

Clinical, Medical & Diagnostic Products



Strategic benefits of multi-market clinical trials with a global CRO

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The medical device industry is leading the way in innovation, creating advanced technologies that improve patient outcomes and the overall quality of care. As healthcare demands evolve globally, companies face a complex landscape characterised by rapid advancements, stringent regulatory requirements, and diverse market needs.

In response to these complexities, a multi-market clinical strategy has evolved as a critical pathway for companies looking to maximise their reach and impact. This strategy involves conducting clinical investigations across various regions, enabling organisations to gather comprehensive data that reflects diverse patient populations and regulatory environments. By engaging with different markets, medical device companies can enhance the depth and breadth of clinical insights while also tailoring their products to meet the specific needs of local communities.

This article delves into the principles that underpin multi-market strategies, illustrating how such an approach can enhance patient access, and improve health outcomes in an increasingly interconnected global landscape.

The necessity of a multi-market approach

The global healthcare landscape presents unique challenges and opportunities, particularly as it pertains to regulatory compliance and the need for diverse clinical data. Managing the complexity of diverse regulatory frameworks while ensuring both patient safety and product efficacy is a critical challenge. However, by adopting a multi-market clinical strategy, organisations can leverage diverse regulatory environments and patient demographics to improve their clinical research efforts.

A multi-market strategy allows for simultaneous clinical investigations across multiple regions. Each market has distinct regulatory bodies, patient populations, and healthcare needs that can significantly influence the development and approval processes for new medical devices. As a result, organisations must understand these regional nuances and design clinical trials that accommodate them, ultimately enhancing market entry success.

One of the key advantages of this approach is the potential for extensive market reach. For instance, Pure Global and MEDlcept have formed a strategic partnership to leverage capabilities across diverse regions such as the US, EU, Africa, and China. By establishing a presence in these regions, they can access a broad spectrum of opportunities. More specifically, the US and EU are mature markets, characterised by advanced healthcare systems and a strong demand for new medical technologies. In contrast, Kenya, an emerging market, offers growing healthcare needs and a dynamic environment for MedTech advancements. Meanwhile, China combines a vast population with a rapidly expanding healthcare infrastructure, creating unmatched potential for market growth. This geographical diversity allows Pure Global and MEDlcept to mitigate market-specific risks and capitalise on regional strengths. Together, these regions offer diverse opportunities for companies looking to expand their global presence.

In fact, this geographical diversity helps mitigate market-specific risks and capitalise on regional strengths. For instance, regulatory pathways in North America may be time-consuming, while Europe's regulatory environment could provide faster approvals. Meanwhile, emerging markets may offer rapid deployment opportunities and real-world data collection, making them particularly valuable for clinical research.

Then, access to diverse patient demographics is a critical benefit of a multi-market strategy. Clinical trials conducted across various regions ensure that the data collected reflects a wide range of genetic, environmental, and lifestyle factors. This diversity strengthens the generalisability and robustness of the clinical findings, making medical devices more applicable to a global patient population. Conducting trials in these diverse regions allows organisations to gather rich, multifaceted data that captures the nuances of different medical conditions, environmental influences, and genetic backgrounds—insights that are invaluable for refining device design and optimising therapeutic protocols. For instance, a medical device designed for cardiac monitoring may need to account for variations in patient responses based on genetics, diet, or regional health trends. Such insights are invaluable for refining device design and optimising therapeutic protocols, ultimately leading to better patient outcomes.

Moreover, incorporating diverse patient populations into clinical trials not only enhances the data collected but also fosters inclusivity in healthcare solutions. As medical devices become more accessible to a broader range of patients, organisations can ensure that their products are effective and relevant to various demographic groups, reducing healthcare disparities in the process.

Streamlined regulatory compliance and resource optimisation

Addressing the complex regulatory landscapes of different regions is a significant challenge in the medical device industry. However, a multi-market clinical strategy can simplify this process. By utilising local expertise and knowledge of regional regulatory requirements, organisations can efficiently manage regulatory submissions and expedite approvals.

Each region has its own set of regulatory standards and guidelines that must be met before a medical device can be marketed. The strict regulatory framework established by the Food and Drug Administration (FDA) and European Competent Authorities under Regulation (EU) 2017/745 (MDR) and Regulation 2017/746 (IVDR), along with ISO 14155:2020 and ISO 20916:2019, is often regarded as the gold standard globally. Understanding these requirements and aligning regulatory strategies across diverse regions enables organisations to facilitate smoother and faster market entry.

For instance, while North America requires comprehensive clinical data demonstrating safety and efficacy, Kenya's Pharmacy and Poisons Board (PPB) and China's National Medical Products Administration (NMPA) offer alternative pathways that may be more adaptable to local market needs. This adaptability allows companies to strategically plan their clinical trials to fit specific regulatory environments, thereby enhancing their chances of success in these markets.

A multi-market clinical strategy can lead to significant cost efficiencies and resource optimisation. Conducting clinical trials in emerging markets is often more cost-effective than in developed markets. Additionally, lower operational costs associated with patient recruitment, site management, and data collection in regions with developing healthcare infrastructures can result in substantial savings. These savings can then be reinvested into further research and development, driving continuous innovation. Collaborative partnerships between organisations can facilitate the sharing of resources, expertise, and infrastructure. This cooperation minimises duplication of efforts and maximises the utilisation of available assets. For example, clinical trial data from one region can inform and streamline studies in another, ultimately reducing overall development timelines and costs.

Ultimately, innovation thrives on diversity and collaboration. A multi-market clinical strategy fosters cross-regional collaboration, bringing together teams with varied perspectives, expertise, and problem-solving approaches. Insights gained from clinical trials conducted in different regions may reveal unique challenges or opportunities that may not be apparent in more developed markets. For example, advanced technological capabilities in developed regions can be leveraged to address specific healthcare needs in emerging markets. This cross-pollination of ideas and expertise accelerates the development of transformative MedTech solutions that are globally relevant and locally adaptable.

Improved patient access and health outcomes

The significance of a multi-market strategy extends beyond mere market expansion. It plays a critical role in addressing global health disparities by improving access to advanced medical technologies in underserved regions. Although developed nations typically enjoy access to advanced medical technologies and extensive healthcare

services, many developing countries encounter significant obstacles in obtaining even basic healthcare. In fact, poor-quality care contributes to between 5.7 and 8.4 million deaths each year in low- and middle-income countries, accounting for as much as 15% of total fatalities. By catering to a broader market, organisations can ensure that innovative medical devices reach diverse populations, including those in underserved regions.

Emerging markets often struggle to access modern healthcare solutions. By bringing these regions into their clinical strategies, organisations can provide life-saving devices and therapies that might not otherwise be available. This focus on health equity addresses urgent needs and also helps organisations establish themselves as leaders in the global health landscape.

Moreover, engaging with local healthcare providers allows organisations to tailor their offerings to meet the specific needs of different communities. This culturally appropriate approach increases the effectiveness of medical technologies and fosters trust with the populations served. For instance, a device designed for diabetes management may need to account for the dietary habits and lifestyle practices of local populations to ensure its effectiveness.

By prioritising patient access and health outcomes through a multi-market strategy, organisations can significantly enhance healthcare equity. Tailoring offerings to meet the specific needs of diverse communities not only ensures the effectiveness of medical technologies but also fosters trust with the populations served.

Advancing global health through multi-market collaboration

In the highly competitive medical device industry, a multi-market clinical strategy can present a significant competitive advantage. The ability to conduct comprehensive clinical research, achieve regulatory approvals, and launch products in multiple key markets simultaneously positions organisations as industry leaders. This strategic approach demonstrates a commitment to global health, regulatory excellence, and patient-centred innovation. Consequently, a strong market presence enhances brand recognition and trust. Regulatory bodies are more likely to engage with and endorse organisations that demonstrate a proactive approach to addressing diverse healthcare needs. This trust translates into increased market share, sustained growth, and long-term success.

Moreover, integrating underserved markets into this strategy presents a significant opportunity to reduce healthcare disparities and improve patient access to advanced medical technologies. By engaging with local healthcare providers and tailoring offerings to meet specific community needs, organisations can foster trust and enhance the effectiveness of their medical technologies.

Ultimately, the benefits of a multi-market clinical strategy - ranging from increased market reach and diverse patient demographics to better regulatory compliance and improved patient access - highlight its importance. By adopting a global mindset and encouraging collaboration across different regions, medical device companies can create effective healthcare solutions, enhance patient outcomes, and achieve lasting success in today's interconnected healthcare landscape.



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