STH Research Informatics Reference Guide

V1.0 12/10/22

Contents

Contacts

- CRIO Research Governance Facilitators
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- CRFM Queries
  - Imogen Wilson – Imogen.Wilson2@nhs.net
- CPMS Queries
  - Jenny Powell – Jenny.Powell1@nhs.net
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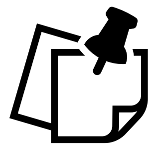
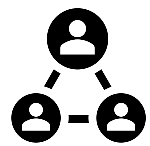
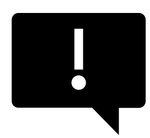
Action Symbols

- Useful information 
- New role 
- Example 
- Action required 

The EDGE System

Directorate Coordinators, Admins and
CCTC research support

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What is EDGE?

- https://www.edge.nhs.uk/
- EDGE a recruitment database and all STH projects are created on the system to collect data about the project for the CRN and for STH
- Where we receive accrual for recruitment of participants, data will need to be recorded on the patient tab
- For projects which do not have any portfolio accrual, we do not need data/datasets to be uploaded
- For PIC sites we do not need data to be upload

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Use of EDGE

- Currently we assign manage access to the administrative teams in EDGE when a project is authorised (CCC).
- We also assign the named recruitment contact in RMS with clinical access
- When you have Manage access you can change who has clinical access and add new staff to the project as required

- We have asked until now that EDGE is generally used only for adding recruitment data by the directorates

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Updating EDGE

- We would like the directorate teams to have more control over EDGE in updating dates, reviewing recruitment and error logs which are present
- EDGE 3 (next EDGE) is also on the horizon and there will be some changes to how the system looks. By familiarising the teams with what is in EDGE we hope that this transition will be easier

- This guidance booklet is to give some background about the functionality of EDGE and the links to other systems in CRIO and the CRN

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GREEN Level

- Project level, there is one of these per study, and we will own the project level if we are Sponsor
- Projects are transferred ownership to other organisations if they are created by someone else (e.g. from the CRN Y&H to STH)
- Data on here relates to the **overall study** (start date/end date etc.)
- Data from CPMS is pushed into Green Level of EDGE. This means that the end date is actually the RECRUITMENT End date (as this is what the portfolio care about)
- You can check if the record if the CPMS primary record by clicking on Settings on Green level
- Individuals can have manage or view access for this tab.
- There are some attributes on GREEN level which can be helpful to review (e.g. CPMS recruitment upload route – via EDGE or straight to CPMS called Manual)

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RED (Pink) Level

- Site level, there is one of these per "site"= NHS Trust/hospital.
- This is usually one per NHS organisation, however for studies recruiting across lots of sites, recruitment might be split across different hospitals (e.g. NGH, Jessops, RHH)
- Recruitment data belongs here and you can find the CPMS data log here too
- Patient tab can be reviewed for those with clinical access to record recruitment data
- When studies are very high recruiting (e.g. a survey) a bulk upload of recruitment data is possible – Speak to the Research Governance Facilitators regarding this
- Staff tab shows the access for each person assigned to the project. At set up, STH adds directorate contacts and the named recruitment contact from RMS to EDGE.
- If you have manage access, you can change access type.
- E.g. if you have multiple nurses / CTA who need to upload recruitment data you can change this

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Patient Tab

- For those with clinical access the patient tab will appear
- This allows you to see all the patients on the study
- You can also click on an individual patient and add specific attributes to them. This can be useful if we need to identify that different teams have recruited different participants
- It could be useful for the study team to record any other study specific information
- You can run reports looking at the patient attributes

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Under this change EDGE belongs to you!

- We would like EDGE to belong to the directorates as a location to keep their records
- If you notice an error in the recruitment window on EDGE and you have manage access, please update this!
- Changing EDGE won't change RMS but we can review the differences
- If you change a date for best practice have evidence saved (alfresco section 12) and a diary entry so RMS can be updated

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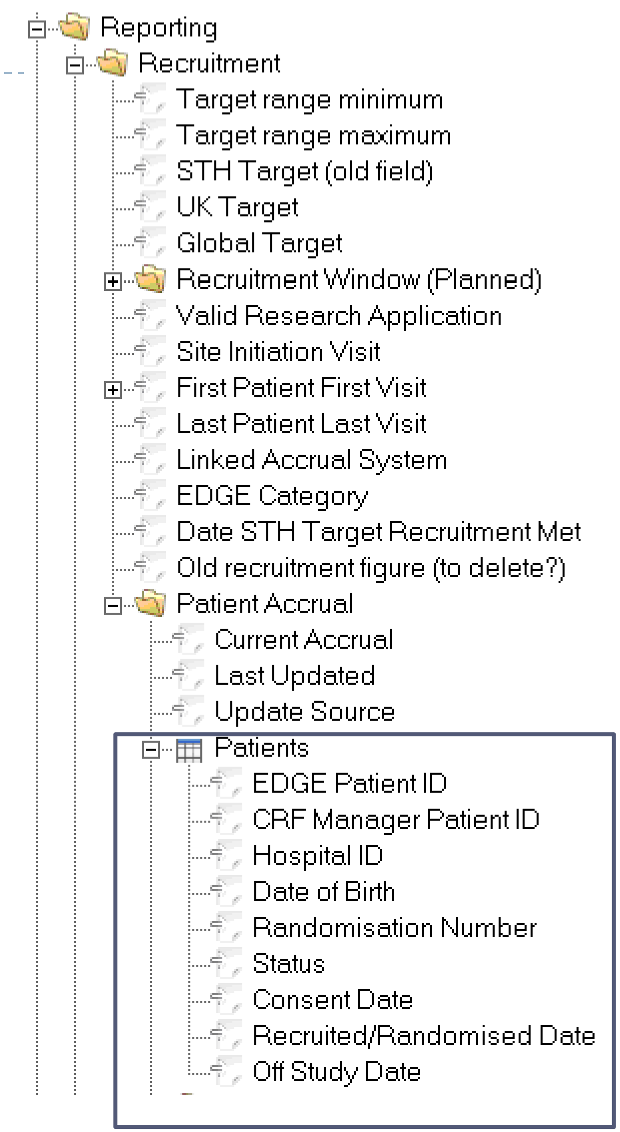
Reports

- If required we can produce reports in EDGE
- These can only be created per data type – e.g. study attributes or patient attributes
  - You would need to match more than report together if you are to create a report with multiple fields from the patient and the study level reports
- Because of this, we suggest that all reports are conducted in RMS (or CRFM if this is what you are looking at).
  - Recruitment data can be pulled into a report using the fields found on Project level RMS
  - Data can be filtered by Recruited/Randomised date by for example financial year to record how many participants were recruited
- This allows all fields present in RMS to be used at the same level as patient data
- If you have queries about reports please contact the Research Governance Facilitators



Definitions for dates

- Recruitment end date
  - **Planned** recruitment end date, is added from OID at the start of the study, is amended as the study progresses via amendments or emails
  - **Actual** recruitment end date is inputted when the study closes to recruitment officially.
    - This is usually complete as part of PID where it is essential this is correct and evidenced
- Actual recruitment end date **cannot** be in the future of planned recruitment end date
  - This looks to the CRN like we have kept recruiting when the sponsor has told us to stop!

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- Overall study end date
  - **Planned end date** is added as per the IRAS form and amended during the study as part of amendments, annual progress reports or emails from the Sponsor
  - **Actual end** for **STH Sponsored** studies is the date on the end of trial declaration
  - **Actual end** date for **externally sponsored** studies can any of: date STH activity stopped (Close out visit), the date the Sponsor notified that the trial had ended or the date on the end of trial declaration.
    - We allow for different dates as we may not always receive overall study end date
- We will use the same approach as recruitment end date where planned end date **cannot** be in the past of actual end date

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Completing EDGE

- Example 1:
- You are told that the study closed on 01/04/2021 as close out visit has occurred and no more patient activity is to occur
  - The planned end date in RMS is 01/01/2021
- Action:
  - Update EDGE planned **and** actual end date to be 01/04/2021
  - Notify CRIO to update RMS to be end date to be 01/04/2021 and select SITE from the drop down

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- Example 2:
- You are told by the Sponsor that the study has now finished as the study has prematurely ended on 01/04/2021
  - The planned end date in RMS is 01/08/2022
- Action:
  - Update EDGE actual end date with 01/04/2021, **leave** planned end date as 01/08/2022
  - Notify CRIO to update RMS end date to be 01/04/2021 and select UK or Global from the drop down depending on information from the Sponsor email
  - Enter 01/04/2021 on regulatory tab ethics, end date

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Closing Studies on EDGE

- If you are updating a study to be ended, please use the status completed
- Notify CRIO to allow emails to be filed and PSTs to be moved from "open" to "ended"
- Please file and correspondence in section 12 and add a diary entry

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CPMS, EDGE AND CRFM

All research support

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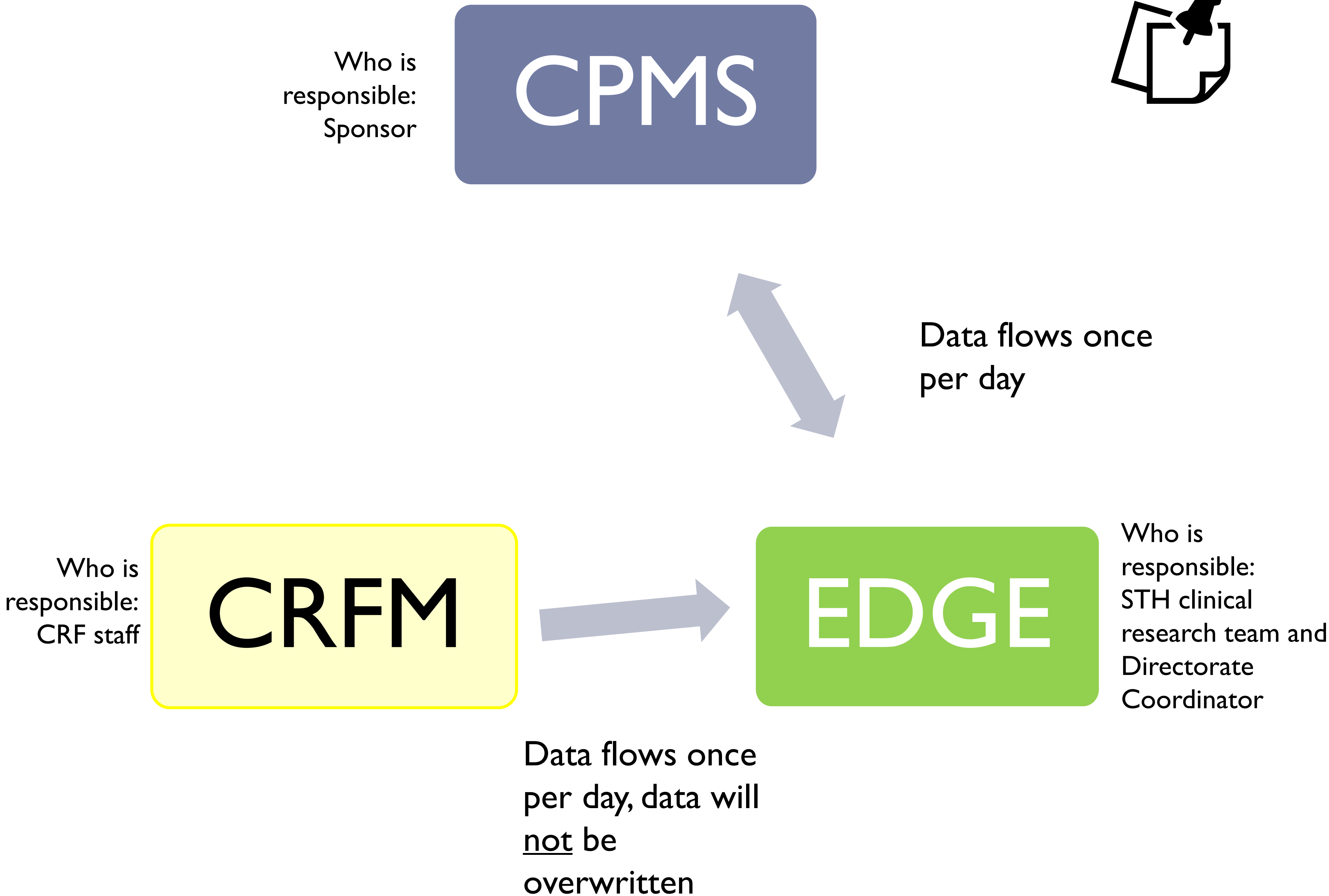
CPMS
Who is responsible: Sponsor
Data flows once per day
CRFM
Who is responsible: CRF staff
EDGE
Who is responsible: STH clinical research team and Directorate Coordinator
Data flows once per day, data will not be overwritten

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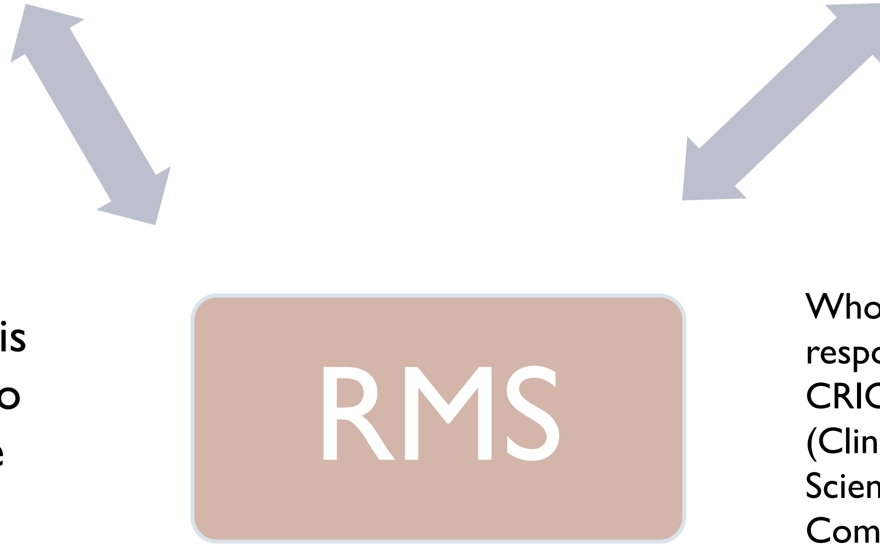
Recruitment data is visible according to the accrual source (reporting tab) from CRFM or EDGE



Who is responsible: CRIO and CReST (Clinical research Scientific Computing team)

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CPMS

- Portfolio projects require recruitment data entering on Central Portfolio Management system (CPMS)
- Recruited = date that participant passes screening
- Consented = date that any participant consents (regardless of eligibility).
- They can be uploaded to in two method, manual (directly to CPMS via the main study contact), or via EDGE (Local portfolio management system – LPMS)
- The data is provided to CPMS in monthly summaries.
- Number of participants consented in a given month and number of recruited participants in a given month (consented participant passes screening).
- This is also visible per Participant type (participant with relevant condition/carer/healthy volunteer etc.)
- The sponsor reviews the data and has the option to accept or reject the number of participants on each month. They cannot edit. A note can be provided to the study team.

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CPMS links with EDGE

- If data is rejected by the Sponsor, one day later the note goes to EDGE under the CPMS confirmation log. This can be viewed and the data corrected.
- Once corrected, one day later it passes back to CPMS to be viewed again by the Sponsor (re-confirmed)
- If this is now corrected the sponsor will accept the data and the accrual will show on CPMS

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CRFM

- CRFM links with EDGE by uploading participants who are have been recruited.
- In CRFM there is one date for recruited which is: date of **consent** of an eligible participant. Eligible participant is those who have passed screening
- Therefore when you add this date in CRFM, the date is in the past. There is no date for recruited (passed screening).
- In EDGE there are more field options which allow consent and recruit to be captured as distinct fields.
- As there is no distinct date in CRFM, the consented date is duplicated in EDGE
  - This can cause issues

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Correcting EDGE

- CRF need to correct the data in EDGE as there is no location for recruited date to be added in CRFM
- Currently, sponsors are rejecting our data as they interpret that less participants have been consented than they expect (only recruited participants make it to EDGE), and participants have the same date for consent and recruit (which doesn't match their database).
- We have tried to discuss this with Sponsor but this doesn't always work

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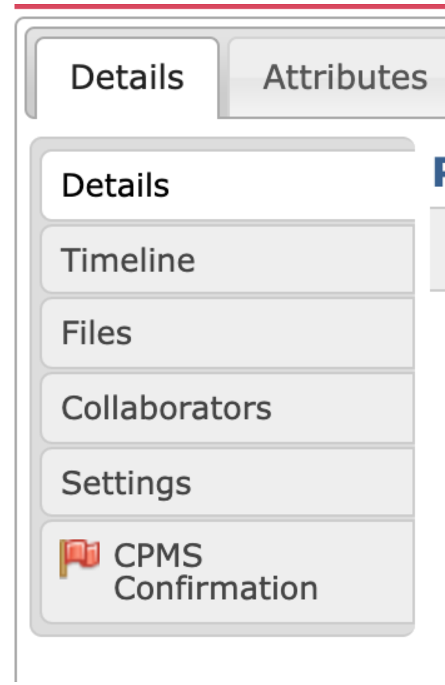
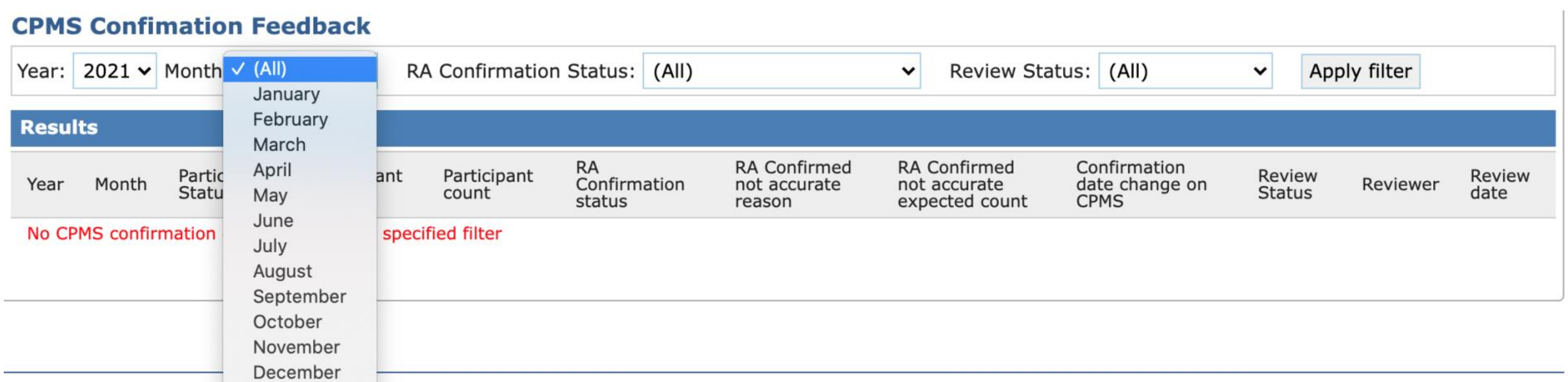
CPMS log

- Error log is found on Red level (bottom left)
- When there is a red flag it means that there are errors
- Update filter to show all months of a given year
- It will show months in summary per participant type





Example

This is the total number of this participant type with this status on EDGE for this month

CONFIRMATION STATUS	SITE NAME	TIME PERIOD	PARTICIPANT STATUS	PARTICIPANT TYPE	TOTAL PARTICIPANTS	CONFIRM AS ACCURATE	CONFIRM AS NOT ACCURATE
Confirmed - Not Accurate	ROYAL HALLAMSHIRE HOSPITAL	Jun 2021	Recruited	Participant with the relevant condition	1		Expected Count 2 Comments for Site EDIT
Confirmed - Not Accurate	ROYAL HALLAMSHIRE HOSPITAL	Nov 2020	Recruited	Participant with the relevant condition	0		Expected Count 1 Comments for Site ADD
Confirmed - Not Accurate	ROYAL HALLAMSHIRE HOSPITAL	Oct 2020	Recruited	Participant with the relevant condition	1		Expected Count 0 Comments for Site EDIT
Confirmed - Not Accurate	ROYAL HALLAMSHIRE HOSPITAL	Mar 2020	Recruited	Participant with the relevant condition	0		Expected Count 1 Comments for Site ADD

This is how many the Sponsor EXPECT to see based on their data

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Reasons for data not matching

- Sponsor will be looking at their data sources to confirm that the recruitment matches their expectation.
- They will be reviewing, Case Report Forms (CRFs/eCRFs), study databases, randomisation platforms and/or consent forms to ensure that the participants have been recruited according to the protocol.
- If the data is incorrect according to their record they will reject it, there is no way for them to correct it themselves.
- CRFM(as applicable) → EDGE → CPMS → EDGE → CPMS

  → = if rejected by sponsor it will be corrected and flow back to CPMS. This occurs until data is accepted

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- It could be wrong because:
  - Sponsor records have recorded an error
  - Site have inputted it into the system incorrectly (typo's/ mismatching participants)
  - The data is from CRFM and we DO NOT have the facility to record the correct recruited / randomised date
- CRF error example:
  - One participant with the relevant condition was consented on 01/04/2022 and passed screening on 01/05/2022. They were randomised on this date and became an eligible recruit.
  - The sponsor will expect to see:
  - April 2022 Status: **Consent**, Participant with the relevant condition → Count 1
  - May 2022: Status: **Recruited**, participant with the relevant condition → Count 1

In CRFM, all that can be shown is:

- Consent of an eligible participant is 01/04/2021
- This date will be added on 01/05/2021 as the day that they passed screening
- On this date the participant moves into EDGE.
- HOWEVER all dates will be 01/04/2021 as this is the only date available
- Sponsor's records will not match and they will reject April and May's monthly count
  - EDGE count would show April 2, when it should say April: 1 and May: 1 (consent and recruited status would be separated)

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Solution

- If a CRF study has data flagged as "not accurate" because the recruited/randomised date is wrong:
  - Email the CRF Lead nurse and request summary data for consent dates and date that participant became eligible recruit / randomised date
  - This should be accessible via the enrolment log
- To input this data please grant yourself CLINICAL access on EDGE using the staff tab on red level
- Update the recruited/randomised dates to match the CRF spreadsheet
  - The consent date should already be correct
- Any issues changing the dates please contact the Research Governance Facilitators

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Directorate Research Teams

- If a study has an error and is managed by research teams in the directorate, please ask the recruitment contact to review the patient data and confirm that this is correct
- Use the Error Counts to identify how many participants the Sponsor are expecting versus how many are present
- It could be a typo, a misunderstanding in the dates or that the Sponsor is wrong

- We need the Sponsor to accept the data in order to have the accrual count

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- We need to make adding a patient to EDGE as real time as possible as this will mean that the data is in front of you and has just occurred
- When a participant is added to EDGE, add to the list of activities to **check the CPMS log** for the previous month
- The participant who has just been added won't be visible yet as it takes one day to move to CPMS. The sponsor will then need to review this data and correct it
- If there is an error or data has not been confirmed yet for the previous month, review error and data in front of you and update EDGE if the date has been inputted incorrectly or a participant has been missed
- If there data has not been approved, you would need email the sponsor
- The next time you add a participant, check again to see if the data has been approved

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STH Sponsored studies

- When STH is the Sponsor, as part of portfolio registration there needs to be a named Recruitment Activity Contact (RAC).
- This person will receive access to CPMS as the study's contact to review and confirm this data
- This can be more than one person but it needs to be requested via the CRN
- At STH there is a requirement for this data to be added to EDGE and CPMS.
- It's best if the same person named for this but there may be times where this it split across the team. Make sure that you are reviewing the data in EDGE **and** CPMS
- This can be more than one person but it needs to be requested via the CRN
- Data in CPMS needs to be confirmed to be counted.

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Data Cut

Directorate Coordinators

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CPMS Data cut

- Each quarter the CRN have a data cut which they use to produce high level reports to NIHR
- These are usually 25th of each Quarter: April, July, October, January
- This recognises the recruitment and set up data present in EDGE and is used to manage activity across the region and nationally
- This is relevant to the Directorates for adding participant data to EDGE and ensuring this is confirmed in CPMS
- This is relevant for portfolio studies only

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Actions required

- A month ahead of each data cut, please get in touch with your recruitment contacts to ensure that they have added all their participants to EDGE
- For studies where STH is Sponsor, ensure that the study recruitment activity contact has confirmed the data in CPMS
- For studies where STH is not the Sponsor, review the CPMS log for your studies to see if any data hasn't been confirmed or has been rejected
- If the data has been rejected, review and correct the data in EDGE against the study record

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Financial data cut

- The April data cut has a financial implication as this relates to how many portfolio accruals the Trust has achieved against our target
- It is essential that the recruitment data is entered for the previous financial year
  - AND CONFIRMED in CPMS
- Ahead of this date, CRIO will send a spreadsheet for all the data not yet corrected
- For these studies, please review the data and send an email to the recruitment contact to accept the data
  - Recruitment contacts can be found on public ODP (open data platform) https://public-odp.nihr.ac.uk by searching for a study
  - You can also ask your Sponsor contact

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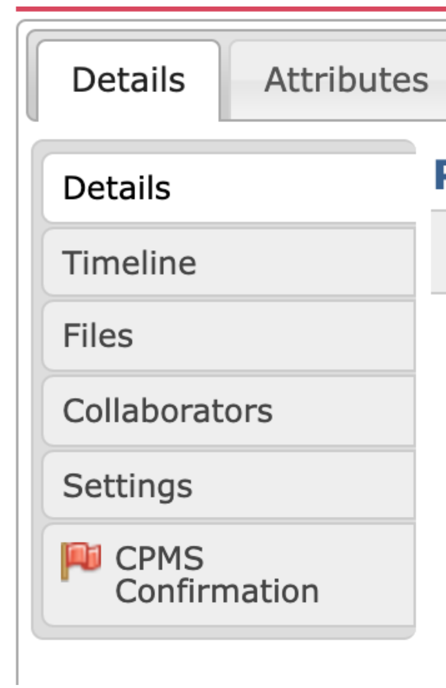

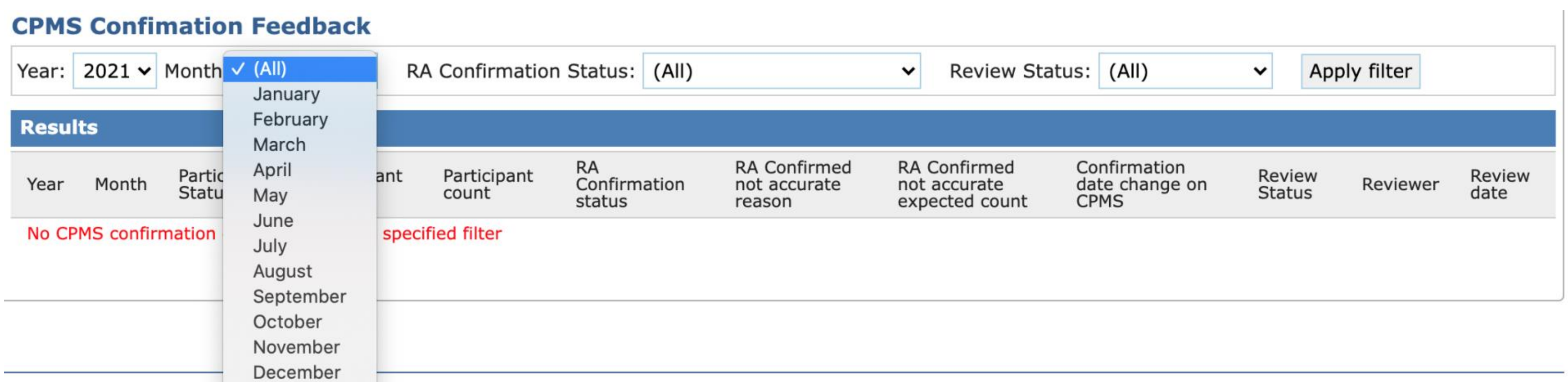

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How to fix it

- Change the dates of each participant where there consent date or recruited/randomised date might be wrong
  - If an error is produced and you can't press save, get in touch with the Research Governance Facilitators
- Check that you have added the right participant type or this is inputted
- Check that participants haven't been duplicated accidentally
  - Use the study ID to confirm and delete a duplicate

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NIHR Metrics

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Performance in Initiating and Delivering

- Every quarter (April, July, October, January)
- Reports on the last year (e.g April Q1 21/22 = 01/04/2021 – 31/03/2022)
- Two reports:
  - Initiating = all portfolio clinical trials which have been activated in the last year
  - Delivering = Commercial portfolio clinical trials which have closed to **recruitment** in the last year
- Submitted to the NIHR Central Commissioning Facility (CCF) on the last day of the quarters month (Friday 5pm before the 31^{st})
- Relates to how well we have met out high level objectives (HLO) set by the CRN

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Reports

- Two reports are produced and split to the relevant departments
  - CRF , CCTC or straight to the directorates if not supported by either facility
- We ask for information about the trial, and reasons for not meeting our targets
- Targets for initiating:
  - HLO 4 – Set up in 40 days (date site selected to date site confirmed)
  - HLO 5 – Recruitment of the first eligible participant (date site confirmed to first patient first visit)
- Target for delivering:
  - Recruiting to the target by the end of the recruitment period

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Data requests

- Where data is not yet inputted into EDGE or data we will ask you to complete this
- This might be first patient first visit, current accrual, recruitment end date, study end date or status
- This data gets updated on RMS and EDGE after the report, however if it is already there, we will just ask you to confirm that it hasn't changed

- We need to know the data AS OF the last date of the reporting period. The report may come to you 2 weeks after the first day of the reporting period, therefore if something has happened in that time, we won't submit it.

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Example

- Quarter 1 2021/22 – 01/04/2021 – 31/03/2022
- Delivering:
  - Study closes to recruitment on the 13/04/2022 and report reaches the directorate on the 17/04/2022.
  - For the purpose of delivering, this study is still open and therefore won't be submitted
- Initiating:
  - Study is given green light on 01/04/2022
  - For the purpose of initiating, this has not yet occurred, so the date will not be submitted

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Reasons

- When we have not met target for initiating or delivering a reason needs to be provided for this.
- Initiating: reason codes are provided (below)
- Delivering are to mirror these reasons but the text can be more detailed

- A) Relevant permissions delayed and not granted in time
  - HRA approval process not completed in time
  - Study-wide review not completed in time
  - Local review not completed in time
  - NHS Research Ethics Committee review not completed in time
  - Medicines and Healthcare products Regulatory Agency (MHRA) review not completed in time
  - CE mark process not completed in time
  - Other regulatory reviews not completed in time

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- B) Study suspended by sponsor
  - Study suspended at all sites
  - Study suspended at this site
- C) Study closed by sponsor:
  - Safety reasons
  - Lack of clinical equipoise, as defined by the sponsor
  - Change in development pipeline within sponsor company
  - Strategic/financial reasons within sponsor company
  - Study-wide recruitment completed
- D) Delays caused by sponsor:
  - Delay in provision of pharmacy manual
  - Protocol amendments
- Delayed site initiation visit
- Delayed confirmation from sponsor of study open to recruitment at site (*i.e.* delays in receiving "Green Light")

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- E) Staff availability issues at site
- F) No eligible participants seen during the reported period
  - Participants sought but no eligible participants identified
  - Strict participant eligibility criteria
- G) Eligible participants seen during the relevant period but did not consent to participate in the trial
- H) Contracting delays
  - Within NHS provider
  - Within sponsor company
  - Other contracting delays
- I) Rare or very rare diseases studies
- J) Other (please describe)

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When you receive the report

- The report will be produced on the first of the reporting month so that the data can be run "as of" the last day of the reporting period
- Directorates and facilities will receive this around 10-14th to allow for the initial report to be produced.
- We will give you 10-14 days to complete the report allowing for on 7-10 days for finalising this for submission
- STH have to submit and check a lot of data so its essential that the queries are sent off on the first day it is received so that there is time for the nursing teams to confirm
- Directorates have very few studies in comparison to the CRF and CCTC, so please do get this returned by the deadline

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Data cleaning

- We will also ask for data when a study is no longer being reported but the details in RMS are out of date.
  - E.g. the status is still in follow up but the end date is in the past
- We ask for this information so that we can close the records to assist with other audits conducted by CRIO
- A study end date for STH Sponsored studies is the date on the end of trial declaration
- A study end date for externally sponsored studies can any of: date STH activity stopped (Close out visit), the date the Sponsor notified that the trial had ended or the date on the end of trial declaration.
  - We allow for different dates as we may not always receive overall study end date

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Actual recruitment end date

- Actual recruitment end date is the date at which recruitment **actually** stopped
- This could be the date that the randomisation platform was shut off
- Or the date in which the last participant rolled over from an open label extension
- This should be notified by the Sponsor and email evidence is required
- If this date is missed we may miss the opportunity to report this study and have it count towards our studies meeting target

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Thank you for helping with metrics

- Metrics is a time consuming activity which takes a lot of resource from the facilities and CRIO during the reporting months
- We appreciate your help in keeping the data clean so that information is clear and there are less queries
- If there is any further training required, please get in contact with CRIO to arrange this before the next period

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Alfresco Filing and Versions

Directorate Coordinators and
admins with RMS access

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Alfresco online and RMS

- Alfresco online and RMS have different capabilities
  - It is best to use RMS wherever possible as there are additional protections to avoid accidental deletion and correct superseding
- Alfresco online allows for creation of new sub folders
  - This is useful for STH sponsored projects where we have more documents, and the files are required to be reviewed by other teams. E.g. Finance and site mNCAs, and SAE folders

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Versions

- Documents should be superseded by the next version of the same document type
- To avoid having lots of documents, you could place a tracked change copy on top of a clean copy followed by the approved clean copy.
  - E.g. Protocol V1.0 Clean → SA1 Protocol V1.1 TC → SA1 Protocol V1.1 Clean
- It is really helpful to prefix documents when they relate to and amendment with the amendment number

EDGE Workflows and Attributes

Directorate Coordinators and CRIO

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Recruitment reporting

- Some projects have different recruitment reporting requirements on the research activity systems (CRFM/EDGE)
- These may be to do with
  - Different directorates being involved
  - Different arms within the same directorate
- These can be dealt with in different ways depending on the set up of the study
  - Via sites (if teams are recruiting in different hospitals)
  - Via arms (set up by sponsor on EDGE)
  - Via attributes (on patient tab)
  - Via prefixes on Study IDs

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CRF studies

- Due to the CRF script it can often be difficult to add attributes or arms and this would need to manually occur
- Therefore often the best approach for this is to use the prefix of study ID
  - E.g. Haematology and Specialised cancer are both recruiting from Weston Park
  - Haem-S01-001 and Canc-S01-002 could be used keeping the same numbers as the sponsor allocate (S01-001) but with a prefix of the directorate involved
  - Sponsors don't see our study ID's but we do need them to match against enrolment logs

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Please get in touch

- If you have any studies which fall into this category as needing different ways to record recruitment across teams, please reach out to the EDGE admins and the best solution can be discussed

Using RMS

Directorate Support
who have access to RMS

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Getting RMS

- RMS is a governance system and it's not given to all of the support service teams unless it is relevant for their role
- This is because managing all research team on RMS would be difficult and ensure there is not misinterpretation of information
- Alfresco is a document repository but it cannot be considered a site file as CRIO do not always received all the required information for the site file

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RMS has different Views

- RMS can be viewed differently by different support services and directorates
- Outside of CRIO most fields are read only
- There are views for projects, people, organisations, directorates and others visible on the RMS main menus
- Most often you will only require Projects

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Project view

- When you click on project view you are met with a query builder
- You can drag in all the fields which exist in RMS into this query builder from the fields tab on the left hand side.
- You can also drag in tasks and set criteria to identify which project have met this
- Once a query has been built this can be saved in the queries tab under the relevant folder
- For directorates there are specific folders for academic directorates

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Viewing a project

- Once you have identified a project, double click on the blue row
- This brings up the project view and you can see different things about the projects
- For individuals who don't use RMS regularly but might want to see what is happening with the study, review the task page and the diary page
- Green ticks are all required in order for a study to be approved. If a clock has been started it means it is with the support service to review
- If the task has not been started it is still with CRIO to review or the directorates to complete

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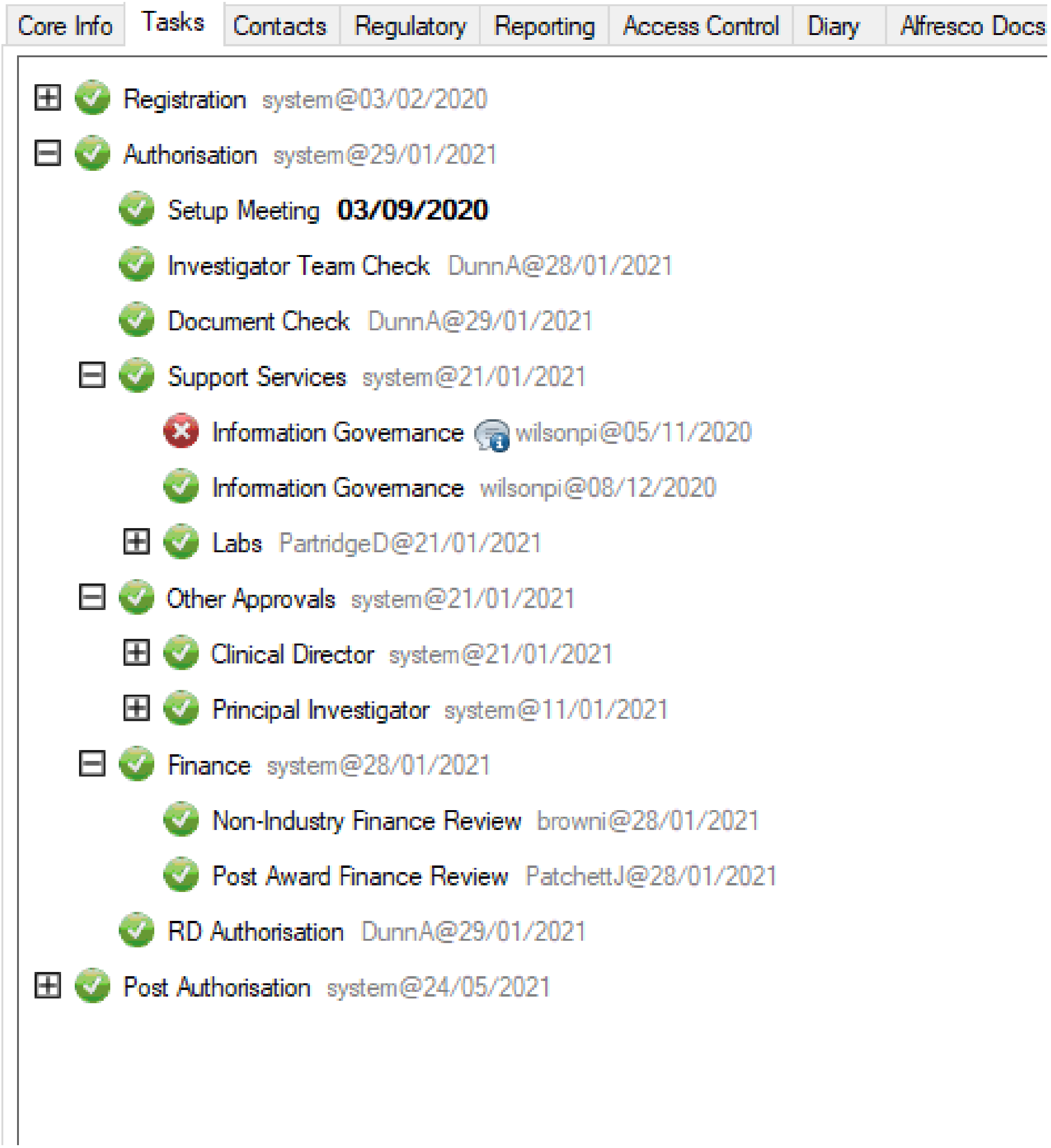

- Rejected tasks need to be restarted and comment can be added by the support service for what the issue is.
- There are tasks for authorisation and post authorisation (amendments)

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Tips and tricks for query building

- Have a look at other peoples queries, you can load these, change some of the fields (e.g. directorate) and save this in your own folder
- In order to have more fields open when you first open Project view you need to create a query and save it in your folder. You then right click on that query and click "save as my basic query".
  - This allows all of those fields to appear when you first open RMS

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Notifications

- RMS has the capacity to send email notifications when certain criteria in a query are met
  - Examples: - When a project has a support service task approved or rejected or when a project closes to recruitment
- This is set as before by building a query and saving it in the relevant folder. Once this is saved you need to right click and click Notifications
  - Once the pop up appears you can right click again in the white box and click "new notification for current user"
  - This makes your name appear. You will need to then right click on your name and click edit to specify the frequency.
  - You want to select "notify on add" so that each time a new project fulfils the query you are emailed.

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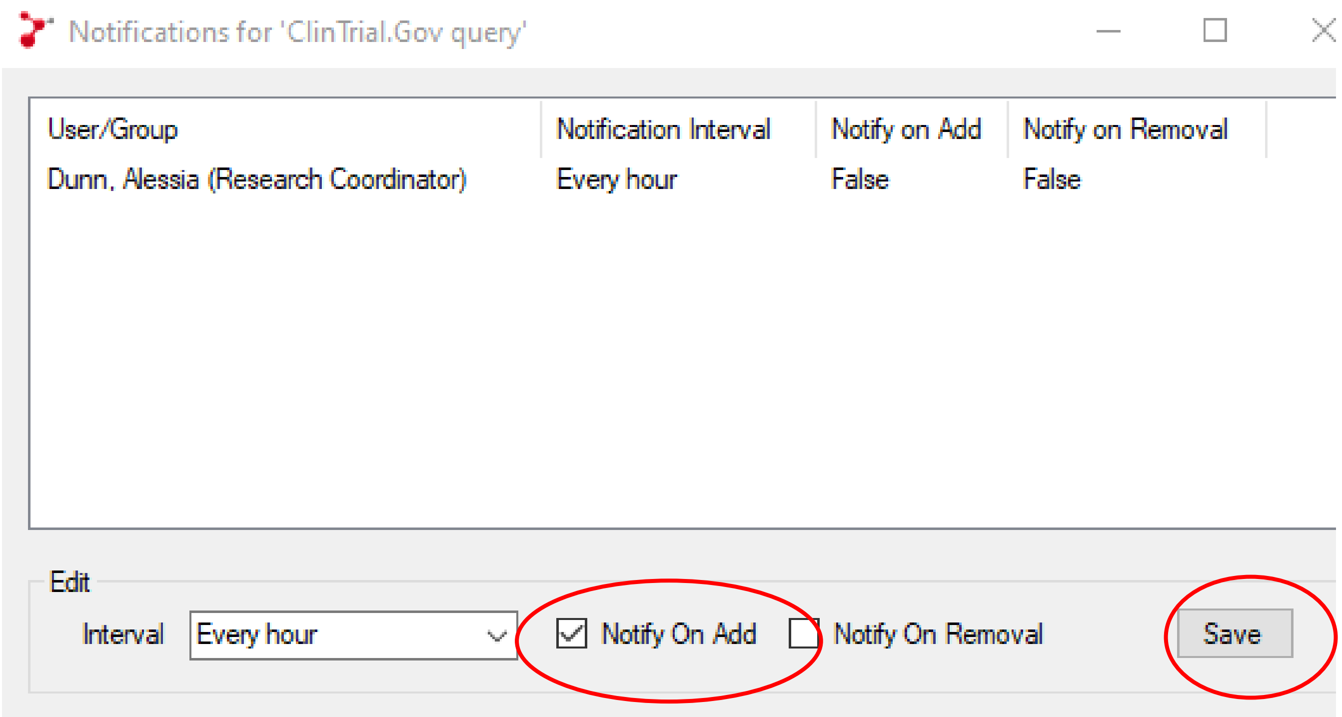

Making queries for tasks can sometimes be tricky, have a look at examples in CRO → Alessia → Coordinator and adapt for your area

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Annual progress report notifications

- A new field has been added under reporting called "Next report due"
- Using this date we can monitor when an annual progress report is due and send a reminder to the PI's ahead of time
- A query is saved under Research Office → Alessia → Annual progress query
- This can be adapted and can be used to produce a notification for annual progress reports due in the next month

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Other RMS updates

- Where relevant to the directorates and support services, new updates will be saved in this guidance

- If you have any queries and questions about RMS and how to use it, please get in touch with the Research Facilitators

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