

MEDICAL OPERATIONS OF THE FUTURE

As Medical Affairs organizations continue to evolve, the 'Medical Operations' or 'Medical Excellence' group is becoming increasingly important. This paper explores how Medical Operations groups can best evolve to meet the needs of a fit-for-future Medical Affairs organization, recognizing the emerging opportunities, the needs of different constituent groups within Medical Affairs, and acknowledging the continued drive for efficiency and cost-saving.



SCAN FOR MORE
INFORMATION





MEDICAL AFFAIRS ENABLES PATIENT-CENTRIC, DATA-DRIVEN DECISION-MAKING ACROSS THE HEALTHCARE ECOSYSTEM

Medical Affairs plays a key role in driving patient-centric, data-driven decision-making across the healthcare ecosystem. This includes development and commercialization decisions within a biopharma company, as well as support to external decision-making through the timely provision and contextualization of high-quality evidence to patients, prescribers, payers and Health Technology Assessment (HTA) bodies. To do this effectively, the Medical Affairs organization must maintain continuous scientific exchange with external stakeholders to ensure they have the information they need to make the best decisions for patients, and to thoroughly understand unmet needs and evidence requirements. This understanding and insight must in turn inform strategies and tactics within the company – and not only in Medical Affairs.

Medical Affairs continues to play this crucial role in a context that has shifted considerably in the past decade – many companies have moved to more specialist portfolios, evidence requirements of external stakeholders continue to increase, and the opportunities provided by new digital capabilities can often be overwhelming. Arguably the most important manifestation of these trends is in the behavior of patients and health care professionals (HCPs): patients have become more proactive in their understanding, interest and engagement with therapeutic sciences through the internet, and HCPs are now expecting and consuming information in a way that is significantly different to what it was even five years ago, while managing the increased information needs of the patients they serve.

“
The **last best experience** that anyone has anywhere, becomes the **minimum expectation** for the experience they want everywhere.

Bridget van Kranlingen, IBM

Historically, the ways in which Medical Affairs organizations have adapted to these opportunities have varied widely; some have made large (albeit sometimes ad hoc) investments in capabilities that augment core processes, while others have waited to see how technologies and best practices evolve. However, given the dynamic nature of the external environment, it is ever more important to take a coordinated approach to introducing capabilities that are strategically relevant for the organization, and provide a demonstrable return on investment. In addition, the apparent growth and increased remit of Medical Affairs organizations across the industry has created new challenges for the operating model. Innovative technologies have increased the need to update legacy systems and processes, and the rapid expansion of teams has often strained the global-local two-way connectivity that is imperative to understanding needs and effectively implementing strategies to address them. The Medical Operations group must therefore ensure that the entire Medical Affairs organization is working in unison as it navigates the challenges and opportunities ahead.



A STRONG MEDICAL OPERATIONS CAPABILITY IS A CRITICAL ENABLER OF AN EFFICIENT AND FORWARD-LOOKING MEDICAL AFFAIRS ORGANIZATION

Medical Affairs organizations have established and evolved 'Medical Operations' or 'Medical Excellence' teams to meet the operational needs of the Medical Affairs function as well as the needs of their external stakeholders as consistently and efficiently as possible. However, in many instances the exact remit of these teams is not always clear, and priorities can shift in a reactive manner based on circumstance and demand. While the specific scope of activities may vary depending on wider organizational structures, the remit of Medical Operations typically includes the following areas:

- Establishing best in class processes with a focus on continuous improvement. This includes the processes for Medical Affairs strategy, planning and insights generation in partnership with the Therapeutic Area (TA) groups
- Identifying and implementing innovative digital solutions with a focus on how external stakeholders want to receive information
- Driving the proactive and continuous assessment of capability needs, gaps and tools. This includes Field Medical capabilities, which are often supported through a focused MSL Excellence team within the Medical Operations group
- Developing and maintaining information and knowledge management systems and platforms to enable effective storage and use of information. While this includes Medical Information and content creation, other important aspects are the management, codification and organizational use of insights to inform strategy, and profiling information to ultimately drive enhanced omnichannel engagement
- Optimizing resource utilization and sourcing strategies, including scanning the external landscape for innovations and strategically important partnerships for the Medical Affairs organization e.g. niche data and technology vendors as well as service providers
- Defining and maintaining a balanced performance management system that includes metrics and KPIs focused on execution, quality and impact of activities
- Defining high-quality standards and enabling robust Medical Governance that recognizes the increasingly digital nature of external interactions and data sharing.

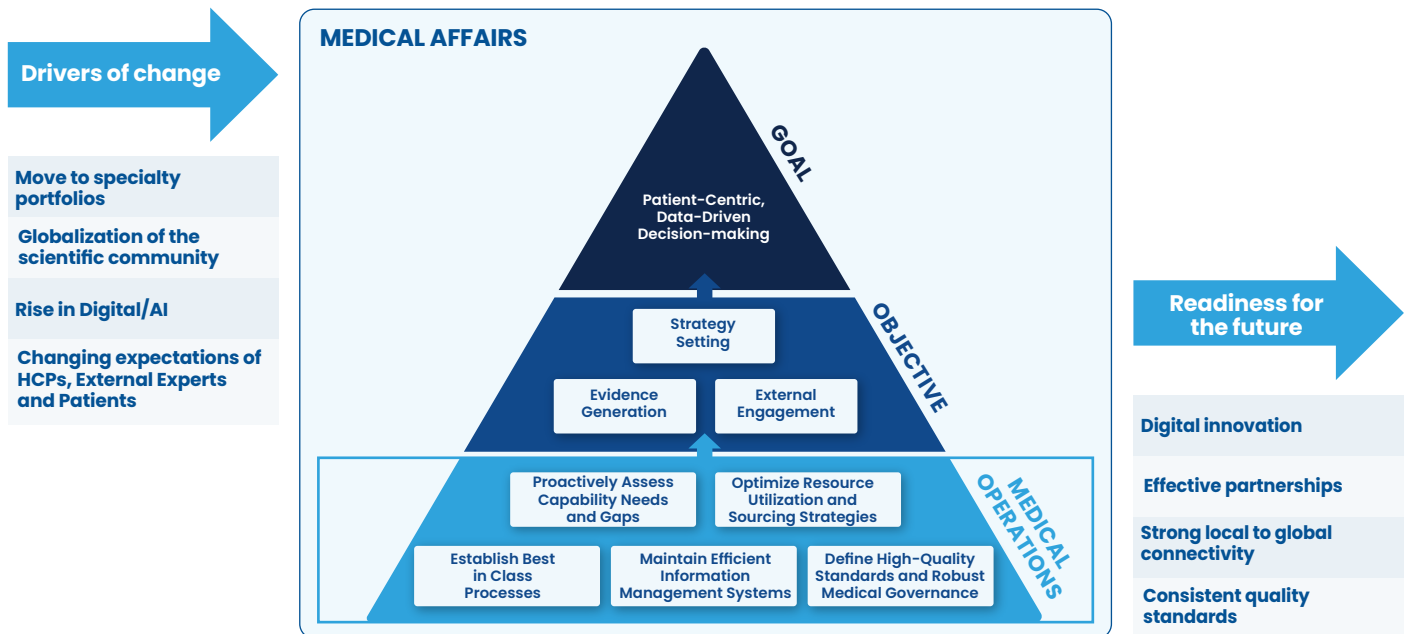


Figure 1: Future readiness for a Medical Operations group

This paper explores how Medical Operations groups can best evolve to meet the needs of a fit-for-future Medical Affairs organization, recognizing the emerging opportunities, the needs of different constituent groups within Medical Affairs, and acknowledging the continued drive for efficiency and cost-saving.

STRONG RELATIONSHIPS WITH MEDICAL AFFAIRS GROUPS IN REGIONS AND THERAPEUTIC AREAS ARE A KEY SUCCESS FACTOR

The following elements are critical for the success of any Medical Operations group:

- Aligned understanding, trust and buy-in to the purpose and value proposition of the group from all levels in the Medical Affairs organization
- Clear definition of the remit of a Medical Operations group and specifically where its remit begins and ends vis-à-vis TAs and Regions
- Ability to coordinate and work effectively across TAs and geographical groups (Regions and/or local teams) to drive quality and consistency.

The ability to work effectively with Medical TAs and Regions and/or local teams is crucial to reassure these groups that their needs will be met effectively and consistently. This will be contingent on the Medical Operations operating model (including its scope and purpose, structure, processes and information management), as well as the ability of key individuals to develop strong trust-based relationships with Medical Affairs groups in the TAs and Regions. The main driver of Medical Operations group structure is the need to enable these interfaces, although the broader organization structure is also a strong influence. The organization structure and associated resourcing determine the degree of centralization that is possible while retaining an ability to cater for specific geographical needs or the needs of specific TAs. Industry trends show a move towards greater centralization; the rationale for this is typically to establish global best practices and to drive economies of scale. Larger companies often have the resources to also maintain groups that directly support Regions or Business Units, with the role to support strategy and process implementation in an aligned manner across the organization. Whatever the chosen operating model is, it must be explicitly supported and enforced by senior management to avoid emergence of duplicative groups within Regions or TAs.

In addition, any organization structure has inherent weaknesses; these must be acknowledged and addressed through clear processes, resource allocation and use of other elements of the holistic operating model (see Figure 2 below).

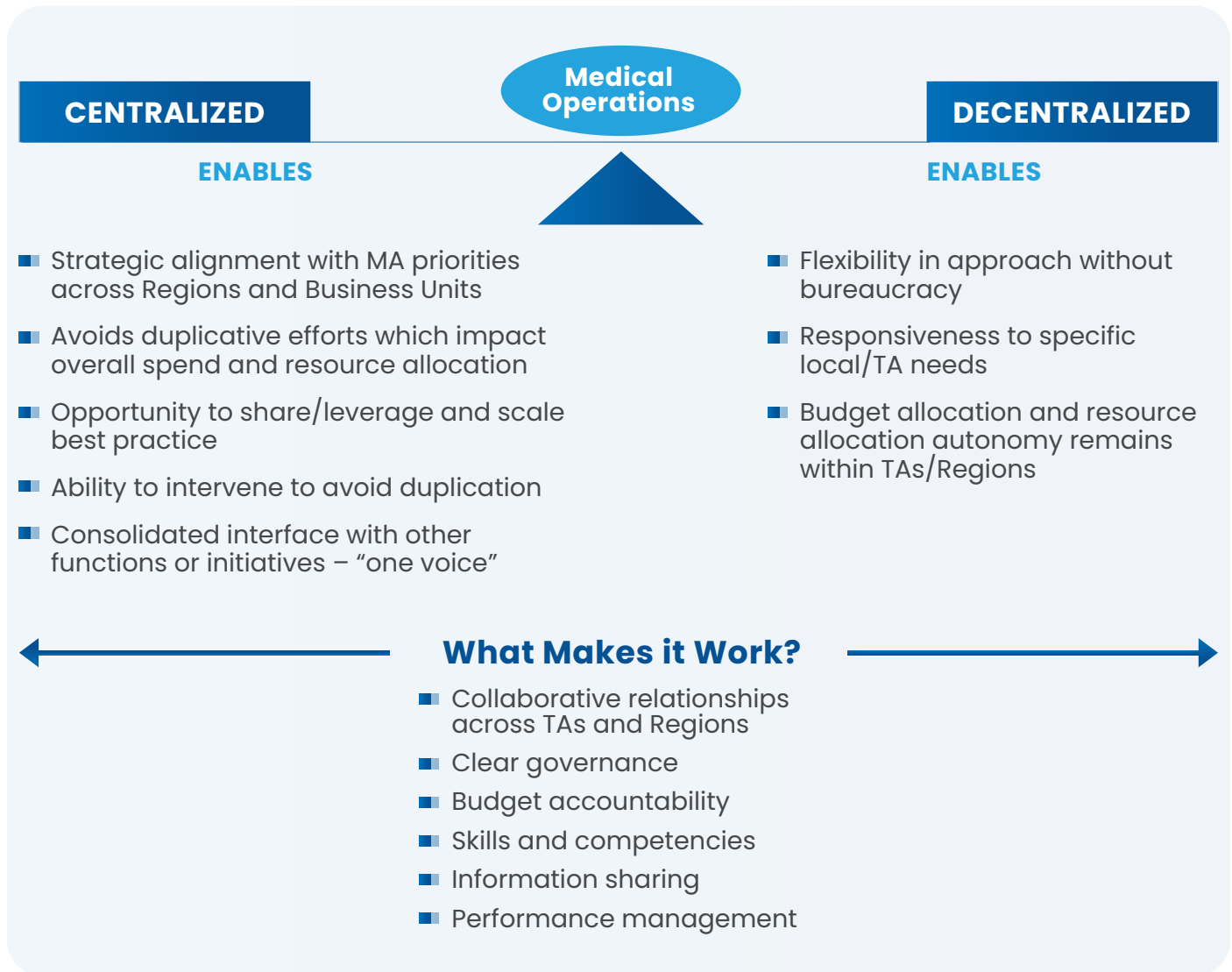


Figure 2: Balancing centralization vs decentralization in Medical Operations structures

THE HEAD OF MEDICAL OPERATIONS ROLE

Many roles require an individual with several key competencies to be successful, but those competencies are not always easy to find in a single individual. Many Global Medical Team Leads require strong Project Managers at their side to complement their scientific strengths. A Head of Medical Operations requires strong execution and implementation skills and will often lead a sizeable team, while working closely with the Head of the Global Medical Affairs. However, the most important attribute that cannot be augmented by other staff is the ability to network, influence and build trust with the TAs and Regions. Without this dialogue, significant effort will be wasted at these interfaces and often duplicative capabilities and processes will emerge.

SEVERAL OTHER ASPECTS WILL CONTINUE TO BECOME INCREASINGLY IMPORTANT

In addition to the fundamentals mentioned above, there are three broad areas that are increasingly important in Medical Affairs organizations that are best managed by the Medical Operations group:

- Driving and coordinating better Medical Affairs planning, as Medical Affairs continues to take a more prominent role in the development and commercialization of medicines
- Understanding and effectively implementing innovation across the Medical Affairs organization
- Building and managing partnerships to leverage external capabilities and resources.

Driving and coordinating better Medical Affairs plans

Medical Affairs planning is not a new concept, but it has never been harder to do effectively. Medical Affairs teams are playing an increasingly prominent role in the generation and communication of evidence, particularly in specialist therapy areas where external stakeholders have complex and globally inconsistent evidence needs throughout the product life cycle. In addition, external scientific engagement has increased in complexity, with a large menu of potential channels available to connect with HCPs and external experts and gain insights from them.

Ultimately, many companies envision integrating these opportunities to take a more personal approach based on stakeholder needs and preferences. The importance of Medical Affairs planning in the optimization of budget and resource use – in addition to associated high-quality execution and performance management – has inevitably increased accordingly. Local insights are a crucial component; the planning process must channel insight and understanding from local healthcare stakeholders into the company consistently to inform strategy.

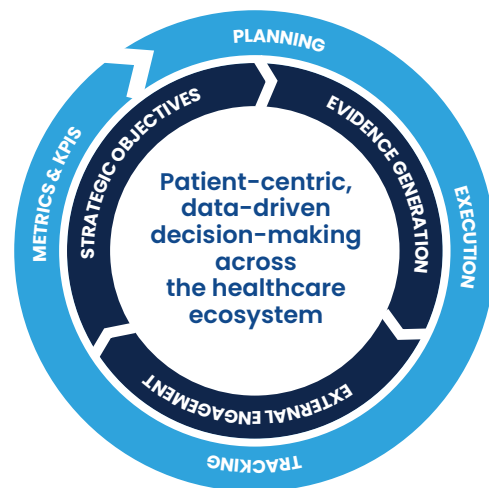


Figure 3: Better medical planning leads to better patient outcomes

In many organizations, the Medical Affairs planning process and its outputs could be considerably improved. For example, there is often a lack clarity on whom the plans are for and how they will be used, which can result in a weak strategic narrative throughout the plan. This narrative is the key link between the scientific context and cross-functional asset objectives (or ‘imperatives’), and hence lays a foundation for indication- and asset-specific medical objectives and tactics that are clearly aligned to achieving the desired outcomes. Other common issues include a lack of consistency in how plans are developed, and an inability to easily track execution against plan in a proactive way. These issues can be particularly frustrating for senior leaders and budget holders who hold responsibilities for the function or franchise, and therefore must review the work of multiple teams, including their respective plans.

Overall, Medical Affairs plans for an asset or product must drive the thinking and alignment within the team, enable clear communication and review with senior leaders and budget holders, and enable effective execution, tracking and performance management. Medical Operations must take a strong role in establishing and enabling an efficient and robust planning process that is of value to the teams themselves, Region-based and TA stakeholders, reviewers and other internal decision-makers. High-quality Medical Affairs plans that clearly describe what will be done and why, and that can easily be reported against, will not only enable efficiencies and visibility within Medical Affairs, but will also enable better interactions within cross-functional and cross-regional teams, and ultimately enhance the credibility of Medical Affairs across an organization.

Understanding and effectively implementing innovation

Innovation in Medical Operations is nowadays primarily associated with the adoption and use of digital technologies. However, 'digital' is a very broad term and, while many subcategorizations are possible, digital opportunities can be usefully categorized according to their potential to enable or improve:

- Process efficiency and automation
- Effective communications (including virtual meetings – both external and internal)
- Gathering, processing and understanding of data and information through machine learning and advanced analytics.

A systematic approach is required in the early stages of innovation adoption where business priorities and opportunities are defined, and innovative technologies are evaluated against business needs according to expected feasibility (including costs) and impact. After a successful proof of concept or pilot, any opportunities for further process optimization, better resource allocation, or improved sourcing strategies should also be identified and systematized. This will ensure that best practices are shared and scaled across the Medical Affairs organization as solutions are implemented.

At the outset of any transformation, Medical Operations leaders must also work closely to understand interdependencies with other functional initiatives. For example, Commercial functions have often been ahead of Medical in adopting digital multichannel and omnichannel external engagement. However, to create the integrated and seamless interface for the external customer that an omnichannel approach demands, a company must personalize its offerings on the basis of customer insight, not functional orientation. A cross-functionally integrated approach is therefore ideal, where possible.

The role of Medical Operations is therefore to not only coordinate and manage the identification, understanding, piloting and wider implementation of innovative technologies, but to also navigate the broader organizational context. Any improvement in the digital capabilities described above will likely impact other aspects of the organization, such as the scientific content development and approval process. As another example, process automation may also enable broader process improvement and will often present opportunities to reconsider outsourcing strategies and resource allocation.

Implementation of enhanced digital engagement capabilities in Medical Affairs

In most cases, 'digital channel' initiatives are built on a vision to provide customers with the information they need, when they need it, and through the channels that they find most convenient. A recent survey showed that two thirds of pharmaceutical company executives believe their companies have ambitious digital plans, but less than half are satisfied with progress. A large majority (80%) also felt that the Covid-19 pandemic had accelerated the need for digital transformation in Medical Affairs¹.

Medical Operations has a crucial role to play across the whole digital transformation life cycle (Figure 4 below), from assurance of the robustness of the insights process that enables a true understanding of customer needs, through vendor/partner engagement, to benefits realization through appropriate metrics and KPIs.

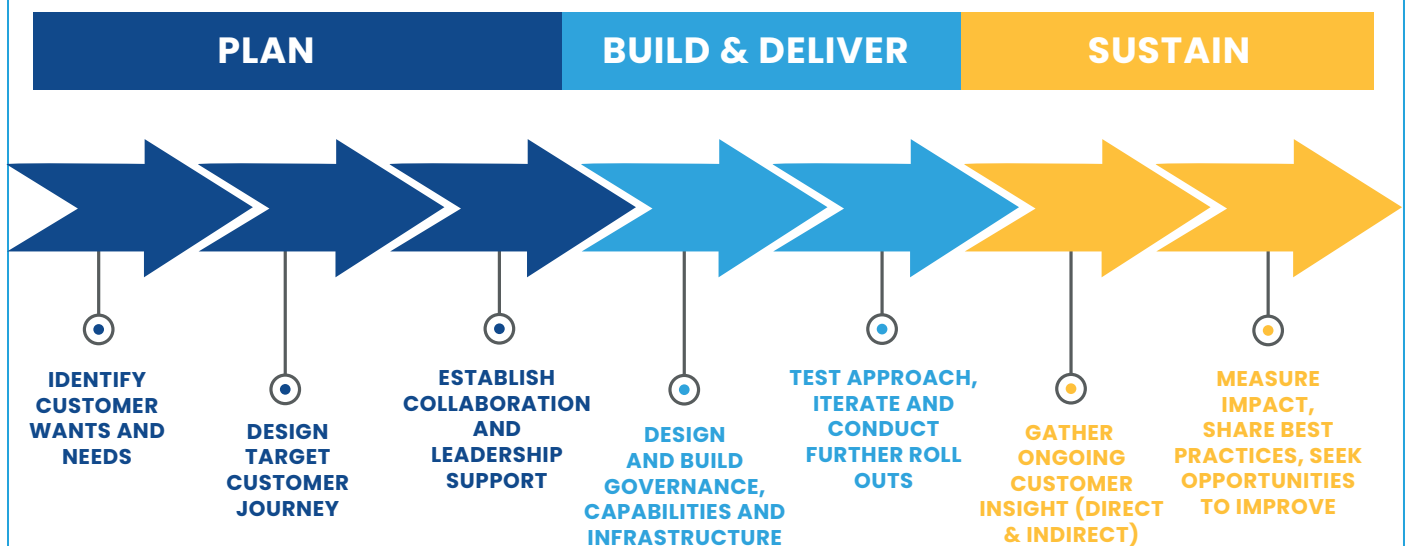


Figure 4: High-level process flow for implementation of new capabilities

The following principles apply to most business transformations; the latter two are especially salient when working on digital engagement change initiatives:

- It is crucial to truly understand customer wants and needs – this requires effective insight-gathering through multiple sources and channels
- A well thought-through strategy is essential, even when experimenting; excessive haste will not yield benefits in the long term
- Senior level sponsorship and buy-in is crucial to ensure resources and space (time and scope to iterate) are made available for innovation
- Pilots and planning must allow for the possibility of failure – provided lessons are learned and adaptations can be made, this can be positive. This can be a hard principle to apply in pharmaceutical companies, where failure outside of negative clinical study results is traditionally not expected
- The challenges are not usually unique to one organization – consider partnering with industry colleagues as well as external vendors to share investments, risks and lessons learned.

¹ Medical Affairs Digital Strategy Council survey of 15 large and mid-sized organizations (2021)

Building and managing external partnerships

There is an ever-expanding array of potential external partners to Medical Affairs, providing both niche innovative capabilities and opportunities to potentially reduce costs. The most important considerations for internal vs. external sourcing decisions and partner selection are unchanged, factoring internal capabilities, perceived sources of strategic advantage, external provider capabilities and cost. However, with the proliferation of specialist providers there are additional risks and challenges in managing multiple partners who are executing different parts of the same process. For example, external scientific engagement typically involves niche providers for external expert identification and profiling, specialist providers using tools such as Natural Language Processing (NLP) for insight generation, and Medical Communications providers managing specific engagement activities such as online advisory boards. This situation requires careful coordination to control costs and gain efficiencies, but also to ensure that the expected benefits of each capability are realized. In addition, as technologies continue to mature, internal groups tend to experiment with new providers, and this can lead to multiple fragmented pilots that don't gain traction or deliver the anticipated benefits – potentially without the knowledge of other parts of the organization. The Medical Operations group must proactively take the lead in scanning the environment, providing guidance on what external capabilities are being explored for selected processes, documenting and sharing learnings, and ultimately converging on a shortlist of strategic partners from what is still a very fragmented landscape of options.

Once partners are identified and engaged, a new set of operational challenges emerge. Technology-related partnership dynamics tend to be quite different to traditional partner engagements such as engagement of a Contract Research Organization (CRO) for a study. Experience of managing this type of partnership is useful, such as in subscription-based contracting for SaaS (software as a service) tools and collaborations to leverage external data sets. In addition, where technology offerings are nascent and/or highly tailored to an organization, it is important to understand their limitations and to be clear on how the partnership will manage and resource the inevitable challenges as new software is developed, users are trained, and functionality is extended to more users and additional capabilities.



Lastly, given the broad applicability of many digital capabilities across sub-functions and geographical locations, companies should generally strive to engage a small number of strategic global providers rather than permit Regions and TAs to work with their own providers. This is yet another area where Medical Operations can add value, by not only finding opportunities for economies of scale, but by also ensuring that external capabilities are globally integrated into end-to-end processes such as the Medical Affairs planning process mentioned previously.

DEFINING THE MEDICAL OPERATIONS GROUP OF THE FUTURE

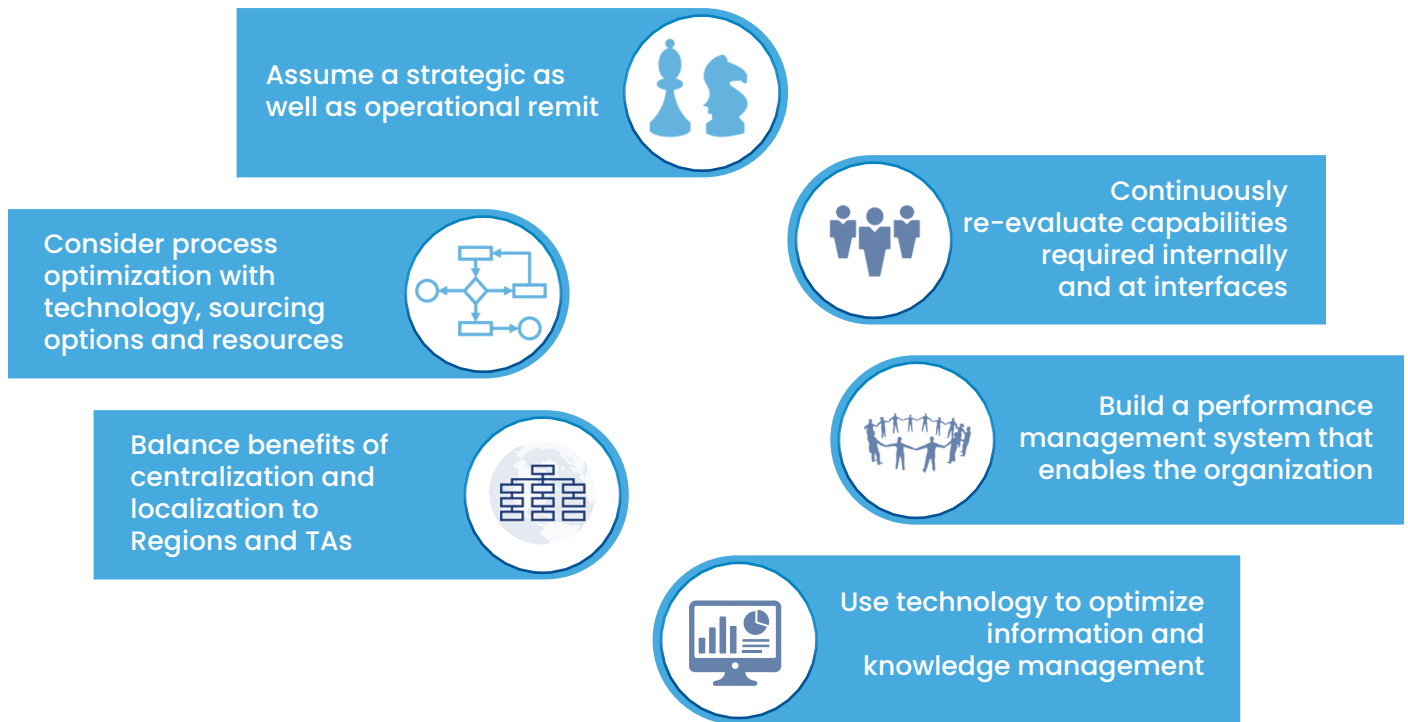


Figure 5: Future considerations for a Medical Operations group

There are several strategic considerations regarding what will constitute a fit-for-future Medical Operations capability:

- The **remit** of a Medical Operations or Medical Excellence group should be strategic as well as operational – many Medical Affairs organizations have been slow in defining and acting on important industry themes such as outsourcing, offshoring, patient centricity and digitalization. One could argue that this could have been avoided if a group such as Medical Operations had the clear remit, resources and capabilities to identify, assimilate, coordinate and plan how to maximize opportunities in these areas in ways that are most impactful for the organization
- Embedding best practice and **process improvement** must be considered in conjunction with technology enablement, sourcing options and reallocation of resources
- **Capabilities** will need to evolve. A mix of individuals with strong competencies in execution as well as relationship building will continue to be required. While expertise in technological innovation is increasingly accepted as a requirement in these groups, the internal capabilities to design and drive holistic organizational transformation programs also need to be strengthened. This will enable the Medical Affairs organization to evolve in a way that focuses on quickly making an impact on internal and external stakeholders without the fragmentation and organizational disruption that can be caused by the implementation of multiple loosely interdependent initiatives

- **Organizational structures** will continue to balance the benefits of centralization and localization, but a trend towards stronger central groups seems inevitable. Within that construct there may be new groups that are dedicated to areas such as digital, insights, real world evidence (RWE) and advanced analytics, but a key principle will be to maintain an organizational structure that optimizes relationships with external partners as well as internal partners
- In increasingly complex matrix organizations within Medical Affairs and across the company, robust **information and knowledge management** will be key to effective integration. This capability must be prioritized and supported by the necessary technology platforms, processes and people
- Establishment and maintenance of robust **performance management** which applies across the organization must be a focus, rather than prioritization of KPIs that are solely reported to upper management. This will require careful design of balanced measures, metrics and KPIs which ensure that all core Medical Affairs capabilities are managed as effectively and efficiently as possible. Oversight of budgets, resources and processes should be covered. The performance management framework should also drive high quality and productive execution of plans, and assess delivered impact in line with asset and indication strategy.



CONCLUSION

The overall remit of Medical Operations has not changed significantly in recent years, but the areas of strategic focus have shifted. The importance of enabling the work of TAs, Regions and local teams remains. However, the proliferation of digital opportunities, the need to optimize productivity and efficiency, and shifting Medical Affairs capability requirements mean that Medical Operations groups must routinely and proactively consider their operating model to ensure that they can optimally support a fit-for-future Medical Affairs function.

To be successful, many Medical Operations groups will require new capabilities as well as additional budget and resources. Fortunately, the business case for investment has never been more compelling.

Synetic Life Sciences is a consulting firm focused on the life sciences industry. We bring a combination of deep health & life sciences expertise with the capabilities, discipline and resources of a leading management consulting firm. Our consulting teams have worked extensively in Medical Affairs and continue to focus on emerging trends, needs and best practices across the industry.

CONTACT

Matthew McLoughlin, CEO

Mary Alice Dwyer, VP North America

Neil Croft, Director

Auntora Sengupta, Manager

✉ admin@syneticlifesciences.com

FURTHER READING

- Performance Management in Medical Affairs (2011), McLoughlin²
- Medical Affairs 2025, The Future of Medical Affairs (2018), Croft and McLoughlin
- Building Medical Insights Capabilities in Medical Affairs Organizations (2022), McLoughlin, Jonkman and Zivkov
- Aspiration vs Actuality: Assessing the progress of digital excellence in Medical Affairs (2021), Medical Affairs Digital Strategy Council

² A Synetic white paper with an updated view on this topic will be published later in 2022

Synetic

Life Sciences



SCAN FOR MORE
INFORMATION



✉ admin@syneticlifesciences.com

🌐 www.syneticlifesciences.com