Hammersmith Medicines Research (HMR) and P1vital collaborate on early phase clinical studies. The outstanding phase 1 experience and facilities of HMR together with the unique CNS experimental medicine expertise and capabilities of P1vital provide a comprehensive solution for early assessment of the safety and potential efficacy of novel CNS compounds.

**Central nervous system drugs**

Since 1993, HMR has done over 730 phase 1 studies, over 200 of which involved compounds with central nervous system (CNS) activity. Many of the studies were first-in-man.

We have experience of a wide range of procedures to assess novel CNS compounds, such as:

- psychomotor tests;
- coordination tests;
- sleep and polysomnography
- ataxiameter;
- body sway;
- erythrocyte cholinesterase activity;
- cognitive function assessment, using a computerised system, such as CDR and Cogstate;
- scopolamine model of dementia;
- saliva flow rate;
- pain models;
- saccadic eye movements;
- critical flicker fusion frequency threshold;
- digit span;
- EEG, with interpretation by consultant neurologist;
- PET, with Imanova, Hammersmith Hospital;
- SPECT, with UC Hospital;
- fMRI, with Imanova, Hammersmith Hospital or Institute of Psychiatry, King’s College Hospital;
- clinical questionnaires, eg POMS, CSSRS, AIMS, Simpson-Angus, Barnes ARS, TFEQIII, BDI and HRS;
Hammersmith Medicines Research

- simple and choice reaction times;
- visual analogue rating scales;
- tyramine challenge tests, to assess MAO-B inhibition; and
- 5-HT$_{1A}$-receptor mediated function tests.

**Types of molecule**

Types of molecule that we’ve studied include:
- dopamine receptor antagonists;
- cannabinoid-1 receptor inverse agonists;
- MAO-B inhibitors;
- anti-convulsants;
- anti-psychotics;
- anti-depressants;
- cholinesterase inhibitors;
- histamine H$_3$-receptor antagonists;
- histamine H$_1$-receptor antagonists;
- 5-HT$_{1A}$ receptor agonists;
- benzodiazepine analogues; and
- GABA inverse agonists.

**Collaboration with P1vital**

P1vital provides a unique range of products and services in CNS experimental medicine to enable client companies to more effectively manage their risk and investment in CNS drug development. The P1vital team has extensive expertise in all aspects of CNS drug discovery and development. This enables P1vital to offer their clients customised experimental medicine solutions including:

- Consultancy and study delivery services to enable clients to assess the clinical efficacy of their early phase CNS development compounds;

- P1vital® Oxford Emotional Test Battery (ETB), a product that can be used to assess antidepressant efficacy from Phase 1 MAD studies in healthy volunteers to Phase 2 POC studies in patients.

P1vital has an expanding portfolio of efficacy biomarkers for anxiety, depression, schizophrenia, cognitive disorders and obesity including:

- Depression: P1vital® Oxford ETB;
- Depression: pharmacological fMRI;
- Anxiety: CO₂ inhalation;
- Schizophrenia: pharmacological fMRI;
- Schizophrenia: bi-conditional learning;
- Schizophrenia: eye tracking;
- Cognitive disorders: Arena & Platform fMRI tasks;
- Obesity: universal eating monitor.

P1vital is expanding its portfolio of validated CNS efficacy biomarkers through a pre-competitive consortium agreement with AstraZeneca, GlaxoSmithKline, Lundbeck, Organon (a subsidiary of Merck) and Pfizer.

P1vital has established collaborations with internationally renowned opinion leaders in psychiatry, neuroscience and obesity, linked through a network of university hospitals and clinical research facilities within the UK. Through its network of key opinion leaders P1vital provides:

- Translational tools for making more rapid and effective decisions in Phase 1 and Phase 2 clinical development of drugs for CNS disorders and obesity;
- Innovative clinical science in collaboration with its university research teams;
- Synergy through combining CNS drug discovery and development expertise with the strong clinical science base in the UK;
- Expertise in clinical project and quality management to recognised industry and regulatory standards.

To discuss your needs, please contact:

Malcolm Boyce, Managing Director
mboyce@hmrlondon.com
020 8961 4130

Hammersmith Medicines Research
Cumberland Avenue
London NW10 7EW UK
Some HMR and P1vital publications


