INTERNATIONAL
PROGRESSIVE MS ALLIANCE

CONNECT TO END PROGRESSIVE MS

An Informational teleconference for investigators interested in the request for applications (RFA) for Improving Well-being in Progressive MS was held on 30 March. Questions and answers from those were collected and are offered below to provide clarification to applicants that might not be clear from the RFA guidelines. If, after reading the RFA and this FAQ document, you still have questions, you are encouraged to contact an Alliance representative for further discussion. A list of contacts can be found at the bottom of this document and of the RFA.

Q&A from the Teleconference

1. *Is there a limit to the number of applications? Is it possible to submit more than 1 proposal? Can an individual investigator be part of more than one network?*
   Answer: Applicants may submit or be involved in multiple applications but can only be the PI on one.
2. *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 all the members that you expect to play a role in the proposal being put forward. Biosketches should be submitted for collaborating investigators and other investigators that will have a substantial role in the network.
3. *Does the budget for the planning award allow for costs associated with preliminary data acquisition?*
   Answer: Planning awards may include preliminary research/data acquisition to support the full efficacy proposal.
4. *How many groups can participate? Will it be looked at more favorably if more groups are part of the network?*
   Answer: The minimum number of sites/groups is 3. No maximum 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 and that the Alliance is seeking optimal collaboration, based on the needs of the work proposed.
5. *Can you please clarify what the 5-page max proposal includes?*
   Answer: Items a-d in the RFA are included in the 5-page planning proposal. This includes 1 page each for aims and deliverables, a description of and rationale for the organizational structure, rationale and description of the future efficacy proposal, planning activities and timeline, and a summary of the proposal.
6. *How many Innovation and Planning Awards are available?*
   Answer: The Alliance intends to fund up to 12 awards based on merit and availability of funds.
7. *Can the PI be in a company?*
   Answer: The PI cannot be from a company, since the award must be administered through a non-profit research organization. However, companies are welcome and encouraged to be part of a network.

8. *Please 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 a number of ways, for example via contributing expertise, 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 individual network.
9. *What is the total funding for the award?*
   Answer: The Innovation and Planning Award will be up to a total of €100,000 Euro. Efficacy Awards will be up to €3M Euro for up to 5 years.
10. *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. Further, we will be able to write an award in USD or other currency that is equivalent to Euro at the time of the agreement.
11. *How should non-published data be handled in an application?*
    Answer: Investigators should use their judgment in submitting non-published data. The Alliance conflict of interest policies are robust and will be in place, as with any other granting organization, and reviews will be done ensuring compliance with these policies.
12. *What general economic categories could be included in the Planning Awards? Please provide some examples of how the Planning Award funds may be spent.*
    Answer: The budget for the Planning Award may contain expenses related to bringing the team together and working on the proposed plan of research, e.g. travel, program management, generating preliminary or additional supporting data (salaries and supplies), understanding that the team will have only 15 months to generate the full research proposal.
    The Planning Award is intended to support the time and effort required to prepare a full Efficacy Award application. There are many ways in which the Planning Awards funds may be spent, for example - facilitating meetings or conferences for collaborators to plan the project proposal, for travel costs for PIs to attend these meetings, administrative costs involved in the creation of a management plan, and where applicable on the collection of pilot data to support the application.
13. *What is the anticipated length of the full efficacy application?*
    Answer: As a major funding application, it is expected the Efficacy Award application will be ~20 pages long. Note, though, that full applications are not due until mid-2024 and applications for the Efficacy Awards will only be accepted from Planning Award recipients.

14. *Do you have an expected profile of a principal investigator? Someone with prior experience with progressive MS or an MS specialists?*
    Answer: We're looking for the best ideas and best science. If you're new to the MS field but have new ideas and new science, you're welcome to apply. At the end of this pipeline, we want things that people with MS can use.
15. *Must all participants be diagnosed with progressive MS?*
    Answer: No. The goal is to end up with implementation or interventions that are specific for progressive MS and if your project includes multiple groups, including one with progressive MS and others with different types of MS, that's not a problem.
16. *Does the efficacy grant have to involve an intervention if the planning grant is focused on validating an outcome measure? And if so, does it need to be a well-established intervention?*
    Answer: If the planning award is focused on an outcome, then we would expect that the efficacy award would have an intervention but likely wouldn't be novel.
17. *Are we allowed to increase the number of teams in Stage 2?*
    Answer: Yes, we envision that stage 2 could look different and these changes would be part of the efficacy proposal.
18. *Are subaward agreements needed for the planning grant application if there are researchers at multiple locations?*
    Answer: We provide one award to the principal investigator, and if you need subawards to work with collaborators, you can work together to set them up.
19. *How many efficacy awards are you planning to make?*
    Answer: We do not have a firm answer at this point, it depends on what kinds of proposals we receive. Keep in mind that the more interesting the project is, the more we can advocate for more funds.
20. *Is the expectation to have an international team?*
    Answer: Not a requirement for this particular RFA, but the team does need to be interdisciplinary.
21. *What are the acceptable interventions? The RFA did not mention pharmacological therapies.*
    Answer: If the intervention is pharmacological but you can demonstrate that symptomatic changes occur, we would consider that to be within scope.
22. *Are early career researchers eligible to apply?*
    Answer: Yes, if you are a qualified investigator at your institution and eligible to apply for awards. Postdoctoral researchers are not eligible; you must be an independent investigator at least at the assistant professor level.
23. *Are multimodal interventions for rehabilitation encouraged to maximize rehab potential? Will physical medicine and rehabilitation teams be involved in the review process?*

Answer: If your proposal includes a multimodal intervention that is great, but not required. We will do all we can to make sure our reviewers are informed about rehabilitation.

24. *Any room for preclinical interventions, or is this human-oriented?*
    Answer: Efficacy awards do need to be human trials. There could be an opportunity for some preclinical work in the planning awards, but the goal is to implement concrete therapies for people with progressive MS.
25. *Are indirect costs allowed for the planning grant and is there a cap?*
    Answer: Indirect costs are not allowed; however, our language allows for other F&A costs. You're welcome to contact us for further discussion and clarification.
26. *How is the Alliance defining "progressive MS" for this RFA?*
    Answer: We are using the traditional view of MS that has no or few relapses and is progressing in terms of symptom severity.
27. *Any insights on whether the planning grants will be divided equally across symptom areas?*
    Answer: We do not have pre-established quotas. The areas are different in many ways, and the research fields are in different places, and we are considering the best opportunities for treating symptoms in people with progressive MS.
28. *How important is it to have preliminary data for the planning proposal?*
    Answer: The planning period was designed to create an expert team and collect preliminary data if it is needed. Thus it's not essential in the first stage.
29. *If we are far enough along and have IRB approval for a small study, can we include a human cohort in our planning award?*
    Answer: Yes, this can be counted as preliminary data for the larger efficacy study.
30. *Are using new/novel outcome measures within scope for this RFA?*
    Answer: Yes, but be sure to include support for why it's useful for progressive MS and how these new measures play into improving a person's well-being.
31. *What is the main focus of the Efficacy Awards: are they primarily focused on translational and clinical work?*
    Answer: The stage 2 Efficacy Awards are designed to support trials testing efficacy on one of two potential pathways:
    a. To study innovative symptomatic treatments using valid, reliable, culturally sensitive and responsive behavioral outcome measures
    b. To develop innovative outcome measures to better quantify the impact of interventions to improve the well-being of people with progressive MS

    Please refer to the RFA for complete information.

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