**I: [Introduction to study] So to confirm do you give me your consent to**

R: Yes.

**I: And do you understand that your participation is voluntary, and your participation can be halted for any time for any reason without penalty?**

R: Yes.

**I: And do you give me permission to quote you anonymously in any outputs resulting from this study, including the sharing of anonymised transcripts?**

R: Yeah.

**I: Do you understand how to raise a concern or make a complaint?**

R: Yes.

**I: Do you understand that any information you reveal that presents an immediate risk to patient safety will be reported accordingly?**

R: Yeah.

**I: Do you give me permission to re-contact you to clarify any information if necessary?**

R: Yes, that’s fine.

**I: And then would you like to be contacted via your email on file with the results of the study when they become available?**

R: Yeah.

**I: Great and then lastly, I’ve been offering if you would like I can also send you after I get it transcribed and do the anonymisation, I like to offer people the opportunity to review the transcript themselves if they would like, would, you, would you like that?**

R: No that’s fine, I’m happy to not receive that yeah.

**I: Great and then great so you’re happy to take part in the study?**

R: Yes, I am.

**I: So okay then we’ll just go ahead and get started. Let me just pull up some notes here and then we will go. Make a quick note to myself. 02:27 Excellent okay so just to get things started, can you just tell me a little bit about your current role and sort of your past roles like your, your history working in sort of the field of clinical trials and clinical trial research management and administration?**

R: Yeah, sure so I’m currently the [an operations director at a CTU at a University]. I’ve been in that role I think it’s about four years and before that I was [a lead trial manager at the same University] and then I’ve been managing trials for about the last 17 years since doing my [degree] that I started, that involved a small trial and so then since then I’ve just gone into that and worked at [various other institutions] and then came to [this University].

**I: Great so it would be great if, you know, I’m primarily interested in sort of how things are currently, but it sounds like you have a lot of experience across a wide range of places so if you’d like to draw on comparisons and how things have shifted through time as you’re answering the questions that would be excellent and really great. I’m very interested in hearing about that as well. So can you just talk a little bit about your current at the CTU just in sort of its structure and organisation and how it sits within the University?**

R: Yeah, sure so our CTU sits in [a University Department]. The CTU [has an executive board that includes me, the director, and the academic and stats lead] and then within the CTU we’re split into functions, so we have a team of statisticians, we have quality assurance, we have trial management which is the biggest function. Then we have developers and we have data managers as well, a team of data, and then all of us then form various teams within that structure to obviously deliver the trials and we’ve got about 40 trials on our books at the moment all at various stages. [We recruit throughout primary, secondary, and tertiary care at different levels] so it’s quite varied. Obviously, a lot of our work is then short-term grants where, you know, the programme grant will be five years, but the actual randomised controlled trial might only be sort of 8, 12, 18 months. The longest one we’ve got came to the CTU in 2013 and that is now in the very last stages of follow-up before we get to the end of trial at the end of this year. So, there’s quite a variety and they cover all different areas of disease. We used to theme in terms of [disease areas] and then behavioural trials. So that’s kind of a very broad CCU. But then obviously sitting in [the University] we are a UKCRC registered trials unit. In [the University] there’s [more than one CTU].

**I: Great and just so to make sure I understand this so the trials, so you have [CTUs] and trials happen but are there also, there’s also generally trials taking place outside of, are there trials taking place outside of CTUs as well?**

R: There are but a couple of years ago. You can’t run a drug study outside of a CTU now for [the University] as a sponsor. They won’t, you’ve got to be a CTU. You can obviously do other studies but as long as they’re not drug ones, they can sit outside of the CTU and it just depends, if you’re doing a randomised controlled trial, obviously they’re usually complex and usually with your funding application would be more supported if you’re saying a CTU is gonna deliver that trial.

**I: Excellent okay and then just so you said, your portfolio in your CTU is about 40 trials or you said?**

R: Yeah.

**I: So is that mainly what we would call, like what would be called a CTIMP like in terms of formally or is it a big mix of-?**

R: Yeah, it’s a mix. So obviously we’ve got some observational, majority are randomised controlled trials. We only have a few which are drug studies and the majority then are, there’s an intervention but it’s not a drug so it doesn’t fall under the MHRA for the majority of ours.

**I: Okay great so be-, now that we sort of have the the structure underway, oh one last question so you’re, you’re sort of, what is your role in just a little bit more about your specific role and sort of like what you do in terms of, you know, looking up the trials individually, like how we-?**

R: Yeah, sure so I kind of get, I oversee all of the functions but going from the trial start I’ll usually help to work up the grant application to get that, so we’ll add to like looking at the logistics and how that would work and obviously within the CTU stats will be involved as well for your sample size. We’ll have that sort of lots of discussion. I’ll then work on the application for the costing side of things, how much it’s gonna cost, get all of the costs from the Clinical Research Network so if they’re supporting. There’s a SoECAT form, there’s actual staff that need costing as well as the non-staff, so I’ll work on that. Once it’s awarded, then I’ll assign it to a team of people milestones are set throughout that and then I’ll just keep oversight that it’s delivering to that and the way it’s delivered then we, I’ll work with the teams to set the standard operating procedure so we’ll be writing the SOPs, make sure the processes are in place and then I’ll be responsible for making sure we’re adhering to all of the guidance so whether it’s legislation or the regulations for trials. Make sure we’re adhering. A lot of my work now is linking more with externals as well in terms of the NIHR, NHS England, you know, different bodies like that and also a lot of work with the UKCRC because they have committees which we’re trying to set processes then nationally so there’s a lot of that work as well.

**I: Okay great so now moving on from some of that sort of structure and function stuff before we get more into the specifics of how sort of these transparency functions operate, you know, within your CTU [and at the University] broadly can you explain to me just to get sort of us thinking in this, in this way sort of why, in your own words, are requirements for the registration reporting of clinical trials in place, like sort of why do we do, why do we care about insuring that these things happen?**

R: Yeah, sure so from my perspective, the initial thing is to prevent that duplication we want to get out there to say we are doing this and to have that known and registered so that there’s no duplication. There’s not wasting of funds, you know, that funder doesn’t fund a similar trial because you’re just ending up with competing trials so you want to get that out there that initially that you are doing that. Then also obviously to help with your recruitment for trials to be able to get people into the trials so that you can answer your question and just to then once you get your result whether it, you know, whichever way it is as long as you’re getting that result out there so that you can show this has been done and there is no need for it to be replicated and obviously the main aim is to improve patient quality of life in whichever trial that you’re running.

**I: Great so okay so now shifting to more of the specifics about some of these transparency issues so if I am sort of a researcher in the department and I want to have an idea for a trial perhaps I’d like say I’ve got my funding all set all ready and I wanna get started can you talk me through the process of sort of like what, if there is one, like what the process looks like for registration so sort of is that on me or is there people in the CTU who would help me with that. Is it like, what does that look like?**

R: Yeah sure so that’s if you’re using a CTU, obviously it’s on the CTU and we don’t, we have a green light process basically, once you’ve got everything in place before your trial is going to go, you have this green light sign off and that then includes registration of your trial and you can’t start your, you can’t recruit any patient until you’ve got the registration in place just because of the publications at least, you know, what publications you can access so that has to be in place and that is reviewed then by a QA Manager. As a Trial Manager, you’ll take your documents to the QA Manager, they will double check everything’s there and then give you the green light to go for your trial. That is also then we report that back to the sponsor as well and obviously our registration numbers are on all of our documents that we submit initially to MHRA, ethics, HRA so it’s, it’s all on there.

**I: Great and so is the, the person in charge of actually like entering that information into the registry would that typically be the Trial Manager in your experience?**

R: Yes, it would. Obviously, there was work with the Chief Investigator and to make sure the information is, they’ll draft it, it’s reviewed by the CI then the Trial Manager will actually enter it because obviously as the trial’s going along there might be changes and amendments so that you would then have to go back to update what you, what you’ve said but obviously the CI is, has to agree to all of that as well so if the CI said no there would be a lot of difficult conversations.

**I: Yeah and that is that ongoing update process so like there’s alterations to, you know, recruitment or to outcomes or something changes about the registration, is it reviewed on a set basis or is it sort of ad hoc as these changes happen, they’ll make the changes or is it once ever six months we review and make all the changes all at once, like what is that process sort of look like generally?**

R: Sure so once your trial has got approval to go, if you’re going to change make any big changes then it’s a substantial amendment so you are changing your documents and you are going again to Ethics, MHRA to get that approval at the same time we all, every time there is a substantial amendment we always update the risk assessment we’ve got and within that that will link to, ‘do we need to change, we need to review what’s been registered and do we need to change that?’

**I: So up until recently you presumably when you did drug, the CTIMPs, that stuff could get put on the EUCTR sort of automatically,**

R: Yes.

**I: that’s obviously not a thing anymore due to Brexit so what registry and perhaps using other registries in addition anyway, so what registries are you typically using in the CTU, you know, understanding that some grants may require some registries, so which registries are you typically like using?**

R: Yeah so, we would use obviously the, would get the ISRCTN and then the ClinicalTrials.gov that that website we would be update, we’d get a registration there. They’re our main ones and obviously with Brexit then, the portals are just changing and there’s a lot, you know it ends up being duplication. Obviously the MHRA are trying to put things in place because obviously at the end of a study, we’ve got some coming to an end and we’d have a year to report the results on the EudraCT system, so, we haven’t yet reported because we haven’t yet used this new [er] the new system but yeah, they’d, we’d it mainly be the ISRCTN that we’d get.

**I: Great okay and then so okay and then so now I’ve done my trial, I’ve completed it what are the requirements for reporting results. We’ll start with getting results up on the registry like you were sort of saying and I understand that’s now for the EU that process may have changed a bit but you can talk a little bit about what that looked like or before for some of these other registries where there’s requirements in place and if there’s not do you still encourage reporting to the registry, sort of how does that look like?**

R: Yes, yeah, so obviously there was a legal requirement before for the drug studies to upload onto EudraCT within 12 months of, so when you get to the end of the trial you have to do your end of trial reports, to your funders, ethics, MHRA. You’re doing that and then you’ve got 12 months to upload your results so obviously we still, we work to that for our drug studies. Non, for the non-drug studies there was never clarity like that but within [the University] especially from…the CTUs, they’d come to an agreement to say it’s good practice obviously to, so we were working to the same way of that you’ve got twelve months for your non-drug studies to then report as well.

There’s also lots of pressure you get now, I’d say more so from the funders to obviously say you need to get your data out there and also to inform the participants as well so your dissemination, your results of your trial to actually, you know, give that directly to the participants. If they don’t want to receive it obviously, you’re giving that to sites as well and then to get your publication out and for a lot of our trials, the trial publication is then our final study report basically so that’s what we always aim to do with all of the trials just to get them published as soon as possible.

**I: Yeah, so, so it sounds like it’s just to make sure I’m sort of categorising this correctly so there’s setting aside when it’s legally required for a moment.**

R: Yeah.

**I: For other types of trials where it’s not, there’s not this legal requirement in place. It’s just, it’s sort of more a culture of strong encouragement both within the broader University and from organisations like funders to report that but there’s no sort of stan-, SOP or policy requirement to do so?**

R: No.

**I: Okay.**

R: There’s no, like with the drug studies, there’s the legal requirement.

**I: Yeah.**

R: There’s none of that for the non-drug. Also, I would say working at other institutions we did a lot of industry-funded trials or especially the early phase trials that I worked on. The funder, the funder would be the manufacturer of the drug and then they’re using an academic unit to run the trial now they because it was early phase as well there would be less transparency about publishing that because it wasn’t in the funders interest if that was a commercial company but it would always be they’d be the Chief Invest-, they’d say they were Chief Investigator-led and obviously that would be a clinician working in the Trust so they would push for the publication but you would have to get approval from the funder to do that.

**I: Right and once again so whether it is or isn’t required, either way is it a similar process to get that reporting out the door to the registration where it’s the Trial Manager working with the CI, would that be what that looks like?**

R: Yes, yeah it is all the publication so obviously the CI would probably lead on that results publication and then it would be the Trial Manager flagging because obviously once you get published people are comparing all these things and can request your data as well so you would want, it all needs to align basically. What’s on your registry needs to align with your publication and also it goes back to your other Trial documents, so your statistical analysis plan needs to have everything in there that you are actually publishing at the end and obviously all of this is inspected as well by the MHRA. They’ll look and they will come up with a critical finding if something doesn’t align.

**I: Great so have there been in your experience in either here, at your current position or in, or in previous positions have there been like a lot of challenges in sort of especially with the legal dead-, like sort of meeting those one year deadlines and getting the results up or alternatively like have you seen experience, have you had experiences where results sort of maybe there are problems with publication or a CI leaving, like just difficulties in getting results out the door one way or another.**

R: Yes I think not so much in this organisation but in others and, like I say, if you link with Industry that gets very complicated and there would be a lot less publications from those units just because the funder wouldn’t sign off on the publication. Then when it’s just purely an academic trial that has been then pushed back from the CI and obviously it’s their grant and it’s their trial but they have delegated the running of to the CTU but when it actually gets to publication that can, you know, there has been where results haven’t got out for, you know, for based on the CIs decision and it’s very hard for a CTU to overturn that. You can have all the discussions and you’ve got the data but it’s very hard to overturn that and similarly it’s very hard for the CTU to get recognition on those papers as well even if you’re all collaborating it will be the CI you know, the researcher which will write that paper with your, with your data you’ve helped collect.

**I: Great and then let’s see where I wanna go next. So great, yeah so having been in this field for a while now and working in, you know, seeing this from a lot of angles and a lot of different institutions what in terms of like these issues and transparency and registration and reporting it’s evolved quite a bit over that time frame and sort of risen in importance and prominence, can you talk about sort of like in your career you’ve seen those changes sort of manifest in how these organisations interact with them and take them seriously or PIs just sort of what how has that changed that you’ve observed throughout your career.**

R: Yeah, I think initially it wasn’t formalised at all in any sort of process and you’d have trials that were run obviously by, you know, the CI secretary type thing and so there wouldn’t be a process in place. Then obviously it changed more so CTUs and trial management became more of a thing and so then processes have been started to put in place but I would think really the biggest change may be like the last sort of five/ten years where it has been more pushed I would say from the funders perspective and patient groups as well, there’s a lot more use and real use of PPI so it makes those sorts of discussion a lot easier because when you’ve also got your patient reps involved in your different committees and actually helping create and review these types of documents they’re very aware so I think that has been the biggest thing. I think the place we’re getting stuck now is obviously we, we report but then it’s that if somebody requested your data how do you do that with it, with all GDPR issues and everything like that. I think that’s where sponsors are getting a bit stuck at the moment with actually sharing it, you know, we have to put in your publication to say, you can share this data and but how that actually happens I think that’s the next tricky part really.

**I: Yeah, so okay, interesting, so yeah so it’s short of shift-, shifted from registration to the results getting out there to now more like how you share data in a responsible way?**

R: Yes, yes.

**I: So focusing in because [the University] is a bit unique in the [CTU structure]**

R: Yeah.

**I: …how much like on these issues like registration and how things get reported like you mentioned a little bit earlier that there is sort of like discussion among the CTUs about what’s best practice, so like what get, to what level and what’s the distinction between what gets managed at the CTU level and what gets managed sort of, either at the University level or at the like inter CTU level if those are distinct in some ways.**

R: Yeah.

**I: So, what does that like look like?**

R: Yeah, I think like I say, [the University] is very different, but I would say for me the difference is the sponsor, [the University] as a sponsor has very little oversight of CTUs. Whereas at other institutions they only have one CTU and the sponsor is heavily involved and monitors and is really knows everything you’re doing. Whereas, [in this University] just the sheer volume of trials they can’t, they don’t have a team big enough to do that so I would say they don’t have so much oversight and I would say it comes down to then the CTU level as to what they are doing apart from the, you know, what’s legislated it comes down to discussing and I would say the only other committee avail-, is the UKCRC so that has the Directors from each of the CTUs and they’ll have agenda items that they’re talking about and then saying everyone’s coming forward saying, “Well we do this and we do this,” and you’re trying to get some sort of consensus between them but again it, it’s very it’s not a formal process that you must do this. It is just good practice that everyone is trying to work towards.

**I: So, so most of that co-ordination, so there is, so basically there’s some coordination at the [sponsor] level but it’s the CTUs are sort of left to themselves to like implement whatever the decisions are to do like whatever best practice and SOPs and things like that?**

R: Yes, because the [sponsor office] will say they’ve delegated to the CTU and then it’s the CTU which will end up having its inspections. Obviously [the sponsor office] get inspected and they have their findings but yeah it will come down to the CTU level.

**I: Great so thinking along those lines, either on a macro or in a micro level in the, in the, your specific in [this] CTU, what do you think works particularly well about how you manage these like trials start-up registration ongoing management processes, like what, what sticks out as like working smoothly and well for how these get managed?**

R: Yeah so we have obviously the leads of each of these functions and we all meet every week and then for each of the trials we obviously have a Gant chart with the timelines and then each lead] we’ll know where, where the task is for that current trial, what is the task, where is it, who is it sitting with and then for us it’s QA having that bit more of independent then oversight. They’ll come in just to review we’re adhering to the processes. So for us having our we have a good number of SOPs, it’s not too many to sort of overwhelm people but it’s a good number that people then know what they need to do. I would say regular training as well so obviously before Covid we would have a training session every week with a title specific content that we’d worked up and then people could put their name down as to they needed training or we could mandate certain people to go on set training, so they’d know the process so if they were about to do trial set up there was certain training that they had to go on but obviously that was all in house. So, yeah, I think it’s that good communication between all of the leads knowing exactly each trial and what point they’re at so and then having that green light for certain things that you’ve got to get that independent review to make sure you’ve followed all the processes.

**I: So that centralised committee within, within the CTU like are you, like who, so you guys meet, are you meeting with the managers to get sort of updates or the CIs, like how are you like getting the feedback on a sort of ongoing basis?**

R: Yes so, we meet with, so all the leads are like senior Trial Managers data lead, nursing lead, stats lead, all of those leads will get together each week so for us from when the tri-, when the CI first has a trial idea, they fill in a form for requesting support. That comes to that group of people. We run through to see, ‘Is it a good question, can we help?’ And we’ll know as well if it’s a call that’s gone out, we’ll know there’s competing ones or whatever so then we can link back to the CI and then start working it up from there and then as soon as then it’s funded, obviously these meetings then have changed focus so that we are focusing on the milestones and that we’ve got everything done so that’s and then obviously we also have within each trial, we have trial management group meetings so that is everyone working on the trial so it’s the CI, all of the CTU people. There might be health ec [economics]. They’ll be different people who come to that meeting and for a CTIMP we’ll have one of those once a month. For the non-CTIMPs it’s usually once every six weeks and we’ll just work through depending on the stage of the trial, work through so that we’re raising and discussing things if there is focus that the CI wants us to make on something else or something different.

**I: Yeah and on the flip side of that is there anything that’s been, you know, difficult or barriers to walk through that make any of these tasks like a bit more difficult or maybe so this can go one of two ways, either something that’s sort of actively been worked to be rectified or so anything that has recently been rectified where you like sort of overcame change some policies or worked differently. Like Covid may have necessitated some changes but [um] but just broadly, like, you know, setting aside the remote working or the work from Covid for a moment like, you know, has there been like any major changes, any major barriers or difficulties that have needed to be sort of overcome for smooth functioning in the wake of, you know, things that have happened over the past few years.**

R: Yeah, I mean, that’s a really tricky one trying to pull apart so main changes for us it’s implications from funders basically. Covid they wanted everything paused but you’ve still got people employed so we were lucky enough that we could redeploy to try and make those things so I guess no and the main barriers for us is always the sites we work with and obviously in [specialty area] for this last year it’s been very difficult to get them to recruit but it has been that we’ve done novel things that we’ve shifted online and we’ve recruited, we’ve gone directly to the participants and cut the, you know, the middle man by not go-, not setting up sites and just going, you know, advertising straight to the participant and recruiting in that way. So that’s led to a lot of novel things, but that necessity was because of Covid really.

**I: Great so building on that a little bit more the previous question so to mention a few like specific instances of things that have sort of may have impacted you, like your job and the way you, like the way the organisation runs trials, so I’m just gonna list, name a few things and I’ll name one and then you can tell me if it’s sort of had it, like what impacts it’s had on the day to day and working on some of these issues and transparency so first of all has Brexit had a major impact thus far, like thus far?**

R: Yes [laughs] just because of trying to get things into the country so if even if we’re doing a study where it’s not a drug study but we’ve got a product we need to get in that’s had an impact and I think just there hasn’t been transparency about and there wasn’t enough time about how these portals would change and what we would need to either register a new trial or get, you know, even going through amendments and things like that it was, there wasn’t a lot of information on that from I think from a national level and also from a sponsor level there was nothing so that, yeah that was tricky.

**I: Can I ask have you started any new CTIMPs in the last, since the beginning of the year when Brexit became official, do you know if you have?**

R: No because all of ours we got in, got in.

**I: [laughs] just before.**

R: So it was like just get it done because we don’t know what it’s gonna look like.

**I: Yeah.**

R: So, we did that, yeah so for us it’s been obviously amendments and the DSEARs, the safety reports that we have to send each year, obviously that process has changed. So for the drugs studies a lot of processes has changed so it’s been very on the job learning without, you know, I kind of say with little instruction really.

**I: So, it might be a little hectic when the first new drug trial post- Brexit comes about and what exactly needs to be done?**

R: Yes.

**I: Okay and then what about when the Science and Technology Committee sent those letters to sort of all the Universities and Trusts a few, like two years ago now or three years ago, did, do you recall what I’m talking about, does that ring a bell?**

R: No, I don’t.

**I: So even that’s interesting to hear. I guess it didn’t make it to the CTU so basically there were hearings about reporting in the Science and Technology Committee in Parliament about how well people were reporting to the EU register specifically and how it should be better and then, yeah.**

R: Right.

**I: I think [this University] was always pretty decent at that so perhaps it didn’t gain the traction where someone, like you didn’t need to hear about it because thinks were functioning well?**

R: Yeah.

**I: What about the, and this might be going back a little bit further, what about the general influence of like the All Trials campaign or other advocacy organisations that focus on these areas?**

R: Yeah I kind of feel like, so this where there’s a bit of a split I would say because you go to sort of conferences and so like the methodology conference, the International Methodology Conference, there’s a lot where you hear researchers saying about something but then there’s people who are doing the job either saying, “We’re doing that,” or “We didn’t have a clue about that.” And there’s a real, you end up with this real divide so I would say I don’t think it had on us a CTU or other CTUs, I think we were aware of it but I wouldn’t say it had an impact but then I think that may be linked to the type of trials you do or who you work with because I think I knew people working in clinical research facilities doing Phase I which were very aware of this and quite worried about it because they knew they weren’t publishing because their industry sponsors wouldn’t allow them.

So, I think it probably had effect there, but I think on the bigger sort of academic units I don’t know that it had, everyone was aware, but I don’t know that it had an impact.

**I: Great and then lastly just sort of have there been reactions or preparations in advance of sort of the HRA’s new sort of Make It Public strategy like where they’re gonna slightly change how registering and dissemination and stuff like that works. Have there been discussions about that?**

R: Yeah, it’s come up, it’s come up a lot with the UKCRC board and everyone, I think as well in the last couple of years a lot more has gone online from the trial teams themselves. So, I know for us even our protocols, every amendment we do, we would, used to email the site and say, “Here, here are the documents.” Now we just put them on the website so they can pull them themselves, so I think and usually then our trial result will go on that website as well, as well as sort of disseminating it, so I think it, I don’t think we as a CTU have too much more to do. We have discussed implications of it so it has been raised, yeah.

**I: Okay great and then so the last section here is just about like training and support and learning so you mentioned training a little bit earlier and just to expand on that a bit. So like how does it look, so if I’m a, so the Trial Managers or even with the CIs what sort of training do they receive on how to interact with registries and about the various requirements and procedures around getting your trial registered and the, not just that you have to do it but how to actually do it, what does that look like within the CTU?**

R: So for the CTU, so that falls to the Trial Managers and so then we did, we do hold training sessions and we had a whole, we had topics and there’d be an hour and a half each week and we’d run through and show actually what it looks like so even at the IRAS system this is how you do it, this is what you need to do. So we would run through the stage from set up to archiving and publication of how you actually do this. So we’d run that initially for the Trial Managers then we opened it up further to other people, other researchers in the Department. Interestingly we’ve never had a CI come on any training like that but I do run the module for the [Trial management course] and that is usually has a lot of NIHR Fellowships on there who are about to run a trial and we run through all of that and actually the site you go to, how you do it but we don’t do it with our CIs.

**I: Yeah, sure.**

R: We kind of do that as an external module and then do it with the Trial Managers but not with the CIs. Obviously, the CIs are aware and because we’ll be pushed to open to recruitment and we’ve had examples where we’ve had to say we can’t because we haven’t yet had, you haven’t reviewed the registration profile that we want to upload, things like that. So, we, because we link it to recruitment usually they will act.

**I: Yeah, I’m interested just as a quick follow-up to that, how aware are CIs generally both now and then I would say like even going back into the past a bit about the, like are they generally aware that they need to be prospectively registering their trials in order to get into a good journal?**

R: No.

**I: Is that generally, no they don’t know.**

R: No and they even within I think probably about three years ago, we did have a CI who pushed to get the trial open, it wasn’t registered, we then had to stop the trial when we found out that he’d recruited somebody. We hadn’t given the green light, he recruited. We had to stop because we hadn’t got it registered and when he realised the impact the publication then suddenly, he was, “You need to make all these changes, you need to do an amendment. You need to do this,” just so we can get it registered and we have to then ignore the first few patients because it didn’t have the registration, so I don’t think CIs are aware of-,

**I: Interesting.**

R: Yeah, of the implication of it.

**I: Very interesting to hear.**

R: And as well, like that example, he soon learnt. [laughs]

**I: Yeah absolutely, yeah do you think that’s something that could like be better communicated, like that’s something, like-?**

R: Yeah.

**I: Yeah.**

R: I think so, I think even from when you get your funding, you know, if you knew within x, you know, months we expect to see this on a registry

**I: Yeah.**

R: Something like that, something to just plant the seed because obviously if they’re not using a CTU, they might not be aware and it’s usually when somebody says, ‘Why do you need to get it registered or-?” And then you’re saying, “Because-,” and you’re explaining it, then they understand it, but I don’t think there is knowledge like that out there. I think CTUs are aware and do that but then the CI, I don’t think does think so much about transparency. They’re just thinking more of, ‘We’ve got to get going and we’ve got get the data and I want a publication but they’re not you know, not thinking so much about the detail.

**I: And that sort of training system you described to me earlier, are you aware of sort of other CTUs have a similar system in place do you know?**

R: Not in [the University]. I know at [another University], so that was a [specific disease area] CTU so it was bigger. There were nearly 200 employees in that CTU and that was a very regimented training process that you couldn’t do a task until you were signed off by the trainer so that is very ad hoc between CTUs as to how they manage to ensure you’re following the process.

**I: But within [your University] as far as you’re aware no one else sort of has as sophisticated of a training?**

R: No, we also a few years ago we started doing this trainee trial manager role and we had hundreds of applicants and we only wanted three that we could then train up and work, you know, work in this way so I think in [at this University] it’s very hard to get experienced Trial Managers because there’s [so much clinical research] but then there’s a lot of people out there who want the training to become a Trial Manager so no and when we did that scheme that linked to this training programme that we started it all at the same time and other CTUs [here] were sort of saying, “That’s a really great idea and we should do that” but they had, they hadn’t yet so.

**I: And then sort of this wrapping up with sort of these last only two questions left. So, when changes happen when sort of like, you know, I don’t know, something about the requirements and the things you need to do. I mean you mentioned it’s been a bit hectic and poor communication with post-Brexit stuff but, you know, as far as that stuff when changes do happen and that starts, needs to get to you, how are you generally like receiving that, whether it’s the MRHA or some other requirement that just in general news about this world of requirements and best practices, like how is that being presented to you. How does that end up in front of you?**

R: Yeah, so usually it’s, I’ll start with, I’ll sign up and subscribe to the differen-, different pages so that will get the notification by email so that’s one of the places then it’s because usually you don’t have time to keep looking at the websites, so you get that notification-,

**I: So, you mean like the MHRA has a mailing list that you can just sign up for it and yeah okay.**

R: Yes, and HRA have one, you know, they’ve each got them so sign up to those. Then I would I say it’s just from networking with other CTUs so like GCP changes are one of the sort of latest things and it goes out for consultation for a while but then it’s out for so long, no-one sort of realises, when it comes in it’s suddenly like, ‘oh well what do they actually include?’ because we all, you know, had input into the consultation so it’s trying to keep track of that but I’d say the networking with the other CTUs is the biggest sort of educational part that people will say, “Oh this is gonna come in or this looks like it’s gonna happen or how are you doing this?” That’s usually the discussions between CTUs; how do you plan on managing this or how are you managing this?” Some changes we are never notified of, so the HRA are notorious for keep changing things to do with amendments IRAS NIHR CRN CPMS that uploads for recruits, notorious for just doing that and it’s a process that doesn’t work and then everyone is suddenly feeding back saying, “We weren’t aware of this. If we had input, we might have been able to help you. Now the system doesn’t work.” So yeah there’s somewhere it isn’t communicated at all and you just feel like, you know, it’s suddenly just a bolt out of the blue.

**I: So, you mentioned that networking between CTUs, is that, you’ve mentioned, UKCRC a few times. Is that the main way to do that pretty much?**

R: Yeah so, they set up sort of their executive board and then they have lots of working groups and different committees underneath. But then I guess it’s as well, length of time of doing the work, trials are quite a small world from CTU perspective and so there’ll be people in [one University] that I know or [another University] or, you know, that you just have worked with over the years and then you just keep that contact and have your own network as well as sort of more formal ones.

**I: And then, yeah, and then like what about just the other organisation that people have sometimes mentioned over the course of these interviews is the, is the Trial Manager’s network, is that also a useful resource for you?**

R: Yeah, it is and they, I link with them quite a lot as well the UKCTMN so I would say yeah that they’re good as well. It’s like a soundboard to try and collate some of the experiences people are having and they’re focus is mainly on like the professional development of trial managers so that is another way of networking as well, yeah.

**I: Mhm okay that’s pretty much it. So one last, one last question though so your role as just because I think amongst the people I’ve talked to so far, it appears to me like your position is, might be relatively like, I guess everyone might call people different things but like having, so you’re sort of like management and administrative like lead for the is that like a right way to describe an operations like almost type person?**

R: Yes.

**I: Do you think that’s a relatively unique position to have in a CTU or do think most CTUs have someone like you?**

R: Yes, most people’ll have, they either call it like CTU Manager or CTU lead or Director of Ops yeah everyone has it’s usually the set up

**I: Okay.**

R: The Director role is usually clinical and its only part time and then you’ve got your person doing the day to day, how are we gonna make this work so I think, I think for us it’s unusual to have an academic lead as well. The units don’t seem to have that. They have a stats lead which obviously then focuses on the publications but they don’t have it as someone who is then Deputy Director in that way so that’s unusual for us.

**I: Okay so yeah, I think that’s pretty much all my questions for today? I just, any final thoughts or anything that like about this that’s been on your mind or that you’d like to share that we haven’t covered today specifically like around like transparency and the management of trials, is anything?**

R: Yeah, I guess it’s that I think Trial Managers are all for it for the transparency. I think there ends up being red tape which help block it but I think the whole AllTrials and transparency in trials, all of that is very good at making those people who block it feel uncomfortable. So I would say, you know, sort of the leads, I know I’ve been in meetings and they worry if something’s coming from Ben’s group, ‘What is he gonna say about us?’ and so I have heard that from a number of places so I think that’s a really positive thing because it is making them uncomfortable and then you think, ‘well why you feel comfortable because you should be doing this and we should all be doing it,’ so I think it’s a really positive thing.

**I: Great and then yeah excellent that’s a wonderful closing thought I think to end on.**