

Building Best-in-Class Capabilities for Medical Affairs



Best Practices, LLC Strategic Benchmarking Research

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Research Objectives & Methodology

A strong Medical Affairs function is essential to meeting current challenges in clinical development, market education, and regulatory compliance. This research – which delivers current comparative metrics, executive insights, and best practices from Medical Affairs leaders throughout the industry - will help companies to improve effectiveness and create high-impact functions that drive business value.

Research Objectives:

- ✓ Illustrate how leading Pharmaceutical and Medical Device companies structure and organize their Medical Affairs functions based on industry and market changes.
- ✓ Identify trends expected to impact the allocation of resources across different Medical Affairs functions.
- ✓ Analyze how regulatory requirements are internalized and managed by Medical Affairs.
- ✓ Describe the success factors and top current challenges regarding Medical Affairs.
- ✓ Identify what percentage of MA budget leading companies allocate for outsourcing spending.
- ✓ Trace how successful Medical Affairs organizations work cross-functionally to enhance effectiveness.

Field Research & Insight Development:

- ✓ Sixty-eight survey responses from Medical Affairs leaders at 50 pharmaceutical and medical device companies in mature markets. The study includes an emerging market segment composed of 15 different respondents.
- ✓ Deep-dive interviews with 7 industry veterans.

Business Objective:

*Budget Allocation
Optimization*

*Medical Affairs Staff
Management & Effectiveness*

Universe of Learning: Research Participants from 2012

This study engaged 68 Medical Affairs leaders from 50 leading healthcare companies. The study also includes a longitudinal comparison with a previous study performed in 2009. Best Practices, LLC analysts conducted deep-dive interviews with seven participating executives to gather additional insights.

Benchmark Class: 2012



Full List of Participating Companies

This study engaged executives from 50 leading healthcare companies. Segmentation analysis was key to examining trends and effective practices. Within the Mature Markets Segment, 41 participants make up the Pharmaceutical Segment, while the Medical Device Segment consists of 12 participants. The Emerging Markets Segment consists of 15 participants working in India, China, Brazil, and Turkey.

Mature Markets Segment:

Pharma Segment:

Abbott	Genentech
Astellas	Gilead
AstraZeneca	GlaxoSmithKline
Baxter	Grunenthal
Baxter Healthcare	Guerbet
Biogen Idec	Ipsen
BMS	LifeCell
Cubist Pharmaceuticals	MAP Pharmaceuticals
Eisai	Methapharm
Endo Health Solutions	Mylan
Esteve	Novartis
Ferring Pharmaceuticals	Novo Nordisk
Forest	Onyx

Pfizer
Sanofi Pasteur
Shire
Shire HGT
Teva
UCB
Upsher-Smith Labs
Valeant
ViroPharma
Xanodyne

Medical Device Segment:

Baxter
Becton Dickinson
Bracco Diagnostics
Covidien
Ethicon
MedImmune
Medtronic
Novartis Vaccines and Diagnostics
Philips Healthcare
Roche Molecular Systems

Emerging Markets Segment:

Abbott	Covidien
Akron Molecules	Janssen
Alkem Laboratories	MSD Pharma
Astellas	Novartis
AstraZeneca	Ranbaxy
Bayer	Sanofi

Universe of Learning: Research Participants from 2009

In 2009, Best Practices, LLC conducted a similar study in which twenty-one leaders at 21 pharmaceutical and medical device companies provided data on their Medical Affairs function. To maximize current insights, this research spotlights key Medical Affairs trends which have occurred over the last three years.

Benchmark Class from Comparison Study: 2009



Participating Companies: Amgen, ApoPharma, Astellas, AstraZeneca, Auxilium, Bayer Healthcare, Bayer Schering Pharma, Becton Dickinson, Bristol-Myers Squibb, Cubist, Esteve, Genentech, Johnson & Johnson, Myriad, Novartis, Pfizer, ProCaps, Savient, Schering-Plough, Solvay, Vertex

Defining Medical Affairs and Key Functions

Best Practices, LLC conducted this cross-industry benchmarking study to identify best practices and innovative methods for developing a Medical Affairs function capable of meeting its diverse goals.

Medical Affairs: Refers to all the functions dedicated to building and maintaining relationships with physicians and the medical community, including, but not limited to, the following:

- **Medical Education:** Responsible for CME & educational grants.
- **Medical Communications & Publications:** Develops or reviews scientific/medical content--including medical journal articles--for communications to healthcare professionals, patients, consumers and payers. Develops/ manages publication plan. Includes Medical Info Call Center.
- **Medical/Clinical Research Operations:** Creates and guides strategy for clinical development programs. Develops and executes investigator and company-initiated clinical studies, including cost-marketing/ Phase IV studies. Includes Medical Directors.
- **Medical/Scientific Liaisons (MSLs):** Non-sales field force responsible for medical relations & training.
- **Outcomes Research:** Collects and analyzes Health Outcomes/ Economics data.
- **Pharmacovigilance/Safety:** Oversees the collection and analysis of information on adverse drug reactions.
- **Thought Leader Management:** Responsible for the identification, recruitment and development of physicians who can influence the medical perspective and practice of their peers.

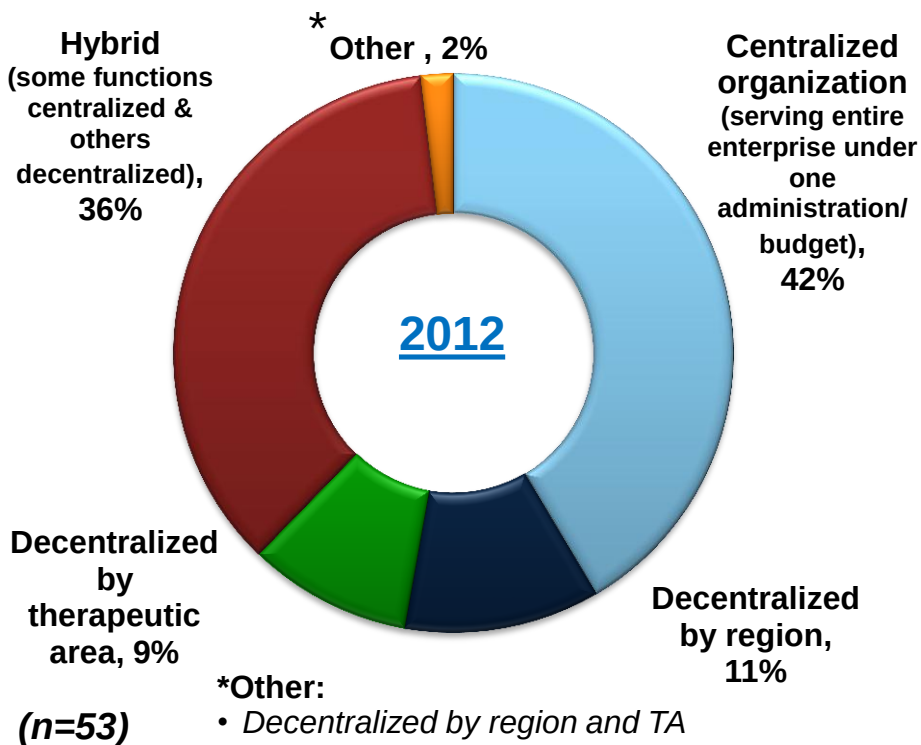
Medical Affairs Structure Typically Centralized

Nearly half of study participants favor a centralized approach for their Medical Affairs structure in 2012, as they did in 2009 as well. A slight trend toward greater decentralization of certain MA functions was observed, mainly due to varying regulatory hurdles encountered within different regions or therapeutic areas.

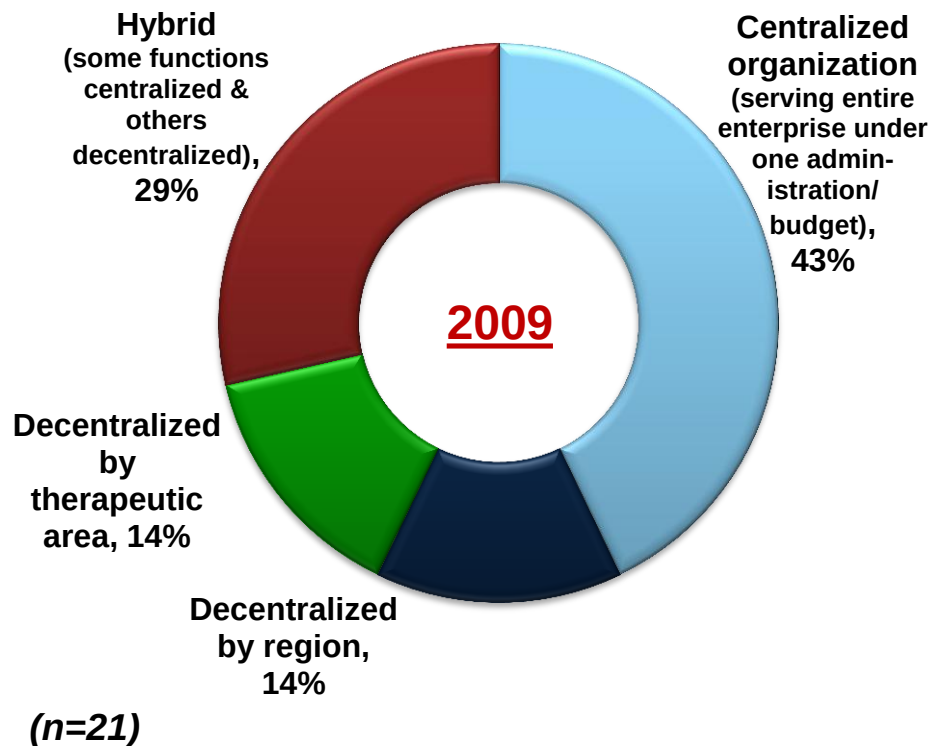
Q. Which of the following best describes the current structure of Medical Affairs at your company?
(choose one)

Current Structure

Mature Markets Segment:



Mature Markets Segment:



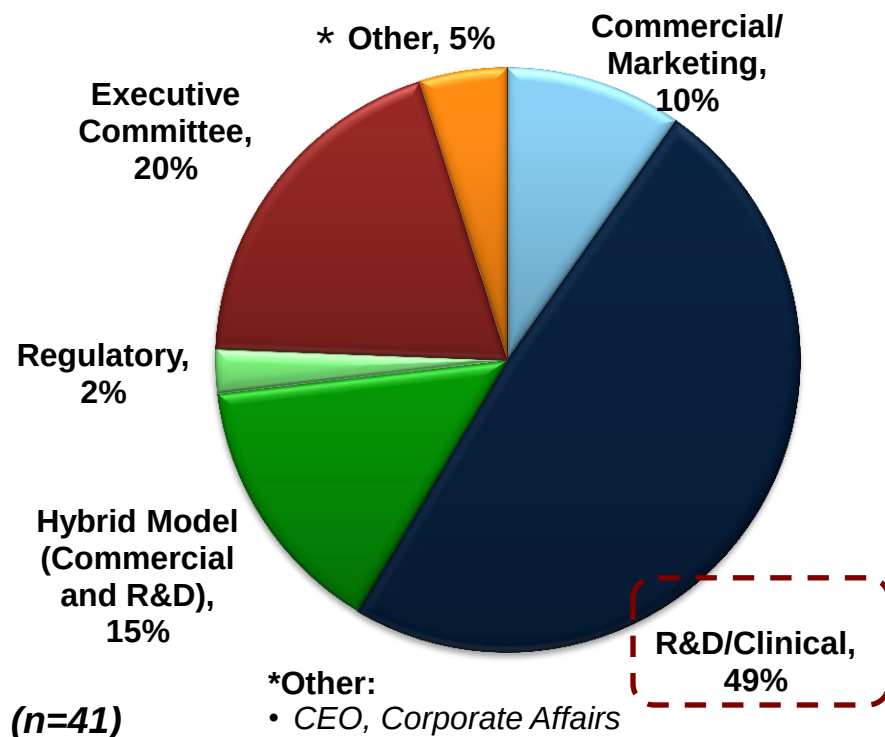
Pharma Medical Groups Often Subsumed into R&D / Clinical

Pharma companies are far more likely to report into R&D/Clinical than their medical device counterparts. Medical device companies mainly report into Executive Committees, as 8 out of 12 respondents noted, whereas 49% of pharma companies report into R&D/Clinical. In general, the trend is for Medical Affairs to separate itself from Commercial.

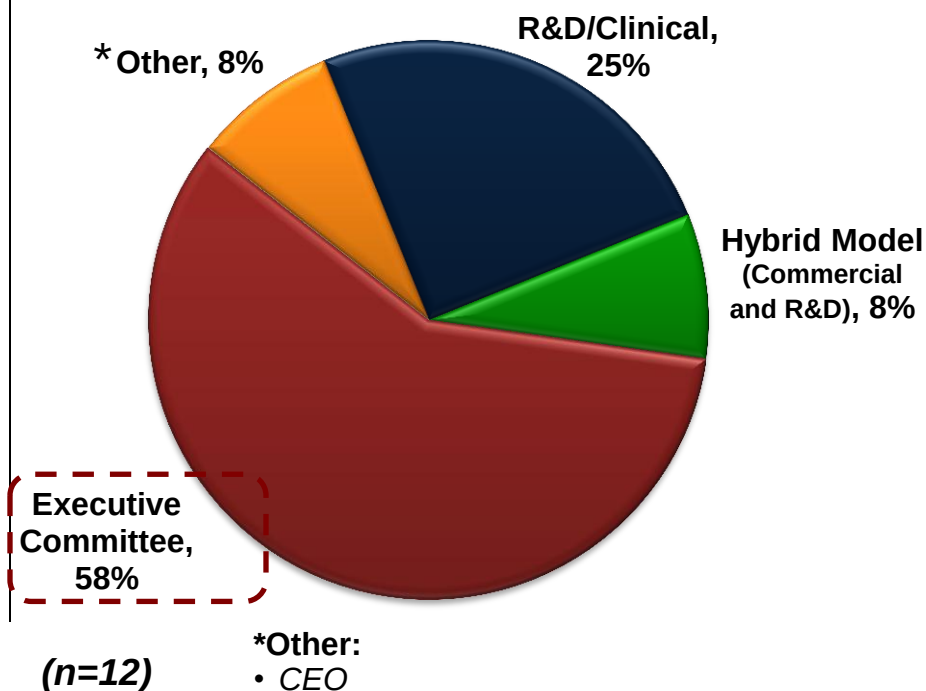
Q. To which group does Medical Affairs report? (choose one)

Reporting Relationship

Pharma Segment:



Medical Device Segment:



Top Medical Affairs Groups Tied to R&D and Commercial Alike

Internally, Medical Affairs serves as an essential bridge between the R&D and Commercial organizations. Externally, Medical Affairs engages providers, payers, and policymakers about issues of shared concern such as the development and use of real-world evidence.

Medical Affairs teams today play a key role in the information flow between the Commercial and R&D operations.

Commercial



- The changing healthcare environment has encouraged the formation of independent Medical Affairs departments.
- However, there is not a rigid set of requirements that dictate how a Medical Affairs department should look or operate.
- As a result, the industry has developed a wide variety of models, all seeking to address intensified public and regulatory scrutiny.

R&D



“Structure doesn’t matter. Medical Affairs needs to be tightly connected to commercial on one hand and R&D at the other. It is not a choice of ‘either or,’ it is really a choice of always ‘both.’ The best Medical Affairs teams have ties to both sides of the company.”

- Interviewed Vice President

Transparency, Coordination, & Alignment Ensure Effective Coordination Between Medical & Commercial

Within any pharmaceutical or medical device organization, there are a host of competing interests as different groups try to demonstrate their value. However, a successful Medical Affairs group is able to navigate through politics and help present a credible message and unified image on behalf of the entire organization.

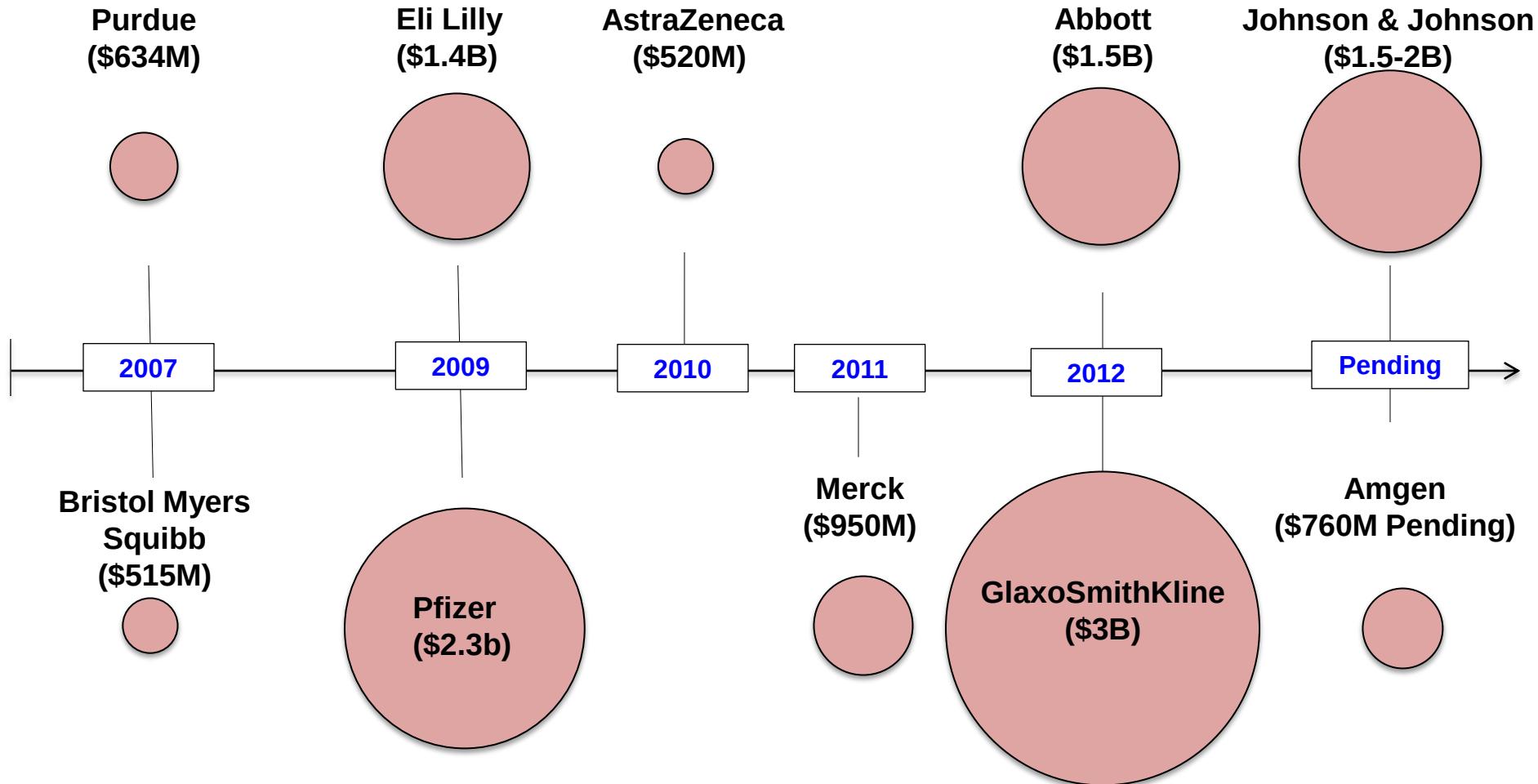


“People have come from different cultures and we are learning, melding and adapting what are the appropriate interactions between commercial and scientific affairs. We keep it pretty separate, but we want to make sure that we look like one entity to our customer. If there is a major event coming up, we want to avoid that the same physician isn’t being contacted by five different parts of the organization. Ultimately, it is about awareness, transparency, coordination.”

- Interviewed Senior Director

Top 10 Biggest Pharma Settlements Since 2007

Many top pharma companies have been forced to agree to large settlements as their marketing strategies and tactics diverged from various compliance standards. Medical Affairs can play a critical role in rehabilitating the credibility of drug manufacturers with regulators, physicians, patients, and payers. For more information, see slide 114.



Pharma Companies See Medical Information Conduit as Critical to Medical Affairs Future

Every Medical Affairs organization is unique. While a few companies are making disproportionately large investments in Clinical Research Operations, Medical Communications and Medical Education, many other pharma Medical Affairs groups are shifting their budgetary focus toward direct relationship based interactions.

Q. What percentage of the total Medical Affairs spend (above) was allocated to each of the following functions in the most recently completed fiscal year? (Total should equal 100%)

Pharma Segment: Spending Breakout

	Medical Communications & Publications	Medical Education	Medical/ Clinical Research Operations	Medical/ Science Liaisons	Outcomes Research	Pharmacovigilance/ Safety	Thought Leader Management	All Other
Max	44%	40%	94%	70%	35%	30%	30%	50%
75th Percentile	15%	20%	40%	30%	9%	10%	15%	7%
Mean	13%	15%	25%	19%	7%	5%	10%	6%
Median	10%	13%	15%	18%	5%	0%	10%	0%
25th Percentile	5%	5%	6%	5%	0%	0%	5%	0%
Min	0%	0%	0%	0%	0%	0%	0%	0%

(n=30)

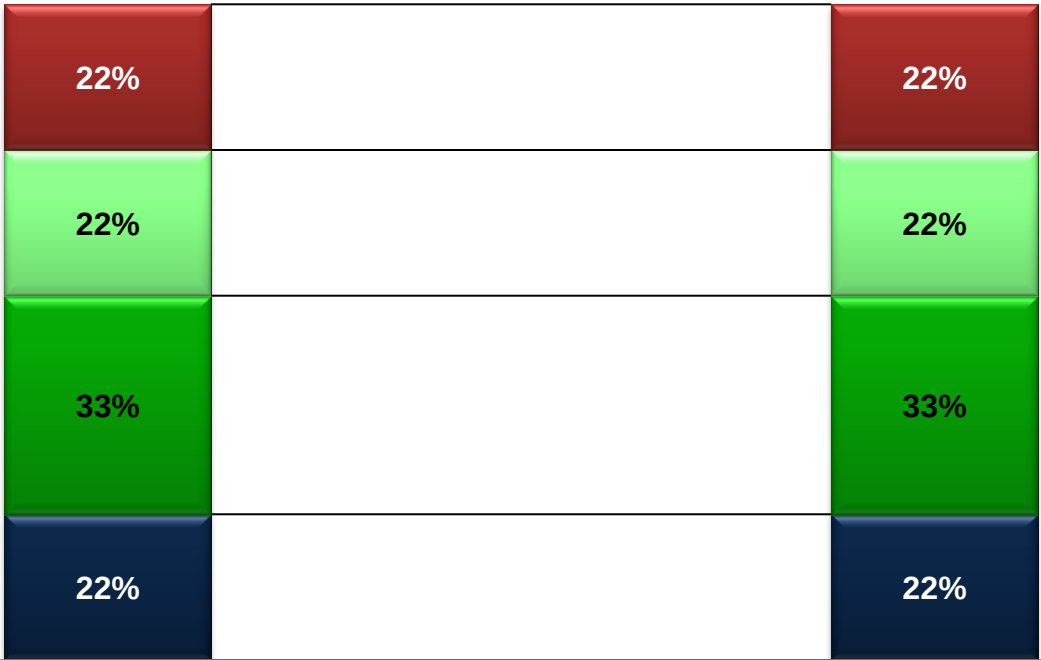
Emerging Market Headcount Consistently Growing

Within the emerging market segment, 33% of companies forecast no headcount growth, while 44% predicted FTE increases and 22% predicted FTE decreases heading into 2013. Again, there seems to be a wide distribution among companies in the emerging market segment, as noted on budgetary questions as well.

Q. What changes have you experienced in budget and FTE resource levels between the past and current fiscal years (2011 to 2012) and what change level do you anticipate between the current year and 2013?

Emerging Market Segment: FTE Level Changes

Decrease by >10% Decrease by 1-10% Stay the Same Increase by 1-10% Increase by >10%



(n=9)

Actual FTE # change from 2011 to 2012

Estimated FTE # change from 2012 to 2013

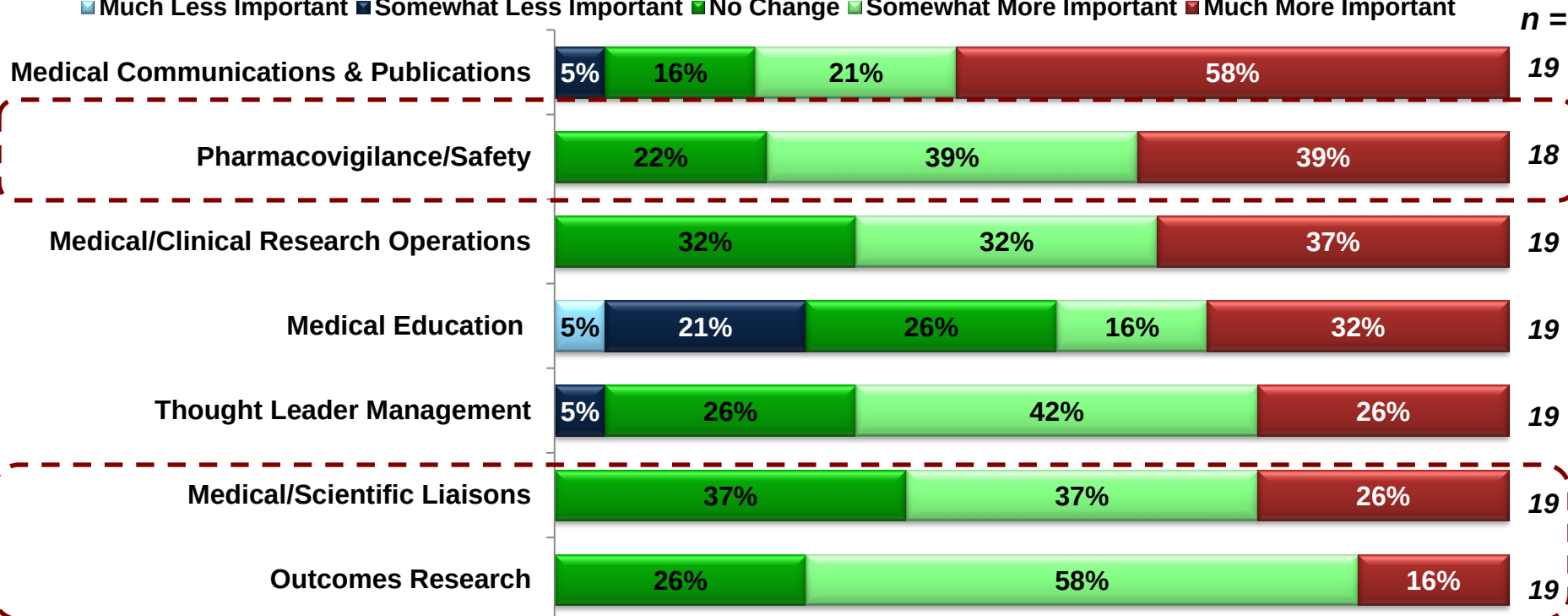
Mature Markets 2009: Medical Communications & Publications on the Rise

In 2009, a majority of the mature market segment believed Medical Communications & Publications was becoming much more important to overall success of the company. In stark contrast to the 2012 perspective, Outcomes Research and MSLs are not rated as important in driving success.

Q. In your recent experience, have the following Medical Affairs functions become more or less important to the overall success of your company? (choose one response for each functional area)

Mature Markets Segment 2009: Importance of Medical Affairs Functions

■ Much Less Important ■ Somewhat Less Important ■ No Change ■ Somewhat More Important ■ Much More Important



Learn More About Our Company:



Best Practices®, LLC is an internationally recognized thought leader in the field of best practice benchmarking®. We are a research, consulting, benchmark database, publishing and advisory firm that conducts work based on the simple yet profound principle that organizations can chart a course to superior economic performance by leveraging the best business practices, operating tactics and winning strategies of world-class companies.

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