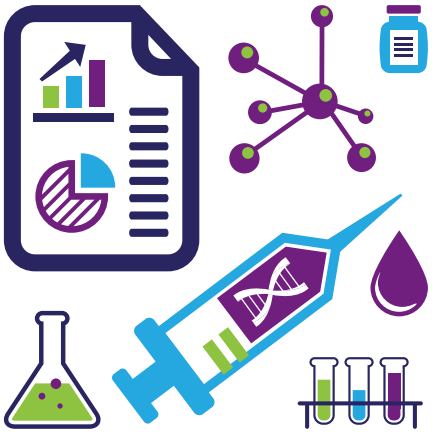
# Plain language summaries: essential in rare disease

## Thank you!

We want to thank all patients, advocates, and caregivers (PACs) for their tireless efforts, unwavering passion, and commitment to bettering people's lives!

## Definition

A plain language summary (PLS) is is a document that presents scientific evidence from a clinical trial written in language that can be understood and used by a general audience of people without specialized training in medicine or science. There are other terms similar or synonymous to PLS, such as patient lay summary and nontechnical summary.[1,2]



## How important are PLSs in rare diseases?

In rare diseases, PACs are playing a more prominent role as well-informed stakeholders and experts in their own right who actively participate in, or even direct, health care decision-making.[3,4] However, it can be challenging for PACs to find easy-to-understand, trustworthy information about complex rare diseases. The PLS is an effective tool to share knowledge with PACs and enable them to become better advocates for themselves and others.

## Are there regulatory requirements for developing a PLS?

*Plain language summaries are valuable tools for patients and caregivers, first and foremost, and they may fulfill regulatory requirements*

Under the European Union (EU) Clinical Trials Regulation 536/2014, effective July 1, 2021, the European Medicines Agency requires that clinical trial sponsors provide a PLS that is understandable to patients, the general public, and experts for all phase 1 through 4 clinical trials.[5] In the United States, while all government documents are required to be written in clear language that the public can understand and use, final rules on PLS requirements for clinical trial reports have not yet been published.[6] There are lingering concerns about PLS documents potentially being promotional; however, it is acknowledged that an objective PLS would be informative and beneficial to the general public.

## Pharma regulatory concerns and solutions

It is important for a PLS to be a factual description of a study and present the results accurately in a way that is clear to the reader. Many journals already offer to publish a PLS or will request a PLS to accompany a publication. The list of journals requiring this is growing.[2] Almost all journals that offer this option require that the PLS be peer-reviewed, usually by the same reviewers who evaluate the manuscript. Alternatively, a PLS developed outside the context of a journal article can be submitted to an independent organization or professional society for review and approval, with appropriate attribution. We recommend that all PLS documents undergo an external independent review prior to publication. In this context, a PLS is considered informational and not a marketing tool.

More and more often, biopharmaceutical companies around the world are proactively preparing PLSs as educational tools when clinical trials are developed and investigators kick off trial enrollment efforts.

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## Who should develop the PLS?

In our experience, the PLS is best developed in the same way as a manuscript: The authors, working with their medical publications agency and potentially an advocacy group, develop the PLS collaboratively—often alongside the article. Involvement of a PAC member in the development process (often as an author) solidifies the utility and perspective of the material.

## Key considerations

When developing a PLS[2,7]:

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| ☐ | **KNOW** your audience | The PLS is intended for a general audience, not specialists who are experts in the field of study. Identify the key issues presented in your publication that will engage and be of interest to your audience. |
| ☐ | **DESIGN** for easy reading | Design the PLS for easy reading using a conversational tone and an active voice. We recommend using language that a middle/high schooler would understand. |
| ☐ | **USE** graphics | Well-designed graphics can facilitate understanding by the target audience. |
| ☐ | **CHOOSE** words carefully | Avoid using technical language, including acronyms, field-specific terminology, and words that have a different meaning in lay usage (eg, "mole," which is an animal in common usage but a scientific unit of measure in medicine; "organic," which most people associate with "natural products" but scientifically means carbon-based chemistry). |
| ☐ | **SUMMARIZE** the publication | The PLS should answer the following questions:<br>• What is this publication about? Remember that the general public will need more context than specialists in the field.<br>• Why does this publication matter? Discuss the importance of the publication to the lay reader. How could this publication affect their health, safety, economics, etc? "What does this mean to me/my child/someone I love?"<br>• What did you discover? Describe the results in plain language.<br>• What is the impact of this publication? Discuss how this publication addresses unmet needs, health, safety, etc.<br>NOTE: Only provide results that are in the original publication; do NOT add or change results in an attempt to make it more understandable to the layperson. |
| ☐ | **TEST** your summary | Test your PLS with at least one PAC community member who will help identify areas within the summary that may need further clarification. Importantly, incorporate their feedback into your PLS. |

## Access to the PLS

Almost all PLS documents are freely available even when the article itself is behind a paywall. This is particularly important for PACs who may not have the financial resources to pay for access.

## How else can I use a PLS?

This will depend on your company's legal/medical/regulatory review process. Some trial sponsors will refer to PLSs in press releases, host them on their corporate website, and/or collaborate with advocacy organizations to make the PLSs available to the community. In addition, some companies will share the PLS in advance with study investigators and encourage them to share the PLS with study participants and their families.

## Outcome

A well-done PLS provides a high-quality and accurate summary of the science to the general audience in clear language they understand and can use.

To expand your rareIQ, contact a rareLife solutions team member at psnyder@rarelifesolutions.com.

**References**


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