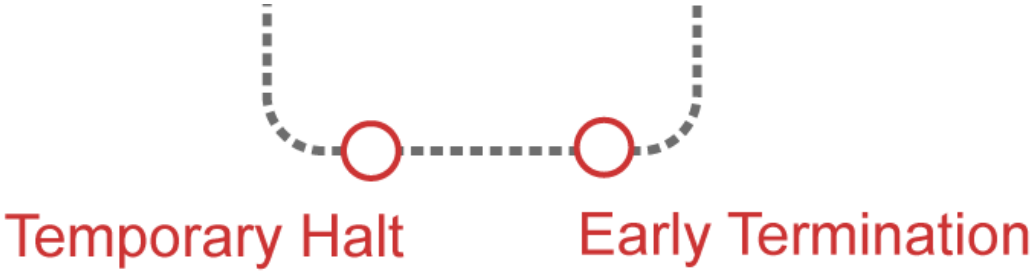
# Early Termination




## 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.

## Early Termination

If a Clinical Trial of an Investigational Medicinal Product (CTIMP) or an IMP/Medical Device trial is terminated before its planned end date, the sponsor should notify the Medicines and Healthcare products Regulatory Agency (MHRA) within 15 days of the global premature end of a trial, using the Declaration of the End of Trial form. All activities, including any outstanding follow-up visits, should be completed before the form is submitted. The Health Research Authority (HRA) website also provides information on notifying other bodies and on arrangements for post-research care.

The timelines for its submission are detailed on the MHRA website. For trials that have used the Combined Review process, the submission to the HRA step-by-step guide provides information on notifying the end of the trial. NHS R&D offices, funders and other stakeholders will also require notification in accordance with

local policies/procedures.

## Non-CTIMPs

A notification to the REC for an early termination is required, and further information on the 'Declaration of the End of Study' is available on the HRA website. In addition, HRA guidance for non-CTIMPs provides additional detail.

## Final Reporting

The sponsor should provide a brief explanation of the reasons for early termination and describe any follow-up measures. Once the end of the study has been declared, no further substantial amendments can be made. A Clinical Trial Summary Report must be prepared in accordance with the guidance set out in the Clinical Trial Summary Report station.