WEBVTT

NOTE duration:"00:20:06"

NOTE recognizability:0.795

NOTE language:en-us

NOTE Confidence: 0.63523139375

00:00:00.000 --> 00:00:02.436 Neurology and euro science at Wild

NOTE Confidence: 0.63523139375

00:00:02.436 --> 00:00:04.318 Cornell medicine, and he'll be

NOTE Confidence: 0.63523139375

00:00:04.318 --> 00:00:06.454 speaking about the Arcadia Dr Houma.

NOTE Confidence: 0.718279295

00:00:07.060 --> 00:00:08.596 Hi I started to see you.

NOTE Confidence: 0.718279295

00:00:08.600 --> 00:00:10.840 Hi thanks for having me

NOTE Confidence: 0.718279295

00:00:10.840 --> 00:00:13.080 excited to part of this.

NOTE Confidence: 0.718279295

00:00:13.080 --> 00:00:15.252 I was gonna talk a little

NOTE Confidence: 0.718279295

00:00:15.252 --> 00:00:17.504 bit about the Arcadia trial.

NOTE Confidence: 0.718279295

00:00:17.504 --> 00:00:20.473 Let me just see you know as

NOTE Confidence: 0.718279295

00:00:20.473 --> 00:00:22.028 everyone seeing my PowerPoint here.

NOTE Confidence: 0.8074075575

00:00:25.520 --> 00:00:26.408 Yes, we can see

NOTE Confidence: 0.6973942

00:00:26.600 --> 00:00:27.480 all right, probably so yeah.

NOTE Confidence: 0.6973942

00:00:27.480 --> 00:00:30.609 So I'm I'm representing the the Arcadia

NOTE Confidence: 0.6973942

1

00:00:30.610 --> 00:00:33.976 piece here and we thought we would talk a

NOTE Confidence: 0.6973942

00:00:33.976 --> 00:00:37.154 little bit today about a couple of things.

NOTE Confidence: 0.6973942

00:00:37.160 --> 00:00:40.224 One is sort of how we got from

NOTE Confidence: 0.6973942

00:00:40.224 --> 00:00:43.120 idea to trial and then some.

NOTE Confidence: 0.6973942

00:00:43.120 --> 00:00:44.610 Some lessons we've learned in

NOTE Confidence: 0.6973942

00:00:44.610 --> 00:00:46.106 conducting the trial, but obviously

NOTE Confidence: 0.6973942

00:00:46.106 --> 00:00:47.894 you know if there's any questions,

NOTE Confidence: 0.6973942

00:00:47.900 --> 00:00:49.335 please feel free to interrupt and I'm,

NOTE Confidence: 0.6973942

00:00:49.340 --> 00:00:49.888 you know we can.

NOTE Confidence: 0.6973942

00:00:49.888 --> 00:00:51.429 We can chat about a lot of different things,

NOTE Confidence: 0.6973942

00:00:51.430 --> 00:00:52.516 but based on.

NOTE Confidence: 0.6973942

00:00:52.516 --> 00:00:55.880 Based on sort of the invitation of the topic,

NOTE Confidence: 0.6973942

00:00:55.880 --> 00:00:58.898 we thought these would be helpful.

NOTE Confidence: 0.6973942

00:00:58.900 --> 00:01:01.476 So the first thing I think to to,

NOTE Confidence: 0.6973942

00:01:01.480 --> 00:01:03.321 uh, you know to maybe talk about

NOTE Confidence: 0.6973942

00:01:03.321 --> 00:01:05.530 is how if you have a trial idea

00:01:05.530 --> 00:01:07.760 and you and you wanna get you know,

00:01:07.760 --> 00:01:08.558 support and funding.

00:01:08.558 --> 00:01:10.154 And it's not just funding right?

00:01:10.160 --> 00:01:11.217 You need to get the buy in.

00:01:11.220 --> 00:01:14.265 You need people to want to participate

00:01:14.265 --> 00:01:16.476 in your trial and helping you

00:01:16.476 --> 00:01:18.590 know sort of help make it happen.

00:01:18.590 --> 00:01:20.290 How you know how?

00:01:20.290 --> 00:01:23.800 How do you build enthusiasm for your idea?

00:01:23.800 --> 00:01:25.216 You know Kevin just talked about some of

00:01:25.216 --> 00:01:26.660 the ways we approached it and inspire.

00:01:26.660 --> 00:01:28.613 There's a lot of different ways to do it,

00:01:28.620 --> 00:01:29.152 I think.

00:01:29.152 --> 00:01:31.123 You know you can talk about a

00:01:31.123 --> 00:01:32.242 compelling clinical question.

00:01:32.242 --> 00:01:34.107 There's two strategies we don't

NOTE Confidence: 0.6973942

00:01:34.107 --> 00:01:35.994 know which ones better you can

NOTE Confidence: 0.6973942

00:01:35.994 --> 00:01:37.449 talk about a patient group.

NOTE Confidence: 0.6973942

00:01:37.450 --> 00:01:39.610 That's a very high need and and that

NOTE Confidence: 0.6973942

00:01:39.610 --> 00:01:42.073 you know you want to try different

NOTE Confidence: 0.6973942

00:01:42.073 --> 00:01:43.933 things because the current therapies

NOTE Confidence: 0.6973942

00:01:43.998 --> 00:01:45.918 just aren't working well enough.

NOTE Confidence: 0.6973942

00:01:45.920 --> 00:01:47.866 There's lots of ways to do it.

NOTE Confidence: 0.6973942

00:01:47.870 --> 00:01:49.472 One thing that I think that

NOTE Confidence: 0.6973942

00:01:49.472 --> 00:01:51.309 we used in our in Arcadia,

NOTE Confidence: 0.6973942

00:01:51.310 --> 00:01:53.368 and that sort of just happened

NOTE Confidence: 0.6973942

00:01:53.368 --> 00:01:55.097 organically is that we were

NOTE Confidence: 0.6973942

00:01:55.097 --> 00:01:56.819 able to sort of hang hang.

NOTE Confidence: 0.6973942

00:01:56.820 --> 00:01:59.068 Our idea on this like pretty easy like.

NOTE Confidence: 0.6973942

00:01:59.070 --> 00:02:01.122 30 second pitch that I think

NOTE Confidence: 0.6973942

00:02:01.122 --> 00:02:02.490 got people people excited.

NOTE Confidence: 0.6973942

00:02:02.490 --> 00:02:05.802 There was like a a concept about it

NOTE Confidence: 0.6973942

00:02:05.802 --> 00:02:09.976 and you know we we started first by by

NOTE Confidence: 0.6973942

00:02:09.976 --> 00:02:13.198 pointing out some of the gaps in our

NOTE Confidence: 0.6973942

00:02:13.200 --> 00:02:15.936 in the prevailing theory of a fib and stroke,

NOTE Confidence: 0.6973942

00:02:15.940 --> 00:02:18.236 and we pointed out that there's a lot

NOTE Confidence: 0.6973942

00:02:18.236 --> 00:02:20.202 of literature coming out that didn't

NOTE Confidence: 0.6973942

00:02:20.202 --> 00:02:22.750 really make sense under the old model.

NOTE Confidence: 0.6973942

00:02:22.750 --> 00:02:23.282 You know,

NOTE Confidence: 0.6973942

00:02:23.282 --> 00:02:25.410 if you if you accepted this idea that

NOTE Confidence: 0.6973942

00:02:25.468 --> 00:02:27.448 you needed the atrial fibrillation,

NOTE Confidence: 0.6973942

00:02:27.450 --> 00:02:29.410 that it wasn't necessary, or.

NOTE Confidence: 0.6973942

00:02:29.410 --> 00:02:30.964 For thromboembolism for

NOTE Confidence: 0.6973942

00:02:30.964 --> 00:02:33.036 cardiac embolism to occur,

NOTE Confidence: 0.6973942

00:02:33.040 --> 00:02:33.922 there were a lot of things

NOTE Confidence: 0.6973942

00:02:33.922 --> 00:02:34.510 that didn't make sense.

NOTE Confidence: 0.6973942

00:02:34.510 --> 00:02:35.182 You know why?

NOTE Confidence: 0.6973942

00:02:35.182 --> 00:02:37.070 Would only 6 minutes of a fit today

NOTE Confidence: 0.6973942

00:02:37.070 --> 00:02:38.939 called a stroke a few months later?

NOTE Confidence: 0.6973942

00:02:38.940 --> 00:02:41.500 Or why would in some cases they fit,

NOTE Confidence: 0.6973942

00:02:41.500 --> 00:02:43.684 appears for the first time after the stroke,

NOTE Confidence: 0.6973942

00:02:43.690 --> 00:02:44.790 even though there was no?

NOTE Confidence: 0.6973942

00:02:44.790 --> 00:02:45.236 You know,

NOTE Confidence: 0.6973942

00:02:45.236 --> 00:02:46.574 even though patients would be monitored

NOTE Confidence: 0.6973942

00:02:46.574 --> 00:02:48.077 for a pair before their stroke,

NOTE Confidence: 0.6973942

00:02:48.080 --> 00:02:50.215 there were some some science

NOTE Confidence: 0.6973942

00:02:50.215 --> 00:02:52.350 coming out about that why,

NOTE Confidence: 0.6973942

00:02:52.350 --> 00:02:52.750 you know?

NOTE Confidence: 0.6973942

00:02:52.750 --> 00:02:54.661 We keep looking for a FIB and and don't

NOTE Confidence: 0.6973942

00:02:54.661 --> 00:02:56.215 always find it in these patients,

NOTE Confidence: 0.6973942

00:02:56.220 --> 00:02:58.152 so we we were kind of pointing

NOTE Confidence: 0.6973942

00:02:58.152 --> 00:03:00.499 out some of these inconsistencies.

NOTE Confidence: 0.6973942

00:03:00.500 --> 00:03:02.552 And and then we also brought

NOTE Confidence: 0.6973942

00:03:02.552 --> 00:03:03.920 together a bunch of

NOTE Confidence: 0.904827201578947

00:03:04.000 --> 00:03:06.328 different studies that some of which

NOTE Confidence: 0.904827201578947

00:03:06.328 --> 00:03:09.305 we had done, some of which had other

NOTE Confidence: 0.904827201578947

00:03:09.305 --> 00:03:11.430 people had done including decades ago,

NOTE Confidence: 0.904827201578947

00:03:11.430 --> 00:03:13.425 and and sort of pointed out that

NOTE Confidence: 0.904827201578947

00:03:13.425 --> 00:03:14.780 all these different studies,

NOTE Confidence: 0.904827201578947

00:03:14.780 --> 00:03:16.848 even though they weren't

NOTE Confidence: 0.904827201578947

00:03:16.848 --> 00:03:18.916 explicitly about this topic.

NOTE Confidence: 0.904827201578947

00:03:18.920 --> 00:03:20.820 Were were, you know,

NOTE Confidence: 0.904827201578947

00:03:20.820 --> 00:03:22.834 should only relationship between

NOTE Confidence: 0.904827201578947

00:03:22.834 --> 00:03:25.494 markers of underlying abnormal atrial

NOTE Confidence: 0.904827201578947

00:03:25.494 --> 00:03:27.932 substrate or atrial cardiopathy and

NOTE Confidence: 0.904827201578947

00:03:27.932 --> 00:03:30.988 stroke independent of a state or even in

NOTE Confidence: 0.904827201578947

00:03:31.062 --> 00:03:33.418 patients without faith it and and that

NOTE Confidence: 0.904827201578947

7

00:03:33.418 --> 00:03:35.450 if you if you sort of thought about it,

NOTE Confidence: 0.904827201578947

00:03:35.450 --> 00:03:38.341 all of this was consistent with this

NOTE Confidence: 0.904827201578947

00:03:38.341 --> 00:03:41.279 concept that maybe you know instead of

NOTE Confidence: 0.904827201578947

00:03:41.279 --> 00:03:44.468 needing to go through this pathway of a fib,

NOTE Confidence: 0.904827201578947

00:03:44.470 --> 00:03:46.825 you can actually have cardiac

NOTE Confidence: 0.904827201578947

00:03:46.825 --> 00:03:48.709 embolus and left atrial.

NOTE Confidence: 0.904827201578947

00:03:48.710 --> 00:03:52.274 Probable embolism sometimes occurring

NOTE Confidence: 0.904827201578947

00:03:52.274 --> 00:03:55.034 even without a triple relation

NOTE Confidence: 0.904827201578947

00:03:55.034 --> 00:03:57.774 before and I think this kind of

NOTE Confidence: 0.904827201578947

00:03:57.774 --> 00:03:59.230 conceptual shift we're saying,

NOTE Confidence: 0.904827201578947

00:03:59.230 --> 00:04:00.310 hey, we have this idea.

NOTE Confidence: 0.904827201578947

00:04:00.310 --> 00:04:01.510 Look at all this information.

NOTE Confidence: 0.904827201578947

00:04:01.510 --> 00:04:02.800 Doesn't this make more sense?

NOTE Confidence: 0.904827201578947

00:04:02.800 --> 00:04:04.540 What do you all think?

NOTE Confidence: 0.904827201578947

00:04:04.540 --> 00:04:07.244 And and then you know if that's true,

NOTE Confidence: 0.904827201578947

00:04:07.250 --> 00:04:08.522 you know then this,

NOTE Confidence: 0.904827201578947

00:04:08.522 --> 00:04:10.430 then this trial would make sense.

NOTE Confidence: 0.904827201578947

00:04:10.430 --> 00:04:12.644 Would be a good way of testing that idea,

NOTE Confidence: 0.904827201578947

00:04:12.650 --> 00:04:13.512 and specifically,

NOTE Confidence: 0.904827201578947

00:04:13.512 --> 00:04:15.667 you know we know anticoagulation

NOTE Confidence: 0.904827201578947

00:04:15.667 --> 00:04:17.999 works for preventing stroke in a FIB,

NOTE Confidence: 0.904827201578947

00:04:18.000 --> 00:04:19.068 but you know,

NOTE Confidence: 0.904827201578947

00:04:19.068 --> 00:04:20.492 wouldn't it also intuitively

NOTE Confidence: 0.904827201578947

00:04:20.492 --> 00:04:22.290 work if you have this?

NOTE Confidence: 0.904827201578947

00:04:22.290 --> 00:04:24.160 This other pathway coming from

NOTE Confidence: 0.904827201578947

00:04:24.160 --> 00:04:26.030 the same left atrial substrate,

NOTE Confidence: 0.904827201578947

00:04:26.030 --> 00:04:27.920 and I think that that really helped

NOTE Confidence: 0.904827201578947

00:04:27.920 --> 00:04:30.139 us get a lot of enthusiasm both

NOTE Confidence: 0.904827201578947

00:04:30.139 --> 00:04:32.161 in the you know concept synopsis

NOTE Confidence: 0.904827201578947

00:04:32.228 --> 00:04:34.130 stage at the peer review stage,

NOTE Confidence: 0.904827201578947

00:04:34.130 --> 00:04:36.360 and then I think crucially,

NOTE Confidence: 0.904827201578947

00:04:36.360 --> 00:04:37.990 even afterwards when you were,

NOTE Confidence: 0.904827201578947

00:04:37.990 --> 00:04:38.718 you know,

NOTE Confidence: 0.904827201578947

00:04:38.718 --> 00:04:41.266 trying to get sites on board and

NOTE Confidence: 0.904827201578947

00:04:41.266 --> 00:04:44.141 get sites to be committed to helping

NOTE Confidence: 0.904827201578947

00:04:44.141 --> 00:04:47.109 to recruit and and enroll patients.

NOTE Confidence: 0.904827201578947

00:04:47.110 --> 00:04:48.694 So I think that's something to

NOTE Confidence: 0.904827201578947

00:04:48.694 --> 00:04:50.202 think about is, you know,

NOTE Confidence: 0.904827201578947

00:04:50.202 --> 00:04:52.338 how do you take your idea?

NOTE Confidence: 0.904827201578947

00:04:52.340 --> 00:04:54.800 And and put it in a way that you can

NOTE Confidence: 0.904827201578947

00:04:54.875 --> 00:04:57.011 like explain very quickly and and

NOTE Confidence: 0.904827201578947

00:04:57.011 --> 00:04:59.778 people can kind of synthesize a lot

NOTE Confidence: 0.904827201578947

00:04:59.778 --> 00:05:05.350 of information under a pretty simple catch.

NOTE Confidence: 0.904827201578947

00:05:05.350 --> 00:05:06.162 All kind of concept.

NOTE Confidence: 0.904827201578947

00:05:06.162 --> 00:05:08.050 So I don't know if I'm making sense,

NOTE Confidence: 0.904827201578947

00:05:08.050 --> 00:05:09.128 but I think that I'd be happy

NOTE Confidence: 0.904827201578947

00:05:09.128 --> 00:05:10.438 to sort of chat more about this,

00:05:10.440 --> 00:05:11.694 but I think that was really

00:05:11.694 --> 00:05:13.415 helpful to us as we were going

00:05:13.415 --> 00:05:14.810 through this whole whole process.

00:05:14.810 --> 00:05:16.770 It also helps you kind of center

00:05:16.770 --> 00:05:18.832 what you're trying to do with your

00:05:18.832 --> 00:05:20.578 trial terms of design and responding.

00:05:20.580 --> 00:05:23.880 Some of the critiques, etc.

00:05:23.880 --> 00:05:25.064 And then you know,

00:05:25.064 --> 00:05:27.228 obviously we we had some pilot data

00:05:27.228 --> 00:05:29.468 that will long strip and Mitch Elkind

00:05:29.468 --> 00:05:31.508 and others had had a David Torch.

00:05:31.510 --> 00:05:33.470 While we're on this paper

00:05:33.470 --> 00:05:35.948 suggesting that you know this idea

00:05:35.948 --> 00:05:37.600 that anticoagulation would help.

00:05:37.600 --> 00:05:39.460 Wasn't just, you know, conceptual.

00:05:39.460 --> 00:05:41.482 We actually had some compelling data

NOTE Confidence: 0.904827201578947

00:05:41.482 --> 00:05:43.780 from the worst trial to support dot,

NOTE Confidence: 0.904827201578947

00:05:43.780 --> 00:05:45.980 so that was very helpful.

NOTE Confidence: 0.904827201578947

00:05:45.980 --> 00:05:47.611 So turning to like the other key

NOTE Confidence: 0.904827201578947

00:05:47.611 --> 00:05:49.252 thing that I think really helped

NOTE Confidence: 0.904827201578947

00:05:49.252 --> 00:05:51.016 us get through the the concept,

NOTE Confidence: 0.904827201578947

00:05:51.020 --> 00:05:51.550 you know,

NOTE Confidence: 0.904827201578947

00:05:51.550 --> 00:05:53.405 sort of a trial proposal stage and

NOTE Confidence: 0.904827201578947

00:05:53.405 --> 00:05:55.276 actually also with conducting the trial,

NOTE Confidence: 0.904827201578947

00:05:55.280 --> 00:05:57.578 is this idea of team leadership

NOTE Confidence: 0.904827201578947

00:05:57.578 --> 00:05:58.727 or team science.

NOTE Confidence: 0.904827201578947

00:05:58.730 --> 00:05:59.330 You know, I,

NOTE Confidence: 0.904827201578947

00:05:59.330 --> 00:06:00.330 I think it's been crucial.

NOTE Confidence: 0.762479268333333

00:06:00.330 --> 00:06:02.410 We both for aspire, you know, Kevin oh,

NOTE Confidence: 0.762479268333333

00:06:02.410 --> 00:06:05.350 Kevin and I working together for Arcadia

NOTE Confidence: 0.762479268333333

00:06:05.350 --> 00:06:08.902 with Mitch Elkind and David terse, well and.

00:06:08.902 --> 00:06:11.788 Will Longstreth for for whom there's,

00:06:11.790 --> 00:06:14.292 you know, will likes to kind of hide in

00:06:14.292 --> 00:06:16.530 the Internet shadow, so I don't I don't.

00:06:16.530 --> 00:06:18.020 I've actually only seen one

00:06:18.020 --> 00:06:19.612 photo of him, but anyway,

00:06:19.612 --> 00:06:22.034 this is will he likes his privacy.

00:06:22.040 --> 00:06:23.744 So you know, we've been a great team.

00:06:23.750 --> 00:06:26.162 We put together this very complicated

00:06:26.162 --> 00:06:28.617 looking algorithm for our grant proposal

00:06:28.617 --> 00:06:31.347 that in practice has worked really well.

00:06:31.350 --> 00:06:32.670 There's a lot of input,

00:06:32.670 --> 00:06:34.670 a lot of different perspectives.

00:06:34.670 --> 00:06:36.425 We have these weekly trial

00:06:36.425 --> 00:06:37.478 Operation committee meetings.

00:06:37.480 --> 00:06:39.624 There's a lot of discussion, but I think.

00:06:39.624 --> 00:06:41.990 Ultimately, it helps to filter things and

NOTE Confidence: 0.762479268333333

00:06:41.990 --> 00:06:43.670 it's it's been it's been very effective.

NOTE Confidence: 0.762479268333333

00:06:43.670 --> 00:06:45.102 So even though we got a little bit

NOTE Confidence: 0.762479268333333

00:06:45.102 --> 00:06:46.240 of pushback from from a stroke,

NOTE Confidence: 0.762479268333333

00:06:46.240 --> 00:06:46.800 net reviewers.

NOTE Confidence: 0.762479268333333

00:06:46.800 --> 00:06:48.480 But when we submitted our grant

NOTE Confidence: 0.762479268333333

00:06:48.480 --> 00:06:50.048 about the complexity of this,

NOTE Confidence: 0.762479268333333

00:06:50.050 --> 00:06:52.052 I think it's worked well given the

NOTE Confidence: 0.762479268333333

00:06:52.052 --> 00:06:54.260 the team and and the relationship.

NOTE Confidence: 0.762479268333333

00:06:54.260 --> 00:06:57.995 So I definitely advise doing this as a team.

NOTE Confidence: 0.762479268333333

00:06:58.000 --> 00:07:00.736 It really helps with a lot of the sort

NOTE Confidence: 0.762479268333333

00:07:00.736 --> 00:07:03.141 of stressful points and the workload

NOTE Confidence: 0.762479268333333

00:07:03.141 --> 00:07:05.420 and plus it's just great to work with.

NOTE Confidence: 0.762479268333333

00:07:05.420 --> 00:07:07.856 You know people that you you respect.

NOTE Confidence: 0.762479268333333

00:07:07.860 --> 00:07:09.860 Uhm, and then you know,

NOTE Confidence: 0.762479268333333

00:07:09.860 --> 00:07:11.966 obviously even the sort of national

NOTE Confidence: 0.762479268333333

00:07:11.966 --> 00:07:14.597 P eyes that are proposing the idea

NOTE Confidence: 0.762479268333333

00:07:14.597 --> 00:07:17.292 you get embedded in this larger team.

NOTE Confidence: 0.762479268333333

00:07:17.300 --> 00:07:19.477 That's been just great to work with.

NOTE Confidence: 0.762479268333333

00:07:19.480 --> 00:07:21.658 You know the NDMC, the NCC,

NOTE Confidence: 0.762479268333333

00:07:21.660 --> 00:07:23.480 we have the Arcadia CSI,

NOTE Confidence: 0.762479268333333

00:07:23.480 --> 00:07:25.710 ancillary studies with this great

NOTE Confidence: 0.762479268333333

00:07:25.710 --> 00:07:26.714 team joining us.

NOTE Confidence: 0.762479268333333

00:07:26.714 --> 00:07:28.930 We have all sorts of cores or measuring

NOTE Confidence: 0.762479268333333

00:07:28.986 --> 00:07:30.780 our biomarkers and then and then.

NOTE Confidence: 0.762479268333333

00:07:30.780 --> 00:07:33.822 Most recently we added a Canadian

NOTE Confidence: 0.762479268333333

00:07:33.822 --> 00:07:35.694 coordinating center with some

NOTE Confidence: 0.762479268333333

00:07:35.694 --> 00:07:38.102 some old sort of colleague, Jeff.

NOTE Confidence: 0.762479268333333

00:07:38.102 --> 00:07:40.278 Julie and David Glass on a Mike Sharma.

NOTE Confidence: 0.762479268333333

00:07:40.280 --> 00:07:42.320 So that's been really great too so I

NOTE Confidence: 0.762479268333333

00:07:42.320 --> 00:07:44.218 think the team part is really key.

NOTE Confidence: 0.762479268333333

00:07:44.220 --> 00:07:45.200 It makes it more fun.

NOTE Confidence: 0.762479268333333

00:07:45.200 --> 00:07:47.559 It makes it more robust even though

NOTE Confidence: 0.762479268333333

00:07:47.559 --> 00:07:49.773 there are more kind of coordination

NOTE Confidence: 0.762479268333333

00:07:49.773 --> 00:07:51.277 costs so to speak.

NOTE Confidence: 0.762479268333333

00:07:51.280 --> 00:07:54.234 I think it's I think it's worth.

NOTE Confidence: 0.762479268333333

00:07:54.240 --> 00:07:54.960 And then persistence.

NOTE Confidence: 0.762479268333333

00:07:54.960 --> 00:07:56.889 I mean, if you if you're trying to fund,

NOTE Confidence: 0.762479268333333

00:07:56.890 --> 00:08:00.090 you know, get a trial through this required.

NOTE Confidence: 0.762479268333333

00:08:00.090 --> 00:08:01.836 Everyone told me that and and

NOTE Confidence: 0.762479268333333

00:08:01.836 --> 00:08:03.669 I'm sort of really living it.

NOTE Confidence: 0.762479268333333

00:08:03.670 --> 00:08:04.206 You know,

NOTE Confidence: 0.762479268333333

00:08:04.206 --> 00:08:06.082 I remember I got married in November

NOTE Confidence: 0.762479268333333

00:08:06.082 --> 00:08:07.960 2014 and like I think right this

NOTE Confidence: 0.762479268333333

00:08:07.960 --> 00:08:09.470 the weekend before my wedding.

NOTE Confidence: 0.762479268333333

00:08:09.470 --> 00:08:12.494 I before I sort of traveled down to Austin.

NOTE Confidence: 0.762479268333333

00:08:12.500 --> 00:08:14.644 I sent off the first email to Claudia

NOTE Confidence: 0.762479268333333

00:08:14.644 --> 00:08:16.728 and Scott with the concept synopsis.

NOTE Confidence: 0.762479268333333

00:08:16.730 --> 00:08:18.146 That was November 2014.

NOTE Confidence: 0.762479268333333

00:08:18.146 --> 00:08:20.904 We submitted the first grant and you know

NOTE Confidence: 0.762479268333333

00:08:20.904 --> 00:08:23.500 a little less than a year later than the.

NOTE Confidence: 0.762479268333333

00:08:23.500 --> 00:08:26.937 The RE submission the notice of award.

NOTE Confidence: 0.762479268333333

00:08:26.940 --> 00:08:28.865 We got our first site in February

NOTE Confidence: 0.762479268333333

00:08:28.865 --> 00:08:31.094 2018 and then it took some time to get

NOTE Confidence: 0.762479268333333

00:08:31.094 --> 00:08:33.028 up to the you know full complement

NOTE Confidence: 0.762479268333333

00:08:33.028 --> 00:08:35.324 of sites were now a 2/3 recruitment

NOTE Confidence: 0.762479268333333

00:08:35.330 --> 00:08:36.905 were hoping to finish recruitment

NOTE Confidence: 0.762479268333333

00:08:36.905 --> 00:08:39.518 by the end of 2022 and have the

NOTE Confidence: 0.762479268333333

00:08:39.518 --> 00:08:41.903 sort of trial end in June 2024.

NOTE Confidence: 0.762479268333333

00:08:41.903 --> 00:08:43.718 So literally a decade long

NOTE Confidence: 0.762479268333333

00:08:43.718 --> 00:08:45.170 long journey so I

NOTE Confidence: 0.845712299411765

00:08:45.250 --> 00:08:47.981 think that's just to be to be expected.

NOTE Confidence: 0.845712299411765

00:08:47.981 --> 00:08:51.086 It's quite a long road.

NOTE Confidence: 0.845712299411765

00:08:51.090 --> 00:08:53.134 I other tips, I think just having

NOTE Confidence: 0.845712299411765

00:08:53.134 --> 00:08:55.140 some sense of grounding about you

NOTE Confidence: 0.845712299411765

00:08:55.140 --> 00:08:57.618 know what you're trying to do because

NOTE Confidence: 0.845712299411765

00:08:57.689 --> 00:08:59.824 the the number of critiques you will

NOTE Confidence: 0.845712299411765

00:08:59.824 --> 00:09:03.310 get a number of ideas will be large.

NOTE Confidence: 0.845712299411765

00:09:03.310 --> 00:09:04.829 You know our our initial grant submission.

NOTE Confidence: 0.845712299411765

00:09:04.830 --> 00:09:05.710 There were eight reviewers.

NOTE Confidence: 0.845712299411765

00:09:05.710 --> 00:09:06.810 They all had great ideas,

NOTE Confidence: 0.845712299411765

00:09:06.810 --> 00:09:08.476 but some of their ideas were literally

NOTE Confidence: 0.845712299411765

00:09:08.476 --> 00:09:09.470 contradictory to each other.

NOTE Confidence: 0.845712299411765

00:09:09.470 --> 00:09:10.690 How do you navigate that?

NOTE Confidence: 0.845712299411765

00:09:10.690 --> 00:09:12.874 If you have to have some sense

NOTE Confidence: 0.845712299411765

00:09:12.874 --> 00:09:14.824 of grounding and and realize that

NOTE Confidence: 0.845712299411765

00:09:14.824 --> 00:09:16.810 you're not going to make everyone,

NOTE Confidence: 0.845712299411765

00:09:16.810 --> 00:09:18.049 it's not that you're going to make

NOTE Confidence: 0.845712299411765

00:09:18.049 --> 00:09:19.331 everyone happy, so you can't.

NOTE Confidence: 0.845712299411765

00:09:19.331 --> 00:09:21.173 You can't accommodate all the ideas.

NOTE Confidence: 0.845712299411765

00:09:21.180 --> 00:09:23.196 Some of them are just going to

NOTE Confidence: 0.845712299411765

00:09:23.196 --> 00:09:24.060 be mutually incompatible,

NOTE Confidence: 0.845712299411765

00:09:24.060 --> 00:09:25.160 and that's that's fine.

NOTE Confidence: 0.845712299411765

00:09:25.160 --> 00:09:27.426 You just have to make a choice and

NOTE Confidence: 0.845712299411765

00:09:27.426 --> 00:09:29.422 and trust that you're you know that

NOTE Confidence: 0.845712299411765

00:09:29.422 --> 00:09:31.760 that you sort of know the the field

NOTE Confidence: 0.845712299411765

00:09:31.760 --> 00:09:34.229 and then you're gonna do the right thing.

NOTE Confidence: 0.845712299411765

00:09:34.230 --> 00:09:35.374 Although it's obviously very,

NOTE Confidence: 0.845712299411765

00:09:35.374 --> 00:09:36.710 very stressful, 'cause you worry that

NOTE Confidence: 0.845712299411765

00:09:36.710 --> 00:09:38.170 maybe you're not making the right choices,

NOTE Confidence: 0.845712299411765

00:09:38.170 --> 00:09:40.530 but at some point you have to have

NOTE Confidence: 0.845712299411765

00:09:40.530 --> 00:09:42.529 some some degree of grounding.

NOTE Confidence: 0.845712299411765

00:09:42.530 --> 00:09:43.434 And then but then,

NOTE Confidence: 0.845712299411765

00:09:43.434 --> 00:09:44.564 I think it's really key,

NOTE Confidence: 0.845712299411765

00:09:44.570 --> 00:09:44.902 you know.

NOTE Confidence: 0.845712299411765

00:09:44.902 --> 00:09:46.064 So you have this sense of grounding.

NOTE Confidence: 0.845712299411765

00:09:46.070 --> 00:09:47.605 You know the overall destination

NOTE Confidence: 0.845712299411765

00:09:47.605 --> 00:09:49.140 you want to go to,

NOTE Confidence: 0.845712299411765

00:09:49.140 --> 00:09:51.632 but I think it's really important for

NOTE Confidence: 0.845712299411765

00:09:51.632 --> 00:09:54.565 a couple of reasons to be flexible

NOTE Confidence: 0.845712299411765

00:09:54.565 --> 00:09:57.540 and adaptive and how you get there.

NOTE Confidence: 0.845712299411765

00:09:57.540 --> 00:09:59.570 The first reason, I think,

NOTE Confidence: 0.845712299411765

00:09:59.570 --> 00:10:01.070 is that hey you will,

NOTE Confidence: 0.845712299411765

00:10:01.070 --> 00:10:02.555 you will get valuable feedback

NOTE Confidence: 0.845712299411765

00:10:02.555 --> 00:10:03.446 from your sites.

NOTE Confidence: 0.845712299411765

00:10:03.450 --> 00:10:04.554 They're there, they're local,

NOTE Confidence: 0.845712299411765

00:10:04.554 --> 00:10:06.210 they're they're dealing with the patients,

NOTE Confidence: 0.845712299411765

00:10:06.210 --> 00:10:07.330 they see what's going on,

NOTE Confidence: 0.845712299411765

00:10:07.330 --> 00:10:09.150 and so they will send information to

NOTE Confidence: 0.845712299411765

00:10:09.150 --> 00:10:10.753 you that you wouldn't necessarily

NOTE Confidence: 0.845712299411765

00:10:10.753 --> 00:10:12.277 have at your disposal.

NOTE Confidence: 0.845712299411765

00:10:12.280 --> 00:10:14.408 And it's good to listen to that

NOTE Confidence: 0.845712299411765

00:10:14.408 --> 00:10:15.819 and and act on it,

NOTE Confidence: 0.845712299411765

00:10:15.820 --> 00:10:19.004 even though it may be kind of inconvenient.

NOTE Confidence: 0.845712299411765

00:10:19.010 --> 00:10:20.858 But but act and modify your

NOTE Confidence: 0.845712299411765

00:10:20.858 --> 00:10:21.782 protocol as needed.

NOTE Confidence: 0.845712299411765

00:10:21.790 --> 00:10:22.201 Until,

NOTE Confidence: 0.845712299411765

00:10:22.201 --> 00:10:24.467 I think strengthened the trial to

NOTE Confidence: 0.845712299411765

00:10:24.467 --> 00:10:25.916 do that and make a more robust.

NOTE Confidence: 0.845712299411765

00:10:25.920 --> 00:10:28.068 But also it helps to generate

NOTE Confidence: 0.845712299411765

00:10:28.068 --> 00:10:29.500 enthusiasm for your trial,

NOTE Confidence: 0.845712299411765

00:10:29.500 --> 00:10:31.500 because it really ideally should

NOTE Confidence: 0.845712299411765

00:10:31.500 --> 00:10:33.100 be a communal experience.

NOTE Confidence: 0.845712299411765

00:10:33.100 --> 00:10:34.258 And I sort of, you know,

NOTE Confidence: 0.845712299411765

00:10:34.260 --> 00:10:36.420 credit Walter Kernan for for this.

NOTE Confidence: 0.845712299411765

00:10:36.420 --> 00:10:38.068 For this sort of phrasing it this way,

NOTE Confidence: 0.845712299411765

00:10:38.070 --> 00:10:38.844 but it's really.

NOTE Confidence: 0.845712299411765

00:10:38.844 --> 00:10:42.348 I mean, people are not doing.

NOTE Confidence: 0.845712299411765

00:10:42.350 --> 00:10:42.992 You know,

NOTE Confidence: 0.845712299411765

00:10:42.992 --> 00:10:44.597 being site investigators in multicenter

NOTE Confidence: 0.845712299411765

00:10:44.597 --> 00:10:46.134 trials for the money, right?

NOTE Confidence: 0.845712299411765

00:10:46.134 --> 00:10:47.846 They're doing it out of a sense of

NOTE Confidence: 0.845712299411765

00:10:47.846 --> 00:10:49.376 service out of being part of science.

NOTE Confidence: 0.845712299411765

00:10:49.380 --> 00:10:50.588 It's exciting. It's fun.

NOTE Confidence: 0.845712299411765

00:10:50.588 --> 00:10:50.890 Yeah,

NOTE Confidence: 0.845712299411765

00:10:50.890 --> 00:10:52.843 I feel that way being part of

NOTE Confidence: 0.845712299411765

00:10:52.843 --> 00:10:54.565 other peoples trials like it's fun

NOTE Confidence: 0.845712299411765

00:10:54.565 --> 00:10:56.209 to to see cool trials happening

NOTE Confidence: 0.845712299411765

00:10:56.209 --> 00:10:57.487 and you feel like OK,

NOTE Confidence: 0.845712299411765

00:10:57.490 --> 00:10:59.728 we enrolled X number of patients.

NOTE Confidence: 0.845712299411765

00:10:59.730 --> 00:11:00.890 You know it feels rewarding.

NOTE Confidence: 0.845712299411765

00:11:00.890 --> 00:11:02.962 So you want to harness that and promote

NOTE Confidence: 0.845712299411765

00:11:02.962 --> 00:11:04.889 that and and take advantage of it.

NOTE Confidence: 0.845712299411765

00:11:04.890 --> 00:11:06.622 So I you know,

NOTE Confidence: 0.845712299411765

00:11:06.622 --> 00:11:09.220 as I was thinking about this.

NOTE Confidence: 0.845712299411765

00:11:09.220 --> 00:11:09.864 Talk today,

NOTE Confidence: 0.845712299411765

00:11:09.864 --> 00:11:10.508 I realized,

NOTE Confidence: 0.845712299411765

00:11:10.508 --> 00:11:12.440 like I really missed the in

NOTE Confidence: 0.845712299411765

00:11:12.510 --> 00:11:14.310 person investigator meetings and I

NOTE Confidence: 0.845712299411765

00:11:14.310 --> 00:11:16.749 think the zoom is just it's not.

NOTE Confidence: 0.845712299411765

00:11:16.750 --> 00:11:18.838 It's a poor substitute and I

NOTE Confidence: 0.845712299411765

00:11:18.838 --> 00:11:20.230 put these like a

NOTE Confidence: 0.778442596551724

00:11:20.311 --> 00:11:23.047 little PowerPoint icon a palm trees

NOTE Confidence: 0.778442596551724

00:11:23.047 --> 00:11:26.427 here because I remember our last Arcadia

NOTE Confidence: 0.778442596551724

00:11:26.427 --> 00:11:29.367 investigator meeting at ISC in Honolulu.

NOTE Confidence: 0.778442596551724

23

00:11:29.370 --> 00:11:33.134 I think it was 2019 and I just remember

NOTE Confidence: 0.778442596551724

00:11:33.134 --> 00:11:35.749 what a great sense of camaraderie this was.

NOTE Confidence: 0.778442596551724

00:11:35.750 --> 00:11:38.150 It was sort of one of these adjunct

NOTE Confidence: 0.778442596551724

00:11:38.150 --> 00:11:39.179 investigator meetings at ISC.

NOTE Confidence: 0.778442596551724

00:11:39.180 --> 00:11:41.420 But a lot of the cipes were there.

NOTE Confidence: 0.778442596551724

00:11:41.420 --> 00:11:42.600 We were having, you know,

NOTE Confidence: 0.778442596551724

00:11:42.600 --> 00:11:44.190 having beers and just chatting and

NOTE Confidence: 0.778442596551724

00:11:44.190 --> 00:11:46.138 people will come up with their ideas.

NOTE Confidence: 0.778442596551724

00:11:46.140 --> 00:11:47.188 And I'd say oh that's a great idea.

NOTE Confidence: 0.778442596551724

00:11:47.190 --> 00:11:48.480 We should think about that.

NOTE Confidence: 0.778442596551724

00:11:48.480 --> 00:11:50.058 It it really?

NOTE Confidence: 0.778442596551724

00:11:50.058 --> 00:11:52.310 I think promotes a sense of camaraderie

NOTE Confidence: 0.778442596551724

00:11:52.310 --> 00:11:53.940 that we're all doing this together,

NOTE Confidence: 0.778442596551724

00:11:53.940 --> 00:11:55.260 and people feel like they have

NOTE Confidence: 0.778442596551724

00:11:55.260 --> 00:11:56.490 a voice in the trial.

NOTE Confidence: 0.778442596551724

00:11:56.490 --> 00:11:57.617 So I think that I don't know.

NOTE Confidence: 0.778442596551724

00:11:57.620 --> 00:12:00.329 I, I really think that in person

NOTE Confidence: 0.778442596551724

00:12:00.329 --> 00:12:01.490 stuff is better.

NOTE Confidence: 0.778442596551724

00:12:01.490 --> 00:12:03.290 But even even without that,

NOTE Confidence: 0.778442596551724

00:12:03.290 --> 00:12:05.408 just meeting with your sites regularly,

NOTE Confidence: 0.778442596551724

00:12:05.410 --> 00:12:07.328 asking them how it's going, hearing them,

NOTE Confidence: 0.778442596551724

00:12:07.328 --> 00:12:09.482 listening closely, you know and and

NOTE Confidence: 0.778442596551724

00:12:09.482 --> 00:12:11.150 incorporating some of that feedback,

NOTE Confidence: 0.778442596551724

00:12:11.150 --> 00:12:13.334 I think that's been very helpful for us.

NOTE Confidence: 0.778442596551724

00:12:13.340 --> 00:12:14.652 You know, in Arcadia,

NOTE Confidence: 0.778442596551724

00:12:14.652 --> 00:12:16.093 Rebecca Aragon, our project manager,

NOTE Confidence: 0.778442596551724

00:12:16.093 --> 00:12:17.398 has been amazing at this.

NOTE Confidence: 0.778442596551724

00:12:17.400 --> 00:12:19.340 She's been having these calls

NOTE Confidence: 0.778442596551724

00:12:19.340 --> 00:12:20.504 with sites periodically.

NOTE Confidence: 0.778442596551724

00:12:20.510 --> 00:12:22.298 One of the eyes, you know, dials in,

NOTE Confidence: 0.778442596551724

00:12:22.298 --> 00:12:23.882 but really Rebecca kind of leads

NOTE Confidence: 0.778442596551724

00:12:23.882 --> 00:12:25.639 the session and she's so good about,

NOTE Confidence: 0.778442596551724

00:12:25.640 --> 00:12:27.710 you know, listening and point things

NOTE Confidence: 0.778442596551724

00:12:27.710 --> 00:12:29.870 out and having having suggestions.

NOTE Confidence: 0.778442596551724

00:12:29.870 --> 00:12:31.556 I think all of these things.

NOTE Confidence: 0.778442596551724

00:12:31.560 --> 00:12:33.912 Are really important for

NOTE Confidence: 0.778442596551724

00:12:33.912 --> 00:12:36.852 making it a communal project.

NOTE Confidence: 0.778442596551724

00:12:36.860 --> 00:12:38.230 We spoke with project managers.

NOTE Confidence: 0.778442596551724

00:12:38.230 --> 00:12:39.475 They absolutely crucial

NOTE Confidence: 0.778442596551724

00:12:39.475 --> 00:12:41.135 our first project manager,

NOTE Confidence: 0.778442596551724

00:12:41.140 --> 00:12:41.736 Irene Ewing,

NOTE Confidence: 0.778442596551724

00:12:41.736 --> 00:12:43.524 really helped us launch the study.

NOTE Confidence: 0.778442596551724

00:12:43.530 --> 00:12:44.474 Sort of single handedly.

NOTE Confidence: 0.778442596551724

00:12:44.474 --> 00:12:44.946 She was.

NOTE Confidence: 0.778442596551724

00:12:44.950 --> 00:12:47.371 She was great and and and then now we

NOTE Confidence: 0.778442596551724

00:12:47.371 --> 00:12:49.782 have Rebecca Aragon and Pam Plummer who

NOTE Confidence: 0.778442596551724

00:12:49.782 --> 00:12:52.450 are a terrific team and they're really.

NOTE Confidence: 0.778442596551724

00:12:52.450 --> 00:12:53.465 I mean, they're the heart and soul.

NOTE Confidence: 0.778442596551724

00:12:53.470 --> 00:12:56.062 They're doing like 90% of the of the

NOTE Confidence: 0.778442596551724

00:12:56.062 --> 00:12:58.587 work now of of making this happen,

NOTE Confidence: 0.778442596551724

00:12:58.590 --> 00:13:01.398 so I think that's a really key thing.

NOTE Confidence: 0.778442596551724

00:13:01.400 --> 00:13:02.864 And then you know.

NOTE Confidence: 0.778442596551724

00:13:02.864 --> 00:13:04.400 Lastly, I just wanted to put

NOTE Confidence: 0.778442596551724

00:13:04.400 --> 00:13:05.900 out this idea that you know.

NOTE Confidence: 0.778442596551724

00:13:05.900 --> 00:13:07.260 Once a trial gets going,

NOTE Confidence: 0.778442596551724

00:13:07.260 --> 00:13:08.649 it it really,

NOTE Confidence: 0.778442596551724

00:13:08.649 --> 00:13:10.501 it just requires constant

NOTE Confidence: 0.778442596551724

00:13:10.501 --> 00:13:12.200 attention and tending to.

NOTE Confidence: 0.778442596551724

00:13:12.200 --> 00:13:13.120 It's not like OK,

NOTE Confidence: 0.778442596551724

00:13:13.120 --> 00:13:14.500 it's going and it's in autopilot

NOTE Confidence: 0.778442596551724

00:13:14.548 --> 00:13:16.052 and I don't mean just the idea of

NOTE Confidence: 0.778442596551724

00:13:16.052 --> 00:13:17.537 like oh you have to constantly,

NOTE Confidence: 0.778442596551724

00:13:17.540 --> 00:13:19.857 after cheerleading for the trial to to,

NOTE Confidence: 0.778442596551724

00:13:19.860 --> 00:13:22.506 you know, get people to recruit.

NOTE Confidence: 0.778442596551724

00:13:22.510 --> 00:13:23.431 That's a given,

NOTE Confidence: 0.778442596551724

00:13:23.431 --> 00:13:25.273 but I'm just talking about the

NOTE Confidence: 0.778442596551724

00:13:25.273 --> 00:13:26.914 fundamental give to basically be

NOTE Confidence: 0.778442596551724

00:13:26.914 --> 00:13:28.504 periodically going down to the

NOTE Confidence: 0.778442596551724

00:13:28.504 --> 00:13:30.340 basement and checking on the boiler

NOTE Confidence: 0.778442596551724

00:13:30.340 --> 00:13:32.233 and checking on the plumbing because

NOTE Confidence: 0.778442596551724

00:13:32.233 --> 00:13:34.398 it things breakdown you know,

NOTE Confidence: 0.778442596551724

00:13:34.400 --> 00:13:36.160 especially with a trial like.

NOTE Confidence: 0.778442596551724

00:13:36.160 --> 00:13:38.589 Arcadia where I think we have a

NOTE Confidence: 0.778442596551724

00:13:38.589 --> 00:13:40.279 relatively complex protocol there are,

NOTE Confidence: 0.778442596551724

00:13:40.280 --> 00:13:40.886 you know,

NOTE Confidence: 0.778442596551724

00:13:40.886 --> 00:13:42.098 there's been frequent changes

NOTE Confidence: 0.778442596551724

00:13:42.098 --> 00:13:43.800 for a variety of reasons,

NOTE Confidence: 0.778442596551724

00:13:43.800 --> 00:13:45.516 and so you know making sure

NOTE Confidence: 0.778442596551724

00:13:45.516 --> 00:13:47.444 sites are staying on top of

NOTE Confidence: 0.778442596551724

00:13:47.444 --> 00:13:48.876 those and aren't overwhelmed,

NOTE Confidence: 0.778442596551724

00:13:48.880 --> 00:13:50.715 especially when they it's not

NOTE Confidence: 0.778442596551724

00:13:50.715 --> 00:13:52.550 the only trial they're doing.

NOTE Confidence: 0.778442596551724

00:13:52.550 --> 00:13:54.104 There's been a lot of staff turnover,

NOTE Confidence: 0.778442596551724

00:13:54.110 --> 00:13:55.338 especially recently with COVID,

NOTE Confidence: 0.778442596551724

00:13:55.338 --> 00:13:57.520 and so you lose this kind of

NOTE Confidence: 0.778442596551724

00:13:57.520 --> 00:13:58.640 implicit learning where you

NOTE Confidence: 0.778442596551724

00:13:58.640 --> 00:14:00.040 know if you enroll in

NOTE Confidence: 0.8603638136

00:14:00.101 --> 00:14:01.972 a trial a few times, you kind of

NOTE Confidence: 0.8603638136

00:14:01.972 --> 00:14:03.820 get some of the basic stuff down,

NOTE Confidence: 0.8603638136

00:14:03.820 --> 00:14:05.584 and you maybe don't have to

NOTE Confidence: 0.8603638136

00:14:05.584 --> 00:14:07.520 refer to every line of the mob.

NOTE Confidence: 0.8603638136

00:14:07.520 --> 00:14:08.768 But then when a coordinator leaves,

NOTE Confidence: 0.8603638136

00:14:08.770 --> 00:14:10.126 you lose that, and it's like

NOTE Confidence: 0.8603638136

00:14:10.126 --> 00:14:11.030 it's starting from scratch,

NOTE Confidence: 0.8603638136

00:14:11.030 --> 00:14:13.235 and some of this stuff is almost

NOTE Confidence: 0.8603638136

00:14:13.235 --> 00:14:15.676 like a living memory bank and and

NOTE Confidence: 0.8603638136

00:14:15.676 --> 00:14:17.812 you have to keep refreshing that

NOTE Confidence: 0.8603638136

00:14:17.886 --> 00:14:20.076 on webinars on calls with sites,

NOTE Confidence: 0.8603638136

00:14:20.080 --> 00:14:21.710 because the same things keep

NOTE Confidence: 0.8603638136

00:14:21.710 --> 00:14:23.014 happening over and over.

NOTE Confidence: 0.8603638136

00:14:23.020 --> 00:14:24.238 If you don't,

NOTE Confidence: 0.8603638136

00:14:24.238 --> 00:14:25.862 there's definitely fatigue among

NOTE Confidence: 0.8603638136

00:14:25.862 --> 00:14:28.000 the trial staff and patients.

NOTE Confidence: 0.8603638136

00:14:28.000 --> 00:14:30.149 And what can you do about that?

NOTE Confidence: 0.8603638136

00:14:30.150 --> 00:14:31.854 And then you know all of this is

NOTE Confidence: 0.8603638136

00:14:31.854 --> 00:14:33.359 happening in the context of what

NOTE Confidence: 0.8603638136

00:14:33.359 --> 00:14:34.895 I would call a distributed system.

NOTE Confidence: 0.8603638136

00:14:34.900 --> 00:14:36.517 You know it's a very American thing.

NOTE Confidence: 0.8603638136

00:14:36.520 --> 00:14:38.626 It's a federal Federated system like

NOTE Confidence: 0.8603638136

00:14:38.626 --> 00:14:41.218 you're not directly in charge of anything,

NOTE Confidence: 0.8603638136

00:14:41.220 --> 00:14:41.569 right?

NOTE Confidence: 0.8603638136

00:14:41.569 --> 00:14:42.616 You're sitting here.

NOTE Confidence: 0.8603638136

00:14:42.616 --> 00:14:45.519 You have our CCS and you have sites.

NOTE Confidence: 0.8603638136

00:14:45.520 --> 00:14:47.572 And I actually think overall it's

NOTE Confidence: 0.8603638136

00:14:47.572 --> 00:14:49.616 a strength because you can sort

NOTE Confidence: 0.8603638136

00:14:49.616 --> 00:14:51.446 of put some parameters and say

NOTE Confidence: 0.8603638136

00:14:51.446 --> 00:14:53.469 in general we want patients with.

NOTE Confidence: 0.8603638136

00:14:53.470 --> 00:14:56.990 Esis and and then you can kind of

NOTE Confidence: 0.8603638136

00:14:56.990 --> 00:14:59.666 trust that sites are are figuring

NOTE Confidence: 0.8603638136

00:14:59.666 --> 00:15:02.368 out how that works in their system.

NOTE Confidence: 0.8603638136

00:15:02.370 --> 00:15:02.850 You know,

NOTE Confidence: 0.8603638136

00:15:02.850 --> 00:15:04.770 like maybe one site is getting CT angiograms,

NOTE Confidence: 0.8603638136

00:15:04.770 --> 00:15:07.806 another side gets MRI angiogram somewhere

NOTE Confidence: 0.8603638136

00:15:07.806 --> 00:15:10.439 else gets ultrasounds and T CD's.

NOTE Confidence: 0.8603638136

00:15:10.440 --> 00:15:12.168 You know it doesn't matter so

NOTE Confidence: 0.8603638136

00:15:12.168 --> 00:15:14.304 much as long as it's sort of

NOTE Confidence: 0.8603638136

00:15:14.304 --> 00:15:15.824 being done at some level,

NOTE Confidence: 0.8603638136

00:15:15.830 --> 00:15:17.030 so I think it's it's.

NOTE Confidence: 0.8603638136

00:15:17.030 --> 00:15:19.284 It helps you be able to function

NOTE Confidence: 0.8603638136

00:15:19.284 --> 00:15:21.709 in the in the context of like

NOTE Confidence: 0.8603638136

00:15:21.709 --> 00:15:23.669 a multi multi state trial,

NOTE Confidence: 0.8603638136

00:15:23.669 --> 00:15:25.784 but obviously also has challenges

NOTE Confidence: 0.8603638136

00:15:25.784 --> 00:15:27.869 'cause sometimes you feel like you're

NOTE Confidence: 0.8603638136

00:15:27.869 --> 00:15:29.997 flying blind and how do you deal

NOTE Confidence: 0.8603638136

00:15:29.997 --> 00:15:32.090 with some of the variation and and

NOTE Confidence: 0.8603638136

00:15:32.090 --> 00:15:33.742 it takes more work 'cause you have

NOTE Confidence: 0.8603638136

00:15:33.742 --> 00:15:36.082 to kind of go site to site to do things.

NOTE Confidence: 0.8603638136

00:15:36.082 --> 00:15:38.346 So I think these are some of the

NOTE Confidence: 0.8603638136

00:15:38.346 --> 00:15:40.446 some of the challenges but overall.

NOTE Confidence: 0.8603638136

00:15:40.450 --> 00:15:42.050 I think it it it.

NOTE Confidence: 0.8603638136

00:15:42.050 --> 00:15:44.048 It's actually helpful for for doing

NOTE Confidence: 0.8603638136

00:15:44.048 --> 00:15:46.438 some of the things we talked about,

NOTE Confidence: 0.8603638136

00:15:46.440 --> 00:15:48.020 like engaging with sites and

NOTE Confidence: 0.8603638136

00:15:48.020 --> 00:15:49.910 I think that's all I've got.

NOTE Confidence: 0.8603638136

00:15:49.910 --> 00:15:52.662 So I'll stop there and see if folks

NOTE Confidence: 0.8603638136

00:15:52.662 --> 00:15:54.244 have questions or thoughts you

NOTE Confidence: 0.8603638136

00:15:54.244 --> 00:15:56.330 know we'd love to kind of discuss

NOTE Confidence: 0.8603638136

00:15:56.330 --> 00:15:58.654 what what you all think about this.

NOTE Confidence: 0.8603638136

00:15:58.660 --> 00:15:58.950 Thank

NOTE Confidence: 0.71404426

00:15:58.960 --> 00:16:00.640 you so much, woman, uh,

NOTE Confidence: 0.71404426

00:16:00.640 --> 00:16:02.712 these were great insights,

NOTE Confidence: 0.71404426

00:16:02.712 --> 00:16:05.302 specially for people like myself

NOTE Confidence: 0.71404426

00:16:05.302 --> 00:16:08.998 and others who are in the process of

NOTE Confidence: 0.71404426

00:16:08.998 --> 00:16:12.568 submitting multicenter studies for funding.

NOTE Confidence: 0.71404426

00:16:12.568 --> 00:16:16.128 So thank you so much for this.

NOTE Confidence: 0.71404426

00:16:16.130 --> 00:16:18.086 I have a question, you know,

NOTE Confidence: 0.71404426

00:16:18.090 --> 00:16:20.670 as a junior investigator,

NOTE Confidence: 0.71404426

00:16:20.670 --> 00:16:24.540 submitting UM for a multicenter study.

NOTE Confidence: 0.71404426

00:16:24.540 --> 00:16:26.583 What were important,

NOTE Confidence: 0.71404426

00:16:26.583 --> 00:16:28.626 like unexpected challenges?

NOTE Confidence: 0.71404426

00:16:28.630 --> 00:16:32.120 Just as a heads up, you know,

NOTE Confidence: 0.71404426

00:16:32.120 --> 00:16:35.585 for me, if the study moves forward,

NOTE Confidence: 0.71404426

00:16:35.590 --> 00:16:38.300 were there any unexpected challenges

NOTE Confidence: 0.71404426

00:16:38.300 --> 00:16:41.010 like important sort of COVID?

NOTE Confidence: 0.71404426

00:16:41.010 --> 00:16:45.350 Obviously, yeah, that you encountered,

NOTE Confidence: 0.71404426

00:16:45.350 --> 00:16:48.248 that would. You know, be UM,

NOTE Confidence: 0.71404426

00:16:48.250 --> 00:16:50.350 definitely important, uh, uh.

NOTE Confidence: 0.71404426

00:16:50.350 --> 00:16:52.228 You know, keep in mind,

NOTE Confidence: 0.71404426

00:16:52.228 --> 00:16:53.608 as the study moves on.

NOTE Confidence: 0.740925732

00:16:54.560 --> 00:16:55.940 No, absolutely I, you know,

NOTE Confidence: 0.740925732

00:16:55.940 --> 00:16:57.180 we definitely had our share.

NOTE Confidence: 0.740925732

00:16:57.180 --> 00:16:58.496 I, you know. So first of all,

NOTE Confidence: 0.740925732

00:16:58.500 --> 00:17:01.825 with the I think from the concept

NOTE Confidence: 0.740925732

00:17:01.825 --> 00:17:04.120 synopsis 2 to the first submission.

NOTE Confidence: 0.740925732

00:17:04.120 --> 00:17:05.972 I mean, there was a usual give and

NOTE Confidence: 0.740925732

00:17:05.972 --> 00:17:07.860 take like our our initial proposal was

NOTE Confidence: 0.740925732

00:17:07.860 --> 00:17:10.300 enrolled like 4400 patients like enroll,

NOTE Confidence: 0.740925732

00:17:10.300 --> 00:17:12.970 randomized everybody with pieces and and

NOTE Confidence: 0.740925732

00:17:13.040 --> 00:17:15.500 people shot that down pretty quickly.

NOTE Confidence: 0.740925732

00:17:15.500 --> 00:17:18.070 So that's fine, we adapted.

NOTE Confidence: 0.740925732

00:17:18.070 --> 00:17:20.486 And then the the the you know grant

NOTE Confidence: 0.740925732

00:17:20.486 --> 00:17:22.956 one in the first time it was OK.

NOTE Confidence: 0.740925732

00:17:22.960 --> 00:17:24.862 But then on the second submission

NOTE Confidence: 0.740925732

00:17:24.862 --> 00:17:26.889 a there there was like literally

NOTE Confidence: 0.740925732

00:17:26.889 --> 00:17:29.325 this down to the wire issue about

NOTE Confidence: 0.740925732

00:17:29.325 --> 00:17:31.524 whether we were going to get study

NOTE Confidence: 0.740925732

00:17:31.524 --> 00:17:33.812 drugs supplied by VMS Pfizer or not,

NOTE Confidence: 0.740925732

00:17:33.812 --> 00:17:35.996 and that was incredibly stressful because,

NOTE Confidence: 0.740925732

00:17:36.000 --> 00:17:36.624 you know,

NOTE Confidence: 0.740925732

00:17:36.624 --> 00:17:38.808 we had two sets of budgets basically

NOTE Confidence: 0.740925732

00:17:38.808 --> 00:17:41.236 and and you know it was a huge $4

NOTE Confidence: 0.740925732

00:17:41.236 --> 00:17:43.360 million line item and and so not

NOTE Confidence: 0.740925732

00:17:43.360 --> 00:17:45.439 knowing which way we're going to go,

NOTE Confidence: 0.740925732

00:17:45.440 --> 00:17:46.520 what will we have to cut?

NOTE Confidence: 0.740925732

00:17:46.520 --> 00:17:48.128 I think we would have had to make

NOTE Confidence: 0.740925732

00:17:48.128 --> 00:17:49.461 really substantial cuts that would have

NOTE Confidence: 0.740925732

00:17:49.461 --> 00:17:50.787 kind of actually impaired the trial.

NOTE Confidence: 0.740925732

00:17:50.790 --> 00:17:52.530 And then we per patient reimbursements

NOTE Confidence: 0.740925732

00:17:52.530 --> 00:17:54.888 so that. I think just be on your toes.

NOTE Confidence: 0.740925732

00:17:54.890 --> 00:17:56.500 You have to really get good at

NOTE Confidence: 0.740925732

00:17:56.500 --> 00:17:57.818 the budgeting and the finances

NOTE Confidence: 0.740925732

00:17:57.818 --> 00:17:58.970 because it's it's part.

NOTE Confidence: 0.740925732

00:17:58.970 --> 00:18:00.506 It's very intricately tide into the

NOTE Confidence: 0.740925732

00:18:00.506 --> 00:18:02.556 success of the of the trial, right?

NOTE Confidence: 0.740925732

00:18:02.556 --> 00:18:05.958 So I think that's the first tip

NOTE Confidence: 0.740925732

00:18:05.958 --> 00:18:08.150 and then just you know personnel.

NOTE Confidence: 0.740925732

00:18:08.150 --> 00:18:11.236 I mean we, you know, I renewing was amazing,

NOTE Confidence: 0.740925732

00:18:11.240 --> 00:18:13.640 and in retrospect I think all along we

NOTE Confidence: 0.740925732

00:18:13.640 --> 00:18:15.800 should have had two project managers.

NOTE Confidence: 0.740925732

00:18:15.800 --> 00:18:16.688 But I think we were just,

NOTE Confidence: 0.740925732

00:18:16.690 --> 00:18:19.420 you know, everyone was learning.

NOTE Confidence: 0.740925732

00:18:19.420 --> 00:18:20.792 He kind of took it on herself

NOTE Confidence: 0.740925732

00:18:20.792 --> 00:18:21.680 for a long time,

NOTE Confidence: 0.740925732

00:18:21.680 --> 00:18:23.822 but I think frankly it was like it was

NOTE Confidence: 0.740925732

00:18:23.822 --> 00:18:25.983 too much and and so then finding out

NOTE Confidence: 0.740925732

00:18:25.983 --> 00:18:28.137 that Irene was low leaving and having

NOTE Confidence: 0.740925732

00:18:28.137 --> 00:18:30.391 to find other project managers was a

NOTE Confidence: 0.740925732

00:18:30.391 --> 00:18:32.812 very stressful time because she, you know.

NOTE Confidence: 0.740925732

00:18:32.812 --> 00:18:34.536 Obviously the project managers

NOTE Confidence: 0.740925732

00:18:34.536 --> 00:18:37.509 do a lot of the day today.

NOTE Confidence: 0.740925732

00:18:37.510 --> 00:18:38.446 So I think.

NOTE Confidence: 0.740925732

00:18:38.446 --> 00:18:41.090 I don't know how you plan for that,

NOTE Confidence: 0.740925732

00:18:41.090 --> 00:18:42.440 but I think having two project

NOTE Confidence: 0.740925732

00:18:42.440 --> 00:18:44.053 managers makes a lot of sense to

NOTE Confidence: 0.740925732

00:18:44.053 --> 00:18:45.379 provide some some kind of buffer.

NOTE Confidence: 0.740925732

00:18:45.380 --> 00:18:47.600 In case you know something happens.

NOTE Confidence: 0.740925732

00:18:47.600 --> 00:18:49.010 Those were the big ones.

NOTE Confidence: 0.740925732

00:18:49.010 --> 00:18:50.464 I'm trying to think of other, you know,

NOTE Confidence: 0.740925732

00:18:50.464 --> 00:18:51.880 and then the other one was we were,

NOTE Confidence: 0.740925732

00:18:51.880 --> 00:18:53.314 you know, we were operating the

NOTE Confidence: 0.740925732

00:18:53.314 --> 00:18:54.630 context of these other trucks.

NOTE Confidence: 0.740925732

00:18:54.630 --> 00:18:56.598 Yeah, and respect.

NOTE Confidence: 0.740925732

00:18:56.598 --> 00:18:58.930 And so how do you know?

NOTE Confidence: 0.740925732

00:18:58.930 --> 00:19:00.460 How do you prepare to respond?

NOTE Confidence: 0.740925732

00:19:00.460 --> 00:19:02.802 If it's positive it's negative, you know.

NOTE Confidence: 0.740925732

00:19:02.802 --> 00:19:04.272 How do you pivot that?

NOTE Confidence: 0.740925732

00:19:04.272 --> 00:19:06.444 That was definitely a big challenge.

NOTE Confidence: 0.740925732

00:19:06.450 --> 00:19:08.105 I think staying you know

NOTE Confidence: 0.740925732

00:19:08.105 --> 00:19:09.429 absolutely on top of.

NOTE Confidence: 0.740925732

00:19:09.430 --> 00:19:10.828 The field and not only in

NOTE Confidence: 0.740925732

00:19:10.828 --> 00:19:11.760 terms of what's published,

NOTE Confidence: 0.740925732

00:19:11.760 --> 00:19:13.830 but also like trials that are on the horizon,

NOTE Confidence: 0.740925732

00:19:13.830 --> 00:19:16.490 and you'd be surprised because,

NOTE Confidence: 0.740925732

00:19:16.490 --> 00:19:18.582 you know, there's clinicaltrials.gov.

NOTE Confidence: 0.740925732

00:19:18.582 --> 00:19:19.628 But frankly,

NOTE Confidence: 0.740925732

00:19:19.630 --> 00:19:21.613 it's it's a little hard to navigate, right?

NOTE Confidence: 0.740925732

00:19:21.613 --> 00:19:23.664 And so one way I found that's

NOTE Confidence: 0.740925732

00:19:23.664 --> 00:19:25.352 useful from knowing about trials

NOTE Confidence: 0.740925732

00:19:25.352 --> 00:19:27.434 and the status of trials actually

NOTE Confidence: 0.740925732

00:19:27.434 --> 00:19:29.010 is just word of mouth,

NOTE Confidence: 0.884612528571428

00:19:29.010 --> 00:19:30.907 because there are trials that you know,

NOTE Confidence: 0.884612528571428

00:19:30.910 --> 00:19:32.236 I, I thought were happening and

NOTE Confidence: 0.884612528571428

00:19:32.236 --> 00:19:33.938 then you talk to people who know

NOTE Confidence: 0.884612528571428

00:19:33.938 --> 00:19:35.208 people who know being there,

NOTE Confidence: 0.884612528571428

00:19:35.210 --> 00:19:36.344 like I actually got trial to Scott,

NOTE Confidence: 0.884612528571428

00:19:36.350 --> 00:19:38.570 struck down for lack of enrollment.

NOTE Confidence: 0.884612528571428

00:19:38.570 --> 00:19:39.998 But you know, it's like there's some.

NOTE Confidence: 0.884612528571428

00:19:40.000 --> 00:19:42.364 Be published, public announcement or or

NOTE Confidence: 0.884612528571428

00:19:42.364 --> 00:19:45.113 a paper you know publishing this trial

NOTE Confidence: 0.884612528571428

00:19:45.113 --> 00:19:48.100 stock so I think just just you know,

NOTE Confidence: 0.884612528571428

00:19:48.100 --> 00:19:51.385 networking and being sort of a

NOTE Confidence: 0.884612528571428

00:19:51.385 --> 00:19:53.410 tightly embedded in your field

NOTE Confidence: 0.884612528571428

00:19:53.410 --> 00:19:55.930 is is helpful for them. Thank

NOTE Confidence: 0.932837925

00:19:55.940 --> 00:19:57.956 you so much, that's very helpful.

NOTE Confidence: 0.932837925

00:19:57.960 --> 00:20:00.880 I don't think there are any other questions.

NOTE Confidence: 0.932837925

00:20:00.880 --> 00:20:03.666 Again, if there anyone has any questions

NOTE Confidence: 0.932837925

00:20:03.666 --> 00:20:06.000 for Doctor Kamal, please reach out.