



REACHING MORE CLINICAL TRIAL PARTICIPANTS THROUGH LOCALIZATION

HOW LIONBRIDGE HELPED AN eCLINICAL SOLUTIONS COMPANY STREAMLINE A DUAL-LANGUAGE CLINICAL TRIAL

LICENSES FOR 4 COAS

DUAL EXPERTISE

END-TO-END SERVICES

The study in question was a double-blind, randomized, placebo-controlled Phase 3 clinical trial evaluating the safety and efficacy of the study drug in adolescents with obesity. The customer hired Lionbridge to perform the COA licensing and localization services.

The study involved four Clinical Outcome Assessments (COAs), requiring both US English and US Spanish language versions. The study sponsor planned to administer one of the COAs to trial participants on paper and administer all other COAs electronically via a tablet, with the customer developing the software. The licensing services included:

- Evaluation of the conditions of use for each COA
- Facilitation of the license acquisition, where applicable
- Delivery of final files, including copies of the original COA instruments and existing translations
- Coordinating review of the electronic version with the copyright holder

The localization services covered translation of various study materials such as email alerts and system pop-ups, as well as migration and screenshot reviews of the eCOA development.

About the Customer

Lionbridge works with a leading eClinical solutions company that offers full-service solutions to pharmaceutical and medical device companies in order to streamline clinical trials. Their technology offerings include:

- Electronic Data Capture (EDC)
- Electronic Patient-Reported Outcomes (ePRO)/ Electronic Clinical Outcome Assessments (eCOA)
- Electronic Consent (eConsent)
- Randomization and Trial Supply Management (RTSM)

This is an emerging customer account for Lionbridge, and a fast-growing competitor in the ever-evolving eCOA market.

The Challenge

The study included four COAs with vastly different licensing needs that required expertise and agility to properly manage. Below is a brief overview of each:

- **Control of Eating Questionnaire (CoEQ)**, which is a relatively new scale, has little information about it readily available. This presented challenges in confirming the conditions of use.
- **Impact of Weight on Quality of Life-Kids (IWQOL-Kids)** has a straightforward licensing process, but it requires the author to review screenshots of any electronic versions. This adds complexity and impacts timelines.
- **Columbia-Suicide Severity Rating Scale (C-SSRS)** requires a license with different entities depending on the mode of administration in the study. It is important to clarify this early on to meet deadlines and review the license agreement carefully to ensure it was completed correctly.
- **Children's Depression Inventory 2 (CDI 2)** requires some particular processes per the copyright holder, such as granting permission based on payment of a formal quote in lieu of an executed license agreement. And, as per the copyright holder's procedure, the CDI 2 handbook is distributed to users in hard copy.

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The Solution

Collaboration between the licensing and localization teams at Lionbridge was a major factor in providing solutions for the project. Lionbridge provided a suite of services tailor-made for the clinical study utilizing COAs in two languages and administering them electronically.

Utilizing years of licensing expertise, research skills, and industry contacts, the Lionbridge team was able to correctly identify the author of the CoEQ. Through multiple communications, Lionbridge established that the CoEQ was not under copyright, meaning a license is not required to use it. Lionbridge secured the original and Spanish versions from the author, which allowed the customer to proceed directly to building the CoEQ in their software.

The author's review and approval of the screenshots was a crucial part of the process for the IWQOL-Kids COA. Because Lionbridge performed the localization services as well as licensing, Lionbridge took all the necessary precautions to ensure the electronic screenshots matched the original paper versions. The screenshot review was quickly approved thanks to coordination by the Lionbridge team, which meant the customer could finalize their eCOA software and proceed with the project.

Lionbridge confirmed early on with the customer how the C-SSRS would be administered and reached out to the proper entity to initiate the licensing process. Lionbridge reviews all drafts of the license agreement to ensure information is properly filled out and any questions are clearly addressed. Leveraging past experience with the C-SSRS, the licensing team quickly raised issues with the licensing agreement to the customer and returned the document when signed incorrectly. This ensured that the fully executed version of the license was correct and did not require a change order.

As licensing experts, Lionbridge can recognize pitfalls and complications early on such as the requirement to print and ship the CDI 2 Handbook. Lionbridge discussed this with the customer, and collaborated on a plan for how to proceed in order to meet deadlines and provide sites with the proper materials.

The Results

With dual expertise in COA licensing and localization, Lionbridge was able to provide end-to-end services for the clinical study and set a high precedent for future work with this customer. The Lionbridge team was proactive in identifying potential issues and presenting solutions to the customer early on so that services could be performed smoothly, efficiently and with respect to deadlines.