THE MICHAEL J. FOX FOUNDATION
FOR PARKINSON'S RESEARCH

Parkinson's Disease Therapeutics Pipeline Program

Request for Applications

Fast Facts

- Funding to accelerate pre-clinical and clinical therapeutic development for Parkinson's disease
- Accepting pre-proposal applications on a rolling basis for faster initial exchange with MJFF on proposed therapeutic ideas
- Office hours available to address questions and partnerships after invite to the full proposal round
- Only open to industry or academia + industry partnerships to foster clearer path to commercialization
- Project Duration: 1 to 2 years for pre-clinical programs, 2 to 3 years for clinical programs

BACKGROUND

Parkinson's disease (PD) affects nearly 1 million people in the US and over 6 million worldwide, with expected increases over the coming decades. PD is highly heterogeneous: individuals experience a wide array of motor and non-motor symptoms, many of which depend on disease severity and duration. Though understanding of PD and its causes is growing, many questions remain. There are no drugs available that alter the progression of Parkinson's disease, and current symptomatic treatments provide limited relief but come with complications and side effects.

The Michael J. Fox Foundation for Parkinson's Research (MJFF) is dedicated to finding a cure for Parkinson's disease (PD) through an aggressively funded research agenda and to ensuring the development of improved therapies for those living with Parkinson's today. Key to our mission is supporting the accelerated validation and de-risking of PD understanding into promising therapies. Strategic MJFF funding fosters a robust pipeline of treatments for improved symptoms management as well as those that may modify disease course. Beyond funding, additional resources such as research tools, open access data sets and connection to MJFF's broad network of scientists, clinicians and the patient community offer added opportunities to enable a program's success.

PROGRAM GOAL

The Parkinson's Disease Therapeutics Pipeline Program advances therapeutic development through pre-clinical and/or into clinical testing of approaches addressing unmet needs of people with PD with clear potential to prevent, stop, or delay disease progression or to reduce the burden of daily symptoms. As the requirements for delivering new treatments into the market depend on specialized expertise and resources, a unique goal of this program is to promote clearer paths to commercialization and market access by the PD community. Therefore, we are only accepting applications from industry groups or academic teams working in collaboration with a dedicated industry partner capable of further commercial development of a promising intervention.

MJFF prioritizes pre-clinical and clinical programs that may slow, stop, or prevent disease progression, efforts that address moderate-to-advanced motor or non-motor symptoms of Parkinson's not well-managed by current treatments such as advanced gait disturbances (e.g., balance issues linked to falls, freezing) and cognitive changes. Activities within scope of this program include:

- **Pre-Clinical**: Identifying, validating and/or developing novel pharmacological and non-pharmacological interventions through pre-clinical development from early screening to pre-clinical characterization and testing.
- **Clinical**: Progressing promising interventions with strong preclinical packages into/through initial clinical assessment exploring pharmacokinetics and pharmacodynamics, safety/tolerability, or early proof of biology and/or clinical efficacy. For novel targets, MJFF is particularly interested in de-risking programs by supporting early proof of concept in patients to gain insight into the therapeutic potential, including exploration of biomarker-based or clinical endpoint-based efficacy.

Any intervention may be considered based on clear patient need, rationale and strong mechanism-of-action understanding. Interventions may be pharmacological (small molecules), biological (biologic, gene therapy) or non-pharmacological including surgical approaches, technology-enabled therapeutics and neuromodulation approaches. Competitive non-pharmacologic proposals will have compelling, existing data from human studies with strong potential for clinical adoption. Applicants may also propose testing of repurposed or repositioned therapies but should propose clear and robust biomarker-enabled testing strategies.

For this program, MJFF **will not consider** proposals focused on the following areas and applicants should continue to monitor MJFF funding calls for future opportunities:

- Applications seeking to identify new intervention targets (e.g., large-scale screening or genomic/transcriptomic analyses).
- Applications seeking to validate a target with only tool compounds or biological manipulations that have no viable path for further drug optimization and development.
- Applications seeking to test reformulation of commercially available drugs via a new route of administration.
- Application seeking to assess efficacy of dietary supplements.

If you are developing a therapy for people with Parkinson's disease and your program aligns with the Foundation's priorities described above, we want to hear from you.

Please submit a pre-proposal via the **MJFF Grant Portal** to see if we are the right partner to help move your therapeutic ideas forward.

PROGRAM CRITERIA

When considering proposals submitted to this program, MJFF prioritizes those with the strongest therapeutic rationale, patient value and preclinical-to-clinical translation potential. Proposals should also fulfill the following criteria:

- The selected therapeutic target or mechanism should have strong biological rationale to be pursued as a therapeutic target for PD, such as a genetic link or based on prior validation data in relevant in vitro and/or in vivo models.
  *Applicants are encouraged to review **MJFF's Target Report** to familiarize themselves with the targets that are currently supported through MJFF programs.
- The proposed therapeutic approach is sufficiently differentiating from and believed to be superior to any of the currently existing therapies in the market or in development.
- The proposal emphasizes how translational biomarkers will be used to monitor target engagement/modulation and hypothesized mechanism of action, as well as consideration of patient enrichment measures that can improve clinical trial design to de-risk further development.
- For applications proposing clinical testing, the proposal has a patient-centered approach incorporating patient voice in the clinical development plan.

FUNDING AVAILABLE

Duration:
1 to 2 years for pre-clinical programs
2 to 3 years for clinical programs

Award Amount:
MJFF funding aims to de-risk selected therapeutic programs leading to faster progress and results, as well as increased chances of attracting follow-on investment. MJFF prioritizes opportunities to complement and share the costs of therapeutic development with like-minded partners with a current or new commitment to PD. As such we have a flexible approach to funding translational and clinical work that is guided by novelty of target and therapeutic approach, the stage of development and the overall priority of the unmet medical need for people with PD. The scope and budget for your study will be discussed with MJFF staff if invited to submit a full proposal and will be a reflection of the above considerations. In general, award amounts for this program may range from $250,000 for smaller, targeted programs to upwards of $2M for larger, multi-stage preclinical and/or clinical programs.

Budgets include direct and indirect costs. For academic and for-profit institutions, no more than 15% or 10%, respectively, may go to indirect costs. Additional details about MJFF's indirect cost policy can be found in the **Application Guidelines** and **FAQ**.

DEADLINES & REVIEW SCHEDULE

The Parkinson's Disease Therapeutics Pipeline Program works in **two stages** with the goal of offering applicants frequent opportunities to propose novel and promising PD therapeutics:

1. Applicants may **submit a pre-proposal application at any time.** Pre-proposals will be reviewed by MJFF within three weeks of submission. This stage is your first and best opportunity to determine if MJFF is the right partner for you.
2. Applicants whose pre-proposal is selected for further consideration **will be invited to submit a full proposal through one of the four review cycles (see full proposal due dates below)**. MJFF staff will work with applicants to define the most flexible and fastest option for review. Invited applicants will have the opportunity to consult with MJFF on proposal development. Funding decisions will be communicated within three months of full proposal submission.

Full Proposal Due Dates	Funding Decision Announced
January 11, 2024	April 2024
March 14, 2024	June 2024
May 16, 2024	August 2024
July 18, 2024	October 2024

Applicants are permitted to submit multiple, unique therapeutic pre-proposals but should NOT submit multiple pre-proposals supporting different stages or aspects of the same therapeutic development program. Applicants are also permitted and encouraged to re-submit a revised pre-proposal that addresses prior feedback provided by MJFF, if applicable.

ELIGIBILITY REQUIREMENTS

The Parkinson's Disease Therapeutics Pipeline Program is currently accepting applications from industry groups or from academic teams working in collaboration with a dedicated industry partner capable of further commercial development of a promising intervention. MJFF accepts applications submitted by researchers or clinicians at the following organization types:

- U.S. and non-U.S. biotechnology/pharmaceutical/medical device companies, or other publicly or privately held for-profit entities.
- U.S. and non-U.S. public and private non-profit entities, such as universities, colleges, hospitals, laboratories, units of state and local governments, and eligible agencies of the federal government **in collaboration** with biotechnology/pharmaceutical/medical device companies, or other publicly or privately held for-profit entities.
- MJFF encourages the inclusion of researchers who span career stages.
- Early career investigators (within 1-7 years of first independent appointment or equivalent) are encouraged to apply and are permitted to serve as Principal Investigator (PI); Post-doctoral fellows are permitted to serve as Co-Principal Investigator (Co-PI). Training and fellowship activities are not supported through this program.

BIOSAMPLE REQUESTS

Investigators are encouraged to leverage MJFF-sponsored biospecimen and cell line collections for their studies. MJFF staff can assist with MJFF's biosample process at both the pre-proposal and full proposal stage. To review MJFF's available biosample collections, refer to the MJFF biorepository **website**.

Investigators should indicate their intention to leverage MJFF's biosamples within their pre-proposal. If invited to submit a full proposal, a formal biosample request will be reviewed in parallel. Requests to access MJFF-sponsored biosample collection(s) without seeking MJFF funding support are welcome to apply through our Access to Biosamples and Data programs. Investigators should contact **resources@michaeljfox.org** to learn about the application process.

DIVERSITY, EQUITY AND INCLUSION (DEI)

In pursuit of our mission to accelerate the development of better treatments and a cure for Parkinson's disease, MJFF aims to support a rigorous research agenda reflecting a wide and diverse range of perspectives on Parkinson's disease and carried out in diverse populations. Diversity may refer to characteristics including, but not limited to, race, religion, ethnicity, sex, gender identity, sexual orientation, socioeconomic circumstance, nationality, geographic background, ability and disability, political ideology and age. Parkinson's is a complex problem; the more angles from which we attack, the greater the chances of finding innovative scientific solutions to benefit everyone living with the disease. As such:

- MJFF strongly encourages applications from a wide and diverse range of investigators, including those who identify as members of groups historically underrepresented in the research enterprise.
- Because research shows that diverse and inclusive teams often outperform homogeneous ones, we ask applicants to share information about the composition of the team or lab that will carry out the proposed work.
- Proposed work should seek wherever possible to include relevant diversity, such as inclusion of sex/gender and genetic ancestry in preclinical studies and inclusive recruitment and retention as well as engagement of historically underrepresented groups in clinical studies.

ADDITIONAL INFORMATION

The **Application Guidelines** provide general guidance on applying for funding from MJFF, though the RFA always supersedes information contained in the Application Guidelines.

MJFF holds an **open access publication policy** requiring articles resulting from MJFF-funded work to be published in a preprint repository, then in an open access forum with free and immediate readership rights.

MJFF requires that the Principal Investigator be the primary applicant (i.e., the person who initiates and takes primary responsibility for the application). All application-related correspondence will be sent to the Principal Investigator.

MJFF will hold office hours to discuss the full proposal development for those invited to submit.

For questions about the application process or project suitability for this call for applications, please email grants@michaeljfox.org.

Thank you for your interest in collaborating with MJFF and your commitment to the Parkinson's community.