

NIHR Clinical Research Network

Confirming Research Activity Data in CPMS

Guidance Document

Version: V1.3

Date: Feb 2020

1. Document Control

This document is issued and updated by the National Clinical Research Network Coordinating Centre.

Readers are responsible to ensure the latest version is being viewed by accessing the master document version from the Study Support Service hub site.

| Document Information | on |
|----------------------|---|
| Document Title | Confirming Research Activity Data in CPMS |
| Version | V1.3 |
| Supersedes | NA |
| Contributors | Nicola McMillian, Research Delivery Facilitator Kaatje Lomme, Business Change Manager, Research Delivery |
| Function | Research Delivery Directorate |
| Effective Date | 18/02/2020 |
| Audience | Study teams, commercial contacts, and network support staff across the UK supporting the Research Activity Confirmation process. |
| Category | Guidance Document |
| Expectation | This document will be used to support the confirmation process and may be amended at any time. |
| Purpose | To support the Research Activity Confirmation process, by providing an overview of the process and a troubleshooting guide for overcoming issues. |

| Change History | Change History | | | | |
|-----------------------------|---|--|--|--|--|
| Version | Description of change | | | | |
| DRAFT V 1.0 (March 2019) | 1st Draft | | | | |
| V1.0 (May 2019) | Final document | | | | |
| V1.1 | Added CRF ID to top tip Added a section on finding the Site ID and Parent Org | | | | |
| V1.2 | Added section 9.8 - zeros [NM] | | | | |
| V1.3 | Section 9.9 added | | | | |

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3. An overview of the new research activity process

The NIHR Clinical Research Network, along with our partner networks in Scotland, Wales and Northern Ireland, collect essential information about the the set up and delivery of clinical research across the UK. Particularly, we gather information about the number and types of participants taking part in research.

Since the launch of the Central Portfolio Management System (CPMS) in 2015, research activity data has been uploaded manually via spreadsheet for all NIHR portfolio studies. With the new research activity process researchers and support staff across the UK will capture research activity data in their Local Portfolio Management Systems (LPMS), including data about the type of activity that has taken place and the date of that activity. This data will then flow directly from across the UK directly into CPMS via a digital feed on a nightly basis.

This guide will take you through the steps required for you to confirm research activity data in CPMS, and provides further information about the confirmation screen functionality, as well as how to troubleshoot issues.

3.1 Research Activity Confirmation

To ensure that we are reporting research activity accurately, the Chief Investigator (or their nominated representative) needs to confirm the accuracy of their study's data in CPMS on a monthly basis.

[Top tip: Multiple members of a team can confirm data. All Chief Investigators, Study Coordinators, Research Activity Coordinators and Company Representatives can access the confirmation screens for their study.]

The CI (or their nominated representative) is able to confirm that the data held is accurate or inaccurate, and can provide additional information about inaccurate data.

Confirmation of the accuracy of the data flows back to the LPMS where the data originated. Data that has been confirmed as inaccurate is then reviewed and corrected by the local team. Finally, any corrected data then flows back to CPMS, where it can be re-confirmed.

4. A step-by step guide to confirming your data

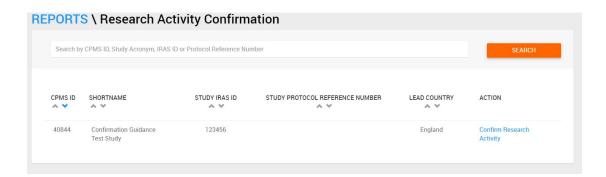
4.1 Locate your study for confirmation

You should first <u>log into CPMS</u>. An introduction to CPMS can be found in <u>the CPMS</u> <u>section under the 'Working in the CRN' header of NIHR Learn</u>.

Once you have accessed CPMS, choose Confirm Research Activity from the left-hand navigation bar. This will take you to a list of your studies.



Once you have located your study, click "Confirm Research Activity" to enter the confirmation screen.



[Top tip: if your study is not listed here as expected, it is likely that it either isn't yet open to recruitment in CPMS, or you have not yet been added to the record as a contact. Please see <u>section 6.2</u> of this document.]

4.2 Check your study details

Upon entering the confirmation screen you will see some of your study details:

CPMS ID: 41297

Short Name: Confirmation Guidance

Protocol Reference: EXAMPLE123456

Actual Recruitment Start

Date:

01/01/2019

Planned Recruitment

Closure Date:

31/12/2019

Study Status: Open to Recruitment

If any of the details held here are incorrect, please see section 8.3.

[Top tip: the Protocol Reference field is only visible for commercial studies, and does not need to be completed in CPMS for non-commercial studies.]

4.3 Set the Research Activity Period

Before starting the confirmation process please amend the Period field to "Until the end of last month".

Period

View All Research Activity





Once you have applied this selection, the data on the screen, in the Confirmation Dashboard (See Step 4) and in the Confirmation Table (See step 5) will automatically remove any data from the current month.

[Top tip: We will receive daily updates of research activity from LPMS and therefore the current month's data is likely to change. We therefore ask that you check only data up until the end of the last month each time you confirm your data.]

[Top tip: if you want to review the data including the current month for any reason, ensure the period is changed back to "Up to date".]

4.4 Review the confirmation dashboard

When you access the study confirmation page, the dashboard provides an overview of all of research activity data we hold for the study to date, unless the period is amended.

| PARTICIPANTS | PROVIDED BY SPREADSHEET (HISTORICAL DATA) | i | PROVIDED ELECTR START DATE: 01 | | | TOTAL PARTICIPANTS |
|-----------------------|--|--------------------------|-----------------------------------|--------------------------------|----------------------|--------------------|
| | | Requires Confirmation | Requires Reconfirmation | Confirmed - Not Accurate | Confirmed - Accurate | |
| Consented 0 | N/A | 1 | 10 | 4 | 122 | N/A |
| Recruited 0 | 4 | 7 | 9 | 2 | 80 | 102 |
| Failed Screening • | N/A | 5 | 2 | 0 | 94 | N/A |

It's a good idea to review the confirmation dashboard once you have set the Period to "Until the end of last month", so you can review the totals up until then.

The totals refer to the total numbers of participants we have received for your study, and whether these have been confirmed or not. Further information about the confirmation statuses is provided in the following sections and in <u>section 6.2</u>.

[Top tip: if your study previously provided research activity data via spreadsheet, you will see this in the dashboard. However, we won't ask you to confirm any of this data. See <u>section 11</u> for information on amending this data.]

[Top tip: Hover over the "i" buttons in the dashboard for more information the dashboard information. <u>Section 6.1</u> in this document also provides information on the definitions of Consented, Recruited and Failed Screening.]

[Top tip: for studies without screening periods, no Failed Screening data will be received. You will still see Failed Screening in the Confirmation Dashboard, but all fields will have a value of zero.]

[Top tip: You will see aggregated totals for the Participant Statuses of Consented, Recruited and Failed Screening. You should also keep in mind that one participant can be counted as consented and also as recruited/failed screening. Therefore, all of your participants that have consented to take part will be in the consented total, and will remain counted towards that total even if they later become a recruited or failed screening participant.]

[Top tip: While we will receive Consented, Recruited and Failed Screening data from English and Northern Irish sites, we will receive only recruited data routinely from Wales and Scotland. Therefore, if data appears to be missing from your consented and failed screening totals and you have Scottish and/or Welsh sites taking part, this may account for the difference. There is no need to flag this as missing data, as this is expected. See section 4.10 for more information on differences in research activity data across the UK nations.]

4.5 Confirm research activity data as accurate

Now that you have set the Period to "Until the end of last month", and reviewed the dashboard totals for your study, you can scroll down the page to confirm your data:



When confirming your data, you will automatically be presented only with the data that Requires Confirmation and Requires Reconfirmation, so that you can focus on the data that requires action. This section explains how to confirm data that Requires Confirmation, which refers to data received for the first time for confirmation. If monthly totals change after being confirmed, the new totals will appear with a status of Requires Reconfirmation. Please see section explains how to confirm data that Requires Reconfirmation. Please see section explains how to confirm data that Requires Reconfirmation.

This data is presented to you via three views:

- Study View: aggregates all of the Consented, Recruited and Failed Screening data
- Study Site View: separates the Consented, Recruited and Failed Screening data by site
- Detailed View: shows all of the data, line by line, by site and month. It is the most detailed view and presents the data exactly as it is received from LPMS.

[Top tip: Keep in mind that this data is only the data received since the last time you confirmed your data, and only shows data up until the end of the last month (as long as you have done Step 3)!]

In order to confirm your data as accurate, simply click the boxes in the Confirm as Accurate column in any view, and then click SAVE.



Once you have saved a line of data as accurate, it will disappear from the view.

[Top tip: select the box directly under "Confirm as accurate" in the Study Site and Detailed Views in order to select all the boxes in the column with one click.]

[Top tip: although we will be able to receive data each month for participants that have been Consented, Recruited and Failed Screening, we may not reliably receive the new Consented and Failed Screening data immediately. If you are finding that your data is very incomplete and it will be too time consuming to identify and log all of the inaccuracies, please concentrate on confirming the Recruited data only and leave these other points as unconfirmed.]

4.6 Confirm research activity data as inaccurate

Should you find that the data you are presented with for confirmation is not what you expected, you can easily review your data to identify where inaccuracies have occurred.



Let's take an example. It is November 2018. You are the CI of a study and you are up to date with confirmation of your research activity data (i.e. in October 2018, you confirmed all of your research activity data up until the end of September 2018). You are therefore confident that the data you are being presented for confirmation this month relates to October 2018.

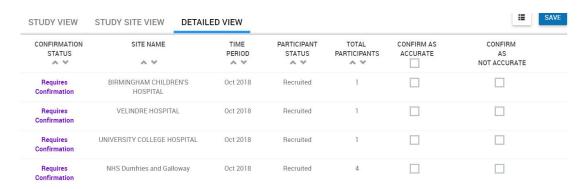
Last month your study consented 1 participant, 5 participants failed screening and 8 participants were recruited. You therefore know that a figure of 7 recruited

participants given in the screenshot above is incorrect.

First of all, given you know that the totals of the consented and failed screening participants is correct, you can go ahead and confirm these lines of data as accurate. This will help you to focus on the data that appears to be incorrect.

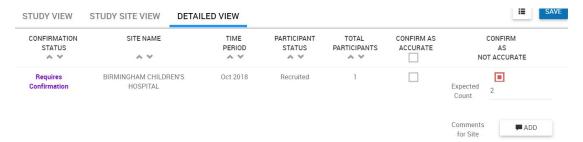
[Top tip: if multiple sets of your data appear to be incorrect, you can use the filter functionality to review different data sets separately. You can also download all of your data as a spreadsheet at any time in order to review it. See section 5.2 for more information.]

Now that you have confirmed the accurate data, you can review the inaccurate data in the Study Site View and/or the Detailed View:



In the detailed view, you now have confirmation that, as suspected, all of the data received for confirmation is for the month of October 2018. You can also see the number of recruited participants at each site for October 2018, and therefore, can easily identify the site total that is incorrect.

Confirming which total is incorrect is easy: simply identify the incorrect row of data, and click the box in the inaccurate column in the Detailed View:



You will then be asked to provide an Expected Count—in this case the missing participant is at Birmingham Children's Hospital, and the count should be 2. You can also provide a comment for the site if you have additional information that may help them identify and rectify the discrepancy. This information is sent back to the LPMS where the data originated to help the local teams identify the discrepancy and amend their data.



You can add any potentially helpful information in this comment box. However, please do not enter anything containing potentially identifiable data related to your participants and include anonymised/pseudonymised information only

[Top tip: It is very useful to include participant IDs in the Comments for Site box where the data you have received is inaccurate. If you are including participant IDs, please use CRF IDs if your study has them.]

Once you have entered all of the information you would like to provide about the inaccurate data, click to confirm the changes. Once you have clicked the confirmation for that line of data is complete and the line of data will disappear from the view.

Once data is saved as inaccurate, the inaccurate confirmation status and additional information you have supplied flows back to the LPMS where it originated so that it can be reviewed and corrected at source.

4.7 Reconfirmation of amended data

At any time while your study is open to recruitment, or when your study is closed but the data is not yet finalised, we may receive updates on a previously confirmed line of data. This data is received into CPMS with the status Requires Reconfirmation.



[Top tip: Since the data received with this status may be from any site and month from across the study recruitment period, it is best to review the data in the Detailed View before providing confirmation.]



All you need to do is confirm that this newly updated line of data is correct according to your records. Once you have reviewed the data you can confirm it as accurate or as inaccurate in the normal way as described in the section 4.5 and section 4.6.

[Top tip: Note that a Requires Reconfirmation line of data effectively replaces any previous line of data for that site, month and participant status. There is no way, and no need, to compare in CPMS what was previously received and confirmed, nor to review which confirmation status you provided previously.]

4.8 Confirming inactivity (zeros)

For any site that has been activated but does not recruit during a month, CPMS will show this inactivity in the confirmation screens. This is to ensure that you have a complete picture of the activity and inactivity for your study across the UK. You will therefore see a zero line of data for each site, participant status and participant type where no activity has taken place.



The example above shows a study that was opened to recruitment with two sites activated in Jan 2019. As the two activated sites did not report any research activity during Jan 2019, on 1st Feb 2019 rows of zero data were generated for the sites.

Any inactivity for a given month will be presented for confirmation at the start of the following month, along with any activity that has taken place.

| STUDY VIEW | STUDY SITE VIEW | DETAILED VIEW | | | | Lii . |
|--------------------------|---------------------------------|----------------|-----------------------|-----------------------|------------------------|-------------------------------|
| CONFIRMATION STATUS | SITE NAME | TIME PERIOD | PARTICIPANT STATUS | TOTAL PARTICIPANTS | CONFIRM AS ACCURATE | CONFIRM AS NOT ACCURATE |
| Requires Confirmation | THE CLATTERBRIDGE CAN CENTRE | ICER Feb 2019 | Consented | 1 | | |
| Requires Confirmation | THE CLATTERBRIDGE CAN | ICER Feb 2019 | Recruited | 0 | | |
| Requires Confirmation | THE CLATTERBRIDGE CAN | ICER Feb 2019 | Failed Screening | 0 | | |

The example above shows data for a site that consented 1 participant in Feb 2019, but did not have any recruited or failed screening activity.

You should treat these lines of data in exactly the same way as the other data you are confirming, i.e. if they are correct, confirm them as accurate; if data is missing, you can confirm the line as inaccurate and provide information on what is incomplete. Note that, as with any activity received, you are not required to check through the inactivity data at a detailed level unless you think something is incorrect.

[Top tip: you may be asked to confirm zero activity for the Failed Screening status, even where your study does not include screening activities. Since you are not expecting any activity for this status, you can simply confirm it as correct. Please see section 9.5 for steps to take if you would prefer to stop seeing Failed Screening lines of data in the confirmation screen.]

[Top tip: you should never receive research activity data, including inactivity data, for a site that has not been activated as a recruitment site on your study. Use the Key Contacts section to contact us if you see data for a site that is not participating in your study.]

[Top tip: while sites in England and Northern Ireland will record data for the Consented and Failed Screening statuses, Scotland and Wales will not be routinely capturing this data. However, you will see inactivity data for Consented and Failed Screening statuses for Scottish and Welsh sites, even where there has been activity. You can simply confirm this data as accurate as it is expected for these sites. If you wish to check on the expected data for any of your sites, please contact us using the Key Contacts section of this document.]

4.9 All data has been confirmed

Once all of your data for the month has been confirmed as accurate or inaccurate, the confirmation area will show no further lines of data:



You can now close CPMS and there is no further action necessary until your data is ready to review next month.

[Top tip: if you have confirmed data in error, you can amend the confirmation status by using the filters in the Detailed View. More information on using the filters is found in section 5.1 and on amending a confirmation status, in section 9.1]

4.10 Differences in research activity data across the UK nations

We will receive confirmation data as described in the steps above from English and Northern Irish sites. This means that we will receive Consented, Recruited and Failed Screening statuses. Wales and Scotland will instead routinely collect only Recruited participant data in their LPMS.

It's therefore important to take account of these differences when confirming data for studies that are taking part in Scotland or Wales only, or are working across more than one nation, especially across nations that have differences in research activity policy.

[Top tip: if data appears to be missing from your Consented and Failed Screening totals and you have Scottish and/or Welsh sites taking part, this may account for the difference. You can easily check this by reviewing the data received from your Scottish and Welsh sites in the detailed view in the confirmation page.]

Note that you will see a zero line for the Consented status for each month for Welsh and Scottish sites, and you may also have a monthly zero line of recruitment for the Failed Screening status. There is no need to flag this as missing data, you can simply confirm these lines as accurate, as they are expected.

Note also, that we will not receive Participant Types from Wales and Scotland, therefore, all of your recruitment from Scottish and Welsh sites will be presented as "Not provided" in the Participant Type field. Your Welsh and Scottish sites will therefore provide a total each month that reflects all of the participants that have been recruited to the study, regardless of the type.

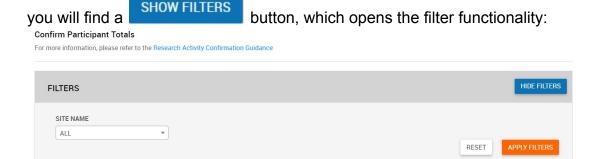
Please review <u>section 5.1</u> and <u>section 5.2</u> for information on how to use this functionality, as it may help you to check your data across different nations' sites. If you need any additional support or have questions about data from any nation, please <u>contact us</u>.

5. Further Confirmation Functionality and Information

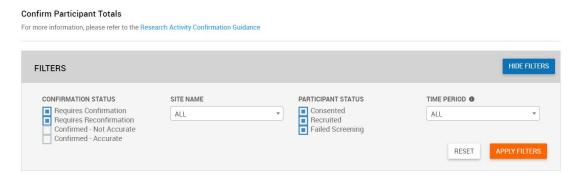
5.1 Filter and sort functionality

In order to make more complex data sets easier to confirm, the confirmation table has sort and filter functionality.

Above the research activity confirmation table in the Study Site and Detailed Views,



Above you can see the filter in the Study Site View. As you can see, in this view you can search for a particular site.



The screenshot above shows the filters available in the Detailed View. As you can see, you can use the filters to filter by Confirmation Status, Site Name, Time Period and Participant Status simultaneously.

Once you have selected the filters you want to apply, click to change the data in the confirmation table. You can remove the filters at any time by clicking RESET

[Top tip: the filter functionality automatically sets and resets to show data that has a confirmation status of Requires Confirmation and Requires Reconfirmation. Use the filters in the Detailed View to see Confirmed - Not Accurate and Confirmed - Accurate data.]

As well as using the filters to display different data sets, you can also use the sort functions, wherever you see to rearrange your data as required.

5.2 Checking the Site ID and Parent Organisation

You can check the Site ID and/or Parent Organisation for your sites at any time by

using the button at the top right hand of the page in the Detailed View, and selecting the Site ID and/or Parent Organisation from the menu selector.

| STUDY VIEW | STUDY SITE VIEW | DETAILE | O VIEW | | | | - | | Ħ | SAV |
|--------------------------|---|--------------|------------------------------|----------------|-----------------------|-----------------------|---|---|---|-----|
| CONFIRMATION STATUS | SITE NAME | SITE CODE | PARENT ORGANISATION | TIME PERIOD | PARTICIPANT STATUS | TOTAL PARTICIPANTS | = | Confirmation Status Site Name Site Code Parent Organisation Time Period | 1 | ΔΤΕ |
| Requires Confirmation | THE ROYAL LONDON HOSPITAL (Benjamin Bloom / Imogen Skene) | R1H12 | BARTS HEALTH NHS TRUST | May 2019 | Consented | 6 | • | Participant Status Participant Type Total Participants | | |
| Requires Confirmation | THE ROYAL LONDON HOSPITAL (Benjamin Bloom / Imogen Skene) | R1H12 | BARTS HEALTH NHS TRUST | May 2019 | Recruited | 6 | | | | |

5.3 Downloading your data as an Excel spreadsheet

You can click the EXPORT ALL LPMS RESEARCH ACTIVITY button to download all of the research activity data for your study as an Excel spreadsheet.

[Top tip: the Excel spreadsheet download will contain all of the research activity data received from LPMS to date for your study; it will not reflect any filters you have selected on the screen, including the Period filter. It therefore may contain data from the current month. It will also exclude any data uploaded manually to CPMS by spreadsheet. Please see section 11 for information on checking and amending any data provided by spreadsheet.]

The excel export will be especially useful if your study involves a large or otherwise complicated data set, as you will be able to manipulate the data easily and compare it to your local central data set.

You can then use the <u>filter functionality</u> to find any lines of data you need to highlight as inaccurate in the CPMS confirmation screens and apply <u>the inaccurate confirmation</u>, and finally you can <u>confirm all of your other data as accurate</u> together.

If you require any additional support with confirmation at any time, please contact us.

5.4 Changing the confirmation contact for your study

We know that teams change and so, if you are confirming data for your study on a monthly basis but need to transfer this role to another person, please contact us using the Key Contacts section to let us know who will be taking over the role. Please provide the new contact's name and email address.

6. Recruitment definitions and site information

6.1 Participant statuses - Consented, Recruited, Failed Screening

We now have the ability to receive Consented, Recruited and Failed Screening data for all studies.

The NIHR definitions of these Participant Statuses is as follows:

Consented: the participant provided informed consent to join a study.

Recruited: the participant provided informed consent to join a study and is taking part in the study (i.e. participants who count towards the sample size of the study as set out in the study protocol and having been deemed eligible according to any screening tests applicable)

Failed screening: the participant has given consent to non standard clinical investigations, procedures or tests relating to a study, but following these procedures was found to be ineligible to take part in the study.

[Top tip: you may be asked to confirm zero activity for the Failed Screening status, even where your study does not include screening activities. Since you are not expecting any activity for this status, you can simply confirm it as correct. Please see section 9.5 for steps to take if you would prefer to stop receiving this data.]

[Top tip: some observational studies will count their consent and recruitment at the same time. For these studies you may receive a line of data for consent and recruitment, but the totals should match.]

[Top tip: You will see aggregated totals for the Participant Statuses of Consented, Recruited and Failed Screening. You should also keep in mind that one participant can be counted as consented and also as recruited/failed screening. Therefore, all of your participants that have consented to take part will be in the consented total, and will remain counted towards that total even if they later become a recruited or failed screening participant.]

Please see <u>section 10.1</u> of this document for more on resolving queries related to the participant status, and our <u>Recruitment Policy Document</u> for more information on the NIHR CRN research activity policy.

6.2 Confirmation statuses

The confirmation statuses in the confirmation screens alert you to the data that require action, and the data that have previously been confirmed.

The definitions of these statuses is as follows:

Requires Confirmation: this is new data that should be reviewed and confirmed as accurate or inaccurate.

Requires Reconfirmation: this is data that was previously confirmed as accurate or inaccurate and has been subsequently updated. It therefore needs to be confirmed as accurate or inaccurate.

Confirmed - Not Accurate: this is data that has been confirmed previously as inaccurate.

Confirmed - Accurate: this is data that has been confirmed previously as accurate.

[Top tip: unless you would like to amend confirmation for the Confirmed - Not Accurate and Confirmed - Accurate data, there is no need to do anything with data with these statuses. For guidance on changing previously confirmed data please see section 9.1 in this document.]

6.3 Participant type

While the majority of studies will be recruiting patients, many will also recruit different kinds of participants, e.g. health care professionals, healthy volunteers or carers.

In order to provide more nuanced reporting, the NIHR CRN in England capture the following participant types:

| Participant Type | Definition |
|---|---|
| Participant with the relevant condition | Participant who has one or more of specified disease(s) / condition(s) under investigation in the study. |
| Participant without condition | Participant who does not have a relevant condition at the point of their entry into the study. |
| Carers | Participants responsible for providing care to another individual; for children this would generally be their parent or guardian. |
| Genetically predisposed | Genetic analysis has revealed for these participants the genes they carry mean they are more likely to develop the condition under study. |
| Pre condition | Participant at clinically defined risk of relevant condition or disease or participant with a condition that can lead to condition under study. |
| Relations | Genetically related to individual with relevant condition / disease (blood relative). |

| Diagnostic, screening or prevention participants | Participants that may have the condition under study now or at some point in the future but this is unknown at the outset of the study. |
|--|---|
| Professionals | Any member of staff who is recruited due to their professional relationship to the patient group /service evaluation etc. |
| Other | Participants who do not fit one of the above categorisations. |

If your study is recruiting more than one participant type, there will be a separate line of data in the research activity table for each site, month participant status (e.g. consent) and participant type:



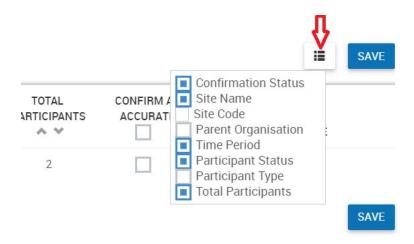
In the example above, the study is recruiting both participants with the relevant condition (i.e. patients) and carers, as reflected in the Participant Type column. Therefore there are two lines of recruited participant data for October 2018.

[Top tip: we will not receive Participant Types from Welsh and Scottish sites, and from many sites across England and Northern Ireland. All of your recruitment from such sites will be presented with "Not provided" as the Participant Type.]

Please see <u>section 10.2</u> of this document for information about what to do if you think the participant types received are not correct for your study.

6.4 Site Code and Parent Organisation

You can view the site code and parent organisation information for your data in the Detailed View of the confirmation table by using the menu button next to the button:



You can also hide any columns you don't wish to view by unchecking them in this menu.

Troubleshooting and support

In this section you will find information on what to do if you need further support to provide confirmation or you have questions about specific aspects of your research activity data.

For general information on the NIHR CRN Recruitment Policy, please see our <u>policy</u> <u>document</u>.

7. Key contacts

For non-commercial research led in England please contact your <u>Local Clinical</u> <u>Research Network</u>.

For commercial research, please contact the Clinical Research Network Coordinating Centre: crncc.support@nihr.ac.uk

For studies led in Wales, please contact: portfolio@wales.nhs.uk

For studies led in Scotland, please contact your local Health Board, or, if you are unsure of your local Health Board contact details, Hannah Wynne: hannah.wynne@nihr.ac.uk

For studies led in Northern Ireland, please contact: NICRNPortfolio@nicrn.hscni.net

If you are unsure who to contact, please contact our Study Support Service Helpdesk: email supportmystudy@nihr.ac.uk or call 0113 343 4555.

8. CPMS access and study information queries

8.1 I can't log in to CPMS

If you are unable to gain access to CPMS, please ensure you are using https://cpms.nihr.ac.uk/ to log in. Please find guidance on logging in the CPMS section (under the 'Working in the CRN' header on NIHR Learn.

For further log in help, please contact our Service Desk: crn.servicedesk@nihr.ac.uk.

8.2 I can't find my study in CPMS

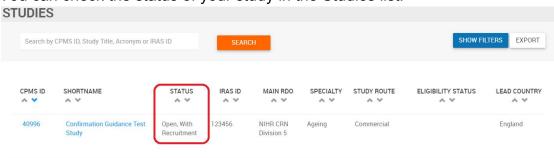
There are two areas of CPMS where you can find your study: the Studies section and the Confirm Research Activity section.



If your study is not listed under either of these sections, or if you do not have access to these sections at all in the menu, please use the Key Contacts section above to contact the relevant team, who can ensure your account is linked to your study correctly. Please provide the details of the study you are trying to access and the email address you are using to log in.

If your study is listed under the studies section, but not under the Confirm Research Activity section (or if this latter section is missing), this suggests that your study is not yet open to recruitment and/or no research activity data has yet been received for the study.

You can check the status of your study in the Studies list:

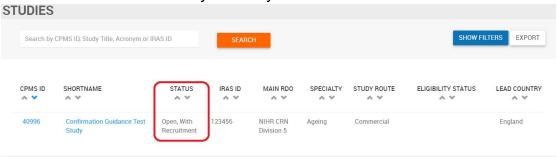


If your study has a status of "In set up—", but should be open to recruitment please let us know. For non-commercial study records, you can open the study in the study record, or contact us using the Key Contacts section above. For commercial studies, please contact us to alert us to the new study status.

If your study is "Open to recruitment" and you are not able to access it in the Confirm Research Activity section, we may not have any research activity data for your study yet. If this is the case for your study and you think recruitment data should have been received, please let us know, using the Key Contacts section above.

8.3 My study is not open to recruitment in CPMS

You can check the status of your study in the Studies list:



If your study has a status of "In set up—", but should be open to recruitment please let us know. For non-commercial study records, you can open the study in the study record, or contact us using the Key Contacts section above. For commercial studies, please contact us to alert us to the new study status.

8.4 My study details are incorrect

Upon entering the confirmation screen you will see some of your study details:

| CPMS ID: | 41295 |
|--------------------------------------|--|
| Short Name: | Research Activity Confirmation Training |
| Actual Recruitment Start Date: | 01/01/2017 |
| Planned Recruitment Closure Date: | 01/08/2019 |
| Study Status: | Open, With Recruitment |
| | |

If your study is a non-commercial study you can amend the majority of these details

in the study record in CPMS. You can access the record using the hyperlink at the top of the page.



If you are unsure of how to amend the details in the study record, or if you are a commercial representative, please contact us using the <u>Key Contacts</u> section to alert us of any change that should be made.

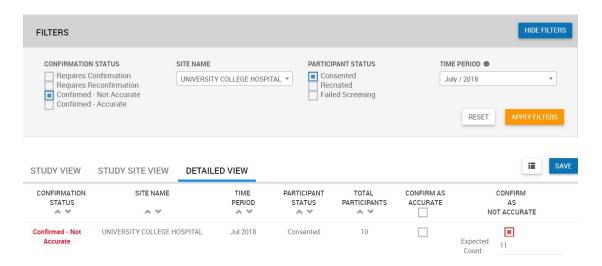
8.5 Changing the Research Activity Contact for your study

If the confirmation role for your study needs to be transferred to another person, please contact us using the <u>Key contacts</u> section. Please provide the new contact's name, title and email address.

9. Confirmation queries

9.1 I need to change a confirmation status

If you have previously confirmed data as accurate or inaccurate [see section 4.5] and section 4.6 for details on how to confirm data] and you want to amend the status, you can easily do so in the confirmation screen.



In the example above, the filters have been used in the detailed view to search for the line of data that needs to be amended.

If the data should be amended to a different confirmation status, all you need to do is check the box to indicate the new status for the row and click save to complete the

change.

If you wish to amend a status back to Requires Confirmation, simply uncheck the box that is currently selected to remove the status and click SAVE.

Note that once you click save, depending on the filters you have applied, the row of data may disappear from view.

9.2 I keep being asked to reconfirm data

As far as possible, we would like data to be received and confirmed only once, to ensure that the process is as simple as possible for confirmers. If you are finding that your data has the status Requires Reconfirmation more than you would like, there are a few things you may want to check:

1. When you are confirming your data, are you ensuring that you set the Period on the confirmation screen to "Until the end of last month"?



If you don't set the Period to "Until the end of last month" before you confirm, you may inadvertently confirm data from the current month. If there is then further research activity received for the current month, it will automatically be logged as data that Requires Reconfirmation. So always ensure you set the Period before you start confirming.

2. Are some of your sites slow to update all of their data for each month or are you confirming too early in the month?

If one or more of your sites tend to be missing data when you come to confirm, only for you to have to log the data as inaccurate and then reconfirm the data once it has been completed, it may be worth contacting your site(s) to agree a date each month for them to complete their previous months' data by. You may find that agreeing a date slightly later in the month will allow your site(s) time to complete the data correctly before you confirm, thus negating the need for you to log data as inaccurate and then having to reconfirm.

[Top tip: Scotland and Wales will upload their data into LPMS on a monthly basis, and therefore, if you have participating sites in Scotland or Wales, you may wish to confirm your data later in the month for the previous month, to ensure that the data is complete.]

If you need any help in contacting your sites, or you think they need additional support in capturing their data, please contact us.

9.3 I've received research activity data from a site that is not recruiting to my study

If you receive research activity data for a site that is not actively recruiting participants into your study, including Patient Identification Centres (PICs), you can mark this as inaccurate in the normal way, and include a note to indicate that the site is not a recruiting site in your study.

It would also be helpful if you highlight this to the relevant team, especially if you are continuing to receive data after you have flagged that the site as not participating via the confirmation screen.

9.4 A recruiting site in my study is missing from the confirmation screen

All sites should start to populate data for confirmation as soon as they open to recruitment. If a recruiting site in your study has been open for more than a month and is not appearing in the confirmation list, please contact the relevant network team so that they can check the details of the site in CPMS and LPMS.

9.5 I'm seeing inaccurate Failed Screening activity

The Failed Screening status should only be used where a study has a screening period, defined as:

★ The study requires participants to give informed consent to non standard clinical investigations, procedures or tests for the purposes of determining their eligibility for the study

We stop generating Failed Screening inactivity if the CPMS study record is flagged as having no screening activity. However, currently for many studies this information is missing or incorrect.

If you would like to update us about the screening status of your study because you are seeing Failed Screening data where you believe you shouldn't, or you expect to see this data but it's not present, please <u>contact us</u>.

9.6 My inaccurate data has not been amended

Once data is saved as Confirmed - Not Accurate, the confirmation status and additional information you have supplied flows back to the LPMS where it originated so that it can be reviewed and corrected at source.

Once the data is amended, it is sent back to the CPMS confirmation screens, which automatically changes the status to Requires Reconfirmation, so you can review and reconfirm it.

We expect inaccurate data to be reviewed and amended by an LPMS user within 2 weeks, and our networks will be monitoring the data to ensure sites are reviewing and amending their inaccurate data promptly.

However, if you find that your inaccurate data has not been amended in a significant amount of time, and wish to follow up on this, please <u>contact us</u>.

9.7 My data set is large or otherwise complicated to confirm

We acknowledge that studies with large or otherwise complicated data sets may be more difficult to review.

In order to help you confirm such data sets, we have provided some additional functionality in the confirmation screens in CPMS.

The first of these is the <u>filter functionality</u>, which allows you to filter by Participant Status and Confirmation Status, as well as to choose a specific site and/or month to review. Please see <u>section 5.1</u> of this document for more information.

Secondly, you can download your complete dataset at any time into an Excel spreadsheet, by clicking on **EXPORT ALL LPMS RESEARCH ACTIVITY ®** .

This will provide you with a spreadsheet containing all of the data we have received electronically to date. You can use the spreadsheet to manipulate the data, review any subsets, and also to make comparisons with data you hold on the study in your team spreadsheets or databases.

We therefore advise that the Excel spreadsheet can be used to identify any inaccuracies more easily than using the confirmation screens for large datasets. You can then use the filter functionality to identify any inaccurate rows in CPMS and confirm them as inaccurate. This will allow you to finally confirm all other data as accurate at the study level, as you will be confident that the remaining data is correct.

It's also worth remembering that for cross-border studies, you may receive different data points. Please see <u>section 4.10</u> for more information.

While we encourage you to provide confirmation for all Participant Statuses as far as possible, if you are finding that your data is very incomplete and it will be too time consuming to identify and log all of the inaccuracies, please concentrate on confirming the Recruited data only and leave these other points as unconfirmed.

Finally, if you need any additional support with confirmation, please <u>contact us</u> at any time.

9.8 There are too many zeros!

In order to provide a complete picture of the research activity for your sites each month, we generate lines of inactivity, or "zeros", so that you can advise where a site should have recruited, but has not provided data, is in the example below.



However, we know that in some cases, working through these lines of data, especially when you have a lot of participating sites but only a few that recruit each month, can be challenging. If this is the case, we advise that you use the sort functionality in the Detailed View to bring the sites with recruitment to the top of the list.

Clicking the down arrow under the total participants column, will change the view from this:



To this:

| CONFIRMATION STATUS | SITE NAME | TIME PERIOD | PARTICIPANT STATUS | PARTICIPANT TYPE | TOTAL PARTICIPANTS | CONFIRM AS ACCURATE | CONFIRM AS NOT ACCURATE |
|--------------------------|------------------------------|----------------|-----------------------|--|--------------------|------------------------|-------------------------------|
| Requires Confirmation | ROYAL SHREWSBURY HOSPITAL | Oct 2019 | Recruited | Participant with the relevant condition | 5 | | |
| Requires Confirmation | KING'S MILL HOSPITAL | Oct 2019 | Recruited | Participant with the relevant condition | 4 | | |
| Requires Confirmation | QUEEN ALEXANDRA HOSPITAL | Oct 2019 | Consented | Participant with the relevant condition | 4 | | |
| Requires Confirmation | QUEEN ALEXANDRA HOSPITAL | Oct 2019 | Recruited | Participant with the relevant condition | 4 | | |
| Requires Confirmation | BRADFORD ROYAL INFIRMARY | Oct 2019 | Recruited | Not Provided | 3 | | |
| Requires Confirmation | GOOD HOPE HOSPITAL | Oct 2019 | Consented | Not Provided | 3 | | |
| Requires | GOOD HOPE HOSPITAL | Oct 2019 | Recruited | Not Provided | 3 | | |

As you can see, the sites that have reported activity are now filtered to the top. This filter has also now changed the way this information is presented in the Study Site View, should you prefer to confirm in that view.

Once you have worked through all of your sites that have reported recruitment, remember to ensure that there are no sites that should have reported recruitment, but have not. If you have any such sites, use the filter functionality to locate them in the Study Detailed View and report the missing recruitment.

9.9 I have "duplicate" lines of data in my data set to confirm

If you have what looks like a duplicate line of data in CPMS, it's usually the case that participant types have been amended in LPMS.

Often this means that Participant Types have been retrospectively added to participants where this was previously unknown. In this case, LPMS will send an update to the original line they sent, reducing this to zero, and a new line with the new participant type included with the number of participants in LPMS included in the 'Participant Count'.

For example:



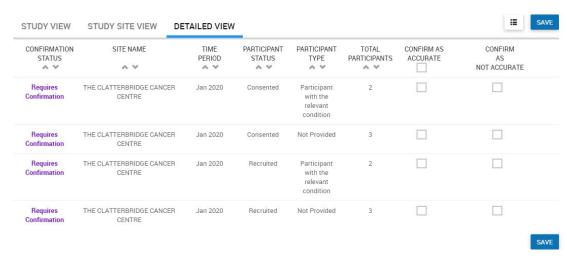
If you had previously confirmed the line without a participant type, then the zero lines will appear as Requires Confirmation instead:



Seeing a zero against 'Not Provided' in this scenario means that the Participant Type was added retrospectively, therefore this 'Not Provided' line can be confirmed as accurate as the data exists against the new participant type. Confirming this information as accurate will not overwrite the data in the line with the Participant Type. The line with the Participant Type will need to be reviewed as usual.

If, however, you have some data against 'Not Provided' and another 'Participant Type' for the same month and site, this means that some of the participants have a participant type listed against them while others do not.

For example:



Each of these lines will need to be reviewed in the usual way.

If the lines you see duplicated appear to be true duplicates, e.g. where you are expecting 3 consents and 3 recruits for January 2020 at Clatterbridge Cancer Centre but receive the following for confirmation:



This suggests there is a problem with our system. Please confirm the lines with the correct Participant Type as accurate, and confirm those with the incorrect type as inaccurate. Please also raise this with <u>your local support team</u>, as they will be able to ensure that issue is resolved.

10. Recruitment policy queries

The NIHR CRN recruitment policy can be found here.

Policy in Scotland, Wales and Northern Ireland may vary, so please contact the relevant administration if you have queries about recruitment in these nations.

10.1 How should my study capture consent, recruitment and failed screening information?

The majority of studies will have clear points of consent, recruitment and screen

failure.

It is important to liaise with your participating sites, at site set-up if possible, to ensure everyone is capturing these data points in the correct way for your study.

For many observational studies, consent and recruitment will take place on the same day, as the participant will consent and begin to take part in the study at the same time. These studies will therefore have equivalent lines of data for consented and failed screening from each site.

[Top tip: although we will be able to receive data each month for participants that have been Consented, Recruited and Failed Screening, we may not reliably receive the new Consented and Failed Screening data immediately. If you are finding that this data is very incomplete and it will be too time consuming to identify and log all of the inaccuracies, please concentrate on confirming the Recruited data only and leave these other points as unconfirmed.]

If you have any questions about how participant consent, recruitment and screen failures should be captured for your study, or if you think you are receiving incorrect data and would like network support to resolve this, please contact us.

10.2 Which participant types should my study capture?

Please see <u>section 6.3</u> of this document for a full list of the participant types we capture in England. It is important to liaise with your participating sites to ensure everyone is capturing these data points in the correct way for your study.

If you have any questions about which participant types should be captured for your study, or if you think you are receiving incorrect participant types in your research activity data and require further support, please contact us.

10.3 Withdrawn participants

If a participant consents and takes part in your study, but later withdraws, the research activity that has been captured up until that point for the participant should remain in the system. There is no need to ask your teams to remove participants from their LPMS, or to flag the inclusion of these participants in your data in CPMS as inaccurate.

For more information on the NIHR CRN Recruitment Policy, please see our policy document.

10.4 My study does not involve consent

Studies that do not involve the informed consent of participants may be eligible for inclusion on the NIHR CRN Portfolio, or the portfolios of Scotland, Wales and Northern Ireland; however, these studies should not usually capture research activity data. Please see our <u>Recruitment Policy Document</u> for more information on different

types of consent and how they should be captured.

If you are have any questions related to consent, please contact us.

11. Manual spreadsheet upload and LPMS queries

11.1 Amending data previously uploaded by spreadsheet

If your study previously captured data using the manual upload method, you can still review, amend and add to this data using the manual upload process.

[Top tip: you can only add and amend data using the manual upload method for the period between your study opening to recruitment and the time the study was changed over to the LPMS/electronic research activity route. You will not be able to add data outside of these dates. If you would like to check the LPMS start date you can do so by going to the CPMS study record and viewing the Design tab. Details of navigating to the design tab are below.]

You can see the totals of your manually uploaded data in the Confirmation Dashboard:

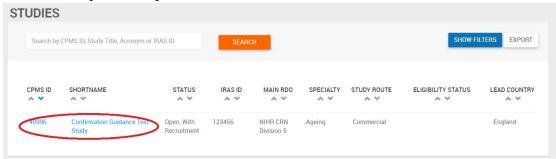
| PARTICIPANTS | PROVIDED BY SPREADSHEET (HISTORICAL DATA) | | PROVIDED ELECTI START DATE: 01 | | | TOTAL PARTICIPANTS |
|------------------------------|--|--------------------------|-----------------------------------|--------------------------------|----------------------|--------------------|
| | | Requires Confirmation | Requires Reconfirmation | Confirmed - Not Accurate | Confirmed - Accurate | |
| Consented 0 | N/A | 1 | 10 | 4 | 122 | N/A |
| Recruited 6 | 4 | 7 | 9 | 2 | 80 | 102 |
| Failed Screening 6 | N/A | 5 | 2 | 0 | 94 | N/A |

If you are a company contact confirming data for a commercially-sponsored study and you think the recruitment totals for the data uploaded by spreadsheet is incorrect, please contact our support team: crncc.support@nihr.ac.uk.

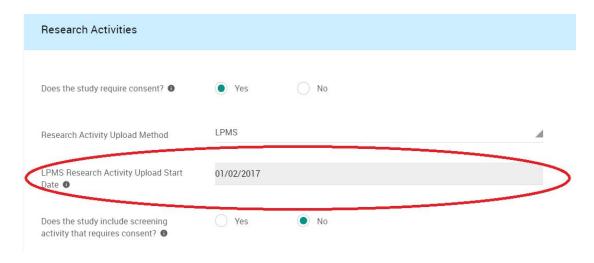
If you are a non-commercial study contact, you can review your manually-uploaded data in the CPMS study record. To find your record, choose Studies in the left-hand navigation bar of the screen in CPMS:



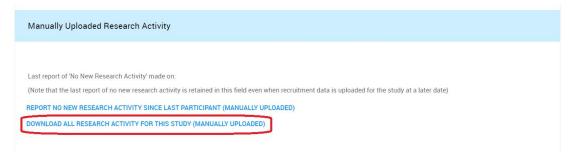
Then locate your study and click the CPMS ID or Short Title:



Once you are in the study record, press and then choose DESIGN . You can check the LPMS start date by scrolling down to the Research Activities section:



If you then scroll further down the screen you will come to the Manually Uploaded Research Activity section. In this section you can download the spreadsheet containing all of the research activity that was uploaded using the manual upload method:



Once you have downloaded the data, if you want to add participants who were recruited prior to the LPMS start date for your study, you can do so and upload the data directly to CPMS, using the Submit Research Activity Data area:



If you are having trouble uploading data using the spreadsheet, or if you require data to be removed or amended, please contact us.

11.2 My study is using the spreadsheet upload only (exception studies)

While the majority of studies will capture research activity data using the electronic process, some studies will continue to upload their data directly into CPMS by spreadsheet. When your study deemed eligible and is added to CPMS, the upload route will be communicated to you.

A guide to uploading your recruitment by spreadsheet can be found <u>here</u>.

If you have any questions about the research activity data upload method for your study, or you are having any problems uploading your data, please contact us.

11.3 LPMS Queries

If you have any queries about using a Local Portfolio Management System, please contact us.