Trial is Abandoned

CTA Submission

Trial is abandoned

Trial Approvals Phase

The Trial is Abandoned station follows the Final Trial Management Documentation station. Abandoning the trial is a good practice process which can be relevant to all trials. This station is part of the 'trial approvals phase' group of stations.

The trial is generally considered to have 'commenced' when any of the trial procedures (such as patient screening/consent) that are set out in the protocol, are initiated*.

In the UK, if the sponsor decides to abandon the trial **before** it commences, the Chief Investigator or sponsor should notify the ethics committee by letter, giving reasons. Details of the notification process to the MHRA (initial e-mail followed by letter) can be found on the <u>'Withdrawal of a Clinical Trial Authorisation' pages</u> of the MHRA website. Other bodies, such as local NHS R&D Offices and funders will also require notification.

*Please note that a trial funder may have a different view on when a trial 'commences' e.g. when payments are released, and this can be several months before any consent or screening processes are undertaken. A funder should be kept informed of all developments and will advise on appropriate processes and requirements.

Further reading:

• The <u>Temporary Halt</u> and <u>Early Termination</u> stations outline the requirements for halting/terminating a trial once it has commenced.