

## 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](#)