

STH EDGE Handbook

Version 3

Contents

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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.



Login

[Forgotten password?](#)

Login

Authorised users only. This system is monitored at all times.

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:

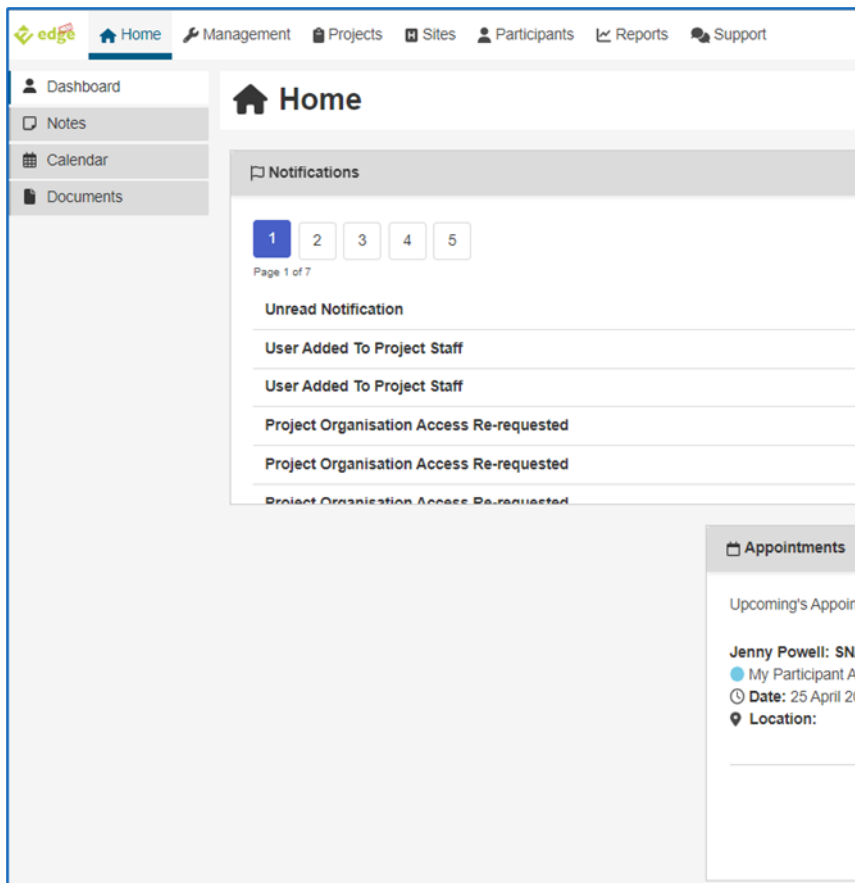
Jenny Powell jenny.powell1@nhs.net
Emily Shiels e.shiels@nhs.net

0114 226 5935

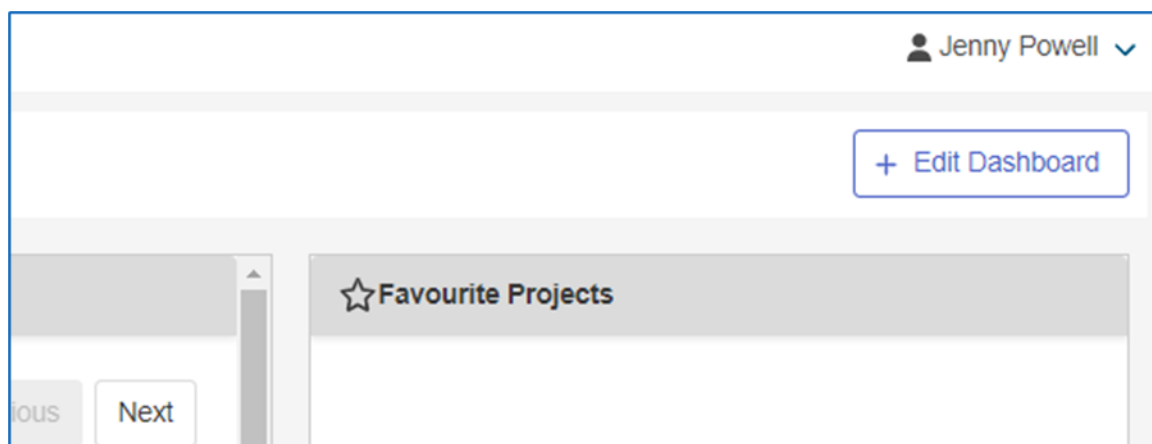
Home Screen

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.


 Profile


 Documents


 Login


 Training


 Qualifications

 Notifications

 Forms

 Delegation Logs

 My Teams

 **Login Details**

Username	jenny.powell1@nhs.net
Access Type	Admin
Active	Yes
Password Expires	Yes
Password Expires On	
Authorised	Yes
Date Authorised	12/12/2022

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.



Reset Password

Please enter the username you use to log in. If the account is found and currently active, we'll send you a link to change your password.

 Username

Request Email

[Back to login](#)

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.

The screenshot displays the EDGE user interface. At the top, a navigation bar includes the 'edge' logo and links for Home, Management, Projects, Sites, Participants, Reports, and Support. A left-hand sidebar lists various user functions: Profile, Documents, Login, Training, Qualifications, Notifications, Forms, Delegation Logs, and My Teams. The main content area is titled 'Personal Details' and contains three sections: 1. 'Personal Details' with fields for 'Full Name' (Jenny Powell) and 'Gender' (Not known), accompanied by a profile picture placeholder and 'Edit'/'Signature' buttons. 2. 'Contact Details' with an 'Email' field (jenny.powell1@nhs.net) and an 'Edit' button. 3. 'Address' with an empty field and an 'Edit' button. Below this, the 'Professional Details' section is visible, featuring an 'Organisation' field with the text 'Sheffield Teaching Hospitals NHS Foundation Trust' and an 'Edit' button. The user's name 'Jenny Powell' is shown in the top right corner of the main content area.

edge Home Management Projects Sites Participants Reports Support

Profile Documents Login Training Qualifications Notifications Forms Delegation Logs My Teams

Personal Details Edit Signature

Full Name Jenny Powell
Gender Not known

Contact Details Edit

Email jenny.powell1@nhs.net

Address Edit

Professional Details Edit

Organisation
Sheffield Teaching Hospitals NHS Foundation Trust

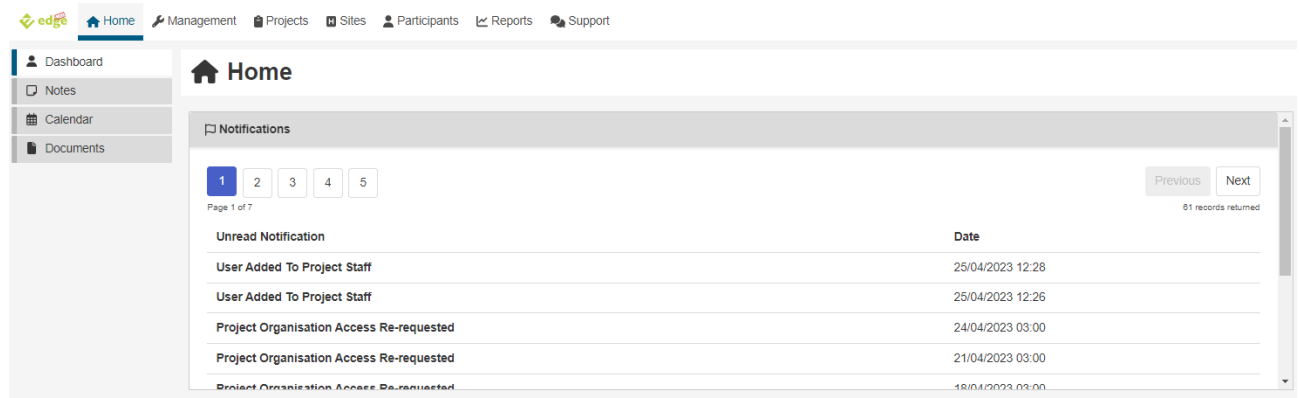
Jenny Powell

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

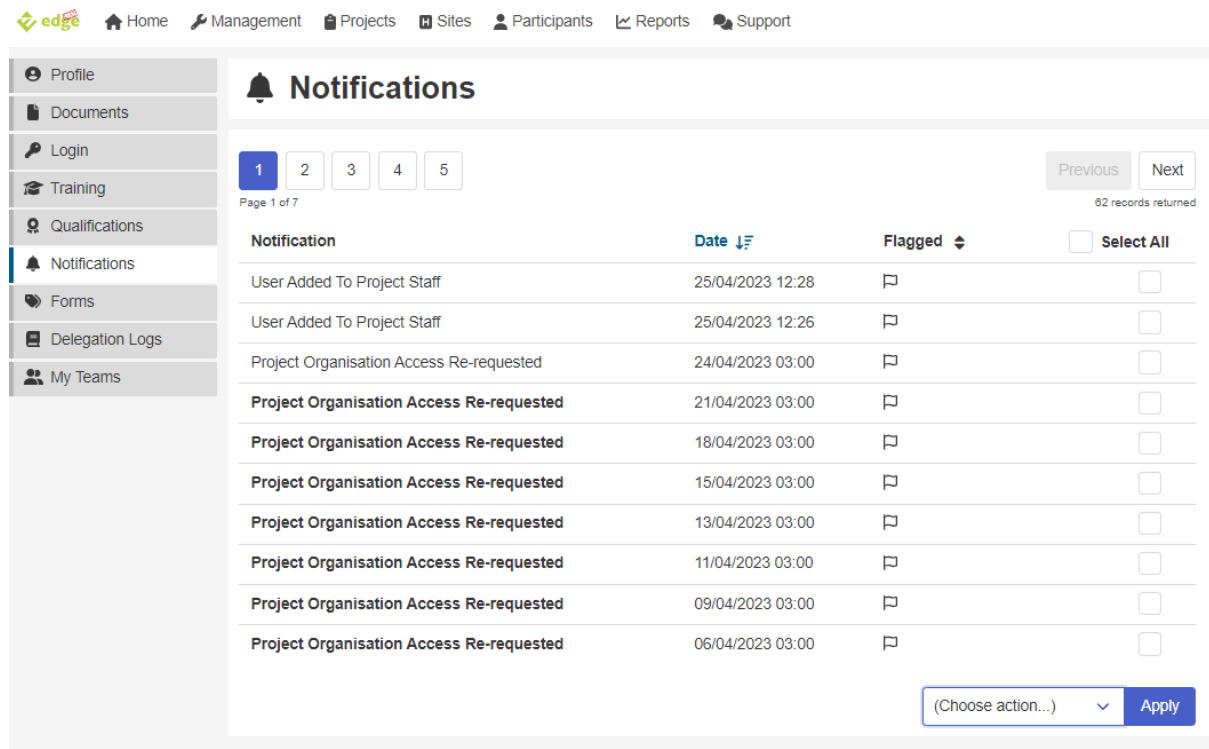
HOME > NOTIFICATIONS

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](#)

edge Home Management Projects Sites Participants Reports Support

Profile Documents Login Training Qualifications **Notifications** Forms Delegation Logs My Teams

Notifications

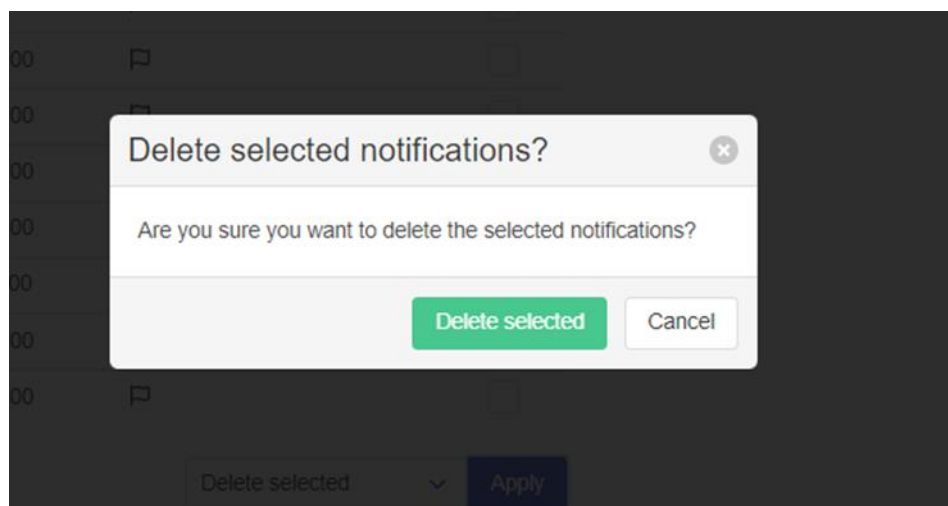
1 2 3 4 5 Previous Next 62 records returned

Page 1 of 7

Notification	Date	Flagged	Select All
User Added To Project Staff	25/04/2023 12:28	Flagged	<input type="checkbox"/>
User Added To Project Staff	25/04/2023 12:26	Flagged	<input type="checkbox"/>
Project Organisation Access Re-requested	24/04/2023 03:00	Flagged	<input type="checkbox"/>
Project Organisation Access Re-requested	21/04/2023 03:00	Flagged	<input type="checkbox"/>
Project Organisation Access Re-requested	18/04/2023 03:00	Flagged	<input type="checkbox"/>
Project Organisation Access Re-requested	15/04/2023 03:00	Flagged	<input type="checkbox"/>
Project Organisation Access Re-requested	13/04/2023 03:00	Flagged	<input type="checkbox"/>
Project Organisation Access Re-requested	11/04/2023 03:00	Flagged	<input type="checkbox"/>
Project Organisation Access Re-requested	09/04/2023 03:00	Flagged	<input type="checkbox"/>
Project Organisation Access Re-requested	06/04/2023 03:00	Flagged	<input type="checkbox"/>

(Choose action...) Apply

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.

edge Home Management **Projects** Sites Participants Reports Support

▼ Search Criteria

Scope
Assigned Projects

Title/Short title

Local Reference

► Project Identifiers

► Core details

► Project type

► Project Status

► Project Phase

Update Results Reset

Search Projects
Assigned projects

Page 1 of 1

EDGE User Test Project

EDGE User Test Project

Project owner EDGE Team

Status Open to recruitment

Local reference 1

NIHR Portfolio Study ID 4334

Clinical Trials Gov

EudraCT

Protocol ID

IRAS Number 191234

REC Number 62/JAP/73

Edge ID 885

SNACK

Studying the effects of a mid-morning snack on mood throughout the day

Project owner Sheffield Teaching Hospitals NHS Foundation Trust

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.


The screenshot displays the 'Overview' page for the '*EDGE User Test Project*'. The page is divided into several sections:

- Left Sidebar:** Contains navigation links for Project Search, Overview, Sites, Staff, Documents, Forms, Workflows, Notes, Finance, Organisations, Collaborators, Criteria, Stakeholders, Statistics, Configuration, Import Participants, Sites Management, and KPIs.
- Header:** Shows the project name '*EDGE User Test Project*' and the owner 'EDGE Team'.
- Overview Section:** Contains 'Core Details' including Short Title, Full Title, Summary, Chief Investigator, Visibility, Status, Project type, Phase, Planned Start Date, Planned End Date, Start Date, and End Date.
- Identifiers Section (Highlighted):** A table listing project identifiers, with an 'Edit' button in the top right corner.
- Geographical Scope Section:** Includes Lead Country, Geographical Scope, and Site Participation Option.
- Participant Types Section:** Includes Genders.

Identifier	Value
EDGE ID	895
Local Project Reference	1
IRAS Number	191234
NIHR Portfolio Study ID	4334
REC Number	62/JAP/73

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).

 [Home](#) [Management](#) [Projects](#) [Sites](#) [Participants](#) [Reports](#) [Support](#) Jenny Powell

Project Search

Overview

Sites

Staff

Documents

Forms

Workflows


Notes


Finance

Organisations

Collaborators

Criteria

 **SNACK**
Owner: [Sheffield Teaching Hospitals NHS Foundation Trust](#)

 **Sites**

[+ Add a new project site](#)

Page 1 of 1

☒ Limit To My Organisation

[Previous](#) [Next](#)

1 records returned

Name	Status	Owner
Royal Hallamshire Hospital	Open	Sheffield Teaching Hospitals NHS Foundation Trust

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.

The screenshot shows the 'Overview' page for a project site. The left sidebar contains navigation links: Sites, Overview, Staff, Documents, Forms, Workflows, Notes, Finance, Collaborators, Metrics & Clocks, Timeline, Delegation Log, Participants, Import Participants, Statistics, and Settings. The main content area is titled 'Overview' and includes an 'Audit Mode' checkbox and buttons for 'Clone Site', 'Swap Site', and 'Transfer Ownership'. The 'Core Details' section lists: Site Owner (Sheffield Teaching Hospitals NHS Foundation Trust), Site Parent (Sheffield Teaching Hospitals NHS Foundation Trust), Project Site Status (Open ()), Site Type (Recruiting Site), Project Site Number, Principal Investigator (Zoe Whiteley), Target Recruitment (250), Participant Data Collection Plan (STH Minimum Dataset), and Participant Identifier Type (Local Number). The 'Approvals' section shows: Approval Process (HRA Approvals), Capacity & capability assessment required? (Yes), Date site invited (24/04/2023), Date site selected (24/04/2023), Date site confirmed (25/04/2023), Date site confirmed by Sponsor (25/04/2023), and Non-confirmation Status. The 'Milestones' section lists: SIV Date, Open To Recruitment, Recruitment End Date (Planned) (01/06/2015), Recruitment End Date (Actual) (31/12/2015), and Closing Date (Planned). The 'Key Staff' section states: 'There are no key staff set up for this Project Site. To add some please go to the Staff page.'

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.

Project Search

Overview

Sites

Staff

Documents

Forms

Workflows

Notes

Finance

Organisations

SNACK

Owner: Sheffield Teaching Hospitals NHS Foundation Trust

Forms

Expand All | Collapse All

test

Sheffield Teaching Hospitals NHS Foundation Trust

Sheffield Specific

Sheffield Teaching Hospitals NHS Foundation Trust

Directorate

Cardiovascular

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.*

Sites

Overview

Staff

Documents

Forms

Workflows

Notes

Finance

Collaborators

Metrics & Clocks

Timeline

Delegation Log

Participants

Recent Participants

H

SNACK

Royal Hallamshire Hospital

Project Site Staff

+ Add a new team

+ Add a new member of staff

Download

Include Deleted Users

Limit To My Organisation

Previous

Next

3 records returned

Page 1 of 1

User	Role	Active	Manage	Clinical	Key Staff	
Dunn, Alessia		✓	✓	✓	×	<div><div></div><div></div></div>
Powell, Jenny		✓	✓	✓	×	<div><div></div><div></div></div>
Shiels, Emily		✓	✓	✓	×	<div><div></div><div></div></div>

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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).

Sites

Overview

Staff

Documents

Forms

Workflows

Notes

Finance

Collaborators

Metrics & Clocks

Timeline

Delegation Log

Participants

Import Participants

Statistics

Settings

H

SNACK

Royal Hallamshire Hospital

Total Accrual

Annual Accrual

Current Status

Off Study

Show Only My Organisation

Download

	Screened	Recruited	Rejected	Withdrawn
Sheffield Teaching Hospitals NHS Foundation Trust				
Royal Hallamshire Hospital	1	1	0	0
Sub-total	1	1	0	0
Total	1	1	0	0

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.](#)

The screenshot shows the 'Participants' page for the SNACK project at Royal Hallamshire Hospital. The left sidebar contains navigation links: Sites, Overview, Staff, Documents, Forms, Workflows, Notes, Finance, Collaborators, Metrics & Clocks, Timeline, Delegation Log, Participants, Import Participants, Statistics, and Settings. The main header includes the SNACK logo and project name. Below the header, there are buttons for '+ Add a new participant', 'Download', and 'Delete all Participants'. A search bar is present with a 'Search' button. A filter dropdown is set to 'All'. The table below shows one participant record:

Name	Date of Birth	Identifiers	Hospital Number	Randomisation Number	Screening Number	Registration Number	Current Status	Current Status Date
O'Connor, James	19/12/1980	Local Number:	123				Consented	15/07/2015

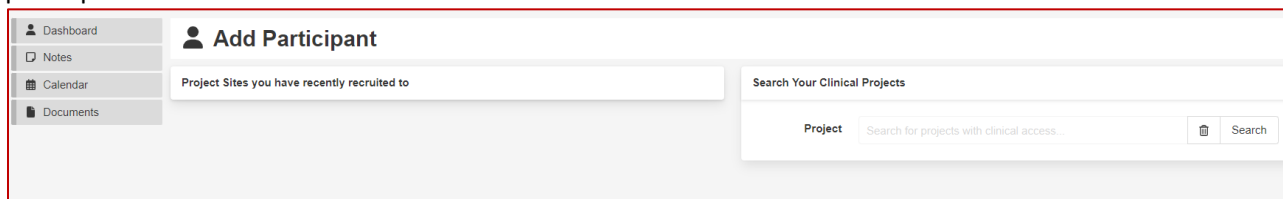
Or by editing your dashboard and adding Add participants as a widget on the EDGE home screen.

[HOME > ADD A PARTICIPANT](#)

The screenshot shows the 'Home' dashboard in the EDGE system. The left sidebar contains navigation links: Dashboard, Notes, Calendar, and Documents. The main content area has a 'Home' header. Below the header, there are two main sections: 'My Reports' and 'Add Participants'. The 'My Reports' section has a 'My Reports' button. The 'Add Participants' section has a '+ Add Participant' button. On the right side, there is a 'Notifications' section with a list of unread notifications, all of which are 'Project Organisation Access Re-requested'.

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.

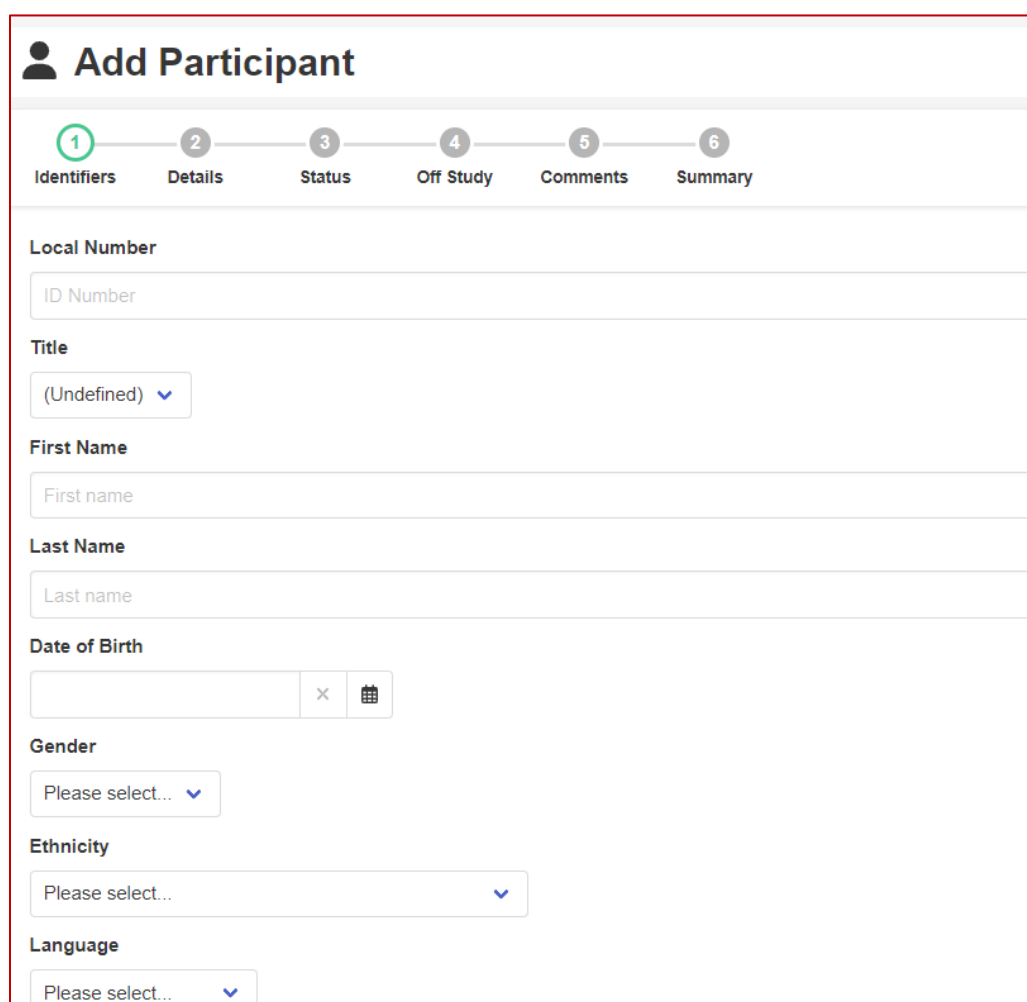


The screenshot shows the top section of the 'Add Participant' page. On the left is a sidebar with links: Dashboard, Notes, Calendar, and Documents. The main header area contains the title 'Add Participant' and a search bar labeled 'Search Your Clinical Projects'. Below the search bar is a dropdown menu for 'Project' and a search button.

Note: If you are unable to find your project or project recruitment site contact your Directorate Coordinatr 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



The screenshot shows the 'Add Participant' form with a progress bar at the top indicating six steps: 1. Identifiers, 2. Details, 3. Status, 4. Off Study, 5. Comments, and 6. Summary. The 'Identifiers' step is currently active. The form fields include: Local Number (ID Number), Title (dropdown menu), First Name, Last Name, Date of Birth (calendar icon), Gender (dropdown menu), Ethnicity (dropdown menu), and Language (dropdown menu).

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.



Add Participant

1

2

3

4

5

6

Identifiers
Details
Status
Off Study
Comments
Summary

Randomisation Number

Hospital Number


Screening Number

Registration Number


Participant Type

Please select...


Project Arms


Search



Consultant


Search

Referring Site


Search

Date Referred

*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.

Add Participant

Participant transfer is not enabled on this project

Status	Date	Actioned By
Pre-Screened		Jenny Powell
Approached		Jenny Powell
Consented		Jenny Powell
Recruited / Randomised		Jenny Powell
Completed		Jenny Powell

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

Add Participant

1 Identifiers 2 Details 3 Status 4 Off Study 5 Comments 6 Summary

☒ Off Study

Off Study Details

There are two top-level reasons for participants when they are off study and these are dependent on which status they have met in their workflow.

If the participant has not reached the status associated with the recruiting trigger, then they will be assigned the rejected reason.

If the participant has reached or passed the recruiting trigger, then they will be assigned the withdrawn reason.

Exit Wizard < Previous > Next

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.

Add Participant

1 Identifiers 2 Details 3 Status 4 Off Study 5 Comments 6 Summary

Comments

Comments

Participant Comments

Add any relevant comments regarding the participant's enrolment on the right-hand side.

Exit Wizard < Previous > Next

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**.

Add Participant

1 Identifiers 2 Details 3 Status 4 Off Study 5 Comments 6 Summary

Exit Wizard < Previous > Finish


Local Number	X	Randomisation Number	X0X0
Name	Mrs Jennifer DiCaprio	Hospital Number	1234
Date Of Birth	29/11/1998	Screening Number	
Gender	Female	Registration Number	
Address		Participant Type	Participant with the relevant condition
Postcode		Consultant	
Email		Referring Site	
Phone		Date Referred	
Mobile		GP Name	
Language		GP Address	
Ethnicity		GP Phone	
		Project Arm	

Status	Date	Actioned by
Pre-Screened	24/04/2023	Jenny Powell
Approached	24/04/2023	Jenny Powell
Consented	24/04/2023	Jenny Powell
Recruited / Randomised	24/04/2023	Jenny Powell


Patient is NOT off study


Exit Wizard < Previous > Finish

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.


TEST 2023
Charles Clifford Dental Hospital
Mrs Jennifer DiCaprio

Local Number: X


Overview


Participant Details

Title

First name

Last name

Date of Birth

Gender

Address

Postcode

Email

Phone

Mobile

Language

Ethnicity

Hospital Number

Randomisation Number

Screening Number

Registration Number

Project Arm

Referring Site

Date Referred

Comments

Participant Type

Consultant

Deceased

Mrs

Jennifer

DiCaprio

29/11/1998


Female


1234


XX00


Participant with the relevant condition

X



Edit



Participant Status


Edit Status




Take Off Study

Status	Date	Actioned by
Pre-Screened	24/04/2023	Powell, Jenny
Approached	24/04/2023	Powell, Jenny
Consented	24/04/2023	Powell, Jenny
Recruited / Randomised	24/04/2023	Powell, Jenny


Identifiers


Add

Local Number	X
--------------	---

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 participants that have been added to the site.

The screenshot shows the 'Participants' page in the SNACK system. On the left is a sidebar with navigation options: Sites, Overview, Staff, Documents, Forms, Workflows, Notes, Finance, Collaborators, Metrics & Clocks, Timeline, Delegation Log, Participants, Import Participants, Statistics, and Settings. The main header includes the SNACK logo and 'Royal Hallamshire Hospital'. Below the header, there are buttons for '+ Add a new participant', 'Download', and 'Delete all Participants'. A search bar is present with the text 'Search for...'. A filter dropdown is set to 'Filter by Participant Status' with 'All' selected. The table below shows one participant: O'Connor, James, born 19/12/1980, with a Local Number of 123. The table has columns for Name, Date of Birth, Identifiers, Hospital Number, Randomisation Number, Screening Number, Registration Number, Current Status (Consented), and Current Status Date (15/07/2015). Navigation links 'Previous' and 'Next' are at the bottom right, indicating '1 records returned'.

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.

The screenshot shows the 'Overview' page for a specific participant, James O'Connor. The header includes the SNACK logo, 'Royal Hallamshire Hospital', and the participant's name 'James O'Connor' with a 'Local Number: 123'. A 'Delete Participant' button is in the top right. The main content is divided into two sections. The 'Participant Details' section on the left lists personal information: First name (James), Last name (O'Connor), Date of Birth (19/12/1980), Gender (Male), Address (123 Lowe Road Sheffield), Postcode (S6 5BB), Email (test@fake.com), Phone (0800000000000000), Project Arm, Comments (Diabetic), Participant Type (Participant without condition), and Deceased (X). An 'Edit' button is next to this section. The 'Participant Status' section on the right shows a table of status changes: 'Approached' on 13/07/2015 by Kapoor, Gaurika, and 'Consented' on 15/07/2015 by Kapoor, Gaurika. It also includes an 'Identifiers' section with a 'Local Number' of 123 and an 'Add' button.

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 with 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.

↑ Participants

i Overview

🛡️ Safety Reporting

📅 Appointments

💰 Finance

📄 Forms

📁 Documents

👤

SNACK

Royal Hallamshire Hospital

James O'Connor

📅 Participant Appointments

+ Add Participant Appointment

Show Previous Appointments

Subject	Date	Time	Duration (min)	Reason	Appointment With	Location	Details	Attended
Test appointment	25/04/2023	12:00	30	Consultation - pre-consent	Jenny Powell			✓

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

< April 2023 >

Today

< >

April 2023

Su	Mo	Tu	We	Th	Fr	Sa
						1
2	3	4	5	6	7	8
9	10	11	12	13	14	15
16	17	18	19	20	21	22
23	24	25	26	27	28	29
30						

CALENDARS

● Personal

○ Organisation

● My Participant Appointments

MY TEAM(S) CALENDARS

▶ ○ STH EDGE ADMIN

PROJECT PARTICIPANT APPOINTMENTS

Project Search 🔍

SUNDAY	MONDAY	TUESDAY
26	27	28
2	3	4
9	10	11
16	17	18
23	24	25

12:00 Pt: James O'Connor: Test appointment

Page 25 of 30

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.

James O'Connor

i

Overview

Delete Participant

Participant Details

Edit

First name

James

Last name

O'Connor

Date of Birth

19/12/1980

Gender

Male

Address

123 Lowe Road Sheffield

Postcode

S6 5BB

Email

test@fake.com

Phone

08000000000000000

Project Arm

Comments

Diabetic

Participant Type

Participant without condition

Deceased

X

Participant Status

Edit Status

Take Off Study

Status	Date	Actioned by
Approached	13/07/2015	Kapoor, Gaurika
Consented	15/07/2015	Kapoor, Gaurika

Identifiers

+ Add

Local Number	123	<div><div>Edit</div><div>Delete</div></div>
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Deceased Participants

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

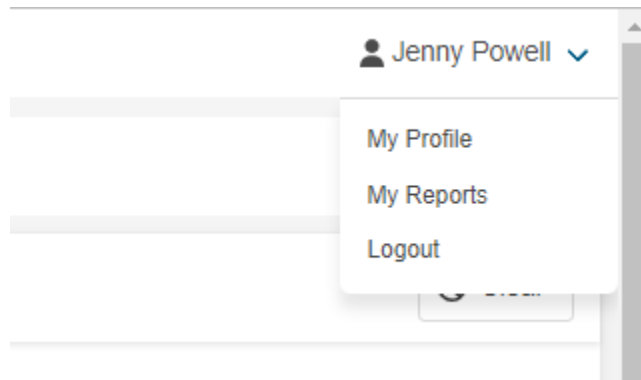
To record that a participant has died during the course of a project, edit PARTICIPANT DETAILS and select the Deceased check box and complete the date of death below as well as their cause of death. When you have completed these details click SAVE.

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.

My Recruitment

Report Criteria

From01/04/2023

×

🗑️

To31/03/2024

×

🗑️

▶ Run

📄 Download

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.

The screenshot shows the 'Shared Reports' section of the EDGE system. On the left is a sidebar menu with icons and labels for 'Recruitment', 'Teams Recruitment', 'Shared' (highlighted with a blue bar), 'Project', 'Site', 'Workflow', 'Appointments', and 'Safety Report'. The main content area has a header 'Shared Reports' with a share icon. Below this is a 'Report Criteria' section containing a 'Report' label, a dropdown arrow, and the text 'Currently Unsupported Report'. At the bottom of the main area is a yellow message box stating: 'No report queries have been shared with this user / team.'

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). <i>Note: If there has been an amendment since Date Study Initiated, then the date of receipt of amendment pack is used.</i>
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.