MAC Clinical Research

JOB DESCRIPTION

NAME:

JOB TITLE: CLINICAL RESEARCH PHYSICIAN

REPORTS TO: Medical Director

FOCUS OF THE JOB: *To fulfil the role of Sub-Investigator and Principal Investigator in sponsor research studies at MAC centres, responsible for conduct of clinical trials in compliance with protocol and GCP ,safety of trial subjects and integrity of trial data.*

KEY SKILLS, KNOWLEDGE AND QUALIFICATIONS REQUIRED:
Full and current GMC registration (essential)
4 years post-graduation experience (essential)
MRCP /MRCGP/MRCPsychiatry (desirable)
Pharmaceutical experience (desirable)
Background in old age psychiatry (desirable)

RESPONSIBILITIES
Clinical activities:

- Fulfil the role of Sub Investigator / Principal Investigator in sponsor research studies at the Centre, as necessary
- Ensure safety and provision of adequate medical care for trial subjects
- Ensure trial related procedures are completed in accordance with ICH-GCP guidelines and in compliance with the protocol
- Make important trial related decisions in consultation with Principal Investigator/Medical Director
- Ensure that Serious Adverse Events/Adverse Events are reported in accordance with ICH GCP guidelines and inform GPs as appropriate
- Assess and review memory clinic patients(only applicable to sites where company operates memory clinics)
- Give feedback on patients' suitability and review telephone screening documents
- Conduct pre-screening chats and assess the suitability of patient
- Review medical records of potential study patients
- Assist with study visits , including taking informed consent, physical examinations and other clinical duties
- Ensure that study documentation is completed, signed off, and actioned, as appropriate
- Review medical reports and lab results etc
- Assist clinical staff members in other clinical activities as required
- Provide on call care or post dosing care to patients as required

- Perform emergency care as appropriate
- Spend adequate time with Clinical Research Associates on monitoring visits
- Ensure timelines for data queries are achieved
- Be available for study close out visits

Management:

- Review draft protocols and Investigator brochures
- Assist in writing Patient information sheets and other documents requiring submission to ethics
- Assist in preparation of feasibility reports for potential projects
- Assist project management group in completion and submission of ethics documents/IRAS
- Attend ethics committee meetings at which MAC studies are under review
- Attend investigator meetings, initiation meetings and Pre Study Site Selection Visits
- Review and draft source documents
- Participate in sponsor and regulatory audits as required
- Arrange , chair and participate in regular meetings with colleagues and customers
- Regularly educate the team (clinical or recruitment) on essential medical information and protocols

Leadership

- Initiate changes in working practices
- Provide practical help and guidance to other staff
- Instil confidence in patients, customers and colleagues
- Provide practical solutions for problems in new studies and new disease areas, supporting colleagues through these difficulties
- Motivate, encourage and train Research Nurses , Research Co-ordinators and Clinical Trials Assistantsto accept a broader role

Commercial Awareness and Contribution to Targets

- Work with Medical Director to drive and exceed targets
- Maintain an awareness of our key customers and market competitors
- Actively seek information about new studies and competitors and share with colleagues
- Be proactive in implementing Company strategy and plans

Professional development

- Maintain a professional attitude and appearance at all times to customers/colleagues
- Ensure that GMC requirements for revalidation are met appropriately to retain license to practice
- Keep abreast of medical literature

- Identify opportunities for self-development ARCP and Dip Pharm Med

Recruitment:

- Develop recruitment strategy with Recruitment team
- Maintain awareness of chat and screen fails and patient drop out rates, taking appropriate corrective action
- Keep up to date with study status, ensuring each stage optimised
- Establish and maintain relationships with local GPs (and consultants) and service providers

Patient and customer care

- Respond to patients' concerns – procedures, new drugs
- Deal with patient complaints in accordance with Company SOP procedure

General:

- Identify priorities; bring issues to the attention of colleagues for the smooth running of the centre.
- Present a positive image if MAC Clinical Research to all external individuals and bodies.
- Set a positive example to all colleagues.
- Share experience and knowledge with colleagues as appropriate and in an appropriate manner.
- Compliance with MAC health and Safety policy
- Compliance with MAC policy on equality and diversity
- To work to the requirements of SI 2004 no 1031 and amendments thereof, which includes Good Clinical Practice
- To work according to MAC SOPs, guidelines and policies
- To work according to current data protection standards and practice good information management. Maintenance of strict confidentiality of patient and business related data.
- To maintain a high level of initiative and personal responsibility, liaising appropriately with team members and managers to ensure your job role is efficiently carried out
- To support the aims of MAC and to represent MAC appropriately in a professional way to all our customers

PHYSICAL, WORK ENVIRONMENT, TRAVEL DEMANDS: *Be available to provide cover for other sites where necessary (for example due to illness or holidays.*

LIMITATIONS AND DISCLAIMER

The above job description is meant to describe the general nature and level of work being performed; it is not intended to be construed as an exhaustive list of all responsibilities, duties and skills required for the position.

Employees signature…… Date…….

Head of Department signature…….. Date…….