

Welcome!

# **Secrets to effective Medical Affairs leadership for launch success**

# Presenters



**Arron Mungul**

Global Medical Capabilities  
BMS



**Gamar  
Akhundova**

Global Medical Director,  
Gastroenterology TA Head  
Abbott



**David Kelaher**

Chief Medical Officer  
Pharmaspectra, an IQVIA  
business

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- The following faculty and planning members do disclose financial relationships:  
David Kelaher, an employee of IQVIA

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# Educational Objectives

This session will provide a learning opportunity for our audience by:

1. Enhancing understanding of the different strategic considerations for product launches
2. Defining the launch archetypes to characterize success
3. Discussing of effective Medical Affairs leadership in launches

# Poll question 1

How many product launches have you worked on?

- a) 0
- b) 1-3
- c) 4-9
- d) 10 or more

# Poll question 2

**How successful were the majority of the launches you've worked on?**

- a) Unsuccessful
- b) Average
- c) Good
- d) Excellent
- e) Don't know

**Why are only 4-6% of product launches considered “excellent”, and why do those predicted for success fail?**



# Launch Excellence Research: Methodology<sup>1</sup>



**>1000** launches<sup>2</sup>

across **8** countries, including the US.



## Analytic tools

MIDAS Sales audit, ChannelDynamics for insight into post launch.



## Definition of “Excellent”

3 quantitative criteria: 1) A steep and sustained launch uptake curve, 2) Promotional out-performance 3) Market share achievement



## Archetypes

Proprietary relationship between unmet market need and product differentiation.

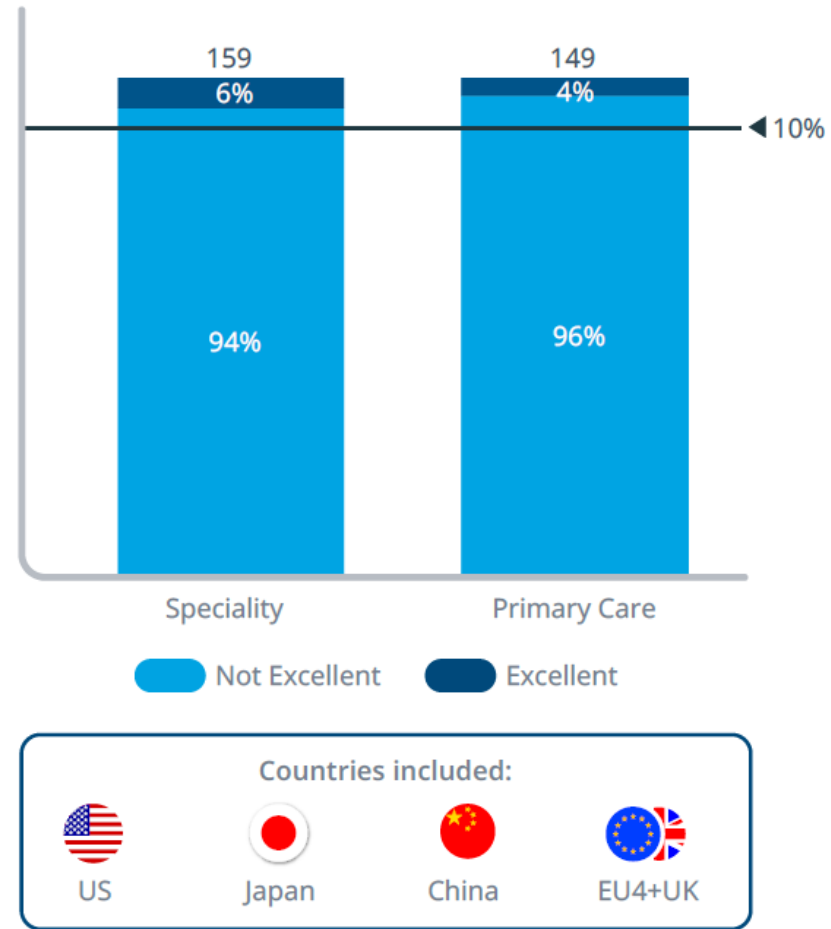


We note that sales figures are a part of the Launch Excellence research, and that sales/revenue is not within the remit or the goal of Medical Affairs. The focus will be on the launch archetypes and the role of Medical Affairs across them.

1. IQVIA publication: Launch Excellence V, VI & VII, 2018, 2019 & 2021
2. IQVIA publication: Launch Excellence I-VII 2007-2021

# Recent launch assessment: Only 4-6% were excellent<sup>1</sup>

Launch Excellence VII  
(2021) evaluated 308  
launches



1. IQVIA EMEA Thought Leadership publication: Launch Excellence VII, 2021

# Product launches do not share the same starting point – a deeper understanding is needed to excel at launch

Pre-launch situation of a product can be categorized by two dimensions

## 1. Market Unmet Need

Level of unmet need in the market/ therapy area is defined by:

- Percent of patients who **do not reach therapeutic targets** on SoC
- Level of **clinical difficulty in treating patients who do not respond** to the SoC
- **Burden/inconvenience/cost** of standard of care

Product  
pre-  
launch  
situation

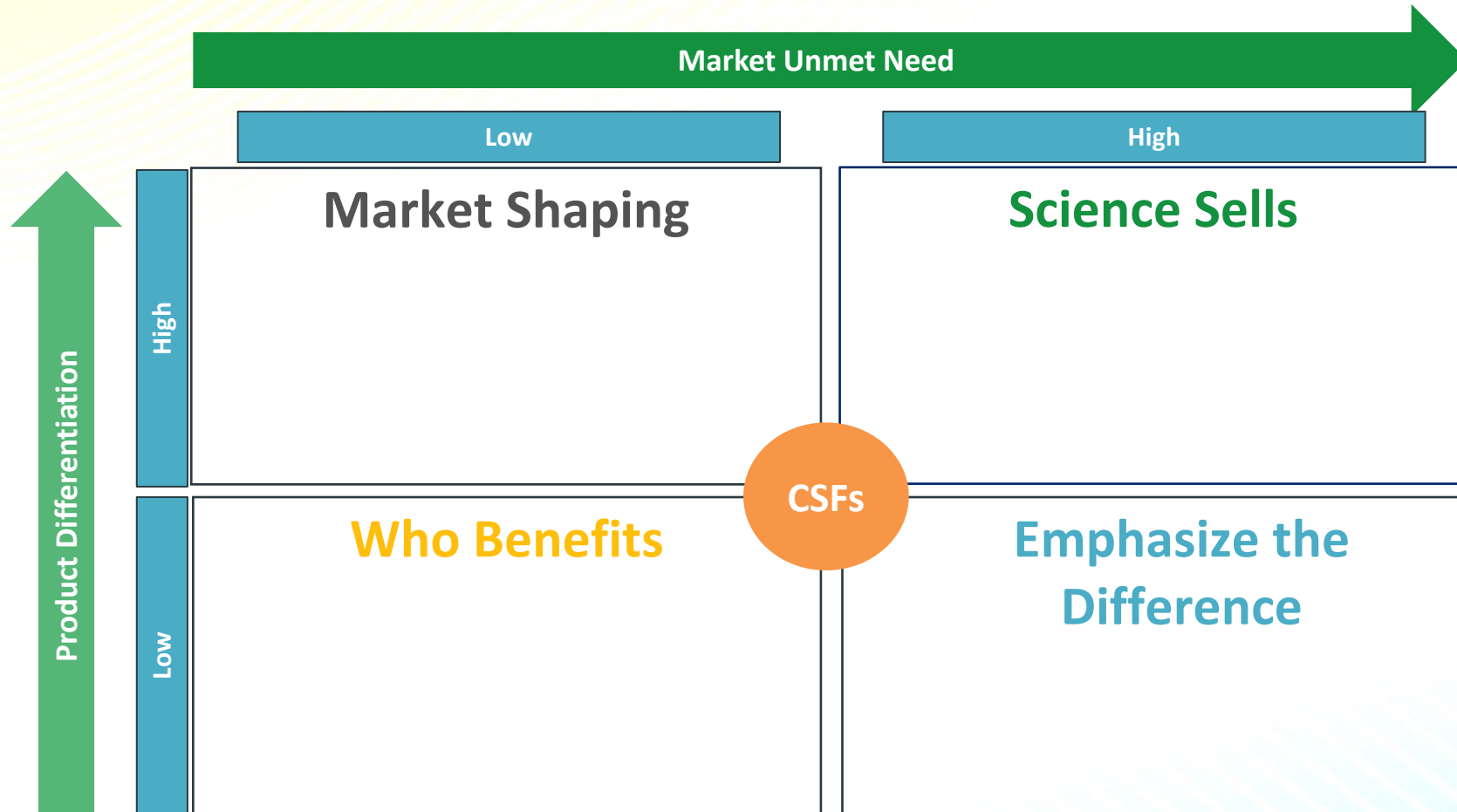
## 2. Product Differentiation

Level of product differentiation can be described by:

- Level of **clinical improvement over standard of care**
- Level of **increase in treatable population**
- Level of **improvement in burden/convenience/cost** to prescriber/patient

Source: IQVIA Launch Excellence, IQVIA internal expertise; Copyright © 2023 IQVIA. All rights reserved

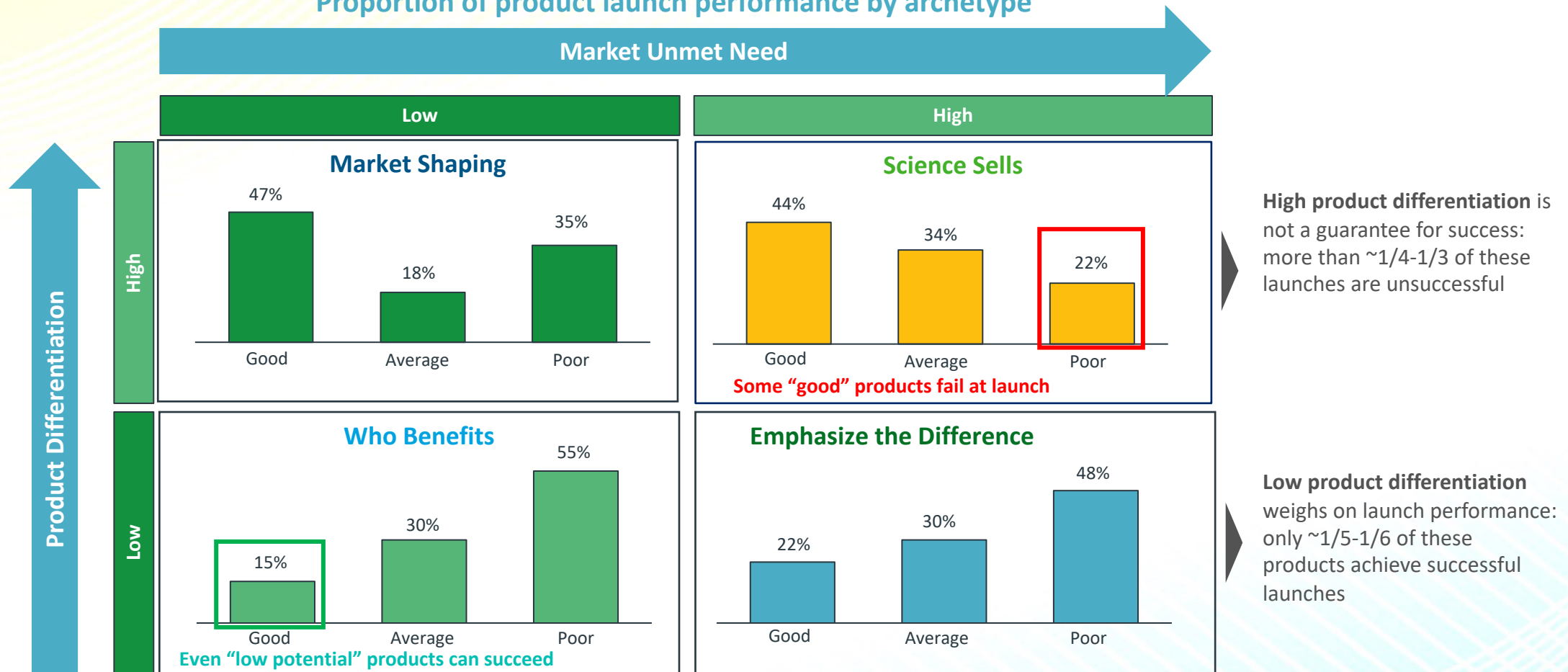
# Classification by archetype helps to ensure good understanding of the pre-launch situation and highlights critical success factors



Knowing the launch archetypes helps identify Critical Success Factors (CSFs), define most effective launch strategy, and facilitates launch planning

# Archetypes help to summarize pre-launch situation and highlight CSFs, though don't always guarantee success

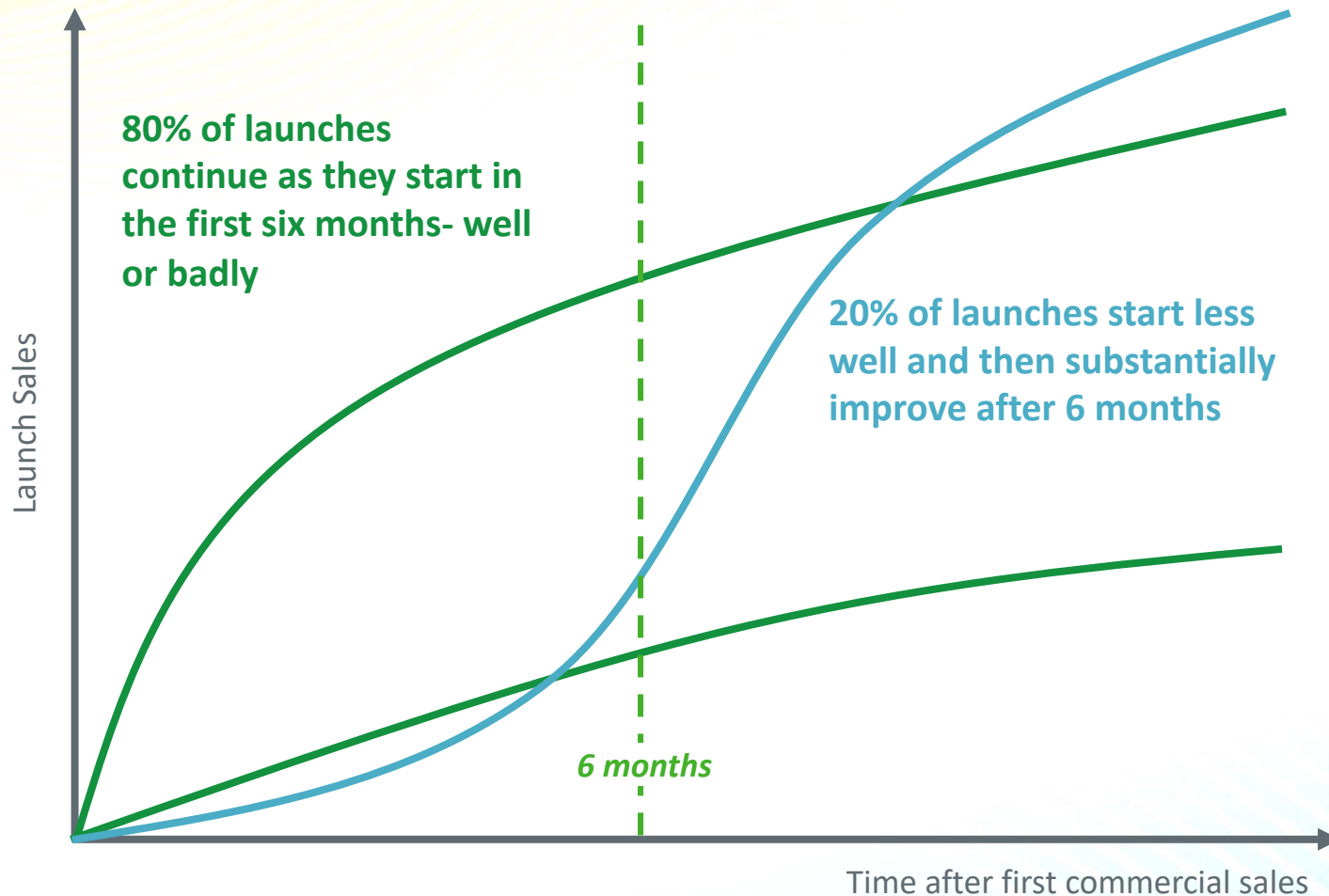
Proportion of product launch performance by archetype



Knowing the launch archetypes helps identify Critical Success Factors (CSFs), define most effective launch strategy, and facilitates launch planning

# The 6 month window: Long-term launch performance is baked early - no substitute for effective pre-launch preparation

It's an 80 / 20 rule



- **80% launches** have their **longer term fate determined in the first six months** of their commercial life
- It is possible to improve after 6-mths: though only ~20% of launches do
- The 80/20 rule has prevailed across time and countries despite the rise of HTAs and payer power

# How have companies developed their strategy to achieve launch excellence?



**Multiple Sclerosis**



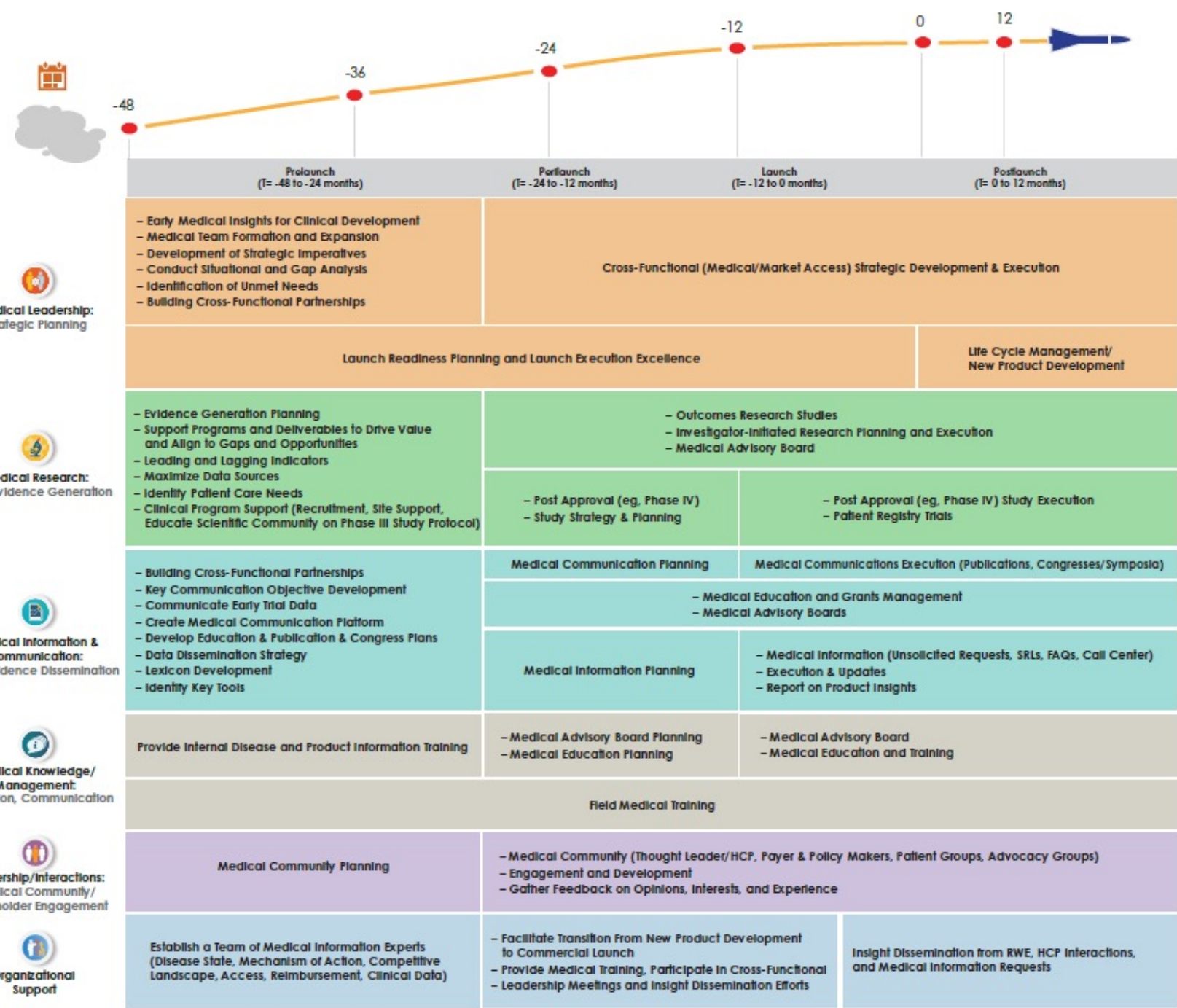
**Chronic Heart Failure**

1. IQVIA EMEA Thought Leadership publication: Launch Excellence VII, 2021

# What role do Medical Affairs leaders play in ensuring launch success?



# MAPS Medical Affairs key activities for launch excellence



Medical Affairs Launch Excellence: Best Practices for Medical Affairs. MAPS White Paper. 2020.

\*Launch is an evolving and fluid process.

# Tracking for launch excellence: Meaningful metrics

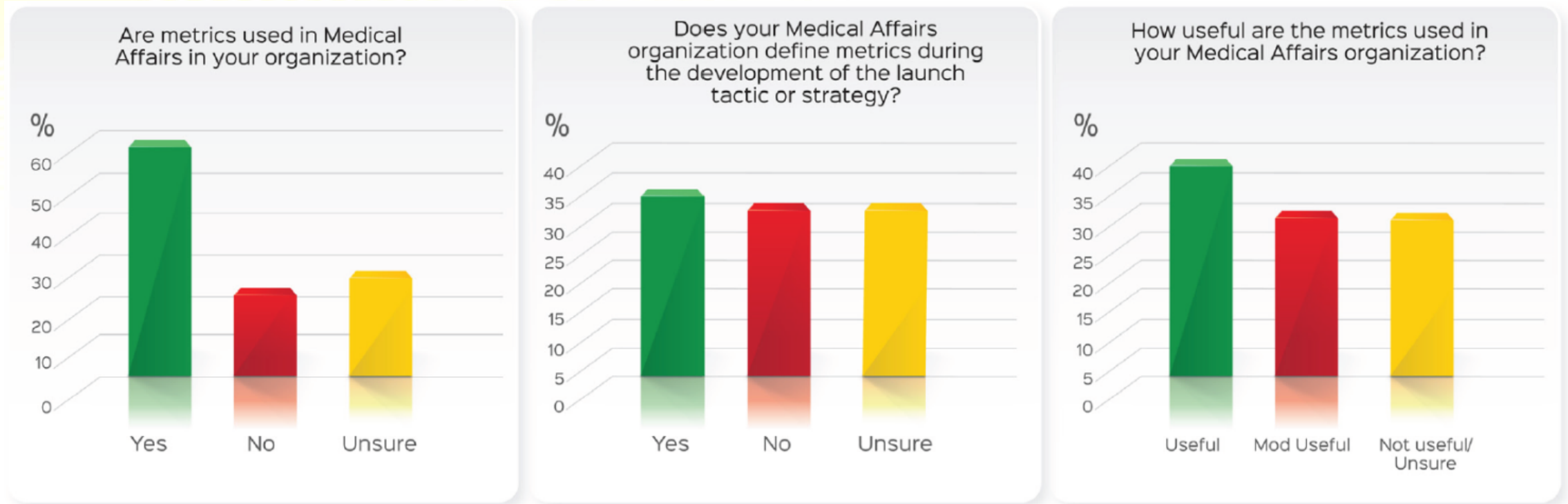


Figure 1. The Use and Usefulness of Metrics in Medical Affairs

Source: The Value and Impact of Medical Affairs: Mastering the Art of Leveraging Meaningful Metrics. A MAPS Whitepaper 2022

# Beyond best practice frameworks: How Medical Affairs shapes launch success

Launch challenges

Internal preparation and alignment

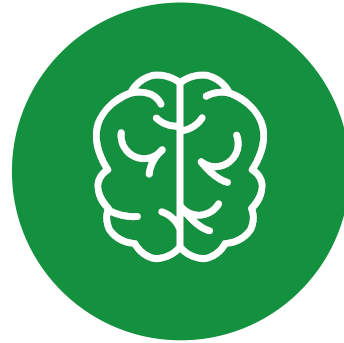
Powerful and pertinent value proposition

Effective and efficient stakeholder engagement



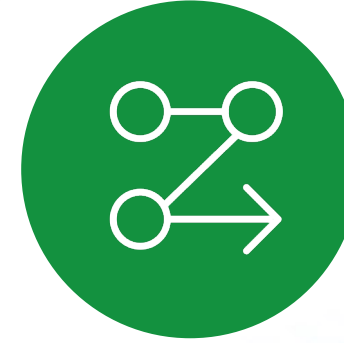
## Launch situation

TA and product expert and own mapping of patient journey (unmet needs and barriers to launch success)



## Strategic product leadership

Identify data gaps and prioritize activities such as evidence generation and dissemination



## Effective partner to external leaders

Collaboration with, and guidance from, KOLs, societies and PAGs to optimize strategy and advocacy

# Specific Medical Affairs roles\* emerge from the critical success factors for each launch archetype

Market Unmet Need 

Product Differentiation 

## Market Shaping

**Low unmet need with High product differentiation**

- Disease/MOA awareness pre-launch
- Raise awareness of disease consequences
- Campaigns/Data to establish superiority
- Aggressive positioning

\*Disease consequences and scientific narrative development

## Science Sells

**High unmet need with High product differentiation**

- Disease/MOA awareness pre-launch
- Optimized pricing
- Risk mitigation plan
- Public policy activity
- PAG engagement

\*MOA awareness and stakeholder engagement

## Who Benefits

**Low unmet need with Low product differentiation**

- Laser focus targeting (prescriber/patient)
- Realistic expectations
- Services to differentiate product
- Consumer focus – access, co-pay offsets/DTC (US)

\*Robust mapping of the patient journey and HCP behavior to identify data gaps.

## Emphasize the Difference

**High unmet need with Low product differentiation**

- Consumer focus
- TAE engagement & advocacy
- Competitive pricing
- Services to differentiate product
- Patient segmentation & targeting
- Comprehensive evidence generation

\*Enriched RWE for patient/PAG education and HCP engagement.

\*Includes insights gathering across CSFs

# Launch Excellence is challenging in an evolving, increasingly complex environment

## Past (2010)

## Present / Future (2020+)

### Stakeholders



Simple sequence, **one at a time**:  
regulator, payer, prescriber



Complex interdependent network with  
**multiple** national & sub-national stakeholders

### Launch types



**2** small molecules, biologics



**6** small molecules, biologics, cell & gene therapies, DTx, controlled substances

### Patient journey (# specialties involved)



**1-2** Dyslipidaemia

Primary care still dominant segment



**3-4+** Autoimmune



**4-5+** Cancer



**7+** Rare diseases

### Evidence requirements



RCT data; **episodic**, event-related  
e.g. approval, reimbursement



Integrated evidence: RCT, RWE, patient generated; **continuous**, over the lifecycle

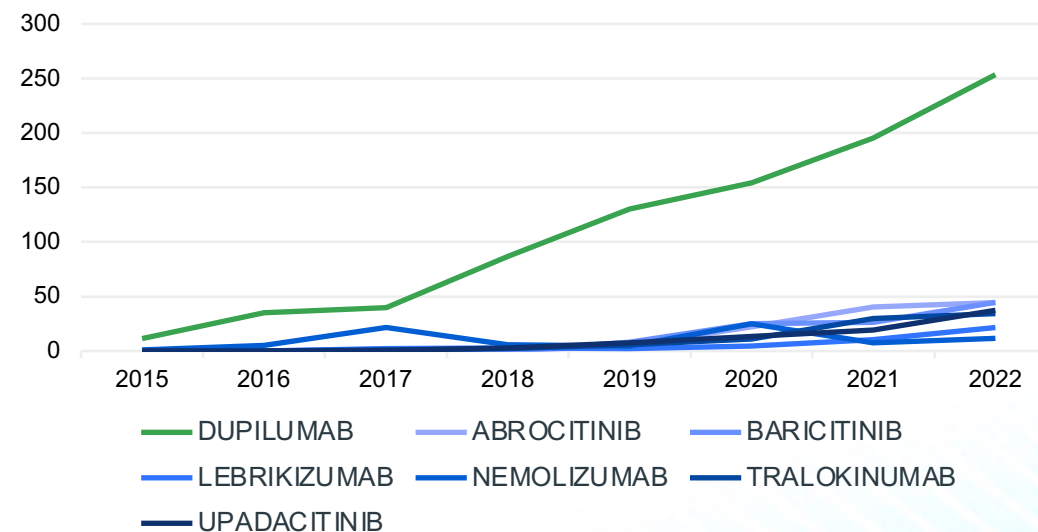
# Excellent launches generate more RWE - Share of Scientific Voice measures and helps to optimize evidence dissemination

# +47%



**Greater volume in total published RWE associated with excellent launches vs all others<sup>1</sup>**

### Share of Scientific Voice (SoSV) analysis in atopic dermatitis<sup>2</sup>



#### Methodology:

1. IQVIA performed a volumetric analysis, for each given launch, of all relevant RWE published through 2019 (search using PubMed & Embase). The publication search focused on three competitive therapy areas: diabetes, immunology, and immuno-oncology. We then overlaid the launch type (excellent, all other) on the findings based on the well-established definitions from our IQVIA Launch Excellence Series.
2. Weighted SoSV score based on product mentions globally (journal publications and scientific meeting presentations) across a sample group of products

# Key take aways

1. Product launches do not share the same starting point, launch archetypes highlight critical success factors
2. Medical Affairs plays a key strategic role in launch preparation and success
3. Activities such as patient journey mapping, stakeholder engagement and RWE development are shown to drive launch excellence

# MAPS Resources on the Topic

- **White Papers**
  - **Medical Affairs Launch Excellence: Best Practices for Medical Affairs. MAPS White Paper. 2020.**
  - **The Value and Impact of Medical Affairs: Mastering the Art of Leveraging Meaningful Metrics. A MAPS Whitepaper 2022**



# Q&A