

RESEARCH RECRUITMENT AND STUDY CLOSURE GUIDE

CONTENTS

- Page 4** Purpose of Guide
- Page 5** High Level Overview of Recruitment Data Process

SECTION 1: UCLH SITE RECRUITMENT

- Pages 6-7** Associating a Patient to a Research Study in EPIC
- Pages 8-14** Adding Participants Directly into EDGE
- Pages 15-18** How to Find UCLH Recruitment Which has been Queried on CPMS using Edge
- Pages 18-25** For UCLH Study Teams How to Rectify CPMS data Which has been Deemed Inaccurate
- Pages 26-29** How to Perform a Single Study Patient Import into EDGE
- Pages 30-31** How to Find a Study's Recruitment Contact/s on Edge

Section 2: Chief Investigator/Central study Team Requirements for UCLH/UCL Sponsored Studies

- Pages 32-33** For portfolio studies, how to tell if your study requires manual uploading of recruitment to CPMS or if the data flows from EDGE into CPMS
- Pages 34-35** Check Who Has the Responsibility of Confirming Recruitment in CPMS or Responsibility for Uploading Manual Recruitment into CPMS
- Page 36** How to Validate Recruitment in CPMS
- Pages 37-39** How to Manually Upload Recruitment in CPMS
- Pages 40-42** How to Confirm No Recruitment Since the Last Upload
- Pages 43-44** How to Find a Study's Recruitment Contact/s on Edge
- Page 45** Annual progress reports

Section 3: Study Closures

- Pages 46-47** UCLH Site Closures
- Pages 47-48** UCLH/UCL Sponsored Study Closures
- Pages 49-51** Change the Study Status in CPMS (if study is NIHR adopted)
- Page 52** Definition of end of study
- Page 52** Declaring the end of a study
- Pages 52-53** Notifying the Research Ethics Committee

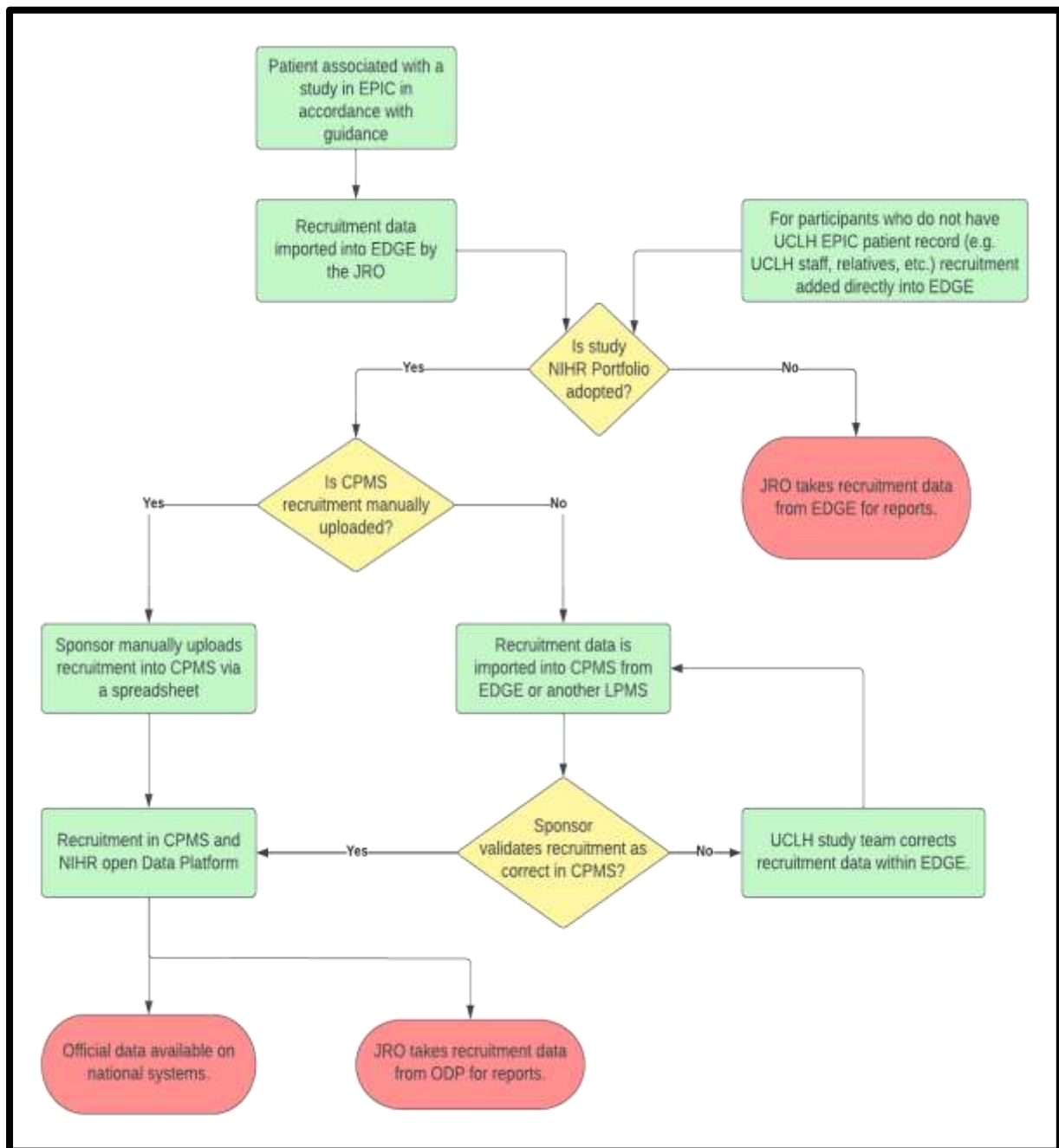
Page 53	Notifying the HRA and HCRW
Page 53	Notifying the MHRA
Page 53	Notifying the MHRA (Devices)
Page 53	Notifying the Confidentiality Advisory Group (CAG)
Page 53	Notifying other Review Bodies
Page 54	Final Report on the Research
Page 54	Final Report to the Research Ethics Committee (REC)
Page 54	Final Report to the MHRA (medical devices)
Page 54	Final Report to other review bodies
Page 54	Informing Participants
Page 55	Publishing Results
Pages 55-56	Post-research Care
Page 56	Other end of study considerations

PURPOSE OF GUIDE

This guide is designed to provide a succinct reference point for the logging of participant recruitment information at UCLH. The guide covers sponsor and host site responsibilities, as well as the data confirmations process.

The guide also covers expected study team actions for the closure of studies. The differing requirements of sponsor and site are outlined.

CHART 1 – HIGH LEVEL OVERVIEW OF THE PROCESS

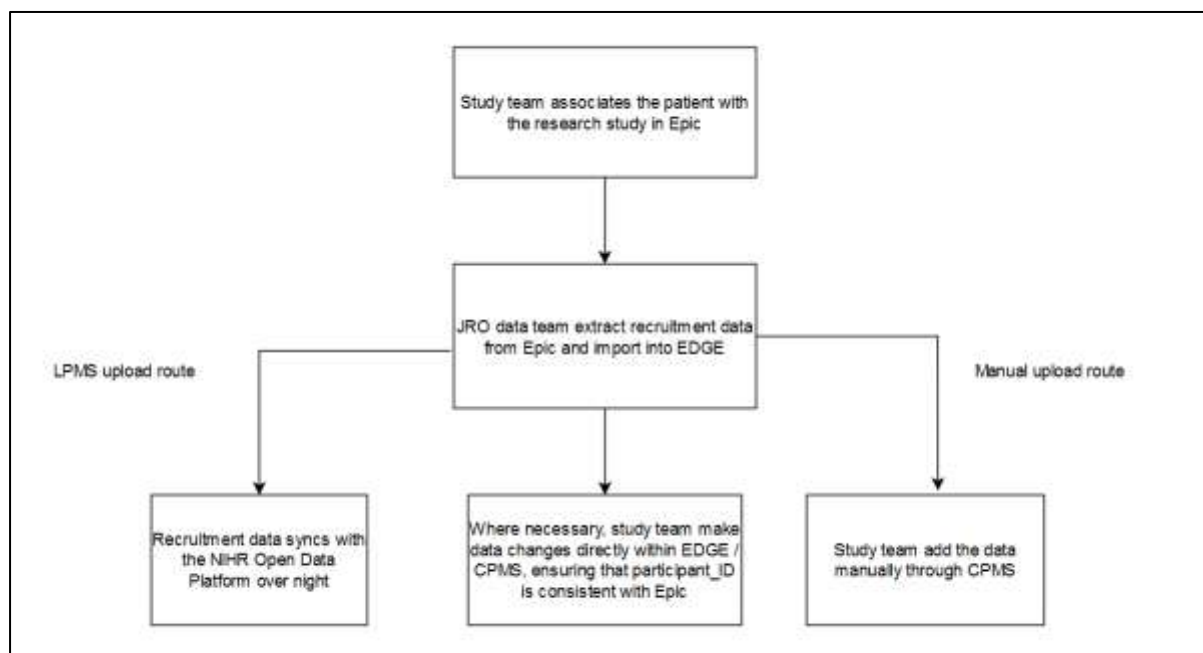


It should be noted that once a study is put into a site status other than ‘open,’ it won’t be possible to manually add further recruitment to EDGE and any recruits that are imported will not sync with CPMS.

SECTION 1: UCLH SITE RECRUITMENT

Chart 2: Overview of site recruitment data capture:

Studies where recruitment is captured on Epic



Associating a Patient to a Research Study in EPIC

1. Open 'Patient Research Studies'
2. Search for your patient
3. Select 'Research Studies' (from the list on left hand side of page)
4. Click 'Add' > A pop-up box will appear
5. Search for the relevant Research Study
6. A smart-form will appear, complete as relevant
7. Update the Participant ID

Please note for portfolio studies this needs to be the participant ID as the sponsor/ Research Activity Coordinator expects to see it. If the participant ID is entered incorrectly this could lead to issues verifying and correcting the data later on.

8. Choose the appropriate status from the drop down list. (NB: The tip sheet defines each of these. A link is available at the bottom of this section).

9. Update the Status effective date with the date that the participant effectively went into the selected status. (By default this will be the date the update is being made).
10. For a participant to be extracted from Epic and imported to EDGE, the following conditions must be met:
 - The patient must have been put into a status of 'Enrolled – active on study' at some stage.
 - The enrolment status at the time the extract is run must be 'enrolled – active on study,' 'enrolled – in follow-up' or 'completed.'

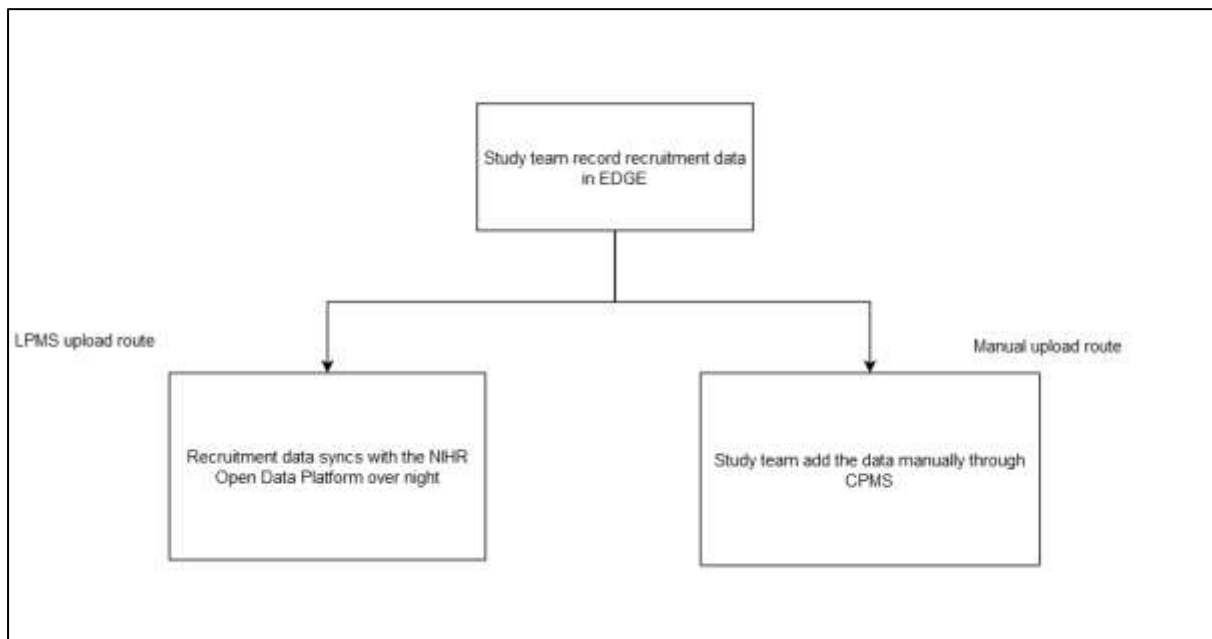
For the above cohort, if the active start date on the enrolment record is 27th November 2022 or earlier, the active start date will be taken as the date of recruitment (in line with guidance prior to the November 2022 Epic update). Otherwise, the status effective date from when the patient went into a status of 'Enrolled – active on study' will be taken as the recruitment date. **Please note for portfolio studies this needs to be the date the Research Activity Coordinator is expecting when they come to verify the data in CPMS. If the Research Activity Coordinator is expecting to see the randomised date in CPMS then use the randomisation date as the earliest 'enrolled – active on study' status effective date.**

A more detailed tip sheet is available here:

https://my.uclh.nhs.uk/Utilities/Uploads/Handler/Uploader.ashx?area=composer&filename=Research_All_Assigning%2bPatient%2bto%2bStudy%2b_2.0.pdf&fileguid=01e3921d-9329-4ec2-be76-6fe4adab216b

Chart 3: Overview of site recruitment data capture:

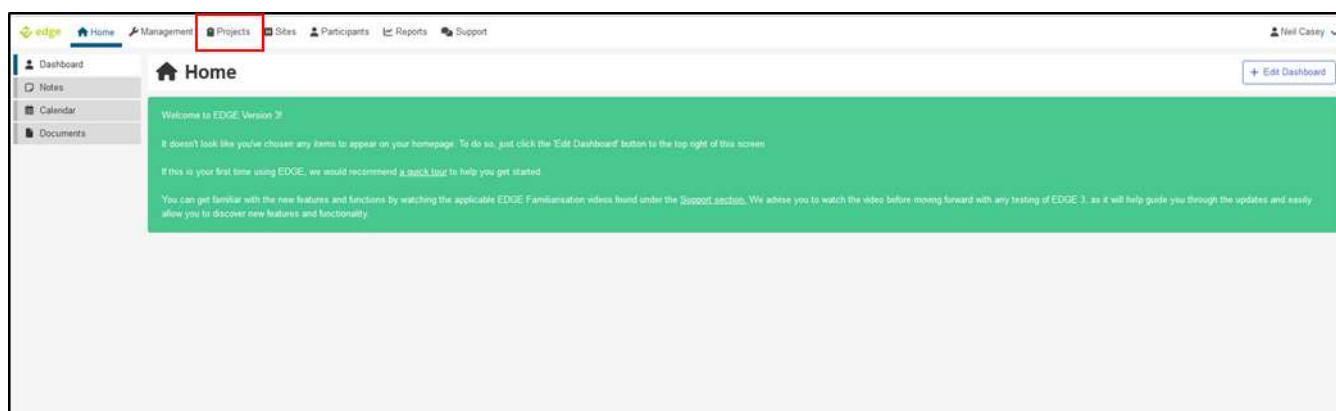
Studies that do not involve UCLH patients



Adding Participants Directly into EDGE

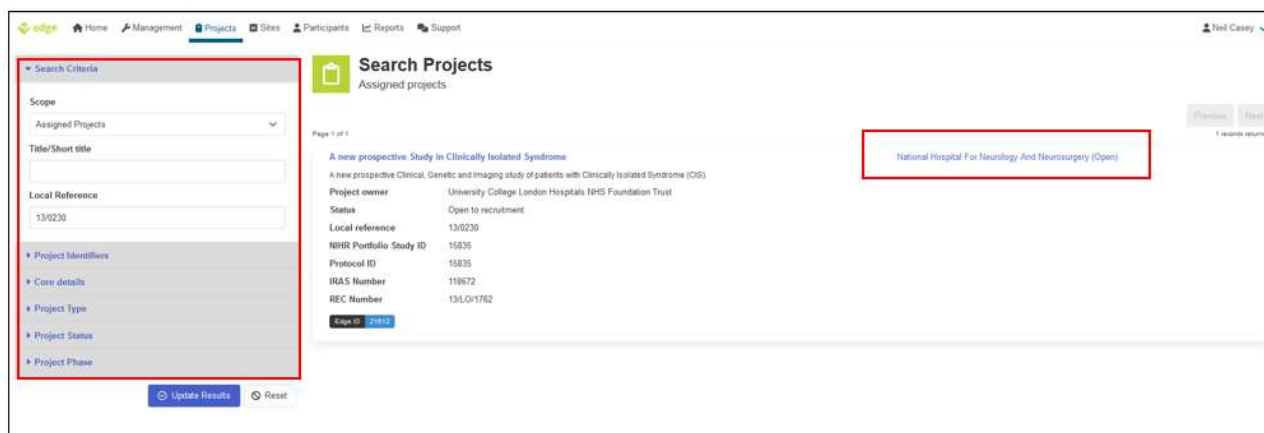
Sometimes a participant cannot be assigned to a study in EPIC as they do not have an EPIC patient record, for example where the study is recruiting relatives or carers of a patient, or NHS professionals; these should be added directly into EDGE.

1. Log in to Edge. If you need an Edge account please contact UCLH.RandD@nhs.net, include at least one study identifier (e.g. EDGE ID, IRAS number, R&D reference or REC reference) per study you require access to.
2. Click on Projects

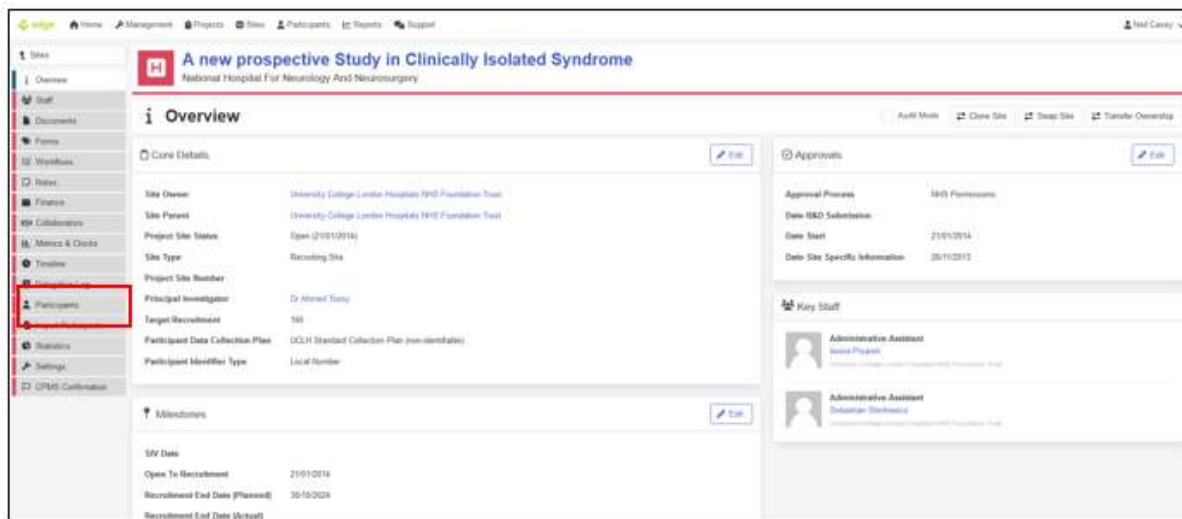


3. Search for your study. Using numbers or references is usually the best way but only try one number or reference at a time. N.B. The R&D number is called “Local Project Reference” in EDGE. Click search. If your study doesn’t appear click on “Global Projects”, if your study appears it means you have not been provided access to the study and need to contact UCLH.RandD@nhs.net asking them to provide you access; if your study still doesn’t appear and you have used all the references individually then contact UCLH.RandD@nhs.net for assistance.

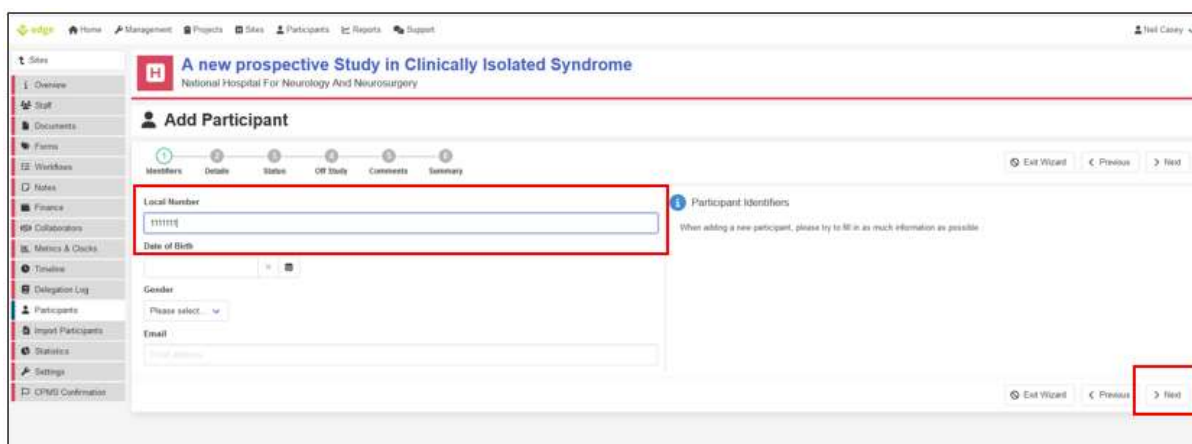
4. Click on the site name.



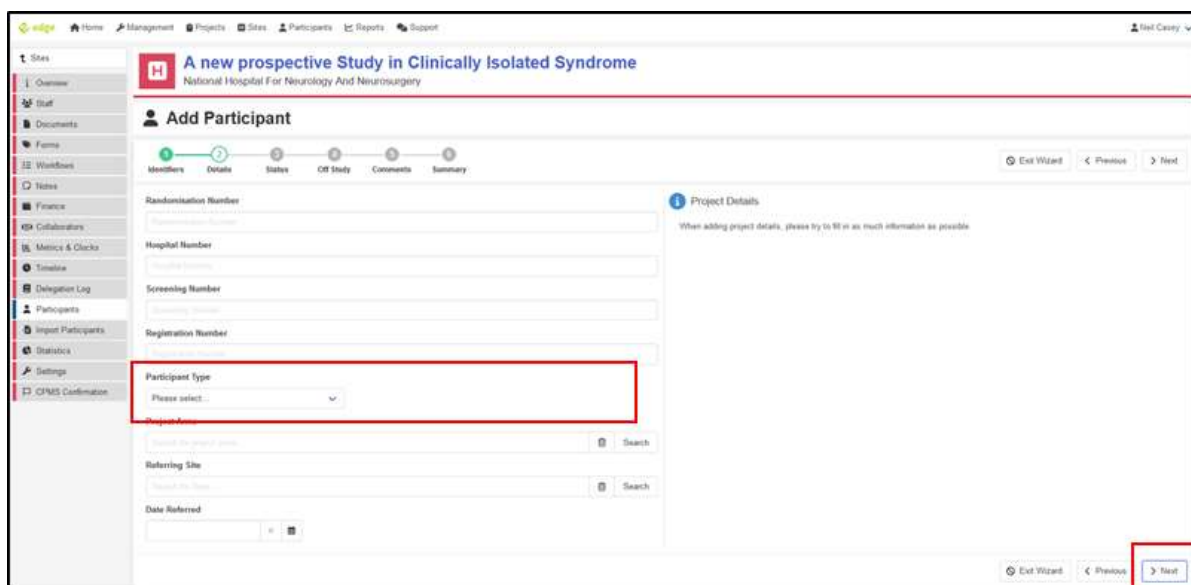
- Click on the Participants tab in the left hand menu. If you cannot see the patients tab email UCLH.RandD@nhs.net requesting clinical access for this study. Then click on “Add a new participant”. **If you need to add lots of participants at once please use the patient import option as described in the next section.**



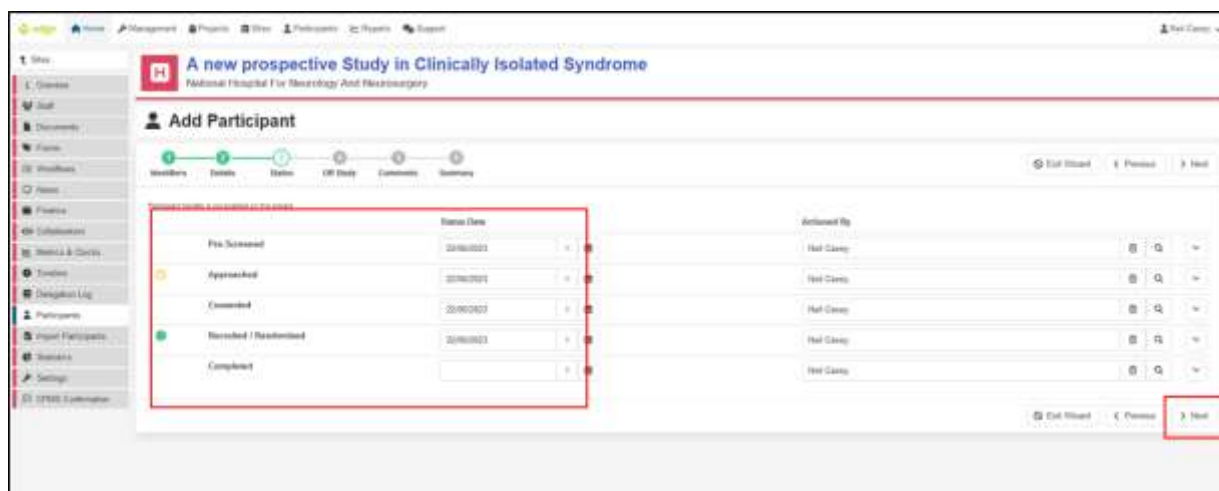
- Put the participants trial ID in the Local Number field and then click next. For portfolio studies the local needs to be the trial ID the Research Activity Coordinator is expecting.



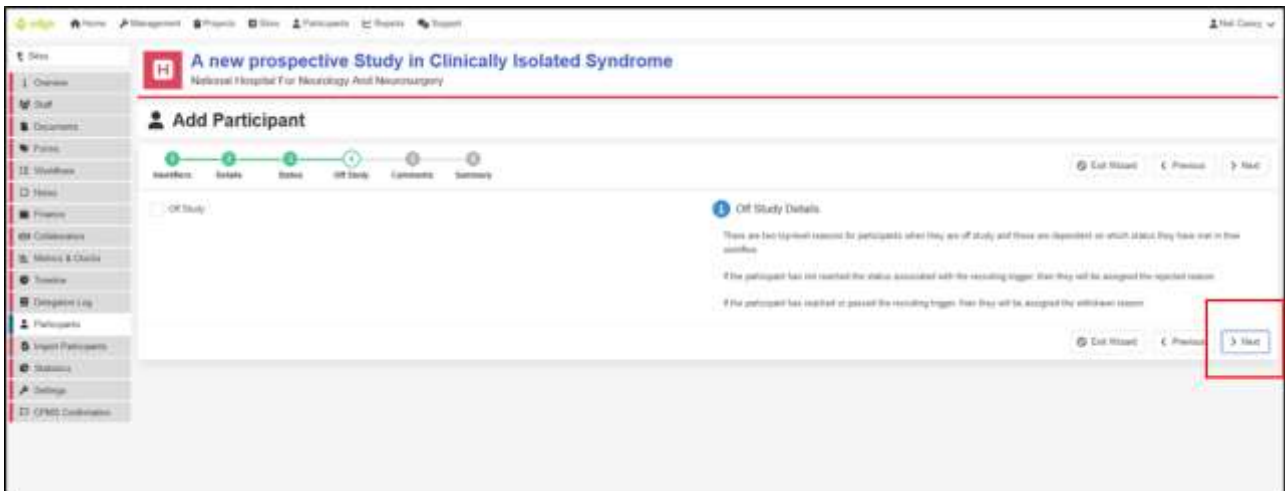
7. Select the participant and click next again.



8. Complete the “Pre-Screened”, “Approached”, “Consented” and “Recruited/Randomised” fields. If the actual dates are available where the patient was pre-screened, consented etc then please add these. Otherwise use the date of recruitment for each field. In portfolio adopted studies this needs to be the date the Research Activity Coordinator is expecting. Click next.

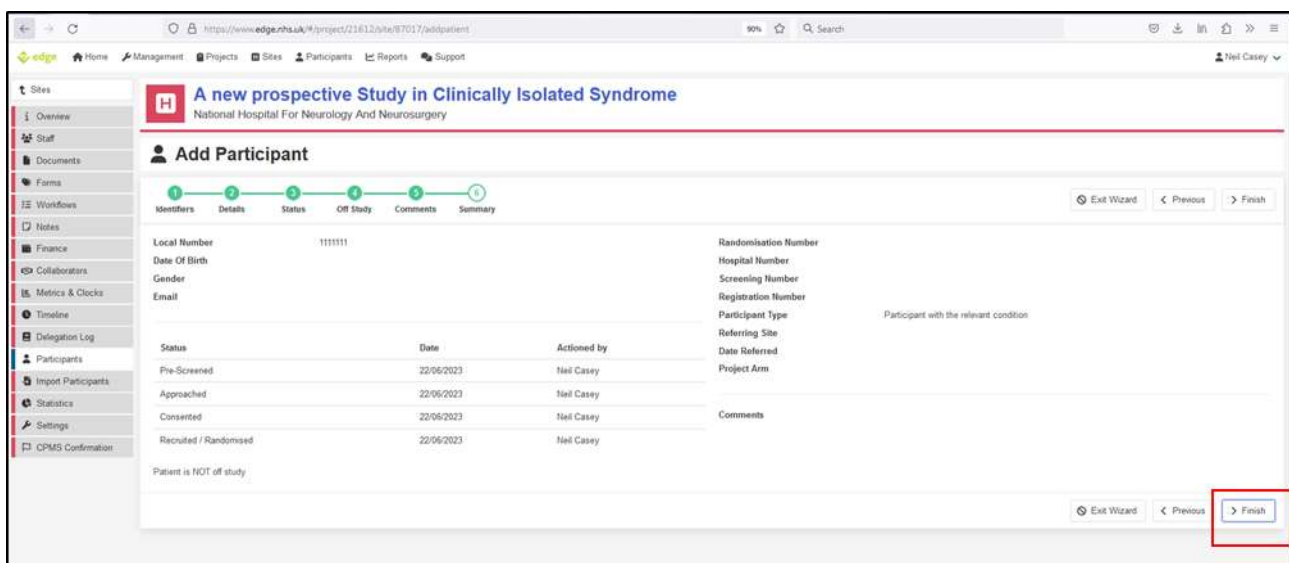


9. Click next.

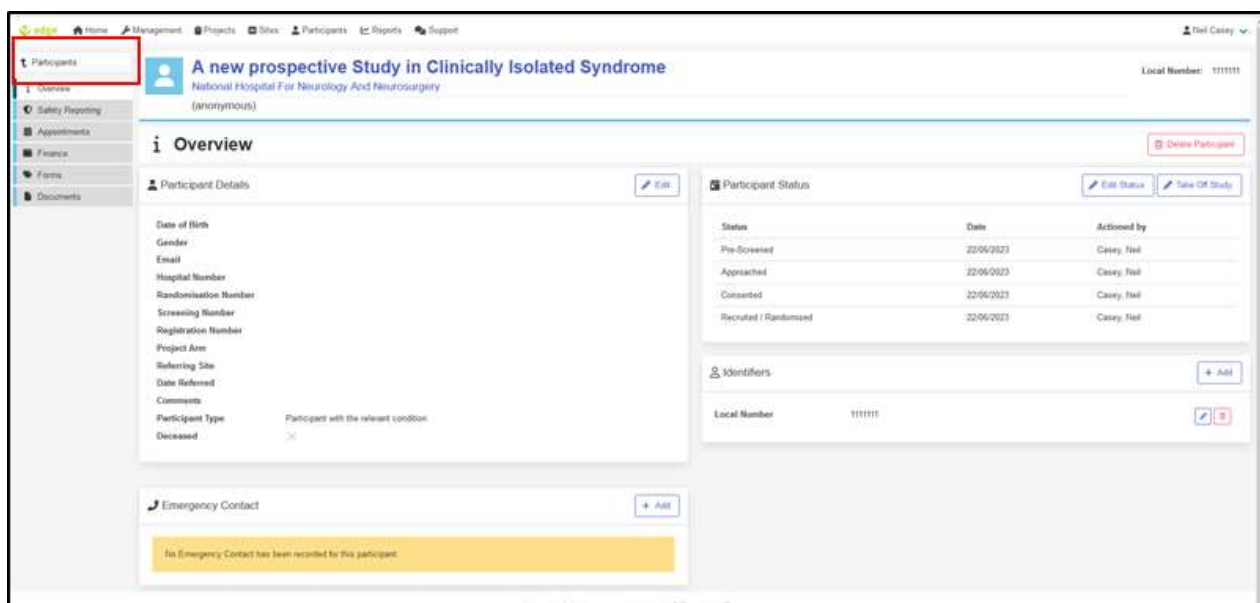


10. Click next again.

11. You will now see a summary of all the data you have entered. If any of it is incorrect you can use the “Prev” to go back and correct the data. Otherwise click “Finish”.



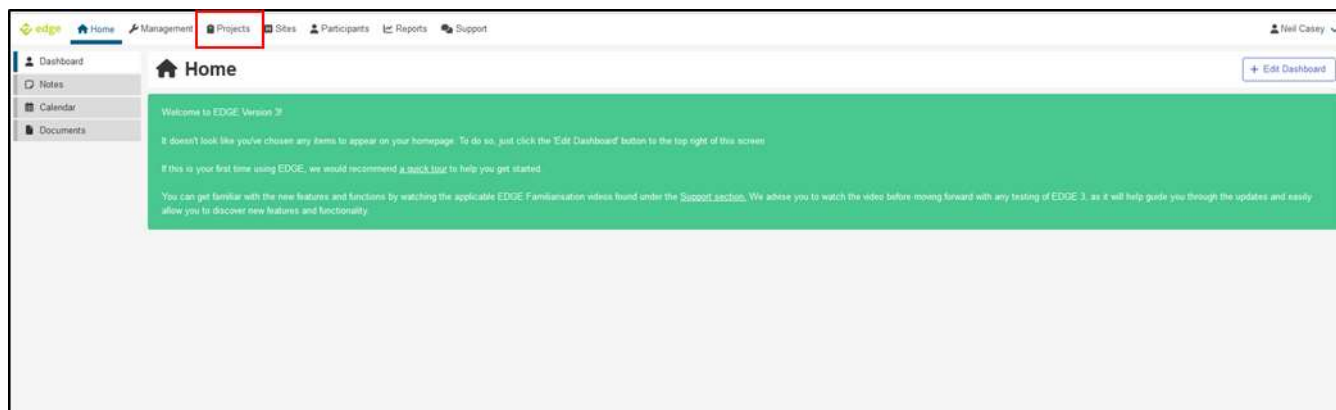
12. Click on participants to get back to your original screen.



13. Your newly added participant now appears in the “Project site patients” list. If there are a lot of participants on your study on the list you can use the search for them by entering the participants trial ID in the search bar and clicking search.

How to Find UCLH Recruitment Which Has Been Queried on CPMS Using Edge

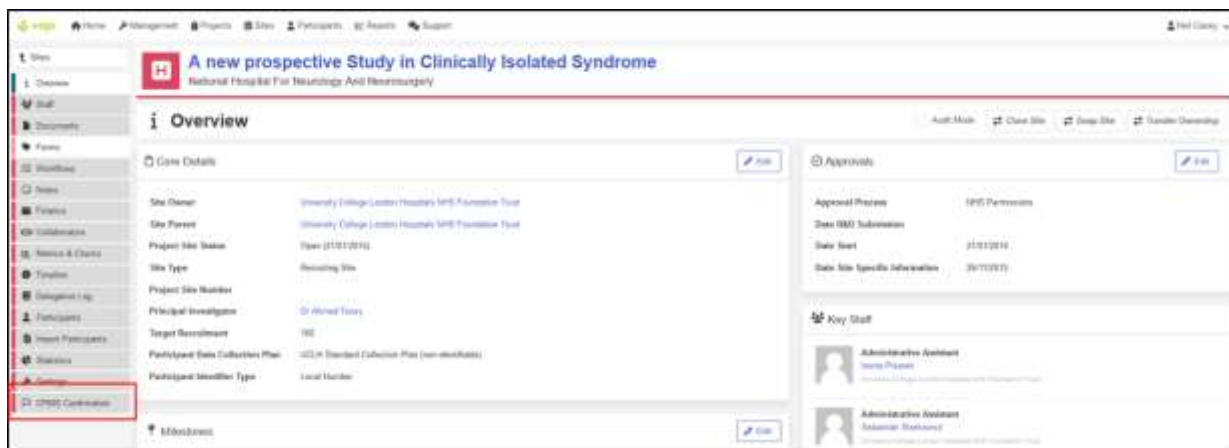
1. Log in to Edge. If you need an Edge account please contact UCLH.RandD@nhs.net, include at least one study identifier (e.g. EDGE ID, IRAS number, R&D reference or REC reference) per study you require access to.
2. Click on Projects



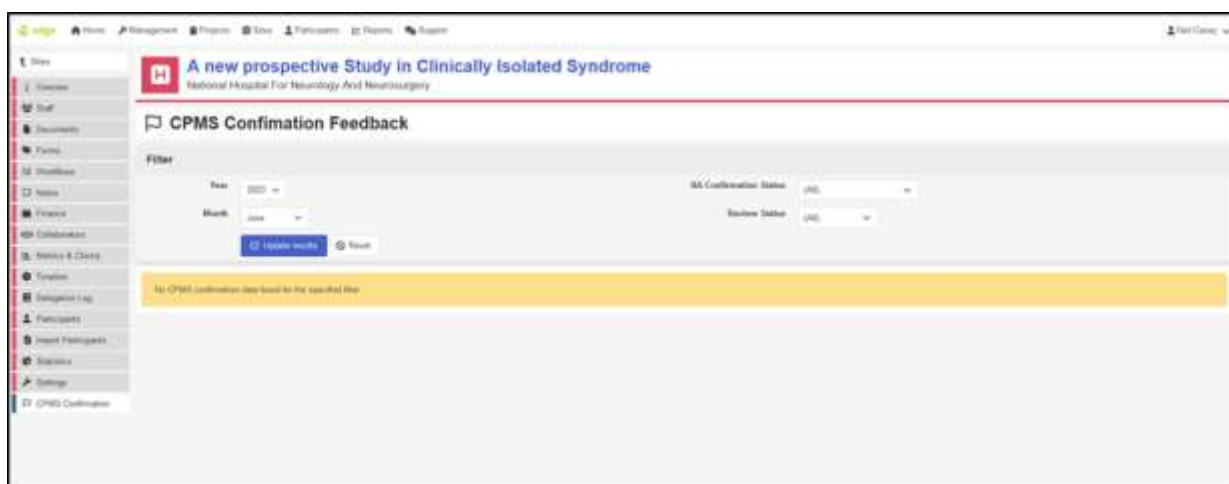
3. Search for your study. Using numbers or references is usually the best way but only try one number or reference at a time. N.B. The R&D number is called “Local Project Reference” in EDGE. Click search. If your study doesn’t appear click on “Global Projects”, if your study appears it means you have not been provided access to the study and need to contact UCLH.RandD@nhs.net asking them to provide you access; if your study still doesn’t appear and you have used all the references individually then contact UCLH.RandD@nhs.net for assistance. Click on the site name.



4. Queried CPMS Recruitment Activity is displayed in the “CPMS Confirmation” tab on the left-hand menu of the site record.



5. Once this tab is open, the “CPMS Confirmation Feedback” list will be shown.



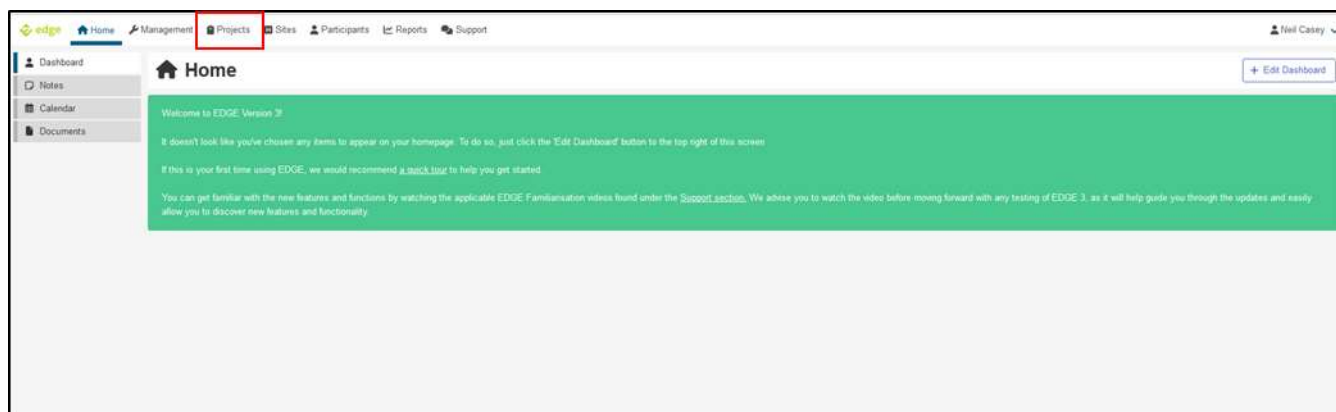
6. Users should use the **filters** to pull outstanding queries. Select “All” for Month and RA Confirmation Status and the appropriate year’s data.
7. Action required is to review all “Confirmed – Not Accurate”. The query will have been added to CPMS by the Research Activity Coordinator. Users should look at the following columns:
 - RA Confirmed no accurate reason: this is a comment added by the Research Activity Coordinator explaining why the data was considered not accurate. In the above example, the Research Activity Coordinator says there are missing recruited and consented participants for the particular month.
 - RA Confirmed not accurate expected count: Research Activity Coordinator states what the number of recruited/consented should be for that month.

8. Site study team now needs to **correct the EDGE recruitment data directly in the Patient tab of the site record**. The team will need to add any missing recruits or consented participants highlighted by the Research Activity Coordinator.
9. If the site team needs more information from the Research Activity Coordinator in order to correct the data, they should get in touch with the Research Activity Coordinator team directly.

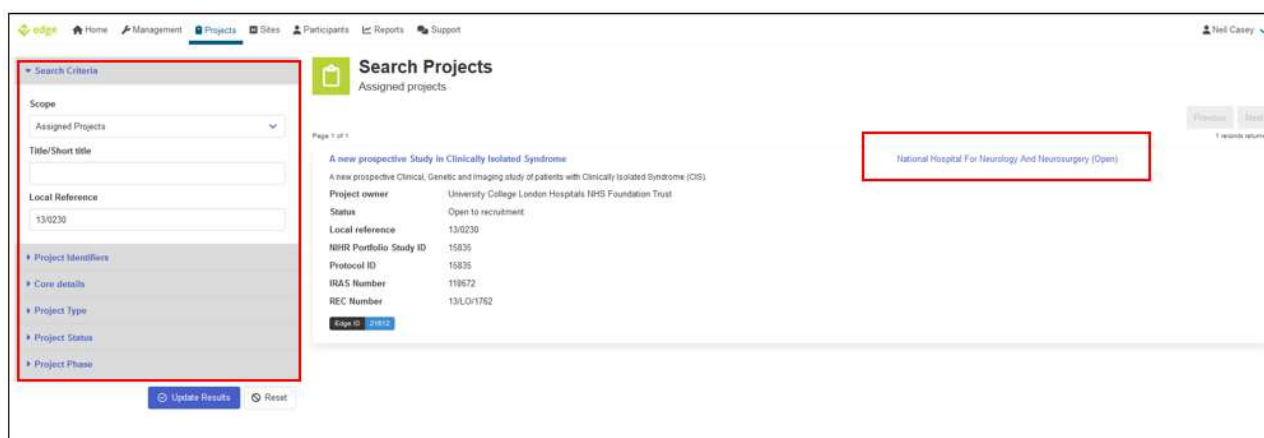
For UCLH Study Teams How to Rectify CPMS data Which has been Deemed Inaccurate

To correct the data you need to delete the recruitment in Edge and then re-add it. The data will be imported into CPMS overnight ready for the Research Activity Coordinator to validate the data then next day.

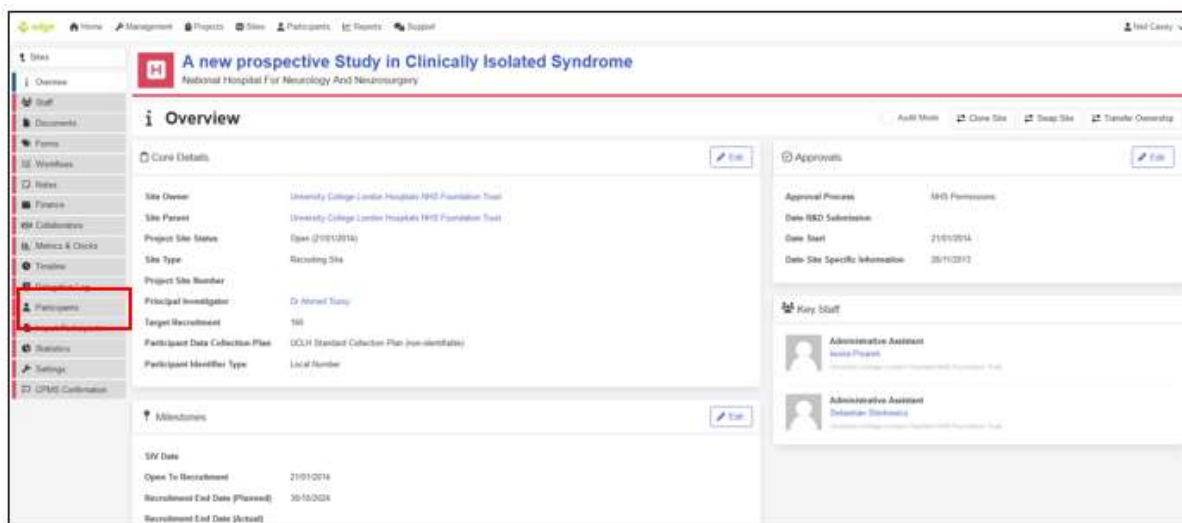
1. Log in to Edge. If you need an Edge account please contact UCLH.RandD@nhs.net, include at least one study identifier (e.g. EDGE ID, IRAS number, R&D reference or REC reference) per study you require access to.
2. Click on Projects



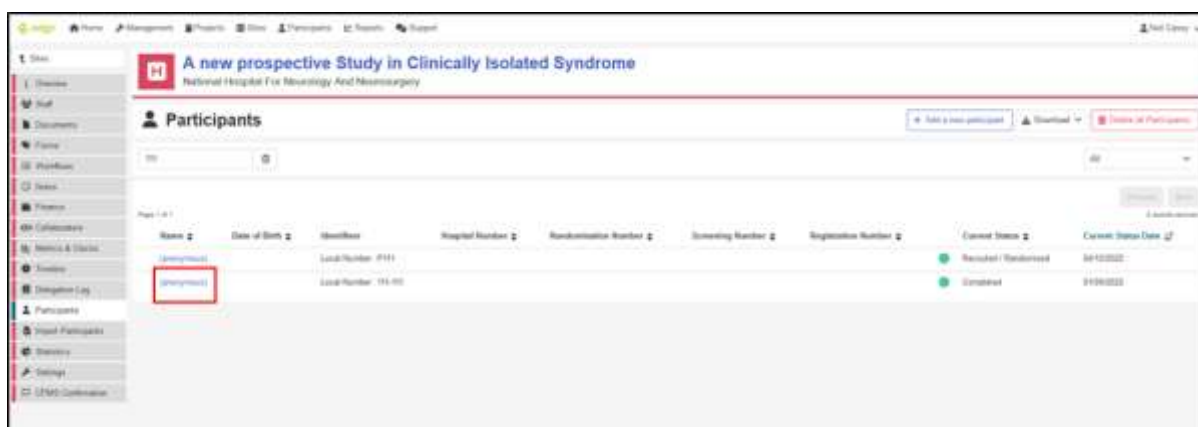
3. Search for your study. Using numbers or references is usually the best way but only try one number or reference at a time. N.B. The R&D number is called “Local Project Reference” in EDGE. Click search. If your study doesn’t appear click on “Global Projects”, if your study appears it means you have not been provided access to the study and need to contact UCLH.RandD@nhs.net asking them to provide you access; if your study still doesn’t appear and you have used all the references individually then contact UCLH.RandD@nhs.net for assistance. Click on the site name.



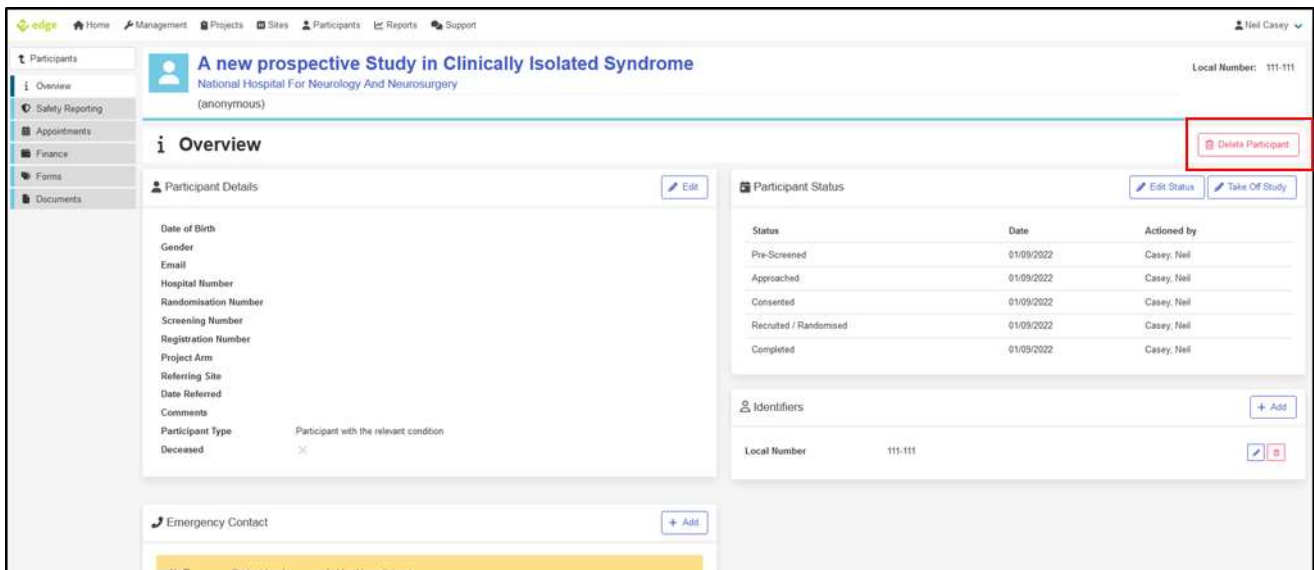
- If you cannot see the “Participants” tab then you do not have the correct access, email UCLH.RandD@nhs.net requesting clinical access to this study. Click on the “Participants” tab.



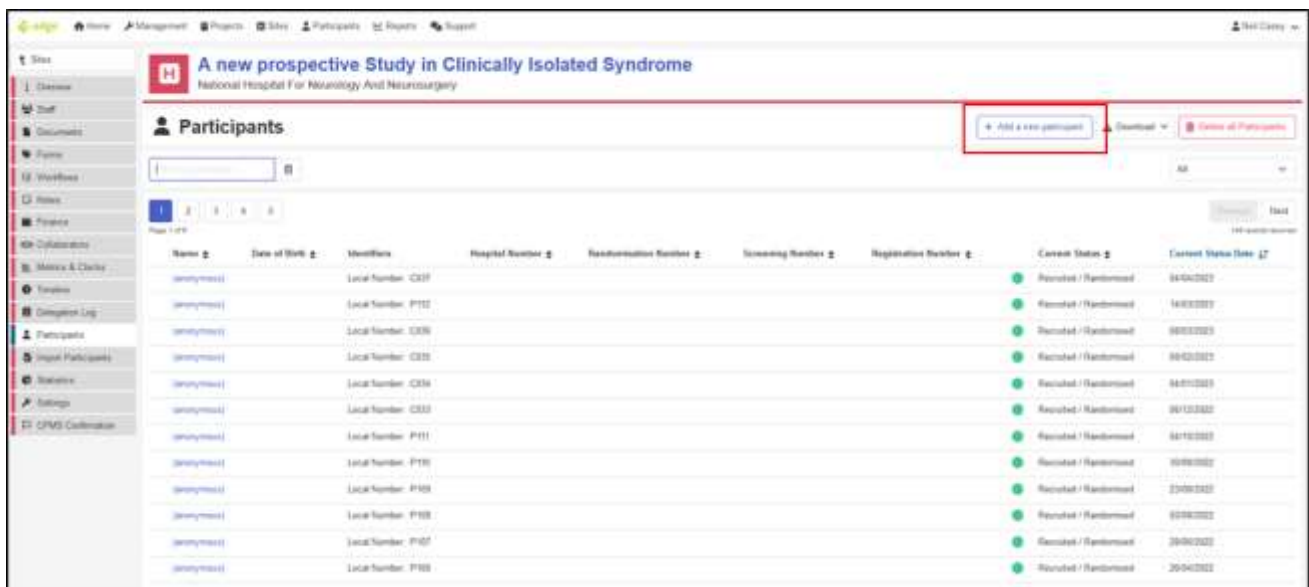
- EDGE now shows a list of participants who have been recruited to this study. If you need to delete all the recruitment click on “Delete All Patients”, please note this is not reversible. To delete an individual participant, click the name on that participant’s row. For example, participant 111-111 was actually recruited in August but the data shows they were recruited in September; this participant needs to be deleted and added correctly. If you see data in the hospital number field, this is not the participants actual hospital number but a number R&D use to track imports from EPIC.



6. Click “Delete Participant”. Confirm you want to delete in the pop-up window.



7. To add a participant, go back to the participant tab. Click “Add a new Participant”



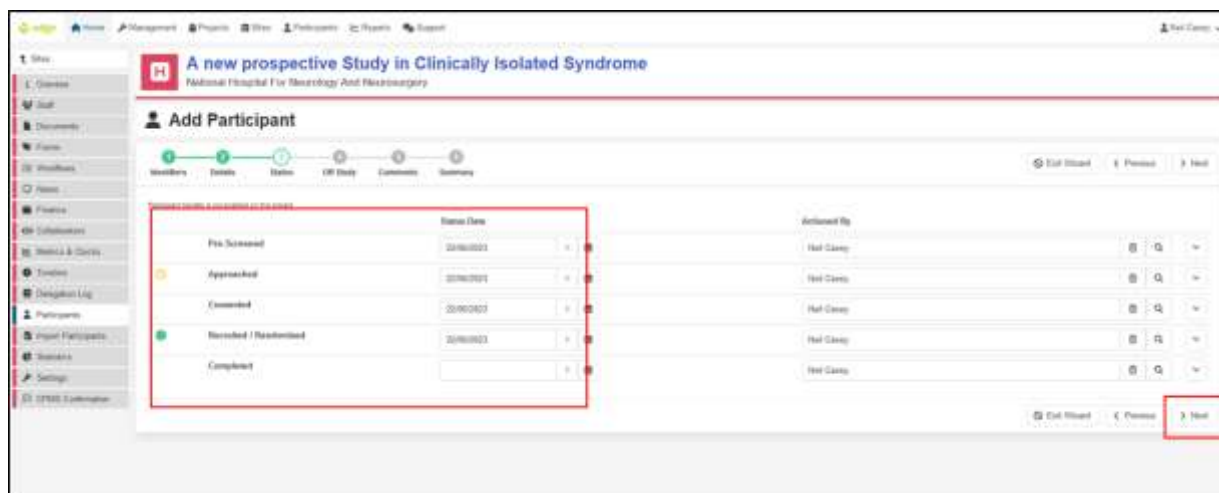
8. Enter the participant's trial ID into the "Local Number" field, click next and then click next again.

The screenshot shows the 'Add Participant' form for a study titled 'A new prospective Study in Clinically Isolated Syndrome' at 'National Hospital For Neurology And Neurosurgery'. The form is in the 'Details' step of a 5-step wizard. The 'Local Number' field is highlighted with a red box and contains the text '1111111'. Below it is the 'Date of Birth' field. To the right, the 'Participant Identifiers' section has a note: 'When adding a new participant, please try to fill in as much information as possible'. At the bottom right, the 'Next' button is highlighted with a red box. Navigation buttons include 'Exit Wizard', '< Previous', and '> Next'.

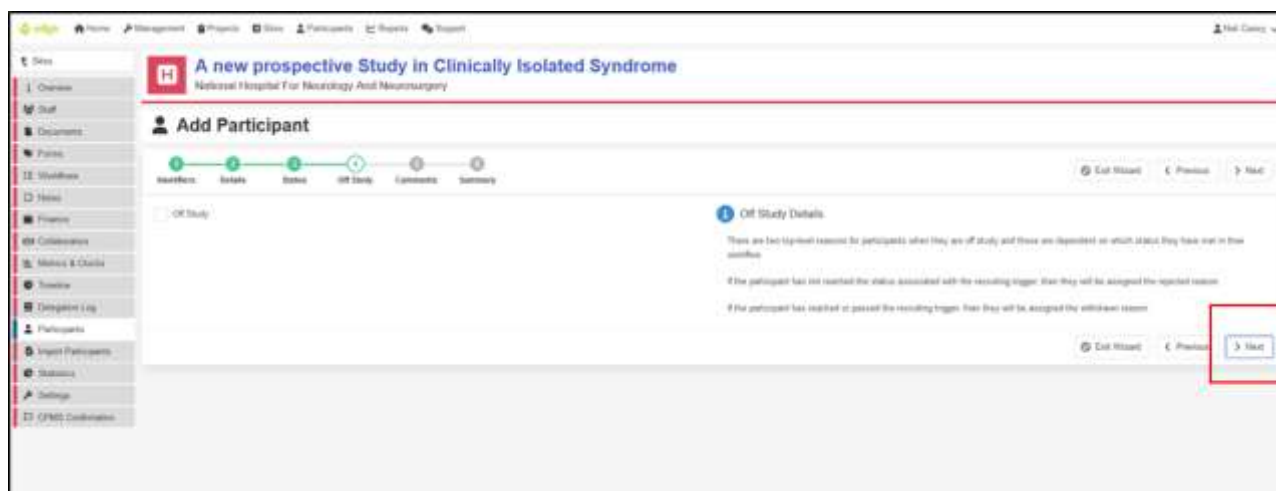
9. Select the correct "Participation type". Click Next.

The screenshot shows the 'Add Participant' form at the 'Details' step. The 'Participation type' dropdown menu is highlighted with a red box and shows 'Please select...'. Below it are fields for 'Referring Site' and 'Date Referred'. To the right, the 'Project Details' section has a note: 'When adding project details, please try to fill in as much information as possible'. At the bottom right, the 'Next' button is highlighted with a red box. Navigation buttons include 'Exit Wizard', '< Previous', and '> Next'.

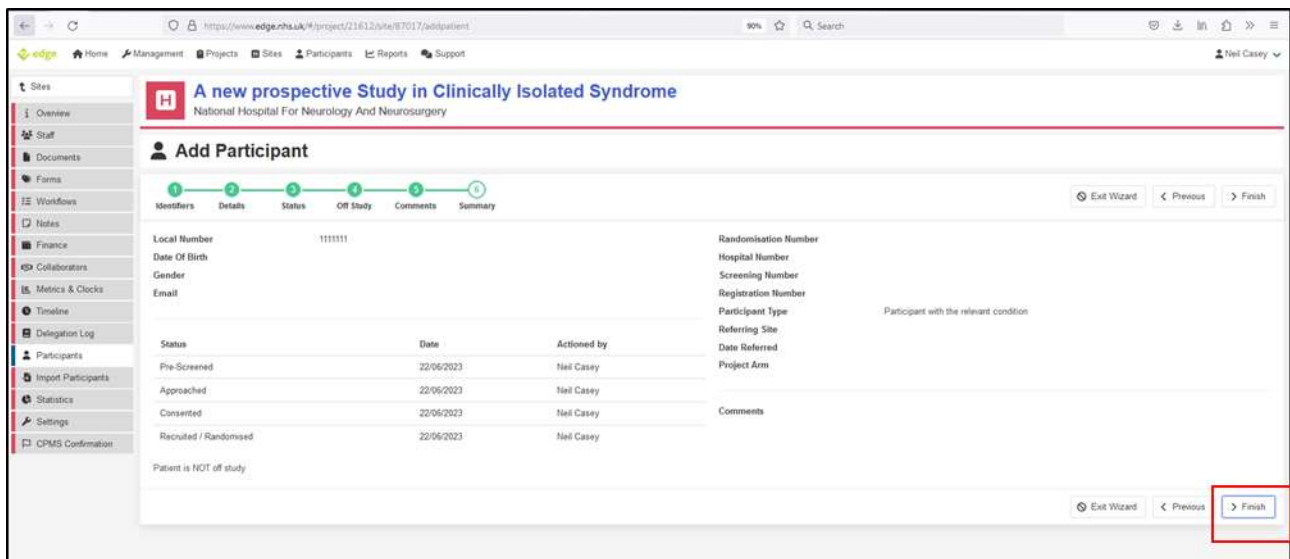
- Complete the “Pre-Screened”, “Approached”, “Consented” and “Recruited/Randomised” fields. If the actual dates are available where the patient was pre-screened, consented etc then please add these. Otherwise use the date of recruitment for each field. In portfolio adopted studies this needs to be the date the Research Activity Coordinator is expecting. Click next.



- Click next.



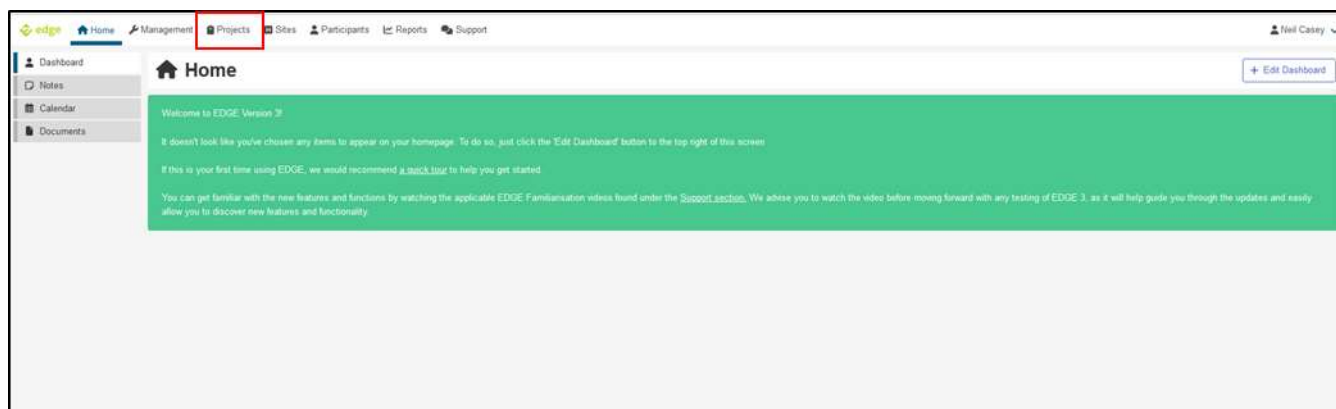
15. Click next again.
16. You will now see a summary of all the data you have entered. If any of it is incorrect you can use the “Prev” to go back and correct the data. Otherwise click “Finish”.



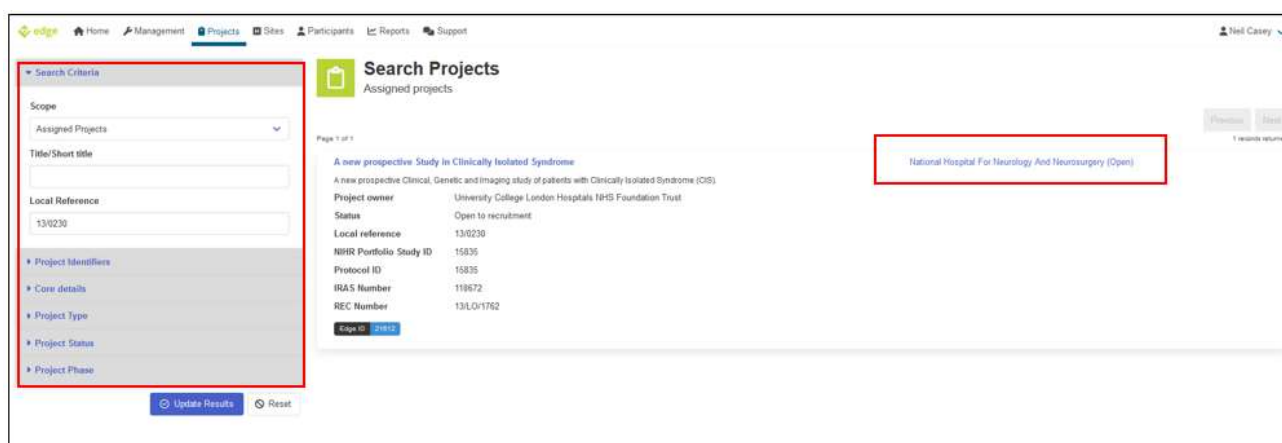
11. Your added participant will now show up on the patient list. The data will be imported into CPMS overnight for the Research Activity Coordinator to then validate.
12. If you need to add several patients it may be easier to add this via a patient import, please see the next section for this.

How to Perform a Single Study Patient Import into EDGE

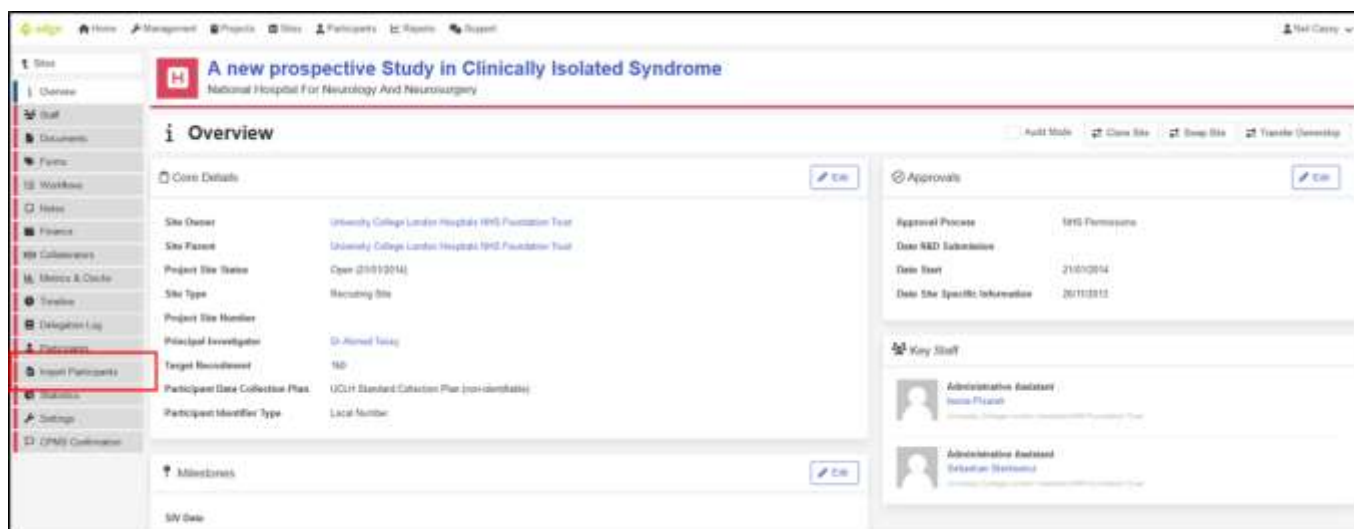
1. Log in to Edge. If you need an Edge account please contact UCLH.RandD@nhs.net, include at least one study identifier (e.g. EDGE ID, IRAS number, R&D reference or REC reference) per study you require access to.
2. Click on Projects



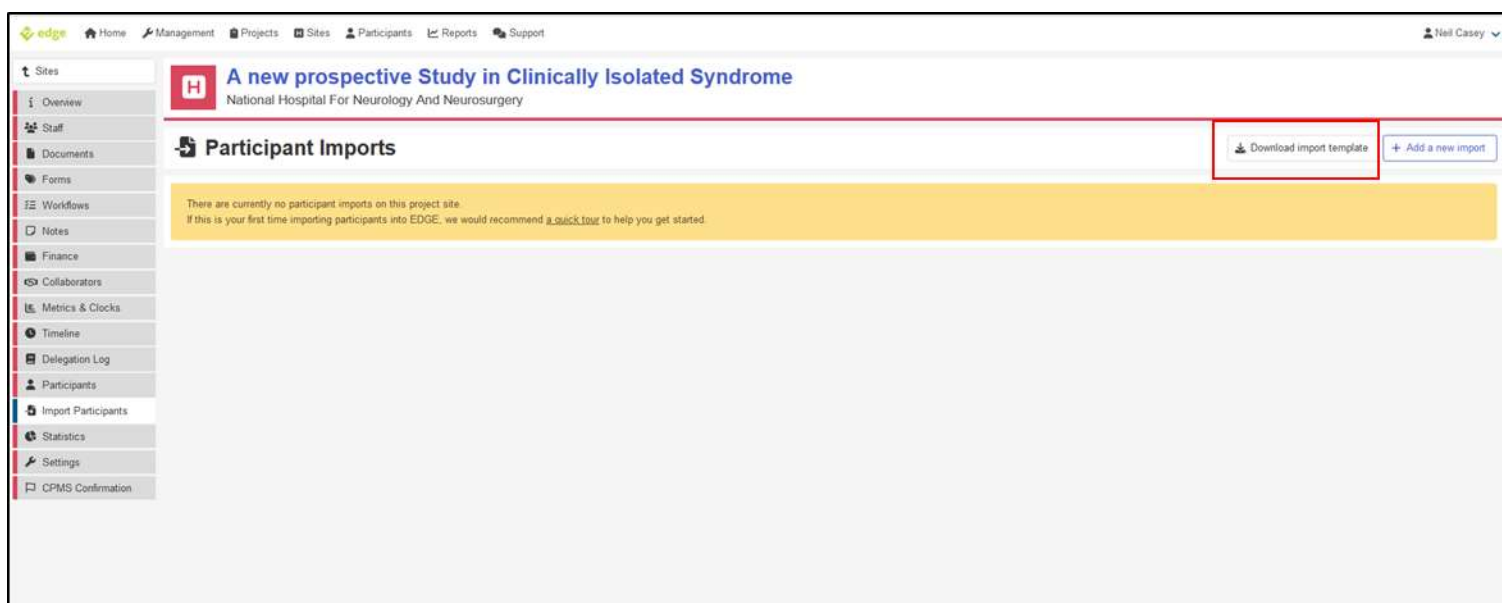
3. Search for your study. Using numbers or references is usually the best way but only try one number or reference at a time. N.B. The R&D number is called “Local Project Reference” in EDGE. Click search. If your study doesn’t appear click on “Global Projects”, if your study appears it means you have not been provided access to the study and need to contact UCLH.RandD@nhs.net asking them to provide you access; if your study still doesn’t appear and you have used all the references individually then contact UCLH.RandD@nhs.net for assistance. Click on the site name.



- Click on the “Import Participants” tab. If you cannot see the tab then you do not have the correct access, email UCLH.RandD@nhs.net requesting clinical access to this study.

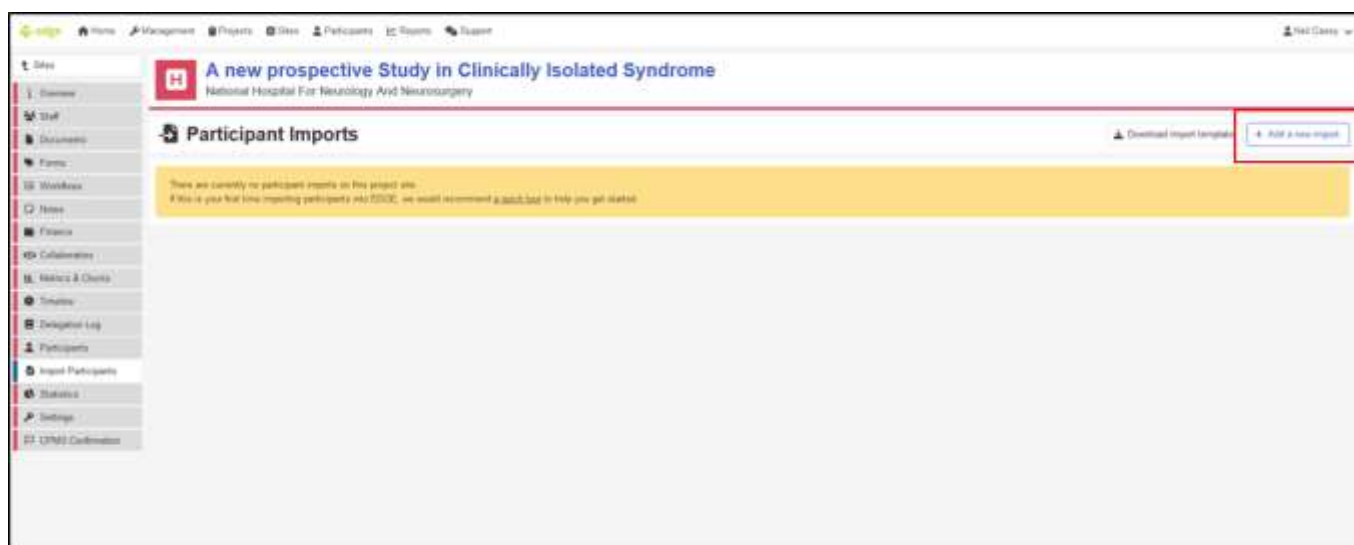


- On the right-hand side click on “Download Import Template”. Open the template in Excel.

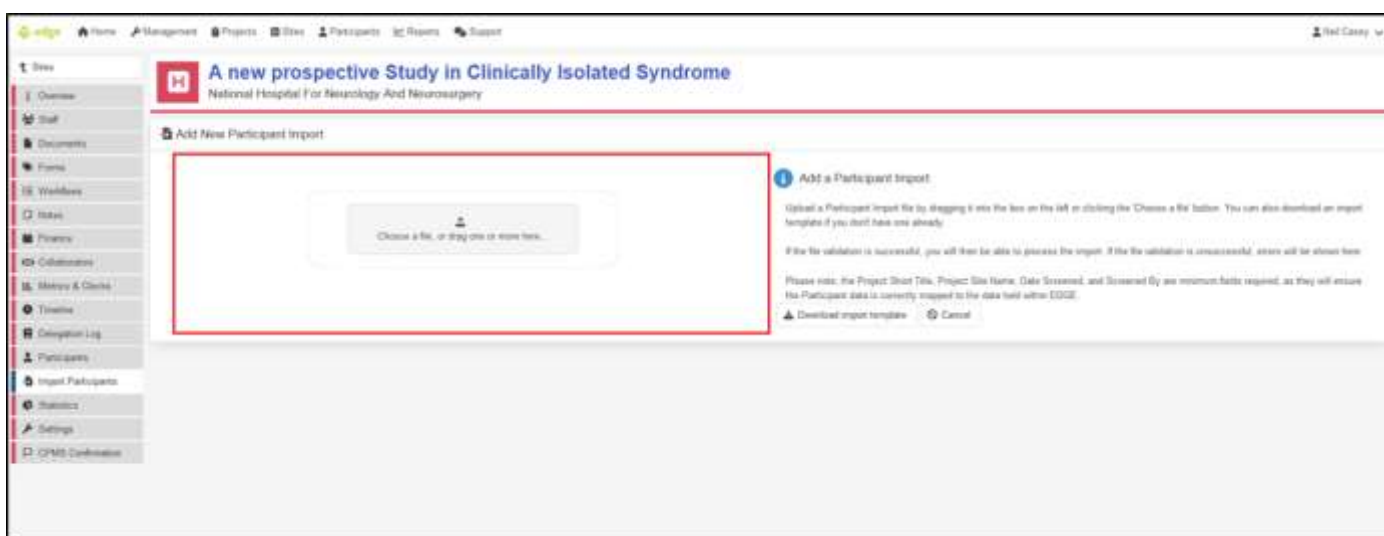


6. Once the download is complete, enter the data into the spreadsheet. You do not need to complete every field; the following fields are mandatory:
 - a. **Identifier Number** – This is the participant’s study ID /randomisation number.
 - b. **Participant Type** (usually “Participant with the relevant condition”), full options are:
 - i. Participant with the relevant condition
 - ii. Carers
 - iii. Condition Controls
 - iv. Diagnostic, screening or prevention participants
 - v. Genetically predisposed
 - vi. Other
 - vii. Participant without condition
 - viii. Pre-condition
 - ix. Professionals
 - x. Relations
 - c. **Pre-Screened Date**. You can use the date the participant was recruited into the study for these and the below dates. You will not be audited on the correctness of your pre-screened and approached dates. The Consent and Recruited / Randomised Date should be the date the participant was consented to the study.
 - d. **Pre-Screened By**. This has to be someone assigned to the study. If you look on the staff tab it will show who is assigned to the study. The name should be in this format “surname, forename title”. You can then copy and paste this information in to the approached by, consented by and recruited/randomised by fields.
 - e. **Approached Date**.
 - f. **Approached By**
 - g. **Consented Date**
 - h. **Consented By**
 - i. **Recruited / Randomised Date**
 - j. **Recruited / Randomised By**

7. After completing the spreadsheet, save it in .csv format. Then click on “Add a new import”.

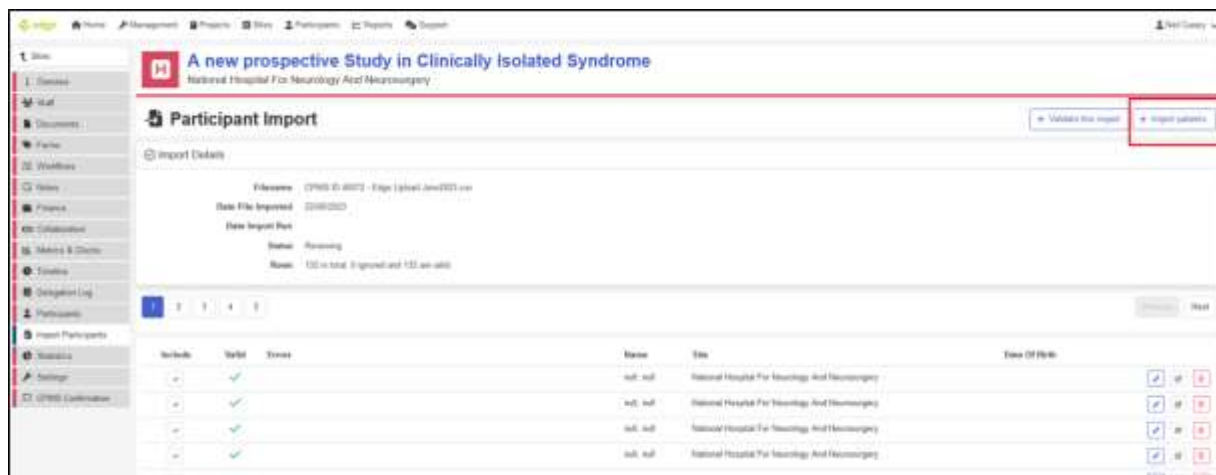


8. Click and select the file or drag the file to the area marked below.



9. Edge will then check your spreadsheet for errors and will display these on the screen. The errors are usually a field has been filled in incorrectly. If you cannot solve the errors please send a screenshot and a copy of your spreadsheet to uclh.RandD@nhs.net so we can assist.

10. If all the rows are valid then click on “Import patients” which is on the right-hand side of the screen. Edge will now import the patients which can take a few minutes depending on how many participants you are importing.

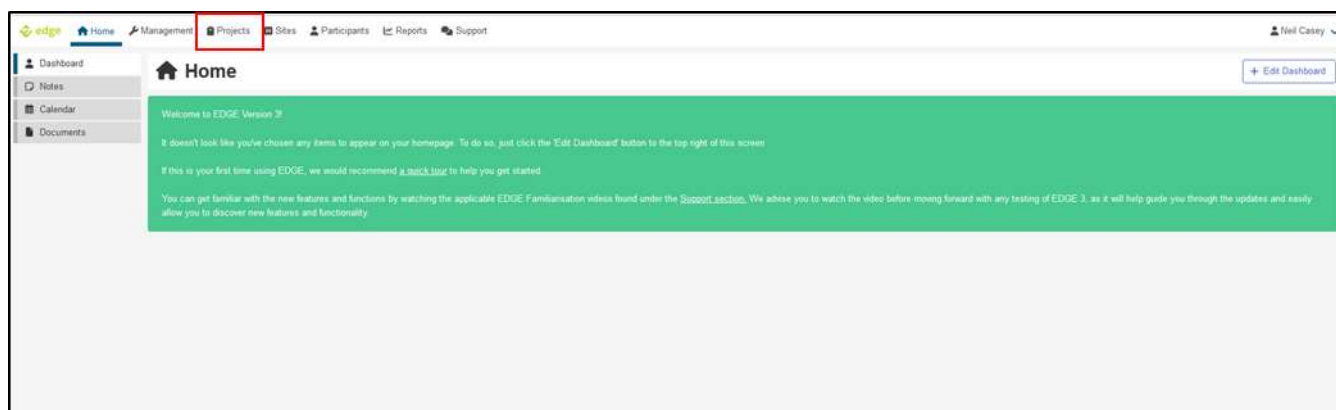


11. The recruitment should now be uploaded but go into the site level of the study and check the “Actual Recruitment” figure is correct. If you have any problems with importing please contact uclh.RandD@nhs.net for assistance.

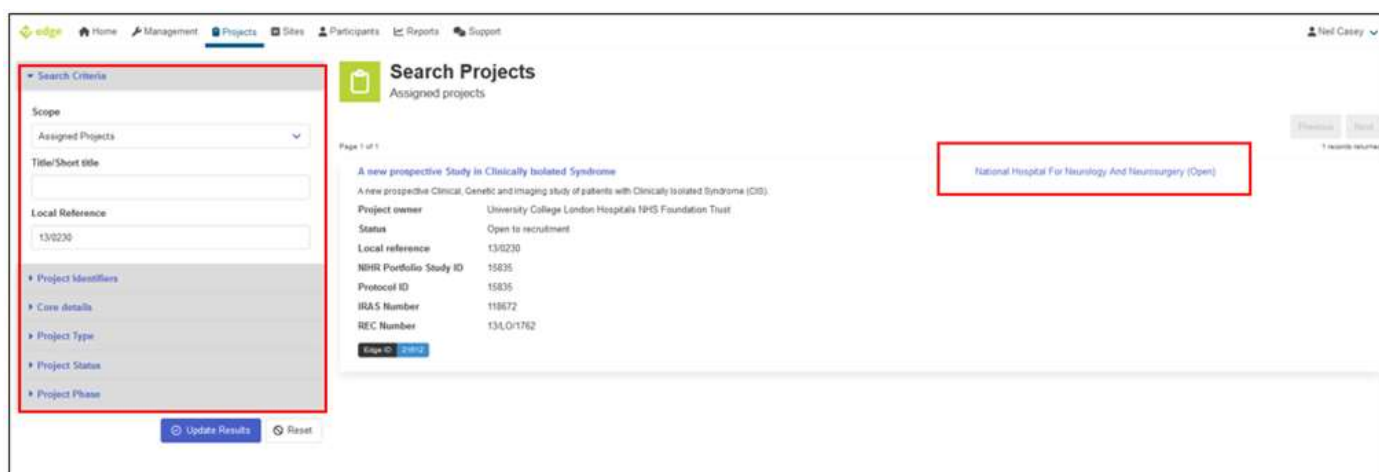
How to Find a Study's Recruitment Contact/s on Edge

Please check you are listed as key staff on EDGE for the projects you work on

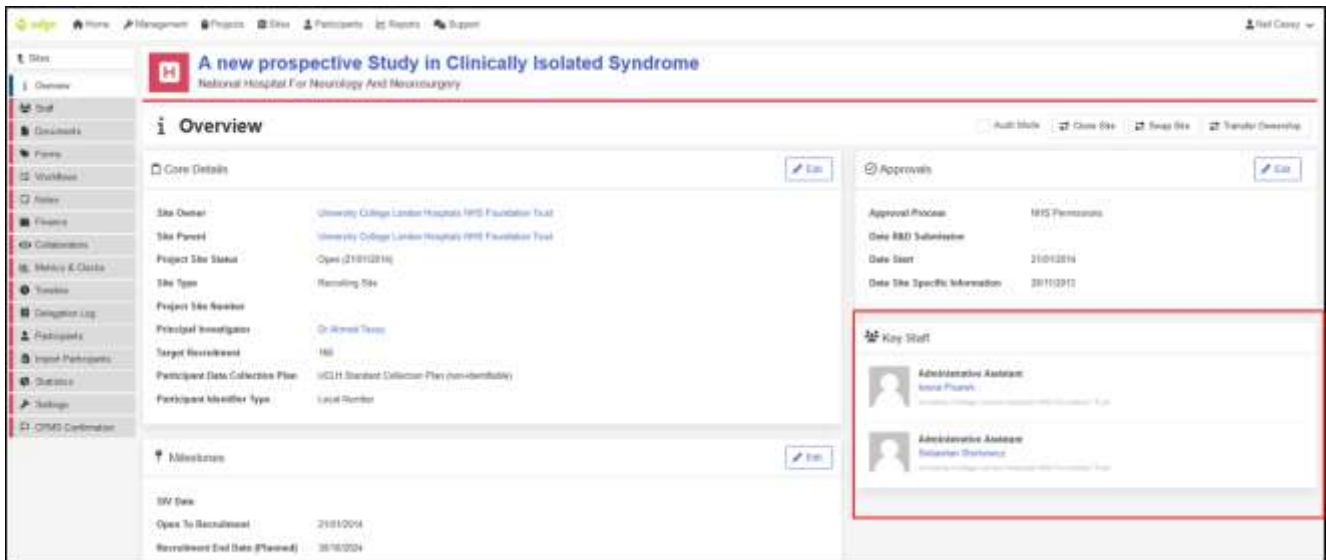
1. Log in to Edge. If you need an Edge account please contact UCLH.RandD@nhs.net, include at least one study identifier (e.g. EDGE ID, IRAS number, R&D reference or REC reference) per study you require access to.
2. Click on Projects



3. Search for your study. Using numbers or references is usually the best way but only try one number or reference at a time. N.B. The R&D number is called “Local Project Reference” in EDGE. Click search. If your study doesn't appear click on “Global Projects”, if your study appears it means you have not been provided access to the study and need to contact UCLH.RandD@nhs.net asking them to provide you access; if your study still doesn't appear and you have used all the references individually then contact UCLH.RandD@nhs.net for assistance. Click on the site name.



4. On the left hand the recruitment contacts are listed under “Key Staff”. Click on their names to find their email address.

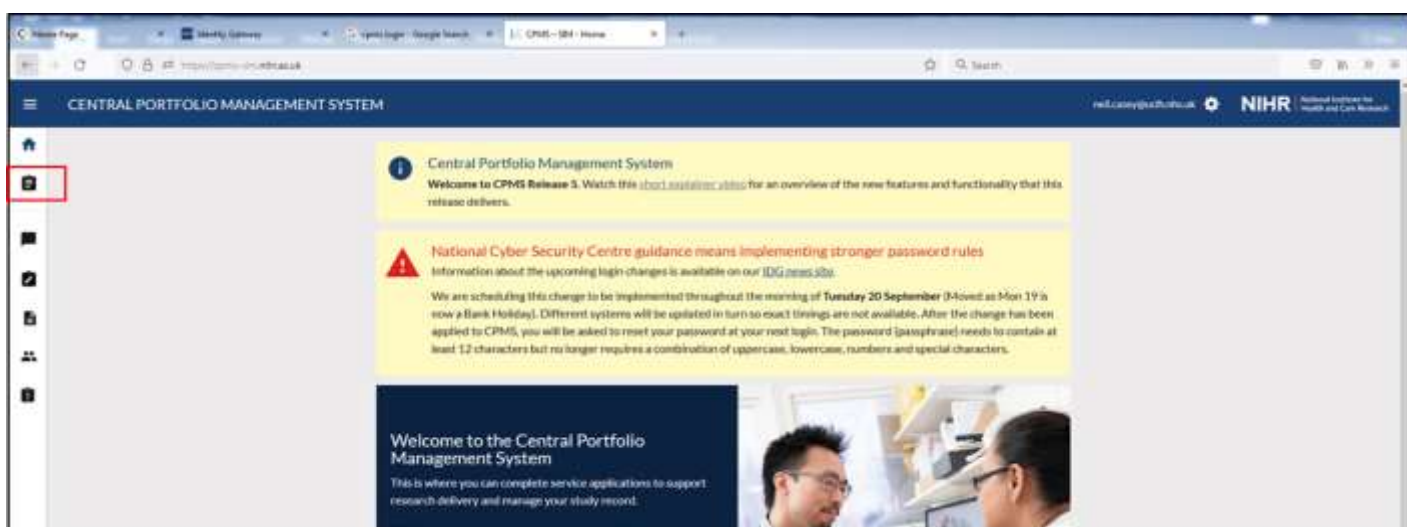


5. If you need to be added as “Key Staff” on EDGE please request this by emailing UCLH.RandD@nhs.net

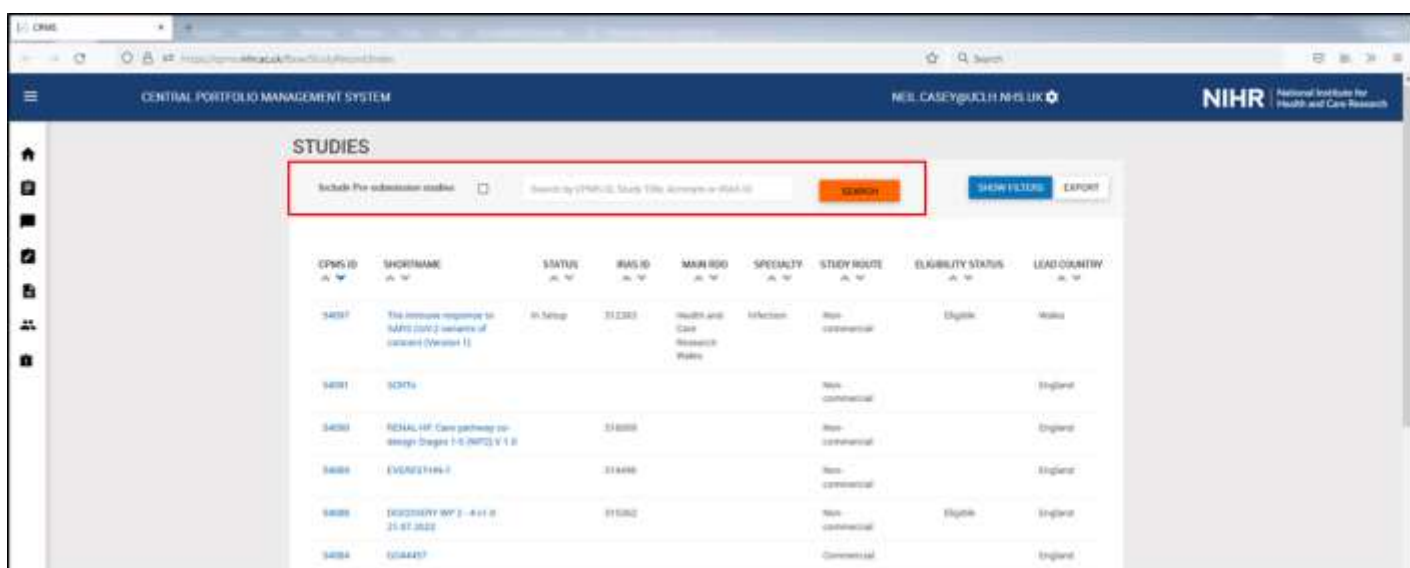
Section 2: Chief Investigator/Central study Team Requirements for UCLH/UCL Sponsored Studies

For portfolio studies, how to tell if your study requires manual uploading of recruitment to CPMS or if the data flows from EDGE into CPMS

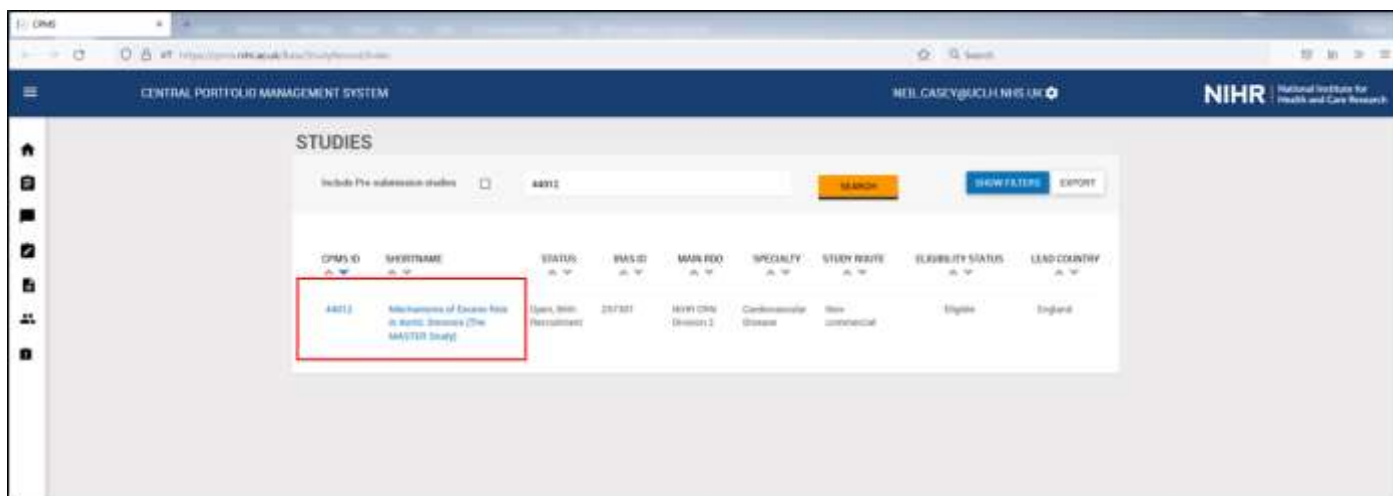
1. Log into CPMS cpms.nihr.ac.uk/ If you need a CPMS account, the Chief Investigator needs to request this by emailing supportmystudy@nihr.ac.uk Quote either the IRAS or CPMS number.
2. Click on the “Studies” tab from the left-hand menu



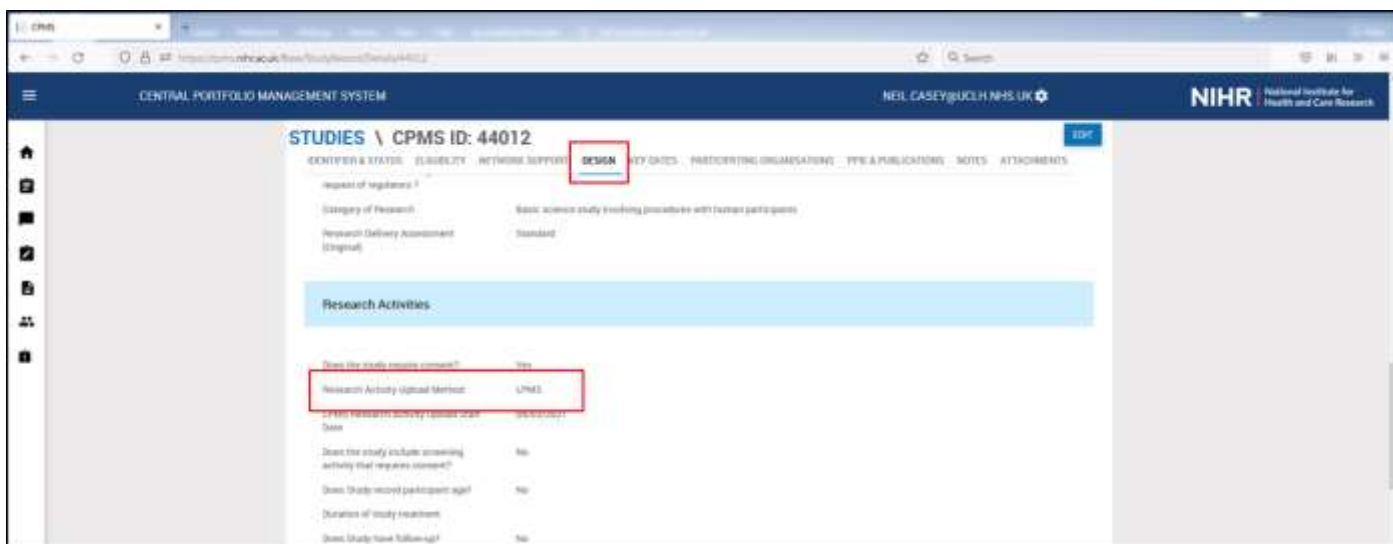
3. Type into the search bar the IRAS or CPMS number. If you do not know these use the short title or full title.



4. Click on the CPMS ID or the Short Name of the study.



5. In the study record click on the “Design” tab and scroll down till you see the “Research Activity Upload Method” field. If it says LPMS then recruitment is uploaded nightly from EDGE; if it says “Manual” then recruitment is uploaded directly by the Research Activity Coordinator into CPMS via a spreadsheet.

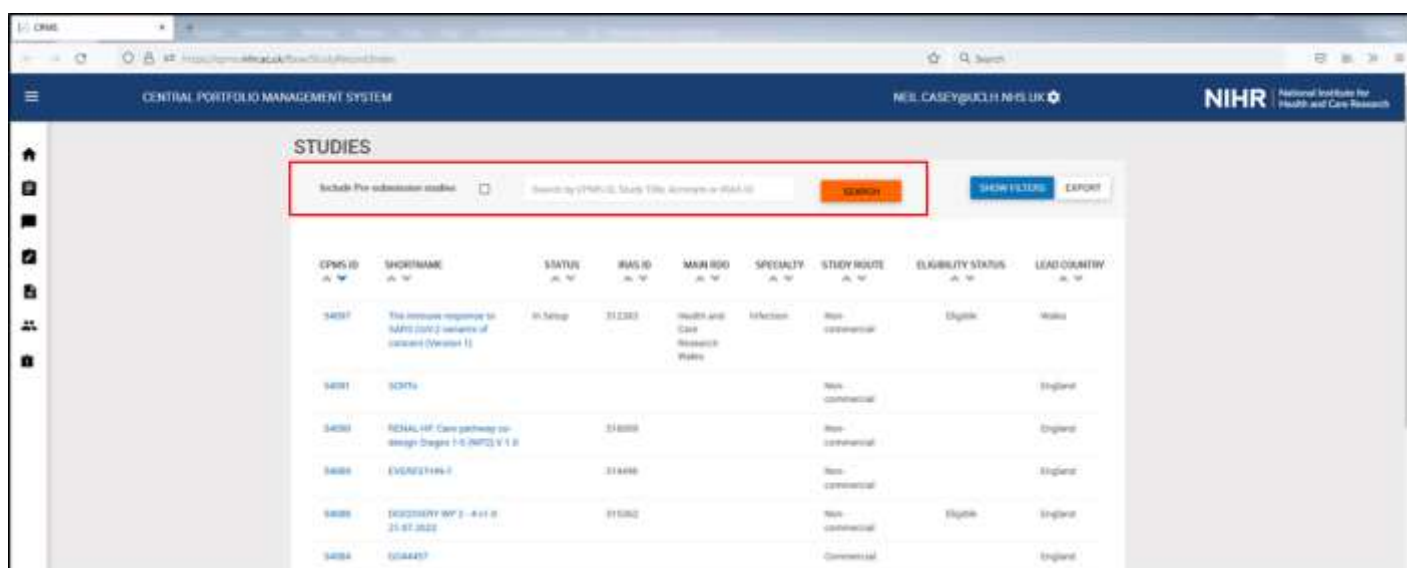


Check Who Has the Responsibility of Confirming Recruitment in CPMS or Responsibility for Uploading Manual Recruitment into CPMS

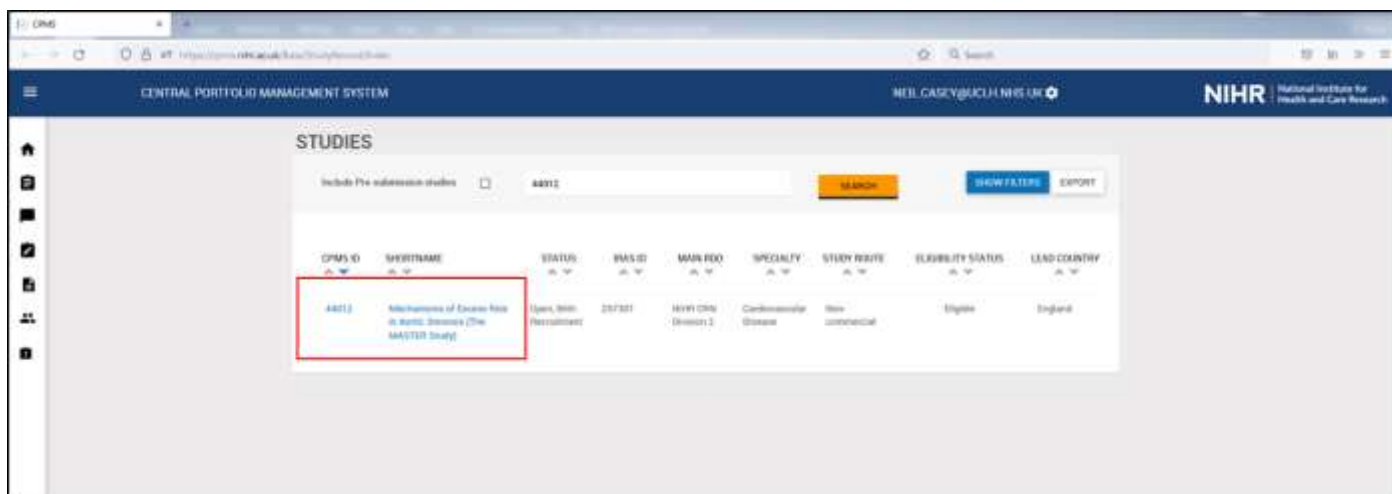
1. Log into CPMS cpms.nihr.ac.uk/ If you need a CPMS account, the Chief Investigator needs to request this by emailing supportmystudy@nihr.ac.uk Quote either the IRAS or CPMS number.
2. Click on the “Studies” tab from the left-hand menu



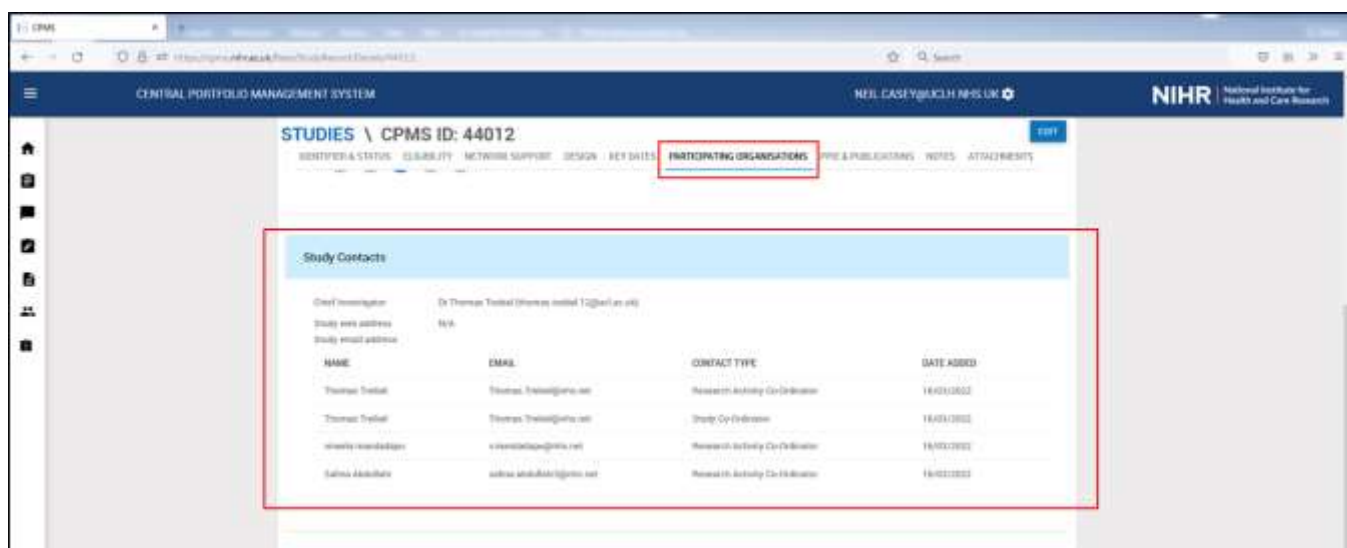
3. Type into the search bar the IRAS or CPMS number. If you do not know these use the short title or full title.



- Click on the CPMS ID or the Short Name of the study.

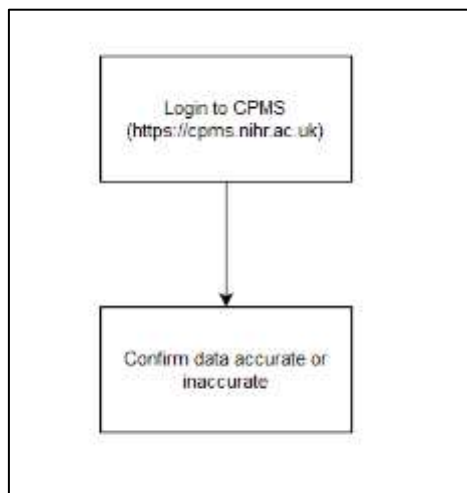


- To see who is responsible for validating recruitment (the Research Activity Coordinator) in CPMS when it is importing from EDGE or who is responsible for uploading recruitment directly into CPMS, click on the “Participating Organisations” tab, scroll down to “Study Contacts”. If your name should appear here the Chief Investigator needs to email supportmystudy@nihr.ac.uk requesting you be given access as the Study Coordinator and/or Research Activity Coordinator. For commercial studies the Research Activity Coordinator is the national Industry Team: crncc.support@nihr.ac.uk



How to validate recruitment as accurate or inaccurate in CPMS

Chart 4: Process to validate recruitment at participating sites



It is essential recruitment is validated/confirmed in CPMS by the Research Activity Coordinator of the study. Recruitment awaiting confirmation and recruitment confirmed as inaccurate are not counted in the study recruitment figures and overall UCLH portfolio recruitment. Recruitment figures play a role in determining the funding UCLH receives from the North Thames Clinical Research Network .

When recruitment is imported from Edge it then needs to be confirmed as accurate by the Research Activity Coordinator (for commercial studies) or the Chief Investigator or the delegated person i.e. Study Coordinator and/or Research Activity Coordinator (for non-commercial studies). Recruitment does not count towards the site and total recruitment and official NIHR figures until the recruitment is confirmed in CPMS.

There is a guide created by the NIHR for this see [Quick guide](#)

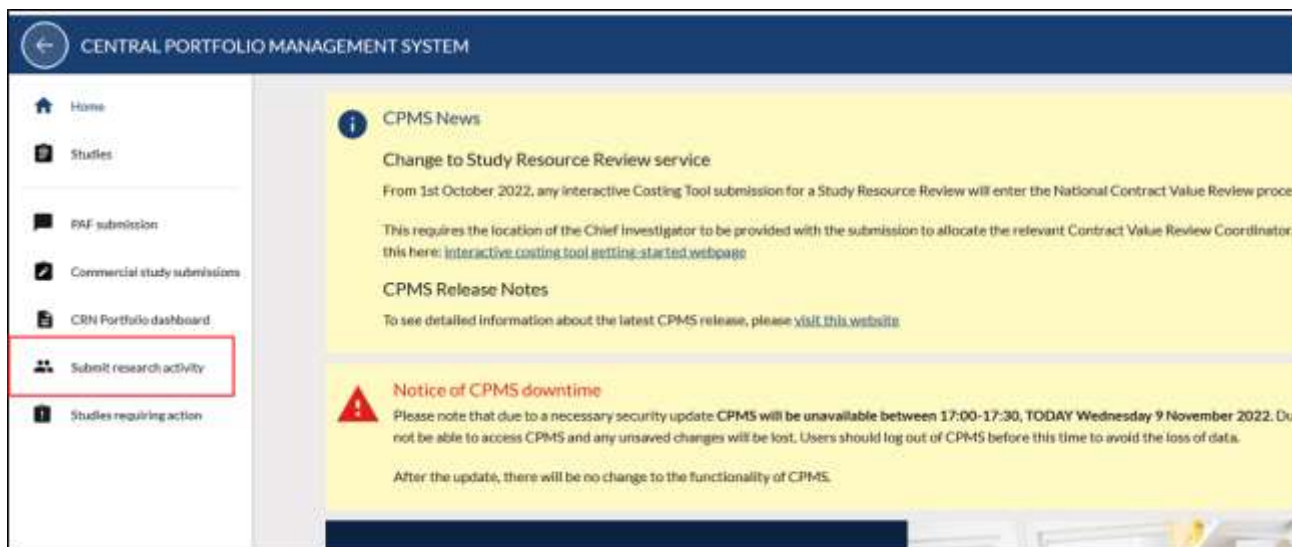
There are also some online training courses [here](#)

Also, a YouTube video created by the NIHR CPMS Product Manager Nicola McMillan https://www.youtube.com/watch?v=UC_8-43oK5U

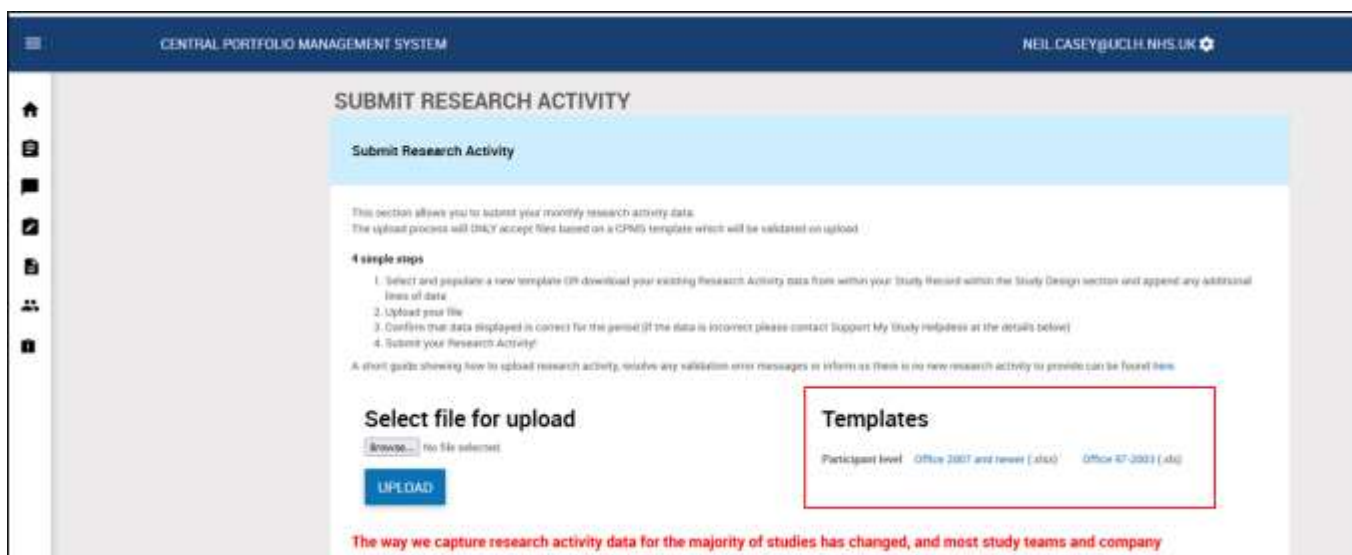
How to Manually Upload Recruitment into CPMS

If your study has not recruited in the previous month this should be noted on CPMS, see section entitled 'How to confirm no recruitment since the last upload' for guidance.

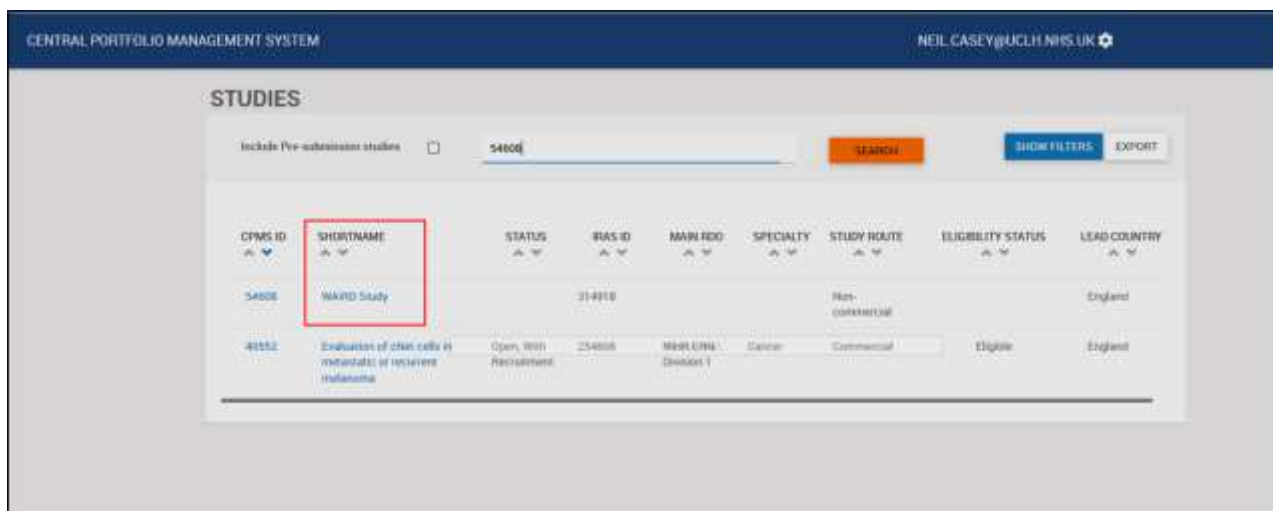
1. Log into CPMS cpms.nihr.ac.uk/ If you need a CPMS account, the Chief Investigator needs to request this by emailing supportmystudy@nihr.ac.uk Quote either the IRAS or CPMS number.
2. Click on "Submit Research Activity".



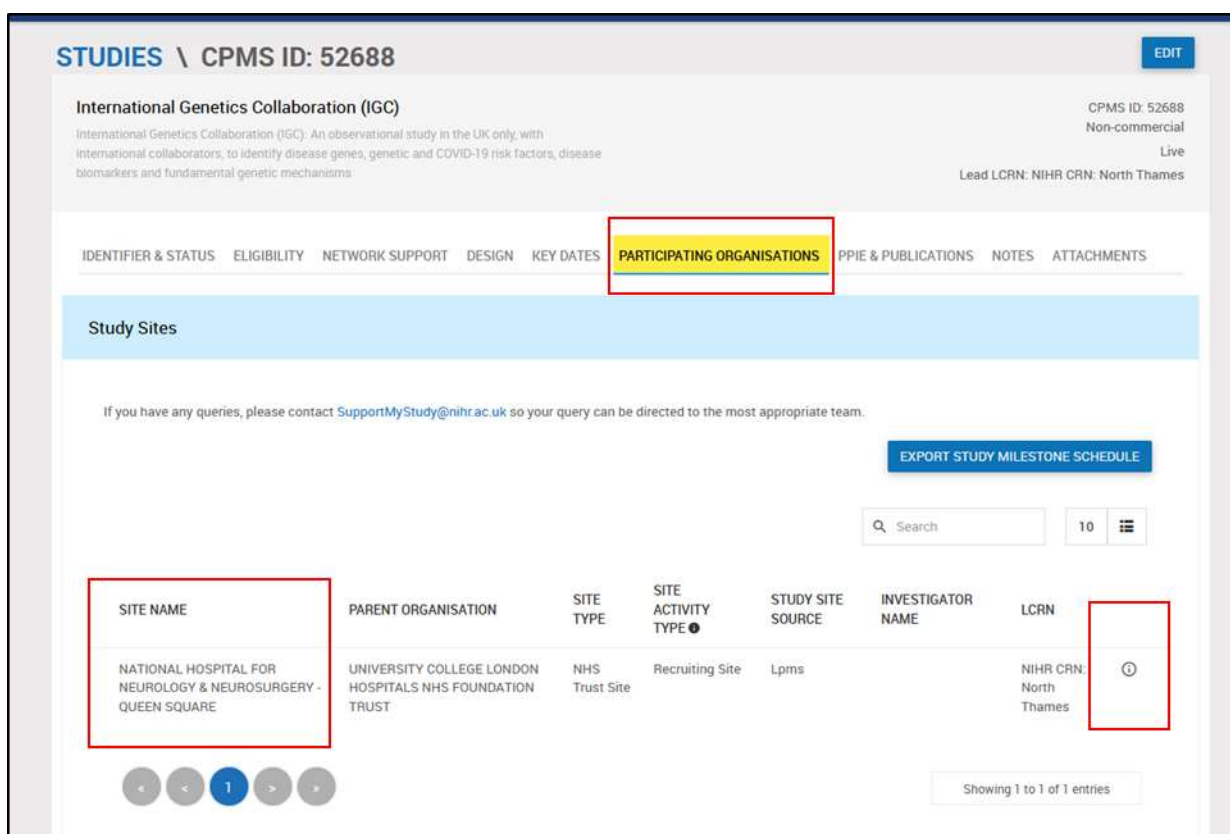
3. Download the appropriate template depending on your version of Excel.



4. Open the template and complete each column for each participant recruited for your study.
 - i. “Study Identifier” is the CPMS/Portfolio ID.
 - ii. “Study Acronym” is the short title on CPMS.



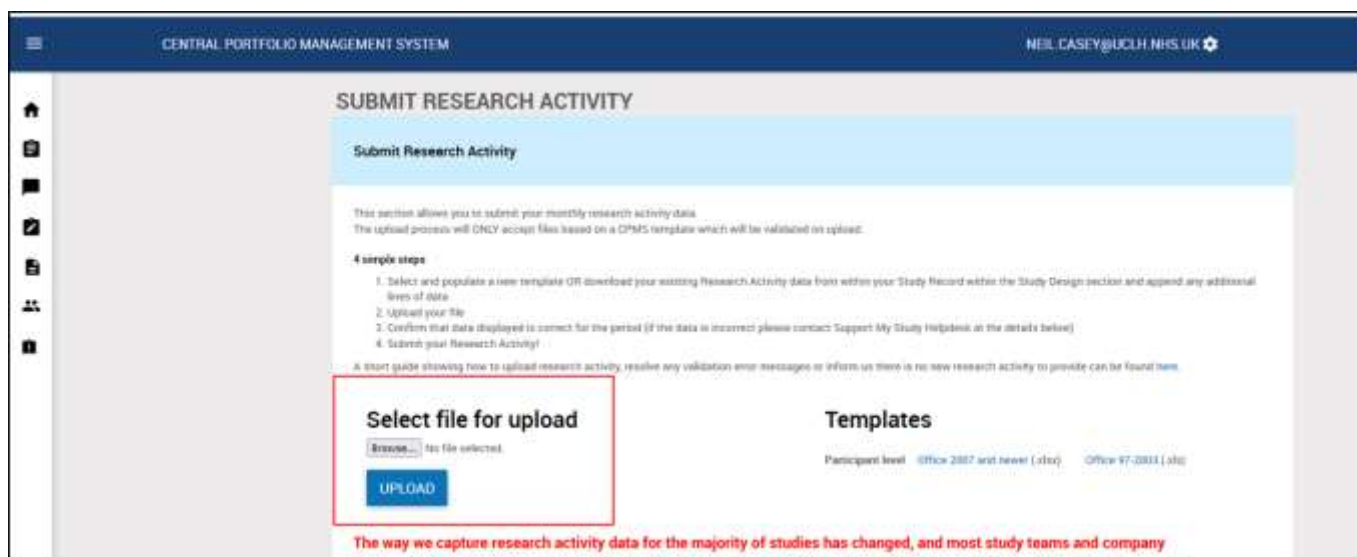
- iii. “Site Identifier”
- iv. “Site Name”. To find the correct site identifier and site name, go to the “PARTICIPATING ORGANISATIONS” tab of your study record on CPMS. Click on the “i” to find the site identifier.



- v. "Activity Date" is the date of recruitment.
- vi. "Participant Type". Select the correct option from:
 - Participant with the relevant condition
 - Participant without condition
 - Pre-condition
 - Professionals
 - Carers
 - Relations
 - Other
 - Diagnostic, screening or prevention participants
 - Genetically predisposed
- vii. "Unique Participant Id" is the participants trial ID.
- viii. "Activity Type" is "Recruitment"

5. Save the completed template.

6. Browse and select your completed template. Click upload.



7. If the spreadsheet is correct the next screen will confirm the upload was validated successfully. Check the number of Recruits uploaded is accurate and the cumulative total matches your records. Click 'Submit' to add the data.

If your spreadsheet was not completed correctly CPMS will show what rows have errors and what the error is. Go back and correct the spreadsheet and re-upload. If you need assistance with correcting the errors, take a screenshot of the error list and send with your spreadsheet to UCLH.RandD@nhs.net

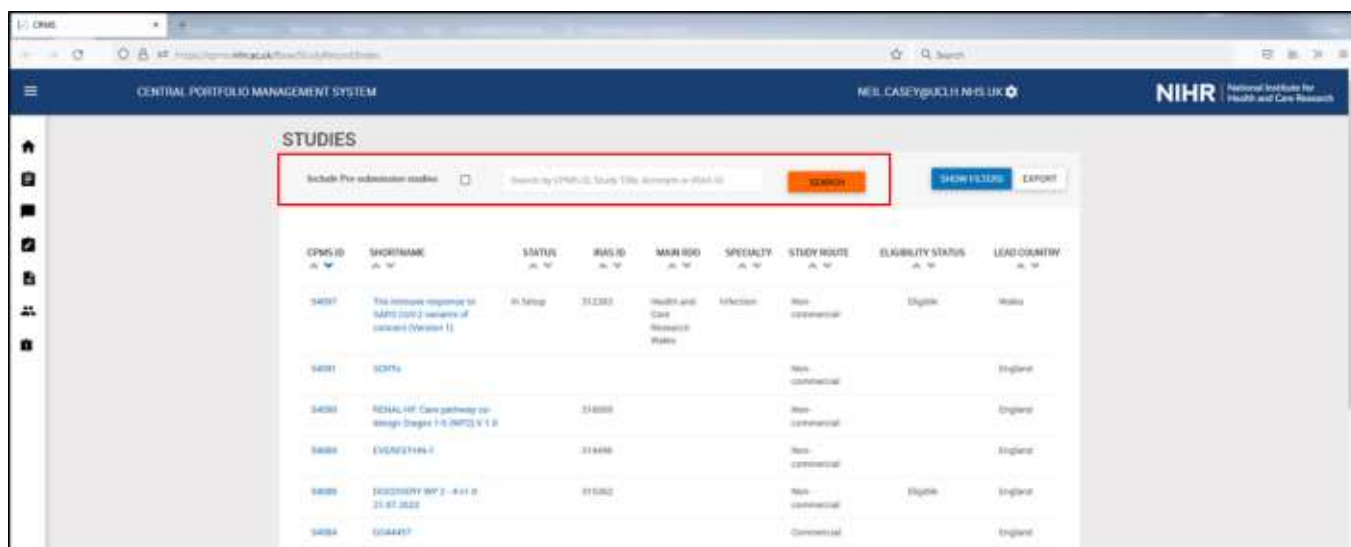
8. The total has now been updated and the following screen should read 'Your Research Activity has been submitted successfully' in a green box.

How to Confirm No Recruitment Since the Last Upload

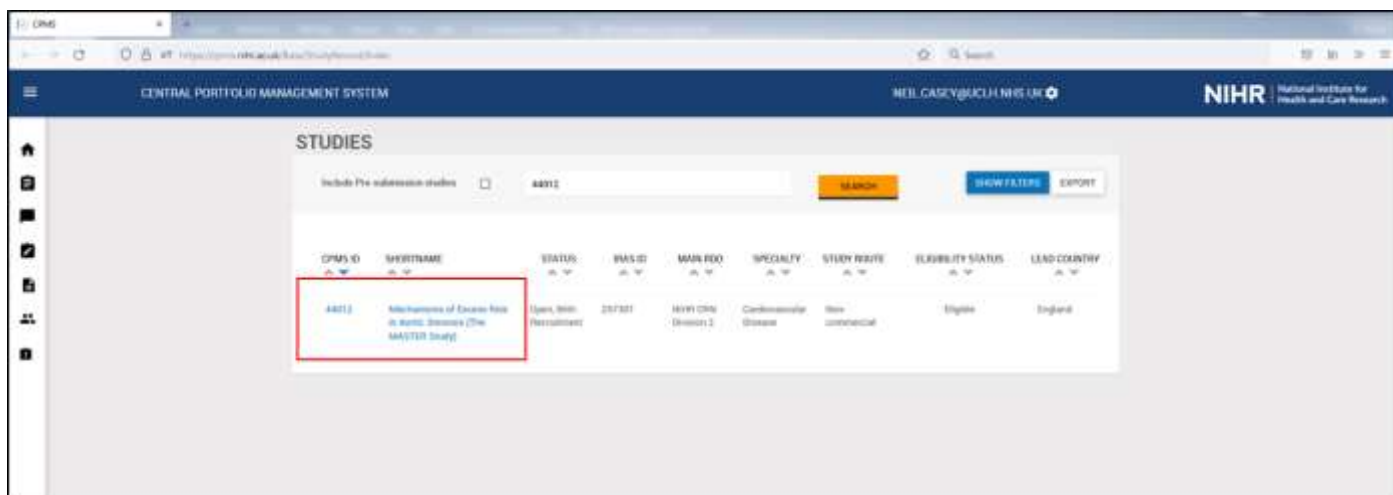
1. Log into CPMS cpms.nihr.ac.uk/ If you need a CPMS account, the Chief Investigator needs to request this by emailing supportmystudy@nihr.ac.uk Quote either the IRAS or CPMS number.
2. Click on the “Studies” tab from the left-hand menu



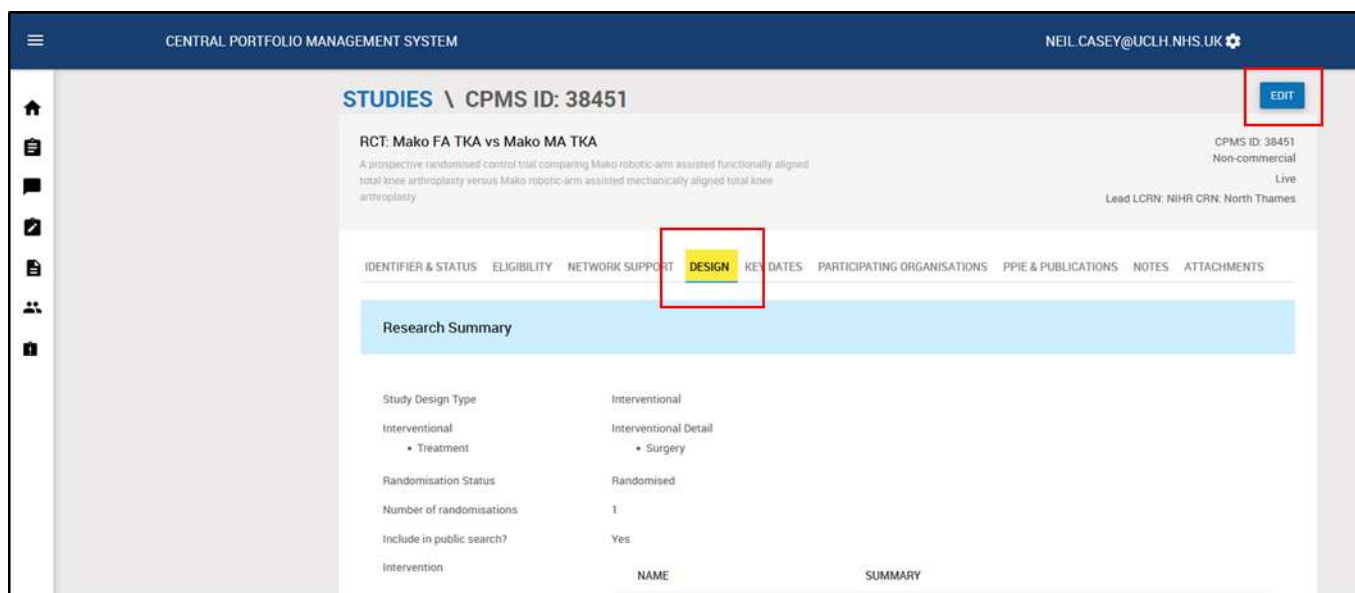
3. Type into the search bar the IRAS or CPMS number. If you do not know these use the short title or full title.



4. Click on the CPMS ID or the Short Name of the study.



5. Go to the “Design” tab. Then click “Edit”.



6. Scroll down and click on “Report No New Research Activity Since Last Participant (Manually Uploaded)”



7. If you would like to provide more information about why there is no new recruitment, you can do this in the 'Notes' tab, adding a note. This will help the Clinical Research Network to identify if they need to take any additional action to support recruitment of participants into your study

ANNUAL PROGRESS REPORTS

Chief Investigators of UCL and UCLH sponsored studies are required to submit annual progress reports to the relevant regulatory agencies. These include information on the number of participants recruited.

The specific requirements, along with submission forms, are available at the link below:

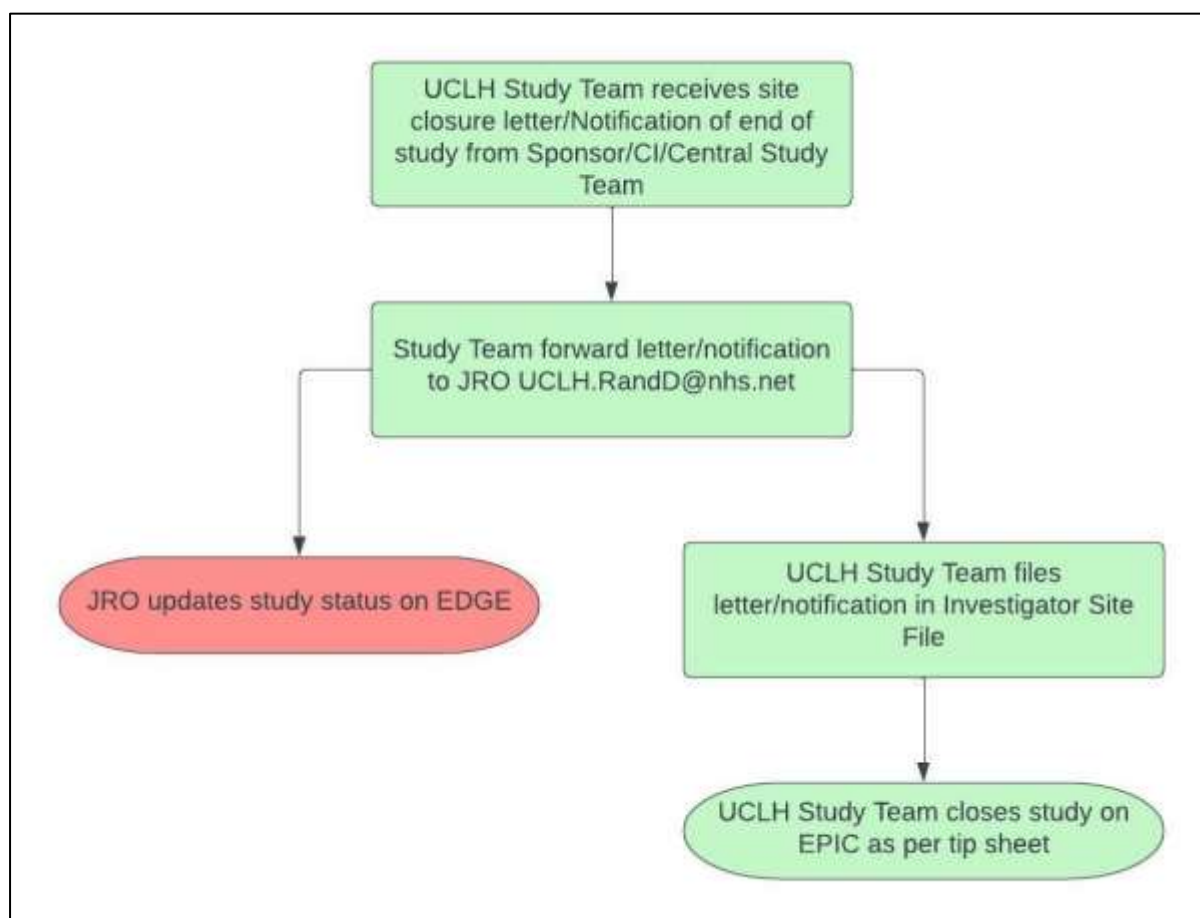
<https://www.hra.nhs.uk/approvals-amendments/managing-your-approval/progress-reports/>

A copy of these annual progress reports must be sent to the JRO via uclh.randd@nhs.net

Section 3: Study Closures

UCLH Site Closures

Whenever a UCLH site status is changed e.g. recruitment completed with no follow up, recruitment completed with follow-up, follow-up completed then the JRO need to be informed by emailing UCLH.RandD@nhs.net



When a site is closed they should receive a site closure letter from the CI or Sponsor, this should be forwarded to UCLH.RandD@nhs.net and filed in the Investigator Site File (ISF). JRO shares this site status change with CRN: NT SSS Team.

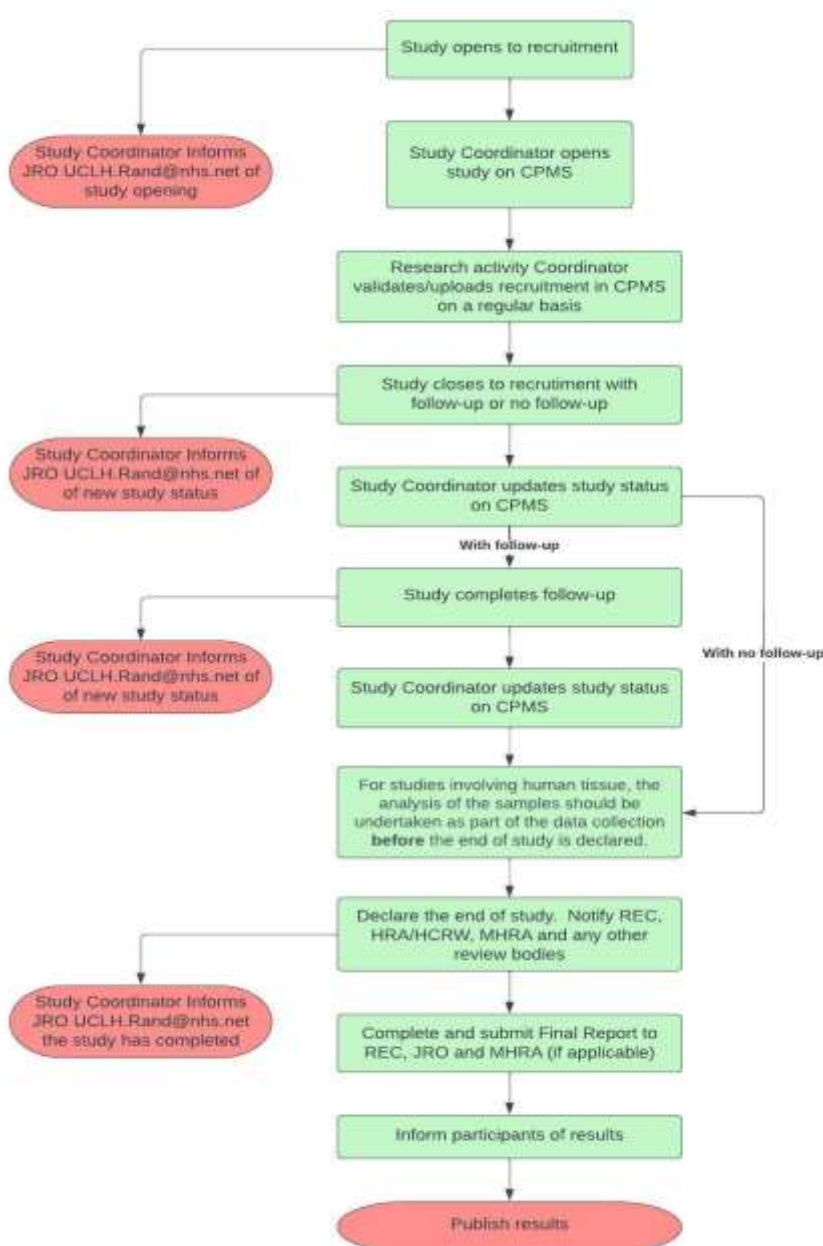
When a copy of the notification of the end of study to MHRA or Research Ethics Committee (REC) is received this should be forwarded to UCLH.RandD@nhs.net and filed in the Investigator Site File (ISF).

The tip sheet for closing studies on EPIC can be found here <https://my.uclh.nhs.uk/Utilities/Uploads/Handler/Uploader.ashx?area=compo>

[ser&filename=Research All Study+Closure+ v1.0.pdf&fileguid=c23a401e-be0c-40d5-b821-b178516e8323](#)

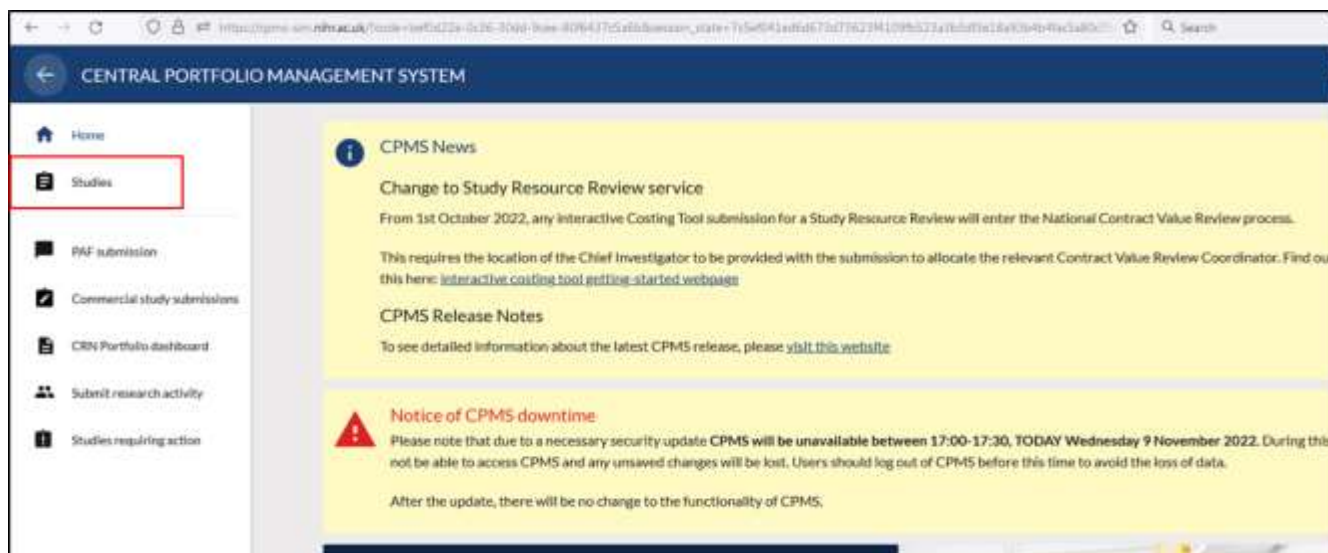
UCLH/UCL Sponsored Study Closures

Whenever a UCLH/UCL sponsored study changes status e.g. opening to recruitment, recruitment completed with no follow, recruitment completed with follow-up, follow-up completed, study suspended, then CPMS needs to be updated and the JRO need to be informed by emailing UCLH.RandD@nhs.net

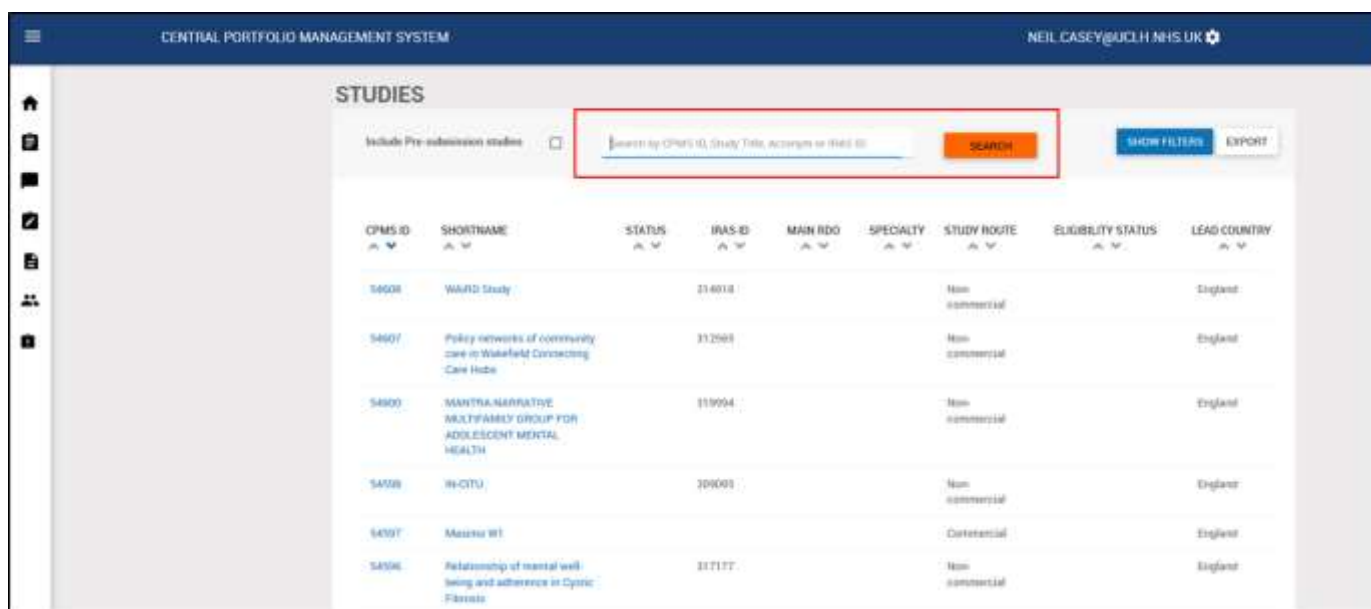


Change the Study Status in CPMS

1. Log into CPMS at www.cpms.nihr.ac.uk/
2. Select “Studies” on the left-hand menu.



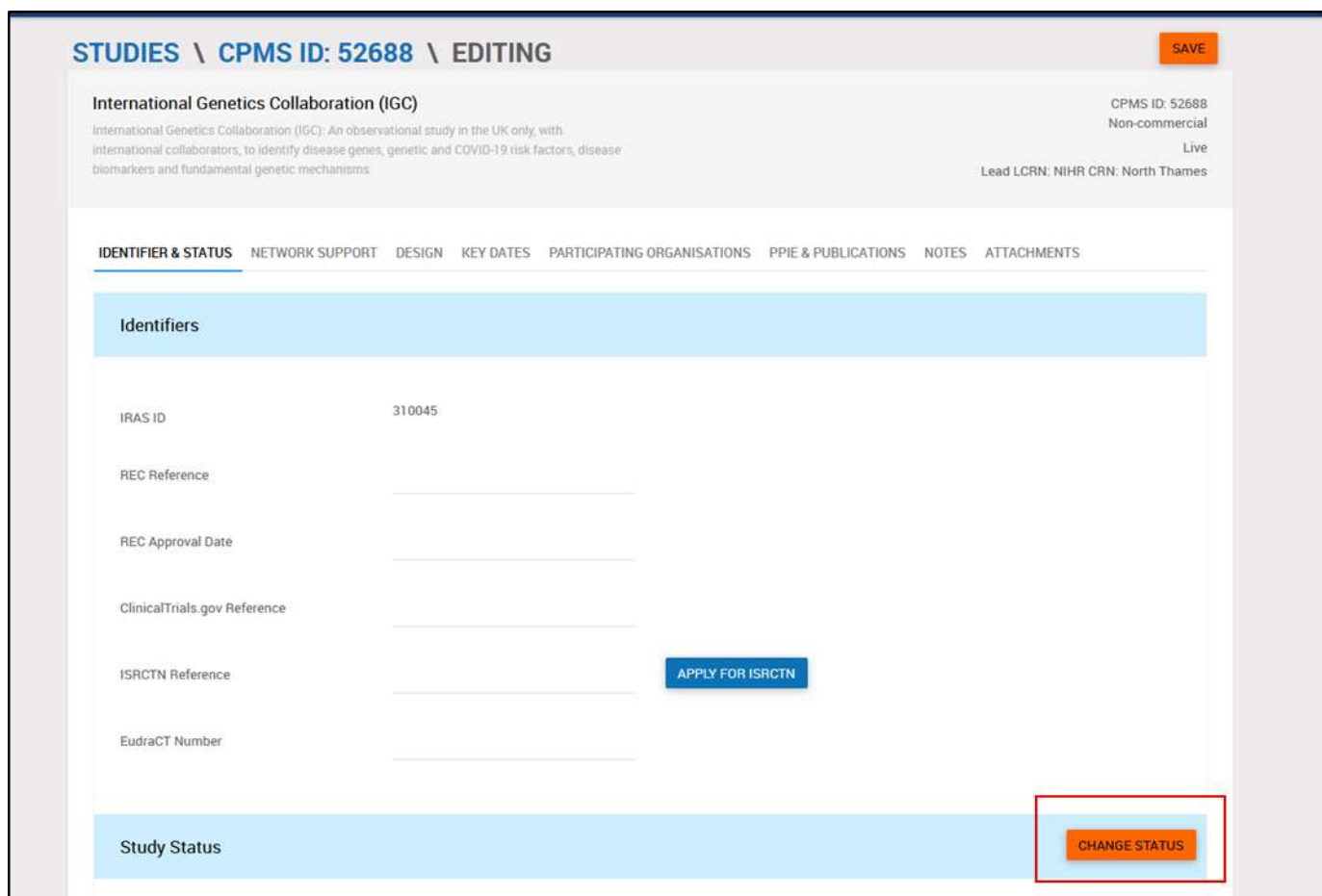
3. Search for your study using the IRAS or CPMS number. Click on the study short name.



4. Click on the “Edit” button.



5. Click on the “Change Status” button.



6. A pop-up window will appear. Select the new status, enter the effective from date and any other information required. Click change.

Change Study Status

Select new study status
Open, With Recruitment

Date effective from DD/MM/YYYY

CANCEL CHANGE

7. Click “save” to confirm your changes.

CENTRAL PORTFOLIO MANAGEMENT SYSTEM NEIL_CASEY@UCLH.NHS.UK

STUDIES \ CPMS ID: 52688 \ EDITING SAVE

International Genetics Collaboration (IGC) CPMS ID: 52688
Non-commercial
Last LDR: MWR DR: Nany Thomas

IDENTIFIER & STATUS NETWORK SUPPORT DESIGN KEY DATES PARTICIPATING ORGANISATIONS PIR & PUBLICATIONS NOTES ATTACHMENTS

Identifiers

IRAS ID	519945
REC Reference	
REC Approval Date	
ClinicalTrials.gov Reference	
ISRCTN Reference	APPLY FOR SRCIN
Subcontract Number	

8. JRO will inform the CRN: NT SSS Team of the closure of this study.

Definition of end of Study

Please copy UCLH.RandD@nhs.net into all correspondence with regulatory bodies.

The definition of the end of the study should be documented in the protocol. For most clinical trials this will be the date of the last visit of the last participant. It may also be the completion of any follow-up monitoring and data collection, as described in the protocol. For international studies, this is the end of study in all participating countries, not just in the UK.

For studies involving human tissue, the analysis of the samples should be undertaken as part of the data collection **before the end of study is declared.**

Any retained tissue for possible future evaluation after the end of study has been declared should be with the appropriate licence and should be undertaken as described in the protocol and within the terms of consent from the donors. Otherwise a new proposal for REC review would need to be submitted.

Any change to the end of study definition after approval has been given for the research should be notified as an amendment to the appropriate review bodies.

Declaring the end of a study

When a study ends you need to notify the review bodies that originally gave approval for it. When and how you submit this notification depends on the review body.

Notifying the Research Ethics Committee

You must declare the end of a study to the Research Ethics Committee (REC) that gave a favourable opinion within 90 days of the study ending using the appropriate form. Final analysis of the data (following 'lock' of the study database) and report usually happens after formal declaration of the end of the study.

Before you complete the end of study declaration form, you should review the plans that were approved by the REC for use of tissue and data collected during the study, providing information to participants, and dissemination of results. If you need to make any changes to these agreed arrangements, you should consider whether an amendment is required before submitting your end of study notification.

For clinical trials of investigational medicinal products (CTIMPs), the same end of trial form is used to notify both the REC and the Medicines & Healthcare products Regulatory Agency (MHRA).

For trials submitted through [combined review](#), you should complete and submit the end of trial form in the new part of Integrated Research Application System (IRAS). This automatically submits the notification to the REC and MHRA. For CTIMP and IMP/Device

trials that were not submitted through combined review, you will need to [complete the form available on the MHRA website](#) and email this to the MHRA and REC.

For all other research, [the end of study declaration form](#) should be completed and emailed to the REC.

Notifying the HRA and HCRW

For studies with both a REC favourable opinion and HRA and HCRW approval, you only need to declare the end of study to the REC, as described above.

For studies that have HRA and HCRW approval, but did not require REC review, you will need to notify us directly when the study has ended. You should email us at approvals@hra.nhs.uk including your IRAS ID and your contact information (phone and email).

Notifying the MHRA

For clinical trials of investigational medicinal products (CTIMPs) the declaration of end of trial must be sent to MHRA within 90 days of the global end of trial date and within 15 days of the global premature end of trial. For CTIMPs submitted through [combined review](#), the end of trial form can be completed and submitted to the MHRA in the new part of Integrated Research Application System (IRAS). This automatically submits the notification to the REC and MHRA. For CTIMPs that were not submitted through combined review, you will need to [complete the form available on the MHRA website](#) and email this to the MHRA and REC.

Notifying the MHRA (medical devices)

Manufacturers are required to email the MHRA when a clinical investigation of a medical device comes to an end.

Notifying the Confidentiality Advisory Group (CAG)

If you have an application with the Confidentiality Advisory Group (CAG), when your study is completed you should email the [confidentiality advice team](#) as soon as possible. The confidentiality advice team will review the information provided, update the approval register and email to confirm they have received the notice.

The application will remain on the approval register on the CAG website for at least 12 months following notification of closure.

Notifying other review bodies

You should check the end of study notification requirements with any other bodies that reviewed or approved the study.

Final report on the research

Please send a copy of your final report to UCLH.RandD@nhs.net

Once you have declared the end of study, and notified the relevant review bodies as described above, you may need to submit a final report of the research.

Final report to the Research Ethics Committee (REC)

All project-based research (not research tissue banks or research databases) that has been reviewed by a REC, needs to submit a final report. This report should be submitted to the research ethics service within 12 months of the end of the study.

If you submitted via [combined review](#), you should complete and submit the final report form in the new part of Integrated Research Application System (IRAS).

All other project-based research reviewed by a REC, should use the [webform on the our website](#). There is no need to submit a CSR to the REC for any CTIMP. The information relevant for the REC is captured in the final report form.

When completing the final report form, use the guidance next to each question to help you. One of the questions in the final report asks for a lay summary of the results. We will publish this [alongside the rest of the research summary on our website](#). We provide [guidance on how to write lay summaries of results](#), which you may find helpful when completing this question.

We may publish aggregate data collected from the final reports on our website, as part of our annual research transparency reporting. This will not contain any personally identifiable information. Further information is available in our [privacy notice](#).

For further information about the final report, [see the questions and answers page](#).

Final Report to the MHRA (medical devices)

If your study was a clinical investigation of a medical device, you should send a copy of the final report to the MHRA when it is available.

Final Report to other review bodies

You should check the final report requirements with any other review bodies that reviewed or approved the study.

Informing participants

Where applicable, people who have taken part in a research project should be thanked for their contribution and told about what it helped the researchers find out.

Providing participants with a summary of the research findings acknowledges and appropriately respects the contribution they have made. See our guidance on [writing a plain language \(lay\) summary of your research findings](#).

Publishing results

Research findings, whether positive, negative, neutral, or inconclusive should be made accessible when the study ends.

Where the main findings are to be submitted for publication in a journal, this should be done within 12 months of the end of study and should be published through an open-access mechanism in a peer-reviewed journal.

For clinical trials of investigation medicinal products (CTIMPs), a summary of results should be published within one year of the end of study. This should be published in the registry where the clinical trial is registered. [There is more information on the MHRA website.](#)

Post-research care

The NHS has the primary responsibility for patient care after research. However, researchers are responsible for explaining and justifying what will happen to participants once they have finished taking part. RECs are responsible for considering the arrangements.

Where research includes a therapeutic intervention, the sponsor should include information about what happens at the end of the study in the participant information sheet. Our existing guidance says that it must be clear whether participants will have continued access to any benefits or intervention that they may have obtained during their participation in the research, once the research study stops.

Interventions here include drugs or devices, whether licensed or unlicensed, and also care delivery pathways, complementary therapies, physiotherapies, dietary manipulations and lifestyle changes. Interventions may include services as well as products.

Unless specific arrangements have been put in place for the supply of a treatment after research, the clinical decision about what happens after the study will come under the normal limitations of the NHS commissioning arrangements.

However, if the sponsor decides to end the intervention for any participants and participants will finish the intervention earlier than set out in the protocol, a substantial amendment is required (an amendment is NOT required if a participant decides to withdraw early, or a clinician withdraws a participant for some reason).

Sponsors should consider whether additional arrangements should be put in place for the post-trial period if any participants were benefitting from the study intervention. If it is a blinded trial, also consider whether to break the blind at the end of the study to inform post-trial care. Sponsors should consider continuing the treatment if any of the following apply:

- it is reasonable to expect that it will be possible to give the study intervention safely after the study;
- it is reasonable to expect a clinically important benefit;

- the intervention is not available through the NHS locally; and
- treatment options are limited.

For controlled trials, consider whether treatment after the trial should only be offered to patients receiving the intervention during the study, or whether it should also be offered to those in the control arm. Particular care should be taken in life-limiting or rare diseases and where alternative treatment options are not available.

Sponsors must make logistical and financial arrangements for continued treatment before confirming the decision about the end of the study, and before informing participants. If there are logistical, financial, safety or legal reasons for not being able to continue treatment, these must be justified to the REC.

Other end of study considerations

You should check whether there are any other actions that need to be taken at the end of the study. You should also check the requirements with any other review body that reviewed or approved the study.

If your study involved human tissue at the end of the study (in line with the protocol and terms of the consent from the donors) you may have agreed to dispose of the human tissue or transfer the tissue to a licensed establishment. You should also ensure any research data and personal data is stored or destroyed appropriately, as detailed in your protocol and in line with GDPR and the Data Protection Act.

With appropriate safeguards in place, you may also enable the sharing of tissue samples and associated data to other interested groups and communities. Sharing data is encouraged as it maximises and respects the contribution of the participant and enables and supports further research. Individual participant-level data (IPD) should normally be shared, provided it is anonymised in accordance with the Information Commissioner's Office anonymisation code of practice.

For more information please visit the '[publication and dissemination of research findings](#)' section.