



# Crafting strategic objectives to guide and measure success

Focus Area Working Group: Medical Strategy and Launch Excellence

## Moderator and presenters



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## Conflict of interest and disclosures

#### The speakers have no conflicts of interest to disclose

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#### Fundamentals of Strategy webinar series





#### Update coming in 2024!



#### https://medicalaffairs.org/content-hub/

## **Educational outcomes**

#### At the end of the session, you will be able to:

- Effectively leverage the product profile and landscape analysis to inform the strategic objectives
- Identify the overall components of robust objectives
- Understand how and when to collaborate on the medical strategy and objective development
- Apply the fundamentals of measuring objectives



## Have you been involved in the development of medical strategy/objectives?

- Yes
- No





# Using the product profile and landscape analysis to inform the strategic objectives

Gorana Dasic, MD, MS Global Medical Affairs Head, Kedrion Biopharma

## Typical medical plan framework

#### Situational Analysis

- Disease State
- Therapeutic Landscape
- Product Profile
- Stakeholder Insights
- Gap Analysis
- SWOT

#### Medical Strategy

- Vision
- Medical Objectives
- Strategic Medical Drivers



#### Tactical and Operational Plan

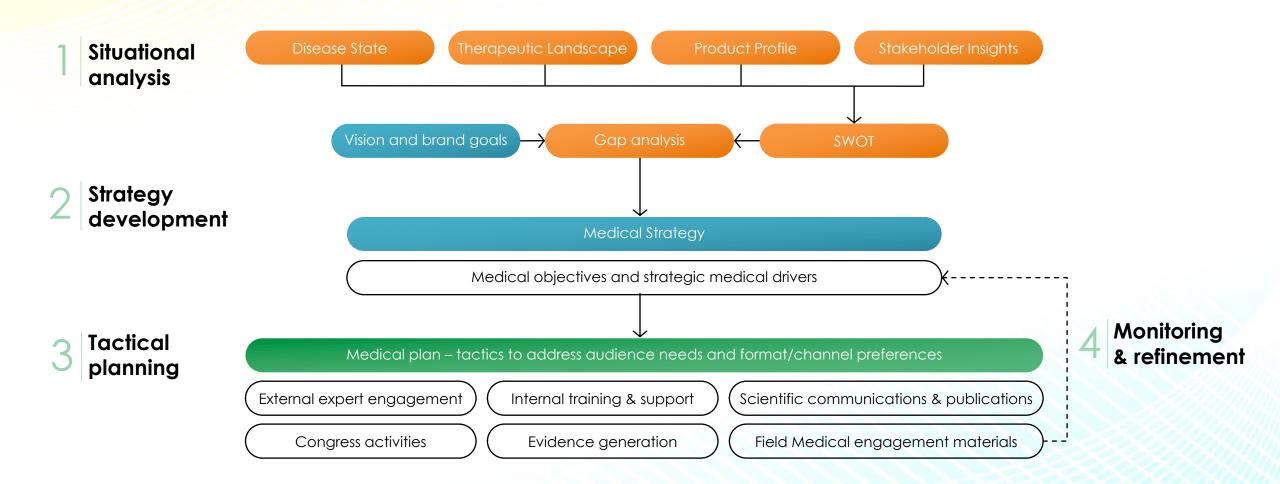
- Medical Affairs Tactics
- Target Audiences/ Stakeholders
- Functional Workstreams



#### Medical Plan Summary

- Medical Plan
   Strategic Overview
- Budgets
- Timelines
- Resources

A robust, strategic medical plan is developed based on clearly defined cross-functional methodology



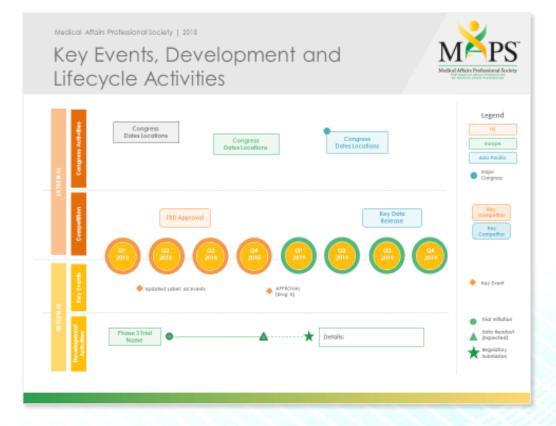
## Your product profile

Medical Affairs Professional Society | 2018



#### Target Product Profile (if Pre-Launch)

Oplimistic			Safely and Tolerability	Dosing/ Administration	
		a (Approvable encipaints)	6 [780]	6 [TBD]	6 [780]
Lorget -	[Patient type] [Line of therapy] [Diagnosfic requirement]	o (18D)	e (780)	e (780)	e (780)
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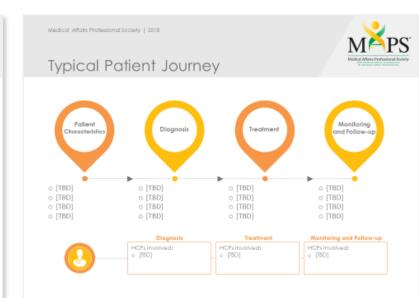
MAPS Medical Affairs Strategic Planning Guide and Template, 2018. Access via <u>https://medicalaffairs.org/maps-strategic-planning-guide-and-template/</u>

## Disease landscape

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Patient Clinical and Treatment Flow (Tree Diagram)

		therapeutic area therapeutic area			
Prevalence/Incidence			(Description and Number)		
Burden of Disease			[Description and Number]		
Diagnosis			[Description and Number]		
Treatment Choice		[Description and Number]			soription Number]
Class/Product Choice	[Description ond Number]	[Description ond Number]	[Description ond Number]	[Description ond Number]	[Description and Number]



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External Stakeholder		
<b>[External expert]</b> [Summary]	[Describe major insights relative to stakeholder perception of value]	[Describe the implications relative to informing medical strategy]
[Healthcare professional] [Summary]		
[Payers/HTA] [Summary]		
(Patients) (Summary)		
Other (eg, advocacy groups, caregivers, etc.) [Summary]		

"All sources (Advisory boards, literature, Field Medical engagement, and others)

MAPS Medical Affairs Strategic Planning Guide and Template, 2018. Access via <u>https://medicalaffairs.org/maps-strategic-planning-guide-and-template/</u>

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## Therapeutic landscape

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Competitive Landscape: Overview

llem			Compelifor B	Competitor C
Company	[780]	lueol	[780]	[180]
Company therapeutic expertise				
Phase of development				
Key clinical trials (ongoing)				
Lounch dates (completed and anticipated)				
Key scientific differentiators				
Strengths				
Weakness				
Regions available				
Cost				



#### Competitive Landscape: Label Comparison



Characteristic		Medical/ Scientific Advantage			
Indication/status	[TBD]	[T80: +=]	[080]	[G87]	[780]
Doxage and administration					
Efficacy					
Side effects/tolerability					
Salety/contraindicated population					
Pharmacokinelics					
Mechanism of action					

\*+ Indicates medical arscientific advantage for product; = indicates product equivalence;-indicates product disadvantage

MAPS Medical Affairs Strategic Planning Guide and Template, 2018. Access via <u>https://medicalaffairs.org/maps-strategic-planning-guide-and-template/</u>

#### Output will help guide medical and scientific strategy by answering key questions



How do we capitalize on or use each strength to differentiate? How do we overcome or stop each weakness

How do we take advantage of each opportunity?



SWOT Analysis: A Useful Tool to Help Define Strategic Business Planning. MAPS Medical Strategy & Launch Excellence FAWG Webinar, 2021.

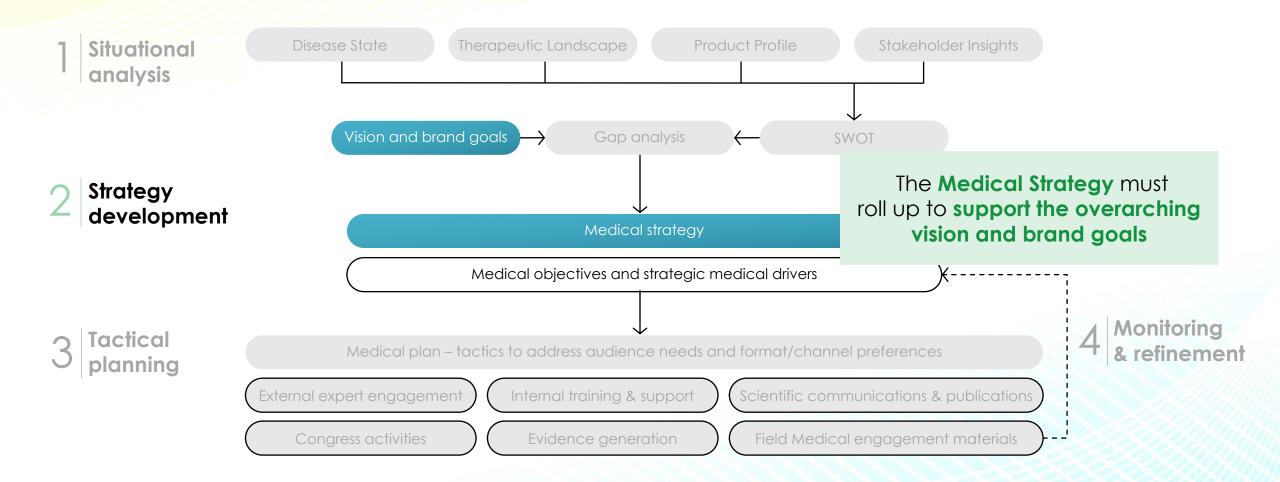
Product Y:	A mAb in a dermatology indication	EXAMIDE
Internal: Product or Company Specific	<ul> <li>Strengths (+)</li> <li>Infrequent dosing (convenience)</li> <li>Part of a portfolio of products</li> <li>Company is a scientific leader in dermatology</li> <li>First-in-class novel MoA</li> <li>Better efficacy versus standard of care in direct H2H studies</li> <li>No unexpected safety signals</li> </ul>	<ul> <li>Weaknesses (-)</li> <li>Delayed launch</li> <li>Not clinically differentiated</li> <li>Misperception of safety concern (driven by competitor messaging)</li> </ul>
External:	Opportunities (+)	Threats (-)
Market- Environment Specific	<ul> <li>Large unmet need and an expanding market</li> <li>Patient preference for less frequent dosing (helps them forget their disease)</li> <li>Patients want improved efficacy from treatment</li> </ul>	<ul> <li>Competitive market that is perception-driven</li> <li>Large competitor companies are well established</li> <li>Price points are lowering due to biosimilars</li> <li>HCPs do not have desire to improve treatment goals (disconnect with patients)</li> </ul>



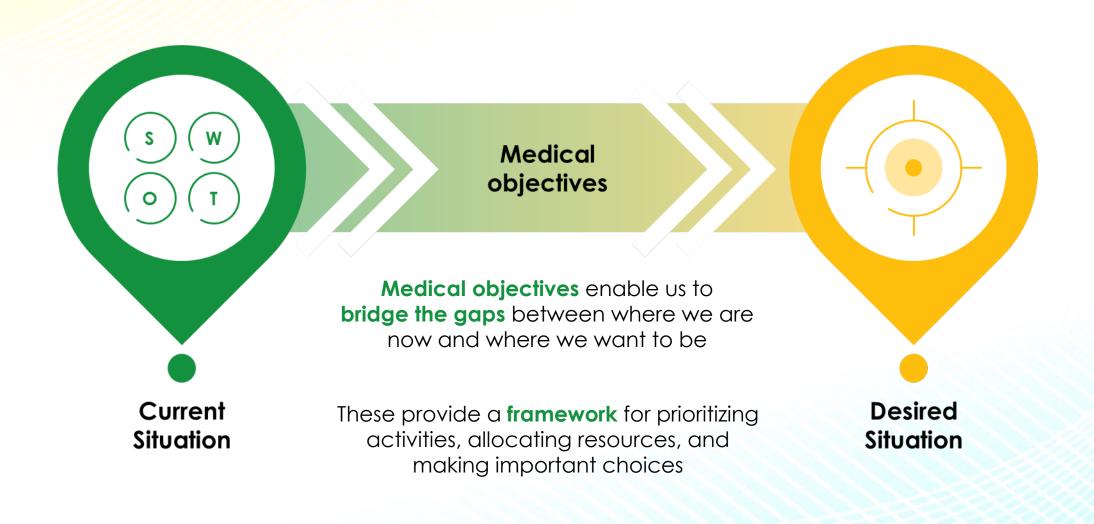


# Components of robust medical objectives

Joe Kohles, PhD Senior Strategy Consultant A robust, strategic medical plan is developed based on clearly defined cross-functional methodology



# Medical objectives provide the overarching strategy that guide medical plan actions



## Strategy versus tactics



- The what
- The why

VS

Tactical and Operational Plan

- The how
- The who



#### Is the following a strategy or a tactic?

## Engage and gain insights regarding unmet needs from urologists as frontline treaters in the prostate cancer space

- This is a strategy
- This is a tactic
- Not sure

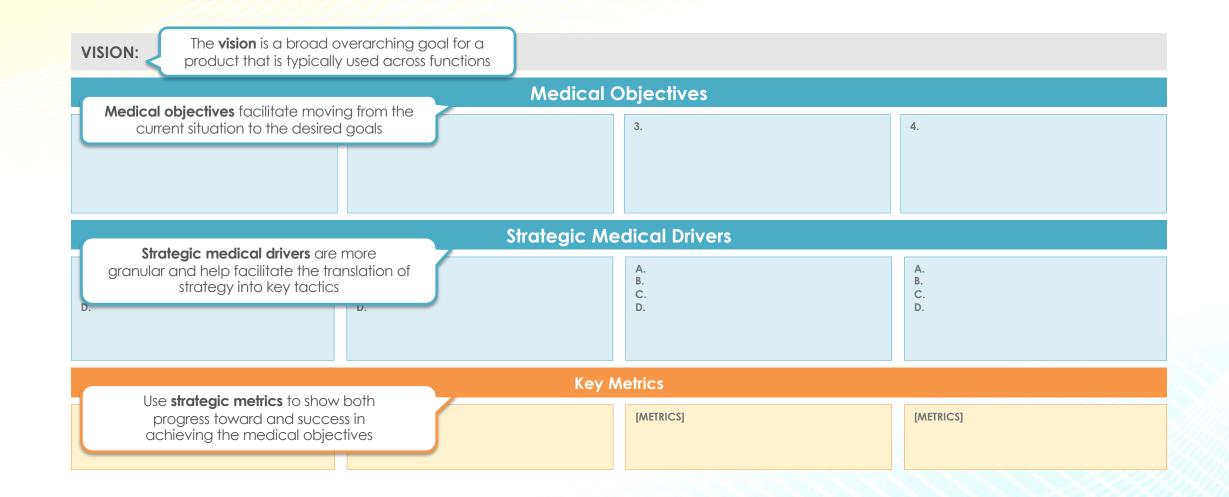


### Is the following a strategy or a tactic?

# Develop a field medical-focused prostate cancer disease state awareness educational slide set

- This is a strategy
- This is a tactic
- Not sure

## Introducing the medical strategy framework



MAPS Medical Affairs Strategic Planning Guide and Template, 2018. The Value of Medical Affairs. Defining Strategic Metrics to Demonstrate Impact. Envision Pharma Group, 2018.

## Attributes of good medical objectives

#### Medical objectives must be:



Aligned with the product vision



Complete: Covering key areas of evidence generation, stakeholder engagement, and communications



Clear and specific: Objectives should be clear, specific, and easy to understand



Measurable: Objectives should be accompanied by metrics that allow progress to be tracked and evaluated



Feasibility: Objectives must be realistic and achievable



**Consistency:** Objectives should align with each other and with the overall strategy of the product

## Medical objectives MUST be strategic and actionable



Engage KOLs in hematology and oncology Improve diagnosis to find more patients early  $\bigcirc$ 

Increase Product Y data awareness and leadership in hematologic malignancies

Improve diagnosis to identify more patients with [rare disease] early by raising awareness of the disease, its early signs and symptoms, and high-risk screening

## The SWOT and associated key actions inform the medical objectives

VISION

[Product Y] provides robust and lasting efficacy for individuals with [the dermatologic condition] with the convenience of a new treatment paradigm

Medical Objectives					
1. Advance understanding of the disease course, burden, and unmet treatment needs of individuals with [dermatologic condition]	2. Communicate additional evidence, beyond the pivotal trial data, on the efficacy and safety of Product Y in comparison to standard of care and current therapies for [dermatologic condition]	3. Partner with medical societies and key dermatologists in the field to advance understanding and update current guidelines on the treatment of [dermatologic condition]			
Strategic Medical Drivers					
<ul> <li>1A. Bring together current knowledge of the new MOA and how it is differentiated from current classes of treatment</li> <li>1B. Communicate data on patient and physician preferences in treatment of [dermatologic condition]</li> </ul>	<ul> <li>2A. Ensure robust differentiation from all other treatments [mechanistic and clinical] through targeted educational programming</li> <li>2B. Proactively communicate safety of Product Y in the context of standard of care</li> </ul>	<ul> <li><b>3A.</b> Complete a KOL mapping and engagement exercise to support goals</li> <li><b>3B.</b> Support need for updated guidelines with medical societies X, Y, and Z</li> </ul>			

## Best practices for medical objectives



Define objectives that align with overall product strategy



Consider the strategy and objectives of commercial, market access, and other cross-functional teams within your organization – but remain focused on the strategy that is best suited to MA teams



Ensure your medical strategy delivers on the needs of the patients, healthcare professionals, other stakeholders, and the organization





# Cross-functional collaboration on medical strategy and objectives

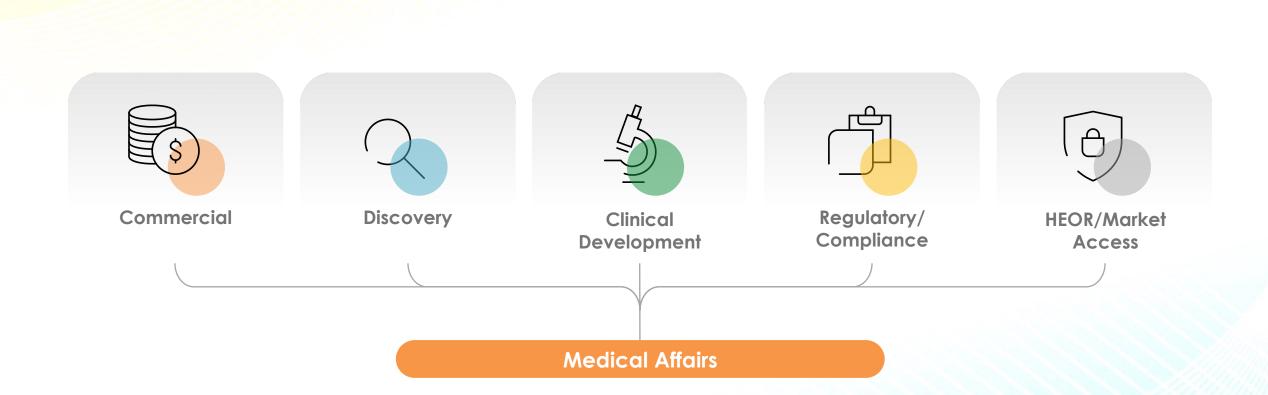
Gorana Dasic, MD, MS Global Medical Affairs Head, Kedrion Biopharma



# Does your cross-functional medical affairs team collaborate and co-create medical objectives in your organization?

- Yes
- No
- Not sure
- It varies

## Key internal partners



## Medical Affairs cross-functional collaboration

#### Medical strategy co-created by the cross-functional MA team

Synchronizing efforts across all MA competencies to achieve strategic objectives







# Applying the fundamentals of measuring objectives

Joe Kohles, PhD Senior Strategy Consultant

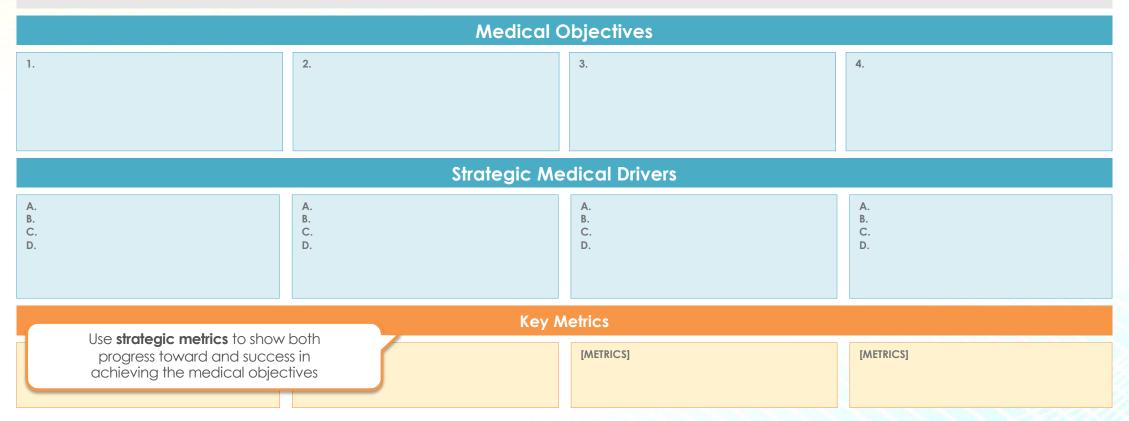


## Are metrics of success defined as an integral part of the medical plan development process at your organization?

- Yes
- No
- Not sure
- It varies

## Align metrics with overall strategic plan and objectives

**VISION:** Establish Product X as the treatment of choice for patients with mild to moderate eczema



MAPS Medical Affairs Strategic Planning Guide and Template, 2018.

The Value of Medical Affairs. Defining Strategic Metrics to Demonstrate Impact. Envision Pharma Group. 2018.

## The value of metrics

#### Effective metrics can:





Demonstrate value to stakeholders



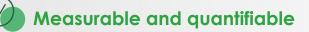
Drive continuous improvement

## Key metrics considerations

#### Ensure metrics are:



Aligned with goals and objectives





Appropriate per function and covering key functions







Aimed for broad impact on stakeholders



Cover the long and short-term



Driving continuous improvement





Adaptable with changing environment

## Use a mix of quantitative and qualitative metrics

#### **QUANTITATIVE** Numerically measurable metrics

- Number and type of MSL activities and engagements
- Number of accepted publications
- Number of downloads of publication enhancements
- Number of symposia or educational opportunities supported
- Number of conversations/interactions with KOLs
- Number of formulary changes
- Number of medical information requests
- Patient or investigator recruitment
- Number of investigator-initiated trials
- Altmetrics (to measure publication impact)



#### QUALITATIVE

Associated with changes in perceptions; cannot be numerically quantified

- Internal and external customer feedback (eg, market research, surveys)
- Insights captured from investigators, advisors, patients, and other external stakeholders that may inform medical strategy, clinical development, or other internal functions
- Changes in formulary decisions or medical policy, or guidelines
- External recognition
  - News/social media coverage
  - What credible KOLs and HCPs in the field are saying at congresses, in publications, and on social media
- Sentiment analysis for Altmetrics
- Benchmarking to other companies

## Example of how to pull through metrics

**Example of goal- and outcome-oriented metrics aligned with strategic objectives** 







Qualitative Metric

**1.** Advance understanding of the disease course, burden, and unmet treatment needs of individuals with [dermatologic condition]

#### **EXAMPLE OUTCOMES-BASED METRIC**

Conduct qualitative research to assess shifts in physician perceptions regarding disease course, burden, and unmet need in [dermatologic condition]

**1B.** Communicate data on patient and physician preferences in treatment of [dermatologic condition]

#### **EXAMPLE GOAL-BASED METRICS**

Present data from a patient preference study at a global dermatology congress this year followed by a publication

Assess impact using social media listening and Altmetrics

Complete two live symposia that include patient preferences for dermatologists and dermatology NP/PAs within 6 months

- Assess the following:
  - Number/demographics of live attendees
  - Number of on-demand views
  - Number of downloaded supplemental materials
  - Number of HCPs that opt-in to receive further information

Leverage both **qualitative** (changes in perceptions) and **quantitative** (numerically measurable) metrics

## Key factors in operationalizing metrics



Establish your baseline for the metric comparison



Determine process and timing for metric assessment



Identify a common tool for metric data collection and evaluation



Keep in constant communication with the functional groups to ensure accountability and proper adjustment to changes in medical plans

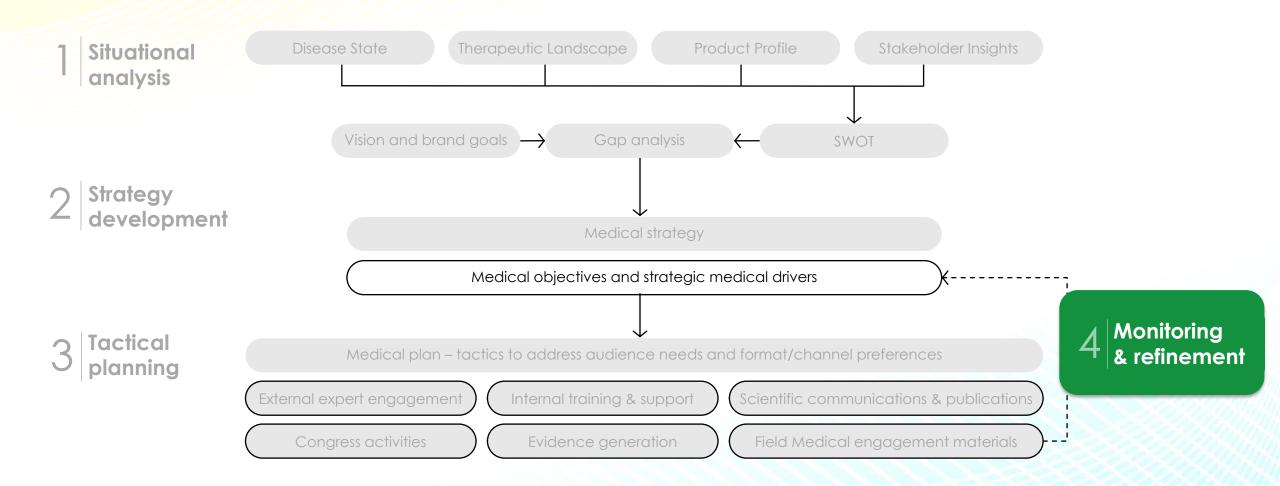


Develop an ongoing communication plan for cross-functional internal stakeholders to highlight achievements and accomplishments of the MA teams, as well as key learnings from the metrics evaluation



Utilize metrics to continuously evaluate and evolve your strategy/tactical plans

## A robust, strategic medical plan is developed based on clearly defined cross-functional methodology







# Summary

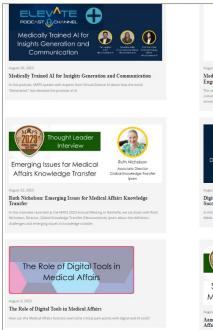
**Emily Howman**, PhD EVP, Medical Strategy, Envision Pharma Group

#### We hope this foundational session will help you to:

- Effectively leverage the product profile and landscape analysis to inform the strategic objectives
- Identify the overall components of robust objectives
- Understand how and when to collaborate on the medical strategy and objective development
- Apply the fundamentals of measuring objectives

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Modular Content in Medical Affairs: The Foundation of Omnichannel Engagement

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Aamir Shamim Choudry: Single Point of Contact Model for Medical Affairs



Grow Engagement with HCPs: Findings from the Wiley HCP Survey In this podcast, listeners will learn practical tips from the experts on the tactics that are driving impact with today's divictants.

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# Reach out to members with any questions and build your network!



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**COMING SOON!** Fundamentals of Strategy webinar series Part 4: Implementation of strategy and monitoring progress











# Thank you!