

Strategic Medical Affairs Outsourcing: Pragmatic Solution in A Fast-Changing and Resource-Constrained World

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Abstract

This review explores the advantages of strategic medical affairs outsourcing and introduces 'Medical Affairs Consultation' as a pivotal concept. The pharmaceutical industry grapples with challenges such as regulatory complexity, cost pressures, and limited internal resources, requiring expertise in various domains. Medical affairs consultation empowers companies to navigate these hurdles, optimize costs, and expand geographically. The global market for medical affairs outsourcing is growing rapidly, presenting significant opportunities, particularly in the pharmaceutical sector. Outsourcing promotes agility and adaptability in this evolving healthcare landscape, while digital platforms enhance collaboration and information sharing on a global scale. However, careful risk evaluation and proactive management are essential for successful medical affairs outsourcing. Various outsourcing models cater to diverse organizational needs, allowing efficiency and effectiveness in specific functional areas. The future of outsourcing in India holds promise, driven by its skilled workforce, internet accessibility, and cost-efficiency.

Keywords: Medical affairs outsourcing, medical strategy, Medical strategic consultation, Medical strategic outsourcing, medical affairs consultation

Introduction

The healthcare sector is rapidly evolving due to a growing need for evidence-based decision-making and advancements in technology. Medical affairs play a vital role in providing reliable information to healthcare professionals and overseeing interactions with key opinion leaders and stakeholders.[1] However, healthcare companies face challenges in efficiently managing their medical affairs operations due to resource constraints and increasing regulatory complexity.[2] Outsourcing specific functions within medical affairs, such as medical writing, publication planning, and key opinion leader engagement, has gained traction to support product development, clinical research, and commercialization efforts. External service providers bring expertise and best practices, relieving the internal teams' workload. Careful selection and management of outsourcing partners are crucial to ensure high-quality output, compliance with regulatory requirements, and alignment with strategic goals.[3] Effective communication and collaboration between internal and external teams are essential for seamless integration and workflow.

This review focuses on strategic medical affairs outsourcing and its benefits in a resource-constrained, rapidly changing healthcare landscape. We introduce the term 'Medical Affairs Consultation' to emphasize the strategic outsourcing of medical affairs activities like medical consultation where doctors diagnose and manage medical conditions for patients, 'Medical Affairs Consultation' involves expert analysis and effective management of healthcare companies' needs to enhance scientific communications and developments.[4]

What is Medical Affairs Consultation?

Medical affairs consultation refers to a specialized advisory service provided by qualified healthcare professionals with expertise in medical affairs. It involves engaging external medical affairs consultants who possess in-depth knowledge and experience in various aspects of medical affairs, including medico-marketing activities, medical affairs strategy, stakeholder engagement, scientific research, clinical development, regulatory affairs, medical information, and pharmacovigilance.[5] These experts collaborate with internal teams to address specific challenges or opportunities related to product development, market access, and post-marketing activities to manage the product life-cycle activities.[6] Figure 1 depicts several functions that can be outsourced in medical affairs consultation.

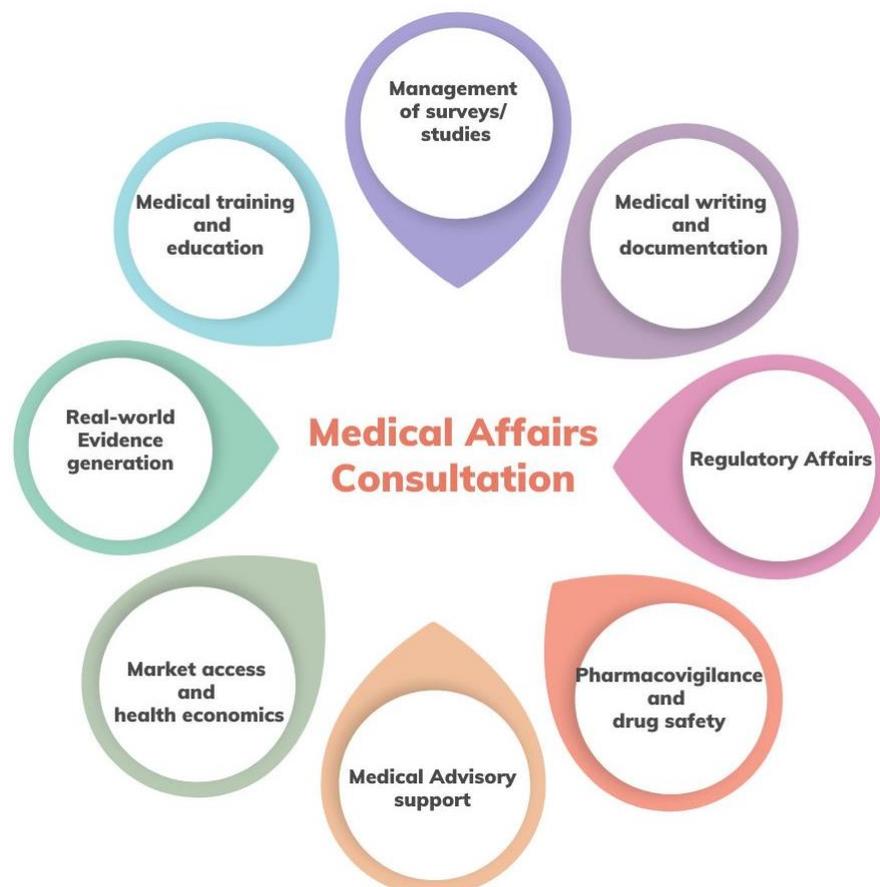


Figure 1. Functions that could be outsourced in medical affairs consultation

Current Status

The pharmaceutical industry faces significant challenges, necessitating the adoption of medical affairs consultation. Challenges include increasing regulatory complexity, cost pressures, resource constraints,

cyber threats, and data breaches.[4] Expertise demands in areas like clinical trials, regulatory affairs, and pharmacovigilance often surpass internal talent availability. In this dynamic era, medical affairs requirements constantly evolve, amplified by social media promotion. Outsourcing taps into a broader talent pool, augmenting internal teams and enhancing efficiency.[7] Figure 2 illustrates the decision-making context for outsourcing to Asian regions, aiding value chain optimization and leveraging expanding markets.

Addressing challenges via medical affairs consultation empowers pharmaceutical companies to navigate complexities, optimize costs, access specialized talent, and expand geographies.

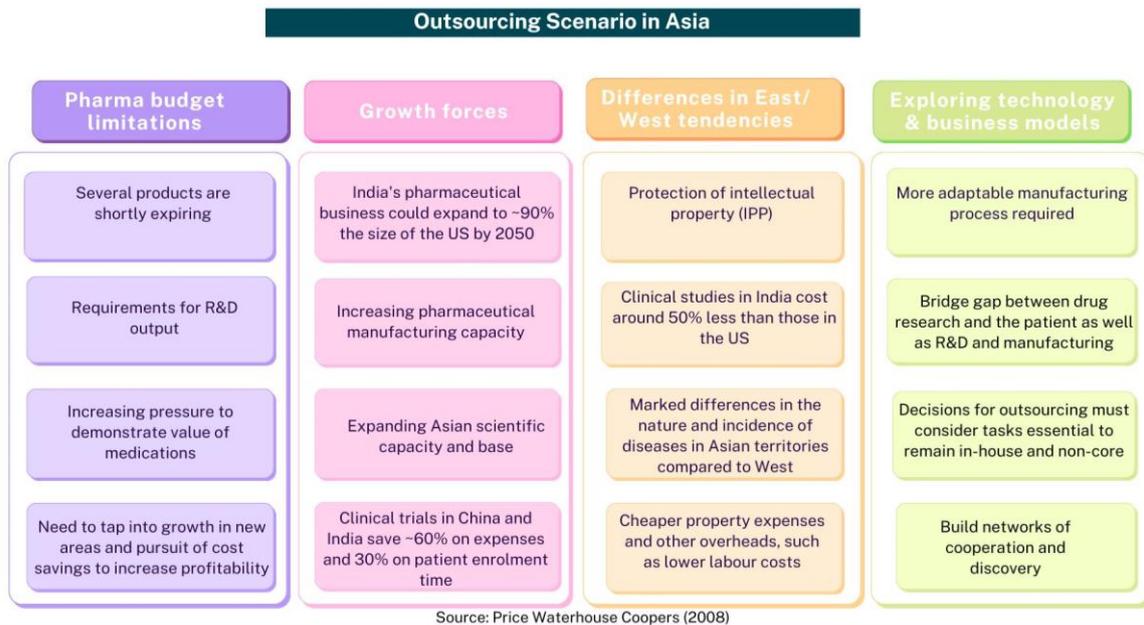
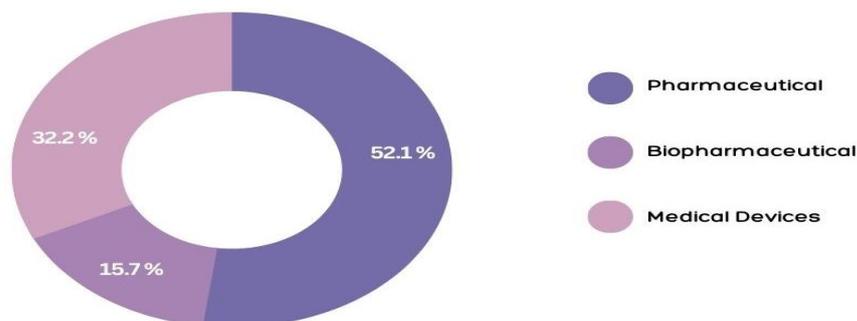


Figure 2. Factors involved in decision-making regarding pharmaceutical outsourcing

Medical affairs consultation gains acceptance as companies increasingly adopt outsourcing to optimize operations in the complex healthcare landscape. The global medical affairs outsourcing market was valued at USD 1.7 billion in 2022, expected to grow at a CAGR of 13.6%.[7] The market expansion is propelled by the rising incidence of diseases, augmenting demand for novel pharmaceuticals, medical equipment, and outsourcing services. Pharmaceuticals account for the largest revenue share, 52.1% in 2022, and are expected to maintain this position (Figure 3).[8]

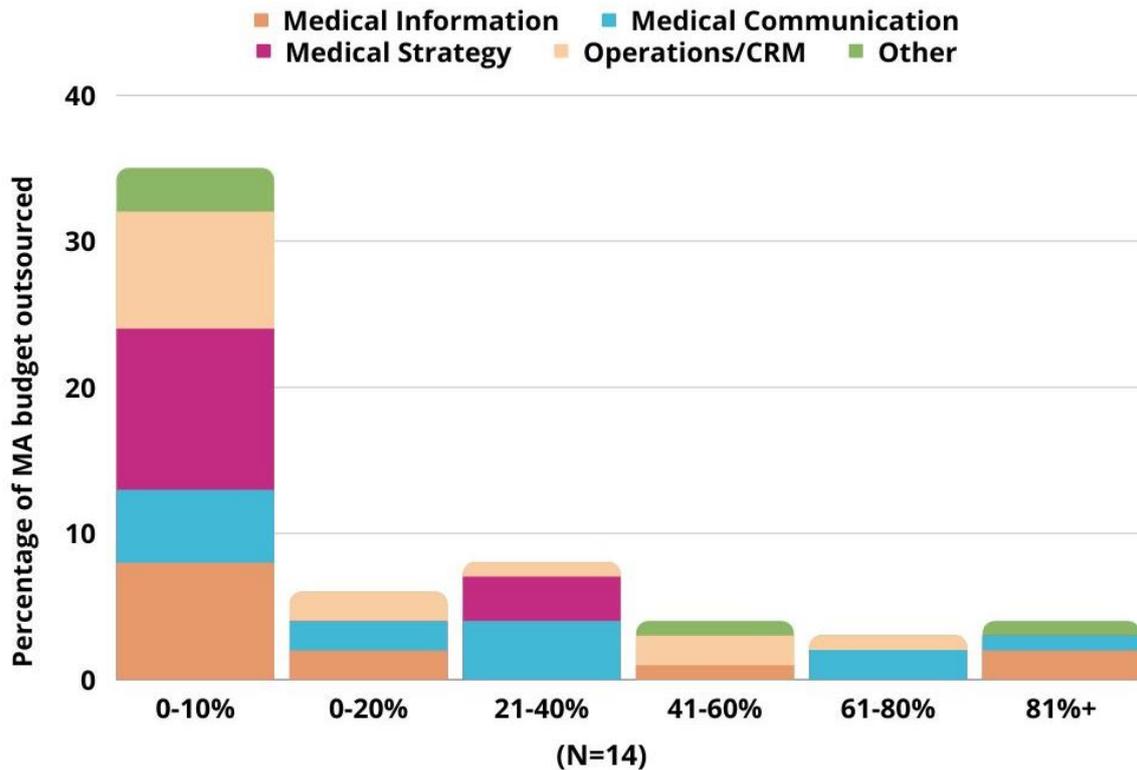
\$ 1.7 Billion, Global Market Size, 2022



Source: Market Analysis Report, Grand View Research (2022)

Figure 3. Medical affairs outsourcing market globally

China and India's pharmaceutical outsourcing markets exhibit significant growth potential, driven by their expanding economies.[7] India's pharmaceutical outsourcing sector is valued at over 20,000 crores, projected to double in the next five years.[9] A 2021 survey by the Medical Affairs Professional Society (MAPS) highlights a growing need to enhance productivity and operations in medical affairs organizations (Figure 4).[10] The sector currently dedicates a small portion of the budget and time to medical affairs operations, indicating room for growth and efficiency enhancement.



Source: MAPS Benchmarking Survey (2021)

Figure 4. Medical affairs outsourcing capabilities

Benefits

Medical affairs consultation offers healthcare organizations the advantage of focusing on core competencies while delegating specialized functions to external providers, enhancing operational efficiency and reducing the burden on internal teams. This strategic approach allows for agility and adaptability in the dynamic healthcare landscape. Moreover, it provides access to specialized professionals with specific expertise and knowledge, ensuring high-quality deliverables and compliance with industry regulations.[10]

Cost savings are another significant benefit, as organizations can avoid infrastructure investments, technology costs, training, and overhead expenses, accessing highly trained experts at a lesser overall cost. In critical milestones like product launches, strategic outsourcing of medical affairs becomes vital for success. It encompasses extensive clinical research, regulatory approvals, market access strategies, and comprehensive marketing campaigns.[11] Considering the substantial costs involved in product development and launch, outsourcing proves financially prudent.[12]

Post-launch and throughout the product life cycle, outsourcing medical affairs functions offers benefits like effective management of post-marketing activities and leveraging specialized resources for real-world

evidence generation.[13] Outsourcing enables flexibility and scalability, allowing organizations to adjust resources according to fluctuating needs, and efficiently adapting to changing requirements.[14] Additionally, for expansion into new markets, outsourcing medical affairs services proves invaluable in navigating varying regulations, cultural norms, and language requirements.

The Role of Digital Platforms for Outsourcing in the Global Village

Digital platforms and activities are crucial in today's interconnected world for facilitating and expediting the outsourcing process, especially in the context of the "global village". Marshall McLuhan came up with the term global village to describe how technology and electronic communication have caused the world to become smaller, allowing for connectivity and collaboration on a worldwide scale. Digital activities and platforms have numerous benefits that make outsourcing easier, more effective, and more affordable.[15]

Healthcare firms can easily and effectively engage with outside service providers through digital platforms. Companies can identify and work with competent individuals and service providers from all over the world via online outsourcing platforms, such as freelancer marketplaces or specialized platforms for medical affairs outsourcing. These platforms make it simpler to share information, manage projects, and communicate securely, which makes it simpler to find compatible partners, negotiate deals, and work remotely. [16]

Regardless of geographical location, real-time collaboration and information sharing are made possible by digital activities and tools. Pharmaceutical firms and their outsourced partners may easily communicate and collaborate thanks to cloud-based document management systems, video conferencing capabilities, and project management software. Due to the effective exchange of project updates, data, and documents made possible by this, barriers due to distance are removed and effective teamwork is promoted. [17]

Additionally, digital platforms and activities offer improved data security and privacy protections, both of which are essential in the outsourcing process. Secure file sharing, strong encryption, and compliance with data protection laws guarantee the security and integrity of sensitive information shared between pharmaceutical businesses and their outsourcing partners.[18]

Impact of Pandemic on Virtual Working in The Outsourcing World

The COVID-19 pandemic significantly impacted the pharmaceutical industry, driving a surge in virtual work adoption due to social isolation needs. Swift shifts to remote work were essential for business continuity and employee safety. Digital tools enabled effective remote work, fostering efficient communication and collaboration. [19]

The pandemic accelerated outsourcing in the healthcare sector, allowing companies to bridge operational gaps and enhance drug development. Critical tasks like clinical trials, data analysis, and regulatory relations were outsourced to maintain productivity and accelerate vital medication delivery. This shift highlighted the benefits of outsourcing and virtual working, improving operational efficiency and flexibility while reducing costs. Digital technologies facilitated seamless collaboration, despite physical barriers, enhancing communication and project management. [20]

The pandemic advanced the implementation of telemedicine and online clinical trials, fostering more remote work and outsourcing in the pharmaceutical sector. Reducing the necessity for in-person visits and promoting continuity of care, telemedicine permitted virtual patient consultations and monitoring. To reduce the stress of site visits and increase patient engagement, virtual clinical trials made use of digital

platforms and remote monitoring technology to collect data from participants in their own environments. [21]

Risks And Challenges

Outsourcing medical affairs services can offer numerous benefits, but it also comes with certain risks and challenges that organizations need to be aware of.

The potential loss of control over crucial operations and decision-making procedures is one of the main issues with outsourcing medical affairs services. Organizations may have limited authority over some operations and strategic direction when relying on external providers. To reduce this risk, it is essential to create transparent governance frameworks and maintain strong oversight. [22] Additionally, the use of complementary workers from the outsourcing partner is a potential long-term solution where an employee can be outsourced to a medical advisor or medical science liaison position.

Successful collaboration between internal employees and outside vendors depends on clear communication. However, due to distance, time zone differences, or technical considerations, outsourcing medical concerns might cause communication problems. Poor communication was cited as the primary cause of outsourcing project failure by 28% of 1,000 respondents, according to a white paper published. [23] Inaccurate or delayed information flow can result in misunderstandings, delays, and less-than-ideal results.

Concerns regarding potential conflicts of interest may arise when using external contractors for medical affairs services. It is crucial to confirm that the outsourcing partner's interests coincide with those of the company. This also needs to be taken into consideration when working with multiple clients with competing interests or therapy areas. Clear guidelines, open contracts, and careful vendor selection can all help to prevent conflicts of interest and preserve the integrity of decision-making processes.

Maintaining regulatory compliance and quality standards while outsourcing can falter due to unawareness of external service providers with the quality requirements unique to the client. Businesses must make sure that the vendors they work with have strong quality assurance procedures, follow all applicable laws, and conform to accepted industry standards. To monitor and reduce quality and compliance concerns, regular audits and performance reviews are essential. [22]

Activities related to medical affairs entail handling sensitive and private data, such as patient information or any other personally identifiable information, findings from clinical trials, and proprietary knowledge. Organizations must set up strict data security protocols and confidentiality agreements when outsourcing medical affairs services to safeguard intellectual property and safeguard patient privacy. In compliance with the applicable laws and regulations, adequate safeguards must be in place to guarantee data protection, storage, and transfer. [24]

It can be difficult to establish a long-term partnership with an outsourcing partner and guarantee service continuity. To minimize disruptions and ensure continuous service, organizations must consider aspects including vendor stability, staff turnover, and succession planning. To promote collaboration, harmonize goals, and address any changing requirements or obstacles, effective relationship management is crucial. Organizations should carefully consider these risks and difficulties before outsourcing medical affairs services. These challenges can be reduced, and a successful outsourcing engagement can be ensured with the support of strong vendor selection procedures, transparent contractual agreements, efficient communication channels, and proactive risk management techniques. A summary of benefits and risks is outlined in Table 1.

Table I. Medical affairs outsourcing: summary of benefits and risks

Benefits	Risks and challenges
Ability to focus on their core competencies	Lack of complete control on day-to-day activities
Substantial cost savings	Issues with communication
Aid in pharmaceutical product launches	Conflict of interest
Helps in post-marketing activities	Quality control and compliance
Flexibility and scalability based on fluctuating needs	Data security and confidentiality
Allows to expand into new markets or regions	Management of relationships and continuity

Models

Different models of outsourcing medical affairs services can be adopted based on the specific needs and goals of an organization. Here are three common models to consider (Figure 5):

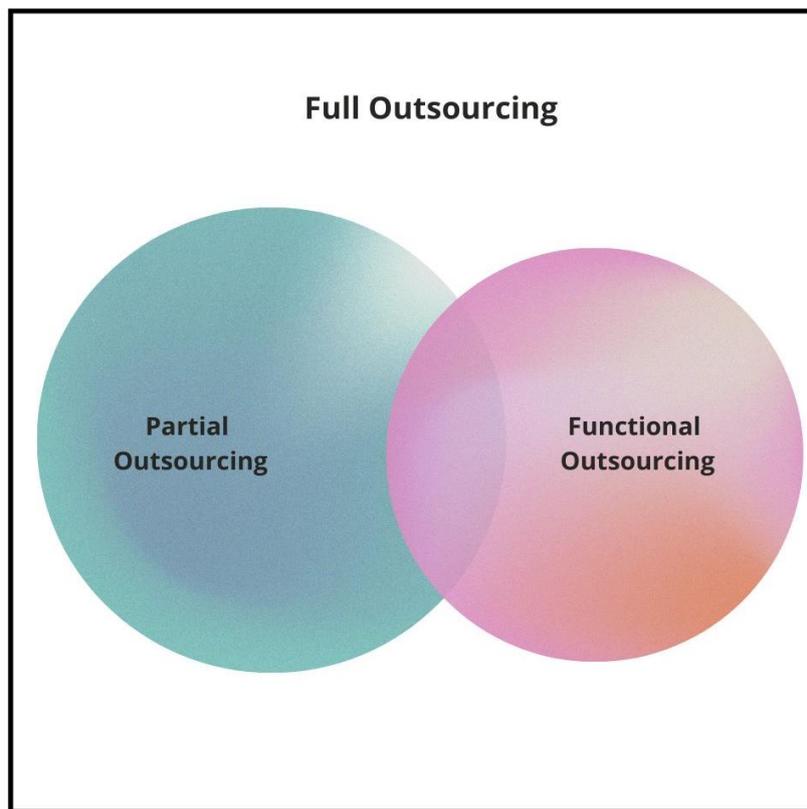


Figure 5. Models in medical affairs outsourcing

1. Full Outsourcing

In the full outsourcing model, an organization gives an outside vendor complete control over the medical affairs department or takes help from them to develop a fully functional medical affairs department. This covers all actions pertaining to medical strategy, scientific communication, evidence generation, stakeholder management, regulatory affairs and compliance. The vendor assumes full accountability for carrying out these duties on the organization's behalf. Full outsourcing can be advantageous for smaller

organizations or those looking for all-encompassing support and medical affairs expertise. It enables a streamlined process and the chance to properly utilize the vendor's resources and expertise. Early-stage and virtual businesses will tend to provide both clinical and nonclinical services using a full-service model. This is because in addition to the fundamental technical disciplines, they also require regulatory and project management knowledge built into the full-service model. [25]

2. Partial/Task-based Outsourcing

In the partial outsourcing model, selected components or subsets of the medical affairs function are outsourced to external contractors while other elements are controlled internally. This model allows organizations to retain control over certain critical functions while benefiting from external expertise and support in areas where additional resources or specialized knowledge are required. For example, an organization may choose to outsource specific activities such as medical information, publication planning, or regulatory submissions while keeping other functions in-house. Partial outsourcing provides flexibility in tailoring the outsourcing arrangement to meet the organizations unique. [26]

3. Functional Outsourcing:

The medical affairs department may outsource certain functional areas to outside suppliers as part of functional outsourcing. Organizations choose to outsource a particular function, such as medical information, or support for pharmacovigilance, as opposed to the entire function or a few specific activities. With this model, organizations can access specialized resources and expertise in certain fields while still maintaining control over other medical affairs. Organizations seeking to improve efficiency and effectiveness in certain areas or with specific demands may find functional outsourcing to be a financially advantageous alternative. [25,26]

Each outsourcing model has its advantages and considerations. The choice of outsourcing model is influenced by a variety of elements, including the organization's size, resources, strategic objectives, and desired level of control over functions. To ensure successful implementation and maximize the advantages of outsourcing medical affairs services, it is crucial for organizations to conduct a thorough assessment of their needs, analyse potential outsourcing partners, and establish clear communication channels and governance structures.

Conclusion

In conclusion, external medical affairs expertise helps organizations navigate resource limitations and evolving medical affairs demands. Medical outsourcing is growing rapidly, presenting a significant opportunity, albeit a small fraction of India's outsourcing industry. Careful risk evaluation is vital, considering reduced control, communication challenges, and data security. Various outsourcing models provide flexibility to tailor arrangements to specific needs. Effective vendor selection, clear communication, and proactive risk management are essential for successful implementation and optimizing outsourcing benefits. Looking forward, India's outsourcing potential is promising, driven by internet accessibility, a sizable remote workforce, top-notch talent, quality outcomes, and cost-efficiency.

Conflict of interest: All authors of this work are employees of Medcafe Solutions, and it should be noted that the directors hold a significant interest in the company.

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