Benchmarking the Pharma Industry’s Medical Affairs Functions
Report Overview

Medical Affairs, as a function, sits at a crossroads in the pharmaceutical industry. The department is expected to act as a bridge between the commercial and scientific arms of an organization. Medical Affairs is further tasked with being the conduit of information between the company and external stakeholders, bringing efficacy and safety data to the medical community as well as gathering insights from the medical community to share internally. All responsibilities must be undertaken while keeping in mind strict regulatory controls and ensuring that medical data are interpreted appropriately.

ISR has designed this report to be used as a benchmarking tool for companies to compare their Medical Affairs functions to those of Top 50 pharmaceutical organizations.

Report Structure:

1. Introduction
2. Understanding the Medical Affairs Function
   - Medical Affairs Employees
   - Medical Affairs Goals and Involvement
3. Medical Affairs Department Benchmarking
   - Division of Work
   - Department Structure
   - Organizational Alignment
   - Outsourcing Behavior
   - Medical Affairs Budget
   - Challenges
   - Future Predictions
4. Best Practices and Recommendations

Methodology:

ISR conducted 60-minute telephone interviews with 15 experienced Medical Affairs professionals at 14 of the Top 50 pharmaceutical companies. Respondents were recruited within North American and European geographies and have an average of 10 years of experience in Medical Affairs.

- North American respondents: 12
- European respondents: 3
- Global Medical Affairs headquarters respondents: 10
- Regional headquarters or country affiliate respondents: 5

The titles below are held by our interviewees:

- Vice President, Medical Affairs
- Executive Director, Field Medical Affairs
- Senior Director, Global Clinical Research and Medical Affairs
- Divisional Head, Medical and Scientific Affairs
- Therapeutic Area Head, Medical Affairs
- Medical Director, Global Medical Affairs (2)
- Director, Global Medical Affairs (3)
- Medical Affairs Director
- Director, Medical Affairs
- Medical Director, US Medical Affairs
- Associate Director, Global Medical Affairs
- Associate Director, Medical Affairs
What you will learn in this report:

- Medical Affairs department operations and structuring, including:
  - Division of work for both global and regional medical affairs
  - Department structure and unique department structures within companies interviewed
  - Organizational alignment and comparison of Medical Affairs placement
  - Outsourcing behavior: services outsourced, vendor selection, reasons for outsourcing
  - Size and source of Medical Affairs budget
  - Future predictions for the department

- Qualities of successful Medical Affairs employees

- Medical Affairs goals and clinical trial involvement

- Best practices for:
  - Hiring
  - Clinical trial involvement
  - Global and regional communication
  - Department structure and function

How you can use this report:

- Determine where your company’s approach to Medical Affairs may be different from a typical industry approach and the benefits and drawbacks that may result.

- Gather information on unique Medical Affairs structures or philosophies employed by other organizations to provide a new perspective from which to consider your company’s philosophies.

- Benchmark your company’s metrics for the size of the Medical Affairs department and budget against those of other companies.
# Table of Contents

## Copyright and Usage Guidelines

## Methodology
- Respondents’ Company Size
- Interviewee Titles
- Interviewee Responsibilities

## Introduction

### Understanding the Medical Affairs Function

#### Medical Affairs Employees
- Educational Background
- Employee Qualities
  - Specific Qualities of Medical Affairs Employees
- Key Takeaways

#### Medical Affairs Goals and Involvement
- Medical Affairs Goals
  - Top Medical Affairs Goals
  - Goals Related to the Company
  - Goals Related to Product Stakeholders
  - Goals Related to Patients
- Clinical Trial Involvement
  - Actual vs. Desired Medical Affairs Involvement Timeline
  - Barrier to Earlier Involvement
- Key Takeaways

#### Medical Affairs Department Benchmarking

##### Division of Work
- Global Medical Affairs vs. Regional Medical Affairs
  - Global Medical Affairs
  - Regional Medical Affairs
- Deviations from Typical Work Flow
- Best Practices for Collaborating on Medical Affairs Work
- Key Takeaways

##### Department Structure
- Common Medical Affairs Global Structure
  - Medical Strategy and Department Leadership
  - Specialized Functions
- Unique Global Medical Affairs Structures
  - Portfolio Team
  - Patient Focused Teams
  - Checks and Balances
- Regional Structures

- Headcount
  - Number of Worldwide Medical Affairs Employees
  - Key Takeaways

##### Organizational Alignment
- Research & Development
- Executive Leadership
- Business Development
- Commercial
- Comparison of Medical Affairs Placements
  - Key Takeaways

##### Outsourcing Behavior
- Services Outsourced
- Is Department Size a Factor?
- Reasons for Outsourcing
  - Limited Resources
  - Strategic Decision
- Vendor Selection
  - Process for Selecting Vendors
- Vendor Attributes
  - Work-Related Attributes Mentioned Most Often
  - Customer Experience Attributes Mentioned Most Often
- Key Takeaways

##### Medical Affairs Budget
- Size of Budget
- Changes to the Medical Affairs Budget
- Source of the Budget
- Insufficient Budget
  - Key Takeaways

##### Challenges
- Demonstrating Value of Medical Affairs
- Effectiveness Metrics
- Compliance
- Talent Management
- Establishing Medical Affairs Planning Process
- Access to the Medical Community
- Key Takeaways

##### Future Predictions
- Increased Sophistication
- Patient Focus
- Increased Prominence

### Best Practices and Recommendations

About Industry Standard Research
Medical Affairs, as a function, sits at a crossroads in the pharmaceutical industry. The department is expected to act as a bridge between the commercial and scientific arms of an organization. Medical Affairs is further tasked with being the conduit of information between the company and external stakeholders, bringing efficacy and safety data to the medical community as well as gathering insights from the medical community to share internally. All responsibilities must be undertaken while keeping in mind strict regulatory controls and ensuring that medical data are interpreted appropriately.

If this sounds like a big job, that's because it is. Industry Standard Research interviewed 15 experienced decision-makers to get a better grasp on the Medical Affairs function. These professionals shared their perspectives on topics such as the role of Medical Affairs within their organizations, how their departments are structured, how the function interacts with other departments within their companies, and key challenges faced by Medical Affairs. ISR also collected figures for department headcounts, budgets, and outsourcing volume.

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Employee Qualities

Specific Qualities of Medical Affairs Employees

**Ability to communicate data**

**Clinical experience**  
An understanding of science

**Attention to detail**

**Experience as a KOL or MSL**  
Ability to learn on-the-go

**Interpersonal skills**

Because Medical Affairs straddles both the commercial and clinical sides of the organization, the qualities of the employees reflect a blend of both sides. Having clinical experience was consistently referenced as a preferred quality of employees. Whether this means being involved in medical research or having experience as a practicing physician, most employees were at least familiar with the language and processes of clinical development. "We want people who have at least spent a year or two in a medical decision making capacity since they will be faced with medical and ethical decisions regularly," said a respondent from a Top 25 company. Multiple companies expressed the sentiment that while medical or clinical experience is preferred, it is not necessarily required since many of the Medical Affairs responsibilities are learned on the job. One respondent from a Top 50 pharma company even pointed out that his "star employee" was a PhD with little medical experience but had a variety of other qualities that made him a valuable asset to the department.

Although Medical Affairs employees are dealing with scientific questions, laboratory data, clinical trial results, and complicated medical regulatory requirements, they also have to communicate this data. Interpersonal skills were repeatedly stressed since maintaining relationships with KOLs, physicians, marketing employees, regulatory bodies, and leadership within the company represents a major function of the Medical Affairs department. Medical Affairs employees are "people who have strong data analysis skills and have the ability to communicate that data with other functions in the clinical development process," said a respondent from a Top 10 pharma company.

The value in a Medical Affairs employee is then the blend of medical/clinical familiarity and the ability to work well with others. The data and results with which Medical Affairs teams are asked to work are complicated and require a scientific eye, but being able to communicate that data to individuals both internally and externally that may not have the same level of medical knowledge is a skill sought by Medical Affairs departments.
Department Structure

Throughout ISR’s 15 interviews, it became clear that while there is no specific structure to which every Medical Affairs department adheres, most interviewees describe departmental structures with a fairly high degree of similarity. In this section, ISR will illustrate typical structures for a Medical Affairs department at Top 50 pharma organizations as well as depict a few ways in which structures vary from the norm.

Common Medical Affairs Global Structure

The majority of employees with whom ISR spoke described a structure similar to the chart below, with slight variations. The number of people in each level below Vice President will vary with the size of the department but the general structure frequently looks like this depiction. Medical Directors and others who work on the medical strategy for a brand are typically therapeutically aligned while there are separate groups for more specialized functions.

Scenario 1

Scenario 2

Separate groups not therapeutically aligned:

- Medical Communications
- Medical Operations
- Medical Publications
- Promotional Review
- Field / MSL
- HEOR
- Clinical Operations
- Medical Information
Vendor Attributes

Though much of what is outsourced is not medically or scientifically driven, a general familiarity with the clinical process was one of the most valued attributes of potential outside vendors. While many of the critical vendor attributes were business process related, customer experience also played a large role.

Work-Related Attributes Mentioned Most Often

ISR asked respondents what they look for in vendors when outsourcing particular Medical Affairs services and much of what was said had to do with the vendor's familiarity with the industry and whether or not they produce high-quality work. As one respondent from a Top 50 company put it, "We look at the quality of their work and their excellence... We want to be able to put them in front of a Key Opinion Leader and not be embarrassed of them."
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