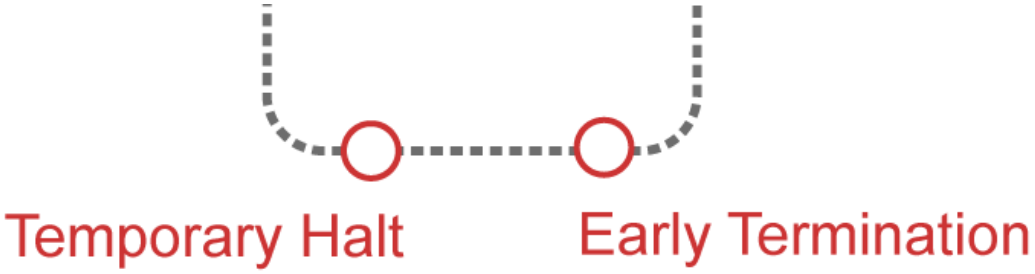
Routemap

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.