

Bridging Borders: IQVIA's Expertise in Global Clinical Trial Management

Unlocking global clinical trials with IQVIA FSP Country in a Box: strategies for seamless expansion

This article is a comprehensive overview of the key considerations and strategies for successful country expansion in global clinical trials. Its purpose is to identify the main challenges organizations face when entering new countries, such as site feasibility, regulatory intelligence, and local knowledge. Emphasizing the importance of geographic diversity, this insightful article highlights key drivers like representative patient population recruitment, regulatory flexibility, cost efficiency, and expansion into untapped markets. IQVIA's FSP Country in a box is a solution to help organizations make informed decisions about target countries for trials and successfully plan and execute expansion of clinical activities into these countries.

Practical considerations for country expansion are explored, including understanding local regulations, ensuring compliance with data management and privacy standards, and finding the right people for trials. The article will stress the importance of addressing country-specific requirements to prevent significant delays, including some of the less-obvious ones such as CRO licenses and local residency status for CRAs in some countries.

Additionally, the article covers logistics and supply management, cultural and language requirements, and financial contracting and payments. It will also showcase the flexibility and tailored support provided by IQVIA's FSP Country in a Box solution.

Navigating the complexities of global clinical trials: Insights from IQVIA's webinar

In today's dynamic clinical research environment, expanding into new countries introduces both promising opportunities and complex challenges. Building on insights shared during our recent [IQVIA](#)

[webinar](#), this article translates expert perspectives into actionable guidance for navigating the intricacies of global clinical trial execution. It highlights practical approaches and emerging trends that can support organizations in making informed, strategic decisions across diverse regulatory and operational landscapes.



Geographic diversity

The need for geographic diversity in clinical trials is driven by several critical factors. Expanding into new regions is essential for accessing representative patient populations, which is increasingly important as the complexity of clinical protocols grows and patient pools shrink. By broadening the geographic scope of their trials, biopharma companies and academic researchers can tap into accessible patient populations, thereby enhancing recruitment and retention rates.

Regulatory flexibility is another significant driver for geographic diversity. Different countries offer varying regulatory environments that can expedite certain trials. For instance, some regions may have streamlined processes or specific incentives that make it easier to conduct clinical research. This flexibility allows organizations to navigate regulatory hurdles

more efficiently and bring new therapies to market faster. Additionally, expanding into next-tier countries can lead to cost efficiencies, as the price tag associated with running clinical trials in top-tier countries continues to rise. By conducting trials in regions with lower operational costs, organizations can reduce their overall expenses while still maintaining high standards of research quality.

Technological advancements, such as decentralized clinical trials and other innovative technologies, also play a crucial role in enabling geographic diversity. These advancements allow trials to be conducted in areas that were previously inaccessible, thereby expanding the reach of clinical research. Furthermore, regulatory harmonization efforts in certain regions aim to streamline processes and reduce the complexity of conducting trials across multiple countries.

By leveraging these technological and regulatory developments, organizations can achieve a more efficient and effective approach to global clinical trials, ultimately driving healthcare forward.

Unlock the potential of your clinical trials by embracing geographic diversity. Access representative patient populations, navigate regulatory hurdles with ease, and reduce costs by expanding into new regions. Leverage technological advancements and regulatory harmonization to drive healthcare forward and achieve more efficient and effective global clinical trials. Cast a wider net and explore new regions to enhance recruitment and retention rates, ultimately bringing new therapies to market faster.

Country selection

The country selection process for clinical trials is a complex and multifaceted endeavor that requires careful consideration of various factors. IQVIA has developed an algorithm to create a “Country Readiness” score, based on various parameters such as operational infrastructure, clinical and healthcare infrastructure, and patient availability. This score helps organizations make informed decisions about target countries for trials. By leveraging evidence-based

metrics, IQVIA ensures that the selected countries are well-suited for clinical research, thereby minimizing risks and maximizing success.

By using this comprehensive and data-driven approach, IQVIA can aid clients make educated and informed decisions on which countries represent feasible and promising targets for clinical trials. This method allows organizations to answer key questions such as which country characteristics enable clinical trials, which countries are most ready for clinical trials, and how to use this information for short and long-term planning. Ultimately, this thorough and strategic process helps organizations create a tangible and achievable country list for their clinical trials, ensuring wider patient access and successful trial execution.

Practical considerations for country expansion

Practical considerations for country expansion are crucial for the successful execution of global clinical trials. One of the primary aspects is understanding local regulations and ensuring compliance with data management and privacy standards such as GDPR in Europe, HIPAA in the US, and LGPD Brazil’s general data protection law. These standards are critical to avoid delays and issues during the country setup phase. Additionally, finding the right people for trials involves more than just qualifications; it requires understanding local monitoring practices, travel requirements, and ensuring cultural fit. Delivering an effective team management approach which is aligned with and considerate of local culture is essential for maintaining a happy, engaged, team. This holistic approach helps organizations navigate the complexities of different regulatory environments and ensures that all necessary compliance measures are in place.

Country-specific requirements also play a significant role in the practical considerations for expansion. Certain countries have unique requirements, such as CRO licenses for local CRAs in some Middle Eastern and Northern African countries, or local residency status for CRAs in Ghana. Understanding these nuances upfront can prevent significant delays and ensure smooth trial execution. Logistics and supply management are equally critical, as issues like drugs getting delayed in customs can severely impact trial timelines. Additionally, understanding cultural and language requirements is vital, especially when dealing with patients in clinical trials. This includes an awareness of the different

languages and cultural specificities that may impact the trial. Financial contracting and payments also require careful attention, as delays often occur during the startup period due to contract signing issues. Understanding local tax laws, legal requirements, and ensuring timely payments to sites can help avoid these delays. By addressing these practical considerations, organizations can ensure a seamless and efficient expansion into new countries.

A COUNTRY EXPANSION EXAMPLE

A client who acquired a new asset in a new therapy area, requiring them to enter a new region with no prior experience. This client faced the challenge of establishing a presence in a region where they had no existing infrastructure or local knowledge. IQVIA implemented a two-stage approach to address this challenge. Initially, IQVIA conducted an asset readiness assessment, including audits and data integrity planning, to ensure that the new asset was well-integrated into the client's operations. Following this, IQVIA performed site identification and feasibility studies, managed the project, and set up FSP managed country teams. These teams were tailored to the client's specific needs and operated within the client's processes and systems.

Throughout the process, IQVIA provided comprehensive support, including training on the new therapy area through their Therapy Area Center of Excellence (TACOE). The client was actively involved in oversight and governance, attending day-to-day activities as part of their knowledge transfer. Over time, IQVIA facilitated a smooth transition, allowing the client to gradually take over the ownership and delivery of the study.

“IQVIA’s FSP Country in a Box solution offers a comprehensive and flexible approach to entering new regions, providing tailored support and expertise to ensure successful clinical trial execution.”

Combining global and local expertise

IQVIA's approach combines extensive global capabilities with local precision to drive healthcare forward. This strategy leverages global reach and local knowledge to address the challenges of entering new countries. By bridging gaps in expertise and infrastructure, IQVIA ensures that clients are set up for success in a streamlined and efficient manner.

Conclusion

Expanding clinical trials into new countries is a complex process that requires careful planning, local knowledge, and a holistic approach. These insights shared, underscore the importance of understanding regulatory requirements, cultural nuances, and logistical challenges. By leveraging IQVIA's extensive global capabilities and local expertise, organizations can effectively navigate these complexities and achieve successful trial execution.

For organizations looking to expand their clinical trials into new regions, IQVIA's Country In a Box solution offers tailored solutions that address the unique challenges of each country. Contact IQVIA today to learn how our custom solutions can support your global clinical trial needs and drive healthcare forward.