

PROTOCOL

Title: Assessing Motor and Non-Motor Features of Parkinson's Disease Using the Roche PD Mobile Application (PPMI Digital Study)

Sponsor: The Michael J. Fox Foundation for Parkinson's Research

Principal Investigator: Kenneth Marek, MD

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PROTOCOL APPROVAL

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**Assessing Motor and Non-Motor Features of Parkinson's Disease Using the Roche PD
Mobile Application
(PPMI Digital Study)**

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1. PURPOSE OF STUDY

The Parkinson's Progression Markers Initiative (PPMI) study is a longitudinal, observational, multi-center natural history study to assess progression of clinical features, digital outcomes, imaging, biologic and genetic markers of Parkinson's disease (PD) progression in study participants with manifest PD, prodromal PD, and healthy controls. The overall goal of PPMI is to identify markers of disease progression for use in clinical trials of therapies aimed at reducing progression of PD disability.

PPMI is a broad program that will include this PPMI Digital Study protocol (using the Roche PD Mobile Application), as well as the PPMI Clinical, PPMI Online, and PPMI Remote protocols. All participants in PPMI may be asked to participate in one or all of these protocols and their enrollment in these studies may occur in varying order. PPMI participants may also be asked to participate in additional PPMI companion studies (as they are developed), which may only involve a subset of PPMI participants based on their cohort designation. This protocol will be focused on the activities of the PPMI Digital study. The Digital study will be a collaboration between the PPMI study and F. Hoffmann-La Roche Ltd (referred to as Roche from here on).

1.1 Primary Objectives

The primary objective of this study is to assess features of Parkinson's disease using a smartphone digital application, with goals including:

- 1) Better understanding of disease progression.
- 2) Detecting subtle, prodromal motor and cognitive symptoms.
- 3) Understanding how PD affects motor functioning in daily life.
- 4) Correlating measures collected using a smartphone application with assessments and participant reported outcomes collected in other PPMI
- 5) Assessing the sensitivity of sensor-based measures collected using smartphones in response to PD medications.
- 6) Derive a risk score for detecting prodromal PD using metrics from the smartphone application along with other clinical and biomarker readouts in PPMI Remote.

2. STUDY OUTCOMES

The primary outcome measures are measures of motor, cognitive and non-motor assessments collected using a smartphone application, including:

- Structured active tasks assessing cognition, speech and voice, tremor, bradykinesia, dexterity, balance, and gait.
- Passive monitoring may assess gait and mobility through frequent movement including location sensor data collection.
- Patient reported outcomes (PROs) administered on the smartphone.

3. BACKGROUND AND RATIONALE

This observational study will collect features of Parkinson's disease using a smartphone digital application to characterize and monitor motor behavior and signs and cognition in PPMI participants. The digital application will enable remote, non-invasive, frequent, and precise measurement of motor and non-motor symptoms (Maetzler et al 2013, Ossig et al 2016). The combined advantages of frequent and objective measurements with a digital application may generate more sensitive

measures of early prodromal symptom onset and symptom progression and fluctuation over time than established, yet typically infrequently administered, clinical rating scales. This smartphone application data will be acquired without the need for participant travel to clinical centers for testing and enable quantification of motor symptoms during daily activities and in the home environment of participants. The application has been used in other clinical trials (e.g., Lipsmeier et al., 2018), and the derived measurements have previously been utilized in several PD studies (Lipsmeier et al., 2018, 2019).

The digital biomarker approach developed by Roche and planned for this PPMI companion study is based on the approach used in NCT02157714 (<https://clinicaltrials.gov/ct2/show/NCT02157714>), NCT03100149 (<https://clinicaltrials.gov/ct2/show/NCT03100149>) and an independent observational study with healthy control participants (Lipsmeier et al., 2018, 2019). In these studies, patients with PD used smartphones and completed daily “active tests”. They were also asked to carry the phone with them throughout the day while the smartphone sensors sampled movement patterns “passive monitoring”. Patients demonstrated very high acceptance (100% of participants agreed to partake in optional smartphone sub study in NCT02157714) and strong adherence (i.e., 61% over 6 months) in the initial deployment (Lipsmeier et al., 2018) and 84.6% over 12 months in a second clinical trial deployment (NCT03100149; Lipsmeier et al., 2019). Sensor-based measures significantly correlated with clinical measures of motor symptom severity (i.e., MDS-UPDRS item and established composite scores), and sensor-based measures detected significant levels of motor symptoms in patients who were rated as having no symptoms at the site visit (Lipsmeier et al. 2018). These results add to a growing body of literature demonstrating that smartphone-based approaches are sensitive to subtle or fluctuating motor signs and can be used to characterize PD symptom severity (e.g., Kostikis et al 2014, Patel et al 2011, Kassavetis et al 2016, Zhan et al 2018, Arora et al 2018).

4. STUDY DESIGN

This is a longitudinal, observational, study involving collection of data through a smartphone application from people with and without Parkinson’s disease. Participants will download the application to their personal smartphone for completion of active tests, surveys, and passive monitoring. The smartphone application will be compatible with most of the widely used smartphone operating systems in Android and iOS. The PPMI program will collaborate with Roche on this project and all digital application data will be securely transferred from participants’ smartphones to secure Roche servers for data processing. All raw sensor data (except audio data from speech tasks for privacy reasons), selected aggregated performance metrics from the smartphone (‘features’), patient reported outcomes answers, adherence, and usability data will be made available to the PPMI study and its partners for further analysis.

5. STUDY POPULATION

This study will include people with and without Parkinson’s disease who are also participating in PPMI. The Digital Study protocol is expected to support more than 500,000 participants globally.

6. RECRUITMENT METHODS

To achieve the recruitment goal, a multi-pronged approach will be employed, including (but not limited to) email invitations to participants in PPMI related studies (PPMI Online, PPMI Remote, PPMI Clinical), myPPMI opportunity tiles, independently managed PD studies, digital and social marketing recruitment efforts to the PD community and general population, and through events or activities conducted by The Michael J. Fox Foundation or other representatives of PPMI.

7. PARTICIPANT ELIGIBILITY

Participants must meet the following criteria to be eligible to participate:

- Age 18 years or older
- Must enroll in myPPMI or be currently participating in myPPMI
- Have a compatible smartphone and are able and willing to download and use the Roche PD Mobile Application. Most smartphones are compatible.

8. OBTAINING INFORMED CONSENT

Potential participants will be asked prior to the consent process whether they have a compatible smartphone that can be used for this study. Potential participants will already have a PPMI ID, as well as a username and password as they will already have been registered with PPMI. Once a potential participant is participating in PPMI the individual will be invited to participate in the PPMI Digital Study prior to viewing the informed consent where they will be required to read the consent. If the individual agrees to participate, consent will be acknowledged electronically. Participants will have the opportunity to save a digital copy of the informed consent, GDPR Addendum (as applicable), and privacy notice (as applicable) for their records.

9. PARTICIPANT ID ASSIGNMENT

All PPMI Digital Study participants will have a PPMI ID created once enrolled. Only this participant number will be utilized to identify the participant on all study-related documentation.

10. STUDY PROCEDURES

The Roche PD Mobile Application will be a free downloadable application compatible with a range of Android and iOS smartphones. Once downloaded, the application actively and passively monitors motor and non-motor symptoms of the participants using smartphone sensors. The application presents participants with “active tests” of motor and cognitive functioning at regular intervals and which involve activities such as, but not limited to, finger tapping, drawing shapes, reaction time tasks, information processing, executive functioning, tremor and bradykinesia measurement, balance, and gait. There are also patient reported surveys that will be completed at recurring intervals through the application regarding motor behavior in daily life.

Passive monitoring of movement and gait may occur in the smartphone background while participants carry their smartphones with them throughout the day. Completion of survey questionnaires in the app will also occur on a recurring basis, as well as active tests. The schedule and frequency of these tests and surveys completed in the smartphone application will depend on an individual’s PD or non-PD diagnosis. Data collected with the Roche PD Mobile Application on participants’ smartphones are encrypted and will be securely uploaded via Wi-Fi or mobile networks (if the

participant agrees to use mobile data) to secure cloud storages and then to secure Roche backend servers for further analysis.

Participants will see their adherence to active testing and surveys on the smartphone dashboard. Study participant adherence will be monitored in a tiered manner. Details of adherence monitoring and informing participants about any observed issues with data collection and adherence to the Roche PD Mobile Application procedures are outlined in a separate PPMI Digital adherence manual.

11. RISKS TO PARTICIPANTS

The most common risk associated with the use of the phone application is that study participants may feel anxious about completing the daily tasks. For privacy reasons, audio data from the voice and speech tasks will not be provided to the PPMI Study Team. Data may be securely transferred between PPMI cores for the required workflows under the PPMI program. Any study data that are made available to researchers external to PPMI will be de-identified and will not contain personal identifiers. There may be other privacy risks that the study team may have not foreseen.

12. POTENTIAL BENEFITS TO PARTICIPANTS

There are no direct anticipated benefits to study participants in this study. However, new information may be generated by the study to support development of better treatments for Parkinson's disease.

13. COSTS FOR PARTICIPATION

There will be no cost to the study participant for participating in this study. Collected data will solely be transferred using Wi-Fi and with the option of using mobile data.

14. PARTICIPANT WITHDRAWALS

Study participants will be informed during the consent process that they have the right to withdraw from the study at any time without prejudice. A participant may withdraw from this study at any time by deleting the app. Withdrawal from this study will not affect the study participant's continued participation in other PPMI protocols. Any information that has already been collected prior to the study participant's withdrawal will not be removed.

15. ADVERSE EVENTS

There will be no adverse event reporting as part of this minimal risk phone application data collection study. All data collected as part of this study are for research purposes only and not for clinical care purposes. There will not be any routine clinical monitoring of the data collected nor any reports looking at trends and/or worsening of a participant's condition requiring medical intervention.

16. PRIVACY AND CONFIDENTIALITY

The privacy of participants will be protected in that each person will have the option to voluntarily choose whether to participate in this study and where assessments are completed. The information being collected will be outlined during the consent process.

17. DATA SHARING AND STORAGE FOR FUTURE USE

PPMI Roche PD Mobile Application collects the following sensor data frequently in the smartphone background during Active Tests and Passive Monitoring:

- Continuous movement data (e.g., accelerometer)
- Continuous location data, not available at the beginning of the study (dereferenced GPS, with an obfuscation schema so that the actual location on a map cannot be identified)
 - Participants may choose to turn background location data off and on at any time.
- Application usage
- Technical information about the smartphone for security and troubleshooting (e.g., battery life, application crash logs)
- Participant ID

In addition, for selected Active Tests the smartphone collects:

- Touch data (during Active Tests only)
- Audio data (during selected Active Tests only, and only when clearly indicated). Audio data will only be used to extract outcome measures for the corresponding task; no audio data will be provided to the PPMI study team.

No video or personal information (e.g., written names, phone #) is recorded.

Data collected on the smartphone are asymmetrically encrypted on the smartphone. The decryption key is not stored on the device. This ensures that after collection, encrypted data can only be decrypted by designated researchers. Encrypted data collected with the smartphone application will be uploaded automatically using a secure HTTPS connection to secure third party cloud servers (Microsoft Azure) and then to a secure Roche data backend. Once transferred, collected data are deleted from the smartphone. The IP address of each smartphone device is stored temporarily in the access layer of the secure third party server. The access layer is provided by Cloudflare while the secure third party server is a cloud server operated by Microsoft Azure. Access attempts are normally kept for 4 hours, but up to a maximum of 3 days for security purposes, e.g. for preventing denial of service attacks. They are then deleted.

The IP addresses are not further transferred from the access layer to the third party server or the Sponsor.

Participant location, retrieved from the device, will be used to ensure proper location and security of participant data.

Data collected for this study will be maintained and stored for 25 years in Roche servers and indefinitely at the study cores and may be transferred and shared across participating PPMI cores for conducting analyses as pertains to the study including, but not limited to, enrollment, compliance, study outcomes and, in combination from the data received from relevant PPMI program studies in which a participant is contributing data, to enable modifications to the predictive prodromal eligibility criteria. All PPMI data will be incorporated into the PPMI database to create a fully harmonized PPMI database. Study information will be accessed only by those who require access as pertains to the individual's role in the study. All organizations

responsible for data storage and review will observe the highest precautions to ensure data integrity and security.

Data obtained during the conduct of this study will be sent to the Laboratory of Neuro Imaging (LONI) in Los Angeles, California, to be stored indefinitely for research purposes. Research data will be made available to researchers to conduct analyses related to PD and other disorders. Researchers will be required to comply with the PPMI data agreement to receive data. All personally identifiable information will be removed before it is shared outside the study.

18. ANALYSIS PLAN

This section gives a brief description of main statistical analysis planned, which can be revised as data starts coming in and its patterns become clearer.

The PPMI Digital Study sensor data will be segmented into active test and passive monitoring segments and submitted to quality control (QC) processes. Quality control processes are used to flag active tests where participants were not compliant with the test execution protocol. Dedicated feature extraction algorithms will be used to extract meaningful information from active tests (e.g., hand turning speed for hand turning task) and passive monitoring (e.g., turn speed when turning while walking in daily life). Algorithm failures due to technical problems will also be indicated by additional quality flags.

Adherence will be quantified as the percentage of completed active test sets during the Focus period vs six scheduled active test sets for each participant available during 30 days every 90 days according to the schedule of assessments.

Raw sensor data and sensor-derived features will be used for analyses in line with the study objectives. This will include but is not restricted to analyses of test-retest reliability, cross-sectional and longitudinal correlations between relevant digital and clinical data, known-group comparisons, sensitivity to change, predictivity of future change in disease status.

19. REFERENCES

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20. Appendix 1 – PPMI (PD) Schedule of Assessments

TEST NAME ON PHONE	Shown to non PD participants?	Test Duration (mm:ss)	TIMING OF ASSESSMENTS FOCUS PERIOD																														TIMING OF ASSESSMENTS CALM PERIOD (OPTIONAL ACTIVITIES in 5 days rotation)																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																						
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21. Appendix 2 – PPMI (Non-PD) Schedule of Assessments

