Stefanie Keto: Welcome to SRAI Shop Talk, a monthly podcast spotlighting the people, practices, and evolving landscape of research administration and the community that works collectively to support it. Whether you're new to the field or a seasoned pro, each episode features insights from experts across institutions, big and small, working in pre-award and post-award compliance, communication, and everything in between. I am Stephanie Keto based at the Office of Post-Award Financial Services at North Carolina State University. This season we're exploring the theme Bridge Builders, Creating Unity Across Roles, Generations, and Technologies.

Welcome back to Shop Talk. This season we are focused on building bridges and the vital connections that keep the research enterprise moving forward. Many research administrators would say that managing a granted contract is difficult and most of them are, but anyone who's worked in clinical trials knows it's the most complex terrain in our field. It's a bridge that doesn't just connect funding to science. It connects patient safety, legal compliance, and complex financial billing.

Today, we are tackling this complex area within our field, managing the lifecycle of clinical trials from the initial spark of funding to the final administrative hurdles of closeout, building a bridge that is both compliant and efficient is a massive undertaking. To help us navigate this journey, I'm joined by two expert architects who know exactly what it takes to keep these projects on track, Anita Trupiano and Jennifer Harry. As published authors for the special clinical trials issue of the JRA, they bring a wealth of institutional knowledge to the table. To get us started, I'd love for you both to introduce yourselves and share the specific lens you're using as we look into the clinical trial landscape. Anita, the floor is yours.

Anita Trupiano: Thank you for having me. I'm Anita Trupiano, and I work with Oncology Research Administration with a focus on regulatory compliance and clinical trial operations. My background includes supporting studies from study startup through closeout. I have a particular focus on IRB oversight, documentation, compliance, staff training, delegation management, and operational readiness. I'm especially passionate about helping research teams translate regulatory requirements into practical workflows that actually work in real life.

Stefanie Keto: Thank you. All right, Jennifer.

Jennifer Harry: Yeah, thanks for having me. My name is Jennifer Harry. I am the Business Operations Director at Seattle Children's Research Institute. I manage four research centers within the Research Institute. So right now I'm focusing on clinical trial management across our groups, and I've kind of worked between Seattle Children's and University of Washington. And so at University of Washington's where I gained

some experience with clinical trial management. I was a business operations director and did the full gamut of clinical trials, budget negotiations, coverage analysis, billing grids, and then also did some regulatory. So consent forms, IRBs, things like that. So I was able to bring that expertise over to Seattle Children's. And so I've partnered really closely with our clinical research support office and really been a resource to our research centers at the organization.

Stefanie Keto: All right, thank you. So the first question I have for both of you revolves more around the funding and budget and negotiations that goes along with clinical trials. So when a PI is preparing to pursue a clinical trial opportunity, what separates studies that are truly achievable from those that look good on paper but create major operational challenges later?

Anita Trupiano: I think achievable studies have realistic infrastructure and alignment. I think that's key. A protocol can look really exciting scientifically, but if the operational infrastructure isn't there, it becomes painfully quickly. So I think some of the key things you have to look for is staffing capacity, PI engagement, the complexity of the pharmacy, image and lab feasibility, specialized procedures, and after-hour safety requirements and satellite site complexity. Enrollment targets don't matter if the operational model can't safely support the protocol, I always think.

Jennifer Harry: Yeah, I completely agree with Anita. And I think the biggest thing, too, is competing studies across the organization and then making sure that you have the adequate patient population to support your enrollment goals.

Anita Trupiano: That's a good point, the population.

Jennifer Harry: Yeah.

Stefanie Keto: You bring up an interesting question, Jennifer, there with the competing opportunities. So does that happen a lot in clinical trials?

Jennifer Harry: We see it with certain disease types. So you may have multiple studies supporting, let's say, Crohn's disease. And so really figuring out who gets put into what study if it's pulling from the same population. And so you may have people that are overlapping in studies and so are they eligible to be in? So I think those are just some considerations to make sure that you just have the right population to support your enrollment goals.

Stefanie Keto: Interesting. So then the next question I have for y'all would be more around budget negotiations. Obviously, budgets for most grants, whether it's clinical trials, I would imagine, or non, are pain points. So where do institutions commonly underestimate costs or struggle during the negotiation process?

Anita Trupiano: I find what is challenging is there's always protocol amendments. You always have to get the track changes, you have to go through the protocol. And a lot of times there's a lot of extra things that they put in there, and then you have to go through budget negotiations again. But if you don't read the protocol and if you don't point it out to the sponsor, it gets overlooked. So I think that's a big gap.

Rutgers Cancer Institute have a great team of negotiators. They don't let too much slide by. And it really is a team effort between managers, coordinators, regulatory, and grants and contracts. It's a whole team of people. But I think study startup documentation work, I think, is a lot overlooked. All of the monitoring visit supports are overlooked a lot. Screen failures and reconsenting are the big ones, I think, from my perspective. But the hidden administrative burden is often where the studies become upside down. Change, a lot of change.

Jennifer Harry: Yeah, I would say for sure, staffing costs are one of the most underestimated things. I think coordinators, it might take them a couple times, but then when you tack on all the queries a sponsor wants and some of the other things that the sponsor requires, that easily can double or triple the amount of time. And so oftentimes when we're trying to manage these in the post-award part. We don't have enough staffing support in the budget to accommodate the actual work that's being done. And then, like Anita said, monitoring visit, all those things are time, and they're usually here two, three days, depending on the studies. And so, really making sure that we're getting a lot of those costs in the budget negotiation piece early to compensate for all those administrative tasks.

Anita Trupiano: I guess another thing that comes to mind is the amount of training has become very extensive. The amount of hours and it's not just the institutional training. Now the sponsors have their own platforms, which adds another layer for complexity of figuring out... The providers having to figure out during their busy day another platform and regulatory keeping after them [inaudible 00:08:54] intense.

Stefanie Keto: Right, right. Well, and it wasn't NIH with the data management that just came out, was it last year or the year before? That was a big push. I'm sure that adds complexity as well.

Anita Trupiano: For sure.

Stefanie Keto: So then, once you get through, I guess the labyrinth of negotiations, you may move forward to, "Hey, we got some money, now we can spend things," where you're trying to get started, but what are some of the common delays or gaps that potentially happen before a study can actually move forward?

Anita Trupiano: Well, that's easy. A lot of it is credentialing delays, expirations, training gaps. Training is a big one. Delegation sometimes isn't finalized. And I guess at the end, the sponsor really wants the documentation and dribs and drabs and usually wait to the end. For me, it's frustrating, but it's part of the program.

Jennifer Harry: Yeah. I would say too, like IRB, all your regulatory things, I think that's why it's always so important to get all those things set up at the beginning when you're setting up a study, because then when it's ready to go, sponsor really just cares about once you have your site initiation visit is starting to enroll. So if you don't have all those things, it just delays that. So it's harder to meet those goals, especially if there's a short enrollment window.

Stefanie Keto: I would imagine that some of that leads into the study startup timeline and how that can move forward with being a major concern in the industry. What processes or strategies have helped your institutions improve the timelines without compromising that compliance or the training aspect that you have to meet?

Anita Trupiano: I think in our institution, what we just implemented was the rapid protocol activation. And we have a special team, study startup team. That's all they do, and they're really quite excellent at it, and it's really working out well. I guess some of the tricks are the startup checklist and ownership. They have the full ownership of starting it up. That makes them really focused. Once they get them started, then it goes to the lead regulatory person. There's also a lot of centralized documentation, so anybody can go there and grab what they need or add to it or take away from it. One of the things is we have a credentialing specialist, so we're very proactive about that, and that's really been helpful. So that's all tricks.

Jennifer Harry: Yeah. We've recently, I guess, for like two, three years now, got to implement a new CTMS. And so that's really helped streamline with some specific task list for study startups. So that's been really helpful to keep everybody on track on what things that need to be done. So that's been pretty helpful to know who does what and when. So when that study is open to accrual, then everybody's all on the same page.

Stefanie Keto: And then once you get everybody on the same page, you got all your little ducks in a row, you've got your funding, it sounds like you have your timelines in check, then it gets to move to the trial gets to become active, correct? And then how does that communication move forward? What breakdowns happen between research teams or other entities on campus, maybe the regulatory offices or investigators?

Anita Trupiano: Well, that's a great question because everybody on the team sees it from a different perspective and a different version of the study. Finance sees budget, regulatory sees compliance, coordinator sees

workflows, PI sees scientific opportunity, and sponsors see timelines. So everybody's working on the same trial, but often completely different realities. That's what I find.

Jennifer Harry: Yeah. I think that's just, again, where the communication has to happen. We have typically a startup meeting once everything to everybody is kind of lines, but yeah, there's still always communication breakdowns that happen regardless of how proactive you try to be. So yeah, we haven't figured out how to solve that yet.

Anita Trupiano: We do also have weekly meetings, and everybody can get to speed on all the trials, so everybody knows in each department, which is helpful, I find.

Stefanie Keto: I think it also probably meeting like that would help, as you say, the finance people care about the money, the regulatory team cares. So knowing what everybody else is responsible for, I could see where that would be very helpful for the team in general. So tip for the listeners, make sure you're meeting.

Anita Trupiano: Yes, it's very helpful.

Stefanie Keto: Yeah. So Jennifer, well, I think both of you relayed or talked about this earlier with budget constraints, but with the shortfalls and maybe not budgeting enough money for everything like that. And of course, trials seem to becoming more complex as time is moving on. So how are your institutions balancing the financial oversight or these compliance requirements, training, to move the studies along?

Jennifer Harry: Yeah. So we're really trying to do more of a financial feasibility at the beginning just to fully understand all the costs for these studies to make sure that we have the resources. And then when they're fully budgeted, it's going back and making sure we have those adequate resources and that we won't potentially find ourselves in a large deficit, especially if we don't meet those enrollment goals. And so really trying to have those communications really at the beginning to fully understand what the impact of the budget is and then what happens when we don't meet our enrollment goals, because ideally, that can potentially become something that could be on the institution to cover if investigators don't have funds to cover deficits for studies.

Anita Trupiano: I think from our perspective, what we've found is role clarity works really well so everybody knows exactly what they're doing. And I think escalating pathways, we have policies in place with that and that helps also, and real-time communication with the meetings help also. And we also have documented workflows, which is useful and well, we like to say realistic staffing. We do the best we can.

Stefanie Keto: I think that's across the board, right? I feel like everybody feels like they're a little overworked and having an extra person would help.

Anita Trupiano: But I think compliance and speed are not opposites at all. I think chaos is what makes them feel incompatible.

Stefanie Keto: Oh, it's like herding cats then, right? Yeah. Okay. So when you are moving out of that day-to-day management and you're looking towards potentially other challenges, you both have mentioned that relying on staffing shortages or not enough staff that can do what they need to. Obviously, it helps to have maybe someone who's more experienced, whether it's a coordinator, administrator, regulatory staff, but where do you see the biggest workforce and training gaps currently?

Anita Trupiano: For us, we have a lot of turnover. There's a lot of coordinator turnover, which just so the workflow goes down. You have to start up all the paperwork. There's a lot of paperwork to be onboarded. And as you said before, the protocol complexity is outpacing the training sometimes. Those are the two big things.

Jennifer Harry: Yeah. I agree for the study teams, the turnover for sure is one thing, but then also thinking about for research administrators in general is just overall training on how to effectively manage clinical trials in the post-award. So I think it's definitely a lot different than a federal grant, which is very clear what your budget is and how much PI effort is and staff time. With clinical trials, it's a little bit different because it's based on your enrollment. So as long as you're enrolling, you're bringing in money to support all the costs to do those studies.

And so I think having that, at least someone within your organization that knows how to do clinical trials that can provide training to others, I think helps with the management to be able to provide financial guidance on how the study's doing, how the funding is, projections and things like that. So the study teams are aware of we have additional funds to bring on new people or whatever needs to happen, but I think it's a team between... The coordination between the research administrators and the study teams and the PIs running the studies.

Stefanie Keto: And just because I don't know this whole realm of research administration because we're primarily not in this field in my world, but you mentioned the clinical trial coordinators. So are they specific to one particular clinical trial or do they work on additional maybe two or three at a time? How does that work?

Jennifer Harry: I know for ours, they usually will have maybe two to three studies, I guess, depending on the complexity of them. Anita, do you have the same thing?

Anita Trupiano: Oh, they have many trials, at least 100, 20 to 100.

Stefanie Keto: Because I was just thinking about what you had said, Anita, about having a high turnover rate of coordinators. And I was just thinking administratively how that training goes, especially if it was just one-on-one project or one trial, it would be, okay, maybe not so bad, but if they're working on a broad spectrum of them, trying to keep them up on this trial versus this trial versus that trial could be an added layer of frustration or complication that goes along with everything.

Jennifer Harry: [inaudible 00:20:33] to navigate because then when one person leaves, that potentially could pause the entire study until you get somebody else on board or retrain so that you're looking at at least another one to two month gap if you don't have other things in place. Yeah.

Stefanie Keto: Stalls the trials and then potentially adds more to the budget, right? So that's another complexity that goes with it. So when you're looking forward on the clinical trials for the future, what changes, maybe like operational, regulatory, financial, or technology do you think institutions are now preparing for?

Anita Trupiano: I think it's not just about adapting to the new technologies, it's integrating it without trying to create compliance risks. We have AI workflow support now coming in and a lot more data complexity, also. So those are all factors.

Jennifer Harry: Yeah. I would say, looking at systems to help manage some of this, I think like I said, we've had a CT mass, which has really helped, because I think every group was trying to manage their own clinical trials in their own way. And standardizing the process has really helped improve workflow. So that has been helpful.

Anita Trupiano: That's a great idea.

Stefanie Keto: I was just thinking of the last time I went to the doctor, I walked in, I sit down, and we have a research facility that I go to for my doctors. And the first thing he asked me when I sat down was, "Hey, is it okay if AI takes notes on this visit?" And I was like, "Um." And so I know that that clearly is now something new that is in the forefront of how when you're looking at technology, how that's going to help. But then I've also heard the negative impacts of AI and how that it's adding more time to them as they're having to go back and review and it's not as beneficial. I don't know if y'all have heard anything about the AI implications in the realm of clinical trials.

Anita Trupiano: Too much, but if they are involved, you always have to check. I think you have to hire more people to check on AI network.

Stefanie Keto: Probably, probably. So now as we're closing out the lifecycle and we're looking at just the lifecycle in general, closeout is the end piece of a project and I'm sure it's the same with clinical trials. So what are some considerations that need to be thought about or applied when you're closing out a clinical trial for reporting or impact?

Jennifer Harry: I would say, just the invoicing piece. I think in between the day-to-day management and then the closeout rate is just making sure that you've invoiced for all the things that need to be invoiced, you receive all the funds, and that's where really the partnership between the study teams and the research administration is really important, that communication piece so that they know what to invoice for and then just making sure we've received all the payments before we can actually do the financial closeout piece.

Anita Trupiano: And I guess I get it from the regulatory point, make sure that all the IP is returned, make sure IRB documentation is closed out. And it's a process, so people don't really leave anything out. So that's good.

Stefanie Keto: So then what would you say is one issue that is in existence in clinical trials right now that people outside of the field underestimate the most?

Anita Trupiano: I don't think that they realize how much the trial depends on operational infrastructure, not just scientific design. I think they think of clinical trials as science and scientific design, but there's a lot of manpower and infrastructure that need to go there to support the clinical trial, the amount of people and large teams.

Jennifer Harry: Yeah, I agree. There's a lot of coordination that needs to happen across all the offices. And I think part of it is making sure that everyone's trained on each of those pieces, so everybody is aware of their role when someone brings in a new clinical trial.

Stefanie Keto: Does cross-training ever happen in this field to help with the, as you mentioned, having everybody know what's going on?

Anita Trupiano: It depends on the institution. I'm at a [inaudible 00:25:41] institution, so we go deep. So when I was at another institution, you go wide. So it depends on institutions.

Stefanie Keto: Yeah. It's that famous phrase, man. It depends. Okay. Well, so the last question that I have for both of you all is we mentioned earlier that you were published in the JRA, and obviously when you go through publications like that, you have your studies and research that you did. So what areas do you think need more research visibility for maybe a potential publication regarding the topic?

Anita Trupiano: I think a good topic is training.

Jennifer Harry: Yeah, I agree. I think my publication was around self-auditing. And so part of what came out of that was the training gaps that are oftentimes associated just in research administration, in general, that really clinical trials aren't necessarily trained. You get training on federal grants and how to do those, but no one really tells you how to do a clinical trial. You either have someone that's showed you or your PI says, "Oh, I want to bring on this trial." And then you kind of have to figure it out.

So I think doing some more trainings on that and then just specifically around what to look at because I think there's a lot of compliance risks that do come with having clinical trials. And so I think if you have the right training in place, we're equipped to understand when things aren't billed correctly or things like that. I think there's a lot of complexity that comes with it that maybe research administrators may or may not know is part of their roles. And so that does create a financial compliance risk for your organization. And so we've tried to look at that and provide some additional training around that for our staff.

Stefanie Keto: Yeah. I think training is important. And I think what goes along with that very well, too, is transparency, too, making sure that you have... Like you said, with the meetings, Anita, sitting down, everybody knows where everybody is and what they're doing and everything along that course as well.

Jennifer Harry: Yeah. And I will say, too, I think it's been really great. At least, in the past couple years, there's definitely been some more sessions at SRAI conferences around clinical trials, which I think have been really great. I think as people get more exposed to clinical trials, people have questions. And so it's great that there are sessions to help people and then build connections across different organizations around how people are doing things, I think is a really great opportunity, one to network, but also learn some new things that you can bring back to your organization to implement.

Stefanie Keto: And maybe spark the interest for someone to want to become a clinical trial coordinator, since it seems like that's a hard position to keep. Well, we are reaching the end of our bridge today. It sounds like managing clinical trials is really not just a series of checkboxes. It's making sure that you're doing everything from the first day, following those regulatory compliance all the way to the closeout and making sure all those things are aligned and that everything is good. So thank you both for coming, Anita, Jennifer. This was great. I think it definitely has provided our listeners hopefully a high level of practical day-to-day operations that help keep trials running safely and successfully.

Anita Trupiano: Thank you. Thank you for having me.

Jennifer Harry: Thank you for having me.

Stefanie Keto: It's clear that managing a clinical trial from the funding to closeout has its hurdles that the research group has to navigate in order to meet the finish line for the research mission. Anita and Jennifer really highlighted the biggest challenges that are facing clinical trials right now, from staffing shortages to the consistent need for specialized training, which requires strong internal foundations. As we all know, the push for transparency is on our shoulders as well as shifting regulatory requirements. The work environment needs to shift to accommodate these changes.

One of the most vital bridges brought up today is the CTMS or the clinical trial management system. For those who are new to clinical trials like me, think of the CTMS as the central nervous system of a trial. It's a specialized software platform that tracks everything from patient enrollment, to protocol compliance, to financial billing and milestones.

Essentially, it's the digital bridge that connects the clinical side of the study with the administrative side, ensuring all data is accurate to allow for a clean closeout. A huge thank you to Anita Trupiano and Jennifer Harry for sharing your expertise and helping us navigate the complexities of this field. To our listeners, whether you're struggling with a staffing gap or a new regulatory hurdle, remember that every bridge you build today makes the enterprise more resilient tomorrow.

A huge thank you, as always, to our wonderful podcast team and everyone who continually contributes to enhancing this podcast. We are proud that this platform brings together people, ideas, and new opportunities in research administration. The conversation doesn't stop here. We would love to hear from you. Please submit your suggestions for future episodes of SRAI Shop Talk to shoptalk@srai.org. Thank you again for listening to this episode. Don't forget to subscribe and help grow our community by sharing. I'm Stephanie Keto and I'll catch you on the next episode.