

Medical Affairs Strategic Planning: Providing a Roadmap for Success

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 MAPS organization or its members.

Introductions



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Learning Objectives



- Value of the Medical Planning Process
- Best Practices on how to develop a medical plan
- Overview of the industry standard medical strategy template and guide

Medical Affairs Strategic Plan Guide Key Sections



GUIDE



Overview

Providing an introduction to the MAPS Medical Affairs Strategic Planning Guide



Situational Analysis

Defining the current situation in terms of the science, product profile, therapeutic landscape, and key insights



Medical Strategy

Defining the vision, strategic medical objectives, and drivers for the product



Tactical and Operational Plan

Translating the strategy into tactics and activities supported by the medical affairs functional teams



Medical Summary

Providing a high-level summary of the strategy, tactical plan, and budget and timing



Next Steps

Providing a high-level summary of the strategy, tactical plan, budget and timing

TEMPLATE



MAPS Medical Affairs Strategic Plan Template

Providing full medical affairs strategic plan template to adapt for planning efforts, including situational analysis, medical strategy, tactical and operational plan, and medical summary

MAPS Medical Affairs Strategic Planning:

Best Practices

Purpose of a Medical Plan



- A core strategy that serves as the guiding light of the medical program, the place that all activities trace back to
- Ensure organizational alignment on what needs to happen and how to get there
- Give guidance to regions and countries on the overall direction they should be headed in
- Explain the rationale for the medical budget to management
- Be the source of metrics that Medical can be measured against

Medical Strategic Plan **Should** ...



Serve as a roadmap clearly communicating the core medical strategy and supporting tactics, encompassing all MA functions and geographies



Explain the rationale for the medical budget to management



Be grounded in a deep understanding of the disease area, the patient journey and the competitor landscape



Be the source of metrics that plan execution can be measured against



Include data generation through data dissemination, considering both internal and external stakeholders, and phase of development

Medical Strategic Plan **Should Not** ...



Be developed in isolation and without engaging other internal and external stakeholders and perspectives



Take 6 months to develop and then be handed off to the regions/countries



Go on gut feel, but rather should be grounded in a proper situational analysis and understanding of the landscape

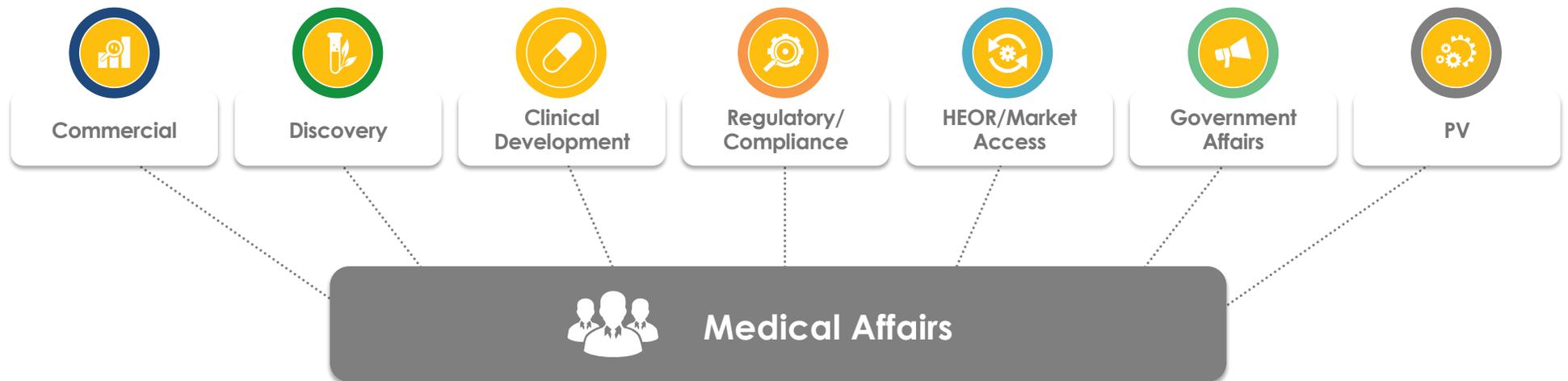


Be a collection of slides that do not interconnect and tell an overall narrative

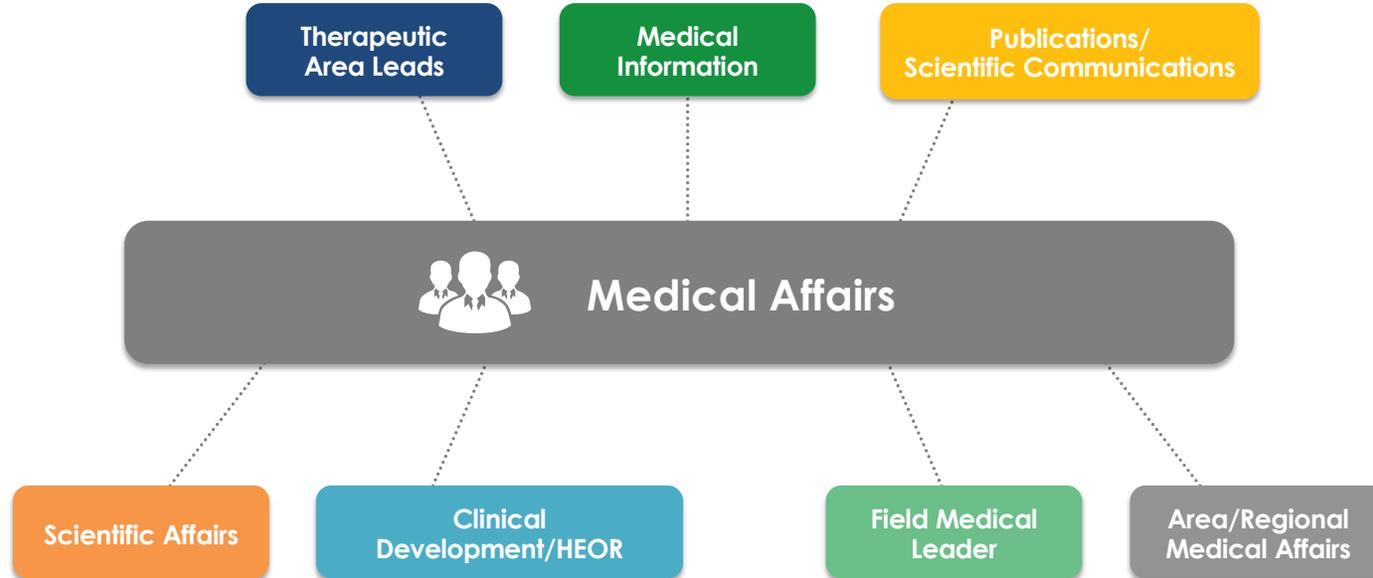


Copy the commercial plan nor utilize commercial jargon

Key Internal Partners



The Global Medical Affairs Community



Goals of a Medical Plan: Vary Depending on the Type of Product and Stage of Lifecycle

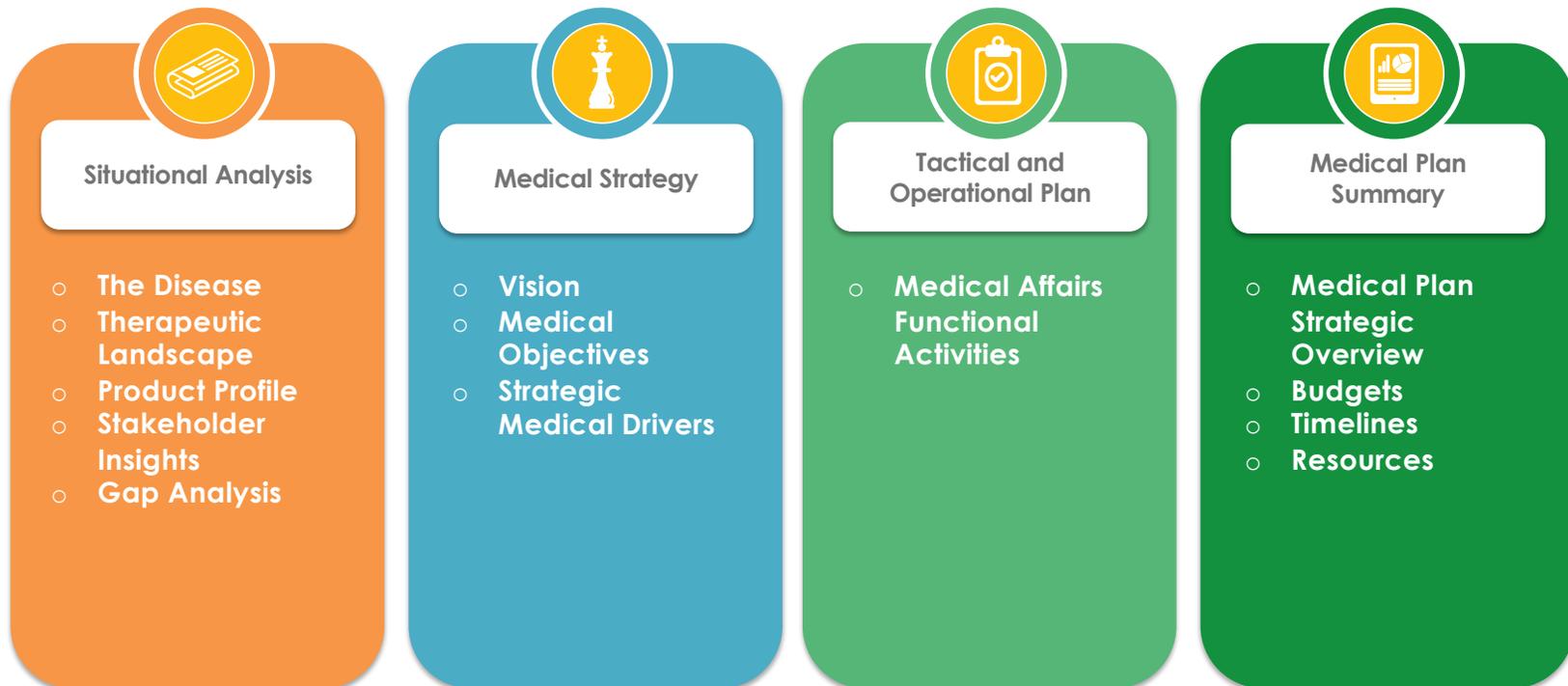


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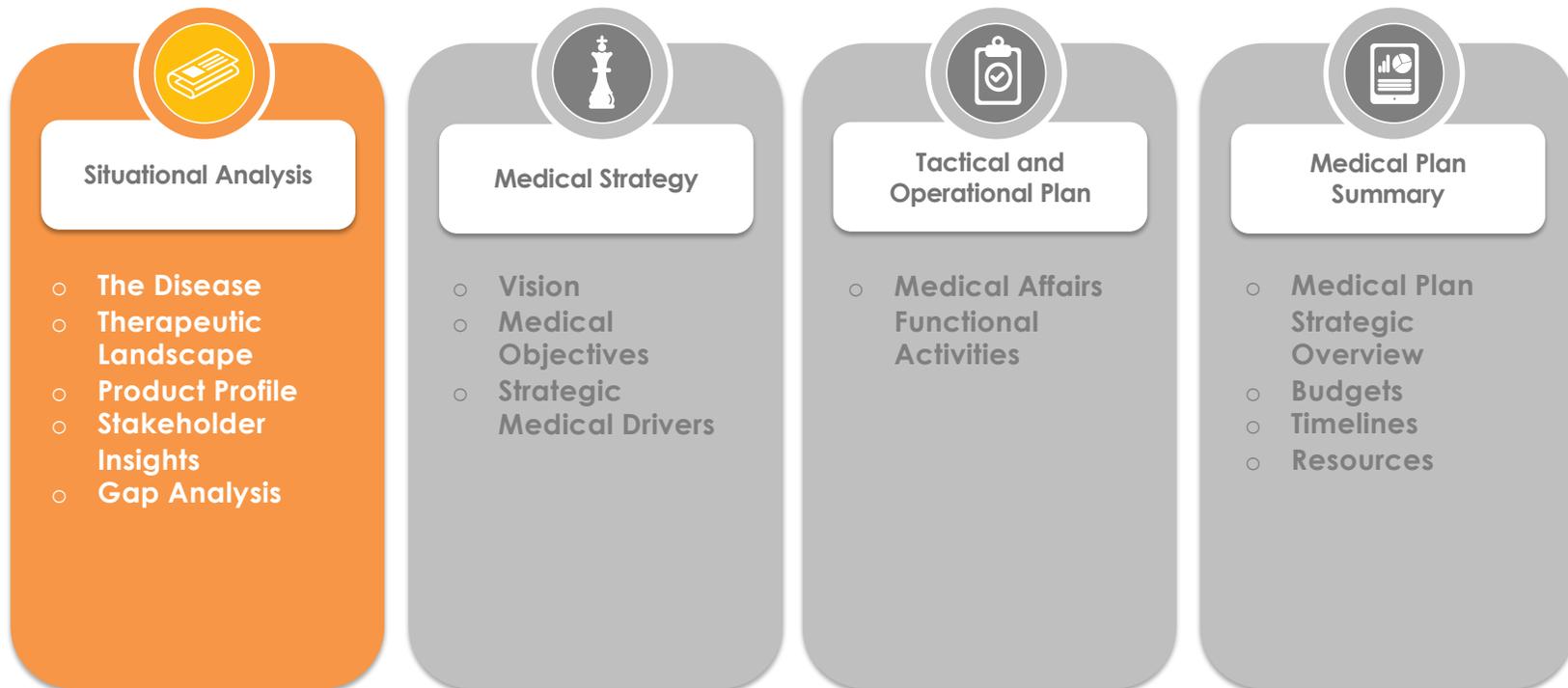
A Medical Strategy can be developed in any part of the lifecycle depending on its purpose.

A general rule of thumb is that earlier is better when developing a medical strategy to ensure alignment and continuity.

What Sections Should be Included in the Medical Plan?



What Sections Should be Included in the Medical Plan?



Your Product

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Target Product Profile (if Pre-Launch)

	Indication	Efficacy	Safety and Tolerability	Dosing/ Administration	Outcomes
Optimistic		o [Approvable endpoints]	o [TBD]	o [TBD]	o [TBD]
Target	o [Patient type] o [Line of therapy] o [Diagnostic requirement]	o [TBD]	o [TBD]	o [TBD]	o [TBD]
Minimal		o [TBD]	o [TBD]	o [TBD]	o [TBD]

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Key Events, Development and Lifecycle Activities

Legend

- US (orange box)
- Europe (green box)
- Asia Pacific (blue box)
- Major Congress (blue circle)
- Key Competitor (orange box)
- Key Competitor (blue box)
- Key Event (orange diamond)
- trial initiation (green circle)
- data readout (expected) (green triangle)
- regulatory submission (green star)

Development Activities: Phase 3 Trial Name (green circle) → data readout (expected) (green triangle) → Defaults (green star)

Key Events: updated label: az events (orange diamond), APPROVAL (Drug X) (orange diamond)

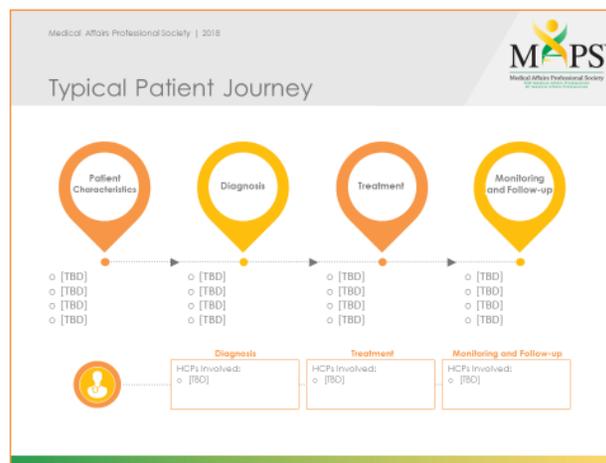
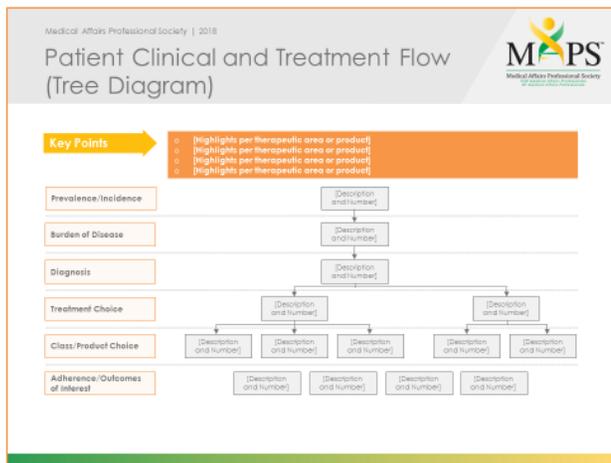
Key Competitor: Q1 2018, Q2 2018, Q3 2018, Q4 2018, Q1 2019, Q2 2019, Q3 2019, Q4 2019

Key Data Release: Key Data Release (blue box)

TBD Approval: TBD Approval (orange box)

Congress Dates Locations: Congress Dates Locations (green box), Congress Dates Locations (blue box)

The Landscape



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Key External Stakeholder Insights*

External Stakeholder	Insight	Implications
[External expert] [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 (e.g. advocacy groups, caregivers, etc.) [Summary]		

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

The Competition



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Competitive Landscape: Overview



Item	Your Product	Competitor A	Competitor B	Competitor C
Company	[TBD]	[TBD]	[TBD]	[TBD]
Company therapeutic expertise				
Phase of development				
Key clinical trials (ongoing)				
Launch dates (completed and anticipated)				
Key scientific differentiators				
Strengths				
Weakness				
Regions available				
Cost				

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Competitive Landscape: Label Comparison



Characteristic	Your Product	Medical/Scientific Advantage*	Competitor A	Competitor B	Competitor C
Indication/status	[TBD]	[TBD; +/- =]	[TBD]	[TBD]	[TBD]
Dosage and administration					
Efficacy					
Side effects/tolerability					
Safety/contraindicated population					
Pharmacokinetics					
Mechanism of action					

*+ Indicates medical or scientific advantage for product; = indicates product equivalence; - indicates product disadvantage

Situational Analysis: Medical SWOT

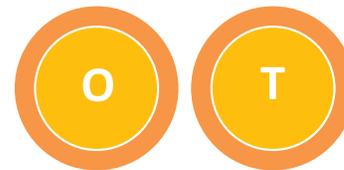
- A Medical SWOT is a collaborative and structured approach to understanding where your product stands in the current environment and disease state – identifying both internal and external factors

It is a combination of:



Internal

Strengths and Weaknesses



External

Opportunities and Threats

Situational Analysis Summary: Medical SWOT

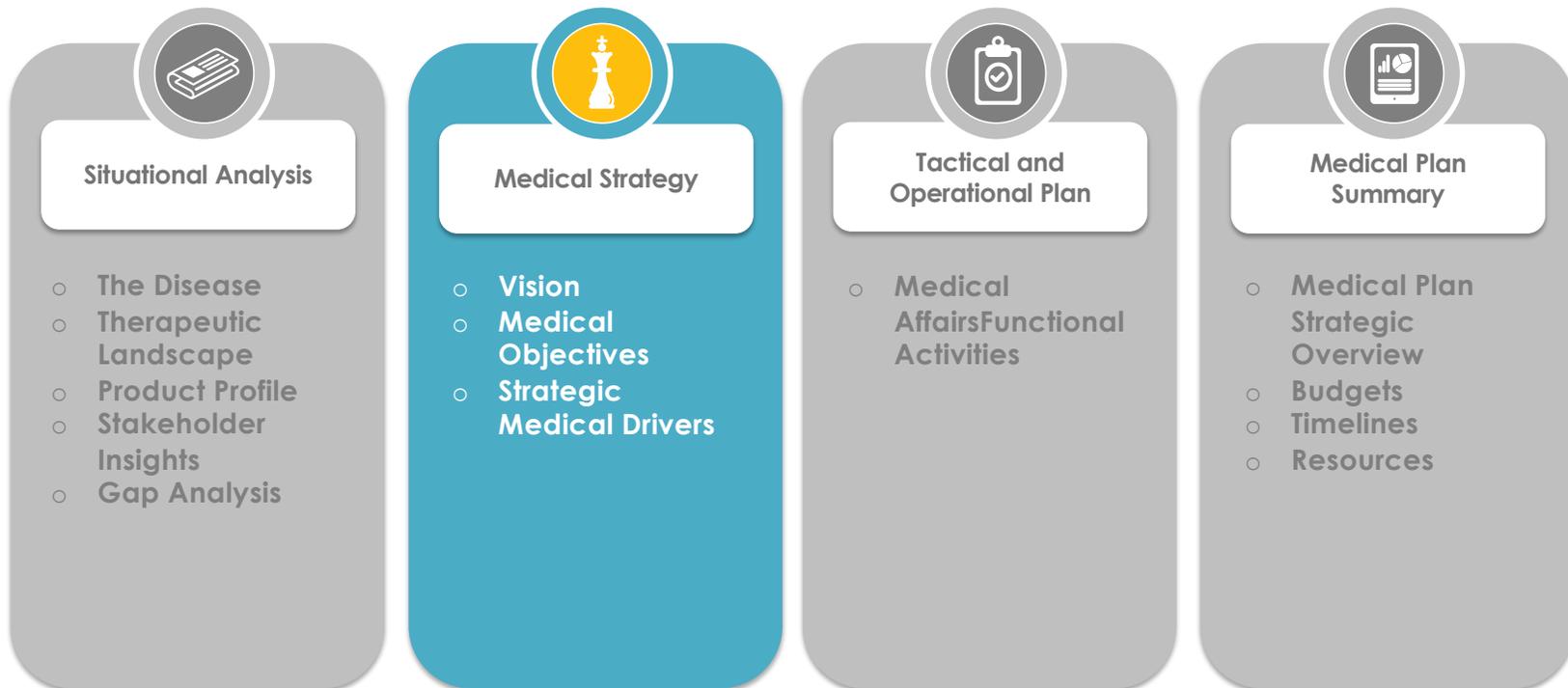


Best Practices for the Situational Analysis



- Ensure collaboration from key medical affairs and cross-functional internal stakeholders (research and development, commercial, market research, etc.) to guarantee up-to-date information for your analyses
- Plan for internal workshops and/or brainstorm sessions with the integrated MA teams to finalize the situational analysis and help identify medical/scientific product challenges, opportunities, and gaps

What Sections Should be Included in the Medical Plan?



Strategy versus Tactic



Medical Strategy

- **The WHAT**

Vs.

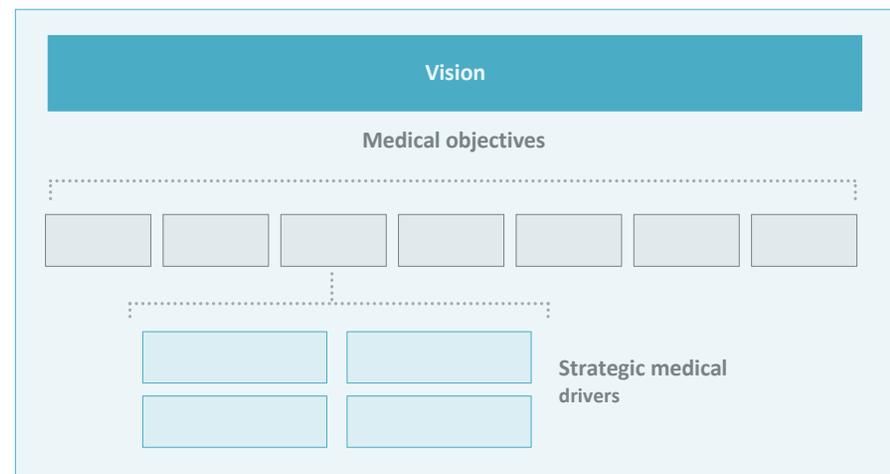


**Tactical and
Operational Plan**

- **THE HOW**
- **THE WHO**

Components and Organization of a Medical Strategy

- **Vision** for a product is a broad overarching goal typically used across functions
EXAMPLE: Establish product X as the backbone of therapy for every patient with disease X
- **Medical objectives** facilitate moving from the current situation to the desired goals
EXAMPLE: Communicate the value to product X to key audiences



Example only

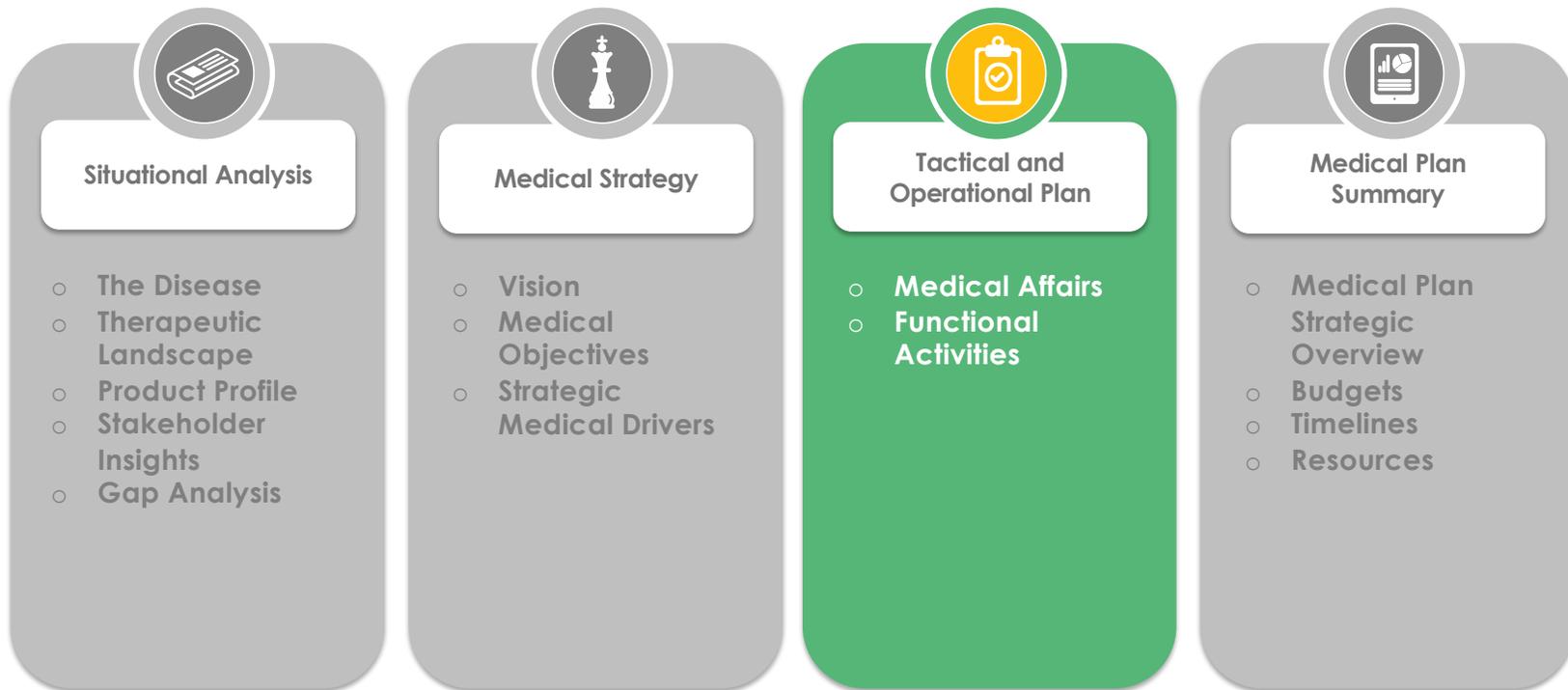
- Like the medical objectives, the **strategic medical drivers** are key objectives, but are more granular and support the associated medical objective – they help facilitate translation of strategy into key tactics
EXAMPLE: Educate urologists on the outcomes measures of clinical trial X for product X

Best Practices for Medical Strategy



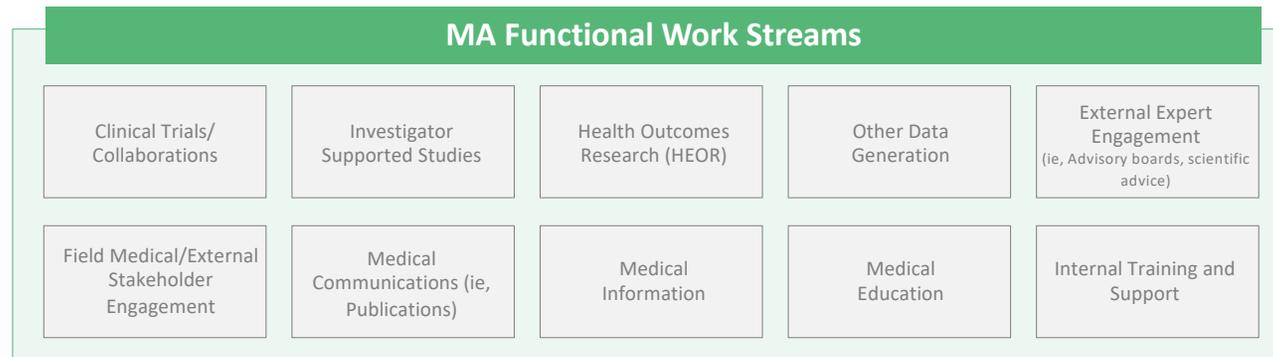
- Define strategies that align with overall product objectives
- Consider the strategy and objectives of commercial, market access, and other cross-functional teams within your organization – but remain focused on the strategy that is best suited to MA teams
- Ensure your medical strategy delivers on the needs of the patients, other stakeholders, and the organization

What Sections Should be Included in the Medical Plan?



Tactical and Operational Plan: Key Considerations

- Identify tactics that encompass **all** MA functions
- Consider phase of development
- Define ownership to MA team members for project definition, management, and accountability
- Ensure to associate budgets and timelines with anticipated initiation and completion dates



Tactical and Operational Plan: Consider the Key External Stakeholders



- A tactical plan is focused on strategy but should be aligned to your stakeholder groups
 - May be broad depending on the therapeutic area
- Communication and education
 - Expanding the knowledge base for your product and therapeutic area helps customers remain up-to-date and ensures the best patient care
- Advocacy and knowledge exchange
 - Advocates and advisors can ensure your data is put fully into context and provide guidance or answers to key questions

Tactical and Operational Plan

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Tactical and Operational Plan: Sample Tactics Template



- Align all tactics with medical strategy
 - Activities must be linked to, and deliver on, the strategic medical objectives and drivers

	Project Description	Driver	Output	Target Audience	Budget	Owner	Year 1				Year 2								
							1	2	3	4	1	2	3	4					
Clinical Trials/Collaborations	[Describe the activity that will be conducted]		[Publication, label change, etc.]						◆										

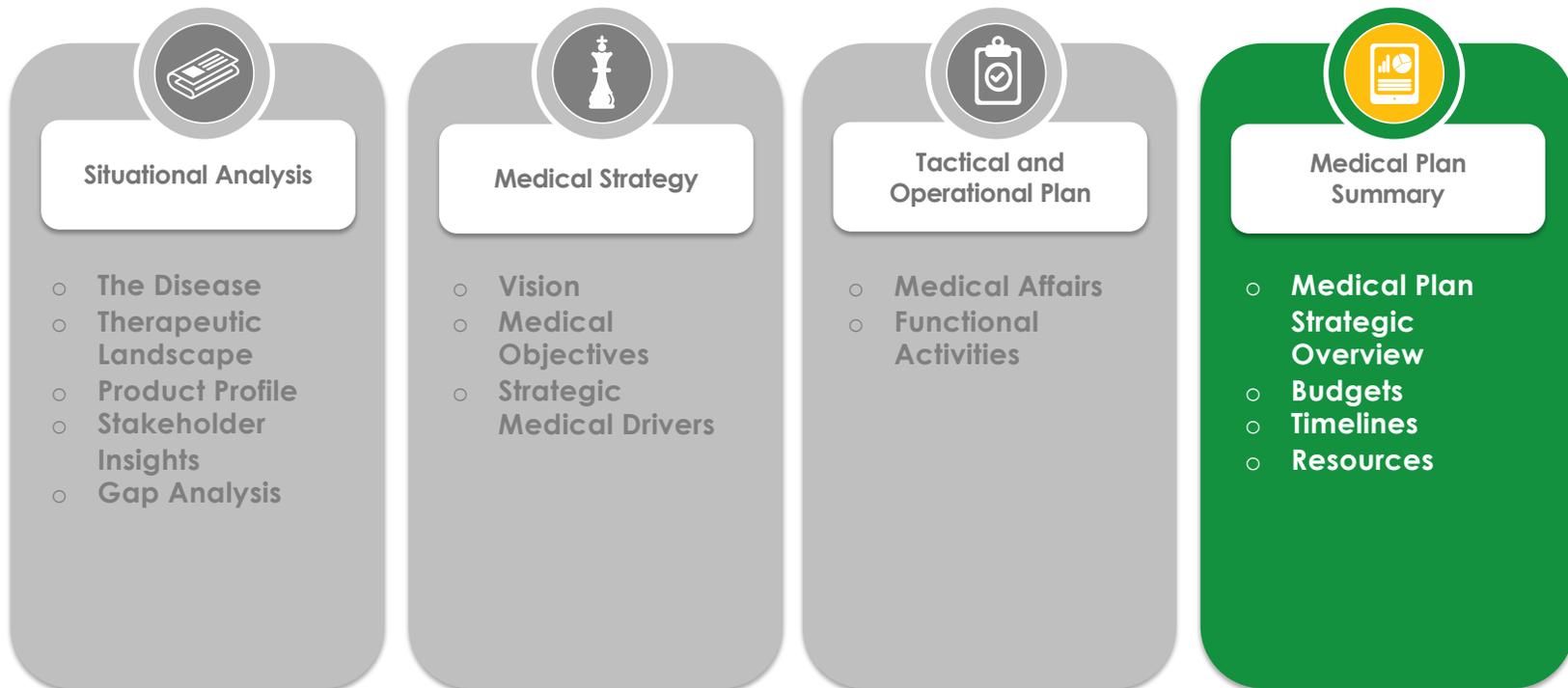
◆ Projected Submission ● Projected Completion

Best Practices for Tactical Plan



- Ensure overall alignment of tactics with the medical strategy
- Realistic timeframe and budgets of tactics
- Cross-functional team buy in and alignment to ensure no duplication of activities or budgets
- Allow time for alignment among Global, Regional, and Country medical affairs stakeholders

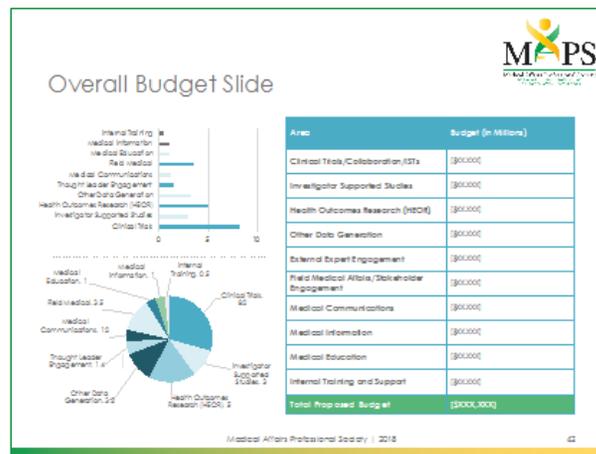
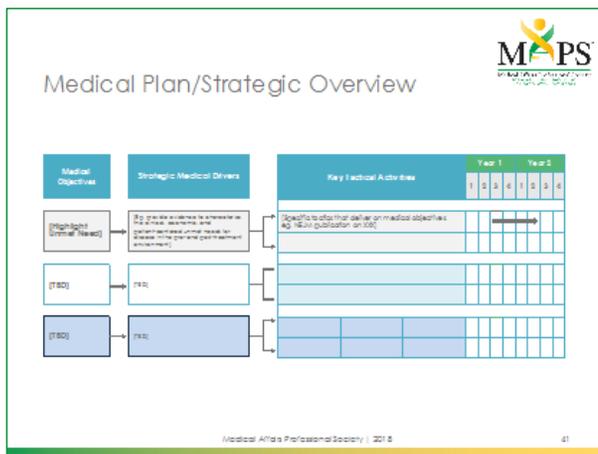
What Sections Should be Included in the Medical Plan?



Medical Plan Summary



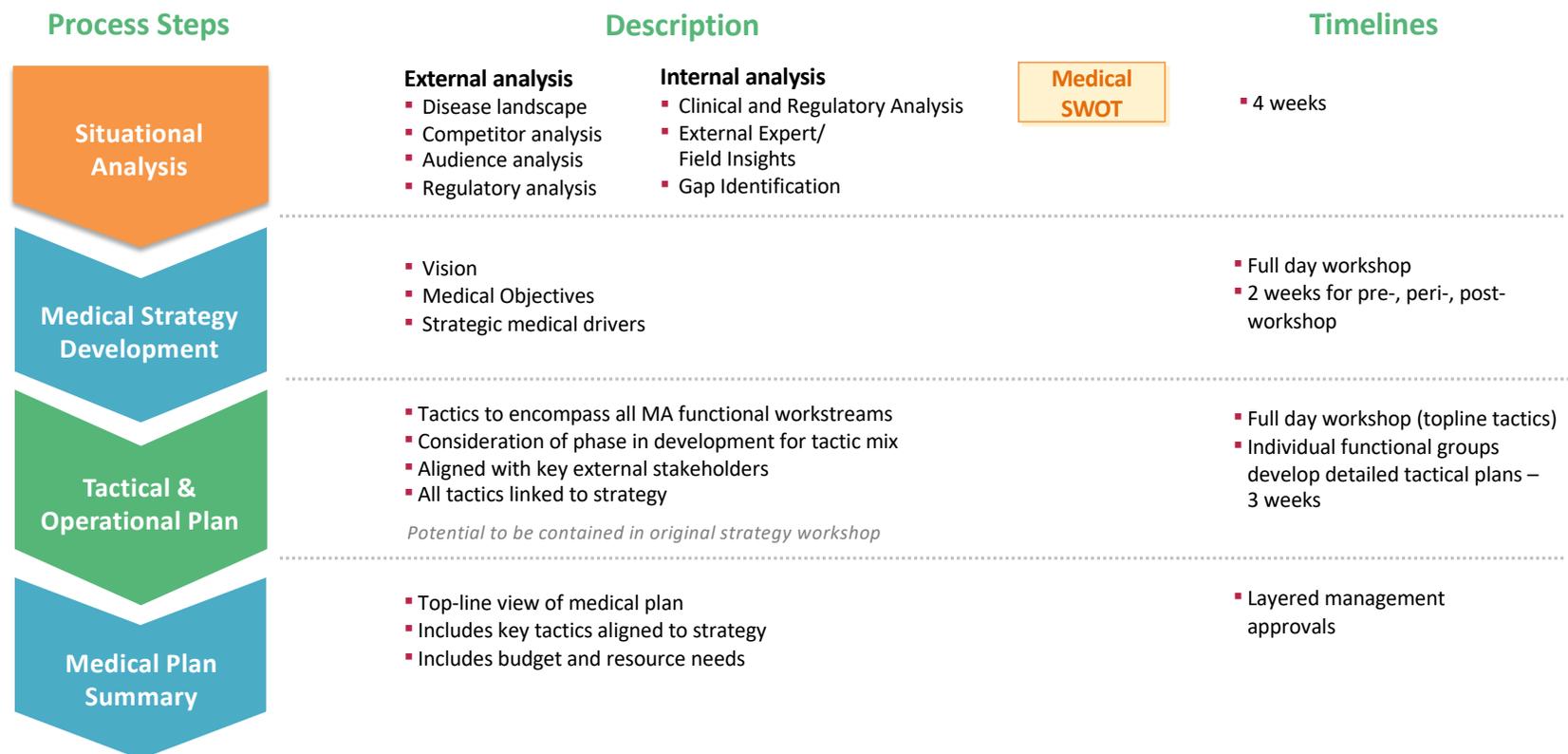
- Helps the MA team to:
 - Guide appropriate personnel and financial resourcing
 - Inform operational and budgetary decision-making throughout the year
- Provides top-line view of the medical plan
 - Can be used for management and other cross-functional internal stakeholder presentations and discussions



Medical Affairs Resource Evaluation/Request

Medical Affairs Group by Location	Challenge/Need	Recommendation	Execution	Target Timing	Estimated Cost
Global	Identified challenge areas from a cross-functional perspective	Recommendation from cross-functional perspective	How and where to execute recommendation	Target year	\$300,000
Region					\$300,000
Country					\$300,000
Total:					\$3,000,000

Roadmap for Medical Plan Development



Next Steps: Executing and Monitoring Your Medical Plans



Consider...

- **Electronic tools** for management of the medical affairs plan across all functional groups
 - Should tie together overall strategy, tactical execution, and metrics
 - Owned by MA functional team members
 - Could be managed by agency partners (if needed)
 - Define key metrics that will demonstrate progress
- **Regular check-ins** with medical affairs functional teams to monitor progress on tactical execution and re-evaluate strategy/tactics based on changes in the market
- **Key reports** to provide status and updates **to the cross-functional internal teams** to demonstrate the value of the medical affairs team

Key Take-aways



- The Medical Plan should be underpinned by a robust core strategy, grounded in an understanding of the product and disease/treatment landscape
- The plan should consider evidence generation through dissemination, as well as internal and external stakeholders
- All tactics in the plan must be aligned to strategy
- By following a defined process to Medical Plan development, resources can be justified, and aligned to the highest priority initiatives