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ALEX MAIERSPERGER: Many of you have pondered the age old question, what do vaccine development, digital marketing, lunch, and patient engagement have to do with each other? Today, we get the answer. I'm your host, Alex Maiersperger. And in season three of the Health Pulse YouTube series, we celebrate leaders changing health care and life sciences for the better.

Today, we get to welcome and celebrate Dr. Tobias Kruse, founder and CEO of Trials24 and Pharma-Lunch. Welcome, Tobias.

TOBIAS KRUSE: Hi, Alex. Thank you for having me. Happy to be here.

ALEX MAIERSPERGER: So you've got a few entrepreneurial ventures under your belt now. Were you born an entrepreneur or is that something that sort of appeared during your journey?

TOBIAS KRUSE: Yeah, actually I was not at all born an entrepreneur. And, if you will, I have even like the most anti-entrepreneurial background that you can imagine. So just let me explain. So about me, like I'm born and raised in Hamburg, Germany, and I was born into a family with steady government jobs. So my mom was a teacher, my dad was also working for the government. And in Germany these jobs are kind of the most risk averse jobs that you can actually have. So it gives a lot of security, so that's the good part, of course. But it also does not really foster an entrepreneurial mindset in the kids born into these kind of families.

And on top of that, I also didn't have any friends doing entrepreneurial stuff, you know? So none of my circle of friends were entrepreneurs. So when I decided to found Trials24, my grandma-- she's 100 years old now and I absolutely love her-- but her first reaction was, Toby, how will you earn money? And my dad also went on top of that and came and he was like, you will have a gap in your retirement later. So that was how I started my entrepreneurial journey.

And so I had no backing of my family, no friends that I knew or something like this. And on top of that, I even decided to bootstrap my company 100% with my own money, with the little money that I had saved after my PhD, which was like 12.5 thousand euros, and that's kind of the minimum that you need in Germany to found a German GMBH company.

ALEX MAIERSPERGER: Were these your first entrepreneurial ventures?

TOBIAS KRUSE: Yeah, actually Trials24 came first. And it's kind of a journey how that even started because it's not that logical to found a service company within the pharma industry with kind of no real background experience. I studied molecular biotechnology at the Technical University in Munich and I did my PhD there. So I was part of the university research team that developed an vaccine against Helicobacter pylori, or in short H. pylori, and I was an absolute scientist there, right?

So I had a protein biochemistry background, I was developing production processes for vaccines. In this case, they were proteins. And my project that I was part of got a big grant from the German government so there was around \$4 million euros, and that's a lot for a German University. So always when you hear German numbers, you can almost 10x it and then you have what it would have been like in the US probably.

So this project went very well and we raised a Series A 2014, which had \$13 million in funding. So again, thinking of something like 100 million euros probably in the US. And then we founded the company in ImevaX and we spun it out of the university. And a colleague and, as I said, were responsible for the production of the vaccine.

And it was quite challenging, but we managed this. And then after that, of course, the clinical trials started. So here's where the journey then really started with Trials24. Because one day-- so our company, everything was dependent on this one clinical trial, right? We had one lead candidate. Everything was riding on this one clinical trial. And then one day, the clin ops team-- you know, I still remember this. Sitting in our open space office and the head of the clin ops team looked up and she was saying like, we need to cancel our first study. Like we don't get the H pylori positive patients.

Now, here's an important piece of information to know why this is so surprising. So Helicobacter pylori has a crazy epidemiology. 50% of the people worldwide have it, and even in industrial nations you have 20% to 30% of the people having it. So how on Earth, with every fourth person running around outside, how on Earth could we have a patient recruitment problem? No one saw that coming.

And as I said, we were a small startup, small company, like 15 people, give or take. So everybody who had a suggestion was actually welcome to bring this one forward, right? And yeah, I looked at what we were doing in terms of patient recruitment, like, coming from the sidelines I was a scientist, had no idea of patient recruitment or anything like this. And I looked at what we were doing and it was all print media, making flyers, running ads in physically printed newspapers. So very, very old and classical ways.

So I asked, like, why don't we do this digital? Like why don't we go to Facebook, Instagram, and Google? And that was in 2015, so these channels already existed for quite a while, right? And now one important point about me to know is why did I have this suggestion? And the reason was that throughout my life I always had some kind of side hustles, right?

When I was a student, I was a multi-year a member of Toastmasters. Maybe in the US you probably it--
ALEX MAIERSPERGER: Awesome.

TOBIAS KRUSE: Toastmasters is a speaker's organization where you're in public speaking. In Germany it's not that well known, but I loved it. Like I was there for three to four years. And then also my next slide has to started because my club here in Munich, the Munich business speakers-- shout out to them-- needed a new website, right? And then I started building websites.

And my latest side hustle back then now when we had the patient recruitment problem was online marketing. I was absolutely fascinated with online marketing. I had no idea what I would ever use it for. It had no practical application to my biotech studies. But I just did it. And now here comes this patient recruitment problem, right, and I realized patient recruitment is also just marketing, but it's in a highly regulated industry.

So everybody calls it a bit different, like they call it awareness campaigns or whatever they call it. But in the core it's still marketing. So you have an offer with your clinical trial and you try to get patients interested and participate in this clinical trial. So at the time, nobody was doing it actually in Germany. So in 2015 we had, I think, three companies that were doing it, they were all doing it a bit differently. And in the US, which is usually 5 to 10 years ahead of the German market, we had also just a few service providers that were doing it. And I really didn't understand that because in the literature it says 50% to 80% of clinical trials have a huge problem with patient recruitment. So I didn't understand why there are so few service providers in this space.

Like an MBA student would probably look at this and think like, wow, there is like all this money is lying on the streets, right? But a good friend of mine-- and I really love this-- he always says, like, you never if it's a green meadow or if it's a graveyard, right? Because all the failed experiments from companies that tried and died, you just cannot see them.

And later I also understood that it's just a highly regulated industry. So in these type of industries, nobody wants to be first. No one knows how these channels work in digital marketing, data protection, information security. You have a lot of compliance issues with pharma companies talking directly to patients. So they shy away from it. And no one-- and on top of this, no one believed even this approach would work.

ALEX MAIERSPERGER: So it sounds like those side projects and the side hustles, as you say, have worked out for you at different times throughout your career. What's a side project you're working on now?

TOBIAS KRUSE: Actually a side project I'm working on now is non-specifically because Trials24 is my side project, my main job, and my hobby all in one. But you're absolutely right.

ALEX MAIERSPERGER: So Tobias, you were on the science side as a protein biochemist developing the vaccines and then jumped into the patient recruitment side of clinical trials. This is seemingly far from that science side and your roots. How do you blend those two together, and is that helped you in creating the company?

TOBIAS KRUSE: Yeah, absolutely. So I can say if I learned one thing as a PhD, it's this. Like I can build a hypothesis and then design and conduct the experiments to prove the point, and then of course communicate this as well. So when we had the company-- at ImaveX-- when we had the problem of patient recruitment, what I then did is like I built a survey for patients that just showed the proof of concept.

So we asked the patients what we needed to know of them. Like do you have H. pylori, do you want to participate in this study, and so on. And the results were so overwhelming. We had 2,500 patients responding in five days. So much more than we needed for our trial. And that showed it was clearly working.

And the fun part of this was even the data that we got out of the survey completely matched the latest peer reviewed publication on the epidemiology of H pylori. So I saw that this approach would work. And we just had one issue. So when you are at the sponsor, you are not allowed to do much of the things internally because you are not allowed to talk to patients and you are not allowed to try to get them into the trial because many trials are run in a double blind fashion. So doctors and patients don't if they got the medication or not. And they also don't want sponsors then to talk to the patients to not influence the results of the trial.

So when I was still at the old company, I thought, like, of course we can outsource this process, right? But the issue was there were no companies that we can outsource this to. So we took a marketing agency here, took a call center there, and I contributed a lot of course to this but they had no pharma background and so on. So it was really hard to explain them all the compliance and quality management and ethical approvals processes.

So at the end of the day, the cool part was this whole digital patient recruitment that I set up in the old company saved the clinical trial, right? Patients came in, they were way more qualified with our online screeners, and we closed recruitment one month ahead of time. And it was like nobody hears of closing clinical trials before the timeline that they actually planned.

And on top of that, we saved over half a million in our budget. And it still took me-- after that experience, it still took me almost half a year to really say, hey, maybe I should find a company.

ALEX MAIERSPERGER: One problem that's popping up as a trend is diversity in clinical trials, it's starting to get a lot of attention. We certainly have to develop and know that drugs work for a whole range of people and backgrounds. How is the work that you're doing creating diversity in clinical trials?

TOBIAS KRUSE: Yeah. Yeah, that's a good question. I mean, the diversity in clinical trials is especially a big topic in the US. I would say in Europe it's a little bit less of a hot topic. But our work definitely contributes to bringing in diversity. Because with the digital recruitment, you have so much more opportunities to target specific age groups, specific ethnicities, and reaching just more patients than you would only have at a certain site.

So let's consider you're opening a lot of clinical trial sites in big cities, right? Let's say New York. And you open this in a certain part of the city where some groups are underrepresented. The chances that these groups are at this specific clinical trial site are pretty low. But if you just bring the awareness campaigns to the other parts of the city, somebody could just drive over there and just take part in this clinical trial. So that's not an issue at all. And with digital patient recruitment, you can enable these types of bringing in more diverse populations to the clinical trial sites.

So if you wait, it's much, much more inclusive, and the hot topic in the industry here is like the decentralization of clinical trials to really bring in patients from everywhere.

ALEX MAIERSPERGER: Given what you've shared already and knowing how much disruption and transformation exists across both the health care delivery side and the life science side, what do you think the future of patient engagement and patient recruitment is going to look like? What should we be anticipating?

TOBIAS KRUSE: Yeah. So I think you should anticipate a lot of innovation ahead. And what I think is that in B2B, or if you want to say like B2P-- so B to patient-- in pharma the issue is that it's probably behind digitalization by 10 to 15 years over the normal business to consumer markets.

So I would give you three statements to this. So one very contrarian take and two normal takes, I would say. So my contrarian statement is I don't think that AI and automation will be a big part here in the next 10 to 15 years. And I will give you my example for this. So if I look at Apple's autocorrect on the iPhone, in Germany it just doesn't work probably. It correct happy birthday every single time that you want to type it in German, right?

And if I see this type of artificial intelligence, I'm very doubtful that all the chat bots and everything that is promised in the health care space will solve these very complex patient situations and patient problems when they would rather talk to a human. Now, that doesn't mean that probably after this time horizon that will play a big part, I just don't see it happening too early.

But what I do see is point number two and three. So digitalization is the big part in-- will play a big part in patient recruitment and patient engagement in pharma in general. So one example is that we also developed an internationally scalable patient CRM solution for our workflows, and we manage this, the sponsor sees everything pseudonymously, and sites can work with the patients.

And just bringing these type of digitalizations into the space is very helpful. Because think about it, in Germany lots of hospitals or doctor's offices are still using paper records. Not electronic, paper records, right? So if you come from this point of view, digitalization will be a huge part.

And the other thing that I think will play a major part in the next 10 to 15 years is the focus on the patient itself. So the word in the industry for this is patient centricity. And patients will play a much, much bigger role in the future. So the FDA just gave out guidelines where they encourage and actually want so-called patient-focused drug development, and they want patient engagement in medical device development. So the regulators are asking pharma companies to actually talk to your patients before you develop any drugs or any medical devices. Now, that sounds a bit crazy because why wouldn't they talk to the patients? But as I said before, it's a highly regulated industry and talking to the patients is more a compliance matter.

So it's not that easy. But it will be a much bigger and will play a much bigger role that pharma companies, medical device companies will talk to the patients and get them into the loop in terms of developing their drugs and medical devices.

ALEX MAIERSPERGER: Tobias, there's so much negativity as well in the news, and certainly you talked about some of the challenges and problems that exist all throughout the health care and life science base. On the opposite end of that spectrum, the optimism for the future is one thing that we try to leave guests with. What are you optimistic about or what's something that makes you optimistic about the future?

TOBIAS KRUSE: I'm absolutely totally optimistic with the entire, for example, what we saw in the corona vaccine development. So I know that is, of course, a controversial topic, but what many people that don't come from the industry might not know of is that the regulatory side of it behind all these clinical trials, all the drug development, it's so regulated and slow. And that pharma companies, regulators all came together, developed the vaccine within one year. It's absolutely amazing. It's absolutely unthinkable before this pandemic.

And I think out of this collaboration, out of this speed improvement in terms of developing drugs, there will be a lot of benefits for patients coming with faster drug development in general in the future.

ALEX MAIERSPERGER: Dr. Kruse, so appreciative of your time. We know that there's infinite demands on your time. We're so glad that you could spend a little bit of it with us today. Thank you.

TOBIAS KRUSE: Thank you so much.

ALEX MAIERSPERGER: And for listeners and viewers, again, we're so appreciative of you joining in. We know there's infinite demands on your time. We know there's so many challenges in the world. We hope that wherever you are you get the chance to see the good or be the good around you. We'd love for you to join the conversation, give us questions, comments, here in the comments on YouTube or at our email address thehealthpulsepodcast@SAS.com. Thank you.