Application for a Clinical Field Trial Licence under Animal Remedies Legislation

For details on completing this application form, please see the ‘Guide to Clinical Field Trial Licence Applications under Animal Remedies Legislation.’

SECTION A: proposed licence holder (i.e. Applicant) and details of The Trial Personnel and locations

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| Proposed licence holder (i.e. applicant):  Address 1:  Address 2:  Address 3:  Telephone number:  E-mail:  Sponsor (if relevant):  Address 1:  Address 2:  Address 3:  Trial Director:  Address 1:  Address 2:  Address 3:  Telephone number:  E-mail:  Please append the CV of the trial director with responsibility for the conduct of the trial in Ireland.  Location(s) where the trial will be conducted (if known): |

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| *This row can be expanded by copying and pasting as many times as required.*  Veterinarians responsible for supervision of animal health and welfare and for treating adverse reactions (if relevant):  Address 1:  Address 2:  Address 3:  Telephone number:  E-mail: |

SECTION B: Information about The clinical field trial

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| Provide the title of the trial (≤200 characters):  Is this a trial which has been requested by a regulatory authority? Yes  No  If ‘yes’ which regulatory authority has requested this trial?  Provide information on the quantities of test drug(s) needed for the conduct of the trial.   |  |  |  |  | | --- | --- | --- | --- | | Product | 1 | 2 | 3 | | Name of product |  |  |  | | Marketing authorisation number (if relevant) |  |  |  | | Total number of units of drug being applied for |  |  |  |   Please append the Summary of Product Characteristics (SPCs) for each product to be used during the trial.  Please append the trial protocol, outlining the trial objectives and expected benefits. Details for each procedure involved in the conduct of the trial should be provided as well as an outline of the flow of procedures. The steps involved should be clearly numbered (from beginning to end) in schematic or illustrative form.  Is this trial being conducted with a masked (blind) design? Yes  No  If ‘yes’ provide details on the label information proposed and the arrangements in place for management of products during the clinical trial.  Information on how each of the 3R principles (replacement, refinement and reduction) has been considered in relation to the trial design should be given.  Replacement:  Reduction:  Refinement:  Has the trial been approved by an ethics committee? Yes  No  If ‘yes’ please provide a copy of the ethical review documentation (trial application and protocol as approved, letter of approval, report outlining queries and any associated correspondence/documentation.  State expected duration of trial work (months):  If more than 12 months, justification for the period given:  State estimated start date of trial work:  Describe the feasibility and the resources available for the trial (≤200 characters): |

Section C: Purpose of The clinical Field trial

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| Describe the overall purpose of the trial (≤ 500 characters): |

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| **C1 : Trial Details**  Where the test product(s) does not have a marketing authorisation, complete the following table in respect of each such product (the information may be provided as separate appendices if preferred):   |  |  |  |  | | --- | --- | --- | --- | | Product | 1 | 2 | 3 | | Name of product |  |  |  | | Composition |  |  |  | | Manufacturer (if known) |  |  |  | | MRL status (set or not) |  |  |  | | Proposed withdrawal period |  |  |  | | Does the product contain a GMO? |  |  |  | | Is the product compliant with EU requirements for TSE? |  |  |  | | Is the product free from extraneous agents? |  |  |  | | Is the product a vaccine or produced by biological means? |  |  |  |   Where applicable in the case of test products that do not have an existing marketing authorisation, provide:   * certificates confirming composition as well as accompanying statements/ licence approvals regarding GMOs, TSE and extraneous agents. * any relevant summary information derived from safety and preclinical trials that help characterise the risks relevant to the usage of the test products for the proposed trial * in the case of a vaccine or biological agent, any relevant summary information related to the production methods, including controls to prevent cross-contamination and checks on the finished product to ensure it does not contain extraneous agents. * an environmental risk assessment in accordance with current CVMP/EMA guidance, where relevant.   Dose, dose regimen, duration of therapy?  Route of administration to be used?  Special equipment needed?  Special precautions to be observed when administering the product(s)?  If a safety trial, is this trial being conducted in accordance with GLP?  Yes  No  If a clinical field trial, is this trial being conducted in accordance with GCP?  Yes  No  If ‘no’ to both questions above, confirm conformance to the Directive requirement for pre-established systematic written procedures:  Proposed observations or measurements to be carried out:  Provide details about the housing, husbandry and care conditions for the animals:  Information on management of unintended effects of treatment:  Information on the proposed withdrawal period(s): |

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| **C2 : Animals to be used**  Species to be used:  Number of animals to be used:  Are the animals owned by the sponsor? Yes  No  If animals are not owned by the sponsor/investigator, will the consent of owner of the animals to be used in the trial be obtained? Yes  No  Have the animals to be used in this trial been taken from the wild?  Yes  No  If ‘yes’ please provide scientific justification for the reasons a wild animal is required?  Are the animals to be used in this trial stray or feral animals of a domestic species?  Yes  No  If ‘yes’ please provide scientific justification for the reasons a stray or feral animal of a domestic species is required.  Have the animals to be used in this trial been used in scientific procedures or research previously?  Yes  No  If ‘yes’ please provide scientific justification for the reasons the animals are to be re-used.  Fate of trial animals following the completion of the trial: |

SECTION d: DECLARATION AND UNDERTAKING

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| *The declaration and undertaking below should be signed by or on behalf of the applicant, or the person who is responsible for the overall execution of the trial and its compliance with the trial licence*.  I hereby **declare** that:   * The information contained in this application is true and correct.   I hereby **undertake** that in the event of the trial licence being granted:   * To ensure fulfilment of the obligations arising by virtue of the terms and conditions of the trial licence. * To submit an application for an amendment if any substantial changes to the trial are required. * To report any trial deviations that have an adverse effect on animal health or welfare, and to report any adverse effects on animal health or welfare to the responsible veterinarian. * To keep written records of all animals used under this clinical field trial licence for a minimum of five years, and to make all written records or trial documentation available to the HPRA upon request or as part of an inspection. * To ensure that the test products are kept securely and used only for the purpose of the trial conduct.   Signature of applicant: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Print/type name:  Date: |

**CHECKLIST**

Trial protocol

Ethics approval and associated documentation (where relevant)

CV (setting out education, training, experience and publication history)

Certificate confirming composition of test products without a marketing authorisation

SPCs for each product with a marketing authorisation to be used during the trial

Statements regarding compliance of test products regarding freedom from GMO’s, TSE and extraneous agents (where relevant) or EPA licence approval (where relevant)

Relevant summaries of safety and efficacy data on test products without a marketing authorisation

If an unauthorised vaccine or biological product, information on the controls employed in production to ensure product is not contaminated with other agents

Evidence of fee payment