#### **Case Study**

# Clinical trial translation: Meeting global clinical research needs

Acolad has been working with two large Clinical Research Organizations (CROs) for over 16 years for their clinical trial translation needs.

The partnership started small, with 4 clinical trials in 35 languages, but the success of the study pilots and collaboration with the study managers strengthened these relationships. Over the years, with proactive account management and customized technology and processes, Acolad has been supporting the CROs growth and built a tailored program geared for the challenges of clinical studies.

### The Challenge

- Growing complexity and number of clinical trials
- Aggressive quality and turnaround targets
- Multiple content formats: digital, print and handwritten
- Diverse audience profiles: patients vs clinicians

During our history working with our customer CROs, they experienced massive growth due to acquisitions and global demand. Now, Acolad is managing over 250 clinical trials a year covering phase 1-4, 57,298,051 words in 2021 into over 200 languages working with more than 1,500 requesters. This growth required global, scalable language services in ever compressing schedules. The complexity and number of trials grew to a volume of 55 requests per day that can include up to 40 languages and hundreds of files per request. All this volume and complexity had to be managed by Acolad under aggressive KPIs for turnaround time and quality. Quality targets were defined around number of translation changes due to linguistic issues: (<2%) and minor (<3%), major (<2%), and critical (<.25%) escalated quality issues.

In addition to the growth in volume, increased complexity, and aggressive KPIs, Acolad also had to contend with a variety of file types (including scanned PDFs with handwritten text and MS Word files) and audiences clinician facing content and patient facing content from various geographies and socio-cultural backgrounds.

# The Solution

Building on trust established from the early successful studies, Acolad's account teams were able to work closely with the study leaders and grow with our customers. This was done through a CRO-customized localization strategy, including the latest language and content technologies and ISO-certified clinical trial translation quality processes and resources.



#### Language & Content Technologies

A combination of Optical Character Recognition (OCR) technology (ABBYY FineReader and OmniPage) and DTP expertise (MS Word, InDesign) allow us to efficiently handle scanned PDF documents and recreate file formats when the source working files are not available.

Over the years, Acolad has developed workflows to make this transformation streamlined and efficient. The application of templates for document types like lab reports and others, also facilitates the creation of documents from scanned PDF files.

Acolad also deployed technology to make sure the increased volumes and complexity could still be produced without sacrificing quality. Besides the standard application of translation memory and the development of customized terminology glossaries, Acolad uses quality assurance automation in its production process to make sure terminology and formatting requirements are being met.

#### **Customized production system for global clinical trials**

The most significant technology solution Acolad developed for CROs is a customized study-centric production system. Through the production system, customers can:



Define study-specific workflows



Track budget and spend



Track turnaround time and other KPIs



Manage study contacts and roles



Store study requirements and instructions for final compliance checks



Store and easily search all study materials, including protocol titles in all languages

Based on the request, type of document required, and original scope of the study, the system can easily identify requests that can flow directly to production and requests that are out of scope and need a quote and approval. Through our study production system, we can also manage timelines and ensure compliance to the agreed timelines and KPIs and generate KPI reports.

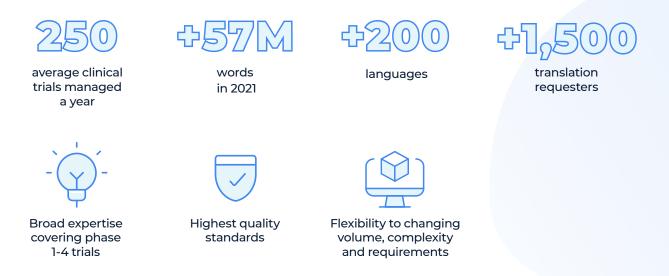
#### **Quality Processes and Resources**

Acolad developed a set of ISO-certified (ISO 9001:2015 and ISO 17100) processes for clinical trials. This includes robust quality and risk management processes.

In addition to our proven clinical trial processes, Acolad has also built a dedicated team of specialized translators with strong clinical expertise. Our recruitment and selection process ensures we onboard only the most qualified linguists and monitor the quality of their translations on an ongoing basis.

Our dedicated project management team in Europe, North America and Asia also have acquired extensive experience in the clinical study space. They keep abreast of all trends and changes in the regulations and adapt our processes as needed to stay compliant.

## The Results



As a result of our continued commitment to our CRO customers and flexibility to meet the changes in volume, complexity and regulatory compliance, Acolad has been able to grow along with our customers adding scalability and maintaining high quality. We do so by consistently delivering to requirements and KPIs and by providing transparency to those KPIs. Our aggressive quality targets are consistently met, if not exceeded.

Through this commitment to our CRO customers, we are well positioned to continue to meet the demands from new regulations such as CTR 536/2014 that will require larger volumes of study content to be delivered in more aggressive timelines. Our tools, processes, and experience allow us to easily meet the demands of the new regulation and ensure that we continue to offer innovation and service into the future.

# Let us help you meet your global clinical trials objectives

Connect to our Life Sciences experts today  $\rightarrow$ 

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