

WEBVTT

00:00:00.000 --> 00:00:02.460 Support for Yale Cancer Answers

NOTE Confidence: 0.85388523

00:00:02.460 --> 00:00:04.920 comes from AstraZeneca, dedicated

NOTE Confidence: 0.85388523

00:00:04.999 --> 00:00:07.344 to advancing options and providing

NOTE Confidence: 0.85388523

00:00:07.344 --> 00:00:10.300 hope for people living with cancer.

NOTE Confidence: 0.85388523

00:00:10.300 --> 00:00:14.000 More information at [astrazeneca-us.com](http://astrazeneca-us.com).

NOTE Confidence: 0.85388523

00:00:14.000 --> 00:00:15.758 Welcome to Yale Cancer Answers

NOTE Confidence: 0.85388523

00:00:15.758 --> 00:00:17.166 with your host doctor

NOTE Confidence: 0.85388523

00:00:17.170 --> 00:00:19.627 Anees Chagpar. Yale Cancer Answers

NOTE Confidence: 0.85388523

00:00:19.630 --> 00:00:21.670 features the latest information on

NOTE Confidence: 0.85388523

00:00:21.670 --> 00:00:24.081 cancer care by welcoming oncologists and

NOTE Confidence: 0.85388523

00:00:24.081 --> 00:00:26.251 specialists who are on the forefront of

NOTE Confidence: 0.85388523

00:00:26.251 --> 00:00:28.430 the battle to fight cancer. This week,

NOTE Confidence: 0.85388523

00:00:28.430 --> 00:00:30.190 it's a conversation about experimental

NOTE Confidence: 0.85388523

00:00:30.190 --> 00:00:31.950 therapeutics with Doctor Pat LoRusso.

NOTE Confidence: 0.85388523

00:00:31.950 --> 00:00:33.942 Doctor LoRusso is a professor of

NOTE Confidence: 0.85388523

00:00:33.942 --> 00:00:36.529 medicine at the Yale School of Medicine,  
NOTE Confidence: 0.85388523

00:00:36.530 --> 00:00:39.764 where Doctor Chagpar is a professor  
NOTE Confidence: 0.85388523

00:00:39.764 --> 00:00:41.150 of surgical oncology.  
NOTE Confidence: 0.85388523

00:00:41.150 --> 00:00:41.580 Pat,  
NOTE Confidence: 0.875094

00:00:41.580 --> 00:00:44.164 maybe we can start off by you telling  
NOTE Confidence: 0.875094

00:00:44.164 --> 00:00:47.622 us a little bit more about what  
NOTE Confidence: 0.875094

00:00:47.622 --> 00:00:49.810 exactly is experimental therapeutics.  
NOTE Confidence: 0.875094

00:00:49.810 --> 00:00:52.288 It sounds so obscure and  
NOTE Confidence: 0.875094

00:00:52.288 --> 00:00:54.570 intellectual and scientific and strange.  
NOTE Confidence: 0.875094

00:00:54.570 --> 00:00:56.310 It isn't obscure for  
NOTE Confidence: 0.875094

00:00:56.310 --> 00:00:58.903 me. I think it is somewhat intellectual,  
NOTE Confidence: 0.875094

00:00:58.903 --> 00:01:01.030 and it is very scientific,  
NOTE Confidence: 0.875094

00:01:01.030 --> 00:01:04.940 and so I hope that I'll be able to  
NOTE Confidence: 0.875094

00:01:04.940 --> 00:01:07.992 explain to you what all that means.  
NOTE Confidence: 0.875094

00:01:08.000 --> 00:01:11.520 So with every cancer drug that we have,  
NOTE Confidence: 0.875094

00:01:11.520 --> 00:01:14.152 that we treat patients for, every cancer

NOTE Confidence: 0.875094

00:01:14.152 --> 00:01:15.930 drug that's commercially available,

NOTE Confidence: 0.875094

00:01:15.930 --> 00:01:19.620 it has to go through a series of testing not

NOTE Confidence: 0.875094

00:01:19.708 --> 00:01:23.148 only in the lab to identify its activity,

NOTE Confidence: 0.875094

00:01:23.150 --> 00:01:25.556 not only in other animal species,

NOTE Confidence: 0.875094

00:01:25.560 --> 00:01:28.178 to make sure that it is safe

NOTE Confidence: 0.875094

00:01:28.178 --> 00:01:29.970 to administer to humans,

NOTE Confidence: 0.875094

00:01:29.970 --> 00:01:31.970 which are called toxicology studies,

NOTE Confidence: 0.875094

00:01:31.970 --> 00:01:35.327 but then it has to go through a series

NOTE Confidence: 0.875094

00:01:35.327 --> 00:01:38.415 of tests in humans first to make

NOTE Confidence: 0.875094

00:01:38.415 --> 00:01:41.710 sure that the drug is safe to give,

NOTE Confidence: 0.875094

00:01:41.710 --> 00:01:44.668 and then to find

NOTE Confidence: 0.875094

00:01:44.668 --> 00:01:47.080 out how active it is,

NOTE Confidence: 0.875094

00:01:47.080 --> 00:01:49.520 either alone or in combination

NOTE Confidence: 0.875094

00:01:49.520 --> 00:01:51.960 with other agents.

NOTE Confidence: 0.875094

00:01:51.960 --> 00:01:55.470 So Phase one clinical trials

NOTE Confidence: 0.875094

00:01:55.470 --> 00:01:57.810 are essentially trials  
NOTE Confidence: 0.875094

00:01:57.905 --> 00:02:01.041 whereby a new drug is tested  
NOTE Confidence: 0.875094

00:02:01.041 --> 00:02:03.849 for the first time in humans.  
NOTE Confidence: 0.875094

00:02:05.782 --> 00:02:08.680 Although the primary objective of a  
NOTE Confidence: 0.875094

00:02:08.767 --> 00:02:11.871 phase one trial is actually to make sure  
NOTE Confidence: 0.875094

00:02:11.871 --> 00:02:15.189 that the drug is safe to give to humans.  
NOTE Confidence: 0.875094

00:02:15.190 --> 00:02:18.158 We are also looking for a lot  
NOTE Confidence: 0.875094

00:02:18.158 --> 00:02:20.229 of other endpoints as well.  
NOTE Confidence: 0.875094

00:02:20.230 --> 00:02:23.618 What kind of activity does it have  
NOTE Confidence: 0.875094

00:02:23.618 --> 00:02:25.670 against specific tumor types?  
NOTE Confidence: 0.875094

00:02:25.670 --> 00:02:28.477 How is the exposure of the drug  
NOTE Confidence: 0.875094

00:02:28.477 --> 00:02:31.645 in man relative to what we saw  
NOTE Confidence: 0.875094

00:02:31.645 --> 00:02:33.990 previously in various animal species  
NOTE Confidence: 0.875094

00:02:33.990 --> 00:02:37.296 and to assure that we have the  
NOTE Confidence: 0.875094

00:02:37.296 --> 00:02:39.302 utmost safety in these trials.  
NOTE Confidence: 0.875094

00:02:39.302 --> 00:02:42.179 Obviously all trials have to be approved

NOTE Confidence: 0.875094  
00:02:42.179 --> 00:02:44.869 by the Food and Drug Administration  
NOTE Confidence: 0.875094  
00:02:44.869 --> 00:02:47.870 before they can be initiated in humans,  
NOTE Confidence: 0.875094  
00:02:47.870 --> 00:02:51.110 and that is the same thing with a  
NOTE Confidence: 0.875094  
00:02:51.110 --> 00:02:54.278 phase one or first in human study.  
NOTE Confidence: 0.875094  
00:02:54.280 --> 00:02:56.124 But what they do  
NOTE Confidence: 0.875094  
00:02:56.124 --> 00:02:58.890 is based on animal trials previously  
NOTE Confidence: 0.875094  
00:02:58.976 --> 00:03:01.844 done with the agent and toxicology  
NOTE Confidence: 0.875094  
00:03:01.844 --> 00:03:05.210 studies that are also previously done.  
NOTE Confidence: 0.875094  
00:03:05.210 --> 00:03:08.096 The FDA works with the sponsor  
NOTE Confidence: 0.875094  
00:03:08.096 --> 00:03:11.180 or the drug company to identify  
NOTE Confidence: 0.875094  
00:03:11.180 --> 00:03:13.296 a safe starting dose.  
NOTE Confidence: 0.875094  
00:03:13.300 --> 00:03:16.835 A dose where we can feel quite  
NOTE Confidence: 0.875094  
00:03:16.835 --> 00:03:19.915 assured that giving that dose will  
NOTE Confidence: 0.875094  
00:03:19.915 --> 00:03:23.310 be safe to humans and to identify  
NOTE Confidence: 0.875094  
00:03:23.418 --> 00:03:27.058 what the most relevant dose will be  
NOTE Confidence: 0.875094

00:03:27.060 --> 00:03:30.126 to go into subsequent phase two and  
NOTE Confidence: 0.875094

00:03:30.126 --> 00:03:32.916 three trials and then hopefully to  
NOTE Confidence: 0.875094

00:03:32.916 --> 00:03:35.694 go into FDA approvals for standard  
NOTE Confidence: 0.875094

00:03:35.694 --> 00:03:37.510 of care treatment.  
NOTE Confidence: 0.875094

00:03:37.510 --> 00:03:40.162 We do various escalation steps along  
NOTE Confidence: 0.875094

00:03:40.162 --> 00:03:44.592 the way to identify a safe dose that  
NOTE Confidence: 0.875094

00:03:44.592 --> 00:03:47.960 can be subsequently brought into a phase  
NOTE Confidence: 0.875094

00:03:47.960 --> 00:03:50.340 two efficacy or a phase  
NOTE Confidence: 0.875094

00:03:50.340 --> 00:03:52.332 two comparative efficacy study  
NOTE Confidence: 0.875094

00:03:52.332 --> 00:03:55.320 which may take anywhere from 3 to  
NOTE Confidence: 0.875094

00:03:55.414 --> 00:03:57.649 10 or 12 escalation steps.  
NOTE Confidence: 0.875094

00:03:57.650 --> 00:03:59.890 So that we're gradually increasing  
NOTE Confidence: 0.875094

00:03:59.890 --> 00:04:02.949 the dose to the point where we  
NOTE Confidence: 0.875094

00:04:02.949 --> 00:04:05.893 identify what a safe dose is that can  
NOTE Confidence: 0.875094

00:04:05.976 --> 00:04:08.816 be subsequently advanced to other  
NOTE Confidence: 0.875094

00:04:08.816 --> 00:04:11.656 phases of clinical trial development.

00:04:15.080 --> 00:04:17.870 So this is really important work,  
NOTE Confidence: 0.88941705

00:04:17.870 --> 00:04:21.569 because this is how we get the drugs into  
NOTE Confidence: 0.88941705

00:04:21.569 --> 00:04:24.538 the clinics that actually provide the  
NOTE Confidence: 0.88941705

00:04:24.538 --> 00:04:28.559 cures that all of us want for cancer.  
NOTE Confidence: 0.88941705

00:04:28.560 --> 00:04:32.745 But it really starts very much in the lab,  
NOTE Confidence: 0.88941705

00:04:32.750 --> 00:04:35.753 so help me to understand and  
NOTE Confidence: 0.88941705

00:04:35.753 --> 00:04:38.330 help our listeners to understand  
NOTE Confidence: 0.88941705

00:04:38.330 --> 00:04:42.040 what goes into  
NOTE Confidence: 0.88941705

00:04:42.040 --> 00:04:44.308 getting a drug even into phase one  
NOTE Confidence: 0.88941705

00:04:44.308 --> 00:04:46.557 because as you describe it Phase  
NOTE Confidence: 0.88941705

00:04:46.557 --> 00:04:48.572 one clinical trials maybe seem  
NOTE Confidence: 0.88941705

00:04:48.572 --> 00:04:50.836 really scary to a lot of patients.  
NOTE Confidence: 0.88941705

00:04:50.840 --> 00:04:52.952 I mean this concept of being  
NOTE Confidence: 0.88941705

00:04:52.952 --> 00:04:54.360 quote first in man.  
NOTE Confidence: 0.88941705

00:04:54.360 --> 00:04:56.817 Many people are thinking  
NOTE Confidence: 0.88941705

00:04:56.820 --> 00:04:59.204 why would I want to be the first

NOTE Confidence: 0.88941705

00:04:59.204 --> 00:05:01.237 ones for you to experiment and

NOTE Confidence: 0.88941705

00:05:01.237 --> 00:05:03.799 see what is safe and what is

NOTE Confidence: 0.88941705

00:05:03.799 --> 00:05:05.979 tolerable and what is efficacious?

NOTE Confidence: 0.88941705

00:05:05.980 --> 00:05:08.724 So let's take a step back before that

NOTE Confidence: 0.88941705

00:05:08.724 --> 00:05:11.506 and kind of lay the groundwork for me

NOTE Confidence: 0.88941705

00:05:11.506 --> 00:05:14.418 in terms of what goes on before that.

NOTE Confidence: 0.88941705

00:05:14.420 --> 00:05:15.772 How do we get

NOTE Confidence: 0.88941705

00:05:15.772 --> 00:05:18.933 to the point of a phase one trial

NOTE Confidence: 0.88941705

00:05:18.933 --> 00:05:21.538 where you're presenting data to

NOTE Confidence: 0.8894367

00:05:21.540 --> 00:05:26.307 the FDA?

NOTE Confidence: 0.8894367

00:05:26.310 --> 00:05:29.650 First a drug is developed in the lab based on a

NOTE Confidence: 0.8894367

00:05:29.738 --> 00:05:33.410 scientific principle or a scientific concept.

NOTE Confidence: 0.8894367

00:05:33.410 --> 00:05:36.962 So I think the best way to describe

NOTE Confidence: 0.8894367

00:05:36.962 --> 00:05:40.066 it would be to use an example.

NOTE Confidence: 0.8894367

00:05:40.070 --> 00:05:42.290 So in many tumor types,

NOTE Confidence: 0.8894367



00:05:42.290 --> 00:05:44.510 primarily non small cell lung  
NOTE Confidence: 0.8894367

00:05:44.510 --> 00:05:46.286 cancer and colorectal cancer,  
NOTE Confidence: 0.8894367

00:05:46.290 --> 00:05:48.510 but other tumors as well,  
NOTE Confidence: 0.8894367

00:05:48.510 --> 00:05:52.694 there is a mutation called KRAS G12C.  
NOTE Confidence: 0.8894367

00:05:52.700 --> 00:05:55.964 And that mutation in large part drives that  
NOTE Confidence: 0.8894367

00:05:55.964 --> 00:05:59.167 tumor and makes it extremely aggressive.  
NOTE Confidence: 0.8894367

00:05:59.170 --> 00:06:01.390 It's taken many, many,  
NOTE Confidence: 0.8894367

00:06:01.390 --> 00:06:05.142 many years for chemists to develop a  
NOTE Confidence: 0.8894367

00:06:05.142 --> 00:06:09.435 drug that can target or inhibit that  
NOTE Confidence: 0.8894367

00:06:09.435 --> 00:06:12.650 mutation from continuing to allow  
NOTE Confidence: 0.8894367

00:06:12.650 --> 00:06:16.518 the tumor to multiply and divide.  
NOTE Confidence: 0.8894367

00:06:16.520 --> 00:06:18.984 So that drug probably  
NOTE Confidence: 0.8894367

00:06:18.984 --> 00:06:21.562 took about 20 years conservatively of  
NOTE Confidence: 0.8894367

00:06:21.562 --> 00:06:24.442 chemists working on trying to figure  
NOTE Confidence: 0.8894367

00:06:24.442 --> 00:06:27.099 out how to target that mutation,  
NOTE Confidence: 0.8894367

00:06:27.100 --> 00:06:29.004 which was extremely difficult

NOTE Confidence: 0.8894367

00:06:29.004 --> 00:06:32.288 because of the way that mutation is

NOTE Confidence: 0.8894367

00:06:32.288 --> 00:06:34.703 pocketed in the DNA of the tumor.

NOTE Confidence: 0.8894367

00:06:34.710 --> 00:06:38.756 Once they identify a compound that can

NOTE Confidence: 0.8894367

00:06:38.760 --> 00:06:41.166 bind to that mutation

NOTE Confidence: 0.8894367

00:06:41.166 --> 00:06:42.770 or attack that mutation,

NOTE Confidence: 0.8894367

00:06:42.770 --> 00:06:45.176 then they have to test it

NOTE Confidence: 0.8894367

00:06:45.180 --> 00:06:46.443 in animal models,

NOTE Confidence: 0.8894367

00:06:46.443 --> 00:06:48.969 tumors in animals that have that

NOTE Confidence: 0.8894367

00:06:48.969 --> 00:06:51.554 mutation to see whether or not the drug

NOTE Confidence: 0.8894367

00:06:51.554 --> 00:06:54.429 is going to work against those tumors

NOTE Confidence: 0.8894367

00:06:54.429 --> 00:06:56.804 inhibit those tumors from growing,

NOTE Confidence: 0.8894367

00:06:56.810 --> 00:06:59.456 preventing those tumors in animals from

NOTE Confidence: 0.8894367

00:06:59.456 --> 00:07:02.256 metastasizing or going beyond where

NOTE Confidence: 0.8894367

00:07:02.256 --> 00:07:04.656 the tumor was originally implanted.

NOTE Confidence: 0.8894367

00:07:04.660 --> 00:07:06.072 Once they do that,

NOTE Confidence: 0.8894367

00:07:06.072 --> 00:07:08.800 and identify that the drug is active,  
NOTE Confidence: 0.8894367

00:07:08.800 --> 00:07:11.411 then we have to take it into  
NOTE Confidence: 0.8894367

00:07:11.411 --> 00:07:13.705 toxicology studies where we test the  
NOTE Confidence: 0.8894367

00:07:13.705 --> 00:07:15.535 drug in different animal species  
NOTE Confidence: 0.8894367

00:07:15.535 --> 00:07:17.835 to make sure that  
NOTE Confidence: 0.8894367

00:07:17.835 --> 00:07:20.449 we can safely give  
NOTE Confidence: 0.8894367

00:07:20.449 --> 00:07:22.663 that drug to the animals without  
NOTE Confidence: 0.8894367

00:07:22.663 --> 00:07:24.958 causing side effects or harms,  
NOTE Confidence: 0.8894367

00:07:24.960 --> 00:07:27.588 and we usually have to do that in two  
NOTE Confidence: 0.8894367

00:07:27.588 --> 00:07:30.229 or three different animal species,  
NOTE Confidence: 0.8894367

00:07:30.230 --> 00:07:32.480 depending on what the drug is.  
NOTE Confidence: 0.8894367

00:07:32.480 --> 00:07:34.832 But back in the olden days I call  
NOTE Confidence: 0.8894367

00:07:34.832 --> 00:07:37.463 it when I first started doing  
NOTE Confidence: 0.8894367

00:07:37.463 --> 00:07:38.939 clinical drug development,  
NOTE Confidence: 0.8894367

00:07:38.940 --> 00:07:41.898 during development of drugs in humans,  
NOTE Confidence: 0.8894367

00:07:41.900 --> 00:07:44.480 we didn't have the scientific

NOTE Confidence: 0.8894367

00:07:44.480 --> 00:07:48.071 basis that we have today and today

NOTE Confidence: 0.8894367

00:07:48.071 --> 00:07:51.263 there's a lot of science that is

NOTE Confidence: 0.8894367

00:07:51.270 --> 00:07:53.730 driving new drug

NOTE Confidence: 0.8894367

00:07:53.730 --> 00:07:55.698 discoveries in the lab,

NOTE Confidence: 0.8894367

00:07:55.700 --> 00:07:57.784 especially with targeted drugs

NOTE Confidence: 0.8894367

00:07:57.784 --> 00:08:00.910 because of the fact that unveiling

NOTE Confidence: 0.8894367

00:08:00.991 --> 00:08:03.637 the human genome several years ago

NOTE Confidence: 0.8894367

00:08:03.637 --> 00:08:06.503 allowed us to better understand the

NOTE Confidence: 0.8894367

00:08:06.503 --> 00:08:09.569 differences between the DNA and RNA.

NOTE Confidence: 0.8894367

00:08:09.570 --> 00:08:12.658 In tumors versus the DNA and RNA in

NOTE Confidence: 0.8894367

00:08:12.658 --> 00:08:15.640 the normal human and what we had to

NOTE Confidence: 0.8894367

00:08:15.640 --> 00:08:18.700 go after in those tumors to prevent

NOTE Confidence: 0.8894367

00:08:18.700 --> 00:08:21.826 them from growing and hopefully from

NOTE Confidence: 0.8894367

00:08:21.826 --> 00:08:24.585 prevent them eventually from even coming

NOTE Confidence: 0.8894367

00:08:24.585 --> 00:08:27.890 about in patients that may be high risk,

NOTE Confidence: 0.8894367

00:08:27.890 --> 00:08:29.382 such as in prevention,  
NOTE Confidence: 0.8894367

00:08:29.382 --> 00:08:32.198 but no matter where the drug ends  
NOTE Confidence: 0.8894367

00:08:32.198 --> 00:08:34.698 up treating advanced stage patients,  
NOTE Confidence: 0.8894367

00:08:34.700 --> 00:08:36.404 patients that have cancer  
NOTE Confidence: 0.8894367

00:08:36.404 --> 00:08:37.256 that's metastasized,  
NOTE Confidence: 0.8894367

00:08:37.260 --> 00:08:39.816 or patients that have had cancer,  
NOTE Confidence: 0.8894367

00:08:39.820 --> 00:08:42.070 but we've removed the tumor.  
NOTE Confidence: 0.8894367

00:08:42.070 --> 00:08:44.638 And we want to prevent the  
NOTE Confidence: 0.8894367

00:08:44.638 --> 00:08:46.350 cancer from coming back.  
NOTE Confidence: 0.8894367

00:08:46.350 --> 00:08:49.486 Every drug that's given to humans in  
NOTE Confidence: 0.8894367

00:08:49.486 --> 00:08:52.446 a general oncology office has to at  
NOTE Confidence: 0.8894367

00:08:52.446 --> 00:08:55.264 first be tested in early phase clinical  
NOTE Confidence: 0.8894367

00:08:55.264 --> 00:08:58.330 trials and back in the olden days.  
NOTE Confidence: 0.8894367

00:08:58.330 --> 00:08:59.036 You know,  
NOTE Confidence: 0.8894367

00:08:59.036 --> 00:09:01.507 we tested a lot of drugs based  
NOTE Confidence: 0.8894367

00:09:01.507 --> 00:09:03.910 on just these high throughput

NOTE Confidence: 0.8894367

00:09:03.910 --> 00:09:06.862 screens in mouse models without a

NOTE Confidence: 0.8902892

00:09:06.949 --> 00:09:09.892 lot of science, there was science there,

NOTE Confidence: 0.8902892

00:09:09.892 --> 00:09:12.602 but today, in 2021 the science

NOTE Confidence: 0.8902892

00:09:12.602 --> 00:09:14.917 has advanced much more

NOTE Confidence: 0.8902892

00:09:14.920 --> 00:09:17.095 that we are even selecting

NOTE Confidence: 0.8902892

00:09:17.095 --> 00:09:18.835 out certain tumor types.

NOTE Confidence: 0.8902892

00:09:18.840 --> 00:09:20.905 Patients that have certain types

NOTE Confidence: 0.8902892

00:09:20.905 --> 00:09:23.640 of cancers based on the science.

NOTE Confidence: 0.8902892

00:09:23.640 --> 00:09:26.405 Because we know even in phase one

NOTE Confidence: 0.8902892

00:09:26.405 --> 00:09:29.385 trials that we may have a greater

NOTE Confidence: 0.8902892

00:09:29.385 --> 00:09:32.517 chance of response and benefit if we

NOTE Confidence: 0.8902892

00:09:32.517 --> 00:09:35.409 only treat patients with those tumors.

NOTE Confidence: 0.8902892

00:09:35.410 --> 00:09:38.690 Going back to the KRAS G12C mutation

NOTE Confidence: 0.8902892

00:09:38.690 --> 00:09:42.819 that I was talking about a few minutes ago,

NOTE Confidence: 0.8902892

00:09:42.820 --> 00:09:46.468 we only included in those phase one trials

NOTE Confidence: 0.8902892

00:09:46.470 --> 00:09:49.776 patients that we knew whose  
NOTE Confidence: 0.8902892

00:09:49.776 --> 00:09:53.329 tumors had that mutation and in non  
NOTE Confidence: 0.8902892

00:09:53.329 --> 00:09:56.825 small cell lung cancer in a phase one  
NOTE Confidence: 0.8902892

00:09:56.825 --> 00:10:00.150 trial we were seeing close to 70-75%  
NOTE Confidence: 0.8902892

00:10:00.150 --> 00:10:03.138 tumor response and in colon cancer,  
NOTE Confidence: 0.8902892

00:10:03.138 --> 00:10:06.162 in patients who had colon cancer  
NOTE Confidence: 0.8902892

00:10:06.162 --> 00:10:09.438 that had the KRAS G12 C mutation,  
NOTE Confidence: 0.8902892

00:10:09.440 --> 00:10:12.856 we were seeing responses about 40 to  
NOTE Confidence: 0.8902892

00:10:12.856 --> 00:10:16.222 50% and many of those patients had a  
NOTE Confidence: 0.8902892

00:10:16.222 --> 00:10:20.198 lot of prior treatments either immunotherapy,  
NOTE Confidence: 0.8902892

00:10:20.200 --> 00:10:20.689 chemotherapy,  
NOTE Confidence: 0.8902892

00:10:20.689 --> 00:10:24.601 or both and yet despite having all those  
NOTE Confidence: 0.8902892

00:10:24.601 --> 00:10:27.220 different cancers be treatments because  
NOTE Confidence: 0.8902892

00:10:27.220 --> 00:10:30.292 their cancers had that one mutation,  
NOTE Confidence: 0.8902892

00:10:30.300 --> 00:10:33.198 there was significant benefit as early  
NOTE Confidence: 0.8902892

00:10:33.198 --> 00:10:36.918 as in the Phase one clinical trial.

NOTE Confidence: 0.8902892

00:10:36.920 --> 00:10:39.460 So even though these trials

NOTE Confidence: 0.8902892

00:10:39.460 --> 00:10:40.984 are primarily toxicity

NOTE Confidence: 0.8902892

00:10:40.990 --> 00:10:43.078 finding studies and finding

NOTE Confidence: 0.8902892

00:10:43.078 --> 00:10:45.688 the recommended phase two dose

NOTE Confidence: 0.8902892

00:10:45.688 --> 00:10:48.120 many times in these trials,

NOTE Confidence: 0.8902892

00:10:48.120 --> 00:10:51.410 if we have a specific target that

NOTE Confidence: 0.8902892

00:10:51.410 --> 00:10:54.537 we're targeting and we can identify

NOTE Confidence: 0.8902892

00:10:54.537 --> 00:10:57.789 patients whose tumors have that target,

NOTE Confidence: 0.8902892

00:10:57.790 --> 00:11:00.475 there is a potential therapeutic

NOTE Confidence: 0.8902892

00:11:00.475 --> 00:11:02.623 benefit for those patients

NOTE Confidence: 0.8902892

00:11:02.630 --> 00:11:05.294 either in terms of their tumors

NOTE Confidence: 0.8902892

00:11:05.294 --> 00:11:07.535 shrinking or staying stable for

NOTE Confidence: 0.8902892

00:11:07.535 --> 00:11:09.480 a prolonged period of time,

NOTE Confidence: 0.8902892

00:11:09.480 --> 00:11:12.469 even at some of the lower doses,

NOTE Confidence: 0.8902892

00:11:12.470 --> 00:11:14.170 because as I said,

NOTE Confidence: 0.8902892



00:11:14.170 --> 00:11:17.609 we have to start low and go high,  
NOTE Confidence: 0.8902892

00:11:17.610 --> 00:11:21.026 and with the initial drug that targeted  
NOTE Confidence: 0.8902892

00:11:21.030 --> 00:11:23.195 KRAS G12C, responses were seen  
NOTE Confidence: 0.8902892

00:11:23.195 --> 00:11:25.740 regardless of what the dose was,  
NOTE Confidence: 0.8902892

00:11:25.740 --> 00:11:27.408 which is extremely encouraging  
NOTE Confidence: 0.8902892

00:11:27.408 --> 00:11:29.910 and that drug is moving forward  
NOTE Confidence: 0.8902892

00:11:29.980 --> 00:11:31.728 hopefully to FDA approval.  
NOTE Confidence: 0.89674205

00:11:32.660 --> 00:11:35.264 So I think that there's a few  
NOTE Confidence: 0.89674205

00:11:35.264 --> 00:11:37.768 things there that you said that  
NOTE Confidence: 0.89674205

00:11:37.768 --> 00:11:39.943 are so important to highlight,  
NOTE Confidence: 0.89674205

00:11:39.950 --> 00:11:42.204 one of which is that our ability  
NOTE Confidence: 0.89674205

00:11:42.204 --> 00:11:45.330 now to figure out what the exact  
NOTE Confidence: 0.89674205

00:11:45.330 --> 00:11:47.981 mutations are and to develop drugs  
NOTE Confidence: 0.89674205

00:11:47.981 --> 00:11:50.476 that will target those mutations  
NOTE Confidence: 0.89674205

00:11:50.480 --> 00:11:52.100 really not only benefits  
NOTE Confidence: 0.89674205

00:11:52.100 --> 00:11:54.568 patients in terms of

NOTE Confidence: 0.89674205  
00:11:54.568 --> 00:11:57.112 lack of side effects and potential  
NOTE Confidence: 0.89674205  
00:11:57.112 --> 00:11:59.521 better efficacy of a drug that  
NOTE Confidence: 0.89674205  
00:11:59.521 --> 00:12:01.005 targets a particular tumor,  
NOTE Confidence: 0.89674205  
00:12:01.010 --> 00:12:03.130 but it also really encourages  
NOTE Confidence: 0.89674205  
00:12:03.130 --> 00:12:04.826 patients to participate in  
NOTE Confidence: 0.89674205  
00:12:04.826 --> 00:12:06.890 clinical trials because you know  
NOTE Confidence: 0.89674205  
00:12:06.890 --> 00:12:10.186 that that drug, at least in animal models,  
NOTE Confidence: 0.89674205  
00:12:10.190 --> 00:12:12.668 has been shown to be efficacious  
NOTE Confidence: 0.89674205  
00:12:12.668 --> 00:12:14.320 against that particular mutation,  
NOTE Confidence: 0.89674205  
00:12:14.320 --> 00:12:16.798 and at least in animal models,  
NOTE Confidence: 0.89674205  
00:12:16.800 --> 00:12:18.448 doesn't have high toxicity.  
NOTE Confidence: 0.89674205  
00:12:18.448 --> 00:12:19.684 And so Pat,  
NOTE Confidence: 0.89674205  
00:12:19.690 --> 00:12:21.710 when you're designing a phase  
NOTE Confidence: 0.89674205  
00:12:21.710 --> 00:12:23.730 one trial and thinking about  
NOTE Confidence: 0.89674205  
00:12:23.800 --> 00:12:25.890 the patients who are eligible,  
NOTE Confidence: 0.89674205

00:12:25.890 --> 00:12:29.322 I think the other thing that was really  
NOTE Confidence: 0.89674205

00:12:29.322 --> 00:12:32.333 critical that you said was not only  
NOTE Confidence: 0.89674205

00:12:32.333 --> 00:12:34.970 how you target the population to  
NOTE Confidence: 0.89674205

00:12:34.970 --> 00:12:36.622 those patients who could  
NOTE Confidence: 0.89674205

00:12:36.622 --> 00:12:38.274 potentially benefit from this,  
NOTE Confidence: 0.89674205

00:12:38.280 --> 00:12:39.104 for example,  
NOTE Confidence: 0.89674205

00:12:39.104 --> 00:12:41.591 those who have a specific mutation.  
NOTE Confidence: 0.89674205

00:12:41.591 --> 00:12:44.538 But also those for whom  
NOTE Confidence: 0.89674205

00:12:44.538 --> 00:12:46.958 standard of care may be falling  
NOTE Confidence: 0.89674205

00:12:46.958 --> 00:12:49.707 short where there may not be other  
NOTE Confidence: 0.89674205

00:12:49.707 --> 00:12:51.812 options who have been through  
NOTE Confidence: 0.89674205

00:12:51.812 --> 00:12:54.368 a number of series of different  
NOTE Confidence: 0.89674205

00:12:54.368 --> 00:12:56.972 regiments and have come to exhaust  
NOTE Confidence: 0.89674205

00:12:56.972 --> 00:12:59.682 standard of care options tell us more  
NOTE Confidence: 0.89674205

00:12:59.682 --> 00:13:02.319 about how you go about designing a  
NOTE Confidence: 0.89674205

00:13:02.319 --> 00:13:05.098 phase one trial in terms of who's

NOTE Confidence: 0.89674205

00:13:05.098 --> 00:13:07.500 eligible and how

NOTE Confidence: 0.89674205

00:13:07.500 --> 00:13:10.181 many patients are eligible and how

NOTE Confidence: 0.89674205

00:13:10.181 --> 00:13:13.628 you kind of figure out how many patients

NOTE Confidence: 0.89674205

00:13:13.630 --> 00:13:15.688 you need to have on that trial

NOTE Confidence: 0.89674205

00:13:15.688 --> 00:13:17.788 to get the information that you

NOTE Confidence: 0.89674205

00:13:17.788 --> 00:13:20.448 need before you can open this up

NOTE Confidence: 0.89674205

00:13:20.528 --> 00:13:23.170 to wider clinical trials?

NOTE Confidence: 0.90262944

00:13:23.170 --> 00:13:25.180 Right, so first of all,

NOTE Confidence: 0.90262944

00:13:25.180 --> 00:13:27.388 there are a limited number of

NOTE Confidence: 0.90262944

00:13:27.388 --> 00:13:29.885 patients that go on the phase

NOTE Confidence: 0.90262944

00:13:29.885 --> 00:13:32.250 one trials because we're really

NOTE Confidence: 0.90262944

00:13:32.250 --> 00:13:34.441 looking for potential side effects

NOTE Confidence: 0.90262944

00:13:34.441 --> 00:13:37.201 of the drug to make sure that the

NOTE Confidence: 0.90262944

00:13:37.210 --> 00:13:40.010 drug is safe to give to patients.

NOTE Confidence: 0.90262944

00:13:40.010 --> 00:13:42.635 So we slowly increase the dose will

NOTE Confidence: 0.90262944

00:13:42.635 --> 00:13:45.462 treat one to three patients and we'll  
NOTE Confidence: 0.90262944

00:13:45.462 --> 00:13:48.384 have to get them through at least  
NOTE Confidence: 0.90262944

00:13:48.384 --> 00:13:50.820 three to six weeks of treatment  
NOTE Confidence: 0.90262944

00:13:50.820 --> 00:13:53.628 before we then can increase the dose  
NOTE Confidence: 0.90262944

00:13:53.628 --> 00:13:56.010 and add another one to three  
NOTE Confidence: 0.90262944

00:13:56.089 --> 00:13:57.877 patients as an example.  
NOTE Confidence: 0.8671301

00:13:59.590 --> 00:14:01.795 And so I wanted to pick up  
NOTE Confidence: 0.8671301

00:14:01.795 --> 00:14:04.374 on all of the things that we  
NOTE Confidence: 0.8671301

00:14:04.374 --> 00:14:07.130 look at in terms of Phase one,  
NOTE Confidence: 0.8671301

00:14:07.130 --> 00:14:09.314 clinical trials and how we actually  
NOTE Confidence: 0.8671301

00:14:09.314 --> 00:14:11.464 get these drugs to market right  
NOTE Confidence: 0.8671301

00:14:11.464 --> 00:14:13.324 after we take a short break  
NOTE Confidence: 0.8671301

00:14:13.324 --> 00:14:15.029 for a medical minute.  
NOTE Confidence: 0.8671301

00:14:15.030 --> 00:14:16.458 Please stay tuned to  
NOTE Confidence: 0.8671301

00:14:16.460 --> 00:14:18.889 learn more with my guest Doctor Pat LoRusso.  
NOTE Confidence: 0.8671301

00:14:18.889 --> 00:14:21.203 Support for Yale Cancer Answers

NOTE Confidence: 0.8671301

00:14:21.203 --> 00:14:23.621 comes from AstraZeneca, working to

NOTE Confidence: 0.8671301

00:14:23.621 --> 00:14:25.800 eliminate cancer as a cause of death.

NOTE Confidence: 0.8671301

00:14:25.800 --> 00:14:29.028 Learn more at [astrazeneca-us.com](http://astrazeneca-us.com).

NOTE Confidence: 0.8671301

00:14:29.030 --> 00:14:31.115 This is a medical minute

NOTE Confidence: 0.8671301

00:14:31.115 --> 00:14:32.366 about smoking cessation.

NOTE Confidence: 0.8671301

00:14:32.370 --> 00:14:34.450 There are many obstacles to

NOTE Confidence: 0.8671301

00:14:34.450 --> 00:14:36.114 face when quitting smoking

NOTE Confidence: 0.8671301

00:14:36.120 --> 00:14:39.039 as smoking involves the potent drug nicotine.

NOTE Confidence: 0.8671301

00:14:39.040 --> 00:14:41.959 But it's a very important lifestyle change,

NOTE Confidence: 0.8671301

00:14:41.960 --> 00:14:43.208 especially for patients

NOTE Confidence: 0.8671301

00:14:43.208 --> 00:14:44.456 undergoing cancer treatment.

NOTE Confidence: 0.8671301

00:14:44.460 --> 00:14:46.704 Quitting smoking has been shown to

NOTE Confidence: 0.8671301

00:14:46.704 --> 00:14:48.739 positively impact response to treatments

NOTE Confidence: 0.8671301

00:14:48.739 --> 00:14:51.109 decrease the likelihood that patients

NOTE Confidence: 0.8671301

00:14:51.109 --> 00:14:53.005 will develop second malignancies

NOTE Confidence: 0.8671301

00:14:53.065 --> 00:14:54.880 and increase rates of survival.

NOTE Confidence: 0.8671301

00:14:54.880 --> 00:14:56.520 Tobacco treatment programs are

NOTE Confidence: 0.8671301

00:14:56.520 --> 00:14:58.570 currently being offered at federally

NOTE Confidence: 0.8671301

00:14:58.570 --> 00:15:00.559 designated Comprehensive cancer centers

NOTE Confidence: 0.8671301

00:15:00.560 --> 00:15:02.290 and operate on the principles

NOTE Confidence: 0.8671301

00:15:02.290 --> 00:15:04.688 of the US Public Health Service

NOTE Confidence: 0.8671301

00:15:04.688 --> 00:15:06.497 Clinical Practice guidelines.

NOTE Confidence: 0.8671301

00:15:06.500 --> 00:15:08.610 All treatment components are evidence

NOTE Confidence: 0.8671301

00:15:08.610 --> 00:15:11.165 based and therefore all patients are

NOTE Confidence: 0.8671301

00:15:11.165 --> 00:15:13.475 treated with FDA approved first line

NOTE Confidence: 0.8671301

00:15:13.475 --> 00:15:15.603 medications for smoking cessation as

NOTE Confidence: 0.8671301

00:15:15.603 --> 00:15:17.863 well as smoking cessation counseling

NOTE Confidence: 0.8671301

00:15:17.863 --> 00:15:20.240 that stresses appropriate coping skills.

NOTE Confidence: 0.8671301

00:15:20.240 --> 00:15:22.790 More information is available at

NOTE Confidence: 0.8671301

00:15:22.790 --> 00:15:24.320 yalecancercenter.org. You're listening

NOTE Confidence: 0.8671301

00:15:24.380 --> 00:15:26.060 to Connecticut Public Radio.

NOTE Confidence: 0.8671301  
00:15:26.060 --> 00:15:26.420 Welcome  
NOTE Confidence: 0.8464511  
00:15:26.420 --> 00:15:28.240 back to Yale Cancer Answers.  
NOTE Confidence: 0.8464511  
00:15:28.240 --> 00:15:30.220 This is doctor Anees Chagpar  
NOTE Confidence: 0.8464511  
00:15:30.220 --> 00:15:32.410 and I'm joined tonight by  
NOTE Confidence: 0.8464511  
00:15:32.410 --> 00:15:34.405 my guest doctor Pat LoRusso.  
NOTE Confidence: 0.8464511  
00:15:34.410 --> 00:15:35.496 We're talking about  
NOTE Confidence: 0.8464511  
00:15:35.496 --> 00:15:36.220 experimental therapeutics,  
NOTE Confidence: 0.8464511  
00:15:36.220 --> 00:15:38.040 and phase one clinical trials,  
NOTE Confidence: 0.8464511  
00:15:38.040 --> 00:15:39.850 and right before the break,  
NOTE Confidence: 0.8464511  
00:15:39.850 --> 00:15:42.335 Pat, we were talking about how you  
NOTE Confidence: 0.8464511  
00:15:42.335 --> 00:15:44.568 go about designing these phase one  
NOTE Confidence: 0.8464511  
00:15:44.570 --> 00:15:46.784 first in man clinical trials and  
NOTE Confidence: 0.8464511  
00:15:46.784 --> 00:15:49.289 we were talking about the fact that,  
NOTE Confidence: 0.8464511  
00:15:49.290 --> 00:15:52.550 you know, it seems to me to be a little  
NOTE Confidence: 0.8464511  
00:15:52.643 --> 00:15:56.075 less scary than it was in previous years.  
NOTE Confidence: 0.8464511



00:15:56.080 --> 00:15:58.943 Because drugs these days are so much  
NOTE Confidence: 0.8464511

00:15:58.943 --> 00:16:01.800 more targeted and there is a lot of  
NOTE Confidence: 0.8464511

00:16:01.800 --> 00:16:03.910 regulation and a lot of preclinical  
NOTE Confidence: 0.8464511

00:16:03.910 --> 00:16:06.766 work in terms of animal studies,  
NOTE Confidence: 0.8464511

00:16:06.770 --> 00:16:09.360 that goes into really making sure that  
NOTE Confidence: 0.8464511

00:16:09.360 --> 00:16:12.319 these drugs are efficacious and not toxic,  
NOTE Confidence: 0.8464511

00:16:12.320 --> 00:16:14.840 at least in a couple of animals  
NOTE Confidence: 0.8464511

00:16:14.840 --> 00:16:16.882 species before it ever hits  
NOTE Confidence: 0.8464511

00:16:16.882 --> 00:16:18.646 phase one clinical trials.  
NOTE Confidence: 0.8464511

00:16:18.650 --> 00:16:21.778 But you were starting to tell us right  
NOTE Confidence: 0.8464511

00:16:21.778 --> 00:16:25.000 before the break about how you design  
NOTE Confidence: 0.8464511

00:16:25.000 --> 00:16:27.355 these phase one clinical trials.  
NOTE Confidence: 0.8464511

00:16:27.360 --> 00:16:29.410 How many patients you involve,  
NOTE Confidence: 0.8464511

00:16:29.410 --> 00:16:31.460 what your inclusion criteria are,  
NOTE Confidence: 0.8464511

00:16:31.460 --> 00:16:33.510 the safeguards that you put  
NOTE Confidence: 0.8464511

00:16:33.510 --> 00:16:34.740 around these trials.

NOTE Confidence: 0.8464511

00:16:34.740 --> 00:16:37.200 Because still, for some patients,

NOTE Confidence: 0.8464511

00:16:37.200 --> 00:16:39.624 this may seem really scary and

NOTE Confidence: 0.8464511

00:16:39.624 --> 00:16:42.529 often is used as a last resort,

NOTE Confidence: 0.8464511

00:16:42.530 --> 00:16:43.679 so can you

NOTE Confidence: 0.8464511

00:16:43.679 --> 00:16:47.858 talk a little bit about that?

NOTE Confidence: 0.8464511

00:16:47.860 --> 00:16:48.680 Oh yes,

NOTE Confidence: 0.8726229

00:16:48.680 --> 00:16:51.140 absolutely. And thank you for the

NOTE Confidence: 0.8726229

00:16:51.140 --> 00:16:54.416 opportunity to do so. So to begin with,

NOTE Confidence: 0.8726229

00:16:54.416 --> 00:16:57.749 how do we design these trials.

NOTE Confidence: 0.8726229

00:16:57.750 --> 00:17:01.170 In terms of finding the dose that we want to

NOTE Confidence: 0.8726229

00:17:01.248 --> 00:17:04.584 start with and how we're going to escalate,

NOTE Confidence: 0.8726229

00:17:04.590 --> 00:17:07.565 that pretty much comes from the toxicology

NOTE Confidence: 0.8726229

00:17:07.565 --> 00:17:10.217 studies that we've done before we get

NOTE Confidence: 0.8726229

00:17:10.217 --> 00:17:12.949 into the clinic before we go in demand.

NOTE Confidence: 0.8726229

00:17:12.950 --> 00:17:15.230 But also exposure of the drug.

NOTE Confidence: 0.8726229

00:17:15.230 --> 00:17:18.062 So what was the exposure that was needed  
NOTE Confidence: 0.8726229

00:17:18.062 --> 00:17:20.739 in the various model systems that we  
NOTE Confidence: 0.8726229

00:17:20.739 --> 00:17:23.880 used in order to see benefit to see  
NOTE Confidence: 0.8726229

00:17:23.880 --> 00:17:26.624 the tumor regress either in the mouse  
NOTE Confidence: 0.8726229

00:17:26.630 --> 00:17:29.758 models or in the in vitro Petri dishes?  
NOTE Confidence: 0.8726229

00:17:30.486 --> 00:17:33.870 Because we know that we have to start safe.  
NOTE Confidence: 0.8726229

00:17:33.870 --> 00:17:36.494 But we also want to make sure that  
NOTE Confidence: 0.8726229

00:17:36.494 --> 00:17:39.476 we can get to an adequate exposure,  
NOTE Confidence: 0.8726229

00:17:39.480 --> 00:17:41.350 because if we can't get  
NOTE Confidence: 0.8726229

00:17:41.350 --> 00:17:42.846 to an adequate exposure,  
NOTE Confidence: 0.8726229

00:17:42.850 --> 00:17:45.856 we are concerned that we may not see the  
NOTE Confidence: 0.8726229

00:17:45.856 --> 00:17:48.314 benefit and oftentimes there is a very  
NOTE Confidence: 0.8726229

00:17:48.314 --> 00:17:51.079 large what we call therapeutic window,  
NOTE Confidence: 0.8726229

00:17:51.080 --> 00:17:54.450 a window or a dose at which we started to  
NOTE Confidence: 0.8726229

00:17:54.538 --> 00:17:58.093 see activity to a dose where we saw side  
NOTE Confidence: 0.8726229

00:17:58.093 --> 00:18:01.289 effects in animals and

NOTE Confidence: 0.8726229

00:18:01.290 --> 00:18:04.602 the easier it is for us to identify how

NOTE Confidence: 0.8726229

00:18:04.602 --> 00:18:07.905 fast we're going to increase our doses.

NOTE Confidence: 0.8726229

00:18:07.910 --> 00:18:11.591 Another thing is we look at the inclusion and

NOTE Confidence: 0.8726229

00:18:11.591 --> 00:18:14.536 exclusion criteria and in terms of toxicity,

NOTE Confidence: 0.8726229

00:18:14.540 --> 00:18:18.092 if we know that the drug preclinically in

NOTE Confidence: 0.8726229

00:18:18.092 --> 00:18:21.579 animals led to some type of a side effect,

NOTE Confidence: 0.8726229

00:18:21.580 --> 00:18:24.064 we have to select out our

NOTE Confidence: 0.8726229

00:18:24.064 --> 00:18:25.720 patients based on that,

NOTE Confidence: 0.8726229

00:18:25.720 --> 00:18:28.480 or do some additional tests to make sure

NOTE Confidence: 0.8726229

00:18:28.480 --> 00:18:31.680 we can hopefully safeguard patients and

NOTE Confidence: 0.8726229

00:18:31.680 --> 00:18:34.008 follow them closely so that

NOTE Confidence: 0.8726229

00:18:34.008 --> 00:18:36.590 they don't have a side effect.

NOTE Confidence: 0.8726229

00:18:36.590 --> 00:18:39.250 But in terms of efficacy as well,

NOTE Confidence: 0.8726229

00:18:39.250 --> 00:18:40.770 it would not be

00:18:41.530 --> 00:18:44.298 in 2021 because we know so much more

NOTE Confidence: 0.8726229

00:18:44.298 --> 00:18:46.988 about the science and how the science

NOTE Confidence: 0.8726229

00:18:46.988 --> 00:18:49.510 is driving the tumor in humans,

NOTE Confidence: 0.8726229

00:18:49.510 --> 00:18:52.214 we want to select out patients that will

NOTE Confidence: 0.8726229

00:18:52.214 --> 00:18:54.829 have the greatest chance of benefit.

NOTE Confidence: 0.8726229

00:18:54.830 --> 00:18:57.371 So back 25 years ago when I

NOTE Confidence: 0.8726229

00:18:57.371 --> 00:18:59.390 started doing Phase one trials,

NOTE Confidence: 0.8726229

00:18:59.390 --> 00:19:02.810 we would do what we called all comer studies.

NOTE Confidence: 0.8726229

00:19:02.810 --> 00:19:05.090 All patients, regardless of the tumor,

NOTE Confidence: 0.8726229

00:19:05.090 --> 00:19:08.338 were allowed to go on phase one trials.

NOTE Confidence: 0.8726229

00:19:08.340 --> 00:19:10.825 Because we didn't know enough about the

NOTE Confidence: 0.8726229

00:19:10.825 --> 00:19:13.609 science that was driving particular tumors.

NOTE Confidence: 0.8726229

00:19:13.610 --> 00:19:15.962 And nowadays in 2021 it's not

NOTE Confidence: 0.8726229

00:19:15.962 --> 00:19:18.846 uncommon for us to design a trial

NOTE Confidence: 0.8726229

00:19:18.846 --> 00:19:21.300 that may only have two tumors,

NOTE Confidence: 0.8726229

00:19:21.300 --> 00:19:23.925 or maybe two tumors and a third

NOTE Confidence: 0.8726229

00:19:23.925 --> 00:19:26.768 arm of tumors that have a specific

NOTE Confidence: 0.8726229

00:19:26.768 --> 00:19:29.721 mutation an like the KRAS G12C  
NOTE Confidence: 0.8726229

00:19:29.721 --> 00:19:32.633 story that I was telling you about.  
NOTE Confidence: 0.8726229

00:19:32.640 --> 00:19:35.608 We knew that the primary tumors that  
NOTE Confidence: 0.8726229

00:19:35.608 --> 00:19:39.046 we needed to go after were the lung  
NOTE Confidence: 0.8726229

00:19:39.050 --> 00:19:41.840 tumors that were either lung cancer  
NOTE Confidence: 0.8726229

00:19:41.840 --> 00:19:44.275 or colon cancer that harbored  
NOTE Confidence: 0.8726229

00:19:44.275 --> 00:19:46.700 this KRAS G12C mutation.  
NOTE Confidence: 0.8726229

00:19:46.700 --> 00:19:49.682 But there are other tumors that  
NOTE Confidence: 0.8726229

00:19:49.682 --> 00:19:52.430 rarely harbor this mutation as well.  
NOTE Confidence: 0.8726229

00:19:52.430 --> 00:19:52.973 Cholangiocarcinoma,  
NOTE Confidence: 0.8726229

00:19:52.973 --> 00:19:56.774 you know various tumors and so we  
NOTE Confidence: 0.8726229

00:19:56.774 --> 00:20:00.186 allowed a third arm or a third  
NOTE Confidence: 0.8726229

00:20:00.190 --> 00:20:02.506 basket of tumors to be enrolled  
NOTE Confidence: 0.8726229

00:20:02.506 --> 00:20:04.524 of those different tumors that  
NOTE Confidence: 0.8726229

00:20:04.524 --> 00:20:06.148 might have that mutation.  
NOTE Confidence: 0.8726229

00:20:06.150 --> 00:20:06.546 Additionally,

NOTE Confidence: 0.8726229

00:20:06.546 --> 00:20:08.526 back in the olden days,

00:20:09.230 --> 00:20:12.030 we used to see patients that had failed

NOTE Confidence: 0.88815093

00:20:12.104 --> 00:20:14.454 everything, even drugs that really

NOTE Confidence: 0.88815093

00:20:14.454 --> 00:20:17.260 were not doing that much for them,

NOTE Confidence: 0.88815093

00:20:17.260 --> 00:20:19.240 but might have been FDA

NOTE Confidence: 0.88815093

00:20:19.240 --> 00:20:20.824 approved for commercial use.

NOTE Confidence: 0.88815093

00:20:20.830 --> 00:20:22.690 But nowadays we realize that

NOTE Confidence: 0.88815093

00:20:22.690 --> 00:20:25.474 that may not be the best patients

NOTE Confidence: 0.88815093

00:20:25.474 --> 00:20:27.579 to put on these studies,

NOTE Confidence: 0.88815093

00:20:27.580 --> 00:20:28.900 especially seeing that

NOTE Confidence: 0.88815093

00:20:28.900 --> 00:20:30.220 we're targeting science.

NOTE Confidence: 0.88815093

00:20:30.220 --> 00:20:32.290 And we're not looking necessarily for

NOTE Confidence: 0.88815093

00:20:32.290 --> 00:20:34.939 patients now that have exhausted everything.

NOTE Confidence: 0.88815093

00:20:34.940 --> 00:20:36.224 But like for instance,

NOTE Confidence: 0.88815093

00:20:36.224 --> 00:20:38.638 we have a trial that only wants

NOTE Confidence: 0.88815093

00:20:38.638 --> 00:20:41.543 patients that have failed what we call

NOTE Confidence: 0.88815093

00:20:41.543 --> 00:20:44.168 frontline therapy for colon cancer or

NOTE Confidence: 0.88815093

00:20:44.168 --> 00:20:46.323 frontline therapy for pancreas cancer.

NOTE Confidence: 0.88815093

00:20:46.330 --> 00:20:48.290 Only one treatment for their

NOTE Confidence: 0.88815093

00:20:48.290 --> 00:20:49.074 metastatic disease,

NOTE Confidence: 0.88815093

00:20:49.080 --> 00:20:51.816 and then we want to bring them on

NOTE Confidence: 0.88815093

00:20:51.816 --> 00:20:54.049 the trial because we know that

NOTE Confidence: 0.88815093

00:20:54.049 --> 00:20:56.783 the farther out you go in terms

NOTE Confidence: 0.88815093

00:20:56.783 --> 00:20:59.053 of number of different treatments

NOTE Confidence: 0.88815093

00:20:59.053 --> 00:21:01.331 that a patient is given,

00:21:01.792 --> 00:21:04.558 many times there's a significant

NOTE Confidence: 0.88815093

00:21:04.558 --> 00:21:07.409 decrease in the ability for that tumor

NOTE Confidence: 0.88815093

00:21:07.409 --> 00:21:10.090 to respond to a certain treatment,

NOTE Confidence: 0.88815093

00:21:10.090 --> 00:21:13.586 and so we're requesting even in early phase

NOTE Confidence: 0.88815093

00:21:13.590 --> 00:21:16.320 once we've gotten to that dose that

NOTE Confidence: 0.88815093

00:21:16.320 --> 00:21:19.481 we want to advance forward instead of

NOTE Confidence: 0.88815093

00:21:19.481 --> 00:21:22.760 just going right into a phase two,



NOTE Confidence: 0.88815093  
00:21:22.760 --> 00:21:26.256 we may do what we call expansion cohorts.  
NOTE Confidence: 0.88815093  
00:21:26.260 --> 00:21:27.391 In that phase  
NOTE Confidence: 0.88815093  
00:21:27.391 --> 00:21:30.030 one trial and where we put only  
NOTE Confidence: 0.88815093  
00:21:30.116 --> 00:21:32.380 patients with colon cancer,  
NOTE Confidence: 0.88815093  
00:21:32.380 --> 00:21:35.296 or only patients with ovarian cancer.  
NOTE Confidence: 0.88815093  
00:21:35.300 --> 00:21:38.333 And only those that may harbor as an example,  
NOTE Confidence: 0.88815093  
00:21:38.340 --> 00:21:39.624 a certain mutation.  
NOTE Confidence: 0.88815093  
00:21:39.624 --> 00:21:42.620 Because we want to move the drug  
NOTE Confidence: 0.88815093  
00:21:42.706 --> 00:21:45.256 through as quickly as possible,  
NOTE Confidence: 0.88815093  
00:21:45.260 --> 00:21:48.221 but as safely as possible so that  
NOTE Confidence: 0.88815093  
00:21:48.221 --> 00:21:50.955 we can hopefully advance that drug  
NOTE Confidence: 0.88815093  
00:21:50.955 --> 00:21:53.715 right into a phase three trial,  
NOTE Confidence: 0.88815093  
00:21:53.720 --> 00:21:56.408 which is a randomized trial looking  
NOTE Confidence: 0.88815093  
00:21:56.408 --> 00:21:59.633 at standard of care versus the new  
NOTE Confidence: 0.88815093  
00:21:59.633 --> 00:22:02.321 drug or standard of care versus  
NOTE Confidence: 0.88815093

00:22:02.321 --> 00:22:03.509 standard of care.  
NOTE Confidence: 0.88815093

00:22:03.510 --> 00:22:06.212 Plus the new drug together so that  
NOTE Confidence: 0.88815093

00:22:06.212 --> 00:22:08.996 we can hopefully advance that drug  
NOTE Confidence: 0.88815093

00:22:08.996 --> 00:22:12.080 to commercialization to make it accessible  
NOTE Confidence: 0.88815093

00:22:12.080 --> 00:22:14.594 to all patients that could benefit  
NOTE Confidence: 0.88815093

00:22:14.594 --> 00:22:17.970 from that drug as quickly as possible.  
NOTE Confidence: 0.84499395

00:22:17.970 --> 00:22:21.127 Yeah, I think that's so important right  
NOTE Confidence: 0.84499395

00:22:21.127 --> 00:22:24.387 in thinking about the fact that even if  
NOTE Confidence: 0.84499395

00:22:24.387 --> 00:22:27.480 you look at our standard chemotherapies,  
NOTE Confidence: 0.84499395

00:22:27.480 --> 00:22:30.672 many of these are drugs that were  
NOTE Confidence: 0.84499395

00:22:30.672 --> 00:22:34.278 developed back in the quote the good old days,  
NOTE Confidence: 0.84499395

00:22:34.280 --> 00:22:36.656 which really aren't targeted and now  
NOTE Confidence: 0.84499395

00:22:36.656 --> 00:22:39.710 that we have these targeted therapies  
NOTE Confidence: 0.84499395

00:22:39.710 --> 00:22:42.818 it may be patients who  
NOTE Confidence: 0.84499395

00:22:42.818 --> 00:22:44.372 have specific mutations.  
NOTE Confidence: 0.84499395

00:22:44.380 --> 00:22:48.013 To really look at clinical trials before

NOTE Confidence: 0.84499395

00:22:48.013 --> 00:22:51.078 they've exhausted all of their options.

NOTE Confidence: 0.84499395

00:22:51.080 --> 00:22:55.166 So Pat, my next question is,

NOTE Confidence: 0.84499395

00:22:55.170 --> 00:22:58.298 do you find that patients are still

NOTE Confidence: 0.84499395

00:22:58.298 --> 00:23:01.190 resistant to looking at clinical trials?

NOTE Confidence: 0.84499395

00:23:01.190 --> 00:23:03.355 Do they have enough information

NOTE Confidence: 0.84499395

00:23:03.355 --> 00:23:06.020 about where to find these clinical

NOTE Confidence: 0.84499395

00:23:06.020 --> 00:23:08.528 trials and for the people who

NOTE Confidence: 0.84499395

00:23:08.528 --> 00:23:11.078 are listening on the radio today

NOTE Confidence: 0.84499395

00:23:11.080 --> 00:23:12.536 who may be thinking,

NOTE Confidence: 0.84499395

00:23:12.536 --> 00:23:15.810 I failed my first round of chemotherapy,

NOTE Confidence: 0.84499395

00:23:15.810 --> 00:23:17.960 or maybe even two rounds,

00:23:20.840 --> 00:23:21.788 and you know,

NOTE Confidence: 0.84499395

00:23:21.788 --> 00:23:24.451 how far do we keep going down the

NOTE Confidence: 0.84499395

00:23:24.451 --> 00:23:27.076 line thinking about the next line of

NOTE Confidence: 0.84499395

00:23:27.076 --> 00:23:29.736 therapy in the next line of therapy,

NOTE Confidence: 0.84499395

00:23:29.740 --> 00:23:32.001 all of which may be less effective

NOTE Confidence: 0.84499395

00:23:32.001 --> 00:23:34.010 versus trying a clinical trial.

NOTE Confidence: 0.84499395

00:23:34.010 --> 00:23:36.775 And how do I get information about

NOTE Confidence: 0.84499395

00:23:36.775 --> 00:23:39.325 what clinical trials are out there that

NOTE Confidence: 0.84499395

00:23:39.325 --> 00:23:42.199 might be well suited to me in my tumor?

00:23:44.720 --> 00:23:47.000 In the Connecticut area obviously you

NOTE Confidence: 0.87484205

00:23:47.075 --> 00:23:50.115 know Yale Cancer Center is an

NOTE Confidence: 0.87484205

00:23:50.115 --> 00:23:52.309 outstanding resource for clinical trials.

NOTE Confidence: 0.87484205

00:23:52.310 --> 00:23:54.285 And you know, contacting somebody

NOTE Confidence: 0.87484205

00:23:54.285 --> 00:23:55.865 at Yale Cancer Center,

NOTE Confidence: 0.87484205

00:23:55.870 --> 00:23:59.191 if you have a GI cancer

NOTE Confidence: 0.87484205

00:23:59.191 --> 00:24:01.810 cancer of the colon or stomach,

NOTE Confidence: 0.87484205

00:24:01.810 --> 00:24:04.978 contacting the GI team to see

NOTE Confidence: 0.87484205

00:24:04.980 --> 00:24:06.960 do they have trials available?

NOTE Confidence: 0.87484205

00:24:06.960 --> 00:24:10.024 Or if you have metastatic disease, your cancer

NOTE Confidence: 0.87484205

00:24:10.024 --> 00:24:12.950 is spread outside of its primary source,

NOTE Confidence: 0.87484205

00:24:12.950 --> 00:24:16.910 contacting our team as an example,

NOTE Confidence: 0.87484205

00:24:16.910 --> 00:24:20.510 and if you contact Yale,

NOTE Confidence: 0.87484205

00:24:20.510 --> 00:24:23.390 they will get ahold of the right physician

NOTE Confidence: 0.87484205

00:24:23.390 --> 00:24:26.510 to be able to answer those questions.

NOTE Confidence: 0.87484205

00:24:26.510 --> 00:24:28.910 You can also go on [cancerclinicaltrials.gov](http://cancerclinicaltrials.gov),

NOTE Confidence: 0.87484205

00:24:28.910 --> 00:24:32.074 a website that is

NOTE Confidence: 0.87484205

00:24:32.074 --> 00:24:34.569 sometimes very difficult to maneuver.

NOTE Confidence: 0.87484205

00:24:34.570 --> 00:24:37.216 You can ask your primary oncologist,

NOTE Confidence: 0.87484205

00:24:37.220 --> 00:24:39.425 but depending on how comfortable

NOTE Confidence: 0.87484205

00:24:39.425 --> 00:24:41.630 they feel in referring you,

NOTE Confidence: 0.87484205

00:24:41.630 --> 00:24:44.591 you're at the disposal and

NOTE Confidence: 0.87484205

00:24:44.591 --> 00:24:48.112 you're at the mercy of them sending you

NOTE Confidence: 0.87484205

00:24:48.112 --> 00:24:51.709 for a second opinion or sending you to

NOTE Confidence: 0.87484205

00:24:51.709 --> 00:24:54.852 a site that may have clinical trials

NOTE Confidence: 0.87484205

00:24:54.860 --> 00:24:59.347 that may not be available to them.

00:25:00.366 --> 00:25:02.906 Sometimes it's very difficult for

NOTE Confidence: 0.87484205

00:25:02.906 --> 00:25:06.019 these patients to find these trials.

NOTE Confidence: 0.87484205  
00:25:06.020 --> 00:25:06.585 Unfortunately,  
NOTE Confidence: 0.87484205  
00:25:06.585 --> 00:25:09.975 of all patients that are diagnosed  
NOTE Confidence: 0.87484205  
00:25:09.975 --> 00:25:12.370 and treated for cancer,  
NOTE Confidence: 0.87484205  
00:25:12.370 --> 00:25:15.212 less than 3% of them are ever  
NOTE Confidence: 0.87484205  
00:25:15.212 --> 00:25:18.139 put on a clinical trial,  
NOTE Confidence: 0.87484205  
00:25:18.140 --> 00:25:20.545 and there are certain communities  
NOTE Confidence: 0.87484205  
00:25:20.545 --> 00:25:21.507 of patients,  
NOTE Confidence: 0.87484205  
00:25:21.510 --> 00:25:23.373 the underrepresented minorities,  
NOTE Confidence: 0.87484205  
00:25:23.373 --> 00:25:26.478 those patients in rural communities  
NOTE Confidence: 0.87484205  
00:25:26.478 --> 00:25:30.196 that have the greatest  
NOTE Confidence: 0.87484205  
00:25:30.196 --> 00:25:32.686 impact of not being offered  
NOTE Confidence: 0.87484205  
00:25:32.686 --> 00:25:35.528 a clinical trial or not being able  
NOTE Confidence: 0.87484205  
00:25:35.528 --> 00:25:38.826 to get access to a clinical trial.  
NOTE Confidence: 0.87484205  
00:25:38.830 --> 00:25:40.261 So I mean,  
NOTE Confidence: 0.87484205  
00:25:40.261 --> 00:25:42.169 there are some organizations  
NOTE Confidence: 0.87484205

00:25:42.169 --> 00:25:44.430 that you can contact  
NOTE Confidence: 0.87484205

00:25:44.430 --> 00:25:47.622 that may help you find a trial  
NOTE Confidence: 0.87484205

00:25:47.622 --> 00:25:50.420 or calling the NCI directly,  
NOTE Confidence: 0.87484205

00:25:50.420 --> 00:25:52.910 but many times it's difficult  
NOTE Confidence: 0.87484205

00:25:52.910 --> 00:25:53.410 unfortunately,  
NOTE Confidence: 0.87484205

00:25:53.410 --> 00:25:55.410 to even maneuver those  
NOTE Confidence: 0.87484205

00:25:55.410 --> 00:25:56.910 avenues of information.  
NOTE Confidence: 0.86626506

00:25:57.960 --> 00:26:00.270 So Pat, you mentioned underrepresented  
NOTE Confidence: 0.86626506

00:26:00.270 --> 00:26:03.608 minorities and I just want to pick up  
NOTE Confidence: 0.86626506

00:26:03.608 --> 00:26:05.841 on this just for a minute because  
NOTE Confidence: 0.86626506

00:26:05.850 --> 00:26:09.042 for many patients who may be  
NOTE Confidence: 0.86626506

00:26:09.042 --> 00:26:10.410 from underrepresented minorities  
NOTE Confidence: 0.86626506

00:26:10.484 --> 00:26:12.308 African American patients,  
NOTE Confidence: 0.86626506

00:26:12.310 --> 00:26:15.208 for example, they may be reluctant  
NOTE Confidence: 0.86626506

00:26:15.208 --> 00:26:17.780 to participate in clinical trials  
NOTE Confidence: 0.86626506

00:26:17.780 --> 00:26:20.150 given historical events

NOTE Confidence: 0.86626506

00:26:20.150 --> 00:26:23.250 that have happened in this country,

NOTE Confidence: 0.86626506

00:26:23.250 --> 00:26:26.806 which have been deplorable in terms of

NOTE Confidence: 0.86626506

00:26:26.806 --> 00:26:30.200 clinical research and how it was conducted,

NOTE Confidence: 0.86626506

00:26:30.200 --> 00:26:33.679 can you alleviate some of their fears

NOTE Confidence: 0.87826794

00:26:33.680 --> 00:26:36.998 and anxieties?

NOTE Confidence: 0.87826794

00:26:37.000 --> 00:26:39.810 Because of some of those

NOTE Confidence: 0.87826794

00:26:39.810 --> 00:26:42.058 previous events that occur,ed

NOTE Confidence: 0.87826794

00:26:42.060 --> 00:26:44.632 especially with minority populations,

NOTE Confidence: 0.87826794

00:26:44.632 --> 00:26:47.847 the Food and Drug Administration

NOTE Confidence: 0.87826794

00:26:47.847 --> 00:26:51.396 the FDA has put very strict rules

NOTE Confidence: 0.87826794

00:26:51.396 --> 00:26:53.915 and regulations in place that

NOTE Confidence: 0.87826794

00:26:53.915 --> 00:26:56.665 will prevent that from happening.

NOTE Confidence: 0.87826794

00:26:56.670 --> 00:27:00.597 And in fact, there are many investigators,

NOTE Confidence: 0.87826794

00:27:00.600 --> 00:27:02.292 epidemiologists and scientists

NOTE Confidence: 0.87826794

00:27:02.292 --> 00:27:05.112 that are trying to understand

NOTE Confidence: 0.87826794



00:27:05.112 --> 00:27:07.080 why underrepresented minorities  
NOTE Confidence: 0.87826794

00:27:07.080 --> 00:27:09.901 are not as well represented and the  
NOTE Confidence: 0.87826794

00:27:09.901 --> 00:27:12.432 number one reason is because they  
NOTE Confidence: 0.87826794

00:27:12.432 --> 00:27:14.916 are not offered a clinical trial.  
NOTE Confidence: 0.87826794

00:27:14.920 --> 00:27:18.070 One of the other reasons is  
NOTE Confidence: 0.87826794

00:27:18.070 --> 00:27:20.170 geographic and financial barriers.  
NOTE Confidence: 0.87826794

00:27:20.170 --> 00:27:23.845 Those are two of the other reasons,  
NOTE Confidence: 0.87826794

00:27:23.850 --> 00:27:26.475 but it isn't because they've  
NOTE Confidence: 0.87826794

00:27:26.475 --> 00:27:29.100 necessarily refused a clinical trial,  
NOTE Confidence: 0.87826794

00:27:29.100 --> 00:27:31.720 the lack of being offered  
NOTE Confidence: 0.87826794

00:27:31.720 --> 00:27:33.816 far outweighs their refusal.  
NOTE Confidence: 0.87826794

00:27:33.820 --> 00:27:35.920 The geographic barriers far  
NOTE Confidence: 0.87826794

00:27:35.920 --> 00:27:37.495 outweigh their refusal,  
NOTE Confidence: 0.87826794

00:27:37.500 --> 00:27:40.650 and in fact there are very,  
NOTE Confidence: 0.87826794

00:27:40.650 --> 00:27:43.465 very slim statistics of the  
NOTE Confidence: 0.87826794

00:27:43.465 --> 00:27:45.717 last 17 FDA approved

NOTE Confidence: 0.87826794

00:27:45.720 --> 00:27:49.820 cancer drugs and less than 4% of all

NOTE Confidence: 0.87826794

00:27:49.820 --> 00:27:53.330 patients that were recruited were black,

NOTE Confidence: 0.87826794

00:27:53.330 --> 00:27:56.834 less than 4% of all patients

NOTE Confidence: 0.87826794

00:27:56.834 --> 00:27:58.586 recruited were Hispanic,

NOTE Confidence: 0.87826794

00:27:58.590 --> 00:28:01.054 and those two underrepresented

NOTE Confidence: 0.87826794

00:28:01.054 --> 00:28:03.518 minorities represent a significantly

NOTE Confidence: 0.87826794

00:28:03.518 --> 00:28:06.200 larger population of cancer patients.

NOTE Confidence: 0.87826794

00:28:06.200 --> 00:28:09.700 And it's important to have

NOTE Confidence: 0.87826794

00:28:09.700 --> 00:28:11.800 underrepresented minorities offered

NOTE Confidence: 0.87826794

00:28:11.800 --> 00:28:14.657 and participate in clinical trials

NOTE Confidence: 0.87826794

00:28:14.657 --> 00:28:18.570 because we need to see if their tumors

NOTE Confidence: 0.87826794

00:28:18.570 --> 00:28:20.725 respond the same way their

NOTE Confidence: 0.87826794

00:28:20.725 --> 00:28:22.880 tumors may have some genetic,

NOTE Confidence: 0.87826794

00:28:22.880 --> 00:28:25.346 or some germline

NOTE Confidence: 0.87826794

00:28:25.346 --> 00:28:27.477 mutation or differences

NOTE Confidence: 0.87826794

00:28:27.477 --> 00:28:29.901 and we need to understand that  
NOTE Confidence: 0.87826794

00:28:29.901 --> 00:28:32.788 and how it impacts their tumors.  
00:28:34.950 --> 00:28:37.530 I think that's so important because  
NOTE Confidence: 0.87897724

00:28:37.530 --> 00:28:40.116 at the end of the day,  
NOTE Confidence: 0.87897724

00:28:40.120 --> 00:28:43.783 once all of these trials are done and these  
NOTE Confidence: 0.87897724

00:28:43.783 --> 00:28:47.019 drugs are marketed as standard of care,  
NOTE Confidence: 0.87897724

00:28:47.020 --> 00:28:49.714 these patients are going to receive  
NOTE Confidence: 0.87897724

00:28:49.714 --> 00:28:51.988 these same therapies that may  
NOTE Confidence: 0.87897724

00:28:51.988 --> 00:28:53.580 have been developed on a  
NOTE Confidence: 0.87897724

00:28:53.580 --> 00:28:57.630 completely different population.  
NOTE Confidence: 0.87897724

00:28:57.630 --> 00:29:00.286 So Pat very quickly in our last minute,  
NOTE Confidence: 0.87897724

00:29:00.290 --> 00:29:03.125 I just want to get one last question in  
NOTE Confidence: 0.87897724

00:29:03.125 --> 00:29:06.036 which is you mentioned financial barriers.  
NOTE Confidence: 0.87897724

00:29:06.040 --> 00:29:07.810 Are clinical trials covered by  
NOTE Confidence: 0.87897724

00:29:07.810 --> 00:29:10.212 insurance or do people have to pay  
NOTE Confidence: 0.87897724

00:29:10.212 --> 00:29:11.904 out of pocket for these drugs?  
NOTE Confidence: 0.8992565

00:29:13.170 --> 00:29:14.334 The drugs themselves,  
NOTE Confidence: 0.8992565

00:29:14.334 --> 00:29:16.274 if they are investigational drugs,  
00:29:17.788 --> 00:29:20.950 they do not have to pay for them.  
NOTE Confidence: 0.8992565

00:29:20.950 --> 00:29:23.300 They will be given free  
NOTE Confidence: 0.8992565

00:29:23.300 --> 00:29:25.650 of charge by the sponsors.  
NOTE Confidence: 0.8992565

00:29:25.650 --> 00:29:26.997 Medicare coverage analysis  
NOTE Confidence: 0.8992565

00:29:26.997 --> 00:29:30.140 covers a lot of the tests that  
NOTE Confidence: 0.8992565

00:29:30.218 --> 00:29:32.658 are needed for clinical trials,  
NOTE Confidence: 0.8992565

00:29:32.660 --> 00:29:35.950 but I think some of the greatest  
NOTE Confidence: 0.8992565

00:29:35.950 --> 00:29:37.923 financial barriers are commuting  
NOTE Confidence: 0.8992565

00:29:37.923 --> 00:29:40.273 back and forth to places  
NOTE Confidence: 0.8992565

00:29:40.273 --> 00:29:42.929 some of the standard of care  
NOTE Confidence: 0.8992565

00:29:42.930 --> 00:29:44.758 copays that are required,  
NOTE Confidence: 0.8992565

00:29:44.758 --> 00:29:47.500 and hopefully we will be able  
NOTE Confidence: 0.8992565

00:29:47.586 --> 00:29:50.610 to work towards getting a lot of  
NOTE Confidence: 0.8992565

00:29:50.610 --> 00:29:53.108 those things funded through new  
NOTE Confidence: 0.8992565

00:29:53.108 --> 00:29:55.898 initiatives that can help patients.

NOTE Confidence: 0.8992565

00:29:55.900 --> 00:29:58.075 Because the patients that need

NOTE Confidence: 0.8992565

00:29:58.075 --> 00:30:00.250 these studies the most sometime

NOTE Confidence: 0.8992565

00:30:00.250 --> 00:30:02.650 are patients that do have

NOTE Confidence: 0.8992565

00:30:02.650 --> 00:30:05.055 a problem gaining access to their

NOTE Confidence: 0.8992565

00:30:05.055 --> 00:30:07.239 copays or paying a babysitter so

NOTE Confidence: 0.8992565

00:30:07.239 --> 00:30:10.404 that they can go and

NOTE Confidence: 0.8992565

00:30:10.404 --> 00:30:12.365 participate in these clinical trials,

NOTE Confidence: 0.8992565

00:30:12.365 --> 00:30:15.445 or drive or pay for parking at the

NOTE Confidence: 0.8992565

00:30:15.445 --> 00:30:18.235 sites that they have to be treated.

00:30:19.800 --> 00:30:20.190 Doctor Pat LoRusso

NOTE Confidence: 0.8549952

00:30:20.190 --> 00:30:22.724 is a professor of medicine

NOTE Confidence: 0.8549952

00:30:22.724 --> 00:30:25.268 at the Yale School of Medicine.

NOTE Confidence: 0.8549952

00:30:25.270 --> 00:30:26.954 If you have questions,

NOTE Confidence: 0.8549952

00:30:26.954 --> 00:30:28.638 the address is canceranswers@yale.edu

NOTE Confidence: 0.8549952

00:30:28.638 --> 00:30:30.986 and past editions of the program

NOTE Confidence: 0.8549952

00:30:30.986 --> 00:30:33.146 are available in audio and written.

NOTE Confidence: 0.8549952

00:30:33.150 --> 00:30:34.299 Farm at [yalecancercenter.org](http://yalecancercenter.org).

NOTE Confidence: 0.8549952

00:30:34.299 --> 00:30:37.372 We hope you'll join us next week to

NOTE Confidence: 0.8549952

00:30:37.372 --> 00:30:39.298 learn more about the fight against

NOTE Confidence: 0.8549952

00:30:39.298 --> 00:30:41.880 cancer here on Connecticut Public Radio.