How Do I Increase My Confidence in Clinical Trials?

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Andrew Schorr:
I mentioned that there are people really around the world, around the Internet watching what we're doing. And they're sending in questions. Carol is our liaison with them. So, Carol, do you have a question from the Internet audience?

Carol Preston:
I do, actually, from a woman named Mary in New York. And I think it's a wonderful, interactive conversation on the benefits of clinical trials. But some people don't have the kind of access that many people in this room and others who are listening have. And there, obviously, is trepidation. So Mary who emails us from New York says that some patients, she didn't use names, she didn't say here, but think that Phase I trials are too risky.

And I believe, Dr. Carbone, you actually used the term guinea pig. Somebody said guinea pig. And a lot of people feel that way. So Phase I, risky, and Phase III, perhaps too random meaning can't get into it, hit or miss. Although, immunotherapy or immuno-oncology is more targeted.

Andrew Schorr:
And where you get to study medicine.

Carol Preston:
Yeah. And so how does a patient increase his or her confidence in these trials?

Dr. Antonia:
Let me just reinforce what David said before about Phase I trials. It's absolutely correct. We don't just pick these treatments out of thin air. Before they're ever given to a person in a Phase I trial, there are years and years of hard work and lots of thought put into these things. The FDA won't even approve it, nor would we even want it to be approved, if we didn't feel that there was some reasonable chance that it could help someone.

People on Phase I trials can benefit. Tom was on a Phase I clinical trial two-and-a-half years ago for stage IV lung cancer.

Andrew Schorr:
Where is Tom? Tom is right over here.

Dr. Antonia:
He remains in complete response. People can benefit greatly from participating in Phase I clinical trials.

Andrew Schorr:
So, David, I have a question for you though. Whether it's Phase I, Phase II, let's say Phase III, and you're studying new medicine like the one that was just approved and others you have in research against more standard approaches.

And I end up getting the standard approach. So I'm feeling left out maybe.

Dr. Carbone:
Yeah. So, unfortunately, really the only way we prove one therapy is better than another is through randomized trials. And it is, a fact, that often randomized trials don't give you or your doctor the choice.

That's the definition of a randomized trial. You don't have a choice. You get randomized to one treatment or another. But the fact is that these trials are very carefully designed so that, even in both arms, the treatment is felt to be safe and efficacious in these trials. And sometimes what's thought to be better actually isn't. And there have been examples of cases where the standard treatment is better than the new treatment.

So I think it's an important part of figuring out for future lung cancer patients which treatment is better. But also, we often are designing our randomized trials with what's called a crossover. For example, the trial that's testing this nivolumab (OPDIVO®) antibody in first line as a first treatment for lung cancer randomized to chemotherapy.

The fact is that when the chemotherapy stops working that people are allowed to cross over to the immune therapy. So even in a randomized trial, we try very hard to give every patient the maximum possible benefit.

Andrew Schorr:
Okay. One other question is so now you're doing all of these trials. You still have a ways to go to figure out which drug when for which person. So you're still trying to figure out, it's like a piano.

And it sounds like you're getting more notes on the piano added to chemotherapy radiation surgery. So you guys are the conductors. How are you deciding which for which person?

Dr. Carbone:
Well, there's an art to medicine, which I like to talk about. And people like Scott and myself who see only lung cancer patients day in and day out, we get a feel for the disease. And we often use treatment approaches that aren't exactly by the script.

And I have many examples of patients who were treated a little bit off-script, because that's just what I felt was the best treatment for them. And they've done very well. So with so many options, it's really impossible to do randomized trials comparing everything to everything else. And so I think, for the foreseeable future, we will have a big dependence upon experience and the art of medicine in picking these treatments.