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PLAIN LANGUAGE SUMMARIES CHECKLIST

A Plain Language Summary of Clinical Trial Results (PLS), is a critical tool in medical communication to help disseminate summarized, easy-to-digest research information to general audiences. This checklist will help guide your PLS development strategy and maximize team efficiencies to create a robust, long-term workflow that works for you and meets your timelines.

CHECKLIST

- 1 ☐ Start a Taskforce
- 2 ☐ Train Your Taskforce
- 3 ☐ Create a Template
- 4 ☐ Retrieve the Data
- 5 ☐ Have a Kick-Off Meeting
- 6 ☐ Make a Timeline
- 7 ☐ Write for Your Audience
- 8 ☐ Be Visual
- 9 ☐ Get It Reviewed
- 10 ☐ Repeat Steps as Needed
- 11 ☐ Do a Thorough QC
- 12 ☐ Localize Content
- 13 ☐ Distribute

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- [ ] **Start a Taskforce**

  Your taskforce should typically consist of nine team members, including a medical writer who is trained in data transparency and health literacy. We also recommend involving a medical program director, patent attorney, regulatory lead, statistician,patient and investigator engagement specialist, and marketing representative.

- [ ] **Train Your Taskforce**

  Build a training program that goes over relevant regulations, highlights, and requirements. The“do’s and do nots” are the most important elements. Remind the team to put themselves into the shoes of the general audience and consider their level of comprehension. Look for accuracy and factual content, and don't focus excessively on formatting or editing.

- [ ] **Create a Template**

  Create efficiency and cut down on editing time by developing a robust template. Involve a patient to provide feedback on the layout so changes can be made proactively. When developing this template specifically for launch in the EU, ensure it aligns with EU CTR Annex V requirements.

- [ ] **Retrieve the Data**

  Obtain and organize all relevant datapoints, including clinical study report (CSR) tables, figures and listings (TFLs), protocol, informed consent form (ICF), template, and any other relevant study material.

- [ ] **Have a Kick-Off Meeting**

  Select your first summary and connect with the taskforce. Have the medical writer produce an outline of what will be required in the lay summary and address any outstanding questions regarding safety, information presentation, etc. This enables the writer to get started with no delays.

- [ ] **Make a Timeline**

  Your timeline should consist of the following phases: authoring, client review, patient review, translation, graphic design, quality control, and dissemination. Following this timeline will become especially critical when the EU CTR enters into full enforcement.

- [ ] **Write for Your Audience**

  The average person has the health literacy of a US 8th grader (LPL 2-3 on IALS). In order to mitigate barriers to comprehension, develop a PLS that targets groups that may not have the same level of health literacy as medical professionals, scientists, or adults with high health literacy. Avoid any technical language, jargon, or complex concepts that could create confusion.

- [ ] **Be Visual**

  Strong visual components can aid comprehension, and complement information provided in your lay summaries. Ensure you include graphic design with each review cycle. This can consist of any infographics, population visualization, or non-promotional materials to make the plain language summary interesting and understandable to readers.

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☐ **Get It Reviewed**

Ensure your plain language summary is easily understood by incorporating patient review. This is encouraged as a means to assess readability and comprehension, catch any errors or complexities, and make any adjustments as required. This review cycle can typically take longer (approx. one hour per plain language summary).

☐ **Repeat Steps as Needed**

You might need to repeat multiple, or all of the above steps before proceeding to the QC and distribution phases. It may take multiple cycles to fully review the PLS. Once your team has repeated these steps, becoming familiar with each phase and eventually conducting several reviews, this process will be come more streamlined.

☐ **Do a Thorough QC**

This phase assesses and identifies errors/ inconsistencies or misalignment with the template. For this phase, we encourage the use of a separate medical writer, or QC-trained personnel to complete QC. Two to three approvers should then have a final look at the completed plain language summary. Select individuals who have not yet seen the summary and will be able to assess objectively.

☐ **Localize Content**

Localizing lay-language is crucial to ensuring universal comprehension depending on where your audiences are based. However, this can present several challenges, such as avoiding re-introducing complex language or terminology. To avoid confusion, incorporate back-translation certification per plain language summary, translating for cultural appropriateness while preserving ease of comprehension.

☐ **Distribute**

Select the appropriate platform and method based on your audience presence. Avenues for distribution can include print, online portals, video, etc. Consider and mitigate any obstacles to effective distribution. For example, printing can be seen as promotional, while some patients prefer to be mailed a hard copy of their plain language summary. Others might require specific accessibility parameters be met in order to understand the document.

While this checklist is not intended to be exhaustive, following this structure will help you build robust, efficient plain language summary development strategies.

For assistance with developing a custom plain language summary workflow that suits your teams, contact us today to discuss how TransPerfect Life Sciences can support.