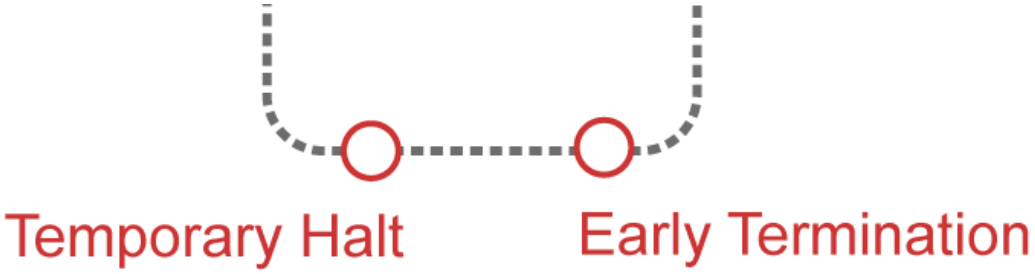
Temporary Halt



Recruitment Phase

Temporary Halt follows the Urgent Safety Measures station and precedes the Early Termination 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 Early Termination. Temporary Halt is a legal requirement which is relevant to all trials. This station is part of the 'recruitment phase' group of stations.

Temporary Halt

A temporary halt is an unplanned stoppage of a trial, or trial activities at one or more sites, where the sponsor intends for the trial to resume.

When a halt occurs, the sponsor must notify both the Medicines and Healthcare products Regulatory Agency (MHRA) and the reviewing Research Ethics Committee (REC) within 15 days by submitting a substantial modification. The full requirements for Clinical Trials of Investigational Medicinal Products are set out in MHRA guidance. This webpage also explains how any proposal to resume the trial is assessed.

Further Reading

- Modifications station.
- MHRA Blog: When is a clinical trial halt not a clinical trial halt?