Presenting secondary endpoints in plain language clinical trial result summaries: Considerations for emerging practice

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Abstract

Background: The European Union Clinical Trials Regulation 536/2014 (EU CTR) requires sponsors to submit summaries of clinical trial results in plain/lay language (Plain Language Trial Summaries [PLTS]). A multidisciplinary working group developed recommendations for defining, selecting, and summarising patient-relevant secondary endpoints in the PLTS.

Considerations: For sponsors who elect to include more than the primary endpoint, emerging practice is to include patient-relevant secondary endpoints, defined as those that were prespecified as secondary endpoints in the protocol, their analysis being described in the protocol or statistical analysis plan, and represent something of particular importance or value to patients. The summarisation of patient-relevant secondary endpoints should reflect the statistical rigour applied to the analysis. Patient-relevant secondary endpoints should be clearly distinguished from primary endpoints in the PLTS, and they should refer to information that exists in the public domain.

Conclusions: For sponsors who elect to include patient-relevant secondary endpoints in the PLTS, emerging practice is to apply a systematic approach for selection and summarisation so that meaningful information is provided to patients in a fair and balanced way.

Introduction

Research has shown that clinical trial participants want to know the results of trials in which they participated. This information recognises participants' contributions, can help them better understand the facts about the clinical trial in which they participated,[1–3] and may affect their willingness to participate in future trials.[4–6] While sponsors are required to post technical/scientific result summaries of completed trials on public registries (e.g., EU Clinical Trials Register, ClinicalTrials.gov),[7,8] the language and format used is not understandable to most trial participants.[9,10]

Article 37 of EU Clinical Trials Regulation 536/2014,[11] once in application, will require sponsors to submit summaries of clinical trial results "written in a manner that is understandable to laypersons" (herein referred to as Plain Language Trial Summary[ies], or PLTS). In their recommendations,[12] the EU Expert Group that convened to provide guidance on the design and writing of PLTS indicates the results section should describe the outcome of the trial, including "the primary endpoint(s) and results by trial arm which were prespecified by the statistical analysis plan (SAP) as a primary endpoint, and additional safety data important to the overall results of the trial" and "should reference the complete list of outcomes based on all endpoints available in the technical results summary for each clinical trial in the EU database including patient relevant secondary endpoints." In a Question & Answer (Q&A) document, the European Commission (EC) on Health and Food Safety Directorate-General indicates that the PLTS should include "the main objectives of the clinical trial and should therefore reflect at a minimum the primary endpoints, and patient-relevant secondary endpoints."[13] No definition of patient-relevant secondary endpoint is provided by either the Expert Group or the EC.

While the requirement to include the primary endpoint(s) is clear, the guidance for nonprimary endpoints is ambiguous, leaving trial sponsors to decide which, if any, nonprimary endpoints may be appropriate for inclusion in the PLTS and how to select them.

Methods

The multidisciplinary working group that developed these considerations met in the context of contributing to the European Forum for Good Clinical Practice (EFGCP) Good Lay Summary Practice Guidelines,[14] sponsored by the European Federation of Pharmaceutical Industries and Associations (EFPIA). In a series of meetings over 8 months in 2020 and 2021, the working group developed the criteria that sponsors can apply in identifying patient-relevant secondary endpoints and a framework for how to evaluate, select, and summarise these endpoints in the PLTS. This article is an independent publication by this working group and was not developed under the auspices of EFGCP or EFPIA. The following questions were explored:

(a) Should secondary endpoints be included in the PLTS?
(b) How can patient-relevant secondary endpoints be defined or determined?
(c) What are the considerations for selecting and including patient-relevant secondary endpoints in the PLTS?
(d) Should additional endpoints (e.g., tertiary, exploratory) be included in the PLTS?
(e) When and how should patient input be obtained?
(f) What are the considerations for summarising patient-relevant secondary endpoints in the PLTS?

Results

The working group proposes a framework, based on emerging practice, to systematically evaluate, select, and summarise patient-relevant secondary endpoints in PLTS, with the goal of producing a PLTS with fair, balanced, and relevant content.

Should secondary endpoints be included in the PLTS?

Considerations for deciding if more than the primary endpoint(s) may be disclosed in a PLTS include: whether the endpoint results have been publicly described elsewhere (e.g., trial documents on public registries), whether the endpoint represents something of particular importance or value to patients, and whether providing the additional information to patients creates the risk of the information being misinterpreted.

How can patient-relevant secondary endpoints be defined or determined?

We acknowledge that the term "patient relevant" cannot be defined in any narrow or strict sense. For the purposes of this article, patient-relevant secondary endpoints were defined as those that were prespecified as secondary endpoints in the protocol, had the statistical analysis described in the protocol or SAP, and represent something of particular importance or value to patients. Endpoints considered of interest to patients are those that reflect their experiences, perspectives, needs, and priorities related to symptoms of their condition and its natural history, the impact on their functioning and quality of life, or their experience with treatments.[15,16]

What are the considerations for selecting and including patient-relevant secondary endpoints in the PLTS?

A PLTS is meant to be a brief, clear, easy-to-read, and understandable summary of trial results for participants and the public. The addition of patient-relevant secondary endpoint results could potentially lead to misinterpretation or confusion of the results from the primary endpoint and cause the reader to give more weight than appropriate to the secondary results.[17] The importance of the secondary endpoints relative to the primary endpoint should not be overstated. In addition, the results should be meaningful to patients. Sponsors are encouraged to consider seeking input from patients, patient advocacy groups, and/or clinical team members. When including only a subset of patient-relevant secondary endpoints in the PLTS, the selection of endpoints should be undertaken and clearly documented prior to knowing the trial results. All endpoints included in the PLTS should be supported by data in the clinical study report (CSR) and described in technical/scientific results summary(ies) posted on public registries, such as ClinicalTrials.gov. To help address these points, emerging practice suggests a predefined, systematic approach for selecting and summarising patient-relevant secondary endpoints as outlined below.

> The importance of the secondary endpoints relative to the primary endpoint should not be overstated.

1. Only patient-relevant secondary endpoints should be summarised in the PLTS.
2. To reduce the appearance of selection bias, decisions about which patient-relevant secondary endpoints to include in the PLTS should be made and documented prior to database lock and before any knowledge of trial results,

including results of interim analyses. Results of posthoc analyses should not be included. Sponsors may consider identifying PLTS endpoints already at the time of protocol development.

3. Develop a PLTS endpoint selection process that can be consistently and transparently applied across trials and therapeutic areas.
4. While it is the sponsor's responsibility to determine final PLTS content, it is suggested that the decision about patient-relevant secondary PLTS endpoints be made with input from other patient-centric sources. Some suggestions for gathering input are listed:
   a. Patient feedback is the most direct method for gathering patient-relevant information. Patient feedback may be obtained through mechanisms available within the sponsor's institution, e.g., ongoing patient engagement activities, market research, or from other sources for investigating patient relevance.[18–22]
   b. Other reasonable alternatives that could supplement direct patient feedback are input from patient advocacy groups, carers, and health care providers.
   c. Input from clinical team members with experience in the disease area and direct involvement in protocol development and execution is another method.[23] Consider including at least one contributor with detailed knowledge of trial-specific statistics to advise on the summarisation of data. Clinical team input can be a valuable way of identifying secondary endpoints that are potentially patient relevant; this may be corroborated through patient-centric sources.

Should additional endpoints be included in the PLTS?

Due to their inherent exploratory nature, emerging practice is not to include tertiary or exploratory endpoints or secondary endpoints that are not considered as patient relevant in the PLTS. Doing so may result in misinterpretation and potentially confuse readers without providing valuable information. In situations where such endpoints are considered important to patients, in lieu of providing results, the sponsor may acknowledge that the endpoints were assessed and comment on next steps or indicate where additional information may be found.

When and how should patient input be obtained?

Direct patient input may be obtained in a number of ways throughout the clinical development process, including, but not limited to the following three different stages:

1. initial creation of research objectives,
2. defining protocol endpoints and their hierarchy for a clinical trial, and
3. selecting patient-relevant secondary endpoints for the PLTS. For the purpose of this article, we focus on Stage 3. Additional information on patient engagement can be found elsewhere.[24–27]

The selection of patient-relevant secondary PLTS endpoints can be done using qualitative and quantitative preference research methods.[28,29] Patients selected to provide input are usually not participants in the trial of interest but should be familiar with the concept of study endpoints and be able to suggest how to describe them in plain

language. To provide the appropriate context, the primary and all secondary study endpoints should be presented to patients to clarify the trial objectives and define expectations for patients' contributions, including that other criteria will be applied to determine final endpoint selection for the PLTS.

For each patient-relevant preference exercise, a list of endpoints and their attributes should be developed. Attributes are features, such as efficacy, safety, duration of effect, duration of use, lifestyle aspects, and other benefit-risk considerations that the endpoints are designed to assess. The endpoints can then be presented to patients for ranking in terms of preference. This will demonstrate their preference for one endpoint relative to the other endpoints.

What are the considerations for summarising patient-relevant secondary endpoints in the PLTS?

All information in the PLTS, including patient-relevant secondary endpoints should be summarised using plain language that is simple, clear, fair, balanced, and non-technical without diluting or changing the meaning or importance of the data. Health literacy and numeracy principles should be followed.[30–32] Further guidance for summarising trial data in lay language may be found at the Multi-Regional Clinical Trials Center[32] and in the TransCelerate Recommendations.[33] In general, consider how meaningful numerical data may be to patients (e.g., number of hospitalisations, number of blood transfusions, survival in months) versus something more abstract (e.g., decimal changes in a clinical index) for which absolute changes may be less meaningful without a lengthy explanation or training in the scientific discipline.

Emerging practice for summarising and presenting patient-relevant secondary endpoints in PLTS involves several important considerations that are outlined below.

Maintain the appropriate context with respect to the primary endpoint(s): Patient-relevant secondary endpoints should be clearly separated and distinguished from the primary endpoint(s) in the PLTS. One way to do this is to place the results for primary endpoint(s) and patient-relevant secondary endpoint(s) in separate sections and name them differently (e.g., "main aim of the trial" versus "other trial results"). Use of visual icons may also help draw readers' attention to the important or main messages (primary endpoint) of the PLTS. Language should be provided that indicates the patient-relevant secondary endpoints were not the main focus of the trial.

Consider how patient-relevant secondary endpoints may have been described in other publicly disclosed trial-related technical/scientific results summaries or patient communications: The summary of patient-relevant secondary endpoints in the PLTS should be consistent with other information that has been publicly disclosed (e.g., trial-related documents posted on public registries, scientific publications, etc.). Although presenting information the same way in all cases may not be possible, the suggestion is to convey information in the PLTS that is consistent with information that has been presented in other trial related patient and public communications.

> All information in the PLTS should be summarised in a fair, balanced, and non-technical way.

Maintain statistical rigour with which the endpoint was analysed and include appropriate level of detail: Tailor the summary of results to the data that are available, the statistical rigour applied to the analysis, and how valuable the numerical results might be to a patient. This can range from simply describing the endpoint with no mention of results to a presentation of numerical results with figures, tables, and graphs. Figure 1 shows an algorithm for deciding how results in a PLTS may be summarised.

When results of non-statistically powered patient-relevant secondary endpoints are presented, these should be accompanied by a clear explanation that the results are preliminary, non-confirmatory, may reflect chance findings, and that no conclusions can be drawn from them (adjust the statement to fit the data). To reduce the risk of readers overlooking these types of disclaimer statements, emerging practice suggests keeping them concise and limiting their use throughout the document. Finally, consider including a statement (and corresponding link) indicating where further information about the endpoint can be found (e.g., link to technical/scientific results summaries on public registries or scientific publications).

Table 1 lays out possible approaches for summarising patient-relevant secondary endpoints in the PLTS and is meant as a guide to help sponsors think through the most appropriate way to describe the data. The examples shown are for illustrative purposes only. The approaches are classified into tiers, ranging from a presentation of numerical results with health-literate graphics (Tier 1, Quantitative Summary) to merely a description of the endpoints with no mention of results (Tier 4, Aggregate Description). The Tiers are not absolute, and there may be more than one way to represent the same data. In all cases, the text in the PLTS should reflect the statistical rigour applied to the analysis and the data and conclusions in the CSR. Avoid using comparative statements (e.g., stating that results in one group were better/worse than in another group).[33] This is particularly important in cases where no numerical results are presented.

Discussion

As noted in the introduction of this article, there is a lack of clarity in guidance between the Expert Group on Clinical Trials and the EU Q&A. Although the recommendation in the Expert

Table 1. Approaches for summarising patient-relevant secondary endpoints in plain language trial summaries

	Levels of Summarisation	
	Tier 1 – Quantitative	**Tier 2 – Semi-quantitative**
Secondary endpoint attribute	• Statistically powered endpoint predefined to confirm a hypothesis or one that was considered in determining sample size of the study.	• Endpoint was not statistically powered to confirm a hypothesis but was statistically analysed to investigate differences (e.g. between groups or from baseline).
Results available	• Statistical results (e.g. p values, 95% CI) provided. • Conclusions can be drawn from the data due to statistical rigour applied to the analysis.	• Statistical results may have been provided. However, conclusions should not be drawn from the data as the study was not designed for this.
Considerations for summarising results	• Consider presenting numerical results (e.g. average, range) including figures, tables, or graphs that meet health literacy principles. • Comparative statements (e.g. more patients had an outcome in one group versus another) may be included if supported by the results and statistical rigour of the analysis (e.g. p value; 95% CI).	• Consider presenting numerical results, but avoid graphical displays (figures, tables, graphs) that could be read in isolation and misinterpreted without appropriate context. • Avoid statements that suggest a conclusive finding.
Examples of endpoint summaries by tier for hypothetical study endpoints		
	Tier 1 – Quantitative	**Tier 2 – Semi-quantitative**
Pain score defined as a reduction from baseline in pain of ≥50% at Week X Plasma concentrations of Treatments A and B	• "At Week X, more patients taking Treatment A (50 of 100 patients, 50%) had a lower pain score than patients taking Treatment B (35 of 100 patients, 35%)." *[Note: statistical rigour allows making a **comparison** between groups, supported by the data.]*	• "At Week X, 50 of 100 patients (50%) taking Treatment A and 35 of 100 patients (35%) taking Treatment B had lower pain scores." **Sample disclaimers:** In the case where results (e.g. p value/CI) suggest a potential difference: • "The results suggest there could be a difference between the 2 groups. Researchers cannot be certain whether the difference between the 2 groups was due to chance or due to the treatment. These results should be confirmed in another study." In the case where the results (e.g. a, p value/ CI) suggest no potential difference: • "The results suggest there may be no difference between the 2 groups. These results should be confirmed in another study." *[Note: **numerical** results are presented, but **no comparison** is made between group – the study was not powered to confirm this – and a **disclaimer** is added about the limitations of the study.]*

Notes: In all cases, text presented in the PLTS should be consistent with the data and conclusions in the clinical study report (CSR).

Endpoints in the results section should have been previously explained/defined, in plain language

Table 1 (continued)

Tier 3 – Qualitative	Tier 4 – Aggregate Description
• Endpoint was not statistically powered or analysed. • For example, secondary endpoints may have been evaluated to assess their potential use as outcome measures in future studies, or they may represent procedures that were particularly burdensome for patients (hence, they are included in PLTS for the patients' benefit).	• Endpoints for which results would not be considered meaningful to patients. For example, PK parameters, disease scores.
• Summary results may have been provided, although, the data may be considered difficult for patients to understand without a lengthy explanation.	• Statistical or descriptive statistics may have been provided, and the data may or may not be considered conclusive (based on statistical rigor applied). • Data are likely not understandable to patients without training in the scientific discipline.
• Do not present any results in any format (textual, numerical, or graphical). • Qualitatively describe the endpoint and indicate why it was measured, and if applicable, what information was learned from it.	• Do not present any results in any format. • Acknowledge (in aggregate) that other patient-relevant secondary endpoints were evaluated (i.e. rather than listing/describing each one separately), briefly describe how the data were used (in aggregate).

Tier 3 – Qualitative	Tier 4 – Aggregate Description
• "At Week X, both groups had lower pain scores." **Sample disclaimers:** • "This study was not designed to provide firm evidence of an effect on pain." • "This study was not designed to confirm if there was a true difference in pain reduction between patients receiving Treatment A or Treatment B. These results should be confirmed in another study." • Instead of summarising the results, another option could be to indicate why the endpoint was assessed and what information may have been gained: • "The researchers learned that measuring pain may be useful for studying drugs to treat X disease. These results should be confirmed in another study." *[Note: **no numerical results** are presented, but rather, a **textual description** of what was observed in each treatment arm/information learned is given along with a **disclaimer** about the limitations of the study.]*	• Researchers also measured the level of drug in patients' blood. Further details can be found at (source)." *[Note: this acknowledges that PK endpoints were assessed but gives **no results**. A statement indicating where **additional information** can be found is included.]*

Abbreviations: CI=confidence interval; PK=pharmacokinetic; PLTS=plain language trial summary

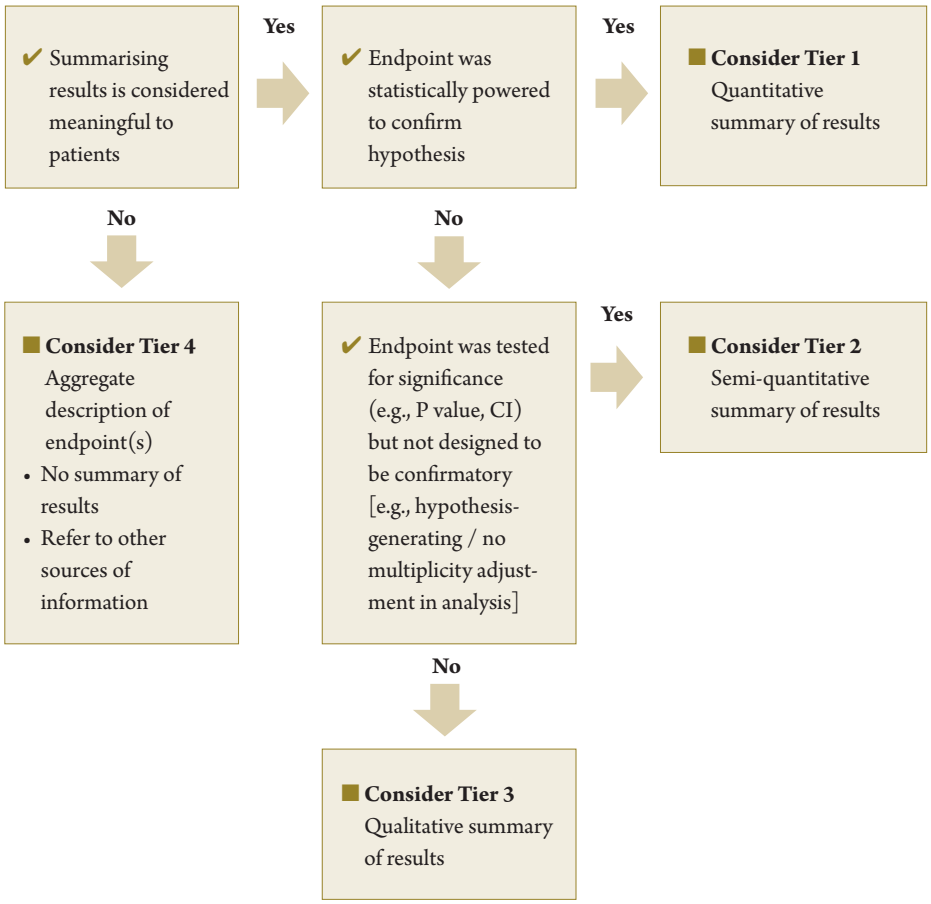


Figure 1. Algorithm for summarising patient-relevant secondary endpoints in plain language trial summaries

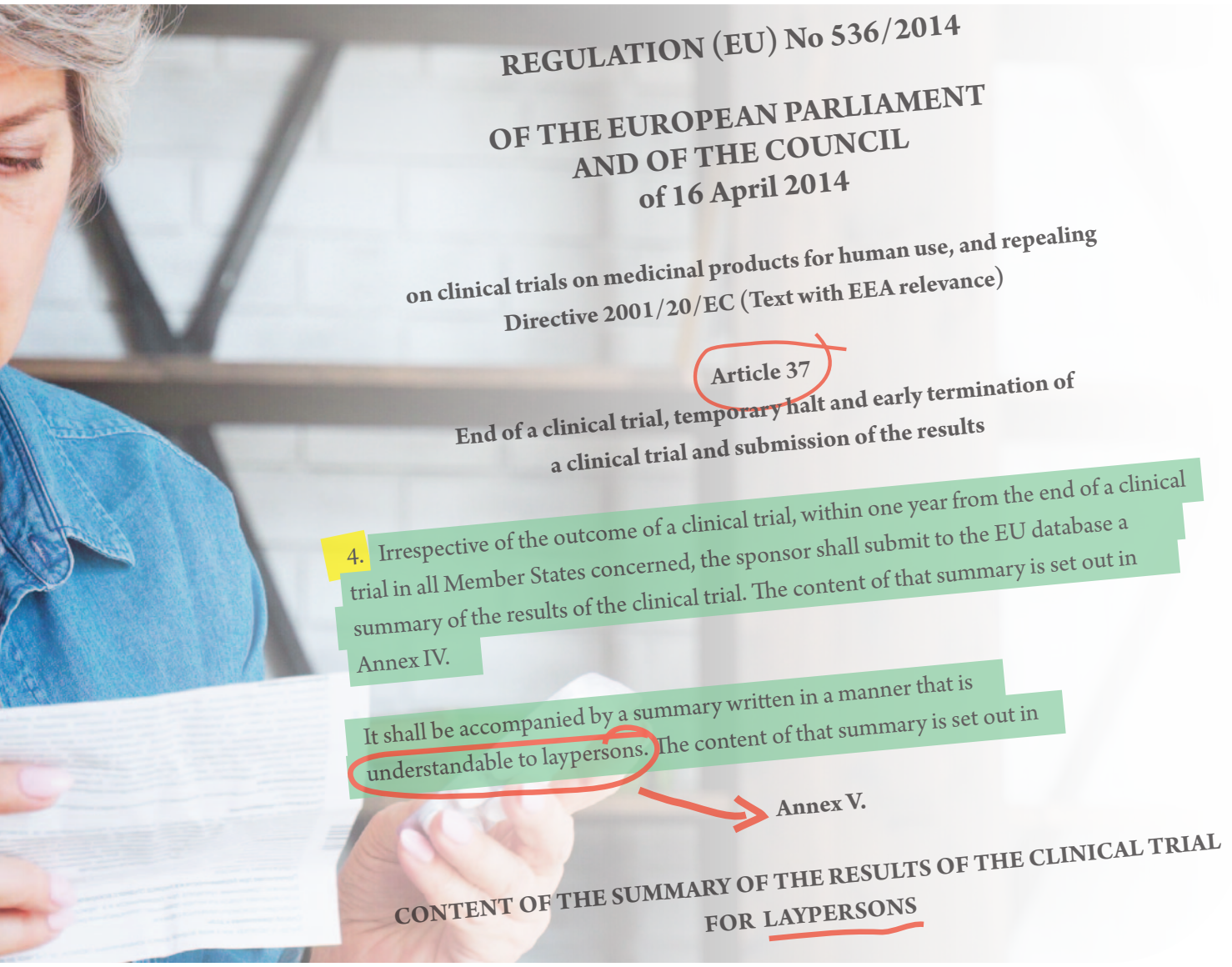
Group on Clinical Trials is to include only primary endpoint results in the PLTS, trial participants may want to know more. While some sponsors will include only results of the primary endpoint in the PLTS, others may elect to also include secondary endpoints. Including more than primary endpoint in the PLTS, or a subset of secondary endpoints, presents the challenge of conveying the additional information concisely in a non-biased, fair and balanced way that patients can easily understand. The working group did not seek to resolve these issues, but rather, to acknowledge they exist and offer considerations for addressing them, based on emerging practice. It is each sponsor's responsibility to interpret and apply the regulatory guidance and determine which endpoints will be included in PLTS and how they will be presented.

Sponsors should predefine a systematic, transparent approach toward the selection of endpoints in PLTS that can be applied across all clinical trials within their organisation.

The working group's recommendation for sponsors who elect to include more than primary endpoint results in the PLTS is to select only patient-relevant secondary endpoints that have been otherwise publicly disclosed. The working group members acknowledge the process of selecting a subset of patient-relevant endpoints is subjective even with patient input. Therefore, to reduce the risk of perceived bias, sponsors should predefine a systematic, transparent approach toward the selection of endpoints in PLTS that can be applied across clinical trials within their organisation and select and document endpoint selection prior to knowing the study results. Results of patient-relevant secondary endpoints should be clearly distinguished from the primary endpoint results in the PLTS and presented in the appropriate context based upon the level of rigour applied to the statistical analysis.

Conclusion

There are important considerations for determining whether to include more than primary endpoints in a PLTS. For sponsors who elect to include patient-relevant secondary endpoints in PLTS, emerging practice is to apply a systematic approach toward the selection and summarisation of patient-relevant secondary endpoints in order to consistently produce PLTS that are meaningful to patients with fair, clear, and



balanced content. It is recognised that adjustments to the considerations described in this paper may be needed if the guidance is clarified and/or new instructions are provided on how sponsors could include patient-relevant secondary endpoints.

Acknowledgements

The authors acknowledge the contribution of the following working group participants: Betash Bahador, Center for Information and Study on Clinical Research Participation (CISCRP); Florence Barbéry, Servier; Silvia Garcia, European Federation of Pharmaceutical Industries and Associations (EFPIA); Kelly McQuarrie, Janssen Research & Development; Catina O'Leary, Health Literacy Media.

Disclaimers

The views and opinions expressed herein are those of the individual contributors and should not be attributed to any organisation or institution with which the contributors are employed or affiliated, or to EMWA.

Conflicts of interest

The authors declare no conflicts of interest.

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