

# Psychedelic Research



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



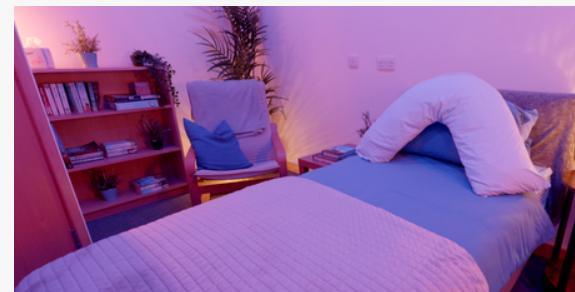
Many of our research staff are fully trained in conducting psychedelic studies.



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), AND Generalised Anxiety Disorder (GAD). 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

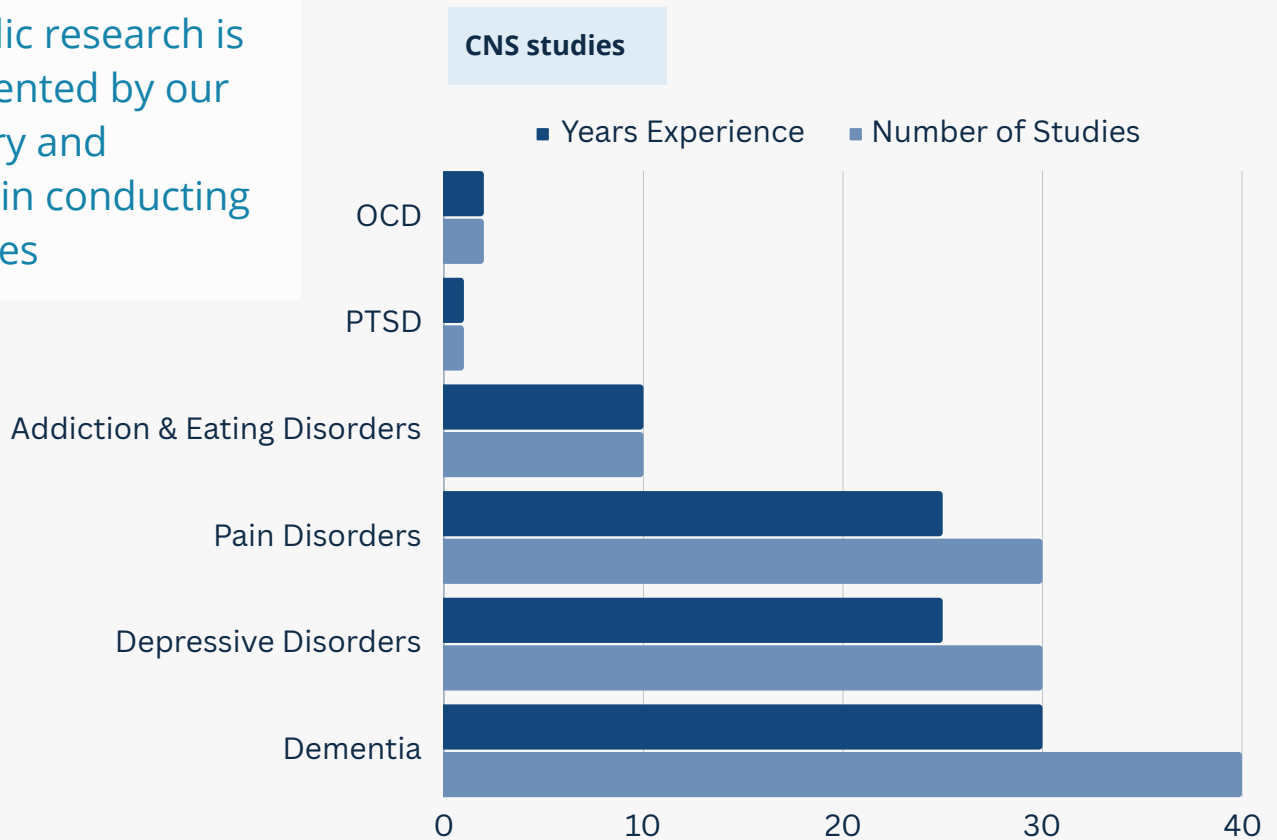
WE HAVE CONDUCTED **14** PSYCHEDELIC & DISSOCIATIVE DRUG STUDIES

**We are proud to be the first company to**



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

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 David Gregory**  
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 psychologist
- 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**

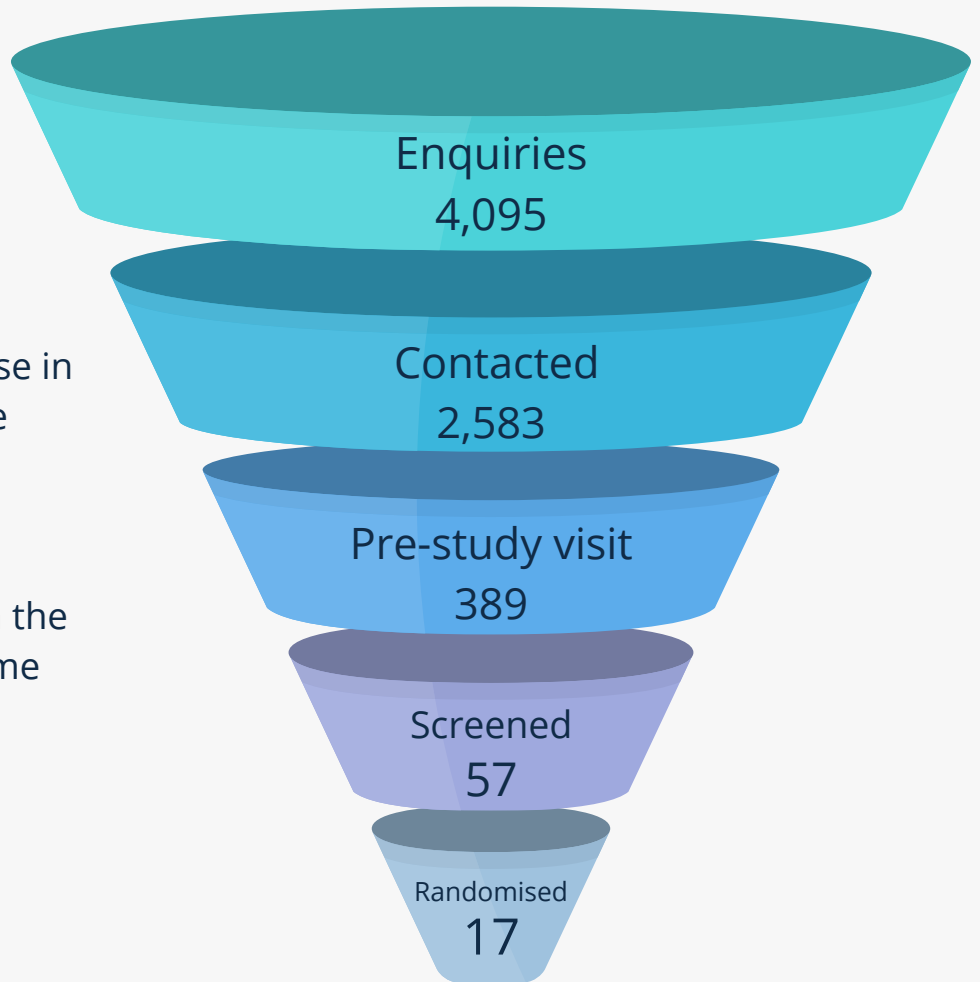
## Case Study

### 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

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



## 3-year summary

**120+**

SPONSORS

**230+**

STUDIES

**40+**

INDICATIONS

**19**

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
- 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**

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