

White Paper

MEDICAL LAUNCH READINESS

Making or Breaking a Successful Launch

MARKUS GORES, PhD, Vice President, Thought Leadership, IQVIA

GORDON DYCE, Senior Principal, Consulting Services, IQVIA

ANA KORAC TRKULJA, MBA, MSc, Associate Principal, Consulting Services, IQVIA



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EXECUTIVE SUMMARY

Much has already been written about the subject of launch readiness, from critical success factors and launch excellence frameworks to tactical roadmaps and launch KPIs. The focus, however, typically tends to be skewed towards commercial activities, with medical launch preparations often not receiving the attention they deserve, considering today's strategic importance of the medical function. Here we discuss common pitfalls in medical launch readiness that pose significant risks to launch success and present experience-based best practices for overcoming them.

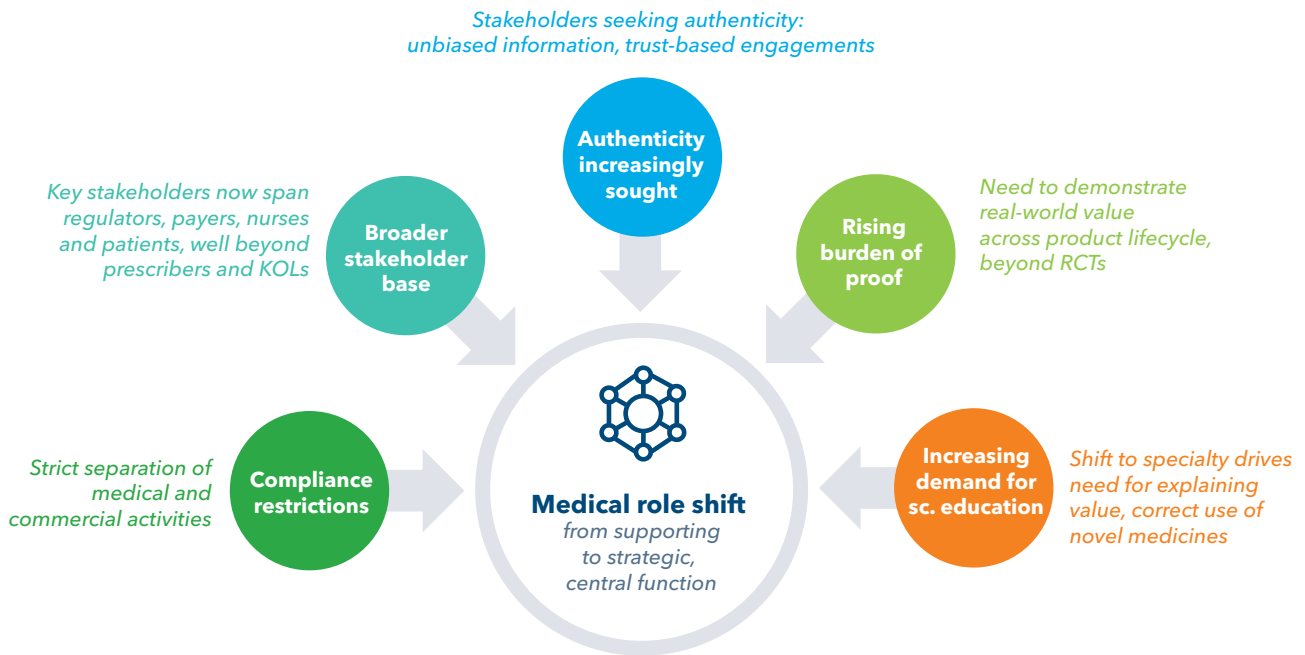


THE RISE OF MEDICAL AFFAIRS

Traditionally, Medical Affairs has played a supporting role in the preparation for launch, largely focussed on ensuring regulatory compliance; responding to

healthcare professionals' enquiries, especially those that fall outside a product's label; and collaborating with investigators on post-launch clinical trials.

Figure 1: Changing Healthcare Landscape and Evolving Role of Medical Affairs



Source: IQVIA

However, dramatic changes in the healthcare environment are redefining the role of Medical Affairs in the preparation for launch (figure 1).

- Ever more stringent compliance requirements demand the strict separation of commercial and medical activities, including both content generation and its dissemination
- An increasingly complex healthcare landscape requires engagement with a broader set of stakeholders, beyond prescribers and KOLs, including regulators, payers, nurses and patients
- Furthermore, those stakeholders are seeking authenticity, in the form of unbiased information delivered via trust-based engagement, un-clouded by commercial objectives
- A rising burden of proof for demonstrating value to regulators, payers and HCPs across the product lifecycle requires the strategic planning and generation of critical, scientific evidence, including RCT data, RWE and patient-generated data (e.g., Patient Reported Outcomes)

- With innovation shifting to specialty care, new products have more complex, scientific communication requirements for educating key stakeholders about their benefits, how and in which sub-populations to correctly use them, and explaining the evidence-generating programmes underpinning their value proposition

Consequently, Medical Affairs has moved centre-stage, and it needs to play a strategic role in launch preparations to deliver against those requirements. This includes adopting a proactive and competitive mindset; becoming the home for deep, novel insight and intelligence for the company; taking the lead in shaping the evidence agenda; and establishing excellence in external engagement and value communication. To fulfil this promise, such a prominent role for Medical Affairs needs to be mirrored in the attention dedicated to, and the rigour demanded of, medical launch preparations.

Yet, in our experience, medical launch readiness efforts all too often fall short of those expectations, with bleak consequences for the prospects of launch success.

MEDICAL LAUNCH READINESS: COMMON PITFALLS TO AVOID

Having supported numerous clients across the industry in their launch preparations, we can draw on a wealth of practical, real-world experience to identify common pitfalls of medical launch readiness. Those lessons learned are further enriched by the insights from our reputable IQVIA Launch Excellence series¹, which has systematically analysed hundreds of launches using extensive, proprietary IQVIA data assets, combined with learnings from expert practitioner interviews, to identify the underlying drivers of launch performance. Specifically, we have observed the following typical shortcomings in medical launch preparations:

- Disconnect between the medical strategy and the broader product strategy; in particular, lack of consideration of different launch scenarios or alignment around the product's value narrative and specific key messages
- Insufficient external validation: Assumptions underpinning the medical strategy are not backed up by robust insights into opportunities and requirements, e.g., the actual unmet needs of different stakeholder types are misunderstood, resulting in focus on incorrect priorities; evolving stakeholder expectations for evidence have not been substantiated, leading to the generation of inadequate evidence (e.g., improper choice of comparator)
- Undue conservatism: Reluctance to commit to resource levels commensurate with the strategic role of medical; unwillingness to invest early in medical resources prior to positive data read-out, with detrimental impact on timely external stakeholder engagement for early disease education and advocacy building; focus on

traditional, face-to-face engagement only, with technology-enabled approaches, e.g., digital communication, grossly underutilised

- Lack of process rigour: Medical launch planning does not systematically or comprehensively address all relevant stakeholders (e.g., KOLs, payers, PAGs, regulators, nurses, patients); objectives, responsibilities, milestones and interdependencies within medical and with other functions are insufficiently defined; resource planning does not track shifting priorities and requirements over the product lifecycle; KPIs are missing, as are enabling tools for monitoring progress against plans
- Competency gaps: Often, competency-building programmes are insufficient for delivering the upskilling and enhancements required to equip the medical function for success in its expanded, strategic role in launch readiness

We have seen first-hand the negative impact on launch performance of inadequate medical launch preparations, which manifests itself in a number of ways: Restricted market access, sub-optimal pricing and reimbursement, poor market preparation and delayed launch timelines, resulting in a flatter and shallower launch uptake trajectory. Furthermore, companies typically incur unnecessary cost and wasted effort due to last-minute gap closing attempts.

Considering the exceedingly high stakes of launching a new product, with typically only one shot afforded at getting it right², pharmaceutical companies have everything to gain from ensuring excellence in medical launch readiness.

EXCELLENCE IN MEDICAL LAUNCH READINESS: WHAT DO LEADERS DO?

We have observed the following best practices emerging from within companies as they prepare for medical launch readiness. Leaders typically exhibit the hallmarks of process excellence, specifically:

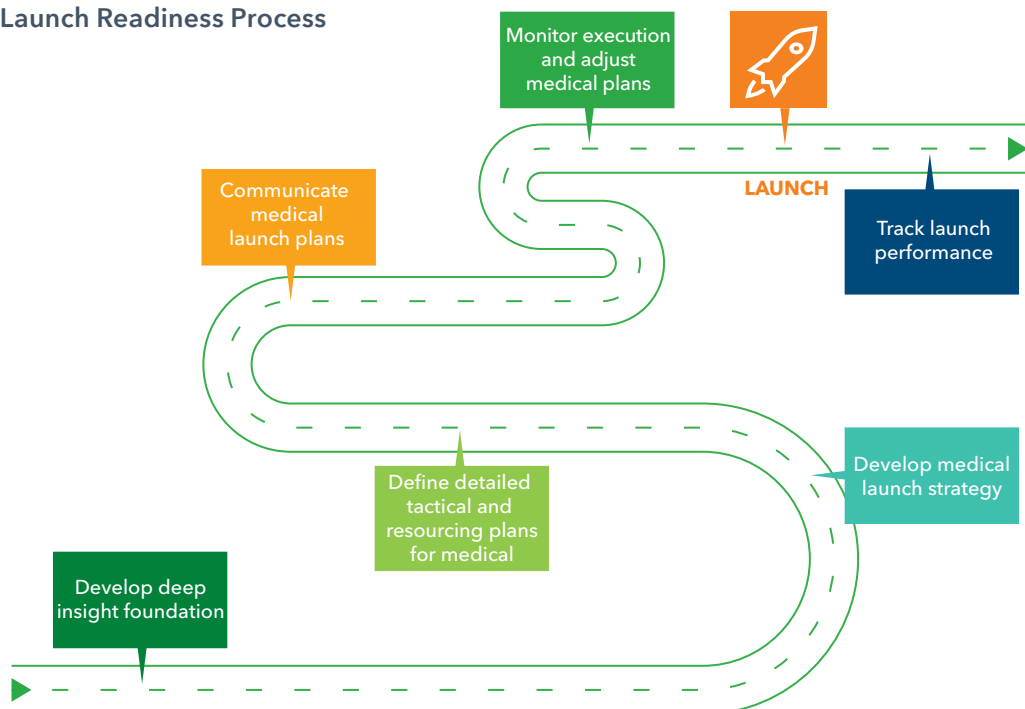
1. Leaders put in place a systematic, robust process with specific focus on planning and delivering medical launch preparations, including clearly defined steps, responsibilities, milestones and timelines (Figure 2). Such a medically-focused process is supported by requisite, state-of-the-art tools, e.g., medical pre-launch framework, interdependency maps, detailed process guidance, centralised medical pre-launch knowledge hub and real-time launch activity tracker, to ensure both transparency and consistency in execution.
2. Leaders establish a fit-for-purpose governance model for the active participation of medical in launch preparations, which enables strong cross-functional strategic and tactical alignment, for example, among medical, development, market access and commercial functions. Furthermore, such a governance model clearly specifies roles and responsibilities for medical and other

functions, at global, regional and affiliate levels, while identifying areas and mechanisms for close collaboration.

3. Leaders ensure strong executive sponsorship for all medical aspects of the launch plan, with the senior leadership team being visibly involved throughout.
4. Leaders enable regular, systematic best-practice sharing and transfer of learnings across launch teams, including establishing platforms for conducting post-launch reviews.
5. Leaders define meaningful medical pre- and post-launch KPIs, which are regularly monitored to assess progress against plans in terms of completed activities, quality, and achieved outcomes; and that enable timely course correction.

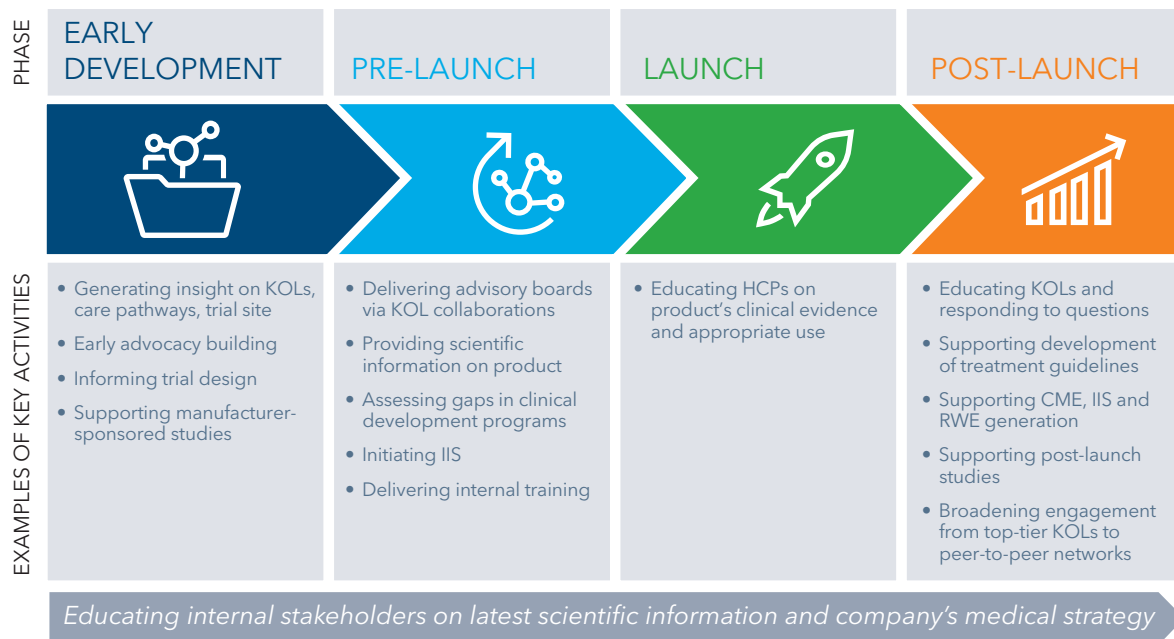
Embedding a systematic, robust process is a key prerequisite for achieving excellence in medical launch readiness. However, such a process in itself is not sufficient; indeed, it needs to be underpinned by fit-for-purpose resource commitments which reflect the dynamic nature of medical responsibilities over the product lifecycle.

Figure 2: Medical Launch Readiness Process



Source: IQVIA

Figure 3: Medical Affairs Activities Evolve Over the Product Lifecycle



Source: IQVIA

MEDICAL RESOURCING FOR LAUNCH SUCCESS

The priorities for the medical function, and consequently the nature and extent of medical activities, change considerably over the product lifecycle (Figure 3).

In early development, medical is focused largely on insight generation, e.g., understanding the disease area, the relevant KOL landscape and care pathways to inform RCT design and enable early advocacy. During the pre-launch phase, however, that focus shifts increasingly towards educational activities including both broad, external engagement of diverse stakeholders such as KOLs, HCPs, payers and patients, and training of internal teams. Post-launch activities continue to focus on KOL and prescriber education, now spanning the handling of product-related queries as well as supporting guideline development, while the generation of additional evidence becomes increasingly important, including post-launch studies, RWE and investigator-initiated studies (IIS).

The release of phase III trial data represents a critical milestone for medical launch readiness, and in turn for medical resourcing requirements, in particular Medical Science Liaisons (MSLs). According to IQVIA

proprietary benchmarks, MSL activity peaks during the pivotal study stage and pre-registration through launch. This is supported by findings from an extensive survey³ of MSLs, with over 50% of respondents identifying phase III, registration and launch, as well as the first year on the market as by far the most critical stages for MSL deployment vs. other points in the product lifecycle.

In order to ensure critical medical pre-launch activities are executed in a timely manner and to high quality standards, companies need to demonstrate early conviction and commitment to invest. Specifically, drawing on our IQVIA proprietary benchmarks, we have identified the following industry best practices for medical resourcing:

- Dedicated global medical roles should be assigned at the start of phase III, typically 3-5 years prior to launch
- Dedicated local medical leadership roles should be resourced 2-3 years prior to launch
- Local MSLs should be in place 18-24 months prior to launch

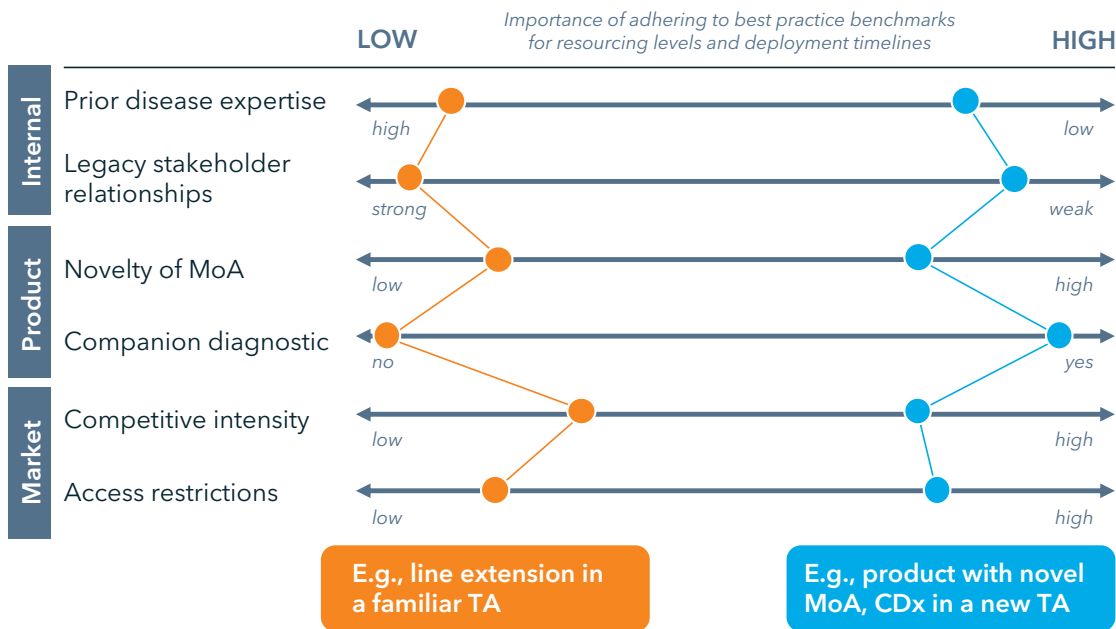
While these benchmarks provide directional guidance, actual resourcing timelines and levels may vary for different launch situations, based on several considerations (Figure 4).

- Familiarity with the disease area, in the case of a line extension or new product entering an existing disease area, allows for a later start of medical activities, due to a lower need for new insights and disease-related activities
- Conversely, a new product entering a new disease area increases the need for competitive intelligence, insight generation, scientific collaborations and medical education, hence requiring greater medical resource levels and an earlier start of medical activities

- The inherent complexity of diseases and therapies is another critical determinant of medical resourcing. For example, rare diseases or regenerative medicine, such as cell and gene therapies, have highly sophisticated scientific communication and education requirements and therefore need greater, dedicated medical resourcing early on
- Additional factors, such as high degrees of competitive intensity in crowded therapy areas or greater complexity due to companion diagnostics, further increase the demand for early medical activities

Recent trends in medical resourcing reflect the need for companies to better manage the inherent risk associated with product development, their

Figure 4: Considerations for Medical Resourcing Levels and Timelines



Source: IQVIA

desire to maximise efficiencies, and at the same time differentiate themselves among competitors. These trends include exploring synergies, both of geographic nature, via global/regional MSL roles covering multiple markets, and within disease areas, while outsourcing of medical roles prior to data read-out is emerging as a flexible strategy for managing uncertainty.

Particularly noteworthy is the emergence of highly specialised medical field roles, aimed at achieving differentiation in external engagement through deeper, tailored domain expertise to better address specific stakeholder needs. Examples include Clinical Trial Liaisons (CTL) who focus on all aspects of evidence generation support; Health Outcomes Liaisons (HOL) who focus on external communication of health economic evidence with payers; Clinical Educators (CE) who provide therapy education and/or product use training for HCPs and patients; and Clinical Science Specialists (CSS) who target mid-level, local/regional KOLs.

Beyond novel in-field roles, the increasing importance of digital activities in medical engagement drives the need for additional, specific expertise, such as digital medical communications specialists or digital medical content curators.

These trends are testament to the growing recognition of the strategic importance of medical launch readiness and the maturing approach to deliver it.

CONCLUSION

Medical Affairs has moved centre-stage and now plays a strategic role in launch preparations that can make or break a successful launch. By establishing excellence in medical launch readiness, through best-in-class processes and fit-for-purpose resourcing, pharmaceutical companies are setting themselves up for maximum launch success. The alternative doesn't bear consideration.

REFERENCES

1. IQVIA Launch Excellence series, bi-annual publications I-V, 2007-2017
2. See 'The 6-month window' when the launch trajectory is set, first identified in our IQVIA Launch Excellence series I, 2007; subsequently confirmed in each bi-annual update, including the most recent publication IQVIA Launch Excellence V, 2017
3. MSL Society, member survey on MSL involvement at different stages of the product lifecycle, 2016

ABOUT THE AUTHORS



MARKUS GORES, PhD

Vice President,
Thought Leadership, IQVIA

Dr. Gores has more than 20 years of experience in life sciences and is an expert in the areas of Oncology, Immunology, HIV, and orphan diseases. He has advised clients on a broad range of topics, including real-world evidence strategy, launch readiness, go-to-market models, brand and commercial strategies, and building enabling organizational capabilities.

Dr. Gores is a frequent speaker on the latest industry trends and regularly engages with senior leadership teams.

Dr. Gores holds a PhD in Pharmaceutical Chemistry from the University of Hanover and has completed a post-doc in Oncology at the University of California.



GORDON DYCE

Senior Principal,
Consulting Services, IQVIA

Mr. Dyce has more than 15 years experience in Consulting for Life Sciences, working with a broad spectrum of biopharma clients and is currently a key leader in IQVIA's launch and organization strategy function.

In his time at IQVIA, he has advised companies on, amongst other things, re-defining the role of Medical Affairs in the cross-functional launch process, building key capabilities for future success of specialty medicines across commercial and medical functions, ensuring medical launch readiness and resourcing for the launch of a new blockbuster.

Mr. Dyce has a 1st Class Masters Degree in Biological Sciences from Oxford University.



ANA KORAC TRKULJA, MBA, MSc

Associate Principal,
Consulting Services, IQVIA

Ms. Trkulja has more than 15 years of experience in life sciences. She leads international engagements that focus on launch and commercial strategy with Pharma and Med Tech clients. She has advised clients on a broad range of topics including launch excellence, medical launch readiness, Medical Affairs capabilities optimization, CDx launch strategies, and brand and commercial strategies among others.

Prior to working for IQVIA, Ms. Trkulja held various senior positions at Roche where she led a number of launch initiatives for key Roche products.

Ms. Trkulja earned an Executive MBA from London Business School and an MSc in Pharmacy from Belgrade University.

CONTACT US

iqvia.com/contactus

