LAY LANGUAGE SUMMARY SOLUTION FOR GLOBAL CLINICAL TRIALS

Promote Transparency and Trust with Accurate, Compliant Lay Language Summaries

Clear, patient-centric communication is important for the safe, efficient, and ethical execution of clinical trials.
What's more, communications targeted at trial participants keep them informed and engaged throughout the trial, acknowledging their contribution to science and public health.

Sharing lay language summaries of clinical trial results is a communication best practice now mandated by regulations. The new EU regulation (EU CTR No. 536/2014) makes aggregate results summaries written in plain language a legal requirement of EU clinical trials. Trial sponsors must publish these results to a publicly-accessible database controlled by the European Medicines Agency (EMA). With an increasing focus on lay language summaries from both regulators and patient advocacy groups, experts in both the EU and the US have developed guidelines on how to produce lay language summaries based on health literacy principles.

Even with the guidelines, the creation of effective and compliant lay summaries requires a unique blend of linguistic and scientific expertise. Your trial summaries must be understandable to a layperson, unbiased in language and framing, and preserving of the scientific validity of the trial results. Additionally, your master summaries must be translated into local languages and meet the same quality standards in each target language.

We're here to help. Our linguistic and scientific experts are experienced in all aspects of global clinical trial content, including scientific and lay content, as well as translation into local language. Our lay language summary solution complies with the EU regulation and current guidelines in EU and US, and our scale supports global clinical development programs.

ARE YOU READY?

Lay language summaries, also known as plain-language summaries, are non-technical, non-promotional clinical trial recaps provided to trial participants and public stakeholders.

When the new EU regulation (EU CTR 536/2014) goes into effect in 2020, these summaries will be required for all interventional trials conducted in EU member states.

Get the linguistic and scientific expertise that ensures quality and compliance with the Lionbridge lay summary Solution for Global Clinical Trials.

LIONBRIDGE

Patient-Centricity in Every Language

Completing lay language summaries is a resource-intensive and time-bound process that can negatively impact your critical path if not managed properly. We'll help you take control of this new requirement and deliver clear, audience-focused communications that accurately reflect your clinical trial results and conform to EU regulations.

We understand the high sensitivity of public disclosure of your clinical research results and the importance of delivering unambiguous, consistent, and unbiased results in all languages. Whether you need a complete authoring solution or translation of your master summaries, we'll make sure you achieve clarity and compliance in every country.

Our **Lay Language Summary Solution for Global Clinical Trials** flexes to meet your needs:

ENGLISH-LANGUAGE MASTER SUMMARY (AGGREGATE) AUTHORING

- **Requirements Development:** Determine scope, templates, readability tests, review, timelines, and instructions
- **EN Master Development:** Complete English-language master summary according to health literacy and linguistic principles and client CSR/reference materials
- **Optional Services:** Readability testing in pilot group featuring target patient or public audience representatives

MASTER SUMMARY (AGGREGATE) TRANSLATION

- **Translation-Only Solution:** Neutral, consistent, and culturally-appropriate translation into target languages from EN-master, following the proven Lionbridge LS clinical translation process
- **Optional Services:** Back translation, comparative review and reconciliation, and clinician review

Your Trusted Global Partner

When you choose Lionbridge, you get an independent partner with no industry ties or commercial interests. We have a successful 20-year track record providing linguistic expertise, validation, and quality translations to pharma, biotech, and medtech industries as well as Contract Research Organizations (CROs) of all sizes.

We deliver compliance, speed, and quality on a global scale with:

- Centralized translation solutions across the enterprise: clinical, regulatory, training, corporate, and marketing
- Service excellence from eight dedicated Life Sciences Centers of Excellence with teams in 46 Production Centers across 26 countries
- A global pool of Subject Matter Experts specializing in Life Sciences with extensive disease-state expertise
- A highly-vetted network of 10,000 translators across 350+ languages
- Extensive clinical trial experience spanning 5,000 participants in 10+ countries
- Scalable infrastructure with comprehensive local experience and measurable quality standards
- Cloud-based proprietary technology platforms, 24/7 Translation Enablement Platform access, FDA/EMA and ISPOR/ISOQOL-certified methodologies
- ISO 9001:2015, ISO13485: 2016, ISO 17100: 2015, and Six Sigma Methodology
- High customer satisfaction rating; 96% of clients renew relationships annually

20 Years of Clinical Trial Plain-Language Expertise

- Patient recruitment and retention materials
- Informed Consent Forms (ICF) and Patient Information Sheets (PIS)
- Patient diaries
- Newsletters
- Patient and clinician educational materials
- Packaging and labeling
- Readability testing
- Patient representative panels

Global Lay Language Summary References

Learn more about lay language summaries, health literacy principles, and specific guidelines for developing patient-centric, compliant summaries for your clinical trials:

- EU: Summaries of Clinical Trial Results for Laypersons recommendations from the CTR 536/2014 expert working group
- US: MRCT Center Return of Aggregate Results to Participants guidance document

Get Started

Contact us today to talk with an expert and learn how Lionbridge can develop a compliant, patient-centric lay summaries process for your organization.

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