Is Clinical Trial Participation Parallel to the Pace of Drug Development?

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Andrew Schorr:
Dr. Schilsky, let's talk about the pace of research. So, first of all, if we don't get enough participation in trials how does that slow drug development?

Dr. Schilsky:
Well, it slows it down enormously because we have to have a certain number of people in each trial to be able to get a reliable answer. And these days it's becoming even more challenging because as we're developing drugs that only target a specific genetic abnormality in the tumor which sometimes is very rare so we may be looking for a genetic abnormality that only occurs in 2 or 3 percent of all people with a certain kind of cancer. First you have to find the people who have that genetic abnormalities, then you have to be able to enroll them in a clinical trial. They have to be willing. They have to meet the enrollment criteria. So it can take a long time, and even a global effort to find enough people to fill out a clinical trial.

And most clinical trials in order to produce a reliable result are going to require a minimum of 50 to 100 patients. Some require many hundreds of patients or even many thousands of patients depending on the question being asked. So you can see if people are not participating it's going to take long time to get those answers.

Andrew Schorr:
Now, Mel, you got imatinib Gleevec in a trial at least three years before it was approved, and it was approved fast because it was such a breakthrough, right? So you literally got tomorrow's medicine today, and it saved your life in the process, right?

Mel Mann:

Yes, because I was past the three years. I was about three years and eight months in my diagnosis, so you add another three years onto that, and I would not have been here.

Andrew Schorr:
Right. In my case, I was in a trial related to chronic lymphocytic leukemia, three-drug combination, and I received that in a Phase II trial 10 years before that was approved. So it was a long time.