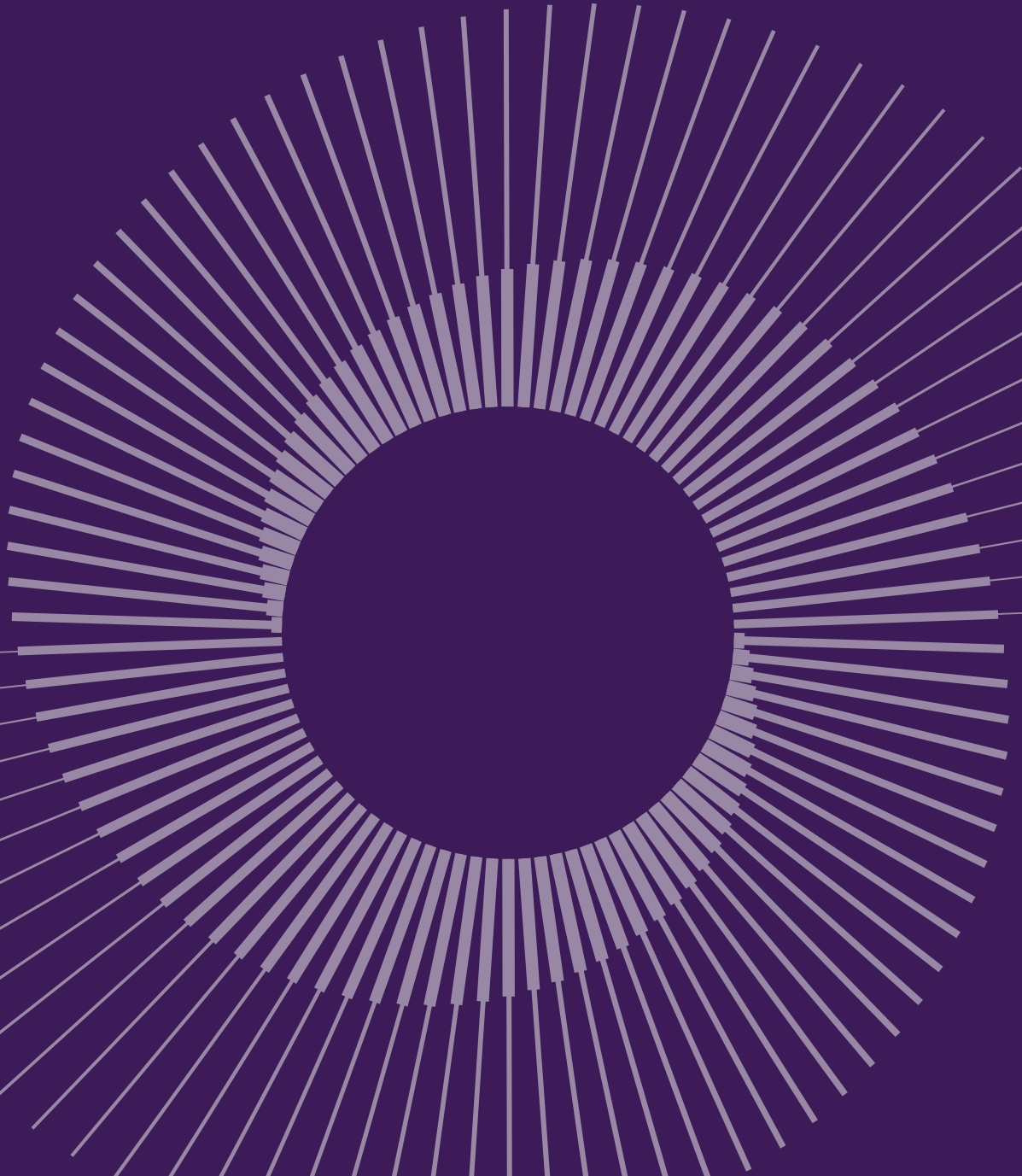


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# Time to Assess and Realign the Focus for Medical Affairs?



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# Introduction

Today's pharmaceutical industry is a complex, globalised and highly regulated ecosystem. This is characterised by increasingly sophisticated drug development approaches, a growing focus on highly specialised (including personalised) treatments, high levels of in-market competition, and a complex interplay of interests between healthcare market stakeholders.

Successfully demonstrating value to healthcare systems requires highly developed capabilities in collaboration, rapid assimilation of scientific and market changes and effective, responsive communication across the pharmaceutical value chain (R&D, logistics, market access, and commercial). Industry observers such as Medical Affairs Professional Society (MAPS) argue that Medical Affairs (MA) is a powerful force in helping pharma to achieve this.

The traditional view of what medical affairs should focus on has changed for many organisations from a 'support' role whose main effort is on providing 'advice' or 'guidance' to other internal departments, towards an externally oriented function bridging the needs of patients and HCPs with the capabilities and focus of the organisation they work for. This evolved focus has been widely discussed and has been further described by way of specific areas:

## Summary of Modern Medical Affairs Capabilities

1. Medical Leadership
2. Capturing and disseminating insight
3. Continuous evidence generation
4. Evidence dissemination
5. Governance and compliance

(MAPS, 2020)

**"The medical and scientific know-how and established external credibility of MA are extremely effective forces that can be leveraged to place patient outcomes front and centre.....It is the interface between internal R&D, commercial, clinical, and regulatory departments, and external entities such as HCPs, scientific experts, patients, caregivers, and payers/decision-makers i.e. a huge variety of stakeholders, each with their own needs."**

Communicating the value of Medical Affairs, A MAPS White Paper, May 28 2020

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## About this research

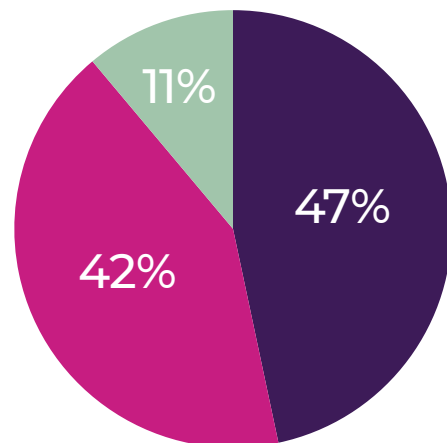
Although helpful definitions for medical affairs capabilities such as these from MAPS have been available and discussed for some time, we noticed that very little evidence exists about the level of emphasis organisations place on them. Additionally, little is published about the progress being made: Where are we now? How are we progressing? Which areas need the greatest additional effort/support?

Triducive implemented a piece of research to understand the views and opinions of those working within Medical Affairs about these very questions. Forty-five professionals working across Pharmaceutical Medical Affairs roles in Europe qualified for the screening and completed the questionnaire (UK n=26, Switzerland n=12, Germany n=5, Denmark n=2).

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### Organisation size

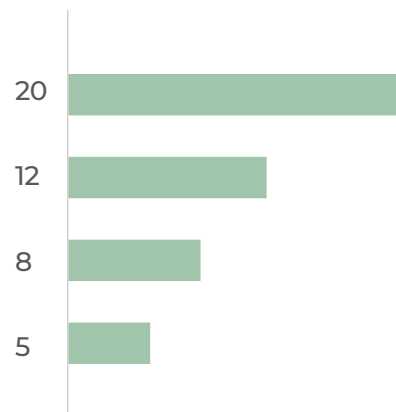
- Large (+10k global employees)
- Medium (1k-10k)
- Small (<1k)



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### Responder roles

- MA Lead, Global or Region
- MA Lead, In-Country
- Field-based MA (e.g MSL)
- MA Organisation Leader, In-Country



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## Executive summary

There are some notable highlights from the research supporting the level of focus and progress being made with the capabilities highlighted:

- ✓ Whilst more progress may be required, **Medical Leadership** is seen as a top 3 focus for organisations right now. Recognition that this is vital for the success of pharma organisations as a whole is an important step towards unlocking the potential of the role.
- ✓ The **ability to proactively seek and capture insights from a range of sources** has become a strong area of competence – highlighting strides made by medical affairs teams to leverage various activities and in embracing technologies to help consolidate them.
- ✓ Similarly, **using a range of channels to reach and engage KOLs** and scientific leaders for the purpose of evidence dissemination is a strength to be built upon. Future medical affairs teams may need to use this strength to expand and incorporate wider HCP audiences.
- ✓ The capability area with the overall highest proportion of positive responses is **governance and compliance**. While this is a critical area for pharma organisations to excel, it may be required to change the way this expertise is delivered in future, to enable medical affairs to ensure sufficient focus is applied to other areas of importance.



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# Detailed results

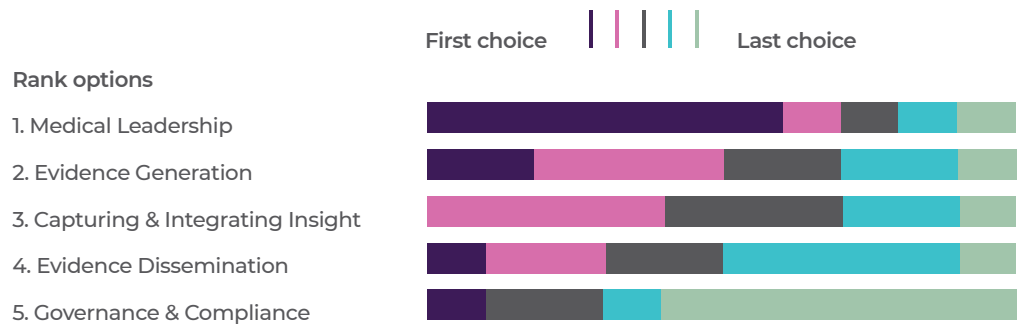
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## Overview

When asked to rank the **importance** of each of the 5 capability areas as a focus for medical affairs there was emphatic support for **Medical Leadership** as number 1 with 70% selecting this as either their first or second-ranked choice. **Evidence Generation** came a close second.

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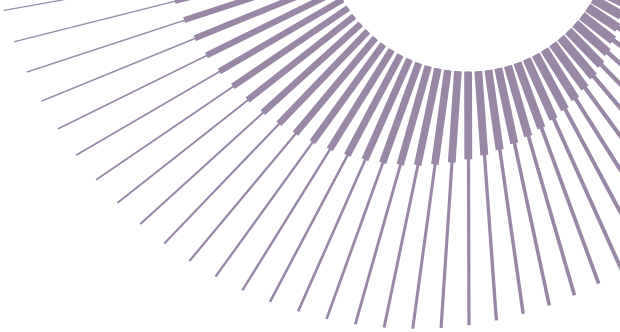
*Q: Please rank the following areas of Medical Affairs activity in the order of importance you believe they should have.*



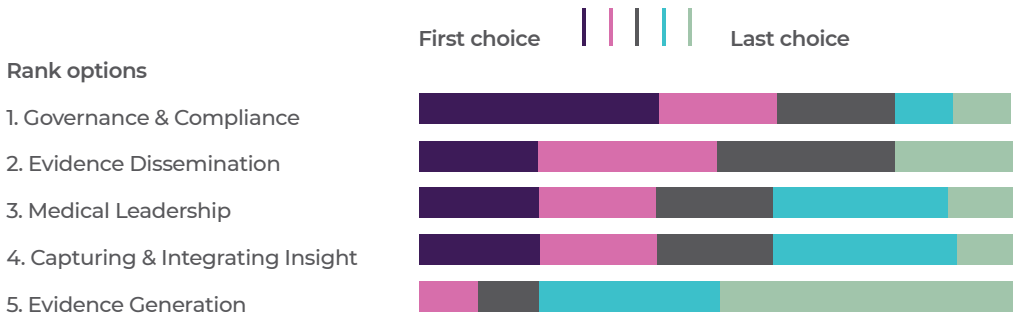
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When comparing these responses to the responder ranking of where the focus **is currently applied**, two key insights emerge:

1. There is a perceived (and perhaps unsurprising) over-emphasis placed on the role of medical affairs to support **Compliance and Governance**.
2. The importance placed on the top 2 areas (Medical Leadership and Evidence Generation) is not as well matched by the emphasis placed on them currently. Perhaps the starkest mismatch is with **Evidence Generation** - positioned firmly as the **lowest current emphasis area**.



Q: Please rank the following areas of Medical Affairs activity in the order of **emphasis you believe they are currently receiving**.



The demand for continuous evidence generation supporting product use throughout the lifecycle is likely to increase. The growth of novel research approaches will also continue and the requirement for more localised (e.g. country-specific) evidence remains. Urgently addressing this capability gap would seem vital to ensure that medical affairs teams can deliver what pharma organisations need.

## 1. Medical Leadership

**Medical Leadership - MA are critical in informing company-wide scientific and commercialisation strategies and co-creating brand strategies, demonstrating exemplary leadership skills to maximise influence over the organisational direction.**

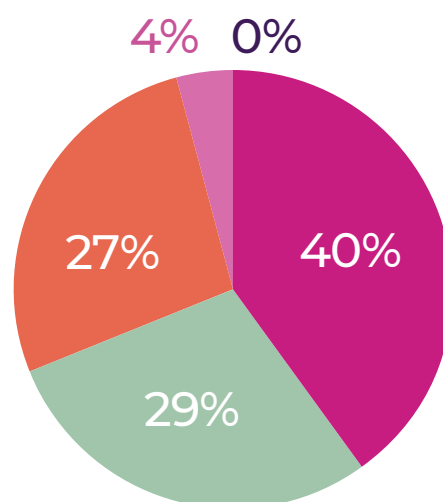
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The response received to the general question of medical affairs' current level of Medical Leadership capability was surprising. Not one response suggested that the level of medical leadership at their organisation was exceptional and 31% rating the capability as below what's needed or poor.

### Level of Medical Leadership

Q: The level of 'Medical Leadership', in general, demonstrated by the Medical Affairs organisation is:

- Exceptional
- Good
- Average
- Below what's needed
- Poor



Delving deeper into specific sub-topics here, responders suggest **room to improve across several areas:**

- Co-leading commercial/brand strategy (& ensuring medical priorities are integrated)
- Winning support & investment for evidence generation
- Championing the voice of the patient and ensuring the organisation acts on this
- Aligning internal stakeholders behind principles of governance to ensure high standards of external engagement

## Medical Leadership - Current Capability

Q: How would you rate the Medical Affairs organisation's capabilities in the following areas?

● Poor ● Below what's needed ● OK ● Good ● Exceptional

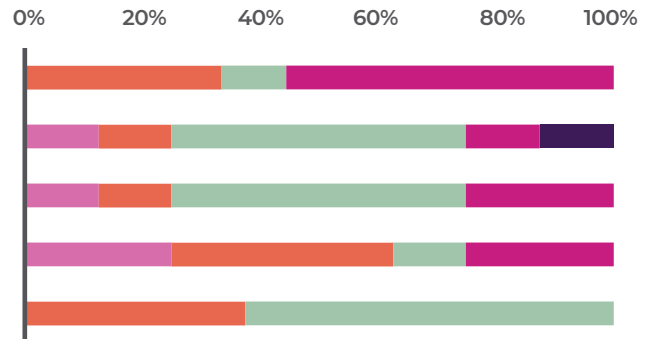
Identifying insight needs that support medical, access and commercialisation strategies

Co-leading commercial/brand strategy, ensuring medical priorities are clearly integrated

Winning support & investment for appropriate evidence generation across the portfolio/product lifecycle

Championing the 'voice of the patient' & leading collaboration across the internal organisation to respond effectively to it

Aligning internal stakeholders behind principles of governance that ensure high standards across all external engagements



It is noticeable that these activities arguably all depend (to a greater or lesser extent) on skills such as strategic/critical thinking and influencing others. These are skills that could be developed with appropriate training, purposeful coaching, and access to relevant experiences. Responders agreed with the need for a wider perspective on core training curricula for medical affairs.

Significantly, they also pointed to the need for greater representation of medics and scientists in senior organisational roles, beyond medical affairs and R&D departments to inspire and role model this broader leadership potential.

## 2. Evidence Generation

**Evidence Generation - Continuous evidence generation which provides information on the safety and efficacy of medicines, as well as addressing data gaps, is an essential component of MA. Medical Affairs lifecycle strategies and plans should start well before first regulatory approval (even before proof-of-concept). Post-approval, there should be an active RWE generation strategy in place that incorporates company-sponsored and investigator-sponsored studies, research collaborations, and Big Data. Evidence generation should be focused on value evidence that informs patients, providers, payers, the public, and policymakers, as well as the impact on patient outcomes. This element includes analysis of evidence generated outside the company.**

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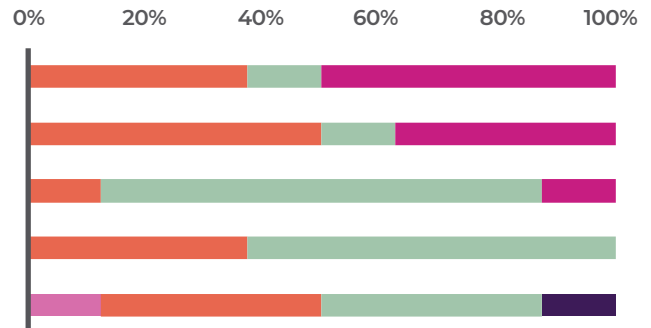


## Current Capability

Q: How would you rate the Medical Affairs organisation's capabilities in the following areas?

● Poor ● Below what's needed ● OK ● Good ● Exceptional

- Synthesising evidence based on analysis of evidence generated outside of the company
- Developing the product lifecycle evidence plan over time
- Considering a diverse range of research approaches to suit evidence needs of the portfolio/product
- Designing research programmes/projects that focus on value evidence
- Establishing a comprehensive product lifecycle evidence plan prior to regulatory approval



When considering evidence generation as a broad capability for medical affairs this can be further broken down into sub-topics spanning the following:

- **Strategic planning:** Establishing an initial evidence plan (i.e. pre-registration) that considers the product lifecycle and developing this over time as required
- **Operational planning:** Considering (and able to employ) a diverse range of possible research approaches to suit the evidence needs of the product or portfolio
- **Wider outcomes:** Designing research programs/projects that focus on value evidence
- **Creativity:** Synthesis of new evidence based on analysis of all externally available evidence (not only that which the company has developed)

The specific capability that medical affairs have the most confidence is well handled is the **synthesis of new evidence based on analysis of all externally available evidence** (58% rate as Good). This suggests that the application and externalisation of approaches such as systematic literature review and meta-analysis are well understood and implemented. By contrast, designing value evidence programs, establishing an early, comprehensive lifecycle evidence plan and consideration of a wide range of research approaches all received very low levels of

responses rated as above 'OK'. This would merit further investigation to understand the nature of the barriers in these areas but support to help teams better understand and introduce strategic challenges into effective evidence scoping activities would seem to be key.

The **types of activities or approaches** where evidence generation should be prioritised may vary across organisations, although there are likely to be some similarities and so responders were asked to rank a selection of techniques/ approaches in order of importance. A prioritised list was generated from this:

1. **Understanding clinical experience & real-world outcomes**
2. **Understanding factors that drive effective utilisation of a medicine (e.g. patient stratification)**
3. Establishing the safety and efficacy of a medicine
4. Understanding, consolidating, and communicating expert opinion about aspects of clinical management
5. Understanding patient experience & patient-reported outcomes
6. Understanding how use of the medicine is impacted by/impacts the clinical care pathway.

Additionally, when questioned about the **proficiency** of each of these areas by MA teams the top 2 areas identified as important performed lowest of all. This raises an obvious need to be addressed.

Both areas may be supported at a foundational level with training about varying relevant research techniques available (beyond traditional approaches) e.g. designing & conducting registry studies or structured Delphi consensus.

In general, some of the general feedback accompanying this section of the survey would support the need for broader organisational alignment on what should be prioritised when it comes to evidence generation, with this discussion needing to be led by the medical affairs team.

### 3. Capturing and Integrating Insights into Organisational Focus

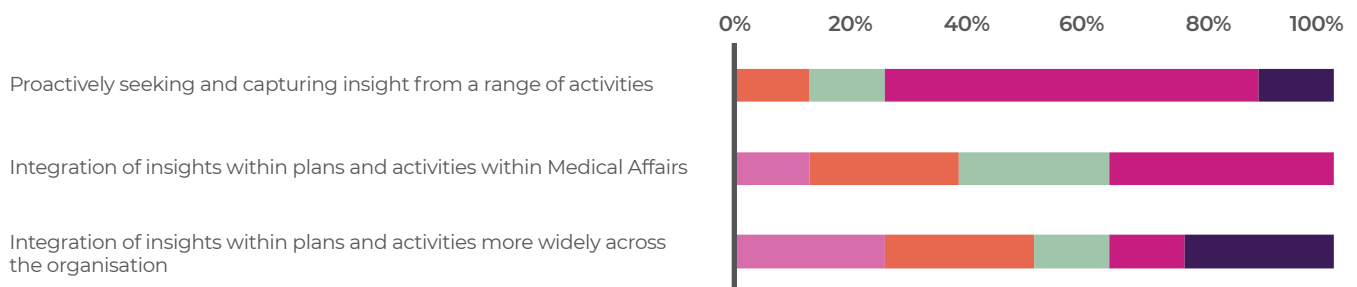
**Capturing and Integrating Insights into Organisational Focus - Capturing high-quality external insights to drive and/or inform medical strategy. Synthesizing and using external insights from a range of sources, enabled by the background, training, and deep-seated scientific expertise that Medical Affairs professionals have of the therapeutic area and patient care. Communicating scientific insights and integrating them into any product or portfolio assessment and/or strategic plan.**

Communicating the value of Medical Affairs, A MAPS White Paper, May 28 2020

#### Current Capability

Q: How would you rate the Medical Affairs organisation's capabilities in the following areas?

● Poor ● Below what's needed ● OK ● Good ● Exceptional



There is good confidence from many but also a noticeable amount of **pessimism when it comes to integrating these insights back into organisational plans and activities**, particularly when this extends beyond the medical affairs team. Given the polarity of responses, it would be reasonable to think that this challenge is one that will benefit from greater discourse across the medical affairs community to understand and disseminate effective strategies.

When asked to rank a pre-defined list of areas for insight capture and integration that responders believed **most focus should be applied** the following prioritisation emerged, with one area standing out clearly:

#### Rank

- 1 **Patient journey(s) & experience of the care pathway** (80% rated this as 1st or 2nd choice).
- 2= Patient outcomes and outcome gaps (13% rated this as 1st or 2nd choice).
- 2= Research, data and evidence gaps (13% rated this as 1st or 2nd choice).
- 4 Insight to inform unmet medical needs (11% rated this as 1st or 2nd choice).
- 5 Disease epidemiology (9% rated this as 1st or 2nd choice).
- 6 Treatment pathways (0% rated this as 1st or 2nd choice).
- 7 Current standards of care (0% rated this as 1st or 2nd choice).

This was also supported by comments made by responders, demonstrating that understanding the patient experience would seem to have overwhelming importance and prominence for pharmaceutical organisations now. It would be interesting however to understand how well-aligned organisations are across departments on this issue.

*“As the emphasis on patients experiences and PROMs is evolving, and technology supports more direct data collection, this should drive MA activities further in this direction.”*

## 4. Evidence Dissemination

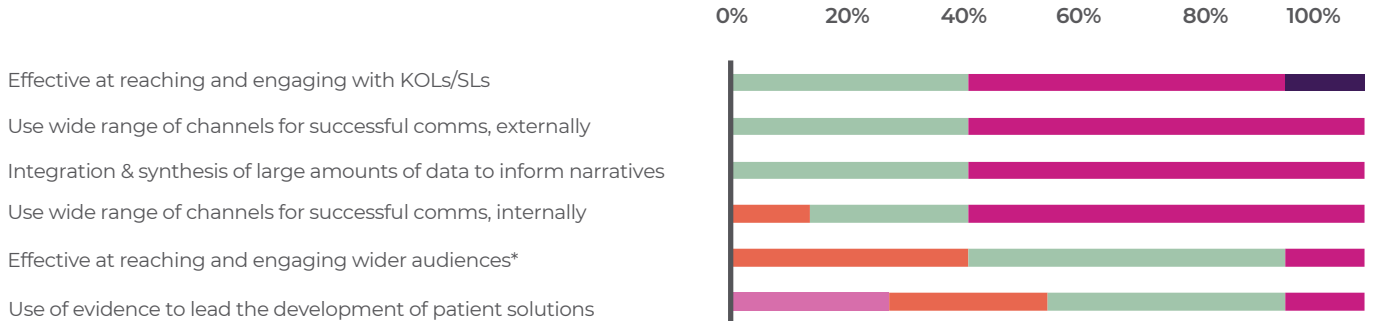
Evidence Dissemination - Evidence communicated to internal and external stakeholders via a wide range of channels (virtual & physical) including, but not limited to, 1:1 scientific exchange, key opinion leader (KOL) engagement, medical information, publications, and continuing medical education. Integration and synthesis of the totality of data to inform the medical and scientific narrative and effectively communicate this information to HCPs and KOLs, payers, and policymakers so that they may utilise it to inform patient care and improve patient outcomes. Development of patient solutions that can be utilised to optimise care.

Communicating the value of Medical Affairs, A MAPS White Paper, May 28 2020

## Current Capability

Q: How would you rate the Medical Affairs organisation's capabilities in the following areas?

● Poor ● Below what's needed ● OK ● Good ● Exceptional



\*Externally, beyond KOLs and clinicians

Given the amount of emphasis that this area is evidently receiving it is not surprising that the results are generally positive for this area with particularly high levels of capability seen with **reaching and engaging scientific leaders with evidence to support decisions**. It is also good to see that there is good capability observed with the use of a range of communication channels. This will likely have seen a boost through and following the COVID-19 pandemic where medical affairs teams were challenged to innovate their approach to stakeholder communication.

Two areas may warrant further efforts to achieve higher capability with evidence dissemination:

1. **The ability to reach and engage wider audiences** (i.e. beyond clinical leaders, often physicians). In future, it will likely be important to consider how medical affairs can optimally support other audiences including specialist nursing and pharmacy HCPs, extending the impact of the role and supporting thought-leaders across the multi-disciplinary team.
2. **Using evidence to lead the development of patient solutions that improve care** is an area that over 20% of responders thought capability was 'Poor', a further 20% thought it 'Below Where Needed' and only 12% thought it 'Good'. This gap may be due in part to the challenges that exist for medical affairs to be able to align and influence the wider organisation (including commercial colleagues) around activities like this that may not appear to have an immediate commercial appeal. This was a sentiment that emerged from the comments that accompanied this section of the survey.

## 5. Governance and Compliance

**Governance and Compliance - Medical quality oversight is a core component of modern-day governance and compliance with a variety of guidelines, codes and regulations. MA also has an essential role in working with internal quality and compliance stakeholders to understand, establish and reinforce internal and external codes of conduct and promote transparency of practices in the regulation of company-wide activities. These activities include, amongst other things, review and approval of material used in evidence dissemination (promotional and non-promotional), independent medical education grants, and independent investigator-sponsored research. Core behavioural and leadership competencies for MA professionals must be established to ensure compliant activities especially as they relate to HCP engagement.**

Communicating the value of Medical Affairs, A MAPS White Paper, May 28 2020

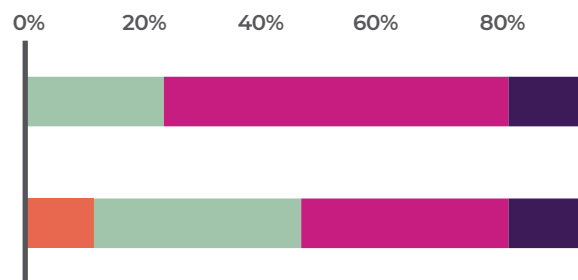
### Current Capability

Q: How would you rate the Medical Affairs organisation's capabilities in the following areas?

● Poor ● Below what's needed ● OK ● Good ● Exceptional

Establishing & reinforcing codes of conduct across the organisation's externally-facing activities

Review and approval of promotional and non-promotional activities and materials in a way that upholds standards and considers risks appropriately






Compared with the previous themes, this area is seen as having the **highest level of capability amongst medical affairs teams**. This has historically taken up a high proportion of medical affairs' time and resources and so this result is perhaps to be expected. From some of the free-text responses in this section, it is interesting to note that several organisations are introducing new, specific roles for promotional review, to take

the load from medical affairs. Some responders also raised the need to act more as a 'consultant' to support the wider business to 'up their game' in this area. The theory provided is this could reduce any over-reliance on medical affairs teams to do all of the thinking and risk mitigation activity when it comes to designing externally oriented communications and tactics.

# Summary recommendations

This research with 45 professionals working in various medical affairs roles helps to provide some initial perspective on the status, progress made and suggested areas where additional progress may lie against critical capabilities for the role.

As a result of this survey a simple overview of the status of each of the 5 capability areas can be presented. Accompanying each area are suggested opportunities to help realise further progress.

Capability area and proposed priority	Potential for further progress
<p><b>Medical Leadership</b></p> 	<ul style="list-style-type: none"> <li>✓ Focus on building core skills such as <b>'critical &amp; strategic thinking'</b> and <b>'positively influencing others'</b> may fundamentally support progress.</li> <li>✓ Organisations that encourage talented medical affairs leaders towards broader leadership roles beyond the MA department will benefit from the impact of <b>positive role models</b>.</li> </ul>
<p><b>Evidence Generation</b></p> 	<ul style="list-style-type: none"> <li>✓ Disproportionate emphasis on capability building with non-traditional research approaches would seem helpful here. Particular emphasis on the following areas of research seem prominent:               <ol style="list-style-type: none"> <li>1. Understanding <b>clinical experience &amp; real-world outcomes</b></li> <li>2. <b>Understanding factors that drive effective utilisation</b> of a medicine (e.g. patient stratification)</li> </ol> </li> </ul>
<p><b>Capturing &amp; Integrating Insights into Organisation Focus</b></p> 	<ul style="list-style-type: none"> <li>✓ <b>Greater discourse &amp; (appropriate) best-practice sharing</b> related to successfully integrating insights gained into wider strategic plans would help medical affairs teams build on this area of strength.</li> <li>✓ Medical affairs should consider how gaining better insights on <b>patient journey(s) &amp; experience of the care pathway</b> can be used to support the business and identify optimal ways of achieving this.</li> </ul>
<p><b>Evidence Dissemination</b></p> 	<ul style="list-style-type: none"> <li>✓ Understanding <b>how best to engage audiences that extend beyond KOLs and scientific leaders</b> is an area that is not yet optimised but is likely to be important in future.</li> <li>✓ Applying insights gained to <b>develop effective patient solutions</b> is a clear opportunity area but may also depend on their ability to align the interests of commercial colleagues to realise this.</li> </ul>
<p><b>Governance &amp; Compliance</b></p> 	<ul style="list-style-type: none"> <li>✓ Consideration could be given to how medical affairs organisations <b>maintain leadership</b> of this critical area while <b>upgrading the organisational awareness and accountability</b> more generally around it. This could enable <b>sufficient capacity for MA to devote to other areas</b>. It may be appropriate for some organisations to assign this responsibility to specific medical affairs sub-specialists entirely.</li> </ul>

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The pharmaceutical industry's success is dependent on the effective functioning of medical affairs teams, and it is critical to ensure that medical affairs professionals have the skills and competencies required to meet the evolving needs of the industry. The role of medical affairs teams in the pharmaceutical industry has evolved in line with these needs in recent years, taking on an increasingly strategic emphasis, as articulated by the 2020 framework proposed by MAPS. The insights gathered from this survey of professionals highlight this growing importance and, importantly some of the specific areas where the biggest gains can be made.

Triducive intend to continue to gather input to the survey from medical affairs colleagues with the aim of publishing an updated perspective on a regular basis. The survey can be accessed [here](#)

Triducive are a health communications agency that focus on supporting life sciences and other private and public healthcare organisations to develop consensus-based insight, evidence and communications.

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