**Borderline CTIMP decision document**

In the event of a borderline CTIMP study the MHRA no longer offer the SCOPE protocol review service. Therefore, any decisions on if the study is a CTIMP should be made by the RGIT senior team as sponsor in conjunction with the CI. In the first instance the CI should provide justification and reasoning as to the categorisation of the study which will then be reviewed and discussed alongside the protocol with the RGIT senior team in the RGIT CTIMP committee.

The CI should complete the following algorithm with details of the decision in each section. The full algorithm can be found [here](https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/949145/Algorithm_Clean__1_.pdf). Further guidance on each question can be found [here](https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/1022203/Mock_examples_to_assist_with_determination_of_a_CTIMP.pdf)

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| --- | --- | --- | --- | --- |
| **A** | **B** | **C** | **D** | **E** |
| **A CLINICAL TRIAL OF A MEDICINAL PRODUCT?** | **A NON-INTERVENTIOANL CLINCIAL TRIAL?** |
| **Is it a medicinal product (IMP)?****Yes ☐ No ☐** | **Is it not a medicinal product?****Yes ☐ No ☐** | **What effects of the medicine are you looking for?****Yes ☐ No ☐** | **Why are you looking for those effects?****Yes ☐ No ☐** | **How are you looking for those effects?****Yes ☐ No ☐** |
| If you answer no to all the questions in column A, the activity is not a clinical trial on a MP. If you answer yes to any of the questions below go to column B. In the Justification section please describe your yes/no decision | If you answer yes to the question below in column B the activity is not a clinical trial on a MP. If you answer no to this question beIn the Justification section please describe your yes/no decision | If you answer no to all the questions in column C the activity is not a clinical trial under the scope of SI 1031. If you answer yes to any of the questions below go to column D.In the Justification section please describe your yes/no decision | If you answer no to all the questions in column D the activity is not a clinical trial under the scope of SI 1031. If you answer yes to any of the questions below go to column E.In the Justification section please describe your yes/no decision | If you answer yes to all these questions the activity is a non-interventional trial which is outside the scope of SI 1031. If your answers in columns A,B,C & D brought you to column E and you answer no to any of these questions the activity is a clinical trial within the scope of the Directive.In the Justification section please describe your yes/no decision |
| A.1 Is it a substance or combination of substances presented as having properties for treating or preventing disease in human beings? A.2 Does the substance function as a medicine? i.e. can it be administered to human beings either with a view to restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action or to making a medical diagnosis or is otherwise administered for a medicinal purpose? A.3 Is it an active substance in a pharmaceutical form? | B.1 Are you only administering any of the following substances? • Human whole blood • Human blood cells; • Human plasma; • Tissues except a somatic cell therapy medicinal product• A food product (including dietary supplements) not presented as a medicine; • A cosmetic product; • A medical device | C.1 To discover or verify/compare its clinical effects? C.2 To discover or verify/compare its pharmacological effects, e.g. pharmacodynamics? C.3 To identify or verify/compare its adverse reactions? C.4 To study or verify/compare its absorption, distribution, metabolism or excretion? | D.1 To ascertain or verify/compare the efficacy of the medicine? D.2 To ascertain or verify/compare the safety of the | E.1 Is this a study of one or more medicinal products, which have a marketing authorisation in the UK? E.2 Are the products prescribed in the usual manner in accordance with the terms of that authorisation? E.3 Does the assignment of any patient involved in the study to a particular therapeutic strategy fall within current practice and is not decided in advance by a clinical trial protocol? E.4 Is the decision to prescribe a particular medicinal product clearly separated from the decision to include the patient in the study? E.5 Will no diagnostic or monitoring procedures be applied to the patients included in the study, other than those which are applied in the course of current practice? E.6 Will epidemiological methods be used for the analysis of the data arising from the study? |
| **Justification:** | **Justification:** | **Justification:** | **Justification:** | **Justification:** |