

# Starting With The Patient in Mind

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## Introduction

Clinical research volunteers in the drug development process have long been perceived as experimental test subjects rather than people. They're often viewed as part of a process that requires only their bodies and bodily fluids rather than their engagement. In our search for efficiency, we can forget that the patient care provided as part of a clinical trial isn't about the disease or the medicine under study — it's about the patient.

The Center for Information and Study on Clinical Research Participation recently surveyed 6,000 health information seekers and research participants about study volunteer perception and experiences. Overall, the results showed significant improvement in public perception of clinical trial safety, trust in the motives of research professionals and appreciation of clinical trial volunteers compared to the last survey, conducted in 2005.<sup>1</sup>

**However, more than one-third of respondents who were deemed ineligible for a study were not told why they failed to qualify.**

Of that group, two-thirds decided not to pursue research opportunities any further. We know that patients who have a positive research experience are more likely to participate in subsequent trials.<sup>2</sup>

## Engagement and Activation

In a recent article in Health Affairs, Editor-in-Chief Susan Dentzer notes that patient engagement is defined by the Institute for Healthcare Improvement as "actions people take for their health and to benefit from care" whereas patient activation is "understanding one's own role in the care process and having the knowledge, skills and confidence to take on that role."

"Wherever engagement takes place, the emerging evidence is that patients who are actively involved in their health and health care achieve better health outcomes and have lower health costs than those who aren't. ... The challenge is encouraging patients and providers alike to embrace engagement and achieve its full potential to improve health and care."<sup>3</sup>

The benefits of educating and empowering patients don't stop at the clinician's door. There are many ways researchers can implement patient-oriented policies and procedures.

## Controlling Perceptions

The emerging evidence is that patients who are actively involved in their health care achieve better health outcomes and have lower health costs than those who don't. Volunteers are more inclined to take part in future trials if they continue to have a positive and engaging experience.<sup>4</sup>

In recent decades, how people learn about clinical trials has changed significantly. Although most clinical trial participants prefer to learn about trials from their primary care physician, only about 20 percent actually get information through this channel. Today, 57 percent of patients get this information via the Web, and many learn from emails, newspapers, radio or television.

Social media also has a major impact on perceptions. Using Facebook, YouTube and other platforms, patients and volunteers may connect with others in similar positions in real time. These digital channels are more heavily used by younger demographics, but trends show we can expect older audiences to move to this channel as time goes on. Social media offers an opportunity for sponsors and research organizations to collaborate and become more transparent about the research with participants.

## Starting With The Patient in Mind

Creating a positive experience for volunteers should begin by designing the protocol with the patient in mind. A protocol that's too tedious or too complex — requiring collection of large numbers of samples, for example — may cause problems with patient retention or recruiting those same patients for future trials. You must consider how the protocol will affect your volunteers' day-to-day lives.

Later, when you recruit volunteers, provide as much information as you can from the earliest stages, including protocol design. Start with a frank discussion about clinical trials, their purpose and intended outcomes; an open panel discussion with volunteers can work well. Before seeking informed consent, talk with each individual about their disease or condition and how it relates to the trial. Tell them about research that has been done and where the current research project fits in. Explain the study drug and the hypothesis, and explain what they can expect.

Through the informed consent process, you are educating participants not just on the study but also on their disease and the entire research process. Person-to-person interaction cannot be

overemphasized — by raising a participant's health literacy, you give them an opportunity to comment intelligently and better manage their care. If you invest in that relationship, everyone benefits.

## Conclusion

When people have positive perceptions about clinical research, our entire industry benefits. You should assume that your study patients and volunteers will tell others — including other potential research subjects — about their experience.

### To help ensure positive experiences:

- Wherever possible, eliminate tedious and unnecessary steps in the protocol
- Give participants as much information about the disease, study drug and clinical trial process as they are willing to assimilate
- Keep participants up-to-date on the trial's progress as well as the ultimate results
- Ask for feedback, and consider informing volunteers how their feedback was taken into consideration

## Endnotes

- 1 CISCPR, Public and Patient Perceptions & Insights Study, 2013, <https://www.ciscrp.org/programs-events/research-and-studies/perceptions-and-insights/>.
- 2 Getz, K., "New Insights into Study Volunteer Perceptions and Experiences to Inform Patient-Centric Clinical Trials," *Clinical Researcher*, Volume 28, Issue 2 (April 2014).
- 3 Dentzer, S., "Rx for the 'Blockbuster Drug' of Patient Engagement," *Health Affairs*, 32, no. 2 (2013):202.
- 4 Ibid.



## About Frenova Renal Research

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