

ISSUE: May 2021



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### How and why did you move into clinical research?

My background prior to moving into clinical research was predominantly information analysis. I have always been interested in research after taking part in numerous research studies, and the opportunity arose at LPFT and I jumped at the chance to apply and was successful. I have been in the team for 2 years and 8 months now.

#### What does your role as Research Governance and Data Coordinator at Lincolnshire Partnership NHS FT entail on a daily basis?

My role is varied, and involves opening studies on EDGE, processing amendments, running reports, keeping track of CPMS confirmations, and archiving site files once studies are closed. I support the delivery team with additional administration for studies. Currently, I support the SIREN study by sending out participants' results on a weekly basis, building new reports in EDGE, and providing up-to-date information to the team on all the hosted studies that we are collaborating on.

# How has your role within clinical research and governance changed over the past 12 months?

It has been a strange past 12 months. LPFT is predominantly a mental health trust, so a lot of our studies paused to recruitment. Our delivery staff supported studies in the local acute Trust,

which led to the steroid treatment being identified to treat COVID-19 patients. Our Trust is involved in Urgent Public Health studies, and I have spent the last 12 months ensuring that participants receive their test results, processing amendments that have been submitted to change documentation for all the studies we are hosting, and making sure that delivery staff have the most up-to-date documentation to ensure that the studies are delivered in a COVID-safe way. There were some studies that continued during the pandemic as participants were on a programme of treatment, and so it is my responsibility to ensure that our staff can continue to deliver studies safely during the pandemic. This includes opening studies, tracking recruitment, ensuring that the team know when studies are open and closed, and providing final reports received to all that have been involved with hosting a study at LPFT.

How do you utilise EDGE in your daily role?

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I use EDGE every day for many things, from uploading GCP certificates for PIs and staff involved with research, to processing amendments, opening new studies, providing letters of access, and running reports for participant recruitment. This is naming only a few. We also use EDGE for evaluation, funding bids, and student projects.

#### We hear that your organisation has a particular way of working with electronic site files in EDGE. Could you explain more about your use of ESFs?

I created a standard folder template that is uploaded when we open on the Red Level and can also be used on the Green Level. All documentation relating to the study is populated into the corresponding folders. Some of these include governance and NHS permissions, study documents, amendments, and localised documents. This ensures that the delivery staff have the most up-todate documentation to hand when recruiting and consenting participants. This has been very handy during the pandemic as everything is available on EDGE and the documentation can be completed electronically. We also use a folder for processing the closure of a study. All archiving information is populated in this folder for future reference. Paper site files should mirror the electronic site file and helps to assist the delivery team during monitoring visits.

# The ultimate goal for all organisations is to be entirely paperless (I am sure). What tips or advice would you offer to anybody who is thinking of starting hosting/using electronic site files in EDGE?

Use a standard folder template and build within these folders for each study. We add additional folders within the study document folder for consent forms, information sheets, recruitment documents, and manuals to name a few. Have an archive folder to move superseded documents into, so that the study team/delivery team can access any superseded documents and that you have a full audit trail.

# As a data coordinator, do you have any EDGE hints or tricks up your sleeve that you perform during the management of your data?

We use an attribute to track amendments from when we receive amendments to when we send confirmation that the amendment has been processed at LPFT. I have created a report that I supply to the senior members of the team, so that they have full oversight of amendments, received and processed. After reading Joanne Adair's Q&A last month, I decided that we would also use the training functionality to enable us to start to track letters of access and to easily run reports. Thanks Joanne for the tip!

### Your favourite functionality to use in EDGE?

My favourite functionality to use is attributes. These allow for tracking the status of work and for reporting purposes. (Can you tell I love a report?!)

## What are your plans for using and developing EDGE within your department over the next 12 months?

Too many to name. But I cannot wait to get EDGE 3 and start using it and developing our research department's plans.

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

Knowing that the research team can find what they need on EDGE! Also, ensuring that information is correct to allow chief investigators to confirm recruitment in order to help find new developments for certain conditions - and to shape the future of the NHS!

#### One thing that always makes you laugh:

My house rabbit. He has kept me sane during the last 14 months - charging about the house, flopping under my desk, and attacking one of my slippers when it's not on my foot! And giving me sassy looks when I don't let him out of his cage first thing in the morning. Whilst I am sitting here writing this, he is sat on the sofa staring at me!

### One personal skill that you've learned over the past year/during the pandemic:

Making candles. I love a candle and a wax melt. I have been making them for a while, but I have been creating pillar candles of yarn balls, knots, and human figures during lock down. I have loads if anyone is interested in acquiring one!

#### And finally, in which way does EDGE resemble your personality?

Efficient and organised. If you spoke to any member of my team, they would say I am super organised, and that I like to dot the I's and cross the T's.

By Ken Brackstone, Clinical Informatics Research Unit (CIRU)