

Step by step guide to using IRAS for CWoW

These are instructions for sponsors participating in the CWOW pilot and using the IRAS development system to submit an application for review.

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This guidance document is still in the early stages of development and we would welcome any comments you may have related to it. Please pass any feedback to cwow@hra.nhs.uk.

IRAS user roles and tasks

As an IRAS User you can be given different roles and responsibilities, either related to a specific project or related to an organisation account. Below are listed the type of roles. Please note: as an IRAS User, you could be one or many of these roles.

Sponsor

In the **key associates** section of the project details page, the role of sponsor organisation **must be the organisation that is going to submit the study**, i.e. it is the organisation undertaking the sponsor's activities. If for example, the sponsor has delegated the role of submitting the application to the CRO, the CRO must be selected as the sponsor. The organisation that is actually sponsoring the study is named in the EudraCT form.

It is crucial that this role is given to the correct organisation as assigning this role has significant consequences in IRAS. Anyone associated with this organisation will be given visibility of all studies belonging to this organisation. The sponsor organisation role is selected from existing options available within IRAS (if your organisation is not listed, please contact helpdesk@myresearchproject.org.uk).



Key associates

Project Funder

Select Project Deputy

Select Sponsor

Figure 1- Screenshot showing the key associates section of the system. Arrow points to 'select sponsor'

Sponsor representative

A sponsor representative should be someone who is authorised by the sponsor organisation to act on their behalf to manage the study and fulfil sponsor responsibilities. A sponsor representative will have visibility of all studies listed under the sponsor role above. It is therefore important that CRO staff are not given the role of sponsor representative UNLESS the sponsor organisation role above is also given to the CRO. Otherwise the CRO would have visibility of studies they are not involved in.

Any organisation can have as many sponsor representative users as needed on IRAS to reflect the actual sponsor office. Any sponsor representative will have access to the full list of their organisation's Sponsored projects list, along with full editable access to the organisation's Task list.

In order to set yourself up and receive approval for becoming a sponsor rep – please follow the instruction below under 'Setting up a profile'.

The Tasks a sponsor rep will be involved in:

- Receiving, reviewing and Approving/Rejecting other 'Sponsor rep' IRAS user requests
- Receiving, reviewing and Approving/Rejecting Project sponsorship requests
- Receiving, reviewing and Approving/Rejecting initial submissions
- Receiving, reviewing and Approving/Rejecting initial submission Re-submissions
- Receiving, reviewing and Approving/Rejecting Amendment submissions
- Access to overview of the study

Chief Investigator (CI)

This is the investigator with overall responsibility for the research. In a multi-site study, the CI has co-ordinating responsibility for research at all sites.

The CI is responsible for the tasks below. However, they may choose to assign some of these to the Project Deputy.

The Tasks a CI will be involved in:

- Creating an IRAS project
- Accepting ownership of an IRAS Project (this must be completed before a Project Deputy can proceed to submit)
- Selecting a Project deputy
- Selecting a sponsor/Legal rep
- Selecting study collaborators
- Completing IRAS question sets
- Uploading study documents
- REC booking
- Submitting an initial submission
- Forwarding to sponsor for submission
- Receiving and reviewing, answering Requests for Further Information (RFI)
- Making a re-submission

- Withdrawing the study
- Creating a new 'project information' amendment
- Creating a new 'admin' amendment
- Contacting a new sponsor and creating a 'sponsor' amendment
- Contacting a new CI and creating a 'CI' amendment
- Updating the project deputy role

Project Deputy (PD)

Project deputy is a new role within IRAS and has been added to allow for different ways of working between organisations. It means that more than one person can have access to edit and manage a project, and allows certain tasks traditionally undertaken by the CI to be assigned to a deputy. For commercially-sponsored studies the PD will usually be the person from the company who is preparing the application in IRAS. For non-commercial research the PD will usually be a trial manager or research nurse.

All projects must have a PD assigned so that there are always two individuals with access to the study for business continuity purposes.

It is still essential for a CI to be assigned to the project. They will need to accept the project (and accept amendments to change the CI if this crops up in the future). CIs can also do any of the tasks needed to set up initial submissions, amendments, withdrawals and addition of project collaborators.

(Note: The PD role is not a new research role, the term is just used to describe a type of IRAS user).

Any person delegated by the sponsor or CI can be the PD of a study. This is not a clinical role – but a clinical person can take the role as required by each project.

The Project Deputy should be a named person using their own individual IRAS account. They will only have access to the study that they are allocated to as PD. This role does not have access to other studies in the CI's portfolio.

There can only be one Project Deputy per project.

The Tasks a PD will be involved in:

- Creating an IRAS project
- Accepting PD role of an IRAS Project
- Inviting a CI to access the project in IRAS
- Inviting a Sponsor / Legal Rep to access the project in IRAS
- Adding study collaborators
- Completing IRAS question sets (only if determined by the sponsor/CI to have relevant training and experience)
- Uploading study documents
- REC booking
- Submitting an initial application
- Forwarding to sponsor for submission
- Receiving and reviewing, answering RFI (only if determined by the sponsor/CI to have relevant training and experience)

- Making a re-submission
- Withdrawing the study
- Creating a new 'project information' amendment
- Creating a new 'admin' amendment
- Contacting a new sponsor and creating a sponsor amendment
- Contacting a new CI and creating a new CI amendment
- Updating the CI role
- Could also be a sponsor contact

Collaborators

Once a project has been set up, it is possible for the CI or PD to add as many 'collaborators' as required to work on that project (see 'making an initial submission' section below for more details). A named collaborator can sign in and work on preparing that application as needed. They can edit the project in the same way as a project deputy, but cannot submit the project, or receive or reply to requests for information.

Collaborators can only access the study that they are allocated to as collaborator. They cannot see other studies in the CI or sponsor's portfolio.

Creating an IRAS account

Navigate to the login page at www.myresearchproject.org.uk/CWOW and click 'Create Account'.

Follow the simple on-screen instructions to create your account. During this process an email will be sent to the address you use to sign up. When received, click on the link in the email to verify your account.

When you have successfully signed up and logged in, you can bookmark the login page using the URL above.

[Please note: During set-up, any communications will be sent from a NIHR email address. This is because the single sign in page used for IRAS is externally hosted.]

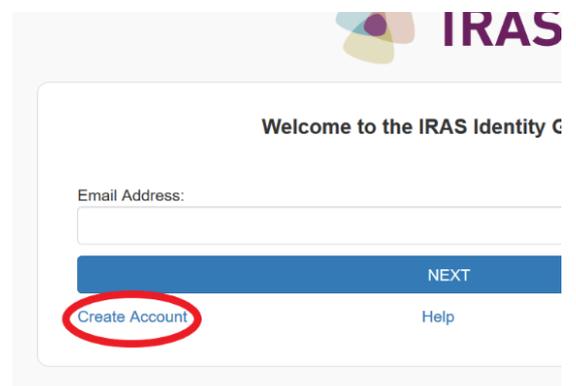


Figure 2-screenshot of system. 'Create account' is circled

Setting up a profile

Once you have created your account you can add more details to your IRAS profile. The email address you add to your profile information will be the email address that emails and notifications are sent to, so it is important that it is kept up to date. The system will automatically add the email address you used to create your account to your profile information. If you later need to change the email address in the profile information section, you will still log in with same email address that you originally used to set up your account. It's important to understand the difference between the two places where email addresses are used:

- Email address for log in – Think of this as your username. This stays the same for all the time that you work on the same set of research studies. If your institution changes its email address you will still use the original email address to log in. If you move to another organisation and will no longer need access to the studies in your account then you will need to create a new account with a new email address as your username.
- Email address in your profile – This is your correspondence email. Keep this up to date otherwise you will not get notifications and correspondence about your applications.

To update your profile information:

- Click your name/initials in the top righthand corner
- Select 'Profile' from the dropdown list
- Below where you have just clicked your username in the top righthand corner, a new button 'Edit profile' will appear - please select.
- On the box please complete relevant information - this information should be kept up to date
- Select 'Update'

In this section, you can also set yourself up as a sponsor representative (sponsor rep) if this is relevant to you. **(Before proceeding, please refer to the 'IRAS roles' section below for a definition of this role to decide whether it applies to you).**

- Click your name/initials in the top righthand corner
- Select 'Profile' from the dropdown list
- On the new page which appears, select 'Edit' (to the right of the 'Sponsor office' header).
- Click on '+ Add organisation' – and start typing the name of the organisation into the box which appears
- Select the relevant organisation from the drop-down list
- Click 'Save changes'

By clicking 'Save changes' the selected organisation will now receive your request to be a sponsor representative and can 'Approve/Reject' via the system. If they select Approve, then you will now have read-only access to the list of the sponsor organisation's Sponsored projects list, along with editable access to the Task list.

If they select Reject, then you will not have access to anything related to the sponsor organisation. Details on how the sponsor can Approve or Reject, is covered in: Key associates - Sponsor - Sponsor roles/tasks

System Navigation

Once you have created your account you will see some tabs across the top of the page:

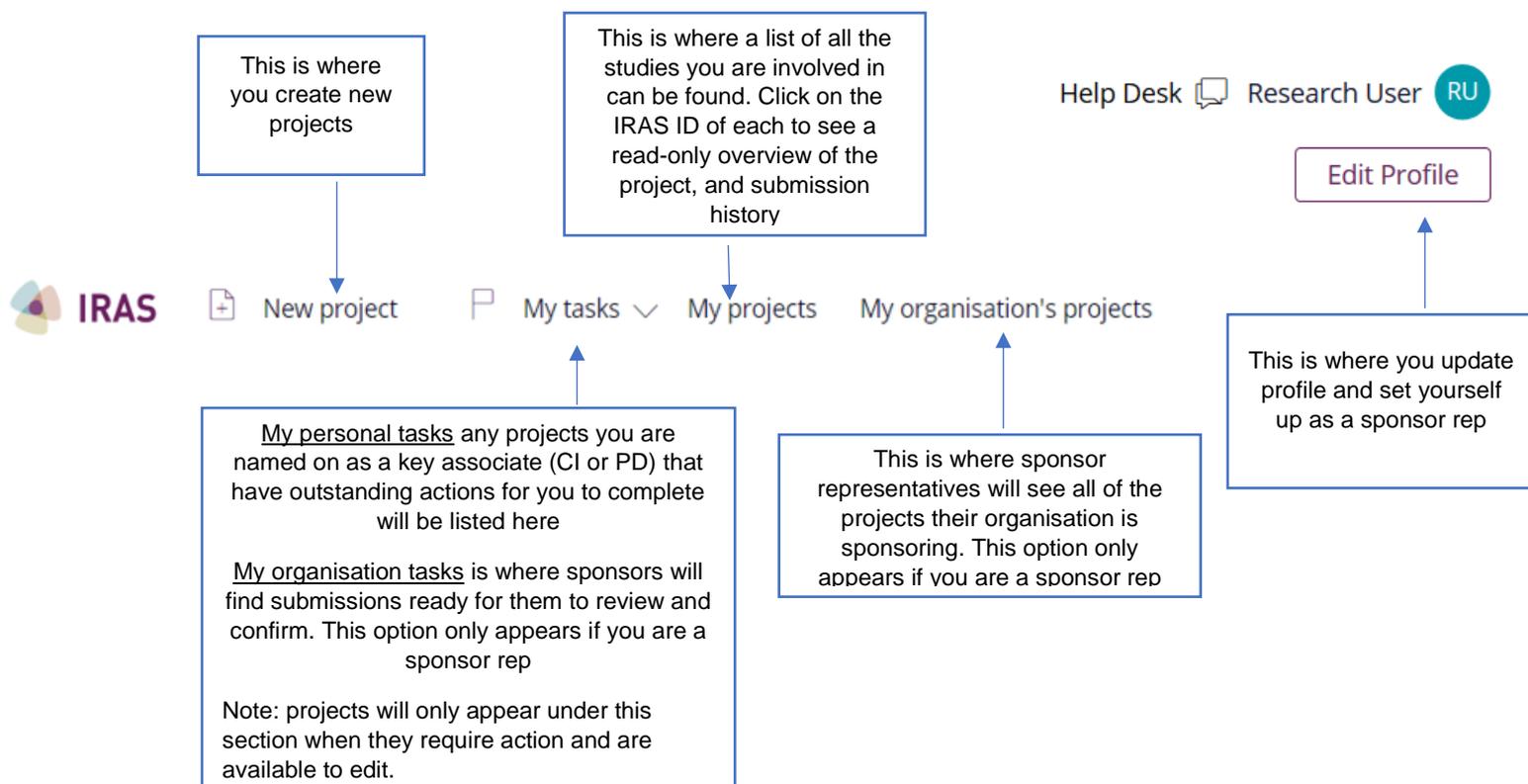


Figure 3- Screenshot of system showing the tabs in the system and describing the activity within each of them.

Applicants: Chief Investigator (CI) / Project Deputy (PD) - If you are working up a submission (initial or amendment), you access the editable work space side of your project from My tasks – My Personal Tasks. When you have pressed Submit and sent the project to the sponsor for review, you can view the submitted project from My projects, but you will not be able to edit.

Sponsor: If you have a task to complete (such as accept a request to sponsor a project, or review and submit a completed application) you access this from My tasks – My organisational tasks

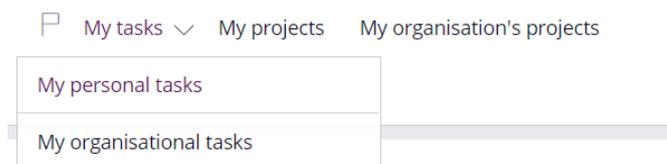


Figure 4-screenshot of system showing the task section

Select the task you wish to complete and begin reviewing. For sponsor rep requests, these can be found at the bottom section of your task list

If for any reason you happen to be a sponsor rep for more than one organisation, your task lists will be separated into organisations.

Making an initial submission

Preparing your application:

The following steps should be completed before you go on to create your project in IRAS for CWoW:

Go to EudraCT to generate your EudraCT number <https://eudract.ema.europa.eu/results-web/>

Use the **current** IRAS system (<https://www.myresearchproject.org.uk/>) or the EudraCT site to complete your clinical trial application form. From this you can generate your application XML and pdf files. Save these to your hard drive as you will need them ready to upload.

Make sure all of the supporting documentation is ready and files are clearly named with date and version number.

Guidance and information on the CWOW pilot and process is found on the [HRA website](#)

When you have completed the above steps you can proceed to IRAS for CWoW (www.myresearchproject.org.uk/CWOW) and prepare your application as follows:

1. Go to the **New Project** tab and follow the options to create a new project. You will need to specify if you are the Chief Investigator or Project Deputy. Once you have selected your role, you will land onto the Project details page. This is where you start to build your project.
2. Answer the questions on the **Project Details** page to reflect the details of your project. You will need to have your EudraCT number ready in order to complete this stage. You need to complete all the fields on the Project Details page before you can proceed.
 - To add the sponsor details, start typing the name of the required sponsor. A blue triangle in the corner of a text box indicates that you need to select from one of the available pre-existing options. Start typing the information you need to enter and select the correct option when it appears (if you are a CRO, please ensure the CRO is set as the sponsor role). For your CI or PD role do the same.
 - Below these questions you will find a set of project filter questions – please answer these, in line with the study scope. At the bottom of the page, click ‘Continue’ if you wish to proceed and ‘Save’ if you wish to return to your set up at another time.



Figure 5-
screenshot
showing the tab

Please note: once you click ‘Continue’ your invitations to the CI / PD / sponsor are sent. Once they have been accepted they will also have oversight of the project via their lists/tasks.

The sponsor will need to accept the project before you can proceed to submission. They will not be able to accept the project whilst it is open in another account, so please make sure you are not working on the project whilst they are accepting it.

3. On the next page (Project dashboard) you will see headers for each of the sections which you now need to complete:

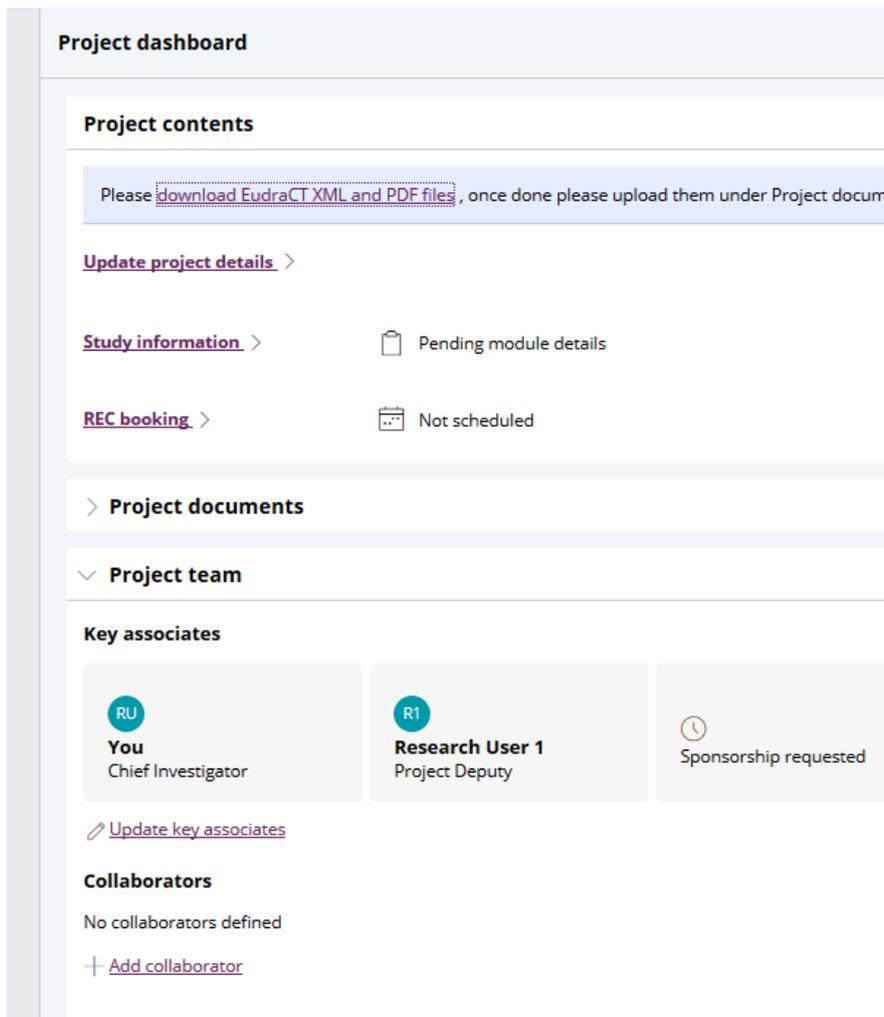


Figure 6- screenshot showing the sections requiring completion

If you are returning to work on your project after logging out, you can access the project dashboard by selecting ‘My tasks’ – ‘My personal tasks’ – project.

Under ‘**Update project details**’ you can make changes to the information you entered here earlier if required.

4. Click ‘**Study information**’. This will take you to a page where you provide more information about the study. Please complete all questions as fully as possible.

If you require further information on any of the questions, you can select the ‘contextual help with questions’ button at the top of the page, which will display guidance where available.

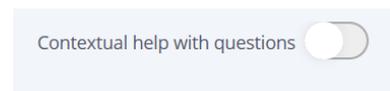


Figure 7-screenshot displaying the ‘contextual help with questions’

When finished, at the bottom of the page click ‘Save and verify’ this will flag up any outstanding questions which still need completing. Once fully completed and no questions are being flagged, please click ‘Update question set’ this will then show a ‘Content verified’ status.

5. **‘Project documents’** is where you will upload supporting documents. You can either drag and drop up to 15 documents at a time or browse if they are in different folders on your computer.

For each document you upload you will need to assign a document type (**please ensure you select the correct document type to ensure the correct documents go to the correct organisation**), and enter the document title, version number and date. For this reason, it is strongly recommended that you clearly name each file with this information to make it easier for you to enter it during the upload process.

The version number / date you enter must match the version number / date on the document. This will be used to validate and will appear on the final opinion letter. If the information does not match, your application may be rejected.

Certain document types are mandatory, which means you will not be able to proceed to submission without uploading them.

If your document type does not match any of the drop-down options, please select ‘miscellaneous’.

It is not possible to go back and edit information once entered. If you make a mistake, please delete the document by clicking the dustbin icon, and re-upload.

6. Under **‘Key associates’** you will see details of the CI and PD with yourself named as your selected role, and you will see the name of the sponsor selected. This will show as a requested status or as a confirmed status. If you need to change any of this information you should return to the Project Details page. Underneath these Key associates you will see a place where you can ‘add collaborators’. This is optional but if you wish to do this, click ‘add collaborators’ and start typing the name of your second named role and the name will appear in the drop-down list – select. You can then choose whether the collaborator will have read-only or editable access.
7. When you think you are ready to submit, click ‘Submit project’ from the project dashboard which will take you to a ‘Check your answers’ page. Scroll down to the bottom of the page and click ‘Verify answers’ this will show anything outstanding via a pink banner at the top of the page – please correct flagged items as instructed. Once complete please click ‘Verify

Figure 8-screenshot displaying the documents section

answers' again and repeat until no pink banner is shown apart from 'you must obtain a REC reference number'.

8. When all of the above steps are complete, and you have your 'Key Associates' in place, 'Project documents' uploaded, and a 'Content verified' status in place next to any questions sets you can proceed to make your booking for the REC meeting. This should be done via cwow@hra.nhs.uk until further notice.
9. When your REC meeting booking has been made, return to the Project Dashboard via My Tasks – My Personal Tasks, and go to the REC Booking section. Click as instructed to display the REC reference number.
10. Return to the 'check your answers' page again and verify answers – this should remove the pink banner as the REC reference has been added. You can now click the 'submit' button. This sends the submission on to the sponsor's account for them to review. If they are happy with the application, they will then make the final submission on to the regulators for review.
11. Please note now the project is submitted you can no longer access the project via 'My tasks' – 'My personal tasks' as this dashboard only appears when you are creating or amending project information or supporting documents. You can now access the project by clicking 'My Projects' – and the project. This is a read only view. If you wish to see the contents of the initial submission. Scroll down to 'Project history' and click into 'Initial submission'. As the relevant authorisations are completed this is where your approvals and time stamps will be shown.

Validation

The application will be validated within 3 days of being received and you will be able to see the validation status in the dashboard. Validation will check whether all of the required documents have been submitted, they can be opened and they are readable. Validation will also check whether the EudraCT form has been signed and dated.

If your application is invalidated, you will need to re-submit the application. Please note that this will generate a new IRAS ID and therefore you will also need to update the IRAS ID on any relevant supporting documents.

Responding to Requests for Further Information

If any questions are raised during review, the reviewing organisation can raise a 'Request for Further Information' (RFI) in which they will ask you to provide additional information or clarification in order that they can proceed.

To respond to an RFI, return to 'My Tasks' – 'My Personal Tasks' and select the project. You will then be able to review the assessor's comments and respond to their queries in the on-screen text

box. You may also need to upload additional documents, updated versions of existing documents, or information to the dataset. In this case, return to the Project Dashboard and add this information in the same way as for an initial submission.

You can then proceed to verify and submit in the same way as before. This will route the project to the sponsor's account for them to review and make the final submission back to the reviewing organisation.

Withdrawing a submission

Before the regulator approves your project, you can withdraw your project. Once the status of the project under My Projects is 'authorised', you cannot.

From 'My projects', select the IRAS ID of the project you wish to withdraw, select 'withdraw' at the top right-hand corner and follow the instructions.

Substantial Amendments

Please note: Only substantial amendment should be submitted via the new part of IRAS. Other amendments should be submitted via the usual route.

Creating a substantial amendment for a trial which has been migrated into the new part of IRAS

All ongoing trials which were submitted under the CWoW pilot prior to the new part of IRAS going live will be migrated into the new part of the system so that substantial amendments can be submitted. Trials will be migrated in phases and you will be informed when a trial is scheduled to be migrated (you will not be able to submit a substantial amendment from being notified that the trial will be migrated until you have been informed that migration has been completed – this should not be more than a day or two).

Once the trial has been migrated, you will need to find the trial in 'My Tasks'. You will need to check that the information which has been migrated over is correct, you will need to upload the **latest versions** of any trial documents (e.g protocol, information sheets) to the project documents section and then you will need to select 'submit'. This will then change the status of the trial to 'authorised' and you will then be able to submit a substantial amendment,

Creating a substantial amendment

From 'My Projects' you will be able to create amendments for any projects with an 'authorised' status.

Click on the IRAS ID of the project and from the Project Details page, select 'New amendment' in the top right-hand corner of the screen.

New amendment

You now have to select the type of substantial amendment

Figure 9-screenshot showing 'new amendment'

- Only pick the 'chief investigator' amendment if you are changing the CI
- Only pick the 'sponsor' amendment if you are changing the sponsor, or sponsor's legal rep
- Only pick 'admin' amendment if you are changing just the contact details for the CI, sponsor, or sponsor's legal rep
- For everything else pick 'project information' (including a new site and PI amendment)

On the next page, select which assessment your amendment relates to:

You will be asked to select whether your amendment relates to Part 1 or Part 2. Please use the following table to identify whether to select Part 1 or Part 2. Please note that if your substantial amendment relates to both Part 1 and Part 2, you should select 'yes' for both.

Part 1	Part 2
Protocol	Recruitment process
Investigator's Brochure	Informed consent process
Compliance with GMP	Participant information
IMPD	Consent form
Auxiliary MPD	Other participant facing documents
IMP Labelling	Questionnaires
Temporary halt to the trial	New/change to investigator/site
Dear Investigator Letter	Letter to GP or treating doctor
Change of sponsor	New site
	Insurance
	Data protection

Figure 10- table detailing examples of part 1 and part 2

You will also need to select whether your amendment requires review by the competent authority (MHRA), REC, or both, and supply a brief summary of the changes involved.

It is very important that you make the correct selections. Where incorrect selections are made at this stage, the substantial amendment will be rejected and will need to be re-submitted.

Click 'Save' and then 'Submit' when you are ready to move to the next step.

This will take you to the Amendment Dashboard.

Study Information

Under 'study information' you need to provide key information about the project. Some of this may be populated from the original application depending on how the application was submitted. Please work through each question ensuring that all fields are completed and confirming that any pre-populated information remains correct.

Project Documents

You will then need to upload supporting documentation. The process for doing this is exactly the same as during the initial submission process and guidance is provided here in the 'making an initial submission' section under Project Documents.

You should upload:

- Cover letter (Mandatory)
- Copy of the signed Notice of Substantial Amendment (Annex 2) Form that you prepared either in IRAS or using the form on the EudraCT website (Mandatory)
- If you have been asked to or need to supply an updated copy of the original application, upload both pdf and xml copies of this as during initial submission
- Copies of all other supporting documentation relevant to the amendment

When complete click 'Next'.

On the following page, click 'Verify Answers'. If any items are outstanding these will be flagged in a pink box at the top of the screen. You will need to address any flagged items before continuing.

When flagged items have been resolved you can continue to click 'Submit'. This will route the amendment to the sponsor's account for them to check and submit for review.

If you need to delete the amendment you can do this by clicking the 'Actions' button in the top right of the screen, and selecting 'Delete amendment'. Deleting an amendment cannot be reversed, and you will need to supply a reason for deleting. Amendments that have already been submitted cannot be deleted.

If you select either CI / sponsor / admin amendments, you will have to complete and receive approvals for these before you can start another amendment.

In order to start a CI / sponsor / admin amendment, no other amendments can be outstanding, and you will first need to wait for approval for those.

You can have more than one ongoing amendment in the project information category, however the same document cannot be included in more than one amendment.

Unlike submitting an initial application, there is no process for the regulator to request further information (RFI) for amendments. However, you may be contacted by email or telephone to provide some information or clarification if this is required before issuing a final opinion.

Glossary

PD – Project Deputy

CI – Chief investigator. This is the investigator with overall responsibility for the research. In a multi-site study, the CI has co-ordinating responsibility for research at all sites.

Sponsor – The person or body who takes on ultimate responsibility for the initiation, management and financing (or arranging the financing) of a clinical trial.

RFI – Requests for Further Information