Clinical Trials as Revenue Drivers: Interview with Matthew Amsden, CEO of ProofPilot

Matthew Amsden is the founder and CEO of ProofPilot, a platform to design, launch, and participate in clinical trials. Nearly everyone accepts the fact that technology has democratized journalism at transportation and retail. Now ProofPilot is trying to democratize clinical trials by making it as easy to design and launch a clinical study as it is to write an email and at the same time turn clinical trial participation into a universally accessible experience leading to a journey of self-discovery.

ProofPilot medical device customers include a combination of consumer and medical brands like Joovv, Asus or Fisher Wallace, Amber and ChiliPAD, and various others. In this interview with Matthew, here are a few of the topics we discussed.

- Why clinical trials are not only feasible but critically important for all health care companies.
- The origin story of ProofPilot and how the company has evolved over time.
- The importance of letting your early customers drive product iterations.
- How clinical trials can become a revenue driver instead of a cost center.
- Various types of remote and hybrid clinical studies that can be conducted on the ProofPilot platform.
- The risky and costly approach to traditional clinical trials and how those can be significantly resolved through a virtual hybrid model.
- Matthew's favorite business book.
- The mentor he most admires and
- The advice he'd give to his 30-year-old self.

All right. Without further ado, let's get to the interview.

Scott Nelson: All right. Matthew Amsden, Founder, and CEO of ProofPilot welcome to the program. Really appreciate you coming on.

Matthew Amsden: Thank you. It's my pleasure.

Scott Nelson: I'm glad that we're finally able to record this because it's a conversation that is sort of our topic in conversation, that's sort of near and dear to my heart just because I'm sort of personally biased towards what you're doing with ProofPilot but having worked together for, gosh, probably close to a year now at least, it'll be fun to kind of riff a little bit about our experiences and learn a little bit more about the origin story, maybe some stuff that I didn't even realize before about ProofPilot but looking forward to the conversation.

Matthew Amsden: Yeah. For anyone who's listening here, at first, I need to say thanks to Scott ProofPilot is where it is today. Without him, I don't think that we would know a lot about what we know now, and he's been one of our biggest champions, though I hope that you actually do a

balanced interview with us. But I just have to say straight out, you've been great, and you've been a huge supporter and we couldn't have done it without you as a customer and a partner.

Scott Nelson: I know. I totally appreciate those kind words. You make me sound way more instrumental than I have been for sure. But no, I appreciate the kind words especially coming from you. So, on that note, I think that serves as a little bit of a nice starting point. So, I'm going to take people back in time to roughly about a year ago. We're knee-deep with Joovv related work and for those that are listening, that's where I spent the better part of the past three or four years focused on is Joovv, which is a direct to consumer kind of wellness in a general health company, even though our product, our class two medical devices, it's very much a direct to consumer kind of wellness play. But this was close to a year ago.

We're recording this in May of 2020. I think, Matthew, if my memory serves me right, you sent us a cold email or sent me a cold email kind of with a reference to Jean Nehme, who's the founder of Touch/Digital Surgery, which recently sold to Medtronic. I think he's an investor in ProofPilot or affiliated with ProofPilot with a pitch around basically sponsoring or running remote clinical trials in a very cost-efficient or cost-effective fashion.

This stood out to me because I know firsthand that clinical trials are super expensive. Doing it the traditional way, and then at Joovv we had an interest in sponsoring more clinical trials, not necessarily for like a definitive regulatory pathway but just to collect more clinical data about our devices and red light therapy in general. So, it kind of stood out and it was good timing, but it really opened up some really interesting things with ProofPilot and allowed us to explore some different channels. So, maybe let's start there and help people understand kind of what ProofPilot is and what your platform and offer looks like today.

Matthew Amsden: So, that is correct. I did. It was one of the very few cold emails I've ever written, but I had been hearing about Joovv on other podcasts and in writing and I believe I had recently read an article about Joovv and its effect on testosterone. My thought process was is this legit? Is this for real? And because of what I do, because of what ProofPilot is which is a platform to design, launch, manage and participate in trials, I thought okay, well let's actually reach out to these folks and see whether or not they are confident enough in their product to actually run trials to support some of these really very powerful claims and stories that I was seeing out there in the press, both social media, press and traditional press.

So, it is true. Jean Nehme is an investor in ProofPilot. We actually shared an office together for a period of time in New York when we were both very young companies. I understood that you had worked together, that was our connection. So, I reached out and you were one of those folks you just kind of got it immediately and by get it immediately, I mean, the following. So, when we think of clinical trials across the board the first thing that comes to mind is Pharma, pills, vaccines, stuff like that. Probably right now in the world that we're living in, we're recording this in May of 2020 so a vast majority of us around the world are still in lockdown, although some of us are starting to enter the world again. We're all looking for solutions to get back to the world that we knew beforehand.

But regardless of whether it's COVID-19 or any other issue, Pharma runs lots of clinical trials on an ongoing basis, about 25,000 a year actually.

So, that's number one. You think Pharma. Number two, when you think clinical trials, particularly folks who are in the industry is big dollar signs. The average Pharmaceutical trial, this is phase three and phase four mostly costs well over ten million dollars. From ProofPilot's perspective, that means only a very small number of the research questions that are out there in the world actually get answered. In fact, when we look across the overall health care ecosystem, only about 30% of medical treatments that are conducted in a US hospital actually have evidence to suggest that they actually work. The gold standard to create that evidence is a clinical trial.

When you move outside of the hospital, which is where most health happens when you look at health optimization when you look at health prevention, there's even less evidence, there are even fewer clinical trials because they're so expensive. So ProofPilot was originally developed with this idea and I say this fully noting that I am a venture-backed startup. So, pardon the colloquialisms here. We started ProofPilot to democratize clinical trials so that we could get answers about what works and what doesn't to improve health much faster. So, circling back to how we became connected. Again, that cold email and it was initially with a dose of, I don't want to say cynicism, but a dose of will they put their money where their mouth is? Will, they actually say, you know, sure, we are confident enough in our product that we actually would like to run some trials on these efforts, and you were.

Scott Nelson: We were indeed, and we'll probably certainly circle back to kind of some of the lessons learned which I think are particularly interesting to most people that are going to be listening to this. But, Matthew, a couple of data points that really stood out based on kind of how you just described the origins for ProofPilot and what you guys are doing is the average cost of a randomized clinical trial at least in Pharma being around 10 million. That cost probably holds true across Biotech and medtech, too, or you know, the numbers are going to be big, nonetheless.

So, your point about very few companies having the capital to allocate towards some of those clinical trials which kind of leads to that second point that you mentioned. Only about 30% roughly of devices are drugs used in a hospital setting are supported by clinical data, which is alarming, to say the least. So, I mentioned all of that and kind of repeating your points, because this is a big need. Not just for industry to support claims around products, but it's a big need for anyone that's like interested in health, wellness, a more invasive procedure inside of hospitals to know that these questions around these products or therapies are being answered based on science.

Matthew Amsden: Right. Look, I'm relatively young at the moment. I'm 45 years old and in good health. I want to stay that way. There are so many things out there right now that I can look at to optimize my health and prevent disease because thankfully at the moment I don't really have any. You look at all the stuff out there and all the claims that are being made, it's very difficult to figure out what's what and what's not. In fact, so difficult that a lot of us just end up making decisions based on blind faith or habits or whoever speaks the loudest or has the biggest fall.

So, a lot of the impetus behind the health and wellness trials that ProofPilot does and we are very much kind of dual focus in the worlds of kind of traditional clinical trials and Pharma and medical devices and Biotech as well as the non-traditional health and wellness space. We do that due to personal interest. We actually want to know what works and there just isn't a lot of data out there because the return on investment for a dietary supplement or a health and wellness device, it's just not there. It's not even there for a lot of the Pharma and medical device world. So, there are a lot of treatments that might work for a very small group of individuals, for very unique disease states that don't get the attention that they deserve from an evidence perspective because there's simply not the return on investment to spend 12 million dollars on a trial.

Scott Nelson: Yeah, there's no doubt and there have to be a lot of people that are listening to this that are in positions to influence whether or not clinical trials get done. But because of that ROI concern. If it's not mandated by a regulatory body and the ROI isn't there the study likely just won't get done. That's kind of sad because there's likely to be so many insights and learnings gleaned from a product or therapy in the marketplace and because you have to look at ROI numbers, it's a critical consideration.

Matthew Amsden: Another thing to note here, is not every clinical trial needs to go to an FDA. Let me put it a different way. Not every clinical trial needs to be done because the FDA requires it. There are a lot of questions out there in the world that do not require an FDA review or FDA approval. In many cases, you'd have to be a masochist to do a trial in the old model if the FDA weren't requiring it. That again means that if the FDA requires we don't get an answer to what works and what doesn't. I think that that's a real blank space in our overall society. We're making a lot of decisions about really important concepts, about what we're doing to prevent illness, what we're doing to treat illness at home in society. We're not using real data to make those decisions because the data isn't there. That's where we really got this concept of ProofPilot going.

Scott Nelson: Yeah, I couldn't agree with you more and I want to here in a minute kind of go back in time and learn a little bit more about the origin stories of ProofPilot and how your company has evolved over the years. But one quick point on this topic is and to kind of wrap up on kind of the first part of the conversation is that what stood out, I'm going to speak from Joovv's perspective, what stood out in initially looking at ProofPilot and what you were trying to do was a couple of things. One of them I already mentioned that from my perspective, being involved in medtech most of my professional career, I know that clinical trials are expensive. They're very expensive to do in a traditional fashion, even a small scale clinical trial is going to be likely hundreds of thousands of dollars when it's all said and done.

So, you know balancing that against a desire to collect more data kind of creates a little bit of a conflict. Those two things typically don't align, or something has to give. Either you have to allocate more funds towards clinical trials or just not do them. So, the fact that ProofPilot was in essence, allowing through a really innovative kind of compelling software platform to fund clinical trials in a remote fashion, it seemed like, wow, this could be a way to actually do some early clinical studies on our products in a very, very efficient way. On top of that, which I think maybe you'll get to as we chat about kind of how ProofPilot has evolved. But instead of just looking at

clinical trials as a cost center that you need to allocate capital. It's a hard cost to get data in return.

We kind of theorize that maybe this actually could be a revenue driver. Joovv is a little bit different just because we serve a direct to consumer kind of wellness audience. But I think it's an important consideration for anyone that's listening that does have a little bit of a similar type of commercialization approach and that by getting customers involved early in some of this clinical data there's a high likelihood that they may actually become customers which is really unique to my knowledge, that hasn't really been explored in great detail previously. So, it's kind of a cool concept where now clinical trials could actually be a revenue driver or at least a breakeven kind of channel four for a lot of companies.

We can kind of get into that in a little bit more detail later on in the discussion. But I wanted to kind of call it out in case, and keep those who are listening or are trying to wonder, like what's the big takeaway, you know, for Biotech, medtech, Pharma companies. So, unless there's anything else that you want to add right now, maybe now's a good time to kind of go back, rewind the clock a little bit and go back and learn a little bit about how you got ProofPilot off the ground and kind of how it's evolved over time.

Matthew Amsden: Yeah, sure. So, first I should say, and this will come to a surprise to a lot of people, I'm actually not a trained researcher. I don't have a Ph.D. I didn't go to university or to college to be a researcher. I have a business background and that business specifically is in service logistics and marketing. But what's really unique about the kind of approach that we take is clinical trials are actually really complex logistical challenges that have a science question built into them. So, as opposed to me being more focused, like a lot of researchers are on my actual research question, like maybe I'm an ophthalmologist or maybe I'm a cardiologist or maybe I'm an immunologist. Someone that their primary focus is on what the research question is. My primary focus is on the research methods, essentially the logistics.

So, I started my career in big public policy research and consulting firm and this was about 10 years ago. At that point, many Western governments identified HIV as a solvable issue. We know what causes HIV. We know how to prevent HIV and so if we experiment with a lot of different things, maybe we can change people's behaviors and actually make HIV go away. Now, that sounds super naïve today but 10 years ago there were a lot of policymakers in the Western Hemisphere in Europe that really thought that. I was one of the younger people in that particular organization and they were noting that I was doing a lot of things online. By online at that point 10 years ago, it meant that I was doing some blogs.

They came to me and said, you know, we're having a hard time engaging our population in the ways that we used to do so. We're having a hard time using traditional clinical trial recruitment techniques to get young, gay men and intravenous drug users into trials. This is a situation where most of the individuals that they were looking for considered themselves healthy. They saw zero incentive to go into a study clinic to be involved in the HIV trial. In fact, many of them were afraid to go into that clinic because they might be outed by someone on the street. So, noting that a lot of the traditional locations that were recruiting tools were closing because this population was

moving online in large numbers, gay men tend to be technology, early adopters. They said you know, can you recruit a couple of people for us online? And we shrugged their shoulders and said, sure.

I didn't really know that there was a whole world at that point in clinical trial recruitment but certainly the world that existed 10 years ago was not looking at online recruitment mechanisms like they are today. We became fairly successful with that and the next step was a number of academic institutions got involved. We became a separate company and they started to say, you know, we're having a really great time recruiting individuals online. Can we collect a little data online as well? We shrugged her shoulders and said sure. A little bit later they said, you know, we're collecting a little bit of data online. Can we do some interventions online as well? Again, we shrugged our shoulders and said sure.

Fast forward to 2012. 2013, we were doing large scale phases two, three, and four trials completely and totally online. Primarily again for a gay male audience looking at various interventions and techniques to reduce and treat HIV. I don't think I'm being overdramatic when I say this, but every single one of these efforts was a complete, unmitigated management disaster. Remember here, I actually came from management, marketing, and business background. So, what I was seeing these researchers go through might have been common to them. It was a completely new challenge for me. I considered a lot of what I saw completely unacceptable. I don't think that anyone of the studies that we were doing could have been more of a problem.

We, at one point, were creating every technology solution from scratch. You know, we were pulling together different open source solutions and we were just layering that software development process on top of the already fraught research planning process. It took a year or more for the researchers to actually design the protocol and then they give us a big Microsoft Word document and say go for it. We take six months and develop the infrastructure and inevitably, two weeks before the study was about ready to launch, the researcher would say, hey, wait, wait, wait, I've got a new idea and they changed that idea in their protocol document and expect that it would take that same 15 seconds to change the research infrastructure that we created.

Anyone who has ever developed software before knows that making a change in a piece of software, particularly an important one, often has a whole variety of cascading effects. So, we were often pushing out software that was very fragile because we were making changes at the last minute. In addition, all of these research studies, because they were designed by researchers, oftentimes in conferences in Microsoft Word, these studies were completely oriented around the researcher. Participants were often treated as an afterthought and they felt like cows that were jabbed with treatments and milked for data.

Then there were all of these inconsistently applied regulations and folklore around these regulations. It made disconnected systems. It made success really difficult in any one of these efforts and for those of us who are part of the LGBT community finding solutions for HIV and sexually transmitted diseases, it's a really important issue. So, what was really frustrating for

every one of these efforts before we got one of these contracts, we would always look for a solution. There simply wasn't one which we found completely bizarre because there are so many of these studies that are launched every year. At about the same time, a lot of non-HIV studies, researchers started to come to us and say, you know, my population is moving online. I want to run a study like the ones that I see you doing in HIV. We go, great and we'd say it's going to be a couple hundred thousand dollars for us to create the research infrastructure and they'd go, oh, I've got $10,000 or I've got $20,000.

So, the very first version of ProofPilot was literally developed for two reasons. The first was I couldn't continue with the chaos that I saw in the research world any longer without a solution that would allow us to be more flexible and adaptable to the research questions that were out there in the world. Secondly, as much as I think HIV is an important issue. There are lots of other issues out there in the world related to health that I'm also interested in and I wanted a way to bring the efficiencies that I saw in business and technology to the world of research. Technology has democratized transportation and journalism and created efficiencies for retail and a whole variety of other sectors. I wanted to bring those same concepts to the world of research and that was where ProofPilot was born.

Scott Nelson: Got it. I love the fact that in kind of hearing you explain some of those origin stories and kind of the early beginnings of ProofPilot basically shipping and getting your product at the time, at least in the hands of researchers really allows you to see two things. One is kind of the maddening logistical nightmares as you kind of explained to them that they go through in running these clinical trials and then also basically letting your customer base tell you what they need. Maybe they weren't overly specific and saying, Matthew, we need this. But based on what they were expressing, you were able to kind of see like this is what would be needed via technology to satisfy this demand. It showcases this concept of the lean startup and Eric Reese's model of shipping early, getting a minimum viable product, even if you don't believe entirely in that idea. But the concept of getting your product in the hands of customers as early as possible to learn and then iterate, make improvements, maybe pivot a bit, etc.

Matthew Amsden: Right. Let's be really clear, though, that the kind of ship early often make mistakes and break things. It's not really something that you can do in a clinical trial. Even though we're bringing the price down quite a bit there often was a lot riding on the results of these trials, whether it was a situation in which an organization was trying to figure out whether or not a product could get an FDA approval or whether it was a government agency trying to make policy. Putting a piece of technology out there and having it not work is really problematic.

So, a lot of what we were doing was creating a solution so we could quickly adapt to trials and as opposed to creating something new every single time and applying fixes in a software development type orientation, we created a platform that would allow us to author in the same way that you might author a blog post or you might do this podcast and allow changes and adjustments very quickly without having to rely on a developer. That approach means that we have a validated system without having to go that kind of let's put something out there and fingers crossed, hope it works because that's really problematic in the health care sector.

Scott Nelson: No doubt. I'm glad you brought that up because I don't want to underappreciate that shipping software is a lot different than shipping something in kind of a regulated health care environment. But from my perspective at least, and I'm sure there are people that would disagree. But the concept of getting some version of your product in health care, it's got to be something that actually is sellable and et cetera. So, maybe the better choice should be a minimum sellable product. But nonetheless, I think that this idea of getting your product in the hands of customers as early as possible in order to glean feedback is critical, I think, to any startup. But it sounds like that was especially true with ProofPilot.

Matthew Amsden: Right. Today, let me tell you a little bit about how we learn and test in a way that allows us to really think about things in a lower risk environment and then bring them to the higher-risk environment. It's a relatively controversial approach that we've taken, and we got a lot of gruff from it, from folks who believe that clinical trials, like serious clinical trials that are really only done by Pharma and a select group of medical devices. ProofPilot as I mentioned at the top of this program, we really have two focuses. The first is that traditional research world. But this traditional research world is really risk-averse. There's a lot of money in whatever research, whatever interventional elements that someone is putting out there into the world. So, those organizations by design because they have to try to de-risk everything else.

That's probably one of the reasons why this concept of a remote and hybrid trial has taken a long time to gain traction within that space is because there's so much risk and whatever that focus item is, that it's really hard to think about experimenting with something different in the actual execution of that trial. So, we don't introduce a lot of innovation from a clinical trial perspective in that particular group that we haven't tested and used and refined many, many times in the health and wellness sector. That health and wellness sector, particularly now, is very open to looking at clinical trials and doing things in new and innovative ways because a lot of them are existing and extremely competitive environments.

Now how many supplement manufacturers are there right now that all create the same vitamin D supplement? They're all looking for ways to kind of switch it up and change and find a competitive advantage, create a little additional credibility. So, a lot of the innovation from a logistical perspective that ProofPilot does we actually do with the health and wellness sector first. In that we learn what's working and what's not from a logistical perspective and can bring it back to the Pharmaceutical and medical device worlds and say, look, you know, we've tried this many times and because our focus is logistics, the logistical component of a clinical trial, we can bring this to you with these lessons.

The scientific questions between health and wellness and the Pharmaceutical industry may be different. The business reasons for doing that clinical trial between the Pharmaceutical sector and the health and wellness sector may be different but the logistical components that make that clinical trial run, they're very similar. So, we're able to bring those lessons to those risk-averse areas. So, when we talk about this world of kind of put things out there early, make mistakes and break things, we don't do that in any sector now.

But in the sectors where we are pushing the envelope a little bit, we're doing it in the health and wellness sector first, where if something doesn't go quite right the product is probably still out there and the primary goal is not an FDA submission. We're able to bring that material back to the Pharmaceutical sector with much less risk than we would have otherwise. So, everybody wins. The health and wellness sector gets credibility and, the innovative field that gives them a competitive advantage. The Pharmaceutical and medical device sector and academics as well get those solutions that have been tested a couple of times in a very similar experience.

Scott Nelson: I love that approach of basically finding those channels or verticals that allow you to maybe experiment a little bit more, move a little bit faster and you mentioned, you know, kind of this general health and wellness kind of segment, which I would include Joovv in that segment. Basically, picking up on key lessons learned and then being able to see what transpires over to maybe a more conservative kind of audience in Pharma, medtech, Biotech. I love it and on that note, Matthew, maybe talk a little bit about, since most of the people listening to this conversation are from that more conservative world. Maybe you can highlight a few recent clinical trials that you've done in partnership with, you know, more conservative Pharma or Biotech or medtech companies.

Matthew Amsden: Yeah, sure. So, I think we're doing two right now that are very applicable. The first is a trial with Eli Lilly where we are looking at the applicability of a medical device and whether or not it has any possibility to predict migraines. We work with the folks at Eli Lilly directly. Every single week we have a telephone call with them. The statistical team is on ProofPilot on a regular basis, churning through the data and there's a ton of it at the moment. The operations team is using ProofPilot to manage the participants, the fulfillment team. This is a completely remote trial is using ProofPilot to manage those who have received the devices and those who have not and all of the recruitment team at Eli Lilly and their contractor contractors they also are directing individuals to ProofPilot to run that trial.

The concept of the trial actually solidified in September of 2019 at the end of September. We launched the trial on December 30th. We were about 80% recruited by early February, I believe and the first individuals, it was a 90-day study. The first individuals are just completing the study now. So, it was a super-fast turnaround including all of the stuff that usually holds things up. So, the protocol went through the same review processes than any other protocol would go through in a large organization. We did go through an institutional review board as every study does on ProofPilot. It's a real big Pharma study. Didn't have an interventional element to it, which is unusual for ProofPilot, but it was something that's Eli Lilly felt was important to do without an interventional element. So, it was just a tracking study. Very proud of that effort and how fast that it came together, and it is one of those that is again, completely virtual in nature.

I should note here that while we are in this world of social distancing at the moment, all but one study on ProofPilot is completely remote in nature. But ProofPilot is a hybrid study platform and by that I mean we support those studies that have both in-person experiences in a traditional study site as well as those experiences within the study that a participant can do at home. It's really cross-channeled that way because the reality is in a normal world most studies are hybrid.

There are a lot of treatments for complex medical devices that you simply can't ship to a person's home. They've got to go somewhere to a medical center, to a study site to receive those treatments or to use that device and ProofPilot supports those modalities as well.

Scott Nelson: Thanks for pointing that out. I think people generally get this concept of running a trial completely remote but the hybrid aspect kind of is a little bit of a modified version of that. But to your point, like one, it's good to know that ProofPilot has the capability of running a trial completely virtual, completely remotely but also has the capabilities of doing it in a hybrid fashion which is probably the more, not probably is the more typical way in Biotech. medtech kind of the conservative arenas of health care. So, I'm glad you pointed that out. Outside of the Eli Lilly example, is there another one that comes to mind? I can't remember exactly the company that you've referenced in the past, the one that does the facial scanning. It's a dermatology company, but maybe to touch on that one or another example that comes to mind is to help people get an idea of kind of what types of companies or studies are being done on ProofPilot now.

Matthew Amsden: Yeah, so the skin study that you're referencing is actually one that we have an unnamed at the moment Pharmaceutical company that we are planning for. But in order to kind of test a number of the functional elements we're actually working with a dietary supplement company that happens to have a couple of special formulations that they feel improves skin, hair, and nail health. So, the study is called the DermAid Study. It is a 90-day study and the real innovation there is at baseline, day 45 and day 90, we have asked individuals who are participating in the study to take multiple selfies in certain kinds of light.

Those selfies are being reviewed by multiple remote dermatologists using a validated scale that would normally be conducted in an in-clinic environment. Some of what we're looking at in this particular study are whether or not this approach can be applied in a Pharmaceutical environment for both traditional dermatology trials that are medical in nature, as well as those products that are from Pharmaceutical organizations but are more cosmetic in nature. That study is really fun, and it has engaged way more men than I thought it would which suggests a high interest there. The adherence to the selfies, it's like 70% which I'm very pleased with. I was really concerned going into it that a lot of folks wouldn't do the selfies and the quality is quite good as well.

Another study that right now is super timely. We have launched a study in and around New York City on a couple of different at home COVID-19 antibody tests. So, as everyone knows right now, testing is a key component to bringing us back to some kind of normalcy. This particular effort is largely based on some of those early HIV studies that we did where we were looking at an at-home HIV test, whether or not someone could actually use the tests, whether or not someone could actually read results and most importantly whether or not those results changed an individual's behavior. So, these COVID-19 antibody tests right now, you have to go to a clinic to get one. They're relatively expensive and right now, who wants to go to a health care setting if you don't have to? So, our hypothesis is that some of these tests can be conducted at home, but the FDA doesn't allow it at the moment.

So, this research study is looking at the applicability, acceptability, validity, and long behavior change of a couple of different at home uses of COVID-19 antibody tests. The results so far have been very, very positive from the perspective of interest. It's a little early now to share much from a results perspective but I'll certainly keep everyone in the loop. This is a study that probably would not have been done for months had we done the traditional model, in large part because there's a lot of other research questions that need to be answered around COVID-19 before you get to the point where can some test used at home?

But it's absolutely essential to get us to a point where we can be testing many millions of individuals because our health care system certainly isn't in a situation where they can do an antibody test on 400 million US residents. It's just the resources that aren't there. So, figuring out whether folks can use those tests at home, I hope we can make a big impact in the world in helping folks and policymakers figure out whether this is an appropriate avenue to explore.

Scott Nelson: Right. I know it seems like there's been a lot of interest around what you're doing with these at home COVID-19 antibody tests. I think again, correct me if I'm wrong but this notion that clinical or remote/hybrid clinical trials were important, you know. I think that was probably something that was trending, or people were beginning to understand that. But the COVID-19 or the Coronavirus related challenges that we're all facing has really sort of like amplified the importance of being able to have, being able to do some of these trials remotely just because of the simple fact that a lot of people are not wanting to go into a hospital or any type of traditional health care setting just because right now that's probably been one of the more dangerous places that you could find yourself in during these times.

Matthew Amsden: A lot of trials at the end of March, not a lot, a vast majority of trials that are out there in the world using traditional approaches are shut down at the end of March. We have a number of academic and industry customers where ProofPilot is now supporting some of the only trials that those organizations are conducting at the moment because all of the other trials have largely shut down. So, yes, the concept of hybrid and remote trials was trending. It was a conversation that was happening a lot at conferences and there was a lot of written material about it in an industry press. But as I mentioned, the group of individuals who are often making decisions, they're very careful about implementing innovations because there's so much risk in what they're actually trialing.

Scott Nelson: On that note, I'm just thinking about even some recent news like I think Jack Dorsey who's he's the CEO of Twitter. I think within the past few days I made a statement around the fact that Twitter employees are no longer even required to come into the office like forever, at least for now anyway. The reason that kind of stands out recently is that I got to think that for most health care companies, even if you're more on the traditional side, in Pharma, Biotech, medtech, the message may be is if you're not already doing or running some type of hybrid or remote trial you really should be doing one, even if it's not specifically for a regulatory pathway. You need to have, you know, some of these things going on in case the scenario unfolds and you're kind of forced to rely on collecting data remotely. So, maybe that's kind of one of the key messages is it's now not that you have to, but it definitely should be if you haven't considered

running a trial previously. I mean, definitely, those conversations should be going on in light of the existing challenges.

Matthew Amsden: One of our advisors in the Pharmaceutical sector the other day essentially said the same which is that a lot of folks considered remote and hybrid trials the new risky thing. Over the past couple of months, the old thing was exceptionally risky. All of those studies shut down and those of us who run trials, when you shut down a trial or you pause it for a moment and you don't collect data in a certain structured way that entire trial might be for nothing because you essentially created a protocol that's no longer active or no longer valid. So, yeah I think it's progressing like a lot of things in this crisis. Remote and hybrid trials are not new, just the same way that online grocery delivery is not new, but it has progressed and forwarded a number of cultures and themes that were just beginning to kind of gain traction. This has just propelled them.

Scott Nelson: There's no doubt and I like that analogy that you just referenced, as the old way, the old traditional way is probably riskier than exploring remote clinical trials right now. It's hard for me to see that really, really changing any time soon and on that note, if you're kind of listening to this conversation or are compelled by it but still kind of thinking I've got a product that is used exclusively in the hospital setting. I'm thinking of myself as an example in my previous role at Medtronic, which was in the endovenous business, so led downstream marketing for a catheter that was used in a clinic. Like normally I would look at that scenario and say, you can't really run a hybrid. Maybe you can run a virtual trial, but it has to be hybrid, but maybe not applicable.

But I would say open up your mind just a little bit, try to be creative because one example on that note is that you could have a cohort of patients that maybe were involved, had a treatment done in a clinic or hospital setting, and then you could similar to kind of that selfie model that you just referenced Matthew, like you could have all of these patients report on, you know, a various quality of life measurements completely remotely out to 60, 90, 120 days post-procedure and that's your example of a hybrid clinical trial. That would be very doable on a platform or on a platform like ProofPilot in a very, very cost-effective way. So, that's like that's a perfect example of exploring some out of the box concepts that maybe are a little bit foreign to most people in medtech and Biotech and Pharma.

Matthew Amsden: You can even take it a little bit further than that. Let's talk about data validity for a moment. Let's kind of go back to the old model where maybe there has been an implant of some sort and one of the things that you're looking at tracking over time is levels of pain. So, you have folks come into a clinic on let's say, every other month or so to actually fill out some papers and answer some questions about their pain levels. It's not uncommon in a lot of trials, particularly in situations in which you're trialing something where whatever the treatment is, is relatively rare or it's very specialized. It's not uncommon to ask people to travel for many hours to come to a study site because their study sites tend to exist in large cities.

They tend to exist in academic medical centers, particularly in situations where it's highly experimental. So, you're asking people to travel for long distances, maybe get on an airplane. I don't know about you, but I've traveled a lot. I'm obviously not doing so right now but any kind

of travel increases, I don't have the pain to start out with. But if I did, I could tell you it's not comfortable for me to travel. So, that results that I go into and I say, you know, after seven hours in traffic or I'm talking about my anxiety levels and my pain levels and maybe my quality of life, those results are not accurate because I've gone through that seven hours in traffic.

I perhaps waited in a waiting room with perhaps some other individuals who are also sick. I've had to take time off work asking those same questions of someone while they're at home in their natural environment or in their office and skipping all of that pain in the neck, getting to the study site, and all that unnecessary bureaucracy of getting into the building. That's actually going to create a lot more realistic results and probably a lot more positive results for whatever your intervention happens to be.

So, yes, you're right, Scott. It's absolutely not realistic for a lot of traditional medical devices, particularly implantable medical devices. You can't do that at home. But the follow-up, you actually not only can you do that at home or remotely I should say but it actually may give you better, more accurate data.

Scott Nelson: No doubt. I would say not even maybe probably highly likely to give you a much better data set that you could use to either make product improvements or for dissemination purposes, which, you know, is critical for the broader health care ecosystem. So, by now if you're listening and you're not kind of on board with the importance of considering a hybrid or virtual clinical trials, please stop the podcast and delete it from your phone because it's pretty obvious at this point that it's pretty crucial for any health care company to consider.

So, Matthew, I know we're kind of we're up against the clock in terms of timing. So, is there anything else that you think would be worthy of covering before we get into this kind of some fun more rapid-fire questions here towards the end of the discussion?

Matthew Amsden: Well, at the beginning of the conversation you talked a little bit for those organizations that are more in the health and wellness space, making clinical trials a revenue driver as opposed to a cost center. Let's just talk very briefly about that. So, one of the innovations that we actually tested with you even a couple of other health and wellness companies at the same time was actually asking participants to make some sort of payments and purchase study supplies to be part of the study. That's a relatively controversial approach, though it's not unprecedented. There have been studies for many years that have asked individuals to pay to participate. Pay to play is often the terminology that's used.

We made that decision for a couple of reasons or decided to experiment for a couple of reasons. I think the most important one is that it helps us do studies that wouldn't otherwise be financially viable to do and that wasn't necessarily the case with Joovv, but it was the case with a number of other companies that we were working with at the same time. Had we not been in a position where we were able to say to that company, what about thinking about charging participants for whatever your product might be, those studies wouldn't be done. So, we wouldn't have any data to or any finding of whatever those interventions happen to be. So, that's issue number one and by the way, what studies get funded by academics or Pharmaceutical? You know, that's a very

fraught process. I don't think it's one that we need to go into here, but it's not every study that deserves funding gets it.

So, finding alternative funding models is a really important concept towards moving forward to what science is. The second issue that I think was more applicable to Joovv is providing study access and devices or interventions within that study for free and compensating individuals for participating in that study is an artificial environment. It's very unlikely in the real world, even if you're in a country with complete and total fantastic health care that's government-supported, it's very unlikely that you are going to be paid to administer treatment and it's also very unlikely that you're going to receive things for free.

There is a big problem in research right now that it's difficult to replicate research results from one research study to another. It's also extremely difficult to replicate research results from a clinical trial to the real world. Payments for components of a research study that's just real life. In real life, an individual is going to pay for treatment. They are going to pay to get services. So, actually using that as part of the research study actually creates a more real-life environment and gets, again, data that actually may be more applicable to what's going to happen in the real world.

In addition, one of the key problems in research studies is adherence and there has been a habit in research studies to use compensation to improve adherence. The converse to that actually asks participants to make an investment themselves in participating in that research study. If someone has a little skin in the game, they're probably far more likely to move forward within the research study and maintain adherence at 30, 60, 92, two years, whatever and that has been borne out several times with a couple of the studies that we've been doing recently. When an individual pays for supplies within the study, they're actually more likely to stick with it. The next kind of wave of studies will actually be comparing the difference between someone being compensated to be in a study versus when someone has been paid. So far, it's been pay or just existing to get the materials for free.

But this whole concept of behavioral economics is really very much embedded within this. So, for those organizations that still feel as though, you know what, I'd really like to do a research study, but we're a bootstrap startup. We just don't have any resources whatsoever. It's lucky if we can get a couple of our products out there into the world much less pay for a research study on them. Really think about this world of asking participants to pay for your product within that research study, because not only will it help you get that research study done and help you support that effort but it's also going to potentially create a more realistic research study results.

Scott Nelson: No doubt and I think those three points that you mentioned, Matthew, of the data probably being a little bit more realistic, compliant, probably being better, because people are from a behavioral psychology standpoint, they've got skin in the game and you combine that with the fact that they're incentivized too because if you're operating under a kind of some form of a pay to play model where they're having to pay upfront, maybe getting the therapy or a device at a discount as an example, there's a lot of synergy with all three of those sort of pillars, if you will, and obviously, I can speak on behalf of Joovv that that's worked out extremely well.

I'm sure that this probably will probably be more case studies coming out with other companies that are showcasing this concept that clinical studies can be a revenue driver. Not to kind of belabor that point but they really can be and matched to the revenue driver, but a really good opportunity to collect very realistic, real-world clinical data. So, I can't stress that enough that. One more reason that any kind of health care company, whether you're operating kind of in a more conservative environment or kind of in a general health and wellness environment that this is a hybrid and/or a remote clinical trial. It should definitely be a consideration for sure.

Matthew Amsden: Right.

Scott Nelson: Well, cool. Sounds good. Well, on that note let's go out and kind of conclude the discussion with kind of some traditional rapid-fire questions that I usually like to ask people don't feel like you have to answer in rapid-fire fashion but these questions are a little bit more, you know, quick-hitting if you will. So, on that note, the first one I like to ask most of my guests is there a business book or really any book for that matter that has been particularly impactful in your either professional career or from a personal standpoint?

Matthew Amsden: I guess it would be more from a personal standpoint. It was a book I read maybe 20 years ago. It was definitely early in high school at that particular point and it was called "On the Way to Timbuktu" written by a men's journal journalist and it was a story of self-discovery going into the jungle, finding Timbuktu in Africa, rowing along various rivers to get there. I think it really solidified the point to me that life is an endless series of personal discoveries. I've really taken that to heart in the work that I do is that the work is really an endless series of discoveries. It's not just an endless series of discoveries in the actual trial results, but it's an endless series of discoveries in how you run your business, how you actually go about living your life.

My great grandfather had the saying, and I am not going to quote him exactly, but the secret to long life, and he lived to be 103. The secret to a long life is maintaining integrity, truthfulness, the [52:23 inaudible], and the inquisitiveness of youth. That book really, it had that level of inquisitiveness, even though at that point the author was probably 30 years older than I was. It was about discovery. And that's what life is. It's really about discovery and that book really solidified it for me.

Scott Nelson: I love that. I've never heard of a heard of the book but definitely jotting it down to look it up on Amazon here, after the conversation. On that note second question, second of the three. Is there a mentor or a colleague, a business leader whether you personally work with them or just watch them from afar that's really been impactful or inspiring, you know, over the last 10, 15, 20 years?

Matthew Amsden: Well, yes, I've just mentioned him, my great grandfather. He was born in a small town in Maine in 1898 I think. He died when I was a junior in college. So, had a very long life and during that time found his way from that small Maine town to New York City, worked his way up in various different retail establishments, eventually becoming the President and CEO of, at that point, the largest retailer in the United States. It was called Grants, which I guess today, the closest equivalent would be Wal-Mart, although Grant's was a traditional kind of post-World

War Two department store. After retiring from business, went to be the assistant secretary of the Navy under Eisenhower, was the patriarch of a huge family that continues 20 years after his death to get together for the Fourth of July every single year and there's about 80 or 90 of us at the moment.

I went to school at the University of Maine. That's where my undergraduate and graduate degrees are from. The library is named after him and as I was growing up and while I was in high school, in my family you don't choose where you go to college. You go to college at the University of Maine and there have been about 100 of us that are his direct descendants who have gone to school there. Every weekend as I was growing up, we would go to visit and spend Saturday afternoon with my grandmother and great grandmother and great grandfather. We would sit in the living room and he would always have Forbes and Business Week out on the table to read. That's a lot of where I learned business principles was sitting there in the living room with him reading those business magazines.

Scott Nelson: That's great! That's great and you said the library is named after him at the University of Maine?

Matthew Amsden: Fogler Library at the University of Maine.

Scott Nelson: I was just going to say I looked it up while we were having this conversation, the Raymond H. Fogler Library. That's really cool. I knew maybe we'd have a chance to get into something that I didn't know about you. So, that's very cool. I love to hear those types of stories. On that note, the last sort of rapid-fire question is if you had the opportunity to kind of go back in time, maybe to your 25 or 30-year-old self, maybe just your early to mid-20s. Is there one or two pieces of advice that you'd give that young man?

Matthew Amsden: Yeah. Just pay attention to everything because I'm very happy in ProofPilot right now but actually pay attention to everything and every life experience will probably impact what you do in the future. So, when I was in college towards the end of college and early graduate school, I actually worked at an airport. I was a gate agent for a couple of international airlines, and I think today that experience influences probably what my next gig will be. So, very happy with ProofPilot now. I'm not going to go anywhere for a good, long time. But clearly with this crisis that we're experiencing at the moment and my experience in logistics and my interest in that space the way we do airline travel is going to need to change a fair bit into the future.

While I'm definitely a slightly nervous traveler, I love the world of the airline industry and that experience, while I was in college with airlines showed me how precise logistics need to be in order for tens of thousands of people to roll in and out and around the world and keep airplanes on the ground for a super short period of time. That service logistics approach very much influenced ProofPilot and I hope someday, not in the immediate future. Probably not in the next decade. I'll be able to take the experience that I have with ProofPilot and apply it to whatever the airline industry looks like in the future.

Scott Nelson: Love it. Pay close attention at every sort of stage or season of life and try to try to learn from it and apply it to the next thing. So, that's really good stuff, Matthew. I'll provide links in the show notes for this episode on medsider.com to ProofPilot as well as any other applicable things that would be worthwhile for those listening to check out. But on that note, where's the best place for people that are listening to learn a little bit more about ProofPilot and/or maybe even reach out to potentially maybe even participate in one of these hybrids or virtual clinical trials

Matthew Amsden: For both situations just go to proofpilot.com if you're interested in participating in a study. We've highlighted a couple of studies on the front page there that you can click the join button and begin the enrollment process. For those of you who are thinking about perhaps maybe creating your study, there is a wealth of information on the site as well. Just click on the researcher button at the top of the page. For additional questions and to get access to start designing a study just reach out via the links there and we'll let you in.

Scott Nelson: Awesome. So, that's proofpilot.com, p-r-o-o-f-p-i-l-o-t.com, proofpilot.com.

Matthew Amsden: You'll notice the link there to the airline industry, the pilots. So, we very much believe that a researcher is essentially a pilot whose primary purpose is to get people from point A to point B safely. Much the same way a researcher is a pilot through a research study to get someone from the beginning of the research study to the end safely and during that process, as opposed to discovery via a new destination, discovering things about your health and your wellbeing in that process. So, the linkage is there that we talked about. We're taking them through.

Scott Nelson: That's great. I had no idea that that was the pilot, the improved pilot was somehow tied to that concept. Very cool. Very cool to know.