Title:

The value and deliverables of Medical Affairs – affiliate perspectives and future expectations

Journal Name:

Pharmaceutical Medicine

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Supplementary Information: The information presented lists key Medical Affairs led activities* and associated timing of initiating the activity, pre- and/or post-launch, respectively.

Medical Engagement / Activity	Description	Timing Pre-launch	Timing Post-launch
Collaborate with Global Clinical Development Teams	Understand the mechanism of action of the innovative medicine including pharmacodynamics and pharmacokinetics from early clinical phases 1 and 2. Review the Clinical Development Plan (CDP) to enable local evidence gap identification. For clinical trial phases 2 and 3, ensure detailed understanding of the dataset to enable evaluation of local market opportunities together with the cross-functional team including competitor differentiation.	**X**	
Key External Expert (KEE) Mapping and Engagement Plan	Desk research to create an overview of the Therapeutic Area (TA) including in-depth mapping of relevant stakeholders in the ecosystem e.g., hospitals, clinics, KEEs, Health Care Professionals (HCPs), Patient Advocacy Groups (PAGs) and more.	**X**	
Company-Sponsored Clinical Trials	Clinical phase 1-3 trial programs and study designs are usually managed by global functions. Affiliate colleagues manage local trial feasibilities, planning, and execution among investigator sites in accordance with Good Clinical Practice (GCP), in collaboration with the Clinical Operations Team. Several activities related to clinical trial execution involve Medical Affairs (MA) teams and provide	**X**	

	useful opportunities for MA colleagues to engage with clinical researchers within the TA. Such activities concern (non-exhaustive): • Country feasibility (evaluation of country ability to perform a clinical trial) • Investigator site identification and feasibility (qualification of investigative sites' ability to conduct a clinical trial successfully) • Pre-trial assessment visits and site initiation visits in which affiliate staff meet the investigators in the clinic, to assess the sites' ability to conduct the trial. MA is usually responsible for review of Trial Protocols including Investigator's Brochure (review existing knowledge of the Investigational Medicinal Product (IMP) to be tested) • National Investigator Meetings		
Engage in Cross-Functional Teams (CFT)	Forming the CFT, typically consisting of the following roles: Commercial/Marketing, Market Access, Health Economy, Regulatory, Pharmacovigilance, Medical Evidence, Medical Affairs, and additional relevant colleagues. Ensure in-depth understanding by the CFT of unmet medical needs in the TA in addition to core data from phase 1,2 , and 3 clinical trials.	**X**	
Introductory Meetings	Introductory meetings are initial meetings with KEEs, where the medical responsible person has an opportunity to introduce themselves, their own merits,	**X**	**X**

	and the company. The aim of the introductory meeting – besides mutual introductions - is to understand the TA better, the unmet medical needs as seen from the HCP perspective, and to understand the clinical and research interests of the KEEs to initiate the thought process concerning future medical collaboration projects. Moreover, it is an opportunity to validate the KEE mapping, and is a starting point for relationship building and engagement planning.		
Disease Insight Visits (DIVs)	Visiting clinics to discuss and understand current medical practices and key challenges. DIVs can occur both face to face and virtual. The objective is to gain an understanding of clinical practices, patient pathways, and validate gathered intelligence and fill knowledge gaps. These visits can be conducted with disease insight questions, often requiring sign off by the local Compliance Review Team. To gain a better understanding of patient flows; referral pathways; characterising risks for disease area; treatment framework and associated costs and risk-tolerances to different treatment strategies.	**X**	**X**
Analyse and provide medical insights in TA including competitive intelligence	Provide a collective overview of current treatment guidelines, clinical practices, and potential evidence gaps in TA through insight-gathering, to enable company prioritization and strategy planning.	**X**	**X**
Clinical Insights Collection and Management	Active listening and capturing insights, when communicating with KEEs in hospital clinics or other scientific/clinical environments. Bringing such data, facts, and observations from the healthcare environment back to the organization through	**X**	**X**

	internal standardized mechanisms, to enable strategic planning. This process is an ongoing activity from the first external engagement throughout the process until medicines are launched in the country.		
Internal Medical Training	MA colleagues are expected to build expert knowledge concerning the TA including understanding of disease pathophysiology, patient journey, medicine mechanism of action, competitive landscape, and are supposed to develop their knowledge early in the planning of implementing innovative medicines in the local market. Closer to the expected launch, broader teams get involved in the preparatory work, which includes frequent trainings typically led by the MA teams to ensure that the internal relevant teams are updated on the key information relevant to the disease management, thereby enabling them to perform their roles in the management of the clinical evidence of the medicine, price, reimbursement, and market access provisioning; marketing and sales activities including KEE engagements; Medical Information; pharmacovigilance and risk management and more.	**X**	**X**
Clinical dossier for the Health Technology Assessment (HTA)	It is an MA responsibility to collect all relevant information for the clinical dossier that is submitted for national reimbursement evaluation/ HTA.	**X**	
Collaboration with Patient Advocacy Groups (PAGs)	Engaging with PAGs to gain patient insights and understand the unmet medical needs from a patient perspective can help to aid in ongoing strategy development.	**X**	**X**

	In the engagement it is key to understand the PAGs perspective on gaps within educational efforts and research. Additionally, motivating patient's involvement in data generation projects, as their input is valuable throughout the process from idea to publication. Moreover, it is key to receive feedback from patients and caregivers on educational material needs (physical and digital) and gain their input on planned, new material for patients and caretakers.		
Scientific Meetings	Scientific meetings are one-on-one engagements, or can be arranged as departmental, clinical meetings with HCPs focused on insights generation regarding specific scientific topics aligned with scientific medical objectives and interests of the KEEs. This is an opportunity to identify and evaluate KEE interests to partner in broader medical activities and clinical research projects.	**X**	**X**
Advisory Board Meetings	Discussion with a contracted advisor group of HCPs, patients, and/or other stakeholders, based on a predefined agenda with the intention to provide advice to the company. Relevant advice is gathered across stakeholder groups to inform on specific research and/or clinical objectives. Advisory board meetings foster peer-to-peer networking and collaboration. The MA team ensures that the advisory board has a clear medical or clinical objective, is non-promotional, and that the number of advisory board meetings and number of participants is justifiable and reflects the nature of the advice being sought. The specific advice needed is closely related to	**X**	**X**

	the lifecycle stage of the medicine, i.e., characterized by planning, implementation, maintenance, closure.		
Consultancy Meetings	Consultancy meetings aim to contract advisors for meetings focusing on specific topic(s). The aim is to gain advisor's input on defined clinical and scientific topics.	**X**	**X**
Data Generation Projects	It is important that early insights from clinicians, patients, and payers are brought into R&D departments and to the CFTs. Information on unmet medical needs in the TAs can help ensure that New Medical Entities (NMEs) are matched with unmet needs from the relevant stakeholders' perspectives. The MA can provide the information back through insight generation, which helps to ensure the ultimate patient access to the new intervention. Data Generation can be obtained through local investigators involved in company-sponsored phase 1, 2, or 3 clinical trials. Continued company-sponsored research may be executed to generate RWE, both with the aim of providing information on disease burden, and further to support local market access and treatment recommendations, and thus respond to early clinical questions.	**X**	**X**
Clinical Data Publication and Dissemination Plan	Local data generation, publication, and dissemination planning. Thorough outline and identification of data gaps in support of improvements of patient access or clinical management can be led by the Medical Affairs team in close collaboration	**X**	**X**

	with other teams with expertise within data science, i.e., Health Economists, epidemiologists, and/or HEOR (Health Outcomes Research) functions.		
Evaluate External Sponsored Research (ESR) Project Applications	Strategically defined research areas of priority may exist in the clinical/medical teams in the company. Such areas can potentially be dealt with through ESRs. ESR projects are typically engaged with through the provision of financial support and/or Investigational Medicine Product (IMP). ESR research is owned by the sponsor - in this case the investigator - i.e., the external part. This implies that the trial sponsor is responsible for the study design and conduct and the company has no influence on the study hypothesis, conduct, analysis, interpretation, and/or publication.	**X**	**X**
Collaborative Research Projects	In case ESR projects are proposed in which the ESR sponsor invites for deeper collaboration, pharma companies may have policies in place to enable a collaboration where both parties share ownership of the study design, study conduct, data analysis, interpretation, and publication.	**X**	**X**
National Clinical Meetings	National forums for investigators to share best practices and to resolve potential recruitment challenges. It is critical to understand the external perspective as this provides key knowledge about the new medicine, in terms of management of benefits and risks. It is important to transfer insights from investigators for internal evaluation as these may impact the use of the medicine in clinical practise. Also, knowledge transfer to bridge KEE/investigator relationships, from clinical	**X**	**X**

	operations to medical affairs following study conclusion can help the MA build relations with investigators for future scientific and/or clinical engagements and partnerships.		
Preceptorship Events (Educational & Observational)	Preceptorship events may be educational or observational and may involve KEEs and/or patients. Preceptorships may be conducted either a non-clinically (educational, academic preceptorships) or clinically (observational preceptorships). Objectives may differ depending on the setting and involved stakeholders, but both may be useful "outside-in" strategic activities. Educational preceptorship events usually aim to outline patient treatment and the treatment journey via discussions and presentations by clinical experts and patients. Observational preceptorship events usually focus on understanding the daily work of a healthcare professional by attending an HCP consultation with a patient as a silent observer.	**X**	**X**
National/International Medical, Clinical, Research Congress Participation	MA professionals occasionally participate in either national or international medical, clinical, and/or research congresses, with the aim to stay updated on clinical advancements within the TA and/or present data themselves. If relevant, pharma companies may invite external partners to join such events in a compliant manner. Such engagement may be particularly beneficial for HCPs in countries and/or regions in which public healthcare budgets are sparse, however where there is a need for continued medical education.	**X**	**X**

Scientific Educational Forums	The scientific educational forum is a medical activity developed in collaboration between MA and KEEs / clinical experts in their scientific field. The purpose is to bring together experts and practitioners within a specific medical field to share novel research, clinical experience, and perspectives and education of (young) professionals. These meetings offer internal learning and identification of new topics to be further explored, and validation of the existing knowledge base. Decisions about the topics, format, and recommended speakers should ideally be taken by an external steering committee to ensure that educational need and research interest of the delegates are reflected in the agenda, and to ensure a collaborative, unbiased approach. Involvement of KEEs in the steering committee who are active in the clinic and/or TA-specific research is crucial for success. This is a valuable activity to demonstrate scientific leadership and to establish the company as credible scientific partner in the specific disease/research area. Moreover, such projects support development of long-term KEE relationships nationally and/or internationally.	**X**	**X**
Receive and Respond to Unsolicited Medical Information Requests	Colleagues within the Medical Information (MI) teams provide scientific, therapeutic, and product expertise to support HCPs, patients, and payers in making informed care decisions. MI thus plays an integral role in evaluating evidence-based medicine, developing medical content, and responding to unsolicited medical information requests about a company's product(s) by providing relevant clinical	**X**	**X**

	data to healthcare providers and consumers [1]. MA professionals sometimes receive such unsolicited requests directly, and upon obtaining the substantial response, often assist in the response delivery.		
Medical Compliance Review	Internal review of promotional materials to ensure company compliance rules and regulations adherence. Such reviews require knowledge of country- and company-specific compliance rules and regulations as well as deep insights of disease and therapy areas. Additionally, when a material owner has developed the material based on input from HCPs, the final document will meet the outside-in principles.	**X**	**X**
Others	Risk Management plans; Early Access Program management	**X**	**X**

*Affiliates must ensure that all local requirements under local law and industry codes are fully met and adhered to for any external activity. Local Medical Advisor policies must be derived and vetted according to local guidance.

Reference: 1. Shah I, Janajreh I, Fung SM. Medical Information Practices Across the Pharma Industry: What Can We Learn from Benchmarking Surveys? Ther Innov Regul Sci. 2020 Nov;54(6):1259-1262. doi: 10.1007/s43441-020-00226-z. **Abbreviations:** CDP: Clinical Development Plan; CFT: Cross Functional Team; DIVs: Disease Insights Visits; ESR: Externally Sponsored Research; GCP: Good Clinical Practice; HCP: Health Care Professional; HEOR: Health Outcomes Research; HTA: Health Technology Assessment; IMP: Investigational Medicinal Product; KEE: Key External Expert; MA: Medical Affairs; MI: Medical Information; NMEs: New Medical Entities; PAGs: Patient Advocacy Groups; RWE: Real World Evidence; TA: Therapy Area