Are Clinical Trial Designs Becoming More Patient-Friendly?

Richard L. Schilsky, MD, FACP, FASCO, FSCT
Senior Vice President and Chief Medical Officer
ASCO

Mel Mann, MBA, M.Ed
Patient Advocate and Long Living #Gleevec Survivor

Cecelia Mann
Community Outreach Volunteer
The Leukemia & Lymphoma Society (LLS)

Andrew Schorr:
One other thing I think that needs to change is we talked about the scientists, whether they're federal government scientists or drug company scientists, and they want to get answers to a whole bunch of scientific questions. So they may say, as you write the protocol I think it is, well, you have to get so many CT scans, and you have to get so many blood tests and stuff like that. And it can become onerous,

What's happening in trial design so that, A, we talked about eligibility, you can get into the trial, but the things you're asking of me may have logistical hurdles as well that you're kind the lightening up on it to get to the key scientific question without all these other bells and whistles that make it tough on me.

Dr. Schilsky:
Yes. I like to think of it as the need to know and the nice to know, right? There are certain things you need to know in the trial to be sure that the treatment is working, the patient is safe and not having any severe side effects and things of that sort. A lot of that stuff is the same stuff that doctors order every day on their patients as part of routine clinical care, and so much of what needs to be collected in clinical trials really aligns pretty well with standard of care.

Now, that said, because clinical trials are research and because there's always new frontiers to explore, sometimes testing in a clinical trial extends beyond what the standard of care is. Sometimes patients are asked to give extra specimens of their blood, of their normal tissues, of their tumor tissues. Extra biopsies might be required, things of that sort. Patients need to understand why they're being asked to do that, what those specimens are going to be used for, how is it going to advance research.

And, frankly, they're very important to expanding the scope of the research. So, for example, oftentimes those specimens are used. If the treatment doesn't work in a patient, having those specimens can help the scientists understand why the treatment didn't work, and that opens up a whole new horizon to explore to potentially make the treatment better in other patients.

Andrew Schorr:
Mel, do you recognize that by being in a trial and the work that you and Cecelia have been doing that you've probably helped thousands of patients by first being in a trial and then you and Cecelia talking about it?

Mel Mann:
Yeah. Yeah. I guess that's kind of hard sometimes. You don't see yourself in that role, but as I look back on it, yes.

Andrew Schorr:
Cecelia, you've probably talked to a lot of people. Have you seen a change where—you've been doing this for a number of years where earlier on people said no, no, no. Are people more receptive? Do you see a change going on? Let's say in the African?American community, do you think people are a little more receptive?

Cecelia Mann:
Yes, I think so. I think they are more receptive, and this has a lot to do with education and awareness, and that's what we are out there doing when we are out there in the community. And the more they hear about it and the more they read about it and the more they can see examples like Melvin, and we know one or two other people that we've met that were also on a clinical trial. One is in our church, and he had a type of leukemia, and we didn't know why he was sick. But he is doing very well.

And so the more we can get those examples out there in the community of successful clinical trial patients, it really helps and goes a long way toward helping people of color relax and come aboard. And I just say, please, do your research, educate yourself and ask questions and please stay open and don't dismiss clinical trials out of hand.

Dr. Schilsky:
And, Andrew, if I could just add to that. I just want to make the point that it's people like Mel who are creating the future. Everything we know about how to treat cancer we learned from the people who participated in the clinical trials. We've been doing clinical trials in cancer for at least 70 years, and all of the standard of care treatments that we have today came from the participation of people in clinical trials. And that's how we make progress. That's how we'll continue to make progress.

So it's the clinical trial participants who, sure, they're in it for themselves. We understand that. They're looking for a new treatment, a better outcome, but they are the heroes of oncology because they are paving the way, trying the course and ultimately making a better future for every cancer patient who follows them.

Andrew Schorr:
Amen. Let me just recap a couple of things, and correct me if I get anything wrong, either of you. So, first of all, Dr. Schilsky, I know there are more trials now than ever before, and they're now looking at these rare subtypes as well, and so if we participate we may get the benefit of tomorrow's benefit today. Cecelia was talking about assistance programs, people to help you sort it out, that you are noticing how there are difference among us about the ways that drugs are effective or not, and that's so important to learn.

If we partner with you, Dr. Schilsky, and the many thousands of oncologists and researchers that you represent, can we get to the goal line faster? In other words, are you hopeful that if we really consider trials and participate in trials and stay in trials and the different groups that we can get closer to cancer cures?

Dr. Schilsky:
Absolutely. I mean, we have more and better cancer treatments today than we've ever had before. We have all sorts of new and hopeful treatments on the horizon. We have to prove that they are safe and effective treatments to get them out there into routine clinical practice, and that's where the clinical trials come in. So the more people who participate in trials the more quickly those trials can be completed and give us an answer, then the more quickly those drugs will make their way into standard clinical practice where everybody can benefit from them.