Personalized Approaches for Understanding, Assessing and Improving Gait in Parkinson’s Disease Research Program

Request for Applications

#### Pre-Proposal

*Please use the template below to create your pre-proposal and upload a single PDF copy with your online submission. Text should be no smaller than 11-pt font and not exceed* ***2 pages. Optional literature references are excluded from the 2-page counting.***

Principal Investigator:

Institution/Company:

Project Title:

**TEMPLATE**

*Text should be no smaller than 11-pt font and not exceed* ***2 pages.*** *You may delete the instructional text in each box of the template to save space.*

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| MEDICAL NEED | What need are you seeking to address in what target population? What is the novelty of approach and patient value proposition?  |
| TARGET/PATHWAY/CIRCUITRY | Please identify the target indication and presumed mechanism of action for the therapeutic being proposed for testing. For pharmacologic interventions, please detail compound composition of the proposed therapeutic. What molecular target, biologic pathway or neurocircuitry is your intervention targeting? How is it linked to PD? How has the functional role of your target/pathway/circuitry been validated and in which PD models?  |
| EXPERIMENTAL PLAN | What stage of development are you at (e.g., Phase 1, Phase 2, etc.)? Please provide a summary of the clinical study design, including the route of administration and relevant data (preclinical and/or clinical) that justifies the progression of the therapeutic through clinical trials. Indicate your plans for collecting the recommended minimal data sets, detailed in Table 1. |
| BIOMARKERS PLAN (as relevant) | Which biomarkers or other measures will you use to establish target engagement/modulation of the therapeutic? How will you establish PK/PD relationship and blood-brain-barrier penetration if your therapeutic is CNS-penetrant?  |
| FUTURE DEVELOPMENT PLAN | Please provide insights on how the proposed clinical study will inform subsequent studies. Outline future clinical development and commercialization strategies following this study, including what additional funding sources you will seek (e.g., government, private/VC, industry partners, etc.). Describe what role patients, care partners and health care professionals will have in these next steps.  |
| INTELLECTUAL PROPERTY | Describe any intellectual property considerations and/or restrictions (i.e. freedom-to-operate) that may impact further advancement of the proposed therapy. For industry/academia collaborations, please describe in a few words your plan to co-advance the therapeutic program, if successful. |
|  PROGRAM NEEDS | How can MJFF support your efforts? Please provide a high-level description of resource needs for your proposed study including a budget estimate. Is there specific access to expertise, advice or reagents that MJFF can help facilitate? |

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| Table 1: Recommendations for minimum data set and protocol |
| Demographic and clinical data | **Gait protocol** | **Gait measures and technology** |
| Minimum requirements |
| *Basic Demographics* * Age at testing
* Disease duration (in years from diagnosis)
* Education (years)
* SOGI
* Race
* Ethnicity
* Descent

*Demographics and Clinical** Visit type
* Height and weight
* MDS-UPDRS (ALL parts separately and total)
* Hoehn and Yahr stage
* Presence of FOG (Yes/No)
* Falls (number of falls in the past six months)
* PDQ-39
* PD-related Pharmacological Therapy: Levodopa Equivalent Daily Dose (LEDD)
* Presence of Deep Brain Stimulator (Yes/No)
* Presence of Infusion pump (Yes/No)
* MoCA
* Able to walk independently (Yes/No) with walking aid (Yes/No). If yes, detail type of walking aid
 | ***Environment and protocol**** Was gait data collected in the clinic (prescribed monitoring) or at home (unsupervised monitoring)?
* Medication status during gait data collection (Off/On)
* Straight-ahead walkway length (in meters)
* Duration of walking
* Dual-task (DT) details\*\*
* Turning strategy (180 turns or cones)
* Walking speed (comfortable, as fast as possible)
* # FOG episodes
* Tremor during testing (Yes/no)
* Dyskinesia during testing (Yes/no)
* Video available (Yes/No)
* Mobile imaging (Yes/No)

*If unsupervised monitoring:* * *Times of levodopa intake during the day*
* *# days and hours per day with sensors*
* *Location of sensors*
* *Presence of motor fluctuations during the day (Yes/No)*
 | ***Proposed measures, all studies:*** * Steps or Stride analysis and # of them included
* Gait Speed (m/s)
* Step time Asymmetry or Swing Time Asymmetry
* Step or Stride length (m)
* Step or Stride time (s)
* Step or Stride time duration variability (SD or CoV) *\*Only if Recommendation #1 is followed*
* Cadence (steps or strides/min)
* Turning: Turn velocity (degrees/s) or # of steps to turn 180 *\*Only if Recommendation #2 is followed*
* Arm swing range of motion (degrees) *\*If available*
* Trunk range of motion while walking (degrees) *\*If available*
* Angle of the foot at heel-strike (degrees) *\*If available*

***Technology -*** *studies should use at least one of the following and record specific information regarding hardware and software used during all measured observations:* * Inertial Measurement Units (record details of sensor location)
* Pressure sensors
* Pressure walkway
* Video analysis
* Motion analysis
 |
| Additional recommended consideration |
| *Note – certain minimum recommended requirements may require licensing the named instruments for study use.*  | *#1: a straight-line path of 10 m (+1 m at each end to accommodate safe turning) for at least 1-minute of walking at a comfortable speed (minimally) with 180-degree turn is recommended**\*\* #2: if adding a concurrent dual-task condition, we recommend one of the following options:* *- Arithmetic: N-back**- Memory: Digit Span Forward**- Language: Letter Fluency**For previous literature of dual-task conditions, see Raffegeau T. et al., PRD 2019, Kelly V. et al., PRD 2012.* | *References and details:**Gait measure recommendations are partly consistent with the* [*NINDS Best Practice for Digital Health Outcomes in PD*](https://www.commondataelements.ninds.nih.gov/sites/nindscde/files/Doc/PD/F3012_Best_Practices_for_Digital_Health_Outcomes.pdf) |