3

eCOA PROVIDERS CASE STUDY

A NEW INTEGRATED eCOA WORKFLOW FOR REDUCED TIMELINES AND ADMINISTRATIVE BURDEN

33% FASTER eCOA MIGRATION

NEW WORKFLOW DEVELOPED

MULTIPLE MATERIAL TYPES TRANSLATED



Lionbridge assisted the customer with translating materials from US English to US Spanish for a Phase 2 study to evaluate the efficacy and safety of an orally administered drug. The drug is intended as a monotherapy in adults with moderate to severe atopic dermatitis. The project scope included multiple files, which included questionnaires, training materials, and menu screens.

To complete the project, Lionbridge performed the following translation and eCOA migration services:

- Forward translation
- Back translation
- Comparative review
- Desktop publishing
- Migration mapping

- Migration and quality assurance
- Platform updates and testing
- · Screenshot review
- Screenshot insertion and quality assurance

Many of these services are standard for eCOA projects, but the Lionbridge team devised a new workflow to address platform updates and testing. Not all Language Service Providers (LSPs) are able to offer this solution. Lionbridge's team worked from within the customer's platform to take on platform updates and provide testing ourselves.

This process replaced the traditional eCOA process, during which an LSP would report issues to customers, leaving them to handle the implementation themselves.



About the Customer

This customer is an industry-leading, decades-old multinational Life Sciences company with a large, international customer base. Thousands of organizations worldwide rely on this large company to help them expedite drug development, ensure product quality and safety, improve commercial effectiveness, get optimal treatments to patients, and improve healthcare access and delivery.

METHODOLOGY



PLANNING

- Project scope and success criteria
- · Kick-off meeting
- Roles and responsibilities
- · Detailed schedule and communication plan
- Escalation points
- · Debrief meeting after completion



MULTIDISCIPLINARY TEAM

- 1 Global COA Director
- 1 Global Program Manager
- 1 Senior Project Manager
- 1 Senior Strategic Language Lead
- 1 Associate Project Manager
- 1 Engineer



COMMUNICATION

- · Biweekly onboarding call
- Status reports
- · Focused troubleshooting emails and calls
- Centralization of information
- Transparency and focus on critical points

The Challenge

This project presented a few challenges. Firstly, it was the pilot project for a new customer. As such, queries arose throughout the process, including ones related to the functionality of the customer's platform. Lionbridge needed to navigate the resolution of these queries without creating any disruptions that could have delayed translation delivery.

Secondly, the project was a pilot for a new workflow type. This type of workflow required high-level, end-to-end support. Migration projects typically require intensive customer collaboration because several steps are outside the LSP's control.

These steps include:

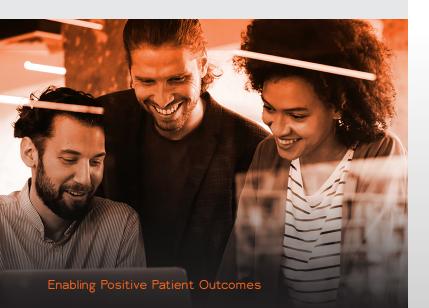
- Updating the customer's platform after migration and before screenshot review
- Generating screen reports
- Implementing edits
- Importing and exporting files throughout the entire process

These tasks are notably time-consuming. They potentially risk the overall project timeline if there is a delayed completion of customer-owned steps.

The Solution

Lionbridge assisted this eCOA provider by dramatically reducing its administrative burden. We took on some time-consuming, traditionally customer-owned steps. We were given access to the customer's proprietary platform, then learned how it worked. To accomplish this, we used training materials provided by the customer. We also collaborated with the customer to resolve some technical issues impacting the project execution.

Upon understanding how to navigate the platform and its functionalities, we designed a workflow with minimal customer touchpoints. With our access, Lionbridge successfully took ownership of many of the traditionally customer-owned tasks, including updating the platform during screenshot review, generating screen reports, and importing and exporting files throughout the process.





"OUR NEW WORKFLOW REDUCED THE PROJECT TIME BY 33% OVERALL."

The Results

By developing and utilizing a new workflow, Lionbridge addressed one of the customer's major pain points — one that many LSPs are not currently targeting. By taking on many traditionally customer-owned tasks, we dramatically decreased this eCOA provider's workload and administrative burden. This freed them up to focus on other important tasks.

A second benefit was that our new workflow saved the customer significant time throughout the project.

Our new workflow reduced the project time by 33% overall. This benefit is crucial when meeting tight clinical trial deadlines. With high-level, end-to-end support, Lionbridge slashed the time that might have been lost to the additional communication between its team and the customer's team. This new workflow ensured that each step was completed immediately after the previous one.

A third benefit was the early delivery of all required translations. Using the new workflow and proper planning, Lionbridge was able to deliver translations for the customer ahead of schedule. We achieved an early delivery despite several source updates and scope changes to the project.

As a future benefit, Lionbridge has proactively and methodically documented this workflow. The documentation will help us continue to achieve the first three benefits for this customer and other eCOA providers. This documentation enhances customer experience by ensuring a smoother, more expedited process.

