Routemap

Permissions & Approvals Obtained

Trial Approvals Phase

Permissions & Approvals Obtained follows the R&D Submission station and precedes the Final Trial Management Documentation station. Ensuring that permissions and approvals are obtained is a legal requirement which is relevant to all trials. This station is part of the 'trial approvals phase' group of stations.

A trial cannot begin until all the relevant permissions and approvals have been obtained and reviewed by the relevant parties (including the funder where appropriate).

Clear evidence of the documents submitted to the approval bodies (the submission package) and the documents that were approved (approval letters referencing the submission package*) need to be retained in the Trial Master File. This will allow auditors / inspectors to confirm that all legal and good practice requirements have been followed.

**For Type A clinical trial (See Risk Adapted Approaches to the Management of Clinical Trials of Investigational Medicinal Products (PDF, 247 KB) (.PDF)), the MHRA may not send the sponsor a formal approval letter. The acknowledgement letter, confirming the trial can go ahead if no objections are raised within 14 days of the application, will act as the authorisation.*

Further reading:

- IRAS station

- CTA Submission station
- Ethics Submission station
- R&D Submission station
- Final Trial Management Documentation station.