

# Clinical Trial Authorisation (CTA) Application Flowchart

## Submission to MHRA

### Notification to MHRA

Sponsor or legal representative submits a notification to MHRA

MHRA send an acknowledgement letter stating the trial may go ahead if an objection is not raised within 14 days from the receipt of notification

If no objection is raised, the acknowledgement letter acts as the authorisation

MHRA raises an objection

Notification is treated as request for authorisation

Sponsor or legal representative to submit a new application

### Application to MHRA for Clinical Trial Authorisation (CTA)

Sponsor or legal representative submits a request for authorisation 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<sup>2</sup>

CTA **not** Approved

CTA Approved **with conditions**<sup>1</sup>

CTA Approved

CTA Approved<sup>1</sup>

14 days<sup>2</sup>

<sup>1</sup>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).

<sup>2</sup>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](#).