STH EDGE Handbook

Version 3

edge

Sheffield Teaching Hospitals NHS
NHS Foundation Trust

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Introduction

EDGE is a web-based accrual reporting system that enables the Clinical Research & Innovation Office (CRIO) 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, even if they have provided consent.

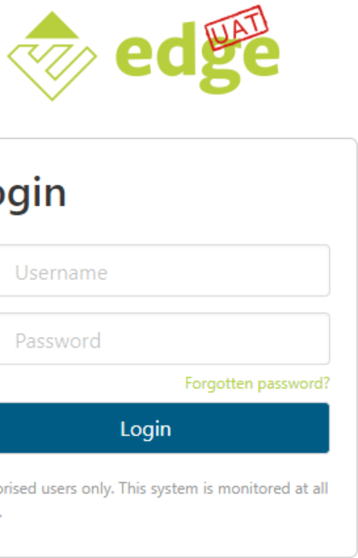
Source:
http://www.crn.nihr.ac.uk/can-help/funders-academics/nihrcrn-portfolio/faqs/

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 (usually: 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.

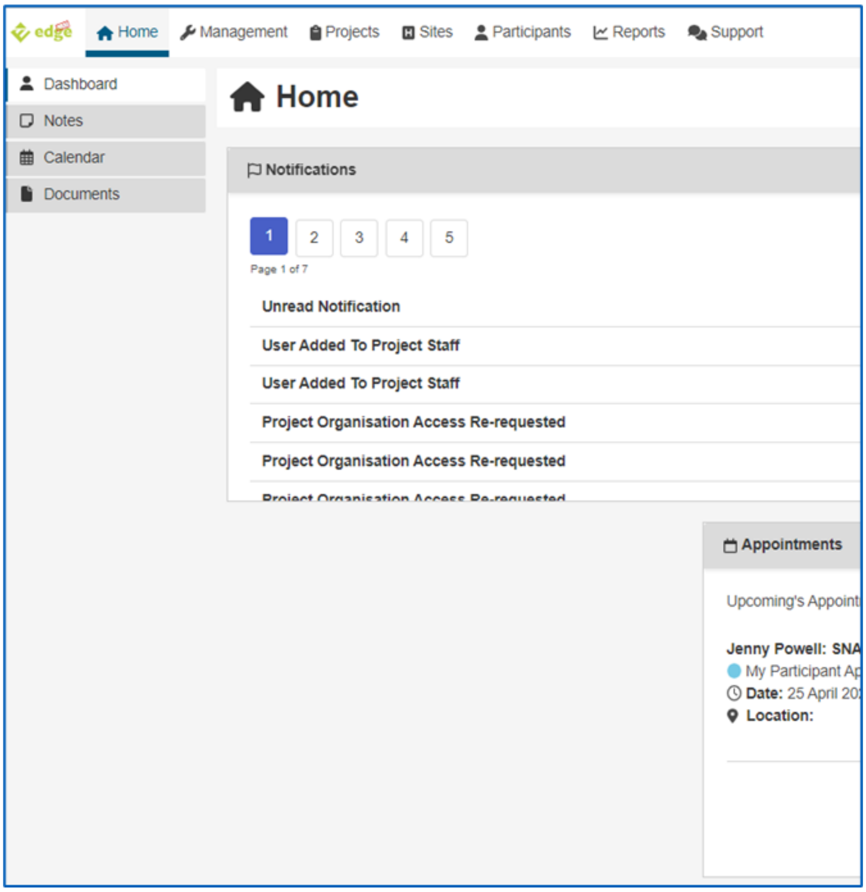
Local EDGE Administrators at STH NHS FT:

Jenny Powell jenny.powell1@nhs.net 0114 226 5935
Emily Shiels e.shiels@nhs.net

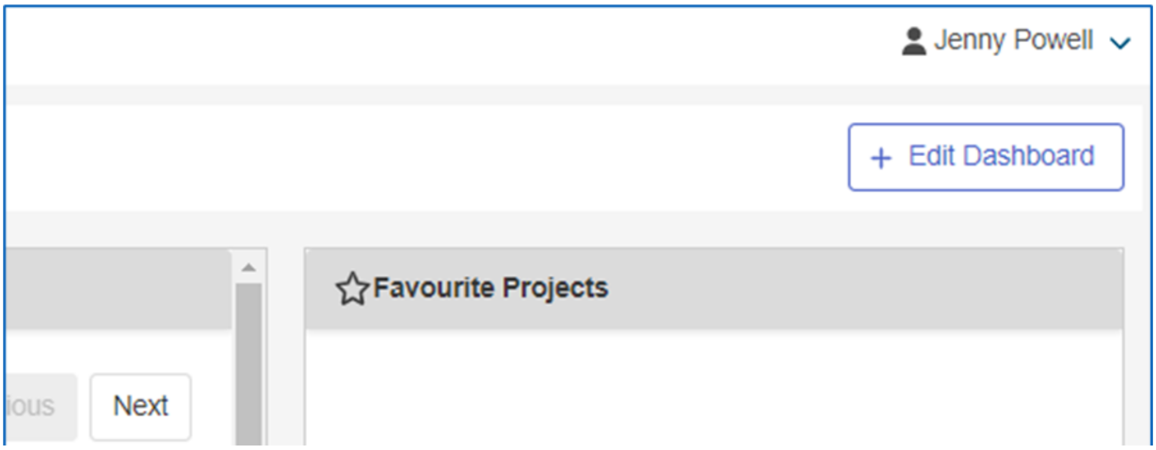
Home Screen

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 will appear in the top right corner of the screen. To securely end your session when you have finished, click the arrow next to your name (which reveals drop-down menu) and press **LOGOUT**.



Security

Changing your password

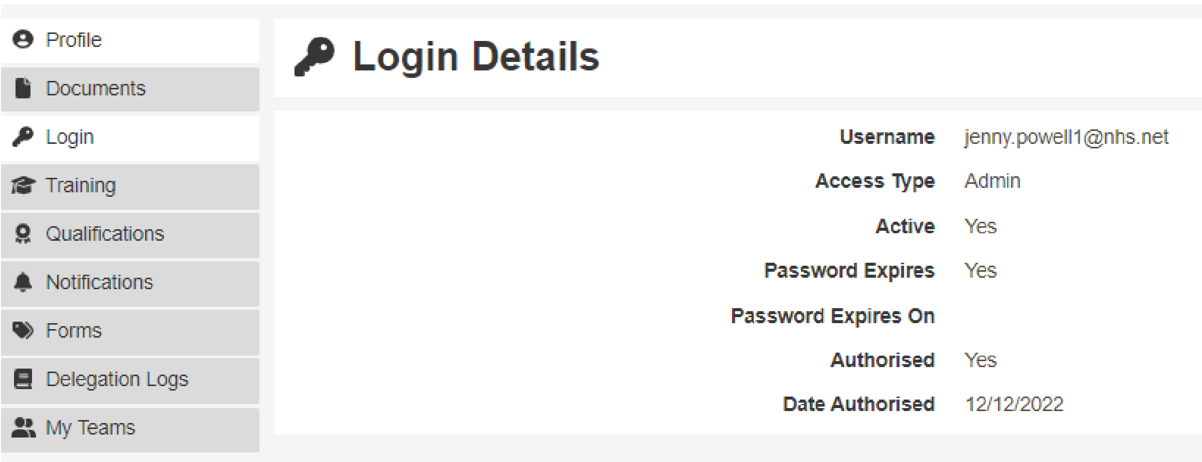
HOME > MY PROFILE > MY LOGON DETAILS > CHANGE PASSWORD

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 1 upper case letter (A-Z)
- At least 1 lower case letter (a-z)
- At least 1 number (1-9) or special character (!$&)
- At least 8 characters in length

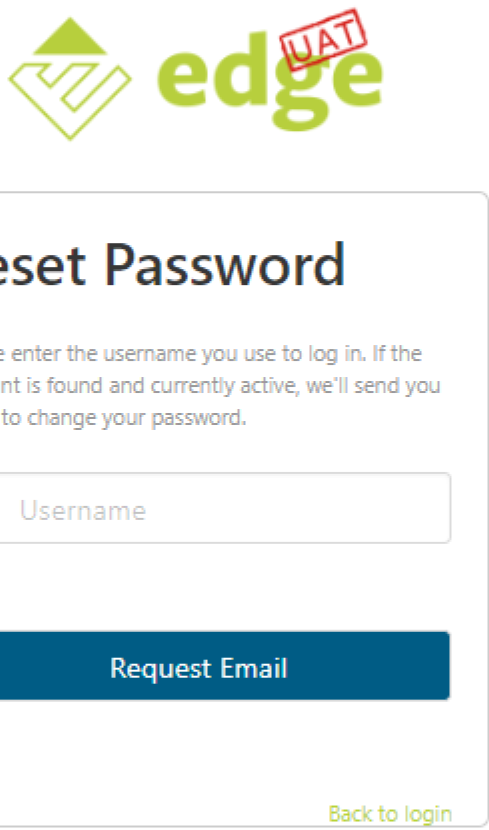
If your password does not comply with the above 4 conditions, it will not be accepted. A symbol will appear next to the unfulfilled criteria. All four must show a green tick next to them before the new password can be applied. You will need to enter your password twice in order to confirm it and then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



Forgotten your Password

If you forget your password, click **FORGOTTEN PASSWORD** on the **LOGIN** screen.

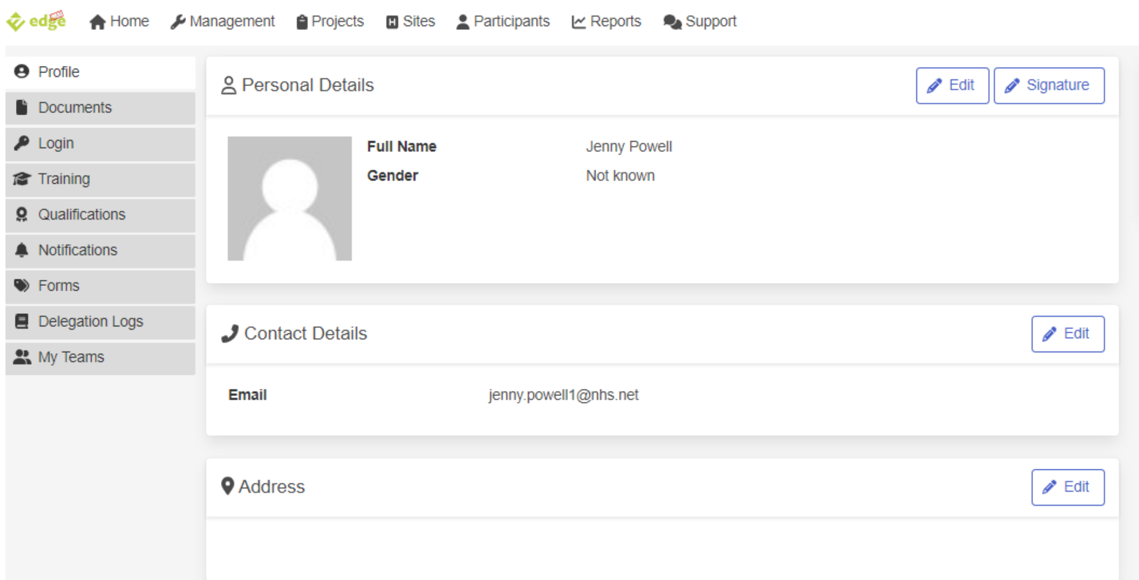
You must know your username (usually your NHS email address) in order to complete this process. If you are unable to log on using the **FORGOTTEN PASSWORD** link, please contact your Local EDGE Administrator in the first instance.

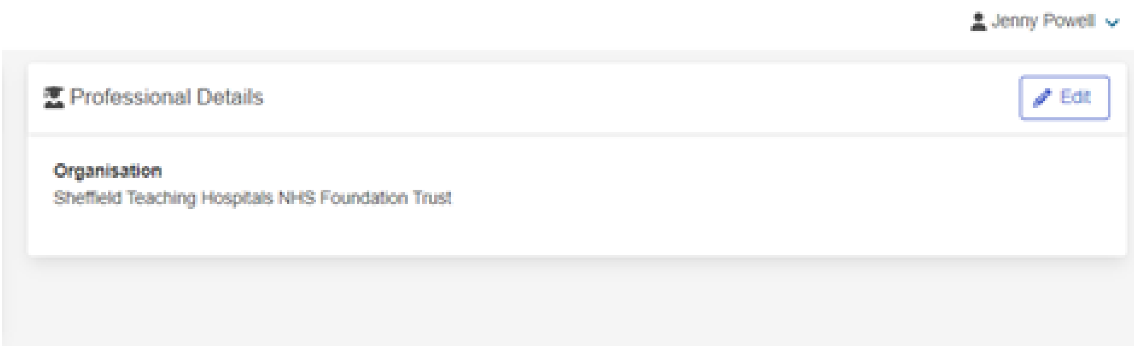


My Details – Updating contact details

HOME > MY PROFILE > EDIT

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.





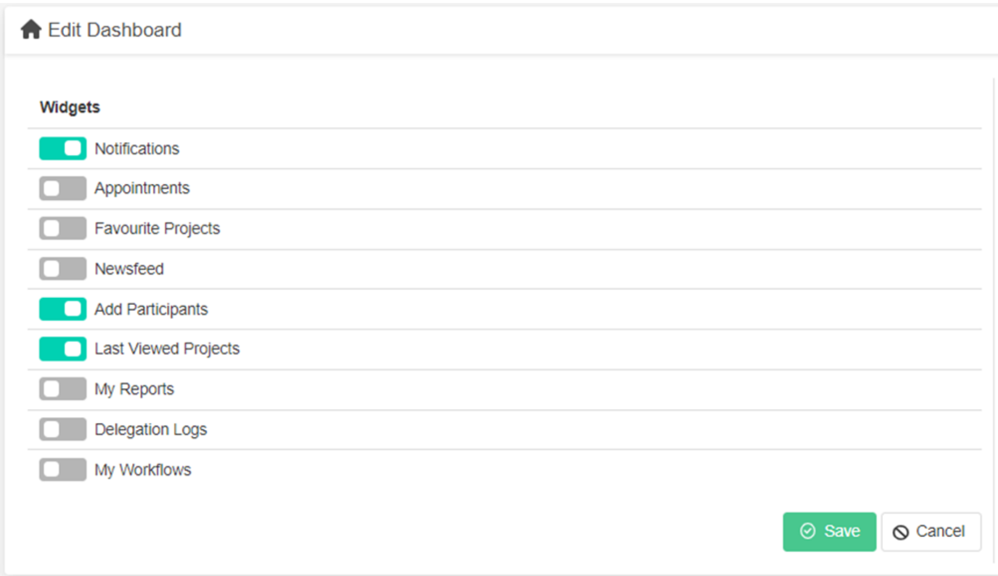
When you have finished, click **SAVE** to apply the changes. If your details change, please ensure you update the system as soon as possible.

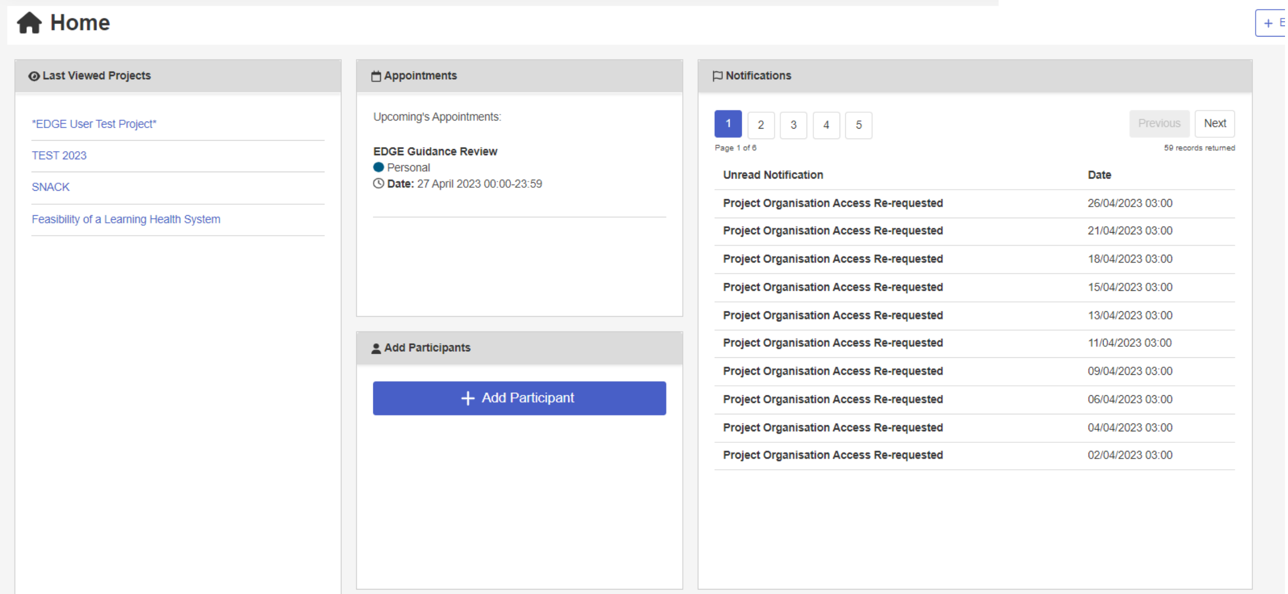
Dashboard

The dashboard contains a series of widgets to offer shortcuts and provide useful overviews concerning your EDGE data. You can also choose the widgets you mostly use. You can drag and drop the widgets to move them and use the arrows in the bottom right-hand corner of each widget to expand/minimise them.

To customise your **Dashboard:**

- Click **Edit Dashboard**
- On your list of available widgets, use the toggle switch to enable/disable them
- Click **Save**

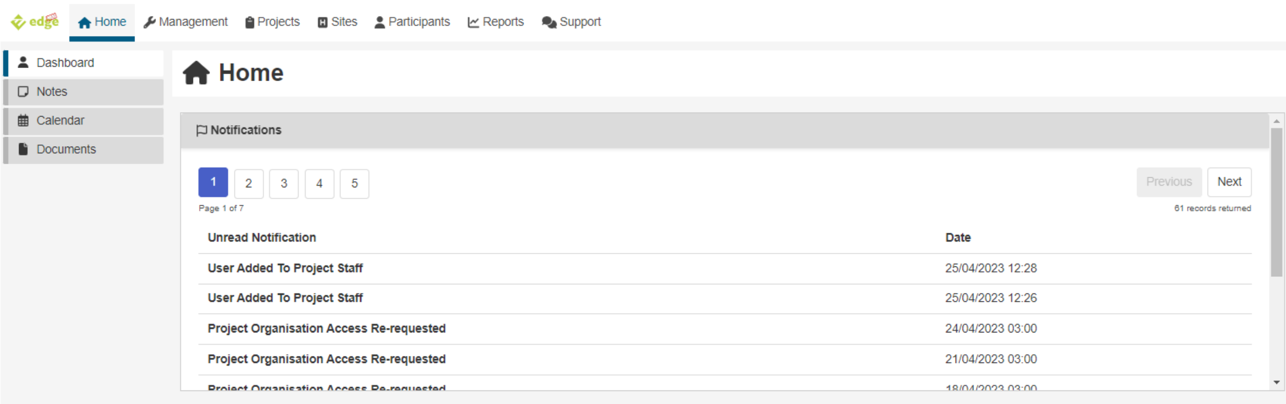




Notifications

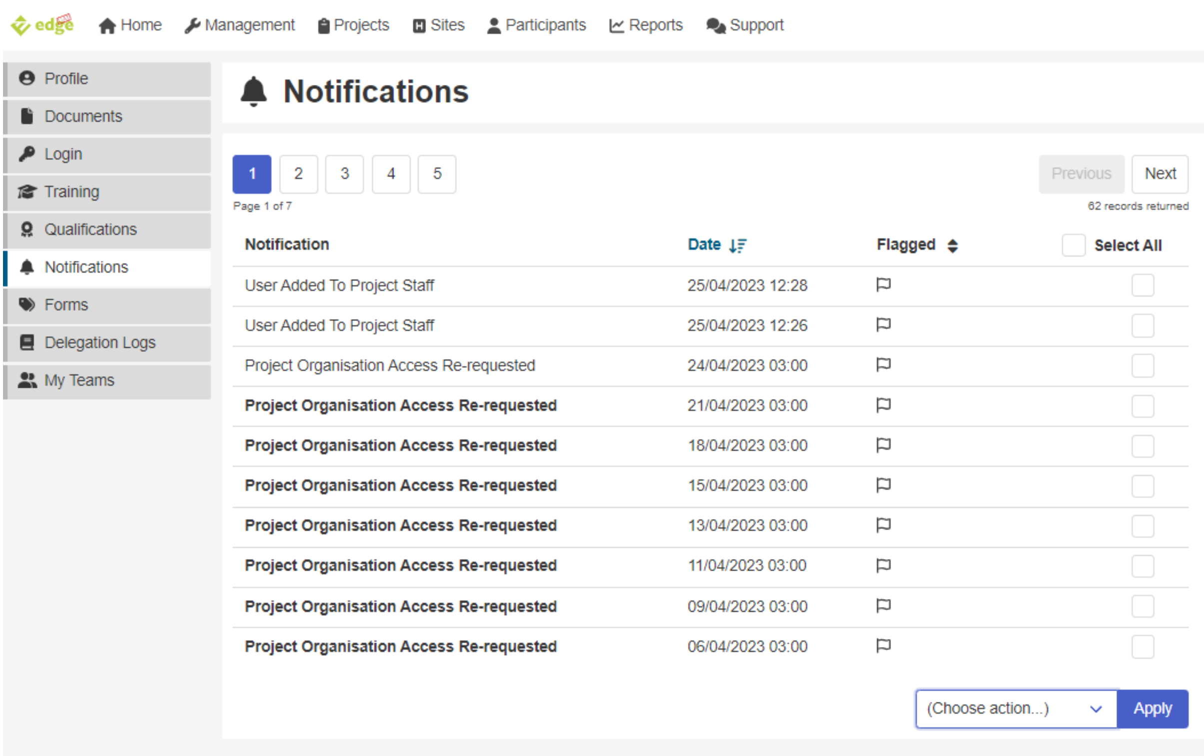
HOME > NOTIFICATIONS

On the home screen, **NOTIFICATIONS** should be selected as a feature on your dashboard so they show on your Home page.

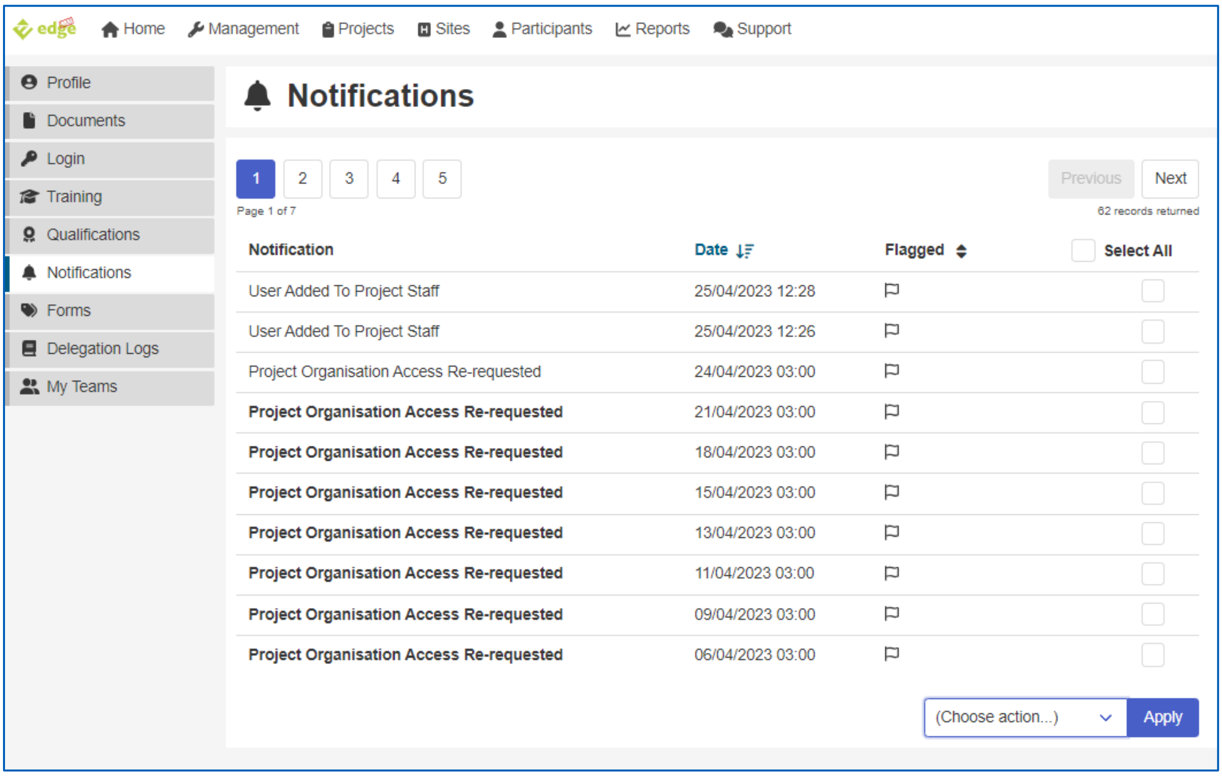


EDGE allows users to choose which notifications they would like to receive. These notifications will help a user to understand the activities that have taken place in the system.

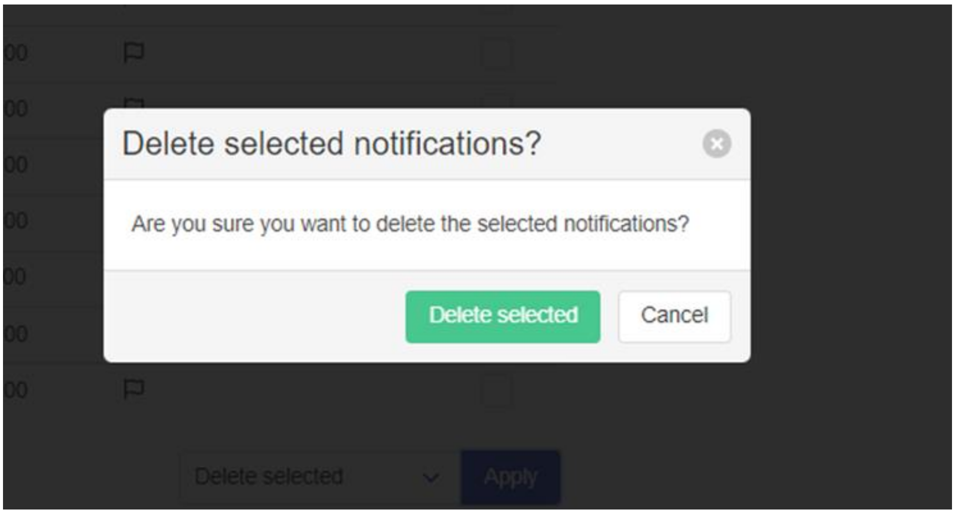
1. Click **Settings**
2. Untick the adjacent box to amend the Receive Internal Notifications
3. Tick or Untick the adjacent box to amend the Receive Email Notifications
4. Click **Save**



To delete notifications from your home page so you only see new ones MY PROFILE> NOTIFICATIONS > SELECT ALL > DELETE



Deletion of notifications cannot be undone. Confirmation is required when choosing to delete all notifications to ensure you do not accidentally delete required notifications.

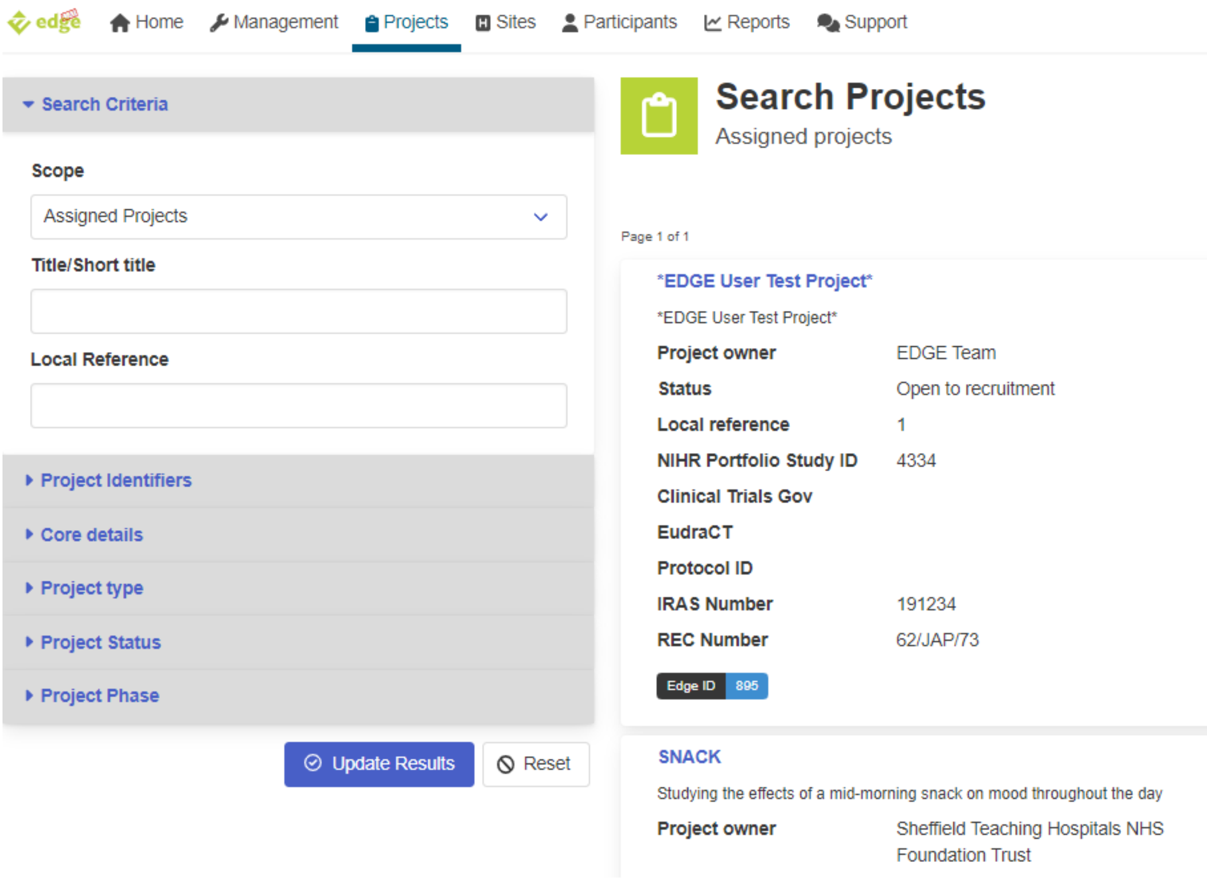


Searching for a Project

PROJECTS

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

Note: if you select the Last Viewed Projects widget for your dashboard. The last 10 projects that you viewed will be displayed on your home screen. Clicking the link will take you directly to that project page.



This will take you to a searching screen, where there are various methods of searching depending on what you are looking for:

Scope:

- Assigned Projects: studies which you have been directly assigned to (you will use this option the most frequently)
- Organisation Projects: studies which STH are involved in
- Global Projects: all studies including those outside of STH

Title/Short title

Local Reference: STH Reference Number (STHXXXXX)

Project Identifiers - data listed below which you may have access to:

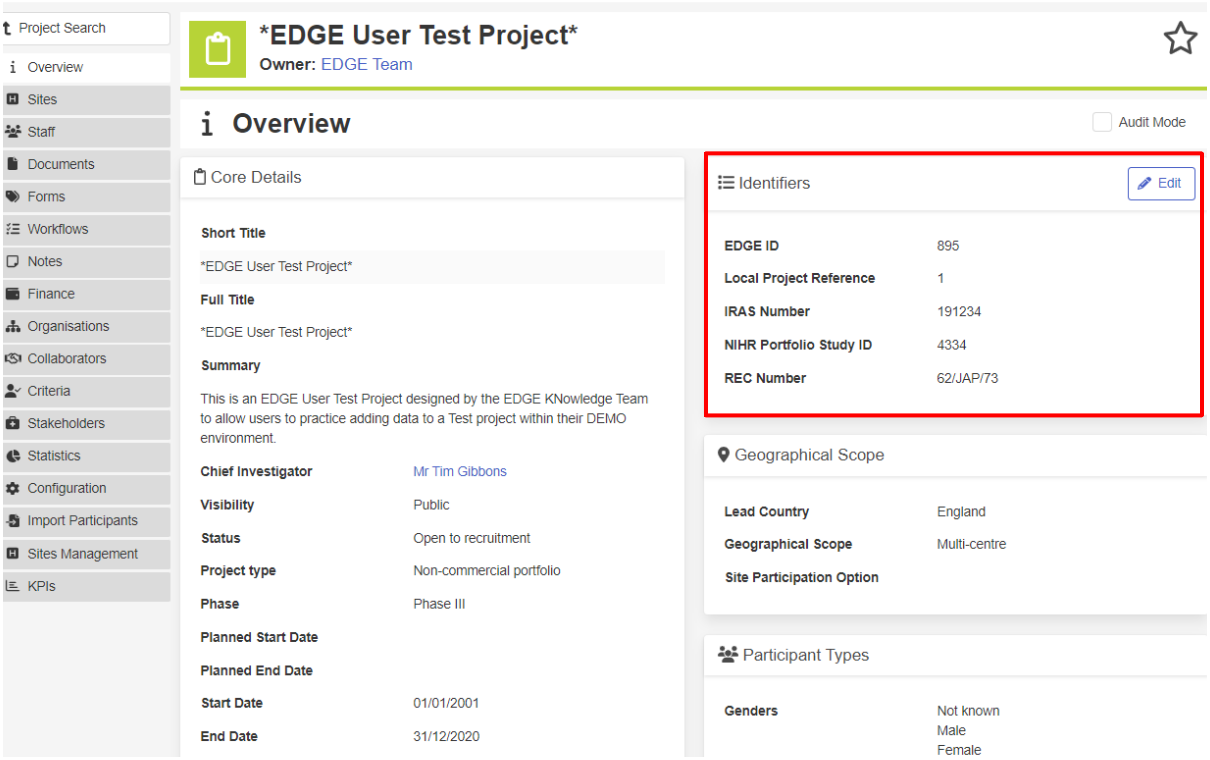
- EDGE ID
- NIHR Portfolio Study ID (if the project has been adopted by the NIHR)
- IRAS Number
- REC Number

Once you have typed in your project identifier(s), you can either press **ENTER** on your keyboard or click **SEARCH** and all studies matching the search criteria will be displayed in the search results underneath. Click on the blue hyperlinked title and you will be able to see the overview of the study depending on your access.

Project Level Information
(Defined by a GREEN Square and underline)

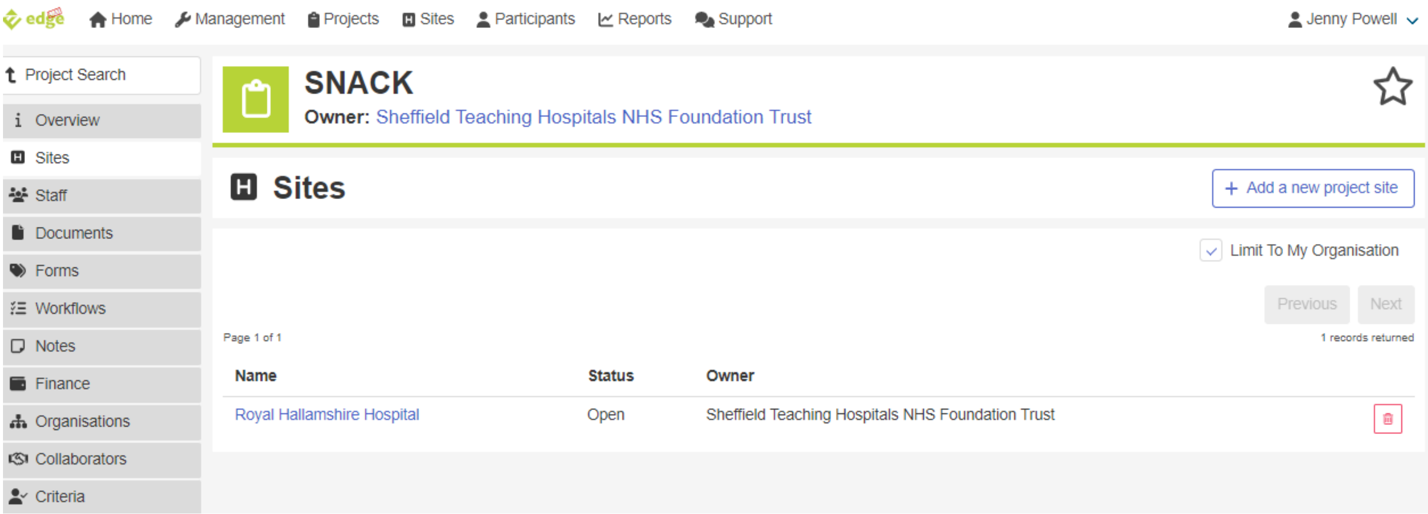
When you first open a study, you will be directed to the details tab at **PROJECT LEVEL**. Information including the Chief Investigator, Sponsor, Funder, Study Status etc. will be displayed.

All key **PROJECT IDENTIFIERS** such as EDGE ID, Local Project Reference, IRAS number, MREC number etc. will be found in the top righthand corner of 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.

To access the **SITE LEVEL** information (where you can upload recruitment), click on 'Sites' on the left hand side and then select the relevant site that consent has occurred in. In most cases there will be only one option (blue hyperlink).

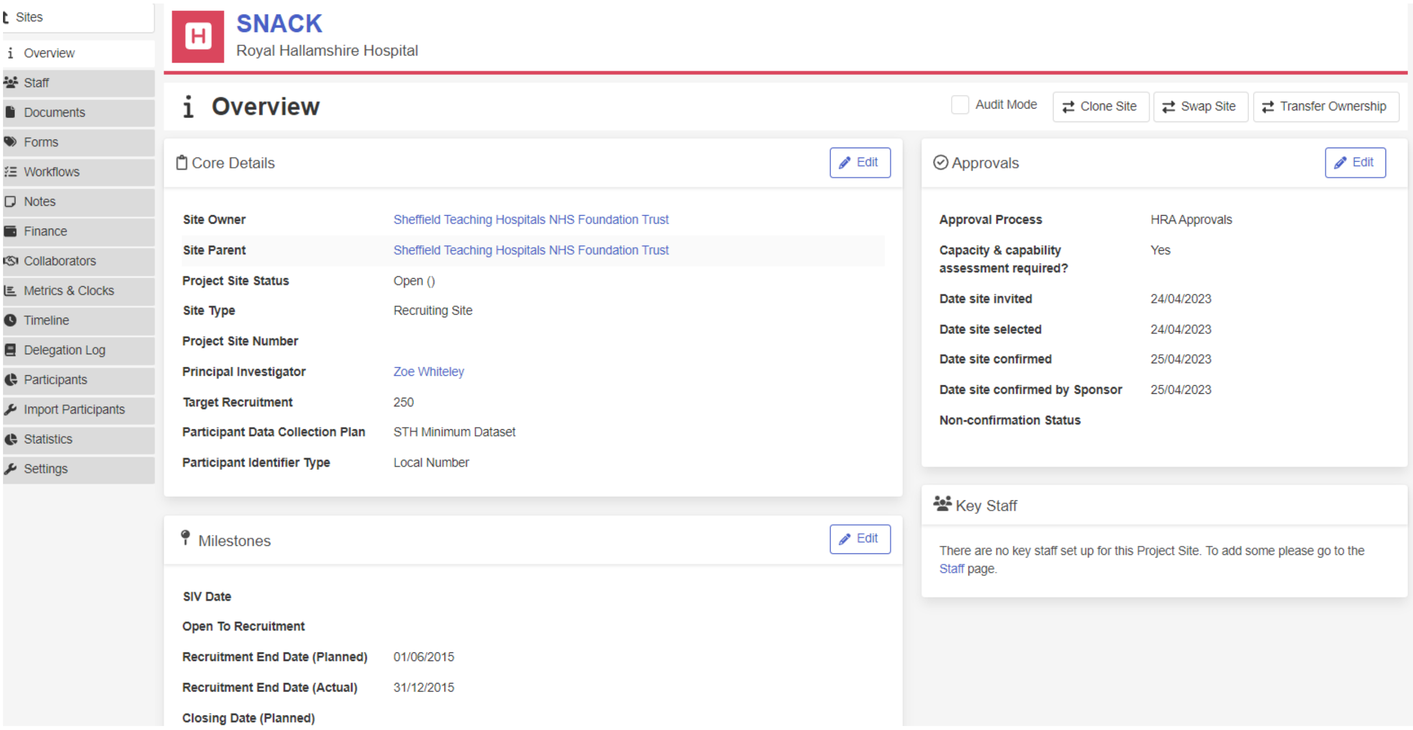


Site Level Information

(Defined by a red box around the Site letter and a red line under the project title)

The **SITE LEVEL** page provides information about the project at **STH** specifically, and is specific to the hospital location of consent. Here details such as the Principal Investigator, the Recruitment Window and Accrual (participants recruited) can be observed. EDGE now refers to participants throughout the site.

If any information provided is incorrect please speak to your local EDGE Administrator.



Definitions of the dates are found on appendix 1:

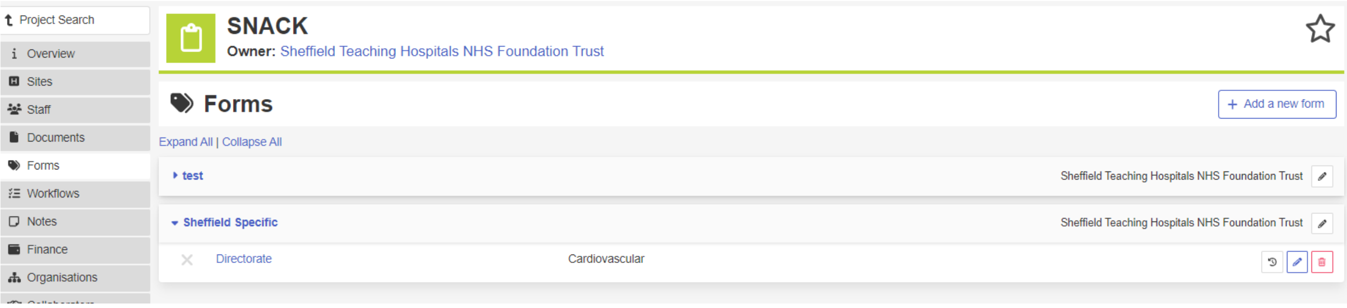
- SIV Date: Site Initiation Visit date (if applicable)
- Open to Recruitment Date: The date the site was opened for recruiting patients
- Recruitment End Date (Planned): Planned site end of recruitment date
- Recruitment End Date (Actual): Actual site end of recruitment date
- Planned Closing Date: The planned date at which all activity at the site will cease
- 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 CRIO will also monitor recruitment and edit site level information using this page

Site Forms

The **FORMS** at **SITE LEVEL** known as attributes in EDGE 2 are reflections of pieces of information which need to be captured at **SITE LEVEL** only. These can be found by clicking the 'FORMS' tab.



You should be able to see 5 possible **SITE LEVEL FORMS**:

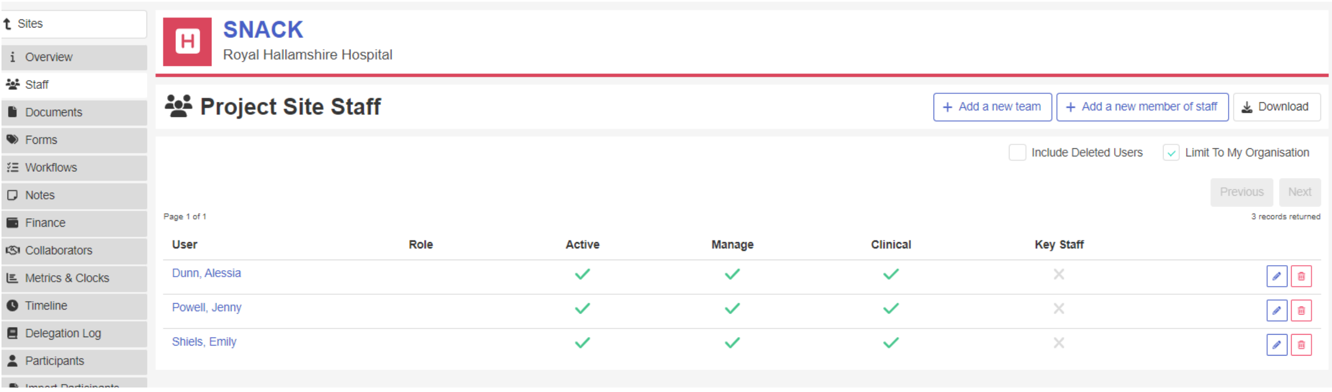
- STH location: the place where the study is primarily taking place, if this is not in either CRF, CTA Team or CCTC please state 'PI Site'
- Target Patient First Visit: this is the first visit date of the recruited patient that means the site target recruitment is met (e.g. if the site hopes to recruit 8 patients, this will be the date the 8th patient has their first visit)
- Last Patient Last Visit
- CRF Manager for Accrual (is the CRF Manager responsible for patient recruitment?)
- No recruitment: please tick 'True' for projects where patient recruitment is not required.

Note: If any information is missing or needs updating, please contact your local EDGE Administrator.

Site Staff

The **SITE LEVEL STAFF** tab contains the names of staff that are assigned to that specific project at their specific **SITE LEVEL**. All users   will be able to view this information, including which individuals have **MANAGE** and **CLINICAL** rights.

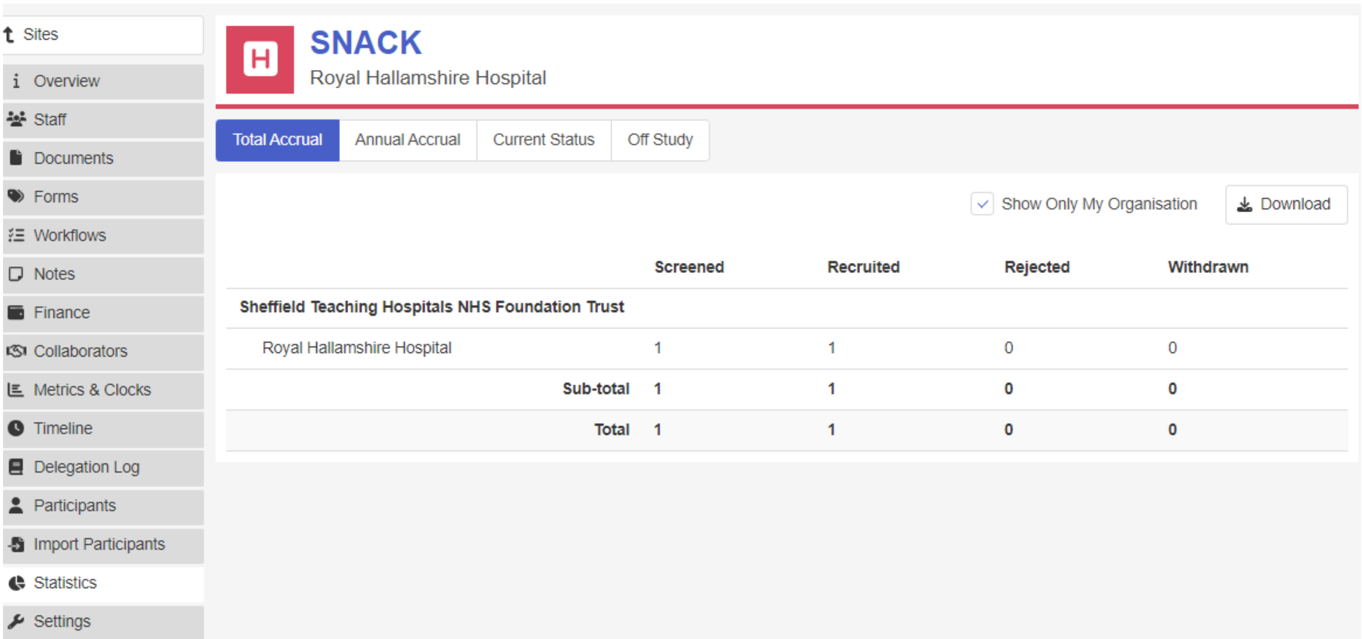
*Note: All staff members at **SITE LEVEL** who will be actively **RECRUITING** patients to a project will need to have **CLINICAL** access. This can include a staff member that is entering recruitment details on someone else's behalf, such as Data Managers and Coordinators. Directorate Coordinators can grant this access for the study team.*



Site Statistics

The **STATISTICS** tab within a project at **SITE LEVEL** ties in with the information presented at the **PROJECT LEVEL** KPIs tab.

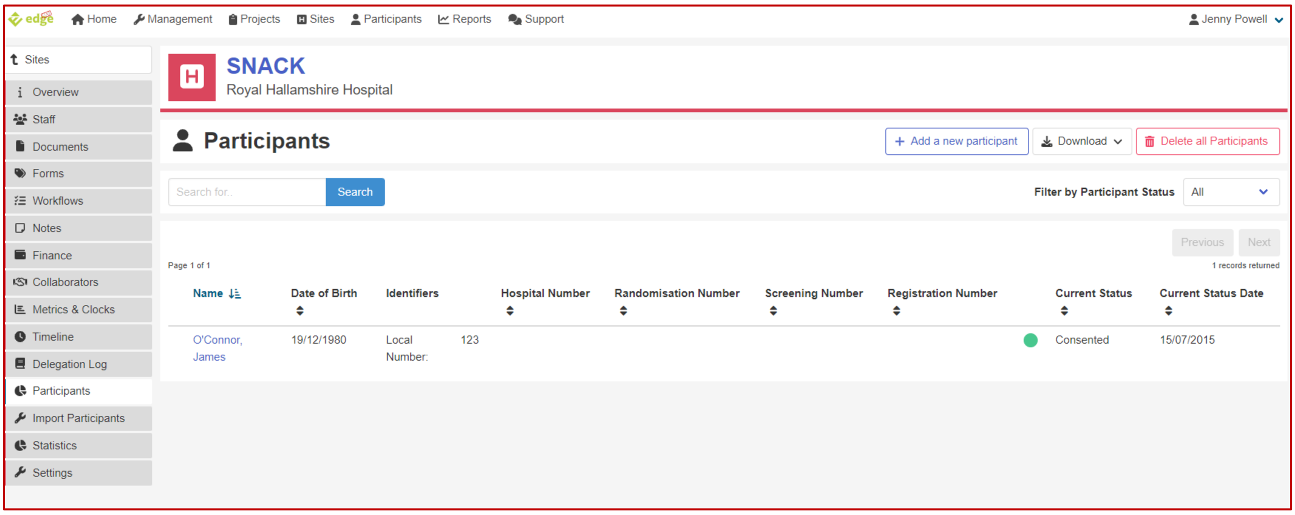
The project's patients and status within the trial can be broken down into **TOTAL ACCRUAL**, **ANNUAL ACCRUAL**, **CURRENT STATUS** and **OFF STUDY** for the patients recruited across the entire study, or for those only recruited at STH (when the 'Show Only My Organisation' box is selected).



Recruiting Participants to a Project and Site

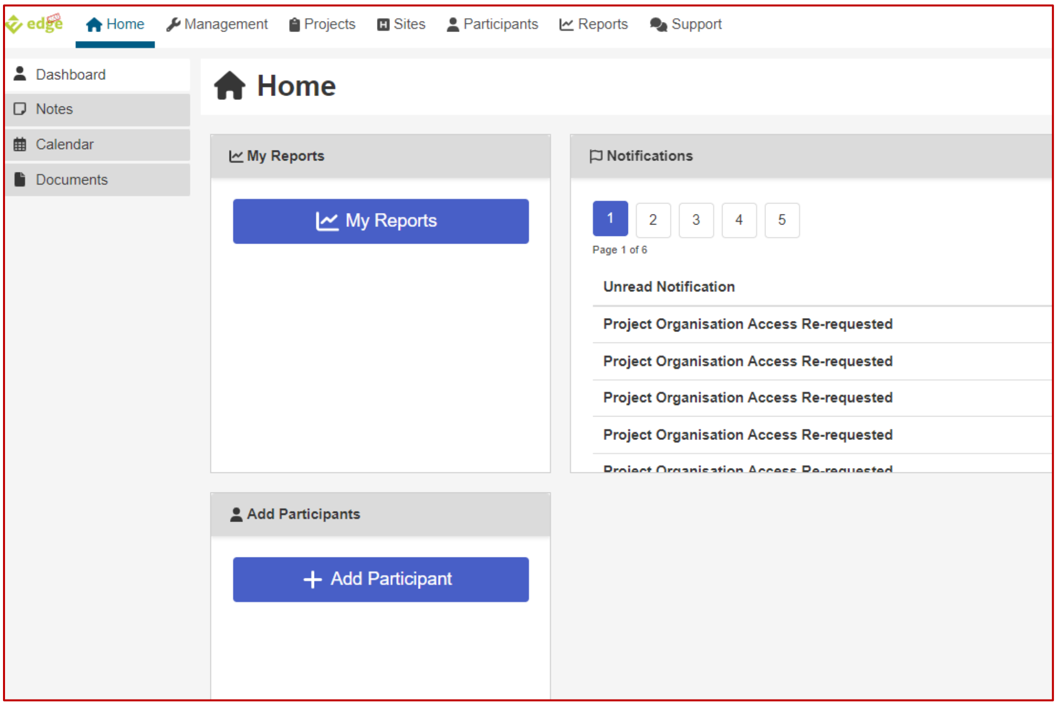
Participants can be added on to EDGE in two different ways. Firstly by locating the Project directly;

HOME > PROJECTS > ASSIGNED PROJECTS > (Select Applicable Project) > SITES > (Select Site) > PARTICIPANTS.



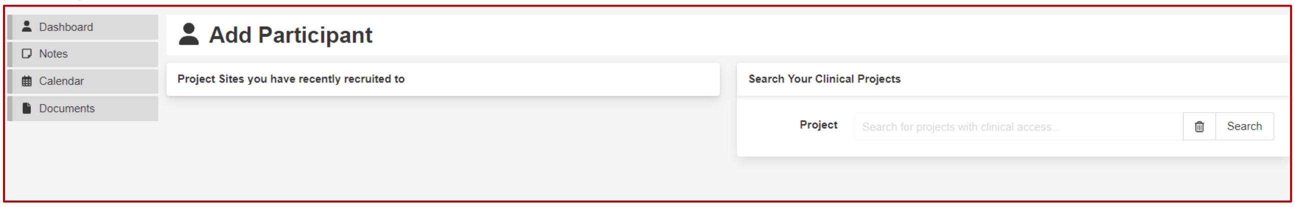
Or by editing your dashboard and adding Add participants as a widget on the EDGE home screen.

HOME > ADD A PARTICIPANT



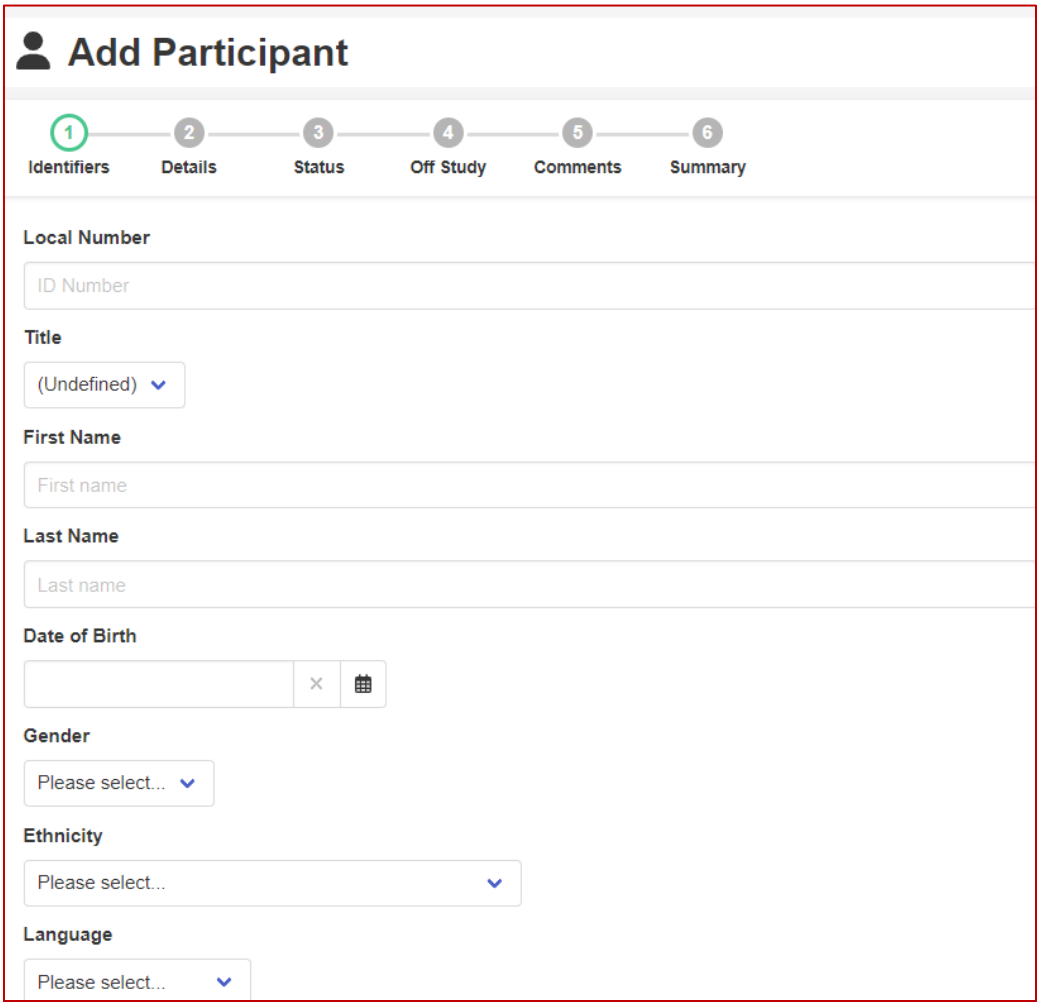
Note: The quick link allows users to add multiple participants to multiple projects quickly and easily without having to locate each project individually from the user's list of assigned projects.

If you use the second method, you will need to select the project you are adding a participant to from the dropdown list you will then see the sites you are assigned to/have clinical access to add participants to.



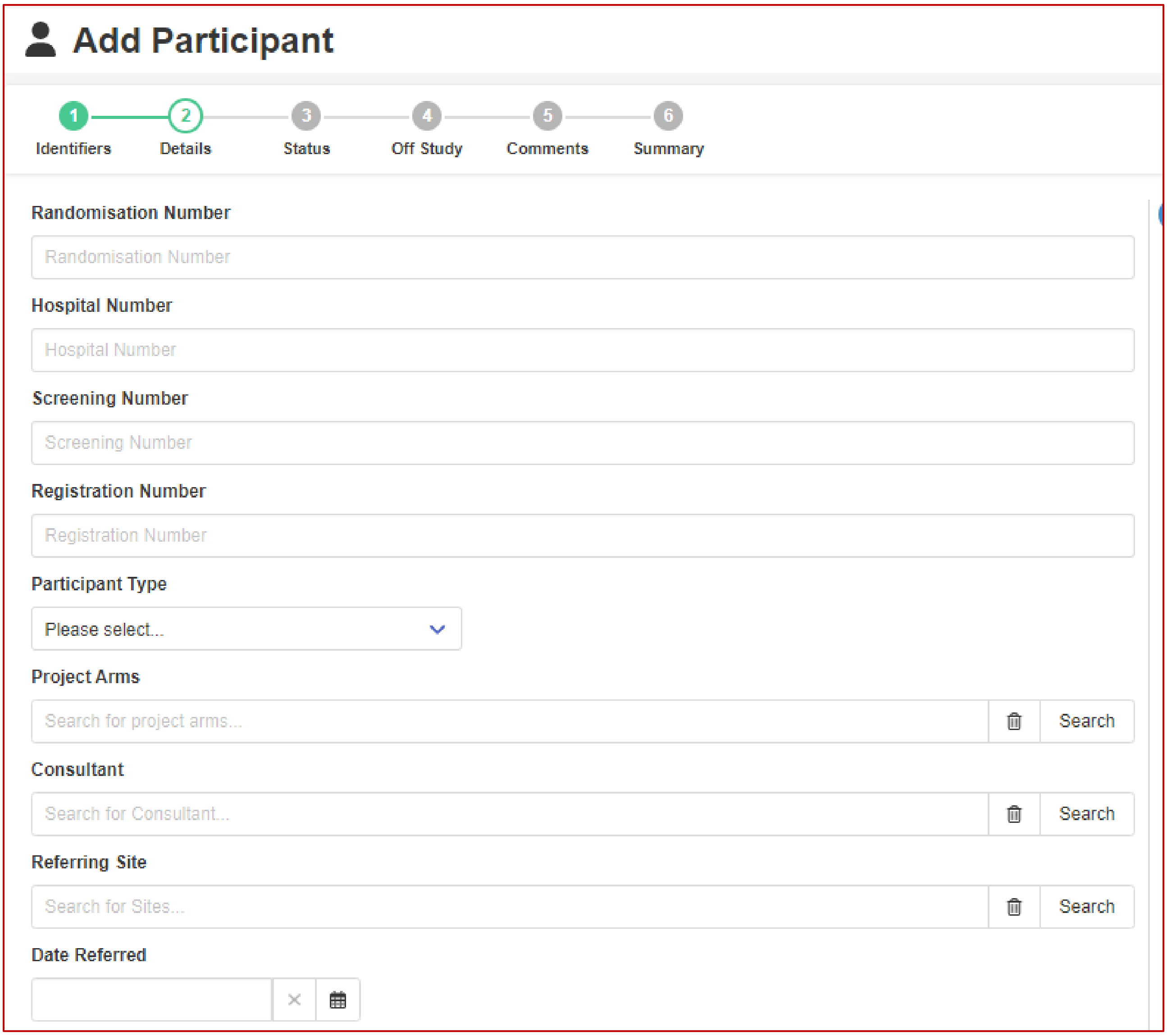
Note: If you are unable to find your project or project recruitment site contact your Directorate Coordinaotr or Local EDGE Administrator and request clinical access at the Project Site level.

You will then be asked to enter the Participant Identifier details.
This will be the Local Number, i.e. a sequence of characters or numeric values used locally to identify a participant. It may also be a randomisation number or Study ID number



You then need to add the participant's demographic information. Please note that Title, Forename and Surname are mandatory fields whilst DOB, Gender, Address, Postcode, Email, Phone and Mobile are optional. All fields can be entered with X, X if your study does not collect this data (e.g. anonymous survey studies).

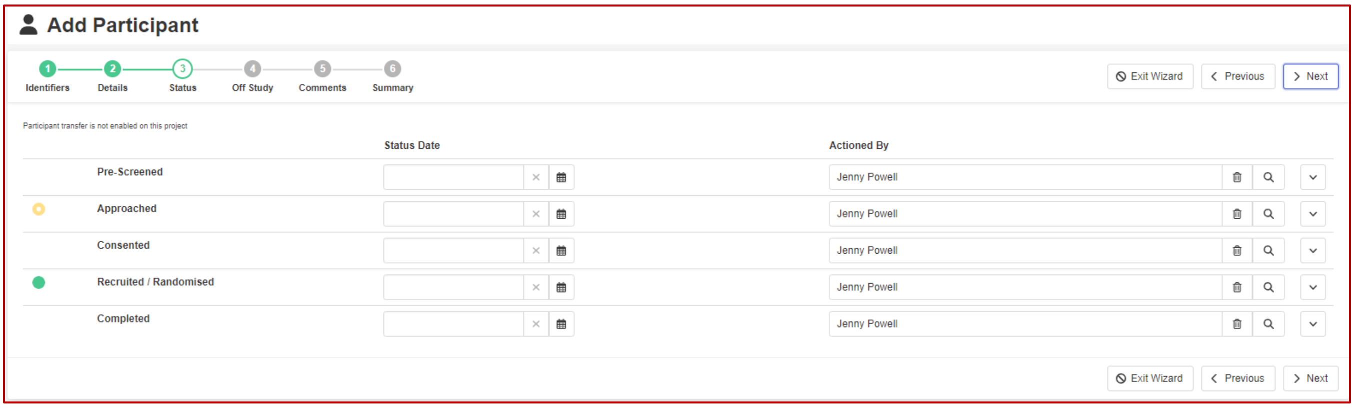
After clicking **NEXT** you will be directed to the **PROJECT DATA** screen to complete the participant's Hospital Number, Project Arm* and Date Referred if applicable. Please note that Hospital Number is mandatory.



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

NB. Project arms are set up by the study Sponsor therefore it may take some time to request these and will need to be agreed by the Sponsor. If participants are already recruited without arms defined, it may not be possible to add these.

After clicking **NEXT** you will be required to complete (or partially complete) the participant's status. These are all the stages that a participant 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.**

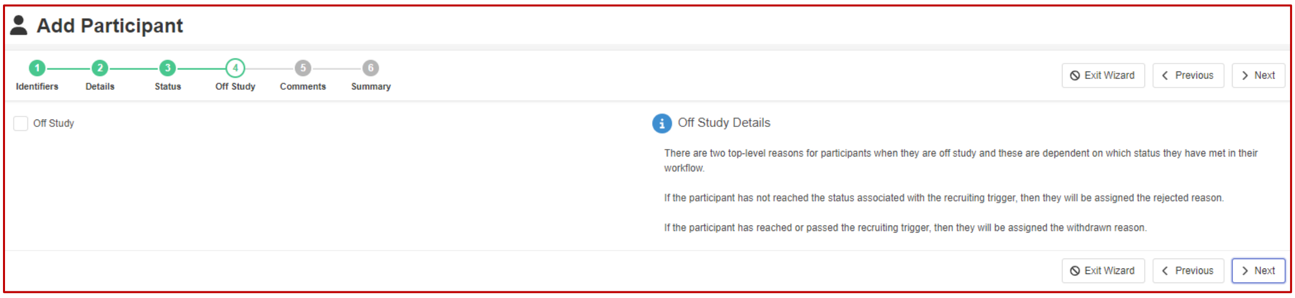
IMPORTANT: Please ensure that **both** the **Consented** date and **Recruited/Randomised*** date is completed for **each** participant, in order to ensure that the participant counts towards a study's accrual total.

***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.

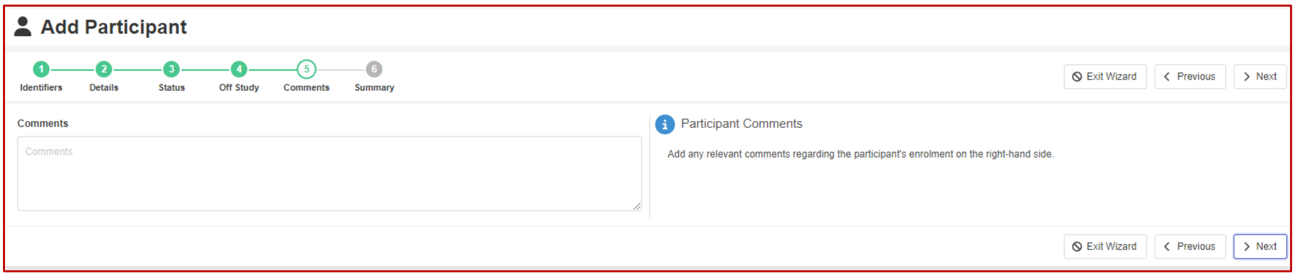
Note: Screen failures do not count as a recruited participant even if they have provided consent.

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

The Off study box is now a tab at this stage as below, if you are adding a new participants you can click **NEXT** to move past this screen

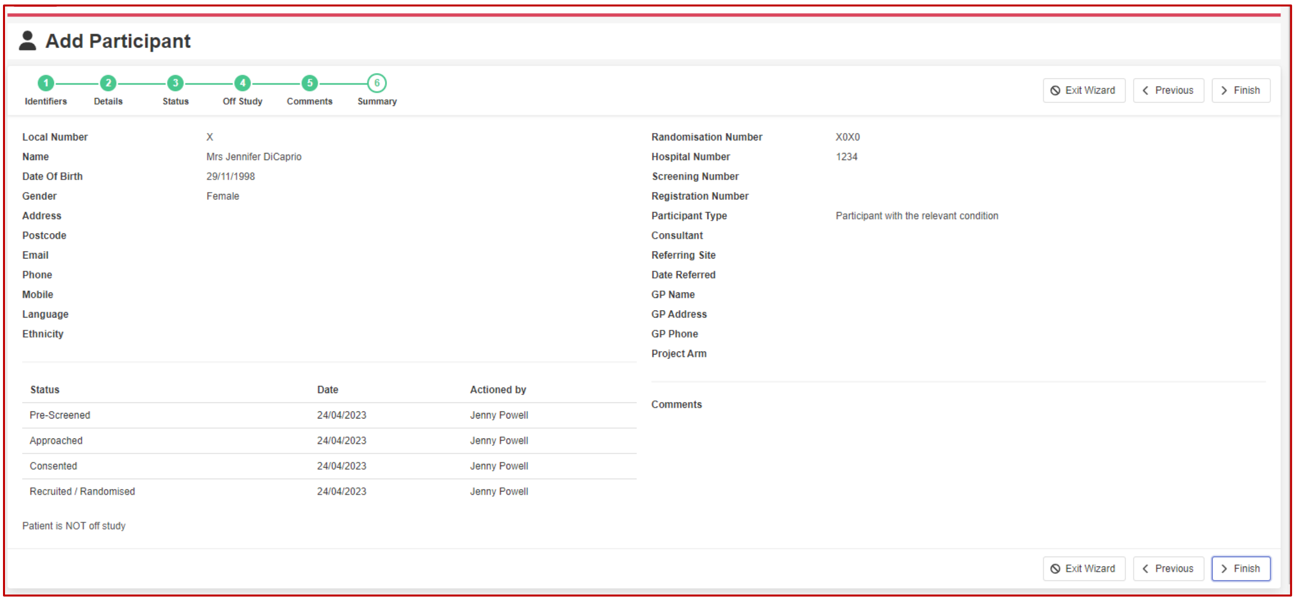


After clicking **NEXT** you will have the option to add some free text comments to record against the participant record. This will only be visible to those who have clinical access.

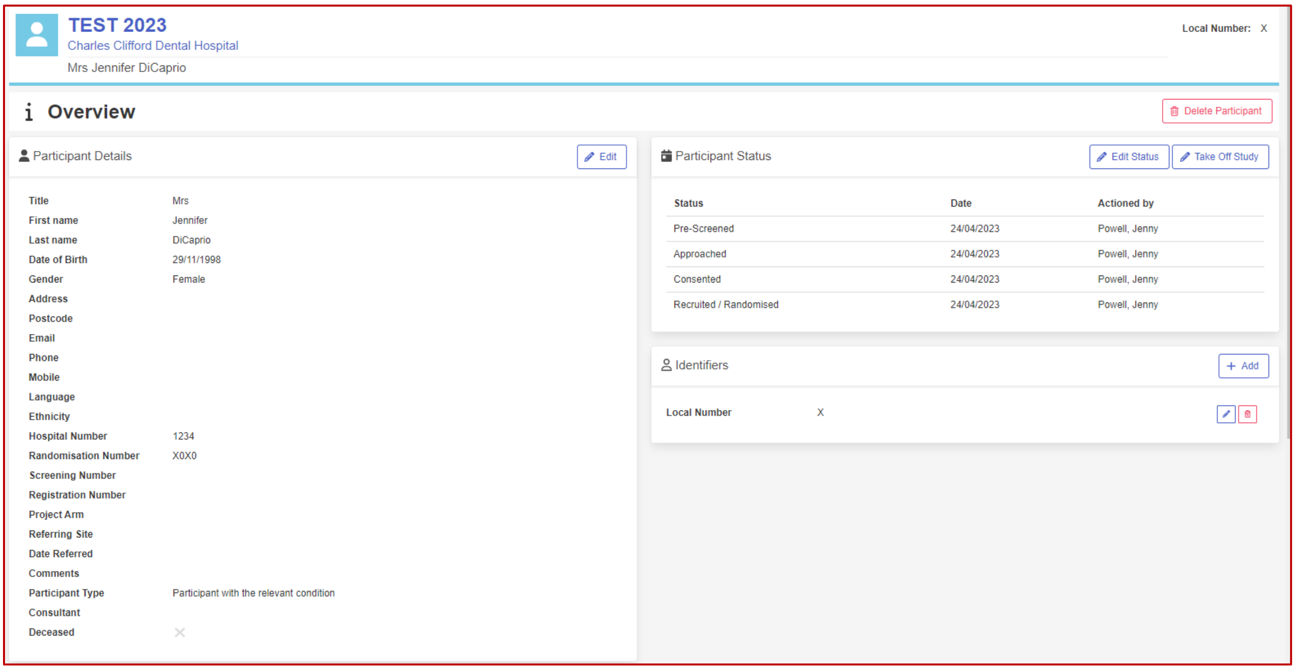


When you have completed the necessary information click **NEXT.**

Before completing the participant's recruitment, EDGE will display a summary page of the information you have entered. To correct or edit this information click the **PREVIOUS** tab, if all the details are correct click **FINISH**. To abandon the participant 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 participant has been added to the Project Site.

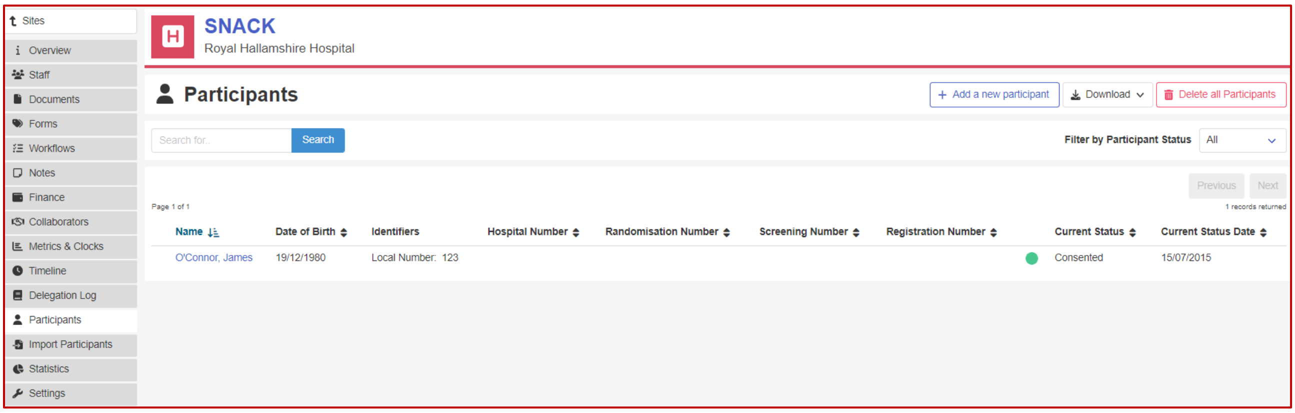


Note:
If you experience problems adding a recruited participant, please contact your Directorate Coordinator, Study Manager or Local EDGE Administrator.

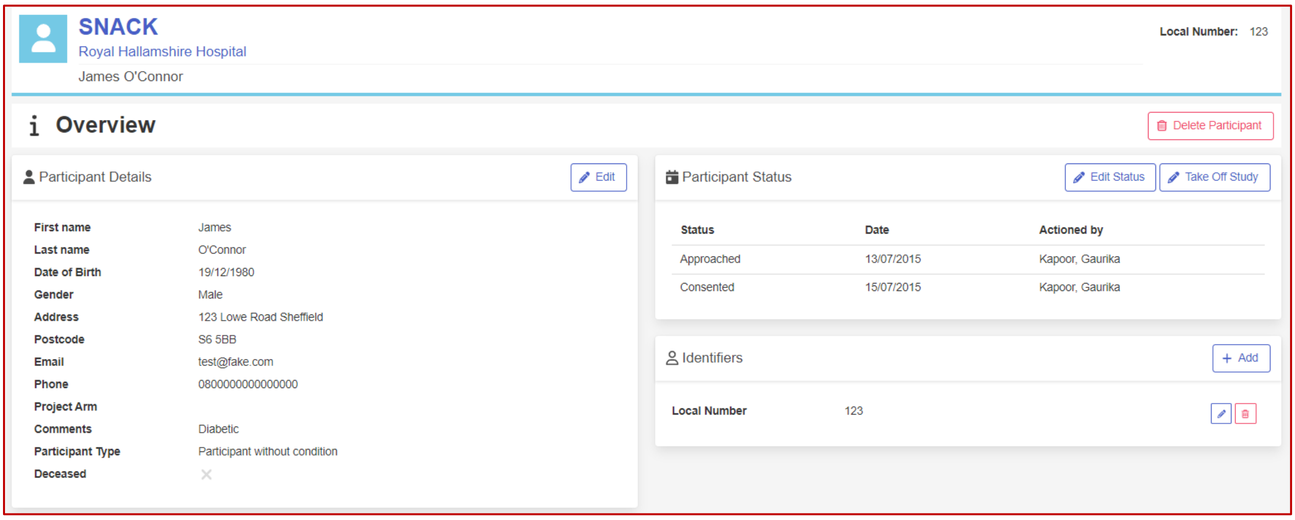
Update Participant Records

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

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



Click the name of the relevant participant and their Overview 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 participant records.

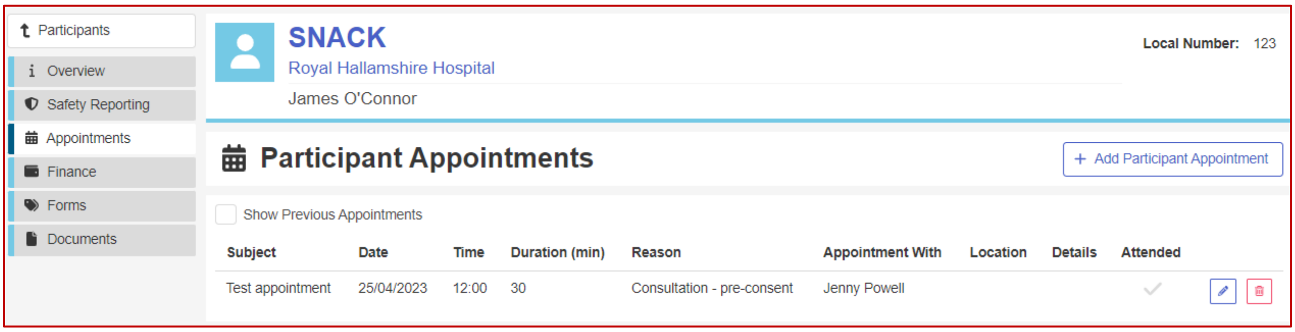


Participant Appointments

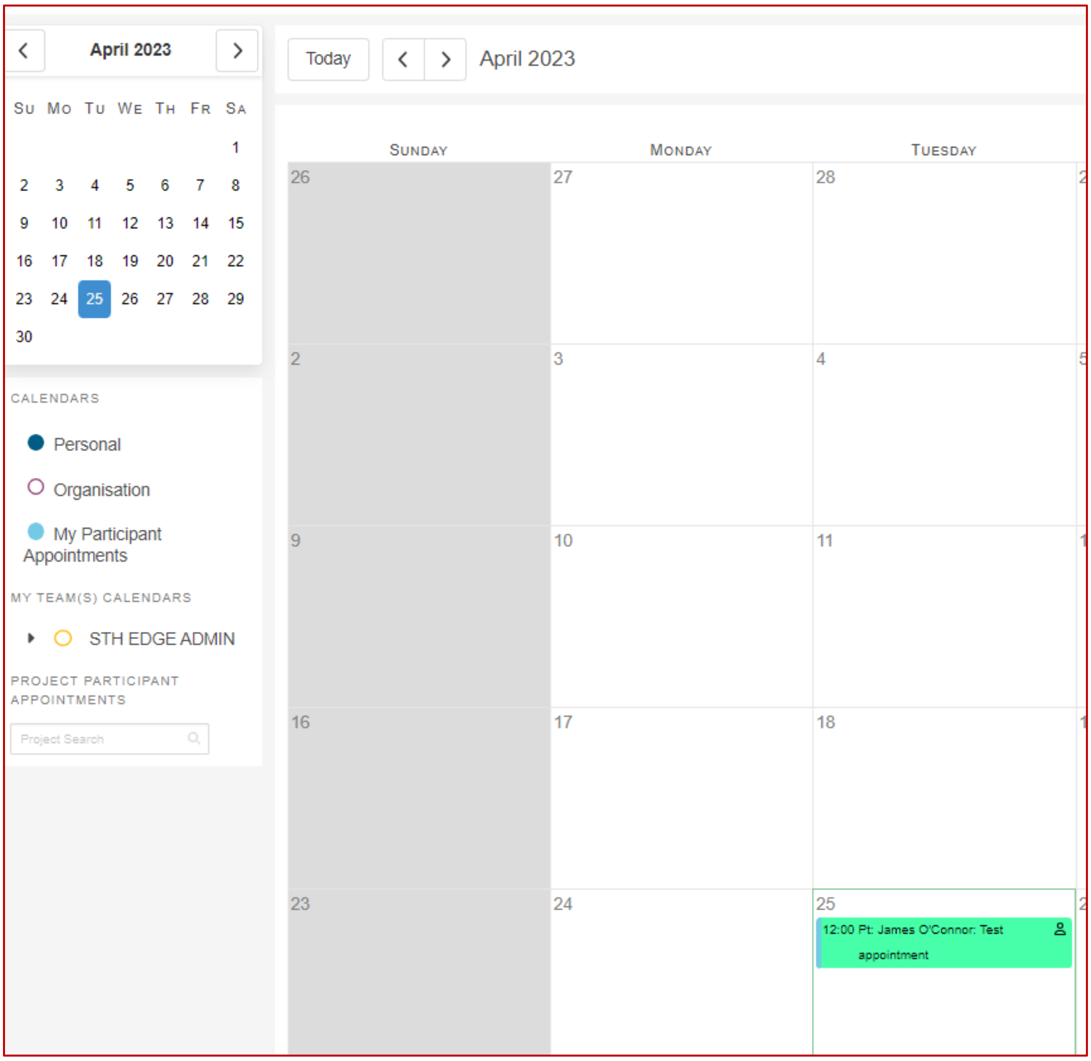
HOME > PROJECTS > ASSIGNED PROJECT (Select Applicable Project) > SITES > (Select Site) > PARTICIPANTS > (Select Applicable Participant) > APPOINTMENTS.

EDGE allows you to record and plan participant visits against individual participant records. Click the **APPOINTMENTS** tab and click **ADD PARTICIPANT APPOINTMENT**. You can populate this will the full schedule of visits or populate it as and when needed.
The **ADD PARTICIPANT 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.



Appointments added to Projects that you have clinical access too will be added to your my participants calender.

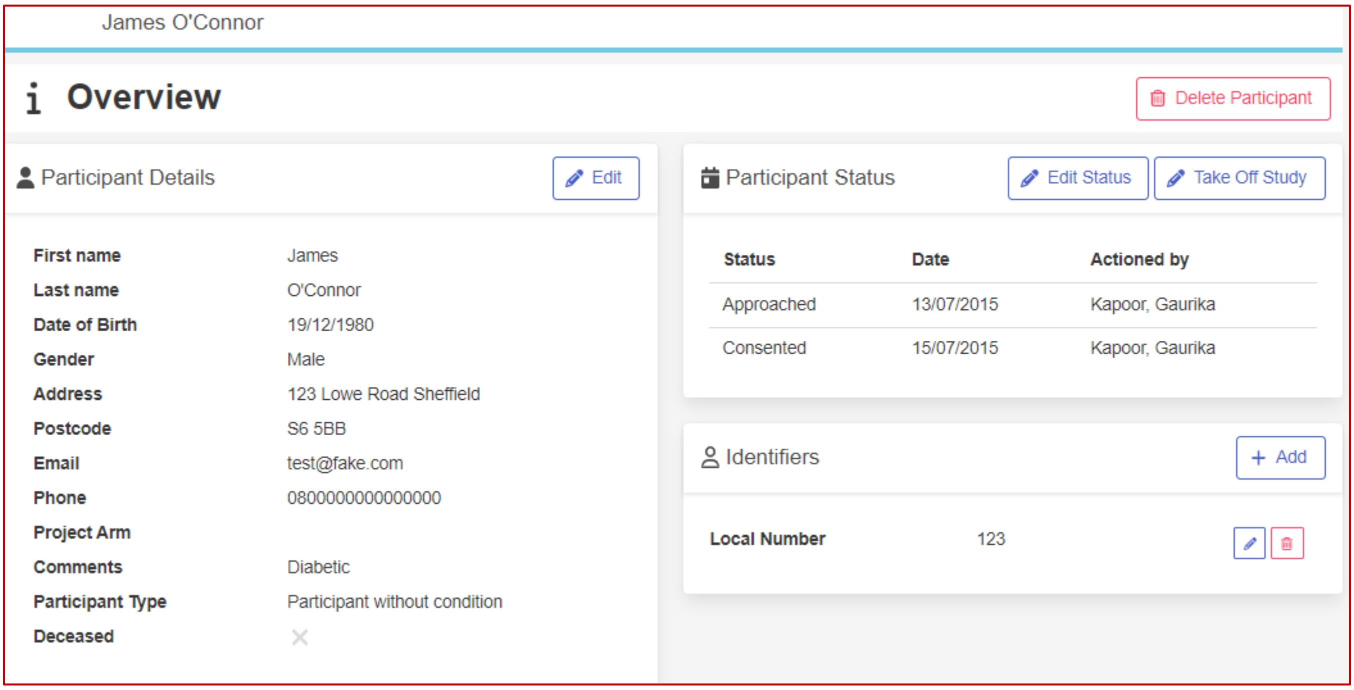


Off Study - Rejected/Withdrawn **Participants**

HOME > PROJECTS > ASSIGNED PROJECTS > (Select Applicable Project) > SITES > (Select Site) > PARTICIPANTS.

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

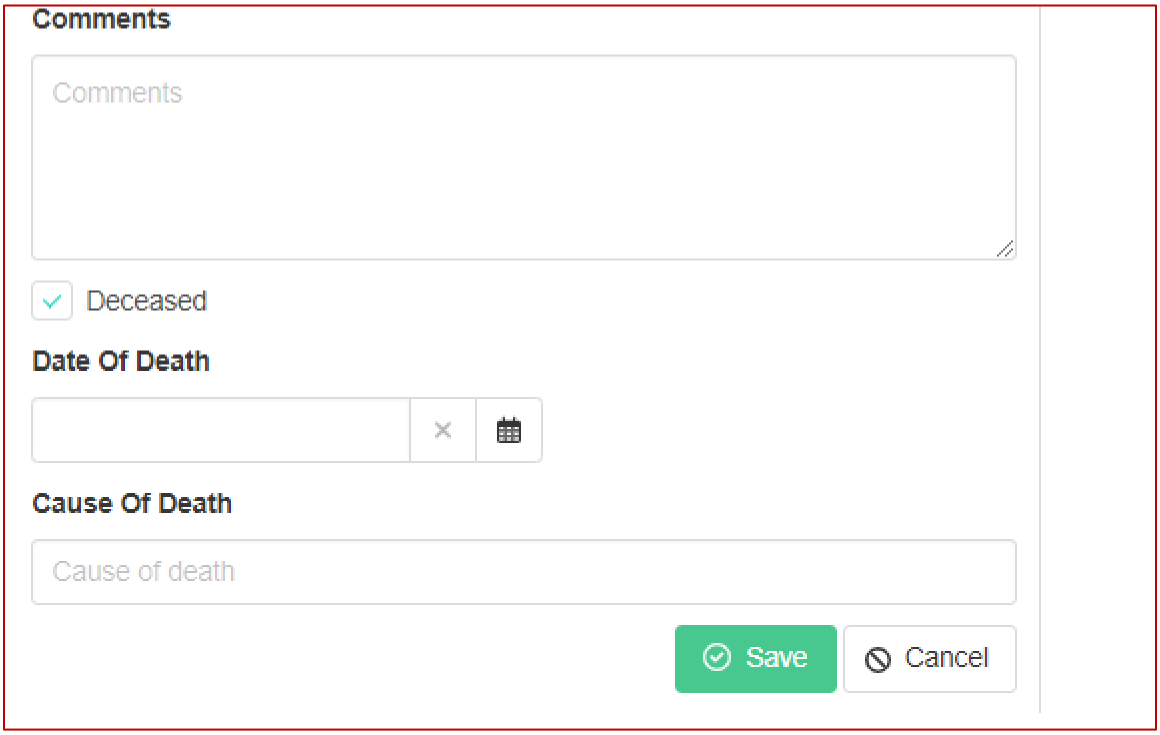
Within the **PARTICIPANTS** tab at project site level click on the highlighted name of the applicable participant to access their record. Click **TAKE OFF STUDY** against the **PARTICIPANT STATUS**. A date, reason for leaving the project and who the participant was taken off study by, will need to be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



Deceased Participants

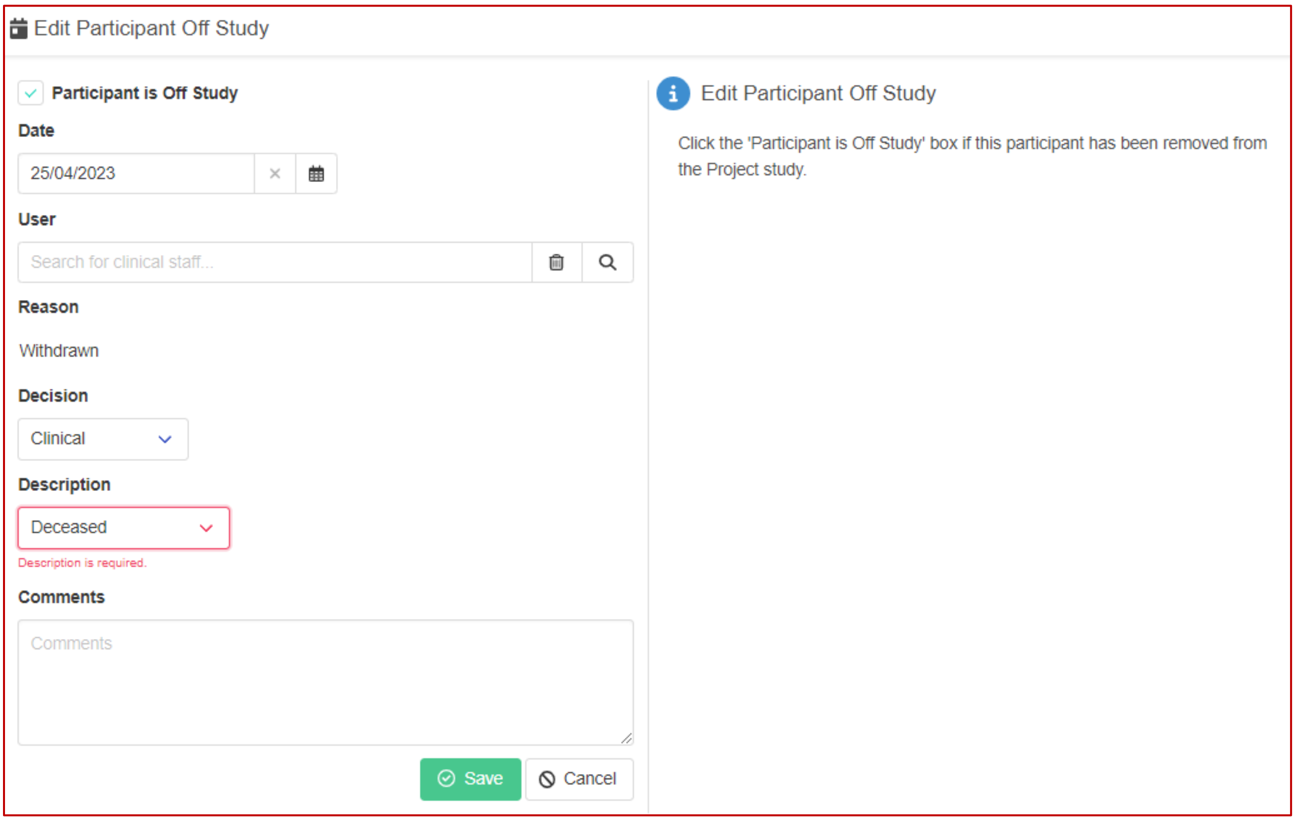
HOME > PROJECTS > ASSIGNED PROJECTS > (Select Applicable Project) > SITES > (Select Site) > PARTICIPANTS.

To record that a participant has died during the course of a project, edit PARTICIPANT DETAILS and select the Deceased check box and complete the date of death below as well as their cause of death. When you have completed these details click SAVE.



The participant will also need to be recorded as being off study with the applicable date and reason code.

Using PARTICIPANT STATUS select TAKE OFF STUDY

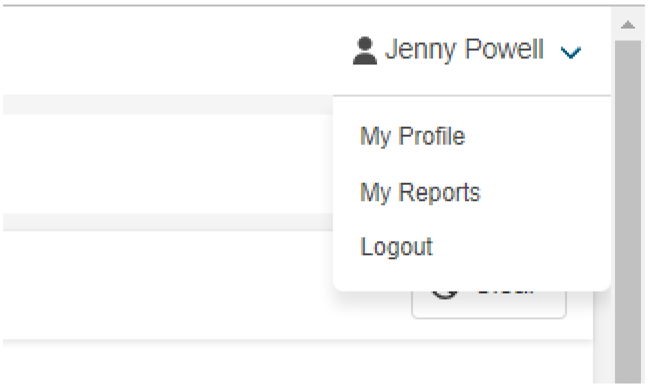


Reports - Recruitment

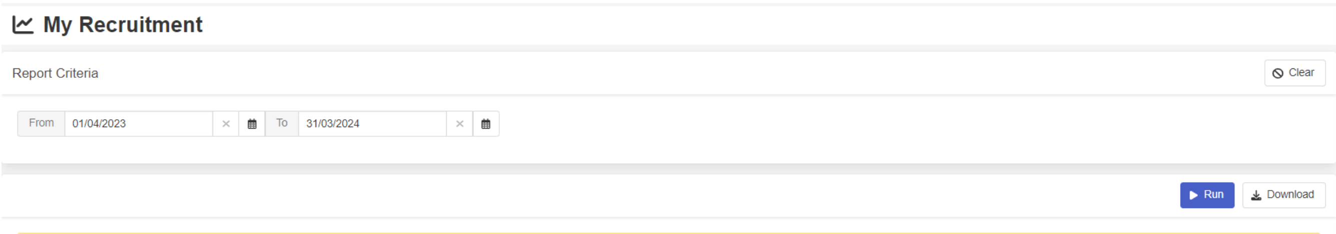
HOME SCREEN > REPORTS > RECRUITMENT

Note: 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 by looking at patients screened, rejected, recruited and withdrawn.



It is necessary to specify the start and end dates for the recruitment window to be observed. 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**. Please note that you can only see recruitment which is associated to **YOUR** name, and not the study as a whole.

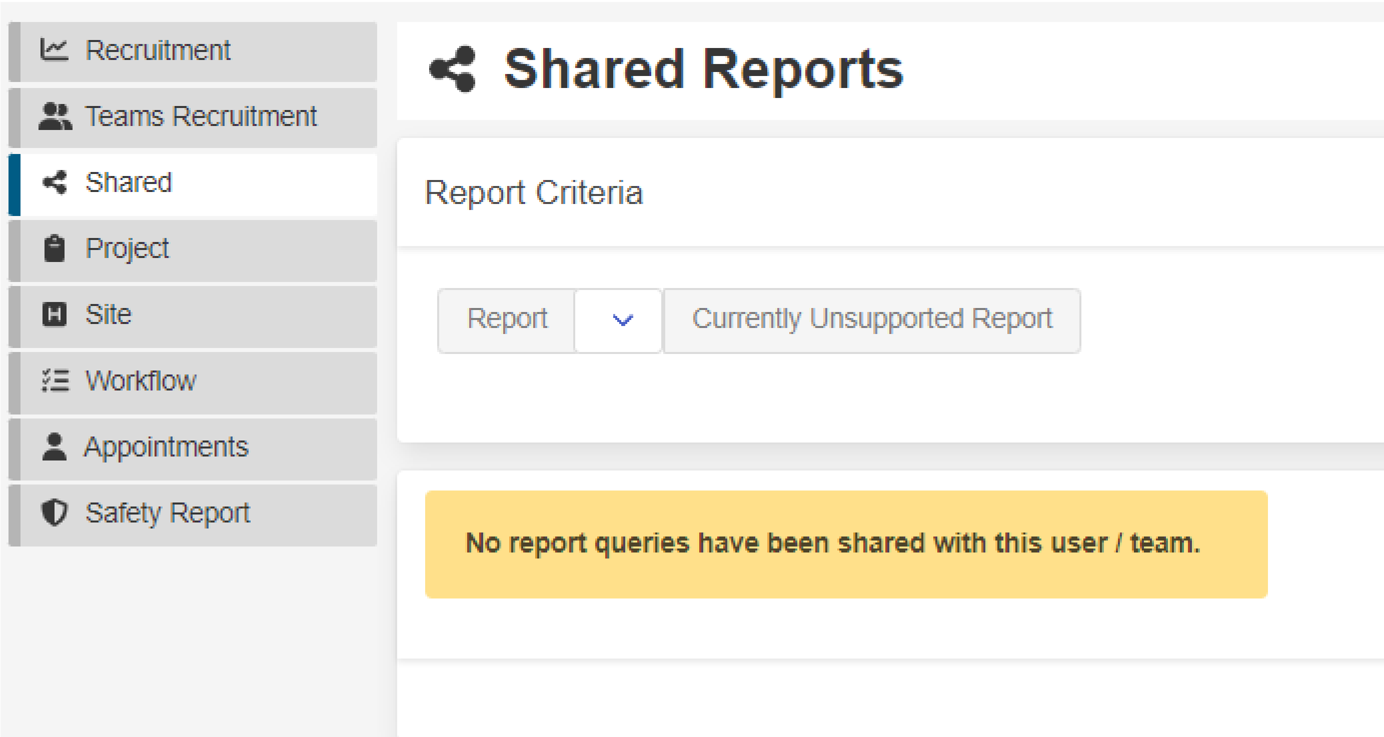


HOME SCREEN > MY REPORTS > SHARED REPORTS

Shared reports are a function controlled by your EDGE local Administrators. Reports are pre-defined by Local Administrator and shared with individual users, teams, and groups of teams or an entire organisation. To request a report please contact your EDGE local administrator.

To run a shared report, click **MY REPORTS** on your home screen and select **SHARED REPORTS**; from the drop down menu 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.

As previously, the results can be exported to **PDF** for printing and distribution or **Excel** for filtering or refining.



Appendix 1 - Definitions of terms used at **SITE LEVEL**, on the Details tab

Name	Description
Date Site Invited	Date of receipt of protocol (either from sponsor or date ready where STH is sponsor), which will be submitted for regulatory review.
Date Site Selected	Date of email from sponsor containing local information pack. Where STH is sponsor: the date of HRA initial assessment letter (or HRA approval letter is no initial assessment letter). *Note: If there has been an amendment since Date Study Initiated, then the date of receipt of amendment pack is used.*
Date Site Confirmed	Date of last contract signature or date of final written agreement of SoA. If STH is sponsor and study has none of these, the date of CCC is used.
SIV Date	Date of Site Initiation Visit.
Open to Recruitment	Date STH is open to recruitment.
Recruitment End Date (Planned)	The expected date STH will close to recruitment.
Recruitment End Date (Actual)	The actual date STH closed to recruitment.
Planned Closing Date	The expected date STH will close the project.
Closed Date	The actual date STH closed the project.