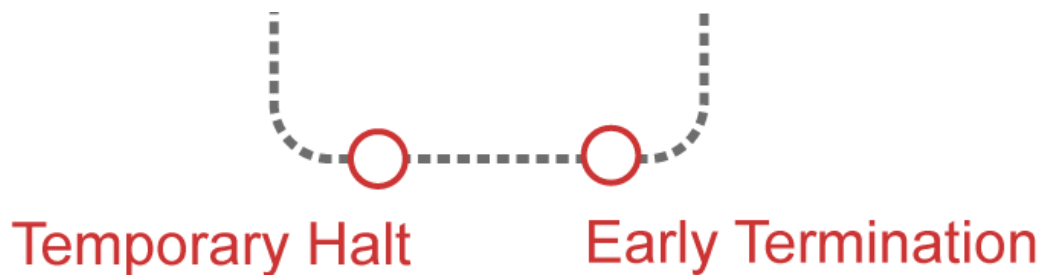


# Early Termination



## Trial Close-Out Phase

**Early Termination** follows the Temporary Halt station and precedes the End of Trial Declaration station. This process occurs in parallel with Safety Reporting, Progress Reporting, Ongoing Management & Monitoring, and GCP & Serious Breach Reporting. It also has the potential to occur simultaneously with an MHRA Inspection, Audit, Substantial Amendments, Addition of New Sites & Investigators, and Temporary Halt. Early Termination is a legal requirement which is relevant to all trials. This station is part of the 'trial close-out phase' group of stations.

If a trial is **terminated early**; before the date specified for its conclusion\*, the sponsor should notify the MHRA **within 15 days** of the global premature end of a trial using the [End of Trial Form](#). The [HRA website](#) also provides information about notifying other bodies and about post-research care.

For trials that have used the combined review process, the [HRA step by step guide](#) provides additional information.

The sponsor should provide a brief explanation of reasons for the early termination and describe any follow-up measures. 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](#). The MHRA website provides further information including how to submit the form.

The Declaration of the End of a Trial Form must also be sent to the ethics committee. NHS R&D offices and funders will also require notification in accordance with local policies/procedures.

For non-CTIMP research, notification to the relevant ethics committee is required.

Further information on the 'Declaration of the End of Study' for CTIMPs and non-CTIMPs is available on the [HRA website](#).

*\*The definition of the end of the study should be documented in the protocol.*

### **Further reading:**

- [Clinical Trial Summary Report](#) station.