Altimetrik

How Medical Affairs is Driving **Pharmaceutical company's decision making & AI/ML's role in enhancing the Medical Affairs'** contribution.

WHITEPAPER

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Introduction to Medical Affairs

Medical affairs is one of the functional area within a life sciences industry that focuses on the communications between the pharmaceutical companies and medical professionals, healthcare providers, patient advocates, patients, medical payers, and so on. Medical affairs' primary role is to provide scientific and clinical information to the medical stakeholders through various channels like field interaction, presentations, standard response documents, congresses, educational sessions, and medical publications.

Medical affairs professionals must engage in extensive research and analysis of research papers, clinical study reports, publication journals, healthcare professional's feedback & other clinical data to derive the medical insights which will be disseminated to healthcare community. These medical insights play a major role in driving company strategies on their products & research initiatives.

Medical affairs professionals will have degrees including PharmDs, PhDs, MD, or other medical education that enable them to understand the clinical trial reports and science behind a product or device, analyze data to derive medical insights, and effectively communicate all these information to medical communities. Apart from technical & academic knowledge, medical affairs professionals should have good presentation & articulation skills to effectively communicate company's objectives and product's scientific details in front of physicians.

The evolution of medical affairs to a core business function

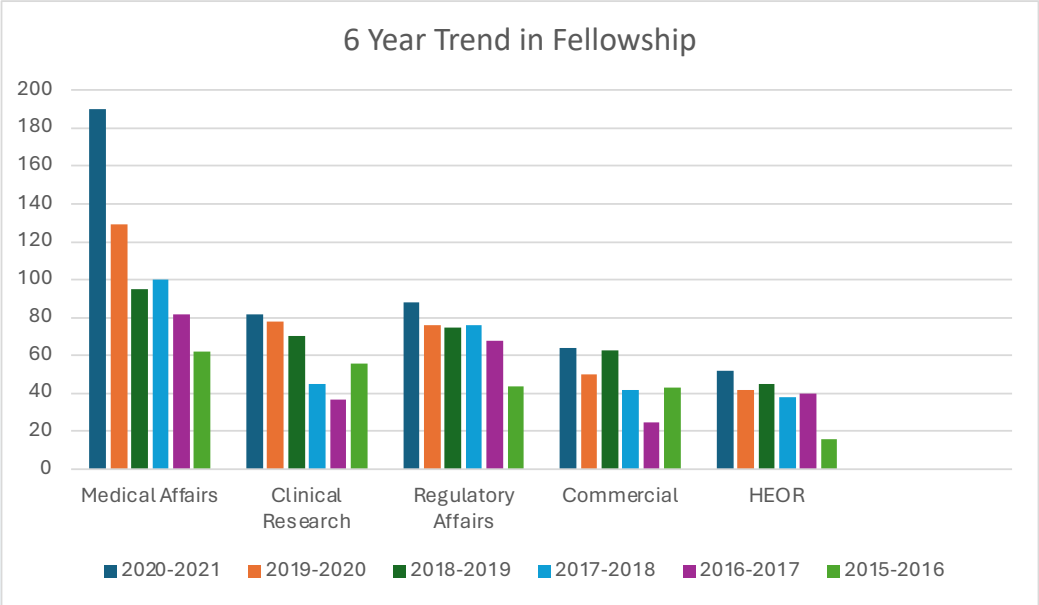
The term “Medical Affairs” was coined by Upjohn Co, in 1967 and since then medical affairs has evolved from an insignificant functional area into one of the prominent departments in pharmaceutical industries.

The importance of medical affairs has grown significantly over the past several years, due to increasing restrictions on communication between healthcare professionals and pharma sales reps which was due to PHRMA guidelines, released in 2009, and the Sunshine Act, released in 2013. These landmark legislations were passed in US, also to prohibit kickbacks paid by drug & device companies to influence the medical communities. As per the medical survey in US, only 47% of physicians are now accessible by pharma sales reps. Only 27% of oncology and 19% of nephrology physicians are fully accessible to reps. Therapeutic areas like oncology & nephrology require thorough knowledge of clinical and scientific aspects of drugs & devices and this is where medical affairs is ideally suited to deliver its expertise.

But the recent changes in the healthcare landscape have increased the responsibilities of medical affairs department with more challenging tasks to perform for their companies. Medical affairs should not only provide clinical & scientific support to medical stakeholders and be the medium of communication between pharmaceutical companies & medical communities, they also have to deliver powerful insights derived from the data captured from(or based on) clinical trial results, drug prescriptions, efficacy of drugs, medical publications, voice of customer, Healthcare professionals (HCPs) or Key Opinion Leaders (KOLs) digital research, customer reach & product campaigns, medical congresses participations and so on. In recent years, medical affairs team must engage with wide range of stakeholders and depending on the type of stakeholder, medical science liaisons (MSLs) must create tailored messages & personalized tactics to effectively deliver the information.

To meet the demands of medical affairs & for their smooth functioning, pharmaceutical companies have increased their investment in medical affairs department. For example, in 2015, 60% of life sciences companies have planned to increase their budget for medical affairs.

Based on IPhO PharmD survey fellowship analysis paper, medical Affairs fellowships are increasing over the decade compared to other functional areas which we can see in below chart that shows 6-Year Trend in Fellowship Positions by Department/Functional Area.



Key functions Of Medical Affairs Team

Over the years, the key functions of Medical Affairs department have become more diverse & multifaceted.

Some key functions of Medical Affairs teams include:

- **Key Opinion Leader (KOL) Engagement**

  Medical Affairs teams build a strong relationship with Key Opinion Leaders (KOLs) and Healthcare professionals (HCPs) of various therapeutic areas. These relationships are established for meaningful peer exchange, seek expert opinions, share scientific data related to company's products and research initiatives, & bring voice of HCPs back to the companies which can help them to enhance their strategies & take informed decisions.

  Key opinion leaders (KOL) are trusted, well-respected individuals who have greater influence on healthcare professionals (HCPs), patients, medical institutions, payers & other medical community members and their sphere of influence will be from local to national level. The treatment of patience, drugs used, diagnosis practised by KOLs are followed by other HCPs as these KOLs will be the experts in their therapeutic areas. KOLs even help in identifying the patients for clinical trials. This is why maintaining a strong relationship with KOLs is essential as it helps medical science liaisons (MSLs) to reach wider audience and have an impactful message related to company's product & research initiatives.

  KOLs have vast experience in their therapeutic areas which they leverage in providing information to medical science liaisons (MSLs) like specific disease states, existing diagnosis & treatments, patient-centric concerns like safety issues, product improvements, ideas for commercial messaging that align with facts & science behind the product, suggestions on clinical trial designs. medical science liaisons (MSLs) use CRM tools like Veeva CRM, CRM Creatio, IQVIA CRM etc or even Microsoft excels for KOL engagement.

• Managing Medical Education

Medical Affairs Professionals are experts in their assigned therapeutic areas, and hence they are responsible in creating the educational content & delivering that content to healthcare professionals (HCPs) & other medical stakeholders. Educational sessions can be delivered in the form of one-to-one or group interaction with HCPs, international speaker programs (ISP's), medical congresses, medical publications, orchestrating seminars, educational websites, email communications, social media posts & so on. Educational content varies based on target audience and mode of training sessions. Educational content topics & purpose may vary based on the drug development life cycle as detailed in below table.

Drug development Phase	Educational Topics & Purpose
Early development	Provide basic details about the drug to keep HCPs informed about the new drug.
Pre-launch	Explain science behind the drug & create more awareness about drug usability, safety, benefits & so on.
Launch	Educate on clinical evidence, efficacy, approved prescription & other therapeutic uses.
Post-launch	Continued medical education related to drug efficacy, safety.

• Deriving Scientific Insights

Medical Affairs teams provide scientific support to internal teams like R&D, marketing teams, & executives of their companies & provide them with medical insights that can be used to improvise their strategies in their respective areas. There will be huge data available with medical affairs team from which they have to derive useful insights that can benefit the business to take informed decisions and eventually help patients for better healthcare experience.

Few examples of medical insights derived by medical affairs teams,

- Sentiment analysis of social media posts of healthcare professionals (HCPs) to understand whether the HCPs are positive, neutral, or negative about the product.
- Knowing the sentiment of Key Opinion Leaders (KOLs) or HCP messages or from surveys given to medical science liaisons (MSLs).
- Analysing the voice of HCPs to understand the drawbacks of diagnostic procedures and their suggestions.
- Derive the insight like most popular brand among the medical publications.
- Comparative study of efficacy of drugs across multiple territories.
- Capturing the safety concern questions asked by HCP to MSL in conference.
- Which websites are widely used to do medical digital research by HCPs.
- Number of likes, shares, clicks, impressions of social media posts related to company campaigns.
- Number of mentions or citations of medical publications in various websites.
- Capturing the data points from patient advocates on primary concerns of patients in participating in clinical trials.

According to a global survey of MSL teams, more than half of them see the collection of scientific insights as core responsibility of medical affairs. Scientific insights include trial design & labelling insights from regulators, economic insights from payers, real-world evidence from patient advocates, and HCP insights.

• Clinical Development Support

The collaboration between Clinical Development and Medical Affairs starts early in the drug development life cycle.

Medical affairs professionals provide clinical development teams with meaningful insights from HCPs, patient advocates, payers, and patients. This information will be leveraged by clinical development team to enhance their clinical trial protocols with patient centric decisions, eventually to have better results and patience safety. This helps in addressing the unmet need of patients and healthcare providers along with adhering to regulatory requirements & standards.

Medical affairs team continue their engagement with different stakeholders to provide informative data points arising out of Real-World Evidence (RWE) studies or Investigator Initiated studies (IIS), typically during phase-4 of clinical trials.

Once the drug is approved, medical affairs team begin providing the medical information to medical communities (KOLs/HCPs) about clinical trial results, efficacy & safety of drug, science behind the drug, approved diagnostic ways and allowed drug dosage & so on. Medical affairs also engage with healthcare buyers to make sure approved drug is included in national formularies & are considered for insurance coverage & use at hospitals.

• Publication Planning

Medical Affairs department plays a vital role in publication planning of the pharmaceutical firms. Medical affairs professionals work with researchers, principal investigators, clinical development department, medical writers, KOLs & HCPs for planning the publications. MA team also engage with clinical communication agencies and PR firms who help in promoting the publications.

In publication planning, medical affairs team must identify the purpose & audience of publication, identify the contributors, content, timelines, compliance & ethical standards, publication tools, target journals & publication agencies and other stakeholders that are required to start the work on publication.

Quality publication planning and its implementation provide benefits across the spectrum:

- Maximize the reach & clarity of clinical data to KOLs & HCPs.
- Fostering consistent delivery of scientific & clinical data about products to HCPs.
- Providing clinical data to regulatory bodies & healthcare payers that includes safety, efficacy, dosage of drugs & other medical insights.
- Creating awareness about the science behind the new drug across the medical community.
- Clarifying and addressing all the issues & questions about product that may affect acceptance from patients.

Medical affairs team also capture how, who & when their publications were used by medical stakeholders. MSLs capture the data points like number of mentions, citations, references of their publications in various websites. They also capture number of downloads, publication views, impressions, clicks, shares over social media platforms. Based on this data, medical affairs can derive the insights to know about the popularity & usefulness of their publication.

- **HEOR Support**

Health Economics and Outcomes Research (HEOR) team focuses on generating evidence to justify the safety & efficacy of the drug in curing the disease based on the clinical trial data and performs cost analysis of the drug based on its therapeutic benefits, cost-effectiveness, and availability of alternative treatments, so that the drug is affordable to patients.

HEOR team help medical payers make strategic reimbursement to pharmaceutical companies. Without adequate reimbursement, a drug may struggle to reach the patients who need it most, despite its proven efficacy and safety.

Medical affairs team support HEOR team by providing necessary information related to product like clinical data, voice of HCPs, feedback from patients & their advocates, medical insights captured during medical congress, HCP interaction notes, publications & so on. Information provided by medical affairs department is useful for payer companies to evaluate whether the product or treatment for which they would be reimbursing, will provide better health outcomes at a better cost when compared with existing drugs or treatment.

- **Medical Data Repository Maintenance**

Medical affairs department creates & maintains the medical data repository which will be having data of all phases of clinical trials, evidence on drug safety, drug efficacy, allowed dosages, KOL & HCP survey data, medical publications, HEOR related data, insights related HCP's engagement & customer reach, HCPs digital research, social media sentiments, company product campaigns & so on.

Whenever HCPs, principal investigators, pharmacists, HEOR team, and other medical community members are seeking answers to questions related to product or require medical information then they consider medical affairs as trustable knowledge repository & single source of truth. Medical affairs may collaborate with pharmacovigilance departments to collect details about investigation, detection & prevention of adverse effects of drug related problems and this data accrued in medical affairs data repository can be used to address the safety related inquiries.

- **Real-World Evidence Generation**

Evidence generation team of medical affairs department gather Real World Data(RWD) which is used to analyse & derive clinical evidence, called Real World Evidence (RWE), about patience health, usage and potential benefits or risks of products & so on.

All data collected routinely on patient health from different sources, are called Real World Data (RWD). The US FDA defines RWD as "Real-world data are data relating to patient health status and/or the delivery of health care routinely collected from a variety of sources. Examples of RWD include data derived from electronic health records, medical claims data, data from product or disease registries, and data gathered from other sources (such as digital health technologies) that can inform on health status".

US FDA define Real-world evidence (RWE) as "Real-world evidence is the clinical evidence about the usage and potential benefits or risks of a medical product derived from analysis of RWD".

Once the RWE is generated, medical affairs disseminate the findings to the healthcare community.

Members in Medical Affairs Team

The Medical Affairs department is formed by various professionals having wide range of educational qualifications, experience, and expertise on specific therapeutic areas which decides the role of the individuals in the medical affairs team.

Some of the key members of the Medical Affairs department include:

- **Medical Information Officers**

  Medical Information Officers handles inquiries from clinicians, patients, KOLs, and other medical community members. They make sure the information that is stored in medical affairs repository is up to date and accurate before delivering it to various stakeholders.

- **Medical Science Liaisons (MSLs)**

  MSLs are field-based Professionals whose primary responsibility is to engage with KOLs & other medical community stakeholders to explain the scientific and clinical findings surrounding the drugs and research initiatives of the company. This role requires lot of regional travelling to build the relationship with KOLs & HCPs and require expert level knowledge related to drug and strong presentation skills. Developing relationships with healthcare professionals, key opinion leaders, medical institutions will remain an important part of the role.

- **Medical Communication Specialist**

  Like an MSL, this role also requires field-based expertise and exceptional communication skills to engage with customer & communicate medical insights. They work with cross-functional teams like marketing, HEOR, sales, R&D to accomplish the company's goal.

- **Medical Director**

  Medical Directors oversee the daily functioning of medical affairs department. They also work closely with other cross-functional teams and in-charge of assuring that department's functioning & operational procedures are in-line with company's objectives. Medical directors may be responsible for a group of KOLs or HCPs in providing required information.

- **Medical Affairs Managers**

  Medical Affairs Managers oversee specific therapeutic areas, product portfolios or disease areas. They manage group of MSLs and are responsible in making sure that all MSLs in the team are adhering to the regulatory guidelines and meeting the objectives of company.

- **Medical Writers**

  Medical Writers are responsible for creating new medical contents or upgrading the existing contents that includes medical publications, presentations or decks used for educational programs, social media post content used for product campaigning, clinical study reports and so on. They should be experts on the topics that They can also be reviewer of medical contents created by other medical writers. They need to follow all the ethical guidelines & regulatory standards while creating the medical content.

The Future of Medical Affairs

The changing landscape in the life science industry has increased the challenges that are faced by medical affairs departments, and it is getting very strenuous in satisfying the expectations of pharmaceutical firms. Physicians too have some serious concerns on dealing with the changing landscape of medical affairs.

Challenges of MSLs & Physicians include

- Availability of abundant of data which is overwhelming for MSLs to derive medical insights and for physicians to effectively utilize the insights in their practise.
- MSLs feel that time constraint is the major factor in reduced in-person interactions with physicians.
- Physicians feel ineffectual & sometimes, irrelevant medical insights being delivered by MSLs.
- MSLs feel the scarcity of alternative strategies to capture the insights from HCPs feedback, opinions & sentiments from social media posts, medical publications, congresses & so on.
- HCPs feel void in keeping them informed from medical affairs teams.
- Amid the work, medical affairs team members must go through education and training programs regularly to keep pace with evolving medical knowledge and technologies.
- MSLs feel lack of innovative tools & skills to complete the challenging work in limited time.

Benefits of Artificial Intelligence & Machine Learning

Artificial intelligence & machine learning are playing a very crucial role in addressing the concerns of MSLs and HCPs. Technology expansion is serving MSLs in most of their tasks like choosing the right KOLs, extracting meaningful & effective insights, enhancing HCP engagement, keeping track of latest developments in the field and so on. AI and machine learning will complement the human intelligence but not replace it.

Some of the benefits of AI & Machine Learning in Medical Affairs area include:

- Deriving insights from MSL notes that were captured during interactions with KOLs or HCPs, or during medical events, telephonic conversations, using latest NLP engines.
- Enhancing quality of video & image creation for medical content assimilated to various medical stakeholders.
- Automating the creation of personalized content & information based on HCP's therapeutic area, knowledge of medical stakeholder, influence of stakeholder and so on.
- Leveraging machine learning models for social media listening to capture precise sentiments from social media posts of HCPs, HCOs, patients, competitor firms.
- The power of Generative AI has helped Medical Affairs Teams to accelerate data analysis of dense scientific documents, technical papers and aggregating them to define the insights, thereby reducing the time & effort at least by 50%.
- Identification of Key Opinion Leaders (KOL) and Digital Opinion Leaders (DOL) who can participate in research or help in patient recruitment who most likely respond to interventions, provide suggestion on chemical design, in finding investigators and so on.

- Sophisticated Natural Language Processing (NLP) algorithms are used for entity recognition, categorization, and sentiment analysis.
- Conversational AI expedites tasks for MSLs like scheduling meetings with HCPs or KOLs, tracking the inquiries & resolving them with required information saving significant time & effort. It also helps in optimizing complex searches over catalog of medical data repository.

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Author's Bio

Mahesh Abbigeri
With 14 years in BI/DWH projects, Mahesh has worked in the Telecom, Banking, and Life-sciences industries as a data engineer, architect, and analyst. His dedication to data and business insights led him to author a whitepaper on Medical Affairs' crucial role in Pharmaceutical success.


linkedin.com/in/mahesh-abbigeri

About Altimetrik

Altimetrik is a pure-play digital business services company. We focus on delivering business outcomes with an agile, product-oriented approach. Our digital business methodology provides a blueprint to manage data as well as develop, scale, and launch new products to market faster. Our team of 6,000+ practitioners with software, data, cloud engineering skills help create a culture of innovation and agility that optimizes team performance, modernizes technology, and builds new business models. As a strategic partner and catalyst, Altimetrik quickly delivers results without disruption to the business.