

“Patient Navigators: Your Guide through the Clinical Trial Journey” (Madeleine Carrier, PharmD, and Dennis Akkaya) [#104]

Brad Power
July 3, 2024

“The goal of the patient navigator is to reduce the complexity surrounding clinical trials, guiding patients seamlessly from their initial intake call through to enrollment. We're here to help patients understand their treatment options beyond standard of care, and address their concerns about participating in clinical trials.” – Madeleine Carrier, PharmD

“We're trying to find and help the patients that are not at an academic center or with a physician that is not doing trials every day.” – Dennis Akkaya

“From attending conferences and establishing partnerships with patient advocacy groups, we're seeing the landscape change. This is a really important time. That's why we enjoy doing webinars and educating people on the fact that aside from your physician, there are resources, such as ours, where you can see your other options.” – Madeleine Carrier, PharmD

Meeting Summary

Patients and caregivers often perceive clinical trials as risky and unpredictable compared to standard treatment. Many fear being treated like “research subjects” in an experiment, without knowing that there should be no compromise on the standard of care in a clinical trial environment. Additionally, clinical trials often provide comprehensive testing at no cost to the patient, offering greater insight into treatment effects.

[Madeleine Carrier](#), a patient navigator at myTomorrows, and [Dennis Akkaya](#), Chief Commercial Officer at myTomorrows, are uniquely qualified to lead a discussion about how patients and caregivers can navigate clinical trials. myTomorrows is a company which helps patients discover and access treatments, bridging the gap between those searching for all possible options and the BioPharma companies who develop them.

Why should you consider a clinical trial?

- **Extra options:** Clinical trials are often used when you have exhausted all standard of care treatments. However, clinical trials should be considered upfront and throughout the whole process of treatment selection, as one of the options that are available and should be prioritized.
- **Access:** By choosing a clinical trial, you may be trying the next therapy in the standard of care much sooner than you would have otherwise. In addition to getting access to medications that are additional options, you can also access options in timing and drug combinations.

What are the challenges that you can face when trying to access clinical trials?

- **Awareness:** Not knowing that there are clinical trial options.
- **Data Availability:** Assembling and sharing medical records, essential for selecting treatments and qualifying for trials. They are often scattered across various healthcare providers.

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- **Testing Requirements:** Enrollment in clinical trials frequently requires specific tests, such as genomic sequencing, which you may not have had.
- **Complex Trial Matching:** Not being aware of your options beyond standard care - clinical trials are not seen as standard considerations when developing treatment plans. The abundance of clinical trial options can make selection a daunting process. Factors to consider include eligibility criteria and the number of required visits.
- **Travel Considerations:** Your ability and willingness to travel to trial sites can vary, impacting your ability to participate.
- **Enrollment Process:** After selecting a clinical trial, you must communicate with multiple entities to complete enrollment, adding to the complexity; uncertainty about who to contact and the information required; you may get a slow response or no response from the clinical trial site.
- **Managing Expectations:** You should understand the probabilities of expected outcomes; watch out for a false hope that a clinical trial will deliver an exceptional outcome.

How can patient navigators assist you in your cancer treatment journey?

- Address any barriers you face in understanding your options
- Explain the clinical trials process and how to get enrolled
- Match you with a clinical trial
- Prescreen you to see whether you will qualify for a clinical trial
- Enroll you in a clinical trial, including helping you collect medical records and sending them to the research site
- Describe the different roles of your medical team members and discuss how relationships with them work, improve your communication with your medical team

What can you do to learn more about patient navigation services?

- See [myTomorrows' service](#) related to clinical trials and the role of patient navigators.
- Read or watch [our discussion with Selin Kurnaz of Massive Bio](#) about finding your best clinical trial.

How can you ensure that you understand your clinical trial options and improve your access to them?

- Ask your provider about prioritizing clinical trials. Consider clinical trials not as your last option, but as your first option.
- Share with other patients and caregivers the advantages of a more proactive consideration of clinical trials.
- See [our discussion with Kevin Freiert of Salem Oaks on educating patients and caregivers about clinical trials](#).

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Meeting Notes

KEYWORDS

patients, clinical trials, trials, patient navigators, physicians, options, site, question, Madeleine, dennis, referrals, journey, companies, report, travel, brad, screening, institution, study, expanded

SPEAKERS

Dennis Akkaya (64%), Madeleine Carrier (25%), Brad Power (6%), David Plunkett (2%), Rob Weker (2%), Roger Royse (1%)

QUESTIONS SUBMITTED VIA CHAT

Allen Morris, David Plunkett, Erika Hanson Brown, Ryan Moon, Robert Weker, Kuldip Ahluwalia, Cheryl Middleton, Clifford Reid, Nusantara

SUMMARY

Patient navigators can play a crucial role in guiding patients through their clinical trial journey, providing personalized support, understanding the patient's journey, and addressing concerns. They can help patients in matching them with clinical trials, raising awareness about trial options, and improving the patient experience. Ideally there should be a dedicated point of contact, medical training, language support, and early education to build trust and facilitate the referral process. Patients should be educated about clinical trial options earlier in the treatment process to make informed decisions.

OUTLINE

Introductions.

- Dennis Akkaya and Madeleine Carrier introduced themselves and discussed patient navigation and clinical trial access at myTomorrows.

Patient navigators' role in helping patients find and access relevant trials.

- Patients can schedule a call with a patient navigator to learn about clinical trials tailored to their medical profile.
- Patient navigators help foster shared decision-making between patients and physicians, potentially leading to enrollment in clinical trials.
- Patient navigators provide dedicated support from initial contact, answering questions and addressing concerns.
- Patient navigators explain clinical trial concepts, address eligibility criteria, and build trust throughout the journey.

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A case example of patient navigation for a cancer clinical trial, emphasizing personalized support and trust.

- A patient was aware of a specific clinical trial for diffuse midline glioma and reached out for support in understanding the enrollment process.
- Madeleine Carrier provided pre-screening and addressed concerns about the study design and placebo arm, facilitating the patient's referral to the site.
- Patient navigators assist cancer patients throughout the treatment journey, providing personalized support and connecting them with relevant resources.

Patient navigation for clinical trials, including intake process, platform, and funding models.

- A systematic approach ensures seamless transition from exploration to potential engagement with clinical trial sites.
- Pharmaceutical companies prefer to work with patient navigators, as they provide a more comprehensive view of trial options for patients.
- A clinical trials navigation service helps patients by providing information on all their options, without promoting any particular company.

Genetic testing and clinical trials for cancer patients, with insights on patient knowledge and awareness.

- Patients often lack knowledge on genetic testing for eligibility criteria in clinical trials.
- Patients at community hospitals may lack knowledge of clinical trial options, while those at academic institutions have more awareness but may need help enrolling.

Barriers to clinical trial participation and ways to overcome them.

- Patients are often unaware of clinical trial options beyond standard care.
- Physicians are stretched thin, unable to keep up with the latest research.
- Patients receive personalized guidance through patient navigators, reducing confusion and uncertainty.
- Navigation services provide a streamlined process for sites, with organized referrals and compliant documentation.

Clinical trial enrollment, patient eligibility, and informed decision-making.

- Madeleine Carrier discusses challenges in ensuring patients qualify for clinical trials, including distance and resource allocation.
- She emphasizes the importance of considering clinical trials upfront and throughout the treatment process.

Clinical trials, patient advocacy, and access to treatments.

- Speakers discuss the importance of educating patients about clinical trials as an option for treatment.
- Patient shares personal experience of benefiting from enrolling in a clinical trial earlier in the treatment process.

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- Madeleine Carrier mentions cross-border referrals for clinical trials, acknowledging complexities such as visas, work permits, and consent.
- Roger Royse asks about trials outside the US, citing the UK's recent RNA vaccine trial launch and the need for coordination and information sharing.

Clinical trial navigation and personalized search reports for patients.

- Patients receive personalized support from dedicated patient navigators.
- Patients can reach out to the team via email or schedule another call for more information after the intake call.

Clinical trials, expanded access, and patient-physician relationships.

- Madeleine Carrier emphasizes the importance of patient-physician relationships in expanded access pathways.
- Patients can involve their treating physicians in the treatment search process at various stages.
- Patients can try expanded access to drugs if they don't fit trial parameters.

Clinical trial matching platform, AI technology, and patient experience.

- Madeleine Carrier emphasizes the importance of supporting referring physicians and patients, not just academic centers.
- She positions the company as a partner that prioritizes patient care and detail in clinical trial matching.
- She emphasizes the importance of patient experience and satisfaction in clinical trial matching, and believes AI technology will play a crucial role in improving the process.
- She predicts that within a couple of years, mature business models will emerge that can provide a seamless and satisfying experience for patients considering clinical trials.

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TRANSCRIPT

Brad Power

A quick little couple housekeeping before we get started. First is that this is not medical advice. This is for information purposes only. You should take the information you get from a discussion like this to your medical team. We are a patient led community and we would appreciate any donations that you might consider making. We're a nonprofit.

I connected with Dennis and Madeleine at an Orphan Drug Congress in Boston. I had had interactions with myTomorrows years ago under different leadership, when it was more of a patient navigation service. Now it has much more of a focus on clinical trials. I chatted with Dennis and Madeleine there and invited them to present. They're going to talk about the work that they do and the services that they provide for navigation and their experience.

Dennis Akkaya 1:43

Thank you, Brad. And thank you for allowing me to share a little bit of how we operate within the space and appreciate everybody's time today.

The image is a webinar title slide with a light green and white background. In the top left corner is the Cancer Patient Lab logo, which consists of a stylized caduceus symbol surrounded by four colored dots (red, green, blue, orange) and the text 'Cancer Patient Lab'. In the top right corner is the 'mytomorrows' logo. A dark green rounded rectangle in the middle left contains the text 'Cancer Patient Lab Webinar'. The main title is 'Fireside Chat – *Patient Navigators:* Your Guide through the Clinical Trial Journey' in a large, bold, dark green font. Below the title is the date 'July 3, 2024'. At the bottom center, there is a small line of text: 'Confidential - All rights reserved - myTomorrows (c) 2024'.

We constructed this today to be like a fireside chat, talking about patient navigators, and how we help guide patients through their clinical trial journey.

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Nice to meet you!

Dennis Akkaya
Chief Commercial Officer

Madeleine Carrier
Patient Navigator

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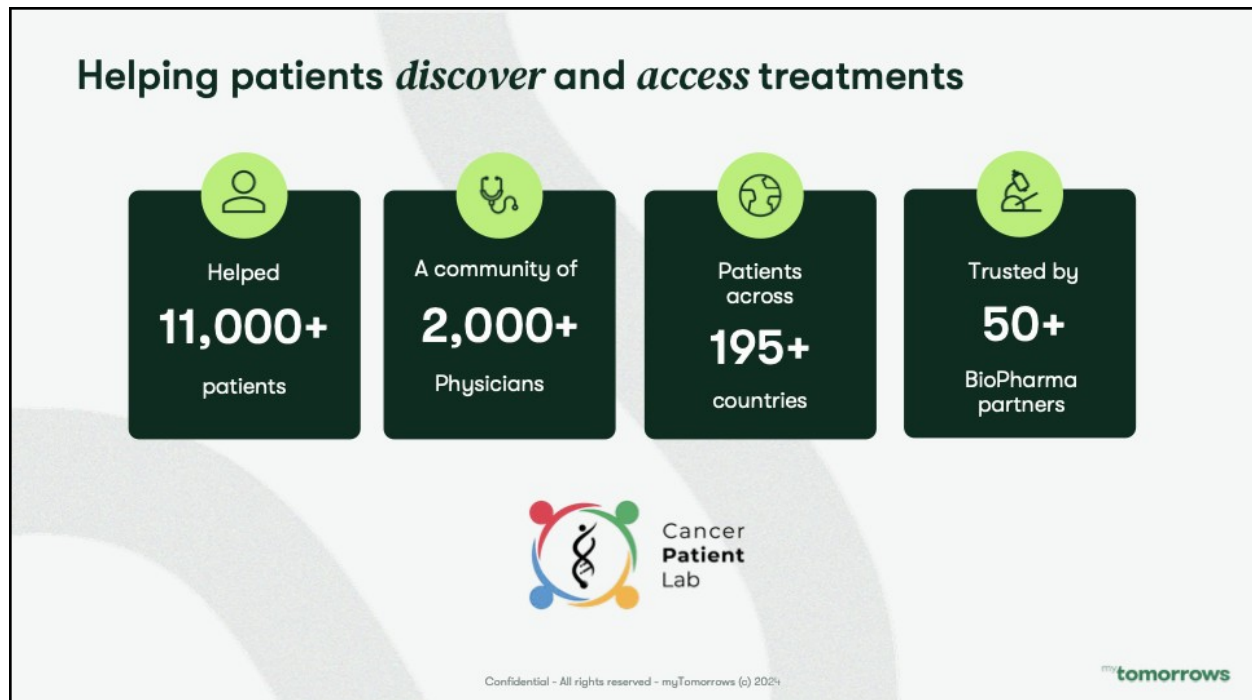
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Just as a matter of introduction, you see me here on the left, but I'm Dennis Akkaya. I'm the Chief Commercial Officer. I've been with the company for nine years, very active in the pre-approval access space, and working in various capacities within the biopharma industry.

Madeleine Carrier 2:41

I'm a pharmacist by training. I work as a patient navigator here at myTomorrows, performing the pre-screening assessments for our patients that are either wanting to explore or access clinical trials.

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Dennis Akkaya 2:55

As an introduction to how our company helps or operates within this space. When Brad and I were talking about what we've achieved over the years, it's important for you to know that you probably get bombarded with a lot of solutions or service providers with a lot of stats, but this is how we view the world: we try to help a lot of patients in their journey.

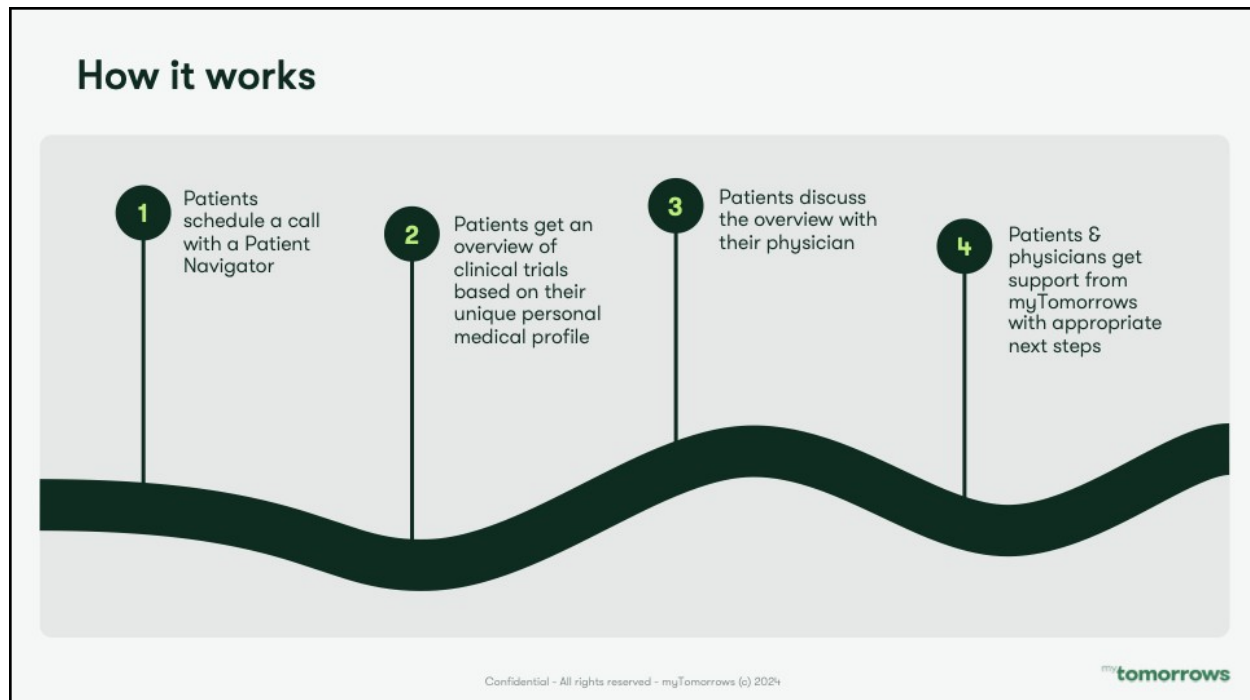
This number that you see here is that we have engaged with 11,000 patients and provide a very high touch service, from the moment that they're interested in a clinical trial all the way to actual enrollment.

Usually patients are also in touch with their treating physicians. These physicians also start to understand how we can help their patients in their clinical trial journey. Usually, if they're satisfied, they tend to come with more patients and situations to understand the clinical trials.

We operate globally from offices in the US as well as Europe. We're very familiar also with cross-border referrals, which we won't discuss today. But it does happen. As you can imagine, there are many patients that are somewhat less fortunate to have access to clinical trials, that sit outside of the Western Hemisphere.

We also collaborate with many biopharma companies that are trying to recruit more patients for their clinical trials. In essence, what we really try to do is help patients discover and access their treatments. I don't want to do too much promotion, but I thought it just might be helpful for you to give you a lay of the land, how we operate, and some numbers to explain our company.

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Brad came to us and said, “We have this patient-led community. We’ve spoken about patient navigators and clinical trial navigation.”

At a very high level, how it works on our side is that what we preferably want is for patients to be able to schedule a call with one of our patient navigators. Madeleine is one of those patient navigators that is based here in the US.

The idea is that, if they schedule a call, our intent is to provide patients an overview of clinical trials that is based on their unique medical profile. We’ll explain a little bit later how that works. But that’s usually as a second step.

We always want to foster a shared decision-making process between the patient and the physician. We want them to go back to the treating physician and say, “It seems that the service has provided me with a more curated list than what I can find on clinicaltrials.gov. We want them to be able to have a discussion with their treating physician.

Then they can potentially pursue one of those trials that are on there. That is something that we would like to be involved in, in the sense that if they have selected one of those trials, or if they have additional questions about those trials, that they could receive adequate requests, whether it’s the patient or the physician themselves, and then we can be part of the journey that goes beyond all the way towards potential enrollments. Again, we’ll have some examples. And as this is a fireside chat, I’ll also be asking Madeleine some questions that might help clarify how that process somewhat works.

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Patient Navigator team

Dedicated point of contact

- When were you diagnosed?
- What is your current treatment?
- (How far) are you willing and able to travel?

- Speak different languages.**
- Have a medical background.**
- Explain the concept of clinical trials and eligibility criteria.**
- Empathetic and kind.**
- Handhold patients through (pre) screening & referral.**
- Coordinate communication between the Medical Care Team and the Site.**

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Dennis Akkaya 6:36

Patient navigators are really critical. This ability allows us to speak with patients and serve them in their journey. It's important for you to understand that whenever patients reach out to us, they have one dedicated point of contact from the moment that they reach out to us. In this case, it could be Madeleine, but we also have other wonderful patient navigators.

On the intake call, usually what we tried to understand is: when were you diagnosed, what are your current treatments, but also very simple questions, like how willing and able are you to travel, because, as you might know, and this is a relatively well-educated group of individuals that know something about clinical trials, but travel distance also impacts the ability for us to present certain trials or for your success in terms of getting into one of those trials.

We know that many patients don't only speak English. Currently, we have between 10 to 12 languages on staff; obviously Spanish, but for a lot of European patients, there are many other languages that we have on staff. That usually really helps.

These patient navigators all are medically-trained and have a medical background. They can be pharmacists, nurses, or some medical doctors. A pharmacist is super important for us, that we provide that level of training, but also that they have that background to fulfill this role.

One of the key things that they do is try to explain the concept of clinical trials. There might be a lot of myths, or perceived barriers to clinical trial participation. Patient navigators can function as a first barrier, or first point of contact to talk about these things. We've learned over the years that the ability to explain what eligibility criteria entail, and why patients aren't eligible for a trial,

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because they might know something, but they have certain questions. Those kinds of questions are really important, early in the journey.

They're very kind and very knowledgeable. That really helps in the conversation, because it is definitely a moment of building trust, and the first person that they speak to outside of their current care journey. It's important that these people know how to answer these questions in the right way because we want to handhold them. There's a whole process from beginning to end in terms of understanding and screening them to be able to refer them to a potential trial.

There's a lot of coordination that needs to happen, whether it's communication or other factors between the medical care team as well as the site to be able to make that successful transition. Our patient navigators have built those kinds of workflows, and Madeleine will explain that later too. That's important for you to understand how these patient navigators operate in this space.

In the chat:

Allen Morris: There are 500,328 trials listed on clinicaltrials.gov. Do you have access to trials beyond these 500k?

Allen Morris: So can I conclude that clinicaltrials.gov is the only repository?

David Plunkett: I found clinicaltrials.gov frustrating to navigate. When I would try searching multiple times with what (I thought) were the same search terms, I would get different results.

Dennis Akkaya 10:04

There's a question about 500,000 trials (on clinicaltrials.gov) from Allen in the chat.

Post discussion edit from Dennis Akkaya:


I can recall saying 100,000 which was too high. We have strict inclusion criteria in terms of what trials we show (no promotional studies, etc.).

You're right. That is a difficult way of navigating all the trials, also within certain diseases. You can have hundreds of listings. The added value of us is that if we provide an overview, they're obviously much more narrow and curated to the profile of the patient. We try to exclude a lot of non-interventional studies. For some diseases there are gaming studies or studies that are not actively recruiting. That is information that on some occasions might not be useful for the patient to present to them. Off the top of my head, we narrow it down to less than 100,000 in terms of actively recruiting trials that we think are presentable to the patients.

We also pull from [EudraCT](https://eudra-ct.eu), or “Eudra” (the European Union version of clinicaltrials.gov, a registry of clinical trials). We also have the ability to add other registries, either from sites or from other WHO (World Health Organization) registries. Currently, what is public is only the clinicaltrials.gov and Eudra. We've annotated and recreated our search engine to provide what we think are the most relevant trials for each disease.

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Patient Story



Disease area:
Diffuse Midline Glioma - H3 K27M mutation

Case: One-to-one support for an adult patient

Challenge: The patient knew about a specific trial but was unfamiliar about the enrollment process.

Solution:

- Provided trial information, verified medical documents, and efficiently pre-screened the patient.
- Addressed concerns about study design and placebo after site connection.
- Facilitated patient-site referral, highlighting the trust and importance of the Patient Navigator relationship.

Our Impact:

- Comprehensive search reports
- Personalized and empathic human support
- Minimizing time spent on preliminary screenings

Personalized support and an easy-to-use platform helps patients discover and access treatments now and in the future.

“It’s impossible to keep up with everything that is being researched around the world. It’s extremely valuable for patients that myTomorrows will look into this for you and give you all your options, so you can discuss them with your physician.”

Patient & Caregiver

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To kick off with a small case example of a patient story: this patient knew about a specific trial within diffuse midline glioma with a certain mutation. We provided one-to-one support for that patient to understand **how to get enrolled.**

The patient was lucky that he knew of one specific trial. I wasn't really sure how he became aware of that trial, but he reached out to us to understand what he should do next. That's where we can provide some value to the patient. We provided a lot of information about the trial, specifically. We verified all the medical documents and information that he was able to share with us. We prescreened the patient on the basis of the information that was known to us about the trial. If that's elaborate enough, then we can do that, because we really want to only involve other players in the referral enrollment process when necessary. We did the **prescreening** upfront with the patient with all the information we had. We were also able to address a lot of concerns about the study design and placebo, after we were able to make the connection with the site.

It's important to understand that usually – I noted before that we have an initial dedicated point of contact – that also stays the case once the patient is already on their journey towards the site. They trust Madeleine. They may have follow-up questions. So it's very natural for some patients to go back to Madeleine as well. I still have a question like, “I'm in this flow at the hospital. But can you help me with this, this, and this?” That shows you that there's still room for improvement and to make this more of a patient-friendly exercise, also upon referral, and all the activities that happen on the site. So those additional concerns were addressed, which was great. We were involved in **facilitating the patient-to-site referral.**

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The trust is not only from the patient, but also from the site and the staff that are there. It's qualitative. The connection is personalized support.

With all the kinds of platforms and systems that we have behind it, it really helps to make that **a very accurate match**. In general, it's very difficult for patients to be aware of all their options, but with the level of knowledge that we provide, if they have a specific question on a trial, but also just in general about trials and if there are other trials that are recruiting. That's something that they are very happy with, and that they can also discuss with their patient.

In the chat:

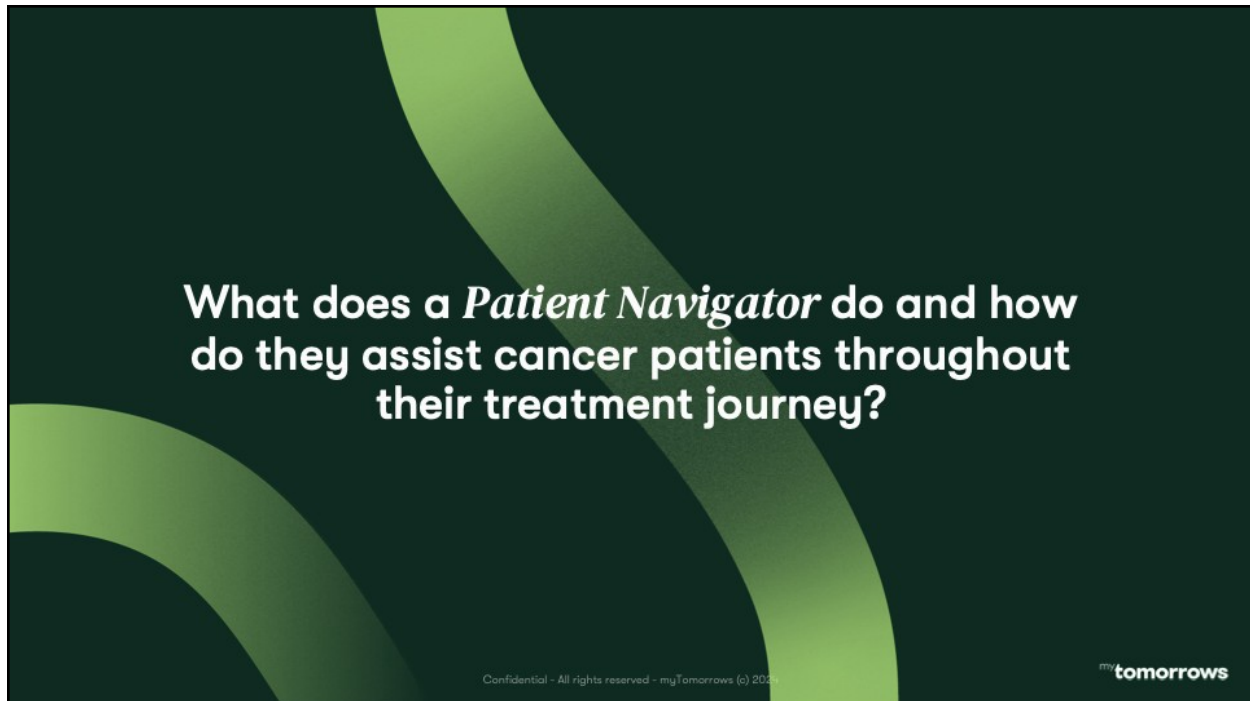
Erika Hanson Brown: Every patient needs a knowledgeable navigator.

Who pays for this service? Does insurance cover?

Dennis Akkaya 14:28

In principle, the companies that work with us subsidize all the patients that reach out to us, so that **patients never pay**, including treating physicians. There are certain parts of patient navigation that are increasingly being covered. Don't give me the exact details. But we're definitely looking into that to see what can be covered and that every patient has access to a patient navigator. We've seen this multiple times. As you can tell from the numbers that we presented, it sounds very simple just to put a patient navigator alongside the patient. It is that valuable for the patient. I would agree that every patient needs a patient navigator. It really helps them in their journey, even though it's maybe just a person listening to the story of the patient to see what the friction and dropoff points are in their journey, maybe to say the same thing that the physician said, but there are endless opportunities where patient navigators can add value. I also don't want to steal too much of Madeleine's story, which also has some interesting things to share.

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With that introduction, I want to ask a couple questions of Madeleine. Hopefully this gave an introduction to how we operate, and how patient navigators are extremely important. As this is a fireside chat, maybe you could explain to the audience, “What does a patient navigator do in your eyes? Although I have already given some examples, how do you assist cancer patients throughout their treatment journey?”

Madeleine Carrier 16:52

You gave a wonderful overview of our process, I'll dive deeper into some more detail.

The goal of the patient navigator is to reduce the complexity surrounding clinical trials, guiding patients seamlessly from their initial intake call through to enrollment. We're here to help patients understand their treatment options beyond standard of care, and address their concerns about participating in clinical trials. Maybe there is no treatment option available for a particular diagnosis, or perhaps the patient has already exhausted all conventional options.

As Dennis mentioned, we have medical backgrounds. We're all very well equipped to explain any information surrounding what a clinical trial is, and the commitment to participate in one, so that patients feel that they are able to make a well-informed decision. But as we mentioned in the beginning of this chat, it is important to note that we can't offer any medical advice, but we can certainly explain any information pertaining to a study.

Our process, as Dennis had mentioned, starts with an intake call during which we gather information about medical history. This could include past treatments and their current condition. That data is collected, stored compliantly in our unique interface tool created specifically for our patient navigators. Following this call, patients are invited to the patient platform, which is their

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own distinct environment. This is for them to upload any relevant medical documents, such as genetic reports or laboratory results. Within this platform patients can also access their treatment search report. This is a comprehensive document detailing clinical trials which they may be potentially eligible for, and based on their ability to travel, expressed during that intake call, because we want to take in all factors for referring patients.

Should a patient express interest in a particular study from that treatment search report, they simply inform their patient navigator, and then from there, the navigator will take proactive steps reaching out to relevant sites via the platform on behalf of the patient to initiate this communication and start that referral process. This systematic approach ensures a seamless transition from exploration to potential engagement with clinical trial sites.

In the chat:

Allen Morris: I may have missed your answer. Who funds your site?

Brad Power: The biopharma companies who are receiving referrals.

Dennis Akkaya 19:10

We try to be available for any patient for any disease in any country. The companies that work with us, where we want to make referrals and get paid by them, fund the ability for us to serve patients if they come in with a disease where we're not very active.

In the chat:

Allen Morris: What biopharma companies are their top referrals?

Allen Morris: For example: Prostate cancer

There are disease areas where we are more active than others. So it depends. What we prefer is to be active with multiple companies within one particular disease. As you can imagine, there might be screen-outs from one trial or one company, or there might be a physician that we have engaged with that has multiple kinds of patients in the future. We aren't disease specialists. But we do like to have some kind of more mass or clout within one disease so that we can leverage some of our investments to attract these patients to find us, so that we can subsidize more patients reaching out to us and also find what trials work for them.

A lot of companies appreciate that we always help patients on their journey if they're a screen-out for their own trial. If the patient's been notified, "Well, you don't qualify for this trial. Good luck!" There are various ways where we are able to do this on a larger scale.

In the chat:

Ryan Moon (he/him): Wouldn't that create a conflict of interest if you're funded by biopharma companies?

The way it works is if we operate on their behalf, our goal is to see if patients are eligible for their trial. It's done through a different journey. But, in principle, when patients reach out to us, we're agnostic in informing them about all their options. They may select one of our clients. We

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can't promote a client's clinical trial. In particular, the report is constructed such that the ones that are most advanced are on top, and there's no way to see which companies are working with us, and which ones are not. An agnostic overview has no way of detecting which ones are being paid by us.

David Plunkett 21:49

In the initial conversations, do you find yourself recommending any testing that might qualify someone for particular trials? For example, if they haven't done genetic testing?

Madeleine Carrier 22:04

During calls, at first intake, I try to assess what information they already know. If they express from a treatment search report, or if they already know of a particular study, and that is a piece of information that we don't yet have but is part of inclusion/exclusion criteria, a lot of times the sites will offer free genetic testing, if they are potentially eligible. So that's a conversation I can have with them. Or if they already have a really good relationship with their treating physician, and they're not worried about finances, they often go by themselves and get that genetic testing done, to see if they are eligible. But a lot of times sites – it's not a blanket statement – will pay for this to be done if they already are deemed potentially eligible based off of the information I've already gathered.

Dennis Akkaya 22:55

For some programs and diseases there is genetic testing available, and we can orchestrate or direct them to where they can get that additional genetic testing so that we can then, as a follow-up call, if once we see that testing, make a much more narrow search. If you only search on a disease with a couple of criteria, the overview might be somewhat less relevant than when you have the exact genetic mutation, so that we can then take a look so that the follow up steps can be more efficient.

David Plunkett 23:27

How common do you find that patients don't know what they should be testing for?

Madeleine Carrier 23:34

I would say it's very rare in this sense, patients really have become advocates for themselves, which I . They do come with a lot of information, a lot of questions. Our chats are usually very productive. I would say it is rare that they are unaware of what is needed to move forward or about their diagnosis in general.

Brad Power 23:59

Is the profile of your typical customer someone who's at a community hospital and is plumbing into the more specialized areas?

In my case, I'm being treated at Dana Farber. Many of the patients here would be at an academic research cancer center. They're very knowledgeable about what the clinical trials are out there. I just had that conversation literally this morning with my oncologist. I wouldn't need

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this service because I'm already getting that service from my oncologist. But 80% of people get treated in a community hospital, so they would not have that same menu of options.

Madeleine Carrier 24:44

I agree with you completely. Those who are at academic institutions or focused institutions do have advantages of knowing information first. Sometimes, though, their direct physician isn't aware of how to actually get them enrolled in a trial. So sometimes they loop into us, regardless of knowing the trial. That is a case where they are aware of their options. They want to know how to then get enrolled. But then on the flip side, as you mentioned, the nation's quite vast, and there are areas where there are concerns about health literacy and not knowing your options. We have a large population of those individuals as well that reach out and are just either newly diagnosed or have run out of options. They're like, “I don't know what to do. This is what I have. This is the information and the reports that I've come with. What now?” We see both sides of it.

In the chat:

Robert Weker: But let's be honest, even at academic institutions, there is often a bias toward trials at that particular institution

David Plunkett: Reacted to "But let's be honest,..." with 👍

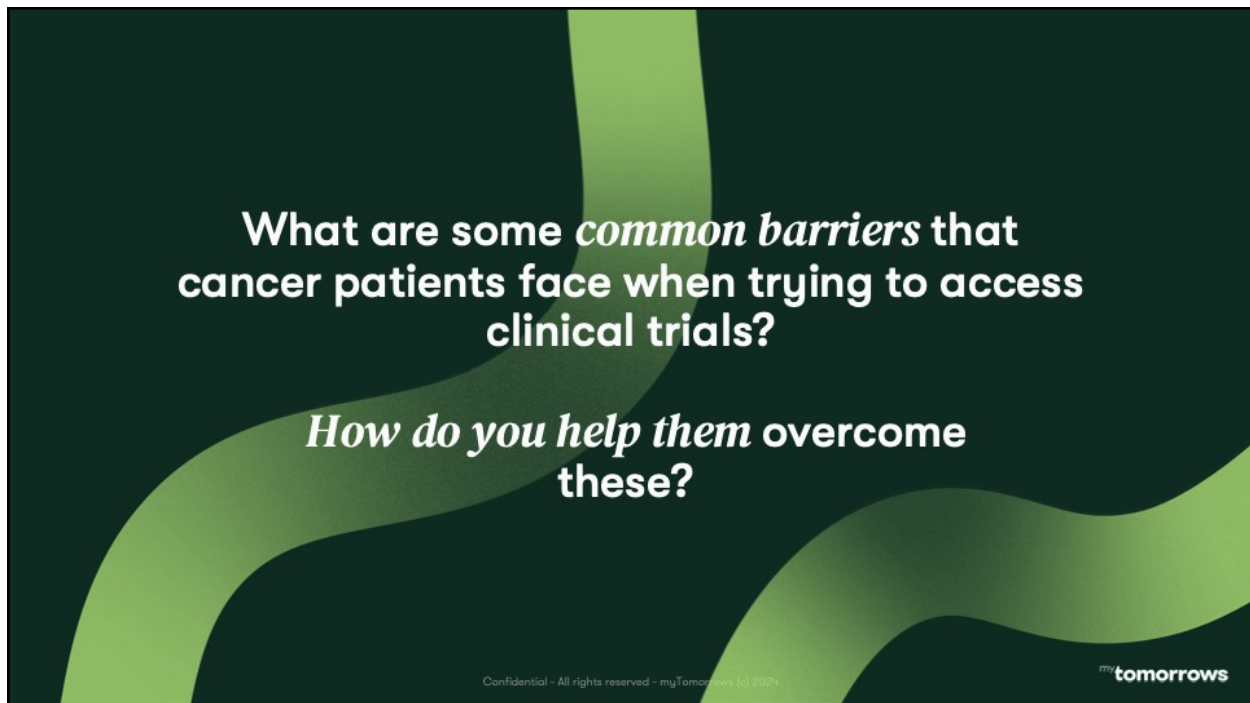
Dennis Akkaya 25:40

There might be a bias to the trials at this institution. Even at some large institutions, I've learned that they're not aware of – let's say it's cancer with a certain mutation, and there are two different departments, one on brain, one on lung – They will sometimes have difficulty understanding what trials are running at other departments within their institution. You probably have access if you're at an institution like that to the best trials. It never hurts to get another overview of all the other trials. Maybe there's something else. I don't know if the institution always would agree, and we definitely don't want to interfere. But at least having that information in a concise report might be helpful for any discussion that occurs in their journey.

From the chat:

Kuldip Ahluwalia: Do you report on patient outcomes (ongoing) for the different clinical trials that you recommend, or do patients have to wait till the pharma company publishes results.

We don't report on the outcomes of the trials. We'll have to wait until the pharma company publishes the results. For companies that we work with, they are learning from the patient experience. They are thinking ahead about how to be more patient-centric, which I would not exclude the ability for them to easily find a way to publish the results or even say “Thank you” to participants.



Dennis Akkaya 27:23

We already talked about some of the barriers that you encounter. But maybe you can chime in a little bit more about that, and also what you do to overcome these barriers that you see regularly.

Madeleine Carrier 27:41

Brad set the stage for this next one. One of our most common barriers we see patients facing is simply, as I mentioned, **not being aware of their options beyond standard care**. They often develop these strong relationships with their physicians, agreeing on treatment plans, and exploring those secondary options. However, once all avenues have been exhausted, there's often a lingering question of, “Well, what now?” Physicians understandably are stretched thin and can't always keep up-to-date on the latest research in the field, even at their own institutions. Currently, **clinical trials are not seen as standard considerations when developing treatment plans**. But they should be incorporated as these too are options. That's where we step in: we bridge that gap by providing patients with the information they need to make these well-informed decisions.

Then on the other hand, I also had mentioned those patients who are aware of a specific trial they'd like to participate in. As demonstrated in our patient case when they came to us, a different barrier emerges: **uncertainty of whom to contact and the information required**. Many patients find themselves in the dark about these next steps and lack that designated point of contact for their questions.

Even when they manage to reach out to a site, they often encounter challenges, such as **a low response rate or no response at all**. Some sites just aren't well equipped to receive this number

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of requests as efficiently and compliantly as they should. Such situations leave patients feeling confused, they often have unanswered questions of, “Did I reach out to the right individual? Were my documents received? Am I ineligible? And if so, for what reason?” While we understand that sites are often overwhelmed, we recognize the importance of providing our patients with this clarity and support.

To address these issues, our patient navigators conducted that thorough pre-screening assessment during the intake call. This ensures that a patient is only presented with those options that they are potentially eligible for, as Dennis had mentioned, in the beginning. We want to avoid instilling **false hope** for those individuals, so we really hone in on those results that they are potentially eligible for. While some criteria may require further evaluation during on site screening, as we can't collect all the information via the phone during that initial assessment, it significantly streamlines that process. Patients also receive from us real time feedback as to why they may not be eligible for a particular study, or their status once they're connected to a site. These are all super valuable insights for patients to know as it helps them make those decisions within that process, and ultimately, all the way through that journey.

Sites enjoy receiving referrals from myTomorrows because our efforts in performing these high level prescreen assessments drastically reduces the burden on the site. It expedites the patient experience. We're trying to make it as easy for all stakeholders involved. Sites have their own unique environment built into our platform to receive those patient referrals in an organized and compliant way. This just eases the referral process for everybody involved.

To summarize, the patient navigator has their own interface, the patient's themselves upload medical documents, and then the site to receive the referral – all compliant and stored in a precise manner so that all the information is easy to read. They're not sifting through medical files. We've honed in on that summary of information that's needed.

Dennis Akkaya 31:06

We want to avoid sending an unqualified patient that is not pre-screened well enough so that the first onset screening, when that occurs, they fail. What we've learned over the years is that sites are hesitant to work with somewhat more novel business models such as ours, because you can always advertise or find patients interested in and in a trial, but how do you know that it's the exact patient? How do we make sure that we are aligned in terms of resource uses that if they get a referral, that there's a very high chance that they can get screened and enrolled into the study? That's something that we're definitely trying to do.

In the chat:

Cheryl Middleton: Is there a way to get into a trial at a distant location but by utilizing a closer/ local location? For example M D Anderson is running a trial that I'm interested in but that's very far away. Is it possible that they'd coordinate with Hopkins (3 hours away) or a local hospital?

Dennis Akkaya 32:02

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That is something that we encounter a lot. If this is run by a certain institution, preferably we're also involved with the sponsor side or the pharmaceutical company side. It is always important to present the case and also the request. You never know. If it's a different institution, they're able to participate in a direct or indirect way. It is important to make these requests. If it's not possible from a location perspective, that at least the ecosystem is aware that there is somebody that is eligible for this trial, but that travel distance wasn't was an issue, so that hopefully one of the stakeholders can go above and beyond and make a creative solution that would make work, which in this case, would involve maybe the patient to be enrolled somewhere nearby.

In the chat:

Clifford Reid: If a patient has poor SOC (standard of care) treatment options and clinical trial options, what do you tell them about the expected benefit of joining a clinical trial vs. their SOC options?

Madeleine Carrier 33:19

Clinical trials are mostly used when they have exhausted all standard of care treatments. I don't often see patients who haven't tried standard of care and are just jumping to clinical trials. To explain the expected benefit: it's just another option. There are many variables to this. It depends on the phase of the study that they are interested in: a phase 3 versus a phase 1. With a phase 3, I can explain a little bit more about past data that has already been established from those previous clinical trials, but as to benefit, that's very case-specific and trial-specific. All of those conversations are very tailored to that patient. I can't really give a full answer, but more of a blanket statement, if that's all right.

Rob Weker 34:20

I find it a little disconcerting, Madeleine, when you said that patients usually look at clinical trials after they have failed all standard of care. I would argue, and I argued in all the referrals I have, that clinical trials should be considered upfront and throughout the whole process, and that at any given point in time, patients need to be making informed decisions around all their options that are available. If they just limit it initially to the standard of care, they are perhaps limiting their possibilities. I guess I'm curious if that's the mindset you also have? How do you encourage patients to be thinking more broadly from the get go?

Madeleine Carrier 35:15

That's a great point. As of right now, I see that that is the landscape that we're in: that people only approach us when all options have been exhausted. From attending conferences and establishing partnerships with patient advocacy groups, we're seeing the landscape change. This is a really important time. That's why we enjoy doing webinars and educating people on the fact that aside from your physician, there are resources, such as ours, where you can see your other options. It is our voice, trying to educate the public and physicians. That's why it's so important that we have these relationships with outsiders and other stakeholders, stakeholders other than patient advocacy groups and physicians, because we are trying to change that

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landscape so that patients understand this isn't a last resort. It should be an option that's explored during standard of care.

Dennis Akkaya 36:14

We've also put effort in the past to share patient stories. The quote was something like, “Consider clinical trials, not as your last option, but as your first option.” We are trying wherever we can to compliantly and to mindfully elevate the discussion about clinical trials. But I would not disagree with you. Sometimes we're a little bit limited to how the system works. And the standard of care in some of the journeys needs to be exhausted before clinical trials might be shared, but we put a lot of effort in educating around clinical trials. That's still needed, and that is the way to go.

These webinars are extremely helpful, but also voices like yourselves to share that thought outside of the companies that are on the service provider side. It will take more to achieve this. But it would be great if clinical trials would be the standard tool in the toolbox that people are presented with.

David Plunkett 37:44

Clinical trials were something I was not aware of. But when my oncologist recommended a clinical trial to me, the advantage was not that I was trying a new therapy, but that I was trying the next therapy in standard of care much sooner than I would have otherwise. I'm enrolled in the [CHAARTED2 \(Chemohormonal Therapy Versus Androgen Ablation Randomized Trial for Extensive Disease in Prostate Cancer\)](#) clinical trial, and I was chosen for the leg that combined both Zytiga (abiraterone, an androgen inhibitor drug) and Cabazitaxel (a chemotherapy), instead of waiting until I failed on Zytiga before trying the next set of chemo. So it's not just medications that are options. There are also options in timing. I got a really good result from that. That's a benefit people should know about.

Dennis Akkaya 38:41

If that is one of the trials that are listed in the reports that we provide, and we can provide some context to that, that always helps patients to consider an option like you described.

Roger Royse 39:06

Do you find trials outside the United States?

The reason I ask: I don't know if you noticed recently, the UK just launched a massive RNA vaccine trial that I didn't know anything about until after it was too late, and I read about it in the papers.

Dennis Akkaya 39:27

It's important to understand that we tried to assess the ability to travel. We prefer not to immediately show trials all over the world. There are complexities in insurance, travel burden to the site, and all kinds of other complexities. But the more information that's available is good. You've discovered this yourself. You want to leave no stone unturned for seeing what potential trials are out there. We do encounter these situations more and more.

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We are able to facilitate cross-border referrals. We're working with some partners to address some of the more technical complexities that come into play, which involve things like visas, work permits, or travel. More importantly the other kind of consent and other complications that arise. We're aware of those struggles for cross-border referrals. A lot of coordination is necessary.

It's something maybe for a future webinar. We could demonstrate how a more seamless experience can be offered to patients. But 80% of the trials are done in the western hemisphere. There are many patients out there that don't live in those countries. Maybe it makes sense for patients to travel to some countries; maybe there are main trial countries and sub-PI (principal investigator, i.e., distributed trials in multiple locations, guided by a lead investigator) models that will be established in the future.

On certain occasions, we might be able to provide trial overviews that are also of some other countries. But, again, it does have extra complexities that we want to share upfront: that there's no guarantee that this can be an easy or successful journey.

Madeleine Carrier 41:47

I've performed several cross-border referrals. It is very complex. As Dennis mentioned, during our treatment search reports, we often try to keep it nationwide. Then if there are no results that are interesting, we can expand our search, but that's only upon the request of the patient and the family themselves.

There are a lot of barriers such as language requirements. Some countries require you to be able to read, speak, and write in that language, and medical visas. It definitely can be done. It is a lengthier process. We are working alongside others to try to make this more seamless and more accessible.

Dennis Akkaya 42:29

Madeleine: how do you ensure that patients and their families are well informed about their options and understand the process well, just to avoid complexities?

Madeleine Carrier 42:51

In the beginning, each patient is assigned a dedicated patient navigator. While we have a whole team, you will have one point of contact. This is to provide that personalized support and eliminate the need for patients to repeatedly explain their case. That's why I mentioned in my response to Clifford, each case is really tailored toward that patient. Even if I have two patients interested in the same trial, their experiences will be different depending on their needs and their concerns. We really take the time to understand each patient's needs and concerns. We answer general questions about clinical trials. We take the time to build upon that relationship. Following each intake call, patients should leave with a clearer understanding of next steps, what to anticipate going forward. At any point a patient can reach out to me or the team via email or schedule another call. Perhaps they didn't ask questions that they wanted to during

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intake, or maybe they've now had a discussion with their physician, and they want to loop them in.

Dennis has also mentioned that our reports are agnostic and are ordered in which the results are displayed, with the most advanced study, Phase 3 first, then subsequently 2 and 1. Within those files, there are clickable links to share more information about each trial, such as description of the study eligibility and site locations. So for understanding that preliminary assessment of the post-TSR (treatment search report, an overview of all the trials) call can be done again with a patient navigator to further explain those options presented in that report.

It's important to note that these results are for clinical trials that they may be potentially eligible for and are based on the information provided. As I mentioned, some criteria aren't easily captured via the phone call. So perhaps the patient didn't have all the information needed to rule out and rule in. This affects the accuracy of the report. We can always go back once they've had other conversations with their HCP (healthcare provider) or new genetic tests done to then refine that search.

In the chat:

Nusantara: If a patient can't access trials due to cross border / travel issues, will expanded access then become an option?

Dennis Akkaya 44:57

Those options are also presented in these reports. Historically, we've always been very strong with expanded access. When a trial is your first option, we have to follow a certain protocol. According to regulations, the standard of care needs to be exhausted, then clinical trials, and only then expanded access. So those are listed at the bottom as the last option. We can debate whether that should be presented in a different sequence. But unfortunately, that's how it is. These are also explained. There is utility for expanded access pathways, and maybe for some occasions where the trial is not running at their sites, that could also be an option. Again, I have to be careful and not promote it, because from an ethical point of view, we need to advance scientific research, and there are some pressures to always push clinical trials forward more than expanded access.

Madeleine, could you explain more about how the relationship works with patients, referring physicians, and community hospitals, and why it works well for them?

Madeleine Carrier 47:04

We encourage patients to involve their treating physicians, who understand their medical history best. Physicians can integrate into our process at various stages. This may entail a one-on-one with a patient navigator. An invitation to our platform can be sent or by simply sharing the treatment search report during their next doctor's appointment to review and aid in that decision-making process. We can set up a three-way call. It's really up to the patient as to how involved they want their physician to be. It does make it better for all parties involved, if they do loop them in earlier, but I would say from experience the best point is after the treatment search

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report call is the most beneficial time to include your treating physician as they can assist with those considerations. If logistics is an issue, such as travel, we want to coordinate that as well to ensure that no unnecessary travel is put on a patient. In regard to community hospitals, if those physicians are at a local institute, they too can be invited to our platform, and they can perform a treatment search report themselves for their patients, and can move us in reverse.

Dennis Akkaya 48:30

On the question about expanded access for those patients that don't fit the trial parameters: if there is an ability to provide the drug outside of a clinical trial, if that's made available by the company, it's not off-label, it could be open to patients with a different indication than what the trial or the drug is being developed for. Most companies tend to do this a little bit later in their development stages, towards phase 3. Some companies have a policy – which is mentioned on the website – that they have a right to decline, so it's by no means a guarantee for getting access to the drug. But they will display their policy on their websites, often next to the clinical trials section within the website. It is an avenue for potential access to the drug.

I don't want to confuse it with “right to try” though. “Right to try” is different legislation, and it's not always only for N-of-1. There might also be group programs where a sponsor or an institution and principal investigator is looking for a group of similar patients. It is something to sometimes explore. You usually have to exhaust a few clinical trials. It is still required to search for trials for consideration before you can move into expanded access. It depends, but it is something that we list.

This part with Madeleine was to explain the importance of being able to help both patients and referring physicians. Referring physicians are becoming an increasingly important target audience for our platform because we know that the academic centers run these trials themselves. They probably have patients at the institution. **We're trying to find and help the patients that are not at an academic center or with a physician that is not doing trials every day.** They might have all sorts of questions, or they still need to know about certain trials. That's where our model provides a lot of value to support the referring physician. We're also looking at a lot of ways that we can support sites where there are a lot of referring physicians.

We just had a webinar for the Hispanic community within neuromuscular to talk about community hospitals and referring physicians, and what kind of barriers they have, and very happily also do one for cancer. In general, the clinical trials sitemap is not the same as where the populations reside, and the less travel burden that we can create for patients, the better.

Brad Power 52:09

How do you position yourself against others who offer similar services?

We had [a session with Massive Bio](#), which offers similar clinical trial matching services.

Dennis Akkaya 52:35

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I can't speak for others, but we want to come across as a partner that can work with patients and physicians. The pharma companies make a lot of these things available. But serving all the stakeholders within the clinical trial ecosystem is what we try to do. Many players are able to build lots of nice technology. Within trial matching, we also have our search engine powered by AI. The care and the eye for detail for the patient journey is what we, as a company, strive to improve every day. We put a lot of emphasis in making sure that the people that deal with patients can do this in the best possible way. So it also comes down to the team. In certain competitive environments, you have the choice to work with many. But we really appreciate when patients have a positive experience with us. Hopefully, it's something that we come across as doing well and learn from especially. Those numbers that were presented on one slide, but we hopefully do that at scale with many patients, and being a partner within this ecosystem.

Brad Power 54:03

Where do you see this area of clinical trial matching going?

Of course, AI is very much in a hype cycle at the moment. So presumably, it could shoulder a lot of the burden of either matching or educating patients or giving them information.

Where do you see the navigation process going?

Dennis Akkaya 54:31

It's a little bit of a hype phase. In two weeks, I'm also going to present why our model is different from others, but I feel that it's maturing, and that we are starting to learn that just attracting patients or creating awareness is only part of the problem. It's really being able to help a patient and speak with them compliantly and gather this information that we've talked about, also to create satisfaction all the way towards the site. So I would see much more mature business models being able to do that.

Being able to get that huge patient pool that are unaware of trials or don't live near to trials also having a great experience in potentially considering a clinical trial. That's the horizon that everybody's aiming for.

Within a couple of years, there will be players, hopefully ours as well, that can do this. But I'm very confident that with this AI technology the necessity and the pressures within the system are going to offer patients a much better journey or experience than they've had thus far.

Madeleine Carrier 56:05

This was a pleasure. I'm so happy that I got to speak with each and every one of you and that it really was an engaging conversation. Thank you for that.

Dennis Akkaya 56:15

Absolutely. I wanted to thank everyone for excellent questions, and we are honored and grateful for this opportunity.

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Chat Discussion

00:11:30 Allen Morris: Almost all bone metastases are osteolytic. Prostate cancer uniquely mainly make osteoblastic lesions

00:19:19 Allen Morris: There are 500,328 trials listed on clinicaltrials.gov. Do you have access to trials beyond these 500k?

00:20:27 Allen Morris: So can I conclude that clinicaltrials.gov is the only repository?

00:21:29 David Plunkett: I found clinicaltrials.gov frustrating to navigate. When I would try searching multiple times with what (I thought) were the same search terms, I would get different results.

00:23:42 erika hanson brown: Every patient needs a knowledgeable navigator. Who pays for this service? Does insurance cover?

00:26:10 Allen Morris: I may have missed your answer. What funds your site?

00:27:54 Brad Power: The biopharma companies who are receiving referrals.

00:28:41 Allen Morris: What biopharma companies are there top referrals?

00:28:52 Allen Morris: their typo

00:29:44 Allen Morris: For example: Prostate cancer

00:29:56 Ryan Moon (he/him): Wouldn't that create a conflict of interest if you're funded by biopharma companies?

00:34:55 Robert Weker: But let's be honest, even at academic institutions, there is often a bias toward trials at that particular institution

00:35:09 David Plunkett: Reacted to "But let's be honest,..." with 👍

00:35:35 Kuldip Ahluwalia: Do you report on patient outcomes (on going) for the different clinical trials that you recommend, or do patients have to wait till the pharma company publish results.

00:39:12 Cheryl Middleton: Is there a way to get into a trial at a distant location but by utilizing a closer/ local location? For example M D Anderson is running a trial that I'm interested in but that's very far away. Is it possible that they'd coordinate with Hopkins (3 hours away) or a local hospital?

00:39:18 Clifford Reid: If a patient has poor SOC treatment options and clinical trial options, what do you tell them about the expected benefit of joining a clinical trial vs. their SOC options?

00:54:09 David Plunkett: "TSR" ?

00:54:26 Nusantara: might be outside of clinical trial as a topic, but if a patient can't access trials due to cross border / travel issue, is expanded access then become an option?

00:56:43 David Plunkett: Still hung up on terminology, sorry. Is "expanded access" the same as "off-label"?

00:57:33 Brad Power: Expanded access is like "right to try" a personalized application for an Nof1 access.

00:57:40 David Plunkett: Thanks.

01:00:40 Cheryl Middleton: this was great! thank you so much

01:00:55 madeleinecarrier: Reacted to "this was great! than..." with ❤️

01:01:18 Nusantara: Reacted to "this was great! than..." with 👍