



Is Some Exclusion Criteria in Clinical Trials Causing Roadblocks?

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Dr. Thompson:

One problem is with the people developing the trials. They were too exclusionary. I was part of one article out of a six-article series in *JCO* about eligibility criteria. There was a study that looked at Kaiser. If we got rid of—there's a creatinine requirement, but the drug is not metabolized by the kidneys. If you get rid of all these things you don't need, they're just cut and pasted—make it much broader—get rid of the exclusions, you can get up to 30 percent higher accrual just with that.

Andrew Schorr:

So I want to mention something. We are working—Cindy, you are, and the International Myeloma Foundation—all of us are working to get patients involved in the dialogue with those of you who develop trials to talk about those things. Do you really need me to come to the clinic that often? Do I really need to get poked that much? Do you really need to measure that which isn't relevant in this? So to try to simplify this both in logistics and requirements so that we're not excluded.

Dr. Trikha:

We have an active effort right now at AbbVie where we're saying, "Why do you need that data? How do you use it in decision-making? How am I going—is it absolutely essential?" Sometimes, the other challenge—being candid with you folks—scientists love to ask questions. We want to do correlative study, because I want to be able to correlate, but how am I going to weed out the medicine that is not going to work?

I think if we could dial that out and say—so we're actively trying to participate—I call it "critical path thinking"—of looking at some of those aspects, and then...So sometimes, I say we need healthy data, we need a wealth of the right kind of data, but at the end of the day it's wisdom.

What wisdom do you create? What is that data teaching me so that my company can make these go/no-go decisions to advance a certain medicine or not?

Andrew Schorr:

We're going to give you wisdom. When we're in a trial, are we fatigued, are we in pain, are we nauseous, are we tired? Whatever it is, we want to tell you.

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