

# Welcome to MAC Clinical Research

Driving Clinical Excellence

• It has been inspiring to witness 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





# About us

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 first 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.

# MAC is a full-service

CRO provider offering solutions across the globe





#### 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** 

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#### 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

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# SCIENTIFIC SOLUTIONS

#### Human Models of Disease

Scientific 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

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#### PHARMACEUTICAL SERVICES

GMP Manufacturing

In-House Pharmacy

**Global Clinical Supplies** 

QP Release

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IMP Management & Distribution

Controlled Drug Services

Laboratory Services Clinical Pathology Bioanalytical Services

Medi

Laboratory Study Design, Methods & Conduct

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

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

# 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.





#### STRATEGIC CONSULTANCY

Therapeutic Area Expertise & Study Development

> Scientific Solutions & Pharmacodynamics

> > Clinical Science & Development

Medical Strategy, Input & Expertise

Statistical Analysis, Planning & Advice

**Medical Writing** 

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.



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 shares 80+ years' experience in clinical research and drug development.

Our team of scientists, clinicians and physicians understands 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.

#### 5-year summary

120

**SPONSORS** 

**STUDIES** 



**INDICATIONS** 

FIRST-IN-HUMAN **STUDIES** 

## Our panel of experts



Dr Mark Dale Chief Executive Officer



Dr John Connell Chief Scientific Officer



Dr Shoona Vincent VP of Clinical Science



Dr Aliya Asher Chief Medical Officer

## 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. Our dedicated facilities include a state-ofthe-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

globally. We have direct sites, wholly-owned MAC locations, and the MAC site network across the world.

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

**C** MAC has considerable experience and a highly developed without hesitation.

> Senior Director and Compound Development Leader, Pharmaceutical sponsor



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

# 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

Multiple Sclerosis Spasticity in MS **Dermatology** Atopic Dermatitis Psoriasis

**Cardiology** Hypertension Hyperlipidaemia

#### Gastrointestinal

IBS 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 Addiction Post Traumatic Stress Disorder

#### Oncology

Solid tumours Haematological malignancies Anti-cancer therapy induced toxicities

Cardiovascular
CNS
Pain
Dermatology
Gastrointestinal
Metabolic
Other
Psychedelics
Respiratory

We have vast experience 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	<ul> <li>Imaging <ul> <li>PET, fMRI, MRS</li> <li>Collaboration with local imaging centre</li> </ul> </li> <li>Laser Doppler Flowmetry</li> <li>Actigraphy</li> <li>Respiratory Function Testing <ul> <li>Basic Spirometry</li> <li>Flow Loops</li> <li>Challenge Studies</li> </ul> </li> </ul>	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 regularise 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 the 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 use 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.

**((** 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.

**((** My experience at MAC has 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**

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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

Patient testimonial



# Science at the heart of everything 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.



#### **MAC Global Offices**

#### United Kingdom – HQ

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Liverpool Lytham St Anr Manchester

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