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29 Lay Summaries of Clinical Study Results

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Introduction

This chapter defines lay summaries for clinical study results, how they came about, their regulatory basis, their content, open questions, and new developments. The chapter summarizes current guidance as well as regulatory differences between the EU and the US. Lay summaries for children are discussed, as are ongoing workstreams to enhance available guidance.

Defining Lay Summaries

A number of terms have been used to describe the same entity: a short document summarizing clinical trial results in a way as to be understandable to the lay public. Various organizations have used different terms, and there appears to be a transatlantic divide in vocabulary.

A lay summary is a short summary of clinical study results using plain language to inform the public. It usually spans some five to 10 pages and describes a clinical study's key features, including the study objective, rationale, demographics, efficacy, and safety results. Generally, a lay summary also provides links to further information.

In the early days of lay summary discussions, a Multi-Regional Clinical Trial (MRCT) working group used the term "research results summary" (RRS),[1] while a TransCelerate working group used "layperson summary" as equivalent to "plain language summary."[2] In the 2014 *European Clinical Trial Regulation* (*EU CTR*), the terms "layperson summary" and "lay summary" are used.[3] Therefore, the European expert group convened to provide guidance and advice on lay summaries' content and writing used the same terms.[4] However, particularly in the US, some object to using the word "lay," as they feel it has a derogatory connotation. Terms such as "plain language trial summaries" (PLTS) and "patient summaries" (PS) are suggested and used as alternatives. The use of the appropriate terminology is complicated by using the same terms in the setting of biomedical publishing.

In fact, a few years before any discussion of clinical trial summaries for the public began, during the advent of the open access movement in scientific publishing, the term "lay summary" was used to describe "a summary of the research alongside articles specifically aimed at the non-expert or lay reader."[5,6] Subsequently, stakeholders often referred to this format as a "Plain Language Summary" (PLS); for example, the *British Journal of Dermatology* one of the first journals to adopt this feature in 2014.[7] The Cochrane Collaboration also has made a PLS a standard element in the reporting of systematic reviews.[8] Currently, an international working group initiated by the Patient Focused Medicine Development (PFMD) collaboration is preparing a guide for creating a PLS, understood as a summary of a research article in easy-to-read language. Thus, the terms "PLS" or "plain language

summary" are being firmly established to describe summaries of research articles in scientific journals.

This chapter discusses "lay summaries," as specified in the *EU CTR* and in the recommendations of the European Expert Group. "Lay summary" is used to refer to a document that describes a clinical trial, its results, and is written in such a way as to be understandable to the public. The use of the term "lay summary" is meant to clearly distinguish this document from a PLS.

Regulatory Background of Lay Summaries in the EU

Lay summaries were introduced as a regulatory requirement by the *EU CTR* 536/2014. For the first time in regulatory history, a law in a major jurisdiction stipulated that sponsors must prepare a document describing the results of a clinical trial in an understandable way to the non-expert, layperson, and the public.

The requirement to provide both a scientific summary and a lay summary is expressed in §37 of the *EU CTR*. The lay summary, together with the scientific summary, the study protocol, and the study report, is to be made available via a public website per §67 of the *EU CTR*. The requirement applies to all clinical trials of all clinical phases "irrespective of the outcome."

The website is to be hosted by the European Medicines Agency (EMA) and is part of the Clinical Trial Information System (CTIS).[9] The CTIS was initially expected to go live in 2016, but its development was substantially delayed, and its launch is now planned for December of 2021.[10] The scientific summary, whose content requirements are specified in Annex IV of the *EU CTR*, and the lay summary must be made available within 12 months after the end of the clinical study, defined as the last patient's last visit (*EU CTR* §2, 26).

Returning Results to Participants

Unlike the EU, the US has no legal framework for providing the public with easy-to-read summaries of clinical studies. One salient explanation for this is that information on the level of an individual study is likely to fall outside of the specifications of the *Federal Food, Drug, and Cosmetic Act* (*FD&C Act*) and 21 CFR Part 202 that regulate prescription drug advertising. Essentially, any information provided about a medicinal product needs to be within the product label, and benefits and risks must be presented in a fair and balanced way. However, clinical trials are usually performed in indications that are not yet approved, and a single trial cannot provide a basis for a comprehensive benefit-risk assessment. Hence, the discussion in the US initially centered on how to best inform study participants about the results of the study in which they have participated rather than on informing the public about the results of trials of investigational products.

Returning results to participants is supported by several studies and reviews[11,12] showing that study participants are only very rarely informed about the study results in which they participated. The wish of study participants to be informed also was acknowledged by FDA. In 2014, in the context of a draft guideline on the informed consent process, FDA expressed interest in the topic: [The] "FDA recognizes that subjects are frequently interested in the aggregate results of the clinical investigation in which they were enrolled. Aggregate research results should be returned to subjects in a clear and comprehensible manner."[13]

Content of Lay Summaries Under the EU CTR

The *EU CTR* provides very limited guidance on the content of lay summaries. The requirements are specified in Annex V (**Table 29-1**). No explanatory information or instructions have been provided.

Recommendations of the European Expert Group

For such an innovative document as the lay summary, the *EU CTR* does not provide sufficient guidance for a compliant implementation.[14,15] Many stakeholders, including sponsors of clinical studies and patient organizations, voiced their concerns and highlighted the need for more comprehensive guidance. Therefore, soon after the publication of the *EU CTR*, the Health Research Authority, a part of the National Health Service in the UK, was asked in 2015 to coordinate the development of further guidance on lay summaries. A large international stakeholder group was formed to develop detailed recommendations on structure and content of lay summaries. The

Table 29-1. Content of Lay Summaries According to Annex V of EU CTR

1	Clinical trial identification, including title of the trial, protocol number, EU trial number, and other identifiers
2	Name and contact details of the sponsor
3	General information about the clinical trial, including where and when the trial was conducted, the main objectives of the trial, and an explanation of the reasons for conducting it
4	Population of subjects, including information on the number of subjects included in the trial in the Member State concerned, in the Union and in third countries; age group breakdown and gender breakdown; inclusion and exclusion criteria
5	Investigational medicinal products used
6	Description of adverse reactions and their frequency
7	Overall results of the clinical trial
8	Comments on the outcome of the clinical trial
9	Indication if follow up clinical trials are foreseen
10	Indication where additional information could be found

efforts to reach a consensus included a global public consultation of a draft in the summer of 2016. A draft version of the recommendations was issued in 2016, the first version was issued in 2017, and a final version became available as the "Recommendations of the Expert Group" in February 2018 (hereafter "expert recommendations").[16]

The recommendations of the European expert group represent the consensus of a large and diverse international stakeholder group but do not have any specific legal status. Nevertheless, the European Commission signified its support by posting the expert recommendations on their website. The European expert group utilized the work done by a multi-stakeholder working group convened by the MRCT (see below). An extensive exchange between these two working groups resulted in the alignment of key recommendations despite each group having a different focus.

The expert recommendations consist of a set of general principles and two annexes, providing detailed guidance and clarifications on many aspects of writing and design of lay summaries. Very importantly, the expert recommendations state that the primary audience of lay summaries is the public. Consequently, lay summaries need to be understandable to people without specific knowledge about the disease, the indication, or the clinical research process. The notion that lay summaries must be understandable to people with low literacy skills influences all aspects of the expert recommendations, particularly the sections on writing style, language, and use of numerical data (numeracy).

Lay summaries must be strictly non-promotional. This central concept is emphasized in various chapters of the expert recommendations. If sponsors were to render lay summaries into promotional material, the value of objectively informing the public about trial results would be lost.

The expert recommendations modify and clarify the requirements provided in Annex V of the *EU CTR*. The content requirements are maintained and expanded, important clarifications are provided, and some new elements are introduced (**Table 29-2**). For example, in the "study name" section, sponsors also are asked to include a short abstract that summarizes the entire content of the lay summary. To ease access to the information provided in lay summaries, the requirements of Annex V are partially rephrased as questions, a common approach for making content more accessible to readers.

As the expert recommendations operate within the EU's legal context, some topics are not mentioned, e.g., the dissemination of lay summaries outside of the CTIS. Also, the question as to whether lay summaries may need Ethics Committee (EC) approval in jurisdictions outside of the EU is not addressed.

The MRCT Return of Results Guidance Document

In 2014, the MRCT initiated a multi-stakeholder workgroup to develop guidance for what they called

Table 29-2. Summary of the European Expert Group Recommendations for Structuring a Lay Summary

No.	Topic	Suggested Content
1	Study name	Clinical phase; disclaimer that this is just one study; include lay title, full title, protocol number, EU trial number, other identifiers.
		Abstract or very short description of the trial, including purpose of the study, what was tested; the intervention and any comparators; the phase of the trial, where applicable; people taking part in the trial, including total number of participants across x countries; topline results: simple description of the result of the primary endpoint, safety: overall statement about the safety findings in the study.
2	Who sponsored this study?	Name of the organization and contact information.
3	General information about the clinical trial	Where was the study done? The countries in which the trial took place, i.e., where participants were recruited. When was this study done? The overall trial start and end dates. What was the main objective of this study? The purpose of the trial, i.e., why the trial was carried out; why the comparator was chosen; any critical changes made during the study; randomization, blinding.
4	What patients/ people were included in this study?	Inside and outside of EU, age and gender breakdown, most important in- and exclusion criteria.
5	Which medicines or vaccines were studied?	Name of trial medicine and comparators(s), including placebo; blinding and randomization arrangements.
6	What were the side effects?	Number and frequency of adverse reactions, i.e., adverse events that were considered to be potentially causally related with the study drug; serious adverse reactions and the most common non-serious adverse reactions; MedDRA terms to be explained in lay language.
7	What were the overall results of the study?	Primary endpoint results, reference to secondary and further endpoints in the technical summary, important safety data.
8	How has this study helped patients and researchers?	Specify patient population, important limitations, e.g., "single study only"; statement on trial status, i.e., interim or final results; describe contribution to the research field.
9	Are there plans for further studies?	Explain whether other related trials are ongoing already, or provide public domain information about related trials.
10	Where can I find more information about this study?	Provide links to helpful websites with further information, such as industry-based websites, university websites, etc.; provide links to other generic sites of related interest, such as other clinical trial registries, European Clinical Trials Register, the Cochrane Library, etc.

"research result summaries." The first version of the guidance was released in 2015.[17] A final version (Version 2.1) was provided in July 2016 and is available on the MRCT website.[18] The MRCT guidance focuses on the return of aggregated study results to study participants "to ensure that study participants are informed about the trial results, that they know that their participation is respected and appreciated and that they understand the value of their contribution to science and public health." Thus, the target audience for the "return of results" is more narrowly defined than in European expert group recommendations that reach out to the public and are more in line with discussions in the US. Returning results to trial participants is seen as a contribution to a much broader effort of regulators, the pharmaceutical industry, the scientific publishing industry, and independent transparency initiatives, such as AllTrials, toward increased transparency and data sharing in clinical research.

The MRCT document is more comprehensive than the recommendations of the European expert group and considers the entire process, including study planning, informed consent, study conduct, and the time after the end of study participation (**Table 29-3**).

Table 29-3. MRCT Guidance on Timing of Information on Lay Summaries

Before study initiation	Start planning for lay summary (timelines, method of delivery, resources, budget)
Study protocol	None or minimal information on lay summary should be included because changes by amendments may trigger review by Research Ethics Committee/Institutional Review Board
Informed consent	Should inform patients about the plan to provide a lay summary and the anticipated timelines
During the study	Periodic updates on study progress (patient newsletters) are recommended that could also mention the availability of a lay summary
End of study	Thank patients for their participation (thank you letter), remind patients of the availability of a lay summary

The MRCT guidance document consists of a main text and four appendices that provide resources about terminology, timing, health literacy, and numeracy. The document provides guidance on content, process, and logistics of the return of results. The special considerations section of the MRCT guidance addresses the return of results to participants of prematurely stopped trials, observational trials, trials in vulnerable populations, and trials in children. These situations are not considered in the recommendations of the European expert group. The MRCT Return of Results Toolkit includes templates and examples for creating a lay summary, examples of neutral language that may be used, and a Research Ethics Committee Checklist.

Due to intensive exchange of information and opinion, there is a lot of overlap and agreement between the MRCT guideline and the European expert group recommendations concerning content and structure of lay summaries (**Table 29-4**).

TransCelerate: Guidance on Non-Promotional Language in Lay Summaries and on the Implementation of Lay Summary Processes

The TransCelerate "Clinical Research Access and Information Exchange Initiative" has developed two important guidance documents: the "Recommendations for Drafting Non-Promotional Lay Summaries"[19] was released in 2015, and the "Layperson Summaries of Clinical Trials: An Implementation Guide" was published in 2016. Five additional assets related to the writing and distribution of lay summaries were created. These materials are publicly available on the TransCelerate website (https://www.transceleratebiopharmainc.com/assets/clinical-research-access-information-exchange-solutions/).

The TransCelerate guidance documents represent an industry perspective and are intended to support sponsors in implementing processes for planning, writing, sign off, and distribution of lay summaries. The TransCelerate definition of lay summaries aligns with that in the *EU CTR* and encompasses the notion of returning results to study participants, consistent with MRCT guidelines and with discussions in the US.

TransCelerate Non-Promotional Language Recommendations

The first TransCelerate guidance document concerns a central aspect: the requirement that lay summaries must be strictly non-promotional. While the existence of such a document is justified in the EU, outside of this jurisdiction, a lay summary might be seen as promotional because it:

- 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 benefit-risk information for the medicine.
- May include a description of the use of an investigational drug or new use for an approved medicine that 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; therefore, there is a risk that the simplified wording may be perceived as misleading.

Table 29-4. Comparison of EU Clinical Trial Regulation and Expert Group Recommendations With MRCT Guidance

	EU Regulation and Expert Group Recommendations	MRCT
Timing of lay summary dissemination	One year after study end (last subject last visit), six months for pediatric trials	As in the EU, coordinated with other disclosure channels
Scope	Clinical trials with one site in the EU	All clinical trials (also devices)
Main audience	General public	Study participants
Language	As a minimum all languages of those European countries in which the trial was performed	All languages for which other study material was provided
Readability level	2–3 of the IALS*	Grade 6–8 (Flesh Kincaid Grade Level)
Template provided	Yes	Yes
Distribution	Posting on EU CTIS** and other channels	Various channels
Key content of lay summaries	Primary endpoint, important safety data, adverse reactions	Primary endpoint, important safety data, adverse events

**Kirsch, I: The International Adult Literacy Survey (IALS): Understanding What Was Measured. Educational Testing Service. December 2001. https://www.ets.org/Media/Research/pdf/RR-01-25-Kirsch.pdf. Accessed 22 September 2020.*
***EU Clinical Trial Information System, latest details available at https://www.ema.europa.eu/en/human-regulatory/research-development/clinical-trials/clinical-trial-regulation. Accessed 22 September 2020.*

- 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.[20]

To maintain the purpose and objective of lay summaries, it is essential that they are non-promotional in all aspects, i.e., in content, style, appearance, and the environment in which they are presented. The recommendations on non-promotional language "… 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."[21]

The TransCelerate Implementation Guide

The TransCelerate implementation guide presents practical options and considerations for the creation of processes around lay summaries, including discussions of the impact on the sponsor's transparency policy, protocol and Informed Consent Form (ICF) writing, the involvement of investigators, the interactions with Institutional Review Boards (IRB) and Ethics Committees (EC), and the need for budget allocation. The implementation guide is particularly helpful in explaining distribution options for lay summaries. It provides guidance and highlights site-based distribution challenges, including the investigators' role and web-based distribution options.

The four appendices provide a sample process flow, an implementation toolkit, a short comparison of guidance documents, and communication tools.

Recent Developments: Good Lay Summary Practice

Although available guidance is generally aligned in core requirements, each has a slightly different focus and addresses a different audience. The key objective of the European expert recommendations was to provide guidance on the requirements set in the *EU CTR*. The MRCT document focuses on the return of results to study participants, with an emphasis on options and opportunities outside of the EU's legal context. The TransCelerate guidance documents provide considerations and suggestions to pharmaceutical industry sponsors on many relevant aspects of the processes associated with lay summaries on a global level. A general "how-to-guide" or "best practice guide" for lay summaries did not exist. Furthermore, the involvement of patients in the lay summary process needed clarification, as did the

aspect that academic sponsors may need guidance on a lay summary process more in line with their institutional contexts.

In 2018, the European Federation of Good Clinical Practice (EFGCP) initiated an international working group to write such a best practice document with support from some 60 organizations, including patient groups, academic sponsors, and pharmaceutical companies. Sponsorship was secured from the European Federation of Pharmaceutical Industries Association (EFPIA). The collaborative efforts led to the release of a draft document, "Good Lay Summary Practice Guideline," for public consultation in July 2020.[22] It provides recommendations for a patient-centric preparation and dissemination of lay summaries and is written for professionals who create these documents. The document comprises more than 100 pages, including five appendices, divided into four sections: planning, development, translation, and dissemination. The final document is expected to become available in December 2020.

Open Questions and New Developments

Endpoint Discussion: Potential Inclusion of Secondary Endpoints

One of the most debated topics is whether secondary endpoints can or should be included in lay summaries. Annex V of the *EU CTR* only mentions that the "overall results of the clinical trial" need to be presented. The European expert group clarified that the primary endpoint as specified in the statistical analysis plan, should be included,[23] and other guidance documents agree.[24,25] Thus, while reporting the primary endpoint is mandated by the *EU CTR*, the inclusion of secondary endpoints in lay summaries is problematic for several reasons:

- Studies are usually not powered to demonstrate differences between treatment groups for secondary endpoints in a confirmatory way, i.e., there is a possibility that an observation captured in a secondary endpoint may be a chance finding despite a p-value below 0.05. Presenting it in a lay summary may therefore be misleading.
- Studies usually have many secondary endpoints, often between 10 and 30. Singling out one of these for presentation in the lay summary amounts to "cherry-picking" as an individual secondary endpoint can only be appreciated in the context of the full study results. Choosing a secondary endpoint with a favorable result would be promotional, violating one of the central pillars of lay summaries.
- If all secondary endpoints were included to avoid cherry-picking, the document would become substantially longer, and it would be difficult to balance the lengthy reporting of efficacy data with a similar level of detail for safety results.
- P-values for secondary endpoints often apply the conventional significance level of 0.05 for each secondary endpoint individually. Quoting such a result as showing a difference is not appropriate because significance levels need to be adjusted for multiple testing.

Patient-Reported Outcomes (PROs), endpoints related to the assessment of everyday functioning, quality of life, or other endpoints reported by patients, are rarely selected as primary endpoints but are commonly included as secondary endpoints. Regardless of endpoint hierarchy, such results are of interest to patients.

Soon after the publication of the *EU CTR*, the European Commission (EC) began issuing a series of questions and answer documents to clarify stipulations in the regulation. In the most recent version, the answer to the question on which endpoints need to be summarized in a lay summary reads "[…] the overall results of the clinical trial should be given. These overall results cover the main objectives of the clinical trial and should, therefore, reflect at a minimum the primary endpoints and patient-relevant secondary endpoints (…)"[26]

For some, the use of the term "patient-relevant" opened Pandora's box, as it could be read as permitting the inclusion of any secondary endpoint as long as it is labeled "patient-relevant." For others, this reply allows the inclusion of interesting results for patients beyond the often more clinically defined primary endpoint.

Essentially, the discussion shifted to the question of how to define patient-relevant secondary

endpoints. Ideally, all endpoints in a clinical study should be relevant for patients, regardless of whether they are clinical laboratory parameters, clinical observations, or reported by patients. Why would any sponsor evaluate endpoints that are not relevant for the intended patient population?

Irrespective of the definition of what characterizes an endpoint as patient-relevant, sponsors must balance the benefit and risks of including secondary endpoints in a lay summary. To prevent the impression of a promotional intention, sponsors need clear, appropriate, transparent, and defendable rules for including secondary endpoints. As a minimum, any secondary endpoint that is included in a lay summary should be:

- Pre-specified in either the study protocol or in the statistical analysis plan to prevent post-hoc picking of results that favor the substance under development
- Evaluated statistically, and appropriately addressing the issue of multiple testing
- Presented in a way that highlights that the secondary endpoint was not the main objective of the study and that there is a possibility that the results are chance findings
- Described in a separate paragraph or a separate section and not be included with the primary endpoint description.

Lay Summaries for Studies in Healthy Volunteers

The *EU CTR* mandates that lay summaries be provided for all clinical studies. This includes studies in healthy volunteers. For many therapeutic areas, with the exception of oncology, Phase I studies to determine initial tolerability and evaluate pharmacokinetics, pharmacodynamics, and drug-drug interactions are usually conducted in healthy volunteers. The pharmacokinetic and pharmacodynamic endpoints in these studies are both difficult to convey and of limited usefulness for non-experts. The safety signals observed in these studies are preliminary and must be confirmed in later phase studies.

The workload associated with writing lay summaries for these trials is considerable. Though it is very hard to obtain reliable estimates, the overall number of clinical studies in healthy volunteers is likely to be very high, far outnumbering the trials in other clinical phases. Furthermore, only 13.8% of all drug development programs across all therapeutic areas lead to approval.[27] Hence, a very large proportion of substances evaluated in Phase I healthy volunteer trials never reaches the market. Providing lay summaries of trials in healthy volunteers is therefore questionable and contributes little valuable information to the public.

On the other hand, the provision of lay summaries is a key element of transparency in clinical research; the requirement of lay summaries for Phase I trials in healthy volunteers may be considered as contributing toward this overarching objective.

Lay Summaries for Children

Only a few sponsors have started developing lay summaries for children in addition to those for adults (**Figure 29-1**). Yet, lay summaries for children are both an ethical obligation and an opportunity to increase the knowledge and understanding of clinical trials in children. The availability of well-crafted audience-focused lay summaries of studies in children may help lower the threshold for parents and children, who, in many jurisdictions, need to assent, to participate in a clinical study.

In the year 2019, 5014 studies in children were posted on ClinicalTrials.gov, representing 18% of all trials. From an ethical point of view, pediatric study participants are to be treated as any other participant and should therefore be informed about the study results. The recommendations of the European expert group encourage sponsors to develop lay summaries for children, particularly in cases when other child-focused information material was prepared. They suggest that more illustrations and graphics be used to help children understand the results. As the target reading level provided in the expert group recommendations for all lay summaries is 12 years of age,[28] all lay summaries should, in theory, be understandable for adolescents.

The writing of lay summaries for children should consider the range of intellectual and emotional development levels among different age groups, e.g., adolescents as opposed to young children, and should present the results accordingly. In trials involving very young infants to those just below 18 years of age, it will be difficult to serve all the age groups' needs with one lay summary. For younger children, the content of a lay summary will

need to be transformed into a narration and contain an adequate graphical depiction, perhaps a comic.

Lay summaries for children also pose a challenge because of the reporting requirements. According to the European pediatric regulation,[29] studies in children must be reported within six months after study end (defined as the last study visit). Thus, the lay summary also will need to be available at this time to ensure a conjunct reporting of the scientific summary and the lay summary, which requires a considerable amount of frontloading.

Summary and Outlook

Most large sponsors have committed to providing lay summaries. Many view this new document not only as a regulatory requirement but also as a unique tool to convey study results to participants and the public, that is, as an opportunity to engage with key stakeholders. Providing useful lay summaries has cost implications and requires skill sets that are not always readily available in the departments that usually generate regulatory documents. Professionals who set out to develop lay summaries need to learn how to write for people with low literacy skills. Thus, writing in plain language should be recognized as a different skill set from scientific or regulatory writing.

As lay summaries need to be visually engaging, lay summary developers should work with graphic designers and graphic artists for optimal results. However, the appreciation of documents that reach out to non-experts should ideally become a part of the company culture, and individuals that need to release and sign off on these documents need to understand and support their objectives, namely informing the public about study results.

Currently, sponsors provide lay summaries as pdf files available for download from either company websites or commercial transparency platforms. While making lay summaries available via the web is a good step toward a broader distribution, the pdf format is not ideal for those who access the internet via smartphones and handheld devices. The next step is to develop lay summaries in a digital format optimized for small-screen viewing.

For audiences with low literacy levels, lay summaries may be conveyed more appropriately in a video format. Additional extensions of the lay summary format are desirable, for example, for vulnerable populations. For example, there are 12 million people in the US above the age of 40 with visual impairments.[30] These individuals would benefit from study summaries in an audible format, such as podcasts, which need to fulfill all the content requirements of a lay summary. In addition, these alternate formats need to be true to the basic pillars of the lay summary effort: providing key factual information about an individual clinical study, in a strictly non-promotional way, in a language that is understood by the public, with links to more detailed information and other transparency channels.

Figure 29-1. Example of a Lay Summary for Children*

*Developed by Boehringer Ingelheim Pharma in addition to a lay summary of the same study for adults. The full lay summary is available at https://trials.boehringer-ingelheim.com/public/trial_results_documents/205/_english_25445LaySummarypdf.pdf#page=1.

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