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Medical Monitor at Clinipace Taiwan

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Medical oversight of projects to ensure applicable Policies/SOPs/WPs, Sponsor/Client directives, national and international guidelines are followed.

Clinipace CLINICAL RESEARCH

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Job Duties And Responsibilities

Job duties differ from project to project and are described in the contract, project-specific Plans (SMP; MMP), and/or other documents agreed with Sponsor/Client. Job duties also comprise any other tasks as defined by applicable Policies/SOPs/Work Procedures (WPs) and in general include but are not limited to the following:

- Medical oversight of projects to ensure applicable Policies/SOPs/WPs, Sponsor/Client directives, national and international guidelines are followed. Providing medical consultation to Sponsor/Client and project team for project activities;
- Maintaining availability to the sites and project team including the Sponsor/Client to ensure that medical questions or medical aspects of project-related questions (e.g. safety, general protocol questions, subjects' eligibility, inclusion/exclusion criteria, screening, randomization, unblinding, dosing, termination and discontinuation, drug specific questions, investigational product/device related questions etc.) are answered or communicated for resolution to the appropriate Sponsor/Client's medical resource. MM does not instruct the site how to manage a patient from medical / clinical prospective, but advises how to understand protocol and other applicable project requirements;
- Participation in development of unblinding process in close collaboration with other departments and/or functional groups;
- Review laboratory results and results of study subject's examinations;
- Develop / update of the written MMP, circulating it for approval within Clinipace and externally (with Sponsor) and maintaining MMP up-to date at all times during the project, follow it and oversee following it by other team members, escalate cases of deviations from MMP;
- Review of project specific plans including Safety Management Plan (SMP);
- Review and advise on project-related documents (e.g. clinical study protocol, clinical study report, Patient Information etc.);

- Medical input/review into project documents (e.g. protocol amendments, informed consent, statistical analysis plan, CSR etc.) from medical standpoint;
- Develop and/or review project related documents and reports, assess and interpret project results;
- Review medical literature in the scope of preparation of project-related documents and input for preparation of the respective documents;
- Review and assessment of issues related to protocol compliance incl. protocol deviation/violation, development of the corrective and preventative actions;
- Advice on and participation in management of protocol deviations/violations;
- Training CRAs and other team members on different topics including medical and/or safety aspects of the project or therapeutic area/indication;
- Training other medical monitors;
- Attendance to internal and external (include Sponsor/Client and/or non-Clinipace personnel) project specific meetings (e.g. Investigator meeting, Kick-off meeting, regular calls etc.);
- Attendance at data review meetings (interim analysis and final data analysis);
- Attendance at and services related to DSMB organization and management, creation of a DSMB charter, memo preparation etc.;
- Medical review of subject's data (presented e.g. in the format of listings, patient's profile etc.) aiming for identification of non-reported AE, clearing the data, clarifying and resolving data inconsistencies, query management etc.;
- Participation in Determination of dose escalation;
- Review of Medical Coding to assure medical reasonability of the codes and re-coding items if it is appropriate;
- Review of the requests from Regulatory authorities and/or Ethic Committees/IRBs and related activities (preparation of responses, participation in meeting etc.) when requested;
- Ensures appropriate safety considerations have been incorporated into the Clinical Event Committee (CEC) process and ensures the applicable CEC information is included in the SMP;
- Triggering discussion, sending out notifications and performing associated activities related to the Risk/Benefit ratio changes;
- Assisting the site staff in recording/reporting of SAEs; SADEs and other medically important safety events;
- Provide input to frequently asked questions log;
- Maintain adequate documentation of interactions with sites, project team, Sponsor/Client and other parties involved;
- Provide availability (to all or any: sites, Sponsor/Client, project teams) via call-in number up to 24 hours / 7 days a week or other schedule as agreed by contract;
- Documenting all communication (interactions with sites, Sponsor/Client, internal team members and external parties etc.) as required per MMP;
- Work closely with other functional groups and departments including but not limited to Safety/Pharmacovigilance, Project Management, Clinical Operations, Data Management, Biostatistics and QA to ensure that medical operational functions are executed effectively as per contract;
- All other tasks and responsibilities allocated to the job title as defined in Policies/SOPs/WPs.
- **Additional Tasks and Responsibilities (as needed):**
    - Data Safety Monitoring Board (DSMB) – review of documents provided to DSMB, support in meeting coordination, participation in meetings;
    - Clinical Event Committee (CEC) – providing medical support for adjudication process and participation in meetings;
    - Responses to regulatory agencies and governments - assisting in preparing safety portions of the responses;
    - Medical Safety Review Meeting (MSRM) – participation in and/ or chairing of the meeting;
    - Safety Evaluation Committees – serving and contributing to the development of risk management activities;
    - Train staff and project teams on different topics incl. procedures related to medical review and interpretation; training on specific indications or therapeutic areas etc.;
    - Assist with and/or support for the safety aspects of all relevant study documents including, but not limited to Investigator Brochures (IB), Informed Consents, Package Labels, Core Safety Information, Protocols, Final Clinical Study Reports (CSR), IND and NDA Annual Reports, Health Hazard Evaluations, Signal Evaluation Reports, Annual Safety Reports, and Integrated Summaries of Safety (ISS) for IND/NDA submissions, etc.;
    - Provide review and input for SOPs and Guidelines;
    - Take part in meeting with existing and Potential Clients, Support business development activities;
    - Support Business Development by providing medical and scientific advice and input incl. preparation to and particiaption at Bid defenses, participation in preparation of the Proposals and / or responses to the Request for Information from Clients etc.

- All other Tasks and Responsibilities assigned to MM in applicable SOPs.

Supervisory Responsibilities

MM may act as Line Manager for the Medical and safety/PV personnel according to the current organization chart and project assignments. In case more than two MMs are assigned to the project, one MM may by Primary MM, assuming more responsibilities e.g. communication with the Client and other functions. Details of the split of responsibilities are described in the MMP.

Job Requirements

- **Education**
  - MD (or equivalent) required, MD/PhD is a plus.
- **Experience**
  - At least 2 years of experience within the clinical arena post-training and preferably at least 3 years in the pharmaceutical, biotech, medical device and/or CROs. CRO experience highly desirable.
  - Experience working in a drug safety / pharmacovigilance or drug development environment performing medical review of clinical and post-marketing data.
  - Prior combined experience as Medical Monitor and Medical Advisor and Safety Physician Pharmacovigilance (or equivalent roles) is highly desirable.
  - Experience or knowledge of safety signal management approaches;
  - Experience in project management and team leadership;
  - Experience in development and delivery of the trainings and presentations.
- **Skills/Competencies**
  - Clinical thinking: ability to perform critical review and answer questions of medical nature from sites, project team (incl. Sponsor/Client) in accordance with ICH GCP guidelines, project specific documents to ensure patient safety, data integrity and successful completion of project;
  - Deep understanding of the scientific basis for therapies and drug-induced diseases. Comprehensive knowledge of medical device, vaccines and drug development process;
  - Deep understanding of safety databases and pharmacovigilance processes;
  - Effective communication: comfortable communicating both inside and outside to company;
  - Mature Management: management with a calm, positive winning attitude and excellent decision making skills;
  - Strong knowledge of the drug/device/vaccine development process;
  - Regulatory guidelines expertise: knowledge of international guidelines and country specific regulatory requirements (FDA, ICH GCP, MHRA, Pharmaceuticals and Medical Devices Agency (PMDA), GVP Modules; respective EU Clinical Trial Directive etc.);
  - Training expertise: able to efficiently train others;
  - People management: able to clearly and efficiently communicate with site and team members;
  - Clinical Management: able to manage clinical projects successfully;
  - Time management: good sense of urgency, prioritization skills;
  - Team player: effective participant as a team member and team leader;
  - Creative and positive leadership: programming team success through establishing and clear articulation of goals;
  - Creative problem solving skills;
  - Effective oral and written communication and presentation skills (at least in English) are compulsory;
  - Coach: a passion to assist others in becoming all they can be; Achievements: ability to define and meet requirements;
  - Integrity: Understanding and acting on principles of honesty, trust and fairness.
- **Capabilities**
  - Proficient in the use of computers and clinical trial management software programs.
  - Ability to drive an automobile and have a valid driver’s license.
  - Must have a credit card that can be used for travel expenses.
  - Ability to work remotely.
  - Ability to travel up to 20%, as needed.

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