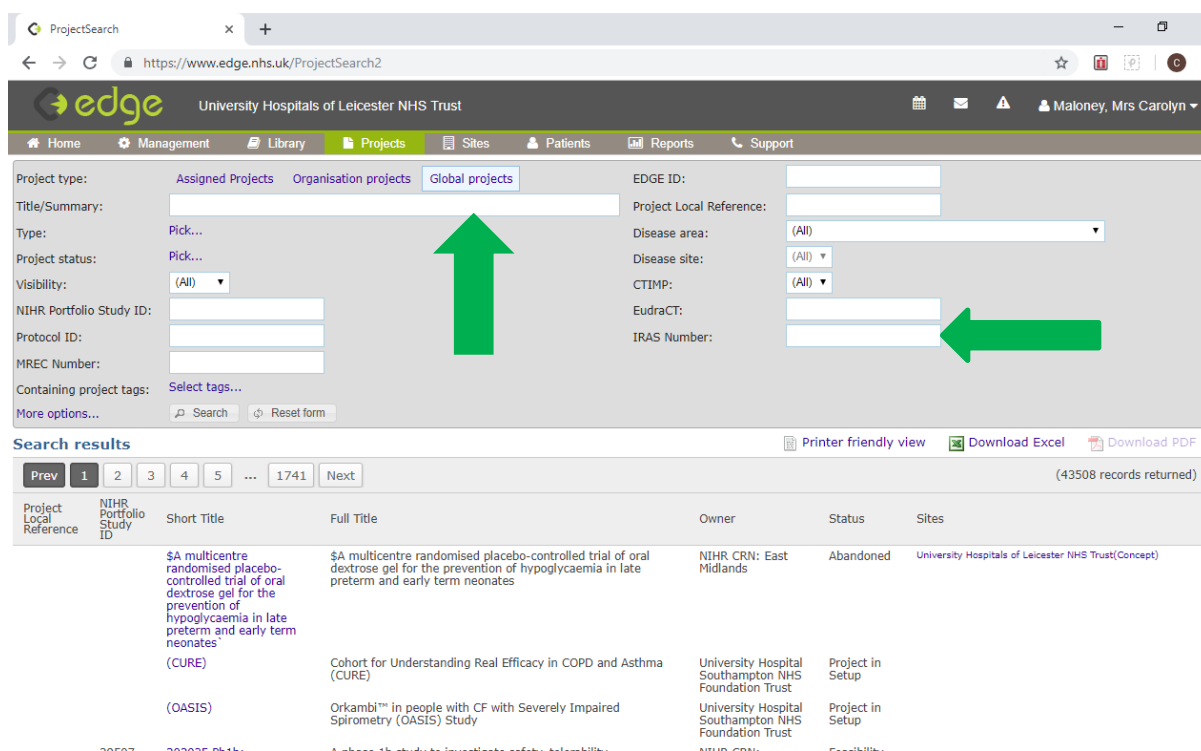


## Appendix 1

### Working Instructions for Adding UHL as a Site – Setting Up a New Study in EDGE

This working instruction is designed to be used by Administrator Users of EDGE where a study has not previously been added at Expression of Interest / Bids and Grants stage. Please see Working Instruction for EOI/Bids & Grants for detailed instructions in these cases. If you do not have Administrator access, please contact the R&I Office.

When a new study is received, EDGE must be searched thoroughly to ensure that the study is not already on the system. To do this, you need to perform a **GLOBAL** search with key words from the Project Title or use the reference numbers for the study. (IRAS/REC/Portfolio ID) Make sure you try more than one search before giving up. Sometimes it's also useful to search with the name of the PI. If you are unable to find the study using the FULL TITLE, try keywords from the title or the SHORT TITLE.

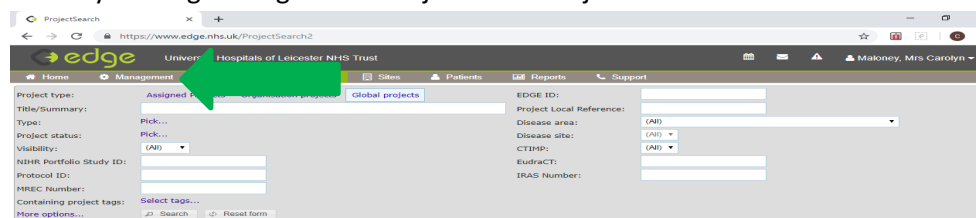


The screenshot shows the EDGE ProjectSearch interface. The 'Global projects' tab is selected, indicated by a green arrow. The search filters on the left include Project type, Title/Summary, Type, Project status, Visibility, NIHR Portfolio Study ID, Protocol ID, MREC Number, and Containing project tags. The search results table below shows a list of studies with columns for Project Local Reference, NIHR Portfolio Study ID, Short Title, Full Title, Owner, Status, and Sites. A green arrow points to the 'IRAS Number' field in the search filters.

Project Local Reference	NIHR Portfolio Study ID	Short Title	Full Title	Owner	Status	Sites
		\$A multicentre randomised placebo-controlled trial of oral dextrose gel for the prevention of hypoglycaemia in late preterm and early term neonates (CURE)	\$A multicentre randomised placebo-controlled trial of oral dextrose gel for the prevention of hypoglycaemia in late preterm and early term neonates	NIHR CRN: East Midlands	Abandoned	University Hospitals of Leicester NHS Trust(Concept)
		(OASIS)	Cohort for Understanding Real Efficacy in COPD and Asthma (CURE)	University Hospital Southampton NHS Foundation Trust	Project in Setup	
			Orkambi™ in people with CF with Severely Impaired Spirometry (OASIS) Study	University Hospital Southampton NHS Foundation Trust	Project in Setup	
			A phase 1b study to investigate safety, tolerability,	NIHR CRN:	Feasibility	

## Where a study cannot be found on EDGE

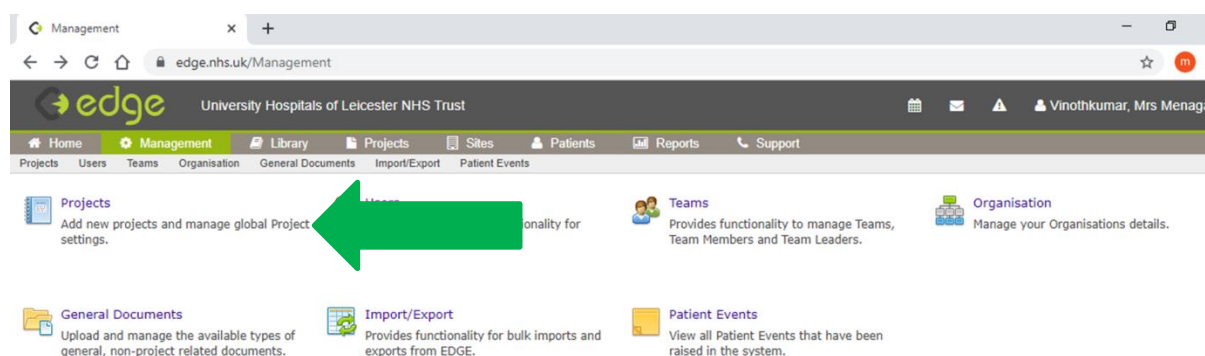
1. When the study cannot be found on EDGE, you need to create a new record. This can be done by clicking Management>Project>New Project.



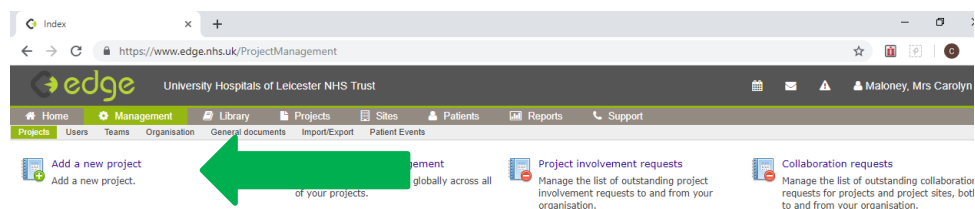
The screenshot shows the 'ProjectSearch' page on the EDGE system. The 'Management' tab is highlighted in the top navigation bar. The main area contains a search form with fields for Project type, Title/Summary, Project status, Visibility, NHR Portfolio Study ID, Protocol ID, MREC Number, and Containing project tags. There are also dropdown menus for Project Local Reference, Disease area, CTRIP, and IRAS Number. A 'Search' button is at the bottom of the form.

Search results (43508 records returned)

Project Local Reference	NHR Portfolio Study ID	Short Title	Full Title	Owner	Status	Sites
		SA multicentre randomised placebo-controlled trial of oral desferrioxamine for the prevention of hypophosphataemia in late preterm and early term neonates (CURE)	SA multicentre randomised placebo-controlled trial of oral desferrioxamine for the prevention of hypophosphataemia in late preterm and early term neonates	NHR CRN: East Midlands	Abandoned	University Hospitals of Leicester NHS Trust(Concept)
		(OASIS)	Cohort for Understanding Real Efficacy in COPD and Asthma (CURE)	University Hospital Southampton NHS Foundation Trust	Project In Setup	
			Orkambi™ in people with CF with Severely Impaired Spirometry (OASIS) Study	University Hospital Southampton NHS Foundation Trust	Project In Setup	
			A phase 1b study to investigate safety, tolerability,		Pending	

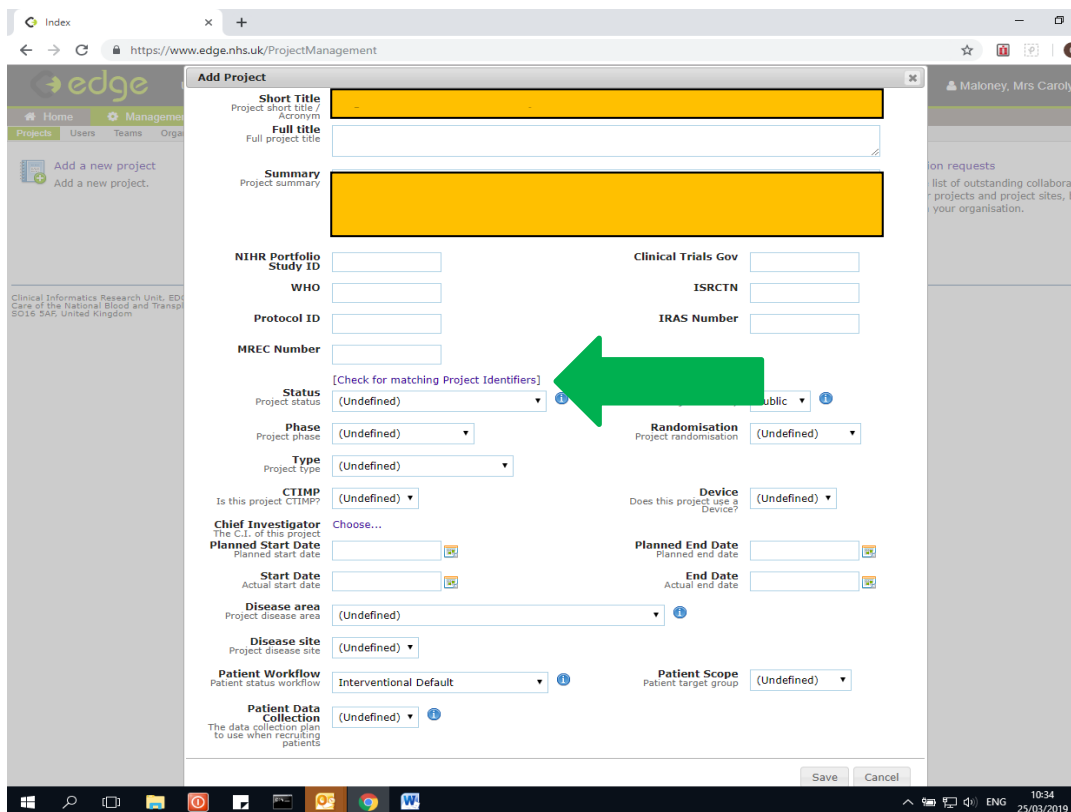


The screenshot shows the 'Management' page on the EDGE system. The left-hand menu has several options: 'Projects' (Add new projects and manage global Project settings), 'General Documents' (Upload and manage the available types of general, non-project related documents), 'Import/Export' (Provides functionality for bulk imports and exports from EDGE), 'Teams' (Provides functionality to manage Teams, Team Members and Team Leaders), and 'Organisation' (Manage your Organisations details). A green arrow points to the 'Projects' link.



The screenshot shows the 'ProjectManagement' page on the EDGE system. The left-hand menu has several options: 'Add a new project' (Add a new project), 'Project involvement requests' (Manage the list of outstanding project involvement requests to and from your organisation), and 'Collaboration requests' (Manage the list of outstanding collaboration requests for projects and project sites, both to and from your organisation). A green arrow points to the 'Add a new project' link.

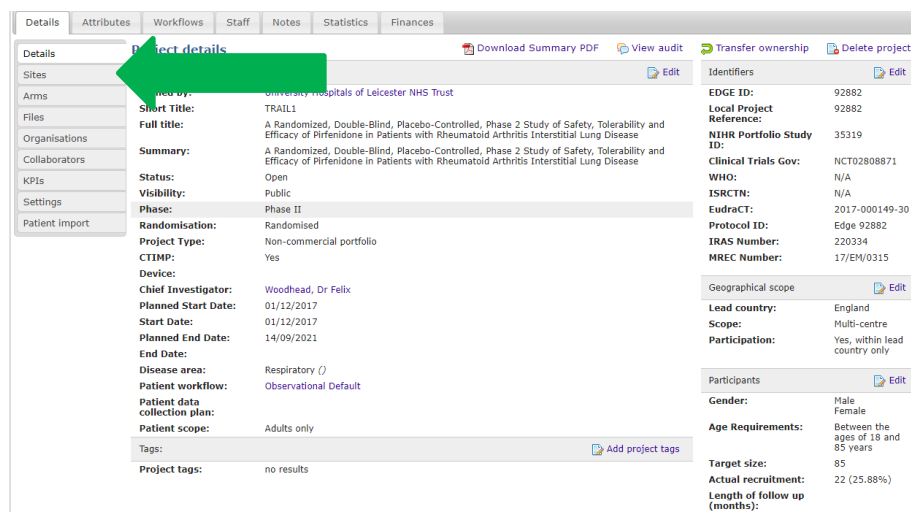
2. A set of fields will be presented to you which must be completed as far as is possible. This information should be available within the study information you have been provided



The screenshot shows the 'Add Project' form in the edge.nhs.uk/ProjectManagement system. The form is divided into several sections with yellow highlights indicating mandatory fields. A green arrow points to the 'Status' field, which is currently set to '(Undefined)'. Other highlighted fields include 'Short Title', 'Full title', 'Summary', 'NIHR Portfolio Study ID', 'WHO', 'Protocol ID', 'MREC Number', 'Clinical Trials Gov', 'ISRCTN', 'IRAS Number', 'Randomisation', 'Planned End Date', 'End Date', 'Disease area', 'Disease site', 'Patient Workflow', and 'Patient Data Collection'. The form also includes a 'Chief Investigator' section with a 'Choose...' button and a 'Patient Data Collection' section with a dropdown menu. The bottom of the form has 'Save' and 'Cancel' buttons. The browser's address bar shows 'https://www.edge.nhs.uk/ProjectManagement' and the system clock indicates 10:34 on 25/03/2019.

3. The highlighted fields are mandated. Please complete as much as possible on all tabs. If there are any fields that you are unsure about, please ask for help from your main contact in Corporate R&I.
4. Before pressing save, please check for duplicate studies. If a duplicate study has been found, please utilise this record. Do NOT generate a new study. If there are more than one duplicate of the same study, please contact UHL Data Team on [RIData@uhl-tr.nhs.uk](mailto:RIData@uhl-tr.nhs.uk)

- When you've completed the Green level front page, you need to add your site as a site i.e. Glenfield Hospital / Leicester Royal Infirmary or Leicester General Hospital. If you know the name of the Principal Investigator, and the specialty where they work, and the location of that specialty, please add the information in the RED level.

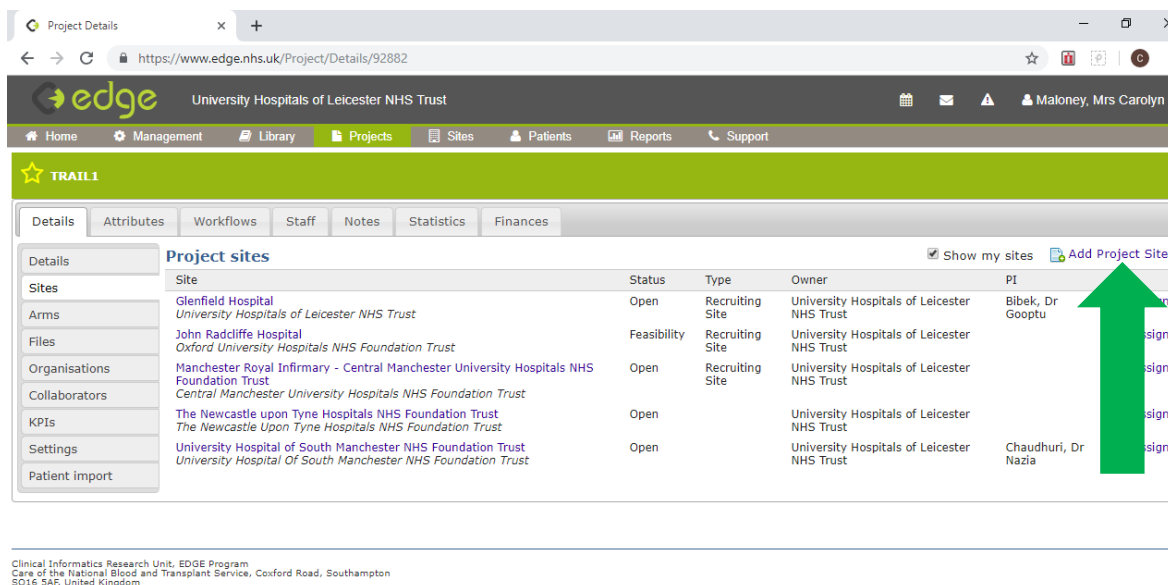


Details	Attributes	Workflows	Staff	Notes	Statistics	Finances	
<b>Project details</b> <a href="#">Download Summary PDF</a> <a href="#">View audit</a> <a href="#">Transfer ownership</a> <a href="#">Delete project</a> <a href="#">Edit</a>	<b>Identifiers</b> <a href="#">Edit</a> EDGE ID: 92882 Local Project Reference: 92882 NIHR Portfolio Study ID: 35319 Clinical Trials Gov: NCT02808871 WHO: N/A ISRCTN: N/A EudraCT: 2017-000149-30 Protocol ID: Edge 92882 IRAS Number: 220334 MREC Number: 17/EM/0315	<b>Geographical scope</b> <a href="#">Edit</a> Lead country: England Scope: Multi-centre Participation: Yes, within lead country only	<b>Participants</b> <a href="#">Edit</a> Gender: Male Female Age Requirements: Between the ages of 18 and 85 years Target size: 85 Actual recruitment: 22 (25.88%) Length of follow up (months):	<b>Details</b> Sites Arms Files Organisations Collaborators KPIs Settings Patient Import	Created by: University Hospitals of Leicester NHS Trust Short Title: TRAIL1 Full title: A Randomized, Double-Blind, Placebo-Controlled, Phase 2 Study of Safety, Tolerability and Efficacy of Pirfenidone in Patients with Rheumatoid Arthritis Interstitial Lung Disease Summary: A Randomized, Double-Blind, Placebo-Controlled, Phase 2 Study of Safety, Tolerability and Efficacy of Pirfenidone in Patients with Rheumatoid Arthritis Interstitial Lung Disease Status: Open Visibility: Public Phase: Phase II Randomisation: Randomised Project Type: Non-commercial portfolio CTIMP: Yes Device: Chief Investigator: Woodhead, Dr Felix Planned Start Date: 01/12/2017 Start Date: 01/12/2017 Planned End Date: 14/09/2021 End Date: Disease area: Respiratory (/) Patient workflow: Observational Default Patient data collection plan: Patient scope: Adults only Tags: <a href="#">Add project tags</a> Project tags: no results		

- RED LEVEL:** If you do not know the name of the Principal Investigator, add the relevant hospital as the site e.g. Glenfield, LRI / LGH, and leave the PI blank. The Support Officers will check the site and the PI when they start working the study up.

### Study status on RED LEVEL.

The status must be set at 'Feasibility' while a study is going through the feasibility process. Once feasibility is complete the study status must be changed to 'Project Site in Set Up'.



Project Details

https://www.edge.nhs.uk/Project/Details/92882

edge University Hospitals of Leicester NHS Trust

Home Management Library **Projects** Sites Patients Reports Support

☆ TRAIL1

Details Attributes Workflows Staff Notes Statistics Finances

Details

**Project sites** ☒ Show my sites [Add Project Site](#)

Site	Status	Type	Owner	PI
Glenfield Hospital University Hospitals of Leicester NHS Trust	Open	Recruiting Site	University Hospitals of Leicester NHS Trust	Bibek, Dr Gooptu
John Radcliffe Hospital Oxford University Hospitals NHS Foundation Trust	Feasibility	Recruiting Site	University Hospitals of Leicester NHS Trust	
Manchester Royal Infirmary - Central Manchester University Hospitals NHS Foundation Trust	Open	Recruiting Site	University Hospitals of Leicester NHS Trust	
The Newcastle upon Tyne Hospitals NHS Foundation Trust The Newcastle Upon Tyne Hospitals NHS Foundation Trust	Open		University Hospitals of Leicester NHS Trust	
University Hospital of South Manchester NHS Foundation Trust University Hospital Of South Manchester NHS Foundation Trust	Open		University Hospitals of Leicester NHS Trust	Chaudhuri, Dr Nazia

Clinical Informatics Research Unit, EDGE Program  
Care of the National Blood and Transplant Service, Coxford Road, Southampton  
SO16 5AF, United Kingdom

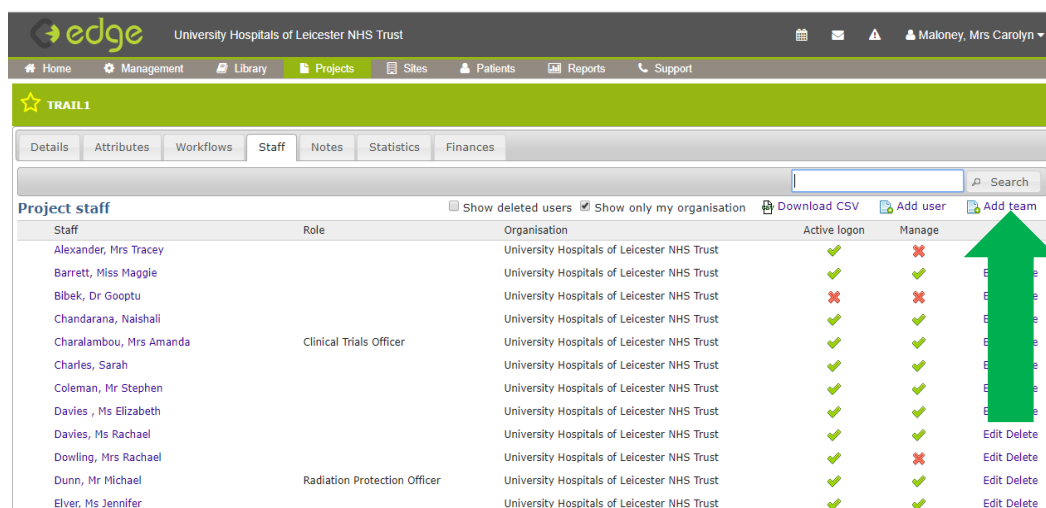
7. Once you have added the relevant UHL site, you must also add the following to the **GREEN** Level:

Teams:

UHL R&I TEAM

Speciality Team

When adding the Team please ensure that you tick Manage in the box



edge University Hospitals of Leicester NHS Trust

Home Management Library **Projects** Sites Patients Reports Support

☆ TRAIL1

Details Attributes Workflows **Staff** Notes Statistics Finances

**Project staff** ☐ Show deleted users ☒ Show only my organisation [Download CSV](#) [Add user](#) [Add team](#)

Staff	Role	Organisation	Active	logon	Manage
Alexander, Mrs Tracey		University Hospitals of Leicester NHS Trust	✓	✗	
Barrett, Miss Maggie		University Hospitals of Leicester NHS Trust	✓	✓	
Bibek, Dr Gooptu		University Hospitals of Leicester NHS Trust	✓	✗	
Chandarana, Naishali		University Hospitals of Leicester NHS Trust	✗	✓	
Charalambou, Mrs Amanda	Clinical Trials Officer	University Hospitals of Leicester NHS Trust	✓	✓	
Charles, Sarah		University Hospitals of Leicester NHS Trust	✓	✓	
Coleman, Mr Stephen		University Hospitals of Leicester NHS Trust	✓	✓	
Davies, Ms Elizabeth		University Hospitals of Leicester NHS Trust	✓	✓	
Davies, Ms Rachael		University Hospitals of Leicester NHS Trust	✓	✓	
Dowling, Mrs Rachael		University Hospitals of Leicester NHS Trust	✓	✗	
Dunn, Mr Michael	Radiation Protection Officer	University Hospitals of Leicester NHS Trust	✓	✓	
Elver, Ms Jennifer		University Hospitals of Leicester NHS Trust	✓	✓	

Study Support Teams must be added as follows:

**Pharmacy:** Where the study is a CTIMP

**Medical Physics:** Where the study is of a device - and / or if a device / piece of equipment is to be used as part of a study

**Imaging:** Where imaging is required as part of study (in IRAS filter page) – and/or where it's part of the study

**Laboratories:** Where samples are to be taken as part of the study (in IRAS filter page) – and / or where part of the study and UHL Pathology is involved

**Nuclear Meds:** Where Radiation Protection is ticked in IRAS

**Radiation Protection:** Where Radiation Protection is ticked in IRAS  
All other Support Departments & Teams to be added by Study Support Officers

#### Attributes (Entities):

**Contracts**

**Data Flows / GDPR**

**Finance Approval**

**Mandatory Category 1, 2, 3 & 4 (please complete Primary Clinical Management Area if known in Mandatory 1)**

**Software / Hardware requirements**

**Other attributes will be added as relevant when required. Attributes will be added by the Study support teams. Please see listings detailing completion responsibilities**

#### Workflows

**Archiving Arrangements**

**CMG Approval**

**Confirm Process Stage 3**

**Contracts Process (W.E.F 01/04/19)**

**Final Contracts Pre-Sign Checks (HRA Studies Only)**

**R&I Finance Approval**

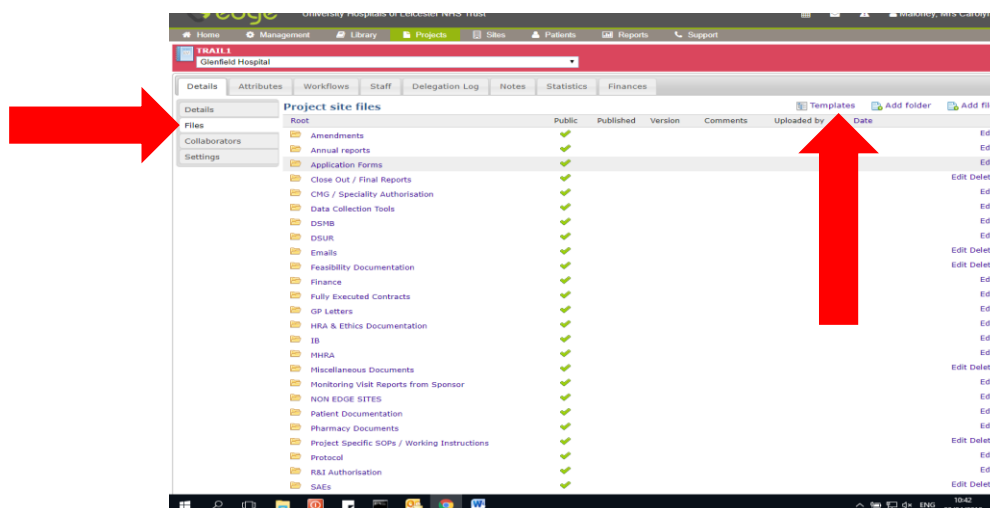
## Study Staff Added

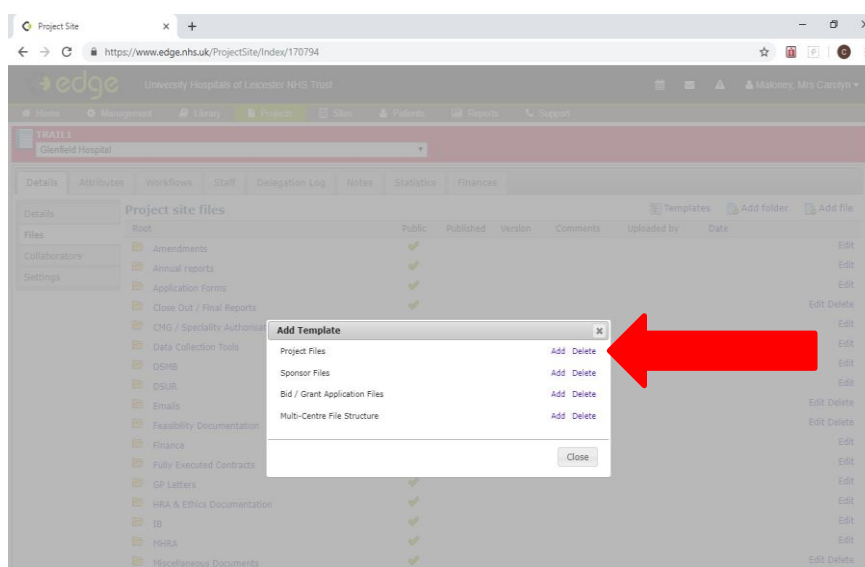
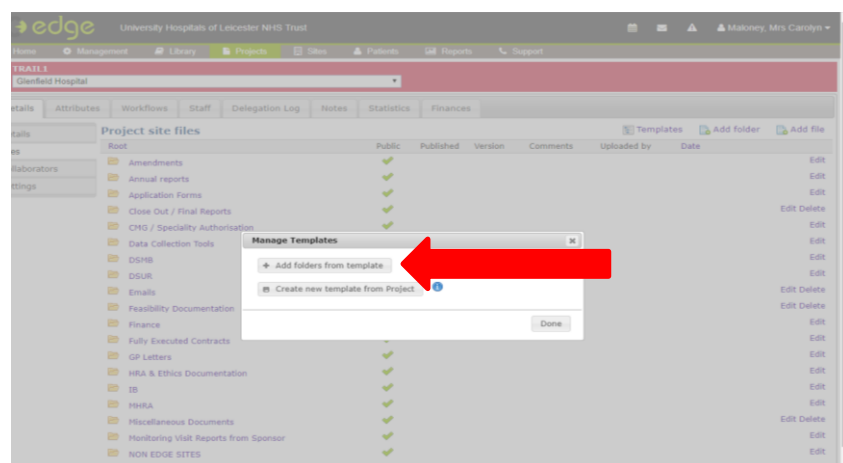
Other attributes will be added as relevant when required. Attributes will be added by the Study support teams. Please see listings detailing completion responsibilities

You add the relevant UHL site based on where the Primary Clinical Management Area resides within the trust, or the main base site of the P.I.

- Once point 7 completed, you must add the following to the **RED** Level:

In Files you need to add the file structure template





Upload any documentation you have received from your shared drives into the relevant EDGE Folder.

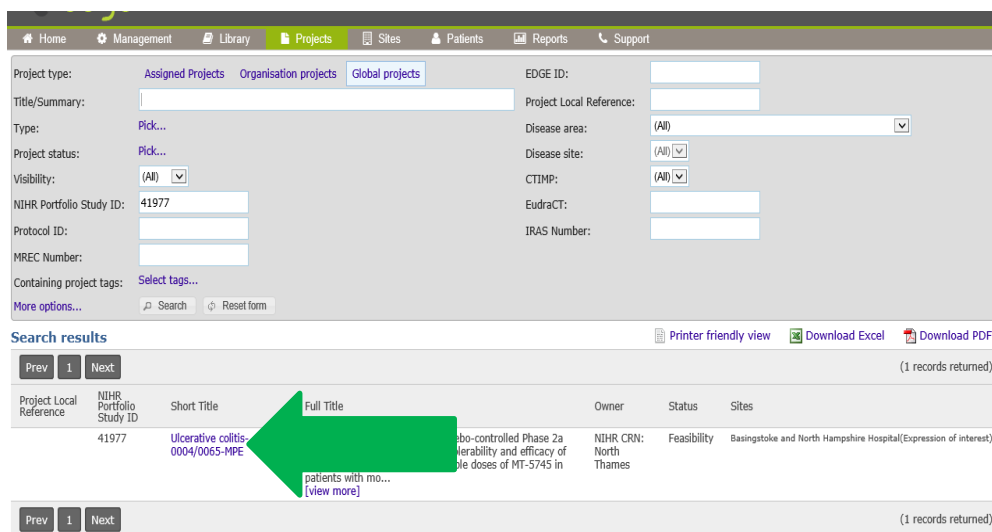
### **Where a project exists on EDGE**

Where a project has already been added to EDGE, you need to request involvement for that study. Follow the screen shots below to show how to do this.

NB. You cannot add anything to the study until we have access to the record.

1. Click on the study link. That will take you through to the main project page in the GREEN level.





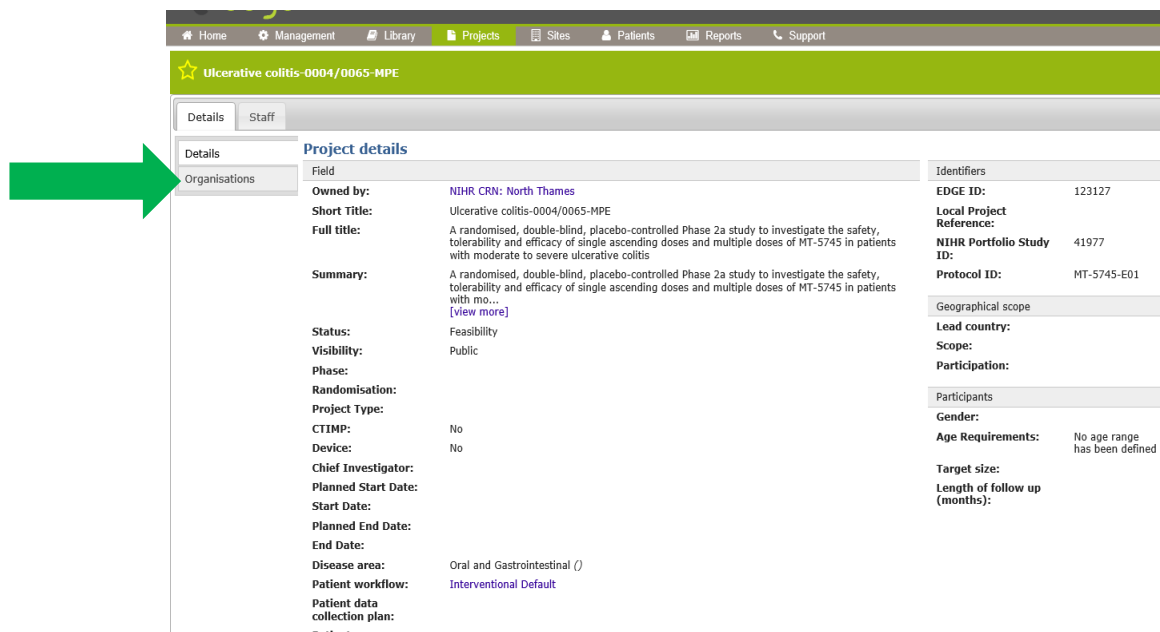
Project type: Assigned Projects Organisation projects **Global projects** EDGE ID:   
 Title/Summary:  Project Local Reference:   
 Type: Pick... Disease area: (All)   
 Project status: Pick... Disease site: (All)   
 Visibility: (All)  CTIMP: (All)   
 NIHR Portfolio Study ID: 41977 EudraCT:   
 Protocol ID:  IRAS Number:   
 MREC Number:   
 Containing project tags: Select tags...  
 More options... Search Reset form

**Search results** [Printer friendly view](#) [Download Excel](#) [Download PDF](#)  
 (1 records returned)

Project Local Reference	NIHR Portfolio Study ID	Short Title	Full Title	Owner	Status	Sites
41977	Ulcerative colitis-0004/0065-MPE	Ulcerative colitis-0004/0065-MPE	Randomised, double-blind, placebo-controlled Phase 2a study to investigate the safety, tolerability and efficacy of single ascending doses and multiple doses of MT-5745 in patients with moderate to severe ulcerative colitis	NIHR CRN: North Thames	Feasibility	Basingstoke and North Hampshire Hospital(Expression of interest)

Prev 1 Next (1 records returned)

- Click on Organisations and then click 'request involvement'. When asked if a CDA is in place, please click 'confirm'. A box asking about partner involvement will come up – please tick both boxes and click 'confirm'.



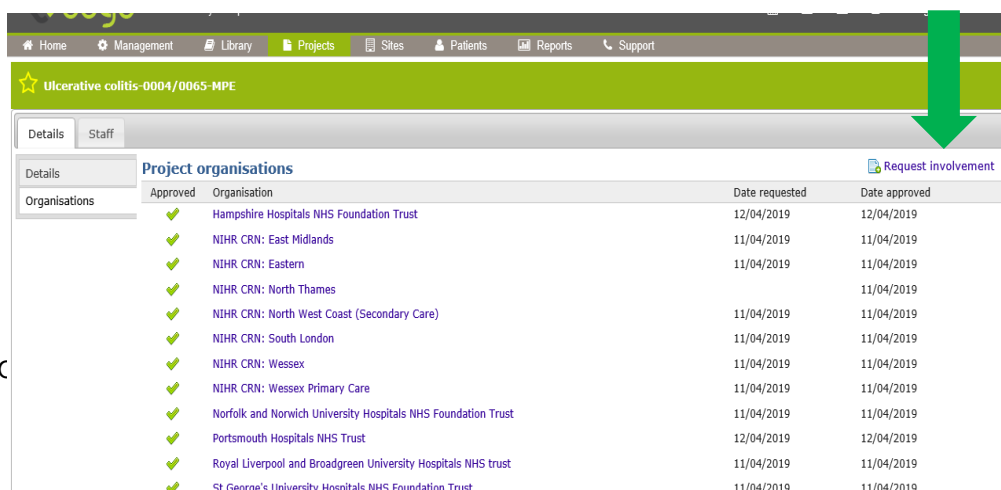
☆ **Ulcerative colitis-0004/0065-MPE**

Details Staff

**Details** **Organisations**

**Project details**

Field	Identifiers
<b>Owned by:</b> NIHR CRN: North Thames	<b>EDGE ID:</b> 123127
<b>Short Title:</b> Ulcerative colitis-0004/0065-MPE	<b>Local Project Reference:</b>
<b>Full title:</b> A randomised, double-blind, placebo-controlled Phase 2a study to investigate the safety, tolerability and efficacy of single ascending doses and multiple doses of MT-5745 in patients with moderate to severe ulcerative colitis	<b>NIHR Portfolio Study ID:</b> 41977
<b>Summary:</b> A randomised, double-blind, placebo-controlled Phase 2a study to investigate the safety, tolerability and efficacy of single ascending doses and multiple doses of MT-5745 in patients with moderate to severe ulcerative colitis	<b>Protocol ID:</b> MT-5745-E01
<b>Status:</b> Feasibility	<b>Geographical scope:</b>
<b>Visibility:</b> Public	<b>Lead country:</b>
<b>Phase:</b>	<b>Scope:</b>
<b>Randomisation:</b>	<b>Participation:</b>
<b>Project Type:</b>	<b>Participants:</b>
<b>CTIMP:</b> No	<b>Gender:</b>
<b>Device:</b> No	<b>Age Requirements:</b> No age range has been defined
<b>Chief Investigator:</b>	<b>Target size:</b>
<b>Planned Start Date:</b>	<b>Length of follow up (months):</b>
<b>Start Date:</b>	
<b>Planned End Date:</b>	
<b>End Date:</b>	
<b>Disease area:</b> Oral and Gastrointestinal ()	
<b>Patient workflow:</b> Interventional Default	
<b>Patient data collection plan:</b>	



☆ **Ulcerative colitis-0004/0065-MPE**

Details Staff

**Details** **Project organisations** [Request involvement](#)

Organisations	Approved	Organisation	Date requested	Date approved
✓	✓	Hampshire Hospitals NHS Foundation Trust	12/04/2019	12/04/2019
✓	✓	NIHR CRN: East Midlands	11/04/2019	11/04/2019
✓	✓	NIHR CRN: Eastern	11/04/2019	11/04/2019
✓	✓	NIHR CRN: North Thames	11/04/2019	11/04/2019
✓	✓	NIHR CRN: North West Coast (Secondary Care)	11/04/2019	11/04/2019
✓	✓	NIHR CRN: South London	11/04/2019	11/04/2019
✓	✓	NIHR CRN: Wessex	11/04/2019	11/04/2019
✓	✓	NIHR CRN: Wessex Primary Care	11/04/2019	11/04/2019
✓	✓	Norfolk and Norwich University Hospitals NHS Foundation Trust	11/04/2019	11/04/2019
✓	✓	Portsmouth Hospitals NHS Trust	12/04/2019	12/04/2019
✓	✓	Royal Liverpool and Broadgreen University Hospitals NHS trust	11/04/2019	11/04/2019
✓	✓	St George's University Hospitals NHS Foundation Trust	11/04/2019	11/04/2019

Details

Staff

Details

Organisations

Project organisations

Request involvement

Approved	Organisation	Date requested	Date approved
✓	Hampshire Hospitals NHS Foundation Trust	12/04/2019	12/04/2019
✓	NIHR CRN: East Midlands	11/04/2019	11/04/2019
✓	NIHR CRN: Eastern	11/04/2019	11/04/2019
✓	NIHR CRN: North Thames	11/04/2019	11/04/2019
✓	NIHR CRN: North West Coast (Secondary Care)	11/04/2019	11/04/2019
✓	NIHR CRN: South Lo	11/04/2019	11/04/2019
✓	NIHR CRN: Wessex	11/04/2019	11/04/2019
✓	NIHR CRN: Wessex F	11/04/2019	11/04/2019
✓	Norfolk and Norwich	11/04/2019	11/04/2019
✓	Portsmouth Hospitals	12/04/2019	12/04/2019
✓	Royal Liverpool and	11/04/2019	11/04/2019
✓	St George's University Hospitals NHS Foundation Trust	11/04/2019	11/04/2019
✓	The Royal Bournemouth and Christchurch Hospitals NHS Foundation Trust	12/04/2019	12/04/2019
✓	University Hospital Southampton NHS Foundation Trust	12/04/2019	12/04/2019
✓	University Hospitals Of Morecambe Bay NHS Foundation Trust	11/04/2019	11/04/2019
✓	Warrington and Halton Hospitals NHS Foundation Trust	11/04/2019	11/04/2019
✓	Wirral University Teaching Hospital NHS Foundation Trust	11/04/2019	11/04/2019

CDA Confirmation Required (NIHR Commercial Studies)

Please confirm that you have read and understood that if this study is NIHR Commercially adopted, a Confidentiality Disclosure Agreement must be in place.

Confirm

**CDA Confirmation Required (NIHR Commercial Studies)**

Please confirm that you have read and understood that if this study is NIHR Commercially adopted, a Confidentiality Disclosure Agreement must be in place.

Confirm

Details

Organisations

Approved	Organisation	Date requested	Date approved
✓	Hampshire Hospitals NHS Foundation Trust	12/04/2019	12/04/2019
✓	NIHR CRN: East Midlands	11/04/2019	11/04/2019
✓	NIHR CRN: Eastern	11/04/2019	11/04/2019
✓	NIHR CRN: North Thames	11/04/2019	11/04/2019
✓	NIHR CRN: North West Coast (Secondary Care)	11/04/2019	11/04/2019
✓	NIHR CRN: South Lo	11/04/2019	11/04/2019
✓	NIHR CRN: Wessex	11/04/2019	11/04/2019
✓	NIHR CRN: Wessex	11/04/2019	11/04/2019
✓	Norfolk and Norwich	11/04/2019	11/04/2019
✓	Portsmouth Hospitals	12/04/2019	12/04/2019
✓	Royal Liverpool and	11/04/2019	11/04/2019
✓	St George's University Hospitals NHS Foundation Trust	11/04/2019	11/04/2019
✓	The Royal Bournemouth and Christchurch Hospitals NHS Foundation Trust	12/04/2019	12/04/2019
✓	University Hospital Southampton NHS Foundation Trust	12/04/2019	12/04/2019
✓	University Hospitals Of Morecambe Bay NHS Foundation Trust	11/04/2019	11/04/2019
✓	Warrington and Halton Hospitals NHS Foundation Trust	11/04/2019	11/04/2019
✓	Wirral University Teaching Hospital NHS Foundation Trust	11/04/2019	11/04/2019

Request Project Involvement

Organisation

The organisation requesting access to this project

University Hospitals of Leicester NHS Trust

Partner access request

Also request access to this Project for the following Partner Organisations?

☒ NIHR CRN: East Midlands

☒ University of Leicester

Save

**Request Project Involvement**

The organisation requesting access to this project

University Hospitals of Leicester NHS Trust

**Partner access request**  
Also request access to this Project for the following Partner Organisations?

☒ NIHR CRN: East Midlands

☒ University of Leicester

Save

Home

Management

Library

Projects

Sites

Patients

Reports

Support

☆ Ulcerative colitis-0004/0065-MPE

Details

Staff

Details

Organisations

Project organisations

Approved	Organisation	Date requested	Date approved
✓	Hampshire Hospitals NHS Foundation Trust	12/04/2019	12/04/2019
✓	NIHR CRN: East Midlands	11/04/2019	11/04/2019
✓	NIHR CRN: Eastern	11/04/2019	11/04/2019
✓	NIHR CRN: North Thames	11/04/2019	11/04/2019
✓	NIHR CRN: North West Coast (Secondary Care)	11/04/2019	11/04/2019
✓	NIHR CRN: South London	11/04/2019	11/04/2019
✓	NIHR CRN: Wessex	11/04/2019	11/04/2019
✓	NIHR CRN: Wessex Primary Care	11/04/2019	11/04/2019
✓	Norfolk and Norwich University Hospitals NHS Foundation Trust	11/04/2019	11/04/2019
✓	Portsmouth Hospitals NHS Trust	12/04/2019	12/04/2019
✓	Royal Liverpool and Broadgreen University Hospitals NHS trust	11/04/2019	11/04/2019
✓	St George's University Hospitals NHS Foundation Trust	11/04/2019	11/04/2019
✓	The Royal Bournemouth and Christchurch Hospitals NHS Foundation Trust	12/04/2019	12/04/2019
✓	University Hospital Southampton NHS Foundation Trust	12/04/2019	12/04/2019
✗	University Hospitals of Leicester NHS Trust	12/04/2019	
✓	University Hospitals Of Morecambe Bay NHS Foundation Trust	11/04/2019	11/04/2019
✗	University of Leicester	12/04/2019	
✓	Warrington and Halton Hospitals NHS Foundation Trust	11/04/2019	11/04/2019
✓	Wirral University Teaching Hospital NHS Foundation Trust	11/04/2019	11/04/2019

Remove

Remove

Make a note to check whether or not UHL has been added as a site. If it's been longer than 72 hours (3 days) email the EDGE administrators that own the record. To do this you need to go back into the study and click through to Organisations. If there is a green tick next to our name then you know we have access to the study.

To chase involvement you need to contact the owner of the record. This can found on the Green Level front page. Click into the hyperlink of the owner organisation and the EDGE Administrator for the owner will be displayed. Send them an email.

Once UHL request has been acknowledged, repeat as above from point 5 onwards

**Where a project exists on EDGE and UHL has been added as a site**

Follow the above instruction from Point 5 onwards.