



# Plain language summaries (PLS) of peer-reviewed publications and conference presentations: practical 'How-To' Guide for multi-stakeholder co-creation

This How-To guide is part of a series of PFMD How-To guides that have been co-created in a multi-stakeholder environment built with the Patient Engagement Quality Guidance as a starting point. All How-To's are connected and provide a full set of instructions on how to involve patients across the research, development, and delivery of medicines.





# Executive Summary

**This How-To guide is part of a series from Patient Focused Medicines Development (PFMD) that provides a set of instructions on how to involve patients in the co-creation of plain language summaries (PLS) of peer-reviewed publications, including journal articles and conference presentations.**

## Section 1 – Introduction and Overview of the work

- Peer-reviewed publications and conference presentations are a means for medical researchers to present their research to their peers, for example, the results of a clinical trial.
- PLS tailor this information so it is suitable for a broader audience in terms of readability and understanding, and are valuable to a broad range of readers, including patients, patient organisations, caregivers, and the general public.
- PLS are also valuable to healthcare professionals (HCPs) and non-specialist physicians to help generate dialogue and more focused communication with their patients.
- Patient involvement and engagement in the development of PLS is often restricted to the later stages of their creation (e.g. the review process).
- The aim of this document is to:
  - Provide a How-To guide for the creation and dissemination of PLS
  - Encourage co-creation with patients at every stage of development of the PLS
- The How-To guide has been co-created with a wide variety of stakeholders, including: patient representatives, industry members, publishers, researchers, medical communication agencies and public officials involved in research bodies.
- The How-To guide is organised into a seven-step approach, and considers the seven quality criteria of the Patient Engagement Quality Guidance (PEQG) in the first four steps. The guide has been developed for anyone who needs to write or contribute to a PLS of a peer-reviewed journal publication or congress presentation.

## Section 2 – Ethical considerations for PLS

- PFMD seeks to foster the involvement of patients in all stages of the medicines life cycle. Given that patients can only fully participate if they are well-informed about current medical developments, PLS of scientific publications and of contributions to legitimate scientific congresses are at the core of this.
- While there is a clear need for scientific results to be shared with the public, it is important this is done in an ethical and responsible way, to avoid the potential for misinterpretation and a negative impact on patient care.

**As such, this How-To guide has identified some key ethical principles that should act as a guide throughout the creation of a PLS.**



## Section 3 – Step-wise approach for PLS co-creation

### Step 1: Rationale and Scope of your PLS

- The justification for the creation of a PLS should be considered (to demonstrate absence of promotional motivation), along with plans for where the PLS will be published, and the resources that will be required for its co-creation.

### Step 2: Identify your target audience

- Knowing the target audience for the PLS is vital to determine what their needs are, and therefore what information it should contain.

### Step 3: Consider dissemination channels for PLS.

- Dissemination of the PLS will also affect content and format, so should be considered early on. Certain channels (such as social media platforms) might work better for certain audiences in terms of reach and engagement.
- PLS should also ideally be submitted for publication in a peer-reviewed journal, and therefore the journal requirements should also be considered before writing begins. This also applies to PLS of conference presentations, where the conference may have content and formatting requirements that must be complied with.

### Step 4: Identify your key stakeholders for co-creation of PLS.

- Consider which of the key stakeholders from your target audience (identified in Step 2 – Identify your target audience) to bring into PLS co-creation. This will help ensure that the PLS is understandable and relevant for each target audience.
- There are various activities in the creation of a PLS that can incorporate co-creation, such as selecting publications/presentations for which to develop a PLS; planning the content of the PLS; writing the PLS; and reviewing the PLS.
- Provided they have some of the relevant skills required, patients should be participants throughout the creation of a PLS.

### Step 5: Write your PLS.

- The PLS should be written with the target audience in mind, to ensure factors like the reading age, type of visual and audio formats, and the type of language you use (based on literacy level) are appropriate.
- Visuals and infographics can help engage the reader, and it is important to think about where these can be used most effectively.
- Readability and suitability tools are available to help check how easy your PLS is to read and understand. It is also helpful to test the PLS with someone from your target audience and ask them to provide feedback.

### Step 6: Disseminate your PLS.

- Once published, the PLS could be disseminated by a variety of sources including the journal that published it, the institutions of the authors, the authors themselves, patients, advocacy groups, medical societies and HCPs.
- The PLS could be shared via social media, print copies, repositories such as PubMed, and other relevant websites.
- However the PLS is shared, it should always reference the scientific manuscript or contain links to the scientific source.

### **Step 7: Track dissemination and measure success.**

- It is helpful to establish a strategy for monitoring the impact of any PLS, and this is an important way to empower the entire process and systematize the assessment of its value and impact.
- Depending on where a PLS is hosted, various metrics will be available to you to track how it is being used.

## **Section 4 – PLS of Conference presentations**

Although focused on PLS of journal publications, much of the guide also applies to PLS of conference presentations. However, there are a few additional considerations such as: extent of patient attendance, other delegates at the conference, PLS for abstract submission, PLS data content, data presentation, posters, conference requirements, metrics to track dissemination, dissemination strategy beyond the conference itself.

## **Section 5 – Considerations for quality PE**

This How-to Guide (as all PFMD How-to Guides) has been built to be used alongside the PFMD Patient Engagement Quality Guidance (PEQG) which defines seven Quality Criteria for good patient engagement. These criteria have been adapted as practical considerations and utilised where they fit best.

## **Section 6 – Acknowledgements**

## **Section 7 – Annexes** (Annex 1 Glossary; Annex 2 Resources for Writing your PLS; Annex 3 Examples of PLS and where to find them; Annex 4 PE Quality Guidance definitions)

To supplement this How-To guide, a number of resources have also been compiled to assist in the creation of PLS, including plain language resources, useful videos and toolkits, and examples for published PLS.



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# Introduction and Overview of the work

[Patient Focused Medicines Development \(PFMD\)](#)<sup>1</sup> aims to improve global health by designing the future healthcare with patients. PFMD focuses on making patient engagement a systematic reality by co-creating needed resources for all stakeholders to embark on and improve their patient engagement journey.

This How-to guide is part of the [How-to Guides series](#)<sup>2</sup> that build from the Patient Engagement Quality Guidance and provide a step by step recommendation to involve patients in specific activities and/or phases in the drug development continuum. Each guide is a standalone tool, but can be combined with each other to form a comprehensive roadmap for patient engagement activities.

Used together with the [Patient Engagement Quality Guidance](#)<sup>3</sup>, it will increase the level of meaningful engagement with patients, improve the relationship between stakeholders and hopefully improve research outcomes overall due to having patients as research partners. These How-to guides are co-created with Patients, Researchers and other relevant stakeholders in the specific phases or activities.

**This How-to Guide applies to peer-reviewed publications and conference presentations on any stages of medicine development.** More PFMD's co-created resources can be found from the [Patient Engagement Management Suite](#)<sup>4</sup> – a comprehensive and interconnected guidance and tools for patient involvement and engagement.

## What is it?

Improved people information was identified by the PFMD consultation as a priority across all phases of the medicine lifecycle. Plain language summaries (PLS) of peer-reviewed publications and conference presentations allow research authors and journal editors to reach a broader audience among patients, patient organisations, caregivers, and the general public.

For Healthcare professionals (HCP), PLS can help generate dialogue, more focused communication with their patients, can help them in a world of information overload to get a quick overview and they can then deep-dive in the full publication. It can also support non-specialist physicians.

Patient involvement and engagement (PE) in the development of PLS is often restricted to later stages of development (e.g. the review process). Our objective was to develop a practical how-to guide that describes the process of PLS creation and dissemination through a straightforward 7-step approach that ensures early patient engagement.

While navigating this stepwise process, the user will be guided towards tailored PLS tools and examples, as well as a methodology to assess the importance of involving patients at each key milestone. The guidance can be used from planning through to the delivery of a PLS to encourage co-creation with the intended target audience.

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<sup>1</sup> Access at: <https://patientfocusedmedicine.org/>

<sup>2</sup> Access at: <https://pemsuite.org/how-to-guides/>

<sup>3</sup> Access at <https://pemsuite.org/peqg/>

<sup>4</sup> Access at: <https://pemsuite.org/>



## How was it developed?

The tool has been co-created with input from a variety of stakeholders with experience in both PE and developing PLS: patient representatives, industry members, publishers, researchers, medical communication agencies and public officials involved in research bodies.

This How-to Guide (as all PFMD How-to Guides) has been built to be used alongside the PFMD Patient Engagement Quality Guidance (PEQG) which defines seven Quality Criteria for good patient engagement. **The seven quality criteria are considered in the first 4 steps of the PLS stepwise approach.**

These criteria have been adapted as practical considerations and utilised where they fit best. See [Section 5 – Considerations for quality PE](#) for more details and how it has been applied throughout the stepwise approach.



**Figure 1.** The 7 Patient Engagement Quality Criteria

## Who is it for?

The guide has been developed for **anyone who needs to write or contribute to a PLS of a peer-reviewed journal publication or congress presentation** that needs to be tailored for a broad audience's readability and understanding. **For patients, patient organisations, caregivers, and HCPs, and the general public, the tool will give more clarity and instruction on how to co-create the PLS.**



Patients



Patient  
organisations



Caregivers



HCPs



General public



PATIENT FOCUSED  
MEDICINES DEVELOPMENT



How-To Guides for  
Patient Engagement

**DRAFT**  
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[Under public consultation](#)

# Ethical considerations for PLS

Appropriate and adequate information for patients is central to PFMD's efforts to foster involvement at all stages of the medicines life cycle. **Patients can only fully participate if they are well-informed about current medical developments, and PLS of scientific publications and of contributions to legitimate scientific congresses are at the core of this.** The interactions of patients and other stakeholders need to be based on the principles of partnership, collaboration, fairness and transparency.

There is a clear need to share scientific results with the public; however, this must be done in an ethical and responsible way. Scientific information is generally provided within a research context. Researchers are trained to evaluate and analyze scientific information.

When scientific information is explained in simple terms and is provided outside of its context, there is an increased likelihood of misinterpretation. Misunderstanding scientific information can lead to unintended and potentially harmful consequences. For example, readers may decide to stop or start medications based on their reading of a PLS without consulting a healthcare professional.

A PLS needs to fulfil all of the ethical requirements that apply to peer-reviewed scientific publications and need to also describe the research context in which the scientific study was conducted. In addition, **the following principles apply:**



Any statement in the PLS should be objective and aligned with the data provided in the scientific publication.



Health literacy and numeracy principles should be applied in the writing and design of the PLS.



The choice of words should be neutral and factual. Superlative and emotional words, phrases and metaphors should be avoided.



The PLS should be free of any commercial bias and must be strictly non-promotional.



For PLS linked to primary scientific publications of clinical trials, there should be a balanced presentation of efficacy and safety data.



The overall objective of the scientific study that is reported needs to be described in the respective PLS.



All data provided in the PLS should also be given in the scientific article. The data presented in a PLS should not go beyond the data provided in the scientific article.







The results of the primary endpoint need to be described and explained in the PLS when reported in the scientific publication. Results of key secondary endpoints could be included if they have been pre-specified in the study protocol or analysis plan, are statistically powered and analysed, and are of particular relevance to patients.



The PLS needs to mention the important limitations of the research or study that is reported in the scientific article.



Appropriate translations should be done that faithfully reflect the content of the PLS. Translations need to be mindful of the cultural diversities between audiences and ideally reviewed by members of the target audience for each language.



The PLS should be inclusive of all genders, nationalities, and ethnicities.



The PLS should be reviewed by members of the public and/or by patients or patient representatives ideally with the condition that was studied in the scientific article.



The PLS should be approved by the lead author (the author who is named first in the author list) of the scientific article, as a minimum. All authors of the scientific article on which the PLS is based should be given the opportunity to review and comment on the PLS.



The authors of the PLS as well as the funding source of the research work and the funding of the PLS should be disclosed in the PLS.



Links to the scientific publication should be included in the PLS.



# Stepwise approach for PLS co-creation



Figure 3. Stepwise approach for PLS co-creation

## Step 1: Rationale and Scope of your PLS

- **Identify objective and justifiable criteria for doing a PLS** to demonstrate absence of promotional motivation e.g. Consider where the source publication fits in the medicine's development continuum (R&D [early phase], preclinical, phase 1–3 clinical development, regulatory submission and approval, post-marketing). The organisation developing the PLS should state openly their plans for PLS development (e.g. study type, disease area, later stage of research). PLS can only be developed for Phase 3 studies if the organisation has limited resources.
- **Consider whether the target journal accepts or mandates PLS, or if the PLS would be easily accessible or only available through a paywall.**
- Include consideration of the journal's open access policies. Authors can pay for the article to be accessible beyond subscribers.
- **In case the journal does not accept a PLS is there a possibility to publish it elsewhere?**
- **Consider and acknowledge whether patients or other target audience members were co-authors or contributors to the publication and/or the corresponding PLS**, or involved in the research design, conduct, and reporting of the results.
- **Consider the resources required for PLS co-creation:** human resources (internal core team including patients, stakeholders, skilled PLS writers, etc.), translations, and budget required; set up an action plan and timelines.







## Step 2: Identify your target audience

It is very important to consider who will be your target audience for the PLS and what their priorities



and needs are. Who are the readers of the journal or other repository/platform where you will submit the PLS?

Consider the following stakeholders and identify your **target audiences**:

	Patient organisations, patient advocates, patients (i.e. patients participating in a clinical trial), carers
	Healthcare professionals (HCP): general practitioners, family physicians, specialists (e.g. paediatricians, geriatricians), nurses, pharmacists, particularly time-poor HCPs or HCPs outside the specialty area for the publication.
	Researchers
	The general public



### Patient and general public perspective

- Do you expect patients or the general public to access and read the PLS by themselves or that they will discuss it with their doctor or a patient organisation representative?
- For patients, how do they learn and what are their expectations?
- What impact could their condition have that is relevant to the PLS – for example, do they have a rare disease or a chronic condition?
- Do they have a specific need for visually accessible or audible versions of the PLS?
- What is the cultural environment?
- Are they part of a hard-to-reach population, and will translation be needed?



### Healthcare professional perspective

If the PLS will be used by HCPs for their understanding of a publication and/or to discuss with a patient, it will be important to adapt it to the expectations of the HCP to enable them to open a dialogue with their patients.

- Be aware of the level of background information HCP's might need to put findings in perspective and discuss appropriately with their patients.
- Consider what type of language will be precise enough and scientifically accurate to ensure they will have the right level of information to explain the findings correctly to their patients.





## Step 3: Consider the dissemination strategy

**It is critical to think about dissemination as soon as a PLS is being considered.** PLS of publications should ideally be submitted for publication in a journal which would allow peer review (including, at some journals, patient peer review) of the content.

We can ask the editors to consider peer review trained people on health literacy principles. **It is therefore important to consider the development and dissemination plan for the PLS alongside the development of the original journal manuscript or congress presentation.**

### Points to consider before writing and submitting your PLS:



#### Dissemination considerations:

- It is important to consider **dissemination channels** before work on a PLS even begins. It is useful to consider your target audiences when thinking about the social media platforms you might like to use (such as Twitter, Facebook, LinkedIn, Instagram, etc.).

This will help define which channels will work best, and how to enhance reach and engagement with your target audience. This might impact the format, platform and style of the PLS, which in turn will affect the internal approval process, compliance requirements and copyright arrangements. This may also be very dependent on the specific target journal as they have very different approaches to PLS and formatted guidelines.



#### Format considerations:

- What formats and types of features will aid the future dissemination of the PLS?**
  - Social media is a tool which technically supports alternative formats to disseminate your work (always considering your targeted audience). Formats such as images, infographics, video and audio are more widely shared on social media than text alone. Keep in mind that some journals can support social media dissemination.
  - Health literacy principles also work well for social media notifications.
  - Consider people that are suffering from disabilities (audio instead of reading a document).
  - Ensure that the format used (images, infographics, video, audio, etc) is reviewed prior to public release and aligned with internal policy and deemed non promotional.



#### Considerations for PLS being submitted to a journal:

- Does the journal you are submitting the source publication to have specific guidelines related to PLS (e.g. length, formatting, etc.)?** If these are available, you will usually find them in the author's instructions on the journal website.
  - If yes:** be sure to refer to these guidelines when developing the PLS.



- **If no:** consider contacting the journal editor to ask what formats they accept PLS in (and even consider submitting elsewhere, if the journal isn't open to the publication of PLS). If no specific guidelines are available, consider the format you can use to include a PLS as part of the original publication:
  - Supplementary materials file
  - Supplementary video
  - Figure or infographic within the main manuscript
- **Will the journal you are submitting allow the PLS to be freely available to readers and free to share after publication?**
  - There are 'Free to Access' journals, these usually allow access without a paywall but might not be as shareable as a full Open Access [OA] article.
  - There are OA journals, or a journal with an OA option.
    - If so, what OA license option is available? The type of OA license will affect how you can use and share the PLS.
    - For more information on the different OA license types, see: <https://creativecommons.org/use-remix/cc-licenses/>
- **If the PLS is included as a Supplementary Materials file, does the journal deposit these with Figshare (<https://figshare.com/>)?**
  - If so, this will assign the PLS its own DOI (Digital Object Identifier).
  - The DOI is an Identifier Number that is used to permanently identify an article or document, meaning it can be cited independently and linked to directly on the web.

Do not hesitate to contact the journal editors to discuss ways to include the PLS and give it visibility.

**In the case that the PLS will NOT be peer-reviewed by the journal, you can consider the following hosting options:**

- **Own organisational site**
- **Third party site**
- **Patient organization sites**
- **Medical society sites or similar**





## Step 4: Identify your key stakeholders for co-creation of PLS

### How to co-create PLS of publications

**Consider which of the key stakeholders from your target audience** (identified in [Step 2 – Identify your target audience](#)) **to bring into PLS co-creation. The aim of co-creation is to ensure that the PLS is understandable and relevant for each target audience.**

#### Key roles for Patients:



##### Patient expert co-author:

Involved in the creation of the PLS with the manuscript author(s) and should have appropriate writing experience and fundamental health literacy skills. Their patient background and understanding of the scientific and medical research offers the author(s) a unique patient perspective, which brings added value to the article.

**When would the patient expert co-author be involved?** The PLS co-author(s) would be involved in the co-creation of the PLS (e.g. patient expert write specific parts and/or the initial draft) before the submission of the document and during the review cycles from the journal.



##### PLS reviewer:

Skills-wise, there may not be much difference between this role and the role of a co-author, but this participant may have a greater awareness of the health literacy levels of the community and the general population, for example:

- More active involvement in patient advocacy and in-depth knowledge of their condition(s) acquired through years of disease management
- Awareness of the level of the public's understanding (e.g. of scientific research)
- Strong engagement supporting patient organisations, including awareness of and experience with different stakeholders
- Ability to provide context-related comments to assist writers in improving the PLS.

The co-author and reviewer could suggest a short list of glossary terms to accompany the PLS to define any scientific and technical jargon, where necessary.

**When is it advisable to involve a reviewer?** The PLS reviewer would be invited by the publisher or journal editor to assess the manuscript of the PLS during the peer review process of the journal article. Consider a minimum number of reviewers to avoid biases by personal opinions.



##### Layperson:

Someone from the public or a patient who is invited to read the PLS and give feedback on their level of understanding of the research topic presented. The layperson could be suggested by the patient



organisation, point of care or caregivers.

**When is it advisable to involve a layperson?** The layperson is the end-user and considered a key player for the optimisation and further dissemination of PLS and to provide constructive feedback (to publishers, authors or patient organisations) to ensure that the audience's needs are met. The lay review should happen at the final draft stage, before submission. Consider a minimum number of laypersons to avoid biases by personal opinions.

#### Co-creation activities can include:

Activity	Benefits of activity	Skills needed
<b>Selecting which publications are most suitable to develop PLS for</b>	<p>Unless resources are available to develop PLS for every publication in a publication plan, there is a risk of being perceived as 'cherry-picking' data for PLS. Some pharma companies may allow this in some situations, perhaps in rare diseases.</p> <p>Transparent, objective selection criteria are required (selection bias is a real concern that can be mitigated if the criteria for selection are clear and the decision is made prior to data read-out).</p> <p>One approach involves asking a panel of target audience members which publications to prioritise for PLS.</p>	<ul style="list-style-type: none"> <li>• Understanding of the different types of data (e.g. preclinical vs. clinical data, real-world evidence, epidemiological, qualitative)</li> <li>• Amongst patients, lived experience of the condition may be helpful if it could influence the selection criteria, e.g. people with a rare condition and few treatment options may be more interested in early-phase data than people with conditions for which many treatment options are available</li> <li>• Acceptance and ability to use health literacy principles is paramount</li> </ul>
<b>Planning the content of the PLS</b>	<p>PLS must accurately reflect the content of the original scientific article in a balanced way, but there is unlikely enough space in the PLS to include everything from the original article.</p> <p>Your target audience can help you to prioritise content from the original article for the PLS, while ensuring that the focus of the PLS accurately represents the scientific article</p>	<ul style="list-style-type: none"> <li>• Understanding of the content of the full scientific article. Understanding or ability to communicate the statistical limitations – e.g. where differences could be incidental, or observations should not be considered conclusive</li> <li>• Understanding of which types of information might be most relevant to the target audience, e.g. safety and patient-reported outcomes may be of high interest to a patient audience</li> <li>• Applying health literacy principles is key</li> </ul>



Activity	Benefits of activity	Skills needed
<b>Writing the PLS</b>	<p>Involving your target audience can help to make sure your PLS is written in a way that suits their needs.</p>	<ul style="list-style-type: none"> <li>• Understanding of the content of the full scientific article</li> <li>• Plain language writing, using health literacy principles, such as numeracy and graphic design skills (may require training)</li> <li>• Providing context for each audience so they can understand how the information may be relevant to them</li> </ul>
<b>Reviewing the PLS</b>	<ul style="list-style-type: none"> <li>• User-testing is the best way to ensure that your PLS is easy to understand and relevant to your target audience. Approaches range from sending your PLS to a reviewer and asking them to provide feedback, to conducting a structured usability test with a focus group that represents each audience.</li> <li>• Invite continuous feedback on the PLS even after it becomes available (e.g. at congresses, or other community-level presentations)</li> <li>• For PLS going to journals, the named authors of the article should be explicitly involved in reviewing and signing off the PLS content to fulfil ICMJE ( International Committee of Medical Journal Editors) requirements for authorship (applies to the journal article)</li> </ul>	<ul style="list-style-type: none"> <li>• Ability to view the PLS from the perspective of a 'general' member of the target audience group</li> <li>• Understanding of what a PLS is, why it is being done and any specific requirements followed during PLS development (may require training)</li> <li>• Reviewing for context to each audience</li> </ul>









## Step 5: Writing the PLS

### How to write PLS of publications

The aim of a PLS is to provide a clear, accessible summary of the content of a journal article or congress presentation, for non-specialist readers.

For those who are used to writing in a scientific style, plain language writing requires both a different skill set and practice. As well as the writing style, you will need to consider how data are presented and how any visuals are designed. There is currently no standard approach, but practical tips and tools are available below to guide you.

### Consider the following key principles when writing your PLS:

-  **Think about your audience.**  
Who you are writing for may influence factors like the reading age, type of visual and audio formats, and the type of language you use (based on literacy level).
-  Ensure that **PLS are balanced and non-promotional**, and describe only what was included in the journal article or congress presentation. Follow the ethical principles outlined above in [Section 2 – Ethical Considerations for PLS](#)
- Check for and follow any requirements provided by the journal or congress** to which you are submitting the PLS.
- If possible, **develop the PLS in parallel with the journal article or congress presentation.**
- Useful tips to test the quality of your PLS:
  - Test it with someone from your target audience.** For example, have them read it and then explain your study to you.
  - Readability tools** (See [Annex 2 – Resources for Writing your PLS](#)) can help you check how easy it is to read, but will not ensure it is easy to understand. They are also not easily applied to texts with many numbers and scientific terms.
  - Suitability tools** (See [Annex 2 – Resources for Writing your PLS](#)) can help you check how easy it is to understand and whether it aligns with key principles for effective health communication.
  - Health literacy principles and methods are available at various resources** (See [Annex 2 – Resources for Writing your PLS](#)).
- Take time to do it right. Your PLS may gain more exposure for your paper than your abstract, so you will want to communicate the relevance and importance of your research in a way that ensures everyone can understand it.



### **Top tips for plain language/health literacy writing**

- Use the active voice
- Use short sentences
- Use simple words and phrases that will be familiar to your target audience, avoid jargon, and give plain-language descriptions for any technical terms
- Use white space (See [Annex 2 – Resources for Writing your PLS](#)) in your content to break information into chunks. Leave space between sections of text and around images and buttons.
- Avoid using too many acronyms ensure explanations for acronyms are clearly mentioned.
- Choose the right tone – you might choose a more conversational tone, but be sensitive around emotive topics
- Keep formatting simple – use bold sparingly, and avoid italics, underlining and capital letters

### **Top tips for helping readers to understand numbers**

- Include only essential numbers
- Don't expect the reader to do any calculations – make the meaning and context clear
- Use whole numbers
- Use natural frequencies (e.g. 1 out of 10 people) and percentages
- Use of simple bar graphs and pie charts with data labels
- Use consistent denominators and time frames

### **Top tips for structuring your PLS**

- Use descriptive question headers to encourage active reading
- Split paragraphs out into short bullets or numbered lists
- Think about using an 'inverted pyramid' structure:
  - What question was the research trying to answer?
  - What did you find?
  - Why does it matter?
  - What is the key take-home message?





### **Top design tips for your PLS**

- Visuals and infographics can help to engage the reader – think about where you can use them most effectively
- Avoid ‘graphic junk’ – every image should have a purpose and help the reader’s understanding
- Maximise white space
- Font size of 12pt or larger (Consider using sans serif fonts to maximize readability for neurodiverse audiences).
- Avoid too many columns of text. Single page-width text is easier to digest and is compatible with accessibility software.
- Use high contrast between text and background – dark text on a white background is easiest to read (Consider colour blind audiences).

### **Checking the quality of your PLS**

The best way to check that your PLS is suitable for your target audience is through user testing exercises. This means getting someone from your target audience to read your PLS and provide feedback to help you improve it. However, there are a range of tools that you can use on your own to check how easy your PLS is to read (readability tools) and understand (suitability tools). Ideally, you should use a combination of all 3 approaches.

#### **Readability tools** (See [Annex 2 – Resources for Writing your PLS](#))

- You can use readability tools to check how easy your writing is to read. Most tools look at features of the text such as word and sentence length, and estimate reading grade level. This is a guide to the number of years of education someone needs to read the text.
- Readability tools are useful to pick up issues that could make your writing harder to read. You can also test and re-test your writing to check for improvements.
- However, they do have limitations:
  - Many of the currently available tools can only score English text
  - The tools all work in different ways so scores can be variable
  - They cannot provide a score for the visuals in your PLS
  - They cannot tell you how easy the content of your PLS is to understand

#### **Suitability tools** (See [Annex 2 – Resources for Writing your PLS](#))

- Suitability tools can check how easy it is for users to understand the meaning of your writing.
- They are self-assessment tools that you complete yourself – so be honest with your scoring, or ask someone else to score for you!
- Read the instructions and questions all the way through before starting – they also contain a lot of useful tips.





## Step 6: Disseminate your PLS

In whichever means the PLS is shared, where policy permits, it should always reference the scientific manuscript or contain links to the scientific source.

### Points to consider after your PLS is published:

#### Who could share it?



#### The journal that published it

Most journals have various social media channels by which they share journal content, and should be encouraged to share the PLS. Some may even issue a press release for particularly interesting work.

Authors of the PLS could also share names of relevant patients, advocates or societies with the journal, and encourage them to mention them in their social media posts, to further increase dissemination of the PLS and also increase awareness of these groups.



#### The institutions of the PLS authors

Where the policies of an author's institution allow, they should share the work. Most pharma companies should be able to share peer-reviewed content without problem. This is a contentious area (even if peer reviewed) particularly if it involves pharmaceutical products as there is a risk in some countries of being accused of direct to patient/public marketing. There is also the risk of off-label promotion. It may be worth acknowledging this and emphasizing more that employees of for-profit companies should follow their publication and social media policies.

Many academic organisations will also have a press office that can be contacted. PLS can be shared via the organisation's social media channels and/or a press release. Depending on the journal publishing agreement, the PLS or a link to it could be embedded in the press release.



#### The authors themselves

As above, where they are able and permitted to, authors should share PLS via their own social media accounts.



#### Patients, advocacy groups and medical societies

Many individual patients and patient groups are very active on social media, so can be a valuable ally in the sharing of PLS. Likewise, relevant medical societies often have very relevant membership and their social media channels are also followed by interested members of the general public.



#### Healthcare providers

These stakeholders should be encouraged to share PLS with their patients.



## Where will it be shared?



### Social media

There are many platforms available to share content (such as Twitter, Facebook, LinkedIn, Instagram, etc.). It is useful to consider your target audiences when thinking about the social media platforms you might like to use. For example, LinkedIn is used more by general practitioners, whereas patients might be more likely to use Twitter or Facebook.



### Print copies

Will the journal in which the PLS is published allow print copies to be made for dissemination? Depending on how the PLS has been published (if the journal holds the copyright, or if it has been published OA under an appropriate license), it may be possible to make print copies of the PLS for distribution via hospitals, surgeries or other locations. However, environmental impact should also be considered against the potential impact of printing and distributing the PLS effectively.



### Repositories

[PubMed](#) offers indexing for PLS of the 250-word abstract-style format, which may be a major consideration for PLS accompanying peer-reviewed manuscripts because it enables wider dissemination and fosters confidence and trust in the PLS within academic and industry circles.

Sites such as [Figshare](#) and [Zenodo](#) allow individuals to deposit content so they can be freely shared with others. In some cases, journals will deposit content themselves, but authors should also check with the journal if they can deposit the PLS themselves if this is not the case.

The Registry of Research Data Repositories (<http://re3data.org/>) provides links to lots of repositories.



### Relevant websites

Depending on the copyright/OA status of the PLS, it may be possible to host it on relevant websites (either in full, or linking to the PLS on the journal website). This could include patient sites, medical society pages or a pharmaceutical company page.



## Step 7: Tracking dissemination and measuring success

Establishing a strategy for monitoring the impact of any PLS developed is an important way to empower the entire process and systematize the assessment of its value and impact. It will allow you to understand which areas need improvements, capture learnings and disseminate the measures to the interested parties (organisations, sponsors, co-creation teams). Dissemination and discoverability will benefit from use of Digital Object Identifier (DOIs), which can be assigned by journals, Figshare and other channels.



Depending on where a PLS is hosted, you will have various metrics available to track how it is being used. Potential sources of these metrics include:



### **The journal**

Many journal articles now include metrics alongside article publications indicating how often an article has been viewed and/or cited. This records when another article has referred to it and therefore included it in their reference list, and is generally used as an indicator of the impact of the article in terms of its influence on other work.

Many also track an article's [Altmetric](#) score, which is a measure of the quantity and reach of the attention it has received online (e.g. whether people have tweeted about it, or mentioned it in a news story or blog). Note, journals generally provide overall article metrics, not individual metrics for supplementary material files (if this is how the PLS has been published), although these might be available on request.



### **Repositories**

If the PLS has also been deposited on one of these websites (e.g. on Figshare), metrics can often be viewed on the platform, including views, downloads and citations. These metrics will be specific to the PLS itself, rather than the article as a whole.



### **Alternative channels / social media**

Alternative tactics may allow you to enhance reach among the target audiences via multiple channels, primarily through social media.

Social media platforms will allow you to measure whether a PLS led to an increase in views, clicks, downloads or sharing, and will give you a better indication of the reach of the PLS among the target audiences that you agreed on at the start of the co-creation of the PLS.



### **Reach via awareness (e.g. in patient organisation newsletters, HCP/PA blogs, medical societies, patient association communications channels, company websites, etc.)**

The success of the dissemination can be measured through alternative channels. The global quality and readability of the PLS can be recognised by patient organisations and HCP societies and HCPs hosting blogs who have decided to disseminate the PLS through their channels.

The popularity of these dissemination channels can be a key indicator that the PLS has achieved the objectives of reaching targeted audiences that may not be accessible through traditional sources (e.g. peer-reviewed journals, social media).





## PLS of Conference presentations

Although focused on PLS of journal publications, much of the guidance provided above also applies to PLS of conference presentations. However, there are a few additional considerations:

- **The likely extent of patient attendance at the target conference. Understand how accessible the conference is to patients:** do they have a specific patient track within the schedule? Is there a reduced cost for patient delegates? Is the congress virtual and therefore easier to access than a live conference that involves travel?
- **Would other delegates at the conference benefit from a PLS of the presentation** (e.g. nurses, pharmacists etc)?
- **Does the target conference request PLS as part of the submission process/package** (this is rare)? Can you liaise directly with the secretariat to ensure they are comfortable with the inclusion of PLS and any specific requirements?
- **Is it feasible to create PLS for all abstract submissions, or can you identify objective and justifiable criteria** for selecting specific PLS to avoid the perception of promotional motivation?
- Will the PLS only contain data from the submitted abstract (which has been reviewed by the selection committee) or will the summary also include additional data from the presentation/poster? As data may not be entirely consistent with those reported in the final manuscript, consider a disclaimer to indicate that the data in the congress PLS have not been peer-reviewed.
- **Understand the needs of the delegates and any specific requirements** that they may have when accessing information (e.g. audio versus visual formats).
- **How will the data be presented at the congress and how will the associated PLS be accessed?**
  - For posters, a brief PLS may appear within the poster. Alternatively, the poster or final slide of a presentation could display a QR code (or web-link if virtual) directing the delegate to a microsite that houses PLS.
- **Understand the specific conference requirements for disseminating PLS during the conference.** Will they allow print materials to be distributed reactively during the congress (e.g. from a relevant patient advocacy stand, or as a poster handout)?
- **Which metrics will be used to track dissemination,** such as PLS page views, downloads, prints, and re-directions to the original scientific abstract.
- **Carefully consider any dissemination strategy beyond the conference itself.** This will help to avoid perceptions of promotion or prior publication before the data are published in full in a peer-reviewed journal.





# Considerations for quality PE

**The Patient Engagement Quality Guidance (PEQG<sup>5</sup>)** was co-created to help all stakeholders set up partnerships and projects collaboratively.

**The seven quality criteria are considered in the first 4 steps of the PLS stepwise approach.**

Below you'll find Considerations for quality PE when you go through the stepwise approach.

Find further information and definitions of each criteria in [Annex 4 PE Quality Guidance definitions](#).



## For **Step 1** consider the following:

As this is the starting point, the project is scoped with clarity and takes into consideration all stakeholders' perspectives (**Criterion 1: Shared purpose**).

An action plan with practical implications (e.g. timing, resources, budget) is shared with all stakeholders. The action plan will require maintenance in the form of regular updates, and continuous communication with stakeholders.

Consider what resources are needed to maintain the appropriate frequency and quality of contact to stay engaged throughout the project (**Criterion 5: Capacity and capability for engagement**).

Think about the tools that can facilitate better communication between participants, such as a platform for sharing, emails, face-to-face/virtual meetings, and calls (**Criterion 2: Respect and accessibility**).

Ensure there is a nominated point of contact who will act as project manager, offering support on things like resourcing, timing, budget, and continuous communication and feedback (**Criterion 4: Roles and Responsibilities**).

<sup>5</sup> <https://pemsuite.org/peqg/>









## For **Step 2** consider the following:

The voice of all identified target audiences, including the representatives of minors (which could be a young patient and/or their parents, caregivers) and hard-to-reach populations should be taken into consideration (**Criterion 2: Respect and accessibility**). Is there a patient organisation that could help you to reach a diverse range of patients, or at least represent their voice?

Choose an easy-to-use platform for document consolidation. If this is not feasible, ensure a direct discussion takes place where their point of view can be captured (i.e. through a face-to-face/virtual discussion, or via a phone discussion).

Ensure that you:

- have open communication channels
-  **For paediatric patients:** consider that to involve young patients in the process to review a PLS there are right organizations to support in the process avoiding any direct relation between the pharma company and the minors. You can refer here eYPAGnet (European Young Person's Advisory Groups Network) or in general the patients organizations. YPAGs have expertise reviewing documents addressed to paediatric patients.
-  **For adult patients:** adapt the frequency of interactions for patients with serious conditions
- have messages that are correctly understood by everyone
- install a feedback process, that can include things like 'teach back' methods or other feedback that ensures the message was actually received correctly.



### Check availability of all involved parties

- ✓ Define the right tool and timing to involve paediatric patients. Considering their disease the right methodology needs to be designed. The role of a facilitator of any meeting or activity with minors will make the process more smooth.
- ✓ Patients with severe conditions and specific treatments might not be available for a given period of time
- ✓ HCPs might not be available at specific times because of the demands of their practice
- ✓ International time zones should be considered, which may necessitate multiple calls to accommodate timing

When identifying the patient target audience for the PLS, a good representation of the demographic diversity of the group should be obtained (age range, ethnicity, gender, medical conditions, education level/health literacy level, etc.) (**Criterion 3: Representativeness of stakeholders**).



If HCPs are a key target audience for the PLS, understand their expectations and needs. These can be different for a pharmacist, a general practitioner (GP), or a specialist. Understand what will help open up the conversation with their patients, and consider providing “how to” checklists and other aids.



## For **Step 3** consider the following:

Make sure that all stakeholders are focused on finding the best way of reaching the audience and that they are aligned with the potential specificities (**Criterion 1: Shared purpose**).

What will be the best strategy to reach the majority of the patient population that will benefit from the publication of the PLS? Make sure that the voice of all identified stakeholders are taken into consideration (**Criterion 2: Respect and accessibility**).



### For paediatric patients

If the PLS is targeted towards **young children (2–6 years old)**, make sure that the language will be simple enough and the format attractive. Think about using short cartoons with as little text as possible and pictograms instead, or cartoon plays. The PLS could also be written targeting the parent or caregivers.

If the PLS is targeted towards **older children (6–12 years old)**, you may want to use animated cartoons with more dialogue. The PLS could also be written targeting the parent or caregivers.

If the PLS is targeted towards **adolescents (12–18 years old)**, you may want to use podcasts, animations or videos and additional social media venues.

Have you considered those who cannot access traditional channels (e.g. those who need an audible or graphic version of the PLS)? Easy Read is another way to ensure accessibility for a variety of populations including those with learning disabilities and hearing impairment.



### For adult patients

Have you considered **hard-to-reach populations**, e.g. those with limited or no access to social media or the internet, elderly populations less familiar with the necessary technologies?

How will you **reach non-native English-speaking audiences** if those are your priority target audience?

Have you considered **those who cannot access traditional channels** (e.g. those who need an audible or graphic version of the PLS)? This includes those with literacy issues (can't read) so infographics may also be important. Easy Read is another way to ensure accessibility for a variety of populations including those with learning disabilities and hearing impairment.



**Ensure all stakeholders have agreed on a consolidated plan to disseminate the PLS** in support of the objectives already agreed in '[Step 2 – Identify your target audience](#)'. The application of this plan will ensure the best chance that the majority of the audiences targeted are reached.

- Consider **access to easy-to-use platforms for collecting feedback and documentation** consolidation. If this is not feasible, ensure proper direct discussion takes place where their point of view can be captured (i.e. direct face-to-face discussion through a close HCP or via a phone discussion).

Have you considered the entire range of stakeholder groups (**Criterion 3: Representativeness of stakeholders**) that will access the PLS in the dissemination process? Ensure there is a continuous check with the objectives agreed when identifying the audiences of the PLS ([Step 2 – Identify your target audience](#)).

In the case that HCPs are key stakeholders of the dissemination of the PLS to patients, check whether you have incorporated their voice on how best to reach them, and how to maximise the chances of reaching them rapidly. Identify their preferred channels (e.g. key opinion leader blogs) or publications (e.g. medical society newsletters). From a pharma company perspective there are limitations to what can be done in terms of dissemination

To be efficient, it is essential to get engagement from the range of stakeholders for dissemination of the PLS. It is therefore important to think about how you can get commitment from all contributors (**Criterion 1: Shared purpose**) and, in the case that some cannot stay involved until the conclusion of the process, how you would replace the experience, knowledge and networks of this stakeholder (**Criterion 7: Continuity and Sustainability**).

- Think about and discuss what each stakeholder needs to stay engaged
- Think about how you will capture the key learnings of the dissemination strategy for this specific population so that it can be shared with newcomers or used in future projects to build on established capacity



## For **Step 4** consider the following:

This step is the starting point for co-creation of the PLS, so the participants have opportunities to share their views and exchange. **Criterion 1: Shared purpose** is agreed upon and transparently communicated. The development of a PLS involves taking into consideration all stakeholders' perspectives. When identifying stakeholders, a good representation of the diversity of the patient target audience (age range, ethnicity, gender, medical conditions) should be obtained (**Criterion 3: Representativeness of stakeholders**).

- Are there any patient organisations that could help you to reach a diversity of patients, or at least collect their voice?
- Have you considered any population which is difficult to reach?



- In the case that you have considered other stakeholders, have you reached a good sample that you will target in priority?
- Consider who could help you reach this group (e.g. national pharmacist or medical societies, nurses associations, community health workers, etc.)

An action plan with practical implications (e.g. timing, resources, budget) should be made available to all stakeholders. The action plan will require maintenance in the form of regular updates and continuous communication with stakeholders. Consider what resources are needed to maintain the appropriate frequency and quality of contact to stay engaged throughout the project (**Criterion 5: Capacity and capability for engagement**).

Find agreement on the tools that all participants will be able to use easily for communication, such as a platform for sharing, emails, face-to-face visits, and calls. Make sure that roles and responsibilities are discussed at the very beginning, including who is initiating, how ideas are captured, how input is consolidated, who is leading discussions around potential conflicting inputs and who is involved in the resolution of those issues (**Criterion 4: Roles and responsibilities**).


Is the role of the patient contributors as co-authors, reviewers and end-users clear and agreed? Check that it is well understood by everyone, bearing in mind that silence does not mean it is understood. This would be done ideally through a meeting, which can also be a teleconference. It might, however, not be possible to have all partners around the table at the same time. In that case, consider what you will do to ensure that everyone is receiving all relevant information, including relevant points raised during the discussions.

Ensure there is a point of contact identified who will act as project manager and be responsible for things like resource, timing and budget and offer continuous support in communication and feedback to all stakeholders (**Criterion 4: Roles and responsibilities**).

Ensure that you have open communication channels (**Criterion 6: Transparency in communication and documentation**):

- That you adapt the frequency of the interactions to a paediatric audience / patient population / other stakeholder groups
- That you put in place what is needed to have enough reactivity to keep everyone engaged and
- That your messages are correctly understood by everyone (**Criterion 2: Respect and accessibility**)

To be efficient, it is important to get engagement from the range of stakeholders for the entire project. It is therefore important to think about how you can get commitment from all contributors (**Criterion 1: Shared purpose**) and, in the case that some cannot remain involved until the conclusion of the process, how you would replace the experience of this stakeholder (**Criterion 7: Continuity and sustainability**).

-  **For paediatric and adult patients**
- Think about and discuss what each stakeholder needs to stay engaged.
- Think about how you will capture the key learnings of developing the PLS for this specific population so that it can be shared with newcomers or used in future projects to build on established capacity.
- Think about the ways the format, repository or dissemination strategy of the PLS could be used to share those learnings with a wider audience focused on PLS for paediatric or adult patient populations.

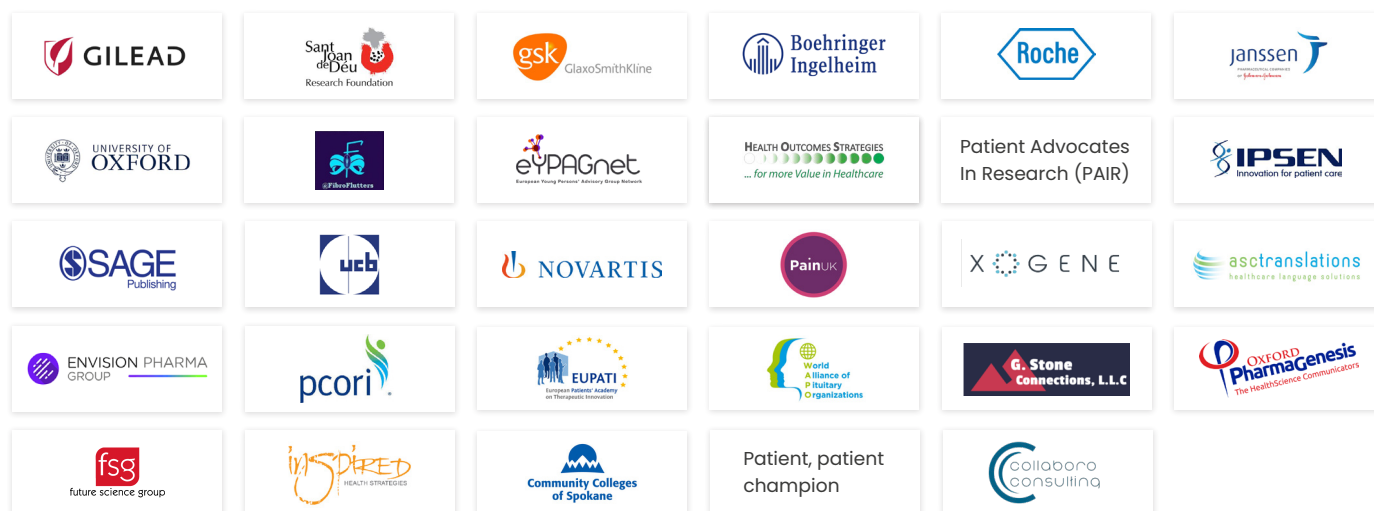
# Acknowledgements

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# Annex 1

## Glossary

### Additional resources

**It is important to consider that the general population is not accustomed to the scientific jargon and terminology commonly found in peer-reviewed research articles. As such, when writing up the PLS, the author needs to be faithful to the research presented, but will undoubtedly also use a minimum amount of technical terminology.**

**It is important to only include terms patients and the public may hear from medical clinics, and any scientific terms should be explained in the PLS. To help the reader better understand and navigate through the PLS, a glossary is also highly recommended.**

A glossary may include scientific terminology, acronyms and other related jargon present in the PLS. Some examples include:

- a simplified definition of a term
  - eg. arrhythmia: irregular heartbeat
- a synonym
  - eg. abdomen: belly, stomach
- acronyms
  - eg. ICU: Intensive Care Unit

Glossary formatting varies from a simple list of alphabetical terms to a table-like structure, and could be suggested by the publisher.

The most important aspect is that the information provided is clear and easy to quickly pick up.

The glossary should also be reviewed by the patient advocates and lay readers involved in reviewing the PLS to ensure that all necessary terms are present, as well as potentially suggesting changes or additional terms. These would then be forwarded to the author for consideration.

## 1. Resources for Lay Terminology Glossaries

Below are resources that can be helpful when looking for lay terms to use in a plain language summary.

- The European Patients' Academy Glossary  
<https://www.eupati.eu/glossary/>  
*Searchable online glossary covering key terms used in medicines development*
- National Institute for Health Research (NIHR) INVOLVE Jargon Buster  
<https://www.invo.org.uk/resource-centre/jargon-buster/>  
*Searchable online glossary provides plain language definitions of terms used in public involvement in research*





- National Cancer Institute (NCI) Dictionary of Cancer Terms  
<https://www.cancer.gov/publications/dictionaries/cancer-terms>  
*Searchable online glossary defining terms related to cancer and medicine*
- Health Technology Assessment International (HTAi) HTAi Consumer and Patient Glossary  
<https://htai.org/wp-content/uploads/2018/02/PCISG-Resource-ENGLISH-PatientandConsumerGlossary-Oct09.pdf>  
*Provides plain language terms for words used in health technology assessment documents*
- The plain language Glossary of Evaluation Terms for Informed Treatment choices (GET-IT)  
<https://getitglossary.org/>  
*Searchable online glossary provides plain language definitions of health research terms*
- <http://www.plainenglish.co.uk/files/alternative.pdf>  
*Provides plain language alternatives to frequently used complex words and phrases, plus a list of 'words and phrases to avoid'*
- Centers for Disease Control and Prevention (CDC) – Everyday Words for Public Health Communication  
<https://www.cdc.gov/other/pdf/everydaywordsforpublichealthcommunication.pdf>  
*Glossary of plain language alternatives for health terms, using real examples of technical sentences rewritten in plain language*
- Stanford University Definitions & Lay Glossary of Medical Terms:  
<https://researchcompliance.stanford.edu/panels/hs/forms/definitions>
- University of Iowa Medical Terms in Lay Language:  
<https://hso.research.uiowa.edu/medical-terms-lay-language>
- University of Florida Glossary of Lay Terms for Use in Informed Consent Forms:  
<http://irb.ufl.edu/irb01/forms/glossary.html>
- University of California Davis Glossary of Lay Terminology:  
[https://research.ucdavis.edu/wp-content/uploads/Glossary-of-Lay-Terminology\\_12-15-14.pdf](https://research.ucdavis.edu/wp-content/uploads/Glossary-of-Lay-Terminology_12-15-14.pdf)
- Loma Linda University Glossary of Lay Terms:  
<https://researchaffairs.llu.edu/responsible-research/human-studies/resources-for-human-studies/handbook-for-human-research-protections-program/glossary-of-lay-terms>
- McLaren Health Care Corporation Human Research Protections Program Glossary of Terms:  
[http://www.mclaren.org/uploads/Public/Documents/Corporate/lay\\_language\\_1.pdf](http://www.mclaren.org/uploads/Public/Documents/Corporate/lay_language_1.pdf)
- University of Kentucky Research Glossary of Lay Terms:  
<https://www.research.uky.edu/uploads/ori-d780000-layterm-pdf>
- VA Portland Health Care System Glossary of Lay Terms for Use in Preparing Consent Forms:  
<https://www.portland.va.gov/research/documents/hrpp/glossary-of-lay-terms.pdf>
- SingHealth DukeNUS Academic Medical Centre Glossary of Lay Terms for use in Consent Documents:  
[https://www.singhealthdukenus.com.sg/research/rice/Documents/Glossary%20of%20lay%20terms%20\[2016-07-26\].pdf](https://www.singhealthdukenus.com.sg/research/rice/Documents/Glossary%20of%20lay%20terms%20[2016-07-26].pdf)
- Lebanese American University Medical to Lay Terminology:  
[https://gsr.lau.edu.lb/irb/forms/medical\\_lay\\_terms.pdf](https://gsr.lau.edu.lb/irb/forms/medical_lay_terms.pdf)
- Think local act personal Jargon Buster:  
<https://www.thinklocalactpersonal.org.uk/Browse/Informationandadvice/CareandSupportJargonBuster/>
- National Institute for Health Research INVOLVE Jargon Buster:  
<https://www.invo.org.uk/resource-centre/jargon-buster/>





## 2. Glossary of terms

Below are definitions of key terms that are used throughout the document. The Glossary is built on the definitions reported in several guidances<sup>6</sup>.

**Analysis plan (also known as Statistical analysis plan):** A document that contains a more technical and detailed elaboration of the principal features of the analysis described in the protocol, and includes detailed procedures for executing the statistical analysis of the primary and secondary variables and other data (Source: FDA, 1998).

**Carer/caregiver:** A person who helps a patient with daily activities, health care, or any other activities that the patient is unable to perform himself/herself due to illness or disability, and who understands the patient's health-related needs. This person may or may not have decision-making authority for the patient and is not the patient's healthcare provider (Source: FDA, 2018).

**Congress:** Regular coming together on a representational basis of several hundreds – or even thousands – of individuals belonging to a single professional, cultural, religious or other group. A congress is often convened to discuss a particular subject. Contributions to the presentation and discussion of the subject matter come only from members of the organising body (ICCA, 2020).

**Conference:** Participatory meeting designed for discussion, fact-finding, problem solving and consultation. As compared with a congress, a conference is normally smaller in scale and more select in character – features which tend to facilitate the exchange of information (ICCA, 2020).

**Healthcare professionals (HCP):** Refers to practitioners, including physicians, nurses, pharmacists, dentists, respiratory therapists, physical therapists, technologists, or any other practitioners or allied health professionals that have a role in using a device for human use (Source: FDA, 1).

**Health literacy:** The degree to which individuals have the capacity to obtain, process, and understand basic health information and services needed to make appropriate health decisions. Health literacy also includes numeracy skills—such as calculating cholesterol and blood sugar levels, measuring

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<sup>6</sup> USA. Food and Drug Administration (FDA). (1998) E9 Statistical Principles for Clinical Trials, Federal Register Volume 63, Number 179. Available at: <https://www.govinfo.gov/content/pkg/FR-1998-09-16/html/98-24754.htm>

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Global. Patient focused medicines development (PMD). [Internet] Available at: <https://patientfocusedmedicine.org/>

EU. European Medicines Agency. (2017) Summaries of Clinical Trial Results for Laypersons. Available at: [https://ec.europa.eu/health/sites/health/files/files/eudralex/vol-10/2017\\_01\\_26\\_summaries\\_of\\_ct\\_results\\_for\\_laypersons.pdf](https://ec.europa.eu/health/sites/health/files/files/eudralex/vol-10/2017_01_26_summaries_of_ct_results_for_laypersons.pdf)

EU. European Medicines Agency. (2010) EU Clinical Trials Register Glossary. Available at: [https://www.clinicaltrialsregister.eu/doc/EU\\_Clinical\\_Trials\\_Register\\_Glossary.pdf](https://www.clinicaltrialsregister.eu/doc/EU_Clinical_Trials_Register_Glossary.pdf)

USA. Food and Drug Administration. (2019) Patient-Focused Drug Development: Methods to Identify What Is Important to Patients Guidance for Industry, Food and Drug Administration Staff, and Other Stakeholders. Available at: <https://www.fda.gov/media/131230/download>



medication doses, and understanding nutrition labels—and knowledge of health topics (Source: FDA, 2018).

**Open access (OA):** A publication that is freely available to read, download, and share (Source: Wiley, internet).

**Patient organisation:** Not-for profit organisations which are patient focused, and whereby patients and/or carers (the latter when patients are unable to represent themselves) represent a majority of members in governing bodies (Source: EPF, 2017).

**Peer-reviewed publication:** A publication written by scientists and evaluated for technical and scientific quality and correctness by other experts in the same field (Source: NIH, Internet).

**PFMD (Patient focused medicines development):** An open, independent global coalition of health stakeholders with aims to transform the way in which we understand, engage, and partner with patients globally in the design and development of research and medicines by focusing on unmet patient needs (Source: PFMD, 2020).

**Plain language summary (PLS):** A non-technical summary of clinical trial results or other content in a journal article or congress presentation. This How-To guide refers to PLS for publications and conferences and do not include PLSs that are created per EU regulations (ie, layperson summaries) that follow a certain regulatory rigor (Reference: EMA, 2017).

**Primary endpoint(s):** The main result that is measured at the end of a study to see if a given treatment worked (e.g., the number of deaths or the difference in survival between the treatment group and the control group). What the primary endpoint will be is decided before the study begins (Source: EMA, 2010).

**Protocol (also known as Study protocol):** A document that describes the objective(s), design, methodology, statistical considerations and organisation of a trial. The term protocol refers to the protocol, successive versions of the protocol and protocol amendments (Source: EMA, 2010).

**Secondary endpoint(s):** Results that are measured at the end of a study, in addition to the main result (primary endpoint) to see if a given treatment worked. Secondary endpoints can explore other aspects of the treatment (Source: EMA, 2010).



## Annex 2

# Resources for Writing your PLS

### Additional resources

## 1. Guides to health literacy and plain language writing

Below are resources that can be helpful when looking for lay terms to use in a plain language summary.

- US CDC plain language resources  
<https://www.cdc.gov/healthliteracy/developmaterials/plainlanguage.html>
- The Multi-Regional Clinical Trials Center Health Literacy in Clinical Research Toolkit  
<https://mrctcenter.org/health-literacy/tools/overview/>  
*Collection of tools aimed at creating clear communication materials for clinical trials. 'Best practices' section contains useful resources on plain language, numeracy, design and usability testing.*
- How to write in plain English – Plain English Campaign  
<http://www.plainenglish.co.uk/files/howto.pdf>  
General guide to the principles of plain language writing, including a summary key points and a list of alternatives to 'words to avoid'
- How to write medical information in plain English – Plain English Campaign  
<http://www.plainenglish.co.uk/files/medicalguide.pdf>  
Gives 'before' and 'after' examples of plain-language medical writing, plus a glossary of medical terms
- Centers for Disease Control and Prevention (CDC) – Everyday Words for Public Health Communication  
<https://www.cdc.gov/other/pdf/everydaywordsforpublichealthcommunication.pdf>
- Consider Patient Information Forum (PIF) resources, especially communicating numbers and risk.  
<https://pifonline.org.uk/resources/>
- Plain Language Summaries of Publications Toolkit – Envision Pharma Group/PFMD  
<https://www.envisionthepatient.com/plstoolkit/>  
*An evidence-based, freely-available resource specific to support development of PLS of publications, including a template, QC checklist for writers, cover sheets for patient and sponsor reviewers, and a guide summarising helpful plain-language glossaries*
- Slides from Jan Seal-Roberts (Publishing Director, Adis | Springer Healthcare) and Sarah Griffiths (Communications Team Leader, Oxford PharmaGenesis) ISMPP Annual Meeting 2020 workshop  
<https://synapse.pfmd.org/resources/patient-lay-summaries-plain-language-summaries-understanding-the-differences-and-how-best-to-use-these-options>  
*An all-in-one overview of the nuances around the Why? What? How? Who? When? on publication plain language summaries, including distinction versus trial results summaries*
- Standards for the reporting of plain language summaries in new Cochrane Intervention Reviews 2013 – Cochrane Methods  
[https://methods.cochrane.org/sites/default/files/public/uploads/pleacs\\_2019.pdf](https://methods.cochrane.org/sites/default/files/public/uploads/pleacs_2019.pdf)  
*A summary of quality standards for PLS of Cochrane systematic reviews, including guidance on content and structure to help writers meet each standard*



- Writing and testing plain language – Model Systems Knowledge Translation Center  
[https://msktc.org/lib/docs/KT\\_Toolkit/MSKTC\\_Plain\\_Lang\\_Tool\\_508.pdf](https://msktc.org/lib/docs/KT_Toolkit/MSKTC_Plain_Lang_Tool_508.pdf)  
*A tool that presents the principles of plain language writing and how to test the reading level of your writing. Includes 'before and after' examples and a glossary of simpler word choices*
- Universal Patient Language Guidance  
<https://www.upl.org/>
- Examples of Active and Passive Voice  
<https://examples.yourdictionary.com/examples-of-active-and-passive-voice.html>

## 2. Maximize white space

- This is a link to the science around white space  
<https://www.interaction-design.org/literature/article/the-power-of-white-space>. An offer for a link to the use of white space in UX will come up as well.
- Another link more simply describes the value of white space  
<https://novacreative.com/5-benefits-of-using-white-space-in-design/>
- An example that could be shown here is from the CDC  
<https://health.gov/healthliteracyonline/display/section-3-4/>

## 3. Useful videos

- MedComms networking webinar – Patient involvement in scientific communications  
<https://networkpharma.tv/2019/11/20/patient-involvement-in-scientific-communications/>  
*Dr Lauri Arnstein (Envision Pharma Group) provides an overview of patient involvement in medical publications, including PLS of publications and patient authorship*
- MedComms networking webinar – Plain language summaries: what are they, and why should we consider including these in our publications?  
<https://networkpharma.tv/2019/05/29/plain-language-summaries-what-are-they-and-why-should-we-consider-including-these-in-our-publications/>  
*Jan Seal-Roberts (Adis Journals) gives the publisher's perspective, discussing what PLS are and the opportunities they can offer*
- MedComms networking webinar – Adapting your writing for patients and the public  
<https://networkpharma.tv/2019/10/16/adapting-your-writing-for-patients-and-the-public/>  
*Hannah Bridges (HB Health Comms LTD) presents the principles of clear, effective plain language communications*
- International Society for Medical Publication Professionals University – The rapid adoption of plain language summaries in medical communications: Hope or hype?  
<https://ismpp.memberclicks.net/ismpp-u---november-2019?servid=10046>  
*Only available for ISMPP members*

## 4. Examples of readability tools

- Readable  
[readable.com](https://readable.com)  
*This paid tool tests readability, spelling and grammar and highlights text to show where potential issues are. It scores the text from A (most readable)–E (least readable) and provides grade levels from other commonly used readability tools*



- Hemingway Editor  
<http://www.hemingwayapp.com/>  
*This paid tool highlights text to show long sentences and other complex areas. It provides a grade score for readability*

The following tools are available at

<https://readabilityformulas.com/free-readability-formula-tests.php>

- **Flesch Reading Ease**  
*Checks average sentence and word length. Gives a score from 0–100 (higher score = text is easier to read). Ideal score is between 70 to 80 (equivalent to school grade level 8).*
- **Flesch–Kincaid**  
*Translates the 0–100 from the previous tool score to a grade reading level. Ideal score is 7 or 8, scores of 12 or more are too difficult for most people to understand*
- **Gunning Fog**  
*Checks average sentence length and number of words of 3 or more syllables. Ideal score is 7 or 8, scores of 12 or more are too difficult for most people to understand*
- **SMOG Index**  
*Measures number of sentences and words of 3 or more syllables. Gives a grade reading level*

## 5. Suitability Assessment tools

The following suitability tools are designed for assessing health information:

- **Patient Education Materials Assessment Tool for Printable Materials (PEMAT-P)**  
<https://www.ahrq.gov/ncepcr/tools/self-mgmt/pemat-p.html>  
*Gives separate scores for understandability and whether the reader can take the correct action after reading (actionability). The actionability score may or may not be relevant for your PLS. Can be downloaded as an Excel file that will calculate the scores for you.*
- **Suitability Assessment of Materials (SAM)**  
<http://aspiruslibrary.org/literacy/SAM.pdf>  
*Focuses on understandability, and includes scores for visuals, layout and cultural considerations.*



## Annex 3

# Examples of PLS and where to find them

## Additional resources

This section provides some recent examples of PLS of publications. PLS are currently very diverse in terms of their content, layout and how they are published by journals. These examples should give you an idea of this range. The list is not exhaustive, but might help you define more easily which type of PLS would best fit your needs.

### Text-only PLS, published within the main article

- <https://rd.springer.com/content/pdf/10.1007%2Fs40744-017-0080-4.pdf>  
*This short text-only PLS sits below the main abstract. Note that the authors have used effective layout principles such as bolded text, question headers and numbered lists.*
- <https://www.dovepress.com/relationship-between-pain-reduction-and-improvement-in-health-related-peer-reviewed-fulltext-article-JPR>  
*This short text-only PLS sits below the main abstract. Note that the authors have split the content out into bullets, rather than using plain text.*

### Text-only PLS, published as a supplement to the main article

- [https://adisjournals.figshare.com/articles/A\\_Randomized\\_Double-Blind\\_Efficacy\\_and\\_Safety\\_Study\\_of\\_PF\\_05280586\\_a\\_Rituximab\\_Biosimilar\\_Compared\\_With\\_Rituximab\\_Reference\\_Product\\_MabThera\\_in\\_Subjects\\_With\\_Previously\\_Untreated\\_CD20-Positive\\_Low-Tumor-Burden\\_Follicular\\_Lymphoma\\_LTB-FL\\_/10282727](https://adisjournals.figshare.com/articles/A_Randomized_Double-Blind_Efficacy_and_Safety_Study_of_PF_05280586_a_Rituximab_Biosimilar_Compared_With_Rituximab_Reference_Product_MabThera_in_Subjects_With_Previously_Untreated_CD20-Positive_Low-Tumor-Burden_Follicular_Lymphoma_LTB-FL_/10282727)  
*This longer text-only PLS is hosted on Figshare, which means it can also be found as a standalone document through Figshare.*

The main article (<https://link.springer.com/article/10.1007/s40259-019-00398-7>) contains a reference to the PLS, which is listed as an enhanced digital feature.

### Text and visuals PLS, published as a supplement to the main article

- [https://static-content.springer.com/esm/art%3A10.1007%2Fs43441-020-00115-5/MediaObjects/43441\\_2020\\_115\\_MOESM1\\_ESM.pdf](https://static-content.springer.com/esm/art%3A10.1007%2Fs43441-020-00115-5/MediaObjects/43441_2020_115_MOESM1_ESM.pdf)  
*This colour text and visuals PLS is hosted by the journal as electronic supplementary material, via a link in the main article (<https://link.springer.com/article/10.1007%2Fs43441-020-00115-5>). Ideally, the main article would contain a reference to the PLS to make it easier to find.*

### Short text and visual PLS, published as a figure in the main article

- <https://academic.oup.com/ofid/article/6/2/ofz007/5288627>  
*This short colour text and visuals PLS is Figure 3 in the manuscript. Ideally it would be the first figure of the manuscript to be more visible, and be saved on a sharing platform like Figshare for easier access. In that case, the PLS should contain a link to the main article, for readers who accessed the PLS first but then wanted more detail about the study.*

### Text and visuals PLS, published within the main article and as a supplement to the main article

- [https://adisjournals.figshare.com/articles/The\\_Association\\_Between\\_Type\\_2\\_Diabetes\\_and\\_Cardiovascular\\_Disease\\_The\\_For\\_Your\\_SweetHeart\\_Survey/7546817](https://adisjournals.figshare.com/articles/The_Association_Between_Type_2_Diabetes_and_Cardiovascular_Disease_The_For_Your_SweetHeart_Survey/7546817)  
*This one-page text & visuals PLS is hosted in two places: on Figshare via a link in the main*



article, and as Figure 1 in the main article (<https://link.springer.com/article/10.1007/s12325-019-0871-9>). Ideally this PLS would also contain a link that readers can follow back to the main article.

#### **Text and visuals PLS, hosted by a patient group after manuscript publication**

- [https://www.acromegalycommunity.org/images/studies/AcroVoice\\_preference\\_study\\_PLS\\_9Jan19.pdf](https://www.acromegalycommunity.org/images/studies/AcroVoice_preference_study_PLS_9Jan19.pdf)

*This text and visuals PLS is based on a journal article ([https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6373299/pdf/11102\\_2018\\_Article\\_933.pdf](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6373299/pdf/11102_2018_Article_933.pdf)) and contains a link to the main article. It was not published by the journal but was instead hosted on a patient group website.*





## Annex 4

# PE Quality Guidance definitions

**The Patient Engagement Quality Guidance (PEQG<sup>5</sup>)** was co-created to help all stakeholders set up partnerships and projects collaboratively. It can be used:

- when having first discussions with new partners to identify and align on shared purpose for the project, roles and responsibilities, accessibility considerations, feedback loop etc.;
- when assessing ongoing projects to see if there are aspects where you could improve to increase the level of engagement and participation;
- when retrospectively assessing completed projects to identify areas of improvement for future projects.



### Shared Purpose

This refers to the project's aims and outcomes that all stakeholders taking part should agree on before starting the project. Consider putting in place processes to help facilitate discussions between all stakeholders to identify each other's values, expectations and objectives, and review and discuss priorities in the planning of the project.

It can be valuable to enable stakeholders to exchange views openly to understand the scope and objectives of the project, acknowledging that some of their objectives may differ. All parties concerned should also have a shared written description of the common goals of the project.



### Respect and accessibility

This refers to (1) respecting each other, and respectful interactions within the project to be established among partners, and (2) openness to and inclusion of individuals and communities (to the project) without discrimination. Considerations to ensure good conditions to implement the project should be made from the beginning.



<sup>5</sup> <https://pemsuite.org/peqg/>





For example:

- simplification of wording
- budget and payment considerations
- cultural adaptations to procedures
- practicalities such as meeting timing, location and format
- accessibility of project materials
- written co-developed rules of conduct

Accessibility to participate may be facilitated by enabling multiple ways to involve stakeholders who could benefit from and/ or contribute to the project.

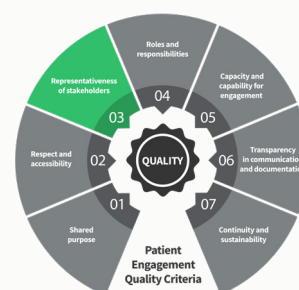
For example, patients with cognitive impairment might need more time to go through project material, or need printed versions rather than electronic documents or PDFs for easier reading.

## Representativeness of stakeholders

This refers to the mix of people you involve, which should reflect the needs of the project, and the interests of those who may benefit from project outputs (for example, target population).

Consider diversity in expertise, experience, demographics, and other relevant criteria for inclusion.

When selecting PE stakeholders, patients, attention will be given to awareness of the diversity required to achieve visible representative voice.



## Roles and responsibilities

This refers to the need for clearly agreed, and ideally co-created roles and responsibilities, in writing, addressing that all aspects of project needs will be established upfront and revisited regularly



## Capacity and capability for engagement

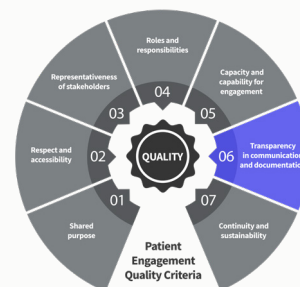
This refers to (1) capacity as having relevant and dedicated resources from all stakeholders (for example, providing a dedicated point of contact by the sponsor and having allocated sufficient time by all stakeholders to allow genuine engagement); and (2) capabilities for all stakeholders to enable meaningful engagement (for example, the level of knowledge, expertise and training stakeholders might need to deliver PE activities throughout the project).

Consider supporting stakeholders to build the required capacity and capabilities for this project in different forms of training both with sponsor organisations and with each stakeholder (for example, helping to understand the context, processes, relevant terminology etc.). Both capacity and capability building are intended to facilitate participation and lower barriers to collaborate. Stakeholders can be given access to learning resources and given dedicated support (if needed). Capability needs may vary depending on the project needs, but also e.g. personal circumstances of PE representatives.



## Transparency in communication and documentation

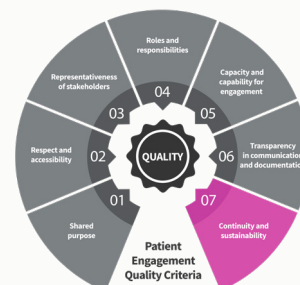
This refers to the establishment of communications plan and ongoing project documentation that can be shared with stakeholders. Communication among stakeholders must be open, honest and complete. In addition, adequate up-to-date documentation must facilitate communication with all stakeholders throughout the project. Consider proactively and openly sharing progress updates throughout the project externally. In addition, communicating outcomes of the project to all stakeholders and how their contribution was of value to the success of the project is critical.



## Continuity and sustainability

This refers to the smooth progression of the project, as well as efforts to maintain ongoing relationships with stakeholders. Consideration should be given for the role of stakeholders beyond a single project.

When starting the project, consider including in your project plan the actions needed for maintaining expected flow of the project from beginning to end. Create a plan to nurture relationships with your partners and stakeholders involved during the project, and when needed and requested, beyond the project as well. For all stakeholders successful planning and personal and organisational resilience should be anticipated.



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