RECOMMENDATIONS FOR DRAFTING NON-PROMOTIONAL LAY SUMMARIES OF CLINICAL TRIAL RESULTS
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TransCelerate Background

TransCelerate BioPharma Inc. is a non-profit organization dedicated to improving the health of people around the world by accelerating and simplifying the research and development (R&D) of innovative new therapies. The organization’s mission is to collaborate across the global R&D community to identify, prioritize, design and facilitate implementation of solutions designed to drive the efficient, effective and high quality delivery of medicines. The biopharmaceutical members of TransCelerate are committed to enhancing public health and medical and scientific knowledge through the sharing and transparency of clinical trial information.

Background

A lay summary (plain language summary) of a single clinical trial is written to be understandable to the general public and may be posted to public websites and/or provided to trial participants after the trial has concluded. The European Medicines Agency (EMA) intends to post these summaries to the European Union (EU) database according to the EU Clinical Trial Regulation (EU Regulation) where the public may view the summaries.\(^1\) At this time, there are no regulatory requirements for lay summaries to be posted outside of the EU nor are there regulatory requirements world-wide for disseminating lay summaries more directly to clinical trial participants. However, sponsors may decide at their discretion to provide them to clinical trial participants.

These recommendations are intended to provide general principles to help sponsors prepare lay summaries in a manner that reduces the risk that the summaries could be perceived as promotional, which would raise regulatory concerns. Adjustments may need to be made for local laws and regulations and any sponsor-specific policies and processes.
Current Issue

There is a potential risk that lay summaries may be perceived as promotional or misleading despite the efforts and intentions of sponsors. This is because a lay summary:

» Describes results of a single trial whereas benefit-risk assessments of a medicine most often require multiple studies, thus, a lay summary could potentially be misinterpreted as providing definitive risk benefit information for the medicine.

» May include a description of the use of an investigational drug or new use for an approved medicine which is not yet approved for that use by regulatory agencies.

» Uses simple or plain language to help understanding by a wide audience. Such simple or plain language can be less precise and, therefore, there is a risk that the simplified wording may be perceived as misleading.

» Presents a concise high level overview of a clinical trial thus, there is a risk that the lay summary could be perceived as misleading by selectively presenting the results.

Several criteria can impact whether language is deemed promotional, including the context in which the language is used, and the nature of the audience to whom the communication is directed.
Recommendations for Using Non-Promotional Language for Lay Summaries

» The overall tone and content should be factual and objective.

» Care should be taken that comments on the outcome of the clinical trial are factual in nature and do not make inferences or assessments. The Neutral Language Guidance section of the MRCT Return of Results Toolkit provides examples of recommended language.²

» Materials should not have a commercial or marketing appearance related to the investigational medicine (e.g., do not use brand colors, brand logos or imagery; however the same concern may not apply to sponsor logos or colors).

» Information should be accurate and not misleading in any way.

» Materials should be fair and balanced (i.e., include information on the efficacy and the safety data from the trial). Materials should also be fair and balanced in terms of formatting (e.g., appropriate detail and prominence of the safety data).

» Care should be taken to ensure that the lay summary is made available in a non-promotional context (e.g. where posted to a sponsor’s website, there should not be links from webpages that are promotional).

» A statement should be added that further information on the trial can be found on ClinicalTrials.gov & the EU Clinical Trial Register so that additional information is readily available.

» A statement should be included stating that results are from a single trial and new information or different results may be obtained from other studies.

» A statement should be included that therapeutic changes should not be made based on the results of a single trial without consulting a healthcare professional.

» Approval status should not be provided in the lay summary. Specific indications and countries where approved should not be provided as indications may vary in different countries which could lead to a promotional concern if stated too broadly.

» If an organization elects to provide translations they should be cautious to ensure that the translated text doesn’t contain promotional language.

» Superlative and enthusiastic words should be avoided (e.g. the most, the best, extraordinary, unsurpassed) as they could lead to a determination that a communication is promotional.
References


2. MRCT Return of Results Toolkit: http://mrctcenter.org/file/524691


4. 21 CFR 202.1 – Accessed on October 23, 2015 and link found here: http://www.ecfr.gov/cgi-bin/text-idx?SID=b7c2389ef5e48e5ac0dcd2769a576cf7&mc=true&node=se21.4.202_11&rgn=div8

5. 21 CFR 201.1 – Accessed on October 30, 2015 and link found here: http://www.ecfr.gov/cgi-bin/text-idx?SID=7e55af2686b6a27397e373a2be8450&mc=true&node=pt21.4.201&rgn=div5

Appendix 1: Learnings from the Promotional Context

There are learnings from communications disseminated within a promotional context that can also help guide us in being non-promotional while providing lay summaries of trial results.

“Promotion” refers to all informational and persuasive activities by manufacturers and distributors, the effect of which is to induce the prescription, supply, purchase, and/or use of medicinal drugs. In other words, the concept of “promotion” may encompass any activity undertaken, organized, or sponsored by the organization which aims to promote the prescription, recommendation, supply, administration, or consumption of the organization’s products through all media, including the internet.

Commercial promotional guidance:

» **Advertising/Advertisement:** Prescription drug advertisements are defined as promotional materials that appear in space purchased by the manufacturer, packager, or distributor. This space may be in print or audio-visual media.

» **Labeling:** Labeling is defined as all labels and other written, printed or graphic matter on the immediate drug container or accompanying the container. FDA interprets this term broadly to include printed, audio, or visual matter descriptive of the drug and containing drug information disseminated by, or on behalf of, the manufacturer.

What does it mean for the summary to **not** be false or misleading or lacking in fair balance?

The Office of Prescription Drug Promotion (OPDP) provide guidance on what is considered promotional, and although not directly applicable to return of results to subjects, it aligns with the spirit of the principles provided in this document by providing clarity on what is promotional and therefore, what may be non-promotional. Similar guidance is provided in the EU Directive 2001/83/EC.

In the promotional context, an advertisement for a prescription drug is false, lacking in fair balance, or otherwise misleading, or otherwise violative of section 502(n) of the act, among other reasons, if it:

» Contains a representation or suggestion, not approved or permitted for use in the labeling, that a drug is better, more effective, useful in a broader range of conditions or patients, safer, has fewer, or less incidence of, or less serious side effects or contraindications than has been demonstrated.

» Contains a drug comparison that represents or suggests that a drug is safer or more effective than another drug however, in a comparator trial the results should be factually stated without inferring the conclusion that a drug is safer or more effective.