



Fibromyalgia Research

MAC Clinical Research has extensive experience in fibromyalgia and chronic pain research, having conducted five fibromyalgia studies and more than 40 pain-related studies over the past five years. Our team understands the challenges associated with pain research and provides sponsors with scientific and operational expertise in the design and delivery of complex studies. Through the use of specialist pain assessments, human pain models and patient-focused study approaches, MAC provides solutions designed to optimise study delivery and accelerate pain research programmes.

Experience in Fibromyalgia

5

STUDIES

210

PARTICIPANTS

3

SPONSORS

Capabilities

We provide in-house, unique scientific solutions to accurately measure the efficacy of pain studies. These solutions are led by industry experts and include Pain Assessments and Human Models of Disease.

Techniques include

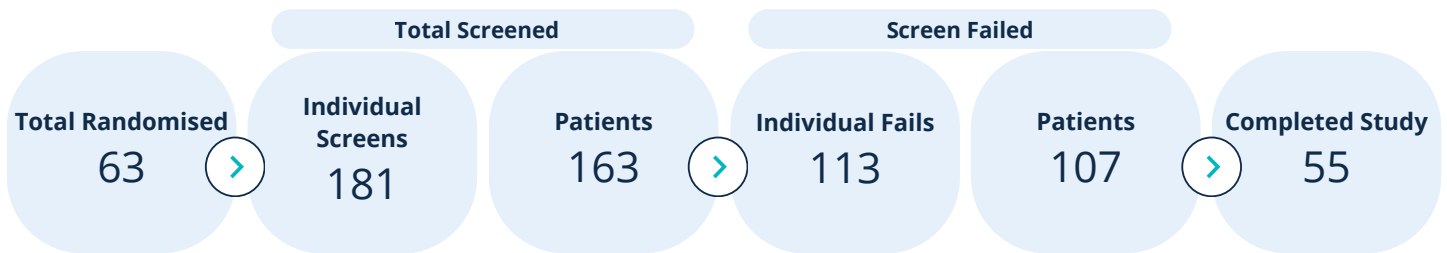
- Quantitative Sensory Testing (QST)
- Focused Analgesia
- Selection Test
- Nerve Conduction
- Pain Rating Scales
- Human Pain Models





Phase II Case Study

A Phase 2a proof-of-concept study assessing the efficacy and safety of the investigational drug in adult participants with severe fibromyalgia syndrome.



Recruitment Summary

The study was struggling due to a protocol requirement for participants to have completed 36 hours of a pain management programme



Sponsor agreed to remove this in March 2023



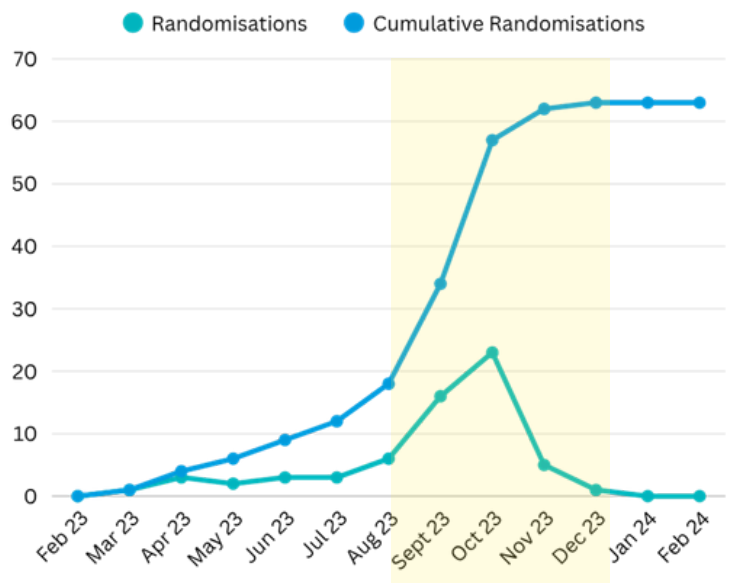
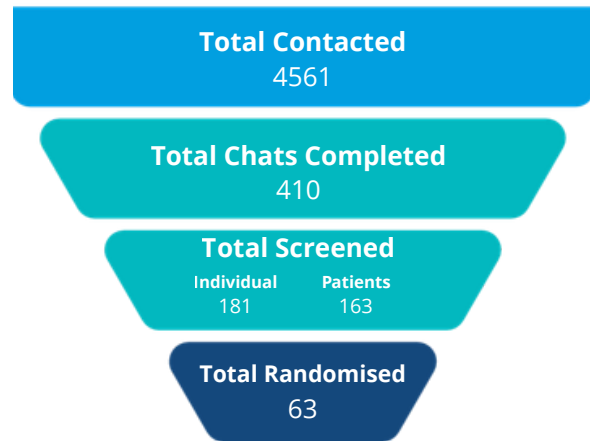
Resubmitted the protocol in April 2023



Received MHRA approval in August 2023



Enabled a sharp recruitment increase and completion two months ahead of the February 2024 forecast.

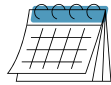




Who participated in the study?

63

PARTICIPANTS



Diagnosed at least 6 months before joining the study

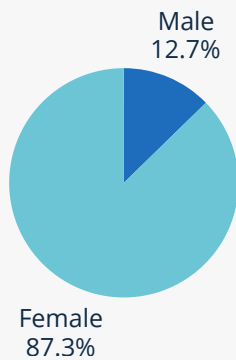
27-67

AGE RANGE

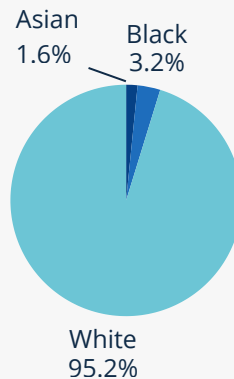


Pain that has significantly impacted their daily life

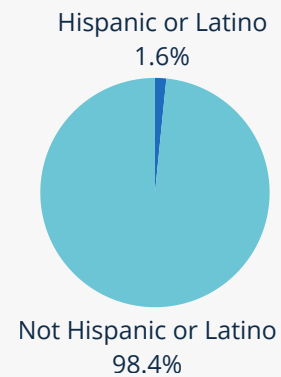
Sex



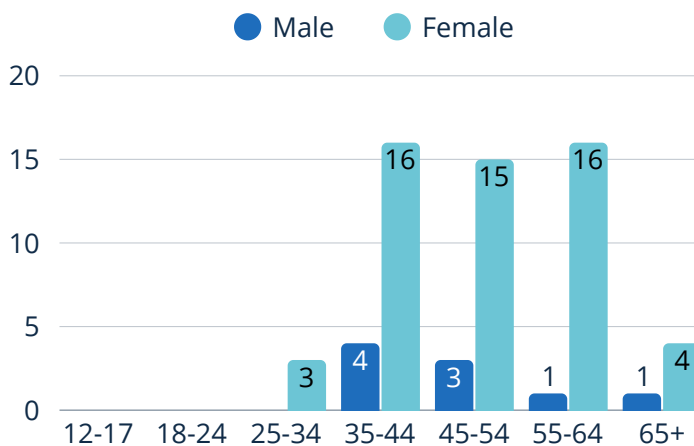
Race



Ethnicity



Participants: Age and Gender



MAC



"I wanted to take part in the clinical trial to help **develop knowledge** and **clinical outcomes** for practitioners and a reliable, **effective treatment** for my condition"

Tracy, Fibromyalgia Clinical Trial Participant





Study Location and Timelines

1 COUNTRY: UNITED KINGDOM



7 CLINICAL SITES



Participants who completed the study were enrolled for less than 9 months



Before study treatment
At least 1 site visit

During study treatment:
Up to 28 site visits

After study treatment
At least 1 site visit

Up to 1 month before starting study treatment

Approx. 7 months

Up to 1 month after completing study treatment

STUDY TIMELINE (NO OF MONTHS.)

TIMELINE



MAC completed the study within 19 months

MAC Clinical Research

- ✓ Over 30 years' experience in conducting clinical studies
- ✓ Full-service CRO with global reach
- ✓ 10 fully-owned research facilities in the UK
- ✓ Experts in healthy volunteer and patient recruitment



5-year summary

120+

SPONSORS

250+

STUDIES

50+

INDICATIONS

20+

FIH STUDIES

Our Services



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 and Endpoint Assessments

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

Clinical Procedures

Sleep Assessments

Psychodelics

Training



PHARMACEUTICAL SERVICES

GMP Manufacturing

In-House Pharmacy

Global Clinical Supplies

QP Services

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

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