

MINI SUMMIT VII: NEW MARKETPLACE CASE STUDY: ENSURING A COMPLIANT PRODUCT LAUNCH

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INTRODUCTION IN GLOBAL LAUNCH EXCELLENCE (GLE) FRAMEWORK, *GLOBAL AND LOCAL LAUNCH PLANNING*

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MERCK

Overview



Global and Local should use similar frameworks, with the *Global Team* providing guidance to set the foundation for focused, Local go-to-market Launch Plans

- *The Global Launch Plan provides the foundation from which to build their local plans*
- *The Local Launch Plan will need to be adapted to fit the needs of each specific market*



This framework offers thought guidance and suggested outputs to help generate insights for each key activity required for compliant and successful launch, which applies for

- **New products**
- **Life cycle management, or**
- **Supporting device**

GLE is rooted in two guiding principles

1

Non-disruptive to existing Business or Planning

At Global, Regional, and Local levels

- Align with currently engaged consultants working with Global Franchise teams by clearly outlining complementary roles and responsibilities in launch planning & tracking
- Ensure alignment with the entrenched Brand Planning Process & framework
- Integrate with other planning processes

2

Harmonizes Global and Regional Launch Preparedness and ensures Consistency and Efficiency

- Embed a standard “core” Launch Planning Framework with built-in flexibility
- Launch Planning Process (LPP) is simple, user friendly and consistent across markets
- Ensure use of simple tools for launch preparedness tracking
- Management Reviews use consistent framework and timelines across brands
- Ensure systematic communication, training and roll out aligned with brand teams
- Clear Deliverables/Accountabilities at Global, Regional, and Local levels by key functions - Marketing, Medical, Communications, Regulatory, etc.

GLE Framework integrates Four Key Pillars, which tightly link with Brand Planning Processes

Situation Analysis

Objective: Provide scientific background and deliver meaningful and actionable **market insights** (e.g., patient journey) vs. simple descriptive characteristics (e.g., size and value of market)

Strategy Development

Objective: Deliver strategy that is clearly **linked back** to the meaningful and actionable **market insights**

Launch Planning

Launch Metrics and Measurement

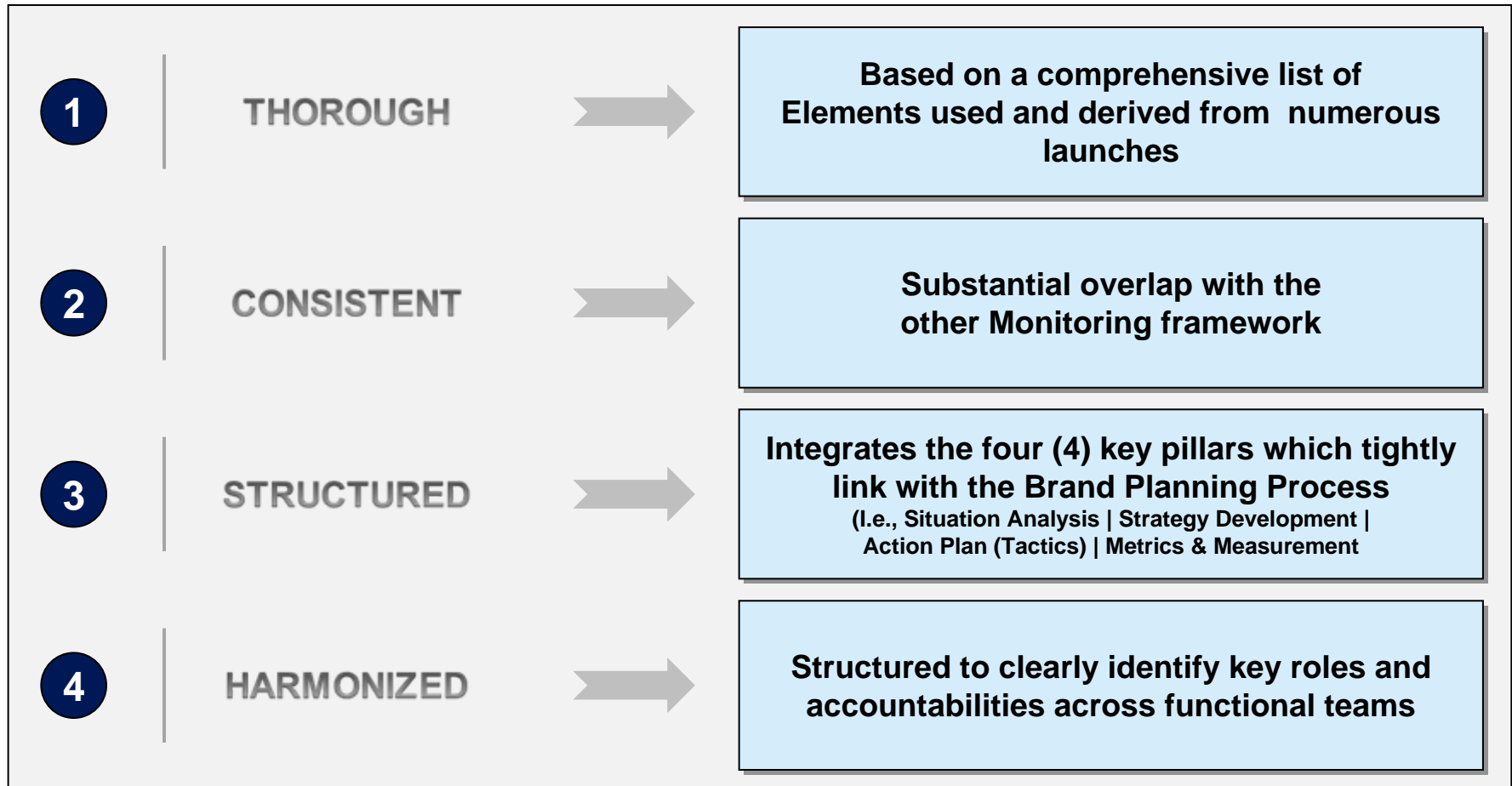
Objective: Create simple **measureable performance indicators** that are **linked back** to growth levers, can guide revisions to strategy, and serve as **input into subsequent Situation analysis**

Action Plan (Tactics)

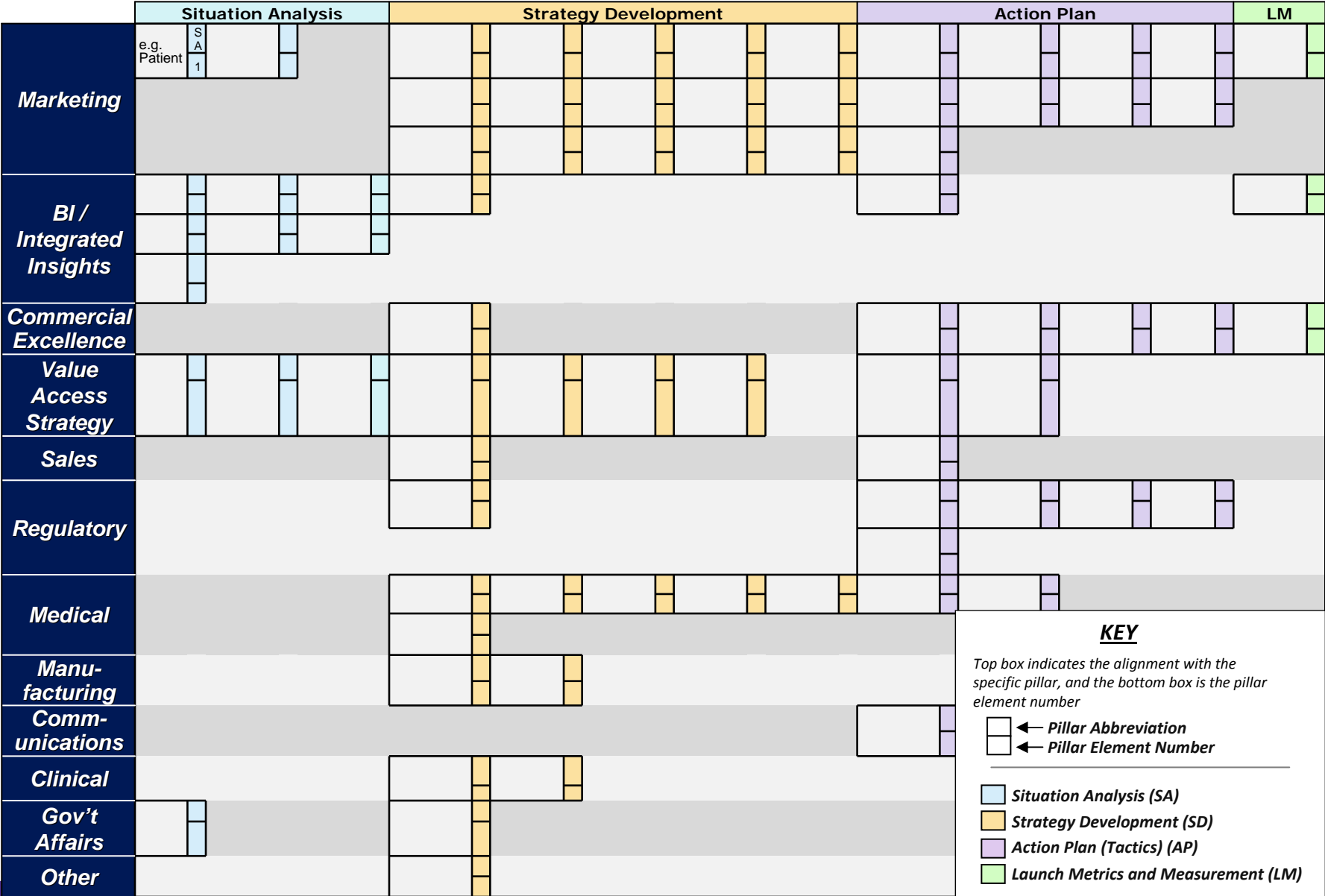
Objective: Develop a clear **activity / tactical plan** and **resource allocation** directly linked to growth levers outlined in strategy

GLE Framework utilizes 77 critical elements of launch success

Product launch is complex with many moving parts. The Global Launch Excellence (GLE) framework establishes a standard approach to launch that ensures alignment, consistency, harmonization and structure.

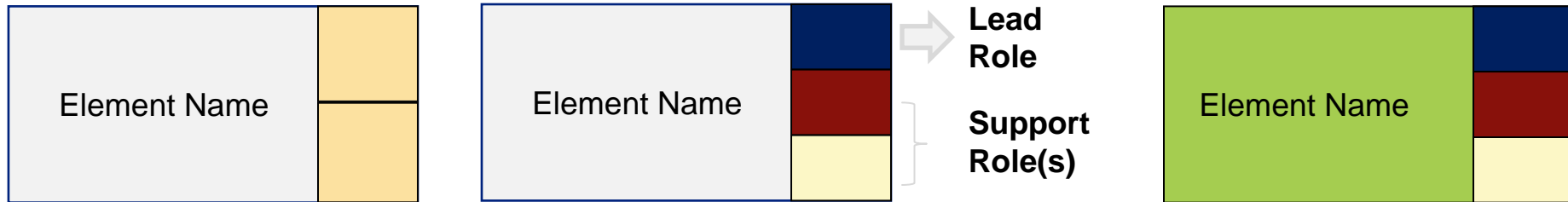


Elements along the launch process and business organization



GLE Framework is structured along the launch process and with in the business to clearly identify key Roles and Responsibilities across functional teams

Launching a brand is a complex and highly cross-functional process involving multiple functional areas across the Commercial organization.



KEY

Top box indicates the alignment with the specific pillar, and the bottom box is the pillar element number

← Pillar Abbreviation
 ← Pillar Element Number

- Situation Analysis (SA)
- Strategy Development (SD)
- Action Plan (Tactics) (AP)
- Launch Metrics and Measurement (LM)

<input type="checkbox"/> Marketing	<input type="checkbox"/> BI
<input type="checkbox"/> Sales	<input type="checkbox"/> Communications
<input type="checkbox"/> Regulatory	<input type="checkbox"/> VAS
<input type="checkbox"/> Medical	<input type="checkbox"/> Clinical
<input type="checkbox"/> Manufacturing	<input type="checkbox"/> Gov't Affairs
<input type="checkbox"/> Drug Safety	<input type="checkbox"/> Commercial Excellence
<input type="checkbox"/> EVD	

← Lead Role
 ← Support Role

Top box indicates the function leading the activity; Bottom boxes indicate support role

KEY

- Global Only
- Global Led with Country Input
- Countries Only
- Regional Input

Hypothetical Scenario: Napa Therapeutics and Lupaxin

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This hypothetical is entirely fictitious.
Any resemblance to actual companies,
individuals, or products is coincidental.

Napa Therapeutics

- Well-funded biopharma focused on immune disorders
- They believe they will receive their first approval soon
- Napa has a Code of Conduct in place, but compliance policies and SOPs are in draft
- They have built out a Commercial function that includes Marketing, Sales, and Market Access (including Health Economics and Outcomes Research). Commercial and Medical are closely aligned in one strategic plan
- Their first Chief Compliance Officer arrived today
 - *That's you – welcome to the company!*

Lupaxin

- When approved, Lupaxin is expected to be indicated for an orphan-designated subset of lupus patients with a specific mutation in the TREX1 gene
- The labeling will indicate that Lupaxin is refractory to an existing generic, trifexa, which has marginal efficacy, but a favorable risk profile
- Lupaxin will have a Black Box Warning in the US regarding kidney effects
- Daily self-injection – chronic treatment
- Pricing likely to be €100,000 per year

Companion and Complementary Diagnostics

- Napa has partnered with Mateo Diagnostics on the development of:
 - A companion diagnostic that identifies patients with the specific TREG1 mutation that will be referenced in the Lupaxin labeling
 - A complementary diagnostic for monitoring of kidney function. This diagnostic will not be identified in labeling, which just refers to careful monitoring of kidney function generally

Patient Support

- The strategic plan for Lupaxin provides for using a third party in Western Europe who will administer:
 - Benefits investigation/reimbursement support
 - Patient counseling
 - Adherence programs
 - Coordination of diagnostic testing
 - Adverse event reporting to Napa

Advisory Boards

- The Lupaxin strategic plan contemplates that the advisory boards would be help in the 6 month period before launch in a number of countries
- The advisory boards would consist of 15-25 HCPs who would hear presentations on Lupaxin, receive clinical updates, and provide input on product messaging
- The advisory boards plan to cover 5% of HCPs in each country, selected by the commercial organization based on potential use of the product
- The chairpersons for each advisory boards would be selected from Napa's customer relations database and compensated for preparation time, making a presentation on clinical developments, and presiding over the meeting

Expanded Access Program

- Napa also anticipates that some patients will experience a delay in coverage for Lupaxin, and they want to find a way to provide those patients with immediate access to the product. Three options are on the table:
 - Providing samples (a “starter kit”) to physicians through a third-party vendor
 - Offering a free trial supply fulfilled directly to patients and subsidizing the cost of the diagnostics
 - Initiating an expanded access trial
 - The trial would enable collection of safety information and real world evidence, but it would also serve as a bridge to covered drug, both for new patients and patients in Lupaxin trials

Field Reimbursement Managers

- Napa is considering hiring Field Reimbursement Managers to assist physicians/patients in navigating coverage and reimbursement challenges for Lupaxin and the companion/complementary diagnostics
 - The FRMs would report to the Market Access function

Clinical Nurse Educators

- Napa is considering hiring Clinical Nurse Educators (CNEs)
 - The CNEs would report to Napa Marketing
 - They would conduct disease education and injection training at rheumatology practices across Western Europe
 - These programs would target both office nurse/PA staff and new start patients
 - They also would focus on helping physicians, staff and patients understand the role of the companion/complementary diagnostics vis-à-vis Lupaxin
 - The CNEs also would provide disease education for patient advocacy organizations across the country

Patient Group Collaboration

- Napa is in discussions with a major lupus patient advocacy group in Germany regarding several potential initiatives:
 - Coordination on advocacy for coverage of Lupaxin by various governments
 - Creating a role for the patient advocacy group in disseminating information about the planned NapaPAP, Napa's Clinical Nurse Educators, and the limited Lupaxin specialty pharmacy distribution network