Medical Governance partner

Job ID
REQ-10066919

11月 20, 2025

Latvia

摘要

Medical Information Responsible:

Provides a high quality technical and coordination support for the response of accurate and timely medical/scientific information to all internal and external inquiring customers of varied medical information requests/requirements across the entire Novartis portfolio.

Serve as single point on contact and OneMed champion for Baltics.

Medical Governance Partner:

Accountability for the Governance of GxP and other regulated medical activities for the assigned geography.

Enablement and support of Medical Affairs business strategy execution by:
- providing sustainable solutions to deliver medical affairs projects/activities.
- providing insights about risks (by navigating and complying within Novartis processes, requirements and local regulations).

- streamlining an efficient communications and co-creation of content shared across G/R/C.
- 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.
- Adapting and creating local processes and procedures, as needed.
- GxP Audit and inspection key point of contact and support.

Field Medical excellence responsible:
- Build Field Medical capability and execution across TAs by standardizing processes, elevating coaching and metrics discipline (IM BEST & iSEC), ensuring compliant scientific engagement, and enabling launch readiness and sustained impact through MSL/FML development and system enablers (OnCore/IM BEST).

Managed access responsible:

Responsible for end-to-end management of selected Managed Access Program (MAP) requests in Baltics as agreed with line manager. Responsibilities include initial assessment, local medical approval, coordinating local regulatory documents and drug shipment to MAP requestor.

About the Role

Medical Information Responsible

- Receive, triage, coordinate the response to inquiries received from external and internal

customers, via the Medical Information communication channels (mailbox, OneMed platform).

- Facilitates providing by subject matter experts medical and technical information to healthcare professionals, consumers and internal staff on a wide range of products and therapeutic areas.

- Lead local deployment or updates of all new tools related to medical information area

- Collect, synthesize and communicate insights relevant for brand or any issues in market place - e.g. enquiry quality and patterns

- Co-own with Baltic Medical Governance Lead creation, maintenance and update local procedures, related to medical information management

- Act as OneMed Champion for Baltics

Ownership of the medical governance related processes:

- Lead the End-to-End medical governance of regulated activities (Grants, MAP, IIT, RC, Interventional and NIS/RWE), in alignment with Medical Affairs strategy and priorities.
- Provide governance support, advice, coaching and expert input to the R/C MA activity owners and teams.
- Understand the systems that enables key governance processes in order to give advice and guidance to activity owners.
- 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.
- Is the R/C expert on MA processes, Novartis standards and R/C regulations.
- Monitor adherence to Novartis processes, standards and R/C regulations.
- Ensure proper classification of the medical activities, in collaboration with ERC if needed.
- Maintain overview and monitor progress of R/C issues, ensure & track escalation and follow-up until resolution.
- Support data quality/integrity in R/C MA.
- Monitor and report KPI/KQI using existing Global systems & tools.
- Proactively identify risk and support risk management and mitigation.
- Oversee and monitor local audit & inspection readiness and execution, in close collaboration with local QA.
- Proactively identify root cause and implement action to improve future audit/inspection performance.
- Track deviation and support implementation/resolution of local CAPA.

- Be the single point of contact for partner functions such as GGO, GDO/TMO, QA, Compliance, Safety, CDO (Clinical Disclosure Office), ERC, Procurement and others.

- Proactively participate in regional/global MGL Network for ensuring continuous improvement (e.g. co-collaborative team to develop materials for onboarding 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 workstream or working group.

- Share common objectives across MGL Network for ensuring a consistent and harmonized governance and training across MA.

- In the capacity of LFRC (Line Function Resource Coordinator) track the execution of GxP onboarding and training plans for MA, work closely with the regional/local CSO/MD

- Assist in all related reporting, recording, reconciliation processes according to current legal and internal requirements. Oversee reporting in internal systems and tracking commitments.

- Act as a GEMS champion for Baltics, assist with system training, access, approval flow and archiving of approved items.

- Assist in Special Projects as needed.

Field Medical excellence responsible:

- Field Medical strategy & operating model: In cooperation with BE&E Translate global Field Medical strategy into a country tailored operating plan; maintain a single playbook (MEEP/iSEA, insights cadence, KPI governance) while preserving TA integration.

- Maintain team time allocation in OnCore and review it at least on quarterly basis, ensuring alignement with Medical Head and communication to the medical team.

- Standards, processes & tools: Own Field Medical process standards (pre-call planning, MEEP, iSEA/SEM, post-visit analysis, insights capture) and ensure adoption via OnCore; drive data quality expectations (logging protocols, quarterly iSEC surveys). Implement the IM BEST KPI framework as the single source of truth for performance and business reviews.

- Stakeholder management: Collaborate with the Medical Head to foster a high-

performance culture based on trust, enabling motivation and capability development for field medical team members.

- Coaching & capability building: Together with Senior medical engagement partner or country head coach medical engagement aprtners with structured field coaching rubrics anchored in iSEA/SEM; design and deliver role-based curricula leveraging OneMSL/STELLAR and Medical Executional Excellence trainings.

- Insights & medical impact: Lead the quarterly insights process (KITs/KIQs, aggregation, implications, actions, cross-functional share-outs) and ensure iSEC trends inform engagement strategy and scientific narrative pull-through. Ensure launch readiness inputs (ME mapping, resourcing, pre-/post-launch KPIs) are embedded into TA plans.

- KPI governance & performance management: Set targets consistent with Region Europe and SERCE dashboards (e.g., ≥10 Days in Field, ≥2 Interactions per DIF, ≥80% Core ME coverage), run monthly/quarterly reviews, and drive corrective actions. Publish standardized FME reports using IM BEST and Power BI in cooperation with BE&E team.

- Compliance, governance & quality: Ensure AE/TC reporting and medical governance requirements in every field engagement and training (local SOPs). Uphold local GxP SOPs and enforce logging/data integrity standards.

- Technology & enablement: Champion field-technology optimization (OnCore CRM hygiene, IM BEST adoption) and new assets (e.g., digital visualization modules) to scale engagement quality.

Cross-functional Cooperation/Coordination:

- Coordinate Medical Governance with other departments and stakeholders within Novartis, (e.g. Compliance, Legal, Marketing, Sales, Purchasing, Finance)

- Cross-functional overview and knowledge exchange across divisions and functions

Country Medical responsible person:

- Act as country medical responsible for selected Managed Access Program requests

- Manage MAP requests timely, with high quality and in compliance with global MAP process

- Coordinate with stakeholders information related to product name, quantity, dosage and check if the details matches with GEMS system along with required approvals e.g. local and global medical approval, physician attestation form (this includes confirmation that all relevant local approvals have been obtained as per local regulations) and Import license (if applicable)

- Provide input to MAP drug supply plan (global, local), MAP strategy plan, MAP exit plan

- Check label adherence to local regulations

- Share and keep logistics details (consignee, importer of records, customs broker, etc.)

- Coordination and transfer of shipment to CO / Physician ' s site / Patient from ESP

- Work in close cooperation with country Medical Engagement partner to coordinate successful execution of MAP requests.

Other:

- Observe strictly any and all applicable internal and external regulations, acts and procedures, including, but not limited to: Internal Rules, Code of Ethics, Corporate Citizenship, BeSure, local industry code etc.

- Responsible for proper and compliant reporting of Adverse Events in order to fulfill all regulatory requirements and ethical obligations including timely forwarding of all spontaneous reports to local Drug Safety Responsible.

- Comply with the GxP quality requirements applicable to his/her area of responsibility, incl. but not limited to proper reporting of adverse events and customer complaints, samples handling as well as any incident that may adversely affect the quality, safety, identity, strength, purity, availability or efficacy of a commercial product or clinical trial material and/or may compromise the Novartis Quality System and the global Novartis reputation

Key performance indicators:

Business Results:

- Speed, quality and compliance of implemented medical governance projects

· Timely development and update of working procedures in medical affairs area

· Speed, quality and compliance in management of selected MAPs

· Deliverables according to set deadlines and priorities

· Relationships and collaboration with all Novartis colleagues, quality and timely feedback

Operational Excellence:

· Execution, track and monitoring of medical governance projects

· Regular analyse of existing medical governance related policies/ processes/ guidance

People, Capabilities, and Management:

· Strong customer focus

· Code of Ethics compliance

Ability to lead project teams, project management skills

Minimum Requirements:

Pharmaceutical industry experience at least 2 years.

Work Experience:

- Collaborating across boundaries.
- Operations Management and Execution.
- Project Management.

Skills:

- Understanding of medical governance types and processes
- Operational experience in Pharma Medical/Clinical departments/ Compliance
- Outstanding customer focus and a willingness to help
- Innovative outlook
- Strong communication, presentation skills, including to senior management
- Experience in cross-functional environment
- Computer skills for planning and development of key presentations
- Strong project management skills and experience

Languages :

- English
- Latvian

Why Novartis: Helping people with disease and their families takes more than innovative science. It takes a community of smart, passionate people like you. Collaborating, supporting and inspiring each other. Combining to achieve breakthroughs that change patients ' lives. Ready to create a brighter future together? https://www.novartis.com/about/strategy/people-and-culture

Benefits and Rewards: Read our handbook to learn about all the ways we ' ll help you thrive personally and professionally: https://www.novartis.com/careers/benefits-rewards

部门
US

Business Unit
General Management

地点
Latvia

站点
Latvia

Company / Legal Entity
LV01 (FCRS = LV001) SIA Baltics, Latvia

Functional Area
Research & Development

Job Type
Full time

Employment Type
Regular

Shift Work
No

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