



# Medical Affairs Transformation in Specialty Pharma: Next-Level Collaboration at the Core

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## Abstract

Pharmaceutical companies with a medical mindset and an empowered Medical Affairs function are well equipped to meet the needs and expectations of patients and society. Yet, as capacity to understand and serve those needs accelerates, so too do expectations. Evidence-based practice, without delay, is expected throughout the development and delivery of medicine, healthcare, and information, and potential sources of evidence are legion. To keep pace and go beyond, to innovate, requires efficiencies. Not the disguised cutbacks of political language, but the collaborative constructive efficiencies of shared learning, forming new evidence bases for further progress. Here, we describe the first year of a medical transformation process at a global mid-sized pharmaceutical company. Beginning with a broad review designed to leverage collective intelligence and focus on meaningful outcomes for patients, this process examined and reshaped the structure, culture, and tools of the medical organization and its interactions within and outside the company. We report the findings of the diagnostic phase, outline the solutions implemented to date, and anticipate the next steps in this dynamic evolving journey.

## Key Points

The multi-faceted strategic role of Medical Affairs is increasingly recognized and relied on within the pharmaceutical industry and healthcare systems.

To effectively harness medical expertise in the data age and make measurable improvements to patients' lives requires new metrics and adaptive nimble approaches.

Optimizing the flow of knowledge to and from Medical Affairs professionals empowers them to co-create solutions and achieve meaningful outcomes for patients.

## 1 Introduction

An increasingly clear vision of near-future specialty pharma (developing medicines predominantly prescribed or initiated by hospital specialists), in which Medical Affairs harnesses the power of the data age, is described in industry and professional society articles [1–8], and peer-reviewed articles [9–13]. With confident yet forward looking leadership and collaborative practice, a digitally empowered medical organization will direct and translate internal and external resources to serve the needs and expectations of patients and healthcare professionals (HCPs), within the pragmatic realities of healthcare systems. Achieving meaningfully improved health outcomes for patients will be at the core. Having evolved from a support function within historically more consumer-based organizations, through a bridge, to a strategic pillar, from reactive to proactive, transforming in response to external pressures and propelled by unprecedented global change and therapeutic advances, medical functions will nimbly deploy novel yet validated approaches to co-create better healthcare that is centered on the patient and rooted in evidence. In so doing, they will ensure their deep medical expertise can be impactful in a noisy world. Pharmaceutical companies must remain relevant amidst healthcare-facing innovations from digital giants. So, how? Not in isolation. A clear consensus also highlights the

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importance of developing deep medical capabilities, especially people, generating and leveraging novel insights, and communicating effectively with all relevant stakeholders. The very pace of evolution in Medical Affairs has contributed to challenges in articulating its value, threatening to hamper cross-functional progression [14]. The impact and value of strong medical organizations anywhere *should* be felt everywhere, to the ultimate benefit of patients and society, if we collaborate at a next level. To that end, we describe a process of medical transformation at a global mid-sized biopharmaceutical company, outlining the initial impetus and steps taken to date, and examining progress toward that near-future vision.

## 2 Approach

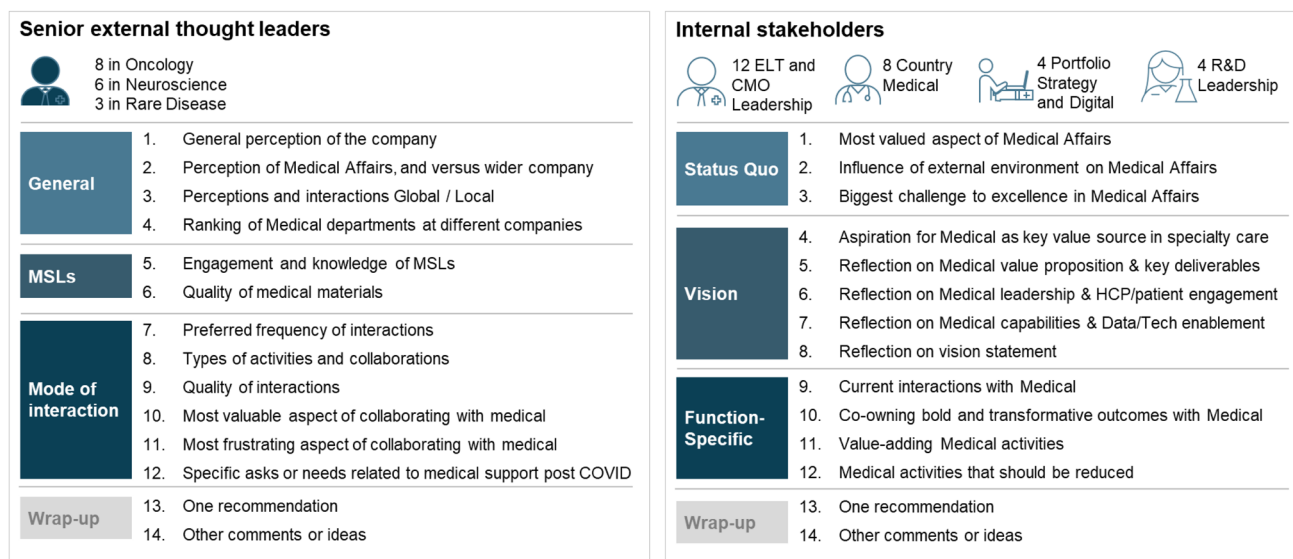
### 2.1 Collective Transformation

Ipsen has a 90-year heritage as a family-owned company and publicly traded business, with an accompanying legacy; of experience, reputation, and relationships, and also of historical perspective and systems. Prior to Q2/2020, Medical Affairs supported internal decision making, but a cultural shift was needed to position the medical organization as a strategic driver of innovation and value alongside research and development, commercial, and market-access functions [1, 2]. This positioning, which reflects the emerging industry-wide vision of medical affairs as we introduced above, was fundamental to achieve our evolving vision—of medical leadership for patients being at the center of everything

we do. Leading in therapeutic area (TA) strategy allows the voice of data to be more effectively leveraged, not only in translating for and between multiple stakeholders but also in ensuring an evidence basis for resource and development decisions, to deliver value and insights for patients, HCPs, and healthcare systems. In March 2020, a newly appointed Chief Medical Officer joined the Executive Leadership Team, enabling medical to “lead from the C-suite”, and a new and empowered Medical Transformation Lead was appointed to further boost medical leadership and ensure deep worldwide implementation. This elevation of medical, essential in reinforcing and executing on its strategic pillar status, was nevertheless a structural tweak. The true cultural shift aimed to leverage collective intelligence throughout the transformative process, and embed this approach within the solutions identified.

### 2.2 Diagnosis and Direction

Rapid initial assessment and benchmarking, facilitated by external consultants, involved representative cross-functional in-depth interviews (Fig. 1); 28 internally and, importantly, 17 with senior external thought leaders with whom Ipsen and key competitors interact, from seven countries and across three TAs. Executive Leadership Team members called for stronger medical partnership in business development, while external interviewees noted that excellent scientific expertise and exchange at a local and global level was hampered by staff turnover and partial under-resourcing. In parallel, an internal survey distributed to 974 staff—global



**Fig. 1** Scope and dimensions of in-depth interviews during initial benchmarking of medical capabilities. *CMO* Chief Medical Office, *COVID* coronavirus disease, *ELT* Executive Leadership Team, *HCP*

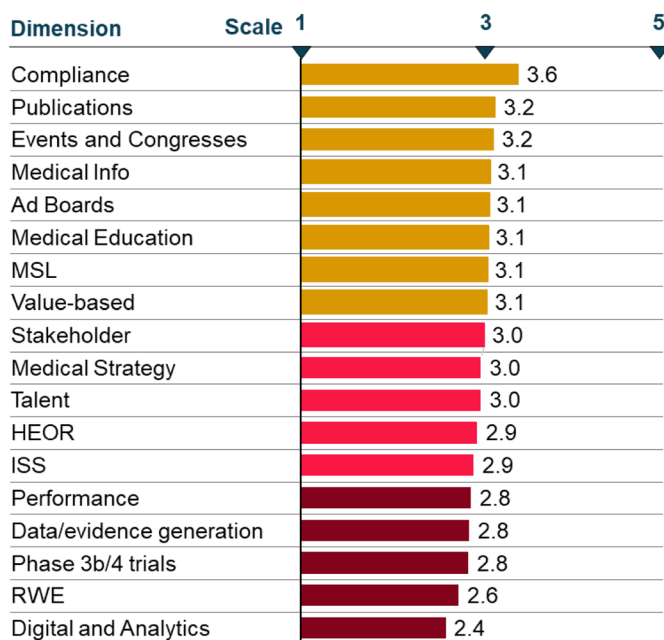
healthcare professional, *MSL* Medical Science Liaison, *R&D* research and development

leadership team, key partners in other functions, and all medical—generated 725 responses (a 74% return rate) (Fig. 2). Capabilities in Medical Affairs were perceived as being at or above the industry standard (score of 3.0) in only eight of 18 dimensions assessed. Average perceptions of medical capabilities were higher among medical affairs staff (3.1; *n* = 378) than non-medical affairs staff (2.7; *n* = 347); 12 of the 18 dimensions scored slightly above average among the former. Overall, ‘traditional’ areas of expertise, including compliance, publications, and medical information and education rated above standard, contrasting with crucial data-centered capabilities including performance tracking, real-world evidence (RWE), and digital and analytics (Fig. 2). The Medical Science Liaison (MSL) and training dimensions scored above or at standard but were acknowledged as being of critical importance for the future impact of the medical organization on patient care. Similarly, it was a priority to strengthen the existing and well-regarded Patient Affairs function. During this phase, the strategic direction of medical transformation was set according to overarching aims and fully embraced by Ipsen’s CEO and Executive Leadership Team, to: measurably improve patients’ lives along the patient journey, as well as HCP experiences; demonstrate medical leadership; advance medical care in long-term collaborations; be at the leading edge of (data and technology enabled) innovation in specialty care; and attract, develop, and retain leading talent.

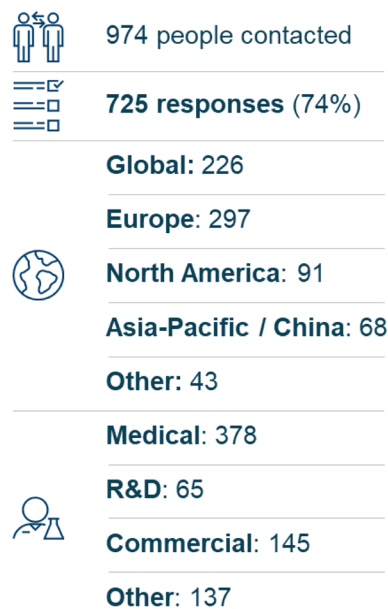
### 2.3 Prescription

Five priority areas for change were identified and six workstreams created (Fig. 2), each with a medical lead. These owners formed a medical transformation leadership team, responsible for driving and monitoring overall progress. Individual workstreams included Executive Leadership Team-nominated partner owners from other relevant functions and geographies. Priorities, set with multi-year horizons, included specific near-term goals within 3-month and 6-month timelines. Changes enacted alongside the rollout of the transformation roadmap included seeking to fill immediate capability gaps: medical professionals with experience in business development, digital professionals with medical experience, and training and knowledge transfer leads. Other re-structuring involved mirroring in the medical organization the structure of TAs as established in the research and development organization, and the international structure of the commercial organization. Within Global Medical Affairs TAs, capabilities were strengthened for external innovation and business development. Medical Excellence, expanded with new training and knowledge transfer roles per TA, was joined within Global Medical Affairs Capabilities by a novel Data, Insights & Strategy function led by an experienced RWE specialist, incorporating the existing Biometry team. Global Medical Affairs Regional was boosted with new regional heads to drive global and local alignment. Patient safety was fully integrated in the

#### Aggregated results (average per dimension)



#### Survey demographics



**Fig. 2** Medical capabilities benchmarking survey. Score of 3 = industry-standard; 5 = best-in-class. Conducted April-May 2020. *Ad* advisory, *HEOR* health-economic outcomes research, *ISS* investigator-

sponsored study, *MSL* Medical Science Liaison, *R&D* research and development, *RWE* real-world evidence

Chief Medical Officer organization retaining a separate dedicated global structure. The voice of the patient was boosted per TA with new resources in Patient Affairs, and a new Global MSL Lead role completed the new medical structure, established after 3 months by late 2020.






A detailed transformation roadmap was rolled out via a dedicated global townhall in September 2020, followed by supportive regional townhalls and cross-functional regional implementation team kick-off meetings to ensure full worldwide implementation. Each workstream included specific goals, activities, and best-practice definitions (Fig. 3), with progress to be monitored via key performance indicators (KPIs). Important in the new culture was that KPIs assessed meaningful metrics [15]; the impact as well as the magnitude of an activity. For example, within the stakeholder engagement workstream, operational KPIs, such as the roll-out of a new tool for collecting insights and the percentage of users accessing it, were accompanied by performance KPIs such as the proportions of countries sharing and applying insights, and stakeholder feedback on the usefulness of gathered insights. Into early 2021, localization of the roadmap was driven through executive-sponsored medical health checks with country managers and medical directors to identify capability and resource gaps.

### 3 Outcomes

#### 3.1 People: Careers, Training, and Knowledge Transfer

A new medical career path tool allows staff across diverse functions to explore how their expertise can be applied and

developed in well-trodden or unique directions. Roles have been mapped within a competency framework, allowing lateral and vertical moves to be plotted, boosting progression opportunities and illustrating the interconnectedness of functions and flow of skills within the organization. New recruitment and fast-track promotion programs have been instigated to encourage attraction and retention of the best talent. Medical-Science Liaison and patient centricity teams have been expanded. Training has been updated to create the Medical Excellence Academy, to systematically train medical staff on core and role-specific capabilities. Integral to this plan has been the hiring of new Knowledge Transfer Leads per TA, to ensure a deep understanding of products, TA, and other critical medical information for all relevant staff. These roles proved challenging to fill, as few corollaries exist, but are rapidly making an impact. As new core training modules come online, the team is working with colleagues in TAs, publications, communications, and medical information to pilot effective ways of providing real-time updates, such as priority data at congresses, new manuscripts, and collective insights. Periodic assessment will measure skill development against defined pillars, and delivery of content in terms of scientific excellence, clarity, and objectivity. This structure will be important to equip staff, and also to ensure staff feel equipped, to provide value in their interactions. Expansion of the medical affairs remit has prompted some industry voices to call for the creation of “super-medics” [16]. Others caution against creating a sense that people must be superhuman to manage emerging technologies and new approaches [17]. Using data-driven approaches to foster both individual development and collaborative expertise will help embed the new organizational culture while protecting and leveraging a bedrock of high-functioning talent.

Priority areas	Workstreams	Best practice definition
 Talent, Organization & Governance	Medical career paths, attraction & retention, Organization & Governance alignment	Drive <b>global and local talent</b> and medical capabilities based on a structured <b>competency and career structure</b> with an <b>expanded range of skills</b> (e.g.: omnichannel engagement, data analytics and innovative RWE)
 Training & knowledge transfer	Scientific content, delivery & assessment	Medical teams <b>consistently demonstrate</b> a diverse <b>core skill set</b> , including: <b>deep medical knowledge, soft skills, business acumen</b> and <b>strategic thinking</b> to partner with commercial and R&D on strategy development
 Country Medical capabilities (incl. MSLs)	Stakeholder engagement & Medical Insights	Broad view of medical influencers with robust <b>TL identification, targeting and engagement</b> (including through digital channels). <b>Highest level of scientific exchange</b> conducted with key TMs, payers, regulators and patient advocates.
	Medical Launch readiness	Clear, aligned, transparent process in place to ensure consistent, <b>pro-active insight gathering</b> through MSL/HCP stakeholder engagement, Ad boards and Med Info LCM and phase 3b/4 plans developed at an early stage (phase 2 or early 3) of product development /according to Medical Launch Readiness Framework
 Quality upgrade for current study landscape	Gap Analysis of all current studies & programs	<b>Clear standards, processes and systems for different type of studies that ensure and track performance, delivery on strategy and compliance</b> at all times
 Data/analytics & evidence	Evidence process, strategy & data infrastructure	Medical insights systematically <b>incorporated into an integrated asset evidence plans</b> to identify data gaps that define late phase clinical programs including 3b/4, RWE, ISS areas of interest and programs. <b>Clear global RWE analytics strategy</b> using <b>multiple data sources and innovative analytical tools</b> and an “integrated data platform”

**Fig. 3** Priority areas, workstreams, and best practices incorporated in medical transformation roadmap. *Ad* advisory, *HCP* healthcare professional, *incl.* including, *ISS* investigator-sponsored study, *LCM*

lifecycle management, *Med Info* medical information, *MSL* Medical Science Liaison, *R&D* research and development, *RWE* real-world evidence, *TL* thought leader

### 3.2 Stakeholder Engagement

The upskilling of medical staff, and provision of tailored training materials, are key to effective engagement, enabling the proactive exchange of knowledge, data, and solutions. Another aspect is identifying who to engage with, when, and how to do so most effectively. A key milestone in the medical transformation was achieved in August 2021, with the rollout of the Thought Leader Identification and Mapping tool, a data-driven application to help find, validate, and select thought leaders based on evidence. The tool increases the ease, visibility, and transparency of profile building, and supports planning for local and global activities with HCPs.

### 3.3 Medical Insights

How to gather, analyze, and effectively use high-quality insights is fundamental to the discussions around usefulness of medical, digital, and pharma [1–4, 9, 13, 18]. Traditional sources such as advisory boards, MSL interactions with HCPs, publications, and congresses are themselves becoming more technologically varied, and are supplemented by new sources created by novel technologies. Making use of these myriad opportunities will require medical staff trained to recognize actionable insights, and systems that can recognize patterns. In June 2021, a new medical insight system went live. Users can input insights as free text or in response to approved surveys, record the source, associate them with predefined tags or with medical objectives, and submit them for review. Reviewers check for plausibility, quality, potential safety events, and compliance of information. A dashboard offers instant analytics and custom reports. Assessing input and addressing feedback from users are integral to the active ongoing development of the system.

### 3.4 Data, Insights, and Strategy

A major new capability established during the medical transformation is the Data, Insights & Strategy function, incorporating the existing Biometry group alongside Epidemiology (with a new head to be recruited) and Data Strategy and RWE. This function will oversee access to advanced data sources, analytics, and machine learning and ensure a strategic approach to data and insights generation. As a first step, integrated evidence plans are being created for priority products by the end of 2021, bringing together data-generation planning across medical, health-economic outcomes research, market access, development, safety, regulatory, and commercial at a global and local level. Externally, RWE is already being used to support label expansions and approvals [19], while pharmaceutical companies and regulators are rapidly adapting to the place of RWE in drug development pathways [20, 21]. Guidelines for reporting randomized

controlled trials using routinely collected data including from registries, electronic health records, and administrative databases were published in 2021.<sup>22</sup> While these technology-based solutions are alluring, a full appreciation of the nature of the data sources, their accuracy, completeness, and relevance are needed to allow insights and RWE to be reliably and transparently used to help bring therapeutic solutions to patients.

### 3.5 Country Medical

Worldwide, country medical health checks have been completed, resulting in profound changes in resource allocation. Investment has shifted substantially from marketing to medical, with a refocused operating model and correctly sized country medical organizations. High-value studies and programs—those most likely to make an impact for patients—have been prioritized, with support provided to rationally end underperforming studies. This step change in ambition, ensuring that all data generation activities are aligned with cross-functional plans and patient needs, aims to provide genuine and differentiated data to support better care. Involving a change in the culture of ongoing support, oversight, and performance management in relation to all forms of data generation, it has been necessary at times to shift from an activity-driven to an outcome-driven mindset, with a focus on tracking and execution across all aspects of medical and clinical operations. Ongoing efforts aim to establish a deep quality mindset and structure, develop a detailed understanding of patient flow and journey, positively influence healthcare systems to improve the standard of care, and improve knowledge transfer from headquarters to countries. Countries also offer the opportunity to pilot new approaches. For example, an innovative virtual launch event platform, hosting regional advisory boards, post-launch events, and a homepage for medical professionals was deployed in Germany.

## 4 Long-Term Follow-Up and Exploratory Analyses

As we reach 12 months since the global launch of the medical transformation, progress has been much faster than might have been envisaged at the outset, in part owing to easier online access to stakeholders and global changes in working practices. Given the legacy of established systems and the traditional focus on developing medicines, a transformation was truly required and has been achieved, undoubtedly owing to great executive support, cross-functional alignment, and a willingness to invest, as well as real engagement with workstreams at a global and local level to translate new ideas and tools into practice. A key learning was that a



diverse range of talented cross-functional colleagues, having been invited to co-create the process and outcomes, have become enthusiastic ambassadors to their respective countries and functions, helping to embed the new culture (and preventing “not invented here” syndrome).

Nevertheless, this new structure and operating model with medical positioned and equipped to anticipate and respond to modern-day and future demands is just a beginning. Fully implementing new integrated data plans including RWE, streamlined global local translation of materials and practices, and ensuring that all new tools are implemented is a longer process. Following through on execution and metrics and ensuring that cross-functional efforts translate into improved outcomes for patients require an ongoing culture of focus, collaboration, agility, and transparency. And of course, innovation. The value of breaking silos is that everyone can learn from each other. Colleagues in research and development have been investigating synthetic trials, and medical is now exploring this area too. Machine learning has provided novel ways of understanding patient journeys and predicting patient outcomes. At the time of writing, leveraging true artificial intelligence in medical affairs remains a future prospect, but the pace of change suggests the future will be here soon, and we should be ready.

We began the transformation to place medical leadership for patients at the center of everything we do. As a dynamic process that evolves according to collective intelligence, this “transformation” must continue, but now as “how we operate”. We will need to balance articulating and measuring specific goals with enabling nimble adaptation. Qualitative outcomes after another 12 months may include unanticipated innovations. The final beneficiaries of our efforts will be patients, with diseases across the TAs our specialty medical affairs teams represent. To measurably improve health outcomes for these people will require proactive internal and external sharing to implement effective strategies at the company and industry level.

## 5 Conclusions and Outlook

The strength of medical affairs has always been collaboration, trust, integrity, and transparency, providing evidence-backed information tailored to the audience. Data cannot speak for themselves. The proliferation of potential inputs and outputs has raised expectations, created a whole set of new languages for medical to translate, and necessitated a sea change not only in how resources must be marshalled but also in how the value of medical activities is demonstrated through comprehensive outcome-based metrics. Continuous leadership development is essential to ensure medical’s full engagement with all stakeholders and an

appropriate flow of information, and effective knowledge transfer is essential to get data to the frontline. Hopefully, our case study points to how other specialty pharma companies can leverage the advantages of a high-functioning medical organization to help drive organizational success and patient-centered outcomes.

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