

MEDICAL AFFAIRS

COMPETENCY MATRIX



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This document serves as a guidance. Scope of activities and required competencies can vary from company to company and between roles within Medical Affairs. This document aims to bring consistency in the way activities and competencies are looked at. Any specific company should decide on the required scope of activity and competencies for that company. This document helps in defining the scope of activity Medical Affairs staff is working in and in defining their personal development plan. Competencies are described per scope of activity and split into 'Basic', 'Experienced' and 'Expert', where 'Expert' holds all competencies including those described under 'Basic' and 'Experienced'.

This document is the end result of a project that involved several brainstorming sessions and review rounds with over 20 MSLs, Medical Advisors and Medical Affairs leaders from different companies in the Netherlands. We thank all participants for their valuable input. Project leads: Maaïke Addicks and Corrie Kroeze.

The NVFG (Dutch Association for Pharmaceutical Medicine) is a non-profit organisation for medical professionals in the pharmaceutical industry. The goal of the organisation is to improve public health by increasing the knowledge, skills and professionalism of its members, which include Clinical, Pharmacovigilance, Regulatory and Medical Affairs professionals.

Disclaimer: Compliance with current laws and regulations and with the internal Standard Operating Procedures (SOPs) of the company is an absolute requirement and will overrule any activities described in this document.

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OVERVIEW AND DESCRIPTION OF

SCOPE OF ACTIVITIES

Medical Scientific Knowledge

Page 5

The Medical Affairs Professional is a scientific expert in designated medical therapy(ies) and related indication areas, as well as in healthcare in general. (S)he has knowledge of Health Economics and Outcome Reporting (HEOR), Patient Reported Outcomes (PRO) and the healthcare and reimbursement systems. (S)he is able to put the knowledge into perspective and apply appropriately.

Internal Scientific Expert

Page 6

The Medical Affairs professional applies his/her knowledge in collaboration with other departments in order to achieve the overall strategic goals of the company.

Exchange of Scientific Information

Page 7

The Medical Affairs professional exchanges scientific information in various ways, with external stakeholders such as medical practitioners, patient organisations and other important stakeholders/decision makers in the Healthcare system. (S)he exchanges information aligned with patients' interests. (S)he gains new insights and puts them into context.

Clinical Studies and Data Collection

Page 9

The Medical Affairs Professional develops, coordinates and supports scientific research and data collection in different phases and situations in order to generate meaningful data.

Patient related activities

Page 10

The Medical Affairs Professional facilitates access to the appropriate healthcare, medication and information for patients. (S)he looks after the patients' interests within the company.

External Expert Engagement

Page 11

The Medical Affairs Professional develops and maintains an effective network of relevant External Experts (e.g. physicians, pharmacists, healthcare professionals (HCPs), Board of Directors of healthcare institutions and research organisations).

Compliance and Ethics

Page 11

The Medical Affairs Professional is aware of and compliant with laws, regulations, company's SOPs and LOPs; (s)he acts as a role model within the company in matters concerning compliance and ethics.

OVERVIEW AND DESCRIPTION OF COMPETENCIES



Knowledge and Science

Holds deep, extensive and current knowledge of healthcare in the healthcare system in general and especially in designated therapeutic area(s). Maintains this knowledge, puts it into context and applies it. Has knowledge of local legislation and regulations, internal SOPs and scientific research and implements this knowledge, maintains it and applies it effectively.



Communication

Exchanges ideas and information clearly and convincingly, so the essence is understood and insights can be achieved by using existing communication tools effectively. Assesses and adjusts to the level and views of conversation partners allowing the use of various conversation, listening, and presentation techniques.



Collaboration and partnership

Strives towards a common goal together with internal and external stakeholders where the collaboration is based on mutual trust and respect and taking ownership. Motivates others to strive for shared goals. Effectively builds and maintains relations and networks.



Strategy and planning

Able to see the bigger picture, to anticipate developments over time, to recognize trends, and to think in scenarios. Develops a mission and vision. Applies the correct resources, time and actions to achieve a goal, monitors progress and adjusts when necessary.



Entrepreneurship

Identifies and proactively creates opportunities and acts on them in order to create value for patients, HCPs and the internal organisation. Acts independently, takes initiative and calculated risks to achieve a goal.



Organizational sensitivity

Understands and senses how the formal and informal company structure works; understands the added value of Medical Affairs for the company and acts to bring desired results.










Social responsibility

Acts in the interest of the patient and the social community; displays strong sense of ethics. Acts with integrity, reliability and ownership for decisions and actions. Promotes compliance with local legislation and regulations and internal SOPs.

SCOPE OF ACTIVITY

MEDICAL SCIENTIFIC KNOWLEDGE

Specification

Specification	Knowledge and science 	Communication 	Collaboration and partnership 	Strategy and vision 	Entrepreneurship 	Organizational sensitivity 	Social responsibility 	★	★★	★★★
								Basic	Experienced	Expert
Scientific expert in the area of designated products and related indication area(s) as well as treatment options and associated medications.	✓							Has scientific knowledge of disease area and knows how to use it.	Regarded as scientific expert by both internal and external stakeholders. Masters knowledge in a way that it can be transferred to others. Able to see connections and put them into context.	Able to act as a peer in conversations with stakeholders and able to add value to the discussions. Has a complete view of the situation in healthcare community and its implications for current and future portfolio.
Maintains knowledge of treatment options and developments in the therapeutic area by literature search, participation in congresses and scientific exchange with external stakeholders	✓	✓		✓				Knows how to obtain new information related to the current portfolio.	Actively keeps track of (new) developments that can influence current and future portfolios in the short or long term.	Proactively seeks extra information; anticipates upcoming information. Acts on and anticipates (new) developments and their implications through understanding of the context and sharing these both internally and externally, solicited as well as unsolicited.
Able to analyse scientific articles, put them into context, and assess them for value and impact.	✓			✓	✓			Understands the intent and essence of a scientific article. Can distinguish between essential and side issues. Has a general understanding of terms like impact factor, meta analysis etc.	Can evaluate the robustness of a scientific article. Understands statistical analysis and can put information into context regarding indication area and treatment opportunities.	Able to put results in broader context within the existing treatment paradigm and translate them into expected impact.
Able to analyse information from congresses, put it into context, and assess it for value and impact.	✓			✓	✓			Independently creates a congress plan with sessions relating to the designated product(s) and indication is aware of other resources and monitors information	Understands the context of congress sessions, able to follow the discussions. Able to put information into a broader context than only designated product or therapeutic area.	Discusses sessions with external local experts. Understands the content and able to translate to the local situation.
Able to analyse information from other channels such as social media, webinars etc, put into context and assess for value and impact	✓			✓		✓		Is aware of other resources and monitors for information.	Gathers and analyses information from other channels and is able to put into context.	Analyses information from other channels, puts into context and is able to recommend actions based on this information.








Specification	Knowledge and science							SCOPE OF ACTIVITY		
	Knowledge and science	Communication	Collaboration and partnership	Strategy and vision	Entrepreneurship	Organizational sensitivity	Social responsibility	★ Basic	★★ Experienced	★★★ Expert
Active participant in cross functional teams; contributes to strategy and activities.	✓	✓	✓	✓	✓	✓	✓	Attends cross functional team meetings; understands the different roles and undertakes activities reactively.	Actively participates in cross functional team meetings; shares insights from interactions with external experts and undertakes activities proactively.	Co-decision maker of Medical strategy and activities in cross functional team. Leads planning of medical activities.
Creates an aligned Medical Plan to support Brand Plan and other internal plans.	✓	✓	✓	✓	✓	✓	✓	Understands design of a Medical Plan and provides input reactively.	Independently creates Medical Plan, including budget; monitors and, when necessary, adjusts the plan over the course of a year.	Able to evaluate the Medical Plan for its impact on internal stakeholders and communicates accordingly.
Translates scientific knowledge and insights into strategies and practice.	✓			✓	✓	✓		Understands which scientific knowledge and insights are relevant to the company.	Translates knowledge and insights into practice.	Proactively translates knowledge and insights into strategies and practice.
Scientific support of internal stakeholders (i.e. marketing, market access, sales).	✓	✓	✓			✓		Provides scientific support to internal stakeholders upon request and under supervision of an experienced colleague.	Independently provides scientific support to internal stakeholders upon request.	Proactively recognises when scientific information is relevant for internal stakeholders and provides support.
Supports Market Access in dossier building and in discussions with Market Access Stakeholders.	✓	✓	✓		✓	✓	✓	Supports Market Access upon request and under supervision.	Independently supports Market Access in dossier building and in discussions with Market Access Stakeholders.	Understands impact of scientific data on Market Access related discussions; knows how to translate the data and acts proactively.
Provides written updates and explanation of scientific topics to internal stakeholders at a suitable knowledge level and focused on departmental interest.	✓	✓	✓	✓		✓		Able to summarize relevant scientific information.	Understands the importance of scientific information for various internal stakeholders. Able to summarize the information at a suitable knowledge level	Understands the importance of scientific information for various internal stakeholders. Able to put the information into context.
Delivers scientific updates and training to internal stakeholders both written and face to face, in line with knowledge level and departmental interests.	✓	✓	✓	✓		✓		Delivers training based on existing materials and under supervision.	Independently delivers training at the correct knowledge level, based on existing material and focused on departmental interests. Able to update and customize existing materials.	Independently develops and delivers training based on available knowledge. Is familiar with diverse training techniques and able to apply them.
Develops materials for exchange of scientific information.	✓	✓	✓	✓			✓	Able to provide input into scientific materials.	Independently develops materials for exchange of scientific information upon request.	Identifies needs and proactively and independently develops materials for exchange of scientific information.
Identifies data or information gaps needed for internal or external stakeholders.	✓		✓	✓				Is aware of short term data or information gaps.	Identifies short term data gaps and formulates actions to resolve gap.	Identifies long term data gaps and is responsible for actions to resolve gaps.

SCOPE OF ACTIVITY
EXCHANGE OF SCIENTIFIC INFORMATION (1/2)

Specification	Knowledge and science							SCOPE OF ACTIVITY		
	Knowledge and science	Communication	Collaboration and partnerships	Strategy and vision	Entrepreneurship	Organizational sensitivity	Social responsibility	★ Basic	★★ Experienced	★★★ Expert
Answers medical questions from healthcare providers and patients and upon request reactively discusses patient cases with HCPs, both orally and by email.	✓	✓					✓	Answers questions in a timely manner based on information in the SmPC.	Asks questions to uncover underlying questions or for specification. Identifies trends and risks based on incoming questions.	Seen as medical expert by internal and external stakeholders; consulted proactively by external stakeholders.
Knowledgeable about processes concerning Adverse Events (AEs). Identifies, analyses and acts on safety signals and AEs. Asks questions in relation to AEs and reports them within specified timelines and in accordance with law and regulations and internal company's SOPs and LOPs.	✓	✓				✓	✓	Compliant with law and regulations and company's SOPs and LOPs regarding AE reporting.	Identifies trends and recognizes hidden AEs.	Identifies trends and recognizes hidden AEs.
Identifies, analyses and communicates trends in response to medical questions and discussions.		✓	✓		✓	✓		NA	Identifies and analyses trends and case studies and communicates them internally.	Able to create a plan for future handling of cases based on analyses of trends and case studies.
Provides written scientific information to various external stakeholders.	✓	✓		✓				Able to provide written scientific information in a standardized format and under supervision.	Independently provides written scientific information to stakeholders and able to tailor the information to the needs of receiver.	Makes communication plan. Accountable for written scientific communication and able to take further actions where applicable.
Reactively provides information on off-label use for non-registered indications or information regarding the pipeline.	✓	✓					✓	Delivers information in a compliant and standardized manner.	Delivers information in a compliant and standardized manner and able to put the information into perspective. Asks further questions to be able to tailor the information to the receiver.	Able to put questions and information into perspective; able to act upon information and identify trends based on questions.
Provides scientific presentations online and offline, taking into account the channel, knowledge level and needs of the audience.	✓	✓			✓			Able to deliver a clear and coherent story. Able to provide structure to a presentation (introduction/ summary/conclusion).	Takes needs of the audience and channel into account. Uses interactive presentation techniques and other tools. Actively seeks feedback.	Designs a presentation audience and channel into account. Flexible in switching topics following questions from the audience. Uses posture, gestures, facial expression and voice to get and retain the attention of the public.
Holds face to face discussions both on and offline on scientific topics with various stakeholders.	✓	✓	✓	✓	✓		✓	Basic medical and scientific knowledge; prepares discussions, makes an agenda and sets SMART goals. Knowledgeable about the structure of a conversation.	Able to tailor the discussion to the needs of other people without losing sight of internal goals. Has in-depth medical and scientific knowledge to have a peer to peer discussion and create follow up.	Able to inspire people; has peer to peer discussions. Able to deal with resistance and to discuss difficult topics in a constructive and friendly manner.

SCOPE OF ACTIVITY

EXCHANGE OF SCIENTIFIC INFORMATION (2/2)

Specification								SCOPE OF ACTIVITY		
	Knowledge and science 	Communication 	Collaboration and partnership 	Strategy and vision 	Entrepreneurship 	Organizational sensitivity 	Social responsibility 	★ Basic	★★ Experienced	★★★ Expert
Organizes scientifically relevant Advisory Board Meetings.	✓	✓	✓	✓	✓		✓	Able to organize an Advisory Board Meeting and achieve pre-defined goals under supervision.	Able to organise Advisory Board Meetings independently and achieve pre-defined goals.	Has organized several Advisory Boards independently, with clear goals and follow up. Supervises others in the organization of an Advisory Board Meeting.
Develops Continuing Medical Education (CME) training together with relevant medical experts for other medical professionals.	✓	✓	✓	✓	✓		✓	Organizes training (CME) under supervision.	Organizes training (CME) independently, judged as 'good' by participants. Independently develops CMEs based on FAQs, trends etc. Formulates learning goals and achieves them by providing structure and content to the training.	Uses various techniques and digital tools (blended learning) in developing state of the art CMEs. Supervises others in organizing CMEs.
Actively gathers insights, understands them and puts them into context.	✓	✓		✓	✓			Formulates new insights based on interactions and able to provide feedback to relevant internal stakeholder(s).	Actively gathers insights, by asking questions during interactions, by listening and questioning further. Able to put new insights into context.	Proactively gathers insights, puts them into context and formulates next steps.
Gathers insights via different channels (for example social media).	✓	✓						Is aware of the different channels for insights gathering.	Proactively gathers insights via different channels and puts into context.	Puts insights from different channels into context and formulates and follows up on actions.
Uses omnichannel approach in external scientific exchange.	✓	✓		✓	✓			Uses different channels for communication, under supervision.	Executes omnichannel strategy successfully.	Designs and executes omnichannel strategy.

SCOPE OF ACTIVITY CLINICAL STUDIES AND DATA GENERATION

Specification								★	★★	★★★
	Knowledge and science	Communication	Collaboration and partnership	Strategy and vision	Entrepreneurship	Organizational sensitivity	Social responsibility	Basic	Experienced	Expert
Supports Clinical Operations studies with site selection, (pre-)feasibility, treatment presentations.	✓	✓	✓	✓	✓			Supports Clinical Operations studies with site selection, (pre-)feasibility, treatment presentations for investigators, under supervision.	Independently supports Clinical Operations studies with site selection, (pre-)feasibility, treatment presentations for investigators.	Independently supports Clinical Operations studies with site selection, (pre-)feasibility, treatment presentations for investigators. Actively involved in issue management and process improvement.
Involved in and supports the approval process for Investigator Initiated Trials (IITs).	✓		✓					Understands approval process and involved in timelines; supports the process under supervision.	Independently supports the approval process and communicates with investigator.	Supports and acts as a decision maker in the approval process for IITs.
Coordinates processes within ITTs (contract, budget, timelines)		✓	✓	✓	✓		✓	Understands processes and timelines.	Independently coordinates processes and able to act on upcoming issues.	Accountable for IITs and decision maker in contract, timelines, issue management etc.
(Co-)develops company initiated study protocols.	✓	✓	✓	✓	✓		✓	NA	Supports development of company initiated study protocols under supervision of an MD/experienced colleague.	Able to independently develop a company initiated study protocol (excluding statistical sections).
Coordinates company initiated studies (contracts, budget, timelines) (PASS, PMOS RWE, etc.).		✓	✓					Understands processes and timelines of company initiated studies.	Independently coordinates company initiated studies and acts on issues.	Accountable for company initiated studies and decision maker in contracts, timelines, issue management etc.
Monitors company initiated study (initiation, monitoring, close out)	✓	✓	✓	✓	✓			Monitors company initiated studies under supervision.	Monitors company initiated studies independently.	Develops a monitor plan for a company initiated studies; executes the plan independently.
Knowledge on and compliant with laws and regulations concerning clinical trials (GCP, GDPR, (Medication Act) etc.).	✓	✓					✓	Knowledgeable on and compliant with laws and regulations concerning clinical trials.	Knowledgeable on laws and regulations concerning clinical trials and able to explain and apply them in practice.	Knowledgeable on law and regulations concerning clinical trials and acts as mentor and sounding board for questions regarding the interpretation of regulations.
Knowledgeable on company's SOPs and LOPs; Able to work with the (IT-)systems relevant for clinical studies.	✓						✓	Completes SOP and LOP training within timelines and displays skills in (IT-)systems relevant for clinical studies.	Displays insight in correct interpretation of LOPs and SOPs and skills in relevant (IT-)systems.	Proactive in the implementation and interpretation of LOPS and SOPS; acts as subject matter expert for relevant (IT-)systems.
Contributes to generation of Real World Evidence (RWE) en Value Based Healthcare (VBHC) data together with internal and external stakeholders.	✓	✓	✓	✓	✓	✓	✓	Basic knowledge of RWE and VBHC; participates in internal discussions.	Able to have constructive discussions on RWE and VBHC with both internal and external stakeholders; proposes RWE/VBHC projects.	Proactive and accountable for RWE/ VBHC projects in cooperation with, and with added value for, internal and external stakeholders.
Writes and supports writing of scientific publications and posters.	✓	✓	✓	✓	✓			Understands the process of developing scientific publications and posters.	Involved in developing scientific publications and posters; able to coordinate the process.	(Co-)author of scientific publications and posters.

Specification	<div style="display: flex; justify-content: space-between; font-size: 8px; font-weight: normal;"> Knowledge and science Communication Collaboration and partnership Strategy and vision Entrepreneurship Organizational sensitivity Social responsibility </div>							★	★★	★★★
	✓	✓	✓	✓	✓	✓	✓	Basic	Experienced	Expert
Sets up compassionate use, named patient and early access programs; coordinates the programs, including scientific judgement of patient inclusion.	✓	✓	✓	✓			✓	Understands regulations and SOPs concerning compassionate use, named patient and early access programs.	Supports initiation and coordination of compassionate use/early access programs. Able to explain programs and related processes to external stakeholders.	Sets up and coordinates compassionate use/early access programs independently.
Provides scientific and practical support to Patient Support Programs (PSP).	✓	✓	✓					Reactively provides scientific and practical support to PSP.	Proactively provides scientific and practical support to PSP.	Defines MA department's involvement in PSP; involved in initiation of PSP.
Contact with patient organisations.	✓	✓	✓				✓	Present at discussions with patient organisations.	Displays sensitivity for internal and external interests; communicates with patient organisations in a compliant way.	Displays sensitivity for internal and external interests; builds relationships with patient organisations in a compliant way.
Represents patients' interests in internal discussions.	✓	✓	✓	✓			✓	Able to make an inventory of patients' needs through various channels (face to face, social media, etc.).	Raises questions in the interest of patients during internal discussions.	Displays insight and understanding in patients' needs and represents those consistently during internal discussions.
Writes or delivers scientific input into patient materials.	✓	✓	✓	✓			✓	Delivers scientific input into patient materials.	Takes a lead in writing of patient materials.	Has personally written 1 or more patient materials; identifies need for patient materials and decides on format and channels to be used.
Supports and/or develops projects that add value to medical practice, together with medical experts and/or institutions.	✓	✓	✓	✓	✓	✓	✓	Able to speak with medical experts about medical practice.	Recognizes and acts on opportunities in medical practice to bring improvement for patients.	Develops, together with medical experts, projects that bring added value; knows how to use opportunities and extrapolate from them.
Executes Risk Minimisation Plans (RMPs).	✓	✓	✓				✓	Understands content and implications of an RMP.	Co-responsible for the execution and documentation of an RMP.	Able to assess if RMP is adhered to; signals problems and acts on them (in collaboration with Regulatory Affairs and Pharmacovigilance staff).
Communicates with HCPs about safety and access to medical therapy via channels approved by the authorities (black box warnings etc).	✓	✓	✓				✓	Correctly communicates with HCPs about issues concerning the safety of or access to medical therapy.	Correctly communicates with HCPs and shows insight in impact on healthcare; able to inform external stakeholders rapidly in case of emergency.	In charge of communication process; develops a communication plan (depending on situation and in collaboration with Regulatory Affairs and Pharmacovigilance staff).

SCOPE OF ACTIVITY EXTERNAL EXPERT ENGAGEMENT

Specification								SCOPE OF ACTIVITY		
	Knowledge and science	Communication	Collaboration and partnership	Strategy and vision	Entrepreneurship	Organizational sensitivity	Social responsibility	★ Basic	★★ Experienced	★★★ Expert
Identifies (new) External Experts (EE), Digital Opinion Leaders (DOL) and rising stars; maps out networks.	✓		✓	✓	✓			Maintains existing networks and contacts.	Identifies (new) External Experts (EEs), Digital Opinion Leaders (DOLs) and rising stars and networks and builds peer to peer relationships	Able to develop an EE network anticipating on future developments. Able to work in an innovative manner.
Makes an EE-strategy and plan based on the Medical Plan.				✓	✓	✓		Executes existing EE-strategy and plan.	Provides input into the development and execution of an EE-strategy and plan	Develops an EE-strategy and plan and supervises others in development of strategy and plan.
Develops and maintains good working relationships with External Experts, health institutions and organisations.		✓	✓	✓	✓		✓	Takes over existing network. Relations based on position within the company.	Builds and maintains a network independently. Relations based on trust and needs.	Has partnerships with network. Is actively consulted. Able to call on network when there is a business need. Peer to peer relationships based on trust and respect.

SCOPE OF ACTIVITY COMPLIANCE AND ETHICS

Specification								SCOPE OF ACTIVITY		
	Knowledge and science	Communication	Cooperation and partnership	Strategy and vision	Entrepreneurship	Organizational sensitivity	Social responsibility	★ Basic	★★ Experienced	★★★ Expert
Responsible for approval of materials with regard to medical scientific content and in compliance with local compliance guidelines.	✓	✓	✓		✓		✓	Aware of, understands and compliant with local compliance guidelines concerning (promotional) materials.	Able to make a weighted decision concerning compliance of (promotional) materials. Able to substantiate and advise on alternatives with integrity.	Able to take accountability concerning local compliance guidelines of (promotional) materials.
Knowledgeable about, compliant with and role model with regard to local laws and regulations. (CGR, Geneesmiddelenwet (Medication Act) and GDPR).	✓						✓	Knows, understands and compliant with the law and regulations.	Able to make a weighted decision concerning law and regulations and able to advise on alternatives with integrity.	Able to take accountability concerning law and regulations.
Knowledgeable about, compliant with and role model with regards to internal company SOPs and LOPs.	✓						✓	Knows, understands and compliant with internal company SOPs and LOPs.	Able to make a weighted decision concerning SOPs and LOPs and able to advise on alternatives with integrity.	Able to take accountability concerning SOPs and LOPs and able to substantiate decisions.
Writes and reviews Medical Affairs related SOPs en LOPs.	✓				✓	✓	✓	NA	Understands the structure and language of SOPs and LOPs. Reviews SOPs and LOPs on content.	Designs and writes SOPs en LOPs, using the correct structure, language and content.

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