



# Leveraging New MAPS Standards & Guidance to Drive Strategic Medical Planning and Demonstrate Value

June 18, 2025

Presented by the MAPS



Medical Strategy & Launch Excellence





## Conflicts of Interest and Disclosures

MAPS is committed to ensuring full disclosure of potential Conflicts of Interest (COI) by session presenters/developers. While a presenter COI is not prohibited nor necessarily harmful to the learner, it is important that this be shared with the learner so the learner may make an informed decision regarding material presented. A COI includes any transaction or relationship which presents, or may present, a conflict between a presenter/developer's - or his/her spouse/life partner's - personal, business or other interests.



## Strategy Domain & Medical Strategy & Launch Excellence Focus Area Working Group

Exemplifies highest level of Medical Affairs asset, launch, and organizational strategic plans and planning capabilities

- Elevate the leadership of Medical Affairs in strategic planning and launch excellence  
*Focus on core competencies and expand planning capabilities*
- Explore how to evolve the role of Medical Affairs in strategic planning and launch excellence  
*Focus on value articulation and factors that impact Medical Affairs' agility*



# Standards & Guidance Documents

- *Strategic Medical Planning*
- *Measuring Value and Impact in Medical Affairs*
- *Launch Excellence*
- Advancing Excellence in Medical Operations
- External Education
- External Scientific Engagement (Field Medical)
- Strategic Integrated Evidence Generation Planning
- Medical Information Best Practices
- Scientific Communications Platforms
- Medical Insights Best Practices



# Educational Objectives

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

- Gaining a thorough understanding of core frameworks of the MAPS Strategic Medical Planning and Value & Impact Standards & Guidance documents.
- Mastering the application of foundational elements in Medical Affairs strategic planning, from strategy development to tactical execution
- Learning how to apply goal-based outcome measures to enhance and communicate the impact of Medical Affairs within your organization







# Thank You To All The Contributors!

**Leah Williams**, Director, Global Medical Education & Communications, Hematology, CSL Behring

**Emily Howman**, PhD, Medical Affairs Consultant

**Joseph Kohles**, PhD, Partner and Strategic Consultant, Amica Scientific

**Arron Mungul**, PhD, Founder, Apogee Life Sciences

**Yi Arnold**, PhD, MBA, Sr. Director, Global Medical Affairs, Integra LifeSciences

**David Kelaher**, Senior Director, Medical Affairs, IQVIA

**Prasun Subedi**, PhD, Channel Access Strategy Lead, Customers & Channels Group, Primary Care, Pfizer

**Eddie Power**, PhD, MBA, GFMD, CEO emPower Medical LLC.

**Clare Jackson**, Independent Consultant

**Charlotte Kremer**, MD, MBA, EVP, and Head of Medical Affairs, Astellas Pharma

**Peter Piliero**, MD, VP, US Medical Affairs, Merck

**Therese McCall**, PhD, MBA, Vice President, Medical Affairs, Assertio Therapeutics

**Amanda Henkel**, PhD, Practice Area Lead, MEDiSTRAVA



## Today's Speakers



**Yi Arnold**

Global Head,  
Medical Affairs  
Integra LifeSciences



**Amanda Henkel**

Practice Area Lead  
MEDiSTRAVA  
(an Inizio Company)



**Emily Howman**

Consultant  
Aoraki Consulting



**Arron Mungul**

Founder,  
Apogee Life Sciences



**Leah Williams**

Global Director,  
Commercial  
Development

*Previously Global Director,  
Medical Education &  
Communications*

CSL Behring



# Strategic Medical Planning

Emily Howman & Leah Williams







## Creating a roadmap for success

- Applying a **robust strategic approach** to medical planning will result in a clear roadmap to success – from “where you are now” to “where you want to be”





# The *Strategic Medical Planning Standards & Guidance* has been updated!

- The *Strategic Medical Planning Standards & Guidance* resource aims to equip Medical Affairs professionals with the knowledge and tools needed to create and execute effective annual strategic Medical Plans
- Key updates include:
  - Improved structure
  - More context and clearer guidance on key Medical Plan development steps
  - Case-based examples
  - Introduction to impact measures (see the *Value & Impact Standards & Guidance* for a deeper dive)
  - Considerations for operationalizing the Medical Plan at the Global, Regional and Local levels





## A strategic Medical Plan is a dynamic “single source of truth”

- ✓ Serve as a roadmap that clearly defines the medical strategy and supporting tactics
- ✓ Grounded in insights and data
- ✓ Provides rationale for budget and resources
- ✓ Creates a high-performing team
- ✓ Ensures objectives are evaluated and reassessed
- ✗ Be developed in isolation, without considering broader internal/external stakeholder perspectives
- ✗ 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



# Cross-functional collaboration is important to ensure alignment with the overarching product strategy

## Internal Partners\*:

- Medical Affairs
- Commercial
- Research & Development
- Market Access
- Legal/Regulatory/Compliance
- Patient Advocacy
- Core Regions/Countries

\*This list is illustrative and does not represent all the internal partners



Avoid generating the medical strategy in a silo



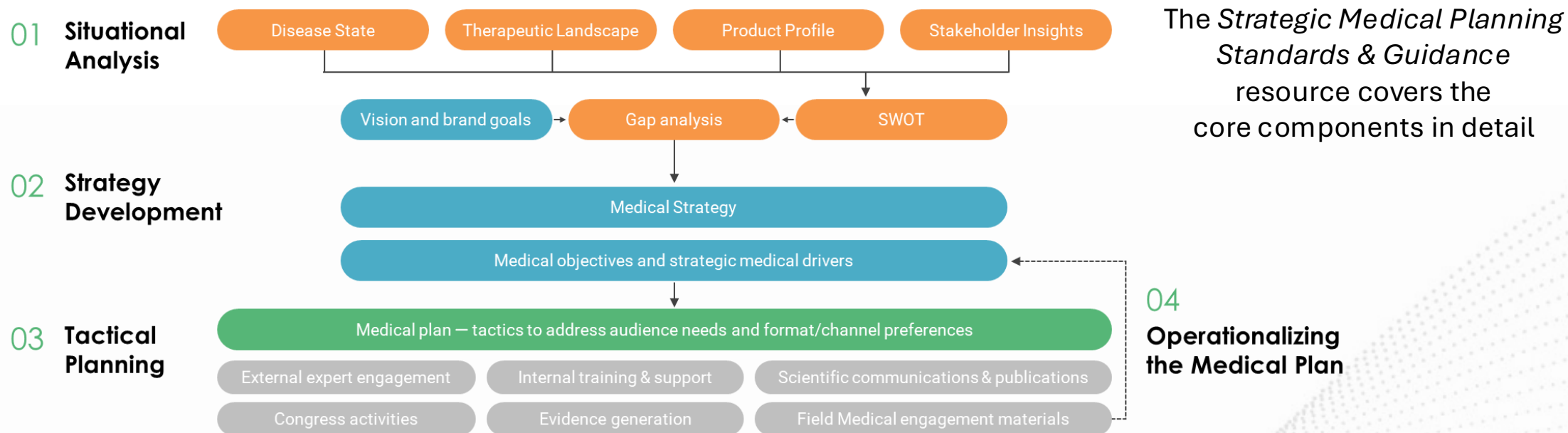
All relevant functions should collaborate early to align functional strategies with the product vision



Core regions/countries should be involved early to contribute to building global objectives and strategies that address specific market needs



# A robust, strategic medical plan is developed based on clearly defined cross-functional methodology







# Four core components of a Medical Plan

Each component of a Medical Plan addresses key questions.





# Situational Analysis

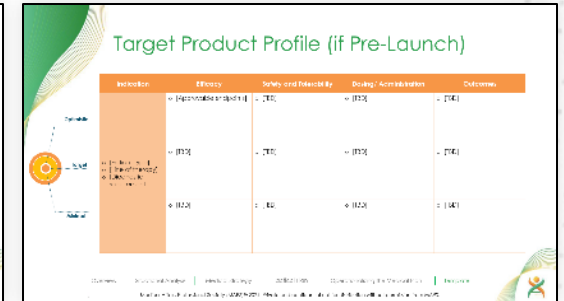
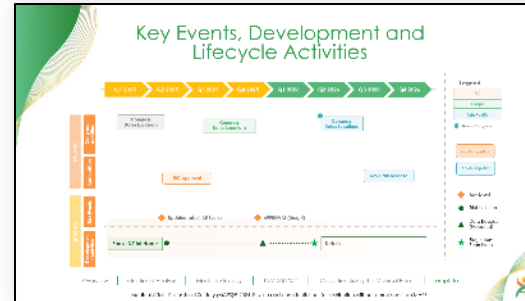
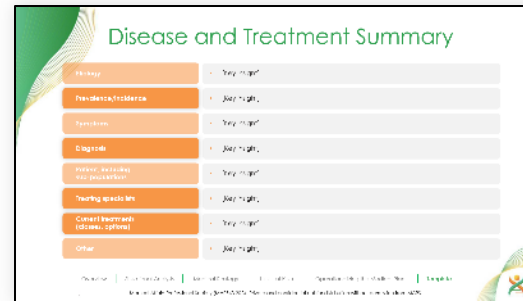
## Situational Analysis

Disease State  
Therapeutic Landscape  
Product Profile  
Stakeholder Insights  
SWOT Analysis  
Gap Analysis



- An in-depth assessment of the current landscape to provide you with a clear understanding of “where you are now”

## Example Template Tools



The resource includes 16 templates to support the situational analysis development



# The **SWOT Analysis** highlights where your product and organization stands in the current environment and disease state

Situational Analysis:  
**Medical SWOT**

Strategic Medical Planning Guide

Key Questions in the Current Disease Space

INTERNAL: Product or Company Specific	Strengths	Weaknesses
	<ul style="list-style-type: none"><li>What does your product or company offer that provides a competitive advantage?</li><li>What are the unique features of your product like mechanism of action or dosing?</li><li>Do you have synergies with other products in your portfolio you can leverage?</li></ul>	<ul style="list-style-type: none"><li>What does your company or product offer or not offer that may be considered a disadvantage?</li><li>What are the clinical challenges or lack of supporting data for your product?</li><li>Is there a presumption your product is not clinically differentiated?</li></ul>

EXTERNAL: Environment Specific	Opportunities	Threats
	<ul style="list-style-type: none"><li>What environmental factors provide opportunities for your product?</li><li>What are the unmet medical needs or gaps in the market that the product can address?</li><li>How could the perspectives of different audiences present opportunities or threats?</li></ul>	<ul style="list-style-type: none"><li>What environmental factors pose challenges for your product, such as competition, perceptions, and regulatory restrictions?</li><li>What are the potential label restrictions or access, pricing and reimbursement challenges?</li></ul>

Overview | Situational Analysis | Medical Strategy | Tactical Plan | Operationalizing the Medical Plan | Template

Medical Affairs Professional Society (MAPS)® 2025. Private and confidential-not for distribution without permission from MAPS.

Medical SWOT Analysis Example\*

Strengths	Weaknesses
<ul style="list-style-type: none"><li>1st in class antibody drug conjugate with unique drug linker technology</li><li>Phase 3 superior efficacy and quality of life vs chemotherapy with no unexpected safety signals</li><li>Less frequent IV dosing vs competitors with potential for subcutaneous administration</li><li>Potential synergies with Company Y respiratory business</li></ul>	<ul style="list-style-type: none"><li>The company is not established in oncology and has no footprint in NSCLC</li><li>Clinician uptake underperformed at launch – lower than anticipated</li><li>Not considered clinically differentiated vs other ADCs and IGH data are lacking</li><li>Misconception of safety concern (driven by competitor messaging regarding class effect)</li><li>Often considered only in later lines of treatment</li></ul>

Opportunities	Threats
<ul style="list-style-type: none"><li>Strong demand for novel combination therapies to enhance overall survival and quality of life</li><li>High unmet need in post-immunotherapy setting and on expanding market</li><li>Patient preference for less frequent dosing and fixed duration of treatment</li></ul>	<ul style="list-style-type: none"><li>Competitive and crowded market that is perception-driven</li><li>Large competitor companies are well established</li><li>Pricing pressures may increase the non-effectiveness threshold and impact reimbursement in some markets</li><li>Off-target effects or other ADCs and associated poor experiences by HCs and patients has diminished the desire to try new options</li></ul>

\*Illustrative only, not intended to be comprehensive.

Overview | Situational Analysis | Medical Strategy | Tactical Plan | Operationalizing the Medical Plan | Template

Medical Affairs Professional Society (MAPS)® 2025. Private and confidential-not for distribution without permission from MAPS.

Situational Analysis Summary:  
**Medical SWOT Analysis**

Core Tool

S	W
Strengths	Weaknesses
O	T

Overview | Situational Analysis | Medical Strategy | Tactical Plan | Operationalizing the Medical Plan | Template

Medical Affairs Professional Society (MAPS)® 2025. Private and confidential-not for distribution without permission from MAPS.

Template Tool



# Medical Strategy

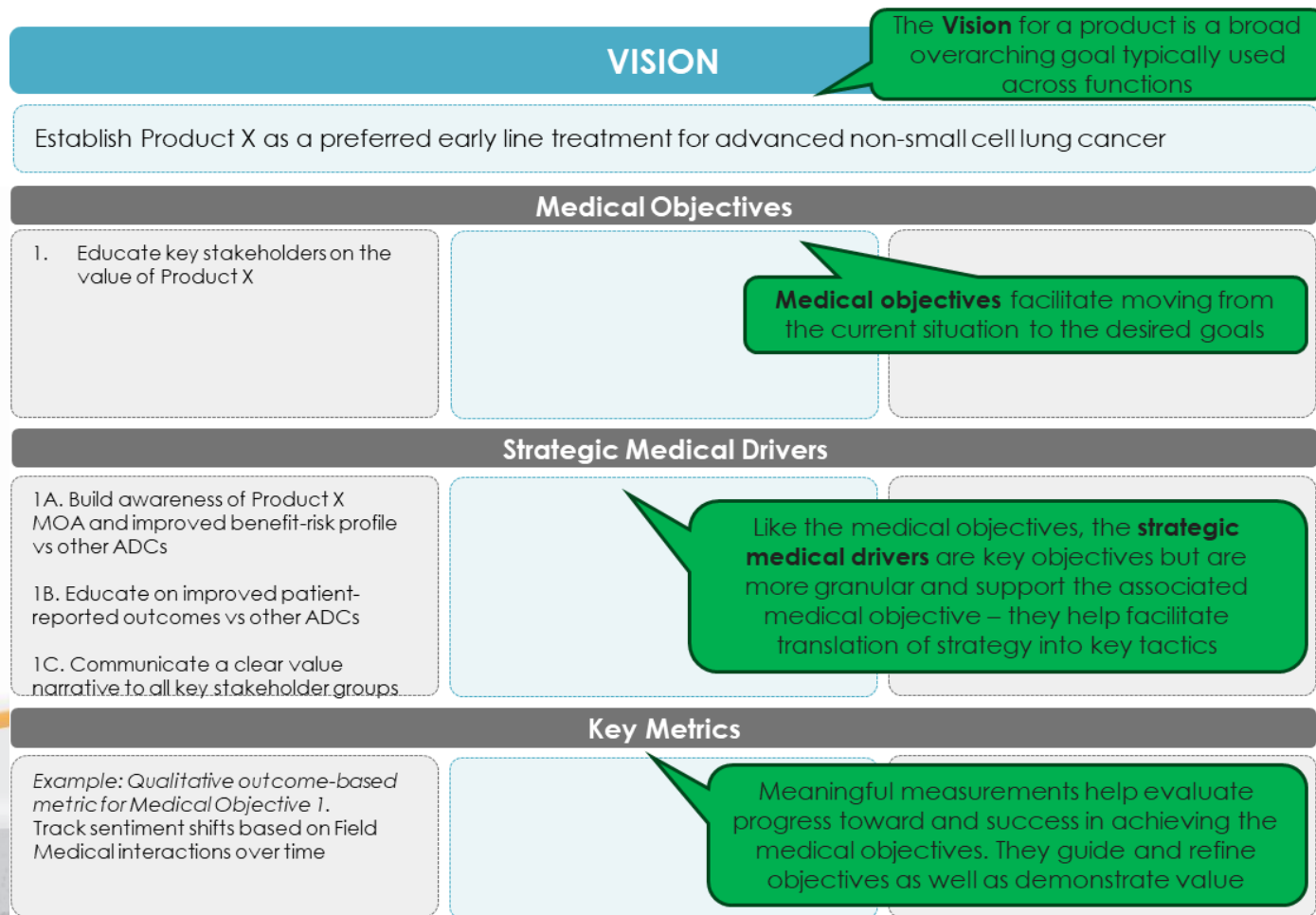


- The Situational Analysis informs the Medical Strategy
- Key components for developing a robust medical strategy include:
  - Aligning to the overall product vision
  - Consideration of where you are currently within the product lifecycle
  - Cross-functional collaboration with commercial, clinical development, regulatory and other teams
  - Objectives should be monitored and refined over time as the landscape changes





## A **Strategy-on-a-Page** provides a snapshot of the overall strategy



**Template Tool**



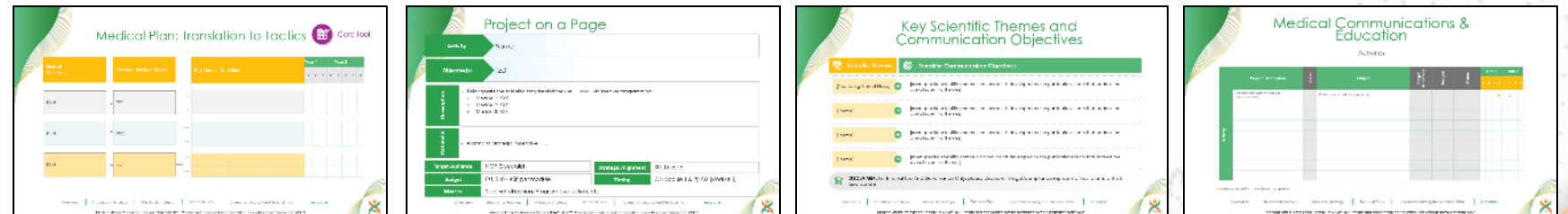


# Tactical Plan



- The Tactical Plan enables you to deliver on the medical strategy
- Identifies activities that encompass all Medical Affairs functions in the cross-functional team, including key market representation
- Defines ownership for project definition, management and accountability

## Example Template Tools



The resource includes 12 templates to support tactical planning



# Operationalizing the Medical Plan

## Operationalizing the Medical Plan

Medical Plan Strategic Overview

Budgets

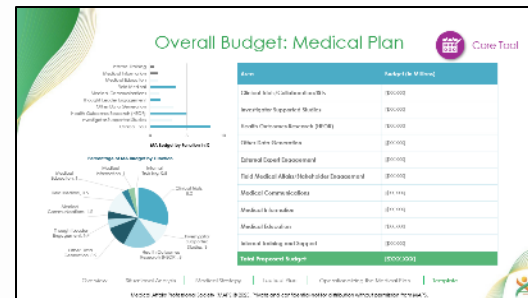
Timelines

Resources



- Your Medical Plan is ready, now you need to implement it!
- Medical Plans will need to be adapted and implemented locally, managed cross-functionally, with regular check-ins, updates and status reports

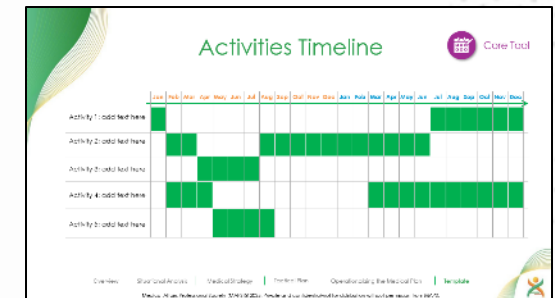
## Example Template Tools



**Tactical Plan on a Page**

This template provides a detailed tactical plan on a single page. It features a table with columns for 'Item', 'Subcategory', 'Amount', and various time periods (e.g., Q1, Q2, Q3, Q4, YTD, FY, etc.).

Item	Subcategory	Amount	Q1	Q2	Q3	Q4	YTD	FY	...
Medical Plan Strategic Overview	Medical Plan Strategic Overview	\$10,000							
Budgets	Budgets	\$10,000							
Timelines	Timelines	\$10,000							
Resources	Resources	\$10,000							



The resource includes 4 templates to support operations



## What does good look like?



**Teams are prepared** with the strategy, resources, empowerment, and accountability they need to deliver



The strategy and plan are kept **top of mind** across the organization



**Proper project management** is implemented to keep on top of plan execution



The **broader organization (Development, Commercial, Management)** is aware of what Medical Affairs will deliver and is kept informed along the way of changes and successes



**Lessons learned from projects** along the way have been applied to the processes to implement best practices



The teams are **keeping an eye on insights and risks** to see how they may affect your plan and are ready to adapt as needed



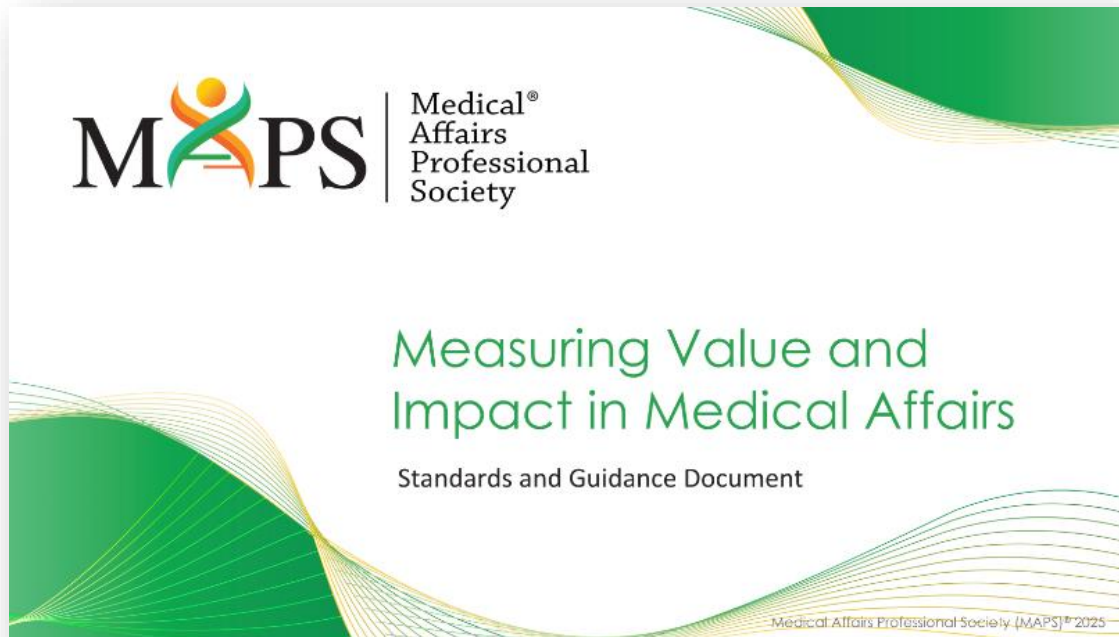
## **Drive Medical Excellence with Purpose in Planning**

*Leverage the roadmap to turn insights to strategy & actionable tactics, unify stakeholders, and deliver measurable value for the product and the patients in therapy area*



# Value & Impact S&G

Yi Arnold & Amanda Henkel



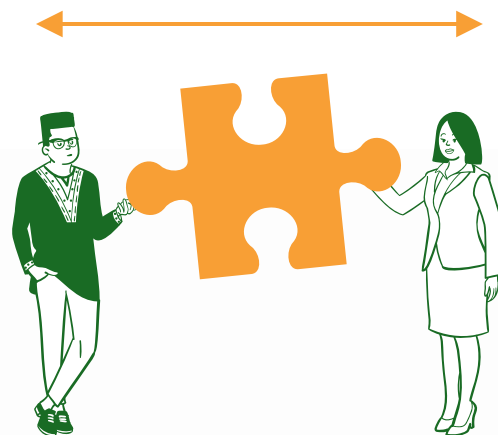




# Why do we need this guidance?

A gap remains between intention and implementation of impact-focused measures

**>3 in 5** Medical Leaders believe advanced patient-centric metrics should be key outcome measures



Yet, **<15%** have adopted these advanced metrics



# Why do we need this guidance?

Drivers for the development of the S&G



Traditional metrics often focus on activity, not outcomes



External expectations are evolving (payers, patients, regulators)



Lack of consistent frameworks limits internal alignment



Risk of 'measurement without meaning'

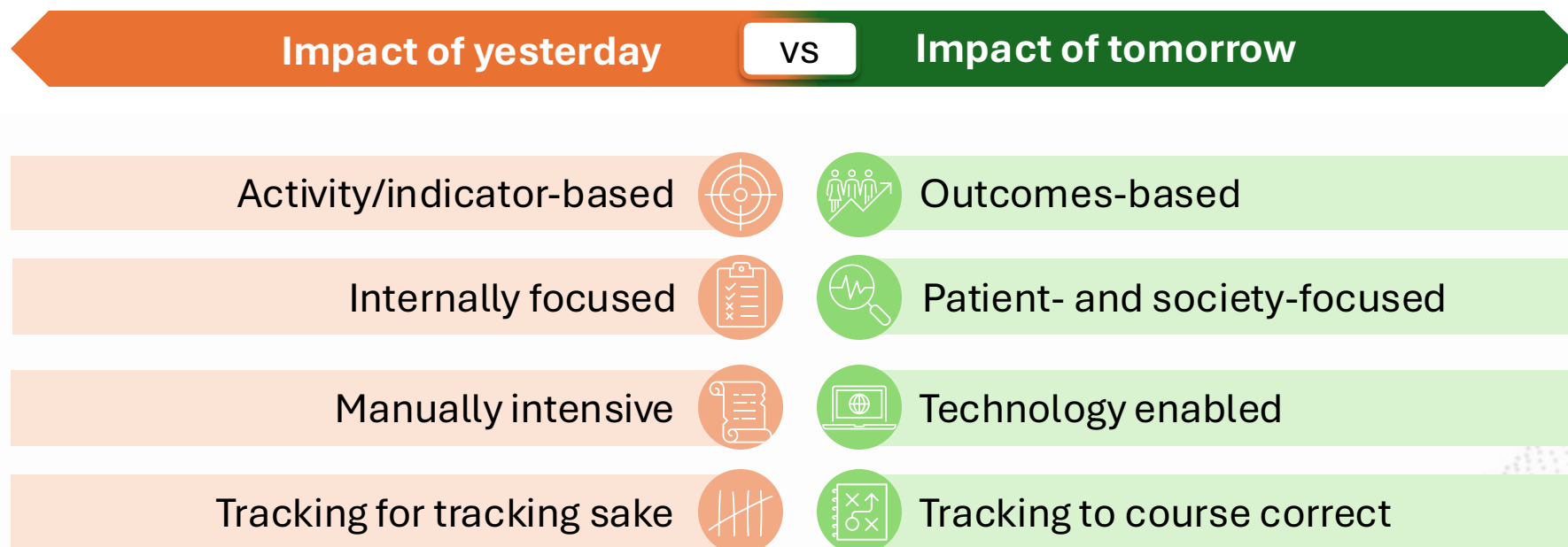


Single definition of value does not encompass the variety of Med Affairs subfunctions



# Defining value and impact

Moving from metrics that count activity to measures that reflect impact





# Defining value and impact

## Practical examples of goal-based vs impact measures

*Company X is launching Product Y in a rare disease indication and has a strategic imperative to improve diagnosis of the disease*

### Quantative and qualitative goal-based measures

*Quantitative:* # unique visits to a disease awareness website

*Quantitative:* # people attending a symposium

*Qualitative:* Shares of an educational campaign on social media

*Qualitative:* Change in physician perceptions following an educational program (assessed via pre- and post-event questionnaires)

### Impact (outcome) measures

15% increase in time to diagnosis (assessed via physician surveys) or increase in diagnosis (assessed via claims database analysis)



# Nuggets in the S&G

## Framework of meaningful measurements

### Framework of meaningful measurements



Qualitative versus Quantitative



Scalar versus Vector



Organizational versus Strategic



Reach, Relevance, and Resonance



Value versus Impact



Measuring versus Monitoring



Internal versus External

The list of possible metric expanding, especially with technologies, highlighting the factors that make the context of a team's specific plans

### Meaningful measures across Medical Affairs\*

Insights		External Education	
Qualitative measures	Quantitative measures	Qualitative measures	Quantitative measures
<ul style="list-style-type: none"><li>• Impact of insights on strategy</li><li>• Actions taken and results achieved based on insights delivered</li><li>• Quality of insights delivered (leadership feedback)</li></ul>	<ul style="list-style-type: none"><li>• Number of competitive intelligence insights</li><li>• Number of actionable insights</li><li>• Number of medical information inquiries</li></ul>	<ul style="list-style-type: none"><li>• Impact of medical content (eg, via Moore's Model and behavioral change measurements/evaluations)</li><li>• HCP recommendations</li><li>• Depending on educational activity:<ul style="list-style-type: none"><li>– Time to diagnosis</li><li>– Time to treatment initiation</li></ul></li></ul>	<ul style="list-style-type: none"><li>• Number of educational events delivered</li><li>• Number of events sponsored</li><li>• Number of speaker trainings</li><li>• Analytics from online resources, number of downloads, frequency of visits to the educational site, etc.</li></ul>

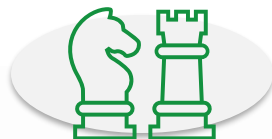
\* Please note, examples only – this list is not exhaustive.





# How can we execute measurement in practice?

To be meaningful, value and impact measurements should align with the strategic plan



## **Understand the need**

*Identify the unmet medical need to help define the strategy and subsequent value measurements*

## **Define the strategy**

*Develop the core strategy, strategic imperatives, and medical objectives*

## **Align stakeholders**

*Align with internal cross-functional partners to ensure a coordinated approach*

## **Determine Medical Affairs measurements**

*Ensure a combination of impact and goal-based measurements that are measurable and relevant*



# Medical strategy: Defining where we want to be and how to assess impact



## Medical Objective

Educate key stakeholders on the value of Product X



## Strategic Driver

Build awareness of Product X and improved benefit-risk profile vs alternative treatments



## Potential Tactics

Develop a simplified MoA animation that links action to improved safety

Conduct a hybrid educational event at global congress X and share materials via various channels (where metrics can be tracked)



## Metrics

Measure improvements in sentiment and changes in treatment practice based on field interactions

Conduct pre- and post-event surveys to assess knowledge and shifts in opinions

Measure the engagement and sharing of materials post-event



## It is important to understand your baseline, prior to tracking and assessing value & impact



Establish your baseline for the measurement



Determine process and timing for impact assessment



Identify a common tool for data collection and evaluation



Keep in constant communication with the functional groups to ensure accountability and proper adjustment to changes in medical plans



Develop an ongoing communication plan for cross-functional internal stakeholders to highlight achievements and accomplishments of the Medical Affairs teams as well as key learnings from the value and impact measurement evaluation



## How can we set ourselves up for success?



Embrace a measurement-driven mindset



Begin with a clear vision of success



Ensure alignment across all subfunctions and cross-functional teams



Foster transparent and consistent communication



Continuously refine and adapt



## **Measure What Matters - Unlock the True Value of Medical Affairs**

*Shift from reporting activities to demonstrating strategic influence and real-world impact through purposeful planning, meaningful measurement, and compelling storytelling*





# Connecting it all

Operationalizing Strategy and Medical Value - Roadmap, Measurement and Optimization



Strategic  
Planning

**Strategic Road Mapping**

**Performance & Adaptation**

**Cross-Functional Alignment**

**Internal Engagement & Visibility**

Medical Value  
& Impact



# Discussion & Q&A: Practical Applications

Arron Mungul (Moderator)

Yi Arnold, Amanda Henkel,  
Emily Howman, & Leah Williams





# Closing Remarks

Yi Arnold

# MAPS Medical Strategy and Launch Excellence FAWG Initiatives

## AVAILABLE ON-DEMAND

### Fundamentals of Strategy Webinar Series

- SWOT Analysis
- Gap Analysis
- Creating Measurable Strategic Objectives

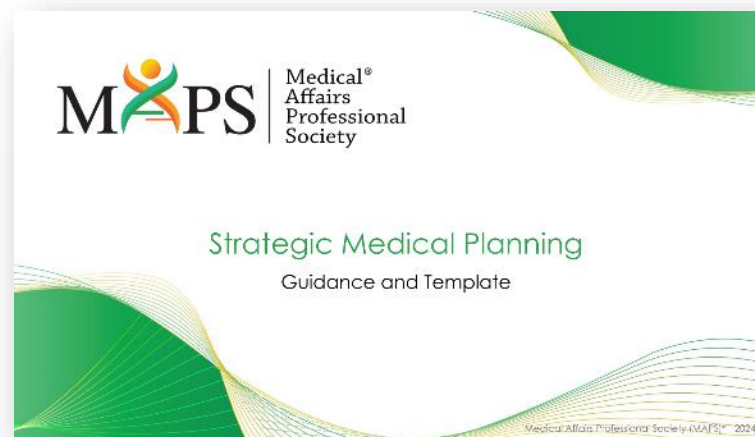
## NEW & UPDATED

### Standards & Guidance Documents

- Measuring Value and Impact in Medical Affairs
- Strategic Medical Planning

## COMING SOON IN 2025!

- S&G Launch Excellence



<https://medicalaffairs.org/knowledge-center/>




# Foundational Resources

MAPS Medical Affairs Professional Society

Search content in the platform

MAPS eCADEMY



FOUNDATIONS IN MA

The **MAPS Foundations in Medical Affairs (MA) Certificate Program** provides a comprehensive overview of the 7 Domains & 42 Competencies of the **MAPS Medical Affairs Competency Framework**, equipping early-career MA professionals to be effective team members, while broadening their perspective of the function and industry as a whole.

FOUNDATIONS IN MA

FULL PROGRAM

7 DOMAINS

42 COMPETENCIES

Foundations in Medical Affairs Certificate Program

FREE

7 courses | 8h 45m

Learning plan

STRATEGY

Foundations in Medical Affairs: Strategy

FREE

EN | 1h 15m

★ 5.0

E-learning

SCIENTIFIC & TECHNICAL KNOWLEDGE

Foundations in Medical Affairs: Scientific & Technical Knowledge

FREE

EN | 1h 15m

E-learning

BUSINESS KNOWLEDGE

Foundations in Medical Affairs: Business Knowledge

FREE

EN | 1h 15m

★ 5.0

E-learning

EVIDENCE GENERATION

Foundations in Medical Affairs: Evidence Generation

FREE

EN | 1h 15m

E-learning

CUSTOMER ENGAGEMENT & SCIENTIFIC COMMUNICATION


Foundations in Medical Affairs: Customer Engagement & Scientific...

FREE

EN | 1h 15m

E-learning

Introduction to the MAPS Foundations in Medical Affairs Program with Travis Hege, MAPS CEO



0:00 / 1:16

Foundations in Medical Affairs: IPP Member

Foundational-level training for the 42 competencies of the MAPS Medical Affairs Competency Framework

1/2

Medical Affairs Professional Society (MAPS)© 2025

39



## Where to Access the S&G and Other Resources

The screenshot shows the MAPS Knowledge Center website. At the top, there is a navigation bar with links: Home, About, Knowledge Center (highlighted), MAPS Community, Events, MasterClass, Partners, Job Postings, and Membership. Social media icons for LinkedIn, X, and Instagram are also present. Below the navigation bar is the 'KNOWLEDGE CENTER' header with a search bar. The main content area is titled 'Select by Medical Affairs Competency Framework' and features seven green buttons with white text and downward arrows: Strategy, Scientific & Technical Knowledge, Business Knowledge, Evidence Generation, Customer Engagement & Scientific Comms, Leadership & Management, and Medical Governance & Compliance. Below these buttons are two dropdown menus labeled 'Select By Type' and 'Select By Topic', followed by an orange 'Clear' button. At the bottom, there are several promotional banners, including one for 'March 11' and another for 'STANDARDS'.

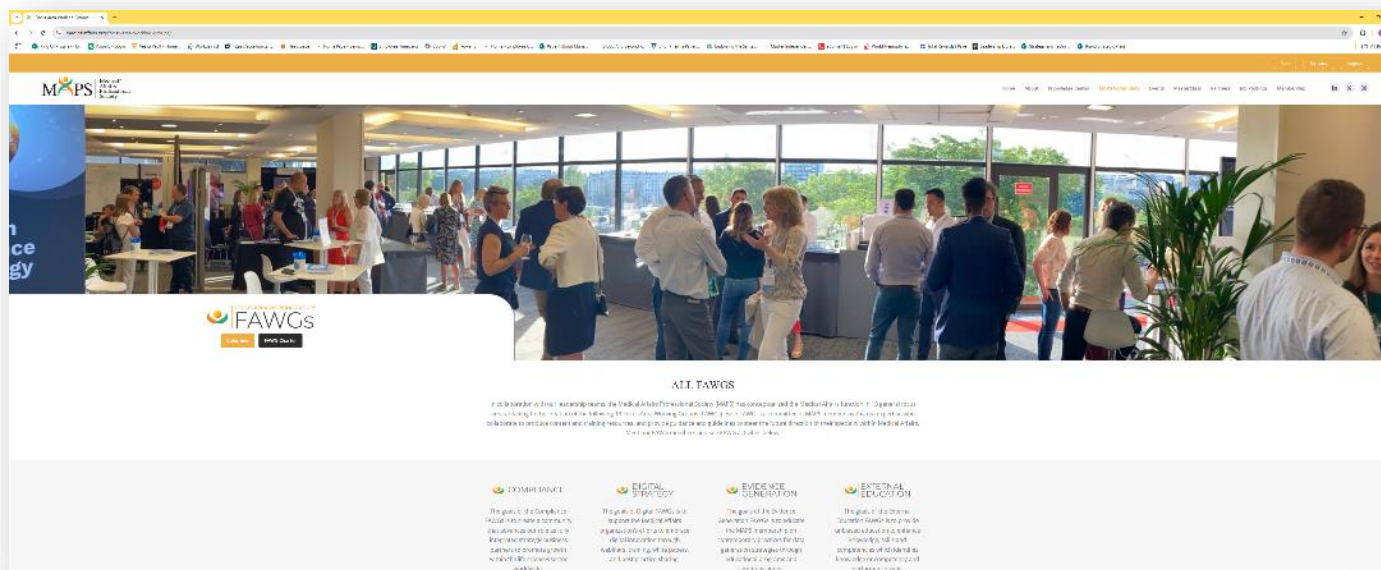
<https://medicalaffairs.org/knowledge-center/>



# MAPS Medical Strategy and Launch Excellence FAWG

Interested in joining the MS & LE Focus Area Working Group? Learn more!

<https://MedicalAffairs.org/focus-area-working-groups/>



# THANK YOU!



Medical<sup>®</sup>  
Affairs  
Professional  
Society

[www.medicalaffairs.org](http://www.medicalaffairs.org)