

Welcome!

# **Complexities Beneath Plain Language Summaries: Challenges and Future Implications**

# Conflict of Interest and Disclosures

- MAPS is committed to ensuring full disclosure of potential Conflicts of Interest (COI) by session presenters/developers
- The speakers have no financial conflicts of interest to report

# Disclaimer

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- This presentation is for informational purposes only and is not intended as legal or regulatory advice.

# Agenda

- **Brief introduction of the speakers**
- **Perspectives and experiences sharing on plain language summaries**
- **Q&A**

# Presenters

## Speakers



**Lisa M. DeTora**

**Associate Professor**  
Hofstra University, USA



**Avishek Pal**

**Global Medical Director,  
Cell & Gene Therapies,**  
Novartis, Switzerland



**Laura Dormer**

**Co-Founder and  
Editorial Director**  
Becaris Publishing Ltd,  
UK



**Raghuraj Puthige**

**Senior Scientific Writing  
Lead**  
Enago Life Sciences, India

# Educational Objectives

**This session will provide a learning opportunity for our audience by understanding:**

- 1: Why plain language summaries (PLS) are complex**
- 2 : Current challenges in harmonizing and developing global guidelines**
- 3 : Future implications**

# Why is it challenging



Plain Language  
Summary



**In depth subject matter knowledge**



**Engaging to hold reader's attention**



**Strong communication skills – simplify technical concepts**



**Clarity and brevity**

# Why no harmonized guidance



**Lack of consensus on best practices: different approaches and recommendations**



**Variation in audience needs and preferences: one-size-fits-all guidance for plain language summaries**



**Complexity of scientific research: difficult to develop guidance that is applicable to all types of scientific research**



**Limited resources: availability of significant time and resources at organization level or individuals**



# PLS and GPP: Academic perspective

*Lisa DeTora,  
Associate Professor,  
Hofstra University, USA*

# Good Publication Practice

- Originated at the turn of the 21<sup>st</sup> century to address key issues in company-sponsored research:
  - Transparency
  - Authorship
  - Publication process
- GPP 2022 is the fourth iteration
  - PLS recommended
- *FREE* to access



The screenshot shows the Annals of Internal Medicine website. At the top, the journal title "Annals of Internal Medicine®" is displayed in a dark blue font. To the right of the title is a "Search Journal" button. Below the title is a navigation bar with links for "LATEST", "ISSUES", "IN THE CLINIC", "JOURNAL CLUB", "MULTIMEDIA", "CME/MOC", and "AUTHORS/SUBMIT". The main content area features the article title "Good Publication Practice (GPP) Guidelines for Company-Sponsored Biomedical Research: 2022 Update" in bold black text, with a "FREE" badge next to it. Above the title, it says "Research and Reporting Methods | September 2022". Below the title, the authors are listed: "Lisa M. DeTora, PhD, MS", "Dikran Toroser, PhD", and "Angela Sykes, MA, MPhil", followed by an ellipsis and a "View all authors" link. Below the authors is the text "Author, Article, and Disclosure Information" and the DOI link "https://doi.org/10.7326/M22-1460".

# GPP 2022 Overview

GPP 2022 reflects the changing role of the publication professional & strengthens core values such as ethics, transparency, inclusivity, accountability and responsibility



Updated guidance on the types of studies that should be published (e.g., HEOR, RWE, translational and biomarker studies)



Information added on the role of patients as authors



Improved and detailed guidance on author agreements, including the removal of the recommendation to limit author numbers

Guidance on working with alliance partners

Advice on the role of social media in publication planning

**Guidance on enhanced content and PLSs for publications**

Clarity of the timing of data sharing to improve transparency

**A detailed supplement includes practical help on various topics**



Publication types



Publication professional roles and professional development



Steering committees



Publication plans



Publication working groups



Authorship and contributorship determination

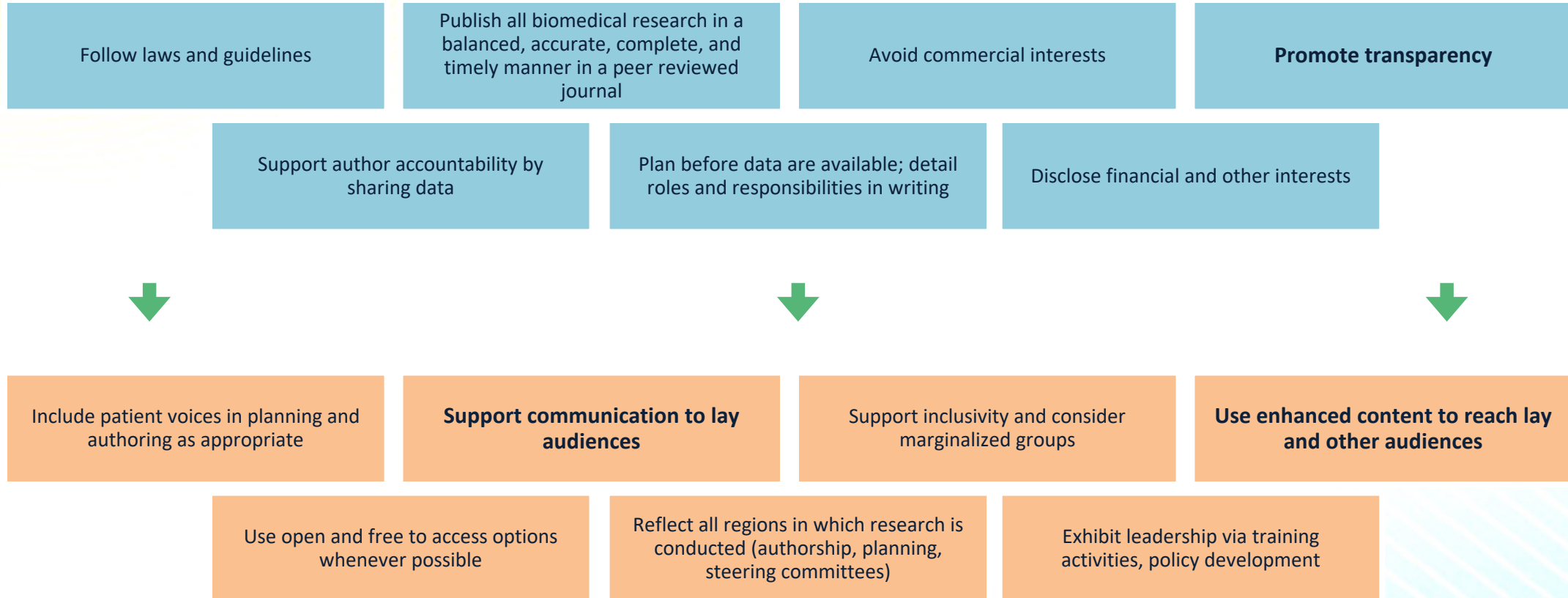


Publication process



Documentation

# Major GPP principles



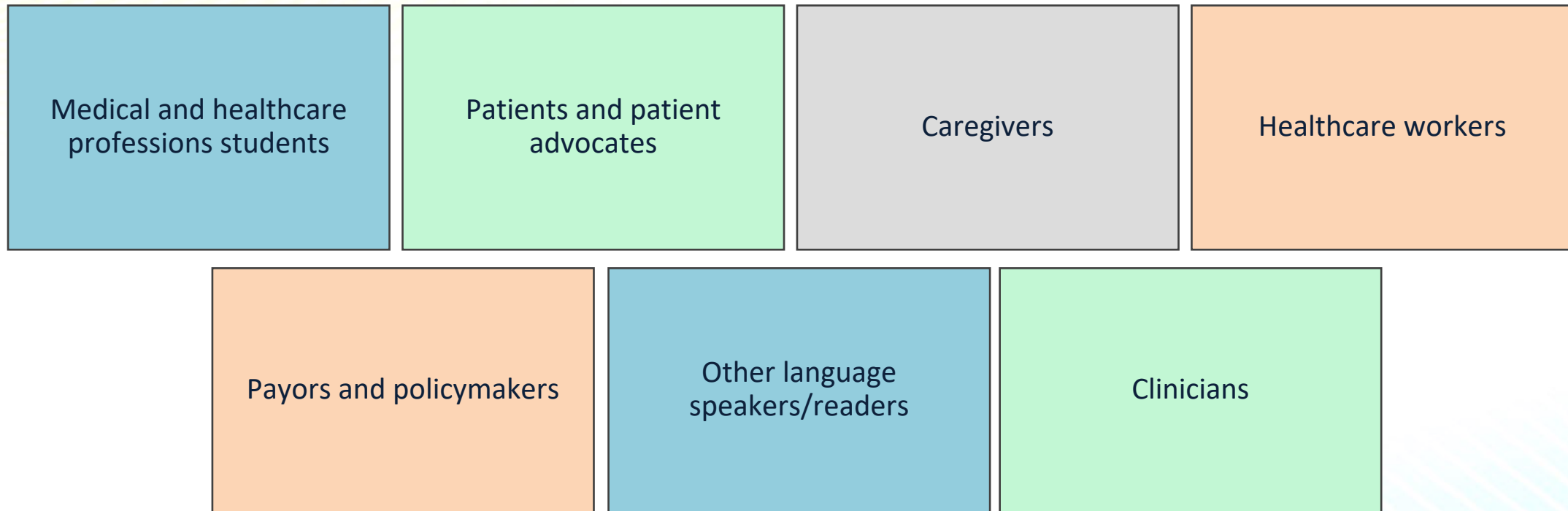
GPP, Good Publication Practice; HEOR, health economics and outcomes research; ISMP, International Society for Medical Publication Professionals; PLS, plain language summary; RWE, real-world evidence. <https://www.acpjournals.org/doi/full/10.7326/M22-1460>

Please note: Slides adapted from materials courtesy of Nucleus Global, An Inizio Company prepared for ISMP U

# GPP 2022 Enhanced Content and PLS Recommendations

- Enhanced content and PLS are encouraged
  - At least abstract-length text PLS for all clinical trial data publications that follow CONSORT format (randomized, controlled trials)
    - Does not preclude additional enhanced content
  - Standalone PLS permissible for other data types
- Plan for PLS and enhanced content at all stages
  - Publication plan
  - Publication process
  - Include appropriate reviewers
  - Consider audiences

# PLS audiences



# Where to find PLS information in GPP 2022

- Main Manuscript
  - Principles to Promote Transparency
- Supplement
  - Section A: Definitions
  - Section E: Publication Plans (Table 2)
  - Section F: Publication Working Groups
  - Section H: Publication Process (Table 6, Standalone Section)

# PLS: Industry perspective

*Avishek Pal*

*Global Medical Director, Cell & Gene Therapies,  
Novartis, Switzerland*



# PLS can be crucial in improving health literacy

Improving **health literacy** can improve **patient empowerment** leading to more effective **shared decision-making**



Office of Disease Prevention  
and Health Promotion

U.S. Department of Health  
and Human Services

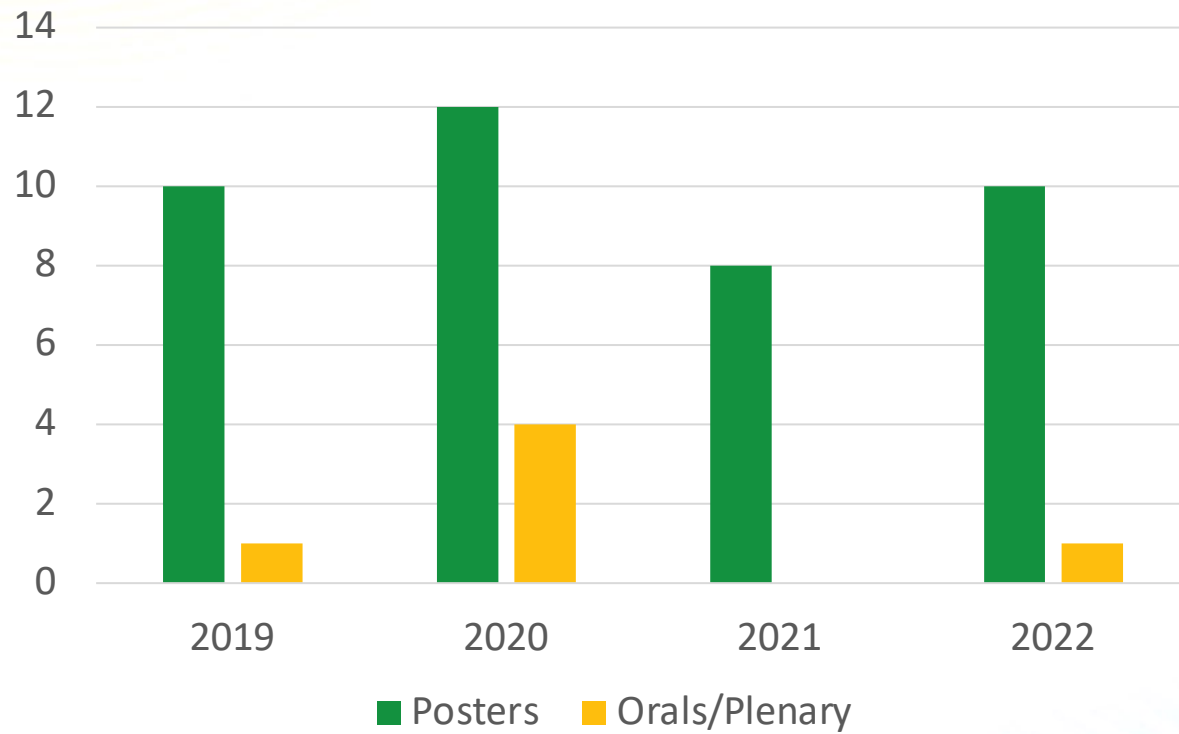
## **PLAIN LANGUAGE: A PROMISING STRATEGY FOR CLEARLY COMMUNICATING HEALTH INFORMATION AND IMPROVING HEALTH LITERACY**

### **Purpose statement**

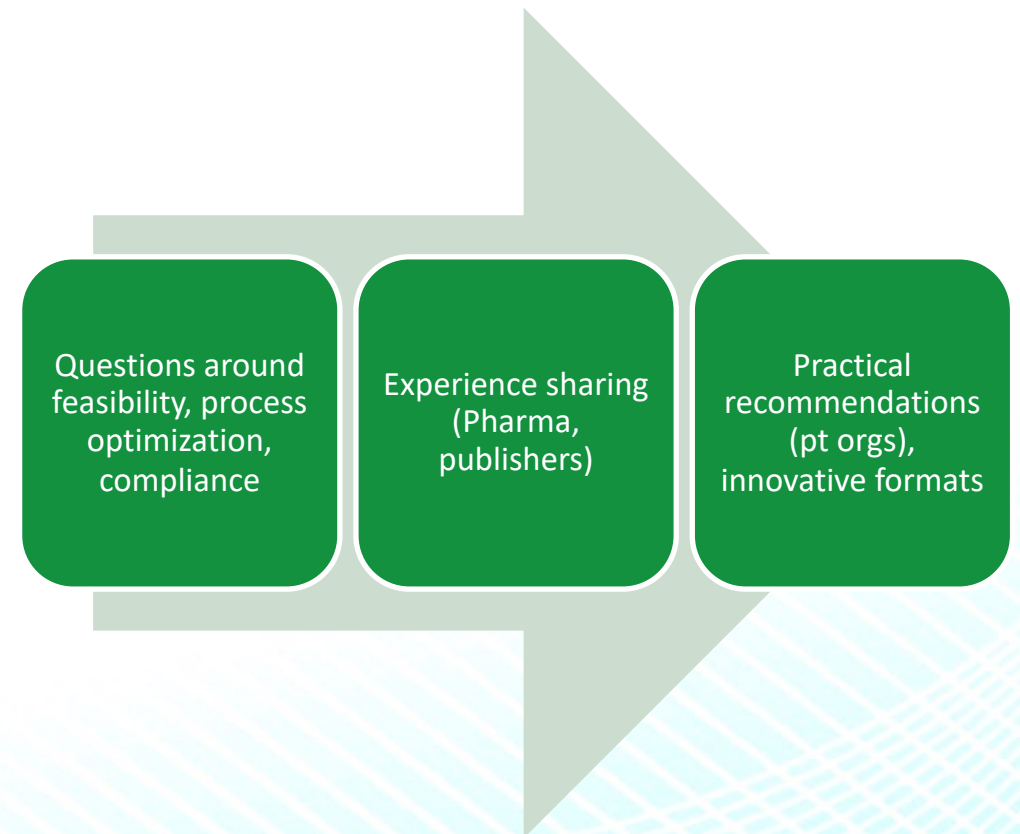
This issue brief describes why plain language is a promising strategy for clearly communicating health information and improving health literacy.

# Interest in PLS is high in the medcomms community

Evolution of coverage at ISMPP over the years

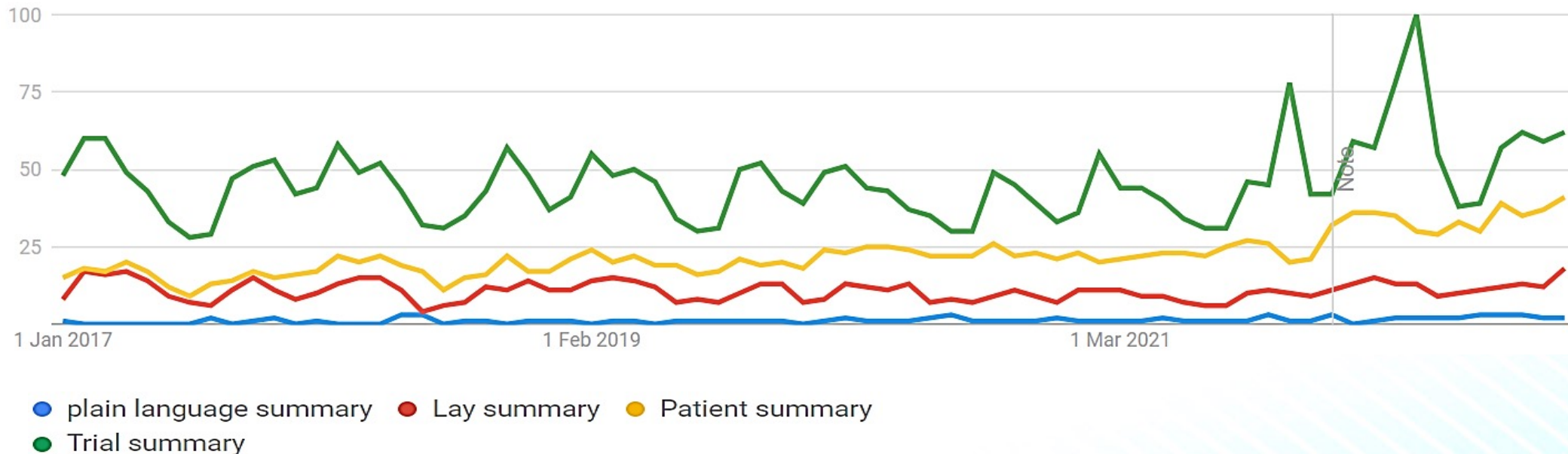


Evolution of themes since 2019



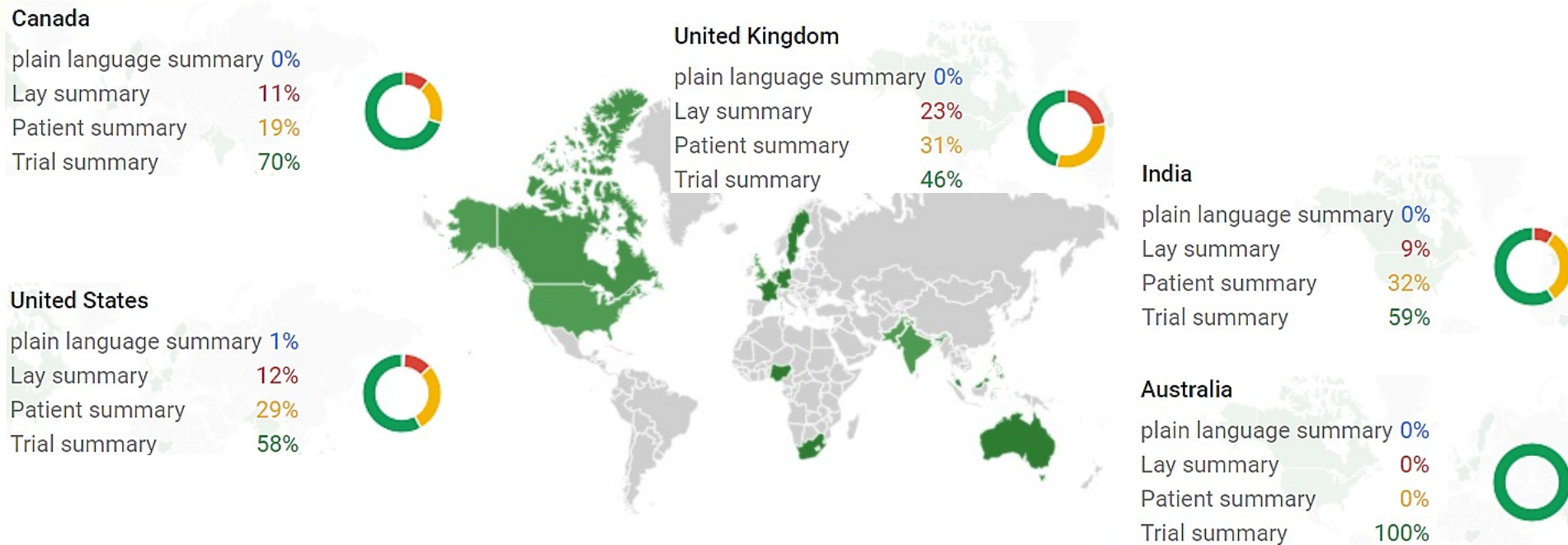
# 5-year Google trends however indicate otherwise!

**Ambiguity still exists in nomenclature when general public search for info**



# 5-year Google trends however indicate otherwise!

## Search is still concentrated in specific regions which mirror medcomms presence

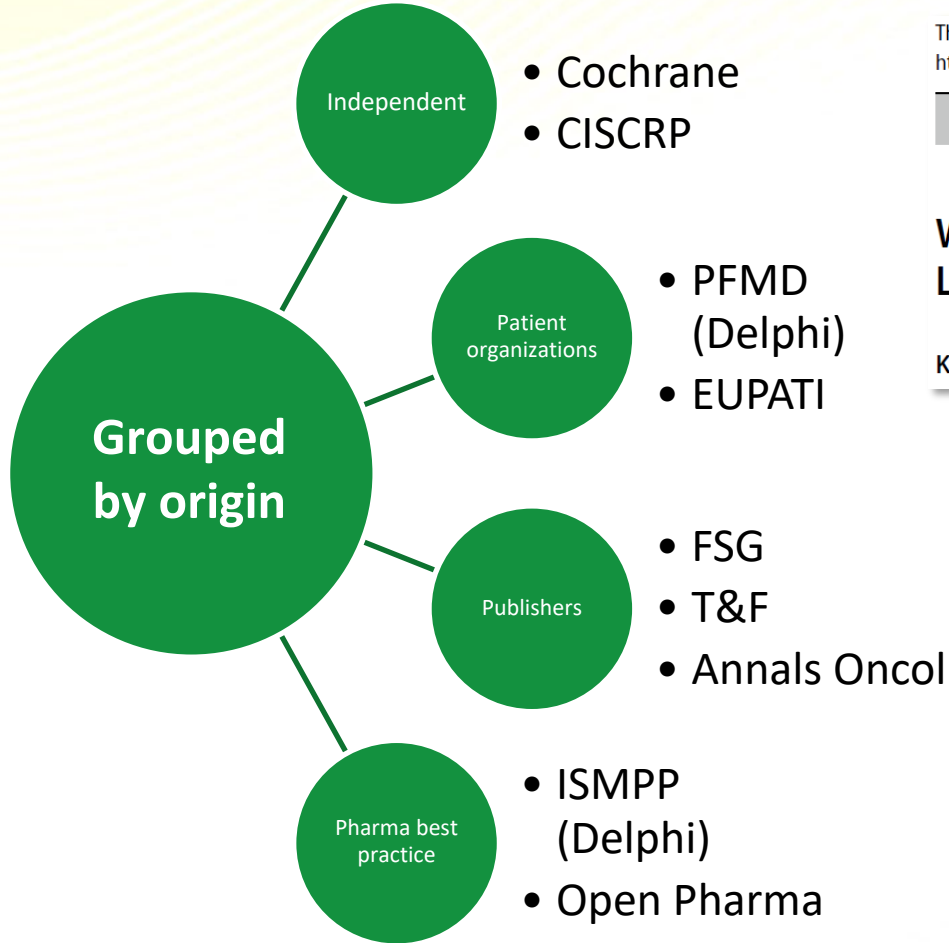


France, Germany, Sweden, Nigeria, South Africa searched only for trial summaries

- plain language summary
- Lay summary
- Patient summary
- Trial summary

<https://trends.google.com/trends/explore?date=2017-01-01%202022-12-21&q=plain%20language%20summary,Lay%20summary,Patient%20summary,Trial%20summary>

# Diversity in guidelines could be challenging



The Patient - Patient-Centered Outcomes Research  
<https://doi.org/10.1007/s40271-022-00606-7>

## SCOPING REVIEW

### What Author Instructions Do Health Journals Provide for Writing Plain Language Summaries? A Scoping Review

Karen M. Gainey<sup>1</sup> · Jenna Smith<sup>1</sup> · Kirsten J. McCaffery<sup>1</sup> · Sharon Clifford<sup>2</sup> · Danielle M. Muscat<sup>1</sup>

We found variation between journals in the content and detail of instructions provided, for example the word count/PLS length, content, structure and recommendations regarding the use of jargon in the author instructions for PLS.

PLS could be improved with consistent instructions developed with the assistance of consumers.

**Reminder: LESS IS MORE!**

# Industry experience-sharing definitely helps

## Pfizer experience<sup>1</sup>

### 1 We approach the key stakeholders involved at each stage:

- Internal company colleagues: medical, clinical, corporate affairs, compliance, legal.
- Patient partners.
- Plain language experts: medical writers, editors, and graphic designers.
- Congress organizers.

### 2 We consider the target audience for APLS at congresses

- Patients and carers are key**
- Patient delegates are powerful drivers of information.<sup>4,7</sup>
- All congress attendees**
- Wider healthcare professional community.
- Non-specialist medical attendees.<sup>5</sup>

### 6 We engage all relevant stakeholders

- Internal company colleagues**
- Include asset-specific, subject-matter experts.
- Medical writers**
- A team trained in the use of plain language includes editors and graphic designers.
- Lead authors of the scientific abstract**
- Given the opportunity to review.
- Patient partners**
- Patients who review the initial drafts bring their experience of health conditions, and are able to user-test APLS.

### 7 Key considerations

- We use a standard template**
- Developed using approved company guidelines and available industry plain language principles.<sup>4,8</sup>
- We use a standardized process**
- To ensure consistency across APLS.

### 11 Reaching the target audience

- Each APLS can be accessed at conferences via QR codes on the scientific presentations.
- Information sheets, including APLS QR codes, are provided upon request.



### 3 We liaise with lead authors

- To secure agreement to develop APLS of the scientific abstracts.

### 4 We secure approval from congress organizers

- To include access to APLS via QR codes on presentations.
- To share APLS reactively via QR codes on information sheets.

### 5 We proactively share timelines

- To inform all stakeholders of the process.

### 8 We ensure that APLS reflect original content of the scientific abstract

- The abstract is used as the data source as it is the enduring, publicly available record.

### 9 We undertake regular plain language training sessions

- For internal and external stakeholders.

### 10 We use plain language and numeracy principles throughout

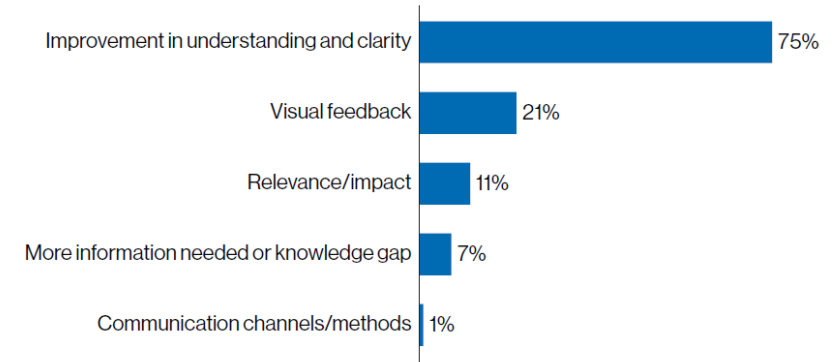
- Simple visuals to enhance understanding
- Avoid jargon
- Use short, simple sentences
- Active voice
- Open-ended questions as headers
- Bullets, not plain text
- Use whole numbers
- Use natural frequencies, such as "1 in 10 people" to represent 10%

- APLS are posted on a microsite until 60 days after the congress, enabling broader audience access to the APLS.
- APLS have been mentioned in a company press release for one congress (ESMO) and posted on the company media page for four congresses in 2019 (ESMO, ESMO Asia, SABCS and ASH).

## Novartis experience<sup>3</sup>

Global Oncology Patient Insights Panel (GOPIP)

Figure 1. Total Comments Received (N=102) for All PL Pieces (n=10)<sup>a</sup>



<sup>a</sup>Some comments were counted in multiple categories, so the total amounts exceed 100%.

## Ipsen pledge<sup>2</sup>

JANUARY 25, 2022

### Our pledge: summaries in plain language for all journal publications

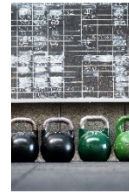
By Will Gattrell

Today, we are broadening our commitment to providing everyone with the opportunity to read and understand our research. From July 2022, we will publish, as a minimum, a 250-word plain language summary alongside all company-sponsored journal publications from human studies.

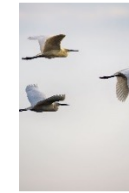
# Questions that still need answers

## Questions from 2021

	<b>PLS guidelines</b> How do we ensure a consistent, optimal, and compliant approach to PLS across different sponsors and regions?	8
	<b>Transparency</b> How do we know which publications to do a PLS for?	6
	<b>Non-promotional</b> How can we ensure that PLS are accurate, balanced, and neutral?	5
	<b>Trust</b> If we <b>don't</b> do PLS, do we risk undermining trust between patients and industry?	4
	<b>Patient and public involvement in PLS</b> How do we best involve key stakeholders in co-creation?	3
	<b>Access to PLS</b> How can we ensure that PLS are easily accessible for all target audiences?	3
	<b>Global considerations</b> How do we ensure PLS are appropriate for different regions and cultures?	3



Nomenclature



Guidelines



Patient involvement



Accessibility

# PLS and article features: a publisher's perspective

*Laura Dormer*

*Co-founder, Becaris Publishing Ltd, UK*



# How can we publish PLS?

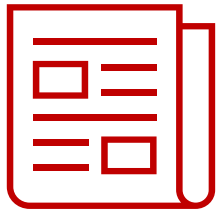
Three methods have emerged for the publication of PLS:



Plain Language Summary **within** a journal article



Plain Language Summary **alongside** a journal article  
(supplementary materials)



Plain Language Summary of Publication as a **standalone** journal article

# PLS within a journal article

- Similar in length to a regular abstract
- Featured within an article alongside the main abstract
- Peer reviewed as part of the article content as usual
- Appear on PubMed

Research Article

For reprint orders, please contact: [info@becaris.com](mailto:info@becaris.com)

## In-hospital mortality in amyloid light chain amyloidosis: analysis of the Premier Healthcare Database

Tiffany P Quock<sup>1</sup>, Anita D'Souza<sup>2</sup>, Michael S Broder<sup>3</sup>, Katalin Bogнар<sup>3</sup>, Eunice Chang<sup>3</sup> & Marian H Tarbox<sup>3</sup>

<sup>1</sup>Health Economics and Outcomes Research, Prothena Biosciences Inc, South San Francisco, CA 94080, USA  
<sup>2</sup>Medical College of Wisconsin, Milwaukee, WI 53226, USA  
<sup>3</sup>Real World Evidence, PHAR (Partnership for Health Analytic Research), Beverly Hills, CA 90212, USA  
\*Author for correspondence: [tiffany.quock@prothena.com](mailto:tiffany.quock@prothena.com)

**Aim:** Describe the clinical and economic burden of hospitalizations for amyloid light chain (AL) amyloidosis. **Materials & methods:** This retrospective analysis used nationally representative hospital discharge data (2017–2020) to report discharge status, resource use and costs for hospitalizations among patients with AL amyloidosis. **Results:** Of 1341 patients identified, 92% were discharged alive and 8% experienced in-hospital death. Compared with the average US hospital stay during 2017–2019 (4.7 days, mean costs of \$13,046 and mean charges of \$54,496), hospital stays for AL amyloidosis were longer and costlier (9.7 days, \$27,098.61, \$111,233.91), especially in patients with in-hospital death (12.2 days, \$44,966, \$182,338.18). **Conclusion:** AL amyloidosis is associated with significant clinical and economic burden.

**Plain language summary:**  
**What is this article about?:** Delayed amyloid light chain (AL) amyloidosis diagnosis is common and associated with poor prognosis and increased healthcare utilization and costs due to disease progression. The study objective was to examine mortality, hospitalization and associated costs.  
**What were the results?:** About 8% of patients hospitalized with amyloid light chain (AL) amyloidosis died in the hospital, of these, 80% had both cardiac and renal involvement versus 54% of patients discharged alive. Compared with the average US hospital stay, the average AL amyloidosis hospitalization is twice as costly and for individuals who died in hospital it is three-times as much.  
**What do the results of the study mean?:** Results suggest that there is still a need for increased awareness of the disease, which may lead to earlier treatment and reduced costs.

> J Comp Eff Res. 2022 Dec 7. doi: 10.2217/cer-2022-0185. Online ahead of print.

## In-hospital mortality in amyloid light chain amyloidosis: analysis of the Premier Healthcare Database

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Affiliations + expand  
PMID: 36476016 DOI: 10.2217/cer-2022-0185  
[Free article](#)

**Abstract**  
**Aim:** Describe the clinical and economic burden of hospitalizations for amyloid light chain (AL) amyloidosis. **Materials & methods:** This retrospective analysis used nationally representative hospital discharge data (2017–2020) to report discharge status, resource use and costs for hospitalizations among patients with AL amyloidosis. **Results:** Of 1341 patients identified, 92% were discharged alive and 8% experienced in-hospital death. Compared with the average US hospital stay during 2017–2019 (4.7 days, mean costs of \$13,046 and mean charges of \$54,496), hospital stays for AL amyloidosis were longer and costlier (9.7 days, \$27,098.61, \$111,233.91), especially in patients with in-hospital death (12.2 days, \$44,966, \$182,338.18). **Conclusion:** AL amyloidosis is associated with significant clinical and economic burden.

**Keywords:** AL amyloidosis; hospitalization; mortality

**Plain language summary**  
What is this article about? Delayed amyloid light chain (AL) amyloidosis diagnosis is common and associated with poor prognosis and increased healthcare utilization and costs due to disease progression. The study objective was to examine mortality, hospitalization and associated costs. What were the results? About 8% of patients hospitalized with amyloid light chain (AL) amyloidosis died in the hospital, of these, 80% had both cardiac and renal involvement versus 54% of patients discharged alive. Compared with the average US hospital stay, the average AL amyloidosis hospitalization is twice as costly and for individuals who died in hospital it is three-times as much. What do the results of the study mean? Results suggest that there is still a need for increased awareness of the disease, which may lead to earlier treatment and reduced costs.

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# Supplementary PLS

- Published within an article's supplementary materials
- Peer reviewed as part of the article content as usual
- Infographic style
  - Mixture of formats: text, graphics, video, audio
- Can sometimes be added post-publication (separate peer review)

The image shows a screenshot of a research article page from the Journal of Comparative Effectiveness Research. The article title is "Ataluren delays loss of ambulation and respiratory decline in nonsense mutation Duchenne muscular dystrophy patients". The authors listed are Craig M McDonald, Francesco Muntoni, Vinay Penematsa, Joel Jang, Allan Kristensen, Francesco Bibbiani, Elizabeth Goodwin, Heather Gordish-Dressman, Lauren Morgenroth, Christian Werner, James Li, Richard Able, Panayiota Thrifillis & Mdr Tulinius. The article was published online on 18 Nov 2021. Below the article information, there is a section for "Supplemental Material" which includes links to a plain language summary (220 KB), supplementary figure 1 (184 KB), supplementary figure 2 (333 KB), and supplementary materials (266 KB). To the right of the supplemental materials is an infographic titled "Long-term effect of ataluren in patients with a specific type of genetic mutation leading to Duchenne muscular dystrophy". The infographic contains text explaining the disease, the drug ataluren, and the results of a study. It also includes a "Why was this analysis done?" section and a "Standard of Care (SoC)" section. The infographic is designed with a blue and orange color scheme and includes icons for a person, a pill, a wheelchair, and a document.

JOURNAL OF COMPARATIVE EFFECTIVENESS RESEARCH, VOL. 11, NO. 3 | RESEARCH ARTICLE Open Access

## Ataluren delays loss of ambulation and respiratory decline in nonsense mutation Duchenne muscular dystrophy patients

Craig M McDonald, Francesco Muntoni, Vinay Penematsa, Joel Jang, Allan Kristensen, Francesco Bibbiani, Elizabeth Goodwin, Heather Gordish-Dressman, Lauren Morgenroth, Christian Werner, James Li, Richard Able, Panayiota Thrifillis & Mdr Tulinius Study 019 investigators M Ryan, K Jones, N Goemans, C Campbell, ... See all authors

Published Online: 18 Nov 2021 | <https://doi.org/10.2217/ceer-2021-0196>

[View Article](#)

### Supplemental Material

[plain language summary.pdf](#) (220 KB)

[supplementary figure 1.pdf](#) (184 KB)

[supplementary figure 2.pdf](#) (333 KB)

[supplementary materials.docx](#) (266 KB)

### Long-term effect of ataluren in patients with a specific type of genetic mutation leading to Duchenne muscular dystrophy

The full title of this article: **Ataluren delays loss of ambulation and respiratory decline in nonsense mutation Duchenne muscular dystrophy patients**

How to pronounce:  
- Ataluren: /ɑːləˈlʊərən/  
- DMD: /diːmdeɪ/  
- Duchenne muscular dystrophy: /duː-ʃɛn ˈmjuːskl-ə-ˈdɪstrə-ˈfɪ-zi/

#### Why was this analysis done?

Duchenne muscular dystrophy (DMD) is a rare genetic disease that affects the muscles and mostly occurs in boys. It is progressive, which means it gets steadily worse over time. DMD is caused by changes in the DNA of the DMD gene. These changes are called mutations. The DMD gene contains the code for the act to make a protein called dystrophin. Dystrophin has an important role in protecting the muscle from progressive damage. Mutations in the DMD gene lead to less or no dystrophin being made, which results in muscle weakness. Over time, DMD causes increasing weakness in the leg, arm, lung and heart muscles. People with DMD have a short life expectancy, often living to 20-40 years old, even with current treatments available. Researchers and doctors are looking for better ways to treat DMD. There are treatments available, and ongoing research is teaching us more about them, especially regarding their long-term effects over several years.

This analysis included participants with a certain type of DMD, called nonsense mutation DMD (nmDMD). A nonsense mutation is a change in the DNA that causes the protein production to stop before it is completed. The resulting protein does not work properly. About 10-15% of children with DMD have a nonsense mutation in the DMD gene and are therefore referred to as having nmDMD.

**Standard of Care (SoC)** is the usual healthcare provided to patients with DMD according to the recommended guidelines. SoC for DMD includes the use of corticosteroids to treat the symptoms of muscle weakness.

**Ataluren** is a drug that is taken by mouth three times every day. It is designed to work by allowing the production of a complete functional dystrophin protein when a nonsense mutation is present in the DMD gene. This helps to protect muscle mass and extend muscle function specifically in patients with nmDMD.

**Loss of walking ability and worsening of lung function** are significant events in the progression of DMD and have a great effect on the lives of the patient and caregiver. Here, we measured the benefit of ataluren by assessing whether the drug could delay the onset of these events.

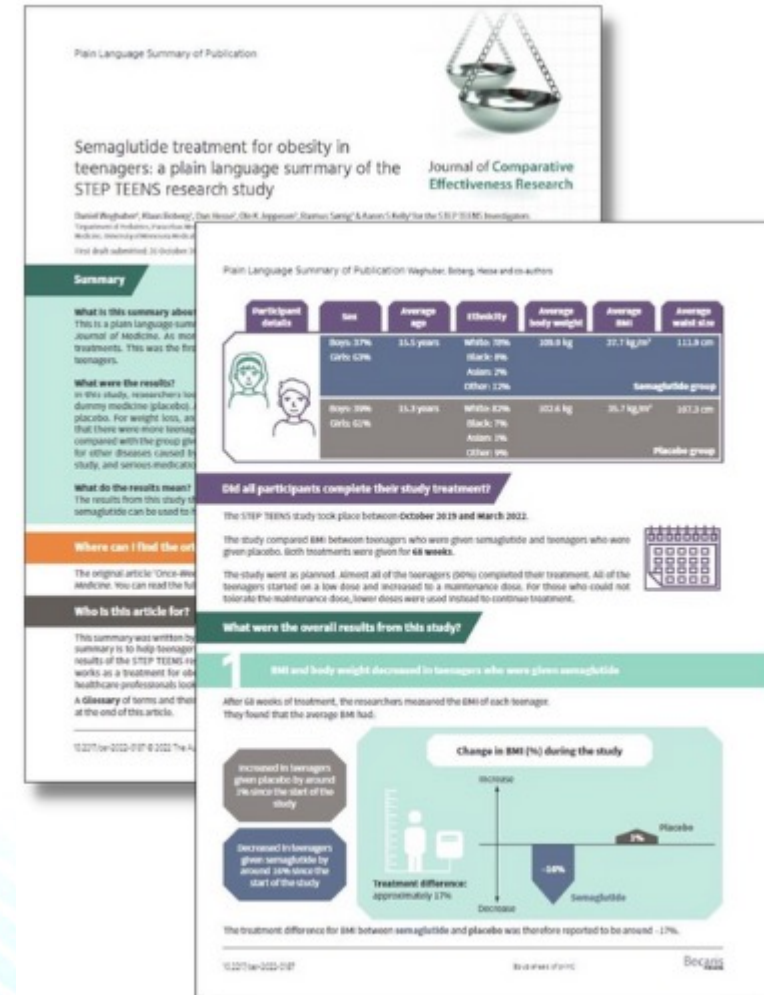
**Study 019** was a multinational clinical trial that included participants who had been treated with ataluren in previous trials and therefore had been taking ataluren for a long time. In Study 019, ataluren was given to participants in addition to SoC. Overall, 66 male patients with nmDMD participated in the study for up to 4.8 years, which took place at 21 clinical sites in 13 different countries.

The Cooperative International Neuromuscular Research Group Duchenne Natural History Study (CINRG DNDHS) collected health information on patients with DMD aged 2-26 years across nine countries between 2008 and 2016 to help understand the natural course of the disease.

\*Ataluren is indicated for the treatment of DMD resulting from a nonsense mutation in the DMD gene in ambulatory patients aged 7 years and older in the European Member States and certain other countries. Ataluren is not indicated for the treatment of DMD resulting from a deletion or a frameshift mutation in the DMD gene. Ataluren is not indicated for the treatment of DMD resulting from a nonsense mutation in the DMD gene in patients with respiratory or cardiac complications. The presence of a nonsense mutation in the DMD gene should be determined by genetic testing. Patients with respiratory or cardiac complications should be monitored closely. See the package insert for more information.

# PLS as standalone articles

- Standalone PLS articles, known as Plain Language Summary of Publication articles (PLSPs)
- Infographic style
  - Mixture of formats: text, graphics, video, audio
- Peer reviewed
  - Readability and accuracy
- Indexed
- Citable (have their own DOI)



# Other types of article feature



Graphical abstracts



Video abstracts



Podcasts



Infographics

# Q & A

The background is split into two main color sections: an orange section on the top left and a green section on the bottom right. The orange section features several thin, white, wavy lines that curve across it. The green section has a subtle, repeating pattern of small, light green circles.

# Thank you