



Medicines & Healthcare products Regulatory Agency

IMP+Device Review Applications for an investigational medicinal product and investigational medical device

Where a proposed study is both a Clinical Trial of an Investigational Medicinal Product (CTIMP) and a Clinical Investigation (CI) of a medical device, applications must be submitted as a “IMP+Device review application” (formerly known as a Combined Devices Review Application).

- 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 IMP+Device reviews to MHRA. The process is intended to bridge the gap between two separate sets of legislation, legislative timescales and system functionalities.

In the long term, MHRA Clinical Investigations and Trials Unit’s intention is to align regulation and processes as much as possible to create a streamlined submission experience for IMP+Device studies.

Core to this intention is:

- MHRA’s collaboration with HRA to develop a new digital service, Plan and Manage Health and Care Research.
- Further process reviews following the implementation of new Clinical Trials Regulations in April 2026.

Until such time, applicants will need to continue to complete information in both the standard (GFI Portal) and new part of IRAS.

MHRA are aware that the IMP+Device review 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 applicant experience.

Making an IMP+Device 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 authorisation in the UK - GOV.UK](#)

[Clinical investigations for medical devices - GOV.UK](#)

Please see the flow diagram in Annex A for a visual representation of the IMP+Device review application process.

For this type of application, the following process must be followed to avoid delay in MHRA review:

Submitting your Application:

1. **Submit the Device** application first via standard IRAS (GFI Portal).
2. MHRA Devices will validate the application and confirm whether the application is valid or whether further information is required. If further information is required you will receive a letter detailing what is outstanding, and the review period will not start until a valid response is received.
3. Once the application is valid, MHRA Devices will write to you to confirm:
 - a. Device review start date (day 0)
 - b. CTIMP application to be submitted on or after (day 14)
 - c. Device review end date (day 60)
4. MHRA Devices will request that **on (or after) at least 14 calendar days**, you **submit the application for the CTIMP** aspect of the study via the new part of IRAS. This allows the review periods for devices and IMPs to be aligned as much as possible.

MHRA Devices Review and Outcome

5. MHRA Devices have 45 days to review documentation and send requests for information (RFIs). MHRA Devices can send as many RFIs as necessary within this timeframe and will give a specific deadline to respond by. It is essential that you contact us as soon as possible if you require clarification.
6. After the 45th day, no further RFIs can be sent by MHRA Devices, however you may still need to respond to previous RFIs sent before this date. Please respond by the deadline given on the letter received.
7. MHRA Devices will separately issue a Final Decision Letter by day 60.
8. The Devices Final Decision Letter will be re-sent along with the CTIMP Final Outcome upon completion of CTIMP review (see section below).

MHRA Clinical Trials Review and Outcome

9. MHRA Clinical Trials have 30 days to review documentation and issue an outcome.
10. If a grounds for non-acceptance (GNA) is received, you will have at least 14 calendar days to respond.
11. MHRA Clinical Trials will assess the response within a minimum of 16 days.
12. MHRA Clinical Trials will communicate the Final Outcome of the MHRA (Clinical Trials and Devices) and the ethics committee decision, usually within 60 days. Please note, where extensions have been requested, this will impact on the final decision timeline.

Version History and Changelog

Version	Release Date	Changes
1	January 2021	First Published
2	January 2026	<ul style="list-style-type: none">• Re-naming pathway from Combined Review to “IMP+Device” Review• New process for IMP+Device study submissions• Process will be reviewed again after introduction of updated Clinical Trials regulations in April 2026
3	January 2026	<ul style="list-style-type: none">• Updates based on HRA comments



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Annex A: IMP+Device Submission and Review Process Diagram

(see next page)

Figure 1: IMP+Device review process flowchart

