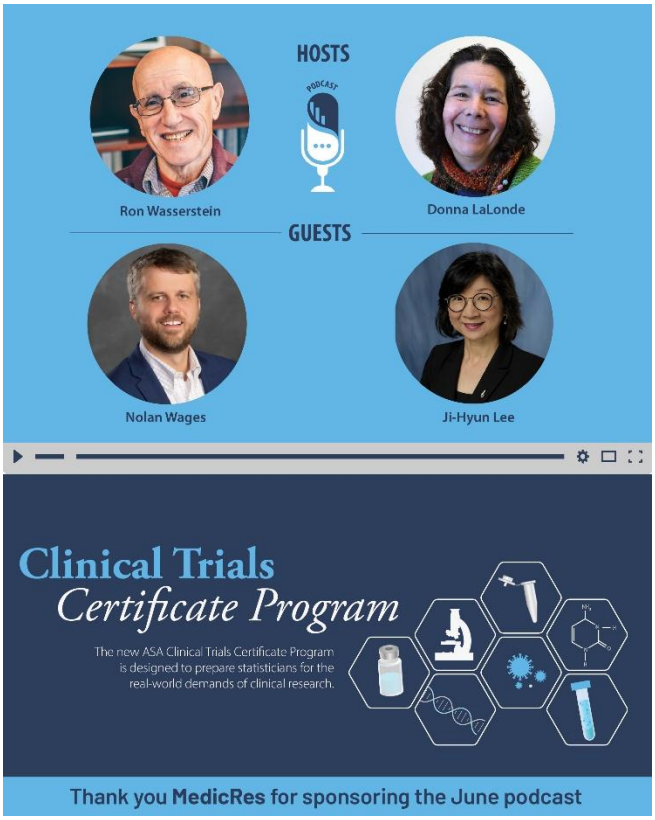
***Practical Significance* | Episode 66: Inside the New ASA Clinical Trials Certificate Program**



Donna LaLonde: Well, everyone, we are super excited to welcome you to the June episode of *Practical Significance* because we get to talk about the Clinical Trial Certificate Program, which we've been planning for well over a year now.

I'm delighted to have Ji-Hyun and Nolan with us to share some insights about how the program developed and what folks can look forward to. But we always start by asking our guests to tell us about their day jobs. So, Nolan, we'll start with you.

Nolan Wages: Thank you so much for having me on. It's a pleasure to be here.

My name is Nolan Wages. I'm a professor in the Department of Biostatistics at Virginia Commonwealth University School of Public Health in Richmond. I also serve as the director of the Biostatistics Shared Resource for VCU's Massey Comprehensive Cancer Center.

My research primarily focuses on the design of early-phase clinical trials in oncology. I do that from a statistical methodology standpoint, as well as through collaborations with cancer center members in designing and analyzing their trials. I also teach clinical trial-related coursework for our PhD program in the Department of Biostatistics.

Donna LaLonde: Great. Thank you. And Ji-Hyun, you probably don't need any introduction to our listeners but tell us about your day job.

Ji-Hyun Lee: Thank you, Donna and Ron, for having me. First of all, I'm very excited to talk about this Clinical Trial Certificate Program and share it with statisticians and data scientists through this podcast.

I am Ji-Hyun Lee, professor of biostatistics at the University of Florida and associate director for Cancer Quantitative Sciences at the UF Health Cancer Institute. Like Nolan, I also lead the Biostatistics and Computational Biology Shared Resource at the Cancer

Institute. Of course, most recently, I served as president of the American Statistical Association.

My daily work, in addition to teaching courses and mentoring students, involves collaborating with clinicians and researchers on cancer clinical trials and translational research. Much of my work focuses on study design, statistical leadership, and helping use data to answer important questions in cancer research and patient care.

You can probably see why this Clinical Trial Certificate Program is very close to my heart, and I am really looking forward to this conversation.

Ron Wasserstein: Well, great, Ji-Hyun. I'm going to stay with you since you actually gave a sneak peek into the Clinical Trial Certificate Program during your address at last year's JSM.

So let's start with the "why." Why did you believe there was a need to build this program?

Ji-Hyun Lee: I have worked in clinical trials for many years, both in academic medical centers and as a faculty member in biostatistics. Over time, I have come to believe strongly that there is still a meaningful gap between academic statistical training and the realities of clinical trial practice.

During my own training, I learned rigorous statistical theory and methodology. But when I entered the world of oncology trials, I quickly realized how much I still needed to learn. For example, when I first heard about Phase I and Phase II trials, I had no idea what that meant. I also wondered, what is a clinical trial protocol, and what do biostatisticians do to prepare for it?

Of course, training programs today are much better and more modern than they were when I was a student a long time ago. But I still see the same challenge when statisticians enter clinical trial settings. It often takes substantial time—really substantial time—mentorship, and collective effort before they fully understand how these studies actually operate.

Clinical trials are not just about statistical methods. They involve regulatory expectations, protocol development, multidisciplinary communication, operational limitations, patient safety, interim decision-making, and interpretation under uncertainty.

At the same time, trials are becoming more complex.

We now see adaptive designs, biomarker-driven studies, and the growing use of AI tools in clinical research. Meanwhile, the demand for statisticians in pharmaceutical companies, CROs, and academic medical centers continues to increase.

So, the ASA wanted to create a more structured pathway to help statisticians gain practical clinical trial experience before entering these environments. The goal is quite simple: to

help our members become more prepared, more confident, and more effective in real clinical research settings.

That's my strong "why" for why we needed this program.

Ron Wasserstein: Thanks very much. Nolan, I know that you are chairing the steering committee that has been involved in the development of the program. Is there anything you would like to add to that?

Nolan Wages: Yes, I think Ji-Hyun covered it very well. Along the same lines as what she shared, many statisticians receive strong theoretical training, but clinical trials require a very specific applied skill set. Things Ji-Hyun mentioned, such as protocol development, navigating regulatory considerations, and even endpoint selection, are not always covered in a structured way in graduate programs.

As a result, people often end up learning these skills informally on the job, which can be inefficient and sometimes inconsistent.

We're trying to bridge that gap with this program and help people translate their statistical foundation into the context of real-world clinical research, where these decisions can directly impact patient care and regulatory approval.

Ron Wasserstein: So, Nolan, both of you have addressed this to a certain extent, but just to build on what you were saying: you had a group in mind when you decided to build this curriculum.

Who would those people be? Early-career professionals who have had the methodological and theoretical training but not practical training? People who might want to switch from what they're doing into clinical trials research? Who were your target audience or audiences?

Nolan Wages: Thank you, Ron, for the question.

The certificate program is really designed to span that spectrum, which is what makes this program unique, in my opinion.

We're targeting quantitatively trained individuals—people with graduate-level backgrounds in statistics, biostatistics, data science, or other related fields. But they could be at very different stages of their careers.

This could include early-career individuals, such as recent master's graduates trying to break into the pharmaceutical or clinical trial space. It could also include mid-career statisticians who may be pivoting from other areas.

We also envision academic researchers who want to be more deeply involved in clinical studies because, as we mentioned, clinical trials require a very specific applied skill set.

So it's less about where you are in your career and more about whether you have the quantitative foundation and want to apply it to clinical trials.

Ron Wasserstein: Ji-Hyun, did Nolan leave out any groups?

Ji-Hyun Lee: What Nolan said is absolutely right. This program is designed to be broad enough to support multiple career stages while remaining focused on practical clinical trial competency.

We also expect interest from academic researchers who already collaborate on clinical studies but want a deeper understanding of trial operations and statistical leadership.

If statisticians focus only on the methodological aspects of trials, our influence can remain limited. But when we also understand the broader clinical, operational, and regulatory landscape, we are better positioned to take on leadership roles and contribute more effectively to decision-making.

In that sense, this program is designed to support multiple career stages.

Donna LaLonde: Great, thank you. And Ji-Hyun, I'll stay with you because I remember well that your theme for your presidential year was "Building Bridges." In talking with you and the other members of the steering committee, I understand that one of the program's goals is bridging statistical foundations and medical research implementation.

Can you say a little bit more about why that bridge is so hard to cross without structured training?

Ji-Hyun Lee: You know how much I love the theme of building bridges, right?

I think the challenge is that the two worlds operate very differently. Graduate programs understandably focus on statistical theory, computation, and methodology. But real clinical trials involve many additional dimensions that are difficult to learn from textbooks or classrooms alone.

For example, statisticians need to understand how protocols are written, how endpoints are selected, and how FDA guidance affects analysis decisions. Many statisticians may not even be familiar with the term "endpoint" because in other settings we often refer to them as primary outcome variables. They also need to understand how data are collected and monitored and how multidisciplinary teams function under pressure.

Even communication becomes critically important.

For example, a statistician may need to explain uncertainty or risk to clinicians, investigators, regulators, or company leadership. Not everyone is trained in our language. Without structured exposure, many people learn these lessons only through trial and error after entering the workforce, which can be stressful and inefficient.

Do you remember our initial meeting with the instructors? I recall Susan Halabi from Duke University saying that many statisticians learn clinical trials through trial and error. Over the years, we accumulate a great deal of practical knowledge.

Now we have a responsibility to pass that experience on to the next generation of statisticians. Otherwise, we risk losing important opportunities to strengthen both our profession and our impact on clinical research.

I feel strongly that this program will be a great way to advance our profession. That's why I am so excited about it and so excited to continue building bridges.

Donna LaLonde: Thanks very much. Nolan, I want to ask you about the structure of the program, but before I do that, do you want to add anything about that transition—the process of walking across the bridge?

Nolan Wages: Sure. Ji-Hyun covered it beautifully. The only thing I might add is that, while she's correct that we often learn these aspects through trial and error, we also tend to learn them under significant time pressure.

We're often working with tight deadlines, and everything seems to be due yesterday. This goes beyond the clinical trial space, but many of us are learning while working under intense time constraints.

I think this program is going to provide people with the time and space to really learn these concepts without feeling the pressure we often experience in our day jobs.

Donna LaLonde: That's great. I want to stay with you to talk a little more about the program structure and how the committee developed it. I know it will be cohort-based and online, but tell me a little more about how you decided on the topics and planned out the certificate program.

Nolan Wages: First, regarding the structure, we wanted something that balanced flexibility with engagement, including engagement with the colleagues who will be participating in the certificate program alongside you.

The two-part weekly model grew out of that goal.

Participants will complete asynchronous material on their own time—things like recorded lectures, readings, and exercises—making the program accessible to people who are

working full time. We then pair that with a live, synchronous session each week. That's where the deeper learning happens through discussion, Q&A, and interaction with instructors, mentors, and peers.

That's really how we wanted to structure the program: combining those two components to create a meaningful learning experience.

The cohort model was also very intentional. Clinical trials are inherently collaborative, as we've already discussed. We wanted participants to learn in a community and build connections, not simply consume content in isolation.

As far as the content goes, Ji-Hyun and I should acknowledge the rest of our committee members who have been working on this with us: Lisa LaVange, Antje Hoering, and Amarjot Kaur.

We had a lot of back-and-forth discussions about the content and what should make the final cut for the program's inaugural year. The topics themselves did not require a great deal of debate, but the sequencing did. We spent considerable time discussing where each topic should be placed and the order in which participants would be exposed to the material.

We had a committee that worked very well together, and through those weekly discussions, we ultimately landed on the structure and content for this first cohort's program.

Ji-Hyun Lee: As Nolan mentioned, we spent a lot of time discussing this.

We wanted the program to be accessible to participants across different locations and career stages, including working professionals. An online format allows for broad participation while keeping the program flexible.

At the same time, we didn't want it to become a passive "watch the videos and move on" experience. Personally, that sounded pretty boring to me.

Clinical trials are highly collaborative, and Nolan emphasized that earlier. Interaction matters. That's why we chose a cohort-based structure. Participants will move through the program together, engage in discussions, solve problems collaboratively, and learn from both faculty instructors and their peers.

We also felt strongly about including a capstone practicum.

We did not want participants to simply memorize concepts. We wanted them to apply their knowledge to realistic clinical trial problems.

In many ways, the structure we built reflects how statisticians actually work in clinical research—through teamwork, communication, and practical problem-solving.

That's why we decided to adopt a cohort-based online program, and it was the result of many thoughtful discussions among the committee members.

Donna LaLonde: That's great. I'll also let our listeners know that the show notes will include a link to the certificate program website so that anyone interested can learn more about the application process and the specific content that will be covered throughout the program.

Ji-Hyun, I want to come back to you because we've worked together on the board for quite a while. One of the first things I learned about you was how deeply you care about the people participating in the research studies you're involved in.

You are constantly focused on the fact that these participants are people, and that they are often going through very difficult circumstances—sometimes the most difficult experiences of their lives.

You always keep that perspective front and center.

So I wanted to ask: when it came to building this curriculum, how did you incorporate that aspect of how you view your research into the design of the program?

Ji-Hyun Lee: You are right. The way I see data is perhaps a little different from how methodological statisticians may view it. To me, each data point reflects a patient's life. That's how I see the data.

Clinical trials are fundamentally about patients. Statistical decisions in trials are not abstract mathematical exercises. They can directly affect treatment development, regulatory approval, and ultimately patient care.

That perspective shaped the curriculum significantly.

Of course, we are teaching emerging statistical methodologies and design principles. But we also wanted participants to understand why all of this matters. Poor endpoint selection, inadequate monitoring, weak data quality, or inappropriate interpretation can have very real and serious consequences.

We also spent time debating balance. There is simply too much material to cover fully in a single certificate program.

The challenge was deciding what is most essential and practical from a patient-care perspective. We focused on areas where statisticians often face steep learning curves in

real-world clinical trial settings while creating a framework that participants can continue to build upon throughout their careers.

At the end of the day, we wanted participants to understand that clinical trials are not just about methods or models. They are about patients and decisions that can affect their lives.

That is my personal hope, and I think the themes of this Clinical Trial Certificate Program are very well aligned with that goal.

Nolan Wages: One thing I would add is that we felt strongly about including a capstone experience, and I think Ji-Hyun mentioned this in one of her earlier answers.

Giving participants the opportunity to work on a real project—designing, analyzing, and interpreting actual studies—helps connect the material to the kinds of decisions they will face in practice and the impact those decisions can have on patients.

We did not want this to be solely a didactic experience with lectures and exercises. We wanted participants to engage in a real-world capstone project. I think that contributes to the mindset that this work is ultimately about patients, and we hope participants leave the program with that perspective.

Ron Wasserstein: Nolan, I'm going to stay with you and take a step back from the Clinical Trial Certificate Program to talk a little more broadly about the statistician's role in clinical research.

You've shared that you direct a cancer center resource and also train students. With those roles in mind, what would you say about the statistician's role in the clinical research landscape?

Nolan Wages: First of all, I think the role is much broader than people sometimes realize.

Statisticians should not be brought in only at the analysis stage. Ideally, we're involved from the very beginning—not just in the design, but in the initial concept of the trial and the research questions being asked.

Ji-Hyun has already talked a little about endpoint selection and other important decisions made on the front end. Statisticians help define research questions, select endpoints, design studies, determine how evidence will be generated, and decide how data will be analyzed. We should be involved throughout the entire lifespan of a clinical trial.

In my experience, many clinical investigators come to me expecting to fit their study into some standard template or traditional trial design.

But a big part of my role is helping them refine their objectives and then tailoring the design to answer the questions they are truly interested in exploring.

Sometimes it feels as though a clinician comes to me trying to fit a question into a design, whereas I want to fit the design to the question. It's really a reversal of that mentality.

Some of the most rewarding moments in my career have been when a collaborator says, "I've never thought about that before." Those conversations often lead us to ideas that were not initially on their radar but turn out to be exactly what they are interested in investigating. We can then tailor a design to answer that question and create something truly innovative.

That means moving beyond default approaches and thinking more creatively about which design is most appropriate.

Statisticians also play a critical role in ensuring rigor and integrity. We've already talked about that. We help ensure studies are designed in ways that produce reliable and interpretable results.

Importantly, we also serve as translators between disciplines. We bridge clinical, operational, and regulatory perspectives in ways that support better decisions for patients.

I believe statisticians need at least some understanding of all those areas for a clinical trial to work effectively. Being involved throughout the entire life cycle of a trial—from initial conception through analysis and publication—and being knowledgeable about the clinical, operational, statistical, and regulatory aspects of research ultimately leads to stronger clinical trials.

Ron Wasserstein: That's great. Ji-Hyun, I know you're also passionate about the statistician's role, so please share some thoughts on that.

Ji-Hyun Lee: First of all, Nolan said it beautifully. That's exactly what I wanted to say.

This is actually a topic I have been advocating for for many years. I believe, as Nolan said, that statisticians should be viewed as central scientific partners in clinical research, not simply as technical consultants brought in at the design or analysis stage. In reality, statisticians are often involved throughout the entire process.

In fact, I experienced this very directly in a recent clinical trial involving immuno-compromised cancer patients.

During the study, interim analyses began showing concerning early safety signals, and those findings became an important part of discussions about patient safety and whether the trial should continue as planned.

Later, after the study received national attention, I found myself spending a great deal of time explaining what a noninferiority trial actually means to clinicians and the public without making the explanation overly technical.

That experience clearly reminded me that statisticians do much more than analyze data.

We help guide scientific decisions, protect study integrity—as Nolan mentioned—and communicate evidence responsibly.

As clinical research becomes more data-intensive and AI-driven, I believe our role becomes even more important.

Nolan Wages: I remember several occasions during initial meetings with clinicians when I would ask questions and eventually get to a point where I would say, "You came here with this question, but it sounds like what you really want to do is this. Is that correct?"

And the clinician would respond, "Yes, but I didn't know we could do that."

I think part of our job is to show them that we can do that. If we're truly at the forefront of innovative trial design, we can introduce our clinical collaborators to approaches and possibilities they may not have considered.

Ji-Hyun Lee: Absolutely, Nolan. The same thing happens in my daily work.

Many initial meetings are filled with questions from statisticians: Why is that? Why do you do it that way? Why did you choose this? Why did you choose that? By the end of the conversation, I often hear, "I never thought about it that way."

I think one of our most important roles is asking thoughtful questions that challenge assumptions and help move research forward.

Ron Wasserstein: Wow. I love all of that.

It reminds me of something I often say when I have the opportunity to speak with students and other groups: it's a great time to be a statistician because we get to do so many interesting things.

And whenever I talk to these groups, it's almost impossible to have a conversation without someone asking about AI.

So I don't think we can let this discussion end without asking about AI as well.

How do you see AI changing clinical trial design, analysis, and many of the other aspects of clinical research we've been talking about today?

Ji-Hyun, let's start with you.

Ji-Hyun Lee: Of course, we can't continue a conversation today without talking about AI.

What I observe is that AI is beginning to influence many aspects of clinical trials, although I think we are still in the early stages.

Right now, I see the biggest impact in areas such as patient recruitment, eligibility screening from electronic health records (EHRs), real-time monitoring, and the management of large and complex datasets.

We are also starting to see new therapies and treatment strategies that incorporate AI algorithms themselves, particularly in personalized medicine and biomarker-driven treatment approaches. These developments create additional challenges for clinical trial design, validation, and evaluation.

But the fundamental principles of clinical trials—careful study design, reliable endpoints, patient safety, and rigorous evidence evaluation—remain the same.

In some ways, AI may actually make statistical thinking even more important because the data and decision-making processes are becoming more complex.

That is another reason programs like this certificate initiative matter. The future clinical trial workforce will need not only strong statistical skills, but also a practical understanding of how clinical research is evolving in the AI era.

Ron Wasserstein: Thank you, Ji-Hyun. Nolan, what are your thoughts about AI these days?

Nolan Wages: My thinking is very much along the same lines as Ji-Hyun's. I think she covered it very well.

I believe the biggest impact of AI will be in augmenting statisticians, not replacing them. AI will help improve efficiency and, as Ji-Hyun pointed out, may automate certain aspects of the clinical trial process.

However, the core responsibilities around study design, inference, and interpretation will still require careful judgment.

Statisticians will play an important role in evaluating and appropriately integrating AI-driven methods into clinical trials.

In some ways, I think that makes the kind of structured training we're offering even more important because people need a strong foundation to use these tools responsibly.

Donnal LaLonde: Well, I can't wait to have the two of you back in about a year so we can do a retrospective on the first cohort of the Clinical Trial Certificate Program.

I'm really looking forward to seeing how it develops over the next few months.

We have traditions on the *Practical Significance* podcast, and one of those traditions is that we always like to end by asking our guests what they're reading, listening to, or watching.

So, Nolan, I'll start with you. What's on your TBR list, playlist, or viewing schedule?

Nolan Wages: On the reading front, I recently finished a book called *Why We Sleep* by Matthew Walker. It explains how sleep is essential for cognitive function, physical health, and overall well-being, and how some of our modern habits can undermine it.

I also regularly listen to a podcast called *Deep Questions* by Cal Newport, a computer science professor at Georgetown University. The podcast explores how to build and maintain a focused life in a world full of distractions. His books are excellent as well, and I've read several of them.

I don't watch a lot of television. Between my job and my three children, there isn't much time for that. But whenever I have a few minutes in the evening, I've been watching the NBA playoffs with my sons.

I know that was a topic on a recent episode of *Practical Significance*—someone was talking about their work related to the NBA. It's been a nice way to unwind and spend time with my family in the evenings.

Ron Wasserstein: And are you a basketball player as well?

Nolan Wages: I was in my younger days.

Donna LaLonde: Ji-Hyun, over to you. What are you watching, listening to, or reading these days?

Ji-Hyun Lee: I recently watched the movie *Project Hail Mary*. I generally don't go to movie theaters, so this was a special event for me.

I'm also not usually a big fan of science fiction books or movies, but this one was a remarkable exception. It brought me to tears and made me think more deeply about statistical thinking as well—collaboration, uncertainty, the meaning of life, and purpose.

Now I'm listening to the audiobook of *Project Hail Mary* by Andy Weir. My next plan is to watch the movie again in an IMAX theater, which unfortunately is not available in the small college town where I live.

Donna LaLonde: That is wonderful.

I also know that you're a musician, so you have to tell me about one piece of music or one artist you're listening to that I can add to my playlist.

Ji-Hyun Lee: Thank you.

Actually, we had our annual concert last Sunday here at the University of Florida Music Hall. We performed a lot of wonderful music, but one piece that moved some people to tears was by Vivaldi.

It's a truly remarkable work. I had never really spent much time listening to or fully appreciating Vivaldi before, but this music was eye-opening for me.

If you have the chance, I encourage you to revisit some of Vivaldi's classic compositions.

Donna LaLonde: That's great. Thank you so much.

And thank you both for a truly wonderful conversation.

Speaking of traditions, we have another tradition on *Practical Significance*, and that is to conclude with Ron's Top 10. So I'll turn it over to my colleague Ron for this month's list.

Ron Wasserstein: Thank you, Donna.

I spend too much time watching sports on television, which means I see far too many pharmaceutical advertisements. After seeing six such commercials in a row during a sporting event, I muted the sound.

In the quiet, I started thinking about pharmaceuticals that statisticians wish existed.

So, here is the Top 10 list of medications statisticians would like to be able to prescribe.

10. Causara (scientific name *correlcausalase*) targets the neural pathway responsible for drawing causal arrows from scatter plots alone. Ask your statistician if Causara is right for your observational study.

9. Openstatix (*datahoardimab*) reduces the territorial response to reasonable data-sharing requests.

8. Designova (*questionnairevir*) treats chronic double-barreled-question syndrome, leading-question disorder, and the dangerous belief that questionnaire design is simply "writing some questions."

7. Thinkyourselfex (*halucitinib*) is indicated for researchers who accept AI output without verification.

6. Simpliva (*simplistipram*) stimulates the principle of parsimony and blocks the receptor that equates model complexity with scientific rigor.

5. Fillgapizzi (*imputimazine)* promotes principled imputation and the willingness to ask why data are missing in the first place.

4. Randomax (*convenisamplide*) suppresses the impulse to sample whoever is nearest, cheapest, or most willing.

3. Allevance *(cherrypickitide*) promotes systematic search strategies, PRISMA compliance, and the discovery of inconvenient evidence.

2. Reproducix (*documentazole*) stimulates natural production of README files, code comments, and data dictionaries.

And the number one medication statisticians wish they could prescribe:

1. Proactiva (*planaheadipine*) lowers everyone's blood pressure by stimulating researchers to engage statisticians early in the research development process.