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

0:0:0.0 --> 0:0:9.140  
Cody Sole

Would you mind sharing a little bit about your professional backgrounds and experience related to Biomarker testing?

0:0:10.460 --> 0:0:11.230  
Patty Hellman  
Yes, of course.

0:0:12.20 --> 0:0:25.850  
Patty Hellman  
Umm, so my academic background is I have the mastery. Well, bachelor in biology and master in pharmaceutics, ecology and then received a PhD in experimental medicine for immunology.

0:0:27.370 --> 0:0:37.650  
Patty Hellman  
Studying T cell and B cell differentiation where I started to look at biomarkers at the time mostly soluble and cell surface protein.

0:0:38.450 --> 0:1:8.690  
Patty Hellman  
Umm are then went 485 years post doctoral training. The first one was in Australia and the Walter likes all. That's the seed working again on MHC restriction. Learning about graph transplantation and oncology. Then the the 2nd post doc at the Howard Hughes Medical Institute in USA working more or less on that topic than I opened my lab. I became the principal in this theater for some years.

0:1:9.220 --> 0:1:24.870  
Patty Hellman  
And then I went to the dark side, working for private companies, mostly biotechs, working in vitro fertilization and Women's Health. Looking at biomarkers for diseases such as endometriosis, looking for genetic and.

0:1:26.160 --> 0:1:32.160  
Patty Hellman  
Something provided by the markers and also sell a cellular biomarkers using closetalk mitry.

0:1:32.860 --> 0:1:42.850  
Patty Hellman  
And then work for protein on the company for about five years, looking at LC MSMS non. I bought this as base.

0:1:44.10 --> 0:2:4.240  
Patty Hellman  
Discovery and validation of biomarkers for multiple therapeutic areas, including oncology and some inflammatory diseases. And then I moved to the central lab business where I became cheap side of the dopfel survey of multiple companies being responsible not only for safety.

0:2:4.960 --> 0:2:33.450  
Patty Hellman  
Ohm testing such as I don't know your analysis in the cology our loads whatever everything that the central lab provides, but also looking at specialized biomarkers such as an atomic pathology for IHC fish for instance. So looking for genomics both using specific panels for deletion or integration of specific sites or no also.

0:2:34.330 --> 0:2:47.870  
Patty Hellman  
Looking at RNA sequencing, looking at different panels for gene expression, looking for very complex slots of Coventry, and then the last one would be soluble protein biomarkers looking at.

0:2:48.640 --> 0:2:57.560  
Patty Hellman  
Multiple platforms and I've been in the central lab businesses, the CSO for over 15 years. So essentially that's my background.

0:2:58.480 --> 0:3:23.590  
Cody Sole  
Awesome. Uh, definitely. Very helpful. And I think we'll have a great discussion since you have background across all BIOMARKER sectors, that's were interesting. And I'm wondering among the four areas that I talked about and we monitoring especially the flows itry and proteomics, genomics and histopathology, where do view will have the biggest growth in the next three to five years?

0:3:25.820 --> 0:3:27.70  
Patty Hellman  
Ohh that's a good question.

0:3:30.860 --> 0:3:31.900  
Patty Hellman  
Hmm.

0:3:33.400 --> 0:3:34.150  
Patty Hellman  
Growth.

0:3:38.380 --> 0:3:53.240  
Patty Hellman  
I think it's gonna be a steady growth. I don't foresee any major spike in any of those four categories. I think it's going to be a steady growth probably and I'm not answering your question, but.

0:3:53.970 --> 0:4:23.380  
Patty Hellman  
Probably a little bit of a drop in terms of addressable market for clinical trials, which genomics we've seen a lot of companies withdrawing a little bit for genomic testing. That was a lot of hypes over the last five years and now the budgets being let's say more limited for our indeed work, anything that is not a must have or the development of a drug is being removed, we see from.

0:4:23.920 --> 0:4:33.50  
Patty Hellman  
The protocols of for clinical studies. So genomics is gonna go down, I think a little bit. So little proteomics is gonna definitely increase.

0:4:33.730 --> 0:4:43.120  
Patty Hellman  
I would say even though it's taking the story as well, and I think even though monitoring using closet telemetries for instance is gonna remain fairly constant.

0:4:43.980 --> 0:5:1.640  
Cody Sole  
Hmm, interesting. So why do you think that? I mean kind of touch upon that just and there's all understand additional like I guess not growth but more like reduction drivers for the genomics business. Is it just because the cost constraints or are there other reasons there?

0:5:3.740 --> 0:5:13.140  
Patty Hellman  
I think it's mostly because of cost. So although to anomic testing cost has been going down over the last 10 years.

0:5:14.120 --> 0:5:21.960  
Patty Hellman  
As most importantly regarding home excitement, for instance, or whole exome sequencing.

0:5:23.170 --> 0:5:25.950  
Patty Hellman  
And also panel they've been going down but.

0:5:27.500 --> 0:5:30.80  
Patty Hellman  
The usefulness of genomics.

0:5:31.60 --> 0:5:36.90  
Patty Hellman  
As a tool for clinical trial and talking about especially late clinical phases.

0:5:42.740 --> 0:5:42.990  
Cody Sole  
Umm.

0:5:37.70 --> 0:5:43.650  
Patty Hellman  
Has not really proven it's the utility so far. I would have one exception.

0:5:44.630 --> 0:5:57.810  
Patty Hellman  
The one exception is when the discovery of a mutation, for instance, or genomic alteration, is leading to a companion diagnostic. So companies like foundation.

0:5:59.30 --> 0:6:0.0  
Patty Hellman  
1.6.

0:6:1.80 --> 0:6:4.770  
Patty Hellman  
Have been extremely successful looking at.

0:6:6.10 --> 0:6:8.210  
Patty Hellman  
The genomic pattern of some tumors.

0:6:9.0 --> 0:6:14.130  
Patty Hellman  
For some biomarkers, such as microsatellite instability, for instance.

0:6:15.290 --> 0:6:20.50  
Patty Hellman  
Also looking at tumor burden mutation burden, TMB.

0:6:20.850 --> 0:6:21.90  
Cody Sole  
Umm.

0:6:20.770 --> 0:6:40.500  
Patty Hellman  
And companies such as foundation medicine have been putting forward panels that can detect those with other markers. But the use the utility of those two markers that I just mentioned and the approval if you have by the FDA of those two biomarkers.

0:6:41.940 --> 0:6:54.830  
Patty Hellman  
To enroll patients not only into trial, but also after approval to provide the right drug to the right patient at the right moment has been, let's say, a paradigm shift.

0:6:55.580 --> 0:7:4.890  
Patty Hellman  
So this type of genomic might continue to go on, but the type of genomic analysis where people thought, OK, let's analyze all the gene.

0:7:5.750 --> 0:7:15.790  
Patty Hellman  
Uh, that are overexpressed or under expressed which specific tumors or yet in the blood using circulating free DNA or circulating tumor DNA?

0:7:36.720 --> 0:7:37.50  
Cody Sole  
Hmm.

0:7:16.550 --> 0:7:39.970  
Patty Hellman  
Uh, just to build hypothesis and to probably consolidate our knowledge about a disease or a mechanism of action of the drug. This is more like a nice to have. It's not a must have versus companion diagnostics is a must have. I think the Nice to have is going down because of cost constraints and also the complexity brings to the the.

0:7:41.270 --> 0:7:47.180  
Patty Hellman  
The clinical trials specifically specifically with IRB approval and consent.

0:7:48.500 --> 0:7:53.190  
Patty Hellman  
To look at the genomic makeup of the tumors.

0:7:54.560 --> 0:7:57.150  
Patty Hellman  
I would, I would say that if there's one.

0:7:58.350 --> 0:8:12.100  
Patty Hellman  
Topic and that topic, but whenever you will, growth is gonna be seen in the future in genomics, it's not necessarily looking at the tumor itself, but it's looking in liquid biopsy looking at circulating.

0:8:12.870 --> 0:8:16.80  
Patty Hellman  
UH-3 DNA or circulating tumor DNA.

0:8:17.380 --> 0:8:24.850  
Patty Hellman  
This is gonna be important because looking at remnants of the tumor DNA and the plasma has two major.

0:8:26.950 --> 0:8:55.380  
Patty Hellman  
Advantages. The first one was it's not invasive. It's much as a biopsy of the tumor. Second one is for diction of relapse. So you can look at the efficacy of a drug. If you see the circulating tumor DNA going down after treatment, it's a good sign. But yet again if you see it coming back up during the treatment or never going down, this is now becoming the pharmacodynamic marker.

0:8:55.900 --> 0:9:26.180  
Patty Hellman  
And as such, it can really inform the physician as to what's the impact of a drug treatment order. You should start to treat the patient again. For instance, if you have a good effect of the drug and for six months to a year and then suddenly you see a spike a the circulating tumor DNA is coming back up, then you could think about drug resistance and that's a sign that the tumor is no overlap.

0:9:26.680 --> 0:9:32.880  
Patty Hellman  
No longer responding to the the drug treatments that you have to go to melted at the treatment, for instance.

0:9:34.650 --> 0:9:39.310  
Patty Hellman  
So that will continue to go on. But again this is very informed.

0:9:40.280 --> 0:10:8.860  
Patty Hellman  
Approaches it's not I, not part of this bias, which I mean is you have a hypothesis. You know what you're looking for? This is very specific to the tumors that you have been detecting or even the mutation that you've been detecting. So I think this type of genomic is gonna continue to go on, but across all genomic tools, I think All in all, the market might go down a little bit in clinical trials and talking.

0:10:10.290 --> 0:10:25.980  
Cody Sole  
Interesting. That's a great insights. And I'm wondering regarding the trends again, just what type of modalities or indications that you have seen increased biomarker testing overall?

0:10:27.120 --> 0:10:28.870  
Patty Hellman  
For by worker testing overall.

0:10:29.310 --> 0:10:29.680  
Cody Sole  
Mm-hmm.

0:10:30.350 --> 0:10:40.840  
Patty Hellman  
Uh, oncology has always been the leader in terms of using biomarkers in the four categories of you mentioned.

0:10:41.490 --> 0:10:53.60  
Patty Hellman  
I think what we're seeing over the last maybe five years is definitely an increase of using soluble protein biomarkers not only in CSS.

0:10:55.510 --> 0:10:57.120  
Patty Hellman  
But also in plasma.

0:10:58.100 --> 0:11:5.340  
Patty Hellman  
For Alzheimer's disease, Parkinson's disease and other type of dementia or central nervous system.

0:11:7.380 --> 0:11:8.730  
Patty Hellman  
Diseases in general.

0:11:9.530 --> 0:11:9.680  
Cody Sole  
OK.

0:11:9.830 --> 0:11:10.370  
Cody Sole  
So.

0:11:9.770 --> 0:11:11.230  
Patty Hellman  
What is that, you know?

0:11:12.110 --> 0:11:23.410  
Cody Sole  
Sorry. Yeah, I know you mentioned oncology as well. Some of the CNS indications. So within oncology, other specific indications or modalities that you have seen the highest growth.

0:11:24.600 --> 0:11:33.120  
Patty Hellman  
Well, can you just describe modality? Because for me modality is very different from any questions or vertical. So I just like to have your definition of modality.

0:11:41.350 --> 0:11:41.750  
Patty Hellman  
OK.

0:11:33.960 --> 0:11:43.50  
Cody Sole  
Right. So I think we've heard, for example, sign gene therapy or some of those protein targeted therapies.

0:11:43.840 --> 0:11:53.300  
Patty Hellman  
OK. So that's very different. So in terms of different communications, that was your initial question. I think CNS is coming up with proteomics.

0:11:54.580 --> 0:12:21.130  
Patty Hellman  
It implies that that's definitely the case now in terms of drug modalities. That's very different. I think that that we will continue to see mostly for oncology, but also for inflammatory diseases like homes disease for instance or ID, inflammatory bowel disease. And CNS, we've gotta continue to see and therapeutic against buttons.

0:12:21.930 --> 0:12:22.630  
Patty Hellman  
Definitely.

0:12:23.770 --> 0:12:25.750  
Patty Hellman  
Coming up, we.

0:12:27.480 --> 0:12:40.580  
Patty Hellman  
I'd like to, I'd like to say cell and gene therapy and selling gene therapy is about a single bucket. OK, everyone is like to bundle those, but cell therapy is extremely different from gene therapy.

0:12:42.310 --> 0:12:52.340  
Patty Hellman  
We have seen a lot of increase in cell therapy, mostly in China, Eric antigen receptor T cells or car T.

0:12:53.40 --> 0:12:59.120  
Patty Hellman  
Or MK natural killer car. Now with macrophage car.

0:13:0.940 --> 0:13:7.140  
Patty Hellman  
I think we will keep seeing an increase in the use of cell therapy especially for oncology.

0:13:7.920 --> 0:13:15.520  
Patty Hellman  
For real generative medicine, tissue remodeling, it's gonna continue, but I don't see this as an increase.

0:13:16.320 --> 0:13:19.530  
Patty Hellman  
Let's go back to apology. I think that for oncology.

0:13:21.30 --> 0:13:28.360  
Patty Hellman  
The user cell therapy is limited by the fact that we so far we have to use a topologist.

0:13:29.250 --> 0:13:34.220  
Patty Hellman  
Cells, which means that your harvesting cells from a given.

0:13:35.70 --> 0:13:36.190  
Patty Hellman  
Subject Or patient?

0:13:36.880 --> 0:13:37.120  
Cody Sole  
Yep.

0:13:36.860 --> 0:13:45.50  
Patty Hellman  
Your bio and generating the South invitro to be reinjected after application of that cells or cell division.

0:13:45.730 --> 0:13:51.30  
Patty Hellman  
So each injection is a medical device and that is a costly.

0:13:51.690 --> 0:13:57.820  
Patty Hellman  
Be a regulatory complex venture and see it takes a long time.

0:13:58.760 --> 0:14:7.330  
Patty Hellman  
I think what's gonna be revolutionizing of the approach where this field in the coming years have started already.

0:14:7.980 --> 0:14:10.940  
Patty Hellman  
It's merging of gene therapy and cell therapy.

0:14:11.760 --> 0:14:22.90  
Patty Hellman  
So injecting gene modifiers that could target T cells or macrophages or Anki cells in vivo.

0:14:22.950 --> 0:14:29.390  
Patty Hellman  
So then you don't need to isolate T cells or NK cells or macrophages or even.

0:14:30.330 --> 0:14:45.700  
Patty Hellman  
Through Python cells from the patient, you just inject your gene with a specific vector into the patient. The gene is making its way to a given cell population by the flying it and then converting it vivo.

0:14:46.360 --> 0:14:50.910  
Patty Hellman  
Your T cell into a car T or your NK cell into NK car.

0:14:51.720 --> 0:14:55.640  
Patty Hellman  
So that's that's I think is very, very promising.

0:14:56.350 --> 0:15:5.140  
Patty Hellman  
And as far as gene therapy alone is concerned, injecting a gene with a vector, for instance, either in plasma or intramuscular.

0:15:5.930 --> 0:15:11.290  
Patty Hellman  
And it has shown to be successful when you have a single gene.

0:15:12.360 --> 0:15:16.540  
Patty Hellman  
You said you you station that is causing a disease.

0:15:17.390 --> 0:15:21.950  
Patty Hellman  
So monogenic disease, but for complex therapy.

0:15:22.640 --> 0:15:26.450  
Patty Hellman  
Uh, it's it has been more.

0:15:27.150 --> 0:15:41.10  
Patty Hellman  
Let's say let let's desirable and probably less efficient and the other thing is Gene Starks City. So the length of a therapy is probably less.

0:15:41.700 --> 0:15:51.530  
Patty Hellman  
And the fear of having off target effect by gene therapy alone is probably something that we all fear, and for instance.

0:15:52.220 --> 0:16:22.10  
Patty Hellman  
Recently, the FDA has been looking at with, let's say, a more scrutiny they use of adenoviruses of vectors for gene therapy because it might cause some side effects for off target effects. So if you talk about cell engine therapy, I think we have to look at them and dependently and just to wrap it up, I think we're cell therapy is going to become more promising.

0:16:22.170 --> 0:16:29.820  
Patty Hellman  
This using gene therapy to target specific cells that can boost the immune system to kill tumors.

0:16:31.30 --> 0:16:37.590  
Patty Hellman  
That's that's gonna be seen as an advanced in medical science in the future.

0:16:38.530 --> 0:17:4.580  
Cody Sole  
Got it, got it. All. Thanks for providing the background and we're definitely very familiar with these approaches since, yes, we're we're we're pretty much all trains with PhD backgrounds. Just wondering, since you did mention with the gene therapy, writing or merging with the cell therapy, assessing off target effects, it's pretty critical. And in that case do still build genomics being used less in that situation?

0:17:11.540 --> 0:17:12.210  
Patty Hellman  
Uh.

0:17:13.640 --> 0:17:21.500  
Patty Hellman  
Yes and no. I don't. I don't see why this would have an impact, because even if you want to target.

0:17:22.180 --> 0:17:23.690  
Patty Hellman  
Specific tumor using.

0:17:24.500 --> 0:17:25.460  
Patty Hellman  
Cell therapy.

0:17:27.470 --> 0:17:28.880  
Patty Hellman  
We know that some.

0:17:30.120 --> 0:17:32.110  
Patty Hellman  
Cell therapies are more efficient.

0:17:32.830 --> 0:17:35.740  
Patty Hellman  
With tumors that have specific.

0:17:36.810 --> 0:17:42.480  
Patty Hellman  
Uh mutations listening? Tumor mutation burden is just one example or MSI.

0:17:43.440 --> 0:17:44.520  
Cody Sole  
Right. I I guess just.

0:17:43.590 --> 0:17:44.760  
Patty Hellman  
Or and then Rd.

0:17:45.840 --> 0:17:58.880  
Cody Sole  
Sorry. Yeah, I guess I was just wondering, since you're gonna use AV other virus to target the tumor cells and then genomics would help potentially to assess off target effects.

0:18:0.780 --> 0:18:1.200  
Patty Hellman  
Well.

0:18:1.850 --> 0:18:2.420  
Patty Hellman  
Again.

0:18:4.180 --> 0:18:8.530  
Patty Hellman  
Genomics were off target effect. No, that's that's too complicated.

0:18:9.250 --> 0:18:13.290  
Patty Hellman  
I mean it's it's tough if you're checking that in a virus into your subject.

0:18:14.10 --> 0:18:24.770  
Patty Hellman  
Especially by intramuscular, to look at what off target effect you might have on liver on brain cells with some side effects there.

0:18:25.740 --> 0:18:36.640  
Patty Hellman  
Is you you gotta be using PK PD markers such as. I don't know. Cytokine storm to look at the effect that you might have on the immune system but.

0:18:37.350 --> 0:18:44.70  
Patty Hellman  
I don't think that one is gonna look at using genomics to look at the ankle operation or integration of.

0:18:44.980 --> 0:18:46.0  
Patty Hellman  
As in the virus.

0:18:46.960 --> 0:18:50.950  
Patty Hellman  
Gene modifiers in all self defenses do is just not there.

0:18:51.680 --> 0:18:53.160  
Cody Sole  
OK, OK, got it.

0:18:51.910 --> 0:18:53.360  
Patty Hellman  
To my knowledge.

0:18:54.280 --> 0:19:0.880  
Cody Sole  
It's all. It's all I will potentially using proteomics ends immune monitoring methods to assess off target effects.

0:19:2.410 --> 0:19:3.80  
Patty Hellman  
Correct.

0:19:3.620 --> 0:19:5.290  
Cody Sole  
OK. That makes sense.

0:19:4.640 --> 0:19:16.660  
Patty Hellman  
Well, I again, I I want to be careful because it depends on the type of vector depends on the gene modifier you have, how many gene modifiers you have. So it's tough to have a blood statement.

0:19:18.680 --> 0:19:18.970  
Cody Sole  
Right.

0:19:17.780 --> 0:19:21.770  
Patty Hellman  
Let's say that is not specific to a condition or an approach.

0:19:22.450 --> 0:19:31.840  
Cody Sole  
Yeah, OK. Just wanna understand a bit more, are there other modalities that potentially have seen increased use of biomarker testing?

0:19:33.940 --> 0:19:34.610  
Patty Hellman  
Well.

0:19:35.470 --> 0:19:39.740  
Patty Hellman  
I think what we're seeing now is the use of.

0:19:43.20 --> 0:19:46.240  
Patty Hellman  
Drug country. So ADC approach.

0:19:47.410 --> 0:19:50.100  
Patty Hellman  
Uh linked to antibodies?

0:19:50.900 --> 0:19:58.270  
Patty Hellman  
But in order to reduce toxicity or off target effect, the people are doing is building now.

0:19:59.700 --> 0:20:3.360  
Patty Hellman  
Antibody drug conjugates that are inactive.

0:20:4.70 --> 0:20:31.960  
Patty Hellman  
But if they come close to a specific tumor that is expressing proteases, for instance, then the protease of the surface of the tumor cells are activating the drug conjugate and making converting it from non-toxic into a toxic conjugate. And then we can target much better the delivery of those drug conjugates into tumor cells, not to normal tissue.

0:20:32.820 --> 0:20:40.370  
Patty Hellman  
So there are several approaches that have been described in the literature about this, and I think this is what we're gonna be seeing in the future.

0:20:41.940 --> 0:20:42.110  
Cody Sole  
In.

0:20:42.190 --> 0:20:42.970  
Cody Sole  
Testing.

0:20:42.790 --> 0:20:44.240  
Patty Hellman  
For therapist came to buttons.

0:20:45.880 --> 0:20:46.590  
Cody Sole  
Yep, OK.

0:20:47.750 --> 0:20:48.620  
Cody Sole  
Just wondering.

0:20:49.720 --> 0:20:59.720  
Cody Sole  
What type of you know, among all the four categories that we talked about that ADC would would be used to assess the ABC's.

0:21:1.130 --> 0:21:2.350  
Patty Hellman  
Definitely don't call it.

0:21:6.920 --> 0:21:7.680  
Cody Sole  
So I mean like.

0:21:5.160 --> 0:21:8.120  
Patty Hellman  
You mean how we gonna be using it?

0:21:8.820 --> 0:21:18.240  
Cody Sole  
I like the genomics proteomics histopathology. I mean monitoring and what are marker methods would be used to assess ADC's?

0:21:21.650 --> 0:21:22.370  
Patty Hellman  
Uh.

0:21:24.330 --> 0:21:30.10  
Patty Hellman  
Again, it depends, but I don't think it well. I could be one of them.

0:21:30.950 --> 0:21:43.260  
Patty Hellman  
Because you need to know whether your tumor expresses that all need to target now, but also the proteins or whatever is required to activate your drug engine. So I sleep for sure.

0:21:44.280 --> 0:21:52.180  
Patty Hellman  
Genomics. Yes, because what you would be looking for is circulating free DNA to see if the tumor burden is going down, for instance.

0:21:53.170 --> 0:21:56.970  
Patty Hellman  
Uh, probiotics are not necessarily an even know monitoring either.

0:21:59.30 --> 0:22:0.380  
Cody Sole  
OK, sounds good.

0:21:59.680 --> 0:22:11.290  
Patty Hellman  
Unless, unless again, unless you're looking at multiple myeloma or AML or AML, then you'll need to know to use flow cytometry.

0:22:12.120 --> 0:22:18.920  
Patty Hellman  
Uh, for sure, because your monitoring a Catholic school disease, cancer disease.

0:22:19.530 --> 0:22:23.20  
Patty Hellman  
So you'll be using in your monitoring, but for solid tumors now.

0:22:30.430 --> 0:22:30.830  
Patty Hellman  
Yeah.

0:22:24.390 --> 0:22:36.850  
Cody Sole  
OK, so it's mainly bit between solo tumor versus hematology. OK, sounds good. Are there any other modalities that came to my mind came to your mind?

0:22:38.620 --> 0:22:41.180  
Patty Hellman  
Not really. Maybe no, not really.

0:22:42.380 --> 0:22:45.70  
Cody Sole  
OK, sounds good.

0:22:46.160 --> 0:22:59.850  
Cody Sole  
And now I just wonder, let me move on to the CRO partners that you have used and if you have any experience or feedback on those specialty CRO's?

0:23:0.690 --> 0:23:1.300  
Cody Sole  
I'm.

0:23:2.640 --> 0:23:4.530  
Cody Sole  
I I believe within your.

0:23:5.770 --> 0:23:7.290  
Cody Sole  
Are you know they're?

0:23:9.840 --> 0:23:11.750  
Patty Hellman  
Are you talking about CRO like?

0:23:12.460 --> 0:23:13.740  
Patty Hellman  
A contract.

0:23:14.520 --> 0:23:18.530  
Patty Hellman  
Uh research organization dealing with.

0:23:19.580 --> 0:23:23.260  
Patty Hellman  
Organizing trials or you're looking at lab fierros.

0:23:29.780 --> 0:23:32.110  
Patty Hellman  
OK so.

0:23:38.780 --> 0:23:39.190  
Patty Hellman  
Ohh.

0:23:24.580 --> 0:23:39.210  
Cody Sole  
We're looking at both, but we'll start from the lab scenarios and they wanna touch upon, you know, like zeros that might be interested in maybe specialized in lab logistics or data management and analysis.

0:23:40.550 --> 0:23:41.0  
Cody Sole  
And.

0:23:40.470 --> 0:23:49.60  
Patty Hellman  
OK, so I don't think I can answer that question specifically for one obvious reason and working for the largest CRO in the world.

0:23:51.700 --> 0:23:52.10  
Cody Sole  
Right.

0:23:50.130 --> 0:24:6.150  
Patty Hellman  
IQVIA and one of the division of IQ VSQ's going solution, which is one of the top two labs CRO's in the world and you are associated with PPD, a competitor of ours. So I don't think I'll be able to answer those questions.

0:24:8.160 --> 0:24:13.250  
Cody Sole  
How? Well, not affiliated with any cereals like PPD mentions.

0:24:13.570 --> 0:24:14.950  
Patty Hellman  
Ohh that's interesting.

0:24:31.250 --> 0:24:31.540  
Patty Hellman  
So.

0:24:15.450 --> 0:24:36.960  
Cody Sole  
Yeah, we are. We only just interested in broad landscape of specialty CRO that you have her with them. We are with PAREXEL, but we are independent agency for consulting purposes and our client has no relationship with any and those large CRO's that you mentioned.

0:24:38.250 --> 0:24:46.730  
Patty Hellman  
OK. But anyway I have not used any other PR's than the one I'm working with, so can't really answer your question there.

0:24:55.430 --> 0:24:55.830  
Patty Hellman  
Umm.

0:24:47.660 --> 0:25:9.270  
Cody Sole  
OK. Then maybe we can circle back to you mentioned other therapeutic areas such as CNS and just wondering the the trends there other than for the omics, I think you mentioned to assess a few targets in the plasma. Are there other growth areas within CNS that you have seen?

0:25:11.650 --> 0:25:16.880  
Patty Hellman  
Well, imaging is picking up a lot using different techniques.

0:25:18.580 --> 0:25:22.650  
Patty Hellman  
And radio omics is coming up as well.

0:25:23.420 --> 0:25:33.560  
Patty Hellman  
Which is for instance, the injection of a radio labeled antibody or drug to see the distribution of the drug and or an antibody to look for our target.

0:25:34.400 --> 0:25:38.990  
Patty Hellman  
So this is going up. It's not offered by our central lab, but.

0:25:39.700 --> 0:25:40.720  
Patty Hellman  
Because it's imaging.

0:25:41.840 --> 0:25:52.560  
Patty Hellman  
Something that is offered usually by very large medical centers, but radio mixes, definitely something that is now thinking.

0:25:53.360 --> 0:25:56.380  
Patty Hellman  
More and more importance and genetical trials with CMS.

0:25:57.590 --> 0:25:58.210  
Cody Sole  
And how?

0:25:57.260 --> 0:25:59.510  
Patty Hellman  
And even on college, you're living. It's starting.

0:26:1.300 --> 0:26:11.400  
Cody Sole  
Interest and and you mentioned both oncology and CNS and for which indications potentially within either oncology, CNS, have you seen the uptake of radiomics?

0:26:12.320 --> 0:26:15.280  
Patty Hellman  
Well, solid tumors in general.

0:26:17.170 --> 0:26:21.320  
Patty Hellman  
And CNS, definitely when people are looking where?

0:26:23.40 --> 0:26:28.860  
Patty Hellman  
For instance, if there's a presence of fossil hotel in CNS.

0:26:29.970 --> 0:26:39.300  
Patty Hellman  
For Alzheimer, that's one example. And we're looking at the distribution of a therapeutic antibodies like those that have been approved so far.

0:26:42.310 --> 0:26:43.240  
Patty Hellman  
For a Z.

0:26:45.610 --> 0:26:46.450  
Patty Hellman  
He's not as Susan.

0:26:52.190 --> 0:27:7.320  
Cody Sole  
OK. And then how do you sponsors the sites? In which trials do they need radio mics or imaging versus just testing about markers that we talked about using proteomics or histopathology and others?

0:27:8.20 --> 0:27:21.560  
Patty Hellman  
I would not be able to tell you this because usually when sponsors are coming to either CRO Lab or CRO, taking care of the Protocol and site management, they already have an approved.

0:27:22.710 --> 0:27:27.950  
Patty Hellman  
Protocol with IRB consent. So how the internal decisions are made?

0:27:28.710 --> 0:27:36.680  
Patty Hellman  
I'm not closer to this. I'm not close enough to that. Definitely. I would say it depends on the mechanism of action that they're drug.

0:27:37.460 --> 0:27:49.680  
Patty Hellman  
Uh, and also the promise of using a technology over another one for the information that brings AB, the cost C practicality. Is this feasible or not?

0:27:50.340 --> 0:27:51.20  
Patty Hellman  
To do this.

0:27:52.10 --> 0:27:52.570  
Cody Sole  
Umm.

0:27:51.860 --> 0:27:57.260  
Patty Hellman  
For instance, if you have a technology that is only available that one of the largest.

0:27:58.540 --> 0:28:9.190  
Patty Hellman  
Center in USA like I don't know, maybe you went to work and the enderson. While it's very tough to recruit patients if there's only one side in the United States that offers that technology.

0:28:10.400 --> 0:28:10.870  
Patty Hellman  
Enrollment.

0:28:12.920 --> 0:28:31.210  
Cody Sole  
Right. Uh, you you did touch upon mechanism action, I understand. You know, you're not super close to the internal decision, but just wanna understand based on experience what type of trials based on the mechanism of action have you seen potentially using additional biomarker tools like radiomics or imaging?

0:28:32.390 --> 0:28:34.560  
Patty Hellman  
Well, they're pick antibodies, as I said.

0:28:37.740 --> 0:28:39.290  
Cody Sole  
Or the old antibodies.

0:28:40.40 --> 0:28:40.550  
Patty Hellman  
Yep.

0:28:40.960 --> 0:28:41.260  
Cody Sole  
OK.

0:28:42.760 --> 0:28:43.850  
Cody Sole  
Sounds skirts?

0:28:45.320 --> 0:29:0.80  
Cody Sole  
And across you know your experience with different clinical trials, I wonder are there specific indications of therapeutic areas that are preclinical support is very important for biomarker testing?

0:29:4.700 --> 0:29:6.950  
Patty Hellman  
Well again, definitely oncology.

0:29:8.350 --> 0:29:11.610  
Patty Hellman  
Even nology in general, so I'm including.

0:29:12.800 --> 0:29:17.590  
Patty Hellman  
Respiratory diseases here, anything that is inflammatory so.

0:29:18.760 --> 0:29:21.190  
Patty Hellman  
IBD Crohn's disease.

0:29:21.740 --> 0:29:22.400  
Patty Hellman  
Uh.

0:29:24.220 --> 0:29:26.950  
Patty Hellman  
Also write this chronicle serratus.

0:29:28.100 --> 0:29:29.250  
Patty Hellman  
Uh, what else?

0:29:33.60 --> 0:29:34.270  
Patty Hellman  
Both have well.

0:29:36.70 --> 0:29:37.80  
Patty Hellman  
Most of the.

0:29:37.970 --> 0:29:39.250  
Patty Hellman  
Autoimmune diseases.

0:29:40.60 --> 0:29:41.520  
Patty Hellman  
I guess the leak for instance.

0:29:42.900 --> 0:29:43.230  
Cody Sole  
Umm.

0:29:42.470 --> 0:29:50.320  
Patty Hellman  
Definitely they need a lot of preclinical support to understand not only the mechanisms of action, but to look at the.

0:29:51.450 --> 0:29:53.250  
Patty Hellman  
Effect of a drug.

0:29:54.620 --> 0:30:0.580  
Patty Hellman  
To confirm it's I think it's easy in vivo, like an animal model or in V Pro.

0:30:1.420 --> 0:30:4.950  
Patty Hellman  
Is in cell based assay for instance, or even biochemistry.

0:30:7.930 --> 0:30:15.620  
Cody Sole  
And that's what stage do sponsor engage with you and for designing or validate assays?

0:30:16.750 --> 0:30:17.940  
Patty Hellman  
That's early enough.

0:30:21.50 --> 0:30:21.420  
Patty Hellman  
Then.

0:30:23.760 --> 0:30:24.310  
Patty Hellman  
So.

0:30:23.190 --> 0:30:25.240  
Cody Sole  
I just wanna understand. I'm sorry.

0:30:25.960 --> 0:30:28.400  
Patty Hellman  
So typically we what's going on is.

0:30:28.740 --> 0:30:29.110  
Patty Hellman  
Yeah.

0:30:30.440 --> 0:30:35.290  
Patty Hellman  
And on Cology during the phase one, which obviously does not have a.

0:30:36.140 --> 0:30:39.30  
Patty Hellman  
Control group all patients are disease.

0:30:41.30 --> 0:30:51.820  
Patty Hellman  
They come to us for phase two because phase one. Usually it's a niche lab or principle investigator driven clinical trial, 30 small scope, 50 patients.

0:30:52.700 --> 0:31:3.50  
Patty Hellman  
Uh, it's rare that a large lab like ours is is being asked to support phase one for oncology, doesn't, it appears from time to time, but it's rare.

0:31:3.780 --> 0:31:11.990  
Patty Hellman  
And what we are seeing is that for this indication oncology and this phase phase one, whether it's one A1B.

0:31:13.510 --> 0:31:15.620  
Patty Hellman  
These sponsors are coming to us.

0:31:16.530 --> 0:31:22.240  
Patty Hellman  
Months before the the trial is launched and they totally underestimate.

0:31:22.970 --> 0:31:33.890  
Patty Hellman  
The time it takes to bring a new assay from scratch to making it operational to meet all the regulatory requirement.

0:31:34.980 --> 0:31:44.820  
Patty Hellman  
It's underestimated, so they don't give us enough time, and I'm talking about this across the industry independently of the company you're we're working with before, I mean.

0:31:46.440 --> 0:31:52.20  
Patty Hellman  
It's too late, so they should come to us. Three Ind.

0:31:52.780 --> 0:31:57.250  
Patty Hellman  
To start looking at the possibility of using a biomarker in our platform.

0:31:58.370 --> 0:32:1.350  
Patty Hellman  
Uh, well, before their ID is approved.

0:32:2.540 --> 0:32:3.330  
Patty Hellman  
That's not the case.

0:32:4.600 --> 0:32:6.270  
Patty Hellman  
For other indications.

0:32:7.730 --> 0:32:14.600  
Patty Hellman  
It's actually they come to us for phase two because phase one is not necessarily done in the central lab.

0:32:16.180 --> 0:32:17.70  
Patty Hellman  
Just one second.

0:32:19.380 --> 0:32:21.970  
Patty Hellman  
They come to us for phase two and again.

0:32:22.710 --> 0:32:28.810  
Patty Hellman  
Umm, this is months before patients are enrolled into phase two. Phase One is already underway.

0:32:29.810 --> 0:32:40.340  
Patty Hellman  
And I would say the same thing. They're coming to us asking for new IHC biomarkers, new genomics, new proteomics or new flow cytometry.

0:32:41.560 --> 0:32:43.170  
Patty Hellman  
A safe and.

0:32:43.900 --> 0:32:45.690  
Patty Hellman  
Hardlines are extremely tight.

0:32:46.670 --> 0:32:50.210  
Patty Hellman  
And at times, the sponsors are neglecting.

0:32:51.230 --> 0:32:52.250  
Patty Hellman  
Practical.

0:32:53.240 --> 0:32:55.780  
Patty Hellman  
And practical.

0:32:57.440 --> 0:33:1.670  
Patty Hellman  
Elements of bringing a platform and or biomarker.

0:33:2.390 --> 0:33:9.60  
Patty Hellman  
To a phase two Phase 3, some of the approaches that at times were asked to support.

0:33:9.830 --> 0:33:14.280  
Patty Hellman  
Are not desirable and not feasible into a global.

0:33:15.40 --> 0:33:29.390  
Patty Hellman  
File global study for many reasons, just to mention one cost mentioned another one sample stability around the world. So for instance, we've been asked from time to time to use Western blood.

0:33:30.60 --> 0:33:35.480  
Patty Hellman  
To enroll patients, so to look at protein that are extracted some cells.

0:33:36.560 --> 0:33:54.530  
Patty Hellman  
Uh to detect the specific variant of a protein using Western blood in a global trial when the stability of a fossil apital, for instance, is probably less than six hours xvo, so that is not feasible. But the sponsor think that.

0:33:55.200 --> 0:34:6.110  
Patty Hellman  
Things are because it it was done in a phase one in a clinic somewhere in the world that it can be extrapolated or extended to various.

0:34:7.50 --> 0:34:21.700  
Patty Hellman  
Central Lab locations around the world, or even centralized the testing, and what lab? It's just not feasible and I think they should consult earlier on with lab people, lab expert.

0:34:22.350 --> 0:34:29.90  
Patty Hellman  
To see whether there approaches sound and whether it will lead to the successful journey in their clinical trial.

0:34:31.70 --> 0:34:31.410  
Cody Sole  
OK.

0:34:32.580 --> 0:34:33.160  
Cody Sole  
Call it.

0:34:35.140 --> 0:34:42.750  
Cody Sole  
And so if I understand correctly on cology they engage assays, one versus others will be at phase two, right?

0:34:43.460 --> 0:34:44.790  
Patty Hellman  
Correct, typically.

0:34:44.840 --> 0:35:0.770  
Cody Sole  
OK, sounds good. And just going back to you mentioned there are a couple of therapeutic areas that is very critical to support sponsors for the preclinical testing. And I wonder what type of support do they need at the preclinical stage?

0:35:2.530 --> 0:35:2.970  
Patty Hellman  
Well.

0:35:5.70 --> 0:35:6.410  
Patty Hellman  
So based assays.

0:35:9.100 --> 0:35:10.760  
Patty Hellman  
Mix using sellable.

0:35:11.720 --> 0:35:13.390  
Patty Hellman  
Detecting soluble proteins.

0:35:15.250 --> 0:35:21.130  
Patty Hellman  
And also using CSS for instance. So look at specific variants of the proteins.

0:35:23.330 --> 0:35:28.190  
Patty Hellman  
Definitely something that is underestimated is using salvage that saying.

0:35:28.500 --> 0:35:32.780  
Patty Hellman  
Umm to look at to predict even know.

0:35:33.680 --> 0:35:34.430  
Patty Hellman  
Duplicity.

0:35:35.230 --> 0:35:42.580  
Patty Hellman  
Which I mean I even know genetically because it took different. It's the same word by using differently and vaccine trials.

0:35:43.220 --> 0:35:48.550  
Patty Hellman  
Sorry, Benoit, you're necessity is the host responding within immune response against the drug.

0:35:50.220 --> 0:36:6.740  
Patty Hellman  
Which might lead to an increased effect or decrease effective binding on the type of immune response against the drug. But now there are multiple assays that are used to predict both cellular and humoral by the antibody.

0:36:7.840 --> 0:36:12.750  
Patty Hellman  
Immunogenicity against a drug. So that's something that should increase in the future.

0:36:14.800 --> 0:36:20.850  
Patty Hellman  
Something else that we've seen coming and going from time to time, but now we're on the upside.

0:36:21.560 --> 0:36:27.60  
Patty Hellman  
Is using 3D organoids to look at pharmacy.

0:36:27.140 --> 0:36:34.120  
Patty Hellman  
So dynamic markers look at the efficacy of some drug modalities.

0:36:35.10 --> 0:36:37.280  
Patty Hellman  
And also for.

0:36:37.840 --> 0:36:40.870  
Patty Hellman  
Uh toxicology prediction.

0:36:41.480 --> 0:36:50.880  
Patty Hellman  
So for instance, using liver cells in vitro as a 3D organoids or better known as Oregon and the chip.

0:36:52.170 --> 0:36:52.580  
Cody Sole  
Umm.

0:36:51.950 --> 0:36:56.980  
Patty Hellman  
So you look at and to predict toxic effects of the drug.

0:36:57.850 --> 0:36:58.310  
Patty Hellman  
So.

0:36:57.820 --> 0:37:28.580  
Cody Sole  
Got it. Umm yeah, I think those make sense and I wonder when you engage with sponsor earlier I preclinical stage how how is the contract and made or you know how how basically how do you get paid in that sense? Is it more like a partnership that you're code developed assay and then they would stick with your CRO particularly throughout the clinical trials or it's just an assay and then it can switch vendor doing their clinical trials?

0:37:30.250 --> 0:37:30.720  
Patty Hellman  
Well.

0:37:31.640 --> 0:37:41.640  
Patty Hellman  
We don't do we don't do a lot of preclinical essentially it's one contract 1 transaction and that's it. Why am I saying this?

0:37:42.360 --> 0:37:51.310  
Patty Hellman  
It's because to predict immunogenecity for instance, you have cell based assay or even ELISA or Italy spots that are being used.

0:37:52.830 --> 0:38:3.350  
Patty Hellman  
But things might be different from the assays that you will be using on patients because you're, you're you could be using those on animal, you could be using those on.

0:38:4.350 --> 0:38:16.870  
Patty Hellman  
Human cells, but for for the go not. And they critical trial. These assays are real rarely translated into similar things for clinical trials on patient.

0:38:17.730 --> 0:38:20.450  
Patty Hellman  
It does happen from time to time, but it's very rare.

0:38:21.120 --> 0:38:25.790  
Patty Hellman  
So essentially, even if we our company is signing up a contract.

0:38:26.540 --> 0:38:53.810  
Patty Hellman  
With a sponsor looking at preclinical support, they would like to have one contract, one transaction. Yes, it might create stickiness if they had their good customer experience to use the same lab or CRO for clinical trials. But usually it's not even the same people either pro let's say procurement, vendor management scientists that are responsible for signing off those deals.

0:38:54.510 --> 0:39:7.920  
Patty Hellman  
So you're there's no connection between preclinical and clinical. Essentially, I would like to see that, but overlaps 1520 years that I've been in this business, I can tell you that they're working in silence.

0:39:8.700 --> 0:39:9.70  
Cody Sole  
Umm.

0:39:9.750 --> 0:39:17.200  
Cody Sole  
Interesting. And does the stakeholders or call points that you mentioned vary by the size of the sponsors?

0:39:19.140 --> 0:39:24.40  
Patty Hellman  
Well, definitely. So if you're using a EBP or emerging biotech.

0:39:25.700 --> 0:39:36.410  
Patty Hellman  
Where you have, I don't know, one chief medical officer, once CEO. And when chief, whatever operating operations, technical operations.

0:39:37.690 --> 0:39:44.900  
Patty Hellman  
And you have one regulatory so that the executive team is like 5 people and then the company is 2550.

0:39:45.980 --> 0:40:1.990  
Patty Hellman  
Uh, you're dealing with the same people, that's for sure. Whereas if you, if you work with top ten pharma, this these are different, almost behaving like different companies preaching to go into. So you're right. But I'm trying to have a general statement over here.

0:40:2.530 --> 0:40:6.80  
Patty Hellman  
Umm, it's usually siloed and not.

0:40:6.890 --> 0:40:9.90  
Patty Hellman  
Necessarily. Harmonize.

0:40:11.0 --> 0:40:20.260  
Cody Sole  
OK, got it. And then how likely do they stick with you on a like from preclinical?

0:40:20.710 --> 0:40:28.800  
Cody Sole  
Umm to clinical child labour marker testing for regardless of the size of the sponsors.

0:40:29.620 --> 0:40:33.690  
Patty Hellman  
Well, we don't do a lot of preclinical. So I I cannot really tell you.

0:40:34.570 --> 0:40:35.400  
Cody Sole  
Yeah. OK.

0:40:34.760 --> 0:40:42.870  
Patty Hellman  
And in fact, if I'm looking at all the the large labs in the world and including out on our PPD eurofin.

0:40:44.490 --> 0:40:45.630  
Patty Hellman  
LabCorp.

0:40:45.930 --> 0:40:46.520  
Patty Hellman  
Uh.

0:40:47.690 --> 0:40:48.490  
Patty Hellman  
Icon.

0:40:49.440 --> 0:41:7.750  
Patty Hellman  
Mostly were all these companies do a little bit of preclinical but not a lot. And then you have partners in preclinical like Charles Rivers, twins that are not doing clinical at all and there are doing almost 100%, they're working 3 clinical. So again it's fairly silo.

0:41:10.350 --> 0:41:12.260  
Cody Sole  
And just wondering.

0:41:13.280 --> 0:41:22.780  
Cody Sole  
Why do you keep your business in the clinical trial testing without expansion to predict preclinical space?

0:41:25.530 --> 0:41:28.510  
Patty Hellman  
Are you telling me there's a lot of extension in three Lincoln, Spain?

0:41:30.150 --> 0:41:31.750  
Patty Hellman  
That that's what you just said.

0:41:29.470 --> 0:41:40.410  
Cody Sole  
I'm wondering like just wondering like what what are the rationale of? You know you're as a granulation do not provide like a lot of services in the preclinical testing space?

0:41:40.820 --> 0:41:43.170  
Patty Hellman  
We're we're getting an into this.

0:41:44.330 --> 0:42:0.480  
Patty Hellman  
But you it's like a pyramid. OK, so if you want to be a large player in preclinical space, you need to have so many competences because the the indications, the therapeutic area, the drug modalities.

0:42:1.880 --> 0:42:10.110  
Patty Hellman  
They vary a lot, and for each of those you need to have a lot of assets or confidence in order to support one branch of the whole 3.

0:42:11.580 --> 0:42:16.330  
Patty Hellman  
So it's more complicated, it's more diversified. It's the base of the pyramid.

0:42:17.60 --> 0:42:21.710  
Patty Hellman  
So typically it's it's easy for any big company to.

0:42:22.450 --> 0:42:24.250  
Patty Hellman  
Expand in one.

0:42:24.980 --> 0:42:34.540  
Patty Hellman  
Drug modality 1 indication but they have a broad spectrum of offering to cover all therapeutic indications.

0:42:36.380 --> 0:42:39.990  
Patty Hellman  
And to cover all drug modality is more of a challenge.

0:42:40.990 --> 0:42:44.920  
Patty Hellman  
And that's why companies like Charles Rivers have been the leaders, or.

0:42:45.660 --> 0:42:46.990  
Patty Hellman  
Very niche.

0:42:47.630 --> 0:42:57.870  
Patty Hellman  
Providers labs that small labs that would provide have a great credibility and let's say gene therapy for monogenic.

0:42:58.540 --> 0:42:59.330  
Patty Hellman  
Diseases.

0:43:2.490 --> 0:43:15.410  
Cody Sole  
Got it. You you didn't mention, I understand it's difficult to provide all the services and preclinical testing across different therapeutic areas and as was modalities. But just wondering what specific?

0:43:16.130 --> 0:43:21.210  
Cody Sole  
Competencies or capabilities you mentioned that are needed for preclinical testing.

0:43:22.780 --> 0:43:26.190  
Patty Hellman  
I think I answered this already from that mistake.

0:43:26.840 --> 0:43:29.760  
Patty Hellman  
Or maybe I I don't understand. Then you ask between your questions.

0:43:30.130 --> 0:43:33.720  
Cody Sole  
Yeah, I was just wondering. Yeah, maybe a particular.

0:43:30.490 --> 0:43:34.350  
Patty Hellman  
Are you asking me what? What type of services are needed?

0:43:35.200 --> 0:43:35.790  
Cody Sole  
Yes.

0:43:36.270 --> 0:43:50.410  
Patty Hellman  
Well, it's the, I don't know. There's 40 years of toxicology that is extremely well known how to do tax studies. There's 25 years, probably of history on what is needed for.

0:43:51.790 --> 0:44:15.870  
Patty Hellman  
Looking at the efficacy of a drug independently, well, depending on the drug modalities. As I said, the new services that are offered recently that I see growing and preclinical space is definitely in vitro 3D organoids that are coming back because they're more efficient to predict toxicology. And if you can see of the drug.

0:44:16.840 --> 0:44:18.920  
Patty Hellman  
I like organ on the chip, for instance.

0:44:19.880 --> 0:44:22.390  
Patty Hellman  
And also prediction of immunogenicity.

0:44:24.870 --> 0:44:29.320  
Patty Hellman  
All the others it's it's well known as well established. Everyone has them.

0:44:30.890 --> 0:44:45.910  
Cody Sole  
OK, sounds good. You did mention other than Charles River, there are some special special niche CRO that are pretty good in the preclinical space. Others specific names that come to my mind.

0:44:46.760 --> 0:44:52.610  
Patty Hellman  
I prefer not to mention names because of the conflict of interest that I might call in.

0:44:53.390 --> 0:45:11.250  
Cody Sole  
Yeah, sure. OK. Sounds good. And then maybe we also go back to the clinical trial testing. I wonder what data storage on nalysis that you, the sponsors frequently requests and needs that CRO's to provide?

0:45:13.870 --> 0:45:14.800  
Patty Hellman  
Well, there's.

0:45:15.830 --> 0:45:19.70  
Patty Hellman  
Two specific areas where.

0:45:19.970 --> 0:45:22.850  
Patty Hellman  
Data generated is let's say.

0:45:24.490 --> 0:45:28.610  
Patty Hellman  
Requiring very specific needs, I would say the first one is genomics.

0:45:30.110 --> 0:45:43.840  
Patty Hellman  
So there's a lot of data crunching there. Analysis that is required so companies like ours not only store data but analyze data. So we have a full department of Bioinformatics for instance.

0:45:44.520 --> 0:45:48.610  
Patty Hellman  
To look at different variants, different deletion insertion sites.

0:45:50.720 --> 0:46:3.120  
Patty Hellman  
Variance mutations that are coming up on the weekly basis update the raw data analysis that we have. Depending on those new findings.

0:46:4.120 --> 0:46:4.620  
Patty Hellman  
Uh.

0:46:6.0 --> 0:46:10.510  
Patty Hellman  
That's very reactive. Also storing data on cloud now.

0:46:11.910 --> 0:46:18.580  
Patty Hellman  
That's very important because data integrity is critical here and also storage for long term.

0:46:19.810 --> 0:46:27.510  
Patty Hellman  
I would say that immuno monitoring is getting there just because companies like ours have now moved into.

0:46:28.500 --> 0:46:33.420  
Patty Hellman  
3040 color analysis using spectral.

0:46:34.140 --> 0:46:38.0  
Patty Hellman  
Photometry, no longer typical flow cytometry.

0:46:39.430 --> 0:46:43.540  
Patty Hellman  
Spectral cytometry is generating a lot more data.

0:46:44.470 --> 0:46:50.390  
Patty Hellman  
Uh, so if you have 40 colors for instance, you can look at up to 2000 different cell subsets.

0:46:51.690 --> 0:47:13.680  
Patty Hellman  
That's a lot of data to crunch a lot of data to look at, so we're now we're using specific tools to analyze self subsets. Some of them are fully automated, others are now using AI, ML or artificial intelligence machine learning. We're also starting to store data on clouds and share.

0:47:15.680 --> 0:47:19.540  
Patty Hellman  
Raw file on clouds with our sponsors.

0:47:21.270 --> 0:47:28.100  
Patty Hellman  
I think that I ain't see is probably next or you know something three is probably next using digital.

0:47:28.930 --> 0:47:37.140  
Patty Hellman  
Apology for instance. So we are seeing a lot of partners bringing digital pathology using predictive tools.

0:47:37.970 --> 0:47:42.390  
Patty Hellman  
Umm that are using not only cell morphology.

0:47:43.590 --> 0:47:51.780  
Patty Hellman  
As a guiding tools to identify tumors, for instance, or even Nash or other indications.

0:47:52.560 --> 0:48:1.530  
Patty Hellman  
But there's a lot of data analysis that is done and storing the data is also important. Even if you use antibodies to stain, for instance, or fish.

0:48:2.730 --> 0:48:4.740  
Patty Hellman  
So that's gonna be the next.

0:48:5.980 --> 0:48:10.510  
Patty Hellman  
I think opportunity for using highly complex algorithm.

0:48:11.310 --> 0:48:13.250  
Patty Hellman  
And also data storage.

0:48:14.10 --> 0:48:27.460  
Cody Sole  
Umm, it mentions spectral flow cytometry, I wonder I are you willing to disclose the software that you use or is it an internal developed software for the sponsors?

0:48:28.310 --> 0:48:30.400  
Patty Hellman  
Well again for competitive.

0:48:41.110 --> 0:48:41.460  
Cody Sole  
OK.

0:48:31.680 --> 0:48:49.860  
Patty Hellman  
Reasons I'm not gonna mention the one we're using, but I can say that we have done the head to head to head comparison with tools available so far and we are also building our own tools that could either work as a standalone or integrate.

0:48:51.360 --> 0:48:54.990  
Patty Hellman  
Data generated using different commercially available tools.

0:48:57.70 --> 0:49:10.100  
Cody Sole  
Got it. And then you mentioned you sometimes share the raw file with the sponsor. So how often do you sponsors just get the raw data analyze themselves versus you provide some of the preliminary analysis to them?

0:49:14.70 --> 0:49:14.410  
Cody Sole  
OK.

0:49:11.70 --> 0:49:27.550  
Patty Hellman  
100% of the time we analyzing data now. Is it possible that they will further refine their analysis on their own after they receive the raw files? Most likely they'll play with it, but we provide the primary analysis.

0:49:28.420 --> 0:49:42.200  
Cody Sole  
OK. And then regarding storing data on the cloud or on premise, do you also maybe charge additionally for that services or it's part of the package when they conduct either flow or genomic services with you?

0:49:43.130 --> 0:49:44.450  
Patty Hellman  
It depends, but.

0:49:53.890 --> 0:49:54.70  
Cody Sole  
Yeah.

0:49:45.130 --> 0:50:4.360  
Patty Hellman  
Independently, whether you include this in the initial package or you charge a a supplement, you're charging for it, right? It's not free. So if you charge more per sample, or if you say, OK, we're gonna cost charge you less for sample, but if you want to store it on cloud, we gotta charge you. It's the same thing.

0:50:5.370 --> 0:50:8.780  
Patty Hellman  
It's just that it's a different line item, but it's the same thing.

0:50:9.530 --> 0:50:15.360  
Cody Sole  
OK, sounds good. Just wanna move forward to another.

0:50:16.190 --> 0:50:32.110  
Cody Sole  
I guess services that's yaros my needs and it's lab logistics. So I'm just wondering how do you support the sponsors for the lab logistics and what are the frequent or services that they request the most?

0:50:33.100 --> 0:50:34.720  
Patty Hellman  
What is lab logistics for you?

0:50:36.260 --> 0:50:36.950  
Patty Hellman  
What is it?

0:50:36.60 --> 0:50:39.440  
Cody Sole  
Yes. So that will umm that will be you know for print.

0:50:38.590 --> 0:50:39.750  
Patty Hellman  
What does it include?

0:50:40.750 --> 0:51:3.770  
Cody Sole  
Right. So we'll think about three different types. So one is preclinical trial, you you have to understand different clinical sites and design and in the middle would be the operational stage. You have samples collected from the side shipped to the lab and monitoring and track the samples versus in the end you might store the samples and build databases for that as well.

0:51:5.580 --> 0:51:7.330  
Patty Hellman  
So within clinical trial.

0:51:8.120 --> 0:51:12.160  
Patty Hellman  
What we provide, for instance, and most of the large.

0:51:13.80 --> 0:51:37.500  
Patty Hellman  
It's a providers are doing the same thing is first we start with kits, so we build kits with the proper components. We call them like tubes to collect biopsies or plasma or serum or whatever it is urine. So we're still we provide specific shifts that we sent to the site. That's #1 #2 we're working with couriers.

0:51:38.210 --> 0:51:49.350  
Patty Hellman  
Ohm in conjunction with couriers to pick up the kids when they've been used to collect patient samples to bring them back to the central lab, for instance.

0:51:50.20 --> 0:52:7.130  
Patty Hellman  
Where we offer sample processing and testing, or we reroute those samples either to long term storage or to niche Laos are third party labs that are doing the analysis on their own. So that's the kind of logistics that we offer.

0:52:9.60 --> 0:52:13.380  
Cody Sole  
And do sponsors ask for additional logistics services?

0:52:15.130 --> 0:52:16.40  
Patty Hellman  
Such as.

0:52:18.20 --> 0:52:23.410  
Cody Sole  
I'm just wondering. We're tracking monitoring or different temperature and requirements.

0:52:24.570 --> 0:52:40.570  
Patty Hellman  
Temperature monitoring is is the best kept secret in clinical trials. Everyone wants it. No one wants to pay for it, so it's not. It's not really useful for every sample, but usually it's part of it's part of the package. If they want it.

0:52:41.630 --> 0:52:42.490  
Cody Sole  
OK so.

0:52:41.680 --> 0:52:42.680  
Patty Hellman  
Yes, we offer that.

0:52:53.330 --> 0:52:53.940  
Patty Hellman  
No.

0:52:43.950 --> 0:52:54.780  
Cody Sole  
God, it's and I know. But still just wanna ask, what will you be willing to share any carriers that's you know that the leaders in this space. OK.

0:52:55.170 --> 0:52:55.840  
Patty Hellman  
No.

0:52:55.280 --> 0:52:57.500  
Cody Sole  
That's that's fine.

0:52:59.0 --> 0:53:0.240  
Cody Sole  
OK. And another.

0:53:0.910 --> 0:53:13.70  
Cody Sole  
Saying that and or just curious, do sponsors typically ask for the CMC bowl analytical testing with you guys together with the ball marker testing?

0:53:14.940 --> 0:53:41.570  
Patty Hellman  
So that's interesting. Again, it's pretty siloed. So I'm not gonna talk about CMC because we don't offer CMC. CMC is looking at the drug itself and releasing the drug for use in patients for instance, we don't do this type of work, but we do a lot of bioanalytical, which means that collecting samples from the patients that have been treated and looking for the presence of the drug into the patients.

0:53:41.690 --> 0:53:46.480  
Patty Hellman  
Tissue or plasma blood fluid? We do that a lot.

0:53:47.100 --> 0:54:0.550  
Patty Hellman  
Uh, we do also our it's different from what you mentioned, but we do a lot of add me work which is administration metabolism expression and distribution.

0:54:1.900 --> 0:54:3.510  
Patty Hellman  
Or distribution expression.

0:54:4.40 --> 0:54:4.380  
Cody Sole  
Umm.

0:54:4.860 --> 0:54:8.540  
Patty Hellman  
Using samples containing a drug.

0:54:9.450 --> 0:54:18.470  
Patty Hellman  
To assess how the drug is gonna be metabolized as a predictive tool. So we do this too. But it's not CMC and it's not by 1.

0:54:19.810 --> 0:54:31.40  
Cody Sole  
Yeah. OK, understood. Uh, seems like there's just less need potentially having 10 test for both my marker as well as the CMC testing.

0:54:31.650 --> 0:54:36.340  
Patty Hellman  
Typically these, yeah, some large labs do this, but typically it's.

0:54:37.470 --> 0:54:45.200  
Cody Sole  
OK. And circling back, I think we'll talk about lab logistics regarding the last phase of sample storage.

0:54:46.120 --> 0:54:51.50  
Cody Sole  
How? What's the view from sponsors perspective of requesting such services?

0:54:52.280 --> 0:54:53.140  
Patty Hellman  
It depends.

0:54:54.220 --> 0:55:5.550  
Patty Hellman  
A lot of sponsors, especially the large sponsors, are asking for labs like ours to keep those long term storage.

0:55:6.920 --> 0:55:9.80  
Patty Hellman  
Others are going to niche.

0:55:9.780 --> 0:55:14.820  
Patty Hellman  
Storage facilities so few I'm sure you.

0:55:13.860 --> 0:55:17.550  
Cody Sole  
What are the drivers of using a different storage facility?

0:55:18.290 --> 0:55:18.590  
Cody Sole  
Booker.

0:55:19.980 --> 0:55:20.140  
Cody Sole  
Look.

0:55:17.60 --> 0:55:23.10  
Patty Hellman  
Cost, cost, cost #1 number 21 tool to monitor.

0:55:24.390 --> 0:55:29.480  
Patty Hellman  
All their assets so dentify exactly where are those samples?

0:55:30.240 --> 0:55:35.480  
Patty Hellman  
How? What's the value? What's the age? What's the temperature which the samples are stored?

0:55:36.40 --> 0:55:46.570  
Patty Hellman  
Uh, a portal or let's say interface to access a database that is very user friendly. These are the the two main drivers.

0:55:47.380 --> 0:55:51.510  
Cody Sole  
And why is store the sample? Just wondering how long do you typically store the sample?

0:55:52.480 --> 0:55:53.910  
Patty Hellman  
10 years, 15 years.

0:55:54.670 --> 0:56:14.40  
Cody Sole  
OK, got it. And just if you are willing to share, just wondering what percentage of your the sponsors approximately with opt in and the sample collection kits versus temperature monitoring options and versus sample storage?

0:56:16.570 --> 0:56:19.830  
Patty Hellman  
Well, it's not one versus the other. It's not war, right?

0:56:20.320 --> 0:56:24.630  
Cody Sole  
Right. Sorry. I mean it's it's a wrong word, just three different numbers potentially.

0:56:25.550 --> 0:56:33.450  
Patty Hellman  
You know what? I I would be hard pressed to give you numbers that I would trust. I am not. I am not close enough to that type of information.

0:56:33.940 --> 0:56:38.420  
Cody Sole  
Yeah, no worries. Uh, I know we're close up on time. Just one last time.

0:56:37.80 --> 0:56:39.450  
Patty Hellman  
Because this is very far from biomarkers.

0:56:40.620 --> 0:56:41.650  
Cody Sole  
Yeah. OK.

0:56:41.440 --> 0:56:42.440  
Patty Hellman  
Testing and talking.

0:56:47.370 --> 0:56:47.850  
Patty Hellman  
Yeah.

0:56:43.530 --> 0:57:4.160  
Cody Sole  
Yeah, OK. Sounds good. I know we read them on time. So just one last question I relatively I wonder what is the average size of a preclinical bomb marker testing versus at different clinical stages, phase one, two and three for clinical testing projects?

0:57:5.990 --> 0:57:7.430  
Patty Hellman  
That our company does.

0:57:8.260 --> 0:57:8.790  
Cody Sole  
Yes.

0:57:10.200 --> 0:57:14.250  
Patty Hellman  
Well, I think it would be less than 5% preclinical.

0:57:23.50 --> 0:57:23.460  
Cody Sole  
Rabbit.

0:57:15.220 --> 0:57:28.620  
Patty Hellman  
And then you can look at clinicaltrials.gov for the rest of the information, because it's we all do the same thing. So you can look at the proportion of Phase 123 and four clinicaltrial.gov. That's exactly what we would do.

0:57:37.800 --> 0:57:39.690  
Patty Hellman  
Ohh the cost. I don't I don't.

0:57:29.840 --> 0:57:39.930  
Cody Sole  
Right. I'm. I'm not. You know, I'm trying to prove any confidential. Just wanna in general. Just regarding the cost per project or the you know the the size of the samples.

0:57:40.650 --> 0:57:52.650  
Patty Hellman  
I don't know. I I honestly don't know. Size of sample with highly highly, highly dependent on the therapeutic area cardiovascular 30,000 samples per phase three, oncology 600.

0:57:53.950 --> 0:58:0.770  
Patty Hellman  
So again, all, there's nothing new here. It's it's how these clinical trials are built.

0:58:5.830 --> 0:58:8.790  
Patty Hellman  
Yeah, I need to jump to the other call, Catherine.