**Request for an opinion on whether a study is a clinical trial of an investigational medicinal product under The Medicines for Human Use (Clinical Trials) Regulations 2004**

Clinical trials of investigational medicinal products (IMPs) in the UK are regulated by [The Medicines for Human Use (Clinical Trials) Regulations 2004 (SI 1031)](http://www.legislation.gov.uk/uksi/2004/1031/pdfs/uksi_20041031_en.pdf)as amended.

This form should be used to request a protocol review with the MHRA in order to obtain an opinion on whether a study involving a medicinal product falls within the scope of the clinical trial regulations and therefore requires a clinical trial authorisation (CTA).

Please complete this form and email it with a copy of the protocol (the document describing the objectives, design, and methodology) to clintrialhelpline@mhra.gov.uk, with ‘Scope - protocol review’ followed by the study title (shortened)’ as the subject line.

**About you**

|  |  |
| --- | --- |
| Organisation name: |  |
| Contact name: |  |
| Telephone number: |  |
| Professional email address: |  |

**About the study product**

|  |  |
| --- | --- |
| Substance(s) under investigation: |  |
| Proposed indication(s): |  |
| Is the product a medicinal product?  | [ ]  Yes[ ]  No: (please note SI 1031 only applies to trials of medicinal products) [ ]  I don’t know: (Please see MHRA guidance “[A guide to what is a medicinal product](https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/506397/a_guide_to_what_is_a_medicinal_product.pdf)” or use the borderline advice form available [here](https://www.gov.uk/guidance/decide-if-your-product-is-a-medicine-or-a-medical-device))  |

**About your query**

|  |  |
| --- | --- |
| is your query related to a **medical device**? | [ ]  Yes[ ]  No |
| If ‘Yes’, is there additionally an active substance under investigation in your study? | [ ]  Yes[ ]  No If ‘No’, do not submit this query for Scope assessment.To get advice on this matter send an email with your query to Devices.regulatory@mhra.gov.uk. |

**About the study**

|  |  |
| --- | --- |
| Protocol title: |  |
| Short title:*(no more than 75 characters)*  |  |
| Phase: |  |
| Primary objective(s): |  |
| Secondary objective(s): |  |
| Exploratory objective(s): |  |
| Protocol attached? | [ ]  Yes[ ]  No |
| **Note:** A draft protocol is considered fundamental to assess and determine if a clinical trial authorisation (CTA) is needed.If a draft protocol is not available, a research proposal could be accepted for review, only if it provides enough information to base the study scope assessment (objectives, design, and methodology). |
| Do you consider the study is a **Clinical Trial of a Medicinal Product** (CTIMP)? | [ ]  Yes[ ]  No |
| Please provide details of the reasons for your consideration.Please base your answer on the MHRA’s online algorithm [Is it a clinical trial of a medicinal product?](https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/317952/Algothrim.pdf) |  |
| Has previous advice been sought on the regulatory scope of this study? | [ ]  Yes (Please attach MHRA opinion email)[ ]  No |
| If ‘Yes’ please provide the date and details of why you consider the clinical trial scope has changed. | Date: |  |
|  |