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Engaging the Public in the Clinical Research Process

CISCRP

THE CENTER FOR INFORMATION & STUDY ON CLINICAL RESEARCH PARTICIPATION

Engaging the Public in the Clinical Research Process

Synchrogenix and the Center for Information and Study on Clinical Research Participation (CISCRP) Partner to Help Pharmaceutical Companies Meet Clinical Data Transparency Mandates

> "Synchrogenix and CISCRP have partnered to provide the industry's preeminent model for lay summary development and global distribution. The partnership offers a scalable solution to address the critical unmet need to disclose lay language trial results to study participants while also fulfilling EU Clinical Trials Regulation requirements for lay summary posting."
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> – Behtash Bahador, Program Manager, Communicating Trial Results, CISCRP

The ethical mandate for clinical trial transparency

The issue of transparency and disclosure of clinical trial data has been growing in importance over the past few years. Clinical trials are essential to developing new therapies for patients. But the individuals that participate in those trial put themselves at risk. In return, the medical community has an ethical obligation to disclose clinical trial information and create transparency around the data. These steps are critical for increasing trust between the public and the industry.

In addition to the ethical mandate for transparency, there is also a business case for treating study volunteers as partners in medical advancement. In surveys of the factors that motivate participation in clinical research, volunteers most frequently cite reasons such as wanting to "learn about their disease," and "feel part of a community." The overwhelming majority of trial participants have positive experiences that they might be willing to share with others, except for one pervasive issue; they expect to be told the overall results of their trial. Unfortunately, most never hear anything back from the sponsor or research center after the last study visit, leaving many volunteers wondering if their participation mattered or was appreciated. The persistent perception that clinical research volunteers are "guinea pigs" rather than people may contribute to low levels of participation in medical research. In fact, the average study has to last for twice the planned duration in order to meet the enrollment target.[1] Increasing the public's trust in the clinical trial process may help increase participation and retention rates, which should help lower the overall cost of drug development.

While clinical research volunteers want to know that their participation mattered, it's not easy for them to find out the results of clinical trials. Section 801 of the Food and Drug Administration Amendments Act (FDAAA) requires sponsors to register and report results at ClinicalTrials.gov. However, these trial results summaries are written using medical terminology that is not accessible to the general public. There is a need for an infrastructure that supports the creation and distribution of lay summaries—brief, plain-language accounts of a clinical trial's design, objectives, and findings.

Both pharmaceutical industry associations and global regulatory bodies recognize the need for greater transparency of clinical research results.

The growing call for public disclosure of research results

- The 2013 Declaration of Helsinki states that "all medical research subjects should be given the option of being informed about the general outcome and results of the study" as part of the informed consent document.
- The Pharmaceutical Research and Manufacturers Association (PhRMA) and European Federation of Pharmaceutical Industries Association (EFPIA) have made commitments to transparency initiatives for layperson summaries. Under these principles, companies agree to enhance public access to clinical study information for any submission following a January 1, 2014 US or EU approval. At a minimum, companies agree to provide the lay summaries of clinical study reports (CSRs) to participating patients.
- According to the new EU CT Regulation, sponsors are required to submit a summary of clinical trial results, including lay summaries to the European Medicines Agency (EMA) database that is scheduled to become active in October 2018.

In a recent survey of study volunteers, 97% wanted to know their trial results; but when surveyed more than two months after aggregate results had been made available on the ClinicalTrials.gov registry, just 9% had been able to learn the results.

Supporting clinical data transparency initiatives

Synchrogenix, Certara's regulatory writing consultancy, and CISCRP—an organization dedicated to educating and informing the public and patients about clinical research—have entered into a partnership to provide lay language clinical trial results to clinical trial volunteers. The partnership will enable CISCRP to dramatically expand their ability to meet sponsor requests while ensuring non-promotional and scientifically accurate communication through CISCRP's proven process and independent, neutral nonprofit status. This new partnership combines Synchrogenix's technology-enabled expertise and clinical writing talents with CISCRP's unbiased governance and dedication to engaging patients and the public in the spirit originally intended of the clinical research process. Indeed, more than two dozen industry sponsors have begun implementing lay-language communication programs with CISCRP.

Educating volunteers on clinical trial results, increasing public trust and support

Over the past five years, CISCRP has developed and tested a program to help sponsors address this unmet need. The program provides ongoing post-trial communication that begins at the last study visit and continues semi-annually until the results are ready. Because the earliest enrolled volunteers may finish their participation years before the end of the study, these occasional brief updates show them that their participation has not been forgotten.

Upon completion of the trial, an editorial panel of medical and health communications experts as well as patient advocates "translates" the technical results into scientifically accurate, non-promotional lay summaries written at a validated sixth to eighth grade reading level. User- and field-testing in the context of global trials shows that volunteers' comprehension of the trial results improves dramatically after independent review of a lay-language summary, and over 90% of volunteers indicate satisfaction with their level of understanding. Likewise, investigative site staff have been enthusiastic about the opportunity to learn study results and communicate them to their patients.[2] The program was recognized in 2013 with a Human Research Protection Best Practice award by the Health Improvement Institute.

Ensuring that all the stakeholders in a clinical trial are fully informed

Clearly, there is a rapidly growing need for sponsors to improve communication and trust with clinical volunteers through providing lay summaries of clinical trial results.

The recently released reprint, *Sharing Clinical Trial Data: Maximizing Benefits & Minimizing Risk*, the Institute of Medicine committee outlined principles for the responsible sharing of clinical trial data. Leading biopharmaceutical companies are now creating Scientific Review Boards to independently assess requests for clinical data and implementing broader clinical trials transparency programs with an emphasis on communications to both the research and lay communities.

Synchrogenix's technology-enabled operational expertise will help CISCRP to continue meeting this need. Synchrogenix's medical writers will develop the text and images for each lay summary and use quality control processes to ensure data and message accuracy. CISCRP will deliver critical, unbiased reviews of reports, engage and interact with investigative sites and manage production, dissemination and communications of reports. This partnership enables the creation of a consistent, sustainable delivery model that will help to ensure that all the stakeholders in a clinical trial are fully informed.

References

1. Kaitin K, editor. 2013. 89% of trials meet enrollment, but timelines slip, half of sites under-enroll. *Tufts Center for the Study of Drug Development Impact Report* 15(1).

2. Hallinan ZP and Getz KA. 2014 Advancing the Research Enterprise: Establishing a New Standard Practice for Disseminating Clinical Trial Results to Study Volunteers. *Clinical Researcher.*

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