COHORT SCIENCE

FULL/LONG TITLE OF THE STUDY

AccessALL: An Integrated, Longitudinal, Decentralised, Population Research Platform with Embedded Disease-Specific Cohorts and Biological Sample Collection

SHORT STUDY TITLE / ACRONYM

AccessALL Research Platform

PROTOCOL VERSION NUMBER AND DATE

Version: 3.0

Date: 15 June 2026

SPONSORS:	Cohort Science Ltd
FUNDERS:	Cohort Science Ltd

SIGNATURE PAGE

Sponsor Declaration

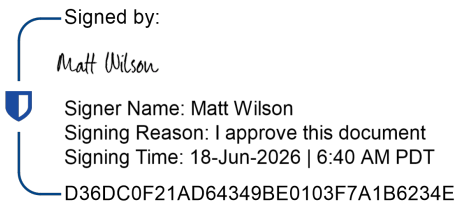
On behalf of the Sponsor, the undersigned confirms that:

- The study protocol has been reviewed and approved.
- The Sponsor accepts responsibility for the initiation, management, and financing (where applicable) of the study.
- The study will be conducted in accordance with:
    - The Declaration of Helsinki
    - Good Clinical Practice (ICH E6 as adopted in the UK)
    - The UK Policy Framework for Health and Social Care Research
    - The Human Tissue Act 2004 (where applicable)
    - The Data Protection Act 2018 and UK GDPR
    - Applicable regulatory requirements

The Sponsor confirms that appropriate systems are in place to ensure regulatory compliance, data protection, and governance of biological samples and associated data (where applicable).

For and on behalf of the Sponsor:

Name: Dr Matt Wilson (CEO)

Signature: 

Chief Investigator Declaration

I confirm that I have read and understood this protocol and agree to conduct the study in accordance with:

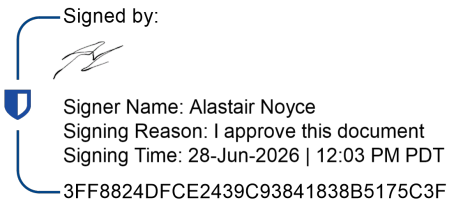
- The approved protocol
- Good Clinical Practice (ICH E6 as adopted in the UK)
- The UK Policy Framework for Health and Social Care Research
- The Human Tissue Act 2004 (where applicable)
- Applicable data protection legislation
- The Sponsor's Standard Operating Procedures

I agree to:

- Protect the safety, rights, dignity, and well-being of participants;
- Ensure informed consent is appropriately obtained;
- Maintain accurate and complete study records;
- Report protocol deviations and safety issues in accordance with Sponsor procedures;
- Ensure that study findings are reported in an honest, accurate, and transparent manner.

Chief Investigator:

Name: Professor Alastair Noyce
Signature:



DOCUMENT HISTORY

Version	Date of Issue	Summary of Change
v1.0	04-March-2026	Initial version 1.0
v2.0	15-May-2026	Company Address Change
V3.0	15-June-2026	CAG approval confirmed. Appendix 3 updated to reflect final Section 251 support (26/CAG/0037) granted by the Secretary of State for Health and Social Care on 15 June 2026.

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KEY CONTACTS

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	• Brook Huxford, PhD Student, Centre for Preventive Neurology **Clinical Leads** • Dr Mark Toshner, Clinical Lead (Cardiometabolic Disease), Victor Phillip Dahdaleh Heart & Lung Research Institute, Cambridge
Committees	AccessALL Management Committee AccessALL PPI Advisory Group AccessALL Participant and Public Involvement Network

SUMMARY

Title	AccessALL: An Integrated Longitudinal Population Research Platform with Embedded Disease-Specific Cohorts and Biological Sample Collection
Internal ref. no. (or short title)	AccessALL - A research platform helping scientists understand health and disease over time.
Study Design	A remote, longitudinal, observational population research platform integrating: ● Electronic Health Records (EHR) ● Electronic patient-reported outcomes (ePROs) ● Clinical outcome measures ● Biological sample collection (where applicable) ● Participant recontact for additional observational research through ethics amendments or separate study-specific ethical approvals The platform supports embedded disease-specific cohorts, healthy population cohorts, and approved sub-studies operating under a unified governance framework.
Study Participants	Adults identified through participating healthcare provider or other participating organisation , including: ● Individuals from the general population without a diagnosed condition, including those participating in healthy population, healthy ageing, or biomarker-driven research cohorts; and/or ● Individuals with specific coded diagnoses (e.g., cardiometabolic disease, Parkinson's disease, or other conditions defined as priority conditions for enhanced data collection Participants may be enrolled irrespective of current disease status and may be dynamically classified into healthy population cohorts, or disease-specific cohorts, during longitudinal follow-up.

	Participation criteria for increased data collection or sub-studies will be defined within the relevant protocol section or amendment.
Planned Size of Sample	No predefined upper recruitment limit is specified.
Follow up duration	Long-term, with participants followed for as long as the research platform remains in place and ethical and governance approvals permit.
Planned Study Period	The study is intended to continue long term for as long as the AccessALL platform remains operational, subject to ongoing ethical, regulatory, and governance approvals. Ethical approval will be maintained through standard HRA annual progress reporting and renewal processes.
Research Question/Aim(s)	**Primary Objectives** ● To create and curate a harmonised longitudinal research dataset integrating: ○ primary care electronic health record data ○ secondary care data (where available and approved) ○ electronic patient-reported outcomes (ePROs) ○ clinical outcome measures ○ biological sample-derived data (where applicable) ○ device and other wearable data ● To enable scalable and equitable identification, recruitment, and retention of participants through decentralised and digitally supported processes. ● To support embedded disease-specific cohorts, healthy population cohorts, and approved sub-studies operating within a unified master protocol. ● To enable dynamic classification and reclassification of participants over time into disease-specific cohorts, or healthy population cohorts based on longitudinal data and predefined governance criteria.

	Secondary Objectives • To support the study of disease trajectories from health and early biological change through to established clinical diagnosis. • To support the study of early and preclinical disease processes through integration of longitudinal health data and biological samples. • To support biomarker research, including genetic and molecular analyses where participants have provided appropriate consent. • To facilitate identification of participants who may be eligible for interventional studies conducted under separate protocols. • To improve diversity and representativeness in research participation through primary care-based recruitment. • To support secure and governed access to pseudonymised datasets and biological samples for approved academic, NHS and commercial researchers, including pharmaceutical or biotechnology companies developing new medicines or healthcare technologies.

FUNDING AND SUPPORT IN-KIND

FUNDER(S)	FINANCIAL AND NON-FINANCIAL SUPPORT GIVEN
Cohort Science Ltd 15 Stukeley Street, London, WC2B 5LT Email: info@cohort.science Phone: +44 (0) 2033 030329	Sole funder and sponsor of the platform

LIST OF ABBREVIATIONS

Table 1. List of abbreviations and definition of terms

Abbreviation	Definition
AccessALL	An Integrated, Longitudinal, Decentralised, Population Research Platform with Embedded Disease-Specific Cohorts and Biological Sample Collection
AE	Adverse Event
CAG	

Abbreviation	Definition
CCD	Confidential Advisory Group
CI	Core Clinical Dataset
CMD	Chief Investigator
COA	Cardiometabolic Disease
CSF	Clinical Outcome Assessment
CS	Cerebrospinal Fluid
DPA	Cohort Science
DPIA	Data Processing Agreement
EHR	Data Protection Impact Assessment
eConsent	Electronic Health Record
ePRO	Electronic Informed Consent
FAQ	Electronic Patient-Reported Outcome
GCP	Frequently Asked Questions
GCLP	Good Clinical Practice
GP	Good Clinical Laboratory Practice
HCI	General Practitioner
HCP	Healthcare Institution (GP Practice(s), Hospital)
HRA	Healthcare Provider (GP)
HTA	Health Research Authority
ICF	Human Tissue Authority
ICH	Informed Consent Form
IDTA	International Council on Harmonisation
NHS	International Data Transfer Agreement
PCP	National Health Service
PIC	Primary Care Physician
PPI	Participant Identification Centre
PRO	Patient and Public Involvement
REC	Patient Reported Outcome
SAA	Research Ethics Committee
SAE	Seed Amplification Assay
SMS	Serious Adverse Event
SNOMED	Short Messaging Service (i.e. text message)
SOP	Systematised Nomenclature of Medicine (clinical codes)
TRE	Standard Operating Procedure
UK GDPR	Trusted Research Environment
	United Kingdom General Data Protection Regulation

KEY WORDS

Longitudinal cohort, master protocol, umbrella protocol, decentralised research, population research platform, observational study, real-world data, sub-study framework, recontactable cohort, long-term follow-up, primary care recruitment, electronic health record-based identification, GP network, healthcare institution, patient identification, decentralised enrolment, equitable recruitment, diversity in research, healthy population cohort, disease-specific cohort, electronic informed consent (eConsent), informed consent framework, participant autonomy, withdrawal rights, Research Ethics Committee, Health Research Authority, ethics approval, UK Policy Framework for Health and Social Care Research, Good Clinical Practice (ICH E6), Declaration of Helsinki, Human Tissue Act 2004, National Data Opt-Out, electronic health records (EHR), primary care data, secondary care data linkage, patient-reported outcomes (PROs), electronic PROs (ePROs), clinical outcome assessments, pseudonymisation, data linkage, Trusted Research Environment (TRE), UK GDPR, Data Protection Act 2018, data processing agreement, role-based access control, data harmonisation, common data model, biological sample collection, biobanking, cerebrospinal fluid (CSF), lumbar puncture, blood sampling, saliva, skin biopsy, Human Tissue Authority, sample processing, long-term storage, international sample transfer, biomarker research, seed amplification assay (SAA), genetic analysis, disease trajectory, early disease detection, subclinical change, longitudinal biomarker profiling, Parkinson's disease, cardiometabolic disease, congenital muscle disease, interstitial lung disease, neurodegenerative disease, multimorbidity, healthy ageing, digital health technology, wearable devices, remote data collection, electronic consent platform, secure research environment, data platform, cohort management system.

Platform Protocol

AccessALL: An Integrated Longitudinal Population Research Platform with Embedded Disease-Specific Cohorts and Biological Sample Collection

1. BACKGROUND

Chronic diseases, including cardiometabolic and neurodegenerative conditions, represent the leading causes of morbidity and mortality worldwide. Despite advances in prevention, diagnosis, and treatment, research recruitment pathways remain fragmented, resource-intensive, and frequently unrepresentative of the broader populations affected by disease. Traditional research models often rely on specialist centres and site-based recruitment, which can limit inclusivity, reduce the generalisability of findings, and create operational inefficiencies.[1]

Increasing evidence demonstrates that many diseases develop across a prolonged trajectory, with biological and subclinical changes occurring years before formal diagnosis. Understanding disease onset and progression therefore requires longitudinal observation across the full spectrum of health into disease, including individuals with established diagnoses, and those without recognised disease at baseline.[2] Integration of routinely collected healthcare data with patient-reported outcomes and, where appropriate, biological samples enables more comprehensive characterisation of these trajectories and may support earlier detection and intervention.[3]

The widespread adoption of secure electronic health record (EHR) systems, digital communication tools, and remote data collection technologies provides new opportunities to identify and engage potential research participants at scale through primary and community care settings. When combined with electronic consent processes, secure data linkage, and appropriate governance oversight, decentralised research models can reduce the burden on healthcare services while improving equitable access to research participation.[4]

Large-scale population research infrastructures that integrate routine healthcare data with longitudinal follow-up have already demonstrated the scientific value of this approach. Resources such as the UK Biobank and national health data platforms have enabled researchers to investigate disease risk factors, genetic influences, and long-term health outcomes across large and diverse populations.[3],[5] These models illustrate the potential for integrated data infrastructures to support discovery across multiple disease domains.

The AccessALL Platform has been developed as a longitudinal population research infrastructure designed to address these challenges. AccessALL operates as a decentralised research framework that:

- Identifies potentially eligible individuals through participating healthcare providers;
- Enables remote engagement and electronic informed consent;
- Integrates electronic health record data with patient-reported outcomes and clinical measures;
- Supports the collection and long-term storage of biological samples where appropriate;
- Facilitates longitudinal follow-up and re-contact for additional ethically approved research activities.

Unlike traditional single-disease registries, AccessALL functions as an umbrella research infrastructure within which disease-specific cohorts (for example cardiometabolic disease, Parkinson's disease, and other conditions), broader health cohorts, and defined patient sub-groups based on clinical history may operate under a unified governance framework. This structure enables increased data collection for certain conditions to be incorporated without establishing entirely separate infrastructures, improving efficiency while maintaining appropriate regulatory oversight and participant protections.

The development of AccessALL builds upon previously established disease-focused research programmes (e.g AccessCMD, AccessPD) that have demonstrated the feasibility of decentralised recruitment, electronic consent, longitudinal EHR linkage, and remote patient-reported outcome collection within UK and international healthcare settings. These programmes have also demonstrated the operational feasibility of embedding sub-studies within a common platform, enabling efficient recruitment, flexible study design, and rapid study initiation. Experience gained from these programmes has informed the governance, technical architecture, and operational processes underpinning AccessALL as a unified population research infrastructure.

The infrastructure is designed to accommodate evolving digital health technologies, biomarker methodologies, and emerging research approaches without requiring fundamental redesign of the underlying governance framework. All activities undertaken within AccessALL will operate under appropriate ethical approval, data protection safeguards, and regulatory compliance, with participants retaining control over their involvement and the use of their data and biological samples. In contrast to traditional large-scale cohorts, AccessALL is designed to support dynamic, study-specific recruitment and repeated re-use of participants within a governed framework, enabling more responsive and efficient delivery of research studies.

This approach aligns with national and international strategies supporting the secure and responsible use of routine healthcare data for research and the development of large-scale population research infrastructures.[6]

2. RATIONALE

Historically, disease-specific registries and research cohorts have been established to address defined clinical questions within individual therapeutic areas. While these approaches have generated valuable insights, they often require separate protocols, governance structures, consent frameworks, data architectures, and regulatory submissions for each disease area. This can result in duplication of infrastructure, inefficiencies in regulatory processes, increased operational burden for participating healthcare providers, and higher patient burden.

At the same time, research is increasingly focused on multimorbidity, longitudinal disease trajectories, and early biological changes across the full spectrum of health into disease. Understanding these processes requires research infrastructures capable of following individuals across the continuum from health, through early biological and clinical change to established clinical conditions.

Furthermore, there is vast opportunity to improve the health and wellbeing with established diagnoses by continuing to build clinical evidence of therapy efficacy in a post approval population that goes beyond Phase 1-3 trials. Current approaches primarily address 'real world evidence'

creation using large datasets such as CPRD which collate routinely collected data from electronic health record systems. However, these datasets cannot efficiently re-identify and re-engage specific patient groups for further prospective data/sample collection

There is therefore growing recognition of the value of integrated population-level research infrastructures that can support multiple disease domains within a consistent governance framework. Such infrastructures enable harmonised data collection, standardised consent processes, scalable recruitment, and proportionate oversight, while maintaining appropriate safeguards for participants.

The AccessALL Platform has been developed to address this need by consolidating existing and future research programmes within a single overarching population research infrastructure. AccessALL supports participation from both healthy population cohorts and individuals with diagnosed health conditions, enabling research across the full spectrum of health and disease.

Rather than establishing separate standalone protocols for each condition, disease-specific cohorts, and biomarker research programmes operate within the parameters of a master protocol and shared governance framework. This approach supports:

- Consistent ethical and regulatory oversight across disease areas;
- Harmonised longitudinal data standards;
- Efficient incorporation of new data collection without unnecessary duplication of infrastructure;
- Reduced administrative burden for participating healthcare providers;
- Improved patient/participant experience;
- Improved scalability and long-term sustainability of research programmes.

Importantly, this consolidated model does not alter the requirement for appropriate review and approval of new research activities. Participants may be identified, invited, and enrolled into AccessALL across a range of disease areas and population groups under the master protocol, provided recruitment activity remains within the approved AccessALL consent, eligibility, data collection, and governance framework.Enhanced data collection based on specific diseases, biological sampling programmes, and sub-studies will operate within the scope of the master protocol and will be subject to Sponsor oversight and Research Ethics Committee review where required. Interventional studies will continue to require separate protocols and regulatory approvals in accordance with applicable legislation. Where a future disease area requires only identification, recruitment, consent, longitudinal EHR linkage, and core AccessALL data collection, this may be managed under the approved master protocol. Where additional disease-specific procedures, questionnaires, biological sampling, return-of-results processes, or material changes to participant burden or risk are introduced, these will be submitted for REC review or amendment as required.

By establishing a unified research infrastructure, AccessALL provides a proportionate and adaptable governance framework capable of supporting observational, biomarker, digital health, and translational research across multiple disease areas and population groups, while maintaining robust participant protections and regulatory compliance.

This infrastructure approach enables AccessALL to support evolving research questions and emerging technologies without requiring repeated establishment of new standalone cohorts. It also

allows disease-specific participant groups to be built within AccessALL in advance of future sub-study proposals, where this activity remains within the approved master protocol and participant consent.

The AccessALL Platform is designed as a long-term national research infrastructure capable of supporting multiple research programmes across the continuum from health and established disease cohorts to future ethically approved research activities. This includes the ability to identify, invite, and enrol participants into disease-specific or population-based cohorts in advance of specific sub-study approvals, where activities remain within the scope of the approved AccessALL protocol and participant consent.

3. FRAMEWORK

3.1. Sponsor and Infrastructure Model

Cohort Science Ltd is the Study Sponsor and becomes the Research Data Controller for AccessALL after participant consent is obtained.

Umedeor Ltd is the appointed Data Processor and Technology Provider for the AccessALL platform. Under formal Data Processing Agreements with each participating Healthcare Institution (HCI / GP practice), Umedeor Ltd provides electronic health record eligibility searches, recruitment communications, eConsent, and integrated data storage services on behalf of the GP practices.

All biological samples collected under the AccessALL platform are stored at the following Human Tissue Authority (HTA)-licensed establishment:

Queen Mary University of London – Centre for Preventive Neurology
Wolfson Institute of Population Health
Charterhouse Square Campus
London EC1M 6BQ

Designated Individual: Professor Alastair Noyce

Cohort Science Ltd does not itself hold an HTA licence. All storage of relevant material under the Human Tissue Act 2004 is conducted under contractual arrangements at the above HTA-licensed establishment.

3.2. Transition from existing cohorts

The AccessALL master protocol is intended to provide a unified framework for existing and future cohort studies, including AccessPD (312555), AccessCMD (334546) and AccessILD (333380). Transition from existing cohorts into AccessALL will take place in phases over time, according to operational readiness and relevant approvals. Until each transition is completed, those studies will continue to operate under their current ethical approvals. Existing participants will be notified and, where required, offered the opportunity to re-confirm or update their consent under the AccessALL framework. Data and samples already collected will continue to be used in accordance with prior consent unless a participant withdraws.

3.3. Identification and Recruitment

Participants will be identified through structured searches of electronic health record data held by participating healthcare providers or other participating organisations. Searches will be conducted by Umedeor Ltd, acting as Data Processor under a formal Data Processing Agreement with each participating organisation, in accordance with inclusion and exclusion criteria defined within this master protocol or in the approved documentation for the relevant embedded disease-specific cohort or sub-study operating under this master protocol. Cohort Science Ltd, as Sponsor, defines the eligibility criteria but does not conduct or have direct access to identifiable EHR data at the point of search.

Potential participants may include individuals from the general population without diagnosed conditions (healthy population cohorts) as well as individuals with specific coded diagnoses defined within disease-specific cohorts.

The resulting list of potentially eligible participants is reviewed and approved by the participating healthcare provider before any contact is initiated. The participating GP practice or other participating organisation retains final responsibility for approving participant contact and remains the data controller for identifiable primary care data. Umedeor Ltd has no independent control over identifiable data and acts solely on the instructions of the relevant data controller.

Initial contact with potential participants will be made on behalf of their participating healthcare provider or other participating organisation using secure communication methods (for example SMS, email, letter, or telephone).

Individuals who express interest and provide informed consent will be enrolled into the AccessALL Platform.

3.4. Data Governance and Data Flow

Umedeor Ltd, acting as Data Processor under a formal Data Processing Agreement with each participating GP practice, has access to identifiable data solely for the purpose of conducting eligibility searches and facilitating recruitment and research operations, on behalf of the GP practice.

Following participant consent, relevant data will be pseudonymised prior to transfer into the secure AccessALL research environment.

The platform operates a segregated data architecture in which:

- Identifiable data are stored separately from research datasets;
- Pseudonymised research data are held within secure, access-controlled environments;
- Role-based access controls and audit logs are maintained;
- Data processing complies with UK GDPR, the Data Protection Act 2018, and applicable governance standards.

Data integrated within the platform may include:

- Primary care electronic health record data;

- Secondary care data (where available and appropriately approved);
- Patient-reported outcomes;
- Clinical measures;
- Device data;
- Biological sample-derived data (where applicable).

National Data Opt-Out is screened and applied by Umedeor Ltd at the point of every eligibility search in accordance with UK GDPR.

3.5. Biological Sample Governance

Where biological samples are collected under the AccessALL Platform, collection, processing, storage, and use will be conducted in accordance with:

- The Human Tissue Act 2004 (where applicable);
- Relevant international regulatory requirements (where non-UK sites are involved);
- Participant consent;
- Sponsor-approved governance frameworks.

Biological samples may be stored in licensed or appropriately approved facilities.

Ownership and permitted use of biological samples and associated derived materials will be defined within the relevant programme-specific agreements and will operate in accordance with participant consent and applicable law.

3.6. Embedded Disease-Specific Cohorts and Sub-Studies

Disease-specific cohorts, for example cardiometabolic disease, Parkinson's disease, and other therapeutic areas, may be established within the AccessALL master protocol.

In addition, population-based research cohorts, including healthy population cohorts and other approved participant groups based on clinical history or study-specific eligibility criteria, may be established within the platform.

Each cohort or sub-study may define:

- specific eligibility criteria;
- additional questionnaires or outcome measures;
- disease-relevant clinical assessments;
- biological sample collection requirements, where applicable.

Sub-studies may be conducted within the framework of the master protocol, subject to Sponsor governance review and Research Ethics Committee approval where required.

Participant classification into cohorts or approved participant groups may occur at enrolment or during longitudinal follow-up, based on updated clinical, demographic, health record, or biomarker information, where available and ethically approved.

Interventional trials will be conducted under separate protocols in accordance with applicable legislation.

This cohort-based structure enables AccessALL to support research across healthy population cohorts, disease-specific cohorts, and other approved participant groups, while maintaining appropriate governance, participant consent, and regulatory oversight.

3.7. Longitudinal Follow-Up and Recontact

Participants may be followed longitudinally through:

- Periodic EHR data refreshes;
- Repeat patient-reported outcome collection;
- Additional clinical assessments;
- Recontact for participation in ethically approved research activities.

Recontact will occur only in accordance with participant consent and applicable governance approvals. Follow up is optional and the participants will not be withdrawn if they don't complete longitudinal data collection.

3.8. Participant Contact Frequency and Communication Limits

AccessALL is designed to generate high-quality longitudinal data while maintaining an acceptable and proportionate burden on participants. To protect participant experience and minimise the risk of survey fatigue and dropout, the following principles and limits apply to all proactive participant contact:

1. Routine platform data collection communications will be issued no more than once per quarter.
2. Condition-specific or medication-specific questionnaires issued under a priority cohort will be only a maximum of twice per quarter. The total questionnaire burden within any single contact episode will not normally exceed 20 minutes.
3. Sub-study invitation communications will be issued separately from routine data collection but will be limited to a maximum of three invitations per sub-study where a participant does not respond. Participants who decline a sub-study invitation will not be re-invited to that sub-study.
4. Across all communication types, participants will not normally receive more than two proactive contacts per calendar month.
5. Non-response to any communication will not result in escalating contact attempts beyond 2 reminders. Reminders will be issued at intervals of 2 to 3 days following the original communication, with all contact concluded within approximately one week.

4. ROLES AND RESPONSIBILITIES

4.1. Study Sponsor

Cohort Science Ltd is the sole sponsor and funder of AccessALL.

4.2. Management Committee

The management committee meets every 8 weeks. The members of the Management Committee are:

- Chief Investigator:
- Cohort Science:
- Umedeor representative:
- Primary Care representative:
- Participant representative:

4.3. Protocol Contributors

- Chief Investigator:
- Cohort Science Ltd:
- Umedeor Ltd:

All personnel involved in participant-facing procedures or data handling will receive study-specific training in accordance with ICH E6(R3) and Sponsor SOPs. Training records will be maintained.

4.4. Patient and Public Involvement

AccessALL is committed to the meaningful and ongoing involvement of patients and members of the public in the design, conduct, and dissemination of research undertaken within the platform. Patient and Public Involvement (PPI) is distinct from research participation: PPI contributors act as partners in shaping the research, rather than as subjects of it.

PPI Group

A PPI Advisory Group will be established to provide input across the lifetime of the AccessALL platform. The group will include individuals with lived experience of one or more of the health conditions represented within AccessALL disease-specific cohorts, as well as members of the general public without a specific diagnosis. Where possible, the group will reflect the demographic and geographic diversity of the AccessALL participant population.

PPI contributors will be recruited through participating healthcare providers, patient organisations, and other appropriate networks. Recruitment, onboarding, and ongoing involvement will be conducted in accordance with NIHR and INVOLVE guidance on good PPI practice. Contributors will be reimbursed for their time and any expenses incurred in line with NIHR payment guidance.

Remit

The PPI Advisory Group will provide input on:

- Participant-facing materials, including the Participant Information Sheet, consent documentation, and questionnaire communications, prior to submission for ethical review and at each subsequent revision;

- The acceptability and appropriateness of questionnaire content and participant burden, including any novel or non-validated instruments proposed for deployment within the platform;
- The design and prioritisation of embedded disease-specific cohorts and sub-studies, where PPI input is sought prior to ethics submission;
- The accessibility and clarity of findings disseminated to participants and the public.

The PPI Advisory Group provides advisory input and does not hold decision-making authority over study operations. Recommendations from the group will be considered by the Management Committee and a record of how PPI input has been incorporated (or reasons where it has not) will be maintained in the study governance documentation.

Meeting Frequency

The PPI Advisory Group will meet quarterly, with meetings scheduled in the first week of February, May, August, and November each year. Additional input may be sought between scheduled meetings where time-sensitive matters arise, for example prior to a protocol amendment submission or the launch of a new disease-specific cohort.

Reporting

A summary of PPI activity and the actions taken in response to PPI input will be included in the annual progress report submitted to the Research Ethics Committee. PPI contributors will receive a plain-language summary of platform activity and findings at least annually.

AccessALL will establish a formal participant and public involvement network to facilitate broader engagement beyond the core PPI Advisory Group. This network will provide opportunities for participants and members of the public to contribute to specific activities including review of materials, questionnaire development, and dissemination work without taking on the ongoing commitment of Advisory Group membership.

A summary of PPIE activity, including the scale of involvement and a record of how PPI input has been incorporated (or the reasons where it has not), will be published annually and included in the annual progress report submitted to the Research Ethics Committee.

AccessALL is committed to upholding best practice in PPIE in accordance with the UK Standards for Public Involvement (NIHR).

5. RESEARCH AIM, OBJECTIVES AND OUTCOMES

5.1. Overall Aim

To establish and maintain a longitudinal, decentralised population research infrastructure that integrates electronic health records, patient-reported outcomes, clinical measures, and (where

applicable) biological samples in order to support observational, translational, and future ethically approved research across multiple disease domains and population groups.

Primary Objectives

- To create and curate a harmonised longitudinal research dataset integrating:
    - Primary care electronic health record (EHR) data
    - Secondary care data (where available and approved)
    - Electronic patient-reported outcomes (ePROs)
    - Clinical outcome measures
    - Device data
    - Biological sample-derived data (where applicable)
- To enable scalable and equitable identification, recruitment, and retention of participants through decentralised and digitally supported processes.
- To provide a governed framework within which disease-specific cohorts, population-based cohorts, (including healthy population cohorts and other approved participant groups across the full spectrum of health into disease), and approved sub-studies may operate under a unified master protocol.
- To enable dynamic classification and reclassification of participants over time into disease-specific cohorts, healthy population cohorts, populations across the full spectrum of health into disease based on longitudinal data and predefined governance criteria.

Secondary Objectives

- To support the study of disease trajectories across the continuum from health, through early biological or clinical change, to established clinical diagnosis.
- To facilitate biomarker research, including genetic and molecular analyses, where participants have provided appropriate consent.
- To support identification of participants who may be eligible for interventional studies conducted under separate protocols.
- To enhance diversity and representativeness in research participation through primary care-based recruitment strategies.
- To support secure and proportionate data access for academic and industry collaborators under approved governance arrangements.

5.2. Outcomes

As AccessALL is an observational research infrastructure rather than a single hypothesis-driven study, outcomes relate to the generation, integration, and utilisation of research data rather than predefined efficacy endpoints.

Primary Outcomes

- Establishment and maintenance of a secure longitudinal pseudonymised research dataset.

- Successful integration of electronic health records, patient-reported outcomes, device, and (where applicable) biological sample-derived data.
- Longitudinal follow-up of participants over time through linked health records and participant-reported information.

Secondary Outcomes

- Characterisation of disease trajectories and factors influencing health and disease progression across the full spectrum of health into disease, for embedded disease-specific and population-based cohorts.
- Identification and evaluation of candidate biomarkers where biological samples are collected.
- Evaluation of digital and remote data collection methodologies.
- Development and evaluation of novel or exploratory participant-reported assessments
- Recruitment and identification of participants eligible for ethically approved sub-studies or interventional trials conducted under separate protocols.

6. STUDY DESIGN AND PROCEDURES

6.1. Study Design

AccessALL is a remote, longitudinal, observational population research infrastructure designed to support research across both healthy population cohorts and individuals with diagnosed health conditions.

Potential participants will be identified through structured searches of electronic health records (EHRs) within participating healthcare providers, according to eligibility criteria defined within this protocol or relevant disease-specific cohorts.

Initial contact will typically occur via secure communication methods (for example SMS/text message, email, or letter) sent on behalf of the participant's recognised healthcare provider. Communications will invite individuals to review study information and consider participation in AccessALL.

Individuals who express interest will be directed to a secure digital interface where they can review the Participant Information Sheet and provide electronic informed consent.

AccessALL is approved by the Health Research Authority for recruitment in England via participating GP practices and other approved healthcare providers. The Sponsor intends to seek separate jurisdictionally-equivalent approvals for recruitment in other countries; the master protocol will be used as a reference document in those applications.

Participants may be enrolled irrespective of current disease status and may be dynamically classified into disease-specific cohorts, healthy population cohorts, or other approved participant groups across the full spectrum of health into disease during longitudinal follow-up.

AccessALL therefore functions as a scalable research infrastructure rather than a single hypothesis-driven study, enabling multiple observational, biomarker, digital health, and translational research programmes to operate under a unified governance framework.

6.2. Core Research Dataset

Participants enrolled in AccessALL will contribute to a Core Research Dataset, which may include:

- Primary care electronic health record (EHR) data
- Secondary care data (where available and appropriately approved)
- Electronic patient-reported outcomes (ePROs)
- Clinical outcome assessments (COAs)
- Digital health data from approved wearable devices and other technologies (where used in embedded disease-specific cohorts
- Other questionnaire-based measures, including Patient-Reported Outcomes, Clinician-Reported Outcomes, Observer-Reported Outcomes. (Note that non-validated instruments, will be subject to Sponsor governance review prior to deployment to ensure scientific appropriateness and that anticipated participant burden remains within the 20 minute limit)
- Biological sample-derived data (where applicable)

Together, these elements form a harmonised longitudinal dataset designed to support observational, biomarker, and translational research across embedded disease-specific and population-based cohorts.

6.3. Embedded Cohorts or participant groups and Sub-Studies

Participants may be invited to take part in additional disease-specific assessments or sub-studies depending on eligibility criteria and participant consent. Participation is optional and the participants will not be withdrawn if they don't consent to join sub-studies.

These activities may include:

- Additional questionnaires, patient-reported outcome measures, or other participant-completed assessments (whether validated or non-validated).
- Remote or in-person clinical assessments
- Biological sample collection (for example blood, cerebrospinal fluid (CSF), saliva, or skin biopsy)
- Digital health data collection (for example wearable devices or other approved technologies)

Wearable devices may be consumer-grade (e.g., fitness trackers or smartwatches) or regulated medical devices (UKCA/CE-marked). The collection and use of data from regulated medical devices will be conducted only as part of a Type II sub-study (or formal protocol amendment) and will comply with the UK Medical Devices Regulations 2002 (as amended), MHRA guidance on digital technologies, and applicable ISO standards for medical device software.

Where wearable devices are used:

- Participants will receive device-specific information and provide additional informed consent.
- Device-derived data will be integrated into the Core Research Dataset only after validation and under secure, encrypted transmission protocols.
- Safety monitoring will follow the AccessALL master protocol adverse event procedures, with device-related incidents (malfunctions, skin reactions, or data inaccuracies) reported in accordance with MHRA requirements where applicable.
- All devices will be used in line with manufacturer instructions and only for purposes consistent with the approved protocol and participant consent.

Where questionnaires are administered, the expected completion time for any individual session will normally not exceed approximately 20 minutes, unless participants provide explicit consent for more detailed assessments.

All sub-studies will operate under Sponsor governance oversight and will be subject to Research Ethics Committee review and approval where required.

7. ELIGIBILITY CRITERIA

7.1. Inclusion Criteria

Participants must:

- Be aged 18 years or older;
- Be registered with a participating General Practice (GP) that has an appropriate Data Processing Agreement in place to support AccessALL;
- Be able to understand the study information and provide informed consent.

Participants may be enrolled irrespective of current disease status, including individuals from the general population without diagnosed conditions as well as individuals with specific health conditions.

Following enrolment, participants may be dynamically classified into disease-specific cohorts, healthy population cohorts, or other approved participant groups across the full spectrum of health into disease based on electronic health record data, biomarker data (where applicable), or other predefined criteria approved within the AccessALL governance framework.

7.2. Exclusion Criteria

Participants will be excluded/not contacted/not engaged if:

- They have recorded a preference in their GP medical record not to be contacted for research;
- They have registered a National Data Opt-Out;
- They are recorded as receiving palliative or end-of-life care at the time of identification;
- They lack capacity to provide informed consent at the time of enrolment.

Additional exclusion criteria may apply to specific embedded cohorts or participant groups and will be defined within the relevant documentation.

7.3. Sample Size

AccessALL is designed as an open-ended longitudinal population research infrastructure, and therefore no predefined upper limit to recruitment is specified.

Sample size is not determined by statistical power calculations, as the platform is intended to support multiple observational, translational, and biomarker research activities over time.

Recruitment will aim to maximise demographic, ethnic, geographic, and socio-economic diversity.

8. RECRUITMENT

8.1. Identification of Potential Participants

Potential participants will be identified through structured searches of electronic health records held by participating GP practices.

Searches will be conducted according to predefined inclusion and exclusion criteria and in accordance with Data Processing Agreements between the GP practice and Umedeor Ltd, acting as data processor.

The GP practice remains the data controller. Umedeor Ltd acts only as its Data Processor under a formal Data Processing Agreement.

Initial Contact

Initial contact with potential participants will occur on behalf of their registered GP practice and may include:

- Short Message Service (SMS/text message)
- Email
- Postal letter
- Other secure communication methods where appropriate

Communications will invite individuals to review study information and consider participation in AccessALL.

Additional recruitment pathways (specialist centres and partner organisations)

In addition to recruitment via participating GP practices, AccessALL may include a pilot pathway to support recruitment through specialist care providers, disease-specific centres, and other approved partner organisations (including non-NHS settings where appropriate).

Under this model, the external organisation will identify potentially eligible individuals based on their own records and governance frameworks and will provide study information and an invitation to participate. All such organisations will operate under appropriate data protection and

governance arrangements consistent with applicable legislation. Interested individuals may then register directly with AccessALL via approved digital channels.

Participants entering via this pathway will undergo appropriate eligibility screening, consent, and onboarding procedures consistent with the AccessALL governance framework. The scope of data collection and participation for these individuals may initially be limited to participant-provided data and study-specific activities, unless and until linkage to primary care or other healthcare records is established in accordance with appropriate approvals and participant consent.

This recruitment pathway will be implemented in a controlled and phased manner, with oversight by the Sponsor. Any expansion of this model, including access to additional data sources, integration with healthcare record systems, or inclusion in specific sub-studies involving additional procedures, will be subject to Sponsor review and, where required, Research Ethics Committee approval or amendment.

This pathway will be evaluated using predefined feasibility measures, including number of organisations engaged, number of invitations issued, number of individuals registering interest, proportion completing consent, completeness of participant-provided data, eligibility confirmation rates, participant experience, and any governance or operational issues identified.

8.2. Participant Reimbursement

AccessALL is committed to equitable and inclusive participation. Where operationally feasible, reimbursement or compensation may be offered to participants to offset reasonable costs or time associated with specific research activities, including biological sample collection or in-person assessments. Any reimbursement arrangements will be clearly described in the relevant participant-facing materials and will be proportionate, non-coercive, and approved by the Research Ethics Committee where required. Reimbursement will not be offered as an inducement to enrol in the core platform.

9. INFORMED CONSENT

9.1. Consent Process

AccessALL utilises secure electronic consent (eConsent) processes.

Potential participants will be directed to a secure digital platform where they will be provided with:

- A Participant Information Sheet;
- Information regarding the purpose and scope of AccessALL;
- Details of data linkage and longitudinal follow-up;
- Information regarding optional biological sampling (where applicable);
- Information regarding risks, confidentiality, and withdrawal rights.

Participants will confirm that they have read and understood the study information and will provide consent electronically by entering their name and date.

Participation is voluntary and individuals may withdraw at any time without affecting their clinical care.

The electronic consent system maintains full version control, timestamped audit trails (including IP address and document version), and provides participants with a downloadable copy of their signed consent. The process complies with MHRA and HRA guidance on electronic informed consent.

To ensure that digital barriers do not preclude participation, AccessALL supports telephone completion of the consent and information provision process for any individual who prefers this route including those who do not own a smartphone, have limited digital literacy, or simply prefer not to use digital tools. Telephone consent is conducted by trained study staff and is recorded in the same way as eConsent, with the same audit trail, version control, and documentation standards. No participant is required to provide a reason for choosing a non-digital consent pathway.

9.2. Capacity to Consent

Capacity to consent is decision-specific and is presumed unless there is evidence to the contrary.

Participants must have capacity at the time of enrolment. Individuals recorded in GP systems as lacking capacity, or receiving palliative or end-of-life care, will not be invited to participate.

Where participants require assistance using digital devices (for example due to physical limitations), practical support may be provided, provided that the participant retains decision-making capacity.

If a participant loses capacity during longitudinal follow-up, no further active data collection will occur. Data collected prior to loss of capacity may continue to be used in accordance with the consent provided and applicable law.

10. ETHICAL AND REGULATORY CONSIDERATIONS

10.1. Ethical Approval

The AccessALL Platform will operate under approval from a UK Research Ethics Committee (REC) and the Health Research Authority (HRA), where applicable.

AccessALL functions as a master population research infrastructure within which embedded disease-specific cohorts, population-based cohorts, and sub-studies may operate under a unified governance framework.

All activities will be conducted within the scope of the approved protocol.

Substantial modifications to the protocol will be submitted for ethical review in accordance with HRA guidance.

Sub-studies or cohorts or participant groups that fall outside the scope of the approved protocol will require additional ethical review and approval where appropriate.

Interventional clinical trials (including CTIMPs or medical device studies) will be conducted under separate protocols and regulatory approvals in accordance with applicable legislation.

Participant identification operates as follows: participating GP practices, as data controllers of their patients' records, conduct (via Umedeor Ltd acting as their Data Processor under a formal Data Processing Agreement) structured SNOMED-coded searches of their electronic health records according to the eligibility criteria in this protocol. The National Data Opt-Out is checked via the NHS England MESH service at the start of every search. Invitations are issued by Umedeor Ltd on behalf of the GP practice; the GP practice retains clinical oversight of the invitation list. No identifiable data leaves the GP–Processor boundary prior to participant consent. Accordingly, this pre-consent processing is performed with Section 251 CAG support.

10.1.1 SUB-STUDY CLASSIFICATION FRAMEWORK

Overview

AccessALL operates as a master population research infrastructure within which sub-studies and disease specific cohorts may be conducted.

Sub-studies are categorised according to the level of additional participant involvement and regulatory impact with a focus on activities involving prospective data collection or participant interaction. This framework supports proportionate governance and ensures compliance with ethical and regulatory requirements.

All sub-studies require approval by the AccessALL Management Committee prior to initiation.

Type I Sub-Studies

(Additional Data Collection Within Approved Scope)

Type I sub-studies involve:

- Additional questionnaires, assessments, or clinical measures already described within the master protocol; and/or
- Biological sample collection procedures already defined within the approved protocol; and/or
- Recontact of participants for activities clearly covered by consent.

These studies operate fully within the scope of the approved AccessALL protocol and do not introduce new procedures or materially alter participant burden or risk.

Governance Requirements:

- AccessALL Management Committee approval;
- Confirmation of alignment with participant consent;

- REC notification or review where required under current HRA guidance.

Type II Sub-Studies

(New Procedures or Material Changes)

Type II sub-studies involve:

- Introduction of new data collection procedures not described in the approved protocol;
- Introduction of new biological sample types or materially different collection methods;
- Substantive changes to participant risk profile;
- Activities outside the scope of the current participant consent.

Governance Requirements:

- Formal amendment to the master protocol;
- Submission for REC review and approval in accordance with HRA guidance;
- Updated participant information and consent materials where applicable.

Interventional Studies

Interventional clinical trials (including CTIMPs or medical device trials) will **not** be conducted under the AccessALL master protocol, and are not to be considered 'sub-studies'.

Such studies will require:

- Separate study protocols;
- Independent ethical approval;
- Applicable regulatory authorisations.

In line with participant consent, individuals enrolled in AccessALL may be offered the opportunity to take part in third-party interventional studies. This activity relates to identification and invitation only and does not constitute a sub-study under this protocol. No additional approval under the AccessALL master protocol is required for such identification and invitation activities, provided they remain within the scope of the approved consent and governance framework.

10.2. Regulatory Framework

AccessALL will be conducted in accordance with:

- The Declaration of Helsinki;
- The UK Policy Framework for Health and Social Care Research;
- Good Clinical Practice (ICH E6, as adopted in the UK);
- The Data Protection Act 2018 and UK GDPR;
- The Human Tissue Act 2004 (where applicable);
- Applicable international regulatory requirements where research is conducted outside the UK.

The Sponsor retains overall responsibility for ensuring compliance with these frameworks.

10.3. Risk Assessment

AccessALL is primarily observational in nature. Risks to participants are considered low and relate primarily to:

- Confidentiality and data privacy;
- Time and inconvenience associated with questionnaires or assessments;
- Potential inconvenience associated with recontact.

Where biological samples are collected, risks may include:

- Venepuncture-related risks (e.g., discomfort, bruising, infection);
- Lumbar puncture-related risks (e.g., headache, bleeding, infection);
- Skin biopsy-related risks (e.g., minor bleeding, infection, scarring).

All clinical procedures will be performed by appropriately trained healthcare professionals in accordance with local clinical governance and safety standards.

Potential risks and burdens will be clearly described in the Participant Information Sheet prior to consent.

10.4. Adverse Events and Safety Reporting

Overview

Although AccessALL is primarily an observational research infrastructure, certain activities within the platform, particularly biological sample collection procedures carry procedural risks that require a defined adverse event reporting framework.

GP practices participate in AccessALL as Participant Identification Centres (PICs) only. Their role is limited to the identification of potentially eligible participants. GP practices are not research sites and do not conduct research procedures within AccessALL. Adverse event reporting therefore applies specifically to activities involving biological sample collection and clinical assessments conducted at designated clinical settings, and not to the identification and recruitment activities conducted by GP practices.

For observational components of AccessALL involving no clinical procedures including EHR data collection, questionnaires, and patient-reported outcomes no formal AE reporting is required beyond standard clinical care pathways.

For sub-studies involving medicinal products or industry-specific safety requirements, additional pharmacovigilance processes may apply as described in the relevant sub-study documentation.

Definitions

An **Adverse Event (AE)** is any untoward occurrence in a study participant that does not necessarily have a causal relationship with the research procedures.

A **Serious Adverse Event (SAE)** is any untoward occurrence that:

- Results in death
- Is life-threatening
- Requires inpatient hospitalisation or prolongation of existing hospitalisation
- Results in persistent or significant disability or incapacity
- Is an important medical event that may jeopardise the participant or require intervention to prevent one of the above outcomes

Reporting Responsibilities

- Participating healthcare professionals conducting study procedures are responsible for identifying and documenting adverse events arising from those procedures within their clinical setting, in accordance with their normal clinical governance and professional obligations
- Adverse events arising from study procedures must be reported directly to the Chief Investigator by the healthcare professional conducting the relevant procedure, in accordance with Sponsor Standard Operating Procedures
- The Chief Investigator is responsible for reporting SAEs to the Sponsor within **24 hours** of becoming aware of the event
- The Sponsor will report SAEs to the Research Ethics Committee and relevant regulatory authorities where required and within applicable timeframes
- Where sub-studies operate under separate protocols with their own Chief Investigator, safety reporting responsibilities will be defined within the relevant sub-study documentation. The AccessALL Chief Investigator retains oversight of platform-level safety governance.

Timeframes

- SAEs must be reported to the Sponsor within **24 hours** of the investigator becoming aware
- The Sponsor will provide a full written report to the REC within **15 days** of becoming aware of an SAE considered related to study procedures

Sub-Study Specific Safety Reporting

Where embedded cohorts or participant groups or sub-studies involve clinical procedures carrying additional risk, detailed adverse event reporting and safety monitoring requirements will be defined within the relevant documentation. All sub-study level safety reporting will operate within the principles and timeframes set out in this section of the master protocol.

Where sub-studies involve medicinal products, pharmaceutical partners, or other activities requiring pharmacovigilance (PV) reporting, the relevant PV responsibilities, processes, and reporting requirements will be defined in the applicable sub-study protocol, agreement, or safety management documentation, in accordance with Sponsor responsibilities and applicable regulatory requirements.

Annual Safety Reporting

The Sponsor will submit an annual safety report to the REC summarising any adverse events related to study procedures occurring during the preceding year, in accordance with HRA guidance.

Urgent Safety Measures

If it becomes necessary to take urgent safety measures to protect participants from immediate harm, the Chief Investigator may take such measures immediately and without prior REC approval. The REC and Sponsor must be notified of any such measures and the reasons for them as soon as possible and within **72 hours**.

10.5. Protocol Deviations and Non-Compliance

Overview

The Sponsor and Chief Investigator are committed to conducting AccessALL in accordance with the approved protocol, applicable regulatory frameworks, and Sponsor Standard Operating Procedures. A systematic approach to identifying, documenting, and managing protocol deviations is essential to maintaining the integrity of the research and protecting participant safety and rights.

Definitions

A **Protocol Deviation** is any unplanned or unintentional departure from the approved protocol, Sponsor SOPs, or applicable regulatory requirements that does not have a significant impact on participant safety, rights, or wellbeing, and does not materially affect the integrity of the research data.

A **Serious Breach** is a deviation that is likely to affect to a significant degree:

- The safety or physical or mental integrity of participants; or
- The scientific value of the study

Participant Identification: Roles, Workflow and Deviation Reporting

Participant identification within AccessALL operates as a two-stage process. Umedeor Ltd, acting as data processor under a Data Processing Agreement with each participating GP practice, conducts structured searches of GP electronic health records using predefined SNOMED codes in accordance with the eligibility criteria set out in this protocol. Umedeor Ltd is responsible for applying National Data Opt-Out screening and exclusion criteria at the point of search. The resulting list of potentially eligible participants is then reviewed and approved by the GP practice before any contact is initiated. The GP practice retains final responsibility for approving participant contact.

GP practices participate in AccessALL as Participant Identification Centres only. They do not conduct research procedures within AccessALL. Their role is limited to reviewing and approving the lists of potentially eligible participants generated by Umedeor Ltd before contact is initiated.

Deviations within the participant identification process may occur at either stage and include but are not limited to:

- Incorrect or incomplete SNOMED code searches conducted by Umedeor Ltd
- Failure to correctly apply National Data Opt-Out screening at the search stage
- Failure to correctly apply exclusion criteria at the search stage
- GP practice approval of contact for individuals who do not meet inclusion criteria or who meet exclusion criteria

Any deviation identified at either stage must be reported to the Chief Investigator and Sponsor immediately and documented in the deviation log.

Identifying and Recording Deviations

- All protocol deviations must be identified, documented, and reported to the Chief Investigator as soon as they are identified
- The Chief Investigator is responsible for assessing the nature and severity of each deviation and determining whether it constitutes a serious breach
- All deviations will be recorded in a deviation log maintained by the Sponsor and will be reviewed as part of ongoing monitoring activities
- Umedeor Ltd is responsible for maintaining records of all searches conducted, opt-out screening applied, and participant lists generated, to support deviation identification and audit

Reporting Responsibilities and Timeframes

- **Protocol deviations** must be documented and reported to the Sponsor as soon as practicable and reviewed at the next scheduled monitoring review
- **Serious breaches** must be reported to the Chief Investigator and Sponsor **immediately** upon identification
- The Sponsor will notify the REC of any serious breach within **7 days** of becoming aware, in accordance with HRA guidance
- Where a serious breach relates to data protection, the Sponsor will additionally notify the Information Commissioner's Office (ICO) where required under UK GDPR Article 33, within **72 hours** of becoming aware of the breach
- Where a deviation or breach involves failure to comply with CAG approval conditions, the Sponsor will notify CAG in accordance with the conditions of the CAG approval

Corrective and Preventive Actions

- For all deviations, the Chief Investigator and Sponsor will assess whether corrective and preventive actions (CAPAs) are required
- CAPAs will be documented, implemented, and reviewed to confirm their effectiveness
- Where a pattern of deviations is identified, the Sponsor will conduct a root cause analysis and implement appropriate systemic corrective measures

- Where a deviation has occurred within the participant identification process, the Sponsor will work with Umedeor Ltd and the relevant GP practice to identify the point of failure and implement appropriate corrective measures before identification activities resume

Sub-Study Specific Deviations

Where embedded cohorts, participant groups, or sub-studies define additional procedures or operate under separate protocols with their own Chief Investigator, deviation reporting responsibilities and any procedure-specific requirements will be set out within the relevant sub-study documentation. All such reporting will operate within the principles and timeframes set out in this section of the master protocol.

11. CONFIDENTIALITY AND DATA PROTECTION

AccessALL will implement appropriate technical and organisational measures to protect participant confidentiality and security of all personal data.

Identifiable data will remain under the control of participating healthcare providers (such as GP practices) or other participating organisations until consent is obtained. Following enrolment, research data will be pseudonymised prior to transfer into secure research environments.

Pseudonymised data will be stored within access-controlled systems using role-based permissions and audit logging.

All data processing will comply with UK GDPR, the Data Protection Act 2018, and applicable governance standards.

Legal basis for processing

Prior to informed consent, the processing of identifiable patient data for participant identification and contact is conducted as detailed in Appendix 3-Data processors and Technical Arrangements.

Following informed consent, the primary legal basis for the processing of personal data and special category (health) data within the AccessALL research platform is the participant's explicit consent (Article 6(1)(a) and Article 9(2)(a) of the UK GDPR). This is supplemented where appropriate by the condition for scientific research processing under Schedule 1, Part 1, Paragraph 4 of the Data Protection Act 2018.

Following participant consent, Cohort Science Ltd becomes the data controller for the research data.

International transfers of consented pseudonymised data and biological samples will be conducted using UK International Data Transfer Agreements (IDTAs), Standard Contractual Clauses, or other appropriate safeguards in accordance with UK GDPR Chapter V and the Data (Use and Access) Act 2025.

A study-specific Data Protection Impact Assessment has been completed for AccessALL in accordance with Article 35 of the UK GDPR. The DPIA identified ten residual risks, all assessed as low following mitigation. These cover re-identification of pseudonymised data, unauthorised access to EHR data during pre-consent processing, data breach during transfer to external researchers, participant inability to exercise withdrawal rights, function creep beyond approved protocol scope, international transfer risk via US sub-processors, loss of data integrity or availability, biological sample loss or mishandling, failure to apply National Data Opt-Out at screening, and non-compliance with CAG approval conditions. Mitigations include segregated data architecture, ISO 27001:2022 certified information security management, Trusted Research Environment controls, tiered withdrawal procedures, the Management Committee governance framework, EU-US Data Privacy Framework and IDTA safeguards for international transfers, HTA-compliant sample storage, and mandatory National Data Opt-Out screening at every eligibility search. The DPIA concluded that processing may proceed subject to the safeguards described in this protocol and the DPIA. The DPIA will be reviewed and updated annually and in the event of any material changes to the study design, data flows, sub-processor arrangements, or applicable regulatory framework, whichever is sooner.

12. RETURN OF INDIVIDUAL RESEARCH RESULTS

AccessALL is a research infrastructure and not a clinical diagnostic service. Individual research results will not routinely be returned to participants. In exceptional circumstances where a finding is analytically valid, clinically significant, and actionable within established clinical pathways, the chief Investigator (or delegate) may arrange re-contact with the participant's GP in accordance with Sponsor governance procedures and applicable regulatory requirements.

Biomarker and genetic analyses conducted within AccessALL are undertaken for research purposes and may not be clinically validated for clinical use.

13. WITHDRAWAL

Participants may choose from the following levels of withdrawal:

- **Partial withdrawal:** AccessALL will cease all proactive contact with the participant and will delete identifiable participant information from the contact management system. De-identified research data collected prior to withdrawal may continue to be used in accordance with the consent provided and applicable law. Stored biological samples will be managed in accordance with participant preference at the time of withdrawal.
- **Full withdrawal:** AccessALL will cease all contact with the participant and will not use their data or samples in any new research activities following withdrawal. Where technically and operationally feasible, de-identified data will be excluded from future dataset releases. It may not be possible to remove data or samples from analyses already underway or completed at the time of withdrawal.
- Participants who do not have internet access may request withdrawal by contacting the AccessALL support team via phone. Once verified, an authorised member of the team will action the relevant changes.

14. BIOLOGICAL SAMPLE COLLECTION AND MANAGEMENT

Overview

Participants enrolled in AccessALL may be invited to provide biological samples to support approved research activities.

Cohort Science Ltd does not itself hold an HTA licence for storage of relevant material. All biological samples are stored in HTA-licensed establishments (or equivalent accredited facilities outside the UK) under contractual arrangements.

Biological sampling is optional and will occur only where:

- Explicit participant consent has been provided;
- The activity falls within the scope of the approved protocol or relevant cohorts or participant groups;
- Appropriate clinical governance and regulatory approvals are in place.

Sampling may occur as part of disease-specific cohorts, population-based biomarker programmes, or approved sub-studies operating under the AccessALL master protocol.

Types of Samples

Samples may include, but are not limited to:

- Whole blood
- Serum and plasma
- DNA and RNA
- Saliva
- Cerebrospinal fluid (CSF)
- Skin biopsy samples
- Other minimally invasive biological specimens required for approved research sub-studies

Derived materials (e.g., extracted DNA, RNA or protein fractions) may also be generated.

Collection Procedures

Samples may be collected in:

- GP practices
- Community clinical hubs
- Hospital settings
- Other clinically appropriate environments

All procedures will be performed by appropriately trained healthcare professionals in accordance with local clinical governance standards and Good Clinical Practice.

Participants will receive written information describing the procedure, associated risks, and post-procedure advice.

Processing and Storage

Biological samples will be processed and stored in licensed or appropriately accredited facilities.

Within the UK, storage will occur in Human Tissue Authority (HTA)-licensed establishments such as university or NHS-affiliated biobanks.

Samples may be stored for short-term analysis or long-term research use consistent with participant consent.

Use of Samples

Samples may be used for:

- Genetic analysis
- Biomarker assays
- Translational and mechanistic research
- Development and validation of diagnostic or digital biomarkers
- Other ethically approved research consistent with participant consent

Sample-derived data may be linked with longitudinal EHR and questionnaire data within secure research environments.

15. DATA MANAGEMENT AND DATA PROTECTION

Data Controllers and Processors

Participating GP practices act as Data Controllers for identifiable patient data within their EHR systems.

Umedeor Ltd acts as a Data Processor under a Data Processing Agreement with each GP practice to support eligibility searches, participant contact, and operational research activities before consent. Following participant consent, Cohort Science Ltd (Sponsor) becomes Data Controller for research data collected within AccessALL.

Data Flow and Pseudonymisation

Prior to consent, identifiable data remain within GP systems.

Following consent:

- Relevant data are extracted according to predefined criteria;
- Data are pseudonymised before transfer to the AccessALL research environment;
- Identifiable information is stored separately from research datasets;
- Secure linkage keys are maintained separately.

Research datasets used for analysis contain pseudonymised identifiers only.

Data Storage and Security

Research data will be stored in secure access-controlled environments with:

- Encryption in transit and at rest;
- Role-based access controls;
- Audit logging;
- Segregation of identifiable and research datasets.

Where Trusted Research Environments are used, access will be governed by approved user roles and monitored through audit procedures.

Data Retention

Research data may be kept for as long as scientifically justified and ethically approved, which may be up to 20 years or longer.

Data will be securely archived or destroyed at the end of the retention period in accordance with regulatory requirements.

16. DATA ACCESS AND GOVERNANCE

Governance Structure

Oversight of AccessALL will be provided by an AccessALL Management Committee appointed by the Sponsor.

The Committee will include:

- Chief Investigator
- Sponsor representatives
- Clinical representatives from participating GP networks
- Disease specific clinical leads
- A patient or public representative
- Data governance advisors

The Committee will review sub-study proposals, data access requests, and governance considerations.

Access to the AccessALL research resource will be underpinned by the principles of the Five Safes framework: safe data, safe projects, safe people, safe settings, and safe outputs. Approved researchers will be required to work within accredited Trusted Research Environments and will not be permitted to export individual-level participant data.

As a condition of data or sample access, approved researchers will be required to return the results of their analyses including negative findings to the AccessALL platform within an agreed timeframe following project completion, for incorporation into the central research dataset. A limited exclusivity period may be granted to allow for publication or other appropriate use of findings prior to return, subject to Management Committee approval

Data Access Applications

Researchers seeking access to AccessALL data or biological samples must submit an application describing:

- Scientific rationale
- Data requirements
- Institutional approvals
- Analysis plan
- Funding sources and conflicts of interest

All applications will be reviewed by the AccessALL Management Committee.

Categories of Access

Access may include:

- Use of existing pseudonymised datasets
- Additional data collection within protocol scope
- Access to biological samples
- Recontact of participants for approved research

Approved researchers may include universities and research organisations, NHS organisations, pharmaceutical or biotechnology companies, and medical technology companies developing new medicines or healthcare technologies. All access is subject to AccessALL Management Committee review and must remain consistent with participant consent.

Activities outside the scope of this protocol will require additional ethical review.

Governance procedures are designed to ensure that all research conducted within AccessALL remains consistent with participant consent, applicable legislation, and the ethical principles of responsible data use.

17. MONITORING AND QUALITY ASSURANCE

The Sponsor will ensure that AccessALL is conducted in accordance with the approved protocol, applicable regulatory frameworks, and Sponsor Standard Operating Procedures.

Monitoring will be proportionate to risk and may include review of recruitment procedures, consent documentation, data security processes, and biological sampling procedures where applicable.

Quality assurance procedures will ensure data integrity, secure data handling, and audit readiness.

18. INDEMNITY AND INSURANCE

The Sponsor will ensure that appropriate indemnity and insurance arrangements are in place in accordance with the UK Policy Framework for Health and Social Care Research.

Participating healthcare providers and partner institutions will operate under their respective institutional indemnity arrangements.

Participants will not incur any costs as a result of participation in AccessALL.

19. PUBLICATION AND DISSEMINATION

Findings arising from AccessALL and associated sub-studies will be disseminated through:

- Peer-reviewed publications
- Scientific conferences
- Public reports
- Lay summaries for participants

Authorship will follow recognised academic guidelines.

Participants will not be individually identifiable in any publication.

The AccessALL Platform is intended to operate as a sustainable research infrastructure capable of supporting evolving scientific questions and emerging technologies over time.

References:

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APPENDIX 1 - AccessBrainHealth SUB-STUDY PROTOCOL

Note: Appendix 1 (AccessBrainHealth SUB-STUDY PROTOCOL) is provided as a separate document.

APPENDIX 2 - Participant Communication and Questionnaire Prioritisation Framework

This appendix describes the framework governing how participants enrolled in the AccessALL Research Platform are identified for, and communicated with regarding, questionnaire-based data collection activities. It sets out the principles by which participant-facing messaging is tailored to ensure that the participant understands why they are receiving information or a request to complete data collection activity.

Communication Type	Data Collection	Prioritisation Basis	Example Participant Messaging
Invitation to consent to join the AccessALL Cohort	Invitation/Consent	Participant identified by Participating Organisation based on condition coding (SNOMED/ICD-10. The most clinically relevant condition used to frame the invitation.	*"You've been invited to participate in an innovative research programme called AccessALL. Researchers are particularly interested in [condition X]."(X = condition the participant is coded for)*
Core data collection	Quality of life, or other validated or non-validated PRO that is not specific to a condition	Sent to all enrolled AccessALL participants regardless of condition. No condition-based prioritisation applied.	*"You've been sent this questionnaire because you're part of the AccessALL research programme."*
Priority condition - elevated data collection	Condition-specific validated PRO (e.g. IWQOL-Lite for T2D / obesity)	Participant has a coded diagnosis matching a priority condition. The most clinically significant condition determines which questionnaire is deployed.	*"You've been sent this questionnaire because you have been identified as potentially having [type 2 diabetes / condition X]"*
Priority medication - elevated data collection	Medication-specific questionnaire, validated or non-validated (e.g. GLP-1 usage/experience survey)	Participant has a coded prescription for a priority medication class.	*"You've been sent this questionnaire because you have been identified as potentially taking a GLP-1 medication such as Ozempic or Wegovy."*
Sub-study consent	Sub-study-specific consent	Participant meets eligibility criteria for a named sub-study (e.g. age band, condition, biomarker status). Sub-study team defines eligibility; AccessALL platform identifies and invites.	*"You've been invited to join this sub-study because we are looking for generally healthy people aged between 60 and 85."*

Communication Type	Data Collection	Prioritisation Basis	Example Participant Messaging
Ongoing sub-study data collection	Sub-study-specific questionnaire or assessment	Participant is an active consented member of a named sub-study. Communication scoped to that sub-study only.	*"You've been sent this questionnaire because you're a valued participant in the [SUB-STUDY NAME] sub-study."*

APPENDIX 3 – DATA PROCESSORS AND TECHNICAL ARRANGEMENTS

Participating healthcare providers, primarily GP practices, act as data controllers for identifiable patient information held in their electronic health record systems prior to participant consent.

Umedeor Ltd is formally appointed by each participating healthcare provider as a Data Processor under a written Data Processing Agreement (DPA) that complies with Article 28 of the UK GDPR. In this capacity, Umedeor Ltd processes identifiable confidential patient information solely on behalf of, and on the documented instructions of, the respective healthcare provider (data controller). Umedeor Ltd has no independent right or authority to use, control, or make decisions about the data for any other purpose.

Pre-consent activities performed by Umedeor Ltd as Data Processor include:

- Conducting structured, protocol-approved searches of electronic health records using predefined eligibility criteria (from this master protocol or approved embedded disease-specific cohorts/sub-studies);
- Applying National Data Opt-Out screening at the point of every eligibility search;
- Generating and sending study invitations (via SMS, email, letter or other approved secure channels) on behalf of the healthcare provider;
- Operating the secure electronic consent (eConsent) platform and participant management systems.

These pre-consent activities are carried out under the lawful basis determined by the data controller (the participating healthcare provider) and are supported by Section 251 Confidentiality Advisory Group (CAG) approval (application reference: 26/CAG/0037). Final approval was granted by the Secretary of State for Health and Social Care on 15 June 2026, following a CAG sub-committee meeting on 15 June 2026, and the legal basis to process the specified confidential patient information without consent is now in effect. The approval is conditional, subject to three specific conditions: (1) provision of a public involvement update at first annual review; (2) provision of an activity update at first annual review; and (3) confirmation of Data Security and Protection Toolkit (DSPT) 'Standards Met' status – which has been confirmed for Umedeor Ltd by NHS England. Participant identification, invitation, contact, and recruitment activities may now proceed in accordance with the approved protocol and the conditions of CAG support.

Umedeor Ltd acts strictly within the terms of the Data Processing Agreement and has implemented appropriate technical and organisational security measures to protect the data. All processing is subject to audit rights by the data controllers and the Sponsor.

Following a participant's informed consent to join the AccessALL platform, relevant data are transferred to Cohort Science Ltd, which then becomes the data controller for the research dataset within the AccessALL platform.

This appendix provides further detail on the operational and legal arrangements referenced in Sections 3.3, 3.4 and 11 of this protocol.

Certificate Of Completion

Envelope Id: D61589DF-8414-8806-80C1-580535BF668E
Status: Completed
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Source Envelope:
Document Pages: 43
Signatures: 2
Certificate Pages: 4
Initials: 0
AutoNav: Enabled
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Electronic Record and Signature Disclosure: Accepted: 11 March 2026 | 05:41 ID: 2ab5757e-88e8-4741-8414-1a8108fda30c		
Matt Wilson matt@umed.org CEO Umedeor Ltd Security Level: Email, Account Authentication (Required), Logged in	Signed by: Matt Wilson Signer Name: Matt Wilson Signing Reason: I approve this document Signing Time: 18-Jun-2026 | 6:40 AM PDT D36DC0F21AD64349BE0103F7A1B6234E Signature Adoption: Pre-selected Style Signature ID: D36DC0F2-1AD6-4349-BE01-03F7A1B6234E Using IP Address: 73.60.105.179 With Signing Authentication via Docusign password With Signing Reasons (on each tab): I approve this document	Sent: 18 June 2026 | 08:39 Viewed: 18 June 2026 | 14:40 Signed: 18 June 2026 | 14:40
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Editor Delivery Events	Status	Timestamp

Agent Delivery Events	Status	Timestamp

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Certified Delivery Events	Status	Timestamp

Carbon Copy Events	Status	Timestamp
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Witness Events	Signature	Timestamp

Notary Events	Signature	Timestamp

Envelope Summary Events	Status	Timestamps
Envelope Sent	Hashed/Encrypted	18 June 2026 | 08:39
Envelope Updated	Security Checked	18 June 2026 | 08:42
Certified Delivered	Security Checked	18 June 2026 | 14:40
Signing Complete	Security Checked	18 June 2026 | 14:40
Completed	Security Checked	28 June 2026 | 20:03

Payment Events	Status	Timestamps

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