



# Strategies for **Successful** **Pharmaceutical Product** **Launches**



Place  
**Online Zoom**



April | Tue | 24 | 2025



9 Pm



10 Pm



11 Pm

# MARKETING *Club* 177<sup>th</sup>

177<sup>th</sup> Marketing Club  
133<sup>rd</sup> Business Club  
40<sup>th</sup> Riyadh Club



CLUB FOUNDER, HOST  
**DR. MAHMOUD BAHGAT**  
LEGENDARY DIRECTOR

## Product Lunch Readiness



JOIN FREE

LIVE WEBINAR

Date

22<sup>nd</sup> April  
2025  
Tuesday

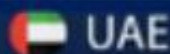
9 pm



10 pm



11 pm



Place  
Online  
Zoom



Instructor  
**Dr. Ahmed Othman**  
Marketing Manager

# Ahmed Othman



2003



2006



2015



2004



2011



2017

2018: PMP





**Ahmed Othman**



2003	Faculty of Pharmacy – Minia University
2004	Abbott Egypt
2006	Riyadh Pharma – Medical Rep.
2009 - 2011	MBA, marketing management -SMU
2011	Riyadh pharma – Product manager
2014	Riyadh pharma – District manager
2015	Makhzani Holding – S&M director
2017	Cooper Pharma – Marketing and BD manager
2018	PMP, Project management institute
2023	Cooper Pharma – GCC Marketing manager





# Objectives and Pay Off



Overview about LR importance



Case studies



Launch readiness articulation



Launch readiness Pitfalls






The 3 A's Model




Free LR Kit





# How many launches have you managed / Participated in ?



[<](#) Activities

 Visual settings

 Edit





When poll is active respond at [PollEv.com/ahmedosman903](https://PollEv.com/ahmedosman903)

How many launches have you run

☐ I didn't run any launches

☐ Partially involved in some launches



Powered by  Poll Everywhere

# Why you are here today?



Who can benefit ?



Image credit: <https://www.facebook.com/3lm.nafe3/>

## What is Launch readiness ?

Launch Readiness is a **framework** designed to help the new product launch team achieve the best possible launch by:

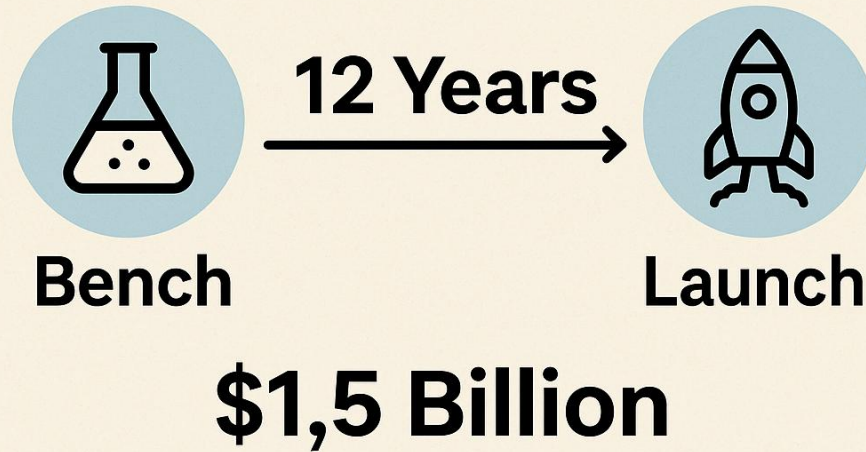
- **Providing a common approach** that incorporates, and highlights launch best practices.
- Helping to identify and gain **alignment** on cross-functional partner roles & responsibilities, deliverables and timing.
- Serving as a **tracking** and communication tool for both the launch and management team.

# Launch & Launch readiness !!!



## From bench to launch

### Drug Development Timeline & Cost



Getting a drug from bench to launch takes an average of 12 years and \$1.5 billion.



# IT CAN TAKE YEARS TO DEVELOP A DRUG

*A launch can fail in a matter of weeks*

## Why Launch is Important ?

81% of future drug sales performance is determined by actions taken during clinical development, **early commercialization**, and **product launch**.



Future sales performance  
determined around launch success

1 M. Corstjens, I. Horowitz, E. Demeire: One bite at the cherry, Journal for Economics of Innovation and New Technology, 2005.

## Why Launch is Important ?

About two thirds of new drugs fail to meet pre-launch consensus sales expectations for their first year on the market.”

Most of these drugs continue to underperform even three years post-launch.



Fail to meet  
launch expectations

3 McKinsey & Company. (2014, March). The secret of successful drug launches.

# Why Launch is Important ?



70%

Continue to lag  
3 years post launch

# Are you / your team and your organization are ready for the launch ?



How do we effectively operationalize our launch strategy?

How do we know we're not missing anything, we have identified the risks—and we are leveraging benchmarks and best practices relevant for this launch?

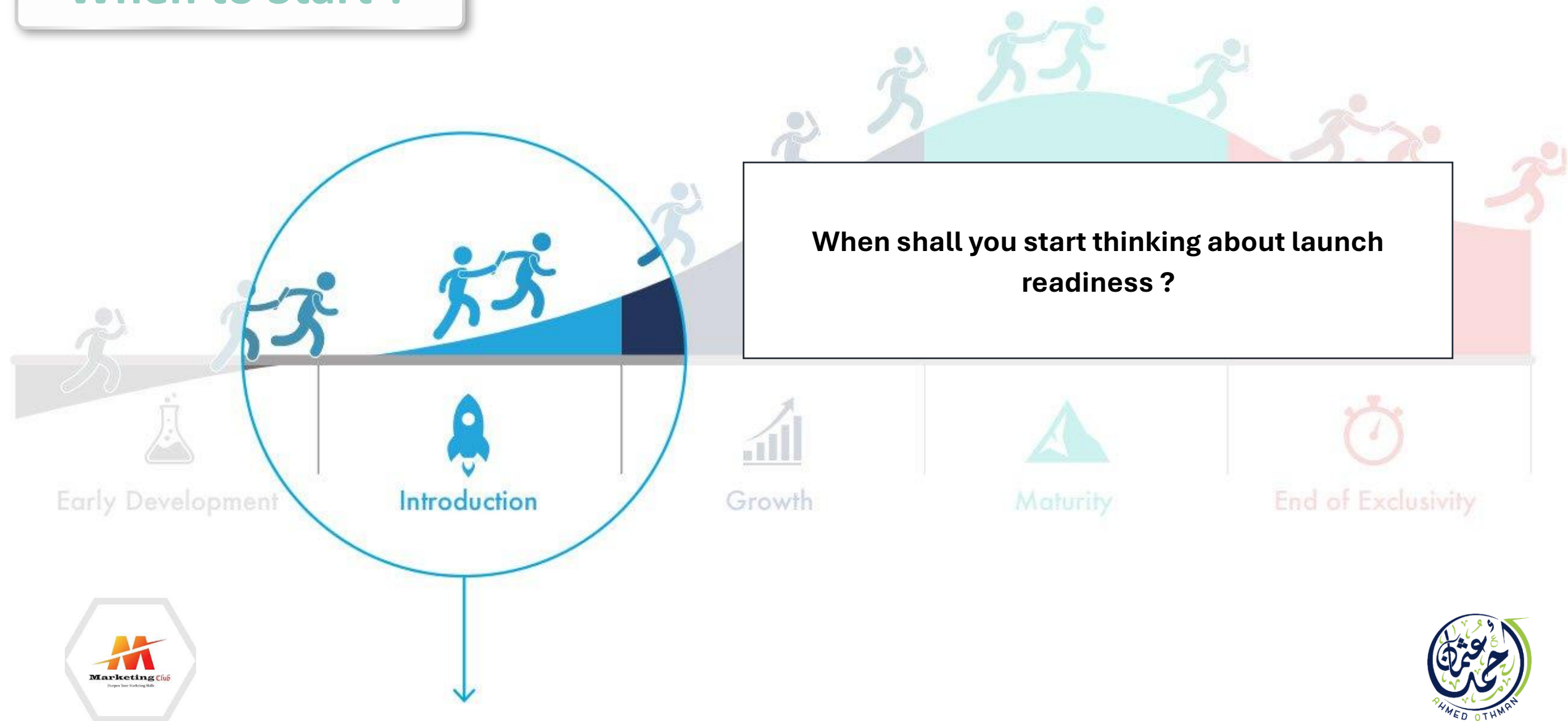
How can we achieve cross-functional alignment—and accountability—on priorities?

Where are the cross-functional interdependencies? How can they be tracked and managed in a changing environment?

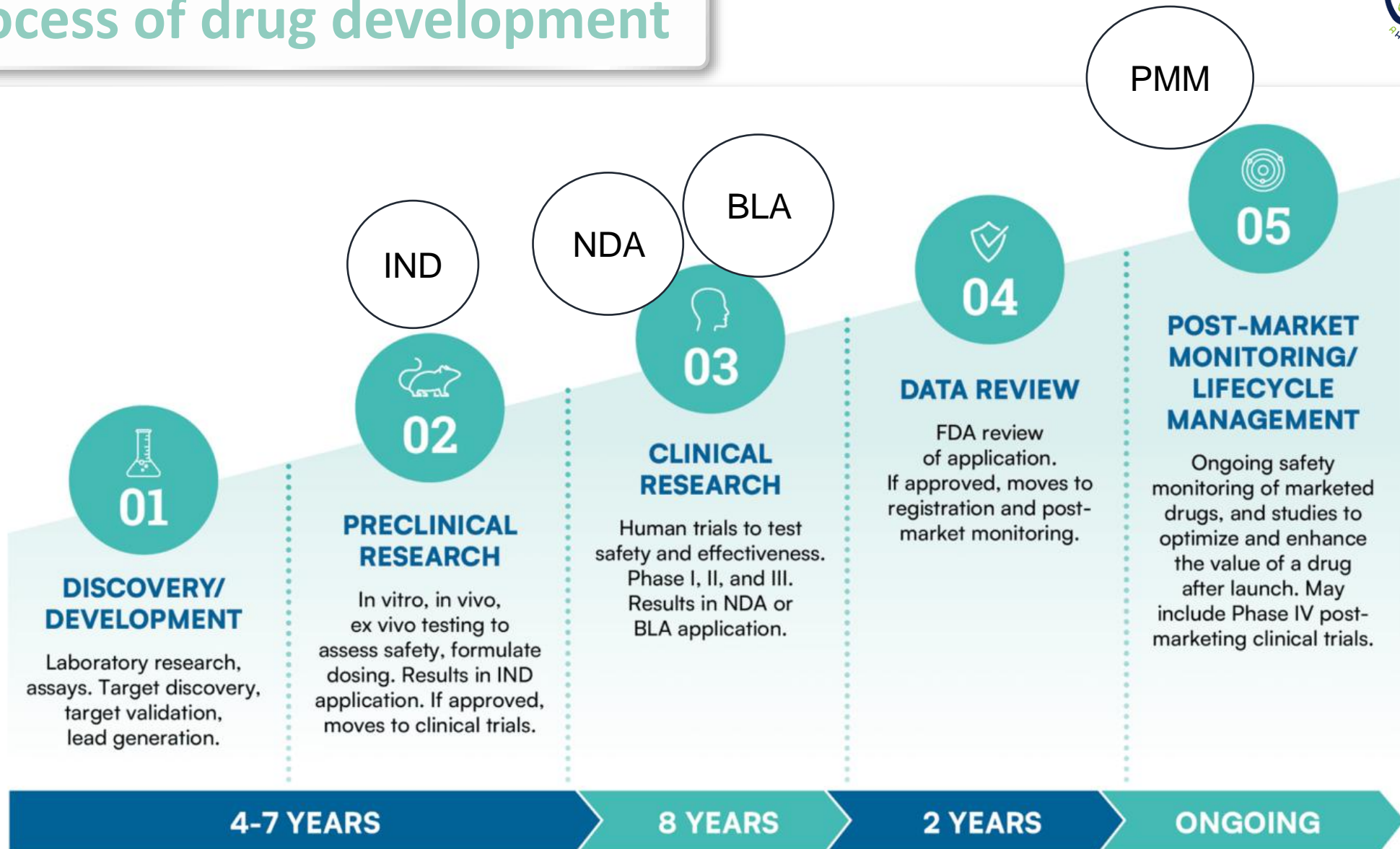
What does good launch excellence mean and how do we achieve it?



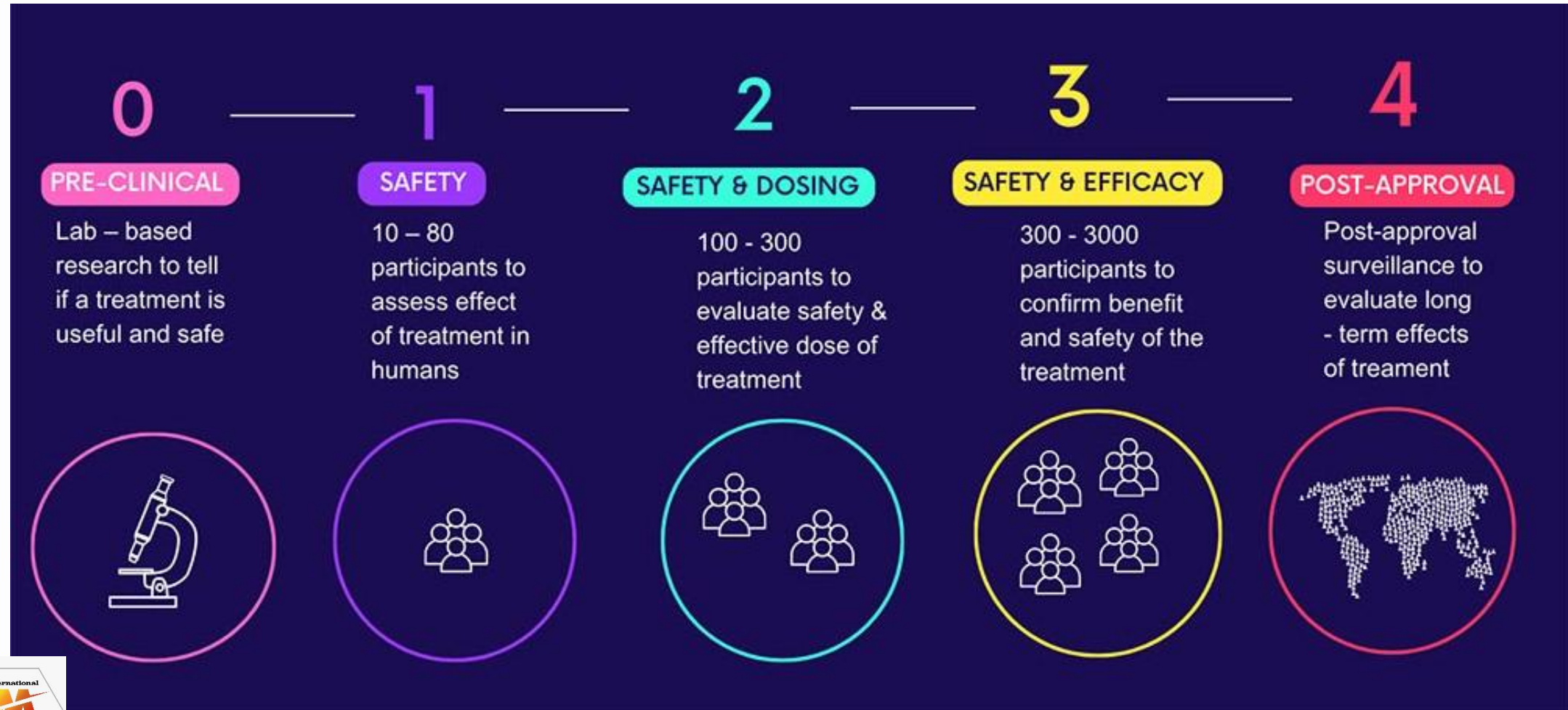
# When to Start ?



# The Process of drug development

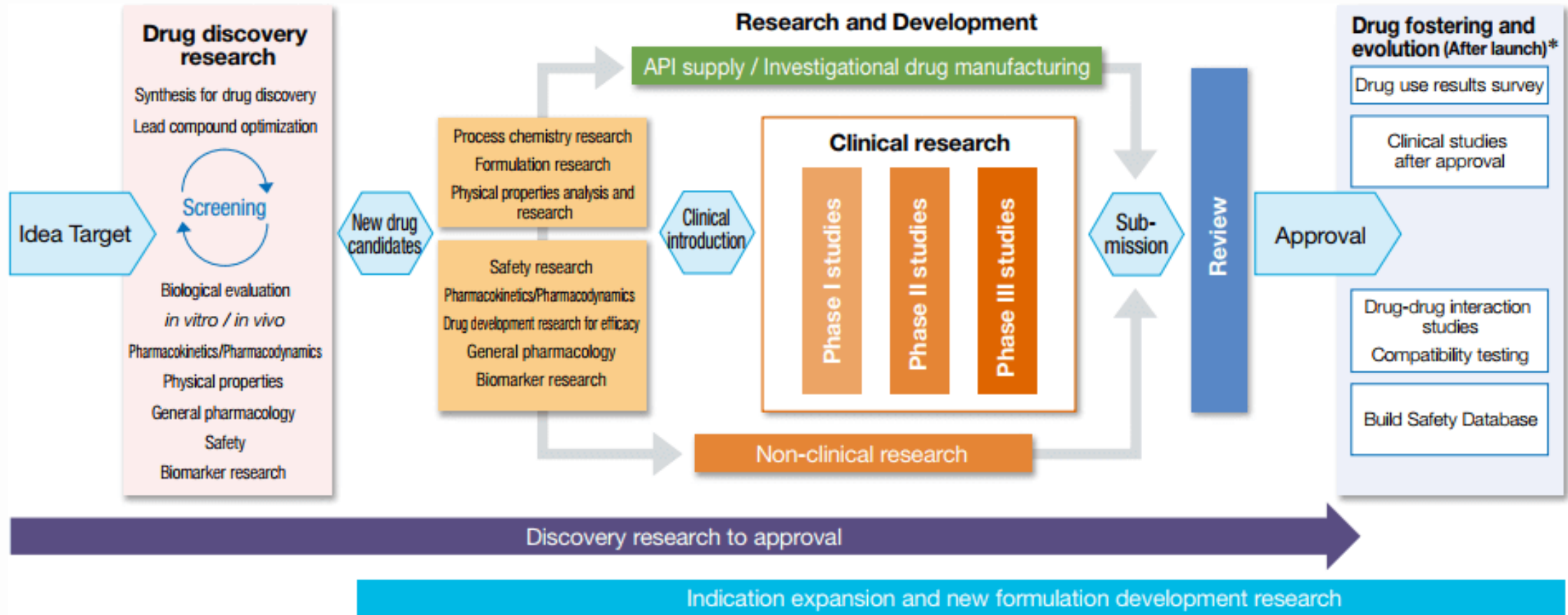


# Phases of a clinical trial



<https://rarediseaseresearch.ie/clinical-trials-explained/>

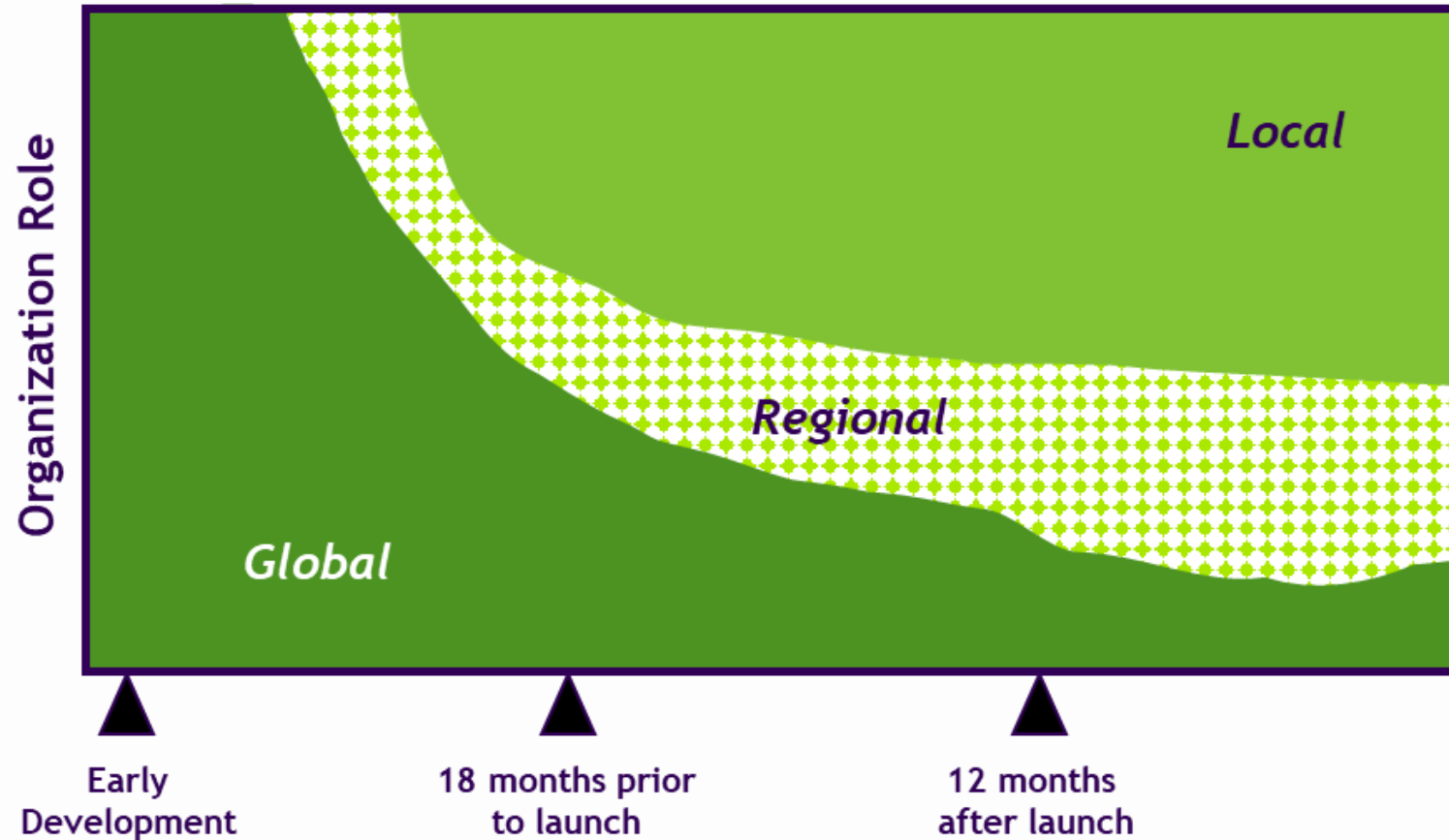
# Phases of a clinical trail



**From bench to launch**

<https://www.eisai.com/innovation/research/research/index.html>

# Levels of involvement



R&D & Medical  
Strategy & BD

Regional Marketing  
Finance

Local Marketing teams  
Market access & Sales team



## Launch readiness articulation

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# Being first generic



## Pros.

**Pricing Power:** The first generic can set a higher initial price before other generics enter the market.

**Revenue Potential:** First movers can secure lucrative tender contracts and higher reimbursement rates. You only need to give an advantage vs the brand, however 2nd and 3rd generics have to compete with other generics as well.

**Competitive Edge:** Capturing a large market share early and building strong relationships with distributors and healthcare providers leads to long-term market dominance.

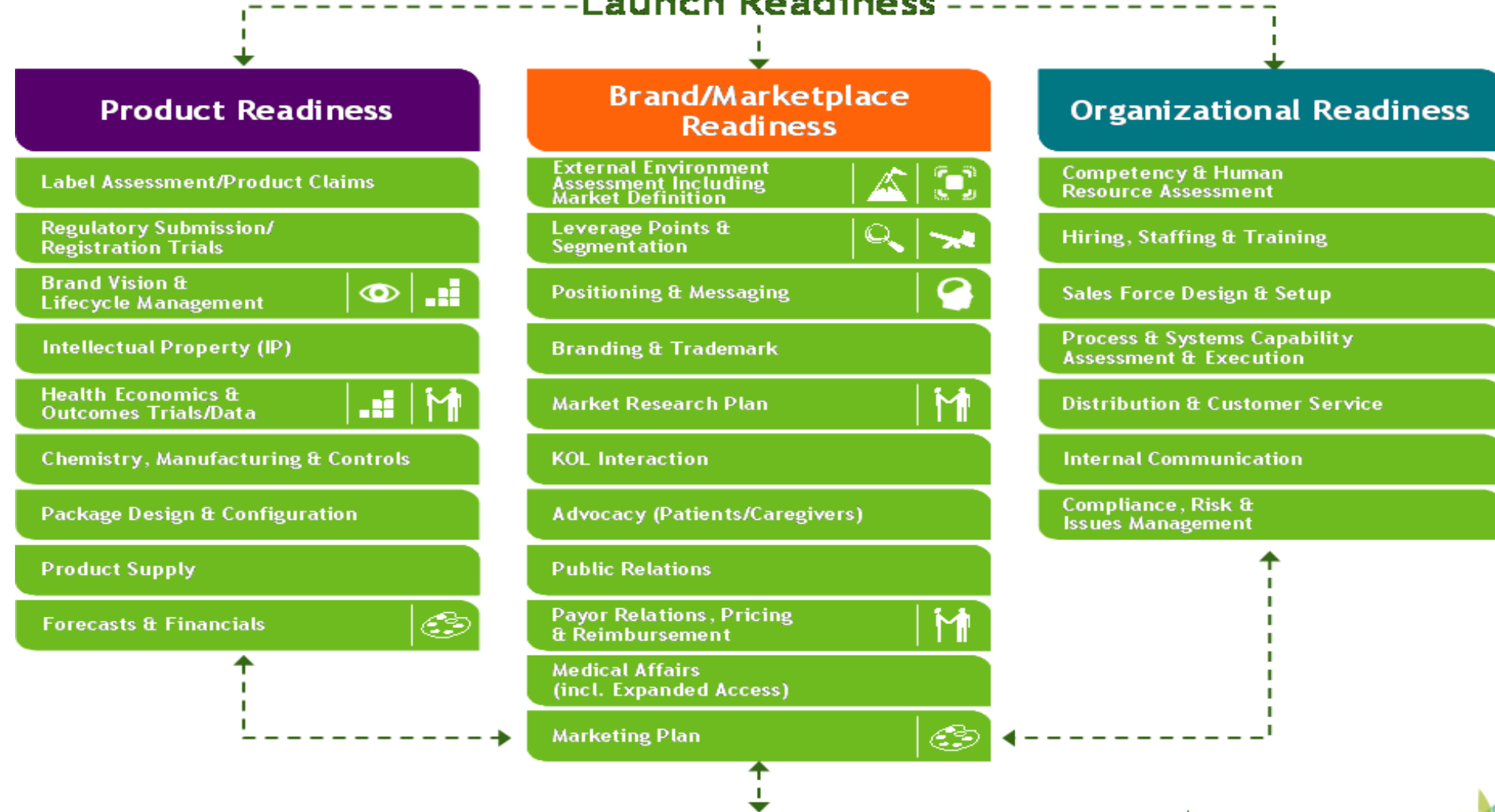
**Easy market access:-**

## Cons

- Higher APIs / Dossier fees.
- Litigation with the innovator company.
- Higher S&M expenses to start converting the Rx behavior from brand to Generic.



## Launch Readiness



Launch Setup & Performance Management

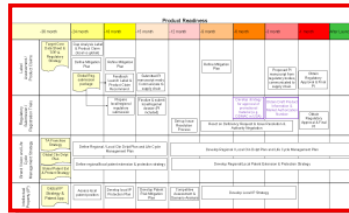
# Launch readiness articulation

Launch Readiness framework



## GAP analysis

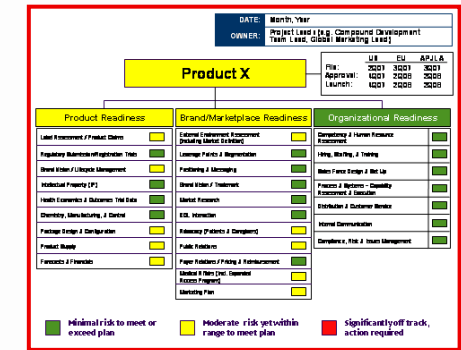
Launch Readiness activity map on prioritized activities



Launch Readiness checklist on prioritized activities

Readiness Pillar	Activity	Launch Readiness Pillar	Launch Readiness Pillar	Launch Readiness Pillar
Product Readiness	Product Development	Brand/Marketplace Readiness	Brand/Marketplace Readiness	Organizational Readiness
Product Development	Product Development	Brand/Marketplace Readiness	Brand/Marketplace Readiness	Organizational Readiness
Product Development	Product Development	Brand/Marketplace Readiness	Brand/Marketplace Readiness	Organizational Readiness
Product Development	Product Development	Brand/Marketplace Readiness	Brand/Marketplace Readiness	Organizational Readiness
Product Development	Product Development	Brand/Marketplace Readiness	Brand/Marketplace Readiness	Organizational Readiness
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Product Development	Product Development	Brand/Marketplace Readiness	Brand/Marketplace Readiness	Organizational Readiness
Product Development	Product Development	Brand/Marketplace Readiness	Brand/Marketplace Readiness	Organizational Readiness
Product Development	Product Development	Brand/Marketplace Readiness	Brand/Marketplace Readiness	Organizational Readiness
Product Development	Product Development	Brand/Marketplace Readiness	Brand/Marketplace Readiness	Organizational Readiness

Launch Readiness dashboard



Situational analysis

Strategy

Tactics

Follow up

# Project charter



## Step 1: Create the project charter (One Page Guide)

A project charter is a formal document that officially kicks off a project.

It explains the project purpose, goals, and scope, outlines key tasks, and identifies who's responsible for what deliverables.



### Project Charter

#### Definition

Leverage Points are opportunities to change or reinforce behaviors to create disproportionate impact. Segmentation is a tool that enables clear choices for aligning specific customers and their needs with our product's unique benefits. Segmentation results in a common framework for defining the market and mapping its economic potential. Segmentation is a trigger for actions in numerous areas: marketing channel selection, sales force allocations, marketing mix etc.

#### Critical Questions

- Phase II –
  - What is the process by which patients enter and flow through the healthcare system?
  - What are the points of leverage where we have an opportunity to influence behavior to drive disproportionate growth for our brand?
  - What specific behaviors do we need to influence in order to create our desired change?
  - What customer segments appear to exist in the market – size, growth, drivers, barriers, unmet needs?
- Phase III and beyond:
  - What specific marketplace behaviors can we change to maximize our potential?
  - Is the segmentation truly actionable? How sustainable is it?
  - Which segments will be most important in our market?
  - How will we sequence the segments?
  - What elements of the marketing mix require adjustment based on learnings from the segmentation exercise?
  - How differentiated and competitive is the value offering for these segments?
  - What messaging resonates best with each segment?

#### Global Deliverables (Input to local)

- Target Product Profile/Target Core Data Sheet (Global & Regulatory) – 24 months before launch
- Global MA strategy – 18 months before launch (Global Strategic Marketing) – to include
  - Identify Leverage Points via Global Buying Process and Behavioral Objectives
  - Preliminary segmentation

#### Local/ Regional Deliverables (Output from local)

- Validate and modify MA Strategy (including Buying Process, Market Definition and Leverage Points & Behavioral Objectives, etc.) based on local conditions – 12 months before launch
- Local Targeting Plan – 9 months before launch (Marketing)

#### Key Performance Indicators

- Milestones & timelines met
- Validation of segmentation
- Implementation of segment-specific strategies at launch?
- KOL review and endorsement of segmentation?

#### Best Practices

- Detailed segmentation performed on relevant customer groups (physicians by specialty, patients) using quantitative and qualitative analytic tools
- Segmentation plan is both actionable and meaningful
- Profiling market based on segmentation prior to launch
- Targeting plan reflects segmentation

#### Linkage to Marketing Approach Choices



[Segmentation](#)



[Leverage Points and Behavioral Objectives](#)

# Project charter



PW: marketingclub



# Activity Map

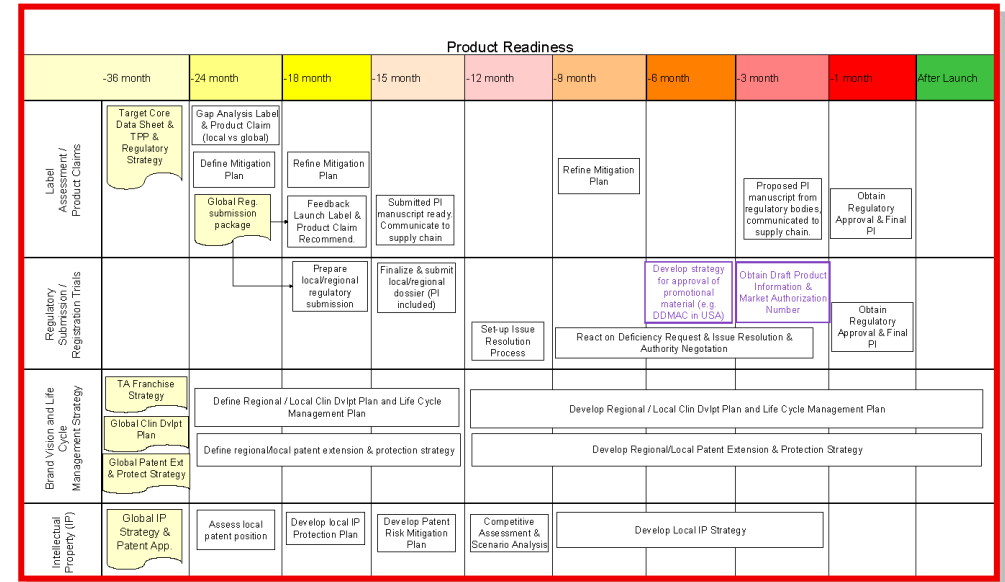


## Step 2: Create your launch readiness activity Map

A detailed Activity Map for each Launch Readiness element provides:

A visual representation of activities and suggested timing (based on best practices)

The global/regional inputs  
Critical activities.



# Activity Map



## Step 3- Create your Critical success factors list



Critical Issues / Action:  
insert Compound/Product Name

DATE:	XX/XX/XX	STATUS:	(insert color)
OWNER:			

Issue: (Describe the issue being addressed)
Owner: (Who owns the metric - Example: Product Brand Director, Project Lead)
Timing of Actions:
Action Status:
Explanation:
Performance Criteria: (Describe the metric and performance status)
Financial Impact: (What is financial impact of metric performance Ex: will miss plan target by \$XMM or X%)
Strategic Implications: (What is impact to Strategic Plan commitments if any.)
Decisions Required: (Are management decisions required prior to or during execution)
Resource Required: (Are financial/people resources required prior to or during execution)

# Create your Launch team

## Step 4 : Launch Team / Task force / Focus group / SteerCo.

Assign team responsibilities and authorities

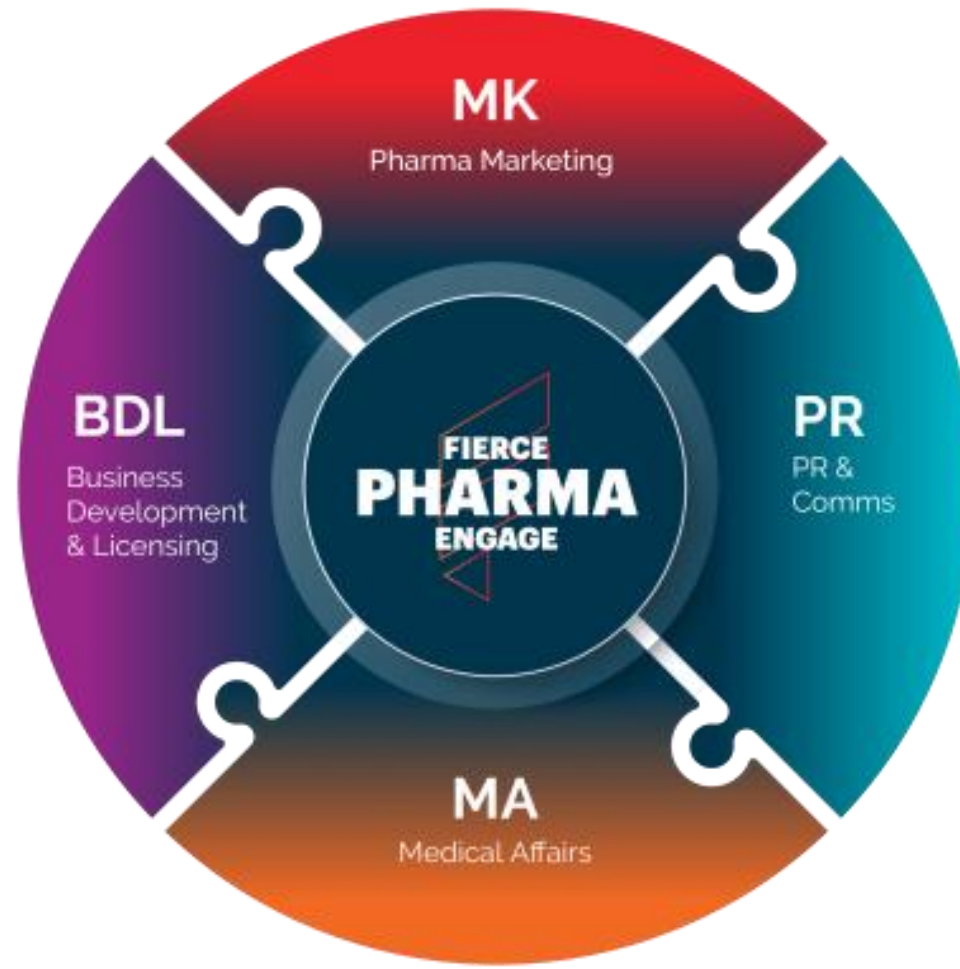
## Launch leader & Launch Champions



Who takes the lead ???

1	<b>The right leader</b> <ul style="list-style-type: none"><li>• The leader is trustworthy, competent, capable and of the right stature</li><li>• Experienced as both a team member and a team leader</li></ul> 
2	<b>Qualified people in their roles</b> <ul style="list-style-type: none"><li>• Individual contributors are qualified and have the right skills</li><li>• You've considered team chemistry</li></ul> 
3	<b>Optimal allocation of team resources (people, budget)</b> <ul style="list-style-type: none"><li>• Team members know what they are supposed to do, and they manage expectations</li><li>• Team has a clear decision-making model, and the escalation path is clear</li></ul> 
4	<b>Explicit ground rules from management</b> <ul style="list-style-type: none"><li>• Management has ensured that the team has everything they need to be successful</li><li>• Between one and two projects is the optimum load</li></ul> 
5	<b>Clear team goals and clear communication</b> <ul style="list-style-type: none"><li>• Have a clearly agreed-upon, measurable goal</li><li>• Have clear objectives and frequent communication</li></ul> 

# Cross functional team

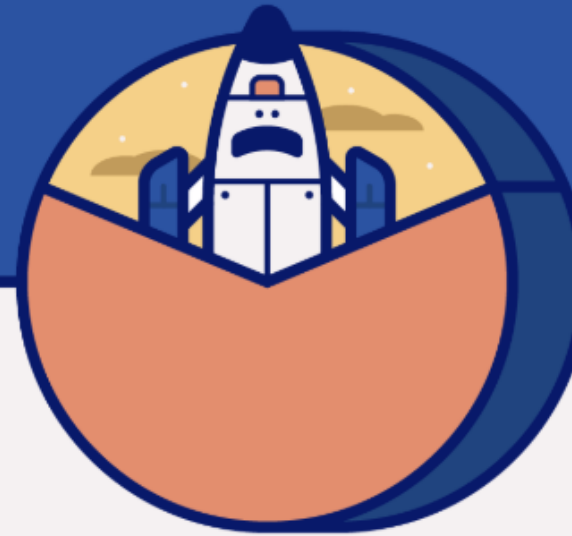


# Choose your market access strategy



## HARD LAUNCH

You launch your product to the entire market with full marketing support and scale.



## SOFT LAUNCH

You launch your product to a small, segmented piece of the market to test your approach.

# Market access and KOLs



KOLs engagement should begin during Phase II

## KOL Engagement Best Practices

Evolving Nature of KOL Discussions:

DISEASE STATE  
AWARENESS



CLINICAL  
RESULTS



THERAPEUTIC  
OUTCOMES



Engaging KOLs:

- Medical congresses and symposia
- Advisory board consultations
- Scientific publications

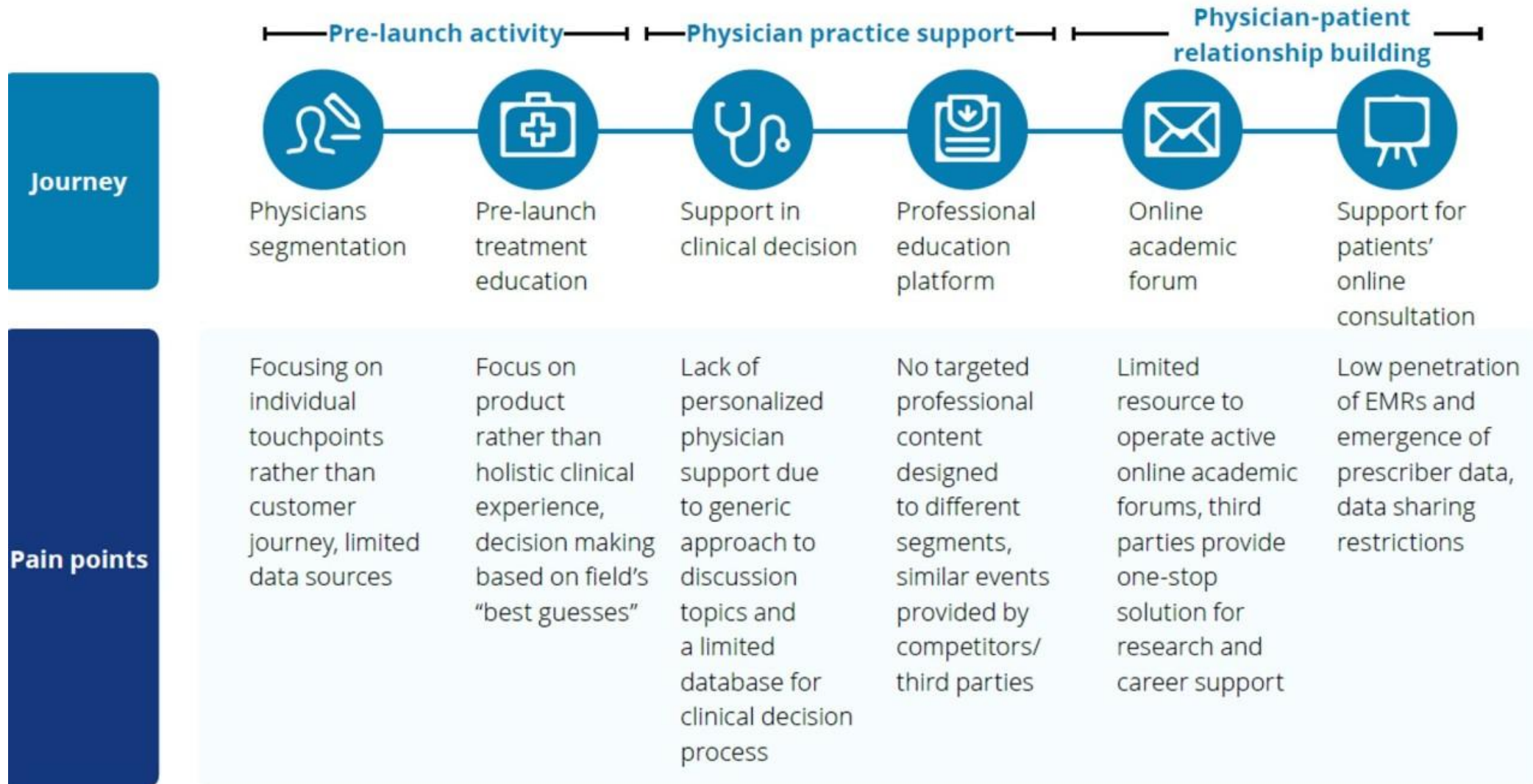
reinforce the validity of the clinical data

Disease state education programs

develop peer-reviewed,  
evidence-based, clinical information.

from disease state  
awareness to education around clinical  
results and, eventually, therapeutic  
outcomes.

## KOL engagement should begin during Phase II



# Follow closely the 3 dimensions

## Step 5: follow up dashboard

DATE: Month, Year

OWNER: Project Leads (e.g. Compound Development Team Lead, Global Marketing Lead)

### Product X

	US	EU	APJLA
File:	2Q07	3Q07	3Q07
Approval:	4Q07	2Q08	2Q08
Launch:	4Q07	2Q08	2Q08

Product Readiness	Brand/Marketplace Readiness	Organizational Readiness
Label Assessment / Product Claims <span>■</span>	External Environment Assessment (including Market Definition) <span>■</span>	Competency & Human Resource Assessment <span>■</span>
Regulatory Submission/Registration Trials <span>■</span>	Leverage Points & Segmentation <span>■</span>	Hiring, Staffing, & Training <span>■</span>
Brand Vision / Lifecycle Management <span>■</span>	Positioning & Messaging <span>■</span>	Sales Force Design & Set Up <span>■</span>
Intellectual Property (IP) <span>■</span>	Brand Vision / Trademark <span>■</span>	Process & Systems – Capability Assessment & Execution <span>■</span>
Health Economics & Outcomes Trial Data <span>■</span>	Market Research <span>■</span>	Distribution & Customer Service <span>■</span>
Chemistry, Manufacturing, & Control <span>■</span>	KOL Interaction <span>■</span>	Internal Communication <span>■</span>
Package Design & Configuration <span>■</span>	Advocacy (Patients & Caregivers) <span>■</span>	Compliance, Risk & Issues Management <span>■</span>
Product Supply <span>■</span>	Public Relations <span>■</span>	
Forecasts & Financials <span>■</span>	Payer Relations / Pricing & Reimbursement <span>■</span>	
	Medical Affairs (Incl. Expanded Access Program) <span>■</span>	
	Marketing Plan <span>■</span>	

■ Minimal risk to meet or exceed plan

■ Moderate risk yet within range to meet plan

■ Significantly off track, action required

## Step 6- After action review:

An After-Action Review (AAR) or report should be conducted by the launch team 3-6 months after launch

build “**corporate memory**” around the strengths and opportunity areas of each launch

### AAR

- An After-Action Review (AAR) should be conducted by the launch team 3-6 months after launch
- The goal of completing an AAR is to share best practices and build “corporate memory” around the strengths and opportunity areas of each launch
- AAR results will be posted to a Corporate Marketing Excellence site so that learnings can be broadly shared

#### Definition

Provide an assessment of the success of the launch team in regards to meeting/exceeding expectations and what activities they would recommend to help better the launch process in the future. Areas to consider for evaluation are, timing and ability to meet critical path deadlines, team dynamics and abilities, interdependent support on other departments and ability to create a sense of urgency, and other areas such as resource allocation and ability to execute.

#### Critical Questions

- Did the launch meet/exceed our expectations? Why? Why not?
- How can we improve the launch readiness process?
- What were the top 3 things that led to a successful launch?
- What would the launch team change in retrospect? Did the team confer with another launch team prior to launching?
- What helped the teamwork as a high performance team?
- If the team would have had more time, what would the team have done?
- If the team were allocated more in financial support, where would they have invested?
- Did we meet the Speed to Launch criteria? When was product/price/reimbursed approved? When was the first sales call made? When was the first shipment made? Could we have launched sooner? What were the obstacles?
- Was the Launch Readiness Tool Kit helpful in guiding your preparation? Which tools were the most valuable? What changes would you recommend?

#### Tools/Process Inputs

- Fill out after action report with team

#### Outputs

- Discuss findings within the team and share them with others in the organization

#### Key Performance Indicators

- Execution of launch team plans
- Ability to hit launch milestones and performance metrics, i.e. Market Share, sales, market placement

#### Best Practices

- Utilizes Launch Readiness Framework and other tools
- Sets and achieves milestones
- Complete After Action Review Report

# G2M Go to Market strategy

## Go to Market Strategy

### Current State Market Analysis

- Industry overview
- Customer pain points
- Channel segmentation

### Alignment of Products & Services

- Competitive landscape
- Identify gaps
- Partner & channel fit

### Market Potential & Projections

- Channel outlook
- Penetration analysis
- Sales forecast

### Recommendations & Roadmap

- Product & service development
- Partner & channel selection
- Branding & marketing

### Account Planning

- Prospect identification
- Sales strategy
- Targeted offer & messaging

## Outcome

Where to play



How to win



What it's worth



How to do it

# G2M Go to Market strategy



Source: Deloitte analysis.

Deloitte Insights | [deloitte.com/insights](https://deloitte.com/insights)

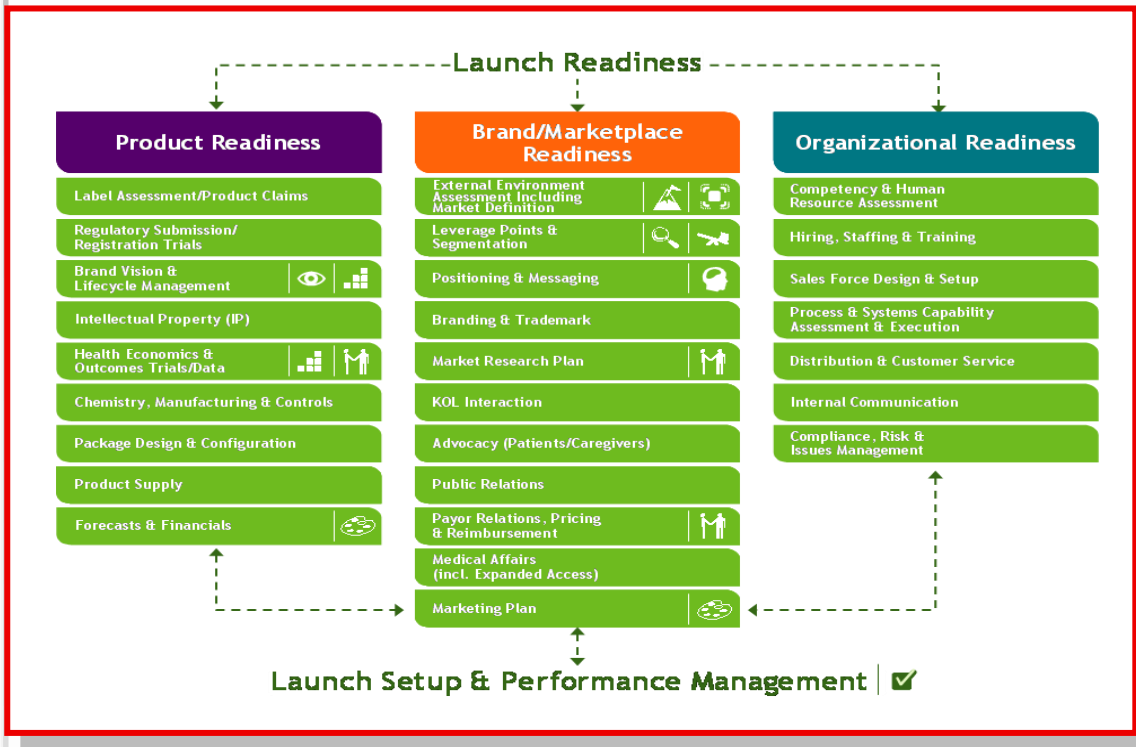
# Linking Marketing Approach and Launch Readiness

- > Marketing Approach guides development of marketing strategy and plans, which are critical in new product launch (and throughout the product lifecycle)
- > Launch Readiness encompasses the **outcomes** of the Marketing Approach, as well as all other commercial and related work necessary to successfully to launch

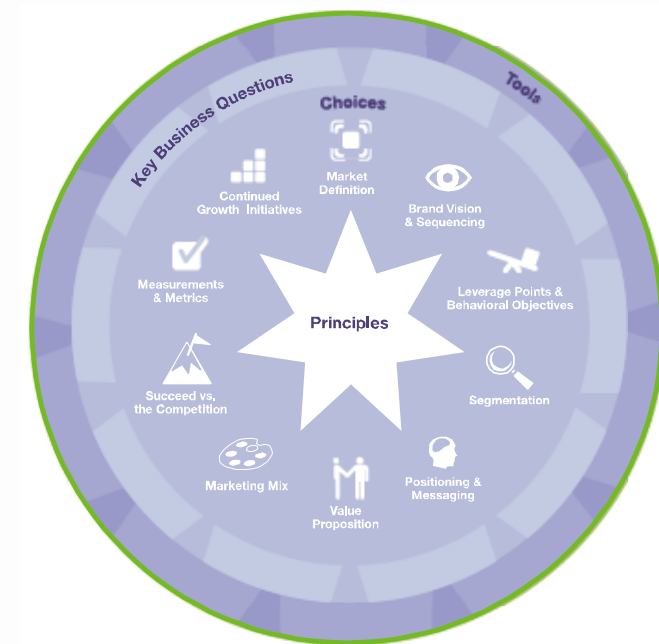


# Linking Marketing Approach and Launch Readiness

## Launch Readiness



## Marketing Approach



## الدنيا ماشية ولا إيه



الراجل ده بيقول حاجات غريبة يا جدم

# The 3 A's Model

## The 3 A's Model

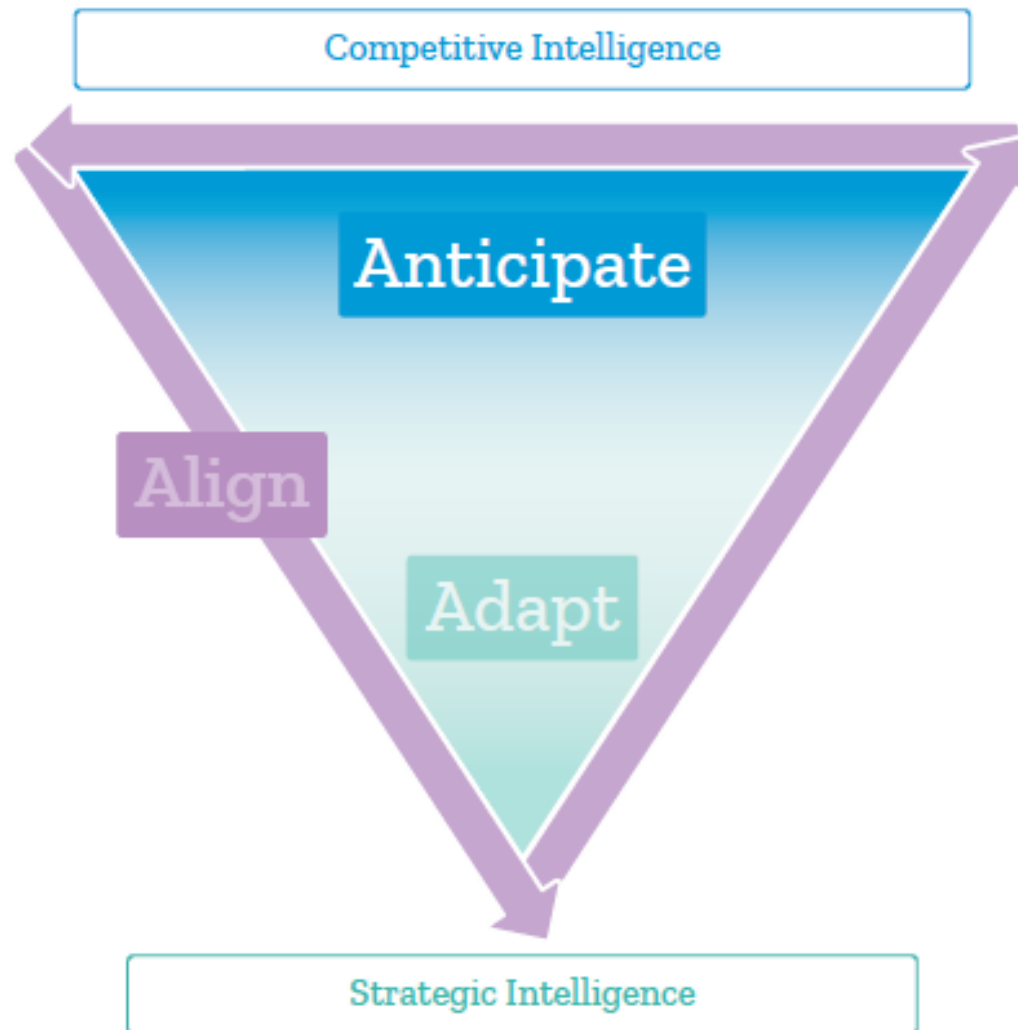
# *The three A's*

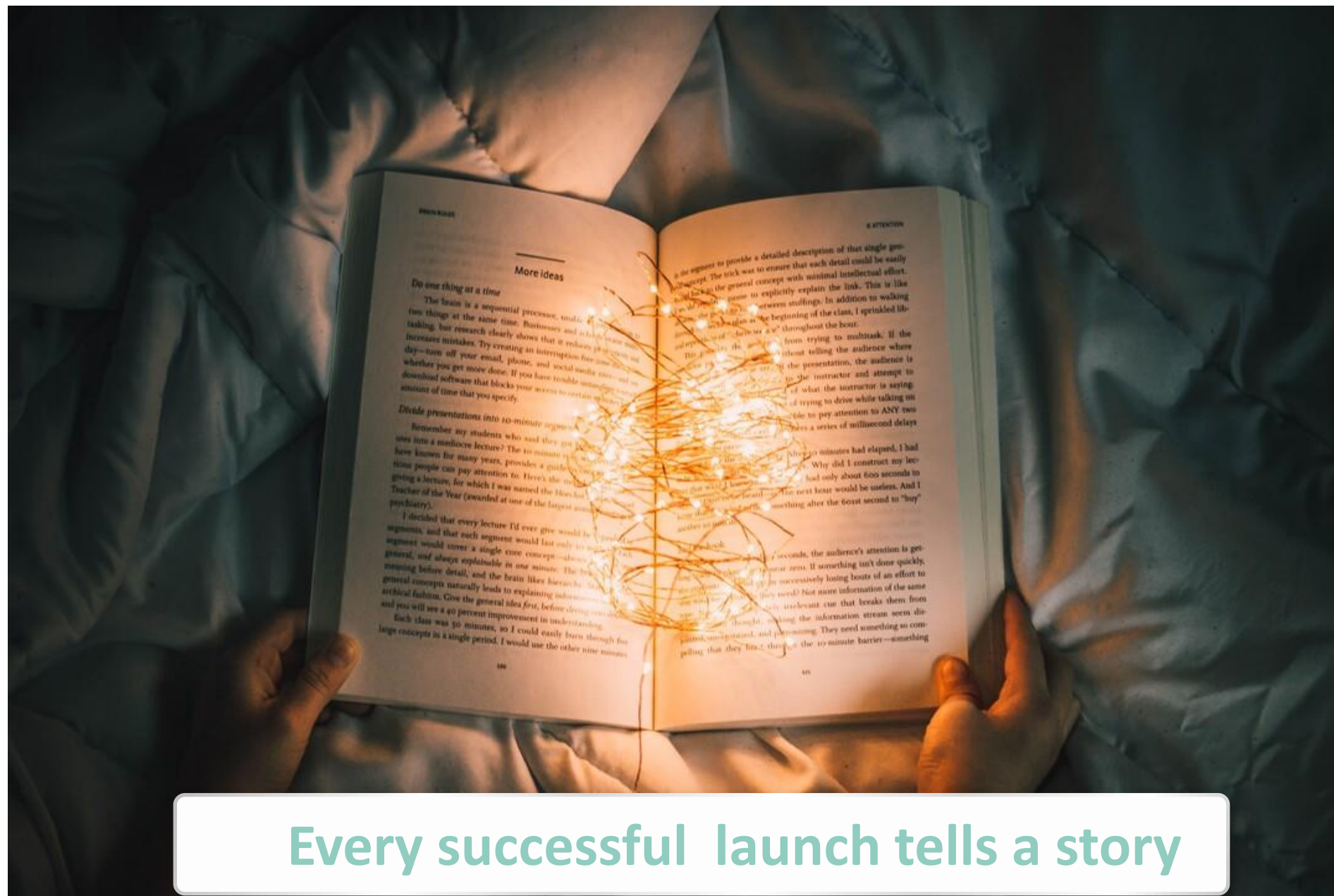
One key factor often seen in failed launches is an inability to recalculate strategies and tactics in the face of a new and unexpected market landscape. This new complication could take many forms:

- A poor awareness of competition and anticipation of competitor moves.
- An inability to adapt to changes, whether from a competitor or the market itself.
- A misalignment between global launch strategies and local realities.

Anticipate and Adapt are positioned from the view of evolving from 'Competitive Intelligence' (in blue) to 'Strategic Intelligence' (in green) from broad information (wide top of the triangle) to refined specific strategic action (point of the triangle). Alignment is required throughout the process of 'Anticipate' and 'Adapt', hence its position and the color code (purple arrow on the outer edge).

# The 3 A's Model





Every successful launch tells a story



## In the Management of Functional Dyspepsia

Dyspepsia  
**With** **Out**  
**Ganaton**

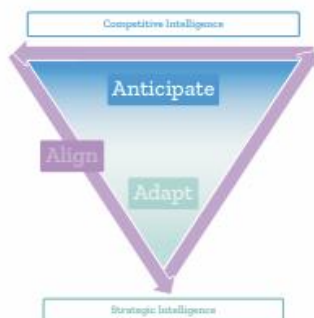


Overcome Your Fears with **Ganaton**



# Anticipate

## Anticipate competitor activity



### Anticipate competitor activity

Competitive landscape  
Competitor deep dives  
Scenario workshop and competitive simulation  
Competitor monitoring

### Anticipate stakeholder drives

Primary and secondary research with key stakeholders, including: patients, prescribers, regulators, key opinion leaders

#### Competitive landscape

Identify direct and indirect competitors in the market

Evaluate the economic and non-economic aspects of key customers, products and company capability of the competitors

Identify competitors' strengths and weaknesses

Specify drug's competitive advantage and map positioning in the competitive landscape

#### Competitor deep dive

Identify most relevant key competitor(s) in the market

Continuously assess all key competitive activities

Identify likely competitor actions and reactions to launch of drug into market

Use competitor assessment to map potential opportunities and threats to the launch

Analyze in-depth secondary resources (SEC filings, scientific publications, clinical trial status etc.)

Secondary Research

Primary Research

Target broad range of stakeholders

Benchmarking and synthesis of findings

Generate strategies via, e.g.:

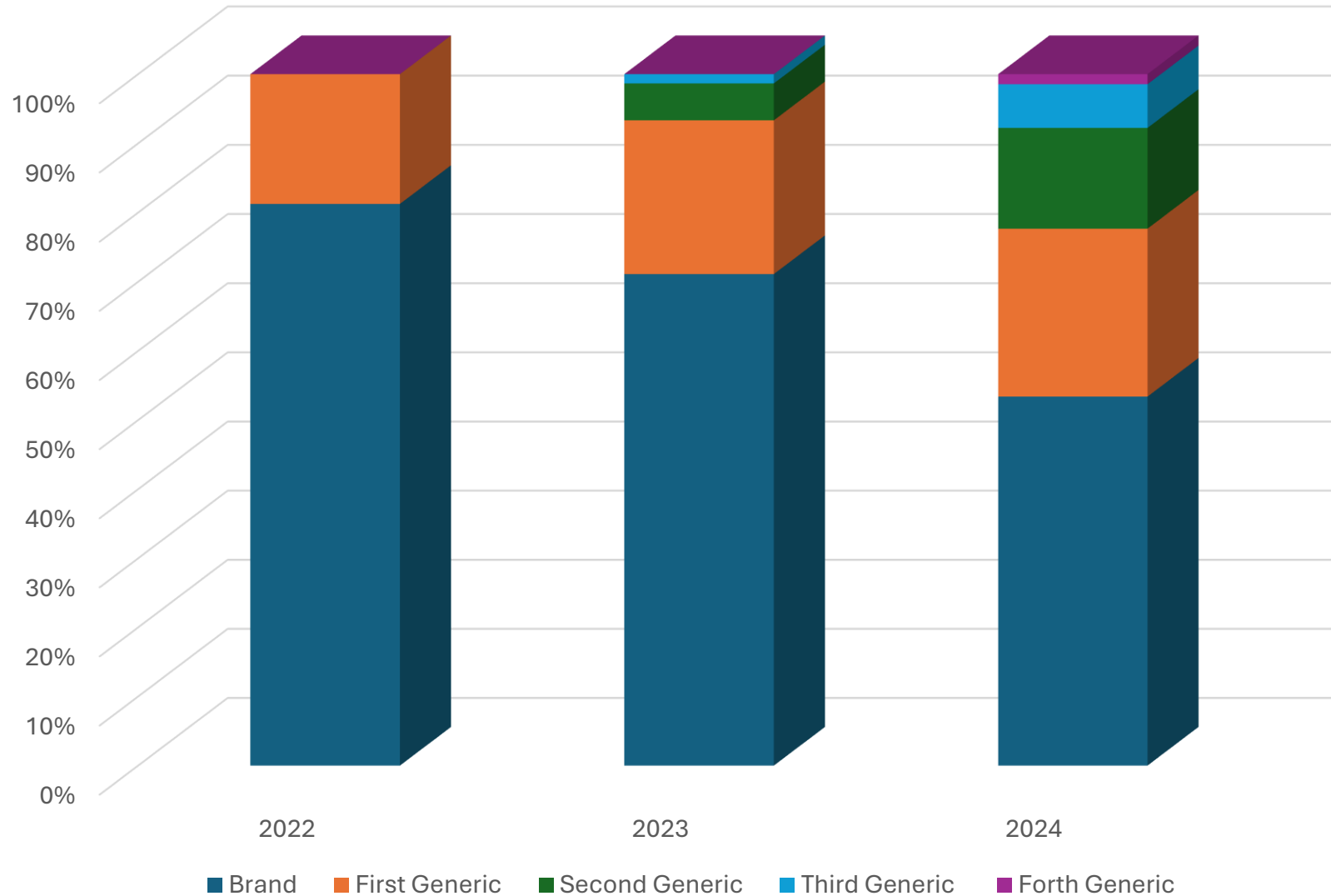
- > Competitor top prioritization plan
- > Market segmentation refinement
- > Patient flow, leverage point analysis
- > Formulation of brand vision positioning

# IP: intellectual property in Pharma

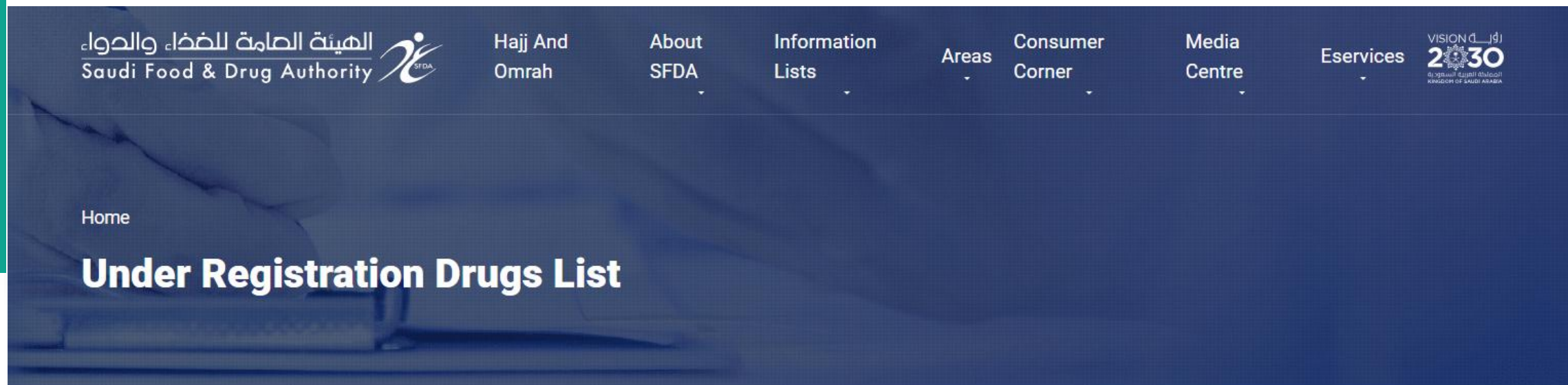
## ROLE OF INTELLECTUAL PROPERTY IN THE PHARMACEUTICAL INDUSTRY



# Importance of IP in Portfolio Planning



# Anticipate



Scientific name

List type



All



Search

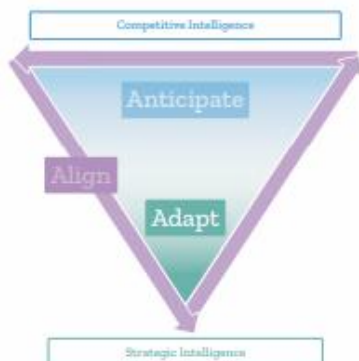
[https://sfda.gov.sa/en/list\\_under\\_registration\\_drugs](https://sfda.gov.sa/en/list_under_registration_drugs)

SFDA

Competitive Intelligence

# A first-mover advantage ?





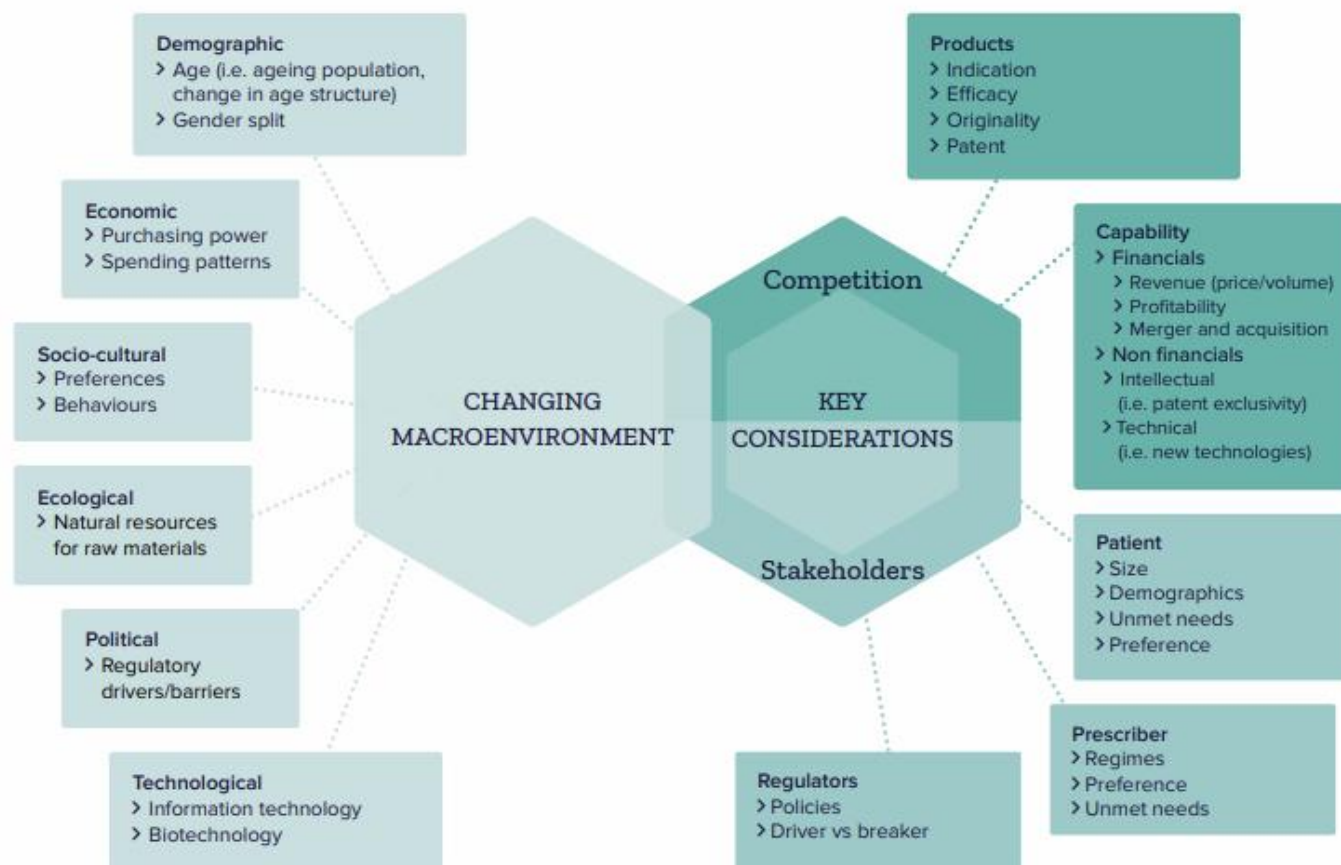
## Adapt your launch strategies with evolving competitive response

Adapt launch strategies according to external changes via continuous competitor monitoring

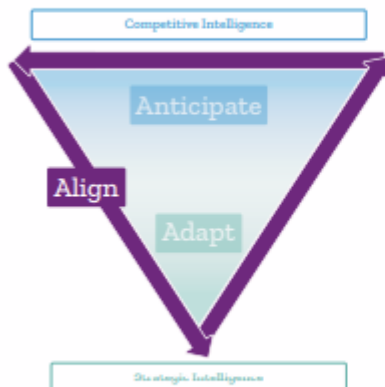
## Adapt your launch strategies with evolving stakeholders' needs

Adapt new marketing, market access, and customer strategies to those who serve as driving forces of the product

What changes or influences might affect your need to adapt your strategy?



# Align

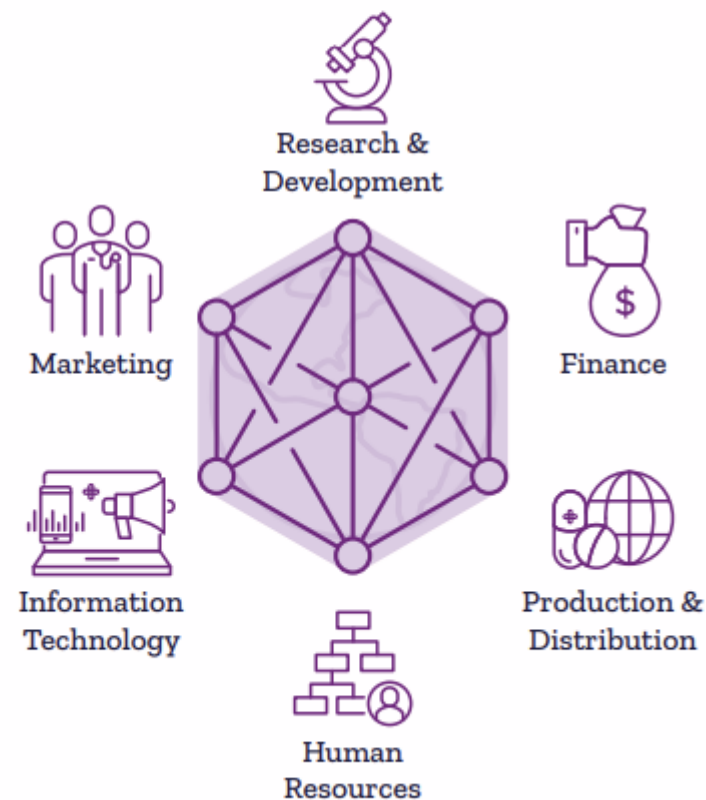


## Align global planning with local realities

Facilitate communication and strategies of regional affiliates in global planning, from an early stage, i.e. Phase 2/3

## Align teams cross-functionally

Facilitate communications and integrate strategies cross functions, i.e. commercial and R&D teams



# Align

# Launch-excellence dimensions



[capgemini.com](http://capgemini.com)

# The 3 A's Model download



# Understanding Launch Excellence

The process of transitioning from the clinic to commercial is unique for every product and company, but there are four consistent elements:

1

Setting your launch strategy

What does success look like?

2

Operationalizing your strategy into a plan that guides the cross-functional team to ensure you're doing the right thing at the right time with the right people

What do we need to do?

3

Building an organizational team and structure that is aligned with, and drives toward, your commercialization goals and objectives

How do we do it?

4

Cultivating operational excellence to execute effectively and efficiently

How do we measure success?



## THE 8 PITFALLS IN PHARMA

# Can Big MNCs fail to launch ?

## - LARTRUVO®

**Drug name:** Lartruvo

**Company:** Eli Lilly

**First approval:** October 2016, U.S. FDA

**Indication:** Soft tissue sarcoma

**Past sales estimate:** \$374 million by 2021

**2020 sales:** None.

Fast track registration

Breakthrough therapy designations

Priority review

Sales Projection:  
\$373.75 million



**Study did not meet the primary endpoints of overall survival (OS) in the full study population or in the leiomyosarcoma (LMS) sub-population; there was no difference in survival between the study arms for either population.**

# Can Big MNCs fail to launch ?

## - Steglatro, Merck/Pfizer

**Drug name:** Steglatro

**Companies:** Pfizer and Merck & Co.

**First approval:** December 2017, U.S. FDA

**Indication:** Type 2 diabetes

**Sales projection:** \$1.09 billion in 2022

**2020 sales:** Not disclosed

crowded field

Late Market entry

Trends changes from  
SGLT2 towards GLP1

No Added Benefit



**Pfizer and Merck struggled to explain why Steglatro couldn't match the benefits of others in its class. Steglatro was safe but offered no cardiovascular benefits**

<https://www.fiercepharma.com/special-report/top-10-drug-launch-disasters>

# Top 15 Drug Launch Superstars



Superstar launches

# THE 8 PITFALLS IN PHARMA

## 1- Starting too late (Specially for Tender business driven products)

Did we start the commercial launch preparation early enough (in mid stage 2 clinical development)?

Did we create alignment early on: internally among the cross-functional teams and externally among key stakeholders by building disease/product awareness?

## 2. Insufficient resources

Are sufficient financial and human resources assigned to the launch, covering different functions/departments and with the right capabilities and launch knowledge?

## 3. Poor stakeholder engagement

Are all key stakeholders identified, are their needs defined and are their roles and impact within the go-to-market strategy understood and acted upon?

Is there an engagement strategy in place to build advocates to endorse the product early on (both KOL and guideline endorsement)?

# THE 8 PITFALLS IN PHARMA



## 4. Limited product value

Is the product value proven by trustworthy data, are sufficient trials conducted and do early customer experiences affirm the product value?

Do we have a clear and compelling value proposition for the product that are tailored to the different stakeholder's/segments' needs?

## 5. Inferior data analysis & insights

Do we have a precise definition of the market opportunity, the market size and the competitive landscape based on data driven insights?

Do we understand the patient journey, and have we identified all the drivers, barriers and leverage points?

Have we identified the right launch KPI's and how to track them?

## 6. Inadequate internal organization

Do we have the right launch team, processes, decision matrices, governance system, policies...in place?

Is the launch driven by a cross-functional decision-making team that is creating adequate communication and alignment within the whole organization?



# THE 8 PITFALLS IN PHARMA



## 7. Ineffective launch mindset & capabilities (Outsource)

Is there a strong internal commitment and common mindset throughout the organization to make the launch a success?

Are we defining the right strategies and tactics by understanding the type of launch, and having an innovative, though realistic and critical mindset, without overestimating our own product and capabilities versus competition?

## 8. Failing to commercialize successfully

Is my positioning and messaging strategy clear and unique, tailored to the key segments and stakeholder groups, and using the optimal and cost-effective communication strategy and omnichannel approach? Do I have a strong go-to-market strategy, that is adaptable to market changes and reactions from competition?



# Launches are harder now than ever before

## LAUNCH ENVIRONMENT OF NICHE MARKET

- \ High unmet needs give significant value creation, though market size maybe limited.
- \ Less competition results from lower number of launches.
- \ More recent launches have longer patent, so less pressure from genericisation and biosimilars.
- \ Research and development is more favoured by payors and regulators, with processes encouraging its approval and access.



## LAUNCH ENVIRONMENT OF MASS MARKET

- \ Less unmet needs gives limited value creation.
- \ More competition means faster, smaller launches.
- \ Competition of drugs intensifies as they approach beyond patent expiry due to generic
- biosimilar drug launches.
- \ Demand of real life data and value creation from
- payors, insurers and regulator intensifies.

# LR check up list

No two launches are the same.



**But the key to every successful launch is a deep understanding of the strategic vision and development of the priorities, people, processes and tools to enable the execution of that vision**

# Launches are harder now than ever before

## LAUNCH ENVIRONMENT OF NICHE MARKET

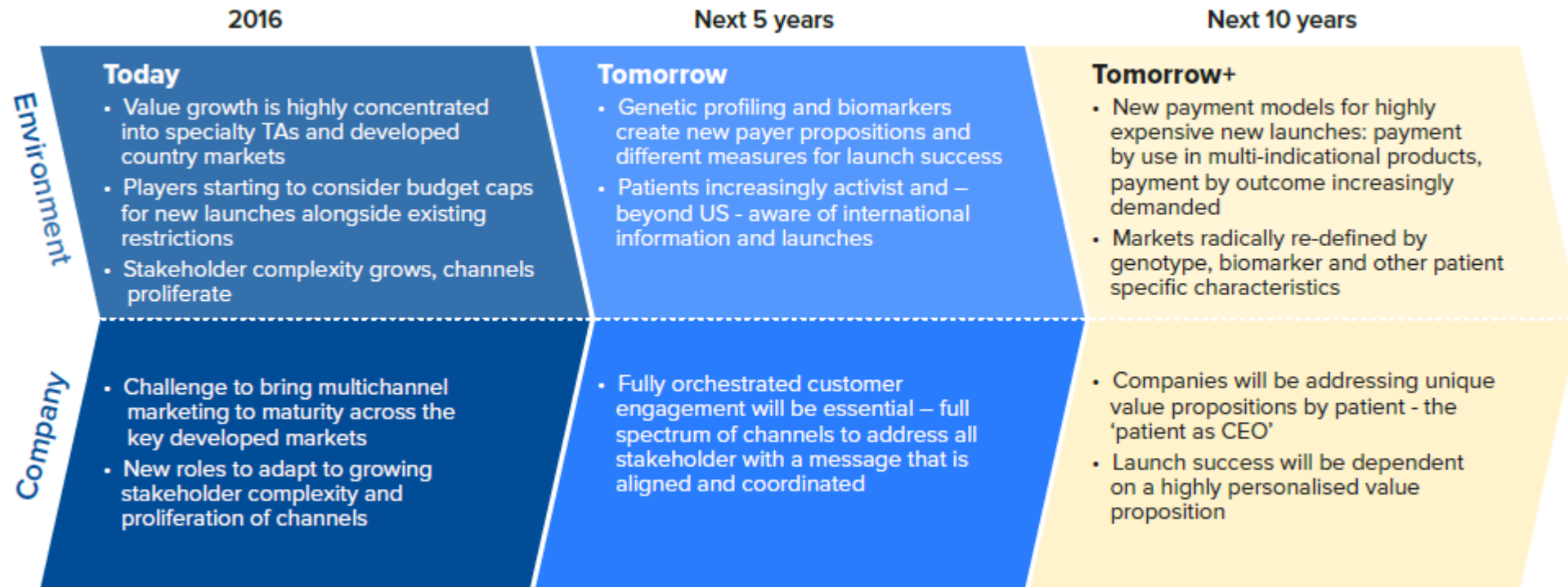
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Figure 14: The launch environment has changed, and rapidly – companies must change too



Source: QuintilesIMS

# LAUNCH READINESS CHECK-UP



## Starting too late

Clinical unmet needs have been identified and verified

☐

The most critical clinical trials in phase 2B & 3 are identified and executed successfully

☐

Clinical trials are successfully executed and investigators are taken 'along the journey'

☐

The launch project timelines and key milestones are identified

☐

There is cross-functional engagement and global and local teams are aligned

☐

Early awareness is established and initial experiences are created

☐

Key launch stakeholders are identified and involved early on

☐

Actions to secure favorable market access are identified and executed

☐

The launch plan considers the therapy area's current & future market access environment

☐

## Insufficient resources

The appropriate financial and human resources are assigned to the launch

☐

The allocated resources are aligned to the type of launch (niche, blockbuster, me-too,...)

☐

The internal roles and responsibilities of everyone involved have been clearly identified

☐

The right level of launch knowledge and experience is recruited or developed

☐

The appropriate size and capabilities of the customer facing teams have been defined

☐

There is an adequate life-cycle management strategy defined

☐

# LAUNCH READINESS CHECK-UP



## Poor stakeholder engagement

The main customers, key players and stakeholders in the market are identified and mapped

☐

The stakeholders are prioritized according to potential impact on the go-to-market strategy

☐

The stakeholders are prioritized according to the different phases of the launch

☐

The impact of each of the stakeholder groups on the go-to-market strategy is assessed

☐

The KOLs are identified and their networks are mapped out

☐

An engagement strategy and action plan for each of the stakeholders is developed

☐

The current and future competitive landscape is known and accounted for in the plan

☐

The current and future role of patients is identified and the launch strategy is patient centric

☐

# LAUNCH READINESS CHECK-UP



## Limited product value

- There is a clear positioning statement of the product defined ☐
- The unique selling proposition and key characteristics of the product are recognized ☐
- Differentiation from existing and other upcoming products is established ☐
- There is a clear view on the clinical investments needed to achieve optimal market access ☐
- The value proposition is verified among different stakeholders ☐
- An efficient and effective communication strategy is developed ☐
- Sufficient data, trials, research,... proves the differentiated value of the product ☐

## Inferior data analyses and insights

- All parameters for accurate forecasting are known and the business opportunity is assessed ☐
- The different steps in the patient journey have been distinguished ☐
- The drivers, barriers and leverage points across the patient journey are identified ☐
- The process of how patients are being diagnosed/tested/referred is known ☐
- The internal & external factors that drive & influence treatment selection are known ☐
- Different patient types are identified and their specific treatment pathway is known ☐
- The strengths and weaknesses of current and future competitors are described ☐
- The needs and wants of all stakeholders (incl. market access) have been identified ☐
- The impact of the current & future market access/reimbursement environment is understood ☐
- Critical market research initiatives to fill knowledge gaps have been executed ☐
- A relevant set of internal and external launch KPIs are being tracked and monitored ☐



# LAUNCH READINESS CHECK-UP



**Failing to commercialize  
successfully**

Current knowledge levels of the stakeholders regarding the disease/product are identified

☐

The right educational campaigns are developed and implemented

☐

The product has a clear and advantageous competitive positioning in the market

☐

A strategy is developed to stimulate the drivers and to tackle the barriers to prescribe

☐

Segments are identified & prioritized and their leverage points are identified

☐

A positioning statement is defined for each targeted segment

☐

The launch team is agile. The go-to-market model is flexible towards (competitive) changes

☐

The key priority areas to invest in first (to optimize the competitive position) are identified

☐

An appropriate pricing strategy is defined in line with reimbursement goals

☐

A communication strategy is defined in line with the launch type (blockbuster vs. niche,...)

☐

The optimal channel mix (incl. digital channels) and required investment levels are defined

☐

Investments in messaging/marketing materials

☐

The launch plan takes the market access requirements sufficiently into consideration

☐

# LAUNCH READINESS CHECK-UP



## Inadequate internal organization

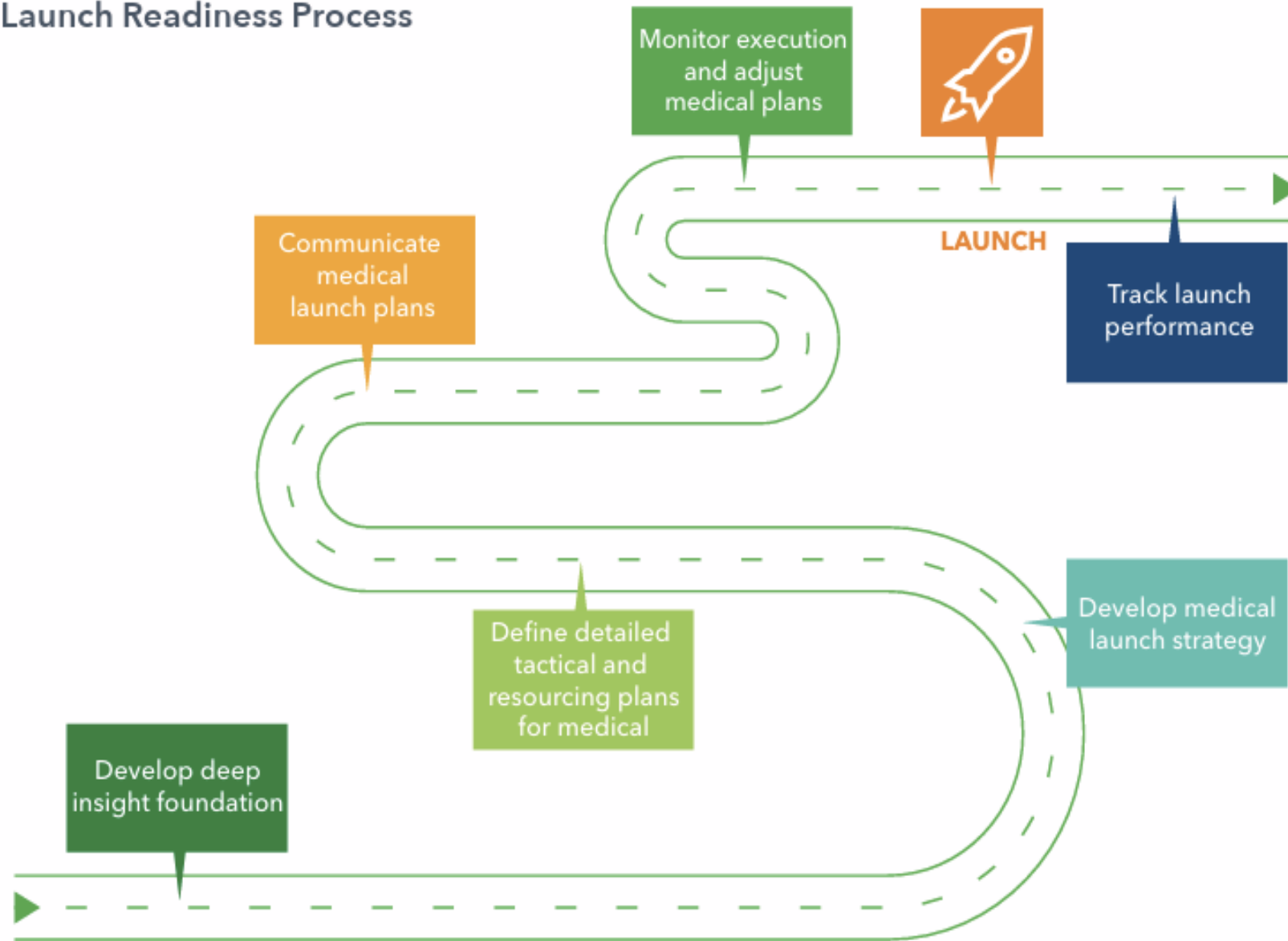
- Key internal launch processes, decision matrixes and governance systems are in place ☐
- Measures are in place to evaluate/monitor launch capabilities and to identify additional needs ☐
- An experienced and capable cross-functional decision-making launch team is set up ☐
- There is clear alignment between global strategies and tactical plans and local realities ☐
- Departments only indirectly involved in the launch process (supply chain,...) are also aligned ☐
- The gaps & development needs within each of the teams/stakeholders are identified ☐
- The right training programs are implemented to fill internal knowledge gaps ☐
- The launch capability development plans are tailored to the needs of the country & product ☐
- Appropriate tools are in place to share best practices among launch teams & countries ☐

## Ineffective launch mindset & capabilities

- A change management strategy & plan is developed to prepare the organization for launch ☐
- The launch type is defined: blockbuster/me-too, niche product/broad indication ☐
- The Launch strategy, tactical plans, teams, resources,... are adapted to the launch type ☐
- Appropriate actions are taken to create a culture of one-team (vision, goals and road map) ☐
- The go-to-market model is embedded and supported in the whole organization ☐
- The right level of commitment for the launch is reached within all cross-functional teams ☐
- Launch teams are stimulated to think out of the box and the company fosters innovation ☐
- Appropriate internal communication flows are set-up between different levels/departments ☐
- Measures are taken to avoid overconfidence and underestimation of competition ☐



Figure 2: Medical Launch Readiness Process



Source: IQVIA

## Launch Excellence Framework

### Shape the ...



**Launch Excellence**

# Blockbusters launches in 2024



## Thirteen potential blockbusters launched or scheduled to launch in 2024

NAME(S)	DEVELOPER(S)	INDICATION	MECHANISM OF ACTION	FDA STATUS	EMA STATUS	2029 SALES FORECAST
aflibercept (Eylea HD)		Wet age-related macular degeneration, diabetic macular oedema, diabetic retinopathy	VEGF inhibitor	FDA approved 18/08/23	European Commission approval 08/01/24	\$1.77bn (G7 countries)
budesonide (Tarpeyo/Kinpeygo)		Proteinuria in adults with primary immunoglobulin A nephropathy	Delayed-release corticosteroid	FDA full approval 20/12/23	European Commission approval (conditional) 15/07/22	\$0.73bn
datopotamab deruxtecan		HR-positive/ HER2-negative and triple-negative breast cancer, non-small-cell lung cancer (NSCLC)	TROP2-directed antibody-drug conjugate	FDA decision pending (breast cancer + NSCLC)	CHMP decision pending (breast cancer + NSCLC)	\$2.70bn (both indications)
efanesoctocog alfa (Altuviiro/Altuvect)		Prophylactic and on-demand treatment of bleeding episodes associated with haemophilia A	Recombinant FVIII replacement therapy	FDA approved 23/02/23	European Commission approval 19/06/24	\$1.77bn
ensifentrine (Ohtuvayre)		Maintenance treatment of chronic obstructive pulmonary disease	Dual phosphodiesterase (PDE)3 and PDE4 inhibitor	FDA approved 26/06/24	Awaiting submission to EMA	\$500-\$750mn
exagamglogene autotemcel (Casgevy)		Severe sickle-cell disease (SCD) and transfusion-dependent beta-thalassaemia (TDT)	Ex vivo CRISPR/Cas9 gene-edited therapy	FDA approved 08/12/23 (SCD)	European Commission approval 13/02/24 (SCD and TDT)	\$1.32bn

lovotibeglogene autotemcel (Lyfgenia)		Transfusion-dependent beta-thalassaemia, severe SCD	Ex vivo lentiviral-based HBB gene stimulator	FDA approved 08/12/23 (SCD)	Awaiting submission to EMA	N/A
mirikizumab (Omvoh)		Moderate-to-severe ulcerative colitis (UC), Crohn's disease	Humanised anti-interleukin-23 antibody	FDA approved 26/10/23 (UC)	European Commission approval 26/09/23 (UC)	N/A (\$0.595 bn in 2023 Drugs to Watch)
niraparib + abiraterone acetate (Akeega)		BRCA-positive metastatic castration-resistant prostate cancer	PARP inhibitor + hormone therapy	FDA approved 11/08/23	European Commission approval 21/04/23	\$2.7bn
Abrysvo (RSVPreF)		Prevention of lower respiratory tract disease (LRTD) caused by respiratory syncytial virus (RSV)	Recombinant bivalent RSV prefusion F vaccine	FDA approved 31/05/23 (adults 60+) & 22/10/24 (adults aged 18-59 years)	European Commission approval 24/08/23 (passive protection of infants from birth to 6 months; active immunisation of adults 60+)	N/A
Arexvy (RSVPreF3)		Prevention of LRTD caused by RSV	Recombinant subunit RSVPreF glycoprotein antigen vaccine	FDA approved 03/04/23 (adults aged 60 and over) & 07/06/2024 (adults aged 50-59)	European Commission approval 07/06/23 (adults 60+) & 29/08/24 (adults aged 50-59)	N/A
talquetamab (Talvey)		Relapsed or refractory multiple myeloma	Bispecific antibody targeting CD3 and GPRC5D receptors	FDA accelerated approval 10/08/23	European Commission conditional approval 22/08/23	\$850mn
zolbetuximab (Vyloy)		HER2-negative, CLDN18.2-positive unresectable locally advanced or metastatic gastric or gastro-oesophageal adenocarcinoma	Claudin 18.2-targeted antibody	FDA approved 18/10/24	European Commission approval 20/09/24	\$1.14bn (G7 countries)

# Tell us your Story

