Early Phase Unit

Driving Clinical Excellence

Contents

Overview

MAC's Early Phase Unit is an MHRA-accredited Phase I 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 Operational Centre of Excellence is the UK's leading EPU for early phase development, first gaining MHRA accreditation in 2016.

We specialise in recruiting and enrolling both patients and healthy volunteers into Phase I-II clinical research studies, where the safety of the study participants is our highest priority. We also ensure the delivery of robust proof-of-concept and efficacy signals to our sponsors.

MAC's Early Phase Unit is based in the heart of the Manchester Research Corridor, within the Manchester Foundation Trust's main site.

A look at our impressive MHRA-accredited unit

Our Early Phase Unit is a purpose-built facility with thirty-two beds for high-intensity safety monitoring arranged in four bays of eight beds, with security-controlled electronics controlling patient flow. Our nurses' station gives a full and uninterrupted view of bays, beds, and subjects, with each bed having a nurse alarm.

The EPU uses an advanced Mortara Telemetry system allowing us to monitor a patient's cardiac rhythm 24/7 and the capabilities to perform Ultrasounds, EEG and Spirometry.

We also have access to Manchester's science corridor, which provides additional facilities such as MRI, DEXA, and X-rays.

The subjects have a lounge to relax in, complete with an area to play tabletop and electronic games. We also have in-house catering and kitchen facilities for taking care of subjects and patients during their time in the Unit.

Patient well-being is our core priority

- Based within the grounds of Manchester Royal Infirmary with hospital resuscitation team support
- Highly trained and experienced Early Phase team
- Specialist techniques are in place including EEG, pharmacodynamic measures, lumbar punctures, and aseptic techniques to support complex procedures
- Specialist Equipment including Mortara Telemetry system and the LOGIQ E9 Ultrasound Imaging System
- GMP and aseptic facilities to support IMP preparation

Our site and study capabilities

We have conducted residential clinical research from our Manchester clinic for early-phase studies since 2008.

Since achieving MHRA accreditation status in 2016, we've gained vast experience in a range of areas including conducting studies involving ultrasound-guided injections, intra-articular temperature assessments, and CSF sampling.

Our EPU studies are First-in-Human (FIH) or involve dose escalation that adheres to our strict code of conduct and intricate procedures, which are MHRA-approved.

TYPES OF STUDIES

- FIH Safety & Tolerability
- SAD & MAD Dose Escalation
- Healthy Volunteer and Early Phase Patient
- Bioequivalence, Drug-Drug Interaction (DDI)
- Method Development
- Psychedelic Treatments

Psychedelic Suites

Our EPU facility includes specialised suites for psychedelic testing, including overnight capabilities, and experienced research staff fully trained in conducting studies of psychedelic treatments.

Our psychedelic testing suites provide an environment conducive to experiencing a safe and relaxed psychoactive experience, with:

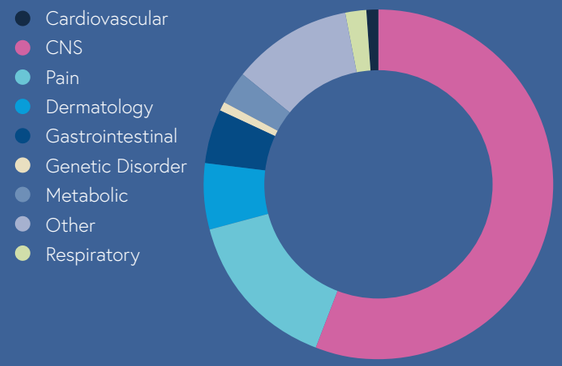
- Private rooms aligned with psychedelic/hallucinogenic research to minimise acute psychological distress.
- Psychiatrists and therapists certified to provide psychedelic treatments and monitor patients for psychological distress throughout the experience.

First-in-Human Studies

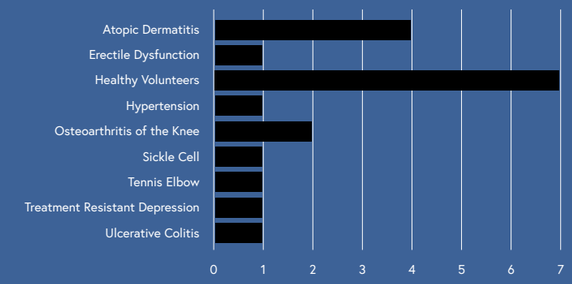
65%
of the studies conducted in our EPU have involved patients (vs. healthy volunteers)

We have conducted FIH studies in **cardiovascular, CNS, pain,** and **dermatology indications,** as well as in healthy volunteers. We also have experience with studies of **psychedelic treatments**.

EARLY PHASE STUDIES BY THERAPEUTIC AREA



FIRST-IN-HUMAN STUDIES



We go above and beyond to add value to and increase the effieciency of your studies

Case study

Integrated Study for a New Topical Eczema Treatment

- Cohort of 12 inpatient healthy volunteers to assess safety and tolerability data, followed by a cohort of inpatient eczema patients.
- Expansion to a cohort of 30 outpatient eczema patients to obtain longer-term efficacy data.
- Outcome: The investigational compound completed Phase I and II under a single protocol within 6 months, providing the client with enough information to sell the asset for further development.

Our experts
Our employees are our key strength

Our unit is approved by the Faculty of Pharmaceutical Medicine, as a training centre for physicians who are studying to become accredited FIH Investigators. We have a team of eight medics on-site in Manchester, highly experienced in clinical research.

All of our senior nurses have extensive experience in clinical research and are supported by a team of highly qualified clinical trial assistants. All clinical staff have an Intermediate Life Support qualification; many also have ALS status. Clinical research continues to become more scientifically complex and tightly controlled. Many studies involve 'umbrella' protocols: studies that combine FIH with First-in-Patient (FIP) studies. We have extensive experience in this area.

EPU Medical Leadership Team

Dr Aliya Asher
Chief Medical Officer

- Education Supervisor and member of Faculty of Pharmaceutical Medicine
- Certificate in Human Pharmacology
- 17+ years' experience in clinical trials
- 300+ studies, 100+ in early phase

Dr Ezanul Wahab
Principal Investigator

- MHRA-accredited FIH physician
- 10+ years' experience in Phase I studies
- 100+ SAD/MAD studies

Dr Giuseppe Fiore
Principal Investigator

- Certificate in Human Pharmacology
- 10+ years' experience in clinical trials including early phase
- 100+ studies as PI/CI

Dr Hamzah Malik
Assistant Director of Early Phase Research

- 6 years in clinical trials, 5 years in early phase
- Certified Principal Investigator - Association of Clinical Research Professionals
- 75+ clinical trials, mainly early phase

Supporting you across the research continuum

Our clinical and operational teams can provide scientific input into development strategies and protocols to help expedite clinical programmes.

WE ARE HIGHLY EXPERIENCED IN BOTH FIRST-IN-HUMAN AND FIRST-IN-PATIENT CLINICAL TRIAL RESEARCH

Our First-in-Human study experience	Our First-in-Patient study experience
• Pharmacodynamics • Integrated studies across healthy volunteers and patients • Proof of Concept • Proof of Mechanism • Medical Device	• Wet and dry biomarkers • Validated human models of disease in pain, migraine, inflammation, cognition, and diabetes • Complex scientific studies with advanced techniques such as Doppler imaging and CSF sampling • Euglycemic Glucose Clamp studies

Understanding patients, outreach, and recruitment

We can access and recruit patients as quickly as healthy volunteers, offering our sponsors a solution to the changing dynamics and needs within modern clinical pharmacology and early phase development. MAC helps clients gain proof of concept as an end-point in patients at the earliest opportunity.

MAC's patient outreach and recruitment programme, MAC EnVision®, and dedicated teams are solely focused on subject and patient communications using MAC's systems and internal databases, proprietary technologies (apps), community outreach strategies, social media, regular media and advertising, direct-to-patient correspondence, and other outreach methods.

Our team regularly reaches out across our established global provider and patient networks; MAC's Healthcare group works with over 285 GP surgeries and CCGs in our region to access patients.

Our study experience has enabled our teams to understand patients' journeys, needs, and motivations across different therapeutic and disease areas.

MAC's dedicated outreach and recruitment teams have unparalleled access to almost **35 million people living across the UK,** and approximately **7 million people near our EPU** in the Manchester area.

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

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 clinical and medical teams are experienced at managing even the most complex early- and late-phase studies, providing high-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.

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