

# Creating a Standard Practice for Communicating Lay Language Trial Results to Study Volunteers

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## Learning Objectives:

1. Discuss the current conditions for disclosing lay-language clinical trial results summaries to study volunteers.
2. Describe a tested and feasible approach to delivering lay language trial results to study volunteers.
3. Identify barriers and challenges research sponsors face in implementing trial results communication programs.

Since its onset, the “patient centrality” movement has prompted a growing number of research sponsors to develop and implement new initiatives intended to acknowledge and amplify the important role that patients play as participants and partners in clinical trials. Among these new initiatives are programs designed to deliver clinical trial results in lay language, non-technical summaries to study volunteers. This article provides context for the critical obligation to provide lay language results to study volunteers, discusses efforts underway to establish standard practices to routinely deliver these results, and describes the anticipated impact of these programs.

## Background

Clinical research volunteers want to know that their participation mattered and that it was appreciated. But historical industry practice among clinical research professionals has sent a very different message to study volunteers. Although clinical trial results are routinely posted online, in compliance with federal law when the drug/device is approved or within a year of study completion, the routine communication of those results is not occurring. Survey research reviewed in the literature shows that, on average, more than 90% of study participants in any given trial report that they never learned about their specific results from study staff or the research sponsor.<sup>1</sup>

In a global survey of more than 5,600 study volunteers conducted in late 2013, the prospect of receiving their trial results was one of the top five reasons for choosing to participate. Among study volunteers from South America and Asia-Pacific countries, the prospect of receiving trial results was rated the most important factor in their enrollment decision, above even quality medical care.<sup>2</sup>

The Declaration of Helsinki has long treated the dissemination of clinical trial results as a moral obligation of the research community to its study subjects, and in the most recent revision states: “All medical research subjects should be given the option of being informed about the general outcome and results of the study.”<sup>3</sup> In March 2011, FDA adopted final amended informed consent regulations requiring informed consent forms to include a statement indicating that data from the clinical trial has been or will be entered into the ClinicalTrials.gov registry.<sup>4</sup> But posting clinical trial results on this public forum does not go far enough.

Assessments on the use of the ClinicalTrials.gov registry show that study volunteers, patients, and the general public are not the primary audience for this information.<sup>5</sup> Not all study volunteers have access to the Internet or the ability to locate their specific trial. Among those who are able to find

their specific clinical trial, interpreting the technical trial results summaries is very difficult.<sup>6</sup> The parties primarily accessing the highly technical information on ClinicalTrials.gov are professional researchers, policymakers, and analysts monitoring data trends.<sup>6</sup>

Recently, European regulators and lawmakers have been especially active in ensuring even greater transparency. In October 2013, the European Medicines Agency (EMA) announced progress upgrading the EudraCT system to allow for the public release of clinical trial results summaries in technical format, with full implementation expected before the end of 2014.<sup>7</sup> The European Parliament will vote in March 2014 on a revised clinical trials directive, including a widely supported provision to require that trial results be provided in lay language, non-technical summaries within a year after the trial ends, regardless of marketing authorization.<sup>8</sup>

Trade associations are also weighing in. In 2013, the Pharmaceutical Research and Manufacturers of America and the European Federation of Pharmaceutical Industries and Associations issued a joint statement expressing the commitment of their members to share “clinical trial results with patients who participate in clinical trials” as one of five Principles for Responsible Clinical Trial Data Sharing.<sup>9</sup> This commitment is intended to begin as of January 2014, and at least one industry sponsor already has committed to release of trial results in lay language for all Phase IIb and III studies starting in 2014 and going forward.<sup>10</sup>

## A Winning Initiative

Clinical research volunteers deserve our full commitment and best efforts to communicate their trial results. Even more, they shouldn't have to search for their trial results on their own, they should receive them directly from their primary partner-in-research — the study staff. Moreover, study volunteers should receive them in a reasonable time frame and in a form that is easy to understand. Although disconcerting for some sponsors, there is no ethical justification for withholding lay language results until marketing authorization has been received. This is the ultimate act of appreciation to those who have given the gift of their participation

so that clinical research professionals can perform their work and public health can advance.

Failure to communicate trial results is also a substantial missed opportunity for the research community to rebuild public trust, and establish and nurture relationships with study volunteers. An overwhelming majority of investigative sites (98%) also want to provide trial results to their study volunteers.<sup>11</sup> They feel that it is not only their moral obligation to do so, but also an essential way to strengthen the relationship with study volunteers and an opportunity to maintain contact with patients who have completed participation.

Study staff feels that patient relationships are compromised when they are unable to provide results. Investigative sites note that they too feel valued as partners when research sponsors share trial results with them. For these reasons, there is a strong business imperative for research sponsors to proactively and routinely communicate trial results.

Ultimately, routinely and systematically communicating trial results summaries in lay language to study volunteers is the right thing to do. Since 2010, the Center for Information and Study on Clinical Research Participation (CISCRP) — in collaboration with research sponsors — has found that communicating lay language trial results summaries can be easily, feasibly, and affordably established as a standard practice within organizations and industry-wide.

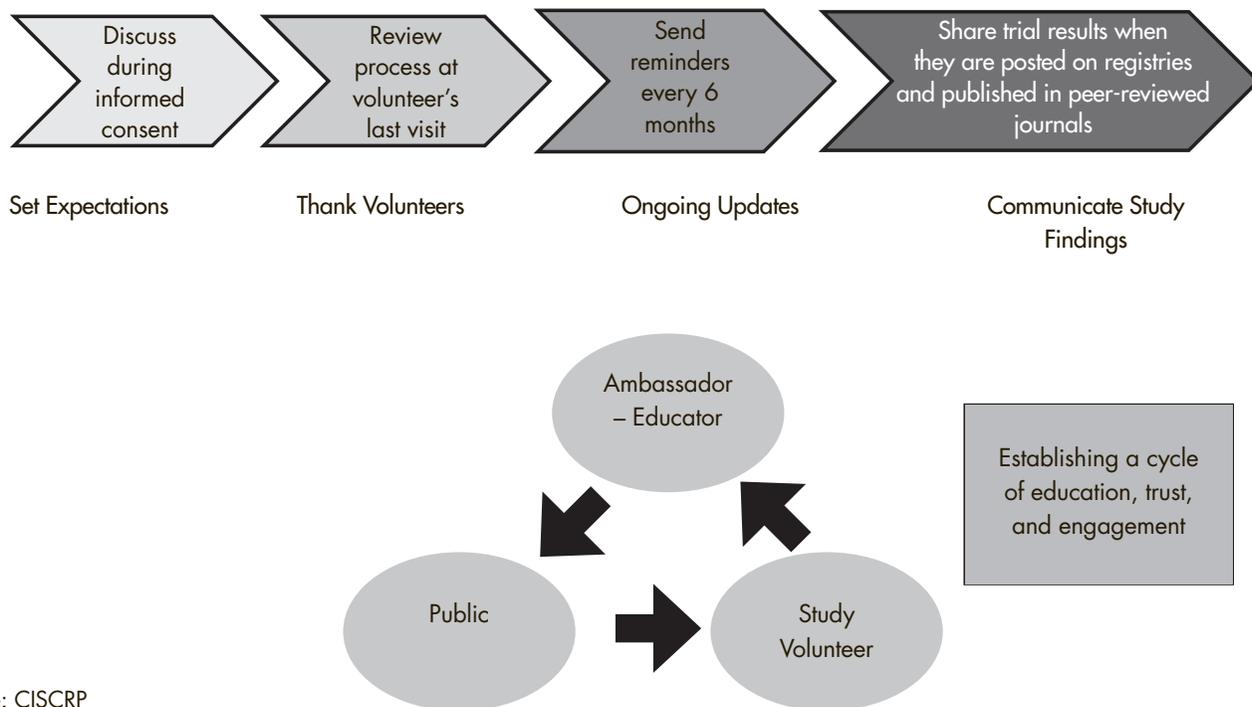
CISCRP began piloting programs with Pfizer in 2010 and with Lilly

in 2011. Results of some of these early pilots are published in *Applied Clinical Trials* and *Expert Review in Clinical Pharmacology*.<sup>11,12</sup> Although early adoption rates were slow, CISCRP has seen the number of sponsors communicating trial results to their volunteers doubling each of the past 2 years, bringing the total to 24 research sponsors piloting or broadly implementing programs at the time of this article's authorship.

The program is designed to integrate easily into established clinical trial practices and the research sponsor's internal clinical trial results publishing practices. The program also engages study staff throughout the process. Study staff initially discusses when clinical trial results will be made

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**Figure 1: Process for Communicating Trial Results to Study Volunteers**



Source: CISCRP

available during the informed consent process. Next, study volunteers receive a reminder and a thank-you note during their last study visit. Generally every 6 months after the trial has ended, volunteers receive a reminder that their study results are being analyzed. An institutional review board or an institutional ethics committee approves all communications that are received by the study volunteers while they are actively participating in the study.

The research sponsor notifies CISCRP once the sponsor has prepared and published a technical summary on [www.ClinicalTrials.gov](http://www.ClinicalTrials.gov), the EudraCT system, or in a recognized peer-reviewed journal. CISCRP's editorial panel — made up of consumer science and medical communication experts, health care providers, and patient advocates — translate the technical/scientific study results into easy-to-understand lay language summaries at a validated sixth- to eighth-grade reading level. CISCRP also manages the translation of the non-technical summaries into patient's native languages. The sponsor's researchers and staff then review the lay language trial results summary for accuracy and consistency with the technical/scientific summary. Next, CISCRP professionally produces printed reports and ships them to study staff to be disseminated to study volunteers.

In evaluations of the program through surveys, interviews,

and focus groups, study volunteers have been very receptive to the program. They have expressed high levels of satisfaction with the lay language summaries. In pre- and post-program comparisons, study volunteers have demonstrated statistically significant improvements in their comprehension of the purpose of their clinical trial and the summary findings of the study.<sup>1</sup>

Investigative site staff also has been very receptive to the program. Since the launch of the program, CISCRP has gathered feedback from more than 50 investigators, study coordinators, and clinical research directors. Only one investigator was opposed to providing lay language clinical trial results summaries, citing his belief that research professionals “know what is best for their patients.”<sup>11</sup>

All other study staff felt that there is a substantial and essential need for a program to communicate trial results in non-technical language, and they appreciated the opportunity to disseminate results to their patients. As one study coordinator put it: “In my 25 years of conducting clinical trials, I have never been able to let subjects know how the study turned out.” Many study staff echoed this sentiment and felt that a program to communicate trial results to study volunteers has the additional benefit of ensuring that site staff is informed of the results.

## Lessons and Insights

During the past several years, CISCRP has learned from working with research sponsors in implementing clinical trial results communication programs. Several key themes are described below:

***It is critical to keep communications to study volunteers unbiased and strictly non-promotional.*** The FDA Amendments Act of 2007 provisionally requires sponsors to post a “summary of the clinical trial and its results that is written in non-technical, understandable language for patients” to ClinicalTrials.gov. As of late 2013, however, no final ruling on this provision has been made. This delay is in large part associated with the government’s challenge in ensuring that the trial results summary not be misleading or promotional as required under the law.<sup>13</sup>

Clearly it is essential that clinical trial results summaries be completely free from bias or promotional language. To address this issue, the independent, non-profit CISCRP convenes an objective editorial panel to “translate” the technical findings. The sponsor’s research staff then provides a final review for accuracy. This approach creates multiple checks against misleading and biased communication, with the sponsor separated from patients by both investigative sites and a patient-focused third party with no vested interest in the study outcome.

***Study staff is a partner in the process.*** Study coordinators and investigators consistently say that they are ultimately responsible for any communications to their patients. This ensures not only patient privacy on the one hand, but also provides an opportunity to strengthen the relationship between study volunteers and study staff. Study volunteers view their relationship with site personnel as a fundamental determinant of a successful clinical trial experience.<sup>14</sup>

As more sponsors begin regularly communicating trial results to their volunteers, it is critical that the central role of the investigative site be recognized and leveraged while minimizing any added burden on study staff. In CISCRP’s program, this is accomplished by providing all patient materials to sites in mail-ready envelopes, so that sharing results with their study volunteers can be as simple as adding an address and a stamp. In certain cases, it may be appropriate to provide

the lay-language summary of results by email, but volunteers report that receiving a printed, hard copy is preferred.<sup>1</sup>

Some investigative sites choose to further personalize each report sent to study volunteers. Handwritten notes and evening events during which the investigator discusses the results with his or her patients using the written lay-language report as a jumping-off point are two examples of these personal approaches that sites have implemented. Even when staff resources do not allow for these additional steps, almost all sites are able to mail a printed report to their study volunteers.

Based on qualitative feedback from site personnel, study staff estimate that their time commitment to support the CISCRP program ranges from an additional 30 minutes to

2 hours per study, with the largest time commitments coming not when sites have high numbers of patients — even sites with 40 or more patients report half-hour time commitments — but when patient records have been moved off-site into archival storage.

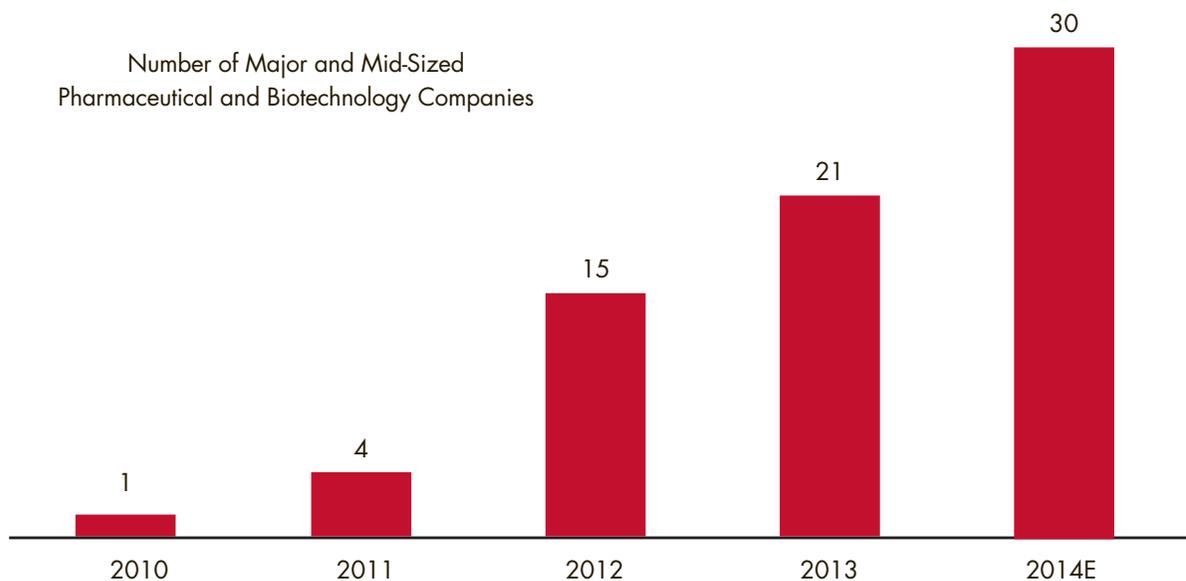
***It is best to introduce trial results communication programs during the study planning stage.*** During a pilot rollout, the CISCRP trial results communication program typically represents an unplanned expense. As a result, it often requires an inordinate amount of time to approve that unplanned expense and to determine what function will cover that expense.

Many research sponsors begin pilot efforts to communicate trial results by identifying a handful of studies that are soon to be or have already been completed. CISCRP has found that the ideal process plans for and integrates trial results communication from study initiation onward. Doing so ensures that the communications process is integrated into the study planning and budgeting process and that study staff are engaged at the outset of the trial.

Committing to communicate trial results at the start of the study also optimizes the value of the program. Among other benefits, study volunteers are reassured that sponsors intend to disclose the trial results regardless of the study outcome (and volunteers are clear that they want to know the results whether positive or negative). For study volunteers, the prospect of learning how the study contributed to the advancement of medical knowledge may also engender a higher sense of commitment to stay in a clinical trial and may

It is essential that clinical trial results summaries be completely free from bias or promotional language.

**Figure 2: Growth in the Number of Sponsors Actively Planning and Executing Trial Results Communication Programs**



Source: CISCRP

help to foster altruistic motivations that are among the most important factors leading to the decision to enroll in a clinical research study. Engagement of study volunteers can be further strengthened with ongoing communication to bridge the gap between their last study visit and the time that trial results are ready to be shared.

***Programs are more easily embraced and supported when they are tied to broader organizational initiatives.*** Most research sponsors who have successfully executed trial results communication programs did so as part of broader, enterprise-wide initiatives to support patient-centricity, patient retention initiatives, or sponsor-site relationship improvement. In many cases, resources are more easily found when the CISCRP program is tied to broader initiatives that have already received organizational buy-in and support. Enterprise-wide initiatives also tend to have more visibility, making it easier to raise initial and ongoing awareness among clinical teams.

## Creating a New Standard

The research enterprise is taking steps to improve transparency of clinical study results for the scientific community (e.g., FDA's proposed TEST Act of 2012; the EMA's planned release of trial data sets, and the AllTrials Campaign call for open data). And more is being done to ensure that clinical trial results are given to study volunteers. To them we owe

not only our sincerest gratitude, but also our respect reflected in our commitment to ensure that they are among the first to learn about the results of studies to which they gave the gift of their participation. A growing number of research sponsors are implementing trial results communication programs. But they are largely doing so voluntarily to honor and thank their study volunteers and in anticipation of regulatory changes requiring them to do so.

Within 5 years, pharmaceutical and biotechnology companies will be routinely providing clinical trial results to study volunteers around the world in response to regulatory mandate, public pressure, and a desire to build stronger relationships with clinical research volunteers. Although at this time clinical trial results are provided a year or so after the clinical trial has ended, within 5 years we anticipate that the duration between study completion and communication of clinical trial results will be compressed. The growing impact of data management technology solutions and patient preference for timely information will prevail.

High levels of study volunteer and investigative site receptivity to this initiative suggest that the communication of clinical trial results may become a means to differentiate the clinical trials experience for participants and may assist in improving volunteer retention rates and study staff morale. During the next several years, research sponsors will primarily focus on providing general clinical trial results to study volunteers. But within 5 years, as the patient centricity move-

ment continues to gain traction and this standard practice evolves, it is conceivable that many sponsors will be piloting and implementing efforts to communicate more detailed, customized, patient-specific study findings.

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