Podcast – Jo Merrifield interviewing Lauren Muir

Transcript

Jo Merrifield speaking with Lauren Muir

Time

0:11: *Welcome to this episode of Clinical Research Career Conversations, brought to you by Edinburgh Clinical Research Facility. My name is Jo Merrifield, and today I am speaking with Lauren Muir, the Research Governance Manager at Edinburgh CRF. Join us as we explore her role and her career journey. Enjoy.*

0:36: (Jo) *Thank you very much for joining me today, Lauren. Lovely to see you. Could you start off by explaining a bit about your role as a research governance manager and why it's so important in clinical research?*

0:48: (Lauren) OK, well, thank you, Jo, for having me. So I'd say in Edinburgh CRF, the research governance manager role is about overseeing the studies that run within our facility. So we look at both external and internal approvals. We look to see that there's ethics in place for studies, that there's MHRA approval in place if a study requires this, and also that it's got local R&D approval so that the health board's happy to take on the study in NHS Lothian, but also we look at the internal approvals and if we're actually OK to do the study at site. So we will make sure it's had its feasibility review, it's had its costings, that it's been to our Operational Management Committee meeting, and that it's also had its service level agreement issued, which is an agreement between us and the PI. So it's checking that it's got both external and internal and ready to go.

1:42: We also continually check when we get amendments through that we've assessed the feasibility, that we can still perform the work at site, that it's costed appropriately and that we're good to go and that we've got the correct versioning of our documents in place. So part of my role is checking that the ethics and your R&D and then the actual physical documents that you've got, like your consent, your PISs, all marry up and they all match so that our nurses, when they're consenting patients, are using the correct versions of the documents and protocols.

2:11: More recently, my role has had more emphasis on costing of commercial studies. So along with IT, R&D Finance, and the research nurse managers, we've been building a tool to look at our costing with a tool called the NCVR, to check that we're maximising what we can get out of commercial studies coming into the CRF.

2:32: Also as part of my role, because we're a Phase 1 accredited unit, I liaise with ICU. So when we've got a Phase 1 study that's approved to go ahead in the Clinical Research Facility at one of our sites, I'll contact intensive care and just say, by the way, this is happening in our facility, just for safety. And also, as part of our Phase 1 accreditation, I'll do a check of our contracts. So I check that there's clauses in place that our PIs will be informed of toxicology data immediately should anything arise, for safety concerns. And that there's appropriate insurance in place for our participants, so that they've got appropriate cover in place should something ever happen on one of these trials.

3:14: So I guess overall, it's overall study management. I've spoken, I suppose, more about my work in the nursing core, but I also have oversight of the other cores within the CRF. So we've got the Genetics core, the Mass Spec core, Imaging, Imaging Analysis and Stats as our other cores. So their studies come through our database system and

I'll keep metrics and manage the feasibilities coming through for them too, and checking that we've got all the right dates, so recruitment dates, the start and end dates for the work and that they've been invoiced.

3:45: And as part of that for the nursing, we do the recruitment reporting. So every month for our nursing input studies, I'll report our recruitment data over to R&D that then feeds into CPMS, which is for our funding that we get from the Chief Scientist Office. So yeah, I think that's probably it.

4:01: (Jo) *Brilliant. So it sounds like you get all the ducks in a row before it starts and then as it goes, you make sure those ducks stay in line, keep together. Grand. And I'm guessing there's so many different studies, aren't there, that happen in the Edinburgh CRF. Every study is slightly different, and you've got to understand the governance landscape to understand what is needed for each individual study.*

4:24: (Lauren) Yeah, so we've got like Genetics - they've got kind of studies that you might be getting samples from Canada. They've got different tissues. The law is obviously different between Scotland and England there too, so you've got to have an awareness of pre-clinical and clinical actually in this role.

4:39: (Jo) *So it sounds like you're busy all the time, I'm guessing. It's never a dull day. So on that line, what does a typical day look like? How do you manage that workload?*

04:48: (Lauren) So probably most people say no typical day. Something can come in and it gets… everything's… you kind of go in with a plan, but it can get thrown out of the window. But I would say towards the start of the month, you might see me kind of more focused on database, checking that we've got all the right dates, and liaising with nurses about what kind of data we've got for the monthly reporting that I do at the start of the month, just our metrics overall. We have our operational management meetings, which are our directors and our core managers, so all of our studies go to this meeting for approvals. That happens every two weeks. So depending on when that OMC meeting is, you'll have me preparing different things. So I'll be preparing the costings or feasibilities just before the meeting and then following the meeting, we'll be issuing the SLAs out to the investigators.

5:40: And then I suppose study submissions coming in can vary from week to week. So some weeks you might get over ten different studies coming in for different cores. Some weeks you might only get one or two. So it's when they come in, doing that initial governance check, doing all their metrics so that it's all in place for our annual reporting. So, it varies week to week and day to day.

6:02: (Jo) *Very good. I like the way you've described it over a month and how it can change depending on the different meetings and the different things you need to do like inputting in the databases, etc. So what do you enjoy most about the role?*

6:15: (Lauren) I like that it's a varied role and that no day is the same and that we have a lot of different trials that we work on. So we do have a lot of cardiovascular, respiratory, neurodegenerative trials, and then a lot of ones coming through with mental health. So we get a lot of different trials because we support a lot of different research teams and also a lot of different personalities and different teams that we get in roles, so working with a wide variety of people. And I like that every day is a school day. I

probably still every day learn something new about clinical research. So yeah, it keeps you on your toes.

6:49: (Jo) *Yeah. But it must be nice learning as you go and you can apply what you may be seeing in another study to oh, this will work here. Yeah, that must be quite satisfying to build that knowledge base and work with that.*

7:02: (Lauren) Yeah. Building more skills over time, I suppose.

7:06: (Jo) *Yeah. And so your favourite bits, what are your… the more challenging bits of the role which you…?*

7:13: (Lauren) I'd say probably juggling a lot of studies. So if you're a trial manager or if you're a liaison nurse working on the study, you get a handful of studies that you manage as your main studies, whereas I have this oversight of… well, within the nursing core, we've got over 100 running at one time. And then in the CRF overall we've got over 300 running. So I suppose it's having that umbrella oversight, and you've got various people coming to you and "where's this approval at?", "where's this one at?", "has this been ever approved?", and you just have to keep them all in your head with what stages they're at.

7:46: So yeah, juggling a lot of different studies at once, and I would say it's probably something felt by most people that work in clinical research, but the frustration of when a study gets withdrawn. So when you've put a lot of work into a study, you've got it costed, you've done all of its governance checks and everything, and then it gets withdrawn because they finished recruiting, or there's lack of funding. But I won't be alone in that. I think everyone at some point in clinical research will have a study withdrawn that they're working on or put a lot of effort into.

8:16: (Jo) *Yeah, that must be really hard. But like we said, hopefully you learn something from that and then you can use it going forward. I guess take some positives from it. But yeah, that must be quite challenging.*

8:27: *What brought you here? Why have you chosen a career in clinical research and what has your journey been to get to this point?*

8:34: (Lauren) So I always had an interest in healthcare and science. So I was a bit of a nerdy kid. I had all the books about how the bond works. So, yeah, always an interest in science. I graduated in 2018 with a degree in biomedical science, and then I got my first job as an in vitro bio safety scientist. So we were working under Good Manufacturing Practice, so GMP. I remember testing various vaccines, cell banks, bulk harvest, genetically modified organisms for different assays, like mycobacteria testing, sterility testing, and bioburden. So I was working in a clean room with the big clean room suit on with the goggles and the mask, working in a grade A isolator, and so completely sterile environment, and testing these products for their sterility and various other tests. As part of that role, I did a lot of CAPAs so corrective and preventative actions. And also it was specifications. So if we got contamination in, for example, a vaccine bank, there would be a big investigation into why that happened and had it been human error that had caused that.

9:47: So I really liked working under the GMP quality management system. So I worked there for a couple of years and then moved on to be a study director of

immunochemistry. So I was in Team ELISA. So we were doing PK and TK assays, so pharmacokinetics and toxicokinetic testing. So we were seeing what happens to the drug concentration over time. So we were developing assays, then validating them against the regulations, and then following that we would get samples and we would test the samples. So most of the work was pre-clinical, but we also did get clinical samples in. So in this role, I was working under Good Laboratory Practice – GLP - and Good Clinical Practice - GCP. So I had all three that I'd worked with through my career.

10:36: And then I was lucky enough to be offered a job in the NHS in the Clinical Research Facility. So that was as Senior Project Assistant overseeing the admin support across the three sites that we had in the CRF. A lot of my role there was process improvement, and I like streamlining processes. And then within a year I was then lucky enough to get the Research Governance Manager job, which is the job I'm doing now.

11:04: So I suppose I've always worked under quality management system of GMP, GLP, GCP. I like the regulations, and that's kind of why I've ended up in this sort of a role. I can't believe I've ended up in this sort of role because I didn't think I would be an office-based person. I thought I would be in the lab.

11:23: *And do you miss the lab?*
(Jo)

11:24: I do, but I like the office-based work too, but yeah, I do. Yeah, long days in the lab, but
(Lauren) I do sometimes miss kind of being in in the nitty gritty, doing the science.

11:37: *That's really interesting to hear how you've gone from that lab work to that office*
(Jo) *space and the learnings of the different regulations along the way. I think that's really interesting. So what continued professional development opportunities have you been able to access during your career? Obviously you've had quite a lot of experiential learning on the job to get where you are. Have you done any additional courses or anything like that that's also helped you?*

12:01: Yeah, so I think I have been lucky enough that I've always progressed within a role too.
(Lauren) So my first job I got to kind of learn straight down from sample receipt to doing the assays to signing off on the certificates of analysis and stuff. So I got to work my way through all the different roles and knew it inside out. And then again here, working in the nursing core, initially doing admin support, I got to kind of see how they work day to day and the different forms and things that they use. Throughout my career I've - I don't know if you would say luckily or unluckily - but I've been involved in MHRA inspections across all three, so GMP, GLP and GCP. So I've been involved in four in my seven years so far.

12:44: I take it as an opportunity. But yeah, I've been questioned by them about decisions I've made on my studies and things. So I do think audits are an opportunity, and a good learning opportunity, and you can also get clarity from inspectors about things that you're maybe uncertain about or if some of the regulations are a bit grey, you can ask them.

13:04: And then yeah, training events, we've obviously got our amazing Education core in Edinburgh CRF. So we do our NRS GCP, so that happens every two years, and then lots of external speakers come in. So I've done a course on ethics approval and how to submit an NHS Ethics application. Also a course on Computer System Validation.

They've been really useful courses that I've attended. I was also lucky enough this year to attend the UKCRF conference in Birmingham. So that was all about collaboration. It had really interesting talks on AI and harnessing machine learning in research, talks about commercial perspectives in the NHS, and then also psychedelics in mental health and stuff and kind of what's happening in that area of research. So it was a really interesting two days to be part of.

13:56: (Jo) *Brilliant. I really like the way you talk about how actually the progression through roles is a really good way of building that experience and gaining that understanding of how things work from the basics right to the higher levels. And also the opportunities like things like conferences - they really give you that breadth of seeing what other people are doing, don't they?*

14:16: (Lauren) You can see the impact of what you work on, because you sometimes sit in your own wee bubble and you don't see the bigger picture. So it's nice to go to these things and see, oh, I worked on that study and…

14:29: (Jo) *Yeah, I can imagine. Yeah, definitely. So what kind of skills and attributes do you think are important for your role? You've talked about how you need to juggle, so I'm guessing planning and organisation is going to be one of those?*

14:42: (Lauren) Yes, definitely organisation. Big fan of a to-do list – I've got about four. But yeah, setting your own priorities for the day and having a plan of what you want to work on, even if it does go out of the window some days. Attention to detail's quite crucial in this role, particularly when you're reviewing the different approval documents, because we do sometimes see mistakes, either with like the Ethics approval if they've maybe approved the wrong version, or the R&D. So just checking that they all marry up and that everything makes sense. And communication and collaboration with all the different teams is crucial in this role because you've got consultants that have worked in clinical research for, you know, 20 plus years, and then you've got people that are coming in, research nurses that are brand new to research, and being able to communicate with them while they're learning the different landscape in clinical research is really important.

15:36: (Jo) *So if someone's listening and thinking, oh, that sounds like me. I've got good attention to detail. This sounds like a job that interests me. What advice might you give someone thinking about a role in research like this?*

15:47: (Lauren) I would say find out what parts of a job you enjoy. And so, I think as I said earlier, I always thought I would be working in the lab. You know, ten years ago, I would have been, nope, I'm going to be in the lab all the time. And I actually even wrote a personal statement to be an accountant and a scientist, and I turned down being an accountant because I was like I can't imagine myself sitting at a desk all day. So that's why I sort of went down the science-y route. But yeah, do some time in the lab, speak to people, ask questions. If you can get the opportunity to shadow different roles, then I would say that's a really good way of seeing what kind of things you enjoy. Do your own research as well and don't always accept that what you see is correct. And I'm sort of a digger when I come in. If I come in and see something being done a certain way, I've always questioned why. I always think independently and question why things might be a certain way. And most importantly, I would say enjoy what you do. I love working in my job, so...

16:44: (Jo) *Oh, that's really good to hear. And I think it's really nice that you show that you can pivot. You don't have to stick with I'm going to be a lab-based scientist for the rest of my life. You can pivot and change and yeah, I think that's a really nice example of that.*

16:56: And so finally, what's the best piece of professional advice that you've ever been given, do you think?

17:02: (Lauren) So this is one I probably still try and follow day to day, but it would be don't sweat the small stuff. Particularly in this role, if your patient's not at harm, and if something has happened like a protocol deviation or something, you've not been able to get blood, there's ways around it. If you work in a supportive environment, you know, you just capture the kind of results there. You don't need to over-worry about things happening. We're all humans. And I'm a worrier naturally. And I suppose over the years, I'm trying to get better at not worrying about every little thing, but yeah, there's ways around, kind of, if something happens, there's a way to resolve it. So don't sweat the small stuff.

17:43: (Jo) *That's brilliant advice, and I can imagine when you've got 300 studies to be thinking about, you just don't have time to do that. So yeah, really, really good advice. Well, thank you so much for talking to me today, Lauren. Lovely to chat.*

17:55: (Lauren) Thank you.

18:02: *I hope you enjoyed today's episode. It was so interesting to hear about Lauren's role as a research governance manager and how her career journey led her into this space. She gave some great insights into moving from a lab-based to an office-based role and how the principles of GMP, GLP and GCP gave her a solid foundation for the work she does now. Lauren also spoke about the value of learning through experience, progressing through different roles to build a deep understanding of processes and systems, and making the most of opportunities like courses and conferences to continue developing skills and knowledge. Thanks for listening. If you enjoyed this episode, don't forget to subscribe, share, and join us again. Until next time, bye.*