

Q&A Coffee Sessions

with EDGE super users

EDGE?



Super User!

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Name: Brendon James

Organisation: Royal Cornwall Hospitals NHS Trust

Job title: Audit and Project Monitoring Officer

Email: brendon.james1@nhs.net

How and why did you move into clinical research?

My wife of almost 25 years is a registered nurse - deputy ward sister to quote her full title - and I am constantly in awe of the help that she and other health professionals provide to their patients, especially since these are roles I know I am not "cut-out" for. After becoming redundant two

and a half years ago, I saw my current role advertised working for the NHS. I thought it would be the perfect marriage of my current skills and my long held desire to want to do something that would help people.

What does your role as an Audit and Project Monitoring Officer at Royal Cornwall Hospitals NHS Trust, entail on a daily basis?

Working as part of a small governance team, I carry out audits and monitor the commercial and non-commercial trials, as well as the 'home-grown' research we have. I track the results of these as well as the actions from external monitoring to identify themes and trends as part of a Quality Management System (QMS), which then helps direct where I go next as part of our audit plan. I use a bespoke in-house designed database called Quad to record the findings/actions and produce reports for use by the senior management team. I also help construct and deliver training solutions and, along with my

colleague, assist the team with archiving.

How do you utilise EDGE in your daily role?

We use EDGE to store copies of key documents from protocols, amendments, templates for PIS/ICF forms, approvals through to monitoring reports/feedback, and archiving details. These are essential to my role in monitoring and auditing and I refer to them daily. The ability to create unique reports which can then be manipulated in Excel also allows me to keep on top of studies that are newly opened or that have recently recruited and may need monitoring.

We've heard about your team's successful use of EDGE as an electronic site file for your sponsored research projects.

How - and why - did you feel the need to utilise EDGE in this way?

We know that becoming paperless is important - essential even. But you have to start somewhere. We have a dedicated Research & Development

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Information Officer, and it was her suggestion that we trial EDGE as an electronic site file for our 'home-grown' research since it combines a move towards a paperless operation, a desire to improve our efficiency in managing our own research projects, and an opportunity to modify the process as needed before looking to use it with our commercial and non-commercial partners. She used to work as part of a research delivery team, so she used her experience to set up EDGE to overcome many of the pitfalls that she had previously encountered, and took time to show our principal investigators how to use EDGE at the onset of a project, meeting with them regularly to support them.

You have also recently started using EDGE as a research archive in the last 6 months. How do you have this set up?

Truthfully, my colleagues have been using EDGE to support archiving for a long time now, but we recently relocated our physical storage and realised that we could use EDGE more fully, including providing a location for key documents in electronic format that weren't included in the original physical archive. First, we created a specific archiving attribute that allows us to record key data that needs to be easy to find both now and in, say, 25 years' time, such as sponsor contact details, retention timelines, destruction dates, location of physical archives, etc. We also ensured that, as part of the standardised folder structure we use, we included an End of Study folder, which provides a simple and easy-to-locate folder for archive related material.

We designed some standardised forms (which also describe the processes and steps to follow) that our colleagues use to inform us that a study is due to be archived that match with our archiving attribute. The governance manager then wrote an archiving SOP that includes detail on how we

use EDGE to support archiving and assigns roles and responsibilities to key staff. We also have a dedicated EDGE archivist alongside our named archivists.

What advantages or "early wins" have your team discovered by using the system as a research archive?

Now that all the essential information is one place, setting up an archiving attribute means that we can now report on whatever we have set in this attribute. There is no more uncertainty on whether that long-forgotten study is still open, and it's easy to find out the sponsor's contact details for a study archived 10 years ago. Tracking retention dates within the attributes means that we can pull regular reports, thus enabling us to contact the sponsor and confirm destruction in a timely manner so that we avoid paying unnecessary storage fees.

We also record any actions that we take in the notes (red level) so that colleagues know what has already been done at a glance. We've also included an archiving folder in the 'Files' section, which is a great place to keep end of study declarations, or perhaps those last few archiving documents that are discovered after sending studies for archive.

What tips or advice would you give to anybody who is thinking about using EDGE as an electronic site file or for archiving research projects? How should they get the ball rolling?

Don't be afraid of change - it is inevitable. We are all going to be moving towards a paperless system. Embrace it early and try. If it doesn't quite work, you have time to adapt and get it right before it becomes compulsory. We created a standardised folder structure that is used for all our studies on EDGE that is similar to the physical ISF, and we run that alongside the more traditional

physical ISF. This helps our staff navigate it because people won't use it if they don't know how, or if it seems too different. Sell the benefits - EDGE can do so much to simplify your workload. Everyone can access the latest protocol or see the latest amendments in an instant from anywhere if you store it on EDGE. No more struggling with access to a shared drive.

Start with simple quick wins and let staff see how easy it is, and engage those staff and build on it. Workflows are great for tracking progress in processing an amendment, for example, and anyone can pick up from a colleague if they know where they are up to. Attributes are brilliant to allow you to pull bespoke reports from EDGE.

What are your plans for using and developing EDGE at Royal Cornwall Hospitals for the next 12 months?

Our QMS manager is currently working on a dedicated EDGE Standard Operating Procedure, which will include role descriptions and operational processes for all of the R&D staff, including our newly appointed EDGE Data Officer, who will ensure that EDGE is accurately maintained and that our staff have appropriate access. However, I think the biggest plan for EDGE is the consolidation of its use for the financial management of our research portfolio. We have already commenced rollout of training to our R&D staff.

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

Cogs!!! People truly underestimate the power of the smallest working part and I have come to appreciate that research is full of cogs: processes, routines, individuals, and data. Separately, many seem tiny and inconsequential, but together, they create the most dynamic machine. An integrated system that produces real results, tangible health benefits, and positive outcomes for patients - and I am a part (albeit it a small one) of it. Oh, and my boss loves cogs!

One great thing that you think clinical research has achieved:

The pandemic answers that question all on its own. We have a number of likely viable vaccines – many already at Phase 3 – one of which is being trialled at our hospital. These are only possible because clinical research has facilitated it.

What clinical research superpower do you wish you possessed?

I would love to be ‘super standardisation man’ and, with a wave of a magical arm, to be able to standardise all those EDC systems into one. Or, if that was sold out, at least be able to make you remember the user names and passwords for them all!

One thing that inspires you:

I am genuinely inspired by that group of people who get up and offer their seat without a second of hesitation on the bus or train, or who rush in front of you to open and then hold the door when you have your hands full, or who cross the room to talk to the person sat on their own who has a look of one with the weight of the world on their shoulders.

Your favourite thing about living in Truro, Cornwall, and why:

I am considered by many to be typically Cornish in that I love where I am from. Whilst I enjoy holidaying and travel abroad – the definition of which is anywhere over the Tamar bridge – I wouldn't *want* to live anywhere else. I live only minutes from the nearest beach, yet I am surrounded by idyllic countryside. We put jam on scones *before* the cream and a certain cider named after a snake (and baby's toy) is produced just down the road... it is paradise!

And finally, in which way does EDGE resemble your personality:

I was going to say that you can fill EDGE up with just about anything – it can just get bigger and bigger. Then, thankfully, I re-read the question!!!! It is sleek, well-designed (looks great in red and green) and everyone that tries it loves it.