**Application for approval of multicenter/
multinational (MCMN) veterinary clinical trial according to Regulation (EU) 2019/6
in several Member States**

**Procedure No.:**

**{MCMN/YYYY/Number}**

***{Study title}***

**<LIST OF QUESTIONS Step I (Day 30)>**

**<APPLICANT’S RESPONSE TO**

**THE COMPILED LIST OF QUESTIONS and MEMBER STATE'S COMMENTS step II>**

**Applicant:**

**Date**: {dd.mm.yyyy}

*[Information on bracketing convention as follows:*

*[text]: Guidance and explanatory notes.*

*{text}: Information to be filled in. To ensure consistency throughout the document font “Arial”, size 11 should be used.*

*<text>: Text to be selected or deleted as appropriate.]*

# I. SUMMARY OF THE DOCUMENTATION

|  |  |
| --- | --- |
| **Name of the investigational VMP:** |  |
| **Study protocol Number:** |  |
| **Active substance(s):** |  |
| **Pharmaceutical form:** |  |
| **Target species:** |  |
| **Procedure Number:** | {MCMN/YYYY/Number} |
| **Lead Authority:** |  |
| **Applicant or Person authorised for communication during the procedure on behalf of the sponsor (phone and E-mail address):** |  |

|  |
| --- |
| **List of the EU Member States where the clinical trials application is submitted:** |
| □ AUSTRIA  | □ BELGIUM | □ BULGARIA | □ CROATIA | □ CYPRUS |
| □ CZECHIA | □ DENMARK | □ ESTONIA | □ FINLAND | □ FRANCE |
| □ GERMANY | □ GREECE | □ HUNGARY | □ ICELAND  | □ IRELAND  |
| □ ITALY | □ LATVIA | □ LITHUANIA | □ LUXEMBOURG | □ MALTA |
| □ NETHERLANDS | □ NORWAY | □ POLAND | □ PORTUGAL | □ ROMANIA |
| □ SLOVAKIA | □ SLOVENIA | □ SPAIN | □ SWEDEN | □ UNITED KINGDOM (NI) |

Timetable of the procedure

|  |  |
| --- | --- |
| Day 0 |  |
| Day 30 |  |
| Day 31 |  |
| Day 60 |  |

# II. COMPILED LIST OF QUESTIONS

[*Information for the applicant:*

*When compiling the list of questions, the applicant is asked to copy in this section each list of questions received from the Lead authority and/or NCA involved* *by mentioning the name of the NCA in the title of the respective list of questions.*

*The answers to all questions raised by the Lead Authority and/or NCAs involved should be provided in this document. The original numbering of the questions raised by NCAs should be maintained in the applicant’s response document.*

*To add MS list of questions the following text should be copied and pasted under the relevant section and the question.*

#### Questions raised by {<Lead Authority> / NCA (Austria, Belgium, etc.)>}

|  |
| --- |
| **Question No**  |

{Insert Question}

##### APPLICANT’s response:

##### MEMBER STATE’S COMMENTS:

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[*Information for the Lead Authority and NCA objecting and raising questions on this MCMN veterinary CT application:*

*Apart from the headings already introduced in the template, subheading, study number should be identified (as relevant), followed by a clear & concise question that identifies and justifies the concern and clearly outlines what is required by the applicant to address and solve the concern raised.*

*Section(s) can be left blanked if there is no question or in case of national assessment handled in a separate procedure.*

### ADMINISTRATIVE PART

**<National issues/requirements>**

*[In case that any national requirements which are classified as non-preventing validation by the respective MS may be remarked also in the LoQ for the sake of completeness that all raised issues will be addressed by the applicant/sponsor. Please see EU MCMN-Application form including Annex regarding specific national requirements.]*

### Investigational veterinary medicinal product

*[Qualitative aspects such as: Qualitative and quantitative composition; GMP-Status (GMP, GMP-compliant, QP-declaration); Manufacturing process; Control of starting materials; Control tests on finished product (potency, purities, impurities); Stability tests; Labelling of IVMP etc.]*

### SAFETY Documentation

**Safety**

*[Justification of the dose, pharmacology, toxicology, user safety data, target animal safety, ecotoxicity, and also when required data for a new external pest control, data for a medicinal product intended for farmed fish and administrated in water.]*

**Withdrawal period (when applied)**

*[Justification of proposed withdrawal period, MRL-status, data on residue studies]*

### study protocol

*[For specifying of further subheadings or details on study protocol please see VICH GL9 Good clinical,* [*link*](https://www.ema.europa.eu/en/vich-gl9-good-clinical-practices-scientific-guideline)*.]*