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**I: So today we’ll be talking about trials transparency in your organisation, we will generally focus on the registration and reporting of clinical trials but if you have other areas of trials transparency you’d like to touch on feel free to include them in your responses. Ultimately, the aim of this research is to identify barriers and best practices to research that can shared with the larger community. So [um] we’ll speak today for right around an hour, around 60 minutes. We may finish, we’ll probably finish a little sooner than that and then I’ll be asking you some questions and I’ll be recording your responses and it’ll be used to inform an analysis for my thesis and hopefully subsequent research publications. So, to confirm you gave your permission for me to interview you today and audio record our conversation?**

R: Yep, that’s fine.

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

R: Yep absolutely.

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

R; Yeah, that’s fine.

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

R: Yeah, yeah that’s fine.

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

R: Of course.

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

R: Absolutely.

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

R: Yeah, that’d be really useful, yes please, yeah.

**I: Sure, and the other thing I like to offer is if people, I can when I get around to getting the transcripts transcribed and the do the anonymisation, I can send you a copy if you’d like to have a look over it?**

R: Yeah, that would be great, yeah that’d be lovely.

**I: Okay, no worries.**

R: If that’s not too, yeah.

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

R: Yeah.

**I: Great, okay so [um] great then to kick us off let me just clean up my desktop here. Okay so kick us off can you just tell me a bit about your role at your organisation?**

R: Yeah, sure, yep, yep so my title is the [deputy R&D director] at [NHS trust] so I oversee all of the research at [the hospital] and we also provide joint research office function between the [academic institution] and [the trust]. So, manage the R&D function so all of the governance, finance, grants that kind of thing. Plus, the delivery function so all of the research nurses, the clinical research facility and the non-clinical delivery team, so data managers, co-ordinators. So, sort of all of that brought together is the Directorate. We also oversee the [research organisation] which is across [the university] and [the Trust]. So, manage about 150 staff across that function and all of the research activity that happens across the [academic research organisation] and [NHS trust].

**I: Great so there’s there’s just to make sure I’m clear so I don’t ask dumb questions later on, the there’s also [university] research that would be outside of your purview as well, just some of it is within**

R: Yeah.

**I: Yeah okay.**

R: Yeah, yeah yes so, we mana-, we would oversee all of the clinical research.

**I: Yeah, oh so everything clinical at [University] would be through, okay.**

R: Just the [academic research organisation].

**I: Oh, just the [academic research organisation] gotcha.**

R: Yeah.

**I: And then and I assume the portfolio of research you manage would include both CTIMPS and non-CTIMPS or just CTIMPS generally?**

R: Yeah both

**I: Both, yeah.**

R: Yeah, absolutely both.

**I: Both great and so how long have you worked in this area?**

R: So at [NHS trust], I’ve been there since [late] 2018 so about two and a half years. Before that, I was at [a different NHS Trust] for a couple of years. So, NHS R&D for probably four and a half to five years.

**I: Great yeah and if you want, if there’s, you’ll see with some of the questions I ask if there’s any comparisons or any, you know, things you’ve learned from one place or compared to a different place, if you want to draw on your previous experience, I’m happy to hear about that as well.**

R: Okay, sure.

**I: And so can you talk about just a bit how the trials transparency sort of like, you know, how registration and reporting functions operate at your organisation. Just a little bit how the structure is?**

R: Yeah, yeah, sure sure I mean obviously it doesn’t always follow exactly the same path. It sort of depends on the nature of the research but broadly speaking we have a registration function within the R&D team and that’s across the [academic research organisation and NHS Trust] where a researcher completes the registration form. The registration form includes, gives us basically the information that we need in terms of signposting to different teams so if we’re likely to be the sponsor of that research obviously it goes to our sort of sponsor assessment function. If we’re a host, if we’re just a site for piece of research then it goes just to that governance team. It also looks at all the costs that are gonna be involved in that piece of research and links in with the Finance team. If it’s going to be using some of our facilities like our clinical research facility or any of our imaging facilities or our manufacturing, it just basically is all, everything in one place and then all of the functions kind of come out from there so we would signpost to everywhere else.

If somebody, if a researcher is applying for funding to, like a grant to run that piece of research then they would also register the grant application at that stage. So sometimes it’s already, we already know a piece of research is taking place and sometimes we know that it’s a piece of research that’s planned that might not take place if the funding isn’t, isn’t there so it sort of all the governance around what the pipeline looks like.

If a researcher is ready to go with a piece of research if it’s got a grant, a grant behind it or it’s got funding behind it, then it would go to our governance team who would work with the researcher to submit the if we’re the sponsor, to submit the IRAS application, work through all of the steps including information governance so any other kind for regulatory requirements we need to do internally and obviously then when we get that approval we work with them to confirm capacity and capability to the governance team. If they’re relying on other departments then that’s obviously a complex process in terms of getting all of those approvals.

If a piece of research comes in and it’s not funded so it hasn’t been through an external peer review, we have a slightly parallel process where we do our own internal peer review and that’s a committee called our [committee name]. Just stop me if I’m going too fast or you need any clarification?

**I: Oh no this is fine, yeah, no this is great.**

R: Okay and then and it’s just, it’s just an extra layer to protect the organisation in terms of, you know, the trial design. ‘Is it kind if the right thing?’ blah, blah blah before it goes off for ethics etc. And then, yeah so then once the trial is approved and we’ve confirmed capacity and capability then we would work with the investigator to see run the trial, if it’s recruiting participants depending on what the requirements are if this is a CTIMP and it’s got and we’re the sponsor then they’ll all sort of reporting requirements etc. We manage all of that with them and then through to kind of trial closure reporting, archiving, publication etc.

**I: So where in that process that you just described sort of like the, you know, the multi-step process would like so understanding that this process has changed a bit with Brexit and CTIMPS and all that**

R: Yeah.

**I: We can into more detail later about how that’s impacted any of your, any of your, you know, procedures and how you’ve coped with that.**

R: Yeah, yes.

**I: But sort of where does the actual like registration function fall like and where does that responsibility sit like in that, you know, does it sit with the trial team itself and then, you know, your team just supports that or is there someone in your team who’s helping, actively helping people manage their registration, you know, to make sure that it shows up on previously, you know, gets, makes its way to the EUCTR or now maybe ISRCTN, clinicaltrials.gov or sort of whichever whatever one’s being used?**

R: Yeah, so [um] so we would that is usually a PI responsibility. So when we confirm capacity and capability with a PI it’s part of the process is that we would say that is their responsibility to register the study on the relevant in the relevant places. So, obviously, as you just said. Would also if it’s an NIHR portfolio study then obviously there’s a reporting requirement to the NIHR in terms of making sure that the details are up to date and recording recruitment and that sort of thing through our, the various systems and databases that we have. So, we would normally outlay, outline those responsibilities of the PI when we say it’s okay to go ahead and then but then that doesn’t always mean it happens obviously, [laughs] I wish it was that simple. [laughs]

So certainly, for the, obviously our main responsibility here is for where we’re the sponsor because if we’re not the sponsor then it’s not our responsibility to ensure that that’s the reporting is, and the registration is all is all happening. Where we are the sponsor, then somebody in the governance team would keep a regular eye on whether those registrations have been uploaded, whether they’re updated etc and would routinely contact study teams to say, you need to update your record or you need to put that record on you need to update that it’s closed etc.

**I: So there is, so you, so there’s a step in process just to make sure I’m understanding, so there’s a step in the process bef-, would this be before trial kick-off, like is there someone making sure like oh you haven’t done your registration yet, you need to do this before you can enrol, like is there anyone sort of making sure at that level or is it more ambiguous than that?**

R: No because it’s not, it’s not so much of a regulatory condition from our point of view when we confirm the go ahead.

**I: Yeah.**

R: So, we would say, ‘We are confirming that you can go ahead on the basis that you do x, y and z.’ As far as I’m concerned generally that’s us pushing the responsibility to the PI or not even pushing it but informing the PI that is their responsibility. From then it’s not, it’s not the R&D Officer’s responsibility to ensure it’s happened. Obviously, that is what we try to do, and we try to pick that up if that’s not, if that’s not happened but we would be saying this is conditional on you doing these things and assuming that that’s then happened. It’s rare actually that they haven’t done, then gone away and done the things they need to do, certainly at the beginning. It’s more difficult to chase up where they haven’t updated the records and that kind of thing.

**I: Yeah, so that’s also interesting and something I wanted to touch back on, so it sounds like there is some capacity for like ongoing nudging of people to make sure their entries are up to date and things like that is that-?**

R: Yeah, I mean it’s a bit, it depends on the pressures within the system at the time. So sometimes, yeah we do try to build that in regularly and we’d have sort of alerts that the team would, would go out and do some of that chasing but it’s not always obviously the top priority on the list of things to do in terms of sponsor’s responsibility so sometimes that’s more ad hoc than other times and it sort of depends on the type of trial as well how much we push it.

**I: Do you have any indication now with the with the and you might not, you might not know to this level of detail but do you have any indication with the movement away from the EUCTR and sort of automatic registration where your, I assume, you know, this only just happened in January so you might not have too many trials that have gone through this process yet but do you get a sense whether people are going towards the ISRCTN or towards clinicaltrials.gov or is there just no no preference?**

R: Not really I mean clinicaltrials.gov is the default really.

**I: Okay.**

R: So, I would assume that that’s the way we would go.

**I: Yeah.**

R: To be honest but-.

**I: But it sounds like the PI has some agency**

R: Yeah.

**I: deciding what’s best for them, yeah.**

R: Yeah, yeah and it depends on the it depends on the trial because it depends, we quite often have, we would quite often work on multi-, you know, multi-country trials where [the Trust] is the only UK site and that’s just the sort of nature of the specialist stuff that we do or sometimes we’ll be the only centre because it’s the only place that accepts those kind of patients. So, it sort of depends a little bit on the trial and where the impact of the results of the trial will be most if you know what I mean?

**I: Yeah.**

R: So, if there’s a kind of European, real European kind of focus on the outcome of the trial because it’s being done in other European Centres then obviously that makes a difference if we don’t think it is or there’s a more of a US based and it’ll be going for sort of regulation through FDA or something like that, then we would do it maybe in that way.

**I: So, and then so do you have resources internally like available like to support -- so if I’m a new investigator and I’m doing maybe my first trial or my first PI and I’m trying like I might not have any idea about how to register, do you have any sort of resources or training available internally for folks like that?**

R: Yeah, we do, we try and support as much as we possibly can. We would sign-, potentially signpost to either sort of mentor type, you know, more experienced to establish researchers or speciality leads to support. Quite often new researchers are doing PhDs and so therefore they have a supervisor and a team around them and so we quite often rely on that network that they have to support them. We wouldn’t be able, we wouldn’t necessarily have the resource to walk everybody through all of the processes.

**I: Yeah.**

R: We hope to build in that sort of sustainability within teams because otherwise you, we’re inventing the wheel every time. But yeah we will always help if we agree to take on sponsorship for a study then we will, we will help but it’s a it’s a drawing a fine line between what we’ve got the resource to help with and what’s the PI’s responsibility and they will still have to do but to be honest that’s not usually a problem with junior kind of less experienced researchers because they’re very, they’ll want to do the right thing and they want to take, it’s more the, more established researchers who feel like it’s slightly low level stuff that somebody else should do for them and that’s where we’re having to say, “No, actually this is clinical input that you need to provide and you need to fill in this box,” and yeah.

**I: Yeah, do you find that oftentimes it’ll be someone else on the study team, once again, you might not have vision to this but is it like a trial manager or someone like that who might be the person who manages that responsibility?**

R: Yeah, I mean it varies. I’d I’d love to be in a position where we had sufficient resource that there was sort of that level of support for every trial which there isn’t but sometimes it would be a Research Fellow, sometimes it might be a Research Nurse or Coordinator. It sort of really depends on the nature of the individual.

**I: Individual research.**

R: Yeah, and that, we don’t have, we don’t tend to sponsor very many multicentre trials at [the NHS Trust] because we don’t have the infrastructure for the sort of trial management side of things or the monitoring. So, we do do some but we would, we don’t have a large team of trial managers and monitors and that sort of thing so we tend to try to push that responsibility out to the study team as much as possible.

**I: Sure so so what, I’m gonna go back real quick so one question I like to ask just to change things slightly before we get back into some more wonky policy-type stuff is, you know, in your, if you were to describe in your own words what is the value of, of like what is the reason for registering, trial registration and requirements to report results, you know, what is, what function are those serving in your own words, you know, how would you describe the value or lack of value or whatever you think about those responsibilities?**

R: Yeah, no that’s a really good point. I mean ultimately, I think it is, it’s just, it’s the principal of kind of good clinical practice and good governance around having robust records and reports of studies and that that is transparent and available. I think that’s really important just from a governance point of view because if you don’t sort of have that principle around everything that we do you could start asking lots of questions about lots of things that are going on and I think, even if the, the individual detail on a study isn’t necessarily relevant or important or anybody’s really looking at it, it’s more of a principal around we conduct everything that we do according to this really high standard and it’s the principle by which we treat patients who are taking part in these studies.

I think from a participant point of view, it’s really important that they, participant’s sign up to research, understanding that that is the framework that we’re working in so that they, there is an understanding and awareness of the contribution that they’re making and it’s not something that’s going into a black hole. Obviously one of the really big difficulties is keeping trial participants informed of things that are happening on trials without them sort of having to interpret scientific papers and knowing what their contribution was so I think it’s really important to be able to say, there is at least somewhere where all of this information is held.

I think it’s also really useful from a sort of UK sort of research base point of view to have somewhere where we know what’s actually going on in terms of the amount of research and the nature of the research that we do and this is one really important mechanism for that along with the NIHR portfolio because otherwise the UK government it would find it much more difficult to sort of measure return on investment and how much patient benefit is being achieved from the UK science base.

**I: Mhm great so does [your institutions] …what you imagine is the expectation for registration and then, you know, I say reporting I’m generally talking about putting results on a registry but it could mean, I could also mean, I don’t know if you also have like expectations in place that the results end up, like that you get involved in how publication gets managed for your studies as well. So you can feel free to sort of touch on either of those aspects of reporting but like to what extent are those expectations built into like the SOPs and stuff of the organisation?**

R: Yeah, so it depends whether it’s a kind of regulatory requirement or a funding requirement or where it’s this is best practice and something we recommend. So, if it’s a reporting or regulatory requirement then absolutely those elements are written into our SOPs in terms of reporting and we have a reporting SOP so that’s, that’s there. In terms of where we think best practice and guidance then we would, what we try to rely on is a good working relationship with investigator in the study team. Of course that doesn’t always mean that they’re going to tell us when they’re about to publish some sort of results, whether that’s interim data or end of trial data and we usually get this at the last minute so we don’t necessarily always have the opportunity to intervene in terms of the target audiences and making the most of those kind of stories but that’s a, that’s kind of the holy grail aspiration which is not unique to, to what we’re doing but then we would, if we do have enough time to intervene in that, then obviously we would be able to work with the investigator to think about how to best disseminate those those outcomes or make sure that the data are represented as you say in in the right place.

**I: Yeah have you run into specific instances in your, you know, career either here or your prior work/job here people sort of weren’t making things available on like reasonable timeframes and you need to like, you don’t need to be specific about a specific job or if someone’s really lagging and they’ve done a trial and even if it’s terminated early, like it had something wrong and they have to get the results out there somewhere but they’re not too jazzed about it or maybe they’ve been rejected from some journals and they’re sort of not feel very motivated or they got busy, you know, any of the multitude of reasons, have you dealt with those before?**

R: Yeah, yeah and that’s sometimes tricky. I would say it’s the exception rather than the rule.

**I: Yeah.**

R: There are only a few cases of where that’s really an issue. Sometimes there’s a bit of a lag and you sort of have to say, “Come on, you really need to get this done and it does eventually happen after a bit of chasing but there’s only really, I’ve only really come across a handful of examples of where you really can’t get anything, get anything done and then we’ve sort of relied on our co-escalation processes in terms of who’s responsible for the individual, who do they report to that kind of thing and we’ve used those channels but it’s very rare.

**I: Yeah.**

R: Usually an investigator understands that and you’re not trying to sell them something that, but you’re right sometimes motivations or whatever might be difficult and if you’ve spent a lot of time and energy investing in a study and perhaps your out-, the outcome of the study is not what you were hoping for your patients then of course that’s a difficult message and sometimes they need some support with how to get that message out and how to move on and make the most of that data, so yeah.

**I: So who so who is the people like in your, you know, in your office broadly that are, so like you’ve mentioned there is support for people doing that, and then there’s also support for like following up just to, you know, if someone’s sort of dragging their feet on requirements, whether they be registration or things like this what like who, where does that responsibility sit, like who is actually working like other roles, like what is, what role is that?**

R: Yes, so it would normally be in our clinical trials team. So we have, the team that’s responsible for all of this is our governance clinical trials and contracts team and it would normally be our clinical trials team so we would normally have a clinical trials what we would call a Clinical Trials Manager but it won’t necessarily always do all of the functions of the classic trial manager in a CTU type function but it does similar things around reporting and then we have a junior member of staff supporting them as well who does a lot of the sort of chasing and keeps all the records maintained so that any one time we could pull off a report of exactly that, you know, where everything’s up to.

**I: Mhm so in terms of like how things operate at the Trust, so you’ve been there for almost like three, three four years you said, so sort of have these policies and focuses sort of evolved in your time being there and if so like how have they changed over over time?**

R: Yeah, I mean I generally I would say the reporting function hasn’t really changed. What’s changed a little bit is the culture in terms of making it clear what’s a PI responsibility because I think there has been, well I think there’s more, certainly more pressure on the central R&D team. There are many more projects the last year obviously the number of projects to do with Covid has absolutely you know, gone crazy so we actually maybe we have in the past done some of the responsibilities or roles, you know, roles and tasks for people where we’ve had the capacity to do that so I think that cultural, there has been a bit of a cultural shift in in us sort of saying actually this is a PI responsibility and ensuring that the sort of people responsible for our researchers, like, their Heads of Department etc also support us with that and our medical director would get involved so that if there are any issues of the PI not taking their responsibility that’s not necessarily something that we would deal with in R&D but I would be able to escalate that through the appropriate channels you know, it’s something if they agree to take on then they need to do that. So, I think that sort of culture of who’s responsible has maybe changed a bit.

**I: And what do you think that like the way that this, the way you have things structured now and you can compare this to, you know, any previous experiences or experiences you see at other institutions, like what do you think is, you know, valuable and works well from the way you currently operate and like what could be potentially be done better? Like is there anything you wish would, that you’re looking to change or improve or build upon you know, moving forward or that you’re thinking about?**

R: Yeah, I mean lots. [laughter] Always room for growth isn’t there. I think we’ve had a core team in place for a long time and we haven’t really reviewed for a long time the structure and function of that team in terms of, ‘Do we have the right size and shape? Do we have the right roles and the right levels?’ Things have changed a lot in terms of the regulation, you know, so it only gets more complicated in terms of the reporting requirements, the data requirements, you know, that kind of thing. So we do want to do a big piece of work around have we actually got that right because I think at the moment what we’re trying to do is just struggle through . I want to reinforce more of that culture of the PI and the relationship between the PI and the research office and really make, the Holy Grail would be that that’s consistent. It’s not consistent at the moment because you’ve got some PIs will shout louder than others and they might get, it might work out differently which isn’t ideal so I think definitely resource. In terms of the sort of processes and the robust governance that we have actually, I think it’s really strong. It often comes across as bureaucratic, but I think that’s the NHS generally. I don’t think that’s necessarily specific to this and, as I said, at the beginning it’s, it’s so important to have that robust framework around everything we do that I don’t necessarily want to take that away but I would like to obviously streamline as much as we possibly can some of that bureaucracy and as things move more digital, more online, you know, there’s much more we can do around e-consent and, you know, confirm using databases to do some of our kind of regulatory stuff rather than lots of paper trails and kind of things so I think making things more efficient, reviewing the capacity of the team and the site sort of structure and continuing to develop that culture where the PI is really clear on their responsibilities would be my kind of three things that I want to work on.

**I: Great and [um] so essentially sort of through your position is a little bit unique in that you have vision on a NHS Trust and a University function even though it’s all clinical. Is there any sort of differences, like is there any differences in working on the people who are operating on the Trust side versus on the, you know, Academic/University side?**

R: Yeah, I mean just because you’ve got two organisations with slightly different processes. I think that’s the only real reason. I mean the motivation and drivers for research is slightly different. In the University, the researchers are employed to do research [er] especially the [academic research organisation] because there isn’t a lot of undergraduate teaching. There is sort of post-graduate teaching but it’s not, sometimes in universities you get that pressure that, you know, the primary function is teaching, and researchers is like additional activity. For, generally, for researchers in the [academic research organisation] research is their primary function, that’s what they’re employed to do.

In the hospital, they’re employed to be clinicians and treat patients and they have full clinical workloads and so there is always that balance between, you know, if you’re a substantive employee of the Trust then you’re probably, you, you’re going to find it harder to carve out time for research. If you’re a substantive employee of the University, then you wonder why nobody did what you want them to do yesterday. So, there’s a bit of a, there’s that balance definitely.

**I: Okay.**

R: But it’s thinking about how to build a culture where you develop clinical academic careers across the two areas and thinking about that balance of time to do academic work if you’re a clinician and clinical work if you’re an academic and trying to build those sort of teams and think about the right kind of structures and sometimes a PI doesn’t necessarily need to do everything themselves as in they need to take responsibility but we were also thinking about, you know, Advanced Nurse Practitioner roles and Fellow roles and trying to get other people involved in that so that it’s not all, all on the Principal Investigator where they’ve got a busy clinical load.

**I: Mhm right so I’m interested about also, so you’ve been working in this space I think it sounds like long enough that you’ve sort of experienced some of these, we’ll call them like events or like things that have impacted the transparency space over the past we’ll say like, you know, decade-ish or so. So like I’d be interested to hear, so we’ve talked a bit about Brexit already and how, I’ll just go down this little list and then we can start and then we can do some -- How has Brexit, like has Brexit done a big change, has that changed much of anything or can I, think NIHR processes have largely remained the same is that correct?**

R: Yeah, that’s right, yeah.

**I: Yeah.**

R: So we haven’t seen a big change of the regulation yet. We may do.

**I: Yep.**

R: So, sort of waiting to see how that pans out. At the moment, no it hasn’t changed anything really. The only thing that has changed is where we actively taking part in research and part of that research requires certain, I don’t know accreditation of a facility for example which previously came under the European Legislation and all of a sudden doesn’t and then that’s kind of, we can’t even though it was the same yesterday and it was fine, it’s now today not fine and suddenly we can’t treat this patient and that’s, it’s those kind of things which you, are blindsiding us a little bit. But I think once the regulators kind of work through that and we’re still working with the MHRA and the Human Tissue Authority as well is quite often involved in sort of accrediting some of those things for us then I think we’ll be okay. But otherwise we haven’t seen a major change in terms of Brexit yet. Obviously, I think it’s too early days.

**I: Yeah.**

R: It’s only, we’re only seeing ad hoc issues with, you know, border control and things just like everyone else but not, not-,

**I: Yeah, yeah but nothing really to like, yeah.**

R: Not regulations and reporting yet, no.

**I: So and then these two kind of go together a little bit but sort of like what has been the influence of, if any, of the AllTrials campaign and then also subsequently the House of Commons sort of like inquiry and looking, well they look at reporting and sent letters things like that, you know, what was the response like to those sort of things? This organisation of some of that might have been at your past organisation but yeah what did that sort of look like?**

R: Yeah interesting so not all of the data that came back to us from those processes were reliable which was interesting so it’s kind of picked up a few discrepancies in terms of how perhaps different groups are accessing those data because we had a few sort of say this trial hasn’t been updated and it had maybe like clinicaltrials.gov or EudraCT but what I, what I find with these and this is a really classic example is it was, there was a lot of momentum around it at the time and obviously we, we had to respond, It was a high level kind of enquiry and we did and it did give us the momentum to make some things happen that we perhaps, people had been dragging their feet a little bit on but, you know, now that’s gone I feel like it was like, oh this is like the worse thing, we need to fix this right now. We’re gonna send high level letters. Everyone’s gonna get involved. It’s gonna come from Treasury blah blah and then, now there isn’t any of that pressure anymore but surely, it's just as bad as it was probably. So yeah sort of take these things with a slight pinch of salt because it does seem, you, you kind of get, it’s a flavour of the month. Somebody somewhere has gone, ‘Oh we’re not reporting properly, let’s do an enquiry. Oh, the enquiry’s found we’re not reporting properly so let’s put loads of pressure on these organisations to get the records straight. Okay there is a bit of activity, but it hasn’t changed the culture in that we’re now going forward, going to have perfect records.’

**I: Yeah.**

R: So I wouldn’t be surprised if we had another enquiry and did another exercise that we probably find ourselves in a rather similar position.

**I: Interesting so you don’t think, so while you said it sort of like it was an impetus for some sort of change like change process improvement, it sounds like the durability of that might not quite be what people might hope for?**

R: Yeah, I think that’s my feeling. I think from, I can, obviously I can only speak from the organisations I’ve been involved in,

**I: Of course.**

R: but I think this already so high on our agenda to do this and to do it right that yes there were a couple of missing records that this sort of gave us a bit but maybe there are organisations that didn’t think it was so important and they’ve had a slightly different experience and managed to use that to put maybe leverage, additional resource I don’t know but for us it more a case and sometimes I think those campaigns can do some damage internally in terms of these kind of letters get written to Chief Executives of organisations who are managing a big portfolio across a complex organisation, don’t necessarily fully understand the research process that’s why they have an R&D Department and then they almost get the impression that somebody in their organisation hasn’t done something right without knowing the full context of the landscape so I do worry about some of these things that go directly to CEOs of Trusts in terms of what kind of reputation, how that comes across reputationally to them in terms of their, their role in the bigger picture, in terms of research so, yeah.

**I: Yeah, interesting so you’d think, so like yeah, because it’s interesting to think like, you know, how much are those Trust CEOs who obviously have a lot of responsibility and a lot of overseeing tons of things like how much are thinking about these sort of functions of the research practice at their institution and**

R: Yeah.

**I: Yeah, I assume it’s highly variable between Trusts but it might, there’s lots to consider and there’s lots to worry about it and it might not always be-,**

R: Yeah.

**I: And then last thing, has there been any sort of movement or thought about the, like HRA Make It Public, like as they move forward like it seems like some processes might be changing or improving as a result of that, has that like spurned anything yet or is it still sort of in a holding waiting pattern and see what happens there?**

R: Yeah, I think we need to see what happens. I’m worried, I am worried about the investment in the HRA not being replicated in the investment in R&D or in delivery because I think what we’ve seen during Covid is it’s amazing we could approve projects so quickly and get them through ethical committee so quickly but that hasn’t always meant that it’s the most robust of processes and my feeling is that the ones that have picked up the mess, well not the mess but the problems are the sites and actually that’s, there isn’t investment into R&D. It doesn’t really come through the Clinical Research Networks. It doesn’t come through central resources, infrastructure funds have all basically gone away. There’s no funding for that anymore but yet the amount of reporting and the amount of kind of responsibility at that level seems to get more. So even though the HRA say they’ve pulled everything centrally and and they’re issuing approval and we’re confirming capacity and capability, actually that hasn’t changed, that hasn’t changed what the Trust need to do as much as HRA sort of said that they would, if you see what I mean, especially from a sponsor point of view. If it’s, if you’re a site then fine, you know, you, you understand that you accept HRA have approved something and the sponsors taken certain responsibilities, okay you can go ahead. But as a sponsor there’s an awful lot still that you would need to do at site kind of organisation level that the HRA is not doing or not doing particularly robustly and it’s just meant we’ve had to submit more amendments to studies because things have been overlooked when things have gone through too quickly for example and that’s again putting the responsibility back on the site and the sponsor to redo the paperwork etc. So, I am worried that there’s a it’s not quite even, the investment that’s going into the HRA and the investment that’s going into site level isn’t matching at the moment, so I do worry about that.

**I: Yeah, so to connect a few threads of things that you’ve talked about. So like, it sounds to me like increased sort of oversight and requirement from the HRA sort of beefing up these procedures making some of these processes for say, registration or feeding back lay summaries or results or things like that more robust sort of shifts, so you’ve talked a lot about the balance between what’s a PI responsibility and what’s a sponsorship R&D office responsibility and those increased regulations may tip the balance back towards the offices without a requisite increase in capacity or resource to handle that?**

R: Yeah.

**I: Is that correct?**

R: That’s exactly how it works.

**I: Yeah.**

R: Exactly it, yeah.

**I: Yeah, okay just wanted to make sure I was connecting those threads** **correctly.**

R: No, that’s great, yeah.

**I: Ah great, okay, excellent and then so in terms of so like when these things happen or when even more mundane sort of like when things are changing like, if a change happens or if there’s opportunities to learn or talk to other people in your area throughout the country about like best practice, do you have outlets that you turn to for that, like so are there, are there any organisations or mailing lists or anything like that where you, that you found useful to sort of, you know, learn from and learn about the newest requirement or best practices from?**

R: Yeah definitely, I mean we tend to rely on the sort of national networks around the R&D forum and the UK RD community obviously as a teaching hospital we have been part of the University Hospitals Association for some time, so there are these kind of networks that we share intelligence with. At more sort of local level within the Clinical Research Network then organisations do work together if nothing else to at least sort of say, “How is this affecting you?” How have you dealt with this change in regulation, or this change in in whatever I mean usually, you know, not enough resource, not enough this, this is difficult blah blah blah but at least you kind of know that you’re on the same page. I think with all the challenges we’ve had recently with relating to the pandemic in terms of that massive increased workload both new projects and having to amend everything and pausing and re-starting it’s been really helpful to the teams doing those functions to know how the rest of the NHS is managing the same situation. Actually we, we’re quite far ahead in [the NHS Trust] in terms of not stopping a lot of stuff but it’s, those teams have been under pressure but being able to talk to other organisations and being able to pass that message back actually they’re doing really well in terms of our patients that is happening, so yeah I think those networks are really important, definitely.

**I: Yeah, it sounds like they’ve been helpful. Like you have learned, and you do learn and feed, feedback in and take from, yeah.**

R: Definitely and we do, obv-, we are, we are also fortunate in that we have [specific types of research facilities] so they have their networks as well in terms of other [research facilities] and, you know, there’s quite a power, there is, there is much more momentum around R&D community I think in the UK now in terms of, you know, there’s annual meetings and that kind of thing happening so there, there are, there are more opportunities to lobby for change and have discussions with NHS England or HRA or whoever us, are implementing those changes so.

**I: Mhm**

R: Yeah.

**I: And I’m interested like so you obviously your office is managing a subset of a University's and then the NHS Trust side but I’m wondering like do you, are you aware of or do you see like I’m very interested in sort of the difference between the NHS, things at the Trust level and things which you have spoken somewhat to already and things at the University level. For things like resource, you spoke a little bit earlier about time resource being one difference, just based on the incentives and the jobs what people are doing. From like a more like overarching like you know, managing that do you, do you feel like it is different working in the NHS compared to some of your colleagues who might be working solely in more academic clinical capacities? Like, like how do those pressures and resource distributions and stuff like, are there differences there or do you think it’s largely like, largely the same kind of just slightly different problems but it’s largely the same, you know, speaking very generally here?**

R: Yeah, I would say very, yeah, slightly different problems but largely the same cultural issues.

**I: Yeah.**

R: Yeah so, before I worked in NHS, I worked in University Research Management before, you know, the most of, the rest of my career so I can directly compare the two. I think it’s the same thing, the problems come down to sort of personalities, multiple pressures, different motivations of individuals motivations of organisations. It’s all, it’s the same kind of fundamental barriers but slightly different depending on the exact thing that you’re dealing with, yeah.

**I: Yeah, but like yeah, okay so you don’t, you don’t, like look longingly at your academic colleag-, you colleagues or anything go, ‘oh they have it easy.’ No, it’s not like that at all [laughs].**

R: Yeah, and I think the NHS and Universities are measured in quite different ways by the government in terms of their success. So, for research, Universities are measured in terms of the performance by their outputs largely in terms of quality of the publications, you know, PhDs that kind of thing. So the currency is more sort of papers, grants, doctoral degrees etc. Whereas, for NHS in research it’s much more about patient recruitment, patient benefit, you know, number of new treatments going into clinical practice. So, there’s, that’s quite a different landscape and so you can obviously get pulled between the two if you’re working at that interface. Because it’s the kind of absolute trick is to try to get those two things to marry and that doesn’t always happen. So yeah, the different, different kind of pressures and I think that you can completely understand why there’s then sometimes a, sometimes they have to play off against each other a bit and that causes conflict.

**I: Great so that, I think that’s pretty much it for my sort of like set questions then I usually just like to ask, you know, is there anything else that you’d like to expand on or that I, you were thinking about that you’d like to say that didn’t quite get asked or that you were planning on me to ask, just sort of any final thoughts or anything like that?**

R: Not really, I thi-, I suppose the only thing that is still a bit of an unknown really is how we can better at communicating the outcomes of research to patients because that’s difficult and in a way for us it’s slightly easier because we tend to be doing more small, small number, early phase studies where we’ve only got, you know, we’ve only got a few participants. We know these families, they come and take part in the trial for a number of years, you know, as follow-on studies and so where we’ve got those relationships, that just happens anyway because they basically they live here and so [laughs] we work with them all the time but I think for a lot of large scale studies where you’re enrolling participants, they perhaps don’t see the benefit even for themselves, you know, they’re doing something for the future generations of people living with those conditions. There isn’t, I don’t feel that there’s a robust framework around how we might do that better because obviously some, some members of the public are, know more about the science than we do and they’re perfectly capable of interpreting scientific paper and some don’t so it’s not just all about lay summaries and you know, but it’s about how do we work better with potentially disease associations and charities and patient advocate groups and the individual participants themselves to share some of that because I’m not sure we routinely do.

**I: Yeah, so I that’s really interesting to hear because in one follow-up to that so pretend, like pretend for a moment that Brexit like hadn’t occurred and it sounds like when the new EU portal, whenever that finally gets off the ground and gets launched in the new EU clinical trial legislation comes into full effect, I believe that like, in addition to the standard tabular results format that the EUCTR supports now, I assume there’ll be something like that in the new system. They’re gonna make lay summaries sort of like mandatory-, mandatory is my understanding.**

R: Yeah.

**I: Do you think that is like a, do you think that’s just like, ‘Oh that’s not gonna help or do you think having those two things like really detailed like tabular results alongside a lay summary in a database, a public facing database, like do you, what do you think about that?**

R: Yeah, I think that it can’t do any harm.

**I: Yeah.**

R: I think, I think it will help. It’s about, it’s about how do we signpost people to that resource.

**I: Mhm.**

R: There will be some really active people who, who are already probably on that, but they’ll be a lot of people who take part or lot of potential people that don’t take part that could take part that we’re gonna need to be more actively marketing those resources and tailoring and driving people to them. So I think it’s about how you use it. I think it definitely definitely is a useful resource.

**I: Yeah.**

R: It’s about how we use it and how we make the most of it and how we drive that engagement will be important in terms of how we recruit participants to these kind of studies in the future.

**I: Yeah because it seems to me, it’s always reporting is always a very rarely unless you’re dealing with like clinical study reports and industry trials do you have, one thing is the definitive account of everything that happened in a trial, like it’s a piecemeal of sort of all these things that are out there together that make up the results.**

R: That’s exactly right, yeah. It’s not as, it’s not as clean as, ‘Oh we’ve got a compound we’re going to try and give this to patients and we’re gonna do Phase I, Phase II, Phase III, oh there it is.’ It’s like lots of different bits coming together from pre-clinical through clinical and then it’s, you know, it’s all of the stuff that you need around the kind of commissioning and it’s just, yeah multi- so multifaceted that it’s not that straight-forward.

**I: Mhm.**

R: Yeah.

**I: Right great so yeah, I think that’s pretty much it and we’re just right about at time.**

R: Perfect, thank you.