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How and why did you move into clinical research?

My background is in applied psychology and I spent several years researching human factors in the military as part of what used to be the Centre for Human Sciences at QinetiQ. This involved designing and running trials, analysing data, and presenting results to our military customers.

We did a lot of work on displays in aircraft cockpits, interactions between air crew in the cockpit, and military command and control teams. After a couple of years at RJAH as a booking clerk, I managed to convince the R&D department that my skills in psychology research were transferable and I am now Research Governance Facilitator here at RJAH. I believe that all research is valuable (clinical or otherwise) and it's a practical way you can really make a difference to people's lives. Research improves stuff - it's as simple as that!

What does your role as Research Governance Facilitator at The Robert Jones and Agnes Hunt Orthopaedic Hospital NHS Trust, Oswestry, entail on a daily basis?

I support researchers at RJAH in setting up studies to ensure that all our sponsored studies are compliant with all the regulations and our own internal quality processes. I conduct capacity and capability assessments for all our hosted studies - trying to meet all the NIHR high level objectives. I process amendments and deal with research passports and letters of access for researchers outside RJAH who want to work within the trust. I undertake the annual research governance audits. I manage all EDGE-related tasks for the Trust, keeping EDGE accurate and up to date, generating reports as required, and managing the R&D research related training. I am Lead EDGE Account Administrator and Super User, and train all RJAH staff in EDGE use and RJAH EDGE processes.

How do you utilise EDGE in your daily role?

It's the first thing I go to in the morning when I switch on my emails and the last thing I shut down at night before I go home! EDGE supports every aspect of my role. We have a study set up attribute so that anyone, at any time, can see exactly where a study is in the C&C process. All the C&C and start up information for all our projects is filed on EDGE. We used to have R&D files,

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but we did away with those and now keep everything on EDGE. Increasingly, as new studies start (and as long as they are non-CTIMPS and the sponsor is agreeable), our trial management files are on EDGE, too. When I set up a study, I use our RJAH site file template and upload all the setup information to the correct sections of the EDGE site file, and then the study support officers maintain the files from that point on. All our amendments are recorded as an attribute on EDGE, giving us an "at a glance" amendment history. Again, all the documentation is uploaded to EDGE. I also use EDGE to support the research passport system as all our letters of access and the researchers CVs and GCPs are recorded on EDGE under user training. Reminders are set up so that the user and the admin teams are notified in advance when they are due to expire. This function is great as we used to constantly chase people for GCP certificates, CVs, and expired letters of access. Now, EDGE notifies them automatically. Of course, they don't always respond! But that function has saved us so much work and enabled oversight of the process. I also do as much of the audit as possible using the files uploaded to EDGE before bothering people to look at their site files. This has also made auditing much easier and more COVID compliant.

We've recently heard about your successful use of the EDGE delegation log for your non-CTIMP studies. Why did you feel the need to roll out this function across your team?

Lee demoed it briefly at EDGE Conference 2020 and I have been trying to implement it ever since. I find delegation logs one of the key things that can delay study setup and affect a site from meeting the NIHR timelines. They always get left until the last minute, however much I nag people to start them earlier in the process! If I had a pound for every time a green light can't be given for a study because

somebody key hasn't signed the delegation log and then somebody isn't in the office that day and the delegation log is stuck on the desk in their office... So, I thought, why not try it? The delegation log being on EDGE makes it accessible to everyone at all times and also gives us full control. I can add people to the log at an earlier stage in the set up process. People then get notified to approve themselves without me having to catch them in the office with a bit of paper. It meant that I had to train some of the PIs to use EDGE, but I started with a couple of PIs who are very open to new ideas and they took to it like ducks to water. It is also COVID-friendly as it doesn't involve one person going round different offices getting people to sign the same bit of paper, and also makes co-ordination easier where staff are working from home.

What kind of advantages and successes have you and your team found in using the EDGE delegation log function?

It's quicker, it's COVID friendly, it's flexible and easy to change, and it's useful where staff are working at home which may be with us for some time yet. Quite often, we find we return a delegation log fully signed to a sponsor and then they return it and ask us to add different tasks to a person's responsibilities and then we have to circulate it round again. This way, EDGE will just notify them they have new roles to approve. I just need to get everybody to update their 'my responsibilities' section under their profile and that will make it even smoother. I am hoping to roll this out for every new non-CTIMPS study we set up. So far, we have not had any sponsors object to either the site file or the delegation log being on EDGE which is good.

What tips or advice would you give to anybody who is thinking about rolling out the EDGE

delegation log function across their team?

Make sure that key staff on your projects are correct, and get the 'my responsibilities' section updated under the profile before you start adding people. This will save you having to tick all the roles when you add people and make it even quicker. Send out user instructions (type 'delegation log' into the search filed on the knowledge base section on EDGE for full instructions) and offer to train people, which literally takes about 5 minutes as it is very easy to use.

What are your plans for using and developing EDGE at RJAH for the next 12 months?

We want to get as many as possible of our site files on to EDGE (with sponsor agreement). This saves space in the office and makes files accessible to all staff. Site files are held in R&D, which means clinical staff can access files from the main hospital building without having to come to R&D. This is how I sold it to them as a time saver. But now it has additional advantages with less footfall in the COVID environment and easier for staff working at home as we all have access to the site file. We currently don't use the finance section and our finance team are not keen to use it fully, but we are looking in to using it to record activity as per discussions at the EDGE working group finance workshop earlier this year. We are also working on some new attributes so that we can report to the Trust on information that is not currently within EDGE.

What aspects of using EDGE has provided pleasure and satisfaction within your role?

Enabling me to be more organised and have better oversight of processes.

What is your "bigger picture?" That is, what do you find most fulfilling about your job?

Ultimately the ability to make a difference to patients' lives, however small that improvement is.

One great thing that you think clinical research has achieved:

Empowering people (the general public - not just clinicians and researchers) so that everyone can get involved and make a difference #BePartofResearch.

One of your greatest personal achievements:

My two fabulous boys who have been so mature about lockdown, really good at self-schooling at home, and not seeing their friends - I am so proud of them!

Your favourite thing about living in Oswestry, Shropshire, and why:

It has to be the lovely countryside and the friendly people.

And finally, and perhaps most importantly, in which way does EDGE resemble your personality:

Organised and meticulous, but pretty laid back and not very complicated!