How to create a new Trial account on the ClinicalTrial.gov Website

Request to create an account

- A ClinicalTrial.gov account can only be created by a registered administrator for the institution (UCL)
- To create an account on the ClinicalTrial.gov website, a requestor must send an e-mail to one of the registered JRO administrators requesting for an account to be created.
- The administrator responds to the requestor's e-mail asking for the following information:
  - Full trial title:
  - Short name/trial code:
  - User Login Name:
  - Full User Name:
  - Phone contact number:
  - User email:
- The requestor completes the information requested by the administrator above and sends this to the administrator.

Creating the account

- The administrator logs onto the ClinicalTrial.gov website (https://register.clinicaltrials.gov.), in Administrative Functions under "User Accounts", clicks on "Create" and completes the fields.
- At the bottom of the field, under "Send automatic (PRS-generated) email messages" Ensure the box is always ticked.
- Click "create". An automatic e-mail is sent to the requestor telling them an account has been created for them on the website. This allows the requestor to log unto the website and complete information regarding their study.
- The administrator sends a confirmation email to the requester "I've created an account for the trial, you should hear from clinicaltrials.gov soon."

Completing the Trial Information

- The requestor completes the mandatory fields to create a trial record.
- Once completed, an automatic e-mail is sent to the administrator to approve and release the study on the website.

Releasing the Trial Information

- Upon receipt of the automatic e-mail notification the administrator logs onto the ClinicalTrial.gov website (https://register.clinicaltrials.gov.), under Administrative Functions "Protocol Records" clicks on "Problems: UCLondon Records". This will take the administrator to next page, click "OK", this will take the administrator to the section where all studies are listed.
- The administrator looks for the study in question and then clicks on "Edit" to enter the trial information.

- The administrator checks the entry for error messages related to the trial details that have been added or missed.
    - Blue notes ( ) are for information only and may be ignored by the administrator.
    - Warning notes ( ) should be addressed by the requestor but don't prevent the release of the trial record and may be unavoidable depending on the specific situation and information added.
    - Error messages ( ), should be addressed as they can prevent the release of the trial record.
- If an error message/s is flagged up, the administrator will neither "Approve" nor "Release" the study but will e-mail the requestor with a request to address the error/s.
- In the case where there is no error message, the administrator clicks on "Edit", and looks for the "Next Action: complete" button then clicks on "Next Action: approve" followed by "Next Action: release".
- The release action sends an automatic e-mail to the requestor telling them that their study has been approved and released on the ClinicalTrial.gov website.
- The administrator follows this up with an e-mail to the requestor that the study has been approved and released and includes the following; "Please note that it is the responsibility of the trials team to ensure the trial information published is accurate and complete."