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# Application form for authorisation of clinical trials of veterinary medicinal products in animals

**Protocol title:**

**Protocol code/number:**

**Phase:**

**Design:**

**Applicant (name and address):**

**Investigators (name and address):**

**Investigational medicinal products (name/code name, if any):**

**Active substance:**

**Manufacturer of the investigational medicinal product:**

**Placebo, if used: manufacturer of placebo:**

**Information on reference documents (usually Investigator's Brochure (IB) or summary of product characteristics (SPC)) to assess whether an adverse reaction is unexpected:**

*Please copy the above if several investigational medicinal products are included in the trial.*

**Trial site:**

**Number of centres in Denmark:**

**Expected start date** date **and expected end date** date

**Will the Clinical Trial be conducted in compliance with the veterinary GCP rules (VICH GL9)?**

**Invoice details:**

**List of appendices (see checklist)**[**http://laegemiddelstyrelsen.dk/en/licensing/clinical-trials/trials-in-animals/**](http://laegemiddelstyrelsen.dk/en/licensing/clinical-trials/trials-in-animals/)

**Applicant's signature (sponsor or on behalf of sponsor)**

|  |  |  |
| --- | --- | --- |
|  |  |  |
| **Date** |  | **Signature** |