Super User Q&A: Sept 2023

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– Heather Wearing, Clinical Trials Auditor, The Royal Marsden NHS Foundation Trust

USER PROFILE

Name: Heather Wearing
Organisation: The Royal Marsden NHS Foundation Trust
Job Title: Clinical Trials Auditor
Email: Heather.Wearing@rmh.nhs.uk
EDGE user since: 2020

01

How and why did you move into your current role within clinical research?

I was previously a Data Manager in one of the clinical research teams here, so had a decent amount of experience of clinical trials and had also been subjected to internal audits. I had a good idea what the auditor role was about and when a vacancy came up it seemed the perfect time to move onwards and upwards. That was over 3.5 years ago and I'm still here! Before coming to the Royal Marsden, I had worked on clinical trials with healthy volunteers in a contract research organisation, and prior to that I had spent 8 years working in molecular epidemiology and antimicrobial resistance for Defra. Just collecting those all-important transferable skills!

02

What does your role as Clinical Trials Auditor at the Royal Marsden NHS FT entail on a typical day?

There's no such thing as a typical day, week, or even month! I have recently undertaken a week-long tissue governance audit of one of the laboratory teams. I'm now in the process of collating my findings and discussing them with the lead auditor who will write the report. I'm just finishing off an audit report for one that I did solo and am reviewing responses to another audit that took place several weeks ago. Some weeks I am allocated to reviewing clinical-trial related incidents which I fit in alongside other tasks such as planning my next audit or updating internal documents. The audit programme is regularly reviewed and adapted, if necessary, and if new risks emerge, I may have to audit a team at very short notice. There are plenty of meetings to go to, training to deliver, and courses to attend. Every day is a school day!

03

How does the patient and research landscape currently look at the Royal Marsden?

We currently have several hundred open trials, and several thousand patients participating in these trials! Being one of the top cancer hospitals in the world, we are fortunate to attract many hosted trials, these are run by what could be termed "big pharma", like GSK, Janssen, or AstraZeneca. We are also incredibly privileged to have sponsored trials, where the Royal Marsden and/or the Institute for Cancer Research run them. Among our trials there are those assessing new medicinal products (first in man), new combinations of medicinal products, medicinal products that haven't been used for particular cancers before, then there are medical device trials, radiotherapy trials, and more excitingly, those trials investigating patients' blood samples and/or the

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genetic make-up of their tumours to try and develop customised, targeted treatments.

04

How do you utilise EDGE in your daily role?

For many of the audits I will pull a report from EDGE to aid in trial selection. For example, if I am auditing a specific research unit, all of their open and closed to recruitment-in follow up trials might be selected, and I can further refine my search depending on what type of trial I want to look at. I might want a report of all trials sponsored by RM and/or ICR so will use EDGE for that.

05

You've been using EDGE for 3+ years now. How has your use of EDGE changed and evolved during this period?

It hasn't changed significantly – I had some excellent training from our R&D team here during my first weeks in the job and since then I've become familiar (and expert!) with customising searches so I can get exactly what I'm after. Other staff in R&D ensure EDGE is up to date and they will help if I have any questions. I'm also not afraid to spend half an hour pottering round EDGE just to see what else I can find!

06

As a Clinical Trials Auditor, what is your favourite functionality to use in EDGE, and why?

I most commonly use the Project Attribute Report function as this allows me to complete a lot of my auditing tasks, so I'd say this is my favourite.

07

What is one tip that you would offer to new EDGE users in a similar role?

Spend some time running searches using different numbers of categories, play around with filtering the results, see how it works best for you – even among my auditor colleagues we all have our preferred ways of using it.

08

What are your/site's plans for using and developing EDGE over the next 6-12 months?

My lovely colleagues who deal with EDGE here tell me that there are plans to encourage support services to use the system, this could be clinical trials pharmacy, the tissue bank, and radiology… watch this space!

09

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

Pay day! No, no… closing audits. Sometimes the whole team might be involved in a big audit that lasts for 2 weeks and all 4 auditors will take part. The findings can be many and varied and it takes a lot of work to collate and categorise all the findings and prepare the final report. Once teams have responded there may be a little bit of back and forth as corrective and preventative actions are mutually agreed. Completed audits are presented at one of the high-level research meetings for comments and approval. Once everything is "ticked off", certificates can be issued to the audited team/s. Everyone loves a certificate, even in electronic format!

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Describe/explain one of your team's recent major achievements:

I guess getting through the last few years in not too many pieces! We had to rapidly amend our 2020 audit programme to take account of people's new working arrangements – fewer people onsite, both in my team and the research teams, meant that there were fewer people available to assist with onsite audits (for ISFs, TMFs, patient trial folders, etc.). We also had to consider physical locations like pharmacy and medical records, and if/how we could audit them remotely. But the whole team (auditors, monitors, QA officers, PV officers) went with the flow and we still fulfilled all of our objectives. Now things are back to "normal" we still make the most of being able to audit remotely (the auditee can email us documents for example) but doing face-to-face audits is so much better for developing and maintaining working relationships.

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One clinical research superpower that you wish you possessed:

A photographic memory!! For things like SOPs, the Human Tissue Act, Trust Policies, etc.

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The best thing about living in London?

I live in Sutton, about 12 miles south of Victoria station. Although it is zone 5 (i.e., classed as London), it feels much more spacious, less busy, and less polluted than central London. For example, it's 10 minutes' walk to my nearest park, 15 minutes' walk to a little wildflower meadow/pasture, and 30 minutes' walk to Nonsuch Park. Public transport is also pretty good, when it runs…and there are lots of decent pubs nearby.

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One thing that inspires you:

The patients. How can they not…? Despite this being a cancer hospital and sometimes the news is not good, there is a feeling of positivity that you don't get in a general hospital. We are all working towards the same goal, to eradicate or at the very least effectively control cancer, and it is thanks to the patients taking part in clinical trials that the research happens, and outcomes continue to improve.