0:0:0.0 --> 0:0:10.910  
Angela Angle  
Great. So another sorry, this transcription will be helpful. Just to hear a little bit more about your background and the types of companies that you worked at as well as the therapeutic areas that you're involved with. That would be great.

0:0:11.910 --> 0:0:21.380  
Andy Avery  
Sure. So you know kind of long time in industry, 25 years plus primarily in a a program management capacity.

0:0:21.880 --> 0:0:38.40  
Andy Avery  
Umm have experience at initial experience at a small privately held CRO. And then I was at fizer for several years and then it'll kind of a larger privately held company and and current currently added emerging biotech company.

0:0:38.660 --> 0:0:54.280  
Andy Avery  
So kind of domains have experience around program management, alliance management, so working with development teams, all the scientists with the procurement groups, that type of thing. And in my current role most of chief of staff to our to our CEO.

0:0:55.540 --> 0:0:57.800  
Andy Avery  
And I've been doing that for for a year as well.

0:0:58.500 --> 0:1:4.10  
Andy Avery  
Umm. In terms of therapeutic areas, primarily in the CNS space?

0:1:5.490 --> 0:1:13.240  
Andy Avery  
Also some experience in in in GI would say those are the two two larger ones and in and kind of the neural.

0:1:15.170 --> 0:1:28.480  
Andy Avery  
Neuroscience space, including, you know, pain and currently products around Prius and and various conditions and think think you know also worked in depression areas like that.

0:1:30.500 --> 0:1:43.100  
Angela Angle  
And within your role in Alliance management, does this include I I guess, partners for testing manufacturing clinical trial services does include all all those sorts of things?

0:1:44.190 --> 0:2:10.20  
Andy Avery  
It does. I mean, usually we we have a we kind of scale our governance if you will depending on the size of the CRO. So obviously the big clinical CRO there are such big you know doing late stage clinical trials or such a big part of our spend that there's a lot of attention to them. But it does include our our contract manufacturers and you know we're in typically in a model with.

0:2:10.140 --> 0:2:19.920  
Andy Avery  
With some level of preferred providers, so we have an in the alliance management, we'll have some governance and interactions with them across our various programs and trials.

0:2:21.460 --> 0:2:22.560  
Angela Angle  
OK, makes sense.

0:2:45.520 --> 0:2:46.120  
Andy Avery  
Mm-hmm.

0:2:23.540 --> 0:2:53.750  
Angela Angle  
Uh, so I I guess I just like to outline how we're thinking about biomarker testing. So we're trying to segment this market into four categories based on the technologies and and but used in the purposes of the testing. Just wanted to run through those and see if they resonate with you or if there's anything else that you would add or or alter to this the the first kind of bucket of tests we're thinking about our immune monitoring tests. So this would include a lot of flow cytometry.

0:2:54.0 --> 0:3:8.790  
Angela Angle  
It would include some more cellular phenotyping, cell based assays, a second bucket would be proteomics, so this would be your mass spec amino assays, protein microarrays, things of those nature.

0:3:9.550 --> 0:3:27.930  
Angela Angle  
1/3 bucket would be genomics, so this would be transcriptomics Q PCR, digital PCR, whole genome sequencing, holcom sequencing and then the last category would be histopathology. So this includes ICC ISH and those slide based sort of methods.

0:3:29.220 --> 0:3:29.790  
Andy Avery  
OK.

0:3:28.740 --> 0:3:39.990  
Angela Angle  
Does does this make sense? Does does this kind of resonated all with how you may think about different types of services or or how else would you think about these biomarker services?

0:3:41.920 --> 0:3:49.490  
Andy Avery  
Yeah, I think that's fine. I just, I I don't know how deep. You know, I don't think I have deep experience in all those those domains.

0:3:50.730 --> 0:4:0.200  
Andy Avery  
But certainly you know, you know, pathology and some of the you know we've done some work with inflammatory biomarkers and things of that nature.

0:4:3.230 --> 0:4:18.670  
Andy Avery  
That's kinda I just don't know how. I I told Tabitha on my entry. Just in terms of the depth of this area. You know, some of the things like proteomics and genomics. I just, I don't have this much deep experience with as compared to histopathology and and and biomarkers.

0:4:28.320 --> 0:4:28.670  
Andy Avery  
OK.

0:4:38.920 --> 0:4:39.260  
Andy Avery  
Umm.

0:4:20.230 --> 0:4:45.420  
Angela Angle  
Yeah, and. And I guess for the experience doesn't necessarily need to be like knowing the the technical workings of the different types of experiments, it could be in terms of are these things that you are these activities that you would outsource as part of the typical programs that you manage or are these paths that are handled internally that your own scientist can handle? And we like to understand some of the new ones there.

0:4:46.470 --> 0:4:47.580  
Andy Avery  
OK, fair enough.

0:4:49.0 --> 0:4:49.470  
Angela Angle  
OK.

0:4:51.60 --> 0:5:13.390  
Angela Angle  
So I guess we can start, you said you have a good one experience on the pathology side. So maybe I could start there and just kind of curious at a high level how you view pathology testing. Is this something that you ever perform in internally at your company is or is this all outsourced? And what do you kind of look for when you go to outsource this type of testing?

0:5:14.630 --> 0:5:16.750  
Andy Avery  
Yeah. So that would be all outsourced.

0:5:18.90 --> 0:5:43.200  
Andy Avery  
At a, you know, kind of at a emerging biotech, I mean we don't have capacity to do that type, that type of of work. You know when we do preclinical work, usually the the you know if we go with like a Charles River or something like that, we would have usually would outsource the the full studies you know, talk studies and all the pathology that goes goes along with it. But that that would certainly be fully outsourced.

0:5:44.950 --> 0:6:4.580  
Angela Angle  
Umm. And I guess when you think about vendors for pathology, are you looking for, I mean you mentioned Charles River, they offer a variety of other types of services. Do you ever use kind of 1 off or specialty providers who are really focused on pathology versus offering more the full service suite?

0:6:9.440 --> 0:6:15.370  
Andy Avery  
Yeah, we probably would consider something like that if it was. If it was, you know, some sort of specialty, some sort of unique.

0:6:16.220 --> 0:6:23.690  
Andy Avery  
Pathology that we needed to do in the context of the, you know, medication and the trials where were doing or if there was some some reason.

0:6:24.920 --> 0:6:26.580  
Andy Avery  
Was trying to think if there's.

0:6:27.790 --> 0:6:34.170  
Andy Avery  
Sometimes even in in talks you can get, you know, there may be specific things that are being looked for that you might.

0:6:34.960 --> 0:6:52.860  
Andy Avery  
Lead you to a specific lab to do the pathology, but I mean most civically. You know, we would package it up with the with the, you know, again the Charles River example. If they're doing the long term talks, we would have them do all the pathology and I give in that circumstance would give it to them, soup to nuts.

0:6:53.640 --> 0:6:53.890  
Angela Angle  
Hmm.

0:7:8.580 --> 0:7:8.990  
Andy Avery  
OK.

0:6:54.910 --> 0:7:9.140  
Angela Angle  
And I I guess for the talk studies, are these like your your typical studies that you would do on not just tissue samples, but you you'll take blood samples, other bodily food samples. Are these tissue based tucks tests?

0:7:11.880 --> 0:7:15.150  
Andy Avery  
We would take all, all different, all those samples.

0:7:18.880 --> 0:7:19.330  
Angela Angle  
OK.

0:7:18.890 --> 0:7:24.900  
Andy Avery  
Yeah. Any you know, kind of, yeah, long term talk, certainly we would do the all the full pathology.

0:7:26.930 --> 0:7:27.340  
Angela Angle  
OK.

0:7:28.620 --> 0:7:51.210  
Angela Angle  
When you think about offering or series that are offering pathology services, I I guess what do you who do you view as leaders in the pathology services in particular and and maybe you might choose a different company because they offer pathology and many other different types of services. But if you're just thinking about pathology, who do you view as strong in that area?

0:7:55.210 --> 0:8:3.130  
Andy Avery  
Well, I guess I do think about again I'm using this like when I think about talks work where we've done, you know the.

0:8:3.880 --> 0:8:19.390  
Andy Avery  
Talks associated you animal pathology. I think about Charles River and and Covance just based on, you know, historical experience. I don't know if a particular CRO comes to mind though, just broadly about any and all pathology services.

0:8:19.730 --> 0:8:20.30  
Angela Angle  
Mm-hmm.

0:8:21.150 --> 0:8:21.500  
Angela Angle  
OK.

0:8:22.810 --> 0:8:25.720  
Angela Angle  
And I guess within Charles River and Covance are there.

0:8:27.190 --> 0:8:31.640  
Angela Angle  
I guess for the pathology work that you have done with them, did they have any?

0:8:32.490 --> 0:8:40.460  
Angela Angle  
Offerings, capabilities, equipment, something that set them apart to make you confident that you can rely on them for the work.

0:8:43.150 --> 0:8:48.720  
Andy Avery  
I mean other than just their scale, you know, historical experience, working with them.

0:8:49.350 --> 0:8:49.610  
Angela Angle  
Umm.

0:8:49.440 --> 0:8:54.210  
Andy Avery  
Umm, you know it's gives you a certain level of confidence, but it's not a.

0:8:55.730 --> 0:8:57.270  
Andy Avery  
You know, it's not like they have.

0:8:58.40 --> 0:9:2.710  
Andy Avery  
Something that's so unique. I mean, there's other companies that can do it too, but.

0:9:4.590 --> 0:9:5.170  
Andy Avery  
You know.

0:9:5.980 --> 0:9:21.520  
Andy Avery  
If we were, you know, when you think about like long term talks, of course energency studies, I mean they're pretty important. So you want to go with a A reasonably large CRO and get a lot of times the historical experience plays a role in terms of having, you know, a level of confidence to use them.

0:9:23.760 --> 0:9:25.370  
Angela Angle  
Yeah, yeah, that makes sense.

0:9:26.90 --> 0:9:41.370  
Angela Angle  
So I guess there's not necessarily any in the histopathology space, no particular technologies or techniques that may be specific to the CNS space or any particular drug that you've worked on in the past. It's more of a.

0:9:42.170 --> 0:9:46.980  
Angela Angle  
General need for this type of service and there are other companies that also offer it.

0:9:49.40 --> 0:10:8.480  
Andy Avery  
Yeah, nothing, nothing comes to mind. I mean, imagine there could be some, you know, there could be some things that are emerging that are more recent that are more sophisticated, I suppose. But I I don't. Nothing's coming to mind where it was, you know, like a special capability they had in the for for his to pathology.

0:10:9.590 --> 0:10:24.560  
Angela Angle  
OK. So I guess other providers like I, are there any tissue specific restrictions like ohh you can't go to this other provider because they don't work with brain tissue samples or some other tissue type often?

0:10:28.970 --> 0:10:30.290  
Andy Avery  
No, I don't. I don't think so.

0:10:31.750 --> 0:10:32.220  
Angela Angle  
OK.

0:10:34.200 --> 0:11:2.700  
Angela Angle  
And then you did mention that you have to have preferred providers and just curious what that process looks like for your company and how specific the preferred provider lists are. If you would have a a list that is specific to biomarker, other bioanalytical testing or with the preferred provider list be these larger full service zeros that you would have run multiple parts of your study?

0:11:7.970 --> 0:11:8.740  
Andy Avery  
So.

0:11:11.750 --> 0:11:17.150  
Andy Avery  
Say that again. So yeah, you wanna know how we kind of structure our preferred providers?

0:11:17.900 --> 0:11:27.290  
Angela Angle  
Yeah. Yeah, maybe we just started at a higher level, like how you go about evaluating and reevaluating overtime vendors on the preferred provider list.

0:11:28.350 --> 0:11:28.740  
Andy Avery  
Yeah.

0:11:29.520 --> 0:11:30.270  
Andy Avery  
So.

0:11:32.600 --> 0:11:33.230  
Andy Avery  
Yeah, we.

0:11:33.320 --> 0:11:48.760  
Andy Avery  
The my most recent experience we tend to break it up a bit. You know, in terms of like we have a few big clinical CRO's we like to use for the the the heavy clinical study lifting.

0:11:50.260 --> 0:12:4.260  
Andy Avery  
And we typically outsourced by by program. You know based on their their expertise. So you think about the icon PRA's and IQ vias and companies like that.

0:12:5.340 --> 0:12:7.100  
Andy Avery  
You know, especially for our late stage.

0:12:8.360 --> 0:12:21.670  
Andy Avery  
Phase three type of studies and then we typically will pick from a small number of of zeros to do things like you know, statistical services and things like that.

0:12:22.380 --> 0:12:23.790  
Andy Avery  
And we.

0:12:24.850 --> 0:12:27.800  
Andy Avery  
We try to use the same companies for.

0:12:28.350 --> 0:12:43.980  
Andy Avery  
Uh, like our electronic data capture systems for our ecoa systems for lab collection. You know, we've broken that up that we use, you know, the same vendor to do all of our lab work across trials.

0:12:45.280 --> 0:12:45.580  
Angela Angle  
Mm-hmm.

0:12:46.530 --> 0:12:47.820  
Angela Angle  
And yeah, go ahead.

0:12:46.160 --> 0:12:48.710  
Andy Avery  
And and then for things like file. Yeah, right.

0:12:50.80 --> 0:13:6.670  
Angela Angle  
I just want to clarify if all the lab work that you mentioned. This includes preclinical lab work, clinical lab work and that is not just the more specific biomarker testing but also more the central lab services that you may just be running standard kind of.

0:13:7.990 --> 0:13:11.410  
Angela Angle  
Metabolic panels. Other basic tests on patient samples as well.

0:13:12.930 --> 0:13:15.800  
Andy Avery  
Yeah. So what we what we do is we'll have.

0:13:16.960 --> 0:13:47.70  
Andy Avery  
Like a typical trial, we'll have samples collected for you know, clinical labs PK, and then things like like biomarkers, right. So we'll have those all collected at the site. They'll all go to our preferred provider for central laboratory services, but then they would only do the, they would only analyze the samples for like the clinical labs PK would go to someone else and biomarkers would go to somebody else.

0:13:49.0 --> 0:13:50.570  
Angela Angle  
OK. That makes sense.

0:13:50.210 --> 0:13:53.170  
Andy Avery  
Does that make sense? So we kind of centralized the the.

0:14:11.550 --> 0:14:11.830  
Angela Angle  
Mm-hmm.

0:13:53.850 --> 0:14:13.560  
Andy Avery  
Processing of samples, but we wouldn't, even though you know, we have a central lab, we prefer they don't do all the assessments for us. They would just typically do the more standard clinical labs and then we usually go to a different preferred provider for PK analysis and then we go to a different one for biomarkers.

0:14:22.450 --> 0:14:22.760  
Andy Avery  
Yeah.

0:14:14.870 --> 0:14:24.60  
Angela Angle  
OK, so the PK provider is typically different than the biomarker providers and both of these are different than the central lab provider.

0:14:24.730 --> 0:14:25.770  
Andy Avery  
You got it? Yeah.

0:14:26.560 --> 0:14:31.80  
Angela Angle  
OK. So then do you have a preferred provider list for each of these three categories of testing?

0:14:34.130 --> 0:14:44.380  
Andy Avery  
Umm, yeah, so those very it's usually one like we've only most recently used a single lab for the for the biomarker work.

0:14:45.260 --> 0:14:45.560  
Angela Angle  
Mm-hmm.

0:14:45.60 --> 0:14:49.440  
Andy Avery  
Umm. And for bioanalytical we used a few different labs.

0:14:50.120 --> 0:14:52.400  
Andy Avery  
Umm. Over the last couple years.

0:14:54.980 --> 0:14:55.430  
Angela Angle  
OK.

0:14:57.300 --> 0:14:58.200  
Angela Angle  
And I guess.

0:14:59.90 --> 0:15:10.830  
Angela Angle  
Just wanted to get a little bit more into the reasoning the separate these out. Is it that the like the central lab provider, they're typically not specialized in these other testing categories or is there?

0:15:11.660 --> 0:15:18.20  
Angela Angle  
Like is the economics more favorable to split out some of the other tests at different providers just here so that the reasoning behind that?

0:15:19.550 --> 0:15:49.460  
Andy Avery  
It's not an economic issue. It's just a yeah, Cape. Well, I'm sure the central lab could probably do it too, but it's a we we just feel more comfortable. Like for PK, for example, having an independent lab, they have all the methods validated and and write the bioanalytical reports and things like that. We prefer to give that as a chunk to a different group than than the central lab. And someone with biomarkers, we've got a.

0:15:59.840 --> 0:16:0.170  
Angela Angle  
Mm-hmm.

0:15:49.800 --> 0:16:3.540  
Andy Avery  
You know company that we've, we've done it analysis with and the smaller that we feel more comfortable with. So it's it's not a cost driven thing. It's just kind of a A capabilities and and comfort level.

0:16:4.60 --> 0:16:6.870  
Andy Avery  
Uh driven. Driven decision.

0:16:8.540 --> 0:16:16.730  
Angela Angle  
And that comfort level is that you or other members of your team that had past experience with these companies or or where does that come from level come from?

0:16:17.850 --> 0:16:31.600  
Andy Avery  
Yeah, comes from from that it it can come from historical usage and and and performance. It can come from you know capabilities assessment and it also can come from.

0:16:33.260 --> 0:16:44.950  
Andy Avery  
You know less so cost, I mean that's always a factor, but unless there's large cost differences, that would necessarily be a driver, but timelines or a big driver. So how quickly can it get done?

0:16:47.850 --> 0:16:49.340  
Angela Angle  
And I guess are there any?

0:16:50.370 --> 0:17:3.350  
Angela Angle  
Technical capabilities or equipment that you're specifically looking for in the capabilities assessment piece or is it I, I don't know, are you having conversations with members of their scientific team to?

0:17:4.190 --> 0:17:6.700  
Angela Angle  
Assess the feasibility of your very specific project.

0:17:9.970 --> 0:17:30.500  
Andy Avery  
Yes, I mean usually it's a cross functional group and and and you know for things like biomarkers and PK heavily driven by our clean farm scientists discussing that and that who's got the best you know has the capabilities and you know who we think does will do it reliably and do it you know fast.

0:17:31.400 --> 0:17:31.640  
Angela Angle  
Umm.

0:17:32.630 --> 0:17:32.980  
Angela Angle  
OK.

0:17:34.330 --> 0:17:38.800  
Angela Angle  
Umm, so I guess four or specifically the biomarker services, I think it'd be helpful if.

0:17:39.660 --> 0:17:53.350  
Angela Angle  
Just had a little bit of detail around who you view kind of as the the main providers like whether you've used them or not. But I guess who do you see as really strong in the biomarker space?

0:17:57.810 --> 0:18:3.400  
Andy Avery  
So you know with with the biomarkers that we've.

0:18:4.380 --> 0:18:7.40  
Andy Avery  
That we've assessed, we've used to come to called air Tech.

0:18:11.910 --> 0:18:12.120  
Angela Angle  
Mm-hmm.

0:18:8.780 --> 0:18:17.150  
Andy Avery  
Which I know was a smaller provider, but we've that's been our our the primary group that we've used.

0:18:19.770 --> 0:18:31.40  
Angela Angle  
And do they offer, I mean, I guess we at the beginning of the call, I talked about the how we're viewing the different types of tests they offer tests across these different areas. So they involved in genomics and.

0:18:32.320 --> 0:18:34.690  
Angela Angle  
Proteomics, pathology. All these types of tests.

0:18:38.430 --> 0:19:0.540  
Andy Avery  
Yeah, I think they're they're general capabilities is fairly broad. So they can do different, you know the you know different types of testing. I mean we've we've mostly used them for these various inflammatory biomarker assessments. But I I believe their services are reasonably broad, but they're not the you know they're not a big, big company.

0:19:1.220 --> 0:19:1.510  
Angela Angle  
Umm.

0:19:2.450 --> 0:19:7.600  
Angela Angle  
And that, yeah, I guess that's clarify. Is it like air like a IR or or how do you spell the company?

0:19:7.570 --> 0:19:11.390  
Andy Avery  
It's. Yeah, it's a EIRTEC.

0:19:13.840 --> 0:19:14.180  
Angela Angle  
OK.

0:19:17.700 --> 0:19:18.720  
Andy Avery  
And they're actually.

0:19:17.240 --> 0:19:19.50  
Angela Angle  
And did they? I guess, yeah.

0:19:20.80 --> 0:19:20.420  
Angela Angle  
Good.

0:19:20.10 --> 0:19:21.200  
Andy Avery  
Yeah, based in the UK.

0:19:23.150 --> 0:19:37.360  
Angela Angle  
And you said they had specialty in the immuno monitoring and inflammatory biomarkers, is that across something that's important for all of your CNS work or is there specific indications that you've worked on that this was really important for?

0:19:38.300 --> 0:19:50.570  
Andy Avery  
I mean, for us, we've primarily we've really been doing inflammatory biomarkers. So that's really the driver for us. But I I believe they offer other, you know types of marker analysis.

0:19:52.470 --> 0:19:52.820  
Angela Angle  
OK.

0:19:54.460 --> 0:20:9.940  
Angela Angle  
Do you know if they, I guess have off the shelf panels that are directly like you're you're directly using those for inflammatory biomarkers or are they offering assay development services that you needed or some of the drugs that you've worked with?

0:20:11.80 --> 0:20:15.120  
Andy Avery  
I I think they have kind of standard panels that they offer.

0:20:15.880 --> 0:20:16.150  
Angela Angle  
Umm.

0:20:17.190 --> 0:20:24.920  
Andy Avery  
And and that we use kind of a the the whole set you know to see what what was this you know we could associate with the clinical condition.

0:20:27.510 --> 0:20:27.800  
Angela Angle  
OK.

0:20:29.560 --> 0:20:35.350  
Angela Angle  
Are there any other companies that you've either evaluated or or used in the past for biomarker testing?

0:20:38.510 --> 0:20:45.110  
Andy Avery  
Nothing coming to mind. I'm trying to remember if we've looked at some of the, you know, any of the bigger CRO or for that.

0:20:45.900 --> 0:20:46.400  
Andy Avery  
Umm.

0:20:48.280 --> 0:20:59.810  
Angela Angle  
Yeah, I think some of the bigger ones that were on your list that we know or at least involved about markers were IQ V or or maybe they're Q2 Q squared division, Covance and Icon.

0:21:0.730 --> 0:21:5.360  
Andy Avery  
Yeah. So we're, we're, we have done some work with the the Q ^2.

0:21:6.220 --> 0:21:6.480  
Angela Angle  
Mm-hmm.

0:21:6.80 --> 0:21:6.790  
Andy Avery  
For.

0:21:8.230 --> 0:21:14.80  
Andy Avery  
If I have that well now it's confusing because there's two companies. There's one, there's the IQVIA Q ^2.

0:21:14.920 --> 0:21:17.650  
Andy Avery  
And there's some. There's another company called.

0:21:19.20 --> 0:21:20.350  
Andy Avery  
22 or something.

0:21:24.620 --> 0:21:25.700  
Andy Avery  
Bear with me a SEC.

0:21:43.650 --> 0:21:45.450  
Andy Avery  
I'm just trying to remember if we're using.

0:21:46.250 --> 0:21:52.50  
Andy Avery  
IQVIA SQ. Square to do, we may have evaluated them for the PK part.

0:21:53.100 --> 0:21:53.380  
Angela Angle  
OK.

0:21:54.600 --> 0:21:58.160  
Andy Avery  
So yeah, I am aware they do biomarkers too, but we just haven't used them.

0:22:1.870 --> 0:22:12.620  
Angela Angle  
I I guess you I did wanna get into some of the PK work, but how overlapping do you view PK testing and biomarker testing? Is this something that?

0:22:13.430 --> 0:22:18.280  
Angela Angle  
I mean, now you're using someone that's specialized more in biomarker testing, but do you see, uh?

0:22:19.410 --> 0:22:22.550  
Angela Angle  
A big advantage in offering both of these capabilities that one company.

0:22:28.300 --> 0:22:35.930  
Andy Avery  
Yeah, I think there's there would be some. I mean, we haven't done that like like I said earlier, we've kind of split them off. But I could see there being some advantages.

0:22:40.820 --> 0:22:41.940  
Angela Angle  
In. Yeah.

0:22:40.640 --> 0:22:44.300  
Andy Avery  
You know to doing both PK and bond market at the same same spot.

0:22:46.120 --> 0:22:56.50  
Angela Angle  
Is that more of like a logistical advantage, or is there typical economic favorability is like to get discounts if you have multiple services done by the same company?

0:22:57.130 --> 0:23:9.990  
Andy Avery  
Yeah, I would think it would be both. It would be a logistical component and there could be a an economic component usually you know we found if we give enough certain amount of volume, we can get some you know some volume discounts.

0:23:11.70 --> 0:23:11.350  
Angela Angle  
Umm.

0:23:10.650 --> 0:23:12.180  
Andy Avery  
Uh, for for the work that we.

0:23:14.160 --> 0:23:29.990  
Angela Angle  
And for the preferred provider agreements are there are actual agreements in place where there's some sort of MSA or or other documents where you may have a three or however many years long contract to do work repeatedly with a company.

0:23:32.330 --> 0:23:47.410  
Andy Avery  
Yes, we have some preferred provider agreements that will specify, hey, we're going to give you this entire program or you know, all the work in a certain, you know, space and and you know, we get some discounts based on that.

0:23:49.270 --> 0:23:52.160  
Angela Angle  
How long do those deals usually last for?

0:23:57.220 --> 0:23:58.830  
Andy Avery  
I would say usually they're in the.

0:23:59.750 --> 0:24:0.390  
Andy Avery  
You know.

0:24:1.380 --> 0:24:8.310  
Andy Avery  
Several years, but not longer than that. You know, they're not like 5 year agreements, but two or three years.

0:24:9.40 --> 0:24:9.840  
Andy Avery  
Like the thanks.

0:24:11.710 --> 0:24:21.790  
Angela Angle  
And is there a more detailed kind of revaluation period after those few years? And I guess how closely are you looking at other companies to potentially switch to?

0:24:23.750 --> 0:24:24.390  
Andy Avery  
So.

0:24:25.380 --> 0:24:43.250  
Andy Avery  
Yeah, I would say, you know it's it's heavily driven by performance. So if we have a vendor, we're having problems with or we think you know and and The thing is there's things can change. You can have a really good experience with a, with a vendor and then they they've got a lot of turnover.

0:24:44.0 --> 0:25:0.410  
Andy Avery  
Or they are moving sites or they merged with another company and so there is even though you have a preferred relationship that can kind of change a bit quickly and so there's always a kind of high level of monitoring of that. And so it's kind of a.

0:25:1.210 --> 0:25:22.620  
Andy Avery  
A regular reevaluation just because you know the the work you're doing is so time critical, important and expensive that you're you're looking at it that way and we we try and have, you know, obviously there's teams on each of the studies and programs. And then we'd like to have overarching governance that were managing the relationship with our, with our providers.

0:25:24.600 --> 0:25:24.840  
Angela Angle  
Umm.

0:25:25.810 --> 0:25:32.540  
Angela Angle  
So I guess for something like bound workers testing, would you have more than one company on this list, or do you just have one preferred?

0:25:33.260 --> 0:25:34.230  
Angela Angle  
Our partner at a time.

0:25:36.70 --> 0:25:42.650  
Andy Avery  
Right now we have a a single preferred provider when when we think about biomarkers and that that's true of PK as well.

0:25:43.960 --> 0:25:44.270  
Angela Angle  
OK.

0:25:45.450 --> 0:25:52.400  
Angela Angle  
And I guess what they're be need is there ever any need for a second or third rider on the list? What would you need that?

0:25:52.270 --> 0:25:59.840  
Andy Avery  
Umm, you know, I think it it probably depends on the scale of your company for. For us as a biotech, there's a lot of value in having.

0:26:0.580 --> 0:26:1.620  
Andy Avery  
Uh, just.

0:26:2.340 --> 0:26:9.620  
Andy Avery  
A single provider in a certain domain so that you know how they work. You know how to look to expect you've got the relationship with them.

0:26:16.180 --> 0:26:16.480  
Angela Angle  
Mm-hmm.

0:26:10.440 --> 0:26:37.170  
Andy Avery  
So just the friction of having you know two or three providers, you know, they'll have their own SOP's around process that that creates work for a smaller company like us that's biotech and fully outsourced for the most part. So we try and get it down to a single vendor to the extent we can that way it's much more intuitive. We know their systems you know how to get them started and they have a monitor them that that type of thing.

0:26:38.0 --> 0:26:38.300  
Angela Angle  
Is it?

0:26:39.740 --> 0:26:40.760  
Angela Angle  
Yeah, that makes sense.

0:26:41.540 --> 0:26:56.700  
Angela Angle  
So you have one vendor for biomarkers, one for PK and then would you have one vendor that handles all the clinical central lab testing and also clinical trial services or is that someone different?

0:26:58.90 --> 0:27:3.710  
Andy Avery  
So we would have we have a central lab that we try and use across trials. So a single provider.

0:27:5.180 --> 0:27:5.550  
Angela Angle  
OK.

0:27:5.710 --> 0:27:7.800  
Andy Avery  
And we did, I remember.

0:27:8.570 --> 0:27:32.720  
Andy Avery  
It's going back four or five years. We we had another one study with a different lab and then you know like when you merge all the data, it's complicated because they have different reference standards. So we we experimented with that one time and kind of didn't like it. So we give all the central labs to a provider and it's not necessarily the labs that necessarily the the the icon or the PPD or their IQ you use.

0:27:35.540 --> 0:27:52.770  
Andy Avery  
So we we typically forced the big clinical CRO to use the providers that we want. So if you know we use you know an ADC vendor, we expect them to use that EDC vendor vendor and for for Central Labs we pre specify who would like to use.

0:27:54.210 --> 0:28:3.300  
Angela Angle  
OK, so one of the largest zeros like icon would be running the trials and instead of relying on either them or one of their preferred.

0:28:4.100 --> 0:28:8.360  
Angela Angle  
Central Lab partners, you would specify the central lab that they should use.

0:28:11.160 --> 0:28:11.470  
Angela Angle  
OK.

0:28:9.110 --> 0:28:25.650  
Andy Avery  
Correct, right. We don't go all in with our the icon and say hey, you can have every aspect, right? We may say, hey, we're going to do the statistics and use one of our two or three crows that we like to do stats with with with labs we we tell them what who who we're going to use.

0:28:26.350 --> 0:28:26.610  
Angela Angle  
Umm.

0:28:27.790 --> 0:28:42.840  
Angela Angle  
Yeah, I guess 1 theme we're trying to understand is how many providers is too many for a relatively smaller or mid sized company and is there from your understanding of of other smaller companies in the space, so they're?

0:28:43.570 --> 0:28:50.670  
Angela Angle  
Is there preference to try to minimize the number of contacts and try to keep everything with one vendor? Or how much flexibility is there to?

0:28:51.430 --> 0:28:58.240  
Angela Angle  
Pick and choose as you're able to do 1 vendor that you prefer for each for a few different categories of work.

0:28:59.350 --> 0:29:10.990  
Andy Avery  
Yeah, that so I guess my question for you talking about the just overall number providers we use, you're talking how many providers do we like to have in a certain space, so how many providers do we want for?

0:29:11.930 --> 0:29:16.960  
Andy Avery  
EDC or clinical monitoring or things like that? Is it more that you're asking?

0:29:18.350 --> 0:29:20.770  
Angela Angle  
Yeah, I guess for a single program.

0:29:21.930 --> 0:29:30.590  
Angela Angle  
Are you comfortable having one vendor for biomarkers, one for PK1, for EDC one for patient recruitment, trial management, Central lab?

0:29:31.480 --> 0:29:34.500  
Angela Angle  
That those kind of individual contact points.

0:29:36.620 --> 0:29:43.150  
Andy Avery  
So yes, we typically like we would have like let's say we take one of our programs. So we have multiple trials.

0:29:43.830 --> 0:29:45.570  
Andy Avery  
Another development activities.

0:30:2.850 --> 0:30:3.140  
Angela Angle  
Mm-hmm.

0:29:46.750 --> 0:30:7.700  
Andy Avery  
We like going with a single clinical monitoring, you know, site startups, monitoring the sites CRO. It's kind of a big CRO, like a icon or QVR PPD or some someone like that. And then we would pre specify the our preferred providers to them.

0:30:8.350 --> 0:30:13.190  
Andy Avery  
For Central Labs, for EDC, for stats.

0:30:14.10 --> 0:30:17.710  
Andy Avery  
It sometimes will let the big zero do the statistics, which it depends.

0:30:18.300 --> 0:30:18.590  
Angela Angle  
Umm.

0:30:20.580 --> 0:30:24.10  
Andy Avery  
Yeah. Again biomarkers, PK, we would pre specify those.

0:30:25.700 --> 0:30:28.830  
Angela Angle  
And then there's the big Zero handle all the.

0:30:30.100 --> 0:30:35.270  
Angela Angle  
I I guess logistics between all the different vendors that you specify or is that something that you handle internally?

0:30:36.820 --> 0:30:47.680  
Andy Avery  
So it's kind of yes to both. I mean we we expect them to coordinate, but we have to you know we hold the contracts with with the central lab.

0:30:48.360 --> 0:30:50.170  
Andy Avery  
So we have to manage it.

0:30:50.970 --> 0:30:53.680  
Andy Avery  
In concert with the with the primary CRO.

0:30:55.750 --> 0:30:56.120  
Angela Angle  
OK.

0:30:57.490 --> 0:30:59.40  
Angela Angle  
So I guess when you, yeah, go ahead.

0:30:57.320 --> 0:31:8.290  
Andy Avery  
It's one of the, you know, potential drawbacks of doing it. The advantage is that, hey, we know the central lab, we know how they work. We've got experience with them. We know their systems. And so we'd like to.

0:31:15.590 --> 0:31:15.870  
Angela Angle  
Umm.

0:31:9.290 --> 0:31:17.360  
Andy Avery  
To go with them, but yeah, it does require additional hand holding if you will because we can't completely defer to the icon. As an example to manage.

0:31:18.410 --> 0:31:18.800  
Angela Angle  
Yeah.

0:31:19.760 --> 0:31:35.570  
Angela Angle  
So I guess for ICON or or other large CRO that offer statistics, central lab services, other things that we've talked about is there just a lack of comfort or experience with their own internal services or I guess what drives the?

0:31:36.500 --> 0:31:42.810  
Angela Angle  
You'd specialize or specify the different vendors for each of these different services for them to work with.

0:31:43.770 --> 0:31:50.990  
Andy Avery  
Yeah, that's it. It's kind of the the, I mean, it sounds good on its face to just go all in, you know and say, hey, you know what?

0:31:52.110 --> 0:31:54.930  
Andy Avery  
Icon or IQVIA just take this entire program.

0:31:55.560 --> 0:31:55.790  
Angela Angle  
Umm.

0:31:55.630 --> 0:32:10.160  
Andy Avery  
But there's always a hesitancy to, especially if we don't have any experience with their stats group, we don't have any experience with their labs. We don't have any experience with it. And so we've we've opted as a biotech to hold on to more control.

0:32:10.910 --> 0:32:11.200  
Angela Angle  
Umm.

0:32:12.160 --> 0:32:18.190  
Andy Avery  
And and also it allows us to to manage the quality. We think a little bit better.

0:32:43.740 --> 0:32:43.990  
Angela Angle  
Umm.

0:32:19.560 --> 0:32:48.200  
Andy Avery  
And so although we have considered programs and we've had zeros come in and pitch and say, hey, we can do it all and use R EDC, you can use RE COA. We'll handle the labs. But ultimately as we go through that RFP process, we almost we we've ultimately ended up pre specifying like I said that a lot of the related vendors and and pick those ourselves. So that that's just the way we.

0:32:48.290 --> 0:32:49.290  
Andy Avery  
We'd like to operate.

0:32:50.500 --> 0:32:56.410  
Angela Angle  
Yeah, that makes sense. Do you know if this is common amongst other small to mid size biotechs?

0:32:57.710 --> 0:33:3.240  
Andy Avery  
I think it's really we we probably we maybe a little bit farther along that than some.

0:33:3.790 --> 0:33:5.760  
Andy Avery  
Uh, small companies, but.

0:33:5.890 --> 0:33:6.190  
Angela Angle  
Umm.

0:33:7.690 --> 0:33:17.500  
Andy Avery  
I think you know, so there's probably biotech companies, a little more comfortable, right, giving more to the to a single CRO than than perhaps we are.

0:33:18.200 --> 0:33:18.450  
Angela Angle  
Mm-hmm.

0:33:20.940 --> 0:33:23.930  
Andy Avery  
And you know my last company, which was bigger?

0:33:24.860 --> 0:33:25.200  
Andy Avery  
We.

0:33:25.870 --> 0:33:33.210  
Andy Avery  
Typically did that too. We we held on to certain things even though we're fully outsourced, we held on to certain.

0:33:34.80 --> 0:33:38.370  
Andy Avery  
Uh, vendors. And so they're ultimately when we outsourced we didn't.

0:33:39.410 --> 0:33:41.730  
Andy Avery  
Typically give it all to 10.

0:33:42.780 --> 0:33:43.210  
Angela Angle  
Yeah.

0:33:44.240 --> 0:33:44.590  
Angela Angle  
OK.

0:33:46.850 --> 0:33:58.720  
Angela Angle  
I did wanna go to some of the PK testing. You mentioned that Q ^2 was was was pretty big in that space. Just curious who else you view as kind of leaders in that testing space?

0:34:4.520 --> 0:34:4.840  
Angela Angle  
OK.

0:33:59.300 --> 0:34:9.350  
Andy Avery  
Yeah. So we've we've used to company called AIT, which is part of Nexelis. What's confusing is it's a Q2 solutions company, but it's not the same as.

0:34:10.590 --> 0:34:11.490  
Andy Avery  
Q ^2.

0:34:11.260 --> 0:34:12.450  
Angela Angle  
Ohh he's great, yeah.

0:34:13.560 --> 0:34:15.90  
Andy Avery  
But it's cute too.

0:34:15.610 --> 0:34:18.830  
Andy Avery  
Umm, so we've we've liked them for PK.

0:34:21.330 --> 0:34:32.90  
Angela Angle  
And do you see overlap with I I guess PK? My understanding is there's a lot of antibody based immuno assays, is there any?

0:34:33.180 --> 0:34:40.670  
Angela Angle  
Noticeable technical overlap with the ability to provide PK services and some proteomics or other biomarker services.

0:34:43.870 --> 0:34:45.610  
Andy Avery  
I don't. I don't know if I can answer that.

0:34:48.570 --> 0:34:48.940  
Angela Angle  
OK.

0:34:48.40 --> 0:34:49.260  
Andy Avery  
You know, you would think the.

0:34:50.250 --> 0:34:50.630  
Andy Avery  
Yeah.

0:34:51.20 --> 0:34:53.510  
Angela Angle  
But you typically view it as kind of a separate activity.

0:34:54.670 --> 0:34:55.940  
Andy Avery  
Yes, we do.

0:34:57.320 --> 0:35:0.290  
Angela Angle  
Are there other activities that you would group with PK?

0:35:1.350 --> 0:35:2.650  
Angela Angle  
That may come from the same vendor.

0:35:9.810 --> 0:35:12.740  
Andy Avery  
Yeah. No. And we usually do it separate.

0:35:14.210 --> 0:35:14.530  
Angela Angle  
OK.

0:35:15.970 --> 0:35:17.120  
Angela Angle  
And for.

0:35:18.930 --> 0:35:22.360  
Angela Angle  
AIT, I guess. What are the?

0:35:23.180 --> 0:35:33.110  
Angela Angle  
Uh, are do they have any technical capabilities or equipment or anything that makes them really strong in this space? Like what led you to select them for a lot of your work?

0:35:35.470 --> 0:35:47.100  
Andy Avery  
So part of it you know is is historically experience and kind of having the also the experience with the methods you know to detect the compound and and the samples you know in blood samples so.

0:35:48.820 --> 0:35:59.810  
Andy Avery  
You know, they already. If we went to the different lab, we have to write transfer and make sure all the methods are kind of revalidated. There's a transfer process, so a little bit of.

0:36:0.650 --> 0:36:1.930  
Andy Avery  
Historical.

0:36:3.450 --> 0:36:14.180  
Andy Avery  
Precedent for for using them. And then yeah, just a lot of it's, you know, being comfortable with timelines too. We had, we were gonna do some some analytics that.

0:36:14.290 --> 0:36:20.500  
Andy Avery  
Umm. At another CRO and they were balking at the the.

0:36:21.660 --> 0:36:25.610  
Andy Avery  
Did it? They weren't gonna be able to do it. And as quickly as we had planned.

0:36:27.220 --> 0:36:27.480  
Angela Angle  
Umm.

0:36:28.530 --> 0:36:33.730  
Angela Angle  
So do you have a lot of the same assays that are transfers are used across multiple programs then?

0:36:35.270 --> 0:36:41.870  
Andy Avery  
Yeah. Yeah. Because we're doing a lot with a single molecule. So a lot of the methods are related to that.

0:36:43.870 --> 0:36:51.960  
Angela Angle  
OK, how often do you need to either transfer in new assays or or have your partner develop new essays for you?

0:36:54.250 --> 0:36:55.160  
Andy Avery  
How often?

0:36:56.170 --> 0:36:58.370  
Andy Avery  
It hasn't been very, very often for us.

0:37:1.650 --> 0:37:1.920  
Andy Avery  
Yeah.

0:36:59.980 --> 0:37:5.570  
Angela Angle  
OK, so there's a lot of tests that you can use repeatedly across programs then.

0:37:6.320 --> 0:37:7.450  
Andy Avery  
Yeah, you got it.

0:37:9.470 --> 0:37:29.80  
Angela Angle  
With I guess I guess one capability that we we're looking at is just that ability to do acid development, develop new assays on a reasonable timeline. And is this an important feature in your opinion on choosing a CRO or do you typically have the essays in house and it's just a matter of transferring them over?

0:37:35.870 --> 0:37:40.620  
Andy Avery  
So we would usually be transferring from lab to lab as opposed to having them in house.

0:37:42.40 --> 0:37:42.430  
Angela Angle  
OK.

0:37:46.760 --> 0:37:48.360  
Angela Angle  
OK, that sounds.

0:37:51.40 --> 0:37:53.330  
Angela Angle  
Let me just look at my other questions.

0:37:55.850 --> 0:38:1.990  
Angela Angle  
I guess of the the vendors that we've talked about for biomarker and PK testing, are there any?

0:38:2.710 --> 0:38:5.40  
Angela Angle  
New offerings or?

0:38:5.910 --> 0:38:16.210  
Angela Angle  
I guess new services that these companies are are trying to advertise either within the scope of services that they're already offering or a JSON services that they're seem to be moving into.

0:38:17.500 --> 0:38:23.100  
Andy Avery  
I'm not. I'm sure there are, but not that I've been, you know, kind of pitched or aware of and and recently.

0:38:24.720 --> 0:38:25.200  
Angela Angle  
OK.

0:38:44.470 --> 0:38:44.860  
Andy Avery  
Mm-hmm.

0:38:25.990 --> 0:38:45.670  
Angela Angle  
And do you see, I guess for a biomarker CRO, are there any services, I mean we talked about Central lab kind of being separate, the PK being separate, curious about other activities, other ones that we're thinking of include imaging services and logistics.

0:38:53.160 --> 0:38:53.690  
Angela Angle  
Yeah.

0:38:49.200 --> 0:38:54.0  
Andy Avery  
Your question is, would it make sense for those to be combined like a lab that could offer both?

0:38:55.230 --> 0:38:55.660  
Angela Angle  
Yeah.

0:38:54.720 --> 0:38:55.800  
Andy Avery  
Yeah, I would think so.

0:38:56.900 --> 0:38:57.200  
Andy Avery  
Yeah.

0:38:59.560 --> 0:39:1.250  
Angela Angle  
And I guess on the imaging side.

0:39:1.930 --> 0:39:2.250  
Angela Angle  
What?

0:39:3.350 --> 0:39:10.880  
Angela Angle  
I guess what zero would typically handle this work? Is it the the same large company that's running your clinical trials, or is it the central lab provider?

0:39:13.880 --> 0:39:16.830  
Andy Avery  
So I haven't done any imaging work recently.

0:39:17.520 --> 0:39:26.220  
Andy Avery  
Umm yeah, I guess we'd initially turn to the big CRO to see if they can do it. Unless it was such like a niche type of thing that you had to go to a.

0:39:31.920 --> 0:39:32.240  
Angela Angle  
Mm-hmm.

0:39:27.70 --> 0:39:33.560  
Andy Avery  
I I don't know if you're doing like pet scans or something or or something that you have to go to a specific vendor for.

0:39:35.830 --> 0:39:43.690  
Angela Angle  
OK, so something general imaging is typically offered by the largest heroes, but if it's something very specific to your.

0:39:44.470 --> 0:39:48.500  
Angela Angle  
Disease area or indication. Then you may have to go to a specialty provider.

0:39:49.340 --> 0:39:50.380  
Andy Avery  
Yeah, yeah.

0:39:51.780 --> 0:39:55.470  
Angela Angle  
OK. And then on the logistics side, would this be?

0:39:57.90 --> 0:39:59.780  
Angela Angle  
I guess transport of samples from the.

0:40:0.440 --> 0:40:7.900  
Angela Angle  
The trial collection sites and to the the bowel marker 0. Or is this something else that you're thinking of?

0:40:12.40 --> 0:40:16.70  
Andy Avery  
Say that again, you're asking about the sample, how the samples flow.

0:40:16.910 --> 0:40:21.80  
Angela Angle  
Yeah. Is that what you think about in terms of logistics offerings or there other?

0:40:22.760 --> 0:40:35.870  
Angela Angle  
Things, I mean kidding, of reagents and materials for trials. That is something that I think is considered under logistics, but curious if it's just kind of the sample management that is most relevant here.

0:40:40.950 --> 0:40:41.980  
Andy Avery  
Yeah, I mean we.

0:40:43.130 --> 0:40:56.580  
Andy Avery  
I imagine there could be some. You know, we we kind of take all the samples at the site, they all go central and then they get they can get distributed out like PK and biomarkers then go out to another lab. So there could be some you know.

0:40:57.380 --> 0:41:1.960  
Andy Avery  
Logistical capabilities that could be advantage of, you know, not having to go through.

0:41:2.790 --> 0:41:4.420  
Andy Avery  
As many steps as I suppose.

0:41:6.90 --> 0:41:6.370  
Angela Angle  
Umm.

0:41:7.870 --> 0:41:14.120  
Angela Angle  
And then right now I guess how is sample management handled for your biomarker and PK providers?

0:41:18.190 --> 0:41:25.140  
Andy Avery  
So that you know the we'll get collected at the site and at and they may be stored there for a.

0:41:26.280 --> 0:41:29.540  
Andy Avery  
Shorter period of time they go into the central lab.

0:41:30.890 --> 0:41:41.200  
Andy Avery  
And then they're batched out to the PK provider or the biomarker provider. So it could be monthly, it could be quarterly or it could be a, you know, certain.

0:41:44.950 --> 0:41:45.210  
Angela Angle  
Umm.

0:41:42.320 --> 0:41:45.870  
Andy Avery  
Time point that we send them out, but they're usually sent out in batch.

0:41:47.940 --> 0:41:50.620  
Angela Angle  
OK. So then there's the central lab.

0:41:51.160 --> 0:41:54.270  
Angela Angle  
Umm, partner, do the logistics.

0:41:55.150 --> 0:41:57.10  
Angela Angle  
Provide the logistics services for that then.

0:41:55.530 --> 0:41:58.350  
Andy Avery  
Yes, exactly. Yeah.

0:41:58.130 --> 0:41:58.430  
Angela Angle  
OK.

0:41:59.570 --> 0:42:8.810  
Andy Avery  
Yeah. So they provide all the kits to the site and the different, you know, we'll have a lab manual and they kind of handle, they all the logistics of centralized with them.

0:42:9.650 --> 0:42:16.800  
Angela Angle  
Umm, so they also do the the storage of samples while you wait for the next batch to be ready for testing.

0:42:17.900 --> 0:42:18.450  
Andy Avery  
Yes.

0:42:20.290 --> 0:42:21.910  
Angela Angle  
OK, makes sense.

0:42:22.280 --> 0:42:39.560  
Andy Avery  
Right. So they go from the site to the they can be stored at the site for a period of time. They may they are it every month. We're gonna send samples in and then they're centrally stored at the central lab and then they will batch them out for PK to a lab and then a different lab. Go batch them out for biomarkers.

0:42:41.370 --> 0:42:42.560  
Angela Angle  
OK, got it.

0:42:46.960 --> 0:42:47.390  
Andy Avery  
Ohh.

0:42:44.630 --> 0:42:56.330  
Angela Angle  
Next I wanted to get into, I guess some pricing estimates and understanding that there could be a pretty big range between programs and in terms of what?

0:42:57.210 --> 0:43:19.410  
Angela Angle  
Umm. Biomarker testing needs there are just wanted to try to get estimates on how much I I guess if you could offer any like per program or per patient how much it may cost on average to in I guess the CNS space to perform the full array of biomarker testing excluding Central Lab and PK?

0:43:25.300 --> 0:43:29.40  
Andy Avery  
Yeah, I'm trying to remember if I know the cost.

0:43:30.970 --> 0:43:34.100  
Andy Avery  
Per sample, I mean I know these are, you know.

0:43:36.900 --> 0:43:37.890  
Andy Avery  
Typically for.

0:43:38.820 --> 0:43:45.730  
Andy Avery  
If I remember correctly, for like a trial and a set of biomarker testing for that trial, it was.

0:43:46.430 --> 0:43:57.550  
Andy Avery  
I half $1,000,000 you know because you get a lot of samples and you do the whole panel of assessment and that includes the analysis and and report writing.

0:43:58.510 --> 0:43:58.770  
Angela Angle  
Umm.

0:43:59.960 --> 0:44:1.210  
Andy Avery  
I don't know how helpful that is.

0:44:0.70 --> 0:44:5.710  
Angela Angle  
Is it for like an earlier stage trial or a later like turned understand the the number of patients and scale?

0:44:12.780 --> 0:44:13.460  
Andy Avery  
So.

0:44:14.580 --> 0:44:17.310  
Andy Avery  
Yeah. For one of our phase threes.

0:44:18.260 --> 0:44:21.10  
Andy Avery  
I'm trying to remember how big that study was.

0:44:22.740 --> 0:44:28.350  
Andy Avery  
Maybe a few 100, but yeah, I think it was half $1,000,000 to do the the biomarker assessment.

0:44:30.160 --> 0:44:30.570  
Angela Angle  
OK.

0:44:33.730 --> 0:44:35.200  
Andy Avery  
I just. I don't know.

0:44:32.80 --> 0:44:35.450  
Angela Angle  
And do you have a sense for, I guess a good?

0:44:36.410 --> 0:44:38.610  
Andy Avery  
No, just sorry, I don't know the cost like per.

0:44:39.350 --> 0:44:42.980  
Andy Avery  
Like per sample or I just don't have that on the top of my head.

0:44:45.550 --> 0:44:45.770  
Andy Avery  
Yeah.

0:44:44.80 --> 0:44:47.950  
Angela Angle  
Yeah, that's alright. The the overall trial cost is is helpful.

0:44:48.900 --> 0:44:51.980  
Angela Angle  
And I guess if you compare like a late stage.

0:44:52.480 --> 0:45:5.670  
Angela Angle  
Umm, cost per trial in an early stage. Are they comparable? Are you doing more tests per patient at the early stage? That may drive a pricing even though there's less patients in those studies.

0:45:7.140 --> 0:45:10.970  
Andy Avery  
Yeah, we might do more if we're doing some more exploratory stuff.

0:45:11.470 --> 0:45:26.870  
Andy Avery  
Umm but yeah, I would think that the actual sample analysis interpretation, reporting would be would be the same be a function of the number of patients, number of samples, but you you could potentially be doing more. Excuse me more early.

0:45:27.880 --> 0:45:28.200  
Angela Angle  
Mm-hmm.

0:45:29.430 --> 0:45:29.840  
Angela Angle  
OK.

0:45:30.970 --> 0:45:31.690  
Angela Angle  
Are there?

0:45:30.770 --> 0:45:32.810  
Andy Avery  
Because if we're doing some explorer, yeah.

0:45:33.110 --> 0:45:50.500  
Angela Angle  
Yeah. Are there any specific tests or or types of tests? I mean, going back to the immune monitoring flow cytometry versus proteomics versus genomics versus Histology tests that are a lot more expensive than the other types of tests, like what drives a lot of the pricing.

0:45:53.760 --> 0:46:3.100  
Andy Avery  
Yeah, I don't. I don't have very in-depth knowledge of that. I would think some of the genomic stuff might be more pricey, but I I just don't have any direct experience with it.

0:46:4.420 --> 0:46:20.910  
Angela Angle  
OK. And I guess for pricing, is this, how does the price typically calculated it? Does the provider think about all the different individual tests and they have some internal price per each test that's offered or is there some sort of?

0:46:21.620 --> 0:46:24.390  
Angela Angle  
Bundle of groups of tests together.

0:46:27.300 --> 0:46:36.250  
Andy Avery  
Yeah. So they would typically take the, the, the number of samples they would expect and whatever the kind of.

0:46:37.140 --> 0:46:45.930  
Andy Avery  
Uh platform analysis they're doing and it would be a multiplication of that, you know, plus what they charge charge for that. And that's what would drive the price.

0:46:46.880 --> 0:46:47.250  
Angela Angle  
Umm.

0:46:48.780 --> 0:46:59.850  
Angela Angle  
And it's the. Is there kind of a a flat fee for each test for the analysis and report generation or is that kind of built into like this is the price per sample that you're paying?

0:47:3.940 --> 0:47:11.210  
Andy Avery  
So yeah, that would be the samples, the number of markers and then usually they would have a discrete cost for.

0:47:12.620 --> 0:47:14.20  
Andy Avery  
The the report writing.

0:47:16.180 --> 0:47:16.460  
Angela Angle  
OK.

0:47:16.520 --> 0:47:18.870  
Andy Avery  
Usually the reports tend to be, you know.

0:47:19.820 --> 0:47:21.950  
Andy Avery  
6070 thousand dollars.

0:47:22.750 --> 0:47:23.740  
Andy Avery  
Seems to be.

0:47:25.410 --> 0:47:29.840  
Andy Avery  
Across all reports seems to be in the ballpark of what what's what it costs.

0:47:31.790 --> 0:47:36.130  
Angela Angle  
Ohh across uh each different test that they're analyzing.

0:47:34.710 --> 0:47:48.940  
Andy Avery  
Yeah, even just seems to matter what even just like in different domains. Like if you're asking a Co to write up a a CSR report, it seems to be in the sixty $70,000 range and that's that. I do remember from.

0:47:50.380 --> 0:47:57.580  
Andy Avery  
The built into the class would be the report writing, you know sixty $70,000 for the report, so that plus the.

0:47:58.660 --> 0:48:6.90  
Andy Avery  
In the analytics, which is a function of the the panel number of markers you're testing for and the number of samples they expect to receive in total.

0:48:7.380 --> 0:48:8.270  
Angela Angle  
OK, got it.

0:48:9.320 --> 0:48:24.550  
Angela Angle  
Does the cost change at all or significantly across different geographies that you're running the clinical trials or having the testing performed like if you had the lab in Europe or the US or in Japan?

0:48:27.750 --> 0:48:38.720  
Andy Avery  
I mean it, wouldn't we? We would all the samples would flow centrally and then go to the lab. So I don't think it'd be a function of what countries would were including in the in the study.

0:48:39.640 --> 0:48:39.920  
Angela Angle  
Umm.

0:48:40.870 --> 0:48:43.900  
Andy Avery  
And yeah, I imagine there could be.

0:48:44.800 --> 0:48:46.480  
Andy Avery  
If there's labs and lower costs.

0:48:47.350 --> 0:48:49.350  
Andy Avery  
You know geographies that could make a difference.

0:48:49.930 --> 0:48:54.0  
Andy Avery  
Mom, but we especially with biomarkers, I mean we'd be a little more.

0:48:55.570 --> 0:49:1.790  
Andy Avery  
Yeah. Again, maybe there's some big form the companies doing so many assessments and be a little different, but we, you know, we would typically be.

0:49:2.660 --> 0:49:8.450  
Andy Avery  
Focus more on, you know, confidence in the quality and the and the timeliness of doing the the assays.

0:49:10.210 --> 0:49:10.530  
Angela Angle  
Yeah.

0:49:11.750 --> 0:49:28.820  
Angela Angle  
When you were evaluating different, uh zeros to use for biomarker services, did you see a big range in pricing for the same tests like your inflammatory marker test? Is this similarly priced across EUR or or how much variation is there?

0:49:30.960 --> 0:49:36.330  
Andy Avery  
There was some variation, but not dramatic. If you know if you're comparing apples to apples.

0:49:38.60 --> 0:49:42.480  
Angela Angle  
So there be like 1020% difference or just just ballpark estimate?

0:49:42.40 --> 0:49:44.340  
Andy Avery  
Yeah. I think umm, yeah.

0:49:45.580 --> 0:49:45.970  
Angela Angle  
OK.

0:49:46.920 --> 0:49:47.490  
Angela Angle  
That's awful.

0:49:50.460 --> 0:50:4.280  
Angela Angle  
And then just going back to stage of development, do you have a sense for like a you mentioned that the half a million for a late stage trial, would it still be about half a million for an early phase trial or more or less than that?

0:50:6.50 --> 0:50:9.690  
Andy Avery  
I would think it would be comparable because it's still samples and.

0:50:10.500 --> 0:50:18.310  
Andy Avery  
And the number of tests. So it's not cheaper because the studies earlier you just have less patience and less samples.

0:50:20.0 --> 0:50:26.310  
Angela Angle  
So the the fewer samples is offset by an increased number of tests to get you about the same pricing.

0:50:27.90 --> 0:50:34.170  
Andy Avery  
Ohh yeah. Well yeah, would be left in that. You know it is a function of the the patient side. So you know if you're doing.

0:50:34.900 --> 0:50:43.470  
Andy Avery  
150 you know, subjects in a phase two and we're doing biomarkers that would cost less than a late stage trial that might have 400 patients.

0:50:44.750 --> 0:50:52.260  
Angela Angle  
OK. So primarily driven by patient size rather than test per patient?

0:50:55.300 --> 0:51:12.320  
Andy Avery  
Yeah. So that you could see a scenario where in phase two, maybe you're doing a little bit more right to see what where you might have an effect and then you might truncate that down in your light stage trial maybe say, hey, we're only going to do these tests versus these tests because we didn't see a an association.

0:51:14.270 --> 0:51:24.360  
Angela Angle  
OK. But it sounds like that truncation of tests is a. Is that a smaller impact on the price than just the number of samples, the number of patients that you're working with?

0:51:26.690 --> 0:51:37.210  
Angela Angle  
I guess we're just trying to understand like if you have one patient from a phase one trial and one patient from a phase three trial, are you spending more on that per patient?

0:51:37.920 --> 0:51:47.10  
Angela Angle  
Like twice as much more per patient in phase one. Or is it maybe 20 or 30% more per patient because you're not eliminating that many tests as you move on?

0:51:48.100 --> 0:51:50.920  
Andy Avery  
Yeah, it's probably more than the 20.

0:51:51.540 --> 0:51:54.450  
Andy Avery  
20 ish percent range as opposed to being like you know.

0:51:55.330 --> 0:51:57.250  
Andy Avery  
Double. You know, we're half.

0:51:58.160 --> 0:52:0.30  
Angela Angle  
OK. Yeah. No, that that's really helpful.

0:52:0.160 --> 0:52:1.120  
Andy Avery  
Right. OK.

0:52:1.620 --> 0:52:1.860  
Angela Angle  
Yep.

0:52:3.860 --> 0:52:24.510  
Angela Angle  
Are there any specific tests within biomarkers that are kind of more commoditized or like simple to get elsewhere or perform internally that you may not be willing to spend as much money on or is it, are you really evaluating the whole package of biomarker testing provided from a single vendor?

0:52:26.280 --> 0:52:31.40  
Andy Avery  
That's more the whole package. And again we we wouldn't have the capacity to do any of that internally.

0:52:32.490 --> 0:52:32.810  
Angela Angle  
OK.

0:52:34.480 --> 0:52:34.820  
Angela Angle  
Got it.

0:52:36.910 --> 0:52:49.980  
Angela Angle  
And then one more question on the pricing contract structure. When you have an agreement to do say a phase three trial and you're gonna have X number of patients doing this menu of tests.

0:52:50.870 --> 0:53:2.880  
Angela Angle  
How much, if any, of the payment is given to the zero before the testing begins? Kind of like the a startup fee, or I don't know if there's some sort of milestone based contract that's used.

0:53:5.520 --> 0:53:10.30  
Andy Avery  
Uh, yeah. Usually it's, yeah, somewhere around 10% upon signature.

0:53:10.870 --> 0:53:11.150  
Angela Angle  
Umm.

0:53:11.640 --> 0:53:25.80  
Andy Avery  
And then you know, it could be a again depends on the bulk of samples and how spread out is it over time, but it could be you pay the bulk of it upon you know delivery of the.

0:53:26.300 --> 0:53:26.710  
Andy Avery  
The.

0:53:47.140 --> 0:53:47.430  
Angela Angle  
Mm-hmm.

0:53:27.680 --> 0:53:52.360  
Andy Avery  
You know, kind of raw data from all the samples or it could be you know that could be chunked out. You know if it's a huge number and if it's over you know 12 months they're going to receive them, it might be you know three payments. So the bulk of it is in the around the sample analysis that usually 1015% up front and then on the back end as the report writing. So you pay out the final balance once you get the report.

0:53:54.190 --> 0:53:55.650  
Angela Angle  
OK. That makes sense.

0:53:57.300 --> 0:54:4.220  
Angela Angle  
And one other, I guess moving on from presence in the last couple minutes, I had one other adjacency area to ask about.

0:54:4.980 --> 0:54:20.170  
Angela Angle  
UM, actually maybe at two if we have time. One is rather than doing biomarker testing for preclinical and clinical stages studies, is there benefit in using?

0:54:22.110 --> 0:54:35.60  
Angela Angle  
Like air tech or or some other biomarker company to help you do biomarker discovery in the earlier R&D phase or do any sort of testing and before preclinical?

0:54:37.950 --> 0:54:43.380  
Andy Avery  
Probably hard for me to answer just because we're not doing any any discovery work currently.

0:54:44.150 --> 0:54:45.560  
Angela Angle  
Umm OK.

0:54:45.950 --> 0:54:51.140  
Andy Avery  
So we're just, we don't have any, you know, ongoing work that early that I could really comment.

0:54:55.30 --> 0:54:55.460  
Andy Avery  
Yeah.

0:54:52.910 --> 0:55:9.600  
Angela Angle  
OK, no problem. And then the other area is CMC testing for like analyzing batches produced of drug produced either drug substance or drug product for use in preclinical or clinical trials.

0:55:10.550 --> 0:55:11.740  
Angela Angle  
Is that something that's?

0:55:12.870 --> 0:55:23.660  
Angela Angle  
Typically handled by any of the zeros that we've talked about offering any other clinical services or is this handled by the drug manufacturer or completely separate 0 for this?

0:55:24.780 --> 0:55:30.70  
Andy Avery  
You're talking about like stability testing and acceptance testing.

0:55:33.20 --> 0:55:33.420  
Andy Avery  
Umm.

0:55:28.310 --> 0:55:33.500  
Angela Angle  
Yeah, stability. Impurity. Yeah. Contaminants. Stuff like that, yeah.

0:55:36.760 --> 0:55:41.70  
Andy Avery  
Yeah, we would use, you know, typically rely on the CMO to that.

0:55:42.750 --> 0:55:44.940  
Angela Angle  
OK. And the CMO?

0:55:47.290 --> 0:55:47.550  
Angela Angle  
Mm-hmm.

0:55:43.920 --> 0:55:50.10  
Andy Avery  
Trying to think if we have it at lab to to to to do any of the analytics testing.

0:55:50.480 --> 0:55:51.0  
Andy Avery  
Umm.

0:55:53.500 --> 0:55:58.90  
Angela Angle  
Does the CMO do it themselves or do they outsource to a different company?

0:55:59.220 --> 0:56:6.340  
Andy Avery  
I think it's some of both. Some CMO's do it themselves. Sometimes they outsource, sometimes we also have a third party lab I think to.

0:56:7.30 --> 0:56:9.380  
Andy Avery  
Confirm what? What's happening?

0:56:10.230 --> 0:56:10.540  
Angela Angle  
Mm-hmm.

0:56:12.90 --> 0:56:12.520  
Angela Angle  
OK.

0:56:12.840 --> 0:56:14.180  
Andy Avery  
It's kind of a combination there.

0:56:15.80 --> 0:56:27.640  
Angela Angle  
Yeah. And then one final clarification on the report generation and data analysis for biomarkers. Is this something that is always done by the CRO or when and what situations would you do the analysis yourself?

0:56:29.500 --> 0:56:31.570  
Andy Avery  
Uh, we wouldn't. We would have them do it.

0:56:32.390 --> 0:56:35.990  
Andy Avery  
Do the analysis, write the report and we typically will.

0:56:36.660 --> 0:56:48.890  
Andy Avery  
You know right protocols and we'll certainly review and and comment and obviously sign off on the on the reports, but we rely on the biomarkers here wrote to to write it all up for us.

0:56:50.10 --> 0:56:55.750  
Angela Angle  
Would they ever need a second zero to do any of the analysis, or is this something that they have in house?

0:56:57.100 --> 0:56:58.990  
Andy Avery  
Yeah, I wouldn't think so, no.

0:56:59.730 --> 0:57:0.100  
Angela Angle  
OK.

0:57:0.810 --> 0:57:1.110  
Angela Angle  
Great.