**I: [Introduction to the study] So just to confirm do you give permission for me to interview you today and audio record our conversation?**

R1: Mm.

R2: Fine for me.

**I: And do you understand that your participation is voluntary, and you can halt the interview at any time for any reason?**

R1: Fine.

R2: Yep.

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

R1: Yep.

**I: Do you understand how to raise a concern and make a complaint that’s in the patient information sheet, participant information sheet if you’d like to check.**

R2: Yeah.

R1: That’s fine.

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

R2: Mm.

R1: Yep.

**I: And do you give me permission to re-contact you with your email on record to clarify any information if necessary?**

R1: That’s fine.

R2: Yeah.

**I: Great and then the last thing is just would you like to be contacted with your e-, via your email on file with any results of this study when they become available?**

R1: Oh yes please.

**I: Great and then I usually like to offer, this isn’t part of the formal consent but I’m going to eventually have all of these interviews transcribed and then I’ll anonymise them and I always like to offer, I’d be happy to share the transcript with you to make sure you’re comfortable with the level to which I’ve anonymised it. Some people like that, some people don’t but it’s up to you?**

R1: I would quite like that, that’d be great.

**I: And [R2]. did you?**

R2: Yeah, that’s fine, yeah.

**I: Yeah, both of you, okay great. So let me just make a note of that so I can put it on my documentation. Great that might not be for a little bit but it’s a, but ah it will happen when, when you go to that point. Okay great so you’re both happy to take part in this study?**

R1: Yep.

**I: Great so we’ll get started then just with our first question is could both of you please just tell me a little bit about your roles broadly and then, and then more specifically how they involve and interact with trials transparency specifically the registration and reporting of clinical trials?**

R2: [R1], do you want to go first?

R1: Will do okay, I’ve Head of Research Governance and Integrity for the [University]. I’ve been here for about [2 years] and previously been [at another University] and have been pretty much involved in transparency for well [laughs] since it become a public issue I think very much. So my role here is to, so I’ve got two teams in the University; it’s the University Research Ethics team who reviews studies that go to University Research Ethics Committees, so don’t go to the NHS or MOD, REC or any, any other REC internationally and then the other team I lead is the Research Governance team and they look after studies that have to have HRA approval including CTIMPs so I’m the, the official sponsor representative for the University so I guess that that seems to feature on all the studies as the, as representative for the University have obviously the sponsor office where we do the sponsor checks so the normal involvement we have is obviously awareness raising so we, we make sure that our researchers are aware in relation to trial registration and that’s been around for a long time. Obviously over the last few years more so in relation to trial reporting to make sure that we’ve got mechanisms in place for trial reporting.

Within the, within the University, we have a quality manual and within the quality manual there are standard operating procedures and as this has become more and more of an issue, we’ve fed more and more things into the standard operating procedures and at the time when they get reviewed, we’ll just make sure it’s up to date from that point of view. From the standard operating procedures downwards, we then have work instructions, and then they’ll work instructions for, for my team to make sure that study closure we make researchers aware and if necessary, support them with any reporting needs. The, we work very closely with the clinical trial units, so there’s [multiple] and obviously [R2] is here for one of them and I hand over to [R2] so all of that work is supported by the clinical trial units for those studies that are supported by the clinical trial unit. So my team has really not that much to do because it’s mostly managed at the, at the clinical trial unit level and I suppose the, the function I have is maybe just helping it’s mostly helping researchers to understand what it is they need to do and if they’re struggling with the systems to provide the right support or indeed often other members of the clinical trial unit have actually supported non-clinical trial unit researchers with, with reporting, with reporting needs, so, yeah, I stop there I think for a minute.

**I: Great.**

R2: And so, my role at the University, I’m Director of [a Clinical Trials Unit]. I’m, I’m a clinician by training and I took over as Director of this unit [over a decade ago]. [laughs] Did say I wouldn’t do it for more then 10 but there you go, so the Trials Unit has been in this establishment for [many] years and started off actually within the Trust and then moved over to the University as an academic Trials Unit and we now have a portfolio of around about a 100 active trials at any one time. Predominately in [disease area], but we’ve also got a part of the Trials Unit that deals with early drug development for [other areas], for a range of different diseases and some devices. So quite a big portfolio and we’re also the [a named national Centre], so we’ve got a big international portfolio as well because 90 odd per cent of [trials in this area] are international.

So as, as the Director I, I so just to say that the Trials Unit runs trials that are predominantly sponsored by the [University] but we also deliver what we call national coordination activities for international sponsors so if our Euro, our academic partners in other countries we collaborate with them on developing a trial, they’re the sponsor say in Germany or France and we deliver it in the UK as a national coordinating centre, so it’s kind of two regulatory roles really.

In terms of obviously transparency, we’re completely committed to getting all our results out and published as soon as we can and so complying with the regulations so since the, you know, the, the introduction of the timelines for the EudraCT uploading when trials are completed we’ve been trying to maintain those timelines and working with [R1] it’s been, it’s been really helpful, you know, sort of getting those targets sent to us so that we know in advance where there’s been some delays or might potentially be some delays. I think that the main challenge we’ve had is that we’ve got a number of trials which I would call legacy trials that we inherited when we took over the [specific area] portfolio. We imported a lot of standing trials from another University who [did not continue this research], to put too fine a point on it, and some of those trials we just closed down because they weren’t really ready to continue but some we needed to continue for patient benefit and the way they were set up was almost pre the current regulations and the, the delegation of responsibility who was doing what was not particularly clear which means there’s a number of trials and it keeps coming up on the, on the spreadsheets where we actually aren’t responsible for the data, we’re just a national co-ordinating centre but we are still listed as the responsible person so failing to respond, to upload but we don’t have the data to upload so it’s a really difficult one but for the ones that we’ve developed since we took over then, you know, we stay compliant with the rules and-,

**I: Excellent so so I assume that the, that [R2], your centre is mainly doing CTIMP research?**

R2: Predominantly, yes predominantly.

**I: Predominantly and [R1] I assume that there’s also non-CTIMP research going on at the larger University would that be correct to say?**

R1: There is. So, the University made a decision before I got here so round about [the mid 2010s] that they wouldn’t run a CTIMP without support of a Clinical Trials Unit and so from then onwards the, the studies really need, CTIMPs, needed to be supported by a Clinical Trials Unit. There are, of course many other studies that are not. And of course, we’ve got [more than one CTU] and they do a lot of research in [specific areas].

**I: Okay great so a question I like to ask to just get us started, like just to early on in these interviews I just, I usually like to get people to sort of explain in their own words what they see as the benefits to registration and reporting of clinical trials, just to sort of explain why is this important, why is this something that’s often required either ethically or legally for people to do? Just in your own words if you could express why you think that is and or why you think that it shouldn’t be, either one?**

R1: Do you want me to go or-?

**I: Yeah, I was just, yeah why don’t you go ahead first [R1] and then we’ll go to [R2].**

R1: Okay, I suppose you have to look at my role, so my role is very much sort of compliance role really. It’s a, it’s making sure that we fulfil our obligation under legislation and guidance to ensure that that you know, we can continue to do research and that the public has confidence in our research. So, so that probably takes me to why I am very keen to make sure that, so trial registration was, I had no problem with trial registration that was relatively easy to understand for researchers that they should register the trial early so you would avoid any, maybe duplication, you could encourage collaboration. It wouldn’t be a waste of resource where lots of people doing the same thing so from my point of view, from a trial registration point of view that made a hell of a lot of sense. I think what researchers didn’t realise, and maybe as a sponsor role I didn’t when I was [at this University], and [my previous University], was that clearly that needed to be maintained so it wasn’t done with just the registration and people should keep this up to date and because they’re so many other things researchers have to do. I think researchers just didn’t, so they kept it up to date with the ethics committee, they kept it up to date with the regulatory authorities and they kept their participants up to date because obviously it’s a continued informed consent process and whatever was agreed to share with them at the end would be shared. I think it was just yet another think to tick a box on the trial reporting. So when, when this became an issue, so obviously initially for there was a big lobby for pharmaceutical industries to be more transparent that even made a lot of sense because clearly there was a lot of data that wasn’t visible to researchers, especially non-commercial researchers and that that was, I saw that as quite positive. Clearly, those people had a hell of a lot of more resource than non-commercial sponsors have and then when it moved on to non-commercial sponsors I, I think I could see why there was a drive to upload the results. I do not agree that that will help our, the general public to understand what’s being done in research. So, I think I have a, I have to a certain extent, maybe researchers look at this register, these registries. I’m not close enough to that anymore so my research career finished long time ago.

**I: Okay.**

R: But I’m not aware that somebody would, ‘Oh I must look at this trial registry to see what results people have actually come,’ because they would get that so my feeling is from my experience, they would get that from professional conferences, so they would go and engage in their professional forum. Mine was in [medical specialty] so you would, you would engage with [the medical specialty] society, you would become aware of the latest research, the latest trials that were ongoing. You would kick off to date with the journals of what’s been published and so as a science, as a scientific researcher I think that would probably be the first port of call you would, you would go to, so I don’t know if I really went to these results. It became for me in my role became a very much compliance thing of, ‘Can we make sure getting this out there?’ and obviously parallel I think we needed to enhance the way in which we fed this back into the public but because of all the publicity around that there was, it actually became a public trust issue, if the University was branded as not publishing results those who, to those who where that was important, even if they didn’t understand the results it would put in question of why we’re not doing it and therefore clearly we needed to make sure we did put this up there to keep the, you know, in tune with what was out there in the public domain. I honestly don’t believe that enhanced what the public new about research or, you know, very limited. I mean I think the, the recent movement form the health service authority in their new strategy, it’s much more promising where we actually have a lot of PPI involvement to say, you know, how can we make this accessible to the public and for our participants or anyone who wants to know about that research to really understand it, not in these sort of weird shapes, the registries show it but actually in, what does it actually mean to me as a carer or to me as a patient you know and really the bottom line of the benefit of that research and what we need to build on.

So I have, I have also some reservations in the way it was done so I’m not a heavy handed compliance person so for me I lobbied heavy against fine and heavy against heavy handed. I think it’s completely the wrong approach. We have a very stressed research community out there anyway who have to deliver so many things in a tight timeframe that the last thing I wanted would put pressure into that community so I have only ever taken a very supportive route through this, and I would fight madly against any regulation, heavy-handed regulation. I think it would achieve the opposite and by doing that we are now, [R2] at [a very high reporting percent]. [laughter]

**I: [R2], why don’t you go ahead and if you’d like to add anything to that about your experiences and sort of you know, understanding the importance of registration and reporting.**

R2: Sure, I don’t think my views verge that much from [R1] to be honest. I completely agree that that the introduction of the registration of trials from the start of the trial was a really important initiative and it did, has helped in terms of searchability of trials, you know, it’s, I think we all use ClincialTrials.gov and ISRCTN to look for trials.

I’m doing a research project at the moment that’s a, that’s doing a, a retrospective look at transcontinental trials and that’s our data source so it’s a really useful resource and I think it probably has helped avoid duplication of effort and that’s, that’s been really good. I think that it’s really important that the results of trials are out in the public domain at the earliest possible opportunity and that’s both in the scientific literature but also lay publications, you know, make sure that we get lay summaries out there. We find ways of feeding it back to the community, not just the participants of the trial but the, the population that might, might benefit from the outcomes of the trial so I feel very passionately about that and, as [R1] said, you know, the move to having greater PPI involvement throughout the trial, you know, we have patient representatives on our trial steering groups, on our trial management groups, not just reviewing patient information sheets but, you know, we’re really trying to move to that holistic approach. That’s said and the other part I think is data sharing, I think making it very visible, the accessibility to data sharing. You know, we have a data sharing policy that’s open on our website and it’s, it’s actually mandated by our funders as well, it’s in the Ts and Cs of our funders and, you know, we’re, you know, we’re at the moment processing multiple applications for data sharing so that we can do, we can get the most out of the data that we collected on clinical trials, so from that point of view, you know, I’m on board with the whole transparency agenda.

What I am not on board with is the way it’s being done at all. I think, you know, I was at the time of the clinical trial regulation being discussed, I was very heavily, am still very heavily involved in policy work with the European Commission and were pushing for the proportionality of the clinical trial regulation to allow us to do academic trials in a much easier way and then Ben Goldacre published his paper and it, it basically highjacked the entire agenda and suddenly the Clinical Trial regulation was about transparency and not about proportionate regulation and that actually was quite frankly damaging because, you know, the MEPs started to think about transparency which was important but started to lose the point that the whole idea of the clinical trial regulation was to reduce the level, make the regulation more proportionate particularly for non-commercial studies that weren’t doing first-in-man studies and so in the end , you know, the rest is history, we ended up with these, with these mandates for upload all the, this data onto the EudraCT and the two things that went wrong with that was that it didn’t achieve the, the purpose it was intended to do and that was to put data in the public domain. First of all, it wasn’t accessible and secondly, as [R1] says, it’s not what, it’s not useful to the public. It might be useful to other people who want to do research and I, I genuinely don’t know how much it’s been used for that, but the actual system wasn’t fit for purpose. It’s really, really difficult to do it so it, it had a huge amount of bureaucracy and resource and there are so many elements of it that actually make it almost impossible to do you know, the head of our clinical trials oversight committee I think was just about having a heart attack trying to put his own, own work onto it and he’s somebody where compliance is everything and he was really frustrated by it.

So what we’ve ended up with is exactly as [R1] said, we’ve got something that we have to comply with that isn’t actually doing what was originally intended, so what we’re doing is satisfying some people that have put an agenda forward for transparency and are publicly shaming Universities for not meeting something which is a tick box exercise rather than the actual agenda which is making data available and, and I think that’s, that’s been a really counterproductive approach and I think we should, need to go back to the purpose of it all which was transparency in clinical trials, making data available to the people who could understand the data and making the data available to the public in a way they can understand it.

**I: Thank you both, those are both great answers and I will, I think I’ll come back to quite a bit of what you both touched on at various points throughout the rest of our conversation today. So just one follow up I wanted to ask on that is just so we talked about, you know, the importance of registration and reporting and I’m wondering based on your responses sort of how would you so, I’m just trying to think of how to phrase this, so basically like we know that it’s pretty widely reported in the literature that often times results don’t get published so what if, something like ‘oh putting these results on a registry sort of isn’t the way to do that’, what, what would you, what do you think or do you have a opinions about what could be a better way to ensure that these results that don’t, you know, historically have not been shared, leading to like publication bias, do get shared. I’d be interested to hear sort of what you think that alternate system or another good way to ensure that sort of thing looks like?**

R2: So, if I can maybe start, I think there

**I: Please do.**

R2: There’s got to be really, there’s got to be very careful language here and I think this is what has caused a lot of the, the difficulties. There’s a difference between getting a trial published and making the data available and I think there’s a real blurring of the margin here, so, you know, we’ve got lots of trials published which the historical ones that didn’t go onto the database but we were told we hadn’t published the data because it wasn’t on the EudraCT registry so so I think it’s, we need to make sure that it’s clear what we’re talking about. Are we talking about getting a trial published or are we talking about making the data accessible?

**I: Sure, so just for the purposes of my question I would say that there’s pretty good evidence that there’s some proportion of trials out there that nothing is made available period on registries, in publications, just, they get lost to time and end up in the file draw like sort of thing.**

R2: So on publication, I think we need to drill down why. So there are some trials it’s almost impossible to get published, you know, they’re, they’re negative. I don’t like the idea of there being negative because every result is a result but the it’s the fact that they haven’t got a result that’s exciting enough for a journal to publish and I think there does need to be an easier mechanism that when you’ve got those trials that are quite frankly have not got an exciting result and the journals either have to be obliged to publish them or there is a mechanism by which they can be published so the papers written and it’s put in the public domain and open access so that’s my first thing so that’s on the publication side and I think that does need to be an obligation because it’s so easy to say, “Well I just couldn’t get it published.” Well, you try maybe put a time period on the time you try to get it published. It’s been rejected by three journals, nobody wants it. there’s a place you can post, done.

In terms of the, the making data available, I think the funders have done a great thing in non-commercial trials in their in their data sharing policies, you know, they won’t fund you unless you sign up to data sharing but I think data is best shared by the people who understand the data so we have collaborative arrangements about, you know, that we can, we get people coming back saying, ‘Oh, you know, we didn’t understand this about your data, can we go over it again’ and it’s more a partnership but I do understand that with Industry that’s a bit more difficult and you want Industry to dump the data there for people to look at and that’s because of the suspicion that people don’t entirely trust the way the data’s been interpreted and I you know, I have some sympathy with that for some Industry, not all Industry and I think in those circumstances, there does need to be, I’ve got no problem with there being data repositories. GSK funded one at one point didn’t it? People, lots of you could put their data in there but it needs to be fit for purpose and that was the problem with EudraCT database, it wasn’t fit for purpose.

It wasn’t really collecting the data in a way then would be usable to find out what people wanted to know which was that analysis correct, was it complete, was it biased? That’s what people want to look at so a fit for purpose way of doing it would be better. I don’t, I don’t know what you want to say [R1]?

R1: I think I agree with [r2], I think it’s like I said so for me the biggest initiative is the recent Health Research Authority Make it Public initiative because that that is addressing how we get it into, into the public in the right way, the way the public might want to have it. And I think generally, I think we’ve seen a lot of really interesting moves towards the open research agenda so the, so what I think is that that more recently we’ve got the Dora principles so the San Francisco Declaration of Research Assessment where we, where we want to, you know, as a, as a University we want to really assess the, you know, the quality of our research and the impact of our research and make sure that that is all done in a very holistic way so it’s not just about figures or about publishing in this journal but actually it’s, it’s about much more than this. So you know, it’s not about an article in Nature which nobody can understand but actually about it’s a, or certainly I don’t, [laughs] there might be clever scientists that do but I certainly struggle with those or but what I am interested in is, you know, what do we do generally as a University to, to have genuine impact with our research and that that is brought out and that is how we evaluate, you know, the, the success of our researchers so it’s, it’s not so focused on on all of those things but actually takes into account all these other, other things as well and I think we’re heading in the right direction and then obviously we have, we have seen things come up now with the reproducibility network and open access to research which actually almost are is research a self-regulating themselves, it’s a scientific community, self-regulating themselves and making themselves open to a scientific debate where this belongs. This is a scientific debate about in my study I found this, or I didn’t find this or I tried this and this didn’t work and there needs to be an open exchange about that and I think that’s the forum in which we will move on research. I mean this, like [R2] said earlier, I mean I have honestly first-hand seen how it, just me, me encouraging and cajoling researchers to put results up has stopped them doing their research. It stopped them actually doing research they should be doing rather than fiddling round with the system that wasn’t fit for purpose and that’s really sad and that and I don’t, I don’t really want that. I want them much more in the space where, you know, you do a study, you do a trial and you, you then look at what was the outcome and where’s the next step, where’s the next gap, how can I collaborate with other people? How can we pool results and, like [R2] said, share the data in the right places? All of that matters and all of that will move us on as a society but I’m yeah not convinced that being compliant with having it on the whatever registry is gonna do anything in that direction.

I think the future is somewhere definitely with something searchable so not so many registries but maybe a interlinked registry so we have, you know, a reliable registry which then feeds into all the others so I’ve said this before, at the moment, our researchers register on three registries, sometimes more and we have, we have put measures in place for that not to happen now but you know, there is just no easy mechanism. So if I do ISRCTN and ISRCTN would then automatically then feed into Clinial.gov or the others or vice versa any of them really interlinking and being a true, a global registry for research, that, that would be fine I think that everybody could, could see that and if you then link that to proper impact, society impact where people are interested could look at that, that would be really good.

**I: And so you’d just while it’s fresh, you said that you’re generally seeing people registering in three registries and you mentioned the ISRCTN, I think earlier you mentioned ClincialTrials.gov and would, would the EUCTR/EudraCT be the third one?**

R1: Yeah so, so but you can’t avoid it.

**I: Before Brexit obviously.**

R1: Take a CTIMP and you have a CTIMP funded by the Americans, you have an obligation to register on Clin.gov. You can’t get round it. You have an obligation to do EudraCT, you can’t get round it because you have to do it here and for the regulation and then, and then you will automatically be on ISRCTN because you apply for HRA approval and portfolio adoption and you’re on it and so therefore you’ve got three registries which you then have to maintain as a researcher so we’ve put a paper in place of saying, ‘Please think about where you register.’ It’s, you know, there is, there’s often not a way of avoiding it.

**I: So presumably though just to make sure my understanding is correct, now with Brexit new, new trials won’t be appearing in the EU system anymore, right?**

R1: Have to if it’s international. So-,

**I: Yes, okay sure if you’re collaborating with European colleagues, yeah.**

R1: the majority of our trials have a European or global element so.

**I: Gotcha, okay thank you very much so taking a step deeper to more practical concerns, I’m really interested in at [your University] sort of like what the process actually looks like. So I’m a new investigator, I come to you or I’m an investigator, I wanna start up a trial, maybe we can talk a little bit about how this process even differs between a CTIMP and a non-CTIMP but what are the sort of the, what’s the start up process in terms of we’re obviously talking about registration here, you know, what does that procedure look like at, a [the University]?**

R2: For a CTIMP, as [R1] said it would be done through a Clinical Trials Unit and the clinical trials unit has, runs to a quality management system with multiple SOPs that comply with the University SOPs and basically, if I put it bluntly the Chief Investigator of a trial is guided through all the steps by a well-trained Trial Management team that pretty much does it all for them so, you know, the, the regist-, the writing of the protocol, the registration of the trial, all the regulatory submissions, everything is done with the Chief Investigator but it’s done by an experienced team and that will go right the way through to the final, it will be the trial management team that do the uploading of the data onto the, onto the final registry and the where we, we, you know, have to work very closely with the Chief Investigators is because they have to sign off the reports, you know, they, we’re not doing it without them up and that has its own interesting challenges when they don’t always, aren’t as timely at that kind of thing as we’d like them to be because they’ve got busy clinical commitments but overall I would say they kind of get their hand held through, right the way through. Is that fair [R1]?

**I: Great.**

R1: Yeah, absolutely so, so and like I said, at the beginning, I’m lucky because obviously the, the Clinical Trials Unit colleagues will, will work this all up. When they’re ready they send it for sponsor review so my team will do the sponsor review to make sure that everything is in place so there is an appropriate registration if that’s required and we record this on our database and then we’ll track it through from our database.

So obviously when it’s a CTU trial, we kind of rest easy because we know it’s all in hand, we will just keep an eye on, you know, how the, how the dates look so we’ll just make sure that the annual reports are done and at the end of the study that that people are aware, you know they’ve got now x amount of months to upload this, depending what sort of trial it is and if there’s any problems that, you know, we can iron this out. So especially the legacy trials I think you might have got involved a little bit more in than other stuff but yeah it, it really is quite smooth now because, because it’s all regulated in very well developed systems, either at the CTU level or University-wide with, with the quality manual that there are sort of regular checks and balances and if there’s a problem it always goes to the clinical trial oversight committee so if something isn’t working or we have difficulties, we put our heads together and we have had several researchers where, you know, it was a legacy trial, it was ages ago. They didn’t have a clue what they were doing with the system and that’s what I said, that in the clinical trial oversight committee, [R2] is in there and she made resource available from the CTU to non-CTU people to, to just help or a member of my team is skilled up to upload results and we’ll do that way so, so it works really quite well now and people are supported so if they don’t know what they’re doing then we can, you know, do it for them and all they need to do is check that they’re happy with, with the results.

**I: And do you require, is it, is registration for non, so CTIMP registrations sort of seems to happen as a matter of fact, it just happens, it’s part of the process for setting up those trials.**

R1: Yep.

**I: For the non-CTIMPs is that like, is that required at [the University] or is just recommended and then those people will come and decide what they wanna do for their non-CTIMP trial?**

R1: You will be aware that obviously there is an obligation for HRA approval to register the first four categories of IRAS so clearly that’s a condition of the approval so we would, we would strongly encourage that, and it needs to, needs to be registered within the remit of what we allow. It’s a bit of an issue at the moment because I’ve withdrawn the free clin.gov for everyone because I don’t want everyone going onto the American registry but it’s, it’s causing researchers an issue because unless their portfolio adopted they will have a cost to register on ISRCTN which is gonna be our preferred registry and we haven’t resolved that yet so if you can figure that one out for me that would be great.

**I: That’s really interesting to hear actually yeah because if you lose, because those obviously would never appear on the European registry anyway. ISRCTN costs money and you don’t want so what’s the, like just could you just elaborate a little bit of why you don’t want people registering on clincialtrials.gov at the moment unless like, you know, required or necessary?**

R: Because it’s quite a big admin burden for the team so we have a University account and we have to make sure that we keep up to date with the clin.gov account and, and so, just the pure workload of letting everybody go onto clin.gov and uploading and then no matter how much they promise me at the beginning, the trial upload initially is not an issue but then maintaining that we get regular reports form from clin.gov to tell us where records are not up to date and we then have to chase every one of those and to give you an idea that’s roughly about 98 records we get it and so I have to get my administrator to send 98 emails to people saying, “Your record is not up-to-date, can you, can you do something about it? Have you got any problems? Can we help you?” And then often these are student studies, they have disappeared and so on, so and because clin.gov obviously there is a threat of a fine for certain trials anyway so I very much steer people away from clin.gov now so we only recently made that decision but clearly the ISRCTN, I understand why they have to charge because clearly they’re not a national registry like in many other countries, they’re not supported by the government like that and I get that but it would be quite helpful if we could have a UK registry that would be free for registration and then actually it would be much easier and if we then build in, so as part of the transparency consultation, the HRA looked for what do we build in as automatic feedback you know, on what do they want uploaded and stuff. That would be quite helpful to do. It’s clearly something for the future but in the meantime I am steering people there but it’s not the easiest of steer because-,

**I: Sure.**

R1: Yeah, you know, if I’ve got a student study, I have to pay £250 quid or whatever it is then actually for them that’s a lot out of their budget.

**I: Mhm. Anything to add [R2] or do you shall we go on?**

R2: No because I’m not so much involved in the CTIMPs, I’ll leave that question to [R1]

**I: Great so I just want to quickly recap on sort of the structure just to make sure, you know, I fully understood sort of what you’ve described. So it sounds like that capacity to meet these registration and reporting requirements and all of that it is very much like, so it exists within the CTUs themselves and then also but if there’s any need for help or there’s need for additional, you know, there’s, interaction and support from Research Governance as well and then Research Governance also support the non-CTU stuff throughout the University wherever that may arise. Is that, is that sort of, there’s like parallel not in like a siloed way but like there’s expertise resting in both places for these sorts of requirements?**

R1: There is, I suppose ours is sort of oversight and monitoring functioning for the overall [University] performance in this area so we will run regular reports to see what it looks like on clin.gov, what it looks on, you know, EudraCT, what it looks on ISRCTN just to, just to make sure that if there is an issue we can pick it up.

**I: Great.**

R2: And I think just to add I think what’s really good because we’ve got this clinical trials oversight committee which is kind of an independently chaired for research governance or the trials units although we’re all represented on it and it’s an agenda item on that meeting so, you know, we talk about it, so we know where we’re up to. [R1] reports what our percentage is and it highlights any issues so it kind of closes the loop. Is that fair to say [R1]?

R1: Absolutely and it’s really nice because the teams, well the oversight committee members are just supportive of the whole process of doing it. They understand the hurdles, they understand that it needs to be done. Yeah, no I think it works really, really well.

**I: And that clinical trials oversight committee is that where this sort of University-wide policies and SOPs emerge from? Is it from that oversight committee or is it from elsewhere?**

R1: So, we have in the University, they have a compliance team, so the compliance team sits in the College, so in one specific College and so the whole quality manual is held within that setting but colleagues from the compliance team are actually on the clinical trial oversight committee.

**I: Okay so it emerges from that, but they are represented in conversation with everyone else who was impacted by those SOPs and those policies?**

R1: And there’s a regular consultation so if an SOP is up for review it will go to the CTUs, it will go to me, it will be discussed at the clinical trial oversight committee and then it will be finalised.

**I: Yeah, it’s just owned elsewhere. Okay great so it sounds like having that body, I think you were both in quite a bit of agreement that having a, a sort of centralised body that collects all the, all the relevant trial performing and adjacent to groups within the University setting that’s been very helpful, like that’s, that would be accurate to say?**

R1: It is

R2: Yeah.

R1: I think the only caveat I would put on it is you have to look at the volume. [This University] has a massive portfolio, I mean honestly it is so research-active not just in the UK, internationally it’s probably one of the Universities who’s got the biggest international trial portfolio. For that, for that portfolio, for someone like me, it is, so as a sponsor representative, it’s really reassuring to have a clinical trial oversight committee so any issues can be discussed there, can go there, we can find solutions there. For a smaller university so I didn’t have it in [my previous position] and our portfolio was just much smaller for the CTIMPs and it can work also that way as long as there is a supportive PVC [Pro-Vice Chancellor] research so you need, you need someone who owns that agenda so here it’s very much carried by the oversight committee and obviously that has quite a lot of influence into senior management committees so it’s heard at senior management level. [At my prior University] we had a very close working relationship with [a senior director] and actually into the, the PVC research so had a soft reporting line to there. As long as it’s owned somewhere on a senior management team agenda, I think it’s fine. With a big portfolio like [this University] I think, you know, I think senior management would drown with the amount of stuff coming through so therefore it’s good to have a, have a separate committee for that. So I think, yeah not everything, what is it, this model doesn’t fit everything, but it works very well for [this University].

**I: For [this University] very well okay, good.**

R1: And for a University who’s got such a big portfolio, yeah.

**I: So you, you talked quite a bit earlier about how the, the sort of administrative task of dealing with these registries and stuff can be very time consuming and you know, burdensome we’ll say. So setting aside that particular sort of we’ll look like critique or complaint at the moment, is there anything else that you find and I don’t want this to just be dealing with the registries just in like in showing that papers get published and that there’s a robust timeline to like, that there’s robust support to people to sort of make things available in any form, be it a publication, be it a, you know, on the registry, be it in other lay forms, sort of whatever the way it, it comes down to, any other barriers that you often come across to ensuring that occurs and and, you know, other ways that you try to address it or ways that you’d like to try and address it or, we haven’t figured out how to address this yet. If that, does that makes sense or just sort of like, how are you supporting, you know, your researchers to make sure that they have like, that this expectation to report exists so then you support them in doing that no matter the form?**

R1: So, from, from my point of view, I think you have to recognise that the main, the main task of the University is to generate knowledge to get the knowledge out there. That’s how we are assessed so, so we don’t have patient care within, within our remit, that’s not what we do so an NHS organisation might have that as their, their primary delivery but actually research is actually very, very close second delivery these days but for the University, that is, you know, education and research bringing it out there in, you know, into society, that is what we do, that is how we judged everyone who works in the University is in their regular reviews, encouraged to, to publish their research. It is how they’re judged; it’s how they’re paid. It’s how they have that escalation in their career. They cannot do that without, without getting it out there so I think it’s really important to see that, that is our, so pharmaceutical companies have a complete different driver. They want to make money, that’s it, therefore what doesn’t make money doesn’t get talked about.

Different in the higher education area; this is, it is our bread and butter. This is what researchers do and therefore they would absolutely try like, like I’ve said, they would try and publish wherever they can because they need to get it out there to be seen you know, to have this assessed in their next reporting round or review round to see where they can to have impact to demonstrated impact as part of the REF so we’re, we’re, you know, we just have had that whole exercise so, so all of that is it is what we do, it is what we’re here for and actually we probably as a University, we do that where no-one else would. So you know, a commercial company might not take research on because it’s not gonna make money. An NHS might find it too risky and that, there is a lot of research stuff can only happen for, within the University sector and then getting that out there in whatever shape is the main driver for this so it’s really, it’s really important that we keep that in context.

R2: I think but Nicholas I think you raise an important point about training of investigators and it’s something that we’ve been trying to address in the trials unit, you know, because it’s always very interesting how you get the most engagement with Investigators when you’re writing the grant application and there’s an absolute deadline that has to be hit to get the grant in and then everything else after that, you know, writing all the documents, all the tedious stuff, you know, from their point of view seems to be, you know, it’s much harder to keep them engaged and then even when it comes to the publication because of the, the other calls on their time, obviously, you know, clinics, patients always come first it because there isn’t a, a genuine deadline like a grant deadline, it’s something that, that sometimes it does go down the agenda and, you know, you find yourself getting chasing them to, to review the, the results section or whatever because we do a lot of helping of the writing the paper for them and so we, we’ve looked at that in quite a lot of detail over the recent years and we, we’ve set much more of a almost a concordat with our investigators from day one. So, you know, the moment we take on the trial, they have to sit and have a two hour interview with us but it’s, it’s very much about this is, this what we can do for you but this is what we expect from you back and that’s everything from, not just writing the grant application but how you respond to all the queries and makes it much more of a close team working so it isn’t investigator out there in the hospital and we’re doing the, the bureaucratic stuff, that it’s actually really clear what those expectations are and I think we have seen a shift by working much more closely with the investigators in that way. We, we’re helping to get them over the, over the bar and, you know, just to give an example, we had an idea that we, we’d lock them in a room for two days to write a grant, a trial protocol and we didn’t quite get that far but we, we definitely had full day meetings and it’s been great with Zoom, where literally going page by page writing the protocol and I think we’re gonna get to the stage of doing that with papers as well. You know, when we get, all, everything’s been analysed and we just need to get that paper over the line, we’ll have a whole day where we write it together online or in a room

**I: Interesting**

R2: and get it out the door. And it is just focusing the time because we, we can’t get away from the fact, clinical academic, clinicians are not given protected academic time, you know, they’re trying at nights and at weekends and that’s really tough for them.

**I: There’s two final points I wanna make sure we get to because you guys have given such great answers, you’ve pre-empted a lot of the questions to ask so we’ve been very efficient today but there’s two, sort of two questions I want to make sure that I get to here. One is so you mentioned [R2] you mentioned at like the CTU that Trial Managers play a huge part in sort of progressing these administrative tasks and these reporting and these, and the dealing with the registries and it sounded like there’s you know, that’s obviously gonna be a function of the research governance team as well as to knowing how to do that and support that so if I’m a Trial Manager or I’m someone else involved in that process and I, you know, start a job [at the University], what sort of training am I getting, what am I being informed about that sort of, those responsibilities, what does that look like?**

R2: So we’ve got a full in house training programme that’s, that’s a kind of rolling programme starting from induction and then there’s training on different aspects of our, our, SOPs and it all revolves around the SOPs and so that’s delivered in house and people come, it doesn’t matter what time of the year you start, you kind of join it and then you join the different bits that are ongoing. But we’re also running a Master’s course in Clinical Trials so it is entirely directed at people who want a career in clinical trials so it’s not a statistics course, it’s not that investigators can't go on it but its more really get on it people who want to become Trial Managers and it’s [relatively new] you know, we’re hoping to expand it and, you know, it’s, we’ve got international people signed up for it as well. So and I think in developing that course, we’ve got dedicated post for training and education within the, the unit who’s one of the co-leads for the course and the training material within that course is also used for the people in-house and, in fact, we allow people to join parts of the Master’s course just to, you know, they’re not actually signed up for the Master’s but go along to lectures and get engaged in it in order to get the parallel training and some of them actually sign up to it as part time as well so do a part time Masters while they’re employed in the unit. So, it’s, it’s definitely evolving, it’s something that we need to do more of but, you know, there’s increasing opportunities to do it.

**I: And is, are there particulars, so if I’m actually sitting down and there’s a module there that’s like this is how you interact with the ISRCTN or this is how you interact with clinicaltrials.gov or does that happen as more of an ad hoc basis once you actually have to interact with those people?**

R2: So, so I couldn’t hand on heart say there’s a module in the Master’s that covers it but I’d be absolutely surprised if there isn’t.

R1: It’s the whole journey so I teach on it for it so it’s the, you, you literally cover the whole journey from, you know, the idea right through to study closure and lots of different people come in so there, they will get different perspectives of researchers of sponsors of, you know, other people who, who play a role and every aspect of that is looked at. So certainly, in my sponsor talks I will mention a, you know, there’d be issues around trial registration, but others will pick it up in a different way so it’s, it’s almost like a spiral learning where you go over territory all the time in the different modules or from different perspectives and stuff.

**I: Yeah, so basically, yeah that’s really interesting to think about so it’s basically being instilled at you at the point of your train-, your training, your academic training in this case for, you know, these are expectations that you of something that are involved in the job of a Trial Manager, and it encompasses that responsibility that’s really interesting to hear. So the last question just as we’re running up on our time here is what does your interaction with organisations outside of your University or CTU , just outside of [the University] itself look like, so where are you supported in terms of your professional organisations or in terms of other contacts you have with other people in the UK or internationally doing this work, what sort of professional support and look like, if it exists and where are you getting that from?**

R2: So I’m, I’m the Trials Unit’s one of the UKCRC registered trials units and so I’m part, so we meet regularly as part of the UKCRC Trials Unit Directors groups so we’re a forum, we get both by emails and we meet currently by Zoom but usually down in London and then part of the UKCRC there are other groups so although I’m on the Director’s group, there’s the Operation Manager’s group, there’s the IT group, you know, a QA group, so lots of them meet and then we’re also because we’re, our Trials Unit is core funded by [funding organisation] and they core funded [a number of] units in total, we meet as a group as a well and it’s a sort of parallel but we’re the CTU Directors and Operations Directors meet and then there are other groups on specific issues but and that’s tries not to overlap with the UKCRC work, it’s when it’s very [disease area]-related so we try to do things that are very [disease area]-related and then at an International level because we do so many European [er] and global trials in [disease area] we link to a number of European Clinical Study groups and I [work in the leadership of a] sponsor’s committee and this is a network of academic institutions around Europe that are non-commercial sponsors for trials and we try to work together to try and standardise the way we sponsor trials across different countries and certainly our University and our contracts department have been very helpful in trying to, for example, work out template contracts as to how we work going forward so that’s where we kind of get that overlap but that’s kind of very much from a CTU perspective. [R1] you’re involved in other things as well, aren’t you?

R1: Yes, so I think my main forum where I engage obviously is the Russell Group Universities, so we have a, we have a, a sort of sponsor, a non-commercial sponsor group there within the, with all the Russell group partners who work together on sharing good practice and that’s been incredibly valuable to have sort of case studies out there. Very early on in my [prior University] career because of the challenges brought by TranspariMED that actually was initially could have been a very bad relationship turned into something really positive where, where actually I said to Till, “Look, I’m gonna write a case study because I need you to change tack. This is, this is not working, you need to help Universities, you cannot just name and shame Universities.” And that’s actually been a really good collaboration in as much that I [contributed to a] case study that went out and then colleagues followed, they wrote their case studies. It was a best practice sharing exercise. How do you overcome these legacy issues where there was no solution and we took that actually into very different fora. So I work very closely, I’m a UK research integrity office advisor so I did those annual conferences and presented stuff there in wherever I was invited for the NHS R&D forum, I did it for NHS R&D Managers, I did it within Europe because the, by then obviously the in Germany the, the Universities were in a similar stage but a little bit behind us so we took a big workshop over there so we did some presentations over there and met with the EudraCT people so EMA people to, to see what could be done to improve things so the having actually the lobbyist working with us rather than against us and making this the best practice sharing forum I think that was actually really essential for many people to help and I today I still, I get contacted by many other colleagues across the UK to say, ‘Oh, you know, you talk there, can you help me do this? or ‘How did you do that? And that’s, that’s been quite helpful to have a really effective best practice sharing forum.

**I: Yeah, that’s great to hear. Yeah, I’m really interested in how these networks support knowledge sharing and best practice sharing so that’s really interesting to hear. So that’s it, I know we’re right up against time here, so I don’t wanna take up too much. I like to give a final opportunity if there’s anything I didn’t bring up that you want to make sure gets said or represented. If there’s anything I sort of didn’t ask that you were expecting me to ask today or points you’d like to be on the record. I’d like to just give a final opportunity for that?**

R1: I’ve probably got just one thing. I think we have a second opportunity to get this right. So if you set this all into context of the WHO requirements and declaration of Helsinki, so at the moment, we’re only doing CTIMPs and we’re monitoring heavy CTIMPS but we have other requirements under the declaration and under WHO expectation. I think it’d be interesting to see how, how we’re gonna manage that going forward because clearly manage it we must but hopefully not in the same way then we have seen it and, and hopefully it can be a co-ordinated approach with the right registries, the right registry approach, the right well what we’ve just all discussed and learning from the, the previous things so I think I’d quite liked to see that, how that, how that shapes up going, going forward to capture those sort of trials that are not CTIMPs but clearly are important surgical trials or important device trials or whatever it is and what and how we’re gonna put it out there.

R2: I haven’t really got anything to add to that Nicholas. I did put the link to our Master’s course into the chat because I thought that might be helpful to what we actually do.

**I: Excellent.**

R: Yep.

**I: Thank you very much, okay great.**