**ProjectXYZ - Clinical Trials Biomarker Testing - CompanyABC**

0:0:0.0 --> 0:0:7.960  
Cody Sole  
Where to start off? Would you mind sharing a little bit about your professional background and any experience related to biomarker testing?

0:0:9.370 --> 0:0:40.20  
Penny Nichols  
Yeah, yeah. You know, I currently laid a biomarkers and Banalis team at a startup biotech company called Azure Biotherapeutics, mainly focusing on developing immunotherapies across a variety of oncology indications. I have previously held a biological or biomarker role for a couple of gene therapy companies developing AV for CNS metabolic cardiovascular disorders, mainly before that. I've also worked at a large molecule banners CRO badge latex.

0:0:40.500 --> 0:0:52.550  
Penny Nichols  
Primarily managing or the GXP by analysis, that also includes biomarkers for a variety of modalities. So so about, I would say six years of experience totally and GXP biomarker and by analysis setting.

0:0:53.360 --> 0:0:55.170  
Penny Nichols  
Still in molecular biologist by training.

0:0:57.60 --> 0:1:5.990  
Penny Nichols  
You know, mainly focused on developing of assets or platforms for biomarkers, PK and you manage in statement of drug development.

0:1:9.390 --> 0:1:16.410  
Cody Sole  
Perfect. And just focus on the modal, you mentioned gene therapy. Are there any other modalities that you have experienced with?

0:1:17.590 --> 0:1:23.280  
Penny Nichols  
Yeah, you monotherapy. So that includes monoclonal antibodies and recombinant proteins or many primary.

0:1:24.520 --> 0:1:26.610  
Penny Nichols  
Immune related cytokines and chemokines.

0:1:28.470 --> 0:1:28.790  
Cody Sole  
Got it.

0:1:29.780 --> 0:1:42.590  
Cody Sole  
Perfect. Thanks for explaining that. And within your role in Bioagilytix S, is that some sort of overseeing the program or you actually doing some hands on work of the testing?

0:1:43.680 --> 0:2:13.830  
Penny Nichols  
It's a. It's a. It's a kind of combination of things. I was a manager of biological operations there where I had a team primarily, you know, taking in the projects for companies such as AstraZeneca, you know, Agenus, gillier for immunotherapies and a lot of a bunch of different startup biotech companies focusing on gene therapies, right where they outsource the work to the CRO to do, to develop any potential biomarkers that they have researched on. So that it's our job is to.

0:2:13.900 --> 0:2:33.340  
Penny Nichols  
Ohh, adopt the platform and develop that assay to truly quantify that by marker along the same lines. So since we're doing the biomarkers, you know I was also focused on doing PK any minute density acid development for the same programs or for the same sponsors. So I've worked with a variety of sponsors when I was advised you take some.

0:2:34.0 --> 0:2:49.850  
Penny Nichols  
That includes some. Like I said, the likes of Ashley Denica, Gilead or even Genentech to some extent. And also the really small startup biotech companies. And then as you can tell my experience, I took that experience to small by the companies to kind of see the other side of things.

0:3:6.40 --> 0:3:6.550  
Penny Nichols  
Yeah.

0:2:51.790 --> 0:3:15.340  
Cody Sole  
That's perfect. And I wonder when you work on the CRO sides, what what are the different in terms of when it's a large pharma sponsor versus a small bowl tech sponsor other you know one prefer one stop shop covering all them and testing in just within your CRO or other special needs from either?

0:3:16.630 --> 0:3:22.460  
Penny Nichols  
Yeah, yeah. I mean definitely, you know, the IT goes without saying that the large, large companies.

0:3:23.150 --> 0:3:55.680  
Penny Nichols  
Of the usually already have, you know, identified a by, you know, just talking about biomarkers, right? They have already identified a biomarker. They are they most likely would also already identify a platform and as a that they wanna pursue or a model that they wanna pursue. So they most probably have also developed it or qualified it in House because they have that they would have that resources right and then they usually come to CRO for validating it you know under GLP or GCLP compliance so that they can use it.

0:3:56.140 --> 0:4:17.190  
Penny Nichols  
For, you know, at least as a primary or secondary endpoint in their in clinical trial and if they wanna use it for enrollment purposes, then they have to, you know look for CRO that have a clear CAP compliant or testing labs. And if they don't have any off the shelves as in place then they you know they they contract it out there.

0:4:17.930 --> 0:4:25.100  
Penny Nichols  
Offer, on the other hand, small or start a body company side. They usually don't have enough in house resources or labs or personnel, right?

0:4:25.790 --> 0:4:27.70  
Penny Nichols  
So they usually go.

0:4:27.800 --> 0:4:58.990  
Penny Nichols  
So Seattle saying that, hey, this is the indication and this is these are the couple of biomarkers that we have identified have been useful in based on the preclinical studies or based on the research that is out there on this particular disease right. And then it comes it's up to the Seattle in in my case it's up to me to kind of suggest what kind of platforms we have experience using right like for example quintrex or MSD or even simple ELISA assay, right? And then they'll make the decision of using.

0:4:59.100 --> 0:5:28.730  
Penny Nichols  
Of the you know, the the little make addition of either evaluating the early feasibility of you know, trying to test out these different platforms and gives which one gives the best sensitivity and go with that or you know they they they they can already make a decision of let's say saying we're going with the what is available out there on this platforms and then choose one particular platform to go forward and validate that particular assay with respect to a particular platform. So that kind of decision making or.

0:5:29.100 --> 0:5:31.470  
Penny Nichols  
Kind of discussions, I'll go through between.

0:5:32.290 --> 0:5:35.790  
Penny Nichols  
Large Monica, also large, but by the companies with a small buttocks.

0:5:36.660 --> 0:5:38.820  
Penny Nichols  
And then there is made made size biotech, right?

0:5:39.570 --> 0:5:51.520  
Penny Nichols  
Nicholas. But it's are usually they follow the same path as last partex they usually they they're they're more likely to outsource the work like large parties rather than a small partech.

0:5:56.120 --> 0:5:56.760  
Penny Nichols  
And one more.

0:5:53.140 --> 0:5:58.200  
Cody Sole  
Gotcha. Thanks for the explanation. That's helpful. I I wonder a lot. Sorry. Yeah, go ahead.

0:5:58.80 --> 0:6:7.840  
Penny Nichols  
Sorry, one more thing I wanna add you know, having said all of this, right, there's always the caveat to it, but if there is if if it is something you could particular company is working on a novel modality, right.

0:6:9.520 --> 0:6:37.490  
Penny Nichols  
And and you know the last companies, usually they don't like to outsource those that kind of work because it's a novel modality. They wanna kind of, you know, keep the books closed as much as they could. So they only go to the CRO for usually phase three or studies or larger studies in their clinical trials. So they'll they'll try to hold up as much as they could and then you know, at that time they'll just transfer the assay to Seattle's for testing for larger, you know, patient.

0:6:37.930 --> 0:6:38.700  
Penny Nichols  
Those samples.

0:6:39.520 --> 0:6:45.570  
Penny Nichols  
So that that that's always a you know the the the the modality is is definitely a big factor.

0:6:46.290 --> 0:6:50.890  
Penny Nichols  
Uh, you know at what stage these companies can outsource the work to CRO's.

0:6:51.690 --> 0:7:8.10  
Penny Nichols  
And and and the other thing is also the if if a particular company is performing a global clinical trial right, that can also dictate them also seem to CR's earlier than later. So there are couple of caveats to the discussion that we just had.

0:7:9.150 --> 0:7:18.700  
Cody Sole  
Yes. Well, thanks for bringing up. That's actually my full question on, you know, when you say noble modalities, what are you specifically referring to?

0:7:20.580 --> 0:7:51.540  
Penny Nichols  
I mean gene therapies, right or or gene therapist is something that we can send our modality is obviously a money based therapeutics now is essentially what's happening in the industry that there is there is some flexibility for for you to keep your books closed as much as you can and not really talk about the work until it's almost ready to until you have confidence in it right from a sponsored standpoint and then you can talk about it in the conferences or outsource it to Seattle.

0:7:51.660 --> 0:8:7.270  
Penny Nichols  
Kind of open the gates so that the world can see what, what, what they've been up to. So that kind of strategic kind of goes into how the work is outsourced to seattles or or the OR the word, what is being spread out outside of a particular company, right?

0:8:7.970 --> 0:8:8.860  
Cody Sole  
Right and.

0:8:8.160 --> 0:8:8.860  
Penny Nichols  
We see that all.

0:8:10.900 --> 0:8:11.610  
Penny Nichols  
Yeah, go ahead.

0:8:12.380 --> 0:8:24.160  
Cody Sole  
Sorry. Yeah, just focused on the say, no modality. Should gene therapy, do you see the needs of potential expanding to CMC testing and all sorts to just one CRO if that zero has that capability?

0:8:25.710 --> 0:8:31.680  
Penny Nichols  
Yeah, see, so when you talk about CMC testing, right, usually it falls within the.

0:8:33.310 --> 0:9:3.340  
Penny Nichols  
We didn't within a city. Umm, OK, we did not. Essentially within Seattle Capability, Seattle CS. So certain assets that are CDM opened up provide the you know the sponsor can decide to take that assay to CRO like bio assays right or biological potency assess you know we call it so those are the kind of things that go outside of a particular CDMO but usually you you know any sponsor right it doesn't matter whether it's a large biotech or small biotech whether you do in house manufacturing or.

0:9:3.430 --> 0:9:11.530  
Penny Nichols  
You know, outsource manufacturing to CDMO. If you try to keep your overall processes in one place when it comes to manufacturing side of things.

0:9:12.690 --> 0:9:17.480  
Penny Nichols  
So the only app is that that that go to CRO are usually.

0:9:19.550 --> 0:9:24.270  
Penny Nichols  
The biological potency assays, so which are usually based on either a cell based.

0:9:25.0 --> 0:9:27.30  
Penny Nichols  
A models or animal based models.

0:9:28.820 --> 0:9:29.70  
Cody Sole  
God.

0:9:29.150 --> 0:9:37.790  
Cody Sole  
Yeah, that makes sense. And then for the other more simpler safety or contamination testing, you were just outsourced to receive Amos.

0:9:38.520 --> 0:9:50.750  
Penny Nichols  
Yeah, City MC most usually. I mean, you know, if if I'm outsourcing my manufacturing to a CDMO and if they cannot provide me a proper, you know, purity identity.

0:9:59.430 --> 0:9:59.780  
Cody Sole  
Hmm.

0:10:20.350 --> 0:10:20.590  
Cody Sole  
Umm.

0:9:51.930 --> 0:10:21.160  
Penny Nichols  
And and and you know all all all that kind of basic analytical testing then that's not the right CDM for me, right. Unless you know this has really some proprietary platform that increases my manufacturing by 10 before then I can make a compromise there of saying that OK, you can just focus on manufacturing. I can take analytical testing somewhere. But usually 8 out of 10 cases right or 8 out of 10 times you want the serial mode to have the basic analytical testing that you just mentioned. Right safety testing.

0:10:21.490 --> 0:10:22.890  
Penny Nichols  
On identity testing.

0:10:24.370 --> 0:10:47.220  
Cody Sole  
Gotcha. So I guess if there were this CRO that you partner with and for all their clinical trial testing and you have CDMO that takes takes care of the manufacturing with some basic analytical testing offered. Are there any type of analytical testing that at the CMC stage you would actually prefer the CRO to test it?

0:10:48.790 --> 0:10:51.260  
Penny Nichols  
Sorry, that's what I don't like. I said. The potency testing.

0:10:52.80 --> 0:10:53.10  
Penny Nichols  
Ohh or or.

0:10:51.980 --> 0:10:53.580  
Cody Sole  
Also, just the potency testing, OK?

0:10:53.800 --> 0:10:57.690  
Penny Nichols  
Yeah, put it testing in simple terms you you hear the word bio assess.

0:10:58.380 --> 0:10:58.720  
Cody Sole  
Mm-hmm.

0:10:58.420 --> 0:11:11.480  
Penny Nichols  
There of essentially have to show that the drug or or or or the molecule that you're developing is is is going to function. The way you're saying it's going to function in an in vitro model.

0:11:13.240 --> 0:11:16.40  
Cody Sole  
And how does it vary by modality?

0:11:18.90 --> 0:11:43.170  
Penny Nichols  
Yeah, yeah. So here's that, that's a great question actually. So for monoclonal antibodies, right, like there are, you know, abandoned number of cell lines that are already available that can show the the function of them. So it's it's really easy to develop a potential asset for oncology indications and infectious diseases and variety of larger indication programs, right.

0:11:43.650 --> 0:12:10.310  
Penny Nichols  
Already scissors or some of or or you know where cell, cell, therapies and gene therapies are currently being used is where these assets are really hard to develop and take much longer time for Carlos to come up with an asset. So the spend is little bit more for radiuses compared to more common indications. I'm not sure if I ask you a question in a way that you wanted to hear, feel free to kind of ask any follow up questions on that.

0:12:10.900 --> 0:12:24.890  
Cody Sole  
Yeah, I think that makes sense. You know, Sandrine therapy, such more novel modalities, you might need more complex and higher spending assays. So you meet additional expertise and potentially, you know, regular CDMO's might not be sufficient to support that.

0:12:25.720 --> 0:12:26.450  
Penny Nichols  
Yeah, and.

0:12:26.90 --> 0:12:26.740  
Cody Sole  
OK.

0:12:28.620 --> 0:12:44.530  
Penny Nichols  
No, you you'd have to the right in in in in in concluding on that. So Syria most usually have, you know, either again 8 out of 10 times have those off the shelf plus cell lines available to you know show the potential of a particular monoclonal antibody or recombinant protein.

0:12:45.510 --> 0:12:59.420  
Penny Nichols  
You know. Ohh, I'd auto vaccine too, right? Whereas they may not have a of the shelves cell line available to show you know potential for particular gene therapy or outer cell therapy. That is true.

0:13:0.90 --> 0:13:14.440  
Cody Sole  
Yep, gotcha. Great. And another point you brought up is the global trial, I wonder, you know, how does it vary by either modality or indication on when the sponsor engaged the CRO?

0:13:16.520 --> 0:13:47.190  
Penny Nichols  
Yeah. So in terms of the global trials, right, I mean, in in this day and age, I mean, it doesn't matter whether you're a rare disease program or a small program or a large program such as oncology or infected thesis. Most of them are going global anywhere, right. So the, the, the, the key difference comes the key difference comes is that with rare diseases, right, the number of patients that you're enrolling is really small, right? So the, the, there is really no room for you to lose any samples.

0:13:47.590 --> 0:14:0.20  
Penny Nichols  
Well, you know, based on the quality of of transit of from the clinical side to the testing lab. So as the radius is sponsor, you're more willing to go above and beyond.

0:14:0.960 --> 0:14:31.730  
Penny Nichols  
To identify CRO that has a really a good global network to receive the samples within a particular time frame so that they can test the samples with quality. Whereas oncology or interested research program right, much larger program. So you have some wiggle room there of not essentially identifying really a big or global network CRO to support your needs across different clinical sites. You can still send all the sample to Central lab and then from Central Lab they can go to a testing lab.

0:14:32.410 --> 0:14:38.100  
Penny Nichols  
Which can be localized in one or two regions across the globe. Does it make sense because it it's just a.

0:14:37.640 --> 0:14:38.210  
Cody Sole  
Yep, Yep.

0:14:38.680 --> 0:14:46.900  
Penny Nichols  
So the radius is sponsors cannot afford to lose any samples they may have to even identify. They may have to identify Seattle that has at least five.

0:14:50.740 --> 0:14:51.420  
Cody Sole  
Yeah, I.

0:14:47.210 --> 0:14:51.730  
Penny Nichols  
A test sites across the globe, right, like in EU in South Africa.

0:14:52.500 --> 0:14:53.630  
Penny Nichols  
Best Canada whereas.

0:14:52.900 --> 0:15:4.410  
Cody Sole  
Yeah, I think that makes sense. It just just wanna fall upon the number of sites. I think you're getting there. Just if you can share the lights, where would you go first in different continents? If you are conducting real disease trial?

0:15:4.290 --> 0:15:4.520  
Penny Nichols  
Yeah.

0:15:5.300 --> 0:15:22.20  
Penny Nichols  
Yeah. And as far as the timing is concerned, right, again, the radiuses as you know most of them are phase 1/2 trials. So it's not a tiered approach of phase one and then phase two and then phase three or phase four, right that you see now. So for rare diseases.

0:15:22.960 --> 0:15:24.930  
Penny Nichols  
And as you know, again most of the.

0:15:26.50 --> 0:15:32.770  
Penny Nichols  
Right. I see this are being captured by new small startup companies or at least majority of them so.

0:15:33.720 --> 0:15:52.510  
Penny Nichols  
By default, you're outsourcing as early as you could within your clinical trial. Saying that I'm gonna go fully validated as is from very first patient that I'm enrolling in my clinical trial with the with the CRO that has a you know test sites across the globe that can support me pretty strongly.

0:15:53.550 --> 0:16:22.180  
Penny Nichols  
Whereas the large programs right, whether you're small or large biotech, you still have some wiggle room, but most of the small biotech companies again just because of the shortage of resources in house, you know they're outsourcing the services to Seattle and and and since they're already outsourcing the services to Seattle, they're saying that, you know, why should we wait until phase two or phase three to validate our ASK is let's go ahead and with fully validated assays from the get go.

0:16:23.70 --> 0:16:27.620  
Penny Nichols  
And and and do everything like we do usually for a rare disease program.

0:16:28.410 --> 0:16:36.700  
Penny Nichols  
And this is better. Again, the large companies are definitely or midsize companies are definitely different here. They usually outsource, I would say.

0:16:38.750 --> 0:16:58.220  
Penny Nichols  
Six out of 10 times, right. They usually only outsource in phase two or or end of phase two or or or the beginning of phase three to see arrows where by that time they already have access to performing well at least qualified assets if not validated. So they're transferring these assets to Seattle.

0:16:58.970 --> 0:17:3.620  
Penny Nichols  
Uh, I'm asking them to validate it for GLP or clear CAP compliance.

0:17:4.430 --> 0:17:8.450  
Penny Nichols  
So then so that they can execute a larger phase three study or face course setting?

0:17:10.320 --> 0:17:21.350  
Cody Sole  
Right. And, you know, I think we're also very interested in the APAC region. If you were to contact the trial, which country would you, you know, start first?

0:17:22.900 --> 0:17:28.260  
Penny Nichols  
I mean, Australia is definitely picking up in that area and Japan is one of the.

0:17:28.850 --> 0:17:36.460  
Penny Nichols  
Umm, you know, at least for the if you are a, it depends on where the sponsor is based. Then right? If you're a US based sponsor.

0:17:37.700 --> 0:17:39.900  
Penny Nichols  
You know, obviously China is not a right.

0:17:41.260 --> 0:17:45.750  
Penny Nichols  
The region to do it, but you you still work with this academic?

0:17:46.870 --> 0:17:48.960  
Penny Nichols  
Or or hospital institutes in China.

0:17:50.80 --> 0:17:50.640  
Penny Nichols  
But.

0:17:51.530 --> 0:18:4.490  
Penny Nichols  
But my friends with, you know, talking to the peers in the industry in general, it's it's really a a hardware to execute a clinical trial in China for for the US sponsor. So focused on Japan, Australia, New Zealand.

0:18:5.320 --> 0:18:36.160  
Penny Nichols  
I'll fill in a regulatory guidances are much more kind of sponsor friendly. They're still what do you call it there, there's, there's still stringent, they're still address all the same. You know line items that FDA or EMA wants you to address, right? But they're much more user friendly in terms of giving access to the sponsor to their clinical trials and there's local IRB or institutional review boards for different physical centers. They are much more.

0:18:36.470 --> 0:18:46.60  
Penny Nichols  
Again, friendly responses then other IRB's, let's say in UK or Japan are so definitely those are the options that people can pursue and obviously.

0:18:46.610 --> 0:19:7.400  
Penny Nichols  
I'll Southeast Asia, right. India is one of the finger where you call up and coming regions where you can enroll patients in a relatively short turn around time. And there's a reason for that. You know the PPD part of Thermo Fisher now has established is is expanding their capabilities there in India.

0:19:21.100 --> 0:19:21.420  
Penny Nichols  
Yeah.

0:19:9.220 --> 0:19:36.560  
Cody Sole  
Gotcha. Well, thanks for that background. That's very helpful. I wanna maybe circle back. I'll just technology overall on how you test ball marker and if you could maybe just at a high level tell us in which modality or which indication you might use multiple technology or method to profile the ball markers?

0:19:38.670 --> 0:19:39.420  
Penny Nichols  
Yeah. So.

0:19:41.160 --> 0:20:7.510  
Penny Nichols  
Some are biological standpoint, right? You know, for forget about the modality. Forget about the therapeutic area or whatever it is from binary call standpoint. The principle is simple is to is to develop, use an asset or develop an assay that can quantitate your target by marker in a simpler form as possible and as fast as you can and also as precisely as robustly as possible, right? So for that reason.

0:20:8.710 --> 0:20:22.840  
Penny Nichols  
You know, eight out of 10 times as much as you could you try to avoid complex platforms or assets you try to use simpler platforms or assets such as MSD or realized like I mentioned immuno acids are the most what do you call it well established.

0:20:24.70 --> 0:20:55.690  
Penny Nichols  
The platforms, but having said that you you may not achieve the the sensitivity that you want to see as far as your disease is concerned, right? Some most of the diseases, especially rare diseases or even oncology indications, right, you may not you know the the amount of expression of a biomarker that is needed to show that it's that your therapy is working. And then the it's it's it's contributing to the improvement of the disease state can be really really really minute in, in, in, in, in the fraction of pictograms or even if I'm.

0:20:55.760 --> 0:21:0.820  
Penny Nichols  
Program from sometimes. So for that reason this new platform such as Queen Terrex stuff.

0:21:1.490 --> 0:21:3.630  
Penny Nichols  
Also, my logic are are are kind of.

0:21:5.90 --> 0:21:28.260  
Penny Nichols  
Being more you know, not not popularized, but adopted by by, by, the by, by the sponsors across different classes of the you know, different. It doesn't matter what size of company you have, it just much more sensitive and useful for you to move forward and make an explanation that this biomarkers are being seen in, in the patients that you're treating.

0:21:29.170 --> 0:21:30.630  
Penny Nichols  
So going back to your question.

0:21:32.130 --> 0:21:39.930  
Penny Nichols  
The standard uh platforms are immuno acids that even I would say that that constitute almost.

0:21:40.890 --> 0:21:44.50  
Penny Nichols  
70% of the biomarker any given biomarker that you see?

0:21:45.410 --> 0:21:59.640  
Penny Nichols  
Some of them are, you know, immunohistochemistry based or histopathology based, which are kind of which can get messier in the clinical trial, right, because you don't essentially want to take biopsies from the patients, it's it's just not friendly.

0:22:0.440 --> 0:22:12.530  
Penny Nichols  
Ohh or feasible at the clinical site level to just take biopsies from the patient on a regular time period. So you still try to stick to the simplest samples that you can use such as blood or plasma serum.

0:22:13.350 --> 0:22:24.120  
Penny Nichols  
And again, going back to immunoassays. Ohh and then there are you know flow cytometry based assets that you can use to again you can still use blood for those kind of biomarkers.

0:22:25.500 --> 0:22:55.280  
Penny Nichols  
And and now nowadays again these biomarkers the this particular class of platform or assays are mainly used only for exploratory purposes at this point of time because validating them is hard that comes to use the spatial genomics or proteomics, right where you're looking at the the at the single cell level, what kind of difference is your end using after you treat a patient or you know in case of oncology it's really useful.

0:22:55.750 --> 0:23:12.150  
Penny Nichols  
Because you want to target a particular T cells or B cells within a patient after you treat them and you wanna see those changes in those target cells, not across the entire body, right? So it's so it's helpful. But at the same time validating these platforms, is it, it can be very challenging.

0:23:12.860 --> 0:23:14.630  
Penny Nichols  
So those are the kind of.

0:23:16.480 --> 0:23:16.900  
Cody Sole  
Yeah.

0:23:16.110 --> 0:23:46.910  
Penny Nichols  
You know, they are made of start from that. I have experience working with like I said in my role, you know immunotherapies right, mainly focusing on using a a certain tissue biopsies or tumor biopsies. So histochemistry flow cytometry and some spatial proteomics work and and the standard and the standard biomarkers ready for if there is a particular cancer indication that I'm pursuing.

0:23:47.890 --> 0:23:48.310  
Penny Nichols  
You know.

0:23:49.500 --> 0:24:7.250  
Penny Nichols  
Again, I'm calling is one of the most widely studied areas right? So there's already a a biomarker that a particular researcher has shown that a particular protein is increasing or decreasing based on the DC state. So I can I can use an immuno assay to do that and and validate that assay.

0:24:8.80 --> 0:24:24.600  
Penny Nichols  
And and use that as my secondary endpoint and then rest of the stuff that I initially mentioned I can use as a as a surrogate by Marcus or exploratory endpoints. And if they if they show me the feasibility during the clinical trial, then I'll adopt them by the end of phase two.

0:24:25.600 --> 0:24:36.790  
Penny Nichols  
To go into the phase three saying that, OK, I have I have identified that within my clinical trial, these biomarkers are actually working and they can tell a story that my therapy is working on these patients.

0:24:37.380 --> 0:24:53.630  
Penny Nichols  
So I'm gonna validate it before I go into phase three. Even it could be challenging. I'm. I'm gonna work with a CRO or I can do it in house. You come a large company and and then I'll use it for phase three. That's the approach. You know that I'm familiar right now in.

0:24:54.610 --> 0:25:6.70  
Penny Nichols  
The flip side for the past before I before I, you know, started my career, started working on immunotherapies in the way diseases, using gene therapies, right. It's much more simpler.

0:25:6.820 --> 0:25:36.750  
Penny Nichols  
Because most of these are already scissors, are genetic disorders, right? So when there is a genetic mutation that leads to a particular defective protein or enzyme in this patients. So that's that's your biomarker. So you can just use a simple immune acid or more sensitive platforms or that kind of you know the next level of immunoassays or printer X or some logic that give you much more almost 100 \* 1000 times more sensitivity compared to MSD or ELISA.

0:25:36.950 --> 0:25:41.560  
Penny Nichols  
So it it, it was much more simpler and easier in Redis scissors.

0:25:43.170 --> 0:25:46.340  
Penny Nichols  
Then it is in, in immunotherapies in general.

0:25:47.720 --> 0:25:48.630  
Cody Sole  
Gotcha.

0:25:47.750 --> 0:25:48.840  
Penny Nichols  
I'm you message.

0:25:49.970 --> 0:25:53.540  
Penny Nichols  
But I I I can, you know, I'll be happy. There are other class of.

0:25:54.590 --> 0:25:56.540  
Penny Nichols  
One last note, the other class of.

0:25:57.330 --> 0:26:21.800  
Penny Nichols  
By Marcus that people do is buy vases again, right. You after you treat a patient with a particular therapy, you take their blood, blood. You collect their blood and you take their cells from these blood and culture them in vitro and develop some sort of in vitro bio as your cell based assay too. So there are other ways of doing it, but that's usually again not preferred.

0:26:40.510 --> 0:26:40.810  
Penny Nichols  
Yeah.

0:26:23.300 --> 0:26:40.880  
Cody Sole  
Yep, I think that that all makes sense. Just a few full of questions on a spatial all makes sides. Is it currently using to assist the next clinical trial or different phases or ready or it's still adds more very much like preclinical space for discovery?

0:26:59.580 --> 0:26:59.930  
Cody Sole  
Umm.

0:26:42.0 --> 0:27:0.500  
Penny Nichols  
It's it's, it's it's. I would say majority of it is currently used to make decisions within the clinical trial to get into the next phase or or or or again like I said mostly exploratory biomarkers as exploratory biomarkers or surrogate biomarkers, right. Like I said any.

0:27:1.320 --> 0:27:6.800  
Penny Nichols  
Has a particular biomarker that you can easily quantitate using immuno acid or other flow cytometry.

0:27:8.510 --> 0:27:15.620  
Penny Nichols  
You know, but looking at single cell changes from mostly genomics or proteomics.

0:27:16.570 --> 0:27:22.130  
Penny Nichols  
But program mix is more preferred over genomics just because of the it's much more downstream, right?

0:27:22.600 --> 0:27:22.920  
Cody Sole  
Umm.

0:27:23.750 --> 0:27:55.740  
Penny Nichols  
It's much more helpful for you as a sponsor to understand, you know, not only the disease, but also what kind of changes is your therapy in using in these patients upon treating right. So it's truly unique to your therapy. So it helps you to make any changes or recommendations if if you're a translational medicine lead like me like who is responsible for this biomarkers and buying houses. I go back to my clinical team and say that hey, you know these are the changes that we are seeing. I think this is more than enough.

0:27:56.100 --> 0:27:58.310  
Penny Nichols  
Of you know, at this particular dose.

0:27:59.140 --> 0:28:22.400  
Penny Nichols  
To justify the the correction of disease state. So we may not need to go to the dose escalation or next term you know increase the dose that we're going to do in another cohort, right? So those are the kind of within the clinical trial decisions can be made again it cannot be made just based on one or two patients data, right. You have to see a significant number of patients showing the same pattern.

0:28:23.540 --> 0:28:36.400  
Penny Nichols  
And following in uh, following within that PK, PD modelling, we call it a you know basically PK is the drug, the presence of drug in a patient and then PD or the biomarkers and immunogenicity and things as such.

0:28:37.530 --> 0:28:37.940  
Cody Sole  
OK.

0:28:37.600 --> 0:28:50.400  
Penny Nichols  
So really in in the within the trial for sure, but also from a platform level right outside of the trial, it also informs your next trial to like you. You know I think that's that's part of your question as well.

0:28:51.250 --> 0:28:52.130  
Penny Nichols  
Ohh discuss.

0:28:50.960 --> 0:28:52.430  
Cody Sole  
Yep. OK, that makes sense.

0:28:59.220 --> 0:28:59.610  
Penny Nichols  
Hello.

0:29:1.590 --> 0:29:1.920  
Penny Nichols  
Yeah.

0:29:0.190 --> 0:29:3.790  
Cody Sole  
Yes, sorry. I thought you were going to comment more.

0:29:3.540 --> 0:29:29.200  
Penny Nichols  
Did discuss much, you know, Discovery is the the the data that you generate from nonhuman primates or you know my models may not be as useful for you. So I would not say you know people people do it but I don't think it says it's as if it's as significant or the the incidence is not as high as people are currently using within the clinic.

0:29:29.810 --> 0:29:51.10  
Cody Sole  
Yeah. OK. That makes sense. And I I just wondering since you also have experience in CNS, metabolic or cardio diseases, I wonder are there any specific indications beyond oncology there might need multiple type of tests that we discussed, amino acids, flows, spatial, even genomics?

0:29:53.280 --> 0:29:54.160  
Penny Nichols  
Yeah. So.

0:29:54.920 --> 0:29:56.690  
Penny Nichols  
Again, it depends on the.

0:29:57.970 --> 0:30:3.780  
Penny Nichols  
The how much your particular disease is studied, right? Even though these are rare diseases like instead of.

0:30:16.590 --> 0:30:17.580  
Cody Sole  
Yeah. OK.

0:30:5.140 --> 0:30:25.300  
Penny Nichols  
With my friends is working on a monogenic disorders where patients have a genetic mutation that leads to the disease, right? So that the link is pretty direct is that you know can take me but but at the same time there are ways to show the surrogate biomarker which is kind of really.

0:30:26.590 --> 0:30:36.0  
Penny Nichols  
You know are being used as a lot of companies for regulatory approval tools, right? So if you, you know, if you have the the luxury as a sponsor, right?

0:30:37.90 --> 0:30:40.90  
Penny Nichols  
Do or to invest some money into your program.

0:30:41.400 --> 0:30:49.90  
Penny Nichols  
And and and and address any stargate by Marcus for exploratory by Marcus. Using other platforms. You know, it's definitely.

0:31:6.420 --> 0:31:6.650  
Cody Sole  
Yep.

0:30:49.780 --> 0:31:18.180  
Penny Nichols  
Ohm is being encouraged now and we have seen examples such as ultragenyx hemophilia trial. They have identified certain new biomarkers of during their trial, right. So the path is being followed, but it's not usually followed by every single sponsor. So in red, this is a therapies when it's metabolic or CNS or cardiovascular that I have worked with, it's usually the MSD, the flow cytometry is to certain extent.

0:31:19.730 --> 0:31:23.760  
Penny Nichols  
And and and and and and the quintrex and some logic are the are the most.

0:31:25.0 --> 0:31:37.400  
Penny Nichols  
What do you call it that they're taking up the market share from MSDN platforms and you know, simpler immunoassay platforms, the contracts and some logics are kind of, you know consuming that market share?

0:31:58.100 --> 0:31:58.590  
Penny Nichols  
Only.

0:31:38.460 --> 0:31:58.730  
Cody Sole  
Right. So actually that's another question I had is what do you think will be the I guess if you look down in three to five years, what type of immunoassays my rise and take share from MSD and if you can compare them and we we heard all link as well, not sure if you have experience in comment on that as well.

0:31:59.700 --> 0:32:1.680  
Penny Nichols  
Yeah, only income is, is is.

0:32:2.420 --> 0:32:31.470  
Penny Nichols  
Ohrling is not being used as a secondary. It's usually only for exploratory biomarkers. They're not being used as a what do you call it? A primary or secondary biomarkers for any decision making at this point of Poling, it's it's kind of a little better. It's all gonna nucleotide based targeting of your particular molecule. So it's helpful. So link is actually helpful in the discovery phase to understand your disease better in relation to your therapy.

0:32:32.220 --> 0:32:40.350  
Penny Nichols  
In clinical, yes, certain sponsor using it, but I think the majority of market share is still quintrex or summer object.

0:32:43.320 --> 0:32:48.250  
Penny Nichols  
Because it's like I said, going back to my initial state opening statement on this particular topic, right.

0:33:8.500 --> 0:33:10.260  
Cody Sole  
OK, that is clear.

0:32:49.980 --> 0:33:19.10  
Penny Nichols  
The simpler the assay, the simpler the targeting of your biomarkers and and more consistent or or or or precise you are or robust you are the the better it is for for you to use a particular asset as a biomarker assay, right. So if you look at it, yeah, if you look at it quintrex or someone or summer scan, right, it's just a next generation of amino acids such as MSD.

0:33:20.630 --> 0:33:23.20  
Penny Nichols  
Right. So that's why it.

0:33:22.30 --> 0:33:23.100  
Cody Sole  
Yep, OK.

0:33:24.640 --> 0:33:43.360  
Cody Sole  
That sounds good. And lastly, before I transition to vendor selection and your feedback on those is you mentioned immunohistochemistry and so taking biopsies from patients and have you seen any trends there are suggest digital pathology or AI analysis?

0:33:44.840 --> 0:33:47.250  
Penny Nichols  
Yeah, that's this is something.

0:33:47.990 --> 0:34:18.200  
Penny Nichols  
You know, in my previous in gene therapy setting, right, I worked on a program that is a, you know, a muscular in nature it's called DMD distance, muscular dystrophy where you know, yes, you had a we had a primary or secondary biomarker that was based on the blood. But we actually really wanted to see the patients muscle. So because there were strong or preclinical data from nonhuman primates and mice.

0:34:18.270 --> 0:34:51.990  
Penny Nichols  
Going on the improvement of of of laminin protein in in the muscles in these animals, right? So there was a push from the regulatory side also from the scientific side for us to show the efficacy of therapy in patients. So we we had to take muscle biopsies. So not not regularly but every six months. And since it's like you know intensive right in terms of collecting the sample we you know we wanted to make sure that the assay actually can perform consistently. So we had to.

0:34:52.480 --> 0:34:55.350  
Penny Nichols  
I'll go with the vendor that was able to develop a.

0:34:56.60 --> 0:35:4.290  
Penny Nichols  
And I say ohh or validated assay and and use an essentially to for for detection of a particular target protein within the muscles.

0:35:6.600 --> 0:35:30.40  
Penny Nichols  
Right. So you mean it's like a mistake can be useful if you really know the size behind your disease and which, which, which which tissue to target. But having said that taking a liver or lung biopsy can be challenging you you you you don't want to do that in in a clinical trial. So usually if it is a muscle or scan.

0:35:31.870 --> 0:35:33.150  
Penny Nichols  
In in some cases.

0:35:34.110 --> 0:35:37.540  
Penny Nichols  
Ohh the the the the spinal fluid.

0:35:38.220 --> 0:35:40.780  
Penny Nichols  
A for CNS indications can be done.

0:35:41.480 --> 0:35:42.760  
Penny Nichols  
Ohh but.

0:35:54.90 --> 0:35:54.300  
Penny Nichols  
That.

0:35:54.360 --> 0:35:55.30  
Cody Sole  
3/4.

0:35:58.200 --> 0:35:58.510  
Cody Sole  
OK.

0:35:55.770 --> 0:36:3.560  
Penny Nichols  
Yeah, you know, we are already doing it right there. There are some that have been showing. Yeah, definitely I think the.

0:36:2.790 --> 0:36:8.170  
Cody Sole  
Other specific companies that you can comment on within AI space.

0:36:14.980 --> 0:36:15.260  
Cody Sole  
OK.

0:36:9.210 --> 0:36:19.760  
Penny Nichols  
No, but I said we are doing it. I haven't directly worked on any companies or evaluated so far, but we, you know, we as as an industry we are looking at you know even.

0:36:20.660 --> 0:36:41.890  
Penny Nichols  
Kind of, you know, reducing the use of animals right in the preclinical side of things and you can come up with an AI based animal study model to look at your disease and therapy. So reducing the number of assays that you're doing or number of animals that you're using in the preclinical side, it's only a matter of time that will translate into the clinical tool in future is what I'm saying.

0:36:42.380 --> 0:36:44.120  
Cody Sole  
Yeah. OK. That makes sense.

0:36:43.990 --> 0:36:49.580  
Penny Nichols  
No, I can follow up, but I do not have any names at the top of my head at this time.

0:36:50.160 --> 0:37:6.720  
Cody Sole  
No worries. I appreciate that. And I I wonder now if we move forward to the CRO selection when you as a sponsor on the select the CRO, what is the process typically look like and what are the selection criteria there?

0:37:8.520 --> 0:37:23.50  
Penny Nichols  
Before I answer that, let me ask you a question. So are you strictly focusing on biomarkers or or or the testing space or the testing side of things or are you focused on in general from a clinical trial feasibility standpoint?

0:37:23.650 --> 0:37:26.320  
Cody Sole  
Ohh, we're more focused in the bond market testing.

0:37:27.290 --> 0:37:57.380  
Penny Nichols  
OK. As far as the, yeah, if if I'm just focusing on the testing and I'm, I'm, I'm and I'm outsourcing to a CRO, first and foremost thing that I'm looking at is is, is expertise of this particular CRO working on on the targets that I'm that I want to validate right for my biomarkers for example like I said, if I'm working on a CNS indications like Parkinson's, no, Parkinson's is known well well known that there's a protein called program.

0:37:57.460 --> 0:38:17.190  
Penny Nichols  
Then that is defective in this patients. So that's the first and foremost thing I look at is that did this CRO worked on this particular protein or validated an assay or supported another program or another sponsor or not right. So that kind of gives me confidence to initiate those conversations surrounding my biomarker of need.

0:38:17.910 --> 0:38:28.770  
Penny Nichols  
And data on you know, I can I can talk about their expertise or experience in a supporting or or or using a particular platform that I'm intending to. If I've already made-up my mind.

0:38:29.960 --> 0:38:33.170  
Penny Nichols  
And thereafter it's the turn around time, the lead times.

0:38:34.890 --> 0:39:6.210  
Penny Nichols  
And and and I'll obviously the prior working relationship goes a long way too because you you as a sponsor, right, you know you you wanna make sure that you're going into a comfortable space rather than a space where everything that comes at using use, right. You don't wanna be, you don't wanna be that person because you don't wanna use that excuse saying that I haven't worked with you before. So I did not know that it works like this. Right. We see that all the time whenever you're working with the new pro the CRO no matter how much you kind of talk it up.

0:39:6.310 --> 0:39:36.140  
Penny Nichols  
Don't in terms of workflows and everything, there's always this new thing that comes when the timing is worse, so you don't wanna be that. So you wanna kind of, you know, be familiar with the particular Seattle. So usually when I even before I, you know I think of all the expertise that I initially mentioned, right. I usually go and talk to the Seattle that I've worked with first like you know, what are the top three Seattle that I've worked with? I'll go and ask them these questions. Hey, do you have experience working on this particular biomarker?

0:39:36.320 --> 0:39:42.90  
Penny Nichols  
Do you have experience on this particular platform and what are you currently times and turn around times?

0:39:47.180 --> 0:39:47.500  
Cody Sole  
Mm-hmm.

0:39:43.200 --> 0:39:55.960  
Penny Nichols  
And you know, can you support me in different geographic locations? So if not like what can we do to work with the central lab, you know, and what what what is your flexibility there? Things are such and then at some point prior.

0:39:55.0 --> 0:39:56.820  
Cody Sole  
Perfect. And what for?

0:39:58.50 --> 0:39:58.490  
Penny Nichols  
Go ahead.

0:39:59.400 --> 0:40:5.350  
Cody Sole  
So I was just wondering why you say you know the top three CRO's. I would you mind sharing sharing with me a list of that.

0:40:6.410 --> 0:40:8.570  
Penny Nichols  
Yeah, that's far as the biomarkers you know.

0:40:9.460 --> 0:40:31.400  
Penny Nichols  
The way I categorized right as a translation with delayed is is the central labs and the specialty labs. Central Labs is the ones that kind of receive all the samples from clinical trial that get tested and then from Central lab the samples get distributed to different specialty labs that includes biomarkers or by analysis, right.

0:40:32.110 --> 0:40:32.530  
Penny Nichols  
So.

0:40:33.740 --> 0:40:42.110  
Penny Nichols  
Your question is about the specialty labs. My preference, at least so far as as a as a as a sponsor based in US.

0:40:43.690 --> 0:40:59.640  
Penny Nichols  
Bioagilytix is is definitely one. If it is, it's my previous employer it it's not because of that I'm prejudice, but there's there's there's quality and and consistency is pretty good and there's a reason why they grew up so fast and in such short time, right.

0:41:0.940 --> 0:41:3.760  
Penny Nichols  
And the other specialty lab is cellcarta.

0:41:4.660 --> 0:41:17.640  
Penny Nichols  
Cellcarta I only used mainly for the flow cytometry based platform. They're really well known previously caprion you know caprion and histogenics and some of the small companies came together and they formed cellcarta.

0:41:19.60 --> 0:41:38.570  
Penny Nichols  
The other CRO is PPD. I'm not a big fan of PPD because they're they're, they're becomes so big that there's a lot of hierarchical step that I have to go through to to even get a contract done on a timely manner. So, but at the same time, you know, I have really good relationships.

0:41:39.910 --> 0:41:54.690  
Penny Nichols  
I'll be within different departments there, so I know if I need a particular assay in a really a short turn around time with with, with really good quality. I I know I can reach out to them. So these are the three specialty labs.

0:41:55.360 --> 0:42:0.40  
Penny Nichols  
Umm that I talked 3 special app that I prefer. But having said that you know.

0:42:0.720 --> 0:42:14.450  
Penny Nichols  
I I tried to go with the best in class right? So not every biomarker or PK or emergency as they can be supported by buyers intakes or cellcarta or PPD. I've also worked with others suggest precision for medicine.

0:42:15.800 --> 0:42:19.370  
Penny Nichols  
Adsorption by systems, which is a part of Pharmaron now.

0:42:20.290 --> 0:42:21.900  
Penny Nichols  
Umm the.

0:42:23.780 --> 0:42:24.860  
Penny Nichols  
Yeah, the other.

0:42:23.910 --> 0:42:38.480  
Cody Sole  
So I so I guess I'll follow up question on because we've heard a few experts consistently mentioned about agilytix and cell Carta. So I wonder how do you compare these two? What are really the strength and weakness of each?

0:42:38.710 --> 0:42:49.860  
Penny Nichols  
Ohh yeah yeah if if you ask me, they're completely different. They're totally different. Biotex is my is, is, is. Actually I would say is.

0:42:50.650 --> 0:43:20.80  
Penny Nichols  
Has more to offer to a sponsor than Cell Carta. By detects can do ligand based assays or which immunoassays biomarkers, PK acids, all those things fall AED, \*\*\*\*\* right. So all those specialty labs fall. So biomarkers is really well experienced in, in, in supporting you as a sponsor. They're also slowly establishing the flow cytometry and cell based and they're also have really good cell based assets at a fundamental level such as.

0:43:25.710 --> 0:43:26.30  
Cody Sole  
Uh-huh.

0:43:20.600 --> 0:43:27.900  
Penny Nichols  
Utilizing antibody assays or potential assets that we talked about right initially to support CMC, but can do that for you.

0:43:28.930 --> 0:43:33.600  
Penny Nichols  
But what they cannot really do with great quality is the flow cytometry.

0:43:34.380 --> 0:43:38.510  
Penny Nichols  
And they they may not be a great central lab for you.

0:43:38.610 --> 0:43:46.330  
Penny Nichols  
No, they are kind of trying to invest in that category, but they cannot, they they do not have that capability now.

0:43:48.730 --> 0:44:13.790  
Penny Nichols  
What else self as far as biologics is concerned and and you know biologics can work on variety of modalities, right? No matter what what what you're indication is, but the lack in they lack expertise in supporting vaccines. They have supported certain vaccine programs but not as strong as other CRO's, right. So those are the kind of throws and conceptualises whereas cellcarta.

0:44:15.360 --> 0:44:40.650  
Penny Nichols  
When somebody talks about cellcarta, it's usually because of their flows that ametric experience. It's usually because of their cell based assays experience, not because of the ligand based assets, which most of the you know biomarkers or amino acids fall under or a DNP cases fall under. So if you, you, you you don't go to cellcarta and ask them to develop a PK asset because unless your PK is a cell therapy, right, it's for cell therapy.

0:44:41.960 --> 0:45:12.300  
Penny Nichols  
So that's where cellcarta kind of, you know, different differentiates itself from other most of the other CRO. But Cellcarta has also established a really good central lab capabilities right because of their presence in Australia, EU and US and Canada, they have established really good central lab capabilities. You know I currently use cell card as a central lab and for most of my flow cytometry needs and I just basics for most of my PK or ligand based.

0:45:12.470 --> 0:45:13.340  
Penny Nichols  
Chinese, right?

0:45:14.30 --> 0:45:14.530  
Penny Nichols  
Ohh.

0:45:15.870 --> 0:45:16.470  
Penny Nichols  
That's how they.

0:45:15.270 --> 0:45:17.330  
Cody Sole  
So it sounds like, sorry.

0:45:18.670 --> 0:45:24.110  
Penny Nichols  
And also cellcarta I think you know even though they have a broader network.

0:45:24.720 --> 0:45:35.220  
Penny Nichols  
Then buy the lyrics at this time, but buy that it did acquire other companies in Australia in in, in, in EU, in the West Coast of US, but still.

0:45:35.970 --> 0:45:50.860  
Penny Nichols  
You know, the cellcarta has a better network in terms of executing your logistics of your samples or whatever, but it's it's it's at the same time it's really smaller compared to bias. It is bias, lyrics is much more bigger than cellcarta at at least at this point of time.

0:45:52.290 --> 0:45:58.730  
Cody Sole  
And what do you say about agilytix is bigger, meaning the expertise in immuno acid proteomics in general?

0:46:3.240 --> 0:46:3.610  
Cody Sole  
OK.

0:45:59.870 --> 0:46:13.590  
Penny Nichols  
No, you just share number of employees or personnel you know and and and and by that they can turn around faster. They can take the projects you know they can initiate the projects faster and they can get things done a little bit faster.

0:46:15.70 --> 0:46:43.770  
Cody Sole  
And so at least based on your description, sounds like for cellcarta you use it for central lab and then flow sites hometree but not others because by actually it's doing better. So what if cellcarta, I mean since they also offer me the essay services based which you told me. So if they actually offer more PKI or other additional assays, would you switch from about agilities 2 cell Carta?

0:46:45.160 --> 0:46:50.270  
Penny Nichols  
No, I mean, you know anyone can say that they can offer a particular assay, right, but I need to.

0:46:51.100 --> 0:47:11.730  
Penny Nichols  
They need to establish confidence with me that they can execute it properly or show me the show me your track record is is what I would ask right with the text. I I know that they have delivered across, you know, variety of programs for the past decade or so that they are really good at like Ann based assets.

0:47:13.240 --> 0:47:13.750  
Cody Sole  
Got it.

0:47:12.980 --> 0:47:42.110  
Penny Nichols  
Same thing. I mean the same reason why I go to cellcarta is because they have shown through an expertise in social demetry yes, I mean you know cellcarta can say now that hey, we are starting this new specialized or focused lab within our company that folks are like an based assets. But I would not outsource to them right now or at least for my main project maybe for exploratory projects if they if they price, if they're pricing is really you know appealing to me.

0:47:45.480 --> 0:47:46.940  
Cody Sole  
Yep, that makes sense.

0:47:42.950 --> 0:47:57.480  
Penny Nichols  
Because I'm taking a chance, right? You know, I'm helping other to everybody. So it it will take time, but I would not do it. The simple answer is that, you know, I already know which CRO are good at what.

0:47:58.670 --> 0:48:2.580  
Penny Nichols  
But I can now get the best out of, so I would stick with that.

0:48:3.420 --> 0:48:5.430  
Cody Sole  
Sounds good and umm.

0:48:3.550 --> 0:48:9.200  
Penny Nichols  
But if but this philosophy is speakable to everyone, right this philosophy.

0:48:8.600 --> 0:48:9.300  
Cody Sole  
Yeah, that makes.

0:48:10.350 --> 0:48:25.900  
Penny Nichols  
This laptop is only you would stay in seven or eight sponsors out of 10. Two out of 10 sponsors. They want to have a one stop shop. They don't wanna deal with multiple CR's, but eight out of 10 sponsors are like me, who wants to have best in class rather than one stop shop.

0:48:26.860 --> 0:48:36.900  
Cody Sole  
Yeah, yeah, that makes sense. And since you brought up the pricing piece, I wonder how do you compare the the offerings from these two companies on the pricing?

0:48:37.100 --> 0:48:37.330  
Penny Nichols  
OK.

0:48:38.30 --> 0:48:39.480  
Penny Nichols  
Pressing it, you know pricing.

0:48:40.500 --> 0:49:10.990  
Penny Nichols  
I didn't want one thing that really stood out to me over the past few years. So or at least over the past one or two years is that by detection cellcarta they used to have this Fe based model guide. You know, if they spend the particular number of days on your particular project, they used to charge you, you know, for that those many number of days. It used to be like that. But now almost all seattles no matter what size or how specialized lab you are, you are following the path of PPD or IQVIA.

0:49:11.230 --> 0:49:21.840  
Penny Nichols  
There, they're charging you. They're charging you FDE based model, but also charging you the project management fee because you know they're focusing on your project, which is kind of.

0:49:23.440 --> 0:49:29.870  
Penny Nichols  
Not really ideal for small companies, but we are setting up to it. You know, for the lack of better terms.

0:49:30.800 --> 0:50:0.900  
Penny Nichols  
But you know it before 2020, right? It was really ideal for me to go to bars latex because, you know, they were charging me for only the time that they're spending on my project, not like on a monthly fee or a yearly fee. Even when there is no work to be done. Right. Because I just want them to be kind of on my project. The. But even though there was no work, so pricing at this point of time, you know, across all the CRO's, it's pretty much same. There's not. There's not much difference.

0:50:1.850 --> 0:50:9.610  
Penny Nichols  
Having said that, there could be a difference based on the the the platform, right? This is what the Seattle start doing nowadays.

0:50:10.750 --> 0:50:25.480  
Penny Nichols  
Is is it? If you're, if you're gonna go on a flow cytometry based platform, it's gonna be more complicated, more number of personnel are involved up front. So even though they're charging me FT days, they're also charging me this project management fee that is little bit higher.

0:50:26.540 --> 0:50:35.240  
Penny Nichols  
So the pricing structure is pretty much frame across Seattle. So I I, I I have at least it used to be different before 2020 or before COVID.

0:50:36.150 --> 0:50:37.360  
Penny Nichols  
But after COVID.

0:50:38.240 --> 0:50:44.950  
Penny Nichols  
And the pricing has been pretty consistent across you know no matter how big or small CRO you are.

0:50:45.940 --> 0:51:15.850  
Cody Sole  
OK. And make sense for the last five minutes, just want to explore some of the Jason sees that you might you might think add on to the existing curls will be helpful. So for example that we kind of touch upon the data analysis piece, but do you think if the CRO can offer let's say a cloud based data analysis platform for you across different bond market testings or flow cytometry analysis genomics or?

0:51:19.230 --> 0:51:19.690  
Penny Nichols  
Yeah.

0:51:16.10 --> 0:51:19.790  
Cody Sole  
The mass spec is the pathology. You name it. Would that be helpful?

0:51:21.800 --> 0:51:22.250  
Penny Nichols  
I mean.

0:51:23.750 --> 0:51:43.700  
Penny Nichols  
The answer is why not, right? But at the same time, you know I'm more interested in the the data management side of things rather than data analysis side of things because I would, I would hire consultant or I would hire a you know in house to focus on data analysis piece of it or I might as well do it.

0:51:59.510 --> 0:51:59.770  
Cody Sole  
Hmm.

0:51:44.650 --> 0:52:5.380  
Penny Nichols  
By getting this, uh, software, so platforms on on my work computer. But if a particular CRO can help me set up a really strong data management or database for my clinical program, that is actually great. That is something I would do more than the data analysis side of things, I mean again.

0:52:4.410 --> 0:52:9.770  
Cody Sole  
And casually bit more about the data management piece, like what type of services are looking for.

0:52:11.140 --> 0:52:36.550  
Penny Nichols  
Yeah, basically the data management is that you know all these clinical data is, is, is has to be regulatorily compliant, right? It it just cannot be shared with everyone you know even with your sponsor, even if you're sponsor, it cannot be shared with it with everyone within my company. So you know there's a date, if you look at any company working on clinical trials, there's this data management team that works with the likes of clinical seattles mostly such as.

0:52:37.470 --> 0:53:2.400  
Penny Nichols  
IQVIA our product so they have this data, clinical data management services on how you manage the data and maintain it and share it with different stakeholders such as you know, PII at the clinical site level and sponsors and within sponsors like you have different clinical development teams and the translational teams that can have access to this database so that the data is confidential.

0:53:29.570 --> 0:53:30.550  
Cody Sole  
Umm OK.

0:53:4.380 --> 0:53:30.640  
Penny Nichols  
And and and you also can bind the data where the test labs are support. You know uploading the data that they're generating from your samples in a blinded manner, right. So you they need to be a proper data management structure and then appropriate database need to be built so that this test labs the for example biomarkers whenever they're done testing, they can upload the results there. So which comes up.

0:53:31.980 --> 0:53:34.670  
Penny Nichols  
Not not before, but after there are spies.

0:53:35.660 --> 0:53:36.640  
Cody Sole  
Father God.

0:53:35.740 --> 0:53:36.670  
Penny Nichols  
But having said.

0:53:37.650 --> 0:53:54.640  
Penny Nichols  
One quick note though is there are dedicated CRO out there that focus on data management such as CERTARA is one of the CRO. If you look at them you'll understand what I'm trying to say here is that because there's a lot more CFR part level compliance that needs to go.

0:53:55.450 --> 0:53:59.650  
Penny Nichols  
Uh, in order for you to use your data before you go for regulatory approval.

0:54:9.770 --> 0:54:10.0  
Penny Nichols  
Yeah.

0:54:0.370 --> 0:54:14.990  
Cody Sole  
Right. So I guess it's more like say, either, but biology by agilytix or cell Carta acquired company like this. Tara, as you mentioned and for data management, would that be basically a nice services at all?

0:54:18.60 --> 0:54:18.370  
Cody Sole  
Umm.

0:54:27.190 --> 0:54:27.550  
Cody Sole  
OK.

0:54:15.960 --> 0:54:34.730  
Penny Nichols  
Yeah, that would be great. And and honestly, it would be a great add-on for a for a Seattle that has established central lab capabilities, not specialty labs, but Central Labs. So I would, I would definitely would be a great benefit for cellcarta more than bias it takes to acquire certain.

0:54:35.750 --> 0:54:36.540  
Cody Sole  
Got it, got it.

0:54:35.690 --> 0:54:36.630  
Penny Nichols  
If it makes sense.

0:54:44.320 --> 0:54:44.650  
Penny Nichols  
Yep.

0:54:37.320 --> 0:54:50.230  
Cody Sole  
OK, I see. Thanks for that feedback. Another idea is imaging services as we've heard potentially there might be and what's your comment on SHIRO'S adding the imaging services?

0:55:3.80 --> 0:55:3.330  
Cody Sole  
OK.

0:54:52.300 --> 0:55:15.130  
Penny Nichols  
So imagine services is mostly for the patient enrollment purposes or central labs. The you know again if the central lab can add on this capabilities that would be great because imaging services are they are kind of a biomarkers but not in the way that we talked about, right they you know for example MRI imaging, there is a specialized CRO called Medidata.

0:55:38.680 --> 0:55:39.490  
Cody Sole  
Yeah. OK.

0:55:15.950 --> 0:55:42.350  
Penny Nichols  
That, that's that's kind of well known in the industry that does the imaging services and analysis and reporting back to the the the Pi who's working on the OR who's treating the patients right. So it's more useful for the central labs where you know where where they do this blood blood chemistry or safety testing, right, not not the specialty testing that we talked about. So again you know.

0:55:44.580 --> 0:55:44.830  
Cody Sole  
Yeah.

0:55:44.50 --> 0:55:57.140  
Penny Nichols  
It has to what I'm trying to say is that it has to be best in class within a part of a CRO that you're already working with, rather than saying that ohh, we're just adding this offering and we're going to have that.

0:55:57.760 --> 0:55:58.470  
Penny Nichols  
Does it make sense?

0:55:57.830 --> 0:56:7.920  
Cody Sole  
Of course. Of course. Yeah. Yeah, that totally makes sense. Lastly, since we have a minute left is the lab logistics, including cold storage or shipping?

0:56:12.410 --> 0:56:12.660  
Cody Sole  
Like.

0:56:8.900 --> 0:56:38.810  
Penny Nichols  
Ohh this is the. This is the whole of the topic for global price. Yes for global transit it's a it's a really a pain point I have. You know first you know you know, hands on experience have dealt with when I was working with gene therapy trials already seen this in EU, South America and Australia this was the biggest pain point but there are really good established logistical vendors that most of the scenarios work with such as Martin and worldwide clinical trials.

0:56:38.880 --> 0:57:8.840  
Penny Nichols  
No other two are really good logistical partners. I think. I think for Seattle's to take on the logistical part of things, mostly others try to avoid it. Just so you know, if you talk to any of the CRO's, they say that we wanna stay away from them as much as we could because we are already dealing with, you know, sponsors, expectations on the on the turning around side of things in terms of testing, in terms of providing services. We don't want to take on logistical things.

0:57:9.600 --> 0:57:9.920  
Cody Sole  
Umm.

0:57:12.990 --> 0:57:13.310  
Cody Sole  
Yep.

0:57:9.850 --> 0:57:30.440  
Penny Nichols  
Because a lot of can be out of their control there, right? The shipping lanes can be really painful. So Mark and and the worldwide shipping have no even if you outsource this aspect of CRO, they still go to market and worldwide to identify proper shipping lines to support my clinical sites.

0:57:39.800 --> 0:57:40.100  
Penny Nichols  
But.

0:57:31.190 --> 0:57:43.340  
Cody Sole  
OK. That makes sense. Well, great feedback there and thanks for bringing stormy with us as usual. It's a pleasure to speak with you and thanks for your time and hopefully we can connect on future projects.

0:57:44.230 --> 0:57:45.870  
Penny Nichols  
Sounds good. Thank you. Have a good day.

0:57:45.990 --> 0:57:47.910  
Cody Sole  
Thank you. Have a good day. Bye. Thanks. Bye.