

CLINICALINGUA CASE STUDY

MANAGING THE COMPLEXITIES OF TRANSLATION FOR CLINICAL TRIALS

GOALS

Deliver and track local review changes to translated documents; review proofs and processing for print production; and provide logistics management and shipment tracking.

SITUATION

With patient materials subject to intense regulatory scrutiny, mistakes in translation can quite literally multiply exponentially according to the number of countries and languages involved. In this case study, our client required logistics management, tracking and delivery of six separate patient materials translated into 86 languages, comprising 516 total components. Adding to the intricacy of the project was local language review of the translations by 68 different sponsor contacts.

SOLUTIONS

ClinicalLingua, an Imperial company, filled the void for this client by ensuring accurate and appropriate translations, coordinating communication and file management on a global scale, and managing the complexities of shipping and tracking the recruitment materials.

IMPLEMENTED SOLUTIONS

- › Delivering translated documents to designated study contacts in MS Word for local review
- › Tracking receipt of the documents by the study contacts and their edits from the local review process
 - › In cases where edits deviated from the approved English source, consultation with the sponsor's project manager for review and approval
- › Reviewing and proofreading proposed edits by the translation teams (sometimes multiple rounds)
- › Following up with local review contacts if past review deadline
- › Formatting final documents for EC/IRB submissions
- › Delivering to local contacts for EC/IRB submissions
- › Tracking approvals from local contacts
- › Printing all components
- › Shipping materials to local contacts for in-country distribution
 - › Tracking and managing individual requests (quantities, additions, deletion of materials)
- › Tracking shipments to ensure receipt at destination

ClinicalLingua also provided weekly updates to the sponsor's project manager, including: status by process step, per language version; language versions for which receipt of local review, feedback or approval was still pending; delivery date of final documents for EC/IRB submission; date of approval; version information for approved documents; date of print completion; date of shipments; shipment quantities; shipment tracking; and delivery of ancillary supply components.

ACHIEVEMENTS

- › Over 65 hours saved by sponsor's internal project manager for tracking, communication, file delivery, and review of materials with local contacts
- › Allowed sponsor's project manager to focus on other aspects of managing the global study
- › 12 weeks total from delivery of files to local teams, to initiation of print and distribution (all language versions)

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MANAGING THE COMPLEXITIES OF TRANSLATION FOR CLINICAL TRIALS (CONT.)

SUMMARY

Managing translation as an outsourced function would have been far more challenging had the sponsor contracted a patient recruitment provider that used a third-party translation vendor. In this scenario, the sponsor's ability to effectively assess quality and internal controls would have been hampered significantly, with every level of management and review slowing the flow of communication and obscuring outcomes.

Through ClinicalLingua Translation Services, Imperial was able to offer, as a single-source provider of strategic services, the benefit of unified standards, central management and streamlined client communication in addition to quality control, communication efficiency, consolidation of file management, and version control.

Exclusive focus in the life sciences

Global network of in-country linguists

In-house translation project management team

ISO 9001:2008 certification

Support for 100+ languages & locales

ClinicalLingua's ISO 9001:2008 certification ensures adherence to the highest global standards in quality.

SERVICES INCLUDE

- › Translation and multilingual publishing services for 100+ languages and locales
- › Translation, review/editing, back translation, and proofreading by teams of fully credentialed linguists specialized in the life sciences
- › Localization by in-country linguists and subject matter experts
- › DTP/formatting in all major software formats for print and web
- › Website translation
- › Management of the linguistic validation process for PRO measures
- › Copyright and language availability assessment for Patient Reported Outcomes (PRO) documents
- › Customized support for the translation review and approval process as needed:
 - › Management of the local review process
 - › Back translation review to verify the equivalence of the translation
 - › Coordination of expert reviews
 - › Pilot testing

PART OF THE FAMILY

ClinicalLingua 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.