POSITION DESCRIPTION

Position Title: Clinical Trials Coordinator
Employer: Baker IDI
Department: Preventative Health
Division: Population Studies and Profiling
Supervisor/Manager: Ms Karen Best, Clinical Trials Project Manager

Date: 11 September 2009

Baker IDI Heart and Diabetes Institute was established in 2008 following the merger of the Baker Heart Research Institute and the International Diabetes Institute. Baker IDI is the nation’s first multi-disciplinary organisation tackling the deadly trio of obesity, diabetes and cardiovascular disease through research, education and patient care.

SUMMARY OF POSITION:
The Clinical Trials Assistant will work on the VIPER-BP study. This study is national, randomised clinical trial assessing a structured management of blood pressure in primary care to determine its safety and efficacy in respect to individualised blood pressure targets. The study aims to recruit 250 general practitioners (GPs) and more than 2,500 patients with hypertension.

The person will work closely with the Clinical Trial Project Manager (based in Adelaide) and the Preventative Health team (based in Melbourne) to implement the study efficiently by providing high level administrative and project support to participating GPs, practices and the study team. The person will be managing study documentation and databases, GP liaison, communication and logistics. This is a complex, high profile project for Baker IDI and its partners, Novartis and Trident. The successful applicant will require excellent organisational and communication skills, and experience in research or clinical trials administration.

STRUCTURE OF DEPARTMENT:
Preventative Health's primary goal is to understand and then respond to the drivers of preventable forms of diabetes and cardiovascular disease with a particular focus on vulnerable individuals and communities; including those from lower socio-economic backgrounds, regional and remote communities, the Indigenous population and communities in low-to-middle income countries in epidemiologic transition.

In order to achieve this goal, the group undertakes a combination of population studies, community screening programs and appropriately powered randomised studies combining advanced risk delineation and disease management. A key goal is to develop cost-effective interventions that translate into real-life.

Preventative Health is currently running the VIPER-BP Study of structured management of blood pressure in primary care to determine its safety and efficacy in respect to individualised blood pressure targets. The study aims to recruit 250 General Practitioners and more than 2,500 patients with hypertension.

NATURE OF ENVIRONMENT:
Baker IDI is an independent, private, not-for-profit research organisation engaged in a broad range of scientific, research, service delivery and revenue-raising activity. It is a project-oriented environment, encompassing a local and multi-site (including interstate) organisational structure. Composition of staff comprises mainly specialist...
scientific personnel engaged in the capacity of permanent, grant specific and casual employment. The South Australian Office is recently established (January 2009) and will grow steadily over the next two years. The VIPER-BP study is deadline driven and has significant targets to reach within tight timelines. There must be rigorous attention to detail by all team members.

SUPERVISORY RESPONSIBILITIES:
Work with support, guidance and/or close direction from the VIPER-BP Project Manager and the wider VIPER-BP Operational Committee team members at Baker IDI. No supervisory responsibilities.

KEY CONTACTS:
Internal:
The successful applicant will work closely with the Clinical Trial Project Manager, Head of Preventative Health and the Preventative Health Team in Melbourne. The General Manager (SA), and other academic and project staff are also based in the Adelaide office.

External:
The external contact will be with practice managers, practice nurses and general practitioners in general practices throughout Australia. There may also be liaison with Trident Research organisation who have been contracted to perform clinical monitoring of the study and Novartis, the industry sponsors of the study. Other external contacts will be with suppliers of goods and services to the project.

TRAVEL REQUIREMENTS:
As required: Local travel, possible interstate travel as required.

KEY JOB REQUIREMENTS AND RESPONSIBILITIES & DUTIES
As requested by the Clinical Trial Project Manager:

1. Assist with recruitment and support of general practitioners and patients
   - Liaise with general practice clinics, either through practice managers, practice nurses or directly with GPs, to ensure they have appropriate information, answers to any queries and understand the requirements of the study
   - Establish the administrative systems to support recruitment and compliance to the protocols by general practices
   - Assist in design of information materials to ensure GP Investigators remain informed about study progress i.e. newsletters, web page.
   - Assist the Clinical Trial Project Manager with promotional activities to recruit new practices as necessary to fulfil the quota of patients

2. Establish and maintain administrative systems and processes
   - Establish document management (filing) systems in soft and hard copy to track communication and recruitment of GPs
   - Establish a financial system to track reimbursement payments to GPs

3. Provide support for reporting and communication
   - Assist the Clinical Trial Project Manager with regular reporting to the VIPER-BP Operational Committee and the study sponsor (Novartis) to inform of progress and activities relating to the study
   - Assist the Clinical Trial Project Manager to liaise with the VIPER-BP Clinical Safety and Efficacy Committee
- Work closely with the Data Management Team in Melbourne to ensure all efficient and effective management of data generated by the study
- Submission of protocol amendments to ethics committee

4. General Administration
- Process and track study related expenses
- Assist with arrangements for teleconferences and meetings, including venue hire, catering and transport if required
- Assist with mail outs and couriering of supplies as required

MEET STATUTORY REQUIREMENTS OF THE COMPANY:
Maintain up to date and accurate knowledge in:
- OH&S legislation
- EEO Legislation
- Privacy Legislation
- Confidential Information Policy
- Baker Medical Research Institute Code of Conduct
- Australian Code for the Responsible Conduct of Research
- Baker IDI Intellectual Property Agreement

PROBLEM SOLVING COMPLEXITY:
- Determination of appropriate communications strategies to a wide range of people, including those at senior level within general practices and the study sponsor organisation
- Establishment and maintenance of systems tailored to the needs of the project
- Ability to handle most queries, but able to effectively determine whether it requires senior involvement
REQUIREMENTS OF POSITION HOLDER

QUALIFICATIONS:

Essential
Required to perform duties at skill level which assumes and requires knowledge or training equivalent to:
- Completion of a degree or higher relevant qualification, with significant relevant work experience; or
- Extensive experience in a broadly focussed specialist position; or
- An equivalent combination of relevant experience and/or education and training

EXPERIENCE:
Essential
- Previous experience in clinical research and/or health care programs
- An appropriate level of clinical research expertise (Career Clinical Trial Administrators are also encouraged to apply)
- Experience working in multi-disciplinary complex projects with a high level of attention to detail

Desirable
- Previous experience in a community–based healthcare setting

COMPUTER SKILLS:
- Experience with Microsoft Office software packages to an Intermediate and competent level
- Experience with Microsoft Access an advantage

COMMUNICATION SKILLS:
Essential
- A high level of interpersonal skills which enable the appointee to liaise effectively with a wide range of people at a variety of levels internal and external to Baker IDI
- Excellent oral and written communication skills
- Demonstrated ability to work effectively both independently and as a proactive member of a team

KNOWLEDGE:
- Excellent planning and organisational skills, including the ability to manage a range of tasks with conflicting priorities.
- Good Clinical Practice (GCP) and International Code of Harmonisation (ICH) Guidelines