DOCTOR'S CROSSING
CARPE DIEM PODCAST
BY HEATHER FORK, MD, MCC

TRANSCRIPT

EPISODE 158 Variety and Familiarity Meet in the Medical Monitor Role

With guest Dr. Jason Steinberg

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JS: "I think many physicians may be in a good position to be a medical monitor. Certainly internists, family medicine doctors, general surgeons would be very useful, especially for medical device trials."

HF: Welcome to The Doctor's Crossing Carpe Diem podcast. If you're questioning your career in medicine, you've come to the right place. I'm Heather Fork, a former dermatologist and founder of The Doctor's Crossing. As a master certified coach, I've helped hundreds of physicians find greater happiness in their career, whether in medicine, a nonclinical job, or something else. I started this podcast to help you discover the career path that's best for you and give you some resources and encouragement to make it happen. You don't need to get stuck at the white coat crossroads. So, pull up a chair, my friend, and let's carpe that diem.

Hi there and welcome back to the Doctor's Crossing Carpe Diem podcast. I'm your host Heather Fork, and you're listening to episode number 158. In this episode, we are opening up the black box of pharma yet again to shed light on a very interesting role physicians have where they get to use their clinical knowledge in a variety of ways.

I call it the black box of pharma because there are a good number of jobs in this industry that you can have but from the job title alone, it is often hard to tell what exactly you would be doing if this were your job.

On the podcast so far we have had episodes already on drug safety, medical affairs, being a medical science liaison, being a principal investigator, as well as talking about medical communications.

Today we are adding to this list with a great episode on the job of being a medical monitor. I am very fortunate to be joined by my former client oncologist Dr. Jason Steinberg, who has been working for the past several years as a medical monitor for one of the large contract research organizations, which are also known as CROs.

Dr. Steinberg is going to talk about why he decided to leave clinical practice, what his day-to-day work is like, the kind of physician who makes a good fit for this role and the basic qualifications needed. It is my distinct honor and pleasure to welcome Dr. Jason Steinberg to the podcast. Hi Jason.

JS: Hi. It's such a pleasure to be here. Good to talk to you, Heather.

HF: Oh, it's a real pleasure to have you. Thanks so much for agreeing to come on the podcast.

JS: Absolutely, my pleasure.

HF: Now, I don't know how you felt about pharma before you got this job or started looking into it, but did it feel in any way, like a black box?

JS: Basically everything outside of clinical medicine felt like a black box to me. Yes. My friends outside of medicine, I was continually surprised at what their day-to-day life was like, what any role outside of medicine was like. So, pharma was included in that.

HF: I have to say, I didn't even really know there was a black box. I know when I was in practice, I never even thought of physicians doing something else, and when I left, it was a situation where no one really talked about options or nonclinical jobs. But since I've been doing this work, it's amazing to me all the different things that we can do and we still are doctors. We never lose that.

JS: Absolutely. That's right. Yeah, I had some impression just because I was in academia for so long as a trainee, I think I was a PGY-7 before I started practice, that there was a bit of a rivalry or academics seemed to think of pharma or industry as not someplace where you sell out but someplace which didn't have the high ethics and morals maybe of clinical practice, especially in academia. It was kind of a slightly negative opinion of it, is what I felt.

HF: Well, we do also sometimes call certain nonclinical areas, the dark side, and then when we go over there it often becomes the lighter side.

JS: Certainly that's been my experience. Yes.

HF: We're happy to have you here and I'd love it if you would like to take us back to the time when you were in practice and connect the dots for us of how you got into pharma.

JS: Sure. Back when I was in practice, my first position out of fellowship was as a generalist, oncologist and hematologist in an academic community hospital in Brooklyn which is a unique place to practice because if you have the resources and cancer, you generally go to Manhattan. So, it tended to be those without as many resources, who would come to our practice in Brooklyn and we were trying to give them the same standard of care that they could get at Sloan or the big cancer hospitals in the city.

I did that for a couple years and a lot of things about the job were very enjoyable, satisfactory, but it seemed that even after a year or two I had done many of the things I

had to look forward to. Treating rare disease, making a rare diagnosis or really getting some repetitions under my belt for the more common diseases, the challenge of it. And it seemed what was still left to do was a lot just, more. More consults, more patients in clinic, more RVUs. That did not appeal to me so much. And I think that's sort of how I ended up at the doctor's crossing as you call it.

HF: Can you talk a little bit about how you felt in terms of your burnout and what was satisfying to you and what wasn't satisfying to you?

JS: Yeah, burnout was definitely a factor. I went to a very clinically focused internal medicine residency program and started to get some exhaustion towards the end of that residency, but still didn't feel any of the depersonalization to use the burnout index categories. Didn't feel depersonalization, still felt a lot of personal accomplishment, just physically exhausted. The work was very demanding.

And then that was a relief somewhat in my chief year, just a little bit of breathing room not to be on call every four days, or on the wards all the time. And you could really expand what you were capable of. I worked on a program to completely change the curriculum for the students there. You got to sit on some boards and some committees and you could really fill up those extra few hours if you're not in the hospital all the time with a lot of important and impactful work.

And then into fellowship, that was also extremely demanding and burnout came back with a vengeance. Worse than ever. Then moving into being an attending, no better, no better. And when I left clinical medicine was after the first wave of COVID in New York.

There was a brief period there where it felt like the world was upside down and then went back to normalcy or near normalcy, and I was still burnt out, still not feeling like I saw a direction forward in clinical medicine. And I think around that time is when I first started working with you.

HF: I remember Jason, when I spoke with you, I think you were working crazy hours. I think there was first one other oncologist helping you, but then I think it was just you for a period of time.

JS: Yeah, I joined a practice of one at a fellowship, so we were two and then that one left and wasn't replaced. But even in larger or mid-sized groups, you're kind of on your own usually. It's not a very collaborative environment as an oncologist. If you have, let's say five doctors in a group, usually one is the head and neck doctor, one is the GI doctor, one is the GU doc. You don't really collaborate on patients. You just do all of the head and neck and your partner does all the GI and you might as well be in different offices kind of.

So, even though I didn't have a partner and that was very lonely, even if I had a few, it might still be pretty lonely just because it's not a very collaborative field. You have to own your patient totally from the moment you first meet them until the end.

HF: Yeah, I remember you were incredibly exhausted. You were working really long hours and you started looking at different options. Before we go into talking about the medical monitor position, I just wanted to ask you, because this was a difficult time. There was COVID, you were really understaffed, overworked. Do you feel like you could have found a different practice setting where you might have actually enjoyed what you were doing?

JS: It was certainly something that was worrying me at the time. Maybe there's something out there I'm just not aware of in clinical practice that would be so much better. Even though I had been looking around trying to look at academic careers and non-academic or different places in the country or more inpatient, more outpatient, and not finding anything, it still was in the back of my mind. Maybe there's something out there. And in retrospect, I don't think there would be something out there for me.

It's hard to practice oncology specifically in a part-time way or in a shift sort of way because the care is so longitudinal. You have to make plans months and years, sometimes many years in advance are your plans. And so, you can't really show up for a shift and decide on the patient's second line chemo regimen or something like that. That would be pretty tough. So it seems like it was really full-time or nothing were my options.

HF: We're going to skip over how you figured out pharma was the right direction and what other things you may have looked at just because of time here. I want to jump into now talking about the medical monitor position. Do you have a way of helping physicians who may not know much about pharma? Think about where this fits into the bigger piece of drug development.

JS: Yes. Yeah, I could. I worked, as you said before, for a contract research organization or CRO. And while it's in the pharma sector, I wouldn't say it's working for pharma. It's not like working for Pfizer or BMS or some company like that. It's a much smaller specialized company, or it doesn't have to be smaller, but a specialized company that runs clinical trials. A very big company might decide to hire a CRO to run a big trial if they don't have or don't want to use their internal resources. And the company I work for specifically focused on biotechs, which were firms that were too small to have the staff to run a clinical trial. They had to hire outside to run their trial for them. There's a lot of pieces that are needed to run a trial. Regulatory, safety, site startup, and medical is one of those many categories.

HF: Yeah, as I mentioned, we've had the drug safety physicians on the podcast, medical affairs, a medical science liaison, which is actually in medical affairs. Medical communications. Well, how would you describe in a nutshell what the medical monitor is doing?

JS: The medical monitor for ongoing trials, essentially how I thought of myself, was the medical and science officer for the trial. Any medically related or scientifically related questions that come up on the trial I should be involved with. If not, I'm trying to decide. That includes essentially all of safety, a lot of patient selection or patient eligibility, how the protocol is written or the investigator's brochure is written. A lot of things go through the medical department because this is a trial using a medicine. Naturally, the medical doctor is central to so much of it.

HF: Now obviously you have a number of different things that you're going to be addressing that could be happening in this trial. Could you give us an idea of what a day in the life might look like, different cases that come across your desk, people you might be interacting with, how you structure your day?

JS: Sure. Maybe I'll choose a day, about one year into my tenure when things were pretty much at a steady state. At that point I was a medical monitor on between six and a dozen or more trials. Some are very small because of what we specialized in. Only enrolling maybe 12 patients total for the trial and some larger, more like in the 100 or 200 range.

And each of those trials has weekly, monthly, quarterly meetings. A lot of the day is, for instance, your weekly internal meeting for trial XXYYZZ1, and then later on in the week you have a one hour meeting with the sponsor, the client, for that same trial. And so, a lot of the day is broken up into meetings. Maybe half the day on average are one hour or half hour meetings.

And the rest of the day, you're producing some work products that are pretty standardized as per medical monitors. You're doing reviews of serious adverse event reports. You are reviewing eligibility checklists to see whether a given patient could be enrolled as a subject in the trial. You might be doing broader data analysis or data management looking in spreadsheets for trends or the safety database. That might be

the other half of your day, but each day it would be fairly different, but usually has at least a couple hours of meetings with the client or with your internal team about a given trial.

HF: Could you give us an example, Jason, of an adverse event report that you might be working on? What is actually happening in the trial that you're having to look at and the kind of decision making that you're doing?

JS: Sure. Every adverse event which is deemed serious, which means in a nutshell you could be hospitalized for it or something more serious, needs to be reported in a formal way on a form where the investigator writes the narrative of the event, gives their grade of the event based on some criteria. We use something called CTCAE. It's the common criteria to grade events like pancreatitis, thrombocytopenia, et cetera.

And then there has to be a determination on relatedness. Is this related to the study intervention or not? And is this an expected event or not? And if it's serious, related to the study intervention and not expected, that is not listed as an expected event in the investigators brochure, then you have to write a more intensive and time-sensitive report called an analysis of similar events. Basically you want to see is this new serious event that's related to the drug part of a signal of a larger trend? You're doing an on the spot safety analysis as new events come in.

As a medical monitor, you review the narrative, you sign off on whether or not you agree with the investigator and all of the packaging of the report and the sending to the regulatory agencies is filed in a different department. And if you have questions that need queries that need to be sent to the site, that's also usually done by the safety department or the clinical department and then it comes back to your inbox.

But some days I might get 20 of those reports, some take longer than others and other days I might only get a few or even none. It really depends on your workload, but it's like

having a very limited consult that you might see in medicine, but very simplified and you have a grading rubric that you can use. You don't have to improvise so much.

HF: Now as I mentioned before, we've done some drug safety episodes and those physicians described writing these kinds of reports, dealing with these adverse events. However, the medical monitor position does this, but they also do other things as well. Do you want to expand just a little bit on some of the other responsibilities of the medical monitor?

JS: Yes, I think this is really one of the main advantages of being a medical monitor. You do safety and you do clinical monitoring and you do data analysis and you do other things. Some of the other things you might be involved in are medical writing for instance. If a protocol needs an amendment, you might be asked to be involved in that. And there's plenty in the protocol that your expertise might be useful for, the eligibility criteria in particular.

There's also, for instance, every time a trial is started, you need to decide what data you are going to input and keep, maintain in a database. Usually when a trial is starting up, I would be working closely with someone called the data manager who's building the database, that sites when they're entering their data for the trial, which data should they be entering and how often and what are the normal ranges and who should get an alert if a value is high or low?

Those are all really things that only a physician is able to say. You're very useful in that process too. That was something I really enjoyed about this job, is the variety on a given day. I might do those safety reviews for an hour and then something else will be coming up in the next hour that might be quite different. So, the medical monitoring role is really central to the trial.

HF: That's a lot in and of itself. And you had also mentioned before when we were talking about the bid defenses that you do when your contract research organization is trying to get pharma companies to run their trials through them.

JS: Yes. When I first joined, I was not the medical monitor on any trials. And in order to start to get some trials of my own, the CRO put me on what are called bid defenses. So that's when you're part of the team. Usually there's a representative from every department, regulatory and safety and clinical trial manager.

We all present to the sponsor, to the company, the biotech or pharma company, who wants to hire a CRO to run a trial. We present to them, showing them how we would do it. And over the course of a meeting, which is usually two or three hours and it's called a bid defense meeting. And that's late in the process during which the sponsor decides on which CRO is going to run the trial. It's usually one of the last meetings before they decide on who gets the contract.

And part of that is the medical portion and you present on things like "How do I think this trial could be more appealing to potential subjects or investigators? How do you see it fitting into the current standard of care? Is there anything that you can change from what you know about their trial?" Give them essentially free advice on how to improve their trial or their protocol.

That is a lot of fun because the trial hasn't started yet, there's no subjects enrolled. You still have a chance to make some tweaks and try and improve things. That's the bid defense meeting where usually I would talk for about 15 or 20 minutes out of a three hour call and be on the call the rest of the time just in case I can answer a question.

HF: Thank you Jason. This is a very nuanced position. You're obviously talking about keeping patients safe, helping with studying trial design, managing the data sets and helping

even looking at how you capture data and like you talked about, when do you alert somebody about a value?

Then there's this whole other piece, which is in the more than marketing and sales realm of bid defenses to get more business. I want to take a quick break to share a specific resource for this podcast and then we'll be right back to talk about who might be a good fit for this job, compensation and how to get started. Don't go away.

Hello my dear listeners. I wanted to let you know about a free resource that I have on the Doctor's Crossing website. This is my pharma resource guide and in it I give brief descriptions about a number of these different roles in pharma so you can learn about them and decide if any of them might be something you'd like to further investigate.

You can find this at thedoctorcrossing.com website, at the freebies tab at the top of the page. I'll also put a link for it in the show notes. Again, that's my pharma resource guide.

All right, we're back here now with my wonderful guest, Dr. Jason Steinberg, and we're going to be looking at how might you think about if this could be a good fit for you. Jason, as we've talked about, this is an interesting job. You use a lot of different skills and abilities. Knowing what you know about yourself and physicians, who might make a good fit for this job?

JS: Great question. I agree. There's many different hats that you have to wear in the job, but what immediately struck me in the position was how familiar so much of it felt to clinical practice. Reviewing an eligibility packet is a lot like doing a chart review for a new consult you're going to see in clinic. And looking back through safety data is a lot like tracking someone's tumor marker through your electronic medical record or something like that.

So much felt familiar that all of the learning curves for those various aspects of the job really went pretty smoothly I felt. Therefore I think many physicians may be in a good position to be a medical monitor. I think oncologists have an advantage because so many trials are in oncology that a lot of funding goes into oncology and oncologists are always sought after in medical monitoring it appears to me. But certainly internists, family medicine doctors, general surgeons, especially for device trials. Medical device trials would be very useful.

In my group of about three dozen physicians maybe three quarters were in oncology and the rest was roughly equally split between dermatology, neurology, internal medicine, and a few internal medicine specialties.

HF: And what would you say about board certification, having an active license, number of years of clinical practice?

JS: I took the job having just passed boards, just passed my medical oncology boards had previously passed internal medicine and two years in practice after fellowship. So, not a ton of clinical experience after fellowship.

And by the way, very little research experience. Essentially no publications. I never enjoyed that, always felt like it was sort of homework on top of the main course, which was clinical practice.

And so, I'm very pleased to learn that I really enjoyed this role in research in general and didn't have to have the face-to-face interaction with a patient to see the direct result still. You could still feel the impact.

My salary was roughly the same coming from an academic community practice in New York. And all of those modifiers reduced my salary, probably. New York academic community. But still it was not a big step down and it was a huge step down in number

of hours. In terms of my hourly wage, if you could calculate it, that went very much up. And my annual salary stayed about the same in the mid-$200,000 range.

HF: And the range that I've seen with my clients who have gone to work for CROs in different positions, but depending on the position and the geography and their specialty and everything, I've seen a range from $200,000 to $300,000-ish and but an average in the mid-$200,000 and that's factoring in bonusing and other things as well.

JS: That's true. I forgot. You can get a bonus. In my clinical practice, I had an RVU bonus technically, but one day I calculated how many patients I would actually have to see to get it and it was impossible. But the CRO actually did get a bonus. I got a good review and then that was multiplied by how the firm did that year and then I got a bonus at the end of the year, which was pretty nice.

HF: Yeah, the bonuses can be pretty hefty. One thing I wanted to just touch upon before we wrap up here is if a physician has been listening to this and they're thinking, “Oh, this might be potentially for me, I want to learn more, I want to start really seeing if there's anything I should do to improve my candidacy.” What are a few steps that he or she could take?

JS: Well, I think even if, like me, you did not have a lot of research experience, it can be important during the interview process to build a narrative or to help explain your trajectory from clinical medicine into this realm of research. What is bringing you from one to the other? What skills do you feel will translate from clinical medicine to this different role? I can say from experience, many skills translate. Your ability to solve complex problems and climb learning curves, which you've been doing since the very beginning of your medical training will translate to this job. I've certainly had that experience myself.

In terms of where to start to look, what I did was I looked on LinkedIn and individual company websites. There's like 10 CROs that are by far the majority of the market share. Some very, very big companies. That's where I started and looked. You can find a listing either on your website or a pretty easy Google search of the biggest CROs and see what roles are available.

HF: And Jason, if you were to quantify and compare your satisfaction from when you were an oncologist to now working in industry, how would you quantify it on a scale of zero to 10 with 10 being really happy and satisfied?

JS: Consistent high scores. I would say you can have good days and bad days or even a good or bad morning or afternoon in either field, but very consistently high scores almost every day at the CRO. Eights, nines, sometimes tens if you really felt like you made a good call or interjected when you were needed. And in medicine I'd have tens days, but I'd also have days that were like a two or one. And so, that brings down the average. I would certainly say that on average my satisfaction with the job has been much higher as a medical monitor, which is a big surprise to me.

HF: And I know this might even be hard to speak to, but what is it aside from the fact that you get more sleep, you have more work-life balance, you don't have the real stress of caring for very, very sick patients, but what is it that's ultimately really satisfying to you about doing this work of the medical monitor?

JS: The impact is there. That was something I could not really see. Maybe that's the black box effect. But you can have certainly a very large impact. And at all those meetings, maybe I seem too dismissive that you have so many meetings, but sometimes you have your 2 cents in the meeting and that determines whether more patients are going to be enrolled on that trial. A patient can get in or not. The trial keeps moving forward at all or not. And you have the vantage point as a medical monitor of seeing all the different sites and all the subjects on the trial. So, you have a scale that you can't really have at the

bedside when you're seeing patients one at a time. This is a trial wide job and you're on 10 trials. So, you feel the impact very strongly and I found that very rewarding and was something I was worried I wasn't going to be able to obtain outside of clinical medicine.

HF: Thank you Jason. This has been a terrific interview. I really appreciate you coming on and sharing your experience with us.

JS: Oh, it's been my great pleasure. Thank you, Heather.

HF: Well, thank you again. And to my dear listeners, thank you for being here. We couldn't do this without you. I appreciate you sharing the podcast, telling other people about it, rating and reviewing it. We want to keep growing it and helping other doctors find their way.

Just a reminder, if you're interested in the pharma freebie resource, and I have a bunch of other freebies on my website, you just go to the freebie tab and then help yourself, take them all if you want all of them. And you can also find the link for the freebie pharma resource in the show notes. Until next time, don't forget to carpe that diem and I'll see you soon. Bye for now.

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Podcast details

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