

Industry Trends in EU CTIS Transparency Documentation

Sponsor experience in developing health literate
protocol and results plain language summaries

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Agenda



Health literate communication – Why It's Important



Process for authoring Plain Language Summaries (PLS)



Strategies for meeting regulatory requirements and incorporating health literacy in PLS

What is health literacy?

Personal Health Literacy

The degree to which individuals have the ability to find, understand, and use information and services to inform health-related decisions and actions for themselves and others.

Organizational Health Literacy

The degree to which organizations equitably enable individuals to find, understand, and use information and services to inform health-related decisions and actions for themselves and others.

The ability to make informed health decisions every day.

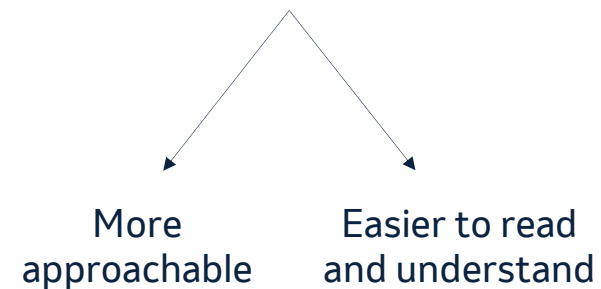




Why does clear communication of health information matter?

- Treats people with dignity
- Respects people, their beliefs, and their cultural practice
- Empowers people as leaders in the own care
- Helps people understand options for treatment so they can make informed decisions

Health literate design choices



Overview of PLS process



Author

Internal team of health literacy medical writers



Reviews & Approval

Lay person, Health Literacy, Non-Promotional Reviews

Clinical Team Review

Legal Review as needed

Final Review and Approval for Public Release



Translate & Upload

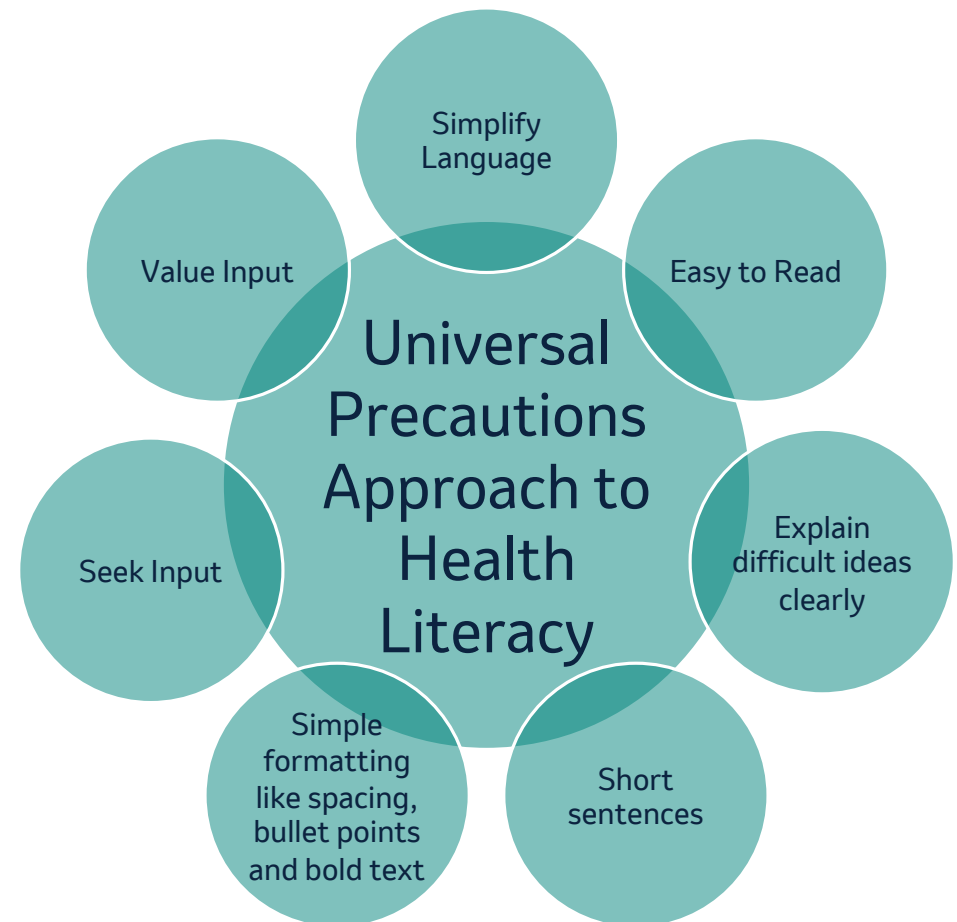
PLS translated into the local languages

Posted to CTIS and where required by regulation

Also available on [Trialsummaries.com](https://www.trialsandsummaries.com) with link on [ClinicalTrial.gov](https://www.clinicaltrials.gov)

How can we make health communication clear?

- Making health communication understandable and actionable is both an art and a science.
- It involves expertise in plain language, design, cultural awareness, and more



PLS communication strategies

Health literacy best practice in action



TEMPLATE DESIGN

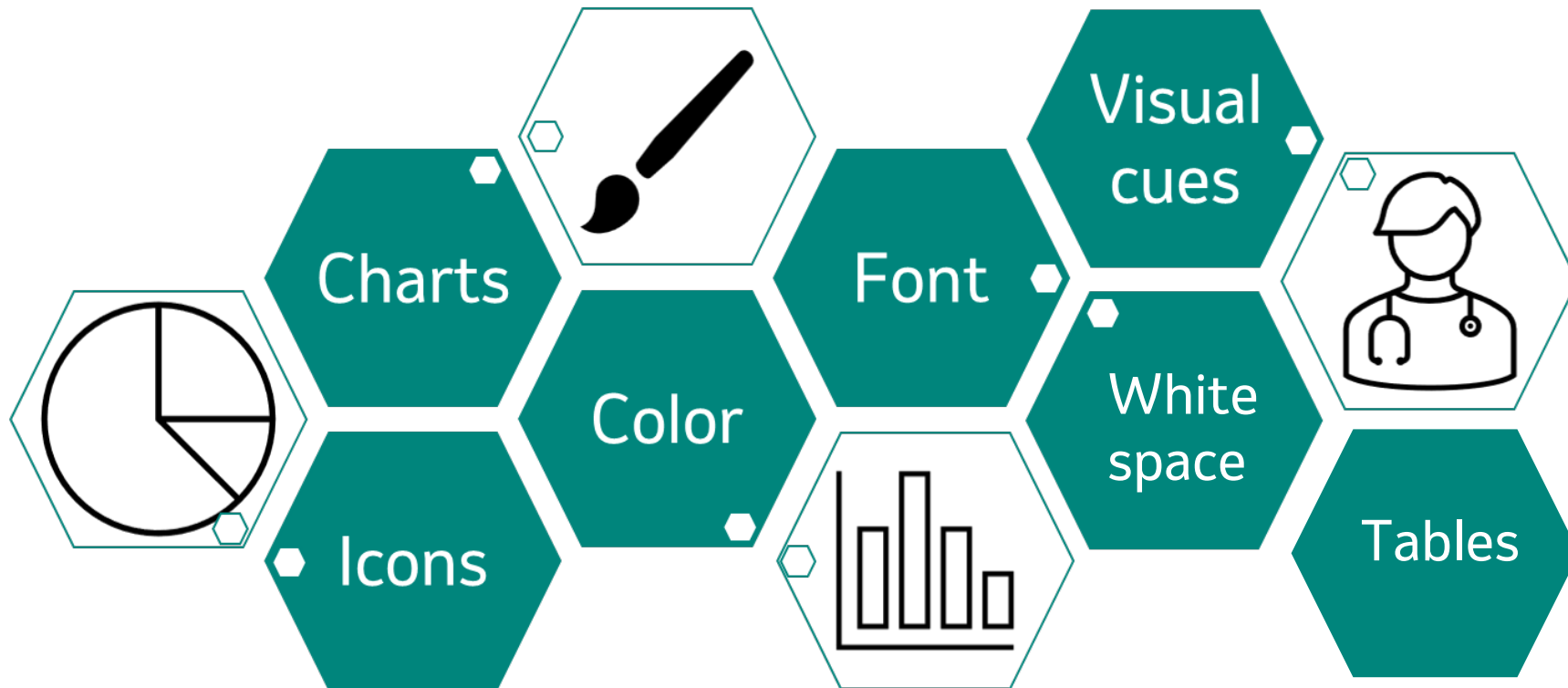


LAY PERSON REVIEW AND
PATIENT PANEL FEEDBACK



STANDARDIZED LANGUAGE

PLS Template Design: EU CTR requirements with health literacy best practice



Protocol PLS Template – 9 required elements

1. EU trial number and full trial title
2. Rationale
3. Objective
4. Primary trial endpoints
5. Secondary trial endpoints
6. Trial design
7. Trial population
8. Interventions
9. Ethical considerations

Confidential	Protocol Plain Language Summary	[Insert Condition]
A clinical study of Lorem ipsum dolor sit amet		
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Results PLS Template – 10 required elements

1. Clinical study identification
2. Name and contact of the sponsor
3. General information about the clinical study
4. Population of participants
5. Investigational medicinal products used
6. Description of adverse reactions
7. Overall results of the study
8. Comments on the outcome of the study
9. Indication if follow-up studies are planned
10. Indication where additional information can be found

Confidential

Summary of Clinical Study Results

A clinical study of Lorem ipsum dolor sit amet consectetur adipiscing elit

 What is a clinical study?

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 Why was this clinical study done?

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The main goals of this study were to learn:

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- Sed do eiusmod tempor incididunt

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Lay Person Review & Patient Panel Feedback



Lay Person Review

- Every PPLS and RPLS undergoes lay person feedback as part of the review process

Patient Advisory Panel

- Understand how patients interpret and understand a PLS
- ***“I think back to when I was diagnosed, and I wish I would have had this information”***

Cultural Competency Workshops

- Engagement of Internal Employees

Our Glossary now Public



Clinical Trials

About clinical trials ▼

Resources ▼

Our medical science

For



NORTH AMERICA

US

English

Español

OTHER COUNTRIES

Glossary of Terms

This glossary is provided to help users understand commonly used healthcare terms and definitions. It is provided for educational and informational purposes only. Terms often have more than one definition, and definitions listed here may be different from those used by healthcare professionals in specific contexts, including in clinical trials. This glossary does not replace your doctor's medical advice. Always talk to your doctor or other qualified healthcare provider about any medical concerns.

<https://www.merckclinicaltrials.com/glossary/>



Standard Language Library Benefits

1

- **Consistency**

- **Promotes Consistency Across Plain Language Summaries**

2

- **Time Savings**

- **Reduces Authoring and Review Time**

3

- **Accuracy**

- **Improves Accuracy by Utilizing Previous Approved Text**

4

- **Readability**

- **Improves Readability and Clarity**

5

- **Translation**

- **Reuse of Text Aids in Efficient Translation and May Reduce Translation Time**

Thank you & Questions

