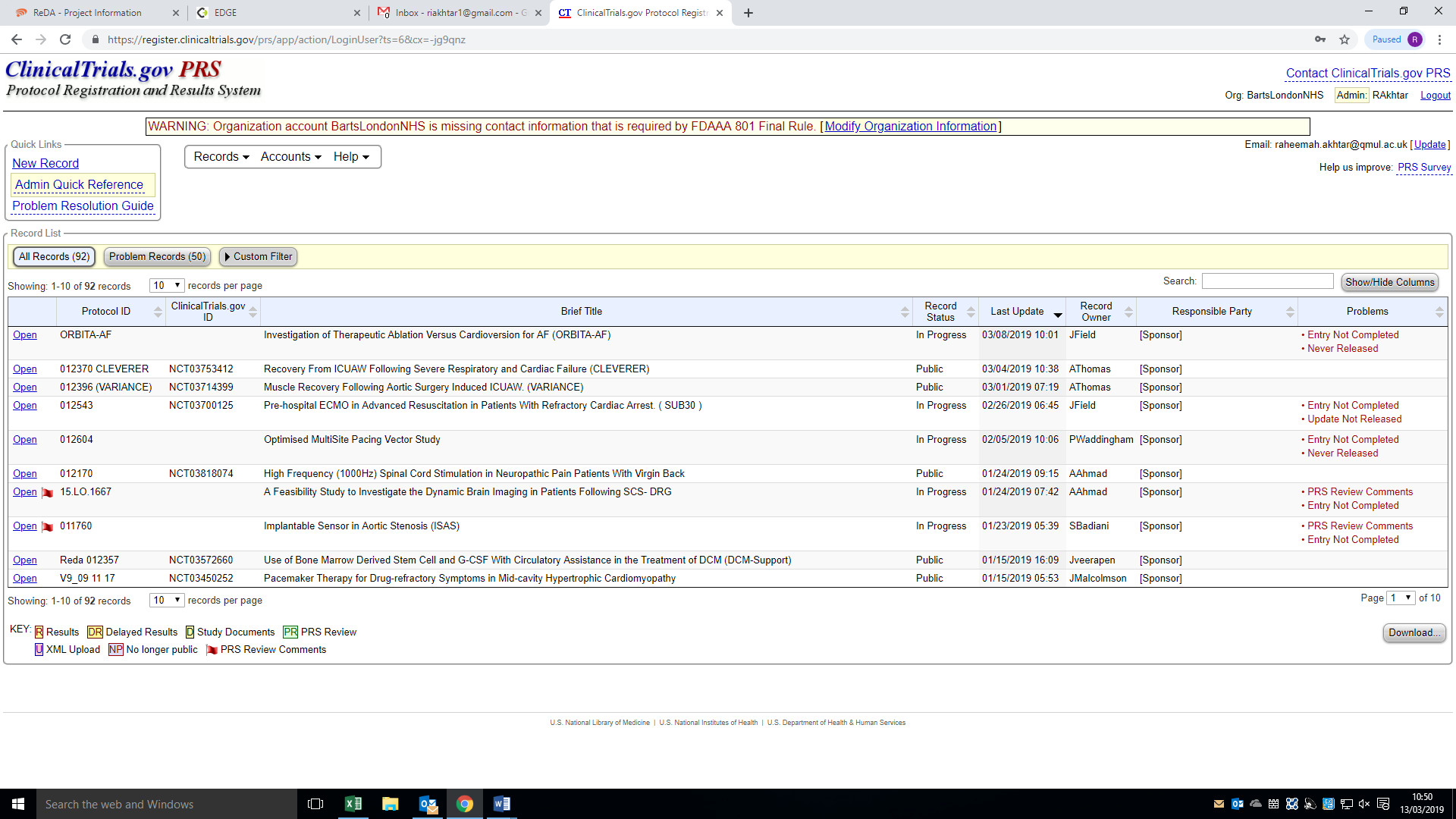
**Clinical Trails.gov**

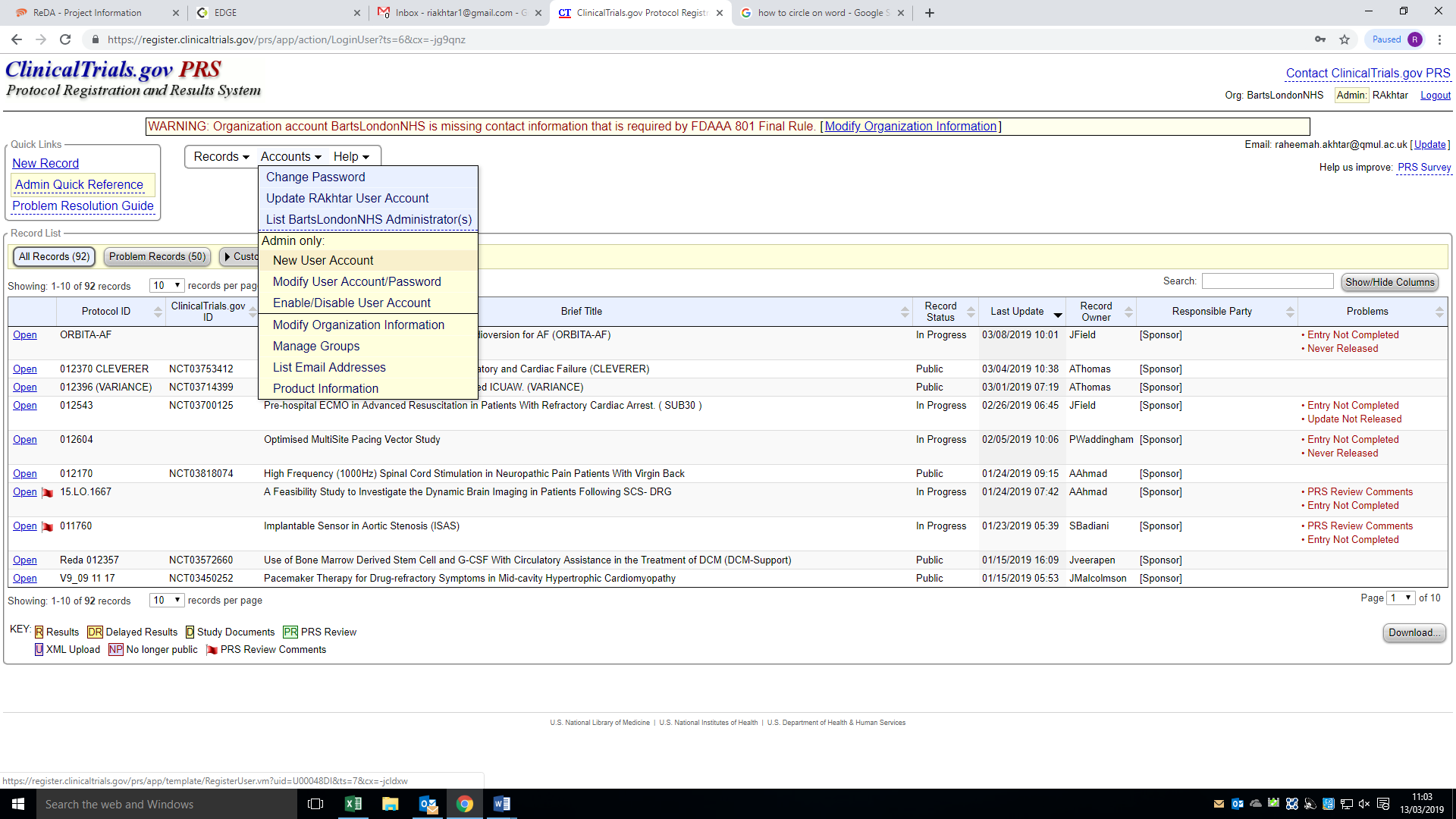
**Registering a new user:**

What to do when you have received a request to create an account for a researcher/study team member to register a study on ct.gov:

1. Establish whether the study is sponsored by Queen Mary University of London (Queen Mary) OR Barts Health NHS Trust (Barts Health).
2. Once this is known, logon to [**https://register.clinicaltrials.gov/**](https://register.clinicaltrials.gov/)and input the appropriate ‘Organization’ i.e. for Queen Mary sponsored study, you would sign in with ‘QueenMaryLondon’. Alternatively, for Barts Health sponsored studies, the ‘Organization’ would be ‘BartsLondonNHS’.
3. Select the ‘Accounts’ dropdown in the top left corner (see screenshot below)

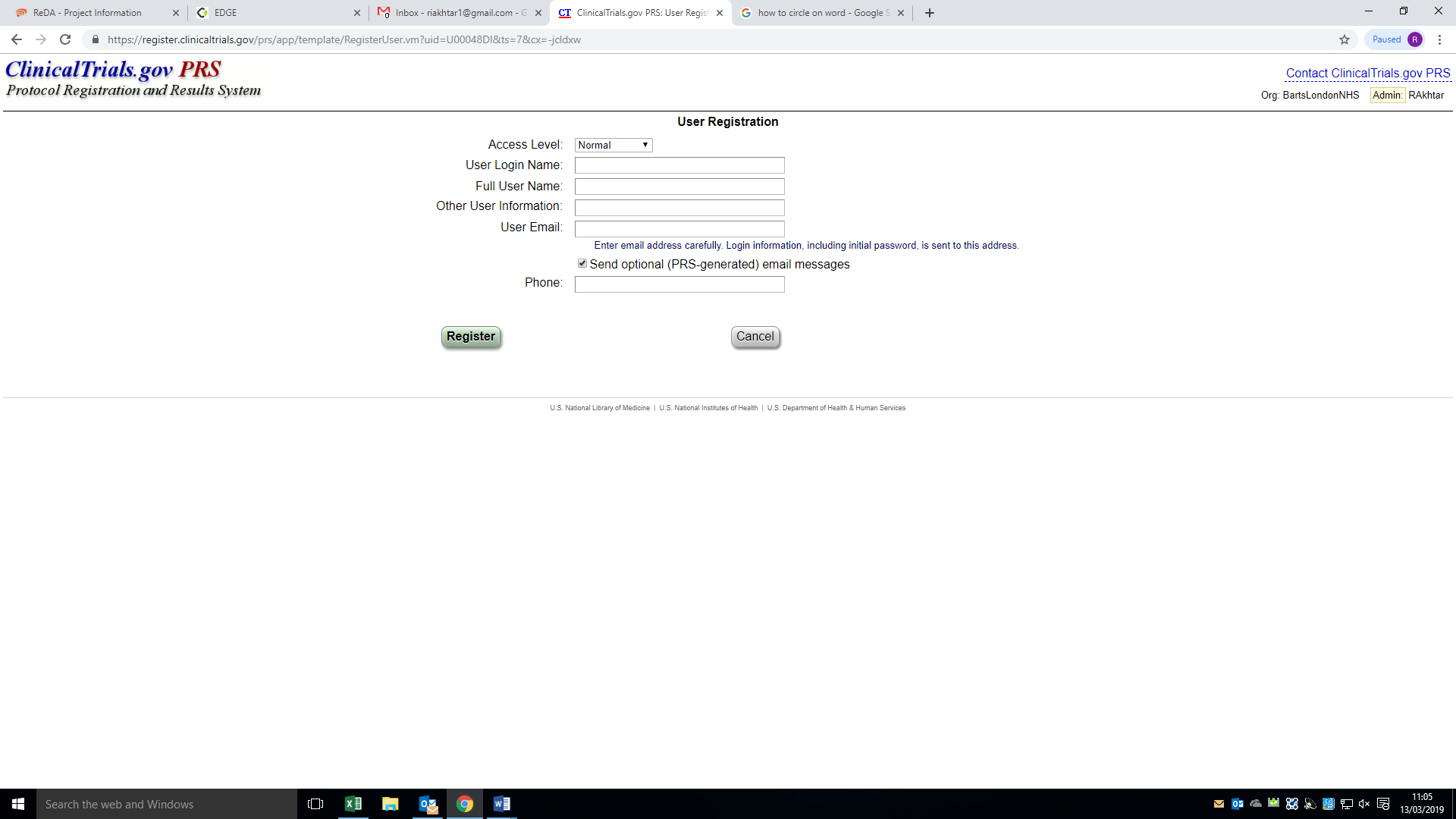


1. Select ‘New User Account’



1. Fill in the below mandatory fields:

* User Login Name: this can be the first initial + the surname i.e. Joe Bloggs would be JBloggs
* Full User Name i.e. Joe Bloggs
* User Email: Must be either Queen Mary or Barts Health email address i.e. [joe.bloggs@qmul.ac.uk](mailto:joe.bloggs@qmul.ac.uk) OR [joe.bloggs@nhs.net](mailto:joe.bloggs@nhs.net)



You should now select ‘Register’ which will send an auto generated email to the user containing their login details.

**NOTE: Only administrators i.e. yourself would have ‘Administrator’ access, otherwise all other users should be given a ‘Normal’ access level.**

1. You can now send the below template email to the user which includes confirmation of registration and some basic guidelines:

“Dear XXX,

I can confirm you have now been registered onto ClinicalTrails.gov and will be receiving an email with your login details shortly. Please ensure that when you are registering your study onto the database, you enter the EDGE reference as the Unique Protocol ID, this should be a 6 digit number with no suffixes.

Once registered, please ensure the below is regularly kept up to date:

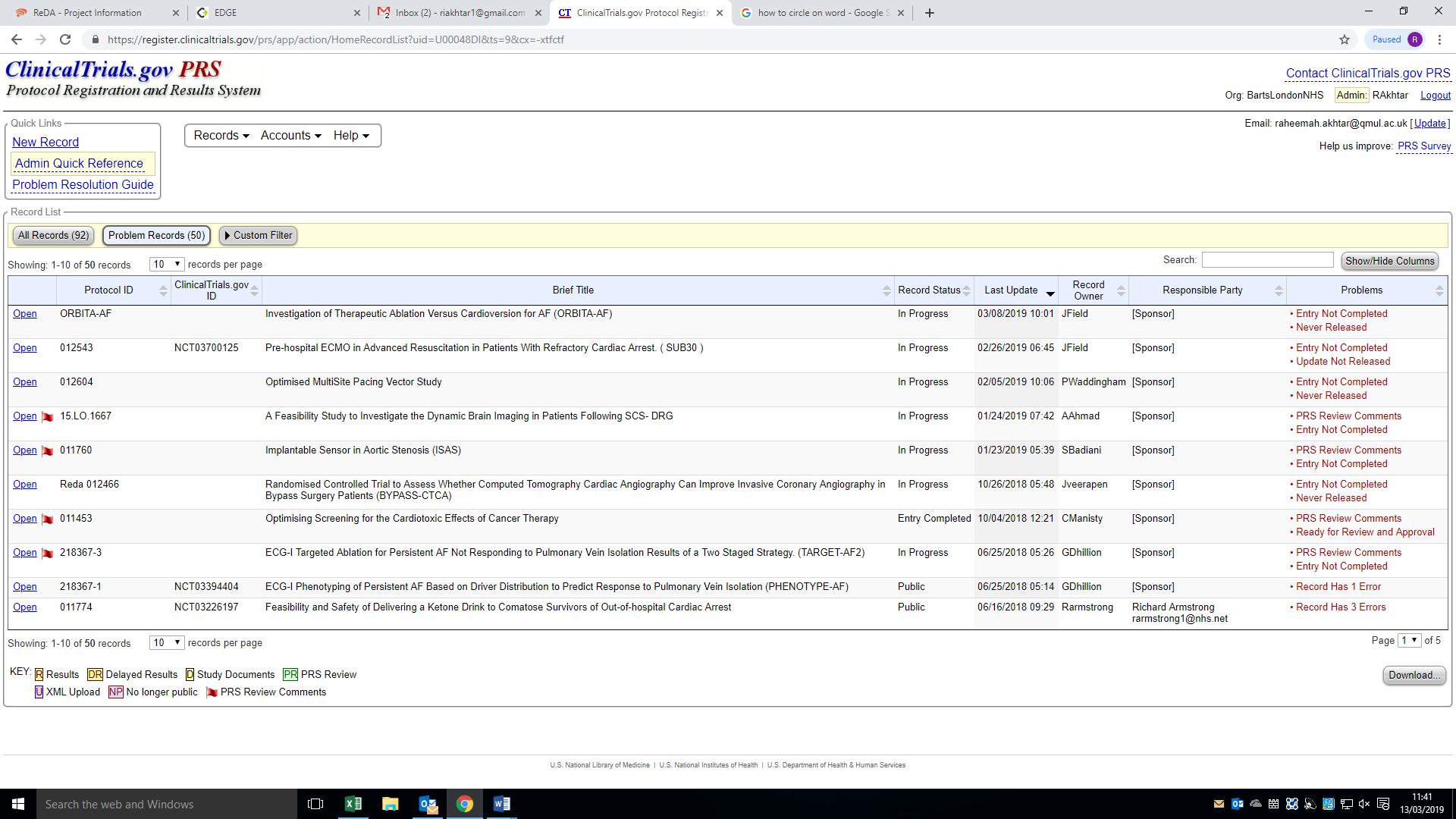
* Recruitment Status, Overall Recruitment Status and Completion Date
* Protocol Amendments made at least every 12 months
* Record Verification Date, to be updated for all not completed trials at least every 6 months even if there are no changes
* Submit summary results no later than 12 months after final data collection

Please do not hesitate to contact me for any further support, alternatively you can also contact the Protocol Registration System(PRS) support team via [**register@clinicaltrials.gov**](mailto:register@clinicaltrials.gov)**.**

1. Once the user registers the study or makes updates to ongoing studies, the Clinical Trials administrator (yourself) needs to APPROVE and RELEASE the record before any changes can be viewed by the other party. Studies that require approving and releasing can be viewed under the problems page or searched using the title in the email notification you receive from the PRS; research team members may also make contact regarding approving and releasing.
2. For ongoing studies any changes and updates will also need to be approved and released by the CT.gov administrator (yourself). The system will not let you release a record if there are errors or contradictions in the data which will be highlighted in red with a warning message. You should contact the research team to rectify the error before the study can be approved and released. Within the database there is a problems page listing all problems with the corresponding study for example:

ERROR: For a completed study, Primary Completion Date Type must be Actual.

ERROR: Anticipated Primary Completion Date cannot be in the past.

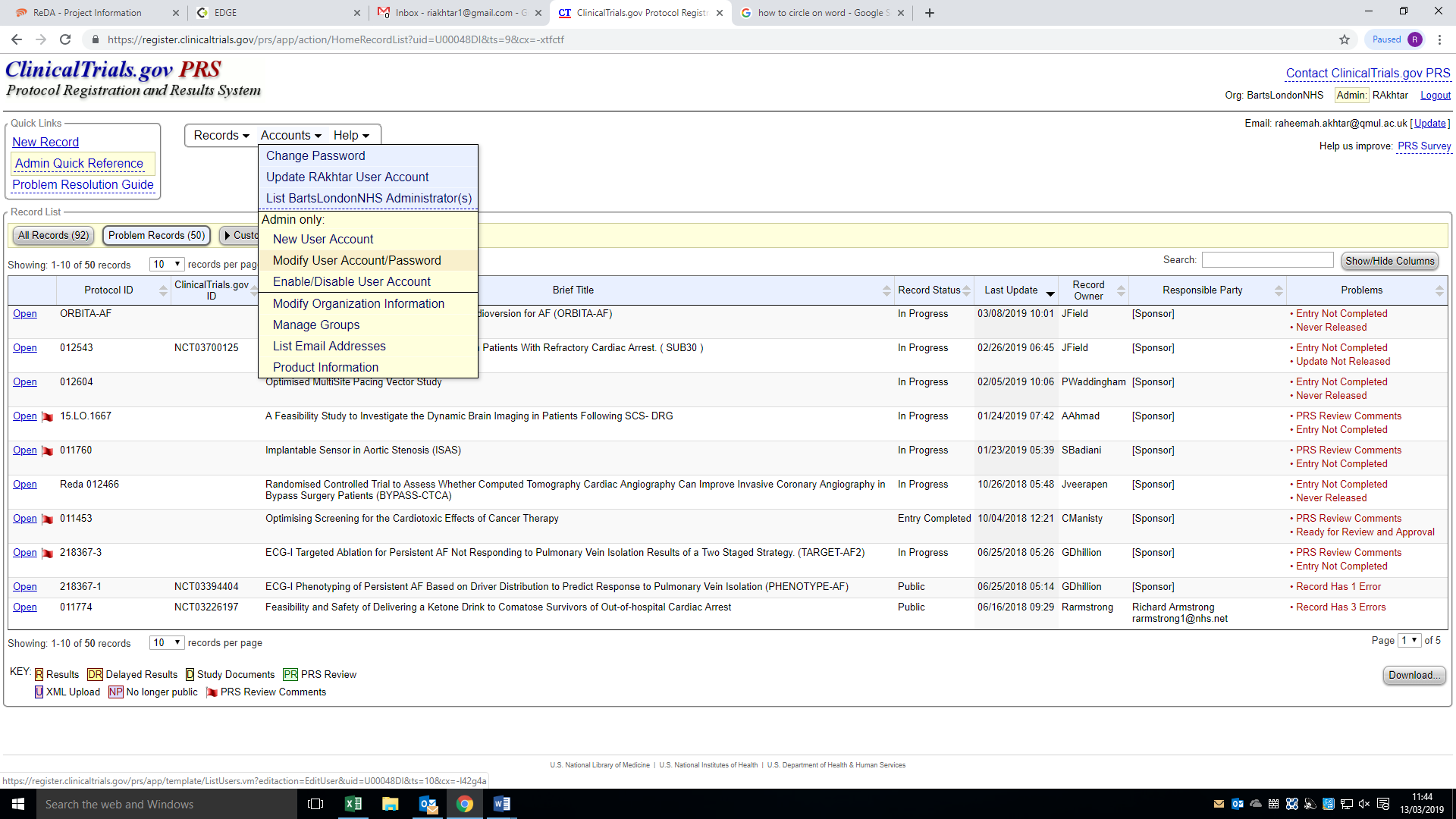


These problems need to be dealt with; usually this requires contacting the study team and alerting them so the necessary amendments can be made. In all cases once a record is approved and released, the entry or changes can be viewed between 2- 5 days. If results are being updated then this change can take up to 30 days to be reflected on the website.

**NOTE: For any issues that you or the research staff need support with, you can contact the PRS team on** [**register@clinicaltrials.gov**](mailto:register@clinicaltrials.gov) **who can assist.**

**Disabling/Enabling a user account:**

For any users who no longer require access to the CT.gov database, please ensure access is disabled (see screenshots below). From the top left drop downs, please select:



You can then select the ‘disable/enable’ button beside the name of the relevant user:

