# Protocol: Personal KinetiGraph® Clinical Validation Study

Clinical Study Protocol

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Study Sponsor: Global Kinetics Pty Ltd

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**Protocol Revision History**

| Revision | Description of Change | Date |
|---|---|---|
| 1.0 | Initial Release | September 1, 2021 |
| 1.1 | Clarifications made during initial review | September 28, 2021 |
| 2.0 | • Updated Sponsor name from Global Kinetics Corporation (GKC) to Global Kinetics Pty Ltd (GK)<br>• Included most recent 510(k) clearance<br>• Added graphics of the Gen 3.0 PKG Watch<br>• Added Docking Station and PKG Portal descriptions<br>• Changed the age criteria to ≥18<br>• Added product usability and satisfaction assessment questionnaire<br>• Added the evaluation of product usability as a Secondary Endpoint | June 23, 2022 |

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# 1 PROTOCOL SIGNATURE PAGE

Title: **Personal KinetiGraph® Clinical Validation Study**

I have reviewed this protocol and agree to adhere to the requirements and responsibilities listed herein. I am trained to the contents of this protocol and the specific use of the devices listed in this protocol. I will ensure that the study is conducted in compliance with the protocol, Good Clinical Practices ISO14155, Declaration of Helsinki, and all applicable regulatory requirements.

_____ _____

Site Principal Investigator Signature Date (DD/MMM/YYY)

_____

Site Principal Investigator Printed Name

## 1. PURPOSE

The purpose of this study is to clinically validate new measures of the Personal KinetiGraph® (PKG®).

## 2. BACKGROUND

### Overview

Patient management is increasingly assisted by and dependent on data obtained from objective measurements of various biomarkers. Monitoring motor activity by continuous collection of accurate, ecologically valid, and functionally relevant objective movement data is critical in a group of neurological diseases, known as movement disorders, in which impaired motor control is central to the disability that movement disorder patients experience. The phenomenology of abnormal movements can vary from too little (akinesia, bradykinesia, hypokinesia) to too much (hyperkinesias), may be fast (myoclonus, tic) or slow (athetosis), regular (tremor) or irregular (chorea) across and within the various movement disorders.[1] In almost all cases, the severity and pattern of abnormal movements will vary, making spot assessments, such as an in-person clinical exam, an often inaccurately representative sample of the patient's typical state or of the movement abnormality's severity and character. The potential for in-person clinic exams to be poorly representative of the patient's actual motor impairment further increases by the unnatural testing and exam items/tasks, often minimally related to motor activities functionally relevant to the patient, in an unnatural environment. Furthermore, the amount of data obtained in a spot exam in the setting of a clinical visit will inherently be very limited. As a result, patient management may be based on inaccurate, ecologically invalid, and functionally irrelevant exam data.

Adding novel sources of data, including objective, ecologically valid, continuous as opposed to spot samples, can optimize patient management. The power and potential of continuous monitoring of movement disorders lies in allowing us to collect accurate, objective data during all waking hours and determine changes in motor behavior relative to anything clinically relevant, such as medication timing, activities of daily living, changes in therapy, and many other factors that can be recorded and correlated with the objectively measured and quantified, analyzed motor functions and behaviors. This approach is nothing short of revolutionary when compared to traditional in-person care in our quest to advise and inform the best possible decision-making in the clinical care of movement disorders.

Parkinson’s Disease (PD) is the most common hypokinetic movement disorder and is a chronic, progressive movement disorder that affects as many as one million people in the United States.[2-5] The main motor (or movement) related symptoms of PD are bradykinesia (slowness of movement), rigidity, tremors and postural instability. Other symptoms include speech and

swallowing difficulties, cognitive impairment, depression or other emotional changes. As the disease progresses, symptoms may interfere with daily activities. Approximately 40% of patients develop fluctuations and dyskinesia after 4-6 years of treatment and 70% after long-term treatment (>9 years). Patients with fluctuations tend to have greater disease severity and disability, and those that fail to derive adequate benefit from medications report poorer quality of life.[6-7]

**Personal KinetiGraph® (PKG®) System History**

Early PKG validation studies were used to obtain initial regulatory clearance/approvals in the US, Europe/UK and Australia.[6-12] The primary research data to support these approvals included the original PKG BKS and DKS algorithm development and comparisons to the Unified Parkinson's Disease Rating Scale (UPDRS) and Abnormal Involuntary Movement Scale (AIMS) against a control group as published in Griffiths et al. 2012.[6] Additional literature references to support substantial equivalence for FDA 510(k) clearance were also provided to FDA.

*Regulatory Clearance*

The PKG Movement Recording System received FDA 510(k) clearance on August 22, 2014 (K140086). The Personal Kinetigraph (PKG) System is intended to quantify kinematics of movement disorder symptoms in conditions such as Parkinson's disease, including tremor, bradykinesia and dyskinesia. It includes a medication reminder, an event marker and is intended to monitor activity associated with movement during sleep. 510(k) clearance for the 2nd Generation of the PKG system was issued by FDA on September 20, 2016 (K161717) for Model: GKC-2000 (Gen 2). The system components were updated to include:

- The PKG Watch (movement data logger)
- The PKG Tablet
- The PKG Clinic Server (Portal)
- The PKG report, and the PKG Accessories.

On March 11, 2022, 510(k) clearance was issued by the FDA, which allows the use of the PKG System continuously in the home environment with clearance of the docking station and dock cable (K211887). Future generations of the PKG Movement Recording System will be cleared by the FDA through the regulatory approval process prior to being utilized in this clinical study. All commercially available versions of the PKG System and associated product instructions for use may be used in this study. The study is a post-market study and the system will be used within its FDA-cleared indication for use.

The current U.S. labelling limits the age of patients who are indicated to use the PKG Watch. Based on feedback obtained from clinicians using this device in routine clinical care and in particular in IRB-approved clinical studies, the age restriction in the cleared indications for use

limit the enrollment of subjects into clinical studies. Additionally, it has been determined that for the clinical studies, that the indication statement including the age not only applies at the point of enrollment, but also at each point in which the PKG Watch is worn in the study over the 3-year follow-up period. Currently, enrolled subjects who are qualified at the start of the study may exceed the age limit as they progress through the required follow-up period. The age restriction was required by FDA in the labeled indications for use, since the ages collected in the age-matched control data provided in *Griffiths et al*. 2012 only included this range in the sample data set. Additionally, the proprietary measures captured on the PKG may vary slightly with age. This makes it important to how these measures have changed over time since the original data published in 2012, change with PD disease progression (e.g., as age increases, PD symptoms may worsen including increase in bradykinesia, decrease in dyskinesia, increase in fluctuations) and to allow for adjustments as needed.

## 3. PRODUCT DESCRIPTION

**Personal KinetiGraph (PKG®) Movement Recording System**

The Personal KinetiGraph (PKG®) Movement Recording System was developed by neurologists at the Melbourne-based Florey Institute of Neuroscience and Mental Health. The product is manufactured and marketed by Global Kinetics (GK).

**The PKG Watch**

The PKG Watch (Figure 1) is a wrist worn medical device that looks like a wristwatch. It contains a rechargeable battery, a triaxial accelerometer, memory, an optional vibration and indicator light-based reminder to the subject when PD medications are due and a means for recording when Parkinson's disease (PD) medications were taken, as well as a capacitive sensor to detect removal from the wrist.

Subjects wear the device for varying periods of time enabling remote monitoring. During this wear time the PKG Watch automatically collects data on the type of movement experienced by the patient 24 hours per day, can remind the patient to register when they have taken their PD medication as prescribed by their physician, and the patient can indicate when he/she has taken each prescribed dose of PD medication.


**Figure 1:** PKG Watch Gen 2.0 PKG Watch Gen 3.0

**Docking Station**

The docking station includes charging and communication functions. At the end of the recording period, the PKG Watch is placed on a cellular-enabled docking station to charge the watch battery and upload the data to the cloud. Data is then processed via proprietary algorithms and output into a PKG Clinician Report and PKG Patient Report.

**PKG Portal**

The PKG Portal is a secure web application that can be used to create new patient records, place new PKG Watch orders, initiate communication with the docking station and access PKG reports. The PKG Portal may also be used by patients to track symptoms, mood and activities of daily living such as exercise, work and social activities during each day the PKG Watch is worn.

**PKG Report**

At the end of the recording period, data are downloaded and analyzed using proprietary algorithms to translate raw movement data collected by the PKG Watch into clinically meaningful results. This output is called a "PKG." The maximum acceleration in each 2-minute epoch is identified and the mean spectral power surrounding this peak is calculated. Algorithms produce Bradykinesia Scores (BKS) and Dyskinesia Scores (DKS) every two minutes. The PKG includes, but is not limited to:

- a scaled record of a dyskinesia score (DKS) representative of dyskinesia plotted against time of day for individual days over the full recording period (Figure 2).
- a scaled record of a bradykinesia score (BKS) representative of bradykinesia plotted against time of day for individual days over the full recording period (Figure 2).
- a record of periods of immobility, which may be indicative of periods of daytime sleep and somnolence, plotted against time of day.
- a record of periods when the patient was not wearing the PKG Watch or when it was 'off-wrist'.
- a record of the patient's self-reported compliance with their prescribed program of Parkinson's disease medication.
- a record of periods of tremor for each day and a tremor summary.

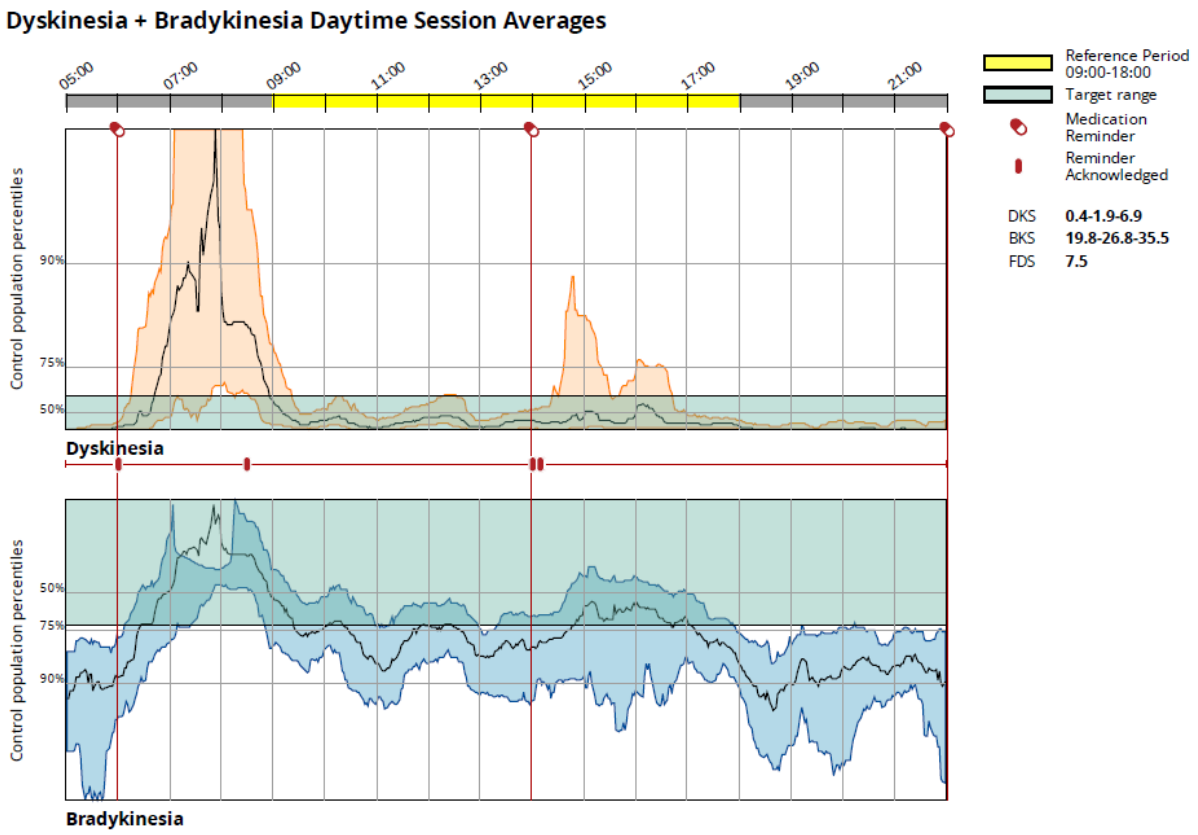


Figure 2: PKG

## 4. STUDY DESIGN

This is a prospective, multi-center, observational research study of the PKG System in patients who are eligible based on the inclusion/exclusion criteria. The clinical validation will require recruitment of both subjects with a diagnosis of a movement disorder such as Parkinson's disease and healthy control subjects who do not have any other neurological disorders that would interfere with data collection. Up to 500 total subjects at up to 2 sites will be enrolled including these two subject profiles. Subjects will be evaluated based on eligibility criteria and data will be collected on study-specific case report forms.

Subjects will be evaluated at a screening visit to confirm they are able to complete the required tasks.

**Table of Assessments:**

| Activities | Screening Clinic or Telehealth Visit | Subject PKG Watch Wear | Follow-up Visit** |
|---|---|---|---|

| | | | |
|---|---|---|---|
| **Informed Consent (MD)** | X | | |
| **Subject Screening Criteria & Enrollment (MD)** | X | | |
| **Demographics & Medical History (Coordinator)** | X | | |
| ***Order PKG Watch for extended PKG Watch Wear (Coordinator)** | X | | |
| **In-clinic validation tests (video, MDS-UPDRS, ePROs, etc.)** | X | | |
| **In-clinic PKG Watch Wear (bi-lateral or unilateral)** | X | | |
| ***PKG Watch Extended Wear (bi-lateral or unilateral)<br><br>(GK fulfillment)** | | X | |
| ***At-home Assessments (surveys, ePROs, diary, etc. by subject or caregiver)** | | X | |
| ***Activity Log** | | X | |
| **Product usability and satisfaction questionnaires** | | X | |
| ***Review of patient assessments** | | | X |

**May be repeated if unable to provide at least 5 full, continuous days of PKG data for each watch*

*** May be performed at clinic, via telehealth visit or phone call per institutional standards*

## 5. SCREENING VISIT

Informed Consent Process

Subjects will be identified and pre-screened from routine clinical care if the Study PI feels the patient would be eligible for this study.

Informed Consent Procedure: A potential participant is identified and the Study PI has a conversation about the study. If the subject is eligible for enrollment and is interested in participating the consent process will take place in the office where the patient will have ample time to decide if they want to proceed. If the subject needs more time to consider, they will be sent home with study information and an informed consent form. Instructions will be provided to mail the signed and dated consent form back to the Study PI in a pre-stamped envelope or per clinic institutional IRB approved procedure.

Subject Screening Criteria

A study investigator will assess each subject's candidacy for the study based on the following subject screening criteria:

Inclusion Criteria - Study subjects must fulfill the following criteria:

- Able and willing to sign a written informed consent for study participation
- Age ≥18 years old Existing diagnosis of a movement disorder or a healthy control subject without diagnosis of a movement disorder

Exclusion Criteria – Subjects with any of the following clinical criteria will be excluded:

- Bedridden, wheelchair confined, or requires the regular use of an assistive gait device (e.g., walker, cane, etc.)
- Occupation that involves repetitive movement or complete immobility (e.g., janitor, construction, or sedentary with no/limited arm movements such as a taxi driver)
- In the investigator's or sponsor's opinion, subject has any unstable or clinically significant condition that would impair the participant's ability to complete the required PKG watch wear (e.g., subject unable to complete PKG wear instructions per Patient Instruction Manual), complete required assessments or interfere with data collection.

Enrollment Criteria

Subjects will be considered screen failures if they do not meet study selection criteria. Subjects who meet all study selection criteria and have documented written informed consent on file will be considered enrolled and continue in the study.

In-Clinic Validation Testing

The Study PI will determine the required validation testing for each subject based upon the validation measure being tested. Subjects may receive video assessment of them walking or performing certain tasks while wearing the PKG Watch or PKG Watches (1 watch on each wrist). Subjects may also receive movement disorder related assessments such as Movement Disorders Unified Parkinson's Disease Rating Scale (MDS-UPDRS), Hoehn and Yahr scale (H&Y), Parkinson's Disease Questionnaire (PDQ-39), Non-Motor Questionnaire (NMSQuest), Freezing of Gait Questionnaire (FOG-Q), The Essential Tremor Rating Assessment Scale (TETRAS), Epworth Sleepiness Scale (ESS), Parkinson's Disease Sleep Scale (PDSS), the Montreal Cognitive Assessment (MoCA) and/ or other electronic patient/clinician/observer/performance reported outcomes (ePRO/ClinRO/ObsRO/PerfO) during this visit including EQ-5D, patient diaries. Each procedure and assessment will be explained to the subject upon enrollment into the study.

PKG Watch for In-Clinic Wear

The study coordinator will have a supply of PKG Watches and docking station available to use for an in-office assessment requiring recording on the PKG Watch and other in-office assessments to be completed simultaneously. The study coordinator will program the PKG Watch for the subject and assist with the fitting. The subject will wear the PKG Watch or PKG Watches (1 watch on each wrist) only for the required in-office testing and leave the PKG Watch(es) with the study coordinator at the end of the visit. The study coordinator will upload the data from the PKG Watch(es). The PKG Watch(es) will be reprogrammed for each subject requiring an in-clinic wear.

PKG Watch Administration for Extended Wear

After the Screening Visit, the study coordinator will order the required PKG System per subject enrolled as required. Upon receiving approval from site (this can only occur after a fully executed consent has been verified by the study coordinator), Global Kinetics (GK) Fulfillment Staff may contact the subject to explain PKG System use, and dispense the PKG System to the subject with a copy of the Patient Instruction Manual. The subject may contact the study site and/or GK Fulfillment Staff with any questions regarding the PKG System.

Concurrent with the PKG Watch wear for extended use, the subject may complete an activity journal of all movements throughout the day and a diary. The activity journal and diary will include recording of activities such as routine exercise like walking or jogging, outside of day-to-day living activities, sleep, medication times, falls, mood, symptoms. In addition, the subject may complete PKG questionnaires regarding their experience and usability of the product. The subject will complete the activity journal, diary and/or questionnaires via ePRO or sign and return the forms to the investigator using the provided stamped, addressed envelope via US mail.

For each cohort (PKG Score) that will be enrolled, Sponsor will indicate to clinical trial site and provide training on the procedures relevant to assessments associated with that cohort. Therefore, refer to the study Manual of Operations for detailed instructions for each assessment required, for each cohort that is being assessed, which will include procedures required for each cohort. Details on video recording and tasks to be completed (e.g., carrying a jug of water) will be detailed in the Manual of Operations.

## 6. FOLLOW-UP VISIT

Once the subject has completed a prescribed wear period indicated by the clinic staff, the subject will return the PKG Watch(es) to GK Fulfillment Staff using the provided stamped, addressed envelope via US mail. The study staff will contact the subject via phone to inform them whether or not they have successfully completed the study. The study staff may also ask

the subject if they had any issues using the PKG System. If, for any reason, the subject is unable to wear the PKG Watch(es) for the prescribed period and per instructions provided, the subject may be asked to complete another wear period by the clinic staff. The subject or caregiver will also be asked to complete another activity journal, surveys and/or ePROs as indicated during the additional wear period.

## 7. STUDY ENDPOINTS

**Primary Endpoint:**
Evaluation of new PKG assessments to be clinically validated including but not limited to gait/walking, Device Assisted Therapy readiness, Percent Time Bradykinesia (PTB), Percent Time Dyskinesia (PTD), fall prediction, disease progression and non-motor symptoms.

The primary endpoint evaluation for the validation of the new PKG measures will include standard calculations including correlation, point in time measurement compared to diaries and activity logs, change in PKG scores from beginning of recording to end of recording period, comparison of results between movement disorder patient recordings and those from healthy volunteer recordings to detect movement associated with movement disorder subjects compared to healthy volunteer subjects.

**Secondary Endpoints:**
Secondary clinical outcomes of interest will include but will not be limited to:

- Evaluation of PKG scores including BKS, DKS, PTT, FDS and PTI on healthy control subjects (non-PD; healthy control) to assess differences by age category.
    - PKG measurements will be recorded and compared across age ranges for subjects enrolled. Age categories of 18-40, from 40-59 years old, 60-79 years old, 80-90 years old and > 90 years old will be evaluated. This will provide a representative sample of subjects with early onset (<60 years), average age (60-79 years) and older subjects (80-90 years) with movement disorders.
- Comparison of PKG scores to standard PD assessments such as MDS-UPDRS, H&Y, PDQ39, FOG-Q, TETRAS, diaries
- Comparison of PKG scores to standard non-motor assessment such as NMSQuest
- Comparison of PKG scores to sleep assessments such as ESS and PDSS
- Comparison of PKG scores to MoCA
- Comparison of PKG scores to standard quality of life measurements such as EQ-5D
- Evaluation of product usability and satisfaction for PKG Watch, docking station and the PKG Portal

## 8. STATISTICS

Due to the nature of this research study, no formal hypothesis will be proposed, nor will a formal statistical analysis be conducted. Rather, this study will examine outcomes of each case and be descriptive in nature.

## 9. INVESTIGATOR QUALIFICATIONS

Physicians participating in this study must be able to conduct an assessment of clinical diagnosis to confirm subject either has a diagnosis of a movement disorder or is a healthy control subject. For the healthy control population, investigator will confirm the subject does not have other neurological disease(s) that would interfere with data collection and analysis.

## 10. INSTITUTIONAL REVIEW BOARD

Each site is required to have Institutional Review Board (IRB) approval prior to starting this study and throughout the course of study conduct. Each site will maintain IRB correspondence including written initial and ongoing IRB approvals.

## 11. PROTOCOL DEVIATIONS

A protocol deviation is defined as a circumstance in which the study investigator, site personnel or subject did not conduct the study according to the requirements of the study protocol. Protocol deviations will be documented on the Protocol Deviation CRF and are to be reported per IRB requirements.

## 12. BENEFIT/RISK ANALYSIS

Results from this study are expected to contribute to the objective evaluation of movement in subjects with PD against a standardized control dataset.

The PKG Movement Recording System and this study present no more than minimal risk to study subjects resulting in a minimal risk determination based on the PKG Movement Recording System, its use in this study, and the following criteria:

- Are not intended as an implant and present a potential for serious risk to the health, safety, or welfare of a subject;
- Are not purported or represented to be for use supporting or sustaining human life and presents a potential for serious risk to the health, safety, or welfare of a subject;
- Are not for a use of substantial importance in diagnosing, curing, mitigating, or treating disease, or otherwise preventing impairment of human health and presents a potential for serious risk to the health, safety, or welfare of a subject.

Adverse events and risks associated with this study are similar to those normally associated with standard clinical care of subjects with PD who wear the PKG watch; thus, additional

adverse events are not anticipated. Current product safety information, including contraindications, warnings, and precautions, are located in the Patient Instructions Manual and Clinical Interpretation Guide.

Although not anticipated, Unanticipated Adverse Device Effect (UADE) will be reported in accordance with 21 CFR 812.150 starting at the point of enrollment for all subjects enrolled into the study. A UADE is defined as any serious adverse effect on health or safety or any life-threatening problem or death caused by, or associated with, a device, if that effect, problem, or death was not previously identified in nature, severity, or degree of incidence in the investigational plan or application, or any other unanticipated serious problem associated with a device that relates to the rights, safety, or welfare of subjects.

Additionally, any complaints regarding any component of the PKG Movement Recording System will be reported to GK and processed per GK's standard post-market surveillance processes and any adverse events associated with the use of the PKG Movement Recording System will be summarized in the final report for this study.

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