Medical Operations: Making the Strategy Work

Presented by the MAPS Medical Strategy & Launch Excellence and Medical Operations Focus Area Working Groups
Presenters

**Arron Mungul (Moderator)**
Founder
Apogee Life Sciences
UK

**Rebecca Lakata**
Medical Excellence & Capabilities Consultant
USA

**Eric Toron**
Executive Director & Medical Operations Lead
Merck
USA

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

**David Kelaher**
Senior Director, Medical Affairs
IQVIA
France
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.
Educational objectives

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

**Objective 1:** Understand the Medical Operations function and its Integration in Medical Strategy

**Objective 2:** Explore Medical Operations as an Innovation Hub

**Objective 3:** Appreciate the Value of Cross-Functional Collaboration
## Today’s agenda

<table>
<thead>
<tr>
<th>Topic</th>
<th>Presenters</th>
</tr>
</thead>
<tbody>
<tr>
<td>The role of Medical Operations leads</td>
<td>Becky and Eric</td>
</tr>
<tr>
<td>Realizing the strategy</td>
<td>Leah and Arron</td>
</tr>
<tr>
<td>Tracking and measuring success</td>
<td>David</td>
</tr>
<tr>
<td>Q &amp; A</td>
<td>All</td>
</tr>
</tbody>
</table>
Question 1

• Do you have a Medical Operations function in your company?
  1. Yes
  2. No
  3. N/A
Question 2

- For those who answered ‘Yes’ to Question 1, does the Medical Operations function directly support your team?

1. Yes
2. No
An overview of medical strategy

1 Situational analysis
   - Disease State
   - Therapeutic Landscape
   - Product Profile
   - Stakeholder Insights

<table>
<thead>
<tr>
<th>Vision and brand goals</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gap analysis</td>
</tr>
<tr>
<td>SWOT</td>
</tr>
</tbody>
</table>

2 Strategy development
   - Medical strategy
     - Medical objectives and strategic medical drivers

3 Tactical planning
   - Medical plan – tactics to address audience needs and format/channel preferences
     - External expert engagement
     - Internal training & support
     - Scientific communications & publications
     - Congress activities
     - Evidence generation
     - Field medical engagement materials

4 Monitoring & refinement
Fundamentals of strategy webinar series

A MAPS Medical Strategy & Launch Excellence FAWG initiative covering 4 key areas of strategic planning:

- SWOT Analysis
- Gap Analysis
- Creating Measurable Strategic Objectives
- Implementation of Strategy and Monitoring Progress

AVAILABLE ON-DEMAND

COMING SOON IN 2024!

https://medicalaffairs.org/content-hub/
Operationalizing a medical plan
The road is not always straight

Current situation

Strategy

Desired situation
The Role of Medical Operations
Medical Operations:

- Enables efficient realization of Medical Affairs strategy across subfunctions.
- Establishes high-quality standards to promote continuous improvement in connecting the organization internally and externally.
- Should be a fit-for-purpose, forward-looking and progressive organization cognizant of the evolving external landscape in a patient-centric and digital savvy manner.
- May include numerous business operational responsibilities, including project management, processes, systems, research management, development of standards and operating procedures, knowledge management, training, business intelligence, digital innovation, Field Medical support, grants processing, medical material review governance, financial management and more.
- Addresses “how” departments, teams, and individuals will execute strategies formulated by therapeutic or product development teams.
- Can be conceptualized as an integrator function that can be leveraged to allow other functions to focus efforts on their primary areas of expertise and priorities.
The remit of MedOps and identification of the Medical Affairs subfunctions it supports will determine the competencies, expertise, and experience needed for the role, especially the optimal mix of scientific knowledge, technological sophistication, and leadership/business acumen.

- Learning agility
- Affinity for adaptation to changing conditions
- Ability to integrate functions across the enterprise (LT)
- Diverse set of technical expertise
### Three Approaches to Structuring Med Ops Department

<table>
<thead>
<tr>
<th>Approach</th>
<th>Benefits</th>
<th>For Consideration</th>
</tr>
</thead>
</table>
| Centralized   | • Global processes and systems implemented centrally and leveraged across geographies, TAs etc.  
• Helps ensure optimal resource utilization, consistent processes, and quality oversight. | • Must ensure systems and processes are malleable enough to allow customization and localization. |
| Decentralized | • Embedding w/ affiliates or functional groups yield more flexibility, faster implementation speeds, high customization to local needs, and high responsiveness. | • Fails to leverage economies of scale with more cost and resource demand.  
• More challenging for consistent strategy / implementation, and avoidance of redundancies. |
| Federated     | • Organized in hubs supporting various levels or teams within the organization.  
• This “hub and spoke” model combines elements of the centralized and decentralized approaches. |                                                                                                                                 |

Regardless of selected model, the key to execution is partnership with all Medical Affairs groups (e.g., Medical Strategy, Medical Communications, Field Medical, Country and Regional Leaders, Finance, Commercial, HEOR).
Medical Operations: Helping to Realize Strategy

• MedOps serves as a bridge, bringing everyone in Medical Affairs together for product and functional planning.

• Keen project management and strategic insight are integral to the Medical Strategy planning process.

• MedOps establishes processes and systems to integrate data that creates valuable and actionable insights for impact on clinical trials, medical strategies, medical education, and patient access.

• Med Ops makes an impact through its application of technology that eases documentation and detects trends.
• MedOps needs to be at the forefront of experimentation and defining applicable use cases in line with business needs, regulations and enterprise guidance.

• Once implemented, MedOps may oversee the continued maintenance and upgrades of digital tools, anticipating the lifespan to ensure timely replacement.
Realizing the Medical Strategy
Biotech/Small Pharma Perspective

- Medical Affairs Operations
  - Is not established equally across all organizations
  - May be disparate within the organization (i.e., SOPs, project management, finances, systems support, innovations)

Importance is to work with what you have and start to build
### When Implementing Medical Strategy...

#### Key Operational Components

- **Setting Expectations**
- **Appropriate Resource Allocation**
- **Organizational Alignment**
  - Cross-functional (outside)
  - Within teams (role vs. responsibility vs. accountability)
  - Within expanded teams (Global-Regional-Local)
- **Tracking Progress**
  - Dashboard
  - Regular check-ins
  - Internal versus external factors
  - Metrics reporting
- **Insights Management and Dissemination**
- **Training and Communication**
Looking Beyond....

Take small steps to build, simplify, clarify, and streamline

Processes  Systems  Innovation
Novel Medical Affairs roles to support local teams

Global Medical Affairs + Medical Operations
- Priority Markets

Global Medical Affairs Interface Lead

Regional Medical Affairs + Medical Operations
- EU
- Asia-Pac
- LatAm
- Middle East + Africa

- Launch
- Insights
- Best practices
- Optimisation
- Data / comms gaps
- Reviewing ISRs
- KOL engagement
- Tactics / budget synergies
Tracking and measuring success
“If you can’t measure it, you can’t improve it.”

Peter Drucker
Management consultant and author
Dashboards are most frequently used to communicate value and drive higher performance tracking of interactions and insights from MSLs and KOLs.

**Why do you believe capturing Metrics is important to Medical Affairs?**

- Communicate value to internal stakeholders: 96%
- Drive higher quality performance: 82.3%
- Improve strategic goal alignment: 82.3%
- Improve long-term MA strategy/forecasting: 70.5%
- Increase accountability: 60.7%
- Improve short-term data-driven decisions: 58.8%
- Communicate value to external stakeholders: 27.4%
- Other: 19.6%

**What types of Activities or Outcomes do you track in your MA Dashboard?**

- MSL/KOL Interactions: 72.5%
- MSL Insights: 52.9%
- Publications: 43.1%
- Investigator Initiated Study Progress: 39.2%
- Medical Information Letters/Topics: 33.3%
- Clinical Study Sites / Progress: 27.4%
- CME Speaker Programs: 27.4%
- Scientific Conference Presenters/Speakers: 25.4%
- Changes in HCP Knowledge / Behavior: 23.5%
- Advisory Board Insights: 23.5%
- We do not have a dashboard: 15.6%
- KOL Sentiment Analysis: 15.6%
- Other: 13.7%
- Share of Scientific Voice: 11.7%

Survey involving 51 representatives from 30 Pharma companies, 10 Biotech Companies, 9 Medical Devices companies and 2 Medical Diagnostics companies.

1. MAPS (Medical Affairs Professional Society) 2023 Medical Affairs Metrics Benchmark.
Meaningful metrics: The ability to track and optimize the strategy is key

Types of metrics currently used in Medical Affairs

Current, primarily quantitative metrics often do not demonstrate the depth and breadth of the work that MA teams do and how MA impacts the company; or these metrics are not used to progress the MA Strategic Plan.

While many MA teams are using metrics at a tactical level, they are not using metrics in meaningful ways that facilitate learning from prior actions and refinement to the strategic approach.

---

1 The Value and Impact of Medical Affairs: Mastering the Art of Leveraging Meaningful Metrics, MAPS, 2021

MA: Medical Affairs
KPI dashboards enable Med Affairs to set and track objectives, and support cross-functional collaborations

**LAUNCH TIMELINE**

<table>
<thead>
<tr>
<th>L-48</th>
<th>L-36</th>
<th>L-24</th>
<th>L-12</th>
<th>L</th>
<th>L+12</th>
</tr>
</thead>
</table>

**CRITICAL ACTIVITIES AT L-24**

- Patient Journey
- Stakeholder Engagement
- MSL Activities
- Publications
- Disease Awareness

**CRITICAL ACTIVITIES AT L-24**

- GTM Strategy
- Value Creation
- Brand Strategy
- Brand Message
- Field Force Profile & Sizing

**PRODUCTS’ MILESTONES**

- PRODUCT X
  - Q4-24
- PRODUCT M
  - Q3-25
- PRODUCT C
  - Q4-26

**PRODUCT X KPI OVERVIEW**

- **KPI**
  - EXPERT ENGAGEMENT
  - DISEASE AWARENESS
  - DIAGNOSIS RATE
  - SHARE OF SCIENTIFIC VOICE (SOSV)
  - COE / LARGE CLINICS

- **Value**
  - EXPERT ENGAGEMENT
  - DISEASE AWARENESS
  - DIAGNOSIS RATE
  - SHARE OF SCIENTIFIC VOICE (SOSV)
  - COE / LARGE CLINICS

- **vs plan %**
  - EXPERT ENGAGEMENT
  - DISEASE AWARENESS
  - DIAGNOSIS RATE
  - SHARE OF SCIENTIFIC VOICE (SOSV)
  - COE / LARGE CLINICS

**PRODUCT X KPI OVERVIEW**

- **KPI**
  - TOTAL MARKET BRAND SALES VALUE
  - COMPETITOR SALES
  - NEWLY DIAGNOSED PATIENT
  - PATIENT INITIATION
  - COMPETITORS CLINICAL PROGRAMS

- **Value**
  - TOTAL MARKET BRAND SALES VALUE
  - COMPETITOR SALES
  - NEWLY DIAGNOSED PATIENT
  - PATIENT INITIATION
  - COMPETITORS CLINICAL PROGRAMS

- **vs plan %**
  - TOTAL MARKET BRAND SALES VALUE
  - COMPETITOR SALES
  - NEWLY DIAGNOSED PATIENT
  - PATIENT INITIATION
  - COMPETITORS CLINICAL PROGRAMS

**PRODUCT X KPI OVERVIEW**

- **Category**
  - BUSINESS INSIGHTS
  - COMMERCIAL
  - MEDICAL
  - MARKET ACCESS
  - HR
  - OTHER

- **Investment**
  - BUSINESS INSIGHTS
  - COMMERCIAL
  - MEDICAL
  - MARKET ACCESS
  - HR
  - OTHER

- **vs plan %**
  - BUSINESS INSIGHTS
  - COMMERCIAL
  - MEDICAL
  - MARKET ACCESS
  - HR
  - OTHER

**CROSS-FUNCTIONAL COLLABORATION**

**TEAM EMPOWERMENT**

**OPERATIONAL AGILITY**

**AUGMENTED INSIGHTS**
Question 3

• If you answered ‘No’ to earlier questions (do you have Medical Operations / does it support you), would you like a Medical Operations function?

1. Yes
2. No
Summary

• Medical Operations plays a key role in realizing the Medical strategy
  – Connect multiple functions for product and functional planning
  – Embed project management and strategic insight
  – Establish integrated processes and systems across the enterprise

• Medical Affairs teams need to be agile to successfully implement the strategy

• Implementation of robust tracking and measurement tools are needed to optimize the strategy and articulate value

• Continuously challenge the operating model to bring organizational alignment from Global to Local teams
Thank you!