**I: [Introduction chat about study] 00:46 So I sent over the patient information sheet and the consent form, did you have a chance to look over those?**

R: I’m really sorry, actually didn’t.

**I: No, no worry at all.**

R: I did skim them. I did skim them I think when you sent them, I was kind of are you going to go over it now and then?

**I: Yeah, yeah, so I can go over it now.**

R: I did skim them, and I did, I was okay with it, was okay with [um] what you had mentioned. I just didn’t look at it in detail.

**I: Yeah, why don’t, well so I’ll go ahead and read you the longer one just so you can make sure you know what you’re getting into, and everything is okay.**

R: Okay.

**I: [talking about the study and data protection etc]**

04:09

**I: To confirm you give your permission for me to interview you today and audio record our conversation?**

R: Yes that’s fine.

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

R: Yes, that’s fine.

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

R: Yes, that’s fine.

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

R: Yes, that’s fine.

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

R: Yes, I do, yeah.

**I: [er] Do you give me permission to recontact you to clarify any information we talk about today?**

R: Yes, that’s fine, yes.

**I: And would you like to be contacted with the email I have on file for you with any results of this study when they become available?**

R: Yeah [um] yes, please that would be great, yes.

**I: Okay and then also the other option I like to give people is once I get the transcript and I’ve anonymised it I can pass that along to you for a look to make sure you’re comfortable with everything if you’d like that as well?**

R: Yes, that’s okay, yeah that’s fine, yeah.

**I: Okay and then [um] and then so are you happy to take part in this study?**

R: Yes, happy to take part in the study.

**I: Excellent okay let me just record you said yes to results, yes to the transcript. Okay great so we’ll go right into the interview then.**

R: Sure yeah, I have to say I’ve never participated in a study sort of like this type before. It’s always been sort of biological research so it’s really interesting so I will apologise in advance if some of the questions you ask, I’m just like I’m like I don’t know how to answer that.

**I: Oh no that’s fine, I mean if something doesn’t make sense or you know, you’d like to have please, ask me I can clarify if there’s something you just don’t know or unfamiliar with that’s potentially interesting in of itself.**

R: Yes.

**I; No worries at all.**

06:19

**I: [um] So just to get us started I was hoping you could just tell me a bit about your role?**

R; Yes so, I’m a Clinical Trial Manager or Coordinator at [a clinical trials unit]. I’ve been a Clinical Manager for just a year so. I’ve been applying for this role for about two years before that and I managed to secure one at the start of lockdown last year and so I’ve been managing three studies as part of my role. This is setting them off, the trial set-up, study set-up. We’re, I’m still learning the ropes on opening different sites and sort of exploring different avenues that are, that are opportunities that have opened up to me as part of the trial management role.

**I: Great so have you been involved at all in, so you’re relatively new to the role, have you been involved at all in registration of clinical trials?**

R: So I’ve had to register all three of the studies that I’m on.

**I: Okay.**

R: And so clinical, clincial.gov.uk is that what you mean? So things like IS, ISRCTN?

**I: Exactly yeah.**

R: Yeah, so, I’ve had to register all three studies, one be, one was an audit, two of them research and each of them with their own sort of baggage of issues. But yeah, all three are being registered onto ISRCTN. That’s one of the ISRCTN we’re spreading the word on, so I think we’re emailing sort of an NIHR representative to get it disseminated and it’s gonna, I’m gonna find out how to get it onto clinical.gov.uk so that it’s sort of available when people look for trials on breast cancer.

**I: Right so as far as, so the ISRCTN is your like primary registration site, though that’s like you-?**

R: Yes, yes so we do it via the Clinical Research Network. So each of the, so of the three studies, two of my studies have received CRN support, so that’s Clinical Research Network support which means that the research nurses and I think there’s a network of people that will help us recruit patients and it’s via that organisation that we’ve applied for the ISRCTN support registration.

**I: Great okay and those are, like are those live register or are they in the process of being registered right now, like-?**

R: They’re in the process of being registered yeah because they only happened last week so I think one of them is a paid, we need to sort out payment and the other one is free, so I just need to more details on our project.

**I: And so I assume these haven’t started yet if they’re not registered or have they all, have the trials enrolled anyone?**

R: Oh yeah so our audit, so the registry audit has started and we’re almost reached, we’re reached our quota of patients and we’re going beyond it because we can and the other two are very close to opening so this week I think starting in March they’ll be close to being opened.

**I: Great okay so just talking about your role a bit more so beyond registration can you talk about what your sort of day-to-day role is in for these three trials you work on?**

R: Yeah so, all three trials don’t, are, do not, are non medicinal based product, we’re not, it’s not a CTIMP so, so-,

**I: Right.**

R; Yeah, they’re non-CTIMPs. One of them’s interventional, one of them’s just observational so we’re collecting, already collected tissue and the registry is we’re just collecting it anonymised data on patients with breast cancer. So in March, back in March when I got the three projects, we started off on a basis with it’s not, it’s not a CTIMP, none of the studies are CTIMP.

**I: Okay**

R: we’re going through why we’re getting these set-up, open and set-up. It turned out that even because these are non-CTIMPs, our methodology was even more scrutinised because I think all the templates, so as far as the day-to-day process, I do the same thing as you would in a, sort of in a CTIMP study so you would write the protocol, you’d write the patient information sheet, the consent form. You’d write the summary sheets and build, build, build and design all the patient leaflets and when you, you do the rest of it and I need to go into a folder to find out the rest of it but it’s a lot of it but because there’s no, all the templates have very strict and very clear sort of guidance for CTIMPs so if you’re a C, if your project is a CTIMP, you know, this is the wording, this is how you would structure it. If it’s a non-CTIMP, nah sort of that’s sort of the wording, it’s sort of, it’s generic.

I think for that reason every document that I did, we’ve had to take it to our Quality Assurance team who have then gone, “Why is this this way? Why is this that way? Why is this terminology used here? Why is that terminology used here?” and what we’ve found in the whole process, so I started this project in March last year. It is approaching March and we’re not yet opened and what we found is that each of the projects have been, each of the projects needed a special quality, a special meeting with a quality manager, quality assurance manager just to make sure that we are definitely within our regulatory framework and that we’re not sort of going under the radar so it’s taken longer for these projects to set up. But I think because the guidance for the template for non-CTIMPs is so generic, my day to day has been sort of fill out a document, get it scrutinised by the CI, by the STC, by QA, by HRA and then just re-do everything because it’s, guidance for non-CTIMPs is so lax that when it comes to crunch time it’s’ “Oh we need to make sure, let’s, let’s retrace our steps and make sure that we’re meeting all the regulatory [um] [um] sort of reg-, regulations.’

**I: Yeah, yeah.**

R: I don’t think I’m I feel like I ‘ve not answered your question but on a day-to-day basis I-,

**I: No that’s fine, great yeah.**

R: Okay.

**I: So, a few follow-ups on that though, so your studies are not CTIMPs but does your, the larger, like some of them are CTIMPs?**

R: Most of them, so most of them are.

**I: Yeah.**

R: Most of them are, yeah.

**I: And then what, just to confirm so you had not worked in Trial Management or like had you worked in clinical trials at all like prior to starting this position?**

R: Yeah, my background is sort of biology, medical biochemistry so I did my degree in medical biochemistry. I was a Research Office Administrator for a good five years. I then took on, I did a Masters in that time in Psychiatric Research, so I learnt sort of epidemiology so got trained in sort of analysis and stuff and then I took on a PhD in in the same office and sort of re-, sort of applied all of my epi skills into this PhD and then sort of learnt a little bit more on anonymised data. So I did a lot of analysis on anonymised data that was collected for clinical purposes, so mental health purposes and then after the PhD, I took a break and then decided I didn’t quite like academia, but I wanted something that was to do with academia but didn’t come with the pressures of academia, if that made any sense.

**I: Sure.**

R: So that but also because I used to be a Research Office Administrator, this tied in really well because the whole project management aspect and I’m still related to academia in a very unpressurised way and this is why Clinical Trial Management sort of I think just works out really well for me and starting off on a non-CTIMP is great but yeah I think next month I get another project that will have sort of a drug, that is a CTIMP but the funding’s only just come through.

**I: Gotcha, gotcha.**

R: Okay.

**I: So, this is your first position working directly in clinical trial management, like this is your first?**

R: Yeah, yeah.

**I: Great so one thing I like to do also to get us started like, you know, early on in these interviews, is I was wondering if you could explain to me in your own words why we have requirements to register and then subsequently report the results of clinical trials, you know, why is that important?**

R: Yeah I mean there’s, this is really interesting question because you can see the contrast between, for me at least, I can see the contrast between research and clinical trials. So in research you can, you can, you know, you’re answering a research question, you might get funding for it, if the funder is not MRC, NIHR, you know, some big-wig funder, there almost is no responsibility to go back and report on what’s happening. Whereas, over here at least, as part of this whole clinical trial process, you have to account for every step so you’ve got to, you know, you have to be, you are doing all the other work and then in the back of your mind you know at some point this might be audited so you are taking account of every action that you do, on, on a daily basis, so all my emails, you know, you can track the email conversations. But I think the onus or the responsibility to the patient is much more in clin-, as part of, as part of the clinical trials. So even though I will never have to interact with the patient, everything that I do and the time that I take on every document at the back of my mind, I know eventually this is going to in the long run help a patient but also this in the long run has the ability to impact a patient negatively So, everything that we do, you know, the patient information sheet if that’s not clear, that can stress a patient out. If we say on the patient information sheet ‘Would you like to be contacted for your results?’ you know, ‘Would you like to be told if something negative comes up?’ all of that has a direct impact on the patients so I think the reason why we have to go back and report on our results is precisely for the impact on the patient is so much sort of more visible or tangible, I think.

**I: And what about so, what about registration specifically, what do you think the purpose of registration is?**

R: Oh, I think again so it could be from in my mind it could be so they could be tracked.

**I: Okay.**

R: But also, for, in a way we see it as beneficial to us. It just makes us a bit more, ‘Hey world this trial exists, please approach us.’

**I: Could you, so you used that word tracked. I was wondering if you could just unpack a little bit by what you meant by tracked?**

R: I think there’s different, so there’s different organisations. I think I mean this from just sort of different angles from a, so from a HRA perspective it would be, you know, if there was an auditor, I think I think our centre got audited before I started and if there was a project that came in to, they saw [this group of studies] which is what I’m managing and they had questions, this would be one way to go back. So they would go back to the to the ISRCTN registration and go right, ‘When did they register? What did they say they would do? What do they, you know, declare that they would do and what have they done and how long has it been?’ That’s’ one way to put it.

In terms of the CI, CI is tracking what the CI had done so, ‘How many, how many projects have they registered that’s under their name but how many have actually reached completion? How many of them have not reached completion?’ and from my perspective it’s just sort of, it’s out there. That’s great, it’s out there, let’s get going, let’s start, let’s open the study, let’s get patients in and let’s disseminate this link, the registration link to as many sort of communities and organisation so that we can get maximise our patient recruitment.

**I: Great.**

R: I guess that’s what I mean by tracked is just it’s, we can be tracked I guess by different entities.

**I: Yeah, okay great so being relatively new to this position, you know, relatively**

R: Yeah.

**I: I was wondering when you sort of entered the position and you got these studies, so you joined them when they were in their beginning phase and you’ve been here throughout the registration, did you get any sort, what sort of if any, training or guidance did you get about the registration process from your organisations.**

R: Specifically, the registration specifically?

**I: Yes.**

R: It was close to minimal, it was close to minimal. It was so I think my line manager, I’ve got a really good line manager and she did talk about it but she talked about it at a point when I was not even ready to think about registration because there were so many other things to unpack already for me from my perspective. She did talk, she did sort of do a little training PowerPoint slide, so she actually did that and then that was it really. Everything else was off the cuff so when it did come to at the time when I had to do the registration, I think I just, once we got the CRN support, we got that email to say, ‘Okay you can now apply for the ISRCTN registration,’ so I just clicked on the link. I think I had to, there was something to sort out about the email addresses and then just went from there.

**I: Alright so it sounds like, you know, they at least made you aware that this is something as a Trial Manager you’ll need to,**

R: Yes, yes.

**I: take care about**

R: Yes, yeah, yeah

**I: but from then it was**

R: learn on your feet, yeah.

**I: Yeah and has there been any like during that process as well has there been any talk or like pre-planning about how the results of the trial would eventually be disseminated, like a plan for that or anything like that?**

R: We’ve got verbal plans so we’ve obviously we’ve sent publication. We are not, if something if any of our individual results come up with something of clinical significance, I think on our IRAS application we’ve said we’re not gonna report it back to the patients and there was, I can’t remember the justification for it, but the clinician, [the centre] had justification for it. Apart from publication, yeah that’s about it.

**I: Okay and then okay great so when you went through that process, you know, you registered, was there any like how did you, how did that process of registering look like in terms of getting the information you needed and feeling like communicating with the study team or your line manager about the information you needed? So like, what did that process look like in terms of, you know, taking the stuff about the trial and getting it into the registry.**

R: It was really straight forward. I found it very human if that makes any sense. I think my first sort of training when I had no idea what they meant. I thought ‘okay this sounds like it’s gonna be a bit more complex. It’s gonna be a bit sort of mechanic,’ but it’s, I think I did run into an issue when I was doing the CPMS [Central Portfolio Management System of the NIHR] registration to apply for ISRCTN and I immediately just contacted my network CRN lead immediately. Got an immediate reply from her to say, “It’s just this that and the other.” There are two emails waiting in my inbox at the moment to say thanks for filling out the form. We just need a few more details on question 6 whatever and it just feels very human if that makes any sense. I think when there was this whole, I couldn’t get into the account to apply for the ISRCTN thing, you know, immediately contacting my line manager and say, “Why can’t I get into the account? I feel I can see things, but I can’t really get into it?” and then, it’s very sort of I don’t know it’s flexible.

**I: Great and what, so it sounds like you had a, in terms of having the information you needed and for the few things you don’t know or you’re following up on it’s, you’ve got very good lines of communication. Is there anything about the way your organisation sort of, you know, manages this process that made it such an easy process for you to, you know, make sure you had everything you needed for the most part it sounds like, you know, to take this on and do it yourself, like what are there any best practices you could articulate that**

R: Okay.

**I: made this really easy for you to do?**

R: I think something I would be surprised if there are other clinical trial centres were not doing what we already do. So we’ve got SOPs, we’ve got templates, we’ve got a very strict way of saving our work and version controlling and we don’t have any TMF [Trial Master Files] but, you know, the [shared] drive, so we’ve got a folder, each project has its own folder. That is very and we’ve got guidance on what folders need to go in, under what which number and what goes into each folder so we’ve got specific guidance. We’ve also got like one document controller who has the final versions of all our documents and if we update, she, you know, she’s got the final sort of version. I think it’s these standards, so having an SOP template, making sure, so when I got these, the training for registration that probably was the right time for me to do that training because it was early enough for me to think there are more steps to do after, even though I had a mountain of work to do. It was right after this mountain goes away, there’s still stuff to do, so it gave me exposure, so I think the way we planned the training for me helped in anticipating what’s next. I think yes so the, the SOPs, the template, the whole process of having, you know, one document controller, making sure that I receive training to know that all documents that I’m doing right now, so the protocol that patient information sheet the rest, the rest of it would eventually come in handy to doing this registration with so much ease because by that time you know which of your studies is, you know, an observational, which, which of them is interventional, the number of patients, you’ve worked out and ironed out all the, all the [um] issues.

**I: Mhm.**

R: I don’t know does that?

**I: Yeah, yeah great and then I’m curious what they are, when you were sort of receiving your very initial training and then, you know, I touched on this a bit earlier but was there an emphasis on making sure that these registrations occurred prospectively? So, like sort of before enrolment or analysis started, was that sort of, was that a focus at all of any of the training or the information you received about registration?**

R: No.

**I: No. Okay.**

R: No, I think the training just happened. I think it was probably because I was reaching a point where I was like, ‘okay I’ve done the protocol now. I need to know what’s happening next.’ So my when I, we have weekly team meetings one to one team meetings with my line manager and we I brought up with her like I need to have awareness of what the each processes are and how they’ll fit in right now so that I can go in going, ‘right okay so now we have to think about the risk assessment, this is how to do our risk assessment form.’ And I think as part of that she then very kindly put in like I think for two months every week she put in training, so she went from I can’t remember how she started it but I think it was sort of, how to do a clinical monitoring form, how to do a risk assessment form’ and even thought here are SOPs, templates and formal training for it, there’s just always like a, the informal conversational training so she did that and one of that was CPMS registry, the ISRCTN registration but it wasn’t, there wasn’t any planning, strategic, there wasn’t any strategy to it.

**I: Alright so there was no emphasis that this should occur before you enrol a patient, like that never really got talked about?**

R: What specifically the registration?

**I: Yeah.**

R: I mean it was covered so I knew that, the emphasis wasn’t on that but I knew it had to happen.

**I: Okay great so you mentioned there that, you know, there’s a lot of, you know, there’s formal training and then there’s sort of things you learn along the way, you might say?**

R: Yes, yes.

**I: Yeah, so you mentioned, like I assume your role has been a little bit unique since it sounds like you’ve pretty much only been in this role since we’ve been in, you know, in lockdown and**

R: That’s correct.

**I: not going into the office on a regular basis but have you much-?.**

R: Sorry. [Referencing background noise]

**I: No worries. Have you had much interaction with other colleagues, you know, aside from your line manager, like has there been any sort of like learning from peers or-?**

R: Yeah, yeah, I’m so glad you asked this question. Yeah so I’ve seen my office once and then the next day we were in lockdown. I’ve seen my colleagues physically once and then the next day I think one of them I’ve seen twice. She came in to take all of her stuff. Actually my line manager once and then that’s about it and she doesn’t like to turn her video on when we have meetings, so I don’t, I don’t even know the right face in my mind at this point.

[background noise]

R; Sorry about that [referencing background noise].

**I: No worries at all, you’re fine.**

R: But yes I did I tried to make an active effort to contact people at the [clinical trials unit] sort of just introduce myself, “I’m new to all of this so it would be lovely to have a tea or coffee would be over online so that I can find out about your project and issues that you’ve got,” So the meeting was specifically to find out what are your stumbling blocks as a Trial Co-ordinator or Senior Trial Coordinator or Data Manager or this that and the other.” I think of all the people I approached I had maybe two meetings because everybody’s trying to [*indecipherable*]. I think what also we were struggling from working from home, it’s not, you know, as a, as a past researcher it was like the most easiest thing for me to work from home because I’m sure you’re, you’re you know, you’re no stranger to this. You just learn to work from home

**I: Yeah.**

R: and you learn to work odd hours and so when this whole thing happened, I was like, ‘okay, cool, I can work from home.’ But I think lots of people were struggling so, they were struggling to meet up with me and also understand like, ‘why do you need training in this way in a lockdown? Like there’s something bigger happening.’ So I started sort of, and I think Twitter was a big help so I started following some Clinical Trial Managers and there is one University’s doing it really well, I think Nottingham, Nottingham University.

**I: Aha.**

R: You know the UKTM, I think this is how they I found out about your study.

**I: Yeah, yeah.**

R: So, I followed a few people as part of the UK, the Trial Manager Network

**I: Right.**

R: and it’s just really interesting to learn about sort of the whole Trial Manager, you know, this whole career development pathway that they’re trying to set up and they’re trying to make it like a valid career pathway for clinical trials. There’s an interesting podcast, there’s an interesting podcast specifically on trial management and I found that more than I think, more than even talking to people, I found listening to those podcasts absolutely lifesaving because there were things that they said that you would, as I was doing stuff, you know, as I was doing stuff I thought, ‘Oh my gosh, ‘ there were so many thoughts going through my head, like ‘am I too slow? Am I too fast? Am I too careless? Have I, have I put in attention to detail?’ Apparently all those thoughts are normal for Clinical Trial Managers and maybe not, you know, maybe humans in general but they covered points in a specific way but had I not listened to those podcasts, I think I’d be a very nervous Trial Manager having not had sort of physical, you know, physically being in an office yeah having those physical interactions with people, you know, when you got the coffee room and you talk to someone and you start collaborating or your next mentor or whatever someone who is going to help you or whatever.

But yeah listening, I think mak- making an active decision, I am going to listen to podcasts because I feel like not enough people are talking to me at the [trials unit] and rightly so, you know, because they’re busy with their own stuff. Lockdowns are weird. I think now if I had to contact them, they’d probably be like, “Yeah, sure, that’s have a coffee” but I don’t need to contact anyone now [laughs] so yeah, the podcast definitely definitely helped.

**I: What sort of podcast is that?**

R: Do you know I haven’t listened to this in a while but it’s on my thing. I’ll just bring it up for you in a second. It’s based in America

**I: Oh okay.**

R: so a lot of their terminology is not the same as ours. I think it’s called clinical trial podcast, but I retweeted, I tweeted. I, you know, it’s literally called clinical trialpodcast.com and listen to these and literally they blow my mind. I’ve retweeted it like with [a host] this guy who, who was organising it and he’s so sweet he keeps retweeting me and going, ‘Just hang in there. You’ll be great. I went through the same thing, don’t worry about it.’ But yeah, definitely I think if you’re really serious about being in clinical research profession and being honest about the issues you go through, listen to these podcasts.

**I: So I have a lot of follow up. I’m trying to choose where to go next so just to quick really clarify one thing on the organisational structure so the CTU that you work in, does that kind of operate as like its own, in terms of like all this training and management like it has its own entity or is any of that done at like the University level, like the University-wide level?**

R: So yeah so it’s a bit confusing to understand in the first sense.

36:01

Right, so yes, the [clinical trial unit] is a separate entity but I think because we’re part part of the university because the way we phrase it in the, in the patient information sheet which is where I get a lot of my understanding is so the University has sort of recruited, or like asked the [trials unit] to help the University run trials but I think we are a separate sort of organisation. We’re just very affiliated to the University so all I feel like I’m employed by the University.

**I: Gotcha.**

R: But

**I: Your trial-.**

R: explanation so I don’t know whether I missed that, you know, that induction where I would, it would have been explained to me on how the [trials unit] sits within the University.

**I: Are your colleagues sponsored by the University do you know?**

R: Yeah, but some trials aren’t.

**I: Okay.**

R: So, I was under the assumption that all trials are but I found out only recently that not all of them are sponsored by the University.

**I: Gotcha okay so you said that you expect that you might end up working on a CTIMP soon.**

R: Yeah.

**I: Do you expect there to be sort of like as that appears to be a little bit more of a complicated process by some of what you’ve described, you know, there’s a lot of paper, particular paperwork and things like that that you talked about earlier, do you foresee having to like get more training and more support to be able to transition or have you sort of covered that alongside doing this other, you know, non-CTIMP trials you work on?**

R: Yeah so, I, the training that my line manager put together and also that we are, we are obliged to do as part of the [trials unit] it covers pharmacovigilance and you know, submitting to MHRA and sort of other, other aspects of managing a CTIMP. I mean even the safety reporting of I’ve done the training for CTIMPs and non-CTIMPs and I think my line manager’s due to cover sort of safety reporting again for CTIMPs as well, so I think all my training covers CTIMPs and non-CTIMPs. It’s just I, I’ve applied just the non-CTIMP for these projects. So I think it’s, if this CTIMP project does come my way but at the minute I think given the workload of my line manager I think it is, and she thinks it is going to come my way, it will just take me a little while to get used to the documents I haven’t done. But yeah it might be a bit more paperwork but in in terms of having, not I guess in terms of the training I don’t feel sort of unconfident that I know how to do it. There’s, having been here for one year I know that there’s enough support and that there’s enough documentation for me to find my way around.

**I: Gotcha and have you been aware, like were there any communications, so you’ve been working for about the last year, so have there been any communications or has any processes like that, have any changes due to things like say the Brexit becoming final or like any other sort of like the HRA strategy, have any of those changes been communicated or things like you should be aware of, like has your organisation communicated any of that to you since you’ve been working there in terms of-?**

R: They did do sort of [trial unit]-wide communication on, you know, working from home practices now some information requests for what, how we’re gonna collect like wet signatures now so we won’t be going to physically collect signatures. We’re not asking people to scan in signatures, we’re doing it by email now so those sorts of things yes. With regards to Brexit, we’re getting I feel like they’re feeding us information on how it’s gonna impact us so we get then again, the government is feeding us information, they’re not giving it to us anyway so we’re doing the best we can. So I think as and when the senior management know what’s happening they do sort of give it to us in one email randomly and it’s up to us to piece it together. In terms of other changes, so our, our organisation’s gone to a merge, so we used to be [two units and now] we’re now merged[…]and we’re going, undergoing all our templates, I think most of our templates and most of our SOPs are going through a merge and I’m involved in the merge of the approvals SOP so that is the approvals for CTIMPs and non-CTIMPs and one of the tasks that we have to try and figure out is how Brexit impacts us. [laughs] I need to figure that out, I have no idea. But I’ve been listening to a few talks and there’s a, there’s some really interesting talks on how Brexit has impacted clinical research and I came across one the other week but I have to listen to it a few times to understand how it’s gonna impact us and I think for now we’re okay because we’re in some kind of like a, we’re in some kind of exempt phase where right now the EU and the UK are the same but until someone goes “no we’re not the same,” all the documentation has to change but I think that we have to wait till June for that.

**I: Yeah, because like it’s interesting to hear people’s responses because in the past, you know, for CTIMPs that all flowed into the EU system so it’s interesting to hear what has changed now it’s no longer flowing into the EU system.**

R: Yeah, I know, I I can’t imagine anyone, all the CTIMPs Managers will be looking forward to the paperwork if there’s major changes.

**I: So to go back to registration once more, when you, when you were learning about registration or as you’ve thought about it and planned for your, you know, your portfolio throughout the registration process, you know, you talked about how there’s there wasn’t really a plan for dissemination beyond publication has there ever been any talk of submitting results to a registry, like making sure that results end up on a registry, has that ever been like talked about or emphasised?**

R: Like a registry as in, like a website?

**I: Like [internet connection lost]**

**Part 2 – Following reconnection**

**I: So, I was asking about whether putting results on a registry like the ISRCTN was something that anyone ever covered?**

R: No, I think that was just an underlying assumption, it’s just an assumption but it’s not sort of a main focus, it’s just yeah that’s gonna happen right at some point.

**I: Okay cool and I’m just curious was there any ever mention of registering on like clincialtrials.gov, you know, like the US registry or anything else?**

R: Yeah absolutely, the only push that ever comes from, it comes from our CI so he, I think maybe every time we bring up ISRCTN he goes, “Okay what about clinical.gov.co,uk? What about-? you know, where else, where else can we, where else can we put this information?” So he’s also looking to contact the NIHR rep, his NIHR rep or whoever, he’s. a connection he’s got to let them know about the [group of studies] and then he will get it disseminated that way somehow, but the push is always from academic, it’s always an academic pushing that’s so, it’s not something that the [trials unit] have, you know, drilled in us but every time I talk to the CI this is what he places emphasis on.

**I: Right okay and then so one thing I also like to ask everyone though we’ve touched on this maybe throughout our conversation but is there anything you feel that your organisation could be doing better in terms of giving you the information you need to do these like, you know, transparency aspects that, you know, the registration or potentially the results reporting. I don’t know, maybe that’s another thing you could touch on is when results do end up, you know, when these studies happen do you, do you know what your role in that process would be, like will you have a role in the manuscript preparation or any other results dissemination?**

R: Yeah it’s really confusing so I, as you know, you know, academics with the, they writing a paper is like gold isn’t it, it’s like ‘right, I need my name on it, I need first author, last author, I need to be somewhere in it’ but I think I don’t know what the role for TM is. I guess it depends on your relationship with the CI so my CI’s pretty good and in the beginning he was like, “Right protocol, we need protocol done,” but then at that point I was like, I cannot even think about publication at the minute, there’s too many other tasks to do for me to think about pub-, because people, I know there are some individuals who put out a publication almost every week but it takes a while to put a publication together and you need, best practice is you work in a team of people but as TM you don’t have that team, team of people but then because it’s, the CI is also very aware of that, actually he is the academic, he’s got academic connections, they need paper out so he’s now taken the whole publication aspect and given it to his clinical whatever students or academics to, so I don’t know, I’m getting a very confused idea on what my role is in terms of, you know, publications or, you know, helping out on manuscripts because there’s this whole, you know, academic mindset of, ‘Oh that means her names gonna be on it and do we want her name on it? Is that a wasted name on it because maybe there could be a clinician name on it and-? You can, I can understand his politics when he speaks and you just think and it’s a reminder for me, this is why I left because this is just not required [laughs] but usually the push for any kind of dissemination is is an academic, is the CI who is obviously responsible for the project.

**I: And have you been able at any point to provide sort of feedback to your line manager or to the CIs about these processes, you know, that we talked about a lot of these sort of administrative processes and stuff?**

R: Yeah.

**I: Yeah.**

R: I think the [trials unit], I don’t know how it is in other centres but with the [trials unit] there’s quite a good understanding of the different sort of types of CIs, the pros and cons of the current SOPs and we have, I have a very good relationship with our Quality Assurance Manager and she, I can go to her, if in the absence of my line manager I can go to her and ask her a question on, “This template says this. I don’t’ see how this even applies to this, can you help?” and she will either go, ‘Oh well this is how it applies,” or she will go, “I see your point. I will note it down for the next formal change.” I have been able to get very good feedback to my line manager who has worked with my CI for the last four years, so she understands him and his ups and downs, his ups and downs. We have been able to sort of manage him sort of together ‘and I’ve been able to give very feedback onto documenting. I mean one of the reasons I was involved in the whole SOP approvals merging was because the approvals SOP, well actually the whole some of the SOPs were so outdated and as I was doing them for my monthly I went, ‘this is not applicable anymore,’ and so I talked to my line manager if I could be involved in any of the updating of the SOPs and the ones that they sent through with the approvals SOPs that need updating. There, there is a very good, there is a very good, there seems to be a very good sort of knee jerk reaction sort of feedback system at the [trials unit] where you can say something and either you’ll be given an answer or you’ll be told actually that’s senior management are discussing it at the minute so we are trying to, well, us juniors are trying to push for a e-TMF because we think, you know, in the lockdown, the – none of my studies have a physical TMF which is like a legal obligation.

**I: TMF?**

R: It’s trial master file so we need-,

**I: Oh okay.**

R: So every document on my projects needs to be printed out and folded like things we did sort of ten years ago and so and we’re trying to push for e-TMF. It’s not that easy, I don’t think and actually I read somewhere that e-TMFs are not as jazzy and fancy as you think they are and they can be even more work than physical TMFs so I don’t know if I want it anymore but you know, it was raised, it was raised at a senior management meeting and my line manager said it is being talked about but there’s budget obviously and, also, so we don’t know which one we’re going for and how it’s gonna change for us but right now our [trial unit] only signed up for physical biomat files which, you know, I’ve had to put in a deviation link, none of my projects have a physical trial master file and won’t have one for a while.

**I: Great so I think that’s, we’re coming up on an hour now and I think we’ve pretty much covered my questions but I always used to like have one last opportunity for you to I like to ask, you know, is there anything, any question that you know, came to mind or that you’re expecting me to ask or just anything else you’d like to mention that we didn’t cover today but you think is relevant to sort of my aim in the study and what we, you know, what I’m interested in.**

R: I mean I, I don’t obviously, you obviously know your project the best probably by now but so what, so what I remember was you were gonna ask on like transparency, so how are you defining transparency at this point?

**I: Yeah so for my, for the auspices of this project, trials transparency is very, you might have been able to guess based on how I, you know, structured some of my questions but it’s very much about the registration and the reporting of clinical trials. So, transparency into, you know, getting those, getting those results, getting the trials registered ideally prospectively so that like, you know, for a lot of the reasons you touched on and then making sure at the end of the trial the results are sort of disseminated in a full and timely manner.**

R: Yes, yeah.

**I: The role, like the study is dealing with the role various people involved in that process aside from the CIs that’s not, they’re the one perspective I’m trying not to get pretty much but how that process works at these various, you know, research institutions.**

R: Okay yeah because I imagine if that even if you’re trying to avoid the CIs you will somehow be known what their opinion is, you know, they’re very good at telling us how, telling us how they feel and how they think things are important. So how did you come across this project if you don’t mind me asking?

**I: I’ve been working in this space, so this is my doctorate, my DPhil is going to be largely into this, it’s in this broad area of registration and reporting**

R: Okay.

**I: and so I’ve done a lot of sort of quantitative-y stuff, I’ve been working in this area for the, since 2017**

R: Okay.

**I: here at Oxford, not and then I started my DPhil in like mid-2018 so I have a lot of background, a lot of interest in it and this is sort of the qualitative, as I consider myself a very mixed-method researcher so I’m doing a lot of work on the numbers of registration and reporting and then this is sort of the qualitative part that’s, you know, what’s going on in the ground. In the UK, because of Brexit and things like that is a particular interesting case study.**

R: Yeah, yeah, yeah, I think it’s, yeah, I just, for me it’s a very unusual research project to have come across. It was interesting to know how you came across it and how you’re finding it? yeah.

**I: Yeah, so this was like, this study this particular part of it, me and my, me and my advisor, my PI have like, we’ve been like, we’ve been like wanting to do this study for a while and it’s sort of is a case, it’s a nice final chapter of my thesis.**

R: Okay so are you in your final year then?

**I: Yeah, I’m wrapping, I’m hoping to be submitting in the Fall ideally.**

R: Oh okay, alright, yeah that’s not too bad then, yeah. You must, you must have some comfort it’s knowing that everyone is stuck inside as well just like you, so you’re not missing out on much. [laughs]

**I: Exactly I don’t know that I don’t know, I’ve been so busy for the last few months and will be for the upcoming months, I don’t know that my life would have been that different from lockdown. [laughter]**

R: Yeah, it’s the best time, it’s best time to stay indoors and do like a PhD or something yeah, yeah.

**I: But yeah, so if there’s nothing else that you know, I can bring up that you want to talk about or address or go back to anything we’ve talked about today?**

R: No, no that’s it, yeah.

**I: Alright, great okay so yeah so that’s it. [recorder switched off]**