



a SYNEOS HEALTH company

Medical Affairs 2025

The Future of Medical Affairs

August 2018



Executive Summary

Medical Affairs stands to be one of the most strategically important and valued functions in a pharmaceutical company, as the nexus of cutting-edge medical, scientific and patient-centred insights that drive strategy and innovation throughout the entire product life cycle.

However, the ability to execute the basic tasks well remains a prerequisite for internal trust and credibility of the Medical Affairs function. Success in this respect requires excellent organisational discipline and structure, and continues to be a challenge in many companies.

This paper addresses both cutting-edge and vital basic levels of maturity for Medical Affairs, outlining platforms for both:

1. A 'fit for future' Medical Affairs organisation, that addresses emerging needs to drive:
 - Patient centred insight generation and communication throughout the product lifecycle;
 - Healthcare product and service advancements; and
 - Technological innovations, and
2. A solid foundational Medical Affairs organisation that gets the basics right, before emerging needs can be tackled. This is the core level of capability, and may be the appropriate target state for small and resource-constrained businesses.

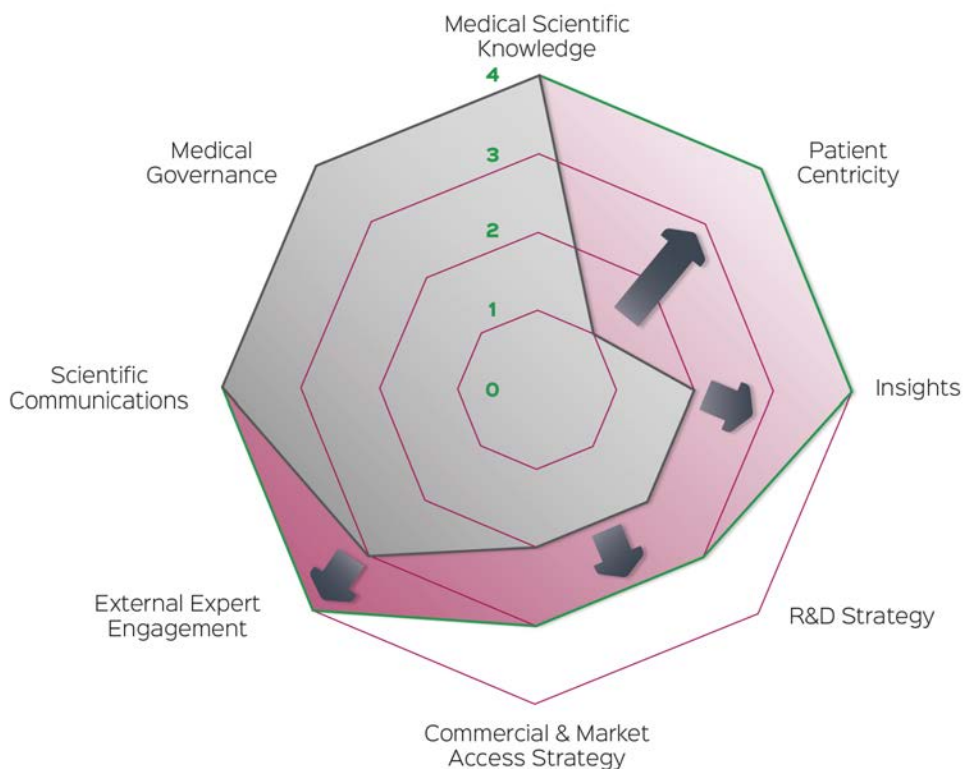
Emerging opportunities for a 'fit for future' group cover a spectrum of high-value disciplines where Medical Affairs should hold a strategic leadership role; these are summarised in [Figure 1](#). Factors that will be critical to successful execution of this role include:

- Sourcing, analysis, internal sharing and strategic use of patient and healthcare system insights, including those enabled by new technologies;
- Leveraging actionable insights to drive product and service definition and differentiation throughout the drug life cycle, in close partnership with R&D and Commercial functions;
- Blending teams of traditional medical-scientific backgrounds with emerging skillsets in person-centric healthcare, use of technology, strategic partnering and collaboration to drive patient-centric innovation and value.

Foundational elements for a credible Medical Affairs capability vary depending on the remit of the group, but will include many of the following:

- Active and value-adding scientific contributions to cross-functional teams and forums;
- Performance management that enables management decision making, by assessing both delivery execution and the value created by Medical Affairs;
- Excellent scientific communication and exchange of expert information on company products and services;
- Generation of high quality evidence, on time, to budget; and
- A robust Medical Governance framework and organisational support to medical and marketing compliance.

Figure. 1 Radar plot showing future development in the strategic role of Medical Affairs. Evolution of these disciplines is further outlined in Figure 6.



KEY

- 0** = Unaware;
- 1** = Aware, understands;
- 2** = Aware, provides input or involved on an ad hoc basis;
- 3** = Involved and supports strategy;
- 4** = Regarded as leading capability in company, accountable for driving strategy for this element.

□ Future □ Present

1. Introduction: The dynamic healthcare environment presents challenges and great opportunities for Medical Affairs

The potential for Medical Affairs functions to contribute to the success of a pharmaceutical company has increased significantly over the last 10 years. This is in part due to external drivers related to compliance and Medical Governance, but also due to an increasingly competitive and cost-constrained environment, focused on value. There is a widely acknowledged opportunity and need for pharmaceutical companies to further differentiate their services through a true understanding of the patient and their healthcare networks, and what these stakeholders want and need.

The opportunity for Medical Affairs continues to evolve. This will be not only through better execution of the current remit, but market challenges which now require genuinely innovative approaches and solutions. The pharmaceutical industry faces a prolonged period of suppressed growth in a highly competitive sector¹, in addition to the threat of major policy changes to drive spending down in its largest market, the USA². The ability to define and develop new sources of value is therefore critical. Medical Affairs is well-placed to drive these value creation strategies such as identification of 'value beyond the pill', generation of innovation through partnerships and pharma becoming a patient-centred information broker. The increasing direct patient use of health monitoring services also raises the threat of new entrants to the market such as health and information technology companies.

Figure. 2 Key internal and external drivers of change for Medical Affairs organisations.



1. EvaluatePharma World Preview 2017, Outlook to 2022 www.evaluate.com/PharmaWorldPreview2017

2. State of the Union 2018 address <https://edition.cnn.com/2018/01/30/politics/2018-state-of-the-union-transcript/index.html>

2. Cutting-edge Medical Affairs groups will be strategic leaders on healthcare insights and evidence strategy

Change creates the opportunity for innovation

To use an oft-quoted phrase: “All things move and nothing stands still”³. There are a number of drivers of change that even cutting-edge Medical Affairs organisations must adapt to now and in the coming years. Some of the most important are outlined in Figure 2. Although change often creates challenges, there will also be important opportunities for Medical Affairs to take on an enhanced strategic role, shaping how it supports the company in future to bring the right medicines and services to the right patients at the right time.

Of all these changes, the shifting role of patients, and the associated HCP (healthcare professional) and payer evidence needs, are arguably the most significant. The increasingly wide and deep sources of evidence available on these needs are also game-changing. These are the areas of greatest opportunity for Medical Affairs.

2a. Validated evidence is the key: Sourcing, management and use of multi-channel data and insight

We live in the ‘Information Age’; information sources and data are everywhere. According to IBM in 2017, 90% of all data in the world had been created in the past two years alone⁴. The amount of data being created by and about patients is similarly rapidly increasing, through technologies that include mobile apps, connected devices and internet activity by patients. Opportunities also exist to collect more informative and patient-relevant data in clinical and observational research.

However, there is no value in data without context and validation, and therefore credibility. Medical Affairs’ effectiveness in acting as custodian of trusted, validated evidence on a company’s products - as well as the external communicator on this science - will be critical to the success of any pharmaceutical company. The topic of evidence and insight management is covered in detail in our white paper ‘Capitalising on Patient Insights’⁵. In summary, the key elements are:

- **Sourcing:** As companies seek to be the integrators of information about their products and services, insights and digital channels are increasingly vital. It is vital to ensure that disparate sources of data, from advisory boards and clinical trials to electronic health records and online forums are captured in a compliant fashion.
- **Curation and analysis:** With the vast array of data sources available, manual analysis is increasingly impractical except in specific individual circumstances such as an advisory board. Regardless of data source, all collected data should ultimately be collated and integrated as part of a holistic knowledge

3. Heraclitus, according to Plato; Cratylus, section 402a

4. IBM, 10 Key Marketing Trends for 2017 <https://public.dhe.ibm.com/common/ssi/ecm/wr/en/wr112345usen/watson-customer-engagement-watson-marketing-wr-other-papers-and-reports-wr112345usen-20170719.pdf> (Accessed 3rd May 2018)

5. Kinapse white paper: <https://kinapse.com/insight/capitalising-on-patient-insights/>

management tool to enable analysis. Third party (and occasionally proprietary) technology can be used to consolidate and analyse disparate sources. The most valuable contribution from Medical Affairs here is the expert input to develop strategically meaningful and testable research hypotheses, and to interpret subsequent research outputs in a medically and scientifically robust way. In the process design phase it is important to define when these steps take place, if / when local input is sought, and when therapy area-specific scientific expertise is required.

- **Use:** Ultimately, better insights should enable better business and healthcare decision-making, with benefits to all stakeholders in the system. Medical Affairs must therefore ensure that these insights are available to all relevant parties. Internally, this means bringing these insights to critical teams and committees to ensure that plans and investment decisions throughout the product life-cycle are robust and evidence-based. It is equally important to ensure that current and validated insights are made available to external customers and stakeholders to optimise patient access and appropriate use of medicines and services.

It is worth noting the price of failure here. If pharmaceutical companies don't hold the most comprehensive insights on their products and associated outcomes and act on them, then another organisation will. New entrants from the technology industry are working increasingly heavily in the healthcare space, particularly in relation to patient insights and health outcomes. This could be disastrous for the pharmaceutical industry as companies risk being reduced to the status of commodity suppliers, distanced from value-based discussions with their key customers – the HCPs, payers, policy makers and patients.

To date, no other function is driving this agenda in a way that ensures that patient and health care insights inform the product life cycle from early development through commercialisation. However, if Medical Affairs executives do not seize and own this opportunity, other functions in the organisation will fill the gap, even though they may be less well equipped to do so. The management of data, information and insights in a company has become too important to allow to happen in siloes or in an ad hoc manner.

2b. Emerging capabilities in Medical Affairs: What worked until today will not work in the world of tomorrow...

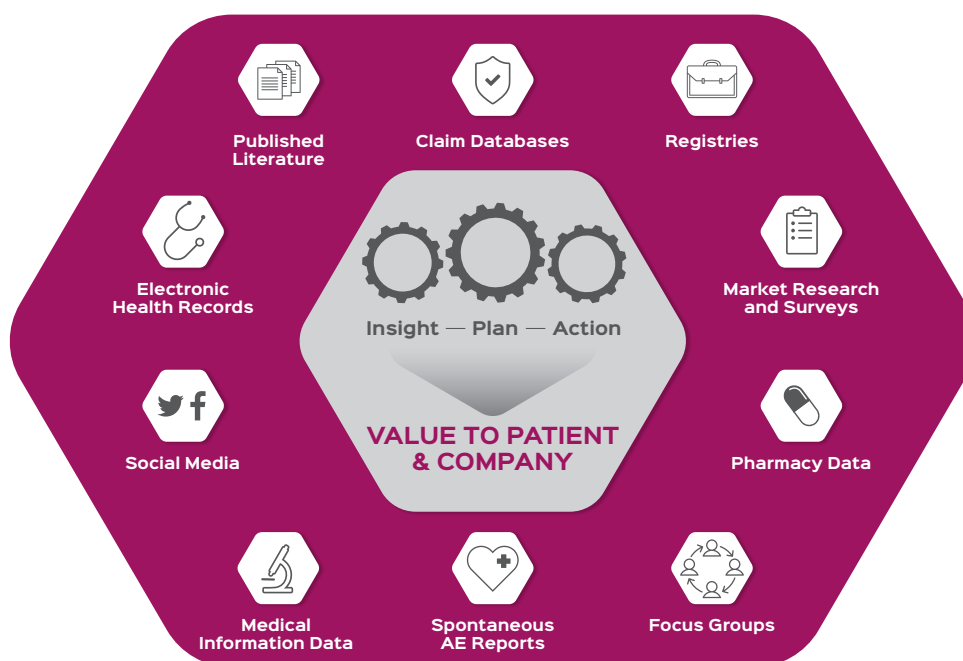
Traditional Medical Affairs capabilities will remain important, but top-performing organisations must add new skills to the mix to gain or maintain a competitive advantage. Some of the most important new skills are outlined below.

2b. i. Understanding and leveraging opportunities with insights, communications technology and automation

Exciting innovations are available in the capture, analysis and synthesis of 'big data'. These tools are not yet used across industry in a systematic way, and text and data analytics are not core competencies of a pharmaceutical company. A few organisations will attempt to make gains by building in-house big data analytics capabilities or investing in digital healthcare providers⁶. However, companies will typically look to external partners for analytics support; providers with a proven record of delivering analysis and insights in the context of pharmaceuticals and healthcare will be of more value in this regard, in contrast to those that focus on 'big data' more broadly.

It is important to recognise that the technology is only an enabler. No matter how smart or innovative the technology, no business problem is solved if the outputs are not interpreted and incorporated into core processes by a capable Medical Affairs team, with business- and patient-centred objectives and outcomes in mind. Future Medical Affairs teams must therefore be knowledgeable and experienced in realising the possibilities enabled by insights and advanced analytics.

Figure. 3 Example sources of data for Medical Affairs insights



6. For example: <http://www.sanofiventures.com/portfolio/portfolio.php>

Although insights management is the hottest topic, technology can enhance Medical Affairs' offering in other ways. For example, although HCPs are distrustful of public social media such as Facebook and Twitter as information sources, they value peer dialogue and specialist forums very highly. Pharmaceutical companies can add value by forming partnerships with digital technology specialists to support communities of interest where gaps exist. A successful example is MSD France's Comuniti platform, which became the country's largest online physician network with 65,000 users registered in 6 months⁷. Through conference attendance, informal discussions and growth in their patient advisory panels, payers, HTA bodies and regulators increasingly indicate they are looking at ways to broaden peer dialogue, particularly on how to better incorporate the voice of the patient in their decision-making; these groups may also benefit from a similar approaches.

Technology is already supporting many organisations to do the same things as before but better; for example virtual advisory boards using state-of-the-art video teleconference suites save time and expense by enabling discussions that feel increasingly like in-person interactions. Virtual meeting technology will increasingly be used in investigator meetings and MSL interactions, enabling more work to be done remotely, so that more institutions can be reached – even those in remote locations – in a cost and resource-effective way. From a day to day operational perspective, technology is being used to improve efficiency and speed, and further opportunities should be sought for automation – in areas such as real-time KPI collection, planning process automation, on-demand Medical Information provision, and promotional material review, for example.

2b ii. Driving patient and customer centricity

From a standing start at the beginning of this decade, it is now almost impossible to find a top executive at an established pharmaceutical company that does not cite 'patient centricity' as a key strategic driving force and critical success factor for their company. As the non-promotional face of the organisation and with country-based staff, many companies have recognised Medical Affairs as the ideal function to spearhead these efforts. This may be in partnership with a Patient Affairs group, as these functions typically provide process support and guidance but do not have the resources to drive on-the-ground efforts.

For Medical Affairs' patient-centric role to be a success, it is vital that teams are imbued with the right capabilities; some of these capabilities are supplementary to those of a traditional Medical Affairs group. Insights management will be an important aspect, as described above. For more direct engagement, knowhow and process support are required to ensure the right patient input is gained at the right time and in the right way; team training is therefore required, and potentially the acquisition of staff with specialist skillsets in patient and customer engagement.

7. social.eyeforpharma.com/content/social-network-physicians-msd-frances-comuniti-win-most-valuable-hcp-or-healthcare

2b iii. External speaking and engagement leadership

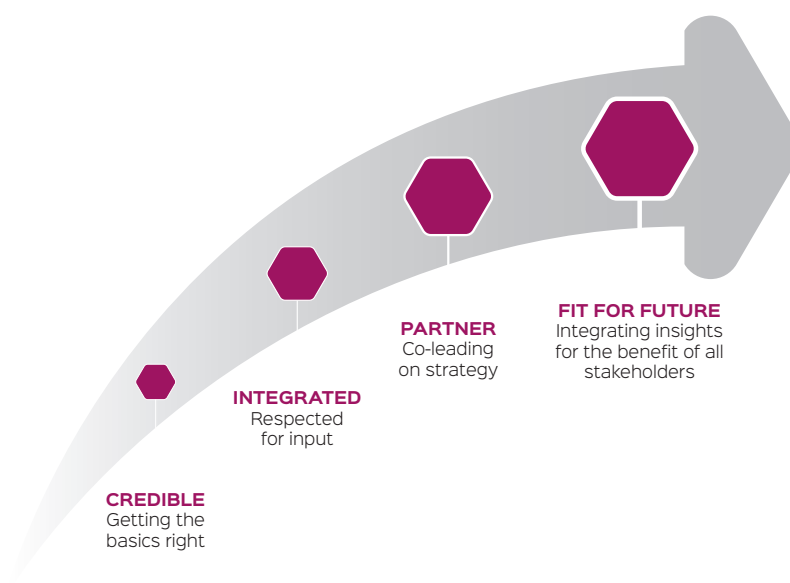
Scientific engagement is a basic function of any Medical Affairs group, and as such is discussed in the section below on core requirements. However, there are also emerging trends in this area. Continuing scrutiny of potential conflicts of interest in industry-physician links and a desire for more trust and transparency will mean that GSK will not be alone in limiting or discontinuing payments to doctors for speaking on their behalf⁸. The result will be an increasing need for pharmaceutical company staff (and Medical Affairs staff specifically) to represent the company's own products and science. In this sense, Medical Affairs will be required to fulfil a role traditionally performed by charismatic external 'opinion leaders'. Given the time and support to take on this role, talented Medical Affairs executives should see this as an exciting opportunity to enhance their skills and status. However, monitoring will be required on the perceived quality and impact of the communications with external audiences, and to ensure there is no pressure for this role to become promotional.

3. What stands in the way? Organisations must first meet the core requirements of Medical Affairs, to be valued and viewed as partners.

Experience suggests that even established Medical Affairs departments do not perform all the basic requirements as brilliantly as they might wish. The industry is also constantly evolving as generics companies move into innovative therapeutics, small start-ups mature into fully-fledged pharmaceutical companies, and some firms face their first launch for many years. This section recognises that many organisations may not have a core Medical Affairs capability in place, but will need one.

The section below outlines some of the core requirements to establishing a credible and valued Medical Affairs capability, prior to developing 'fit-for-future' capabilities.

Figure. 4 Conceptual evolution of core Medical Affairs capabilities



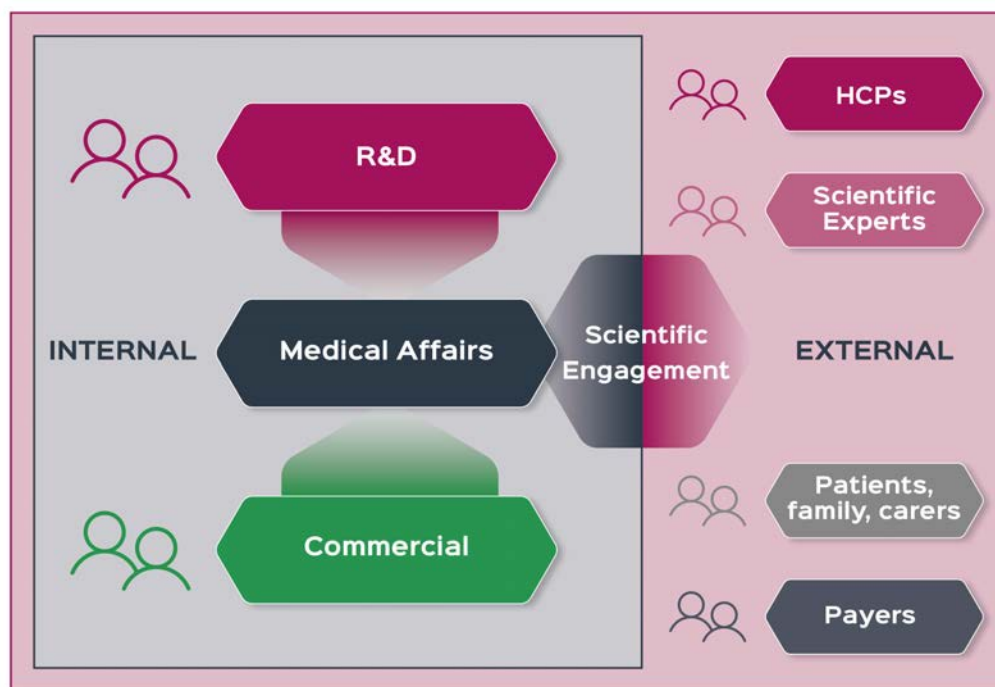
8. BMS China has already done so, for example:

<https://www.fiercepharma.com/pharma/bristol-myers-scraps-doc-payments-china-after-last-fall-s-fcpa-settlement>

3a. Effective internal and external partnering is critical

Medical Affairs manages two critical interface points for pharmaceutical companies as shown in Figure 5. One is the link between the evidence and resources that the company holds and the various external customers; importantly but not exclusively HCPs, scientific experts, patients and increasingly payers. The second is the internal bridge between R&D and Commercial - both the functions and the respective pre- and post-authorisation phases that each function is broadly accountable for. Medical Affairs is therefore the best-placed function to co-ordinate transparent evidence-based and two-way dialogue across all external stakeholders, and to translate external insights into internal strategies and tactics. This does not mean that other functions will have no role in managing engagements relevant to their work, but Medical Affairs are best placed to take the integrative role across the business for non-promotional science-based discussions.

Figure 5 Medical Affairs is the critical non-promotional scientific bridge between the pharmaceutical company and its external customers, and for insights and evidence generation strategy between functions within the company. All of these interactions should be considered two-way.



3b. Non-promotional exchange of information with scientific experts

External scientific experts and HCPs are increasingly disinterested in receiving only product-focused and promotional information. However, they are interested in balanced scientific information and knowledge that is shared directly by peers and experts^{9,10}. Research shows that HCPs want a peer dialogue, and to receive information in convenient ways that they choose^{9,10}. Medical Affairs executive presence at key medical conferences is a critical avenue for this engagement.

9. Kinapse HCP interviews

10. 'Pharmaceutical industry: HCP engagement', EPG Health Media (2015)

Field-based Medical Scientific Liaisons (MSLs) also have a critical role to play here; MSLs have been shown to have more valued and more deep discussions with HCPs than sales representatives^{11,12}.

Pharmaceutical companies can also act as co-ordinators and enablers of independent information provision and professional communities of interest to discuss the disease area and science. Although company staff cannot and should not influence the discussion to their own ends, being the co-ordinator allows companies to participate and gain first-hand insights from the resulting dialogue.

A NOTE ON MEDICAL EDUCATION

There will be continuing scrutiny on the rationale for industry sponsorship of Medical Education. Support of Medical Education is of limited benefit to pharmaceutical companies, beyond supporting a mission to ensure appropriate use of medicines and potentially associated reputational benefits, and industry funding is associated with conflicts of interest, particularly when the company influences content and participation decisions^{13,14}. Pharmaceutical company-sponsored Medical Education therefore carries reputational risk for companies, and leads to scepticism over the quality and impartiality of HCP training. Unfortunately, at present a large amount of physician training is still reliant on support from the pharmaceutical industry¹⁴. We expect that industry will ultimately limit funding of Medical Education to cases where physician training would otherwise suffer excessively due to a lack of alternative funding sources. In these cases it will likely be administered at arm's length by third parties, even where there is no legal requirement to do so.

3c. Performance management that demonstrates the value of Medical Affairs to the organisation, and enables informed decision making

In the past, executives would often state that 'the value of Medical Affairs can't be measured'. This has long been shown to be false, although attempting to assign a value to the function in terms of dollars is unlikely to be a useful exercise. With appropriate tools and approaches, performance in all Medical Affairs disciplines can be measured. This must be done in a smart way, recognising that the most important things to measure are not always those that are most easily quantified. The best-performing companies in this area have robust sets of metrics that assess both execution ('have we done what we have said we would do?') and impact ('have we met our objectives and made a meaningful difference?') based on quantitative and qualitative criteria as appropriate.

This topic is discussed in detail in the white paper 'Performance Management in Medical Affairs'¹⁵.

11. Moss and Black (2013), Therapeutic Innovation & Regulatory Science 47(2):203-208

12. MSL Society survey, quoted in <http://www.pharmavoices.com/article/2016-05-msl/>

13. Lo B. et al. (2009) 'Conflict or Interest in Medical Research, Education, and Practice'

14. Fugh-Berman A, Hogenmiller A. (2016) J Med Ethics. 42(3):172-3

15. 'Performance Management in Medical Affairs', Kinapse. Available on request.

3d. Evidence generation: Late stage studies and Investigator-Initiated Studies

Many – but by no means all – Medical Affairs organisations are accountable for study conduct in Phase IIIb/IV. Where Medical Affairs is responsible for studies and not purely supporting strategy development, it is critical to have processes in place to ensure robust planning, approval and conduct oversight of all studies within the organisation's remit. Input and insight from countries and partner functions, and alignment of activities across countries where appropriate, are critical success factors.

Investigator-initiated study approval and funding is another area where Medical Affairs organisations typically take accountability. This is to ensure study funding decisions are based on scientific merit and not commercial considerations. Studies should align with company areas of focus but must not duplicate or replace company-sponsored research. Once again, robust and traceable processes must be in place that define the governance model. These processes should further stipulate that study progress reports are provided, and that payments are only made when contractual milestones have been met. Similar measures are required for other external scientific research grants and awards.

3e. Medical Governance

In addition to the roles listed above, Medical Affairs has a critical risk assurance role, notably in:

- Support to in-country compliance through local Medical Directors
- Provision of medical and scientific training, e.g. to Commercial staff
- Review of promotional and scientific materials.

Robust processes and frameworks are required for all these activities to ensure consistency and quality across the organisation.

We expect that highly efficient organisations will deploy dedicated groups for work that is important but less strategic, such as promotional material review. This will reduce time spent by more highly strategic and costly senior physician roles. Use of trusted expert outsourcing providers for more transactional Medical Affairs activities can also enable greater internal staff focus on high-value activities, and may reduce costs.

Regardless of the approach used, governance and compliance efforts must adapt to manage the volume and risks of increased use of digital communication channels in addition to traditional print media.

4. Reaching the target state for your Medical Affairs organisation

In summary, successful leaders must articulate, demonstrate and communicate Medical Affairs' value to peers, while driving accountability, effective partnering, and operational excellence at all levels in their organisations. Key characteristics of 'core' and 'fit for future' organisations are summarised in [Figure 6](#).

True Medical Affairs leadership will lie in acting as the nexus of insights and information on patient and health care practice needs, as well as the most informed global scientific experts to drive product and service development. This will be a core role in ensuring pharmaceutical companies remain strategic players in healthcare for years to come, despite new entrants from the technology and broader healthcare sectors. Successful delivery will require a Medical Affairs mission and set of objectives that are clearly understood by all internal and external partners, fit for future capabilities, and robust performance management. With these elements in place, no senior pharmaceutical executive will ever again be uncertain of the role and value of Medical Affairs in their organisation.

Figure. 6 Evolving Medical Affairs capabilities

CATEGORY	FOUNDATIONAL	FIT FOR FUTURE
Medical Affairs vision and strategy	Clear and communicated vision and mission for Medical Affairs, including its critical role in supporting the broader organisation. Function-level objectives in place with regular progress reporting to senior company management.	As left. Perceived as strategic leaders on all scientific and product / service-related topics and engage with partner functions on this basis.
Medical / scientific knowledge	Strong knowledge of medical/scientific therapy areas.	Unparalleled knowledge of medical/scientific therapy area and healthcare business requirements e.g. access drivers.
Patient centricity	Awareness of company efforts in patient centricity - typically Commercial-led initiatives such as patient support programmes.	Drive key elements of patient engagement strategy to ensure patient perspectives are factored in company processes and decisions throughout the product life cycle.
Insights	Valued contributions to product team strategy based on qualitative or anecdotal observations gained from the field.	Lead on insights: Document, codify, analyse and integrate insights from a wide variety of sources and drive their integration into product strategy. Expertise in areas of patient centricity and use of analytics technology.
R&D strategy	Awareness of R&D; able to drive Phase IIIb/IV studies and oversee ISSs as appropriate.	Expertise in R&D strategy; ensure real-world insights drive Phase II/III R&D strategies, including Real World studies, in addition to Phase IIIb/IV study oversight.
Commercial and Market Access	Awareness of commercial needs; able to provide input to product strategy - including market access initiatives - based on medical / scientific knowledge and inputs from the field.	Commercially astute; co-lead on differentiation based on unique patient and healthcare insights. Key role in scientific partnerships and acquisition due diligence. Highly expert on evidence generation and engagement approaches to meet patient and market access objectives.
External engagement	Partner with external scientific experts on specific tactics as agreed with the product / brand team.	Lead on external expert engagement strategy; engage in and co-ordinate peer dialogue on a range of therapeutic area issues. Medical Affairs team may include former external experts / opinion leaders.
Scientific Communications	Lead on scientific communication strategy on company products based on company and competitor data, engaging external experts as appropriate.	Drive scientific communications; increasingly act as external voice on all relevant scientific evidence regardless of source, leveraging deep healthcare insights to enhance credibility.
Medical Governance	Strong awareness and anticipation of Medical Governance requirements. Own the governance system / framework, defining requirements and ensuring it is implemented in all aspects related to appropriate use of company medicines.	As left.

About Kinapse

Kinapse, a Syneos Health™ company, is recognised as a leading advisory and operational services provider to the global Life Sciences industry. Founded by professionals from the biopharmaceutical sector, the company provides its services across the full R&D and commercialisation life-cycle, collaborating with its clients to improve the lives of patients, through a unique Advise – Build – Operate delivery model.

19 of the global top 25 life sciences companies rely on the breadth of Kinapse's world class advisory and operational services to analyse, implement and perform a wide range of projects and programs across global markets, delivering quantifiable business benefits and operational success.

Headquartered in the UK, Kinapse has over 700 staff located in Europe, India and USA.

For more information, get in touch... hello@kinapse.com

Key Contacts



Neil Croft
**Senior Manager,
Medical Affairs Advisory
Services Lead**

neil.croft@kinapse.com
+44 (0) 208 946 7600



Matthew McLoughlin
**Head of Advisory
Services**

matthew.mcloughlin@kinapse.com
+44 (0) 208 946 7600

kinapse 

a SYNEOS HEALTH company



Follow us on twitter [@kinapseglobal](https://twitter.com/kinapseglobal)



Follow us on LinkedIn www.linkedin.com/company/kinapse