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

0:0:0.0 --> 0:0:5.980  
Courney Sanders  
Would you mind sharing a little bit about your professional backgrounds and experience related to biomarker testing?

0:0:9.460 --> 0:0:14.10  
Jamie Garcia  
Sorry, could you repeat the question there? Was that message in the background?

0:0:13.70 --> 0:0:14.20  
Courney Sanders  
Oh, OK.

0:0:14.650 --> 0:0:25.550  
Courney Sanders  
Sounds good to start off the conversation, would you mind sharing a little bit about your professional backgrounds and experience related to biomarker testing?

0:0:27.220 --> 0:0:54.370  
Jamie Garcia  
Sure. So I'm a trained medical scientist, having majored in hematology. I've been working in diagnostic research laboratories in my initial career. Then for the last 2025 plus years have been working in either farmer or CRO industry in running clinical trials predominantly in the area of oncology.

0:0:55.540 --> 0:1:6.110  
Jamie Garcia  
And as you know, there's significant amount of testing that's undertaken in clinical trials, in particular in early phase clinical trials, which is what I focus on.

0:1:20.100 --> 0:1:21.120  
Jamie Garcia  
Yeah, sure.

0:1:10.160 --> 0:1:21.470  
Courney Sanders  
Would you mind also sharing a bit about what type of therapeutic modalities that you work with, for example? So in gene therapy or antibodies as was you know?

0:1:22.890 --> 0:1:53.460  
Jamie Garcia  
Yep. So we work across the the spectrum and my experience very much reflects the, I suppose that the transition development of therapeutics is against more specifically and oncology. So started with chemotherapy, then we've moved to targeted therapies, the likes of EGFR, etcetera, the EGFR. Then where of more recent times than working.

0:1:53.550 --> 0:1:59.160  
Jamie Garcia  
On monoclonal antibodies ADC cell therapy.

0:2:0.260 --> 0:2:7.210  
Jamie Garcia  
Cache therapy oncolytic viruses and and gene therapy as well.

0:2:7.840 --> 0:2:9.650  
Jamie Garcia  
So across the spectrum.

0:2:11.290 --> 0:2:13.500  
Courney Sanders  
Rates and regarding gene therapy it is.

0:2:14.620 --> 0:2:19.520  
Courney Sanders  
You know, with viral vectors or gene modified cell therapy, just want to clarify that.

0:2:20.310 --> 0:2:21.190  
Jamie Garcia  
Uh, both.

0:2:21.900 --> 0:2:24.530  
Courney Sanders  
OK. Perfect, great.

0:2:26.70 --> 0:2:32.810  
Courney Sanders  
And just overall waiting, all the clinical trials that have experience with Kinsley.

0:2:34.270 --> 0:2:38.720  
Courney Sanders  
What type of farmer could testing services do you have experience with?

0:2:39.850 --> 0:2:47.330  
Courney Sanders  
For example, in new monitoring that involved in flows autometric or proteomics, genomics, or histopathology.

0:2:48.490 --> 0:2:59.200  
Jamie Garcia  
Yeah. Again, experience in most so flow cytometry immunohistochemistry are still very.

0:2:59.380 --> 0:3:19.490  
Jamie Garcia  
Umm, important and significant and and I, I suppose also looking at and I'm not sure if this is of interest NGS testing, mutational testing with patient tumor samples and looking at.

0:3:19.590 --> 0:3:39.20  
Jamie Garcia  
Uh, so input trips in China and samples again pre and post therapy as as well as looking at other pharmacodynamic markers that that are predominantly in the peripheral blood.

0:3:46.260 --> 0:3:46.610  
Jamie Garcia  
Mm-hmm.

0:3:40.640 --> 0:3:54.830  
Courney Sanders  
Awesome, yes and yes. Is definitely one of the areas we would like to have a conversation with us as well. So thanks for bringing that up and maybe we can start with immune monitoring. The flow cytometry particularly, I wonder.

0:4:7.20 --> 0:4:7.420  
Jamie Garcia  
Uh.

0:3:55.200 --> 0:4:7.610  
Courney Sanders  
And the regarding, let's say the number of markers that you look at for flow cytometry, does that vary by modality that you mentioned or you have experience with?

0:4:8.490 --> 0:4:34.500  
Jamie Garcia  
Yeah. Yeah, it varies by modalities and also disease in particular, as we're looking at the hematological type malignancies and Thomas and left hernias sweet, we seem to have a lot more requirements for flow cytometry, larger panel. And when we're looking at minimal residual disease etcetera as well.

0:4:36.680 --> 0:4:47.810  
Jamie Garcia  
But again, when we're looking at some of these more immune driven and therapies, we we do include a a number of.

0:4:47.910 --> 0:4:50.960  
Jamie Garcia  
And flow cytometry panels.

0:4:53.570 --> 0:5:2.700  
Courney Sanders  
So what do you say for hematology or minimal residual diseases and it involves larger panels. What number are we looking at here?

0:5:4.200 --> 0:5:5.30  
Jamie Garcia  
Ohh that's.

0:5:5.360 --> 0:5:12.780  
Jamie Garcia  
And that's that's quite a difficult to give you specific numbers, but probably sort of 10 plus.

0:5:13.740 --> 0:5:13.980  
Courney Sanders  
OK.

0:5:14.780 --> 0:5:15.410  
Courney Sanders  
10 plus.

0:5:16.550 --> 0:5:24.520  
Courney Sanders  
And do you perform any sort of data analysis yourself or you know with a partner?

0:5:25.830 --> 0:5:44.840  
Jamie Garcia  
Umm, uh, we will have our Biostatistics and biometrics and medical team that would be undertaking those analysis, so I don't do those analysis specifically, but we we have experts that are able to analyze that.

0:5:46.280 --> 0:5:46.690  
Courney Sanders  
Right.

0:5:47.740 --> 0:6:1.750  
Courney Sanders  
And just looking forward into maybe three or five years from now, what potential technologies arising or emerging that you think might replace or complement the current flow cytometry?

0:6:4.510 --> 0:6:5.200  
Jamie Garcia  
Ohh that.

0:6:6.140 --> 0:6:6.950  
Jamie Garcia  
Uhm.

0:6:8.660 --> 0:6:18.490  
Jamie Garcia  
The difficult question with regards to flow cytometry, I can't really see any changes. I think that is just.

0:6:18.670 --> 0:6:23.400  
Jamie Garcia  
And I am a mainstay that that will continue when.

0:6:23.820 --> 0:6:43.810  
Jamie Garcia  
Uh, probably staying the same the the only other sort of technology is, you know, looking at circulating tumor cells. That's probably an additional add-on that can support, in particular, when we're looking at disease monitoring and minimal residual disease.

0:6:55.410 --> 0:6:55.800  
Jamie Garcia  
Mm-hmm.

0:6:45.570 --> 0:6:58.940  
Courney Sanders  
That makes sense. I guess one idea we've heard is potentially there's a need towards higher number of markers per panel, which my needs like spectral flow or sital.

0:7:2.900 --> 0:7:4.60  
Jamie Garcia  
Yeah, yeah.

0:7:0.500 --> 0:7:5.770  
Courney Sanders  
To assess that, do you think there's a need in oncology space there? Hmm.

0:7:6.80 --> 0:7:16.370  
Jamie Garcia  
Yeah, yeah. As you were therapies, you were targets are being developed. Yeah, I think that's that's actually a very good, a very good point and and quite relevant.

0:7:18.160 --> 0:7:30.830  
Courney Sanders  
And maybe just a brainstorming there a little bit more. Why did you say that? You know what type of specific therapy or a modalities that you think would benefit the most?

0:7:29.360 --> 0:7:30.950  
Jamie Garcia  
Yeah, I I.

0:7:31.730 --> 0:7:39.600  
Jamie Garcia  
Umm I I suppose when we're looking at, you know, these newer therapies such as ADC's in particular.

0:7:40.60 --> 0:8:9.390  
Jamie Garcia  
Umm, there's a group you know growing panels of those being made available. Also just sort of understanding newer targets but that are coming through that impact on the immune reaction or the tumor environment. I expect that, yeah, these these men were targets that are, you know, still potentially in the research area may become a more clinical significant.

0:8:10.980 --> 0:8:11.430  
Courney Sanders  
Mm-hmm.

0:8:11.500 --> 0:8:15.760  
Courney Sanders  
So if I understand correctly, it's more useful Preclinical Research.

0:8:16.270 --> 0:8:27.840  
Courney Sanders  
And how about for, let's say clinical development, do you see an immediate use of such technology to assist clinical stage bound marker testing?

0:8:28.850 --> 0:8:42.860  
Jamie Garcia  
Yeah, yeah, I I do. And I suppose that the stage more in the early phase, oncology these sorts of testing and panels etcetera and just sort of undertaking the phase one phase two.

0:8:43.420 --> 0:8:52.430  
Jamie Garcia  
I'm looking also at the the pharmacodynamics you know, making sure that the right level.

0:8:52.950 --> 0:9:6.160  
Jamie Garcia  
Uh, it's therapy is is reached and and targeting those those cells, so. So yeah, probably more in the earlier phase clinical trial. So I think phase one and up to phase two.

0:9:7.530 --> 0:9:12.230  
Courney Sanders  
So early phases and your modalities that makes sense.

0:9:12.300 --> 0:9:12.670  
Jamie Garcia  
Umm.

0:9:13.400 --> 0:9:18.760  
Courney Sanders  
And how do you compare the spectral flow cytometry versus cycle?

0:9:21.610 --> 0:9:27.700  
Jamie Garcia  
I this is sital. I'm not familiar with first site talk.

0:9:29.780 --> 0:9:30.930  
Courney Sanders  
At the site off.

0:9:32.850 --> 0:9:33.940  
Courney Sanders  
Actually that.

0:9:34.760 --> 0:9:40.210  
Courney Sanders  
I mean, but if I guess if you have a general comment on spectral flow that hometree, that'll be fine as well.

0:9:41.90 --> 0:9:47.0  
Jamie Garcia  
Yeah. Yeah. So umm, I I suppose we're looking at sort of general flow cytometry, a lot of our.

0:9:47.120 --> 0:10:0.700  
Jamie Garcia  
I'm current labs, academic centres etcetera, have those capabilities. They're pretty much standard of as care. And I I don't think we need to convince.

0:10:1.70 --> 0:10:15.870  
Jamie Garcia  
Umm uh, researchers and physicians on the importance of a flow cytometry and we can, I suppose, help track patients and disease.

0:10:16.550 --> 0:10:19.250  
Jamie Garcia  
As as well as the fictive therapies.

0:10:20.470 --> 0:10:28.340  
Courney Sanders  
Yep, OK. Sounds good. And so calling back to them NGS that you mentioned.

0:10:28.920 --> 0:10:29.210  
Jamie Garcia  
Umm.

0:10:29.110 --> 0:10:36.10  
Courney Sanders  
I'm I guess, what for what specific purpose are you using the NGS or other?

0:10:35.960 --> 0:10:36.260  
Jamie Garcia  
Yeah.

0:10:36.710 --> 0:10:41.0  
Courney Sanders  
Genomic testing like PCR for the clinical stages.

0:10:41.930 --> 0:10:48.920  
Jamie Garcia  
Yeah. Yeah. So this is becoming increasingly more popular.

0:10:50.30 --> 0:11:21.400  
Jamie Garcia  
It needs to be something that wasn't undertaken as standard of care, but we're seeing large government initiatives to support the uptake of NGS testing and I believe this is really based on tailored and personalized medicine. So if we're able to undertake, you know, a detailed ingest testing panel.

0:11:21.690 --> 0:11:31.40  
Jamie Garcia  
Of patients tumour tissue for, for example, and determine the specific mutations. We can then obviously.

0:11:32.470 --> 0:11:52.660  
Jamie Garcia  
Uh, prescribe the the most appropriate and tailored therapy. These therapies are so expensive, you know, for example, when we're looking and thinking about immunotherapies and other antibody therapies, which can be thousands and thousands of dollars per cycle.

0:11:53.220 --> 0:12:3.690  
Jamie Garcia  
And if if we can prescribe the right therapy that's tailored, we can also say governments money when it comes to reimbursement to therapies.

0:12:4.990 --> 0:12:15.0  
Jamie Garcia  
So I I see this continuing to grow even with regards to the number of clinical trials that we are running.

0:12:15.400 --> 0:12:31.670  
Jamie Garcia  
Uh. A large number of them require specific mutations and that perhaps aren't necessarily standard of care. So there are a large number of mutations. You know, when you look at Melanoma, lung cancer, breath, wrath, EGFR.

0:12:32.250 --> 0:12:34.420  
Jamie Garcia  
And this standard of care.

0:12:35.460 --> 0:12:36.920  
Jamie Garcia  
And uh, it helps.

0:12:37.690 --> 0:12:51.540  
Jamie Garcia  
Plan their treatment pathways to which therapy modality is being used as newer target should being identified, and newer therapies that target those we we're really seeing that in that.

0:12:51.740 --> 0:13:1.190  
Jamie Garcia  
I, you know, clinical development stage that we are needing to undertake this thingy testing, there's there's obviously.

0:13:1.280 --> 0:13:2.860  
Jamie Garcia  
And that's the thing.

0:13:3.340 --> 0:13:9.40  
Jamie Garcia  
Uh testing panels that are FDA approved.

0:13:10.190 --> 0:13:21.40  
Jamie Garcia  
Like the foundation one. So so that I I just really almost see as being part of a companion diagnostic.

0:13:24.780 --> 0:13:46.590  
Courney Sanders  
So it sounds like you're gonna use that to, let's say, exclude as part of basically patient eligibility criteria before rolling in rolling to the trials. So make sure and the ones I receiving those complex modality are like I guess accurate or properly assessed.

0:13:48.0 --> 0:13:49.150  
Courney Sanders  
Mm-hmm. And.

0:13:46.50 --> 0:14:3.150  
Jamie Garcia  
Absolutely. Yeah. Yeah. Obviously, if that patient doesn't have that mutation and that drug ohh mode treatment modality works directly on that mutation it there's no point giving that patient the the therapy.

0:14:4.200 --> 0:14:17.380  
Courney Sanders  
Right, right. And do you see uh and just being used for just general assessments of either safety or efficacy of therapy after treatment?

0:14:17.70 --> 0:14:17.490  
Jamie Garcia  
Yeah.

0:14:18.600 --> 0:14:19.270  
Jamie Garcia  
And.

0:14:20.20 --> 0:14:24.810  
Jamie Garcia  
No, I don't see that as an efficacy.

0:14:25.580 --> 0:14:32.600  
Jamie Garcia  
Umm I as as an efficacy measurement, but we do know that with NGS testing.

0:14:33.130 --> 0:14:46.670  
Jamie Garcia  
A patients tumour and mutation can change during the course of their treatment modalities so their their treatment path so they may have certain mutations.

0:14:47.930 --> 0:15:16.840  
Jamie Garcia  
Pride treatment. They receive certain treatment and that mutation may change, so we could also be appropriate to consider retesting after certain lines of therapy to to see if the the patient has either developed new or I should say the cancers have developed new mutations or changed their mutations. So yeah, where we're seeing a large group of evidence.

0:15:16.950 --> 0:15:18.610  
Jamie Garcia  
That that, in fact, is the cake.

0:15:19.440 --> 0:15:24.470  
Courney Sanders  
Mm-hmm. And would those be the targeted sequencing or more like whole genome sequencing?

0:15:25.460 --> 0:15:28.630  
Jamie Garcia  
Uh, probably more along the lines of whole genome sequencing.

0:15:29.510 --> 0:15:29.730  
Courney Sanders  
OK.

0:15:30.720 --> 0:15:34.180  
Courney Sanders  
OK, that sounds good. Umm and within genomics?

0:15:35.240 --> 0:15:43.460  
Courney Sanders  
Are there any specific technology that you think are merging? Some examples that we've heard are like spatial genomics or transcriptomics.

0:15:45.430 --> 0:15:56.400  
Jamie Garcia  
Not that that I have have heard of, but probably more laboratory base than than my than my role in the clinical side.

0:16:3.330 --> 0:16:3.670  
Jamie Garcia  
Umm.

0:15:57.150 --> 0:16:12.700  
Courney Sanders  
Yeah, OK. Sounds good. I'm moving towards histopathology like, I mean, fluorescent test or immunohistochemistry, are there particular use cases that should think that you use more frequently than others?

0:16:15.10 --> 0:16:43.770  
Jamie Garcia  
Look, I I I think our if you know histochemistry is still main mainstay it's it's been around for for a long time. But there's a number of you know FDA approved and testing programs and platforms and and and I still see that as continuing and and staying as you know many companion diagnostics.

0:16:45.470 --> 0:16:54.560  
Courney Sanders  
OK. Are there any major trends that might impact such testing such as digital pathology or AI assistant analysis?

0:16:55.330 --> 0:16:57.810  
Jamie Garcia  
Yeah, I I, I, I see a lot of.

0:16:58.70 --> 0:16:58.850  
Jamie Garcia  
Umm.

0:17:0.40 --> 0:17:7.450  
Jamie Garcia  
Shift to AI and and I I I feel that that will definitely become more.

0:17:7.900 --> 0:17:17.870  
Jamie Garcia  
Uh. More useful lized and as as we, you know, get more experience with this and and collect additional data.

0:17:19.850 --> 0:17:20.420  
Courney Sanders  
Got it.

0:17:22.280 --> 0:17:29.440  
Courney Sanders  
And do you see a more used in clinical trials actually or again potentially more preclinical stages?

0:17:31.0 --> 0:17:36.390  
Jamie Garcia  
I think in the clinical trials, but also with some of these.

0:17:36.510 --> 0:17:58.400  
Jamie Garcia  
I'm, you know, testing programs also used in the clinical setting. So when submitting an application, for example to the FDA for a therapy that is targeted, having a companion diagnostic to.

0:17:58.520 --> 0:18:8.550  
Jamie Garcia  
And to to confirm the appropriateness of the therapies so, so it can also be an area that's used in the clinic.

0:18:10.760 --> 0:18:11.50  
Courney Sanders  
OK.

0:18:10.150 --> 0:18:40.40  
Jamie Garcia  
You know, I I suppose I had perfect example is without immunotherapies, our P ones, PDL ones, the for a patient is prescribed those therapies which are extremely expensive and we have the companion diagnostic of that PDL 1 testing and the the two must go hand in hand if the patient doesn't have the appropriate level of positivity for that PDL one, they don't qualify to receive that.

0:18:40.130 --> 0:18:40.600  
Jamie Garcia  
Therapy.

0:18:42.410 --> 0:18:57.740  
Courney Sanders  
And for an ideal, I guess companion diagnostic tests, for example period one, I think of using a PCR by like molecular based or proteomics based or pathology based test to go along with it.

0:18:58.890 --> 0:19:4.330  
Jamie Garcia  
Yeah, yeah, I am, I suppose as.

0:19:4.790 --> 0:19:32.280  
Jamie Garcia  
Umm, you know, these therapies are are more widely used. You know, looking at the more pathology based testing and is is definitely the the the way to go you know having these companion diagnostic hits that assay is can be established within local laboratory. I think he's he's key.

0:19:33.370 --> 0:19:34.620  
Courney Sanders  
And why is that?

0:19:35.640 --> 0:19:52.750  
Jamie Garcia  
Just umm the usage is so widespread that you know, again looking at that PDL, one there, PDL 1 therapies, stands of caring melanomas, lung cancer, head and neck, colorectal.

0:19:54.10 --> 0:19:55.280  
Jamie Garcia  
HCC.

0:19:57.0 --> 0:20:13.140  
Jamie Garcia  
So many patients have access and and need to to be tested. So I think having a a testing kit that's that's easily to set up that potentially may not require.

0:20:13.650 --> 0:20:15.360  
Jamie Garcia  
And uh.

0:20:16.670 --> 0:20:17.760  
Jamie Garcia  
Challenging.

0:20:17.880 --> 0:20:23.460  
Jamie Garcia  
And modalities, EVE is the, you know, that's the way she goes.

0:20:25.660 --> 0:20:43.440  
Courney Sanders  
OK, so if I understand correctly, it will be take a biopsy from the patients and then you have a kid that can easily do single targets for example, this one PDL 1 staining on the sample to quickly assess if the patients have the mutation or not is that.

0:20:44.130 --> 0:20:45.480  
Courney Sanders  
Idea OK.

0:20:44.20 --> 0:20:45.680  
Jamie Garcia  
Yeah, that's right. Yeah.

0:20:46.390 --> 0:20:53.760  
Courney Sanders  
Sounds good. Lastly, do you perform any amino acids or mass spectrometry on?

0:20:55.160 --> 0:20:57.690  
Courney Sanders  
Like relative ball marker testing clinical trials.

0:20:59.370 --> 0:21:3.500  
Jamie Garcia  
Uh, could, uh, sorry, could you repeat that? It's glitched.

0:21:3.80 --> 0:21:14.960  
Courney Sanders  
Yes, uh, yes. So do you perform any of the mass spectrometry or immunoassays for biomarker testing during clinical trials?

0:21:15.880 --> 0:21:17.160  
Jamie Garcia  
Yes, we do.

0:21:18.780 --> 0:21:23.200  
Jamie Garcia  
And uh, it again. More in the early phase clinical trial.

0:21:24.590 --> 0:21:31.270  
Jamie Garcia  
Umm, where? Where? You know, looking at proof of concept wanting to understand.

0:21:31.860 --> 0:21:32.520  
Jamie Garcia  
And.

0:21:34.150 --> 0:21:47.110  
Jamie Garcia  
The antibody levels, etcetera or detection of antiviral antibodies etcetera, again dependent on the type of therapies. So yes, they're they're all.

0:21:47.250 --> 0:21:50.370  
Jamie Garcia  
Umm, you know, pharmacodynamic.

0:21:50.920 --> 0:21:51.620  
Jamie Garcia  
Uh.

0:21:52.720 --> 0:22:6.280  
Jamie Garcia  
Assessments and often sort of part of a study, secondary objectives, for example, so they they are key to supporting the Russian male of the study.

0:22:8.190 --> 0:22:21.880  
Courney Sanders  
Right. So are there a specific type of immunoassays that you prefer such as olink MSD or some other source of immuno assays that you use?

0:22:26.970 --> 0:22:27.280  
Courney Sanders  
OK.

0:22:22.770 --> 0:22:29.660  
Jamie Garcia  
Uh, I I can. That's probably a bit too technical and I'm more clinically focused on, sorry.

0:22:29.870 --> 0:22:43.800  
Courney Sanders  
Yep, understood. Uh, great. So, you know, among all about marker testing that you use, how often do you perform multiple biomarker analysis on the same sample?

0:22:45.260 --> 0:22:45.770  
Jamie Garcia  
Uh.

0:22:44.850 --> 0:22:47.760  
Courney Sanders  
And my very by stage of developmental modality.

0:22:48.840 --> 0:22:57.10  
Jamie Garcia  
Yeah. And again, quite common to utilize more than one bio marker.

0:22:59.540 --> 0:23:1.770  
Jamie Garcia  
Obviously in the preclinical Phase II.

0:23:1.870 --> 0:23:15.530  
Jamie Garcia  
Umm, uh, I think the the the number in amount is the, you know, potentially greater but once we move into the clinic again in that early phase setting, looking at a couple of biomarkers is.

0:23:16.250 --> 0:23:18.860  
Jamie Garcia  
Is quite standard.

0:23:20.330 --> 0:23:33.630  
Jamie Garcia  
And you know what we find in clinical trials is that samples are collected from patients and patients are advised that they are stored for future analysis. So.

0:23:34.70 --> 0:23:45.400  
Jamie Garcia  
And as as more and more information becomes available, we we're seeing that our sponsors are also sort of undertaking more detailed and additional biomarker.

0:23:46.880 --> 0:23:48.80  
Jamie Garcia  
Assessment.

0:23:51.130 --> 0:23:51.830  
Courney Sanders  
Got it.

0:23:53.140 --> 0:23:58.410  
Courney Sanders  
And I'm all these tests we talked about. What percentage of those?

0:23:59.320 --> 0:24:3.520  
Courney Sanders  
Programmable test the outsource versus conducting those in house.

0:24:5.320 --> 0:24:9.20  
Jamie Garcia  
Yeah, I'd probably say about 80% are outsourced.

0:24:9.750 --> 0:24:10.260  
Courney Sanders  
Mm-hmm.

0:24:10.930 --> 0:24:17.800  
Courney Sanders  
Are there specific type of test you prefer, outsource versus in house?

0:24:19.170 --> 0:24:33.420  
Jamie Garcia  
No, I uh, I'm currently working as as within a as CRO, so I think it's really dependent on the biotech company and what their capabilities are so.

0:24:34.440 --> 0:24:41.830  
Jamie Garcia  
We sort of see small to mid size biotech companies often just don't have that laboratory capability.

0:24:42.350 --> 0:24:47.880  
Jamie Garcia  
And and looking at laboratories to to support.

0:24:49.290 --> 0:24:49.680  
Courney Sanders  
Mm-hmm.

0:24:50.50 --> 0:24:51.870  
Jamie Garcia  
That the the essays.

0:24:54.0 --> 0:24:56.370  
Courney Sanders  
So that Yep, the the the film makes sense.

0:24:56.870 --> 0:25:11.240  
Courney Sanders  
Umm. And I guess when you you potential sponsor reach out to your organization. What type of factors typically they consider when they select a URL?

0:25:13.0 --> 0:25:19.250  
Jamie Garcia  
So when selecting a CRO obviously capability this first and foremost.

0:25:21.550 --> 0:25:37.580  
Jamie Garcia  
You know, uh can can siaro undertake all tasks that are required based on the scope of services needed. Cost I believe is very important as well and.

0:25:37.850 --> 0:25:50.640  
Jamie Garcia  
And reputation as well and past experience. You know, if the CRO's worked on similar compound similar therapies that plays a big factor in.

0:25:51.740 --> 0:25:54.0  
Jamie Garcia  
In giving them additional confidence.

0:25:54.840 --> 0:26:7.380  
Jamie Garcia  
And also yeah, local reputation is is key. Often sponsoring companies will speak to investigators that.

0:26:8.10 --> 0:26:12.680  
Jamie Garcia  
Uh, you know, to to learn more about CRO capabilities.

0:26:14.550 --> 0:26:28.850  
Courney Sanders  
Yeah. Interesting. When you bring up the local reputation, and since you're based in Australia, I wonder, you know, how do pharma company typically choose CRO's within APAC region?

0:26:30.520 --> 0:26:50.430  
Jamie Garcia  
Yeah. I I think although all all the comments that I made before is is very important. I I think when we're talking about APAC and in particular Asia or we're focusing on some of our Asian regions.

0:26:51.330 --> 0:27:11.890  
Jamie Garcia  
Having a strong local presence is very important. There's significant cultural differences, say between Australia and New Zealand, and our Asian neighbors. So having local teams with that local expertise and understanding those local.

0:27:12.950 --> 0:27:15.780  
Jamie Garcia  
Oftens traditions and.

0:27:16.710 --> 0:27:31.480  
Jamie Garcia  
Uh is is very important, especially when it comes to engagement of investigators and key opinion leaders that obviously our sponsors want to support the study so. So that is very important also having.

0:27:31.600 --> 0:27:46.890  
Jamie Garcia  
And a strong regulatory expertise in each specific countries key when we're looking at having studies approved by the various regulatory authorities across the APAC region.

0:27:48.280 --> 0:27:48.940  
Courney Sanders  
Hmm.

0:27:49.200 --> 0:28:0.970  
Courney Sanders  
So I wonder among you know, all the Asia Pacific areas, what are the you know, the common geographies that formal about tech typically conduct clinical trial too?

0:28:1.920 --> 0:28:17.660  
Jamie Garcia  
Yeah. And I tend to tear our countries across Asia pack. And so when I'm talking about tier one countries and regions, these are countries and regions that have.

0:28:18.50 --> 0:28:18.800  
Jamie Garcia  
And.

0:28:20.830 --> 0:28:48.980  
Jamie Garcia  
An excellent reputation for conducting high quality research have access to patients, have well established clinical research units and groups and infrastructure to support complex clinical trials. So these phase one, sorry, these tier one regions, I would classify Australia, New Zealand, South Korea, Taiwan, Hong Kong and Singapore.

0:28:49.780 --> 0:29:1.400  
Jamie Garcia  
And and then T2 again, countries that have the expertise but perhaps aren't as well experienced.

0:29:1.800 --> 0:29:13.180  
Jamie Garcia  
Umm and perhaps don't have that higher level of reputation. You know, I'd include Malaysia, Thailand, Philippines.

0:29:13.820 --> 0:29:26.60  
Jamie Garcia  
I'm always include India there, but they're regions and countries that that are developing and very much coming.

0:29:26.460 --> 0:29:39.570  
Jamie Garcia  
Umm into, you know, higher levels of experience and and getting better reputations. We also find these tier two countries also have lower.

0:29:40.300 --> 0:29:48.560  
Jamie Garcia  
Umm. Reimbursement or availability of your therapies, so some pharmaceutical or biotech companies?

0:29:49.420 --> 0:30:11.970  
Jamie Garcia  
Don't prefer to work in those regions just because when it if they're potentially looking at commercialization, then maybe less commercial benefit, but also investigators may have less experience in working with newer therapies and understanding toxicities etcetera these new therapies.

0:30:12.880 --> 0:30:23.590  
Courney Sanders  
Yep, that makes sense. Um, I just I I guess I've one full question on where do you put Japan, China, on your tearing systems?

0:30:25.430 --> 0:30:34.40  
Jamie Garcia  
Uh, sorry. Where do I with China? Where would I place China? I I I think it was at the question where I would place China and yeah.

0:30:35.680 --> 0:30:36.330  
Jamie Garcia  
OK.

0:30:37.410 --> 0:30:37.730  
Jamie Garcia  
Yeah.

0:30:32.440 --> 0:30:39.880  
Courney Sanders  
Yeah, China and Japan, since I think these are the two countries that we we typically here but haven't heard from your.

0:30:38.760 --> 0:30:48.520  
Jamie Garcia  
Yeah, yeah, yeah. They're so, so Chinas, a huge region and.

0:30:50.40 --> 0:30:56.450  
Jamie Garcia  
Again, because of the population we have, you know, availability of large patient pools.

0:30:58.780 --> 0:31:1.650  
Jamie Garcia  
We we see a lot of sponsors, not.

0:31:3.150 --> 0:31:5.700  
Jamie Garcia  
Wanting to consider China.

0:31:6.380 --> 0:31:21.190  
Jamie Garcia  
I'm purely based on the perceived challenges of the regulatory requirements. So so China is different to to most of our other APAC countries in that.

0:31:21.420 --> 0:31:26.960  
Jamie Garcia  
Umm for for example, if you would run a phase one study X China.

0:31:27.780 --> 0:31:58.500  
Jamie Garcia  
In most of our other countries, the regulatory authorities will accept that data and accept a a later phase study to to be run, whereas in China will need to include specific phase one data for Chinese patients. Also in China you are not able to export patient samples. So if you have a central laboratory X China patient samples.

0:31:58.560 --> 0:31:59.560  
Jamie Garcia  
Can't be shipped.

0:32:0.410 --> 0:32:30.380  
Jamie Garcia  
So that then means, from a logistical perspective, you would need to have two central laboratories established and accredited, one to test China population and 1X China. And also just the regulatory startup requirements to initiate a study significantly more complex and more time consuming and cost so depending.

0:32:30.470 --> 0:32:40.90  
Jamie Garcia  
On what if it's a sponsor strategy is it may not be appropriate to consider China. So, so we find.

0:32:50.860 --> 0:32:51.190  
Courney Sanders  
Umm.

0:32:40.970 --> 0:33:3.400  
Jamie Garcia  
Probably only about 20% of our on the, you know, want to consider China, especially in that earlier phase clinical development if it is part of their strategy, then China will be bought in usually a little bit looser. Japan is also sort of similar to China, it has quite.

0:33:5.260 --> 0:33:5.840  
Jamie Garcia  
Unique.

0:33:6.500 --> 0:33:23.820  
Jamie Garcia  
I've requirements, regulatory requirements, data requirements and just the cost of running trials in China are in Japan are probably, you know, five times the cost of running trials in other regions.

0:33:24.530 --> 0:33:26.880  
Jamie Garcia  
So again.

0:33:27.130 --> 0:33:29.810  
Jamie Garcia  
Umm, we we often see.

0:33:29.890 --> 0:33:30.480  
Jamie Garcia  
Umm.

0:33:31.720 --> 0:33:55.80  
Jamie Garcia  
Study sponsors just not open to including the likes of Japan or China until they get to that later development and they they feel that they're in a position to perhaps consider later stage development and from a commercialization point, it's worth their while to invest in trials in those two countries.

0:34:4.830 --> 0:34:5.60  
Jamie Garcia  
Yeah.

0:34:13.270 --> 0:34:13.550  
Jamie Garcia  
Mm-hmm.

0:33:56.760 --> 0:34:14.70  
Courney Sanders  
Yep, thanks for very detailed explanation there. I just wanna full of question on your tier one countries. I guess if I were a sponsor and I only have limited budgets on conducting clinical trial in one country, where would you recommend?

0:34:15.670 --> 0:34:29.250  
Jamie Garcia  
Umm, I would probably recommend Australia and the reason I say that is that the Australian government has a very generous RND research rebate.

0:34:30.60 --> 0:34:46.110  
Jamie Garcia  
So umm, if the company qualifies and it's dependent on the amount of revenue they make per year. But again assuming a sponsor is a startup company with limited or no income.

0:34:46.700 --> 0:35:1.210  
Jamie Garcia  
And then the government research rebate is I I think around 43%. So for every dollar that is spent in Australia in clinical research.

0:35:2.620 --> 0:35:24.320  
Jamie Garcia  
43% of that can be given back as a rebate to a sponsor. The sponsor doesn't need to be in Australian sponsor, they just need to have a local entity and there are a number of companies that work with sponsor companies to establish these entities. I I think the cost is.

0:35:24.750 --> 0:35:42.850  
Jamie Garcia  
Yeah, it's it's not a significant cost and it virtually as long as you have an address, a local address and that's a virtue that can be a virtual address. That company can then followed by for the rebate for every dollar that's spent in Australia, so that.

0:35:43.360 --> 0:35:48.890  
Jamie Garcia  
And the the money that is spent in Australia can include.

0:35:50.430 --> 0:35:55.640  
Jamie Garcia  
And is CRO costs investigator grants and?

0:35:56.480 --> 0:36:25.310  
Jamie Garcia  
Uh, any vendors, any laboratory work that's done in Australia. So it can really be a significant and cost saving for companies. And you know we find in where where I work that a number, a large proportion of smaller biotech companies come to Australia for that reason. Other key reasons is just the reputation.

0:36:25.730 --> 0:36:55.360  
Jamie Garcia  
Like quality research and high quality of investigators and key opinion leaders and yeah, very much a proven track record in recruiting well, especially in these earlier phase studies, Australia also has probably one of the fastest and most efficient startup timelines to conduct a trial. So our regulatory authority.

0:36:56.200 --> 0:37:25.550  
Jamie Garcia  
And is isn't a highly involved in approving clinical trials. Most of the responsibilities placed on ethics committees that will review and approve study protocols, and that process of obtaining Ethics Committee and regulatory approval can range on average from 8 to 12 weeks. Whereas if you're looking at, you know, comparing that to the US.

0:37:36.100 --> 0:37:36.420  
Courney Sanders  
Umm.

0:37:37.950 --> 0:37:38.390  
Courney Sanders  
Got it.

0:37:26.80 --> 0:37:46.140  
Jamie Garcia  
Ohh other Asia Pacific countries and regions where sort of looking at you know an average of five to six months start up timeline and so so there the the main factors and cost obviously investigative grant costs can be.

0:37:46.270 --> 0:37:52.550  
Jamie Garcia  
And Ohh can be higher compared to say other Asian countries.

0:37:54.40 --> 0:38:3.110  
Jamie Garcia  
But uh, it again with that uh R&D rebate that the government provides that yeah, really traded off.

0:38:4.410 --> 0:38:23.660  
Courney Sanders  
Yeah, that makes sense. And thank you again for very detailed explanation in the APAC region and why selecting certain places I want to circle back to when you say you outsource 80% of file marker testing, I wonder which cryos do typically outsource those tests too and why?

0:38:25.410 --> 0:38:27.200  
Jamie Garcia  
Umm I.

0:38:38.480 --> 0:38:38.710  
Courney Sanders  
Yeah.

0:38:28.280 --> 0:38:51.860  
Jamie Garcia  
It's it's very hard. My my company, which is that I work with as a CRO, has its own specialist combinatory. So a lot of the work is, is obviously given to to our company as as part of full service program. But accasionally we we do look at other.

0:38:52.360 --> 0:39:18.910  
Jamie Garcia  
Umm, other laboratories to to outsource and that really is based on capabilities. Do they have the capabilities to conduct those specific assays or the ability to develop the essay and have that available and also location where the patients, where are the samples coming from?

0:39:19.980 --> 0:39:35.740  
Jamie Garcia  
It's extremely expensive to ship a lot of these samples that need to be maintained at specific temperatures, refrigerated or frozen. So sample logistics is the key consideration.

0:39:37.140 --> 0:39:38.280  
Courney Sanders  
Yep, that makes sense.

0:39:38.620 --> 0:39:39.890  
Courney Sanders  
And sorry.

0:39:38.0 --> 0:39:43.90  
Jamie Garcia  
So yeah, so looking at labs that have locations?

0:39:43.750 --> 0:40:9.760  
Jamie Garcia  
You know, across the world, if we're looking at a global study, I think is is really important. It is important in making a decision or for example, if we're just looking at an Australia only study would be looking at probably more likely locals specialist laboratories in Australia. Again there's that R&D rebate quicker turn around times because there's less transit time and.

0:40:10.690 --> 0:40:14.250  
Jamie Garcia  
Uh, you know more cost effective from the logistics?

0:40:23.450 --> 0:40:23.730  
Jamie Garcia  
Umm.

0:40:16.210 --> 0:40:39.750  
Courney Sanders  
And within your own full service kind of lab or just waiting those scope within their scope. If you look in the future three or five years online, where do you think you will expand the service? Is that you know analytics or sample logistics as as you mentioned before or anything else?

0:40:40.880 --> 0:40:46.360  
Jamie Garcia  
I I think it really is with the testing capabilities as we're getting.

0:40:48.230 --> 0:41:0.360  
Jamie Garcia  
More and more requests for biomarker analysis I I think that is probably the the way we will go.

0:41:2.70 --> 0:41:13.750  
Jamie Garcia  
The the NGS testing I I think is something that is becoming more and more requested. So I see that as being a a large growth.

0:41:14.810 --> 0:41:15.210  
Courney Sanders  
Umm.

0:41:14.700 --> 0:41:15.300  
Jamie Garcia  
Umm.

0:41:16.200 --> 0:41:22.630  
Jamie Garcia  
Yeah, not too sure about the AI that that definitely is an area that's that's growing, but.

0:41:22.960 --> 0:41:27.360  
Jamie Garcia  
Umm. Yeah, not sure from from a laboratory perspective.

0:41:28.640 --> 0:41:29.570  
Courney Sanders  
Got it, got it.

0:41:31.600 --> 0:41:35.370  
Courney Sanders  
Great. And the way outsourced to other vendors?

0:41:36.820 --> 0:41:44.310  
Courney Sanders  
Are there specific vendors that you are outsourced to or you know you consider as top or best in class type of vendors?

0:41:45.140 --> 0:41:47.800  
Jamie Garcia  
Yeah. So as a as a CRO.

0:41:48.920 --> 0:42:6.420  
Jamie Garcia  
We can only go to vendors that that we have been, that have vendor assured which means our QA department has gone and ordered those. So we do have a handful of of those laboratories and.

0:42:7.860 --> 0:42:12.110  
Jamie Garcia  
Uh laboratories that you know that we commonly use.

0:42:14.0 --> 0:42:16.490  
Jamie Garcia  
Three uh 360 biolabs.

0:42:18.280 --> 0:42:19.610  
Jamie Garcia  
I which.

0:42:22.130 --> 0:42:22.500  
Jamie Garcia  
We.

0:42:23.160 --> 0:42:27.680  
Jamie Garcia  
Yeah, we we use quite often they're vendor assured.

0:42:28.550 --> 0:42:28.920  
Courney Sanders  
Umm.

0:42:28.350 --> 0:42:29.20  
Jamie Garcia  
And.

0:42:30.790 --> 0:42:32.510  
Jamie Garcia  
Bio agilytix.

0:42:36.310 --> 0:42:39.840  
Jamie Garcia  
They have capabilities global.

0:42:42.630 --> 0:42:52.860  
Jamie Garcia  
So we we only really have and admitted number of laboratories that we would, yeah recommend again based on our.

0:42:53.20 --> 0:42:56.60  
Jamie Garcia  
I'm on the fact that they need to be vendor assured.

0:43:11.890 --> 0:43:12.220  
Jamie Garcia  
Umm.

0:42:56.950 --> 0:43:17.260  
Courney Sanders  
Yep, Yep, got it. So I wonder for the 360 bio labs and bio agilytix, would you mind sharing you know why I guess other than vendor assurance, what specific, let's say capability or any other advantages make your organization prefer outsourcing to them?

0:43:18.200 --> 0:43:26.600  
Jamie Garcia  
Yeah, I'm I think cost competitiveness is important. And again, we have a that.

0:43:27.130 --> 0:43:43.10  
Jamie Garcia  
And the R&D rebate in Australia is important to many sponsors, so they obviously have local labs capabilities in Australia. They also have the ability to establish and validate new essays.

0:43:43.670 --> 0:43:44.480  
Jamie Garcia  
And.

0:43:45.790 --> 0:43:56.960  
Jamie Garcia  
They they really, you know, have best in class bioanalytical capabilities. So and they have a very good.

0:43:57.670 --> 0:44:1.620  
Jamie Garcia  
Reputation, the global and cost.

0:44:2.410 --> 0:44:11.370  
Jamie Garcia  
And yeah, they're they're capabilities. If they don't have an essay, they can even establish those essays.

0:44:12.70 --> 0:44:25.540  
Jamie Garcia  
But, umm, you know, yeah, they they can very much do end to end from PK PD to immunogenicity biomarkers and you know cell based assays as well.

0:44:27.510 --> 0:44:28.220  
Courney Sanders  
Got it.

0:44:28.860 --> 0:44:29.290  
Courney Sanders  
I'm.

0:44:28.300 --> 0:44:31.560  
Jamie Garcia  
So I yeah. So I think when yeah sponsor.

0:44:31.930 --> 0:44:44.310  
Jamie Garcia  
Umm yeah, look at those key factors and and sometimes sponsors have their own labs that they've been working with and you know we won't have that choice.

0:44:46.110 --> 0:44:48.40  
Jamie Garcia  
Of recommending a a laboratory.

0:44:49.200 --> 0:44:56.890  
Courney Sanders  
Yeah, that was actually going to be my full question, like in what situation would you recommend a lab outside of your organization?

0:44:58.550 --> 0:44:59.110  
Jamie Garcia  
Umm.

0:45:0.200 --> 0:45:30.510  
Jamie Garcia  
Yeah, it it again outside our own organization. If our laboratory doesn't have the capability and unable to establish, then obviously we would look outside our organization or it's or at times it really is the sponsor may want to manage the lab and identify the lab or they have a lab that they've used. So, so that's probably the main times when whenever we're asked.

0:45:30.590 --> 0:45:36.310  
Jamie Garcia  
To recommend a laboratory, we will always request 3 quotations.

0:45:36.890 --> 0:45:44.920  
Jamie Garcia  
Umm, so the sponsor can have a good understanding of crop cost comparisons as well.

0:45:46.750 --> 0:45:47.570  
Courney Sanders  
That makes sense.

0:45:46.290 --> 0:45:47.780  
Jamie Garcia  
And we're very transparent.

0:45:48.410 --> 0:45:49.880  
Jamie Garcia  
Yeah. To what?

0:45:57.350 --> 0:45:57.610  
Jamie Garcia  
Hmm.

0:46:5.180 --> 0:46:5.550  
Jamie Garcia  
Sure.

0:45:49.500 --> 0:46:9.770  
Courney Sanders  
Yep, Yep, that's going to work with you guys. We do have another few company, our list. Just wanna run the the list by you to see if you've heard of them and and just, you know, just see if there's additional feedback there. Another company is called Q2 or Q Square Solutions.

0:46:11.760 --> 0:46:13.630  
Jamie Garcia  
No, no, I haven't heard of them.

0:46:14.570 --> 0:46:17.260  
Courney Sanders  
OK and cell Carta.

0:46:18.550 --> 0:46:20.160  
Jamie Garcia  
Yes, I've heard of Cellcarta.

0:46:22.80 --> 0:46:28.830  
Courney Sanders  
OK. And so what's your feedback there and maybe like why your organization are not using them?

0:46:31.260 --> 0:46:41.680  
Jamie Garcia  
Uh, it again? I think it's just dependent on the requirements. We we have heard of them and.

0:46:42.620 --> 0:46:46.880  
Jamie Garcia  
It's a sponsor. Specifically asks for them and and.

0:46:51.520 --> 0:46:51.800  
Courney Sanders  
OK.

0:46:47.670 --> 0:46:55.710  
Jamie Garcia  
Then they used I. I just feel that I'm there potentially more.

0:47:9.100 --> 0:47:9.460  
Courney Sanders  
Umm.

0:46:56.300 --> 0:47:13.640  
Jamie Garcia  
And biomarker driven when we often look at using specialist labs, we like to do the one lab do all which can include PKP's as well. And my understanding is I don't believe so Carter has those capabilities.

0:47:21.550 --> 0:47:22.710  
Jamie Garcia  
They yeah.

0:47:15.150 --> 0:47:23.760  
Courney Sanders  
Got it. So about agilytix or 360 bio labs when at providing APK services, OK.

0:47:23.810 --> 0:47:24.970  
Jamie Garcia  
Yeah, yeah.

0:47:26.270 --> 0:47:26.530  
Courney Sanders  
All it.

0:47:25.790 --> 0:47:33.130  
Jamie Garcia  
It just makes logistics so much easier. It's one less than door to manage. Obviously if they couldn't form the.

0:47:33.230 --> 0:47:37.120  
Jamie Garcia  
And the specific essay, then yes, you know, we would look at.

0:47:37.620 --> 0:47:39.540  
Jamie Garcia  
And we would look at that.

0:47:40.630 --> 0:47:42.600  
Courney Sanders  
Yeah. OK. That makes sense.

0:47:43.480 --> 0:47:45.470  
Courney Sanders  
Umm great.

0:47:46.150 --> 0:47:47.350  
Courney Sanders  
And when?

0:47:48.510 --> 0:48:10.660  
Courney Sanders  
We we touch upon the NGSS one potential high growth area. You you wanna expand it to other specific modalities that you think will grow or in needs of more ingest capabilities or other additional therapeutic areas other than oncology that you might be interested in?

0:48:12.40 --> 0:48:13.710  
Jamie Garcia  
Uh, yeah. Well.

0:48:14.110 --> 0:48:30.520  
Jamie Garcia  
Umm I I think NGS testing is just growing, not not only in oncology but obviously any potential genetic abnormality. I think rare diseases as well.

0:48:31.80 --> 0:48:31.710  
Jamie Garcia  
Umm.

0:48:32.870 --> 0:48:38.980  
Jamie Garcia  
As as we're learning more and more about the genome and I, I suppose.

0:48:39.860 --> 0:48:41.850  
Jamie Garcia  
Uh disease?

0:48:42.280 --> 0:48:44.560  
Jamie Garcia  
Uh, pathology.

0:48:45.360 --> 0:48:48.590  
Jamie Garcia  
The NGS testing really is.

0:48:48.850 --> 0:49:0.900  
Jamie Garcia  
And yeah, valuable. And and you know some of these genetic diseases that are being treated with gene therapy products etcetera.

0:49:3.90 --> 0:49:9.270  
Jamie Garcia  
I I see NGS testing being important in in that as well.

0:49:11.30 --> 0:49:30.300  
Courney Sanders  
And others specific again, either modality or therapeutic areas, and the sponsors have approached to you that might needs multiple types or categories of biomarker testing, you know including NGS, histopathology and.

0:49:31.180 --> 0:49:32.890  
Courney Sanders  
Umm. Flow cytometry.

0:49:34.470 --> 0:49:55.880  
Jamie Garcia  
Yeah. Again, in some of our early phase clinical trials, we're seeing the NGS testing to confirm the patient population that we're specifically looking at and then utilizing a mixture of other specialist essays to support PD.

0:49:56.190 --> 0:50:5.570  
Jamie Garcia  
Umm. Uh. With what? Aaron, you know, he's the chemistry. We're looking at a DC antibodies and looking at at at those as.

0:50:6.210 --> 0:50:10.190  
Jamie Garcia  
And yeah, part of understanding the UM.

0:50:11.710 --> 0:50:15.230  
Jamie Garcia  
And and and providing us with both secondary.

0:50:15.960 --> 0:50:43.560  
Jamie Garcia  
Objectives and, you know, making sure we're reaching the target, what those levels were. Targets are comparing toxicity to to to levels of of of these therapies that are circulating. So I I, I, I see them all working in tandem, each providing information for different aspects of the patients treatment path.

0:50:45.80 --> 0:50:56.80  
Courney Sanders  
So you mentioned preclinical discoveries, I wonder at what stage does your organization engage with sponsors and support them?

0:50:57.630 --> 0:50:58.280  
Jamie Garcia  
Yes.

0:50:57.100 --> 0:50:58.650  
Courney Sanders  
Or any type of testing.

0:50:59.670 --> 0:51:30.380  
Jamie Garcia  
Yeah. So we usually support sponsors just before they're ready to get into the the clinic. So there preclinical testing has been done and they're putting together their packages for regulatory submissions. Our company gets involved or can get involved at that stage undertaking gap analysis, making sure there's sufficient preclinical toxicology data.

0:51:30.600 --> 0:51:34.420  
Jamie Garcia  
And we have consultants that support.

0:51:34.660 --> 0:51:52.350  
Jamie Garcia  
I can prepare clinical development plans to to assist sponsors. So we yeah, very much start getting involved. Once that preclinical top sync package is available or being collated.

0:51:54.470 --> 0:51:56.670  
Courney Sanders  
So are there any needs?

0:51:56.780 --> 0:52:6.370  
Courney Sanders  
And you've heard, potentially from sponsors that they might need help from you guys early on at preclinical stage?

0:52:7.960 --> 0:52:9.510  
Jamie Garcia  
No, no.

0:52:10.720 --> 0:52:11.250  
Courney Sanders  
OK.

0:52:10.440 --> 0:52:13.10  
Jamie Garcia  
No, we really are a clinical stage company.

0:52:13.730 --> 0:52:24.650  
Courney Sanders  
Yeah, OK, sounds great. UM. And through all the clinical trial stage, do you also provide central lab type of service?

0:52:25.750 --> 0:52:27.810  
Courney Sanders  
You know, provide any routine testing.

0:52:29.50 --> 0:52:31.590  
Jamie Garcia  
Uh, yes, we do.

0:52:31.810 --> 0:53:2.530  
Jamie Garcia  
And it's it's probably more for latest phase clinical trials, but we find that just standard, you know, safety bloods that as routine sites will prefer to have those done locally just because they need those results quickly. And the turn around time that having them done centrally aren't aren't acceptable. So we'll often have sites doing their local blogs.

0:53:2.620 --> 0:53:22.990  
Jamie Garcia  
And then shipping to the central lab as well. So usually only safety bloods are usually only considered for registration of study. It's not the sort of earlier phase studies. I can't even recall the last time I had a study that included central safety Bloods.

0:53:24.280 --> 0:53:28.850  
Courney Sanders  
Either and what is the requirement of the turnaround time there?

0:53:30.350 --> 0:53:32.440  
Jamie Garcia  
Well, you know.

0:53:47.840 --> 0:53:48.150  
Courney Sanders  
OK.

0:53:34.90 --> 0:53:55.60  
Jamie Garcia  
Depending on on patients, especially oncology patients that they're undergoing therapy, if they're anemic or they're platelet counts are low, you you want to have that result available within an hour and you know so. So I would talk, I would consider less than 24 hours would be a turnaround time that's required.

0:53:55.960 --> 0:53:59.620  
Jamie Garcia  
So obviously, sending to a central lab, that won't be done.

0:54:0.620 --> 0:54:16.610  
Courney Sanders  
Yep, got it. And actually I forgot I'm asking about the turn around time and for bond marker testing as well and what are typical you know turn around time that sponsors requests for the bomb marker testing.

0:54:17.850 --> 0:54:23.260  
Jamie Garcia  
Yeah, and usually around 7 to 14 days.

0:54:24.740 --> 0:54:29.890  
Courney Sanders  
OK, that'll consider being sufficient for all type of testing.

0:54:28.750 --> 0:54:31.100  
Jamie Garcia  
Acceptable. Yeah, yeah.

0:54:31.610 --> 0:54:35.540  
Courney Sanders  
Are there particular tests that might require faster turn around?

0:54:37.600 --> 0:54:57.60  
Jamie Garcia  
Ohh look sometimes when they're inclusion exclusion criteria and again you know talking specifically about oncology where a patient can't wait 10 days to get a result to to confirm their eligibility, that could be an issue, yeah.

0:54:57.230 --> 0:54:58.580  
Courney Sanders  
Yeah, that makes sense.

0:54:59.800 --> 0:55:14.220  
Courney Sanders  
Also, I wonder among all the about micro testing we mentioned other specific requirements on the level of customization or customers actually prefer or sponsors actually prefer more off the shelf tests.

0:55:16.40 --> 0:55:30.230  
Jamie Garcia  
Again, I think it really depends on the asset that's being developed, but in most cases there are off the shelf testing. So kicks that that can be validated and established.

0:55:31.970 --> 0:55:41.960  
Courney Sanders  
I guess when you say assets are those, you know potentially more complex asset assets like cell therapy needs customization. Are there any you know just level of detail there?

0:55:40.500 --> 0:55:54.30  
Jamie Garcia  
Yeah. Yeah, yeah, yeah. So so again, obviously, yeah, customization, when it comes to cell therapies, but also just newer therapies that have been developed, newer targets and.

0:55:59.440 --> 0:55:59.800  
Courney Sanders  
Mm-hmm.

0:55:54.310 --> 0:56:14.80  
Jamie Garcia  
That, that they're just not available yet. So so we've worked on a couple of compounds and that's I suppose where the biotech or the sponsoring company is often working with a laboratory or or research group to to establish those approaches.

0:56:21.780 --> 0:56:22.670  
Jamie Garcia  
Yeah. Thank you.

0:56:15.320 --> 0:56:29.810  
Courney Sanders  
Yep, that makes sense. Great. I want to respect your time. I know we're already almost right there. So I wanna thank you for your time and appreciate all the details on the APAC region specifically. So hopefully we will connect on future projects.

0:56:30.630 --> 0:56:32.760  
Jamie Garcia  
Sounds great. Thank you very much for your time.

0:56:33.480 --> 0:56:35.280  
Courney Sanders  
Thank you. Have a good day. Bye.

0:56:34.920 --> 0:56:36.120  
Jamie Garcia  
Take care. Bye bye.