

Changing Landscape and Future of Medical Affairs Post COVID-19 Pandemic Era

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ABSTRACT

A striking change in the external stakeholders' engagement due to unexpected scenarios as a result of COVID-19 pandemic has hurled the medical affairs (MA) function into innovative strategies of scientific engagements and patient-centric activities. Expansion of MA functions including rising regulatory and compliance inspections, an increased patient centricity and more requirements for RWE, have created the importance of medical affairs not just being the support function but as a trusted strategic pillar in the pharmaceutical and healthcare industry. There is certainly a silver lining due to strong digital transformation within these adverse times. The present review is focused on digital transformation for dissemination of medical information and its advantages over traditional ways. In today's pandemic era HCPs have embraced the idea of virtual CMEs and digital storytelling which has necessitated the MA function to become more agile, adapted and look for collaborations. Both the exponential and radical improvements are required to strengthen this transition, in the new normal of a post-COVID era. The digital innovation in three key vitals viz. HCP engagement, external partnerships and data generation will allow MA to become future fit as a strategic leadership function. Moreover, the recommendations from executive committees of renowned international societies such as APPA, IFAPP, MAPS and MSLS, who have contributed for MA function to create their own standard operating procedures (SOPs), policies which are relevant for industry, are also discussed.

Key words: COVID-19, digital transformation, massive open online courses, medical affairs, omni-channel; real- world evidence

INTRODUCTION

The COVID-19 pandemic has caused substantial damage to human life and a considerable aftermath on the health-care system has been observed because of the high infection rates, complications, hospitalization. The lockdown affected the medical infrastructure which interrupted the reach of appropriate treatment to the patients. This led to the evolution of the medical affairs (MA) functions which is now considered as an important pillar in bridging the gap between Research & Development (R&D), health-care practitioners and patients. The spread of COVID-19 has created a paradigm shift in the working schedule for medical affairs (MA) professionals in the pharmaceutical and healthcare industry.¹

Medical Affairs as a Key-leadership Function in Pharmaceutical and Healthcare Industry

Medical affairs (MA), which was considered as a supportive function only in the past, has emerged as a fundamental function in the last few years for the pharmaceutical and healthcare industry.¹ Medical affairs function has a wide spectrum of roles and responsibilities within the pharmaceutical industry. It acts as an internal bridge between R&D and commercial functions, an external bridge between the organization and external stakeholders. MA function is also involved in investigator-initiated (IIS) research,

generation of phase IV real-world data (RWE), health economics and outcome research (HEOR), scientific publications, continuing medical education activities (CMEs), and alliances with patient organizations.² There is an inclination shift in the industry from sales function to MA function for external interactions due to preferences of healthcare professionals (HCPs) for non-promotional and scientific rendezvous by the industry. The main goal of the non-promotional activities conducted by MA function with HCPs, academia and medical associations is to optimize clinical practice and leverage scientific information through various associations.² The professional groups such as Medical Affairs Professional Society [MAPS] are strongly advocating for the medical affairs' role and providing exchange platforms on international, national and local levels. MAPS has provided specific guidelines for the functioning of the MA profession, emphasizing on the value of MA as medical and scientific leadership, representing the RWE clinical needs of HCPs, patients, and other stakeholders.³

Medical Affairs Function during COVID-19 Pandemic Era: Constraints and Challenges

The healthcare industry has constantly facing multiple constraints and challenges due to the COVID-19 pandemic affecting entire spectrum of care in context to timing and requirement for healthcare services, the disconnection with patients', the waves of reoccurrence, and inclination towards telecommunication and telemedicine.⁴

A far greater impact on people with chronic conditions (PWCD) has been observed not only in terms of worse clinical outcomes with COVID-19 infection but also more poor quality of care due to interruption in continuity of appropriate healthcare services.²

The MA affairs has also been significantly affected due to pandemic bringing out new challenges and demands to cater patients' quality of care. Even though the use of

repurposed drug was common during the pandemic but only MA function can respond to unsolicited off-label enquiries. A remarkable decrease in direct access to HCPs and healthcare institutions and a substantial increase of virtual interactions has been observed. The patient-physician interaction has shown major changes leading to the patient-centricity precedence for MA function. Patients have increasingly been exploring convenient tools and guidance for self-management.² In a recent survey by Medical Science Liaisons (MSLs) in Asia-Pacific approximately 38 % of clinicians specified the necessity for virtual patient education tools.⁵ The travelling account of Medical Science Liaisons (MSLs) have reduced or stopped with limited face-to-face (F2F) interactions and they are involved more into office-based responsibilities owing to the saving of time through virtual interactions and limited access to HCPs.^{1,6}

Transformation of Medical Affairs Function in the COVID-19 Pandemic

The skills and competencies of MA function have drastically changed during this pandemic era. There is an emergence of "New Medical Affairs" with specific expertise, some of which are listed below:

1. Digital platforms:

This will be the basic requirement for any MA colleague going forward in the near future. However, the use of digital platforms is not limited to scientific communication only but would include the use of artificial intelligence (AI), evaluate Big data, incorporate data analytics in insights, and exploring digital models in MA function. This would signify that a fast learning capability, adaptation to modern technology and integration of digital functions in all professional activities will be a requisite by MA colleagues.^{7,8}

2. Focus on patient-centricity:

The patient-centric approach plays a pivotal role in today's healthcare environment.

Augmenting patient access and optimizing the use of medical treatment by demonstrating value to practitioners and payors during the life cycle of each product. Collaborations and partnerships with a wider range of healthcare stakeholders to understand better the different patients' needs so as to provide a substantial value to the patients.⁹

3. Agility, Adaptability, Collaboration:

MA teams, to be competent and successful in this current situation, will be required to be agile, swiftly adapt to the changing working environment, accept cross-functional associations, be updated of developments in the external environment, and innovative in providing ideas for superior the quality of care. Moreover, they should focus on business leadership and strategic approach together with a necessity to incorporate the current learnings both within and outside the core medical sphere.¹⁰

Whilst the MA teams adapted to the evolving healthcare settings quickly, HCPs across India also shaped themselves to the novel ways of interaction with pharmaceutical organizations. An online pan-India survey was conducted between 8 December, 2020 and 25 February, 2021 which involved 191 HCP respondents from different medicine specialties, which aimed to understand the HCP requirements and opinion in the changing environment. The survey looked for the response on the type of content, delivery formats, and significance of the same to clinical practice. One of the components of this survey was to obtain feedback on the virtual platforms for the distribution of the scientific data used by MA teams during the COVID-19 pandemic. The main virtual channels included educational programs with a limited number of participants, telecommunication messages, e-mails, virtual one-to-one dialogue, and extensive scientific events. The main findings of the survey are illustrated in Figure 1.⁶

Opinion of HCPs on the Paradigm Shift in Healthcare Brought by MA

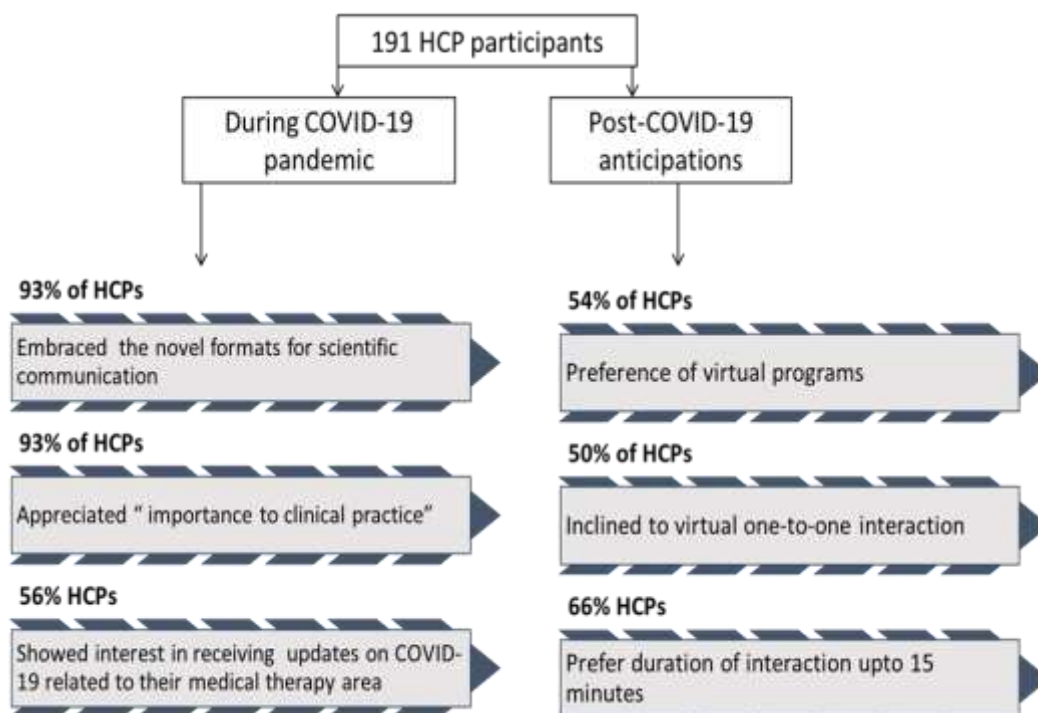


Figure 1. Findings of a pan-India healthcare professional survey⁶ (Adapted from Ghosh *et al.* 2021)

Emerging Role of Digital Solutions for Medical Affairs Function during the Pandemic Era

The pandemic has necessitated a digital healthcare system which is pliant to future challenges. This can be achieved by implementation of digital solutions, such as telemedicine, machine learning, artificial intelligence (AI), virtual learning, connected healthcare devices, and natural language processing^{2, 11} A remarkable positive effect has been observed by virtual medical education online courses and digital storytelling delivery practices in better patient management by the HCPs during this pandemic era.

Virtual Medical Education by Massive Open Online Courses (MOOCs)

➤ **Due to the COVID-19 pandemic, webinar usage by HCPs has increased by between 300%¹² and 3250%¹³ in 2020 versus 2019.^{12,13}** Insight and perspectives for virtual Continuing Medical Education (CME) platforms have transformed since the onset of the COVID-19 pandemic and there is a probability of persistence of new ways of conducting medical education post-pandemic.¹⁴ Figure 2 illustrates the inclination of HCPs towards preferred choices of conducting CMEs during and post-pandemic era.

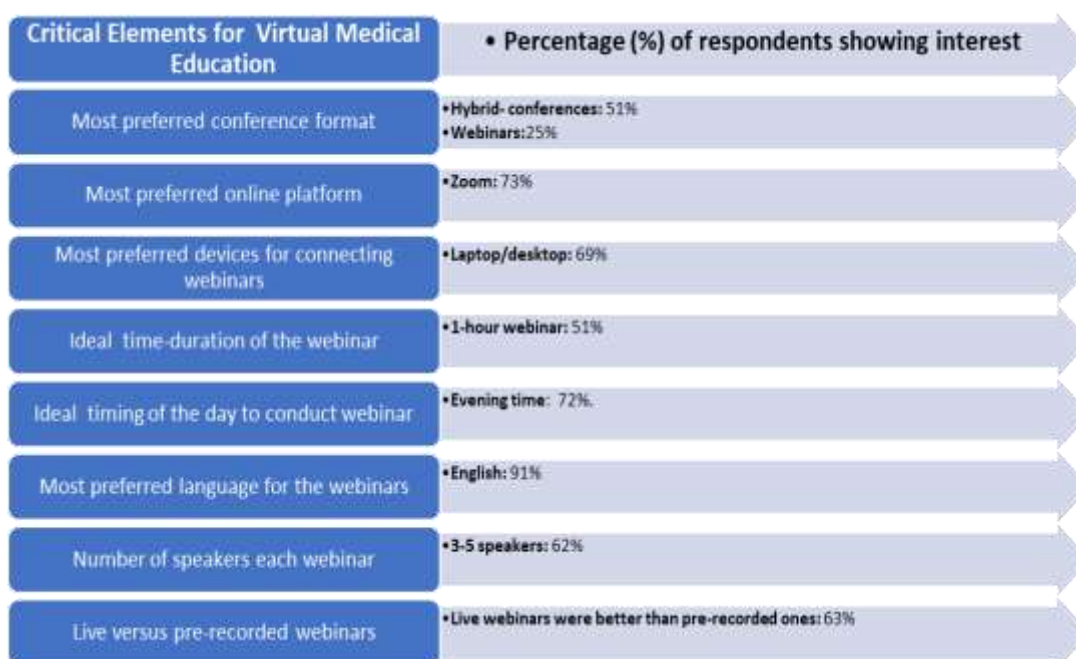


Figure 2: Findings of a survey on the use of innovative models for virtual medical education among 526 urologists from 56 countries during and post-pandemic era¹⁵

The findings of a cross-sectional, internet-based survey on 326 physicians showed that satisfaction among HCPs was higher for international conferences and teaching courses versus events sponsored by pharmaceutical companies (74.5 % vs 41.4 %, $p \leq 0.001$). This significant discrepancy might be due to the higher number and frequency, and overlapping activities of pharmaceutical-sponsored meetings, and therefore apparent biases. Contrary to this, international conferences occur annually

and without commercial biases with eligibility of higher CME accreditation, than pharmaceutical-sponsored events.¹⁶ This provides useful insights for MA function in improving and planning virtual online CME activities during and after the pandemic. As online CMEs are need of the hour with great inclination from physicians, MA function should focus on developing customized virtual medical education content, and launching specific medical education programmes based on current

clinical practice needs. Massive open online courses (MOOCs) are a cost-effective way to disseminate information in the form of easily accessible content to HCPs, providing the flexibility to their hectic schedule. MOOCs can be defined as online learning platforms where courses are accessible at negligible or no cost, and outreach is for large numbers of learners. Furthermore, to achieve desired results, MOOCs functionality should be optimized for learners to raise queries, discussion forums for different practice and related issues, local data, and networking options with fellow learners and for research purposes.¹⁷ An evidence-based example of MOOCs is ASPIRE (the Asia-Pacific Initiative for Rheumatology Nurse Education)¹⁸ which is an independent faculty-driven initiative in the Asia-Pacific region developed by rheumatologists to overcome the challenges in managing their patient caseload and the identification of the evidence-based practices signifying the importance of nurses in clinical practice. A strategic approach was taken by the distribution and implementation of existing modules for expanding the reach of ASPIRE program. This was facilitated by endorsement learning modules and other resources by the Education Committee of APLAR—the Asia Pacific League of Associations for Rheumatology. The endorsed educational material such as tutorial videos for disease assessments, and pre-and post- knowledge assessment tests were published on its website with an Implementation Toolkit to make sure a reliable training structure (http://www.aplar.org/education_page/aspir-e-implementation-toolkit/).¹⁸ The success of ASPIRE workshop trainings was evaluated by a before-after-control-impact survey, and a significant increase in knowledge (by 30%) and confidence (by 29%) ($p < 0.001$ on a participant level) was observed.¹⁹

➤ **Impact of Digital Delivery of Scientific and Educational Information to HCPs: Digital Storytelling Methodology**

There has been a shift in the format of medical publications since the pandemic from traditional to novel methodologies by accepting digital innovation to enrich the quality with animated figures, e-posters, and author videos. An increased observance of digital transformations in medical and health education storytelling such as the presentation of medical data in the form of fascinating infographics and animated figures make data even more exciting and also augment shared decision making.²⁰ Digital storytelling allows better health decisions by knowledge sharing and critical thinking for available evidence-based data with patients, HPCs, caregivers, and policy makers.^{20,21} Recently plain language summaries (PLS) have gained interest and are becoming an established part of company-sponsored research publications. PLS are short abstracts of peer-reviewed medical publications but written in lay-man language so as to be easily understood by patients and caregivers.^{22,23} Open Pharm, a multi-sponsor collaboration of publishers, pharmaceutical companies, non-pharmaceutical funders, patients, academicians, and regulators, has provided set of key recommendations for PLS. Among many formats of PLS text-based formats are the mostly noticeable through indexing in search engines such as PubMed.²²

➤ **Implementation of Digital Transformations Post-pandemic Era**

The digital transformation in MA can be empowered by adequate infrastructure plus training to boost the capabilities and making the MA team digitally literate together with the support by senior leadership. It also requires a strategic shift in medical critical aspects. Big data, real-world evidence (RWE), artificial intelligence (AI), and partnerships in patient-centered ecosystems will play a crucial role reshaping the MA function strategy, defining success factors, key performance indicators and metrics.⁸ Metrics for digital transformation can be of two types: quantitative and qualitative.

These metrics should be evaluated in defined intervals. Quantitative metrics can include number of software users relative to the number of licenses purchased, number of processes carried out, and productivity indicators.²⁴ Qualitative metrics can include digital literacy acquired (expertise and knowledge), attitudes, trust, satisfaction, and behaviours.² Insights from RWE can be synthesized by the use of AI.⁸ For example, now-a-days, digital key opinion leaders have a large reach via digital strategies and are augmenting the position of “traditional” HCPs whose academic papers and medical presentations lead renowned congresses and journals. In this scenario, engaging HCPs with the blended skills and expertise of both traditional and digital leaders will be one of the important needs to be catered by the MA function.²⁵

➤ **Changing Panorama of MA Function in the Future Decade**

MA function has gained significant importance owing to the rapid digitalization during COVID-19. It is presumed that MA will be the third strategic pillar of the pharmaceutical industry together with its Research & Development and commercial and business functions owing to rapid generation of scientific evidence-based data and the intricacies in routing scientific information with stakeholders and eventually improve patient outcomes.² MA main functionalities can be broadly categorized into three areas—HCP engagement, external partnerships, data generation. These are also briefly illustrated in Figure 2.²

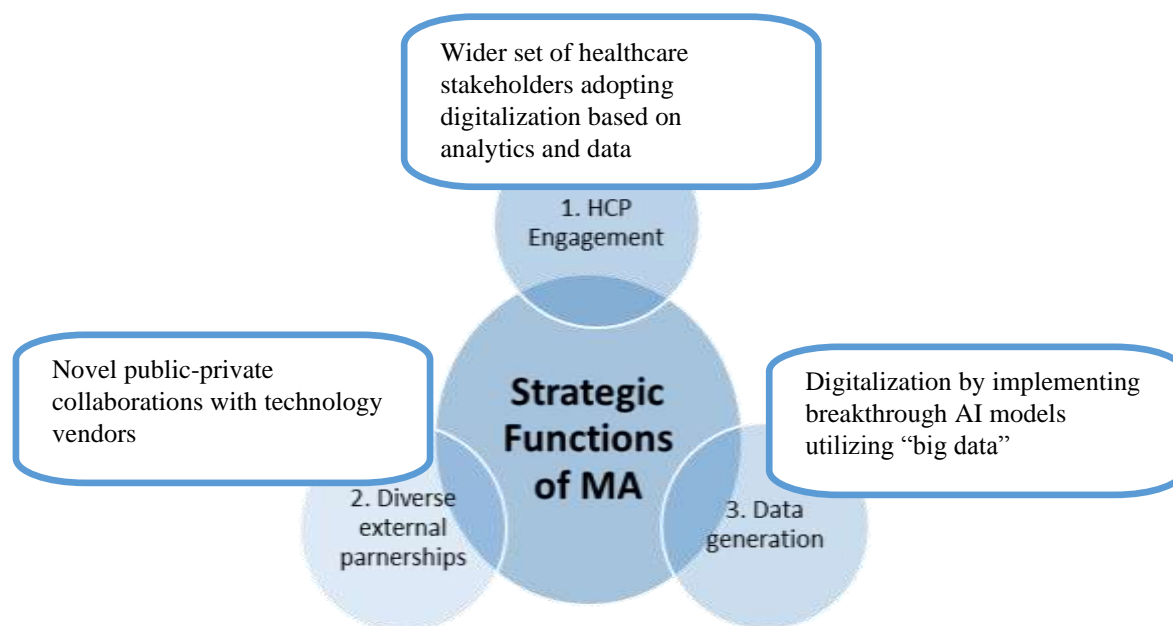


Figure 2 Fundamental strategic leadership for medical affairs in next 10 years ² (Adapted from Furtner *et al.* 2022)

Essential Abilities of MA to Succeed in the “New Normal”

The MA function will require an adaptation to the changes in the working environment in healthcare industry after pandemic era to succeed in the “new normal” which would include:

- Foresee and addressing the changing medical and scientific information requirement of HCPs in real time.⁶
- Preparing the medical information department for the unexpected spike for scientific information and queries.⁶
- Capability in reducing the turn-around-time from international to local

- functionalities with agile cross-affiliations.⁶
- Expertise in areas further than specific therapies which would include developing guidelines, government policies, and recommendations of global and local bodies.⁶
 - Leveraging multi-channel engagement models.^{26, 27.}
 - Establishing distinctive features such as polls and break-out sessions to resolving

webinar and digital relate weariness.^{26, 27.}

- Implementing real world analytics for evidence-based data generation.^{8, 10}

Moreover, MA teams would need to sharpen specific skills and accept digital innovation to be competent to meet the expectations of various stakeholders (Figure 3).

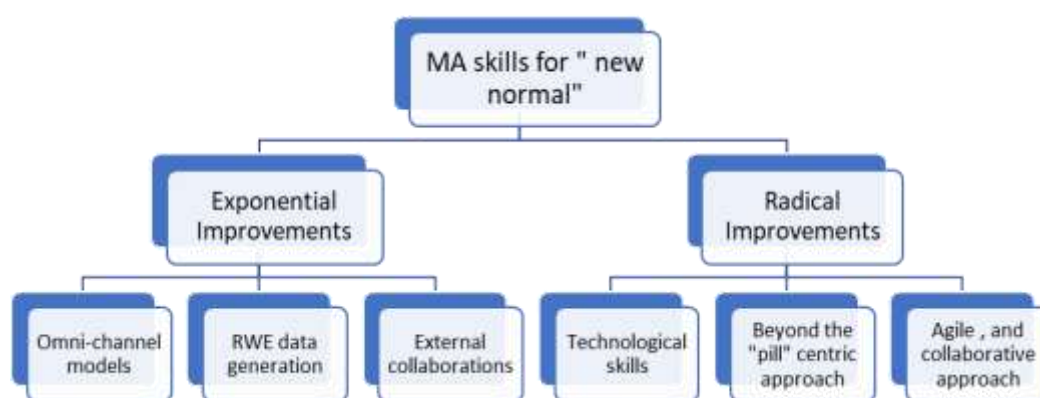


Figure 3. Requisite expertise and skill sets for MA function post-pandemic era⁶ (Adapted from Ghosh *et al.* 2022)

Key Recommendations from the Guidelines APPA, IFAPP, MAPS and MSLS Executive Committees

The assurance of the industry integrity and ethical standards is extremely important during dissemination of medical and scientific communications to external stakeholders. This can be achieved by developing concrete guidelines for MA teams to create their own standard operating procedures (SOPs), codes of conduct and policies which are relevant for industry. Some of the eminent executive committees working collaboratively to develop such strategies to assist the MA teams in the industry are Australian Pharmaceutical Medical and Scientific Professionals Association (APPA), International Federation of Associations of

Pharmaceutical Physicians and Pharmaceutical Medicine (IFAPP), Medical Affairs Professional Society (MAPS) and the Medical Science Liaison Society (MSLS).²⁸

Summary of Key Recommendations²⁸

1. Identification of medical experts according to their specialty and academic recognitions, their publications quality, designations and rankings in apex bodies and societies, their clinical practice experience, their participation in the development of treatment guidelines with specific societies, and participation in clinical trials.
2. Sharing insights from the field force with medical and concerned members of the marketing teams to provide support

for the development of strategies for research medical, brand &, launch plans and medical communications materials.

3. MSLs play a vital role throughout the lifecycle of a product: during clinical development, launch and pre- & post-launch.
4. Dissemination of misleading or false scientific information should not be done. Skipping or selecting the information which by default might be misleading for the stakeholder is not recommended.
5. Treatment prescription to patients or advice on treatments is not recommended for MSLs.
6. Reporting of adverse events by MSLs should be done within 24 hours during external stakeholder interaction.
7. The MSL bridges the gap between the company and the healthcare system by recognizing unmet clinical needs, providing information on mechanism of action, efficacy and safety of new molecules and at the same time aiding in identifying apt patient profiles that might benefit from the new drug. However, the discussions with main stakeholders on these aspects should be non-promotional, highly scientific and unbiased in nature.
8. MSLs are required to maintain independence from sales and promotional-based activities.
9. Sales targets should not be the key performance indicators for MSLs.
10. The reporting of MSL function to MA is strongly recommended to maintain their independence and exhibit that their role is mainly non-promotional and therefore they may involve themselves in even off-label but apposite, scientific interactions.

CONCLUSION

The transformation of pharmaceutical industry is inevitable due to the tremendous challenges and changes in the healthcare system due to COVID-19 pandemic. Medical affairs have huge prospects in

leading and expanding the digital transformation in the pharmaceutical industry. Presumably, the future of MA is brilliant, which envisages it to become the third strategic pillar of the pharmaceutical industry together with its R&D and commercial functions. To become competent, medical affairs need to embrace technological advances, express digital literacy and change in the mindset, expand partnerships and collaborations across the healthcare industry, expertise to business leadership, acquire knowledge and self-development, and the ability to generate RWE with AI technology and analytics.

Declaration by Authors

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