Temporary Halt Temporary Halt Early Termination

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.

A **temporary halt** of a trial is a stoppage of the trial or a stoppage at one or more sites which is not envisaged in the approved protocol and where there is an intention to resume it. When a trial is temporarily halted, the MHRA and the reviewing ethics committee must be informed **within 15 days**. The notification should be made as a substantial amendment using the notification of amendment form, clearly explaining what has been stopped and the reasons for the suspension. The report should also explain the scope of the halt (e.g., stopping recruitment, interrupting treatment). The <u>MHRA website</u> provides further information.

Further reading:

• Substantial Amendments station