Medical Governance Lead

Job ID
REQ-10041393
Feb 19, 2025
Malaysia

Summary

Lead governance & oversight of Innovative Medicines and Oncology Medical Affairs (MA) at country level in order to ensure duly planning, implementation and monitoring of Global Medical Standards and Metrics at country level.
Enable and support MA business strategy execution.
Act as the centre point of medical contact on governance for GxP activities (MAP, NIS, IIT, RC, LIS, Grants) and other regulated activities (including P3, ISRM)for Country and for related functions and internal stake-holders (GGO, QA, Safety, ERC, Legal, Procurement and others).
Brings operational efficiency and robust, accelerated decision making at the country level through new country medical governance pathways.
Provide leadership and direction to ensure that all Medical Information / OneMed activities comply with the various local regulatory/legal/industry requirements, as well as Novartis policies and procedures.
MGL is supported by a G/R/C Medical Governance network, with a OneNovartis mindset, through a shared sense of inspiration and curiosity, while enhancing communication pathways and a reduced ‘noise’ from global to countries with clarity on priority actions.

About the Role

MAJOR ACCOUNTABILITIES

- Lead the End-to-End medical governance of regulated activities (Interventional and NIS/RWE, IIT, MAP, RC), in alignment with Medical Affairs strategy and priorities.
- Act as the country expert on MA processes, Novartis standards and country regulation.
- Monitor adherence to Novartis processes, standards and country regulations.
- Support data quality/integrity in country MA.
- Coordinate processes for medical information services, aligning CPO needs with Novartis requirements, including appropriate handling of potential adverse event and product complaint reporting.
- Provide Governance support, advice, coaching and expert input to the country MA activity owners and teams by:

- providing sustainable solutions to deliver MA projects/activities.
- providing insights about risks (by navigating and complying within Novartis processes, requirements and local regulations).
- monitoring and giving feedback to improve processes, systems and capabilities, with clear quality and performance metrics, a defined follow up and escalation process to accelerate country support and decision making.

- Ensure proper classification of the medical activities, in collaboration with ERC if needed.
- Oversee and monitor local audit & inspection readiness and execution, in close collaboration with local QA.
- Track deviation and support implementation/resolution of local CAPA.
- Proactively identify root cause and implement action to improve future audit/inspection performance.
- Understand the systems that enables key governance processes in order to give advice and guidance to activity owners.
- Be the single point of contact for partner functions such as GGO, GDO/TMO, QA, Safety, ERC, Procurement and others.
- Proactively participate in regional/global MGL Network for ensuring continuous improvement (e.g. co-collaborative team to develop materials for on-boarding on processes, to develop “How To” materials, review of SOP/guidelines, involvement in Tools development associated to medical project, improve or develop new KPI/KQI…). Might lead/co-lead work stream or working group.
- Represent Medical Information function in management/cross-functional meetings and represent CPO in Medical Information / OneMed Global/Regional meetings
- LFRC (Line Function Resource Coordinator): Tracking of execution of GxP on-boarding and training plans for MA, working closely with the local CSO.
- Advise and guide the activity/business owner to implement processes related to due diligence, governance and oversight of Third Parties engaged in Evidence and Data Generation Activities.

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Division
International
Business Unit
Innovative Medicines
Location
Malaysia
Site
Selangor
Company / Legal Entity
MY01 (FCRS = MY001) Novartis Corporation (Malaysia) Sdn. Bhd. (19710100054)
Functional Area
Research & Development
Job Type
Full time
Employment Type
Regular
Shift Work

No
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