

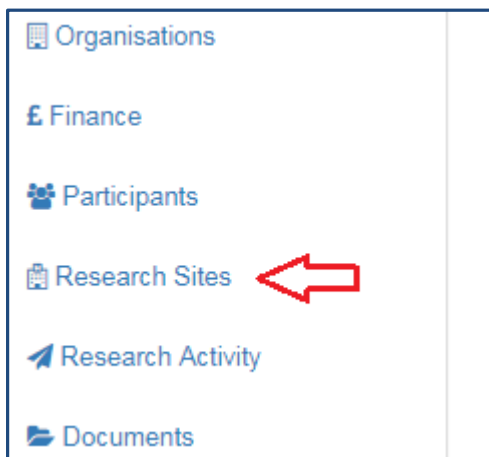
Guidance for Assigning Research Sites, Uploading Site Capacity and Capability and Setting Site Status

RPEAK has been sending dates for confirmation of capacity and capability (C&C data) from your Trust to CPMS since November 2017 and you have been able to assign Research Sites in R-Peak for a Project Record since November 2018. This should be done for all portfolio studies you are invited to or that are confirmed or not confirmed by your Trust after this date.

Beginning May 2019, Participant Recruitment Activity will be sent from R-Peak into CPMS. As part of this change, the Site Status will need to be set to recruiting for portfolio studies once green light from the sponsor representative is received.

Assigning Research Sites

To add the Research Sites to the record, navigate to the R-Peak Project Record and locate the Research Sites section on the left hand side menu bar under Project Navigation.



This page will show you the research sites in Greater Manchester associated with the study. If your research site(s) is not listed, click on the 'Add Site to Study' option to select a research site. The list will include all Greater Manchester Research Sites and GP Practices. To find your research site, type into the 'Search for a site name' box.

Select a research site to add to (R04454)

| Site Name | Trust Name | |
|-------------------------------|--|------------------------|
| MANCHESTER ROYAL EYE HOSPITAL | MANCHESTER UNIVERSITY NHS FOUNDATION TRUST | select |
| MANCHESTER ROYAL INFIRMARY | MANCHESTER UNIVERSITY NHS FOUNDATION TRUST | select |
| MANCHESTER ROYAL INFIRMARY | SALFORD ROYAL NHS FOUNDATION TRUST | select |

Select the site you want to add. Select 'Activity Type' to indicate your site type and submit.

Add research site to study (R04454)

Cpms Id: 30406

Study Site: MANCHESTER ROYAL INFIRMARY

Study Organisation: MANCHESTER UNIVERSITY NHS FOUNDATION TRUST

Activity Type:

Site Status:

Study Site Status Date:

Deleted:

Deleted Reason:

Uploading Site Capacity and Capability

R-Peak Users who have permissions to edit date fields on the Project Record are able to upload C&C data. To upload C&C data, navigate to the 'Trust Specific Details' page of the R-Peak Record and click the following button:

[Upload Site Capacity and Capability](#)

After ticking the button you will enter the below screen.

| | |
|---|---|
| Cpms Id | 30406 |
| Outcome | Will Participate |
| Study Site | ROYAL MANCHESTER CHILDREN'S HOSPITAL (MANCHESTER UNIVERSITY NHS FOUNDATION TRUST) |
| Site Selected Date | 06/01/2017 |
| Date Site Ready To Start | 14/02/2017 |
| Site Confirmed Date | 19/01/2017 |
| Site Invited Date | 21/07/2016 |
| First Patient First Visit Date | 15/03/2017 |
| Dates Not Required | <input type="checkbox"/> |
| Back Upload View Submission History | |

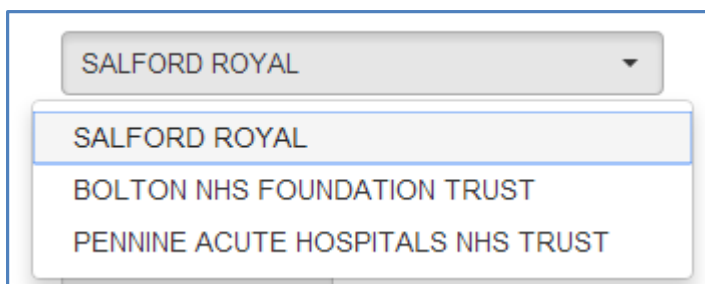
Most of these fields pull data from the date fields on the Project Record. If you need to edit this data, you need to go back to the original field to update the information. These include:

| Upload C&C Field | Project Record Field |
|--------------------------------|---|
| Site Selected Date | Site Selected Date under Trust Specific Details |
| Date Site Ready to Start | Actual Start Date under Trust Specific Details |
| Site Confirmed Date | Site Confirmed Date under Trust Specific Details |
| Site Invited Date | Site Invited Date under Trust Specific Details |
| First Patient First Visit Date | This field will pull the data from Project Participants. It will pull the first consent date on any Participant Record whose Status is not listed as a Screen Fail. |

The 'Outcome' field is where you will record whether your Trust will participate in the study. The options are:

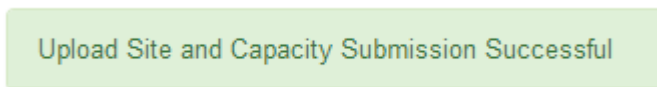
| |
|-------------------------|
| Will Participate |
| Will Not Participate |
| Not Selected By Sponsor |

The 'Study Site' field is where you select which Site within your Trust you are sending C&C data for. The drop down field shows a list of all Greater Manchester area Sites that are associated to the CPMS Record for this study.



The 'Dates Not Required' box should be ticked if your Trust is not required to confirm capacity or capability or if all dates are not required to be uploaded.

Once you have reviewed your C&C data and are ready to upload, select the 'Upload' button. If your transmission is successful, you will see this message:



You can also view the Submission History by selecting that button. The Submission History will look like this:

| Submission History | | | | | | | | | | | |
|----------------------|---------------|---------------------|--------------------|---------------|---------------------|--------------------------|---------------------|---------------------|--------------------------------|--------------------|--|
| User | Upload Result | Date Uploaded | Outcome | Study Site | Site Selected Date | Date Site Ready To Start | Site Confirmed Date | Site Invited Date | First Patient First Visit Date | Dates Not Required | |
| Elizabeth.Mainwaring | Failed | 02/11/2017 15:04:11 | WillNotParticipate | SALFORD ROYAL | 19/04/2017 00:00:00 | 09/06/2017 00:00:00 | | 19/04/2017 00:00:00 | | False | |
| Elizabeth.Mainwaring | Success | 02/11/2017 15:26:50 | WillNotParticipate | SALFORD ROYAL | 19/04/2017 00:00:00 | | | 19/04/2017 00:00:00 | | False | |
| Elizabeth.Mainwaring | Success | 23/11/2017 15:16:25 | WillParticipate | SALFORD ROYAL | 19/04/2017 00:00:00 | | | 19/04/2017 00:00:00 | | False | |

NOTE: If the study is recruiting at multiple Sites within your Trust, you will need to upload C&C data for each Site. The C&C data transmitted should be the same for all Sites.

We would suggest that you upload C&C data at three time points for each study:

1. Following confirmation of capacity and capability from your Trust
2. Following receipt of green light to recruit participants from the Sponsor
3. Following recruitment of the first participant

Requirements:

In order to upload C&C data to the R-Peak Project Record must have a CPMS ID entered and a Research Site for your Trust will need to be associated in CPMS. If either of these items is not recorded, you will get the following error message:

Upload Site and Capacity not available

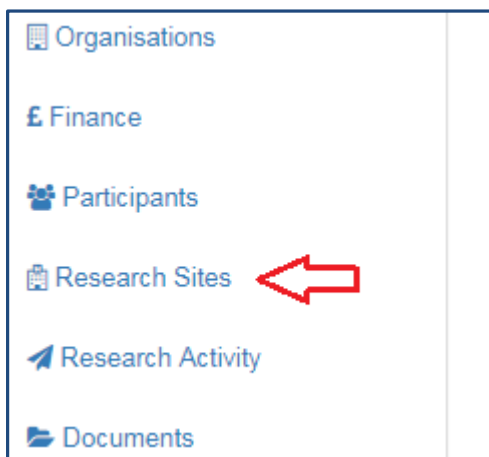
This study requires a CPMS ID and a Study Site to upload Site and Capacity information

Updates:


It is possible that C&C data will need to be updated. For instance, you may have uploaded the date that the first participant was consented, but they later screen failed. If this occurs and the Participant status is changed to 'Screen Fail,' the 'First Patient First Visit Date' should now pull in the consent date for the second participant. You will need to resend the C&C data to upload the new recruitment date.

Setting Site Status

R-Peak Users who have permissions to edit date fields on the Project Record are able to set the Site Status. To set Site Status, navigate to Project Record and locate the Research Sites section on the left hand side menu bar under Project Navigation.



Select the Update button next to the Study Site you need to set the status for.

| Research sites associated with study(R04454) | | | | |
|--|--------------------------------------|--|-------------|--|
| CPMS ID | Study Site | Study Organisation | Site Status | Site Status Date |
| 30406 | ROYAL MANCHESTER CHILDREN'S HOSPITAL | MANCHESTER UNIVERSITY NHS FOUNDATION TRUST | | Update  |

Select Recruiting or No longer recruiting from the 'Site Status' dropdown menu and enter in a 'Study Site Status Date'. The date you enter should be the date that the status recruitment status changed.

| | |
|-------------------------|--|
| Cpms Id: | 30406 |
| Study Site: | ROYAL MANCHESTER CHILDREN'S HOSPITAL |
| Study Organisation: | MANCHESTER UNIVERSITY NHS FOUNDATION TRUST |
| Activity Type: | All Site Activities |
| Site Status: | Recruitment Status not yet set |
| Study Site Status Date: | Recruitment Status not yet set |
| Deleted: | Recruiting |

You should set the Site Status at two time points for each study:

1. Following receipt of green light to recruit participants from the Sponsor
2. Following confirmation from the Sponsor that your site has closed to recruitment for the study