



Clinical Trial MythBusters: How Have Clinical Trials Evolved?

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Andrew Schorr:

Dr. Wakelee, we've gone through a transition in the way trials are run, and maybe the relationship between patients and sponsors and investigators now and the government, where I think there's a lot more dialogue, even now, in how a trial should be designed, they're asking patients about, "Would you be in a trial if it has this many CT scans or this many visits to the clinic, or etc." So, have we made a transition where the patient voice, do you feel now, is heard?

Dr. Wakelee:

Well, there are always different perceptions of that. As someone who's been caring for patients who have been participating in clinical trials for approaching two decades now, I don't think we were ever in a time where the patient voice wasn't heard. You know, patients have always been at the root of the trials, and the reason for doing the trials isn't just to develop the drug—it's to help more patients who have the disease, and I think it's important to remember that that's always been the basis of it.

I think that the awareness of asking patients, that has changed, and I think that the—most physicians obviously try very hard to establish very close relationship with their patients as they're trying to help them on their journey with their disease, and so from an individual patient-to-physician interaction, I don't think that's changed.

I think that, as we look at the trials, it's—what we're looking at has evolved some, so we do, for many of the trials, now, have questionnaires that are trying to get at the quality of life and side effects and some of the more subtle side effects that patients might be experiencing, and so, that's an important part of it, and there is more asking of patients in the design of the trials, to get some input there.

But honestly, the complexity of the trials, if anything, has increased, and the selectivity of some of the trials has increased, the complexity has increased, so from that perspective, I think in some ways we've made it harder, occasionally, for patients to participate than it was in the past.

At the same time, there's so many more studies available, and so many things that really are making improvements that we didn't really even dream about 15, even 10 years ago, so. Things always evolve, but I think that, you know, there are two sides to it at all times, too.

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