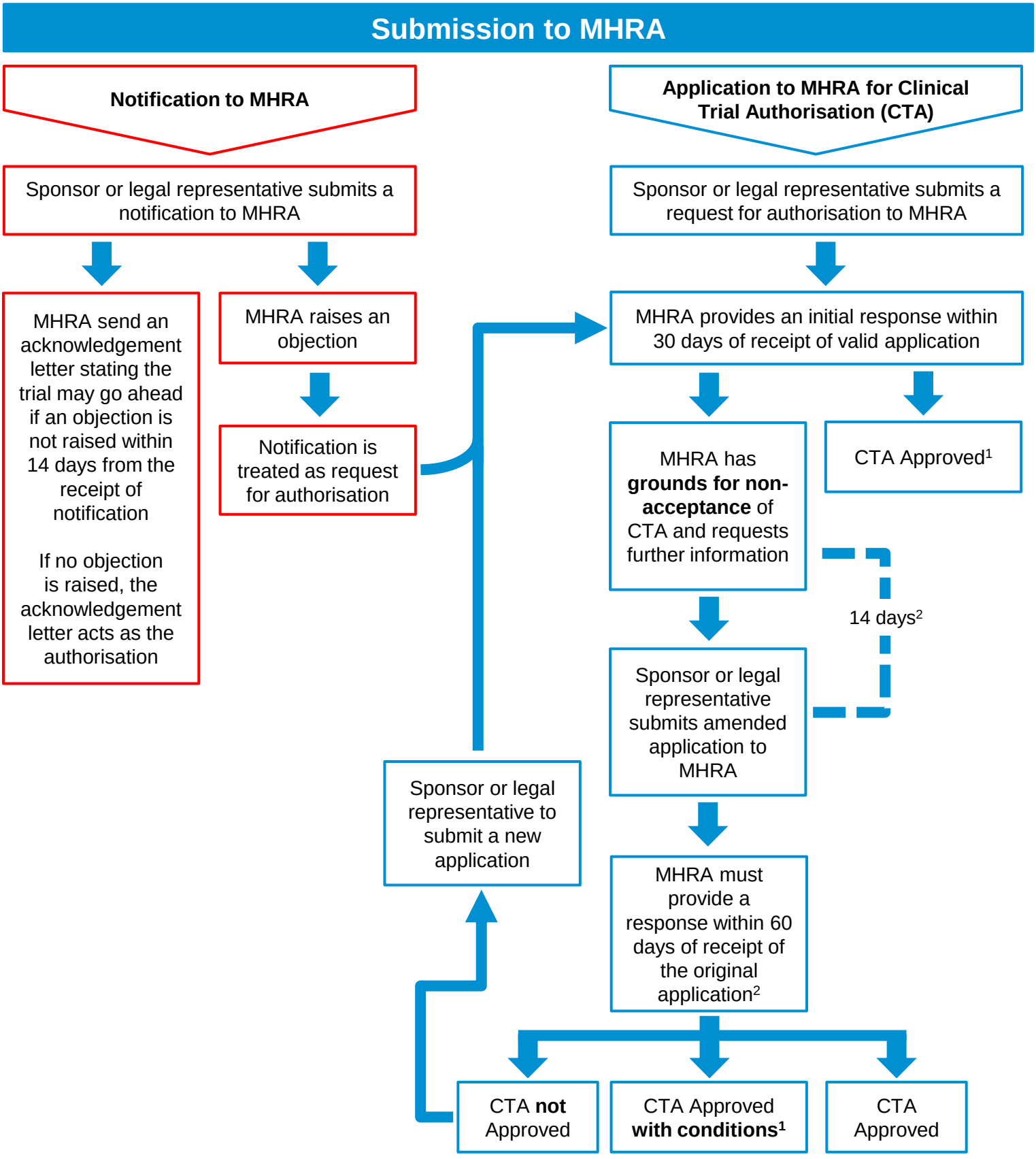
Clinical Trial Authorisation (CTA) Application Flowchart



[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.