

MAC: Driving Clinical Excellence

Psychedelic Research



We have specialised research facilities for psychedelic testing including overnight capabilities.



Many of our research staff are fully trained in conducting psychedelic studies.



We are experienced in a number of psychedelic and dissociative drugs.

Our expertise

- > Delivery of studies with complex designs and outcomes.
- Manufacturing (fully certified MIA (IMP) MHRA facility) and distribution of all classes of controlled substances with shipment globally (same day within the UK). MAC has 8 facilities with Schedule 1 licences.
- Expertise in different therapy areas including Major Depressive Disorder (MDD), Post-Traumatic Stress Disorder (PTSD), Treatment Resistant Depression (TRD), Generalised Anxiety Disorder (GAD) and Social Anxiety Disorder (SAD). In addition, we have extensive experience in conducting studies in psychedelic naïve and non-naïve healthy volunteers.
- Set and Setting is critical, all of our clinics provide an environment that is secure, safe, and relaxing.
 - Private rooms aligned with psychedelic/hallucinogenic research to minimise acute psychological distress.
 - Our psychiatrists, therapist and facilitators oversee psychedelic treatments and monitor patients for psychological distress throughout the experience.







Psychedelic Studies

WE HAVE CONDUCTED 15 PSYCHEDELIC & DISSOCIATIVE DRUG STUDIES

We have experience in:

- ✓ Ibogaine
- ✓ Psilocybin
- ✓ DMT/D3 DMT
- ✓ IV Psilocin
- ✓ Ketamine

- √ LSD
- ✓ D3 analogue of Psilocybin
- ✓ R-MDMA
- ✓ NMDA (R-enantiomer /racemic NMDA)

We are the first company to

- -Dose Ibogaine in a clinical environment in the UK
- -Dose 50mg Psilocybin
- -Dose Deuterated DMT (IV/IM)



CNS studies

Our experience in psychedelic research is complemented by our rich history and expertise in conducting CNS studies





Rater Capabilities and Experience

Safety Assessments CSSRS/BDS/S-STS

Semi-structured Interviews/Efficacy Assessments/Global and Clinical Outcome Assessments

MADRS/HAM-A/HAM-D/MMSE Cognitive Battery/PANSS/CDR CGI/CGI-S Hachinski Ischaemia

Diagnostic assessments MINI/SCID/NPI

Complex neuropsychiatric scales YBOCS/BABS/CAPS-5



Psychedelic Scales including Pharmacodynamics (PD)

- Drug Effects VAS (Visual Analog Scale)/SDI (Subjective Drug Intensity)/ Intensity Rating Visual Analogue Scale (IRVAS)
- 5-Dimensional Altered States of Consciousness Rating Scale (5D-ASC)
- Patient Education Session Manual (PESM)
- Mystical Experience Questionnaire (MEQ30)
- Polysomnography (PSG)
- Clinician-Administered Dissociative Symptoms Scale (CADSS)
- Profile of Mood States (POMS)
- Bond-Lader VAS (Mood Rating Scale)
- Drug Effects Questionnaire (DEQ)
- Addiction Research Center Inventory-49 (ARCI-49 item Brief Scale)
- Positive and Negative Symptom Scale Positive Scale (PANSS)
- Challenging Experience Questionnaire (CEQ)
- Blinding Integrity Questionnaire (BIQ)
- Scale for the Assessment and Rating of Ataxia (SARA)
- Ego Dissolution Inventory (EDI)
- Challenging Experience Questionnaire (CEQ)
- Short Opiate Withdrawal Scale of Gossop (SOWS-Gossop)

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- Objective Opiate Withdrawal Scale of Handelsman (OOWS-Handelsman)
- Drug History Questionnaire (DHQ)
- Addiction Severity Index (ASI)
- Heroin Craving Questionnaire Short Form 14 (HCQ-SF-14)
- Strassman Hallucinogen Rating Scale (HRS)
- Patient Elicitation Narrative of Ibogaine, and Prochaska Stages of Change (SOC)
- Spielberger's State-Trait Anxiety Inventory Trait Subscale (STAI-T)
- Warwick-Edinburgh Mental Well being Scale (WEMWBS)
- Post-treatment Changes Scale (PTCS)
- Psychedelic Predictor Scale (PPS)
- Dysfunctional Attitude Scale (DAS)
- Ruminative Responses Scale (RRS)
- Social Connectedness Scale Revised (SCC-R)
- Psychological Insight Scale (PIS)
- Emotional Breakthrough Inventory (EBI)
- Ecological momentary assessments (EMAs)/Face emotion recognition task (FERT)/ Reward functioning



Our Medical and Scientific Experts



Dr Aliya Asher Chief Medical Officer



Dr Shoona Vincent VP, Clinical Science



Dr Sandosh Gnanalingam Psychiatrist

Our people are one of our key strengths, equipped with a diverse range of experience and skill-sets. Our experts provide deep knowledge and understanding of conducting psychedelic research.

We have:

- > Psychiatrists with experience in psychedelics
- > In-house psychologists
- > Attendants/Facilitators/Dose Session Monitors
- > Psychotherapists
- > Dedicated Clinical Rating Specialists
- > Registered nursing staff
- > Assistant Psychologists/Psychedelic Attendants



Our specialist team treat participants with compassion and empathy with the ability to reduce anxiety and distress



We provide training & support programs both nationally and on a global scale

Case Study

MDD population treated with an oral psychedelic Conducted at Psychedelic Centre of Excellence in Liverpool

Study Outcomes

- 57 participants screened, 17 randomised
- This study saw a huge response in participants with many people willing to travel significant distances to take part. This demonstrates that national interest in psychedelics within the UK is fast approaching the same scale as the US.



Participant Motivations

Healthy Volunteers

- Monetary incentive
- Support development of new treatments
- Curious about psychedelics

Patients

- Support development of new treatments
- Open to exploring treatment through psychedelics

MAC Clinical Research





Full-service CRO with global reach

10 fully-owned research facilities in the UK

Experts in healthy volunteer and patient recruitment



120+ **SPONSORS**



STUDIES

50+ **INDICATIONS**

20+ **FIH STUDIES**

more information

Our Services HΟ CLINICAL RESEARCH PHARMACEUTICAL **SITE & PATIENT SCIENTIFIC STRATEGIC** SERVICES SERVICES SOLUTIONS SERVICES CONSULTANCY **Project Management** Participant Recruitment Human Models of Disease **GMP** Manufacturing Therapeutic Area Expertise & Study Development **Clinical Operations** Scientific and In-House Pharmacy Participant Retention **Endpoint Assessments Scientific Solutions** Site Monitoring Site Management **Global Investigator Sites Global Clinical Supplies** Cardiovascular Assessments & Pharmacodynamics Trial Feasibility Cognitive and Neuropsychological Network of Fully-Owned QP Services Assessments **Clinical Science** Investigator Sites Pharmacovigilance Dermatology Assessments & Development IMP Management & Distribution Sleep Laboratory Imaging Assessments **Regulatory Affairs** Early Phase Unit Medical Strategy, Neurophysiology Assessments **Controlled Drug Services** Psychedelic Testing Suites Phase I - IV Research Facilities Pain Assessments Input & Expertise **Biometrics** Other Assessments Laboratory Services **FDC** Memory Assessment Research Centre Statistical Analysis, Data Management Clinical Pathology **Clinical Procedures** Planning & Advice **Bioanalytical Services** SAS Programming Biostatistics Sleep Assessments Medical Writing Medical Writing Psychedelics Laboratory Study Design, Vendor Management Methods & Conduct Training Randomization and Trial **Supply Management Digital Solutions** Electronic Patient-Reported Outcomes (ePRO) Visit macplc.com for Follow us on social

eConsent **Medical Monitoring**