MAC CLINICAL RESEARCH

Site & Patient Services

macplc.com

MAC's Site & Patient Services

Enrolling the *right* participants at the *right* sites and keeping them in the trial remains one of the most challenging hurdles in clinical research.

MAC understands:

- **Participant motivations, journeys, and treatment pathways**
- **That every study has a different need, participant profile, and most suitable site attributes**
- **Where to best place your study to increase participant recruitment and give your trial the best chance of success.**

Our Site & Patient Services division offers:

Participant Recruitment

Participant Retention

Global Investigator Sites

Network of Fully-Owned Investigator Sites

Sleep Laboratory
Early Phase Unit
Psychedelic Testing Suites
Phase I - IV Research Facilities
Memory Assessment Research Centre

In addition to our connections with sites and site networks across the globe, we also offer our fully-owned network of early and late phase clinics, including specialist units in the UK

Participant Recruitment

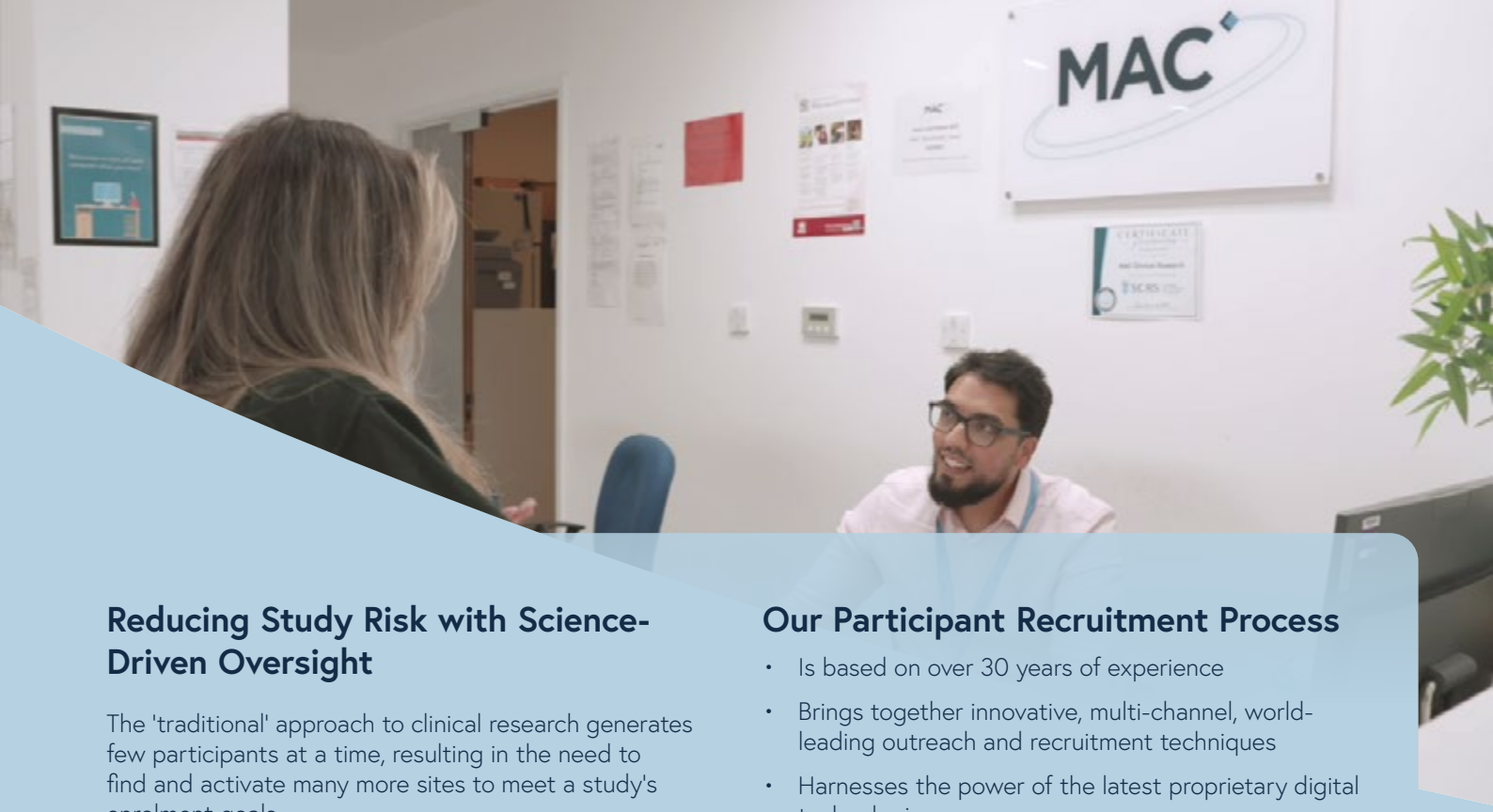
Our in-house, dedicated recruitment solutions make connecting with participants for your study easy, allowing you to significantly improve timelines and bring your treatment to market faster.

MAC EnVision®

MAC EnVision® is made up of a specialised participant engagement team and a purpose-built software platform to find accurately characterised, eligible participants with ease and precision.

Our MAC EnVision® Team

- Provides patient-centric protocol assessments to identify any criteria considered to be barriers to recruitment, providing realistic timelines based on current and suggested criteria.
- Strategically and successfully plans for each study, including participant recruitment and retention strategies, allowing sponsors to reach endpoints quicker.
- Uses EnVision Symphony®, our in-house engagement software suite, with AI integration to enhance operational efficiencies such as pre-identifying participants, and ensuring a seamless journey from start to finish.
- Closely monitors participant engagement and recruitment deliverables throughout the study.
- Provides real-time review of on-going recruitment strategies based on participant engagement and 360 feedback data.
- Focuses on the participant and gains insight into their care.



Reducing Study Risk with Science-Driven Oversight

The 'traditional' approach to clinical research generates few participants at a time, resulting in the need to find and activate many more sites to meet a study's enrolment goals.

- ✓ We recruit more participants across fewer sites than studies where recruitment is conducted via other methods (hospitals or care trusts).
- ✓ We collaborate with each of our global sites, allowing us to exceed sponsor expectations.
- ✓ We accelerate study timelines, offering sponsors a chance to bring their products to market and help patients faster.

With access to almost 35 million people within 20 minutes of MAC's UK site locations and millions more globally, we are the largest and leading company for participant recruitment and study conduct services.

Our Participant Recruitment Process

- Is based on over 30 years of experience
- Brings together innovative, multi-channel, world-leading outreach and recruitment techniques
- Harnesses the power of the latest proprietary digital technologies

This is what sets us apart from other CROs and site networks, allowing us to quickly and efficiently identify and recruit participants into small or large-scale studies.

We use proven outreach and recruitment methods to ignite study interest:

- Correspondence to our extensive database of participants
- TV, radio and print advertising
- Digital and social media platforms to enhance our outreach
- Targeted recruitment and carefully selected media, as determined by study-specific criteria
- Strong and long-established relationships, thorough work ethic, and decades of clinical research experience
- Network of NHS and third sector partnerships supporting study recruitment across numerous therapy areas
- Our dedicated, multi-channel and multilingual contact centre in the UK, which offers highly skilled team members focused on delivering the right participants to the right studies
- Development of robust and proven recruitment materials to boost engagement and retention.

Our Recruitment Hub

Our Recruitment Hub is MAC's in-house contact centre, dedicated to recruiting volunteers for our trials. Our multi-channel approach ensures ease of communication with volunteers via telephone, email, text, or web chat. Our team of over 30 highly trained specialists consistently receives best-in-class satisfaction scores from volunteer feedback.

Having an in-house recruitment team means our clients don't have to worry about additional external data privacy concerns. It allows us to react quickly to their study's needs without the challenges and delays you may find with outsourced services.

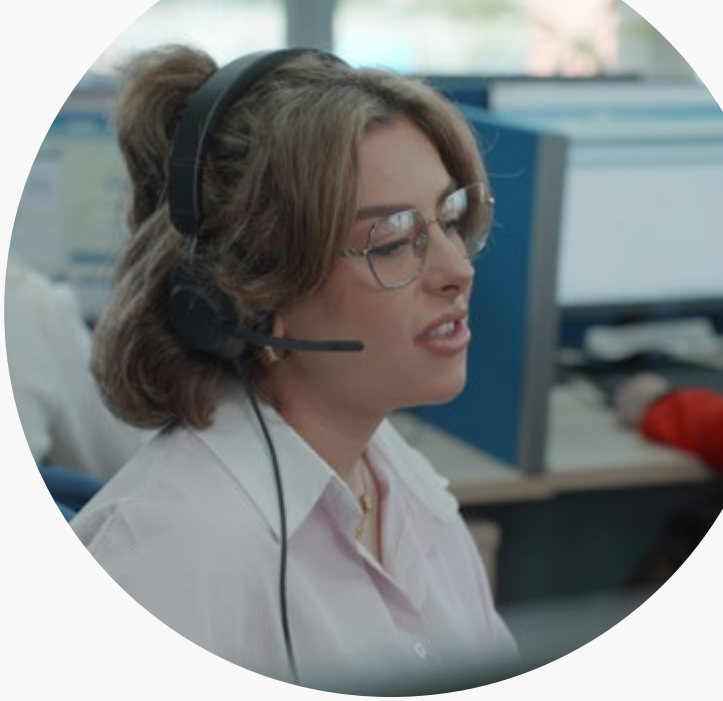
The clinical trial recruitment specialists allocated to your study have a two-fold philosophy: to focus on participants and to successfully deliver your clinical trial.

> "My treatment could not have gone as well as it did without the staff being a cohesive ensemble. Staff made me feel comfortable, informed, and relaxed throughout the entirety of the trial, completely overriding my initial concerns about clinical trials. The experience has been such a positive one.

Clinical Trial Participant

> "My experience on the trial was fantastic; the staff were very friendly and helpful, and you get on well with the other people doing the trial. By taking part, I was able to contribute to [potentially] helping people in the future.

Clinical Trial Participant



Participant Retention

We use effective techniques, including clear and valuable communications, to assist patients and healthy volunteers from randomisation through to study completion.

We recognise the value of every study participant

We understand that participating in a clinical trial is an important decision. MAC retention efforts start long before a study commences and continue throughout the study to ensure both participant and sponsor satisfaction. Our specialist team builds relationships with participants throughout the duration of a study.

Evaluate, correct, re-evaluate

We continuously evaluate the reasons for participant withdrawal, using primary data from our own participant feedback and secondary data from industry analysis. Our close relationship with participants helps ensure that they remain in the trial, as most issues are resolved through:

- Simple communication methods, such as 24-hour telephone assistance for all clinical trial participants
- A participant-focused website
- Ensuring all volunteers feel confident and well-informed about the trial process for the duration of the study.
- Courtesy calls before appointments
- Transport arrangements to and from the clinics
- Unrivalled hospitality whilst at our study sites

By combining this focus on participants with our attention to all study services, we help them remain motivated, enthusiastic, and happy, resulting in a higher than industry standard retention rate.

Many participants are happy to consider taking part in further clinical trials. In fact, 14% of participants who took part in a MAC study over the past three years went on to join other trials with us.

› Our proactive approach assists in guiding participants to complete the trial, participate in further research, and inform friends and family of the services we provide

› Our proven retention approach ensures that clinical trial data is complete and gathered within study timelines

MAC has a 94% retention rate for studies lasting less than a year and 88% retention rate for long-term studies. This exceeds the industry average which is 75%.

**Source: https://healthcaresuccess.com/blog/healthcare-marketing/overcoming-clinical-trial-marketing-challenges-patient-recruitment-retention.html

Global Investigator Sites

We can contract and work with any investigator or research site around the world through:

- **Proven, robust site identification procedures**
- **Experienced feasibility and site identification specialists**
- **Excellent personal relationships that we create and build with site staff, recognising that each team member and site offers immense value toward your study's success**
- **Our in-house database, to detail a unique set of requirements to identify only the most suitable sites for inclusion in your trial**

From our inception as a memory assessment centre and investigator site, we understand the challenges faced by investigators in a clinical trial and apply this knowledge and understanding to support the sites we collaborate with. This collaboration results in expert navigation of those challenges to successfully mitigate any study risk.

"Recruiting participants for clinical research remains one of our greatest challenges. Despite the critical importance of these studies, we often face hurdles in reaching diverse populations, addressing potential participants' concerns, and maintaining engagement throughout the research process. Our success hinges on building trust, improving communication, and demonstrating the tangible benefits of clinical research to the communities we serve.

At MAC, we have a rich history of successful participant recruitment. It's our sweet spot and forms a unique part of our execution strategy, allowing us to consistently meet and exceed the expectations of our Sponsors.

Nicola Armitstead, Vice President of Site Clinical Operations

Network of Fully-Owned Investigator Sites

MAC owns and operates a growing number of dedicated research sites throughout the UK. Several of these are specialist units.

Phase I-IV Research Facilities

- Serving a broad participant demographic, MAC sites cover a large geographic area with ease of access to each of our facilities
- Each MAC site hosts an experienced, professional workforce fully committed to conducting high-quality clinical studies
- This approach to study conduct offers sponsors significant efficiencies and cost savings by reaching more participants across fewer sites, which helps to expedite study timelines

Our dedicated research sites are modern, fully furnished and well-presented throughout. They feature temperature-regulated rooms, advanced laboratory services, and a full complement of sample storage solutions. MAC's research sites host an impressive repository of medical technologies and healthcare equipment, enabling effective execution and seamless delivery of all clinical trial activities.

We can accommodate studies that include both residential and day-case protocol criteria. Our exceptional, professional, compassionate staff understands participants' needs and expectations, providing participants and study monitors with a welcoming, pleasant, and dependable environment in which to participate in research activities.

Our sites are not only optimally placed for enhancing participant recruitment but also include many state-of-the-art facilities. Many of our sites hold Schedule 1 licences, have specialist treatment rooms for psychedelic-assisted therapy and sleep studies, and even on-site GMP pharmacies. Our MHRA accredited early phase unit is also home to our in-house laboratories. Other features of our sites include:

- ✓ **Private, en-suite rooms for overnight capabilities**
- ✓ **Memory Assessment Research Centres**
- ✓ **Free parking and access to local transport**
- ✓ **A participant -centric, relaxed and comforting atmosphere**

Sleep Laboratory

Our state-of-the-art sleep laboratory is registered by the Care Quality Commission (CQC) and tailored to conduct specialised sleep research studies.

Our sleep lab enables us to generate accurate, diagnostic sleep study reports in a comfortable, safe, and private environment.

We offer our study sponsors and participants:

- ✓ The latest sleep technology, proven to deliver high-quality research data
- ✓ A participant sleep profile, by identifying or ruling out potential sleep disorders
- ✓ Assessments for a wide range of sleep conditions, including:
  - Sleep Apnoea
  - Narcolepsy
  - Parasomnias
  - Excessive sleepiness
  - Insomnia
  - Snoring
  - Restless Leg Syndrome
  - Sleep-related seizure disorders
  - REM sleep behaviour disorders

Our team of specialists includes:

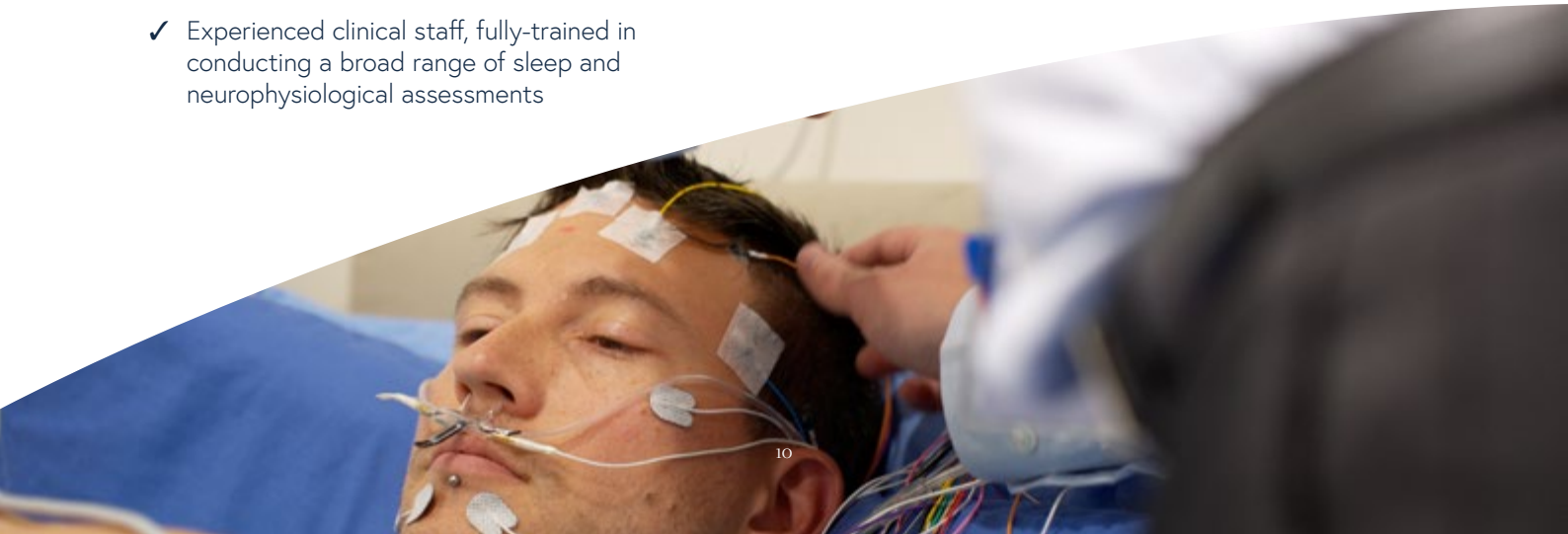
- ✓ Sleep physiologists and technicians
- ✓ Neurophysiologists
- ✓ Experienced clinical staff, fully-trained in conducting a broad range of sleep and neurophysiological assessments

Sleep Laboratory Overview

We can perform a full range of sleep analyses and other sleep-related services, and our lab offers the following:

- Sound-proof rooms
- Light-proof entrance via a vestibule
- Fully controllable lighting
- Infra-red HD video system
- Xltek® HD PSG system and Natus® SleepWorks
- Intravenous blood sampling
- Leg electrodes to record movement for limb movement disorder (RAT and LAT)
- Body position analysis by body position sensor and video
- Intercom system
- Air-conditioning and ventilation

Regulated by CareQuality Commission



Early Phase Unit

MAC's Early Phase Unit (EPU) is an MHRA-accredited Phase 1 centre, located within and supported by the Manchester University Foundation Trust. Our EPU conducts First-in-Human (FIH) studies in both patients and healthy volunteers, working across a range of therapeutic areas.

Our experience and expertise in participant recruitment for studies conducted at our EPU showcases our ability to conduct large, early-phase studies in specific patient populations, where inpatient stays and safety monitoring are required.

Safety is our watchword, and our spacious unit was built with this in mind. We are situated in a building dedicated to the advancement of medical science, equipped with a state-of-the-art Mortara Cardiac Telemetry system, and can send 24-hour data online. We also provide prompt review of 24-hour cardiac holter monitoring, with direct access to a cardiology team if there are any anomalies.

Our staff are our strength, and our EPU is approved by the Faculty of Pharmaceutical Medicine (FPM) as a training centre for physicians who are studying to become accredited FIH Investigators. We have several on-site physicians as well as senior nurses with extensive experience in clinical research. Our medical and study staff are supported by a team of Clinical Trial Assistants (CTAs).

Clinical research continues to become increasingly scientifically complex and more tightly controlled. Many studies involve "umbrella" protocols, which combine FIH with First-in-Patient (FIP) studies. Our extensive experience with this type of study, as well as with operationalising adaptive designs, enables our EPU to manage studies involving high-level scientific techniques, such as EEG, surgical insertion of temperature probes, and pharmacodynamic (PD) parameters. We don't have to divide participants into cohorts (unless specified in the protocol), and we offer clients/sponsors total flexibility with the ability to run the unit with just 1 participant in-house if necessary.

MAC is the only private company with 24/7 emergency support from a hospital resuscitation team

All of our physicians are ALS-trained

All of our clinical staff are ILS-trained

Overview of the Early Phase Unit

- 32 beds for high-intensity safety monitoring, arranged in four bays with eight beds in each
- 4 individual rooms in one area, flexible for use as screening, consulting, or overnight rooms
- 2 rooms with 3 beds each can house participants and/or carers
- Electronic security to control participant flow
- Participant lounge, dining area, and kitchen
- Nurse alarms at each bed
- Nurses' station with 360-degree view of bays
- 8-channel, 5- and 10-lead, wireless, centrally monitored telemetry system (by Mortara)
- Automated 12-lead ECG capture that transmits information to central over-reader
- Dedicated laboratory area with alarmed temperature monitoring throughout the building, with dial-out in case of temperature issues

Psychedelic Testing Suites

MAC has specialised research facilities for psychedelic drug testing, including overnight capabilities. For early-phase, self-contained studies, we have isolated areas housed within our MHRA-accredited unit.

This enables us to deliver studies involving hallucinogenic compounds, ranging from FIH through to proof-of-concept studies in vulnerable patients, which include sensitivities around addiction intervention studies. For late-phase studies, we provide fully staffed, self-contained, isolated areas within our bespoke research centres. This enables us to deliver studies that require a high level of individual attention and care, such as those with hallucinogenic compounds, to larger populations across a wider geographical area.

We control the number of staff who work on these studies and interact with participants. All staff, including our in-house psychiatrists, receptionists, and participant-facing investigators, are trained to handle the inherent complexities of CNS and other high-contact studies to minimise the placebo effect.

The environment within the dedicated areas is conducive to experiencing a safe, relaxed, hallucinogenic experience. The rooms are specifically designed to minimise acute psychological distress, and all staff who connect with the participant are trained to maintain this "set and setting." During a session, the focus is on psychologically supporting participants and ensuring data is collected to the highest standard.

> "Truly an ensemble team – I could not have felt as at ease as I did had everyone not been working together so well. The same attitude of professionalism, compassion, and participant involvement exists with every person I had the pleasure of being with, perfectly balancing levity with scientific rigour and integrity. They make an environment at the psychedelic ward that was always open, calming, and warm."
>
> Psychedelic Drug Trial Participant

We also support the manufacturing and distribution of all classes of controlled substances at our fully certified MIA (IMP) and MHRA facility, with shipment globally (same day within the UK). MAC has 8 facilities with Schedule 1 licences.

Our patient engagement team members are highly experienced in recruiting participants with:

- Alcohol dependence
- Anxiety disorder(s)
- Depression/Major Depressive Disorder (MDD)
- Migraine (e.g., cluster headaches)
- Obsessive-Compulsive Disorder (OCD)
- Opioid addiction
- Post-Traumatic Stress Disorder (PTSD)
- Smoking cessation
- Treatment-resistant depression (TRD)

MAC's Memory Assessment Research Centres

MAC shares the fundamental belief that all people with cognitive impairment have a right to assessment, diagnosis, and participation in clinical research.

To act on this, in 1988 we opened our initial Memory Assessment Research Clinic (MARC). This was one of the first specialist memory clinics in the UK, offering diagnostic assessment services in response to the growing demand for research focused specialist services. Since then, the clinic has developed into the MARC Network with clinical and research capacity across our sites. That network has:

- Assessed over 4,000 patients with memory disorders
- Been involved in many of the world's leading Alzheimer's disease clinical trials
- Contributed to the development of common, well-known treatments
- Expanded our clinic services to each of our research sites, enabling us to continue to provide first-class service to our clients and patients
- Offered significant support to the NHS post-covid waiting list initiative
- Provided a training ground for clinical raters to sharpen or maintain their skills in a real-life environment
- A database of potential research participants who have an existing relationship with us

Diagnostic Assessments Offered

Through this MARC Network, MAC Clinical Research offers free cognitive assessment services in all our research sites across the UK. These assessments mirror the NHS standard for specialist services and are undertaken by MAC practitioners who have NHS training and clinical experience. Our practitioners form a multidisciplinary team that cuts across psychiatry, clinical psychology, specialist nursing, expert neurophysiology and neuroimaging interpretation and dementia focussed occupational therapy.

All clinical staff practice within a multi-disciplinary framework for assessing and managing Alzheimer's disease and other memory disorders. They have extensive experience in clinical research and have a wide range of capabilities to provide discipline specific assessments alongside gold standard cognitive tests, neuropsychological assessments, and rating scales, such as:

- ACE-III (The Addenbrooke's Cognitive Examination 3rd edition)
- MoCA (The Montreal Cognitive Examination)

The full catalogue of primary care short assessment scales such as 6-CIT, Mini-ACE, Basic Boxfiller and GPCog.

The expertise of our clinical team is further enhanced by our contracting with local NHS memory services to offer rapid-access memory clinics as part of the NHS waiting list initiative.

MAC actively promotes research into Alzheimer's disease and other cognitive disorders and has an impressive track record in this highly specialised area of research.

Our Staff

MAC employees follow a proven and successful business management model, guided by:

- An extensive library of company policies and standard operating procedures (SOPs)
- A comprehensive training framework encompassing ICH GCP guidance
- Clinical governance of each site, following a centralised management structure

Our highly experienced professionals lead, conduct, and direct studies to ensure we maintain the highest quality standards and achieve successful study outcomes.

MAC employees operate our bespoke Participant Pathway Management System (PPMS), offering integrated Care and Data Management Services across multiple sites and business functions within the organisation. Our PPMS ensures that our sponsors and participants achieve study milestones both on-budget and on-time, whilst providing sponsors with prompt, high-quality, multi-site study data.

> “We approached MAC to help support our study where recruitment was falling behind schedule. Once the study was initiated at all MAC sites, recruitment rates exceeded that expected and greatly contributed to bringing our study back on track, saving us time and cost. Their site teams were enthusiastic, engaged, diligent, and showed great attention to detail. They really took on board the concept of a partnership for running our study and understanding our needs.

Associate Director, Clinical Operations, Biotech Sponsor

MAC Clinical Research

Your dedicated partner in clinical research

Strong track record and reputation with over 30 years of experience

Access to a wide reach of patients and volunteers

- Specialist in-house recruitment
- Multiple points of contact and engagement
- Access to almost 35 million people within 20 minutes of our facilities
- 7 million people and 27 universities within 1 hour of MAC EPU

High-performing recruitment deliverables

- Consistently outperforming other sites and countries
- We're often used as a rescue site for other studies

Quality data

- Expert team of statisticians and analysts
- Purpose-built software platform

Expertise

- Accurate feasibility and patient delivery
- Study execution delivered within time, quality, and budget expectations

MAC Clinical Research is one of Europe's largest contract research organisations (CRO), taking a science-based approach to clinical research.

Science at the heart *of everything we do*

Our experienced clinical and medical teams are capable of managing even the most complex studies, with Early Phase and Late Phase capabilities, and providing the best quality data for your research.

Headquartered in the UK with offices globally, we conduct studies both through our fully-owned network of dedicated research sites in the UK and through contracting with sites across the globe. We offer the global clinical study management you need to meet your clinical outcome goals.

MAC

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CYBER ESSENTIALS CERTIFIED

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