Position: Regional Medical Monitor (RMM)
(Equivalent to Director position)
Job Family: Clinical Research Clinician (Medical Doctor)

JOB SUMMARY

The Regional Medical Monitor (RMM) represents BU Clinical and is dedicated to local/regional medical oversight in clinical trials of high medical risk. They also contribute to management of significant medical/safety issues in non high risk studies. RMMs ensure global consistency of medical oversight of study sites in their assigned region.

RMMs support Clinical Leads of a Study (CLS) with country intelligence input to any clinical development program, country strategy, and protocol design.

The RMM may also act as RMM Study Lead. In this role, the RMM is the main RMM point of contact to the CLS for overall study related issues, and representing the RMMs assigned to the study he/she leads.

Conducts all activities and makes decisions that are in accordance with Company policies & SOPs, Pfizer Values, & global regulatory guidelines (including cGMP/cGLP/cGCP), environmental guidelines, as appropriate, etc.

JOB RESPONSIBILITIES

As Individual Contributor RMM:

1. Program country strategy, pre-feasibility and site selection (all studies)

· Provide scientific and technical input, from a regional perspective, on the Program Feasibility, Country Strategy, and Protocol Design summarizing any country intelligence (e.g. standards of care, or other medical relevant information) through the CLS.

· Discuss about best sites to consider for planned clinical trials in the countries for which they are responsible (e.g. via Pfizer Site Recommendation/iMAP process), and supports the CLS in reviewing the proposed list of study sites for the relevant countries.

2. Medical issues

· Is responsible for medical issue resolution understood as:

Significant medical issues (all studies)

 Potential/actual critical medical qualifying quality issues (QQIs, request of CLS for non high risk studies)

 Complex safety issues (request of the CLS for non high risk studies)

 Corrective And Preventive Actions (upon request of the CLS)

Other medical issues (high risk studies)

 Reactive medical support to facilitate ethics/regulatory approvals

 Medical questions from investigator/monitor/Compliance Oversight Lead

 Protocol Deviations with potential medical/safety implications

 Addressing unusual data for major endpoints or for safety

 Study interruption relating to benefit/risk

 Review of study documents / translations (e.g. ICD) only when requested by AP due to significant changes to medical wording

 Helping investigators to understand how patients in his/her medical practice can be recruited ie. align with protocol inclusion/exclusion criteria

3. Training (high risk studies) • Attends investigator meetings of the protocols he/she is responsible for when possible
In agreement with the CLS, can present some agenda items (e.g. role of the RMMs, safety procedures)

· Address specific investigator knowledge gaps during site visit
· Provide the retraining associated with significant medical site quality issues (e.g. as part of site based Corrective and Preventive Activities)
· Site initiation visits when associated with a specific need to address risk to quality / patient safety (agreed with clinician)

4. Site Visits /contact with sites

Targeted site visit (or other contact forms as needed) to address specific medical issue or need (high risk studies – but also for all studies for critical medical issue)

 Follow up on Serious Adverse Events to enable clear narrative

 Potential / actual Qualifying Quality Issues

 Protocol Deviations and/or Protocol Specific Quality Review Visit findings with potential medical impact

 Identified specific investigator re-training need
 Accompany auditor on targeted audit where specific medical expertise is required
 Other (e.g. need for medical review of patient notes, audit findings)

Proactive site visit (or other contact forms as needed) to address potential site based risk (high risk studies)

 When agreed with CLS
 When consistent with specific risk mitigation plans
 Ideally conducted in conjunction with site monitor

Pre-inspection site visit (high risk studies)

As RMM Study Lead:

As an RMM Study Lead (RMMSL), the individual is responsible globally for country-level medical oversight of a high medical risk study and represents the group of RMMs from different countries to the CLS/global Study Team.

The RMMSL ensures timely communication between CLS and all assigned RMMs (including occasional meetings) for overall study related issues. This may include presenting RMM activities to the CLS, sharing risk management tools (such as the RMM Medical Oversight and Integrated Quality Management Plans), study updates, safety reports, best practices and lessons learned, compiling from country RMMs local information requested by the CLS.

Facilitates consistency and alignment of RMM medical oversight across countries

1. Create and maintain RMM Medical Oversight Plan, and track RMM activities versus plan
2. Ensures systems up-to-date with RMM role (Study Monitoring Plan, risk management tools, etc.)
3. Participate in global study team meetings, as required
4. Develop/contribute to a 'Frequently Asked Questions' document or similar to standardize responses to medical queries.

May provide training to other RMMs, on behalf of the CLS, when indicated.

Shared with the line manager, may coach/mentor less experienced RMMs.

EDUCATION AND EXPERIENCE

The RMM must have a medical degree (MD or equivalent) and professional qualification from a recognized medical school, be licensed by a health authority to prescribe medicines (independent of supervision) for at least one year (post "intern/houseman" year) and utilized that license to prescribe medicines in a patient care setting for an aggregate duration of at least one year, and always been in good standing with his/her licensing Health Authority. She/he must have training in ICH/GCP principles and in global and local policies relevant to the role (e.g. SOPs).
Experience in Phase 2 - 4 clinical development in the pharmaceutical industry and/or at a CRO, or in clinical / academic practice, including practical experience in clinical trial strategies, methods and processes.

TECHNICAL SKILLS REQUIREMENTS

· Deep knowledge of clinical development in Japan, principles of ICH/GCP, and experience in the management and reporting of adverse events and SAEs
· Experience in regulatory audits preferred
· Thorough knowledge of Japanese regulations applicable to clinical development including Ethics Committees' standards
· Practical knowledge of clinical trial strategies, methods and processes
· Native level of Japanese language skills including reading, writing and speaking capabilities; business proficiency in English