Medical Affairs

The Roles, Value and Practice of Medical Affairs in the Biopharmaceutical and Medical Technology Industries

By: Medical Affairs Professional Society

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Medical Affairs

Medical Affairs is one of the three strategic pillars of the pharmaceutical and MedTech industries, but while clear career paths exist for Commercial and Research and Development, there is no formal training structure for Medical Affairs professionals. Medical and scientific expertise is a prerequisite for entry into the function, and many people transitioning into Medical Affairs have advanced degrees such as PhD, MD, or PharmD. However, these clinical/scientific experts may not be especially well-versed in aspects of industry such as the drug development lifecycle, cross-functional collaborations within industry, and digital tools that are transforming the ways Medical Affairs generates and disseminates knowledge. This primer for aspiring and early-career Medical Affairs professionals equips readers with the baseline skills and understanding to excel across roles.

Features:

- Defines the purpose and value of Medical Affairs and provides clear career paths for scientific experts seeking their place within the pharmaceutical and MedTech industries.
- Provides guidance and baseline competencies for roles within Medical Affairs including Medical Communications, Evidence Generation, Field Medical, Compliance, and many others.
- Specifies the "true north" of the Medical Affairs profession as ensuring patients receive maximum benefit from industry innovations including drugs, diagnostics and devices.
- Presents the purpose and specific roles of Medical Affairs across organization types including biotechs, small/medium/large pharma and device/diagnostic companies, taking into account adjustments in the practice of Medical Affairs to meet the needs of developing fields such as rare disease and gene therapy.
- Leverages the expertise of over 60 Medical Affairs leaders across companies, representing the first unified, global understanding of the Medical Affairs profession.

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The Roles, Value and Practice of Medical Affairs in the Biopharmaceutical and Medical Technology Industries

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Preface

In 2016, a handful of Medical Affairs leaders across industry realized the profession was without a society. There is a society for anesthesiologists, a society for microbiologists, and even the National Association of Professional Pet Sitters (NAPPS). Why was there no nonprofit professional association for Medical Affairs? These leaders visioned the potential of Medical Affairs and knew that to reach this potential the function needed to speak with one voice, advocating for the profession while providing a structure to mentor the next generation of leaders. The result was the founding of the Medical Affairs Professional Society (MAPS). Of this book's editors, Kirk Shepard was one of the founders and Charlotte Kremer joined the leadership structure in the organization's first months. The purpose of the MAPS organization was and remains similar to the purpose of this book: To demonstrate the impact of Medical Affairs in the biopharmaceutical and MedTech industries while providing resources to equip Medical Affairs professionals with the knowledge and skills necessary to support efforts to create better patient outcomes and bring value to their organizations while progressing their careers toward leadership roles.

The fact is, Medical Affairs is the least understood of industry's three functional pillars. Research and Development discovers new health innovations. Commercial markets and sells them. But what does Medical Affairs do? The answer is that people within Medical Affairs do many things. For example, a PharmD student might find a fellowship in industry that leads to a role as a Medical Science Liaison, working out of a home office to conduct scientific exchange and provide expert advice to healthcare professionals to benefit patients by guiding clinical care. Or an MD might transition from leading clinical trials at an academic medical center into a similar role managing Medical Affairs-sponsored clinical trials. Or a basic researcher might decide their heart lies in writing about science and leverage their skills and knowledge with academic journals into a position in Medical Affairs publications.

In part, the diversity of Medical Affairs is what makes it difficult to understand. Even within the profession, the three Medical Affairs professionals in the previous examples might have only a cursory understanding of what their colleagues do in other subfunctions (in this case, Field Medical, Evidence Generation, and Medical Communications). This is true despite the benefits of close collaboration between these groups; for instance, a research study by an Evidence Generation team could form the basis for a journal article by Publications, with Field Medical team members communicating the results to healthcare professionals. Thus, another purpose of this textbook is to create an understanding of the profession *within* the profession.

As Medical Affairs comes to better understand and appreciate its own impact, a new generation of Medical Affairs leaders with primary business skills in addition to the core competencies of scientific and clinical acumen are representing this value to C-suite leaders. Traditionally, pharmaceutical and MedTech companies were structured to prove the value of their products to the very defined populations that participate in clinical trials. The thinking went that if a drug or device worked in trials, it would work across populations, and beyond monitoring adverse events, healthcare professionals were largely left to sort out the nuances of clinical use themselves (in consultation with sales reps). Medical Affairs collaboration at the leadership level ensures that company strategy doesn't end with approval but encompasses the use of new drugs, devices, and diagnostics in the real world. In fact, Medical Affairs input even in the earliest stages of development ensures the voices of patients, clinicians, caregivers, and others are represented across every phase of the innovation lifecycle. Meanwhile, Medical Affairs is uniquely equipped to provide context for the real-world value of emerging innovations for consideration by payers and reimbursement agencies.

If R&D develops drugs and Commercial sells them, then Medical Affairs ensures that health innovations benefit patients, transforming science into real-world clinical outcomes. As such, Medical Affairs activities encompass factors of real-world use and value that can define whether a

promising drug, device, or diagnostic impacts the lives of thousands (or, increasingly, is lifechanging for the few hundred patients for whom a target treatment is developed), or whether this same promising product is misunderstood, misused, and mis-valued such that it ends up relegated to a company's dusty shelf for occasional use.

By involving the healthcare community in industry innovation and then helping this same community make the best use of the resulting products, the diverse Medical Affairs subfunctions unite with a single purpose: To benefit patients. Leadership, research, communication, and Medical Affairs' partnerships with individuals and organizations power the industry's ability to serve real people in the real world with real innovations that make a population-scale difference in improving quantity and quality of life.

The authors and editors of this book, along with the MAPS organization, hope this textbook is an important milestone in the evolution of Medical Affairs – a coming of age for the profession, both for the individuals and groups within the function and in helping industry and society understand our promise and purpose. From enterprise-level industry leaders to acquaintances at a dinner party, we are all patients. We all benefit from Medical Affairs. This book details how.

About the Editors

MEDICAL AFFAIRS PROFESSIONAL SOCIETY

MAPS is the premier nonprofit global Medical Affairs organization *for* Medical Affairs professionals *by* Medical Affairs professionals across all different levels of experience/specialty to engage, empower, and educate. Together with over 11,000 Medical Affairs members from 300+ companies globally, MAPS is transforming the Medical Affairs profession to increase its value to patients, HCPs, and other decision-makers.

Kirk Shepard has more than 25 years of experience in the pharmaceutical industry. He is a board-certified medical oncologist and hematologist physician. Until recently, he was Chief Medical Officer, Senior Vice President, and Head of Global Medical Affairs OBG at Eisai Pharmaceutical Company. Dr. Shepard's experience in multiple therapeutic areas includes operational and strategic product development from Phases I through IV and the diverse disciplines of Medical Affairs and product commercialization, such as leading compliance and SOP/policy efforts, health economics and outcomes research and patient access, data generation, field-based medical teams (MSLs), PV/safety, medical communication and publications, patient advocacy, and public relations. In 2015, he was selected as one of the 100 Most Inspiring People in the Pharmaceutical Industry (PharmaVOICE). Before his pharmaceutical career, Dr. Shepard served as a staff physician in the Department of Hematology and Medical Oncology at the Cleveland Clinic Foundation, where he supervised numerous studies in oncology and symptom control. He has more than 50 medical publications in journals and books. Dr. Shepard earned his bachelor's degree from Cornell University in Ithaca, NY, and his medical degree from the University of Cincinnati Medical School in Cincinnati, OH. He completed both his internship and residency in internal medicine at Case Western Reserve University in Cleveland, OH, and fellowships in hematology and oncology at the University of Chicago Hospitals and Clinics in Chicago, IL.

Charlotte Kremer, MD, MBA, is formerly the Executive VP and Head of Medical Affairs for Astellas, recently retired. In this role, Dr. Kremer provided leadership for the Medical Affairs organization globally. Dr. Kremer joined Astellas in 2012 with 20 years of experience in the pharmaceutical industry. Prior to Astellas, she held the position of Vice President, Therapeutic Area Head for Ophthalmology, PVD, Rare Diseases and Neuroscience at Pfizer. While at Pfizer, she successfully led and executed the clinical development and global medical programs in these respective areas. Prior to joining Pfizer, Dr. Kremer held positions of increasing responsibility providing medical support, developing Phase 3b/4 clinical trials, and initiating and directing a Medical Liaison program at Organon Pharmaceuticals, both in the Netherlands and in the United States. A native of the Netherlands, Dr. Kremer received her medical degree from the University of Utrecht, The Netherlands. She went on to receive her Diploma in Pharmaceutical Medicine (DPM) from Universite Libre de Bruxelles. After transferring to the United States, Dr. Kremer completed the Executive MBA program at New York University's Leonard N. Stern School of Business. Kremer is now Chief Medical Officer of the Medical Affairs Professional Society (MAPS).

Garth Sundem is Director of Communications and Marketing with the Medical Affairs Professional Society (MAPS). Previously, he held positions of increasing responsibility in communications at the the University of Colorado Cancer Center, writing more than 500 articles on topics ranging from basic science to cancer survivorship. Garth has written and ghostwritten more than a dozen mass-market books for publishers including Crown, Three Rivers, Ben Bella, Workman

Publishing, and Free Spirit Press, on topics including math humor, pop science, and psychology (full list at Amazon). He has been featured on Good Morning America, NPR, CBS, BBC, and the Discovery Channel (among others), has written for outlets including the *New York Times*, *WIRED*, *Scientific American*, *Sky & Telescope*, and *Men's Health* (among others), and was a core contributor at sites including GeekDad.com and PsychologyToday.com. He graduated summa cum laude from Cornell University.

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Section 1

Medical Affairs in the Pharmaceutical and MedTech Industries

1 What Is Medical Affairs?

Kirk Shepard, Charlotte Kremer, Robin Winter-Sperry, Danie du Plessis, and Peter Piliero

Learning Objectives
After reading this chapter, the learner should be able to:

- Articulate the impact of Medical Affairs to industry, society, and patients
- Conceptualize the distinct subfunctions that make up Medical Affairs
- Understand the individual roles that make up Medical Affairs teams, including the ability to see where the readers' skills and backgrounds might match these roles

WHAT IS MEDICAL AFFAIRS?

Medical Affairs is a function within the biopharmaceutical, consumer healthcare, and MedTech industries that sits alongside other functions including Research and Development (R&D) and Commercial as one of the strategic pillars of the industry. R&D develops new drugs, devices, and diagnostics; Commercial markets and sells these products; and Medical Affairs, being largely externally facing, generates and communicates data that help healthcare professionals (HCPs), payors, policymakers, and others make informed decisions that ensure the best use of products to benefit patients. In this way, Medical Affairs generates much of the data outside of the regulatory clinical trials and works from an explicitly patient-centric perspective, ensuring the voice of the patient drives organizational actions while working primarily through HCP interactions to ensure patients and patient groups are appropriately informed about and engaged in the development and use of new health innovations, thus playing a vital role in providing scientific evidence and understanding to appropriately change clinical practice.

Just as there are many roles within R&D and Commercial, individuals working within Medical Affairs are responsible for many activities, especially including the following:

- Communicating unbiased, evidence-based expert scientific and medical information to HCPs, scientific leaders, patient advocacy groups, payors, network providers, policymakers, and others within the healthcare ecosystem
- Bringing insights from external sources including healthcare professionals, opinion leaders, advisory boards, patient advocacy groups, and more back to the organization to better inform product strategy and decision-making in areas such as education, research, development, compassionate use, and publications
- Generating new data about marketed and emerging treatments, often using Real-World Evidence (RWE), Health Economics and Outcomes Research (HEOR), Investigator-Initiated Studies (IIS), or pre- and post-approval studies that may support product registration or can be non-registrational in nature
- Collaborating with industry leaders from other functions including R&D, Commercial, and Business Development to drive the strategic direction for the organization to benefit patients

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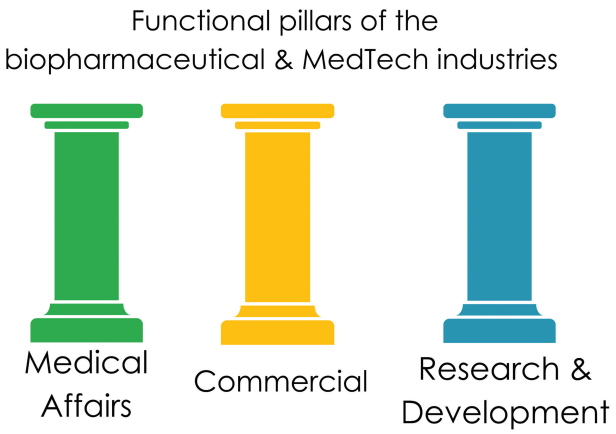

FIGURE 1.1 Functional pillars of the biopharmaceutical and MedTech industries

WHO WORKS IN MEDICAL AFFAIRS?

Medical Affairs is primarily composed of medical and scientific professionals, many of whom have advanced, Doctoral-level degrees, usually in the life sciences. Supporting these scientific experts are a range of roles including data analysts, communications specialists, experts in adult education, technologists, business leaders, administrative associates, and many more. Some Medical Affairs professionals enter the function immediately upon completion of their training; others come to the function having worked elsewhere in healthcare, industry, business, or academia. Many Medical Affairs roles are external-facing and tend to attract individuals who are naturally drawn toward relationship building and scientific exchange with peers in the healthcare community. Other roles are involved in evidence generation and knowledge creation through studies, research projects, or analyses and often appeal to those with technical and scientific backgrounds. Still other roles are involved in strategic leadership, offering opportunities for individuals to lead goal-directed teams to plan and execute impactful Medical Affairs tactics. Thus, the skills and training required for a successful career in Medical Affairs are varied and depend on the specific role within the function but often include a mix of scientific, technical, business, leadership, and emotional intelligence expertise.

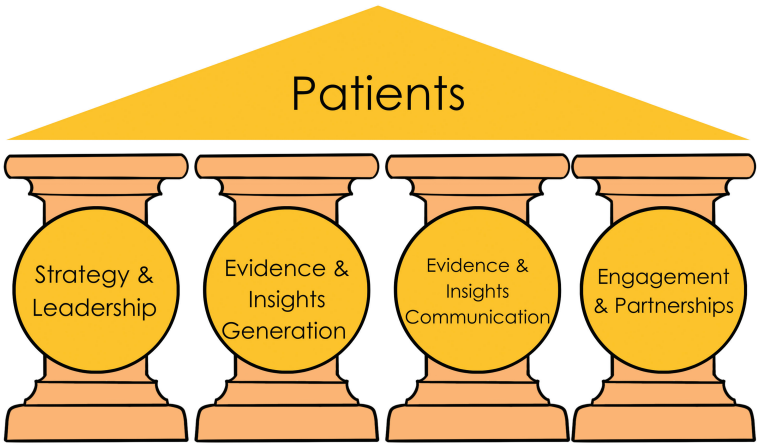

FIGURE 1.2 Core pillars of Medical Affairs

THE HISTORY AND CURRENT PRACTICE OF MEDICAL AFFAIRS

The concept of a Medical Science Liaison (MSL) started at the Upjohn Company in 1967 as a primarily executional role within the industry's Commercial/Marketing function. At Upjohn and then elsewhere, experienced and scientifically oriented sales reps were designated as MSLs to answer more in-depth scientific questions about the appropriate use of drugs and devices. Later, these early MSLs whose expertise grew from sales experience were replaced by MSLs with scientific and medical degrees. With increased regulation, scrutiny, and complexity of the pharmaceutical industry, the MSL function moved out of Commercial and into the new function called Medical Affairs, which now takes the lead in providing HCPs and others within the healthcare ecosystem with non-promotional, accurate, and fair-balanced scientific information. This direct interaction with HCPs, not incentivized by product sales, with the intent to improve clinical outcomes for patients was the genesis and remains at the heart of the Medical Affairs function.

In addition, in the 1980s, it became clear that the unbiased, scientific expertise of Medical Affairs had value beyond just these direct interactions with HCPs, and Medical Affairs teams started to grow even more into the external-facing voice for the organization's scientific communication and exchange. When HCPs reached out to the organization to ask questions about the real-world use of drugs, devices, and clinical research, it was Medical Information teams working within Medical Affairs that provided (and still provide) the answers; when there were identified data gaps in our understanding, Evidence Generation groups within Medical Affairs built the capability to design and conduct post-approval studies to generate and disseminate new knowledge; and as it became clear that HCPs were only one of many audiences in need of expert, data-driven context describing the real-world use of emerging treatments, Medical Affairs developed greater capabilities in Scientific Communications, Publications, External Education, and more.

Meanwhile, industry realized that Medical Affairs was positioned to not only communicate the organization's scientific narrative externally but to listen to stakeholders in the broader healthcare ecosystem and bring knowledge in the form of "insights" back to the business. At first, insights were most often generated in the scientific exchange between MSL and HCP; however, as the Insights function within Medical Affairs evolved, teams grew more sophisticated in generating patient insights, growing to the point at which Medical Affairs now represents the voice of the patient within industry, contributing patient-centric endpoints to registrational clinical trials, and helping industry co-develop new health technologies along with the patient populations they will eventually benefit.

Today, the scientific complexity of treatments has increased, with new drugs and devices targeting specific patient populations. For some time, we've known that the safety and efficacy data from registration trials, performed with a narrow and carefully selected patient population, may not perfectly generalize to a real-world patient population that includes individuals with diverse geographic, racial, ethnic, age, compliance, comorbidity, and treatment journey characteristics. Medical Affairs with Clinical Development has particularly been focused on improving the diversity of patient populations for our studies. Studies themselves have also evolved to include the use of Real-World Evidence (from patient registries, electronic health records, and many other sources) alongside clinical trials, first to answer non-regulatory questions and increasingly with impact on regulatory decisions such as label expansion. At the same time, audiences desiring medical and scientific information have further expanded to include, for example, patients and patient advocacy groups, and all audiences expect near real-time, accurate information presented across a range of channels.

Medical Affairs is the function within the broader biopharmaceutical industry best positioned to help external stakeholders make sense of treatment complexity; it is the function best positioned to answer questions of real-world safety and effectiveness; it is also positioned to identify gaps in product knowledge to determine the need for future studies; and it is the function best positioned to not only disseminate scientific knowledge but to also listen and respond to external stakeholders' need for information.

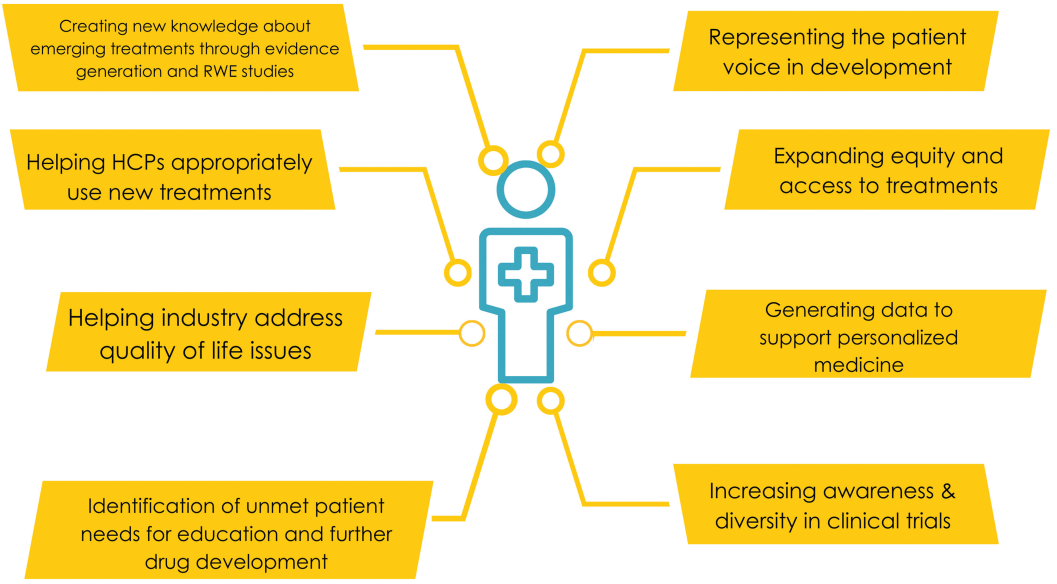

FIGURE 1.3 How Medical Affairs benefits patients

These changes in the fabric of healthcare and society have elevated Medical Affairs to the point of no longer being simply a support group providing responsive, ad hoc information, education, and promotional material review. With the expertise to better understand the challenges faced by patients, HCPs, and other stakeholders, the ability to address any gaps in understanding of data, and the means to contextualize these matters for clear communication by the company, Medical Affairs is now clearly one of the strategic pillars of the healthcare industry.

ROLES AND TEAMS WITHIN MEDICAL AFFAIRS

As we have seen, Medical Affairs is responsible for a broad range of actions generally related to ensuring the most appropriate real-world use of emerging health technologies, in terms of both safety and efficacy and also to promote patient-centric and caregiver-centric factors of overall well-being. Within Medical Affairs, these actions and responsibilities are "bucketed" into subfunctions in various ways across companies of different size, geography, disease area, and phase of treatment development (among other factors). In fact, even more so than for R&D and Commercial functions, there is no single structure for Medical Affairs – and even roles within teams may differ across organizations.

The Medical Affairs Professional Organization (MAPS) conceptualizes the practice of Medical Affairs as the collaboration of 13 fairly distinct subfunctions, each of which will be covered in depth in a chapter of this book. That said, this visualization is only approximate, as even this designation remains malleable as organizations apply different weights and different structures to their Medical Affairs departments. For example, HEOR, Pharmacovigilance and Compliance may sit within or be independent from Medical Affairs; some organizations consider Insights a deliverable within Field Medical; some companies choose to create designated Patient Centricity teams, while others embed Patient Centricity representatives within subfunctions or consider Patient Centricity a guiding principle rather than a subfunction, and see it as the backdrop for *all* Medical Affairs activities; finally (though by no means exhaustively), some leaders consider specific implementations of Medical Affairs such as its practice in Rare Disease or in MedTech as distinct enough to be considered on their own (as covered in this book), whereas others consider these situational implementations to be outgrowths of traditional Medical Affairs practices. No matter how Medical Affairs is structured and which subfunctions are grouped or considered independent, it is important to promote

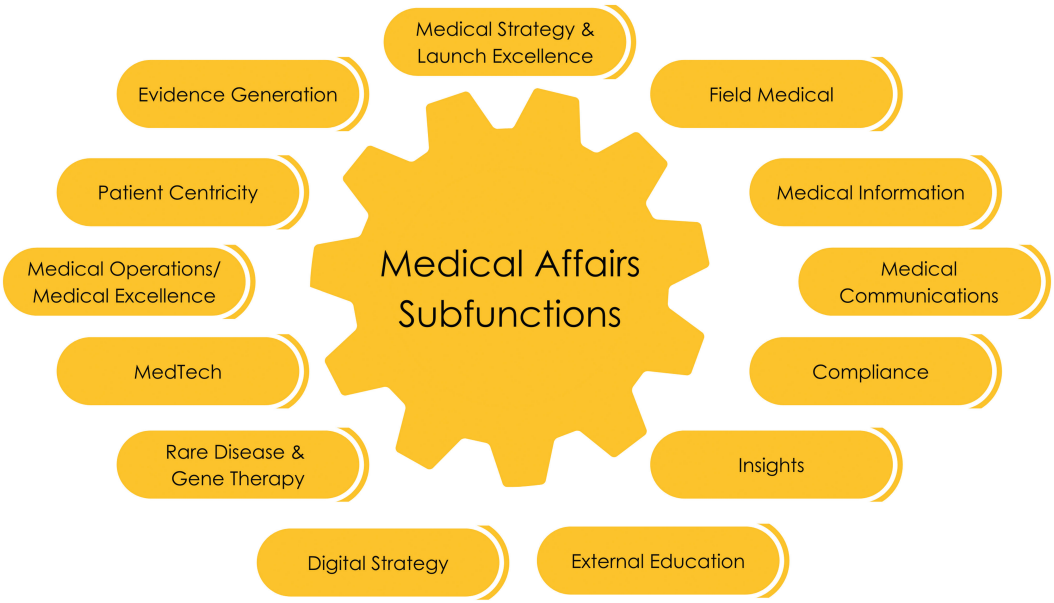

FIGURE 1.4 Medical Affairs subfunctions

strong collaborations between teams, departments, and geographies, and even with groups beyond Medical Affairs such as those in Commercial and R&D. With this in mind, please consider the following figure an overview of Medical Affairs teams and/or activities, but by no means an exhaustive catalog of possible roles or structures within the function.

Medical Strategy and Launch Excellence

(See Chapter 6)
Medical Strategy leaders represent the value and impact of Medical Affairs alongside counterparts in R&D, Commercial, Market Access, and other functions. These leaders often have medical/scientific training and organizational experience, with the addition of business or leadership training. Especially important in Medical Strategy is the planning that takes place to support the development, launch, and lifecycle management of products. For example, Medical Strategy leaders may provide input into registration study design to ensure data generated is clinically relevant to payors, HCPs, and patients; or roles within Medical Strategy may identify new projects needed to enrich understanding of a medicine's safety and effectiveness beyond the data generated in a registration trial; or this role may help to define communication/education strategies to ensure that patients, providers, and payors outside the organization receive timely and trustworthy information. The strategic plans created by Medical Strategy and then disseminated across affiliates tend to be structured around the timeline of product launch, with specific "component" plans and activities in the pre-launch, peri-launch, launch, and post-launch phases.

Evidence Generation

(See Chapter 7)
In the biopharmaceutical and MedTech industries, R&D generally oversees Clinical Development, with more basic research leading to phase 1, 2, and 3 clinical trials needed for registration. Medical Affairs professionals work in Evidence Generation to design and oversee scientific studies aimed at enriching understanding of treatment safety and effectiveness, especially in real-world populations.

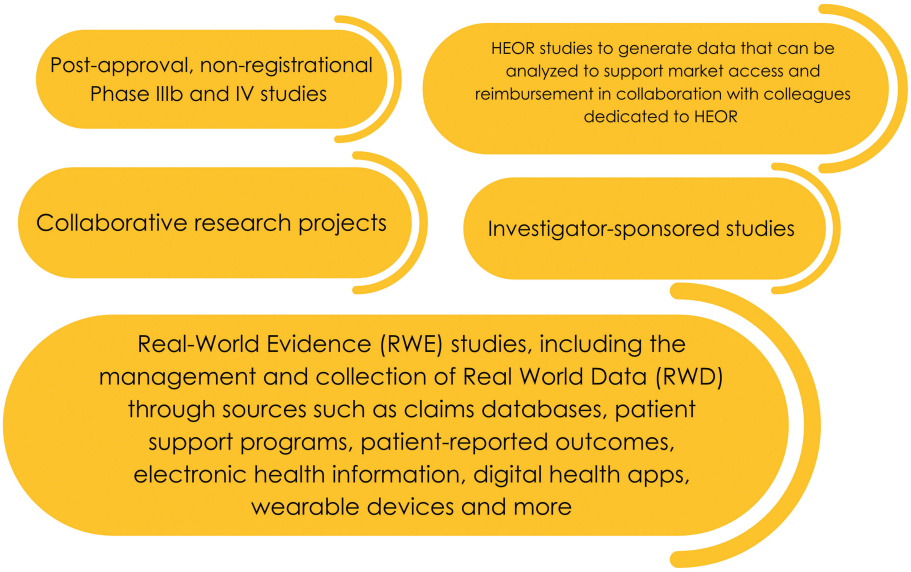

FIGURE 1.5 Studies and analyses often managed by Medical Affairs

Historically, the research/trial activities of Clinical Development and Evidence Generation groups within Medical Affairs were seen as a passing of the baton, with Clinical Development bringing a drug to registration and Medical Affairs taking the "handoff" at that point. However, Medical Affairs Evidence Generation teams are becoming increasingly involved earlier in the development lifecycle, for example, by helping to provide patient-centric context for the burden of disease, ensuring the inclusion of patient-centric endpoints in early-phase and registrational clinical trials, and increasing study patient population diversity. Today, a variety of studies may be managed by Evidence Generation teams.

External Education

(See Chapter 9)
The External Education team provides unbiased education addressing therapy or knowledge/education gaps for various audiences such as HCPs, payors, patients, and caregivers. Traditionally, External Education activities were presented in face-to-face formats including seminars or programs. Increasingly, these events are presented virtually or through technology platforms designed for the purpose. External Education teams may produce "company-led education" events or may choose to sponsor proposals from external groups such as scientific and patient advocacy societies for "independent medical education." These events often offer Continuing Medical Education (CME) credits or other professional accreditation for HCPs. Through these activities, the goal of an External Education team is to ensure accurate and unbiased understanding of treatment and disease science to help HCPs and other individuals and groups within the healthcare ecosystem make the best clinical and policy decisions to benefit patients.

Field Medical

(See Chapter 10)
Field Medical teams are composed primarily of scientific and medical experts known as Medical Science Liaisons (MSLs) or by similar titles. MSLs continue the traditional role of engaging HCPs and healthcare decision-makers (face-to-face and now, increasingly, through virtual interactions),

to ensure scientific understanding of new medicines. An equally important role for Field Medical is listening to HCPs and others outside the organization and returning these learnings to the organization as "insights," which can influence additional education, decision-making, research activities, and medical and company strategies. In addition to scientific exchange and insights, the Field Medical team may contribute to concise, timely, and trustworthy communication materials, respond to questions from HCPs, patients, payors, and other external groups in a non-promotional manner, provide research support, and help provide context for HCPs' patient care decisions. Working in Field Medical requires staying informed about recent treatment and scientific advances within an MSL's designated therapeutic area. In addition to scientific expertise, Field Medical professionals must be expert communicators.

Insights

(See Chapter 11)
The term "insights" describes understanding that comes from outside the organization that can influence organizational actions and strategies. For example, analysis of MSL/HCP interactions might uncover a common misunderstanding about a new medicine that could be addressed by an External Education program; or an insight may identify patients in a disease community that have discovered how to manage side effects that allow them to stay on treatment or elucidate important trends. Insights may also identify unmet needs in patient populations, which may form the basis for future drug/device/diagnostic development. These insights come from many sources such as from MSLs working in Field Medical or from questions posed to Medical Information teams. The ever-increasing volume of insights combined with a growing appreciation for the importance of insights in driving strategy has led many Medical Affairs groups to create teams specifically dedicated to the analysis of data, often using Machine Learning and Augmented/Artificial Intelligence technologies. In this way, the Insights team helps determine what observations from the external environment are actionable – in other words, how a clinical development plan or strategy can change in response to the external environment and, very importantly, to measure the impact of these changes for the purpose of communicating the value of insights with internal stakeholders.

Medical Communications

(See Chapter 8)
These professionals develop and execute comprehensive strategic plans for the release of clinical trial results and other relevant data and scientific information to the scientific community via abstracts, posters, manuscripts, presentations, and publications. They align plans with the release of clinical trial results and safety updates at medical meetings and develop a consistent medical communication platform (narrative) and lexicon (dictionary) to describe the value proposition of a therapeutic agent within a disease state or therapeutic area. As society evolves toward a model of healthcare decision-making shared between patients and providers, the audience for a Medical Communications team within Medical Affairs is changing, as well, requiring updates to both the formats and outlets that Medical Affairs uses to communicate with its essential audiences. No longer is the journal publication the endgame for data communications, which now includes appropriate online release, patient summaries, infographics, and connection to omnichannel interactions.

Health Economics and Outcomes Research (HEOR)

Increasingly, Medical Affairs professionals with expertise in epidemiology, economics, data analytics, Real-World Evidence, and related fields generate data and insights to provide context and information for payors evaluating the value of industry innovations. Depending on organization structure, HEOR teams may be within or outside Medical Affairs (often combined with Evidence Generation) and may support product reimbursement and collaborate with colleagues in Commercial to create

the Core Value Dossier, which summarizes the value proposition including safety, efficacy, and economic information for new drugs, devices, and diagnostics.

Medical Operations

(See Chapter 14)
Medical Operations coordinates across all Medical Affairs areas/teams and defines processes, policies, documentation, and reporting on key activities and may be responsible for budget planning/oversight. Some activities may include technology training, program management, status and metrics reporting to internal stakeholders, compliance meeting planning, contracting, business analytics and intelligence, grants administration, congress and meeting planning, and more. For example, a Medical Operations team may work with the contracting of academic researchers in collaboration with a Medical Affairs Evidence Generation group. Many of these roles may be specific to Medical Operations or can be broken out into their own functional areas.

Digital Strategy

(See Chapter 15)
In Medical Affairs, the term Digital describes a true paradigm shift in the way organizations, teams, and individuals conceptualize problems and go about creating solutions. In this way, Digital is a mindset, a philosophy, and a way of thinking that goes beyond any single technology. At the same time Digital is not a strategy that exists in a silo; rather, it enables Medical Affairs strategy to be taken to the next level. In short, Digital describes the emerging reality of technology embedded in and enabling the ways we think and work as individuals, teams, and society. Medical Affairs professionals working in Digital may collaborate with and support the activities of other groups or may demonstrate new possibilities that drive organizational thinking and strategy.

Medical Information

(See Chapter 12)
Medical Information teams are composed of drug/device/diagnostic experts who, in most companies, develop responses to anticipated or actual questions received from HCPs, patients/caregivers, payors, and others to provide evidence-based, scientifically balanced non-promotional information in a timely manner. Thus, Medical Information is primarily a responsive role – an expert resource that prepares answers to medical and scientific questions and trends. When answers do not exist, the Medical Information team may identify knowledge gaps that can lead to further studies and education opportunities. Proper analysis of medical information questions may also be a source of medical insights. Like many areas of Medical Affairs, Medical Information teams are making increased use of digital tools and formats such as webinars, interactive platforms, video summaries, omnichannel interactions, etc. to respond to the need for virtual interactions and real-time responses. The scientific knowledge communicated by Medical Information is subject to significant regulatory oversight to ensure accuracy and lack of bias, creating the need for documented processes within the function to identify questions, develop responses, and distribute these responses efficiently and compliantly.

Compliance/Legal/Ethics/Medical Governance

(See Chapter 16)
The Pharmaceutical Industry is highly regulated, with clear separation between Medical and Commercial activities. In other words, regulations ensure that Medical Affairs does not engage

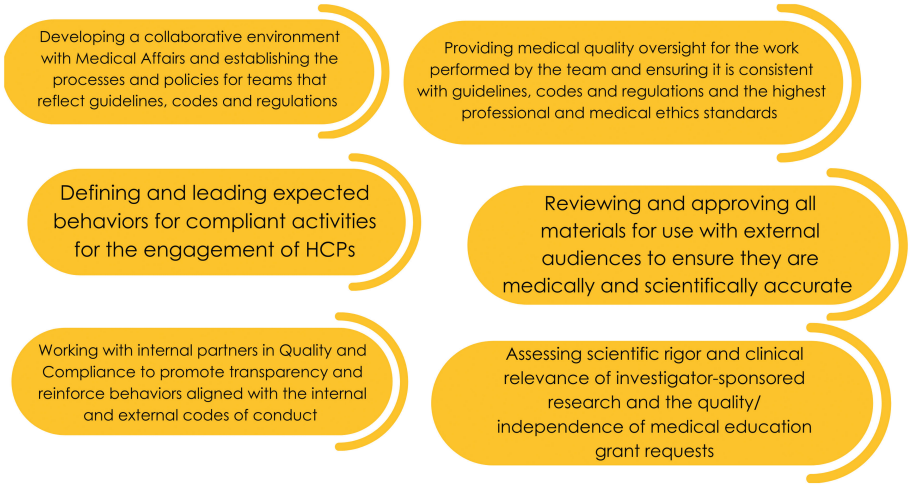

FIGURE 1.6 Example compliance activities within Medical Affairs

in marketing activities. Note that Compliance teams commonly exist at the organizational level in addition to working specifically within Medical Affairs, and that final accountability for compliance varies across geographies. In fact, even within Medical Affairs, Compliance teams that exist as independent entities may be augmented by compliance specialists embedded across Medical Affairs teams.

ROLES OUTSIDE LARGER/ESTABLISHED PHARMACEUTICAL COMPANIES

In addition to roles in large pharmaceutical companies, Medical Affairs professionals work in smaller biopharmaceutical organizations (often targeting new or emerging areas such as rare diseases or oncology) and in Medical Technology companies, both of which will be described in later chapters of this textbook. In both of these somewhat specialized implementations of Medical Affairs, structures and practices are distinct from those in traditional or more established pharmaceutical companies. For example, in the space of rare diseases or genetically distinct disease subtypes (as in oncology or other personalized medicine applications), patient groups are often even more intimately involved in drug development, requiring additional engagement provided by Medical Affairs teams. Medical Affairs professionals working in smaller companies may have to "wear multiple hats," while sometimes overcoming education barriers including unfamiliarity with emerging treatment paradigms such as gene-directed therapies. However, working in emerging areas or underserved populations also offers Medical Affairs professionals the opportunity to play an important role in providing treatment options for patients who are often without an existing therapy. In MedTech, technology-powered diagnostics and devices tend to require significant training for skilled use, and product hardware/software is updated frequently (as opposed to pharma in which products are more static and use depends more on identifying the most appropriate populations and situations than it does on technical skill). Also, whereas Medical Affairs professionals in pharma tend to cultivate a deep expertise in one product, Medical Affairs professionals in MedTech may be generalists, providing education and training on a range of devices. MedTech also comes with its own set of regulatory concerns based on categories such as implantables, combination products, and internet-connected medical devices. In these roles outside traditional pharmaceutical companies, the goal of Medical Affairs remains the same: to generate, evaluate, and communicate data to benefit patients.

WHAT SKILLS ARE NEEDED FOR A SUCCESSFUL MEDICAL AFFAIRS CAREER?

The chapter of this book on careers will describe in depth the educational backgrounds and skill sets of professionals commonly employed in Medical Affairs, as well as the possible career paths through industry. Here we seek to overview these skills, which are commonly referred to as "competencies." In short, the wide range of Medical Affairs roles require a wide range of competencies. However, almost all historic roles (e.g., MSL) and most current Medical Affairs roles require advanced scientific training in the mechanisms and clinical uses of emerging treatments. That said, roles in operations or compliance may require business and/or legal acumen instead of or in addition to scientific acumen. And roles in Medical Strategy (and elsewhere) may require leadership skills. Thus, each role has a unique path for the training and further development of Medical Affairs competencies – and many Medical Affairs professionals continuously augment these competencies as they adopt different roles and even different careers within the function. Broadly speaking, Medical Affairs competencies fall into the following categories:

Scientific and Clinical Knowledge
Competencies in this category should be considered the baseline for entry into most Medical Affairs positions. Accordingly, most Medical Affairs team members will hold advanced (preferably terminal) degrees in a field related to life sciences, often MD, PharmD, PhD, or RN. Medical Affairs professionals will use scientific and clinical acumen to perform studies and analyses within Evidence Generation teams, to engage in cutting-edge scientific exchange with HCPs and key opinion leaders, and to disseminate knowledge through scientific outlets such as academic journals and congresses (among many other uses).

Technical and Technological Knowledge
In addition to the therapeutic, scientific, and clinical expertise that defines the Medical Affairs function, Medical Affairs professionals are increasingly expected to be proficient with new and emerging technologies for use in communicating complex ideas to stakeholders with varying scientific understanding. Specifically, the generation and availability of data in all forms will require increasing sophistication in organization and analysis. For this reason, engineering, data science, and computer science are growing to sit alongside scientific and clinical acumen as Medical Affairs core competencies.

Strategic Vision
As Medical Affairs assumes an increasingly strategic role within the organization, the competencies needed for a successful career in the function are expanding beyond scientific and technical skills to encompass the skills needed to develop Medical Affairs strategy and collaborate with other organizational leaders to drive company direction. The capability of Strategic Vision includes skills/competencies needed to demonstrate the value/impact of the Medical Affairs function in alignment with the organization's overall strategic direction.

Business Knowledge
Individuals within Medical Affairs increasingly collaborate with, inform, and are informed by the activities of other functions within the organization. Knowing how Medical Affairs activities and strategic priorities fit with those of Marketing/Commercial/Access, R&D, Executive Leadership, and business development and with the wider landscape of the healthcare ecosystem is essential in recognizing opportunities for collaboration and delivering value.

Evidence Generation
While Evidence Generation is often a discrete role within Medical Affairs, professionals across the function will need to know the basics of research and data analysis strategies and activities. In short, Evidence Generation is the knowledge engine that Medical Affairs uses to refine and create new understanding of product and disease state science. As such, all

Medical Affairs professionals need at least a basic understanding of clinical trial and Real-World Evidence study design, analysis, and reporting.

Compliance
All aspects of the biopharmaceutical and MedTech industries take place within the framework of global, regional, country, and local regulations. While compliance teams at the organizational and functional level will oversee Medical Affairs activities, it is essential for all Medical Affairs professionals to have a basic understanding of the regulatory framework that sets guardrails for their activities and the highest professional ethics and standards.

Customer Engagement and Scientific Communications
Medical Affairs is the external-facing voice of the organization's scientific communication activities. As such, the true impact of activities including Evidence Generation, such as HEOR/RWE, or pharmacovigilance, is only realized when information reaches external stakeholders in ways that create new understanding or actions that benefit patients. With the mechanics of scientific exchange and communication changing at the pace of technology, Medical Affairs professionals require a flexible set of competencies that allow engagement with these external audiences in the scientific and healthcare landscapes.

Leadership and Management

In a way, it's easy to focus on knowledge and technical/scientific skills – these are discrete topics that can be taught and learned. But realizing the full value of these skills requires the personal and emotional intelligence skills needed to collaborate with peers and lead teams. There is growing awareness within the function and within the industry as a whole that competencies that might have previously been known by the dismissive term "soft skills" (such as listening skills and learning agility), are no less essential than the abilities needed to generate and communicate data. Historically, Medical Affairs leadership grew organically from demonstrated scientific and clinical acumen; increasingly, Medical Affairs leaders add primary leadership and business training (e.g., MBA) to advanced scientific degrees.

THE FUTURE OF MEDICAL AFFAIRS

In the future, Medical Affairs will solidify its transition from executional to strategic, and the function will come to represent the voice of the patient within industry. Medical Affairs will not only disseminate evidence but also lead evidence generation activities that inform the real-world use of marketed and emerging treatments. The function will solidify its role as industry's external earpiece, gleaning insights from our interactions with the healthcare ecosystem that drive understanding of patient, payor, and provider needs and opinions. To realize this vision of Medical Affairs at the center of drug development and commercialization, the function will need to expand its capabilities to encompass the ability to engage with external stakeholder groups beyond the traditional audiences of HCPs and scientific leaders, especially including the need to develop compliant systems for engaging with patient associations and even directly with patients, themselves. Building capabilities may be accomplished in part by making the strategic case for the adoption of advanced technologies, in part by upskilling the existing Medical Affairs workforce, and also by seeking to hire Medical Affairs professionals with primary competencies in areas of growth such as digital technologies, data analytics, epidemiology, HEOR, and business acumen. With collaboration from Medical Affairs leaders across organizations and powered by Medical Affairs professionals across focus areas and all levels of experience, the function will continue to progress toward a future in which Medical Affairs benefits industry and society while ensuring that patients become and remain the essential reason for everything we do.

REVIEW AND SUMMARY

Medical Affairs is the least understood of the biopharmaceutical and MedTech industry's three major functions (which also include R&D and Commercial). In part, this is because R&D and Commercial are so easily understood: R&D creates new health technologies and Commercial markets them. This dynamic is also visible in the metrics used to track the impact of industry functions, with R&D generally measured against the drugs/devices/diagnostics it is able to bring to market, and Commercial generally measured against the revenue these innovations create. How does one define Medical Affairs? How does one measure (and message) its impact? The answers have to do with the essential mission of Medical Affairs to leverage science to benefit patients. Through scientific and clinical acumen, technological expertise, and growing skills in business and leadership, Medical Affairs is emerging as an essential strategic partner in industry and the voice of the patient *within* industry, ensuring drugs, devices, and diagnostics have real-world purpose and demonstrated impact for the patients who need them.

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