Combination Therapy Funding Call FAQs

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

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 Internation 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.