

# Welcome to MAC Clinical Research

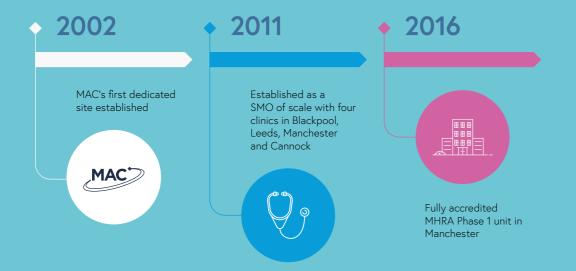
**Driving Clinical Excellence**Your Dedicated Partner in Research

Your fierce passion for patient care and scientific advancement.

In addition to being our fastest recruiting site, your performance in every other aspect of the study has been nothing short of exceptional!

I am truly proud to be able to partner with a site of your calibre.

**Clinical Project Manager**, Research & Development Pharmaceutical sponsor

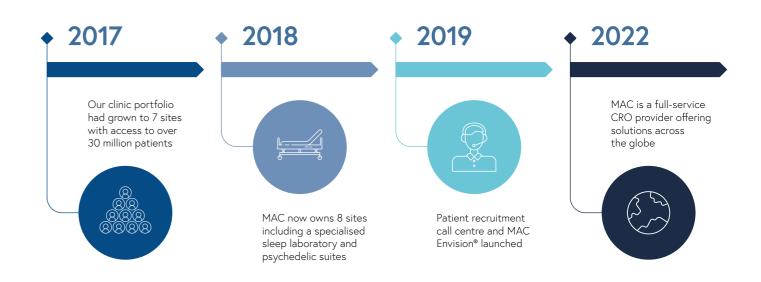




MAC Clinical Research is a leading contract research organisation dedicated to accelerating clinical trials to develop new and improved treatments for patients.

Established in 1988 as one of Europe's firstever memory assessment centres, we have a vast and rich history of becoming the UK's neuroscience centre of excellence, expanding into a fully owned network of sites, and gaining expertise in patient recruitment.

Today we are a full-service CRO providing site and patient services with complete solutions covering a wide range of therapeutic areas.



 $^{\circ}$ 



## CLINICAL RESEARCH SERVICES

Project Management

#### **Clinical Operations**

Site Monitoring Site Management Trial Feasibility

#### Pharmacovigilance

**Regulatory Affairs** 

#### **Biometrics**

EDC
Data Management
SAS Programming
Biostatistics
Medical Writing

#### Vendor Management

Randomization and Trial Supply Management

#### **Digital Solutions**

Electronic Patient-Reported Outcomes (ePRO) eConsent

**Medical Monitoring** 



## SITE & PATIENT SERVICES

**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



## SCIENTIFIC SOLUTIONS

**Human Models of Disease** 

## Scientific Services and Endpoint Assessments

Cardiovascular Assessments
Cognitive and Neuropsychological
Assessments
Dermatology Assessments
Imaging Assessments
Neurophysiology Assessments
Pain Assessments
Other Assessments

## Rare diseases Sleep Assessments

**Psychedelics** 

Training



## PHARMACEUTICAL SERVICES

**GMP Manufacturing** 

In-House Pharmacy

**Global Clinical Supplies** 

**QP** Release

IMP Management & Distribution

**Controlled Drug Services** 

**Laboratory Services** 

Clinical Pathology Bioanalytical Services



## STRATEGIC CONSULTANCY

Therapeutic Area Expertise & Study Development

Scientific Solutions & Pharmacodynamics

Clinical Science & Development

Medical Strategy, Input & Expertise

Statistical Analysis, Planning & Advice

**Medical Writing** 

Laboratory Study Design, Methods & Conduct You can select a fullservice solution or pick and choose from our services to suit your needs. Speak with our friendly team to discuss your requirements. Alternatively, scan the QR code to complete our enquiry form.



## STUDY DELIVERY

To start your journey, MAC provides study feasibility across a wide range of therapy and disease areas.

As a CRO, we take our 30 years of experience to offer full service, tailored and global solutions for your programs. We are able to take your compound through all phases of clinical trials - up to and including phase 3 registration/pivotal studies as well as phase 4 trials. Our approach allows you to build the study your way, working with quality sites globally and ensuring delivery every time.

# With a wide range of solutions, we provide a truly bespoke service:

Our offering is well suited to the needs of biotech and pharmaceutical companies who are looking to achieve their corporate and study-related objectives, with an experienced, flexible high-performing partner.

We understand
the importance of
selecting a partner
who can deliver with
confidence and give
your trial the attention
it deserves. We are
dedicated to ensuring
your studies are
prioritised and our
sponsors receive a
personal service.

Our ability to upscale effort and resources to achieve success is part of what sets us apart.

## Our experts

Our medical leadership team share 80+ years' experience in clinical research and drug development.

Our team of scientists, clinicians and physicians understand the complexities of clinical studies, the requirements to work alongside patients across many patient populations and therapeutic areas, as well as the treatment pathways and personal motivations to participate in clinical research studies. We have a team of over 30 clinical research physicians who offer scientific input to sponsor protocols as required and can act as Principal and Chief Investigator where MAC sites are used.

3-year summary

**SPONSORS** 

**STUDIES** 

**INDICATIONS** 

FIRST-IN-HUMAN **STUDIES** 

## Our panel of experts



Dr Mark Dale Chief Executive Officer



Dr Shoona Vincent VP of Clinical Science



Dr John Connell Chief Scientific Officer



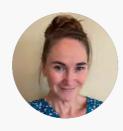
Dr Aliya Asher Chief Medical Officer

#### **Experienced PI's**



Dr Ezanul Wahab Principal Investigator

- · MHRA-accredited FIM physician
- +10 years' experience Phase 1 studies
- 100+ SAD/MAD studies



Dr Sandy Connell Medical Director

- +16 years' experience in various therapeutic areas
- 40+ studies as PI & CI

## Our sites

MAC is unique as a CRO with a fully-owned network of clinical sites.

Our dedicated research facilities enable studies to be located at the highest performing sites to expedite developments within budget and with the highest quality data. We are open to partnering with any site globally and can use our own sites, where appropriate, to bolster recruitment. We own 8 dedicated research facilities including a state-of-the-art Early Phase Unit, a specialist sleep laboratory, psychedelic testing suites, and Phase I – IV clinics.

#### Our early & late phase site capabilities

- Site Director
- Principal Investigator & Physicians
- Nurse & Clinical staff
- Can act independently or as a group
- Can run outpatient studies

We provide CRO solutions network across the world.

#### Global reach

globally. We have direct access to high-performing sites, wholly-owned MAC locations, and the MAC site

Our Early Phase Unit is MHRA- accredited for First-in-Human studies

**(**C MAC has considerable experience and a highly developed clinical infrastructure to conduct early and late phase clinical trials for depression. This has led to a track record of success in antidepressant trials and allows me to recommend MAC without hesitation.

> Senior Director and Compound Development Leader, Pharmaceutical sponsor

## Our therapeutic experience and expertise

#### **Cognitive Disorders**

Alzheimer's Disease (mild to severe) Agitation with Alzheimer's Disease Prodromal/Early Onset Dementia Parkinson's Disease-Related Cognitive Dysfunction Mild Cognitive Impairment

#### **Psychiatric Disorders**

Major Depressive Disorder Mixed Depression Bipolar Disorder Generalized Anxiety Disorder Social Anxiety Disorder Depression with Erectile Dysfunction Obsessive Compulsive Disorder Post Traumatic Stress Disorder Bulimia

#### Pain

Complex Regional Pain Syndrome Fibromyalgia Migraine Post Traumatic Neuralgia Post Herpetic Neuralgia Peripheral Neuropathy Diabetic Neuropathic Pain Osteoarthritis of the Knee Psoriatic Arthropathy Tennis Elbow

#### Sleep

Insomnia with Depression Narcolepsy

#### Parkinson's Disease

Mild to Moderate Parkinson's Disease

CNS

Pain

Dermatology

Metabolic

Psychedelics

Respiratory

Other

#### **Multiple Sclerosis**

Spasticity in MS

#### Dermatology

Atopic Dermatitis Psoriasis

#### Cardiology

Hypertension Hyperlipidaemia

#### Gastrointestinal

Pouchitis Ulcerative Colitis Crohn's Disease

#### Metabolic

Diabetes - type 1 and 2

#### Respiratory

Asthma COPD

Chronic Refractory Cough

#### Women's Health

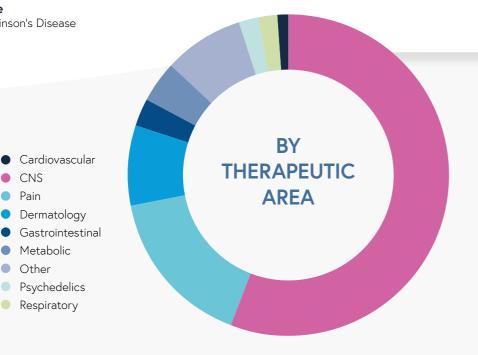
Post Menopausal Vasomotor symptoms (VMS) & Low Bone Mineral Density (BMD)

#### **Psychedelics**

Healthy Volunteers Treatment-Resistant Depression Major Depressive Disorder Opioid Addition Post Traumatic Stress Disorder

We have vast experience in conducting complex and scientifically challenging First Time in Human (FTIH) studies.

- The majority of our studies involve central nervous system (CNS) indications.
- Our core area of expertise is in Cognitive Disorders and Dementias such as Alzheimer's Disease, as well as studies in pain.
- We have specialised research facilities for psychedelic testing including fully trained staff and overnight capabilities.
- We have expanded into many other therapeutic areas and can work in any area of research.



## Specialist scientific techniques

THERAPEUTIC AREA				
Pain	CNS	General		
TECHNIQUE				
Quantitative Sensory Testing (QST)  • Thermal Thresholds/ Tolerance  • Pressure Pain Threshold/ Tolerance  • Stimulus-induced pain  • Pain Matching  • Hyperalgesia/Allodynia  Focused Analgesia Selection Test  Nerve Conduction  Pain Rating Scales  Human Pain Models	Cognitive Testing  Neuropsychological Assessment Psychometric Assessment  Saccadic Eye Movements  Postural Stability  EEG  Evoked Potentials  Pupillometry	Imaging PET, fMRI, MRS Collaboration with local imaging centre  Laser Doppler Flowmetry  Actigraphy  Respiratory Function Testing Basic Spirometry Flow Loops Challenge Studies	Exercise Testing Continuous pH monitoring Continuous Core/ Skin Temperature Monitoring Bleeding Time Punch Biopsy	Platelet Aggregometry Glucose Tolerance Testing Subjective Rating Scales  • Mood • Personality • Abuse Liability • Sleep

## Our approach to minimising the placebo response

In clinical trials the placebo response happens when patients/healthy subjects in the 'placebo' arm of the study show significant improvements in their condition/response to an experimental model.

MAC conducts placebo response training with all front-end staff, to ensure they understand what it is and what the implications are for data output as well as other methods such as:

**Ensuring appropriate patient selection** for minimum risk:

#### **Patient Training**

- · Managing their expectations.
- · Removing influences.

#### **Modifying our Patient Interactions**

- · Keeping neutral behaviour towards patients.
- · Controlled environment that is comfortable but not 'overcaring'.

#### **Optimal Study Design**

- Standardised information conveyed to subjects to regularize expectation.
- Appropriate logistics (number of groups/group size) and timing (pharmacodynamics).
- Appropriate measures (mix of objective and subjective endpoints) and baseline inclusion criteria.
- Reduce overall group variability as much as possible.
- Use only highly trained testers for subject ratings, try to stick to same tester per patient.
- Limit principal rater access to patient information, AEs etc. Limit contact to test sessions (blinded raters).

### MAC EnVision®

Specialised In-House Recruitment

Patient recruitment remains a key challenge in clinical research, often leading to inefficiencies and delays. At MAC, we strive to overcome these issues and deliver quick and accurate recruitment solutions.



Our highly effective recruitment centre, MAC EnVision®, uses science-driven insights paired with innovative software and a team of specialists to find volunteers and patients with accuracy and precision.

#### Patient recruitment and retention expertise

- > Centralised and field-based recruitment team with expertise in targeted advertising and recruitment strategies.
- > Dedicated therapy-specific recruitment and healthy volunteer teams.
- Marketing and Media Teams with specialist skillsets in outreach channels with the use of integrated campaigns to raise awareness of research.
- Access to multiple databases including our own comprehensive database of over 100k patients and volunteers, in addition to NHS FarSite, a database specific to clinical trial recruitment.

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.

Patient testimonial

been excellent. All of the staff have been very friendly and accommodating. I will be making myself available for further studies.

Patient testimonial



# 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 30m people within 30 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

## Science at the heart of what we do

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

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.



- macplc.com
- +44 (0) 161 275 9966
- info@macplc.com

#### **Registered Offices**