JOB DESCRIPTION LEAD CRM ID&V TA

Background:

The Dengue Program of Global Public Health of Janssen R&D is developing a promising novel anti-DENV small molecule that has now moved to a phase II stage of clinical development for the prophylaxis and treatment of Dengue fever.

Job Description – Key Responsibilities:

The Lead CRM (Clinical Research Manager) provides guidance and leadership to representatives of various internal and vendor functions involved in the initiation, conduct/execution and/or finalization of Phase 0 (e.g. Epidemiological studies), Early Development (ED) and Phase IIa studies for the Dengue Program.

The Lead CRM is responsible for the operational management of Early Development & POC clinical trials (conducted either in parallel or sequentially), which can either be company sponsored studies or collaborative studies and he/she:

- Gives input/feedback on study design and clinical study protocol, in collaboration with Disease Area Scientist(s) and other internal partners
- Participates in the identification and selection of clinical sites and Service Providers, and leads Site feasibility and vendor selection
- Closely follows up on timely execution and finalization of contracts/work orders/change orders with sites and vendors, in partnership with Janssen R&D Procurement, and reviews study contract proposals for approval, in collaboration with budget owner
- Assures timely submission to Competent Authorities (i.e. HA and EC/IRB), before, during and after conduct of the study, in collaboration with experts of relevant functional areas of J&J or of the vendor
- Co-develops or reviews study documents such as ICF, Case Report Forms, Pharmacy Manual, Medical Review Plan, …
- Participates or contributes to Investigator Meetings and Site Initiation Visits, where applicable
- Leads the recurrent Clinical Working Group Meeting in which clinical operation aspects and action items cross internal functions are being discussed
- Organizes Medical Data Review meetings and Dose Escalation Meetings, if applicable
- Performs co-monitoring visits when desired/required
- Develops, tracks and keeps oversight on study budget and keeps study budget within pre-agreed limits
- Reports trial status, progression and operational issues to the Clinical Team (CT) and Compound Development Team (CDT), as appropriate
- Serves as the primary point of contact for Service Providers (vendors)
- Ensures cross-trial consistency in management and conduct of studies
- Reviews study documents such as the Clinical Study Report, abstracts, study posters, study manuscripts, as applicable

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The Lead CRM is responsible for the operational management of Phase 0 / Epidemiological clinical trials (conducted either in parallel or sequentially), which can either be company sponsored studies or investigator-sponsored collaborative studies, and he/she:

- Participates in meetings with the study-dedicated Scientist(s) to discuss study rationale, (scientific) objectives and scope, and ensures translation into realistic study design
- Owns the operational implementation of disease –specific assay systems, if applicable
- Identifies the minimal needs and leanest processes, and to strive for a proportionate study budget, depending on the complexity and specifications of the Phase0 study.
- See also the Key Responsibilities listed for ED & Phase-IIa studies, where applicable.

The Lead CRM leads and coaches a sub-team of CRMs who manages Dengue Phase 0, ED and POC studies. He/she has the clinical operations oversight on the ED Dengue Program.

The Lead CRM contributes to the development and improvement of procedures and processes for Phase0, ED and Phase IIa studies, in the scope of the company's efforts towards continuous quality improvement and harmonization, where required.

Accountabilities and Direct Interactions:

The Lead CRM is a member of the Dengue Clinical Team (CT, with focus on clinical operations). He/She shares study statuses, escalates issues and looks for buy-in & endorsement to proposed clinical operation solutions and/or mitigation plans for potentially upcoming issues.

He/she translates the strategy outlined by the CDT into a clinical operational roadbook, for individual studies and/or for the Dengue ED Program.

The Lead CRM is a member of the Dengue Compound Development Team (CDT, with focus on strategy). He/She evaluates practical consequences of (changes in) strategies outlined by the CDT.

The Lead CRM reports into the Dengue Compound Development Team Leader (of Global Public Health) and the Early Development Operational Leadership of Infectious Diseases.

The Lead CRM is a member of the cross-functional Matrix Team chaired by the Global Project Lead for Dengue.

The Lead CRM chairs the Clinical Working Group Meeting.

Education & Experience:

Minimum a Master's degree in life sciences such as pharmacy, biology, biotechnology, etc. Preferentially a PhD degree in one of these domains.

A minimum of 7 years of:

- Clinical Trial experience in the Early Development environment - in pharmaceutical industry or CRO – with focus on clinical study management and clinical operations, is required.
- Experience working in a matrix organization, including in an international and virtual setting is required.
- Experience in management of external vendors is required.

A minimum of 2 years of:

- Experience in program management and/or in management of complex projects is an important asset.

A minimum of 2 years of:

- Experience in the management of a clinical operations focused program team (people management, i.e. coaching of study-dedicated CRMs)

Knowledge of:

- Early Development, Phase I and Phase II environment is a must
- Translational Medicine and/or epidemiological studies is a strong asset
- Infectious Diseases is an important asset

Competencies & Skills:

- Feels comfortable when interfacing with scientists at J&J (Dengue team)
- Has ability to prioritize tasks and to work with short timeframes for deliverables
- Has strong organizational skills to cope with multi-tasking
- Has a pragmatic approach and a high problem-solving attitude and satisfaction
- Displays goal-oriented approach without losing the attention to details.
- Has good communication skills and is strong in setting clear objectives and gaining alignment on divergent issues
- Has good presentation skills, and feels comfortable to present status updates in CDT and CT Meetings
- Demonstrates expertise in working cross-culturally and is inclusive within the sub-team he/she manages
- Has the ability to manage several studies simultaneously and to identify priorities
- Has the ability to work under pressure to meet deadlines
- Has the ability to advise, persuade and negotiate with colleagues in a supportive and constructive fashion
- Has excellent decision-making skills
- Is fluent in written and spoken English

Extra Requirement:

- Willingness and ability to travel up to 15% of the time, defined by business needs.
- Willingness to adjust working hours in order to facilitate trans-Atlantic collaborations (Asia, US, …), if needed

If interested, you can apply via the Johnson&Johnson Careers Website.