White Paper

In the Thick of It: Medical Affairs, Strategic Partner to Other Functions

Creating internal value along the lifecycle through unique insights and relationships

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Introduction

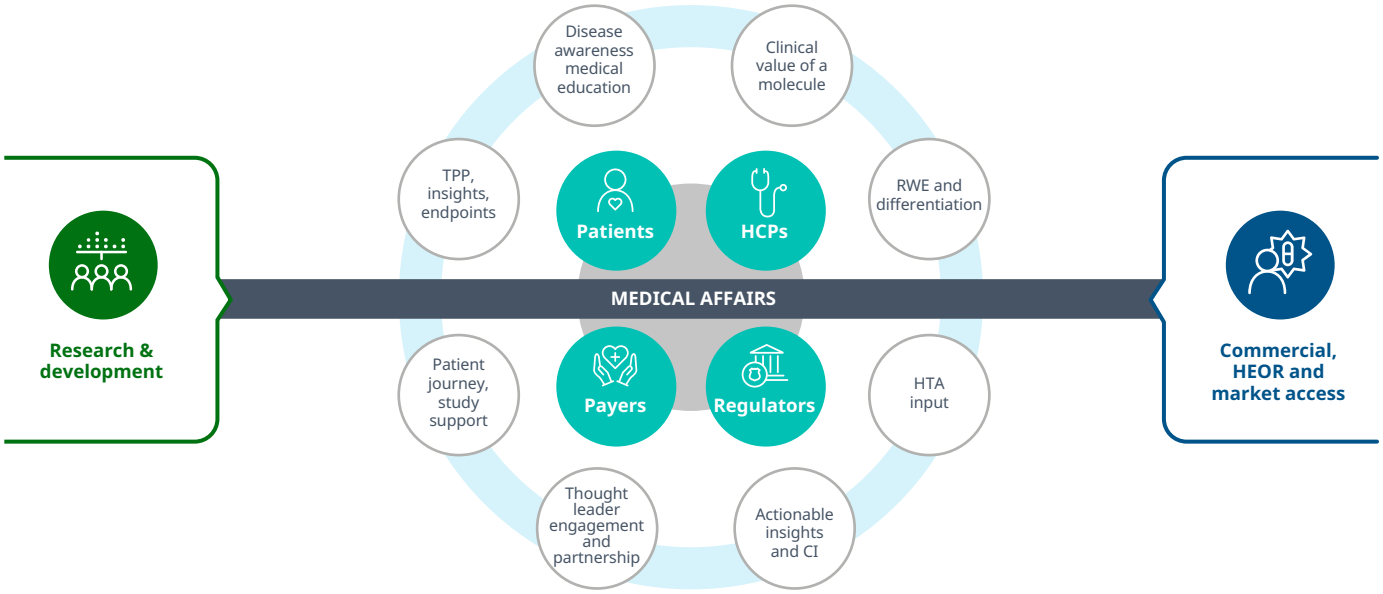
Medical affairs has come a long way since its humble beginnings. Established as a support function separate from commercial, its original focus was to provide scientific information in response to HCP enquiries for pharmaceutical products that were on the market and to compliantly address any unsolicited off-label questions.

Dramatic changes in the environment have fundamentally transformed the role of medical in recent years, as multiple trends converged: The rise of specialty care leading to more complex innovation, relentlessly increasing pressure on healthcare budget; a higher evidence burden driven by more demanding stakeholders, including the empowered patient; the proliferation of data through digitisation; and widening implementation science gaps. As a result, medical affairs is emerging as a more strategic, pro-active function with an expanded remit (see Figure 1)[1,2], while its value during the critical launch preparation phase has been increasingly recognised.[3,4]

However, many biopharmaceutical companies have yet to capture the full potential of medical affairs by systematically embedding it along the entire asset lifecycle as a strategic partner to other functions to optimise each stage of asset journey. In particular, medical is often underutilised in the earlier stages of the lifecycle, such as pre-launch and further upstream in clinical development, and during holistic, asset-level strategic planning.

As pressures on the biopharmaceutical industry continue to intensify, for example, shrinking white space due to increasing competition in many therapy areas, declining R&D productivity[5], or the impact of recent healthcare reforms, such as the U.S. Inflation Reduction Act (IRA)[6] or the German statutory sick fund finance stabilisation act (GKVFinStG), it is imperative for companies to systematically embrace the unique internal value of medical affairs as a strategic lifecycle partner.

Figure 1: Expanding remit of medical affairs as bridge between functions



Source: IQVIA EMEA Thought Leadership.

The unique internal value of medical affairs as strategic partner to other functions

Medical education, evidence generation, its dissemination and the external engagement of key stakeholders deservedly receive a lot of attention as critical responsibilities of medical affairs, to build advocacy, facilitate health system partnerships and, ultimately, enable optimal patient care.[1]

However, beyond its externally focused remit medical has an equally invaluable, yet often underutilised, internal role to play as a strategic partner to other functions, including R&D, market access, HEOR and commercial, making critical contributions at each key stage of an asset's lifecycle.

Fundamentally, medical affairs adds internal value as a partner to other functions in three ways:

1. **Enabling better strategic decisions and operational execution**, by providing a deep understanding and education on, for example, the underlying science, disease, care pathways, clinical practice, treatment landscape, patient journeys, competitive intelligence; and insight into healthcare stakeholders and their unmet needs, including external experts (EEs), HCPs, payers, providers/IDN, patients, patient organisations and advocacy groups.

   These deep medical insights, especially understanding underlying drivers and barriers of the patient journey, complement typical business intelligence and commercial insight, e.g., those based on traditional primary market research, to provide a rich, holistic foundation not only for decision making and execution, but ultimately enabling healthcare innovation to reach patients.

2. **Driving alignment around a common agenda focussed on optimal patient and health systems outcomes**, by acting as a bridge to connect different functional stakeholders at key decision points in the asset lifecycle, especially orchestrating integrated evidence planning across R&D, market access, HEOR and commercial, or for example as the 'voice of the patient' in strategic brand planning and when developing the overarching asset strategy.

3. **Leveraging its unique relationships with key healthcare stakeholders** to support other functions in achieving their objectives, for example, by facilitating engagement such as making introductions to EEs concerning speakers' bureaus, or as potential speakers for peer to peer events organised by commercial, through outreach to steering team members of patient advocacy groups (PAGs) to secure collaboration on shaping patient support programmes (PSP), or by leveraging relationships with PIs to improve patient recruitment for trials.

The unique value of medical derives from its deep expertise, healthcare stakeholder relationships and being in tune with the real world.

Beyond its formal scientific expertise and understanding of disease and treatments, the unique value that medical brings as a partner derives from its deep relationships with healthcare stakeholders and the nature of its external engagement while being in tune with the real world:

- The relationships medical establishes with key healthcare stakeholders are trust-based and free of any potential commercial conflict of interest or perceived bias.

- Medical has access to senior, influential stakeholders who are sometimes hard to reach for other functions, e.g., leading EEs, key decision makers on HTA, guideline setting bodies, board members of national or international societies or steering committees of PAGs.

- Medical has the credibility to engage peer-to-peer and can do so already very early on in the asset lifecycle. By fostering a balanced understanding of an asset's MoA and its clinical risk/benefit as a new treatment, upon unsolicited requests, medical not only builds trust with EEs but also potential advocacy.

- Furthermore, medical interactions typically last longer than those with sales reps, while a survey by the MSL Society found that 58% of HCPs rated MSL interactions as more valuable, and a further 18% of HCPs saying these are much more valuable than sales rep visits.[7] Such setting allows for in-depth discussions on a range of topics, including asking probing questions to explore specific issues, gather intelligence on competitive dynamics and understand HCPs' beliefs, preferences and their rationale for treatment choices as well as their perceptions of patients' unmet needs, yielding valuable, actionable insights.

- Medical engagement strengthens relationships by delivering additional value to HCPs beyond the sharing of scientific and clinical information, e.g., by extending invitations to conferences, offering trial participation, co-authorship of publications or sponsorships for setting up registries or IIS, or unrestricted grants for medical educational activities.

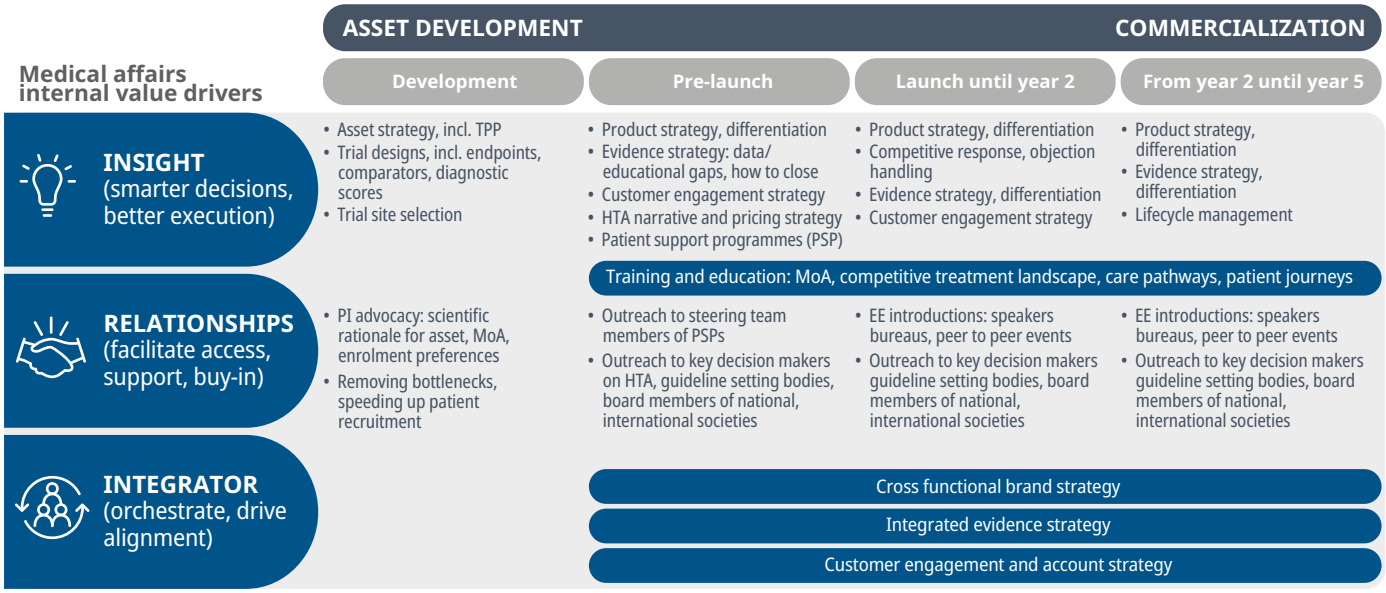
Through its engagement, medical gains a deep understanding of the practical realities within the healthcare system as experienced by HCPs and patients, including clinical practice, care pathways, patient journeys, competitive dynamics, and patients' unmet needs. This positions medical as the 'voice of the patient' within a company, ensuring patient engagement at every stage of the lifecycle to capture and incorporate their perspectives and experience via patient-centred solution.[8]

This grounded, authoritative real-world perspective provided by medical is invaluable to complement both the primary focus of R&D on addressing regulatory requirements and the business mindset of commercial to avoid any organisational blind spots in decision making.

Medical affairs: delivering internal value to other functions along the asset lifecycle

Medical affairs has a critical, internal role to play as a strategic partner to other functions along the entire asset lifecycle, from development through to commercialisation, and it has valuable, specific contributions to make at each key lifecycle stage. These draw on the three value drivers underlying the role of medical affairs as an equal partner seeing eye to eye with other functions, as elaborated earlier – insight, relationships and its role as integrator to drive alignment (see Figure 2).

Figure 2: Medical affairs — Strategic lifecycle partner to other functions



Source: IQVIA EMEA Thought Leadership.

DEVELOPMENT

Opportunities for medical affairs to add significant value already exist during early clinical development, however, these are often underappreciated. Informed by its real-word perspective, medical can advise on important, early strategic choices, for example:

- Supporting development of an asset's target product profile (TPP) in a way that reflects real unmet need while being differentiated vs. the standard of care (SoC) and the emerging competitive landscape.
- Providing input on trial designs to ensure endpoints also include those that are meaningful in clinical practice, matter to patients, e.g., proposing relevant clinical outcomes assessments (COAs), patient reported outcomes (PROs), health-related quality of life (HRQoL) measures, and help differentiate a product once on the market.
- Together with market access, advising on the right comparators to demonstrate meaningful value, especially to payers and HTA bodies, which is informed by a deep understanding of country-specific ecosystems and treatment algorithms.
- Advising on diagnostic scores and tools to incorporate in the trial protocol, for example, making sure relevance in routine clinical practice is considered vs. solely focusing on complex or theoretical instruments driven by R&D and regulatory requirements.

Furthermore, by understanding the relationship networks and influence dynamics of potential investigators within the EE universe and the wider health system, e.g., membership of guideline setting bodies, HTA advisory boards or boards of national or international societies, medical affairs can bring a complementary, qualitative dimension to enrich the process of trial site selection.

By working alongside the more operationally focused roles of Clinical Research Associate (CRA) and Clinical Trial Educator (CTE), MSLs complement their remit in supporting clinical trials. MSLs can build rapport and trust with PIs through scientific engagement and create buy-in and advocacy for a strong scientific rationale for the asset, MoA and enrolment preferences, while leveraging the MSL-PI relationship has the potential to remove bottlenecks and speed up patient recruitment.

Finally, early MSL engagement with trial sites already lays the groundwork for the pre-launch phase. Beyond providing trial support, it allows MSLs to establish external partnerships with EEs who are not investigators, e.g., to cultivate EE networks of positive advocates at the time of launch and to drive early share of scientific voice[9], or to support investigator-initiated studies (IIS).

Such early stakeholder education, relationship- and advocacy building creates a receptive environment for subsequent, key launch readiness activities which, ultimately, will enable the stronger uptake of new therapies after launch.

Opportunities for medical affairs to add significant value already exist during early clinical development. Informed by its real-word perspective, medical can advise on important strategic choices.

PRE-LAUNCH

As previous IQVIA research has shown, launch excellence proves elusive for most, with fewer than 10% of launches achieving this much coveted title.[10] To add to the challenge, 80% of all launches have their long-term fate determined during the first six months on the market, after which their sales trajectory is set. This means the stakes are high because the vast majority of launches are only afforded one shot at success.[11]

The foundations for launch success are laid during the critical pre-launch phase, when the quality of key decisions and the quality of executing launch preparations have profound and long-lasting impact on an asset's future commercial prospects.

The role of medical affairs is paramount in enabling the best possible decisions on key strategic pre-launch issues by bringing to bear its unique insight, relationships and role as integrator to drive alignment, for example:

- As part of an integrated brand team, refining the product strategy and helping to sharpen an asset's differentiation through a deep understanding of disease, treatment landscape, patient journeys and clinical practice, especially in crowded markets or against other competitors in the same class with seemingly 'similar' profiles.
- Orchestrating integrated evidence planning across R&D, market access, HEOR and commercial, including identifying evidence gaps to close to be able to demonstrate value and differentiation, e.g., defining study designs and high impact outcomes measures for clear differentiation, such as patient-relevant QoL instruments.
- Providing critical input to market access, e.g., knowledge of underlying science, disease, treatment paradigms, guidelines and understanding of patient journeys, patient characteristics and target population size, to shape the narrative for HTA submissions.
- Leveraging its expert perspective, including foundational quantitative analysis, on burden of disease, cost of illness, the standard of care, clinical practices and how those practices drive patient outcomes and healthcare costs to inform the launch pricing strategy. Such insight and supporting evidence helps pricing and market access teams understand the benefits a new product can offer to patients and HCPs and the quantifiable value it will bring to healthcare systems.
- Advising on design of patient support programmes (PSPs) focussed on addressing the most serious bottlenecks and barriers patients experience along the patient journey.
- Closer to launch, developing compliant, integrated customer engagement strategies and tactical plans across functions to enable seamless, orchestrated omnichannel engagement.[12]

Throughout the pre-launch and early post-launch phase, medical has an important role to play in embedding a broad knowledge foundation by providing training and education to brand teams, market access, the salesforce and field medical teams on the disease, the asset's MoA, competitive treatment landscape, care pathways and patient journeys, to equip the organisation for the launch.

The foundations for launch success are laid during the critical pre-launch phase. Medical affairs is instrumental in enabling the best possible pre-launch strategic decisions.

LAUNCH AND THE FIRST TWO YEARS ON THE MARKET

Once the product enters the market, the contributions of medical as a partner to other functions shift towards navigating contact with reality, for example:

- As partner in an integrated brand team, continuing to refine product positioning and differentiation while additional, post-launch real-world evidence for the asset is typically limited or immature. Consequently, a deep understanding of the competitive treatment landscape, patient journeys and unmet needs becomes even more valuable to find a compelling and viable angle for differentiation, especially insight shared from MSLs' deep scientific engagement with HCPs including around existing data and responding to unsolicited requests to discuss off-label use.
- Providing a scientific basis for shaping the approach to objection handling.
- Sharing intelligence on competitive activities, e.g., new data releases, and interpreting their implications to inform how to respond.
- Evolving compliant, integrated customer engagement plans based on new customer insight and competitive intelligence to deliver unique HCP experiences across functions and touch points via orchestrated omnichannel engagement.
- Establishing an effective feedback loop that monitors the evolving evidence landscape to identify potential gaps, inform refinement of evidence plans and support dynamic evidence generation.
- Providing practical support to other functions, e.g., making introductions to EEs to support commercial in proposing and briefing speakers for a speakers' bureau or commercial peer to peer events.

As during the pre-launch phase, providing training and education to brand teams, market access, the salesforce and field medical teams continues to be a key role for medical to ensure the organisation is fully aware of the latest competitive trends in a fluid environment and understands their implications.

COMMERCIALISATION: FROM YEAR TWO UNTIL FIVE YEARS POST LAUNCH

Even after the immediate launch phase, medical continues to make many of its valuable contributions to other functions already started at earlier stages, in particular playing its part in the integrated brand team and facilitating ongoing refinement of plans based on the latest insight and stakeholder feedback.

At this stage in the product lifecycle, typically new data becomes available, e.g., from phase IV trials or real-world studies, often in the context of a dynamic environment, with other new launches potentially reshaping the competitive landscape or changing the standard of care. A key role for medical is translating this new data into a compelling narrative to further substantiate a product's value proposition and sharpening its differentiation against the evolving competitive landscape to sustain its growth trajectory, especially in the absence of direct comparative data.

In addition, lifecycle management becomes relevant at this point, for example, label and indication expansion, which also need to be translated into an integrated brand strategy, including a clinical narrative and revised customer engagement plans.

As these compelling examples clearly demonstrate, drawing on its insight, relationships and role as integrator to facilitate alignment, medical is uniquely placed to add significant value to other functions as the authoritative strategic partner along the entire asset lifecycle.

How to systematically embed medical affairs as strategic partner to other functions

Biopharmaceutical companies must fundamentally re-evaluate the way medical affairs is positioned within their organisations and how other functions engage with it to capture its tremendous potential as a strategic partner.

To achieve this, they must focus on five critical priorities (see Figure 3):

1. **Cross-functional governance:** Set up integrated asset and brand teams including medical, with clearly defined cross-functional composition, functional roles, remit, responsibilities and decision rights.

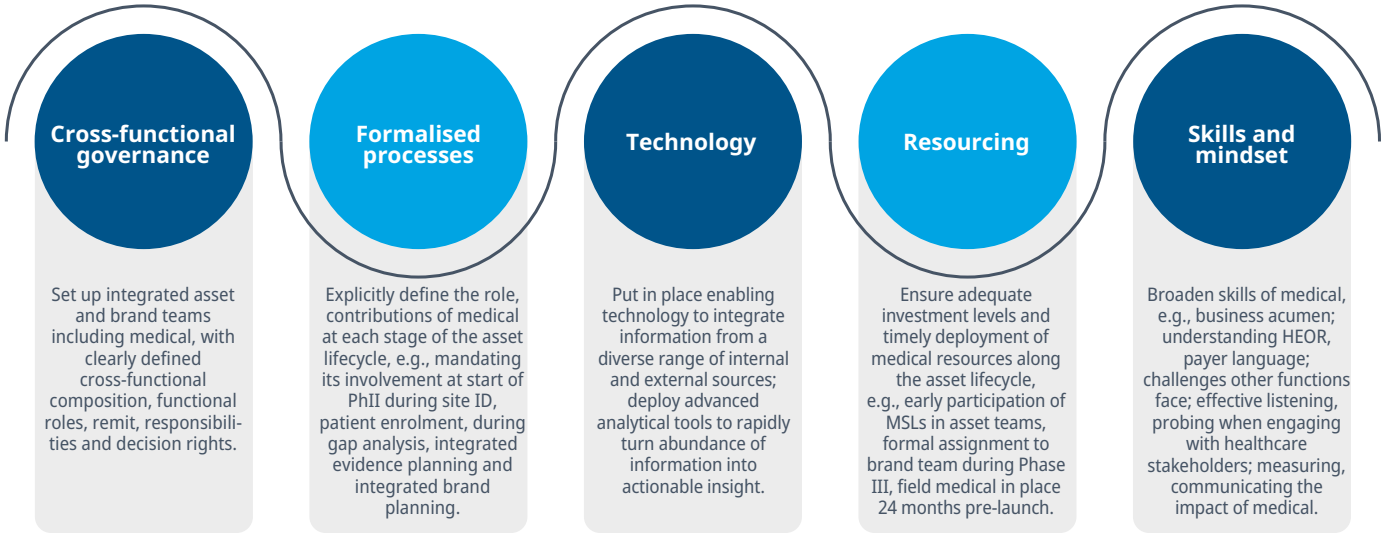
2. **Formalised processes**: Explicitly define the role and contributions of medical at each stage of the asset lifecycle, e.g., mandating its involvement and input at the start of phase II during site identification and patient enrolment for trials, or during integrated brand planning.

3. **Technology**: Put in place enabling technology, supported by adequate resources and streamlined processes, to integrate information from a diverse range of internal and external sources including structured and unstructured data[13,14], e.g., literature reviews, intelligence gathered by field medical, feedback from ad boards, RWE or other medical information, social media and newsfeeds; and deploy advanced analytical tools, e.g., NLP, AI[15,16], combined with expert review, to harness the abundance of information and rapidly turn it into actionable insight (see Figure 4 and case study).

4. **Resourcing**: Ensure adequate investment levels and timely deployment of medical resources along the asset lifecycle, for example, to make sure MSLs are available to already participate in asset teams during clinical development, followed by formal assignment to a brand team during phase III and being in the field to engage with EE at least 24 months before launch.

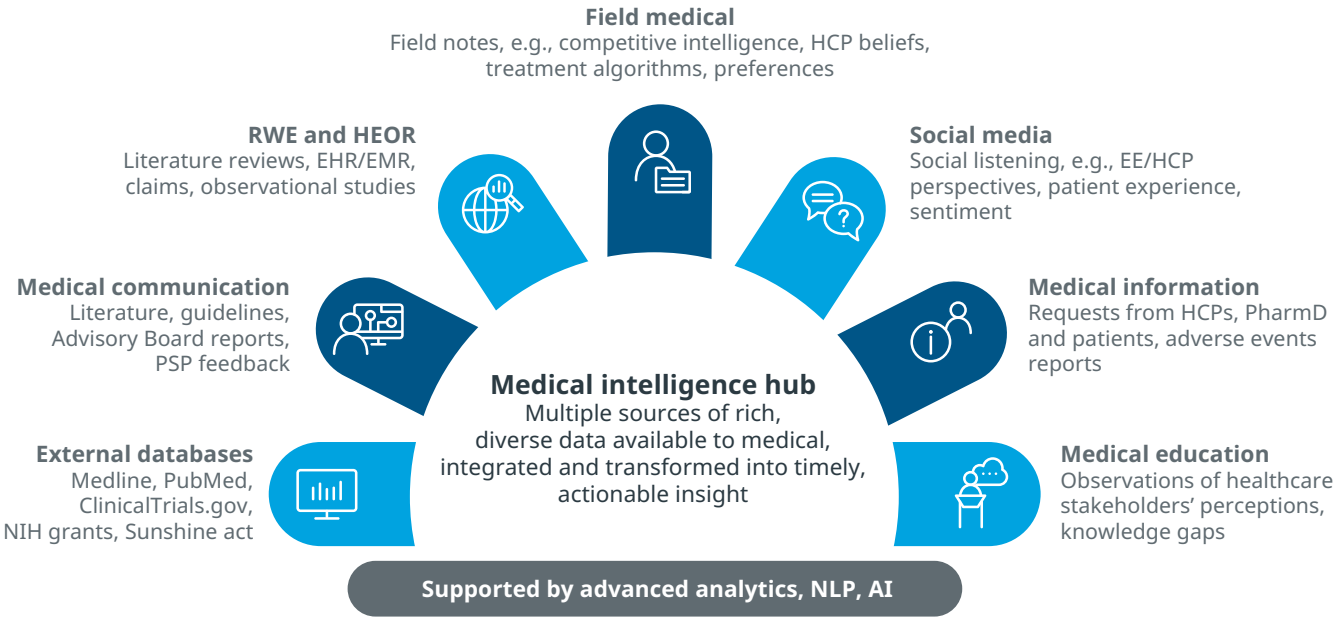
Actual resourcing levels and deployment timelines depend on the specific launch situation. For example, entering a new disease area or greater complexity due to the introduction of a new biomarker and need for a companion diagnostic would require even earlier medical deployment, as would launching a novel therapy into an underdeveloped market with limited disease understanding, awareness of patient unmet need and immature care pathways, or when entering a highly competitive environment (see Figure 5).

Figure 3: Systematically embedding medical affairs as a strategic partner — Five critical priorities



Source: IQVIA EMEA Thought Leadership.

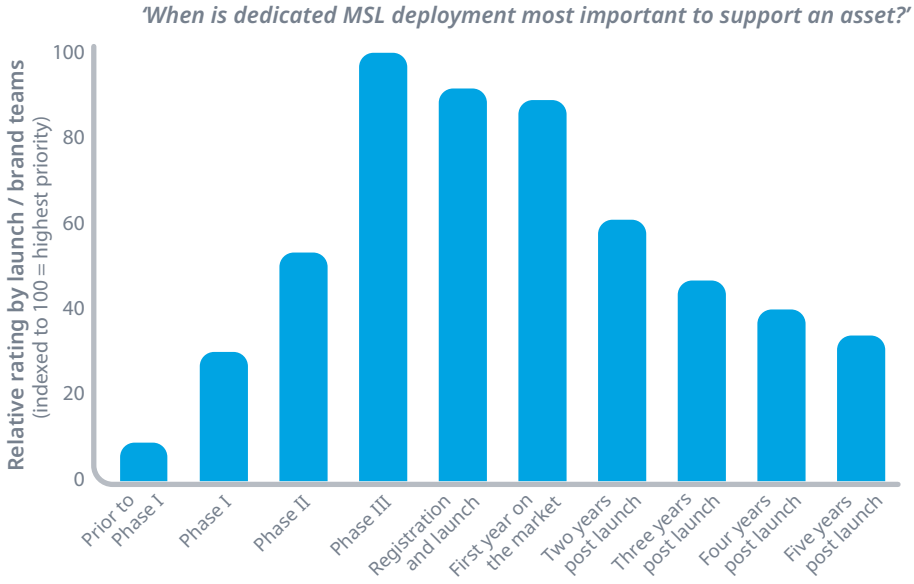
Figure 4: Medical intelligence hub to generate actionable insight



Notes: PSP: Patient Support Programme; EHR: Electronic Health Records; EMR: Electronic Medical Records.
Source: IQVIA EMEA Thought Leadership.

5. **Skills and mindset**: Broaden the skills of medical, e.g., to include business acumen and an understanding of the challenges other functions tackle as part of their remit and where medical can add most value; effective listening and probing when engaging with healthcare stakeholders to gather deeper insight or becoming better at measuring and communicating the impact of the contributions made by medical to support the case for change and help other functions understand its value.

Figure 5: Medical resourcing and deployment along the asset lifecycle



Considerations for medical resourcing levels and deployment

Even earlier medical deployment needed, when...

- Entering a new therapy area
- Introducing a novel biomarker and companion diagnostic alongside a new drug
- Launching into an underdeveloped market with limited disease understanding, awareness of patient unmet need, immature care pathways
- Entering a highly competitive environment

Source: IQVIA EMEA Thought Leadership, IQVIA proprietary benchmarks; IQVIA white paper: Medical Launch Readiness, 2019

Case study: IQVIA NLP solutions for medical affairs

ISSUE

Over 80% of biomedical data is unstructured text. Conventional keyword searches are unsuitable to mine the huge volume of complex textual data to extract insight.

Unlocking the value of rich, unstructured and typically inaccessible data across multiple external and internal sources is critical to generate novel and timely insight for medical affairs.

SOLUTION

IQVIA Natural Language Processing (NLP) provides technology solutions that transform textual data, e.g., in documents or databases, into normalised, structured data suitable for analysis or integration into existing workflows, data warehouses or dashboards.

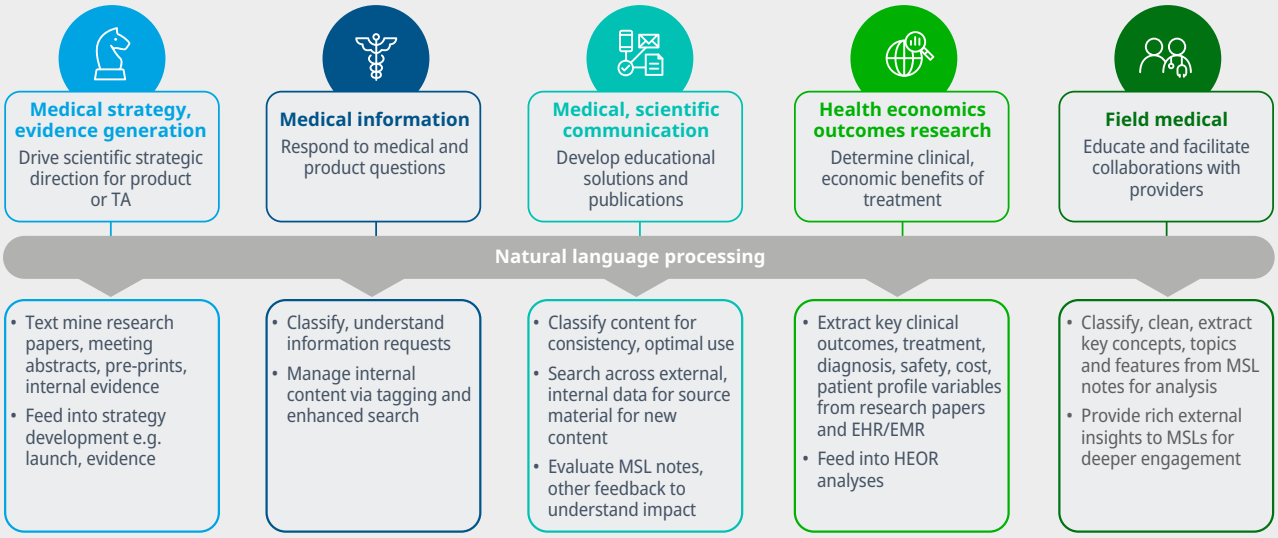
USE CASES

IQVIA NLP offers three main solutions to help medical affairs teams make better, data-driven decisions[17]:

1. **Medical Intelligence Hub**: Collate, manage and share insights from across multiple sources to provide a consistent baseline for global and regional medical affairs teams. NLP-enhanced search and rich visualisation enables rapid access to TA-specific information, surfacing of key medical topics, tracking of own and competitive brands and sentiment in the market for contextual analyses or comparing the latest science across multiple products.
2. **NLP for Interaction Data**: Using automated and semi-automated approaches, unlock insights from MSL notes and medical information requests that can feed into databases or intelligence hubs, e.g., identifying topics of interest or concerns raised during HCP interactions, or systematically analysing call centre feeds for root causes of reported side effects, e.g. pre-existing conditions vs. ADR.
3. **NLP for Real World Insights**: Extract and normalise real-world data points and insights, e.g., from high volume of published literature or rich variables in EHR transcripts; for example, comprehensively mapping the evidence landscape for IBD in a given geography by extracting health outcome data from scientific sources to identify gaps and inform new study designs.

IQVIA NLP solutions provide efficiency and speed while unlocking novel insights for medical affairs from previously inaccessible data to enable better, rapid decision-making, tailoring of content and targeting of HCP engagement in a highly dynamic competitive environment.

Figure 6: NLP applications for medical affairs



Source: Linguamatics, an IQVIA company

Finally, to overcome entrenched, function-centric legacy behaviours and bring about the necessary change, top-down C-level sponsorship and role modelling by senior leadership throughout will be important.

Faced with an increasingly unforgiving environment which challenges the industry's business fundamentals, it is imperative for biopharmaceutical companies to systematically embed medical affairs as a strategic lifecycle partner to other functions. The headroom for accommodating sub-optimal decisions and execution by missing out on the unique value of medical is shrinking fast.

Faced with an increasingly unforgiving environment, it is imperative for biopharmaceutical companies to systematically embed medical affairs as a strategic lifecycle partner to other functions.

References

1. Their finest hour: Medical affairs in a disrupted world; IQVIA white paper, 2022; https://www.iqvia.com/library/white-papers/their-finest-hour-medical-affairs-in-a-disrupted-world
2. The Future of Medical Affairs 2030; Medical Affairs Professional Society, 2022; https://medicalaffairs.org/future-medical-affairs-2030/
3. Medical Launch Readiness: Making or breaking a successful launch; IQVIA white paper, 2019; https://www.iqvia.com/library/white-papers/medical-launch-readiness
4. Rabea, M. (2022) Understanding the Factors that Impact the Pre-Launch Phase and New Product Launch Excellence in the Pharmaceutical Industry. American Journal of Industrial and Business Management, 12; 10.4236/ajibm.2022.121007
5. Global trends in R&D 2023; IQVIA Institute report: https://www.iqvia.com/insights/the-iqvia-institute/reports/global-trends-in-r-and-d-2023
6. See The Whole Board: The Inflation Reduction Act of 2022, and the complex chess game now in play for pharmaceutical manufacturers; IQVIA white paper, 2022: https://www.iqvia.com/locations/united-states/library/white-papers/see-the-whole-board
7. Key Opinion Leaders Reveal the Value of Medical Science Liaison, Medical Science Liaison Society (MSLS); survey of 203 KOLs across 33 specialties based in the U.S., 2021
8. M. New, J. Paty, M. Reaney, Harnessing Patient-Centered Science to Improve Health Outcomes and Commercial Pharma Success; Applied Clinical Trials, 1 November 2022: https://www.appliedclinicaltrialsonline.com/view/harnessing-patient-centered-science-to-improve-health-outcomes-and-commercial-pharma-success
9. Laudano J, Dutton G, Leveraging Medical Affairs Analytics to Enhance Engagement and Demonstrate Value. The Journal of the Medical Science Liaison Society, 19 October 2021; https://themsljournal.com/article/leveraging-medical-affairs-analytics-to-enhance-engagement-and-demonstrate-value/
10. Launch Excellence VI: Launch Excellence in a Disrupted World; IQVIA white paper 2019; https://www.iqvia.com/library/white-papers/launch-excellence-vi
11. IQVIA Launch Excellence series, bi-annual publications I-VI, 2007-2019
12. Medical Affairs' Next Frontier: Unlocking Omnichannel Engagement; IQVIA white paper, 2022; https://www.iqvia.com/library/white-papers/medical-affairs-next-frontier-unlocking-omnichannel-engagement
13. McLoughlin M, Jonkman M, Zivkov M., Building Medical Insights Capabilities In Medical Affairs Organizations; Medical Affairs Professional Society, 2021; https://medicalaffairs.org/wp-content/uploads/2022/09/Building-Medical-Insights.pdf
14. McLoughlin M, Jonkman M, Zivkov M. Moving to an integrated, holistic approach to insights-related activities in medical affairs; Medical Affairs Professional Society, 2021; https://medicalaffairs.org/wp-content/uploads/2022/05/Holistic-Integrated-Insights.pdf
15. What could ChatGPT mean for Medical Affairs? Linguamatics blog, 9 February 2023: What could ChatGPT mean for Medical Affairs? | Linguamatics
16. ChatGPT, Large Language Models and NLP – an Informatics Perspective in Healthcare; Linguamatics blog, 22 March 2023: ChatGPT, Large Language Models and NLP – an Informatics Perspective in Healthcare | Linguamatics
17. Linguamatics: Pharma Insights with our NLP Insights Hub; https://www.linguamatics.com/products/pharma-insights-hub

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Markus has over 20 years of experience in life sciences, advising clients in all major geographies on a broad range of topics, including real world evidence strategy, launch readiness, go-to-market models, brand and commercial strategies, and building enabling organisational capabilities.

Markus is a frequent speaker on the latest industry trends and regularly engages with senior leadership teams of pharmaceutical companies.

Prior to his current role in Thought Leadership, he has held leadership positions within IQVIA Real World Solutions and QuintilesIMS Consulting Services (formerly the IMS Consulting Group).

Markus holds a PhD in Pharmaceutical Chemistry from the University of Hanover and has completed post-doctoral research at the University of California.

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Reinhard has more than 15 years of Medical Affairs experience in the pharmaceutical industry, holding country-level, regional and global roles. He has successfully covered all facets of Medical Affairs, including launch readiness, digital transformation, RWE generation, medical education, MSL excellence and medical strategy, and was responsible for leading Medical Affairs teams with direct accountability to senior management.

Reinhard has broad knowledge of healthcare ecosystems and deep therapy area expertise spanning cardiology, neurology and immunology.

Prior to his current role, and before moving into Medical Affairs, Reinhard gained experience in drug discovery and pre-clinical development in the pharmaceutical industry.

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