

Launch Readiness 2020 – Ensuring Strategy & Value from Global to Local Perspective

Disclaimer



The views expressed in this Webinar are those of the presenters, and are not an official position statement by MAPS, nor do they necessarily represent the views of the presenters' employers, the MAPS organization or its members.

Introductions



Roseann Peluso Nguyen, Pharm.D.
Global Medical Affairs Director
Global Commercial Strategy Organization
Janssen Global Services, LLC

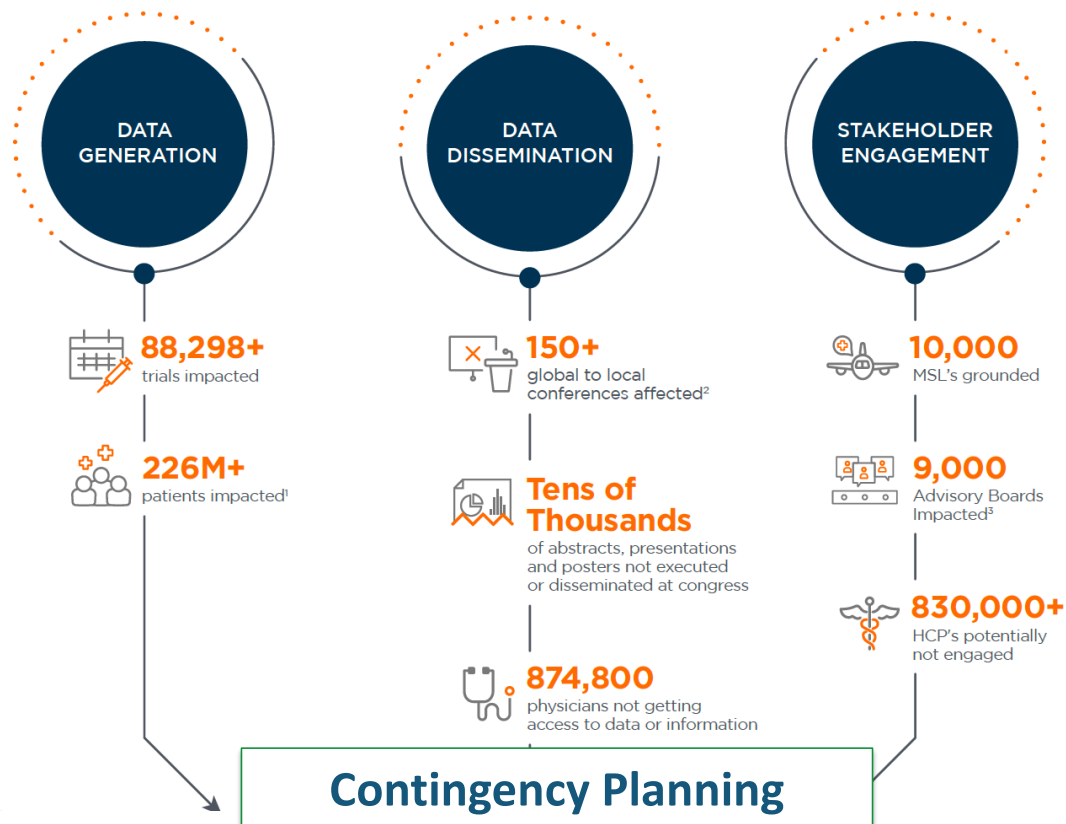


Vimal Patel, Pharm.D.
National Director
Field Medical Affairs
Incyte



Anna Walz
CEO / Founder
MedEvoke

COVID-19 Impact on Key Functions



Medical Affairs Professional Society | 2020

Launch Readiness 2020 Ensuring Strategy & Value from Global to Local Perspective

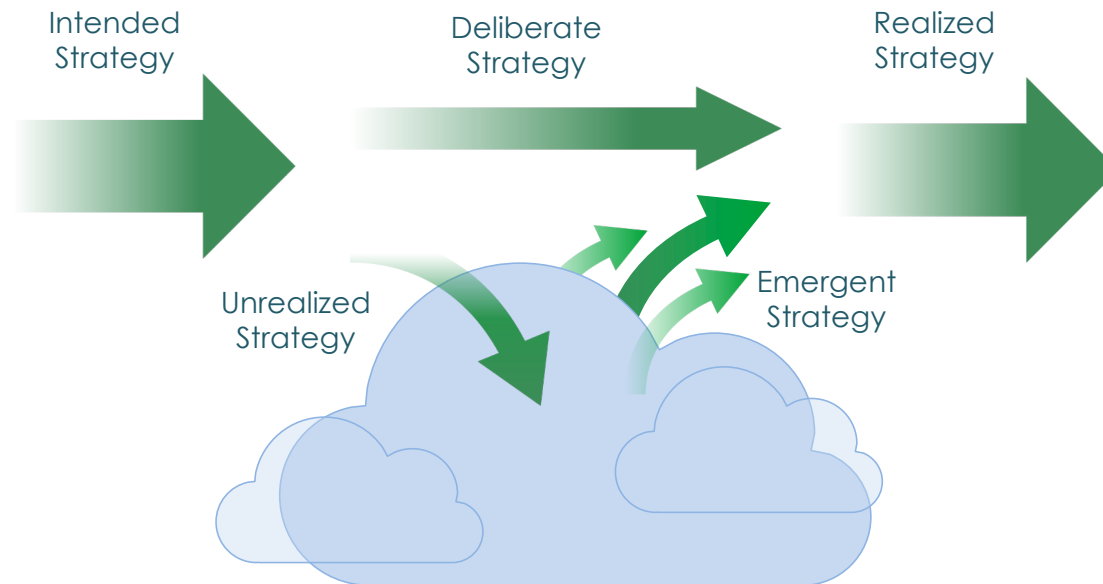


What is Strategy Related to Launch?

1. Medical Affairs Launch Readiness
 - What is the role for medical affairs in launch readiness?
 - Who is part of launch readiness and how is it accomplished?
2. Execution of Global Strategic Plans at the Regional Level
 - How do local affiliates impact the global strategy?
3. Demonstrating Value & Impact for Medical Affairs
 - What performance measures (KPIs) can we use to refine strategy?



Launch Strategy: A Defined Plan of Action + Capitalizing on Market Shifts

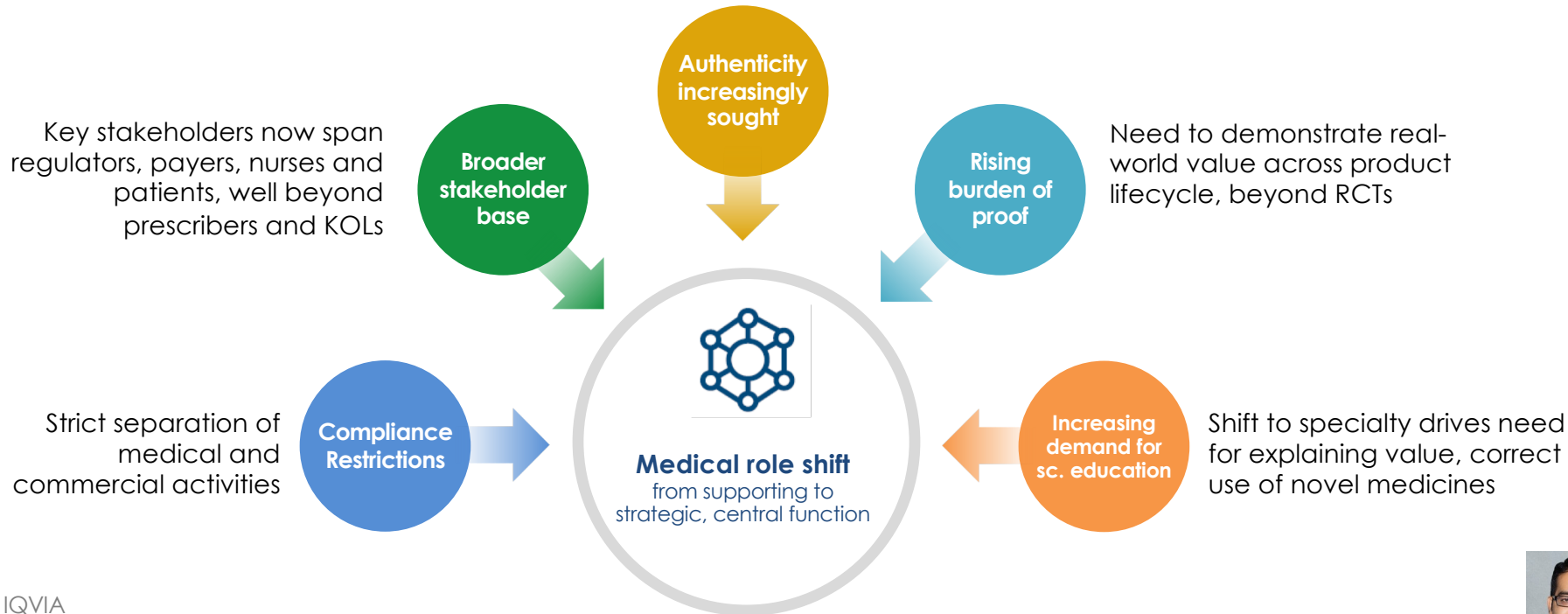


Mintzberg, H. & J.A. Walters. 1985. Of Strategies, Deliberate and Emergent Strategic Management Journal. 6 (3), 257-272.



Changing Healthcare Landscape and Evolving Role of Medical Affairs

Stakeholders seeking authenticity:
unbiased information, trust-based engagements

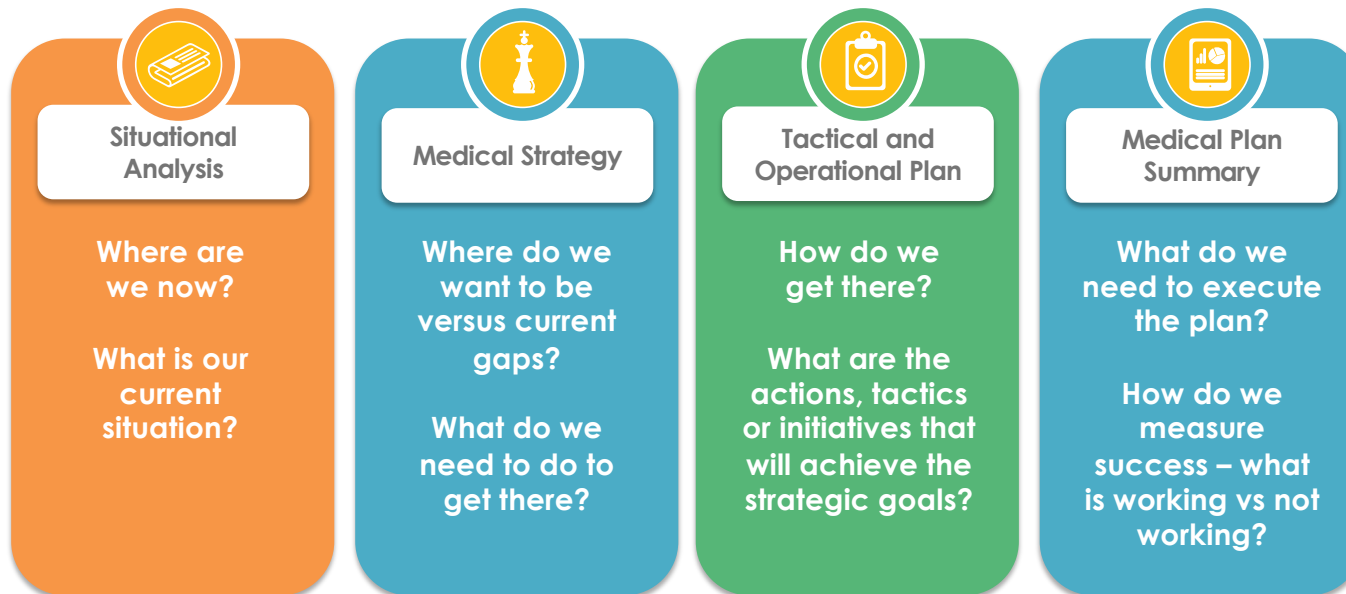


Source: IQVIA

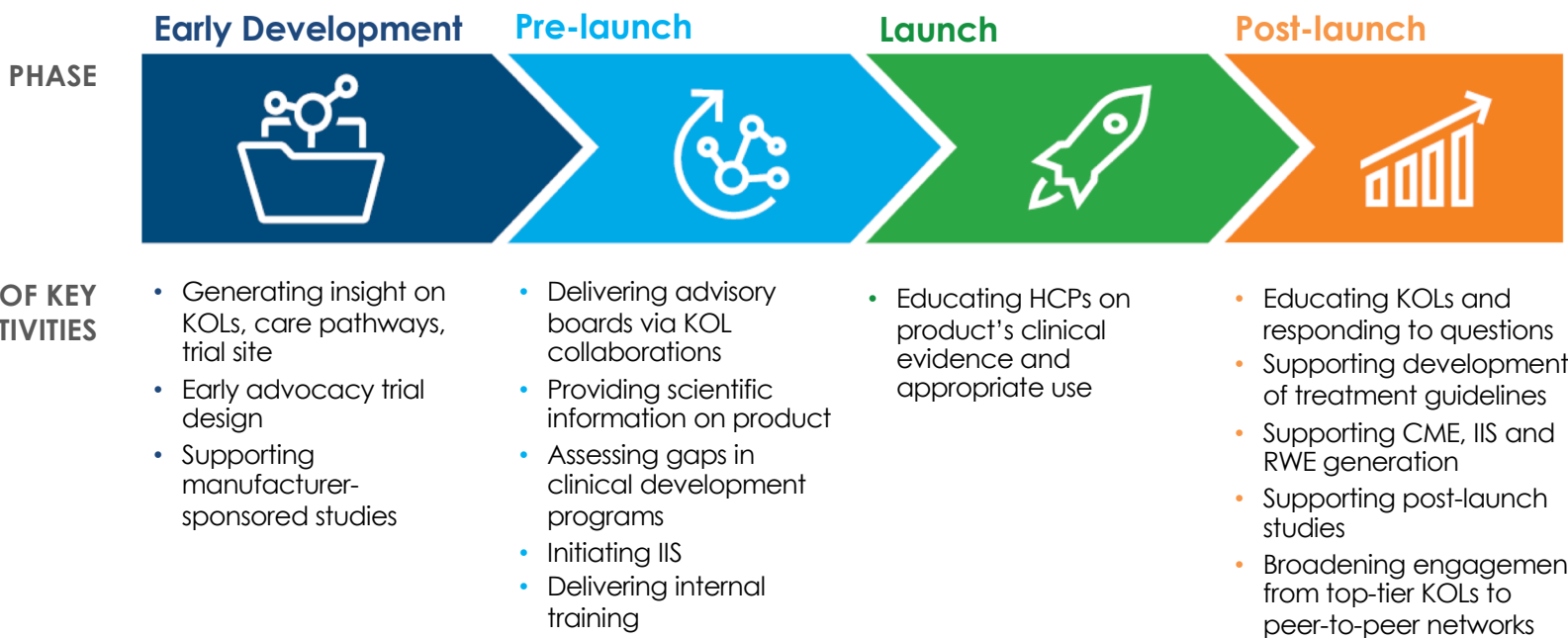


Medical Affairs Launch Readiness

Building a Defined Plan for Medical Affairs



Medical Affairs Activities Evolve Over the Product Lifecycle

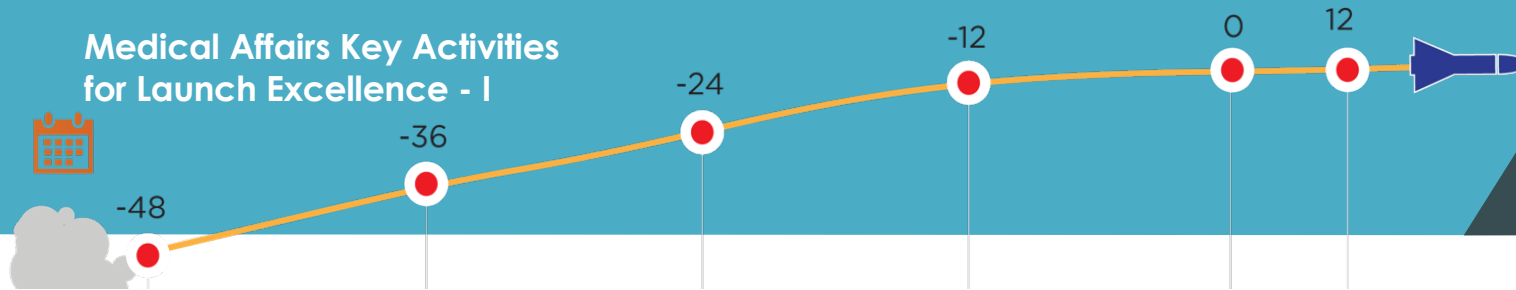


Educating internal stakeholders on latest scientific information and company's medical strategy

Source: IQVIA

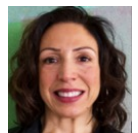


Medical Affairs Key Activities for Launch Excellence - I

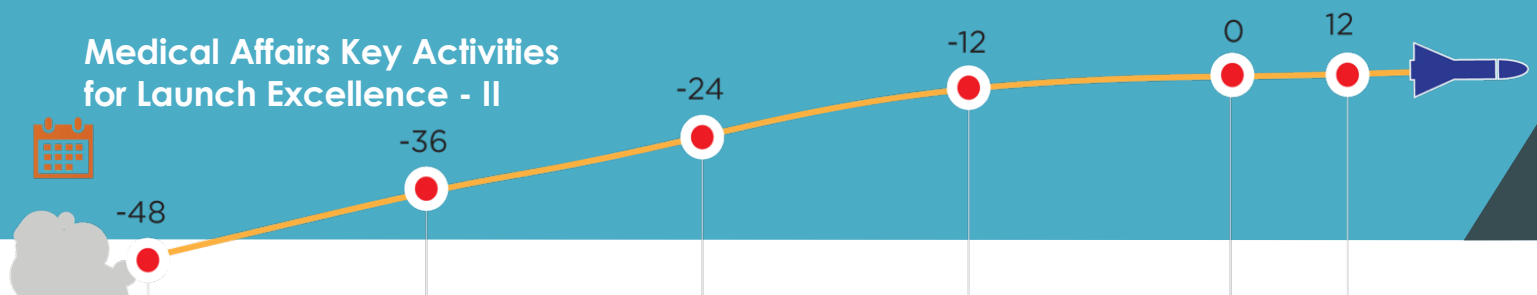


	Pre-launch (T=-48 to -12 months)	Launch (T=-12 to 0 months)	Post-launch (T=0 to 12 months)
Medical Leadership: Strategic Planning <ul style="list-style-type: none"> • Early Medical Insights for Clinical Development • Medical Team Formation and Expansion • Development of Strategic Imperatives • Conduct Situational and Gap Analysis • Identification of Unmet Needs • Building Cross-Functional Partnerships 	<ul style="list-style-type: none"> • Cross-Functional (Medical/Market Access) Strategic Development & Execution 		
	<ul style="list-style-type: none"> • Launch Readiness Planning and Launch Execution Excellence 		<ul style="list-style-type: none"> • Life Cycle Management/ New Product Development
Medical Leadership: Data/Evidence Generation <ul style="list-style-type: none"> • Evidence Generation Planning • Support Programs and Deliverables to Drive Value and Align to Gaps and Opportunities • Leading and Lagging Indicators • Maximize Data Sources • Identify Patient Care Needs • Clinical Program Support (Recruitment, Site Support, Educate Scientific Community on Phase III Study Protocol) 	<ul style="list-style-type: none"> • Outcomes Research Studies • Investigator-Initiated Research Planning and Execution • Medical Advisory Board 		
	<ul style="list-style-type: none"> • Post Approval (eg, Phase IV) Study Strategy & Planning 	<ul style="list-style-type: none"> • Post Approval (eg, Phase IV) Study Execution • Patient Registry Trials 	

Farhood et al., Medical Affairs Launch Excellence Best Practices for Medical Affairs. 2019. Medical Affairs Professional Society. Medical Affairs Professional Society | 2020



Medical Affairs Key Activities for Launch Excellence - II

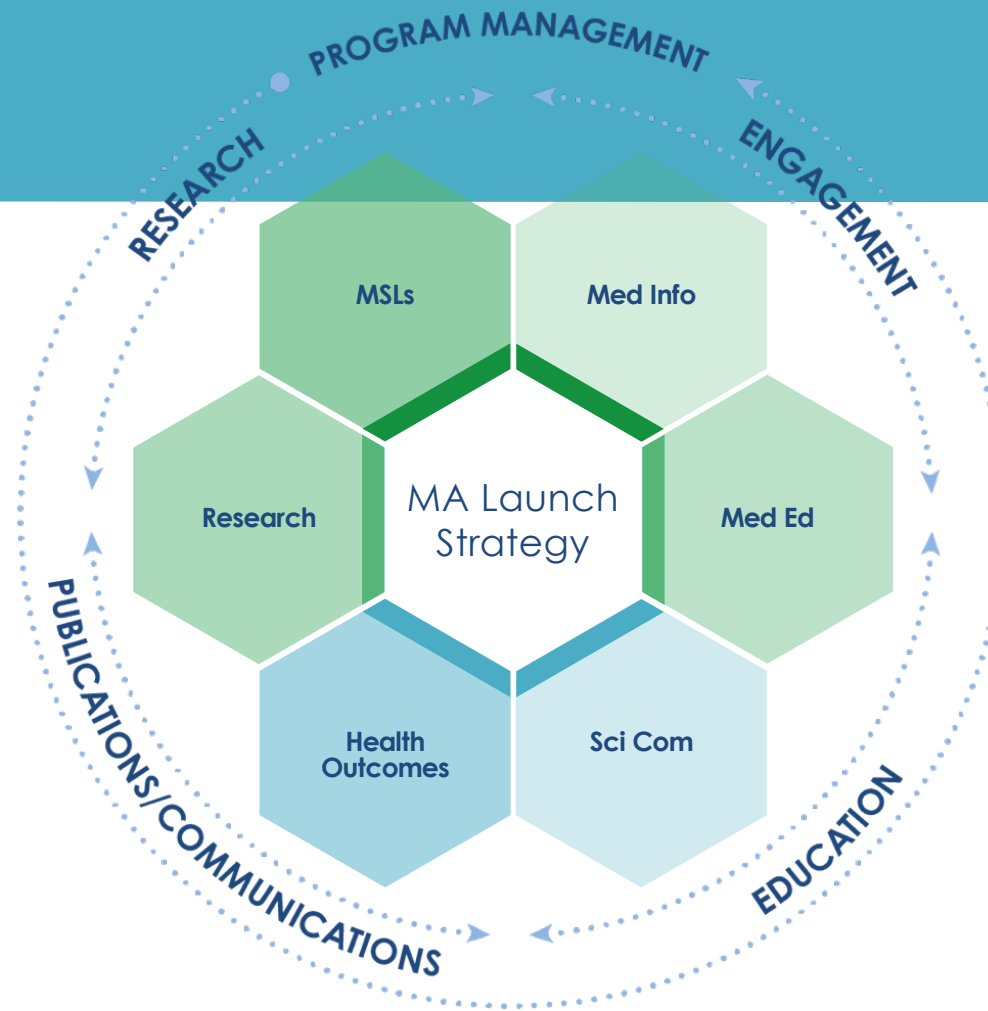


	Pre-launch (T=48 to -12 months)	Launch (T=12 to -0 months)	Post-launch (T=0 to 12 months)
Medical Information & Communication: Data/Evidence Dissemination	<ul style="list-style-type: none"> Building Cross-Functional Partnerships Key Communication Objective Development Communicate Early Trial Data Create Medical Communication Platform Develop Education & Publication & Congress Plans Data Dissemination Strategy Lexicon Development Identify Key Tools 	<ul style="list-style-type: none"> Medical Communication Planning Medical Education and Grants Management Medical Advisory Boards 	<ul style="list-style-type: none"> Medical Communications Execution (Publications, Congresses/Symposia)
Medical Knowledge/Management: Education, Communication	<ul style="list-style-type: none"> Provide Internal Disease and Product Information Training 	<ul style="list-style-type: none"> Medical Information Planning Medical Advisory Board Planning Medical Education Planning 	<ul style="list-style-type: none"> Medical Information (Unsolicited Requests, SRLs, FAQs, Call Center) Execution & Updates Report on Product Insights Medical Advisory Board Medical Education and Training
Partnership/Interactions: Medical Community/ Stakeholder Engagement	<ul style="list-style-type: none"> Medical Community Planning 	<ul style="list-style-type: none"> Field Medical Training 	
Organizational Support	<ul style="list-style-type: none"> Establish a Team of Medical Information Experts (Disease State, Mechanism of Action, Competitive Landscape, Access, Reimbursement, Clinical Data) 	<ul style="list-style-type: none"> Medical Community (Thought Leader/HCP, Payer & Policy Makers, Patient, Advocacy Groups) Engagement and Development Gather Feedback on Opinions, Interests, and Experience Facilitate Transition From New Product Development to Commercial Launch Provide Medical Training, Participate in Cross-Functional Leadership Meetings and Insight Dissemination Efforts 	<ul style="list-style-type: none"> Insight Dissemination from RWE, HCP Interactions, and Medical Information Requests

Farhood et al., Medical Affairs Launch Excellence Best Practices for Medical Affairs, 2019, Medical Affairs Professional Society.



Medical Affairs



Medical Affairs Launch Excellence



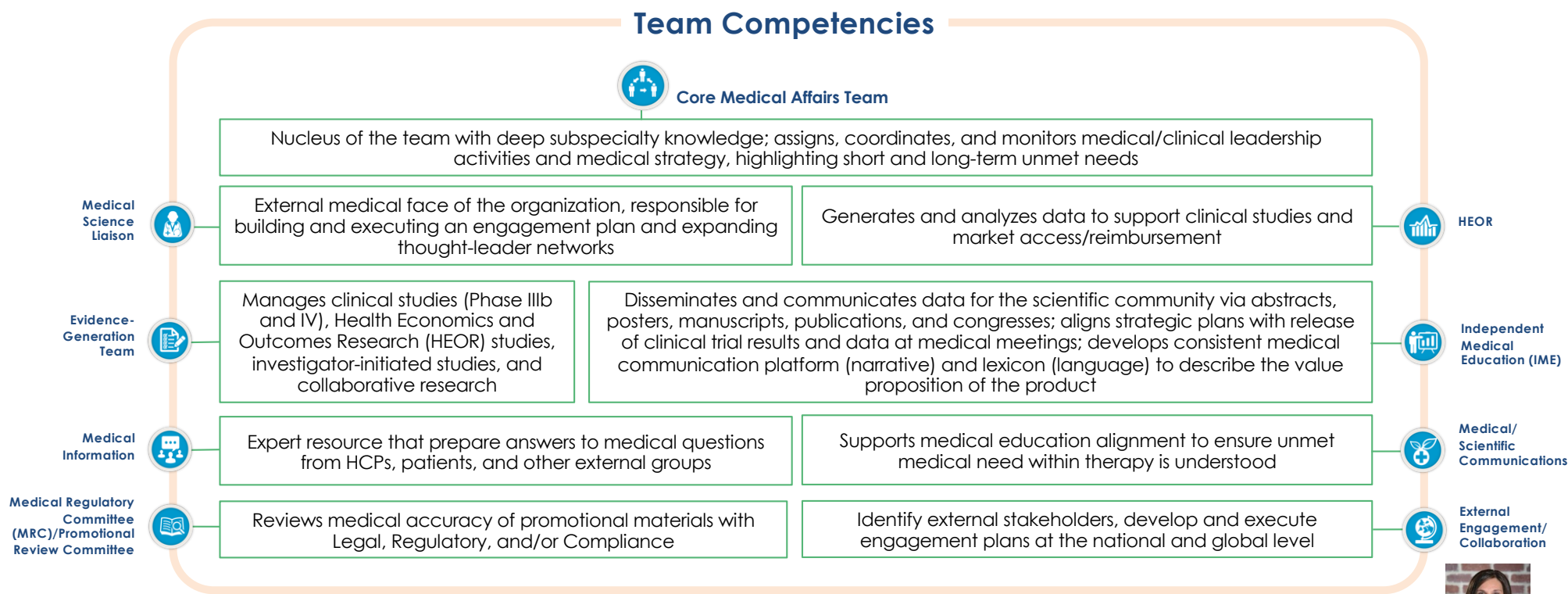
- Based on defining the activities, processes, and behaviors required for a high-performing team
 - Behaviors can be leveraged and measured to provide guidance over time
- Requires optimal alignment across countries, therapeutic areas, and management for
 - Efficiency
 - Effectiveness
 - Compliance
 - Consistency
 - Best practice
- Requires that a launch strategy be in place and that it is understood, accepted, and applied throughout the organization

By showcasing excellence, the Medical Affairs community establishes its role within the pharmaceutical industry and can further create opportunities to expand its responsibilities and contributions post-launch.

Tebbey PW, Berheiser JK, Mattick RN. Brand momentum: the measure of great pharmaceutical brands. J Med Market. 2009;9:221-232.



Medical Affairs Launch Team Structure & Competency Considerations



Farhood et al., Medical Affairs Launch Excellence Best Practices for Medical Affairs. 2019. Medical Affairs Professional Society.

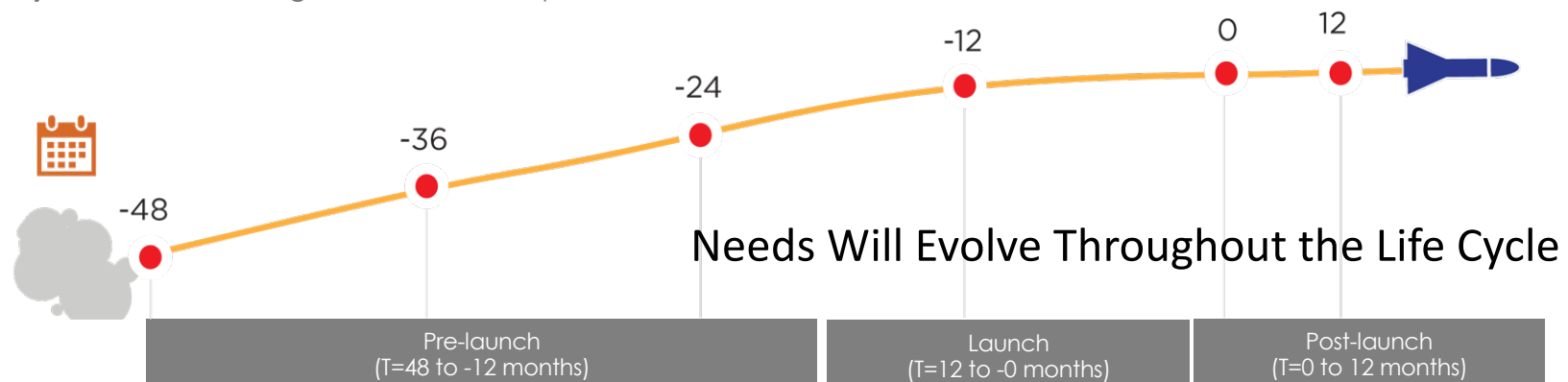


Optimal Time to Begin Medical Affairs Launch Strategy Planning Is as Early as Proof of Concept



Factors that impact timing

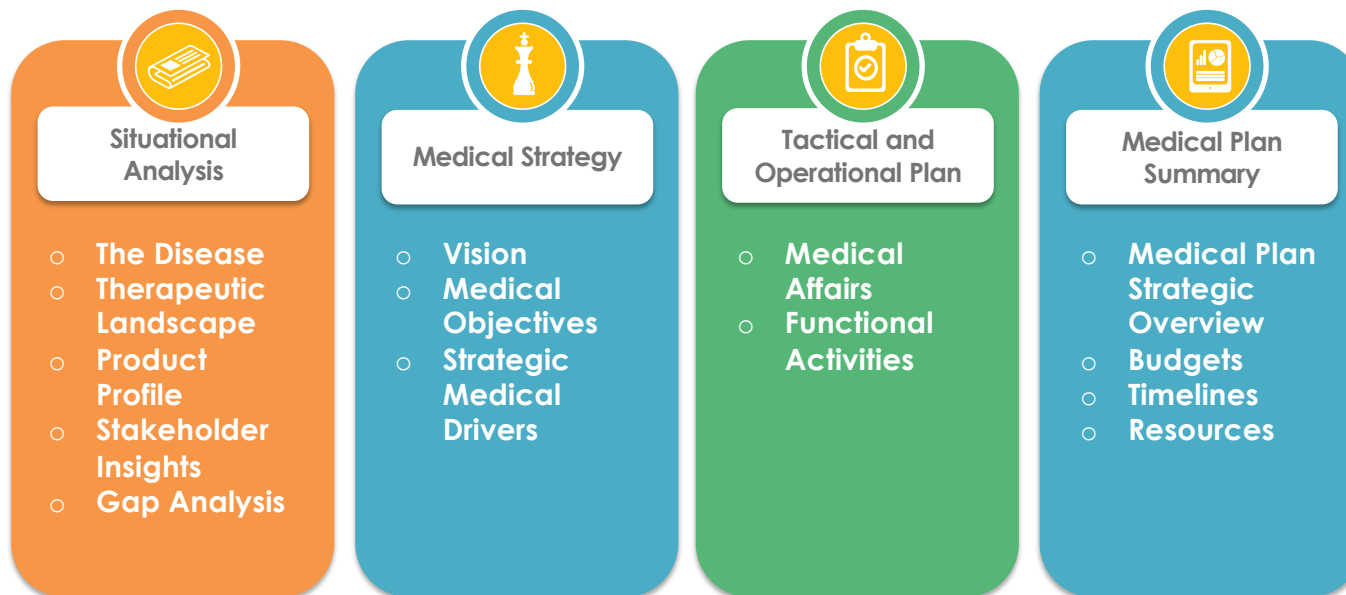
- Level of disease-state awareness
- Need for market preparation
- Company experience, type, and size
- Global launch sequence
 - Core countries should be involved with strategic planning discussions very early to contribute to building global objectives and strategies and address specific market needs



Medical Affairs Professional Society | 2020



Medical Affairs Strategic Planning Overview: Content

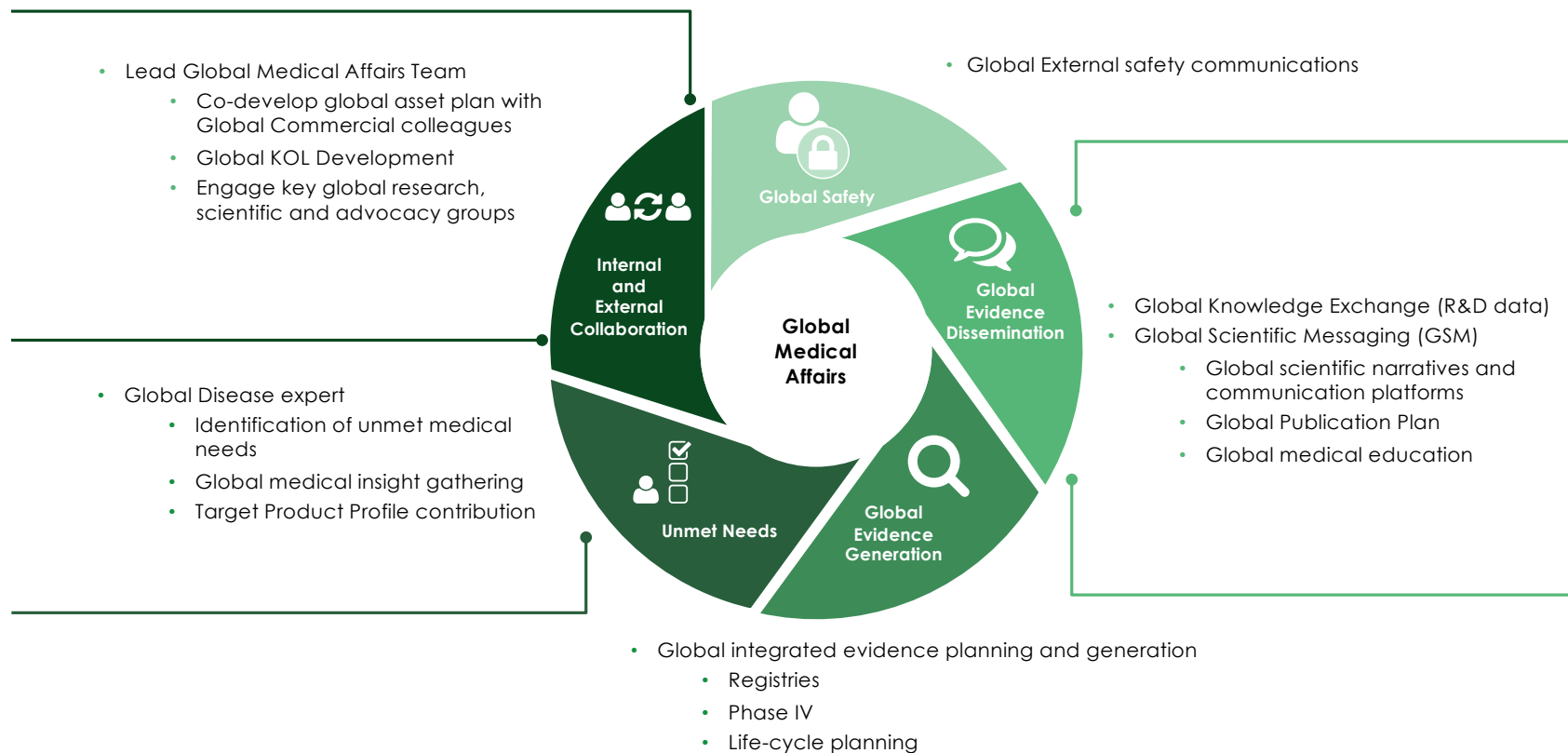


Execution of Global Strategic Plans at the Regional Level

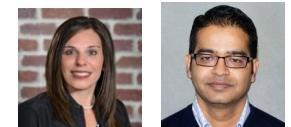
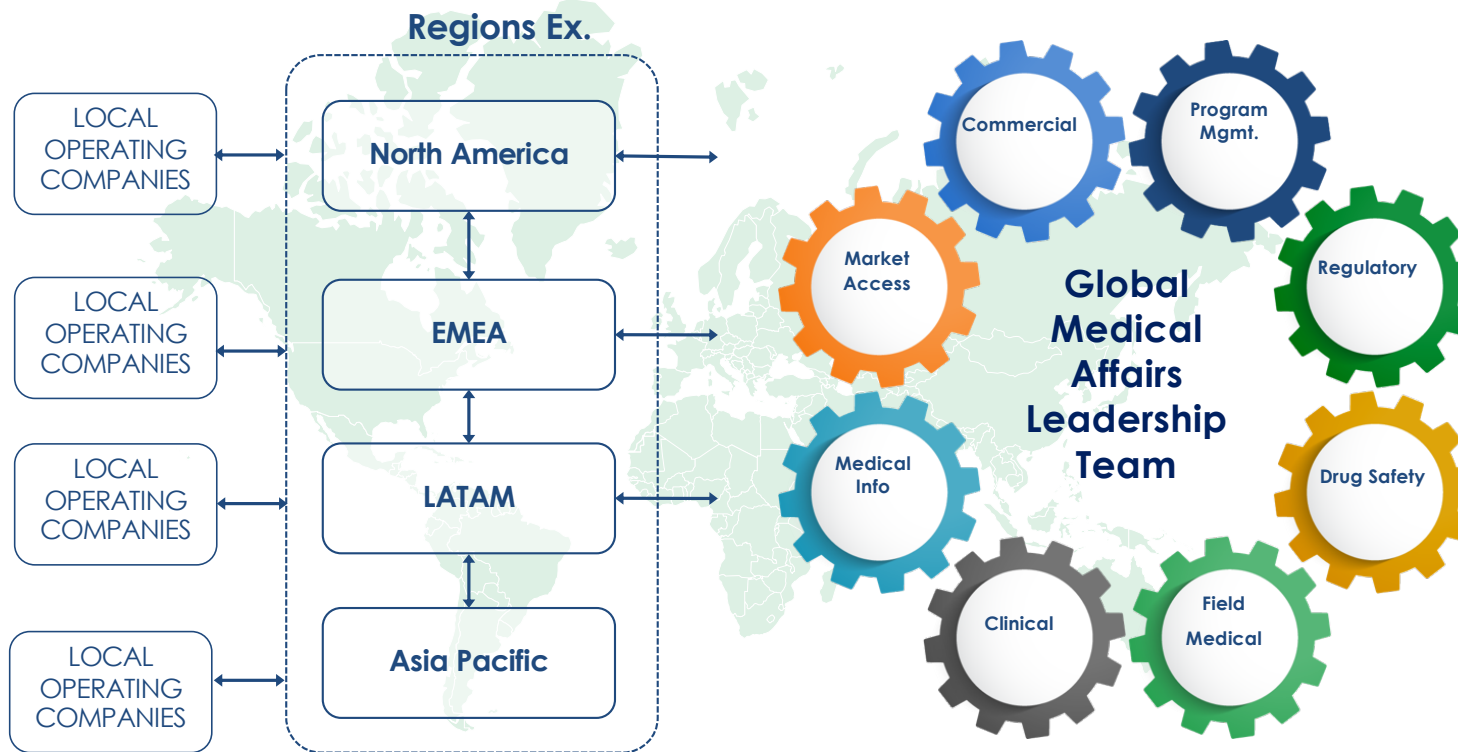
GMA's Critical Role in Preparing The World For A New Therapeutic



Global Medical Affairs: Key Roles & Responsibilities



Local & Regional Input Essential to Global Medical Affairs



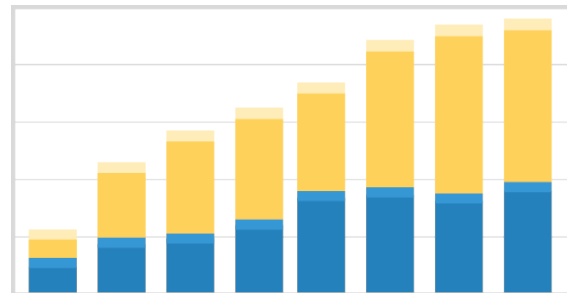
Demonstrating Value & Impact for Medical Affairs

Traditional Approach to Planning

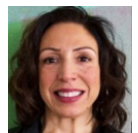
Inward Looking, Volume Based (e.g.)



Prior Year Plans
(What we did before)



Volume of Contribution
(How much did we do last year and how it compared to others)



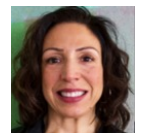
Traditional Approach to Measuring Impact

Volume-based, Inward Looking (e.g.)

Publication Volume



Journal Impact factors



Traditional Approach to Measuring Impact



Medical Activities	Sample Metrics	Limitations
Scientific Communications	Data disseminations (e.g. slide decks)	No Assessment of impact over time
Field Medical	Prescriber Interactions	Limited and/or potentially biased sample size
Clinical/Medical Strategy	Field Medical Insights	Limited and/or potentially biased sample size
Publication strategy	Number of congress attendees or journal impact factors	One dimensional assessment of output



Determining the Success of the Medical Strategic Plan

Analysis & Insights



- Outcomes-based metrics are needed to access the impact of the medical strategic plan objectives
- KPIs evaluate performance of efforts
- Analyze quantitative KPIs against each milestone
- Determine adjustments needed based on ongoing assessment

KPIs=Key performance indicators



Evolved Measures Drive Strategic Decision Making

Implementing 3-D Perspective of Impact

Scientific Publications



Congress Exchange



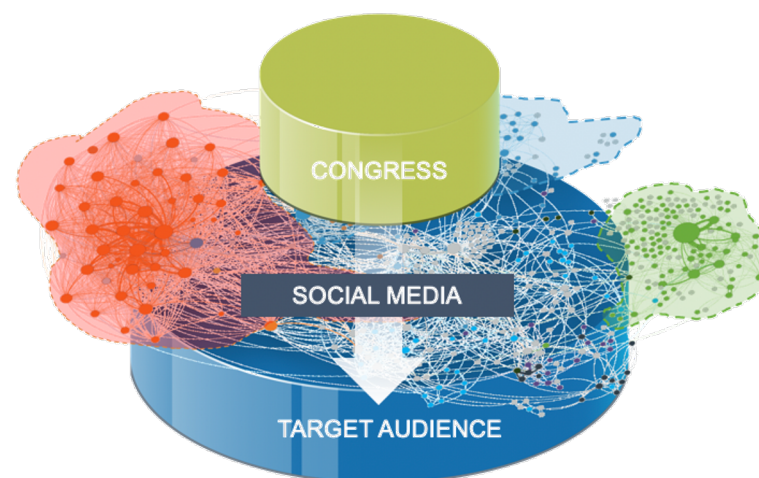
Digital Impact



Impact Assessed Across the Scientific Communications Continuum

...Allows for Data Informed Strategic Planning

- Track the actual impact of product research and publications on your physician prescriber base
- Use data to drive direction during planning cycles for new and established products
- Encourage cross-function teams to apply insights from data to adjust scientific communications focus



Medical Affairs Assessing Impact

Measuring Impact and Uptake of Efforts

Assessing your strategy with key checkpoints:



- What has been the impact of our efforts thus far?
- What have our competitors done?
- Should we stay the course or shift gears?
- Am I under- or over-resourced in certain area?
- Do I have the right KOLs/DOLs?
- Does our proposed strategy resonate outside our organization?
- What topics resonate with which external stakeholders?
- Do my strategic imperatives match up with my proposed plan?



Medical Affairs Assessing Impact To Evolve Medical Strategy & Planning



Strategic Implications & Recommendations



Evolved Strategic Planning: Creating a Clear Path Forward

- ✓ Use insights to inform strategic & functional plans
- ✓ Track performance against benchmarks & KPI's
- ✓ Monitor through quantitative & qualitative measures
- ✓ Evolve plans by utilizing progress insights to maximize impact and optimize efficiencies
- ✓ Implement & incorporate updates to strategic & tactical plans during yearly cycles
 - Encourage cross-function teams to apply insights from analysis to adjust scientific communications focus

