**I: [Introduction to study] So to confirm do you give 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: Yeah.

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

R: Yes.

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

R: Yes.

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

R: Yes.

**I: which we don’t expect to happen but and then do you give me permission to recontact you to clarify any information if necessary?**

R: Yes, no problem at all.

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

R: I suppose.

**I: Great and then and then lastly would you like me to share, when I have, when I go through the anonymisation of the transcript would you like to receive a copy to review before I move forward with it?**

R: Yes please.

**I: Okay great no problems. Are you happy to take part and get started?**

R: Yep.

**I: Excellent okay great so just to get things started can you first just quickly give me a bit about your role and your role at your organisation?**

R: Okay so I’m [head of the research office] which basically means Head of R&D from a regulatory perspective, so my team are responsible for sponsorship setting up studies and monitoring quality of studies.

**I: And how long have you worked in this area?**

R: I’ve been within R&D for about [over 15 years].

**I: Okay great and yeah so if you have you always been at the same organisation or have you worked in other organisations in the past.**

R: I’ve worked at other organisations.

**I: Yeah, so just to say if at any point it’s useful for you to sort of draw a contrast or draw an experience from either other organisations, comparisons or contrasts or how things have changed over time I’m happy to hear about those as well if you’d like to draw on that during any of your responses. It doesn’t just have to be limited to your current organisation though that’s mainly what we’re gonna be talking about but if that’s useful, I’m happy to hear about that as well.**

R: Okay.

**I: So can you talk about how sort of your office, your R&D office at the, at the organisation sort of fits into the broader like trials transparency, like how do you manage trials transparency just broadly. We get into more details later but sort of what does that look like in terms of like at your organisation.**

R: This organisation is very large, spread out across [multiple] hospitals now so from that perspective, [my office] is the central hub and then we have [research teams] out in the various hospitals and they have shall we say more of the personal contact with, with the researchers especially obviously at this current time so although the research office has the regulatory responsibilities for transparencies then some of that is delegated. So for example, if we’re looking at registering a trial it’s the [research team] who are responsible for registering it that my office will oversee that it has been done so we’ll chase them to make sure it is registered if we haven’t got, you know, an ID number or any acknowledgement on our central, centralised system to say that trial has been registered. From that perspective as well obviously we do try and chase up at the end of a study as to reports that have gone in and obviously any publications that been made but it’s probably, you know, if you’re looking into transparency, it’s not an ideal situation because often that is, you know, something that might get dropped if we’re really pressurised etc. We know it’s not ideal but it’s, if you’ve got a limited staff resource or then that is often how we what will happen because from that perspective if the Chief Investigator of a study, the responsibility would sit, should sit with them for actual publishing and, you know, the study because it’s for their academic advancement as well as obviously patient care that we’re doing these studies so there is that expectation that it’s, it should be the Chief Investigator driving that aspect. I probably say in the last two to three years we have emphasised that more to Chief Investigators etc that they need to, it’s their responsibility to do that and if they don’t or if they, you know, need to stop a study without finalising the prot-, you know, finishing the protocol, the original protocol, then we would do want a good explanation as to why and in fact something with well we’re mid-instigation at the moment is to make sure that shall we say there’s potential penalties for those researchers that don’t comply with our expectations and obviously the general HRA expectations. So, in other words if they don’t complete appropriate transparency on a study then we’ll consider not sponsoring future studies that they’re leading on and that sort of thing, so we have tightened up on that. I have to say, a few years ago we weren’t sort of chasing up on these sorts of things but we definitely are now.

**I: Excellent, yeah great and I’ll dig in and follow up a few aspects of that sort of as we move on. Just to, but just to quickly touch on one thing immediately on that, what sort of was there an inciting incident or a specific pressure or you know, influence that led to sort of this change that, you know, to take that step to be a little bit more proactive and following up on some of these reporting and registration and transparency requirements over the last couple of years.**

R: Yeah so, you know, it was the, it was the pressure from the HRA and obviously we’ve had the instance where it was the CTIMPs and making sure that trials on the EudraCT were uploaded and unfortunately [we performed poorly], on that specifics and, you know, it in some ways it is a struggle because of the nature of the studies that we often will support and also the circumstances of our Trust so we had difficulties around that simply because we’d just [restructured] and what we found is [one of our sites] did not have good records of what had happened and it, it was very difficult shall we say.

So we had the difficulty of [restructuring] and then just the practical difficulties, you know, my staff were going round in circles with the EudraCT trying to get things uploaded and we just couldn’t get access to some of the systems you know, we couldn’t, and it was, we’d go from, you know, one, we’d get, we’d get somebody’d respond to an email and they’d say, “Go to such and such,” and we’d go to them and you’d just go round in a circle just and even when we did manage to get access sometimes because it was a set field that you had to respond to and complete again, it didn’t always quite match with how, you know, I mean they’re made for, you know, you’ve got your two or three hundred participant commercial trial. That’s, you know, really the basis for that whereas we were sponsoring some studies that were low numbers, rare diseases, you know, small cohorts, you were never gonna get those numbers but from our perspective we wanted some evidence to say what, you know, these patients are being treated with is, you know, positive or negative because we do a lot of [studies in areas with smaller populations] so there won’t be the patient cohorts, you know, within the UK to deal with that but obviously you’re looking for a way forward in their treatment so some of those sort of smaller studies just didn’t fit into the grid of a natural CTIMP for the Eu-, EudraCT reporting. So I mean what we found it was a lot easier when we learnt that we could upload publications because often that we’d got publications, but we just haven’t got, you know, there weren’t we hadn’t uploaded the data as they wanted in the system so when we knew that there was for the older trials, we could just upload a publication that was great news for us I have to say.

**I: Good okay and just real to touch, just for context, the portfolio of your, of the whole Trust, the, that’s like, so I assume that contains both CTIMPS and non-CTIMPs**

R: Yes.

**I: and roughly like, you don’t need to give me the exact number but just like ballpark, like how many trials would you say are being actively like overseen at a, at given point in time generally?**

R: Oh trials?

**I: Like really rough estimate, you can ballpark it, very round-,**

R: I’d probably say it’s about 50 to maybe 50 to 60 if we count the four categories, top four categories

**I: Yeah.**

R: out of our sponsored studies.

**I: Okay yeah and then one question I like to ask people, a slight change of pace, we’ll come back to some of the more organisational details in a bit but one I like to ask people just sort of at this stage and get us thinking also along these line is could you explain to me in your own words sort of why do, why are there sort of requirements and responsibilities and ethical responsibilities laid out there for the registration and reporting of clinical trials, just sort of in your own words, why do we have these requirements, why are they seen as important?**

R: Okay I’d say from from a trial perspective if there’s an expectation that you think there’s a question to answer from a trial perspective, you the patients do you, you know, honour of actually participating in that, having lots of tests done, you know, their time and effort should be rewarded in publishing that results whether, you know, for positive or negative against, you know, whatever your initial hypothesis was so that 1) the evidence is out there for future treatment, 2) if it’s a negative one that somebody doesn’t re, redo that study somewhere along the lines and so I think, you know, there is that ethical imperative that you should publish. I’d also say if you’re talking about transparency it’s only common courtesy that if you’ve got 20 or 40 patients in a study that you actually tell them the outcome of that whether that’s in person at their next visit, in a newsletter, in we’ve, we’ve had, some of our studies we’ve had, you know, general meetings afterwards where the Chief Investigators presented to the patient cohort etc so I think, you know, there’s, there’s various ways you can do it but if you’re asking them to participate then you should tell them what’s happened at the end.

**I: Great and what about registration, like what do you think to justifications and reasons for registration are?**

R: From a registration, I think it’s just a matter of so that people don’t repeat something that’s obviously concurrent because it’s not just they should do that review prior to actually setting their own protocol up but obviously if it’s not published then if there’s a title at least then they can check that out as well.

**I: Great so pivoting back to sort of, some of the details of how these things actually work, so if I’m a PI at one of your [hospitals] in your organisation and I want to start a trial like I want, I have an idea for a trial, perhaps I’ve secured some funding and I wanna go ahead, what, what like what does the sort of interaction look like mainly focusing on these transparency elements like these start-up, he’s getting registered and making sure that all happens. Like what is that sort of look like as a member of like someone who’s seeking sponsorship and getting sponsorship from your, from the, your office, what does that start-up process look like for me and how, how would I go about registering a trial?**

R: Okay so we, if we’re looking at someone writing a grant then the [research team] has people who will advise about what a grant is, what we need to do for that, for that grant. We have, if it’s a trial then and that they want us to sponsor, we have a committee that will look at that particular trial. Prior to that we’ve got guidance and they’ll have actually met with both the [research team] and the sponsorship team to go through what the trials about, you know, what they’ll need, how are they going to go about it and obviously part of that conversation are it’s sort of the regulatory aspects of what they need to do and who will do what for them about registering and about our expectations about you know, publication and involvement of participants depending what funding scheme they’re going for.

**I: Sure.**

R: We have a very active patient and public engagement team called [name removed] so they’ll probably be involved in the grant process. Part of that is making sure that, you know, that patient interaction and participant interaction is good. So in some respects it depends how that person is in their career progression. If they’ve done lots of trials, they’ll know the principles. If they’re a newbie, we do quite a bit of hand holding in in the process so we advise and we tell them what they should be doing etc and we see that as if they’re a new person we want to develop them along the right lines so they think the right way and understand our expectations as sponsor because we find if we do a lot of work on that first trial that they do, it saves us a lot of subsequent work than all the others so it’s learning process I’d say.

**I: Sure and is that interaction so if you’re dealing with someone less experienced who hasn’t sort of done this before and, you know, if it’s a C-, CTIMP, well not anymore but prior to just a few months ago they would have to have dealt with the European infrastructure and they would have had to dealt with HRA requirements and infrastructure and things like that. Is that interaction sort of coming with your central office or with the people sort of at their, their, the main hospital that they’re sort of interested in, like where’s that first level of interaction coming from?**

R: The, the shall we say the day-to-day interaction is with the [research team], but the regulatory interaction is with the central research office. So, from that perspective if we were looking at in the last sort of couple of years, we, we have changed the structure slightly in the fact that non-CTIMP sponsorship responsibilities used to sit out with the research teams. We’re just develop, we’re developing the sponsorship team that’s centrally and so that all sponsorship is, is dealt with primarily with the central office. However, the CTIMP side of trials it always, well for last ten years, but the actual oversight of that. So, for example, when the, you know, EudraCT was submitted and, you know, documents to MHRA that was done by the central research office rather than the clinician’s group and their group just to make sure that we had that oversight of everything that was going in.

So we had an MHRA inspection in [the early 2010s] and from the comments that we got there, we decided to centralise it to have that control so we’ve, we keep that so for example the study team will work on the protocol etc but that, the sponsorship team will review all that prior to myself signing off for submission to HRA so that we have all that aspect covered.

We also make sure that all the different aspects of things that we want from a sponsor, we have workflows within documentation to make sure that all these things are covered prior to signing off and sending to ethics. So basically, we do, we don’t leave things to after ethics, we try and do things up front so that when we submit to ethics we just need to respond to the comments and then basically we’re ready to start the trial as soon as we get HRA approval.

**I: Excellent, okay great and is the idea generally that your it’s like the expectation being communicated that registration should be prospective like before enrolment?**

R: Yes, absolutely yeah. So, so we’ll always check because of-, often it’s been, you know, quite a while, we will, one of the, when I say we, we work on task based work flows so one of the tasks on a sponsored trial is register you know, on the relevant websites so we, so we can check that and then obviously if we’ve if they’ve come, if someone has completed that task we’ll check that we actually have, you know, a relevant ID numbers and we know exactly which website it is that they’ve registered on.

**I: Great.**

R: So, we do have that, so we will know at the point where we confirm capacity and capability whether that registration has actually taken place and they’ve got another or whether it’s in, in progress because obviously sometimes they’ll say, “Oh we’ve applied but we just haven’t got anything back yet.”

**I: So, it’s, it’s actually like for you, for the way it’s sort of built in to your procedures**

R: Yes.

**I: that’s like a box that needs to be checked before you can even enrol your first patient?**

R: Yeah.

**I: Okay great and do you find that works, that works well, like you’re happy with sort of how that works and-?**

R: I think it works relatively well. I’m, I’m not saying a 100 per cent, you know, because there’s always, you know, something that sneaks by, but I think I’m, I’m relatively comfortable that we’ve got that working well.

**I: Mhm and for things, so now, nowadays things, there will be nothing appearing on the EudraCT system anymore so with that in mind, what, so you you work for the regulatory for MHRA submissions and things like that, you centralise that. What if it’s either a non-CTIMP or under the new system if they’re using a registry like clinicaltrials.gov or the ISRCTN, does that then sit with the study team or would that also sit with your office?**

R: Well again if it’s classed as the top four, if it’s a non-CTIMP, it’s still will, it’s the same process so that, that won’t be any different. I think obviously the difference is we just need, we need to, shall we say, the oversight that we provide for CTIMPs, just for the nature of what a CTIMP is, it’s often a lot closer oversight from the central team and the expectation is that the research team will update progress on the actual website as to how they go along because they’re, they’re the one who knows the detail as to where they are in that progression and, again, I think it’s better in some teams than others how much they progress. But it is something that we are now sort of regularly checking that about if a study is if a trial is closing, you know, that they make sure that that is updated, and we are, do a regular check every so often as to what is the status of our trials on the various websites so we’re doing that to make sure it’s done.

**I: So just so, I’m clear so I know that makes perfect sense but just to make sure I’m clear so as like the person so say you have a trial registered on clincialtrials.gov is the person interfacing with clincialtrials.gov like is it your team prompting someone from the study team to do that or is it actually someone from your team who’s the one saying, “Oh is, this trial is it done?” and they say, “Yes,” and then someone from your office goes and actually does the, the changing and the PRS back end system of clinical trials.gov.**

R: Yeah, so it, it’s the [research team] that will do the changes.

**I: Okay.**

R: It’s my team that will make sure that it’s not done, you know, that we chase it and we make sure that it is done. Obviously, there might be some instances where we assist the chief investigator to make sure it is updated so I mean obviously it’s not, so we ignore it but if it needs help because obviously if people have come and gone and if somebody’s not registered so they don’t have access to the system, we’ll, we’ll happily sit with a researcher and update them because my staff have got that, a number of them have got access rights so that we can update the systems.

**I: Great and then you mentioned earlier in my initial question when you were sort of discussing, you were talking about you’ve been a lot more proactive about, in recent years about following up about results and trying to get your hands on publications when they come out and just keep track of all that, these sorts of what happens with results dissemination? So could you talk about your experience with that, sort of how that’s worked so far since you’ve started to try to like, you know, has there been any pushback or have there been any difficulties in trying to get like get those. You said, you mentioned staffing being one problem where if you don’t have the time that might be a thing that gets held up less which, you know, is absolutely valid and then, you know, are there other, are there other things as well as you’ve interacted with investigators or you’ve tried to manage such a large organisation where like, you know, just difficulties you’ve seen as you’ve tried implement this?**

R: Yeah so I mean, so I mean it is, it is, you like anybody some investigators are more engaged than others and more responsive than others and obviously as we are shall we say a bit more remote from you know, because we don’t sit with them, it’s not as though we chat daily with them etc then sometimes getting responses back can be difficult so and yet, you know, others are very responsive so I think that’s it, it’s dealing with the individuals involved, I think that’s the, the sort of challenging thing and I think it’s just sometimes I find it’s, it’s in the nature of research in the fact you’ll finish the patient interaction, you might, you’ll do the analysis, you send a final report to ethics and then, you know, you’ll look somewhere to publish. You send it to a publication so it’s also sort of, you know, that time lag that you get, you know, naturally get when, you know, you’ve finished your actual work but you’re doing the analysis and then preparing it for publication etc that, you know, it’s making sure that you do follow up to the, you know, to that publication. I mean sometimes we find that unfortunately people can, you know, be like a couple of years before something comes out and I, I didn’t actually mention, I should have mentioned, we got together a transparency group [a few months ago] to look at how we could improve things and on that we’ve got an investigator to make sure that we’ve got, you know, a researcher’s views on how we might improve things and what we might need to do. So, one of the things that we are hoping to instigate I’ll probably say in the next year because we’re still trying to get lots of our studies restarted, we haven’t finished all that yet.

**I: Sure.**

R: What we’re trying to do is get, get a website so that what we didn’t want was to lose the patient, the participant aspect in telling them about what’s happened and so some of what that, that group have looked at is how can we tell the patients because obviously you can tell the patients a rough outline of what has happened in the study prior to full publication in a journal. So that’s one of the things that we’re thinking of doing within the website, you know, our own website is have a page where we’ll have our studies and say, and put just a small bit about ‘oh this is what happened’ and obviously if we have a full publication put in the link if it’s publicly available so that people if they want that sort of detail they can look at it but just so that we’ve got something where if somebody thinks ‘oh I was in that study, I wonder if they’ve got any information?’ that they can go on the website and look at that sort of thing so we’re sort of developing it at the moment deciding what is the key information that we put on there and that in a way is a bit of a stopgap.

But the other side it will also cover the studies where, for example, we’re sponsor but the relatively small studies or, you know, yes they might be for the benefit for our patients but maybe it’s very “our Trust-centric” shall we say in how we do things and those types of things are obviously the ones that are harder to get any public proper formal publication in the public arena so we thought well as we’ve got quite a number of those types of studies, we’ll make sure that we’ve got somewhere to put those results rather than you know, them just dwindling away so that’s the idea. Obviously, I think some of that will depend on what the HRA come up with because if theirs is similar then it might be that we just put links to the HRA page, to the relevant study but as we haven’t quite heard what their website is going to be like then I think we’ll probably just push ahead for our patients.

**I: Well so I’m wondering though did you think like the registries could serve that purpose because, you know, like even though no new stuff will appear on the EudraCT system, older results can be put there and then the ISRCTN and clinicaltrials.gov which I assume are the other two that would be most of your reg-, anything that’s registered would appear on**

R: Yeah.

**I: one of those two would have spaces to sort of put results in one, in some form or another or are there issues that would prevent you from not wanting to put them there, I guess that’s what’s of interest to me?**

R: Yeah, I think the issue that I have is the fact that there isn’t a single database. So, if, if we’re, we’re looking at it from shall we say a participant perspective, if they want to find it then it’s like how would they know which three websites to look for. And then should they be spending their time trawling, ‘Oh I’ve looked at one, it’s not on there. I’ll look at that one, I’ll look at that one.’ So, I suppose that that was part of the reasoning why we thought we’d do something so that if, if they were [a patient at our Trust] they’d come to [our Trust] and then they, you know, it could go, then we’d put the links in. So I think that is one of, I’d say that’s a challenge because it’s like, well you know, just also if, I have say from a management perspective it’s a pain because you’ve not got to just check that you’ve got one website up to date from a sponsor perspective, you’ve got to check all three of those just to go, ‘Okay, that one’s on that one, that trial’s on that one,’ and so actually if you’ve got one single place to go to look for results and to make sure that we’re up to date etc, obviously it makes it a lot easier.

**I: Right.**

R: Plus, the fact is it’s, you know, just from a resource perspective it’s like well okay who has access to clinicaltrials.gov to, you know, who can actually do something and get on there to upload. So, I think that is one of the issues and then obviously making sure that the data that you’ve got is in line with what the website expectations are around, you know, what needs to uploaded. And I think that’s also one of the reasons why centrally we leave the updating to the research teams because across the [multiple] hospitals we’ve got [different focuses] as well as there’s more general hospitals, you know, updating shall we say disease specific things is across those specialities is not something that we can, we can do or have the expertise to do so that’s another reason why we, you know, we delegate it down to the research teams so that they can, you know, put something meaningful in there when they’re uploading them. Sorry, I’ve gone off track.

**I: No, no, that was all gold to me. It was great stuff, very valuable, so let’s see some of these we’ve, we’ve touched on already, so I don’t wanna repeat. So as, you know, you’ve been in your position for a bit and you’ve seen different organisat-, how different organisations function and you’ve noted that sort of the changes in recent years were spurned by this interest from Parliament and from you know, the Parliamentary committee and and I’m wondering sort of like what the, like what is top level sort of support so like even above or like I don’t exactly know what the structure looks like so this maybe, maybe be coming from you and your office or is there levels above you that sort of, like what does the support look like for putting resource into, you know, creating this transparency group and things like that, you know, like what does that look like at your organisation?**

R: Well the, the Exec who’s in charge of the Research and Innovation in our Trust [description about past negative interaction with transparency issues removed as disclosive]. [They are] then obviously very much engaged in that so it is something that we include on our, we have [a committee on research governance] so it’s a question, it’s something that we, that meets quarterly and we’ll regularly put where we are with the sort of trials transparency, you know, that we’re obviously when we got to [high performance] on EudraCT and as part of that we also worked on clincialtrials.gov etc trying to move get closer, you know, to [high performance] on those so it’s something that we are expected to report on. Oh sorry [received call]

**I: No worries.**

R: Just let me [interview paused]

**I: Excellent, welcome back.**

R: Sorry about that. I’ve got this on my laptop, and I’ve got the sun coming in and I went and pressed the wrong blimin’ leave button so I don’t think I’ve been in a meeting when I’ve got a call before and not managed to shut it off. So, this technology for you. It’s not good.

**I: Yeah, no worries at all. So I think we’re reaching sort of the last few questions I have here. We’ve touched on a lot of my potential questions sort of through some of our other conversations so one question, one sort of question in follow up, one thing of what we’ve talked about already. So, you said, you mentioned how, you know, if someone’s having some difficulty, they don’t know how to use sort of clinicaltrials.gov or whatever in the, in that process, that sort of registration process. You know, you’d be happy to have someone from your office sit down with them sort of provide that, sort of sit with them, show them how it works, give them what they need. Is there a sort of any more like well my first question is whose gen-, who’s generally doing that, is that like a Trial Manager or is that the PI or does it just vary based on the study team involved, like who’s the actual doing interfacing like with that?**

R: It, so the actual, the actual person who had probably upload that would be a Study Coordinator within the trial team.

**I: Okay.**

R: The people giving the sort of support and help if they needed help would be my team, the sponsorship team.

**I: Okay.**

R: Simply because they they’ve done it a number of times, so they’ve got the experience and unfortunately the study coordinators are a group that there’s quite a relatively high turnover of staff. So, it is, you know, often you would need to do some training with them.

**I: And you just sort of do that on a one off more ad hoc, like if they ask for it they give it rather than it sort of being a proactive thing to give?**

R: Well within the Trust we have some training programmes that are specifically for study co-ordinators and actually some of the nurses come as well. And that covers, you know, whole series of topics. Overall, it’s sort of two and a half days’ worth of training on, on various topics so one of those is, you know, one of the sessions is around sponsorship so that they understand what the role of the sponsorship team is within [the Trust] and the responsibilities that come with a sponsor. Part of that is obviously transparency so we go through about who’s responsibility it is to register, how we work that, how it’s integrated. So, from that perspective people are trained on that but obviously there’s a difference between, you know, shall we say a teaching session and this is what’s required and an actual doing session.

**I: Sure, sure, sure.**

R: So then, then they know to come to sponsor team to, you know, if they, they get stuck, if they don’t know what they’re doing. That’s how we work it within the Trust so usually anybody who’s, who’s new to the Trust would be would go on that sort of within their first six months. So hopefully we capture people.

**I: Great and then they know who to ask and where to ask essentially if they’ve got issues?**

R: Yeah.

**I: Great. So my last questions are just sort of about outside support, so, you know, keeping up like this space changes a bunch, new regulations, especially with recent developments with Brexit and things like that and the HRA like new guidance’s and the Make It Public stuff that they’re doing what is your sort of like process for hearing about, you know, when things change or when new regulations come into about, like how do you make sure you’re kept up to date on sort of the newest developments and what’s required.**

R: Okay so a lot of it through the R&D forum. You know and keeping touch with their newsletters and obviously the HRA newsletter that they send out. I [take part in] the Research Champions group; I don’t know if you’d heard of that?

**I: Maybe in passing but if you want to elaborate that would be fine.**

R: Yeah, so that is basically, it’s now run by the HRA and its basically quarterly meetings of representatives from each of the different network areas. So we’re not network staff but we’re R&D staff and the champions basically is they’ll often have workshops to sound out what our views are or how we’re finding things or to introduce something and say what do you think about that? How is it done? But also, so that they can shape things before they’re brought out generally, but also they use that meeting to give updates from R&D forum from the CRN [NIHR Clinical Research Network], from NIHR so that they can have, you know, they’ve got representation from the R&D community about what is happening, you know, shall we say, I’ll say on a national level but it’s an English levels so.

**I: Sure.**

R: So that is part of you know, where we learn. I think the other side is because we want to link in with this then anything that HRA R&D forum have done around transparency, there’s been a couple of workshops then some of my sponsor team have sort of gone to those and we’ve learnt and for example I think there’s a two-day transparency conference in November coming up, things like that. So it’s a virtual one so we’ll be, you know, enrolling on to that. So that’s the sort of thing where we’re learning and I think because we’ve got quite good contacts with other R&D officers, you know, that’s quite useful so when we were having such difficulties around the EudraCT, you know, we were talking to somebody at [another Trust] who who’d managed to do it and got a few tips off them and it’s, so there is that sort of interaction about what, what is required and what what’s changing and because it’s such a hot topic then I think there is, there is sufficient information. So I know that for example, my sponsorship manager just forwarded a newsletter on transparency now that’s come out so it’s, it’s just sort of keeping up with that and what we do is we use this, the transparency committee to look at what’s coming out, what’s changing so that we can, we can look and say, ‘Well do, what do we want to focus on? Does that match with what we’ve already thought about doing?’ So it’s trying to, trying to be joined up. I think the problem I have which is when, you know, when I was talking about having, transparency being on the group, research Governance committee agenda is it’s about staff resource because we’re just altered, as I said in the last couple of years, we’ve changed responsibilities and teams around then it’s potentially saying, ‘Well actually have we got enough resource for the spons-, to cover the sponsorship we’re doing?’ And, and so probably from a managerial perspective that’s my next aspect to say, “Well actually we’re doing, the set-ups fine, you know, they’re looking after a study while it’s done but actually we’re still probably need a bit more resource to do that final bit or to do it shall we say, I should say to do it, but I should say to do it to the standard I’d like it to be done.”

**I: To iterate it and do it better even, yeah.**

R: Yeah and I think that’s a, that’s a problem because, you know, it’s, if you look at sponsorship then you can’t put sponsorship costs in a lot of the grants that we have and yet the expectation is that you do need staff to do the sponsorship responsibilities and so that is, you know, part of what we’re trying to get right at the moment, making sure that actually people appreciate what sponsor is responsible for, appreciate that actually there’s a cost to that so if we, we need as we want to do it because we want to sponsor studies for our researchers, we need to think how we get some money back to do that. Obviously, we can do it through, we get some through RCF [NIHR Research Capability Funding] etc but that it’s how much can you use for that sort of resource. Because not everything’s NIHR. [laughter]

**I: So I’m just gonna ask one final question here and then we’ll wrap up. The, I just wanted to know, so you’re without saying so just so I don’t have to go and redact this later, you’re obviously affiliated with your local, like there’s some connection to the local University what does that like relationship sort of look like and does that play into anything we’ve talked about today at all, like is there connections there or is there like a different any different processes or procedures that the University is involved or is just a Trust, like I just wanna make sure I understand how that relationship works because it’s not something I’ve been able to touch on a ton so far in my interviews.**

R: So obviously we do work with our university colleagues, a lot of the activity is done via clinical academics. I’d probably say obviously because they’re academically led then they want to publish. I’d probably say some of the gaps on their side is about talking, you know, feeding back to patients. If I’m perfectly honest on the transparency agenda I’m not quite sure where they’re up to and what they’re doing. If I, to honest in the last year because of Covid etc then we’ve had a lot less interaction with the University because obviously but saying that I am, we I do know my governance colleagues and the sponsorship people very well. In fact, we’re meeting with them this Friday and so, you know, it’s one of those things that I could probably pick-up, but I think from our, from our perspective then we expect the University to be pushing their employees about transparency, you know, we’ve talked quite a bit about lack of resource, so you don’t, I’m not spending my resource chasing up there’s.

But I’d also say that obviously one of the things we need to say is a lot of the Universities, clinical studies will involve our patients so there’s that imperative that we probably need to pursue but I think it was more that we wanted to get our house in order and then we can potentially say to the University, ‘Okay we’re doing this, what are you doing about those studies where we’re hosting for you?’

**I: Yeah, and I assume, am I correct in saying that’s sponsorship that governs sort of who has the ultimate responsibility for making sure all these things happen because I assume things can involve the Trust but be sponsored by the University in which case, they take ownership and vice versa things can involve the University but the Trust has ownership as sponsor, is that correct?**

R: Yes, yes so so I think with what we found it was in quite interesting actually because I think the models of hospital do differ about who sponsors what. So, I think in some areas you find the University sponsors, you know, anything clinical. I think in other areas, you’ll get that the, the Trust would potentially sponsor clinical studies so up until probably about 3 or 4 years ago, our University would not sponsor CTIMPs so that meant that if a clinical academic wanted a CTIMP then it was the Trust that would sponsor it for them. That thankfully is now changing, they’re University are now taking on responsibility for their clinician’s work and I think it’s what we also found with the [recent restructuring] was that for any activity in the Trust in one of the hospitals, one of the Trusts that emerged everything was sponsored by the Trust, nothing by the University and actually a lot of the activity was University-based.

**I: Okay.**

R: So again, that’s one of the things that we have altered over the last two or three years that we’ve been clear as to what should be sponsored by the Trust and what should be sponsored by the University so obviously we’re still dealing with lots of studies that you look at them go, ‘actually they’re really University-stuff.’ So, you know, and that’s where we work closely with our colleagues because obviously sometimes we might need a bit of shall we say pressure put on from a University side as to, you know, to meet expectation.

**I: Sure great, okay so that’s, that’s the end of my questions. I usually just like to close out to say offer you the opportunity if there’s anything I sort of didn’t cover or anything else you’d like to touch on on these topics that you think would either be useful to know or that you were hoping to say and didn’t come out with anything I asked?**

[laughter]

R: I don’t think so, I think we’ve, we’ve covered everything, so I think I’ve covered everything yeah.

**I: Great excellent.**