Science 37®

INSIGHT BRIEF

Decentralized Clinical Trial Technology—How to Accelerate eCOA Implementation.

Authors:

Lisa Charlton
Senior Director, Product, Science 37

Daniel Herron
Global VP, Strategic Accounts and Clinical Outcomes, Lionbridge Life Sciences

The Agile Clinical Trial

Before COVID-19, the clinical trial space was already increasingly implementing remote data collection. Regulatory agencies across Europe and North America began publishing best practice guides that included recommendations for both paper and virtual formats.

"Virtual trials have been in use for nearly a decade, but only recently did the industry see the scale of benefits it delivered," said Lisa Charlton of Science 37. "COVID-19 restrictions increased awareness for trial support outside the brick-and-mortar site—proving the model works."

Evidence for decentralized trials' success

A more remote approach to clinical trials improves speed, retention, and diversity. While decreased time recruiting provides broader access to patients and investigators, broadening the field of participants.

Charlton noted that clients working with Science 37 experience enrollment 21 times faster, a tripling of patient diversity, and nearly 30 percent higher participant retention over the lifespan of a study. This increase results in earlier data collection, expanded data points, and more accurate conclusions for a broader group of potential patients.

"Increased participant recruitment and retention means better outcomes for everyone," said Lionbridge's [Dan Herron]. "Language is a key element to unlock universal access."

Technology implementation must match the pace of decentralized trials

A key benefit of decentralization is the ability to execute faster. Technology capabilities and vendor support enable faster implementation of trials, greater speed to go live, and accelerated timelines.

Faster execution has significant cost benefits. With an accelerated implementation of trial technology, study teams are gaining three to four months of study startup time, potentially equating to $120M and $240M in Opportunity Cost Savings.

Electronic clinical outcome assessments (eCOA) are critical to decentralized trials as they capture the patient voice, but they are a challenge to quickly implement. Multiple stakeholders must adhere to myriad procedures from copyright permissions to IRB/EC submissions and translations.

Standard eCOA processes often require a series of time-consuming steps, including Licensing, Design, Build, Author Approval of Screen Shots, Testing / UAT and Translations, IRB/EC submissions, and Deployment. On average, an eCOA process takes 12-16 weeks to complete without licensing and translations (for US English).

> eCOA implementation is complex because of the number of stakeholder requirements. The only way to simplify the process is through preparation, standardization, and reuse.
>
> **Lisa Charlton**
> **Senior Director, Product, Science 37**

Licensure paths and the importance of timing

The impact of cascading timing and required translations makes licensing a priority for any administrator. A reliable baseline estimate for obtaining licensing is four to six weeks from first contact with the copyright owner to license execution. This timeframe will extend based on scope, the number of translated languages, and administration modality.

The flow of COA licensing can require an overwhelming number of ongoing conversations, which is why using an experienced vendor saves time and resources. Lionbridge maintains an internal eCOA Information Library that tracks conditions of use and copyright information for all of the licensing services we have provided to COAs. “This library is constantly maintained and updated to ensure the information is as accurate and diverse as possible,” said Herron.

Science 37’s library of pre-configured and/or pre-approved assessments aligns with the information provided by licensing services. This pre-configured, pre-approved eCOA library allows study teams to accelerate towards translations, improving timelines.

Language and licensing

Administrators need to know every facet of their assessments when considering electronic measuring and reporting across linguistic barriers. Here are several key pieces of the eCOA translation process (whether PRO, ClinRO, ObsRO, or PerfRO):

The translation steps for the Lionbridge methodology typically include the following components:

1. **Conceptual Analysis:** The process of creating a detailed explanation of terms and concepts presented in the source text. Concept Definitions (also called Concept Elaborations) may include background information on the source COA measure, the study in which it will be used, the target population, and challenging concepts. They capture the items' conceptual meaning to reduce literal translation, reduce ambiguity, and increase global harmony. Concept Definition also includes creating a set of instructions for the resources involved in a Linguistic Validation project enabling them to produce colloquial translations that are easily understood by the general population and/or specific targeted reading levels or ages.
2. **Dual Forward Translation:** One translator produces the first forward translation while another independently produces a second one.
3. **Reconciliation:** The key in-country consultant, with the project manager and input from the forward translators, reconciles the two translations to produce the optimal forward translation.
4. **Back Translation and Comparative Review:** A third translator back-translates the translation into English while blinded to the original instrument. The original instrument and back translation are reviewed, and modifications are made as necessary.
5. **Clinician's Review:** A review of the translation by a medically qualified expert. Rather than general linguistic issues, Clinician Review focuses on checking and refining the accuracy of the therapeutic area-specific content, ensuring correct usage of medical terminology, and maintaining the required style.
6. **Cognitive Debriefing:** The process of testing the translation of a PRO or an ObsRO measure on a small group of respondents to check the understandability, interpretation, and cultural relevance of the translation and test any translation alternatives. Lionbridge's Cognitive Debriefers are native speakers of the target language, fluent in the source language, and experienced in qualitative interviewing and/or cognitive interviewing techniques.
7. **Harmonization:** The continuous process of identifying and dealing with any translation discrepancies between different language versions, ensuring consistency and conceptual equivalence between the source and target language versions and across all translations.
8. **Proofreading and Format Check:** In-context proofreading is performed on the formatted files while the layout is checked for conformity to the original instrument.

These steps take time, so licensing these COAs early is critical. Partnering with a licensing broker can help expedite this process by getting documents into the translation queue as quickly as possible.

The Science 37 Operating System streamlines clinical trial administration, including licensure, and with the help of Lionbridge, provides translations as well.

About Science 37

Science 37, Inc.'s (Nasdaq: SNCE) mission is to enable universal access to clinical research, making it easier for patients and providers to participate from anywhere. Since 2014, we've pioneered decentralized and agile clinical trial approaches and having conducted more than 125 agile clinical trials, we're helping forge the future of research. The Science 37 Operating System (OS) supports today's more agile clinical research design, enabling up to 21x faster enrollment, 28% better retention, and 3x more diverse patient population.

To learn more about our solutions, and how we can help you implement Agile and Decentralized Trials, visit www.science37.com, or email science37@science37.com.

About Lionbridge Life Sciences

Speed, breadth of knowledge and quality of translation set Lionbridge Life Sciences apart. At every touchpoint on your go-to-market journey, from drug or device development to the moment your product makes its way safely and effectively to patients worldwide, Lionbridge helps you get there faster—with less risk. Our extensive experience in global clinical trial translation, linguistic validation, life sciences marketing and more ensures that your translations are accurate and in compliance across languages, markets and cultures.

Learn more at www.lionbridge.com.