

GD059 Resolving CPMS Confirmation Queries

1. Background

Data is sent to CPMS (Central Portfolio Management System) from EDGE every night with any changes to the data which have been recorded in EDGE in the previous 24 hours. This will include any participants added to EDGE, updated on EDGE, or deleted from EDGE.

A count of the participants on EDGE for each month automatically sends to CPMS and is marked as 'accurate' or 'not accurate' by the lead study team.

If the participant recruitment data is marked as 'accurate', the data will count towards the recruitment target and be counted in the national metrics and, where applicable for non-commercial studies, any excess treatment costs are able to be paid.

If the data is marked as 'not accurate' this is known as 'Recruitment activity (RA)' or 'CPMS Confirmation' queries. These queries need to be resolved in the financial year that they are raised in. If the queries are left outstanding, the recruitment will not be counted in the national metrics and any excess treatment costs will not be paid.

It is therefore highly important that all CPMS Confirmation queries are resolved in a timely manner. Please see below for the guidance on how to resolve them.

2. Recruitment Activity Statuses

- a. There are three types of Recruitment Activity (RA) status in CPMS:
 - **Consented** – the day that informed consent was received.
 - **Recruited** – the day that participants were randomised. If randomisation is not a requirement for this study, this will be the same day that participants were consented.
 - **Screen Fail** – the day that participants, after their consent, are no longer eligible for the study.
- b. It is these statuses that are linked with CPMS every 24 hours.

2.1 Participant Type

- a. Each participant in Edge should be assigned a Participant Type
- b. This field can be found in the Overview page of each participant record

- c. The above RA statuses are recorded from Edge to CPMS for each Participant Type, per month, per site

3. Identifying CPMS Confirmation Queries

- a. Once marked as "not accurate" in CPMS, the queried data will appear in a report that is regularly run by the Research Governance Team.
- b. The report will include a number of study identifiers and also the following important fields:
1. RA Date – this is the month which the queried data was recorded in
 2. Activity type – this will be one of the three statuses listed in Section 2
 3. RA in Edge – this is the Recruitment Activity recorded in Edge within the month identified
 4. Expected RA – this is the expected Recruitment Activity for that Participant Type
- c. All of the above can also be identified via the CPMS Confirmation Tab on the Red Level in Edge. The flag icon on the tab menu will turn red if there is an unresolved query (see image). Also in this tab, you can update the Review Status from "To be resolved" to "In progress" or "Resolved". Please note, changing this review status is for local reporting only and will not update any changes in CPMS, this has to be done in Participant records in Edge, as described in Section 4.
- d. The report will identify any queries by the month the RA took place, it will not identify specific participants. It is therefore important to note any RA in the neighbouring months either side of the query as this may provide an answer as to any discrepancies.



4. How to Resolve CPMS Confirmation Queries

- a. Once the CPMS Confirmation queries have been identified, try the following steps to resolve them:

4.1 Check dates

- a. Start by comparing the dates in Edge with the Screening/Enrolment Log/Consent Forms. The dates in Edge should match. The dates can be found on the Participant Overview Tab.
- b. Pay particular attention to the dates of consent, randomisation and, if applicable,

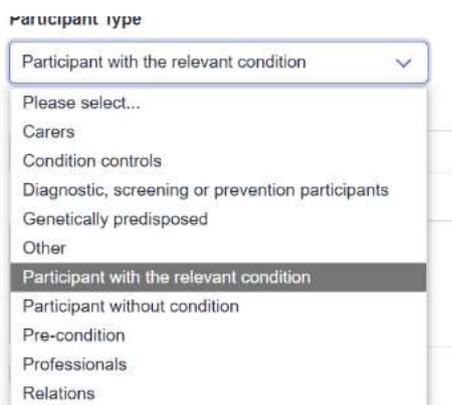
| Status | Date | Actioned by |
|------------------------|------------|--------------|
| Pre-Screened | 15/11/2023 | Hodge, Emily |
| Approached | 15/11/2023 | Hodge, Emily |
| Consented | 15/11/2023 | Hodge, Emily |
| Screened | 15/11/2023 | Hodge, Emily |
| Recruited / Randomised | 15/11/2023 | Hodge, Emily |

screen failures. Ensure none of these dates have been left blank when the relevant Recruitment Activities have taken place.

- c. If there is an error/missing date in Edge, be sure to update it accordingly. This update should then be uploaded in CPMS upon the next automatic upload.
- d. If all dates match the Screening/Enrolment Log/Consent Forms, please try the next step below.

4.2 Participant Type

- a. As CPMS searches for each RA status by Participant Type, it is essential that this field is completed for each participant.
- b. If a participant is not assigned a Participant Type, CPMS will not receive a record of that participant, generating a Confirmation Query.
- c. The field can be found in the Overview Tab on the Participant Level.
- d. The following Participant Types are available:



- e. Most interventional studies are likely to include "Participant with the relevant condition". However if there are healthy volunteers or other groups, please select the most appropriate type from the drop down list.
- f. Once the Participant Type has been updated, the changes will be uploaded to CPMS upon the next automatic upload.
- g. If the query still persists after following these steps, please contact the Research Governance Team.

4.3 Screen Failures

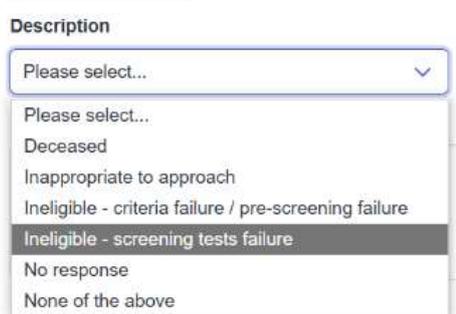
- a. If a participant has screen failed, it is important to ensure their Edge record has been appropriately updated. If not, this can create CPMS Confirmation Queries.
- b. In order to do this correctly and to prevent a query, please follow the steps below:

- c. Under the Overview tab of the relevant participant, select “Take Off Study”.

NB: If a participant has screen failed, they have been found no longer eligible prior to randomisation. Therefore, it is important that the date “Recruited / Randomised” is left blank before they are taken off the study.



1. Tick “Participant is Off Study”
2. Complete the date this happened
3. Add your name under User
4. Select “Clinical” from the Decision drop down
5. Finally select the Description from the drop-down menu. Please note, if this screen fail has occurred after consent, the correct option to select is “Ineligible – screening tests failure”. Please see picture below.



If the incorrect Description is selected, this can generate confirmation queries.

If none of the above steps have resolved your CPMS Confirmation Query, please contact the Research Governance Team.