Parallel Review applications for an investigational medicinal product study and an investigational medical device study

July 2026

This guidance page applies when a study is both a Clinical Trial of an Investigational Medicinal Product (CTIMP) and a Clinical Investigation (CI) of a medical device.

Where this scenario arises, studies should be submitted to MHRA as a "Parallel Review" application (formerly known as a combined trial of an investigative medicinal product and an investigational medical device).

- See MHRA's guidance on clinical investigations and linked flow charts to determine whether your study is a clinical investigation of a medical device requiring notification to MHRA.
- With respect to medicinal products, see MHRA's guidance on when a Clinical Trial Authorisation (CTA) is needed.

This guidance describes the latest iteration of the process to submit a Parallel Review application to MHRA. The process is intended to bridge the gap between two separate sets of legislation, legislative timescales and system functionality.

In the long term, MHRA Clinical Investigations and Trials Unit's intention is to align regulations and processes as much as possible to create a streamlined submission experience for medicinal product and device studies. This will be done in coordination with the Health Research Authority (HRA) and the ongoing development of the new Plan and Manage Health and Care Research service.

Prior to the launch of the Plan and Manage Health and Care Research service, Parallel Review applicants will need to continue to complete information in both the standard IRAS and new part of IRAS.

This page provides detailed instructions for applicants on how to complete their applications if they involve either ionising radiation or an investigational medical device. If after reviewing this page you still have questions regarding your Parallel Review application please see the following webpage for contact details: Integrated Research Application System.

Please note:

- For the purposes of this guidance, MHRA Clinical Investigations team will hereafter be referred to as 'MHRA Devices'
- The MHRA Clinical Trials team will hereafter be referred to as 'MHRA Medicines'

MHRA are aware that the Parallel Review assessment process has historically been complex to navigate. We are committed to seeking ongoing feedback from applicants, both now and into the future, with the aim of improving the applicant experience.

Submitting a Parallel Review Application

The following guidance assumes some basic prior knowledge of Clinical Trials of Investigative Medicinal Products (CTIMPs) and Clinical Investigations of medical devices (CIs). Please ensure you review the following webpages prior to submitting your application for the latest guidance:

Clinical trials for medicines: apply for approval in the UK - GOV.UK

Clinical investigations for medical devices - GOV.UK

After having reviewed this guidance, and the associated links at the top of this page, if you are still unsure whether your study qualifies as both a CTIMP and a Clinical Investigation please contact CI-applications@mhra.gov.uk.

The instructions below show the steps that are required for submitting a Parallel Review application, and what to expect when receiving an outcome. These steps are divided into the following sections, with more details on each step provided in the guidance below:

1. Completing the Medicines and Healthcare products Regulatory Agency (MHRA) Devices form in standard IRAS, and gathering associated documentation

2. Pre-Application Devices Validation

3. Uploading the MHRA Devices form and supporting documents along with your CTIMP application in the new part of IRAS

4. Responding to Requests for Further Information (RFI)

5. Receiving an Outcome

Please see the flow diagram in Annex A for a visual representation of the Parallel Review application and assessment process.

Step 1: Completing the Medicines and Healthcare products Regulatory Agency (MHRA) Devices form in standard IRAS, and gathering associated documentation

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 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 only (the full IRAS form is not required.) If your project also involves the use of ionising radiation, please see additional guidance below.

Once completed, you should go to the MHRA Devices form 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 uploaded in step 2, as part of your submission.

Further guidance on which documents are required can also be found here:

- Guidance on compiling a submission
- MHRA Clinical Investigations guidance under the sub-heading 'Validation Checklist'

Please note: The IRAS ID generated in standard IRAS is only for the purposes of generating this form. You should use the IRAS ID generated in your combined review application in the new part of IRAS (this will appear as a seven number reference, e.g. 1001234) as the correct IRAS ID for this study.

The new IRAS ID should be notified to MHRA Devices via email CI-applications@mhra.gov.uk once confirmed.

Step 2: Pre-Application Devices Validation

Parallel Review applications first require a pre-application validation (or 'pre-validation') of the clinical investigation document package, prior to formal submission in new IRAS. This pre-validation will be conducted by MHRA Devices.

To commence pre-validation, please contact CI-applications@mhra.gov.uk, requesting a ShareFile link in order to upload your documentation. Please include the phrase “Devices Pre-Validation – ShareFile request” within the title of this email.

MHRA Devices will proceed to check your submission meets the requirements. Please note: this pre-validation process is to check that all the necessary documentation required for the CI submission is available – it is not a formal review. Following MHRA Device’s check, you will be contacted directly by email, and any outstanding documentation will be requested.

Once validation is complete and all CI documentation requirements have been met, MHRA Devices will provide a list of documents they have checked as part of the pre-application validation.

These are the documents that must be submitted as part of your application, and **you must not make any changes to these documents after MHRA Devices have confirmed validation**. Any changes at this point will invalidate your submission.

Step 3: Uploading the MHRA Devices form and supporting documents along with your CTIMP application in the new part of IRAS.

Uploading documents to the new part of IRAS is done per standard processes for clinical trials – if you would like further information on how to do this, please see HRA’s step-by-step guide.

Once you are ready, upload your clinical trial documents, the MHRA Devices form and your clinical investigation documents (these will be listed in your pre-application validation confirmation email). All clinical investigation related documents should be uploaded to new IRAS as the document type; ‘**Miscellaneous: MHRA only**’.

IMPORTANT: Some documents will need to be sent to both MHRA Devices and the REC (such as the participant 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, it should be uploaded and categorised as usual for your clinical trial application. The same PIS should then be uploaded again, this time to be sent to MHRA Devices, with the document type ‘Miscellaneous: MHRA only’.

After you have submitted your complete documentation package (including both clinical investigation and clinical trial documentation) via the new part of IRAS, MHRA Medicines will validate your application within seven calendar days of submission. You will be contacted during validation if any additional documentation is required in relation to the CTIMP.

MHRA Medicines Assessment

Once your application has been successfully validated, you will receive an acknowledgement letter via e-mail confirming that you will be notified of:

- the licensing authority's decision, and
- the research ethics committee's opinion,

within 30 calendar days from the date of validation.

If the licensing authority is unable to approve the application, or if the Research Ethics Committee is unable to issue a favourable opinion, a Request for Further Information (RFI) letter will be issued to you via e-mail and communicated in IRAS.

Under the Parallel Review application process, an RFI letter will always be sent. This is to align the review process and timelines between MHRA Devices and MHRA Medicines and REC.

You can check the status of your application at any time via IRAS.

MHRA Devices Assessment

Parallel to MHRA Medicines assessment, MHRA Devices will assess your application and issue any requests for information (RFIs) within 60 calendar days of receipt of a valid application.

Step 4: Responding to Requests for Further Information (RFI)

Once the review of your application has started, you may receive RFIs on your application separately from both MHRA Medicines and Devices teams.

RFIs from MHRA Medicines and the REC will be issued in the new part of IRAS, in the usual way (please see the responding to requests guidance for more details).

RFIs from MHRA Devices will be managed **outside of the IRAS system via email.** The applicant contact listed on the MHRA Devices form will be sent an RFI letter via email 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 your MHRA Medicines RFI responses in IRAS.

Please withhold responding to the MHRA Medicines RFI issued until all email RFIs have been resolved with MHRA Devices, and they have instructed you to submit the response to the RFI from MHRA Medicines and REC.

Requests for extensions to the MHRA Medicines RFI deadlines should be made to the MHRA Medicines team using the following email address clintrialhelpline@mhra.gov.uk.

Requests for extensions to the MHRA Devices RFI deadlines should be made to the MHRA Devices Handler that has issued the request. Please note: MHRA Devices

cannot extend statutory 60 day deadlines for issuing final outcomes for clinical investigations, but RFI deadlines may be extended where it is possible to do so.

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 MHRA Medicines and REC RFI response. Updated versions should be clearly identifiable through 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.

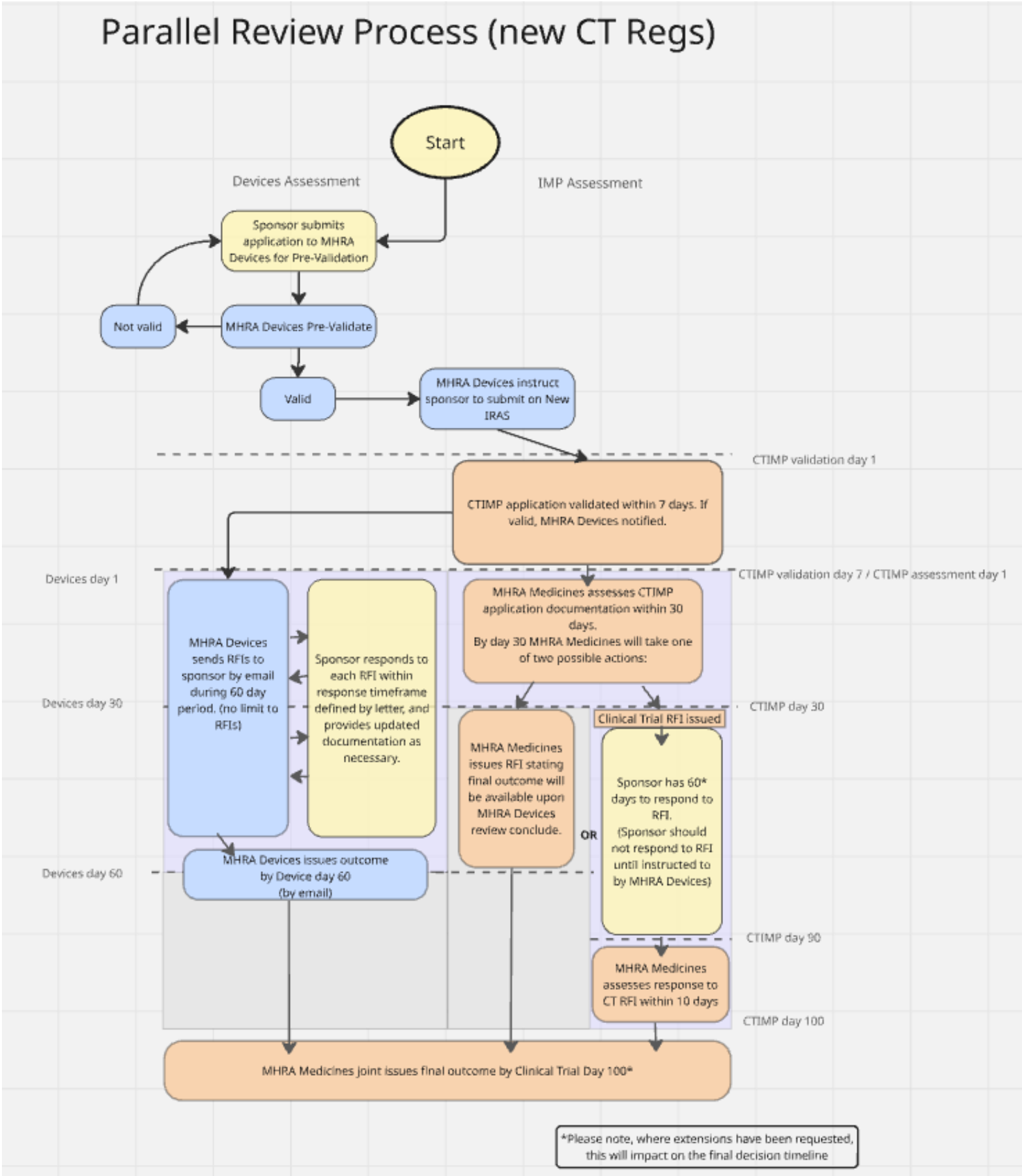
Step 5: Receiving an Outcome

Due to differing legislative timeframes for MHRA Medicines and MHRA Devices, you are likely to receive two separate outcomes.

MHRA Devices will issue a final decision to the CI aspect of the application within 60 calendar days of receipt of a valid application. This will be communicated via email to the applicant and HRA.

A final decision to the full Parallel Review application (CTIMP, Devices and ethics), will be issued within 10 calendar days beginning with the date of the sponsor response to the MHRA Medicines RFI being submitted, stating that the application is either approved, approved with conditions, or not approved. This will be communicated via email and through IRAS. The MHRA Devices outcome letter will be attached again for your reference.

Annex A: Flowchart of the Parallel Review Process



Additional Guidance

Amendments/Modifications and making changes to a Parallel Review trial

Changes to your Parallel Review trial may require notification and approval from MHRA Devices, MHRA Medicines and REC.

Changes to the device part of your trial are called amendments, and changes to the MHRA Medicines or REC part of your trial are called modifications.

Amendments/modifications should be submitted to each division (MHRA Devices, MHRA Medicines and REC) as per the guidance available for that division and via the normal routes. For further information please see:

- IRAS modification guidance
- MHRA Devices guidance on amendments which can be found here
- MHRA Medicines guidance on modifying a clinical trial approval available here

Please note:

- MHRA Devices only require amendments relating to the device CI aspect of the Parallel Review trial to be submitted to them for review.
- MHRA Medicines only require modifications relating to the medicine CTIMP aspect of the Parallel Review trial to be submitted to them for review.
- Where notifiable changes have been made to both the medicinal and medical device components, parallel amendments/modifications should be submitted to MHRA Devices and MHRA Medicines via their respective routes.

If an amendment/modification affects documentation from a different division (MHRA Devices, MHRA Medicines, REC), then please ensure that updated versions of duplicated documents match and are communicated to each division accordingly.

Parallel Review trials that also involve the use of ionising radiation

If a Parallel Review trial also involves the use of ionising radiation both processes **outlined above should be followed in conjunction**. i.e. the *'Ionising Radiation and Devices form for combined review of combined trial of an investigational medicinal product and an investigational medicinal device'* should be selected in the project filter for question 2. The *'Ionising radiation for combined review form'* the '*MHRA Devices Form'* and the ARSAC form (if required), should be selected for project filter question 4.