Medical Affairs Launch Excellence Guide and Templates

Best Practices for Medical Affairs

Acknowledgments

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Practical Tools and Insights

- These templates are intended to serve as a tool to provide launch excellence guidance and recommendations to Medical Affairs professionals
- The activities listed and recommendations provided should be tailored based on the individual organization, product, and market landscape
- The views and information provided do not reflect the position or views of any one individual or company
- The **Medical Affairs Launch Excellence Guide and Templates—Best Practices for Medical Affairs** with sample complementary templates provides a starting point for launch excellence planning

Medical Affairs Launch Excellence Templates

Customizable templates will support information sharing, add value by providing structure and consistency of thinking during planning and communication, and create common expectations for each functional area.

Strategic Imperatives (SIs)

Step-by-Step Instructions

1) Discover: Reading through the existing scientific compendium, certain themes related to required foundational knowledge or needs, ownable stakes or value, or even aspirational goals should become obvious.

2) Synthesize: For a communication strategy to be effective, there must be at least 1, and no more than 8, major strategic imperatives. From analysis of the compendium, compile imperatives that best establish the brand's proposition.

3) Edit: By definition, strategic imperatives are precise, concise, singular, and measurable. For each synthesized imperative, the verbiage is pared down to a single sentence or phrase that captures only the essential elements of the concept, avoiding compound statements and statements that speak too broadly or generically.

4) Categorize: Assign a category for each strategic imperative. This is a 1- to 4-word description that identifies the need the SI speaks to.

5) Review: Review the strategic imperatives with the team and obtain final approval and sign-off.

Scientific Compendium is a collection of a product's scientific narrative and the annotated references that support each message.

Strategic Imperative—Example

Category example SI 1
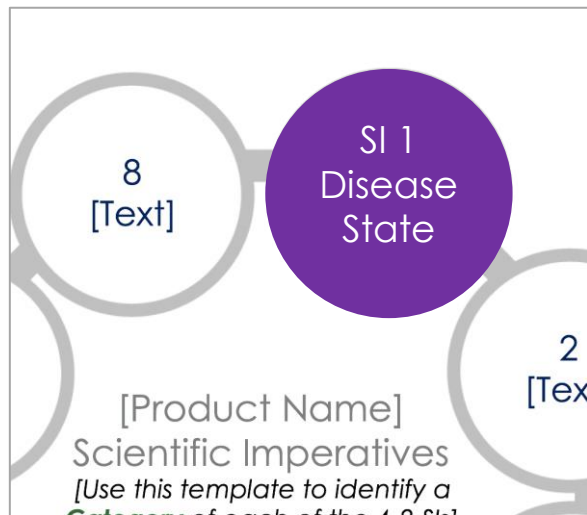
Full-text version of strategic imperative

SI 1 — An anticoagulant alternative is needed for VTE treatment, prophylaxis, and stroke prevention with improved treatment outcomes

SI 2 — [Text]

[Product Name] Strategic Imperatives

Derive 4 to 8 strategic imperatives from the scientific compendium that are concise (less than 15 words), meaningful, singular (refrain from compound statements), and impactful.

SI 1	[Text]	SI 5	
SI 2	[Text]	SI 6	[Text]
SI 3		SI 7	
SI 4		SI 8	

[Product Name] Strategic Imperatives

[Use this template to identify a *Category* of each of the 4-8 SIs]
Example: Burden of Disease

8
[text]

1
[text]

2
[text]

3
[text]

4
[text]

5
[text]

6
[text]

7
[text]
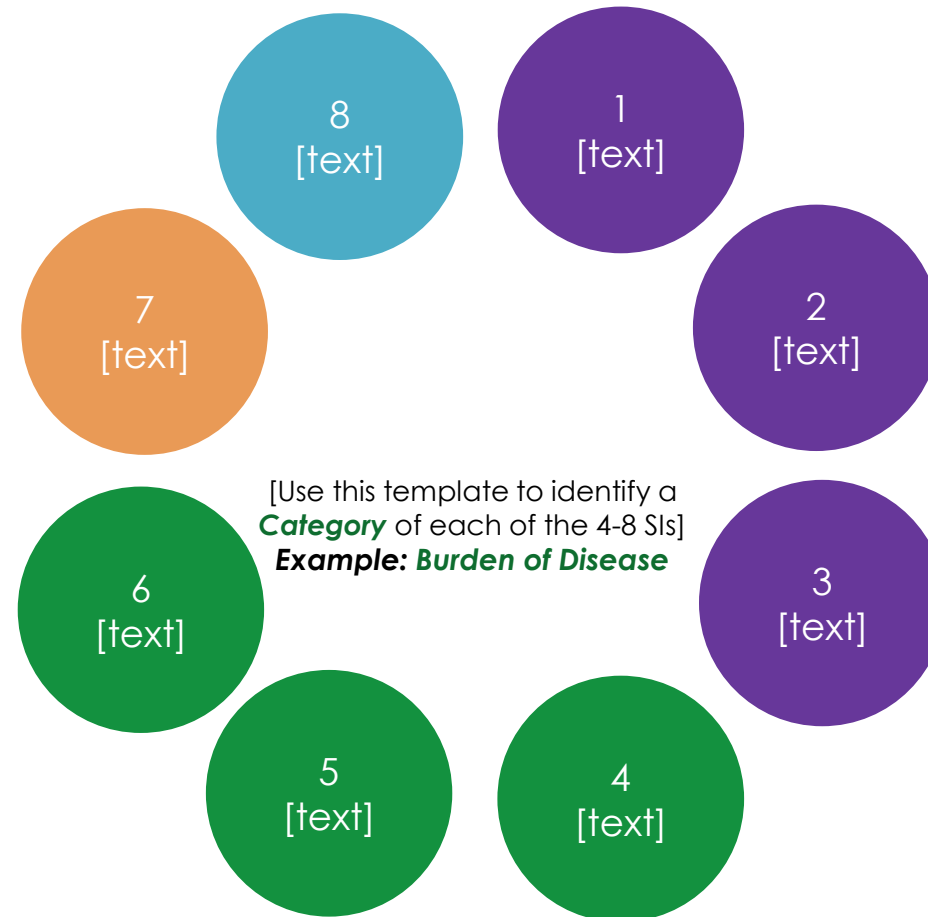
[Product Name]
Strategic Imperatives

Insight Collection

Source of Information	Frequency	Insight Description	Strategic Imperative Supported	Strategic Impact	Action Taken/Resolution
Key Opinion Leader					
Healthcare Professional					
Digital Opinion Leader					
Payers					
Advocacy Group					

SI 1	SI 2	SI 3	SI 4	SI 5	SI 6	SI 7	SI 8
XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX

Scientific Exchange Plan

Name of Opinion Leader	Strategic Imperative Supported	Scientific Interests	Investigator-Sponsored Studies/Collaborative Research	Company-Sponsored Research	Ongoing/ Planned Publications	Advisory Boards/Steering Committees	Congress Presentations	CME Activity

SI 1	SI 2	SI 3	SI 4	SI 5	SI 6	SI 7	SI 8
xxx	xxx	xxx	xxx	xxx	xxx	xxx	xxx

Competitive Landscape

Product	Company	Phase of Development	Key Differentiation Features	Key Clinical Trials	Launch Date	Regions of Availability and Cost	Strengths and Weaknesses

Competitive Landscape

Characteristic	[Your Product]	[Competitor A]	[Competitor B]	[Competitor C]
Indication/Status				
Dosage/Administration				
Efficacy				
Side Effects/Tolerability				
Safety				
Contraindicated Population				
Pharmacokinetics				
Mechanism of Action				
Cost				
Advantage/Disadvantage/ Equivalent (to launch product)				
Other				

Unmet Medical Need

	Current Unmet Need	Strategic Imperative Supported
Disease Management	• [TBD] • [TBD]	
Safety	• [TBD] • [TBD]	
Tolerability	• [TBD] • [TBD]	
Effectiveness	• [TBD] • [TBD]	
Access	• [TBD] • [TBD]	
Data Generation Gap	• [TBD] • [TBD]	
Other	• [TBD] • [TBD]	

SI 1	SI 2	SI 3	SI 4	SI 5	SI 6	SI 7	SI 8
XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX

Functional Area Medical Objectives and Related Tactics

Strategic Imperative Supported (SI)	Functional Medical Objectives (MO)	Tactics

SI 1	SI 2	SI 3	SI 4
[TBD]	[TBD]	[TBD]	[TBD]

SI 5	SI 6	SI 7	SI 8
[TBD]	[TBD]	[TBD]	[TBD]

Functional Medical Objectives (MO)

1. [TBD]

2. [TBD]

Tactics

1. [TBD]

2. [TBD]

[Country/Region] Medical Affairs Tactics—[Functional Area] Initiatives

Strategic Imperative Supported	MO	Tactic	Target	Description	Key Performance Indicator	Q1	Q2	Q3	Q4
XXX							X		
XXX									X
XXX								X	
XXX									
XXX									
XXX									
XXX									

SI 1	SI 2	SI 3	SI 4	SI 5	SI 6	SI 7	SI 8
XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX

External Stakeholder Engagement Considerations

- What criteria are used for characterizing regional, national, and global stakeholders?

- What is the geographic engagement plan?

- Is there sharing of the relationships (regional vs national vs global)?

- Is there a plan for engaging with emerging thought leaders?

Belief in Science Supporting Products

Influence

Regional	National	Global

SI 1	SI 2	SI 3	SI 4	SI 5	SI 6	SI 7	SI 8
xxx	xxx	xxx	xxx	xxx	xxx	xxx	xxx
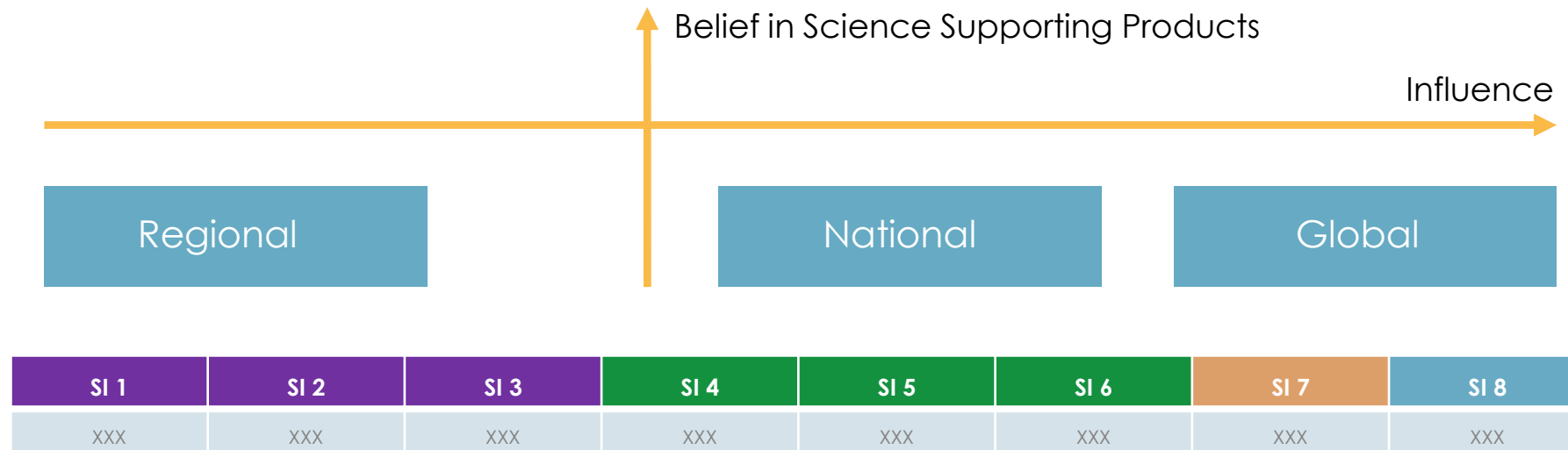
Medical Information Plan

FAQ	FAQ Description	Audience	Training Status	Strategic Imperative Supported
[TBD]	[TBD]		[TBD]	

SI 1	SI 2	SI 3	SI 4	SI 5	SI 6	SI 7	SI 8
xxx	xxx	xxx	xxx	xxx	xxx	xxx	xxx

Launch Timeline—Target [Date]

2020			2021											2022		
Q4			Q1			Q2			Q3			Q4			Q1		
Oct	Nov	Dec	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec	Jan	Feb	Mar

Label Assumptions:
- [TBD]
  - [TBD]
- [TBD]
  - [TBD]

Launch Dashboard—Metric Monitoring

Priority	Status	Strategic Imperative Supported	Deliverable	Accountable	Due Date	Key Interdependencies
1	🟢					
2	🔴					
3	🟠					
4	🟢					
5	🔴					

Risk	Mitigation

SI 1	SI 2	SI 3	SI 4	SI 5	SI 6	SI 7	SI 8
XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX