Gilvetmab Grant Program Frequently Asked Questions

MERCK Animal Health

General Program Information

What is the Gilvetmab Product Grant Program?

The Merck Animal Health Gilvetmab Product Grant Program provides gilvetmab for well-planned research projects aimed at advancing the science of immune checkpoint inhibitor therapy in veterinary medicine. The program specifically focuses on advancing understanding of gilvetmab' s role across cancers and factors that may predict a patient's likelihood of benefiting from treatment.

Does this program provide funding for my research?

No, this is a product grant only. The program provides gilvetmab at no cost but does not provide monetary funding for research activities. Recipients must secure their own funding to conduct the study.

What types of studies are you looking for?

We seek proof-of-principle or proof-of-concept studies with readily measurable outcomes that address practical, clinically relevant questions in veterinary oncology. Studies must demonstrate immediate applicability to clinical practice and be designed to gather meaningful information within a two-year timeframe. Studies that do not involve clinical use of gilvetmab in dogs will not be reviewed.

Eligibility

Who can apply for this grant?

Eligible applicants include:

- Board-certified veterinary medical oncologists from the American College of Veterinary Internal Medicine (ACVIM) or the European College (ECVIM)

- Board-certified veterinary radiation oncologists
- Board-certified veterinary surgical oncologists
- Board-certified veterinary internal medicine specialists (with demonstrable canine cancer experience)
- Board-certified veterinary dermatologists (with demonstrable canine cancer experience)

What types of organizations are eligible?

Eligible organizations include higher education institutions (public and private), nonprofits (with or without 501(c)(3) status), and for-profit organizations (including small businesses).

Where can the research be conducted?

Projects must be conducted in the United States of America, excluding its territories and possessions.

Application Process

How many applications will be reviewed per cycle?

A maximum of 25 applications will be reviewed per cycle. Applications exceeding this cap will not be reviewed unless an earlier application is withdrawn.

What types of applications will NOT be reviewed?

Applications will not be reviewed if they:

- Request active pharmaceutical ingredient (API) for purely non-clinical applications
- Do not involve the canine model
- Involve stage II or III canine oral melanoma (due to ongoing clinical trials)

Do I need IACUC approval to apply?

You need proof of ethical committee review (e.g., IACUC approval). For institutions without a formal IACUC, you must provide evidence of completion of a Good Clinical Practice (GCP) course for Veterinary Clinical Trials and a signed statement of ethical treatment of animals.

Award Requirements

How long do I have to complete my project?

All research projects must be completed within 24 months of enrolling the first patient. This includes enrollment of all patients and analysis of all data.

Do I need to have funding secured before applying?

No, full funding is not required at application submission. However, **you must demonstrate adequate funding within 6 months of award notification.** Gilvetmab shipment is contingent upon proof of funding.

What happens if I can't secure funding within 6 months?

If you fail to secure adequate funding within 6 months of receiving the award, you must explain why and specify how much additional time you need. The review panel reserves the right to withdraw the award.

Can I make changes to my research protocol after being awarded?

Yes, but you must submit a formal protocol change request and receive approval from Merck Animal Health before implementing any changes. You cannot make protocol modifications without prior approval from Merck Animal Health. Implementing changes prior to approval by Merck Animal Health may result in revocation of the award.

How quickly do I need to start enrolling patients?

You must begin enrolling patients within 3 months of obtaining funding.

Product Reporting

How will the gilvetmab be shipped?

Approximately 1/4 of your total requested gilvetmab will be shipped at a time, with regular progress updates required to ensure continuous availability for your project.

What reporting is required?

You must submit progress reports every 6 months until project completion and you must present complete data to Merck Animal Health at grant completion.

Can I sell the gilvetmab provided?

No, you are prohibited from selling gilvetmab provided for the research project. The product is intended solely for use in your approved research project.

What about adverse events?

You must report all adverse events associated with gilvetmab use to Merck Animal Health at 1-800-224-5318 or uspvgilvetmab@merck.com using the provided adverse event reporting form.

Publication and Data

Am I required to publish my results?

Publication is encouraged but is entirely at your discretion. However, you must present complete data to Merck Animal Health at grant completion.

Do I need client consent forms?

Yes, you must use client consent forms for extra-label use. Merck Animal Health must review and approve the client consent forms and may add additional language as deemed necessary.

Timeline and Deadlines

When will award decisions be announced?

Award decisions will be communicated by email approximately one month after the close of the application window.

How long do I have to sign the award agreement?

Selected recipients must sign and return the award agreement within 30 days of notification.