**I: So just to get us started can you tell me a bit about your role?**

R: Yeah, I’ve been at [my University] for probably 20, just over 20 years. I’ve been running the clinical trials unit there for more than 15 years now, so I started in that role just as the clinical trial came in and the remit of the unit is, you know, NIHR, UKCRC clinical trials, large multicentre clinical trials typically. We started out specialising in [disease area] within one school of the University over the years we, we made the case that it made sense to expand and support other, other areas and so now we support trials across the whole of [the University] and yeah so we, we basically work with statisticians, data managers, trial managers running a range of clinical trials, everything from early, you know, pre-registration device trials through to big multicentre pragmatic, you know, international late phase studies, so every every myriad of everything.

**I: And that includes CTIMPs, you’ve got to run CTIMPs as well, yeah?**

R: Yeah, yeah. Now [this University] is unusual in that we have a separate sponsor office, well I don’t know how unusual this is actually, there’s a separate sponsor office so obviously every organisation will have some sort of sponsor office but in many places they’re very, I don’t know what the right word is, tick box light touch, very much NHS R&D, you know, go through checks, sign off but really not very involved in the actual conduct. Unusual at [this University] they, they put together a joint office purely for CTIMP responsibilities back in, I don’t know, 2004, something like that and so that group is very heavily resourced but only focused on CTIMPs and so we’ve ended up with, with a, you know, a huge, I think there’s something like 35 full time staff just overseeing the CTIMP studies of which there’s probably about 80 or 90 at any one time so it’s a very high level of oversight. And so there’s a bit of a two tier thing where CTIMPs I’m sure you’re aware, you know, [the University] will have perfect reporting of CTIMPs. It’ll be [perfect] because there’s this huge resource that of course everything must be reported because there’s so much manpower and it’s very telling actually, it’s a very good you know, yeah, it’s, yeah, it’s a 15-year study and what happens when you highly control one element and don’t control the other element.

So non-CTIMP studies are largely left to their own devices organisationally. And so, as a CTU many years ago, I’m sure you know CTUs well enough to know that, you know, a CTU might run half a dozen studies and in some places, they will be very much, you know, pick out the cream of the crop. They want the high impact, you know, big hitting good papers and shouldn’t and could take the best ideas and make them great which is good. We took a slightly different approach which was yes do those studies but many years ago we also looked across the organisation and thought well there are lots of researchers trying to do research well and they simply don’t have the infrastructure to do it well.

And even with the best will in the world they’ll fail and so we decided to do things like provide randomisation services cheaply to those studies, even if we did nothing else [and there were some anxieties about, ‘Oh but, you know, couldn’t they run a study really badly and the CTU had supported it.’ It’s like well, ‘they could but they’ll have run it a little bit better if we take randomisation, make it independent.’

**I: Yeah.**

R: It would run a little better if we’d run an EDC [Electronic Data Capture] system and then actually involved in designing their data collection packs so all of those things will makes things a little better and so we’ve been running that as a strategy for many many years and right from the first study back in 2004, 2005, you know, we, we decided to mandate that if a study used our randomisation system, we wouldn’t make the system live until we saw their public register.

So, in a very simple way, it just became an easy control to scoop up as many of the study’s organisationally as we could. At the very least, let them use our randomisation service and as part of that process we would just sit there going, “You still haven’t got your registration, we’ll make it live, just need your registration. Do you want us to help us with your registration but register it? “And actually, that worked, worked well because it was very apparent back then that more than half of investigators had no idea about the Journal Editor’s statement. They didn’t know they were meant to register their trial. It wasn’t ill intent; they just didn’t know.

**I: Yeah of course.**

R: And actually, that was a very easy way of making people aware of that and our main concern was the people didn’t get to the end of the study and found they couldn’t publish it so that was a quick easy hitter but that only hit the studies that happened to come to the CTU. I mean we’re now, I think we’re now providing randomisation for about half of all trials across the organisation but not a 100 per cent of them.

**I: Yeah okay and then just so I understand organisationally, so I understand about how the, you have like sort of the, the Super organisation that sits on top of [the University] and a few of the other Trusts and manages the CTIMPs and then, is it just, you guys have one single CTU because I know some Uni’s also break up their CTUs and will have multiple so you have one big one?**

R: No, we’ve, we’ve managed to have one thankfully so avoided, we’ve avoided [multiple]. [laughs] [Short non-relevant interlude with identifying information removed] Yeah, it gets a bit well the trouble is you think, you know, the multiple teams of QA Managers and uff yeah doesn’t make sense. Anyway, so no we’ve been, we’ve been fortunate we’ve managed to hold it one which has helped but we’re not mandatory and I think that’s the key and we’ve and there have been mutterings over the years of making investigators work with our CTU and I’ve always resisted those because I never think that’s the way to do things. I think there has to be academics must have choice.

**I: Right.**

R: So, we’ve never been mandatory, we, we have no particular desire to be mandatory but we’re happy to help whoever comes. What the University has lacked historically is a proper central governance structure for all other research. That isn’t CTIMPs because there’s the College Ethics Committee and obviously there’s a sponsor signatory for ethics applications that go through REC but really there’s not, historically, not been much scrutiny of those and so there’s no mechanism to chase to make sure that they are reported and things like that so, you know, back, back in the day when the AllTrials initiative first sort of appeared it was us that drove getting [the University] to sign up to it. It was us that sort of tried to get the organisation a bit more engaged with the idea that that this is, that this is an issue that isn’t going away.

**I: Mhm.**

R: There is a problem here. Yes, we’ve solved registration up to a point but it’s still not there, but the world is catching up, you know, the ethics committees, it’s becoming normal to register trials but publications still weren’t brilliant and the timeline to publication wasn’t great. There was a bit of a roadblock organisationally in that there was one person who just didn’t see there was a problem and I think what they really meant was they could see there was a problem but couldn’t see that there was a way of solving it without spending money

**I; Yeah okay.**

R: and and took great pride in never spending money. [laughter] That persons’ left and actually that’s affected a huge amount of change

**I: Interesting.**

R: So the [name] who I put you in contact with, I’m not sure if [they’ve] been back in touch with you but [they’re] charged with setting up a sort of integrity governance for all research across the University and so in the long run I think it’s [their] office that will probably be tasked with making sure that there are systems to track things through. In the meantime, you know, things have happened, so things like when you’re putting a grant in there are trigger points where the various forms and processes you go through alert you to the fact that there’s an expectation everything will publish, that, you know, everything must be registered, that, you know, all that sort of thing. I still think it should be driven through ethics quite frankly, I think it would be more efficient to do it at national level.

**I: Great.**

R: But that’s me.

**I: So that’s all excellent stuff and we’ll come back. I’ll touch back on a lot of what you just said throughout.**

R: That’s fine.

**I: why you think registering and reporting clinical trials like is important, why, why is this something we should care about and do?**

R: Well, I think the, I think the effect of publication bias I think is fairly evident when you look at the data and the number of trials that are missing from, from the evidence base and I think there’s been a very good job by AllTrials to make people aware of that, to publicise it. I think that it’s probably a bigger issue in many ways for Industry because I think the trials that don’t publish in the public sector mostly not exclusively but mostly are trials that don’t matter

**I: Mhm okay.**

R: and I’ve tended to find over the years because I’m paying quite a lot of attention to this internally, the ones that fall by the wayside not always but most of them tend to be small feasibility type studies and I definitely lose interest in it. It’s rare of big definitive interesting studies, even if it’s a negative result to fall by the wayside. It does happen but it’s it’s more rare.

**I: Sure.**

R: And on the whole, I’ve tended to find, and this is entirely anecdotally, when you speak to investigators it’s clear that the ones that have fallen by the wayside is because they’ve made a judgement that clinically it really isn’t gonna make much difference to anybody, even if that was out there in the world.

Whereas the reasons for publication bias within Industry are very different. The reason their results don’t become public or didn’t become public historically were for very different reasons that are likely more damaging. I think it’s still good practice to get them all out there, but I think, you know, the trials that we end up chasing for publications and for results mostly are negative and but more importantly mostly are very poor quality.

**I: . What so, what does and then you said also that your office is also willing to offer help for registration and things like that can you just talk about, a bit more about what that looks like to me. So I’m an investigator, I’m looking at getting a trial started. I want to, you know, work with the CTU.**

R: Yeah.

**I: From a registrations standpoint sort of like what does that process like look like?**

R: Yeah if it’s a CTIMP then well up until recently that would have been EudraCT and so the Uber office with loads of money does that so we don’t worry ourselves too much about that because they can sort those out. So, for the non-CTIMPs people have to choose usually between clincialtrials.gov and ISRCTN. Sometimes it’s simply us reminding us that it’s a funder requirement of their funding body that they go to ISRCTN and they just haven’t noticed because they didn’t’ read the letter properly. [laughs] and sometimes that if that’s NIHR funded, they pay for it and again people often haven’t picked up on the fact that there’s a system for that. You just need to do it but it’s not that difficult. So signposting is what all that most people need. For the ones that want to go to trials.gov again pointing them in the direction of the sort of administrator within the organisation who controls that so that they can help them if they get stuck. We find people have more trouble with trials.gov than all trials, oh sorry than ISRCTN just because I don’t know, ISRCTN they’re a bit more human, you can actually speak to people. Trials.gov, from what I gather they send communications out to people and literally they can’t interpret the words that are being said, they don’t know what they’re being asked to do and they just get, really sent up a roadblock so I prefer to send people to ISRCTN and so what we’ve done more recently because the vast majority of studies are being scooped up and get to ISRCTN either by through the funders or whatever, it’s working quite well and so the few that fall by the wayside we decided that what we would do is we’ve set up an arrangement with ISRCTN where we pre-pay for registrations so that rather than the investigators having to fiff faff about, figuring out how to pay them because that seems to be the biggest barrier. [laughs]

**I: Interesting yeah no I was, I was actually gonna ask a follow-up about that yeah, interestingly that.**

R: It sounds ridiculous but, you know, people go to trials.gov because they can’t be faffed figuring out how to pay ISRCTN.

**I: It’s like, it’s what about 300 quid or so right to register?**

R: Yeah, it’s not very much, it’s not very much. So, some of them end up putting another credit card and then reclaiming it and all sorts of but they’re just, they just can’t bare to navigate the administration of trying to pay them.

**I: Right.**

R: So, we said well, you know, that appears to be as far as I can work out the biggest problem so we’ll pay them for I don’t know, 20 or 30 registrations up front and that way we can just say to people, ‘Here’s, here’s your number’ and we’ll just cross charge you.”

**I: Yeah.**

job done.

**I: Interesting okay.**

R: I think we’re the first organisation ISRCTN have done that with, but we said we’d try it out for a while see how it goes because it’s not many studies now, so we may as well just try find an easy solution for those. I’d rather we go to ISRCTN, I don’t like trials.gov

**I: British word would be faff about registering on clincialtrials.gov, is that like would that be accurate?**

R: Investigators like trials.gov because it’s free.

**I: Sure, but from a, from a doing it, like why do you dislike it?**

R: I don’t, I don’t even think it’s more bureaucracy and faff. I think there’s a lack of intelligence coming back from trials.gov

**I: Okay.**

R: you know, when, when I interact with ISRCTN there’s a flexibility and a thoughtfulness about them so they will recognize that if they’ve been trying to contact an investigator for the last ten years to get the result of a trial and that investigator has long since moved on from [the University] and, you know, they’re probably findable somewhere in the world. If I can track down a paper that looks like the primary paper and I can reasonably read it and say yes, I believe that this paper links to that trial, they’re perfectly comfortable with me emailing them and saying, as far as I can figure out this one goes with that one and somebody will actually read the paper and see whether they agree, and they will link it even if the person who set up the account isn’t there to do it. No chance in hell with trials.gov.

**I: Right sure.**

R: Just not gonna happen [laughs] or they expect that it’s your decision whatever you like and it’s like a bit of, a bit of iteration would be nice because, you know, with the ISRCTN, you know, they can see, you know, somebody in the organisation’s trying to sort this out. The person who ran the study is long long gone and we’re just trying to do a sweep through and tidy up loose ends from old studies but it feels a bit more collaborative and a bit more can do.

**I: Interesting.**

R: Than than trials.gov.

**I: So the process sort of you’ve described it sounds like, so are you essentially guaranteeing, by working in the for the trials you work with specifically are you sort of ensuring that all those registrations are also prospective, like is that essentially built into the process?**

R: Yeah so, they’re all prospectively registered built into the process. We have an escalation path in our SOPs where if a study is about to start and they haven’t got the registration visible to us as in we can’t see it physically with our eyeballs on website the administrators will escalate it to me before the randomisation system goes live so occasion they’ll make an exception where, you know, they’re telling me, “We’ve sent it all but the payment hasn’t gone through but we’ve done it I promise.”

**I: Right the date will show up as prospective when it goes live, yeah.**

R: Exactly so, you know, with those ones we, we have a process where we’ll make an exception, let the study start recruiting on the expectation that any day now this is gonna appear in the public domain so, you know, but if, and we also I think we have a process where if a study’s exempt from registering for some reason we’ll allow those to go ahead but all of that is built in because again the administrators don’t know which, which are okay and which aren’t. They just follow a process of it’s either there or it’s not and that’s that.

**I: And do you have processes in place, once again I assume this would be mainly for non-CTIMPs and CTIMPs probably mostly work through the main larger office, but do you have processes then to about updating like how are registries then maintained over the course of the study?**

R: Again, depends on what we’re doing, so if all we’ve done is a randomisation service then, for a study then what we will do is I mean the randomisation service goes up that’s the end of it as far as we’re concerned until the study ends and then the administrators would keep bothering the investigator for the primary paper so even if all we’ve done is a £500 randomisation service they just get these really irritating emails from us saying, “Have you published yet? Have you published yet? Did you get one, oh well done you, you’ve finished, have you published yet though? [laughs] ‘Our records suggest that you’re about to publish, have you published?’ [laughs] Thanks for coming.

**I: [laughs] Right.**

R: [laughs] It’s surprisingly effective.

**I: I bet.**

R: but I mean they log everything so they just, you know, every quarter they do a sweep through and contact everybody where and if they say we’re not going to publish for another year, we just put it back by a year and then we’ll turn up again, going ‘Hello, us again.’ So we do that on everything, everything where we’ve done randomisation. If we’re not otherwise involved in the study, then we wouldn’t pick up if they do a protocol change and they don’t update the register.

**I: Uh-huh.**

R: But if we have also built them a database system for the study, then a protocol change that changes the eligibility criteria should trigger the database to be updated and as part of that process they would check back to see if they’ve updated them in the protocol have they updated their public register so there would be a prompt to the team. Again, their responsibility to do it but we would prompt them to say, you know, we’ve notice you haven’t, you might want to do that.

**I: Yeah.**

R: If we hadn’t of done the database as well and then if we have any people involved in the studies, you know, Trial Managers, statisticians, health comms or whatever then I would expect yes and TMGs, that would be routinely picked up and and dealt with.

We do get involved in in externally sponsored CTIMPs where there is no, our, our sponsor office wouldn’t be involved in those and as of for those we just do exactly the same, we, we don’t do anything differently.

**I: will closing out a study on the, on it be also like a built into that process, like switching the trial status to completed or anything like that, yeah.**

R: For the studies where we’re actually running them, yes. For the studies where we’ve got the publications what we started doing is that with ISRCTN and trials.gov, I think every, it’s either once every six months or once a year, we pull off everything unpublished organisationally and we do a sweep through to see if there’s any that we’ve got a record that they’ve been published that are not showing as having results on the register.

**I: Mm interesting okay.**

R: And it’s quicker for us to do it as a sweep through everything and this is where I found ISRCTN incredibly helpful because they were perfectly happy for us to in fact, they were so helpful because they’re downloading function wasn’t working properly for me and I couldn’t everything that I wanted nicely and so they did me an export. And they were comfortable with us just updating the whole spreadsheet, sending it back to them and they would just go through it which was, it’s helpful just [laughs] And in some cases because the reason I first started talking to them years ago was because within the [our organisation] our email addresses have all changed in one part of the organisations, so they were chasing investigators on email addresses that that didn’t exist anymore.

**I: Oh interesting.**

R: And so, we first got in touch with them because we could see all these registrations, saying, ‘Oh contacted so and so at this email address, no response, no response.’ And I thought, ‘Well you’re never gonna get a response. They’re going into the abyss; they’re not going to be going anywhere.’ And so we’d contacted them and sort of given them a list of all the updated email addresses of all those investigators because a lot of them were still at [the University] and yeah periodically whenever we had time we sort of dipped in and had but it’s not been very, it’s been a case of just fitting it in when there’s time with, you know, we’re, we’re not tasked with doing it organisationally, we’re not, it’s not necessarily our responsibility but we’ve sort of done sweeps through because it’s, it’s a sensible thing to do and until the organisation gets itself to a point where it does do it systematically which I’ve always thought is bound to come eventually so it’s just doing what we can on no resource until they sort of wake up and get there or ethics takes it over, I don’t mind which.

**I: something might never find its way into a journal, would you accept, like they just said, ‘Okay we’ll write it up and stick it on ISRCTN and that will be resolved,’ Like would that sort would you, would your office be happy with that?**

R: Yeah there’s a few teams where we’ve gone back to them and said, “Look if you’re really are never gonna publish and I’ll tell you this is almost always where it’s PhD student project. Almost always, so where we can with student projects, we’ve tried to make sure that the thesis goes into ETHOS.

**I: Sure.**

R: So, if it’s been written up in the PhD thesis and it’s in ETHOS, I think ISRCTN don’t accept that that’s a publication.

**I: Yeah.**

R: But I sort of think well it’s not bad, it’s out there. It’s written up somewhere and it’s publicly available so in my mind it’s probably the best they’re gonna get.

We have pointed a few PhD supervisors because usually by the time we find these ones these PhD students have long given up on academia. They’re now working in a bank somewhere. They’re ain’t gonna do anything about this. [laughs] Yeah they’re primary school teachers now [laughs] so they’re not gonna do anything about it and quite frankly it was a student project

**I: Right.**

R: it’s a learning exercise and I do think there needs to be recognition that there is, should be a separation between what is meant to be a learning exercise and a clinical trial. And we have worked really hard to try to make sure we don’t have Phd students doing things like CTIMPs because you can’t let a CTIMP fail so how can you let a PhD student do it as their project without giving them an unfair advantage over other PhD students so I think there’s a lack of recognition that that PhD student projects are different. You must be allowed to do a bad PhD, you know, if you and your supervisors elect to do an unpublishable PhD then it should be unpublished beyond the dissertation write-up and there is a process to get dissertations into the public domain and I actually don’t see why that isn’t good enough but a couple of supervisors I have gone back to them and said, “Look, ISRCTN have a process for you to upload the results, but you have to put it all into their format

**I: Yeah.**

R: and they’ve made mutterings about, ‘oh they’ll try and find somebody to look at it.’ but the chance of them actually doing it I think are pretty slim.

**I: is it been kicking and screaming or has it just been sort of like they just do it because you tell them they have to or how has it looked and changed over the years?**

R: In the early days it was interesting, the early days when they didn’t know about the Journal Editor’s statement the early response was, you know, “Aren’t they being ridiculous? What a lot of nonsense. We’re academics, don’t you know type thing.” That wasn’t, that that waned fairly quickly the the biggest objection was having to pay out money.

**I: Okay.**

R: So this sort of idea there was some kind of a money making scam so you know what people can be like. Again, who owns ISR, who owns ISRCTN, who’s benefiting from it. This idea that somebody was making a profit on the back of whatever so there was a bit of that in the very early days. Once you pointed them to the Journal editors’ statement they tended to hush up. I think once they could see that it was, you know, it really was the Journal Editors, let’s not, you know, they’re not, they’re not peeing around here, this is what they mean. They’re not joking, just do it. So actually, I think most people accepted that this is a good thing in principle and the main resistance was the actual bureaucracy of doing it, not the principle. A few people objected because they felt that would make their ideas public and that others could then steal their ideas. So early on there was a few, certainly the, the sort of the more novel, earlier type stuff and there was a sort of suspicion that somehow this would be damaging to them because people would know about the research too early. But like I say, it was very clear that that world has changed so just get used to it move on, you know. You don’t get that anymore but in the early days there was definitely an element of that. What other? Definitely the early days this idea that, you know, well they didn’t believe the journal editor would really not publish a good trial just because it wasn’t registered and I think a few had to be made examples of before they really believe that did in fact happen.

**I: Yeah, and I believe that they have at least some of, some of them.**

R: Oh yes, no we had one, we had one when somebody turned up at out office had been rejected for not registering and it was a trial we hadn’t been involved with but she was just completely distraught because she knew nothing about it and I was like well, ‘should have come to us.’ [laughs] But it was, you know, they just end up in a worst journal. So really from the early days we just always framed it that this something that’s really important to do unless you’d like to publish in the Beano.

**I: Yeah.**

R: So, if you want to publish in the Beano, you go nuts and carry on but if you want to publish anywhere halfway decent then this what you need to do and that’s your choice. If you’re not bothered about publishing in a good journal and you’re happy to go to one that none of these important journal editors care about then don’t register.

**I: Right or register late.**

R: You can’t use our systems.

**I: Yeah.**

R: Yeah exactly.

**I: Great so in terms of so it sounds like a lot of the, so if when people are actually say like entering the registration information like onto, onto the ISRCTN or clincialtrials.gov or uploading results there if that’s a requirement or if they were just choosing to or whatever [who, so who is generally, is that like sitting within the study team usually or yeah?**

R: Yep, in the study team, yeah and I know some organisations have sort of got people to do it for them.

**I: Yeah.**

R: If you try to get, the only way that people can do it for you is you literally have a process where somebody’s handing it to them. They’ll get it wrong, even with our own group, the administrators don’t have to go to the investigators to get the publications. They will, they will quite often do a search on PubMed. They’ll try and find it themselves, but they still have to go back to the investigator say, you know, we’re looking for the primary paper. Is this the primary paper?

**I: Yeah.**

R: And, you know, we’ve, we’ve had post-docs in our team who have sat down to look at two or three papers trying to work out which one is the primary and, you know, they’ve struggled because you might have two or three ISRCTN registrations that are quite similar involving the same team and you’re trying to discern and then they haven’t quoted their blessed registration number in any of them [laughs] and so the trouble is the moment you turn it into a administrator click button, you’ll just get mistakes, things uploaded against the wrong entries which is why, you know, I can’t help thinking it would make more sense to have this done through the ethics committees, the HRA because then, you know, it’s attached to the correct project and then only those studies that don’t go through NHS Ethics are left to scoop up.

Yeah, no like I say I was just trying to minimise it and I still think it’d be daft to have, I mean I already know some organisations are employing, you know, staff just to data on the registries but the moment you do that you detach it from the actual academics doing it and then they’ll just do it wrong.

**I: What are you so, how aware are you of like the HRA’s plan to sort of get involved like in the Make it Public and like their sort of future plans for like ensuring that perhaps registration does become a bigger part, are you familiar with that?**

R: No, I know there’s been various consultations and I’ve been because at one point they wanted to make it the MHRA responsibility and I remember, you know, sending back copious comments on some consultation saying, ‘No, no, no, you know, this isn’t just about medicines. What about everything else?’

**I: Yep.**

R: And the only commonality we have is that every piece of, every clinical trial with human participants goes through an ethics committee and that is, that is the common path and if that’s the common path that has to be path for, you know, it can’t even be the NHS. We do studies in prisons, we do studies in schools, we do studies in the community. It, it can’t be the NHS or the Universities, it must be the ethics committees to my mind but I’ve no idea what they’ve actually decided to do. I’ve always assumed at some point registration would become a condition of ethics approval and at some point, rather than closing ethics at last patient, last visit or doing an end of study declaration when you’ve locked your dataset which isn’t the end of the study. The end of the study is when you have presented your results to the world.

**I: Right.**

R: So, to me they’ve always closed them too early. The study isn’t finished until the study is published and if you have to keep paying or doing annual reports then then it keeps it focused in the front of your mind. It’s a bit like that annoying email saying, ‘Have you finished yet?’ If you keep getting a reminder that that your study is still open because you still haven’t published year after year after year then sooner or later, you’ll give up and publish it. [laughs]

**I: how to work with the registries gets built, like is there training at [the University] or is it just sort of like people talk or people just figure it out, like what does that look like?**

R: I think the R&D Offices, or the NHS R&D offices will guide people through the process but from what I can gather I don’t log into the systems anymore and they’ve changed so much since I last did, but from what I can gather talking to Trial Managers it’s all pretty intuitive.

**I: Okay.**

R: There’s a click button to say, is it going to ISRCTN so it will automatically transfer if it’s being funded by NIHR

**I: Yeah.**

R: and then we’ve worked out some mechanism with ISRCTN so that if it’s not being funded then we can gift them one of our pre-paid spots.

**I: Yeah.**

R: And, and that way every time there’s a protocol amendment that that should automatically flow because those two things being connected together would make a lot of sense but I don’t know if they’re planning on doing. I mean I don’t know if it’s going to be an opt in system where people can choose to use it or what the plans are.

**I: So you have like a, you have that I don’t know exactly what you call a knowledge management system for trials or so that integrates like sort of directly with ISRCTN, like sort of?**

R: Yeah, I think from what the ISRCTN, from discussions with ISRCTN and the Trial Managers it sounds as if when you’re doing your IRAS application if you click something to say that your funder is covering the cost of IRSCTN, I think it auto populates from one to, but I could be wrong.

**I: Yeah okay.**

R: But I certainly got the impression it was a very seamless easy process certainly for NHIR funded studies and depending on when the team to go and get the registration, I think some will have gone ahead and done it in advance of doing that step. I think it’s a bit haphazard I think as to how it flows but I, it’s not, no study has not been able to do it or has hit a massive roadblock. Payment seems to be the biggest problem as people’s excuses to why they didn’t do it.

**I: And so, it seems like from what you’ve been saying between, you know, the, the sort of unique way your CTU office operates in providing these services and having the overarching structure for CTIMPs sort of like where is that sort of thinking and innovation coming from within like the broader, like family of organisations. Like is it like top down, is it bottom up, like where is that thought coming from, leadership on that?**

R: Very, very much bottom up because the, what drove the CTIMPs sponsor office was of course the legislation and you’ll all go to prison a couple of years if and so when the regulation came in there was lots of, you know, whipped up hyper-anxiety about the MHRA, lots of investment, great that’s, that’s all to the good but it the downside of that is it also created a mentality that if there isn’t a regulator who’s going to put you in prison then it doesn’t matter and so one of the things we’ve been battling against and the chap who’s left, it’s good that he’s left. He only heard the voice of the CTIMP studies.

**I: Okay.**

R: So, every time we would try to be heard because we were in Faculty whereas the CTIMP group were in the core of the College. We’ve now moved over there as well so it makes it easier as well but we, because we were in Faculty, you know what it’s like when you sit in Faculty, there’s layers and layers to get through before anybody hears anything you say and so you’ve got somebody in the core of the organisation saying, here we have the regulation trials. It’s all about the regulator trials, the regulators, the regulators and we’re just a voice in the wilderness screaming, “But what about good science, what about good science, what about good science?” and of course there’s no penalty for bad science. So as long as they’re getting grants and they’re getting publications and REF is looking okay, where’s the incentive to chase the grotty little trials that didn’t publish. There isn’t an actual incentive, and nobody is driven particularly organisationally but it’s a good thing to do. You know, my argument is very simple, if you’ve got junior researchers doing those little feasibility studies, doing their PhDs, learning good practice from day one sets them up to be good investigators. If they learn on day one it doesn’t really matter then you send them out into the world thinking that actually it doesn’t matter. So, you, know, I think it’s bad training to let people believe that it doesn’t matter but I accept that that’s because I’m working in trials. I do understand, I step back, I look from an organisational perspective, there isn’t much of an incentive.

**I: And then in terms of sort of like outside influences so like these processes, like sort from outside of the organisation, so it sounds since there’s the CTIMPs office and there’s their own thing, the whole, any changes due to Brexit, probably not a huge impact for you would that be fair to say?**

R: Yeah.

**I: Yeah and then you mentioned sort of All Trials, we talked about the HRA strategy already but can you discuss what it was like when…[removed non-vital identifying sentence]…Parliament kind of got, or the, you know, the SciTech Committee got involved, like what was the, how did the organisation respond to that?**

R: They thought they were great because they looked at CTIMPs.

**I: Okay.**

R: So, it just reinforced the fact there’s no problem here

**I: Yeah okay**

R: and again, we just keep repeating that there’s as much of a problem here as, you know, CTIMPs great, we’re, we’re a bit ahead of the game but there is still a problem and it’s only a matter of time before that problem emerges and whether that comes through the HRA or ethics or where, sooner or later it, you know, it’s going to get to the point where it become apparent, so the freedom of information requests have helped so whatshisname I’ve forgotten his name. Who’s that chap that always does the freedom of information requests?

**I: Oh yeah, yeah TranspariMED, Till Bruckner.**

R: Till, yeah. So again, you know, I actually find it quite helpful when he sends in those requests because it brings it back on the agenda. Because it’s a reminder that that it’s not just CTIMPs, there are other studies and so I think what happened, I think Till had sent in a request about something about what are our policies for all trials and of course the organisation automatically sends it to the CTIMP people who answer it only about CTIMPs and what was good is he he kept coming back going “Na, na, I’m not only talking about CTIMPs, what about everything else?”

**I: Right.**

R: And its good because it reinforced exactly what we’d been saying for a long time which is there’s a wider problem here. Luckily that all coincided with the chap who was obstructive leaving and someone else coming in whose a bit more mindful that that actually this, there’s a wider piece here and so he’s now pushed for budget to set up a team within [an internal] group to really focus on lots of things, not just this but this is definitely on the agenda as this isn’t, you know, something that we can ignore. And we’ve done exercises and going through, cause he’s asked me about what is the cause, what is, from our experience of what we’ve seen what are the things that are affecting trial publications, what’s delays, what’s blocking them and it’s like I say the majority it’s PhD student, maternity leave bizarrely is a huge barrier.

**I: Yeah.**

R: But but organisationally there should be a strategy to deal with the fact that if somebody’s goes off on maternity leave without publishing their trial, what happens next.

**I: Yeah.**

R: I think our record is like seven or eight years. We had two trials that were oh painfully long. They did, they both got published in the end and again it wasn’t because anyone was being awful

**I: Yeah.**

R: it’s just that the results weren’t very interesting and then life gets in the way.

**I: Yeah I find it really interesting to hear when people talk about things like that because like, you know, here’s all these legal requirements out there that people comply with one way or another, they tend to get it figured out eventually but right the ethical responsibility, like the WHO says publish somewhere, something, even if it’s not a paper yet within a year, like your primary results and it just seems like there’s a lot of barriers and like that’s not, no-one is enforcing that, that’s sort of just a norm like an ethical principle but yeah.**

R: Yeah, And I think, I think a year is optimistic.

**I: Mhm.**

R: I work on a two-year run in my head, so I don’t get too het up until something hits the two-year barrier and then I start to get irritated with them but then maybe I’m too optimistic because a year, well it depends on when you define the end of the trial but if you’re looking at database log or last patient last visit by the time you’ve done the analysis and you’ve been rejected a couple of times, a year isn’t very long and so I only really start to worry when things start to teet-, teeter over the two-year mark personally but in that’s the face of there’s so much out there that needs tidying up that you know, when it goes beyond two years I start emailing because again administrators emailing investigators saying have you published has an effect but if they ignore them sooner or later somebody has to email them where they’re more likely to pay attention. And so, having an escalation path to be able to sort of, you know, either have me email then or if that doesn’t work get somebody who will scare them a bit more to email them.

**I: And that’s, that works? like I assume**

R: Oh, like that works beautifully, oh yeah.

**I: Escalate like get someone, it depends who you get the email from, like in the end sometimes yeah.**

R: Well if they’re, you know, if the Head of Research for the organisation, Professor whoever contacts them saying, “You know, we have been informed, you, we’re a bit-,” and it’s usually phrased nicely “bit concerned about this one, apparently it’s been hanging around for a while, what’s going on?” then, you know, that that makes you sit and I mean it’s difficult there’s no reward for publishing your trials. If you know it’s going to be going into a grotty journal, it’s going to do nothing for your REF impact. It’s not going to generate your grant income and you’re trying to avoid getting culled in the next round of academic culling, I can completely understand why they’re going to prioritise writing more grants over tidying up the loose ends of an old paper.

**I: Yeah, it’s interesting, so not really a question but just a reflection on that I’m interested to see how funders then if a funder might pay a lot more attention to your record it sort of changes that balance of priority then, right, where it seems like some of the major UK funders maybe starting to pay attention to sort of that moving forward so.**

R: Yeah, and I think but I think there’s a very big difference between you did a HTA trial and never published it which I think would be almost impossible. It would be almost impossible to have a major NIHR HTA EME grant and never publish it. That’s, that’s unheard of because the funders drive it. It’s the little RfPB [Research for Patient Benefit] feasibilities that that can wane but more likely the ones that really don’t get published are the ones where you’ve got a little pot of money from industry or charity or PhD student project and nobody’s driving it and the reality is NIHR are only going to pay attention to studies that weren’t published that they funded.

**I: Yeah.**

R: That isn’t a problem or that isn’t the problem.

**I: Yeah.**

R: And we have started to look back ourselves when requests come into see, you know, are they on our list of people who didn’t publish something previously.

**I: Oh interesting, okay.**

R: And it’s not, not formally part of our thing but I have a little nose just to see but they rarely come back because the people who fall by the wayside, generally it’s because they’ve given up, they’re not going to be academics, they’ve gone away.

**I: Yeah.**

R: You know, I find myself contacting jobbing clinicians, going, “Do you remember that study you did in 2007? Have you still got the dataset? You know, I realise you’re in Dorset now, but you never did publish it.” [laughs]

**I: Yeah, what is the response to that when you sort of have to do that retrospective that like people long gone outreach?**

R: Depends, depends where they’ve gone to, so if they’re still in academia it’s kind of like, ‘oh yeah-,’ all sorts of excuses like, you know, my email got archived so I can’t understand, I can’t figure out how to unarchive the dataset because it’s buried in my email somewhere to “I’ll, I’ll try and get to it.” The latest one is “I’ve got Long Covid, can’t do anything.”

**I: Wow.**

R: Nobody, in fact I don’t think anyone has ever said, they don’t think it should be published.

**I: Right. No just outright refusals**

R: They just don’t have the time.

**I: It’s not just saying, like yeah.**

R: No, there’s a couple who’ve been honest and have said, “It’s never going to be published” and those are the ones who said, “Look here’s the format the data would need to be put into ISRCTN,” and I find it a bit irritating that they want the raw data in a very specific format that involves work to get it into that format.

**I: Yeah, if I, if I remember correctly, they kind of ask for like, it’s almost like a slightly more detailed abstract. right, is kind of what they ask for, it’s kind of like a long, like a three-page abstract kind of thing or two, two yeah.**

R: Yeah, but you’re effectively taking all the data breaking it down by trial arm and presenting it in tables. Somebody would have to spend some time on it to get it into that format.

Trials that are abandoned, I have a bit of bugbear with trials that are abandoned because if trial didn’t reach anywhere near its target, they still want, if anybody was randomised, they still want to present it that way. Now if you randomise six patients into a study and then the study died, what, what for?

**I: Yeah, I think yeah, no I mean it’s interesting to hear that perspective because like, you know, I think that there is some value in just having a record of what happened, Even if it was done and failed out there in the public, right?**

R: But, but the barrier to getting that out there is getting somebody to spend the time, putting it into that format and I don’t think that that, I don’t think it’s better to have nothing over, because at the moment that means they get nothing.

**I: Yeah.**

R: If they would accept that there are some historic trials where it’s gone beyond x number of years, where you say, “Look even if it’s a paragraph to say, we started the study. We recruited six people. It died a death, we never even collected any outcome data, or we got 23 people, or we analysed it, there was nothing to see, nothing to see here, it was a mess.” But usually it’s because it was such a flippin’ mess and sometimes, they don’t even have the datasets anymore, they’ve lost them, or, you know, it’s somewhere but they can’t lay their hands on it and I don’t know if you saw the paper [a colleague] wrote. [They] wrote up…a paper saying he found himself at a dinner party I think with Ben Goldacre on one side and Ian Chalmers on the other [laughs] and had to admit that he had a proper, a real proper solid unfunded trial, an unpublished trial much to his embarrassment and shame and they ended up going back and publishing it, but [they] wrote up the fact that [they] had had a unpublished trial and, you know, hands up it can happen to anyone.

**I: Yeah, I think that’s interesting, I, I may have head that, that maybe ringing a bell. They all kind, sometimes they mash together in my head these stories but that sounds somewhat familiar. So the last thing I want to touch on in our last few minutes here is just so when you, do you look outside your organisation for like any support or inspiration or best practices from the broader community whether it be in the UK or even broader than that or even just within [your area], you know, is there any, like are you looking at professional organisations or like the CR-, UKCRC or things like that for like any, any guidance or inspiration or best practice.**

R: Can’t say I have, I have, I know, I know some organisations have employed people to make sure trials are registered and published. I don’t know of any Universities are doing that, I think it’s mainly the NHS Trusts but I haven’t paid a huge amount of attention it’s just something that verbals a lot. I mean I’ve always worked on the basis in the long run it’s not going to particularly be our problem because I think in the long term it will be solved in national level through the HRA or something like that so, you know, I’ve, I’ve never it’s always felt as if it’s just a holding pattern, do what we can until it’s solved properly.

**I: Yeah.**

R: I put that paper into the chat.

**I: Yes, I saw it thank you. So there’s it’s most of like what your doing is just sort of like, it’s very within and based within the organisation and like you’re not, like looking outside too much. I guess,**

R: Yeah, and partly, partly because I’m mindful that because I’ve been in post for so long a lot of the people are people I know or knew before they left. So the vast majority of people I’ve been emailing I’ve at least had email contact or met them in the past and so it’s more likely I’ll get a response if it’s me emailing saying, “Hey Paul do you remember me?” or, you know, “Hi Professor Blah, how’s it going over there in Oxford, there’s this trial you didn’t publish.” But because they would have known me at some point, I just think that there’s an opportunity to try to get some of those done in a timescale whereas five years from now or ten years from now, I think that opportunity may be lost either because people will have retired or died or, you know, whatever and so we thought actually, ‘let’s just sweep through, make the historic stuff as good as we can and hopefully the prospective stuff will sort itself out.

**I: Yeah, so it sounds like that you think that also like from what you just said and also based on like drawing on some of the earlier things you said about the ISRCTN like having a relational, like relationships sort of matter in doing this kind of work yeah**

R: Yeah.

**I: Would you agree with that, yeah?**

I: Yeah no I think, I think we’ve, we’ve never had a lot of hostility about it because I think the investigator is because of the way we will frame it and the way we phrase it, you know, it’s very much presented as, you know, you register your trial so that you can get it published in the best possible journal so you can have the best audience, the greatest impact factor. You want to do things correctly, do it right, you know, when we chase for publications, we reinforce how important it is that others know about their work. Occasionally, I’ve been a little bit naughty where I’ve emailed somebody whose just totally ignoring the administrators and then I will just email them out of the blue saying ‘Oh dear Professor Blah, you know, or Dr whoever I wonder if I could speak to you. I understand that you ran a trial about x some years ago, I wonder if I could discuss it with you.” They answer with ten minutes because they think you want to know because you’re planning another trial. [laughter] But every single time I’ve done that, they come straight back to me. They always seem a bit sad when I just want to know when they’re going to publish it. [laughter] but but, you know, but they don’t disagree, they know that it should be published. They just don’t get around to it.

**I: Okay, yeah great and then sort of I think this is going to be my last question. If a big, something happened so like, you know, let’s just pretend that the HRA makes some new requirement about registration and that like, you know, got around, how do you think so sort of like how would you hear about that and what would the practice of you like self-educating about that lor maybe you’re not self-educating like, what is the process of you sort of like internalising and making that part of the structure that’s SOPs and whatnot, what would that look like?**

R: Yeah, I mean if it was done through the HRA then it would probably be the NHS R&D offices that would hear about it first because things tend to get cascaded to them. I presume that [my colleague] in the sponsors office must get information cascaded in the same way, I don’t really know. We would probably hear about it through the UKCRC, they usually publicise things that change so it would probably come out through, through them and usually there would be some kind of consultation exercise, if they just change it so we’d probably hear about it through that so yeah.

**I: Okay.**

R: You would hear it sooner or later somewhere along the way.

**I: Great so that that’s all sort of like my planned topics to get through. I usually just like to give one final offer if there’s anything that like you’d like to add or like put a bow on from things we talked about, anything that we didn’t get back to or anything that you thought that you might wanna talk about that I didn’t ask about today? Just a chance to wrap up.**

R: No, I think I think that’s okay. I think, I think the PhD student project is one that needs to raised because there’s a lack of recognition that a PhD is meant to be a learning exercise and yes, it might generate some useful evidence but there is no requirement for PhD student to publish their PhD so why do we require PhD students doing a clinical trial to publish their PhD beyond ETHOS? And I do think that they should write it up in a PhD thesis, I would prefer that they publish but usually the ones that haven’t published are the ones where, you know, it wasn’t great, there was nothing very exciting, they underrecruited, it did badly and I just think [poor internet connection] you know, would you expect the supervisors to go and write that up. It just, it just feels like there’s a lack of recognition that there is a difference between a teaching or or we say that actually PhD students shouldn’t be running trials.

**I: Yeah right, I guess suppose that’s the other option. [laughs]**

R: Yeah, and that’s the way we’ve gone with CTIMPs.

**I: Yeah.**

R: because, you know, we feel quite strongly that if a PhD student runs a CTIMP then what you’re doing is pushing them in a position a) where they could be sat in front of an MHRA inspector which I don’t think is fair to any PhD student and you’re setting them up to not fail. You cannot let them fail.

**I: Yeah.**

R: And to me that just works completely contrary to all of academia where people must be allowed to fail when they’re learning and so I think across the organisation I think there’s an acceptance that that CTIMPs are off the table for PhD students, but we still get PhD students running other trials.

**I: Yeah of course.**

R: And at times well and successfully and they produce good data but then what happens if they fall by the wayside, who’s, who’s meant to pick that up? Or you send a very clear message for your PhD supervisor it will in fact fall to you and you, you are expected to do it and there is an obligation on the supervisor but there needs to be some clarity on that because the supervisors just shrug their shoulders and say, “Well the student’s gone so, you know, there we go,”

**I: Yeah alright.**

R: Yeah.

**I: And it sounds like that clarity, just one follow-up on that clarity, do you think that that should be at like the like national level or do you think like organisations should be like turning around to and like making that like sort of being clear about those expectations to their Faculty and students.**

R: Do you know, do you know this is where there’s disconnect because what you tend to find in Universities is there tends to be and I don’t know if this is your experience as well, there tends to be a line between education and research in, in a University and so the education side are the ones that deal with all the PhD students and all of the rules and everything around PhD students. They have absolutely no understanding of any of this stuff.

**I: Right.**

R: You know, the struggle to know if a PhD student is even doing the trial because they’ve got so many and you know, even I’ve had discussions in the last year with our own PhD people that process PhD applications saying, you know, at the very least could they collect data on whether PhD students are doing trials as a PhD because they have no way of knowing. There’s no trigger, there’s nothing, there’s nothing in the system to even alert anybody to the fact that a student might be planning on doing a CTIMP and so things can and have fallen through the net but when I’ve gone back to try and work out well where in the system can we catch this so it couldn’t happen again is actually quite difficult because you realise the people on the educational side is, you know, as far as they’re concerned this is a PhD student doing and as long as supervisor’s happy then that’s fine but the supervisors don’t realise this could be an issue, you know, where exactly is this information going to be cascaded.

**I: Yeah, it seems like there may be an opportunity through ethics there to like-,**

R: It’s too late by the time they get to ethics because now they’re in post doing their PhD. By the time they get to ethics, they’re a year down the line, it’s too late.