Unlocking the Power of Real-World Data, A Conversation with Gadi Lachman, CEO and founder of TriNetX

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Episode Highlights

- Gadi has joined Frederic to delve into the essential role Real-World Data (RWD) plays in revolutionizing the healthcare industry
- From unraveling the essence of RWD to illustrating its tangible impact through real-life examples, Gadi showcased TriNetX's profound influence on pharmaceutical companies
- TriNetX has continuously expanded its data repository while optimizing its customers' clinical trial success, from protocol design to site selection to patient recruitment
- Navigating the labyrinth of data privacy and regulations, Gadi has outlined how TriNetX seamlessly adheres to major regulatory standards like HIPAA and GDPR, enabling operations in over 20 countries
- Gadi is a fervent advocate for the integration of AI into the RWD landscape, foreseeing its pivotal role in structuring and harmonizing data
- Gadi envisions creating innovative avenues for clinicians and researchers to interact with and query the TriNetX's database, facilitating more informed decision-making

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Episode Transcript

Frederic Laurier (00:06):
Welcome to another episode of Crossroads by Alantra, where we delve into the forefront of digital health.

In this session, we have the privilege of hosting Gadi Lachman, the CEO and founder of TriNetX, a pioneering force in Real-World Data (RWD) repositories for life sciences and healthcare. Gadi will lead us through an in-depth examination of Real-World Data (RWD), explaining its profound impact on healthcare practices. Through compelling examples, he'll show us how this data is not just informative but also transformative. Join us as Gadi shares insights into TriNetX's global expansion journey, navigating the intricate web of regulations across different countries and the impact of AI.

I hope you find this interview as enlightening and insightful as we did. Welcome to Crossroads.

(00:56):
We are delighted to host Gadi Lachman, founder and CEO of TriNetX, in today's podcast.

Gadi thanks so much for carving time out your busy schedule.

Gadi Lachman (01:04):
Hello my friend, an honor to be on your podcast. Thank you for having me.

Frederic Laurier (01:08):
Thank you for having accepted.

For the benefit of our listeners Gadi, can you quickly walk us through your bio? Well, I'll walk us through your bio, but after that, could you walk them through what TriNetX is about?
Hopefully, I got most of your bio right. You were born and raised in Israel, came to the US for your MBA around 9/11, if am not mistaken. Pretty timely, unfortunately. After a stint in investment banking, you moved into the corporate world with a special focus on healthcare. Before founding TriNetX, you worked at the likes of TriZetto, Eliza and Amwell.

Probably best to hear it from the horse's mouth, so could you give us a short introduction on TriNetX please?

Gadi Lachman (1:51):
Absolutely. Happy to.

So TriNetX is a 10-year journey to build the world largest platform for clinical trials, solving the massive problems that could be done much better with access to global data and in a sophisticated way to generate insights from their data and software, topped with really smart people that can even help you ask the right questions.

Pharma industry, don't need to say much about that, but if you look at a large pharmaceutical company, they basically have 2 major businesses; (1) R&D side, where they develop new life saving therapies and (2) once those have been successfully completed, where they market them and you can see what's working better, what's working less and making adjustments to save patient lives.

Episode Transcript

(02:55):
TriNetX was formed to democratize the world's data, to bring a massive clinical global data set and access to patients to help pharma companies deliver the development faster, cheaper and with more quality, so to do a better job on the R&D side of their business. Then once those drugs are live and saving people lives, to help pharma companies understand how their drug behaves in the real world with many more patients, many more countries than they were tested in. This is TriNetX in a nutshell.

Frederic Laurier (03:36):
Taking a step back, you just touched on Real-World Data (RWD). Can you describe to the audience, in simple terms, what Real-World Data (RWD) is about? How has it evolved since the foundation of the company 10 years ago? Can you also shed some light on the differences between RWD and RWE (which stands for Real-World Evidence)? Shall we think of them as simple synonyms?

Gadi Lachman (04:01):
Excellent. I never heard the term RWD, Real-World Data, in my life until I joined this subset of healthcare vertical, which is the life sciences industry.

So, what everybody else in any vertical, especially in healthcare, just calls “data”, in life sciences there is “data” and there is “RWD data”. “Data” is, historically and mostly, what's collected during a clinical trial, or in a test for a new drug on new therapy. Then “RWD” is what everybody else in healthcare calls “data” which is the data generated from everyday care, normal people, any facility, any interaction with the health system. You get sick, you visit a hospital, everything that happened to you there, that's what this industry calls “RWD data”.

I'm not sure I'm going to do justice to the difference between the “D” and the “E” but realistically, one is the data, the raw, the core asset itself and all those facts that are being generated when humans interact with the healthcare system. Evidence is what you can infer from the data, what you can analyze the data, what you can learn from the data, is historically called “evidence”.

But for all intents and purposes, it’s what's happening in the real world with real patients and real medications and real surgeries and procedures and everything. How can that asset be helpful in the life sciences, life cycle of development and marketing and selling of drugs. That's the industry where we operate.

Frederic Laurier (05:45):
And terminology is just that, right? What we care about is how this data can help.
This leads me to my next question: can you explain what the main use cases are for your various datasets and provide real-life examples of how they have positively impacted drug research or patient outcomes?

Gadi Lachman (06:06):
This is a great question, and I would answer everywhere so, I'll give you just some very specific examples on the pharma R&D side where they develop new drugs and therapies, and then on the post-approval side where those are live in the marketplace and there's a lot of insights that need to be generated there.

Episode Transcript

(06:23):
On the R&D side, and I'll draw from the experience of TriNetX, we help large pharmaceutical companies and obviously support large CROs (Contract Research Organization) mainly on the R&D side in the following 3 areas:

1. Feasibility and protocol design

We, with our data, with our analytics and with our people help pharma design better and more efficient protocols that have inclusion/exclusion criteria that, on the one hand, answer the scientific and commercial question of what needs to be the purpose of the drug, the label, everything that you need to hit your target for. Then on the other hand, maximizes the catchment, the amount of patients that are eligible for those studies and doesn't reduce them for the wrong reasons.

We've became the fact of the way pharma is designing protocols. Almost all large pharma and almost all our CROs, when they designed the protocol and do their feasibility on the TriNetX platform, they maximize the inclusion/exclusion criteria so that the largest amount of patients could be eligible for that study. These have massive implications down the road when pharma is coming to recruit those patients. Those studies are more successful.

There's another big thing with protocols, they often get amended. Every time you amend the protocol it's a setback of anywhere from 6 to 12 months in the development cycle of their drug. One large pharma told us, and actually announced publicly, that, since they've started to make all their protocols be written on the TriNetX platform as a gate to becoming live protocols, they have reduced the number of amendments by half. This is a massive impact on the time it takes to bring a new drug to market faster. So, protocol design feasibility is one very important area where auditability impacts drug development.

2. Site selection

We have hundreds of sites in more than 200 countries all over the world, from the US to Latin America, many countries in Europe and many countries in Asia and Africa. So, we are helping pharma go to the sites that have the most patients that are wanting for those studies, and they will respond quickly. They will accept those studies more; they will find a PI (Principal Investigator) and all that process is just going to happen faster with sites where it's going to be more successful.

I have a lot of examples there where pharma is awarded their studies to the TriNetX network sites, those usually are being accepted within 2 or 3 weeks, as opposed to the industry standard which is 2 to 4 months. I will also say that even a quick no is very valuable because nothing happens, nobody wastes time. All good, move on to look for other sites.

There's another big difference with us, which is those trials are being awarded and offer to the clinical trials offices at those sites, and they're finding the best PI (Principal Investigator) for the job who works at the site. From a business standpoint those relationships extend very deep to make that trial allocation process more efficient.

Episode Transcript

(09:43):

3. Patient recruitment

We use our data, and our sites use our data and our software to find the most, the largest amount of patients eligible for their protocol. Then they go about recruiting them. Anecdotally, we just learned for a large pharma, one of our largest sites in Belgium, that just recruited 2 patients of a study that was awarded to them through the TriNetX platform. It's just an anecdote, but it's a very nice proof that when you use data, you use software and analytics, it actually moves the needle all the way from feasibility, to trial allocation, to sites, and to patient recruitment. That workflow just becomes more successful, so that's a great job on the R&D side. I'm just proud of the team.

The other one on the R&D side has to do with External Control Arms. When you are in a lot of rare disease or oncology studies, there are ethical and also operational questions. Do you want or can you recruit patients for the control arm of the study? And just as an example, if you recruit a patient for the placebo arm, you're pretty much taking responsibility on the outcome and, as much as this is good for mankind and for future generations, for that particular patient, it's a very difficult ethical question. We have just delivered, also another example, two very large control arms for an oncology study for a top 5 pharmaceutical company in Germany and other countries in Europe, and we have actually recruited a lot of patients for those control arms. This just makes you feel good because you use normal patients, normal care, in all those key countries in Europe and you don't have to spend the effort on recruiting that control arm, you can just focus on people taking your experimental drug. So, that's another very powerful use case that I just like seeing. I think it's just better for mankind, makes you feel, you know, good at the end of the day that you're doing things like that.

And then, on the post-approval side, we help pharma answer a ton of clinical questions; who is taking my drug versus the 4 other competitor drugs? Is my drug being taken by more elderly people, younger people, different ethnics? What is the difference in the usage of my drug? And also, what is the outcome differential between my drug and other pharmaceutical drugs or other procedures, versus surgery, versus other types of care? And so on and so forth. We see all the drugs that are in the market. We at TriNetX are the first to see them launched because we go after clinical data, that's directly connected to the hospitals, and we can help pharma learn what's really happening.

It's also something very interesting when you do a clinical trial phase 2 phase 3 study, with 200 patients, 400 patients, maybe thousands of patients, in that study, which is a very lab environment, because it was very hard to get those patients into those studies. But now your drug has been approved and something that was tested on a couple of hundreds or a couple of thousands is now being taken by tons of thousands and hundreds of thousands of people and it's also people that you didn't have in your study. So, let's say you tested it on patients ages 30 to 60 just as an example. Now, there's an 80-year-old patient that's taking your drug; what's the impact on that 80-year-old person? Because now this drug is in the wild and it's helping people that maybe their makeup was not exactly what you had in your study, which is fine, but helping pharma learn with Real-World Data it's almost like a continuation of the clinical trial if you will, but now in the wild.

Episode Transcript

Frederic Laurier (13:51):
It's a feedback loop to some extent, right?

Gadi Lachman (13:53):
Exactly it's amazing. Exactly what you said.
It's a feedback loop and it's also a way to accelerate the design and the delivery of new lifesaving therapies into the market because, for example, with COVID-19 you didn't have 12 to 15 years to develop those drugs, those vaccinations that it usually takes. You just do the development faster, making sure it doesn't kill people, It's not poison and there are no bad effects. All good. But then you unleash it to the wild. Why? Because of the urgency, because people are dying. And then, in the wild, you're doing your almost continuation of your clinical trials now with hundreds of thousands of people. So, we were part of that, we were part of the development of almost any COVID vaccination or drug, and we helped with this quick feedback loop, to your point, showing pharma what's working, how is it working, risks associated with things, and so on and so forth. I think it's huge because in the future, with heavier usage and of Real-World Data on the backend, you potentially could accelerate from 12 to 15 years to maybe 3 to 5 years. And they just rely more heavily on RWD at the back end to make sure the right things are happening.

Frederic Laurier (15:05):
Magic happens only if you get the data from patients. As of today, you've collected information on over 200M patients, which is just mind boggling in terms of just sheer size, in 20+ countries. Initially, were hospitals hard to convince in terms of granting you access? Has it become easier as you have become a known quantity to hospitals?

Gadi Lachman (15:34):
Beautiful question.

In any and every innovation you first start with those that are, you can say, more brave, willing to see the risk and the problem and understand they need to do something to fix it. Then after you get some adoption, it goes viral and it becomes much easier, because, you know, the first hospital in Italy is much more difficult to get than hospital #9 in Italy, because then they trust the process.

We have a very heavy investment and focus on patient privacy on regulations around patient and data privacy in healthcare all over the world, GDPR, HIPAA, all that. On one hand, we're a very conservative company and our hospitals and HCO (Health Care Organization) partners really appreciate that. On the other side, you need to bring a lot of data to those that are the researchers on the clinical side (pharma, HCOs, CROs) because without that, they cannot do their job and we doubt that there will not be new lifesaving therapies.

We walk a fine line between patient privacy laws, which we respect tremendously, and the need to put massive amounts of deidentified and anonymized data in the hands of researchers. We do that very carefully. We have a very big infrastructure to protect that privacy and comply with the GDPR, HIPAA and other regulations in all those countries.

Episode Transcript

Frederic Laurier (17:14):
Which country is the hardest to deal with data privacy and get approval? The EU has the reputation of being the hardest, has that been your experience?

Gadi Lachman (17:27):
I love the EU and I love GDPR because, people often think that GDPR is harder than HIPAA, which in a couple of instances, it's just more detailed or maybe stricter, but what I like about GDPR is that the EU is pushing forward the usage of data for clinical research. They've put it as a target, something that they want to facilitate and push, they're saying: "here is our framework". It's GDPR, its other country specific privacy laws, if you comply with this framework and if you make the right definitions of who you are and what is the level of anonymization of the data you're dealing with, then you're good to go.

We designed the architecture in such a conservative way that we want to comply with the strictest country out there, and if you do it, then you are good with all the countries.

Frederic Laurier (18:28):
Does it make it a higher bar to have an integrated clinical trial design across boundaries and geographies, if you have to deal with the GDPR constraints in the EU or constraints imposed in the US, being HIPAA or others. Does it make it harder for you to have it into a single repository that you can offer to big pharma that want to run trials across borders?

Gadi Lachman (18:55):
This is great because part of our mission at TriNetX is data harmonization, standardization of data and processes and languages. So, it's very difficult to install our solution and harmonize it. Even in 2 instances in the US, you just need to do a bunch of translation and mapping and this and that, and we're very good at that but it doesn't make it easy. Now we need to harmonize data from Japan to Germany, to Italy, to Spain to the UK, to Poland, to Brazil, to Israel, to the US, Taiwan and is a massive undertaking. This is where we spend most of our time and we became good at that, in harmonizing that data.

When a pharma user is logging into the TriNetX platform, or when my pharma customer is buying data from TriNetX, they rely on us to already do the quality and harmonization and standardization work across all those countries. What we serve them is something that is very easy and simple for them to work with because we have already done all the mapping. It's a great question because it's a huge challenge and it's actually also fascinating.

Even when you harmonize simply a standard of care, it's very different between countries. A same disease patient, walks into a US doctor office, and a UK and an Italian doctor office, and may get similar suggestions or not, depending on a lot of things. We can see that. We can see the cohorts of those disease patients and the different treatments that they're taking in all those countries. That's okay because at the end of the day, once we harmonize the data, the pharma business is really local. Pharma sees each country as its own market where they have to develop and then they have to sell and compete and market their drugs. So, they're benefiting a lot from the fact that we have the country's specific data, because if you just take data from the US and think it's applicable across the planet, it's just not. As much as we think the world is one place and one big happy village, it's actually very local. So, we make that jump, local versus harmonized sets, pretty well and it's just very valuable to any researcher.

Episode Transcript

Frederic Laurier (21:35):
Pharma is the one end market where really they see the planet as one market, one integrated market. To your point, Healthcare tends to be localized, but for pharma they really want information from all the main geographies.

You mentioned before, when we did the preparation call, that you're no technologist. I understand that both of us have our common limits in the field of technology.

I would hate not to ask you about what AI (Artificial Intelligence) has meant for your business in terms of data management. You talked about harmonizing the data. Have the newest tools helped at all with that on that front? And secondly, how are you thinking of integrating AI in the decision-making process for clinicians?

Gadi Lachman (22:25):
I'll take a step back to tell you where I think it fits.

Every company in my space, but also in and almost all verticals, can be analyzed in answering the questions of: what does it do? And how does it compete and how does it differentiate in each of the following 3 layers: data, software/analytics and services? So, for example, TriNetX differentiates with data because we have the only global network out there that has very rich clinical data. For us, the second layer, software/analytics, this is where you allow people to interact with the data and generate insights. The last layer, services, is that sometimes you have to deliver a complete project A to Z, and we are able to do that as well by having very smart people to help write the questions, design the study and then deliver it to you where they need to take care of the software and they need to take care of the data, so AI/ML are huge advancements.

We use a lot of AI and ML in many different ways. I'll just give you a few examples. We use it in how we mine and structure data, so when you have structured data after a few mapping iterations, it's good to go. When you're dealing with unstructured, the more sophisticated your AI/ML is the more significant level of insights and data. You can pull from the unstructured data such as physician notes and things like that, so we use it there. So, it's a use case of mining data. The other use case we're implementing now a lot of ML into so we will enable the pharma user to interact with our data and with our networks in ways that are much more natural to them, in other words, having a conversation with the data.

A lot of the AI/ML for us is, in a way, interacting with the data in a much more expanded way if you will, and also on the generation of reports and answers. We see massive value in AI/ML. So, I'm very excited about that. I'm very excited about that not as an engineer, because I'm not, or a clinician, because I'm not that either, but as a businessperson. I just think it makes this unknown scary world of clinical data and the world of algorithms and sophisticated analytics to something that more or less sophisticated users can now generate those insights and I think it's just going to exponentially increase the amount of insights, correlations, learnings that are going to be generated from the data we already have. That's another very exciting point because what I already have in TriNetX can do so much more with that level of analytics that are coming into market now. So, we are extremely excited about that as well as our customers.

Episode Transcript

Frederic Laurier (25:40):
One last question, or maybe two questions combined into one, and then we'll let you go Gadi. You've been extremely generous with your time. Aside from supplying data, what else do you think pharma companies are expecting from vendors such as yours? Do you feel that, at some point, they would see consolidation amongst data vendors in a favorable light? Would they expect it?

Gadi Lachman (26:05):
Great Question. First of all, I say pharma is exciting, is expecting me to deliver data, to deliver insights and to deliver patients into their clinical trials. We do all of those 3 and this is extremely valuable for them, especially when you look at the global scale and the footprint, doing it consistently in all those countries. It's a great question about consolidation. Every industry goes through cycles of innovation. It's a funnel. A few survive and few get profitable. We are growing fast and we are profitable, and this is very important to keep running a sustainable business. I definitely expect consolidation in my space to happen. It's just natural.

Bigger is better. I think my pharma customers, my CROs customers, even my HCOs customers would love less vendors and more use cases and more value from each of them. Also, when you combine forces strategically, then there is an integration at the backend business processes, data and software, that just happens because you are closer to all of these and there's just a lot of value that's created there.

Frederic Laurier (27:20):
A little bird is telling me that maybe you're going to be part of that consolidation play, but we'll see.

Gadi, it's been a real pleasure having you on the podcast. Thank you so much for having taken the time, and I look forward to seeing you very soon.

Gadi Lachman (27:34):
My friend, thank you for having me. It's been an honor. Talk soon. Thank you, sir.

Frederic Laurier (27:39):
Thank you for listening to another episode of Crossroads by Alantra. Today, we dove deep into the world of Real-World Data (RWD) and explored the significant impact TriNetX is making.I would like to highlight a few key points from our conversation to underscore the importance and the impact of these topics. First off, RWD provides immense value to pharmaceutical companies. It helps streamline protocol design, increasing efficiency, and aids in site selection for clinical trials as well as supporting patient recruitment.

We can't overlook the huge impact TriNetX has by providing pharma companies with data on how their medications perform in the real world, affecting millions of lives. The value of these insights is truly incredible.

Lastly, let's not forget about the future. As we gather more data and leverage AI, the potential benefits for society are immense. We're on the brink of tremendous advancements, and it's exciting to think about what lies ahead.

If you would like to learn more about Digital Health please subscribe to this podcast and feel free to reach out. Thank you for joining us on this episode. Until next time, stay curious and stay informed.
Take care.

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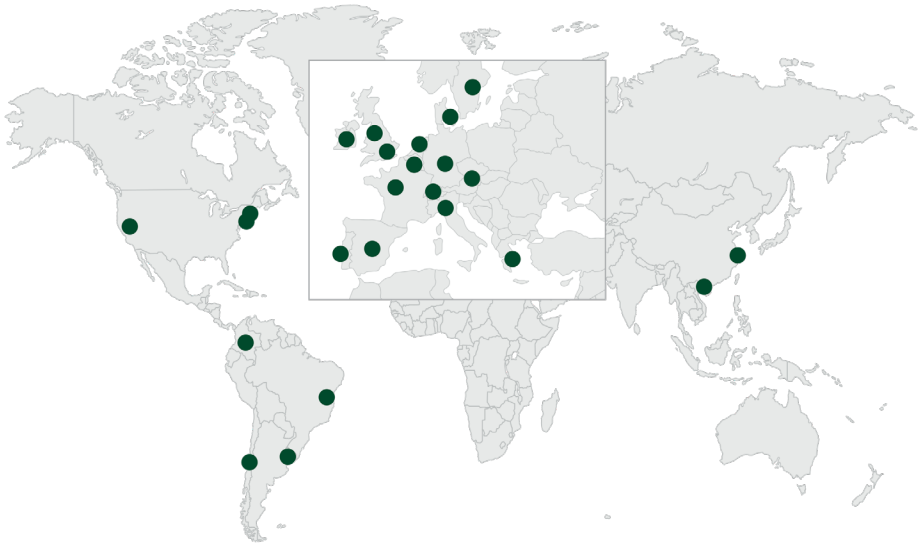

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