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PROGRESSIVE MS ALLIANCE

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An informational teleconference for investigators interested in the request for applications (RFA) for Experimental Medicine Trials was held on 31 January. Questions asked during the teleconference, and their respective answers, are offered below. If, after reading the RFA and this FAQ document, you still have questions, you are encouraged to contact an Alliance representative for further discussion (listed at bottom of document).

Q&A from the Teleconference

1. *Are preclinical studies supported with a Development Award?*
   Answer: It depends on the type of preclinical study. This funding call is not intended to support animal studies, development of a therapy, or preclinical toxicity studies. However, the Alliance will consider funding studies that focus on assembling a network for a trial, validating outcome measures (biologic, imaging, or electrophysiologic), or validating targets.
2. *What are the eligible costs for a Development Award?*
   Answer: Development Award expenses are flexible. Appropriate budget items may include salary support, consumables, patient care costs, and travel; groups using this Award to set up a Trial may use funds to hold a team meeting, and/or to use for regulatory audit costs. Large equipment costs are prohibited.
3. *Are Phase 1 studies allowed?*
   Answer: Yes, but they must incorporate a mechanistic response. This would include Phase 1 trials that look at specific mechanisms, or try to identify and validate targets, pathways, and/or measures. Early safety studies without a mechanistic component are out of scope.
4. *What is the target population for this RFA, i.e., is this limited to traditional PPMS or SPMS phenotypes?*
   Answer: No, this is not limited to traditional phenotypic definitions of primary progressive and secondary progressive MS. The Alliance recognizes the shifting landscape understanding progression and progressive MS. We embrace a wider view of what progressive MS is; however, for example, the Alliance is not looking to study mechanisms of focal inflammation or new lesions classically associated with RRMS with this Experimental Trials mechanism.
5. *Are you looking for a specific kind of study design, i.e., single arm, open label, etc.?*
   Answer: This is not something the Alliance is limiting. External peer review will provide an appropriate scientific assessment of what groups propose and will evaluate accordingly. We welcome innovation.
6. *Are novel trial designs a requirement?*
   Answer: No, this is not a requirement.
7. *Are indirect costs allowed and is there a cap?*
   Answer: Indirect costs are allowed when requested and required by Institutional policy. Indirect costs may not exceed 10% of total direct costs requested (i.e., an award for €100,000 will have €10,000 in indirect costs and €90,000 in direct costs) and cannot be used in connection with funds requested or expended for purchase, modification, or installation of equipment. Please reach out to Alliance staff if you have additional questions about our indirect cost policy.

8. *Is co-funding allowed?*
   Answer: Yes. The Alliance has no opposition to co-funding; leveraging additional funds or piggybacking onto ongoing trials is encouraged.
9. *Is this funding call coordinated with other funding agencies? Can we submit to other funding agencies for additional funding?*
   Answer: This call is not coordinated with other agencies. However, there are other award mechanisms around the world and investigators are welcome to combine applications. We welcome collaboration with other agencies and any issues with potentially overlapping funding will be addressed at the time of award. Please indicate in the appropriate area of the application if you are submitting an identical or overlapping proposal to another agency.
10. *Can the PI be in a company?*
    Answer: The PI cannot be from a company since the award must be administered through a public institution or non-profit research organization. However, companies are welcome to be involved in a project as a sub-contractor or other type of collaborator.
11. *Can you provide more information about the expected role of a commercial partner?*
    Answer*:* A commercial partner may be listed as a co-investigator on the application, and is not expected to contribute financially but may contribute in other ways. For example, companies might contribute by sharing expertise, or by providing in-kind support, tools, equipment, infrastructure, reagents, etc. The specific details of how a commercial partner may contribute will be dependent on the structure of each project.
12. *Is there a limit to the number of applications a person can submit? Can an individual investigator be part of more than one project?*
    Answer: Applicants may submit or be involved in multiple applications but can only be the PI on one application.
13. *If a team/network already exists, do we need biosketches for all the members?*
    Answer: It would be helpful to reviewers to have a complete understanding of the key personnel that you expect to play a role in the project. Biosketches should be submitted for collaborating investigators and other investigators that will have a substantial role in the project.
14. *How many researchers can participate? Will it be looked at more favorably if more researchers are part of the project?*
    Answer: No maximum number of investigators or collaborators has been established. Applicants are encouraged to assemble the disciplines and experts that are needed to effectively execute the work. The Alliance recognizes that there are many ways to establish a network based on the needs of the work proposed.
15. *Can you please clarify what the 5-page max proposal includes?*
    Answer: Items a-c in the RFA are included in the 5-page planning proposal. This includes an overview of the proposed research (background, rationale with evidence, research objectives, and description of the experimental design for the award), a statement of expected outcomes and deliverables, and a work plan with timeline. References should be listed immediately following the narrative and do not count towards the 5-page limit.
16. *How many Development Awards are available?*
    Answer: The Alliance anticipates funding up to 10 awards based on merit and availability of funds.

17. *What is the total funding for the award?*
    Answer: The Development Award provides €100,000 Euro for up to 18 months. Experimental Medicine Trial Awards provide up to €1.5M Euro for up to 3 years of research.
18. *How should we go about drafting our budget in Euro if our country uses a different currency?*
    Answer: Applicants should estimate their budgets in Euros using a tool such as https://www.xe.com/currencyconverter/convert/?Amount=1&From=USD&To=EUR. We will make awards based on rates effective at the time of the award.
19. *How should non-published data be handled in an application?*
    Answer: Investigators should use their judgment in submitting non-published data. The Alliance confidentiality and conflict of interest policies are robust and , as with any other granting organization, reviews will be done ensuring compliance with these policies.
20. *Are we allowed to increase or change the project team when we move from a Development Award to an Experimental Trial Award?*
    Answer: Yes, we envision that a full Experimental Trial award could look different and/or require additional expertise compared to an initial Development award, and these changes would be captured in an application for the full Experimental Medicine Trials award.
21. *Are subaward agreements needed for the development award application if there are researchers at multiple locations?*
    Answer: We provide one award to the principal investigator, and the PI is responsible for setting up sub-awards, if needed.
22. *Is the expectation to have a multi-national team?*
    Answer: A multi-national team is not a requirement for this particular RFA.
23. *Are early career researchers eligible to apply?*
    Answer: Yes, if you are a qualified investigator at your institution and eligible to apply for awards, you may submit an application. Postdoctoral researchers are not eligible to serve as a PI; you must be an independent investigator at least at the assistant professor level, or equivalent.

Please refer to the RFA for complete information.

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