RDPAC Medical Affairs Subgroup Work Instruction
Good MSL Practice

Instructions：

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Approved by RDPAC in 2023 April

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In order to standardize the practice and position the value of Medical Science Liaison, RDPAC Medical Affairs subgroup developed this work instruction. This work instruction is aligned with RDPAC Code of Conducts and the General Principle and Guidance of Medical Affairs developed by RDPAC Medical Affairs subgroup.

1. MSL's Value

Medical science liaison (MSL) acts as a field-based expert, enhances scientific exchange and develop trusted, value co-creating partnership with external stakeholders* to address important medical and scientific unmet needs, inform better clinical decision and improve patient outcomes. MSLs also bring back external stakeholder's insights to contribute to company strategy direction and make scientific contribution in patient access. (*Will be described in detail in 2.1 section)

2. MSL's Role & Responsibilities

2.1 External stakeholders of MSL

The external stakeholders of MSL may vary among different companies. Generally, the external stakeholders of MSL including scientific experts (some companies may use the name of scientific leader, therapeutic expert, thought leader, key opinion leader, etc.), HCPs (Healthcare Provider), pharmacists, clinical investigators, payers, policy makers and patient organizations.

2.2 MSL activity category

MSLs focus on external stakeholders' related scientific activities. MSLs' responsibilities and activities may vary among different companies, but usually can be categorized into 4 main categories as below.

1) Scientific exchange
    a) Information sharing and knowledge exchange
    b) Medical Education
    c) Third party congress
    d) Support for interactions with payers, patient organizations and other stakeholders
2) Insights generation
    a) Advice seeking
    b) Insights collection and analysis
    c) Contribute to company strategy
3) Clinical trial support
    a) Company Sponsored Trial
    b) Investigator Initiated Trial (IIT)
4) Cross functional support and therapeutic/scientific training

2.3 MSL's interaction with external stakeholders

1) Acceptable
    a) Be ethical and scientific balance
    b) Reactively answer unsolicited off-label questions with appropriate disclaimer.
    c) Confidential information can only be shared with a confidentiality agreement is in place

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d) Materials used should be approved under applicable guidelines and SOPs and documented

2) Unacceptable

a) Initiate activities intended to promote product
b) Ride along on routine sales calls or participate in the development or execution of sales commercial target plans & strategies
c) Drive discussion of off-label subjects
d) Attend a program in anticipation of an opportunity to drive discussion of off-label information

2.4 MSL's working plan

1) MSL's working plan is to address unmet medical needs regarding the appropriate use of company products and in the general therapeutic area, it should be based on medical strategy and must be separated from any specific marketing or commercial plan. Based on central working plan, MSL can develop regional working plan of field medical activities and indicate the high-level percentage of time to be allocated to those activities.

2) MSL's working plan should include SE profiling/mapping, SE engagement, medical insights, education events and internal interactions etc., it should be updated periodically according to individual company's request.

3) SEs are key stakeholder of MSL, MSL should conduct SE profiling/mapping and develop SE engage plan to meet the unmet medical needs and identify opportunities for collaborations between the company and SEs.

a) SE is HCP who is a medical or scientific professional who meets approved predefined criteria, is recognized by their peers as a leader in their field and has established the credibility to act as an insight provider within the scientific or healthcare community.
b) MSL conduct profiling/mapping to SEs to validate SE information and then engage with them to meet the unmet medical needs, collect insights to better understand a therapeutic/disease area, determine SE's expertise and interest in becoming an advisor, investigator, speaker, or in conducting other activities based on the legitimate business needs of company.
c) When conducting SE profiling/mapping and engage with SEs, MSL must follow all applicable laws, codes, regulations and company policies. Profiling and engagement can help to appropriately use our medicine/new indication and must not be used to induce prescribing, nor to prompt or solicit questions about any pre-approval medicine or any other off-label information. SE profiling and engagement information can be shared within medical team and with internal stakeholders as appropriate.

4) MSL may initiate interactions with other external stakeholders who are not designated as SEs when: 1) Answering the scientific needs of the HCP. 2) Fulfilling a specific medical objective relating to speakers, investigators or access decision makers. 3) Executing a medical initiative as instructed by medical management.

3. Scientific exchange

The aim of the MSL scientific exchange is to meet the needs of external stakeholders, for fair and balanced, accurate information related to company existing and future portfolio and therapeutic areas.

MSLs interactions with external stakeholders can be conducted by face-to-face visits, email or virtually. It should be focused, fair, balanced, evidence-based, and informative in a non-promotional way.

Materials used by the MSL must have a non-promotional look and tone, and should avoid product-specific brand colors or logos, should be approved under applicable guidelines and SOPs and be archived with a reference number for tracking. MSLs activities should be tracked in a standalone management tool including supporting materials.

3.1 Information sharing and knowledge exchange

1) Proactive sharing:
   a) Newly released on-label data or safety-related updates on the product, e.g., updates on a change in package insert or other safety-relevant update.
   b) Engage in medical/scientific discussions with external stakeholders at scheduled events (e.g., medical initiated events, investigator meetings, congresses, etc.)
   c) Provide clinical trial information for ongoing or future involvement to investigators.
   d) Advanced information in disease area.
2) Reactive sharing:
   a) Answer unsolicited medical and scientific questions from external stakeholders, including off-label information. Ensure that off-label information is provided only to the extent required and only to the external stakeholder who asked the question. It should include appropriate disclaimers (e.g., Disclaimer related to the use of off-label information).
   b) Inform on not yet approved line-extensions of already marketed products, and no marketed products in pipeline.
   c) MSLs can answer medical information queries on company products when they have the knowledge to do so. Additional research needed to answer the query can be forwarded to MI colleagues or assigned qualified personnel.
   d) MSL may discuss competitor medicine data with external stakeholders when necessary, in order to provide a complete and balanced response to an unsolicited question. Discussion must include reference(s) for the information about the non-company medicine and must not be disparaging.

3.2 Medical Education

MSLs can proactively provide education on a particular disease and/or associated treatment algorithms, e.g., disease area information, mechanism of action, new pathway, burden of illness, unmet needs, general scientific topics, novel diagnostic/predictive/prognostic biomarkers and product related safety and on-label information etc. The education activity can be conducted either through face-to-face or digital channel. All materials must be approved under applicable guidelines and SOPs.

3.3 Third party congresses

MSL can provide briefing to speakers on the scientific background for the presentation.

3.4 Support for interactions with payers, patient organization and other stakeholders

1) MSLs may attend payer discussions and provide scientific support to the Market Access team during these discussions (e.g., on MOD/MOA) upon initial request only from Payer.
2) MSL can be invited to provide suggestion on disease area or disease specific topics by request for educational events initiated by patient associations, or support Patient Advocacy Groups (PAG)

Ad Boards on medical and scientific/clinical topics by request. MSL should avoid interacting with patients directly.

3) Play a supporting role in preparing medical presentations to other stakeholders (regulatory bodies, insurance companies etc.) upon request

4. Insight generation

4.1 Insights collection and analysis

MSLs could collect and analyze insights from external stakeholders during scientific exchange activity, to better understand a therapeutic/disease area, determine the external stakeholder's expertise and interest in becoming an advisor, investigator, speaker, or in conducting other activities based on the legitimate business needs.

4.2 Advice seeking

Seek advice from external stakeholders, or organize and attend Advisory Board meetings to obtain advice.

4.3 Contribute to company strategy

Provide scientific/clinical insights, expertise, and support for the development of the company strategy, including medical strategy, brand strategy, R&D strategy, etc.

5. Clinical trial support

5.1 Company Sponsored Trial

1) MSL may support PI recommendation, site selection, site feasibility assessments, site development plan, Site Initiation Visits (SIVs), recruitment and retention strategies, and enhancement of site management in company sponsored trial.
    a. During trial planning stage, MSL can be consulted on real world check of protocol feasibility and may recommend potential investigators to Clinical Operations. Upon request, collaborate with clinical operation to conduct Potential Site feasibility Assessment Visits of recommended investigators.
    b. MSL may support to present related molecule overview used in the trial if requested to do so by responsible study personnel at SIV. However, presentation of the protocol overview at the SIV should be conducted by responsible study personnel.
    c. MSLs may answer scientific questions that arise during the conduct of a trial, respond to unsolicited questions from an investigator on an investigational product when they have been trained on the medicine. However, questions specifically about the protocols should be forward to the local study team if raised by investigator to MSL.
    d. MSL may support follow up-and sharing of results post-trial with investigators.
2) MSL may forward any unsolicited medical insights learned during a visit with an HCP to the appropriate functional study manager.
3) MSL must not suggest potential investigators based on their potential to purchase, prescribe, or recommend company medicines, make commitments regarding funding, site selection, authorship, or publication support.

4) MSL should not discuss protocol-specific questions, specific patients or individual patient results with the investigator or site staff, provide any medical advice to investigator/site staff on medical care for specific patients, unless MSL has been assigned specific role in the trial and completed necessary training.

5.2 Investigator Initiated Trial (IIT or other terms for same situation from different companies e.g., ISR, IIS, IST, etc.)

1) The unsolicited and independent nature of IITs should be preserved, and MSLs must not suggest that investigators seek support for an IIT.
2) When supporting IIT, MSLs may provide general information to an applicant on the concept submission process (like IIT template, internal approval process, etc.), engage in scientific discussion regarding the research topic and communicate company strategy with respect to the disease area, inform the applicant if the proposed concept is within the medical strategy and any other similar is currently under consideration but details must not be revealed.
3) MSLs may help to review the concept prior to submission if requested by the applicant while may not assist in writing protocol synopses or filling IIT forms.
4) MSL must make it clear to the applicant that MSL is not responsible for the approval of concepts and therefore cannot make any definitive statement in this regard. Instead, MSL may serve as a liaison between the internal company review committee and the applicant, forward new information regarding proposals pending applications. MSL may support the ongoing IIT management by responding to or directing requests from the HCPs to relevant internal staff.
5) When supporting IIT, MSL must not encourage potential investigators apply for funding based on their potential to purchase, prescribe, or recommend company products.

6. Cross functional support and therapeutic/scientific training

MSL may provide therapeutic/scientific training to other functions such as Commercial, Market Assess, Regulation, Public Affairs, Policy team and Clinical Research team per request. The information of the training material should be objective, balanced and comprehensive, and be limited in the disease within the current product labeling. All materials should be appropriately reviewed and approved under applicable guidelines and SOPs.

7. Interaction with commercial

7.1 MSLs may not attend joint stakeholder calls with commercial field personnel. Joint calls may be permitted in cases such as MSLs may introduce a Sales representative to a SE, or be introduced to the SE for the first time by the Sales representative; special projects needed scientific support.

7.2 MSLs and Sales may share limited high-level information about past and future external stakeholders' visits, but they cannot share specific details of the discussion, especially if it contains off-label information.

7.3 MSL may connect with Product Managers on a strategic level, such as when participating in Brand Team meetings to discuss stakeholder needs and insights.

7.4 MSLs cannot be actively engaged in the development or execution of sales commercial target plans and strategies.

7.5 MSLs may attend scientific sections at internal sales meetings if MSL participation is requested /required and if the MSL plays a specific role linked to their medical and scientific competencies. MSLs should not participate in discussions on sales performance.

7.6 Proper firewalls must be in place to safeguard against any link between MSL activities and sales objectives.

8. MSL's qualification

8.1 MSLs should have advanced medical and scientific education, training and experience. Mature interpersonal skills and good scientific communication skills are required. MSLs' CVs should be documented in company system and periodically updated.

8.2 It is recommended that, before working independently in the field, a MSL should be qualified on therapeutic knowledge, related company policies and procedures, scientific presentation skills, and communication skills. Qualification process could be conducted by individual company.

8.3 MSL should continuously upgrade their knowledge and working skills by attending scientific congress, taking training courses, self-learning, and line manager's coaching. MSLs attendance to continuously training should be documented systematically.

9. MSL's performance measurement

9.1 MSLs performance measurement should never be linked to commercial targets.

9.2 MSL's performance measurement could be based on their contribution in ensuring safe and appropriate disease management and patient benefits. It may be demonstrated in multi-dimensions and links to specific MSL activities including knowledge exchange, insights generation, clinical trial and internal support. Digital solution usage also could be considered as an encouraged dimension for performance measurement. MSL's performance may be tailored based on various product life cycle, therapeutic area and medical strategy which MSL engages in.

9.3 MSL's performance measurement, for example, may be considered with combination of quantitative, qualitative and impact metrics.

1) Examples of quantitative metrics include number of SEs engaged, interaction with SEs, scientific presentations to HCPs, and medical insights collected, etc.;

2) Examples of qualitative metrics include satisfaction expressed by SEs on MSL's professionalism, scientific presentation, medical events and positive feedbacks from internal stakeholders on MSLs' work, clear and actionable insights etc.; `

3) Examples of impact metrics include medical strategy or clinical study designed/ modified based on medical insights captured and reported by MSLs, SE's awareness improvement, data generation etc.;

10. Looking Forward to the Future of MSLs

With the transformation of healthcare landscape and advancement of science & technology, business models of healthcare industry are starting to evolve both around and beyond the "product", and the MSL's value proposition, role & responsibility, working pattern are continuously evolving as well.

10.1 Digital transformation

The COVID-19 pandemic accelerated the digital transformation of the whole healthcare industry. This trend is occurring not only in clinical practice, but in Medical Affairs & MSL's working model. For future MSLs, "Digital" will mean more than the tools used to accomplish a task—it will be a philosophy or way of thinking that integrates all field-based actions and broadens our view of what is possible.

1) Omni-channel engagement

"One-size-fits-all" stakeholder engagement model is becoming past tense. In the future, MSLs will conduct an improved scientific exchange and engagement with SEs in a hybrid model. Virtual interactions are becoming a new normal and replacing more and more traditional face-to-face interactions, informed by analytics and data. Meanwhile, MSL will deliver the tailored-made, personalized scientific content to SEs, HCPs and other healthcare stakeholders in their preferred engagement channel and timeslot at proper frequency. Besides, the centralized content library can ensure the strategic and message consistency in different channels. By leveraging omni-channel engagement, MSLs can reach and expand stakeholders to broader layers and geography coverage.

2) Smart insight generation

The traditional channels to collect medical insights such as face-to-face SE interaction, advisory board meeting, are still important in the future. Meanwhile, some new channels to collect insights are emerging and becoming more and more important, e.g. more and more companies are trying to gather patient insights through advanced analytics and big data, behavioral economics to identify unmet need, and online patient communities and social listening.

10.2 Diverse range of stakeholders

Target stakeholders of MSLs are reaching beyond SE & HCPs to a broader and more diverse range of stakeholders such as payer, investigator, patient advocacy groups, policy maker, etc.

1) Payer

a. Generally speaking, payer means different layers of Healthcare Security Administration which charge for drug reimbursement list update & negotiation, volume-based pricing & purchasing and the policy development of healthcare security funding & payment. Besides, commercial insurance, innovative payment solution and patient benefit management models are emerging in some specific therapeutic area.

b. Working closely with HEOR team, MSL can communicate with payers about the disease burden, clinical and economic evidence and value of products in improving relevant patient outcome. Be leveraging regional real-world insights, MSL can evaluate regional comparative effectiveness of treatment options and provide an opportunity for regional patient access.

2) Investigator

a. Investigators are the healthcare professionals who are responsible for the execution of clinical studies in site. Investigators are responsible for the quality of studies, safety and relevant rights of study subjects and ensure the study operation is in accordance with study protocol and the applicable regulatory requirements such as GCP. Investigators include principle investigator (PI), site investigator, sub-investigator (Sub-I), etc.

b. Abiding by applicable laws, codes, regulations and company policies, MSLs may work with investigators to provide scientific support on disease management and study operation, organize or attend investigator meeting, etc.

3) Patient advocacy group (PAG)

Accompanied with the evolution of "Patient-Centric" business model, Patient Advocacy Groups (PAGs) are growing very fast and becoming a more and more important stakeholders in policy shaping and patient engagement. a. PAGs are often organized by the patients with some specific diseases, provide community help/support to patients and represent the patient voice publicly. They conduct patient education activities, share disease knowledge and even do their own research to track their own data and monitor their own outcomes. b. Abiding by applicable laws, codes, regulations and company policies, MSLs may work with PAGs to provide scientific content on disease management and organize patient advisory board meeting, etc.

4) Policy maker

a. Policy maker means different layers of health authorities other than payers, such as Heath Commission, Medical Products Administration, Hospital Administration, etc.

b. Abiding by applicable laws, codes, regulations and company policies, MSLs may communicate with policy makers about the disease knowledge and evidence/value of products as appropriate.

5) Digital Opinion Leader (DOL)

a. DOL means someone who has wide influence on digital platforms who has the ability to disseminate "medical information" and shift follower/public opinions through innovative ways. He or she maybe the scientific expert who has rich clinical experience and disease knowledge, but they also maybe someone who has little or no scientific or medical training.

b. Abiding by applicable laws, codes, regulations and company policies, MSLs may communicate with DOLs and provide scientific content on disease management as appropriate.

10.3 Regional strategic leadership

In most cases, MSL has been the regional scientific leader and a key contributor to regional strategy. In the future, MSLs could maximize medical impact and build up medical leadership by becoming the hub of SE management in field, supporting R&D project and activity, understanding and grasping the opportunity to shape a better regional strategy to ensure the company success in the region.

10.4 Sustainable career development

Nowadays, MSL often seems as the "ticket for entry" to a career in Medical Affairs. Many MSLs would seek for next career opportunities after working as a MSL in field for several years. In the future, MSL will become a life-long, sustainable growth career pathway which could be continuously developed and contributed through their expertise, highly respected by internal and external stakeholders. With the career advancement, the role & responsibility and competency requirement & proficiency level of MSL will upgrade accordingly.

These trends are ongoing now and will keep evolving in the future. To capture the opportunities and address the challenges accompanied with these future changes, MSLs need to build digital mindset and relevant capabilities and become more business savvy and agile. Meanwhile, medical leaders should endeavor to anticipate what the future will look like for MSL function and develop a more systematic and comprehensive approach to help MSLs grasp the future trends and maximize their value in field.

Abbreviations

Acronym	Definition
CV	Curriculum Vitae
DA	Disease Area
HCP	Health Care Professional

IIT	Investigator Initiated Trial
LCT	Life Cycle Team
MA	Medical Affairs
MI	Medical Information
MOA	Mechanism of Action
MOD	Mechanism of Disease
MSL	Medical Science Liaison
PAG	Patient Advocacy Groups
P&MA	Payor&Market Access
RDPAC	R&D-based Pharmaceutical Association Committee
SIV	Site Initiation Visit
SOP	Standard Operating Procedure
TA	Therapeutic Area
SE	Scientific expert
DOL	Digital Opinion Leader