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# Step by step guide to using IRAS for combined review

Last updated on 4 Aug 2021

This page provides guidance to support applicants in using the new part of IRAS to make applications and manage projects through the [combined review](#) process (formerly known as Combined Ways of Working (CWoW)). This guidance is updated regularly so if you have printed or saved this page as a pdf the information may be out of date. The current version of the guidance can always be found on the [HRA webpage](#).

Applications which are being made under the combined review process must be prepared and submitted using a new part of Integrated Research Application System (IRAS) and therefore applications should not be created in the standard part of IRAS.

Combined review will become the way that new Clinical Trials of Investigational Medicinal Product (CTIMP) applications are submitted from 1 January 2022. The service is open now to all CTIMP sponsors and applicants. Where new CTIMP applications are planned, these should be made via the combined review service.

Even if you do not have any applications coming up, there are still important

Even if you do not have any applications coming up, there are still important differences to be aware of in order to prepare for the changes.

If you are familiar with preparing applications in the standard part of IRAS you will notice that the functionality and processes in the new part of IRAS are considerably different. These changes facilitate a more streamlined and efficient service, but at the outset you should expect to spend some time learning and becoming comfortable with this new way of working. It is therefore essential that, regardless of your previous experience, you read through this guidance prior to starting work in the system and refer back to it at any point should you need clarification along the way.

This guidance document is still in development and we would welcome any comments you may have related to it. Please pass any feedback or queries to [cwow@hra.nhs.uk](mailto:cwow@hra.nhs.uk).

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## Creating an IRAS account

[Navigate to the login page](#)

This site uses the same login as you would usually use for making bookings and submitting amendments for studies outside of the combined review process, so if you already have an account for either of these things you should use the same login details here. The system also shares the same login details as some NIHR services – you can find more information to help you determine whether you already have an account by clicking the ‘Help’ link.

If you do not already have an account, click ‘Create Account’ and follow the simple on-screen instructions. 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.

If you encounter any difficulties in logging in or creating an account, click on ‘Help’.

[Please note: During account 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.]

## Setting up your profile

Once you have created your account you can add more details to your IRAS profile.

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 each time you log in and is currently not possible to change: if your email address changes you will still use the original email address as your username to log in.
- Email address in your profile information – The email address you add to your profile information will be your correspondence email address that all emails and notifications are sent to, so it is

important that it is kept up to date otherwise you will not get notifications and correspondence about your applications.

To update your profile information:

- Click your initials on the circular button in the top right-hand corner

- Select 'Profile' from the drop-down list
- Below where you have just clicked your username in the top right-hand corner, a new button 'Edit profile' will appear - please select.
- Complete with up-to-date relevant information
- Select 'Update'

If you move to another organisation and will no longer need access to any of the studies in your account then you will need to create a new account with a new email address as your username. In a future release there will be an update to accommodate email (username) changes.

Sponsor Representatives:

In the profile section, you can also request to act as a sponsor representative

**IMPORTANT:** this role will only apply if you are working for or on behalf of the sponsor's office, and will allow you to have a read-only view of all the projects belonging to sponsor, as well as the ability to approve or reject requests to add other sponsor representatives and complete outstanding sponsor tasks. You should only complete the following steps if you are sure they apply to you or you have been specifically advised to do so.

- Click your initials on the circular button in the top right-hand 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 entire 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.

CROs should not set themselves up as a Sponsor Representative if they will only work on a proportion of studies from that sponsor.

If your request is rejected and you believe you should have been granted access, please discuss this with the sponsor office directly.

## 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.

These roles allow the flexibility for more than one person at a time to have access to work on preparing and managing a project, from different teams or organisations as required without the need to transfer between users. It also allows control over the level of access each user has so that some can edit the application whilst others who just need to check on the project's progress can have read-only access.

## Chief Investigator (CI)

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

Within IRAS, the CI is responsible for the tasks below. However, they may choose to assign some of these to the Project Deputy (see next section).

It is 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). It will not be possible to proceed to submission unless a CI has been assigned to and accepted the project in IRAS.

Key tasks a CI may perform in IRAS are:

- Creating an IRAS project
- Accepting ownership of an IRAS Project (this must be completed before the project can be submitted)
- Adding a Project Deputy
- Adding a Sponsor Group organisation to the project in IRAS (or assigning Sponsor Group Organisation to their own organisation if appropriate)
- Selecting study collaborators
- Completing IRAS question sets
- Uploading study documents
- REC booking
- Forwarding the application to the Sponsor Group Organisation work manager for submission
- Receiving, reviewing and answering Requests for Further Information (RFI)
- Creating a new amendment
- Updating the Project Deputy role as required
- Submitting final reports

## Project Deputy

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

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

All projects must have a Project Deputy and Chief Investigator assigned so that there are always two individuals with access to the study for business continuity purposes.

Any person delegated by the sponsor or CI can be the Project Deputy 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 – the system is not designed to support the use of joint or shared accounts. The Project Deputy will only have access to the studies that they are allocated to. This role does not have access to other studies in the CI's portfolio.

There can only be one Project Deputy per project.

If required, the Project Deputy can select a new Project Deputy from the drop-down list (My tasks > My personal tasks > (select project) > Update key associates). As soon as this is done, the current Project Deputy will lose the access and the new Project Deputy becomes the Project Deputy who will automatically take over access and management of the project. The exception to this is if the application has been submitted for review. In this case you will need to wait for the application to be approved and then you will be able to change the Project Deputy role.

Key tasks a Project Deputy may perform in IRAS are:

- Creating an IRAS project
- Accepting Project Deputy role of an IRAS Project
- Inviting a CI to access the project in IRAS
- Adding a Sponsor Group organisation to the project in IRAS (or assigning Sponsor Group Organisation to their own organisation if appropriate)
- 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
- Forwarding to Sponsor Group Organisation application manager for submission
- Receiving, reviewing and answering Requests for Further Information (RFI) (only if determined by the sponsor/CI to have relevant training and experience)
- Creating a new amendment
- Updating the CI role
- May also undertake a separate role as a Sponsor Group Organisation contact if appropriate
- Submitting final reports

## Sponsor Group Organisations

A Sponsor Group Organisation can be any organisation that is registered in the system who has been delegated the responsibility of acting on behalf of the sponsor.

The Sponsor Group Organisation roles are:

- **Sponsor** (this role also covers the Sponsor's Legal Representative for a non-UK based Sponsor within the EAA)
- **Global Sponsor** (for non-UK sponsors outside the EAA or approved country list) – please note: this type of sponsor can be added as free text. The Global Sponsor has no oversight of the project within IRAS and does not need an IRAS account.
- **Co-sponsor**
- **Clinical Research Organisation (CRO)** or
- **Clinical Trials Unit (CTU)**

The purpose of the Sponsor Group Organisation role in IRAS is purely for managing the application in IRAS. Adding Sponsor Group Organisations allows these organisations to have oversight of the project in IRAS, and to assign the sponsor or delegate with responsibility for submitting the application and managing sponsor tasks in IRAS. You may have a single Sponsor Group Organisation involved in your project, or you may have several.

As many sponsor group organisations can be added to the project as required, but only one of these must be assigned the responsibility of 'managing the project work on behalf of the sponsor' (see screenshots below) – **this must be the organisation that is going to submit the study.**

If for example, the sponsor has delegated the role of submitting the application to the CRO, the CRO should be allocated responsibility for managing the project work. This sponsor role can be undertaken by the same person acting as Project Deputy if required, for example in the case of a CRO responsible for both preparing the application and submitting it for review they would undertake the role of both Project Deputy (allowing them to prepare the application), and sponsor group organisation CRO role (allowing them to submit the application).

As long as at least one organisation has been allocated to a sponsor group role and given responsibility for managing the application, you do not need to assign a sponsor group role to the actual sponsor if they do not need to work on the application in IRAS. You should only add additional sponsor group organisations to your project if they will need to access the application in IRAS.

The Sponsor Group Organisation is initially assigned when the CI or Project Deputy selects 'New Project' from the top of the home page. One of the questions here asks them to select a Sponsor Group Organisation. This will send a request for sponsorship to that organisation which will ask them to confirm that they will undertake a Sponsor Group Organisation role on the study, and if they will manage the work in IRAS. The organisation who will 'manage the project work' will receive any sponsor related tasks to action in the 'My Organisation Task list' and will be responsible for

sponsor related tasks to action in the 'My Organisation' task list, and will be responsible for submitting the application.

If you select 'No' to the 'will you manage project work' question, a further question will appear asking you to identify which organisation will, as there must be one Sponsor Group Organisation assigned with this responsibility.

Once the selected sponsor organisation receives and accepts the invitation to join the study they will be able to manage the sponsor group roles, and add other sponsor group organisations as needed - the CI or Project Deputy no longer has control over the 'Sponsor Group Organisation' management.

If the Sponsor Group Organisation refuses the invitation, it is sent back to the project dashboard, and the CI or Project Deputy will need to reassign another Sponsor Group Organisation.

This screenshot shows what an initial 'Accept Sponsor Group Invite' and 'Accept IRAS Work Invite' will look like in the Sponsor's account under 'My Organisational Tasks' :

Task	Task ID	IRAS ID	Short title	Chief investigator
<a href="#">Accept IRAS Work Invite</a>	<a href="#">P-1517628</a>	1517628	test	Lokesh.IRAS
<a href="#">Accept Sponsor Group Invite</a>	<a href="#">P-1517644</a>	1517644	Test App 15/01	Show.Tell

[Long description](#)

If this organisation indicates that they will not manage the project work, they must select the organisation that will.

Sponsor group organisations are selected from existing options available within IRAS - if your organisation is not listed as an option, please contact [helpdesk@myresearchproject.org.uk](mailto:helpdesk@myresearchproject.org.uk)

Global Sponsor roles do not need an IRAS account, however when adding a global sponsor, a legal representative organisation needs to be specified. If the legal representative organisation does not accept the invite prior to the submission to the regulators, then the legal representative organisation will be removed as part of the submission process.

Once you have identified the Sponsor Group Organisation that is managing the project work, that Organisation only will have access to a new workspace located in 'My organisation's projects'.

Clicking the 'Edit Sponsor Group' button will then allow the sponsor group organisation user to add other types of Sponsor Group Organisations (as needed) and assign roles.

To 'edit' roles, click the pen icon beside each organisation. If required, the responsibility for managing the work in IRAS can also be reassigned to a different sponsor group organisation.

To add additional organisations, click 'Add Sponsor Roles' add the organisation and select their role.

**Please note: any Organisations added to the project at any stage (except Global Sponsors) will always**



**receive an invite to join the project, and if confirmed will have read-only access to the project.**

Currently, none of the Sponsor Group Organisation details are shared with the regulators when you submit your application. They will only receive the Sponsor details that you enter into the application form (the Clinical Trial Dataset). This may change in the future as IRAS is developed.

The sponsor group organisation is selected from existing options available within IRAS - if your organisation is not listed, please contact [helpdesk@myresearchproject.org.uk](mailto:helpdesk@myresearchproject.org.uk).

## Collaborators

Once a project has been set up, the CI or Project Deputy can 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.

It is not recommended that users create 'generic' email accounts for multiple users to access the system, but instead make use of this function and add as many staff as required as collaborators via their individual accounts.

Collaborators can only be added up until the application has been submitted and not after that, even for substantial amendments.

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

When adding an individual to a project, either as CI, project deputy or collaborator, start typing their email into the relevant field and then select it from the menu. If their email does not appear it means they do not have an account set up in IRAS or they have an account set up under a different email address – in this case you will need to contact them to check that they have an account and confirm the username.

## System Navigation

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



New project

My tasks

My projects

My organisation's projects

Help Desk



Research User



**Edit Sponsor Group**

Close

New project	My tasks	My projects	My organisation's projects	Edit sponsor group	RU
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New project	My tasks	My projects	My organisation's projects	Edit sponsor group	RU
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My personal tasks any

<p>This is where you create new projects</p>	<p>projects you are named on as a key associate (CI or Project Deputy) that have outstanding actions for you to complete will be listed here</p> <p>My organisation tasks is where sponsor group organisations will find projects they have been assigned to.</p> <p>Note: projects will only appear under this section when they require action and are available to edit.</p>	<p>This is where a list of all the studies you are involved in can be found. Click on the IRAS ID of each to see a read-only overview of the project, and submission history</p>	<p>This is where sponsor group organisations will see all of the projects their organisation is sponsoring. This option only appears if you have been assigned a sponsor group role</p>	<p>Sponsor Group Organisations can edit or add to the sponsor group roles here</p>	<p>This is where you update your personal profile and contact details</p>
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Your view will differ here depending on which roles you have been assigned.

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

Sponsor group organisation: If you have a sponsor 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. Select the task you wish to complete and begin reviewing.

## Making an initial submission

### Preparing your application:

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

- [Go to EudraCT](#) to generate your EudraCT number (Although the UK is no longer an EU member state, a EudraCT number is still required for all CTIMPs in order to be processed by MHRA. More

state, a EudraCT number is still required for all CTIMPs in order to be processed by MHRA. More information is available on the [Imperial College London website](#).

- Make sure all of the supporting documentation is ready and files are clearly named with date and version number.
- Read the general guidance on the combined review process found on the [HRA website](#).

When you have completed the above steps you can proceed to [IRAS for combined review](#) and prepare your application.

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 be taken to 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 group organisation details, start typing the name of the required sponsor group organisation. 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 and will be responsible for submitting the application, please ensure the CRO is set as the sponsor group organisation role). If you are not sure who to enter at this stage you can leave it blank – you will be able to add this information later. For your CI or Project Deputy role do the same.
  - You will need to enter a study end date – it does not matter at this stage if you do not know the exact date, please just enter a best estimate. It can be amended later if required.
  - 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.

Please note: once you click 'Continue' your invitations to the CI / Project Deputy / sponsor group organisation are sent. Once they have been accepted they will also have oversight of the project via their lists/tasks.

**The sponsor group organisation and CI 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 including:

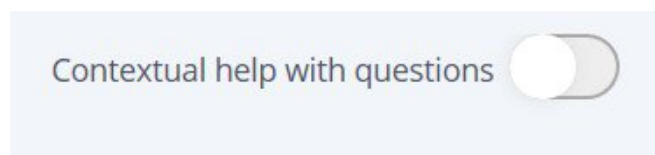
- project contents
- study information
- clinical dataset
- REC booking

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. You will not be able to change the sponsor group organisation if they have already accepted the project – after this any sponsor group changes can only be made by the sponsor group.

4. Click **'Study information'**. This will take you to a page where you provide more information about the study. 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.



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, click 'Update question set' this will then show a

'Content verified' status.

5. Click **'CWOW Clinical Dataset'**. You must complete this dataset in full in order for the application to be submitted.

You can complete the question set in any order you prefer. When working on a section, click 'save and verify' before navigating away from the page or logging out. This will save your responses and will also flag in red any incomplete or incompatible responses. When the page is complete and all fields under that section are verified, the section will be marked as 'content verified' so that you can see at a glance it is complete. You will still be able to make changes prior to submission if required.

6. If you have used the EudraCT site to prepare an application (e.g. in the case of projects also taking place in EU countries where the same information will apply to the UK application), you will still need to fill out the CWOW Clinical Dataset in IRAS. To do this click the 'Import EudraCT XML' button on the Project Dashboard. You can then upload an xml file of the application which will populate all data fields in the CWOW Clinical Dataset. You should then check through the dataset to ensure that all fields are appearing as expected and make any corrections as required, and answer any additional questions present in the CWOW clinical dataset but not on the EudraCT form.

7. **'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. You can add documents at any point whilst preparing your project, up until submission.

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 review body**), and enter the

document title, sponsor 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 part of validation once submitted and will appear on the REC 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.

In the unlikely event that your document type does not match any of the drop-down options, please select 'miscellaneous' and select which review body the document is relevant to.

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.

8. On the Project Dashboard, under 'Key associates' you will see details of the CI and Project Deputy with yourself named as your selected role, and the sponsor group organisations. Each will have a requested status or as a confirmed status. If the request from the CI or Project Deputy to a sponsor organisation has not yet been confirmed, you have the option to withdraw the request by clicking 'update key associates' and selecting the appropriate option. If the role has been confirmed this option will no longer appear. Further information on adding a sponsor group organisation and collaborators is found in the 'User Roles and Tasks' section further up this page.

NOTE: Currently a PDF of the application is generated at the point the applicant submits (sends through to the sponsor for final review and submission), this means there is no option to create a PDF of the draft project. For sponsor QC pre-submission, please add the QC reviewer as a 'collaborator' so that they can view and update as needed.

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

10. 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. Navigate to 'REC Booking' on the project dashboard and read the booking guidance that appears on that page, then when you are ready to book, click the 'Create Booking' button.

When you come to select your REC slot, if there is no REC availability suitable for your booking, please contact [cwow@hra.nhs.uk](mailto:cwow@hra.nhs.uk) to make a manual booking.

For manual bookings, you will also need to import the REC booking details into your project manually to link the booking with the application. To do this, navigate back to the project dashboard and against REC Booking – Not Scheduled, click the small box with an arrow in – this will import the REC reference to your project and update the REC booking status.

11. Return to the 'check your answers' page again and verify answers – this should remove the pink

banner as the REC reference has now been added. You can now click the 'submit' button. Please note that this does not submit the project for regulatory review – it sends the submission on to the sponsor group organisation responsible for managing the submission for them to review. If they are happy with the application, they will then make the final submission on to the regulators for review. It is important that the sponsor group organisation responsible for manages the submission does so in a timely manner to ensure that they make the final submission before the cut-off date for the REC expires. Staff from the sponsor group organisation can be added as collaborators to allow early and ongoing oversight.

12. 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.

13. Sponsor group organisation review and submission. When the application has been submitted to the sponsor group organisation responsible for managing the submission's account they will find the project under My Tasks – My Organisational Tasks, with an outstanding task to confirm submission. They can then review the completed dataset and if happy with it, check the radio button labelled 'I confirm this submission', then the 'submit' button. This will submit the application to the regulator for review. In making this confirmation and submitting for review, they are providing a declaration equivalent to that at section I1 of the EudraCT Clinical Trial Application Form as follows:

'I hereby confirm that /confirm on behalf of the sponsor (delete which is not applicable) that:

- the information provided is complete;
- the attached documents contain an accurate account of the information available;
- the clinical trial will be conducted in accordance with the protocol; and
- the clinical trial will be conducted, and SUSARs and result-related information will be reported, in accordance with the applicable legislation.'

If the sponsor group organisation reviews the application and wishes to request updates to the dataset before it can be submitted, they can select 'I do not confirm this submission' and then provide details of the required updates in the 'Reason for not confirming' box. Clicking the Submit button will then transfer the application back so that it can be edited as necessary.

## 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.

If your application is invalidated, you will need to re-submit the application.

## 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. Exceptionally (for example if the response is very lengthy or contains images or tables), you may provide your responses in a separate document, in which case you just need to add a comment to the text box to confirm this. 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. If you need to go back to the screen with the RFI text boxes, you will need to select 'Update RFI details'.

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 of the RFI back to the assessors.

## Withdrawing a submission

You can withdraw your project at any point up until it is approved. Once the status of the project under My Projects is 'approved', 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: Currently only substantial amendments should be submitted via the new part of IRAS. Other amendments should be submitted via the usual route.**

## Creating a substantial amendment

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

Help Desk 

**New amendment**



You now have to select the type of substantial amendment from the following:

- chief investigator
- sponsor group
- administrator
- project information
- extend study end date

You should:

- only pick the 'Chief investigator' amendment if you are changing the CI
- only pick the 'Sponsor Group' amendment if you are changing the sponsor or sponsor's legal representative
- only pick 'Administrative' amendment if you are changing just the contact details for the CI, sponsor, or sponsor's legal rep
- only pick 'Extend study end date' if you will be extending the end date of the study
- for everything else pick 'project information'

On the next page, select which review 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

Part 1	Part 2
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	Insurance
N/a	Data protection

NB For NHS sites, addition of a site or PI is a non-substantial amendment.

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. The process for this is very similar to making the initial submission. 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 Amendment Tool (Mandatory) (NB – the Annex 2 Form is no longer used)
- 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 type cannot be included in more than one amendment.

If you prepared your application using the CWOW clinical dataset in the system (ie if the initial application was prepared after 31 December 2020), you should also update the corresponding questions in the dataset when making your 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.

### **Important note on amendments for projects originally submitted prior to 31 December 2020**

If you are submitting a substantial amendment for a project where the original application was prepared before 31 December 2020, the study information and CWOW clinical dataset sections in your project will not be complete as it was not in use at the time you made your application. However, in order to proceed to create and submit an amendment your project dataset must be verified by the system as complete.

The verification is turned off for these question modules, until you press save at the bottom of any page. It is recommended that you do not click any of these blank questions or press 'save' as doing so will activate verification and mean that you cannot proceed with your amendment until you have completed the entire dataset.

## Reporting

Development Safety Update Reports (DSUR) can be submitted within IRAS.

Go to 'My Studies – My Projects' and open the project you wish to submit a report for.

Click the 'Reporting' button from the top right side of the screen.

[Reporting](#)[New amendment](#)

Click the 'DSUR' option. The following page will be automatically populated with the project's IRAS ID and EudraCT number.

Enter the details of the applicant submitting the report, and upload supporting documents. You will need to attach at least one cover letter in addition to the DSUR report itself.

Bulk upload: If you wish, you can also add the IRAS IDs for any other projects you would like to include in this report. This avoids the need to make a separate report for each project individually. If you are doing this, you must take care to not duplicate any IRAS IDs on this page – **if the report contains any duplicate IRAS IDs it will be rejected by the system** and you will need to go back and prepare a new DSUR from scratch. In addition, **if you enter the IRAS ID of any project which has not yet received an 'approved' status, the submission will be automatically rejected**, and you will need to go back and prepare a new DSUR from scratch.

After submission you will find a record of the DSUR under 'Project History' on the project details page. You can check here to confirm the status of your submission (pending / invalidated / completed etc) and you can also see details of any requests for further information (INRFI) – these will also flag up as clarification requests under 'My Tasks'.

If preferred it is also possible for you to continue to submit DSURs via the Human Medicines Portal where necessary (for example where different organisations have oversight of the reporting functions). Please note you should **either** submit DSURs for a project in IRAS **or** on the Human Medicines Portal, not both.

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