**FULL/LONG TITLE OF THE STUDY**

**AccessPD: A ‘next generation registry’ in Parkinson’s Disease**

**SHORT STUDY TITLE / ACRONYM**

AccessPD

**PROTOCOL VERSION NUMBER AND DATE**

Version: 4.0
Date: 15 May 2025

| | |
|---|---|
| **SPONSORS:** | Cohort Science Ltd |
| **FUNDERS:** | Cohort Science Ltd |

**SIGNATURE PAGE**

The undersigned confirm that the following protocol has been agreed and accepted and that the Chief Investigator agrees to conduct the study in accordance with the principles outlined in the Declaration of Helsinki, Good Clinical Practice (GCP) guidelines as set out by the International Council for Harmonisation (ICH E6 R2), 21 Code of Federal Regulations (CFR) Parts 11, 46, 50, and 56, the Sponsor's Standard Operating Procedures (SOPs), and other regulatory requirements. Any changes to the approved procedures will only be made if necessary to eliminate immediate hazards and/or to protect the safety, rights, or welfare of participants.

I agree to ensure that the confidential information contained in this document will not be used for any other purpose other than the evaluation or conduct of the investigation without the prior written consent of the Sponsor.

I also confirm that I will make the findings of the study publicly available through publication or other dissemination tools without any unnecessary delay and that an honest, accurate and transparent account of the study will be given; and that any discrepancies from the study as planned in this protocol will be explained.

I agree to keep records on all subject information collected during the study in accordance with the current GCP, local and national regulations.

**For and on behalf of the Study Sponsor:**

Signature: Date:
..... ...../...../.....

Name (please print):
.....

Position:
.....

**Chief Investigator:**

Signature: Date:
..... ...../...../.....

Name: (please print):
.....

## DOCUMENT HISTORY

| Document | Date of Issue | Summary of Change |
|---|---|---|
| AccessPD protocol | February 16, 2023 | Initial version 1.0 |
| AccessPD protocol | April 20, 2023 | Version 1.1:<br>Section 8.1.1- changed inclusion criteria to ≥ 18<br>Appendix 2- revised to clarify details regarding nested projects |
| AccessPD protocol | May 8, 2023 | Version 1.2:<br>Added Dr Anil Jina as uMed representative<br>Clarified 'nested' projects throughout |
| AccessPD protocol | June 27, 2023 | Version 2.0<br>Addition of references related to inclusion of Canadian site |
| AccessPD protocol | May 15, 2025 | Version 4.0<br>● Clarified and expanded the subject population to explicitly include individuals with Multiple System Atrophy (MSA), Progressive Supranuclear Palsy (PSP), and Corticobasal Syndrome (CBS).<br>● Added greater detail on the governance, roles, and responsibilities of study personnel, including clarification of Chief Investigators and the AccessPD Management Committee.<br>● Expanded description of sub-study types (Type I, II, III), including guidance on consent and IRB requirements.<br>● Enhanced details on electronic consent (eConsent) and data privacy protections, including compliance with HIPAA and 21 CFR Part 11.<br>● Included a more comprehensive description of data collection (EHR, PROs, COAs, biosamples, etc.) and added Schedule of Activities in Appendix 4.<br>● Updated dissemination policy to include quarterly participant newsletters and publication authorship guidance. |

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## KEY REGISTRY CONTACTS

| | |
|---|---|
| **Chief Investigator** | Dr Alastair Noyce<br>Email: a.noyce@qmul.ac.uk<br>Phone: +44 7595 676891 |
| **Principal Investigator** | Dr. Anil Jina<br>Email: anil.jina@cohort.science<br>Phone: +1 617 301 1396 |
| **Sponsor** | Cohort Science Ltd<br>8 Warner Yard, London, EC1R 5EY<br>info@cohort.science<br>+44 (0) 2033 030329 |
| **Funder(s)** | Cohort Science Ltd<br>8 Warner Yard, London, EC1R 5EY<br>Email: info@cohort.science<br>Phone: +44 (0) 2033 030329 |
| **Key Protocol Contributors** | Dr. Alastair Noyce<br>Email: a.noyce@qmul.ac.uk<br>Phone: +44 7595 676891<br><br>Dr. Anil Jina<br>Email: anil.jina@cohort.science<br>Phone: +1 617 301 1396 |
| **Committees** | AccessPD management committee<br>accesspdcommittee@cohort.science<br><br>Members include:<br>Dr. Alastair Noyce (Queen Mary University of London)<br>Dr. Matthew Wilson (uMed)<br>Dr. Anil Jina (Cohort Science)<br>Dr. Vijaykumar Elango (Primary Care representative) |

## REGISTRY SUMMARY

| | |
|---|---|
| **Registry Title** | AccessPD: a 'next generation registry' in Parkinson's Disease |
| **Internal ref. no. (or short title)** | AccessPD |
| **Study Design** | Research database<br>Integrated clinical research platform<br>Research registry<br>Observational study |
| **Study Participants** | Patients with a coded diagnosis of Parkinson's Disease or parkinsonism (e.g.progressive supranuclear palsy, multiple system atrophy, etc) +/- additional prescription data in their health records. |
| **Planned Size of Sample** | No upper limit |
| **Follow-up duration** | 20 years |
| **Planned Study Period** | 20 years |
| **Research Question/Aim(s)** | 1. To build a registry of participants with a diagnosis of Parkinson's Disease or Parkinsonism.<br>2. To create a core clinical dataset including questionnaire data, and other linked clinical data.<br>3. To improve equitable access to research opportunities for participants. |

## FUNDING AND SUPPORT IN KIND

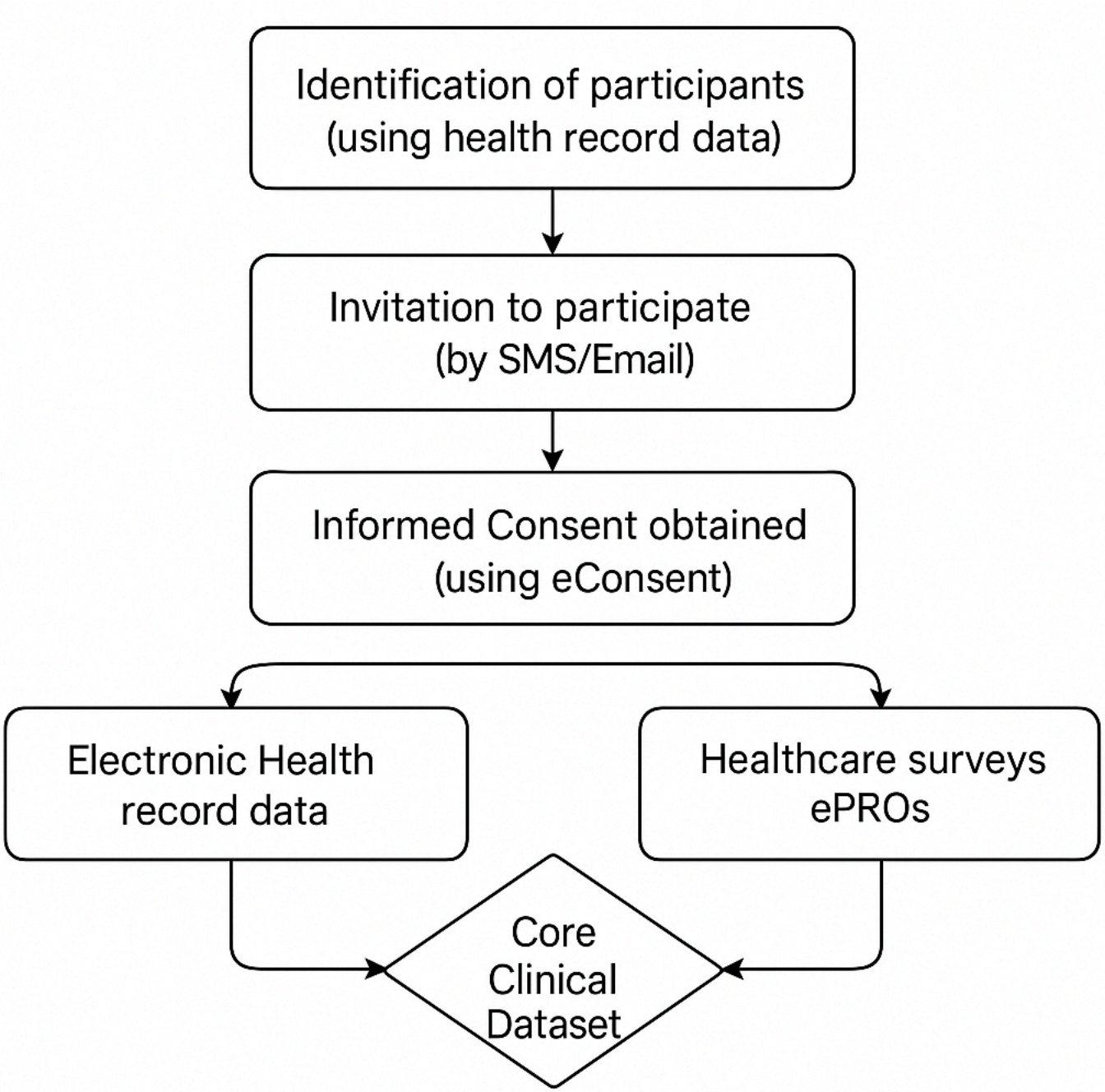
| **Funders** | **Financial and non-financial support** |
|---|---|
| Cohort Science Ltd<br>8 Warner Yard, London, EC1R 5EY<br>Email: info@cohort.science<br>Phone: +44 (0) 2033 030329 | Sole funder of the registry |

**Table 1. List of abbreviations and definitions of terms**

| Abbreviation | Definition |
|---|---|
| CCD | Core Clinical Data |
| CFR | Code of Federal Regulations |
| CLIA | Clinical Laboratory Improvement Amendments |
| PD | Parkinson's Disease |
| MSA | Multiple System Atrophy |
| COA(s) | Clinical Outcome Assessment(s) |
| CS | Cohort Science |
| EHR | Electronic Health Record |
| FAQ | Frequently Asked Questions |
| GCP | Good Clinical Practice |
| HCI | Healthcare Institution |
| HCP | Healthcare Professional |
| HIPAA | Health Insurance Portability and Accountability Act |
| ICF | Informed Consent Form |
| ICH | International Council on Harmonization |
| IRB | Institutional Review Board |
| MoCA | Montreal Cognitive Assessment |
| NHS | National Health Service |
| PCP | Primary Care Physician |
| PI | Principal Investigator |
| PPI | Patient Public Involvement |
| PROs | Patient Reported Outcomes |
| SMS | Short Messaging Service (i.e. text message) |
| SOP | Standard Operating Procedure |

**KEYWORDS**
Parkinson's Disease, Multiple System Atrophy, registry, research database, tissue bank, observational studies, clinical trials, medical devices

**REGISTRY FLOWCHART**



**REGISTRY PROTOCOL**

**AccessPD: A 'next generation registry' in Parkinson's Disease**

## 1 BACKGROUND

Parkinson's Disease (PD) is the second most common neurodegenerative disease worldwide after Alzheimer's Disease. Evidence from the Global Burden of Disease Study suggests that it may be the fastest-growing neurological disorder worldwide[1]. Risk factors for PD include genetic determinants, environmental risk factors (e.g. pesticide exposure and head trauma), and comorbidities (e.g. type 2 diabetes)[2–4]. However, there is much more work to be done to understand the determinants of PD risk and progression. The clinical course of PD has been well studied in some patient groups, but not all[5]. As with most common diseases, most of the investigation into PD has been undertaken in affluent, White populations residing in Europe and North America. Underrepresented ethnic groups and people living in areas of high deprivation have been systematically under-recruited[6].

Other forms of parkinsonism, including atypical variants such as progressive supranuclear palsy (PSP), multiple system atrophy (MSA), and corticobasal syndrome (CBS), share overlapping features with PD, particularly in the early stages, leading to frequent misdiagnosis. These conditions are typically more aggressive, have distinct pathophysiologies, and are even more poorly understood than PD[7–9]. Inclusion of individuals with atypical parkinsonism in research is essential to improve diagnostic accuracy, characterise disease-specific progression patterns, and develop targeted interventions.

Previous registries for Parkinson's Disease, as well as other disease areas, have been limited in their utility as a result of several factors including:

- Representation within the registry population: As described above, many registries are not representative of the true population affected by the disease.
- Sustainability: The manual tasks undertaken by sites associated with recruiting to and maintaining a registry are often prohibitive to creating a large and comprehensive registry dataset that has the power to undertake meaningful subgroup analyses.
- Re-engagement: The challenges of re-identification and re-engagement of participants at scale further limits the ability to collect additional data and consent into external studies.

Here we outline a protocol for a 'next generation registry' for patients at risk of or with a diagnosis of Parkinson's Disease or other forms of parkinsonism (including MSA, PSP, and CBS) recorded in primary care, henceforth referred to as AccessPD. This registry is optimised for delivery using a research technology platform that has already deployed across a large number of GP practices in England, allowing the issues identified with traditional registry models to be mitigated. The registry will be able to provide a platform for research and for monitoring health outcomes via linkage to health records and to data captured from patients at home. This will act as a much needed catalyst for implementation research.

## 2 RATIONALE

The main aim of this project is to develop an interactive, virtual, decentralised registry for participants with PD and associated diseases. The registry will be used to build a cohort of participants and collect a core clinical dataset. Participants can then be offered the potential to be involved in further research opportunities (e.g. observational studies, medical device studies or clinical trials of investigational medicinal products).

## 3 FRAMEWORK

Cohort Science is the study sponsor for AccessPD and has a Registry Participation Agreement in place with each participating healthcare institution (HCI). The Registry Participation Agreement does not require electronic medical record data held by an HCI to be shared directly with Cohort Science. In accordance with an individual's right under HIPAA to access their own health information, Cohort Science will simply facilitate submitting, on the patient's behalf, a signed patient access request to each HCI to release health information to support research.

AccessPD utilizes the services and technology of uMed Technologies Inc. (uMed) to minimize cost and effort for HCI's to recruit study participants and maximize patient access to research. uMed will facilitate patient outreach under the direction and on behalf of a designated researcher at the HCI to request research consent and authorization from eligible research participants. uMed does not identify or communicate independently with patients for research unless specifically requested to do so by a HCI. Once a patient has consented, uMed will be responsible for ongoing patient engagement and collection of eCOAs and ePROs.

Both uMed Technologies (a Delaware Corporation) and Cohort Science (a UK Limited Company) are subsidiaries of the UK parent company Umedeor Ltd.

The intent of AccessPD is to create a 'next generation registry' that collects a core clinical set of data from consented patients (AccessPD Core Clinical Data [CCD]), consisting of clinical data from their electronic health records (EHR) and relevant Patient Reported Outcomes (PROs) and other information obtained via questionnaires. It will also bring research opportunities to patients, who can participate. Decisions regarding the ongoing conduct of the study, inclusion of new research opportunities ('sub-studies'), data and participant access requests, manuscript writing and dissemination of results will be taken by the AccessPD management committee. A summary of the workflow and process for AccessPD can be found in **Appendix 1.**

Academic and commercial research teams may also submit proposals for 'sub-studies' to the AccessPD management committee. A sub-study is defined as a project that is undertaken with a researcher external to Cohort Science. Decisions regarding the conduct of these sub-studies will be made by the AccessPD management committee. Further details of the governance model for different types of sub-studies can be found in **Appendix 2**.

## 4 ROLES AND RESPONSIBILITIES

### 4.1 Study Sponsor

- Chief Investigator (UK): Professor Alastair Noyce, BMedSci, MB BS MSc MRCP PhD FHEA; Professor in Neurology and Neuroepidemiology, Queen Mary University London (QMUL)
- Chief Investigator (US): Anil Jina, MD (Secretary, Cohort Science)
- Vijaykumar Elango, MB BS MRCGP, Executive Partner, Modality Partnership, UK (Primary Care representative, UK)
- Matthew Wilson, MB BS (CEO, uMed)

### 4.2 Registry Management Committee:

- Dr. Alastair Noyce, BMedSci, MB BS MSc MRCP PhD FHEA (Chief Investigator UK)
- Dr. Anil Jina, MD (Chief Investigator, US)
- Dr. Matthew Wilson, MD (CEO, uMed)
- Dr. Vijaykumar Elango (Primary Care representative)

### 4.3 Patient and Public Involvement (PPI) Group

AccessPD will undertake regular PPI group consultations to capture broader feedback on the activity taking place within the registry.

## 5 PROTOCOL CONTRIBUTORS

- Chief Investigator (US) : Anil S Jina, MD
- Chief Investigator (UK): Professor Alastair Noyce, BMedSci, MB BS MSc MRCP PhD FHEA; Professor in Neurology and Neuroepidemiology, Queen Mary University London (QMUL)

Cohort Science Ltd has input on the registry design and conduct; data analysis and interpretation; manuscript writing and dissemination of results.

After initial setup, the AccessPD Management Committee will control the final decisions about the conduct of the registry, the inclusion of 'sub-studies', data analysis and interpretation, manuscript writing and dissemination of results.

## 6 RESEARCH AIMS

1) To establish a virtual, decentralised, integrated clinical research registry for PD.
2) To collect a core clinical set of data from consented patients (AccessPD Core Clinical Dataset [CCD]), consisting of clinical data from their EHR and relevant PRO's and other information obtained via questionnaires.
3) To collaborate with third parties to offer research opportunities to participants who are registered with AccessPD in the form of 'sub-studies'.

## 7 REGISTRY DESIGN

Potential participants will be identified by designated HCP(s) at a contracted HCI from EHR according to the study inclusion and exclusion criteria outlined below (section 9). The initial contact will be via short message service (SMS)/text and/or email sent by uMed on behalf of the patient's HCI, which will invite potential participants to join AccessPD. Potential participants will receive a link in the SMS to view information about AccessPD on their smartphone or computer browser. This information will include the aims of the registry and steps required to participate, which includes consent to enroll in the registry and providing HIPAA authorization. Potential participants may also receive a letter sent by uMed or an electronic communication sent by their HCI as a precursor to receiving SMS communications about AccessPD. Registration, information provision, consent to participate and research activities will all be managed online in a decentralized fashion.

### 7.1 Core Clinical Dataset (CCD)

AccessPD will invite participants to complete PRO's, COA's and other questionnaires. Data from their EHR records will also be linked to the registry and together this will form the core AccessPD CCD. The aim is for core data to be collected at baseline and at 6 monthly intervals.

### 7.2 Sub-Studies

Depending on the sub-studies and research projects that are linked to AccessPD, participants may be invited to complete additional PRO's, COA's or questionnaires. These may be self-reported or involve remote or in-person clinical assessment. Participants may also be invited to collect biosamples (e.g.

blood tests, DNA tests) or have data collected via wearables or medical devices. A list of potential data collection items is provided in Appendix 3.

# 9 SAMPLE AND RECRUITMENT

## 9.1 Inclusion criteria

- All patients with a coded diagnosis of PD and/or parkinsonism (e.g.progressive supranuclear palsy, multiple system atrophy, etc) +/- additional prescription data
- Aged ≥18 years old.
- Identified through a healthcare provider participating in AccessPD in the US.
- Able to provide consent to participate.

## 9.2 Exclusion criteria

- Patients with dementia or receiving palliative/terminal care.
- Patients who have recorded a preference in their medical record that they do not wish to be considered for research or contacted regarding research opportunities.
- Patients who have recorded a preference not to share data for research.

## 9.3 Size of sample

The sample size will be as high as possible and is not based on statistical power calculations. Recruitment is currently planned in the UK and US, with an overall goal to enroll up to 10,000 individuals with PD between these two countries.

## 9.6 Consent

Participants will provide informed consent through an electronic consent (eConsent) process that has been designed to be compliant with all applicable regulatory requirements, including 21 CFR Part 11 and the Health Insurance Portability and Accountability Act (HIPAA). Potential participants will be identified by their healthcare provider and contacted via secure electronic means (e.g., SMS, email, or patient portal) to review information about the AccessPD registry. The eConsent process will present study information in an accessible, participant-friendly format, including details on the purpose of the registry, data collection procedures, privacy protections, participant rights, and withdrawal options. Participants will electronically confirm their understanding and consent by entering their name, date of birth, and date on the secure eConsent platform. This process ensures a fully traceable and auditable consent record. Participants will also provide separate HIPAA authorization to allow access to and use of their health information for research purposes. Participants may contact the study team at any time for clarification or support and may withdraw their consent without penalty at any stage of the study.

## 10 ETHICAL AND REGULATORY CONSIDERATIONS

This study will be conducted in compliance with all applicable U.S. federal, state, and local regulations governing the ethical conduct of research involving Real-World Data (RWD), including adherence to the Declaration of Helsinki, the International Council for Harmonisation (ICH) Good Clinical Practice (GCP) Guidelines (ICH E6 R2), and relevant FDA regulations outlined in 21 CFR Parts 11, 50, 54, and 56. Participant privacy and confidentiality will be strictly protected in accordance with the Health Insurance Portability and Accountability Act (HIPAA), and applicable state privacy laws. Real-World Data utilized will be de-identified or pseudonymized, with rigorous safeguards in place for secure data storage, management, and transmission. Institutional Review Board (IRB) approval will be obtained prior to data collection, and any significant amendments affecting participants' rights, safety, or data integrity will undergo IRB review and approval prior to implementation.

### 10.1 Assessment and management of risk

The risks associated with this Real-World Data (RWD) study primarily relate to data privacy, confidentiality breaches, and data integrity issues. A comprehensive risk assessment has been conducted, and appropriate measures have been implemented to mitigate these risks. Participant data will be pseudonymized or fully de-identified, as applicable, and managed in compliance with relevant regulations, including HIPAA and applicable data protection legislation. Robust data security protocols, including encryption, secure data transfer, role-based access control, and routine audits, will be employed to minimize the risk of unauthorized access, misuse, or loss of data. All study personnel handling data will receive appropriate training in data management practices and confidentiality obligations. An ongoing review and monitoring process will be maintained to promptly detect and address emerging risks throughout the study lifecycle.

### 10.2 Potential Benefits

Although participants may not benefit directly from being in this registry, participation may empower them to learn more about their condition, support or add to existing diagnoses where more may be learnt about their condition, and they may feel more supported because of their involvement in the research. Participants may be offered other research opportunities through sub-studies which they may also benefit from.

### 10.3 Protocol compliance

This protocol provides a written guide for the conduct of the project. Deviations from the protocol (if they occur) will be recorded by date, alongside a description of the deviation and will be available for audit. Given the observational and data-driven nature of this research, deviations typically involve inaccuracies, incompleteness, delays, or unauthorized alterations in data extraction or data transfer processes.

### 10.4 Data privacy and participant confidentiality

This study will be conducted in full compliance with applicable data protection regulations, including HIPAA, as well as relevant ethical guidelines. Participant privacy and confidentiality are fundamental to the design and governance of this study.

All identifiable data will be processed only with the participant’s explicit informed consent and in accordance with applicable laws. Personally identifiable information (PII) will be pseudonymised prior to analysis and sharing, and access to such data will be limited strictly to authorised personnel

involved in the conduct of the study. No identifiable data will be shared with external researchers or third parties without lawful basis and additional appropriate safeguards.

Data privacy is managed through:

- Robust agreements between the sponsor, healthcare institutions, and approved third-party vendors (e.g. such as uMed),
- Encryption of data at rest and in transit,
- Access controls and audit trails to monitor data use and prevent unauthorised access,
- Role-based access to systems housing confidential data,
- Regular compliance reviews and adherence to industry-standard information governance frameworks (e.g., ISO 27001).

Where the sponsor or its partners access participant data, such access will occur under appropriate legal frameworks and will serve specific, ethically approved research objectives. Data access for sub-studies or collaborative research will be governed by the AccessPD Management Committee, with transparency and participant engagement at the core.

Participants will be fully informed of how their data will be used, including any intended future uses, data sharing arrangements, and their rights to withdraw. Upon withdrawal, no further data will be collected, and existing data will remain in the study database.

This registry is committed to high standards of transparency, ethical oversight, and participant empowerment while enabling responsible access to data to support innovation in Parkinson's Disease research.

### 10.5 Data Retention

In accordance with HIPAA requirements, registry data will be retained for a minimum period of 7 (seven) years after the registry has been completed.

### 10.6 Access to the registry dataset

AccessPD aims to create a sustainable registry model that incentivizes academic and commercial researchers to engage with the registry and develop new ideas, diagnostics and therapies that can improve the lives of patients with PD.

Researchers will be provided access to the CCD once their credentials have been validated and a description of the intended project that will use the registry data has been provided to the registry management committee.

## 11 DISSEMINATION POLICY

### 11.1 Dissemination policy

- Cohort Science Ltd will manage and be responsible for the pseudonymised CCD.
- Any external researcher wishing to publish based on data from AccessPD will need approval from the registry management committee.
- Each patient enrolled in the study will receive quarterly newsletters updating them on the progress of AccessPD, including the number of patients enrolled and high-level results from the study. It will also include information from scientific conferences and meetings where data from the study is being presented, medical publications of study data, research institutions who are partnering with AccessPD and general updates on PD.

### 11.2 Authorship eligibility guidelines and any intended use of professional writers

Cohort Science and uMed will be acknowledged as the sponsor and facilitating technology platform respectively in any publication using registry data.

## 12 REFERENCES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## 13. APPENDICES

Appendix 1- Summary of Workflow and Process
Appendix 2 - Governance of Sub-studies run within AccessPD
Appendix 3 - Data Collection
Appendix 4 - Schedule of Activities

# Appendix 1: Summary of Workflow and Process

**Step 1**:
uMed (uMed Technologies Inc) puts in place an appropriate agreement with a participating Healthcare Institution (HCI) to allow uMed to undertake tasks including patient outreach, engagement and support services for the HCIs.

**Step 2**
The study sponsor (Cohort Science) enters into a study agreement with the participating HCI.

**Step 3**
uMed, with the approval and on behalf of the HCI, will contact potential participants and ask them to enroll in AccessPD. This includes a link to study information and an electronic consent workflow. uMed acts on behalf of the provider to automate this outreach via text, email, and letter. Once consented, Cohort Science will send participants study questionnaires and other outcome assessments as outlined in the protocol. Data collected from participants is consolidated with health record data.

**Step 4**
External researchers can engage with AccessPD through ‘sub-studies’ which enables access for those external researchers to pseudonymised data and additional data collected from subgroups within the AccessPD population to support analyses of specific research questions.  All sub-studies that provide access to data will need to be approved by the AccessPD Management Committee.

# Appendix 2: Governance of Sub-studies run within AccessPD

Sub-studies will be categorised into 3 types:

**Type I** sub-studies will enable research teams external to AccessPD to access the existing pseudonymised study dataset only. Access will be granted subject to review of the request by the AccessPD Management Committee. As these sub-studies only utilise existing data and consent is already obtained for this purpose, the participant does not need to opt-in.

**Type II** sub-studies will enable research teams external to AccessPD to access the existing anonymised study dataset and collect additional information which is already described and contained in the protocol, but not included in the core study dataset. Participants presented with the opportunity to provide additional data will be required to opt-in to such activities.

**Type III** sub-studies allow sub-groups of patients within AccessPD to be recruited for studies designed to collect information not contained in the existing protocol (e.g. additional PRO's, clinical assessments, imaging, diagnostics, biosample collection, wearable technologies or medical devices [for measurement purposes only and within its current marketing authorisation]). These sub-studies would require an amendment to the AccessPD protocol. Participants who wish to be part of these sub-studies will be required to consent to the sub-study.

**Note**. Any interventional drug or medical device studies recruiting participants identified through AccessPD will be conducted as standalone trials with their own protocols and independent ethics committee approval.

**SUMMARY TABLE**

| Sub-study Type | Description | New IRB/REC Approval Required? | New Participant Consent Required? |
|---|---|---|---|
| **Type I** | Use of existing pseudonymised dataset as defined in the current protocol | No | No |
| **Type II** | Additional data collection using methods already described in the current protocol | Not usually, but may require notification | Yes (opt-in for additional data) |
| **Type III** | Additional data collection beyond what is described in the current protocol | Yes (Protocol Amendment + IRB approval) | Yes (new consent form for the sub-study) |

# Appendix 3: Data collection

**Electronic Health Records (EHR)**

All participants recruited will have the following information extracted from their EHR or answer questions to provide more details:

- Demographics (Age, sex, ethnic group, race, education (level/years))
- Comorbidities
- Vital signs (weight, height, blood pressure, heart rate)
- Current and previous medications
- Date of symptom onset and first symptom
- Date of diagnosis and setting (primary or secondary care)
- Name of specialist and/or treatment center
- Surgery for PD, type of surgery, date
- Other personal medical history
- Family medical history
- Social history (including diet, physical activity, smoking, alternative medicine, exposure to pesticides and insecticides, zip code, Townsend Score of social deprivation)
- Mortality
- Hospitalization rate
- Progression of disease

**Clinical Outcome Assessments (COAs) and Patient Reported Outcomes (PROs):**

The following assessments may be used:

| **Scales** | | |
|---|---|---|
| **Name** | **Domain** | **Duration** |
| MDS Unified Parkinson's Disease Rating Scale<br>1. Non motor aspects of daily living<br>2. Motor aspects of daily living<br>3. Motor examination<br>4. Motor complications | Multi-domain | 30 mins |
| Unified Multiple System Atrophy Rating Scale (UMSARS) | Multi-domain | 30 mins |
| Hoehn & Yahr scale | Motor severity | 5 mins |
| The Schwab and England ADL (Activities of Daily Living) | Mobility | 10 mins |
| The Barthel Index (BI) | Activities of Daily Living | 5 mins |
| Clinical Impression of Severity Index for PD (CISI-PD) | Severity | 5 mins |
| Non-Motor Symptom Scale | Non-motor symptoms | 15 mins |

| | | |
|---|---|---|
| Non-Motor Symptoms Questionnaire | Non-motor symptoms | 7 mins |
| SCOPA-AUT | Autonomic function | 15 mins |
| Hospital Anxiety Depression Scale or similar | Mood | 5 mins |
| Montreal Cognitive Assessment | Cognition | 10 mins |
| RBD screening questionnaire, Epworth Sleepiness Scale | Sleep questionnaires | 5-10 mins each |
| Wearing off assessment | Motor symptoms | <10 mins |
| PDQ-39 (including PDQ-8) | Quality of life | 10 mins |
| EQ-5D-5L and EQ-5D-5L Visual Analogue Scale | Quality of life | 10 mins |
| MERQ-PD-B or PD-RDU-Q | Environmental Risk factors | 10 mins |
| Kings Pain Scale | Pain | 10 mins |
| **Objective tests** | | |
| UPSIT smell test (40-item) | Olfaction | 20 mins |
| 6-item (PREDICT-PD) smell test | Olfaction | <5 mins |
| BRAIN test | Motor keyboard tapping task | <5 mins |
| Selected cognitive tests | Cognition | Varies |
| **Patient and caregiver questionnaires/interviews regarding:** | | |
| Patients' experience with their disease (signs, symptoms and limitations) | | |
| Patients' treatment experience of their disease | | |
| Disease status | | |
| Disease risk factors | | |
| Psychometric interviews<br>● Concept elicitation interview (CE), participants will be asked about their usual experiences with their disease and its physical and daily life impacts.<br>● Cognitive debriefing (CD), interview, participants will be asked to review select digital measures of activity and answering follow up questions on the clarity, relevance, and alignment between the measures themselves and the day to day functional impairments they experience. Participants will also be asked how much change in each measure would be meaningful. | | |

**Biosamples:**

The following biosamples may be collected:

- DNA sampling (saliva, cheek swab, blood)
- Blood sampling (regular lab tests - hematology, biochemistry, etc.)
- Blood sampling (specialized lab tests)

# Appendix 4: Schedule of Activities

| Procedures | Screening | Baseline | Every 6 Months | Unscheduled |
|---|---|---|---|---|
| Informed consent | x | | | |
| Demographics (captured from patient and via EMR) | | x | x | x |
| Medical history (captured from patient and via EMR) | | x | x | x |
| Core PROs / Questionnaires | | x | x | x |
| Supplementary PROs / Questionnaires | | | | x |
| Contact for participation in 3rd party studies | | | | x |