FDA Center for Veterinary Medicine

Office of Minor Use and Minor Species Animal Drug Development (OMUMS)

Minor Use/Minor Species (MUMS) Grants

- What are they?

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What are MUMS Grants?

Money to defray the costs of safety and effectiveness studies needed to support a New Animal Drug Application (NADA) for products for minor uses and minor species
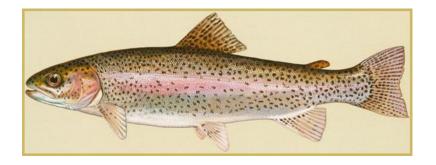
Who is eligible to apply?

1. Pharmaceutical sponsors developing MUMS drugs for FDA approval

   - The sponsor must have already opened an Investigational New Animal Drug (INAD) file with FDA/CVM

   - The sponsor must already hold a MUMS designation granted by FDA/CVM/OMUMS for that drug for a specified intended use

   - CVM's Office of New Animal Drug Evaluation (ONADE) must have already reviewed and accepted the study protocol

2. Their research partners

   - The sponsor needs to submit a letter to the INAD file identifying the partnership

What kind of studies can be funded?

1. Clinical effectiveness studies

2. Target animal safety (TAS) studies

3. Human Food Safety studies (residue, toxicology, microbial)

4. Environmental safety studies

5. Certain manufacturing studies supportive of effectiveness or TAS

How much grant money is available?

- The amount is always dependent upon available funding

- The Statute authorizes $2 million (or more)

- Authorization ≠ Appropriations

- Appropriation typically varies from $500,000 to 1 million/year

- Grants are available for:

  - Up to $250,000 for up to 2 years (applicant needs to justify why they need funding for more than 1 year)

  - Up to 250,000 for up to 3 years only for long-term toxicological studies

When are the application periods?

- There are two open application periods per Fiscal Year (FY)

- The second open period in FY has the money left over from the first round

- Funding Opportunity Announcement #PAR-21-179 contains detailed information about application dates:

https://grants.nih.gov/grants/guide/pa-files/PAR-21-179.html

FY2022 Part 1 open period: 5/28/2021 to 7/30/2021

FY2022 Part 2 open period: 12/3/2021 to 2/4/2022

FY2023 Part 1 open period: 5/27/2022 to 7/29/2022

FY2023 Part 2 open period: 12/2/2022 to 2/3/2023

What is the process?

FIRST: FDA/CVM/OMUMS must "designate" the product for a specific intended use at the request of the pharmaceutical sponsor

    AND

    FDA/CVM/ONADE must review and accept the study protocol

THEN: Allow up to 6 weeks to obtain the registrations that are needed to apply (note: do #1 and #2 below first):

1. Acquire a DUNS number
2. System for Awards Management (SAM): must renew registration annually
3. eRA Commons: applicant and all Program Directors/Principal Investigators - one-time registration
4. http://www.grants.gov: one-time registration

Applying for a MUMS grant

There are multiple options to submit your application through Grants.gov. You must use one of these submission options to access the application forms:

1. Use the NIH ASSIST system to prepare, submit and track your application

2. Use an institutional system-to-system (S2S) solution to prepare and submit your application to Grants.gov and eRA Commons to track your application

3. Use Grants.gov Workspace to prepare and submit your application, and eRA Commons to track your application

Applying for a MUMS grant

- Don't wait until the last minute to apply. Allow time to fix unexpected errors in the application

- Resource SF424 (R&R) Application Guide (Research Instructions)

  https://grants.nih.gov/grants/how-to-apply-application-guide.html

What happens next

- The FDA's Office of Acquisitions and Grant Services (OAGS) retrieves the applications and they are then screened for eligibility by OMUMS

- An Objective Review Panel evaluates qualified applications for scientific and technical merit based on criteria defined in the Funding Opportunity Announcement

- Following completion of the review process, FDA/OAGS will inform you of the approval status of your application and whether they will fund it in full or partially, based on availability of funds

- If the MUMS Grant Program does not fund your application, you may reapply in the next round

How long to spend MUMS grant monies?

- Grantees need to use the money during the 12-month performance period that follows the date of the award

- Multi-year funding can be approved for long-term, more complex studies

More information:

Designation:

https://www.fda.gov/animal-veterinary/development-approval-process/minor-useminor-species#designation

Designations List:

https://www.fda.gov/animal-veterinary/minor-useminor-species/designations-list

Questions about the MUMS Grant Program:

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MUMS Grant Funding Opportunity Announcement:

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