

Podcast – Jo Merrifield interviewing Liz Craig

Transcript

Jo Merrifield speaking with Liz Craig

Time

0:10: Welcome to this episode of *Clinical Research Career Conversations*, brought to you by *Edinburgh Clinical Research Facility*. I'm *Jo Merrifield*, and today I'm joined by *Liz Craig*, a senior trial monitor from the *ACCORD* sponsorship office in *Lothian*. She discusses the role of a monitor in the academic clinical research setting, describes her own career journey, and outlines key skills and attributes required for a successful trial monitor. Enjoy.

0:44: Hi Liz, thanks for joining me today. Maybe you could start off by telling us what it is to be a monitor in a clinical trial.

0:51: Sure, thanks for having me, Jo. So the role of a clinical trial monitor - really we're focusing on two main areas within a clinical trial. So we want to make sure that the patients who are in the clinical trials are safe, and we also want to make sure that the data is good quality, so that when we're making decisions from the results of the trials, that we know those results are sound and that they're good.

1:11: We are really making sure that what the site teams are doing in the hospitals matches what the approved protocol and the regulatory requirements say. And so what does that look like in practice? Well, we're either going on-site to hospital sites and doing on-site monitoring visits where we are checking the medical records and making sure that the data that's recorded for the trial is correct, verifying it with the source data. Or we're doing remote monitoring where we have oversight of data from the office. We're looking over the data that's been collected for the trial, looking for anything. Ordering any missing data that might cause consequences further down the line.

1:51: Here in Edinburgh we have a risk-based monitoring strategy. So everything that we do is based on a risk assessment that then tells us how frequently we're going to go and monitor trials that we're sponsoring here, how often we're going to go on-site, how much remote monitoring we're going to do, and where the risks are within the trial design. So depending on the trial that you're monitoring, your visits could look really different. Some trials we're going to want to look at absolutely everything, on some of our riskier Phase 1 trials. And then for other less risky Phase 4 trials, we're maybe going to look at a specific section of the data to make sure that that's right.

2:29: We have a focus on safety across all of our trials when we're monitoring, and we're really following that risk-based monitoring strategy that we design for each trial to make sure we're focusing on the things that matter within that individual trial.

2:44: Different types of visits that we do, we're involved in the trial from the beginning until the end. So we start off with the risk assessment and site feasibility, making sure that hospitals can actually deliver the protocols that we have. Then we go on site initiation where we are training site teams and just making sure the logistics work at site level. We're then doing our routine monitoring throughout the study according to the monitoring plan, and we also do triggered monitoring visits as well. So often there's things that come up unexpectedly during the course of the trial, so we might have to

go in and look at something specific at that point. And then we're involved in close-out and archiving as well.

3:22: So we're involved in the whole lifecycle of the trial from beginning to end, which is rewarding, I would say, in being able to see it through all the way.

3:32: And yeah, that's really the kind of day-to-day job. As I say, depending on what your trial that you're monitoring, what you're doing is different. So we have trials with IMPs (Investigational Medicinal Products) in them, we have device trials, we have trials with lots of samples, trials, you know, there's lots of different things, so it's very varied the role. And you come across new things all the time that you don't expect. And that's kind of our role here in an academic setting, but I know if you go and work in a clinical research organisation or an industry monitor, that role can look a bit different as well. So there's a lot of variety within the role.

4:12: *It sounds like there's a lot of travel and working with different teams, and that must be a rewarding part of the job as well?*
(Jo)

4:19: Yeah, absolutely. There can be a lot of travel. We monitor sites across the UK. So we see lots of different things. And one of the really interesting things is seeing how different places do things differently. So it's really interesting to go and meet lots of people, talk to them about how they deliver their research, see what works and what doesn't work. It's always amazing, I think, how much variety there is in the ways that you can deliver the same trial.

4:48: *OK, that's interesting. And you're obviously a senior trial monitor, so what is the difference there? What does your role entail?*
(Jo)

4:57: So as well as having our own portfolio of trials that we monitor, we're also looking at managing the portfolio as a whole. So here within the sponsor's office we have between 30 and 40 regulated trials that we are managing, delivering the monitoring on. So we have to make sure that there's enough resource within the team to deliver the monitoring that we have, and that's quite challenging when you're doing a risk-based system. So it's not a one size fits all. We also have the people management aspect, so we're managing the other clinical trial monitors within the team, doing things like appraisals and all the people management aspects. We get brought into any major issues that come up. So if we have something like a suspected serious breach come in, then the senior monitor will be involved in the investigation into that. And just any big sponsor decisions, we'll get together as part of the team to be involved in that too.

5:51: So those are the kind of main differences. We're the main point of escalation for the monitors if they have any issues that they identify on site that they want to chat through. And we also maintain oversight of the monitoring that's going on across the portfolio, so reviewing reports from the monitors and just picking up any issues that we have within the team.

6:10: *And you say you've got 30 to 40 studies - how many monitors are in your team?*
(Jo)

6:15: So there's two senior monitors within the team and then there's six clinical trial monitors. So there's eight of us in total, which is a good number. It's grown hugely over the last ten years that I've been in this job.

6:27: *So what led you to work in clinical research, and why specifically into monitoring?*

(Jo)

6:34:

(Liz)

So, I kind of happened into clinical research by accident. I did biology at university and I enjoyed the human aspects of it. And we came across clinical trials in a few of the modules I did and it was an interesting subject. But once I graduated, I really needed a job. So I applied for lots of different jobs. Some of them were science-based, some of them weren't. And I ended up getting an interview to go and work for a research team at Ninewells Hospital, University of Dundee, and they did asthma and COPD research. It wasn't really an area I knew anything about, but I got the job and I worked there as a clinical trials assistant. It was a patient-facing role, so I was consenting people into trials, I was doing respiratory function tests, taking blood samples, things like that. And it was a great environment to introduce you to the kind of regulatory side of things and how clinical trials worked. It was a busy group. It was quite exciting. There was always lots of things going on. And I just kind of caught the bug from there. I think some people find the clinical trial environment challenging to work in because it is so highly regulated. So I think it's either something that you like, to have these kind of very narrow boundaries that you're working between, and it was something that I enjoyed. I liked to make sure everything was just so. I liked to kind of dot the I's cross the T's and have everything documented well, and that was something that I think some people can find frustrating. But for me it just suited my way of working. So I think that's why I stayed in clinical research and ended up in the monitoring role, because it kind of suited those aspects of how I was working.

8:17:

(Jo)

Yeah. So did you go from the clinical trials assistant role to a monitor then?

8:22:

(Liz)

Yeah, so I worked in the clinical trials assistant role in Ninewells and then I did the same role in St Andrews Community Hospital, but there was a little bit more, almost like trial management involved in that, doing ethics submissions, setting up a research office over there that hadn't existed before. So I had the patient facing role and a bit more kind of project management as well. So after doing that for three years, I came to the monitoring role and yeah, that's been me ever since.

8:53:

(Jo)

Brilliant. So what do you find most satisfying about the role? You've already said how you like to dot the I's and cross the T's on things, but what do you really enjoy about the role?

9:01:

(Liz)

So I think, I mean, a lot of the things when you go on site and do the monitoring role, you're finding little things. There's maybe like a slight discrepancy in the data. There's maybe something that doesn't have a GCP correction and sometimes it can feel, you know, a little bit pedantic when you're raising these things. And although they're important from a regulatory point of view, clinically, they're not that important in the big picture. But sometimes you do find important things. So, you know, finding things like cases of research misconduct or safety issues within the trial, and those feel important. Helping site teams who are maybe struggling with compliance and supporting them to improve things, to improve systems, and then being able to kind of go back and see how well things are going after that. That is really satisfying, but also you just feel like it's helpful to the delivery of these trials and hopefully long term it's going to support the delivery of good research, which I think is the important thing.

10:01:

And it's really just playing a little role in delivering these trials, some of which are hopefully going to improve care for patients. Not losing sight of the big picture when

you've got your head in the data and the important thing is actually that yeah, we're helping to deliver these trials.

10:16: Yeah. And it sounds like it's very much a supportive role as opposed to laying down the law and being...
(Jo)

10:25: Absolutely. Yeah, that's how we like to play it. And I think it's really important that, from a monitoring perspective - and I hope the teams that we monitor see it like this - they might, they might not, but that we are, we see ourselves as kind of part of the team delivering this research and, you know, this is a place that people can come to discuss issues to, you know, we have a very kind of open culture here that... you know, things happen within trials and that's just life and that's what keeps us here in a job.

10:50: And there's no judgment here. It's really about supporting teams to deliver this research to the best quality that we can. And some things probably feel a little bit pedantic. Others are important long term. So yeah, we do try and be as supportive as we possibly can and integrate ourselves into the research teams.

11:09: And you say you've done this role for a number of years. Have there been any memorable trials or moments that have really stood out for you?
(Jo)

11:16: Yeah, I mean, so many, and I don't want to pick favourites, name dropping certain trials but, you know, any of the trials that I've worked on, and there's like hundreds of trials, and I think you learn something from every single one that you work on. But the ones that have had an impact on clinical care, have changed care for the better, are ones that stay with me, that I'm proud of being involved in. And then, you know, there's some big kind of Phase 1 studies that we've done - First In Human studies - and things like that, that are... yeah, they feel important when you do them, and you want to remember those studies. And then I guess there's the ones where you do get the big findings that, it's not what we're going out to look for, but yeah, things like the research misconduct or serious breaches that you go on site and find, you know, that's important and meaningful and you do kind of remember those and hopefully learn from them too.

12:12: So we've talked about the good things about the role, but what are the challenges that you face?
(Jo)

12:16: Sure, I mean it is a challenging role, and I think it's something that is either for you or it's not. And you know, we have to work under considerable pressure a lot of the time. There are lots of difficult conversations to be had with research teams. A huge part of the role is building relationships and making sure that we have that supportive relationship with teams, otherwise things can be very defensive and difficult when you're doing the monitoring role. You have to concentrate for long periods of time on what can be pretty arduous data sets and medical notes and so yeah, there's a lot of intense concentration involved.

12:58: And things come at you unexpectedly. I love that. To me, no day is ever the same and you can come in with a plan for your day and it can be completely blown out the water by an email that's like, this has gone wrong and you're like, oh right, OK, this is going to take a bit of work to look into and work out with the team.

- 13:12: And there's new things that come up all the time. I'm still looking at studies and being like, you know, issues that come in and you think, oh, I've never come across that before in the last ten years of doing this senior trial monitor's job. So you never know everything.
- 13:27: *Yeah, every day is a school day.*
(Jo)
- 13:29: Yeah, absolutely. And I think for me that kind of thing keeps it fresh and exciting and, you know, it's interesting. But I think if you don't like to work in that way, it can be overwhelming that you never quite know the answers to everything.
(Liz)
- 13:43: *And I guess, with the way that innovation and clinical trials etc is just changing all the time, isn't it? So you're kind of having to learn on the spot.*
(Jo)
- 13:52: Yeah, absolutely. And changes to regulations, changes to, you know, the systems that we're working with, the ways that we're working, you know, mad things that are coming in now like AI and stuff, which just completely change a lot of things that we're working on. And it is fast paced and it's, for me it's interesting, but I can see if you don't enjoy that kind of working, it can be quite a stressful role.
(Liz)
- 14:15: *Yes, yeah. And we've already spoken a little bit about advances, things like AI, but how have you seen the role change over the last ten years while you've been in your role?*
(Jo)
- 14:27: It's changed massively. Like when I first started monitoring, all the medical notes pretty much were on paper. We were handling paper case report forms, collecting the data, you know, ECRFs were there, but the main method of data collection was still paper, and a lot of the checks we were doing were paper. And now it's shifted. Usually, you know, we've got electronic medical note systems, we've got electronic prescribing systems. A lot of the data capture we do is directly into electronic case report forms. So the role has shifted massively with the electronic systems, and that comes with its pluses. So I don't have to spend ages deciphering handwriting anymore, which is nice. I remember having, you know, medical notes where there was just squiggles on the page and you've got maybe two or three nurses around you and you're being like, what does this say and nobody can work it out, you know, that kind of thing. So legibility of data has definitely improved the electronic systems. But it comes with its challenges as well. All of the different sites just about use different electronic health record systems. We have to do training on those, which takes up time. We have to navigate around them on a visit, which also can be quite challenging. And even the, you know, the sites in Scotland all have the TRAK care system, but they all use it in different ways. So the data is not going to be in the same place each place you go. So yeah, it comes with its pros and its cons, I think.
(Liz)
- 15:54: The other thing that's really changed is the kind of trial designs that we're working on. So you've got a lot of these novel trial designs, platform trials, you know, seamless Phase 1, Phase 2, all of these new trials that really streamline delivery of clinical trials within the research landscape, but they also are really challenging from a monitoring perspective. These platform trials that are adding new IMPs and taking away old IMPs, they don't really fit with the standard operating procedures that we have for site set up and close out and you have to constantly think around that and work around and try and improve the processes that we have here to make sure that we're catching everything within these designs and stuff as well.

- 16:39: And they're challenging to resource because they're really multiple trials in one study. Yeah, things have changed hugely, and I hope they've changed for the better. But there are challenges that come with that for sure.
- 16:52: *Yeah, sure. And obviously since the pandemic, there's been a lot more remote working. Is that the same for monitoring as well? Do you have to travel less now than you used to or...?*
(Jo)
- 17:03: I mean, we've definitely got back to on-site monitoring. I mean, we did use remote monitoring before the pandemic. And so we've gone back to how we were working before, I would say really. I'm a big advocate for on-site monitoring. I think there's some things that you just can't see from the office, from sitting here and looking at data, and it's important to go out and meet the teams and build those relationships.
(Liz)
- 17:29: We're also really conscious of the impact that a lot of remote monitoring has on site teams who already are struggling in places for resource. So we don't want to add to that. So we take a trial-by-trial approach. It depends on the data, it depends on the design, and so we try and utilise the remote monitoring where we can. But also, yeah, I'm a firm believer in the advantages of on-site monitoring in some situations and just actually going and seeing the facilities and meeting the team and looking - I was going to say holding the medical notes in your hand, you can't do that anymore really - but you know, seeing everything in person and getting a feel for how things are working.
- 18:10: *Yeah, I can understand that. So if someone's listening and thinking, oh that sounds an interesting career, who do you think should consider a role in monitoring and what skills and attributes would be good for the role?*
(Jo)
- 18:22: I think the reason for getting into monitoring should be that you want to support research delivery and that you have an interest in trial design and delivery and research as a whole. If you want to get into it because you want to go and check up on things and have a bit of a power trip, that is the wrong reason. So I think that's important. If you care about the detail, if you have good attention to detail, you like things to be right, but you can also still be pragmatic about decision-making and things, if you work well under pressure and you enjoy challenges and fast-paced working and things maybe not necessarily going exactly how you'd plan them. If you enjoy that way of working, I think it's a good role for you. And yeah, if you're a good communicator, we have a lot of quite complex findings that we have to document and then communicate to teams in a way that they can understand them and to support them to resolve them. So you need to be a good communicator. You spend a lot of time writing reports. So those are all kind of big, big parts of the job. And you like people, you like building relationships and seeing different people, meeting different people, going different places.
(Liz)
- 19:35: *Yeah. And you don't necessarily need a clinical background, do you, to get into a role like this?*
(Jo)
- 19:41: No, I think it can be useful to have some sort of understanding of research delivery at a patient-facing level. I think it does... having that background has certainly helped me to be able to see ways to resolve findings and help teams from that perspective, just having a bit of understanding, but absolutely not. I mean, we've got people in the team who've come in from nursing backgrounds, but we've got people in the team

who have come in from quality assurance backgrounds, working in labs. As long as you have some sort of clinical research experience, then you can learn on the job.

20:19: *Yeah, grand. And what opportunities are there for monitors to progress in their careers?*
(Jo)

20:24: So I think within an academic and an industry setting, there's probably different progression opportunities. Obviously in an academic setting, because this role is involved in the full life cycle of the trial, and you're doing a bit of project management, there's opportunities to go off into trial management roles. I know some people who previously worked as monitors who now work in trial management. There's opportunities to go into lab-based roles and research governance, any of the aspects involved in research trial delivery, because we cover a wide scope. You get good experience in approvals and all of the things that you need for that kind of research governance side as well. Obviously, there's opportunities with R&D here too, and opportunities to move up to a senior trial monitor role and into more of the research governance roles as well.

21:14: *And finally, what tips would you give any aspiring trial monitor?*
(Jo)

21:19: I think just get any kind of clinical trial experience that you can. Any understanding of an aspect of the clinical trial delivery pathway is going to help you when you come into monitoring. Obviously go away and do your good clinical practice course, you know, have a good understanding of the regulations and regulatory environment to try and get some experience of working on different types of trials if you can.

21:43: There are courses out there that you can do around monitoring as well to get some experience, and that's certainly how I decided that the job was for me when I was working as a clinical trial assistant. I did some of the online courses that focus on monitoring and things and I thought like, yeah, this is something that I get and I enjoy. So that can be a useful tool as well.

22:05: *Great. Well, thank you so much for talking to me today, Liz. Thank you.*
(Jo)

22:08: Thank you for having me.
(Liz)

22:15: *My thanks to Liz for an interesting discussion about the role of monitors in clinical research. She gave us a really clear understanding of what monitoring involves, from safeguarding participants and data quality to supporting site teams and having to adapt to the challenges of each study. We heard how varied the role can be, the satisfaction of seeing a trial through from start to finish, and the importance of skills like attention to detail, communication, and resilience. Liz also shared some practical advice for anyone considering monitoring - gain some trial experience, make use of training opportunities, and come into the role with the mindset of supporting the research delivery.*

22:58: *Thank you for listening to Clinical Research Career Conversations. If you'd like to hear more insights into the different roles that make research happen, don't forget to follow and share the podcast. Until next time, bye.*