Medical Affairs Strategic Planning: Providing a Roadmap for Success

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Introductions

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Envision Pharma Group

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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

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

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

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MAPS Medical Affairs Strategic Planning:
Best Practices

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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 rational 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

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

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

- Explain the rationale for the medical budget to management

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

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Medical Strategic Plan Should Not ...

- Be developed in isolation and without engaging other internal and external stakeholders and perspectives
- Go on gut feel, but rather should be grounded in a proper situational analysis and understanding of the landscape
- Copy the commercial plan nor utilize commercial jargon
- Take 6 months to develop and then be handed off to the regions/countries
- Be a collection of slides that do not interconnect and tell an overall narrative

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Key Internal Partners

- Commercial
- Discovery
- Clinical Development
- Regulatory/Compliance
- HEOR/Market Access
- Government Affairs
- PV

Medical Affairs

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The Global Medical Affairs Community

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

**PRE-LAUNCH**
- Ensure understanding of the treatment landscape
- Determine gaps in evidence and communications
- Knowledge and relationships with key external stakeholders
- Deliver pre-launch market shaping communications

**PERI-LAUNCH**
- Ensure all key medical stakeholders are knowledgeable and prepared for launch
- Deliver on programs that are filling known gaps in evidence and communication
- Ensure the value story is complete and the evidence supports reimbursement

**POST-LAUNCH**
- Continually monitor data and communications gaps and deliver on programs that address
- Grow and maintain stakeholder relationships
- Monitor landscape and competition trends and address as appropriate

**NOTE:**
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?

- **Situational Analysis**
  - The Disease
  - Therapeutic Landscape
  - Product Profile
  - Stakeholder Insights
  - Gap Analysis

- **Medical Strategy**
  - Vision
  - Medical Objectives
  - Strategic Medical Drivers

- **Tactical and Operational Plan**
  - Medical Affairs Functional Activities

- **Medical Plan Summary**
  - Medical Plan Strategic Overview
  - Budgets
  - Timelines
  - Resources

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Your Product

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

<table>
<thead>
<tr>
<th>Indication</th>
<th>Efficacy</th>
<th>Safety and Tolerability</th>
<th>Dosing/ Administration</th>
<th>Outcomes</th>
</tr>
</thead>
<tbody>
<tr>
<td>[Patient type]</td>
<td>[T0]</td>
<td>[T0]</td>
<td>[T0]</td>
<td>[T0]</td>
</tr>
</tbody>
</table>

### Key Events, Development and Lifecycle Activities

- **Q1 2019**: IRB Approval
- **Q2 2019**: Key Date Release
- **Q3 2019**: FDA Approval
- **Q4 2019**: Phase 3 trial

**Legend**
- (T0): key event
- (T1): minor event
- (T2): informational
- (T3): major event

**Key Dates**
- 2019
- 2020

**Details**
The Landscape

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### Competitive Landscape: Overview

<table>
<thead>
<tr>
<th>Item</th>
<th>Your Product</th>
<th>Competitor A</th>
<th>Competitor B</th>
<th>Competitor C</th>
</tr>
</thead>
<tbody>
<tr>
<td>Company therapeutic expertise</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Phase of development</td>
<td></td>
<td></td>
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<tr>
<td>Key clinical trials (ongoing)</td>
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<tr>
<td>Launch dates (completed and anticipated)</td>
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<tr>
<td>Key scientific differentiators</td>
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<tr>
<td>Strengths</td>
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</tr>
<tr>
<td>Weaknesses</td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Unique features</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cost</td>
<td></td>
<td></td>
<td></td>
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</tr>
</tbody>
</table>

### Competitive Landscape: Label Comparison

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Your Product</th>
<th>Medical/Scientific Advantage*</th>
<th>Competitor A</th>
<th>Competitor B</th>
<th>Competitor C</th>
</tr>
</thead>
<tbody>
<tr>
<td>Indication/status</td>
<td>70</td>
<td>70, 70, 70, 70, 70, 70, 70, 70, 70, 70</td>
<td>70</td>
<td>70, 70, 70, 70, 70, 70, 70, 70, 70, 70</td>
<td>70</td>
</tr>
<tr>
<td>Usage and administration</td>
<td></td>
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<td></td>
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<tr>
<td>Efficacy</td>
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<tr>
<td>Side effects/likability</td>
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<td></td>
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<tr>
<td>Safety, contraindicated population</td>
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<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pharmacokinetics</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Mechanisms of action</td>
<td></td>
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</tbody>
</table>

* Indicates medical or scientific advantage for product = Indicate 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

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Situational Analysis Summary:
Medical SWOT

- S: [TBD]
- W: [TBD]
- O: [TBD]
- T: [TBD]

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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.

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Strategy versus Tactic

Medical Strategy
- The WHAT

Tactical and Operational Plan
- THE HOW
- THE WHO

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**Components and Organization of a Medical Strategy**

<table>
<thead>
<tr>
<th>Vision</th>
<th>Medical objectives</th>
<th>Strategic medical drivers</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Vision</strong> for a product is a broad overarching goal typically used across functions</td>
<td><strong>Medical objectives</strong> facilitate moving from the current situation to the desired goals</td>
<td><strong>Strategic medical drivers</strong> are key objectives, but are more granular and support the associated medical objective – they help facilitate translation of strategy into key tactics</td>
</tr>
</tbody>
</table>

**EXAMPLE**: Establish product X as the backbone of therapy for every patient with disease X

**EXAMPLE**: Communicate the value to product X to key audiences

**EXAMPLE**: Educate urologists on the outcomes measures of clinical trial X for product X

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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
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**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

**MA Functional Work Streams**

- Clinical Trials/Collaborations
- Investigator Supported Studies
- Health Outcomes Research (HEOR)
- Other Data Generation
- External Expert Engagement (ie, Advisory boards, scientific advice)
- Field Medical/External Stakeholder Engagement
- Medical Communications (ie, Publications)
- Medical Information
- Medical Education
- Internal Training and Support

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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: Sample Tactics Template

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

<table>
<thead>
<tr>
<th>Project Description</th>
<th>Driver</th>
<th>Output</th>
<th>Year 1</th>
<th>Year 2</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clinical Trials/Collaborations</td>
<td>[Describe the activity that will be conducted]</td>
<td>[Publication, label change, etc.]</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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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
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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

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# Roadmap for Medical Plan Development

<table>
<thead>
<tr>
<th>Process Steps</th>
<th>Description</th>
<th>Timelines</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Situational Analysis</strong></td>
<td><strong>External analysis</strong>&lt;br&gt;- Disease landscape&lt;br&gt;- Competitor analysis&lt;br&gt;- Audience analysis&lt;br&gt;- Regulatory analysis</td>
<td><strong>Medical SWOT</strong>&lt;br&gt;- 4 weeks</td>
</tr>
<tr>
<td><strong>Medical Strategy Development</strong></td>
<td><strong>Internal analysis</strong>&lt;br&gt;- Clinical and Regulatory Analysis&lt;br&gt;- External Expert/Field Insights&lt;br&gt;- Gap Identification</td>
<td><strong>Full day workshop</strong>&lt;br&gt;- 2 weeks for pre-, peri-, post-workshop</td>
</tr>
<tr>
<td><strong>Tactical &amp; Operational Plan</strong></td>
<td><strong>Vision</strong>&lt;br&gt;- Medical Objectives&lt;br&gt;- Strategic medical drivers&lt;br&gt;- Tactics to encompass all MA functional workstreams&lt;br&gt;- Consideration of phase in development for tactic mix&lt;br&gt;- Aligned with key external stakeholders&lt;br&gt;- All tactics linked to strategy&lt;br&gt;&lt;br&gt;<code>Potential to be contained in original strategy workshop</code></td>
<td><strong>Full day workshop</strong>&lt;br&gt;- Individual functional groups develop detailed tactical plans – 3 weeks</td>
</tr>
<tr>
<td><strong>Medical Plan Summary</strong></td>
<td><strong>Top-line view of medical plan</strong>&lt;br&gt;- Includes key tactics aligned to strategy&lt;br&gt;- Includes budget and resource needs</td>
<td><strong>Layered management approvals</strong></td>
</tr>
</tbody>
</table>
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

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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