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# Conducting Clincal Trials in UK Under new Notification Scheme

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## ABSTRACT

The budding regulatory professional who has just stepped in the new horizon of pharma field, may find starting and conducting clinical studies and getting relevant authorization or approval in the United Kingdom complicated and time-consuming process, which it is actually. But this article will help them giving an insight on what steps are followed to conduct clinical trial in general, how to apply for a clinical trial authorization in UK, what documents required in a nutshell and how to get clinical trial approval with less effort, and in more smooth and efficient manner. We all know that time for pharma field is equivalent to money, as pharma companies use to have a huge expenditure in research and development of a medicine and to recover that huge expenditure they would seek for regulatory approval as faster as they can manage so that they can market the drug, once the safety and efficacy data is established through clinical trials. And thus this article will aid to new regulatory professionals who are interested to involve in the regulatory activities pertaining to clinical trials in a highly regulated market like United Kingdom and thus with better understanding with regulatory process they can save the time of company and can go through this complex system successfully.

**Keywords:** UK MHRA, Clinical Trial, Notification Scheme.

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# INTRODUCTION

Clinical Research in recent decades has become an important integral component of any modern health service which incorporates evidence-based practice. For a budding or new drug regulatory professional who has just stepped in the regulatory affairs field, may feel it an overwhelming task. Getting clinical trials authorization for any investigational medicinal product has become a complicated procedure, especially due to recent increased safety measures and regulations by research ethics committees, R&D offices and regulatory bodies. The primary goal of any regulatory body is 'patient safety', which is the result of the introduction of new legislations and amendments, both nationally and within the European Union. But with a little effort to look insight of the process, and taking steps forward in systematic and timely manner one can easily approach to these approval processes and get the desired trial approval in full efficient manner.

In UK, New products which are still in development phase need a license before they can be tested on human subjects and this license is called clinical trial authorization. And for this an applicant can file the Clinical trial authorization (CTA) application using notification scheme which will be dealt in further section.[2,3,4]

**Steps Involved in Clinical Trials (In General):**

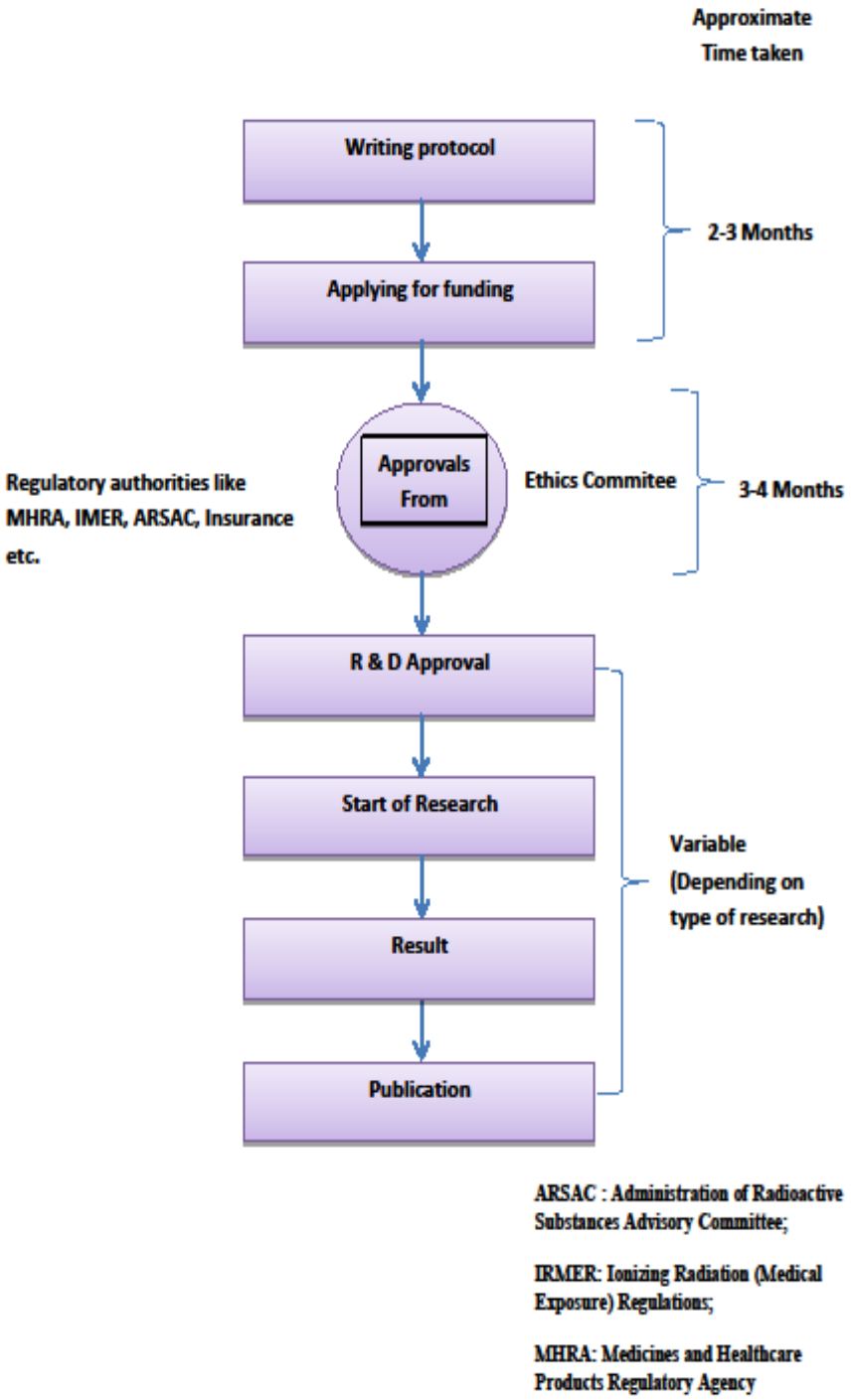
Any Clinical study usually starts with a hypothesis or an assumption, typically conjured up by the researcher. Once the proposed hypothesis is in place, a number of key steps need to be taken considering the type and complexity of the study, which usually includes - writing a protocol, applying for funding, and obtaining relevant approvals from ethics committees, R&D and relevant regulatory bodies. Getting regulatory approval is one of the most important step for conducting any clinical trial.[1]

**MHRA Approval**

"Medicines for Human Use (Clinical Trials) Regulations 2004 (SI 2004 no 1031)" is the relevant legislation for clinical trials in UK. European Clinical Trials Directive : Directive 2001/20/EC gives the rules and guidance on Good Clinical Practice in the conduct of clinical trials on medicinal products for human use[1].

**Procedural Steps**

- The application must be made by the sponsor or by someone authorized to submit the request on his/her behalf. If the sponsor is not established in the European Community then he/she must have a legal representative.




Steps Involved In Clinical Trial (In General)[1]

- Applicants should submit electronic documents on disk, with one PDF file for each document. All disks should be sent to: Information Processing Unit, Area 6 Medicines & Healthcare products Regulatory Agency 151 Buckingham Palace Road, Victoria, SW1W 9SZWhen MHRA receives an application for a Clinical Trial Authorisation (CTA), it is usually validated. If the application is not valid (e.g. incomplete information is supplied) then the person making the application will

be contacted and told that there are deficiencies and If the deficiencies are minor, It may be asked to provide the missing information. If the deficiencies are major, it may be required to resubmit a complete application.

- Once the application is valid the assessment period will begin and an acknowledgement letter will be sent to the person submitting the application. This is the person named in Section C1 of the clinical trial application form. The assessment period starts from the date of receipt of a valid application.
- The initial assessment will be performed within 30 days. For the purposes of this calculation, the day of receipt of the valid application by the Clinical Trials Unit is day 0. Applications for phase 1 healthy volunteer studies will be assessed and processed within an average of 14 days or less.

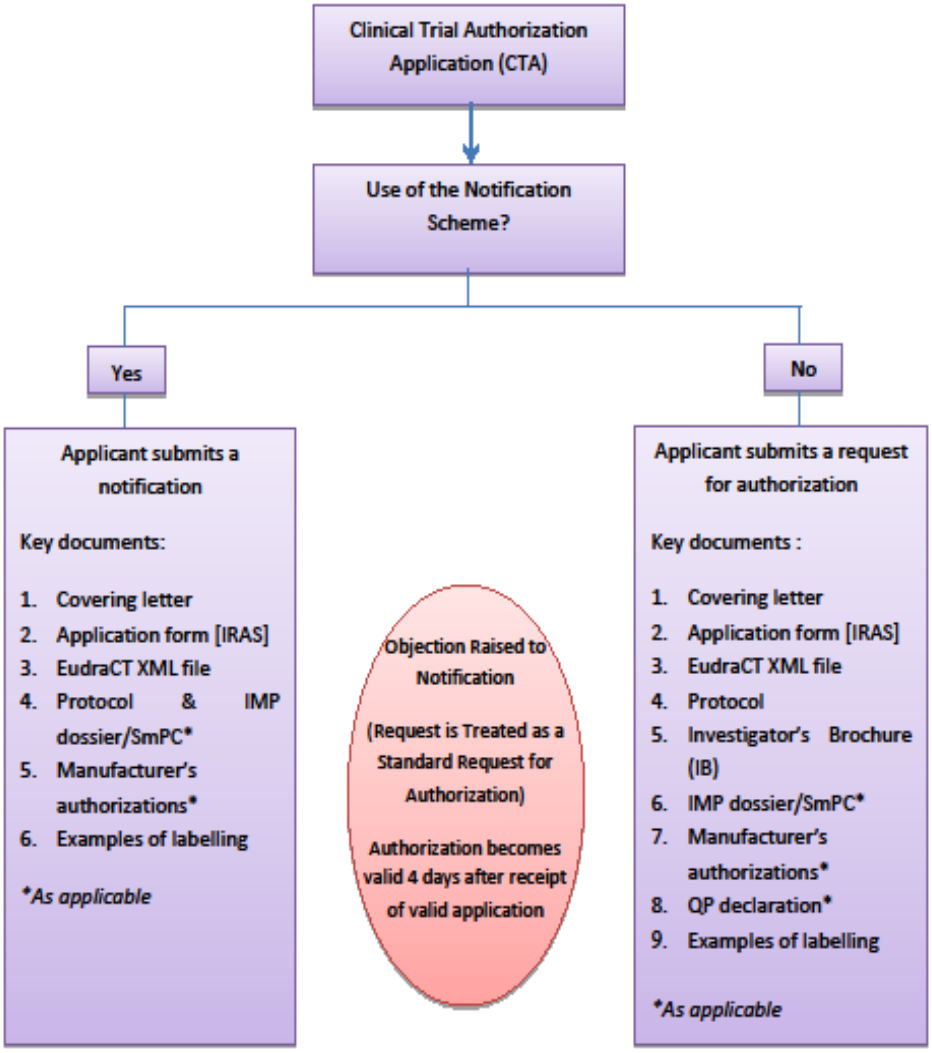
When the application has been assessed (within 30 days) the applicant will be sent a letter informing them of one of the following:

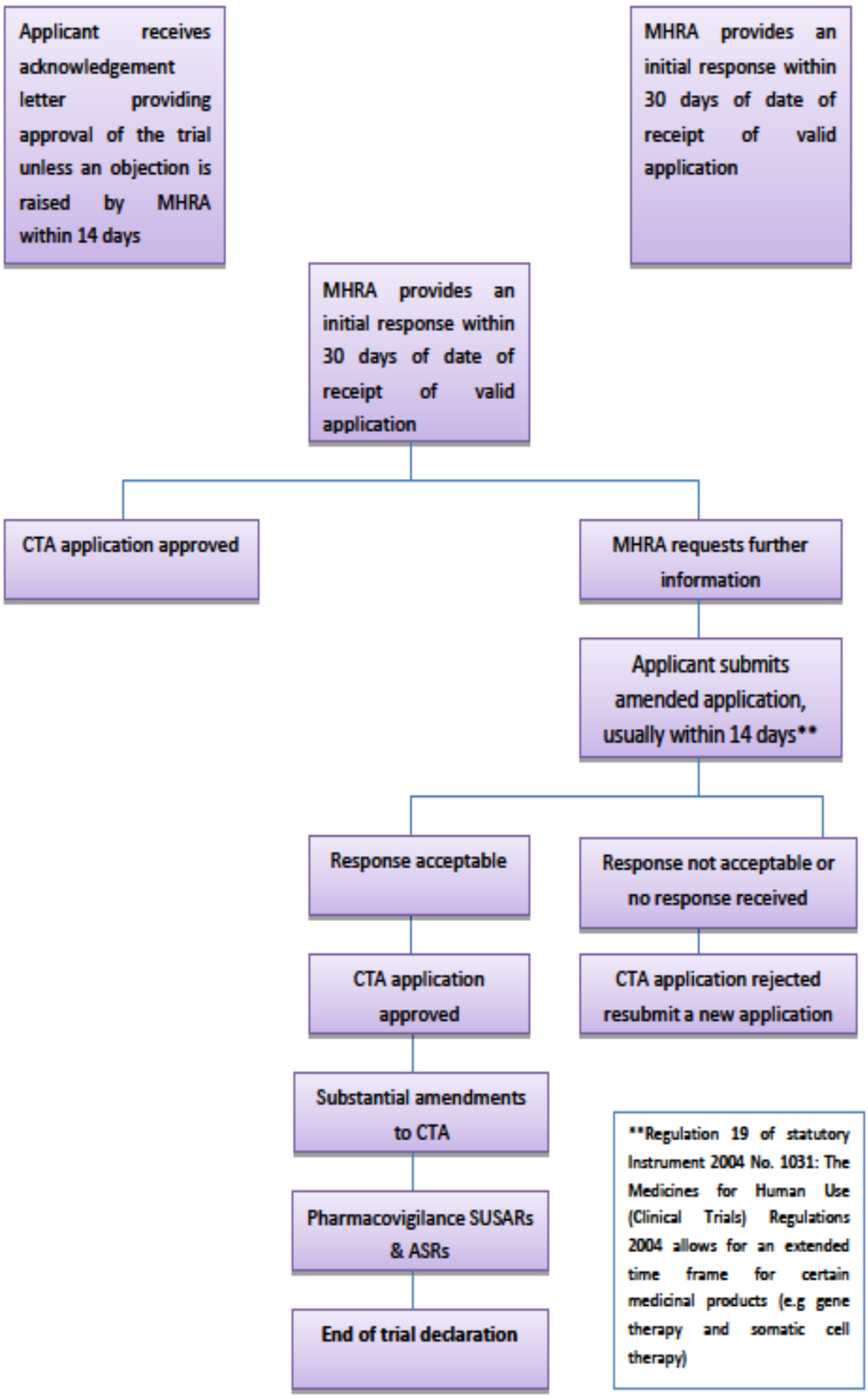
1. Acceptance of the request for a clinical trial authorisation.
2. Acceptance of the request for a clinical trial authorisation subject to conditions.
3. Grounds for non-acceptance of the request for a clinical trial authorisation.

- All clinical trials also require a favourable opinion from an Ethics Committee. For information on Ethics Committees, please see the: National Research Ethics Service (NRES).
- Application should be made using EudraCT Version 8, More information regarding Version 8 can be found at EudraCT website.
- An application to be considered as valid, a submission should contain a file for each of the following documents, Details on the documentation required in a Clinical Trial Authorization application are :
  - Covering letter
  - Clinical Trial Application + valid xml
  - Protocol
  - Investigator Brochure (IB) or document replacing the IB
  - Investigational Medicinal Product Dossier (IMPD)
  - Non investigational medicinal product dossier-IMPD (if required).
  - Scientific advice - A summary of scientific advice from any Member State or the EMA with regard to the clinical trial (if available).
  - EMA Decision - A copy the EMA's Decision on the decision of the Paediatric Investigation Plan and the opinion of the Paediatric Committee (if applicable).

- The content of the labelling of the Investigational Medicinal Product-IMP (or justification for its absence)
- Proof of payment
- Manufacturer's authorisation or Importer's authorization plus QP declaration on GMP for each manufacturing site[5,6,7,8,9].

**FLOWCHART FOR CLINICAL TRIAL AUTHORISATION[10]**






## CONCLUSION

A clinical trial authorization in UK will involve considerable time and patience to prepare dossier, filling and giving appropriate response in order to fasten the approval procedure. Although the regulatory procedure in United Kingdom seems to be complicated, but with proper understanding of approval procedures and the regulatory needs, a CTA approval can be easily

approached. I hope this article will serve its intended purpose to fasten the clinical trial authorization approval procedure and will provide insights and tips for new regulatory professionals. So that they can file for clinical trial market authorization in UK with full confidence without hassles and can give their maximum outcome which in turn will save the time of the company and can open the gates of revenue to market the drugs once their safety and efficacy profiles are established.

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