGRATED SERVICES AND TECHNOLOGY INCLUDE

- › Translation, editing, back translation and proofreading
- › Medical writing, graphic design and layout
- › Localization and cultural adaptation
- › Management of the local review process
- › Expert medical review
- › Copyright assessment and linguistic validation of PRO instruments
- › Website translation and layout
- › Industry leading technology, including:
  - › Web-based project management system with client portal
  - › Translation memory software to reduce timelines and control costs
  - › Text verification software for greater quality assurance
- › As a member of the Imperial Family of Companies, ClinicaLingua delivers what other translation providers cannot:
  - › Extensive experience with print-ready DTP/formatting
  - › Global print and production facilities
  - › Comprehensive fulfillment and logistics services
  - › A family approach where personal attention is still a priority

PART OF THE FAMILY

ClinicaLingua is part of the Imperial Family of Companies, which also comprises DAC Patient Recruitment Services and Imperial Graphics. With 60 years of combined experience supporting more than 40 therapeutic areas in over 100 countries, our family of companies offers a fully integrated suite of clinical research support solutions, as well as company-specific, independent service offerings. Imperial offers the strength of three companies, through the simplicity of one contract and the convenience of one point of contact.