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

WEBVTT

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<v Penny Southworth>This with a, you know, high level overview of your professional expertise and background that will be great to get it started and we can go from there.</v>

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Tammy Ackerman Yes, so I currently work as a head of the R&D and the medium sized company also has a clinical partner in R&D of a large health care universal service provider.</v>

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Tammy Ackerman Uh, my partnership comes from the years of working in himont. I'm a trained hemond, and before this company in Biopharma, I was also working with multiple top 20s over the past 22 years.</v>

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Tammy Ackerman And my work is primarily focused in immuno oncology and oncology, but I've done also immunology as well as CNS specifically in multiple sclerosis as well as Alzheimer's.</v>

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Tammy Ackerman But I've done other immune mediated diseases, including but not limited to, some dermatology work in my research and development work. I'm your typical clinical development person, so essentially I started my career as a what you may call a medical monitor and my responsibilities were in fact conducting the day-to-day activities of the clinical trial.</v>

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Tammy Ackerman Working with clinical operation, then I rose through the ranks into a strategy and also into leadership of R&D. One of the responsibilities I have is identifying, managing potentially large and small massive service agreements with the contract research organizations, central laboratories and specialty labs associated with the clinical trials.</v>

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<v Penny Southworth>Perfect, OK, yeah. Excellent overview. Very excited to dive into this topic with you. So maybe at you know kind of starting at a fairly high level, if you look at some of the needs and clinical trial biomarker testing sort of across the industry for the immuno space. I'm curious to know are there two or three trends related to you know this space that you're monitoring most closely or that you think is you know kind of impacting how we do things? Just kind of curious to hear.</v>

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<v Penny Southworth>You know what's at the top of your mind when you think about this subject.</v>

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Tammy Ackerman Yeah, I don't know about the word trend because I'm not entirely sure what we mean by a trend in in clinical development in the industry. We're more looking at the need and the need usually as to lead itself to primarily.</v>

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Tammy Ackerman Launching our product, so if you look at it backwards, we're looking at potential opportunity of using the biomarkers to either be a tool of prognostic and diagnostic or be a tool associated with our clinical trials.</v>

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Tammy Ackerman Uh, efficacy. Primarily the efficacy endpoints and or via the arrogate associated with.</v>

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Tammy Ackerman Safety mitigation.</v>

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Tammy Ackerman So essentially in a bigger picture, contract research organizations have been taken over a vast amount of activities in the industry across the board using contract to search organizations and or what you may call an app source system to do the day-to-day activities of what you may call the central lab set of responsibilities is not unusual.</v>

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Tammy Ackerman As a matter of fact, health authorities, they like it FDA, EMA, TGA P DMA. Not only do they like it, they encourage it to use the central lab for many reasons. Standardization, centralization associated with the analysis, chain of custody and other threes. So using Central Labs using Cryos using app source, that's pretty much in the direction of where we are going also.</v>

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Tammy Ackerman In addition to that, almost all trials they're supposed to be.</v>

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Tammy Ackerman Multi Center and most of the center is nowadays you try to spread them around.</v>

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Tammy Ackerman From the big centers of excellence, medical centers teaching hospitals that they may have the capability of running certain biomarkers and or diagnostic tracers, which is genomics and what have you, but it's simpler, cheaper, easier to run it centrally. So we tend to run that essentially and also we have the capability of running that with the flexibility.</v>

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Tammy Ackerman That we could look at a spectrum of potential opportunity of these biomarkers because quite frankly we may be when we're writing our protocols, we may be looking at few items but soon to be known there are other potential markers and or indicators they may be looked at. So again it gives you the luxury of writing up your central lab.</v>

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<v Penny Southworth>Yeah.</v>

00:05:30.880 --> 00:05:54.780

Tammy Ackerman Uh profile in such a way for your trial to kind of have a more comprehensive venue associated with it. So if if that makes sense as what you called it a trend, that's what I've seen in the past progressively at least probably 15 years prior to that, we were less into this game.</v>

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<v Penny Southworth>Yeah. OK, yeah. No, that's super helpful. So really kind of key take away there. Outsourcing is sort of the standard and only increasing in terms of an importance is there, is there a particular time at point during the drug development process when it typically goes from an in house type of assay to outsource, is that when it goes from you know preclinical to the clinical stage or is the outsourcing occurring you know even even at the preclinical, what's the sort of temporal?</v>

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<v Penny Southworth>Time point at which you know the outsourcing starts for a particular program.</v>

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Tammy Ackerman Yeah, that's a good question. I think, I mean, these are all good questions, but that's that's interesting. The question is where, when and what the scale up of this app sourcing process over the past, probably 1050 years, I've seen again not in the increase, but the trend has been kind of moving away from keeping an in house from the preclinical into clinical. But definitely the ramp up comes into the clinical even from early stage development phase one to phase three so.</v>

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Tammy Ackerman You know, in the in differently, I would say small, medium sized companies they they do the benchmark preclinical outsource all the way through nowadays you rarely would see a company that has in-house capabilities. I mean maybe some indicators early on but then after that to scale it up they have to outsource it, but definitely into clinical trials phases one through three, this is all you know year to outsource.</v>

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<v Penny Southworth>Yeah. And so I guess that's a an interesting.</v>

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<v Penny Southworth>You know thing for these service providers to think about, you know obviously with the goal of trying to, you know become a preferred partner and and try to provide as as much of the you know service across the lifecycle as possible does it does it make the most sense for them to try to get in, you know during the the preclinical phase, are they more likely to be able to you know follow the program assuming they do a good job during the preclinical and phase one, are they more likely to be you know selected as the phase two and and then phase three providers.</v>

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Tammy Ackerman Well.</v>

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Tammy Ackerman Just like anything else, once you get used to and comfortable with the vendor, it's better to stay with them as best as you can.</v>

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Tammy Ackerman Truth to be told, is not all vendors. They can actually scale up as quickly as you want. When it comes into large scale phase twos and threes.</v>

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Tammy Ackerman So it's not unusual that despite the fact that you wanna stay with them throughout your preclinical all the way through your, let's say your face too.</v>

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Tammy Ackerman You, you, you have the you're forced to go to another vendor because of scale up costs and everything else.</v>

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Tammy Ackerman But if you could maintain that relationship from the benchmark earlier stage preclinical all the way through your pivotal and and and potentially outsource system of phase three and or into submission, then the answer is absolutely yes. It definitely helps and makes everything running much smoother I would say and comfortable truth to be told is our early stage development vendors.</v>

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Tammy Ackerman Usually I would say 50 at least 50% of the time change over time as the scaling changes within the.</v>

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<v Penny Southworth>Got it. And Sue there really there it's it's kind of a nice to have to be able to stick with the same vendor across the development cycle, but both there will be an evaluation of potential vendor options at each stage.</v>

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<v Penny Southworth>And also you know, if you're if you were not the preferred vendor for the preclinical, that doesn't mean you couldn't eventually be the the preferred vendor when it gets to to face or so there's really there's really the opportunity to kind of.</v>

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<v Penny Southworth>When business leader in the cycle but then you know if you win the business earlier, definitely not guaranteed to keep it as you go through. So you have to maintain those high levels of of service and and be able to do the things that the client needs.</v>

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Tammy Ackerman Well, truth to be told is.</v>

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Tammy Ackerman I mean, you have to look at the KPC that you have, the KPC's, the key procurement criteria, the small medium size companies are more, I would say.</v>

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Tammy Ackerman Ohh, financially driven, in other words, cost is more important than anything else as opposed to larger companies that they're less of cost more of longevity of relationship.</v>

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Tammy Ackerman But again, companies that they do low scale.</v>

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Tammy Ackerman Hi specific high precision.</v>

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Tammy Ackerman Laboratory outsourcing services.</v>

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Tammy Ackerman Are entirely geared a little bit differently than large volume franchise.</v>

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Tammy Ackerman The central lab systems and you know that's that's not unusual.</v>

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Tammy Ackerman Uh, but then again, depends on how sophisticated your precision medicine is actually pushing through.</v>

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Tammy Ackerman Because this this.</v>

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Tammy Ackerman This concept of ohh I need, you know lab work depends if they're a assays are readily available. They're CDH CDRH if you will certify.</v>

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Tammy Ackerman So.</v>

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Tammy Ackerman You know you you could. You could say they're labs are GLP. You could use this for pivotal trial which early states you don't really need a GLP lab but it's a good to have type of situation.</v>

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Tammy Ackerman Truth to be told is yes. At any stage you know there, there's opportunity for companies to enter and and and come strong.</v>

00:11:50.980 --> 00:12:20.730

<v Penny Southworth>Got it. OK. No. As you're thinking about your needs kind of broadly across this specific clinical trial, let's see, let's say you need biomarker services, you know, to help with immune response monitoring or immune monitoring. But then also you know, maybe you also need a genomic biomarker or proteomic biomarker for the same program. Are you interested or or more likely to want to use the same vendor across both of those needs?</v>

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<v Penny Southworth>Or or do you kind of pick the preferred vendor for each? You know each element of the the trial what's what sort of the thinking around. If there's any synergies available with you know, the same service provider covering multiple biomarker needs.</v>

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Tammy Ackerman The preference is always there to use the same vendor as much as possible because of the ease of everything, and also because of.</v>

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Tammy Ackerman I would say MSA agreement that you have and everything else the master service agreement that you have.</v>

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Tammy Ackerman That's the preference. Does it happen that we have to deviate from that preference? The answer to that is yes. The question is, you know, how often and what kind of triggers that.</v>

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Tammy Ackerman In small, medium size companies, usually it's cost turn around and also availability of of of of what we need. These three items are pretty much the governing factors as far as the cost is concerned. In my experience I could probably in general sell out the differential of about 2025%. Anything more than that, you know, we still have to bet it out and we have to kind of figure out if that cost can justify to.</v>

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Tammy Ackerman Diversified the vendor or stayed with the same vendor as far as time, turn around time and also availability if the essays are available. If they can do the volume that you want in the timeline that you want if they're.</v>

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Tammy Ackerman Uh, you know they have a proven track record in the type of essays that the large volume assays. Those are the questions, the technical capabilities come into the picture. But in general, mostly all of these.</v>

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Tammy Ackerman Companies, you know your life CRO's definitely, regardless of who does it, they can do the job. I've never had a situation that our feed, something that the large errors states had no to us. Whether the volume was low or the cost was bedded low or it was something that it was not, you know, it wasn't monumentally different. So I haven't had a chance for the large CRO to say no.</v>

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Tammy Ackerman Not because they have the facilities is because they they always outsource a lot of the small work to multiple, if you will laugh.</v>

00:14:37.910 --> 00:14:40.100

Tammy Ackerman Uh. I mean, even Covance and?</v>

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Tammy Ackerman Quintiles. Well, now IQ via seniors health. Then you know I3. These are, you know, the companies that they have access to multiple labs at the same time. So they could, you know, they could figure out a logistics, but usually that comes with a cost as opposed to if you go directly to the smaller vendors, your precision for medicine types because they've bought a lot of labs and they can do a lot of work or.</v>

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Tammy Ackerman You know other companies, let's say.</v>

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Tammy Ackerman Uh.</v>

00:15:13.770 --> 00:15:15.760

Tammy Ackerman I I don't know.</v>

00:15:17.240 --> 00:15:32.880

Tammy Ackerman The South care care that you mentioned in Queen track, these are smaller, if you will, immune analytics, especially the the latest satellite, different offices that I was told that they they kind of acquire as a part of the system so.</v>

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Tammy Ackerman Uh.</v>

00:15:35.470 --> 00:15:47.460

Tammy Ackerman Preferences there. But then again the KPC change in small medium size company for the big companies, but at the end it's a matter of availability and also you know compliance with what you want.</v>

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<v Penny Southworth>OK.</v>

00:15:53.290 --> 00:16:12.370

<v Penny Southworth>Umm one other question, maybe before we get to some of the the feedback on the specific vendor actually maybe one or two. Well curious to understand you know when you're kind of in the earlier stages of these types of programs, the ability for the vendor to work with you to develop a a custom.</v>

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<v Penny Southworth>Assay versus things that are more off the shelf and whether or not it's it's valuable to have more things off the shelf or if it's more valuable to be able to do you know, custom work ideally obviously you know somewhat rapidly. You know I'm curious to know what your thoughts would be or recommendations to these companies in terms of being flexible versus having a lot of off the shelf options.</v>

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Tammy Ackerman Well, at the early stage development, it's OK to go with off the shelf and that's that. I'm sorry, custom made and and the reason is again you're in the exploratory stages of where you go. But you know once you have data that potentially you need to.</v>

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Tammy Ackerman It it conversation of pivotal studies or going towards registrational expose approach then you know off the shelf is what you should be worried about because at the end, if not, what's gonna happen is first you have to validate the essay and validation of essay is gonna take.</v>

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Tammy Ackerman A long time and and and convincing of CDRH and convincing of of your theaters, and usually that conversation comes in if if you're doing a custom made as a part of your Type C communication with the agency. Especially in this study in the start of your phase two event and the phase two meeting into phase three meeting.</v>

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Tammy Ackerman So again, that that's it's a matter of the stage of where you are versus the preference that you gotta go with off the shelf or custom made. But sometimes off the shelf is not available.</v>

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Tammy Ackerman And sometimes office shelf is too expensive.</v>

00:18:08.340 --> 00:18:17.680

Tammy Ackerman And sometimes off the shelf is not where you want to go because you may wanna use that essay, as you said, as a potential opportunity of companions.</v>

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Tammy Ackerman A device for your drug and I've I've had NBA that we have to go through that process, which means it's it behooves you to to go through a GLC facility and have the device, the essay itself, as a companion device, as a part of the.</v>

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Tammy Ackerman The the the NDA approach so that that costs a lot of money. Well, as I should say, a lot of money, but they cost money, time, effort but it gives you a commercial edge as opposed to you know your competitor also all depends I would say.</v>

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<v Penny Southworth>OK.</v>

00:18:58.980 --> 00:19:30.090

<v Penny Southworth>OK. Well, I think I'll have a a follow up question on one of those on on part of that. But I I think it might make sense to come back to it on the other. The other general question I had was around kind of the global presence or global reach of the the CRO's and the important of you know having local infrastructure in areas like the APAC region for example or Europe. You know again smaller to medium sized biopharma, are they may be.</v>

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<v Penny Southworth>Less interested in those global capabilities by chance or you know how, how important or unimportant is that.</v>

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Tammy Ackerman Well.</v>

00:19:39.050 --> 00:19:46.290

Tammy Ackerman Depends on your clinical trial. It's unavoidable for you, especially in oncology immunology.</v>

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Tammy Ackerman Space.</v>

00:19:49.230 --> 00:19:51.710

Tammy Ackerman To not be global.</v>

00:19:52.880 --> 00:19:55.950

Tammy Ackerman In other words, you don't see that many face one too.</v>

00:19:56.750 --> 00:20:01.890

Tammy Ackerman I mean, phase one. Yeah, you could. You could you, you could say I'm. I'm gonna stick with the US only.</v>

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Tammy Ackerman But comes to faith. You know, 1D/2, you have to go global because accrual is a major issue. Once you go global, you have to have at least global logistics to get your sensor lab going.</v>

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Tammy Ackerman And obviously the first question is can they?</v>

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Tammy Ackerman Service this study.</v>

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Tammy Ackerman If it's global and where and what region, and so and so forth, so the the answer to that is the logistics.</v>

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Tammy Ackerman Versus the need versus the type of the study and and where you are in the stage governs if it has to be global and or where global to have that presence or logistics capabilities, companies like covan.</v>

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Tammy Ackerman Uh, they have. You know, they've they've traditionally had the global presence.</v>

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Tammy Ackerman It doesn't mean they have labs in every country. It just means that samples they could actually travel in, the proper approach and they get where they're supposed to go and they would be universally analyzed. And that universality and the certification of compliance associated with the facilities that they have, that defininitely takes the question out, if you're going to use that data for registration purposes.</v>

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Tammy Ackerman Other companies may not have that, so that's important.</v>

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Tammy Ackerman So it all depends, but yes.</v>

00:21:34.030 --> 00:21:38.820

Tammy Ackerman By now, almost every player that they do not provide.</v>

00:21:39.540 --> 00:22:04.380

Tammy Ackerman That level of global capability, they cannot grow and they cannot outgrow themselves from probably early stage development. Preclinical into later stage development and the need for registrational which is you know large and I would say larger in sample numbers and larger in cost value proposition.</v>

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<v Penny Southworth>Uh-huh. Are there any differences with the different geographies in terms of the needs of the?</v>

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<v Penny Southworth>The trailer the vendor so like for example, if you're, you know if you have sites in Europe are are things treated differently or done differently versus if you have sites in the Asia Pacific region, do you have to do things differently or what you know what should the vendors understand about the differences if there are any?</v>

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Tammy Ackerman I don't know what you mean by differences. If you mean the the techniques by which the samples they have to be analyzed, usually they're not. They're all the same technique. So essentially there's a universal approach.</v>

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Tammy Ackerman From a sample acquisition to logistics of transportation into.</v>

00:23:16.650 --> 00:23:16.960

<v Penny Southworth>Yeah.</v>

00:22:53.130 --> 00:23:17.620

Tammy Ackerman Uh, safekeeping and and storage as well as the analysis, data acquisition and analysis of the data and data storage and production of the data. So these are all validated process and used pretty much across the board globally. If you're in Africa versus you're in Asia or oceanic or US or.</v>

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<v Penny Southworth>Yeah. OK. So it is, it is pretty consistent globally.</v>

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<v Penny Southworth>In any situations, are there requirements to perform any of the testing locally? You know whether that's the regulator's prefer that, or is it completely reasonable to have your site in Japan? But you know.</v>

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<v Penny Southworth>Evaluate the sample in Europe or in the US. Are there ever any kind of like requirements around?</v>

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<v Penny Southworth>Being more local with the analysis to the trial site.</v>

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Tammy Ackerman Well.</v>

00:23:55.990 --> 00:24:12.350

Tammy Ackerman There are two ways to look at this conversation. Number one is the need of those advances. Are they prognostic and and if time lapse is an issue or not, because sometimes the sample from the time that it gets acquired process.</v>

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Tammy Ackerman Sense.</v>

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Tammy Ackerman Stored analyzing come back May may. There may be a a lag time which in fact actually eats into the time associated with the treatment to the patient. So if it's local to be done or locally or the bestially to that nation or that geography.</v>

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Tammy Ackerman That time.</v>

00:24:35.460 --> 00:24:36.890

Tammy Ackerman Is, is is safe?</v>

00:24:37.610 --> 00:24:44.690

Tammy Ackerman So in those I would say more than rare. I would say occasion. Then you have to have a local labs you know.</v>

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Tammy Ackerman At at the disposal of the site.</v>

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Tammy Ackerman But in General, no, it's not unusual to get the acquired you, you would acquire the sample in one place and send it somewhere else. Have it analyzed and data stored in the 3rd place and final analysis is done by the sponsor in the 4th place. That's not really unusual.</v>

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<v Penny Southworth>Got it. So it's really pretty global in terms of the supply chain in the activities, OK.</v>

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<v Penny Southworth>OK. Wanted to get some thoughts on specific.</v>

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<v Penny Southworth>Senders if you know if I name a few of them, you know the maybe the one or two things that comes to mind or that you associate it.</v>

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Tammy Ackerman Sure.</v>

00:25:29.570 --> 00:25:31.230

<v Penny Southworth>With them, I'd be interested to hear.</v>

00:25:31.870 --> 00:25:33.700

<v Penny Southworth>You know what you're thinking about them so.</v>

00:25:35.430 --> 00:25:36.410

<v Penny Southworth>I'm just checking here.</v>

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<v Penny Southworth>Which one do you? You said you had some.</v>

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<v Penny Southworth>Past experience with if you think about yeah. Bio Agilytix cell Carta.</v>

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<v Penny Southworth>Precision for medicine.</v>

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<v Penny Southworth>And immune analytics.</v>

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<v Penny Southworth>Just kind of curious if you could go eat through each of those and you know what are your like two or three thoughts about them or or what do you think of them for?</v>

00:25:59.780 --> 00:26:09.690

Tammy Ackerman Well, we categorically precision for medicine has become more and more a larger, if you will provider then the other three biogenetics.</v>

00:26:10.740 --> 00:26:12.620

Tammy Ackerman So Carta and immune analytics.</v>

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Tammy Ackerman I'm categorically precision medicine is a large and I would say immune analytics is a medium size and the other two are kind of smaller ones. What does it mean? That means the total number of the samples that they would be able to analyze for you are in the smaller.</v>

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Tammy Ackerman Scale.</v>

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Tammy Ackerman The time to turn around, it's it. It needs to be negotiated to see how fast they can do it. The spectrum and the techniques that would use are entirely.</v>

00:26:43.020 --> 00:27:05.970

Tammy Ackerman More specialized in a smaller provider such as you know biogenetics and and and so Carta immune analytics versus a large organization like precision as opposed to, let's say, lab for. And I don't know Covance, so they play a different role as far as the.</v>

00:27:07.510 --> 00:27:14.820

Tammy Ackerman Other items like. In other words, you would say, well, would they be able to do a complete panel of of of let's say?</v>

00:27:14.910 --> 00:27:15.240

Tammy Ackerman Umm.</v>

00:27:16.580 --> 00:27:39.050

Tammy Ackerman Immune panel for you as opposed to there are some panels. They cannot do. The answer to that is yes. So that that has to be well thought out prior even a large system like Covance may not be able to do those specific precise type of panels that you want to run or a larger spectrum of biomarkers that you want to run.</v>

00:27:40.180 --> 00:27:41.100

Tammy Ackerman Or or.</v>

00:27:41.750 --> 00:28:11.450

Tammy Ackerman Or last but not least, going back to the previous question that you had some of these very specific type of biomarkers that you want to run. They are prognostic and diagnostic tools at the time of treatment of the patient. So what happens is if you don't have a local presence to produce that, then you wouldn't be able to treat the patient. And I can give you examples of that when in clinical trials we have faced that. Having said that you know, yes, these are all sompanies.</v>

00:28:11.700 --> 00:28:29.070

Tammy Ackerman Cost is always important, so lower scale, higher cost usually you know is is, is is in the early stage and or specific type of trials but large scale low cost is when we go routinely through the.</v>

00:28:30.010 --> 00:28:46.250

Tammy Ackerman Yeah, I would say evolution of the development. You know, when you're on on the road, you know, say you're face to be into three that that's when you talk about you know large scale, low cost as opposed to before that which is high cost, low scale.</v>

00:28:47.960 --> 00:29:04.540

<v Penny Southworth>Got it. OK, but accuracy being being key there. So for bioagilytix until Carta you, I I think you were kind of alluding to their maybe known for having niche capabilities or or being really specialized. What for each of those companies, what do you think of their niche being?</v>

00:29:06.890 --> 00:29:08.140

Tammy Ackerman I think there are equally.</v>

00:29:09.900 --> 00:29:12.010

Tammy Ackerman A specific in in the type of.</v>

00:29:12.670 --> 00:29:42.500

Tammy Ackerman OK. Probably I mean, so if if you look at the biomarkers biomarkers by and large, whether there are glycoproteins proteins agilysys of methylated systems, so whatever they are the type of molecules that they are the more precise deviation of the type of an item that you can use and potentially you could get a larger panel of the type of markers that you can get, you could come up with with a sample and you're looking across the board in early stage.</v>

00:29:42.620 --> 00:30:04.910

Tammy Ackerman And you're looking to find, I would say, a needle in a haystack of a value. So, you know, that's not unusual to kind of look at it, but as opposed to something else, let's say you're talking about, you know, a plasmid here and type of protein of a specific protein associated with your own mechanism of action. That's not entirely that.</v>

00:30:05.110 --> 00:30:20.240

Tammy Ackerman You know that in I would say difficult. So even, you know, companies, larger companies, they can do it. So it's very difficult for me to say, oh, these people are very good at, let's say proteins and do other.</v>

00:30:21.150 --> 00:30:51.360

Tammy Ackerman Groups are better in, in glycoproteins and metadata systems, and so and so forth. It's not unusual to get it across, but the larger the panel, the more I would say precision discussion comes in and and the more precision we talked about, the more accuracy we need to come up come about. But accuracy usually is within a confidence interval of getting something, but more of a precision, in other words.</v>

00:30:51.640 --> 00:30:57.460

Tammy Ackerman Do we detect it? Have we detected across? Would we be able to detect that panel?</v>

00:30:58.180 --> 00:31:07.910

Tammy Ackerman In the period of time that we needed to get it detected. So these are small companies, yes, they're nice, but they're not differentiator of one another to my knowledge.</v>

00:31:09.280 --> 00:31:35.230

<v Penny Southworth>OK, even across the different types of technologies or or types of biomarker analysis that you would be doing so like for example, genomics versus proteomics versus histopathology versus, you know immune monitoring. Do you ever think of any of them as being better or worse at one of those or is that consistent with what you said they they all can kind of do all of them?</v>

00:31:36.340 --> 00:31:42.460

Tammy Ackerman No, I I I apologize if I you know, if I impress by saying they all can do all of them.</v>

00:31:43.730 --> 00:31:48.480

Tammy Ackerman First of all, they all cannot do all of them. They don't claim to be doing all of them.</v>

00:31:49.180 --> 00:32:00.690

Tammy Ackerman They claim to be able to do all of them with their so-called partners, so essentially that you know they own in House labs for one or two items and then they they farm out the others.</v>

00:32:02.370 --> 00:32:03.730

Tammy Ackerman Last but not least.</v>

00:32:05.310 --> 00:32:22.430

Tammy Ackerman There are companies that they could do more precise work, for instance, doing instead of doing the PCR they can do next generation sequencing instead of doing one type of PCR that could do another assays of PCR and negotiated for that.</v>

00:32:22.880 --> 00:32:37.070

Tammy Ackerman Uh, instead of at at the different cost as you just mentioned, you know IC versus you know if you wanna use ICM and in the in the absence of that you do PCR and NSG.</v>

00:32:38.390 --> 00:32:43.930

Tammy Ackerman And next generation sequencing NGS. So you know it depends.</v>

00:32:44.710 --> 00:32:55.410

Tammy Ackerman It's not unusual for the need to be and and then we have to kind of mix and match the providers in order to get what we want.</v>

00:32:56.420 --> 00:33:19.700

<v Penny Southworth>Giving and kind of alluding back to the questions earlier, it would there be any ways for the smaller companies like bioagilytix like cell Carta to try to demonstrate to you that they could be more of a like a comprehensive solution across, you know, the different needs that you have for a trial. So you you don't have to do as much as?</v>

00:33:20.960 --> 00:33:22.830

<v Penny Southworth>As much mixing and matching.</v>

00:33:24.750 --> 00:33:30.460

Tammy Ackerman Well, first of all, you try to avoid mixing match as much as possible. Even we go sometimes to compromise.</v>

00:33:31.150 --> 00:33:46.930

Tammy Ackerman The the scientific and and clinical direction. Because of that, in other words, because of the available timeline available in milestone available cost valuable of what's available. In other words science and medicine sometimes suffers because of that.</v>

00:33:48.300 --> 00:34:05.970

Tammy Ackerman Can they do anything to convince us that they're a better partner and absolutely they do it all the time. So yes, if if a vendor has that capability, scientific in outside tific use scientific capability to go toe to toe with us and help us out to understand.</v>

00:34:06.630 --> 00:34:18.090

Tammy Ackerman You know, why should we go with them and and what's the differentiator and why would our direction change because of that differentiator absolutely is going to be a great help.</v>

00:34:24.320 --> 00:34:26.030

<v Penny Southworth>OK and.</v>

00:34:28.850 --> 00:34:38.380

<v Penny Southworth>Again, is there anything related to the timing of, you know, when these vendors get involved in the programs that can help with?</v>

00:35:01.450 --> 00:35:01.700

Tammy Ackerman Yeah.</v>

00:34:39.530 --> 00:35:04.960

<v Penny Southworth>Then you know kind of setting themselves up for success. So like for example, would you be going with would you be more likely to go with like a cell Carta or a bioagilytix in the early phases of development like preclinical phase one and then more likely to go with a bigger player later on or or what are the dynamics for some of the smaller vendors in terms of you know kind of setting them up for success to follow the molecule?</v>

00:35:06.280 --> 00:35:08.170

Tammy Ackerman The larger the.</v>

00:35:09.070 --> 00:35:24.740

Tammy Ackerman The pool of the samples, the larger the vendor should be, that kind of rule of thumb, that doesn't mean we follow that all the time or not, which means the smaller pool earliest stage, earliest stage means more niche boutique, if you will, vendors.</v>

00:35:25.990 --> 00:35:26.490

Tammy Ackerman Again.</v>

00:35:27.430 --> 00:35:38.000

Tammy Ackerman It's not unusual for us to do preclinical early stage clinical with one and then switch to another not only for the volume but the cost and the turnaround. Last but not least.</v>

00:35:38.660 --> 00:35:53.280

Tammy Ackerman Having GLC facilities in in the time frame that we want as well as their assets are actually approved CDRH or EU assays, so we have to be worried about that. Those types of things also.</v>

00:35:54.770 --> 00:36:12.380

Tammy Ackerman Last but not least, if they're with us during the early stage, they could actually help us with a large stage, large case transfer also, but that early stage that they're with, you know they they they provided such a valuable if you will.</v>

00:36:12.800 --> 00:36:22.390

Tammy Ackerman Uh, knowledge and and and service that it's not unusual for us to stick with them throughout our R&D for multiple programs at the same time.</v>

00:36:28.630 --> 00:36:29.450

<v Penny Southworth>Yep, OK.</v>

00:36:39.260 --> 00:36:39.450

<v Penny Southworth>OK.</v>

00:36:41.640 --> 00:36:45.530

<v Penny Southworth>Let's see. Any other thoughts or recommendations on?</v>

00:36:46.450 --> 00:36:48.420

<v Penny Southworth>If you you know if you knew that.</v>

00:36:49.110 --> 00:36:58.860

<v Penny Southworth>So Carta or Bioagilytix was, you know, was on the line. What would you say to both of those companies to try to?</v>

00:36:59.740 --> 00:37:08.040

<v Penny Southworth>Uh, improve their offerings as as much as possible, or to be, you know, positioned the best to support, you know, your type of organization.</v>

00:37:09.650 --> 00:37:09.990

Tammy Ackerman Well.</v>

00:37:10.650 --> 00:37:23.580

Tammy Ackerman If if you would have put me in charge of one of these labs and you would say OK today, which direction do we go in order to have, you know, a Better Business success, if you will. I would work a little bit backwards if that's the question.</v>

00:37:24.420 --> 00:37:29.520

Tammy Ackerman I would say work this concept a little bit backwards. Ask yourself the question.</v>

00:37:30.290 --> 00:37:36.590

Tammy Ackerman Look at the number of the clean trial that registered clinical trials company sponsored. That's #1.</v>

00:37:37.250 --> 00:37:59.260

Tammy Ackerman And then among those, look at which area of what, what's the therapeutic area, what are the indications? What are the type of analytics that goes into those type of trials and gear yourself towards that big chunk of business and then work backwards and ask yourself the question of all of that, which one?</v>

00:38:00.490 --> 00:38:04.090

Tammy Ackerman I would say cease and which one are famine, in other words.</v>

00:38:04.880 --> 00:38:18.250

Tammy Ackerman Which one of these type you would say? Ohh you know what? You know next generation sequencing associated with let's say colorectal is more important than anything else because that's the niche market.</v>

00:38:18.950 --> 00:38:32.690

Tammy Ackerman Or that's something that no one else is doing because everybody else is doing IT and health authorities are OK with it. Then I would go to and GGS and then kind of work backwards. So essentially you have to look at what the trend is.</v>

00:38:33.380 --> 00:38:43.710

Tammy Ackerman Where the companies are, where the need is kind of work yourself backwards and and try to concentrate in those areas rather than what everybody else and everybody can do it.</v>

00:38:45.170 --> 00:39:03.610

Tammy Ackerman Most companies are are capable to do, let's say PCR. A lot of companies they can do you know protein detections, they can do a complete let's say neural panel biomarkers but not that many of them they can do you know precise immune models of let's say CNS.</v>

00:39:04.360 --> 00:39:11.190

Tammy Ackerman Looking flame systems. So if you look at it from that perspective, these are the companies that they can, they can work with.</v>

00:39:11.700 --> 00:39:33.680

Tammy Ackerman Uh, I mean large trials three, 4000 in Alzheimer's, there are two or three mark, you know markers that you have to look for. I remember when Biogen was saying that they can't find the vendor to do it. So it's very important to kind of see where the trend is, where this space is demanding and kind of gear yourself towards it. And for our studies.</v>

00:39:34.430 --> 00:39:35.680

Tammy Ackerman The need is going up.</v>

00:39:36.710 --> 00:40:05.340

Tammy Ackerman You know, I I I. That's what I do. I do immunology and immunology and oncology. So the need is there and we're going more and more into precision medicine. I mean you hear that all the time, but truth to be totally is over the past 15 years, they need is such a high ramp up. There is not one clinical trial that I haven't been involved with for almost 1015 years. That biomarker biomarker analysis was a part of one of the endpoints. So it is what it is.</v>

00:40:06.260 --> 00:40:20.110

<v Penny Southworth>Yeah, you mentioned NGS sounds like kind of an important technology going forward. Are there any other like two to three technologies that you think might be really key to have you know over the next 5 or so years?</v>

00:40:22.910 --> 00:40:31.000

Tammy Ackerman Well, I said NGS because you know the precision accuracy as opposed to a differentiator of IC and and and and PCR.</v>

00:40:31.710 --> 00:40:33.380

Tammy Ackerman But outside of that, you know?</v>

00:40:34.530 --> 00:40:40.350

Tammy Ackerman Large volume sequential essays for the for the markers and the market detection.</v>

00:40:41.400 --> 00:40:56.780

Tammy Ackerman You know, if you can run multiple samples in in, in series in a short period of time and with precision and accuracy, you could actually read through the panel as quickly as you wanted. Obviously, it's gonna be a great venue.</v>

00:40:57.940 --> 00:41:07.870

Tammy Ackerman One thing that we have to understand is whatever we design in a clinical trial at one point or another, it has to become a part of a standard of care.</v>

00:41:08.500 --> 00:41:12.790

Tammy Ackerman It's a company that can actually design something and think about scaling it.</v>

00:41:13.390 --> 00:41:20.220

Tammy Ackerman And that scaling would actually be able to be used at the center of service or at the point of service.</v>

00:41:21.010 --> 00:41:33.460

Tammy Ackerman This that's somebody would be a very successful company. It's truth to be told that if something is not done at the center of Excellence, but tomorrow if I wanna treat these patients at the moms and Pops oncology center.</v>

00:41:34.120 --> 00:42:03.570

Tammy Ackerman I can't always send the marker wait for the marker to end answer, then go back and and digress myself from the treatment management of the patient. It becomes, you know, I have to be able to send it, get my values with 4472 hours, just like a CBC and then proceed with treating the patient one way or another as opposed to sending it and wait for it for weeks to get me an answer. That means the cancer patient is in the state of limbo. What are they going to get or you know.</v>

00:42:04.070 --> 00:42:21.550

Tammy Ackerman Bad. I don't know. Sorry. Exit my patient. I mean, they're they're literally boiling on their skin. And I can't do anything but just some method tracks or whatever to cool it down. So these are the this is where I think the trend is going to go and have the companies are focusing.</v>

00:42:23.830 --> 00:42:42.340

<v Penny Southworth>OK, alright, very, very hopeful with our last 15 minutes or so. I'm curious to understand maybe some of the adjacent type of offerings that a biomarker vendor might be able to offer in addition to their, you know their typical biomarker analysis.</v>

00:42:44.230 --> 00:42:54.460

<v Penny Southworth>That services and understand what these adjacencies if there's any, you know, potential synergies that might exist or you know ways that you might be able to.</v>

00:42:55.350 --> 00:43:02.370

<v Penny Southworth>Leverage that relationship around the you know the the biomarker needs to some of the other applications, so.</v>

00:43:07.840 --> 00:43:08.060

Tammy Ackerman Sure.</v>

00:43:23.380 --> 00:43:23.640

Tammy Ackerman Yeah.</v>

00:43:04.210 --> 00:43:33.560

<v Penny Southworth>I'll just kind of go through that and maybe you know one by one and and get your thoughts on on the needs earlier. You talked a little bit about how some of these biomarkers are kind of playing a companion diagnostic role and potentially being developed as companion diagnostics for the products that are in development. What do you think about the biomarker company offering that additional capabilities so that they could be a you know the companion diagnostic?</v>

00:43:34.580 --> 00:43:40.300

<v Penny Southworth>Offering you know, at the time of the the products launch, is that something that would be of interest?</v>

00:43:42.570 --> 00:43:45.820

Tammy Ackerman I mean that if if the same developer.</v>

00:43:47.010 --> 00:43:48.510

Tammy Ackerman The same partner.</v>

00:43:49.790 --> 00:43:57.960

Tammy Ackerman All of a sudden it says, OK, you're the biopharma. You're developing the drug. But I can give you the biomarker companion diagnostics.</v>

00:43:59.050 --> 00:44:00.310

Tammy Ackerman Essay or the tool.</v>

00:44:00.960 --> 00:44:07.360

Tammy Ackerman And we could partner up and we're capable to do that together. That's as good as gold because.</v>

00:44:08.250 --> 00:44:18.050

Tammy Ackerman Again, everybody wants to stay in lane. We're via farmers and then there would be an exchange obviously in the process, whether it's gonna be a cold licensing or what have you.</v>

00:44:18.660 --> 00:44:24.050

Tammy Ackerman So that that, that's that's big, that's huge. Plus it gives it commercial advantage to both parties.</v>

00:44:27.300 --> 00:44:29.650

<v Penny Southworth>OK. So it sounds like there would be a lot of value there.</v>

00:44:30.410 --> 00:44:30.670

Tammy Ackerman Yep.</v>

00:44:31.980 --> 00:44:32.370

<v Penny Southworth>OK.</v>

00:44:36.340 --> 00:44:39.230

<v Penny Southworth>We already talked about it a little bit, but.</v>

00:44:39.790 --> 00:45:00.270

<v Penny Southworth>Uh needs outside of the clinical trials going and looking at things that are, you know, preclinical phase or other kind of like supplementary research needs that aren't directly part of a clinical trial. Would you see that as a a good adjacency for these biomarker testing companies?</v>

00:45:01.420 --> 00:45:16.970

Tammy Ackerman If you can dashboard yourself to produce those type of additional so-called transaltion services, if you will, initial consulting services, I would call it for the lack of better term. If you could provide that with the intention of dashboard yourself into the process.</v>

00:45:26.700 --> 00:45:27.250

<v Penny Southworth>Yeah.</v>

00:45:17.920 --> 00:45:28.770

Tammy Ackerman Because don't forget once, once you're in with the developers or developing company, over time, you're part of the team. That would be a big bag to the sponsor.</v>

00:45:29.990 --> 00:45:49.110

<v Penny Southworth>Got it. So the difference in the need for those types of services are that you need more of the customized developed assay. So there is a lot of good sense into going into those agencies, but the need is is maybe slightly different than sort of your bread and butter clinical trial.</v>

00:45:50.580 --> 00:45:53.010

Tammy Ackerman Right. Well, your, your contact.</v>

00:45:51.750 --> 00:45:53.010

<v Penny Southworth>Where you'd want to wear a pit.</v>

00:45:54.590 --> 00:45:55.640

Tammy Ackerman I would, I would say.</v>

00:45:59.450 --> 00:46:04.040

Tammy Ackerman Once your dashboard yourself as a cutting edge company that you're not just.</v>

00:46:05.320 --> 00:46:08.470

Tammy Ackerman A franchise organization of providing bread and butter.</v>

00:46:09.430 --> 00:46:22.260

Tammy Ackerman That obviously brings you to a different level of a partner rather than a company that I would say ohh you know I could, I could do a a I don't know connective tissue protein assays and that's that.</v>

00:46:23.500 --> 00:46:26.940

Tammy Ackerman Everybody can do it. You know? Why should I be worried about? I could just get it from.</v>

00:46:27.660 --> 00:46:27.980

Tammy Ackerman You know.</v>

00:46:28.710 --> 00:46:30.400

Tammy Ackerman I don't know. Uh, parking albers.</v>

00:46:34.110 --> 00:46:34.420

<v Penny Southworth>Yeah.</v>

00:46:32.410 --> 00:46:41.490

Tammy Ackerman Catalog book. So if if you can move yourself away from that, obviously it it becomes more and more of of of of a partnership value.</v>

00:46:42.410 --> 00:46:42.910

<v Penny Southworth>Got it.</v>

00:46:42.210 --> 00:46:48.010

Tammy Ackerman Because don't forget all the sponsors, they have all very good scientists on staff to help them out either.</v>

00:46:50.490 --> 00:46:50.870

<v Penny Southworth>Yep.</v>

00:46:52.440 --> 00:47:24.590

<v Penny Southworth>OK. That makes sense. And kind of a related idea that's slightly different would be for the you know specialized biomarker testing company to offer more broad central lab services you know with the idea being that they could kind of meet all the diagnostic and testing needs across the clinical trial but they would be doing some of these you know kind of less sophisticated types of lab lab tests associated with the trial. Any thoughts on whether or not that would be?</v>

00:47:24.840 --> 00:47:25.490

<v Penny Southworth>Of value.</v>

00:47:28.300 --> 00:47:32.640

Tammy Ackerman Well, there are two 222 venues to look at this.</v>

00:47:45.650 --> 00:47:45.860

<v Penny Southworth>Yeah.</v>

00:47:33.790 --> 00:48:03.320

Tammy Ackerman The big vendors such as LabCorp, Covance, IQVIA and so and so forth, they already have that. The question is, what's the differentiator here in this conversation? Your answer would be bringing OK the the space is expanding. This space is becoming more and more plentiful. Therefore there is a catch up game that these large organizations like Covance, LabCorp, they have to do. If the panel was, let's say 28.</v>

00:48:03.620 --> 00:48:07.580

Tammy Ackerman Item specific now it's 128 items specific.</v>

00:48:08.240 --> 00:48:23.600

Tammy Ackerman We're not everybody has that kind of capability or grandpa in technology and and and serial sequencing and so on and so forth. Not someone comes in and swoops it off and they said, oh, I can do a central of this. Well, obviously they're gonna be the winner. The question is.</v>

00:48:25.700 --> 00:48:26.890

Tammy Ackerman Are we willing to?</v>

00:48:27.610 --> 00:48:39.300

Tammy Ackerman It does this space have the capacity for it. The answer is yes. In other words, biopharmas and the space of R&D has the capacity for it. The other question is it a major advantage?</v>

00:48:40.000 --> 00:48:43.230

Tammy Ackerman To be honest with you, I have to do some analytical, if you will.</v>

00:48:43.310 --> 00:48:43.570

Tammy Ackerman Uh.</v>

00:48:44.780 --> 00:48:50.570

Tammy Ackerman Fielding of this conversation, but from the face of it, what I hear absolutely, I mean the better.</v>

00:48:51.830 --> 00:48:54.940

Tammy Ackerman The more plentiful of a central lab service that I have.</v>

00:48:55.710 --> 00:48:59.320

Tammy Ackerman The easiest life becomes for me when I'm designing the protocol.</v>

00:49:01.890 --> 00:49:12.130

<v Penny Southworth>Got it. So like for example, if a company like biologics or cell, Carta said, we're also gonna be able to do your central lab services, it sounds like that would be.</v>

00:49:13.480 --> 00:49:15.340

<v Penny Southworth>A nice a nice addition.</v>

00:49:16.750 --> 00:49:17.380

Tammy Ackerman Absolutely.</v>

00:49:18.260 --> 00:49:34.450

<v Penny Southworth>OK. And then on that point, are you and you know other companies you know kind of like your size, is it the same person making the decision about your biomarker testing needs as as the central lab testing needs?</v>

00:49:36.100 --> 00:49:43.710

Tammy Ackerman At different stages are different people. At the end of budget comes out of someone like me. As the head of R&D.</v>

00:49:44.300 --> 00:49:54.240

Tammy Ackerman But if you're early stage, you're scientific group, your Chief Science Officer group, if you will, they make the critical decision, who the vendor should be.</v>

00:49:54.930 --> 00:49:58.090

Tammy Ackerman And then, you know, discuss it with, with with the bigger.</v>

00:49:58.930 --> 00:50:01.560

Tammy Ackerman System like the head of the R&D.</v>

00:50:03.420 --> 00:50:15.880

Tammy Ackerman But when it comes to the clinical trials phases one through three, that capacity diminishes from earlier stage to the late stage from scientific group to clinical Operation Group.</v>

00:50:16.610 --> 00:50:24.900

Tammy Ackerman So there is a transfer of of power of of the signature people. But at the end it comes from the budget. The cord decision maker at the end.</v>

00:50:25.640 --> 00:50:31.120

Tammy Ackerman Is going to be head of the R&D, whether it's gonna be a chief medical officer, Chief operating officer.</v>

00:50:31.800 --> 00:50:47.240

Tammy Ackerman Or you know there there is a a a a head of R&D in the in the system which actually the CMO, the VP of Operations and the Chief Science Officer, they're all kind of report to that person and not necessarily the CEO.</v>

00:50:49.480 --> 00:50:56.960

<v Penny Southworth>Yeah. OK. That makes sense. So depending on the stage, obviously the size of the company might also influence that. It may or may not really be the same.</v>

00:50:58.720 --> 00:50:58.960

Tammy Ackerman Yeah.</v>

00:50:58.010 --> 00:51:00.300

<v Penny Southworth>Uh, individual, OK.</v>

00:51:01.130 --> 00:51:18.200

<v Penny Southworth>What about some of the kind of like wrap around needs after the sample has been analyzed and this would include things like data management, bioinformatics, analytics, you know which could go kind of all the way up to.</v>

00:51:19.110 --> 00:51:30.770

<v Penny Southworth>You know, even sort of like the biostats needed to understand what the the results mean for the trial. Would you be interested in getting those types of services from?</v>

00:51:32.180 --> 00:51:34.240

<v Penny Southworth>You know a biomarker vendor.</v>

00:51:37.700 --> 00:51:51.510

Tammy Ackerman The smaller company that you are, the more you need those services to be provided by someone, and usually it's better to be provided by the laboratory vendor rather than someone else.</v>

00:51:52.640 --> 00:51:57.430

Tammy Ackerman It's not unusual. We just get the data and we regurgitate data including.</v>

00:52:00.170 --> 00:52:01.820

Tammy Ackerman I'll buy that as you mentioned.</v>

00:52:02.650 --> 00:52:08.200

Tammy Ackerman Done in house or done by by a statistics service provider.</v>

00:52:22.970 --> 00:52:23.380

<v Penny Southworth>Yeah.</v>

00:52:09.250 --> 00:52:27.150

Tammy Ackerman But yes, if if all of those they can be done in house, it's cheaper, simpler, easier for us. We just give them the shell or we just have a conversation on Friday, the fast for the analysis and they do A-Z of it. They acquire the data, they store the data, they analyze the data, they just give us the.</v>

00:52:28.250 --> 00:52:29.660

Tammy Ackerman Raw result in that set.</v>

00:52:32.350 --> 00:52:43.870

<v Penny Southworth>Got it. So it sounds like that would be of a value. And again similar question, would you be the one making the decision for that type of service or is it a different entity within the organization who does that part of it?</v>

00:52:46.600 --> 00:52:47.410

Tammy Ackerman OK so.</v>

00:52:48.700 --> 00:52:51.450

Tammy Ackerman This part that you know.</v>

00:52:53.660 --> 00:52:54.990

Tammy Ackerman Data storage.</v>

00:52:56.460 --> 00:52:57.350

Tammy Ackerman And now it says.</v>

00:52:59.070 --> 00:52:59.890

Tammy Ackerman Usually.</v>

00:53:00.810 --> 00:53:02.740

Tammy Ackerman It's it's a part of the.</v>

00:53:05.160 --> 00:53:20.060

Tammy Ackerman A part of the bigger RP, so essentially it's it's the same people who make the decision which lab they go with. They make the decision where to how to acquire the data, where to store the data, how to analyze it and who analyzes it right.</v>

00:53:20.700 --> 00:53:29.310

Tammy Ackerman And these are the same people. And again depends on where you are in the stage. If you're early stage, it's your, you know chief Science Officer group.</v>

00:53:29.990 --> 00:53:36.060

Tammy Ackerman And at the end, the head of the operation makes the decision. But for those ancillary services.</v>

00:53:36.790 --> 00:53:39.300

Tammy Ackerman The cost is, you know, a A.</v>

00:53:40.670 --> 00:53:41.410

Tammy Ackerman A fraction.</v>

00:53:42.380 --> 00:53:49.760

Tammy Ackerman Maybe 2030%, but still it's not as big or bigger than the actual analysis.</v>

00:53:50.620 --> 00:54:02.840

Tammy Ackerman Depends on if you want to do a lot of fancy work and multiple cuts and all of that good stuff. So the cost goes up, but it's not the big cost that part. So same people will make the decision for that part.</v>

00:54:05.550 --> 00:54:09.140

<v Penny Southworth>OK, so there's there is good overlap, it sounds like.</v>

00:54:10.960 --> 00:54:12.940

<v Penny Southworth>Yeah, OK. Yeah.</v>

00:54:09.870 --> 00:54:14.150

Tammy Ackerman Yeah, it's it like it wrap around type. Yeah. Decision making process, yeah.</v>

00:54:14.410 --> 00:54:14.800

<v Penny Southworth>OK.</v>

00:54:15.490 --> 00:54:24.100

<v Penny Southworth>What about some of the other lab logistics things like cold storage? You know, curious to know if that would be a value from the same vendor.</v>

00:54:26.410 --> 00:54:34.920

Tammy Ackerman Well, that's definitely a becoming more of a challenge. Believe it they're not. Then whoever like you just said cold storage.</v>

00:54:35.500 --> 00:54:39.970

Tammy Ackerman Because you know your your minus 3070 degrees cold storage.</v>

00:54:40.090 --> 00:54:46.880

Tammy Ackerman A. Your your super cool system, all centers of excellence they have.</v>

00:54:48.320 --> 00:55:09.890

Tammy Ackerman Logistical challenges they the the space is limited, so they can't keep the samples and stuff like that for a long period of time, so things have to go and and be kept somewhere, so whoever provides those logistics are as good as gold for operation because that could become a headache. And I've seen it. That's like the weakest link in the bigger picture.</v>

00:55:12.570 --> 00:55:15.830

<v Penny Southworth>So having a really effective solution, there could be.</v>

00:55:18.070 --> 00:55:19.200

<v Penny Southworth>Of a lot of value.</v>

00:55:20.590 --> 00:55:21.770

Tammy Ackerman Absolutely yes.</v>

00:55:29.780 --> 00:55:47.580

<v Penny Southworth>This one I think is going a little farther afield, but it may leverage this similar technologies and this would be analytical services related to more of like the manufacturing or commercial stage. So like CMC types of services, would you see potentially any synergies there?</v>

00:55:49.730 --> 00:55:50.130

Tammy Ackerman Well.</v>

00:55:51.590 --> 00:55:52.340

Tammy Ackerman Don't forget.</v>

00:55:52.940 --> 00:55:56.170

Tammy Ackerman Anything that we use for the CMC as a part of the compliance process.</v>

00:55:57.280 --> 00:56:09.550

Tammy Ackerman Has to be somehow tied up with the R&D and it's it's it's it's, it's a part of our ID application and and and updated information then what have you so.</v>

00:56:10.790 --> 00:56:14.240

Tammy Ackerman If if a company is helping us in research and development.</v>

00:56:14.960 --> 00:56:17.820

Tammy Ackerman For these laboratory services.</v>

00:56:18.630 --> 00:56:20.550

Tammy Ackerman They already have the end with us.</v>

00:56:21.190 --> 00:56:30.760

Tammy Ackerman Then they could come in for the CNC. The problem with this conversation is usually the CMC is done by CDMO and CMO.</v>

00:57:00.410 --> 00:57:00.720

<v Penny Southworth>Umm.</v>

00:56:31.460 --> 00:57:01.190

Tammy Ackerman We, the sponsor, doesn't really make the final decision at that stage. We could make recommendations, we could even go as much as having a strong recommendation. I've never seen it that we would say, hey, you know senjen, you're my CDMO, you're my CML for manufacturing. But I'm sorry to tell you for these types of services, you gotta go with Covance because, you know, I haven't seen that so long as you know.</v>

00:57:01.470 --> 00:57:04.900

Tammy Ackerman Across continue measure this CMOS and CDMO they manage it.</v>

00:57:07.740 --> 00:57:08.250

<v Penny Southworth>OK.</v>

00:57:10.180 --> 00:57:23.620

<v Penny Southworth>I think we're really close at the time. I'm curious to know, do you have any other thoughts around just like relevant adjacencies for the biomarker testing companies where they, you know, if they tacked on this additional service it would?</v>

00:57:24.280 --> 00:57:26.170

<v Penny Southworth>Uh, you know, would add a lot of value.</v>

00:57:31.850 --> 00:57:32.900

Tammy Ackerman I think whoever.</v>

00:57:33.590 --> 00:57:34.590

Tammy Ackerman Has been.</v>

00:57:35.340 --> 00:57:47.480

Tammy Ackerman The most scientific exchange partner with us, they have had a better chance of of acquiring, at least for early stage development type of service.</v>

00:57:48.770 --> 00:57:49.900

Tammy Ackerman Of of these laugh.</v>

00:57:50.790 --> 00:57:52.720

Tammy Ackerman They've been very strong in doing that.</v>

00:57:54.550 --> 00:58:01.180

Tammy Ackerman Their customer service, their technical customer service, their support of technical customer service. Whoever can provide that.</v>

00:58:01.780 --> 00:58:05.930

Tammy Ackerman So having a effective people that they know exactly what they're selling.</v>

00:58:06.700 --> 00:58:13.440

Tammy Ackerman And they can help us to look for what we need, because not always we have that scientific knowledge, as I said.</v>

00:58:14.400 --> 00:58:26.690

Tammy Ackerman Those those type of vendors, it's a small and I always tell them, you know, jokingly and sometimes seriously it's a very small investment on their part to have knowledgeable people to help us.</v>

00:58:28.100 --> 00:58:34.190

Tammy Ackerman Making the decision as opposed to leaving it to us to make the wrong decisions.</v>

00:58:34.870 --> 00:58:36.970

Tammy Ackerman And blame them switch vendors.</v>

00:58:45.110 --> 00:58:45.430

<v Penny Southworth>Sorry.</v>

00:58:38.590 --> 00:58:49.300

Tammy Ackerman So I would say it behooves them to keep us in line with our scientific decisions. So because of that, whoever actually proposed a strong value to that front is is a winner.</v>

00:58:50.380 --> 00:59:05.650

<v Penny Southworth>Yeah. And I also like to earlier how you were suggesting kind of following the pipeline. So taking a look at what's going on on clinical trials that Gov and trying to be best positioned to serve the needs of where the the trends are in clinical trials, which I thought was a really good.</v>

00:59:06.600 --> 00:59:11.980

<v Penny Southworth>Suggestion OK. Any other any other thoughts? This has been a really helpful conversation so thank you.</v>

00:59:13.820 --> 00:59:22.120

Tammy Ackerman No other thought. As I said early engagement, continuous engagement, looking at the, the, the telltale signs of where the.</v>

00:59:23.480 --> 00:59:26.360

Tammy Ackerman The trends are going as far as the R&D.</v>

00:59:27.520 --> 00:59:29.970

Tammy Ackerman Value proposition and and expenditures.</v>

00:59:30.630 --> 00:59:43.120

Tammy Ackerman Then these labs are, you know, more and more. They becoming a more critical, I would say a stronger hold of of critical failures of the support of the R&D and beyond I would say.</v>

00:59:45.560 --> 00:59:46.040

<v Penny Southworth>Got it.</v>

00:59:49.610 --> 00:59:49.950

Tammy Ackerman I think.</v>

00:59:48.170 --> 00:59:51.380

<v Penny Southworth>OK, perfect. I think that it.</v>

00:59:52.980 --> 00:59:53.570

Tammy Ackerman Sure.</v>

00:59:55.140 --> 01:00:02.230

<v Penny Southworth>OK. Well, yeah, thank you again for the time. The insights. We really appreciate it. Go ahead and.</v>