“Finding the Best Clinical Trial” (Selin Kurnaz, Massive Bio) [#14]

June 22, 2022
Brian McCloskey and Brad Power

“*The way that you've built your whole value chain is one of the more complete solutions that I've seen*.” – Brian McCloskey

Meeting Summary

Selin Kurnaz, PhD, Co-founder and CEO, and Czerny Cohen, Vice President of Clinical Operations, Massive Bio, shared their experience in helping cancer patients in "Finding the Best Clinical Trial". The “best clinical trial” is the one that is the best fit, based on each patient’s unique profile. Their mission is to increase access for patients to explore all of their treatment options, not just standard of care therapy, but also clinical trial options. That means that Massive Bio must help each patient assemble all of that patient’s relevant health data, and also provide clinical coordination, helping patients fill in any gaps in their health information, such as helping them get a DNA sequencing of their tumor tissue if they don’t already have it, and overcoming financial and logistical issues to get access to the clinical trial (the “last mile”). Massive Bio’s services are especially valuable to help patients who do not have easy access to academic research cancer centers, and to reduce the burden of pursuing additional treatment options when the patient just got the overwhelming stress of an intial cancer diagnosis or a relapse diagnosis.

Typical challenges patients face in getting access to clinical trials are overcome by Massive Bio’s services:

1. **Trial awareness:** Patients may be steered to the standard of care, overlooking other valuable options, such as new treatments in clinical trials. Massive Bio provides education to patients on what additional options clinical trials make possible.
2. **Data collection**: The patient’s health records, which are critical to treatment selection, and often spread out among different healthcare providers. Massive Bio gets a fews bits of personal contact information and authorization from the patient, then pulls the relevant detailed data from the patient’s medical records.
3. **Tests**: Tests, especially genomic sequencing, are often required to meet clinical trial enrollment, and many patients haven’t had these tests. Massive Bio helps patients get the basic tests needed for clinical trial access.
4. **Trial matching:** There are many clinical trial options, making selection a complex decision. Massive Bio finds the best fit for the patient using their software, taking into account inclusion and exclusion criteria for the clinical trials and the number of visits the patient will need to make. Massive Bio goes beyond the clinical trial descriptions on clinicaltrials.gov to review detailed descriptions of the clinical trials, some of which are provided by their pharmaceutical partners.
5. **Travel distance**: The willingness and ability of a patient to travel to a clinical trial site can vary greatly. Massive Bio establishes a travel radius up front and enters it into the matching process.
6. **Trial enrollment**: After selecting a clinical trial, patients need to communicate with five contacts to enroll. Massive Bio handles these communications on behalf of the patient.

Sometimes this extends to being an advocate for the patient to accelerate the enrollment process.

7. **Travel and accommodation**: The patient may have trouble getting to the site and spending time there, including paying. Massive Bio works with the patient to find solutions to logistics problems.

Advanced prostate cancer patient Brian McCloskey went through Massive Bio’s process, and they identified three clinical trials that fit him, one of which his oncologist is the lead investigator on. He was very impressed with the ease of interaction in working with Massive Bio. “The way that you've built your whole value chain is one of the more complete solutions that I've seen.”

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Meeting Notes

SUMMARY KEYWORDS

patient, clinical trials, clinical, oncologist, therapy, journey, patient advocates, trial, NGS, bio, medical records, enrollment, terms, company, matching, site, questions, information, massive, imaging

SPEAKERS

Arturo Loaiza-Bonilla MD, Anonymous Caregiver, John Powers, Aubrey Kelly, Brian McCloskey, Czerny Cohen, Selin Kurnaz

Brian McCloskey 00:05

Welcome everybody. I'm Brian McCloskey of the Prostate Cancer Lab. I'm pinch hitting for Brad Power. Today, I'm excited to have Selin Kurnaz, who is the Co-Founder and CEO of Massive Bio. Massive Bio is an AI-powered oncology platform that connects patients to clinical trials, while improving patient participation rates for Big Pharma. They capture all relevant patient data, including complete medical history, genomic profiling, plus clinical trial preferences, such as geographical location, to recommend the best fit clinical trials for patients to discuss with their medical oncologists. Additionally, they offer clinical coordination, continuous monitoring, and

community support to help patients navigate the complexities of the clinical trial process. So as a patient, I went through their impressive matching process just a couple of weeks ago. I'll present their clinical trial recommendations next week to my oncologist. And I'm looking forward to hearing her feedback and working through the journey with Massive Bio. So I'm really excited to have Selin join us. She's going to talk about why she created Massive Bio, and what Massive Bio has to offer to patients. Selin, thank you so much for joining us.

Selin Kurnaz 01:56

Thank you very much Brian for the opportunity to speak today. I'm the Co-founder and CEO of Massive Bio. Before I talk about the journey, I'd like to introduce my VP of Clinical Operations, Czerny Cohen. You know why I founded the company, but I think the real star here is Czerny. She's going to describe our patient process, and how we care about the patients, and how we manage their journey. Why don't you introduce yourself, and I'll provide a brief intro about myself, the company, and then we'll move forward?

Czerny Cohen 01:56

Hello, everyone. My name is Czerny Cohen. I am Massive Bio's Vice President of Clinical Operations. What that means is that I oversee all our nurses in case management and the “last mile”, which is the AI matching portion, as well as the enrollment concierge portion of the company. I oversee all of our patient interactions, and I have ownership for all of the enrollment. My background is in hematology nursing with bone marrow transplant, both auto and allogenic, as well as clinical trial infusions. I will be talking later about the rest of Massive Bio's onboarding process, as well as our services, after Selin.

Selin Kurnaz 03:27

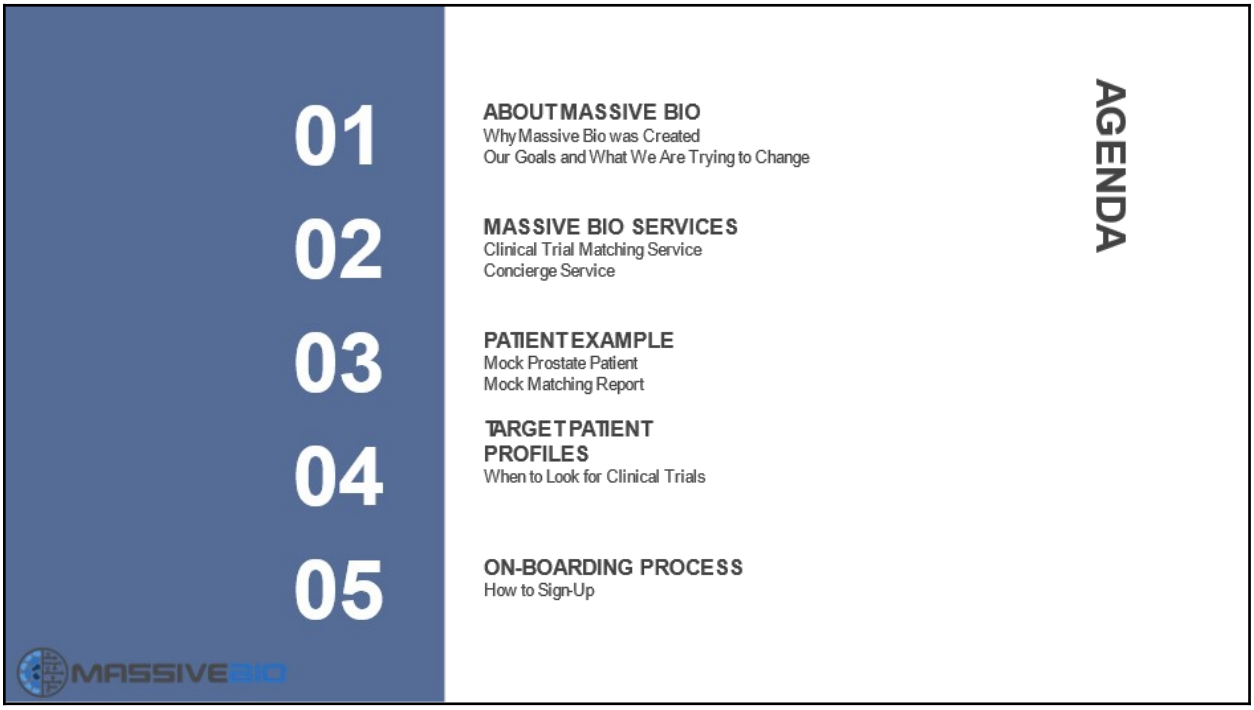
Thank you so much, Czerny. You're going to hear a lot from Czerny about her journey with patients.

I'm the Co-founder and CEO of Massive Bio. I come from a very heavy engineering background. After going through a lot of engineering, I spent about 14 years in strategy, operations, and transactions. My role prior to founding Massive Bio was one of the co-founders of Ernst and Young Private Equity Value Creation. At that time, I thought that I was going to open my own investment management firm and invest in growth stage businesses. I had a very well-articulated vision seven years ago about what my future was going to look like, but God had a completely different plan. God's plan was that my uncle was diagnosed with prostate cancer. So until that point in time, cancer did not hit the family. That was definitely an earth-shattering journey for us. And I lost my aunt to cancer six months ago. This is not just a business for us; this is really a personal passion. That's the reason why we are getting together with patient communities to try to explain why we have been in this field. We founded the company about seven years ago based upon that personal frustration. On-my-knees frustration with cancer care. You're going to three different places. You're getting three different results. There is no clarity in terms of how you're going to prescreen to a trial. And if you are eligible, what are you going to do? That can be very, very frustrating. In the last seven years, we have been trying to empower cancer patients to get access to clinical trials, regardless of their location or their financial stability. We are really engineering the patient enrollment value chain. We are capturing patient identification and then we get a consent from the patient, which is not a consent for a particular study. That consent is for us to be able to collect their medical records. If they have NGS tested-that's great. But if they have not been NGS [next generation sequencing]

tested, then we help the patient to get NGS tested to the extent it's available. After we do base pre-screening, we do the last mile. In the last mile, we set up the appointment with the site and we look at any logistical issues that need to be resolved. Or, we look at any financial issue that needs to be resolved in order to "de-bottleneck" the system from identification to enrollment. We're seeing the inclusion/exclusion criteria [for the clinical trial] must be fulfilled, but at the same time, you lose 75% of the patients in the funnel of the journey of clinical research when those patients are struggling from operational, logistical or financial matters. So those are the things that we are focusing on. We are patient advocates in that sense, but we are not the patient advocates on the emotional aspect of this. We're supporting patient advocates with evidence-based medicine and providing a scale infrastructure to make sure that whatever the patient wants to do in their clinical trial enrollment journey, we provide the foundation for them to get there, instead of an exercise in their mind that they would like to do.

We are 70 people as a company. We are operating in 12 countries in addition to the US. In addition to the US and Canada, we are in France, Italy, Germany, Spain, Poland, Romania, Israel, Greece, Brazil, and Turkey. We have people that are speaking the local language so that the patients have that local vibe when they're interacting. In terms of the organization, we have people that are on the marketing side, and the digital engagement side, and then patient advocates. When the patients are onboarded to our call center, they are speaking with the patient advocates to talk about the importance of the clinical trial, and what the journey is that awaits them. After that, they're in the medical records collection and in case management. After that, they're in the last mile. So that's kind of more on the patient journey side. In addition to that, we have the provider journey. We also have a dedicated team that is working directly with the physicians of the patients or the referring physicians that will refer the patients to the clinical trial. I appreciate everyone's time and the opportunity, and I'll pass the baton to Czerny for her clinically-oriented insights and analysis.

Czerny Cohen 14:00



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Czerny Cohen 14:07

I want to go over step-by-step what really Massive Bio is all about. Selin did a very thorough job talking about our vision and our mission.

My only addition is that the clinical staff who are at Massive Bio right now really came to the company because we saw this issue that Selin saw personally while working in the system. I worked for a big cancer research center in California for most of my career, but then I had to move to South Carolina to a community practice. I had patients who did not know what a bone marrow transplant was. That is something that is already part of the standard of care. So the patient would not know what clinical trials were. It was very real to me to see the discrepancy between the access of someone living near a big cancer center and near a community hospital. Unless you're living near City of Hope, MD Anderson, or MSK, the patient really has very limited resources. So the issues that we're trying to solve here are really two pronged: we want to make sure that all oncology patients have the capacity to explore all of their options, not just standard of care therapy, but also clinical trial options.

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I think we have to remember that all of the standard of care therapy also came from being in clinical trials. Anything that's leading edge right now will be from any clinical trials. The other prong is the concierge enrollment. Our AI was built to take in any patient's medical record. We look at all of the diagnostic factors, whether that's lines of therapy, the types of therapy that they've had, their pathology, and their comorbidities. The AI takes all of those factors and screens it against the inclusion and exclusion criteria of all of these clinical trials based on their cancer type. Our limiting factor would be the travel radius the patient sets. We have patients who are willing and able to travel all throughout the United States. If you're a US patient, we give a very comprehensive report, but we also accommodate the patient to the degree possible. There are patients who only want to travel 75 miles because they don't want to be that far away from their family. Depending on the complexity of their disease and of their history, we can tailor it based on that probable radius. But the other issue with the healthcare system right now is that even if a patient knows about clinical trials, and they know exactly what kind of clinical trial, they find it hard to even get referred or enrolled to these trials. There are at least five people you have to speak to, and for a patient to even fully grasp which individuals they need to contact to get referred to these clinical trials is difficult for someone already in such a vulnerable position. It's just heartbreaking the amount of work they need to do to be screened for any clinical trials that they want to participate in. So, the second part of our services is exactly that. Once we give that matching report, and go over that with them or with their oncologists, they pick one. Then they come back to us and say, “this is the clinical trial I want to participate in.” We do the rest of the work from there. We figure out who the points of contacts are, we're the ones who do the outreach. We're the ones who do the scheduling of the appointment for the screening, which does take quite a bit of effort in terms of pulling together several different individuals to get this going. Our goal is to make sure that the patient doesn't do anything other than be present at that screening.

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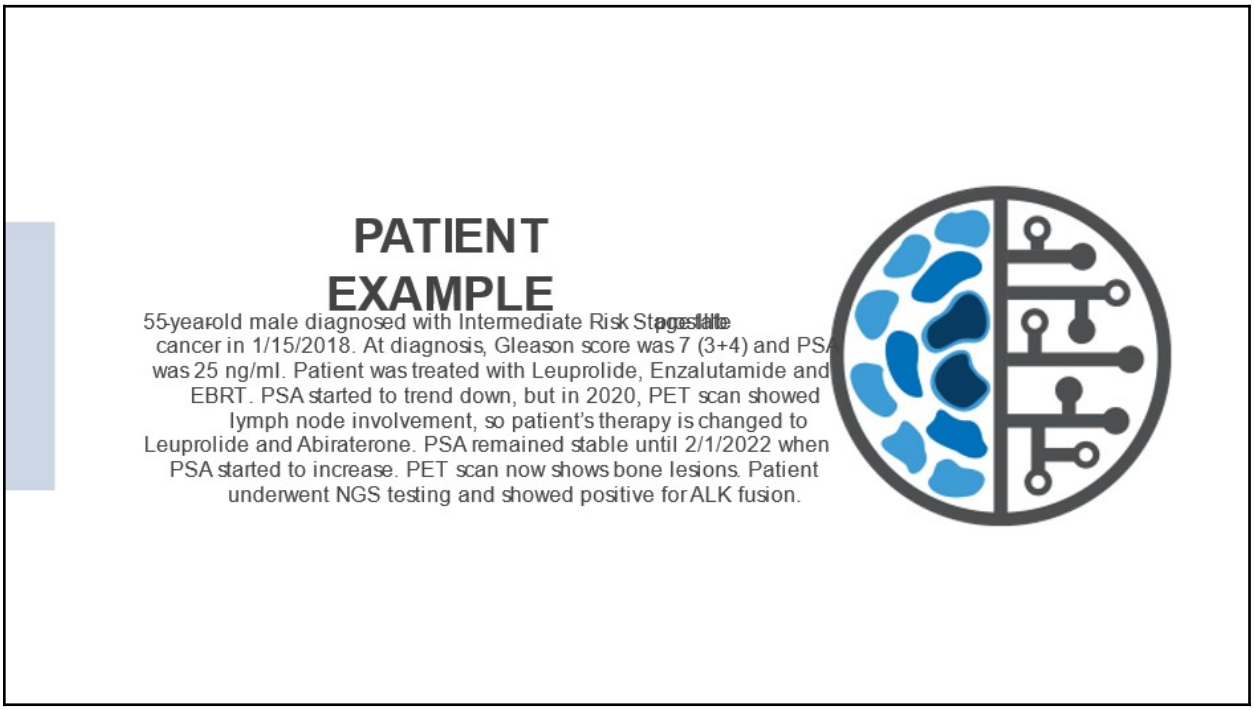

Here is a patient example. We have a 55-year-old male diagnosed with prostate cancer. They went through Leuprolide and Enzalutamide plus EBRT as their first line therapy. Their PSA started to trend down. But then in 2020, their PET scan showed lymph node involvement. Then they changed it to abiraterone and leuprolide. The PSA remained a little bit stable, but then around February 2022, the PSA started to increase. Now the PET scan is showing bone lesions. At this point, the patient is considering other options for this metastasis. They did get NGS tested, and it showed positive for an ALK fusion. A lot of our prostate patients will come to us with a very similar type of history going through two different lines of therapy. They come to us with either lymph node metastasis or more progressive disease. A lot of our patients right now, if they are not near or being treated at a huge cancer center, they probably do not have an NGS test, or do not even know what NGS testing is. So part of what we do is have an educational campaign for NGS testing. NGS testing is genomic testing. It shows your tumor profiling. It shows any fusions or alterations and mutations of the cancerous tumor. This is good because a lot of the clinical trials right now are essentially targeted therapies.

Czerny Cohen 21:53

Once we have all of the medical records and history, we put that into our system and the AI does its work. Then an oncology research nurse supervises all of the matching. Once that is done, the patient receives a clinical trial matching report.

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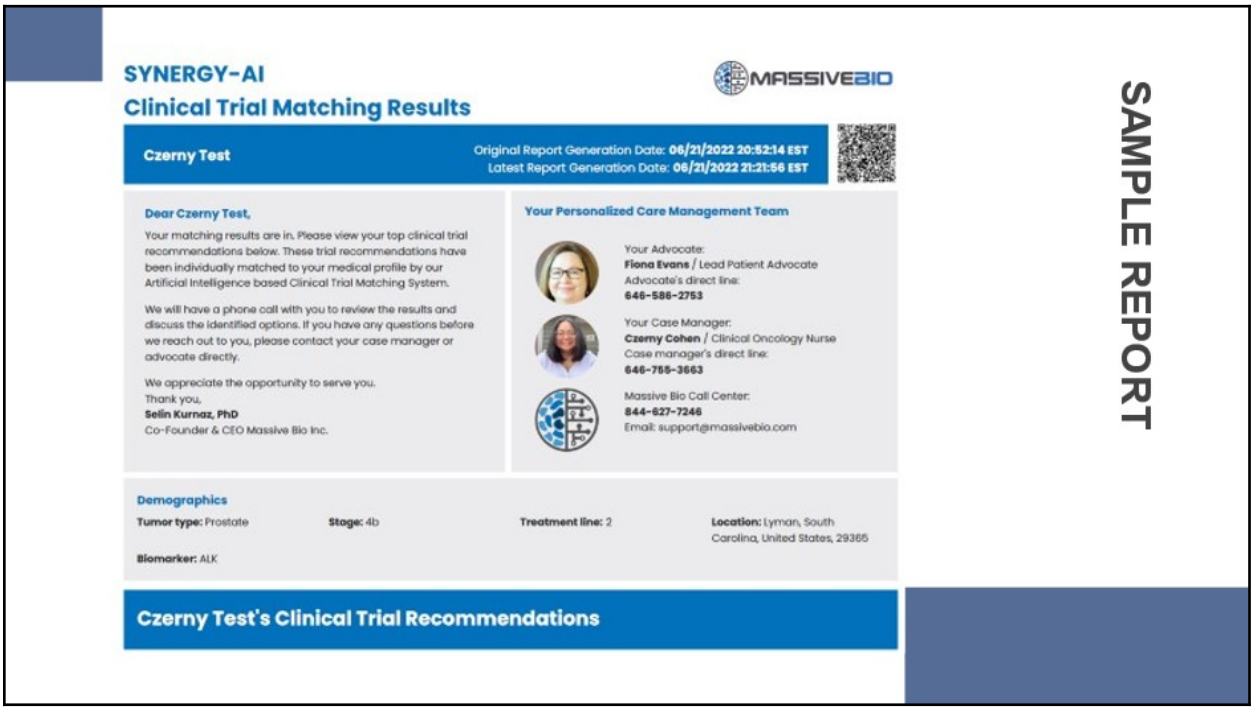
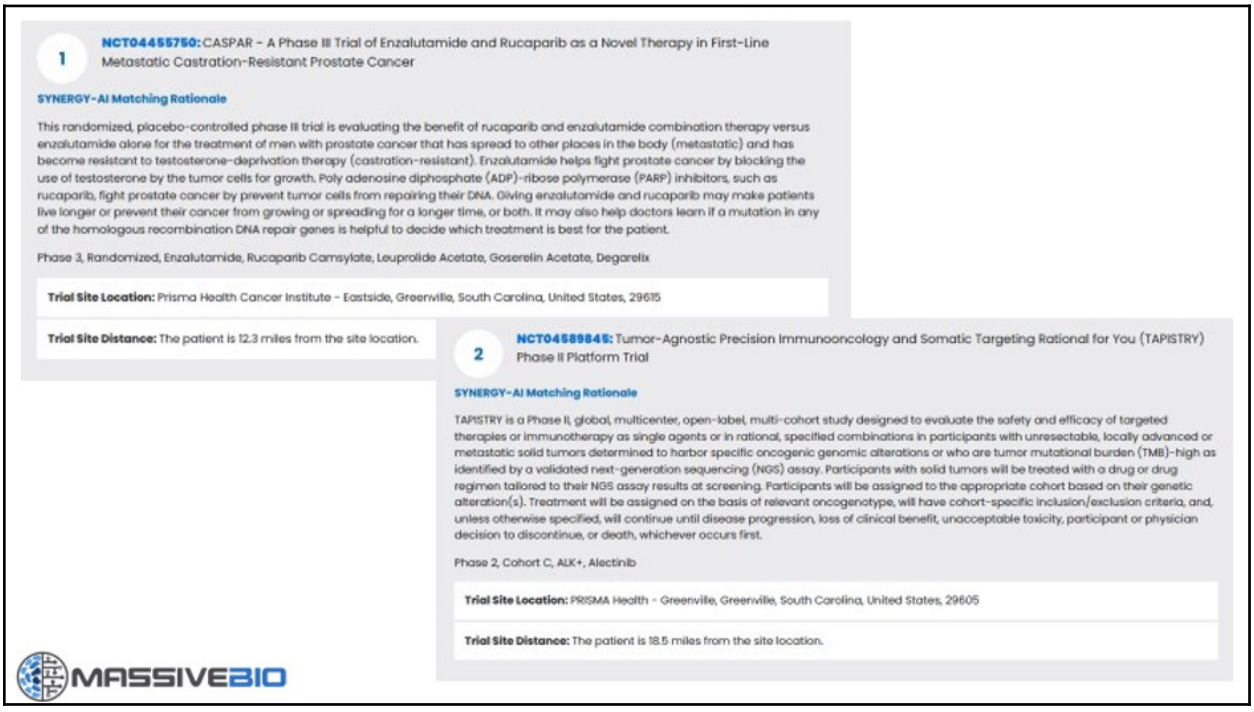


The first page will always be the same. It'll give you a good rundown of who is in your care team with Massive Bio and who is the patient advocate that's assigned to you. That's the case manager that's assigned to you. We provide contact information should the patient need to get a hold of them. But the more substantial part is providing the clinical trials that were matched to you.



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For this test patient, I picked two separate trials that are very common for prostate cancer patients. The first one is CASPAR. A lot of prostate patients are metastatic castration resistant. It means that you've gone through androgen deprivation therapy, and yet your PSA is increasing, as well as your disease is progressing. At that point, the patient needs to know what to do next. There are several prostate cancer clinical trials that are built specifically for this, and CASPAR is one of them. This is a targeted therapy. The trial tells you what the therapy is, what phase the trial is, what the trial location is, and how far that is from your home. We have a lot of patients who just go by trial site distance. These are patients who are less able to grasp the science behind the clinical trials. All that matters to them is proximity to their home. But we do have other patients who are really digging into the rationale behind this matching. The other portion that I want to talk about is this second match right here. This is what I'm talking about with NGS. We have a big NGS initiative right now with all of our solid tumor patients. There's a big push right now for personalized care, precision medicine. That is incredibly applicable within the clinical trial world. For this patient, the patient got NGS tested, and it shows that their tumors are positive for the ALK fusion. There is a specific trial with a specific cohort that is targeting an ALK fusion with a drug, alectinib. This is something that a lot of our patients are incredibly excited about. Because if you think about it, it just seems like it's a drug specifically made for them. There are drugs available right now that are FDA approved that are targeted therapies. A huge portion of the clinical trial world is this targeted therapy, precision medicine. Unfortunately, a lot of the community practices, the non-academic practices, are not very good at doing NGS testing. Not necessarily out of neglect, but rather, they're so inundated with the day-to-day work, and they're so underfunded. They do not have the time to keep up with all of this development. We're acting as that bridge. Once the patient comes to us and we determine that they do not have NGS testing, we are the ones coming up with the forms and sending them to their doctors so that all the doctor must do is send it in with their signature and schedule it for the patient. The NGS testing is not only for clinical trials, but it can also develop or dictate the best course of their standard of care therapy.

Czerny Cohen 27:15

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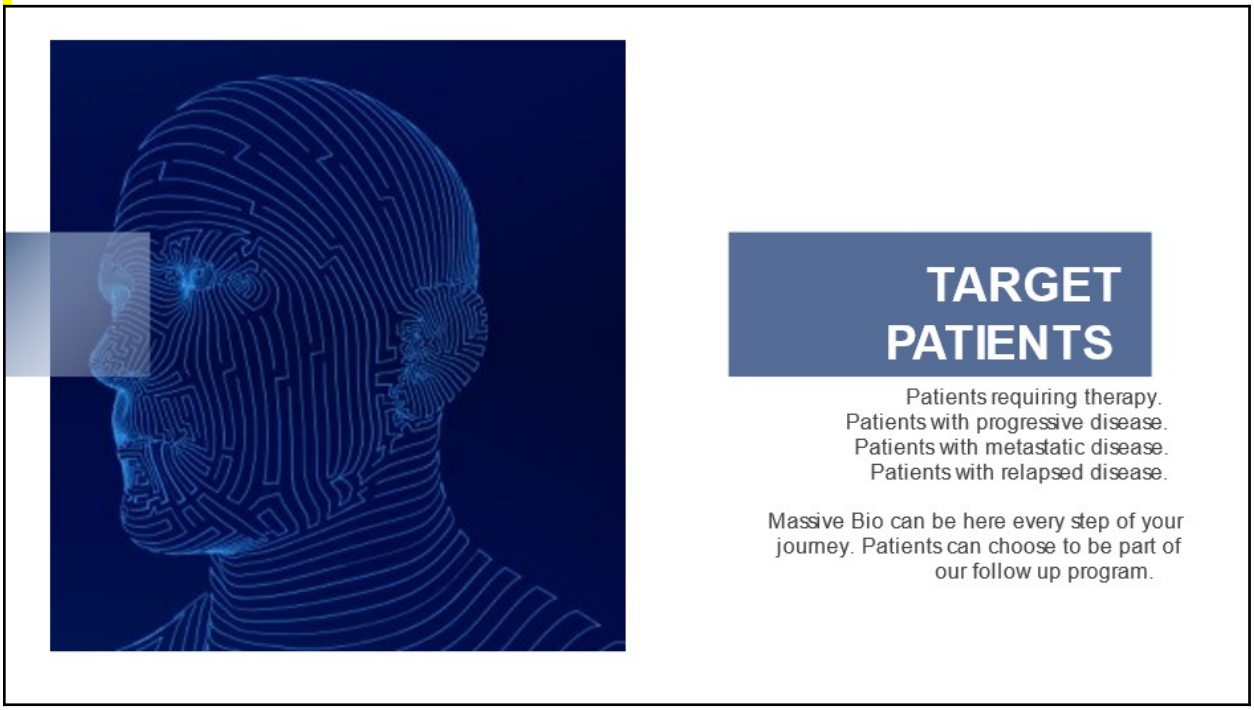

Our target patients are those requiring therapy with progressive and metastatic disease or with relapsed disease. This is the bulk of clinical trials right now: locally advanced metastatic solid tumors or relapsed refractory hematologic tumors. Massive Bio is trying to be part of every step of that journey. We have a significant portion of our patient population who are in our system for the follow-up program. They're either currently under therapy or currently in remission. If under therapy, that means they're receiving something, and they don't know what the outcome of that therapy is quite yet. So they have not progressed. Massive Bio does not recommend stopping a therapy that is on-going where you don't know what the outcome of that therapy is. Whether you're under active therapy or you're under remission, we have a follow-up cadence with you, so that our patient advocate will continually check up on you to make sure that you're still doing okay. If you are still under remission, or if your therapy ended up putting you in remission, that is great. The patient advocates ask the patients whether or not they still want to be followed up with. If they do, then we have a cadence according to what the patient is requesting. Once that patient progresses, it's a very overwhelming time. Clinical trials right now are kind of an afterthought. If a patient does progress, we are there to remind them that they have other options, other than the standard of care, should they want to explore it. It might be during a time when they probably aren't even thinking about clinical trials at all.

Czerny Cohen 29:42

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This is our onboarding process right now. It starts with signing up. All we require in the beginning is contact information. We just need your name, phone number, email address. Once we have all of that, a patient advocate calls you, emails you or texts you, depending on your preferred communication medium and explains to you the entire process and ensures that you don't have any questions. That process is really to make sure that there is informed consent. We want to make sure that as we are collecting your records, and we're matching you for these reports, that you understand what we are trying to do, and we do have that consent from you. Once that consent form is signed, we try to retrieve records. In the United States, it's a lot easier because our patients have access to My Chart or something of the sort, or they can give us their physician's information. Our medical records personnel can do all the work. We request the records; we follow up with the medical records office up until we retrieve those records. Outside of the US, it's a little bit harder depending on the country. We are usually not able to just retrieve physician information and request records that way. We generally rely on the patients themselves to send us the records. Regardless, once we retrieve those records, it then goes to all the nurses. The nurses are the ones working with the AI and making sure that everything is working properly. That is where the matching takes place. And that's when the matching report goes to the patient. Once that matching report is released to the patient, the nurse calls them and confirms receipt of the report and asks if he/she has any questions. Usually the patient says he/she wants a few days to look it over and then they'll call back with some questions. Once they talk it over, the patient usually wants to go to their oncologist to ensure that whatever clinical trial that they're entertaining is suitable for their needs. Once the oncologist and the patient are on board with a specific trial, then they can come back to us and say I want this trial. At that point we go with the referral, and we stay with the patient the entire time throughout the referral and up until enrollment. The referral portion is about 30 days and that's a lot of time. That's where a lot of the obstacles take place. There could be financial challenges in terms of how the patient is going to get to the site that could be 150 miles away. We must resolve travel and accommodation issues. We must coordinate with the treating oncologist as well as the physician investigator to make sure that everything's done accordingly. It's possible that some of

the tasks and imaging can be done closer to their home. So, there's a lot that happens in that 30 day period of referral up until enrollment and when the first dose happens.

But to begin the process, it's just the simple link for patients to sign up with Massive Bio. We have a separate sign-up link for Prostate Cancer Lab patients. But there's also a general link on our website where they can enter their information and have the patient advocates reach out to them. And that is our entire onboarding process. Any questions?

Brian McCloskey 34:28

I'll kick us off Czerny. Thank you so much. That was an awesome review of the services you provide Selin. Thanks so much for providing the background in terms of why you've created Massive Bio. As I mentioned at the beginning, I am a patient, and I did go through your process just a couple of weeks ago. I've gone through the whole AI matching component. You guys have provided three recommended clinical trials for me. They're very interesting. Actually, one of my oncologists is a principal investigator on one of them. That might have been by design, I'm not sure. But I have two questions as I prepare for this next phase in my journey. The first is: Do you get involved in discussions with my medical oncologists about the recommendations that you've made? And then related to that, how do I know what information that I submitted was included in your AI matching engine? I submitted about nine documents that had everything from my own medical record information, multiple sequencing reports, etc. But what I don't know is, which of all of those did you use in the recommendation?

Czerny Cohen 35:59

The first question about working with your oncologist, we do that on a case-by-case basis. Some of our patients are very hesitant for us to speak with their oncologist. And they want to take it themselves and speak to their oncologists. But we do have patients who are hands off. They don't really want to do anything. They say, "I want you to talk to my oncologist about this." That is also something that we do. It just depends on the decision of the patient.

In terms of your second question, we get from 10 pages to 100 pages of medical records depending on the patient and the country. First, we typically look at your last two progress notes from your oncologist. That gives us a breakdown of all the oncology medications that you've had. All that goes into the system, not only as the individual medication and therapies, but also as a whole in terms of how many lines of therapies that you have because that's also very big in the inclusion/exclusion criteria of a lot of clinical trials. On top of that, it also gives us an idea of your comorbidities. The biggest concerns are any active infections, cardiovascular disease, kidney disease that may hinder you from participating in the clinical trials. All that information is contained in one progress note, but we may need to go through five progress notes to figure out how bad the comorbidity is to enter it into the system. It really depends on how well your oncologist, or your primary care provider is documenting your disease. In your case, I know that you had multiple genomic analyses. So, we took all of that and entered all of that into the system. Every single one of them was entered into the system so that it basically takes out everything that you're not positive for, and it matches everything for which you are positive. Additionally, we go through the pathology of the disease because each clinical trial will always have a certain pathology or a certain series of pathologies for each cancer type. Imaging plays a key role too. The most important to us is your very last imaging after your last therapy. For example, if a patient was on treatment until March, their imaging is usually not until about the second week of May. It's about six weeks after your last dose depending on the cancer type and the therapy. So that is how we assess the current state of your disease. The most current information drives screening. A lot of the screening that we do is pre-screening. We look at the inclusion/exclusion criteria of your current state. But at the same time, once you have that screening date with the PI, they're going to look at that all over again. Even your labs, CBC, and sometimes your imaging will be repeated to make sure that they have the most up-to-date screening. So, it depends on how it's documented within your medical records is the short answer.

Selin Kurnaz 40:46

Cerny has done an awesome job covering this from a clinical standpoint. The only thing that I would add in terms of comparison with the other companies in the market, is that other companies are typically doing these things in two ways. One of them is that they are not collecting all the medical records and all documents. They are only looking for three or four criteria: your cancer type, cancer stage, and all that type of information. Because of that, they come up with many clinical trials options which you still need to have some level of a clinical team in order to find which are those two or three most promising trials. Point number two is that I've seen a lot of companies that are pursuing a digital pre screener, so the patient is self-reporting. And then there's other information that the patient is self-reporting. We believe that you must go to the source of the medical records, as opposed to self-reported information. That’s the reason why Czerny's team is spending a significant amount of time upfront to acquire the medical record, going into deep prescreening, and then providing the concierge service. This is how we are differentiated from what's in the market.

Anonymous Caregiver 42:45

Hi, thanks along the same lines, that was really helpful to explain, you're doing sort of a deeper clinical front-end analysis. My question is about the back end. Are you doing keyword search? Are you working against clinicaltrials.gov? Or do you have access to data sets and results from the various clinical trials? Or what is it you're matching against on the back end?

Selin Kurnaz 43:12

We are matching against two types of data. One of them is clinicaltrials.gov and their inclusion and exclusion criteria, but we are not just looking at two or four criteria. We go in depth with the inclusion and exclusion criteria at clinicaltrials.gov. For the trials that are sponsored by our pharma partners, they give us their detailed, 160-page clinical trial protocols so that we can identify or parameterize all that's relevant for the patient. There are two types of information that's important. One of them is from a clinical standpoint, the inclusion/exclusion criteria. The second is the frequency of visits, so that we understand if the patient needs to go into a site every other week. We want to know if there's any flexibility in the logistics. In addition to Czerny as our clinical star, I also have my chief medical officer and co-founder on the phone, Arturo Loaiza-Bonilla, MD. We are a digital tech health company, but there's a significant amount of oversight and know-how with the actual clinical people about what we do. We believe in technology for scaling and adaptability, but technology is not going to be able to solve this issue without Czernys or without Arturos. They're gods in clinical know-how, but you still need to go into the minutiae of the operational issues to get over the hump on that last mile so that the identified patient gets enrolled. When you consolidate the tech side, the clinical sophistication, plus the operational side, that's where the magic happens to engineer the patient enrollment value chain and get patients into clinical trials.

Anonymous Caregiver 45:36

Okay, great. I'm hearing another advantage that you added which is that you can go deeper than what's currently available on clinicaltrials.gov. due to your partnerships where you have access to unpublished information about trials. That's awesome.

Selin Kurnaz 45:50

Yes, we go very, very deep. Czerny is in discussions with pharma and their clinical people, and we've learned that their detailed protocols aren't good enough. Czerny may review 37 protocols and only two protocols may meet her standards. She's identifying all the gaps and holes in the protocol to enable stratification on the patient volume. We will go back and forth to figure out what's the right answer.

Aubrey Kelly 46:37

So first off - thank you, thank you. It was a phenomenal overview. I think that there are two advantages that you guys offer, particularly compared to your competitors. With a few screening criteria, your competitors are pushing patients into screening. It's kind of kicking the can down the road and it's adding to the patient burden. It's not being smart about all of the information that you have. As a result, patients are going through needless traumatic stressors. They already have a cancer diagnosis, or they're potentially going through relapse, and now they

must be the expert to differentiate clinical trial options on imperfect data. Massive Bio can leverage its technology, but also the manpower to do a lot of the heavy lifting to make it seamless for the patient. Czerny, you highlighted what's not on clinicaltrials.gov that is so critical for patients to overcome participating in clinical trials. That is really insightful for pharma companies. That's a mirror that pharma needs for early-stage drug development. There's a phenomenal opportunity to reduce the burden on the patient. Secondly, there's an opportunity for pharma to improve their clinical trial design. Just a general comment, but I really, really liked the model.

Selin Kurnaz 48:33

Those are very valid comments. In fact, the day before we went to ASCO, there was a military action that happened at the company. Czerny, can you provide details?

Czerny Cohen 48:46

The clinical trial site called the patient and said the available appointment was four to five weeks from now, when this patient failed the last line of therapy and was progressing quickly. Everyone was livid. No one could quite understand the thought behind that. For someone to say to a cancer patient who is literally dying that I need you to wait five weeks to even be screened, not even to get the treatment, to be screened for this clinical trial was unacceptable. It turns out that pharma also did not know that site was that backed up. After speaking with Arturo, he was able to say this doesn't make sense even from a PI standpoint. Arturo has been a PI for several clinical trials. It didn't make sense to wait for a singular main PI when there are many sub PI's who could probably see this patient tomorrow. And that's exactly what we did. We just needed to light a fire under them. You're reminding them that you have an obligation to this patient, and not just to this patient, but also to the FDA regulations that you're supposed to be following. So that last mile to enrollment is the most frustrating part of this. It's not even the matching that's hard. That's a to a, b to b, c to c. It's hard to imagine how a patient and their family can go through the referral process. I'm frustrated with the process, and this is my job. It was a grueling 24 hours to just get to where we needed to be.

Selin Kurnaz 49:42

So that's the kind of brute force that we have to apply in order to get through these challenges. We must be able to apply that because we have the clinical staff to defend the case with their staff.

Arturo Loaiza-Bonilla, MD 52:20

Nice to see everyone. One additional component is prioritization. Before we get a new program, we have a system which analyzes the competitive landscape of a trial. We look at the clinical barriers, logistics, but also our report is prioritized based on the patient needs. There's plenty of clinical trials the patient may be eligible for, but it may not necessarily help them to make a difference in their journey. We put in effort scientifically, based on the patient's needs. Not only the closest clinical trials to them, but also considering a biomarker that is emerging that we know may make a difference. It could be a case where the patient has not completed the associated test. But if that test is completed, then we can really make a difference in the patient's outcomes and potentially the patient gets into the trial. All those things have been built into the platform and under the concierge services. Whatever the sign was backed up, the concierge services can follow up. That's exactly what I strive for, to make sure that patients

coming to us seeking help can really make a difference in our system as well to make it better every day.

Selin Kurnaz 53:53

Czerny is our VP of clinical operations, and Arturo is our chief operating officer. They're there everyday, hand-in-hand, to deal with these kinds of problems every single minute of our lives. I work a lot on the pharma side. As Czerny was saying, they were not aware of a lot of issues, so I had to pick up the phone and call the VP of Clinical Ops at the pharmaceutical company to help them make progress. Those are all the kinds that each of us are pushing from different directions.

Brian McCloskey 54:47

Do you capture patient response information directly once they're in a clinical trial? Or are you dependent upon the clinical trials itself reporting information about patients? And is all of that information going back into your recommendation engine?

Selin Kurnaz 55:00

We are getting that information directly from the patient. We are not an agency for FDA reporting in that sense. But we have a follow up, as Czerny was mentioning, with patients to understand what happened in their journey. For example, they may not like the clinical trial, or they may want to go into another clinical trial. We have one patient that we put into a trial that he didn't like, so he went into another trial. This process can repeat itself. We provided them a virtual tumor board because they ended up not wanting to do a trial at all. You have to work with the patient's wishes in terms of how they feel and what they want to do.

Selin Kurnaz 55:06

You'd also be surprised how many questions they have, even after they sign that consent form at the site and after they do the entire screening process, which is also a very educational process for them. That's another thing that we try to do. Even with that first dose, they come back to us with questions and we try to answer them to the best of our ability. If we don't have the answer, then we can get that answer for them. Make sense?

Brian McCloskey 56:24

I can say that having gone through the beginning part of your process, it was super easy onboarding. Just enter basic dog tag information: first name, last name, email address contact information and your team really took the ball and ran with it from there. Again, I'm early in my journey in terms of working with you, but I must tell you that I'm super impressed. Through all the conversations that we've had at the Prostate Cancer Lab with so many experts that we're moving towards combinatorials. Getting access to combinatorials goes together with clinical trials. The way that you've built your whole value chain is one of the more complete solutions that I've seen.

Selin Kurnaz 57:12

The reason why we are very comprehensive is that we're trying to do clinical research without having a clinical research mindset. We're trying to engineer this service, or really reverse

engineer the process, and look at what should be structured that we want, where we are at, and how we can close that gap and constantly innovate in this field. It's just so mind boggling that in this age, this is not a forward-looking field. The drugs are there, but how are you going to get the drugs and how are you going to get access to the clinical trials? The information is not there. I think there's a misconception that if we develop these clinical trials, 13,000 of them, and put them into clinicaltrials.gov, that somehow, it's going to make itself work. It's not working.

John Powers 58:21

This is John Powers. I just got a couple questions. I came out of an engineering background like you. I was in wireless for 14 years at Motorola. When we talk about reengineering and whatnot, I'm on the same page. I've also been in the medical field for the last 16 years. What I see specifically for precision medicine is that although there may be a lot of alternatives, the physician who's in charge of the treatment plan is very reluctant to ever make a change. So it really becomes incumbent on the patient to ask for change, and that can create a hostile situation. I've worked this from both sides as a device vendor and then I started working with hospital groups directly that were my customers that were doing precision medicine because I wanted to get on the genomic side. It's a hard push because you have people that are extremely emotional for obvious reasons. They're trying to get better, and they're getting conflicting information from the folks that are viewing it that are experts. So how do you break through that? And the other piece is how do you scale this? I worked a lot with specific centers doing precision medicine, and they had dedicated personnel who work with the drug companies to get either free drugs or just any kind of drugs, and it didn't scale. It's exactly what Czerny's talking about. I've worked all over the world with hospitals. I'm now in Orange County. You've got plenty of opportunities in California. I'd love to work with you guys on how to scale this or hear your opinions on that. Because that's the biggest problem because drug companies don't want to deal with it.

Selin Kurnaz 1:00:18

On the scale side of it, unfortunately, there is no kind of pill that I can say is THE pill that's going to kind of scale everything. You are going to go into different chunks of scaling. For example, we are trying to scale the patient identification side, bringing these different real time data sets in order to be able to do early diagnosis when those patients could potentially be eligible for a trial. And then you're scaling the technology on the prescreening side, to make sure that you can put 10,000 patients into a system that can process these results in six to seven seconds. That's the scaling that you do. The most difficult scaling is on the last mile part because in the last mile, you are not going to be able to completely take out the human factor. We are trying to standardize, streamline, and learn from the experience for these N-of-1 patients, so that we can use those learnings. For example, if we have that patient that typically takes five weeks, but we can reduce it to two days, that's a learning experience for us that we can apply to the next patient. However, one thing that I would say is that, while scale is important, leveraging data and technology, don't forget that even the largest trillion-dollar companies in the world have a human component. They have employees that enable processes. It's not that technology will replace 99% of the required processes. Technology is a significant aspect, but we have to accept the reality that on the last mile, there is no way to shortcut human interaction. That said, we need to make that human touch as efficient and effective as possible. Those are kind of the things that we are doing right now in terms of the scale. It's the connectivity to the different data systems providing that artificial intelligence for the prescreening side. And then really trying to standardize and streamline. I was even talking to bot companies to integrate their technology

into our call centers so that the patient talks with a bot as opposed to a human being. But again, it's just like one step at a time.