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REGULATORY

Success Story

AstraZeneca takes an innovative approach to trial results summaries

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AstraZeneca

What Are Trial Results Summaries and Why Are They Necessary?

Trial results summaries, also known as plain language summaries (PLS) or lay language summaries, convey what happened during a clinical trial in easy-to-understand language. Best practices dictate that PLS are written at a fifth- to eighth-grade reading level. What's more, PLS must be available in the same language as the patient's informed consent.

PLS should include information about the purpose, results, and other trial facts. The language should be simple, factual and neutral; it must be free of any editorial or commercial content. In addition, the information in PLS should not be selective; both positive and negative results must be included. Lastly, PLS cannot make pre-approval claims of safety or efficacy.

In the European Union (EU), clinical trial regulation requires all sponsors with studies in the EU to provide plain language summaries (PLS). This includes low-interventional/ interventional trials and Phase 1 to Phase 4 trials taking place in at least one site in the EU. Under the regulation, PLS must be posted within 12 months of completion for adult trials, and within six months for pediatric trials.

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A Corporate Commitment – and Challenges Along the Way

AstraZeneca made a commitment in 2015 to deliver PLS in advance of the European Medicines Agency (EMA) policy coming into play, says Julie Holtzople, Clinical Trial Transparency Operations Director. Many other sponsors have followed suit, taking a proactive approach to clinical trial disclosure and transparency. The statistics explain why. According to a 2017 (CISCRP) study[1], 72% of the respondents said they want a summary of their results, 91% thought receiving results was really important, and 53% said they had never received a summary of results. "Our leadership made that commitment, and then we had to go figure out how to do it," Holtzople says.

"Figuring out how to create the summaries with the support of a partner that has done this a lot wasn't the hard part." The hard part, she says, was the resistance from trial sites on distribution of PLS. One reason for the pushback was that a year or more had lapsed since trials had ended, and the focus had moved on to newer trials or the original researchers were no longer employed. Asking trial sites to own distribution meant they had to track and update contact information, which was asking a great deal. On top of that, the sites were asked to mail the PLS to participants. According to Census Bureau statistics[2], about 12 percent of the U.S. population moves annually. So effectively reaching participants by mail presented logistical challenges.

That's when Holtzople began thinking about hosting PLS on a website to take the burden off the trial sites. "A lot of folks now, particularly the younger generation, are no more than 3 feet from a smartphone," she notes, adding that hosting PLS online would make them easily accessible. Technological distribution also would allow people to opt in or out of receiving information.

Holtzople relates her own family's personal story, recounting how her young son participated in a clinical trial but they never received any results. Even though she is employed in the pharmaceutical industry, she could not remember the name of the trial's sponsor. That made her determined to make it easy for families and patients to find study information in a centralized repository. Having a vendor manage this central repository would put some distance between the AstraZeneca and its promotional materials.

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> **Julie Holtzople, Clinical Trial Transparency Operations Director, AstraZeneca**

AstraZeneca's Requirements for a Trial Results Summary Portal

- Reliable, permanent, on-demand distribution of PLS
- Unbiased and non-promotional context
- An experience focused on the needs of the patient and trial participant
- Automated import of clinical information
- Multi-language website
- Communicates updated information directly to trial participants
- Rapid setup with low cost of ownership

Why Citeline?

AstraZeneca was impressed by the TrialSummaries.com track record and commitment to clinical trial transparency. One major advantage that TrialSummaries.com offered compared to an internal site was translation into multiple languages. English is used by 1.7 billion people around the world, but statistics show[3] that only 20% of people are native speakers of the so-called universal language.

Web localization — modifying site content to blend with a visitor's language and culture — also offers a new search engine optimization (SEO) technique.[3] Having keywords in a local language increases the chance of a higher ranking in the search engines, meaning the content will be more easily found online.

Through the TrialSummaries.com development cycle, Holtzople says AstraZeneca engaged with patients and patient advocates to get their feedback, using both online surveys and interactive sessions. "Their voice mattered," she says. In order for clinical trials to be accessible, the website itself must be accessible — and patient feedback revealed that the website colors needed to be tweaked for the visually impaired.

Holtzople says the overwhelming request from participants was whether other sponsors' results would be available on TrialSummaries.com. They appreciated the simplicity of the site compared to ClinicalTrials.gov, where they had difficulty finding clinical trial information.

Key Portal Capabilities

For the Patient

- Central location to find trial results summaries
- Intuitive and welcoming site in local language
- Option to subscribe to be notified of new information
- Assured privacy

For the Sponsor

- High-availability, multi-sponsor and multi-lingual hosted solution
- Neutral and non-promotional environment
- Patient-centered site design
- Email subscription option to notify participants of new information

For the Site Staff

- Reduce administrative work
- Save time and money on printing
- No issues with site staffing/turnover post-study (summaries typically not available for a year or more)

If You Build It, Will They Come?

AstraZeneca printed thank-you cards to distribute to study participants at trial sites, either at the start or the end of the study. This card thanks the patients for their participation and also directs them to their specific study on TrialSummaries.com, encouraging them to sign up to be notified by email — in the language of their preference (typically in the language used for informed consent) — when the trial results summary is available.

It's important to note that this information is stored in Citeline's secure database, in keeping with HIPAA patient data privacy regulations. And, reflecting the non-promotional environment of TrialSummaries.com, the information is also not shared with the sponsor. The same applies to anyone who visits the website, searches for a trial, and signs up to receive email notifications.

Sample postcard design for illustration purposes only.

While AstraZeneca is moving more and more toward digital access for trial summaries, it still offers participants the option of receiving a print copy of the summary. That way, patients can receive study information not only in the language of their choice but in the format of their choice.

Summariz-ing It All Up

Website analytics provide AstraZeneca visibility into visitor traffic relating to its listed studies. While the data are not granular to the individual visitor level, they do reveal information about where visitors are coming from, what language they use, and which studies they view.

TrialSummaries.com is designed to be a centralized, non-promotional location for clinical trial information, which is why AstraZeneca decided to host its studies and summaries there. Holtzople sees a risk mitigation by providing public access summaries vs. directly pushing results to individuals. Providing public access, she notes, does not require IRB or ethics reviews, which can offer varying interpretations of the study. “We need one view of the results,” she says. “If you have multiple versions, you dilute the data.”

Multiple language translations is another reason AstraZeneca went with TrialSummaries.com. With website translations available in a variety of languages, plus more to come, TrialSummaries.com gives patients the access they want and sponsors like AstraZeneca the transparency they need.

While it’s likely that AstraZeneca will see cost savings as it continues to transition from print to digital trial summaries, Holtzople says cost savings was not the motivation behind this project. “We did this as a process improvement, a quality improvement, a risk mitigation, the right-thing-to-do-for-patients initiative.” And while AstraZeneca’s participation is geared toward patients, the fact that caregivers, researchers and the general public can access its trial information is a plus. “We’re all patients, one way or another,” she concludes.

Sources:

1 https://www.ciscrp.org/headline-perceptions-insights-study-march-2018/
2 https://www.census.gov/newsroom/press-releases/2015/cb15-47.html
3 Birch River Design Group

To learn more about Trial Summaries, visit www.trialsummaries.com

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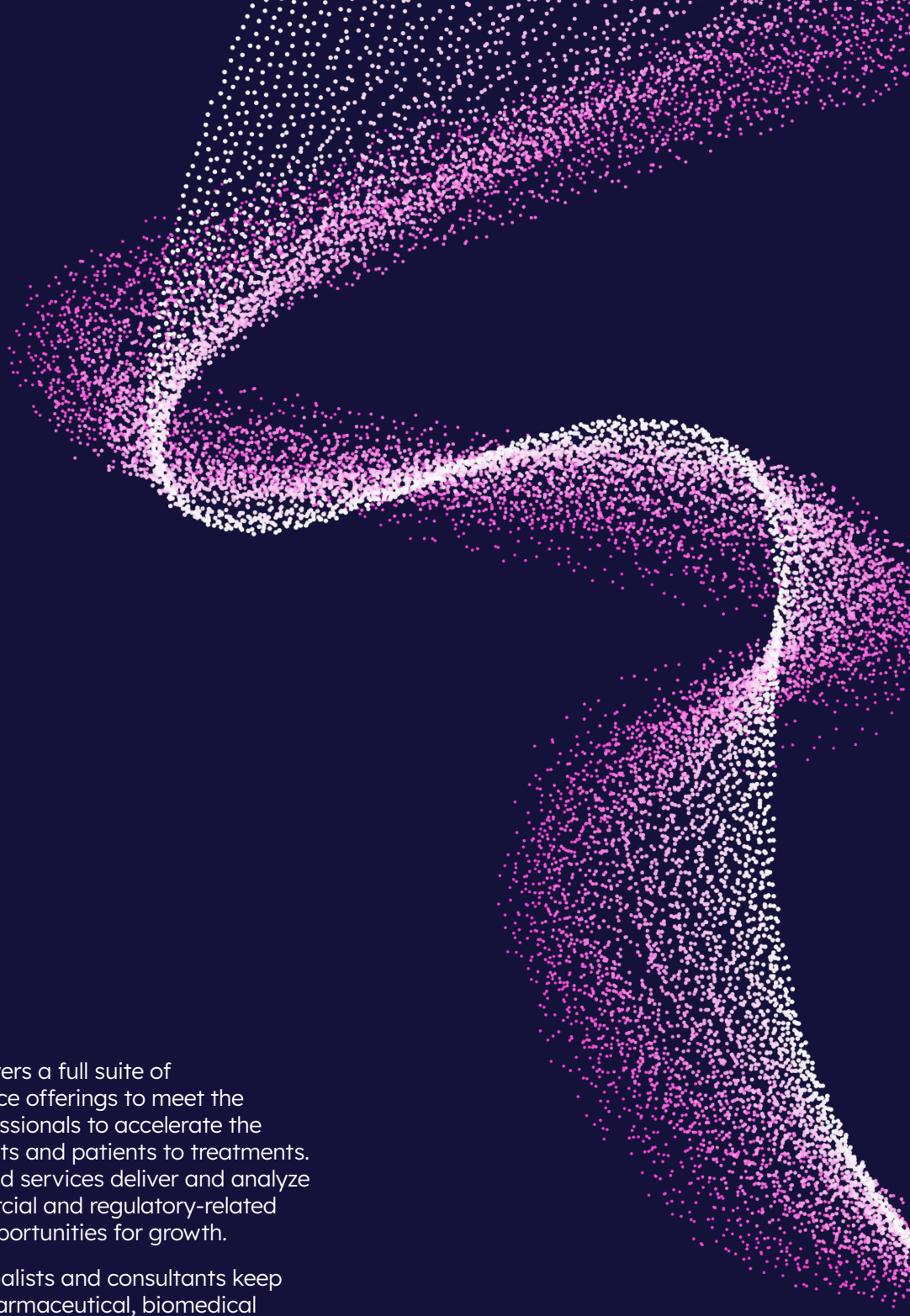

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