

PP05 Plain Language Summaries, Patient Engagement, & the EU Clinical Trials Regulation: Meeting the Challenge

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Get to Know Plain Language Summaries

Plain Language Summary (PLS): A document that presents the aggregate results of a clinical trial to a common or lay audience

Guided by the Clinical Trials Regulation 536/2014: European Union

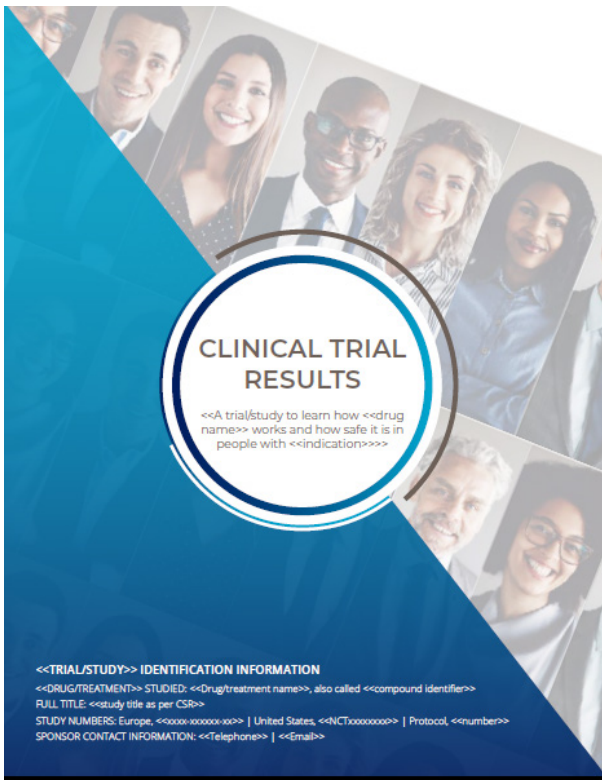
- Article 37 requires a **“summary that is understandable to a layperson”** within 1 year of study completion, within 6 months of study completion for Pediatric studies, and within 30 months of study completion for non-therapeutic Phase 1 studies in the local language of each EU country where the trial took place
- Guidance is expected to become regulation in **January 2022 (initially required new trials only)**
- Within 1 year, PLS required for all studies

Characteristics:

- Highly technical/scientific language from Clinical Study Report translated to Common/Plain language
- Audience: patients, caregivers, participants of study, and general public
- Written at a 6th to 8th grade reading level with attention to health literacy and numeracy
- Assumes audience has no previous knowledge of medical conditions, treatments, or conduct of study

Annex V of the EU Clinical Trials Regulation:

- Clinical trial identification
- Name and contact of Sponsor
- General information about the clinical trial
- Population of subjects
- Investigational medicinal product used
- Description of adverse reactions and their frequency
- Overall results of the clinical trial
- Comments on the outcome of the trial
- Indication if follow up clinical trials are foreseen
- Indication where additional information could be found



Meeting the Challenge: PLS Smart Template

Graphics created by authors; increased flexibility, use of glossaries

Patient Engagement: What & Why

- Patient engagement refers to any activity or tool used to engage people and get them involved in their own health care
- Increase patient/study participant trust in sponsors and the research process
- Bring patients from the “outside looking in” to active knowledge, input, and participation

It is the right thing to do for patient stakeholders

“As a result of the growing interest and willingness of patients to actively contribute to medicines development, more and more patients are interested in becoming involved in pharmaceutical industry-led medicines R&D across all functions throughout the medicines R&D lifecycle from pre-approval to post marketing activities.”

Warner K, et al. EUPATI Guidance for Patient Involvement in Medicines Research and Development (R&D); Guidance for Pharmaceutical Industry-Led Medicines R&D. Front Med (Lausanne). 2018 Oct 9;5:270. doi: 10.3389/fmed.2018.00270. PMID: 30356834; PMCID: PMC6190844.

“Public interest in medicines R&D was greater than public knowledge, which suggests that attempts to increase public knowledge will be welcomed.”

Parsons S, et al. BMJ Open 2015;5:e006420. doi:10.1136/bmjopen-2014-006420

Meeting the Challenge: Podium Electronic PLS Review System

- Podium:** Secure electronic platform for patient, caregiver, patient advocate, and clinician review of PLS at Draft 2
- Anonymous patients and caregiver reviewers supplied by patient advocate partner (Rare Patient Voice) who screens and **selects them based on the disease studied:** *Distinct advantage over repeated use of pre-set and re-used reviewer group. This is true patient engagement; reviewers have a vested interest in the disease studied.*

Plain Language Summary

- Audience: patients, caregivers, study participants, general public
- Assumes wide/public audience has no knowledge of medical conditions, treatments, or conduct of study

PODIUM

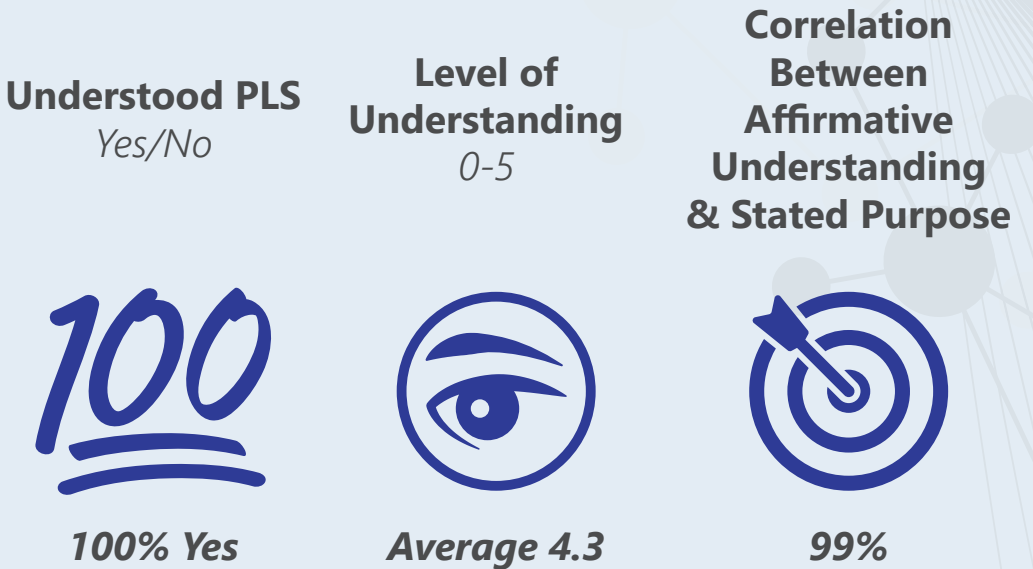
Patient Engagement

- Open, anonymous review of PLS
- Survey to assess content comprehension, promotional appearance, solicit suggestions

A survey was conducted to assess and validate reviewer comprehension:

Level of Reviewer Understanding of PLS from 105 Individual Reviews

- Automatic download and collation of comments & survey results
- Data shared with Sponsor, PLS edited based on reviewer input
- PLS certified as patient reviewed



“Patients want to learn everything they can about their health. Unfortunately, much of the available literature is so complex that is not usable for patients. Synchrogenix is working with Rare Patient Voice patients to incorporate their voices into clinical trial summaries. This is a wonderful way to ensure that important scientific data is available to patients in a clear and understandable format.”

- Pam Cusick, Vice President, Business Development, Rare Patient Voice

“I felt like everything was easy to understand and had the right amount of detail for readers to clearly understand without feeling overwhelmed.”

- Anonymous patient reviewer



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