**I: Introduction to study**

00:43

**To confirm you give permission for me to interview you today and audio-record our conversation?**

R: Yes.

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

R: 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: Yep.

**I: Do you give me permission to re-contact you to clarify any information if necessary?**

R: Yes.

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

R: Yes please, yes.

**I: And then another option I like to give people is just when I get these transcribed and I do the anonymisation of them [um] which I haven’t started yet so it might be a little bit but regardless I can email you the transcript if you’d like to review it?**

R: Yes please, yeah that’d be good.

**I: Sure, so I’ll mark you down for that. Okay and then great so you are happy to take part in this study.**

R: Yep.

**I: Great, excellent so that is that. Great so to just get started with the, to get started with the interview can you just briefly tell me about your role and, you know, how you interact with trials transparency in your role, at your organisation?**

R: Yeah so, I’m the Quality Manager for [a healthcare organisation’s] clinical trials [department], so we oversee some of the sponsor responsibilities for CTIMP trials that are sponsored [within the organisation] and I’m responsible for like our SOPs which include registering trials on a publicly accessible database and then at the end of the study having the results published on there for EudraCT, I’m the person that actually does the EudraCT upload and post the results on there.

**I: Great so do you in your portfolio are you managing both CTIMPs and non-CTIMPs?**

R: Just CTIMPs.

**I: Just CTIMPs, okay great and then so about how long have you been in this role?**

R; About a year now.

**I: And were you working in related areas prior to that like in this general area of like research governance?**

R: Yeah, I’ve been in clinical trials for nine years now.

**I: Great and did your previous roles deal with like registering and reporting and things like that as well?**

R: I was a [trial monitor] one of our [trial monitor] duties was to register, to get the EudraCT number and do the MHRA submissions which then leads to it being registered on EudraCT and to follow up with the investigators and ask for the results at the end of the study.

**I: Great so and then in terms of [clarifying how sponsorship among named organisations works]?**

R: [Trials are sponsored by the University or an NHS Trust] depending on how they’re set up.

**I: Great and then so, so you, just to make sure I understand because I don’t want to mistake things when I ask further questions.**

R: Yeah.

**I: So, all of those flow into [your organisation] and then that’s where you, where you sit is just above everything.**

R: Yeah.

**I: Great okay so is there someone else at the organisation who would handle like the non-CTIMPS or like are there SOPs and things like that covering non-CTIMPs or is there someone else at the organisation who handles that?**

R: Yeah, so non-CTIMPs would be split by the Trust so each trust will have their own personal department who does that, same with [the University], there’s a whole separate department that does non-CTIMPs.

**I: Gotcha, okay so those are-,**

R: It’s only CTIMPs that are all merged into one [laughs] yeah.

**I: Gotcha do you know, do you have any idea of like the, the rationale, the reasoning for that or-?**

R: [um] So the [office] which I oversee that only looks after CTIMPs because we look after the regulatory responsibilities.

**I: Okay.**

R: So that’s more why it was more the MHRA responsibilities, and I know there’s recently device studies are now more heavily, heavily regulated and the [University] is looking at having something similar in place but for the moment it’s just the CTIMP studies.

**I: Gotcha great so I’ll come back, I’ll circle back to some more detail about exactly how you manage and register and report and things like that and what that looks like**

R: Yeah.

**I: but one broad question I like to ask at the top of these interviews can you just explain to me in your own words why there are, you know, requirements for the registration and reporting of clinical trials, like why does this, why do these requirements exist and why are they important or why are they not important?**

R: Yeah I wasn’t expecting that, yeah so yeah I think it’s really important 1) to avoid duplication because I know, especially at the moment and with all the Covid studies, investigators in the country even around the world may come up with the same idea and I suppose you want to stop having identical or even very similar ideas and studies running in parallel if you only need one, for example.

**I: Mhm.**

R: So I suppose that’s important so if you are thinking of doing a study you could do a search, see if anyone’s looked at that particular drug and that particular area before: 1) It would help with the basis of your research for like background and what’s been done before and what needs to be done further like a review, do like a literature review for example, see how it can be improved or 2) you might see someone’s done it and didn’t work so you might think ‘oh it’s a good idea but maybe not worth doing.’

And then other important factor is transparency I think the participants in the trials as well, just to see, so they can see the study there in it has been officially registered, the results are made available so if they want to see them, they can. Their doctors can see them if anyone has any questions or any, wants their information, it is available for them to see basically. I don’t think anything should be secret when it comes to people’s care in that way.

**I: Great so let me just see where I want to go next here. So what in terms of like the hierarchy at your, at your organisation like how much is above and how much is, like where are you in these sort of like hierarchy of trial governance and research like where does, just trying to understand where you sort of sit in relation to who is above you and who is below you or-?**

[Detailed explanation of organisation structure removed as identifiable. The participant works primarily on a certain category of trials within the organisation.]

**I: Gotcha absolutely and okay great so I think now maybe we’ll get into a bit of like the, the details of sort of how your SOPs operate and like how registration and then eventual reporting fits into that. So starting with registration so if I’m a trialist and I wanna start a trial within the [organisation], what does that process look like for me sort from the beginning?**

R: So we become involved once you have your funding application fully signed.

**I: Okay.**

R: So, whoever’s sponsoring your research, the [contracts] team would help with all the funding, get the agreements signed etc. At that point, you would come to my team once you’ve got all your funding and the first thing we do is we have a kick-off meeting and in that meeting one of the items on the checklist is that the trial has to be registered on a publicly accessible database and that the results have to be published within twelve months or six months if it’s a paediatric trial. So we make that very clear from the beginning that’s what needs to be done and then as we move through the set-up process so you get your REC approval, you get your MHRA approval, you get your R&D approval before we issue the green light for recruitment we will, so when, it’s a bit more complicated now because before it’d be on EudraCT and we know the MHRA has put it on EudraCT, that’s fine.

**I: Right.**

R: Now we have to go back and ask have you put it on ISRCTN or clincialtrials.gov and just remind them it needs to be on there before we can green light them for recruitment and then obviously six weeks can tell them it has to be on there legally six weeks after they recruit their first patient to be in the terms of their REC approval, so we do make it clear throughout the process that it does have to be registered.

**I: And then what, is there any, has there, post-Brexit and post leaving the EMA infrastructure, has there been any, like do you, have you noticed for the few that have started in these four months since then have you, is there any preference amongst your investigators for clinicaltrials.gov or the ISRCTN, just curious?**

R: So, our preference is the ISRCTN

**I: Okay.**

R: and that’s what we would recommend and now when I provide a quote for trial costing, I include the registration fee in there just to make them aware that it’s like a £270 fee to go on there

**I: Yeah.**

R; unless their NIHR funded, yeah.

**I: Yeah, okay great so and is there a reason for steering people towards the ISRCTN, more than clincialtrials.gov?**

R: It’s to do with clincialtrials.gov. I know we don’t come under the FDA regulations, but they said there could be a financial penalty if you don’t report within the timelines. Obviously, we would encourage, and we do tell investigators they need to report in those timelines, but I think it’s just in case there is a financial penalty that comes onto the [sponsor].

**I: It just feels safer, yeah?**

R: Yeah, yeah.

**I: Gotcha, great okay and then so as far as the actual, some, maybe this has changed a bit in the time since with once again leaving the EMA infrastructure but perhaps you could draw, tell me a little bit of what it was like before and after but like, so who’s the actual person doing the registering usually, like who is actually like typing the information into the database and sending it off, is it you, is it someone else?**

R: So before when it was EudraCT it would be the [trial monitor] would registrar for the EudraCT number and then it’s actually the MHRA who types in and fills in the database so as sponsor you don’t have access to edit that, the MHRA do it, and when you do an amendment, they also amend it for you on there. Post, not having access to that anymore, it’s the investigator or the investigator team that we ask to register on a database and do the updating.

**I: Right so the investigator is just sort of in charge. They may delegate it but it’s their responsibility?**

R: Yeah.

**I: Okay great and just so I understand so the way that it used to work so basically you would file paperwork with the MHRA and then they would do the official typing it into but like all that information would be sort of like file-, filed in some way?**

R: Yeah, so when you apply to do a trial, you fill oƒut. It’s called an CTA Annexe 1 form that’s where all your trial information goes and then when you look on the EudraCT clinical study register, you know, it has that table, that information is pulled directly from that form, so I imagine they just upload it.

**I: Gotcha so they just like, yeah, pull that form in and then I assume they turn it into the XML that gets sent off to the EMA, yeah.**

R: Yeah, we send them the XML yeah and I imagine they just forward that on or post that some way, yeah.

**I: Yeah gotcha, okay excellent so what procedures, so now that I’m registered and my trials underway, what procedures do you have in place to ensure, like is there, or is there any procedures in place to ensure that the record stays updated over time?**

R: So previously that would just happen automatically when you did an amendment to the MHRA, they’d upload the, so basically every time you do an amendment you update that XML and they would just post that.

**I: Okay.**

R: Now we don’t have a formal procedure in place yet, but I imagine it will be every time there’s an amendment, we’ll tell the investigator they have to go and update that information on that database.

**I: Gotcha.**

R: We haven’t had a study that’s hit that point yet

**I: Okay.**

R: So still fairly new yeah.

**I: Yeah great and then and then I guess I assume you wouldn’t have had studies that have hit the completion point yet that have started post so if you can talk about how it used to function and how you think it would function moving forward but**

R: Yep.

**I: But when it actually comes and you said you have experience entering things into the EudraCT so, you know, my trials finished, how does that wrap up procedure start to look like to get you the results on time and to then, you know, make sure they get up and in inputted and all that.**

R: Yep so once the trials finished and the database is locked so all the data’s clean, the data’s locked it gets like exported to go off to the statistician to do their thing so at that point we would remind the Investigator, “You’ve got 12 months to get this published to get the report back to me,” and we have a template basically EudraCT is not very user-friendly and it, it’s just not very nice so we have made a word template of basically all the information that needs to go in there. So I send that off the investigators and say this is the format I need the data in to like the adverse events for example, it’s a very specific format that I need it and then once we hit about the nine-month mark, we will send them monthly reminders, “If I haven’t had your report yet, I’m gonna need it in the next three months.” And normally at 11 months, we’ll start asking them weekly for that report, just because I need time to upload it as well, especially if it’s a big multi-centre study because you can’t just attach something to you that you have to physically type in every single entry.

**I: Tabular, yeah.**

R: Yes [laughs] it takes time so I, yeah so, I just let them know I need time to be able to do that to meet the deadline.

**I: So how was that, it’s not the way things function anymore but how was that working-, just curious like how was that working? Were people generally getting things to you on time or was there a lot of chasing involved, like how did that look especially with such a big portfolio I assume?**

R: Yeah, it did vary generally everyone was pretty good in getting that information to us or if for example they were waiting for like analysis of a lab endpoint for example that they didn’t have yet, I would just say, “Send me what you’ve got. I can start inputting that in and then once you’ve got me the last bit that will be like a half hour job rather than the two-day job it is to enter all the information.” So yeah, we do work with our investigators to try and make it easier for them as well but generally people are pretty good. It’s normally like I say if there’s been a delay somewhere along the line, there might be a delay in data cleaning. It might be a delay in some lab analysis. It might be the statistician wasn’t available so there are various delays but generally the investigators are pretty good at getting the results to us in the timeframe.

**I: Yeah, and have you ever had a situation where you uploaded some results and then updated them because you have that capability too, right?**

R: Yeah.

**I: Yeah.**

R: I have done that in the past yeah so if, if we hit our twelve months and I might have all the primary endpoint analysis I’ll enter that in and then if the secondary endpoint comes at a later date, I will update it to put that information in there as well.

**I: Excellent and then so that, the reminder emails and that monitoring process sort of how is that managed, like what is the actual like way you like is there just a big spreadsheet or, you know, how do you do that?**

R: Yeah so, I have a spreadsheet that has all our live studies on. Once they get completed, they move onto a new tab and I have a column for CSR deadline and then once we hit that month of when it’s due, they move to a separate tab for basically uploads and that’s how I track it. So I would go in there every month see what’s due or due to be due soon and keep on top of it that way and at the same time all of our trials have a dedicated [trial monitor] on them and there’d be the ones who’d be emailing the investigators and chasing the data so I would just tell them, “Oh, this is when the CSRs due, please can you put a calendar reminder in your diary to chase them every month,” for example and that’s, that’s how it’s managed.

**[Short clarification section removed for potentially identifiable information]**

R: [The trial monitors are] the ones who would go to site and do the source data verification, so they check the medical record matches the database.

**I: Gotcha okay and then so now that EudraCT and the EMA are out of the picture do you have a sense of what putting results on the ISRCTN or clinicaltrials.gov will, will look like moving forward?**

R: I imagine it will be similar in the way we would remind them and chase them for upload results, and also, as sponsor we need a copy of the results I’m not a hundred per cent sure without looking what format it goes into each of those registries.

**I: Mhm.**

R: So, we can still provide them with our template, or they can use their own template depending as long as the results are published, and we receive a copy but yeah without doing it I can’t say for certain exactly what they’ll look like, but we would still chase them and make sure the results are uploaded and that we receive a copy as well.

**I: But it sounds like that might sit with the investigators now that it’s not that, like I know that there’s you can still put things, results on the EudraCT so eventually all those will get wrapped and submitted but**

R: Yeah.

**I: but the moving forward for these other registries it sounds like that will, that onus will fall on the investigator most likely unless something changes between now and-?**

R: Yeah, most likely it’s difficult because for EudraCT I would be the contact point so when I log in I see all those trials that for the other databases I don’t have them in my personal registry for example

**I: Yeah.**

R: and I’m not sure if I could access them, so yeah that’s something we’re gonna need to explore down the line whether we [ask] the investigator to do it or whether we automatically get given access to all those trials so we can do the uploads ourselves.

**I: Okay.**

R: That’s something that yeah, we still need to look into and determine how we’re gonna do it.

**I: Great so and then is, so does your involvement end in in terms of like results dissemination, does your involvement end at the getting them into a, like reg-, like pretending that EudraCT is still the primary mode of functioning**

R: Yeah.

**I: Does that sort of end at getting that on the registry or is your like office involved in like following up on publications and things like that as well at all?**

R: Yeah, no we end at posting on there, yeah, because we do the regulatory responsibilities everything else fell under the CI so they’re yeah, they do their own publications or depending on their funder agreement where they need to publish, who they need to tell that. The onus for that all lies on them, yeah.

**I: Great and so one thing I’m particularly interested from you, from your experience is unique to some of the other people I’ve chatted with for this study so far is is has there, is there any sort of differences in your job in dealing with the University versus dealing with the NHS Trust or is it all pretty uniform in the way like the organisation runs?**

R: Yeah, it’s pretty uniform so our SOPs cover all the organisations, and I wouldn’t, we’d, our office doesn’t treat them differently, they’re all treated the same. There might be certain nuances but largely they’re all treated exactly the same and there wouldn’t be a difference.

**I: And they’re all, yeah and they don’t like there’s not more sort of like complications or working with an NHS Trust in the University or anything like that, no, okay?**

R: No.

**I: So I’m interested what you hear works particularly well and particularly not well about the way, like are there, what would you like to see improved and what do you think works particularly well about the way organisation does this like manages these processes for registration and reporting?**

R: Yeah, I suppose that’s a difficult one to answer at the moment, but I think moving forward if we could have access to those registries to do the uploads ourselves that would be good in a way that we can remain responsible for it. It’s a difficult one to answer because the trial, I don’t have the trial results, I can’t make someone analyse their data any quicker or get back to me any quicker and I don’t see how as an organisation or an institution that could be managed either. It’s just the investigators know the rules, they know their workloads largely they do get them to us on time, so I suppose the system does work. It’s just when there’s unforeseeable delays in there.

**I: Right okay and then so you said, so you’ve been in this role for a year you said and then**

R: Mm mm.

**I: were you at the, were you at [this institution] even like in your prior position as well, yeah?**

R: Yeah, yeah.

**I: And then so over the time that you’ve been there have you noticed sort of changes in the way that these processes work like, like have things changed for the better or for the worse like over the time you’ve been at the organisation because it sounds like you’ve been in one form or another interacting with these processes like all along so like, you know-,**

R: Yeah so not since I’ve been there but I think a couple of years ago now when it was published about how bad the, especially the University sector was at publishing results there has been a big improvement and we did manage to chase everyone and get all our backdated results uploaded which was good so yeah, now there’s a firm process in place which as I said we make people aware right from the beginning this is a requirement it has to be done and we remind then throughout so there has been a big improvement in the past couple of years.

**I: So that focus sort of arose from that attention that got put on the like the processes for that?**

R: Yeah, yeah, I don’t think I don’t think people realised the extent to how much data was missing for example, or who’s responsibility it might have been to ensure that was on there so for some of them the data had been published in a journal for example.

**I: Right.**

R: We hadn’t closed the loop and put it on the database and some of that was due to the EudraCT not being very user friendly.

**I: Right sure so it sounds like yeah like EudraCT was one of the, in terms of, we’re talking barriers, the EudraCT itself would it be fair to say that was a barrier?**

R: Yeah, and then once we got the results, the backlog of entering all that data in, yeah and one of my colleagues did [give advice] on how to get results uploaded into EudraCT because they know other institutions were having similar problems and difficulties in doing that.

**I: Yeah no I know that [this institution] has been a bit of a model I think for how to, how to do this really well so that’s why, part of the reason I was, you know, very excited to talk to you that it’s really brought it together over the recent years and become a leader in the coun-, within the country and within Europe I would say and like, you know, at least meeting those regulations and navigating that process which I know can be very difficult.**

R: Yeah.

**I: So, what so when that change was sort of happening to the extent that you’re aware, like did that involve a lot of buy-in from sort of like high level, like high level people at the, at the either the individual institutions or the, like where did that pressure sort of come from, was it-?**

R: I’m not sure I wasn’t involved in that process to be honest or those discussions so I couldn’t say without making assumptions.

**I: Yeah, no worries, I wouldn’t want you talk about things you you’d don’t know, you aren’t aware of but in the off-, in the chance you were. Alright, let’s see, okay yeah so talking about how so with registration falling to the, to the individual trialist and now potentially some of that results reporting responsibilities and the inter-, ongoing interactions with the registries what sort of like training or like onboarding to people to familiarise them with that processes like what, what to what extent does that happen and what does that look like and are you involved at all in that?**

R: So I suppose we don’t give training on like the databases themselves. All of our Chief Investigators do CI responsibility training and one of the items in there will be that they have to register it and do have the results available but we don’t give specific training in that, no.

**I: Yeah, so you don’t say like this is how clinicaltrials.gov works and how you work or something like that?**

R: Yeah.

**I: Yeah, okay?**

R: No, we let people navigate that themselves.

**I: Sure, sure sure. Are you aware of the individual institutions sort of do that sort of thing at all, just if you’re aware?**

R: I’m not sure and again it will depend on us so some of our studies will have Trial Managers and I know that will be their responsibility and if that Trial Manager sits within like a CTU or a CRO they may do that or have training on that but again it depends on how each individual study’s set up, yeah.

**I: Okay and then what so when you are in this job and you, like are there maybe you don’t have such a good answer since you’ve been, it sounds like you’ve only been in this role for about as long as Covid’s going on**

R: Yeah.

**I: but like are you involved, are there external resources to your organisation that you rely on to try to, to like under-, to like essentially, do your job better to improve it, like understanding the regulations or understanding the like best practices for dealing with these sorts of things, you know, are there any professional organisations or outside places you go for that?**

R: No apart from like the MHRA and the HRA webpages, blogs not really. We do have [some in-house training resources] but we would just check the MHRA and the HRA web pages or if it’s we have some European studies, the EMA web pages.

**I: Mm so there’s like a good would, would you say there’s like a good sort of knowledgebase within the organisation that you feel like you can turn to for questions or issues like with the-?**

R: Yeah, yeah.

**I: Great and then let me like go through my questions here and make sure there’s nothing else I want to make sure I touch on. So, are there any like just while we’re talking, so are there any sort of specific examples of, you know, you don’t have to go into detail about the exact trials themselves but just like experiences from being in this world for, you know, in a year and dealing with the requirements, where like is there any sort of individual experiences that have stuck out to you about this process that you might want to tell me about or, you know, just like, you know, this was, this happened this way and I found it instructive or just in anything you might wanna convey?**

R: Yeah I suppose the last year like we said has been different to how it would usually be 1) because of Covid and 2) because of Brexit so at the moment there are a few studies where results outstanding but that’s because they’ve been delayed due to Covid so the trial finished, database has been locked but a lot of the lab analysis, the labs have all got redirected to Covid work so they haven’t been able to analyse the research samples, so for example we might have a big multi-centre study so they take samples throughout the trial. They get stored at the site and then once the trials finished that all gets transferred to the central labs and they do a big bulk analysis and we have a few studies where that’s been delayed because of Covid so we haven’t been able to upload the results because of that or even in some cases the data cleaning hasn’t been able to be finished because the hospital sites don’t let the monitor’s on to look at the data because they’ve got a no visitor policy.

**I: Gotcha.**

R: So, at the moment there are delays to reporting and I did contact the EMA about this and they kind of just said upload them when you have them [laughs] like okay. [laughs]

**I: Yeah that’s sort of the, I think that’s a difficulty with EMA compliance with something you won’t have to worry about in short enough time or worry much about but the fact that other than something like getting public attention to the matter, there’s really no like repercussion from the EMA from not, from not, that’s why it was sort of allowed to be bad until someone pointed it out there was no repercussion for not doing so.**

R: Exactly. Right and then I suppose more recently with the new trials asking investigators to make sure they’re registered and to show me a link to the registration so I can check, a few of them have come back saying we have a EudraCT number and I have to explain, “Oh yes the MHRA still asks for a EudraCT number but that doesn’t mean it’s actually registered on EudraCT and that’s causing a lot of confusion because why we do have a number if we’re not registered so my EudraCT registration covers me and then you have to send them the link to the MHA website where they’ve updated the information to say, ‘not the case anymore,’ so I think there is some confusion of why do we still get that number if we’re not registered on there. So, I don’t know if that’s going to change moving forward if the UK will have its own numbers they give out or their own version of EudraCT rather than using different databases.

**I: I assume that would be pre-, so anything that started since January 1st I assume wouldn’t be getting EudraCT numbers at all?**

R: No, you still get if you-,

**I: You still get a EudraCT number.**

R: If you start a trial today you still have to get a EudraCT number, yeah.

**I: Does it go into the back end EudraCT system still?**

R: Yeah, so basically anyone can register for a number

**I: Okay.**

R: but to actually get on the database that’s what the regulatory so once you have your regulatory approval like your MHRA approval, that’s when they post it on there. So there might be lots of numbers that are never used.

**I: Oh yeah that’s interesting.**

R: So, you can-,

**I: But they’re still giving out, I guess they just haven’t made a process for new numbers, yeah**

R: Yeah, they-,

**I: but that’s interesting, I wonder if those numbers are still officially given to the EMA or essentially the MHRA is just making their own numbers, that’s really interesting to hear. I had not heard about that yet, that’s really interesting.**

R: I think that’s the main identifier they use they just haven’t changed it so that’s just they’ve stuck to it yeah and that’s causing confusion.

**I: Interesting, very interesting to hear that. So I think one other question so you mentioned that the investigators you deal with have generally been pretty good about staying on top of things but I’m just curious do you ever hear anything from that side, so I’m not sort of for this study I’m not speaking with investigators, I’m mainly just speaking with the governance and research integrity staff and people like that, even Trial Managers but not investigators directly but I’m interested to hear if you hear second hand any complaints or like whinging from from investigators about some of these requirements or-,?**

R: Yeah so, I suppose the, the main complaint would be that the 12 months does seem to go very quickly.

**I: Okay.**

R: Especially if it’s a paediatric study and you’ve only got those six months there’s a lot to fit in to that window, obviously depending on the complexity of the trial but we have some studies that are over like 60 sites and it’s just you have to get all that data collated into one which can take time and I suppose very, very occasionally we have a few investigators who are not ready to publish yet and they might wanna do a second phase of their trial and they’re a bit concerned that if they put this information out there that I suppose in a way someone might steal their idea if that makes sense they might have done like a small feasibility study, ‘Does this drug do that?’ and the results, ‘oh it looks like it might do, we need to explore that further.’ I think sometimes they may worry that someone else might see that and take that opportunity. I don’t think that’s ever happened and when we explain it’s a legal requirement, we have to publish the results they’ve all been fine but yeah, I have had in the background sometimes that concern comes up. Also, some journals won’t publish if the results are already published and if their, if their journal submission isn’t quite ready yet that can cause a few issues and again, they have to explain it so a legal, legal requirement.

**I: Yeah so, I’m interested have you ever heard of that happening, someone getting a, someone having difficult publishing because the results went on the EUCTR first?**

R: Yeah so, I’m not involved in that directly, but I know in the past [there have been rumours of] this journal has turned them down because it’s been published, or some people have tried to push forward their publication because of our deadline to post.

**I: Yeah, that’s interesting to hear because I’ve heard that fear before, but I’ve never ever had anyone show me sort of an example of it in the flesh as it were, like actually say technically the good journals aren’t, like at least a lot of the journals that sign onto the ICMJE aren’t supposed to do that, they’re-,**

R: Yeah, but there is that fear and is a worry and I don’t know a specific example, but I think it may have happened in the past which has made people cautious.

**I: Interesting. Great and then just-,**

R: And we do try to explain what we post isn’t the same because it’s just like more of breakdown summary of results whereas in the journal have all the background all of this needs that whereas ours is just very simple statistics

**I: Yeah, there’s no interpretation, there’s no, there’s very little methodological detail as it were.**

R: Yeah, there’s no like discussion or anything in there or-, yeah.

**I; Great so just to, one other thing I wanna touch on just to make sure my understanding is correct, so concerning Brexit so the MHRA has like within anyone, not just a clinical trial but essentially like the UK is sort of still operating like a lot of those laws exist still as if we were part of Europe but they’re just for the UK now as it were, right?**

R: Yeah.

**I: So they’ve chosen to maintain those six and twelve month deadlines that existed for the EMA, do the clinical, the European Clinical Trial Directive but now they’re just saying they just have to appear somewhere like on a registry. It’s not EudraCT anymore that they have to show up on?**

R: Yeah, and they do give ISRCTN and clinicaltrials.gov as an example on their website as well.

**I: Okay great so yeah I think I am pretty much, that’s pretty much all I wanted to touch on but I usually like to just ask is there anything that you’d like to mention about, you know, the topics I might be interested in that I didn’t talk about or that you’d like to, something you were expecting me to ask and I didn’t or a nice thing, answer you had thought about and prepared that I didn’t get, give you a chance to talk about?**

R: No, I don’t think so. I suppose the only other thing I recently went on like an EMA training day for the new EU regulations that they’re bringing out and when they got to the results sections, it looked like you just uploaded a PDF [laughs] so that was very good news. So hopefully in the future if it’s just, if the investigators just write out their results and you upload a PDF that would be a lot easier and a lot user-friendly for people. I imagine that would help with the posting of results.

**I: So that’s for the new system that will come online sometime in the near future.**

R: Yeah, it’s [laughs]

**I: So, I assume, I guess one more follow-on question on that regard, I assume [with your institution being large] I assume you may still be interacting with the EMA system. You don’t have to for all of your trials, but I assume you’ll have trials where you’re the primary sort of site that have European co-, like there’s stuff that will still end up but via the other countries, right?**

R: Yeah, yeah because we do have international studies, yeah so when it happens in another country it’ll still be registered on EudraCT and followed up in that regard but again because there’s new laws now so if you’re a UK sponsor you have to have a co-sponsor or a legal rep in the EU to do trials there.

**I: Yeah.**

R: So, when we have a co-sponsor, that because their responsibility to make sure it’s registered and published and same if we have a legal rep, we’ll have an agreement with them and that will be one of the services that we ask them to provide to do the registration and posting of results.

**I: Great so none of, like you, like none of the constituent sponsors of your organisation would or like never say never but usually would not be ever listed as the sponsor on a, on one of the like, a EudraCT registration anymore would be your partner in that country that would be listed as the sponsor.**

R: Yeah.

**I: Okay great excellent so if there’s nothing else, I going to shut off the recording.**