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

0:0:29.200 --> 0:0:43.870  
Pat Green  
I'm currently responsible for what translational biomarkers in the department that is concerned with discovering and developing biomarkers. Optional trials. I've been doing this for around 15 years and several companies.

0:0:44.520 --> 0:0:56.460  
Pat Green  
And the company where I'm now is a mid size company and as I said, it's involving discovery and development biomarkers and assisting in the outsourcing for clinical trials whenever needed.

0:0:59.150 --> 0:1:5.750  
Courtney Sanders  
Would you mind explaining a little bit on the therapeutic areas that you work with as well as the modalities?

0:1:7.240 --> 0:1:14.510  
Pat Green  
Yeah, sure. So we we mostly worked in the area of information and oncology.

0:1:15.850 --> 0:1:30.120  
Pat Green  
Beside that, there's some efforts in cardiovascular and scenes as well and that is in principle what I've done also for the last 15 years, not a companies. These therapeutic areas have the key focus for biomarkers in general.

0:1:31.310 --> 0:1:44.860  
Pat Green  
Modalities, mostly ligand based assays or protein detection, although in some occasions we also looked at nucleic assets, looked at gene expression RNA.

0:1:46.560 --> 0:1:50.780  
Pat Green  
And and to a minor extent, metabolites.

0:1:53.920 --> 0:2:7.270  
Courtney Sanders  
Gotcha. And do you work with specific type of therapeutic modalities such as small molecules or M RNA parties such as those ones?

0:2:14.500 --> 0:2:14.860  
Courtney Sanders  
OK.

0:2:8.300 --> 0:2:20.810  
Pat Green  
So so my my experience, both preclinically and clinically is only with regard to small molecules. I have very limited experience and exposure to biologics or any of the other therapeutic modalities.

0:2:21.600 --> 0:2:23.910  
Courtney Sanders  
That's perfect. Thanks for explaining that.

0:2:25.190 --> 0:2:33.910  
Courtney Sanders  
So you touch upon you use different services for protein your class and and metabolics detections.

0:2:34.690 --> 0:2:37.230  
Courtney Sanders  
Umm, I wonder what type of.

0:2:37.920 --> 0:2:41.170  
Courtney Sanders  
Tools do you use for such pharma protesting?

0:2:42.870 --> 0:2:57.390  
Pat Green  
And as I said, when it's regarding protein, it's mostly ligand based assays as antibody detection and there's different platforms that we are using, but the basic the basic principle is elisa like detection.

0:2:58.190 --> 0:3:1.440  
Pat Green  
And for nucleic acids?

0:3:2.310 --> 0:3:4.40  
Pat Green  
That can be Q PCR.

0:3:5.10 --> 0:3:34.460  
Pat Green  
Again, different platforms can be used here, but the basic principle here is is qualitative quantitative PCR and we have started to introduce more and more sequence based transcriptomics so RNA seek and if it's Histology based it's spatial transcriptomics. It's a bit of a a special derivative of sequencing, but again basically the same platform sequence based metabolomics.

0:3:35.120 --> 0:3:37.570  
Pat Green  
We don't do that in House, but it's almost like base.

0:3:46.60 --> 0:3:46.670  
Pat Green  
Mm-hmm.

0:3:39.180 --> 0:3:57.790  
Courtney Sanders  
Perfect. Uh. I would like to just ask a few full question though on those on each technology here. So for Eliza, other specific type of panels that you always test for and do you have any needs for multiple any level of multiplexing?

0:3:59.960 --> 0:4:17.250  
Pat Green  
And Multiplex panels. We actually rarely used in a clinical setting in the preclinical setting as to explore which biomarkers we would like to concentrate on, we're using Multiplex panels. Same thing for immunohistochemistry.

0:4:17.830 --> 0:4:37.430  
Pat Green  
Umm, but when we focus on introducing and implementing them in clinical trials, we normally switch back to a single Plex and that's in all the cases where I've been personally involved in in clinical trials is always been single Plex based assays also for Histology or immunohistochemistry.

0:4:39.490 --> 0:4:46.450  
Courtney Sanders  
Or the other specific type of elizas that you prefer to use, such as MSD.

0:4:48.770 --> 0:4:57.0  
Pat Green  
So MD is something we use that's very reliable platform. It also switches easily from from Multiplex to single Plex.

0:4:57.620 --> 0:5:14.970  
Pat Green  
And we also have a lot of experience with singulex and plasma residence measurements. And then there's another platform which the name escapes me at the moment, but we also use a very another platform which is again very sensitive and measurement.

0:5:16.200 --> 0:5:17.860  
Pat Green  
Again, the name escapes me will come back.

0:5:18.660 --> 0:5:23.330  
Courtney Sanders  
You know, we've heard also all link as another platform for Eliza's.

0:5:23.60 --> 0:5:26.290  
Pat Green  
We don't you we don't use that we use another one.

0:5:27.120 --> 0:5:32.420  
Pat Green  
I'm I'm. I'm going to look that up and I'll I'll give the money because I forgot the name.

0:5:31.770 --> 0:5:32.480  
Courtney Sanders  
OK, perfect.

0:5:33.180 --> 0:5:40.690  
Courtney Sanders  
Thank you. Umm, so I wonder why do you choose those specific platforms versus ones like old link?

0:5:44.0 --> 0:5:51.800  
Pat Green  
That's a good question. We have been, of course expert exposed to all link, but we believe that the other platforms.

0:5:51.880 --> 0:6:7.190  
Pat Green  
Umm, are sufficiently sensitive and reliable and give robust results as compared to all link. And I know I know that other companies have been using this and using specifically. If you're thinking about Multiplex but we we haven't done that yet.

0:6:15.660 --> 0:6:16.140  
Pat Green  
Exactly.

0:6:17.280 --> 0:6:17.510  
Pat Green  
Thanks.

0:6:9.290 --> 0:6:26.190  
Courtney Sanders  
I see. And even with the preclinical testing used, the platforms that you mentioned before instead of OK, good. So if I understand correctly the the the biggest and many info and for all link is the sensitivity there.

0:6:28.90 --> 0:6:46.770  
Pat Green  
That's partially the the issue, and of course is the platform is very suitable for for multiplexing. Looking at multiple proteins at the same time and we in principle and in our strategy as to you know based on our previous experiences, don't see a real benefit in multiplexing in clinical problems.

0:6:47.430 --> 0:6:47.710  
Courtney Sanders  
OK.

0:6:48.520 --> 0:6:59.460  
Courtney Sanders  
Got it. And do you typically use a custom marker for Eliza or off the shelf panels will be sufficient?

0:7:1.850 --> 0:7:3.580  
Pat Green  
And can you explain that again?

0:7:6.850 --> 0:7:7.280  
Pat Green  
Yes.

0:7:4.650 --> 0:7:16.460  
Courtney Sanders  
Uh for Eliza's do you typically use the off the shelf panels, or do you actually design and pick the marker that you would like to test for clinical trials?

0:7:17.470 --> 0:7:47.980  
Pat Green  
The letter we we rarely use off the shelf panels when we have panels we normally establish themselves when when we do use them, there may be some occasions where we use off the shelf predefined panels. But in the clinical trial setting, as I said before, we normally go back to singleplex measurements and we also normally go through a separate validation of the off the shelf assay so that that that might be some significant changes.

0:7:48.60 --> 0:7:49.670  
Pat Green  
In the in the way the essay has been.

0:7:50.520 --> 0:7:54.90  
Pat Green  
Be deployed as compared to the commercially available solution.

0:7:56.500 --> 0:8:9.180  
Courtney Sanders  
Gosh, I would. Would you mind explaining a little bit? So let's say if you purchase a single marker, Eliza, and how do you change that for your own clinical trial testing?

0:8:10.630 --> 0:8:31.860  
Pat Green  
Well, what we normally do in our in our first set up in the feasibility is to look how the essay performs to our needs and also dependently with with you know how the commercial product was marketed. Sometimes of course you complete relying on the complete kit, but there are of course particular aspects of the essays that we can change.

0:8:33.640 --> 0:9:0.810  
Pat Green  
And that's what we'll do. There are certain aspects in the protocol and the assay protocol as being presented by the vendor, which we might change to our own needs and this can already be, for instance difference in the sample that is plus more CRM functions if we might deviate there from the vendor and develop the essay specifically for another need.

0:9:2.790 --> 0:9:10.790  
Courtney Sanders  
And you mentioned sample types, other specific sample types that need frequent adjustments on the protocols.

0:9:25.660 --> 0:9:25.910  
Courtney Sanders  
OK.

0:9:12.380 --> 0:9:28.520  
Pat Green  
Well, I think our in our experience with any commercial product, we always go through very rigorous testing and every protocol needs to be adapted to our own needs, even if assays are being.

0:9:28.600 --> 0:9:55.100  
Pat Green  
Uh being commercialized as diagnostic assays for a particular purpose because as you know, the diagnostic has been approved for, right particular use and mostly in our case we have other context of users. So we always go through a rigorous testing and we always look at the parameters and might change them might be simple changes might be more more dramatic changes in how the essay is being deployed.

0:9:56.510 --> 0:9:58.520  
Courtney Sanders  
Got it. Perfect. Thanks for explaining that.

0:9:59.800 --> 0:10:8.960  
Courtney Sanders  
Moving on to mass spec, other specific sample types that you typically use for metabolomics.

0:10:11.400 --> 0:10:21.10  
Pat Green  
No, it's mostly what it's kind of if it certainly in the screening phase, it's what's standardly available, can be plasma samples or can be serum samples also depends little bit again.

0:10:21.610 --> 0:10:40.260  
Pat Green  
And what what the questions are we we have embarked quite a few times on urinary analysis. That's quite a challenge. So it can be urine, it can be plasma or serum and in some cases particularly on the question again, it can also be seen as.

0:10:41.170 --> 0:11:10.860  
Pat Green  
The cerebral spinal fluid. Uh. Again, it's very context and therapeutic area specific obviously and to some extent again depending on the question we might look directly with mass spec in tumors. What I said in the beginning, then when I was talking about ELISA or lying binding assays that we mostly use that for proteins, there are exceptions. We also have a few examples where we use mass spec for protein detection or peptide detection, so.

0:11:11.100 --> 0:11:18.230  
Pat Green  
In this particular case, again, it could also be solid tissue that we might be using as an input for measurement proteins.

0:11:20.110 --> 0:11:24.270  
Courtney Sanders  
Got it. Got it. And other specific.

0:11:24.970 --> 0:11:32.990  
Courtney Sanders  
Challenges at differences when the sample inputs is plasma serum versus CSF.

0:11:35.520 --> 0:12:4.970  
Pat Green  
Yes, yes. And the the matrix has a has a huge impact even between species. So even if you move from plasma from from Reds or dogs to to humans, we see in some occasions marked differences between the asset performance. Not always but sometimes. So yes, moving from CF to plasma to serum has the potential depending on what you're measuring. Some proteins are in different.

0:12:5.50 --> 0:12:14.990  
Pat Green  
If you are measurement plasma and serum, but some are very much affected by the differences in these in these matrices. So in short entries, yes we we do see marked differences.

0:12:16.940 --> 0:12:17.620  
Courtney Sanders  
And.

0:12:18.780 --> 0:12:29.730  
Courtney Sanders  
I want. Are there any specific many ads that you face currently when you use mass SPECT to detect any of the analyze.

0:12:32.480 --> 0:12:50.70  
Pat Green  
And particular needs. UM, what what we see is a major hurdle in deploying Mustang specifically for proteins is the is the sample throughput. So we have had a few occasions where we were able to.

0:12:52.170 --> 0:12:53.0  
Pat Green  
Design.

0:12:53.120 --> 0:12:57.660  
Pat Green  
And the the perfect type of essay with a very good performance.

0:12:58.880 --> 0:13:19.800  
Pat Green  
But the sample throughput is just too low and and that is intrinsic to the platform. So there, there, there, of course we're looking. We're looking forward to improved technology or essentially maybe in some cases, if it's across the effective to outsource it so that we can overcome the limitations that we have in our own laboratories.

0:13:24.300 --> 0:13:24.770  
Courtney Sanders  
Got it.

0:13:26.830 --> 0:13:39.530  
Courtney Sanders  
Great. And if you look into the future, three to five years from now, do you what are the major trends within the mass spec space that you foresee?

0:13:40.980 --> 0:14:7.610  
Pat Green  
Cool. That's a tough question. I'm not a mask. Thank expert. I'm more like a general biomarker expert. Well, I I think what what we will see and we will see a similar as to the sequencing space is that the technology will advance where the sample throughput is. I just said will improve the costs will go down and the sizing of the instruments also making it more.

0:14:8.10 --> 0:14:38.560  
Pat Green  
Uh. Usable in in clinical trial settings, because that's also one of the limiting factors. If you develop an assay from mass bank, so mass spec based assays. Of course heavy limitation in their deployability, you will relying on quite advanced laboratory settings and not all occasions can provide that. So that's that's clearly where the trend is slowly moving and the costs will come down therefore so the.

0:14:38.640 --> 0:14:55.880  
Pat Green  
The uptake of such technologies will will take place, but at the moment it's still quite an advanced technology. Costly, limited throughput in some cases, so that that is certainly something that will change in the next five years as we have seen with sequencing.

0:14:58.290 --> 0:14:59.730  
Courtney Sanders  
Yep. Perfect.

0:15:1.380 --> 0:15:1.940  
Pat Green  
It.

0:15:3.350 --> 0:15:3.660  
Courtney Sanders  
Fine.

0:15:12.370 --> 0:15:12.680  
Courtney Sanders  
OK.

0:15:4.590 --> 0:15:13.180  
Pat Green  
No, I want just wanted to say I just looked it up very quickly because I forgot the name. So what we what we are also using very much is quanterix as a plan.

0:15:14.290 --> 0:15:14.770  
Courtney Sanders  
Yep.

0:15:21.120 --> 0:15:21.340  
Pat Green  
Umm.

0:15:16.220 --> 0:15:31.950  
Courtney Sanders  
Yeah, we'll definitely would like to touch upon contacts later as as CRO. But I'm wondering you do does your company deploy their technology in house or do you outsource to quanterix for the services?

0:15:33.20 --> 0:15:43.520  
Pat Green  
That's a very good question and it's that is probably dealt with differently in other companies as I've seen that also we do measure in House.

0:15:44.940 --> 0:15:48.390  
Pat Green  
And that is mostly an evaluation of cost.

0:15:49.50 --> 0:16:18.870  
Pat Green  
And and utility. So to make a rough rough cut where we certainly will not deploy our own internal leverages laboratories as soon as they are part of the medical and regulatory decision making. So anything that is considered as a research exploratory again one has to be very careful with the term exploratory, but if it's truly exploratory then we we we mostly will try to measure that in house for cross reasons.

0:16:19.570 --> 0:16:22.170  
Pat Green  
And to some extent also for quality reasons.

0:16:25.90 --> 0:16:26.440  
Courtney Sanders  
OK, got it.

0:16:25.770 --> 0:16:27.530  
Pat Green  
And and the rest of outsourced.

0:16:42.20 --> 0:16:42.220  
Pat Green  
Umm.

0:16:28.880 --> 0:16:59.510  
Courtney Sanders  
Yep, OK, sounds good. I just have another few questions on the technology piece and we'll move on to the CRO selection. Parts of the discussion. So you mentioned the RNC can spatial sequencing, what do you deploy those technology in specific therapeutic areas such as oncology, CMS or other particular modalities?

0:16:59.620 --> 0:17:2.40  
Courtney Sanders  
That you use those technology with.

0:17:3.810 --> 0:17:34.320  
Pat Green  
Yeah, we have probably lagging behind a little bit with the mainstream utility of sequencing in the clinical space. So we are mostly positioning it in our cology, both the bulk RNA seek also the single cell RNA seek or the spatial transcriptomics. These are all things that we are deploying in your quality space and most of this is really in the preclinical space, but in some occasions we have started to use it.

0:17:34.400 --> 0:17:37.610  
Pat Green  
In very exploratory manner in in.

0:17:38.540 --> 0:17:39.600  
Pat Green  
In the clinical space.

0:17:40.680 --> 0:17:49.790  
Pat Green  
Outside of oncology, we do a lot also in inflammatory diseases, but that that mostly has been really in the preclinical stage. Again this can be.

0:17:50.600 --> 0:18:2.770  
Pat Green  
Animal models, but can also be clinical specimen that we obtain and that which we further explore. But this is not normally defined more as preclinical activities to support the clinical.

0:18:4.550 --> 0:18:5.670  
Pat Green  
And outside of that.

0:18:4.550 --> 0:18:5.720  
Courtney Sanders  
That makes sense.

0:18:6.650 --> 0:18:6.890  
Courtney Sanders  
Yep.

0:18:6.430 --> 0:18:14.400  
Pat Green  
Yeah. And outside of that, see you, Ness, is, is, is something that is emerging, but this is definitely only utilizing the preclinical space.

0:18:16.120 --> 0:18:30.630  
Courtney Sanders  
Gotcha. So if you were to, you know, just look three to five years from now and do you see this type of sequencing being utilized in other therapeutic areas outside oncology in clinical trials?

0:18:31.730 --> 0:19:2.440  
Pat Green  
It definitely and and as I said, this is already happening, certainly with other companies. It's well published and it's mostly in the level of exploration clinical research. It has outside of oncology at the moment, very little application in a sense of through decision making or medical diagnostics. But it's coming, it's coming fast and logically the more molecular defined diseases on collagen and inflammation and menology.

0:19:3.300 --> 0:19:32.750  
Pat Green  
Or or rapidly picking this up and and implementing these in clinical trials and even in medical decision making. And I would foresee that with the advances that being made in molecular diagnostics, that CNS will follow very quickly. And of course, what I didn't mention is the cardiovascular space and there of course, we already have examples where we're seeking sequencing is being deployed. But yes, in the next five years, this will certainly be picked up.

0:19:33.130 --> 0:19:41.260  
Pat Green  
In other therapeutic areas and and will certainly also influence the the medical decision making as we know it now.

0:19:43.210 --> 0:19:57.640  
Courtney Sanders  
So I'm interested in what you mentioned, CNS, cardiovascular. Do you see those indications deploy multiple types of measurement that we discussed for about marker in the future as well?

0:20:0.560 --> 0:20:13.310  
Pat Green  
Umm can you can you rephrase that question again because I was disturbed, let's just go to call and I don't know how to take that call off my phone, so it's beeping and little bit in the background. So can you please sweep. It's very glad that's gone now.

0:20:13.860 --> 0:20:14.250  
Pat Green  
Now.

0:20:12.420 --> 0:20:20.790  
Courtney Sanders  
Of, of course, of course, of course. So I wonder, you know, we've discussed multiple type of ways to measure.

0:20:23.650 --> 0:20:24.290  
Pat Green  
Mm-hmm.

0:20:27.470 --> 0:20:28.340  
Pat Green  
Mm-hmm.

0:20:20.950 --> 0:20:38.140  
Courtney Sanders  
And bio markers. So Q PCR sequencing, mass spec, ELISA, etcetera. What do you see in the in the next three to five years? Which indication would utilize multiple different ways of measuring by market in the clinical trials?

0:20:39.440 --> 0:21:10.110  
Pat Green  
Ohh, I think if you're looking at the area of ecology that's already using multiple types of biomarker, that's become quite common. It's a very advanced way of trying to understand the full the full picture, both tumor as well as the query. So that is for for real already happening I think in the other spaces this is this is also already happening the pick up very quickly. Of course the differences between oncology and the other therapeutic areas is the disease tissue.

0:21:10.970 --> 0:21:28.50  
Pat Green  
Which which makes us rely a little bit more on the standard body fluids that one can access and therefore more standard technologies are being applied. But I I think there is no difference between any of the therapeutic areas that we have been discussing so far in using multiple modalities.

0:21:28.710 --> 0:21:51.990  
Pat Green  
Umm, the trend towards measuring uh looking at different modalities and not relying just a single readout or single platform is clearly being recognized. It's just all from a question of complexity in clinical trial setting as well as costs. But there's a clear interest to look at multiple modalities in a clinical trial setting.

0:21:53.560 --> 0:22:4.660  
Courtney Sanders  
Within CNS, for example, I wonder what are the main challenges to use multiple tools to assess our markers.

0:22:5.860 --> 0:22:30.830  
Pat Green  
While it's the relevant, I mean in most cases, everything that we're doing here is, is is being questioned by the the the relevance with regard to the biological relevance and if you're thinking about drug development in what is the relevance of what you're measuring as a form of dynamic effect, specifically in CNS, of course, as you will understand that the disease is in the brain or in the peripheral nervous system.

0:22:31.870 --> 0:22:46.610  
Pat Green  
They are normally not easily accessible and anything that we measure is remotely connected to what's happening in the brain. So the closest we can get to the brain with regard to the platforms we've just mentioned is cerebral spinal fluid.

0:22:47.300 --> 0:23:4.850  
Pat Green  
And and I think that that will remain a challenge for quite a while and the, the, the true question has always been with this measurements, how relevant are they and how do they actually reflect what's happening specifically in certain brain areas.

0:23:5.540 --> 0:23:18.40  
Pat Green  
That's also why I believe that in these areas, but again, there's also an oncology very, very common imaging, of course plays an important role as to complement the other findings that we have.

0:23:20.10 --> 0:23:20.360  
Courtney Sanders  
Yep.

0:23:23.340 --> 0:23:23.850  
Pat Green  
Exactly.

0:23:21.130 --> 0:23:29.760  
Courtney Sanders  
The family for the CNS imaging. Who's you know, how about cardiovascular? Then what are the main challenges there?

0:23:31.330 --> 0:23:33.930  
Pat Green  
And cardivascular in to some extent.

0:23:35.10 --> 0:24:4.670  
Pat Green  
Again, the tradition there the, the the field has, uh, quite a lot of experience with the number of soluble biomarkers. And as these biomarkers, if it's now concerning the hard, the long already other vascular system, the shedding into the block is clearly reflected in some of the biomarkers that we know and probably ANP troponin and such. And since there have been so many large.

0:24:4.740 --> 0:24:18.130  
Pat Green  
Bodies and reef and build expert experience and expertise over the last you know 30-40 years and they're quite they have quite a good utility here again. Of course the limitation sometimes may be the.

0:24:19.160 --> 0:24:48.770  
Pat Green  
The diseased tissue itself being the heart or any of the other tissues, are more difficult to assess, and certainly biopsies are almost impossible or very difficult to achieve. So to get a true idea about the disease, tissue would always be a limitation. Here again, imaging sometimes may overcome some of the problems and there's all kinds of related technologies and imaging where you can get a better view on what's happening in the tissue. But I think here in the area is where there's quite.

0:24:48.870 --> 0:24:56.440  
Pat Green  
A good number of examples of soluble biomarkers that that have a clean utility, diagnostic wise, but also as pharmacodynamic.

0:24:57.430 --> 0:24:57.820  
Courtney Sanders  
Hmm.

0:25:11.660 --> 0:25:12.610  
Pat Green  
Yeah, absolutely.

0:24:58.440 --> 0:25:12.930  
Courtney Sanders  
Got it. So if rather than correctly, there are a few established farm marker for cardiovascular and diseases. And are these fairly recognized in the field to measure as endpoints or OK?

0:25:13.880 --> 0:25:29.450  
Pat Green  
Yes, absolutely. Yes. Even as endpoint sometimes or safety by markers or diagnostic buying marks, disease progression biomarker. So, so prognostic biomarkers and that's and so in the the, the, the, the field is quite rich in a number of Primark cars indeed.

0:25:30.830 --> 0:25:33.570  
Courtney Sanders  
Got it, got it. Perfect. Thank you for explaining that.

0:25:37.810 --> 0:26:3.270  
Courtney Sanders  
So last question, there is just overall football market testing. Uh, what are the major trends for the testing itself regarding technology? So we've heard from other experts such as spectral flow or site off that might be increasingly adopted in the fields. Any trends that you foresee?

0:26:5.210 --> 0:26:21.640  
Pat Green  
Or in in the air that we would just mentioning in relating to the more traditional platforms. I I think yes to what you already heard from the other expert site of certainly coming up. So single cell measurements become more and more important.

0:26:22.860 --> 0:26:35.810  
Pat Green  
Being it now done with platforms like side door or single cell sequencing, these of course have the the drawbacks that they're still costly and complex to implement in the clinical trial setting.

0:26:36.600 --> 0:26:44.650  
Pat Green  
So I would consider the more the exploratory 2 exploratory platforms that will will that will mature over time.

0:26:45.960 --> 0:26:50.780  
Pat Green  
I you know, I don't have an exhaustive list of old and new technologies that are coming up.

0:26:52.240 --> 0:27:3.820  
Pat Green  
But I think in in the spaces that we already mentioned before, they will improve like we've seen the sequencing and it's the same thing for the state already.

0:27:4.990 --> 0:27:7.250  
Pat Green  
Traditionally used lagging buying type passes.

0:27:7.970 --> 0:27:8.360  
Courtney Sanders  
OK.

0:27:9.240 --> 0:27:28.610  
Courtney Sanders  
Sounds good. Now on the move until the outsourcing part of the conversation, we touched a little bit. I wonder would you my explaining what type of marker testing that your company are more likely to outsource to your CRO?

0:27:33.210 --> 0:27:39.360  
Pat Green  
On the top of the list would be mass spectrometry, because we don't really have the set up.

0:27:39.880 --> 0:28:0.370  
Pat Green  
And to provide this and within our own syndicate files and there there is a number of other reasons which we might, you know step on with regard to the the validation and quality aspects of biomarker measurements. So mass spec definitely we have all this outsourced mastic based biomarker assays.

0:28:3.0 --> 0:28:14.740  
Pat Green  
Partially, we do that also for the lagging based essays for the sequencing as I've been in the beginning with just start to merge to use that more frequently in in a quality trials.

0:28:15.890 --> 0:28:19.680  
Pat Green  
There it depends. It depends, I would say mostly.

0:28:20.440 --> 0:28:26.990  
Pat Green  
We have outsourced this so far because also again the capacity we have internally is just not sufficient.

0:28:27.630 --> 0:28:31.860  
Pat Green  
And to to deploy it in for clinical trial measurements.

0:28:32.700 --> 0:28:42.630  
Pat Green  
And it's the same thing for Q PCR. So autumn modalities to measure RNA based molecules, we would be using outsource partners.

0:28:44.150 --> 0:28:56.250  
Courtney Sanders  
Got it, got it. And I wonder how do those outsourcing needs change by development stage at each clinical phases?

0:28:58.170 --> 0:29:27.190  
Pat Green  
One of the most important criteria for us as a as a mid size company where costs of course play a role is to keep as much as we can have internal it has, it has a number of advantages also with regard to specifically designed essays that we have developed and validated in House to keep them in House and use them as long as we can as we define them exploratory so in and let's say in the early technical development.

0:29:27.270 --> 0:29:33.350  
Pat Green  
This one Phase 2 proof of concept. Most of these will if, if.

0:29:34.710 --> 0:29:45.10  
Pat Green  
The throughput allows that maybe we measured in now, so most of the protein based assays ligand based assays and that just mentioned from different platforms are measured in house. It's very cost effective.

0:29:47.0 --> 0:30:9.780  
Pat Green  
If if we are moving into phase three or if we are talking about biomarker switch are part of the diagnostic cascade or are considered to maybe in the future play a more important prominent role in the approval, then we will certainly take an early decision to outsource that to a suitable contract research organization.

0:30:11.940 --> 0:30:13.450  
Courtney Sanders  
Interesting and.

0:30:14.130 --> 0:30:24.500  
Courtney Sanders  
I I wonder when you outsourced your CRO especially at the later phases, what are the criteria that you look at?

0:30:28.40 --> 0:30:38.950  
Pat Green  
Mostly the familiarity, of course, with the essay itself, the organization and they are familiar with the particular aspects of assays.

0:30:39.580 --> 0:30:43.0  
Pat Green  
And if they have a good quality process in place.

0:30:44.170 --> 0:31:12.900  
Pat Green  
So that's more the the experience we will always will do an audit in this particular case and make sure that we understand the processes within such a CRO. But these are very important aspects. And lastly, somewhat connected, we of course have now a wider variety of see rows that in principle for the more let's say sympathy type of essays can provide services and then costs do play a role, but costs in the end.

0:31:13.300 --> 0:31:18.470  
Pat Green  
He's a factor that sits lower than any of the other aspects and just mentioned.

0:31:21.550 --> 0:31:29.580  
Courtney Sanders  
And how important is the CRO is able to provide multiple type of services that you need?

0:31:31.260 --> 0:32:1.990  
Pat Green  
Well, ideally the way that we are doing a contracting and our vendor selection is is trying, we're looking at a clinical trial. Again, it depends on what type trial it is because it's just phase one, then it's generally not so complex. It's a single unit and then we're looking at if the zero can provide multiple of these services and makes the contracting easier. And also with regard to the price negotiations. So we tried to kind of keep things very simple. We tried to make sure that all that we want to measure.

0:32:2.90 --> 0:32:13.150  
Pat Green  
Including the overall clinical trial operations are with a single vendor. This is not always possible and that means that we have to work with multiple zeros.

0:32:13.800 --> 0:32:19.990  
Pat Green  
And again, it also depends on the platform. What we see is that certain platforms are handled by very specific zeros.

0:32:21.190 --> 0:32:42.360  
Pat Green  
This is for the protein based based assays as well As for the nucleic acid based nucleic acid based platform, but also for the mouse spec. If you're talking for instance about metabolomics, we end up with a very small number of zeros that are suitable actually to to be to be included in our clinical trial operations.

0:32:44.980 --> 0:32:50.290  
Courtney Sanders  
Got it. Interesting. So you really look at the platform of the technology specifically?

0:32:51.590 --> 0:32:58.620  
Courtney Sanders  
Of course, when it cuts you can you trying to consolidate that makes sense. I want to address specific, sorry.

0:32:59.700 --> 0:33:19.10  
Pat Green  
No, I just wanna say the perform of course is key. I mean what once once we have selected the biomarker and have gone through the initial validation of the essay it the platform becomes fixed, we would not change the platform because of course and therefore the platform is becoming the determinant for which Earl we choose.

0:33:20.330 --> 0:33:31.500  
Courtney Sanders  
And the does your do your internal teams decides which platform first after validating the bar marker or it's a partnership with another CRL.

0:33:32.940 --> 0:34:2.670  
Pat Green  
No. The way we are working is pretty much in internal setup where we are setting the pace for what platforms we're using. It might be in again with some exceptions if the platform is something we don't have that we will rely on interacting with the zero. But so far these have been very few cases for that was the case mostly we do the selection of the biomarkers, the feasibility studies looking at different platforms and the performance of the platforms.

0:34:3.70 --> 0:34:14.220  
Pat Green  
Then finally deciding which platform you choose for the particular purpose, and then use that platform to validate the biomarker assay to be deployed in a clinical trial.

0:34:16.10 --> 0:34:25.660  
Courtney Sanders  
Got it, got it. Well, thanks for explaining another question on the criteria. What's your view on the geographic coverage over CRO?

0:34:27.320 --> 0:34:57.80  
Pat Green  
Yeah, that that of course is in. So it's an interesting question. I mean the the biggest heroes you're working with and then normally with shipment, it doesn't really matter where this situation sometimes you see with like we had it in the past with Covance, which is not part of LabCorp, that specific genomic activities were centered in Seattle and approaching based SSML mostly then now in Geneva for us that doesn't really matter that much of course.

0:34:57.150 --> 0:35:1.880  
Pat Green  
Reflected in the shipment costs, but that's something that the zero will take care of.

0:35:3.700 --> 0:35:32.520  
Pat Green  
If you're now speaking specifically, let's say geographically the difference between Asia and specifically China and the rest of the world that, that that's a big issue as you probably are very well aware of from interviewing other other consultants. The China of course is posing particular challenges if we want deploy it in phase two and phase three trials where we will rely on specific solutions.

0:35:32.600 --> 0:35:53.790  
Pat Green  
That's for China, and not every CRO can provide that to us and that that is really sometimes a challenge where we might decide to drop it overall with regard to certain sites in China, because the overall cost benefit is just not there for the exploratory part. If it's however we.

0:35:54.750 --> 0:35:59.540  
Pat Green  
And amendatory biomarker for medical decision making or regulatory decision making.

0:36:0.370 --> 0:36:7.520  
Pat Green  
Then we have to. But then of course we we are really sometimes challenged by the solutions that can be provided on China.

0:36:9.390 --> 0:36:27.190  
Courtney Sanders  
Yeah. So that's a good point. Since we've heard across different discussions as well. So I'll South China within a pack, are there preferred region that you do ball marker testing like as you prefer region for CRO to have the ball marker testing?

0:36:28.540 --> 0:36:32.930  
Pat Green  
Umm, no. We have very good experience with different.

0:36:33.30 --> 0:37:2.960  
Pat Green  
And different companies in different geographic locations, none particular. So on a European basis or even in the former Eastern Europe or US, we we don't have any particular preference. It's mostly overall that we will be looking at the references of the CRO, our own references, our own experiences. And as I said, in most cases we will do an audit to make sure that it's fulfills the standards that we sent.

0:37:4.750 --> 0:37:14.300  
Courtney Sanders  
We've also heard there is a trans potentially moving away from conducting trials in East Europe. And do you see that?

0:37:15.580 --> 0:37:20.70  
Courtney Sanders  
You know, due to the war and other factors, do you see that as a trend as well?

0:37:21.210 --> 0:37:50.750  
Pat Green  
Umm, So what is it difficult one? It depends. You know there is a there is a global competition for patients and depending on which diseases you are studying or doing clinical trials and you might not have that luxury. And as you know there is a certain differences in geographical prevalences of certain diseases. If we're talking about rare diseases or orphan diseases, you don't have that luxury at all. You're already happy that you can find patients.

0:37:50.890 --> 0:37:52.420  
Pat Green  
Like that will be able to.

0:37:53.20 --> 0:38:21.10  
Pat Green  
And B, including your clinical trial, so in some cases, if we are talking about more common diseases and looking from it from a regulatory perspective, yes, you may avoid certain countries where you know that it's more cumbersome where the clinical, the hospital setting doesn't really allow for more advanced types of of clinical trials. And if biomarkers are really important like in oncology you you might decide to.

0:38:21.90 --> 0:38:26.810  
Pat Green  
And steak to two countries where, you know at least the technologies are.

0:38:27.470 --> 0:38:35.150  
Pat Green  
All of that in a more advanced state, but in general I think that is not certainly not based on biomarkers decision we would make.

0:38:36.710 --> 0:38:52.320  
Courtney Sanders  
OK, great. And lastly, you mentioned CRO's just ship samples around to different clinical sites for testing. I wonder how does that impact the turnaround time, is that top of minds when you consider 0?

0:38:54.810 --> 0:39:6.640  
Pat Green  
Yeah, it below the shipping normally is not really a stumbling block in the sense of your working with the large zeros, they it it fits within a protocol defined.

0:39:6.720 --> 0:39:19.30  
Pat Green  
And and time determinants and most assays that we have implemented, developed and implemented do allow for for some delay between.

0:39:19.600 --> 0:39:49.200  
Pat Green  
And original taking and and and shipment and final measurement. This has mostly has to be done within within a month and that is generally not really a problem with regard to the shipment time switch at most. Maybe go for 3-4 days. Again you can you can improve on this by express shipments, it just will increase the cost and you just have to be very conscious about the time aspects, how important it is to have these measurements done within a certain.

0:39:49.600 --> 0:39:54.580  
Pat Green  
Number of days mostly this is not the not the issue however.

0:39:55.650 --> 0:40:25.520  
Pat Green  
To give you an example, if the biomarker is part of the inclusion criteria, then the testing may friends not take place in the central laboratory, but will be done locally because the decisions have to be almost imminent. So in cardiovascular stays if you're measuring certain biomarkers as an inclusion criteria, it will be measured locally and the deep the data will be used for the selection of the patients.

0:40:25.670 --> 0:40:28.900  
Pat Green  
So there, there will be no or limited shipment.

0:40:29.920 --> 0:40:34.910  
Courtney Sanders  
And how fast do you need it to be for the patient enrollment criteria?

0:40:35.800 --> 0:40:46.710  
Pat Green  
As fast as possible, as I said, normally this is being part of the overall medical assessment in this really has to be, you know, within within hours to maximally a day.

0:40:47.440 --> 0:40:48.30  
Pat Green  
And.

0:40:48.750 --> 0:40:50.820  
Courtney Sanders  
OK. So less than 24 hours.

0:40:51.610 --> 0:40:51.910  
Pat Green  
Yeah.

0:40:52.780 --> 0:40:53.910  
Courtney Sanders  
Got it right.

0:40:54.930 --> 0:41:4.680  
Courtney Sanders  
And, you know, among all the testing that we talked about, would you mind sharing the top 3 testing provider that you consider?

0:41:9.130 --> 0:41:10.60  
Courtney Sanders  
Yes, searles.

0:41:7.110 --> 0:41:11.190  
Pat Green  
I mean zeros that that would be yes.

0:41:11.670 --> 0:41:16.280  
Pat Green  
And I think on top it would be a LabCorp.

0:41:16.470 --> 0:41:24.290  
Pat Green  
And obviously that's also one of the bigger ones that has uh really a large variety of technologies that they can provide.

0:41:24.830 --> 0:41:34.880  
Pat Green  
Uh medpace is zero. We have been working with quite a lot, and then there's a number of smaller ones which which we have been working with.

0:41:35.0 --> 0:41:46.580  
Pat Green  
And also recently we have done a few things with seniors health and IQVIA. It depends a little bit on the setting that Corp of course is a very.

0:41:47.550 --> 0:41:56.490  
Pat Green  
Logical choice, but has cost implications. Then in some cases just not possible to to work with them because of the time constraints.

0:41:57.450 --> 0:42:8.420  
Courtney Sanders  
Hmm and I work makes those companies you think the leaders in the industry and how do they differentiate them themselves?

0:42:10.290 --> 0:42:24.690  
Pat Green  
Well, in the case of LabCorp and then as I said, LabCorp has uh for I think it's already 6 years included covens and we've worked a lot with covens, which sits at a similar level of what we know now with LabCorp. It is just.

0:42:25.830 --> 0:42:35.60  
Pat Green  
Their level of understanding the space, specifically the the biomarker space, they have advanced laboratories and several parts of the world.

0:42:35.720 --> 0:42:49.30  
Pat Green  
Umm, they they. They're just on their reliability. In our experience, the preferred partners and that's where they stand out to the smaller ones. Another aspect of course is a set before.

0:42:49.910 --> 0:43:19.620  
Pat Green  
If they really provide an overall larger package, it's much easier to work with them because in principle they cover most of our needs rather than having multiple zeros working on the same trial because of limited availability of certain biomarker assays. So we've had that in the past where the the I think it was Matt Pace where they simply were not able to do all the biomarker assays and the clinical trial and that.

0:43:19.720 --> 0:43:23.690  
Pat Green  
Left to the decision to not work with them, we thought it would be too complicated.

0:43:25.640 --> 0:43:28.130  
Courtney Sanders  
Yep, OK, that sounds good.

0:43:29.390 --> 0:43:34.380  
Courtney Sanders  
Also, I would do have a a few of most specialized testing CRO.

0:43:34.450 --> 0:43:42.510  
Courtney Sanders  
Rome and names here. I just want to run that by you to see if you've heard them and if you've had any specific feedback on those.

0:43:44.450 --> 0:43:45.220  
Courtney Sanders  
Umm the.

0:43:49.240 --> 0:43:49.700  
Pat Green  
OK.

0:43:46.340 --> 0:43:50.160  
Courtney Sanders  
No, I have. I do have a list, so I would just say them.

0:43:51.10 --> 0:43:53.140  
Courtney Sanders  
The first is about agilytix.

0:43:55.160 --> 0:43:59.170  
Pat Green  
I know them. Uh, we've been talking to them. We have not used them so far.

0:44:0.540 --> 0:44:1.630  
Courtney Sanders  
And why is that?

0:44:3.180 --> 0:44:16.300  
Pat Green  
And it's simply never really fit to our needs. And as I said, we we have been working pretty much with the other bigger ones and they provided our needs and we we prefer to have a number of things.

0:44:17.0 --> 0:44:31.250  
Pat Green  
Uh combined with all the other activities like LabCorp, of course, is taking care of not just about analytics, but much more aspects. And it's just the experience that led us to stick to that solution.

0:44:31.930 --> 0:44:36.90  
Courtney Sanders  
Yep. OK. Next one is cell Carta.

0:44:38.90 --> 0:44:40.910  
Pat Green  
None of them have not have not worked with them.

0:44:42.270 --> 0:44:42.680  
Courtney Sanders  
OK.

0:44:44.110 --> 0:44:45.570  
Courtney Sanders  
Precision for medicine.

0:44:47.640 --> 0:44:55.50  
Pat Green  
Yes, again, I know them. And I also know what they're doing. We have been talking to them, but funny, we have not worked with them yet.

0:44:56.300 --> 0:44:57.770  
Courtney Sanders  
OK then.

0:44:59.650 --> 0:45:5.170  
Courtney Sanders  
Do you have any specific impression or either cell Carta or precision for medicine?

0:45:6.620 --> 0:45:19.630  
Pat Green  
No. Other than that I know what they're doing. And as I said, we have been talking to them. I I don't have any particular thoughts or or that's the reservations toward them. I think they're they're in in some of the nice areas, certainly like precision for medicine.

0:45:20.350 --> 0:45:23.570  
Pat Green  
Umm, it just hasn't occurred.

0:45:25.300 --> 0:45:42.730  
Courtney Sanders  
And I understand you're currently working with large provider LabCorp. I wonder what additional services spell agilytix or sell cartel would to offer for you to consider using their services.

0:45:45.200 --> 0:46:12.180  
Pat Green  
Well, you know, the whole the whole thing could trial operations aspect is quite complex as you as you very well know. And so I I mostly involved in the biomarker aspect and the bioethics around that. So there is multiple aspects that play a role in the final vendor selection, some of the things where I even not consulted consultation that I gave within the company is truly around to buy marker so.

0:46:12.840 --> 0:46:22.20  
Pat Green  
And it's difficult for me to say what aspects would make them more suitable. I think they are niche companies and therefore they are suitable and.

0:46:23.840 --> 0:46:47.920  
Pat Green  
Hasn't come up particularly for us to to work with them, but I don't. I don't see any particular aspects which they could reasonably improve. I mean they are of course not easily going to compete with the big ones like LabCorp or the other ones I just mentioned. And that's also not their intention. So now I think that would not be able to give you a particular direction there.

0:46:49.240 --> 0:47:1.30  
Courtney Sanders  
So if I understand correctly, within your company there are other departments together with yours. Make the decision of which CRO to also.

0:46:58.930 --> 0:47:1.680  
Pat Green  
Yes, yes, yes, yes.

0:47:2.380 --> 0:47:2.880  
Pat Green  
Definitely.

0:47:2.70 --> 0:47:4.540  
Courtney Sanders  
And what are those aspects that you consider?

0:47:6.720 --> 0:47:25.300  
Pat Green  
When is it just send said before. If you're looking at clinical trials and the the keying of the clinical trials and how biomarkers are being used, unless they're the biomarkers are the key biomarkers for diagnosis or endpoints, everything around it.

0:47:26.560 --> 0:47:38.280  
Pat Green  
Is is let's say 2 lower priority. The most priority goes to the overall clinical trial operations aspect, patient recruitment, patient monitoring.

0:47:40.790 --> 0:47:43.690  
Pat Green  
Shipment, et cetera, et cetera, so.

0:47:44.190 --> 0:47:51.980  
Pat Green  
And if biomarker do not play a huge role in that, we'll be also don't have a large influence on the final vendor selection.

0:47:53.520 --> 0:48:2.590  
Courtney Sanders  
So what are the specific I guess types of trials that my power ties for marker testing?

0:48:4.910 --> 0:48:20.890  
Pat Green  
Well, what? What? We see a lot. Of course in in the oncology spaces where both from a diagnostic perspective as well as drug development and monitoring that the there there is an increased utility of biomarkers and an increased importance.

0:48:21.680 --> 0:48:41.820  
Pat Green  
And where, of course, by Marcus also very, very defined play a huge role is in a number of rare diseases where it's either a genetic determinant or clear biomarker that is part of the diagnostic cascade there.

0:48:42.700 --> 0:48:51.380  
Pat Green  
There of course you will rely on specific zeros because the combination of the biomarkers and how you want to run your trial.

0:48:52.250 --> 0:49:10.740  
Pat Green  
And but running trials in the rare disease and often disease space is is very particular and therefore the the the final vendor selection will also rely a lot on their experiences in this space, because again, it's it's it's very particular on the biomarker itself there.

0:49:13.220 --> 0:49:30.870  
Pat Green  
May or may not play an important role in the final uh vendor selection, but again, overall, I would say in rare disease spaces and oncology that that's that's where we would be looking more closely at the overall package and the importance of biomarkers is more important.

0:49:32.970 --> 0:49:41.60  
Courtney Sanders  
But it's and then makes sense. Are there well known rare disease and CRO's?

0:49:44.100 --> 0:49:44.850  
Pat Green  
And.

0:49:47.150 --> 0:50:12.660  
Pat Green  
Well, again, it depends a little bit on which rare diseases you're looking at. We had we had with regard to our trials in a few but again here we also eventually ended up with the bigger ones who because of their existence and their long long term experience off also have experience in these in these rare diseases. So I would not immediately be able to mention you one.

0:50:13.730 --> 0:50:28.260  
Courtney Sanders  
Yeah, but understood. So it sounds like going to like CRO is really the broader clinical trial supports or logistics plays more important role when you select URL, is that a fair statement?

0:50:29.160 --> 0:50:58.950  
Pat Green  
That's a fair statement and that and that to some extent may be very company specific. I would think that depends again on on the, the, how the company is set it up and how the structure of the company works. I would think from small to mid size companies, certainly the smaller ones, what you've just sent is clearly the case. It will be very much clinical trial operations determined by markers depending on the disease may not play a huge role again.

0:50:59.10 --> 0:51:0.80  
Pat Green  
There are exceptions.

0:51:1.640 --> 0:51:10.720  
Pat Green  
But the overall clinical operations aspect play the most important role in the vendor selection. That's also my experience in in the company where I work now.

0:51:12.70 --> 0:51:24.320  
Courtney Sanders  
OK, gotcha. So let's say within LabCorp or smaller metaphase, what are the challenges or a many ads when you use their services?

0:51:26.20 --> 0:51:55.430  
Pat Green  
Well, whatever CRO you're choosing, you have Jenna bigger or smaller, or certainly the bigger ones have the downside of maybe lacking a little bit of flexibility. So if you're working with biomarker setup, which we have very much tailored to our needs, it may be more difficult to work with the bigger ones as compared to the smaller ones. That's logic. And that's also where when you're talking about by politics and the other ones that there might be a likelihood that.

0:51:55.590 --> 0:52:21.230  
Pat Green  
These are the companies who would be selecting in the future. So I think size has a clear advantage. Experience has a clear advantage. Sometimes it lacks and the flexibility and what we see it becomes much more difficult to get to a final set of that. We really prefer and it might take considerably longer to get to a desired outcome with the bigger ones as compared to the smaller ones.

0:52:23.660 --> 0:52:28.610  
Courtney Sanders  
So imagine in the future you might use some of those more smaller specialized CRO.

0:52:30.100 --> 0:52:36.430  
Courtney Sanders  
In that case, which one really jumps out that you might have for the discussions?

0:52:37.350 --> 0:52:38.370  
Courtney Sanders  
For outsourcing.

0:52:40.490 --> 0:53:1.930  
Pat Green  
I think precision for medicine is something we have been looking at for for a while, you know, with regard to what they do. And there is again one or two other companies which specifically operate in the nucleic acid sit based testing which have, you know, with regard to their sequencing workflows, specific set up for the clinical and just again escapes my.

0:53:2.800 --> 0:53:10.820  
Pat Green  
My memory, which one that is? But I think that that's one of the reasons why we might be talking more to precision medicine in the future. Precision for medicine.

0:53:11.850 --> 0:53:25.410  
Courtney Sanders  
Hmm. And for regarding the sequencing or new class that testing, is it because LabCorp cannot support that specific expertise or what are the reasons why you're considering those?

0:53:24.860 --> 0:53:28.170  
Pat Green  
Then in in principle they can on paper.

0:53:29.350 --> 0:53:56.490  
Pat Green  
But we have been speaking to a number of companies who, which is that their business model and with regard to the sequencing, not the technology, but the whole sequencing, the annotation and also the the data aspects. So a term that of course is very important these days is GDPR and specifically with sequencing that requires quite specific setup and that's the reason why we also been talking to other companies.

0:53:57.910 --> 0:54:10.100  
Courtney Sanders  
Got it. Awesome. Uh, well, I wanna. I know. We read up on time. So I wanna thank you for the the past and our discussion. It's been really helpful. I hope we can connect on future projects.

0:54:11.220 --> 0:54:18.800  
Pat Green  
You're very welcome, and likewise it always shop. It's my mind to based on the question. So thank you and I'm happy that I could provide some some help here.

0:54:20.320 --> 0:54:22.130  
Courtney Sanders  
Thank you and have a great day. Bye.

0:54:22.400 --> 0:54:23.420  
Pat Green  
You too. Bye bye.