Landscaping the terminology of lay and plain language document types

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PLAIN LANGUAGE SUMMARY OF THIS POSTER

There are three main types of plain language documents that medical publications professionals may work on. These are:

- regulatory Lay Language Summaries (LLS)
- publication-associated Plain Language Summaries (PLS)
- Plain Language Summaries of Publications (PLSP).

Although these document types all have different purposes and audiences, they often get confused because of the similar names. In this poster, we outline the main differences between each of the three documents and present the different names used to refer to regulatory LLS, totalling 16 different names. We also show examples of the different literacy levels used in regulatory LLS and publication-associated PLS.

Medical publications professionals need to be aware of the differences in plain language document types and need to be precise when discussing these. Standardization could help avoid confusion.

INTRODUCTION

Regulatory Lay Language Summaries (LLS), publication-associated Plain Language Summaries (PLS) and Plain Language Summaries of Publications (PLSP) are three different document types, with distinct purposes, scope and audiences.[1–3] This landscaping review outlines the variations of terms in use and aims to provide clarity on terminology.

CONCLUSIONS

- Evidently, there is confusion regarding terminology; medical publications professionals need to be aware of these differences and ensure precision when referring to these three document types to avoid further confusion.
- Medical publications professionals are in a strong position to educate, explain and encourage accuracy of terminology.
- Standardization of terminology is necessary for further clarity and to promote appropriate usage.

METHODS

- Official websites of the 38 full and affiliate corporate members of the European Federation of Pharmaceutical Industries and Associations[4] (EFPIA, which provides good practice guidance[5] on LLS per the European Union Clinical Trials Regulation no.546/2014, Annex V mandate[1]) were manually searched for variations of LLS terminology; this search was performed on 16 February 2022.
- Readabilityformulas.com was used to compare the readability of similar-length excerpts of regulatory LLS and publication-associated PLS examples, selected from the same oncology therapy area where authors of this poster were involved in drafting.

RESULTS

Document distinctions

	Regulatory LLS	Publication-associated PLS	PLSP
Purpose and audience	Mandated summaries of clinical study reports for study participants (typically a target reading age of around 9–13 years)	Brief jargon-free summaries, primarily of peer-reviewed publications, for broad non-specialist readers (typically a target reading age of around 14–18 years)	Full-length, standalone secondary manuscripts that 'translate' previously published primary manuscripts into plain language with visual formatting often targeted at a patient audience (typically of a variable reading age)
Scope	Reports on one study only with a focus on primary endpoints and safety	Covers the content of the associated manuscript	Covers one primary manuscript and may include the patient voice and patient-authors for a wider scope
Location	Intended to be hosted on the central CTIS portal,[6] but are currently hosted in a variety of places such as sponsor websites and other portals	Hosted with the associated publication, either embedded within the manuscript or in the supplementary materials Text-based and concise PLS can be indexed on PubMed if formatted and tagged correctly	Currently only published by Future Science Group journals
Guidelines and criteria	Outline mandated in EU CTR no.546/2014, Annex V mandate[1]	Formats vary by author and journal preferences, but best practice and convention encourage text-based and concise PLS that are peer-reviewed alongside the manuscript[2]	Author guidelines available from Future Science Group[3]

CTIS, Clinical Trials Information System; EU CTR, European Union Clinical Trials Regulation; LLS, Lay Language Summary; PLS, Plain Language Summary; PLSP, Plain Language Summary of a Publication.

Terminology landscaping

The landscaping analysis revealed that among 29 EFPIA members with information on LLS publicly available on official websites, there are 16 different terms for LLS in use and 5 of these EFPIA members use more than two terms for the same meaning. This includes 9 instances of using the term PLS to describe LLS. This indicates a lack of clarity and precision in official communications and a need for standardization. Additionally, PLS and PLSP may also be used interchangeably.

Term for regulatory LLS in use	Number of EFPIA members using the term
Plain language summary	9
Lay summary	4
Trial results summary	4
Lay language summary	3
Clinical trial summary	2
Layperson summary	2
Clinical trial results	1
Lay summary results	1
Plain language results	1
Plain language study results summary	1
Plain language summary of results	1
Plain language summary of study results	1
Summary of clinical trial results	1
Summary of clinical trial results for laypersons	1
Trial lay summary	1
Trial summary for patients	1

Example readability comparisons

REGULATORY LLS

Researchers are looking for a better way to treat cancer. Before a drug can be approved for patients to take, researchers do clinical studies to find out how safe it is and how it works.

The study drug, AZD4635, is being developed to treat some cancers. In this study, the researchers compared a capsule form of AZD4635 with a liquid form of AZD4635, both taken by mouth. They wanted to learn how the different forms of AZD4635 acted in the blood of healthy participants. The participants also took a drug called lansoprazole. Lansoprazole is a medicine that is normally used to help with acid reflux or heartburn. It changes the acidity of the stomach and may affect how much AZD4635 gets into the blood.

The main questions the researchers wanted to answer in this study were:

- Was the amount of AZD4635 in the participants' blood similar when given in each form?
- What medical problems did the participants have during the study?

The answers to these questions are important to know before other studies can be done that help find out if AZD4635 improves the health of people with cancer.[7]

Readability consensus: 12–14 years old

PUBLICATION-ASSOCIATED PLS

Cabozantinib and regorafenib are treatments approved for some patients with advanced hepatocellular carcinoma (HCC), a type of liver cancer, after disease progression despite prior sorafenib treatment. Cabozantinib, regorafenib and sorafenib are tyrosine kinase inhibitors (TKIs), meaning that they slow cancer progression by targeting specific ways that tumors grow. Cabozantinib and regorafenib offer benefits to patients compared with placebo (i.e., no treatment) for those who have progressed despite sorafenib treatment. No clinical studies have compared cabozantinib and regorafenib directly. This study compared the efficacy and safety of cabozantinib and regorafenib using data from trials of each drug versus placebo: CELESTIAL for cabozantinib and RESORCE for regorafenib. These two trials were similar—both involved patients with progressive advanced HCC who had received previous cancer treatment. There were some important differences, but these were minimized using statistical methods (matching and adjustments/"weighting") allowing outcomes to be meaningfully compared. One difference that could not be removed by the statistical methods was that patients who were intolerant to prior sorafenib were excluded from RESORCE but were eligible for the CELESTIAL trial. In the otherwise matched populations, treatment with cabozantinib was associated with similar overall survival and significantly longer progression-free survival than regorafenib. Rates of diarrhea were significantly lower for regorafenib than cabozantinib, suggesting that regorafenib may be better tolerated, but this may reflect the exclusion of sorafenib-intolerant patients from RESORCE. These findings cannot replace a head-to-head study, but may help in guiding decision-making between cabozantinib and regorafenib in patients with progressive advanced HCC after soraftenib treatment.[8]

Readability consensus: 18–19 years old

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