CLINICAL OUTCOME ASSESSMENT (COA) SOLUTIONS

Accurate, patient-focused clinical outcome assessments in every language and location

Clinical outcome assessments (COAs) are a critical requirement of global clinical trials, needed to provide evidence of the benefits of a treatment on clearly defined aspects of how a patient feels or functions. Capturing this subjective data requires precise assessment instruments, standardized processes, cultural competence, and translation accuracy.

Clinical studies with diverse patient populations need a COA partner with both scientific and linguistic expertise. The right partner will help you establish an optimal approach to COA implementation, manage document deadlines and mid-study changes, and identify and address COA risks across studies. An effective global COA strategy can enhance your data quality, improve regulatory compliance and acceptance, and help bring your products to markets faster.

Lionbridge Life Sciences has the linguistic quality, industry experience, and global operating model needed to support the full range of your COA activities, from pre-study planning through trial start-up and beyond. From copyright and licensing to rater training support, translation and linguistic validation, and eCOA services, our best-in-class COA solutions are compliant, patient-centric, and ready to meet your global needs.

LIONBRIDGE

Best-in-class COA Solutions

Lionbridge has a successful and long-standing track record of providing linguistic expertise, validation, and quality translations to the pharma, biotech, and medtech industries, as well as to contract research organizations (CROs) of all sizes.

Each of our COA solutions is aligned with industry standards and best practices and follows our rigorous SOPs for quality, speed, and security.

Copyright & Licensing Support

Reduce the administrative burden of securing permissions and licenses and improve consistency, visibility, and compliance with copyright and IP requirements across your studies. Services include:

- Support with the development of budget assumptions for licensing and linguistic/subject matter expert work for the required COAs
- Facilitation and coordination of the licensing process for paper-based and electronic instruments
- Collaboration with instrument developers, copyright holders, publishers, and key opinion leaders
- COA library management

Translation & Linguistic Validation

Achieve harmonization across languages and ensure your assessment instruments are properly adapted for multiple cultures. Services include translation and linguistic validation for:

- Measures across the four COA types: patient-reported outcomes (PROs), clinician-reported outcomes (ClinROs), observer-reported outcomes (ObsROs), and performance outcomes (PerfOs)
- Accompanying COA materials including administration manuals, scoring guides, and booklets
- Diagnostic, efficacy, safety, and other types of instruments
- Inputs from simple patient diaries to complex assessment batteries, across all therapeutic areas and indications

Rater Training Support

Support consistent and thorough rater training across all study sites with translated multimedia materials and on-site language support. Services include:

- Translation of rater training and assessment materials (rater experience surveys, training slides, vignettes, quizzes, interactive didactics)
- Translation and adaptation of training video transcripts, including video subtitling and voice-over
- Interpreting and language support at Investigator Meetings (IMs), site, and individual rater training sessions
- Transcription of audio files

eCOA Services

Streamline multilingual electronic reporting with document and device translation and validation services. eCOA Services include:

- Paper-to-electronic text migration
- Measurement equivalence testing
- Translation and localization of supplemental materials (device labels, patient quick reference guides, site manuals, posters)
- Screen report verification and harmonization
- IVRS/IWRS/ePRO linguistic validation, including voice recording

Global Quality, Compliance, and Reach

- Nine dedicated Life Sciences Centers of Excellence
- 46 Production Centers across 26 countries
- Highly-vetted network of 10,000 translators supporting 350+ languages
- Cloud-based proprietary technology platforms, 24/7 Translation Enablement Platform access
- FDA/EMA and ISPOR/C-PATH/ ISOQOL-compliant methodologies
- ISO 9001:2015, ISO 13485:2016, ISO 17100:2015, and Six Sigma Methodology
- High customer satisfaction rating; 96% of clients renew relationships annually

Therapeutic Area Expertise

- Cardiovascular
- Dermatology
- Dental & Oral Health
- Hematology
- Geriatrics
- Endocrinology
- Gastroenterology
- Gynecology
- Immunology
- Vaccines
- Oncology
- Pediatrics
- Psychiatry/Psychology
- Rare Diseases
- Rheumatology
- Urology

Get Started

Contact us today to talk with an expert and learn how Lionbridge can help you with compliant, patient-centric COA services for global clinical trials.

LIONBRIDGE.COM

LIONBRIDGE