Gilvetmab Product Grant Application Instructions

MERCK Animal Health

Thank you for your interest in applying to the Gilvetmab Product Grant Program. As a reminder, this grant program provides free product (gilvetmab) necessary to complete a proposal objective and does not provide funding.

Below you will find the complete instructions for the content, form, and process of application submission. Your application should be typed according to the guidelines indicated below and converted to a PDF file format.

*****To submit your completed PDF format application, please e-mail the application and all relevant supporting files to GilvetmabGrant@merck.com.*****

Application and Submission Information

Content and Form of Application Submission

It is critical that applicants follow the instructions in the product grant opportunity announcement. Applications that are out of compliance with these instructions may be delayed or not accepted for review.

Non-Responsive Applications

Applications with the following attributes will be deemed non-responsive and will not be reviewed.

- Applications that request active pharmaceutical ingredient (API) for purely non-clinical applications
- Applications that do not involve the canine model

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- Applications that involve stage II or III canine oral melanoma (see Ongoing Clinical Trials link on the Gilvetmab Product Grant Program website for information regarding ongoing clinical trials)

Page specifications

- Single-spaced, 12-point font, 1" margins, printable on 8.5" x 11" pages; applications exceeding specified page limitations will not be considered.

Instructions for Application Submission

To apply for this product grant opportunity, applicants must prepare and submit the following sections as part of their application. All documents should be typed according to the specified page limits, converted to PDF format, and submitted electronically.

Required Sections

1. Cover Page (Limit: 1 Page)
   Include the following information:
   - Title of the proposed study
   - Name, affiliation, email, and postal mailing address of all investigators
   - Underline the name of the investigator to whom the product will be shipped
   - Anticipated number of dogs to be treated
   - Anticipated time frame for study completion
   - Estimated cost of the study and anticipated sources of funding
2. Project/Performance Site Locations (Limit: 2 Pages)
   Identify all locations involved in the planned project, including clinics, reference laboratories, and animal facilities, if applicable.
3. Study Objectives/Scientific Hypothesis(es) (Limit: 1 Page)
   Provide a concise overview of the study objectives and hypothesis(es). Include an impact statement that outlines the significance of the research.
4. Research Plan (Limit: 5 Pages)
   Summarize the proposed project, including:

- Background information
- Study design
- Justification for the number of animals needed
- Expectations for results
- Methods of analysis
  - Include a milestone-driven plan with clearly stated deliverables within the two-year timeframe.

5. **Timeline (Limit: 2 Pages)**
   Outline a maximum of 24 months for project completion from the time of first patient enrollment. Provide a timeline with a study calendar that highlights key dates and activities necessary to complete the trial and analyze the data. Note that the 24-month timeframe does not need to include publication, but preference may be given to projects that include a publication timeline.

6. **References (Limit: 1 Page)**
   List pertinent literature references related to the proposed study.

7. **Budget (Limit: 1 Page)**
   Outline expected expenditures for the project.

8. **Current and Pending Support (No Page Limit)**
   Include a list of any current and pending sources of funding for this project. Full funding for the project is not required at the time of application submission, but proof of such will be required prior to shipping gilvetmab to award recipients. Proof must be provided within six months of proposal acceptance. Owner-funded studies are not recommended and will only be considered if significant documentation is provided that demonstrates a historical caseload and expenditure by owners that align with the required timeframe.

9. **Biographical Sketch (Limit: 2 Pages Each)**
   List all personnel involved in the project and explain their roles.

10. **Client Consent Form (No Page Limit)**
    Include a copy of the proposed client consent form.

11. Ethical Committee Oversight (No Page Limit)
    Provide proof of ethical committee review of the proposed project (e.g., IACUC approval). For institutions without a formal IACUC, evidence of completion of a course on Good Clinical Practice (GCP) for Veterinary Clinical Trials and a signed statement of ethical treatment of animals are required.

Merck Animal Health reserves the right to modify or discontinue the Program at any time without notice. All Merck Animal health decisions relating to the Program are final.

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