**I: [Introduction to study]**

**00:38**

**I: So, do you confirm that you give me your permission to interview you today and audio-record our conversation?**

R: Yep, that’s fine.

**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: Yes.

**I: And do you give me permission to quote you anonymously in any outputs resulting from this study including the sharing of the 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 any information you reveal that presents an immediate risk to patient safety will be reported accordingly?**

R: Yes.

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

R: Yes.

**I: And would you like to be contacted with the results of the email, the results of the study with your email on file, when those are available?**

R: Yes, yeah that’d be useful.

**I: Great and then the last thing I just like to offer is when I get the transcripts back from transcription and I do the anonymisation, I’m happy to send that to you or if you would like to have a look over and just make sure you’re comfortable that it, you know, doesn’t have any remaining identifiable information?**

R: Yeah, sure that’s fine, yeah.

**I: Sure, okay great. So you’re happy to take part?**

R: Yeah definitely.

**I: Excellent so we’ll just go ahead and get started then. So so first question is just can you tell me a bit about your role at the University?**

R: Okay so I’m the Head of [research integrity, governance, and ethics processes], so I’m based in a department called [department name] broadly similar terms in most organisations, I guess. It’s, the department as a whole deals with research governance, contracts, pre-awards, research development, technology transfer all those sorts of parts and my role in that is those three areas: research governance, research integrity and research ethics. So research governance side which is what this is relevant to is research involved with the NHS and the kind of the sponsor representative part of the University’s function and then we have a kind of research integrity part which is to do with our code of practice across the whole University and the plethora of other policies, procedures that are relevant to all research not just clinical research and then ethics is the management of our, secretary to our open research integrity and ethics committee at the University which there then oversees the school’s ethics committee, so that’s kind of broadly the role, the background to it. And then in terms of clinical trial transparency so the research governance side is you sponsor representatives so yeah, we kind of agree on behalf of the University sponsorship. We deal with insurance so set up and initiation processes attend trial management group meetings, all those sort of normal things you’d expect from a sponsorship role.

**I: Great and about how long have you been working in your current role and then in this area in general?**

R: So the area in general [over 15] years something like that and then my current role so I’ve been Head of the group for [less than five years].

**I: Okay, great and so if one thing I like to just tell people if, you know, if at any point during the questions I ask you today you have sort of reflections based not just on your current role but past work, past work and or comparisons of how things have changed over time and you’d like to add those that’s perfectly fine, I’m very happy to hear about anything like that as well and then lastly so just so I have an idea the recent, the clinical research portfolio for your, for your University is, does it generally include CTIMPs and non-CTIMPs?**

R: Yes, so CTIMPs and non-CTIMPS would come through my team for sponsorship, yeah so in that respect there’s no delineation in terms of within the team but yeah similar to a lot of other organisations we do then, once those requests come in, we do kind of separate out the clinical trials and have a different more intense set of processes around those.

**I: Great and this could be very rough numbers but about, in any the current moment or at any given point in time, what would you say roughly is the size of your trial portfolio and then what percentage are CTIMPs, very rough?**

R: Yeah, rough of the top of my head so it’s interesting that you ask the questions so the way that we operate our database actually is quite blunt, actually it’s CTIMPs or non-CTIMPs so there are things in the non-CTIMP which we still call a trial but they’re not really searchable within our, our kind of, our kind of database system at the moment. So in terms of CTIMPs ongoing we’d have somewhere between 10 and 15 at any one time and then if you kind of include broad clinical trials at, probably that number would probably double

**I: Okay.**

R: I would imagine within the context.

**I: Great.**

R: The non CTIMPs I guess roughly speaking ongoing at any one time would be a bit of a guess but I reckon it’s probably at this point in time around 200-ish.

**I: So that would include like observational research and things like that?**

R: Yeah. It’s pretty much anything we have to act as sponsor for.

**I: Okay great.**

R: Broadly speaking we tended to work out the whole package or anything we act as sponsor for ranging from CTIMPs to as you say observational, questionnaire-based studies we’re probably reviewing for sponsorship somewhere just below 10 a month maybe.

**I: Okay.**

R: So that’s kind of broadly what we’re talking about obviously then some end very quickly, some go on for years, you know, all that kind of context.

**I: Great so the first question I do l like to ask is a little bit less a little bit more esoteric I guess we can say but then we’ll get into the particulars of the organisational policy but I was just hoping if in your own words you could explain sort of why do you think we have requirements around the registration and reporting of clinical trials and place sort of, why do people consider that a thing worth regulating and a thing worth doing?**

R: That’s a, that’s a very very good question. It’s basically it’s basically protecting the health of the kind of the patient population I suppose. It’s for, it’s for their benefit is the starting point. You know, making sure that we’re, we’ve got all the correct most up-to-date knowledge that’s available for people to use both from clinicians and members of the public. Nowadays, most people when they find out they’ve got a particular condition they’re straight online and look stuff up aren’t they? So having that available for potential patients and family members to look up, but also they’re treating clinicians, is essentially is key particularly in this field and clinical trials range massively don’t they in in terms of what they do but, you know, at the very sharp end they’re things that are fundamental to people’s lives Yeah, it’s a pretty basic, it’s as basic as that and as stark, stark as that. And then it’s, you know, making sure, very much linked to that, the broader knowledge is out there and available to people and it, it can be built on, it can be checked, it can be, you know, it can be replicated, all those sort of things which are key to open research more generally.

**I: Excellent, great and then do you see if they’re like do you see any downside to making these requirements sort of more in the regulatory putting it in a regulatory structure I guess would be a way to put it?**

R: Not specifically about putting it into regulatory structure. Clearly putting in a regulatory structure creates a lot of work around that. I hesitate to say some of that bureaucracy because I think it’s an essential thing and

**I: Sure.**

R: bureaucracy has quite a negative connotation around it doesn’t it, it’s kind of like, ‘oh it’s just some pointless, pointless bit of paperwork,’ but yeah the only negative is not so much that it’s regulated, it’s the it’s the level of work required around it to make sure that you’ve got adequate processes and I see that the more negative and we’ll probably come onto this later in the interview I’m guessing is really related to the catch-up work for all the historic stuff, that’s the challenge, you know, kind of saying, putting a line in the sand saying, “Okay from this point forward, we’ve got processes to deal with this and, you know, it’s been correctly costed etc etc,” and so I think going forward most organisations are probably now fairly comfortable. It’s trying to clear the backlog that is more, more the issue, but I don’t think that’s, that’s a downside from making it like a regulation as such.

**I: Yeah, I got you yeah, we may circle back around to that later**

R: Yeah.

**I: But so, okay so just to get us started talking about processes and procedures. So, if I’m a, like say I’m a PI at the University and I’ve gotten, we’ll set aside funding as a barrier for now, we’ll say I’ve gotten my funding, I can, I want to start up a trial, what does that process, what are my first sort of steps?**

R: Okay so from a regulatory point of view and interactions with my team, the first steps we’d, we’d well we’d have the simplest level, we’d have what’s called our sponsorship application form asks a whole host of basic questions about, ‘Okay, what’s the study involve? The timings of it, you know, is it a CTIMP or not, which members of staff are involved, are you using a Trials Unit?’ all those sorts of things, you know, that’s the very basic starting point and we would do a sponsorship review and a broad risk assessment and then a staged process of yes in broad principle we’re happy to act as sponsor and then you’d have further stages such as, you know, happy for you to go to MH-, to ethics and our MHRA for their review and then kind of a final one about approval to commence as well. This is going to sound very simplistic and then in the middle of that you obviously have a, you obviously have a kind of initiation process which will depend on the risk level of study, so the more risky studies, we’re heavily involved in that initiation process. The less risky studies we might delegate that to the research team themselves but certainly anything in the realm of clinical trials we would either be doing an initiation process or receiving evidence to a Trials Unit for example about their initiation process and those processes would include specifically reference to, ‘Has it been registered, has the trial been registered on an appropriate registry and is there a process in place an awareness that it requires doing in terms of maintenance?’ So is there, is there kind of that process in place and we’d also raise it at that stage around making sure at the end of the trial that actually you know, that there is a, there is consideration up front that by the time you get to the end of the trial, you’ve got this, this requirement for people to do. So, I mean that’s that’s broadly what the regulatory process is. When we’re talking about clinical trials and sort of CTIMPs certainly we have a specific policy that involves a trials unit so there are whole load of stages that trials units go through as well in terms of that set up process which is related to what my team do but it’s, yeah it’s not it’s not necessarily exactly the same thing so they’ll have a risk assessment group, they’ll have had a stats group review, they’ll have a load of SOPs that need doing, database development, all those sorts of bits of work will happen during the set up but within a trials unit environment.

**I: So, the trials unit might have some sort of parallel or processes that sort of run separate from your office just because they work like, they just have their own internal processes essentially to deal with some of this stuff and beyond.**

R: And where possible we tie those in so for example we only have one trials unit within the University and we have a combined risk assessment process with them so if it’s going through that trials unit we sit on their risk assessment group and therefore the risk assessment is one process rather than doing theirs then doing ours, so, yeah, there are some combined elements to it. It’s getting a little bit more complicated in the very, very near future because we’re just setting up a joint research office with our [local NHS body] as well, so they’ll be additional processes I’d imagine that’ll come out of that.

**I: Okay great yeah that’s I might ask more about that a little bit later as well. So it sounds to me just to make sure I’m clear in what you just described, so is registration is proving that sort of ‘I’ve registered my trial and it’s, and it’s up here, look it’s on the registry’, is that sort of a requirement before they can go ahead with the trial or is it just something that you make them aware that they have to do and then it’s up to them to ensure that it happens?**

R: No, yeah, it’s a requirement, you know, they have to show kind of evidence that it’s done so and that will be from from an initiation meeting, kind of initiation check list point of view that will be documented specifically on there, done on this date by this person and obviously we cross check it on the actual relevant database itself or registry itself anyway.

**I: Yeah, great and the so the actual registration processes is that, so the actual, you know, entering the words, typing into the database itself, is that, that’s generally done by someone on the study team not someone in your office?**

R: Yes, yes that’s a study team one so if you’re talking about the main the three three main ones I suppose you just, the European database, the ISRCTN and clinicaltrials.gov

**I: Yes.**

R: So the European database will have the broad sponsor, you know, if we need to change people’s access and requests, certain individuals will have that responsibility within my team. Individual researchers actually do the updating and then ISRCTN again searches and clincialtrials.gov we host the the institutional admin but individual researchers are still doing the, and the actual inputting of data and information.

**I: Great and that’s usually done I assu-, is that usually done by like a Trial manager or like the PI or some, something like that?**

R: Generally speaking, yeah yeah, sort of Trial Manager, Research Coordinator, those sorts of functions. Occasionally you get a keen Chief Investigator who’s used to the system and happy to do it

**I: Okay.**

R: but generally speaking it’s it’s Trial Manager/Coordinator-type functions.

**I: And do you have any processes in place so say I’m a new Trial Manager or Research Co-ordinator or someone in that sort of a role**

R: Yep.

**I: and you know, this responsibility falls on me but I’ve never done it before. Do you have any sort of like mechanism by which you like help that person or train them or is it something that they might learn from colleagues or, you know, what does that look like?**

R: Yeah, I think I wouldn’t say we have specific training as such but it generally it’s linking in with colleagues and also through our Trials Unit, they’ve got SOPs related to what to do and which process. So, if someone’s from outside the Trials Unit we share that SOP with them and, you know, if it’s the Trials Unit more than happy for us to do that.

**I: Great, yeah and then when you have so obviously for a while everything would go right, not everything, but CTIMPs would go right to the European registry and sort of**

R: Yeah.

**I: that would be the automatic sort of registration process. Obviously not a thing anymore since come January and the finalisation of Brexit so are people generally, do you find for new research that’s been set up since then, are they using clinical, do you push people towards clinicaltrials.gov or the ISRCTN more or is it pretty evenly split just based on what they do?**

R: Historically clincialtrials.gov seem to be the one that everyone knows about. I personally try and push people to ISRCTN.

**I: Okay.**

R: My preference I guess is partly a preference thing I found ISRCTN much easier to navigate and also interact with clinicaltrials.gov. I probably will use the word it’s more bureaucratic and there’s so many more steps to the process but yeah my guidance to people has been use ISRCTN if at all possible.

**I: Great and just in your, so your office is working on, focusing on that sort of research governance tasks, how many people are generally in your office like work roughly in that, including yourself, are working in that area?**

R: We’ve got, I’d say dealing with this two to three, dealing with the kind of registry oversight.

**I: Great so and then when it comes to the end of the trial and that reporting process which you touched on a bit already, you know, the EU process up until we don’t have to, like it’s now ended but up until then sort of and I assume every once in a while, you might get something that to do that needs results on clincialtrials.gov as well so that’s seems from what you’ve described earlier it’s built in to your processes and your SOPs and do you have a way to sort of and you also mentioned ongoing updates and sort of like,**

R: Yeah.

**I: you know, and yeah just updates, do you, can you explain a little bit how that sort of ongoing monitoring and like post registration requirements, how you, how you manage that?**

R: So the, again going the simplest way of us tracking that or at least triggering consideration of it would be in relation to when amendments come through so whenever we have amendments that can be requested from researchers we have to have a section sort of saying have you considered whether this requires updating on the relevant registry so they’ll have to, they’ll have to physically answer, “Yes I’ve considered it.” And then obviously we can follow that up with them if we think actually there is something very specific needs to be updated if they’ve changed key parts about the kind of inclusion/exclusion criteria or those sorts of things which are quite fundamental to it.

So, we have a check during the amendment process whether that’s relevant or not, whether they need to update it. The other part, we also for all of our CTIMPs we are, we sit on the trial management groups for all of those and also then for our, kind of our interventional clinical trials we also kind of sit on the trial management groups for those as well so it’s normally speaking a standard agenda item which you may just flick through and go, “Yeah that’s fine, yeah, we don’t need to do anything there,”

**I: Sure.**

R: or every once in a while you go, “Actually we need to update that status there,” you know, it started late and the end dates coming up or, you know, all those sorts of things, you know might have standard points so those are the two key mechanisms, so our amendment process because we have to approve all amendments anyway and then sort of sitting on TMGs [trial management groups] just to make sure people have got it in their minds kind of always that these registries need maintaining.

**I: And then when it comes to the results reporting, how is that worked, because I know some people think that, you know, the EUCTR requirement, even the clincialtrials.gov requirement is, you know, a year like, you know, is that difficult? Have you found that that’s difficult for your PIs to meet generally or are they able to meet that pretty well, what’s the sort of experience you’ve had with that?**

R: Yeah, I’d say if I want to talk an idealised world it shouldn’t in theory be that difficult. Experience of the last year which maybe well some of it’s definitely Covid impacted

**I: Of course.**

R: in terms of people being able to do it. [It’s been, it’s been challenging and part of the issue if you take just a non-Covid, pre-Covid out,

**I: Sure.**

R: take pre-Covid time, try get my words right, pre-Covid, one of the issues actually and one of the learning certainly within our Trials Unit which majority of our trials that need registering run through our Trials Unit was actually not being too keen to close your ethics and MHRA on the trial. What we were finding was that the Trial Managers might be very keen to close a trial down but actually the data cleaning and data queries to site hadn’t been completed so, you know, by the time that had been completed and done you might have been six months down the line again and then you’re really sort of chasing your tail trying to then do all the analysis ready for publication and do the stuff for the registry so I think that’s a learning that came out of relatively recently that we need to be kind of more, give more consideration to that when we actually want, when we actually declare the end of trial to make sure that that twelve-month trigger doesn’t stop too early.

**I: Great.**

R: But, yeah, I mean the biggest single issue for people doing it is resource and expertise because people are so familiar with the whole process of I’ve got to an analysis and I’m gonna publish and they’re very familiar with that process but the actual number of people who are familiar with again this is what it means for putting it up on a registry which is different and it’s and it’s a specific format and there’s also, you know, specific knowledge in terms of how you technically do it. The people kind of go, ‘Oh I’m not so sure about that.’ So I think that’s the single biggest issue is the kind of the people and the time to do it.

**I: Yeah, sure and just to make sure I understood based on something I picked up in your response there, so the registration requirement just that we touched one earlier is that for all, that’s for CTIMPs and non-CTIMP clinical research or is that only for CTIMPs?**

R: t’s for, it’s for so CTIMPs absolutely and then it’s for interventional clinical trials as well.

**I: Yeah okay.**

R: I’d say yeah that’s, that’s less strong from our point of view in terms of making sure those registrations and the entries on the registries are up to date and accurate. CTIMPs we’re kind of much more on top of.

**I: Sure.**

R: But the obviously clinical trials vary massively and kind of our involvement in them we found in the past we might be listed as a sponsor when we’re not a sponsor or you might have an investigator who’s registered against themselves or another organisation so there’s quite a lot of cleaning up still to do I think around some of those other registries.

**I: Great and you’ve touched about this on some of your responses already but you know, you’ve mentioned some recent developmental changes or improvements and I’m interested about hearing that process and like, you know, what currently isn’t working so well that you’re hoping to address. You’ve just mentioned how you know, where you declare end of trial and where you think about, you know, how that relates to results reporting. Are there, are there things that have sort of you’ve changed and altered in recent years to improve or things that you’d like to see improve that are sort of on your to do list as it were?**

R: So, I get, so two questions of things we’ve done to improve the situation and then-?

**I: And then moving forward do you have anything sort of on the docket, yeah?**

R: So, in terms of what we’ve done to improve the situation, over the last few years there’s kind of a policy level, we’ve updated our Research Integrity and Ethics code of practice which is applicable across the whole University to explicitly set out the requirements for registering and maintaining and then publishing results on registries for clinical trials, that’s kind of explicit part of our top level University code of practice. Then have so SOPs and guidance in place, some of these processes I’ve referred to are in the last three or four years so in terms of amendments that that was like relatively recent, it’s probably actually, probably more than three years, I think I’ve lost a year with Covid, I don’t know what’s-,

**I: Yeah, I think we all have.**

[laughter]

R: It could have been five years ago yeah so given those relatively recent additions what we’ve also done recently is raise the profile within the University rather than just being my team and the relevant clinical investigators, actually there are status, I’ve been using the EU trial tracker actually is a very good tool for our perspective and a benchmark is using that and reporting in to so there’s two main of sub groups we report into, one is our open research, we’ve got our [research operations oversight group] and we’ve also got a [trial governance oversight group] so reports into both of those and both of those groups report into our overarching [research integrity and ethics committee] so it got College Deans of Research and then the Pro-Vice Chancellor of Research chairs the kind of the University level committee as well so actually that information’s being fed up to senior individuals at the University rather than previously not that long ago, it was really kind of just dealt with a one to one basis between us and the research team so that’s definitely of benefit and that’s, you know, that’s one of the good things I think also about the Science and Technology Committee focusing on this particular area, actually it focuses minds at the senior level within the University and suddenly they become interested and say, “Oh what’s going on in this area, what’s happening?” and that pressure can come from down as well as us, from kind of up and across.

**I: And and oh sorry no, please go ahead.**

R: No, no, you go on.

**I: I was going to say have you found that’s that’s really interesting to hear have you found at that senior level interest so it sounds like it’s become more routine now sort of feeding that information back up to them have you found that their interest in the topic has persisted like even post the Parliamentary letters and stuff, like are they, has it, has it been a persistent interest or was it a very focused interest in response to those letters that has?**

R: That’s very true, very interesting question.

**I: Yeah. [laughs]**

R: Hard to answer really, we we’re still reporting up and I think because our, if you look at the UK/EU trial tracker our percentage is roughly holding, there hasn’t, there’s been less pressure back down from them to say, “You need to sort this out.” But I think when we started the process of trying to clear our old trials, we were down at about 40 per cent I think of our new trials having actually reported, then we climbed up to about 80 per cent. I think we’re hovering around low seventies at the moment so another a couple of trials in the last year have come onto it. I think because of that those numbers I haven’t had much direct input from those senior individuals but yeah, they are still receiving those reports and they are still keeping an eye on it.

**I: Right sure and the so yeah so you mentioned earlier, and this is where we’ll circle back around to it that dealing with the retrospective reporting requirements of those EU guidelines was a bit difficult. Can you just talk about some of the issues you ran into trying to do that, like what I can imagine what many of them are but I’d like to hear.**

R: Yeah, you’re probably very familiar all of them, aren’t you? [laughs] It started off from our, our perspective, we were, we obviously ran reports off using, you know, the trial tracker, using EUCTR itself and actually we kind of started, we did a, we’ve done an enormous spreadsheet which also has ISRCTN and clinicaltrials.gov so there’s a whole variety of issues cropped up when we created this big spreadsheet so from you know, incorrect data so end data were wrong on the, on the kind of European database for example so we had a process of contacting the MHRA and getting them to update the system which was very slow to start with and then kind of I think they put some extra staff on and then suddenly it all happened at once. It was also then trying to kind of, trying to deal with those very simple projects which had, had finished pre-, my memory fails me, it was pre-2013 wasn’t it, July 2013?

**I: Yeah, it was, it was July 2013 or 14 but yeah something like that.**

R: Something like that so making sure we then sort of cleared those out and go okay, well here’s these have published, let’s get them on, on the system and then the other challenge is sometimes an ongoing challenge is the ones that have a EudraCT number but never started.

**I: Mhm.**

R: So, you know, registers, still registered as not having completed so that was a very specific challenge. Very fundamentally the biggest issue with the historic trials is getting time for people to actually go back and do this work because they’ve obviously moved on, either some cases moved on out of the University, so it’s virtually impossible to kind of rectify that situation or they’ve kind of, they’ve moved onto other projects within the University therefore actually trying to find some time within that realm to do this work becomes challenging. So yeah trying to think the question is, the question was around the challenges weren’t we what we faced at the time. So, firstly res-, probably the trying to work out what the issue was. That’s where we created the massive spreadsheet and going ‘Okay, here’s what we need to deal with.’ Then it was going, ‘Well okay which ones can we do, which ones can we address in a very simple straightforward manner?’ so they were our it could of ones have already published that we could just upload the results for or the ones that never started and we can put a kind of equivalent statement up that at least sort of gets that off our back. And then we’re then working on the ones that actually historic studies that that need to upload results which might have been in two categories, one might have been they have published and one might mean they haven’t published, you know, and the haven’t published is probably the biggest challenge because that will generally mean that the data’s sat in a file somewhere and thankfully we only have one or two of those. And, and we’re trying to find solutions to deal with those so, you know, for example, one we managed to go through and use a master student so we created a project and supervisor and actually they kind of they did that process of analysing the results and uploading them etc so yeah that was an interesting project.

**I: Interesting.**

R: But I think that’s, that’s quite challenging to do so if you have to have appropriate, you have to have access to the data for a start but also you need someone who’s an appropriate supervisor and it just so happened that the Chief Investigator was still with us and could supervise that work along with a statistician. And then probably the next biggest challenge in terms of doing that work is within our centre for trials research they are over the last year they’ve been very challenged with their statistics support and resource. And they’re from our mind, they’re generally the key people because you know they’re from [clinical trial unit] and I’d say they, they’re the bulk of what I said earlier, the bulk of our clinical trials. They you know, they’re the statisticians are the ones with the expertise on EudraCT for example and uploading results and dealing with it and, obviously, they do the analysis generally for the trials so normally speaking that that kind of upload of results relies on them so any diminishing of their availability and resource has a knock-on impact. More recently, like I referenced Covid a couple of times, actually more recently some of our challenges have been with our historic trials actually getting access to the data so we have one specific one where the database was held by another organisation it took over, well over a year for us to get the database transferred to us.

**I: Oh, interesting.**

R: to be able to do the upload and then another example would be actually, you know, where hard copy data’s coming in and that’s sat in the office and we’re all working from home so we can’t actually access the office to go in and do the data cleaning. On top of a lot of NHS organisations didn’t have the time to respond to data queries anyway.

**I: Yeah.**

R: So that’s probably on, you know, those are probably the main things at this point in time as to why our kind of our percentage is dropped back a bit. It’s not this, it’s dropped off the forefront of our minds, it’s the fact that there, there are challenges which in terms of resource and then accessing that data to be able to do it.

**I: Yeah so, you’ve sort of, you’ve picked off the easy ones and now you’re dealing with what trying to finish the hard ones.**

R; Yeah definitely, definitely.

**I: Yeah well it’s nice to hear though that it sounds like you’ve had some success even with some of these more difficult trials and sort of, very interesting to hear about like the masters student project and that’s yeah really interesting to hear about so we’ve mentioned a couple of things, Brexit came up at one point and we’ve mentioned sort of the impact of the House of Commons, the Parliamentary Committee letters had could, just add a few other sort of major events of the last couple years have you felt any impact on so we’ve talked about how with the, with the, with Brexit being fully completed now and the losing access for future registration on the EU system, has that impacted your procedures, is that something you’ve had to adjust to at all really?**

R: Not really so far, I don’t think it’s had a massive impact the biggest impact was just the uncertainty because-, we’ve had three, we had three Brexits basically didn’t we? We’ve had three different dates in the end and it was, it was more to do with people kind of coming up with questions, ‘Okay, well what happens after Brexit? Are we even going to have access to EudraCT at all to upload the ones that are already registered on there?’ and ‘What happens after Brexit, do you, are we still going to get a EudraCT number and if we do get EudraCT number does that commit us to still entering information on the database?’ so it was more to do with the uncertainty of the information coming out of it rather than necessarily the procedures for doing it and uploading results and all the rest of it.

**I: Yeah so, my understanding and correct me if I’m wrong, my understanding is the current procedure looks a lot like the old procedure. It’s just that the trial doesn’t eventually go to the EMA anymore, is that correct, yeah?**

R: Yeah.

**I: Yeah and then the other thing I wanted to ask is have you began sort of making any preparation or has anything ch- or I know there’s not a whole load of detail on this yet but [what about updates to national requirements]?**

[Short, non-essential clarification that included identifiable information removed]

**I: Right okay and that so I assume like, you know, you’re aware of the Make it Public,**

R: Yeah.

**I: the name of the new campaign. Is it still too early times for that or has there been any changes or reaction to that yet?**

R: Yeah, for much, still a bit too early times at the moment it’s exactly what the context is. I think there was a was it this week or next week? I think it was yesterday, I think there was a HRA consultation process, like a Webinar specifically on this topic the ‘Make It Public’ which unfortunately no-one in my team was able to attend but it’s certainly on our radar but yeah, we haven’t specifically adapted processes yet for it.

**I: Yeah, and then just to circle back around to one of the things you talked about earlier, you talked about that you’re in the process of sort of setting up a joint research office with your local NHS, you know, organisation. How has that like, you know, I’ve spoken to people throughout this project, you know, at both the NHS side and the University side and I’m always interested to hear about sort of the challenges or the like efforts to sort of unify some of these transparency polices and procedures across organisations.**

R: Yeah.

**I: Has that been something you’ve, you know, what has that looked like or is that something you’ve even dealt with in this process to date?**

R: Yeah, well I mean at this stage, the actual specifics of it we haven’t dealt with yet so the idea is, just give you a bit of context in terms of our joint research office, we’ve got a physical office which we haven’t yet moved into which we’ll move into in [the near future] and then from that we’ll then start combining some of our processes within to review at some point next year saying we are a formal joint research office. So we’re some way of in terms of having combined processes however you know, we’ve been working closely for a long time so for example when I’ve had information from yourself orTranspariMED is the other example, the Science and Technology Committee, I’ve shared that information with our Health Board to make sure they have similar processes to us and make sure they’re kind of there, they’re doing similar check and going, ‘Okay well how do we rate on this, you know, how many of our due trials have reported results and how are we doing on clincialtrials.gov?’ So yeah, in terms of information sharing and awareness that’s happened already. In terms of the actual processes, we haven’t addressed that part of it yet.

**I: Great and yeah and I guess one last question, so I’m gonna ask some questions but I don’t wanna lose this thought before we move on do you feel, so it sounds like, you know, a lot of, there’s been a lot of innovation and process improvement going on over the last, you know, couple of years you’ve mentioned and it seems like, you know, quite a bit of that was in response to the Parliamentary letter sort of something processes changed. So do you feel like, you know, the processes has improved enough that moving forward you are confident that you will get in a, you know, some of the problems you’ve discussed so far with the older trials were things sort of, when there was no processes to track these things they could easily, you know, be in a filing cabinet somewhere or someone could leave. Do you feel confident that, you know, the processes have been approved enough that that is no longer like a risk moving forward?**

R: I’m not sure you have a status ‘no longer a risk’

**I: Well at least a drastically reduced risk perhaps?**

R; Yeah, yeah, yeah, definitely.

**I: Yeah.**

R: So CTIMPs 100 per cent I’m, I’m confident, you know, that that we have processes in place. Where, where I want to see us improve and that will be probably part of our joint research office discussions is, is that kind of range of projects which are interventional clinical trials which don’t necessarily have all of the exact same processes. Most of them do apply but I wouldn’t be as confident with those ones than the CTIMPs.

**I: Great and one last one question on this section so when it comes to results off the registry we’ll call them so if I want to publish a paper is your office involved in that process or procedure or is that solely just the PIs are in charge of that, and they publish those papers?**

R: Yeah, we’re not involved in that at all.

**I: Okay great so you mentioned that so that you do some information sharing with your local NHS organisation. When, I think the sort of last section here that I’m interested in hearing about is how do you, is more about that how do you learn about and keep on top of, you know, how all these regulations and rules are changing and then start thinking about how that impacts your organisation and what you need to do to respond to that? That will be my first question**

R: Okay.

**I: so how do you learn and stay on top of the news as it were?**

R; So I’ll go, I’ll go back a bit and and kind of reference a couple of things so the Science and Technology Committee was definitely of use to us. What I’d say is before that actually, you know, we’d started this work anyway, what the Science and Technology Committee part did was really focus the minds, you know, and actually it became an issue which Institutions were interested in rather than individuals within Institutions and so that was definitely kind of benefit from that perspective. In terms of keeping updated, actually, I can I found I can’t stand Freedom of Information requests because it just consumes your time. I’ve actually found those coming have helped as well. So, I mentioned TranspariMED earlier, so, we we had a flurry over a period of two years of freedom of information requests and those helped obviously in terms of focusing people’s minds but actually they helped with information raising within the organisation and my own knowledge. Likewise, the you know, the trial tracker website has key information on so in terms of external resources those two sites I actually found quite useful when I was starting out on this going, ‘Okay what do we need to improve and how do we do it?’ In terms of other knowledge, I’m also part of probably two key groups from a Russell Group perspective I sit on the Russell Group Research Integrity Forum which has cropped up at occasionally but also the, the we’ve got a Russell Group get the name right, Association of University Research Sponsors I think it’s called. So we have that as well which again these sorts of topics will come up, we self-define what our agendas are each time but this sort of thing will come up over time I think it’s been a specific topic and I think for example we’ve had information from [colleagues at other universities] I think they did a presentation at some point […] But, anyway, they shared that information with us so yeah in terms of knowledge from my peers within the UK that’s kind of the route for getting information from them and then there’s kind of the groups such as yourself and the TranspariMED seem to be quite quiet at the moment ominously those have been very useful and the Science Technology Committee and then within the university itself it’s primarily a link with our Trials Unit because they have dedicated individuals who work on Quality Assurance and Regulatory Affairs who are now building up specific expertise on EudraCT, ISRCTN and clinicaltrials.gov so I have that level of interaction with them as well.

In terms of both learning and keeping on top of where we’re at with our registries, I have monthly meetings with our [CTU] so with the Director and the Head of Quality Assurance and this is a regular agenda item on it so it highlights individual projects but also talks about latest knowledge of things that we can do and adapt so an example would be when we’ve got, got information about work around from I think it was [a colleague at another university] actually, in terms of those, those trials which never started

**I: Yeah.**

R: but you have to, but you have to enter results on for it to be marked up as entered results.

**I: Yeah.**

R: So, she developed a work around and we shared information around that between our Trials Unit and kind of myself on that and how we might do that.

**I: Great and excellent so you actually covered most of the questions I was planning on asking in that in that response, so that was great. So yeah I think that actually pretty much covers much of what I want to talk about today so my final question is always is there anything else you’d like in this area or about that, you know, about your organisation that you’d like to share that, you know, I didn’t ask about or were you expecting me to ask about and I didn’t or just anything else you’d like to say in closing before we finish up.**

R: The only thing I’d comment on is from our perspective in terms of EudraCT and the European database although we still have some outstanding trials to do that’s probably the simplest end of the spectrum and it’s the clincialtrials.gov which I’m finding much more complicated because it’s got a such a wider range of projects and individuals who registered them and probably a longer backlog of areas to address so that’s probably a bigger challenge for us than, than the clinical, the European database.

**I: Interesting.**

R: So just yeah broad observation on that, I think that’s probably our bigger challenge going forward.

**I: Yeah, and then you found that like comparative, you mentioned earlier but just to reiterate you found compared to the ISRCTN which you feel like is a lot simpler to interface with and work with.**

R: Yeah well, my example with the ISRCTN is we had a couple of trials which we’d already published so I just contacted ISRCTN, emailed the administrator and they said, “Yes send us that we’ll up, and we’ll update the entry for you.” Boom, done. Whereas, the in comparison clincialtrials.gov maybe that sort of thing, you can obviously attach a a publication if you want to but it doesn’t count as results being published and you’ve got to go through the whole process of the researcher does something and then we authorise it and release and then it goes back to them and then they have some questions that we’ve done something wrong and then there’s a whole, yeah there’s a whole rigmarole around it.

**I: Right sure excellent alright so I think that’s pretty much it**. **I’m going to stop the recording.**