ARTICLE

From trial to market: Strategic site selection for biotech success

A KEY QUESTION

How can biotech companies unlock commercial value and cost efficiencies throughout clinical development?

KEYWORDS Strategic Trial Placement, Clinical Trial Cost Optimization, Biotech Commercialization Strategy, Country-Specific R&D Incentives, Regulatory Strategy, Market Access Planning

Clinical trials represent the most resource-intensive and critical milestones in product development. Drug development sponsors face the challenge of balancing scientific focus, regulatory requirements, operational necessities, and financial considerations while accelerating innovation and maximizing return on investment.

Recognizing that biotech sponsors often turn to clinical research organizations (CROs) to advance their products in clinical development and align with their overall commercialization goals, this white paper highlights how sponsors can guide their objectives by:

- **Understanding country-specific factors and associated costs**
- **Capitalizing on country research and development (R&D) incentives**
- **Accounting for country-level legislation that unites clinical research activity with favorable commercialization conditions**
- **Maximizing the value of their CRO collaboration to gain operational expertise and critical insights**

Learn how sponsors and CROs can efficiently facilitate strategic trial placement to reduce costs, achieve the right label, and enable market access for novel products.

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Examining the relationship between clinical program costs and country placement

To promote efficiency and the delivery of a clinical development program, sponsors must understand the costs associated with a specific trial or program. At a high level, clinical program costs are broadly categorized as:

Direct costs

Direct costs are dedicated either to outsourcing or insourcing and typically account for ~40-50% of an overall study budget. They are influenced by the resource type and location, which affect hourly rates and task alignment.

Contact types can be tailored to project needs to include either a unitized model, a fixed price, or time and materials. A unitized model provides the most predictable and adaptable cost model for clinical services, while focusing on time and materials (T&M) is typically the preference for consulting.

Indirect costs

Depending on the direct costs, the countries, and the services, the remaining percentage for a trial can range from ~40-60%. Indirect costs account for investigator fees, which are driven by setup and protocol-specific activity costs. These costs vary widely within a study, up to three to four times, between countries such as the U.S. and India or China.

Figure 1: An example of country ranking of overall costs (direct and indirect costs) for running a clinical trial.

COUNTRY	REGION	OVERALL COST ANALYSIS Direct and Indirect	X TIMES HIGHER India as baseline	DIRECT CRO and ancillary costs	INDIRECT Investigator fees and associated costs
Japan	Asia Pacific	Most Expensive	3.4		
United States	North America		2.8		
Germany	Western Europe		2.2		
Israel	Western Europe		2.1		
Australia	Australia/NZ		2.1		
United Kingdom	Western Europe		1.9		
Spain	Western Europe		1.8		
South Korea	Asia Pacific		1.7		
Brazil	Latin America		1.7		
Greece	Eastern Europe		1.7		
Peru	Latin America		1.7		
Poland	Eastern Europe		1.6		
Chile	Latin America		1.6		
China	Asia Pacific		1.6		
Colombia	Latin America		1.5		
Romania	Eastern Europe		1.5		
Thailand	Asia Pacific		1.5		
Argentina	Latin America		1.5		
South Africa	Africa		1.4		
Ukraine	Eastern Europe		1.3		
India	Asia Pacific	Least Expensive	1		

Indirect costs also include vendor services, such as safety and esoteric testing, imaging, translation costs, and digital services (eCOA, ePRO, and televisits). Indirect costs must be evaluated for their value and impact, for example, in terms of how they support:

- Patient recruitment and retention
- Data quality and overall trial integrity
- The volume of available patient data in real time

Based on patient recruitment and retention expectations in each country, sponsors should also consider both direct and indirect costs and account for year-over-year inflation rate adjustments.

By managing costs and incorporating tactical imperatives—such as regulatory strategy at the country or regional level, key opinion leader (KOL) engagement, and asset exposure to preferred physician specialties and defined patient groups—sponsors are better equipped to optimize outcomes.

Choosing trial sites to leverage favorable commercialization

In recent years, some countries have implemented legislation and mechanisms to encourage clinical research by providing tax benefits during the delivery of clinical programs, as well as facilitating favorable reimbursement and access conditions. Drug development sponsors should be aware of this legislation and the opportunity it creates to:

- Increase the efficiency of spending during trial planning and execution
- Support the commercialization of their products when determining clinical trial locations

The most well-defined example of this is in Germany, where the 2024 German Medical Research Act, known as the Medizinforschungsgesetz, established benefits in terms of product pricing based on the level of local R&D and trial enrollment. Further, since Germany is part of the EU, the EU-CTR (Clinical Trials Regulation) process for trial applications also provides a predictable timeline for regulatory trial approval and opportunities to streamline the ethics submission process and initiate the study efficiently across the EU.

Country selection for trial participation should follow a data-driven approach, evaluating several factors against cost implications, such as:

- The start-up timeline and available recruitment months
- Patient accessibility and availability
- Local treatment pathway and standards of care
- The competitive trial environment
- Trial complexity and local expertise
- Digital maturity and decentralized clinical trial (DCT) readiness

Spotlight on Germany

The Medizinforschungsgesetz offers commercial incentives to encourage local clinical trials:

Flexible pricing negotiations: If a drug development sponsor can demonstrate that at least 5% of patients in a product's trial were enrolled in Germany, the product will benefit from relaxed pricing guardrails during reimbursement negotiations. This enhances pricing flexibility, allowing for more favorable reimbursement terms. As Europe's largest pharmaceutical market, successful market access negotiations in Germany are key to optimizing commercialization.

Confidential reimbursement prices: If a sponsor can demonstrate local R&D activities and accept a 9% discount on the price determined through the German Health Technology Assessment (HTA) process, they are eligible to keep their reimbursed price confidential. As Germany's reimbursement prices often serve as reference prices in other countries, unfavorable pricing outcomes have previously led some manufacturers to withdraw products from the German market to avoid price erosion elsewhere. Allowing confidential pricing, even at a 9% discount, could incentivize commercialization in Germany, knowing that any pricing agreement will not impact international markets.

Beyond Germany, other countries offer market access incentives to encourage local clinical and economic studies, for example:

- In **Taiwan**, the government has proposed a markup of up to 10% on the drug price when clinical trials are conducted locally, and up to a further 10% if a local pharmacoeconomic study is conducted
- In **Belgium**, the "Pact of the Future" is a strategic agreement aimed at creating a stable framework for pharmaceutical R&D investment. Specifically, the measure emphasizes a sustainable, patient-oriented drug policy, ensuring more affordable drugs and accelerated reimbursement procedures, which shorten the process by more than 50 days
- In **Brazil**, a new law, called 14.874/24, took effect in 2024. It offers several benefits to sponsors conducting clinical trials in this country, including the simplification of the assessment process, more predictable start-up timelines with a compression to 24 weeks, which is comparable to the EU-CTR, and clarification of post-trial investigative drug and overall treatment commitments

Many other strategically important countries such as Australia, the United Kingdom, Spain, France, and China continue to evolve regarding:

- **Clinical trial approval processes**
- **Tax incentives during asset clinical development**
- **Opportunities to secure favorable pricing and market access through early patient asset experience**

As our industry awaits to understand the long-term impact of the Medizinforschungsgesetz in Germany on market access strategy, we may see other markets adopt similar measures to incentivize local clinical trial enrollment through commercialization benefits.

Making patient enrollment decisions to meet regulatory expectations

Regulatory expectations represent another key factor in informing decisions in a clinical trial. When selecting global trial sites, sponsors and CROs must respond to the evolving expectations of regulatory health authorities to facilitate successful submissions.

For example, in oncology, it is critical to stay engaged with regulators. **Vinay Pradad, MD,** the newly appointed CBER Director, said, ***"Unfortunately, if you take a look at all the oncology trials that come to us, only about 20% of the population is derived from the United States ... We'd like to see robust increased enrollment in the United States."***

Sponsors and CROs should understand that the expectations for U.S. cancer patient enrollment are likely to increase, depending on the indication and trial design.

Beginning with the end in mind

Making tangible differences in clinical development and capitalizing on commercial opportunities requires foresight that extends beyond obtaining license approval. To deliver seamless operational planning and program execution, CROs and sponsors must consider how to increase the value of their spending while incorporating pricing and market access strategies.

To support these goals, Fortrea:

- Enables cross-functional collaboration between clinical and operational trial planning
- Delivers market access insights, a country medical affairs mindset, and strategic and operational regulatory know-how
- Ensures trials are cost-effective in placement and support long-term commercialization goals
- Leverages data partnerships to integrate global real-world evidence that supports post-trial value demonstration and payer engagement

Beginning with the end in mind, our team seamlessly collaborates with sponsors to help define clinical and commercial success factors that ultimately meet development goals, maximize value, and manage costs effectively.

How Fortrea leverages country-specific capabilities

To help maximize value and return on investment at each step in a clinical development plan, Fortrea works to:

- Apply actionable data insights to deliver studies effectively
- Create predictive recruitment models based on historical and real-time data
- Optimize site and investigator selection through performance analytics
- Integrate disease epidemiology with a comprehensive understanding of the patient journey, standards of care, and access to comparators

Coupled with comprehensive cost insights and strategies designed to optimize market access, we can help deliver successful clinical trial outcomes.

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