White Paper

Expanding Clinical Trials into New Territories: Exploring the Keys to Success

Maximizing geographical reach by leveraging expertise, technology, and local experience

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Table of contents

Introduction

For as long as societies have existed, people from all walks of life have been compelled to travel abroad — for leisure, commerce, education, or perhaps to start a new life in a foreign land. Venturing into new, unfamiliar regions introduces new sights, sounds, languages and cultures, ultimately rewarding us with an enriched understanding of the world in which we live.

Yet no matter what the motivating factor is for venturing overseas, one cardinal rule stands the test of time: the more prepared and informed the traveler is about the destination country, the greater the chances of a successful journey.

The logic is simple: understanding local norms, laws and attitudes helps ensure the traveler remains on the proper course and avoids precarious setbacks. Sound contingency planning is also necessary as a safeguard in the event the journey doesn't go as planned.

Nowhere are these principles more relevant than in today's clinical trials, as sponsors and their CRO partners increasingly seek to expand their geographical reach to conduct medical research.

Conducting clinical trials in less charted research destinations — for example, within Latin America, Asia, Africa, and Eastern Europe—provides significant opportunities to develop treatments for more diverse patient populations, achieve greater operational efficiencies, maximize flexibility, accelerate overall delivery, and achieve many other potential benefits for medical science. And with today's increasingly innovative tools, data, capabilities, and technologies, the opportunity to achieve success conducting clinical research overseas has never been greater.

That being said, without robust experience, local expertise and planning, sponsors will likely encounter unforeseen issues that can cause delays, added costs, compliance risks, and—in the worst-case scenario—compromise patient safety.

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Therefore, whether utilized as a full-service offering (FSO) or functional service provision (FSP) partner, it is highly beneficial for sponsors to collaborate with a CRO that possesses a strong global footprint, has in-depth local experience and insights, and sufficiently robust capabilities. This combination helps to ensure the successful design and delivery of quality clinical studies in an expansion country.

Having conducted clinical trials in more than 67 countries across a broad range of therapeutic areas, we at IQVIA have written this paper with the goal of sharing key insights, challenges, and best practices for successfully expanding clinical research into new markets.

But first, let's delve into some of the key factors driving the trend of geographic expansion.

Key drivers of country expansion

There are 6 main drivers fueling pharmaceutical companies to conduct research into new territories (see Fig. 1), and are listed below:

- Patient recruitment and diversity
- Regulatory flexibility
- Cost efficiency
- Access to untapped markets
- Technological advancements
- Regulatory harmonization

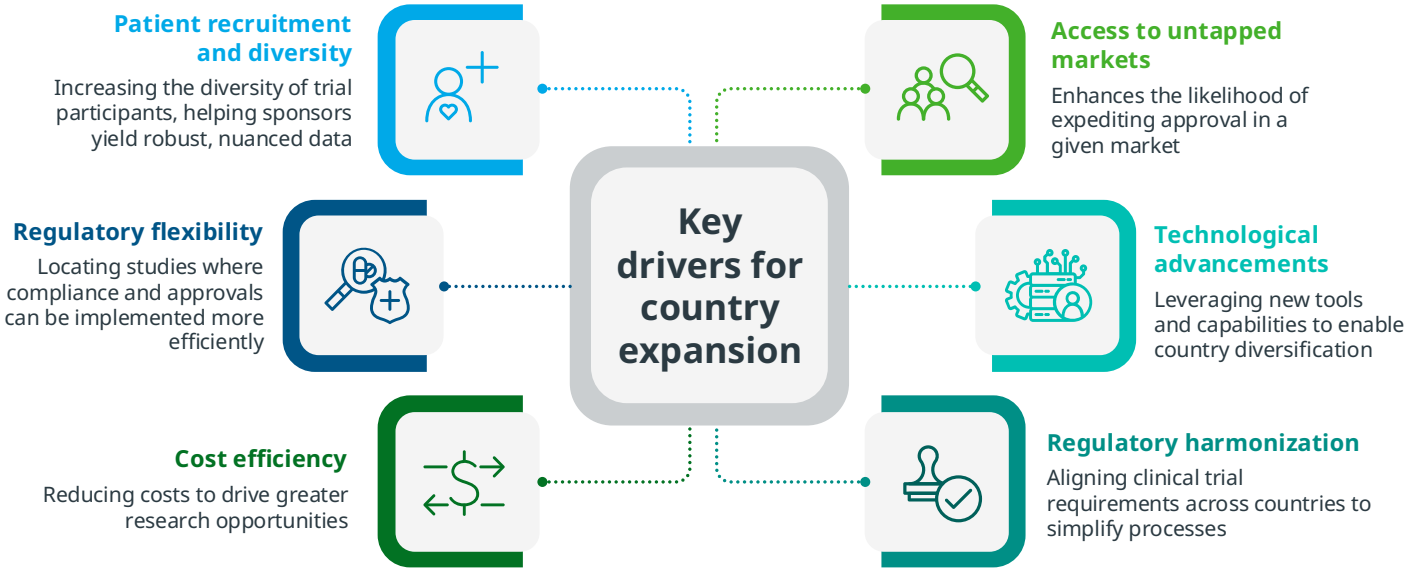
Patient recruitment and diversity

Expanding geographical reach can provide sponsors new avenues to access and recruit a greater volume and broader range of key patient population groups.

Keep in mind that the increasing complexity of today's protocols (which can include highly specific inclusion criteria), often limit the available pool of potential participants, making it more challenging to meet recruitment targets. For example, consider breast cancer trials, which often stratify their inclusion criteria by molecular subtypes—such as HER2-positive, triple-negative, or BRCA-mutated. Expanding the country mix for these type of trials has the potential to engage a greater volume of participants, significantly accelerate enrollment, and reduce timelines without compromising quality.

Additionally, since many diseases and treatments impact patient populations differently—often due to variations in genetics, lifestyle, and environments—increasing the diversity of trial participants through geographic expansion can help sponsors yield more robust, representative data that enhances the development of more precise, targeted treatments

Figure 1: Key drivers of geographic expansion in clinical trials.



Regulatory flexibility

Just as no two countries are identical in terms of their history and culture, each has its own unique regulatory environment, processes, sensitivities, and legal requirements. Expanding geographies potentially empowers sponsors to preferentially include countries where compliance and approvals can be implemented faster, more efficiently, and at reduced cost. This, of course, assumes the sponsor and their CRO partner have local regulatory intelligence, which enables a careful assessment of the target country's regulatory framework—ensuring a well-informed country selection and a robust implementation plan.

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Cost efficiency

From the planning phase through to database lock and beyond, the cost burden associated with conducting clinical trials has never been greater. Expanding research to a prudently selected blend of

countries—once again, assuming the right expertise and resources are in place—can significantly reduce the costs of compliance, site activation and oversight, clinical monitoring, and other key operational components within the continuum. This expansion creates opportunities to accelerate the development of new medical treatments in a cost effective manner while enhancing the diversity and scope of clinical trials — providing more comprehensive data for regulatory approvals and patient care.

Access to untapped markets

Many countries mandate establishing local clinical data in order to approve an Investigational Medicinal Product (IMP) in their markets. For example, some regulatory agencies in parts of Asia, including Japan, will not approve certain molecules if studied exclusively in non-Asian populations. This is due to physiological differences in the local population—ie, smaller bone structures and lower body mass index (BMI)—compared with other races and ethnicities. Therefore, generating high-quality data in a local population can enhance the likelihood of meeting approval requirements in that market, potentially bringing an added commercial opportunity

Technological advancements

The significant technological advances occurring within the clinical trial ecosystem are introducing new opportunities to optimize the efficiency and quality of clinical research conducted overseas. The vast range of novel capabilities now facilitating country diversification include: AI/ML-driven enrollment modeling and scenario planning, which can accurately and efficiently predict country-specific enrollment rates; Integrated Risk-Based Monitoring, which supports sites by harnessing Healthcare-grade AI® to detect and predict risks in near-real time; and Q&A chatbots that answer protocol-related queries to help enhance compliance. These and other novel technologies can relieve site and patient burden, harmonize quality controls and data flow, and further ensure the success of geographic expansion.

Regulatory harmonization

Last but not least, country expansion is being fueled by a growing trend to align clinical trial requirements across different countries to in order to simplify regulatory processes and encourage multi-country collaboration in research. The European Union Clinical Trials Regulation (EU CTR) and Accelerating Clinical Trials (ACT EU) program are key examples, aiming to streamline and standardize clinical trial processes to enhance quality, speed, and efficiency on a global scale.

"The most powerful question you can ask is, 'what am I missing?'"

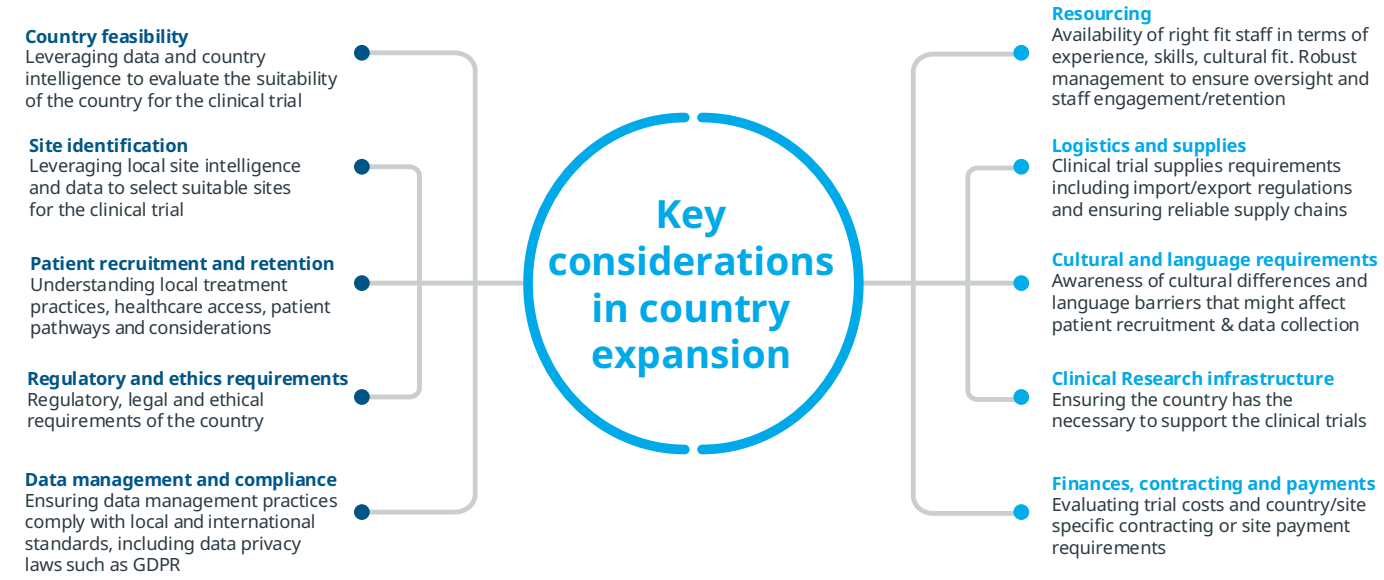
— Tim Ferriss, Tools of Titans.

Matching countries to trials: the importance of scrutinizing every variable

Making a well-informed decision on whether a country is feasible for a clinical trial is a significant undertaking that requires careful planning, foresight, and robust data-driven intelligence. Extensive experience in conducting research in the target country is key, as well as a nuanced understanding of local practices, regulatory framework, local culture, and language.

As the range of factors that ultimately make or break success in a country expansion are vast—and, at times, elusive—nothing can be taken for granted. Figure 2 (below) provides an overview of key considerations that must be accounted for in country selection.

Figure 2: Critical elements when starting a clinical trial in a new country.



Balancing FSO and FSP solutions in country expansion

Before delving into the key considerations and criteria for country selection, it's worth pointing out that either full-service (FSO) or functional service provision (FSP) delivery models (or a combination of both) can be successfully leveraged to operate clinical trial overseas. The choice depends on the sponsor's available resources, capabilities, and level of global experience.

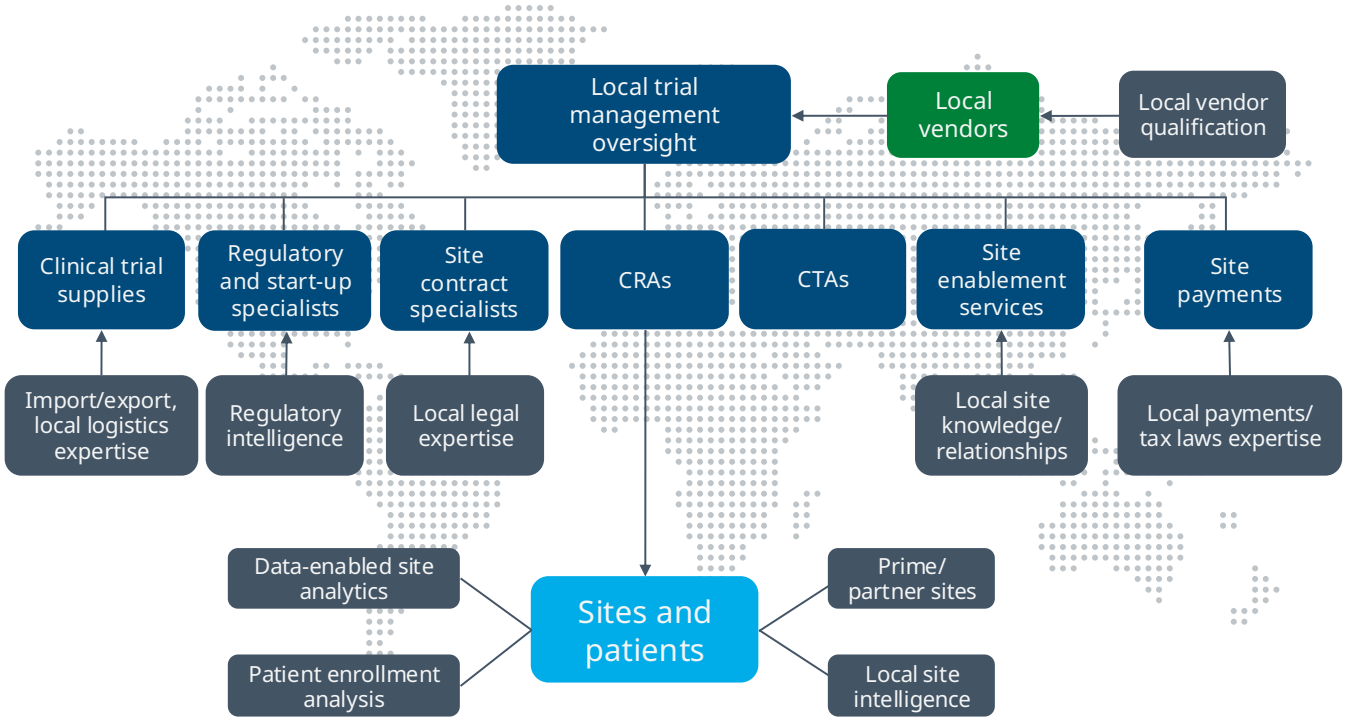
Considering the complexities involved, smaller pharma companies (or companies with a limited global footprint or experience) are likely best suited to leverage a full-service delivery offering with a highly experienced CRO partner.

On the flip side, sponsors who have developed global capabilities in-house (as many larger pharmaceutical companies have), FSP with an experienced CRO can provide sponsors more agile, modular solutions that fill critical gaps and connect the various roles, functions and processes.

"For sponsors who have developed extensive global capabilities in-house, FSP with an experienced CRO can provide more agile, modular solutions that fill critical gaps and connect the various roles, functions and processes"

Irrespective of which delivery model is deployed, a significant number of capabilities are required to effectively set up, operate and integrate an effective clinical trial ecosystem in an expansion country (See Fig. 3 in next page).

Figure 3: Roles, functions and information required for a new country setup.



Let's now review some the of key considerations in country selection that must be planned for and solved in order to mitigate risks and ensure successful delivery.

Assessing country infrastructure

Not surprisingly, the first order of business in assessing the feasibility of a target country is determining whether it has the sufficient infrastructure necessary to conduct an end-to-end clinical trial. This requires a comprehensive assessment of key factors, such as internet and cellular connectivity, transportation networks, operational and medical infrastructure, availability and expertise of sites, vendors, and personnel, supply chain, and a range of other variables.

Knowledge of the local healthcare funding (as well as how patients access medicines) is important, as it shapes the local strategy and ultimately the success of the country's research programs.

Since there are many less obvious yet equally pivotal factors impacting the quality of a country's infrastructure (ie, a fragmented healthcare system or suboptimal health records), sponsors and CROs should leverage prediction modeling that is tailored to the therapeutic area being studied.

Enrollment modeling and scenario planning

Successful patient enrollment in clinical trials requires verifying a sufficient pool of eligible patients, understanding their healthcare pathways, and identifying competing trials or treatment protocols that might impact their eligibility. It is also important to consider the local healthcare environment, including infrastructure and cultural attitudes.

Data-driven strategies and community engagement are keys to optimizing recruitment and building trust. A particularly relevant recent development is the application of GenAI agents performing enrollment modeling — within minutes — while also enhancing the accuracy of predicting country-specific enrollment rates.

"Ensuring an expansion country has a robust population suited to the trial protocol is critical, but only a starting point, as patient volume does not necessarily translate into successful recruitment."

Site intelligence and identification

In addition to ensuring a sufficiently robust patient pool is available in a target country—and enrollment rates have been carefully analyzed and considered—sponsors and CROs can partner to identify an ample number of strategically-located, capable sites suitable for the trial protocol. Achieving this requires a CRO with a quality global site network (and partner sites), local site intelligence and analytics, strong existing local site relationships and, of course, an intimate knowledge of the local sensibilities and culture of site operations. It is important to have local historical data and experience to select the highest-performing sites — enhancing the likelihood of timely recruitment and retention.

Regulatory and startup

Irrespective where a trial is conducted, every link within the trial continuum—from design and planning through to database lock—will involve country-specific regulatory, ethical, and legal compliance. As regulations can vary considerably from country to country—ranging from logistics, documentation of the Active Pharmaceutical Ingredient (API), handling of Trial Master Files (TMFs or eTMFs), data privacy rules, and so forth — it is important to have a granular understanding of the specific regulatory requirements prior to selection.

Robust site intelligence is critical to informing the decision and mitigating potential regulatory hurdles that can delay startup timeline by weeks or months—or even derail the clinical research program entirely.

Navigating the logistics, trial supplies, and supply chain

Different countries have diverse supply chains, logistics, and import requirements — including different approval processes, documentation, and licenses — all of which must be planned for and realistically factored into timelines well in advance. These variations impact not only the Investigational Medical Product, but also items such as lab kits, replacement devices, resupply shipments, as well as disposal and handling of biomedical waste, which requires clear, simple instructions with graphics to ensure quick comprehension. Delivering trial supplies across diverse global regions can be highly complex; it is therefore important for sponsors to choose a partner with a combination of global logistics support capabilities, and local regulatory and shipping expertise. This helps to avoid traps (ie, customs delays) and ensure smooth delivery and ongoing availability of clinical trial materials at investigator sites.

Finances, contracting, and payments

In addition to assessing the overall costs of conducting a trial in a particular country, sponsors and CROs must understand local or site-specific contracting requirements and considerations, including how local finances are conducted when doing business with sites and other third-party vendors. Lack of anticipation of contracting considerations and/or underestimating the challenges of making global site payments, for example, can lead to costly delays, overdue payments, and disgruntled sites.

Once again, local expertise and experience help to effectively manage contracts, payment processes, tax regulations, and legal obligations. Optimally, sponsors work with a CRO partner that offers local contracting and payment services that manage and predict requirements to ensure accuracy, compliance, and efficiency across complex, global clinical trials.

"Agile, modular FSP solutions with a global CRO partner are an optimal choice for a sponsor looking to fill critical gaps and interconnect the various roles, functions, elements and processes in a target country."

Staying on course: patients, sites, and data management

Once the critical elements determining country-readiness have been fully vetted and understood, a well-informed decision can be made in terms of country selection. In addition to the aforementioned checklist, there are 3 key areas of focus that are critical to expedite startup and keeping operations running smoothly: optimizing patient recruitment and retention; local site enablement and management; and data management and compliance.

Customizing—and optimizing—patient recruitment and retention

Recruiting and retaining patients for clinical trials in diverse cultures presents unique challenges that require tailored approaches. As alluded to earlier, a country which possesses a large patient population suited to the trial protocol does not inherently translate into successful recruitment. To overcome these types of challenges, sponsors and CROs should implement localized enrollment and recruitment strategies that account for cultural and community differences (as well as local healthcare practices). This requires a CRO partner with in-depth knowledge and experience around local treatment practices, healthcare access, patient and regulatory pathways—as well as an understanding of the sensitivities, stigmas, and norms within that culture.

For example, health conditions that are discussed openly in Western societies may carry social stigmas in other regions, requiring careful consideration. As mentioned earlier, country-specific forecasting models must be leveraged to identify underlying root causes that could delay patient enrollment, and inform targeted solutions that mitigate recruitment gaps. In addition, sponsors and CROs require the resources to deploy the optimal, culturally-appropriate mix of tools and services for each pivotal point within the trial journey.

"Sponsors and CROs must implement localized enrollment and recruitment strategies that account for cultural differences and local healthcare practices."

Remember, irrespective of country and cultural differences—whether the United States, Europe, Latin America, or Asia—localized strategies ultimately must accomplish the same three goals: motivate patients to participate; engage and support sites; and provide personalized solutions. Recruitment tools and methods must be relevant, accessible, and align with the sensibilities of the patient population being targeted.

"Sophisticated country-specific forecasting models should be utilized to identify underlying root causes that could delay patient enrollment — and inform targeted solutions that mitigate recruitment gaps."

As with any trial, site staff and primary investigators (PIs) in new countries require customized support, training, and tools to optimize delivery, provide exceptional patient care and ensure the generation of reliably clean data from start to finish.

In expansion countries, the types of site support required can vary significantly from region-to-region. For example, a site located in rural India or Africa may require transportation assistance to ensure patients and staff can readily travel to and from the site location, and/or require support from community specialists to enhance trial awareness in the community to boost recruitment.

Modern technologies also can play a key role in relieving site burden in expansion countries, such as eSource, eConsent, and Health-grade GenAI®, which provides insight-driven data that can expedite recruitment and reduce screen-fail rates. As mentioned earlier, Integrated Risk-Based monitoring provides sites rapid and accurate risk detection signals by connecting remote monitoring with targeted analytics to support CRAs and sites in their local time zones and languages.

Consistency and excellence in data management and compliance

Independent of where a clinical trial is located, patient privacy must be protected throughout the course of the study. Privacy and data protection laws can vary widely between countries—ranging from well-established data protection frameworks (similar to the General Data Protection Regulation [GDPR] in the European Union and the Health Insurance Portability and Accountability Act [HIPAA] in the United States), while other locations have laws that are less clearly defined and/or evolving. Again, awareness and familiarity around these laws at the local level facilitates adherence.

Finally, data quality is always of paramount importance.

Conclusion

As we've covered throughout this paper, expanding the geographical reach of medical research—and creating a more diverse country mix—provides sponsors and CROs alike the potential to develop safe and effective treatments for a broader range of patients—faster and more efficiently.

But as with any worthwhile undertaking, achieving success requires expertise, thorough due diligence, comprehensive planning, and proper execution to minimize potential risks.

And not to be forgotten, it also requires Innovative thinking.

At IQVIA, we are committed to driving innovative ideas and connected solutions that enhance the quality and predictability of clinical research design and delivery—bringing novel science and improved outcomes for patients to help drive healthcare forward.

About the authors

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Ian has 28 years in clinical research and has worked in Pharma Companies and CROs in that time in a number of operational and leadership roles. Ian has spent the last 18 years working in IQVIA in Clinical, Project Management, Regulatory & Start up roles with the last 4 years leading the setup, implementation and oversight of Clinical FSP Models.

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Gary's 25 year career in the pharmaceutical development industry has spanned multiple roles in Analytical Development and Lab Applications in DMPK and Bioanalysis and has spent the last 16 years with IQVIA. The majority of these 16 years has been spent on developing strategic relationships with customer, service providers and research professionals from healthcare and government.

In his current role as Head of Clinical FSP Go To Market, Gary is responsible for ensuring market awareness IQVIA's deep expertise in providing agile and cost-effective resourcing models, providing our global biopharma customers with truly global solutions.

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