



# Measuring Value and Impact in Medical Affairs

Standards and Guidance Document





## Acknowledgments

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Those named above contributed the Value and Impact Guidance Document in their personal capacity. The views expressed and guidance provided in this document and the associated presentation are their own and do not necessarily represent the views of their named employers.



## Using this guidance document

This resource is intended to provide Medical Affairs teams the rationale for meaningful value and impact measurements, as well as tips to support these

- The recommendations provided should be tailored to the individual organization, product, and treatment landscape
- The views and information provided do not reflect the position or views of any one individual or company



## Rationale and purpose

- Ensures accurate, consistent language for discussing value and impact measurements
- Provides a framework for identifying and implementing value
- Supports appropriate selection of value and impact measurements (including quantitative and qualitative measures)
- Provides a foundation for training and ensuring alignment across Medical Affairs subfunctions





# Terminology: Going beyond "metrics" to "meaningful impact and goal-based measures"

Using the right terminology is essential to be consistent in the way we communicate Medical Affairs value

Term	Definition/use	Example
Impact (outcome) measures	<ul> <li>A measurable variable used to assess the progress and effectiveness of activities in achieving their intended clinical impact (the desired end outcome)</li> <li>Typically aligned to strategic imperatives or medical objectives</li> <li>Often the result of several initiatives/activities that cumulatively show impact, rather than from a single initiative</li> <li>More difficult to measure than goal-based metrics, particularly as several cross-functional stakeholders may contribute to these outcomes (including stakeholders outside of Medical Affairs)</li> </ul>	Increase in diagnosis of a rare disease following a disease awareness educational program
Goal-based measures	<ul> <li>Typically defined as a "quantifiable measure that is used to track and assess the status of a specific process" or a "standard of measurement by which efficiency, progress or quality of a plan, process, or product can be assessed"</li> <li>Often operational or tactical, and are specific to a single activity         <ul> <li>Metrics can be qualitative and are often considered to be leading indicators that help predict future performance or outcomes, enabling you to plan and make strategic decisions</li> <li>Metrics can also be quantitative "counting" measures, which are typically considered to be lagging indicators that give insight into past performance or outcomes, measuring what you have already achieved</li> </ul> </li> </ul>	Qualitative "perception" measures: Feedback obtained from an advisory board or actionable insights gained via MSL interactions  Quantitative "counting" measures: Number of abstracts submitted or number of visits to a website page





## Goal-based versus impact measurements

- Company X is launching Product Y in a rare disease indication and has a strategic imperative to improve diagnosis of the disease
- To address this strategic imperative, the company has developed a disease awareness program comprising multiple elements
- Several measurements can be used to demonstrate the success of the program
  - Longer-term impact measures that are aligned with the strategic imperative and demonstrate the clinical impact
  - Shorter-term qualitative and quantitative goal-based measures (some of which may act as a surrogate for the impact measure)

#### Goal-based measures

Quantitative: Completion of 4 x educational events

Quantitative: Number of unique visits to a disease awareness website

Quantitative: Number of people attending a company-sponsored symposium

Qualitative: Requests for slide content following an educational event

Qualitative: Shares of the educational campaign on social media

Qualitative: Change in physician perceptions following an educational program (assessed via pre- and post-event questionnaires)

#### <u>Impact measures</u>

15% increase in time to diagnosis (assessed via physician surveys)



Meaningful measurements
capture not only that
something has been done,
but also its effect





## Questions addressed in this resource

1. Why do we need to show the value of Medical Affairs?



2. How do we define value in Medical Affairs?



3. What measurements are Medical Affairs subfunctions using today?



4. What meaningful measurements should we be assessing?



5. How is impact measured across Medical Affairs subfunctions (example measures)?



6. How can we set ourselves up for success?







1. Why do we need to show the value of Medical Affairs?



## An evolving landscape is driving clinical outcome-based care

The biopharmaceutical and MedTech industries are at a pivot point where they need to go beyond simply proving the effectiveness of the drugs and devices they produce

- Increasing requirements for treatment protocols, guidelines, and medical governance all put pressure on the industry, urgently calling for both transparency and evidence of value
- Biopharma and MedTech need to deliver innovation that benefits society; the focus needs to shift to patients and engaging with society, to safely introduce new products that address the priority needs of patients and healthcare systems
- Healthcare decision-making is shifting from a model driven by individual HCPs influenced by KOLs to a model of shared decision-making with payers and patients

As Medical Affairs becomes an increasingly critical part of organizations, and responsibilities continue to grow, Medical Affairs teams are striving to develop new and relevant value measurements that demonstrate the effectiveness and efficiency of their function; however, it can be challenging to identify concise and consistent analytics that communicate the full range of benefits and expertise that Medical Affairs brings to the table.

Additionally, it can be challenging to ascertain how individual functions are contributing to impact when working on shared cross-functional objectives and goals (eg, was the impact due to interventions by Medical Affairs, Marketing, or other cross-functional teams, or a combination of cross-functional efforts).





## Medical Affairs adds significant value to the biopharmaceutical and MedTech industries

Medical Affairs is the function within the broader biopharmaceutical industry best positioned to:



Listen and respond to external stakeholders' need for information



Identify gaps in product knowledge and data to determine the need for future studies



Disseminate scientific knowledge



Answer questions of real-world safety and effectiveness



Helps external stakeholders make sense of treatment complexity



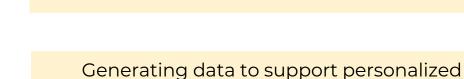
## Medical Affairs brings benefits to the patient

Representing the patient voice in development

Helping HCPs appropriately use new treatments

Helping industry access quality-of-life issues

Identify unmet patient needs for education and further drug development



Increasing awareness and diversity in clinical trials

medicine

Expand equity and access to treatments

Creating new knowledge about emerging treatments through evidence generation and RWE studies



## Meaningful measurements bring value to both internal and external stakeholders



Communicate the overall value of Medical Affairs



Ensure alignment with HCP priorities and needs



Demonstrate impact on the patient (experience and outcomes)



Enable us to evaluate the success of our efforts



Create a framework for innovation

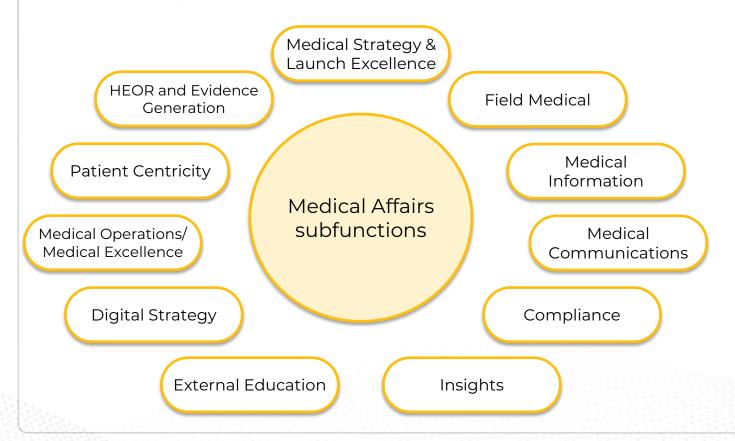


Help drive improvements in all aspects of planning and execution within the biopharmaceutical and MedTech industries

The impact of Medical Affairs in clinical, scientific, and digital spaces will depend on the function's ability to effectively measure the strategies it employs to collect and integrate information and then communicate it both within and outside of the organization



The diverse range of roles in Medical Affairs makes it challenging to provide a single definition of value

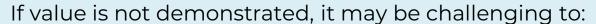


Every Medical Affairs team member should be working towards a common set of broad outcomes or strategic objectives; however, the methods by which these outcomes can be achieved and measured will differ by function/department





# Risks and challenges from not having appropriate mechanisms for value definition



- · Acquire sufficient resources and influence direction setting
- Demonstrate reasons to invest in Medical Affairs
- Engage in mutually beneficial interactions with external stakeholders



Value-generating activities can result in cost avoidance and increase scientific impact:

- Mitigate risk of regulatory penalties and cost of uncertainty
- Minimize wasted resources; eliminate costs associated with suboptimal processes
- Maximize efficiencies with external stakeholders, increasing awareness and understanding of the company's value proposition

When measurements are poorly integrated across the function or organization, and have magnitude but no direction, Medical Affairs teams run the risk of measurement without meaning



2. How do we define value in Medical Affairs?



# Key considerations and guiding principles for defining value













## Understand the need

Identify the unmet medical need to help define the strategy and subsequent value measurements



Develop the core strategy, strategic imperatives, and medical objectives

## Align stakeholders

Align with internal cross-functional partners to ensure a coordinated approach

## Determine Medical Affairs measurements

Ensure a combination of impact and goal-based measurements that are measurable and relevant



# Understanding stakeholder perspectives/viewpoints can inform needs



Company: May look for collaborations with HCPs, research consortiums, or patient advocacy groups



HCPs: May look to advance science, patient care, or outcomes, and engage in mutually beneficial partnerships



Patients: Look for access to treatment, health outcomes, QoL, health equity support, and to feel that their views are represented, and their voice is heard



Payers: May look to understand patient-relevant benefit versus predetermined treatment comparators



Healthcare systems: Considers the overall value in the context of wider societal needs





# To demonstrate value, the medical plan and objectives must align with the organization's broader strategic imperatives



A focused and prioritized medical plan must align and support the organizational strategic imperatives, and recognize the medical and scientific opportunities and challenges relating to both the therapy area and product/portfolio



Medical objectives or strategic medical drivers should be influenced by, and aligned to, the priorities and unmet needs of external stakeholders – HCPs, patients, and payers – in the therapeutic space



Focused strategic medical objectives will maximize the overall medical value to the external stakeholders, while upholding the scientific integrity of and confidence in the product and company that supports it



Each Medical Affairs subfunction will need to identify how they can partner and execute on the medical strategy to determine how they can contribute to outcomes



# To deliver organizational value, cross-functional alignment is critical



Achieving alignment means that everyone in the organization is working towards the same goals and objectives



Ensures the entire organization has the same expectations of what the Medical Affairs team will deliver



Coordinated efforts are more likely to result in an impact on clinical practice



Accelerates the achievement of patient-centric goals

Potential benefits of cross-functional alignment

- ✓ Provides a clear direction and set of priorities
- ✓ Increases knowledge sharing
- ✓ Improves productivity
- ✓ Efficient use of resources
- ✓ Promotes transparency





# To be meaningful, value and impact measurements should align with the strategic plan



- Meaningful measurements help us to evaluate the success of our efforts, and assess impact and influence on future decision-making and outcomes
- It is important to define how closely a tactic or initiative delivers on its purpose, as
  described in the Medical Affairs strategic plan, through functional medical objectives that
  support the strategic imperatives
- Alignment between a tactic and the measurement used to assess it provides actionable insights, helping teams identify and communicate the impact of successful actions to the Medical Affairs or cross-functional product teams
  - Offers the opportunity to rethink and reprioritize efforts shown to be less successful
- Meaningful measurements capture not only that something has been done, but also its effects
  - For example, measurements associated with data-generation communications may inform regulatory, reimbursement, and global market access requirements



Meaningful measurements are needed (for each stakeholder) to assess the impact of the medical strategic plan and its objectives

#### Establish



Establish meaningful measurements to evaluate the performance of the medical strategy plan

#### Analyze



Analyze impact and goal-based measures against each milestone

#### Adjust



Determine adjustments needed based on ongoing assessment



## Regular review of the medical plan ensures ongoing relevance and value



Inform decision-making and drive strategy through evidence

**Implement** updates to activities and tactics cross-functionally





**Execute** activities against plans

**Update** plans and activities as the landscape evolves





**Monitor** through a baseline of quantitative and qualitative measures





# Consider the hierarchy of measurements within your medical plan

- Meaningful measurements for strategy evaluation and refinement are key for optimizing results
- Gaps can subsequently be identified and filled to improve outcomes

# Medical Objectives Strategic Medical Drivers Tactical Plan

- Determine measures that align with the medical objectives to:
  - Evaluate the progress of the medical plan (for example by using the SWOT analysis as a foundation)
  - Identify gaps or course corrections and inform future medical objectives
- Typically, these measurements assess **impact** (eg, increase in time to diagnosis of a rare disease)
- Goal-based quantitative and qualitative measures provide a holistic view
  - Quantitative measures can be used to establish a baseline and assess performance longitudinally over time
  - Qualitative metrics can gauge stakeholder perceived value, needs or knowledge gaps
- Typically track **operational or tactical activities** (eg, assess how interactions with various stakeholders change over time across various channels to ascertain whether knowledge gaps have been closed effectively)

For further information on how to use measurements to evaluate and refine medical strategy, please refer to the **Medical Strategy Stands and Guidance Document**, available to download from the MAPS Knowledge Center



A Strategy-on-a-Page

strategy



The **Vision** for a product is a broad overarching

> goal typically used across functions

Medical strategy: Defining where we want to be and how to assess impact

Establish Product X as a preferred early line treatment for advanced non-small cell lung cancer **Medical Objectives** Medical objectives facilitate moving from the current situation to the desired goals. Educate key stakeholders on the value Tailored objectives for individual functions of Product X may be required. These need to roll up to support the overarching medical objectives **Strategic Medical Drivers** format provides a great summary of the overall 1A. Build awareness of Product X Like the medical objectives, the strategic MOA and improved benefit-risk profile medical drivers are key objectives but are vs other ADCs more granular and support the associated 1B. Educate on improved patient-reported medical objective – they help facilitate outcomes vs other ADCs translation of strategy into key tactics 1C. Communicate a clear value narrative to all key stakeholder groups **Key Metrics** Meaningful measurements help evaluate Example: Qualitative outcome-based progress toward and success in achieving metric for Medical Objective 1. the medical objectives. They guide and

**VISION** 

For more information on how to use measurements to evaluate and refine medical strategy, please refer to the Medical Strategy Standards and Guidance Document, available to download from the MAPS Knowledge Center

Track sentiment shifts based on Field

Medical interactions over time

refine objectives as well as demonstrate

value





## All tactics link to the strategy







Strategic Driver

**Build awareness** of Product X and improved benefit-risk profile vs alternative treatments



Develop a simplified MoA animation that links action to improved safety

Conduct a hybrid educational event at global congress X and share materials via various channels (where metrics can be tracked)

**Metrics** 

Measure improvements in sentiment and changes in treatment practice based on field interactions

Conduct pre- and post-event surveys to assess knowledge and shifts in opinions

Measure the engagement and sharing of materials post-event

For more information on how to use measurements to evaluate and refine medical strategy, please refer to the Medical Strategy Standards and Guidance Document, available to download from the MAPS Knowledge Center





## Template: From strategy to measurement





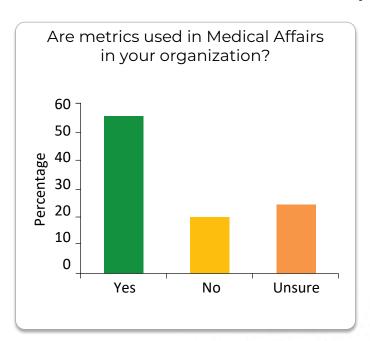
3. What measurements are Medical Affairs subfunctions using today?

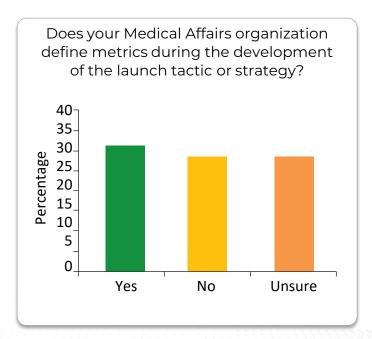


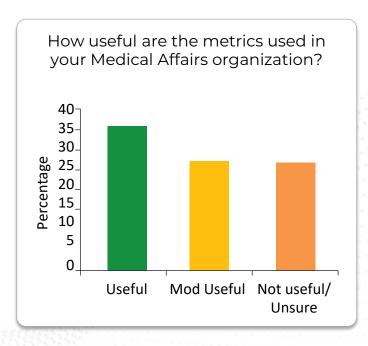


# Only one-third of Medical Affairs organizations define metrics during the development of their tactic or strategy

#### Results from a small pilot survey of MAPS members conducted in 2021 (n = 25)







· Survey shows poorly integrated, fragmented use of metrics, with little consensus on best practice



# Current status of impact measurement in Medical Affairs

Medical Affairs is necessarily independent from traditional sales-based metrics because of the non-promotional function of the role



To date, many measurements that have traditionally been used to determine success in Medical Affairs are quantitative and designed to measure effort versus effectiveness



Quantitative measurements are typically not outcomes based and rarely show the impact on the patient (or value to the HCP)





## Understanding, measuring, and communicating impact has long been debated and considered difficult to categorically define

Challenging to measure

Public health (eg, reducing disease burden by XX% in X years)

Patient health (eg, demonstrating patient outcomes as a direct/indirect effect of medical activities)

Competence (eg, improved HCP practice, empowered cross-functional partners due to medical initiatives)

Knowledge (eg, advancing HCP understanding on disease/treatments)

Satisfaction (eg, HCP satisfaction, value of MSL visits/ insights/education programs/ad boards)

Touchpoints or volume (eg, # of MSL visits/insights/education programs/advisory boards or # of abstracts/publications/company-sponsored symposia, etc.)

Impact (outcome) measures

Qualitative (competency, knowledge, perception) measures

Quantitative (counting) measures

Easy to measure



Medical Affairs teams are under increasing pressure to demonstrate value – both internally and externally – yet most traditional measurements only capture quantity, not quality, and are not outcomes based





4. What meaningful measurements should we be assessing?



#### MAPS 2030 Medical Affairs vision for metrics and KPIs

Defining the right metrics and KPIs to demonstrate how Medical's actions drive forward the organization's strategic priorities has been a longtime challenge for the function. Without an obvious success metric such as sales revenue or regulatory approvals, Medical Affairs has depended on measuring what we do (eg, number and frequency of MSL interactions or number of publications) rather than measuring impact.

Future Medical Affairs teams will combine quantitative and qualitative metrics to measure and report not only what we do but also the impact to patients and the organization. However, the function's focus will need to remain on delivering value rather than becoming myopic in its desire to report on its value.







A combination of measures is important to help predict future performance or outcomes, enabling you to plan, course-correct, forecast, and set goals

#### **Impact measures**

- Changes in rates of diagnosis
- Changes in the treatment paradigm
- Increased rates of biomarker testing
- Improved patient outcomes (overall survival, safety)
- Changes in guidelines or medical policy
- Reimbursement of product



#### Drawbacks of only using impact measures:

- Challenging to measure
- Often long-term; demonstrating clinical impact can take a considerable amount of time
- Difficult to identify the contribution of a single initiative
- Can be challenging to show the contribution of Medical Affairs (vs other cross-functional partners)

#### **Qualitative measures**

- Internal and external stakeholder feedback (via advisory boards/surveys)
- Actionable insights captured from investigators, HCPs, advisors, patients, payers, and other external stakeholders that may inform medical strategy, clinical development, or other internal functions
- Sentiment analysis for altmetrics
- Benchmarking to other companies
- External recognition: scientific credibility, news coverage, social media coverage and/or reach

### $\uparrow$

#### Drawbacks of only using only qualitative measures:

- Potential for biased interpretations due to the subjective nature of data collection and analysis
- Time consuming to perform
- Often require skilled professionals to conduct interviews and qualitative analysis
- May pose challenges for resource allocation and scalability

#### **Quantitative measures**

- Number and type of MSL activities and engagements
- Number of accepted publications
- Number of symposia or educational opportunities supported
- Number of interactions with HCPs
- Number of medical information requests
- Patient or investigator recruitment
- Altmetrics to measure publication impact

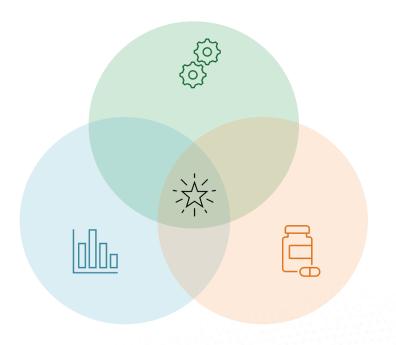


#### Drawbacks of only using quantitative measures:

- Do not capture subjective experiences or the broader context surrounding the data
- · Measure quantity over quality
- Can reward inefficient use of time (eg, if assessing proportion of MSL time in the field)
- Does not acknowledge the ability to gain insights and enhance understanding
- May encourage unnecessary activities



# To impact clinical practice, multiple interventions (and measures of success) may be required



- Individual activities don't always bring about substantial clinical change, instead multiple interrelated factors are often involved
- When measures of success are being determined, it is important to keep this in mind as several activities may ladder up to create impact (and more than I impact indicator may need to be considered)
  - For example, assessing clinical outcomes in addition to assessing the effectiveness of the specific intervention





# Identifying what to measure: Not all surrogate measures are equal

Stronge predictors of impact



of impact

## Symposium or virtual event

**Enduring change**: Long-term attendee follow-up (via surveys or MSL visits); requests received for slide content

Change in knowledge, attitude, or skills: Pre- and post-event evaluation surveys

**Engagement**: Questions asked or submitted; interactions via audience response systems

**Audience reach**: Number of delegates attending; duration of attendance

### Website

**Users taking action following site visits**: Proactive mentions of site; registration or consent for contact; content downloads; net promoter score

**Engagement**: Video views (number, duration); user journey/pages viewed; time spent per visit to website; users returning to the site; bounce rate

**Number of users reached**: Reach and uptake by target audience; number of site visits; number of unique visitors







Qualitative versus Quantitative



Scalar versus Vector



Organizational versus Strategic



Reach, Relevance, and Resonance



Value versus Impact



Measuring versus Monitoring



Internal versus External

The list of possible metrics is long and everexpanding, especially with developing digital technologies, highlighting the need to understand the factors that make metrics meaningful within the context of a team's specific strategies and tactical plans







## Qualitative versus Quantitative



Scalar versus Vector



Organizational versus Strategic



Reach, Relevance, and Resonance



Value versus Impact



**Measuring versus Monitoring** 



Internal versus External

### Description

- It can be difficult to calculate and communicate the success of initiatives measured with qualitative measures
- Strategies should seek to gain the best of both – formalizing qualitative measures and quantifying the impact of Medical Affairs actions
- Impact measurement assesses not only "what was done?" but also "what is the impact of what was done?"

- Qualitative: Change in understanding following education event as measured by prelearning and postlearning test
- Quantitative: Number of target attendees at a medical education event







Qualitative versus Quantitative



Scalar versus Vector



**Organizational versus Strategio** 



Reach, Relevance, and Resonance



Value versus Impact



Measuring versus Monitoring



Internal versus Externa

### Description

- Related to qualitative vs quantitative measures, scalar metrics show size, whereas vector metrics show both size and direction
- Scalar metrics demonstrate quantity of actions, but not their impact (eg, the number of publications)
- Capturing the impact of a publication (eg, through altmetrics) could help transform these scalar metrics into vector metrics

- Scalar: Number of sponsored published manuscripts available online
- Vector: Measurement of online reader behavior, network interactions with content, and social media







Qualitative versus Quantitative



Scalar versus Vector



Organizational versus Strategic



Reach, Relevance, and Resonance



Value versus Impac



Measuring versus Monitoring



Internal versus External

### Description

- An important question: "Where does a metric sit in the hierarchy of the Medical Affairs strategic plan?"
- Topline goals such as increased adoption of a product might sit at the organizational level, whereas the different groups within Medical Affairs, including Publications, Field Medical, and HEOR may each use strategic metrics to support the adoption of that product (such as guideline inclusion, data dissemination, medical education)

- Organizational:
   Empowerment and education of patients/caregivers on disease state and treatment options
- Strategic: Patient Advocacy Groups knowledgeable about disease state and proactive in seeking product information







Qualitative versus Quantitative



Scalar versus Vector



Organizational versus Strategic



Reach, Relevance, and Resonance



Value versus Impact



Measuring versus Monitoring



Internal versus Externa

### Description

- Reach (extent of audience exposure), relevance (alignment to your audience), and resonance (engagement with your audience) combine a HCP's reach with their relevance in a disease area to predict their resonance
- How many times something is accomplished is multiplied by the impact of each iteration to determine an overall measure of success

- A KOL with a significant publication history in neurology may have impressive reach, but if the medical group is focused on oncology, the KOL may have little relevance, decreasing their resonance in the oncology space
- Number of live symposium attendees, in the right specialty, who are actively engaged with the educational content of the event: Reach, relevance, resonance







Qualitative versus Quantitative



Scalar versus Vector



Organizational versus Strategic



Reach, Relevance, and Resonance



Value versus Impact



Measuring versus Monitoring



Internal versus External

### Description

- Medical Affairs teams speak of metrics to demonstrate the value of the function
- With increased prominence with the organization, teams have an opportunity to shift value to the more compelling language of demonstrating impact
- This shift can influence the design of a team's metric framework, with a focus on measurements to drive opportunity and innovation rather than metrics meant to justify the value

- Value: Medical information responses handled
- Impact: Improved HCPs' understanding of appropriate use of a product, minimizing adverse events and discontinuations







Qualitative versus Quantitative



Scalar versus Vector



Organizational versus Strategic



Reach, Relevance, and Resonance



Value versus Impac



Measuring versus Monitoring



Internal versus Externa

### Description

- Some metrics are standalone absolutes, whereas others are only relevant in relation to change (eg, whether you are progressing or regressing towards goals)
- Measuring and monitoring metrics can be cyclical and even periodic, with feedback from monitoring influencing the next iteration of metrics
- Monitoring metrics present special challenges in implementation and interpretation – with considerations such as who will measure the outcome, and how often, what changes are meaningful, etc.
- These must be answered in the strategic plan

- Measuring: All medical/brand teams have been trained on the product label on the day of FDA approval
- Monitoring: All medical/brand teams have been trained on subsequent product label updates on the day of issuance







Qualitative versus Quantitative



Scalar versus Vector



Organizational versus Strategic



Reach, Relevance, and Resonance



Value versus Impact



**Measuring versus Monitoring** 



Internal versus External

### Description

- Internal metrics demonstrate the impact on other stakeholders within the organization and must be designed from the perspectives of these stakeholders; for example, commercial may prioritize reporting on HEOR value, whereas R&D may prefer insights generated by Medical Affairs leading to additional clinical studies
- External metrics describe the impact on stakeholders outside the organization and are similarly designed from the audience's perspective
- When aligning metrics with the strategic plan, it is useful to keep these audiences in mind, so metrics match the motivations of various internal and external audiences

- Internal: All medical functions have contributed as needed to the strategic plan at the agreed milestone dates
- External: KOL engagement plan has resulted in >50% KOL appreciation for disease-state nuances by the launch or measuring the increase in knowledge in a patient advocacy community around the effectiveness of investigational agents due to an external education program





# It is important to understand your baseline, prior to tracking and assessing value and impact











Establish your baseline for the value and impact measurement (aligned with the Medical Strategy) Determine process and timing for impact assessment Identify a common tool for data collection and evaluation

Keep in constant communication with the functional groups to ensure accountability and proper adjustment to changes in medical plans Develop an ongoing communication plan for cross-functional internal stakeholders to highlight achievements and accomplishments of the Medical Affairs teams as well as key learnings from the value and impact measurement evaluation

### Additional points to consider:

- Who will do the measuring and how often?
- What types or magnitudes of changes over time are meaningful, and what actions should be taken based on these changes?
- Does a baseline exist against which to compare current and future measurements, and, if not, how will baselines be established?
- At what point will the value and impact measurements return meaningful insights?





# Impact must be measured compliantly within Medical Affairs



- As some value and impact measurements may be new to Medical Affairs teams, it is important to work with compliance teams to find an appropriate solution
- While it is vital for Medical Affairs teams to measure their performance as related to the strategic plan, they should also be vigilant to ensure the measures they are using do not raise compliance or ethical concerns
- Compliance concerns with measurements typically arise due to the potential for these metrics to be misused or misinterpreted in ways that violate regulatory requirements or ethical standards
- Frequent compliant concerns include:
  - Data privacy data should be collected in compliance with privacy regulations such as HIPAA, GDPR, and other applicable laws
  - Commercial measures Medical Affairs impact cannot be linked to revenue or number of prescriptions, but must focus on value to physicians, patients, and society

Proactively consult and collaborate with your compliance team, but don't use compliance concerns as a reason to not consider measurement!



# Just because something can be measured doesn't mean it should be!

Eventually, a strategic planning process with meaningful measurements at its core will generate more measurements than are feasible to implement

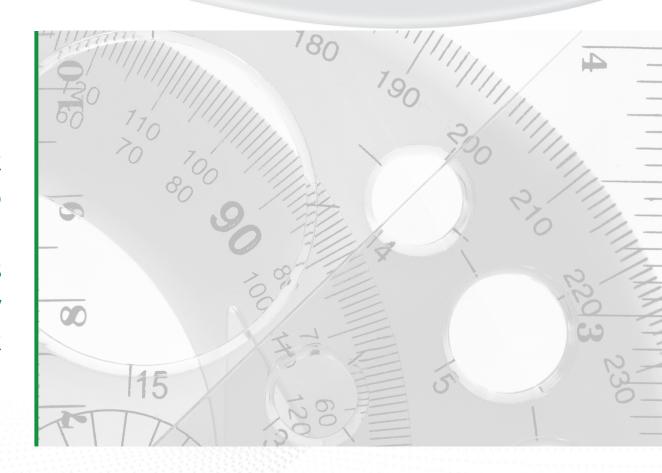
Remember every measurement incurs costs in time, budget, and the risk of less useful measurements overshadowing crucial ones



Similarly, the act of measuring assigns value, potentially incentivizing behaviors. Hence, it's crucial to assess if a value and impact measurement may unintentionally promote negative actions



By aligning quantitative and qualitative measures with impact measures, it is possible to effectively track the progress and outcomes of Medical Affairs contributions and show how strategy translates into impact

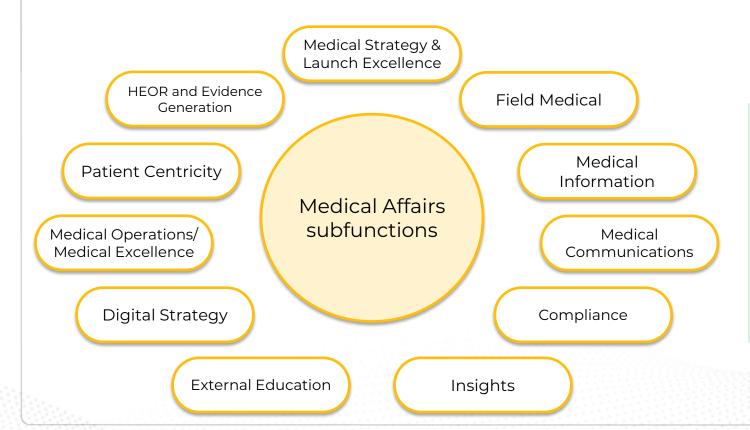




# 5. What measurements are used across Medical Affairs subfunctions?



# Meaningful measurements differ across Medical Affairs



Medical Affairs functions should be working towards a common set of broad outcomes or strategic objectives. The following slides provide examples of qualitative and quantitative measures across some of these functions, allowing teams to identify activities that will make a difference and to spend time more effectively



### **Medical Strategy and Launch Excellence**

# Validation or feedback on strategy from external experts/advisors KOL willingness to participate in programs/studies/speaker trainings Quantitative measures Key Medical Affairs deliverables executed according to the planned timeline Number of internal presentations and Q&As developed

## • 360 cross-functional reviews

# Number of internal presentations and Q&As developed Number of inputs reflected in Clinical Development Phase 2/3 studies, based on information gained in Medical Affairs advisory boards

### **Field Medical**

Qualitative measures	Quantitative measures	
<ul> <li>Structured insights questions to identify key strategic questions</li> <li>Actions taken after MSL engagements</li> <li>External expert endorsement of MSLs</li> <li>Number of requests for repeat or follow-up interactions</li> </ul>	<ul> <li>Number of scientific meetings or KOLs visited in a month/quarter</li> <li>Number of days in the field</li> <li>Average amount of time per interaction</li> <li>Number of actionable insights</li> <li>Number of competitive intelligence insights</li> <li>Number of interactions during a congress</li> <li>Number of interactions with investigators</li> </ul>	

<sup>\*</sup> Please note, examples only – this list is not exhaustive.





### Medical Information **Qualitative measures Ouantitative measures** Customer satisfaction Service level - Rating on material received Inquiry volume - Likelihood of calling this • Response turnaround time · Number of new medical company again Rating on contract center information requests employee - Comparisons to other companies • Newly identified actionable insights • Type of medical information inquiry

## \* Please note, examples only – this list is not exhaustive.

### Medical Communications

# Qualitative measures Quantitative measures

- Symposium or event feedback/evaluations
- Altmetrics/engagement with publications
- Editorial comments, news stories, social media sharing and sentiment analysis
- Guidelines amends or updates
- HCP interaction with scientific content at a medical booth
- Market research Knowledge, Attitudes, and Practices (KAP) research assesses understanding of physicians, including what they know, their attitude, and practice
- Share of scientific voice (how does visibility compare to a set of comparators?)

- Number of publication acceptances
- Number of symposia; attendance at symposia
- Number of abstracts per scientific conference
- Number of interactions during a congress or post-congress
- Number of HCP visits to the medical scientific booth
- Number of post-congress reports developed



# Qualitative measures Impact of insights on strategy Actions taken and results achieved based on insights delivered Quality of insights delivered (leadership feedback) Quality of insights delivered information inquiries

#### **External Education Qualitative measures Quantitative measures** • Impact of medical content (eq. Number of educational events via Moore's Model and delivered behavioral change · Number of events sponsored measurements/evaluations) Number of speaker trainings HCP recommendations Analytics from online Depending on educational resources, number of downloads, frequency of visits activity: - Time to diagnosis to the educational site, etc. - Time to treatment initiation

\* Please note, examples only – this list is not exhaustive.



#### Digital strategy **Quantitative measures Qualitative measures** Interaction and sentiment with Web: User journeys, social media posts conversions, bounce rates, Surveys and feedback scores • Views and dwell time; what is • E-mail: Receipts, opens, clicks of most interest • Event apps: Interactions, • Share of digital voice (what are scores, contact detials HCPs and individuals talking collected about online?) • Social media: Volume, shares · Sentiment reach (unaided scientific dissemination) what percentage of medical experts drive dissemination of publications/education?

### Medical Operations/Excellence

Qualitative measures	Quantitative measures
<ul> <li>Consistency of approaches across geographies and therapy areas</li> <li>Team perspectives on processes and platforms/resources</li> <li>Cross-functional and senior leadership feedback</li> <li>Industry benchmarking</li> </ul>	<ul> <li>Uptake and use of resources</li> <li>Delivery of agreed activities on time (and aligned to the Medical plan)</li> </ul>

<sup>\*</sup> Please note, examples only – this list is not exhaustive.





#### **HEOR and Evidence Generation Qualitative measures Quantitative measures** • Types of proposal submitted • Number of patients enrolled in for investigator-initiated study • Turnaround time for proposals studies Willingness of internal and · Speed of updates to internal external partners to engage in education resources collaboration analysis Number of investigators/study Feedback from internal sites partners regarding the IEP Number of clinical trials development process supported by Medical Affairs Feedback from internal and Number of core value dossiers external stakeholders submitted to payers regarding the value of the evidence Real-world evidence sources that validate evidence from clinical trials

Qualitative measures	Quantitative measures
Insights and feedback from advocacy groups and patients (eg, via advisory boards, surveys, etc)	<ul> <li>Number of patient advocacy group interactions</li> <li>Number of patient lay summaries developed</li> <li>Number of patient advisory boards held</li> </ul>

**Patient Centricity** 

<sup>\*</sup> Please note, examples only – this list is not exhaustive.



6. How can we set ourselves up for success?



# A measurement mindset is critical to success

- Medical Affairs teams need to establish a measurement mindset
- However, demonstrating measurable impact is challenging, and may require a longer timeframe than more traditional quantitative measurements
- Furthermore, success is harder to achieve; as such, it is critical that teams understand that if a KPI is not achieved, this does not equate to failure but represents an opportunity to learn





# Operationalizing strategy and meaningful value and impact measurements



It is critical for Medical Affairs subfunctions to align on how to execute the tactical plan, as well as track and assess the associated impact



Ensures a level of accountability within each subfunction and systematic assessment of whether the group is on track or requires adjustments in their plans



It is important to gain an understanding of what the baseline may be for any pertinent measurements; in particular, those that are measuring a change in attitude or perception (compared over time as impact is assessed)



# Planning an activity should start with reverse engineering – keep the end goal in mind

- What do you want to achieve with the activity? Are the objectives clearly defined and linked to the medical plan?
- Is the activity the most effective activity to achieve the desired outcomes?
- What are the best predictors of impact? Can surrogate predictors of impact be used? How do we assess the cumulative effect of multiple activities?
- What worked well in the past? What learnings can we identify from previous activities and measurements of impact?





# Checklist of things to consider



Are all team members aligned with the current medical plan and the defined value and impact measurements?



What can be measured from a cross-functional perspective?



Are the selected measurements appropriate, and will they bring value to the organization?



How should value and impact measurements be tracked and reported?



How often should goals be reassessed for relevance to landscape changes (eg, quarterly)?



How should progress towards broader strategic objectives be assessed outside of the tactical measures?

Make it relevant, timely, and easy... and optimize opportunities for feedback from cross-functional teams to identify best practice





# Communication of successes and applying learnings are critical to success

## **Communicating successes**

- ✓ Set clear expectations with the broader organization regarding what can be expected from Medical Affairs and when it will be delivered
- ✓ Communicate successes, milestones, and insights across the organization to keep senior leadership informed
- ✓ Consider regular updates to key stakeholders in commercial and clinical development

## Learn and implement changes

- ✓ Hold regular team meetings with Medical Affairs sub-functions to monitor on tactical execution, discuss challenges, and next steps
- ✓ Take time to reflect on lessons learned after each project is completed and refine your approach for future tactics
- ✓ Share data and insights across the team to assess the medical plan's effectiveness in achieving goals
- ✓ Encourage open communication and feedback to re-evaluate the strategy and tactics as needed
- ✓ Share best practices and knowledge within the organization



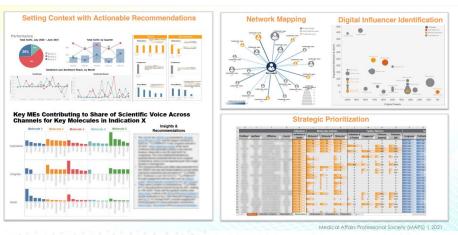


# How can technology help?

Technology can provide a mechanism to capture and record the measurement approaches and results of activities being conducted

- Medical Affairs dashboards provide a single location to catalog planned tactics as well as identified value and impact measurements, including comparison to baseline assessments
  - Provides a wealth of data and insights
  - Straightforward and fast to complete
  - Supports tracking across workstreams
  - Useful for reporting to senior management
- Different datasets can be used to analyze impact, including real-world databases (eg, claims databases)









## What do we need to succeed?



Common understanding of our bold vision and alignment with strategy (and cross-functional teams)



Visionary and determined senior medical leaders to drive change



Elevated performance expectations for HCP experiences and patient outcomes



New robust meaningful measures and data analytics platforms

Value and impact measurements must be regularly evaluated, continuously adjusted/improved (for relevancy), and integrated into decision-making processes.



# Key takeaways/summary



When operationalized, prospectively designed meaningful measurements can enhance how our industry can improve patient outcomes, delivering on the strategy that medical drives as part of wider cross-functional teams alongside R&D and commercial teams



Identification of more outcome-focused measurements (impact measures) enable us to better understand the value Medical Affairs creates for patients, HCPs, and the organization

A focus on quality is required; more value is obtained from a combination of qualitative and quantitative measures than on quantitative measurements alone



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