

Whitepaper

LAY SUMMARIES



START PLAIN LANGUAGE SUMMARIES EARLY OR GET LEFT BEHIND

Kasim McLain | Manager, Disclosure Services, Safety Risk Management

Jennifer Pilgrim | Senior Transparency Lead, Medical Writer

Jessica Alamdari | Associate Manager, Corporate Quality



The difference is in the data.™

IN JULY 2019

The European Union (EU) Clinical Trial Regulation No. 536/2014 will go into effect,

requiring all sponsors, including academia, conducting clinical trials in the European Union to draft lay or plain language summaries for phase 2-4 clinical trials. These lay summaries need to be published to the new Clinical Trials Information System that will be hosted by the European Medicines Agency (EMA) within 12 months from the close of each clinical trial.

The regulation will become applicable 6 months after the European Commission confirms that the Clinical Trials Information System is fully functional. "Any sponsor with a clinical study that is set to complete after the regulation goes into effect will need to be in compliance," said Kasim McLain, Manager, Disclosure Services at MMS,

and former Manager, Clinical Disclosure Lead at GlaxoSmithKline. "With the ever-changing landscape of clinical trial disclosures, it is not clear if there will be retrospective requirements for studies that have completed before July 2019." McLain explains further, "If a clinical study ends in July 2018, it's not clear at this point if a lay summary will need to be submitted for that study when the regulation goes into effect one year later, in July 2019. Retrospective disclosure has been required as a part of other EU legislation in the past."

If retrospective disclosure comes into play, sponsors have the potential to be hit with a large backlog of studies when the clinical trial regulation goes into effect.



EXPERT INSIGHT

Why, in your opinion, are lay summaries becoming more and more important in the pharmaceutical industry?

“Industry-wide, there seems to be a move towards greater transparency and an emphasis on providing patient-centered services. At MMS, we believe that lay summaries are a natural extension of that effort. In the European Union (EU), lay summaries will soon be a required document for all clinical trials. Any sponsor who conducts research in that region will need to produce lay summaries, and it's recommended that they start early to work out any issues in advance.

Jennifer Pilgrim, Medical Writer and Transparency Lead at MMS

DEVELOPING PROCESSES AT A SPONSOR LEVEL

"Each sponsor should currently be developing their own internal processes for drafting lay summaries."

- Kasim McLain

Part of this development should include drafting and defining a lay summary template, and gathering input from a variety of parties, including, regulatory teams, legal, the medical monitor, third-party experts, and more. Following the finalization of the template, a process for reviewing each lay summary should be ironed out, according to McLain, prior to submitting the summary to patients and the agency.

"There could be 10 reviewers for a single lay summary," explains McLain. "Commonly, I have seen a global medical lead, multiple clinicians,

multiple statisticians, and the portfolio attorney all review the plain language summary for a clinical trial. Each stakeholder may want the lay summary to focus on something different, and reaching a consensus requires a robust review and approval process not to mention time for all these reviews and edits."

Additionally, these summaries need to be non-promotional in nature, and each person needs to be comfortable with the data being disclosed. Determining who should be involved in the review process to work through questions regarding promotional language, the intended audience, and the technicality of data is a key step in the process.

As the composition of a clinical team and legal review is different for each sponsor, creating an appropriate workflow for review that is consistent across the organization ahead of time becomes vital. This is where a pilot program helps.



EXPERT INSIGHT

It can be hard to distinguish between promotional and non-promotional language, can you help us understand how to do so effectively?

“Sure! It is very important that lay summaries are not perceived as promotional in any way. That is a vital aspect of our review process at MMS for any **lay summary** that we draft. To ensure that lay summaries remain non-promotional, the writer should choose language that is factual and objective. Rather than attempting to interpret the results of the clinical study or make inferences for the reader, it is preferred to objectively present the results of the study. Additionally, it is imperative to avoid using language such as “best” or “better”, which could be perceived as promotional. The goal is to ensure that the information chosen to present in a lay summary is balanced and accurate, and we have **lay person reviews** to ensure that happens.

Jennifer Pilgrim, Medical Writer and Transparency Lead at MMS

CREATING A PILOT PROGRAM

"A pilot program is recommended for all sponsors."

"A pilot program is recommended for all sponsors this year to test out the internal process and gain valuable patient feedback before the legislation goes into effect," said McLain. McLain recommends starting with five lay summaries. Once delivered to patients, she advises Sponsors to collect feedback to determine if the lay summary is valuable to and easily understood by the patient population. This feedback may serve to guide the evolution of the lay summary process within sponsor organizations.

Identifying why a full year is needed for a pilot program, McLain mentions that, once the process is underway and summaries have been drafted for different types of trials, sponsors "may elect to report different subsets of data, take a different approach to displaying data graphically, and revise their template."

Two areas that change the most throughout the

pilot process are the types of endpoints and the subset of safety data that sponsors decide to report. First, Sponsors must make a critical decision regarding which endpoints to report. A Sponsor who initially decides to report data for both primary and secondary endpoints may ultimately decide that they are reporting an overwhelming amount of information, explains McLain, resulting in an agreement to report data for only primary endpoints. Second, it's important that Sponsors decide whether to report all adverse events (AEs), AEs that could be attributed to study drug, or those occurring at a specified frequency threshold.

"No matter what is decided, it is important to adopt a uniform approach that is properly defined and employed across all summaries," said McLain. "Otherwise, it may look like the Sponsor is cherry-picking and reporting favorable data only."



EXPERT INSIGHT

What do you see in the future for lay summaries in the next 5-10 years?

"There will be great deal of opportunity in the next five to 10 years with lay summaries, particularly as the EU regulation takes effect. I expect that other countries outside of the EU may begin requiring lay summaries, as well. For instance, the UK may write their own requirements for lay summaries once Brexit."

Jennifer Pilgrim, Medical Writer and Transparency Lead at MMS

TRAINING THE CLINICAL TEAM

“Adopting increased clinical trial disclosure and transparency and making it a priority is a way to demonstrate a dedication to patients and how they are helping advance science.”

“Guidance regarding what is to be disclosed in a lay summary is very brief and open-ended,” said McLain. “Training is key to ensure that data are reported uniformly across clinical programs and trials.”

Due to the nature of clinical trials, a single clinical team may only have one lay summary to review and approve per year. However, these teams still need to be trained on what a lay summary is, its intended use, and how to review a lay summary.

“Training clinical teams takes time, depending on how many teams there are, and yearly refresher courses should occur to make sure each team member understands what is being asked of them,” said Jessica Alamdari, Associate Manager, Corporate Quality, MMS. “When implementing our lay summary process, each stakeholder was tracked and periodically reminded to take the necessary training in a specified amount of time.” The added turnover within clinical teams makes it

vital for implementing yearly refreshers as well.

As additional **clinical trial disclosures** and transparency regulations are put into effect, more deliverables are anticipated in more formats. For lay summaries, documents are written at a six- to eight-grade level, and, on the surface, they appear to be simplistic in nature. However, the summaries are extremely nuanced and must be drafted to serve the needs of their target audience – the patients. To put lay summaries in a format and language that patients understand, McLain suggests “giving the process a year before it’s finalized in order to meet regulatory requirements.”

“Transparency should not be seen as just a regulatory requirement,” said McLain. “Adopting increased clinical trial disclosure and transparency and making it a priority is a way to demonstrate a dedication to patients and how they are helping advance science.”



EXPERT INSIGHT

When looking at developing a lay summary template, what are some of the key components that sponsors should consider including?

“The EU Clinical Trials Regulation lists 10 elements that should be included in a lay summary. Sponsors who are writing lay summaries for the European market should incorporate each of these elements into their template. Additionally, sponsors should consider the needs of their audience when developing the template. This means that they should make sure that the lay summary is easy to read and understand. It is recommended to write lay summaries at a six to eighth-grade reading level, and we use simplified graphics to help explain the information. This is certainly not an easy task with many therapeutic areas, especially complex endpoints and analyses.”

THE ULTIMATE LAY REVIEWER CHECKLIST FOR LAY SUMMARIES

Lay review is an essential step in the plain language (PLS) writing process

The reason being that it is extremely important that the PLS, or lay summary, is written in a patient-friendly, easy-to-understand style. Lay reviews also provide the medical writer with invaluable information to ensure that the document meets these standards.

Generally, lay reviewers are those with a non-science background. However, it is vital that lay reviewers are trained to know what to look for. When getting started, lay reviewers should ask themselves these questions while reviewing a plain language summary:

- ☒ Is the following addressed: Who, What, Where, When, Why, How?
- ☒ Is the text ordered logically and not redundant?
- ☒ Is the main purpose of the study obvious at first reading?
- ☒ Are short sentences used?
- ☒ Is the text appropriately broken up in paragraphs or bullet points?
- ☒ Are everyday English words used instead of complex language?
- ☒ Are complicated medical terms defined at first use?
- ☒ Are simple verbs used, such as "buy" instead of "purchase"?
- ☒ Are the timing of events clearly defined?
- ☒ Are graphics easy to read and understand?
- ☒ Are graphics consistent with the message in the text?
- ☒ Can all graphics be understood on their own, without having to read the text?
- ☒ Is the text non-promotional, including no suggestion of efficacy, safety, or intended use, or no persuasive wording to emphasize safety or efficacy?

Print out this page and provide it for lay person review.



Follow the link to review an expertly-crafted **lay summary template**.

About MMS

MMS is an award-winning, data-focused CRO that supports the pharmaceutical and biotech industries with a proven, scientific approach to complex trial data and regulatory submission challenges. Strong industry experience and a data-driven approach to drug development make MMS a valuable CRO partner, creating compelling submissions that meet rigorous regulatory standards. With a global footprint across four continents, MMS maintains a 97 percent customer satisfaction rating and was named as the Best Global Biotech CRO in the 2018 International Life Sciences Awards.

For more information, **visit www.mmsholdings.com** or follow MMS on LinkedIn.

