WEBVTT

NOTE duration:"01:26:10"

NOTE recognizability:0.927

NOTE language:en-us

NOTE Confidence: 0.9603804

00:00:00.000 --> 00:00:04.680 So welcome everybody and to the folks online,

NOTE Confidence: 0.9603804

00:00:04.680 --> 00:00:06.936 this is the program for Biomedical

NOTE Confidence: 0.9603804

00:00:06.936 --> 00:00:08.920 Ethics evening Ethics Seminar series.

NOTE Confidence: 0.9603804

00:00:08.920 --> 00:00:10.720 We're going to give it just one or two

NOTE Confidence: 0.9603804

00:00:10.720 --> 00:00:12.639 more minutes as folks come into the room,

NOTE Confidence: 0.9603804

00:00:12.640 --> 00:00:14.662 both this room here at Cohen

NOTE Confidence: 0.9603804

00:00:14.662 --> 00:00:16.822 Auditorium as well as the virtual room.

NOTE Confidence: 0.9603804

00:00:16.822 --> 00:00:19.431 So in just a couple of minutes, I'm going to,

NOTE Confidence: 0.9603804

00:00:19.431 --> 00:00:21.442 I'm going to introduce our our guest tonight

NOTE Confidence: 0.9603804

00:00:21.442 --> 00:00:23.556 Professor Miller and and we'll get started.

NOTE Confidence: 0.9603804

00:00:23.560 --> 00:00:25.102 So thank you very much for

NOTE Confidence: 0.9603804

00:00:25.102 --> 00:00:27.130 joining us in the room and online.

NOTE Confidence: 0.9603804

00:00:27.130 --> 00:00:28.586 And for those online, what are we

NOTE Confidence: 0.9603804

00:00:28.586 --> 00:00:30.327 having in the room tonight for dinner?

NOTE Confidence: 0.9603804

00:00:30.330 --> 00:00:34.327 We've got lobster and Steamship Roast beef.

NOTE Confidence: 0.9603804

00:00:34.330 --> 00:00:35.890 Look at that. That's nice.

NOTE Confidence: 0.9603804

00:00:35.890 --> 00:00:37.246 And look at that. That's great.

NOTE Confidence: 0.9603804

00:00:37.250 --> 00:00:39.522 And pizza from all of four New Haven's

NOTE Confidence: 0.9603804

00:00:39.522 --> 00:00:41.609 4 finest pizzerias all out there.

NOTE Confidence: 0.9603804

00:00:41.610 --> 00:00:42.410 So keep that in mind.

NOTE Confidence: 0.9603804

00:00:42.410 --> 00:00:44.048 Next time, join us in Cone.

NOTE Confidence: 0.9603804

00:00:44.050 --> 00:00:46.850 We'd love to have the in person

NOTE Confidence: 0.9603804

00:00:46.850 --> 00:00:49.642 community here. What's that? Oh, great.

NOTE Confidence: 0.9603804

00:00:49.642 --> 00:00:50.800 There you go. Great Lobster.

NOTE Confidence: 0.9603804

00:00:50.800 --> 00:00:52.330 They're they're eating it right up.

NOTE Confidence: 0.9603804

00:00:52.330 --> 00:00:53.797 I don't know who's going to clean this up

NOTE Confidence: 0.9603804

00:00:53.797 --> 00:00:55.376 with all these lobsters on the floor, but.

NOTE Confidence: 0.9603804

00:00:55.376 --> 00:00:56.360 We'll deal with that.

NOTE Confidence: 0.9603804

00:00:56.360 --> 00:00:57.416 We'll give it one more minute

NOTE Confidence: 0.9603804

00:00:57.416 --> 00:00:58.480 and we will get started.

NOTE Confidence: 0.9603804

00:00:58.480 --> 00:00:59.160 I'll be right back.

NOTE Confidence: 0.94629164

00:01:43.400 --> 00:01:45.040 So good evening and welcome.

NOTE Confidence: 0.94629164

00:01:45.040 --> 00:01:46.760 My name is Mark Mercurio.

NOTE Confidence: 0.94629164

00:01:46.760 --> 00:01:48.342 I'm on the director of the Program

NOTE Confidence: 0.94629164

00:01:48.342 --> 00:01:49.479 for Biomedical Ethics here at

NOTE Confidence: 0.94629164

00:01:49.479 --> 00:01:50.514 the Yale School of Medicine.

NOTE Confidence: 0.94629164

00:01:50.520 --> 00:01:52.110 Welcome to the folks in the

NOTE Confidence: 0.94629164

00:01:52.110 --> 00:01:53.640 room and the folks online.

NOTE Confidence: 0.94629164

00:01:53.640 --> 00:01:55.120 It's a pleasure tonight

NOTE Confidence: 0.94629164

00:01:55.120 --> 00:01:56.600 to introduce our speaker,

NOTE Confidence: 0.94629164

00:01:56.600 --> 00:01:59.168 who I'll get to in just a moment to

NOTE Confidence: 0.94629164

00:01:59.168 --> 00:02:00.680 let you know how this is going to work.

NOTE Confidence: 0.94629164

00:02:00.680 --> 00:02:01.934 And I think many of you

NOTE Confidence: 0.94629164

00:02:01.934 --> 00:02:02.770 are familiar with this.

NOTE Confidence: 0.94629164

00:02:02.770 --> 00:02:03.970 And just a minute,

NOTE Confidence: 0.94629164

00:02:03.970 --> 00:02:05.466 I'll introduce Jen Miller,

NOTE Confidence: 0.94629164

00:02:05.466 --> 00:02:09.050 our guest for tonight and then we will.

NOTE Confidence: 0.94629164

00:02:09.050 --> 00:02:11.738 Professor Miller will speak for 45 minutes,

NOTE Confidence: 0.94629164

00:02:11.738 --> 00:02:12.410 plus or minus.

NOTE Confidence: 0.94629164

00:02:12.410 --> 00:02:13.170 We'll see how it goes,

NOTE Confidence: 0.94629164

00:02:13.170 --> 00:02:14.325 a PowerPoint presentation.

NOTE Confidence: 0.94629164

00:02:14.325 --> 00:02:16.973 After that we'll have a Q&A session for

NOTE Confidence: 0.94629164

00:02:16.973 --> 00:02:19.450 the room as well As for the folks online.

NOTE Confidence: 0.94629164

00:02:19.450 --> 00:02:20.214 For the folks online,

NOTE Confidence: 0.94629164

00:02:20.214 --> 00:02:22.170 you won't be able to do this through chat.

NOTE Confidence: 0.94629164

00:02:22.170 --> 00:02:24.130 I would ask that you submit your

NOTE Confidence: 0.94629164

00:02:24.130 --> 00:02:25.782 questions through the Q&A function

NOTE Confidence: 0.94629164

00:02:25.782 --> 00:02:28.709 and then I will read the questions to

NOTE Confidence: 0.94629164

00:02:28.709 --> 00:02:31.488 Professor Miller and we will go until.

NOTE Confidence: 0.94629164

00:02:31.490 --> 00:02:32.210 For a little while,

NOTE Confidence: 0.94629164

00:02:32.210 --> 00:02:33.290 I'll see how the questions go,

NOTE Confidence: 0.94629164

00:02:33.290 --> 00:02:34.770 see how the conversation goes.

NOTE Confidence: 0.94629164

00:02:34.770 --> 00:02:36.366 But if it's still going at 6:30,

NOTE Confidence: 0.94629164

00:02:36.370 --> 00:02:37.210 I will be stopping it.

NOTE Confidence: 0.94629164

00:02:37.210 --> 00:02:37.774 So you're wondering,

NOTE Confidence: 0.94629164

00:02:37.774 --> 00:02:39.090 is this going to go on forever?

NOTE Confidence: 0.94629164

00:02:39.090 --> 00:02:40.158 The answer is no.

NOTE Confidence: 0.94629164

00:02:40.158 --> 00:02:42.113 Sometimes it feels like we stop too

NOTE Confidence: 0.94629164

00:02:42.113 --> 00:02:43.889 soon because we're really into it.

NOTE Confidence: 0.94629164

00:02:43.890 --> 00:02:45.210 But to respect everybody's time,

NOTE Confidence: 0.94629164

00:02:45.210 --> 00:02:46.690 we do quit at 6:30.

NOTE Confidence: 0.94629164

00:02:46.690 --> 00:02:47.926 But right now we're just getting

NOTE Confidence: 0.94629164

00:02:47.926 --> 00:02:49.210 we're just at the beginning.

NOTE Confidence: 0.94629164

00:02:49.210 --> 00:02:50.128 And I'm delighted to tell you.

NOTE Confidence: 0.94629164

00:02:50.130 --> 00:02:51.866 So let me tell you about my

NOTE Confidence: 0.94629164

00:02:51.866 --> 00:02:52.882 friend Jennifer Miller, PhD.

NOTE Confidence: 0.94629164

00:02:52.882 --> 00:02:53.970 She's an associate professor

NOTE Confidence: 0.94629164

00:02:53.970 --> 00:02:55.717 in the old School of Medicine

NOTE Confidence: 0.94629164

00:02:55.717 --> 00:02:57.357 in the Department of Medicine.

NOTE Confidence: 0.94629164

00:02:57.360 --> 00:02:59.411 She's also the director of a program

NOTE Confidence: 0.94629164

00:02:59.411 --> 00:03:00.880 called Good Pharma Scorecard,

NOTE Confidence: 0.94629164

00:03:00.880 --> 00:03:03.330 as well as an organization

NOTE Confidence: 0.94629164

00:03:03.330 --> 00:03:04.800 called Bioethics International.

NOTE Confidence: 0.94629164

00:03:04.800 --> 00:03:05.520 I don't know about you,

NOTE Confidence: 0.94629164

00:03:05.520 --> 00:03:07.040 but when I was in college and afterwards,

NOTE Confidence: 0.94629164

00:03:07.040 --> 00:03:09.128 I figured out a pretty early on that

NOTE Confidence: 0.94629164

00:03:09.128 --> 00:03:10.815 the smartest people on campus were

NOTE Confidence: 0.94629164

00:03:10.815 --> 00:03:12.960 two different people and I was neither.

NOTE Confidence: 0.94629164

00:03:12.960 --> 00:03:14.440 There were the physics majors,

NOTE Confidence: 0.94629164

00:03:14.440 --> 00:03:15.917 I would say 3, the physics majors,

NOTE Confidence: 0.94629164

00:03:15.920 --> 00:03:18.636 the math majors and the philosophy majors,

NOTE Confidence: 0.94629164

00:03:18.640 --> 00:03:20.290 and one rarely encounters someone who

NOTE Confidence: 0.94629164

00:03:20.290 --> 00:03:21.640 actually develops expertise in both,

NOTE Confidence: 0.94629164

00:03:21.640 --> 00:03:23.340 so.

NOTE Confidence: 0.94629164

00:03:23.340 --> 00:03:25.260 Professor Miller actually did her

NOTE Confidence: 0.94629164

00:03:25.260 --> 00:03:27.180 Bachelorette at Fordham in Physics,

NOTE Confidence: 0.94629164

00:03:27.180 --> 00:03:29.301 then went on to study bioethics at

NOTE Confidence: 0.94629164

00:03:29.301 --> 00:03:31.572 Duke and at Harvard and eventually

NOTE Confidence: 0.94629164

00:03:31.572 --> 00:03:34.146 received her PhD at the Regina

NOTE Confidence: 0.94629164

00:03:34.146 --> 00:03:36.580 Apostleorum Pontifical University in Rome.

NOTE Confidence: 0.94629164

00:03:36.580 --> 00:03:38.580 She then founded Bioethics

NOTE Confidence: 0.94629164

00:03:38.580 --> 00:03:41.145 International and became a a well

NOTE Confidence: 0.94629164

00:03:41.145 --> 00:03:43.010 respected authority on the bioethics

NOTE Confidence: 0.94629164

00:03:43.010 --> 00:03:45.258 and the Pharmaceutical industry

NOTE Confidence: 0.94629164

00:03:45.260 --> 00:03:47.420 and our relationship with them.

NOTE Confidence: 0.94629164

00:03:47.420 --> 00:03:49.820 She also developed expertise and has

NOTE Confidence: 0.94629164

00:03:49.820 --> 00:03:51.420 spoken on artificial intelligence.

NOTE Confidence: 0.94629164

00:03:51.420 --> 00:03:54.228 And on bioethical issues with data

NOTE Confidence: 0.94629164

00:03:54.228 --> 00:03:55.900 sharing and on clinical research,

NOTE Confidence: 0.94629164

00:03:55.900 --> 00:03:58.538 she joined the REL faculty a few years ago.

NOTE Confidence: 0.94629164

00:03:58.540 --> 00:04:00.017 She came here from, I believe NYU,

NOTE Confidence: 0.94629164

00:04:00.020 --> 00:04:02.140 right Jen, and she came here from NYU.

NOTE Confidence: 0.94629164

00:04:02.140 --> 00:04:04.300 It's a marvelous addition to our

NOTE Confidence: 0.94629164

00:04:04.300 --> 00:04:05.492 faculty and I'm really pleased

NOTE Confidence: 0.94629164

00:04:05.492 --> 00:04:06.740 that she agreed to spend some

NOTE Confidence: 0.94629164

00:04:06.780 --> 00:04:07.820 time with us this evening.

NOTE Confidence: 0.94629164

00:04:07.820 --> 00:04:10.356 So I give you Doctor Jennifer Miller to

NOTE Confidence: 0.94629164

00:04:10.356 --> 00:04:12.460 discuss equity and biomedical research.

NOTE Confidence: 0.94629164

00:04:12.460 --> 00:04:13.700 Please welcome Jennifer Miller.

NOTE Confidence: 0.9603804

00:04:21.150 --> 00:04:24.110 Thanks Mark for that generous introduction.

NOTE Confidence: 0.850495952

00:04:24.110 --> 00:04:26.310 So as Doctor Mercario mentioned,

NOTE Confidence: 0.850495952

00:04:26.310 --> 00:04:28.554 today I'm going to talk about

NOTE Confidence: 0.850495952

00:04:28.554 --> 00:04:30.449 equity and biomedical research and

NOTE Confidence: 0.850495952

00:04:30.449 --> 00:04:32.429 focus on two areas in particular,

NOTE Confidence: 0.850495952

00:04:32.430 --> 00:04:34.655 diversity and fair inclusion in

NOTE Confidence: 0.850495952

00:04:34.655 --> 00:04:36.309 clinical trial enrollment and

NOTE Confidence: 0.850495952

00:04:36.309 --> 00:04:38.223 fair access to the benefits of

NOTE Confidence: 0.850495952

00:04:38.223 --> 00:04:40.270 research on a global level. Thank

NOTE Confidence: 0.931867433333333

00:04:44.950 --> 00:04:47.650 you, so for those who are. Meeting CME,

NOTE Confidence: 0.931867433333333

00:04:47.650 --> 00:04:49.650 there'll be 3 program objectives.

NOTE Confidence: 0.931867433333333

00:04:49.650 --> 00:04:52.018 First, I hope you walk away with the

NOTE Confidence: 0.931867433333333

00:04:52.018 --> 00:04:54.572 an ability to describe key ways for

NOTE Confidence: 0.931867433333333

00:04:54.572 --> 00:04:56.462 evaluating the adequacy of clinical

NOTE Confidence: 0.931867433333333

00:04:56.534 --> 00:04:59.028 trial diversity and representation,

NOTE Confidence: 0.931867433333333

00:04:59.028 --> 00:05:02.210 ways to analyze the degree to which women,

NOTE Confidence: 0.931867433333333

00:05:02.210 --> 00:05:04.442 older adults and racial and ethnic

NOTE Confidence: 0.931867433333333

00:05:04.442 --> 00:05:05.930 minoritized patients are fairly

NOTE Confidence: 0.931867433333333

00:05:05.995 --> 00:05:07.687 included in clinical research,

NOTE Confidence: 0.931867433333333

00:05:07.690 --> 00:05:09.322 and a better understanding of how

NOTE Confidence: 0.931867433333333

00:05:09.322 --> 00:05:11.008 to evaluate fair access to the

NOTE Confidence: 0.931867433333333

00:05:11.008 --> 00:05:12.368 benefits of clinical research among

NOTE Confidence: 0.931867433333333

00:05:12.368 --> 00:05:14.049 low and middle income countries.

NOTE Confidence: 0.924403873076923

00:05:17.870 --> 00:05:20.586 OK, so countless studies have shown a

NOTE Confidence: 0.924403873076923

00:05:20.586 --> 00:05:23.308 lack of diversity in clinical research,

NOTE Confidence: 0.924403873076923

00:05:23.310 --> 00:05:26.746 including our own. In general,

NOTE Confidence: 0.924403873076923

00:05:26.746 --> 00:05:29.930 we tend to test new medicines in vaccines

NOTE Confidence: 0.924403873076923

00:05:30.013 --> 00:05:32.649 on patients who are healthier, younger,

NOTE Confidence: 0.924403873076923

00:05:32.649 --> 00:05:35.681 and more likely to identify as white and

NOTE Confidence: 0.924403873076923

00:05:35.681 --> 00:05:38.622 male than real world US patients with

NOTE Confidence: 0.924403873076923

00:05:38.622 --> 00:05:40.990 the studied conditions and diseases.

NOTE Confidence: 0.9603804

00:05:43.700 --> 00:05:46.380 Other populations are also underrepresented.

NOTE Confidence: 0.9603804

00:05:46.380 --> 00:05:49.388 Policy efforts to improve clinical

NOTE Confidence: 0.9603804

00:05:49.388 --> 00:05:52.298 trial trial diversity span decades.

NOTE Confidence: 0.9603804

00:05:52.300 --> 00:05:56.844 Early efforts include in 19/19/83

NOTE Confidence: 0.9603804

00:05:56.844 --> 00:05:59.164 published guidelines from the FDA

NOTE Confidence: 0.9603804

00:05:59.164 --> 00:06:00.988 on the importance of including older

NOTE Confidence: 0.9603804

00:06:00.988 --> 00:06:02.859 adults age 65 years and older,

NOTE Confidence: 0.9603804

00:06:02.860 --> 00:06:06.174 which was finalized in 1989 and

NOTE Confidence: 0.9603804

00:06:06.174 --> 00:06:08.058 all the way through more recently

NOTE Confidence: 0.9603804

00:06:08.058 --> 00:06:09.670 with President Biden signing the

NOTE Confidence: 0.9603804

00:06:09.670 --> 00:06:11.500 Food and Drug Omnibus Reform Act,

NOTE Confidence: 0.9603804

00:06:11.500 --> 00:06:13.252 or FEDORA for short.

NOTE Confidence: 0.9603804

00:06:13.252 --> 00:06:15.442 Newly requiring research sponsors to

NOTE Confidence: 0.9603804

00:06:15.442 --> 00:06:17.686 submit diversity action plans for

NOTE Confidence: 0.9603804

00:06:17.686 --> 00:06:20.278 their pivotal trials and other later

NOTE Confidence: 0.9603804

00:06:20.347 --> 00:06:22.019 stage trials outlining enrollment

NOTE Confidence: 0.9603804

00:06:22.019 --> 00:06:25.147 goals for the first time by age,

NOTE Confidence: 0.9603804

00:06:25.147 --> 00:06:26.998 sex, race, ethnicity,

NOTE Confidence: 0.9603804

00:06:26.998 --> 00:06:30.083 geographic location and socioeconomic status,

NOTE Confidence: 0.9603804

00:06:30.090 --> 00:06:32.844 along with rationales for setting each

NOTE Confidence: 0.9603804

00:06:32.844 --> 00:06:35.968 goal and plans for how the sponsor

NOTE Confidence: 0.9603804

00:06:35.970 --> 00:06:38.090 aims to meet enrollment targets.

NOTE Confidence: 0.936816775

00:06:41.710 --> 00:06:44.428 We've had a lot of policy efforts and at

NOTE Confidence: 0.936816775

00:06:44.428 --> 00:06:47.557 the same time there's been substantial

NOTE Confidence: 0.936816775

00:06:47.557 --> 00:06:50.590 documentation on patient barriers and

NOTE Confidence: 0.936816775

00:06:50.590 --> 00:06:53.070 facilitators to trial participation.

NOTE Confidence: 0.936816775

00:06:53.070 --> 00:06:55.030 I'll just name a few.

NOTE Confidence: 0.936816775

00:06:55.030 --> 00:06:59.412 One are the use of overly restrictive

NOTE Confidence: 0.936816775

00:06:59.412 --> 00:07:01.856 inclusion exclusion criteria when

NOTE Confidence: 0.936816775

00:07:01.856 --> 00:07:04.300 designing trials in protocols.

NOTE Confidence: 0.936816775

00:07:04.300 --> 00:07:05.464 So for example,

NOTE Confidence: 0.936816775

00:07:05.464 --> 00:07:07.016 many trials include blanket

NOTE Confidence: 0.936816775

00:07:07.016 --> 00:07:08.708 exclusions for certain comorbidities

NOTE Confidence: 0.936816775

00:07:08.708 --> 00:07:11.058 or for concomitant medication use.

NOTE Confidence: 0.936816775

00:07:11.060 --> 00:07:11.912 So for example,

NOTE Confidence: 0.936816775

00:07:11.912 --> 00:07:13.616 you could have high blood pressure

NOTE Confidence: 0.953192257142857

00:07:16.060 --> 00:07:17.896 or another common condition

NOTE Confidence: 0.953192257142857

00:07:17.896 --> 00:07:20.191 and thereby be precluded from

NOTE Confidence: 0.953192257142857

00:07:20.191 --> 00:07:22.099 enrolling in a clinical trial.

NOTE Confidence: 0.953192257142857

00:07:22.100 --> 00:07:25.406 They're also known rural and urban

NOTE Confidence: 0.953192257142857

00:07:25.406 --> 00:07:27.458 gaps in clinical trial site locations.

NOTE Confidence: 0.953192257142857

00:07:27.460 --> 00:07:29.986 Most of our clinical trials particularly

NOTE Confidence: 0.953192257142857

00:07:29.986 --> 00:07:32.679 in oncology take place on the coasts.

NOTE Confidence: 0.953192257142857

00:07:32.680 --> 00:07:34.540 In in large academic medical

NOTE Confidence: 0.953192257142857

00:07:34.540 --> 00:07:36.400 centers and in major cities.

NOTE Confidence: 0.938833110952381

00:07:43.490 --> 00:07:45.898 And so given the amount of policy

NOTE Confidence: 0.938833110952381

00:07:45.898 --> 00:07:47.989 efforts that have targeted improving

NOTE Confidence: 0.938833110952381

00:07:47.989 --> 00:07:49.961 diversity in clinical research

NOTE Confidence: 0.938833110952381

00:07:49.961 --> 00:07:52.610 and the well documented barriers,

NOTE Confidence: 0.938833110952381

00:07:52.610 --> 00:07:54.367 many experts have started wondering you know,

NOTE Confidence: 0.938833110952381

00:07:54.370 --> 00:07:56.498 what else can we do to improve

NOTE Confidence: 0.938833110952381

00:07:56.498 --> 00:07:57.410 clinical trial diversity?

NOTE Confidence: 0.938833110952381

00:07:57.410 --> 00:07:59.420 And there was a paper that came out in New

NOTE Confidence: 0.938833110952381

00:07:59.476 --> 00:08:01.348 England Journal of Medicine this month.

NOTE Confidence: 0.938833110952381

00:08:01.350 --> 00:08:03.247 That said, you know what's very important

NOTE Confidence: 0.938833110952381

00:08:03.247 --> 00:08:05.309 is to to find why we're aiming,

NOTE Confidence: 0.938833110952381

00:08:05.310 --> 00:08:07.160 why we're striving for diversity

NOTE Confidence: 0.938833110952381

00:08:07.160 --> 00:08:08.270 and clinical research.

NOTE Confidence: 0.938833110952381

00:08:08.270 --> 00:08:09.926 And we wrote a similar paper

NOTE Confidence: 0.938833110952381

00:08:09.926 --> 00:08:11.510 led by Tom V Varma,

NOTE Confidence: 0.938833110952381

00:08:11.510 --> 00:08:13.054 brilliant medical student here

NOTE Confidence: 0.938833110952381

00:08:13.054 --> 00:08:14.984 at Yale with Kamara Jones,

NOTE Confidence: 0.938833110952381

00:08:14.990 --> 00:08:17.670 Carol Oladele and myself asking

NOTE Confidence: 0.938833110952381

00:08:17.670 --> 00:08:20.350 the saying the same question,

NOTE Confidence: 0.938833110952381

00:08:20.350 --> 00:08:22.444 stating the same problem when you

NOTE Confidence: 0.938833110952381

00:08:22.444 --> 00:08:24.480 read these policy guidance documents.

NOTE Confidence: 0.938833110952381

00:08:24.480 --> 00:08:26.700 Most of them fail to explain

NOTE Confidence: 0.938833110952381

00:08:26.700 --> 00:08:28.668 why clinical trial diversity is

NOTE Confidence: 0.938833110952381

00:08:28.668 --> 00:08:31.164 critical and why racial and ethnic

NOTE Confidence: 0.938833110952381

00:08:31.164 --> 00:08:33.000 representation in clinical research

NOTE Confidence: 0.938833110952381

00:08:33.000 --> 00:08:34.635 in particular is important given

NOTE Confidence: 0.938833110952381

00:08:34.635 --> 00:08:36.857 race is a social construct and is

NOTE Confidence: 0.938833110952381

00:08:36.857 --> 00:08:38.435 often grouped with sex and age,

NOTE Confidence: 0.938833110952381

00:08:38.440 --> 00:08:43.078 which are biological variables or attributes.

NOTE Confidence: 0.938833110952381

00:08:43.080 --> 00:08:46.608 And we are pretty worried that the

NOTE Confidence: 0.938833110952381

00:08:46.608 --> 00:08:48.555 existing guidance could unintentionally

NOTE Confidence: 0.938833110952381

00:08:48.555 --> 00:08:50.730 endorse a biological basis for

NOTE Confidence: 0.938833110952381

00:08:50.730 --> 00:08:52.035 race and ethnicity.

NOTE Confidence: 0.938833110952381

00:08:52.040 --> 00:08:54.290 So we worked pretty hard to.

NOTE Confidence: 0.938833110952381

00:08:54.290 --> 00:08:56.325 Provide some missing arguments for

NOTE Confidence: 0.938833110952381

00:08:56.325 --> 00:08:58.360 why racial and ethnic representation

NOTE Confidence: 0.938833110952381

00:08:58.420 --> 00:09:00.370 in clinical research is essential,

NOTE Confidence: 0.938833110952381

00:09:00.370 --> 00:09:02.176 although I'm going to say that Aaron

NOTE Confidence: 0.938833110952381

00:09:02.176 --> 00:09:04.372 Schwartz and colleagues in New England

NOTE Confidence: 0.938833110952381

00:09:04.372 --> 00:09:06.330 Journal of Medicine did it better.

NOTE Confidence: 0.938833110952381

00:09:06.330 --> 00:09:08.034 So basically we said the same

NOTE Confidence: 0.938833110952381

00:09:08.034 --> 00:09:09.170 thing that they did,

NOTE Confidence: 0.938833110952381

00:09:09.170 --> 00:09:11.070 that improving clinical trial diversity

NOTE Confidence: 0.938833110952381

00:09:11.070 --> 00:09:12.970 was critical for three reasons.

NOTE Confidence: 0.938833110952381

00:09:12.970 --> 00:09:16.180 One was enhancing trust in medical

NOTE Confidence: 0.938833110952381

00:09:16.180 --> 00:09:20.090 research and research institutions.

NOTE Confidence: 0.938833110952381

00:09:20.090 --> 00:09:21.578 So it's not just.

NOTE Confidence: 0.938833110952381

00:09:21.578 --> 00:09:24.042 How a technology is How a technology

NOTE Confidence: 0.938833110952381

00:09:24.042 --> 00:09:25.986 is developed affects who adopts it.

NOTE Confidence: 0.938833110952381

00:09:25.990 --> 00:09:28.265 And there have been studies that show

NOTE Confidence: 0.938833110952381

00:09:28.265 --> 00:09:30.390 that underrepresented patients are

NOTE Confidence: 0.938833110952381

00:09:30.390 --> 00:09:33.950 more likely to are less likely to

NOTE Confidence: 0.938833110952381

00:09:33.950 --> 00:09:35.930 trust medical evidence when they're

NOTE Confidence: 0.938833110952381

00:09:35.930 --> 00:09:37.470 underrepresented in clinical research,

NOTE Confidence: 0.938833110952381

00:09:37.470 --> 00:09:39.168 and less likely to believe a

NOTE Confidence: 0.938833110952381

00:09:39.168 --> 00:09:40.870 drug will be affected for them.

NOTE Confidence: 0.938833110952381

00:09:40.870 --> 00:09:42.892 And their doctors are less likely

NOTE Confidence: 0.938833110952381

00:09:42.892 --> 00:09:45.332 to prescribe and use medicines when

NOTE Confidence: 0.938833110952381

00:09:45.332 --> 00:09:47.180 their patients are underrepresented

NOTE Confidence: 0.938833110952381

00:09:47.180 --> 00:09:49.028 in in research samples.

NOTE Confidence: 0.965971112222222

00:09:51.890 --> 00:09:54.022 Further, clinical trial diversity

NOTE Confidence: 0.965971112222222

00:09:54.022 --> 00:09:56.687 is critical for promoting fairness,

NOTE Confidence: 0.965971112222222

00:09:56.690 --> 00:09:59.738 for providing equal opportunities or fair

NOTE Confidence: 0.965971112222222

00:09:59.738 --> 00:10:02.330 opportunities to participate in trials.

NOTE Confidence: 0.965971112222222

00:10:02.330 --> 00:10:04.130 And in the New England

NOTE Confidence: 0.965971112222222

00:10:04.130 --> 00:10:05.210 Journal Medicine paper,

NOTE Confidence: 0.965971112222222

00:10:05.210 --> 00:10:08.476 they note that by increasing infrastructure

NOTE Confidence: 0.965971112222222

00:10:08.476 --> 00:10:11.006 and building capacity to participate

NOTE Confidence: 0.965971112222222

00:10:11.006 --> 00:10:14.243 in clinical trials among community hospitals,

NOTE Confidence: 0.965971112222222

00:10:14.243 --> 00:10:16.527 you're you're also improving

NOTE Confidence: 0.965971112222222

00:10:16.527 --> 00:10:18.680 infrastructure for for care.

NOTE Confidence: 0.965971112222222

00:10:18.680 --> 00:10:20.720 And also, clinical trial diversity is

NOTE Confidence: 0.965971112222222

00:10:20.720 --> 00:10:22.600 critical for generating biomedical knowledge,

NOTE Confidence: 0.965971112222222

00:10:22.600 --> 00:10:26.416 for developing equitable access to and

NOTE Confidence: 0.965971112222222

00:10:26.416 --> 00:10:28.960 representation of medical evidence.

NOTE Confidence: 0.935479503333333

00:10:33.480 --> 00:10:35.928 So while there's been some preliminary

NOTE Confidence: 0.935479503333333

00:10:35.928 --> 00:10:38.188 work describing why diversity in

NOTE Confidence: 0.935479503333333

00:10:38.188 --> 00:10:40.758 clinical trial enrollment is important,

NOTE Confidence: 0.935479503333333

00:10:40.760 --> 00:10:43.535 there hasn't been a lot of work defining

NOTE Confidence: 0.935479503333333

00:10:43.535 --> 00:10:47.210 what good representation looks like.

NOTE Confidence: 0.935479503333333

00:10:47.210 --> 00:10:50.494 And so back in 2001, in October of 2001,

NOTE Confidence: 0.935479503333333

00:10:50.494 --> 00:10:51.700 the editors of the New England

NOTE Confidence: 0.935479503333333

00:10:51.748 --> 00:10:52.684 Journal of Medicine actually

NOTE Confidence: 0.935479503333333

00:10:52.684 --> 00:10:54.330 called this out and says that said,

NOTE Confidence: 0.935479503333333

00:10:54.330 --> 00:10:56.906 that we need a conversation about what

NOTE Confidence: 0.935479503333333

00:10:56.906 --> 00:10:58.600 constitutes acceptable and reasonable

NOTE Confidence: 0.935479503333333

00:10:58.600 --> 00:11:00.728 representative in clinical research.

NOTE Confidence: 0.935479503333333

00:11:00.730 --> 00:11:01.472 And similarly,

NOTE Confidence: 0.935479503333333

00:11:01.472 --> 00:11:03.327 the National Academies of Science,

NOTE Confidence: 0.935479503333333

00:11:03.330 --> 00:11:04.602 Engineering and Medicine published

NOTE Confidence: 0.935479503333333

00:11:04.602 --> 00:11:06.845 its report in May of last year

NOTE Confidence: 0.935479503333333

00:11:06.845 --> 00:11:09.053 also saying that we need to have a

NOTE Confidence: 0.935479503333333

00:11:09.053 --> 00:11:11.005 conversation on what constitutes

NOTE Confidence: 0.935479503333333

00:11:11.005 --> 00:11:12.087 appropriate representativeness.

NOTE Confidence: 0.923722994545455

00:11:15.520 --> 00:11:18.110 And so Tanvi Varma, Kerry Gross and

NOTE Confidence: 0.923722994545455

00:11:18.110 --> 00:11:20.760 I wrote a paper on this very subject

NOTE Confidence: 0.923722994545455

00:11:20.760 --> 00:11:22.320 sort of asking clinical trial diversity

NOTE Confidence: 0.923722994545455

00:11:22.368 --> 00:11:23.800 will you know it when you see it.

NOTE Confidence: 0.944397352941176

00:11:25.960 --> 00:11:27.584 And so the first thing to that we

NOTE Confidence: 0.944397352941176

00:11:27.584 --> 00:11:29.242 worked on was conceptualizing what

NOTE Confidence: 0.944397352941176

00:11:29.242 --> 00:11:30.838 does adequate representation mean.

NOTE Confidence: 0.945742727272727

00:11:33.360 --> 00:11:35.334 And in the literature there are

NOTE Confidence: 0.945742727272727

00:11:35.334 --> 00:11:37.560 two leading ways to conceptualize

NOTE Confidence: 0.945742727272727

00:11:37.560 --> 00:11:39.021 adequate representation which

NOTE Confidence: 0.945742727272727

00:11:39.021 --> 00:11:41.456 we call the country population

NOTE Confidence: 0.945742727272727

00:11:41.456 --> 00:11:43.779 approach versus the condition based.

NOTE Confidence: 0.945742727272727

00:11:43.780 --> 00:11:46.260 Approach The country population approach,

NOTE Confidence: 0.945742727272727

00:11:46.260 --> 00:11:47.540 as the name suggests,

NOTE Confidence: 0.933139058333333

00:11:49.940 --> 00:11:52.150 argues that the trial participant

NOTE Confidence: 0.933139058333333

00:11:52.150 --> 00:11:53.918 demographics should mirror a

NOTE Confidence: 0.933139058333333

00:11:53.918 --> 00:11:55.899 country's population demographics.

NOTE Confidence: 0.933139058333333

00:11:55.900 --> 00:11:59.844 So for the the US this would mean

NOTE Confidence: 0.933139058333333

00:11:59.844 --> 00:12:02.740 enrolling 50.5% female trial participants,

NOTE Confidence: 0.933139058333333

00:12:02.740 --> 00:12:04.540 13.6 black identifying

NOTE Confidence: 0.933139058333333

00:12:04.540 --> 00:12:06.820 participants and the like.

NOTE Confidence: 0.933139058333333

00:12:06.820 --> 00:12:09.778 And this would be condition neutral,

NOTE Confidence: 0.933139058333333

00:12:09.778 --> 00:12:12.652 so regardless of a trial's indication

NOTE Confidence: 0.933139058333333

00:12:12.652 --> 00:12:15.170 or targeted condition or disease.

NOTE Confidence: 0.933139058333333

00:12:15.170 --> 00:12:17.434 The condition based approach,

NOTE Confidence: 0.933139058333333

00:12:17.434 --> 00:12:18.566 in contrast,

NOTE Confidence: 0.933139058333333

00:12:18.570 --> 00:12:20.390 suggests the trial participant

NOTE Confidence: 0.933139058333333

00:12:20.390 --> 00:12:22.210 demographics should mirror those

NOTE Confidence: 0.933139058333333

00:12:22.210 --> 00:12:25.101 of the patient population with the

NOTE Confidence: 0.933139058333333

00:12:25.101 --> 00:12:27.486 studied condition or targeted disease.

NOTE Confidence: 0.946291746

00:12:30.290 --> 00:12:33.426 And here you can just see two

NOTE Confidence: 0.946291746

00:12:33.426 --> 00:12:34.770 different research papers.

NOTE Confidence: 0.946291746

00:12:34.770 --> 00:12:37.686 Each have used the respective approaches.

NOTE Confidence: 0.946291746

00:12:37.690 --> 00:12:39.450 For the country population approach,

NOTE Confidence: 0.946291746

00:12:39.450 --> 00:12:41.412 there's a paper here with the

NOTE Confidence: 0.946291746

00:12:41.412 --> 00:12:43.340 senior author was Janet Woodcock.

NOTE Confidence: 0.946291746

00:12:43.340 --> 00:12:44.300 And that was pretty recent.

NOTE Confidence: 0.946291746

00:12:44.300 --> 00:12:46.580 And then the other condition based

NOTE Confidence: 0.946291746

00:12:46.580 --> 00:12:48.806 approach dates back much earlier to

NOTE Confidence: 0.946291746

00:12:48.806 --> 00:12:51.334 2013 with the paper led by Doctor Rita

NOTE Confidence: 0.946291746

00:12:51.402 --> 00:12:53.500 **** who was at the FDA at the time.

NOTE Confidence: 0.945285195

00:12:56.820 --> 00:13:00.540 So while both of these approaches are common,

NOTE Confidence: 0.945285195

00:13:00.540 --> 00:13:03.615 they applying them yields markedly

NOTE Confidence: 0.945285195

00:13:03.615 --> 00:13:05.460 different enrollment goals

NOTE Confidence: 0.945285195

00:13:05.460 --> 00:13:07.900 that we're not talking about.

NOTE Confidence: 0.945285195

00:13:07.900 --> 00:13:10.590 So in the paper we.

NOTE Confidence: 0.945285195

00:13:10.590 --> 00:13:12.403 We did two trials till we showed

NOTE Confidence: 0.945285195

00:13:12.403 --> 00:13:14.094 two trials and apply these two

NOTE Confidence: 0.945285195

00:13:14.094 --> 00:13:16.096 approaches to show how how you'd get

NOTE Confidence: 0.945285195

00:13:16.158 --> 00:13:17.950 markedly different enrollment target.

NOTE Confidence: 0.945285195

00:13:17.950 --> 00:13:19.550 So in case A,

NOTE Confidence: 0.945285195

00:13:19.550 --> 00:13:22.934 we said there's a Melanoma trial

NOTE Confidence: 0.945285195

00:13:22.934 --> 00:13:25.966 that enrolled 500 patients and we

NOTE Confidence: 0.945285195

00:13:25.966 --> 00:13:27.906 applied the country population approach

NOTE Confidence: 0.928512966666667

00:13:30.070 --> 00:13:34.544 and for if you use the general

NOTE Confidence: 0.928512966666667

00:13:34.544 --> 00:13:38.588 population you would aim to enroll.

NOTE Confidence: 0.928512966666667

00:13:38.590 --> 00:13:40.526 14% patients identifying as

NOTE Confidence: 0.928512966666667

00:13:40.526 --> 00:13:42.946 black for the Melanoma trial,

NOTE Confidence: 0.928512966666667

00:13:42.950 --> 00:13:45.350 but if you use the condition based approach,

NOTE Confidence: 0.928512966666667

00:13:45.350 --> 00:13:48.766 you would be aiming to enroll .5%

NOTE Confidence: 0.928512966666667

00:13:48.766 --> 00:13:51.390 patients identifying as black.

NOTE Confidence: 0.928512966666667

00:13:51.390 --> 00:13:55.107 And if you look at the multiple myeloma case,

NOTE Confidence: 0.928512966666667

00:13:55.110 --> 00:13:57.931 if you use a country population approach

NOTE Confidence: 0.928512966666667

00:13:57.931 --> 00:13:59.829 for patients identifying as Latino,

NOTE Confidence: 0.928512966666667

00:13:59.830 --> 00:14:03.610 you'd aim to enroll 19% patients

NOTE Confidence: 0.928512966666667

00:14:03.610 --> 00:14:05.550 identifying as Latino for.

NOTE Confidence: 0.928512966666667

00:14:05.550 --> 00:14:06.950 Sorry, the country population approach.

NOTE Confidence: 0.928512966666667

00:14:06.950 --> 00:14:08.707 And if you use a conditionbased approach,

NOTE Confidence: 0.928512966666667

00:14:08.710 --> 00:14:09.990 you'd aim to enroll 9%

NOTE Confidence: 0.880944143

00:14:12.950 --> 00:14:15.926 Country targets are 28 times greater

NOTE Confidence: 0.880944143

00:14:15.926 --> 00:14:17.910 than the conditionbased approach.

NOTE Confidence: 0.880944143

00:14:17.910 --> 00:14:19.695 And in the multiple my little mother's

NOTE Confidence: 0.880944143

00:14:19.695 --> 00:14:22.670 a 200% difference in enrollment targets.

NOTE Confidence: 0.92992658

00:14:28.410 --> 00:14:31.352 And so a group of us set out to try and

NOTE Confidence: 0.92992658

00:14:31.352 --> 00:14:33.764 flesh out what good representation looks

NOTE Confidence: 0.92992658

00:14:33.764 --> 00:14:36.731 like and how to conceptualize adequate

NOTE Confidence: 0.92992658

00:14:36.731 --> 00:14:39.536 diversity targets and enrollment goals.

NOTE Confidence: 0.92992658

00:14:39.540 --> 00:14:41.718 So we set, so we developed a measure and

NOTE Confidence: 0.92992658

00:14:41.718 --> 00:14:44.147 then we applied the measure to benchmark

NOTE Confidence: 0.92992658

00:14:44.147 --> 00:14:46.367 the adequacy of representation for pivotal

NOTE Confidence: 0.92992658

00:14:46.367 --> 00:14:48.222 trials supporting novel oncology products

NOTE Confidence: 0.92992658

00:14:48.222 --> 00:14:52.100 approved by the FDA between 2012 and 2017.

NOTE Confidence: 0.92992658

00:14:52.100 --> 00:14:54.165 And this study again was led by

NOTE Confidence: 0.92992658

00:14:54.165 --> 00:14:56.059 Tanvi done with Michelle Mello,

NOTE Confidence: 0.92992658

00:14:56.060 --> 00:14:57.578 Joe Ross who's in the room,

NOTE Confidence: 0.92992658

00:14:57.580 --> 00:15:00.940 Carrie Gross and myself.

NOTE Confidence: 0.92992658

00:15:00.940 --> 00:15:03.495 And so we had three main outcomes

NOTE Confidence: 0.92992658

00:15:03.500 --> 00:15:04.349 for the paper.

NOTE Confidence: 0.92992658

00:15:04.349 --> 00:15:06.047 The first thing we wanted to

NOTE Confidence: 0.92992658

00:15:06.047 --> 00:15:07.878 do was assess transparency.

NOTE Confidence: 0.92992658

00:15:07.880 --> 00:15:09.320 Could we determine from

NOTE Confidence: 0.92992658

00:15:09.320 --> 00:15:11.186 public sources the sex, age,

NOTE Confidence: 0.92992658

00:15:11.186 --> 00:15:13.316 and racial and ethnic identity

NOTE Confidence: 0.92992658

00:15:13.316 --> 00:15:14.594 of trial participants?

NOTE Confidence: 0.92992658

00:15:14.600 --> 00:15:14.933 Second,

NOTE Confidence: 0.92992658

00:15:14.933 --> 00:15:16.265 we looked at representation

NOTE Confidence: 0.92992658

00:15:16.265 --> 00:15:17.597 using the second approach,

NOTE Confidence: 0.92992658

00:15:17.600 --> 00:15:19.232 the country population approach,

NOTE Confidence: 0.92992658

00:15:19.232 --> 00:15:21.272 looking to see whether trial

NOTE Confidence: 0.92992658

00:15:21.272 --> 00:15:22.456 participant demographics mirrored

NOTE Confidence: 0.92992658

00:15:22.456 --> 00:15:24.604 those of the US patient population

NOTE Confidence: 0.92992658

00:15:24.604 --> 00:15:26.997 for the studied condition or disease,

NOTE Confidence: 0.92992658

00:15:27.000 --> 00:15:29.766 which we calculated by using a

NOTE Confidence: 0.92992658

00:15:29.766 --> 00:15:31.610 participation to prevalence ratio.

NOTE Confidence: 0.92992658

00:15:31.610 --> 00:15:33.850 And then we did a fair inclusion measure,

NOTE Confidence: 0.92992658

00:15:33.850 --> 00:15:36.226 which was the average of the

NOTE Confidence: 0.92992658

00:15:36.226 --> 00:15:37.414 transparency and representation

NOTE Confidence: 0.92992658

00:15:37.414 --> 00:15:39.550 scores and we reported results on

NOTE Confidence: 0.92992658

00:15:39.550 --> 00:15:41.730 the trial product and sponsor level.

NOTE Confidence: 0.92992658

00:15:41.730 --> 00:15:43.206 And so this is the characteristics

NOTE Confidence: 0.92992658

00:15:43.206 --> 00:15:44.730 of the sample we looked at.

NOTE Confidence: 0.92992658

00:15:44.730 --> 00:15:47.850 So between 2012 and 2017,

NOTE Confidence: 0.92992658

00:15:47.850 --> 00:15:50.570 the FDA approved a total of 59 products,

NOTE Confidence: 0.92992658

00:15:50.570 --> 00:15:53.420 39 drugs and 20 biologics sponsored

NOTE Confidence: 0.92992658

00:15:53.420 --> 00:15:55.984 by 25 unique pharmaceutical

NOTE Confidence: 0.92992658

00:15:55.984 --> 00:16:00.019 companies which targeted 16 broad.

NOTE Confidence: 0.92992658

00:16:00.020 --> 00:16:01.764 Oncology indications based on

NOTE Confidence: 0.92992658

00:16:01.764 --> 00:16:04.380 a total of 64 pivotal trials,

NOTE Confidence: 0.92992658

00:16:04.380 --> 00:16:06.660 a median of 1 pivotal trial per product.

NOTE Confidence: 0.9402536

00:16:10.100 --> 00:16:14.412 And here's what we found on the first column,

NOTE Confidence: 0.9402536

00:16:14.412 --> 00:16:17.534 you can see what we found on the trial level.

NOTE Confidence: 0.9402536

00:16:17.540 --> 00:16:20.408 While 100% of pivotal trials were

NOTE Confidence: 0.9402536

00:16:20.408 --> 00:16:23.699 transparent about the sex of participants,

NOTE Confidence: 0.9402536

00:16:23.700 --> 00:16:25.940 only 67% transparently reported.

NOTE Confidence: 0.9402536

00:16:25.940 --> 00:16:29.986 The age and proportion of older adult

NOTE Confidence: 0.9402536

00:16:29.986 --> 00:16:34.160 participants and only 41% the race and

NOTE Confidence: 0.9402536

00:16:34.160 --> 00:16:37.160 ethnic identity of trial participants.

NOTE Confidence: 0.9402536

00:16:37.160 --> 00:16:39.048 In terms of representation,

NOTE Confidence: 0.9402536

00:16:39.048 --> 00:16:41.288 81% of pivotal trials supporting

NOTE Confidence: 0.9402536

00:16:41.288 --> 00:16:43.498 the Oncology Products Nurse sample

NOTE Confidence: 0.9402536

00:16:43.498 --> 00:16:45.080 adequately represented women,

NOTE Confidence: 0.9402536

00:16:45.080 --> 00:16:47.000 but only about a quarter,

NOTE Confidence: 0.9402536

00:16:47.000 --> 00:16:49.432 26% adequately represented older

NOTE Confidence: 0.9402536

00:16:49.432 --> 00:16:52.120 adults patients aged 65 and older,

NOTE Confidence: 0.9402536

00:16:52.120 --> 00:16:54.955 and only 10% racial and

NOTE Confidence: 0.9402536

00:16:54.955 --> 00:16:56.656 ethnic minoritized patients.

NOTE Confidence: 0.9402536

00:16:56.660 --> 00:16:58.300 And then when you look at fair inclusion,

NOTE Confidence: 0.9402536

00:16:58.300 --> 00:17:00.236 both aside from women,

NOTE Confidence: 0.9402536

00:17:00.236 --> 00:17:03.370 the numbers go slightly down on the

NOTE Confidence: 0.9402536

00:17:03.370 --> 00:17:05.500 sponsor level, on the company level,

NOTE Confidence: 0.9402536

00:17:05.500 --> 00:17:06.780 on the fair inclusion measures,

NOTE Confidence: 0.9402536

00:17:06.780 --> 00:17:08.052 we found 50,

NOTE Confidence: 0.9402536

00:17:08.052 --> 00:17:09.996 only 54% of sponsors,

NOTE Confidence: 0.9402536

00:17:09.996 --> 00:17:11.092 pharmaceutical companies

NOTE Confidence: 0.9402536

00:17:11.092 --> 00:17:12.736 fairly included women,

NOTE Confidence: 0.9402536

00:17:12.740 --> 00:17:15.932 20% older adults and 4% racial

NOTE Confidence: 0.9402536

00:17:15.932 --> 00:17:17.500 and ethnic minoritized patients.

NOTE Confidence: 0.93824092

00:17:26.450 --> 00:17:28.322 And here you can see that

NOTE Confidence: 0.93824092

00:17:28.322 --> 00:17:29.570 in terms of representation,

NOTE Confidence: 0.93824092

00:17:29.570 --> 00:17:31.238 patients identifying as Asian

NOTE Confidence: 0.93824092

00:17:31.238 --> 00:17:33.323 are much better represented than

NOTE Confidence: 0.93824092

00:17:33.330 --> 00:17:35.370 patients identifying as Latino or

NOTE Confidence: 0.93824092

00:17:35.370 --> 00:17:37.410 than patients identifying as Black.

NOTE Confidence: 0.9402536

00:17:39.530 --> 00:17:42.090 What you also see here is

NOTE Confidence: 0.9402536

00:17:42.090 --> 00:17:43.978 that the transparency around

NOTE Confidence: 0.9402536

00:17:43.978 --> 00:17:46.328 patients identifying as Native,

NOTE Confidence: 0.9402536

00:17:46.330 --> 00:17:49.648 Hawaiian or Alaskan native is really low

NOTE Confidence: 0.9402536

00:17:49.650 --> 00:17:52.428 and so we couldn't actually benchmark

NOTE Confidence: 0.9402536

00:17:52.428 --> 00:17:54.860 the representation of these groups.

NOTE Confidence: 0.9402536

00:17:54.860 --> 00:17:56.138 In clinical trials,

NOTE Confidence: 0.9402536

00:17:56.138 --> 00:17:58.694 because we didn't know the percentage

NOTE Confidence: 0.9402536

00:17:58.700 --> 00:18:00.900 of patients identifying in these

NOTE Confidence: 0.9402536

00:18:00.900 --> 00:18:02.636 groups amongst trial participants

NOTE Confidence: 0.9402536

00:18:02.636 --> 00:18:05.228 and also we didn't necessarily know

NOTE Confidence: 0.9402536

00:18:05.228 --> 00:18:07.820 the incidence rate for the condition

NOTE Confidence: 0.9402536

00:18:07.820 --> 00:18:09.908 for these groups because of the

NOTE Confidence: 0.9402536

00:18:09.908 --> 00:18:12.060 limitations in the CDC databases.

NOTE Confidence: 0.9553487

00:18:18.170 --> 00:18:20.528 When you talk with pharmaceutical companies,

NOTE Confidence: 0.9553487

00:18:20.530 --> 00:18:24.310 often an anecdote that will come up

NOTE Confidence: 0.9553487

00:18:24.310 --> 00:18:27.004 is that well was an acknowledgement,

NOTE Confidence: 0.9553487

00:18:27.004 --> 00:18:28.588 well, maybe. We didn't get it

NOTE Confidence: 0.9553487

00:18:28.588 --> 00:18:29.673 right in the premarket studies,

NOTE Confidence: 0.9553487

00:18:29.680 --> 00:18:31.493 but if you had just looked at

NOTE Confidence: 0.9553487

00:18:31.493 --> 00:18:32.760 the post marketing studies,

NOTE Confidence: 0.9553487

00:18:32.760 --> 00:18:35.056 that's when we focus on clinical trial

NOTE Confidence: 0.9553487

00:18:35.056 --> 00:18:37.438 diversity and things would look a lot better.

NOTE Confidence: 0.9553487

00:18:37.440 --> 00:18:40.928 And so again our same group with the

NOTE Confidence: 0.9553487

00:18:40.928 --> 00:18:43.104 addition of some other researchers

NOTE Confidence: 0.9553487

00:18:43.104 --> 00:18:45.536 here at Yale took a look at premarket

NOTE Confidence: 0.9553487

00:18:45.536 --> 00:18:47.739 and post marketing studies and found

NOTE Confidence: 0.9553487

00:18:47.739 --> 00:18:49.574 that all things considered post

NOTE Confidence: 0.9553487

00:18:49.641 --> 00:18:51.477 marketing studies were generally

NOTE Confidence: 0.9553487

00:18:51.480 --> 00:18:53.280 worse in terms of representation

NOTE Confidence: 0.920856104

00:18:56.360 --> 00:18:58.448 that paper. Was led by Tom

NOTE Confidence: 0.920856104

00:18:58.448 --> 00:19:00.220 B and Josh Wallach, right.

NOTE Confidence: 0.920856104

00:19:00.220 --> 00:19:02.480 Joe, do you remember?

NOTE Confidence: 0.920856104

00:19:02.480 --> 00:19:08.328 Yeah, so here's where a lot of my work

NOTE Confidence: 0.920856104

00:19:08.328 --> 00:19:10.472 focuses is developing on account,

NOTE Confidence: 0.920856104

00:19:10.472 --> 00:19:12.024 is developing accounting ability

NOTE Confidence: 0.920856104

00:19:12.024 --> 00:19:14.117 measures and using them to benchmark

NOTE Confidence: 0.920856104

00:19:14.120 --> 00:19:16.364 pharmaceutical companies on those

NOTE Confidence: 0.920856104

00:19:16.364 --> 00:19:19.169 using those measures to incentivize

NOTE Confidence: 0.920856104

00:19:19.169 --> 00:19:21.920 or catalyze improve behaviors.

NOTE Confidence: 0.920856104

00:19:21.920 --> 00:19:23.330 And so I run something called

NOTE Confidence: 0.920856104

00:19:23.330 --> 00:19:24.550 the Good Pharmace scorecard that

NOTE Confidence: 0.920856104

00:19:24.550 --> 00:19:25.720 Mark mentioned at the outset.

NOTE Confidence: 0.920856104

00:19:25.720 --> 00:19:27.519 Which is an index that ranks and

NOTE Confidence: 0.920856104

00:19:27.519 --> 00:19:29.094 rates biotech pharma met device

NOTE Confidence: 0.920856104

00:19:29.094 --> 00:19:30.984 companies on their bioethics and

NOTE Confidence: 0.920856104

00:19:30.984 --> 00:19:32.118 social responsibility performance.

NOTE Confidence: 0.920856104

00:19:32.120 --> 00:19:32.792 It helped.

NOTE Confidence: 0.920856104

00:19:32.792 --> 00:19:35.144 It aims to help set and communicate

NOTE Confidence: 0.920856104

00:19:35.144 --> 00:19:37.357 clear bioethics goals and targets,

NOTE Confidence: 0.920856104

00:19:37.360 --> 00:19:39.000 track progress on those goals,

NOTE Confidence: 0.920856104

00:19:39.000 --> 00:19:40.800 recognize where there are best practices,

NOTE Confidence: 0.920856104

00:19:40.800 --> 00:19:44.520 and catalyze better behaviors were needed.

NOTE Confidence: 0.920856104

00:19:44.520 --> 00:19:46.370 And because there appeared to

NOTE Confidence: 0.920856104

00:19:46.370 --> 00:19:48.394 be market and guidance failures

NOTE Confidence: 0.920856104

00:19:48.394 --> 00:19:50.679 to address the clinical trial

NOTE Confidence: 0.920856104

00:19:50.679 --> 00:19:52.030 diversity problem I built,

NOTE Confidence: 0.920856104

00:19:52.030 --> 00:19:53.320 we built these measures into the

NOTE Confidence: 0.920856104

00:19:53.320 --> 00:19:54.200 Good Pharma scorecard.

NOTE Confidence: 0.911667625

00:19:58.010 --> 00:19:59.888 I'm hoping that the Good Pharma

NOTE Confidence: 0.911667625

00:19:59.888 --> 00:20:01.772 scorecard will help move the needle

NOTE Confidence: 0.911667625

00:20:01.772 --> 00:20:03.767 on clinical trial diversity as it has

NOTE Confidence: 0.911667625

00:20:03.767 --> 00:20:05.850 on other research ethics concerns,

NOTE Confidence: 0.911667625

00:20:05.850 --> 00:20:07.530 notably on clinical trial

NOTE Confidence: 0.911667625

00:20:07.530 --> 00:20:09.210 transparency and data sharing.

NOTE Confidence: 0.911667625

00:20:09.210 --> 00:20:10.530 So trial registration,

NOTE Confidence: 0.911667625

00:20:10.530 --> 00:20:12.000 results reporting, publication,

NOTE Confidence: 0.911667625

00:20:12.000 --> 00:20:14.950 and commitments to sharing individual

NOTE Confidence: 0.911667625

00:20:14.950 --> 00:20:17.950 patient level data from trials.

NOTE Confidence: 0.911667625

00:20:17.950 --> 00:20:18.982 On those measures,

NOTE Confidence: 0.911667625

00:20:18.982 --> 00:20:20.702 the good pharma scorecard has

NOTE Confidence: 0.911667625

00:20:20.702 --> 00:20:21.830 had measurable impact.

NOTE Confidence: 0.911667625

00:20:21.830 --> 00:20:23.924 Half of low scoring large companies

NOTE Confidence: 0.911667625

00:20:23.924 --> 00:20:25.320 will improve their procedures

NOTE Confidence: 0.911667625

00:20:25.378 --> 00:20:27.366 within 30 days of getting a low

NOTE Confidence: 0.911667625

00:20:27.366 --> 00:20:28.710 Good Pharma scorecard results.

NOTE Confidence: 0.911667625

00:20:28.710 --> 00:20:30.610 And the industry median scores

NOTE Confidence: 0.911667625

00:20:30.610 --> 00:20:33.021 have risen year after year on

NOTE Confidence: 0.911667625

00:20:33.021 --> 00:20:35.576 those measures since we began

NOTE Confidence: 0.911667625

00:20:35.576 --> 00:20:38.590 benchmarking for the 2012 approvals.

NOTE Confidence: 0.911667625

00:20:38.590 --> 00:20:42.045 And it's widely cited and used in annual

NOTE Confidence: 0.911667625

00:20:42.045 --> 00:20:45.520 reports human rights due diligence.

NOTE Confidence: 0.911667625

00:20:45.520 --> 00:20:49.004 Reports and social media accounts

NOTE Confidence: 0.911667625

00:20:49.004 --> 00:20:50.236 when companies score well.

NOTE Confidence: 0.933065457142857

00:20:53.960 --> 00:20:58.314 So that's why we broke up the

NOTE Confidence: 0.933065457142857

00:20:58.320 --> 00:21:00.344 diversity performance scores and

NOTE Confidence: 0.933065457142857

00:21:00.344 --> 00:21:03.188 aggregated onto the company level and

NOTE Confidence: 0.933065457142857

00:21:03.188 --> 00:21:05.036 introduced a rating system on this.

NOTE Confidence: 0.933065457142857

00:21:05.040 --> 00:21:07.672 So here you can see some companies

NOTE Confidence: 0.933065457142857

00:21:07.672 --> 00:21:10.080 scored in the top 25% and got

NOTE Confidence: 0.933065457142857

00:21:10.080 --> 00:21:11.528 a gold rating somewhere above

NOTE Confidence: 0.933065457142857

00:21:11.528 --> 00:21:12.992 the median and received a silver

NOTE Confidence: 0.933065457142857

00:21:12.992 --> 00:21:14.397 rating and the rest are unrated.

NOTE Confidence: 0.9301902

00:21:19.560 --> 00:21:22.536 And now we have a grant from the FDA

NOTE Confidence: 0.9301902

00:21:22.536 --> 00:21:24.527 Oncology Center for Excellence through

NOTE Confidence: 0.9301902

00:21:24.527 --> 00:21:28.800 the Cersei program led by Joe Ross.

NOTE Confidence: 0.9301902

00:21:28.800 --> 00:21:33.253 And here we're looking to identify positive

NOTE Confidence: 0.9301902

00:21:33.253 --> 00:21:36.518 deviant trials and sponsors leaders,

NOTE Confidence: 0.9301902

00:21:36.520 --> 00:21:38.914 trials that have gotten it right

NOTE Confidence: 0.9301902

00:21:38.914 --> 00:21:40.510 that have adequately represented

NOTE Confidence: 0.9301902

00:21:40.579 --> 00:21:42.736 specific demographic groups to set

NOTE Confidence: 0.9301902

00:21:42.736 --> 00:21:44.720 up a qualitative study to go in and

NOTE Confidence: 0.9301902

00:21:44.788 --> 00:21:47.036 interview them to see how they did it.

NOTE Confidence: 0.9301902

00:21:47.040 --> 00:21:49.440 What were the factors antecedent

NOTE Confidence: 0.9301902

00:21:49.440 --> 00:21:51.330 behavior strategies that they think

NOTE Confidence: 0.9301902

00:21:51.330 --> 00:21:53.700 enabled them to achieve top performance

NOTE Confidence: 0.9301902

00:21:53.700 --> 00:21:55.800 and perform better than peers.

NOTE Confidence: 0.94151146125

00:21:58.920 --> 00:22:01.816 So as part of that process we extended

NOTE Confidence: 0.94151146125

00:22:01.816 --> 00:22:04.758 our sample from just looking at 2012 and

NOTE Confidence: 0.94151146125

00:22:04.760 --> 00:22:07.171 20/17/2012 through 2017 FDA oncology

NOTE Confidence: 0.94151146125

00:22:07.171 --> 00:22:10.040 product approvals to a full 10 year sample,

NOTE Confidence: 0.94151146125

00:22:10.040 --> 00:22:13.542 the 2012 to 2021 approvals and

NOTE Confidence: 0.94151146125

00:22:13.542 --> 00:22:16.350 this is preliminary results.

NOTE Confidence: 0.94151146125

00:22:16.350 --> 00:22:18.951 I was really curious to see if things had

NOTE Confidence: 0.94151146125

00:22:18.951 --> 00:22:21.046 gotten better because another anecdote was,

NOTE Confidence: 0.94151146125

00:22:21.046 --> 00:22:22.470 well, those are old trials.

NOTE Confidence: 0.94151146125

00:22:22.470 --> 00:22:23.550 Those are you know,

NOTE Confidence: 0.94151146125

00:22:23.550 --> 00:22:25.590 approvals that happened back in 2017.

NOTE Confidence: 0.94151146125

00:22:25.590 --> 00:22:27.486 If only you had looked at

NOTE Confidence: 0.94151146125

00:22:27.486 --> 00:22:28.750 the more recent approvals,

NOTE Confidence: 0.94151146125

00:22:28.750 --> 00:22:30.988 things would look a lot better.

NOTE Confidence: 0.94151146125

00:22:30.990 --> 00:22:33.069 And So what do you guys think?

NOTE Confidence: 0.94151146125

00:22:33.070 --> 00:22:36.470 Do you think they look better anyone?

NOTE Confidence: 0.93824092

00:22:38.710 --> 00:22:41.912 So this sample looks at 111 products

NOTE Confidence: 0.93824092

00:22:41.912 --> 00:22:45.517 sponsored by 70 unique companies.

NOTE Confidence: 0.93824092

00:22:45.520 --> 00:22:47.520 Based on 121 pivotal trials

NOTE Confidence: 0.93824092

00:22:47.520 --> 00:22:49.120 that enrolled over 40,

NOTE Confidence: 0.93824092

00:22:49.120 --> 00:22:50.888 about 40,000 participants and

NOTE Confidence: 0.93824092

00:22:50.888 --> 00:22:53.098 each novel oncology product was

NOTE Confidence: 0.93824092

00:22:53.098 --> 00:22:55.317 approved based on one pivotal trial,

NOTE Confidence: 0.93824092

00:22:55.320 --> 00:22:56.560 median of 1 pivotal trial.

NOTE Confidence: 0.729229988

00:22:59.760 --> 00:23:01.240 Hear it from this slide.

NOTE Confidence: 0.729229988

00:23:01.240 --> 00:23:04.276 Again, this is not published yet.

NOTE Confidence: 0.729229988

00:23:04.280 --> 00:23:06.373 The what you see is that patients

NOTE Confidence: 0.729229988

00:23:06.373 --> 00:23:08.249 identifying as Asian are consistently

NOTE Confidence: 0.729229988

00:23:08.249 --> 00:23:10.089 overrepresented and remember that

NOTE Confidence: 0.729229988

00:23:10.089 --> 00:23:12.400 representation was calculated by using

NOTE Confidence: 0.729229988

00:23:12.400 --> 00:23:14.475 that participation to prevalence score.

NOTE Confidence: 0.729229988

00:23:14.480 --> 00:23:16.820 Where you compare trial participant

NOTE Confidence: 0.729229988

00:23:16.820 --> 00:23:18.692 demographics to the patient

NOTE Confidence: 0.729229988

00:23:18.692 --> 00:23:22.440 population demographics in the US.

NOTE Confidence: 0.729229988

00:23:22.440 --> 00:23:24.240 So taking out patients identifying

NOTE Confidence: 0.729229988

00:23:24.240 --> 00:23:26.040 as Asian for a second,

NOTE Confidence: 0.729229988

00:23:26.040 --> 00:23:30.084 here you can see that female women are

NOTE Confidence: 0.729229988

00:23:30.084 --> 00:23:31.994 generally well represented in research,

NOTE Confidence: 0.729229988

00:23:32.000 --> 00:23:34.264 but older adults remain

NOTE Confidence: 0.729229988

00:23:34.264 --> 00:23:35.396 under underrepresented.

NOTE Confidence: 0.729229988

00:23:35.400 --> 00:23:38.000 Patients identifying as black and

NOTE Confidence: 0.729229988

00:23:38.000 --> 00:23:40.080 Latino also remain underrepresented

NOTE Confidence: 0.729229988

00:23:40.080 --> 00:23:42.646 with no statistical statistically

NOTE Confidence: 0.729229988

00:23:42.646 --> 00:23:44.010 significant changes.

NOTE Confidence: 0.729229988

00:23:44.010 --> 00:23:45.090 Over the 10 year period

NOTE Confidence: 0.9352219

00:23:54.100 --> 00:23:58.780 that was a very US centered presentation

NOTE Confidence: 0.9352219

00:23:58.780 --> 00:24:03.962 and I'm we're not getting it right

NOTE Confidence: 0.9352219

00:24:03.962 --> 00:24:07.620 here and how are we doing elsewhere,

NOTE Confidence: 0.9352219

00:24:07.620 --> 00:24:10.100 It's something I was been sort of asking.

NOTE Confidence: 0.9352219

00:24:10.100 --> 00:24:14.060 So the first step in answering that question

NOTE Confidence: 0.9352219

00:24:14.060 --> 00:24:17.259 was understanding a bit more of where

NOTE Confidence: 0.9352219

00:24:17.260 --> 00:24:20.400 our clinical trials are taking place.

NOTE Confidence: 0.9352219

00:24:20.400 --> 00:24:24.868 And so we did a study looking at

NOTE Confidence: 0.9352219

00:24:24.868 --> 00:24:27.658 where our novel drugs and biologics

NOTE Confidence: 0.9352219

00:24:27.658 --> 00:24:30.355 approved by the FDA in 2012 and 2014

NOTE Confidence: 0.9352219

00:24:30.355 --> 00:24:32.437 were tested on the country level.

NOTE Confidence: 0.939582706666667

00:24:35.680 --> 00:24:38.123 And what we found is that these

NOTE Confidence: 0.939582706666667

00:24:38.123 --> 00:24:40.103 novel products were tested in a

NOTE Confidence: 0.939582706666667

00:24:40.103 --> 00:24:42.318 median of 26 different countries.

NOTE Confidence: 0.957025933333333

00:24:47.150 --> 00:24:48.774 And these trials enrolled

NOTE Confidence: 0.957025933333333

00:24:48.774 --> 00:24:50.560 about 300 participants each,

NOTE Confidence: 0.957025933333333

00:24:50.560 --> 00:24:52.985 a meeting of 300 participants.

NOTE Confidence: 0.957025933333333

00:24:52.990 --> 00:24:56.376 Roughly 20 of these

NOTE Confidence: 0.957025933333333

00:24:56.376 --> 00:24:58.224 countries were high income,

NOTE Confidence: 0.957025933333333

00:24:58.230 --> 00:24:59.430 a median of six were upper,

NOTE Confidence: 0.957025933333333

00:24:59.430 --> 00:25:00.742 middle and one low,

NOTE Confidence: 0.957025933333333

00:25:00.742 --> 00:25:02.382 middle and 0 low income.

NOTE Confidence: 0.9421404875

00:25:06.030 --> 00:25:08.352 And so now another question we need to ask

NOTE Confidence: 0.9421404875

00:25:08.352 --> 00:25:10.107 ourselves as ethicist is this the right

NOTE Confidence: 0.95836772

00:25:12.150 --> 00:25:15.270 way to situate multiregional clinical trials?

NOTE Confidence: 0.9301903

00:25:18.230 --> 00:25:20.467 And how do we, how do we start

NOTE Confidence: 0.9301903

00:25:20.467 --> 00:25:21.910 thinking about that question

NOTE Confidence: 0.936228356

00:25:21.910 --> 00:25:24.790 After we did our study,

NOTE Confidence: 0.936228356

00:25:24.790 --> 00:25:27.990 Jonathan Kimmelman's group led by

NOTE Confidence: 0.936228356

00:25:27.990 --> 00:25:30.950 Awan did a similar study in file

NOTE Confidence: 0.936228356

00:25:30.950 --> 00:25:32.390 and similar findings that most of

NOTE Confidence: 0.936228356

00:25:32.390 --> 00:25:33.743 our clinical trials are taking

NOTE Confidence: 0.936228356

00:25:33.743 --> 00:25:35.108 place in high income countries.

NOTE Confidence: 0.947572539090909

00:25:37.990 --> 00:25:41.342 And so do we need to increase geographic

NOTE Confidence: 0.947572539090909

00:25:41.342 --> 00:25:45.042 representation and research Joe Millum and I.

NOTE Confidence: 0.947572539090909

00:25:45.042 --> 00:25:49.030 Explored this question for BMJ Global

NOTE Confidence: 0.947572539090909

00:25:49.030 --> 00:25:51.835 Health and asking is this uneven

NOTE Confidence: 0.947572539090909

00:25:51.835 --> 00:25:54.670 distribution of trial sites by geography

NOTE Confidence: 0.947572539090909

00:25:54.670 --> 00:25:58.150 and income level and ethical concern.

NOTE Confidence: 0.947572539090909

00:25:58.150 --> 00:26:03.601 And we suggested that it was for two reasons.

NOTE Confidence: 0.947572539090909

00:26:03.601 --> 00:26:07.533 One, has the pandemic illustrated very well?

NOTE Confidence: 0.947572539090909

00:26:07.533 --> 00:26:09.819 The patients who can benefit from

NOTE Confidence: 0.947572539090909

00:26:09.819 --> 00:26:12.258 many of these new interventions are

NOTE Confidence: 0.947572539090909

00:26:12.258 --> 00:26:14.253 not limited to wealthier regions.

NOTE Confidence: 0.947572539090909

00:26:14.260 --> 00:26:16.934 1/3 of the drugs that we reviewed

NOTE Confidence: 0.947572539090909

00:26:16.940 --> 00:26:19.700 treated infectious disease diseases like

NOTE Confidence: 0.947572539090909

00:26:19.700 --> 00:26:21.356 tuberculosis which disproportionately

NOTE Confidence: 0.947572539090909

00:26:21.356 --> 00:26:24.290 affects low middle income countries and

NOTE Confidence: 0.947572539090909

00:26:24.290 --> 00:26:27.090 the other 3/4 of drugs were for non

NOTE Confidence: 0.947572539090909

00:26:27.090 --> 00:26:29.334 communicable diseases which are also highly

NOTE Confidence: 0.947572539090909

00:26:29.334 --> 00:26:30.978 relevant to low middle income countries.

NOTE Confidence: 0.947572539090909

00:26:30.980 --> 00:26:34.522 Given that 3/4 of deaths now occur

NOTE Confidence: 0.947572539090909

00:26:34.522 --> 00:26:37.448 in them and at the same time there

NOTE Confidence: 0.947572539090909

00:26:37.448 --> 00:26:39.727 are concerns that trial data may

NOTE Confidence: 0.947572539090909

00:26:39.727 --> 00:26:41.595 not extrapolate across geographies.

NOTE Confidence: 0.947572539090909

00:26:41.600 --> 00:26:43.076 And product effectiveness can

NOTE Confidence: 0.947572539090909

00:26:43.076 --> 00:26:44.921 vary substantially by region and

NOTE Confidence: 0.947572539090909

00:26:44.921 --> 00:26:46.708 we just named one example,

NOTE Confidence: 0.947572539090909

00:26:46.708 --> 00:26:48.678 the PEN Avalent rotavirus vaccine,

NOTE Confidence: 0.947572539090909

00:26:48.680 --> 00:26:51.445 which had markedly different efficacy

NOTE Confidence: 0.947572539090909

00:26:51.445 --> 00:26:54.280 rates in low middle income countries

NOTE Confidence: 0.947572539090909

00:26:54.280 --> 00:26:57.920 compared to high income with preventing

NOTE Confidence: 0.947572539090909

00:26:57.920 --> 00:27:01.370 severe rotavirus gastroenteritis and 64% of

NOTE Confidence: 0.947572539090909

00:27:01.370 --> 00:27:03.995 vaccinated children in Subsaharan Africa,

NOTE Confidence: 0.947572539090909

00:27:04.000 --> 00:27:07.232 51% in Asia in compared to in comparison

NOTE Confidence: 0.947572539090909

00:27:07.232 --> 00:27:10.848 to 98% in high income countries.

NOTE Confidence: 0.947572539090909

00:27:10.850 --> 00:27:12.980 And similar efficacy variations have been

NOTE Confidence: 0.947572539090909

00:27:12.980 --> 00:27:15.746 found for other vaccines ranging from polio,

NOTE Confidence: 0.947572539090909

00:27:15.746 --> 00:27:18.186 cholera, yellow and yellow fever,

NOTE Confidence: 0.947572539090909

00:27:18.186 --> 00:27:21.210 as well as drugs including antimicrobials.

NOTE Confidence: 0.947572539090909

00:27:21.210 --> 00:27:23.285 Often the explanations for the

NOTE Confidence: 0.947572539090909

00:27:23.285 --> 00:27:24.530 variance are unknown.

NOTE Confidence: 0.947572539090909

00:27:24.530 --> 00:27:26.755 They might occur because of

NOTE Confidence: 0.947572539090909

00:27:26.755 --> 00:27:28.706 social determinants, for example,

NOTE Confidence: 0.947572539090909

00:27:28.706 --> 00:27:30.290 dietary nutritional differences,

NOTE Confidence: 0.947572539090909

00:27:30.290 --> 00:27:31.472 differences in healthcare,

NOTE Confidence: 0.947572539090909

00:27:31.472 --> 00:27:33.048 delivery and the like.

NOTE Confidence: 0.936956778

00:27:42.600 --> 00:27:45.360 Research ethics often relies on the

NOTE Confidence: 0.936956778

00:27:45.360 --> 00:27:48.334 social value principle or the social

NOTE Confidence: 0.936956778

00:27:48.334 --> 00:27:50.974 value requirements that states clinical

NOTE Confidence: 0.936956778

00:27:50.974 --> 00:27:54.680 research is ethical only if it generates

NOTE Confidence: 0.936956778

00:27:54.680 --> 00:27:56.270 generates generalizable knowledge

NOTE Confidence: 0.936956778

00:27:56.270 --> 00:27:59.280 that is expected to promote health.

NOTE Confidence: 0.936956778

00:27:59.280 --> 00:28:02.800 Traditionally, this requirement has

NOTE Confidence: 0.936956778

00:28:02.800 --> 00:28:06.320 been interpreted quite permissively,

NOTE Confidence: 0.936956778

00:28:06.320 --> 00:28:07.418 provided a study.

NOTE Confidence: 0.936956778

00:28:07.418 --> 00:28:09.980 Was expected to generate data that can

NOTE Confidence: 0.936956778

00:28:10.048 --> 00:28:12.856 benefit someone or some populations health.

NOTE Confidence: 0.936956778

00:28:12.860 --> 00:28:15.572 It's been understood to have social

NOTE Confidence: 0.936956778

00:28:15.572 --> 00:28:18.020 value and more recently we've been

NOTE Confidence: 0.936956778

00:28:18.020 --> 00:28:19.940 starting to ask who should benefit,

NOTE Confidence: 0.936956778

00:28:19.940 --> 00:28:22.260 for whom should the value accrue

NOTE Confidence: 0.90976504631579

00:28:25.860 --> 00:28:28.268 and by what This is Doug McKay and

NOTE Confidence: 0.90976504631579

00:28:28.268 --> 00:28:30.398 Kate Saylor have raised this issue

NOTE Confidence: 0.90976504631579

00:28:30.398 --> 00:28:32.460 in a particular salient way and

NOTE Confidence: 0.90976504631579

00:28:32.460 --> 00:28:33.900 noted that this is just unfair,

NOTE Confidence: 0.90976504631579

00:28:33.900 --> 00:28:37.460 that we haven't been asking The Who question.

NOTE Confidence: 0.90976504631579

00:28:37.460 --> 00:28:39.260 Sure. No, I don't mind.

NOTE Confidence: 0.92767435

00:28:41.900 --> 00:28:45.580 So do you mean is it,

NOTE Confidence: 0.92767435

00:28:45.580 --> 00:28:47.350 is it at the code to do it or is

NOTE Confidence: 0.92767435

00:28:47.412 --> 00:28:49.296 that the code the funnet research,

NOTE Confidence: 0.92767435

00:28:49.300 --> 00:28:51.185 you know, so something benefits

NOTE Confidence: 0.92767435

00:28:51.185 --> 00:28:54.930 just children or just just we say

NOTE Confidence: 0.92767435

00:28:54.930 --> 00:28:57.540 that it has to benefit everyone?

NOTE Confidence: 0.92767435

00:28:57.540 --> 00:28:59.528 In terms of the ethics of doing

NOTE Confidence: 0.92767435

00:28:59.528 --> 00:29:01.154 the research or finding it,

NOTE Confidence: 0.92767435

00:29:01.154 --> 00:29:03.089 I just want the following.

NOTE Confidence: 0.92767435

00:29:03.090 --> 00:29:06.150 I ask do me a favor,

NOTE Confidence: 0.92767435

00:29:06.150 --> 00:29:08.450 just repeat the question.

NOTE Confidence: 0.92767435

00:29:08.450 --> 00:29:09.850 So, so

NOTE Confidence: 0.942540668181818

00:29:09.850 --> 00:29:13.578 I think the question was who is the

NOTE Confidence: 0.942540668181818

00:29:13.578 --> 00:29:16.892 target audience for the question and the

NOTE Confidence: 0.942540668181818

00:29:16.892 --> 00:29:20.370 short answer is we didn't answer that.

NOTE Confidence: 0.942540668181818

00:29:20.370 --> 00:29:23.925 We asked the apriori question which was in

NOTE Confidence: 0.942540668181818

00:29:23.925 --> 00:29:26.125 it was more oriented from the sponsor level.

NOTE Confidence: 0.942540668181818

00:29:26.130 --> 00:29:28.978 How should you think about what

NOTE Confidence: 0.942540668181818

00:29:28.978 --> 00:29:31.090 are the ethical considerations?

NOTE Confidence: 0.942540668181818

00:29:31.090 --> 00:29:32.598 When situating your clinical

NOTE Confidence: 0.942540668181818

00:29:32.598 --> 00:29:34.483 trials on the country level,

NOTE Confidence: 0.942540668181818

00:29:34.490 --> 00:29:38.594 it was more that and we come to this

NOTE Confidence: 0.942540668181818

00:29:38.594 --> 00:29:41.915 conclusion which is we suggest that

NOTE Confidence: 0.942540668181818

00:29:41.915 --> 00:29:43.805 you should think about the distribution

NOTE Confidence: 0.942540668181818

00:29:43.805 --> 00:29:45.721 of the disease burden across the

NOTE Confidence: 0.942540668181818

00:29:45.721 --> 00:29:48.087 globe and ideally your your trial site

NOTE Confidence: 0.942540668181818

00:29:48.087 --> 00:29:49.987 locations should correlate with the

NOTE Confidence: 0.942540668181818

00:29:49.987 --> 00:29:52.048 disease distribution is what we suggest.

NOTE Confidence: 0.94226628

00:29:55.650 --> 00:29:57.282 So very preliminary cut

NOTE Confidence: 0.94226628

00:29:57.282 --> 00:29:58.710 and analysis and then.

NOTE Confidence: 0.94226628

00:29:58.710 --> 00:30:00.410 Hoping just to raise awareness

NOTE Confidence: 0.94226628

00:30:00.410 --> 00:30:02.088 about this issue and challenge

NOTE Confidence: 0.94226628

00:30:02.088 --> 00:30:04.090 others to think about it as well.

NOTE Confidence: 0.941930773333333

00:30:07.770 --> 00:30:09.090 So that was the first question, right?

NOTE Confidence: 0.941930773333333

00:30:09.090 --> 00:30:10.770 Where are we conducting our trials?

NOTE Confidence: 0.941930773333333

00:30:10.770 --> 00:30:13.062 How should we be thinking about

NOTE Confidence: 0.941930773333333

00:30:13.062 --> 00:30:14.834 situating our clinical trial site

NOTE Confidence: 0.941930773333333

00:30:14.834 --> 00:30:16.564 locations on the country level?

NOTE Confidence: 0.941930773333333

00:30:16.570 --> 00:30:18.850 But then at the same time,

NOTE Confidence: 0.941930773333333

00:30:18.850 --> 00:30:20.202 I was sort of wondering, well,

NOTE Confidence: 0.941930773333333

00:30:20.202 --> 00:30:22.554 what happens to these countries that

NOTE Confidence: 0.941930773333333

00:30:22.554 --> 00:30:24.330 participate in clinical research?

NOTE Confidence: 0.941930773333333

00:30:24.330 --> 00:30:27.000 Do they get access to the

NOTE Confidence: 0.941930773333333

00:30:27.000 --> 00:30:29.310 products that they helped test?

NOTE Confidence: 0.941930773333333

00:30:29.310 --> 00:30:32.950 So the next piece of that study after

NOTE Confidence: 0.941930773333333

00:30:32.950 --> 00:30:34.910 we found out where all the trials

NOTE Confidence: 0.941930773333333

00:30:34.910 --> 00:30:36.687 were located was to go to the the

NOTE Confidence: 0.941930773333333

00:30:36.687 --> 00:30:38.469 equivalent of their FDA sites and

NOTE Confidence: 0.941930773333333

00:30:38.469 --> 00:30:40.882 see if the product that had been

NOTE Confidence: 0.941930773333333

00:30:40.882 --> 00:30:42.702 tested in the country received,

NOTE Confidence: 0.941930773333333

00:30:42.710 --> 00:30:44.010 if it received regulatory approval

NOTE Confidence: 0.941930773333333

00:30:44.010 --> 00:30:44.790 in that country.

NOTE Confidence: 0.950316896

00:30:47.350 --> 00:30:49.779 And what we found that of the

NOTE Confidence: 0.950316896

00:30:49.779 --> 00:30:51.358 70 countries contributing trial

NOTE Confidence: 0.950316896

00:30:51.358 --> 00:30:53.226 participants for FDA approvals,

NOTE Confidence: 0.950316896

00:30:53.230 --> 00:30:55.090 7% received market access to

NOTE Confidence: 0.950316896

00:30:55.090 --> 00:30:56.950 the drugs they helped test.

NOTE Confidence: 0.950316896

00:30:56.950 --> 00:30:58.762 Within one year of FDA approval

NOTE Confidence: 0.950316896

00:30:58.762 --> 00:31:00.230 and 31% within five years.

NOTE Confidence: 0.909192383333333

00:31:03.510 --> 00:31:05.886 And we looked for a subsample

NOTE Confidence: 0.909192383333333

00:31:05.886 --> 00:31:08.550 at 7 years and didn't find

NOTE Confidence: 0.909192383333333

00:31:08.550 --> 00:31:10.269 any significant improvements.

NOTE Confidence: 0.934503085714286

00:31:13.630 --> 00:31:16.702 When we broke up the sample by high income,

NOTE Confidence: 0.934503085714286

00:31:16.702 --> 00:31:18.382 lower middle income and upper

NOTE Confidence: 0.934503085714286

00:31:18.382 --> 00:31:19.390 middle income countries,

NOTE Confidence: 0.934503085714286

00:31:19.390 --> 00:31:21.988 you find that high income countries

NOTE Confidence: 0.934503085714286

00:31:21.990 --> 00:31:23.690 were more likely than lower

NOTE Confidence: 0.934503085714286

00:31:23.690 --> 00:31:25.390 middle income countries and upper

NOTE Confidence: 0.934503085714286

00:31:25.450 --> 00:31:26.788 middle income countries.

NOTE Confidence: 0.934503085714286

00:31:26.790 --> 00:31:28.190 To get product access

NOTE Confidence: 0.878460833333333

00:31:35.260 --> 00:31:36.178 and then when you bring it,

NOTE Confidence: 0.878460833333333

00:31:36.180 --> 00:31:37.980 break it up by geographic location.

NOTE Confidence: 0.878460833333333

00:31:37.980 --> 00:31:41.980 Unsurprisingly, you find that Eastern

NOTE Confidence: 0.878460833333333

00:31:41.980 --> 00:31:45.660 European countries, Western Europe,

NOTE Confidence: 0.878460833333333

00:31:45.660 --> 00:31:50.660 Canada got 100% or close to it access

NOTE Confidence: 0.878460833333333

00:31:50.660 --> 00:31:52.762 to the products they helped test

NOTE Confidence: 0.878460833333333

00:31:52.762 --> 00:31:55.774 by five years post FDA approval,

NOTE Confidence: 0.878460833333333

00:31:55.780 --> 00:31:58.220 in contrast to other countries

NOTE Confidence: 0.878460833333333

00:31:58.220 --> 00:32:01.356 like those in Africa that had zero.

NOTE Confidence: 0.878460833333333

00:32:01.356 --> 00:32:04.794 Percent access and then the Middle

NOTE Confidence: 0.878460833333333

00:32:04.794 --> 00:32:06.870 East falling in the middle and

NOTE Confidence: 0.878460833333333

00:32:06.870 --> 00:32:09.938 Central and South America also

NOTE Confidence: 0.878460833333333

00:32:09.938 --> 00:32:11.066 towards the middle of the pack.

NOTE Confidence: 0.907177226

00:32:16.190 --> 00:32:18.910 And other studies, this one not done by

NOTE Confidence: 0.907177226

00:32:18.910 --> 00:32:21.523 our group went to see that even if if

NOTE Confidence: 0.907177226

00:32:21.523 --> 00:32:22.988 a product was commercially available,

NOTE Confidence: 0.907177226

00:32:22.990 --> 00:32:25.482 was it affordable, which is right.

NOTE Confidence: 0.907177226

00:32:25.482 --> 00:32:27.234 So you could submit a product

NOTE Confidence: 0.907177226

00:32:27.234 --> 00:32:28.110 for regulatory approval,

NOTE Confidence: 0.907177226

00:32:28.110 --> 00:32:30.396 get approval to market the product.

NOTE Confidence: 0.907177226

00:32:30.400 --> 00:32:31.280 But the next question is,

NOTE Confidence: 0.907177226

00:32:31.280 --> 00:32:34.836 is it accessible And a piece of

NOTE Confidence: 0.907177226

00:32:34.836 --> 00:32:36.360 accessibility is affordability.

NOTE Confidence: 0.907177226

00:32:36.360 --> 00:32:39.318 And these this study shows that

NOTE Confidence: 0.907177226

00:32:39.320 --> 00:32:41.504 all the products but one product

NOTE Confidence: 0.907177226

00:32:41.504 --> 00:32:43.434 that they analyzed cost more than

NOTE Confidence: 0.907177226

00:32:43.434 --> 00:32:45.102 the monthly minimum wage and all

NOTE Confidence: 0.907177226

00:32:45.102 --> 00:32:46.636 the countries where they were

NOTE Confidence: 0.907177226

00:32:46.636 --> 00:32:48.809 tested and 12 cost five times more

NOTE Confidence: 0.907177226

00:32:48.809 --> 00:32:50.399 than the monthly minimum wage.

NOTE Confidence: 0.907177226

00:32:50.400 --> 00:32:51.800 But they only focused on

NOTE Confidence: 0.907177226

00:32:51.800 --> 00:32:52.640 Latin American countries.

NOTE Confidence: 0.907177226

00:32:52.640 --> 00:32:55.694 So now we're taking our sample and looking,

NOTE Confidence: 0.907177226

00:32:55.694 --> 00:32:57.703 trying to look at affordability for all

NOTE Confidence: 0.907177226

00:32:57.703 --> 00:32:59.719 of the countries that hosted trials.

NOTE Confidence: 0.956354935333333

00:33:03.490 --> 00:33:05.510 So they concluded that most

NOTE Confidence: 0.956354935333333

00:33:05.510 --> 00:33:07.126 pharmaceutical products tested in

NOTE Confidence: 0.956354935333333

00:33:07.126 --> 00:33:09.527 Latin America are unavailable and

NOTE Confidence: 0.956354935333333

00:33:09.527 --> 00:33:13.010 unaffordable to most of the populations.

NOTE Confidence: 0.956354935333333

00:33:13.010 --> 00:33:15.446 And then we did a study

NOTE Confidence: 0.956354935333333

00:33:15.450 --> 00:33:17.494 led by Reshma Ramachandra,

NOTE Confidence: 0.956354935333333

00:33:17.494 --> 00:33:20.049 who's an assistant professor in

NOTE Confidence: 0.956354935333333

00:33:20.050 --> 00:33:22.090 internal medicine here at Yale,

NOTE Confidence: 0.956354935333333

00:33:22.090 --> 00:33:24.415 looking at the COVID vaccines

NOTE Confidence: 0.956354935333333

00:33:24.415 --> 00:33:26.275 that were recommended for

NOTE Confidence: 0.956354935333333

00:33:26.275 --> 00:33:28.380 emergency use authorization by

NOTE Confidence: 0.956354935333333

00:33:28.380 --> 00:33:30.464 the World Health Organization.

NOTE Confidence: 0.956354935333333

00:33:30.470 --> 00:33:31.868 And we were curious, you know,

NOTE Confidence: 0.956354935333333

00:33:31.870 --> 00:33:34.110 where they were tested,

NOTE Confidence: 0.956354935333333

00:33:34.110 --> 00:33:36.265 where they authorized for emergency

NOTE Confidence: 0.956354935333333

00:33:36.265 --> 00:33:38.870 use in the countries hosting trials

NOTE Confidence: 0.956354935333333

00:33:38.870 --> 00:33:41.492 in support of their FDA approval.

NOTE Confidence: 0.956354935333333

00:33:41.492 --> 00:33:44.078 And then were there inequities in

NOTE Confidence: 0.956354935333333

00:33:44.078 --> 00:33:47.166 delivery or procurement of supplies.

NOTE Confidence: 0.956354935333333

00:33:47.166 --> 00:33:50.546 And while we found that most of the,

NOTE Confidence: 0.956354935333333

00:33:50.550 --> 00:33:53.273 if not all of the vaccines were

NOTE Confidence: 0.956354935333333

00:33:53.273 --> 00:33:54.790 authorized for emergency use,

NOTE Confidence: 0.956354935333333

00:33:54.790 --> 00:33:56.498 generally speaking in the

NOTE Confidence: 0.956354935333333

00:33:56.498 --> 00:33:58.633 countries where they were tested.

NOTE Confidence: 0.956354935333333

00:33:58.640 --> 00:34:01.264 We found inequities in

NOTE Confidence: 0.956354935333333

00:34:01.264 --> 00:34:02.720 procurement of supplies

NOTE Confidence: 0.910506685714286

00:34:08.440 --> 00:34:09.959 and so a question for us is,

NOTE Confidence: 0.910506685714286

00:34:09.960 --> 00:34:11.440 is this ethically problematic,

NOTE Confidence: 0.948879371428571

00:34:13.760 --> 00:34:15.984 the gaps between where we test drugs and

NOTE Confidence: 0.948879371428571

00:34:15.984 --> 00:34:18.237 where they become available for patients,

NOTE Confidence: 0.928512966666667

00:34:23.550 --> 00:34:25.158 and So what do we know?

NOTE Confidence: 0.928512966666667

00:34:25.160 --> 00:34:27.080 From some bedrock principles and ethics.

NOTE Confidence: 0.928512966666667

00:34:27.080 --> 00:34:28.475 So bedrock principle of research

NOTE Confidence: 0.928512966666667

00:34:28.475 --> 00:34:30.183 ethics is that the benefits and

NOTE Confidence: 0.928512966666667

00:34:30.183 --> 00:34:31.773 burdens of research should be shared

NOTE Confidence: 0.928512966666667

00:34:31.773 --> 00:34:33.640 equitably by the people affected by it.

NOTE Confidence: 0.928512966666667

00:34:33.640 --> 00:34:36.358 This is in the CIOMS guidelines,

NOTE Confidence: 0.928512966666667

00:34:36.360 --> 00:34:38.005 and that a corollary of that principle

NOTE Confidence: 0.928512966666667

00:34:38.005 --> 00:34:39.680 is that to avoid exploitation,

NOTE Confidence: 0.928512966666667

00:34:39.680 --> 00:34:41.650 research should not ordinarily be

NOTE Confidence: 0.928512966666667

00:34:41.650 --> 00:34:43.620 conducted in a national population

NOTE Confidence: 0.928512966666667

00:34:43.680 --> 00:34:45.787 that does not stand to benefit from

NOTE Confidence: 0.928512966666667

00:34:45.787 --> 00:34:47.419 the knowledge or the interventions

NOTE Confidence: 0.928512966666667

00:34:47.419 --> 00:34:49.417 to be gained from the study.

NOTE Confidence: 0.928512966666667

00:34:49.420 --> 00:34:50.625 The interesting thing about these

NOTE Confidence: 0.928512966666667

00:34:50.625 --> 00:34:52.060 principles is they sound really good,

NOTE Confidence: 0.928512966666667

00:34:52.060 --> 00:34:53.992 but they don't specify the type of

NOTE Confidence: 0.928512966666667

00:34:53.992 --> 00:34:55.660 benefit that needs to be provided,

NOTE Confidence: 0.928512966666667

00:34:55.660 --> 00:34:56.620 how much benefit,

NOTE Confidence: 0.928512966666667

00:34:56.620 --> 00:34:58.860 or exactly who should receive the benefit.

NOTE Confidence: 0.941801815384615

00:35:01.700 --> 00:35:03.597 And in theory, you could argue that

NOTE Confidence: 0.941801815384615

00:35:03.597 --> 00:35:05.178 there's two camps in this space.

NOTE Confidence: 0.941801815384615

00:35:05.180 --> 00:35:07.525 There is the responsiveness requirement

NOTE Confidence: 0.941801815384615

00:35:07.525 --> 00:35:10.420 camp in among ethicists in the

NOTE Confidence: 0.941801815384615

00:35:10.420 --> 00:35:12.363 Fair Benefits Framework group.

NOTE Confidence: 0.941801815384615

00:35:12.363 --> 00:35:14.878 On this issue, the responsiveness

NOTE Confidence: 0.941801815384615

00:35:14.878 --> 00:35:17.890 requirement is imposes content restrictions.

NOTE Confidence: 0.941801815384615

00:35:17.890 --> 00:35:20.380 On that benefit that can provide

NOTE Confidence: 0.941801815384615

00:35:20.380 --> 00:35:22.586 be provided and argues that the

NOTE Confidence: 0.941801815384615

00:35:22.586 --> 00:35:25.156 type of benefit matters and that it

NOTE Confidence: 0.941801815384615

00:35:25.156 --> 00:35:28.450 should probably include the product

NOTE Confidence: 0.941801815384615

00:35:28.450 --> 00:35:30.170 that the country helped test.

NOTE Confidence: 0.941801815384615

00:35:30.170 --> 00:35:32.046 In contrast to the fair benefits framework,

NOTE Confidence: 0.941801815384615

00:35:32.050 --> 00:35:34.536 which I think you can argue in

NOTE Confidence: 0.941801815384615

00:35:34.536 --> 00:35:36.366 some ways is content neutral,

NOTE Confidence: 0.941801815384615

00:35:36.370 --> 00:35:38.735 it doesn't specify what the

NOTE Confidence: 0.941801815384615

00:35:38.735 --> 00:35:40.545 benefit has to be,

NOTE Confidence: 0.941801815384615

00:35:40.545 --> 00:35:43.660 but rather specifies the process by which.

NOTE Confidence: 0.941801815384615

00:35:43.660 --> 00:35:45.865 You must follow to identify the benefit

NOTE Confidence: 0.941801815384615

00:35:45.865 --> 00:35:48.365 and that it should be a collaborative

NOTE Confidence: 0.941801815384615

00:35:48.365 --> 00:35:50.591 partnership with the country and a

NOTE Confidence: 0.941801815384615

00:35:50.659 --> 00:35:53.065 transparent collaborative partnership in

NOTE Confidence: 0.941801815384615

00:35:53.065 --> 00:35:55.940 identifying and agreeing upon benefits.

NOTE Confidence: 0.941801815384615

00:35:55.940 --> 00:35:57.215 The responsiveness requirement

NOTE Confidence: 0.941801815384615

00:35:57.215 --> 00:35:59.340 framework usually responds to this

NOTE Confidence: 0.941801815384615

00:35:59.340 --> 00:36:01.739 and says that's nonsense on stilts.

NOTE Confidence: 0.941801815384615

00:36:01.740 --> 00:36:04.420 How could you possibly?

NOTE Confidence: 0.941801815384615

00:36:04.420 --> 00:36:06.667 Think that a low income country has

NOTE Confidence: 0.941801815384615

00:36:06.667 --> 00:36:09.340 any kind of negotiating power with a

NOTE Confidence: 0.941801815384615

00:36:09.340 --> 00:36:11.480 multinational major pharmaceutical company.

NOTE Confidence: 0.941801815384615

00:36:11.480 --> 00:36:15.166 Given that pharma companies can just shop

NOTE Confidence: 0.941801815384615

00:36:15.166 --> 00:36:17.973 around for a different trial site location.

NOTE Confidence: 0.941801815384615

00:36:17.980 --> 00:36:20.265 The fair benefits framework also

NOTE Confidence: 0.941801815384615

00:36:20.265 --> 00:36:22.093 implies that quantity matters.

NOTE Confidence: 0.941801815384615

00:36:22.100 --> 00:36:25.080 And so they might argue that, well,

NOTE Confidence: 0.941801815384615

00:36:25.080 --> 00:36:27.180 if a country only contributes,

NOTE Confidence: 0.941801815384615

00:36:27.180 --> 00:36:29.004 you know, 10 participants,

NOTE Confidence: 0.941801815384615

00:36:29.004 --> 00:36:32.097 which is entirely possible and likely that.

NOTE Confidence: 0.941801815384615

00:36:32.097 --> 00:36:35.768 That country may not be owed as much as a

NOTE Confidence: 0.941801815384615

00:36:35.768 --> 00:36:38.214 country that supplies more participants,

NOTE Confidence: 0.941801815384615

00:36:38.214 --> 00:36:39.350 say 100,

NOTE Confidence: 0.941801815384615

00:36:39.350 --> 00:36:39.830 right?

NOTE Confidence: 0.941801815384615

00:36:39.830 --> 00:36:42.710 And so the amount of participants

NOTE Confidence: 0.941801815384615

00:36:42.710 --> 00:36:43.946 for them might correlate with the

NOTE Confidence: 0.941801815384615

00:36:43.946 --> 00:36:44.990 amount of benefit that's owed,

NOTE Confidence: 0.9077899

00:36:48.350 --> 00:36:49.748 regardless of which camp you've fallen.

NOTE Confidence: 0.9077899

00:36:49.750 --> 00:36:51.923 None of this is likely happening, right?

NOTE Confidence: 0.9077899

00:36:51.923 --> 00:36:54.388 There's likely not collaborative partnership.

NOTE Confidence: 0.9077899

00:36:54.390 --> 00:36:57.455 There's not likely transparent collaborative

NOTE Confidence: 0.9077899

00:36:57.455 --> 00:36:59.907 partnerships around determining benefits.

NOTE Confidence: 0.9077899

00:36:59.910 --> 00:37:00.885 So it's really.

NOTE Confidence: 0.9077899

00:37:00.885 --> 00:37:02.920 So that's you know, something that

NOTE Confidence: 0.9077899

00:37:02.920 --> 00:37:05.110 I'd like to start investigating is

NOTE Confidence: 0.9077899

00:37:05.110 --> 00:37:06.790 what do these contracts look like?

NOTE Confidence: 0.9077899

00:37:06.790 --> 00:37:07.875 Are there countries that are

NOTE Confidence: 0.9077899

00:37:07.875 --> 00:37:09.136 doing better than others, right?

NOTE Confidence: 0.9077899

00:37:09.136 --> 00:37:11.066 Are certain countries able to

NOTE Confidence: 0.9077899

00:37:11.066 --> 00:37:12.640 achieve and procure consistent

NOTE Confidence: 0.9077899

00:37:12.640 --> 00:37:15.100 access to products that they help

NOTE Confidence: 0.9077899

00:37:15.100 --> 00:37:17.070 develop than others and if so, how?

NOTE Confidence: 0.936899133333334

00:37:20.710 --> 00:37:22.630 So wrapping up,

NOTE Confidence: 0.936899133333334

00:37:22.630 --> 00:37:27.030 I focused on two sides of a coin.

NOTE Confidence: 0.936899133333334

00:37:27.030 --> 00:37:30.026 In one case we were selling products.

NOTE Confidence: 0.936899133333334

00:37:30.030 --> 00:37:32.410 Two populations without testing

NOTE Confidence: 0.936899133333334

00:37:32.410 --> 00:37:35.410 adequately or at all in those

NOTE Confidence: 0.936899133333334

00:37:35.410 --> 00:37:37.270 populations and then the other case

NOTE Confidence: 0.936899133333334

00:37:37.270 --> 00:37:40.228 we were testing and not selling.

NOTE Confidence: 0.946962474444445

00:37:44.510 --> 00:37:47.212 So I have raised more questions than

NOTE Confidence: 0.946962474444445

00:37:47.212 --> 00:37:49.138 I've answered because we're at that

NOTE Confidence: 0.946962474444445

00:37:49.138 --> 00:37:50.860 stage and some of these issues.

NOTE Confidence: 0.946962474444445

00:37:50.860 --> 00:37:52.100 So I'm just merely going to end with,

NOTE Confidence: 0.946962474444445

00:37:52.100 --> 00:37:54.249 we really need a lot more work

NOTE Confidence: 0.946962474444445

00:37:54.249 --> 00:37:56.009 amongst us ethicists to conceptualize

NOTE Confidence: 0.946962474444445

00:37:56.009 --> 00:37:57.939 what constitutes fair access to

NOTE Confidence: 0.946962474444445

00:37:57.939 --> 00:38:00.121 the benefits of clinical research

NOTE Confidence: 0.946962474444445

00:38:00.121 --> 00:38:02.531 and then how to operationalize

NOTE Confidence: 0.946962474444445

00:38:02.531 --> 00:38:03.900 that conceptualization. Thanks.

NOTE Confidence: 0.932202818

00:38:09.220 --> 00:38:10.740 Are you ready for it?

NOTE Confidence: 0.932202818

00:38:10.740 --> 00:38:14.312 All right, Thank you so much,

NOTE Confidence: 0.932202818

00:38:14.312 --> 00:38:16.240 Doctor Miller, lots of questions.

NOTE Confidence: 0.932202818

00:38:16.240 --> 00:38:17.660 I invite you now.

NOTE Confidence: 0.932202818

00:38:17.660 --> 00:38:19.060 Should we stop the share?

NOTE Confidence: 0.944566485714286

00:38:23.970 --> 00:38:25.489 And that's, that's all That looks good.

NOTE Confidence: 0.944566485714286

00:38:25.490 --> 00:38:27.324 And that all that looks even better.

NOTE Confidence: 0.944566485714286

00:38:27.330 --> 00:38:28.210 Great. We're all there.

NOTE Confidence: 0.944566485714286

00:38:28.210 --> 00:38:30.339 Except now if we could turn the screen off so

NOTE Confidence: 0.944566485714286

00:38:30.339 --> 00:38:32.290 that we don't have Jen behind Jen behind Jen.

NOTE Confidence: 0.944566485714286

00:38:32.290 --> 00:38:33.526 That was like the Quaker votes.

NOTE Confidence: 0.944566485714286

00:38:33.530 --> 00:38:36.250 They're all there. Thank you, Sir.

NOTE Confidence: 0.944566485714286

00:38:36.250 --> 00:38:37.370 All right, thank you.

NOTE Confidence: 0.944566485714286

00:38:37.370 --> 00:38:38.370 That was a great talk.

NOTE Confidence: 0.944566485714286

00:38:38.370 --> 00:38:39.410 This is really interesting stuff.

NOTE Confidence: 0.944566485714286

00:38:39.410 --> 00:38:40.730 I'm like taking notes here,

NOTE Confidence: 0.944566485714286

00:38:40.730 --> 00:38:42.050 an old man, you know,

NOTE Confidence: 0.944566485714286

00:38:42.050 --> 00:38:42.995 8 hours into the work day and

NOTE Confidence: 0.944566485714286

00:38:42.995 --> 00:38:43.850 10 hours into the work day.

NOTE Confidence: 0.944566485714286

00:38:43.850 --> 00:38:45.170 And you got me taking notes.

NOTE Confidence: 0.944566485714286

00:38:45.170 --> 00:38:46.730 So I will invite you all,

NOTE Confidence: 0.944566485714286

00:38:46.730 --> 00:38:48.805 please online to contribute your

NOTE Confidence: 0.944566485714286

00:38:48.805 --> 00:38:50.880 questions to the Q&A function.

NOTE Confidence: 0.944566485714286

00:38:50.880 --> 00:38:51.390 And, and,

NOTE Confidence: 0.944566485714286

00:38:51.390 --> 00:38:53.175 and I'm going to take the prerogative

NOTE Confidence: 0.944566485714286

00:38:53.175 --> 00:38:55.272 of asking the first one and then invite

NOTE Confidence: 0.944566485714286

00:38:55.272 --> 00:38:57.317 you guys also to kind of jump in here.

NOTE Confidence: 0.944566485714286

00:38:57.320 --> 00:38:59.080 So here's I was thinking as you went to this

NOTE Confidence: 0.944566485714286

00:38:59.120 --> 00:39:00.760 and your last slide really touched on it,

NOTE Confidence: 0.944566485714286

00:39:00.760 --> 00:39:02.680 Jen, I was thinking, all right,

NOTE Confidence: 0.944566485714286

00:39:02.680 --> 00:39:03.778 looking at this from the point

NOTE Confidence: 0.944566485714286

00:39:03.778 --> 00:39:05.160 of view of I'm a manufacturer,

NOTE Confidence: 0.944566485714286

00:39:05.160 --> 00:39:06.728 I've got this new drug for a

NOTE Confidence: 0.944566485714286

00:39:06.728 --> 00:39:07.922 certain disease and I'm thinking

NOTE Confidence: 0.944566485714286

00:39:07.922 --> 00:39:09.560 this is going to be really good.

NOTE Confidence: 0.944566485714286

00:39:09.560 --> 00:39:11.280 And it strikes me that,

NOTE Confidence: 0.944566485714286

00:39:11.280 --> 00:39:11.494 well,

NOTE Confidence: 0.944566485714286

00:39:11.494 --> 00:39:12.992 this one thing is clear as this

NOTE Confidence: 0.944566485714286

00:39:12.992 --> 00:39:14.520 drug is going to be expensive.

NOTE Confidence: 0.944566485714286

00:39:14.520 --> 00:39:17.374 So now I think perhaps I'm damned

NOTE Confidence: 0.944566485714286

00:39:17.374 --> 00:39:19.510 if I do and damned if I don't.

NOTE Confidence: 0.944566485714286

00:39:19.510 --> 00:39:20.282 Because here's the deal.

NOTE Confidence: 0.944566485714286

00:39:20.282 --> 00:39:22.372 If I test this in a country where in fact

NOTE Confidence: 0.944566485714286

00:39:22.372 --> 00:39:24.308 they're not going to be able to afford it,

NOTE Confidence: 0.944566485714286

00:39:24.310 --> 00:39:25.630 or many won't be able to afford it,

NOTE Confidence: 0.944566485714286

00:39:25.630 --> 00:39:27.268 most won't be able to afford it,

NOTE Confidence: 0.944566485714286

00:39:27.270 --> 00:39:29.610 that kind of smacks of exploitation, right?

NOTE Confidence: 0.944566485714286

00:39:29.610 --> 00:39:30.710 That would be your testing,

NOTE Confidence: 0.944566485714286

00:39:30.710 --> 00:39:32.142 but not selling framework.

NOTE Confidence: 0.944566485714286

00:39:32.142 --> 00:39:35.659 So if I test this in a in a in

NOTE Confidence: 0.944566485714286

00:39:35.659 --> 00:39:37.269 a much lower income country,

NOTE Confidence: 0.944566485714286

00:39:37.270 --> 00:39:39.589 that seems wrong.

NOTE Confidence: 0.944566485714286

00:39:39.590 --> 00:39:40.918 And if I don't test it in a

NOTE Confidence: 0.944566485714286

00:39:40.918 --> 00:39:41.798 lower income country, well,

NOTE Confidence: 0.944566485714286

00:39:41.798 --> 00:39:43.142 now it's not good because I didn't do.

NOTE Confidence: 0.944566485714286

00:39:43.150 --> 00:39:44.550 If the disease burden is

NOTE Confidence: 0.944566485714286

00:39:44.550 --> 00:39:45.670 significant in that country,

NOTE Confidence: 0.944566485714286

00:39:45.670 --> 00:39:47.176 I'm supposed to be looking at

NOTE Confidence: 0.944566485714286

00:39:47.176 --> 00:39:48.180 the global disease burden.

NOTE Confidence: 0.944566485714286

00:39:48.180 --> 00:39:50.294 So it seems I can't really win.

NOTE Confidence: 0.944566485714286

00:39:50.300 --> 00:39:52.982 And the response from those who

NOTE Confidence: 0.944566485714286

00:39:52.982 --> 00:39:56.059 know this stuff well would be what?

NOTE Confidence: 0.944566485714286

00:39:56.060 --> 00:39:56.900 How do I get around this?

NOTE Confidence: 0.944566485714286

00:39:56.900 --> 00:39:57.380 It's going to,

NOTE Confidence: 0.944566485714286

00:39:57.380 --> 00:39:57.700 you know,

NOTE Confidence: 0.944566485714286

00:39:57.700 --> 00:39:59.100 do I should do I test it in a low

NOTE Confidence: 0.944566485714286

00:39:59.144 --> 00:40:00.628 income country when I know they're not

NOTE Confidence: 0.944566485714286

00:40:00.628 --> 00:40:02.499 going to be able to afford it very well?

NOTE Confidence: 0.944566485714286

00:40:02.500 --> 00:40:05.033 Or do I just test it here and

NOTE Confidence: 0.944566485714286

00:40:05.033 --> 00:40:06.417 I know I'll be able to sell it,

NOTE Confidence: 0.944566485714286

00:40:06.420 --> 00:40:08.310 but then someone's going to criticize

NOTE Confidence: 0.944566485714286

00:40:08.310 --> 00:40:10.500 me for not testing it more globally?

NOTE Confidence: 0.9402536

00:40:21.280 --> 00:40:23.923 Yeah. So ideally we would want every

NOTE Confidence: 0.9402536

00:40:23.923 --> 00:40:27.147 patient needs a product to be able to

NOTE Confidence: 0.9402536

00:40:27.147 --> 00:40:29.040 afford and access the products, just

NOTE Confidence: 0.9352219

00:40:29.680 --> 00:40:30.520 move it up a little higher.

NOTE Confidence: 0.938815971428571

00:40:31.240 --> 00:40:34.796 And in some ways that question is,

NOTE Confidence: 0.938815971428571

00:40:34.800 --> 00:40:38.328 was an inspiration for looking for

NOTE Confidence: 0.938815971428571

00:40:38.328 --> 00:40:41.448 where new products were tested.

NOTE Confidence: 0.938815971428571

00:40:41.450 --> 00:40:43.574 Under a hunch that if we tested a product

NOTE Confidence: 0.938815971428571

00:40:43.574 --> 00:40:45.515 locally that it might be more likely that

NOTE Confidence: 0.938815971428571

00:40:45.515 --> 00:40:47.288 we would submit the product for sale,

NOTE Confidence: 0.938815971428571

00:40:47.290 --> 00:40:48.610 make it commercially available

NOTE Confidence: 0.938815971428571

00:40:48.610 --> 00:40:49.930 and then you know,

NOTE Confidence: 0.938815971428571

00:40:49.930 --> 00:40:53.330 we could work on affordability down the road.

NOTE Confidence: 0.938815971428571

00:40:53.330 --> 00:40:55.490 But I got stuck on the first piece

NOTE Confidence: 0.938815971428571

00:40:55.490 --> 00:40:57.630 because it turns out we're not testing

NOTE Confidence: 0.938815971428571

00:40:57.630 --> 00:41:00.030 and then we're not submitting for

NOTE Confidence: 0.938815971428571

00:41:00.030 --> 00:41:02.330 regulatory approval and then affordability

NOTE Confidence: 0.938815971428571

00:41:02.330 --> 00:41:05.970 is really done far down the road.

NOTE Confidence: 0.938815971428571

00:41:05.970 --> 00:41:07.874 So it's really hard to talk about

NOTE Confidence: 0.938815971428571

00:41:07.874 --> 00:41:09.831 affordability if you're not even submitting

NOTE Confidence: 0.938815971428571

00:41:09.831 --> 00:41:11.279 products for regulatory approval.

NOTE Confidence: 0.938815971428571

00:41:11.280 --> 00:41:11.566 Somewhere.

NOTE Confidence: 0.938815971428571

00:41:11.566 --> 00:41:12.996 So in the ideal world,

NOTE Confidence: 0.938815971428571

00:41:13.000 --> 00:41:16.208 you would do all of those and we're just

NOTE Confidence: 0.938815971428571

00:41:16.208 --> 00:41:18.280 really far away from that right now.

NOTE Confidence: 0.938815971428571

00:41:18.280 --> 00:41:19.980 And the affordability question is

NOTE Confidence: 0.938815971428571

00:41:19.980 --> 00:41:21.680 very pertinent and salient one,

NOTE Confidence: 0.938815971428571

00:41:21.680 --> 00:41:24.382 especially as we start developing the gene

NOTE Confidence: 0.938815971428571

00:41:24.382 --> 00:41:26.357 therapies which are incredibly expensive

NOTE Confidence: 0.938815971428571

00:41:26.357 --> 00:41:29.560 in the US and difficult to develop.

NOTE Confidence: 0.60401547

00:41:31.720 --> 00:41:32.160 Thank you.

NOTE Confidence: 0.897582406428571

00:41:34.620 --> 00:41:35.894 The the next question will go to

NOTE Confidence: 0.897582406428571

00:41:35.894 --> 00:41:37.178 Joe Finn's and then I'm going to.

NOTE Confidence: 0.897582406428571

00:41:37.180 --> 00:41:38.698 I shouldn't mention names on this,

NOTE Confidence: 0.897582406428571

00:41:38.700 --> 00:41:40.374 but I haven't figured out how to do this

NOTE Confidence: 0.897582406428571

00:41:40.374 --> 00:41:41.494 without this whole thing popping up.

NOTE Confidence: 0.897582406428571

00:41:41.494 --> 00:41:43.019 If you can get rid of the side screens too,

NOTE Confidence: 0.897582406428571

00:41:43.020 --> 00:41:44.012 that would be great.

NOTE Confidence: 0.897582406428571

00:41:44.012 --> 00:41:45.432 In case somebody wants to

NOTE Confidence: 0.897582406428571

00:41:45.432 --> 00:41:46.548 submit a question anonymously.

NOTE Confidence: 0.897582406428571

00:41:46.548 --> 00:41:48.396 But now Joey's been out as year

NOTE Confidence: 0.897582406428571

00:41:48.396 --> 00:41:50.099 but I'll read his question anyway.

NOTE Confidence: 0.897582406428571

00:41:50.100 --> 00:41:51.340 Thank you for your talk.

NOTE Confidence: 0.897582406428571

00:41:51.340 --> 00:41:53.772 1 area that I missed as an ethical

NOTE Confidence: 0.897582406428571

00:41:53.772 --> 00:41:55.260 justification for equity and inclusion

NOTE Confidence: 0.897582406428571

00:41:55.260 --> 00:41:57.654 is that we can learn a lot more

NOTE Confidence: 0.897582406428571

00:41:57.654 --> 00:41:59.699 scientifically from a diverse sample.

NOTE Confidence: 0.897582406428571

00:41:59.700 --> 00:42:01.120 We will see variance,

NOTE Confidence: 0.897582406428571

00:42:01.120 --> 00:42:02.895 more we will see variance.

NOTE Confidence: 0.897582406428571

00:42:02.900 --> 00:42:04.492 More information on basic

NOTE Confidence: 0.897582406428571

00:42:04.492 --> 00:42:06.482 mechanisms or adverse events that

NOTE Confidence: 0.897582406428571

00:42:06.482 --> 00:42:08.658 may impact certain populations.

NOTE Confidence: 0.897582406428571

00:42:08.660 --> 00:42:11.255 Why hasn't the clear scientific

NOTE Confidence: 0.897582406428571

00:42:11.255 --> 00:42:12.812 utility slash instrumentality

NOTE Confidence: 0.897582406428571

00:42:12.812 --> 00:42:15.195 been more prominent in the

NOTE Confidence: 0.897582406428571

00:42:15.195 --> 00:42:17.300 arguments in favor of equity.

NOTE Confidence: 0.897582406428571

00:42:17.300 --> 00:42:17.819 I think it's

NOTE Confidence: 0.905272572222222

00:42:17.820 --> 00:42:20.592 always been there I I rarely

NOTE Confidence: 0.905272572222222

00:42:20.592 --> 00:42:23.849 see it missing, but I right?

NOTE Confidence: 0.905272572222222

00:42:23.849 --> 00:42:25.394 Isn't it part of the

NOTE Confidence: 0.905272572222222

00:42:25.394 --> 00:42:26.321 generalizability arguments that

NOTE Confidence: 0.905272572222222

00:42:26.321 --> 00:42:28.010 you need to make sure that our.

NOTE Confidence: 0.905272572222222

00:42:28.010 --> 00:42:29.710 The clinically distinct groups are

NOTE Confidence: 0.905272572222222

00:42:29.710 --> 00:42:31.226 represented in the medical evidence,

NOTE Confidence: 0.905272572222222

00:42:31.226 --> 00:42:33.210 so I I haven't really seen it missing.

NOTE Confidence: 0.9301902

00:42:35.570 --> 00:42:36.050 But

NOTE Confidence: 0.941168454545455

00:42:38.130 --> 00:42:39.544 on the other side, I've seen it

NOTE Confidence: 0.941168454545455

00:42:39.544 --> 00:42:40.810 in the ethical justification,

NOTE Confidence: 0.941168454545455

00:42:40.810 --> 00:42:42.567 but I haven't seen as many studies

NOTE Confidence: 0.963734866666667

00:42:47.170 --> 00:42:51.104 showing how pervasive different reactions

NOTE Confidence: 0.963734866666667

00:42:51.104 --> 00:42:53.539 or different efficacy profiles are

NOTE Confidence: 0.963734866666667

00:42:53.539 --> 00:42:55.490 for different demographic groups.

NOTE Confidence: 0.967089333333333

00:42:58.100 --> 00:43:01.867 Other questions, Bonnie, wait,

NOTE Confidence: 0.967089333333333

00:43:01.867 --> 00:43:03.349 wait one second. So that the

NOTE Confidence: 0.967089333333333

00:43:03.349 --> 00:43:04.778 folks online can hear you too.

NOTE Confidence: 0.967089333333333

00:43:04.780 --> 00:43:08.060 So put that microphone on close. OK.

NOTE Confidence: 0.939745266666667

00:43:08.740 --> 00:43:10.530 Again, thank you. You're talking

NOTE Confidence: 0.939745266666667

00:43:10.530 --> 00:43:11.962 about a really important

NOTE Confidence: 0.939745266666667

00:43:11.962 --> 00:43:14.020 issue and I'm wondering about

NOTE Confidence: 0.93824092

00:43:16.260 --> 00:43:18.002 the point you just made, for instance,

NOTE Confidence: 0.93824092

00:43:18.002 --> 00:43:19.800 that you want to have various

NOTE Confidence: 0.93824092

00:43:19.800 --> 00:43:21.255 sorts of representative groups

NOTE Confidence: 0.93824092

00:43:21.255 --> 00:43:23.430 represented in your data sample

NOTE Confidence: 0.93824092

00:43:23.430 --> 00:43:25.200 because then you would know a lot

NOTE Confidence: 0.93824092

00:43:25.200 --> 00:43:27.228 more about how this particular.

NOTE Confidence: 0.93824092

00:43:27.228 --> 00:43:28.614 Medication or therapy

NOTE Confidence: 0.9553486

00:43:28.620 --> 00:43:30.340 might affect those groups,

NOTE Confidence: 0.94629158

00:43:30.820 --> 00:43:34.698 but I'm also thinking about groups

NOTE Confidence: 0.94629158

00:43:34.698 --> 00:43:37.764 that may be unusual in that they're

NOTE Confidence: 0.94629158

00:43:37.764 --> 00:43:40.100 rather insular in their behavior.

NOTE Confidence: 0.94629158

00:43:40.100 --> 00:43:41.972 Like I'm thinking about religious groups

NOTE Confidence: 0.94629158

00:43:41.972 --> 00:43:44.060 or their insular in their genetics.

NOTE Confidence: 0.94629158

00:43:44.060 --> 00:43:45.860 Same thing with religious groups,

NOTE Confidence: 0.94629158

00:43:45.860 --> 00:43:47.260 various immigrant groups,

NOTE Confidence: 0.943607993333333

00:43:49.500 --> 00:43:52.218 groups where they tend to focus

NOTE Confidence: 0.93268961

00:43:52.220 --> 00:43:53.780 in one particular location.

NOTE Confidence: 0.950317

00:43:54.490 --> 00:43:56.695 So you're going to have a whole bunch of

NOTE Confidence: 0.950317

00:43:56.695 --> 00:43:58.473 different genetic and environmental and

NOTE Confidence: 0.950317

00:43:58.473 --> 00:44:00.323 behavioral factors that are particular

NOTE Confidence: 0.950317

00:44:00.330 --> 00:44:03.530 to those groups that may not be captured

NOTE Confidence: 0.950317

00:44:03.530 --> 00:44:08.170 if you have these wide ranges of age,

NOTE Confidence: 0.950317

00:44:08.170 --> 00:44:10.118 race, etcetera, gender.

NOTE Confidence: 0.950317

00:44:10.118 --> 00:44:12.596 And I'm wondering how you deal with

NOTE Confidence: 0.950317

00:44:12.596 --> 00:44:14.970 those kinds of diversity issues because

NOTE Confidence: 0.950317

00:44:14.970 --> 00:44:17.190 there may be important differences.

NOTE Confidence: 0.950317

00:44:17.190 --> 00:44:19.290 Yeah. So the guidance documents are

NOTE Confidence: 0.950317

00:44:19.290 --> 00:44:20.788 starting to acknowledge that, right.

NOTE Confidence: 0.950317

00:44:20.788 --> 00:44:23.109 And so when you look at the at

NOTE Confidence: 0.950317

00:44:23.109 --> 00:44:24.709 Fedora includes geographic location,

NOTE Confidence: 0.950317

00:44:24.710 --> 00:44:28.118 socioeconomic status and some of the

NOTE Confidence: 0.950317

00:44:28.118 --> 00:44:30.390 different variables you mentioned,

NOTE Confidence: 0.950317

00:44:30.390 --> 00:44:32.734 you know how many variables we need to

NOTE Confidence: 0.950317

00:44:32.734 --> 00:44:36.046 add is is and and I have a very crude

NOTE Confidence: 0.950317

00:44:36.046 --> 00:44:37.630 conceptualization of of diversity,

NOTE Confidence: 0.950317

00:44:37.630 --> 00:44:40.576 right, just focusing on those big

NOTE Confidence: 0.950317

00:44:40.576 --> 00:44:42.450 categories because we haven't

NOTE Confidence: 0.950317

00:44:42.450 --> 00:44:44.750 even gotten those right yet.

NOTE Confidence: 0.950317

00:44:44.750 --> 00:44:47.010 And so and it's.

NOTE Confidence: 0.950317

00:44:47.010 --> 00:44:48.914 It it's really hard to benchmark how

NOTE Confidence: 0.950317

00:44:48.914 --> 00:44:51.130 we're doing on the other representations

NOTE Confidence: 0.950317

00:44:51.130 --> 00:44:53.250 groups based on public data.

NOTE Confidence: 0.946543225

00:44:56.410 --> 00:44:58.630 Yeah. And so, you know patients

NOTE Confidence: 0.946543225

00:44:58.630 --> 00:45:00.006 with disabilities, pregnant women,

NOTE Confidence: 0.946543225

00:45:00.006 --> 00:45:01.596 women who are lactating and

NOTE Confidence: 0.946543225

00:45:01.596 --> 00:45:03.021 not an adequately controlled

NOTE Confidence: 0.946543225

00:45:03.021 --> 00:45:04.689 and not taking contraception,

NOTE Confidence: 0.946543225

00:45:04.690 --> 00:45:05.810 all those groups have been

NOTE Confidence: 0.951754628571429

00:45:08.170 --> 00:45:10.170 known to be underrepresented in

NOTE Confidence: 0.951754628571429

00:45:10.170 --> 00:45:11.558 clinical research that I didn't

NOTE Confidence: 0.951754628571429

00:45:11.558 --> 00:45:12.930 talk about all the all the groups.

NOTE Confidence: 0.93019015

00:45:16.770 --> 00:45:17.330 You get the mic

NOTE Confidence: 0.932202825

00:45:20.010 --> 00:45:21.690 you get the hand mic so you don't have to

NOTE Confidence: 0.931308283333333

00:45:23.850 --> 00:45:25.164 I just had coffee so I don't want to

NOTE Confidence: 0.94360801

00:45:25.850 --> 00:45:26.489 subjected to my

NOTE Confidence: 0.8459070125

00:45:28.730 --> 00:45:29.890 I think that was

NOTE Confidence: 0.955348624

00:45:30.050 --> 00:45:32.910 a great presentation really compelling

NOTE Confidence: 0.955348624

00:45:32.910 --> 00:45:35.970 really an important issue And what

NOTE Confidence: 0.930782091176471

00:45:35.970 --> 00:45:38.040 I what I wanted to ask is sort of

NOTE Confidence: 0.930782091176471

00:45:38.040 --> 00:45:40.208 you know I think there there are a

NOTE Confidence: 0.935221836

00:45:40.210 --> 00:45:41.862 lot of not I think I know

NOTE Confidence: 0.935221836

00:45:41.862 --> 00:45:42.718 the data demonstrate there

NOTE Confidence: 0.935221836

00:45:42.718 --> 00:45:44.180 there are a lot of these like.

NOTE Confidence: 0.935221836

00:45:44.180 --> 00:45:47.230 Really big system level problems

NOTE Confidence: 0.931867328333333

00:45:47.270 --> 00:45:49.202 and and I think a lot of

NOTE Confidence: 0.931867328333333

00:45:49.202 --> 00:45:51.190 times we as as individuals

NOTE Confidence: 0.94654311125

00:45:51.190 --> 00:45:53.885 feel a little bit almost like this

NOTE Confidence: 0.94654311125

00:45:53.885 --> 00:45:55.732 paralysis like the problem's so big

NOTE Confidence: 0.94654311125

00:45:55.732 --> 00:45:57.830 like what can we do about it. And

NOTE Confidence: 0.9360604075

00:45:57.830 --> 00:45:59.702 and I and I was wondering if you could

NOTE Confidence: 0.9360604075

00:45:59.702 --> 00:46:01.148 speak a little bit about that like

NOTE Confidence: 0.9360604075

00:46:01.148 --> 00:46:02.988 I I know that there is data showing

NOTE Confidence: 0.946004003333334

00:46:02.990 --> 00:46:04.638 that for example trials,

NOTE Confidence: 0.946004003333334

00:46:04.638 --> 00:46:06.698 clinical trials led by women

NOTE Confidence: 0.946004003333334

00:46:06.698 --> 00:46:09.231 tend to have more gender as well

NOTE Confidence: 0.946004003333334

00:46:09.231 --> 00:46:11.380 as racial and ethnic diversity.

NOTE Confidence: 0.946004003333334

00:46:11.380 --> 00:46:13.414 And that you know some proposed

NOTE Confidence: 0.946004003333334

00:46:13.414 --> 00:46:15.579 solutions are trying to recruit more

NOTE Confidence: 0.946004003333334

00:46:15.580 --> 00:46:17.724 women and individuals underrepresented

NOTE Confidence: 0.946004003333334

00:46:17.724 --> 00:46:20.473 in medicine and and science or or

NOTE Confidence: 0.946004003333334

00:46:20.473 --> 00:46:22.450 minoritize populations into these

NOTE Confidence: 0.946004003333334

00:46:22.450 --> 00:46:24.372 positions of leadership to help with that.

NOTE Confidence: 0.946004003333334

00:46:24.372 --> 00:46:26.426 So again, that's not so much individual

NOTE Confidence: 0.946004003333334

00:46:26.426 --> 00:46:27.982 but at least institutional rather

NOTE Confidence: 0.946004003333334

00:46:27.982 --> 00:46:29.457 than like so broadly systemic.

NOTE Confidence: 0.946004003333334

00:46:29.460 --> 00:46:31.264 But can you speak a little

NOTE Confidence: 0.946004003333334

00:46:31.264 --> 00:46:32.374 bit realizing that you know,

NOTE Confidence: 0.946004003333334

00:46:32.380 --> 00:46:33.892 no one person can fix this but

NOTE Confidence: 0.946004003333334

00:46:33.892 --> 00:46:35.608 what are some things that that

NOTE Confidence: 0.946004003333334

00:46:35.608 --> 00:46:39.620 maybe we can do as as individuals?

NOTE Confidence: 0.946004003333334

00:46:39.620 --> 00:46:41.060 Or as institutions, you know,

NOTE Confidence: 0.946004003333334

00:46:41.060 --> 00:46:42.700 within our own institution to

NOTE Confidence: 0.946004003333334

00:46:42.700 --> 00:46:44.340 maybe advance this cause forward.

NOTE Confidence: 0.935061938461539

00:46:45.540 --> 00:46:48.018 Yeah, so there's a lot of documentation

NOTE Confidence: 0.935061938461539

00:46:48.018 --> 00:46:50.859 of theories on barriers and facilitators,

NOTE Confidence: 0.935061938461539

00:46:50.860 --> 00:46:52.580 and some of them are more than theories.

NOTE Confidence: 0.935061938461539

00:46:52.580 --> 00:46:55.220 But the short answer is evidence

NOTE Confidence: 0.935061938461539

00:46:55.220 --> 00:46:58.420 based action is still needed,

NOTE Confidence: 0.935061938461539

00:46:58.420 --> 00:47:01.414 which is part of the reason that we want to

NOTE Confidence: 0.935061938461539

00:47:01.414 --> 00:47:03.790 do the positive deviant study where we find

NOTE Confidence: 0.935061938461539

00:47:03.854 --> 00:47:06.222 out the trials that got it right, right,

NOTE Confidence: 0.935061938461539

00:47:06.222 --> 00:47:09.316 the ones that were able to adequately.

NOTE Confidence: 0.935061938461539

00:47:09.320 --> 00:47:11.275 Represent patients identifying as Latino

NOTE Confidence: 0.935061938461539

00:47:11.275 --> 00:47:14.080 or black or older adults 65 and older,

NOTE Confidence: 0.935061938461539

00:47:14.080 --> 00:47:17.746 75 and older to go into study, you know,

NOTE Confidence: 0.935061938461539

00:47:17.746 --> 00:47:20.528 how did they do it and then be able to

NOTE Confidence: 0.935061938461539

00:47:20.528 --> 00:47:22.240 develop generalizable best practices

NOTE Confidence: 0.935061938461539

00:47:22.240 --> 00:47:24.160 that can be implemented by everybody.

NOTE Confidence: 0.935061938461539

00:47:24.160 --> 00:47:26.920 We don't actually have that evidence

NOTE Confidence: 0.935061938461539

00:47:26.920 --> 00:47:27.720 based guidance.

NOTE Confidence: 0.935061938461539

00:47:27.720 --> 00:47:31.052 So I can tell you the barriers and

NOTE Confidence: 0.935061938461539

00:47:31.052 --> 00:47:33.536 facilitators that you could address that

NOTE Confidence: 0.935061938461539

00:47:33.536 --> 00:47:35.564 are already documented in the literature

NOTE Confidence: 0.935061938461539

00:47:35.564 --> 00:47:37.940 but aren't necessarily evidence based yet.

NOTE Confidence: 0.935061938461539

00:47:37.940 --> 00:47:39.500 So when if you're designing trials,

NOTE Confidence: 0.935061938461539

00:47:39.500 --> 00:47:41.924 you're going to be looking at your protocol

NOTE Confidence: 0.935061938461539

00:47:41.924 --> 00:47:43.450 inclusion exclusion criteria, right?

NOTE Confidence: 0.935061938461539

00:47:43.450 --> 00:47:46.460 Did you cut and paste certain exclusions?

NOTE Confidence: 0.935061938461539

00:47:46.460 --> 00:47:47.444 Because you've always done it and

NOTE Confidence: 0.935061938461539

00:47:47.444 --> 00:47:48.579 that's the way things have been done.

NOTE Confidence: 0.935061938461539

00:47:48.580 --> 00:47:49.900 If you're on the IRB,

NOTE Confidence: 0.935061938461539

00:47:49.900 --> 00:47:52.560 you're going to be looking for those

NOTE Confidence: 0.935061938461539

00:47:52.560 --> 00:47:53.700 unnecessary exclusion criteria,

NOTE Confidence: 0.935061938461539

00:47:53.700 --> 00:47:55.910 overly restrictive.

NOTE Confidence: 0.935061938461539

00:47:55.910 --> 00:47:57.178 Your trial site locations,

NOTE Confidence: 0.935061938461539

00:47:57.178 --> 00:47:59.080 you can invest in infrastructure to

NOTE Confidence: 0.935061938461539

00:47:59.136 --> 00:48:00.696 make sure that community hospitals

NOTE Confidence: 0.935061938461539

00:48:00.696 --> 00:48:02.670 are able to participate in trials.

NOTE Confidence: 0.935061938461539

00:48:02.670 --> 00:48:05.029 And it's not just the large academic

NOTE Confidence: 0.935061938461539

00:48:05.029 --> 00:48:08.286 medical centers that are hosting trials.

NOTE Confidence: 0.935061938461539

00:48:08.286 --> 00:48:11.506 Workforce diversity as you mentioned,

NOTE Confidence: 0.935061938461539

00:48:11.510 --> 00:48:14.708 working on ensuring inter that we're

NOTE Confidence: 0.935061938461539

00:48:14.708 --> 00:48:16.840 not discriminating consciously or

NOTE Confidence: 0.935061938461539

00:48:16.920 --> 00:48:19.602 unconsciously you know against certain.

NOTE Confidence: 0.935061938461539

00:48:19.602 --> 00:48:22.140 Groups that were offering the the

NOTE Confidence: 0.935061938461539

00:48:22.215 --> 00:48:24.580 opportunity to participate in trial

NOTE Confidence: 0.935061938461539

00:48:24.580 --> 00:48:26.945 consistently and fairly to all

NOTE Confidence: 0.935061938461539

00:48:26.950 --> 00:48:29.170 demographics who qualify for trials

NOTE Confidence: 0.935061938461539

00:48:29.170 --> 00:48:31.390 that were addressing language barriers,

NOTE Confidence: 0.935061938461539

00:48:31.390 --> 00:48:35.520 right to trial enrollment that we have

NOTE Confidence: 0.935061938461539

00:48:35.520 --> 00:48:37.310 translation translators available.

NOTE Confidence: 0.953671466666667

00:48:39.430 --> 00:48:42.806 Other barriers are child care

NOTE Confidence: 0.953671466666667

00:48:42.806 --> 00:48:44.598 and elder care sometimes.

NOTE Confidence: 0.953671466666667

00:48:44.598 --> 00:48:45.582 And transportation, right.

NOTE Confidence: 0.953671466666667

00:48:45.582 --> 00:48:47.999 If you want to participate in a trial,

NOTE Confidence: 0.953671466666667

00:48:48.000 --> 00:48:49.960 you have to be able to get to a trial,

NOTE Confidence: 0.953671466666667

00:48:49.960 --> 00:48:53.376 you have to have care for

NOTE Confidence: 0.953671466666667

00:48:53.376 --> 00:48:56.116 any dependents that you have.

NOTE Confidence: 0.953671466666667

00:48:56.120 --> 00:48:59.120 Distrust has to be addressed.

NOTE Confidence: 0.953671466666667

00:48:59.120 --> 00:49:02.080 There's distrust that's

NOTE Confidence: 0.953671466666667

00:49:02.080 --> 00:49:04.160 heightened in certain groups,

NOTE Confidence: 0.953671466666667

00:49:04.160 --> 00:49:05.312 justifiably so,

NOTE Confidence: 0.953671466666667

00:49:05.312 --> 00:49:09.344 in in research and in in medical

NOTE Confidence: 0.953671466666667

00:49:09.344 --> 00:49:11.399 institutions given prior injustices.

NOTE Confidence: 0.9805072

00:49:17.320 --> 00:49:21.280 Literacy, right. And an awareness of trial

NOTE Confidence: 0.9805072

00:49:21.280 --> 00:49:23.080 opportunities because studies show that

NOTE Confidence: 0.94830432

00:49:25.520 --> 00:49:26.528 there's conflicting evidence,

NOTE Confidence: 0.94830432

00:49:26.528 --> 00:49:30.792 but a lot of studies show that an equal

NOTE Confidence: 0.94830432

00:49:30.792 --> 00:49:33.752 interest in participating in trials

NOTE Confidence: 0.94830432

00:49:33.752 --> 00:49:37.079 but an unequal opportunity to enroll.

NOTE Confidence: 0.94830432

00:49:37.080 --> 00:49:38.840 So there's there a few, thanks.

NOTE Confidence: 0.94830432

00:49:39.640 --> 00:49:41.080 Let's hear from Steve, please.

NOTE Confidence: 0.94830432

00:49:41.080 --> 00:49:44.599 And then Jack and then we have all right.

NOTE Confidence: 0.94830432

00:49:44.600 --> 00:49:45.680 Steve and then Jack and

NOTE Confidence: 0.94830432

00:49:45.680 --> 00:49:46.840 then lady on the left. I'm

NOTE Confidence: 0.9553487

00:49:49.640 --> 00:49:51.716 getting older and things happened long,

NOTE Confidence: 0.9553487

00:49:51.720 --> 00:49:52.936 longer and longer ago.

NOTE Confidence: 0.9553487

00:49:52.936 --> 00:49:55.080 But my memory is that the the,

NOTE Confidence: 0.9553487

00:49:55.080 --> 00:49:57.861 the idea of Fair benefits first

NOTE Confidence: 0.9553487

00:49:57.861 --> 00:49:59.966 started cropping up because people

NOTE Confidence: 0.9553487

00:49:59.966 --> 00:50:02.059 started realizing that most trials

NOTE Confidence: 0.9553487

00:50:02.059 --> 00:50:04.140 fail and you've got populations who

NOTE Confidence: 0.9553487

00:50:04.140 --> 00:50:06.407 are going to be subject to research

NOTE Confidence: 0.9553487

00:50:06.407 --> 00:50:08.696 risks and they're never going to get

NOTE Confidence: 0.9553487

00:50:08.696 --> 00:50:10.683 the drugs because the drugs never

NOTE Confidence: 0.9553487

00:50:10.683 --> 00:50:13.960 going to prove to be efficacious.

NOTE Confidence: 0.9553487

00:50:13.960 --> 00:50:16.200 So you want to give them some fair

NOTE Confidence: 0.9553487

00:50:16.200 --> 00:50:18.145 benefit instead and that might be

NOTE Confidence: 0.9553487

00:50:18.145 --> 00:50:19.800 building of infrastructure and that

NOTE Confidence: 0.9553487

00:50:19.800 --> 00:50:21.528 might be training of nursing staff

NOTE Confidence: 0.9553487

00:50:21.528 --> 00:50:23.565 or it might be any one of the things

NOTE Confidence: 0.9553487

00:50:23.565 --> 00:50:25.120 that you just sort of went through

NOTE Confidence: 0.94629164

00:50:27.600 --> 00:50:30.560 and that could be happening.

NOTE Confidence: 0.94629164

00:50:30.560 --> 00:50:32.597 I'm probably pretty sure that it's not,

NOTE Confidence: 0.94629164

00:50:32.600 --> 00:50:33.520 but that could be happening.

NOTE Confidence: 0.94629164

00:50:33.520 --> 00:50:34.997 If you look at your data saying,

NOTE Confidence: 0.94629164

00:50:35.000 --> 00:50:37.212 oh, they test this in these poor

NOTE Confidence: 0.94629164

00:50:37.212 --> 00:50:38.565 countries and those countries

NOTE Confidence: 0.94629164

00:50:38.565 --> 00:50:40.599 never get access to the drug,

NOTE Confidence: 0.94629164

00:50:40.600 --> 00:50:43.918 well okay, but maybe they're getting.

NOTE Confidence: 0.94629164

00:50:43.920 --> 00:50:45.399 Nursing training instead,

NOTE Confidence: 0.94427896

00:50:47.440 --> 00:50:49.120 would that satisfy you if

NOTE Confidence: 0.94427896

00:50:49.120 --> 00:50:50.800 that were in fact happening?

NOTE Confidence: 0.94427896

00:50:50.800 --> 00:50:52.753 As I say, I suspect it's not

NOTE Confidence: 0.94427896

00:50:52.753 --> 00:50:53.920 actually happening that much,

NOTE Confidence: 0.94427896

00:50:53.920 --> 00:50:55.996 but if people were getting some

NOTE Confidence: 0.94427896

00:50:55.996 --> 00:50:58.755 kind of non drug fair benefit as

NOTE Confidence: 0.94427896

00:50:58.755 --> 00:51:00.930 a result of having participated

NOTE Confidence: 0.94427896

00:51:00.930 --> 00:51:02.520 in trial, is does that,

NOTE Confidence: 0.95635504

00:51:02.880 --> 00:51:05.024 Yeah, it's entirely possible

NOTE Confidence: 0.95635504

00:51:05.024 --> 00:51:06.960 that there have been schools and

NOTE Confidence: 0.95635504

00:51:06.960 --> 00:51:09.640 playgrounds built everywhere, right?

NOTE Confidence: 0.95635504

00:51:09.640 --> 00:51:11.760 Ventilators don't need it, right?

NOTE Confidence: 0.95635504

00:51:11.760 --> 00:51:14.428 The Sarfax in case.

NOTE Confidence: 0.95635504

00:51:14.430 --> 00:51:16.776 But if if you're in the

NOTE Confidence: 0.95635504

00:51:16.776 --> 00:51:17.949 fair benefits framework,

NOTE Confidence: 0.95635504

00:51:17.950 --> 00:51:21.130 you also would like a transparent

NOTE Confidence: 0.95635504

00:51:21.130 --> 00:51:22.498 collaborative partnership, right?

NOTE Confidence: 0.95635504

00:51:22.498 --> 00:51:24.038 In in determining and identifying

NOTE Confidence: 0.95635504

00:51:24.038 --> 00:51:25.530 benefits that are shared and

NOTE Confidence: 0.95635504

00:51:25.530 --> 00:51:26.790 the part and like you said,

NOTE Confidence: 0.95635504

00:51:26.790 --> 00:51:28.710 it's just not transparent.

NOTE Confidence: 0.95635504

00:51:28.710 --> 00:51:31.478 So we don't know if there are schools

NOTE Confidence: 0.95635504

00:51:31.478 --> 00:51:32.750 and playgrounds all over the place.

NOTE Confidence: 0.9402536

00:51:34.910 --> 00:51:39.818 Personally, I'm I'm more on the.

NOTE Confidence: 0.9402536

00:51:39.820 --> 00:51:40.860 Responsiveness principle,

NOTE Confidence: 0.9402536

00:51:40.860 --> 00:51:44.500 that framework that I think you you

NOTE Confidence: 0.9402536

00:51:44.500 --> 00:51:46.215 that's it's the benefit should include

NOTE Confidence: 0.9402536

00:51:46.215 --> 00:51:48.068 the product that you helped test, right,

NOTE Confidence: 0.9402536

00:51:48.068 --> 00:51:50.516 Because you clearly have a patient

NOTE Confidence: 0.9402536

00:51:50.516 --> 00:51:52.380 population there who needs the product.

NOTE Confidence: 0.946004114285714

00:51:55.060 --> 00:51:56.580 But you would give a followup question, no,

NOTE Confidence: 0.871046528571429

00:51:57.620 --> 00:51:59.216 you can't do that in the trial.

NOTE Confidence: 0.87014822

00:51:59.620 --> 00:52:02.940 Thanks. Oh yeah, it's then. Yeah.

NOTE Confidence: 0.87014822

00:52:02.940 --> 00:52:04.820 Well, that's why I said and do and.

NOTE Confidence: 0.4055748

00:52:08.790 --> 00:52:15.070 OK. All right, Jen, thank you very much.

NOTE Confidence: 0.4055748

00:52:15.070 --> 00:52:18.829 Now my assumption based on very limited

NOTE Confidence: 0.4055748

00:52:18.829 --> 00:52:22.038 information was years ago that drug

NOTE Confidence: 0.4055748

00:52:22.038 --> 00:52:26.070 companies did studies in in low income,

NOTE Confidence: 0.4055748

00:52:26.070 --> 00:52:27.934 middle income countries because

NOTE Confidence: 0.4055748

00:52:27.934 --> 00:52:30.264 it was cheaper that way.

NOTE Confidence: 0.4055748

00:52:30.270 --> 00:52:32.934 And so that's understandable.

NOTE Confidence: 0.4055748

00:52:32.934 --> 00:52:36.363 Now just to look at it from an economic

NOTE Confidence: 0.4055748

00:52:36.363 --> 00:52:38.149 perspective if we're talking about.

NOTE Confidence: 0.4055748

00:52:38.150 --> 00:52:39.980 Only distributing within

NOTE Confidence: 0.4055748

00:52:39.980 --> 00:52:43.030 this country to rural areas,

NOTE Confidence: 0.4055748

00:52:43.030 --> 00:52:44.730 to smaller community hospitals,

NOTE Confidence: 0.4055748

00:52:44.730 --> 00:52:46.430 that sort of thing.

NOTE Confidence: 0.4055748

00:52:46.430 --> 00:52:48.626 How do the costs work out?

NOTE Confidence: 0.4055748

00:52:48.630 --> 00:52:51.501 Does does it cost any more for

NOTE Confidence: 0.4055748

00:52:51.501 --> 00:52:53.847 the companies to do that away

NOTE Confidence: 0.4055748

00:52:53.847 --> 00:52:55.670 from academic medical centers?

NOTE Confidence: 0.4055748

00:52:55.670 --> 00:52:57.870 Does that add anything to?

NOTE Confidence: 0.4055748

00:52:57.870 --> 00:53:00.178 Is that if it costs more,

NOTE Confidence: 0.4055748

00:53:00.178 --> 00:53:00.829 is that it?

NOTE Confidence: 0.4055748

00:53:00.830 --> 00:53:02.930 That would be a disincentive it seems

NOTE Confidence: 0.4055748

00:53:02.930 --> 00:53:05.506 like or for all I know it's cheaper,

NOTE Confidence: 0.4055748

00:53:05.510 --> 00:53:06.350 but I'm just asking.

NOTE Confidence: 0.930190315

00:53:08.000 --> 00:53:08.560 So, yeah,

NOTE Confidence: 0.936229028

00:53:10.800 --> 00:53:12.360 well, let's talk about the ethics first and

NOTE Confidence: 0.936229028

00:53:12.360 --> 00:53:13.878 then we'll talk about the empirical data.

NOTE Confidence: 0.936229028

00:53:13.880 --> 00:53:18.418 So I think from the you might have been

NOTE Confidence: 0.936229028

00:53:18.418 --> 00:53:20.000 able to tell what I'm going to say, right.

NOTE Confidence: 0.936229028

00:53:20.000 --> 00:53:22.496 I I think cost is not the right framework.

NOTE Confidence: 0.936229028

00:53:22.496 --> 00:53:24.288 I think that we should be thinking

NOTE Confidence: 0.936229028

00:53:24.288 --> 00:53:26.078 about this as it's the right thing to

NOTE Confidence: 0.936229028

00:53:26.078 --> 00:53:27.924 do because we need the medical evidence

NOTE Confidence: 0.936229028

00:53:27.924 --> 00:53:29.544 to be developed generalizable medical

NOTE Confidence: 0.936229028

00:53:29.544 --> 00:53:31.559 evidence for clinically distinct groups.

NOTE Confidence: 0.936229028

00:53:31.559 --> 00:53:34.880 We need trust, right and.

NOTE Confidence: 0.9201268

00:53:40.150 --> 00:53:41.210 We need uptake of products.

NOTE Confidence: 0.9201268

00:53:41.210 --> 00:53:42.150 There was another one.

NOTE Confidence: 0.9201268

00:53:42.150 --> 00:53:45.348 I'm blanking on the second one.

NOTE Confidence: 0.9201268

00:53:45.350 --> 00:53:50.278 So I think cost is not is

NOTE Confidence: 0.9201268

00:53:50.278 --> 00:53:51.590 not the priority, right.

NOTE Confidence: 0.9201268

00:53:51.590 --> 00:53:53.516 I think those other values and

NOTE Confidence: 0.9201268

00:53:53.516 --> 00:53:55.589 goods are going to trump cost.

NOTE Confidence: 0.9201268

00:53:55.590 --> 00:53:57.150 But on the cost question,

NOTE Confidence: 0.9201268

00:53:57.150 --> 00:53:59.150 I haven't seen an empirical

NOTE Confidence: 0.9201268

00:53:59.150 --> 00:54:00.164 study addressing that.

NOTE Confidence: 0.9201268

00:54:00.164 --> 00:54:02.620 It's an anecdote that flies around a lot.

NOTE Confidence: 0.9201268

00:54:02.620 --> 00:54:03.700 It will cost too much.

NOTE Confidence: 0.9201268

00:54:03.700 --> 00:54:06.058 It'll cost more to run a more diverse trial,

NOTE Confidence: 0.9201268

00:54:06.060 --> 00:54:07.620 more geographically diverse,

NOTE Confidence: 0.9201268

00:54:07.620 --> 00:54:09.700 more demographically or diverse.

NOTE Confidence: 0.9201268

00:54:09.700 --> 00:54:12.213 And Joe and I and Kerry were

NOTE Confidence: 0.9201268

00:54:12.213 --> 00:54:13.860 just exchanging emails saying,

NOTE Confidence: 0.9201268

00:54:13.860 --> 00:54:14.390 you know,

NOTE Confidence: 0.9201268

00:54:14.390 --> 00:54:15.980 we really should do that study

NOTE Confidence: 0.9201268

00:54:15.980 --> 00:54:18.033 because we have a lot of that data

NOTE Confidence: 0.9201268

00:54:18.033 --> 00:54:19.673 collected where we have the trial

NOTE Confidence: 0.9201268

00:54:19.673 --> 00:54:21.636 scored on diversity and we have the

NOTE Confidence: 0.9201268

00:54:21.636 --> 00:54:23.220 trial start dates and end dates.

NOTE Confidence: 0.9201268

00:54:23.220 --> 00:54:24.924 And is there a way to look at

NOTE Confidence: 0.9201268

00:54:24.924 --> 00:54:26.799 whether the more diverse trials and

NOTE Confidence: 0.9201268

00:54:26.799 --> 00:54:28.534 whatever variable you're looking at,

NOTE Confidence: 0.9201268

00:54:28.540 --> 00:54:30.442 geography, race, ethnicity?

NOTE Confidence: 0.9201268

00:54:30.442 --> 00:54:31.076 Age,

NOTE Confidence: 0.9201268

00:54:31.076 --> 00:54:33.610 whether they were slower or

NOTE Confidence: 0.9201268

00:54:33.610 --> 00:54:35.815 more costly to run in some way,

NOTE Confidence: 0.9201268

00:54:35.820 --> 00:54:38.340 but I I haven't seen that data.

NOTE Confidence: 0.9201268

00:54:38.340 --> 00:54:41.175 Has anyone else seen that those data?

NOTE Confidence: 0.9201268

00:54:41.180 --> 00:54:41.468 Yeah.

NOTE Confidence: 0.9201268

00:54:41.468 --> 00:54:44.308 But I think you it's an important study

NOTE Confidence: 0.9201268

00:54:44.308 --> 00:54:47.419 to do not because cost it's a justifier.

NOTE Confidence: 0.9201268

00:54:47.419 --> 00:54:49.980 But to get rid of that that myth,

NOTE Confidence: 0.933361064666666

00:54:50.340 --> 00:54:51.774 it has to be addressed because

NOTE Confidence: 0.933361064666666

00:54:51.774 --> 00:54:53.282 that's going to be the objection

NOTE Confidence: 0.933361064666666

00:54:53.282 --> 00:54:55.025 of those people who wanted to plan

NOTE Confidence: 0.933361064666666

00:54:55.025 --> 00:54:56.557 to run the studies and so you

NOTE Confidence: 0.933361064666666

00:54:56.557 --> 00:54:59.740 have to be able to to address it.

NOTE Confidence: 0.933361064666666

00:54:59.740 --> 00:55:00.850 And and deal with it

NOTE Confidence: 0.943235348148148

00:55:03.690 --> 00:55:06.301 so. So while Jack is handing the

NOTE Confidence: 0.943235348148148

00:55:06.301 --> 00:55:08.268 microphone off I'll remind everybody

NOTE Confidence: 0.943235348148148

00:55:08.268 --> 00:55:11.364 that we can get CME credit by texting

NOTE Confidence: 0.943235348148148

00:55:11.442 --> 00:55:13.776 the text code for tonight's session

NOTE Confidence: 0.943235348148148

00:55:13.776 --> 00:55:17.828 is 36149 and to accomplish that you

NOTE Confidence: 0.943235348148148

00:55:17.828 --> 00:55:19.354 it's written in the chat portion I

NOTE Confidence: 0.943235348148148

00:55:19.354 --> 00:55:20.800 hear believe you can see the phone

NOTE Confidence: 0.943235348148148

00:55:20.800 --> 00:55:22.337 number that you need to call on the

NOTE Confidence: 0.943235348148148

00:55:22.337 --> 00:55:23.930 code and you can do that it's two O

NOTE Confidence: 0.938576366666667

00:55:27.250 --> 00:55:29.860 34429435. And then you, when texts

NOTE Confidence: 0.938576366666667

00:55:29.860 --> 00:55:34.900 to that 36149 to get CME credit,

NOTE Confidence: 0.928512966666667

00:55:35.420 --> 00:55:36.380 Chuck, I go back to you.

NOTE Confidence: 0.928512966666667

00:55:36.380 --> 00:55:38.114 What happens if the empirical study

NOTE Confidence: 0.928512966666667

00:55:38.114 --> 00:55:40.206 says that it's more costly to do

NOTE Confidence: 0.928512966666667

00:55:40.206 --> 00:55:41.500 to conduct diverse trials? Then

NOTE Confidence: 0.93421556

00:55:42.340 --> 00:55:44.700 we say dad costs more.

NOTE Confidence: 0.93421556

00:55:44.700 --> 00:55:46.060 But it's worth it's important

NOTE Confidence: 0.9301902

00:55:48.060 --> 00:55:52.420 to do. You just want to know you need a mic,

NOTE Confidence: 0.9301902

00:55:53.340 --> 00:55:54.500 right? We have it. No, it's you.

NOTE Confidence: 0.9301902

00:55:54.500 --> 00:55:56.020 This is all you want the way.

NOTE Confidence: 0.948879371428571

00:55:58.570 --> 00:56:00.280 It's a curiosity rather than

NOTE Confidence: 0.948879371428571

00:56:00.280 --> 00:56:01.250 a justification. Yeah. It

NOTE Confidence: 0.9201268

00:56:04.450 --> 00:56:09.440 is planning your moral strategy that

NOTE Confidence: 0.9201268

00:56:09.440 --> 00:56:13.930 you have to know what your opponents. If

NOTE Confidence: 0.946543225

00:56:13.930 --> 00:56:15.670 moral persuasion fails,

NOTE Confidence: 0.946543225

00:56:15.670 --> 00:56:18.570 it will save you money.

NOTE Confidence: 0.946543225

00:56:18.570 --> 00:56:21.168 Yeah, or it won't cost more.

NOTE Confidence: 0.946543225

00:56:21.170 --> 00:56:25.314 Yes, Yes. No, I I agree.

NOTE Confidence: 0.946543225

00:56:25.314 --> 00:56:26.610 I agree. I agree.

NOTE Confidence: 0.942083309090909

00:56:30.080 --> 00:56:33.344 I have to apologize at first since my

NOTE Confidence: 0.942083309090909

00:56:33.344 --> 00:56:35.950 English is Limited Head Out Miller.

NOTE Confidence: 0.942083309090909

00:56:35.950 --> 00:56:37.800 My Major is Bell Essex,

NOTE Confidence: 0.942083309090909

00:56:37.800 --> 00:56:40.800 especially AI Essex and Clinical Essex.

NOTE Confidence: 0.942083309090909

00:56:40.800 --> 00:56:45.108 So my question is as there was

NOTE Confidence: 0.942083309090909

00:56:45.108 --> 00:56:47.688 research about the comparison of

NOTE Confidence: 0.942083309090909

00:56:47.688 --> 00:56:50.662 enrollment goals using two approaches

NOTE Confidence: 0.942083309090909

00:56:50.662 --> 00:56:53.134 to achieving Adequate Adequate.

NOTE Confidence: 0.942083309090909

00:56:53.140 --> 00:56:54.430 Representation in research,

NOTE Confidence: 0.942083309090909

00:56:54.430 --> 00:56:58.201 I would love to know do you think that

NOTE Confidence: 0.942083309090909

00:56:58.201 --> 00:57:01.870 it will be meaningful or helpful to

NOTE Confidence: 0.942083309090909

00:57:01.870 --> 00:57:06.086 do a research about the comparison of

NOTE Confidence: 0.942083309090909

00:57:06.086 --> 00:57:08.402 using AI tools and the traditional

NOTE Confidence: 0.942083309090909

00:57:08.402 --> 00:57:11.299 ways in the recruitment or the

NOTE Confidence: 0.942083309090909

00:57:11.299 --> 00:57:14.059 retention process in clinical trials,

NOTE Confidence: 0.942083309090909

00:57:14.060 --> 00:57:16.106 Since I think maybe AI tools

NOTE Confidence: 0.942083309090909

00:57:16.106 --> 00:57:18.760 could help us to solve a lot of

NOTE Confidence: 0.942083309090909

00:57:18.760 --> 00:57:20.240 problems in the clinical trials.

NOTE Confidence: 0.942083309090909

00:57:20.240 --> 00:57:21.890 So I would love to know

NOTE Confidence: 0.942083309090909

00:57:21.953 --> 00:57:23.357 your opinion about that.

NOTE Confidence: 0.942083309090909

00:57:23.360 --> 00:57:26.559 Well, there's certainly a lot of efforts

NOTE Confidence: 0.942083309090909

00:57:26.560 --> 00:57:29.000 to apply a I to tackle this problem.

NOTE Confidence: 0.942083309090909

00:57:29.000 --> 00:57:31.660 I think it's a little early to

NOTE Confidence: 0.942083309090909

00:57:31.660 --> 00:57:33.120 see how helpful they will be.

NOTE Confidence: 0.942083309090909

00:57:33.120 --> 00:57:35.095 So some just some descriptive

NOTE Confidence: 0.942083309090909

00:57:35.095 --> 00:57:38.092 information I've heard of right using

NOTE Confidence: 0.942083309090909

00:57:38.092 --> 00:57:41.653 various algorithms and and natural

NOTE Confidence: 0.942083309090909

00:57:41.653 --> 00:57:44.585 language processing programs to

NOTE Confidence: 0.942083309090909

00:57:44.585 --> 00:57:47.348 identify patients that might qualify.

NOTE Confidence: 0.942083309090909

00:57:47.348 --> 00:57:50.390 For trials and notifying A clinician

NOTE Confidence: 0.942083309090909

00:57:50.474 --> 00:57:52.720 that their patient qualifies and

NOTE Confidence: 0.942083309090909

00:57:52.720 --> 00:57:55.240 that they giving them an opportunity

NOTE Confidence: 0.942083309090909

00:57:55.240 --> 00:57:57.046 to enroll their participants.

NOTE Confidence: 0.942083309090909

00:57:57.046 --> 00:57:58.012 More so,

NOTE Confidence: 0.942083309090909

00:57:58.012 --> 00:58:00.427 I've heard about decentralized trials

NOTE Confidence: 0.942083309090909

00:58:00.427 --> 00:58:03.382 and using digital tools right to to

NOTE Confidence: 0.942083309090909

00:58:03.382 --> 00:58:06.154 allow participants to enroll in trials

NOTE Confidence: 0.942083309090909

00:58:06.154 --> 00:58:08.678 rather than setting up right major

NOTE Confidence: 0.942083309090909

00:58:08.680 --> 00:58:11.725 clinical trial sites like we currently do.

NOTE Confidence: 0.942083309090909

00:58:11.730 --> 00:58:13.370 But that too has hurdles.

NOTE Confidence: 0.942083309090909

00:58:13.370 --> 00:58:15.010 One of them is an ethics related one,

NOTE Confidence: 0.942083309090909

00:58:15.010 --> 00:58:17.010 in that with decentralized trials

NOTE Confidence: 0.942083309090909

00:58:17.010 --> 00:58:20.170 currently you have to use an IRB at each

NOTE Confidence: 0.9654121

00:58:22.290 --> 00:58:26.090 each participation.

NOTE Confidence: 0.9654121

00:58:26.090 --> 00:58:28.529 I don't know what you're calling it a center,

NOTE Confidence: 0.9654121

00:58:28.530 --> 00:58:29.724 whereas right when in the clinical

NOTE Confidence: 0.9654121

00:58:29.724 --> 00:58:31.250 trial you can use a centralized IRB.

NOTE Confidence: 0.9654121

00:58:31.250 --> 00:58:34.610 So in some ways these things will look there,

NOTE Confidence: 0.9654121

00:58:34.610 --> 00:58:35.874 they're going to help,

NOTE Confidence: 0.9654121

00:58:35.874 --> 00:58:37.770 but there's still some bureaucratic mess.

NOTE Confidence: 0.9654121

00:58:37.770 --> 00:58:39.054 Do you have ideas of how

NOTE Confidence: 0.9654121

00:58:39.054 --> 00:58:40.210 you think AI would help?

NOTE Confidence: 0.9402536

00:58:42.780 --> 00:58:46.803 I know that there is tools called Mando AI

NOTE Confidence: 0.9402536

00:58:46.803 --> 00:58:50.348 that help to help the recruitment process

NOTE Confidence: 0.9402536

00:58:50.348 --> 00:58:52.972 in the clinical trials and it is used,

NOTE Confidence: 0.9402536

00:58:52.980 --> 00:58:58.120 It was used in some in some centers, yeah.

NOTE Confidence: 0.9402536

00:58:58.120 --> 00:59:00.206 Right. So it could in theory offer

NOTE Confidence: 0.9402536

00:59:00.206 --> 00:59:01.800 more opportunities to individuals,

NOTE Confidence: 0.9402536

00:59:01.800 --> 00:59:02.956 right, by identifying them.

NOTE Confidence: 0.9402536

00:59:02.956 --> 00:59:04.690 But it it it that wouldn't

NOTE Confidence: 0.9402536

00:59:04.749 --> 00:59:06.679 necessarily fix an underlying cause,

NOTE Confidence: 0.9402536

00:59:06.680 --> 00:59:08.455 which it would probably be

NOTE Confidence: 0.9402536

00:59:08.455 --> 00:59:09.875 applying the inclusion exclusion

NOTE Confidence: 0.9402536

00:59:09.875 --> 00:59:11.437 criteria in the trial protocol,

NOTE Confidence: 0.9402536

00:59:11.440 --> 00:59:13.715 which in itself could limit who qualifies,

NOTE Confidence: 0.9402536

00:59:13.720 --> 00:59:16.220 right. So there's blanket exclusions

NOTE Confidence: 0.9402536

00:59:16.220 --> 00:59:18.164 for certain comorbidities, polypharmacy,

NOTE Confidence: 0.9402536

00:59:18.164 --> 00:59:21.272 then older adults might be more likely

NOTE Confidence: 0.9402536

00:59:21.272 --> 00:59:23.384 to be unable to qualify, right?

NOTE Confidence: 0.9402536

00:59:23.384 --> 00:59:24.914 Or other different demographic groups.

NOTE Confidence: 0.9402536

00:59:24.920 --> 00:59:27.620 So applying a I to.

NOTE Confidence: 0.9402536

00:59:27.620 --> 00:59:28.925 Problematic inclusion exclusion

NOTE Confidence: 0.9402536

00:59:28.925 --> 00:59:32.060 criteria could double down right on or

NOTE Confidence: 0.9402536

00:59:32.060 --> 00:59:35.932 triple down a I down on the problem.

NOTE Confidence: 0.9402536

00:59:35.932 --> 00:59:36.780 And yeah,

NOTE Confidence: 0.9352219

00:59:37.780 --> 00:59:39.140 I want to switch gears a little bit,

NOTE Confidence: 0.9352219

00:59:39.140 --> 00:59:41.364 Jen, because I don't know if you folks

NOTE Confidence: 0.9352219

00:59:41.364 --> 00:59:43.458 are really aware of the the the work,

NOTE Confidence: 0.9352219

00:59:43.460 --> 00:59:45.308 the earlier work that Jen did when we

NOTE Confidence: 0.9352219

00:59:45.308 --> 00:59:47.555 first met in Bioethics International and

NOTE Confidence: 0.9352219

00:59:47.555 --> 00:59:50.740 this notion of the of the scorecard.

NOTE Confidence: 0.9352219

00:59:50.740 --> 00:59:52.144 And and I was so pleased when I when

NOTE Confidence: 0.9352219

00:59:52.144 --> 00:59:53.447 you saw that that as a result of

NOTE Confidence: 0.9352219

00:59:53.447 --> 00:59:54.817 a low score half of the companies,

NOTE Confidence: 0.9352219

00:59:54.820 --> 00:59:56.674 you know we can see the glass is half

NOTE Confidence: 0.9352219

00:59:56.674 --> 00:59:58.696 full here that people do respond to this.

NOTE Confidence: 0.9352219

00:59:58.700 --> 01:00:00.374 But this was as far as I know that

NOTE Confidence: 0.9352219

01:00:00.374 --> 01:00:01.538 you were the first one,

NOTE Confidence: 0.9352219

01:00:01.540 --> 01:00:03.220 this is even before you got your PhD,

NOTE Confidence: 0.9352219

01:00:03.220 --> 01:00:04.894 you were the first one who was doing this

NOTE Confidence: 0.9352219

01:00:04.894 --> 01:00:06.700 work and it's it's really quite interesting.

NOTE Confidence: 0.9352219

01:00:06.700 --> 01:00:10.048 So could you talk for a minute or two

NOTE Confidence: 0.9352219

01:00:10.048 --> 01:00:12.898 about what the scorecard entails and how

NOTE Confidence: 0.9352219

01:00:12.898 --> 01:00:16.888 how you evaluate A pharmaceutical company?

NOTE Confidence: 0.9352219

01:00:16.890 --> 01:00:17.532 What are the,

NOTE Confidence: 0.9352219

01:00:17.532 --> 01:00:18.816 what are the criteria that you're

NOTE Confidence: 0.9352219

01:00:18.816 --> 01:00:20.169 looking for and how they get scored,

NOTE Confidence: 0.9352219

01:00:20.170 --> 01:00:20.569 if you will.

NOTE Confidence: 0.9352219

01:00:20.970 --> 01:00:21.450 Yeah,

NOTE Confidence: 0.9603805

01:00:23.690 --> 01:00:28.974 thanks. So this, the scorecard started

NOTE Confidence: 0.9603805

01:00:28.974 --> 01:00:32.009 out very humbly as a tool to bridge

NOTE Confidence: 0.9603805

01:00:32.009 --> 01:00:34.125 asymmetries of information about

NOTE Confidence: 0.9603805

01:00:34.125 --> 01:00:36.770 the performance of pharma companies,

NOTE Confidence: 0.9603805

01:00:36.770 --> 01:00:39.170 a lot of the media.

NOTE Confidence: 0.9603805

01:00:39.170 --> 01:00:41.473 And the court cases build a pretty

NOTE Confidence: 0.9603805

01:00:41.473 --> 01:00:43.355 damning picture of pharma companies

NOTE Confidence: 0.9603805

01:00:43.355 --> 01:00:45.729 and the settlement agreements,

NOTE Confidence: 0.9603805

01:00:45.729 --> 01:00:47.688 corporate integrity agreements.

NOTE Confidence: 0.9603805

01:00:47.690 --> 01:00:48.755 But when you would speak

NOTE Confidence: 0.9603805

01:00:48.755 --> 01:00:49.607 with the pharma companies,

NOTE Confidence: 0.9603805

01:00:49.610 --> 01:00:51.298 they would say, well,

NOTE Confidence: 0.9603805

01:00:51.298 --> 01:00:52.564 those are outlier

NOTE Confidence: 0.956067514285714

01:00:55.090 --> 01:00:58.470 rogue companies in an

NOTE Confidence: 0.956067514285714

01:00:58.470 --> 01:01:01.005 otherwise good industry.

NOTE Confidence: 0.956067514285714

01:01:01.010 --> 01:01:02.438 Or if you spoke to the

NOTE Confidence: 0.956067514285714

01:01:02.438 --> 01:01:03.890 company that had the scandal,

NOTE Confidence: 0.956067514285714

01:01:03.890 --> 01:01:07.340 that was a rogue employee.

NOTE Confidence: 0.956067514285714

01:01:07.340 --> 01:01:09.115 Or an outlier department in

NOTE Confidence: 0.956067514285714

01:01:09.115 --> 01:01:10.535 an otherwise sound company.

NOTE Confidence: 0.956067514285714

01:01:10.540 --> 01:01:12.644 And so it was really hard for those

NOTE Confidence: 0.956067514285714

01:01:12.644 --> 01:01:15.041 of us who weren't in the industry

NOTE Confidence: 0.956067514285714

01:01:15.041 --> 01:01:17.100 to understand what was going on.

NOTE Confidence: 0.956067514285714

01:01:17.100 --> 01:01:19.354 And another talking point was those are

NOTE Confidence: 0.956067514285714

01:01:19.354 --> 01:01:21.498 old issues that have been resolved.

NOTE Confidence: 0.956067514285714

01:01:21.500 --> 01:01:23.892 And so the good from a scorecard in

NOTE Confidence: 0.956067514285714

01:01:23.892 --> 01:01:26.418 some ways started as a prevalent study

NOTE Confidence: 0.956067514285714

01:01:26.420 --> 01:01:29.690 starting with clinical trial transparency.

NOTE Confidence: 0.956067514285714

01:01:29.690 --> 01:01:31.598 Which is aware that companies weren't

NOTE Confidence: 0.956067514285714

01:01:31.598 --> 01:01:33.580 being honest and truthful about the

NOTE Confidence: 0.956067514285714

01:01:33.580 --> 01:01:35.220 safety and efficacy information about

NOTE Confidence: 0.956067514285714

01:01:35.220 --> 01:01:37.397 new medicines and vaccines that they

NOTE Confidence: 0.956067514285714

01:01:37.397 --> 01:01:38.913 were selectively selectively reporting

NOTE Confidence: 0.956067514285714

01:01:38.913 --> 01:01:41.240 trial outcomes or selectively reporting

NOTE Confidence: 0.956067514285714

01:01:41.240 --> 01:01:44.810 trial trial results and trial outcomes.

NOTE Confidence: 0.956067514285714

01:01:44.810 --> 01:01:48.026 And so I just set out with Joe.

NOTE Confidence: 0.956067514285714

01:01:48.030 --> 01:01:48.783 Way back when,

NOTE Confidence: 0.956067514285714

01:01:48.783 --> 01:01:49.787 like a decade ago,

NOTE Confidence: 0.956067514285714

01:01:49.790 --> 01:01:51.710 more than a decade ago,

NOTE Confidence: 0.956067514285714

01:01:51.710 --> 01:01:54.430 to figure out what does honesty and

NOTE Confidence: 0.956067514285714

01:01:54.430 --> 01:01:57.045 truth telling look like in the context

NOTE Confidence: 0.956067514285714

01:01:57.045 --> 01:01:58.556 of clinical trial results, right.

NOTE Confidence: 0.956067514285714

01:01:58.556 --> 01:02:00.020 How do you operationalize

NOTE Confidence: 0.956067514285714

01:02:00.020 --> 01:02:01.000 these these principles?

NOTE Confidence: 0.956067514285714

01:02:01.000 --> 01:02:03.440 We we talked about in values that we

NOTE Confidence: 0.956067514285714

01:02:03.498 --> 01:02:06.005 talked about in bioethics and how you

NOTE Confidence: 0.956067514285714

01:02:06.005 --> 01:02:07.830 develop accountability measures around there.

NOTE Confidence: 0.956067514285714

01:02:07.830 --> 01:02:10.143 And so the first thing is what's the goal,

NOTE Confidence: 0.956067514285714

01:02:10.150 --> 01:02:10.382 right?

NOTE Confidence: 0.956067514285714

01:02:10.382 --> 01:02:11.310 Honesty and truth telling.

NOTE Confidence: 0.956067514285714

01:02:11.310 --> 01:02:12.752 What does that look like in the

NOTE Confidence: 0.956067514285714

01:02:12.752 --> 01:02:13.790 context of medical evidence,

NOTE Confidence: 0.956067514285714

01:02:13.790 --> 01:02:15.564 registering trials,

NOTE Confidence: 0.956067514285714

01:02:15.564 --> 01:02:17.338 results reporting?

NOTE Confidence: 0.956067514285714

01:02:17.340 --> 01:02:19.356 Publishing results and then that changed

NOTE Confidence: 0.956067514285714

01:02:19.356 --> 01:02:21.941 to act to include sharing of individual

NOTE Confidence: 0.956067514285714

01:02:21.941 --> 01:02:24.299 patient level data and clinical trials.

NOTE Confidence: 0.956067514285714

01:02:24.300 --> 01:02:26.456 So you get these accountability measures and

NOTE Confidence: 0.956067514285714

01:02:26.456 --> 01:02:29.082 we use them to benchmark pharma companies.

NOTE Confidence: 0.956067514285714

01:02:29.082 --> 01:02:33.010 And what we found was that most companies

NOTE Confidence: 0.956067514285714

01:02:33.100 --> 01:02:36.220 did not meet the measures that we developed.

NOTE Confidence: 0.956067514285714

01:02:36.220 --> 01:02:40.371 And so we got all these companies

NOTE Confidence: 0.956067514285714

01:02:40.371 --> 01:02:43.537 together back in 2009 and then

NOTE Confidence: 0.956067514285714

01:02:43.537 --> 01:02:45.756 again in 2000 and I don't know.

NOTE Confidence: 0.956067514285714

01:02:45.760 --> 01:02:47.140 Early 2000, maybe 12,

NOTE Confidence: 0.956067514285714

01:02:47.140 --> 01:02:48.520 and said what happened?

NOTE Confidence: 0.956067514285714

01:02:48.520 --> 01:02:51.040 You guys said this was an outlier problem,

NOTE Confidence: 0.956067514285714

01:02:51.040 --> 01:02:54.520 a rogue company, an old issue.

NOTE Confidence: 0.956067514285714

01:02:54.520 --> 01:02:57.080 Why aren't you scoring better?

NOTE Confidence: 0.956067514285714

01:02:57.080 --> 01:02:59.240 And there was this backandforth dialogue,

NOTE Confidence: 0.956067514285714

01:02:59.240 --> 01:02:59.440 right?

NOTE Confidence: 0.956067514285714

01:02:59.440 --> 01:03:00.640 Oh well, you and you know,

NOTE Confidence: 0.956067514285714

01:03:00.640 --> 01:03:02.040 it was sort of scratching their heads.

NOTE Confidence: 0.956067514285714

01:03:02.040 --> 01:03:03.420 And then the meeting ended and

NOTE Confidence: 0.956067514285714

01:03:03.420 --> 01:03:04.591 we held another meeting and

NOTE Confidence: 0.956067514285714

01:03:04.591 --> 01:03:05.797 they came back and they said,

NOTE Confidence: 0.956067514285714

01:03:05.800 --> 01:03:06.610 well, you looked,

NOTE Confidence: 0.956067514285714

01:03:06.610 --> 01:03:07.960 you measured the wrong thing.

NOTE Confidence: 0.947030216190476

01:03:10.050 --> 01:03:12.332 And we were looking at all trials

NOTE Confidence: 0.947030216190476

01:03:12.332 --> 01:03:13.310 where pharmaceutical companies

NOTE Confidence: 0.947030216190476

01:03:13.366 --> 01:03:15.292 disclosing the results of all trials

NOTE Confidence: 0.947030216190476

01:03:15.292 --> 01:03:17.090 supporting FDA approval of products.

NOTE Confidence: 0.947030216190476

01:03:17.090 --> 01:03:17.650 And we said, oh, well,

NOTE Confidence: 0.947030216190476

01:03:17.650 --> 01:03:19.342 what trials should we have looked at, right.

NOTE Confidence: 0.947030216190476

01:03:19.342 --> 01:03:21.814 They said just the trials and

NOTE Confidence: 0.947030216190476

01:03:21.814 --> 01:03:24.689 patients for the approved indication.

NOTE Confidence: 0.947030216190476

01:03:24.690 --> 01:03:25.802 And before that they said, well,

NOTE Confidence: 0.947030216190476

01:03:25.802 --> 01:03:27.674 actually legally we're not required to

NOTE Confidence: 0.947030216190476

01:03:27.674 --> 01:03:29.586 disclose all the all the trial results.

NOTE Confidence: 0.947030216190476

01:03:29.586 --> 01:03:31.085 We just followed the law, right.

NOTE Confidence: 0.947030216190476

01:03:31.085 --> 01:03:32.735 And so this is an opportunity

NOTE Confidence: 0.947030216190476

01:03:32.735 --> 01:03:33.838 for a little education.

NOTE Confidence: 0.947030216190476

01:03:33.838 --> 01:03:36.180 Oh, so for ethics for you means minimal

NOTE Confidence: 0.947030216190476

01:03:36.180 --> 01:03:38.242 compliance with the law, right.

NOTE Confidence: 0.947030216190476

01:03:38.242 --> 01:03:40.708 What is ethics? Yeah.

NOTE Confidence: 0.947030216190476

01:03:40.708 --> 01:03:43.265 And so we realized that the good

NOTE Confidence: 0.947030216190476

01:03:43.265 --> 01:03:44.540 pharma scorecard could also create

NOTE Confidence: 0.947030216190476

01:03:44.540 --> 01:03:45.860 a knowledge exchange platform,

NOTE Confidence: 0.947030216190476

01:03:45.860 --> 01:03:48.104 right, where we could have this

NOTE Confidence: 0.947030216190476

01:03:48.104 --> 01:03:49.226 bidirectional education and

NOTE Confidence: 0.947030216190476

01:03:49.226 --> 01:03:50.979 dialogue on what good looks like.

NOTE Confidence: 0.947030216190476

01:03:50.980 --> 01:03:52.540 Is it just minimal compliance with the law,

NOTE Confidence: 0.947030216190476

01:03:52.540 --> 01:03:55.137 but is the law even being met?

NOTE Confidence: 0.947030216190476

01:03:55.140 --> 01:03:57.580 And so the next paper that we did,

NOTE Confidence: 0.947030216190476

01:03:57.580 --> 01:04:00.058 we added an analysis of legal compliance.

NOTE Confidence: 0.947030216190476

01:04:00.060 --> 01:04:01.128 We'd actually already done it in

NOTE Confidence: 0.947030216190476

01:04:01.128 --> 01:04:02.250 advance because I kind of figured

NOTE Confidence: 0.947030216190476

01:04:02.250 --> 01:04:03.482 that would be their pushback, right?

NOTE Confidence: 0.947030216190476

01:04:03.482 --> 01:04:05.596 And when we put up the slide,

NOTE Confidence: 0.947030216190476

01:04:05.600 --> 01:04:06.280 we showed that you know,

NOTE Confidence: 0.947030216190476

01:04:06.280 --> 01:04:08.597 less than half of companies were meeting

NOTE Confidence: 0.947030216190476

01:04:08.597 --> 01:04:10.480 minimal legal requirements for transparency.

NOTE Confidence: 0.947030216190476

01:04:10.480 --> 01:04:12.272 And so you know, you would just

NOTE Confidence: 0.947030216190476

01:04:12.272 --> 01:04:14.078 year after year sort of chip away.

NOTE Confidence: 0.947030216190476

01:04:14.080 --> 01:04:16.052 That's too expensive, right,

NOTE Confidence: 0.947030216190476

01:04:16.052 --> 01:04:18.448 to conduct a more diverse trial.

NOTE Confidence: 0.947030216190476

01:04:18.448 --> 01:04:20.560 Our competitors will get more investments,

NOTE Confidence: 0.947030216190476

01:04:20.560 --> 01:04:21.130 you know.

NOTE Confidence: 0.947030216190476

01:04:21.130 --> 01:04:24.938 So now we look at whether more ethical

NOTE Confidence: 0.947030216190476

01:04:24.938 --> 01:04:26.414 companies can financially outperform

NOTE Confidence: 0.947030216190476

01:04:26.414 --> 01:04:29.110 their peers and it turns out they do,

NOTE Confidence: 0.947030216190476

01:04:29.110 --> 01:04:31.120 but that hasn't been published yet.

NOTE Confidence: 0.947030216190476

01:04:31.120 --> 01:04:33.450 There's alpha.

NOTE Confidence: 0.947030216190476

01:04:33.450 --> 01:04:33.708 Yeah.

NOTE Confidence: 0.947030216190476

01:04:33.708 --> 01:04:35.256 So the good pharma scorecard started

NOTE Confidence: 0.947030216190476

01:04:35.256 --> 01:04:37.093 as the way to bridge asymmetries

NOTE Confidence: 0.947030216190476

01:04:37.093 --> 01:04:38.773 of information about the ethical

NOTE Confidence: 0.947030216190476

01:04:38.773 --> 01:04:40.330 performance of pharma companies.

NOTE Confidence: 0.947030216190476

01:04:40.330 --> 01:04:41.598 But then we turned,

NOTE Confidence: 0.947030216190476

01:04:41.598 --> 01:04:44.220 we turned out that there were pervasive.

NOTE Confidence: 0.947030216190476

01:04:44.220 --> 01:04:44.584 Genuine,

NOTE Confidence: 0.947030216190476

01:04:44.584 --> 01:04:46.040 widespread and current ethics

NOTE Confidence: 0.947030216190476

01:04:46.040 --> 01:04:47.496 problems within the sector.

NOTE Confidence: 0.947030216190476

01:04:47.500 --> 01:04:48.940 So we turned our question to

NOTE Confidence: 0.947030216190476

01:04:48.940 --> 01:04:50.220 how do you reform them?

NOTE Confidence: 0.947030216190476

01:04:50.220 --> 01:04:51.670 And there are many reform

NOTE Confidence: 0.947030216190476

01:04:51.670 --> 01:04:52.780 strategies out there, right?

NOTE Confidence: 0.947030216190476

01:04:52.780 --> 01:04:53.260 Passing laws.

NOTE Confidence: 0.947030216190476

01:04:53.260 --> 01:04:54.460 But as I just mentioned,

NOTE Confidence: 0.947030216190476

01:04:54.460 --> 01:04:57.616 they weren't sufficiently moving the needle.

NOTE Confidence: 0.947030216190476

01:04:57.620 --> 01:04:58.688 There's civil society activism,

NOTE Confidence: 0.947030216190476

01:04:58.688 --> 01:05:00.023 which there had already been

NOTE Confidence: 0.947030216190476

01:05:00.023 --> 01:05:01.608 in the space of clinical trial

NOTE Confidence: 0.947030216190476

01:05:01.608 --> 01:05:03.140 transparency with Ben Gold Acres work,

NOTE Confidence: 0.947030216190476

01:05:03.140 --> 01:05:03.654 for example,

NOTE Confidence: 0.947030216190476

01:05:03.654 --> 01:05:05.453 in London with the All Trials campaign.

NOTE Confidence: 0.87641155625

01:05:07.820 --> 01:05:09.620 And then there's a lot of different tools,

NOTE Confidence: 0.87641155625

01:05:09.620 --> 01:05:11.328 but they weren't working just like in

NOTE Confidence: 0.87641155625

01:05:11.328 --> 01:05:12.620 clinical trial diversity for 10 years,

NOTE Confidence: 0.87641155625

01:05:12.620 --> 01:05:14.300 right? No, no statistical,

NOTE Confidence: 0.87641155625

01:05:14.300 --> 01:05:15.980 at least significant changes

NOTE Confidence: 0.87641155625

01:05:15.980 --> 01:05:18.140 in in in representation.

NOTE Confidence: 0.87641155625

01:05:18.140 --> 01:05:19.370 And so that leads you to

NOTE Confidence: 0.87641155625

01:05:19.370 --> 01:05:20.580 ask what else can you do?

NOTE Confidence: 0.87641155625

01:05:20.580 --> 01:05:22.914 And almost every industry has used

NOTE Confidence: 0.87641155625

01:05:22.914 --> 01:05:24.081 an accreditation certification

NOTE Confidence: 0.87641155625

01:05:24.081 --> 01:05:26.311 rating or labeling program as a way

NOTE Confidence: 0.87641155625

01:05:26.311 --> 01:05:27.829 of communicating what good looks

NOTE Confidence: 0.87641155625

01:05:27.829 --> 01:05:29.378 like benchmarking and signaling.

NOTE Confidence: 0.87641155625

01:05:29.378 --> 01:05:31.082 Performance on measures including

NOTE Confidence: 0.87641155625

01:05:31.082 --> 01:05:33.034 hospitals which was pioneered in

NOTE Confidence: 0.87641155625

01:05:33.034 --> 01:05:34.888 some ways by Harlan Krumholz here,

NOTE Confidence: 0.87641155625

01:05:34.890 --> 01:05:36.426 right with a hospital quality measurements

NOTE Confidence: 0.87641155625

01:05:36.426 --> 01:05:38.277 which is part of the reason I was

NOTE Confidence: 0.87641155625

01:05:38.277 --> 01:05:39.930 excited to come to Yale many years ago,

NOTE Confidence: 0.87641155625

01:05:39.930 --> 01:05:43.498 several years ago and Joe and Joe's

NOTE Confidence: 0.87641155625

01:05:43.498 --> 01:05:45.480 work and we also have an environmental

NOTE Confidence: 0.87641155625

01:05:45.480 --> 01:05:47.332 performance index where we rank countries

NOTE Confidence: 0.87641155625

01:05:47.332 --> 01:05:48.808 on their environmental performance.

NOTE Confidence: 0.87641155625

01:05:48.810 --> 01:05:50.922 What is what does good look like and

NOTE Confidence: 0.87641155625

01:05:50.922 --> 01:05:53.370 how are different countries performing.

NOTE Confidence: 0.87641155625

01:05:53.370 --> 01:05:55.308 So that so then we thought

NOTE Confidence: 0.87641155625

01:05:55.308 --> 01:05:56.277 we'll we'll develop.

NOTE Confidence: 0.87641155625

01:05:56.280 --> 01:05:57.520 An accreditation or a certification

NOTE Confidence: 0.87641155625

01:05:57.520 --> 01:05:58.512 or rating or ranking,

NOTE Confidence: 0.87641155625

01:05:58.520 --> 01:06:01.448 it turned into a ranking that's

NOTE Confidence: 0.87641155625

01:06:01.448 --> 01:06:04.066 now a rating and a label.

NOTE Confidence: 0.87641155625

01:06:04.066 --> 01:06:06.072 You get a badge because pharma

NOTE Confidence: 0.87641155625

01:06:06.072 --> 01:06:07.252 companies created their own badge

NOTE Confidence: 0.87641155625

01:06:07.252 --> 01:06:08.439 and tweeted when they scored.

NOTE Confidence: 0.87641155625

01:06:08.440 --> 01:06:09.260 Well, so we were,

NOTE Confidence: 0.87641155625

01:06:09.260 --> 01:06:10.490 we thought we better create our

NOTE Confidence: 0.87641155625

01:06:10.532 --> 01:06:11.712 badge for them. That's standardized.

NOTE Confidence: 0.87641155625

01:06:11.712 --> 01:06:13.920 And now there's a badge you can display

NOTE Confidence: 0.87641155625

01:06:13.920 --> 01:06:15.396 and it goes into annual reports,

NOTE Confidence: 0.87641155625

01:06:15.400 --> 01:06:16.639 as I mentioned.

NOTE Confidence: 0.87641155625

01:06:16.639 --> 01:06:18.704 And it's become pretty widespread

NOTE Confidence: 0.87641155625

01:06:18.710 --> 01:06:19.984 across the sector and it looks bad

NOTE Confidence: 0.87641155625

01:06:19.984 --> 01:06:21.350 if it makes it into your annual

NOTE Confidence: 0.87641155625

01:06:21.350 --> 01:06:22.514 report one year and then it's

NOTE Confidence: 0.87641155625

01:06:22.558 --> 01:06:23.741 not in it the next year, right.

NOTE Confidence: 0.87641155625

01:06:23.741 --> 01:06:26.390 So and then we rely on the help of everyone.

NOTE Confidence: 0.87641155625

01:06:26.390 --> 01:06:28.150 So if there no eyeballs on the scorecard,

NOTE Confidence: 0.87641155625

01:06:28.150 --> 01:06:29.386 it doesn't have as much impact.

NOTE Confidence: 0.87641155625

01:06:29.390 --> 01:06:30.942 So it really have to work with the

NOTE Confidence: 0.87641155625

01:06:30.942 --> 01:06:32.790 media to get attention on the scorecard.

NOTE Confidence: 0.87641155625

01:06:32.790 --> 01:06:34.365 It's been a journey and now we're

NOTE Confidence: 0.87641155625

01:06:34.365 --> 01:06:35.855 trying to work with investors that's

NOTE Confidence: 0.87641155625

01:06:35.855 --> 01:06:37.825 why we're looking to see if if

NOTE Confidence: 0.87641155625

01:06:37.825 --> 01:06:39.565 ethical performance is correlated

NOTE Confidence: 0.87641155625

01:06:39.565 --> 01:06:41.305 with financial performance on

NOTE Confidence: 0.87641155625

01:06:41.305 --> 01:06:42.430 the firm level

NOTE Confidence: 0.9403956075

01:06:43.350 --> 01:06:44.244 or negatively correlated.

NOTE Confidence: 0.9403956075

01:06:44.244 --> 01:06:46.140 Is that what you're saying? Yeah.

NOTE Confidence: 0.950317

01:06:46.140 --> 01:06:47.220 Well, that would hopefully not.

NOTE Confidence: 0.950317

01:06:47.220 --> 01:06:50.256 Yeah. So the, the spoiler alert,

NOTE Confidence: 0.950317

01:06:50.260 --> 01:06:52.672 it's preliminary is that many of

NOTE Confidence: 0.950317

01:06:52.672 --> 01:06:54.620 the measures are correlated with

NOTE Confidence: 0.950317

01:06:54.620 --> 01:06:55.430 positive financial performance,

NOTE Confidence: 0.950317

01:06:55.430 --> 01:06:57.580 which is what we were hoping to find.

NOTE Confidence: 0.84398575

01:06:58.260 --> 01:06:59.412 That's exciting. That's wonderful.

NOTE Confidence: 0.84398575

01:06:59.412 --> 01:07:00.852 I congratulate you on that.

NOTE Confidence: 0.84398575

01:07:00.860 --> 01:07:02.414 I mean I say that's exciting stuff

NOTE Confidence: 0.84398575

01:07:02.414 --> 01:07:04.539 is to be doing something to be to be

NOTE Confidence: 0.947441742857143

01:07:06.740 --> 01:07:08.480 cutting a new trail that

NOTE Confidence: 0.947441742857143

01:07:08.480 --> 01:07:09.340 others haven't. Yeah,

NOTE Confidence: 0.91780058

01:07:09.340 --> 01:07:10.528 everyone's, everyone's cutting.

NOTE Confidence: 0.91780058

01:07:10.528 --> 01:07:13.300 It's been good to talk with them.

NOTE Confidence: 0.93220288

01:07:13.420 --> 01:07:14.140 It's great. We have a,

NOTE Confidence: 0.93220288

01:07:14.140 --> 01:07:15.100 Jackie, have a question.

NOTE Confidence: 0.936899066666667

01:07:17.310 --> 01:07:18.150 We don't mind.

NOTE Confidence: 0.943607983333333

01:07:22.510 --> 01:07:23.188 Thank you, Chris.

NOTE Confidence: 0.894919806666666

01:07:25.830 --> 01:07:28.334 Although George Bush looks,

NOTE Confidence: 0.894919806666666

01:07:28.334 --> 01:07:32.042 George Young Young George Bush looks,

NOTE Confidence: 0.894919806666666

01:07:32.042 --> 01:07:35.474 perhaps looks better in retrospect compared

NOTE Confidence: 0.894919806666666

01:07:35.474 --> 01:07:38.790 to what's happened subsequently before.

NOTE Confidence: 0.894919806666666

01:07:38.790 --> 01:07:41.910 Eight years ago, 10 years ago,

NOTE Confidence: 0.894919806666666

01:07:41.910 --> 01:07:43.818 I really thought that.

NOTE Confidence: 0.894919806666666

01:07:43.818 --> 01:07:46.680 He was pretty much a disaster

NOTE Confidence: 0.894919806666666

01:07:46.778 --> 01:07:49.384 except for PEPFAR and which is

NOTE Confidence: 0.894919806666666

01:07:49.384 --> 01:07:51.820 really as near as I can tell,

NOTE Confidence: 0.894919806666666

01:07:51.820 --> 01:07:53.740 a pretty amazing accomplishment.

NOTE Confidence: 0.894919806666666

01:07:53.740 --> 01:07:55.990 So maybe Jack, if you would,

NOTE Confidence: 0.894919806666666

01:07:55.990 --> 01:07:58.241 you're referring to the work and about AIDS

NOTE Confidence: 0.894919806666666

01:07:58.241 --> 01:08:00.376 research and from the president in Africa,

NOTE Confidence: 0.894919806666666

01:08:00.380 --> 01:08:01.270 etcetera, yes,

NOTE Confidence: 0.894919806666666

01:08:01.270 --> 01:08:04.024 if you could give us because not

NOTE Confidence: 0.894919806666666

01:08:04.024 --> 01:08:05.858 everybody may have be familiar with it,

NOTE Confidence: 0.894919806666666

01:08:05.860 --> 01:08:07.590 not everybody was, you know.

NOTE Confidence: 0.894919806666666

01:08:07.590 --> 01:08:08.660 Paying close attention when the

NOTE Confidence: 0.894919806666666

01:08:08.660 --> 01:08:09.990 young George Bush was doing stuff.

NOTE Confidence: 0.894919806666666

01:08:09.990 --> 01:08:11.726 You could give us a four sentence

NOTE Confidence: 0.894919806666666

01:08:11.726 --> 01:08:13.360 summary of Pepsi or A2 sentence

NOTE Confidence: 0.894919806666666

01:08:13.360 --> 01:08:14.468 summary of that program.

NOTE Confidence: 0.894919806666666

01:08:14.470 --> 01:08:15.340 Maybe one sentence,

NOTE Confidence: 0.894919806666666

01:08:15.340 --> 01:08:16.790 one sentence would be fine.

NOTE Confidence: 0.894919806666666

01:08:16.790 --> 01:08:18.902 Yeah, it was presidents.

NOTE Confidence: 0.894919806666666

01:08:18.902 --> 01:08:20.826 Well, I don't remember that.

NOTE Confidence: 0.894919806666666

01:08:20.826 --> 01:08:23.310 I can't possibly repeat the the type,

NOTE Confidence: 0.894919806666666

01:08:23.310 --> 01:08:24.795 the full title.

NOTE Confidence: 0.894919806666666

01:08:24.795 --> 01:08:28.902 At any rate it was money for treatment

NOTE Confidence: 0.894919806666666

01:08:28.902 --> 01:08:33.762 of HIV in Africa and it was a a gift

NOTE Confidence: 0.894919806666666

01:08:33.762 --> 01:08:36.590 from the United States and George Bush.

NOTE Confidence: 0.894919806666666

01:08:36.590 --> 01:08:39.006 Authorized it and made sure that it went

NOTE Confidence: 0.894919806666666

01:08:39.006 --> 01:08:41.383 through as near as I near as I can tell.

NOTE Confidence: 0.894919806666666

01:08:41.390 --> 01:08:43.430 So and it's estimated right that

NOTE Confidence: 0.894919806666666

01:08:43.430 --> 01:08:46.910 that saved 20 million lives a lot.

NOTE Confidence: 0.894919806666666

01:08:46.910 --> 01:08:47.270 So,

NOTE Confidence: 0.936899071666667

01:08:49.430 --> 01:08:52.846 so my question is did any of that

NOTE Confidence: 0.936899071666667

01:08:52.846 --> 01:08:56.470 money go into testing within Africa?

NOTE Confidence: 0.936899071666667

01:08:56.470 --> 01:09:00.229 That's one question. And then the

NOTE Confidence: 0.936899071666667

01:09:00.229 --> 01:09:04.350 second question is if we are to ever.

NOTE Confidence: 0.942083309090909

01:09:07.730 --> 01:09:10.621 Donate. If we are ever to become

NOTE Confidence: 0.942083309090909

01:09:10.621 --> 01:09:13.170 generous enough again to have a

NOTE Confidence: 0.942083309090909

01:09:13.170 --> 01:09:15.870 PEPFAR like initiative for other

NOTE Confidence: 0.942083309090909

01:09:15.870 --> 01:09:18.810 illnesses in low income countries,

NOTE Confidence: 0.942083309090909

01:09:18.810 --> 01:09:22.596 are you would it would it make sense

NOTE Confidence: 0.942083309090909

01:09:22.596 --> 01:09:25.450 to you to incorporate the research

NOTE Confidence: 0.942083309090909

01:09:25.450 --> 01:09:28.930 arm of that into that funding which

NOTE Confidence: 0.9402536

01:09:29.850 --> 01:09:33.441 so I don't know how the PEPFAR

NOTE Confidence: 0.9402536

01:09:33.441 --> 01:09:35.120 spending. Was allocated.

NOTE Confidence: 0.9402536

01:09:35.120 --> 01:09:40.296 But if you do look at trial locations,

NOTE Confidence: 0.9402536

01:09:40.296 --> 01:09:44.295 the trials for HIV are geographically

NOTE Confidence: 0.9402536

01:09:44.295 --> 01:09:48.784 on the country level, the most diverse.

NOTE Confidence: 0.9402536

01:09:48.784 --> 01:09:51.360 So it's it's possible,

NOTE Confidence: 0.9301902

01:09:56.440 --> 01:09:59.152 yeah. So your question raises a

NOTE Confidence: 0.9301902

01:09:59.152 --> 01:10:01.892 really interesting one about whose

NOTE Confidence: 0.9301902

01:10:01.892 --> 01:10:03.587 responsibility it is to fund.

NOTE Confidence: 0.9301902

01:10:03.590 --> 01:10:05.262 Global clinical trials, right.

NOTE Confidence: 0.9301902

01:10:05.262 --> 01:10:07.770 And to ensure that clinical trials

NOTE Confidence: 0.9301902

01:10:07.840 --> 01:10:09.416 are taking place in countries

NOTE Confidence: 0.9301902

01:10:09.416 --> 01:10:10.508 with high disease burden,

NOTE Confidence: 0.840085076

01:10:13.950 --> 01:10:17.335 the FDA is the US, the SPOT trial

NOTE Confidence: 0.840085076

01:10:17.335 --> 01:10:19.945 sponsors and it's an unanswered question.

NOTE Confidence: 0.840085076

01:10:19.950 --> 01:10:22.286 I would say I'd like to see the

NOTE Confidence: 0.840085076

01:10:22.286 --> 01:10:24.350 pharma company just pay for it, right.

NOTE Confidence: 0.954629885714286

01:10:26.390 --> 01:10:27.714 I think primarily it's

NOTE Confidence: 0.954629885714286

01:10:27.714 --> 01:10:28.707 their first responsibility.

NOTE Confidence: 0.954629885714286

01:10:28.710 --> 01:10:30.494 They're the ones profiting

NOTE Confidence: 0.954629885714286

01:10:30.494 --> 01:10:32.332 off of marketing a product.

NOTE Confidence: 0.954629885714286

01:10:32.332 --> 01:10:34.970 I'd like to see if that happen first.

NOTE Confidence: 0.938815971428571

01:10:38.730 --> 01:10:41.404 What what do you think about that?

NOTE Confidence: 0.938815971428571

01:10:41.410 --> 01:10:43.195 Because if you, if you have a

NOTE Confidence: 0.938815971428571

01:10:43.195 --> 01:10:45.090 government come in and pay you that,

NOTE Confidence: 0.938815971428571

01:10:45.090 --> 01:10:46.742 you're just kind of speaking to whose

NOTE Confidence: 0.938815971428571

01:10:46.742 --> 01:10:50.490 responsibility it is. Exactly. Yeah.

NOTE Confidence: 0.931448125

01:10:50.490 --> 01:10:54.674 No, I I I think whatever we could.

NOTE Confidence: 0.931448125

01:10:54.680 --> 01:10:55.920 Contributions from the Pharmaceutical

NOTE Confidence: 0.931448125

01:10:55.920 --> 01:10:57.160 industry would be great.

NOTE Confidence: 0.931448125

01:10:57.160 --> 01:10:58.918 What how do we incentivize that?

NOTE Confidence: 0.931448125

01:10:58.920 --> 01:11:00.240 How do we build that in?

NOTE Confidence: 0.9309053875

01:11:00.280 --> 01:11:01.477 Well, that's what I'm trying to do

NOTE Confidence: 0.9309053875

01:11:01.477 --> 01:11:03.000 with the good pharma scorecard, right.

NOTE Confidence: 0.9309053875

01:11:03.000 --> 01:11:06.618 So one of the pieces is looking at that's why

NOTE Confidence: 0.9309053875

01:11:06.618 --> 01:11:09.760 I teed up the conceptual piece which is well,

NOTE Confidence: 0.9309053875

01:11:09.760 --> 01:11:11.560 first the the empirical where

NOTE Confidence: 0.9309053875

01:11:11.560 --> 01:11:13.000 are we testing products.

NOTE Confidence: 0.9309053875

01:11:13.000 --> 01:11:14.872 The second piece was conceptually where

NOTE Confidence: 0.9309053875

01:11:14.872 --> 01:11:16.945 should we be testing products, right.

NOTE Confidence: 0.9309053875

01:11:16.945 --> 01:11:18.775 And I hint that I think.

NOTE Confidence: 0.9309053875

01:11:18.780 --> 01:11:20.586 That site selection to track the

NOTE Confidence: 0.9309053875

01:11:20.586 --> 01:11:22.380 burden of disease on the country

NOTE Confidence: 0.9309053875

01:11:22.380 --> 01:11:24.508 level and then the next piece is to

NOTE Confidence: 0.9309053875

01:11:24.574 --> 01:11:26.804 go in and see I'm going to find no,

NOTE Confidence: 0.9309053875

01:11:26.804 --> 01:11:28.700 but do site selections correlate with

NOTE Confidence: 0.9309053875

01:11:28.700 --> 01:11:29.974 disease burden, it's going to be no.

NOTE Confidence: 0.9309053875

01:11:29.980 --> 01:11:31.612 And then the and then the next piece

NOTE Confidence: 0.9309053875

01:11:31.612 --> 01:11:33.621 is to build it into the good pharma

NOTE Confidence: 0.9309053875

01:11:33.621 --> 01:11:35.594 scorecard right to rank companies on

NOTE Confidence: 0.9309053875

01:11:35.594 --> 01:11:37.864 whether their site selections are

NOTE Confidence: 0.9309053875

01:11:37.864 --> 01:11:40.504 correlating with the burden disease and

NOTE Confidence: 0.9309053875

01:11:40.504 --> 01:11:43.976 then to look at countries to see if some

NOTE Confidence: 0.9309053875

01:11:43.976 --> 01:11:46.370 countries are better at getting sites.

NOTE Confidence: 0.9309053875

01:11:46.370 --> 01:11:48.832 Than others with with high burns

NOTE Confidence: 0.9309053875

01:11:48.832 --> 01:11:51.364 of disease and why right barriers

NOTE Confidence: 0.9309053875

01:11:51.364 --> 01:11:53.690 and facilitators for hosting trials

NOTE Confidence: 0.9309053875

01:11:53.690 --> 01:11:55.175 or barriers and facilitating yeah

NOTE Confidence: 0.9309053875

01:11:55.175 --> 01:11:56.363 to selecting certain sites

NOTE Confidence: 0.937375796666667

01:12:02.570 --> 01:12:03.788 but it but remember just because

NOTE Confidence: 0.937375796666667

01:12:03.788 --> 01:12:05.436 you have a trial site doesn't mean

NOTE Confidence: 0.937375796666667

01:12:05.436 --> 01:12:07.008 that the product gets submitted for

NOTE Confidence: 0.937375796666667

01:12:07.008 --> 01:12:08.830 marketing then it doesn't mean that it's

NOTE Confidence: 0.937375796666667

01:12:08.830 --> 01:12:10.570 affordable that there's enough supply.

NOTE Confidence: 0.9301902

01:12:16.660 --> 01:12:21.844 I I just wonder about tactics for addressing

NOTE Confidence: 0.9301902

01:12:21.844 --> 01:12:24.460 the lack of representation in trials,

NOTE Confidence: 0.9301902

01:12:24.460 --> 01:12:27.162 because I kind of wonder whose fault

NOTE Confidence: 0.9301902

01:12:27.162 --> 01:12:30.780 it is or who's best situated to fix it

NOTE Confidence: 0.917003876923077

01:12:33.260 --> 01:12:35.618 is. For example, if if some

NOTE Confidence: 0.917003876923077

01:12:35.618 --> 01:12:38.178 pharma company has a Pi at Yale.

NOTE Confidence: 0.917003876923077

01:12:38.180 --> 01:12:40.376 It might just be that the Pi at Yale

NOTE Confidence: 0.917003876923077

01:12:40.376 --> 01:12:42.577 has a really hard time recruiting

NOTE Confidence: 0.917003876923077

01:12:42.577 --> 01:12:44.505 a representative number of black

NOTE Confidence: 0.917003876923077

01:12:44.505 --> 01:12:46.935 patients from the New Haven community.

NOTE Confidence: 0.917003876923077

01:12:46.940 --> 01:12:49.433 So then whose fault is it that the recruiting

NOTE Confidence: 0.917003876923077

01:12:49.433 --> 01:12:51.619 is not sufficiently representative?

NOTE Confidence: 0.917003876923077

01:12:51.620 --> 01:12:53.480 Well, maybe it's the company's

NOTE Confidence: 0.917003876923077

01:12:53.480 --> 01:12:55.340 fault because they should find

NOTE Confidence: 0.917003876923077

01:12:55.340 --> 01:12:57.620 PI's in places where that are,

NOTE Confidence: 0.917003876923077

01:12:57.620 --> 01:12:58.592 where minority communities

NOTE Confidence: 0.917003876923077

01:12:58.592 --> 01:13:00.536 are more dense on the ground.

NOTE Confidence: 0.917003876923077

01:13:00.540 --> 01:13:02.475 Maybe that means finding API

NOTE Confidence: 0.917003876923077

01:13:02.475 --> 01:13:05.523 in in rural areas of the South

NOTE Confidence: 0.917003876923077

01:13:05.523 --> 01:13:07.579 that are predominantly black.

NOTE Confidence: 0.917003876923077

01:13:07.580 --> 01:13:09.939 I also was just curious whether you

NOTE Confidence: 0.917003876923077

01:13:09.939 --> 01:13:12.465 knew whether some of this lack of

NOTE Confidence: 0.917003876923077

01:13:12.465 --> 01:13:14.637 representation is due to pharma companies

NOTE Confidence: 0.917003876923077

01:13:14.709 --> 01:13:18.260 relying on disease groups for recruiting,

NOTE Confidence: 0.917003876923077

01:13:18.260 --> 01:13:20.530 because I sort of strongly

NOTE Confidence: 0.917003876923077

01:13:20.530 --> 01:13:22.800 suspect disease groups of not

NOTE Confidence: 0.917003876923077

01:13:22.881 --> 01:13:24.860 being particularly representative

NOTE Confidence: 0.917003876923077

01:13:24.860 --> 01:13:27.980 of the people with the disease

NOTE Confidence: 0.917003876923077

01:13:27.980 --> 01:13:30.996 burden because they're largely

NOTE Confidence: 0.917003876923077

01:13:30.996 --> 01:13:33.640 fundraising vehicles for pharma.

NOTE Confidence: 0.917003876923077

01:13:33.640 --> 01:13:35.600 So they're probably disproportionately

NOTE Confidence: 0.917003876923077

01:13:35.600 --> 01:13:37.070 wealthy and therefore,

NOTE Confidence: 0.917003876923077

01:13:37.070 --> 01:13:38.790 I would guess disproportionately

NOTE Confidence: 0.917003876923077

01:13:38.790 --> 01:13:40.510 white and so on.

NOTE Confidence: 0.947441742857143

01:13:40.750 --> 01:13:43.180 Right. And in some cases getting

NOTE Confidence: 0.947441742857143

01:13:43.180 --> 01:13:44.790 royalty royalties from products.

NOTE Confidence: 0.947441742857143

01:13:44.790 --> 01:13:46.790 If you think about Cystic

NOTE Confidence: 0.947441742857143

01:13:46.790 --> 01:13:47.590 Fibrosis Foundation,

NOTE Confidence: 0.947441742857143

01:13:47.590 --> 01:13:50.750 that's a really interesting model.

NOTE Confidence: 0.947441742857143

01:13:50.750 --> 01:13:52.510 Yeah, I guess, Steve, I wouldn't look at.

NOTE Confidence: 0.947441742857143

01:13:52.510 --> 01:13:54.750 So when you say whose fault is it,

NOTE Confidence: 0.947441742857143

01:13:54.750 --> 01:13:57.638 is that, is that your.

NOTE Confidence: 0.947441742857143

01:13:57.638 --> 01:13:59.046 Yeah. Yeah, that's right.

NOTE Confidence: 0.947441742857143

01:13:59.046 --> 01:14:01.342 What's the root of the the problem?

NOTE Confidence: 0.947441742857143

01:14:01.350 --> 01:14:03.950 So we can strike at it, right.

NOTE Confidence: 0.947441742857143

01:14:03.950 --> 01:14:06.926 The, the, the roots are so

NOTE Confidence: 0.947441742857143

01:14:06.926 --> 01:14:08.910 pervasive and so systemic,

NOTE Confidence: 0.947441742857143

01:14:08.910 --> 01:14:12.270 but it's hard to find a dominant route.

NOTE Confidence: 0.947441742857143

01:14:12.270 --> 01:14:14.678 And so I think going back to Sarah,

NOTE Confidence: 0.947441742857143

01:14:14.678 --> 01:14:16.910 Doctor Hall's question is that we need to go,

NOTE Confidence: 0.947441742857143

01:14:16.910 --> 01:14:17.430 you know,

NOTE Confidence: 0.947441742857143

01:14:17.430 --> 01:14:19.510 we all need to be doing something right.

NOTE Confidence: 0.947441742857143

01:14:19.510 --> 01:14:22.258 And so part of it is, as you mentioned,

NOTE Confidence: 0.947441742857143

01:14:22.258 --> 01:14:24.802 selecting diverse sites on

NOTE Confidence: 0.947441742857143

01:14:24.802 --> 01:14:26.710 the geographic level,

NOTE Confidence: 0.947441742857143

01:14:26.710 --> 01:14:28.710 sites where there are diverse

NOTE Confidence: 0.947441742857143

01:14:28.710 --> 01:14:29.510 patient populations,

NOTE Confidence: 0.947441742857143

01:14:29.510 --> 01:14:31.470 Yale happens to be one of them,

NOTE Confidence: 0.947441742857143

01:14:31.470 --> 01:14:33.723 right, which is.

NOTE Confidence: 0.947441742857143

01:14:33.723 --> 01:14:36.540 Helpful for us making sure

NOTE Confidence: 0.947441742857143

01:14:36.540 --> 01:14:37.940 that our workforce is diverse,

NOTE Confidence: 0.947441742857143

01:14:37.940 --> 01:14:38.220 right,

NOTE Confidence: 0.947441742857143

01:14:38.220 --> 01:14:39.620 so that we're recruiting and

NOTE Confidence: 0.947441742857143

01:14:39.620 --> 01:14:40.740 retaining A diverse workforce.

NOTE Confidence: 0.947441742857143

01:14:40.740 --> 01:14:43.140 But that starts you know that's

NOTE Confidence: 0.947441742857143

01:14:43.140 --> 01:14:44.660 also systemic challenge that

NOTE Confidence: 0.947441742857143

01:14:44.660 --> 01:14:46.820 starts really on and early on

NOTE Confidence: 0.947441742857143

01:14:46.820 --> 01:14:48.919 in life and generations passed.

NOTE Confidence: 0.947441742857143

01:14:48.919 --> 01:14:50.991 So it's the roots are so deep and

NOTE Confidence: 0.947441742857143

01:14:50.991 --> 01:14:53.137 so multipronged on this challenge.

NOTE Confidence: 0.947441742857143

01:14:53.140 --> 01:14:54.952 I can't really tell you which

NOTE Confidence: 0.947441742857143

01:14:54.952 --> 01:14:56.331 route to strike most.

NOTE Confidence: 0.947441742857143

01:14:56.331 --> 01:14:59.529 You know we have to strike all of them.

NOTE Confidence: 0.947441742857143

01:14:59.530 --> 01:15:01.768 Or what are all of them?

NOTE Confidence: 0.947441742857143

01:15:01.770 --> 01:15:03.660 But but we are trying to

NOTE Confidence: 0.947441742857143

01:15:03.660 --> 01:15:04.605 answer that question

NOTE Confidence: 0.95434229

01:15:06.730 --> 01:15:08.330 with the positive deviant study, right?

NOTE Confidence: 0.95434229

01:15:08.330 --> 01:15:10.130 Seeing that the trials that did get it right,

NOTE Confidence: 0.95434229

01:15:10.130 --> 01:15:11.480 you know for the sponsors who

NOTE Confidence: 0.95434229

01:15:11.480 --> 01:15:12.690 did get some something right,

NOTE Confidence: 0.95434229

01:15:12.690 --> 01:15:13.434 right one measure right,

NOTE Confidence: 0.95434229

01:15:13.434 --> 01:15:14.364 how did they do it?

NOTE Confidence: 0.95434229

01:15:14.370 --> 01:15:16.855 So at least we can start developing

NOTE Confidence: 0.95434229

01:15:16.855 --> 01:15:18.450 generalizable knowledge for best

NOTE Confidence: 0.95434229

01:15:18.450 --> 01:15:21.530 practices that have worked in the past.

NOTE Confidence: 0.95434229

01:15:21.530 --> 01:15:23.090 Which which route would you strike? Site

NOTE Confidence: 0.948304246

01:15:25.930 --> 01:15:28.090 selection seems to be really important.

NOTE Confidence: 0.94226628

01:15:28.660 --> 01:15:31.316 That's a popular one.

NOTE Confidence: 0.94226628

01:15:31.316 --> 01:15:33.060 Yeah, maybe the implementation

NOTE Confidence: 0.94226628

01:15:33.060 --> 01:15:34.500 of decentralized trials and.

NOTE Confidence: 0.9301902

01:15:37.060 --> 01:15:39.220 But that also introduces more inequities,

NOTE Confidence: 0.9301902

01:15:39.220 --> 01:15:40.284 right, The digital divide.

NOTE Confidence: 0.9301902

01:15:40.284 --> 01:15:41.880 But only some people have access

NOTE Confidence: 0.9301902

01:15:41.930 --> 01:15:43.420 to Internet and it's complicated.

NOTE Confidence: 0.9452853

01:15:47.020 --> 01:15:48.700 They just keep coming.

NOTE Confidence: 0.9452853

01:15:48.700 --> 01:15:50.700 No silver bullets. Bring it on. Jack.

NOTE Confidence: 0.933858215555556

01:15:52.820 --> 01:15:54.305 I'm. I'm fascinated.

NOTE Confidence: 0.933858215555556

01:15:54.305 --> 01:15:57.275 Well, I'm delighted to hear that.

NOTE Confidence: 0.933858215555556

01:15:57.280 --> 01:15:59.320 That good performance on your,

NOTE Confidence: 0.933858215555556

01:15:59.320 --> 01:16:04.013 on your measure correlates with success,

NOTE Confidence: 0.933858215555556

01:16:04.013 --> 01:16:07.957 if am I interpreting what you said correctly.

NOTE Confidence: 0.933858215555556

01:16:07.960 --> 01:16:11.662 And so I want to know what how much

NOTE Confidence: 0.933858215555556

01:16:11.662 --> 01:16:13.926 of that do you think is cause and

NOTE Confidence: 0.933858215555556

01:16:13.926 --> 01:16:16.502 effect is and you know we when we

NOTE Confidence: 0.933858215555556

01:16:16.502 --> 01:16:18.310 hear about hospitals that perform

NOTE Confidence: 0.933858215555556

01:16:18.310 --> 01:16:21.005 well and they do score well on

NOTE Confidence: 0.933858215555556

01:16:21.005 --> 01:16:22.680 their performance evaluations,

NOTE Confidence: 0.933858215555556

01:16:22.680 --> 01:16:25.865 they tend to be hospitals that are.

NOTE Confidence: 0.933858215555556

01:16:25.870 --> 01:16:30.090 Doing well, but they're also hospitals

NOTE Confidence: 0.933858215555556

01:16:30.090 --> 01:16:32.700 that have that are adequately staffed

NOTE Confidence: 0.933858215555556

01:16:32.768 --> 01:16:35.141 and they have good cash flows and

NOTE Confidence: 0.933858215555556

01:16:35.141 --> 01:16:37.390 they are capable of addressing the

NOTE Confidence: 0.933858215555556

01:16:37.390 --> 01:16:40.846 performance measures and making sure that

NOTE Confidence: 0.933858215555556

01:16:40.846 --> 01:16:43.150 everything's getting recorded correctly.

NOTE Confidence: 0.933858215555556

01:16:43.150 --> 01:16:46.112 Is it possible that the that the

NOTE Confidence: 0.933858215555556

01:16:46.112 --> 01:16:47.556 pharmaceutical companies that are

NOTE Confidence: 0.933858215555556

01:16:47.556 --> 01:16:50.245 doing well or that are that are seem

NOTE Confidence: 0.933858215555556

01:16:50.245 --> 01:16:52.422 to be morally superior are actually

NOTE Confidence: 0.933858215555556

01:16:52.422 --> 01:16:55.398 just able to to address your.

NOTE Confidence: 0.933858215555556

01:16:55.400 --> 01:16:59.065 Your scorecard better and it I I

NOTE Confidence: 0.933858215555556

01:16:59.065 --> 01:17:01.972 suppose in a way we don't care if you're

NOTE Confidence: 0.933858215555556

01:17:01.972 --> 01:17:04.731 leading to moral improvement as long as

NOTE Confidence: 0.933858215555556

01:17:04.731 --> 01:17:06.880 you're leading to better performance.

NOTE Confidence: 0.933858215555556

01:17:06.880 --> 01:17:10.240 And so we'll let people just

NOTE Confidence: 0.933858215555556

01:17:10.240 --> 01:17:13.320 fake it until they make it or.

NOTE Confidence: 0.9402536

01:17:15.110 --> 01:17:16.937 Well, it's a little early to talk

NOTE Confidence: 0.9402536

01:17:16.937 --> 01:17:18.748 about the results of the Alpha study,

NOTE Confidence: 0.9402536

01:17:18.750 --> 01:17:20.870 but I we did control,

NOTE Confidence: 0.9402536

01:17:20.870 --> 01:17:22.558 so did various snapshots.

NOTE Confidence: 0.9402536

01:17:22.558 --> 01:17:24.668 Again it's it's very preliminary,

NOTE Confidence: 0.9402536

01:17:24.670 --> 01:17:28.107 but I held constant for large companies.

NOTE Confidence: 0.9402536

01:17:28.110 --> 01:17:29.634 So just looking at the largest

NOTE Confidence: 0.9402536

01:17:29.634 --> 01:17:31.261 companies by market cap and you

NOTE Confidence: 0.9402536

01:17:31.261 --> 01:17:32.389 still see an outperformance.

NOTE Confidence: 0.9402536

01:17:32.390 --> 01:17:34.651 So in so there you would have

NOTE Confidence: 0.9402536

01:17:34.651 --> 01:17:36.110 controlled for in theory

NOTE Confidence: 0.9553487

01:17:38.350 --> 01:17:40.402 some level of resource

NOTE Confidence: 0.9553487

01:17:40.402 --> 01:17:42.454 resource access to resources.

NOTE Confidence: 0.9553487

01:17:42.460 --> 01:17:44.580 You still see a correlation,

NOTE Confidence: 0.94025356

01:17:49.260 --> 01:17:52.850 yeah, but. But I don't mean

NOTE Confidence: 0.94025356

01:17:52.850 --> 01:17:54.858 to incentivize that companies

NOTE Confidence: 0.94025356

01:17:54.860 --> 01:17:55.856 don't have to do the right

NOTE Confidence: 0.94025356

01:17:55.856 --> 01:17:56.900 thing when it doesn't pay right.

NOTE Confidence: 0.94025356

01:17:56.900 --> 01:17:57.908 We want them to do the right

NOTE Confidence: 0.94025356

01:17:57.908 --> 01:17:58.540 thing no matter what.

NOTE Confidence: 0.94025356

01:17:58.540 --> 01:18:00.820 But it helps and that it's

NOTE Confidence: 0.94025356

01:18:00.820 --> 01:18:03.379 another lever to pull if it's also

NOTE Confidence: 0.94025356

01:18:03.380 --> 01:18:05.084 not going to be more expensive

NOTE Confidence: 0.94025356

01:18:05.084 --> 01:18:06.220 and possibly even profitable.

NOTE Confidence: 0.815453432

01:18:07.700 --> 01:18:10.430 Right? Gentlemen back there, please.

NOTE Confidence: 0.815453432

01:18:10.430 --> 01:18:11.630 Oh wait before you speak,

NOTE Confidence: 0.815453432

01:18:11.630 --> 01:18:13.070 excuse me just one second because

NOTE Confidence: 0.815453432

01:18:13.070 --> 01:18:14.919 it occurs to me there's a disclosure

NOTE Confidence: 0.815453432

01:18:14.919 --> 01:18:16.587 that I should have given here.

NOTE Confidence: 0.815453432

01:18:16.590 --> 01:18:18.424 I am talking about the wonderful work

NOTE Confidence: 0.815453432

01:18:18.424 --> 01:18:19.859 your organization does the Bioethics

NOTE Confidence: 0.815453432

01:18:19.859 --> 01:18:21.647 International scorecard and I actually on

NOTE Confidence: 0.815453432

01:18:21.647 --> 01:18:23.467 the Advisory Board of this organization.

NOTE Confidence: 0.815453432

01:18:23.470 --> 01:18:26.033 So I should disclose that however the the,

NOTE Confidence: 0.815453432

01:18:26.033 --> 01:18:27.838 the payment checks are are

NOTE Confidence: 0.815453432

01:18:27.838 --> 01:18:30.030 still in the mail apparently.

NOTE Confidence: 0.815453432

01:18:30.030 --> 01:18:32.843 So this is a a a volunteer service but

NOTE Confidence: 0.815453432

01:18:32.843 --> 01:18:34.695 just as a disclosure because I didn't say

NOTE Confidence: 0.815453432

01:18:34.695 --> 01:18:36.223 that at the beginning and I should have,

NOTE Confidence: 0.815453432

01:18:36.230 --> 01:18:37.830 I apologize for that Sir.

NOTE Confidence: 0.815453432

01:18:37.830 --> 01:18:38.700 Please go ahead.

NOTE Confidence: 0.815453432

01:18:38.700 --> 01:18:39.570 Not a problem.

NOTE Confidence: 0.815453432

01:18:39.570 --> 01:18:41.928 Thank you for the interesting talk.

NOTE Confidence: 0.815453432

01:18:41.930 --> 01:18:44.597 I think the scorecard is super cool

NOTE Confidence: 0.815453432

01:18:44.597 --> 01:18:47.245 because it's sometimes tough to like

NOTE Confidence: 0.815453432

01:18:47.245 --> 01:18:49.161 translate research into actually

NOTE Confidence: 0.815453432

01:18:49.161 --> 01:18:51.171 changing how organizations and

NOTE Confidence: 0.815453432

01:18:51.171 --> 01:18:53.167 corporations are actually working.

NOTE Confidence: 0.815453432

01:18:53.170 --> 01:18:55.445 And I think it's cool that you've

NOTE Confidence: 0.815453432

01:18:55.445 --> 01:18:58.116 like gotten in and you can sort of add

NOTE Confidence: 0.815453432

01:18:58.116 --> 01:19:00.687 layers to the to what a good score is.

NOTE Confidence: 0.815453432

01:19:00.690 --> 01:19:02.650 But I guess the question is like,

NOTE Confidence: 0.815453432

01:19:02.650 --> 01:19:05.674 what does it take to reach

NOTE Confidence: 0.815453432

01:19:05.674 --> 01:19:07.690 consensus in the bioethics?

NOTE Confidence: 0.815453432

01:19:07.690 --> 01:19:08.503 Community or like,

NOTE Confidence: 0.815453432

01:19:08.503 --> 01:19:10.709 what does it take for you to say

NOTE Confidence: 0.815453432

01:19:10.709 --> 01:19:12.445 this is the next thing that needs

NOTE Confidence: 0.815453432

01:19:12.445 --> 01:19:14.330 to be added to the scorecard?

NOTE Confidence: 0.815453432

01:19:14.330 --> 01:19:15.975 Because it seems like there's a lot

NOTE Confidence: 0.815453432

01:19:15.975 --> 01:19:17.552 of frameworks for evaluating some of

NOTE Confidence: 0.815453432

01:19:17.552 --> 01:19:19.202 these things that aren't entirely like

NOTE Confidence: 0.815453432

01:19:19.202 --> 01:19:20.807 this is the right way versus this.

NOTE Confidence: 0.815453432

01:19:20.810 --> 01:19:22.553 So I'm just curious what you think

NOTE Confidence: 0.815453432

01:19:22.553 --> 01:19:24.234 are the next steps for you to

NOTE Confidence: 0.815453432

01:19:24.234 --> 01:19:25.324 be able to say like,

NOTE Confidence: 0.815453432

01:19:25.330 --> 01:19:28.326 and now here's the next big priority.

NOTE Confidence: 0.815453432

01:19:28.330 --> 01:19:28.810 Yeah,

NOTE Confidence: 0.9553487

01:19:28.810 --> 01:19:30.474 so priority setting, right?

NOTE Confidence: 0.9553487

01:19:30.474 --> 01:19:32.554 Because we'd like to address

NOTE Confidence: 0.9553487

01:19:32.554 --> 01:19:35.835 everything now, but we can't.

NOTE Confidence: 0.9553487

01:19:35.835 --> 01:19:38.320 So there are a couple of factors.

NOTE Confidence: 0.9553487

01:19:38.320 --> 01:19:39.700 So what are the factors that

NOTE Confidence: 0.9553487

01:19:39.700 --> 01:19:41.678 sort of drive decision making?

NOTE Confidence: 0.9553487

01:19:41.678 --> 01:19:43.196 One is practicality,

NOTE Confidence: 0.9553487

01:19:43.200 --> 01:19:45.240 it doesn't mean those are the right drivers.

NOTE Confidence: 0.9553487

01:19:45.240 --> 01:19:46.720 What what can we measure,

NOTE Confidence: 0.9553487

01:19:46.720 --> 01:19:49.910 where can we get data or where do

NOTE Confidence: 0.9553487

01:19:49.910 --> 01:19:52.033 we need to work in the interim to

NOTE Confidence: 0.9553487

01:19:52.033 --> 01:19:53.384 make sure that the data that we

NOTE Confidence: 0.9553487

01:19:53.384 --> 01:19:54.876 can get the data in the future.

NOTE Confidence: 0.9553487

01:19:54.880 --> 01:19:57.136 So for example if you look at the

NOTE Confidence: 0.9553487

01:19:57.136 --> 01:19:58.880 clinical trial diversity measures,

NOTE Confidence: 0.9553487

01:19:58.880 --> 01:20:01.180 they only looked at oncology.

NOTE Confidence: 0.9553487

01:20:01.180 --> 01:20:03.535 Because the CDC publishes publishes

NOTE Confidence: 0.9553487

01:20:03.535 --> 01:20:06.520 the CR database with the cancer

NOTE Confidence: 0.9553487

01:20:06.520 --> 01:20:08.613 incidence data by some demographics.

NOTE Confidence: 0.9553487

01:20:08.613 --> 01:20:09.937 But outside of oncology,

NOTE Confidence: 0.9553487

01:20:09.940 --> 01:20:12.726 it's really hard to get incidence

NOTE Confidence: 0.9553487

01:20:12.726 --> 01:20:15.456 data for conditions by demographics.

NOTE Confidence: 0.9553487

01:20:15.460 --> 01:20:17.749 And so you're right to point out

NOTE Confidence: 0.9553487

01:20:17.749 --> 01:20:20.369 how small steps we have to take and

NOTE Confidence: 0.9553487

01:20:20.369 --> 01:20:22.420 how do we prioritize those steps.

NOTE Confidence: 0.9553487

01:20:22.420 --> 01:20:25.816 So that's why we prioritize oncology

NOTE Confidence: 0.9553487

01:20:25.820 --> 01:20:28.774 part of it was a practical data.

NOTE Confidence: 0.9553487

01:20:28.780 --> 01:20:29.968 Access consideration.

NOTE Confidence: 0.9553487

01:20:29.968 --> 01:20:33.460 It happens to also be major

NOTE Confidence: 0.9553487

01:20:33.460 --> 01:20:36.580 disease burden for for the US.

NOTE Confidence: 0.9553487

01:20:36.580 --> 01:20:41.380 Other considerations are public health goals,

NOTE Confidence: 0.9553487

01:20:41.380 --> 01:20:42.256 ethical imperatives?

NOTE Confidence: 0.9553487

01:20:42.256 --> 01:20:44.884 What data do we already have

NOTE Confidence: 0.9553487

01:20:44.884 --> 01:20:47.458 that we can leverage quickly?

NOTE Confidence: 0.9553487

01:20:47.460 --> 01:20:48.980 What's ripe for change?

NOTE Confidence: 0.9553487

01:20:48.980 --> 01:20:49.740 What's salient?

NOTE Confidence: 0.9553487

01:20:49.740 --> 01:20:51.336 What are people paying attention to?

NOTE Confidence: 0.9553487

01:20:51.340 --> 01:20:54.960 But we have behind all this are is it

NOTE Confidence: 0.9553487

01:20:54.960 --> 01:20:58.940 with a 20 year old dissertation that maps.

NOTE Confidence: 0.9553487

01:20:58.940 --> 01:20:59.300 You know,

NOTE Confidence: 0.9553487

01:20:59.300 --> 01:21:00.380 except for maybe cutting edge things,

NOTE Confidence: 0.9553487

01:21:00.380 --> 01:21:02.000 but there hasn't really been much

NOTE Confidence: 0.9553487

01:21:02.000 --> 01:21:03.908 cutting edge problems that you know,

NOTE Confidence: 0.9553487

01:21:03.908 --> 01:21:06.448 300 pages of things that would be good

NOTE Confidence: 0.9553487

01:21:06.448 --> 01:21:09.740 to to address right to advance patient,

NOTE Confidence: 0.9553487

01:21:09.740 --> 01:21:12.940 public global health and justice

NOTE Confidence: 0.9553487

01:21:12.940 --> 01:21:15.016 for for people around the world.

NOTE Confidence: 0.9553487

01:21:15.020 --> 01:21:17.015 And we're just chipping away at it.

NOTE Confidence: 0.9553487

01:21:17.020 --> 01:21:20.100 So the ordering is,

NOTE Confidence: 0.9553487

01:21:20.100 --> 01:21:23.180 is mostly practical salience,

NOTE Confidence: 0.9553487

01:21:23.180 --> 01:21:27.000 health needs and justice considerations.

NOTE Confidence: 0.9553487

01:21:27.000 --> 01:21:28.280 And resources.

NOTE Confidence: 0.913994776666667

01:21:32.240 --> 01:21:35.079 So my memory also goes back a long way

NOTE Confidence: 0.913994776666667

01:21:35.080 --> 01:21:39.190 and I'm remembering when there were a lot

NOTE Confidence: 0.913994776666667

01:21:39.190 --> 01:21:41.200 of research was not necessarily coming

NOTE Confidence: 0.913994776666667

01:21:41.200 --> 01:21:44.252 out of funding either by pharma or by

NOTE Confidence: 0.913994776666667

01:21:44.252 --> 01:21:47.310 government that there was a sense that

NOTE Confidence: 0.913994776666667

01:21:47.310 --> 01:21:50.017 you needed homogeneity in your subjects

NOTE Confidence: 0.913994776666667

01:21:50.017 --> 01:21:52.999 because the more variation you had,

NOTE Confidence: 0.913994776666667

01:21:53.000 --> 01:21:54.160 the harder it was going to be to

NOTE Confidence: 0.913994776666667

01:21:54.160 --> 01:21:56.064 draw any conclusions. And of course.

NOTE Confidence: 0.913994776666667

01:21:56.064 --> 01:21:59.341 One easy way to get more homogeneous

NOTE Confidence: 0.913994776666667

01:21:59.341 --> 01:22:01.690 populations is some of the really

NOTE Confidence: 0.913994776666667

01:22:01.690 --> 01:22:03.690 egregious examples we have in bioethics

NOTE Confidence: 0.913994776666667

01:22:03.690 --> 01:22:05.980 from syphilis studies or mental health

NOTE Confidence: 0.913994776666667

01:22:05.980 --> 01:22:09.962 patients and so on in the conversation,

NOTE Confidence: 0.913994776666667

01:22:09.962 --> 01:22:12.570 of course, has shifted over those years to

NOTE Confidence: 0.913994776666667

01:22:12.570 --> 01:22:15.610 say some of this is just not allowable.

NOTE Confidence: 0.913994776666667

01:22:15.610 --> 01:22:17.992 But there's still a concern, I think,

NOTE Confidence: 0.913994776666667

01:22:17.992 --> 01:22:20.449 with the sense that you may be

NOTE Confidence: 0.913994776666667

01:22:20.449 --> 01:22:22.210 doing racial targeting.

NOTE Confidence: 0.913994776666667

01:22:22.210 --> 01:22:23.986 So I'm wondering about.

NOTE Confidence: 0.913994776666667

01:22:23.986 --> 01:22:27.221 How some of the ideas have changed

NOTE Confidence: 0.913994776666667

01:22:27.221 --> 01:22:30.042 and what may help some change more

NOTE Confidence: 0.913994776666667

01:22:30.042 --> 01:22:32.778 and what directions you would like

NOTE Confidence: 0.913994776666667

01:22:32.778 --> 01:22:36.005 to see things changing in that may

NOTE Confidence: 0.913994776666667

01:22:36.005 --> 01:22:39.182 get incorporated into some of the

NOTE Confidence: 0.913994776666667

01:22:39.182 --> 01:22:41.890 scorecarding or the advocacy work or ways

NOTE Confidence: 0.913994776666667

01:22:41.890 --> 01:22:45.538 in which we should be doing our studies.

NOTE Confidence: 0.913994776666667

01:22:45.538 --> 01:22:47.810 Yeah, I think the big changes

NOTE Confidence: 0.913994776666667

01:22:47.810 --> 01:22:49.490 on that social value principle,

NOTE Confidence: 0.913994776666667

01:22:49.490 --> 01:22:49.871 right,

NOTE Confidence: 0.913994776666667

01:22:49.871 --> 01:22:52.538 where we were very permissive in the

NOTE Confidence: 0.913994776666667

01:22:52.538 --> 01:22:54.199 interpretation where we didn't ask.

NOTE Confidence: 0.913994776666667

01:22:54.200 --> 01:22:56.804 That justice question of who should

NOTE Confidence: 0.913994776666667

01:22:56.804 --> 01:23:00.360 be benefiting right we we defined,

NOTE Confidence: 0.913994776666667

01:23:00.360 --> 01:23:01.895 we justified clinical research if

NOTE Confidence: 0.913994776666667

01:23:01.895 --> 01:23:03.918 it had a potential to generate

NOTE Confidence: 0.913994776666667

01:23:03.918 --> 01:23:05.618 generalizable knowledge that could

NOTE Confidence: 0.913994776666667

01:23:05.618 --> 01:23:07.743 help someone or some populations

NOTE Confidence: 0.913994776666667

01:23:07.801 --> 01:23:10.348 health and we didn't think about as

NOTE Confidence: 0.913994776666667

01:23:10.348 --> 01:23:13.204 much whose health and the fairness

NOTE Confidence: 0.913994776666667

01:23:13.204 --> 01:23:15.200 considerations in there And because of

NOTE Confidence: 0.9654121

01:23:17.400 --> 01:23:21.232 various recent tragedies we've

NOTE Confidence: 0.9654121

01:23:21.232 --> 01:23:24.920 been starting to rightfully.

NOTE Confidence: 0.9654121

01:23:24.920 --> 01:23:26.640 Ask those justice questions.

NOTE Confidence: 0.958703166666667

01:23:29.320 --> 01:23:32.885 And those justice questions are

NOTE Confidence: 0.958703166666667

01:23:32.885 --> 01:23:35.120 trumping the old ways of thinking,

NOTE Confidence: 0.958703166666667

01:23:35.120 --> 01:23:36.440 which, from what I heard,

NOTE Confidence: 0.958703166666667

01:23:36.440 --> 01:23:37.812 the way you contextualize it and correct

NOTE Confidence: 0.958703166666667

01:23:37.812 --> 01:23:39.760 me if I didn't interpret this correctly,

NOTE Confidence: 0.958703166666667

01:23:39.760 --> 01:23:43.680 was that science and this sort of

NOTE Confidence: 0.958703166666667

01:23:43.680 --> 01:23:46.192 pristine lab experiment was more

NOTE Confidence: 0.958703166666667

01:23:46.192 --> 01:23:48.632 important than these justice questions.

NOTE Confidence: 0.958703166666667

01:23:48.640 --> 01:23:51.232 And that balance of science and

NOTE Confidence: 0.958703166666667

01:23:51.232 --> 01:23:54.136 justice has has changed, is changing.

NOTE Confidence: 0.958703166666667

01:23:54.136 --> 01:23:57.076 At least it's changing now.

NOTE Confidence: 0.958703166666667

01:23:57.080 --> 01:23:59.768 And it turns out that that science

NOTE Confidence: 0.958703166666667

01:23:59.768 --> 01:24:02.289 question may no longer be valid

NOTE Confidence: 0.958703166666667

01:24:02.289 --> 01:24:04.439 because that that science didn't

NOTE Confidence: 0.958703166666667

01:24:04.439 --> 01:24:09.080 may not be generalizable to many,

NOTE Confidence: 0.958703166666667

01:24:09.080 --> 01:24:10.676 if any, you know many people.

NOTE Confidence: 0.958703166666667

01:24:10.680 --> 01:24:14.010 And so the even the scientific

NOTE Confidence: 0.958703166666667

01:24:14.010 --> 01:24:17.415 validity of that, that, that.

NOTE Confidence: 0.958703166666667

01:24:17.415 --> 01:24:20.356 Overly controlled setting is coming

NOTE Confidence: 0.958703166666667

01:24:20.356 --> 01:24:22.940 into play right And the pushes for real

NOTE Confidence: 0.958703166666667

01:24:23.012 --> 01:24:25.964 world data and and other ways of of

NOTE Confidence: 0.958703166666667

01:24:25.964 --> 01:24:29.110 developing knowledge are really strong.

NOTE Confidence: 0.958703166666667

01:24:29.110 --> 01:24:30.220 We're really far away from

NOTE Confidence: 0.958703166666667

01:24:30.220 --> 01:24:31.108 using real world data.

NOTE Confidence: 0.958703166666667

01:24:31.110 --> 01:24:33.070 It's been fun to sort of model what

NOTE Confidence: 0.958703166666667

01:24:33.070 --> 01:24:34.867 you can and cannot do with it.

NOTE Confidence: 0.958703166666667

01:24:34.870 --> 01:24:37.530 But I think yeah this sort of

NOTE Confidence: 0.958703166666667

01:24:37.530 --> 01:24:40.038 reordering and revaluing of of goals

NOTE Confidence: 0.958703166666667

01:24:40.038 --> 01:24:42.446 is is rightfully taking place more

NOTE Confidence: 0.958703166666667

01:24:42.446 --> 01:24:45.110 widely than it has in the past.

NOTE Confidence: 0.9603804

01:24:49.040 --> 01:24:50.680 The researchers in

NOTE Confidence: 0.9603804

01:24:52.760 --> 01:24:54.340 the population at large.

NOTE Confidence: 0.9603804

01:24:54.340 --> 01:24:56.800 I'm curious about where you're seeing

NOTE Confidence: 0.9603804

01:24:56.800 --> 01:25:00.514 that change happening and ways in which

NOTE Confidence: 0.9603804

01:25:00.514 --> 01:25:03.910 that can be addressed to help achieve the

NOTE Confidence: 0.9603804

01:25:03.910 --> 01:25:05.629 goals that that you're advocating for.

NOTE Confidence: 0.9603804

01:25:05.629 --> 01:25:07.207 Well, where is it taking place

NOTE Confidence: 0.9603804

01:25:07.207 --> 01:25:08.559 as an empirical question?

NOTE Confidence: 0.9603804

01:25:08.560 --> 01:25:11.256 And I don't have, I like to answer

NOTE Confidence: 0.9603804

01:25:11.256 --> 01:25:13.240 empirical questions with empirical data,

NOTE Confidence: 0.9603804

01:25:13.240 --> 01:25:15.720 which I don't have it at my fingertips.

NOTE Confidence: 0.9603804

01:25:15.720 --> 01:25:18.120 But certainly I can just comment right on,

NOTE Confidence: 0.9603804

01:25:18.120 --> 01:25:18.600 on anecdotally,

NOTE Confidence: 0.9603804

01:25:18.600 --> 01:25:20.682 you see it on the policy level, right.

NOTE Confidence: 0.9603804

01:25:20.682 --> 01:25:23.898 You've seen it over 40 years as sort

NOTE Confidence: 0.9603804

01:25:23.898 --> 01:25:27.852 of growing wealth of policy efforts

NOTE Confidence: 0.9603804

01:25:27.852 --> 01:25:32.160 to target injustices in these areas.

NOTE Confidence: 0.9603804

01:25:32.160 --> 01:25:34.337 You see it in the literature that's

NOTE Confidence: 0.9603804

01:25:34.337 --> 01:25:36.253 getting published more and more studies

NOTE Confidence: 0.9603804

01:25:36.253 --> 01:25:37.993 and focusing on the problems, right.

NOTE Confidence: 0.9603804

01:25:37.993 --> 01:25:39.537 A lot of the studies focus on the

NOTE Confidence: 0.9603804

01:25:39.537 --> 01:25:40.834 problems and now ethicists are at least

NOTE Confidence: 0.9603804

01:25:40.834 --> 01:25:42.326 some of us are starting to look at

NOTE Confidence: 0.9603804

01:25:42.326 --> 01:25:43.736 what does we know there's a problem,

NOTE Confidence: 0.9603804

01:25:43.736 --> 01:25:45.216 what does good look like?

NOTE Confidence: 0.9603804

01:25:45.220 --> 01:25:45.511 Right.

NOTE Confidence: 0.9603804

01:25:45.511 --> 01:25:47.548 And how do we track and measure

NOTE Confidence: 0.9603804

01:25:47.548 --> 01:25:48.540 progress on goals?

NOTE Confidence: 0.9603804

01:25:48.540 --> 01:25:50.460 So I think it's happening on many levels.

NOTE Confidence: 0.9603804

01:25:50.460 --> 01:25:51.975 I think the more interesting

NOTE Confidence: 0.9603804

01:25:51.975 --> 01:25:54.120 question might be where is it not

NOTE Confidence: 0.9603804

01:25:54.120 --> 01:25:55.818 happening that it needs to happen.

NOTE Confidence: 0.9603804

01:25:55.820 --> 01:25:58.800 So I'd have to think about

NOTE Confidence: 0.9603804

01:25:58.800 --> 01:25:59.660 that and get back to you.

NOTE Confidence: 0.938995675

01:26:01.420 --> 01:26:04.500 Thank you. I think that that's our time.

NOTE Confidence: 0.938995675

01:26:04.500 --> 01:26:06.100 This was a fascinating evening.

NOTE Confidence: 0.938995675

01:26:06.100 --> 01:26:07.815 Thank you so much, Doctor Jennifer Miller.