TRIAL SUMMARIES
CITELINE REGULATORY

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White Paper

Trial Summaries
Improving Patient-Centric Communications

July 2023

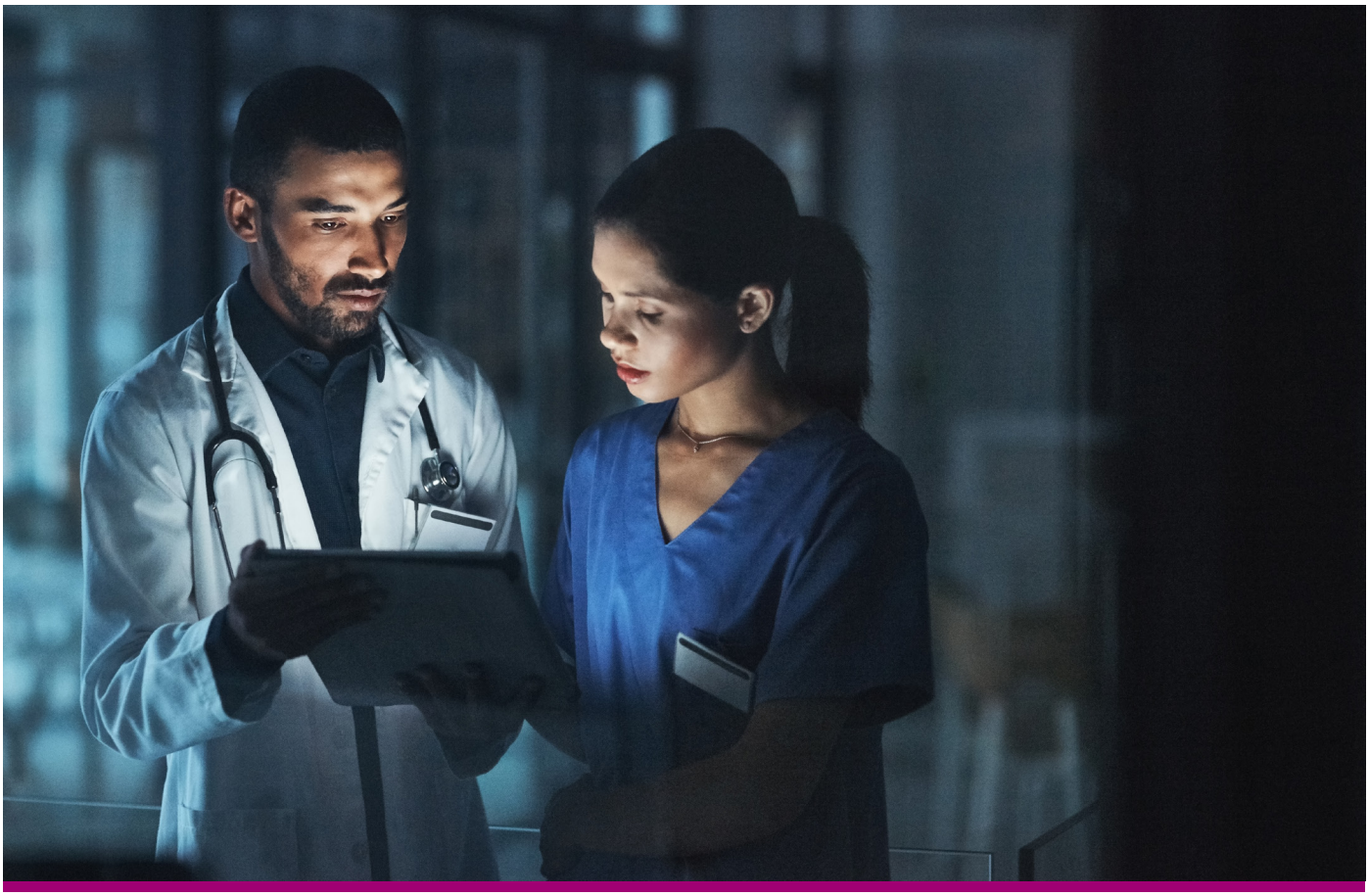
Contents

Executive Summary

Clinical trial sponsors continue to be faced with numerous challenges as they work to improve patient education and engagement throughout the clinical research process. These interactions have a direct impact on a trial participant's perception of the care they are receiving in a clinical trial as well as their overall satisfaction with the experience.

Pressure to improve communications and to expand transparency efforts continues to come from trial participants, patient advocates, researchers and industry transparency advocates. As the complexity of clinical research continues to grow, so does the need to communicate more efficiently and effectively with trial participants and the general public.

This paper discusses the challenges inherent in the current practices of providing trial results summaries to trial participants. It presents an alternative approach to distributing trial results summaries that takes advantage of commonly used technologies to more quickly, efficiently and reliably provide trial results summaries to trial participants. The benefits of this approach to clinical trial sponsors, patients, and their relationship with each other are also discussed.



Introduction

Trial results summaries, often referred to as plain language summaries, are brief explanations of an individual clinical trial written in easily understandable language. Trial results summaries differ from the information typically posted on ClinicalTrials.gov or the EU Clinical Trials Register in that the information is less technical and geared toward a different audience. The objective of a trial results summary is to effectively communicate pertinent information in a clinical trial including the trial population, investigational medicinal product and the overall results. The audience for this document is primarily trial participants; therefore, the language used should be non-technical in nature and easy to understand.

Trial sponsors are increasingly focused on patient engagement, with a growing understanding that sharing results of clinical studies with the trial participants is the ethical thing to do. In addition to the evolving transparency policies, plain language trial results summaries are required by law in certain regions. The European Clinical Trial Regulation (EU No. 536/2014) requires sponsors to provide a clinical trial results summary that will be published in an EU-wide database. Annex V of the regulation provides an outline for the content of the trial results summary as noted below.

Annex V of the European Clinical Trial Regulation[1]:
The summary of the results of the clinical trial for laypersons shall contain information on the following elements:

Content of the Summary of the Results of the Clinical Trial for Laypersons

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.

The concept of clinical trial transparency has evolved to include trial participants as a key stakeholder and identifies them as a critical audience whose data must be presented in a different, non-technical and non-promotional format. The timetable below illustrates the evolution of clinical trial transparency toward patient-centric communications.

1. Regulation EU No. 536/2014 on clinical trials on medicinal products for human use, Annex V https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32014R0536

Important Dates in the Evolution of Patient-centric Transparency

Year	Event
2000	Launch of ClinicalTrials.gov
2001	EU Directive 2001/20/EC specified the creation of EudraCT for clinical trial registrations
2007	FDA Amendments Act required posting of trial results for approved products on ClinicalTrials.gov by 2008
2012	European Commission required posting of technical summary results for trials conducted in at least one EU member state on EudraCT; functionality to support this is available in 2014
2013	Pharmaceutical Research and Manufacturers of America (PhRMA) and the European Federation of Pharmaceutical Industries and Associations (EFPIA) publish a commitment by member companies to publish clinical trial results summaries for products approved in the US and EU
2014	European Clinical Trial Regulation Article 37 required sponsors to provide clinical trial results summaries in a format understandable by laypersons to be made available in the EU Portal and database
2015	Policy 0070 became the publication of clinical study reports (CSRs) and clinical submission documents by the EMA
2017	Effective date of the FDA Amendments Act Title VIII Final Rule
2018	Launch of the EU Portal, including access to the trial results summaries
2018	EMA's policy 0070 temporarily suspended
2021	US FDA takes first enforcement action on trial reporting, with a notice of noncompliance to Acceleron Pharma
2022	https://pink.pharmaintelligence.informa.com/PS145602/Here-At-Last-A-New-Era-For-Clinical-Trials-In-The-EU EU Clinical Trial Regulation takes effect Jan. 31 and the Clinical Trials Information System (CTIS) for reporting study information goes live
2022	The World Health Organization (WHO) proposes to harmonize how the summary results from clinical trials are reported in registries
2023	Sponsors are mandated to report new clinical trial applications into EU's CTIS starting Jan. 31
2023	Health Canada announces plans to create a new clinical trials search portal
2023	Phased re-start of the EMA's policy 0070
2025	As of Jan. 31, all ongoing trials that had been approved under the previous EU Clinical Trial Directive must be transitioned to CTIS

Business Challenge

Clinical trial sponsors have an ethical obligation to provide clinical trial results summaries to trial participants. Trial volunteers are the backbone of clinical research and should be treated as such throughout the clinical trial process. Current practices often do not help sponsors fulfill their ethical, corporate and legal obligations and commitments in a reliable manner.

Sponsors must efficiently and accurately communicate trial results information to trial participants. This requires that trial results summaries are:

- Created using language that is easily understood by the general public
- Distributed in a timely manner
- Made available in a non-promotional, unbiased context

Most sponsor teams have spent time focusing on the content of the trial summaries to ensure they are meaningful and easily understood. However, few sponsors have assessed their current practices for getting this information to the intended recipient. Effective distribution and availability in a non-promotional context are major challenges that are often still overlooked at the patient's expense.

TransCelerate, a nonprofit organization comprised of biopharmaceutical companies, published 12 recommendations for using non-promotional language in trial results summaries. One of the recommendations, also supported by the Federal Drug Administration (FDA) and Multi-Regional Clinical Trials (MRCT) Center, addresses the context in which a trial results summary is published:

"Care should be taken to ensure that the lay summary is made available in a nonpromotional context."

The context in which the information is presented is critical to the use and effectiveness of a trial results summary. Some clinical trial sponsors post their trial results summaries on their own branded websites. This allows the sponsors to maintain control over the content from creation to publishing. However, posting trial results summaries to a branded website poses its own challenge, because the website is typically designed to promote the sponsor's products, creating an environment in which site visitors may perceive the trial results summaries as making claims about efficacy and safety.

The next challenge lies in the mechanism for getting the trial results summaries to trial participants. Traditional methods rely on study site staff to mail paper copies of trial results to participants once the trial is completed. This typically happens about a year after the study closes. Often, the trial documentation at the site has been archived and must be requested from offsite storage in order to obtain contact information for trial participants. Particularly for larger trials, this can be a very time-consuming and tedious task. Since this usually occurs a year later, quite often, trial participants may have relocated in the interim so results summaries that are mailed are returned to the study staff or distributed without any confirmation of receipt.

Trial Summaries: Improving Patient-Centric Communications

CISCRP, The Center for Information and Study on Clinical Research Participation, is a nonprofit industry organization founded in 2003 and dedicated to engaging the public and patients in the clinical research process. CISCRP is a proponent of developing trial results summaries communication programs that improve volunteer patient experiences. The organization has done research on patient communications and has reported the following:

- 88% of trial volunteers would participate in a clinical trial again[2]
- The top way (46%) that people report finding out about a trial is via the internet[2]
- 91% of participants wanted to know the results of their clinical trial, yet only 8.9% had been able to find out, even though technical results had been posted to ClinicalTrials.gov for over two months.[3]

The ability to access trial results summaries has a significant impact on the health literacy of clinical trial participants. The logistics of maintaining contact information, distributing trial results summaries, and the actual responsibility for managing the information is left in the hands of study site staff. This takes ownership and access to critical health information away from trial participants. This less-than-ideal scenario plays out around the world every day. Information is not received at all or not received in a timely manner.

2. CISCRP Clinical Research Charts and Statistics
3. 2021 Perceptions and Insights Study, https://www.ciscrp.org/services/research-services/perceptions-and-insights-study/

Proposed Solution

Providing trial results summaries in a timely manner is a great way to acknowledge trial participants' contributions. It enables participants to understand the trial and use the data collected about their health. Responsible sharing of trial results summaries is a generally accepted guiding principle in the industry. In fact, in 2013 the PhRMA and EFPIA jointly published Principles for Responsible Data Sharing[4] which described member commitments as:

"In order to help inform and educate patients about the clinical trials in which they participate, biopharmaceutical companies will work with regulators to adopt mechanisms for providing a factual summary of clinical trial results and make sure the summaries are available to research participants."

In order to fulfill these commitments, it is important for clinical trial sponsors to leverage technology to replace current paper-based practices and to present trial results summaries in a non-promotional context.

Citeline's Trial Summaries portal takes advantage of the common accessibility of the internet to connect patients to their trial results summaries. The Trial Summaries portal is an easy-to-use website where clinical trial sponsors can post trial results summaries for patients and the general public to access.

Patients in a particular trial can subscribe to receive email reminders about the trial results summaries and their availability once the trial is complete.

4. PhRMA & EFPIA Joint Publication, 2013

Business Benefits

For trial participants and clinical trial sponsors, there are numerous benefits to this simplified approach.

Trial Participant Benefits

- The Trial Summaries portal demonstrates to trial volunteers that their participation is appreciated and important to the clinical research process.
- It facilitates improved understanding of trials by making the results summaries readily available via the web.
- This approach facilitates patient engagement and education while reducing the delays inherent in traditional paper-based processes.
- The ability to subscribe to trial results summaries empowers the trial participants to manage the frequency and amount of information they want to receive in follow-up to the study.
- Trial participants can always access their trial results summaries online; no need to keep track of a paper copy.

Sponsor Benefits

- The Trial Summaries portal supports clinical trial sponsors' ethical, corporate and legal obligations to communicate trial results to trial participants.
- The Trial Summaries portal provides a direct and controlled channel for sponsors to publish trial results summaries efficiently, thus ensuring alignment with other approved disclosure content.
- The portal offers a non-promotional and unbiased context in which the trial results summaries are presented.
- This approach eliminates costly, time-consuming, unreliable and rarely tracked paper-based distribution through study site staff.

Summary

Trial results summaries are an important deliverable in the clinical research process. As clinical research continues to expand and become more complex, plain language communications become increasingly important to patient education and engagement. A web-based solution such as Citeline's Trial Summaries portal provides a compelling alternative to ineffective and unreliable processes that demand an upgrade to a new standard of practice.

Improve Patient-centric Communications

Contact the experts at Citeline to learn more about the Trial Summaries portal and how you can improve patient engagement end education.

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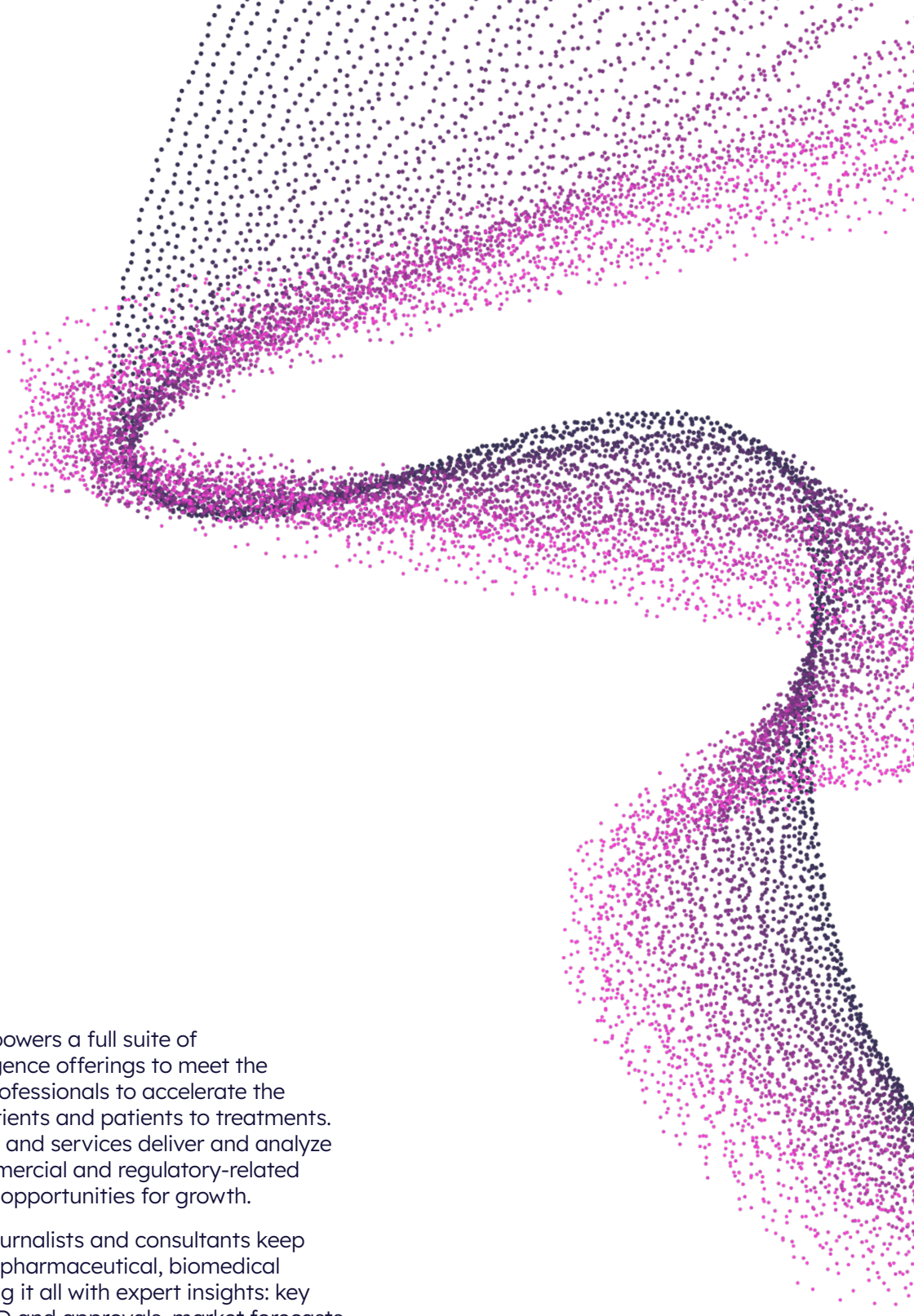

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