The Role of Medical Affairs in The Value-Based Healthcare Ecosystem

Best Practices, Strategic Benchmarking Research & Analysis

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Over 70 Experts Worldwide Contributed to This Study Through a Survey, Interviews and a Roundtable Meeting Discussion

Benchmark Study Companies

Medical Affairs Role In The Value-Based Healthcare Ecosystem

ISSUE

BUSINESS ISSUE: Payers, Physicians, Patients and other key stakeholders are increasingly considering **v**alue beyond clinical effectiveness and safety in their decision making. Medical Affairs organizations must respond to this new value-based healthcare ecosystem. In support of this business issue, This study assesses:

- The Effect of External Value-Based Mindsets
- Medical Affairs Role In the Value-Based Ecosystem
- Value-based Activity Prioritization
- Key Facets of External Collaboration & Engagement
- Progressing Value-Based Internal Collaborations
- Medical Affairs & Value Based Contracts
- HEI & FDAMA S114
- Success Factors & Pitfalls for Value-Centric Operations

METHODOLOGY: Best Practices, LLC engaged 70 industry professionals from 50 companies through a benchmarking survey, focus group interviews and round-table discussion.

All data has been sanitized and aggregated for the confidentiality purposes.

ANALYSIS

Select key insights uncovered from this report are noted below. Detailed findings are available in the full report.

1. 4 organizational emphases to the value-based ecosystem emerged :
    1. Optimizing data acquisition strategy to address key value-levers
    2. Developing holistic value propositions for external engagement
    3. Internal value-based collaboration
    4. Prioritizing patient centricity

2. Priority internal collaborations start with Market Access. Top collaborations are executed by co-developing the medical value story, supporting dossier & HTA submissions

3. Medical Affairs takes a supportive role with Value-based contracts. VBCs are anticipated to grow for more complicated treatments, calling for greater Medical Affairs involvement

4. The primary benefit of FDAMA S114 has been increased proactivity with HEI for payers. Head-to-head trials were ID'd as the most essential HEI type, although only 52% of companies proactively share these

Medical Affairs Can Bridge the "Value Gap" Through…

01 **Optimizing Data Acquisition Strategy & Supporting Evidence Gaps with RWE, Ph. IIIB/IV, HEI**

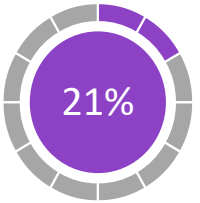
02 **Prioritizing Patient Perspectives of Value**

03 **Supporting & Aligning Value Narratives Internally**

04 **Communicating Holistic Value Propositions Across External Groups**

A Patient Centric Approach Can Change The Perceptions of Value Among Multiple External Stakeholder Groups

Q5. Please tell us how your Medical Affairs group operates in a value-based environment?



4 **Prioritizing Patients**

- Medical Affairs must serve as the voice of the patient across strategic value-based initiatives
- Patient centricity, engagement, and partnership with advocacy can significantly influence a broad group of external decision makers
- Patient reported outcomes should form a part of value-based data acquisition strategy

- We have to bring value to patients. To do this we have to understand our patients holistically, understand the disease , understand their unmet needs, ultimately understand the Patient flow throughout
- We identify value as patient experiences and patient outcomes. MA's role therefore is to utilize their skills and experience to drive strategy and initiatives in those domains in a cross functional manner
- Medical Affairs brings patient centricity to strategic initiatives with real world outcome based studies and accompanying communications

Success in This Changing Value-Based Environment Will Require Medical Affairs to Partner Extensively

Q9. In your experience, which internal group(s) must Medical Affairs work with to succeed in this new value-based environment?

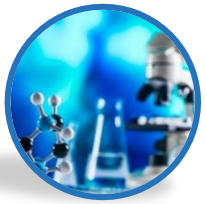
Internal Partners

Market Access:
95%

Patient Advocacy:
82%

Top 5 Internal Collaborations

Clinical Development:
82%



Compliance:
68%

Government:
64%

"My group is a payer focused medical team that is really working with regional and national payer audiences. We're talking about the whole value proposition, whether it be for a value based contract or any other kind of value driven component of that. In collaboration, There's two components that are critical. One is that we do have to work closely with Access & HEOR as we're talking about these value-based propositions and we need to bring in their expertise.

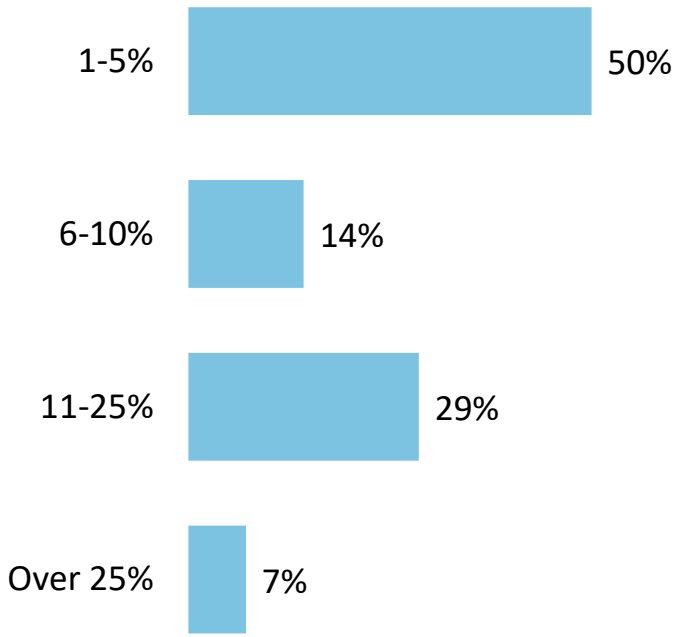
"But as important or maybe even more important, we have to have the medical component as part of that discussion. For example, if we're talking about any kind of outcomes based contracting or value based contracting, if we don't have solid clinical end points, either based on our phase three clinical trials or other things we're seeing in the real world to support those VBCs, it won't move forward. As such, Medical is really an integral component of those conversations."

Executive Director, Medical Affairs

Value Based Contracts Continue to Grow Within Organizations

Q17. Roughly, what percent of product contracts are value-based contracts at your company?

% of Contracts Under Value-Based Contracts



N=14

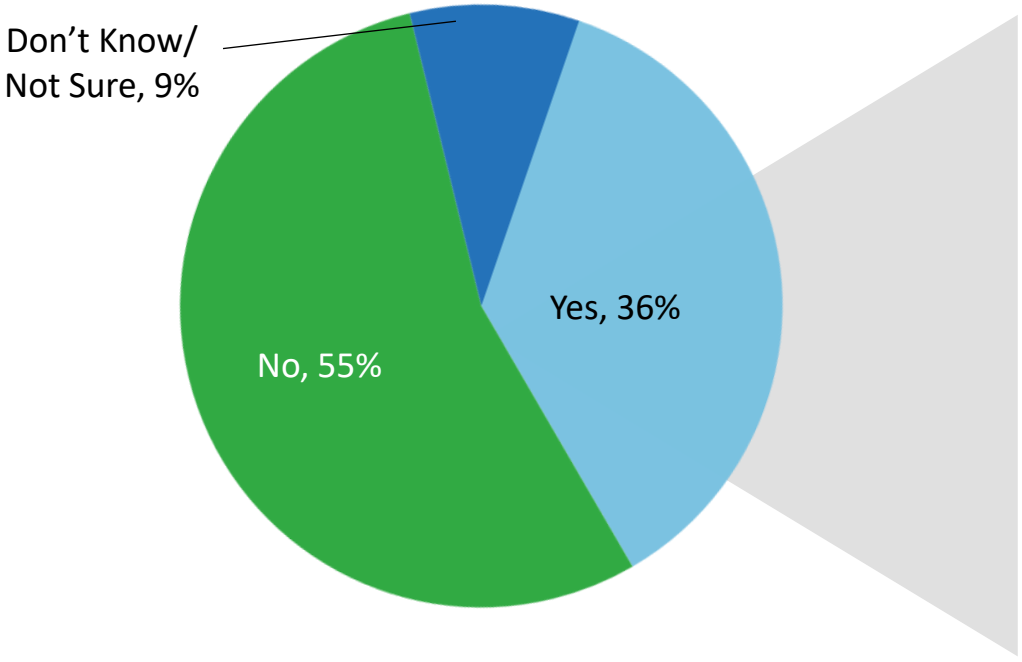
N=15

Only 1/3 Of Medical Affairs Organizations Find a Positive Impact from FDAMA S114, With Benefits Predominantly Due to Increased Proactivity

Q25. Has your group so far benefited from the amendments to S114 of FDAMA?

Q26. How has your group so far benefited from FDAMA S114 amendments?

Medical Affairs Benefitted from FDAMA S114



Benefits from FDAMA S114

- *"Possibility to communicate evidence-based indirect treatment comparisons"*
- *"Ability to proactively communicate HEOR data"*
- *"Pre-PDUFA proactive initiatives"*
- *"Possibility of broader use"*

N=22

Most Medical Experts See Positive Changes On the Horizon to FDAMA S114

Q29. What do you think are the highest potential changes to FDAMA S114?

Potential Changes to FDAMA S114

Classify on-label vs off-label products

Clarify the appropriate audience

Broaden the definition of economic benefit to value benefit

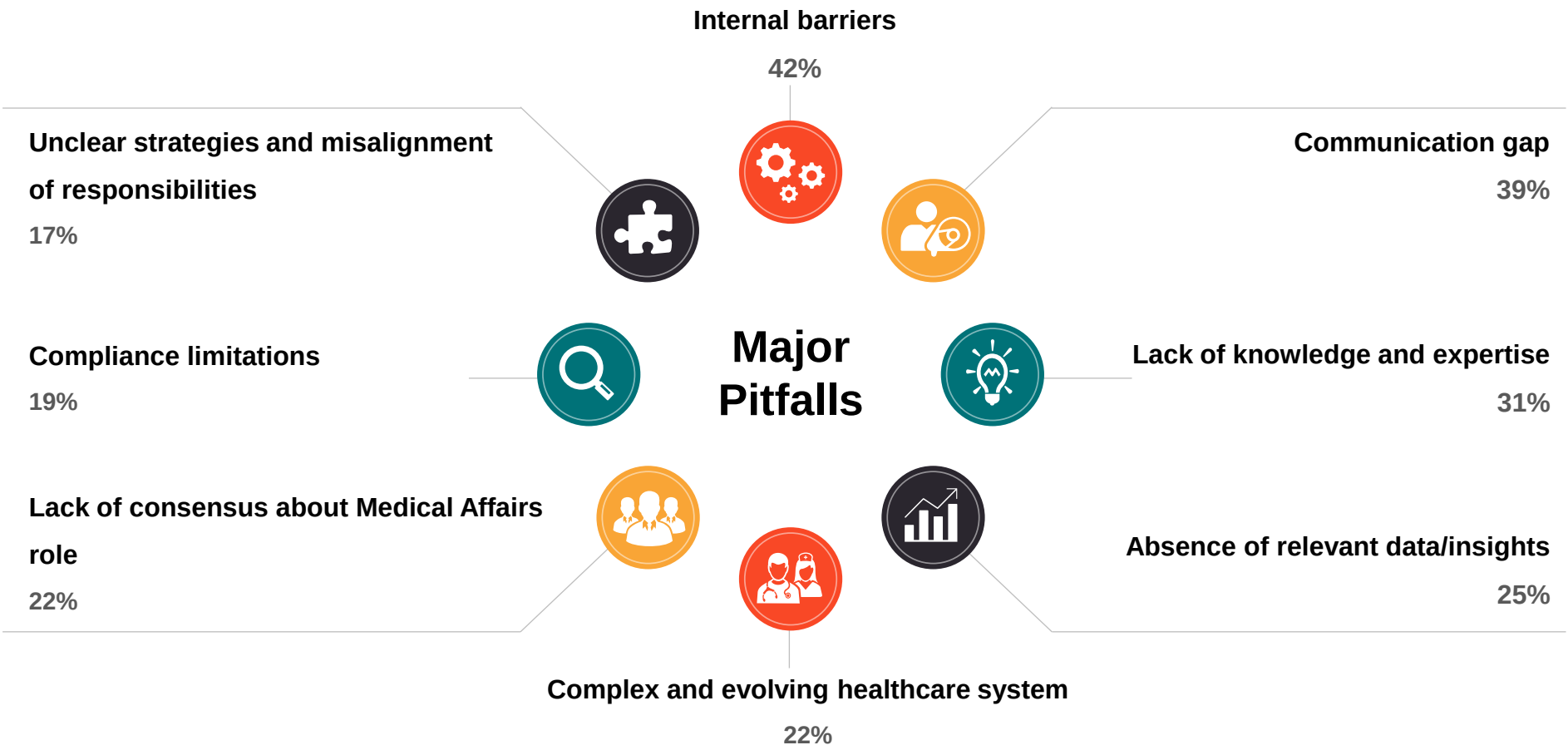
Expand types of tools to communicate the value of interventions

Focus on timeliness of data collection

Make more patient centric and RWE data available

Internal Barriers, From Resourcing to Value-Focused Collaboration Are Major Pitfalls

Q33. What are the major pitfalls for Medical Affairs preventing value delivery?



N=36

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