

Essential Elements of a “Best-in-Class” Medical Information Organization

<https://medicalaffairs.org/medical-information-standards-guidance/>

Speakers and Panel



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- The following faculty and planning members do disclose financial relationships- *Riggins, Pienaar, DeSantis, Jindia*

Educational Objectives

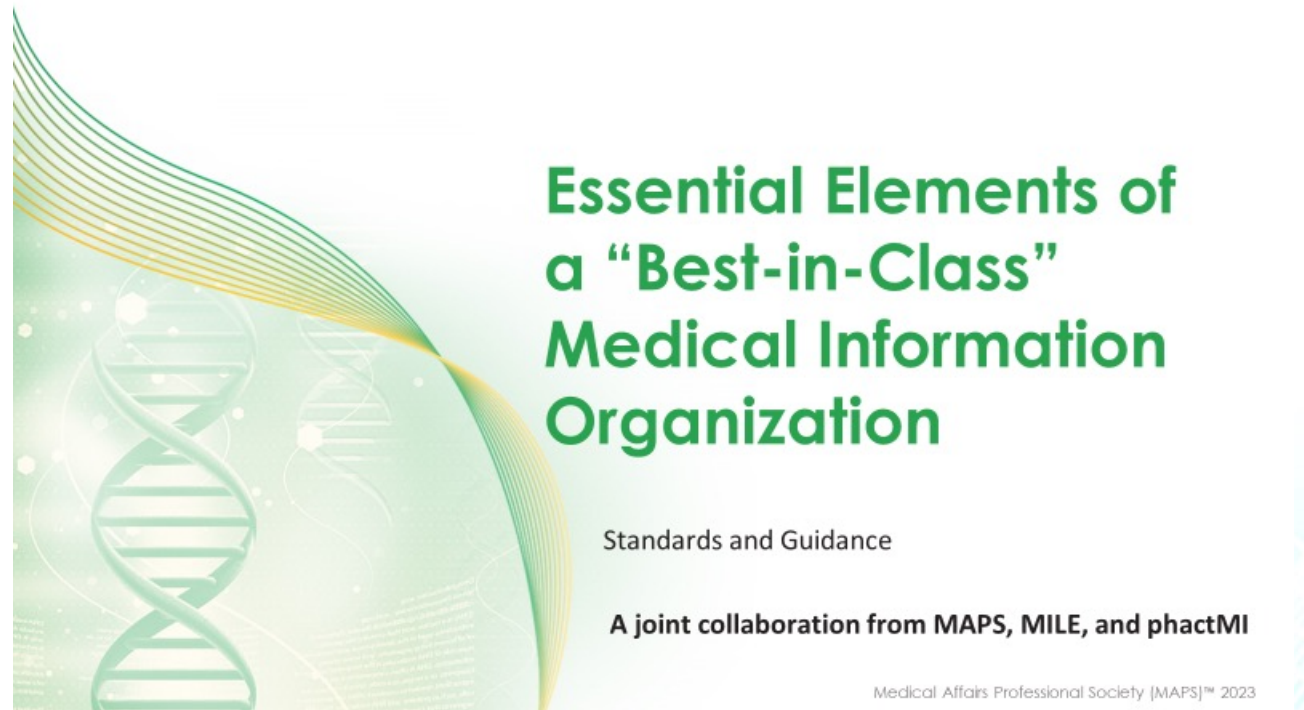
- Establish a blueprint for building a “best-in-class” Medical Information organization
- Create global consistency and harmonization of standards and operational excellence for the industry
- Identify the value of Medical Information for internal stakeholders and external customers
- Elevate the practice of Medical Information across the industry through collaboration, insights, and innovation

Agenda

- 1 Overview of Webinar
Standards and Operational Excellence
- 2 Collaboration: Internal, External, and Emerging Customers
Q&A
- 3 Insights and Voice of the Customer
Q&A
- 4 Innovations and Opportunities in Channels and Content
Q&A
- 5 Wrap-Up

Joint Collaboration Standards and Guidance

- Rolled out by MAPS in March '23
- Detailed look at “best-in-class” medical information practices
- Living document
- Uses
 - Creating new MI depts
 - Redesigning MI
 - Onboarding new employees
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Standards and Operational Excellence (SOE)

Efficiency and Effectiveness are Critical Foundations

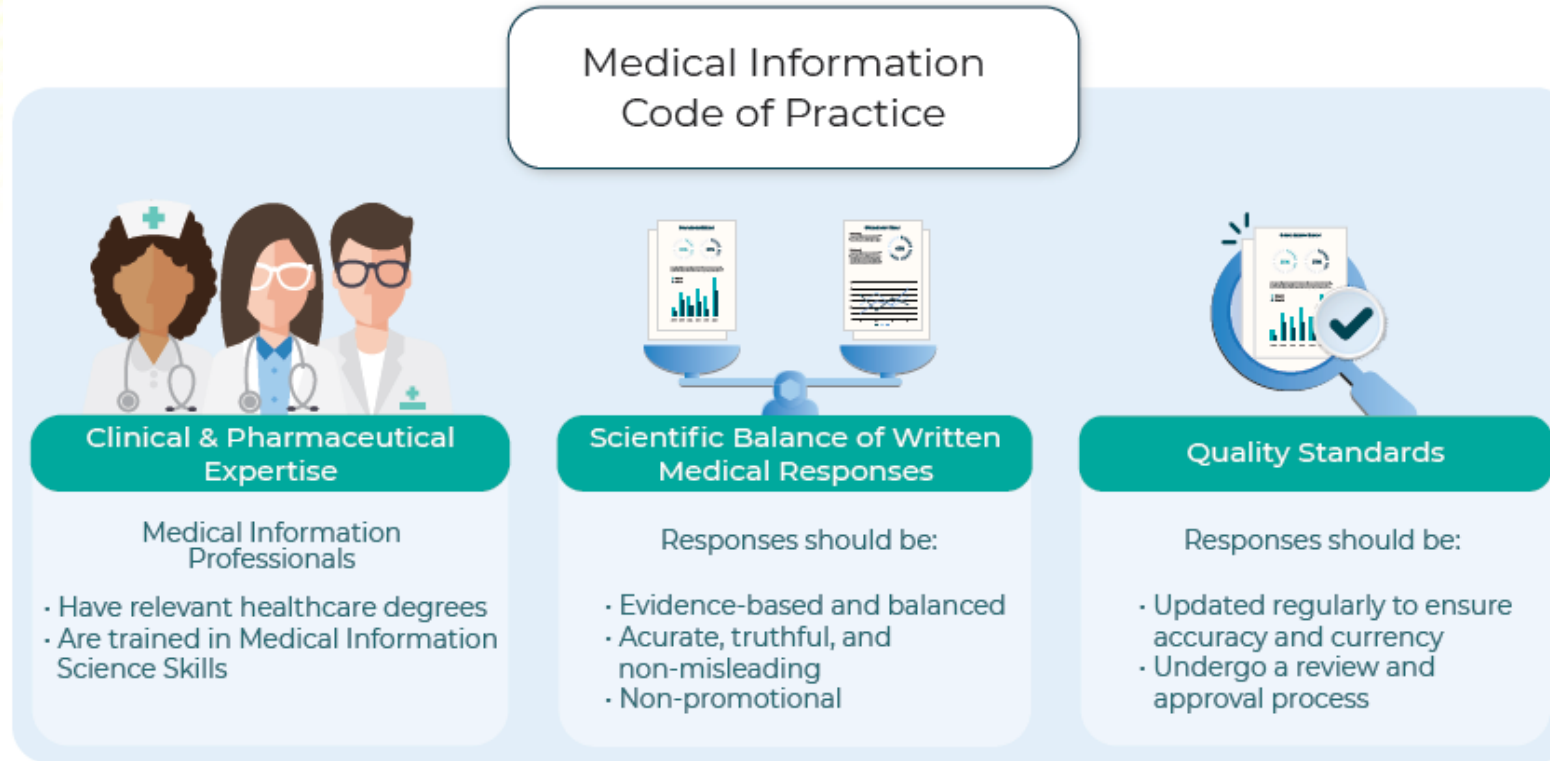
Medical Information (MI):

- An Essential Function of Medical Affairs
 - Serves as the “face” of the manufacturer to many external customers
 - Supports the information needs of HCPs, patients, and caregivers
 - Responds to unsolicited questions about the manufacturer’s products
- Provides Value both Internally and Externally
 - Informs clinical decision making, supporting appropriate, safe, and effective use of medicines
 - Supports scientific exchange
 - Responds to unsolicited requests for both on- and off-label information
 - Builds scientific and medical reputation and trust with customers
 - Works in close collaboration with key stakeholders including early participation in preparing for product launches

*Our **INTERACTIONS**
with our
CUSTOMERS
enable us to **SHARE**
VALUABLE INSIGHTS
with internal
stakeholders to help
SHAPE the
MEDICAL STRATEGY
and the safe and
effective use of our
products*

Medical Information Code of Practice

Responding to HealthCare Professional Requests



What's Included in SOE?

- Regulatory Guidance for Medical Information
 - Responding to unsolicited requests
 - Scientific exchange
 - Reporting AEs and PQC's
 - Regulatory concerns and challenges
- Role Qualifications: Who are MI Specialists?
- MI Activities, Staffing Needs, and Org Models
- Contributions of MI that are Assessed and Reported
- Managing the MI Inquiry Process using DRESS (Define, Research, Evaluate, Synthesize, Share)
 - Inquiry intake
 - Developing responses
 - Responding
 - Quality management
- Metrics: Key Performance Indicators

Appendix 1:

Regulatory Guidance and Groups

Appendix 2:

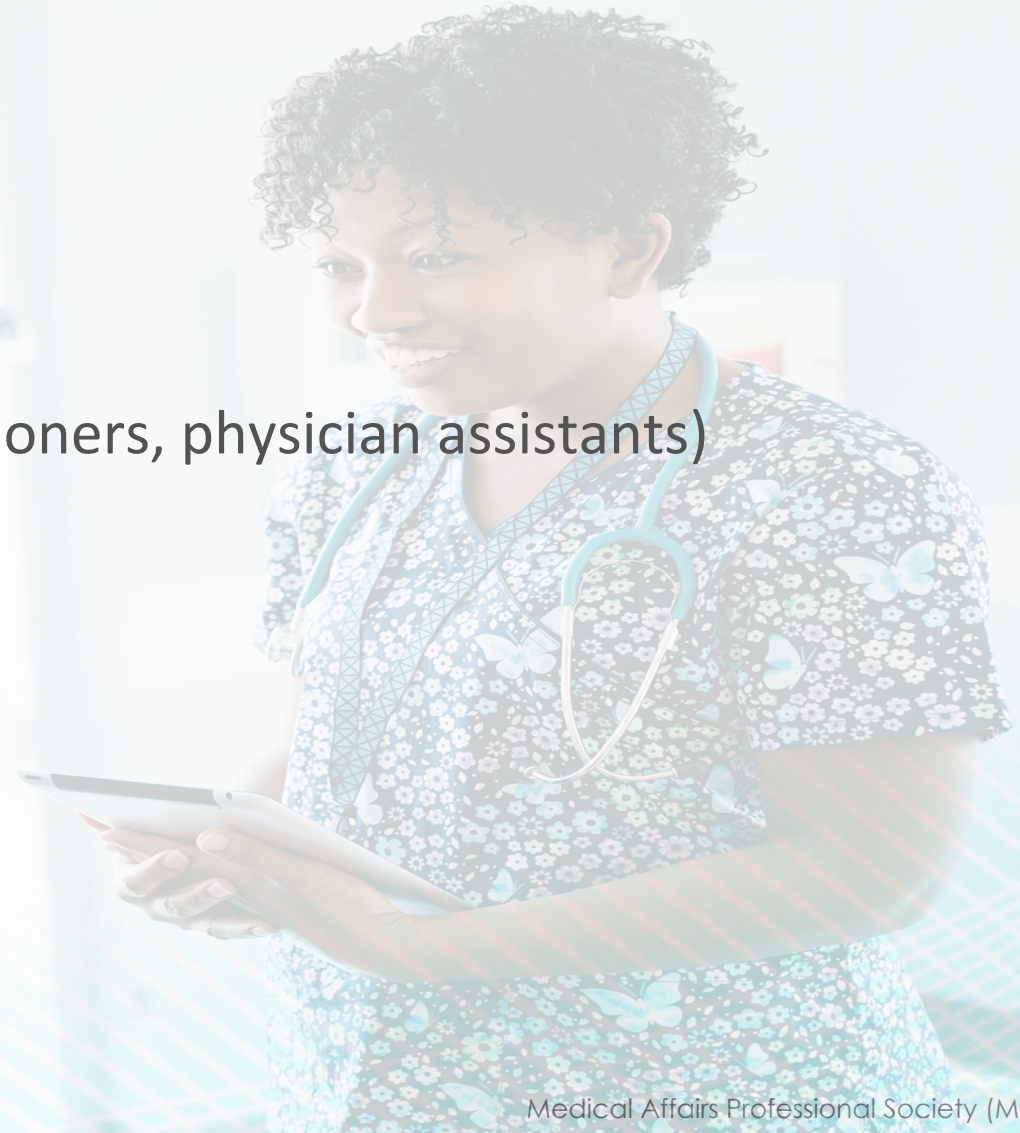
Scientific Response Documents

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Collaboration: External, Internal, and Emerging Customers

External Customers

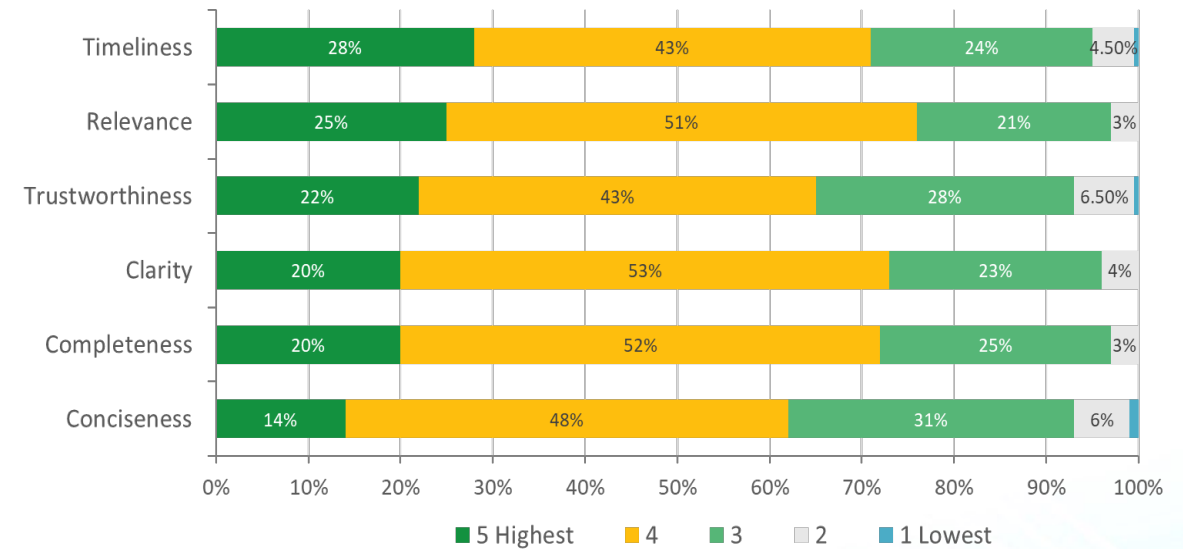
- Healthcare Professionals
 - Physicians
 - Pharmacists
 - Nurses
 - Other prescribers (e.g., nurse practitioners, physician assistants)
- Life Science Professionals
 - Research scientists (i.e., PhD's)
 - Non-HCP formulary decision makers
- Patients/Caregivers
- Payers



External Customers: What Is Important to HCPs

Supporting the Peer-to-Peer Interaction

- MI needs to be aware of HCP customer needs and preferences
- Timeliness, relevance, and trustworthiness are expected by HCP customers
- Surveys are often used to solicit feedback on customer preferences and feedback
- Continuously monitor for changes in trends of types of HCP customers and adapt to their needs accordingly
- HCP customer interaction channel preferences may change over time, particularly with the ongoing emergence and prevalence of digital channels



Patients

- Seek information to increase understanding about their medical conditions, illnesses, treatment options, and medications to be more involved and empowered in managing their medical care
- Results in more patients contacting pharmaceutical MI functions about medicines they have been prescribed or are already taking and to understand product pipelines and early/compassionate use access
- Pharmaceutical MI functions are also obliged to provide a service that
 - offers information that is accurate, factual, based on evidence, fair, balanced, up to date, and non-promotional
 - offers information that does not raise unfounded hopes of successful treatment or be misleading with respect to the safety of the product
 - operates in a professional, ethical, and transparent manner that can ensure the patients' safety and the appropriate, informed, and rational use of the medicines, contributing to the provision of high-quality healthcare

Patient MI Responses

- MI responses for patients should be:
 - limited to on-label information only
 - tailored to the specific request
 - accurate, fact/evidence-based, and non-misleading in content and tone
 - non-promotional, fair balanced, in a format with an appropriate grade of health literacy, written with plain language and adjusted to the level of patient's literacy and understanding
 - not in any way suggest, or be perceived to suggest, any medical, diagnostic or treatment advice, or any recommendation to change the prescribed medicine or treatment course.
- Requests must be handled using professional judgment to use the right sources of information, language and relevant signposting for the specific enquirer and enquiry type.

Internal Stakeholders and Business Partners

- Medical Affairs
- Commercial/Marketing/Sales
- Publication Planning
- Safety
- Quality Assurance
- Business Technology
- Pharmaceutical and Clinical Development
- Manufacturing
- Finance
- Legal
- Regulatory
- Compliance

Facilitated Inquiries

- Medical Information commonly serves as a scientific center of excellence and supports sales and medical with further research relating to unsolicited requests for information received during commercial/medical activities.
- Depending on company policy, responses can either be provided back to internal colleagues for delivery to customers or responded to by the Medical Information function.

Key Challenges in Meeting Customer Expectations

- Awareness
- External competing resources
- Regulations
- Lack of clear guidance and standards

Emerging Collaborations and Partnerships

Cross Industry Collaborations:

- **Facilitating collaboration** between pharmaceutical companies as well as the wider healthcare sector
- Helping **raise standards** in the provision of medical information
- **Simplifying access** to this information through innovative solutions

Innovative Solutions

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The Drug Information Database

Your primary source for current, **evidence-based drug information** to support effective clinical decision making

Search over 3,000 product labels and drug information responses



phactMI is a **non-profit organization** established by Drug Information experts across the pharmaceutical industry. Our goal is to provide healthcare professionals with the most accurate, up-to-date drug information.

[LEARN MORE ABOUT OUR CODE OF PRACTICE >](#)

Advancing access to trusted medicines information

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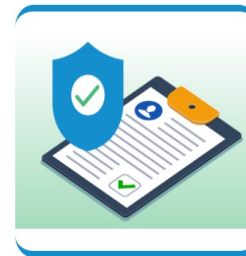
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Current Publications

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Below you can learn about and access the industry papers MILE have developed and published.



Principles for Provision of Medical Information to Patients

In July 2023 MILE's Medical Information (MI) Patients Standards Taskforce developed a set of principles and implementation framework for handling interactions with patients, caregivers, and members of the public related to unsolicited requests for medical information. These principles will provide considerations for pharmaceutical MI functions to define the scope of activity and how to develop responses to unsolicited MI inquiries, in order to better meet the needs of patients, caregivers, and members of the public.

[Access Publication](#)

Collaboration: External, Internal, and Emerging Customers

Insights and Voice of the Customer

Polling Question

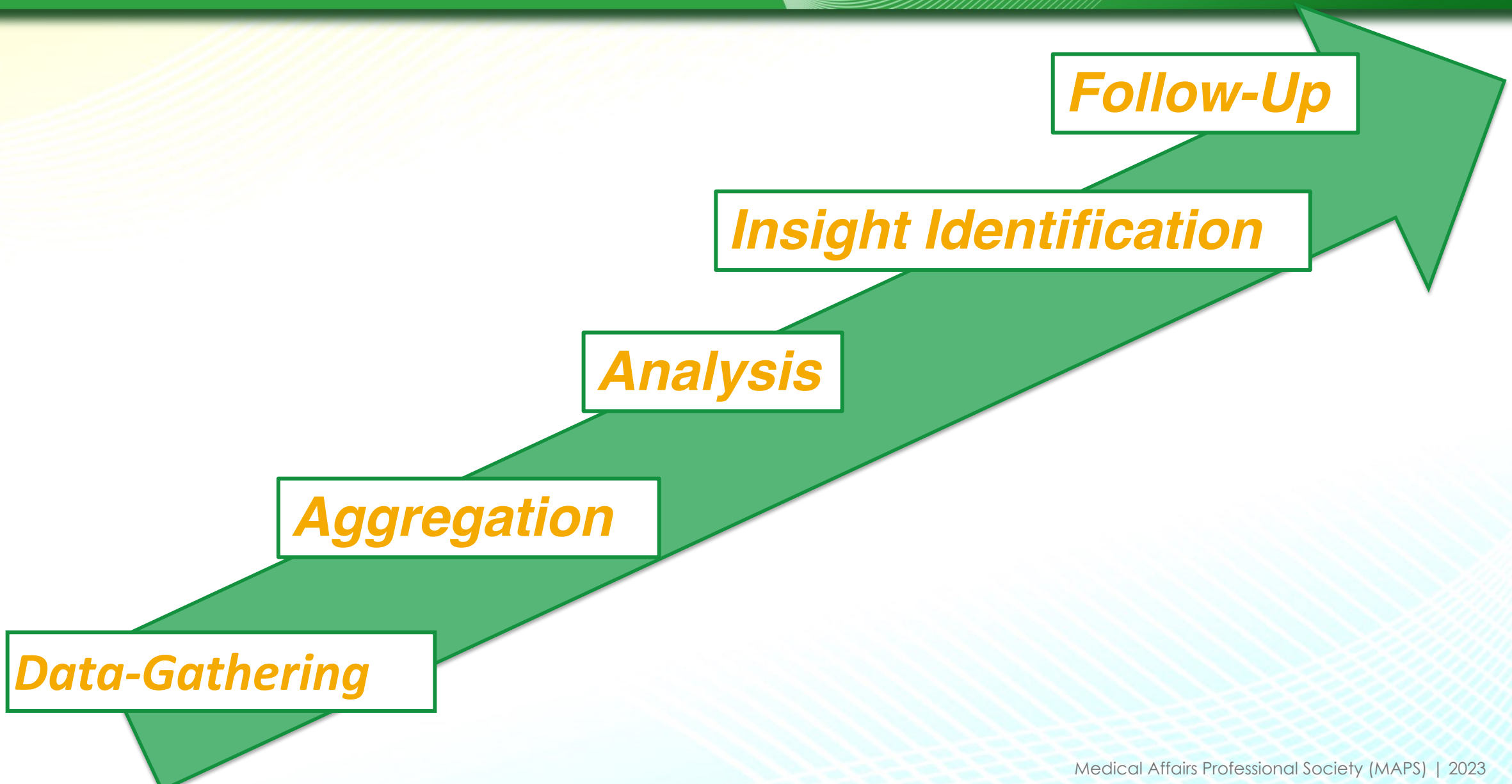
Who do you collaborate with on your insights? (select all that apply)

- Field Medical
- Commercial
- Clinical Development
- Therapeutic Area Medical

Importance of Insights and Medical Information's Role

- Gathering information/data regarding customer inquiries, preferences, and needs is vital
- Information that both informs and is actionable is often referred to as an... **Insight**
- MI can play a strategic role in the gathering, analysis, and distribution of medical insights that helps to shape the medical/commercial strategy, as well as provide meaningful input to the research and development and regulatory strategies
- MI actionable insights are combined with Field Medical Insights capturing a more holistic view of Medical Affairs insights
- Actionable insights define opportunities for functional area tactics by:
 - Defining gaps in data or the communication of that data
 - Enhancing content for both providers and patients
 - Improving access to information that will inform critical decisions and improve patient outcomes

The Steps in Insight Development



Data-Gathering

Aggregation

Analysis

Insight Identification

Follow-Up

Where Do Insights Lead?

Insight

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graph TD; Insight[Insight] --> Left[Can have direct application for MI functions and can lead to information gaps that can be addressed by new or updated MI content (SRDs, FAQs, or patient-specific content)]; Insight --> Center[Could be relevant for wider MA functions including identifying focus areas for MSL or MA materials (e.g., educational gaps regarding the TA and or product, or training/educational materials on how to optimally administer the product or how to optimally use a device). Insights may also spark ideas for new clinical studies or refine the scope or execution of a study already being designed]; Insight --> Right[Can have implications beyond MA (e.g., highlight the need for further stability studies, stimulate market research, shape marketing campaigns)];
```

Can have direct application for MI functions and can lead to information gaps that can be addressed by new or updated MI content (SRDs, FAQs, or patient-specific content)

Could be relevant for wider MA functions including identifying focus areas for MSL or MA materials (e.g., educational gaps regarding the TA and or product, or training/educational materials on how to optimally administer the product or how to optimally use a device).

Insights may also spark ideas for new clinical studies or refine the scope or execution of a study already being designed

Can have implications beyond MA (e.g., highlight the need for further stability studies, stimulate market research, shape marketing campaigns)

And who leads it?

Voice of the Customer

- Keep in mind the voice of the customer
- One of the major sources of insights
- The story is about them

Insights and Voice of the Customer

Innovations and Opportunities in Channels and Content

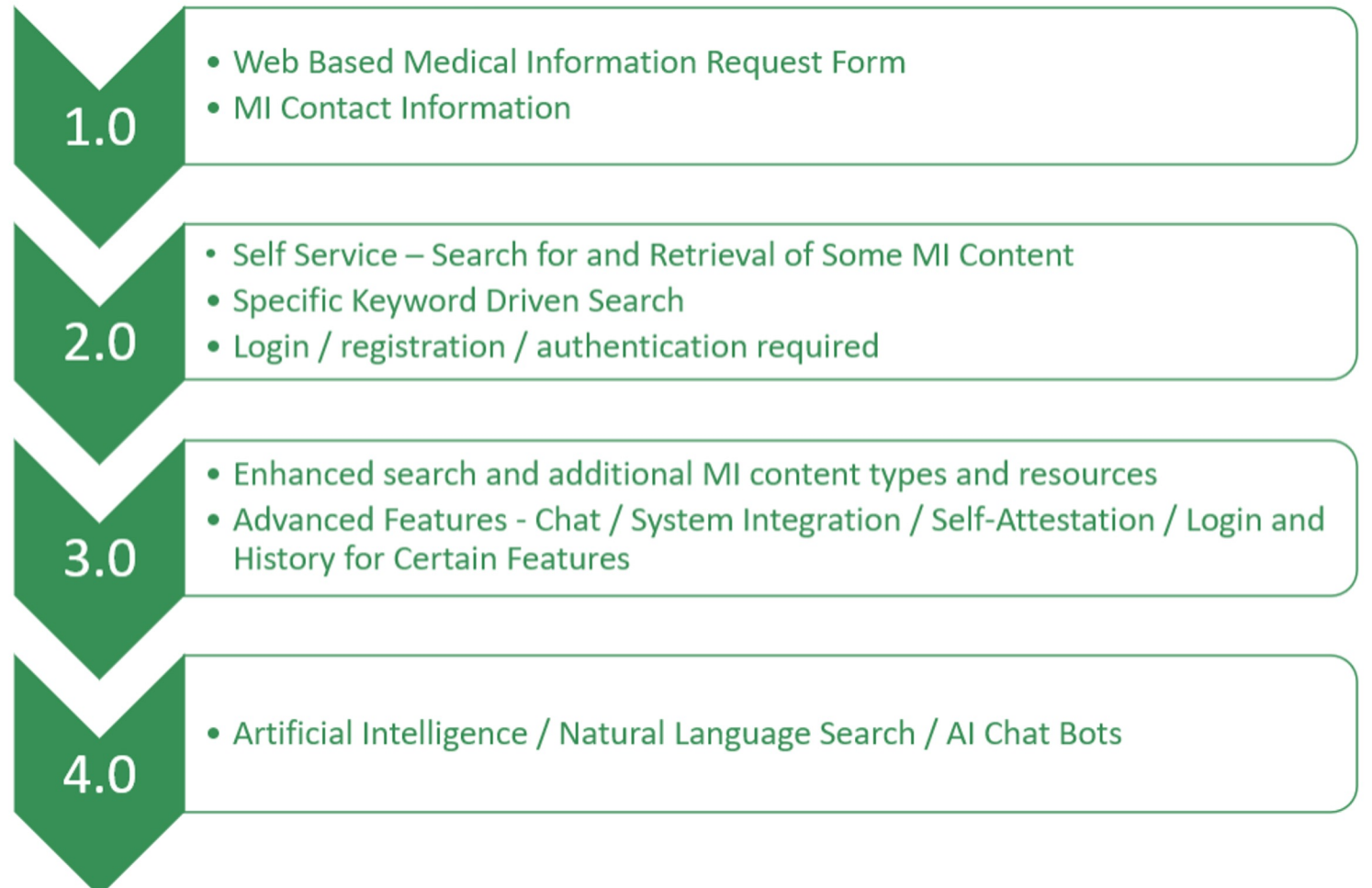
Innovations in Channels

- Multichannel vs. Omnichannel Approach
- Goal of an Omnichannel Customer Engagement Strategy:
 - The right information
 - To the right audience
 - In the right format
 - At the right time
 - Via the right channel
- Opportunities in Digital Channels
 - Chat, AI Driven Chatbot
 - Webforms and MI websites – self-service
 - Video conferencing
 - Instant messaging apps
 - Social media

Self-Service/Web Portals with Chat/Chatbot

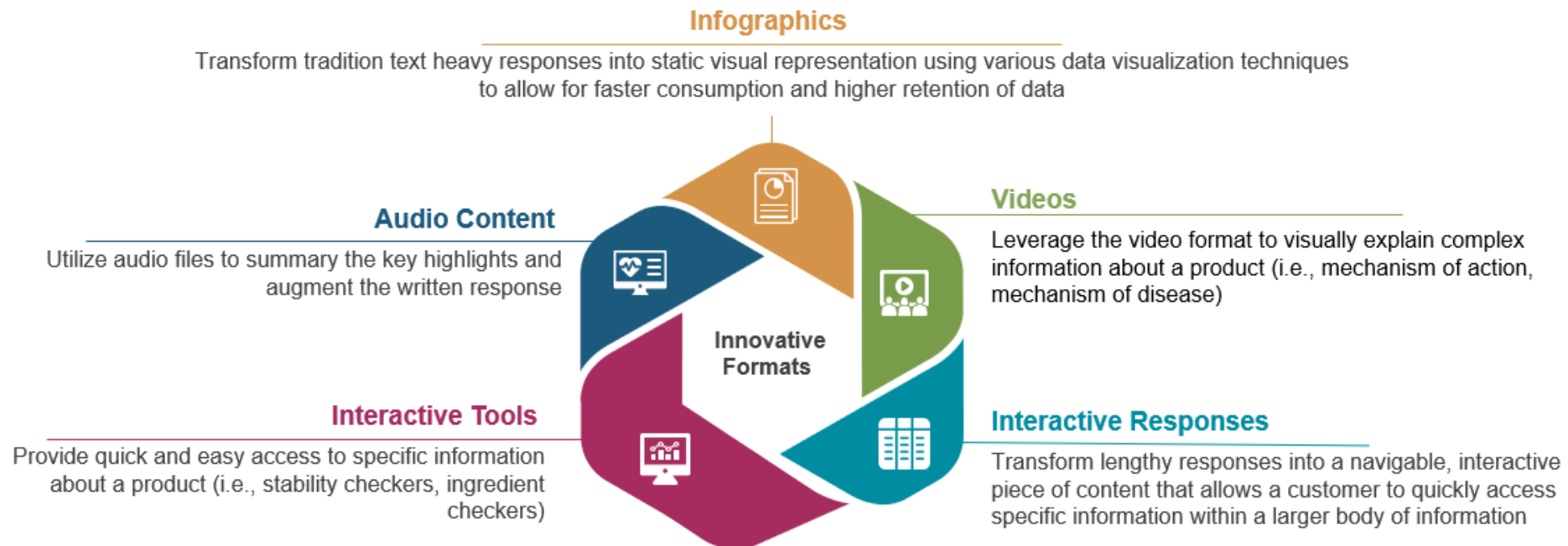
- Web portals provide self-service functionality for HCPs and in some cases the ability to **chat**, interact in real time via **video** or **chatbot**

Evolution of Web Portals



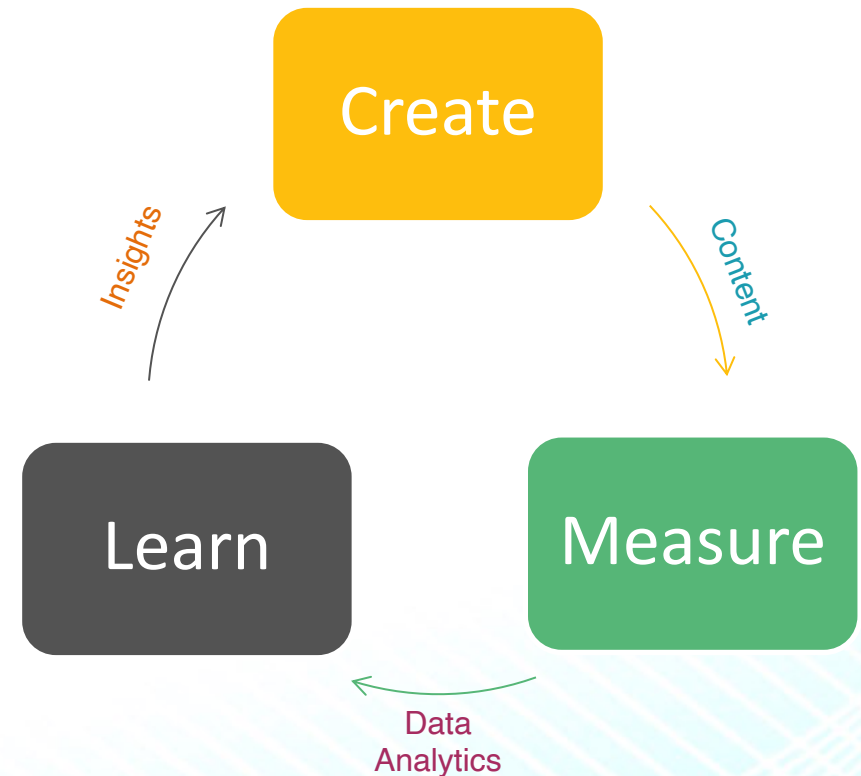
Transformation of Scientific Content

- Understanding of the channels through which content is consumed
- Content personalization - variable content formats to allow for customer preference (infographics, videos, interactive tools/responses, audio....)



Obtaining Customer Feedback to Continually Improve Content

- Scientific content transformation does **not** stop with innovation
- Insights must be generated from content utilization & customer interactions to:
 - Identify unmet customer needs
 - Continually improve content value and impact



Innovations and Opportunities in Channels and Content

Wrap-Up

REMEMBER

- MI Standards and Guidance is a **LIVING** document
 - Share with us what’s missing, changed, or evolving
 - Are there gaps?
- Many ways to use MI Standards and Guidance to help you be a “Best-in-Class” Medical Information organization

For example:

- Creating new MI depts from scratch
- Redesigning MI depts
- Onboarding new employees
-

