

# IMPERIAL

## Clinical Project Manager in Neuropsychopharmacology and Experimental Medicine

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| <b>Department/Division/Faculty:</b>          | Division of Clinical Neurology, Department of Brain Sciences                                                                                                                                                                                                                                                                                                                                                                                 |
| <b>Campus/Location:</b>                      | Hammersmith Campus ( <a href="#">East Acton</a> ) and <a href="#">White City Campus</a>                                                                                                                                                                                                                                                                                                                                                      |
| <b>Job Family/Level:</b>                     | Professional Services Level 3b ( <a href="#">Salary scales</a> )                                                                                                                                                                                                                                                                                                                                                                             |
| <b>Responsible to:</b>                       | Dr Gregory Scott                                                                                                                                                                                                                                                                                                                                                                                                                             |
| <b>Line management for:</b>                  | N/A                                                                                                                                                                                                                                                                                                                                                                                                                                          |
| <b>Key working Relationships (Internal):</b> | Study team members, including Dr Gregory Scott (Chief Investigator), Dr David Erritzoe (Co-Investigator), Professor Paresh Malhotra (Co-Investigator), study researchers; Research, technical and administrative staff involved in the Centre and the Department; Clinical and operational staff within the Imperial Clinical Research Facility (Imperial Healthcare NHS Trust); The Imperial Research Governance and Integrity Team (RGIT); |
| <b>Key Working Relationships (External):</b> | Study team clinical and non-clinical collaborators (including Dr Lloyd Bradley, Dr Damon Hoad, Prof Robin Carhart-Harris, Dr Chris Timmerman); Recruitment partners at NHS and non-NHS organisations (e.g., The Royal Hospital for Neurodisability, Putney); Study PPI advisory group                                                                                                                                                        |
| <b>Contract type:</b>                        | Part-time (50% FTE), and fixed-term until 31 March 2030                                                                                                                                                                                                                                                                                                                                                                                      |

### Background

This post is part of an exciting Medical Research Council (MRC)-funded Experimental Medicine study, “N,N-Dimethyltryptamine (DMT) for Disorders of Consciousness (DoC)” (DMT-DoC). In people with DoC, this study

will investigate the effects of intravenous DMT on measures of neural complexity, neuroplasticity, and awareness. The study aims to pave the way to a new class of treatment for DoC, increase our understanding of the neural mechanisms of consciousness, and inform the design of clinical trials.

This post will be based within the Division of Neurology (Department of Brain Sciences) with direct line management provided by Dr Gregory Scott. The post holder will primarily be working on the DMT-DoC study. This placebo-controlled study involves administering intravenous DMT and a saline placebo to patients with DoC. We will record electroencephalography (EEG) alongside other physiological and behavioural measures before, during, and after drug/placebo administration. This study will be hosted by the Imperial Clinical Research Facility, recruiting participants from NHS and non-NHS units. The post holder will work closely with the Research Governance and Integrity Team (RGIT) at Imperial College to ensure that the regulatory, legal and quality control aspects of the study are met.

## Purpose of the Post

The post holder will be responsible for all aspects of study management. Duties will include leading on the development of study documentation, regulatory submissions, monitoring progress and performance of the study and recruitment from participant identification centres, ensuring efficient recruitment and reliable data collection. This will be achieved through implementing / adapting established procedures to ensure the study is conducted in accordance with contractual agreements, study protocol, study-specific processes and systems, SOPs, regulatory and ethical requirements and GCP guidelines, as well as delivered to time and within budget constraints.

The post holder will liaise closely with the study team and participant-facing staff including the Post-doctoral Research Associates and Research Assistants. The post holder will also support coordination of patient and public involvement and engagement (PPIE) and study monitoring activities, and attracting further research funding to the group. This is a key post that will help ensure that the study is delivered on-time according to projected milestones, and is conducted to the highest scientific, ethical and regulatory standards. Furthermore, the post holder will also support other work within the group.

## Key Responsibilities

### *Study Management and Monitoring*

- Be responsible for all coordination, administrative activities, and data management to ensure the efficient running of the study.
- Ensure that the study is conducted in compliance with protocol, overall clinical objectives, Good Clinical Practice (GCP) and SOPs, and is run according to agreed timelines.
- Initiate, establish and maintain good communication between all key stakeholders e.g. study team, RGIT, funder, academic collaborators and staff at participating sites.
- Implement the principles of GCP for clinical studies and ensure that all study personnel work according to them.
- Prepare or assist with applications for initial approvals and ensure on-going adherence to the requirements of the regulatory bodies i.e. NHS Research & Development, Medicines and Healthcare products Regulatory Agency (MHRA) and Research Ethics Committee (REC), and submit amendments as appropriate.

- Maintain study records including the Study Master File.
- Contribute to the development of all study documentation, including Study Protocol, Patient/Consultee Information Sheet, Consent Form, GP letter and any other study materials as appropriate.
- Oversee effective and efficient recruitment within the study.
- Work together with other members of the group to ensure that data collection systems are provided in a timely way and work efficiently.
- Develop and implement comprehensive procedures for timely and clear reporting of study status including progress and recruitment rates.
- Ensure compliance with Schedule 1 Misuse of Drugs Regulations (Home Office) under the terms of the study-specific license, with support from license holder and delegated individual.
- Liaise with pharmacies/manufacturers and ensure timely supply of investigational drug to site.
- Ensure the necessary, regulatory compliant, procedures and documentation are in place for the procuring, receipt and distribution of drug/placebo to sites and that drug accountability takes place.
- Co-develop standard operating procedures (SOPs) for the initiation and coordination of the study.
- Set up the study sites and conduct initiation visits as required.
- Develop systems to monitor recruitment, retention and adherence rates.
- Liaise with participant identification centres and other partner sites to implement mitigation strategies for under-performance, as appropriate.
- Develop a risk-based monitoring plan and conduct central, remote and on-site monitoring visits, according to the plan and in line with the study risk assessment.
- Write monitoring visit reports and ensure action points are followed up with sites in a timely manner.
- Ensure necessary reporting of adverse events, expedited SAE/SAR/SUSAR, reporting and submission of Annual Safety Reports.
- Coordinate and support the activities of the Study-related meetings e.g. Project Management Group, Safety Review Group, Study Steering Committee meetings.
- Review and sign off on site initiation, monitoring and close out reports produced by the Study Monitor.
- Manage timely and efficient procedures for collection, entry and monitoring of study data.
- Conduct site close out visits and ensure appropriate plans for archiving are in place.
- Provide cross-study cover within the team as required.
- Assist in preparation of presentations and publications.
- Assist with the preparation and conduct of inspections and internal audits.
- Write, maintain and adhere to SOPs for the studies (e.g. collection, transportation and storage of blood samples) to ensure compliance with regulatory requirements.
- Keep up to date a tracking system for participant visits.

## *Data Management*

- Together with the study team develop and maintain the study database.
- Manage timely and efficient procedures for collection, computer entry and verification of all participant data, raising queries for missing or incomplete data as appropriate.
- Ensure quality and completeness of data using appropriate quality control measures.
- Assist in the production of written reports as required by the Sponsors and CI.
- Submit accrual figures to relevant groups.

## *Finance & Contracts*

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- Monitor study finances, reviewing expenditure against budget and ensure adherence to terms of all relevant contracts in collaboration with the Co-Investigators and Chief Investigator.
- Oversee payments made to e.g., investigators, partner study sites, suppliers, and assist with development of payment / tracking systems to ensure accountability.
- Monitor contractual arrangements (including the development of new contracts) with outside organisations e.g. non-NHS organisations as required.

## *General*

- Undergo any training deemed to be necessary for the full execution of study duties.
- Train site staff in study documentation, record keeping and regulations.
- Liaise with other team members to assist with the smooth running of relevant studies and to ensure support for other associated staff as necessary.
- Represent the team at meetings as required.
- Be familiar with the relevant clinical literature and keep up-to-date with literature relating to clinical research / study methodology.
- Willingness to work out of normal working hours (including weekends) if the requirements of the project demand.
- Observe and comply with all College policies and regulations, including the key policies and procedures on Confidentiality, Conflict of Interest, Business Continuity, Data Protection, Equal Opportunities, Ethics related, External Interests, Financial Regulations, Health and Safety, Imperial Expectations (for new leaders, managers and supervisors), Information Technology, and Smoking.
- Perform any other duties which may be required that are consistent with the nature and grade of the post as required by the Chief Investigator and/or line management.

## *Other Duties*

- To assist with general study activities
- To assist with general group activities
- To attend relevant meetings
- To undertake appropriate administration tasks
- To undertake any necessary training and/or development
- Perform any other duties which may be required that are consistent with the nature and grade of the post as required by the Chief Investigator, or Head of Division/Department

Where Imperial or funder conditions necessitate, you will be required to complete timesheets for your work on projects in a timely manner.

## Person Specification

| Requirements                                                                                                         | Essential (E)/<br>Desirable (D) |
|----------------------------------------------------------------------------------------------------------------------|---------------------------------|
| Candidates/post holders will be expected to demonstrate the following:                                               |                                 |
| <b>Education</b>                                                                                                     |                                 |
| An undergraduate level degree in science or relevant professional experience in the science and/or university sector | E                               |
| A post-graduate degree (MSc/MRes/MBA/PhD) in Neuroscience/Psychology or related discipline                           | D                               |

## Experience

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| Proven clinical trial/project management experience gained in experimental medicine, phase II and/or phase III randomised trials of an investigational medicinal product.                                                                                                               | E |
| Proven experience of conducting experimental medicine studies/clinical trials of Investigational Medicinal Products (CTIMP), including data collection                                                                                                                                  | E |
| Experience of working with patients with a neurological or mental health disorder                                                                                                                                                                                                       | D |
| Proven experience of coordinating addiction-related and/or psychedelic studies or those involving Schedule I drugs                                                                                                                                                                      | D |
| Working knowledge of the current EU Clinical Trials Directive, Medical Device Directive, UK Clinical Trials regulations, Principles of GCP, Data Protection Act and Research Governance Framework legislation and proven ability to apply these to the coordination of clinical studies | E |
| Evidence of preparing regulatory and ethics submissions, writing/amending protocols, patient information sheets, case report forms (CRF) /electronic CRF, and other relevant trial management documentation.                                                                            | E |
| Evidence of strong IT literacy (e.g., MS Office and OpenClinica)                                                                                                                                                                                                                        | E |
| Experience of data entry and data management processes using electronic CRF                                                                                                                                                                                                             | E |
| Evidence of familiarity with Home Office regulations for Schedule I drugs                                                                                                                                                                                                               | D |
| Experience of working within the NHS or academic clinical research setting                                                                                                                                                                                                              | D |
| Evidence of basic understanding of the Human Tissue Act.                                                                                                                                                                                                                                | D |
| Demonstrated success in the management of study budgets                                                                                                                                                                                                                                 | D |
| Experience in recruitment of patients e.g. liaison with consultees/recruitment partners                                                                                                                                                                                                 | D |
| Evidence of managing projects, ensuring delivery according to schedule, budgetary and governance requirements                                                                                                                                                                           | D |
| Experience of financial management, including the ability to manage large budgets                                                                                                                                                                                                       | D |

## Skills & Abilities

|                                                                                         |   |
|-----------------------------------------------------------------------------------------|---|
| Strong motivational skills                                                              | E |
| Proven ability to organise and prioritise workload to meet deadlines                    | E |
| Evidence of ability to work independently as well as part of a team                     | E |
| Evidence of effective communication, negotiation, presentation and interpersonal skills | E |

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| Ability to work accurately and methodically with meticulous attention to detail                                                            | E |
| Proven excellent organisational and time management skills to effectively handle conflicting priorities and ensure tight deadlines are met | E |
| Willingness to work flexibly outside of office hours on occasion e.g. for travelling to and from sites                                     | E |
| Willingness to undergo any training deemed to be necessary for the full execution of trial duties                                          | E |
| Discipline and regard for confidentiality and security at all times                                                                        | E |
| Willingness to take part in public engagement and media engagement                                                                         | E |

## Further Information

Please note that job descriptions cannot be exhaustive, and the post-holder may be required to undertake other duties, which are broadly in line with the above key responsibilities.

[Our values](#) are at the root of everything we do and everyone in our community is expected to demonstrate Imperial:

- Respect
- Collaboration
- Excellence
- Integrity
- Innovation

Employees are also required to comply with all Imperial policies and regulations.

We are committed to equality of opportunity, to eliminating discrimination and to creating an inclusive working environment for all. We encourage candidates to apply irrespective of age, disability, marriage or civil partnership status, pregnancy or maternity, race, religion and belief, gender reassignment, sex, or sexual orientation. You can read more about our commitment [on our webpages](#).

Imperial is a proud signatory to the San-Francisco Declaration on Research Assessment (DORA), which means that in hiring and promotion decisions, we evaluate applicants on the quality of their work, not the journal impact factor where it is published. For more information, see <https://www.imperial.ac.uk/research-and-innovation/about-imperial-research/research-evaluation/>

Imperial believes that the use of animals in research is vital to improve human and animal health and welfare. Animals may only be used in research programmes which are ultimately aimed towards finding new treatments and making scientific and medical advances, and where there are no satisfactory or reasonably practical alternatives to their use. Imperial is committed to ensuring that, in cases where this research is deemed essential, all animals in our care are treated with full respect, and that all staff involved with this work show due consideration at every level. [Find out more about animal research at Imperial](#).

**[October 2026]**