Landscaping the terminology of accessible language document types

Sarah Griffiths[1], **Ama Appiah**[1], **Adeline Rosenberg**[1], **John Gonzalez**[2], **Slávka Baróniková**[2]

1 Oxford PharmaGenesis Ltd, Oxford, UK

2 Galápagos NV, Mechelen, Belgium

doi: 10.56012/cbxl1493

Correspondence to:

Sarah Griffiths

sarah.griffiths@pharmagenesis.com

Abstract

There are three main types of accessible language documents that medical writers and medical publications professionals may work on. These are regulatory lay summaries, publication-associated plain language summaries (PLS), and standalone plain language summaries of publications (PLSPs). Although these document types have different purposes and audiences, they are often confused because of the similar names. Here, we outline the main differences between the three document types and present the different names used to refer to lay summaries across 58 pharmaceutical companies, totalling 22 names. We also show examples of the different literacy levels used in lay summaries and publication-associated PLS. Medical publications professionals need to be aware of the differences between these accessible language document types and the importance of being precise when discussing these. Standardisation of terminology could potentially help to avoid confusion.

Introduction

Accessible language document types are central to achieving improved transparency in reporting clinical trial data in regulatory documents and publications. Efforts for improved transparency come as the pharmaceutical industry and adjacent industries are increasingly recognising the value of patient and public involvement and non-expert engagement, as well as the role accessible language plays in enabling dialogue between stakeholders.[1] With this in mind, there are three main types of accessible language documents, among others, that medical writers and medical publication professionals may generally work on. These are:

- Regulatory lay summaries[2]
- Publication-associated plain language summaries (PLS)[3]
- Standalone plain language summaries of publications (PLSPs).[4]

These three different document types each have their own distinct purpose, scope, and audience; however, there is limited clarity regarding the terminology used when referring to these documents.

Regulatory lay summaries: a deep dive

Accessible disclosure of clinical trial results to trial participants through the regulatory sharing of Lay Summaries – either direct to participants or through posting to online portals – is of great value to participants and those involved in medical decision-making as well as pharmaceutical companies and other research sponsors.[5] Previous work highlights the demand from participants for the timely and accessible communication of clinical trial results.[6-8] This is a move that has the potential to improve health literacy, empower patients, and build public trust, particularly in the pharmaceutical industry.[9,10] Simultaneously, communication with patients in this way may promote participant engagement, recruitment, enrolment, and retention in clinical trials.[11] The development of lay summaries is mandated by Article 37 of the EU Clinical Trials Regulation 2014/536, which indicates that "irrespective of the outcome of a clinical trial, within one year from the end of a clinical trial in all Member States concerned, the sponsor shall submit to the EU database a summary of the results of the clinical trial… *accompanied by a summary written in a manner that is understandable to laypersons.*"[2] Although this regulation was released in 2014, it came into effect in January 2022 after the launch of the EMA's Clinical Trials Information System, an online portal designed to aid the dissemination of such summaries.[12] Official Good Lay Summary Practice (GLSP)[13] was published in 2021, by the GLSP Roadmap Initiative,[14,15] co-led by the European Federation of Pharmaceutical Industries and Associations (EFPIA) and the European Forum for Good Clinical Practice. Despite recognition of the development of lay summaries as best practice, explicit legislation has not yet been introduced beyond the EU. For instance, although the inclusion of lay summaries is not specified in the FDA Amendments Act,[16] which legislates the disclosure of clinical trial results in the USA, the FDA encourages the production of "plain language summaries" of aggregate results and has provided draft guidance for voluntary development.[17] In the UK, the Health Research Authority, a division of the National Health Service, "asks" research sponsors to submit "plain language summaries" as part of final research reports that are published on the Health Research Authority website.[18] Additionally, the UK's National Institute of Health and Care Research requires "plain English summaries", in the style of publication-associated PLS, to be submitted alongside research proposals.[19] Despite legislation and guidance from these regulatory bodies, previous research has indicated that the accessibility of lay summaries to patients is lacking and initial compliance with the EU Clinical Trials Regulation has been low, though this may improve with the legislation now in effect.[7,20] Furthermore, lay summaries have been referred to using varying terminology across the industry, leading to a lack of consistency in official communications and potentially to confusion among lay and non-

> Regulatory lay summaries have been referred to using varying terminology across the pharmaceutical industry, leading to a lack of consistency in official communications and potentially to confusion among lay and non-expert readers.

Table 1. Document distinctions

	Regulatory lay summaries	Publication-associated PLS	Standalone PLSPs
Purpose and audience	Mandated summaries of clinical study reports for study participants (typically a target reading age of approximately 9–13 years)	Brief, jargon-free summaries, primarily of peer-reviewed publications and occasionally congress materials, for broad non-specialist readers (typically a target reading age of approximately 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 variable reading ages)
Scope	Reports on one study only, with a focus on primary endpoints and safety	Summarises the content of the associated manuscript	"Translates" 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,[12] but are currently hosted in a variety of places including 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 alongside the abstract when tagged correctly	Currently published only by Future Science Group and Becaris Publishing journals
Guidelines and criteria	Outline mandated in Annex V of the EU CTR 2014/546,[2] with official guidance in the Good Lay Summary Practice[13]	Formats vary with author and journal preferences, but best practice and convention encourage text-based and concise PLS that are peer reviewed alongside the manuscript, at a minimum[3,24-26]	Author guidelines available from Future Science Group[4,27]

Abbreviations: CTIS = Clinical Trials Information System; EU CTR = European Union Clinical Trials Regulation ; PLS = plain language summaries; PLSP = plain language summary of publication

expert readers. In this article, we have chosen to align with the terminology used in the official GLSP guidance.[13]

Objective

The aim of this landscaping analysis was to outline the variation in terms used specifically to refer to lay summaries across a selection of pharmaceutical companies, with consideration given to geographic region, and to provide clarity on terminology and distinctions between the three accessible language document types.

Methods

As a sample selection of the pharmaceutical industry, we performed a landscaping analysis by identifying 38 full and affiliate corporate members of EFPIA[21] and 43 pharmaceutical companies that were ranked in the Bioethics International 2021 Good Pharma Scorecard for transparency and data sharing.[22,23] Accounting for overlap of pharmaceutical companies listed in both sources, this gave a final sample size of 58. We then conducted a manual search of official company websites for mentions of lay summaries and recorded the variations of terminologies in use. This search was performed on August 10, 2022.

To aid in clarifying distinctions between accessible language document types, we used readabilityformulas.com to compare the readability of similar-length excerpts of an example lay summary and an example PLS for comparison. These two examples were selected from within oncology, based on the authors' involvement in the drafting and development of the documents.

Results

Document distinctions and example readability comparisons

Clarification of document distinctions is provided in Table 1.[2-4,12,13,24-27] As an example of the differences in readability and target reading ages between lay summaries and PLS, selected excerpts[28,29] showed the readability consensus was 12–14 years old for the lay summaries and 18–19 years old for the PLS (Figure 1,[28] Figure 2[29]).

Regulatory lay summary terminology landscaping

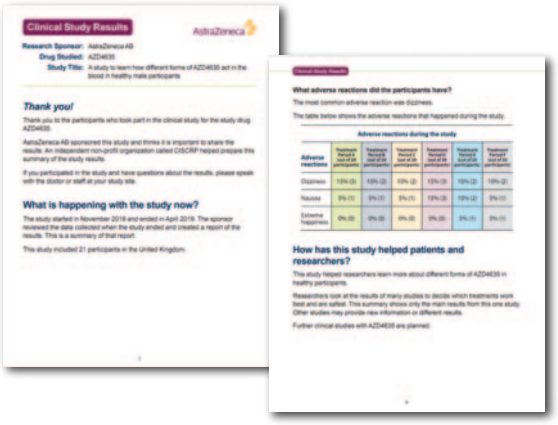
The landscaping analysis revealed that among the 58 pharmaceutical companies whose websites were searched, 56.9% (n = 33) had information on lay summaries publicly available on official websites, whereas 43.1% (n = 25) did not. Of those with publicly available information, there were 22 different terms for lay summaries in use, with 15 companies using two or more different terms for the same document type (Table 2). The two most common terms in use were "plain language summary", with 12 instances of companies using the term to refer to lay summaries, followed by "Lay Summary", with eight instances of use. Additionally, the terms

PLS and standalone PLSP may be used interchangeably.

When considering the geographic region of each pharmaceutical company's global headquarters, there appeared to be greater online transparency of lay summary practices among European companies (regardless of EU membership status) and Asian companies, compared with North American companies. There were also differences in terminology preferences, with "plain language summary" being the term most commonly used by North American and Asian companies, "lay summary" by European companies in EU member countries, and "clinical trial results" by European companies in non-EU member countries. European companies in EU member countries exhibited the greatest variation in terms used for lay summaries (Table 3).

Discussion

Our results reveal a considerable lack of clarity and precision in terminology relating to communications around lay summaries, demonstrating a need for standardisation. The lack of definition and precise description may be particularly problematic and lead to confusion for patients, participants, and non-expert readers when trying to find lay summaries online. Additionally, many of the individual company websites, portals, and databases for indexing their lay summaries were not user-friendly. Some were not clearly labelled and some took multiple clicks to reach the final documents, creating a long and


Clinical Study Results

AstraZeneca

Thank you!

What is happening with the study now?

What adverse reactions did the participants have?

How has this study helped patients and researchers?

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:

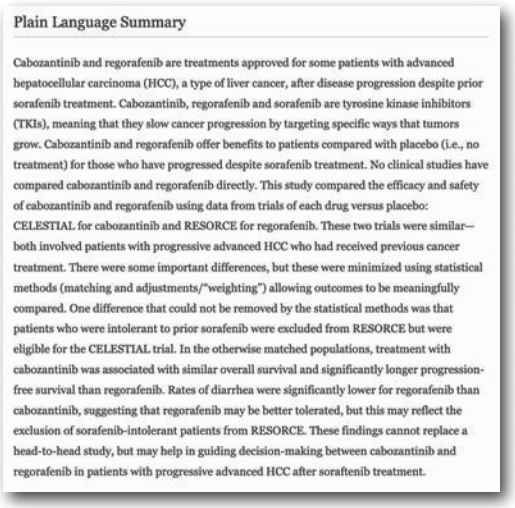
- Was the amount of AZD4635 in the participants' blood similar when given in each form?
- What medical problems did the participants have during the study?

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.

Figure 1. Visual example and excerpt of a lay summary[28]

Table 2. Terms for lay summary in use

Term for lay summary	Number of pharmaceutical companies using the term	Term for lay summary	Number of pharmaceutical companies using the term
Plain language summary	12	Study results summary	1
Lay summary	8	Plain language summary of trial results	1
Layperson summary	3	Plain language summary of clinical trial results	1
Clinical trial results	3	Plain language summary of results	1
Clinical trials results summaries	2	Plain language study results summary	1
Clinical study results	2	Plain language clinical result summary	1
Trial results summary	2	Lay language summary	1
Lay summary results	2	Clinical trial summary	1
Summary of clinical trial results for laypersons	2	Plain language results	1
Lay readable summary	1	Clinical results summary	1
Trial summaries for patients	1	Summary of clinical study results	1
Summary results in plain language	1	Lay patient summary	1
Summary of clinical trial results	1		



Plain Language Summary

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.

"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 sorafenib treatment."

Figure 2. Visual example and excerpt of a PLS[29]

The official Good Lay Summary Practice guidelines acknowledge this confusion in terminology and advise sponsors to distinguish between these document types, indicating that "plain language summary" refers specifically to publication-associated PLS and not regulatory lay summaries.

sometimes complicated process to find the relevant information. Although the manual searches of company websites yielded 43.1% (n = 25) with no mention of lay summaries (or related terms) publicly available online, we are personally aware of at least two of these companies that are distributing lay summaries directly to their clinical trial participants. This indicates unclear online transparency policies that do not necessarily reflect real-life practices; it is unknown how many of the other companies with no publicly available information online fall into this same category. With regard to variations by geographic region, we believe some of these may possibly be attributable to cultural differences in the connotations of the words "lay" and "plain" and to potential interpretations of "lay" being considered condescending or patronising; we are anecdotally aware of examples of this.[30] Such variation may also be related to only one geographic region (European, EU member countries) having explicit legislation that requires and outlines Lay Summaries, whereas others have only guidance or even no input from regulatory bodies.

The limitations of our analysis firstly include the manual aspect of the search, which may have introduced human error. Although automation would have systematised the methods, the lack of consistent language referring to Lay Summaries and the different locations across pharmaceutical company websites meant that human interpretation was needed in the search. Secondly, the selection of the methods of the sample cohort likely introduced biases and may not be representative of the wider industry; EFPIA member organisations are known to have improved rates of results reporting compared with the industry as a whole.[31] Further, results reporting of unregistered epidemiological and observational studies and medical devices are also not represented by this cohort. Thirdly, the limited global representation of the sample selection did not allow for robust conclusions to be drawn for geographic regions beyond Europe and North America and focused on English language lay summaries. Future analyses should include a larger sample size with greater

Table 3. Variation in terminology by geographic region

Geographic region	Number of pharmaceutical companies	Number of pharmaceutical companies with lay summary information publicly available		Number of different terms for lay summaries in use	Most common term for lay summaries in use (count)
North America	24	10	(41.7%)	11	Plain language summary (4)
Europe (EU member countries)	18	12	(66.7%)	13	Lay summary (5)
Asia	8	6	(75.0%)	6	Plain language summary (4)
Europe (non-EU member countries)	6	4	(66.7%)	7	Clinical trial results (2)
Middle East	1	1	(100%)	1	Plain language summary (1)

representation from outside Europe and North America, as well potentially as broadening the scope of the sponsors to included biotech companies and academic funding bodies.

Overall, due to the sheer range of terminology in current usage, there is likely substantial confusion regarding accessible language document types, leading to overlapping and ambiguous language to refer to different, non-interchangeable documents. The official GLSP guidelines acknowledge this confusion in terminology and advise sponsors to distinguish between these document types, indicating that "plain language summary" refers specifically to publication-associated PLS and not regulatory Lay Summaries. It is also acknowledged that these distinctions only exist in reference to document types, whereas the adjectives "lay" and "plain" as they relate to the level of accessibility of language are considered to be synonymous.[13] Medical writers and medical publications professionals need to be aware of these differences and ensure precision when referring to regulatory lay summaries, publication-associated PLS, and standalone PLSPs to avoid further confusion. The medical writing and medical publications profession – including EMWA and other medical writing and publication professional societies, organisations, regulators, and pharmaceutical trade groups – is in a strong position to educate, explain, and encourage accuracy of terminology. Regulatory bodies such as the EMA could also provide more explicit guidance and communications to streamline terminology. Ultimately, we believe collaborative efforts from across the pharmaceutical industry and adjacent industries, such as medical communications and medical devices, are needed to standardise terminology in order to aid clarity and comprehension and to promote appropriate usage.

Medical writers and medical publications professionals need to be aware of these differences and ensure precision when referring to regulatory Lay Summaries, publication-associated PLS, and standalone PLSPs to avoid further confusion.

Acknowledgements

This analysis was originally presented in a poster at the 53rd EMWA Conference, May 3–7, 2022, in Berlin, Germany. It is available online: https://doi.org/10.6084/m9.figshare.19635312.v4. These results were also presented at the EMWA MedComms Special Interest Group Meet & Share meeting on October 19, 2022. These slides have been included in the supplementary materials. The authors thanks Chris Winchester of Oxford PharmaGenesis; Andrea Rossi, freelance consultant; Ellie Challis of PTENUKI Patient Group; Lisa Chamberlain James of Trilogy Writing & Consulting; Priti Nagda of Taylor & Francis Group; and Art Gertel of MedSciCom for reviewing and providing feedback on a version of this article.

Disclaimers

The opinions expressed in this article are the authors' own and are not necessarily shared by their employers or EMWA.

Disclosures and conflicts of interest

The authors declare no conflicts of interest. At the time of data analysis, Ama Appiah was an employee of Oxford PharmaGenesis and has since resumed studies at the University of Oxford.

Data availability statement

For inquiries about data and other supplemental information, please contact the corresponding author.

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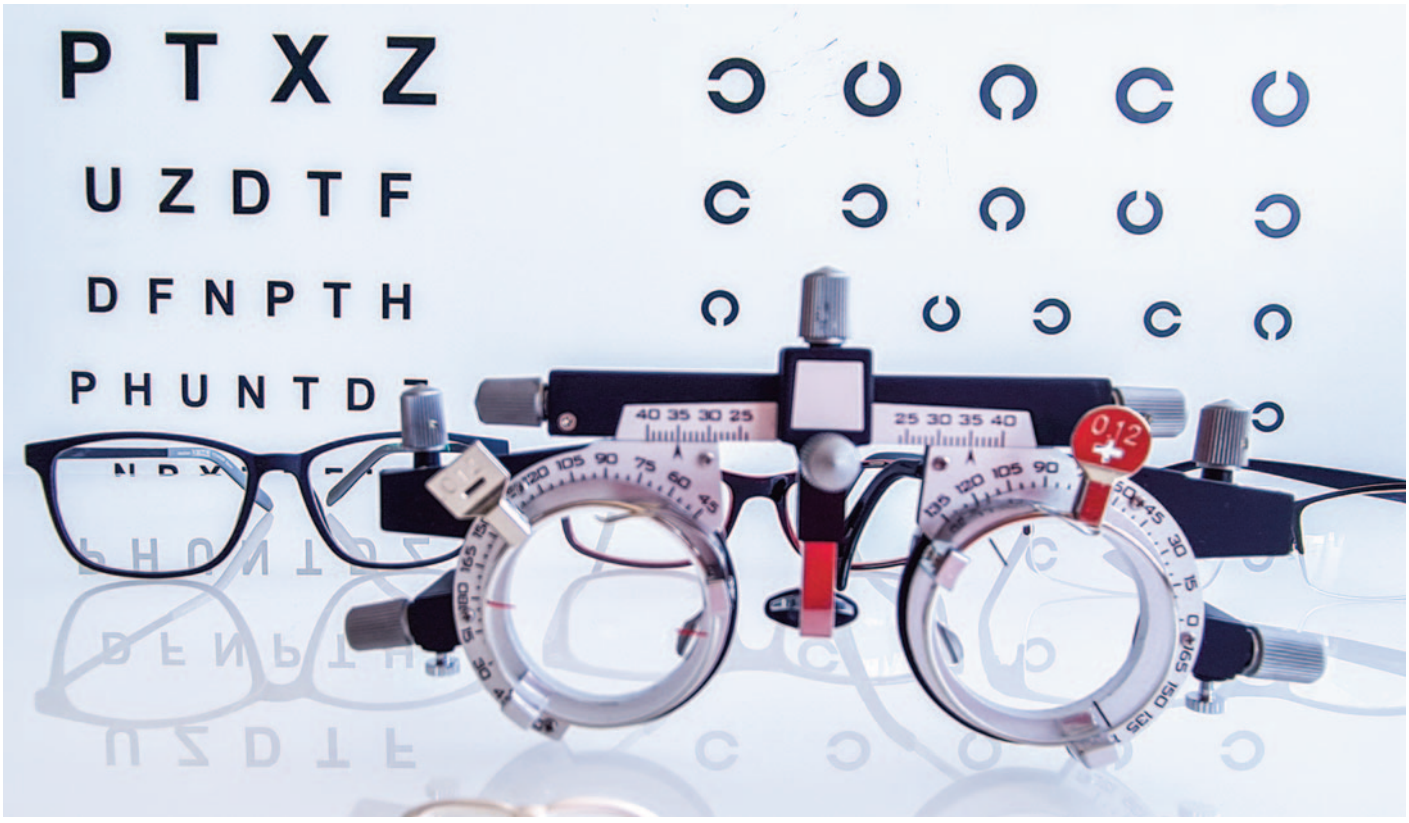

Author information

Sarah Griffiths is a Communications Director at Oxford PharmaGenesis and is content lead of the Patient Engagement Team. She develops all three accessible language document types, presenting on them at societies and congresses. She serves on the Future Science Group Advisory Panel for standalone PLSPs.

Ama Appiah was an intern at Oxford Pharmagenesis in the summer of 2022 where she contributed to research regarding accessible language document types and assisted team members in the process of developing them. Ama has since returned to her studies as a medical student at the University of Oxford.

Adeline Rosenberg is a Senior Medical Writer at Oxford PharmaGenesis where she is regularly involved in developing all three accessible language document types. She has co-authored several peer-reviewed publications on publication-associated PLS and presented on the topic at EMWA and the International Society for Medical Publication Professionals (ISMPP).

John Gonzalez runs a publications/medical affairs consultancy and is currently on assignment as a Publications Lead with Galapagos NV. Originally trained as a pharmacist, John has worked in the publishing, healthcare agency, and pharmaceutical industry sectors. His work interests include publications policy, strategy, guidelines, ethics, and communication with patients.

Slávka Baróniková is a scientific publications leader at Galapagos NV (Belgium), where she established the process for PLS for scientific publications developed by the company. She has also co-authored manuscripts on PLS and presented about PLS at EMWA and the International Congress on Peer Review and Scientific Publication, 9th Congress, Chicago, IL, in 2022.