SaTH Improvement Hub

The Shrewsbury and Telford Hospital NHS Trust

# Rationalisation of capturing data for a participant's research journey

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**Abstract: In order to reduce duplication of data during a participant's research journey a review of the use of Excel Spreadsheets versus the EDGE Local Performance Management System (LPMS) was completed. The EDGE LPMS can provide 100% of the same functionality as Excel Spreadsheets but in different formats. It can also provide a clear audit trial; reducing GDPR breaches and aiding reporting of a participant's research journey. However, there are some concerns about using EDGE alone. Data was duplicated for 70% of research projects.**

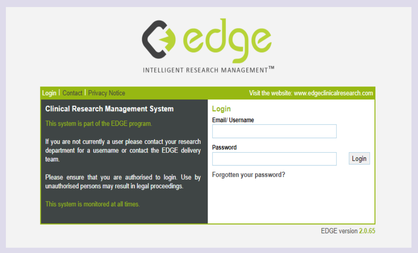
## SMART Aim

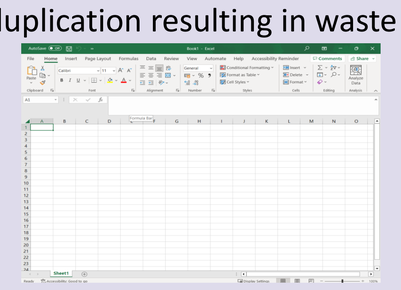
To rationalise the use of data capture systems by ensuring all new research projects are not duplicated by the 1st March 2023.

## Plan

Currently, the Research & Innovation (R&I) team use Excel spreadsheets (named "Patient Logs") to record screening, recruitment and follow-up visit information about a participant's research journey. The team also has access to a research Local Performance Management System (LPMS) called EDGE on a secure NHS platform, which is database to capture all research activity at the Trust. This is reported directly to Sponsors and the National Institute of Health Research (NIHR) so our recruitment performance can be monitored. There is inconsistency within the team on the use of the Excel Patient Logs and EDGE and there is a risk of duplication resulting in waste of resource. There is also a GDPR risk and difficulty in collating information for reporting purposes.

This project aims to pilot the feasibility of using EDGE as a system to record the same information that is captured in Excel Patient Logs, and to determine if only one data capture system can be used.



## Do

A review of the functionalities within the Excel patient log and EDGE was undertaken; functionalities were matched and gaps between the 2 systems were identified. New functionalities were created in EDGE to address the gaps and relevant R&I staff were provided with training. A total of 10 new research projects were selected and 10 R&I staff were asked to enter the data into EDGE that they would have usually enter on the Excel Patient Log. The EDGE data was then reviewed, and feedback was obtained from the R&I staff.

## Study

A total of **21** fields were identified in the Excel patient log (Hospital number, Name, Date randomised, Trial no., Date consented, Date registered, Trial Arm, PIS Version, Consent Version, Added to EDGE, Any EDGE Costs, Added to diagnostic box & annotation in notes, Consent form sent to patient, Annotation in notes, GP letter sent and scanned to PORTAL, Surgeon letter sent and scanned to PORTAL, Consent/PIS/Randomisation letter scanned to PORTAL, Patient on another trial, Original Consent and randomisation form filed, Consent checklist filed, Notes marked with sticker, Screening/Baseline Visit). When comparing these with the fields with EDGE, it was identified that **100%** of them could be captured, although it was necessary to create EDGE attributes/forms for some of the fields to address gaps.

It was discovered that the Excel Patient Log is also used to collect screening and track follow-up visit information, which led me to investigate whether EDGE could be used to capture this data. The answer was **"yes",** but at times in a different formats.

| Screening | Visits |
|---|---|
| • Patient details and demographics can be entered in minimal form to comply with GDPR.<br>• "Pre-screening" and "Approached" dates, as well as "Comments" can be captured.<br>• Patient EDGE attributes/forms can be created against the patient to log document information if required.<br>• A patient can be logged as "off the study" if they don't progress. | • An entry into "Follow-up" date or "off the study" date can be captured.<br>• Real time and future visits can be added as "Appointments" to detail type of appointment, who with, date, time and any comments.<br>• There is the option to add appointments to a calendar, which can be shared with appropriate departments and research staff.<br>• Staff can access their own personal calendar on a daily/weekly basis to see what appointments are due.<br>• Details of these appointments could be printed off and put in the medical notes if necessary. |

It was also discovered that consent forms can be uploaded onto EDGE, along with other documentation if necessary. . EDGE can also be used for the management of Delegation Logs. EDGE is a secure, auditable system where usernames and passwords are required to access it; users are issued different access rights dependent on their role. EDGE also has a reporting functionality.

Of the **10 new research projects** trialled, new EDGE attributes/forms were added for **80%** and appointments were added for 50%. Recruitment and follow-up visit data was duplicated on EDGE and the Excel patient log for **70%** of the research projects (20% had not recruited; 30% did not have follow-up appointments).

**10** R&I staff piloted the use EDGE in place of the Excel Patient Log (not all screening and visit functions were tested by each person) and I obtained feedback from **7** of these. **14%** were happy to use it to collect screening information and **100%** were happy to use it to capture recruitment data. **86%** captured real time and future visit data and felt it was straightforward and easy to complete after the visit. **42%** preferred for using the Excel patient log; the main reason for this was that data for all participants and progress along their research journey can be viewed holistically. **14%** said they would use EDGE to store research documents.

## Act

The current EDGE version 2 system is due to be updated to version 3. All data collected in EDGE 2 will be transferred to EDGE 3 and this project will not be impacted by EDGE 3. A DPIA for EDGE has been approved by Information Governance. EDGE Leads at the Trust may require some additional training on the system to learn more about its functionalities. The findings of this project will be presented to the R&I Senior Management Team and a decision about the most appropriate data capture system will be made.

**Acknowledgements**

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