

End of Trial Declaration



Trial Close-Out Phase

The End of Trial Declaration station follows the Early Termination station and precedes the Statistical Data Analysis station. This station follows the parallel processes of Safety Reporting, Progress Reporting, Ongoing Management & Monitoring, and GCP & Serious Breach Reporting, and also potentially an MHRA Inspection, Audit, Substantial Amendments, Addition of New Sites & Investigators, Temporary Halt, and Early Termination. The End of Trial Declaration is a legal requirement which is relevant to all trials. This station is part of the 'trial close-out phase' group of stations.

For CTIMPs that were not submitted through the Combined Review process, an [End of a Trial Form](#) must be sent to the MHRA within 90 days of the global end of the trial that is documented in the protocol*. Once the 'end of trial' has been declared, no further substantial amendments are possible and a Clinical Trial Summary Report must be produced within the timelines detailed in the [Clinical Trial Summary Report station](#). Further details relating to 'end of trial' requirements, including the requirements a local end of trial declaration, can be found on the [MHRA website](#).

The [End of a Trial Form](#) must also be sent to the ethics committee and further information can be found on the [HRA website](#). NHS R&D offices will also require notification in accordance with local policies/procedures.

For CTIMPs were not submitted through the Combined Review process, the [End of Trial Form](#) is completed and submitted in IRAS. The HRA website

***Note:** The definition of the end of the trial should be documented in the protocol. The [HRA website](#) provides guidance on this definition.

For non-CTIMP research, notification to the relevant ethics committee is required. The 'Declaration of the End of Study' for non-CTIMPs is available on the [HRA website](#).

Further reading:

- [Early Termination station](#)
- [Clinical Trial Summary Report station](#)
- [Substantial Amendment station](#)