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How and why did you move into clinical research?

I joined the clinical trials team at Lakeridge in 2015. The team was expanding due to funding received from The Canadian Cancer Clinical Trials Network (3CTN). 3CTN is a pan-Canadian initiative to improve patient access to academic trials across Canada. Healthcare is my second career, I originally worked in publishing. Prior to joining Lakeridge, I did some project work for centralized staff scheduling and payroll in a

couple of community hospitals. A colleague encouraged me to apply for the research position - it seemed interesting and I was ready for a new challenge. The implementation of EDGE really helped to define my role.

What does your role as Clinical Research Associate & Information Manager at Lakeridge Health entail on a daily basis?

I manage the day-to-day financials for the oncology and nononcology studies at Lakeridge. This includes reviewing contracts, budgets, and protocols to develop payment trackers to ensure that all billable items are invoiced appropriately, and that all automatic payments are received per the contract. I reconcile the accounts receivable on a per-study basis and prepare reports for internal stakeholders. As the EDGE administrator, I am responsible for managing the system, including the initial set up of the system for use at Lakeridge. I was the lead in defining the use of the application. I am also the site trainer; I set up new user profiles and provide training and first line technical support to local users. I set up new

studies in the system and maintain the study record. I maintain the Library which includes creating Entities and Workflows for use by the regulatory staff. I create reports at the project and patient level and I perform routine system audits. As the Trial Liaison, I am also responsible for ensuring recruitment targets are achieved for academic studies. I work with academic sponsors and regional partners to identify upcoming academic studies and strategically plan for our resources. As the 3CTN Site Coordinator, I maintain relationships with regional partners to increase awareness and enrolment in 3CTN Portfolio Trials.

How has your role within clinical trials changed over the past 12 months?

COVID definitely changed the way we operated. Recruitment to most studies was halted, some patient visits went virtual, and study start-up was paused for most of last year. Financially, we took a big hit, so my role involved much more reporting. I have been busy enhancing existing reports and creating new reports to assist with study selection, workload, recruitment, and meeting financial goals.

How do you utilise EDGE in your daily role?

I use EDGE all day every day. I use EDGE to track all our research activity, ethics and regulatory activity, patient activity, and project activity. We use a combination of Workflows and Entities for reporting. Since we started using EDGE we have eliminated hundreds of Excel trackers and replaced them with entities and workflows. The patient attributes are used in place of Excel trackers to record patient activity and provide the details for invoicing.

You have been using EDGE at your site for 6 years now. In which ways has your use of EDGE changed and evolved over this period?

We implemented EDGE in 2015, and the intention was to use it to track our recruitment data. Once we started adding our patients to EDGE, we began thinking about everything else we tracked - either manually or electronically - and wondered if we could capture this in EDGE. We started with ethics and regulatory and expanded to patient activity. We decided to use workflows to track ethics and entities to track patient activity. Using EDGE in combination with our billing system has improved our financial position.

What kind of challenges have your time encountered during implementation of EDGE during this time, and how did you manage these challenges?

The biggest challenge during the implementation was getting staff buy-in. There was a great deal of resistance to a CTMS. Many of the staff were used to manual tracking and not comfortable with moving to an electronic system.

Demonstrating how using EDGE to eliminate paper tracking and Excel trackers simplified processes and took less time helped most staff realize that the change was beneficial. There are still a couple of holdouts that I'm determined to win over.

What is your favourite functionality to use in EDGE, and why?

My favourite functionality in EDGE is attributes. I use attributes at the project level to track project-specific charges that might otherwise be missed. At the patient level, I use attributes to capture all activity that requires financial reimbursement.

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

At our site, we would like to explore using EDGE reporting to help simplify the internal transfers of funds to supporting departments/physicians. We are also going live in December with a new EMR. I am interested in seeing how EDGE can be used in conjunction with the new EMR EPIC. Personally, I would like to learn more about Microsoft Power BI and using it to create more visual EDGE reports.

One hope for the future of EDGE and information management?

I would like to see an integration of patient and project attributes in EDGE Reporting. It would be lovely to run one report instead of combining reports to get both patient and project data.

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

The most fulfilling aspect of my job is being able to provide information on demand. The reporting capabilities of EDGE make it easy to provide quality reports for management and P.Is to make informed decisions about current and future studies.

One of your team's greatest achievements:

I would say the greatest achievement of our team is the dedication our physicians have to the patients and bring alternative treatment options to them. Our physicians are so engaged in research; they are our greatest champions.

One clinical research superpower that you wish you possessed:

It would be amazing if there was a signing superpower - some kind a spell that could be put on people anytime you needed a signature from them.

One thing that people might not know about you:

When I became a Grandma, in true Grandma fashion I started scrapbooking. My daughter caught the scrapbooking bug and it is now something that we love doing together. I might try knitting next.

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

One skill that I have tried to master this year is flexibility. I haven't exactly perfected it but I think there has been improvement. With so much change in policies, procedures, and working conditions, it is hard to keep up and stay positive.

By Ken Brackstone, Clinical Informatics Research Unit