ISMPP University

The Rapid Adoption of Plain Language Summaries in Medical Publications: Hope or Hype?

November 20, 2019, 11:00 EDT, 16:00 GMT

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Mark Your Calendars

We updated the Transparency Educational Series!

This is the **ONE STOP** Source on Data and Financial Transparency for Publication Professionals. **NOW UPDATED!**

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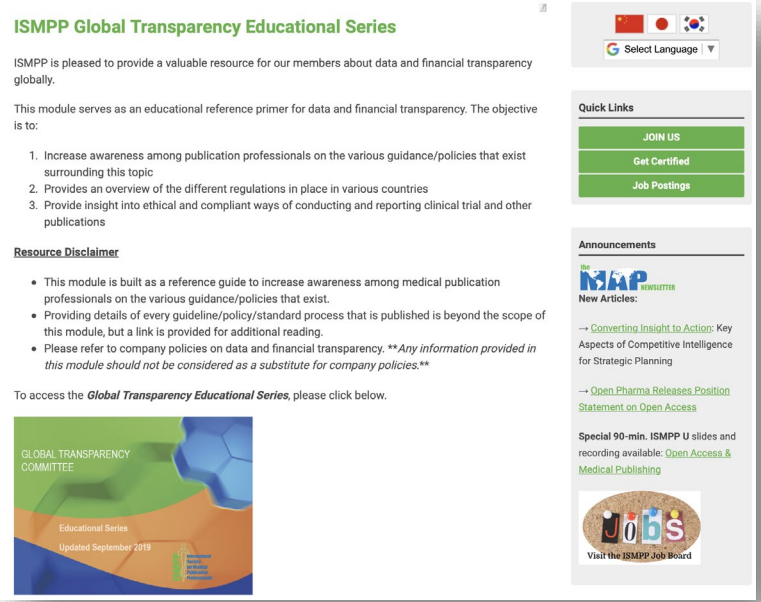
Are you aware of the changes to the US Sunshine Act?



ISMPP Global Transparency Educational Series

ISMPP is pleased to provide a valuable resource for our members about data and financial transparency globally.

This module serves as an educational reference primer for data and financial transparency. The objective is to:

1. Increase awareness among publication professionals on the various guidance/policies that exist surrounding this topic
2. Provides an overview of the different regulations in place in various countries
3. Provide insight into ethical and compliant ways of conducting and reporting clinical trial and other publications

Resource Disclaimer

- This module is built as a reference guide to increase awareness among medical publication professionals on the various guidance/policies that exist.
- Providing details of every guideline/policy/standard process that is published is beyond the scope of this module, but a link is provided for additional reading.
- Please refer to company policies on data and financial transparency. ***Any information provided in this module should not be considered as a substitute for company policies.***

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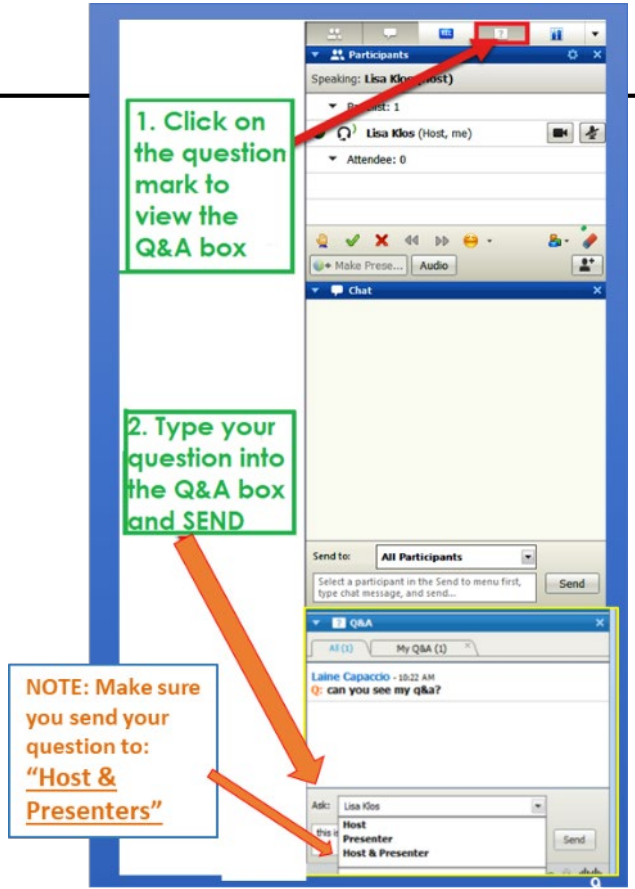
- To ensure anonymity and that all presenters receive your question, please choose the drop down box option:

  "Host & Presenters"

  Otherwise, all audience members will be able to see your submitted question
- We will make every effort to respond to all questions



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Disclaimer

Information presented reflects the personal knowledge and opinion of the presenters and does not necessarily represent the position of their current or past employers or the position of ISMPP

Objectives for this ISMPP U

At the end of this session, participants should be able to:

- Understand the role and value of plain language summaries in communicating data from medical publications
- Appreciate the issues facing medical affairs and publications teams in implementing a robust PLS development and review process in consideration of both compliance and emerging best practices
- Consider how best to integrate and implement PLS within the publication plan, also recognizing the diversity and rapid evolution of positions and perceptions among journal publishers and congresses.

Tom Gegeny

- Tom Gegeny, MS, ELS, MWC, ISMPP CMPP™, joined Envision Pharma Group in 2006 and is currently a Senior Scientific Director and Team Lead. He has over 20 years of experience in medical communications, including previous roles as Executive Director and Senior Editor at The Center for AIDS Information and Advocacy in Houston and as Publications Specialist with the Houston Academy of Medicine–Texas Medical Center Library. He is a fellow of the American Medical Writers Association (AMWA) and served as AMWA President in 2009–2010. He also served as president of the Board of Editors in the Life Sciences (BELS) for 2015–2017. Tom has led workshops and given presentations at numerous meetings and conferences including ISMPP, AMWA, CSE, TIPPA, DIA, and others.

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Kelly Soldavin

- Kelly Soldavin is a Medical Editor for the publisher Taylor & Francis Group and currently manages *Current Medical Research & Opinion* and the *Journal of Drug Assessment*, both PubMed/MEDLINE-indexed, peer-reviewed journals that publish original research focused on new and existing drugs and therapies across a range of therapeutic areas. Kelly has a special interest in open science and ethical and transparent publishing, and she has spoken on these topics at the International Publication Planning Meeting (TIPPA), as well as the Special Libraries Association (SLA) Annual Conference. She is also a member of the ISMPP Social Media and Web-based Metrics working group, leading the Patient Engagement in Social Media project. Prior to joining T&F in 2017, Kelly spent 14 years in the veterinary medicine publishing industry as an Editorial Director for peer-reviewed journals and resources focused on small animal clinical medicine.

Avishek Pal

- A microbiologist by training, Avishek started off as a publication writer with GSK Vaccines nearly 13 years ago. Avishek's work has included publication development, medical communications planning and strategy across varied disease areas spanning vaccines, oncology and pharma. He is currently Associate Director, Publications Excellence in Global Medical Affairs at Novartis Pharma. Avishek is a ISMPP Certified Medical Publication Professional™ (CMPP) and a member of the ISMPP U Committee.

Plain Language Summaries

Thomas Gegeny
Envision Pharma Group

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Why Plain Language Summaries (PLS)?

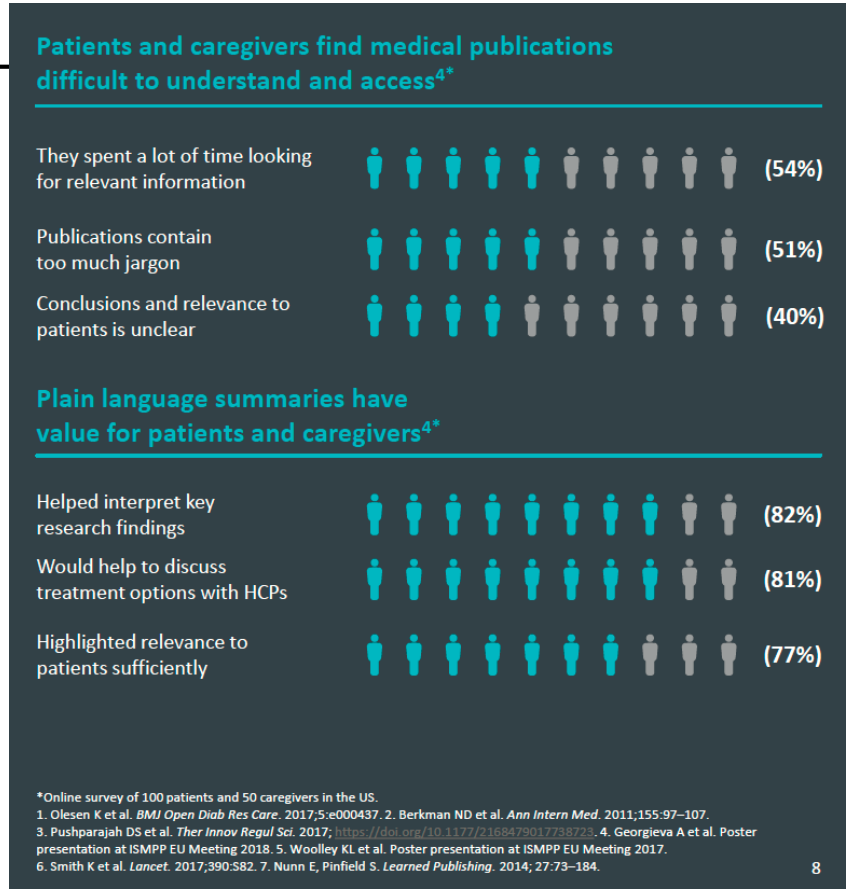
The importance of the patient voice. . . .

Patient centricity and involvement in medicines development

- Benefits of patient involvement at early stages have been established
  - Clinical trial design
  - Data safety review and input
  - Patient surveys and advisory boards
  - Market research
- Virtually absent in publications and other communications of research studies/data

Patients are actively seeking and sharing scientific content

- **Patients are actively seeking and sharing scientific content**, including medical publications – but these are rarely clear, accessible, or relevant to patients[1–3]
- **Accessible scientific content has the potential to improve outcomes for patients by:**
  - Helping interpret key findings
  - Helping discuss treatment options with HCPs
  - Highlighting relevance to patients
  - Empowering patients to participate in treatment decisions



1. Georgieva A, et al. Poster presentation at ISMPP EU Meeting, 2018.
2. Woolley KL, et al. Poster presentation at ISMPP EU Meeting, 2017.
3. Smith K, et al. *Lancet* 2017;390:S82.

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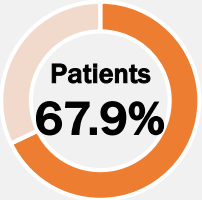
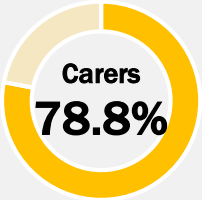
Patients want to understand published research, but it isn't that easy. . .

IN A SURVEY OF PEOPLE WITH FRIEDRICH'S ATAXIA AND THEIR CARERS*:

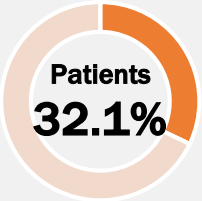
Most patients and carers were interested in scientific publications related to their condition





Few could understand scientific publications

Few considered the Internet (eg, Facebook, discussion forums) to be a useful source for better understanding



PUBLICATION: *TO MAKE CONTENT AVAILABLE TO THE PUBLIC*

ms Stream Meet other MSers ▾ Shift your outlook

The Lancet , which ?

November 29, 2017 at 3:21 pm

rachaellouise

Hi everyone ,

Just wondering what publications publish the latest medical research and trials?

Is the lancet a good publication and are any of you signed up to it in order to view the articles ?
Just had a look and it won't let me fully read the articles .Thanks

Rachael xx

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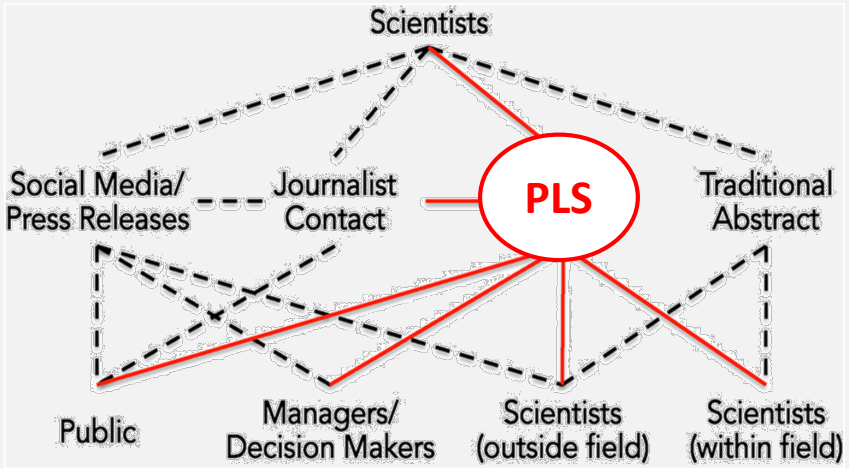
PLS can enhance potential communication pathways between scientists and the public[1]



- PLS can expand the potential audience of scientific content beyond scientific communities
- For example, the traditional abstract can reach other scientists but not the public
- Accurate, relevant PLS can help enhance communication pathways and reduce risk of information being misinterpreted or misrepresented

- - - - - Connections between scientists and end users

Communication pathways between scientists and other end users

Kuehne LM, Olden JD. *PNAS.* 2015;112(12):3585-6.

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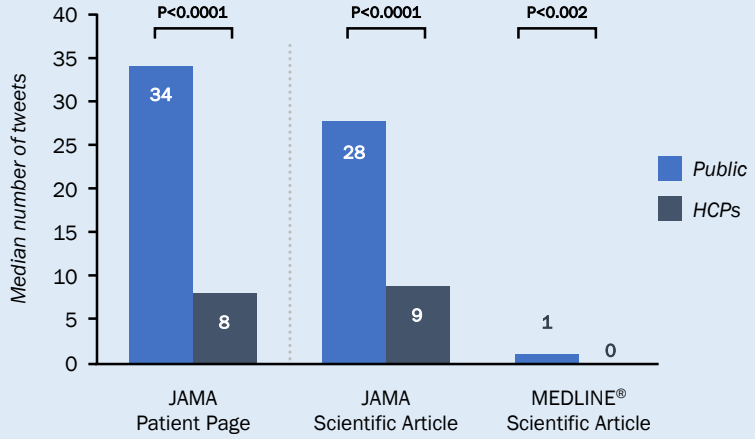
Patients and the public can amplify content sharing

Public outperforms HCPs[1]

The public tweets more than HCPs do about JAMA Patient Pages **AND** about related scientific articles



"Patient-to-patient exchange over Twitter and other social media is the fastest and most direct route to disseminate latest evidence and best practice."

Kawaldip Sehmi
CEO, International Alliance of Patients' Organizations

1. Woolley KL et al. Poster presentation at ISMPP EU Meeting 2017. January 17-18, 2017

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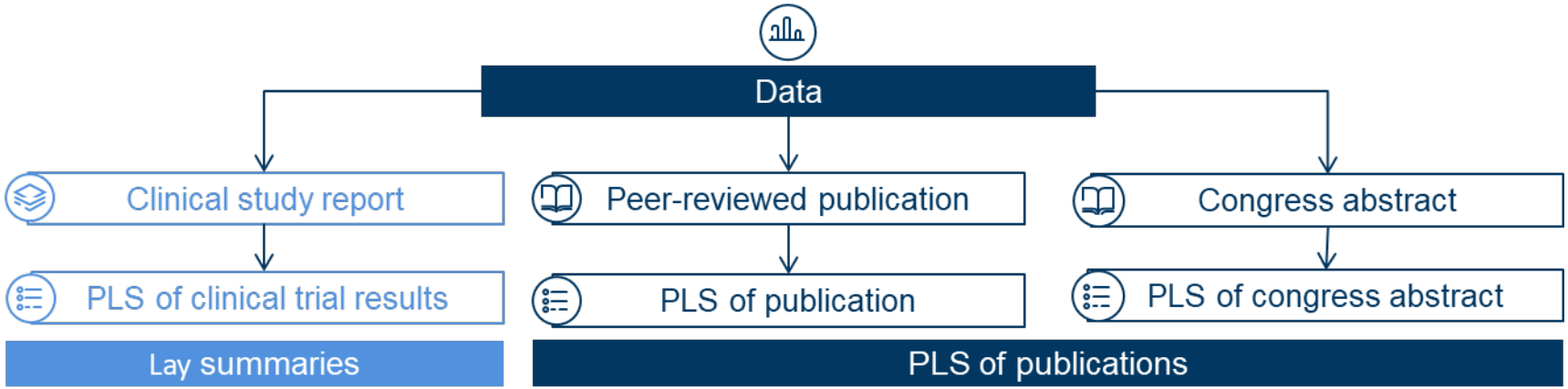
Three types of plain language summaries can broaden data dissemination



- The European Union (EU) Clinical Trials Regulation of 2014 requires sponsors to provide summary results of clinical trials in a format understandable to laypeople[1, 2]
- The FDA recognizes their importance but does not mandate them[3]

- Not currently mandated
- Increasingly being explored by journals and industry
- For example, ADIS journals will accept a PLS submitted by the authors

1. European Commission. Clinical trials - Regulation EU No 536/2014. https://ec.europa.eu/health/human-use/clinical-trials/regulation_en. Accessed February 7, 2019
2. European Medicines Agency. Clinical trial regulation http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/general/general_content_000629.jsp. Accessed February 7, 2019
3. Food and Drug Administration. Draft FDA guidance on provision of plain language summaries. https://mrctcenter.org/wp-content/uploads/2017/06/2017-06-13-MRCT-Draft-FDA-Guidance-Return-of-Aggregate-Results.pdf. Accessed October 8, 2019

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Why develop and disseminate PLS?

- Build trust
- Facilitate shared decision-making
- Reduce risk of misinformation
- Raise awareness of study findings

SHARE REAL-WORLD RESEARCH ACROSS THE WORLD

Lay summary of clinical trial results

Clinical trial results

PLS of publications

Clinical trial results
+
Real-world evidence
Systematic reviews
Narrative reviews
Epidemiology studies
HEOR studies
Case studies etc…
& non-EU studies

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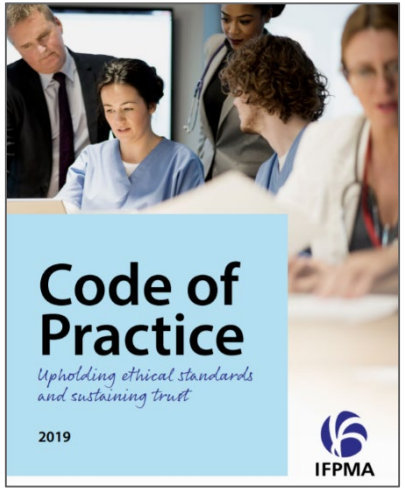
Overcoming compliance concerns – Communication of results is not promotion



18 | IFPMA Code of Practice

3. **Pre-Approval Communications and Off-Label Use**

No pharmaceutical product shall be promoted for use in a specific country until the requisite approval for marketing for such use has been given in that country.

This provision is not intended to prevent the right of the scientific community and the public to be fully informed concerning scientific and medical progress. It is not intended to restrict a full and proper exchange of scientific information concerning a pharmaceutical product, including appropriate dissemination of investigational findings in scientific or lay communications media and at scientific conferences. Nor should it restrict public disclosure of information to stockholders and others concerning any pharmaceutical product, as may be required or desirable under law, rule or regulation.

"FDA: "It has long been FDA policy not to consider a firm's presentation of truthful and non-misleading scientific information about unapproved uses at medical or scientific conferences to be evidence of intended use when the presentation is made in non-promotional settings and not accompanied by promotional materials…"

FDA Memorandum – Public Health Interests and First Amendment Considerations…January 2017; p 21.

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How to consider PLS for publications?

Finding your place on the learning-growth curve. . . .

Access to PLS is rapidly evolving

- Some congresses are encouraging patient attendees and are supporting the experience of patient delegates
- The EU Clinical Trials Regulation requires trial sponsors to provide PLS of clinical trial results, expected to go into effect from 2020
- Some publishers/journals are beginning to encourage and allow PLS of peer-reviewed publications; trends indicate greater interest and sharing on social media

ASCO specifically encourages patients, survivors, caregivers, and advocates to attend

ASCO® AMERICAN SOCIETY OF CLINICAL ONCOLOGY

bitors)

Patient advocates may register to attend the 2019 Annual Meeting at a reduced rate. There is no onsite approval for the patient advocate rate. Each individual must be approved by ASCO staff in order to register at this reduced rate. Those that are approved will receive a registration code and instructions. Registration rates, deadlines, criteria, and instructions are available on the **Patient Advocate** section of the ASCO Annual Meeting website, under 'Special Rate Categories.'

Patient advocate registration includes:

- Access to all Educational Sessions and Scientific Sessions
- Access to Poster Sessions
- Access to 2019 ASCO Annual Meeting Videos and Slides
- Access to the Patient Advocate Lounge, Room S402
- Downloadable Meeting Materials: *ASCO Educational Book, Annual Meeting Proceedings Part I*, Annual Meeting Program, and the *ASCO Daily News*, including *Annual Meeting Proceedings Part II*
- Ability to purchase a **Ticketed Session Pass**

Summary results of clinical trials will be available in EU database

Summaries of Clinical Trial Results for Laypersons
26 January 2017

1. Introduction

The EU Clinical Trials Regulation 536/2014 (Article 37) (EU CT Regulation) requires sponsors to provide summary results of clinical trials in a format understandable to laypersons. These layperson summaries will be made available in a new EU database once it becomes available and is approved according to the timelines set forth in the Regulation. Prior to this Regulation and the creation of a new EU database, the EudraCT Results data model, launched in July 2014, had been used for posting of scientific results written in technical language under the Commission Guidelines 2012/C 302/03, which was not easily accessible or understandable to the layperson.

Annex V of the EU CT Regulation sets out ten elements that must be addressed in the lay summaries. This document includes guidance and templates to help authors writing these lay summaries. Consistency in the way trial results are presented will help improve familiarity and comprehension by the general public, participants, patients, and others.

2. Scope

This document provides sponsors and investigators with guidelines and templates for the production of summaries of clinical trial results for laypersons. These guidelines will only apply to lay summaries included in the EU database. The lay summary section of the EU database will be publicly available. The general public are expected to be the primary audience for the lay summaries. The lay summaries may also be accessed by others, such as research participants, healthcare professionals, and academics. Given this wide audience, the summaries will need to take into account the average literacy level of the general population, provide simple explanations, and apply other measures to support health literacy[2].

3. Responsibility of sponsor

It is the responsibility of the trial sponsor to ensure that the lay summary is developed and submitted to the EU database within the timelines required by applicable regulation.

Adis and other journal publishers offer a PLS that can be published with the manuscript

ADIS RAPID+ Instructions for authors

Brief Reports

Brief reports describing a clinical study, or new insights into clinical management, diagnosis, or treatment are welcome. Brief reports detail studies that are smaller in scale and patient numbers, and may report limited pilot data that warrant the need for further investigation. Authors are encouraged to use these sections when submitting the manuscript: Introduction (including the research hypothesis), Methods, Results, Discussion and Conclusion.

Letters to the Editor

Letters will be considered on a case-by-case basis. These include, but are not limited to, letters commenting on a recently published paper. Letters are limited to one comment and one response by the authors of the original paper if they wish to respond. These will be reviewed and approved by the journal's Editorial Board.

PLAIN LANGUAGE SUMMARIES

Plain language summaries (PLSs) are intended for readers requiring a succinct, simplified overview of a manuscript (such as informed patients and caregivers, and scientists outside of the field who may not have an in-depth knowledge of the topic). The aim of PLSs is to assist in understanding the scientific content and overall implications of the manuscript. While some prior understanding of the topic may be assumed, shorter sentences without ambiguous or unnecessarily complex terms are recommended, as well as use of the active voice. PLSs should be up to 250 words in length, and be placed after the Abstract of the article under the heading: 'Plain Language Summary'. PLSs should be submitted to the relevant journal alongside the respective article in order for the PLS to be published after the main abstract – but if submitted retrospectively, will be published as an accompaniment to the article via a linkout positioned underneath the abstract. All PLSs are peer-reviewed, either at the same time as the submitted article or later if submitted separately.

Please find examples below:
https://link.springer.com/article/10.1007%2Fs40744-017-0080-4
https://link.springer.com/article/10.1007/s40120-018-0096-x

PLSs can be structured at the authors discretion, and may include subheadings for clarity if appropriate.

ENHANCED DIGITAL FEATURES

To further encourage readership, every paper is accompanied by a bulleted summary slide, highlighting the key points of the article. The journals also have the capability to publish:

- Slide decks (providing an overview of the paper);
- Videos (providing an accurate representation of the article/demonstrating a procedure);

Professionals

Case study: PLS of congress abstracts (APLS) Accessed via QR codes at ASCO 2018

THE CHALLENGE

- Patients are demanding access to the latest scientific information and becoming more involved in major scientific congresses (eg, ASCO, ESMO)
- Pharma client wanted to address this unmet need and demonstrate a compliant, tangible commitment to patient involvement

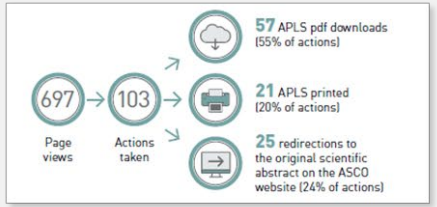
THE SOLUTION

- Accessible, understandable, usable PLS of 12 scientific abstracts
- Scan the QR code to access the PLS
- View the PLS on a device
- Menu options to:
  - Download the PLS
  - Print the PLS, or
  - Access the original scientific abstract (redirected to the ASCO website)

THE IMPACT

- Every APLS was accessed
- APLS access peaks aligned with the corresponding research presentation day
- The most viewed APLS corresponded with the cancer types with the highest profiles at ASCO

Every APLS was accessed



AUTHOR: 'There has been strong interest in the PLS from non-MD attendees, specifically RNs, and Patient Advocacy Group attendees who believe this is an important step'

Chari, et al. ISMPP EU Meeting 2019. London, UK.

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Journal variation in *what*, *who*, *when*, wh*ere*

Assessment of 10 journals from different publishers identified as having PLS using eLIFE

Terminology

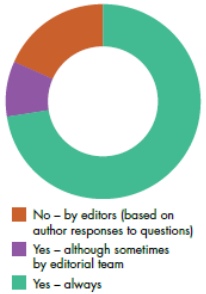
9 different terms for PLS were found

Annals of the Rheumatic Diseases refers to both 'patient summaries' and 'lay summaries'; *Autism Research* has changed from 'lay abstracts' to 'scientific summaries for families with ASD', and more recently to 'lay summaries'

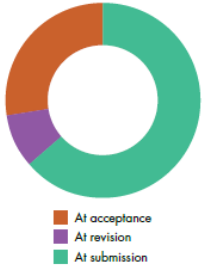
Some terms do not intuitively make the intended audience clear (eg 'significance statement', 'author summary'), meaning lay readers may overlook them

Requirements

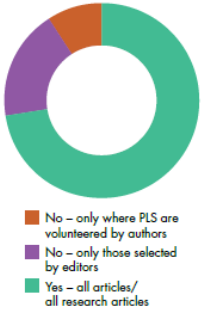
Are PLS developed by authors?



When are PLS required?

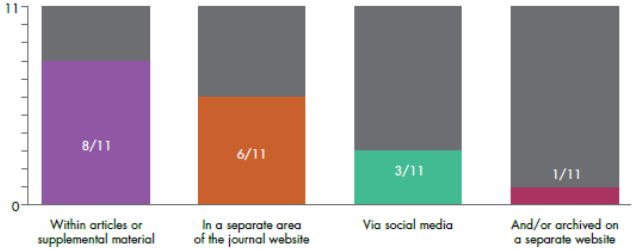


Are PLS required for all research articles?



Location

The sharing mechanism/location of PLS varies:



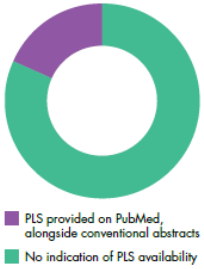
Accessibility

All PLS are **freely accessible**, with the exception of *ACS Infectious Diseases* – e-mail follow-up determined that these PLS are only for the press, and are not publicly available

PLS published within articles are freely accessible, even when the main article sits behind a paywall

PubMed visibility

Are PLS noted on PubMed?



Fitzgibbon et al, ISMPP EU 2019.

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What about format?

Plain Language Summary

Rheumatoid arthritis (RA), psoriatic arthritis (PsA), and axial spondyloarthritis (axSpA) are common rheumatic diseases that can lead to deformities and joint destruction. RA, PsA, and axSpA share many symptoms, including pain, stiffness, fatigue, and reduced physical function, which can lead to a substantial physical and emotional burden on patients with these diseases. Comprehensive assessment of disease burden from both physician and patient perspectives is important for helping make decisions about treatment and disease management. Currently, more research has been done to evaluate the impact of disease on patients with RA compared with patients with PsA or axSpA, and few studies have compared disease burden across patients with these diseases.

This study compared disease burden in patients diagnosed with RA, PsA, or axSpA enrolled in the US-based Corrona RA and PsA/SpA registries. In this real-world population, patients with PsA or axSpA had a longer time from symptom onset to diagnosis than patients with RA, suggesting that PsA and axSpA may not be as well recognized in clinical practice compared with RA. Patients with PsA or axSpA had a disease burden comparable to or greater than that in patients with RA when assessed using common patient-reported outcome measures; however, disease burden in patients with PsA or axSpA appeared lower when assessed using RA disease activity measures. These results provide physicians with important insights into the impact of RA, PsA, and axSpA and highlight the need for disease-specific clinical measures and management strategies to better control disease in patients with PsA or axSpA.

VS

?

Abstract

Introduction

Rheumatoid arthritis (RA), psoriatic arthritis (PsA), and axial spondyloarthritis (axSpA) are three common inflammatory rheumatic diseases that can lead to deformities and joint destruction. Few studies have compared disease burden across patients with these diseases. The objective of this study was to compare disease burden in patients with RA, PsA, or axSpA in routine US clinical practice.

Methods

This study included adults with RA, PsA, or axSpA enrolled in the Corrona RA and PsA/SpA registries between March 2013 and March 2018. Patient and clinical characteristics at enrollment were compared between patients with RA vs. PsA and RA vs. axSpA using *t* tests or Wilcoxon rank-sum tests for continuous variables and χ^2 or Fisher's exact tests for categorical variables.

Results

A total of 11,350 patients with RA, 2003 with PsA, and 495 with axSpA were included. Patients with RA had shorter mean symptom and disease duration (9.4 and 7.6 years, respectively) than those with PsA (11.2 and 8.4 years) or axSpA (16.7 and 9.8 years). Patients with PsA had lower mean physician global assessment (18.6 vs. 27.3), higher patient global assessment (43.2 vs. 36.9), comparable pain (38.9 vs. 39.5), and lower fatigue (41.1 vs. 43.4) scores than those with RA. Patients with axSpA had comparable mean physician global assessment (25.5 vs. 27.3) and higher patient global assessment (50.2 vs. 36.9), pain (46.1 vs. 39.5), and fatigue (48.3 vs. 43.4) scores than those with RA.

Conclusions

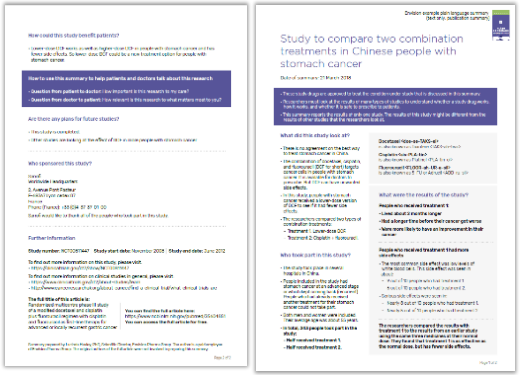
Disease burden in patients with PsA or axSpA was comparable to or greater than that in patients with RA on the basis of common patient-reported outcome measures but appeared lower when assessed using RA disease activity measures, suggesting that disease-specific approaches to care are needed to optimize disease management.

Mease, P.J., Liu, M., Rebello, S. et al. Rheumatol Ther (2019). https://doi.org/10.1007/s40744-019-00172-9

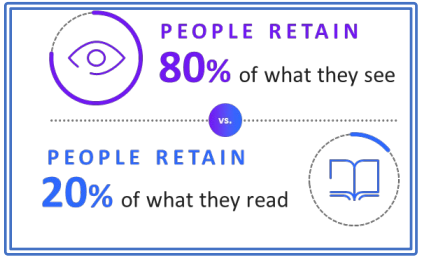
Different format options for PLS

Text-only PLS :

Impactful layout to optimize the reader experience

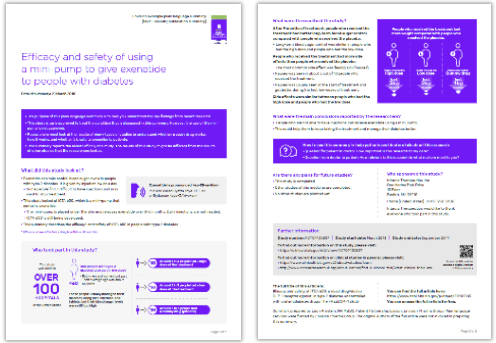


- Different weights and styles of text help show reader which information is important
- Call-outs using contrasting colors to draw attention to key messages
- Clear sections using color block sand divider lines
- Use of bullets and spacing



Text and visuals PLS :

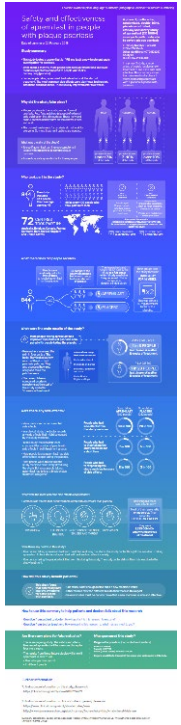
Visuals can enhance communication of key data points



- Including visuals to help communicate key points; this is especially beneficial when it comes to comparing data

Full infographic PLS :

Fully engages the reader; digital options

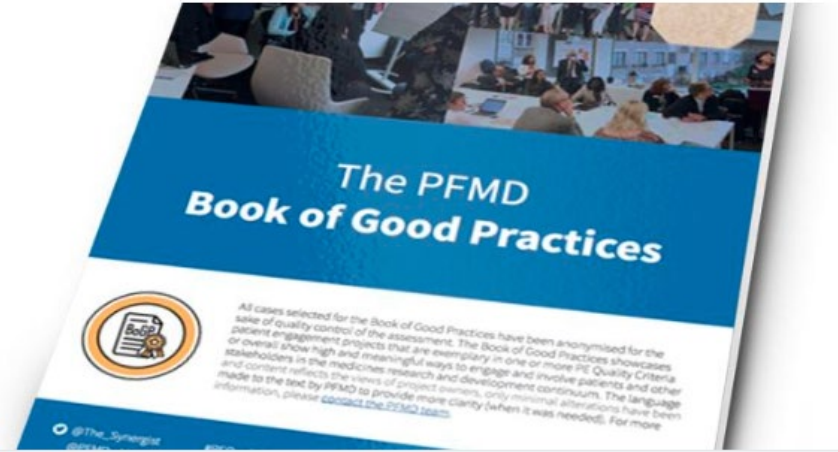


Increase in resources available

Patient Focused Medicines Development (PFMD)
220 followers
1w

+ Follow

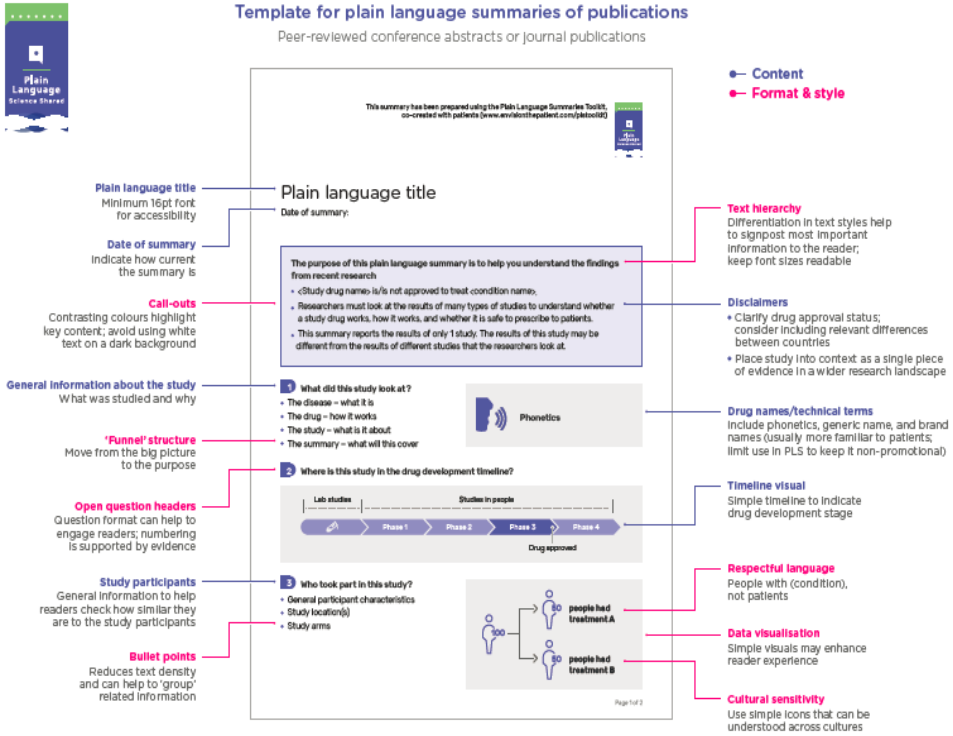
Mobilisation of the #patientengagement community interested to share their work in a non-competitive & anonymised space is crucial. Discover inspiring initiatives engaging #patients in 'The Book of Good Practices' launched by Patient Focused Medicines Development (PFMD).



The Book of Good Practices in patient engagement – 2019 New

patientfocusedmedicine.org

https://www.envisionthepatient.com/plstoolkit/



Addressing the need for PLS in publications

WHY?

- Information that is easy to access and understand can prevent misinformation
- People have a right to information that is about them: transparency builds trust
- PLS can increase the reach of data to different audiences and are often shared on Social Media
- By empowering patients, PLS can facilitate shared decision making

HOW?

?

Addressing the need for PLS in publications

WHY?

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HOW?

- Work with legal teams from the outset to ensure a compliant plan that avoids 'cherry picking' of data for PLS
- Consider the optimal format and communication channels for PLS including open access journals and congresses
- Combine scientific understanding, plain language expertise, graphical communications skills, and patient partner insights

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Audience Poll (1)

Have any clients or associates inquired about developing a PLS for a journal publication or congress presentation?

A. Yes

B. No

C. I'm not sure

Audience Poll (2)

Have you worked on developing a PLS for a clinical trial or publication/presentation of data?

A. Yes, directly (writing, editing, or reviewing)
B. Yes, indirectly (as part of team planning/implementation)
C. No, not at all

Plain Language Summaries

Kelly Ann Soldavin
Medical Editor
Taylor & Francis Group

ISMPP International Society for Medical Publication Professionals™

Plain Language Summaries

The Five Ws
Answering key questions about PLS

The Challenges
Assessing struggles to develop & disseminate

Tips & Best Practices
Proposing solutions for the challenges

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Disclosure Statement

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an **informa** business

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The Five Ws of Plain Language Summaries

Answering key questions about PLS

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WHAT are PLS?

"Plain language descriptions of the design and aggregate results of individual **clinical studies.**"[1]

PLS can also describe or be used in[2-5]:

- **Original research** beyond clinical trials
- Narrative and systematic **reviews**
- Case **reports**
- Congress **abstracts**
- Research **proposals**
- Grant or faculty **applications**

Plain Language Summary
FMCH 7600
John McGrory

Can e-cigs help me to quit smoking?

Quitting smoking is one of the best things we can do for our health. By quitting, we lower our chances for heart problems, lung problems, cancer, and many other issues. But it isn't easy. Your doctor can provide advice and tools to help you as you try to quit. Recently, some companies have claimed that using electronic cigarettes, or e-cigs, can help you quit smoking. Here's what we know about e-cigs so far.

What is an electronic cigarette (e-cig)?

There isn't a perfect answer because e-cigs come in a lot of different forms. They can look like cigarettes, pipes, metal tubes, or even like USB sticks. In general, they are handheld devices that have a battery and a space for liquid. The liquid is usually nicotine with some flavoring and other additives. The battery heats up the liquid into a vapor, and the user inhales the vapor. This is why e-cigs are sometimes also called "vapes" or "vaporizers".

Are they safe?
E-cigs haven't been around long enough for us to say whether they are safe or not, in the long term. Many experts believe that they are less harmful than smoking normal cigarettes but more harmful than not smoking at all. They are not safe for people who are pregnant. In most states, they are illegal to have for people under the legal smoking age.

Can e-cigs help me quit smoking?
Scientists and doctors have done several studies to see if people who use e-cigs are able to quit. These studies show that when you check on people after 6 months, they are more likely to quit if they are using nicotine e-cigs than if they tried quitting "cold turkey". However, most studies have not shown e-cigs to be better than other quitting tools, like nicotine gum or patches. You should try the other tools before e-cigs because they have more research supporting them and are FDA approved.

Reprinted from:
https://conservancy.umn.edu/handle/11299/114743

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WHO reads PLS?

Patients and **clinical study participants**, plus[6]:

- General public
- Patient advocates
- Researchers
- Students and faculty
- General clinicians
- Therapy area specialists
- Healthcare professionals
- Publishing professionals

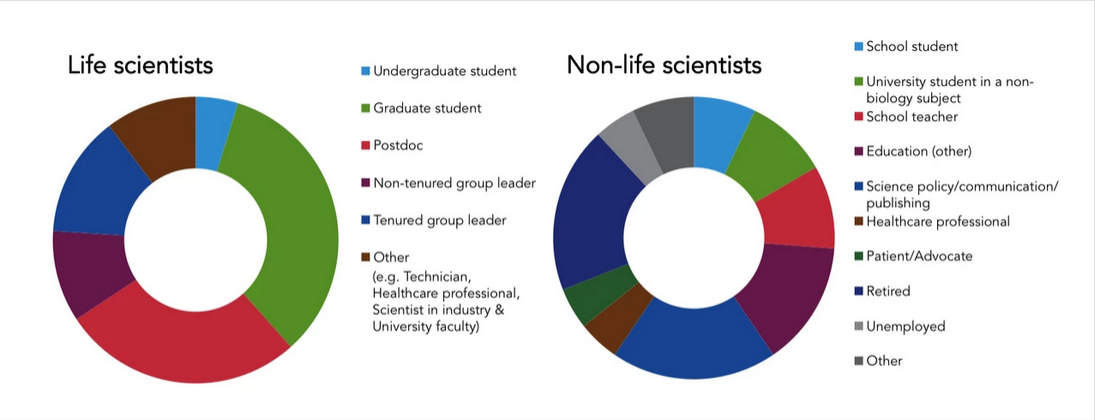

Figure 1: What is your current job role? 271 respondents are currently working in the life sciences or biomedicine (left), while 42 respondents have other roles (right).

Reprinted from:
https://elifesciences.org/inside-elife/19c97b89/plain-language-summaries-results-of-the-2016-elife-digest-reader-survey

WHY create PLS?

"The goal of a lay summary is to aid **study participants** [patients] and the **general public** in understanding clinical study results."[1]

"Enhance communication pathways between scientists and the public."[7]

"Make scientific advances understandable and accessible to all."[8]

"Provide something that is simple and actionable."[9]

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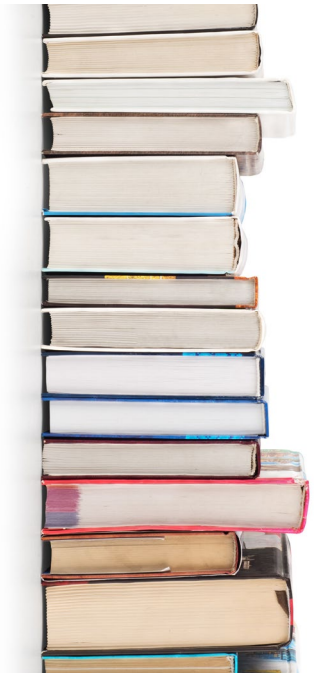
WHERE can you find PLS?

- Alongside published, peer-reviewed **articles**
- Congress **poster presentations/abstracts**
- Government agency online **repositories**
- Pharmaceutical company/healthcare **industry websites**
- Medical **school archives**, such as UMN's
  https://conservancy.umn.edu/handle/11299/114743
- **Social media**, as additional route or only route

WHEN? The timeline of the PLS



1975	Flesch-Kincaid readability test created; produces grade level scores that predict level of education required to read selected text
1998	Plain Language Action Network begins providing plain language training to US government agencies
2010	Plain Writing Act (US) requires use of plain language for information disseminated to general public[1,10]
2014	EU Clinical Trial Regulation 536/2014 requires a summary—in a "format understandable to laypersons"—be posted to EU portal within 1 year of clinical trial end; goes live in 2020[1,11]
2015	Medical Research Involving Human Subjects Act (Netherlands) states that a scientific summary, including lay summary, be submitted within 1 year of study completion[1,12]
Current	National Institutes of Health (US) requests that dissemination of information on NIH-funded clinical trials be "broad, transparent, timely, and responsible"[1,13]

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The Challenges of Plain Language Summaries

Assessing struggles to develop & disseminate

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Challenges in Development

1. **NOMENCLATURE.** PLS are identified by a wide variety of names that are used interchangeably or depending on context, such as intended audience or specific format[1,14,15]

2. **GUIDELINES.** There is no standard approach to writing and formatting PLS, including guidance on language and quality, nor agreement on who should be authors

3. **COMPLIANCE.** Are PLS considered promotional materials? Is a company's legal team going to prevent development and publication of PLS?

4. **PATIENT ROLE.** There is also no consensus on the patient's role in developing PLS. Should they be authors? Review the PLS prior to publication? Act as peer reviewers after submission to a journal?

- Plain language summary
- Lay summary
- Patient summary
- Scientific summary
- Lay language summary
- Significance statement
- Trial results summary
- Patient content
- Non-technical summary
- Layperson summary
- Simple summary

Challenges in Dissemination

1. **SELECTION.** Should all studies, articles, and presentations have PLS? Or only selected ones? How do you select which ones need a PLS?

2. **JOURNALS.** Not only is it difficult to determine which journals publish PLS, there are also a wide variety of approaches in PLS policies.[2]

3. **ACCESSABILITY.** Most PLS are open access (freely available); however, 11% of journals do not make PLS available or place them behind a paywall.[7]

4. **VISIBILITY.** There are no easy ways to find PLS, whether searching a journal website, PubMed, social media, or through a search engine, such as Google.[14]

No PLS

Journal **does not publish** PLS

Journal **considers** PLS on ad hoc basis

Journal **provides guidelines** for PLS

Journal **selects articles** that will have PLS

Journal **requires PLS** upon *acceptance*

Journal **requires PLS** upon *submission*

PLS Required

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Tips & Best Practices for Plain Language Summaries

Proposing solutions for the challenges

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Establishing Consensus

Nomenclature. Use the term “plain language summary” consistently across medical publishing and the industry

Guidelines. Create a set of standard guidelines and best practices for development and dissemination of PLS

Patient Role. Determine the ways in which patients can contribute to PLS as authors and reviewers

Journals. Develop registry of journals that provide PLS, including their PLS policies

Accessibility. Mandate that all PLS be published open access.

Visibility. Encourage publishers of PLS to host them together or develop search function on their website that allow PLS to be easily identified.

Tips on Getting Started

- ✓ **Develop pilot program** that identifies 2 to 3 opportunities for PLS or, during pub planning, identify which papers will have PLS
- ✓ **Educate colleagues** in order to create support and buy-in for PLS
- ✓ **Determine type** of PLS and select studies:
  - Clinical trial results, manuscript, or poster
  - Phase II/III studies are better than Phase 1 or HEOR
- ✓ **Realize that the needs of patients with rare diseases** are uniquely met by PLS
- ✓ Remember that the PLS process mirrors publication development—**involve the same people** in both processes
- ✓ **Identify audience needs** by involving patient reviewer and patient groups
- ✓ **Consider choosing a medical writer** as an author—they typically have the best skill set for writing PLS

Addressing Compliance Concerns

- ✓ Talk with your legal team and explain regulatory drivers (EU Clinical Trial Regulation and US Plain Writing Act)
- ✓ Set up appropriate firewalls—do not mix PLS with other promotional materials
- ✓ Include all study data in PLS to avoid any appearance of "cherry picking"
- ✓ Add legitimacy to PLS by:
  - Using EMA process/template
  - Publishing PLS in peer-reviewed journal
- ✓ Ask yourself: "Am I reporting data or advocating for a product?"

FDA U.S. FOOD & DRUG ADMINISTRATION

Plain Writing at Work

Share | Tweet | Linkedin | Email | Print

At FDA, we are working to create letters, reports, web pages, and other public documents using Plain Language Principles to ensure plain, clear writing. We are dedicated to providing you with:

- reader-friendly information that you can easily understand,
- documents in which you can easily find the information you need, and
- information you can readily use and act on.

EMA = European Medical Agency

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Advice on Writing & Format

- ✓ Contact journal editor for info on policies, format, and submission of PLS
- ✓ Have the PLS written for the 8th grade level; use Readable.com to help gauge academic level of writing
- ✓ Refer to Universal Patient Language (www.upl.org)
- ✓ The most effective PLS include infographic elements; best practice is fully infographic with digital options
- ✓ Take a look at these other resources:
  - PLS Toolkit: www.envisionthepatient.com/plstoolkit/
  - PLS Tool: https://ktdrr.org/resources/plst/
  - The Book of Good Practices: https://synapse.pfmd.org/book-of-good-practices
  - Summaries of Clinical Trial Results for Laypersons[16]

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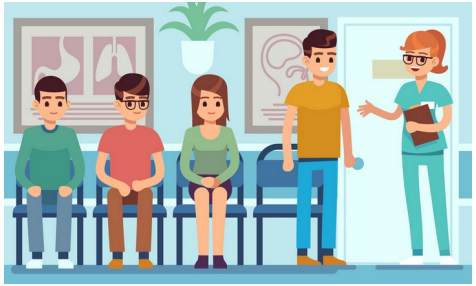
Delivering the PLS

- ✓ Ensure the PLS is published Open Access or made freely available
- ✓ Determine how the PLS will be accessed. Best practice is stand alone publication with its own DOI, linked to full manuscript
- ✓ Discuss HTML tagging and search engine optimization (SEO) with editor/production team
- ✓ Send PLS to clinical trial participants and patients
- ✓ Distribute PLS through social media channels, but tailor its format for that audience
- ✓ Create patient portal where PLS of all clinical trials are hosted
- ✓ Consider additional outlets for PLS: medical info patient response letters, patient society communications, patient web portals
- ✓ Partner with patient advocacy organizations
- ✓ ASCO 2018: PLS were accessed by QR code on poster—all PLS were accessed; most on the day of presentation



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Key Takeaways

- Plain language summaries make scientific information understandable to all.
- Patients are actively seeking and sharing current medical research. They should play a key role in the PLS conversation.
- Consensus on nomenclature, patient role, and best practices in PLS development and dissemination is needed.
- Involve the entire publication team, including journal editors, in PLS planning.
- Many options exist for PLS distribution—determine how best to reach your intended audience.

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THANK YOU!

Questions

- To ask a question, please type your query into the Q&A box
- To ensure anonymity, before sending please choose the drop-down box option, "Hosts and Presenters." Otherwise, **ALL** audience members will be able to see your submitted question

Thank You for Attending!

- We hope you enjoyed today's presentation.
- Please check your email for a link to a survey that should take only a few minutes to complete.
- We depend on your feedback and take your comments into account as we develop future educational offerings. Thank you in advance for your participation!

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