

 **P2P PLATFORM TRIAL**

**Letter of Intent**

Path To Prevention (P2P) | Letter of Intent for Partnership

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| **Date of Letter:****Letter of Intent (LOI) Purpose:** |
| **Company/ Sponsor Name:****Company Address:****Contact Person:****Email:****Phone:****Send Completed LOI to** P2Ppartnerships@michaeljfox.org. The Michael J. Fox Foundation for Parkinson’s Research (MJFF) treats all LOI, applications, research projects and associated research information as Confidential Information. See [here](https://www.michaeljfox.org/news/application-guidelines) for full terms of MJFF’s confidentiality policy.  |
| **Investigational Drug / Compound****Name:****Class/mechanism of action:****Regulatory Status: ☐ US IND ☐ EU CTA ☐ Other \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_****Molecule type: ☐** Small molecule **☐** Biologic **Route of administration: ☐** Oral **☐** Intravenous **☐ Other \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_****Investigator Brochure is provided with this LOI (preferred). ☐** Yes **☐** No**If no, please attach a summary of the current investigational plan for the compound/ drug.****What is the current clinical development status of the investigational drug?****☐** Discovery **☐** Phase 1 **☐** Phase 2 **☐** Phase 3**Are there any ongoing clinical studies? ☐** Yes **☐** No**If yes, when will the data from this study be available and what phase of clinical development? \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ (mm/yyyy) ☐** Phase 1 **☐** Phase 2 **☐** Phase 3**Is there adequate drug supply available to support 24+ months study for 200-250 participant doses in 2026-2028 ☐** Yes **☐** No**Is there adequate placebo supply available to support 200 participant doses in 2026-2028** **☐** Yes **☐** No |
| **Briefly describe the relevance of the therapeutic target/pathway in Parkinson’s disease (PD) and rationale for efficacy in prodromal PD:** *(If additional space is needed you may attach additional pages, Maximum 1 page)* |
| **Indicate whether you have a biomarker of target engagement/modulation with which to set relevancy of the dose/dosing regimen for therapeutic evaluation. If so, please confirm whether the biomarker is reflective of brain target occupancy. If not, briefly describe how you selected the therapeutic dose/dosing regimen.**  |

*\*Please attach any additional pages as a single document.*