

## Communicating trial results to study volunteers: what does the future hold?

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With the April 2014 vote to require layperson summaries of clinical trial results on the European clinical trials database [1], EU lawmakers presented the global research enterprise with a critical opportunity to restore public trust and engage study volunteers as our greatest advocates and ambassadors.

Although some research sponsors will view the new regulations with trepidation, more than two dozen major and midsize biopharmaceutical companies are already planning and implementing programs for communicating trial results to their study volunteers in lay language. In this article, we share best practices and lessons learned at the nonprofit Center for Information and Study on Clinical Research Participation (CISCRP) over the course of 5 years' collaboration with these sponsor companies, and look toward the future of post-trial communication as an important means of engaging patients as partners in the research process.

### Patients as partners?

The overwhelming majority of study volunteers (95% globally) have sufficiently positive experiences that they would consider participating again [2], and there is every indication that former volunteers would be willing to share those positive experiences among others considering participation, were it not for one sadly consistent pattern: research shows that 90% of study volunteers want to be told how their participation contributed to medical science [3], yet most never receive the results of their clinical trial after participation has come to an end [4,5]. As a result, the

end-of-study experience leaves most volunteers feeling forgotten and abandoned by the clinical research enterprise.

It is no surprise, then, that nearly 40% of the global public agreed in a 2013 survey that study volunteers are “experimental test subjects, not people” [2]. Fortunately, there is growing recognition within the clinical research enterprise that long-term success depends not on better recruitment advertisements and retention strategies, but on understanding and meeting the needs of the volunteers who make clinical research possible. Above all else, the research enterprise must demonstrate to volunteers that their participation mattered.

One of the greatest opportunities inherent in the EU Clinical Trials Regulation is for the entire research enterprise to unite around a commitment to transparency and engagement with patients and the public, with the promise that communicating trial results in lay language will be a standard and expected element of conducting clinical research. Clinical research volunteers in Europe will benefit greatly by this practice. It is likely that the American public will soon demand a similar response from the US FDA.

### Beyond the clinical trials regulation: what study volunteers want & need

Although government-sponsored trial registries have been an important step toward greater transparency, they have thus far served primarily the needs of clinical research professionals [6]. The Clinical Trials Regulation should begin to change that; at



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the same time, however, it risks perpetuating the current environment of public mistrust, misunderstanding and disengagement if sponsors mistake regulatory compliance for meeting the needs of study volunteers.

Research with study volunteers and investigative site personnel suggests four essential criteria for a successful post-trial communication program that honors and respects volunteers as partners in the research process.

Trial results summaries should be delivered to volunteers as a printed report, at least for the near term. While electronic access to trial results summaries is valuable, currently it is the printed format that the majority of study volunteers most want and value [4,7]; and our estimates, from providing printed reports in global studies, show that the added cost is small at a fraction of a percent of the typical study budget. Delivering a printed report not only ensures access to the results, but appears to serve as a physical demonstration of appreciation.

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Investigative sites must be engaged in the dissemination process. Volunteers confirm that relationships with site personnel are fundamental to a positive trial experience [8], and study coordinators and investigators consistently report not only that they must ultimately be responsible for the communication of results to their patients, but that doing so provides an opportunity to deepen the relationships developed over the course of a clinical trial. Dissemination processes must, however, be designed to minimize any burden on-site staff [9].

Research sponsors must adopt mechanisms for assuring regulators and study volunteers that trial results summaries are unbiased and strictly nonpromotional. In the FDA Amendments Act of 2007, the US Department of Health and Human Services was charged with determining whether lay-language trial results summaries can be included on ClinicalTrials.gov “without being misleading or promotional” [10]. This determination is still pending. The approach CISCRP recommends and follows begins with the technical results summary prepared by the sponsor for government registries; then, in CISCRP’s role as an independent nonprofit organization, an objective editorial panel is convened that includes medical and consumer health communication experts, patient advocates and specialists who ‘translate’ the technical findings into everyday language, following a template developed through extensive user testing to maximize understanding [4,11].

Post-trial communication must become an ongoing engagement with study volunteers. Most sponsors that are currently providing trial results summaries also commit to ongoing post-trial communication, which begins at the last study visit and continues semi-annually until the results are ready. Because earlier enrolling study volunteers may wait years for the study to finish and the results to be ready, these occasional brief updates provide an important reassurance that even though volunteers’ active participation has come to an end, their contribution has not been forgotten [4].

More than 20 of the top 50 industry sponsors globally are already implementing processes that meet these criteria. Although not required by the Clinical Trials Regulation, it appears likely that additional sponsors will soon follow suit in order to best engage and honor study volunteers.

### Future perspective

Successfully engaging patients as partners through post-trial communication will require commitments from across the research enterprise. First and foremost, regulators must provide clear guidance. While industry sponsors have committed to “sharing results with patients who participate in clinical trials,” as part of the PhRMA/EFPIA Principles for Responsible Clinical Trial Data Sharing [12], this commitment was couched in language suggesting that it may only be fulfilled where explicit regulatory permission is given.

To date, most of the countries in which clinical research is regularly conducted have failed to provide such guidance. The lack of clarity from the USA – whose ClinicalTrials.gov registry holds seven-times as many records as the next largest government registry [13] – may be especially harmful. It would appear that the continued silence of the FDA on layperson summaries is directly contributing to trial results information being withheld from study volunteers by some sponsors.

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For other stakeholders, ensuring study volunteer access to trial results will primarily require adjustments to existing policies and procedures. Sponsors will align study volunteer communications with overall publication policies, identify process owners within the organization and plan for communications from the start of the study. Offering trial results as part of the informed consent document, an ethical requirement under the Declaration of Helsinki [14], will help minimize any

burden on research site personnel [9], and reassure volunteers that the study sponsor intends to be fully transparent, regardless of the study outcome.

Ethics committees, in turn, will be able to help sponsors and sites evaluate communication plans to ensure they best meet the needs of study volunteers. It has been our experience that most ethics committees do not expect to review the lay-language summary of trial results – which reflects publicly available information being provided to people who are no longer enrolled in a trial – but appreciate being apprised of communication plans and receiving a copy of any communications for their records. Ethics committee policies and regulatory guidelines will need to confirm and clarify this stance.

As new policies and procedures are adopted over the next 3–5 years, we anticipate that efforts to communicate trial results to study volunteers will not only become standard practice, but continue to transform to best meet volunteers' needs. Among other changes, the time between study completion and communication of results will be compressed with the assistance of improving data management technologies, better aligning with patient preference. Sponsors will also expand efforts to provide treatment assignment information to study volunteers alongside the summary of the overall results. Already, some sponsors have begun integrating treatment assignment communications with other post-trial engagement activities,

as well as exploring mechanisms for providing even more detailed, patient-specific study findings. As clinical research and clinical practice data converge, we anticipate the integration of this data into a single unified electronic health record that patients and their healthcare providers can routinely access.

These efforts will also intertwine with other patient-centric activities – from patient engagement in protocol development, to implementation of patient satisfaction metrics in continuous improvement models and the development of participant alumni communities – helping to raise the public's understanding of and openness to clinical research participation. Perhaps most important of all, we anticipate that forward-thinking members of the research enterprise will begin taking every opportunity to say 'Thank You' to study volunteers. This is not, however, something that can or should be regulated. It is simple human courtesy.

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