STH EDGE

Training Handbook

Version 1.5

(20 May 2016)

Contents

Introduction

The Clinical Research Office, Sheffield (CRO) has implemented a new research database called EDGE to manage accrual reporting for all research studies.

EDGE is a web-based accrual reporting system that enables the CRO to track accrual for each study held in Sheffield Teaching Hospitals NHS Foundation Trust efficiently and effectively through a centrally held database.

EDGE also enables researchers to monitor their recruitment targets by inputting screening and recruitment information into one central place.

Definition of Recruitment

Recruitment is the enrolment of an eligible participant who meets the study's inclusion criteria, into a research study. Each participant who has both provided informed consent and is taking part in the study should be recorded as a recruit.

Note: Screen failures do not count as a recruited participant.

Source:
http://www.crn.nihr.ac.uk/can-help/funders-academics/nihrcrn-portfolio/faqs/

http://www.crn.nihr.ac.uk/wp-content/uploads//crnadmin/Recruitment-data-leaflet.pdf

Logging in to EDGE

www.edge.nhs.uk

Please enter your username (by default: your email address) and password as found in your registration email in to EDGE and click **LOGIN**. If you cannot locate your registration email from EDGE, please check your Junk email folder before contacting your local EDGE Administrator.

If this is the first time you have logged in to EDGE, you will need to change your password and set your security questions.

For any assistance with logging in, contact your local EDGE administrator.

Local EDGE Administrator at STH:

Natasha Ottley - Natasha.ottley@sth.nhs.uk - 0114 226 5930

Zoe Whiteley - Zoe.whiteley@sth.nhs.uk - 0114 271 2572

Home Screen

HOME

The home screen has shortcuts to the most frequently used parts of the system. The grey task bar at the top contains all the functions of EDGE. Each tab on the grey task bar has sub-sections to help you navigate.

Your name and organisation will appear in the top right corner of the screen. When you have finished your session, click **LOGOUT** below your name to close your session securely.

Security – Changing your password

When logging on for the first time, you will be using a password which EDGE has automatically generated for you. Please change this password in **MY LOGON DETAILS** to something which you will remember.

Your password must meet the following criteria:

- At least eight characters long
- Uppercase characters (A-Z)
- Lowercase characters (a-z)
- Numbers or symbols (1 -9)

If you password does not comply with the above 4 conditions, it will not be accepted. A symbol will appear next to the unfulfilled criteria. All four must show a green tick next to them before the new password can be applied. You will need to enter your password twice in order to confirm it and then click **SAVE** to complete.

Security – Security questions

EDGE enables you to set up two security questions for your account so that you can re-set your own password at the log in screen, should you need too.

These questions can be anything but must have an answer you will remember and should not be too generic. Please note that your security question answers are case sensitive.

When you have set up your two questions and answers, click **SAVE**.

Forgotten your Password

www.edge.nhs.uk

If you forget your password, click **FORGOTTEN YOUR PASSWORD** on the **LOGIN** screen and follow the on-screen prompts and security questions to reset it. You must know your login (email address) in order to complete this process. If you are unable to log on using the **FORGOTTEN YOUR PASSWORD** link, please contact your Local EDGE Administrator in the first instance.

My Details – Updating contact details

When you first access EDGE, please ensure that all of your contact details are correct, including contact number and address. To update your information, click **EDIT** in the top right corner and amend the details.

When you have finished, click **SAVE** to apply the changes. If your details change, please ensure you update the system as soon as possible.

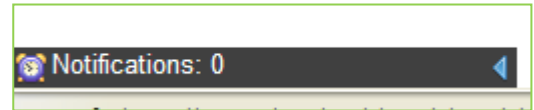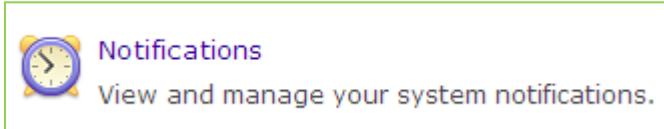# Notifications

HOME > NOTIFICATIONS

Once at the home screen, the notifications area in the bottom left corner of the browser window will inform you of any activity that has taken place since you last logged on which may require your attention.

To access this information, click the grey **NOTIFICATIONS** tab and you will be directed to the five most recent notifications and the actions required. To see all pending notifications, click on the **NOTIFICATIONS** icon on the home screen.

Searching for a Project

PROJECTS

To search for a project, click on the 'Projects' Tab at the top of the screen.

Note: The last 10 projects that you viewed will be displayed at the bottom right of the home screen

There are two methods of searching:

Assigned projects (projects which you have been assigned to) and Organisation Projects (studies which STH is involved in).

You can search for a project in a number of ways (this is the same on both the assigned and organisation search)

a) Title/Description
b) Project Local Reference (STH Number)
c) NIHR Portfolio Study ID (if the study has been adopted by the NIHR)
d) Chief Investigator
e) MREC Number

Once you have typed in your method of searching, click **SEARCH** and all studies will be displayed in the results underneath. To open your study, click on the blue title on the left hand side, under the 'Title' column.

Project Level Information (Defined by a GREEN Border)

When you open a study, you will see the page below. The information on this page is at **project level**, so it will list the Chief Investigator, Sponsor, Funder, study status, whether the study is multicentre, type of study, etc. The STH Number is also on this page.

Note: You will not be able to edit this page. If you do notice any mistakes, please contact your Local EDGE Administrator, who can arrange for the information to be changed.

Site Level Information **(Defined by a RED border)**

To upload recruitment to the study, you will need to access the project at **site level**.

To do this, click on **SITES** on the left hand side of the screen at project level and click Sheffield Teaching Hospitals NHS Foundation Trust in blue text.

You will then see the **Site Level** window as shown below:

You can also go straight to the site page from the search page (as described on p12 of this manual). To do this, search for the project and click on the site name in blue text down the right hand side, under the 'Sites' column.

Once you have clicked on Sheffield Teaching Hospitals NHS Foundation Trust, you will see the page below. The information on this page is at **site level**, and will list information such as the site status of the study, who the Principal Investigator is and site target recruitment.

The definitions of the dates at site level are as follows:

- R&D Submission date: Date of valid SSI form submission(if applicable)
- Start Date (NHS Permission): Date STH issued R&D approval
- SIV Date: Site Initiation Visit date (if applicable)
- Open to Recruitment Date: The date the site was opened for recruiting patients
- Recruitment End Date (Planned): Planned site end of recruitment date
- Recruitment End Date (Actual): Actual site end of recruitment date
- Planned Closing Date: The planned date at which all activity at the site will cease (end date from SSI form)
- Closed Date: Actual date when all project activity at site closed

This page will identify when the first patient was recruited to the study and then self-populate the recruitment clock and actual recruitment. It will give you your recruitment percentage and from this you can work out if you are on course to meet your recruitment target.

Note: The CRO will also monitor recruitment using this page

Site Attributes

The attributes at site level are reflections of pieces of information which need to be captured at site level only. For STH, the extra attributes captured are:

- STH Directorate
- Target Patient First Visit Date – For e.g., if the study has a target recruitment of 50 patients, then this would be the date the 50th patient was recruited/randomised
- Last Patient Last Visit Date

Site Staff

The Site level staff tab contains the names of staff against assigned to that project at their specific site level. Users will be able to view this information, including who has clinical rights*.

*All staff members at site level who will be actively recruiting patients to a project will need to have clinical access. This can include staff who are entering recruitment details on someone else's behalf, such as Data Managers and Coordinators.

Site Statistics

The statistics tab within a project site level ties in with the information presented at the project level KPIs tab. It breaks down the total project recruitment at a specific site across all users at that site. The Total Accrual, Annual Accrual and Current Status take a real-time snapshot of the project's patients and their status within the trial.

Recruiting Patients to a Project & Site

Patients can be added on to EDGE in two different ways. Firstly by locating the Project directly;

HOME > PROJECTS > ASSIGNED PROJECTS > (Select Applicable Project) > SITES > (Select Site) > PATIENT

Or by using the quick link on the EDGE home screen;

HOME > ADD A PATIENT

Note:
The quick link allows users to add multiple patients to multiple projects quickly and easily without having to locate each project individually from the user's list of assigned projects.

If you use the second method, you will need to select the project you are adding a patient to from the drop down list then select STH as the Project Site, and then click **NEXT.**

Note:
If you are unable to find your project or project recruitment site, please contact your Local EDGE Administrator and request clinical access at the Project Site level.

After clicking **NEXT**, you will be asked to enter the Patient Identifier details.

This will be the Local Number, i.e. a sequence of characters or numeric values used locally to identify a patient. It may also be a randomisation number.

After clicking **NEXT** you will be asked to enter the patient's demographic information. Please note that Title, Forename and Surname are mandatory fields whilst DOB, Gender, Address, Postcode, Email, Phone and Mobile are optional.

When the patient's details have been completed, click **NEXT**.

After clicking **NEXT** you will be directed to the **PROJECT DATA** screen to complete the patient's Hospital Number, Project Arm* and Date Referred if applicable. Please note that Hospital Number is mandatory.

*The Project Arms are defined at Project Level. If no Project Arms are available in the drop down list when adding a patient, you should contact your local EDGE Administrator to add the Arms. Please ensure that Project Arms are added to EDGE prior to adding patients to the study record and that they are taken directly from the Protocol using the exact naming convention.

After clicking **NEXT** you will be required to complete (or partially complete) the patient's status. These are all the stages that a patient may pass through on your Project.

This must be filled out in numerical order, starting with the date box at the top. Enter a date against the applicable fields. Please note that there cannot be any blanks in between two dates. For some types of studies, you may have the same date for more than one stage and this is acceptable, as long as they are in order.

If you are completing this on behalf of another member of staff then select their name in the drop down box to reference this activity against them. If you are trying to reference another user in the drop down box but their name is not available, contact your Local EDGE Administrator so that they can add that user to the Project site with Clinical access. Once you have completed the necessary information click **NEXT.**

IMPORTANT: Please ensure that **both** the **Consented** date and **Recruited/Randomised***
date is completed for **each** patient, in order to ensure that the patient counts towards a study's accrual total.

*Recruitment is the enrolment of an eligible participant who meets the study's inclusion criteria, into a research study. Each participant who has both provided informed consent and is taking part in the study should be recorded as a recruit.

Note: Screen failures do not count as a recruited participant.

After clicking **NEXT** you will have the option to add some free text comments to record against the patient record.

When you have completed the necessary information click **NEXT.**

Before completing the patient's recruitment, EDGE will display a summary page of the information you have entered. To correct or edit this information click the **PREV** tab, if all the details are correct click **FINISH**. To abandon the patient recruitment and remove all the data click **CANCEL**.

After clicking **FINISH**, a notification will appear in the top right corner of the screen to inform you that the patient has been added to the Project Site.

Note:
If you experience problems recruiting a patient, please contact your Study Manager or Local EDGE Administrator.

Finding Patients

HOME > PATIENTS

Users with clinical access on EDGE will be able to search for their patients by using the **PATIENTS** tab. This will display results for patients that have been added to project sites for which that user has Clinical access.

Administrators and Users will **NOT** be able to access patient information for Projects or Sites outside of their organisation or projects within their organisation for which they do not have clinical access.

To begin searching for a patient record, click the **PATIENT** tab from the **HOME SCREEN** of EDGE. If searching by name alone has returned multiple entries, you can click the **ADVANCE SEARCH** function to refine your search criteria further by date of birth and patient identifying number.

When you have located the patient record that you are looking for, click on the patient's name and this will take you to their record. From there you can access further details about the patient. There is also a hyperlink which will take you to the project site which they have been added from, where you can access their full patient record.

Update Full Patient Records

HOME > PROJECTS > ASSIGNED PROJECT (Select Applicable Project) > SITES > (Select Site) > PATIENTS

To update or amend a patient record or complete a patient's recruitment information, find the patient's name or identifying number from the list under the **PATIENT** tab at the Project Site. This list will contain all patients that have been added to the site.

Click the name of the relevant patient and their high level record will be opened. To edit or amend details, click **EDIT** next to the appropriate section. All Clinical Users at the Project Site Level can amend patient records.

Patient Appointments

HOME > PROJECTS > ASSIGNED PROJECT (Select Applicable Project) > SITES > (Select Site) > PATIENTS > (Select Applicable Patient) > APPOINTMENTS

EDGE allows you to record and plan patient visits against individual patient records. Click the **APPOINTMENTS** tab and click **ADD**. You can populate this will the full schedule of visits or populate it as and when needed.
The **ADD PATIENT APPOINTMENT SCREEN** requires you enter data regarding the visit, including the subject, a start and end date as well as the event type and there is a free text field for comments.

If the Global Event box is left un-ticked, this appointment will only be displayed when a user looks at this individual patient's diary.

If the Global event box is ticked, then this will publish the appointment into the Global Calendar of every user who has Clinical access for that project at STH. Therefore, if you work across numerous projects, then you can look in your global calendar and see appointments for all patients on trials you are working on.

Off Study - Rejected/Withdrawn Patients

HOME > PROJECTS > ASSIGNED PROJECTS > (Select Applicable Project) > SITES > (Select Site) > PATIENT

If a patient does not complete their participation in a project due to being rejected (clinician decision) or withdrawing (patient decision) you can record this against the patient record in EDGE.

Within the **PATIENTS** tab at project site level click on the highlighted name of the applicable patient to access their record. Click **EDIT** against the **PATIENT STATUS** record and select **OFF STUDY.** A date, reason for leaving the project and who the patient was taken off study by, will need to be applied in order to record and report on withdrawal and rejection rates across the whole project.

Deceased Patients

HOME > PATIENTS > (Find Applicable Patient) > PATIENT DEMORGRAPHICS

To record that a patient has died during the course of a project, you must first locate their record at either the project site through the **PATIENTS** tab or via the **FIND PATIENTS** function on the **HOME SCREEN**. Upon locating the correct patient record, click their name to display their **FULL PATIENT RECORD**. Click **EDIT** within the **PATIENT DEMOGRAPHICS** section.

Within the **EDIT PATIENT DEMOGRAPHICS** window, check the box next to deceased and complete the date of death below as well as their cause of death. When you have completed these details click **SAVE**.

The patient will also need to be recorded as being off study with the applicable date and reason code. To perform these actions refer to the **OFF STUDY – REJECTED/WITHDRAWN PATIENT** section.

My Calendar

HOME SCREEN > MY CALENDAR

The calendar allows you to manage your study appointments within EDGE. To add an entry, click **ADD EVENT** and type the title, start and end time (you can select 'all day event' if necessary), category, location, any extra details and recurrence type.

If the information is applicable to other users, tick the **GLOBAL EVENT** box to make it visible to other users of the project in the **GLOBAL CALENDAR**. Other users may also send information to your calendar by using the global event function. You will be informed of this in your **NOTIFICATIONS** tab when you log in to EDGE.

If you are part of a team on EDGE, you will be able to see the personal diary entries of those who are in your team. If you want to view these entries, tick the box with the team name on or tick the specific user out the team whose calendar you want to view.

Global Calendar

HOME SCREEN > GLOBAL CALENDAR

The Global Calendar allows users to keep track of Trust-wide appointments (e.g. training and reporting deadlines). This calendar is linked to the **MY CALENDAR** section which manages personal schedule entries. The **GLOBAL CALENDAR** is populated by checking the **GLOBAL EVENTS** box when adding an entry in **MY CALENDAR**.

To view the entrant of a global appointment, click **SHOW OWNER**. Each calendar entry will produce, below its title, the user who has added that entry.

Reports - Recruitment

HOME SCREEN > MY REPORTS > MY RECRUITMENT

This feature is available to all users but results will only be displayed for users with Clinical Access at a Project Site

My Reports > My Recruitment allows individual users to report on their activity across a range of projects over a monthly basis looking at patients screened, rejected, recruited and withdrawn.

This can form part of a user's personal as well as their department's performance statistics. The report can be downloaded to an **Excel** spread sheet or **PDF**.

HOME SCREEN > MY REPORTS > MY PROJECTS ACCRUAL

This feature is limited to Users assigned as a Principal Investigator at Site Level

A Principal Investigator (PI) using EDGE will be able to monitor their own monthly recruitment figures across all projects and sites through the **MY PROJECT ACCRUAL** function. This report provides project recruitment information at all project sites within the organisation, in real time.

HOME SCREEN > MY REPORTS > MY TEAMS RECRUITMENT

This feature is limited to assigned Team Managers

You can produce staff recruitment reports for all studies you are assigned to as a Team Manager. These reports can be filtered and sorted to reflect recruitment by projects, teams, sites or individual members of staff. Each of these reports can be downloaded into **Excel** for further sorting or into **PDF** format for distribution.

Please note that if you wish to include a Team Leader's recruitment figures into the report, they must be added as a Team Member also. Being a Team Leader will allow them to run the report but will not automatically include their own recruitment into it.

HOME SCREEN > MY REPORTS > SHARED REPORTS

This feature is accessible by all EDGE users

Shared reports are a function controlled by your EDGE local Administrators. Reports are predefined by Local Administrator and shared with individual users, teams, groups of teams or an entire organisation.

To run a shared report, click **MY REPORTS** on your home screen and select **SHARED REPORTS**; from the drop down select the report you would like to run and click **SUBMIT QUERY**. This will generate a list of results based on the criteria defined by your EDGE Local Administrator.

The results can be exported to **PDF** for printing and distribution or **Excel** for filtering or refining.

Support

In the first instance all queries should be directed to your local EDGE administrator:

Natasha Ottley
0114 226 5930
Natasha.ottley@sth.nhs.uk

Zoe Whiteley
0114 271 2572
Zoe.whiteley@sth.nhs.uk

Please also contact us if you have any feedback regarding this handbook.

Appendix 1 - Definitions of terms used at site level, on the Details tab

Name	Description
Recruitment end date (Planned)	The date that recruitment is planned to end at a specific site
Recruitment end date (Actual)	The date that recruitment has actually stopped at a specific project site
Closed date	The date the project site closes
Recruitment (My Org) First patient recruited	The date the first patient was recruited on to a project by **STH**
Recruitment (Any Org) First patient recruited	The date the first patient was recruited onto a project by **any** Trust
Recruitment (My Org) Actual recruitment	The % recruitment that has taken place within **STH**
Recruitment (Any Org) Actual recruitment	The % recruitment that has taken place within **any** Trust
Recruitment (Any Org) Recruitment clock (days)	The number of days that have elapsed between the NHS permission date and the first patient being recruited at **any** Trust.
Recruitment (My Org) Recruitment clock (days)	The number of days that have elapsed between the NHS permission date and the first patient being recruited at a specific site by **STH.**