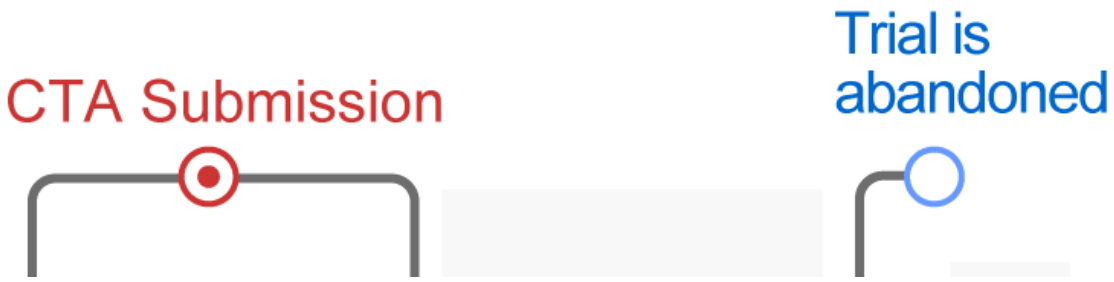
Routemap

CTA Submission



Trial Approvals Phase

CTA Submission follows the IRAS station and precedes the Ethics Submission station. The process occurs in parallel with Ethics Submission and R&D Submission. CTA Submission is a legal requirement for trials within the Clinical Trial Regulations scope. This station is part of the 'trial approvals phase' group of stations.

In the UK, a Clinical Trial Authorisation (CTA) from Medicine and Healthcare Products Regulatory Agency (MHRA) is required for a Clinical Trial of an Investigational Medicinal Product (CTIMP) and for combined trials of an investigational medicinal product and an investigational medical device (IMP/Device trials).

For these types of trial, there is now a single application for both Clinical Trial Authorisation and Research Ethics Committee (REC) opinion. Applications for combined review are prepared and submitted in a new part of the Integrated Research Application System (IRAS). The HRA website contains information on the combined review process.

The Clinical Trial Notification Scheme:

The MHRA will process the application based on the type of the trial (Type A, B or C) as described in Risk Adapted Approaches to the Management of Clinical Trials of Investigational Medicinal Products (PDF) (.PDF).

For certain Type A trials, the Clinical Trial Notification Scheme pages of the MHRA web site describe the process and timelines for the CTA application. Once the application is sent to the MHRA, it will be acknowledged with an accompanying note to say that the trial may go ahead after 14 days from receipt of notification if no objections have been raised. The acknowledgement letter will act as the authorisation.

For Type B and C trials, the notification scheme is not applicable and each application will be fully assessed by the MHRA. They will provide an initial response within 30 days of receipt of a *valid* application, with an average of 14 days for Phase 1 healthy volunteer studies. The MHRA CTA Page lists the documents required for a valid application.

Further reading:

- Permissions & Approvals Obtained station.