A GUIDE TO ESTABLISH MEDICAL INFORMATION

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INTRODUCTIONS

Medical Information (MI) is a critically important customer-facing function that services both internal and external stakeholders, including patients, caregivers, healthcare professionals (HCPs), and payers. MI teams are committed to ensuring the safe and effective use of biopharmaceutical companies' products by providing timely, accurate, scientifically-balanced and evidence-based information in response to unsolicited requests for medical and scientific information.

This guide is focused on providing considerations for emerging biopharmaceutical companies when needing to establish a MI function during both pre-launch and post-launch timeframes. Note: There are many factors that may impact MI function and services, including budget, resourcing model, responsibilities of MI team, potential inquiry volume, Medical Affairs and organization structure, global vs. regional, if the product will be co-promoted or out-licensed in certain regions, etc. All possible scenarios are not covered in this guide but essential considerations that need to be tailored to each company's specific situation are included.

This guide was developed in collaboration with **EVERSANA, phactMI, and MILE.**

EVERSANA

EVERSANA is a leading independent provider of global services to the life sciences industry. The company's integrated solutions are rooted in the patient experience and span all stages of the product life cycle to deliver long-term, sustainable value for patients, prescribers, channel partners and payers. EVERSANA has been providing global Medical Information services and contact center support for 25+ years.
https://www.eversana.com/

phactMI

A 501 (c)(6) corporation, is a collaboration of pharmaceutical company Medical Information leaders that are dedicated to supporting HCPs in their commitment to provide quality patient care. At phactMI, we understand that HCPs have a wide range of medical information needs, and we are supportive of the spectrum of drug information providers.
https://www.phactmi.org/home

MILE

Dedicated to the provision of accessible, accurate and balanced medical information that supports the work of HCPs and the patients they serve. As an industry association, we bring together leaders committed to the creation of innovative medical information solutions that reflect evolving trends in this crucial area of the pharmaceuticals business.
https://www.mile-association.org/

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CONSIDERATIONS OVERVIEW

The Magna Carta for Medical Information has been Graves, et al. 2000 article titled The Core Curriculum for Medical Communications Professionals Practicing in the Pharmaceutical Industry.[1] As the value and impact of MI professionals has expanded so have responsibilities, accountabilities, and areas of support. Cadogan, et al. 2009 article titled *The Changing Roles of Medical Communications Professionals: Evolution of the Core Curriculum, described this development.*[2] More recent publications have demonstrated the expanding role of MI, including DeLuca, et al. 2025 article, titled ***Benchmarking Medical Information Services Beyond the Unsolicited Requests: A phactMI Benchmarking Survey.***[4]

- MI Team Responsibilities
- Organizational Structure
- Globalization



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MI Team Responsibilities

MI Primary Responsibility

Provide responses to ***unsolicited*** requests for medical information that meet the following criteria:

- Scientific in nature (scientifically balanced)
- Truthful, non-misleading, accurate, and non-promotional
- Consistent with guidelines and industry best practices
- Tailored to answer only the specific question(s) asked



Exit

MI Core Areas of Support

- **Responding to Unsolicited Requests for MI**
  - **MI Contact Center (MICC) oversight, management, training, and operational support.**
  - **Processes for handling escalations**
  - **Oversight of operations and systems: MI database; Congress tools; etc.**
- **MI Response Document Development and Management**
  - **Scientific Response Documents (SRDs):** Company approved evidence based, truthful, accurate, scientifically balanced, non promotional, and non misleading written responses to anticipated unsolicited inquiries for specific information for HCPs.
  - **Frequently Asked Questions (FAQs):** Company approved evidence based, truthful, accurate, balanced, non-promotional, and non-misleading verbal responses to anticipated unsolicited inquiries for specific information. These are typically used as the Contact Center call scripts but may also be leveraged by Medical Scientific Liaisons (MSLs) and other members of Medical Affairs.

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MI Core Areas of Support (cont.)

- **Patient Response Documents (PRDs):** Company approved evidence based, truthful, accurate, scientifically balanced, non promotional, and non misleading written responses to anticipated unsolicited inquiries for specific information for patients and caregivers.
- **Custom Response Documents (CRDs):** Written response documents narrowly tailored, evidence based, truthful, accurate, scientifically balanced, non promotional, and non misleading to address specific unsolicited requests for medical information when an SRD does not exist.
- **Cover Letters, Email Templates, etc.:** Additional materials included as part of a written response package.

Adverse Event (AE) and Product Complaint (PC) Support

- **MICC is typically responsible for identification, intake, and handling of AE and PC reports**
- **It is important to collaborate with Pharmacovigilance (PV) and Quality to develop the process, procedures, and training for the handling of AE and PC reports**
- **The phone number that appears within the labelling (e.g. Package Insert) typically goes to the MICC**

To report SUSPECTED ADVERSE REACTIONS, contact COMPANY at 1-888-777-XXXX or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

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MI Core Areas of Support (cont.)

- **Metric and Insight Generation**
  - It is important for the MI team to establish core operational metrics, key performance measures (KPI), and service level agreements (SLAs)
  - Operational metrics are important for measuring performance, budget management and planning, resource management and planning
  - Other metrics like insight generation and measures are important to demonstrate the value and impact of MI

> An insight is the deeper understanding of the why behind trends of information that lead us to determine if an action is warranted.[3]

Exit

MI Core Areas of Support (cont.)

- **Medical Congress Support**
  - Ensure appropriate resources and materials are available for the MI booth
  - Staff, capture, document, and respond to unsolicited requests received in the MI booth
  - Fulfill written MI requests and triage other inquiries accordingly
  - Handle reporting of any AE or PC received
  - Generate post–congress report

MI Team Possible Additional Responsibilities

MI teams typically have a strategic role that extends beyond inquiry management and operational support.

The responsibilities typically vary and often include the following:

- **Oversight and management of digital channels, like the Medical Portal**
- **Development of Academy of Managed Care Pharmacy (AMCP) Dossier and paper materials**
- **Drug Compendia and Guideline / Pathway submission, review, monitoring**

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MI Team Possible Additional Responsibilities

- **Addressing and correcting misinformation**
- **Support Medical, Legal, Regulatory Review Committee process**
  - **Function as Medical Reviewer for review and approval of promotional, non-promotional, and medical affairs materials**
  - **Establish and manage Medical Materials review and approval processes**
- **Development and maintenance of MSL slide decks and management of the Medical Affairs slide library**
- **Establishment and oversight of company virtual library and medical resources**
- **Literature surveillance and literature alerts for Medical Affairs strategy and competitive intelligence**
- **Support and lead Medical Affairs training**
- **Support the development of Publications**

In 2023 phactMI distributed a survey to member companies to gather additional MI team responsibilities and the results were published in 2025 in the article by DeLuca, et al., titled Benchmarking Medical Information Services Beyond the Unsolicited Requests: A phactMI Benchmarking Survey. [4]

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Organization Structure

- Organizational structures and strategies for Medical Affairs, and MI specifically, vary across companies. In most cases, MI sits within the broader Medical Affairs function, though it may also operate as a standalone group or be embedded within Medical Communications or Medical Affairs Operations and Excellence. A company's overall strategy and level of investment in resources significantly influence how MI is structured and how its operations are delivered. This includes decisions around the use of third-party vendors and service models versus building internal capabilities with dedicated full-time staff. Additionally, the defined roles, responsibilities, and accountabilities of MI personnel play a key role in shaping this operating model.
- Understanding a company's strategy will be critical in budget planning / management, resource planning, and vendor evaluation / selection / management.
- phactMI has conducted benchmarking surveys regarding MI team structures and is refreshing this research in 2026.[5]

Marasigan, K., Doshi, S. & Fung, S. Pharma Collaboration for Transparent Medical Information (phactMI™) Benchmark Study: Results of Organizational Structure and Resourcing of Medical Information Services in Support of Building Departmental Strategies. *Ther Innov Regul Sci* 54, 1269–1274 (2020). https://doi.org/10.1007/s43441-020-00143-1

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Organization Structure (cont.)

- In the publication DeLuca et al., 2025 there is an example of a full-time employee resource benchmarking model based on the various responsibilities an MI professional may have.[4] It is not uncommon for an emerging biopharmaceutical company to only have one dedicated MI team member (Director, Sr. Director, Executive Director of Medical Information) having the accountability of establishing and managing all aspects of the function plus also having additional responsibilities as described above. This requires the MI professional to have advanced project and time management skills, a drive for operational excellence, strong vendor evaluation and management skills, the ability to prioritize, and be results-driven. The organizational structure and number of internal MI full time employees (FTEs) will drive dependency on vendors, the need to leverage contractors / consultants, and the impact, timing, and planning of various MI initiatives.

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Globalization

- When an MI function is first established, the focus is typically on one country or region. Often the initial focus is on the United States since regulatory approval and commercialization usually happens first within the US. However, due to harmonization of regulatory filings and the electronic common technical document, it is common for other global regulatory agencies to receive new drug / biologic application filing simultaneously or shortly after US FDA filing.

EMA: European Medicine Agency Health Canada Swissmedic
TGA: Therapeutic Goods Administration (Australia)
PMDA: Pharmaceutical and Medical Devices Agency (Japan)

- It is important to understand the company's strategy for commercialization and global distribution. This can impact decision-making when selecting an MI Database, MICC service provider, approach to content development and need for Global Response Documents (GRDs), etc. The company's goal may be to commercialize globally on its own, out-license the product to another company, or establish a co-promote agreement. These strategies can impact MI operations, workflows, and processes.

Exit

Globalization (cont.)

- Globalization standards are important to ensure consistent, compliant, scientifically accurate information to HCPs, patients, and internal stakeholders across multiple countries, languages, and regulatory environments. The benefits of globalization standards include consistency, speed, efficiency, better metrics / KPIs / insights, regulatory compliance, and improved customer experience. However, challenges persist. Ensuring consistent content and messaging can be difficult when product labeling, approved indications, and even product names vary across countries. In addition, local language requirements, data privacy considerations, and other country-specific laws and regulations can further influence MI practices.
- Content development and management is one of the key considerations in globalization. An article published in 2026 by Wnorowski et al, presents consensus-based best practices for creating, maintaining, and localizing GRDs.[7]

Wnorowski, S., Niemoller, F., Glaetzer, A. et al. Best Practices for Medical Information Global Response Documents from phactMI and MILE. Pharm Med (2026). https://doi.org/10.1007/s40290-025-00598-3

Exit

Globalization (cont.)

Some of the key takeaways include the following:

- Focus on a single topic (or tightly related topics) to simplify localization.
- Develop GRDs in a label-agnostic manner so they can be used globally.
- Local teams base SRDs on GRDs, swapping in local label info as needed.
- Use the best available scientific evidence, starting with peer-reviewed literature plus data-on-file (DOF).
- Start GRD development 12–15 months pre-launch using anticipated FAQs.
- Localization requires adding local labels, disclaimers, and local studies, including translations.
- Local review is needed for new localized responses, unless only labels/disclaimers have changed.
- Collect structured feedback regularly from affiliates and incorporate improvements.
- Maintain internal guidelines for authoring, reviewing, formatting, and style.
- Peer-review GRDs whenever new data is added (internal or external if needed).

TIMELINES

The amount of time to establish an MI function from the ground up can vary greatly. Ideally starting 18 to 24 months before regulatory approval and commercialization of a new product is recommended. However, based on the company and when the MI Lead is hired, the timeframe may be cut to as short as 6 months, provided there is sustained focus and dedicated effort. Regardless of the time allotted, the key is to establish a project plan and work backward from your MICC go-live date. Most emerging biopharmaceutical companies want to have MICC go-live at or by the regulatory approval date. For example, for the US this would be the PDUFA (Prescription Drug User Fee Act) date. It is important to note that some products may not be commercialized and in the market until several months after the regulatory approval date. There may also be a need to go-live with the MICC and have MI operations established long before the regulatory approval date. Drivers for this can include: 1) clinical trial recruitment and the need to have the contact center support this activity; 2) the timeframe for when MSL and sales representatives will be in the field; and 3) data release, publication and medical congress plans.

Some considerations that are going to impact timelines are the following:



An illustrative outline of some of the core activities for MI to focus on during establishing MI operations for launch preparation is available on the next page. Open Illustration

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TIMELINES (cont.)

MI Database

- Internal vs. leverage MICC
- Establishing one country / region vs. globally
- Validation. Validation can add 3 to 6 months to any database project.
- Need for customization vs. configuration
- Other systems and databases currently being used in the ecosystem: AEs, PCs, MSL CRM, Sales Rep CRM, System for Review and Approval of Materials. Will systems be integrated?

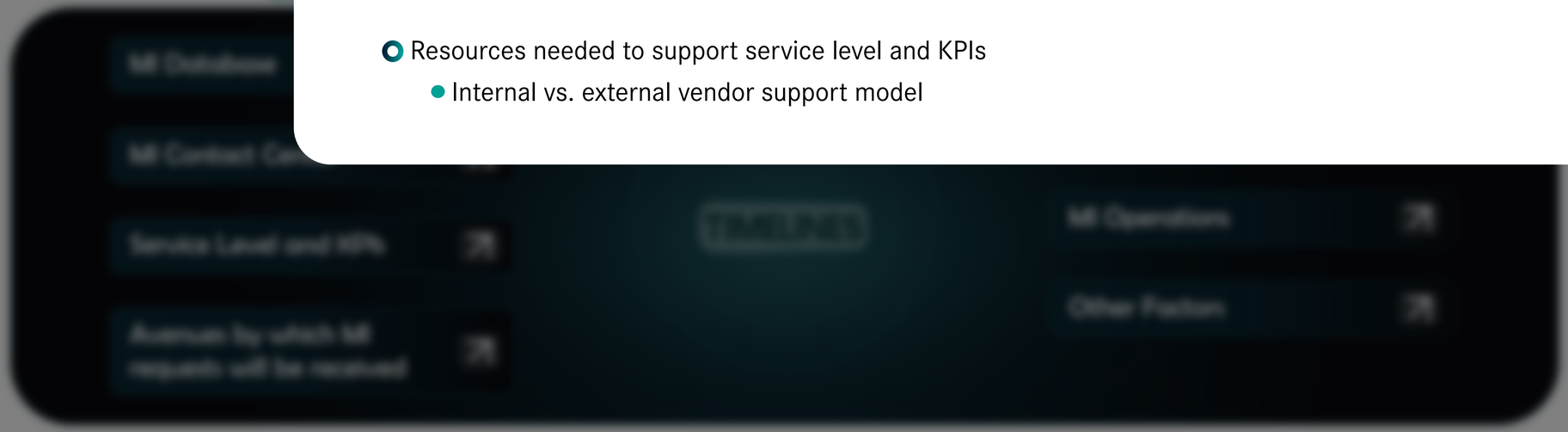
TIMELINES (cont.)

MI Contact Center

- What will be the model and approach?
  - Dedicated service model, shared service model, or hybrid service model
  - Global vs. regional vs. US only
  - What is the contact center vendor’s timeline for establishing MICC operations for a new client? Often varies from 8 to 16 weeks based on complexity.
- What activities need to be performed and managed by a third-party contact center vs. handled by internal staff?
- Anticipated inquiry volume
- Will the contact center also support AE and PC intake and triage?
- Are there other activities which the contact center will be required to support?

TIMELINES

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An illustrative outline of some of the core activities for MI to focus on during establishing MI operations for launch preparation is available on the next page.

TIMELINES (cont.)

Service Level and KPIs

- Resources needed to support service level and KPIs
  - Internal vs. external vendor support model

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TIMELINES (cont.)

Avenues by which MI requests will be received

- Phone Number / toll-free number; phone tree / Interactive Voice Response (IVR); will the toll-free number be utilized by other departments; what other contact centers might the company be utilizing (e.g. Patient Services / Hub Services: Co-Pay Card; Customer Support; Patient Assistance; Specialty Pharmacy; etc.)
  - Will the toll-free number and corporate IVR be established internally vs. leveraging 3rd party contact center to support?
  - Which other contact centers will be established and when will they go live?
- Triage from MSLs; which CRM system will be used (e.g., Salesforce / Veeva)?
- Triage from Sales Reps; which CRM system will be used (e.g. Salesforce / Veeva)?
- Web Request Form on Corporate Website and/or Branded and/or Disease Websites
- Email Address
- HCP Self-service portal
- Non-HCP Self-service portal
- Chat: Live chat; Chat Bot; Video Chat; Voicebot
- Social media

TIMELINES

TIMELINES (cont.)

MI Content Development

- Pre-approval and post-approval materials
- Content for HCPs, patients / caregivers / consumers, payers
- Global vs. regional vs. US Only. If global, approach to localization and translation.
- Content for various channels, contact center FAQs, written response documents for email and medical portal; scripts and answers for live chat, chatbot, voicebot
- Will modular, interactive, or traditional styled content be developed?
- More details are provided in section on Content Development. Open CDM section

TIMELINES (cont.)

MI Operations

- Establishing Standard Operating Procedures (SOP)
  - Common ones often include
    - Handling of Unsolicited Requests for MI
    - MI Content Development & Management
    - Medical Booth Staffing
- Training
  - Internal training of MSLs, sales reps, other contact center regarding procedures for handling unsolicited requests for MI. Also handling of AEs and PCs.
  - Training of contact center on applicable company SOPs, therapeutic areas, products

TIMELINES (cont.)

Other Factors

- MI staff are often responsible for other activities beyond handling unsolicited requests. This can include the following:
  - Drug Compendia Submission
  - AMCP Dossier Development
  - Medical, Legal, Regulatory Review Committee Support
    - Medical Reviewer on Promotional Review Committee (PRC)
    - Establishing and managing Medical, Legal Regulatory (MLR) review process for Medical Affairs, Medical Review Committee (MRC)

An illustrative outline of some of the core activities for MI to focus on during establishing MI operations for launch preparation is available on the next page. Open Illustration

PRE-LAUNCH (~12-18 months prior to approval)

LAUNCH

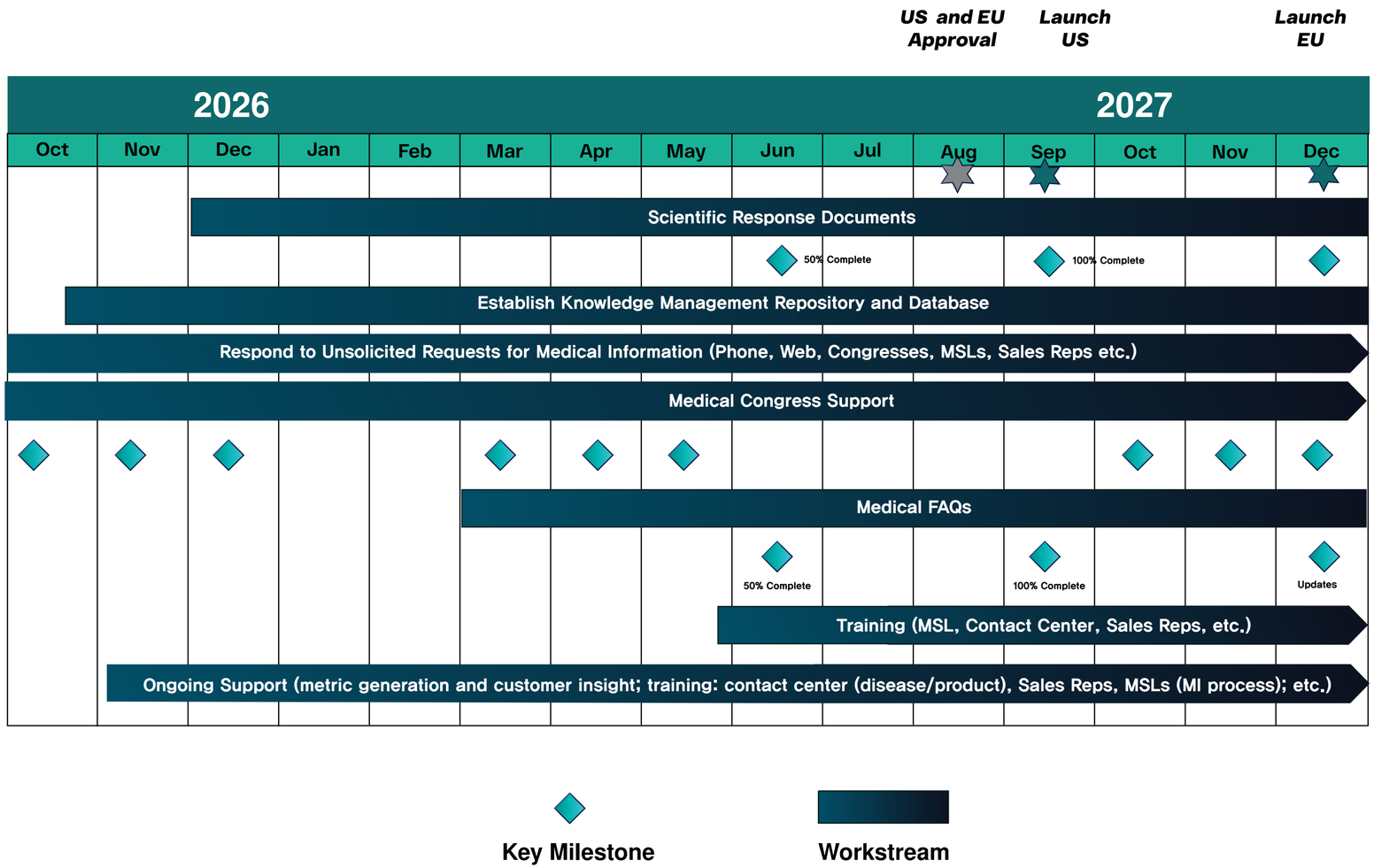


- Understand disease, unmet medical needs, place in therapy, market & competitor landscape
- Conduct a comprehensive bibliographic literature search and retrieve relevant publications on product information, disease, standards of care, treatment guidelines, competitors, etc.
- Establish search strategy/keywords for literature alerts and disseminate newly published article citations of interest to internal stakeholders
- Establish knowledge management repository for electronic files
- Assemble BLA/NDA documents (e.g., draft label(s), ISE, ISS, CSRs), abstracts, posters and publications into a comprehensive and relational data tracking file
- Integrate MI objectives and launch tactics into Medical and Commercial launch plans
- In collaboration with Medical Directors, Sci Comm & Commercial, identify key congresses requiring MI support and develop booth content; booth coverage schedule coordinating with MSLs; develop pre-con training deck; establish lead capture system; staff booth; capture and process leads
- Ensure access to scientific platform, publication plan and strategy. Important to know timing of manuscripts, abstracts, posters, oral presentations, etc.
- Ensure access to Clinical Development plan and timeline for any ongoing or planned studies; also, Medical Affairs life-cycle management plan

- Develop initial set of FAQs to address filing status and availability
- Identify a list of HCP Scientific Response Documents (SRDs) and corresponding FAQs in the following categories: disease, efficacy, safety, long-term use, comparative data, coadministration with other medications, dosing & administration, pharmacology (PK/PD), special patient populations, storage, stability & compatibility, etc.
- Develop a project plan and assign a priority ranking for the development of each SRD
- Review clinical data from available resources (eCTD: regulatory submission (e.g. BLA/NDA; published medical literature) and summarize into appropriate SRDs and FAQs
- Develop FAQs for non-HCPs (consumers/patients). Determine need for non-HCP SRDs.
- Establish process for review and approval of MI resources and obtain cross-functional review committee approval for all documents sanctioned for pre-approval use
- Establish workflow and database configuration for inquiry handling (phone, email, web, tablet, MIRF)
- Establish contact center support process, triage guidelines, etc.
- Document, process, and address unsolicited requests for information
- Develop metric and customer insight reports; make sure database is configured with new product info
- Establish Open Payment reporting process with compliance if not already established
- Establish process for journal article ordering and obtaining copyright permissions
- Determine need for AMCP Dossier (pre-approval and post-approval versions) and other payer materials and response documents

- Train sales force, field medical, etc. on unsolicited request handling and triage process
- Update all response documents to reflect regulatory approved labeling (e.g. USPI, SmPC)
- Obtain review committee approval of updated response documents
- Upload approved response documents into MI database and other applicable data repositories, etc.
- Train MICC on disease-state, treatment guidelines, product information/labeling, competitive landscape and approved MI response documents
- Send Package Insert to publishers of compendia (AHFS, ePocrates, Medscape, First Databank, Lexi-Comp, Up-to-Date, Medical Letter, Micromedex, etc.)
- Respond to all incoming unsolicited requests
- Update resources based on new data and publications and obtain review and approval of documents
- Track departmental metrics related to inquiry volume, processing times and workload
- Track volume of and trends within commercial-facilitated medical inquiries (monitor for compliance with policies and SOPs)
- Disseminate metric and customer insight reports to internal stakeholders
- Staff MI Booth at designated Congresses
- Monitor treatment guidelines, disease-state literature, and product-specific data presentations/publications and update MI response documents accordingly (at least annually)

Illustrative Timeline



COLLABORATION

Coordination and collaboration are essential for effectively establishing MI operations. Below are just some of the functions that require consulting and collaborating with.

FUNCTION	SUPPORT
Procurement	Assist with running request for information (RFIs) and request for proposals (RFPs)
IT	Evaluation of technology and systems, including IT Security Questionnaires and assessment
Quality	Leading Vendor Qualification Audits. Also input into processes for Product Complaint (PC) handling and assessment of MI Contact Center for ability to support PC handling
Pharmacovigilance	Guidance on post-marketing handling of Adverse Events (AEs) and assessment of MI Contact Center for ability to support AE handling. PV requirements for handling AEs can impact MI Contact Center operations, for example is AE turnaround time 24-hrs or within 1 business day.

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COLLABORATION

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FUNCTION	SUPPORT
Legal / Compliance / Data Privacy	Support to establish Master Service Agreement (MSA) and Statements of Work (SOWs). Plus, guidance on data privacy handling, including establishing Data Processing Agreement (DPA).
Commercial	It is important to understand the timing of the product launch and commercialization efforts as this will impact inquiry volume. Important items to consider include are there going to be Patient Services / Hub Services, Specialty Pharmacy, and other types of support like Co-pay cards, etc.
Medical Communications / Medical Strategy & Directors / Field Medical	MI should have access to the Scientific Platform, Integrated Medical Communication Plan, Strategy Publication Plan, Congress Plan, Medical Plan, etc. MI should also contribute to development of these plans.

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CONTACT CENTER SERVICES

One of the most important decisions in building out MI operations is selecting an MICC partner. The MICC staff is often going to be front line and customer facing across all channels established by MI. Finding a strategic and collaborative MICC partner is critically important.

In 2021 EVERSANA and phactMI conducted a survey to assess current trends and areas of consideration when selecting and partnering with a global MICC service provider. The results of this survey were presented at DIA Medical Affairs and Scientific Forum in March 2022. One question focused on which features were most important when considering and evaluating a MICC service provider. Listed below are the survey responses for the most important features in rank order:

- Robust quality monitoring and quality assurance program
- Robust training and development plan for MI staff
- Advanced data analytics, metrics, and customer insight reporting tools
- Advanced telephony system(s)
- Customer Satisfaction Surveys (e.g., post call and electronic)
- Staffed by pharmacists
- Customizable and flexible staffing models (shared, fully dedicated, and hybrid staffing models)
- Ability to integrate MI database with other client systems (e.g., Veeva Vault, Veeva CRM, ArisGlobal, Argus, Salesforce, etc.)
- Global Service Provider (hubs in US, EU, JAPAC, etc.)
- US based contact center agents handling US calls and inquiries
- Staffed by nurses
- Live chat capabilities
- Ability to offer integrated PV services related to post-marketing AE reporting
- Ability to offer tiered staffing model (Tier 1: frontline allied health or life science professional; Tier 2: escalation to HCPs)
- Ability to offer integrated patient services contact center
- Staffed by other healthcare, allied health, or life science professionals
- Ability to develop and provide a MI self-service web portal

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CONTACT CENTER SERVICES

- Ability to develop innovative content for response documents (e.g., infographics; video; recorded presentations; etc.)
- Writing service for SRDs, FAQs, CRDs
- Ability to develop global value dossiers and AMCP dossiers
- Ability to support and staff MI exhibit booths at Medical Congresses
- Ability to develop and provide MI services training for field teams (sales reps, MSL, HEOR, liaison, etc.)

Other considerations also often include

- Years of experience
- Global leadership team
- Company and leadership team involvement in MI and Medical Affairs professional community (DIA, MAPS, PIPA, phactMI, MILE, etc.) and staffing knowledgeable of industry trends, best practices, and global regulatory requirements
- Attrition and staff turnover rates and staff tenure
- Employment of FTEs vs. Contractors or Sub-Contractors
- Telephony / CCaaS platform
- MI Database utilized
- Ability to offer other services such as other Medical Affairs services / PV / Quality / Regulatory / Commercial / Market Access
- Scalability, flexibility, customizability
- Cost structure and ability to offer different staffing options and staff structures
- Technology / Innovation / Digital focus
- Ability to demonstrate both value and quality
- Ability to offer a true end-to-end MI solution
- Audit and Inspection Readiness
- Timelines for implementation (often can range from 10 to 20 weeks depending on complexity and requirements)
- Language capabilities

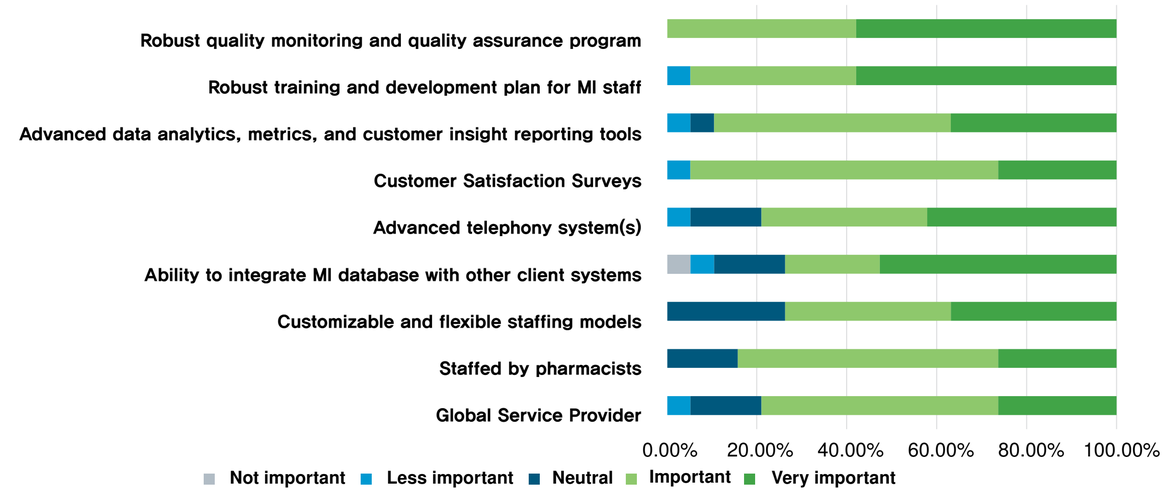
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CONTACT CENTER SERVICES

Often when evaluating MICC, a RFI or RFP that includes a comprehensive list of questions should be submitted to several different MICC providers to evaluate services and capabilities. Once a preferred vendor is selected, a vendor qualification audit or vendor qualification questionnaire should be completed.

Figure. Most valued criteria for evaluating MICC service providers[8]



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CONTACT CENTER SERVICES

There are numerous MICC service providers. Some are global, regional, local only so it is important to understand the locations of the staff and the actual countries and regions the MICC supports.

Table. MICC Vendors*

MICC Vendors
4C Pharma Solutions
Alphanumeric
C3i Solutions
Cactus
EVERSANA
Indegene
Inizio
IQVIA
Med Communications
Medical Vigilance Solutions
Oriola
PPD (Thermo Fisher Scientific)
PrimeVigilance
ProPharma
Rocky Mountain Poison & Drug Safety
The Medical Affairs Company (TMAC)
Uniphar

*Note: List might not be all inclusive. Regional and country specific contact centers also exist.

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CRM/ MI DATABASE

CUSTOMER RELATIONSHIP MANAGEMENT (CRM) / MI DATABASE (SYSTEM)

Making a decision on an MI Database includes multiple factors. First, determine if the plan is to bring a database "in-house" or if the plan is to leverage the database provided by the contact center.

ADVANTAGES

- Your company chooses the system
- Complete control of configuration and any customizations
- Own who has access internally and externally
- Easier to switch contact center providers
- Complete ownership of the data

DISADVANTAGES

- Responsible for managing system issues and downtime
- Responsible for managing user access and permissions
- Responsible for validating and maintaining validation
- Responsible for evaluating new releases, implementing and validating new releases
- Longer time to implement and validate
- High cost to implement and maintain
- Need internal IT support and resource support to maintain
- Responsible for building and providing training both internally and externally

Often it will be more cost effective and quicker to implement leveraging the MICC database. This includes more operational efficiency for the Contact Center since their staff are already trained on the MI Database and are leveraging it for multiple clients. The Contact Center might also have Computer Telephony Integration (CTI) with their contact center as a Service (CCaaS).

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CRM/ MI DATABASE

When making a decision about the database, it is important to align with the contact center evaluation. If the decision is to the leverage the vendor MICC database, it will be important to know the following:

- Is the contact center open to working in your database
- Is there a cost associated with working in the client's own database?
- Does the contact center have experience working in the database of choice?
- How many user licenses will the contact center need?
- Will the contact center partner with you on determining the configuration and testing the system? This is often critical because the contact center agents will often be primary users and not internal staff.
- What type of training requirements will be needed for training the contact center staff?

If the decision is to use the contact center's database there are also questions and considerations, including the following::

- What is the database that is being utilized?
- How long has the contact center been using that system?
- Is the system validated?
- Does the system have global capabilities?
- Does the system allow for client specific configuration and / or customization?
- Can the client have access to the database?
- Can the contact center database be integrated with the client's other systems?
  - Field CRM (e.g., Salesforce, Veeva Vault)
  - Content Management System (e.g., Veeva Vault PromoMats or MedComms)
  - Safety Database via E2B Integration (e.g., Argus, ArisGlobal, Veeva Safety)
  - Quality Database (e.g., Trackwise, Mastercontrol)
- Can the contact center database provide periodic data export into the client's Central Data Warehouse / Data Lake?
- Does the system have standard metric reporting and ability to build custom reports?

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CRM/ MI DATABASE

- Does the contact center offer an advanced data analytics dashboard solution?
- Does the contact center have its own Business Transformation / IT team that supports and manages the database or is the contact center dependent on the database provider?
- Is the database integrated with the CCaaS system?

There are a limited number of MI Database solutions on the market today:

- IRMS MAX from Anju
- Veeva MedInquiry
- Mavens Medical Information Cloud
- SciMax MI from SciMax Global
- Nexentria
- ArisGlobal LifeSphere Medical Information
- Salesforce (customized for MI)

When conducting a database evaluation there are several factors to consider, including the following:

- Inquiry capture from various channels (phone, email, web, chat, CRM, etc.)
- Global Inbox or does the system need to be integrated with email system like Outlook?
- Response Generation
  - How are response packages managed and put together with in the system?
- Content Management
  - Within system
  - Ability to integrate with another CMS
- Configurable vs. Customizable
- Ability to Integrate with Other Systems
  - Open APIs
  - XML
  - E2B

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CRM/ MI DATABASE

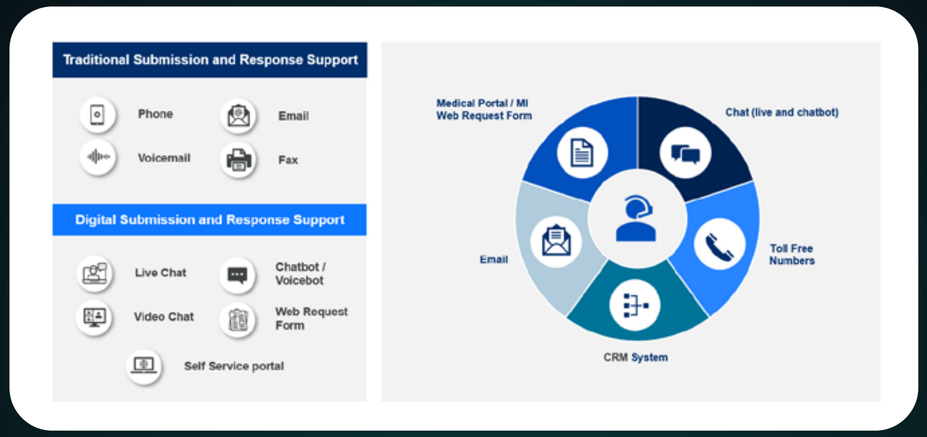
- Reporting and Metric Capabilities
  - Within system
  - Ability to export to Central Data Warehouse / Data Lake
  - Ease of use with other analytic platforms, e.g., Qlik, Spotfire, Tableau, PowerBI
- Data Privacy / Protection / Retention
  - How configurable?
- Customer Support Model
- Validation Support
- Enhancements / Releases / Roadmap
  - Number of releases each year
  - How easy it is to upgrade to latest version and associated costs?
  - Support model for upgrade
- Cost Model
  - Configuration / customization / implementation cost
  - License Cost
  - Support Cost
  - Validation Cost
  - Integration Cost
  - Upgrade Cost
  - Other Cost

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TECHNOLOGY / CHANNELS

When making a decision about the database, it is important to align with the contact center evaluation. If the decision is to own and bring the database in-house, it will be important to know the following:



Determining the channels and their respective implementation timelines will be an important consideration and may impact MI Database and MICC decisions.

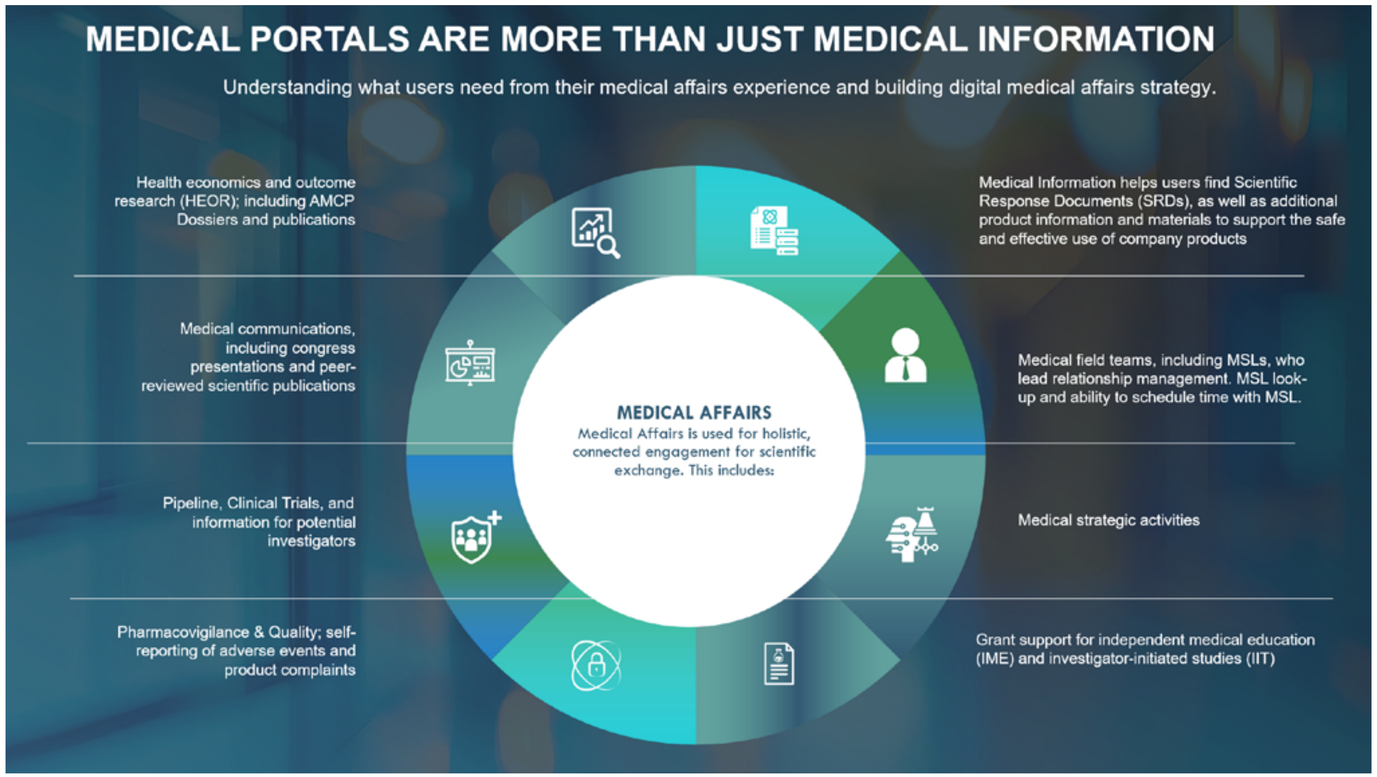
Having either a multichannel or omnichannel approach will also impact the content development strategy and tactics. Having content that is digital-friendly and appropriate for self-service channels such as medical portals, chatbot, voicebot, and even live chat is different than just FAQs for MICC and SRDs to send via email.

An important component of a Medical Affairs omnichannel approach is establishing a Medical Portal. Different options available for Medical Portals include fully customizable solutions, as well as, configurable solutions that can increase speed to implementation and reduce cost. Additionally, Medical Portals are more than just MI and require cross functional collaboration from Medical Affairs. There are also several functional considerations to be taken into account.

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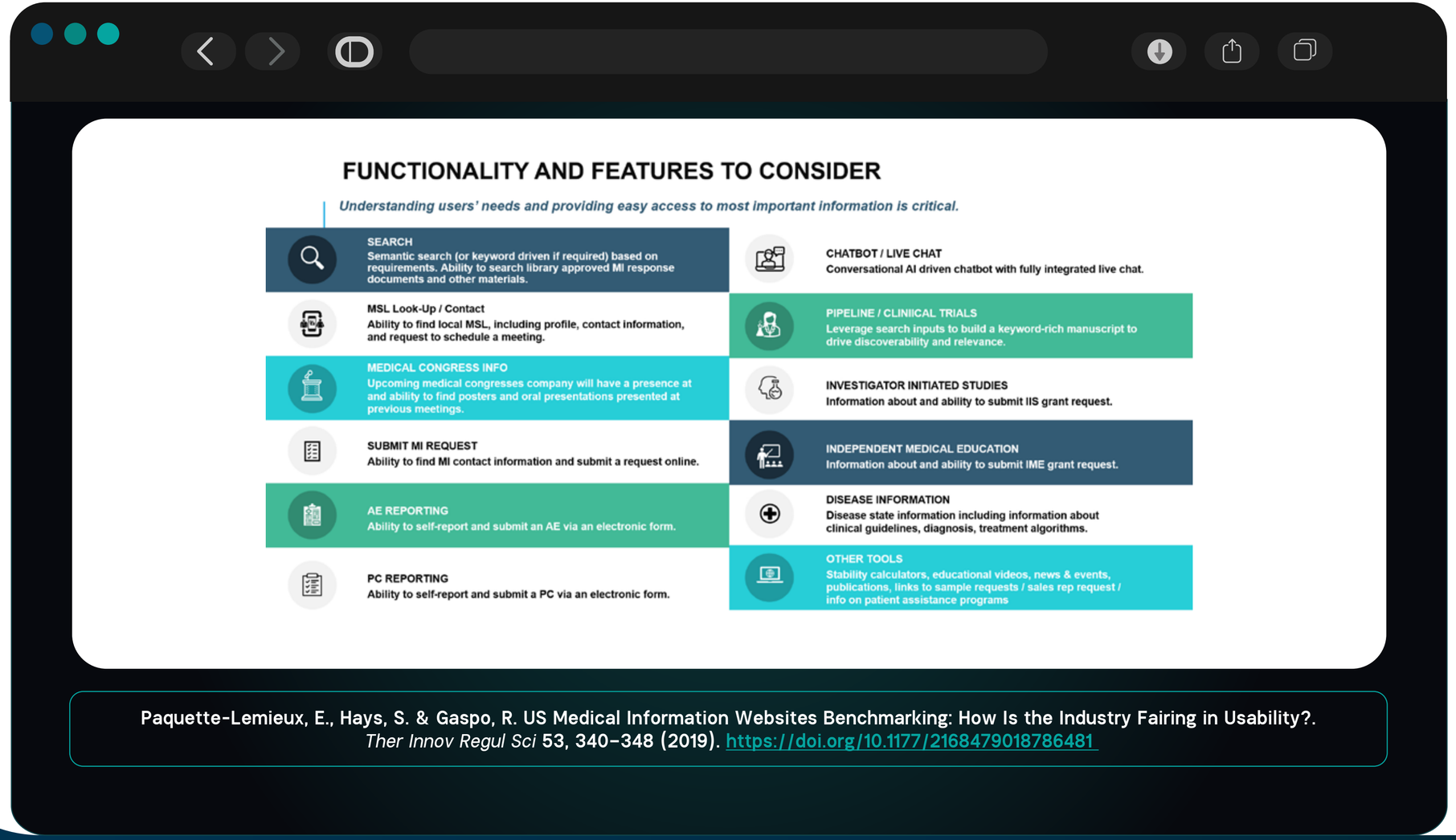
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CONTENT DEVELOPMENT AND MANAGEMENT

MI content development strategy is an important component of establishing the MI function. Core content includes developing SRDs and FAQs. Often a set of FAQs is developed for answering HCP questions, and another set is developed for answering patient / caregiver / consumer questions. Even though these are core materials, companies need to also consider the need for GRDs, which was touched on earlier in the Globalization section, PRDs, and an efficient process for CRDs. Additionally, there are accompanying documents such as cover letters, email templates, customer satisfaction surveys, etc. that also need to be developed and maintained.

How the content is developed, formatted, and accessed also needs to be determined. For example, if SRDs will be available for self-service on medical portals or chatbots, developing them in a more interactive and digital friendly format will be important. Also, will the FAQs only be utilized by the contact center or will the FAQs also be used by MSLs or at medical booths at congresses? If so, developing the FAQs in a more interactive and enhanced format may be applicable. Additionally, considerations should be made as to how the FAQs will be provided to the contact center, as individual FAQs or in one comprehensive master file. If channels such as live chat, chatbot, and voicebots are also being considered, you often cannot just pick up and utilize your SRDs and contact center FAQs as is. It will be important to develop derivative content for each channel or alternatively consider creating content using a modular approach. If content is available to artificial intelligence (AI) engines and search engines, then keywords, formats, structure, machine readability, source quality and credibility, recency, and traceability among other things, need to be considered and implemented as applicable.

These decisions impact content strategy, approach, technology needs, etc. One approach is to follow a component-based authoring and modular content strategy. Leveraging AI has also become a cornerstone for content development. AI can be leveraged for summarizing data to create the components and modules, literature surveillance and search, searching data-on-file and knowledge base, converting HCP content to consumer-friendly content, translations, etc.

There are numerous benchmarking papers and publications regarding best practices for MI content development (see Table below). phactMI has also built a Content Development Hub for member organizations on their member portal that has toolkits and resources for developing MI content. There are also shared learning presentations and videos available regarding modular content and component authoring implementation.

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CONTENT DEVELOPMENT AND MANAGEMENT

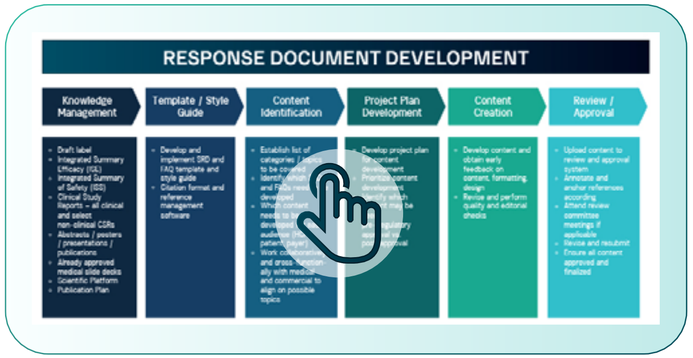
Table: Publications related to best practices, industry trends, and customer preferences in relation to MI response documents and content development

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Wnorowski S, et al. Best practices for medical information global response documents from phactMI and MILE. *Pharmaceut Med.* 2026:40, 87–94. [Web Link]
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Fung SM, et al. Survey of health care practitioners' preferences for medical information: collective insights for impacting patient care. *Ther Innov Regul Sci.* 2016;50(5):569-576. [Web Link]

The planning and process development for MI response documents includes multiple steps (see Figure below):

- Knowledge Management
- Template / Style Guide Development
- Content Identification
- Project Plan
- Development
- Content Creation
- Content Review & Approval

The timelines for content development can vary. Some pre-approval materials may need to be developed, and development can often begin once a new drug application (NDA) or biologics licensing application (BLA) is filed. See Figure below for Illustrative Timelines.



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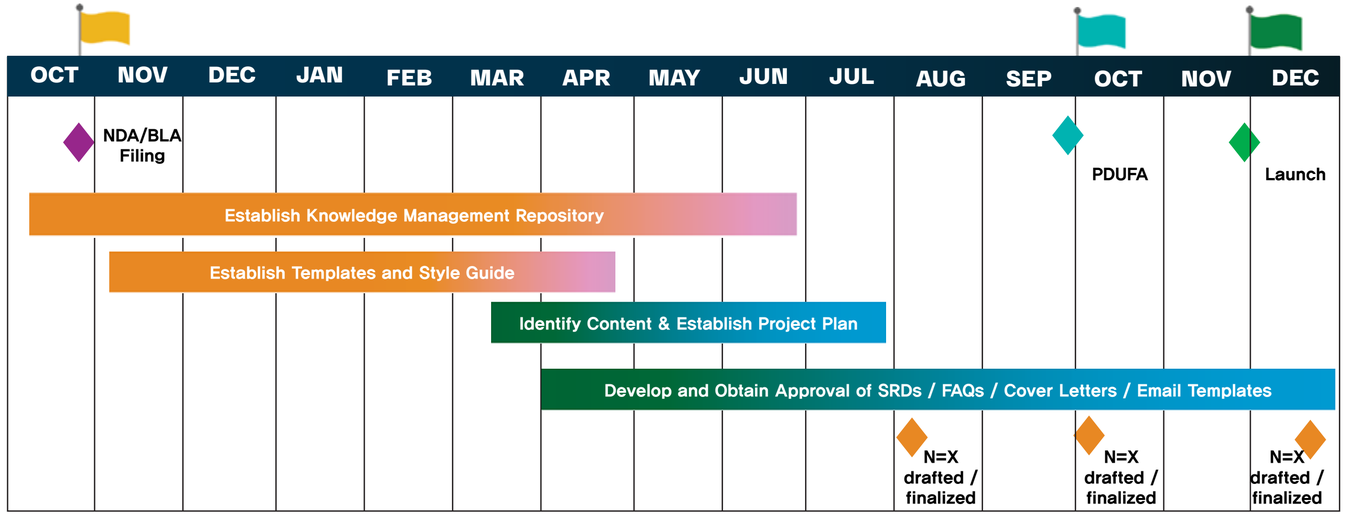
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RESPONSE DOCUMENT DEVELOPMENT

Knowledge Management	Template / Style Guide	Content Identification	Project Plan Development	Content Creation	Review / Approval
◦ Draft label ◦ Integrated Summary Efficacy (ISE) ◦ Integrated Summary of Safety (ISS) ◦ Clinical Study Reports – all clinical and select non-clinical CSRs ◦ Abstracts / posters / presentations / publications ◦ Already approved medical slide decks ◦ Scientific Platform ◦ Publication Plan	◦ Develop and implement SRD and FAQ template and style guide ◦ Citation format and reference management software	◦ Establish list of categories / topics to be covered ◦ Identify which SRDs and FAQs need to be developed ◦ Which content needs to be developed for each audience (HCP, patient, payer) ◦ Work collaboratively and cross-function-ally with medical and commercial to align on possible topics	◦ Develop project plan for content development ◦ Prioritize content development ◦ Identify which content may be need pre- regulatory approval vs. post-approval	◦ Develop content and obtain early feedback on content, formatting, design ◦ Revise and perform quality and editorial checks	◦ Upload content to review and approval system ◦ Annotate and anchor references according ◦ Attend review committee meetings if applicable ◦ Revise and resubmit ◦ Ensure all content approved and finalized

CONTENT DEVELOPMENT AND MANAGEMENT

Illustrative Content Development Timeline



STANDARD REVIEW

FDA NDA / BLA Review Timelines

PRIORITY REVIEW



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CONTENT DEVELOPMENT AND MANAGEMENT

One key step in content development is identifying which content is going to be developed and establishing a project plan. Different approaches exist to content development. Two common strategies include, producing a robust and comprehensive content library to hopefully limit escalations and custom response development, or to create a limited number of key SRDs and adjusting and adding once inquiries are received.

Often the first step is understanding what information is in the draft label and identify content to be drafted across the following categories:

- Efficacy
- Safety
- Disease State
- Storage / Stability
- Use in Special Populations
- Dosing and Administration
- Concomitant Medications / Conditions
- Pharmacology (PK / PD)
- How Supplied
- Ingredients / Allergens

Then, the next step is often establishing a project plan for development. The plan can be as simple as the tracker below:



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CATEGORY	TITLE	DOC ID #	PRIORITY	1ST DRAFT	2ND DRAFT	FINAL DRAFT	REVIEW/ APPROVAL	FINALIZED
DISEASE								
	Disease State Overview							
	Natural History Study Results							
	Treatment Guidelines							
EFFICACY								
	Efficacy and Safety Overview							
	By study; By Indication; By Efficacy Endpoint							
SAFETY								
	Topics based on safety profile; boxed warning, contraindications, warnings & precautions; most common AEs							

CONTENT DEVELOPMENT AND MANAGEMENT

SRD CHECKLIST

- Determine which SRDs will be needed pre-approval vs. post-approval.
  - Typically, pre-approval will only provide answers to questions in which the data and information are already publicly available. Once approved the use of data-on-file is acceptable (depending on the region/country SRDs are used in)
- Determine need to develop non-HCP (consumer/patient friendly) SRDs, otherwise known as PRDs
  - This may be based on the type of product; how administered; if there is direct to consumer (DTC) advertising; etc.
- Determine if any SRDs need to specifically be developed for payers.
- Determine if SRDs will be used as GRDs. This will determine template, structure, and the content to include.
  - If GRDs are developed, then decide if the GRDs need to be localized or if the GRDs will be appropriate for use as is.
    - This may be driven by how close the labels (e.g. USPI and SmPC) are aligned.
    - And, if a translation is required.
  - Also, beyond the GRDs some regional/country specific SRDs may need to be developed.
- Ensure SRD template and style guide is in place.
  - Title; Introduction; Summary; Table of Contents (hyperlinks); Body; Reference Section; Appendix if applicable
  - Determine all details including font size, spacing, color palette, headings/sections, use of infographics, figures, tables, graphs, interactive content, etc.
  - Determine the platform the SRDs will be developed in (e.g. Word vs. component-based authoring software)
  - Format considerations should also include if documents will be available on self-service portal; mobile application; etc. and if they will be allowed to be indexed and viewed by search engines and large language models (LLMs).
- If consumer SRDs (PRDs) are developed, need to consider different formats and layouts.
  - Need to ensure written at the appropriate reading level
  - Leverage infographics when applicable

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CONTENT DEVELOPMENT AND MANAGEMENT

FAQ CHECKLIST

- Determine which FAQs will be needed pre-approval vs. post-approval.
  - Typically, pre-approval will only provide answers to questions in which the data and information are already publicly available.
- Separate FAQs may need to be developed for HCPs vs. non-HCPs (patients/consumers).
  - Non-HCP FAQs should be written in consumer-friendly language, often focused on labeled information.
- Determine if FAQs and SRDs will be developed for the same topic or if FAQs are only going to be developed for topics in which an SRD does not exist.
  - If both being developed, the FAQ should be brief with the key information and be linked to the SRD for additional information.
- Determine if FAQs will be only used verbally by the MICC or if they will also be used for live chat or chat bot.
  - This may influence the structure of the response, length, etc.
  - If being used for live chat or chat bot, determine which FAQs are appropriate to use via these channels.
- Determine if FAQs will be used by other departments within Medical Affairs (e.g. MSLs). This may also influence which FAQs need to be developed.
- Determine if FAQs will be used locally or globally.

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VENDOR SELECTION AND MANAGEMENT

Vendor selection and management are critical for MI organizations, particularly as services become more global, technology-enabled, and subject to increasing regulatory scrutiny. Tactical execution and strategic operations are critical for the MI function. External vendors frequently support the core activities of MI such as contact center operations, content development / management, literature surveillance / monitoring, and digital solutions.

While outsourcing can deliver scalability, specialized expertise, and operational efficiency, it also introduces contractual, compliance, and governance complexities that require careful planning. The contracting process may vary depending on the nature of the services, the level of automation or technology involved, and the regulatory footprint of the activity. However, a structured, risk-based, and cross-functional approach remains essential to ensure quality, compliance, and continuity of service.

The Importance of a Structured Contracting Framework and Why Contracting Matters in MI

MI operates within a highly regulated environment where accountability ultimately remains with the Marketing Authorization Holder (MAH), regardless of whether activities are performed internally or outsourced. Contracts therefore serve not only as commercial agreements but as critical governance tools that clearly define responsibilities, quality expectations, key performance indicators, service level agreements, data management & protection obligations, and oversight mechanisms.

A well-designed and robust contracting framework supports clear allocation of roles and responsibilities, regulatory inspection and audit readiness, consistent quality standards across vendors, and appropriate oversight and escalation pathways, while aligning vendor performance with business objectives and patient safety expectations.

The Importance of a Structured Contracting Framework and Why Contracting Matters in MI

Although organizational approaches may differ, vendor engagement for MI services typically follows a defined lifecycle, from initial needs assessment through contracting and ongoing oversight. A structured lifecycle supports transparency, proportionality, and alignment with regulatory expectations.

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VENDOR SELECTION AND MANAGEMENT

Illustrative Vendor Contracting Process

Lifecycle Phase	Key Activity / Document	Purpose within MI & PV	Definition / Notes
Planning & Needs Assessment	Needs Identification	Defines the scope, criticality, and regulatory impact of the services to be outsourced.	Includes assessment of patient safety impact, data access, and technology reliance.
	Confidential Disclosure Agreement (CDA) / Non-Disclosure Agreement (NDA)	Enables the secure exchange of confidential information during early vendor discussions.	Typically executed prior to sharing detailed service or system information.
Market Engagement	RFI (Request for Information)	Gathers high-level information on vendor capabilities, experience, and service models.	Used to inform vendor shortlisting; not a binding commercial document.
Vendor Evaluation	RFP (Request for Proposal)	Requests detailed proposals covering service scope, quality systems, technology, and pricing.	Forms the basis for structured vendor comparison.
	Bid Defense	Allows shortlisted vendors to clarify proposals and respond to detailed operational and compliance questions.	Often involves MI, PV, Quality, IT, and Procurement stakeholders.
	IT Security Questionnaire	Assesses information security controls, system architecture, and data protection measures.	Particularly relevant for digital, automated, or data-driven services.
Due Diligence & Qualification	Vendor Qualification Questionnaire	Evaluates quality management systems, regulatory experience, and training frameworks.	Depth should be proportionate to service risk and criticality.
	Vendor Qualification Audit	Verifies the vendor's quality systems through on-site or remote assessment.	Commonly required for regulated MI and PV activities.

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VENDOR SELECTION AND MANAGEMENT

Illustrative Vendor Contracting Process (cont.)

Lifecycle Phase	Key Activity / Document	Purpose within MI & PV	Definition / Notes
Contracting	Master Services Agreement (MSA)	Establishes overarching legal and commercial terms governing the vendor relationship.	Typically supplemented by service-specific documents.
	Service Level Agreement (SLA)	Defines service performance expectations, metrics, and reporting requirements.	Supports ongoing performance monitoring and escalation.
	Statement of Work (SOW)	Describes the specific services, scope, timelines, and pricing.	May be modular to allow future scope changes.
	Quality Agreement	Allocates quality responsibilities, audit rights, and deviation management processes.	Critical for inspection readiness.
	Data Processing Agreement (DPA)	Defines data protection roles and responsibilities in line with applicable regulations.	Addresses data flows, security, and cross-border transfers.
	Pharmacovigilance Agreement (PVA) / Safety Data Exchange Agreement (SDEA)	Defines responsibilities for the exchange of safety information, adverse event reporting, monitoring, and reconciliation between partner organizations.	Mandatory, legally binding document that outlines the responsibilities for exchanging safety data, monitoring, and reporting adverse events between partnering organizations.
Implementation & Oversight	Vendor Management and Oversight Plan	Establishes governance structures, oversight activities, and escalation pathways.	Supports ongoing compliance, performance review, and continuous improvement.

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VENDOR SELECTION AND MANAGEMENT

Risk-Based Contracting Considerations

Not all vendor engagements carry the same level of regulatory or operational risk. MI organizations increasingly apply a risk-based approach when determining the extent of due diligence, contractual detail, and ongoing oversight.
Risk considerations may include:

- Impact on patient safety or regulatory reporting
- Access to and storage of personal or sensitive data
- Degree of autonomy delegated to the vendor
- Use of digital, automated, or AI-enabled solutions
- Geographic footprint and subcontracting arrangements

Aligning contractual rigor with risk helps maintain compliance while avoiding unnecessary complexity.

Cross-Functional Collaboration: A Critical Enabler

As mentioned in an earlier section, collaboration is critical. Vendor contracting for MI services relies on close collaboration across multiple internal functions. Procurement typically leads vendor sourcing and commercial discussions, while Legal, Compliance, and Data Privacy functions ensure contractual and regulatory requirements are met. IT and Information Security teams play a key role where digital platforms or data processing are involved, and Finance supports budgeting and financial governance. Quality, Medical Affairs, Safety, and Regulatory colleagues may also be engaged depending on the services in scope.
Early and ongoing cross-functional involvement supports efficient contracting, clearer accountability, and smoother implementation.

Looking Ahead: Contracting as an Enabler of Innovation

As MI continues to evolve, vendor contracts must increasingly support digital innovation, automation, and new operating models, while maintaining robust governance and regulatory compliance. Well-structured and proportionate contractual frameworks, combined with clear oversight and cross-functional collaboration, help ensure that innovation enhances – rather than compromises – quality, data integrity, and patient safety.
By viewing contracting as a strategic enabler rather than a purely transactional exercise, MI organizations can establish resilient vendor partnerships that support both operational excellence and sustainable long-term transformation.

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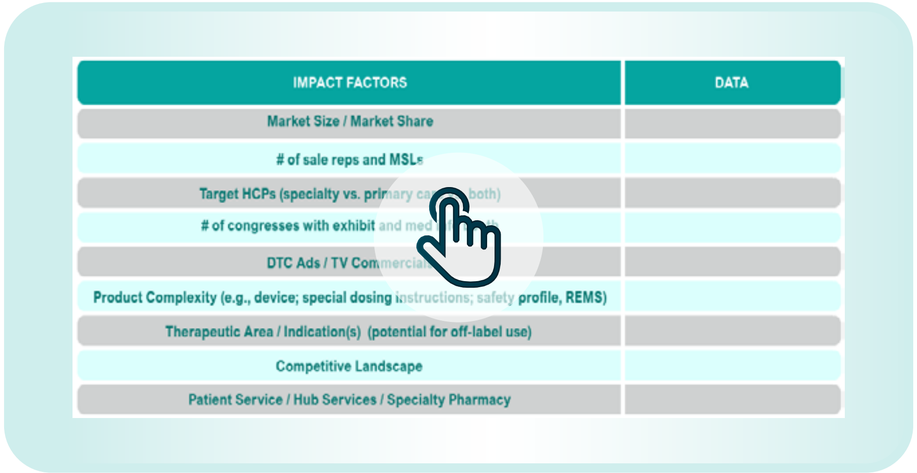
BUDGET PLANNING AND MANAGEMENT

Budget planning and management can be complex and challenging especially when first establishing MI operations and preparing for first product launch. One of the main drivers of the budget will be determining which activities and support will remain internal and which will require third-party vendor support. The main driver of this will also be based on the company's positioning regarding number of internal FTEs that will be supporting MI and which other non-MI direct activities the MI team will also be responsible for.

Two additional drivers are technology and the number of available channels for MI handling, including the actual anticipated volume of MI cases and AE / PC reports.

Estimating inquiry volume is not a perfect science. Many factors influence the volume of MI inquiries, including therapeutic area, specific indications, market size, market penetration/share, patient access or patient services support, number of sales representatives, number of MSLs, number of medical congresses where the team will have a presence, and if there are plans for DTC advertising.

AE and PC reporting are typically linked more to product complexity (e.g., safety profile; drug/device combination) and number of p rescriptions and patients on medication. Involvement of Specialty Pharmacy and Patient Hub services may also impact AE/PC reporting. Typically, AE/PC reports are a significantly smaller portion of the requests received, 5% to 10% of the volume.



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BUDGET PLANNING AND MANAGEMENT

Factors Impacting Case Volume

IMPACT FACTORS	DATA
Market Size / Market Share	
# of sale reps and MSLs	
Target HCPs (specialty vs. primary care vs. both)	
# of congresses with exhibit and med info booth	
DTC Ads / TV Commercials	
Product Complexity (e.g., device; special dosing instructions; safety profile, REMS)	
Therapeutic Area / Indication(s) (potential for off-label use)	
Competitive Landscape	
Patient Service / Hub Services / Specialty Pharmacy	

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AUDIT AND INSPECTION READINESS

There are not many specific laws and regulations for MI. However, since MI is a customer facing group and is responsible for identifying and handling the intake of AE and PC reports, which are highly regulated, it is important for MI to maintain a state of audit and inspection readiness.

Audits generally evaluate whether MI operates in a compliant, consistent, and documented manner aligned with global regulations and internal SOPs.

KEY FOCUS AREAS:

Governance & SOP Framework

- Established clear and current MI policies and SOPs
- Defined roles, responsibilities of internal staff and external vendors
- Clearly defined approval pathways for materials, including version control
- Defined training curriculum and training documentation

Scientific Content Quality

- Process for developing and maintaining MI response documents, ensuring accuracy and appropriate referencing
- Defined review and approval for MI response documents
- Consistency across channels (email, phone, website, chat)

Intake & Response Processes

- Proper inquiry documentation and storage
- Turnaround times and compliance with service levels
- Documentation of all interactions in the MI system
- Defined processes for AE and PC report handling, including reconciliation
  - Additionally process by which all channels adequately monitored for potential AE and PC reports

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AUDIT AND INSPECTION READINESS

Vendor Oversight

- Contracts (MSA and SOW) outlining services, roles, responsibilities
- Quality monitoring and performance metrics
- Training records
- Periodic audits and Corrective and Preventive Actions (CAPA) follow up

Systems & Technology

- Audit trails, data integrity, controlled access
- Validation of MI databases / CRM systems
- Secure storage of source documents
- Processes for ensuring data privacy

Core Elements of MI Inspection Readiness

Documentation Always in a "Ready" State

Every system, record, and SOP should be inspection ready at all times–not just during audit season.

- Audit trails, data integrity, controlled access
- Validation of MI databases / CRM systems
- Secure storage of source documents
- Processes for ensuring data privacy

Inquiry Management Excellence

Inspectors will often select a sample of MI cases and review:

- Quality of medical response
- Accuracy of references
- Compliance with regulatory boundaries (e.g., unsolicited vs. solicited)
- Appropriate identification, handling and documentation of AE and PC reports

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AUDIT AND INSPECTION READINESS

A high functioning MI team should be able to:

- Pull complete inquiry logs quickly
- Provide traceable evidence of review/approval
- Demonstrate consistent decision making

Training & Competency Assessments

Auditors may ask:

- "Show me that every MI specialist is qualified to respond."
  - Maintaining CVs/resumes, job descriptions, and having defined training curriculum and certification process are important
- "How do you ensure scientific accuracy and compliance?"
  - What is periodic review process of MI response documents?
  - How often are materials updated?
  - What is process for reviewing and updating MI response documents if new regulatory label is approved?
- Key readiness components:
  - Annual competency assessments
  - Therapeutic area certifications
  - System training, including having a training curriculum and establishing Learning Management System (LMS)
  - Documentation of remedial training if any gaps were found

Quality Management & Monitoring

MI should maintain a robust Quality Program including:

- Periodic QC, review, and updating of response documents
- Monitoring of case documentation
- Monitoring of call recordings / call logs
- Established process for Quality Non-conformance (QNCR) and CAPAs with clear owners
- Defined Service Level Agreement and KPIs, including applicable metric reports and dashboards (e.g., turnaround time, AE and PC reporting compliance)

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AUDIT AND INSPECTION READINESS

Mock Audits & Inspection Readiness Drills

To prepare your team:

- Conduct simulated interviews for MI Specialists
- Test the ability to pull documentation quickly
- Audit 10–20 random MI cases
- Validate vendor oversight artifacts
- Review cross functional interfaces (Pharmacovigilance, Quality, etc.)

Outcomes should be captured in a formal Audit Report and any CAPAs clearly identified.

Common Audit Findings in MI (Industry Trends)

Typical findings include:

- Inadequate documentation of interactions
- Inconsistent response content across channels
- Outdated MI response documents still in circulation
- Lack of appropriate or timely escalation of AE / PC reports
- Insufficient vendor monitoring and oversight
- System audit trails not comprehensive

Avoidance strategies

- Strong SOP governance
- Clearly defined review and approval workflows
- Regular QC of call notes and response letters
- Periodic system validation

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AWARENESS / TRAINING

Once the MI function is established, have a plan and strategy to build both internal and external awareness of the function and services. Internally awareness is typically built via training on processes and procedures for submitting unsolicited requests for MI to MICC. Often the training is focused on field teams, sales representatives and MSLs, but should expand to all customer-facing teams and individuals. Often training is provided to these same teams regarding how to appropriately identify and handle post-marketing AE and PC reports.

External awareness can be more challenging. The phone number that appears within the labelling for reporting an AE often goes directly to the MICC; however, it is important to also make the phone number and contact information for MI available in other places. The phone number and contact information should also be listed on the company website within the "**Contact Us**" section. Including the avenues to contact MI within MI response documents, including cover letters, within the SRDs, etc. is also a way to reactively build awareness.

If the plans include adding additional digital channels for MI, including a medical portal, live chat, chatbot, etc. it will be even more important to have a strategy to build awareness of these channels externally. Most companies now have social media handles for Medical Affairs and often these channels are leveraged to build awareness and drive traffic to the company's medical portal. Additionally, contact information on all channels should be made accessible to search engines and LLMs so that your information will readily appear in online searches and AI/ LLM responses. It will be important to consult and collaborate with legal, regulatory, and compliance regarding this.

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VALUE AND IMPACT

Medical Information is a critically important customer-facing function that supports the safe and effective use of company products. It is important for medical information teams to demonstrate their value across their organizations and to be seen as an important strategic player. Gaining actionable metrics, customer insights, and customer satisfaction are critically important for demonstrating value.

Metrics and analytics are typically categorized in four distinct but interrelated areas.

Operational Metrics

Operation-related metrics such as inquiry volume, volume by channel, volume by customer type, abandonment rate, average handle time, and turnaround times are extremely important because they help with resource modeling, budget planning, and measuring performance and operational efficiency

Key Performance Indicators and Service Level Agreements

Indicators of performance based on contractual agreement. Typically, AE / PC turnaround time; phone call service level; live call success rate; call abandonment rate; first contact resolution.

Actionable Insights

Customer insight analysis which includes looking at types of questions by audience, including by category and topics; plus looking at trending, data gaps, off-label use related questions, etc.

Identification of customer insights and data gaps are extremely valuable because they can be shared back within the organization to help with life cycle management, publication planning, data generation and analysis, educating future clinical trial development, and also identify possible internal training needs.

An insight is the deeper understanding of the why behind trends of information that lead us to determine if an action is warranted.
Approach: INvestigate, Scrutinize, Identify, Take Action, and Enlighten (INSITE).
Cadogan, A.A., Lau, J., Wnorowski, S. et al. Defining Insights. *Ther Innov Regul Sci* 57, 1229–1237 (2023). https://doi.org/10.1007/s43441-023-00554-w

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VALUE AND IMPACT

Customer Satisfaction and Experience

Measures regarding customer satisfaction and customer experience are critically important to further demonstrate the impact and value of services being provided. MI Measurements may include customer satisfaction score (CSAT), net promoter score (NPS), first contact resolution (FCR), customer effort score (CES),and sentiment analysis.

Other options often include asking survey questions regarding whether the information impacted clinical decision making; or to gain specific feedback on content and materials being provided.

Guillot, P., Shea, J., Shoemaker, S. et al. Medical Information Delivering Improved Customer Experience: A Guide. *Pharm Med* 37, 111–119 (2023). https://doi.org/10.1007/s40290-023-00469-9

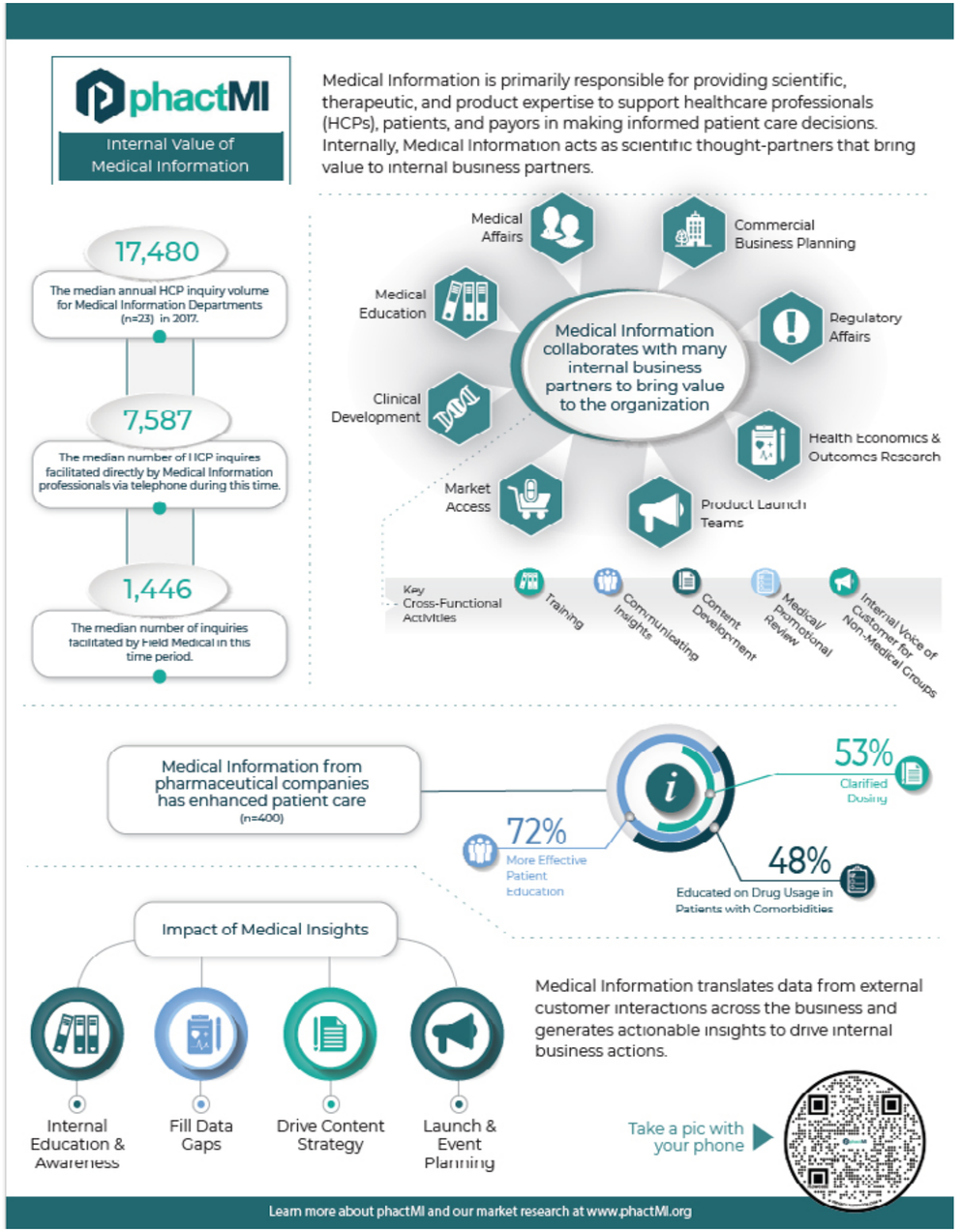
Value

There are some additional resources available that focus on demonstrating Value of Medical Information.

- MAPS ELAVATE article titled The Value of Medical Information to Internal Stakeholders: https://medicalaffairs.org/elevate-articles-value-medical-information/
- phactMI Internal Value of Medical Information infographic
- Jindia, L., Keane, S., Wnorowski, S. et al. Enhancing Patient Care II: The Clinical Impact of Medical Information Services. *Ther Innov Regul Sci 56*, 483–491 (2022). https://doi.org/10.1007/s43441-022-00385-1
- Albano D, Follman S, Patel Y, et al. Enhancing Patient Care: Value of Pharmaceutical Medical Information Services.*The Journal for Nurse Practitioners*, (2021); 17, 840-845. https://doi.org/10.1016/j.nurpra.2021.01.009
- Albano, D., Soloff, A., Heim, K. et al. A Theory on the Relativity of Factors Impacting the Utilization of Medical Information Services From the Pharmaceutical Industry. *Ther Innov Regul Sci* 50, 554–559 (2016). https://doi.org/10.1177/2168479016640019
  - This article explored a couple different calculations for Utilization, Value, and Impact
  - **Utilization** = (awareness) x (access) x (trust)
  - **Value** = (number of interactions) x (impact)
  - **Impact** = % of HCP indicating will be used in clinical decision making

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phactMI
Internal Value of Medical Information
Medical Information is primarily responsible for providing scientific, therapeutic, and product expertise to support healthcare professionals (HCPs), patients, and payors in making informed patient care decisions. Internally, Medical Information acts as scientific thought-partners that bring value to internal business partners.
17,480
The median annual HCP inquiry volume for Medical Information Departments (n=23) in 2017.
7,587
The median number of HCP inquires facilitated directly by Medical Information professionals via telephone during this time.
1,446
The median number of inquiries facilitated by Field Medical in this time period.
Medical Affairs
Commercial Business Planning
Medical Education
Regulatory Affairs
Medical Information collaborates with many internal business partners to bring value to the organization
Clinical Development
Health Economics & Outcomes Research
Market Access
Product Launch Teams
Key Cross-Functional Activities
Training
Communicating Insights
Content Development
Medical/ Promotional Review
Internal Voice of Customer for Non-Medical Groups
Medical Information from pharmaceutical companies has enhanced patient care
(n=400)
53%
Clarified Dosing
72%
More Effective Patient Education
48%
Educated on Drug Usage in Patients with Comorbidities
Impact of Medical Insights
Internal Education & Awareness
Fill Data Gaps
Drive Content Strategy
Launch & Event Planning
Medical Information translates data from external customer interactions across the business and generates actionable insights to drive internal business actions.
Take a pic with your phone
Learn more about phactMI and our market research at www.phactMI.org

VALUE AND IMPACT

Metrics

In the table below are some common MI related metrics and an overview of common contact center metrics.

IMPACT FACTORS	DESCRIPTION
MI CASE METRICS	
Case / Inquiry Volume	Case volume represents the total number of customer contacts. One case can include multiple inquiries.
Case Volume by Customer Type	HCPs vs. non-HCPs
Inquiry Volume by Category and Topic	Looking at each inquiry by Category (e.g., Efficacy, Safety, Special Populations, etc.) and Topic.
Case Volume by Source	How the request was received, phone, email, chat, CRM, etc.
Case Volume by Handling / Response Method	How the customer was responded to, phone, email, live chat, etc.
Case Volume by Rep vs. Non-Rep	Looks if the request came directly to MI or if it was forwarded from sales rep or MSL
Total MI, AE, PC, and Non-MI Cases	Analysis of case type, MI, AE, PC, non-MI, or combination

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Metrics (cont.)

In the table below are some common MI related metrics and an overview of common contact center metrics.

IMPACT FACTORS	DESCRIPTION
MI CASE METRICS (cont.)	
Number of Escalations	Number of cases escalated, typically represents an approved response isn't available
Response Type (standard vs. custom)	Examines if response provided was an approved standard response or custom response
Turnaround Time	Turnaround time can look at fulfillment of the MI request and also the timeliness of AE and PC report triage.
Case Volume by Customer Location	State / Country of the requester
Case Volume by HCP Type	Pharmacist, Nurse, Doctor, Physician Assistant, Nurse Practitioner, etc.
Case Volume by Specialty	Analysis by HCP specialty, Oncology, Neurology, Ophthalmology, etc.
Document Utilization	Which approved SRDs, FAQs, PRDs, publications, etc. are utilized and distributed most often

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Metrics (cont.)

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IMPACT FACTORS	DESCRIPTION
MI CASE METRICS (cont.)	
Quality Monitoring / Assurance Metrics	Will depend on how the quality monitoring program is de-fined, but should look at the results
CONTACT CENTER METRICS AND CUSTOMER SATISFACTION	
Service Level	% of calls received by contact center that are answered by an agent within a defined time frame e.g., 80% of calls answered within 30 seconds
Average Speed to Answer	The average time it takes for an agent to answer an incoming call after it enters the queue. Total Wait time for Answered Calls divided by Total Number of Answered Calls

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Metrics (cont.)

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IMPACT FACTORS	DESCRIPTION
CONTACT CENTER METRICS AND CUSTOMER SATISFACTION (cont.)	
Abandonment Rate	The percentage of callers who hang up before reaching an agent, often indicating customer frustration, long wait times, or poor routing.
Live Call Success Rate	The number of calls answered live as a percentage of the total number of calls (answered calls, abandoned calls) received during normal business hours.
Call Duration	Total time speaking to the customer
Average Handle Time	Total call time + total hold time + total after call work time divided by the total number of calls
Wrap Up time	Average after-call work time
AUR	Average Agent Utilization Rate

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IMPACT FACTORS	DESCRIPTION
CONTACT CENTER METRICS AND CUSTOMER SATISFACTION (cont.)	
Occupancy	Individual average % or % team average occupancy time (factors in average handle time and wrap up time)
First Contact Resolution (FCR)	Number of calls resolved on first attempt divided by total number of calls received. Can also be used for all case types. Resolved Cases on First Contact divided by total cases.
First Response Time (FRT)	Total time waiting for all inquiries divided by the total number of inquiries
Customer Effort Score (CES)	Measures customer effort on solving their problem / getting an answer to their question. % Easy minus % Difficult

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Metrics (cont.)

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IMPACT FACTORS	DESCRIPTION
CONTACT CENTER METRICS AND CUSTOMER SATISFACTION (cont.)	
Customer Satisfaction (CSAT)	Number of satisfied customers divided by number of surveyed responders
Net Promoter Score	A widely used metric that measures customer loyalty, satisfaction, and perceived brand value by asking how likely customers are to recommend a company to others on a 0–10 scale. It categorizes customers into Promoters (9-10), Passives (7-8), and Detractors (0-6). NPS = % Promoters - % Detractors
Sentiment Analysis	Automated process of using Natural Language Processing (NLP) and machine learning to identify, extract, and quantify subjective information—such as emotions, attitudes, and opinions—from text data.

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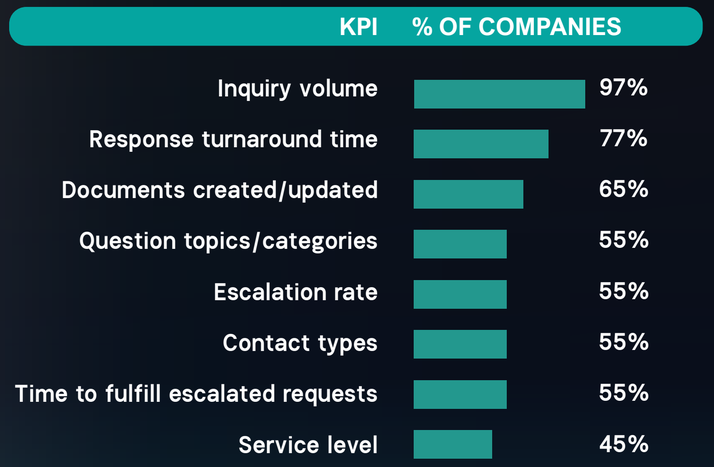
VALUE AND IMPACT

Metrics (cont.)

Results from Tamburri et al. published in 2026 demonstrated that 61% (19/31) of companies distinguish between metrics and KPIs.

Top KPIs Focus on Operational Excellence

The most frequently reported KPIs are:



Most common customer-focused metrics include:

- Inquiry volume (74%)
- Response turnaround (71%)
- Customer satisfaction surveys (68%)
- Service level (68%)
- Abandonment rate (58%)
- Escalation rate (52%)

Customer satisfaction surveys were administered by 68% (21/31) of companies. Advanced Customer Experience Metrics include:

- 53% assess patient impact
- 37% measure how information was used
- 37% track other outcome measures
- 32% measure likelihood to recommend
- 21% use sentiment analysis
- 21% assess trust
- 11% use a Net Promoter Score (NPS)

Tamburri, R., Sendi, M.K., Glaetzer, A. et al. Benchmark Survey on Content Development and Key Performance Indicators: A phactMI Benchmarking Survey Update. *Innov Regul Sci (2026)*. https://doi.org/10.1007/s43441-026-00999-9

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COMPENDIA / GUIDELINES / PATHWAYS

MI is often asked to take the lead or be involved in both Drug Compendia and Pathways submissions, as well as monitoring these databases for accuracy of information presented.

Drug compendia are independent reference sources used by:

- CMS (Centers for Medicare & Medicaid Services) and commercial payers for coverage decisions
  - Note: CMS recognizes specific drug compendia as authoritative sources for determining medically accepted indications, especially for off-label uses
  - CMS-Approved Drug Compendia:
    - American Hospital Formulary Service – Drug Information (AHFS-DI)
    - National Comprehensive Cancer Network (NCCN) Drugs & Biologics Compendium
    - Micromedex DrugDex
    - Clinical Pharmacology (Elsevier/Gold Standard)
    - Lexi-Drugs (Wolters Kluwer)
- Clinicians for dosing and off-label guidance
- Health systems for formulary decisions

Example Drug Compendia:

- American Hospital Formulary Service-Drug Information (AHFS-DI)
- Micromedex
- UpToDate Lexidrug
- Clinical Pharmacology
- National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium
- Epocrates
- Medscape
- Red Book
- First Databank
- PDR (Physicians' Desk Reference)
- MPR (Monthly Prescribing Reference)
- Multum Drug Database
- Facts and Comparison
- Medi-Span

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COMPENDIA / GUIDELINES / PATHWAYS

Each Drug Compendia has its own requirements and submission process.

Often the information needed will include the following:

- Clinical trial summaries
- FDA-approved labeling
- FDA approval date and product commercial availability
- List of key publications
  - Peer reviewed studies supporting efficacy and safety
- Pharmacologic and therapeutic class information
- How Supplied and product identifier (NDC / UPC / NHRIC) & barcode
- Pricing data (WAC, AWP, etc.)
- High resolution product images, packaging and the product

Guidelines and Pathways are also critically important as being listed in respected guidelines (e.g., NCCN, ADA, IDSA) signaling that your product is backed by strong evidence and expert consensus. Inclusion in clinical guidelines shows that a product's efficacy and safety have been vetted by expert panels, boosting trust among HCPs. Also, inclusion in guidelines demonstrates that a product meets accepted standards of care, which payers use to justify coverage decisions and reduce prior authorization barriers. Guidelines influence treatment pathways across institutions and health systems, helping your product reach more eligible patients.

There are many different Guidelines / Pathways from different medical organizations and each has different requirements for submission. It is important to research the guideline submission requirements before beginning to develop the package of information to be provided.

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OTHER RESPONSIBILITIES

MI teams may be tasked with multiple other responsibilities, including the following:

- The Academy of Managed Care Pharmacy (AMCP) dossier is a standardized, evidence-based document used by pharmaceutical manufacturers to submit clinical and economic data to US healthcare decision-makers (HCDMs) for formulary placement and reimbursement. It supports informed, transparent, and objective evaluation of new or existing drugs, biologics, and devices. The latest version (5.0) includes guidelines for digital therapeutics, real-world evidence (RWE), and health equity. https://www.amcp.org/resource/amcp-format-formulary-submissions-guidance. This may also include preparing an eDossier, via FormularyDecisions®, https://www.amcp.org/resource/amcp-format-formulary-submissions-guidance.
- MLR support
  - MI may be asked to perform all medical and scientific fact-checking of promotional and non-promotional materials
  - MI team members may be asked to serve as the signatory Medical Reviewer
  - MI may be responsible for establishing the processes and procedures, including running Medical Materials Review Committee (MMRC / MRC)

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Associations

- phactMI - https://www.phactmi.org/
- MILE - https://www.mile-association.org/
- MAPS - https://medicalaffairs.org/
- DIA - https://www.diaglobal.org/
- PIPA - https://pipaonline.org/
- PVN-MI - https://www.pvn-mi.org/

Conferences

- US
  - Q1 Productions: Annual Life Science Medical Information
  - DIA Medical Affairs and Scientific Communications Forum (MASC)
  - MAPS Americas Annual Conference
- Europe
  - DIA Medical Information & Communications Conference
  - PIPA Annual Conference
  - MAPS EMEA Annual Conference

Reports / Position Papers

- MILE - Principles for Digital Provision of Medica Information for Healthcare Professionals
- 2022 Canadian Medical Information Benchmarking
- A FRAMEWORK FOR THE DIGITAL PROVISION OF MEDICAL INFORMATION IN CANADA
- MILE and Avayl: AI in Medical Affairs today
- MAPS The Value of Medical Information to Internal Stakeholders
- phactMI Internal Value of MI
- phactMI External Value of MI
- phactMI Trends in Medical Information
- phactMI Patient Focused Whitepaper
- PIPA Selecting the Appropriate PV or MI Vendor: A Comprehensive Guide

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  - FDA DRAFT GUIDANCE: Addressing Misinformation About Medical Devices and Prescription Drugs Questions and Answers Guidance for Industry. July 2024.
  - FDA GUIDANCE: Drug and Device Manufacturer Communications with Payors, Formulary Committees, and Similar Entities. June 2018.
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  - PIPA Guidance Document: Responding to Patient Enquiries
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  - Medical information in the pharmaceutical industry. Recommendations of the first Guide of Good Health Information Practices in the Spanish Pharmaceutical Industry
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  - Position Paper - Medical Information by the Researching Pharmaceutical Companies in Germany
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  - Guidelines for Industry - Handling Requests for Medical Information in Canada

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