Clinical Research

With Todd Nicklas
Episode 49

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Introduction (00:01):

Welcome to the Healthcare Leadership Experience Radio Show with your host Lisa Miller. This week, the Healthcare Leadership Experience will be hosted by Jim Cagliostro. Jim brings over a decade of critical care nursing experience at highly regarded medical facilities across three states. During his time at the bedside, he observed both the good and bad of hospital operations in several regions, giving him a unique insight and perspective on the healthcare industry.

Jim has been a part of the VIE Healthcare team since 2018, where he's made patient care and the patient experience a top priority. He has observed that keeping patients at the center of healthcare can transform the patient experience and lead to success for any health system, big or small. Here's your host Jim Cagliostro.

Jim Cagliostro (00:49):

Hi, this is Jim Cagliostro, and you're listening to the Healthcare Leadership Experience Radio Show on Healthcare Now Radio.

Today's guest is Todd Nicklas, senior clinical trial manager and head of clinical operations at Travena. Travena is a small bio pharmaceutical company based in the King of Prussia, Pennsylvania area, focusing on developing medicines to address the critical needs of patients with central nervous system disorders. And just a little bit about Todd.

Jim Cagliostro (01:17):

He has previously worked in a few large academic medical institutions in heart research for 10 years. And he will pull from that experience to give us a good context of how research impacts hospitals, clinicians, and patients. So this is something Todd and I have discussed, the research side of things, but it's an area of nursing, it's an area of healthcare that I'm not so familiar with. So I'm glad we have Todd with us. I'm excited. Thank you for joining us today, Todd.

Todd Nicklas (01:42):
Yeah, thanks for having me, Jim. I appreciate it.

Jim Cagliostro (01:43):

We'll jump right into it with maybe a three-part question. Why is clinical research important to hospitals, hospitals, physicians, patients? Basically, why is clinical research important in the healthcare industry?

Todd Nicklas (01:55):

Yeah. Thanks Jim. That's a great question. And I think a lot of people don't really think through this and don't appreciate it, but I think there's a few impacts on the hospital side of things. You know, first and foremost, maybe I'll focus on the fact that physicians and patients have access to cutting-edge new technologies and that's brand new technologies and medicines that maybe are a few years down the road in development, or maybe that just got approved and that hospital has it ready to go in their formulary and ready to be used.

Todd Nicklas (02:21):
They're maybe ahead of the game versus other hospitals around their area. And that might get people excited to come to their institution. I worked in clinical research on the hospital side for about 10 years, and some patients would come to our hospital for the very reason of trying out a research medication or trying to work with a physician that's doing a trial with us with a medication. Got them excited to come to that institution versus maybe their own hospital that they're at.

Todd Nicklas (02:45):

I'll give you another example and maybe some people have heard of this now we can do valve surgeries through catheter, rather than cutting your chest

open. And they're called TAVR surgeries. And people for a bit were nervous about it, but now it's becoming a mainstay for people that are moderate to severe disease valves and meet certain criteria. So it puts you on the spectrum of, "Hey, look, this hospital can do TAVR procedures. Maybe I should consider going there." And you know what? Maybe that patient stays at that hospital for years down the road. And that grows that relationship. So it could be a huge impact there, I would say it.

Todd Nicklas (03:15):

It also establishes partnerships with upcoming pharma companies, device companies that are getting close to an approval and they're willing to try out something, but they're willing to be one of the first adapters of that medication or that device. And then that builds that relationship early on, rather than a hospital that gets late in the game. And then people will say, "Well, do I want to go to a hospital that has 10 years of experience with it, or they just started last month?" You're going to have a hospital that's really well respected in that landscape.

Jim Cagliostro (03:43):

Great. That TAVR procedure is something my, my own mom had done. And I imagine 20, 30 years ago, it's something that you're not considering for the closest hospital down the street, but it's something that they've been doing for a little while now.

Todd Nicklas (03:56):

Yeah, yeah. It is great to see that develop into the real world. Another great thing, I would say, is a fair amount of hospitals have translational bench research and they want to translate that into real life scenarios and putting it in patients and giving it to patients. So you see something that maybe was developed 30, 40 years ago. You and I worked at Penn State Hershey Medical Center for a few years, and I love the story in the, I believe it was the 1970s. They were working on the first total artificial hearts.

Todd Nicklas (04:22):

And this device was pretty primitive at the time. It's developed a good bit as of today, but they put it in a cow and they have a neat story that it was a pneumatic system. It was an air compressed system and they plugged it in, it was back in the 70s, they had the plugs in and I guess some electrical problem happened, and the cow dropped like it was dead because the power went out

and somebody thought to blow on the pneumatic tubing that was in the back of the machine to have the blood pump for that cow and, to bring it back to life until they get the electrical power back on.

Todd Nicklas (04:53):

And the cow lived for weeks and months after that. But it gets people excited, "Oh, Hershey Med's doing this? And look at this neat story." And then the years to come, the cow survived, they put it in patients a few years after that, but it's doing great and people can get that now at home. They can actually go home with a total official heart and a driver. They put it in a backpack and go around with it. So to see that progress is so neat and you could be the first few hospitals to be on the board for that and offer it to patients all around your area, all around the country or all around maybe the east or west coast.

Todd Nicklas (05:24):

So that's pretty neat. One other thing I'll say maybe too, is that, and maybe this kind of goes along with what I just said is, physicians that are so used to certain procedures, certain medications, certain devices, they might have good outcomes and they might do fine. But what if there's a new medication that gives them 50% better outcomes or 50% less hospital burden where people are coming into the hospital, 70% less, or pick a number. Why wouldn't that be something that's a top priority or a top consideration in your mind?

Todd Nicklas (05:53):

I worked with the CardioMEMS device, which was a really neat device that was bought by a larger company. But at the time, it was the small company that was running it. And it's a device implanted into your pulmonary artery to measure heart pressures, and to tell you when your heart pressures are not doing well, and even if you're not symptomatically feeling that change. And it would alert the patients and alert... You could actually remotely send the information to a physician at your hospital.

Todd Nicklas (06:17):

And the biggest reason why it got FDA-approved was the fact that it was reducing re-hospitalizations, readmissions, and even people coming back for ER

visits, even for heart failure. So why wouldn't that get hospitals excited saying, "Hey, we can reduce our heart failure admissions by X percent." That's less burden on the hospitals, less burden on the doctor, nursing staff, supplies, beds.

Jim Cagliostro (06:39):

Just the cost too. That's a big, hot topic right now. Minimizing readmissions to minimize costs for hospitals.

Todd Nicklas (06:45):

Yeah. And I'll give you another unique example, but as you probably can tell, I've been in the cardiac research field for about 10 years. And that's the experience I'd like to talk about, is that there were medications that came out a few years ago, Jardiance, Farxiga, a couple others in the diabetic space to help with diabetic fluid balance. But they also, when they were studying it, saw that it actually could help heart failure patients and their fluid balance. So what they did was, they started to do clinical trials with these medications and found that diabetic patients that also had heart failure on board, it helped both sides of the coin.

Todd Nicklas (07:18):

And it got actually approved, actually not too long ago, I don't think, for heart failure. So people think, well just cardiac or just space, but hey, there might be some cross examples between different therapeutic areas that are really interesting. And I'll say too, and I think that your team at VIE and some of the people that have come on this podcast before have mentioned is that, you're not also just looking at forward looking medications that are coming down the pike, but you're also looking at clinical research and present practice.

Todd Nicklas (07:43):

You know, present practice, what am I doing that's good, not good? Maybe there's some problems with my patients in a real-world evidence type of protocol that I might be able to realize where I just, otherwise I'm assuming they're doing okay. But maybe there's a subpopulation that's suffering or having some problems that if I look at it through clinical research lens at the present scenario, I can learn from that and say, "Oh, I should do things differently because of what I found from the study." So clinical

research, even in that regard, past, present, and future, clinical research can look at any of those vantage points.

Jim Cagliostro (08:14):

That's great.

Todd Nicklas (08:15):

With physicians, I think this kind of plays into some of the things I've mentioned, but physicians, they have an exciting way to jump into new technologies. Let's say they're a surgeon or new interventionalists that are putting in stents in your heart or something, maybe there's a different nuance that they can do and learn that might help their general skillset — and also help them learn how to implant that device. I worked in heart failure in cardiac interventional work, and there was definitely device that we'd implanted that were slightly different than therapies that were out there.

Todd Nicklas (08:46):

And so took a little bit of skill, but were similar in some scope, and I'll save some time, we'll go into those examples, but it helped the physician to get a unique perspective and a little bit of even hands on different skill set that it was really neat. I remember a surgeon I talked to that had been a surgeon, I think over 40 years, maybe close to 50. And I remember him saying, "If I'd continue to do what I learned 50 years ago as a resident physician, I'd be fired, or taken to court, or put in jail.

Todd Nicklas (09:13):

If I don't move with the flow of research and data that's coming out in new practices and new procedures, it's not going to go well for me. I have to move with the times, and I have to learn what is best for my patients." And I appreciate that example. And I mentioned before, people staying for a procedure or a research device or medication at that hospital, they might stay there also for the physician, "Hey, this doctor, so and so, they helped me with this research study and man, I got to have really close care and frequent visits and frequent check-ins, blood work, free tests, whatever. I really like this physician a lot.

Todd Nicklas (09:46):

I never met them before, but now I have." And it might really bring that relationship about where they stay with that physician for years, not just that hospital. It helps physicians learn about the disease population too, that there

might be a niche in that disease population that they don't work with as much, but maybe if they do a clinical research study in that field, that they might bring some of that unique population. I was at UPenn, in heart failure, we had sarcoidosis and amyloidosis patients, they are really unique, inflammatory diseases that you don't see a lot.

Todd Nicklas (10:13):

And to see those physicians work with these types of studies, to understand that pathophysiology, I think just all the more help them understand cardiac disease in general and heart failure and such. So it was neat to see that.

One example, I think maybe the listeners appreciate, and Jim, you might know this working in cardiac as well, but in 1929, there was a physician named Dr. Forceman in Germany, and he actually...

Todd Nicklas (10:37):

There's some mixed stories about this, but he actually performed the first catheterization on himself. What he did was he actually took a fully catheter and put it into a vein in his arm and threaded the... because he believed that this was a doable procedure. This was 100 years ago, 1929. And he threaded it up to about where he thought it would be in the heart, where it should be in the heart, and he walked over to the radiology department to get an x-ray, to verify where it was and confirmed.

Jim Cagliostro (11:02):

That's great, that's great.

Todd Nicklas (11:05):

That's 100 years ago, it's a crazy example to give, but he was willing to say, "Hey, I'm a physician. I'm in the research field. I know what I know about anatomy, physiology. I really think there's benefits here down the road." He was definitely forward-looking and risky, but he did this and tried it on himself. Research has come a long way. Certainly that's remotely the case, but he took a leap of faith and it worked out for him over time, yeah.

Jim Cagliostro (11:29):

That's great. If you're just tuning in, you're listening to The Healthcare Leadership Experience Radio Show on Healthcare Now Radio, and I'm your host Jim Cagliostro.

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Jim Cagliostro (11:55):

So Todd, you mentioned that Dr. Forceman and performing the basically experiment or the research on himself. Especially in the time of COVID we hear a lot about clinical trials. So I think a topic that I wanted to address with you and see just your thoughts on it, has there been historical hesitancy from the public's perspective in terms of participating in clinical trials? What's the general sentiment today, at least in your opinion?

Todd Nicklas (12:21):

Yeah. I actually will answer that first, but I don't know if I really completely gave you a good answer to your question about why is clinical research important to patients. But I think that'll play into your question about the historical hesitancy in participating in trials, because there's some things explained in that'll show that there shouldn't be as much hesitancy as there is today, but patients can actually have a lot of benefit when they're out of options.

Todd Nicklas (12:45):

You know, I worked in heart failure and transplant where people are at the end of their rope and last-ditch options with heart failure. And there's certain cures and certain wins that they could have with UPenn did a study in a multiple... Hospitals did a study where they would have patients be able to get hepatitis C hearts from donors that had hepatitis C. But the goal was that if they did receive that heart, that they could get a treatment that would immediately get rid of the hepatitis C.

Todd Nicklas (13:11):

And it would open the doors to more options when you're waiting on a heart transplant for years, and you never know if you're going to make it to get a heart or not. I remember talking to the second patient that got it at UPenn, and he was ecstatic about how he got... I think he got a heart within two weeks of signing up with the study and it would've been months and months. So yeah, it was a leap of faith. It was a little bit of nerves with him, but he read the consent form. He talked with his physicians, he understood the safety behind it, and what he could know and not know at the present. And he made his own decision.

Todd Nicklas (13:39):

Clinical research is very focused still today on the patient first and safety first. You can quit a trial at any time and you can work with the physicians to do so. And I'll talk about this a little further down the road, but I think a big hesitancy is the fact that research in the past, maybe 30, 40, 50 years ago, there were times where people wouldn't tell people that they were doing... Physicians or clinicians wouldn't tell people that they were doing a trial on someone, or wouldn't be as transparent about the risks and the benefits, or maybe say, "Oh yeah, this is the next best thing, but not really tell both sides of the equation of saying, "Well yeah, but we don't know X, Y, Z about it."

Todd Nicklas (14:15):

But nowadays, I've given patients consent forms that are 20 to 26 pages long, just to say every single thing about the study and how your data is going to be shared and confidentiality and safety, benefits, visits, little bit of everything. So, I think it's really developed even the last 10 or 15, 20 years, but I think that's a big hesitancy in the past is, if you think about the Tuskegee studies in the 1930s and 40s come up pretty often here. I know that was about 80 years ago, but that's a big one where people were not told at all about multiple things.

Todd Nicklas (14:50):

And actually, we won't go into all of it, but it was really unethical. And even I remember I had to do a paper in college on Stanley Milgram, and he did some interesting psychological studies that really messed up in 1960s, and really messed up the participants because they were actually making the participants

think that they were harming someone in another room, where actually it was all pretend, but it was to assess their psych response to everything. But nowadays, there's so many things you have to get approved and reviewed and peer reviewed.

Todd Nicklas (15:19):

And the review boards that approve these studies now, they have lay people and scientists, physicians, pharmacists, nurses, regulatory people. They really try to have a very broad scope of people on that board to say yes or no to a certain study. And it's really neat to see the change. I do appreciate. And there's been times where I've had to fight and advocate for my patients to say, "Hey, I don't think this patient knows enough about what they're saying yes to."

Todd Nicklas (15:46):

Jim, I've actually had patients say to me, "Oh, yeah. I love doctor so and so. If doctor so an so says it's good for me, it's good for me." And I say, "Listen, you can't take that approach because it's your body, it's your decision. You're supposed to read this consent form in its entirety, because it's a legal document. And I agree that you have a great relationship, but it's your call at the end of the day and it's going to impact you and not the-

Jim Cagliostro (16:09):

And I think that's a big cultural thing and maybe a generational thing, where say 100 years ago is, "Okay, doctor, whatever you say." I still know people that are like that in my own family. "Whatever the doctor says, I'll do it," but we encourage, "Hey, ask questions." We want to make sure you know. Like you said, it's your body. That's important in research too, yeah.

Todd Nicklas (16:27):

Yeah. And the other thing, well, I guess maybe I mentioned this a little bit, but there's different aspects of clinical research that are also really important that we haven't touched on yet. Let's say a study is saying this medication's going to cure cancer or something. I know this maybe a broad topic, and let's say it doesn't, but let's say it learns five other sub bullets or secondary objectives as we might call them or secondary outcomes.

Todd Nicklas (16:49):

There still might be a lot of different things about that study that people from the public might say, "Oh, that was a dud. Didn't cure cancer, or it didn't jump through the hoops of what we were hoping it to," but we might have learned certain things about a certain bodily process in your cholesterol levels or certain pharmacokinetics of how your body breaks down the medication. There's all kinds of things we could learn and that might lead us to the next study that might help get it FDA-approved and might help it be efficacious.

Jim Cagliostro (17:17):

Right. I love that point.

Todd Nicklas (17:18):

Yeah, it's something to think about. And then people might not know this as well from a... Well, actually I should say from industry or academic hospital side. There's a lot of quality control measures in place. And I'm not saying that it makes it perfect across the board. We still see ethical issues pop up here and there. I know just a few years ago there was a large hospital that they found one of the oncologists had manipulated a lot of the data. It still pops up, right? I do get that.

Todd Nicklas (17:42):

We do need to squash that when we come across it, but there are so many quality control measures that you have to be aware of and check boxes and review and re-review, and we send around... On the industry side, you have to send around people that are monitoring and assessing and auditing these studies and frequently and 100% of the data, and getting back to you on X, Y, Z, so then you have it ready to report. So, there's a lot that is done today to make sure the quality is top notch. And like I said, it's not perfect, but it's getting a lot, lot better, and it's developed in an impressive way over the years to really get the answers that we need and nothing else.

Jim Cagliostro (18:20):

That's great. Well, I think in your conversation, I'm just thinking about, I haven't really stopped to consider this much, but definitely from a patient perspective, even at the bedside, clinicians don't necessarily think about or consider all the

research that goes into where medicine is at today.

Jim Cagliostro (18:36):

I think everyone listening here acknowledges medicine, the healthcare landscape, it's always changing. But I know I don't pause enough to think about, or even take the time to look into the research that's gone into getting us to where we are today.

I did want to ask you, we have a few minutes left here, and I wanted to ask you-

Todd Nicklas (18:54):

Yeah, sure.

Jim Cagliostro (18:55):

... more broadly, what challenges again, in your opinion, do you believe exist for clinical research today? What challenges exist?

Todd Nicklas (19:03):

Yeah, I'd say a few that I could focus on here for the time we have is I've learned this, especially, I'd say in the last five years acutely, is that we sometimes you set up a trial or set up a protocol. And this goes into a little bit what I was talking about, learning secondary objectives, not just sometimes our primary endpoint that you hit and meet. We sometimes don't know how to set up a protocol right to answer the questions that we think are there.

Todd Nicklas (19:26):

There's a lot of things we try to look at early on in some of the early data to say, "Oh, I think we should study it in this manner or in this population or this dosage amounts," or what have you. But it might actually not be the right question or the right protocol structure. And I've seen protocols fail and studies end up flat on its face when actually it probably was and can be a good product, but it just wasn't set up the best way to get the best answers for the FDA and for the industry to really understand and make a good decision on it.

Todd Nicklas (19:56):

And I think that's a tough thing to know because one, it wastes cost and money to put all that forth, that effort, if you're not really learning a lot from it, and it's not slam dunk at the end of the day, but we don't know what we don't know sometimes. And it is speculation. There's so much money that has to go into these trials.

I looked up a 2018 study, they said that 12% of drugs in clinical development stages get approved, 12%.

Jim Cagliostro (20:18):

Wow.

Todd Nicklas (20:19):

And it costs about $2.6 billion on average to get a drug from the very first stages of it being studied, maybe in animals or even before that to getting it FDA-approved. So people don't understand that it takes so many different iterations of trials and money and understanding all the, how does it affect your kidneys? How does it affect your heart? How does it affect your brain? How is it broken down? How effective is it? All these studies have to be done for the FDA to make a good decision.

Todd Nicklas (20:45):

And, sometimes knowing how to asset in a protocol could make or break protocol, the development of that some people might just toss it aside and say, "Well, we can't develop that anymore because we don't have the money for it and we missed the target on this." So that's a tough one, I would say upfront.

Jim Cagliostro (20:59):

Yeah.

Todd Nicklas (20:59):

One of the thing I'll say too is the processes, the regulations, the red tape. We mentioned the review board has to review this, but there's a lot of studies you have to do. And sometimes you have to do extra studies you think that aren't really necessary, but you still have to do them. And there's a lot of... You have to

go through legal and regulatory hoops and battles. So it takes some time. It takes some patience, it takes some money, like I said, and that could be a tough thing, but at the end of the day, it's good for the patients.

Todd Nicklas (21:22):

Good for the United States, because I'll say the FDA is probably one of the tighter regulatory bodies across the world. There's definitely medications, you probably know this, medications and devices that have been approved in Europe that have not been approved over at the United States for reasons of, "Hey, we don't think it was effective enough or we don't think it was safe enough, and we had these arguments." So, we understand that their purpose behind in the reasoning is to make sure that the patients are getting what they're told they're getting.

Jim Cagliostro (21:46):

That's great.

Todd Nicklas (21:46):

Yeah. I guess another thing too I'll just mentioned is enrolling diverse populations can be difficult. In young, healthy volunteer studies, you can usually get the 20 to 45 year old subjects that are willing to try a healthy volunteer study, but you have to have no medical issues, no medications you're taking. So that can be tough. It can be tough enrolling certain demographics, or there might be a study where men versus women, women might not want to sign up for a study as much as a man for various reasons and or vice versa.

Todd Nicklas (22:15):

It depends on the medication or the device, what it's kind of asking and doing. So you kind of have to look at that up front and say, "What do I need to do to make it diverse enough to really understand how it affects the population broadly? Pediatric populations are really difficult to enroll for various reasons. Obviously being yet to get the parents' consent. They really don't want to dive into research if they can avoid it because they're in a precious four-year old or precious six-year old that they don't want to have go through it.

Todd Nicklas (22:39):

So that can be really difficult. And it's known the pediatric studies enroll very slowly for that reason. And duly noted, global trials can be tough because there's so many logistics with getting medications to Asia, to Europe, to Australia wherever, but hey, that could pay off and get really good, broad understanding of the demographics for how your medication's working. So, there's a lot of things there that have to be figured out and planned ahead.

Jim Cagliostro (23:03):

That's great. Any other barriers, as we finish up here, anything else you think that would serve as a barrier for clinical research? Anything that stands out before we close up here?

Todd Nicklas (23:11):

I think people across the board are still hesitant to research in the sense that they think they're their Guinea pig. I came across it a lot where people would say, "Are you just trying this out on me because I'm a Guinea pig and I'm just saying yes to it?" And the misconception I think is because, until there's a big cure for cancer or a big cure for something major where people are saying, "Wow," from a societal perspective, like we really now appreciate research and understand I think COVID vaccine a little bit, but it also has some political components to it where people were like, "Look at the impact of the COVID vaccine."

Todd Nicklas (23:39):

But then some people kind of are worried about different sides of how that data has landed. But I think when there's big things that really hit the clinical medical world where people are like, "Wow, this is great that we have research that people are willing to do." Then you get the sense of people jumping all in. We actually had that in 2020, 2021 where people are, were really banging down the doors to say, "I want to do research," because they saw how much COVID was affecting the world, and how maybe their participation in a research study could help our understanding of it.

Todd Nicklas (24:08):

I also asked myself, what if every single person, this is hypothetical. What if every

single person said yes to clinical research, to every study they've been offered? We would have really no delays or the delays might be on the industry side or the boots on the ground and having to do the trials, and not the patients enrolling. We have lots of patients not meet criteria. I think it's like 70% of the people tend to not meet the criteria. And then another 30% to 50% tend to decline the study. So, when you already take those numbers down, let's say you have 1,000 people that would meet the criteria.

Todd Nicklas (24:40):

It's going to limit you depending on how big of a study you want to run if people say no. And like I said at the beginning, safety is first, their decision is first. But wouldn't that be... I just hypothetically like to ask myself because that would really remove a barrier that could really lift and help research world. And like I said, we felt it a little bit in 2020, but it would be neat to see going forward some of the sentiment toward clinical research get better. And understanding and respecting the physicians and the scientists that are trying to help the world get through whatever disease process they're studying.

Jim Cagliostro (25:08):

That's great, Todd. I really appreciate your perspective. Just in terms of the research side of things, again, it's something I think we don't often stop to think about, but it's such an important part of healthcare. There are so many other questions I'd love to ask in terms of raising money for the research, and how do you overcome people's skepticism when it comes to clinical trials, but we don't have time for that today, but I do want to have you back, but we really appreciate it.

Jim Cagliostro (25:30):

Thank you for being on the show today, Todd, and thank you for our listeners who spent time with us today. And if you have any questions about VIE, or if you want to reach out to me, I'm on LinkedIn. Todd Nicklas is also on LinkedIn. You can reach in there. In the show notes, you'll see some of these contact information.

We love helping hospitals save money, and we're hoping that this show today was a practical, tactical, and maybe had some strategy for you and ways that you can take and use in your organization. So we look forward to having you join

us on other shows and, Todd, again, we'd love to have you back. Thank you for joining us.

Todd (26:03):

Thank you, Jim.

Outroduction (26:04):

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MEET JIM CAGLIOSTRO

"Healthcare in this country is very complex. We cannot succeed or move forward unless we are willing to work together to achieve better patient outcomes."

James joined VIE Healthcare Consulting in 2018 and brings to the role over a decade of critical care nursing experience at highly regarded medical facilities across three states. During that time, he observed both the 'good and bad' of hospital operations in a number of regions, giving him a unique insight and understanding which he brings to our clients. That insight means he prioritizes patient care.

He has observed for himself and throughout his career that hard work makes a tangible difference in the lives of patients. While at Stanford, he was extensively involved in training staff on patient care with Ventricular Assist Devices and Total Artificial Hearts, which reinforced the importance of education and preparation in order to excel.

It is this, coupled with his experience at the bedside in reputable facilities, that has prepared him to be flexible and work on a 'patient first' basis. Underpinning that drive for meeting patient needs is an understanding of the critical requirements for clear and direct communication within and between healthcare organizations.

James has a BSc in Nursing from Messiah College and a Master's in Health Education from Penn State. He also has 7 years of critical care experience at Hershey Medical Center (PA) and Stanford Hospital & Clinics (CA) and 3 years of PACU/perioperative/surgery center experience in NJ.

MEET TODD NICKLAS

"My passion lies with orchestrating the right internal and external personnel to be a united team to provide timely, accurate, verifiable, and scientifically rigorous data. I thoroughly enjoy working with and connecting with personnel who have an excellent work ethic, strive for success and honesty, and who truly enjoy their job and the results. I find immense value in trying new things, and wearing new hats, as I grow into the various roles that come my way.."

Todd is a clinical research nurse with experience in:

Cardiology, Cardiothoracic Surgery, Cardiology Rare Disease and Genetic Diseases, Pulmonary, Transplant, Electrophysiology, Vascular Medicine/Surgery, CNS, Intensive Care, COVID-19. I've also done cross-departmental work with Diabetes, HIV, Interventional Radiology, basic science and bench labs.

His trial experience includes IITs, RCTs, observational, genetic disease, FIH/SAD/FE/MAD including Phase 1 - 4/RWE. Strong in both device and pharmaceutical interventional research development. I've worked with interventional research devices, implantable monitoring/tech, and wearables, and educating the patients and ancillary staff on such.

He's had the privilege of running studies in the OR, cath lab, EP lab, EP device clinic, ICU setting, vascular surgery suites, outpatient bays, cardiac device clinics, biopsy lab, inpatient infusion settings, ultrasound and ECHO imaging procedural areas, and exercise physiology bays for cardiac testing.

Management experience includes managing a group of 3 research coordinators and 6 work study students while heading up the UPenn Heart Failure group. He also helped to co-manage 3 other research coordinators in other cardiac departments who needed management, mentorship, and backup. He has and continues to manage part time and full time consultants on the industry side, and assess short term needs for resourcing to report to upper management when needs shift and resources are acutely needed.