NHS
Gloucestershire Hospitals
NHS Foundation Trust

Managing Research 03 – Trial management system using EDGE

IT IS THE RESPONSIBILITY OF ALL USERS OF THIS SOP TO ENSURE THAT THE CORRECT VERSION IS BEING USED

All staff should regularly check the Research & Development Webpage for information relating to the implementation of new or revised versions. Staff must ensure that they are adequately trained in the new procedure and must make sure that all copies of superseded version are promptly withdrawn from use unless notified otherwise by the SOP Controller.

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http://www.gloshospitals.nhs.uk/en/About-Us/Research--Development/

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Author:	Janet Forkes	signature
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Version History Log

This area will be updated with details of all changes made to the SOP whether due for full review or not.

Version	Details of Change	Date Implemented
1.0	Original SOP 18	29/08/2013
2.0	Review and update, along with reorganisation of SOPs	01/02/2017
3.0	Rebranding to GHNHSFT, updating contact details and reference documents	31/03/2018

This SOP will be reviewed every two years unless changes to any relevant legislation require otherwise

Contents

Uncontrolled when printed

1. Introduction, Background and Purpose

The Gloucestershire Hospitals NHS Foundation Trust has been provided with a license and access to the EDGE Research Management Tool by the West of England Clinical Research Network (WoECRN) to record study details, governance processes, recruitment figures and other study activity.

The purpose of this SOP is to provide information about the EDGE system and how to undertake the various tasks that might be required on the system to manage research projects.

More specific information about other details will be provided via EDGE training.

2. Who should use this SOP?

Anyone undertaking work on NIHR Portfolio research projects should be familiar with this SOP and the details of processes required to facilitate EDGE effectively. This includes Investigators, Nurses, Clinical Studies Officers, R&D Managers and Administrative teams

3. When this SOP should be used

This SOP should be referred to as soon as a submission is made for local participation in a trial, whether sponsored by a Gloucestershire NHS Trust or hosted locally.

4. Using EDGE

4.1 Database Administrator and Users

The Database Administrator(s) (Research Managers – Governance based at Gloucestershire Research Support Services) has access to certain functions of the database that other local users do not. The level of access for each user is initially set and can be amended by the Database Administrator at any time.

4.2 To access the EDGE system

Request an account from the Database administrator or you may be notified that one has already been set up for you.

To access the system, visit the web address:
https://www.edge.nhs.uk/Account/Index?ReturnUrl=%2f

See appendix 1 Figure 1 for an example of the log on page

4.3 Accessing trial (project) information

The Database Administrators will request collaboration from the trial owner for hosted trials or will add a new Sponsored trial (project) to EDGE.

Entities and Workflows will be added as required.

4.4 Adding patient details/ trial status

It is the responsibility of the Research Team to enter patient information contemporaneously regarding:

- Pre-screening
- Approached
- Consented
- Screening
- Recruited/ randomised
- On treatment
- On follow-up
- Completed
- Off study

NB For patient identification do not use full names in the Name column only initials/ Date of Birth/ Local Number / Hospital Number then any screening / trial numbers if the patient gets that far in the trial work up.

4.4 Running reports

The Database Administrators can assist research teams in running reports to interrogate the data on EDGE by creating public reports that the teams can then run as required or can provide specific reports on request.

4.5 Amending details

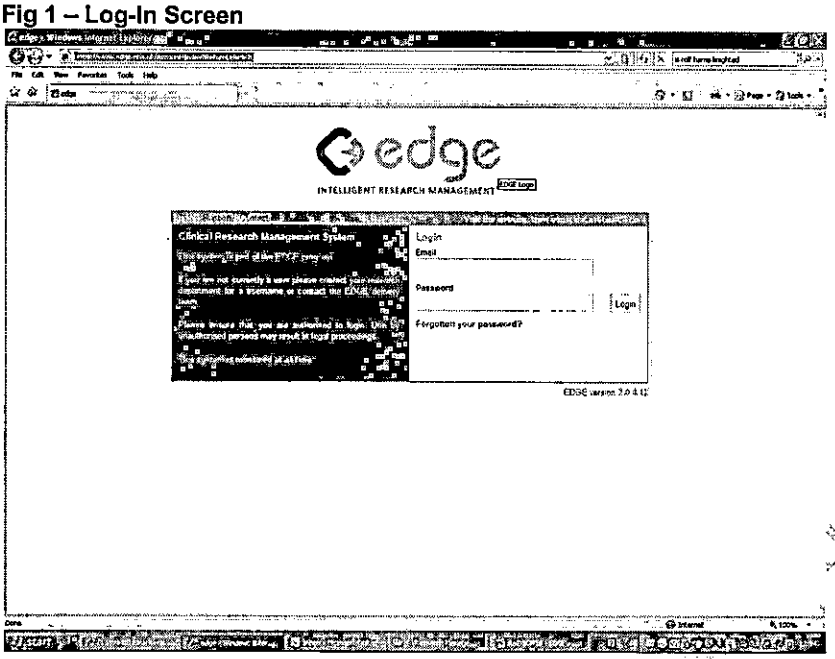
Dependent upon the change/ amendment required, the research team may need to request the Database Administrators assistance to make the changes or may be able to edit information themselves (further information is given during EDGE training).

5 Related SOPs and Documents

https://www.edge.nhs.uk/Account/Index?ReturnUrl=%2f

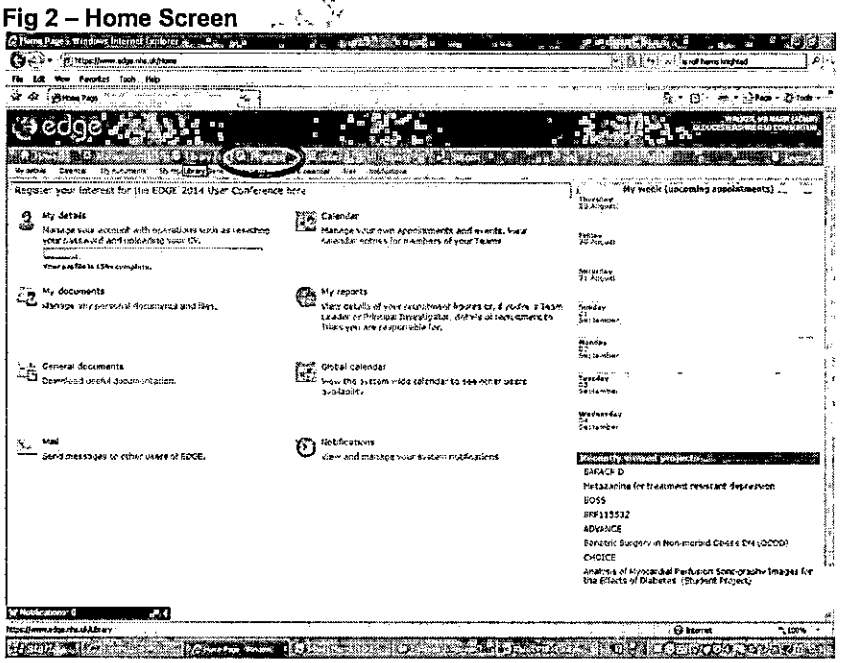
Appendix 1

Fig 1 – Log-In Screen



- When a user has been identified an account can be set up by an EDGE administrator (ADMIN) from the R&D Office.
- Enter EMAIL and PASSWORD in the appropriate boxes and click "Login" or press Enter.
- If you have problems logging in, contact the R&D Team or click "Forgotten your password" to reset.
- Once logged in your Home Screen should look similar to Figure 2, although not all options will be available to all users, depending on administration rights:

Fig 2 – Home Screen



Appendix 2 Adding and Activating Users to EDGE (By R&D team only)

1 Adding a User

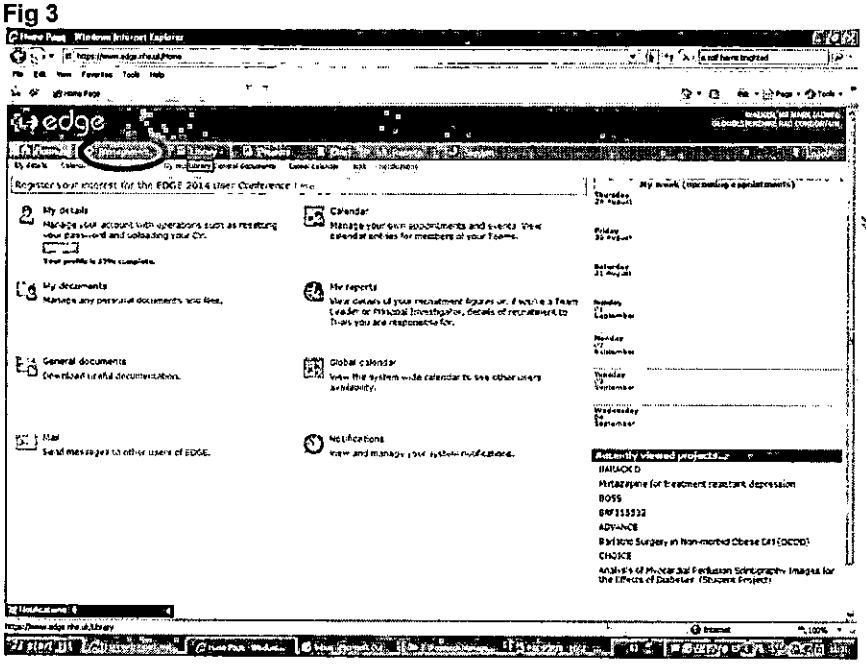
a. Much of the access and set-up below relies on users being added to the EDGE system prior to adding studies. Although users can be added at anytime, it is preferable that they are added as soon as they are identified.

b. To add a user to the EDGE System:

Log in as per section 4

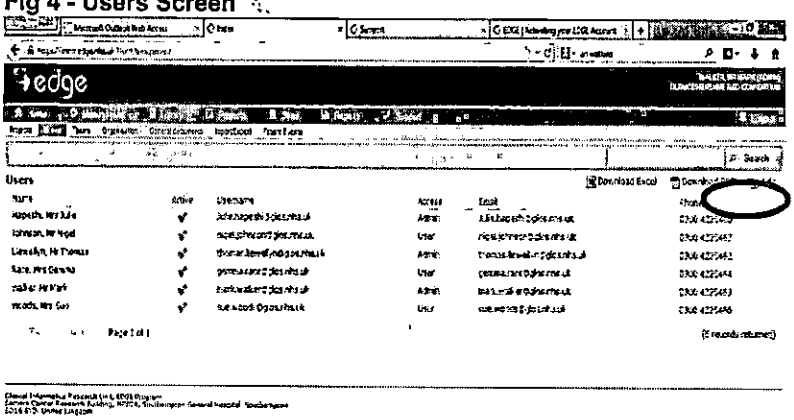
On the Home Screen, select MANAGEMENT as in Fig 3.

Fig 3



- On the MANAGEMENT SCREEN select the USERS icon
- On the USERS Screen, select "Add" as in Fig 4 below.

Fig 4 - Users Screen



- Complete the Pop up form with as much information as possible. An email address is required for correct set-up.

- The user will now be added to the list of users under the USERS menu.

2 Activating a user

- A user must be activated before they can access EDGE.
- Under the USERS menu, select the user that requires activation.
- Within their profile, select the LOGON DETAILS tab
- In the LOGON DETAILS screen, select Add Logon and complete the pop up form.
- Passwords should be set to never expire and access should be set to USER, unless a new administrator is being added.
- The user will now receive an email explaining how to activate their account.
- If it is felt that a particular user is set-up with incorrect access, contact the R&D Team to discuss.

Appendix 3

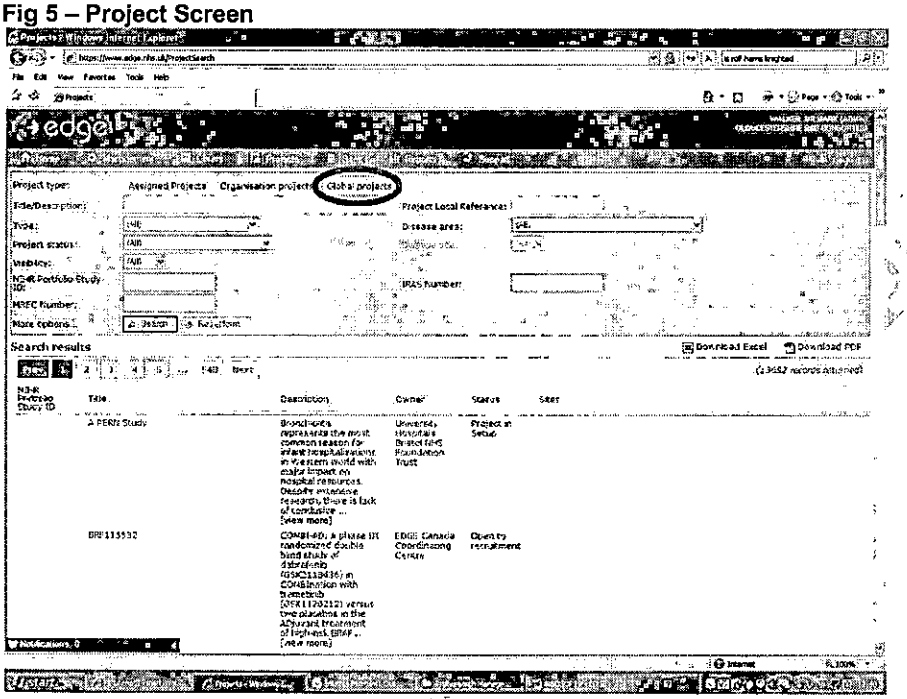
1. Adding a new hosted study (R&D team only)

a. To add a new study to the EDGE system, the user needs to REQUEST COLLABORATION from the study owner.

b.Select PROJECTS from the Home Screen as Highlighted in Fig 2. Appendix 1.

c. Select GLOBAL PROJECTS from the Projects Screen as Highlighted in Fig 5 below.

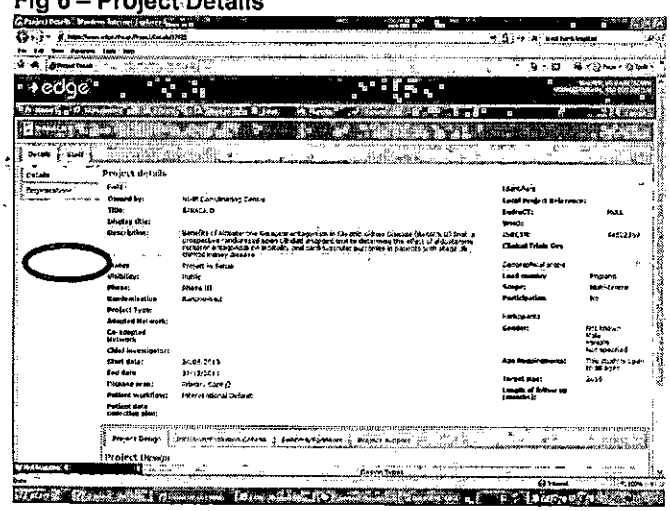
Fig 5 – Project Screen



d. The study can be searched for using a variety of fields, depending on the data available. The appropriate study can be selected from the list that is generated from the search.

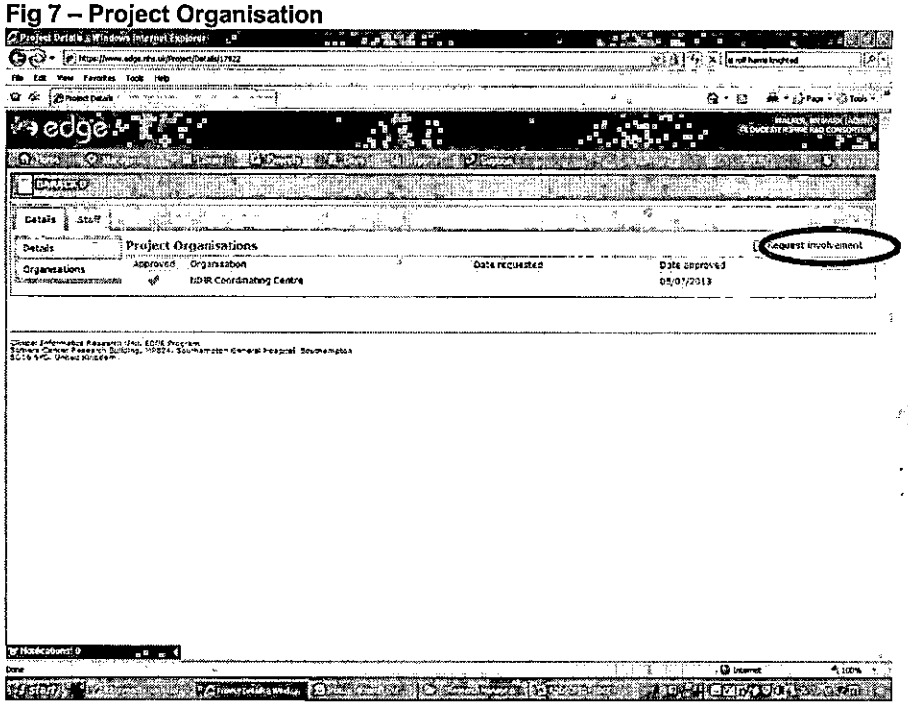
e. Selecting the study will produce the PROJECT DETAILS screen, which lists a variety of top-level information about the study, select ORGANISATION from the left hand menu, as highlighted on Fig 6 below.

Fig 6 – Project Details



f. On the subsequent PROJECT ORGANISATION screen, select REQUEST INVOVLEMENT on the top right of the screen as highlighted on Fig 7 below.

Fig 7 – Project Organisation



g. Confirm the Organisation that is making the request and ACCEPT.
h. The Project Organisation screen will update with the organisation name.
i. At first the name will have a Red Cross by it, to show that the request is pending. The request can take up to 24 hours, but is of often less than 2 hours.
j. When the request is accepted, the system will update to show a green tick beside the R&D Consortium and the requester will receive a notification through the EDGE system that this has occurred.

2. Adding a new sponsored study (R&D team only)

a. Select MANAGEMENT from the Home Screen as in Appendix 1 Fig. 2.
b. From the next screen select PROJECTS and then ADD NEW PROJECT.
c. Follow the onscreen instructions to add a new project.
d. This is only required where one of the Gloucestershire Trusts is acting as Sponsor.

3. Assigning Access Rights and Users to a Project

At the point a study collaboration request is accepted, users will not be able to access all the data relating to the study. Users must be allocated to the study

record by the EDGE Admin users - usually the R&D Managers and the Associate Director of R&D.

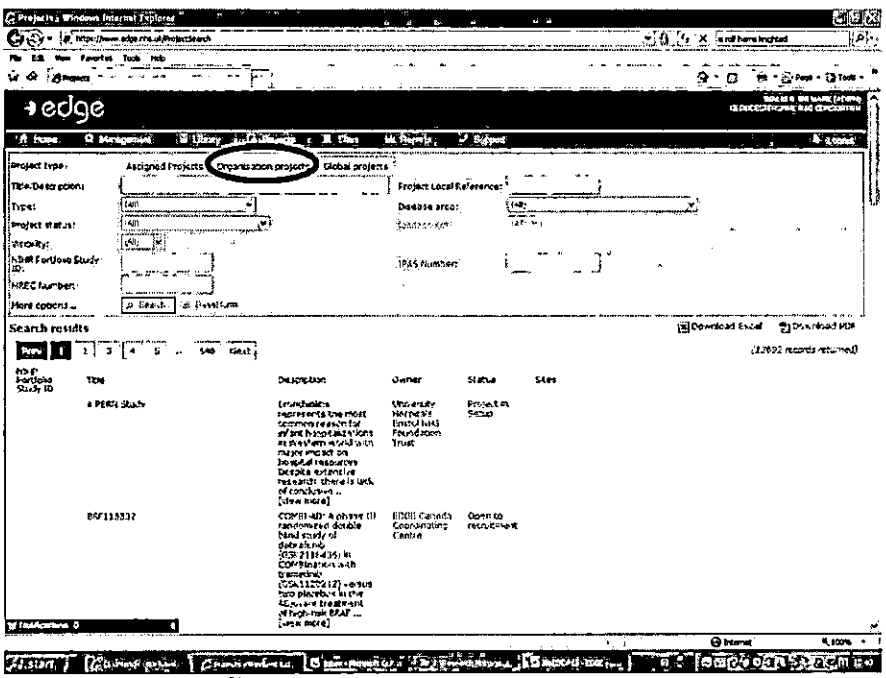
Appendix 4
1. High Level Access

High level access allows access to the global data regarding a study. In the first instance only the R&D Managers will need this access

To add users:

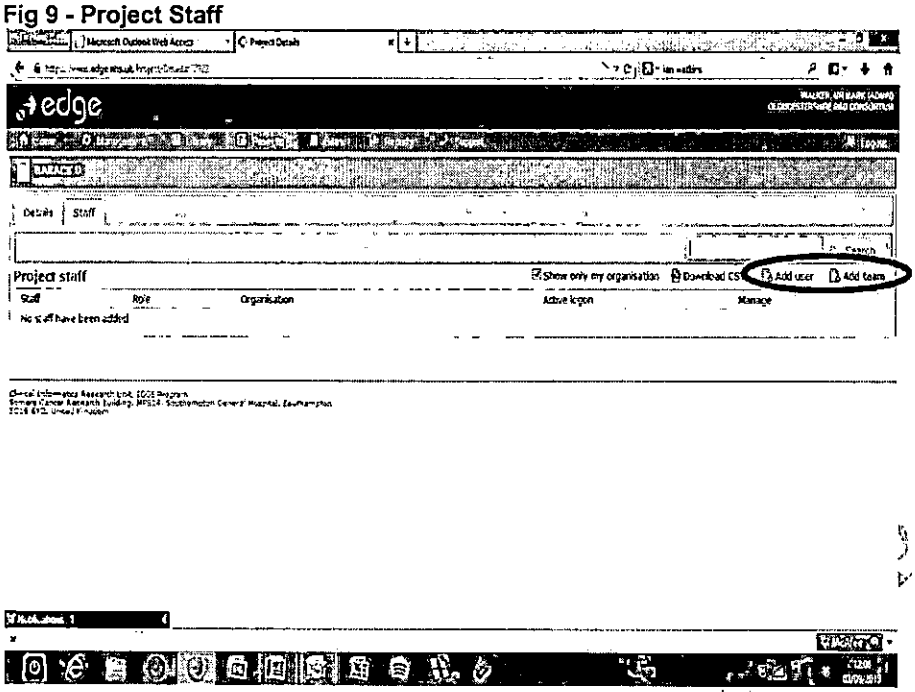
- Select PROJECTS Tab from Home Screen (Appendix 1 Fig 2.)
- The project has not yet been assigned to any sites within the Consortium, so will not show up under the ASSIGNED PROJECTS tab. Click ORGANISATION PROJECTS as in Fig 8 below

Fig 8 - Organisation Projects



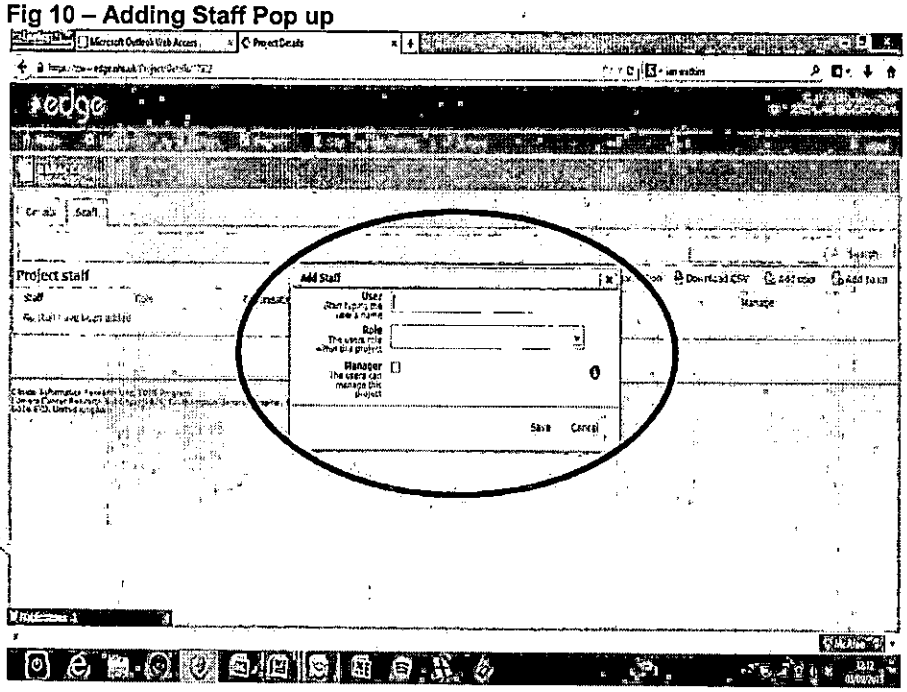
a. Simply select the appropriate study from the list, or search using the search fields on the top half of the page.
b. On the STUDY TITLE pages there will be just two tabs; DETAILS and STAFF. Select STAFF.
c. The next page will state that no staff have been assigned.

Fig 9 - Project Staff



d. To add a user or a team of users click ADD USER/ADD TEAM as marked on Fig 9
e. This will bring up the screen in Fig 10

Fig 10 – Adding Staff Pop up



f. The system will ask for the USER/TEAM. This will auto-complete for EDGE users already in the system. If the name does not auto-complete, they can be added to the EDGE user list as in Appendix 3.
g. ROLE can be selected from a drop down list. Choose the most appropriate for the study in question.

h. MANAGER should be checked for all users who need to edit/add data to EDGE. Those without MANAGER rights will only be able to view records.
i. Where appropriate CLINICAL will be available to be selected for users who will need access to patient information.
j. Only one ADMIN is required to be added at this level in order to provide access to the local data.

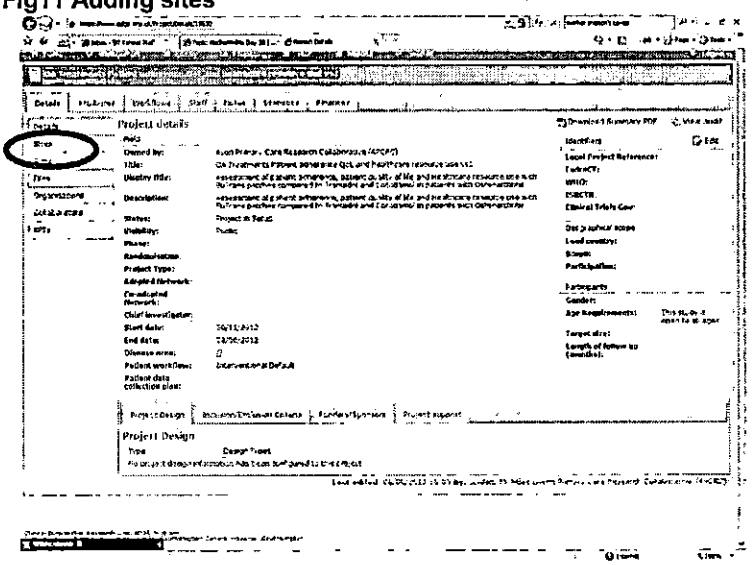
2 Local Access

a. Subsequent users (other R&D staff, local clinical staff) should be added to the site specific details for the project that can be added once the site is assigned as per Section 8
b. Local Users can be added using the steps described in Section 1 above. However, they will be added on the local information pages with a red banner.
c. Teams can be added as users to avoid replicating the steps numerous times. Allocation of ROLE, MANAGER STATUS and CLINICAL STATUS can all be added for the team in one go if required.
d. If one member of the team needs changing, select EDIT in relation to the staff member you wish to edit and make the applicable changes.

3 Adding Sites (R&D Only)

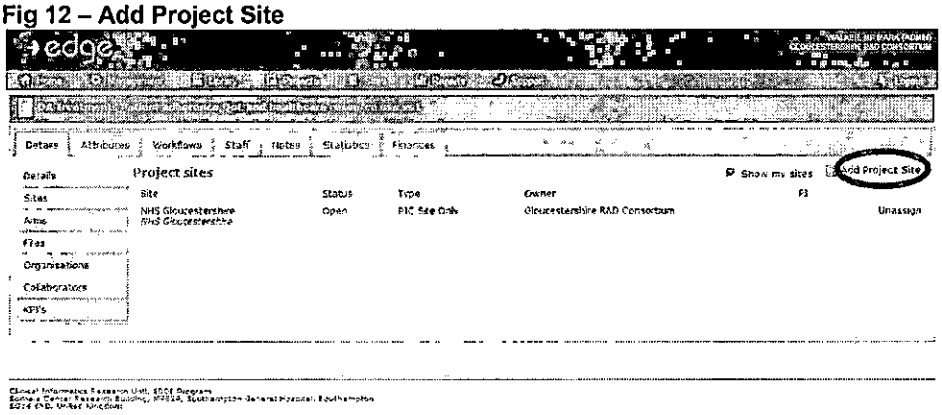
a. Once at least one ADMIN has been associated with the study at the high level, sites can be added.
b. On the STUDY SCREEN, select SITES form the DETAILS tab as in Fig 11.

Fig11 Adding sites



c. Choose ADD PROJECT SITE from the right hand side of the screen (Fig. 12) and add all information to the pop up form.

Fig 12 – Add Project Site



d. Chose the site that is hosting the study.
e. R&D SUBMISSION date should be completed for the date that the R&D team is informed of being a site by the Sponsor
f. PLANNED recruitment/closure dates should be taken, as applicable, from the IRAS form or, preferably, the SSI form where available.
g. Some data cannot be added until study completion, but all other fields must be completed.
h. Once a site has been added it will show up on the PROJECT SITES screen. Clicking the name of the site will take you through to the site specific PROJECT SITE DETAILS pages for the study.
i. Site specific pages are denoted by a red banner at the top of the page.

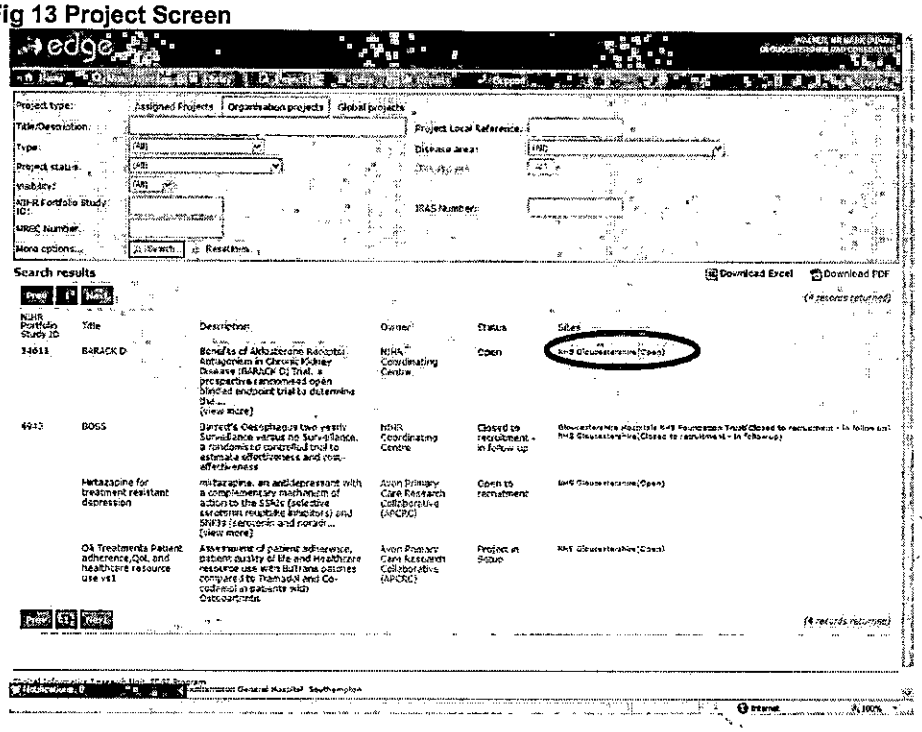
4. Adding Workflows and Entities (R&D Only)

a. Once a site has been added, the EDGE "Study Details" Entity for recording information about the study and the Workflows for recording activity must be added to the local study pages.
b. All studies must have the Entity added, but not all Workflows will be relevant.

4.1 To add the EDGE Entity

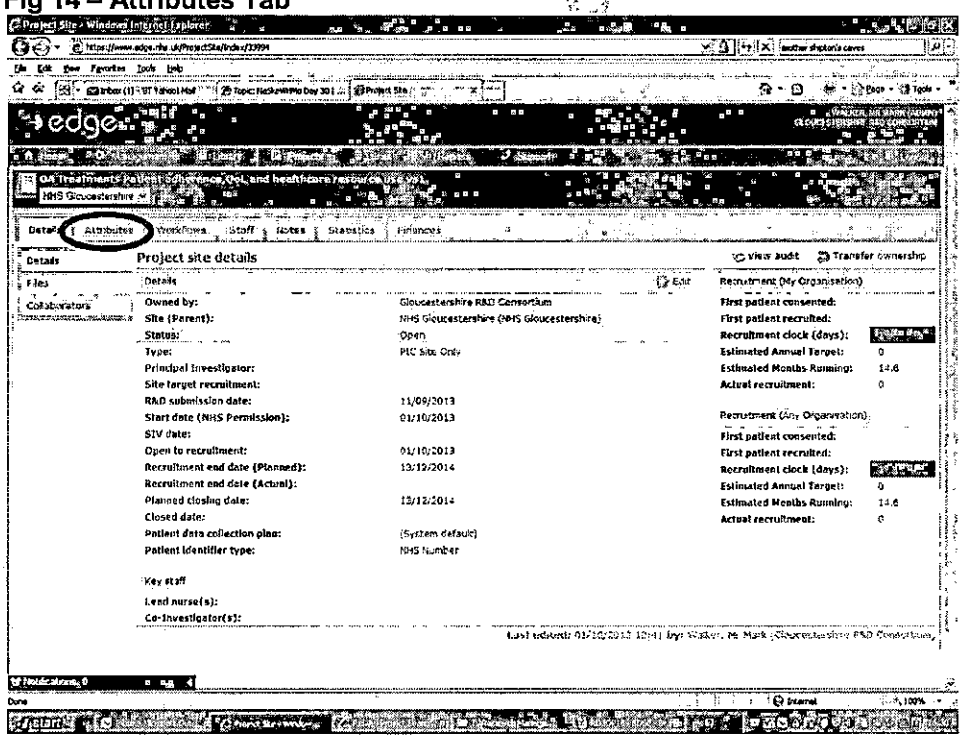
a. Ensure you are logged into the local pages which will have a red banner at the top of the page. This can be access from the Project Screen via the local link on the right hand of the screen as highlighted in fig 13.

Fig 13 Project Screen



b. From the PROJECT SITE DETAILS page, select the ATTRIBUTES tab.

Fig 14 – Attributes Tab



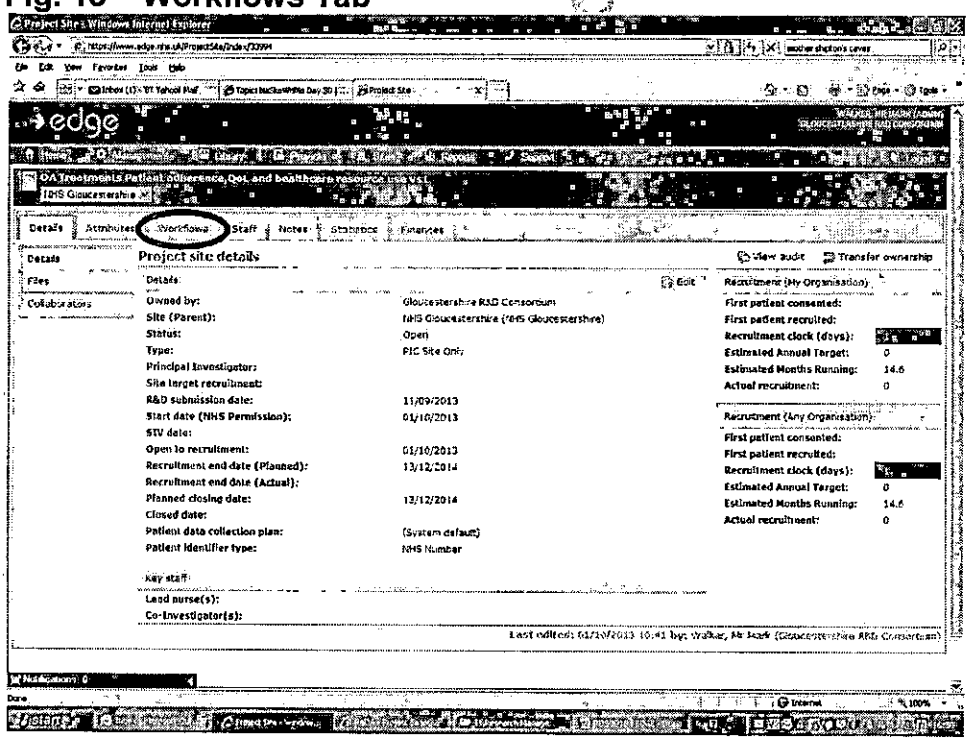
i. On the next screen, on the far right, select ADD.
ii. On the window that opens, select STUDY DETAILS from the drop down box.
iii. A new window will open with the full list of entity FIELDS.
iv. Scroll to the bottom of the list and tick "SELECT ALL"

v. Complete data in as many as possible and then Click SAVE in the bottom right of the form.
vi. If the form will not save, scroll to the top to see any WARNING MESSAGES that will explain which mandatory fields require completion.
vii. After clicking SAVE the Entity "STUDY DETAILS" will be added to the list and can be edited at any time to update missing data and change the project status.
viii. Where possible, and where no information applies, fields should be completed as "NOT APPLICABLE" or "N/A".
ix. Where information is expected, but not available at time of entry, record as "NOT AVAILABLE AT TIME OF ENTRY".
x. For data that is not known and which is expected to be unknown at any point it should be marked as "UNKNOWN"
xi. Other Entities can be chosen (when developed) by choosing an alternative from the drop down list in section 9.3.5
xii. Entries should be marked as PUBLIC to ensure accessibility to collaborating organisations such as Sue Ryder.

4.2 To add a Project WORKFLOW

From the PROJECT SITE DETAILS age, select the WORKFLOWS tab.

Fig. 15 – Workflows Tab



- On the next screen, on the far right, select ADD
- On the window that appears, open the drop down list and chose the appropriate WORKFLOWS:
  - **R&D Trust Approval/Assurance** – Add for ALL studies

- **Risk Assessment – Hosted Studies –** Add for ALL hosted studies other than PIC studies which will be LOW RISK by default.
- **Risk Assessment – Sponsored Studies –** Add only for studies sponsored by a local trust.
- **Scientific Review** – Add for all locally sponsored studies that require scientific review.
- **Set-up Study File –** Add for ALL studies.
- **Amendments –** Add when relevant
- Click SAVE for all relevant WORKFLOWS.
- Further workflows will be added to the system as it is developed and can be added by repeating the steps outlined above and choosing the appropriate workflow.
- Entries should be marked as PUBLIC to ensure accessibility to collaborating organisations such as the Sue Ryder.

Appendix 5 Process diagram