

Aligning Medical Information and Field Medical

Presented by the MAPS Medical Information FAWG

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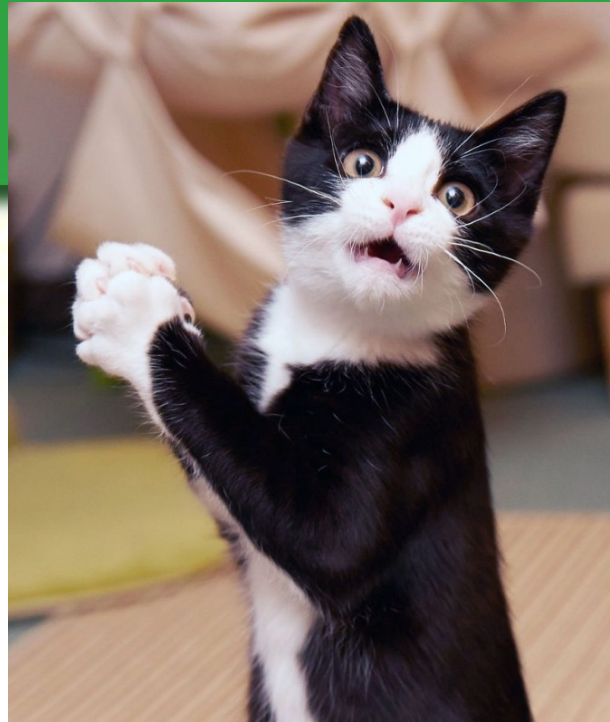
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Educational Objectives

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

- Understanding the efficiencies to be gained from aligning MI & MSL teams
- Discussing various structure considerations
- Bringing awareness to the challenges



“There are more ways to kill a dog than hanging.”

- John Ray, *Collection of English Proverbs*; 1678

“As it is said, ‘There are more ways than one to skin a cat’, so are there more ways than one of digging for money.”

- Seba Smith, *The Money Diggers*; 1840



“She was wise, subtle, and knew more than one way to skin a cat.”

- Mark Twain, *A Connecticut Yankee in King Aurther’s Court*; 1889

Rationale

Requires Nearly Identical Backgrounds and Competencies

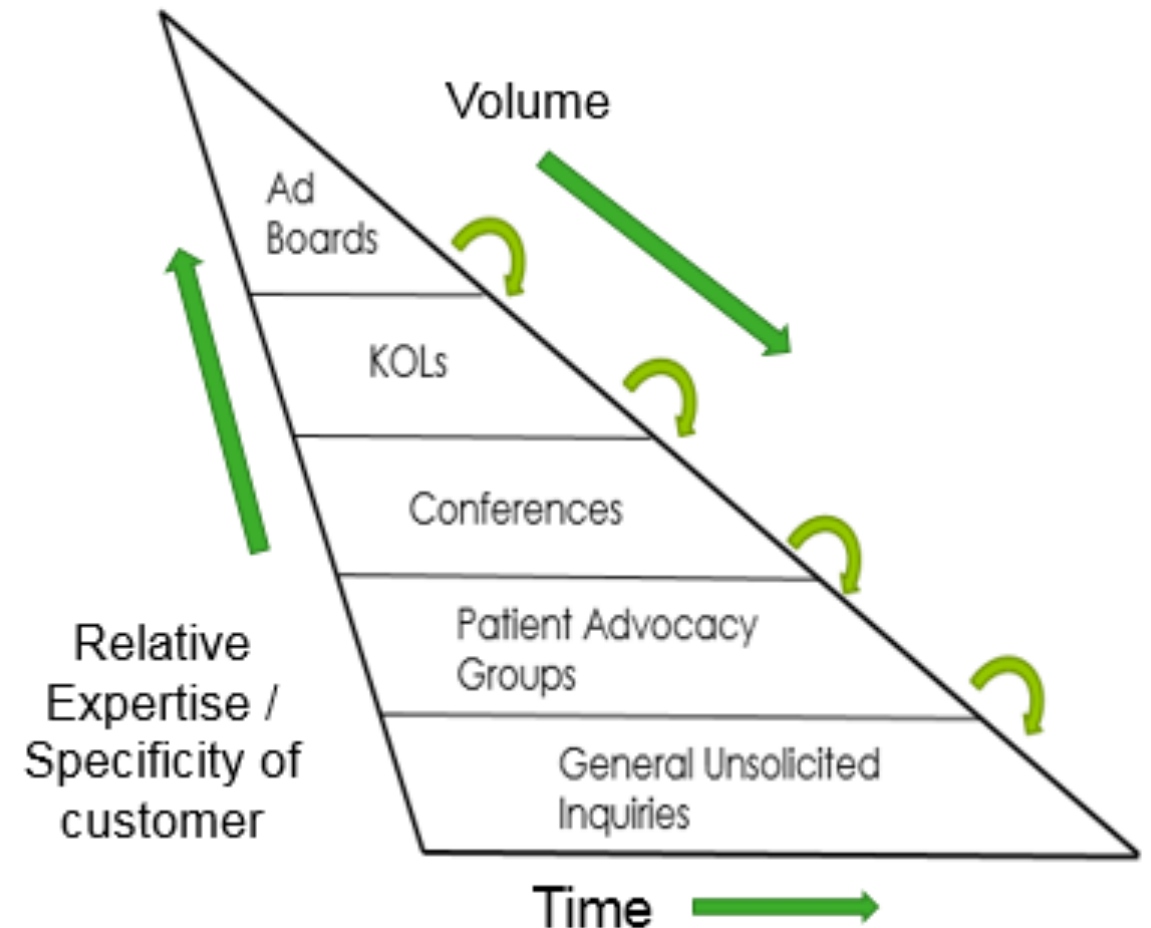
	Medical Information	MSL
Therapeutic Area Knowledge	✓	✓
Identifies and addresses unmet medical needs	✓	✓
Data dissemination	✓	✓
Health Care System Knowledge	✓	✓
Competitive Intelligence	✓	✓
Engage with HCPs	✓	✓
Highly credentialed	✓	✓
Exposed to innovative medical developments	✓	✓

Complimentary Key Stakeholders Provide More Complete View for Insight Collection and Analysis

All Medical Affairs functions can listen for the Voice of the Customer

Medical Information	MSL
<ul style="list-style-type: none">• May have more interactions with patients• Typically interacts with general practitioners• Some Conference support• Large and diverse customer base• Experience with medical innovations	<ul style="list-style-type: none">• Focus is typically on key opinion leaders• External key stakeholders are typically more specialized• Some Advisory Board and Conferences• Fewer clinicians engaged• Early exploration of medical innovations

Voice of Customer Hierarchy Model



Medical Information and MSL Communication Governed by Same FDA Guidance's

Responding to Unsolicited Requests...

1. Medical departments often have a large body of information including data that is off-label; such information may be of use to others outside the company.
 - a. Firms are capable of responding to requests in a truthful, non-misleading, and accurate manner.
 - b. This information may be in the best interest of public health.
 - c. Responses to unsolicited requests should be generated by medical personnel, with specialized background in responding to unsolicited requests.

Distributing Scientific and Medical Publications...

1. Distributing scientific journal articles that include information on unapproved uses is not evidence of an intent that the product be used for that unapproved use.
 - a. Deliver separate from promotional information.
 - b. Questions referred to Medical Officer or department.

Guidance for Industry
Responding to Unsolicited Requests for
Off-Label Information About
Prescription Drugs and Medical Devices
DRAFT GUIDANCE

This guidance document is being distributed for comment purposes only.

Guidance for Industry
Distributing Scientific and
Medical Publications on
Unapproved New Uses —
Recommended Practices

REVISED DRAFT GUIDANCE

Polling Question

Of the two, which is the more impactful activity for

Medical Information:

- A. Respond to unsolicited requests for information
- B. Analyze requests for insights to guide strategy

MSL teams:

- A. Respond to unsolicited requests for information
- B. Analyze engagements for insights to guide strategy

Alignment

What is Alignment?

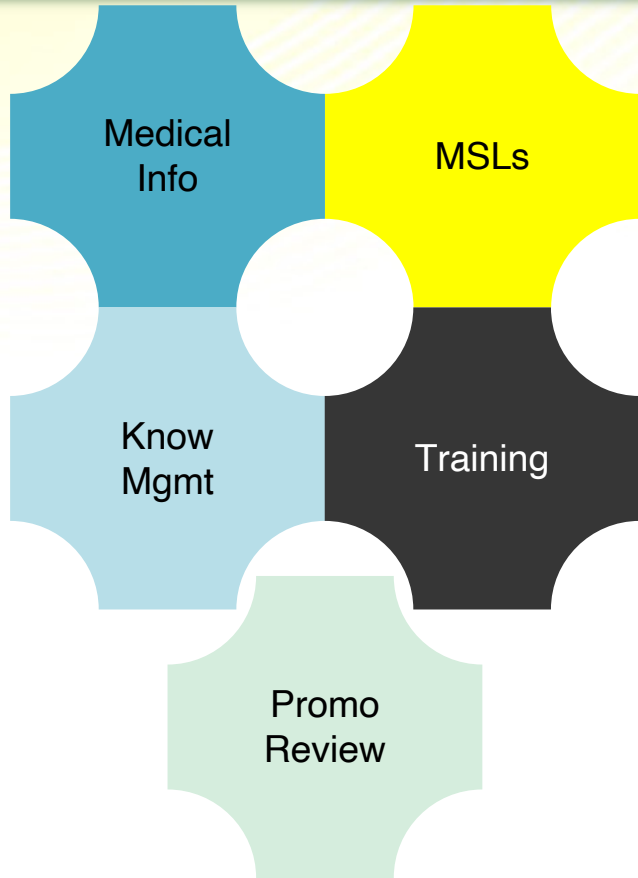


Efficiency

Broad Scope of Medical Affairs Provides Many Different Alignment Opportunities



Opportunities To Leverage Economies of Scope Through Alignment or Reporting



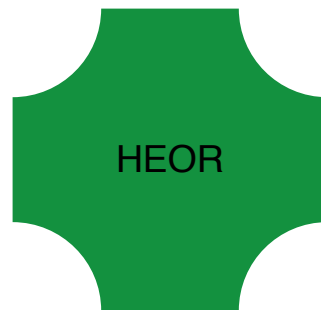
Scientific Engagement

- Product and disease knowledge
- Leading edge of emerging data



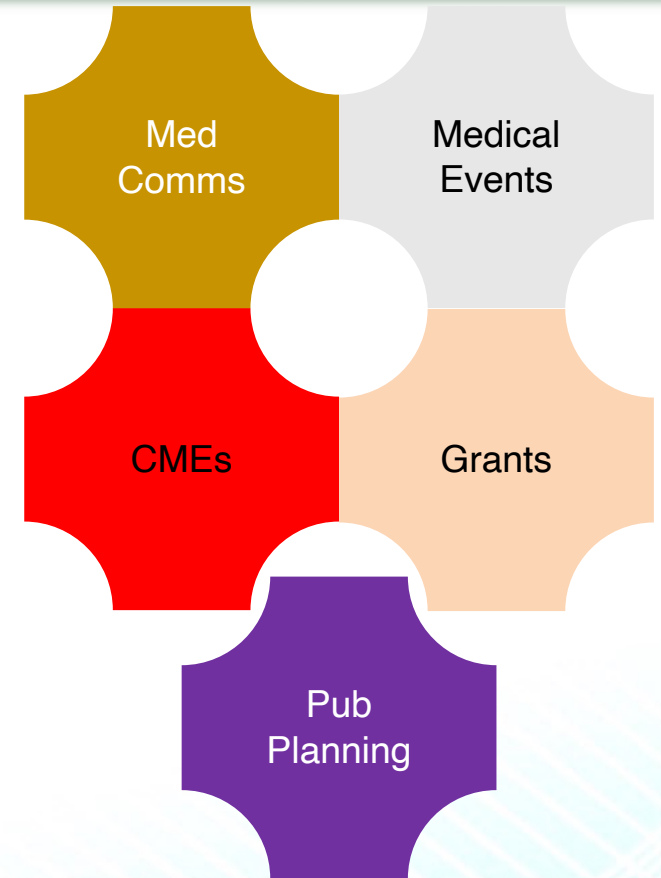
Strategy

- Landscape understanding
- Lifecycle management



Health Economics

- Outcomes Research expertise
- Knowledge of access environment



Operations

- Operational & Systems expertise

Polling Question

At my company, Medical Information and MSL teams are:

- A. Separate and siloed
- B. Separate but aligned
- C. Closely aligned/Same structure

Challenges

Challenges

Discussion



Hyper-alignment

Strengthens commonalities
Risks weaknesses

Writing

Voice of Customer
Clinician Interaction
Advisory Boards

Executive Expectations

Setting Proper Expectations

Resourcing

Cross-Functional Relationships
Value
Strategy/Tactical Planning

MAPS Resources on the Topic

- **Podcasts**

- Advancing Field Medical Skills Episode 1: Leading Through Change
- Expanding Capabilities in Medical Information

- **Elevate Articles**

- The Value of Medical Information to Internal Stakeholders
- Building Medical Insights Capabilities in Medical Affairs Organizations

- **White Papers**

- Challenging the Status Quo: Evolving Medical Affairs Through a Capability-Centric Model
- Promoting Best Practices for Medical Science Liaisons Position Statement from the APPA, IFAPP, MAPS, and MSLs

Conclusion

- **Build a structure that best aligns with your Medical Affairs culture, size, and goals.**
- **Consistent and reliable exchange of scientific information**
- **Acknowledge and plan for challenges presented by hyper-aligning and executive expectations**

Thank you!