

Combination Therapy Funding Call FAQs

1. Will you be considering drug + life style adjustment combinations in this call?

No. While we appreciate the potential of different types of interventions (for example, diet, exercise, devices, etc) in a combination approach, for this call we are only considering drug combinations.

2. Do you consider a supplement or vitamin as 'a drug'?

Yes, we would consider these as part of a drug combination.

3. Can biotech/commercial companies apply?

Yes, but applications from, or in-collaboration with, commercial entities are required to submit a commercial entity form as part of their application.

4. Can applicants use tool compounds, to include combination drugs, to test a novel model and universal mechanism underlying Parkinson's?

Applicants are able to submit funding requests of this nature however for preclinical projects, priority will be given to those that are closer to clinical evaluation.

5. Would you require a four arm preclinical study? (placebo+placebo, placebo+drug A, placebo+drug B, drug A+drug B)

This could be considered appropriate depending on the nature of the combination. While the placebo is not required in combination with each drug, we would want to see each individual drug tested alone (verses placebo) in order to demonstrate any synergistic effect in the combination of the drugs.

6. In order to move forward from preclinical testing, must the combination of the two drugs perform better than each drug singularly?

Ideally yes, but this may differ on a case-by-case basis. For example, one drug may have an associated side effect and a combination may reduce those side effects while eliciting the same response.

It should be noted that this will be a competitive funding pool and that rationale will be compared to other rationales. The greater the potential for disease modification, the stronger an application will be viewed.

7. Are you considering drugs on the International Linked Clinical Trials (iLCT) list?

We would be very open to combinations of iLCT evaluated molecules. A list of the generic drugs and supplements evaluated by the iLCT committee can be found in supplemental file 1 from the paper ['Twelve Years of Drug Prioritisation to Help Accelerate Disease Modification Trials in Parkinson's Disease: The International Linked Clinical Trials Initiative'](#).



More information about the iLCT process can be found on our [website](#).

8. Would it be possible to include drugs that haven't been prioritised by the iLCT committee?

Yes, this would fit within the remit of this funding call. The agents being tested do not need to have been evaluated by the iLCT committee. The combination can be made of completely novel drugs. We are looking for drug combinations with a strong rationale – the stronger, the better. In preclinical studies, priority will be given to those applications closest to clinical testing.

9. Does the drug have to be a fixed combination or can they include two drugs that are given by different forms of application?

The combinations do not have to be fixed, for example given by a single route of administration at one specific time point. Drug combinations may need to be administered in parallel or at different timepoints. They might also have different routes of administration.

10. In clinical testing, are you considering only symptomatic people with Parkinson's or can patients with a prodromal form of Parkinson's such as REM behaviour disorder also be included?

We are looking for drug combinations that could potentially have a clinical effect in either people with Parkinson's or people at risk of Parkinson's. However, in this funding call, prioritisation will likely be given to applications aimed at people currently living with Parkinson's.

11. Is there a specific amount of money allocated to preclinical and clinical projects?

A total of £2 million has been allocated to this funding call as a whole. There is not a specific amount of money dedicated solely to preclinical or clinical projects. All projects will be evaluated independently by a review panel and ranked based on their rationale and supporting evidence. Therefore it is possible that the £2 million is allocated solely towards preclinical or clinical projects, or a mix of both.

However, in the event that the evaluation panel determine there to be fundable projects above a total of £2 million, it is the decision of the Cure Parkinson's Trustees whether to fund additional projects.

12. Can the call include a gene or cell therapy in combination with a drug?

No. For this call, we are solely requesting applications for drug+drug combinations.

13. Will single drug, rationally designed dual-target inhibitors that act on multiple pathways related to Parkinson's be considered?

All applications must include at least two or more drugs being tested in combination. This could be a novel combination of monotherapy drugs or it could involve a combination drug combined with another individual drug. At least two or more drugs must be involved.

Single drugs that are designed to act on multiple pathways are not eligible for this funding call if they are being tested alone, but can be submitted to Cure Parkinson's [Quarterly Research Grant Funding Programme](#).

14. Do the drugs included in the combination have to be FDA or MHRA approved or can they be drugs that are going through the drug development process?

Drugs do not have to be FDA or MHRA approved, investigational drugs are permitted. However, clinically, Cure Parkinson's does not fund first-in-human, healthy volunteer studies. For an investigational drug to be included in a combination for this call, there must be a clear route to the individual clinical testing of the investigational drug within five years.

15. Are chemical structures expected to be included in the application forms?

No, chemical structures are not necessary to be included in the expression of interest application. However, all Cure Parkinson's employees and members of the independent review panel are bound by a non-disclosure agreement (NDA) if applicants wish to share sensitive information.

16. Is it compulsory for preclinical applications to have involvement from people with Parkinson's (PwP)?

Yes. People with Parkinson's are central to the ethos of Cure Parkinson's and as such we like to see involvement of PwPs in aspects of the proposals or projects. Clinically, this could be consulting with PwPs about trial design or additional tablets required for the study. Preclinically, involvement could include a focus group to determine whether the known side effect profile of a drug is acceptable. It is not required to have PwP involvement before submitting an expression of interest application, however a clear plan for how to include them ahead of a full submission or during the project is required.

17. Is it possible to include the purchase of equipment as part of the budget?

No, Cure Parkinson's only fund costs directly related to the project and does not support indirect costs, investigator travel, or overheads (ongoing operating expenses of the host organisation e.g. lab space, equipment, existing staff time). Preclinical projects can request up to a total value of £300,000 and clinical projects in the region of £1 million.

18. What types of preclinical models can be used?

Cure Parkinson's will accept both *in vitro* and *in vivo* preclinical models. Justification should be given for the use of specific models.

19. Should applications be targeted towards Cure Parkinson's therapy targets?

No, applications do not have to fit within the therapy targets defined on the Cure Parkinson's [website](#). Novel ideas are welcomed providing the combinations are rationally designed and well supported.

20. Are natural compounds able to be included in a combination?

Natural compounds are able to be included in a combination however we would suggest providing evidence to show that it has been safely used in humans previously.

21. Can drugs that are currently in clinical trials as a monotherapy be included as part of a combination?

Yes, this is possible. For example, the Australian Parkinson's Mission II is currently investigating doxycycline and ambroxol in combination (ACTRN12623000843651). There are also ongoing clinical trials testing these agents as monotherapies in Parkinson's.

22. For preclinical projects, is it possible to test multiple combination therapies in one application?

Cure Parkinson's will not fund large-scale drug screens for this funding call. Furthermore, the independent review panel will be assessing the scientific rationale behind each combination. It is possible to submit two expression of interest applications, however there is a maximum limit of 2 applications for each named principal investigator.