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"Patient Centricity" Must Be More than a Cliché: A Letter to the Clinical Research Community

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Like many of you, I am bombarded with articles on the topic of "patient centricity." By the sheer volume of these articles, one would think the important role played by patients in clinical trials is a freshly discovered concept. Of course, it is not. For decades, courageous patients have raised their hands to support clinical research in a very personal way — by volunteering to subject themselves to the uncertain risks of new drugs, devices or therapies. So, how do we treat these patient heroes? Listening carefully to their voices, it's evident that our treatment falls far short of what they deserve. I would like to ask perhaps the most important question: "Who speaks for the patient volunteers?"

As an industry, we often celebrate successful trial outcomes with emotionally touching patient stories placed in the media. After publicizing a success, it is easy to ignore the reality that the majority of trials fail, and therefore, for the majority of participants, the outcome of the trial does not result in any treatment benefit for them. Of course, while disappointing, those of us who support clinical research understand that "negative" outcomes still help researchers focus future efforts. But, after making a one-, two- or even three-year commitment to a trial, consider the participant's sense of disappointment that this chance for a cure has been lost.

Look up the word "hero" in a dictionary, and you will find: "A hero is a person who is admired or idealized for courage, outstanding achievements, or noble qualities." I believe that research participants fit this definition perfectly— except for the "admired or idealized" part — don't you? We can do a lot better on recognizing the essential contributions of research participants.

So, what can our industry do to demonstrate its respect and appreciation for its heroes? First, we must acknowledge that the term "patient centricity" has become little more than a cliché, with no real power as a call to arms to challenge the status quo. Oh, there have been well-intentioned attempts to add meaning, such as with the UK's NHS patient mantra, "No decision about me, without me." But to many patients, it's just lip service from an industry that seems to charge too much and care too little. We must convince them otherwise through our actions, not our words. Second, the biopharma industry is no stranger to soliciting patient views of specific clinical trial designs, generally for the purpose of facilitating patient enrollment or retention in the trial. However, if we really plan to center our thinking around trial volunteers, here is a set of changes we must adopt:

- **Streamline Informed Consent Forms**. We must make these forms understandable and clear. Today, up-to-40-page documents filled with medical and legal terms and ambiguities make it difficult for patients to understand exactly what they are committing to, and equally challenging for investigators to explain. We must adopt plain language consent forms, prefaced by three-page executive summaries. IRBs can help by requiring this step.
- **Return of Trial Results to Patient Participants**. It is inconceivable, but true, that patients who volunteer to participate in a trial seldom receive the results of that trial. At the present time, only 2% of clinical trials return their results to study volunteers. CISCRP has been a leading advocate for this initiative, an initiative that we at WCG support, and one we believe should be adopted far more widely.

- **Patient Steering Committees Supporting Trial Design**. Sponsors should create and empower a committee of patients and patient advocates to provide insights about study design, endpoint selection, and patient burden throughout the development of new therapies.
- **Participant Confidentiality in Recruitment**. The collection of data to assess study eligibility must be conducted with a commitment to ensuring patient confidentiality and strict adherence to protecting patient information. Narrow consent for the use of patient data must be the standard. Patients should not fear that their clinical information will be marketed to commercial patient recruitment organizations or the biopharmaceutical industry.

At WCG, we believe the patient's voice is the most important voice in a clinical trial, and we are working to ensure its deep resonance within the industry. To support this goal, we have created a Division of Patient Advocacy. You will hear more about this in the coming months.

I began this letter with the question: "Who speaks for the patient volunteers?" Obviously, the patients speak for themselves; we just need to listen much better. I guess what I'm really asking is, "Who else can they trust?" The correct answer should be "Us." We all must take responsibility, down to the person, for improving the patient's experience in clinical research. This not only the right and moral thing to do, but it will also lead to greater success for the entire clinical research enterprise.

We must remember that sweeping change occurs through the small efforts of many individuals. Just as no snowflake feels responsible for an avalanche, we are all responsible for shaping the clinical trial landscape with our decisions and actions. It's up to us to put patients at the center of everything we do. It's up to us to imbue "patient centricity" with real meaning.

Author

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