Medical Affairs Launch Excellence
Best Practices for Medical Affairs

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1. INTRODUCTION

The role of Medical Affairs within the healthcare landscape has clearly evolved over the last 20 years, to its present incarnation as an integral part of today's digital health landscape. In today's market, working with Medical Affairs is no longer just an option, but essential for ensuring success in fostering development in pre-launch preparation; perilaunch, to develop one coherent voice with multiple internal and external stakeholders across channels; and postlaunch, for effective maintenance of the portfolio, and continued growth.

Where Medical Affairs may have served in a scientific support role in years past, now it is one of the key drivers of all efforts, positioned at the nexus of Regulatory, Clinical, Market Access, and Commercial needs, as a bridge to all and as a strategic partner with Commercial. This has occurred in large part because the days of successfully launching a new product based solely on making it available through regulatory approval and marketing efforts no longer exists. That approach is no longer feasible due to the increasing complexity of the changing healthcare landscape, considering key decision-maker needs and the evolving demands of patients, payers, and healthcare providers (HCPs).

So, let's review the traditional role of Medical Affairs and the expanded role of Medical Affairs as it exists today.

In the past, Medical Affairs has historically worked in collaboration with pharmaceutical, biotech, and medical device companies to:

- Provide feedback on protocols for investigational drugs or new indications of approved drugs
- Disseminate data and knowledge from clinical trials
- Develop relationships with external stakeholders

While these areas of influence still exist, the role of Medical Affairs has evolved from a support role to that of principal driver, collaborating with internal stakeholders (global corporate colleagues and associates) helping to affect decision making. External stakeholders (such as external experts, medical and professional organizations, physicians, patients, caregivers, managed care affiliates, advocacy groups, payers, social media influencers, and policy makers) have set increasingly higher bars for the levels of scientific evidence needed to support a product's value proposition prior to launch. Medical Affairs has addressed this change in an ever increasingly restrictive healthcare market. For that, in addition to understanding the disease area, an in-depth understanding of healthcare systems, as well as both internal and external stakeholder requirements, is key.[1]

> " The biggest change in Medical Affairs in the last 10 years is that we now have a seat at the table as strategists. We are in less of a supportive role. Now we are seen in a proactive strategic position. Medical Affairs has always had external experiences dealing with clinical trials and patients. Now, we can drive decision-making actions by bringing information from external sources into the company to generate strategy. "
>
> Ramin Farhood, PharmD, MBA VP, Head of Global Medical Affairs, AveXis

Previously, conventional commercial approaches focused on demonstrating a differentiated value proposition, while targeting HCPs and patients as applicable, Medical Affairs mainly supported product registration, launch activities, and inline marketing efforts. Supporting these activities required strong medical expertise and ability to interpret and communicate clinical data to a targeted healthcare community; however, Medical Affairs provided limited input on strategy.

Notable changes have impacted the healthcare system resulting in a need for more sophisticated approaches that emphasize the role of evidence-based medicine, with compelling clinical and real-world data at the core, and cultivating health outcomes research for long-term data analysis **(Figure 1).**
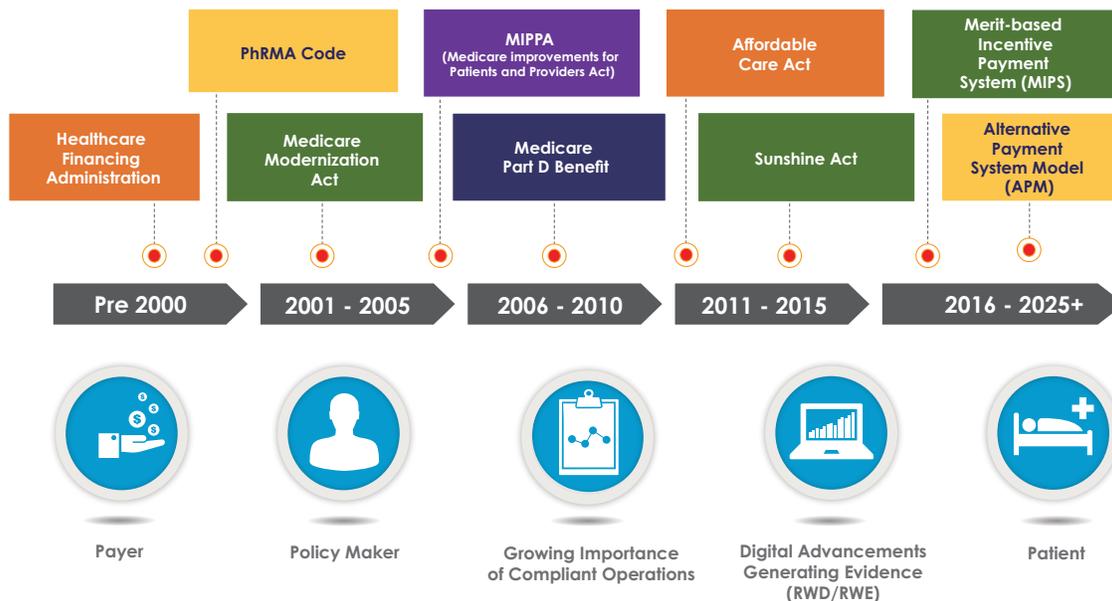

Figure 1. Changes in the Healthcare Landscape: 20 Years

In today's market, the imperative vision for Medical Affairs is to have a seat at the strategic table early in product development, and contribute to the target product profile (TPP), which drives clinical research efforts, along with statistical clinical data and insights from the competitive landscape to develop the medical launch strategy.[2]

The earlier Medical Affairs can engage in the product development process the more impact they have on the success by identifying and communicating critical issues and gaps to support short- and long-term planning. With a deep understanding of the current standards of care, knowledge of product attributes, customer insights, and ongoing rigorous analysis of the competitive landscape throughout the product life cycle, Medical Affairs has become a valuable strategic partner. Medical Affairs Professionals have become experts in understanding complex science, translating that information into a meaningful narrative for a diverse audience, and defining product value within a heavily regulated healthcare system. With the solid foundation of medical insights, Medical Affairs can most effectively produce real-world solutions that ultimately advocate for patients' health needs.

❚❚ The imperative vision for Medical Affairs is to participate in product strategy discussions early in the product development phase. Beginning strategic planning as early as five years prelaunch enhances Medical Affairs' ability to identify and communicate critical issues and gaps to support short- and long-term planning. ❚❚

Greg Keenan, MD Former Vice President, Medical Affairs and US Head Medical Officer, AstraZeneca

With early and ongoing involvement, Medical Affairs is critically positioned as a fulcrum of information, managing the flow of information into and out of the company, able to leverage this to inform strategy and engagement. Medical Affairs can take the lead in establishing a road map to ensure a successful product launch, all with unmatched expertise in data generation, data dissemination, external stakeholder engagement, and organizational support throughout the product life cycle.

Addressing unmet need is paramount for both patients and HCPs, including clinicians, physician assistants, nurse practitioners, and pharmacists within the industry. Today more than ever, guidance by Medical Affairs is crucial to help create the best possible outcomes, particularly when it comes to addressing the knowledge needs of HCPs throughout the product life cycle. With increased focus, Medical Affairs can better advocate for patients through early clinical development efforts in Phase II and Phase III. Keeping HCPs informed of the shifting payer landscape is also essential. Attention to these aspects will help provide a stable focus on what is best for the patient population over time, to support their outcomes and quality of life.

Among all the activities that Medical Affairs leads, in this guidance document we seek to define the key elements that support launch excellence and discuss how to build, execute, and measure the impact of these elements over time.

2. MEDICAL AFFAIRS LAUNCH EXCELLENCE

There is no single definition of "launch excellence." Indeed, all factors involved in attempting to quantify the success of pharmaceutical launches must first address launch readiness—the steps taken toward an optimal launch effort and a necessary precursor to launch excellence. Launch excellence requires optimal alignment of launch strategy and execution to drive efficiency; effectiveness; compliance; consistency and best practices across countries, therapeutic areas, and management; all while allowing flexibility to accommodate market changes. It is critical that a launch strategy be in place, is understood, accepted, and applied throughout the organization to ensure clarity of the steps to be taken.

Launch excellence is achieved by defining the activities, processes, and behaviors required for a high-performing team that will mobilize and focus organizational efforts in preparation for and throughout the launch phase. Individuals who demonstrate commitment and support of the agreed upon organizational objectives and aspirations will contribute to the development of a high-performing team whose relevant and reliable actions can be leveraged and measured over time.[3] Optimal alignment across affiliates, regions, and countries can improve efficiencies, effectiveness, compliance, consistency, and best practices. By showcasing excellence, launch teams can achieve organizational objectives maximizing patient reach, improving outcomes, providing credibility, and contributing to the long-term stability of the organization. Through launch excellence efforts, the Medical Affairs community establishes its role within the pharmaceutical industry and can further create opportunities to expand its responsibilities and contributions postlaunch.

Global launch excellence is a strategic process that strives to achieve:

- A globally, regionally, and locally launch plan aligned with all strategic components—Clinical, Regulatory, Medical, and Commercial and Compliance Optimization—and prioritization of resources that aligns with overall organizational vision and aspirations

- Robust processes, systems, and tools to support execution

- Systematic and structured communication channels (internal and external) to ensure successful implementation

- Common expectations and "shared goals" of "excellence"

- A clear understanding of the clinical data differentiator and the underlying value proposition, to support strategy beyond the clinical offering

- A shift from volume-based to value-based healthcare delivery focusing on quality care and health outcomes that benefits patients, providers, payers, suppliers, and society

Medical Affairs leaders are required to identify and measure key performance indicators (KPIs). In the past, quantitative activity metrics used were based exclusively on product performance in the market, such as revenue, which is far from optimal given the complexity of identifying the direct impact of Medical Affairs. Today, outcomes-based metrics to assess the impact of the strategic plan are needed. Medical Affairs needs to establish these based on the objectives of their medical strategy plan.

Determining success of the strategic process requires Medical Affairs to:

- Establish launch KPIs to evaluate the performance of the medical strategy plan such as, landscape preparation, publication planning, Medical Science Liaison (MSL) activities, data generation, patient outreach programs, impact of data disseminated on clinical practice, and bridging the knowledge gap
- Analyze all quantitative KPIs against each milestone
- Determine adjustments needed based on ongoing assessments

3. LAUNCH EXCELLENCE MEDICAL AFFAIRS TEAM

With deep expertise, members of the Medical Affairs launch excellence team skillfully collaborate with various functional units and contribute strengths upon which a successful launch can capitalize. Having clearly defined responsibilities, cross-functional team member contributions will lead to efficiencies and reduce duplicative efforts. Medical Affairs can then lead by ensuring that everyone understands and supports relevant concepts and by aligning medical communications around those concepts. Launching a new product requires expertise from many regional, national, and global colleagues as well as external contacts, and Medical Affairs can help streamline objectives.

❚❚ The communication process established within the medical strategy results in the synthesis of relevant concepts and educational messages that are accepted by all members of the team. **❚❚**

Tricia L. Gooljarsingh, PhD, CMPP, Senior Director, Ironwood Pharmaceuticals

As a core member of the launch excellence team, Medical Affairs can coordinate the needs of internal and external stakeholders, sharing information with cross-functional teams and providing data to support strategy **(Figure 2)**. Through this, Medical Affairs helps to solve problems, shape the launch ecosystem, build relationships, and positively affect work satisfaction goals. In this expanding capacity, Medical Affairs may help direct external strategic partners to provide services that ensure comprehensive analysis of therapeutic areas, treatments, and landscapes. The core medical team will expand beyond the physician-expert role to a more customer-facing, evidence-generation role (see **Figure 3** for key Medical Affairs functional skills). Throughout product life cycles, strategic partners can provide valuable insights to the core teams based on their functional skills.

Figure 2. Core Launch Excellence Team

Medical Affairs Functional Skills

Core Medical Affairs Team

Nucleus of the team. Leaders in supporting alignment of corporate vision, deploying change management as needed and optimizing direction, both internal and external, based on evolving and influencing factors

Medical Science Liaison

External medical face of the organization, responsible for building and executing an engagement plan and expanding thought-leader networks

Generates and analyzes data to support clinical studies and market access/reimbursement

HEOR

Evidence-Generation Team

Manages clinical studies (Phase IIIb and IV), HEOR studies, investigator-initiated studies, and collaborative research (hypothesis, objectives, etc)

Disseminates and communicates data for the scientific community via abstracts, posters, manuscripts, publications, and congresses; aligns strategic plans with release of clinical trial results and data at medical meetings; develops consistent medical communication platform (narrative) and lexicon (language) to describe the value proposition of the product

Medical/Scientific Communications

Medical Information

Expert resource that prepares answers to medical questions from HCPs, patients, and other external groups

Supports medical education alignment to ensure unmet medical need within therapy is understood

Independent Medical Education (IME)

Medical Regulatory Committee (MRC)/ Promotional Review Committee (PRC)

Reviews medical accuracy of promotional materials with Legal, Regulatory, and/or Compliance

Identifies external stakeholders, and develops and executes engagement plans at the national and global level

External Engagement/ Collaboration

Extensive subspecialty knowledge, capable of designing and understanding clinical trials; assigns, coordinates, and monitors medical/clinical leadership activities and medical strategy, highlighting short- and long-term unmet needs

Scientific Expertise
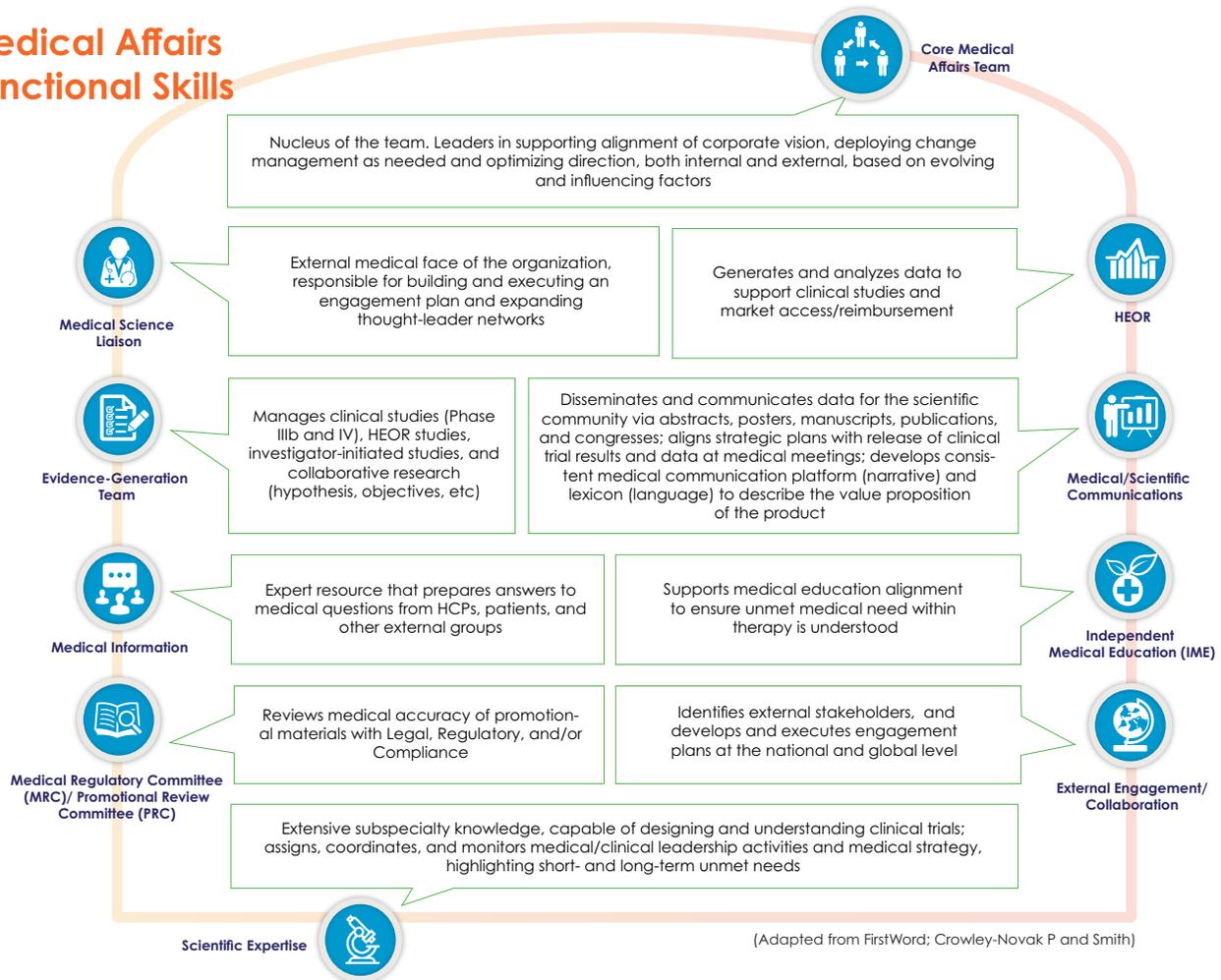
(Adapted from FirstWord; Crowley-Novak P and Smith)

Figure 3. Medical Affairs Functional Skills[4,5]

4. MEDICAL AFFAIRS LAUNCH STRATEGY DEVELOPMENT

A successful launch strategy is dependent on 3 core components and Medical Affairs plays an important leadership role in adding value in each area**:**

1. Strategic plan development early in the product life cycle

2. Assessment of future market and competitive landscapes

3. Establishment of strong product/profile narrative

Medical Affairs needs to identify internal and external partnerships, utilize medical expertise in the clinical data, disease, product, and healthcare market, and serve as the primary communicator of critical evidence-based information to define value.[6] The link forged between Medical Affairs, Clinical Development, and Commercial cannot be underemphasized as launch procedures are developed and implemented. Medical Affairs engagement in launch planning can vary among organizations. The optimal time to begin is as early as proof of concept (Phase II/IIB). Working closely with Clinical Research and Development and Global Marketing, Medical Affairs has a unique opportunity to take an active role in development of the product, initiating strategic planning well before a targeted launch plan **(Figure 4)**.

> **❚❚** Complex scientific communication challenges coupled with unique regulatory and cultural differences between regions can make alignment across a global Medical Affairs organization seem impossible. But it doesn't have to be because Medical Affairs can help make early decisions on the product that can lead to future successes. **❚❚**
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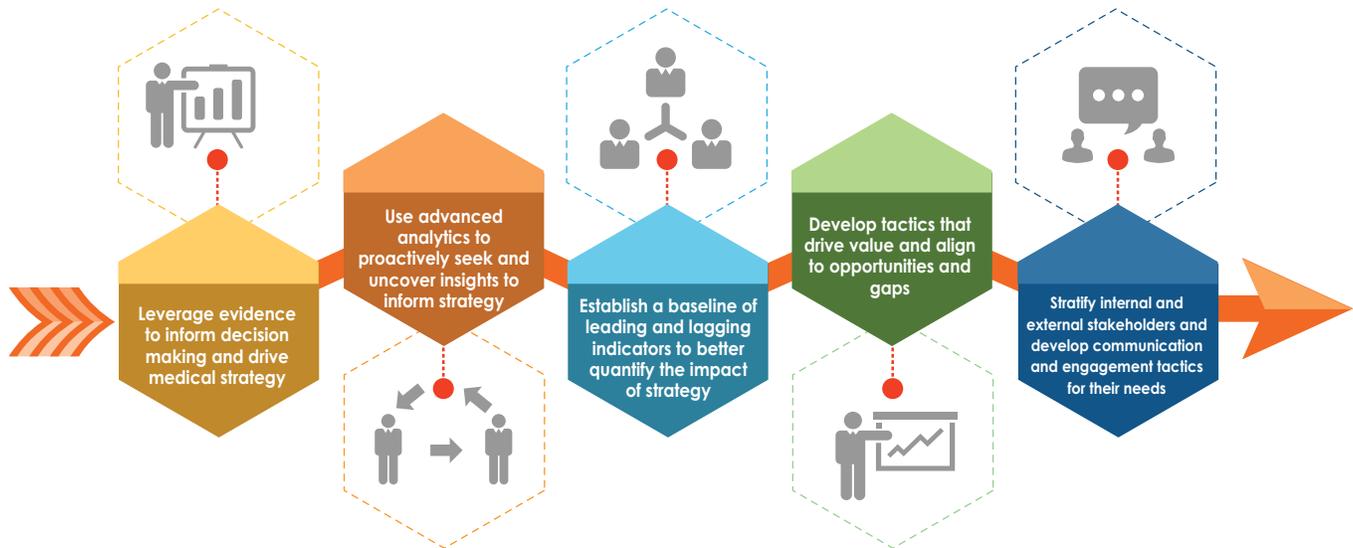> Anna Walz, CEO and Founder, MedEvoke

Figure 4. Establishing a Strategic Medical Plan

Core countries are best involved with strategic planning discussions very early on as well. By engaging with core countries, Medical Affairs can build global objectives and strategies that are relevant to country needs and ensure postlaunch success and effective uptake. Countries will address the perspectives of their respective country's market needs, and Medical Affairs will add to its breadth of knowledge accordingly. This includes information about economic value, payer landscape, and competitive landscape based on disease treatment, country-specific healthcare systems and medical guidelines, drug coverage requirements, and regulatory environments for each market. Each country has different uptake processes, market beliefs, and customer insights that can support launch excellence.

As healthcare moves from a volume-based to value-based reimbursement focus, healthcare providers are incentivized to provide the best care at the lowest cost, improving patient quality of care and satisfaction. Making this shift requires a clear understanding of patient needs and ongoing assessment of data to demonstrate beneficial impact across stakeholders **(Figure 5)**.

NEJM Catalyst (catalyst.nejm.org) © Massachusetts Medical Society

Figure 5. Value-Based Healthcare Benefits[7]

For launch success, it is essential that Medical Affairs prepares a product for market with great attention to detail. Building a launch medical strategy road map around the Four Pillars of Core Responsibility will create a high-performing team, organize and define the steps needed to navigate through global challenges, and identify critical success factors **(Figure 6)**. The medical strategy road map will ensure strategic objectives are identified and plans are evaluated by KPIs.
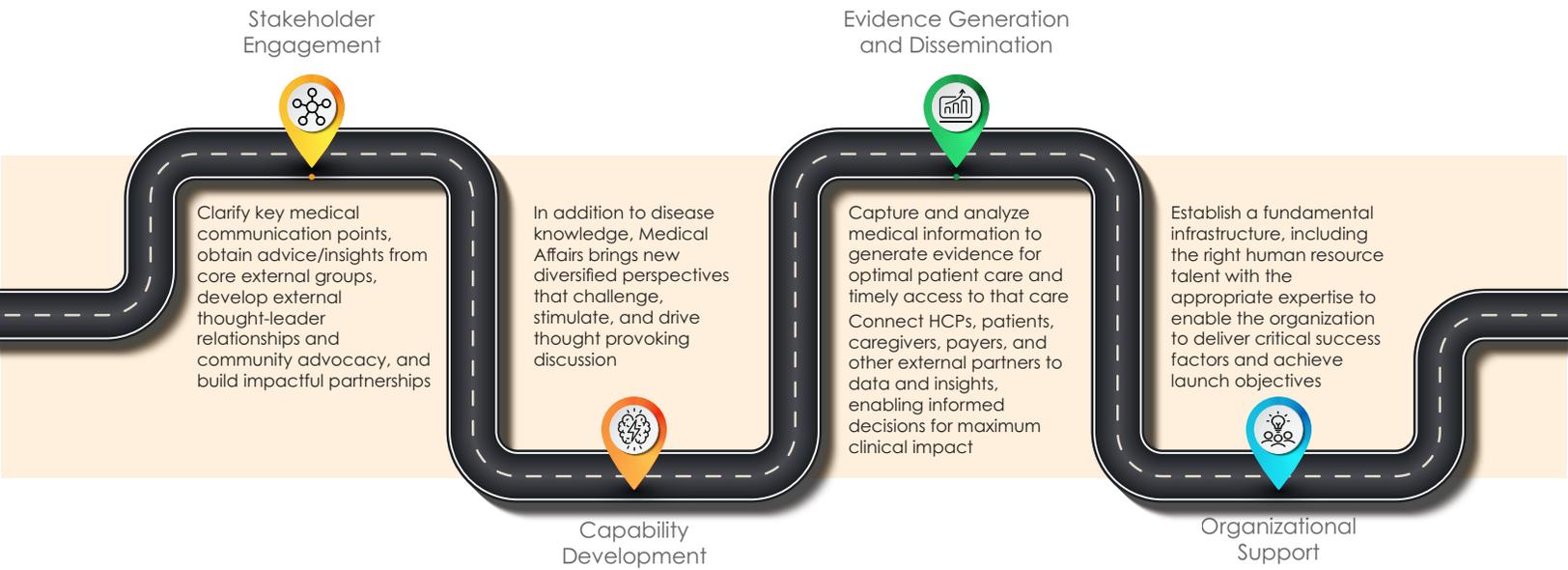
5. BUILDING A MEDICAL STRATEGY ROADMAP

Stakeholder Engagement

Evidence Generation and Dissemination

Clarify key medical communication points, obtain advice/insights from core external groups, develop external thought-leader relationships and community advocacy, and build impactful partnerships

In addition to disease knowledge, Medical Affairs brings new diversified perspectives that challenge, stimulate, and drive thought provoking discussion

Capture and analyze medical information to generate evidence for optimal patient care and timely access to that care Connect HCPs, patients, caregivers, payers, and other external partners to data and insights, enabling informed decisions for maximum clinical impact

Establish a fundamental infrastructure, including the right human resource talent with the appropriate expertise to enable the organization to deliver critical success factors and achieve launch objectives

Capability Development

Organizational Support

Figure 6. The Medical Strategy Road Map

A. Organizational support

Medical Affairs contributes to the foundational infrastructure that enables an organization to deliver critical success factors and medical strategic imperatives. During pre-launch, team members become medical information experts on the disease state, mechanism of action, competitive landscape, treatment access issues, reimbursement issues, and clinical data. As the medical information link, Medical Affairs facilitates the transition from new product development to commercial launch, serving as the operational bridge and command center of communication, expertly identifying priorities, and providing strategic direction that supports the organization in navigating through the treatment landscape. Initiatives that provide organizational support typically include medical training, participation in cross-functional leadership meetings, and insight dissemination.

B. Capability development

Identifies talent with disease knowledge and diverse perspectives to create and support thought-provoking and stimulating dialogue that drives new ideas and solutions.

C. Evidence generation and dissemination

Medical Affairs collaborates with Clinical Development to identify gaps that research strategies will address. Medical Affairs provides invaluable expertise in evidence generation, providing input into clinical trial design and endpoints for a comprehensive clinical development program and works with Health Economics and Outcomes Research (HEOR) counterparts to build economic evidence (cost models, burden of disease metrics, claims database analyses, and patient-reported outcomes). Medical Affairs also anticipates building a real-world evidence (RWE) plan once the product is approved.

> **❚❚** Now, we can drive impactful decision-making actions by bringing insights and information from external sources into the company to influence strategies. **❚❚**
>
> Meg Heim, RN, MAS, VP, Head of North America DCV Scientific Communications, NA DCV Medical Affairs, Sanofi

Clinical differentiators distinguish new products from other competitive products in the portfolio. The main goal is to continually monitor the ever-changing research findings and novel clinical endpoints that support the medical communication plan and medical strategy before moving on to specific tactical activities. Continual engagement with key stakeholders is critical to this effort.

Medical Affairs leads the development of the medical communication platform and lexicon to ensure cohesive dissemination of evidence across multiple functions, enabling informed, confident decision making with maximum clinical impact. Medical Affairs is also responsible for synthesizing and communicating medical and health economic information to support launch, payer access, and reimbursement decisions.

In all communications, Medical Affairs ensures that accurate and unbiased information is provided. At the center of the development process, Medical Affairs brings internal and external stakeholders together and unites them around a consistent, evidence-based point of view. Disseminating this key information to HCPs will help them better understand the clinical impact products can have on their patients.

In addition to developing content to support product use, Medical Affairs can monitor the impact on contributions in both the scientific exchange (medical peer-reviewed content, posters, abstracts, publications) and in digital domains (social media amplification of scientific discussion), which have become the echo chambers of science. Web-based and digital platforms continue to provide HCPs with valuable access to information in the new and advancing digital world.

Regular assessment of both the scientific exchange and digital domain allows for the gathering of insights into provider and payer perspectives and related marketing activities. Monitoring efforts in this way allows Medical Affairs to rapidly identify and address issues as well as measure impact and validate alignment to strategy. Having this constant "pulse reading" of the therapeutic landscape allows Medical Affairs to have credible scientific exchanges over time that can evolve with a changing disease dynamic, noteworthy events, or evolving new classes of therapy that would drastically change the landscape.[8]

D. Stakeholder engagement and key customer insights

Medical Affairs plays a critical role in clarifying key clinical messages to develop thought leader and community advocacy partnerships. Insights are gained from external stakeholders and organizations via peer-to-peer interactions. Based on these interactions, Medical Affairs can assess implications and determine appropriate solutions.

Initiatives that support thought-leader and decision-maker engagement may include engagement plans, medical forums, roundtable discussions, external medical expert mapping (where experts are located within the evidence spectrum), post-congress scientific exchange, and peer-to-peer programs. Medical Affairs relies on gathering intelligence/insights from these experts to help identify gaps within the landscape that can be addressed by the product, as well as adjust medical strategies as needed.

> **❙❙** Medical Affairs needs to embrace digital technology. Our field is data driven. And when we want to explain our product, we tend to pile on the data. Instead, we should develop a cohesive narrative. Use the data on a digital platform to tell a medical story that can be understood by the healthcare provider and a value story that can be understood by the payer. **❙❙**
>
> Lobna Salem, MD, MBA, Chief Medical Officer, Developed Markets, EMB, Upjohn Pfizer

Medical Affairs then assesses that impact, looking for opportunities to support strategy. In addition, Medical Affairs supports clinical trials by identifying and engaging with external medical experts who serve as investigators and provide input on design, site identification, and enrollment.

External thought leader and influencer identification, relationship building, and engagement are efforts that create critical communication channels between Medical Affairs and the external medical and scientific exchange. During early phases of development, Medical Affairs establishes strategic partnerships for activities necessary to support the product life cycle. Coordinating clinical data release will maximize scientific data dissemination and understanding as well as familiarity with a product's medical value proposition.

Today's HCPs consume a substantial amount of on-demand, high-quality medical content digitally as the need for rapid access to information and transparency increases. Review of social media platforms will provide additional insight into what is being said, who is saying it, how it is being communicated, and with how much impact. With increased use of social media platforms to disseminate scientific information and in certain instances share opinions, there is a need to identify key digital opinion leaders and understand the most resonant topics of discussion.[9] Digital opinion leaders (DOLs) are important external stakeholders who are driving and influencing the dissemination of science through unique and varied channels. DOLs may be

HCPs who have the capability to influence a much larger network of stakeholders including other HCPs, payers, advocacy groups, and patients. It is critical to identify, understand, and engage with them, as they can yield a powerful breadth and depth of influence including clinical decision making.

It is also essential to focus on engaging payers to define the value of therapies. Medical groups are asked to deliver robust medical information to managed care organizations, group purchasing organizations, and the newly forming pathway groups that define treatment protocols. Engagement can occur via the core medical group staff, through specialized Medical Science Liaisons, and all other subspecialties within field medical groups.

The Medical Affairs Key Activities for Launch Excellence table provides a sample of key activities to support launch excellence based on projected timeframes of launch preparedness **(Figure 7)**. To initiate a launch plan, it is critical to assess timing and resources to accommodate the best plan for optimal data generation, dissemination, and engagement.

Timeline markers: -48, -36, -24, -12, 0, 12

	Prelaunch (T= -48 to -24 months)	Perilaunch (T= -24 to -12 months)	Launch (T= -12 to 0 months)	Postlaunch (T= 0 to 12 months)
Medical Leadership: Strategic Planning	– Early Medical Insights for Clinical Development – Medical Team Formation and Expansion – Development of Strategic Imperatives – Conduct Situational and Gap Analysis – Identification of Unmet Needs – Building Cross-Functional Partnerships	Cross-Functional (Medical/Market Access) Strategic Development & Execution		
	Launch Readiness Planning and Launch Execution Excellence			Life Cycle Management/ New Product Development
Medical Research: Data/Evidence Generation	– Evidence Generation Planning – Support Programs and Deliverables to Drive Value and Align to Gaps and Opportunities – Leading and Lagging Indicators – Maximize Data Sources – Identify Patient Care Needs – Clinical Program Support (Recruitment, Site Support, Educate Scientific Community on Phase III Study Protocol)	– Outcomes Research Studies – Investigator-Initiated Research Planning and Execution – Medical Advisory Board		
		– Post Approval (eg, Phase IV) – Study Strategy & Planning	– Post Approval (eg, Phase IV) Study Execution – Patient Registry Trials	
Medical Information & Communication: Data/Evidence Dissemination	– Building Cross-Functional Partnerships – Key Communication Objective Development – Communicate Early Trial Data – Create Medical Communication Platform – Develop Education & Publication & Congress Plans – Data Dissemination Strategy – Lexicon Development – Identify Key Tools	Medical Communication Planning	Medical Communications Execution (Publications, Congresses/Symposia)	
		– Medical Education and Grants Management – Medical Advisory Boards		
		Medical Information Planning	– Medical Information (Unsolicited Requests, SRLs, FAQs, Call Center) – Execution & Updates – Report on Product Insights	
Medical Knowledge/ Management: Education, Communication	Provide Internal Disease and Product Information Training	– Medical Advisory Board Planning – Medical Education Planning	– Medical Advisory Board – Medical Education and Training	
	Field Medical Training			
Partnership/Interactions: Medical Community/ Stakeholder Engagement	Medical Community Planning	– Medical Community (Thought Leader/HCP, Payer & Policy Makers, Patient Groups, Advocacy Groups) – Engagement and Development – Gather Feedback on Opinions, Interests, and Experience		
Organizational Support	Establish a Team of Medical Information Experts (Disease State, Mechanism of Action, Competitive Landscape, Access, Reimbursement, Clinical Data)	– Facilitate Transition From New Product Development to Commercial Launch – Provide Medical Training, Participate in Cross-Functional – Leadership Meetings and Insight Dissemination Efforts		Insight Dissemination from RWE, HCP Interactions, and Medical Information Requests

*Launch is an evolving and fluid process.

Figure 7. Medical Affairs Key Activities for Launch Excellence*

6. GLOBAL MEDICAL AFFAIRS STRATEGIC ALIGNMENT

Organizational strategic alignment with Commercial is critical to all efforts. It is accomplished when Medical Affairs forms strategic partnerships across departments to develop the globally aligned strategy and to determine what the current situation is, what the desired situation is, and how we get from one to the other using medical strategic imperatives to tap potential select markets worldwide. Medical strategic imperatives, driven by critical success factors, function to align Global Medical Affairs initiatives.

When developing a strategy, Medical Affairs examines disease type; identifies patients, diagnostic guidelines, product characteristics and differentiators (eg, administration, efficacy, safety, pharmacokinetics, mechanism of action, and cost), competitors; and determines the product portfolio. Medical Affairs advises on alignment of strategy from the foundation of the clinical trial plan and develops consistent language to describe clinical trial results. A fully developed strategy will communicate a single clinical message that will form the basis of the value proposition supported by a uniform lexicon.

A solid unified organization-wide road map requires a single strategic direction, which is built on the cooperative efforts lead by Commercial with significant input from Medical Affairs incorporating both critical success factors and medical strategic imperatives. Once strategic direction is finalized, a continuous collaborative effort between Commercial and Medical Affairs is essential to evaluate a full landscape overview to define unmet needs, attain key customer insights, and develop a Strengths, Weaknesses, Opportunities, Threats (SWOT) analysis to transparently identify opportunities for success. This information will drive a clear, tactical delivery plan for each unit within Medical Affairs.

For effective global alignment, a thorough analysis of the resources available from country to country is needed, as it will impact product launch and all postlaunch activities. Maintaining institutional knowledge and using analytic skills to translate historic data for its effective use must take into account timing factors and all other considerations specific to each country within the global plan to ensure launch effectiveness.

Each functional area should be challenged to identify key medical objectives that work to successfully implement the strategic imperatives. This makes the imperatives more accessible to day-to-day operations and allows a line to be drawn for individual tactics. A narrowed approach makes the critical success factors relatable to tactical activities. Tactics need to be developed from objectives and strategies that can be readily identified by functional area.

Developing a medical narrative early in a product's life cycle is essential for determining critical success factors and creating a market-shaping platform that addresses the unmet medical need. **(Figure 8)**. The medical narrative serves as the foundation particularly for complex therapeutic areas requiring long-term education and messaging to establish a successful product niche.

| Unmet Medical Need | Medical Narrative | Brand Critical Success Factors | Functional Area Medical Objectives | Functional Area Tactics |

Figure 8. Functional Area Objectives

7. ROLLOUT STRATEGIC PLAN CUSTOMIZED BY REGION

Organizational stakeholders need to be informed of rollout tactics, time lines, and deliverables. As companies vary by size, number of employees, corporate cultures, product lines, and financial resources, there is no one-size-fits-all approach for executing tactics and developing tools for a global launch. However, by assessing learnings and best practices throughout the launch process, Medical Affairs can be well prepared to address any needs that arise.

8. MEASURING MEDICAL AFFAIRS STRATEGY IMPACT AND VALUE

Medical Affairs has an important part in driving market entry as many crucial activities should occur well in advance of the launch. The impact of the medical strategy should be re-examined regularly to reflect emerging new data, changing treatment paradigms, and shifting market forces. It is imperative to have a continuous feedback loop following the launch, too, as new product line extensions or indications surface. Ongoing monitoring will ensure product messages and the clinical promise remain consistent, measures can be put in place to overcome challenges, maintain relevance in the marketplace, and provide a basis for conscientious well-founded decisions.

Determining KPIs will measure the success by which functional area objectives and tactics can be evaluated. KPIs associated with data generation may include how tactics address payer and regulatory needs, demonstrate value, meet local and global market access requirements, and articulate the value proposition with supporting evidence. KPIs associated with data dissemination may include the ability to create differentiating product value and the development of medical information to address FAQs. The ability to assess relationships with external medical experts through engagement and understanding is key to guiding development and refining content.[10]

Today, Medical Affairs professionals have access to an array of powerful, global data sources (publications, conference presentations, clinical guidelines, registry data, the social/digital exchange). By filtering, interrogating, extracting sentiment, and monitoring such data, powerful insights can be yielded into competitive activity, uptake of medical strategy globally and/or regionally, and identify gaps in resourcing and scientific communications.

When overlaid onto medical imperatives, the insights gleaned from these data analyses can validate medical launch strategy plans and be used as KPIs against the plan, ultimately providing another avenue by which Medical Affairs can demonstrate impact and value for the launch excellence process.

Analytics and insight synthesis aid in this, aligned around a common set of medical imperatives that serve as the foundation for search strategy and analytics for affiliates.

Analytics and insight synthesis will demonstrate impact and value ensuring:

1. Analysis of communication efforts in the global scientific and digital exchange, quantitatively and qualitatively **(Figure 9)**

   a. Internal efforts/programs/insights

   b. Congresses/journals

   c. Digital domains

2. Tracking the impact efforts have on the therapeutic space, to determine how future efforts should be incorporated into medical plans

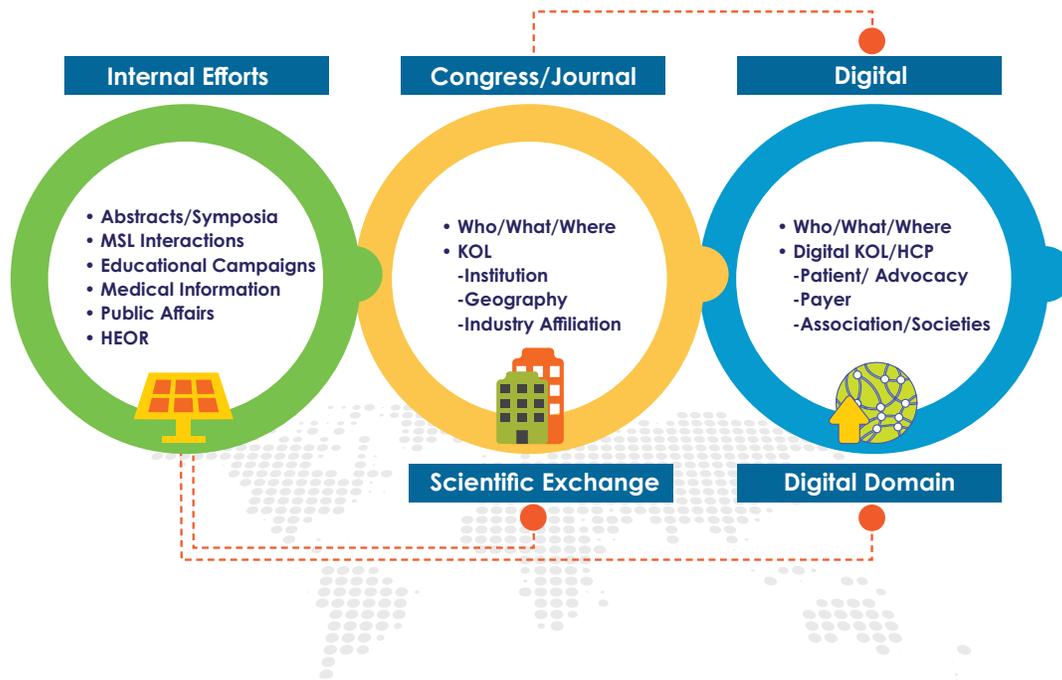3. Review of ongoing data assessments and insights against medical plans

Figure 9. Internal Communication Efforts Influence Scientific Exchange

9. A NEW AND GROWING VISIONARY ROLE FOR MEDICAL AFFAIRS IN LAUNCH EXCELLENCE

A product launch is a critical strategic undertaking for Medical Affairs. With crowded therapeutic markets and a restricted promotional environment, Medical Affairs is positioned to have an increasingly visionary role in launch preparedness and strategic planning to affirm the clinical value of new therapies. The need for more sophisticated approaches that emphasize the role of evidence-based medicine, with compelling clinical and real-world data at the core, and health outcomes research for long-term data analysis has dramatically changed the role of Medical Affairs. Now, Medical Affairs leaders need to implement the new paradigm, excel as strategic partners with Commercial, and collaborate with Regulatory, Clinical, and Market Access on scientific strategy. Having a seat at the table early in the strategic planning process provides Medical Affairs an opportunity to take the lead on product development as experts in current standards of care, product attributes, and the global competitive landscape, over the short- and long-term life cycle of the product.

In this evolving capacity, Medical Affairs must address the increasing complexity of the changing healthcare landscape, key decision-maker needs, and the evolving demands of patients, payers, and HCPs. As internal and external stakeholders set increasingly higher bars for the levels of scientific evidence needed to support a product's value proposition prior to launch, it is critical that Medical Affairs understands the disease area, has an in-depth understanding of healthcare systems, and internal and external stakeholder requirements to take the lead in establishing a strategic road map. This is where Medical Affairs' expertise in evidence generation, evidence dissemination, stakeholder engagement, and organizational support is most valuable.

> **❚❚** The imperative vision for Medical Affairs is to have a seat at the strategic table early in the product development phase, and to be well positioned to take the lead on scientific strategy development. **❚❚**
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Launch excellence requires optimal alignment of strategy and execution to drive efficiency, compliance, and best practices across countries and therapeutic areas, while accommodating market changes. It is critical that a well-prepared launch strategy be in place, and is accepted and applied throughout the organization to ensure clarity of steps required by all if launch excellence is to be achieved. Monitoring the impact of both the scientific exchange and digital domains, which have become the echo chambers of science, provides a pulse reading of the therapeutic landscape. This allows Medical Affairs to have credible scientific exchanges that evolve along with

the changing disease dynamic, noteworthy events, and evolving new classes of therapy. Medical Affairs also plays a critical role in identifying key digital opinion leaders and decision makers, clarifying clinical messages, assessing implications, and determining appropriate solutions as needed.

Functional area experts must identify key medical objectives that work to successfully implement strategic imperatives. Utilizing easy-to-use, customizable templates during the strategic planning process will provide structure, support consistency in communication, and help create common expectations for each functional area during planning. Sample templates for launch excellence planning can be found **here**.

The impact of the medical strategy should be re-examined regularly to reflect emerging new data, changing treatment paradigms, and shifting market forces. It is imperative to have a continuous feedback loop following the launch too, as market dynamics continuously change. Ongoing monitoring will ensure product messages and the clinical promise remain consistent. Measures can be put in place to identify and overcome challenges, maintain relevance in the marketplace, and provide a basis for well-founded decisions. Complex therapeutics driven by ever-evolving science require an ongoing collaborative effort to ensure alignment of a product's medical platform with its commercial strategy.

While COVID-19 has had a major disruptive impact on all aspects of life on a global level, Medical Affairs professionals play a pivotal role in ensuring that timely and accurate, evidence-based scientific information continues to be available and communicated to HCPs to meet the needs of and protect the health and well-being of their patients. As the course of the pandemic evolves and challenges arise, there are also new opportunities. Adapting and finding innovative solutions to gain insights, share information, and assess the healthcare landscape has never been more critical.

Seemingly, the world has gone digital overnight. Digital platforms have become the new communication method for interacting with customers for rapid and often real-time information sharing. Data are key and digitalization is now the norm. Virtual engagement with HCPs is a necessity rather than option. Physician and patient communication have gone digital with online visits. How clinical trials are being conducted is being reassessed. Advocacy groups are creating and providing virtual support initiatives. New opportunities exist for data dissemination as seen in the rapid release of prepublication data, analysis, and results. Face-to-face medical education initiatives, advisory boards, and professional society meetings are now being conducted in a virtual setting.

Medical Affairs must continue adapt and gain competencies in the digital arena as we have been thrust into this new norm. As Medical Affairs professionals, we must continue to prove our adaptability, proactive, strategic, and technologically savvy capabilities, to ensure that patient needs are addressed and they continue to receive the optimal healthcare available.

As treatment paradigms and market influencers change, and the patient voice becomes more pronounced and influential, so must the role of Medical Affairs professionals. Medical Affairs Professional Society (MAPS) offers colleagues a forward-thinking environment that provides innovative and interactive learning and development programs and virtual communities to share ideas and experiences. Network with other professionals and partner to develop best practice papers, as Medical Affairs grows in vision. Join and engage in the growing MAPS community to gain expert insights that can be immediately applied to your organization.

Glossary of Terms

DOLs   Digital Opinion Leaders

FAQs   Frequently Asked Questions

HCP   Healthcare Provider

HEOR   Health Economics Outcomes Research

KPI   Key Performance Indicator

MSL   Medical Science Liaison

R&D   Research & Development

RWE   Real-World Evidence

SWOT   Strengths, Weaknesses, Opportunities, Threats

TPP   Target Product Profile

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