**Combined Review applications for a Combined trial of an investigational medicinal product and an investigational medical device (IMP/Device trials)**

Until the functionality for investigational medical devices is introduced into the new part of IRAS, all applications for IMP/Device trials will require applicants to complete information in both the standard and new parts of IRAS.

**Pre-Application Devices Validation**

IMP/Device trials will require Pre-Application validation from Medicines and Healthcare products Regulatory Agency Devices Division (MHRA Devices) prior to completing your combined review application in IRAS. If you believe your IMP/Device trial project requires submission to MHRA Devices you should ensure that you contact them first to discuss Pre-Application Validation in good time. You can contact them at: CI-applications@mhra.gov.uk. In your email, please use the subject line; “CI/CT – Devices Pre-Application Validation”.

**Making Combined Review Application for an IMP/Device trial**

The instructions below show the steps that are required for making an IMP/Device trial application via the combined review service. These steps are divided into the following sections -

1. [Completing the Medicines and Healthcare products Regulatory Agency (MHRA) Devices form in standard IRAS, and ensure you have all the associated documents ready as per the checklist](https://www.myresearchproject.org.uk/help/hlpcombinedreview.aspx#STEP1)
2. [Send your documents via an email link to MHRA Devices for Pre-Application Devices Validation](https://www.myresearchproject.org.uk/help/hlpcombinedreview.aspx#STEP2)
3. [After liaising with MHRA Devices, upload the MHRA Devices form and supporting documents to your combined review application in the new part of IRAS.](https://www.myresearchproject.org.uk/help/hlpcombinedreview.aspx#STEP3)
4. [Responding to Requests for Further Information](https://www.myresearchproject.org.uk/help/hlpcombinedreview.aspx#STEP4)
5. **Completing the Medicines and Healthcare products Regulatory Agency (MHRA) Devices form in standard IRAS, and ensure you have all the associated documents ready as per the checklist**

As part of your application you will need to include the ‘MHRA Devices form’ as a supporting document. **This can only currently be completed and generated in standard IRAS.**
	* Create a new project in [standard IRAS](https://www.myresearchproject.org.uk/Signin.aspx) and complete the project filter questions.
	* For **project filter question 2** - select the ‘Ionising Radiation and Devices form for combined review of combined trial of an investigational medicinal product and an investigational medical device’. (please select this option even if your project does not involve ionising radiation)
	* For **project filter question 4** - select the Medicines and Healthcare products Regulatory Agency (MHRA) Devices Division form.
	* Complete the MHRA Devices form (If your project also involves the use of ionising radiation, please see the [section below](https://www.myresearchproject.org.uk/help/hlpcombinedreview.aspx#IONDev)). Ensure section F2 of devices form is ticked confirming MHRA may discuss the application with the research ethics service and relevant REC. Once completed, you should go to the forms submission tab and follow the instructions. Selecting the ‘proceed to submission’ button **will not** submit the form electronically. Instead, it will generate a pdf file of the MHRA Devices form.

	The MHRA Devices form will also contain a checklist tab, which will provide a useful list of supporting documents. Documents marked as mandatory must be submitted in all cases for the application to be valid. All documents and this checklist should be sent to MHRA for Pre-Application Validation.
	* **Please note:** The IRAS ID generated in standard IRAS is only for the purposes of generating this form. You should only use the IRAS ID generated in your combined review application in the new part of IRAS (this will appear as a P-number reference). The new IRAS ID should be provided in the cover letter of the device’s application.
6. **Send your documents via an email link to MHRA Devices for Pre-Application Devices Validation**

Once you have generated your MHRA Devices form in standard IRAS this form, along with all the required supporting documents, should be sent via a link to MHRA Devices for pre-application validation. To request the link to upload the documents please email: CI-applications@mhra.gov.uk quoting the following in the subject line of your email “CI/CT pilot – Devices Pre-Application Validation”.

MHRA Devices will then check your submission is valid. You will be contacted by them directly via email. Please note this is a validation process to check all the necessary documentation required for the CI submission is available, it is not a formal review.

At the end of their validation check the MHRA will provide you with a list of documents they have checked as part of the pre-application validation. These are the documents that will be expected to be submitted as part of your combined review application. **You must not make any changes to these documents after MHRA Devices have confirmed validation.** Any changes between devices pre-validation and submission to medicines will likely invalidate the submission.
7. **After liaising with MHRA Devices Upload the MHRA Devices form and supporting documents to your combined review application in the new part of IRAS.**

Once confirmation that your application is valid has been received from MHRA Devices you will then need to finalise your combined review submission in the [new part of IRAS](http://www.myresearchproject.org.uk/CWOW). This part of the application process is completed in the normal way and can be prepared in parallel whilst seeking validation from MHRA Devices. Please visit our [step-by-step guide](https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/clinical-trials-investigational-medicinal-products-ctimps/combined-ways-working-pilot/step-step-guide-using-iras-combined-ways-working-cwow/#preparing) for further information on how to prepare your combined review application.

Once you are ready to upload your supporting documents, the MHRA Devices form and all documents that require submission to MHRA Devices (these will be listed in your pre-application validation confirmation email) should be uploaded and categorised as the document type; **‘Miscellaneous: MHRA only’.** Before uploading, please ensure that no changes have been made to any of the MHRA Devices documents since confirmation that they are valid from the MHRA Devices team.

**IMPORTANT:** Some documents will need to be sent to both MHRA Devices and the REC (such as the patient information sheet (PIS)) where this is the case, these documents will need to be **uploaded onto the system twice.** You must ensure all duplicated documents are identical.

For Example, when uploading the PIS. The PIS should be uploaded and categorised as usual for your combined review application. The same PIS is then uploaded again, this time to be sent to MHRA Devices with the document type; **‘Miscellaneous: MHRA only’**. This will ensure the documents are reviewed by the appropriate bodies.
8. **Responding to Requests for Further Information**

Once your application has been submitted for review, any RFIs from MHRA Medicines and the REC will be issued in the new part of IRAS, in the usual way (visit the [step-by-step guide](https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/clinical-trials-investigational-medicinal-products-ctimps/combined-ways-working-pilot/step-step-guide-using-iras-combined-ways-working-cwow/#preparing) for more details) while RFIs from MHRA Devices will be emailed directly to you. **You will need to withhold responding to the MHRA Medicines/REC RFIs until all email RFIs have been resolved with MHRA Devices, and they have instructed you to submit the response to the RFI from Medicines and REC.**

RFIs from MHRA Devices will be managed **outside of the IRAS system via email**. You will be contacted directly with letters requesting clarifications or further information as necessary. Once all RFIs from MHRA Devices have been addressed you will receive a confirmation email and will be instructed that you can now provide all your responses in IRAS. A final decision on the application (MHRA medicines, MHRA devices and REC) will be issued within 10 days of your RFI submission in IRAS.

If you are required to make changes to your MHRA Devices form you can log into the standard part of IRAS, select the project, and amend the information in the form accordingly. Authorisations will need to be re-signed.

Once updated, a pdf file of the form can be generated again, [as per the instructions above](https://www.myresearchproject.org.uk/help/hlpcombinedreview.aspx#STEP1)

**Please ensure any changes to your supporting documents as a result of the MHRA Devices review are updated in the new part of IRAS as part of your combined review submission. Updated versions should be clearly identifiable though your document management nomenclature.** You will need to remember to ensure that any updated versions of duplicated documents (required for both REC and MHRA Devices submissions) match.