Offshore Outsourcing: An Innovative Model to Improving Medical Information Operations

Introduction
This article reviews Medical Information (MI) with regard to the current landscape, what it entails, how it has grown in complexity, and how it lends well to an offshore outsourcing model. Key learnings and recommendations are provided for best practices that should be considered when employing this model. Finally, 2 case study examples demonstrate how establishing an integrated working relationship between a pharmaceutical company and a functional service provider (FSP) can result in the successful management and processing of MI.

Medical Information Landscape
MI is scientific and clinical information related to the usage, efficacy, and safety of a medicinal product, which is provided by a pharmaceutical company in response to unsolicited inquiries from healthcare professionals (HCPs), payers, managed healthcare organizations, and consumers. Some examples include product inquiries regarding ingredients, site of absorption, drug interactions, use in off-label populations, and dosing outside the recommended dose. Over the years, there has been an increasing focus by regulators and consumer groups for pharmaceutical companies to be transparent in their communications with patients, healthcare providers, and the general public. Moreover, the use of internet and social media sites has increased product and disease awareness among consumers and provided another vehicle to connect with pharmaceutical companies.

The complexity of fulfilling MI obligations is further compounded as pharmaceutical companies are expanding their foothold in global geographies. Hence, there is an ever-growing pressure on MI services to meet the need for increased volumes of work, and provide information across different regions that is consistent, but still maintains a level of customization relevant to customers in that country. This can be a challenge when considering the nuances of different countries in terms of approved indications, approaches to treatment, and market competitors.
The Process of Medical Information

Tenets that Govern Medical Information

Dissemination of information to HCPs needs to be fair, accurate, and scientifically balanced with the purpose of enabling rational and safe use of medicinal products. The US FDA governs responses to unsolicited requests for off-label information and provides guidance under Guidance for industry: responding to unsolicited requests for off-label information about prescription drugs and medical devices. Furthermore, the FDA guidance on Good Reprint Practices explains that the dissemination of published information describing off-label use in medical journals, scientific references, publications, and other forms of reprints should be made available in a truthful, non-misleading, and unbiased manner.

Medical Information Triggers

The dissemination of MI involves a multifaceted process that usually occurs when a pharmaceutical company receives an unsolicited inquiry from an HCP or a consumer. Inquiries can be triggered by questions regarding a product’s black box warning, labeling change, new indication, new product launch, completion of a landmark/pivotal study, newly published or revised clinical guidelines, publications with potentially negative data, data that can have a significant clinical impact, media events (TV, print), or legal issues. Medical inquiries can also be triggered by an HCP or consumer regarding the continued availability of products when a company is acquired or divested.

Medical Information Process Flow

Inquiries are received by the pharmaceutical company or its representative, and entered into a database for tracking and subsequent follow-up (Figure 1). When a customer contacts the call center directly, an immediate verbal response can be provided if the answer is straightforward, such as a dosing or administration query. If a written response is required, it often involves researching the scientific literature, creating a medical information response document, review, and approval (Figure 2).

Four Steps to Creating a Written Medical Information Response

Step 1. Literature Search and Evaluation

A medical information specialist conducts a detailed and thorough literature search using company repositories and external literature search engines such as PubMed and EMBASE. Depending on the type of inquiry, the product label, clinical practice guidelines, or disease state related information may also be helpful in compiling the response. In some cases, information may be needed from department personnel such as regulatory, manufacturing, and drug safety.

There is broad agreement on the relative strength of the principal types of literature. It generally follows the hierarchy of evidence based medicine (EBM; Figure 3). However, for MI responses, randomized controlled trials (RCTs), especially the pivotal studies, tend to rank at the top with observational studies and expert opinion still at the base of the pyramid. Review articles and meta-analyses can be included based on their relevance to the inquiry being researched. The prescribing information for the product is given preference when it can be used to respond to an inquiry, since it is FDA approved and readily available to customers.

Step 2. Drafting of Response

Once the relevant literature has been identified, a response is created to address the HCP’s specific question. As medical writers synthesize all of the relevant data, they should consider the audience, and provide unbiased, balanced data presenting both positive and negative studies. The data presentation should be clear, organized, and sequenced in accordance with the quality of the data. For topics that have a plethora of available information, a brief summary at the beginning of the MI response can help the reader navigate the response.

Figure 2. Workflow for Creating Medical Information Responses

Figure 1. Routing of Medical Information Inquires
Step 3. Review and Approval

The resulting written communication is then submitted to the medical and legal/compliance groups for their review and approval. Once all the reviewers have commented and agreed upon the response, the approved response is sent to the customer.

Step 4. Repository of Responses

MI services should be able to triage and easily retrieve previously created responses. Since the same queries can be asked repeatedly, being able to harness previously written MI responses is important not just for efficiency, but also for ensuring consistency. This entails maintaining a database of approved responses that are easily accessible. In addition, such responses are periodically updated or archived, as necessary.

Offshore Partnering: An Innovative Approach

While the workflow described above may seem straightforward, depending on a company’s product portfolio, geographic reach, volume, and complexity of inquiries, the various activities can put a considerable drain on a pharmaceutical company in terms of expertise, resources, oversight, and costs. Those involved in the process require knowledge and expertise of the various “moving parts” such as therapeutic area (TA) adeptness, awareness of the regulatory environment, medical writing skills, and tools/databases management proficiency. In addition, the complexity is further compounded since various stakeholders involved in the MI workflow may be located in different geographic regions around the world, creating silos of information and disconnected processes.

Outsourcing to an external offshore FSP has become a practical solution since the function of MI lends itself well to an outsourcing model. This strategy provides a ready pool of highly skilled and knowledgeable personnel and resources that can be deployed on an as-needed basis, the availability of which is particularly advantageous. Cost, quality, and time are typical parameters used to define success in outsourcing projects. There is no shortage of a technically skilled workforce in countries like India and China, and labor is less expensive than onshore. This model optimizes costs and maximizes impact without compromising quality and customer service.

Benefits of Offshore Outsourcing of Medical Information

- Customized services based on company’s short- and long-term needs: Of the several components involved in MI (call center, inquiry case management, medical writing, repository maintenance of MI responses), companies can customize which functions they retain in-house and which they outsource, based on their needs.

- Specialization in MI services drives efficiencies: FSPs invest in their people, processes, technologies, and tools. Their highly skilled specialists employ best practices and drive process efficiencies. By partnering with pharmaceutical companies of all sizes and types (generics, branded, biologics, devices), specialists share best practices across therapeutic areas (TAs) and regions to deliver consistent results.

- Flexible resourcing to accommodate volume fluctuations: An FSP can quickly reallocate resources to respond to the ongoing challenges of fluctuations in the number of MI inquiries when there is a product launch or as the lifecycle of a product changes, minimizing the burden on the company of hiring, training, infrastructure, and other overhead costs and tasks.

- Seamless integration of global resources and processes: An FSP provides unified processes and a centralized team to interface with multiple countries and teams (call centers, local and regional MI departments, legal, sales reps), thereby eliminating redundancy, filling in process and resource gaps, improving efficiency, and potentially reducing costs.

- Continuous improvement in quality, consistency, and metrics: Since MI services are a core activity for the FSP, they are constantly striving for innovation and methods to make the process quicker and more efficient, while ensuring quality and timely deliverables.

Management of MI activities requires a unique combination of specialized knowledge of regulatory requirements for dissemination of scientifically balanced information and the medical information process, as well as the skill of crafting medical responses tailored to a specific question. The growing demands, needs, and expectations of MI mean that pharmaceutical companies have to implement successful strategies to meet current demands while planning for future growth. The examples below demonstrate how 2 pharmaceutical companies have partnered with a trusted FSP for MI services.
Large Global Pharmaceutical Case Study

Background

A top 5 global pharmaceutical company delivered their MI services through dedicated MI teams in the US and Europe, who were charged with responding to medical inquiries from HCPs and consumers around the world. In response to the company’s global expansion, a third center was established in Asia to support the emerging markets and Asia Pacific (APAC) countries, taking on the task of providing MI services for drugs distributed specifically in these regions. The emerging markets and APAC region encompassed 85 countries in Latin America, Middle East, Africa, Commonwealth of Independent States, China, Hong Kong, South Asia, and Asia Pacific. MI support for 15 products spanning 4 TAs was needed.

In order to manage the volume of inquiries and deliver quality responses in a cost-efficient manner, the Asia team immediately evaluated the merits of outsourcing to an FSP specializing in MI and medical communication. Although the company had not outsourced MI work previously, it had experienced success working with an FSP, outsourcing other activities such as developing product launch tool kits and writing clinical documents.

European Union, Emerging Markets, and Asia Pacific Success

The use of an offshore FSP improved the MI workflow for the pharmaceutical company and increased efficiency since the FSP maintained a central database of shared responses. By the end of the year, another TA comprising 5 products was transferred from the in-house European Union (EU) MI team to the FSP. The FSP gradually increased its span of activity for the emerging markets, APAC and EU regions with the addition of another 4 TAs (10 products) in the second year and 2 TAs (4 products) in the third year of the outsourcing partnership.

US Expansion

Additionally, in the third year, the US MI center, which worked independently from the other regions, added 6 products across 2 TAs, and then a third TA to the scope of MI services being outsourced to the FSP. The FSP was able to respond quickly to the increase in volume by adding additional specialists who were trained and coached by the initial team. The engagement and partnership continued to evolve between the pharmaceutical company and the FSP, with each focusing on their respective core responsibilities.

Process Flow for Responding to Queries

The processes and workflows established by the company and FSP were optimized to foster collaboration and streamline information acquisition and exchange, thereby delivering efficiencies and cost reductions (Figure 4). The FSP team of medical writers and reviewers were specialized in different TAs relevant to the company’s product portfolio. Queries generated from HCPs and consumers were submitted to the company’s local country, and were then uploaded to a customized software application, which tracked inquiries and served as a repository for approved responses across all countries. The FSP team was able to view and respond to all the queries related to the assigned TAs via this application.

If a query was frequently asked, it had an approved response in the MI repository which could be retrieved and used to respond to the HCP. Queries that did not have an existing response were researched, and a customized

![Figure 4. Medical Information Process Flow for Global Pharmaceutical Company](image-url)
response was created. Once approved by the company’s centralized MI team in the US, EU, or APAC, the FSP sent it to the local country from where the inquiry originated for dissemination to the HCP or consumer.

**Benefits for the Pharmaceutical Company**

By establishing clearly defined roles and processes with an overall governance model that facilitated continuous improvement, the partnership with the FSP resulted in the following benefits to the pharmaceutical company:

- A robust global repository of product information, which was updated with new data and information on a continual basis
- Improved turnaround time and quality of communication due to qualified, trained, and dedicated MI writers at the FSP who were knowledgeable about the company’s products and established a rapport with the local country and other key stakeholders
- Integrated MI function for all countries by streamlining global processes and employing tools that facilitated unification and collaboration
- Minimal oversight of MI activities since the FSP staff was effectively integrated with the company’s MI culture, processes, and work principles, and functioned as an extension of their team

"**Mid-sized US Pharmaceutical Case Study**

The branded division of a mid-sized pharmaceutical company provides another example of a successful MI outsourcing project. The goal for this company was to consolidate their MI and pharmacovigilance (PV) services under a single FSP. The scope of work included providing a call center for MI and PV, processing MI requests and subsequent dissemination of responses, and processing adverse event and product complaint reports. By selecting a single FSP to manage all of their MI and PV activities, the pharmaceutical company achieved a streamlined process, resulting in significant cost reduction and efficiency gains.

**Establishing the Partnership**

The company and FSP began their partnership 2 months prior to the call center going live. During this time the processes, work instructions, and templates were established. Several live, web-based product training sessions were conducted by the company to review the products and frequently asked questions, and also provide an opportunity for the FSP to pose questions. In addition, the call center and medical writers completed self-learning product training modules.

Team members from the FSP were on-site at the company to gain a better understanding of the workflow and interact with stakeholders. Since the MI outsourced services were being transitioned from one FSP to another, the transfer of documents and records from the former FSP occurred 1 month prior to the new call center going live.
One year after the partnership between the company and FSP started, the company launched a new product. This resulted in an increase in the number of MI inquiries, and the FSP added additional members to the call center to accommodate the influx of work. This permitted the company’s Medical Affairs group to focus on other priorities and initiatives related to the product launch, rather than diverting resources to MI.

**Process Flow for Responding to Queries**

Unlike the previous example, all inquiries from HCPs, consumers, and sales representatives are submitted to the FSP’s call center. Inquiries are logged in a central database and then handled per the workflow in Figure 5. A sales force automated tool is used by sales representatives to submit unsolicited MI questions from HCPs. This software automatically generates a daily report of the unsolicited questions which is transmitted to the call center. This is an example of how the FSP, even though it is an independent entity, can be integrated with the company, which results in improved efficiency. Once the MI response has been sent to the HCP, the FSP notifies the sales representative.

**Process Optimization**

Since the process flow was clearly established at the beginning, there was no disruption to the day-to-day provision of MI when the new call center went live. Start-up costs and time invested by the company were higher initially, but decreased over time as processes, workflows, and trust between the organizations were established. Despite the early collaboration and preparation between the company and FSP, there were aspects of the process that the FSP could continually strive to enhance and optimize for further improvement and efficiency. The collaboration with a nimble FSP who is able to customize their services based on the needs of the company has resulted in a partnership that has been in place for over 5 years.

**Checklist for Establishing a Successful Partnership**

Several key factors contributed to the success of these outsourcing projects. Table 1 list some recommended best practices to consider when partnering with an FSP and establishing an optimized process model for MI responses.

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**References**

