DNDi GARDP Southern Africa

Advert for the Regional Clinical Regulatory Affairs Consultant

Position	Regional Clinical Regulatory Affairs Consultant
Contract Term	October 2023 – December 2024
Contribution	Maximum 80 hours per month

Description

The clinical regulatory affairs consultant for Sub-Saharan Africa will provide regulatory strategic and tactical leadership for drug development projects, including health authority interactions, regulatory submissions, clinical trial applications and other regulatory requirements in line with GARDP objectives, timelines and budgets.

Tasks and Responsibilities

1. SNIP Africa

- Conduct online workshops with select regulators and ethics committee representatives: focusing on those with direct relevance to the SNIP project and on members of ethics committees responsible for sites that will not primarily be involved in NeoSep 2. The workshops are to determine facilitators and barriers to rapid risk-appropriate evaluation of study documents and activities, to enable adaptive platform trials.
- Conduct online workshops with non-regulatory stakeholders who may act as important allies in promoting the implementation of novel trials to address treatment of infections with epidemic potential affecting infants and young children, e.g., the African Medical Association, Africa CDC, relevant working groups of WHO and GAP-f. The workshops are to understand their concerns about adaptive platform trials in neonatal sepsis and to brainstorm solutions.
- Actively feed observations and insights from the above to a designated organization, that will synthesize these findings with additional findings from other consortium members, into a roadmap for addressing on-going research implementation challenges within SNIP-AFRICA.

2. Other

- Preparation and submission of local Clinical Trial application to regulatory authorities (RA) and IRB/IEC as soon as possible to obtain all necessary regulatory approvals within defined timelines.
- Primary responsible person for communication with RA and IECs during the clinical trial lifecycle.
- Assess and communicate the impact of relevant regulatory policies, regulations, country legislation in relation to the GARDP product portfolio.
- Develop new regulatory affairs policies, processes, and standard operating procedures for the GARDP RA system.
- Support the articulation of the regulatory requirements for the early access programs.
- Attend project team meetings (in absence of the HEAD of RA) to provide technical guidance and support on regulatory activities.
- Organize and management of regulatory documents and records for the GARDP products.

Point of Contacts and Interactions

The DGSA point of contact for the Regulatory Affairs consultant point is the Head of Office of DGSA with the functional point of contact being the Head of Regulatory Affairs of GARDP. He / She works closely with the GARDP programmes & project teams.

Position Requirements:

Knowledge and Skills:

Good understanding of the regulations, directives and guidance supporting clinical Research and Development.
Strong working experience with a variety of regulatory authorities is required, with real first-hand experience of managing clinical trial applications and product registrations with different regulatory authorities.
Experience with regulatory authorities, ethic committees and Ministry of Health.
Ability to work on several projects, retaining quality and timelines and can prioritize workload with minimal supervision.
Strong ownership and oversight skills.
Good negotiating skills and the ability to identify and resolve issues, using flexible adaptable approach. Ability to establish and maintain effective working relationships with co-workers, managers and clients.
Strong software and computer skills, including MS Office applications.

Education and Experience:

Bachelor's degree in pharmacy / Science or Master's degree.
Minimum 5 years' experience in Regulatory Affairs for international markets and clinical trial activities related to medicines.
Regulatory affairs and clinical trials experience in Sub-Saharan African countries is mandatory.

Closing Date: 30 September 2023

If interested, please send your resume / CV to email address – tpillay@gardp.org

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