**I: [Introduction about study] So if you have no further questions, I’ll just run through the consent questions.**

R: Yes, go through the consent please.

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

R: Yes.

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

R: I understand.

**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, I give permission.

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

R: I understand.

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

R: Yes

**I: And do you give me permission to recontact you to clarify any information if necessary?**

R: No problem at all.

**I: And great and lastly would you like to be contacted via the email we’ve been in touch using with any results from this study as they become available?**

R: That would be lovely, thank you

**I: And then so last thing, you’re happy to take part in this study?**

R: Yes.

**I: The last thing I like to, this isn’t part of the official consent but the last thing I like to offer is I just check to see if [um] once I go ahead and get, you know, my interview transcribed, I’m offering if if people like I can send them a copy of the transcribed manuscript and you can just look it over and make sure you’re happy with everything but there’s no requirement to do that if you don’t want to?**

R: You know what that will be quite interesting although I probably won’t like hearing my voice but yeah if you don’t mind, I’ve not done that before yes so it’d be nice to.

**I: Sure I will, once I’ve done that I haven’t worked out the exact details of how I’m going to implement that but I think I might do it after I anonymised so that way you can just check and make sure I haven’t left anything in that you feel uncomfortable with or that might you know, identify if I use it.**

R: No, you know, what that would be really handy. You can even share, if you don’t mind how you anonymise the recording. I don’t know how you would do that to be honest.

**I: Oh, so the recordings once we get them transcribed, the recordings are just gonna be deleted.**

R: Oh okay.

**I: So those won’t be shared, just the transcripts that I will hand anonymise.**

R: No that’s fine, yeah thanks.

**I: So, we’ll just go ahead and get started then. So yeah to reiterate we’ll be talking about transparency, trials transparency and we’ll focus on registration and reporting of clinical trials but if there’s any other area of trials transparency you would like to touch on, you can feel free to include those in your responses and just ultimately the aim of those research is to identify sort of barriers and best practices to research [um] that can be shared with the larger community of UK, you know, public research institutions to inform the discussion and plans for improvement. So we’ll start right off, can you go ahead and tell me about your role?**

R: Right so yeah, I’m a part time Trial Manager, so I’ve just finished a project with [disease area] and I’m moving on, starting a new job with [a different disease area]. It’s still in the same team but yeah, it’s just a different project.

**I: Great and so sort of how long have you been involved in you know, the world of trial management and clinical trials?**

R: Right, so being a Trial Manager, so I started in [the mid 2010s] and I finished that project in 2020 and then starting the [new project] as a Trial Manager again from [early this year] for a year contract. I don’t know if you’re aware, but Trial Managers or Trial personnel is only on a fixed term contract. We can never have a permanent contract

**I: Okay.**

R: so it’s kind of like an ongoing, kind of like on a I think the maximum we can get is two years as such but and then it’s kind of like ongoing until funding finishes and then you apply for a different job type thing so. But with clinical trials process type thing I’ve been I was, I am an R&D Officer for the NHS, so I started that back in [early 2000s], so technically in a way I’m kind of like, you know, been doing this like for 20 years.

**I: Okay great so can you tell me either through your role as a Trial Manager or through your R&D Officer roles how you’ve been involved with the registration and reporting of trials?**

R: Right the registration, what do you mean? Can you define what you mean by registration, registration to where?

**I: To a trial registry such as the EUCT, EudraCT, EUCTR or clincialtrials.gov or the ISRCTN, any of those like, you know, there’s various other ones too but that’s yeah.**

R: Yes so with my Trial Manger with [disease area] I’ve used the clinicaltrials.gov and with that yeah that proved difficult completing but at the same time because, you know, I find because of the terminology used, the different aspect of explaining things, completing the forms online and although, you know, there’s guidance and you know, definition for each terminology yeah I kind of like found it quite difficult at the beginning, at the start until you kind of get familiar and thereafter then you have to basically do, review every year for clinicaltrials.gov to make sure it’s obviously live real information.

Whereas, now with the [new disease area], I’ve just registered this study with ISRCTN

**I: Right.**

R: and yeah so with that I find it more straight forward in a sense because I think the terminology and probably because I’ve done it before with clincialtrials.gov then there’s similarity to that and kind of the expectation you kind of like, you know, recognise and understand so for both I’ve done and I’ve not done any, kind of like, I’ve done kind of like [disease charity], you know, NIHR registration but I don’t know if that’s the kind of thing that you’re looking for?

**I: Yeah, no, the, the what you described is perfect. So just to build off so this is in your role as a Trial Manager, it was your responsibility to like fill out and maintain those registrations on clincialtrials.gov or the ISRCTN?**

R: Yes.

**I: Okay great and is that stan-, do you know if that’s standard at your institution for the Trial Manager to be sort of in charge of that?**

R: No idea [laughs]

**I: No idea, okay, but for you it is. [laughs]**

R: [laughs] Yes, I assume the majority will because I can’t see the CI doing that or the sponsor although In the [University] it is not mandatory but it’s strongly recommended plus obviously the fact that if you want to publish, you know, the ISR [em] the, you know, in the top ten journals then you need to have a public registration.

**I: Yeah, and this, may be less, slightly less relevant now because we’re living in a post-Brexit work but did you have any interaction with the EudraCT the EudraCT and EUCTR system for getting the trial, like filing through the, like getting the ethics and the approvals to the MHRA which then goes through to the EudraCT system?**

R: Yes so we did two trials that I’ve ben involved with, they’re both non-commercial so non-CTIMPs studies.

**I: Okay great.**

R: So, I’ve not been involved in the MRHA, but I’ve been involved in the sponsor and ethics approval registration submission and, you know, attended all the meetings and stuff like that but yes.

**I: Yeah, okay and then they were, but so the studies you’ve been involved in are non, non-CTIMPs?**

R: Yes, non-CTIMPs.

**I: Okay great but just to be clear some, so you’re [University] does do some, does also do CTIMP research right?**

R: Oh yes, yes, oh yes.

**I: And you mentioned as an NHS R&D Manager do you, have you like interacted with these maybe not as directly but like from a policy perspective would any of these registration areas and things like, like dealing with registration and things like that?**

R: Not from the R&D perspective because we are kind of like the end process of approval.

**I: Gotcha, okay.**

R: Although we, you know, as R&D officers then we need to check whether all the approvals are in place before we can issue R&D approval.

**I: Right okay gotcha and then so I just wanted to make sure I understand so for that role are you like where are you affiliated to as in R&D, like I know it’s the NHS but where specifically like within the NHS?**

R: Research and Development Office so we’re kind of like the final hurdle in clinical, you know, approval process, so we check like the project, the applications got sponsor approval, ethics approval if required because not all trials or studies require ethics approval. They might just need University approval or so if it’s a start they won’t need any of that but and then we need to have kind of like have the all the other, for example Caldicott approval or public benefit approval, you know, just all these different things that are required, you know, to make sure the, the regulatory process is in place for before the study starts.

**I: Great yes and so that’s working for the N, the general NHS not for like a specific institution?**

R: That is for the whole, so the NHS, well as you know there’s different Trusts in each region so yeah, so for us, for me, it’s [local NHS institution].

**I: Gotcha.**

R: So, all the hospitals within that region within that zone.

**I: Okay great so one thing I’m interested in is hearing people sort of describe in their own words why they think requirements for the registration and eventual reporting of clinical trials are in place so I was, that’s my next question can you explain why you think, just from your own understanding of the topic, why we register trials and why we make sure that they are reported.**

R: Yeah, for me it’s transparency and for information for of the public especially of the researchers in general and the participants.

**I: Okay and then and then so like how like so what about what, why is that transparency important?**

R: To make sure that the regulation is followed correctly and if there’s any query then you can go back to it and ensure that it can be looked at.

**I: Gotcha, okay great and then so okay, so switching back to your role as a Trial Manager, so can you talk me through, you did a little bit of this already but to get into a bit more detail. So can you talk me through the process of how sort of, you know, you, you’re starting the trial and you need to register it, what does that process look like, you know, what is, what is the, the step-by-step sort of what that would look like on a, on a somewhat broad level. You know, I don’t need to know exact details but broadly what does that process look like for you?**

R: Yes so, I’ll just go back to the recent one that I’ve done with ISRCTN.

**I: Okay.**

R: That process so what’s, how I started that is well get permission for, from the CI to for the payment because ISRCTN’s got payment to it whereas clincialtrials.gov is free. So got confirmation of payment for that that he’s happy for me to register on the ISRCTN, the reason I’ve chosen this time the ISRCTN is because it’s more UK/European rather than American and also in a way because we don’t need to review it on a yearly basis although obviously you have to make sure, you know, it’s part of our responsibility to make sure it is up to date. And then after that I got in touch with ISRCTN, went online, did all the payment from me and did as much as I can and then liaised with the CI where information that needs to be done and in, you know, I completed the form and got his verification with all that and then we submitted to ISRCTN as requested and then ISRCTN actually got back to us quite quickly and very helpful in the matter as well with some of the queries that they have and I have to admit this time round with Covid, it took us a while to kind of like gather all the information. So, again, directly liaising with whoever was in ISRCTN this, you know, same person that I was dealing with, you know, from the beginning all the way to approval, it’s the same person so again that kind of like help the process and yes so got back eventually. Took us a wee bit longer than expected but we got there. Got our approval and here we are. We just need to start the study.

**I: Excellent, yeah so a few a few follow up questions on that. So you so it sounds like you haven’t started this study yet so where in the process did of like getting this trial off the ground did registration come in, you know, was it before ethics, after ethics, like how much of the trial had already sort of gone through other steps. Was, you know, was registration early or later in the process of getting all this set up?**

R: Yeah, so right from the beginning when I was kind of asked to join this study, I mentioned straight away that we need public registration to make sure if we want to publish, you know, that we get, you know, we get accepted for this. So, you know, I explained that to the CI and then so right from the beginning I mentioned that in terms of the actual submission or, you know, completion of the form, I did that actually after ethics it’s because again of the Covid situation.

**I: Okay.**

R: Getting information from different, you know, source and different people and kind of like getting all the information together but yes so, I did that after ethics and and I think yeah I did it after receiving favourable opinion from ethics.

**I: Great so there was like, you may have got during normal times, non-Covid times, it may have gone a better quicker, like-,?**

R: Yes.

**I: Yeah, okay and**

R: I was hoping to submit and get approval from IRSCTN at the same time, you know, after my sponsor approval.

**I: Mhm.**

R: So I can kind of like, you know, I was hoping to do parallel submission, IRSCTN and ethics so I was hoping like, you know, that at the end that I can both and then update the protocol with the number but yeah it just didn’t work out like that.

**I: Yeah, no okay that’s fine and then what sort of support or like so it sounds like, you personally had some familiarisation, some familiarity with registration from past experience but like what support or how is [your University] involved in this process, you know, how did they, like are they checking or are they providing you with resources or they doing anything to make sure that you’re registering and registering correctly.**

R: You mean like the sponsor, [the University] sponsor?

**I: Yeah, so yeah like-,**

R: Yeah.

**I: Yeah, is it like, I assume that there’s a research office there or something that might you know, like a sponsorship office who might well I don’t know that’s what I’m asking, you know, are they offering any support on this, yeah?**

R: Yeah, so for us, so part of the sponsor approval is recommendation to register in the public registration. It’s strongly recommended because of the, you know, the condition or publication but that is, that responsibility is basically delegated to the CI, i.e. the registration.

**I: Yeah.**

R: The CI has delegated it to the Trial Manager. [laughs]

**I: Right, yeah.**

R: So then in terms of support all we need to do is basically inform, you know, once we’ve gone through the process, all we need to do is inform the sponsor that we’ve got our approval and then they just yeah, set up their own system,

**I: And then once the study gets going and maybe you know about this more from your past the last study you worked on you know, you mentioned that ongoing like update requirement for clinicaltrials.gov is there anyone reminding you about that, you know, once, once you have, like you’ve taken the recommendation. You have registered, is there any ongoing support, you know, reminding you to do, to check your updates or reminding you to interact with the registry in any way?**

R: Yes, so in terms of the clinicaltrials.gov because you need a yearly update check, you know, for that system then the sponsor has somebody receiving information or checking on a yearly basis if this is, you know, safe still up to date so they get in touch with me

**I: Okay.**

R: and ask them to check the system and then the CI will have to verify it and then, and then after the CI’s verification then the sponsor I think needs to seal it, approve it or something, you know, whereas ISRCTN, I don’t know how it would work because I, as far as I know, you don’t need to check every year.

**I: Yeah.**

R: So, I don’t know how and what support that would be, you know, for ISRCTN but definitely we will need the, say, the registration.

**I: Yeah okay great so now moving on maybe once again this is something where you have a bit more experience from you’re the past trial rather than this one since this one hasn’t gotten off the ground yet, quite yet but what what’s been your experience as a Trial Manager in being involved with the results reporting of the trial, have you had any experience interacting with that process in in any form?**

R: Yeah, so with my Trial Manager hat on for the [disease area] we’re just in the middle I think we’re, I’m just waiting for as I say, the final draft report, you know, publication any time hopefully in the next week or two. We’ve not actually properly published yet so in terms of putting the report together I kind of left that with the research team because I’m kind of like, I’m off the contract.

**I: Right.**

R: That’s kind of like, so that’s part of the problem with Trial Managers because our contract kind of like really is not until say the, you know, writing in the publication type of things.

**I: Right.**

R: So, we don’t really get involved in that.

**I: Yes.**

R: For me anyway, you know, it’s, not in my case.

**I: Sure, sure so there was no sort of interest like at least when you as far as your job is concerned, no-one since you were the person who interacted with the registry there was no did anyone ever talk about putting the results on the registry because you can do that at clinicaltrials.gov.**

R: Yeah as, so basically, I was involved in that study until database lock and then throughout, you know, obviously I’ve informed them that would be one way of putting it, you know, publishing it but the problem rests that study, we didn’t actually register on the public registration until a year later.

**I: Okay.**

R: Because we thought because this is a non-CTIMP then it wasn’t a, say, a requirement only for CTIMPs so when we, when I registered when we were kind of like, you know, registering for protocol publication to [a prestigious journal] they informed us that we have to be, you know, the registry has to be done before recruitment.

**I: Right.**

R: So, going back to all the information for public registration yeah didn’t realise that is kind of like applicable to all [eh] trials, clinical trials.

**I: Oh, that’s such really interesting to hear.**

R: Yes.

**I: Could you expand on that a little bit please because I would love to hear more about sort of like what was the reaction of the larger research team to like learning to essentially hearing about that. I assume that was quite a, a little bit of a shock maybe?**

R: A shock, very disappointed. Very especially for my part because I didn’t kind of like, I didn’t join the study until six months after the study started.

**I: Right.**

R: So as soon as I start, I did ask that but there was no, it was not in the priority at that time. The priority was recruitment, you know, opening sites and recruitment, that was the priority so that was the task I was given straight away although at the back of my mind, I should ask, you know, this should have been registered but it’s not but anyway so very disappointed because of that we, I mean we’re trying again, we’re trying to get in touch again with [prestigious journal]and see if they would. Unfortunately, we’re not hearing back after that initial, you know, contact with [prestigious journal] and that because we’re not registered within, is it three, I can’t, is it three months before recruitment or something like that, there is a timeline?

**I: It’s usually, so as far as the publishing in journals, I mean individual journals might have different policies. From, from my understanding it’s just, you know, as far as the ICMJE is concerned**

R: Yes.

**I: just any, any time before the first patient is enrolled is generally considered okay.**

R: Alright, I think on [prestigious journal] we were given a timeline before recruitment.

**I: Gotcha.**

R: Yeah, I think it was three months if not more so yeah, we are really disappointed, so we ended up publishing the protocol in the [another journal], yeah.

**I: Yeah.**

R: So yes, we’re in this conundrum now hence with the new study that I’ve got I registered before, you know, straight after as soon as I can, with that lesson learned, very hard lesson learned.

**I: Interesting, yeah but it sounds like you weren’t, it sounds like you arrived at the study after that that decision would have already had to have been made, right, that was the last one?**

R: Yes.

**I: Yeah.**

R: Yes, unfortunately it was still me as Trial Manager got blamed for not registering. [laughter] so yes.

**I: So, what did the, just to really quick touch on that one more time, the CI of that study you were dealing with what was their sort of like reaction to that to that situation where they didn’t, the trial didn’t get registered when it was supposed to and like, yeah?**

R: Really frustrated, really in a way angry because, you know, because the study that we’re doing is, you know, we were really hoping for a high impact because we want to contribute to this the changes in the standard of care, you know, and more information about this, you know, so yeah really disappointed, really but at the same time, you know, what can we do. It’s done, we just have to move on but again we are at this stage now, so I don’t know, because I’ve not been in the, obviously I’ve not been in touch with team I just spoke to the person kind of like co-ordinating all of that that report writing. I think they had several meetings to date, and I think he’s gonna try, I asked him to push again for [prestigious journal] or somebody else within that top ten and see if they would consider again because we’re hoping because the report is actually quite positive. So maybe we’re hoping that, you know, they will kind of like look at the result and hopefully ignore the yea

**I: the late registration?**

R: yeah misunderstanding.

**I: Yeah sure and then so you haven’t so so that’s talking about journal publications so just when you had left the team or even if you’ve heard anything else since then if you’ve been in touch so like is there currently no plan to put the results on clincialtrials.gov in that like, you know, their, their tabular format or is there, or do you think someone will do that eventually?**

R: I hope somebody will do that or I can do that on their behalf because I’m the only one was kind of like really know how to use the system so once I start again because I’m working with the same more or less team then maybe, you know, I’m pretty sure the CI will give that job to me if, you know, because I think for me, I would probably push for that too especially if we can’t go into the top 10.

**I: Interesting okay and yeah, okay yeah that was very interesting so**

R: In what Nicholas, in what way, how is it interesting?

**I: Oh just interesting to hear a story like that, you know,**

R: Yes.

**I: about where a retrospective registration, you know, came about and hearing what the team had to deal with for that and, you know, how it led to you being a lot more proactive about it in this, in the next one to, you know, learning from that and just an interesting anecdote.**

R: Yeah. I mean so far from the interviews that you’ve done am I currently the only one that has, that has done it retrospectively.

**I: So, you’re the only you’re actually the first Trial Manager I’ve spoken with so far. I’ve spoken with some people in some other positions so you, I have no-one to compare to.**

R: Oh, okay that yeah no for me, that’s more interesting I can like really hear from you after you’ve finished the, you know, the study you’ve got because yeah that’s something I really kind of like want to know because it’s still, this, you know, that kind of like recommendation has been there for, I don’t know, say the last ten years, is it? Would you say ten years?

**I: I think it came, I believe the ICMJE one came out in I believe it was announced in 2004 and came into effect in 2005, I believe.**

R: Yeah, so yeah so that’s kind of like ten years when I started the study. And it was interesting that the sponsor, I’m not blaming the sponsor, you know, there’s nobody to blame that that wasn’t kind of like pushed at the beginning. and also because this study was under the clinical trials unit. Then, you know, again because that’s kind of like, their, in a way, say remit you know, under a sponsor’s delegation that it wasn’t again kind of like put as a priority because of the consequences of publication.

**I: Yeah, so it sounds to me though like the institution now more, they, they more proactively encourage you to do it like than they probably did back then, would that be fair to say?**

R: I would say that’s fair to say. I don’t know that I was me…[audio cut-out]…because I was really kind of like annoyed [laughs] you know, that I was blamed for something that I started six months after recruitment.

**I: Right.**

R: So yeah so, I was not happy and I kind of like yeah did voice my opinion and ever since yeah say the process and the procedure’s been changed slightly and now it is recommended. Although they’re saying it’s not mandatory, it’s recommended because nobody else is saying it’s mandatory. Everyone, you know in all the different organisation are saying, ‘recommended’ so that’s what they’re following.

**I: Right and then I guess up until recently if you had been working on a CTIMP it would have automatically been registered on the, in the EU process?**

R: Exactly.

**I: Yeah.**

R: You see ‘cos I think that was the difference because this is, although it’s a investigational clinical trials it’s still considered as a non-CTIMP so for all CTIMP, all our studies are registered under obviously the EudraCT, so that was okay because that’s considered as one of the public registration whereas non-CTIMP even up to now, I know there’s still a lot of non-CTIMP that has not been registered.

**I: Yeah.**

R: which is again I don’t know where at the moment you are, which again I would be really interested to know the result and the effect of that. Is that something that you would be gathering and putting together?

**I: So I’m only probably going to be talking in this study to like 10 to 15 people so I’m not going to get a big comprehensive but a lot of my other work has dealt with you know, checking trial registration and then clincialtrials.gov specifically but mainly for ones covered by the law which your trial probably wouldn’t have been in the US and then also on the EU register. So, your, sort of, there’s trials you’ve worked on it sounds like are hitting that like non-CTIMP, not covered by the American law sort of sweet, potential sweet spot of like stuff that, you know, I that’s tough to look at. Now I know that others, some other researchers have done some work to look at non-CTIMP registration in the UK and they, I think that those results are relatively recent. They used HRA, you know, research ethics data and and I think it was like a third of non-CTIMPS were not being registered so it definitely, you know, definitely backs up what you’re saying some of the research out there.**

R: So, Nicholas, so the HRA registration because obviously the study is was registered under the HRA or the ethics committee and also with the NIHR,

**I: Yeah.**

R: you know, the National institute Research Centre so this study that I was talking about it was registered with them before obviously recruitment but I wasn’t sure if that is considered as public registration you see. That’s all we’ve so would you consider that as public registration? So it’s just for me, you know, if we can go back to [prestigious journal] for that [disease area] study, can we say it’s like actually you know, what we’ve registered, this is the registration date, would you-?

**I: So so those, I know so the pol-, I assume that the policy because [prestigious journal] is like one of the I believe their one of the ICMJE members so they probably go by either ICMJE policy or stricter sounds like maybe even and that requires registration on a, like WHO approved registry, like clinicaltrials.gov or the ISRCTN or these other ones so something like the HRA, like they don’t, they’re not like acting in the same way as those other registers do.**

R: Yeah.

**I: I mean yes, so it’s difficult for me to say, you know, what you might be able to say to [prestigious journal] or not that might you know be able to work but yeah.**

R; Yeah no sorry I mean you probably can hear my frustration, you know, in the matter but yeah it’s, it’s tricky because it’s not, it’s not black and white, you know, in a way so I think that is possibly some of the frustration from say researchers old an experienced one and especially for new researchers, you know, navigating this process it is really quite difficult because recommendation, what does recommendation really means, you know?

**I: Yeah.**

R: A recommendation means then you don’t actually really need to do it until you realise when you’re doing what you want to do i.e., publication then, you know, your result is not accepted so yeah it’s a hard lesson learned, you know, when it, when something like this happens but yeah, I don’t know again if this is something that you know that it would be part of your say result recommendation, you know, the different aspect of say the negative impact of the process and recommendation that they use and they do, sorry.

**I: Yeah well, we might talk-, we might cover that a bit more as we work though the interview her so but so just a quick follow up on what you just said though so was your, was the CI on the project a new, what, what were they an experienced or were they relatively new CI for the last project?**

R: I would say relatively experienced CI

**I: Okay.**

R: as a CI goes. Everything is kind of like say delegated to the next in line.

**I: Okay interesting okay great.**

R: Yes, very interesting. [laughs] I’m finding that as well.

**I: So, I’m interested so when you, you know, registered that trial and registered this one as you’ve gone through that process now on two different registries did you sort of have to figure it out yourself or did you get any sort of training or support in in doing that?**

R: I figured that out myself.

**I; Okay and there was no, the institution offered sort of no guidance or what to do, they just like,**

R: There’s some guidance offered-,

**I: they just you get a login.**

R: Yeah, no sorry there’s a guidance on the website for both for clincialtrials.gov and ISRCTN so, you know, what I’ve done is they’ll loaded that and kind of gone through the the process. In terms of support from say the sponsor or the previous study, say the clinical trails unit. So, from the sponsors point of view no, I didn’t really get any support although I’m aware that any questions I have, you know, I can ask them but at the same time I was under the impression that it’s your responsibility so get on with it type thing.

**I: Yeah.**

R: You know, at the time of completing the form and getting approval because basically we know the study more than they do like in the details. In terms of the clinical trials unit yeah as it’s kind of like, I would have thought they would have put that as my priority, you know, to register because again doing, they are experienced CTU but, again, I think it’s to do with the non-CTIMPs CTIMP

**I: Okay.**

R: and what the sponsor recommendation. So if the sponsor’s not kind of like push for it then the CTU is kind of like put that on the back burner because obviously there’s lots of other things to do so yeah.

**I: And, and, yeah and interesting to so in that original in the past study, the previous study you worked on there was sort of no push back from the REC, from the ethics committee about not having a registration in place as far as you know?**

R: No because even now what I’m seeing from the recom, you know, approval letter is a recommendation. It’s not a mandatory.

**I: Interesting okay.**

R: So again, so it’s sponsor recommendation, it’s an ethics recommendation so, you know, as a researcher what do you do? I mean you choose, you know, what is mandatory and you get on with the mandatory and then leave the recommendation at a later date.

**I: So what about so I, you know, you’re working like you said, your institution has like a relatively developed, like a pretty busy CTU and they do lots of trials, is there any talk amongst it or any sort of like whether formal or informal information sharing about this sort of thing, sort of amongst the trial managers or the researchers or whoever on the various trials. Is there anything like that going on?**

R: Yes so when this happened to me I immediately informed all my colleagues in the CTU that even though for non-CTIMP, you know, studies I basically says for all studies that we’re doing it has to be registered in a public register, i.e.. ISRCTN or clincialtrials.gov, you know, depending obviously on funding. But yeah so that was, as soon as that basically happened to me, I shared that information to all and now as far as I know, you know, that is part of all studies in that CTU.

**I: And what was like the response to hearing about that, you know, what was the like like what did your colleagues, what was the reaction to that when you sort of shared that out?**

R: I think it’s because they knew that I was kind of blamed for it although they know that I didn’t start with the study they couldn’t really say anything because we’re all employed by the CTU [laughs] and the managers were there, you know, and I can’t obviously blame my line manager for not pushing for me to register in the study.

**I: Yeah.**

R: So, it was just given as kind of like a positive feedback of my experiences, you know, on our weekly meeting basically.

**I: Yeah, interesting okay and then so I’m wondering that since now you’ve sort of been through this once in a very, you know, disappointing negative way and now it sounds like it’s been a more productive and proactive one this time.**

R: Mm.

**I: I’m wondering though how do you feel you could be better supported or informed or people who are doing this, these registration and stuff at your institution in general, you know, what, what could be improved about that process?**

R: I think for me is if the publishers, you know, if this is their criteria as part of their, you know, acceptance for publishing results then I think they need, I think this is where the problem arises. They can’t say it’s in a way it’s mandatory, you know, this is what I’ve been told Nicholas that’s why it’s recommended at the moment but I just don’t understand why, you know, like say for example, you know, the top ten journals saying that, you know, they won’t accept but you know, the sponsors and ethics and see all the approval sectors is still saying recommended if the result is negative to the researchers. So I think it’s more like the yeah clarification and that process and what is really what the researchers need to do to make sure, you know, it’s plain sailing for them.

**I: Yeah so, it’s, it’s confusing for you, it sounds like it’s sort of confusing or there’s a disjoint there for you**

R; Yeah.

**I: that this would be such an important requirement for the journals but your institution doesn’t call it a requirement, they call it a like an optional step or a recommended step?**

R: Yes.

**I: Yes okay.**

R: Unless you’ve done that then, you know, you won’t read that recommendation as anything but recommendation.

**I: Yeah, interesting and then so has there been any like are you aware that your institution anything and this could be either at, you know, [the University or NHS organization] if you’ve heard anything about like has there been any recent developments or recent changes or communications to staff about anything regarding registration or results reporting recently?**

R: Yes so when this happened to me because I was speaking to the sponsor about it and because it so happens to that the new governance manager is new to the post and like, she’s from a different [institution] moving into our [institution] as the Governance Manager and she so she sent out a, we have a newsletter to, you know, researchers in [the University and NHS organization] recommending to ensure before recruitment that they register their studies into public registration if appropriate so, you know, so because I think there’s still a lot of student studies that is obviously not being registered and staff studies that’s not being registered because it’s not appropriate or I don’t what that really means because I thought all studies has to be registered one way or another onto a public recognised register. So again, there is still that for me, disjointed as you said, you know, information for researchers but at the same time you don’t want to put another layer to the researchers you know, forms, documents to complete before they can start the study.

**I: Right if you don’t have to right.**

R: So yeah so actually that’s a newsletter and again the sponsor I think did say a drive an exercise, you know, where I think everything’s registered from then on and I think we, as [the University], I think we were named I don’t know what year it was I was informed this when I attended they UKTMN, I don’t know if you’ve heard of that, UK Trial Manager’s Network?

**I: Yeah of course, yep.**

R: conference that the University was top register, you know, of studies. It’s like whoho, that’s brilliant so.

**I: Yeah and I’m curious about so that’s another thing I wanted, yeah so they even though you haven’t been directly involved in it for your two, you know, examples of, you know, going through this registration process but are you familiar with the EU that obviously not well people can still report so it’s still relevant but with the process of mandatory reporting of results to the EU register, like are you aware of that from your colleagues doing it or has it been something that your institution has talked about at all?**

R: For all CTIMPs yes definitely and say high profile studies it’s the non-CTIMP is considered kind of like, I mean don’t get me wrong, it’s coming to that because I keep asking, you know, you know, for example, if my studies going to be monitored or audited or, you know, kind of like because I’m following say the CTIMP procedure rather because before just non CTIMP kind of like process as such.

**I: Yeah.**

R: So now the sponsor is, our sponsor anyway is starting to look at, you know, like say doing same process for CTIMPs and non-CTIMPs studies.

**I: Mhm so it sounds like the CTIMPs were a lot more, like looked after and this sort of thing is a lot more, it’s, I don’t want to say taken seriously but it’s, like it’s a lot more sort of comprehensive around CTIMPs than it is around non-CTIMPs?**

R: Yeah, I think it’s to do with the legal aspect Nicholas.

**I: Yeah.**

R: So, you know, I think that’s what it is, and I think it’s because I don’t know, I mean, how non-CTIMP is really seen previously.

**I: Mhm.**

R: So it’s just for me a, I mean all clinical trials are, you know, are using patient notes, patient safety, patient, you know, wellbeing so it should really be treated as one but although we’re not using a drug you know, substance so but still, you know, the process should be the same but I think, yeah I think I mean part of it is, you know, is resources. I think that’s one, you know, I mean I know that is one of the factor is resources. It’s just, you know, normally there’s one sponsor each in each [organisation], you know, luckily you have two or three but most it’s probably just this one person dealing with thousands of applications, you know, CTIMPs and non-CTIMPs and staff and student research.

**I: Right okay and then so we’ve talked a little bit about you know, I’ve mentioned a couple of times Brexit happening but have you since you’ve been working in this area for a little bit I’m wondering if sort of if you’ve heard of or and if it’s impacted your work at all, some of the you know, there was the letters from the that the House of Commons Science and Technology Committee sent out to a bunch of sponsors about registering and reporting. There’s the recent HRA strategy. I’m wondering if and then of course how Brexit might impact some of these things. I’m wondering if these have crossed your, you know, your inbox and Universe at all and in what ways and how if it’s impacted anything that you’re doing concerning these areas?**

R: As Trial Manager, as far as I know, I’ve just been proactively asking about it but I’ve not really been given any say instruction of how to deal with things apart from carry on as it is, nothing’s changed.

**I: Okay.**

R: And then in terms of the R&D that on it’s more or less the same, so the NHS Board is kind of like telling us that, you know, “Business as usual, we’ll let you know when things basically start happening because there still is, it’s still under negotiation.” So, in terms of like the data, contract, [um] samples, drugs, you know, all of that [um] storage, it’s all still being apparently discussed, and no proper policy or framework is in place yet, that’s my understanding to date.

**I: Okay and then, you mentioned UKTMN earlier and I’m wondering talking about either that resource or other resources like is that like a resource you go to learn about this sort of thing or are there other resources you go to learn about, you know, registration reporting things like that, you know, what resources like UKTMN do you go to and how do those work as far as informing you about these sorts of things, trial transparency topics?**

R: Yeah, I I’m relying on mainly when I was doing my previous study under the instruction guidance of the CTU Managers, you know, the seniors and the Directors and with that, with that the UKTMN because I’m a member. At the time as well, in one of the say meeting, workshop that we did it touched base on public registration. I think that was the, somebody from, somebody came and talked to us about, it was the last UKTMN conference I was there and somebody came and talked about public registration. I can’t remember who it was.

**I: It might have been me. [laughs]**

R: Was that you? Yeah I was gonna say, well, you know, you did a really good presentation but no so I was quite glad because I was at the time that’s just you know what happened, you know, where I’ve basically gone through, you know, with my own studies and when I was there, when I was speaking to some of the Trial Managers there again it’s the same kind of like scenario as CTIMP definitely they register on EudraCT so public registration they’re safe but with the non-CTIMP studies in their CTU not all is registered because it’s not recommended, well it’s not mandatory.

**I: Yeah.**

R: So we were in the same kind of like position but when you mention it I think everyone’s kind of like yeah in a way not taken aback but they’ve got more understanding of really the importance of it and I kind of like, you know, I explained to them what happened to my, you know, my experience and they were kind of like, ‘Oh okay then,’ you know, it’s something that they have to kind of think back and kind of make sure it doesn’t happen to the [um] and that group there was [em] because they were all like CTIMPs and non-CTIMPs so I think the majority of them did register before recruitment.

**I: Yeah.**

R: But in terms of [the university] sponsor and CTUs I don’t know what the other, you know, group, clinical groups are doing in because that’s something what would be really quite nice is to have a network within the University, but I don’t know if that’s gonna happen.

**I: Right.**

R: It’s, you know, share kind of like, share learned lessons type thing.

**I: Yeah, you’re not getting any-.**

R: At the moment, there’s nothing like that.

**I: Yeah, okay so you weren’t getting like from like UKT, UK the Trial Managers Network, you weren’t sort of getting anything, there was no like, like you went to the conference, and you talked to people but there was nothing sort of like, no education or proactive outreach about this sort of thing to the network as far as you saw?**

R: No, not from then up till now, no.

**I: Okay right.**

R: But it was because I think in a way it’s been touched on, you know, I think peoples moved on from it.

**I: Yeah Okay so that was actually I believe my final question but I usually just like to give an opportunity, you know, is there anything else that’s on your mind about what we’ve talked about today or anything else that’s popped up that you were expecting for me to ask but I didn’t ask about all of this?**

R: Yeah, I think I asked earlier on it’s like, you know, from the other interviews that you’ve done what is their understanding, their perspective of clinical registration, public registration?

**I: Yeah so, I’ve talked to mainly people from like a research governance point of view so far so-.**

R: Research Governance so what is there? So that’s interesting.

**I: Yeah, yeah so I mean it’s still, you’re only my my third interview overall so it’s still very early in the process but yeah it’s interesting to hear the different perspectives about like from you, who’s the one doing the actual registration, to like them, who are the people who are sort of setting the guidance and the policy and make, and, you know, and the people in charge of sort of making sure that this stuff happens and the communication about it. So yeah you know, it’s tough for me to sort of say anything holistically now because like I said I’m still pretty early on in my interviews.**

R: Yeah, yeah.

**I: but yeah, you know, that’s the, when I. when I send my results, I hope it will be chock full of answers like that for you. [laughs]**

R: [laughs] No because that would be really interesting you know, hearing it from, are you including ethics as well in this process?

**I: I’m not, it I haven’t talked to them I haven’t practically reached out to like ethics committees or anything like that, I’ve mainly focused on like research governance, trial managers and I’m hoping to maybe talk to some research integrity office people as well.**

R: Yeah, yeah.

**I: But that is sort of the main focus but if, if, it came, if like, so for example a lot of other people were like, ‘Oh you should talk to an ethics committee about this,’ then I might go and try to look, you know, I can, I can adapt as I hear more things from people.**

R: No, you see for me it’s not ethics responsibility, it’s the sponsors responsibility ultimately, you know, as part of the say the GCP, you know, concern and the UK framework it’s the sponsor. I’m sure somebody, research governance will possibly argue that. The other thing is it would be interesting to know what the CIs perspective?

**I: Yeah so, I’m specifically avoiding CIs for this study just because I want the institutional perspective and I wanna leave, I want to get everyone but the CIs basically. [laughs]**

R: Yeah no that’s fine, I don’t blame you. What about Clinical Trials Directors?

**I: Yeah, yeah so that’s like, that’s I would definitely talk to like I’d put in touch with the clinical with a direct-, like a CTU director or someone like that, yeah that’s also, even if that is also a PI, that’s. I would definitely talk to someone like that if I got put in touch as well, yeah.**

R: Yeah no it’s just again because, you know, for me it’s the people in the lead should be directing this recommendation, you know, for all trials but this, at the end of the day in a way part of it is being blamed on say the workers rather than the leaders but as they’re the one who’s supposed to be, you know, making sure but yeah I mean, it’ll be interesting Nicholas to receive information from you in time.

**I: Absolutely and yeah and very interesting to hear your perspective so thank, thank you very much. [recording switched off]**