I: [Introduction to study]

**So to confirm to you both give your permission for me to interview you today and audio record our conversation?**

R2: Yes.

R1: Yes.

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

R2: Yes

R1: Yes.

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

R2: Yes.

R1: Yep.

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

R1: Yeah, I think so.

R2: Yes, yes.

**I: It’s all in the information sheet if you need to refer back to it.**

R2: Yes.

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

R1: Yep.

R2: Yes.

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

R2: Yes.

R1: Yeah.

**I: Would you like to be contacted via your email on file with any results of this study when they become available?**

R2: Yes please.

R1: Yes, it’d be interesting, yeah.

**I: Great and then a, a last and then also I also offer everyone, you don’t have to do this if you don’t want but if you would like after I finish getting the transcripts transcribed and doing the anonymisation, I can share them back to you to make sure you’re comfortable with the way I’ve anonymised everything and that you, you are happy with your responses and that’ll be, you know, not tied back to you?**

R2: Yeah.

R1: Yeah, that’d be great.

**I: Yeah sure, I will, I will just note that down for my records, one moment. Okay great so you’re both happy to take part?**

R1: Yeah.

R2: Yeah [laughs]

**I: So I was hoping that just to get started here so just a few quick notes so I’m going to ask you mainly about your current organisation and sort of the current state of play as it were but either of you have past experiences either from previous positions you’ve held at, at this organisation or other organisations that you would like to reflect on about how things have changed or evolved over time that’s, I’m very happy to hear about that as well and that’s sort of like the main thing I like to say and then if there’s other, you know, I’m mainly focusing on registration and reporting but if there’s other aspects of trials transparency and sort of research integrity that you feel are relevant to the questions I ask you can feel free to touch on those as well. So I was hoping, firstly, could each of you just quickly tell me a bit about your role and your position?**

R2: Has [the respondent] frozen or is he there?

R1: Yeah.

**I: Yeah, I can still hear you, so you’re good, yeah.**

R1: Okay yes so I’m [name] I’m the R&D Manager for [NHS Trust] and I have, I suppose in a nutshell I have corporate responsibility from an operational point of view for all of the research that we do, clinical research that we do across our hospital sites which includes [various sites] and I head up a small team of, R&D team, which includes [R2’s] branch of that which [R2] will introduce [themselves] in a minute looking after the QA side so ultimately, I’m, if you like, sponsor representative for want of a better phrase.

R2: I’m [name], I am R&D QA manager working with [R1] and two other people, two monitors. There’s a small QA team, four of us and been in post for oh I think [over a decade] now but and we sit within the main R&D group, but we are a sort of separate and we mainly look after the house sponsored, the Trust sponsored CTIMPs.

**I: Okay great.**

R2: We sometimes venture into the more higher risk non-CTIMPs but it is mainly the CTIMPs.

**I: Gotcha okay great and so I think you may have mentioned [R2] but how long both like been working roughly in the area of like, you know, clinical trials, research management and administration?**

R1: For me it is thirteen years.

**I: Okay.**

R2: It’s a bit longer, I’ve worked in other research departments but I’ve been in R&D since about 2012 I think it was [R1] wasn’t it?

R1: Yeah.

**I: Okay great and then just so I get a sense of your organisation, what is roughly the size of your portfolio of trials at a given time. I don’t need an exact number, like a rough, rough estimate and like what proportion of that is CTIMPs versus non-CTIMPs generally.**

R1: So, across the board including things that we host, so not everything we sponsor, we’ve probably got about 450 active studies in different phases at any one time. Probably about 80 of those, 80-90 of those are Trust sponsored and then breaking that down into the CTIMP category of those 90 probably might be half a dozen that are, are CTIMP. Sometimes that fluctuates so we’re not, we’re not a huge Trust in that regard but that can fluctuate some years up to probably doubling that maybe twelve studies.

**I: Okay, yeah so it varies but like a relatively low proportion of your entire portfolio is CTIMPs at any given time?**

R: Yeah.

**I: Okay, great so to get things started we’ll come back to a lot, more of the particulars about how the organisation sort of manages the day to day of doing a lot of this work but the first thing I like to ask is just is, is if each of you could in your own words explain to me sort of the importance of registration and reporting of clinical trials sort of like, why is this something we care about? Why is it something we often require? Just in your own words like could you both just give an idea of like in your mind why is that important?**

R1: I think one of the things I notice from my role and [R2] may have a different view is that there’s so much focus operation on getting things up and running and started for research and so much time taken with that and the regulatory side that it’s often an overlooked element but actually when you stop to think for a second it’s more important to some extent than the transparency is more important that some of the earlier elements yeah because essentially without that integrity of data sharing the research is meaningless in my mind. You know, you could have a really good, it can, both, both ends of the spectrum, you can have a really good well designed, robust regulatory type project which doesn’t go anywhere because it’s, it’s not publicised. It’s not replicated, it’s not tested then again you could equally have somebody who might be wanting to hide results for a particular reason or a particular purpose or commercial gain and actually that just stifles research so I think from, from my point of view, there’s no point us doing the work, there’s no point us putting the energy in and the effort into doing that work and also actually you lose sight of the fact of why we’re doing the research. I think that’s my biggest grievance I would say from all of these processes that you get so wrapped up in what we have to do, the hurdles we have to jump through that we forget that actually the results matter to patients. And not just patients of now but patients of the future so actually without those results being available the new treatments are not going to be available to our patients or they are and they’re gonna be available and cause some issues for patients further down the line.

R2: Well I can’t, you know, I haven’t got a lot to add to that because I agree entirely with what [R1] has said but looking at it even from our single centre Trust sponsored CTIMP studies, as [R1] says, historically we’ve been focusing on getting them set up but we’re running into GCP and UK regs and that’s been a very important part and you might think well a single centre study in one of our academic departments, ‘what difference is that gonna make to the world?’ but it needs to be out there because other people like yourselves that go and look on research and I think ‘oh I’ve got an idea for a study here,’ it might already have been done and nobody’s put it out there, the bad and the good results, so you know, the multicentre stuff yes that’s obvious but it’s also our single centre stuff as well I think that we, you know, we need to, it needs to be there, it needs to be out there and is just as important as the multicentre stuff, yeah.

**I: Yeah great.**

R1: It’s also a skill as well, it’s also a skill that our researchers need to herd and develop, you know, it’s part of being an academic. It’s the complete package. It isn’t just getting the data into a system and pressing a button to say that’s the result. It’s about articulating that result to an audience, and I think that’s that’s really important.

R2: Mm.

**I: And what about sort of registration, so that’s the results dissemination part, why, why do we sort of have these requirements about registration which is sort of more on the start-up side you were maybe referring to earlier with, along with the, like your GCP training and your audit set up and all that sort of things, why do we, why do we register trials?**

R1: I think again as [R2] said, I think you know, it’s, it’s to show the general community of what’s happening, what the intentions are for that research and you would hope maybe naively that that would inform future research collaborations strategies within organisations and groups to network but it’s, it’s also important to know that you’re not duplicating work so I think it’s, it’s really important that there’s a registration there but also I think as well just from a behavioural point of view, setting that stall out very early on that this is a formal process and a formal requirement and giving it the same credibility as you would when any researcher expects to put an ethics application or an application into the MHRA, that is a registration in itself, that application is an acknowledgement that we have an intention to do something and we’re seeking regulatory approval but sometimes, they’re viewed in different ways. They’re viewed as I’ve gotta do that because that’s, that’s the law, it’s regulatory and the registration side is equally as important and will be part of the submission and the law so I think that’s that would be my view on it. And I think just you have to register a trial, especially a drug trial. All trials should be registered but especially a drug trial because the competent authorities need to know what’s going on out there and what we’re using and what we’re testing so it it’s, there’s got to be a central point at which you can go on and say, ‘Right we are aware, the MHRA for example in this country are aware of this trial and we, you know, we expect it to come through to be approved [um] and we know what’s going on and the safety issue as well.

**I: Great so now coming back into speaking about more of the specifics about, you know, you’re your organisation. So can you talk me through the process of how sort of a trial gets set up, you know, you mentioned that that can be quite an onerous thing so if I’m a PI, let’s, let’s say I have my grant funding already and I come and I say, ‘Alright, I wanna do a trial.’ What, what is that process look like?**

R1: So it starts with a, [R2] you can correct me if I’m wrong with some of these things, but it starts with a sponsorship request form, so we would ask the applicants fill in a form detailing what their intentions are, what the topic is, some of the resources that they’re gonna need and details of the funding that they have in place and then from a, if it’s a CTIMP for example, [R2] and [another colleague] that, the trial monitor, will review some of that early documentation, that protocol help steer the protocol in terms of making sure it meets the requirements that we have as a sponsor, review all of the other documentation prior to submission to ethics and MHRA that will be a iterative process back and forth and then culminating in a submission that we’re happy with to sign off to go to the regulatory approvals. In parallel with that we’d be working alongside the team to understand, you know, if there’s third parties involved with Trials Units and different third-party vendors. We’d be working alongside that for contracting and vendor assessments and then as part of the process as well we’ll be setting up a monitoring plan, so we’ve got the oversight of what’s happening with that activity, risk assessments you’d be doing [R2] I think as well from an ongoing point of view. What we can also do is we have a, a sponsor oversight group that meets every month and we would then be [putting that on the list of new studies for application to discuss with the oversight group.

And then ultimately once we’re happy the sponsor then signs off a green light for that to commence and then the monitoring plan will commence once they’ve started culminating in the close out visit and then from a reporting point of view at the end [R2] can probably talk through so the reminders that we have in place for our CIs and PIs that’s, that’s in a crude, in a crude sort of process that’s, that’s all the process.

**I: Sure, sure.**

R1: Is there anything else that I’ve missed [R2]?

R2: No, I think that’s broad, broadly it, yes, yeah. There is tooing and froing.

**I: Yes, so during that process so does like just in terms of sequencing so you have, you know, so you request sponsorship and does ethics happen alongside that or would ethics happen after sponsorship has already agreed to?**

R1: Yes.

R2: Sorry yeah it would happen after the sponsorship request form we’d, we’d study that, we’d look at a draft protocol. We’d in principle would agree to sponsor it [R1]. wouldn’t we? I mean the final, the final agreement to sponsorship is signing off the IRAS form which [R1] will do and then the submissions take place.

**I: To the, in that to start, kicks off the ethics process.**

R2: Yes, yeah.

**I: Okay great and then sort of now as you move into ethics and there’s more active monitoring of the things that need to be done so like where does, say like, you know, registration for like where does that sort of then enter the picture as a, as a thing for both I understand it’s different processes so I’d be interested to hear about how you handle it for both CTIMPs and non-CTIMPs and what your processes are for ensuring that that happens or what that looks like?**

R2: Well historically we’ve always had to have a EudraCT number with our CTIMPs and we tend to do that so that we have some control over checking to see whether they’ve been reported or uploaded on to the EudraCT system. But at that time, we also encourage if they want to put it on clincaltrials.gov or ISRCTN or whatever so that is usually on the protocol and the completed in the IRAS form, Is that the sort of thing you were asking about?

**I: Yeah so basically for a CTIMP obviously up until Brexit, up until earlier this year there was an automatic, automated process for registration but so you’re saying that even if you did a CTIMP if they wanted to they could also put it on the ISRCTN or clincialtrials.gov, you’re happy to be supportive of that**

R2: Mm.

**I: and then for non-CTIMPs is that sort of just a thing they have to do themselves or would formally require them to sort of, no you need to like register here at some point, like we’re telling you need to do this?**

R2: Yeah, well, the ethics letter approval letter usually states that it has to be registered on somewhere.

**I: Okay.**

R2: Now forgive me if that’s not for non-CTIMPs [R1] I know it is for CTIMPs but-,

R1: Yeah, yeah for non-CT, I think, I think where where we’re going with this is that the, for the CTIMPs it’s an automated process, for non-CTIMPs it’s not, so our safety net that we rely on is the ethics process to basically remind the applicant and I think it’s fair to say that there’s a mixed response and we don’t necessarily police that from a resourcing point of view, we don’t necessarily have the res- we haven’t directed resource to that yet for non-CTIMPs. CTIMPs certainly, non-CTIMPs less so. We do get it’s a mixture so from my perspective overseeing things from a more higher up level I do see quite a lot of the non-CTIMP applicants will take that advice from the ethics committee and will, and will see it as a mandatory thing to do and actually register. So, I have, I’m one of the authorised users for clinicaltrials.gov to issue licences access that system so again centrally a lot of people will come to me and say, “I want to register the study. It’s part of medics application,” but what we haven’t necessarily got I don’t think for non-CTIMPs is that joined up approach where it triggers it so even as we’re talking now, I’m thinking, you know, that’s just something we would potentially add to the sponsorship request.

**I: Sure.**

R1: So that actually it ties it in. Does that answer the question?

**I: Yes, yes absolutely and so the okay yeah and now so touching back, [R2] may have touched on this a little bit in one of her prior responses or maybe it was[R1], one, maybe both of you did but coming along to trial close out so there’s obviously this, once again up until recently this EU requirement for CTIMPs to put them on the register so it sounds like that was, you had a formal close out process. You sort of chased that and ensure that, can you tell me a bit how that operated and how that looked in your experiences with that when it was, when it was still happening?**

R2: Right, well we always had it as a reminder for the close out monitoring visit, we, you know, on our check list so at that point the investigators would be reminded that they have got the year to upload results onto whichever websites they said in their application form, their IRAS application form. We would also put in, we’d only, we use Outlook so we’d put in three six and nine and twelve month reminders that came up to us to the R&D QA team and we would then email the investigators to say, “look do you know, you’ve now got nine months in order to, not only the summary which we need to send to REC but also to upload the, the reports, the results onto the websites, the databases.”

We have it in the we have a formal agreement between PI and sponsor for our single site studies and it’s in there as well. They’re signing up to agree to do that they upload results. We have it for a CI sponsor for our multicentre studies as well which we sponsor so we have it, we have it in our data management plan again that they are agreeing to do this so they’re all just, they’re all just paper reminders but we, we do our best to highlight this is something that we have to do and try and keep track of it ourselves. We are looking in the future to try and get slightly more sophisticated automated reminders and things like that but that’s where we are at the moment.

**I: Great and what has been, and so do you do those reminders just for CTIMPs or do you kind of push people to upload results no matter where they’ve, no matter the type of, like because you obviously you only have your deadline for things that are regulated, everyone else can sort of take a bit more time if they need it.**

R2: Yeah.

**I: But so is that process just for CTIMPs generally?**

R2: CTIMPs and high-risk non-CTIMPs but the vast majority, we the QA team does not oversee.

**I: Yeah okay, gotcha right because you mainly focus on those very very limited group.**

R2: We do. We only have limited resources; there are only three, just recently four of us and we, obviously our CTIMPs have to be our main priority.

**I: Yes, great.**

R2: Yeah.

**I: And then so I’m wondering how do PIs tend to respond to that sort of reminder process. Are they, like they do push back on it? Are they fed up with it and then like or are they happy to do it and they like the reminders, and it keeps them honest, it’s like, you know, what’s the general reaction been to that, that you’ve seen?**

R1: It’s mixed isn’t it and I think again depending on the clinician and the area, you know, some will, some will just ignore the reminders others will respond back with a holding statement that says, ‘You know, I’m on call so I’ve got this commitment at the moment but I’ll do it within x time frame,” and you can sort of take your foot off the gas a little bit and I think what we, so it is a mixed bag and it’s, it’s almost just that relentless communication but to be fair, you know, we, we’re a small team but actually we build relationships with those clinicians so we can, we can push and we know how far to push things before we have to have conversations and things and one of the things that we have started to do recently, pre-pandemic I suppose, was using the sponsor oversight group to escalate any issues because I think ultimately if we think we can control it we will do but if it comes peer to peer from a clinician so our, the member of, the chair of the oversight group is our R&D Director who is a clinician and academic so if he, if they get a letter from a peer saying look, you know, pull your socks up, you know, why haven’t you done this it adds a bit more weight to it.

**I: Okay.**

R1: So, we give them, we’re quite polite and maybe we need to, we need to not be as polite, but we try and give every opportunity for them to, you know, hit the milestone and do it but ultimately we have had I think, I think there’s two occasions we’ve had to write a letter

R2: Yes.

R1: and a combination of that and a couple of more prods from us and it did the trick, I think.

R2: It did, yes, yeah it helped, yeah.

**I: Great and then what was your, like I understand, so for CTIMPs, you know, the new requirement came about and there was sort of like a retrospective, you know, requirement to report as well. Like, can you talk about what was the process for dealing with that, you know, and trying to keep up with that. I don’t know exactly what your like situation was with what you were reporting at that time and stuff but you know, did you have a, like was that, was that a mountain to climb and what did that look like?**

R2: Mhm.

R1: Yes [R2’s] got the scars. [laughter]

R2: I’m still getting flashbacks [laughs] yes, yes it was, our percentage of reported trials it was evidence to see it was [a lower] per cent for EudraCT that was a EUTrackers, ClinicalTrials.gov was probably the same sort of percentage-wise I would, would you say [R1], yeah.

R1: Yeah.

R2: And yes, it was a, a mountain to climb. We realised we’d, we’d not kept a close enough eye on this and it was just blanket approach of just getting everybody to try and do, to upload results and it, I mean I have to say we now stand at for the CTIMPs for EudraCT, we now stand at [a much higher] percent [R1], the last time we looked.

R1: Yeah.

R2: So, there are some that obviously haven’t, we’ve got a couple that are out there. We tried to do as much as we could ourselves but obviously we need the clinicians, we need the investigators doing the bulk of it but we did help where we could and that’s why we sort of tried to take control of certainly EudraCT as well as ClinicalTrial.gov because [R1] manages that and so does [another colleague] our monitor but we sort of took control and I took control of the, the studies on EudraCT so I could send them out and know what was happening and keep an eye on things and it was just, it was a slog if I’m honest but we are getting there, you know, and hopefully implementing things going forward it will never get to that situation again.

**I: Yeah, do you feel like that’s, or do you feel like this, it was sort of you know, a slog as you’ve described but also led you some like positive process improvement and iteration of your internal processes that have improved the way you go about monitoring, like is that, would that be fair to say?**

R2: Oh, I think so, [R1] I leave that up to you, you know.

R1: Yeah no I think, I think what it’s done, it’s done that, it’s definitely done that in terms of, you know, revising some of the processes and tweaking the processes and tightening things at that end but I think more, more than that going back to my earlier point, it actually made us sit back and think this is an important issue rather than and it’d been overlooked I think, you know.

**I: Mhm.**

R1: So I think that’s what I took away from it was actually there is no point us doing, you know, it’s half a job isn’t it, you know, you can, you can do really well and get a flying report from the MHRA saying that you’re compliant in everything else , everyone’s happy, the funders are happy but that last bit of getting that information available and fully accessible is just as important and I think we probably well I can only speak for myself, but from my point of view, it was probably overlooked so I think that’s the biggest thing that the media attention around that and the, the intensity of getting that sorted in in a short space of time me really and actually that’s started to transverse, you know, to some degree onto the researchers themselves as well. They, they’re pre-empting the questions that we’re gonna ask them, you know, they’re pre-empting sending us drafts of reports. They’re, you know those sorts of things, they’re realising, you that’s equally important from that point of view.

**I: Mhm**

R2: No sorry I was going to say we always had sort of a process to try and get the clinical trials summaries in on time but that

**I: The REC,**

R2: Exactly.

**I: like the REC requirement.**

R2: Yes, yeah but obviously we didn’t follow that through with the reporting so, you know, we always had that sort of process and reminders and that was our sort of aim to get the clinical trials summaries in on time.

**I: Sure.**

R: We just needed to take it that step further.

**I: And as far as any like publications arising from this work, you know, in a journal like is that all pretty much left to the, like you guys are pretty hands off when it comes to that stuff or do the, do the PIs like do the PIs mainly own that process or are you guys involved in that process in any way?**

R1: I think we used to be hands off and that again that’s a by-product, a positive by-product of this whole process is that we probably were hands off, it was a bit like we’ve done our bit, onto the next study and what this has shown us is we implemented a, a I suppose it’s, it’s still 90 per cent with the investigators but that 10 per cent, that quality control process of getting a draft manuscript, making sure that actually they, their methodology, you know, a classic example is that their methodology is as it was in their protocol and as per ethics, they haven’t deviated. ] Is it the correct sample size? Have they mentioned the Trust in in and the proper funding as, as per contract etc etc so it’s a, it’s not a rigorous scientific critique of the paper but it’s a quality control governance check if you like that we do and we get, we get the R&D Director to sign that off don’t we as well?

R2: We do, and we get an independent statistician to look at the stats section to make sure that they sort of followed what they said they were going to do. I mean it doesn’t do hugely in depth, but he will make, you know, reassure us that it’s as it should be.

**I: Is that, has that, how has that process gone exactly? Have you considered, has that, has extending QA into like publications do you feel like it’s, it’s generally been well received and like gone smoothly or has it been like difficult to sell? I’m just, that’s like a relatively unique, relatively unique I feel like I’ve heard so I’m interested to hear like how it’s gone.**

R2: I think we, we’ve had, how many since we’ve implemented [R1], 3 or 4?

R1: Yeah.

R2: Yeah.

R1: I think so.

R2: And it’s like with all investigators, you know, it’s not something else for us to do. We’re putting another step in the process.

**I: Uh-huh.**

R2: But on the whole it’s been positive, I think it;’s-,

R1 Yeah, I think we’ve, I think with a lot of these things we were helped by the fact that it was actually a finding in our last MHRA inspection, so it gave us that weight, so it wasn’t just us saying, ‘We’d like to do this because it’s the right thing to do. Actually, it’s something that we all picked up on and, you know, very, to give you a classic example it’s just, it’s that quality control thing that actually, you know, someone copies and pastes from a previous publication in the same area of disease and forgets to proofread it, you know and you find actually it’s got the wrong sample size in it, it’s got whatever. That will obviously be picked up when it’s, you know, critiqued and reviewed and all the rest of it but it was that embarrassment factor really of actually, we, we’re sponsoring the study. We should, we should have had oversight of that, and we should have picked that issue up. We’ll probably still miss certain things because we’re not clinical but we’ve got a safety net, we’ve got the, we’ve got the clinician as the R&D Director, we’ve got our very basic, you know, ten point or whatever it is QC check and I think that will evolve over time as we get more and more of those through but I think like [R2] says, it’s probably seems a bit of a chore but actually we’re, we’re thankful that we can say well actually it’s an MHRA, we’ve been told to do this, it’s part of our MHRA Cappa [um] so.

**I: Great so we’ve talked a lot so far about things that have worked, you know, processes that have improved and worked really well that you’ve put in place but I assume, you know, as things change and you adapt to first this EU stuff, then the EU stuff going away, then you know, the MHRA Make It Public strategy is sort of also changing a lot of or might change a lot, some of the requirements around some of these things. Have there been any like sort of things you’ve implemented that, you know, you needed to iterate and change like it sort of didn’t work right the first time and you needed to, like what, or like have there been significant barriers stood along the way that have sort of made things not work as smoothly as you might like?**

R2: I think at the moment it’s, it’s the old thing of the response and interaction of investigators. I don’t mean to sound as though I’m blaming them but, you know, you can only be as good as the response you get and no matter how much you chase something up sometimes, it doesn’t always work and you don’t always get the end result and I think we always know as things change, it’s going to be a changing process isn’t it [R1], I mean we’re always tweaking processes and and we will do, continue to do so as, as the requirements, you know, changes so-,

R1: No just to add to that [R2] I think you’re right that one of the things that we’re conscious of is that yes, we’re trying to hit this target of getting 100 per cent transparency so we will throw whatever we can at it to make sure we do it but one, we did that as a reaction to, you know, the Parliamentary issues and all of those sorts of things but it shouldn’t ever get to that point where it’s just, oh someone’s given us a kick up the backside so we’re gonna, we’re gonna spend six months on this. It should be a continuous process, so I think that’s part of what we’ve learnt but also I think there is a point where if it isn’t a two-way interaction with the investigators then it lessens the credibility of that task in a strange way because the investigators think, ‘Well that’s R&D QA team, they’ll get on with it you know, it just comes out the other end and I don’t have to do anything with it.” So, I think that’s something which we’ve got to be careful with. We’ve done a little bit of that when we were trying to get our percentage up to 80 but there are 1 or 2 that are left are the ones that we physically cannot intervene on because we, we’re not-,

**I: For one reason or another yeah.**

R1: Yeah, yeah.

R2: Mm.

R1: So it will always have to be a team approach with the clinicians and I think that’s probably where our next phase is gonna have to be is that we’ve got all the paperwork that says yes you will adhere to this, you will do this, this and this but how do we get that relationship up with them to such an extent that they’ve got the resource and the time to put into this and then that leads onto the whole issue of, you know, the seriousness of which you take this which is [internet connection lost]

R2: He’s frozen.

R1: I was frozen.

R2: Yeah.

**I: You’re back now so you were saying the seriousness of which you take it and then it cut off.**

R1: Yeah so, we talked about the seriousness in terms of should we implement any sanctions as a sponsor.

R2: Yeah, mm.

R1: So, you know, again we do, we’re not a sponsor that, we’re an academic sponsor or an NHS sponsor, we don’t really have the power to sort of say, we’re going to cut your funding off or we’re not going to do this. It’s not in our best interest to some degree but, you know, there are things that we could do that might help smooth that path but we always use that as a last resort. You know, I don’t, I don’t really want to be in position to say we’re not gonna sponsor any more of your work. We’re not gonna do this and this because actually weighing it up that could be even more detrimental.

**I: Mhm.**

R2: Yeah, we’re there to facilitate research aren’t we and encourage it so it would be a big step to take.

**I: But those are in a, in a drastic situation those sort of are on the table now nowadays**

R2: Yeah.

**I: in a, in a disagreeable but drastic situation.**

R2: Yeah.

**I: So just on a mechanics question so if I am registering, like I need to upload my information to EudraCT on the, on the initial, you know, XML file that gets sent off to MHRA or the results or say I’m, you know, registering on the ISRCTN or the clincialtrials.gov or wherever, is that something like as the PI am I or someone on my team, my study team, the actual one doing that aspect or is any of that actually like done by, so I know you said you’re the administrator on the ClinicalTrials.gov account, is that just you giving them access to then register it themselves essentially.**

R1: Yeah.

**I: And it works the same way with the EUCTR and the EudraCT?**

R2: Yeah.

**I: Okay is there any sort of training or resource that offered that people, so they know how to use them or is just pretty much based on like their familiarity with it or that they, like is their responsibility to sort of understand how to use those systems?**

R2: The later I think, yes, we don’t have any training in place. It was very much a steep learning curve for all of us actually but [laughs] no definitely the latter is, you know, their responsibility to learn how to access these things and how to-,

R1: Yeah, I mean it’s not, it’s not a great rationale but

R2: Mm.

R1: the vast bulk of the certainly the CTIMPs ones are quite a closed circle of people that within certain academic areas that within our teams that we work on so you will get the same PIs who should be more familiar with the system as they go on but we don’t I don’t think, we don’t offer any sort of formalised step by step screenshots of this is what you should do. Having said that, you know, we we do work very closely with some of the investigators so we would just basically get them round the table, and we’d go through the form with them.

R2: Mm.

R1: So when that’s happened on several occasions so it’s not, it’s not a 100 per cent true we leave them to their own devices.

**I: Gotcha.**

R1: They do get some support but it’s not, I would say not formalised.

**I: It’s individualised, like they can come to you with questions that you’re then happy**

R1: Yeah.

**I: and they tend to be aware like your resource that they can go to with those, with those issues, yeah.**

R1: Yeah.

R2: Yeah.

**I: Great and then can you talk a little bit about sort of like what did, does the like, like top level support at your institution look like, how do they view these, you know, aspects as a priority so like some of these things involve you, you guys, you know, this is a tension, there’s always a tension between imposing more requirements on the PIs and but not overburdening them. Is there any like how does the support look like from the, from, you know, a level above, sort of maybe you [R1] or multiple levels above you for implementing some of these new measures and for these new steps in the process, you know, what does that look like?**

R1: I think it’s a case of that there’s that trust that we would get on with it and we’re doing what we’re doing. One of the things that we did, I can’t remember when it was but when everything hit the fan so to speak and there was a big explosion of this, we did get quite a lot of communication down from our Chief Exec who was interested in, you know, not being called in front of Parliament basically so we did get quite a lot of, you know, where are we at? Can you give us an update?” And what we used to do very, very simply was we would do a screenshot of the EUtracker for example or really good graphic that we could visualise and say to the, to the Executive team, “This is where we’re at.” And what we do as well, [R2] would do a little mini report that would provide a forecast of where we were gonna be, so I think from a operational level we got that support as in backhanded support, as in get this done, basically.

**I: Mm okay.**

R1: But in terms of actual support of the mechanics of, you know, put this system in place, it’s left to us to do that to achieve it and that’s where the R&D Director would come in and say and we pretty much operationalise that through the oversight group by, by saying, “Look, we’ve got Professor X who hasn’t done what he should be doing? How do you want us to take this forward, you know, do we write to them? Do we give them another month?” you know, those sorts of things so I think I think it would be unfair to say there isn’t any support. There is support for research in general.

**I: Sure yeah.**

R1: But, but when it comes down to the specifics of transparency, policy or any of the SOPs around that they, they’re not necessarily gonna want to see what we’re doing other than what’s the results; are we, are we actually achieving what we should be doing?

**I: Great and that oversight that sponsor like oversight committee is that that’s been in place for a long, you know, that’s not a new development that’s always sort of been in place or is that, or is that relatively new?**

R1: When was that? [Within the past few years].

R2: Yes [within the past few years].

**I: Oh so that’s a relatively new development.**

R2: It was fairly new yes, yeah.

**I: Ah okay was that sort of in response to some of this stuff that happened over the last couple of years or is that just sort of a natural thing that arose other, otherwise?**

R1: It came, it came again out of our [recent] inspection for the MHRA predominately but then actually it was the, it was the appropriate place to tie in the transparency work as well so very early on we made the decision in our terms of reference to look at the transparency issues and make sure they were on a standing agenda item for that. So, at the moment it’s a bit of, that that item is pretty much stuck at [the current] per cent with a couple of studies where we’re pulling our hair out, you know, ‘where, where do we go with this?’ type thing but yeah-,

**I: Are those very old studies just I assume they’re like very old ones yeah.**

R2: Yeah.

R1: Yeah.

R2: We have a bit of an issue as well with, with our percentage, I mean I don’t know probably shouldn’t talk numbers, but we do have an issue with some studies we had quite a, a flux of studies that actually started but they didn’t take off really. There was no reasonable data to get, we ended them prematurely because there was no recruitment or somebody left and there weren’t the resources to, to backfill this person and you can’t sort of get these off the system because you can’t load any data and I’ve put a letter on saying, an explanation onto the EudraCT website explaining why there was no data but they’re constantly there and I know they were going to look at this. It wasn’t just our problem, it seems to be fairly common problem so we have things like that that are affecting our numbers and I know this isn’t all about numbers but it, it does exist and we’re never going to, at this point in time never going to have a 100 per cent because of these studies.

There’s [ a few] studies isn’t there [R1] that applies to, so sorry that was just a little bit of an interlude I know but just to explain the numbers really.

**I: Yeah so great so we’re approaching the end here and I just wanted to do a few have a few more questions here so we talked a little bit about, we’ve, we’ve chatted about quite a bit about, you know, the impact that that Parliamentary committee had and how, you know, you plan to adapt to the new HRA strategy. Just to touch really quickly on Brexit and moving away from the EudraCT system that, you know, no new registrations will be going through that that system anymore as of this year, has that sort of impacted, like how, have you needed to move and adapt to that yet or is still too early and you haven’t really had to change anything as a result of that yet and you’re still sort of waiting for any more?**

R2: Yeah, I would say that’s our situation [R1] wouldn’t you?

R1: Yeah.

R2: Yeah.

**I: Okay great and the last area I touch on, I like to touch in these is just so when new developments sort of in these areas occur when there’s no requirements or things like that what is your route and mechanism for hearing, hearing about them, like, you know, if something were to change about the requirements or the HRA gave more information about lay summaries that they’re expecting, things like that what would be the ways that you would hear about those?**

R1: So, we, MHRA will be the blog, MHRA blog that we, we sign up to and we get the daily, daily emails on those. HRA updates again, HRA newsletters part of the R&D forum as well we get messages via that. And we’d also I think from my perspective I would probably hear about it at some of the networking events so part of the UKRD which is the, the group of R&D Directors and R&D Managers networking nationally so it would probably be brought up there as agenda item and depending on the, on what the change was as well, they, that group sometimes offers speakers to come in and do training and do sort of seminars on what the changes involve etc etc.

We also have locally within [our local area a clinical research network], we have something called [name of org] which is all the R&D managers across [multiple local] organisations and every quarter we also get the HRA representative to come and give us a what’s changed this month or what’, what’s coming. Regulatory update if you like and I do recall some of the transparency stuff coming through that route

**I: Interesting.**

R1: via, via the HRA.

R2: Yeah.

**I: And so it sounds like these networks, like you mentioned the R&D forum and you mentioned this local…network those are sort of pretty important for like keeping on top of things and yeah.**

R1: Yeah

**I: And then what, sorry go ahead please.**

R2: No, no we always try and attend the symposium as well, the MHRA symposium ‘cos that often you hear about things but that often clarifies it for you, you know, they go into things that you’ve read about or you’ve heard about that they can, they can dot the i’s and cross the t’s.

**I: And what about peer contact so what like have you heard from your peer institute, like do you have communications either within or outside of, you know, something like the R&D forum where you share knowledge and best practice or if you questions, does that, does that occur at all?**

R: Yeah, I mean I think that’s probably what this [local group] is really for.

**I: Okay.**

R: So, we get, they invite speakers to give a bit of a session but it’s, it’s predominately also about you know, tell us who’s doing what with that. Has anyone implemented it yet? So, it’s a forum where we can raise questions and go, we, we’re stuck on this. So, we might go to that forum and say, “We’ve got lots of studies that terminated early, you know, do they want to know how we get round that, how we report it, how we notify?” so there’s a lot of that happening I think through those sorts of groups but I suppose the only disadvantage with that is it’s almost about it being an issue for everyone, you know, there isn’t, there isn’t a huge amount of time to go through everyone’s sort of list of issues that they have so it has to be such a prominent issue that affects, you know, 80, 90 per cent of the people for it to be discussed almost. It’s not that frequent but that, that is definitely a forum for that.

**I: Mhm and then yeah so the very last question for a NHS organisation that I like to ask for the Trust, so you’re obviously University Trust so you have some connection to the local University does that, how does that relationship manifest in any of your like SOPs, like is there because I assume some stuff kind of gets, is there co-sponsorship with the University or is there some stuff is going on at the Trust but it’s sponsored through the University, like and what does your role in that sort of research look like?**

R1: Yeah, I mean it’s again, CTIMPs there’s no University sponsorship for CTIMPs, always, always diverts to the Trust currently. There’s no co-sponsorship despite the fact that probably 90 per cent of the CTIMP work is university employed academics.

**I: Okay.**

R1: so they, you know, it’s not a criticism but they are risk-averse, you know, they, they don’t have the structure in place to do that at the moment. For non-CTIMPs there is a movement towards some of the work being sponsored by the University and it’s largely on a case by case basis [internet connection lost]

R2: He’s gone again.

**I: Mm.**

R1: Back.

**I: So a case by case basis.**

R1: Yeah so, it’s assessed on a case by case basis. In terms of the processes and how they interact between the two it hasn’t happened yet

**I: Okay.**

R1: and I think probably along with some of the finances side of things the University have probably got a fairly robust system for publications because of their Research Excellence Frameworks and all the things they have to report on for that sort of stuff so it’s something that we will I think have to unify at some level. I think there’s some to put it into context there’s some bigger discussions ongoing about trying to create a Joint Research Office.

**I: Ah okay.**

R: And that, that would be with the idea of not necessarily a physical building that everyone sits in but a unifying of those processes and taking the best bits from both sides. I think if you put it into a very brief description, NHS is very, very from our point of view is very good at the, the GCP, the compliance bits all those sorts of things where the University [infrastructure isn’t equipped for this element] and then you might need to change that and say the University’s got more robust publication issue policies and things that we need to learn from so there’s, there’s a natural marriage that we could have probably have.

**I: And there’s a model for that, some other institutions have those joint sort of research office. Great so that is all my questions today. If there’s anything else, any final think you’d like to note or mention or anything I didn’t ask that you’d like to comment on?**

R1: Not that I can think of.

R2: No.

**I: Okay, great.**