Sponsor or legal representative submits a notification to MHRA

MHRA provides an initial response within 30 days of receipt of valid application

MHRA has grounds for non-acceptance of CTA and requests further information

Sponsor or legal representative submits amended application to MHRA

MHRA must provide a response within 60 days of receipt of the original application

CTA Approved

CTA Approved with conditions

CTA not Approved

1 The clinical trial is treated as being authorised only if the conditions specified in the notice of acceptance are satisfied. SI 1031 Regulation 18 (4).

2 Regulation 19 of Statutory Instrument 2004 No. 1031: The Medicines for Human Use (Clinical Trials) Regulations 2004 allows for an extended time frame for certain medicinal products (e.g. gene therapy and somatic cell therapy).

For advice on the process for submitting changes to the documentation for a trial that occur during the MHRA evaluation of the CTA, see the MHRA web pages.