KPMG oucru

Roadmap to the future of Clinical trials in Vietnam

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Foreword

Over the last two decades, Vietnam has expanded access to healthcare and strengthened its public health system. The country now provides health coverage to 95 percent of its population, creating a strong platform for the next phase of its development. This achievement reflects sustained investments in primary care, infrastructure, and public health delivery.

The next challenge involves moving from broad access to higher-quality, innovation-driven healthcare. Clinical trials represent a strategic pathway to achieve this goal. They serve not only as a tool for validating new therapies but also as a foundation for long-term capability building in research, education, and health system development. As more countries compete for a share of global research investment, Vietnam has a clear opportunity to position itself as a regional leader in clinical trials.

National policy has begun to reflect this ambition. Resolution No.57, issued in 2024, outlines a long-term commitment to supporting science, technology, innovation, and digital transformation. It sets a target for research and development (R&D) funding to reach 2 percent of GDP by 2030, with at least 3 percent of the national budget allocated to R&D efforts. This is a strong signal that Vietnam is preparing to scale its innovation capacity, including the clinical trials sector.

This report offers a roadmap for turning potential into action. It draws from international case studies and identifies practical reforms that can accelerate Vietnam's progress in clinical trials. These include regulatory streamlining, investment in clinical infrastructure, and targeted efforts to develop and retain research talent. It also highlights the importance of strengthening public–private collaboration to ensure that reforms are sustainable and scalable.

KPMG and OUCRU are grateful to the many experts, government representatives, and industry stakeholders who contributed to this report. Their insights reflect a shared ambition to build a clinical trial sector that delivers value for patients, supports economic growth, and enhances Vietnam's position in global health research. We hope this report will support continued dialogue and decision-making, and we look forward to seeing the next chapter of Vietnam's healthcare journey take shape.

Sincerely,

Luke Treloar
Partner, Head of Strategy
Head of Infrastructure, Government and Healthcare (IGH)
KPMG Vietnam

Prof. Guy Thwaites
Director
Oxford University Clinical Research Unit, Vietnam

Background

Vietnam's healthcare sector is rapidly evolving, driven by robust Gross Domestic Product (GDP) growth, an expanding middle class, and significant foreign investment. Vietnam has a population of more than 100 million and continues to improve its healthcare infrastructure. These strengths position the country to use clinical trials as a key driver of innovation and better patient outcomes. Clinical trials are essential for defining the optimal us of new and old therapies, ensuring their safe and sustainable use and accelerating access to highly effective treatments. In this context, Pharma Group plays a pivotal role in Vietnam, fostering strategic partnerships and advocating for necessary policy discussions to overcome existing hurdles.

Objective

The primary objective of this report is to highlight essential policy reforms and improvements that will advance clinical trials in Vietnam. The report outlines actionable strategies to address challenges such as regulatory inefficiencies, funding shortages, and limited workforce capacity. The goal is to create an enabling environment that not only attracts global sponsors and enhances public health but also drives economic growth by positioning Vietnam as a regional hub for clinical research.

As Vietnam's clinical trial capabilities expand, the country stands to realize significant economic and social benefits, including increased foreign direct investment (FDI), job creation, improved patient outcomes, and a strengthened reputation as a clinical trial hub in the region.

Report Structure

The report consists of 5 sections: the existing clinical trial ecosystem in Vietnam; the barriers hindering growth of clinical trials; peer market benchmarking and actionable insights for Vietnam; the economic and social value of clinical trials; and proposed recommendations to transform and accelerate the clinical trial landscape in Vietnam.

Executive Summary

Vietnam's clinical trial sector has the potential for transformative growth. There is a strategic opportunity to reposition the nation as a regional hub for clinical research, innovation, and healthcare excellence. As the economy accelerates, and healthcare infrastructure expands, robust clinical trial activity will drive medical advances and R&D developments, generate substantial economic value, and directly enhance the well-being of Vietnamese citizens.

Key insight

Vietnam's clinical trial sector has the potential to become a regional hub, but significant challenges must be addressed through strategic reforms. This report outlines the opportunities, barriers, and actionable steps to unlock Vietnam's clinical research capabilities, delivering economic and healthcare benefits.

Growth Potential

Vietnam boasts a population of nearly 100 million, offering a diverse patient pool for clinical trials. Coupled with rapid economic growth (GDP growth averaging 6-7% annually) and a growing middle class, the country is increasingly attractive to domestic and international sponsors. Rising foreign direct investment in healthcare further signals Vietnam's potential as a clinical research destination.

Current Challenges

Despite these strengths, the sector faces substantial hurdles. Regulatory inefficiencies, such as slow and fragmented approval processes, delay trial initiation. Infrastructure limitations, including a scarcity of Good Clinical Practice (GCP)-certified facilities, restrict capacity. Additionally, a shortage of trained professionals (e.g., clinical investigators) and inadequate funding mechanisms undermine competitiveness compared to peers like Malaysia and Singapore.

Strategic Reforms

To overcome these barriers, Vietnam can adopt targeted reforms. Streamlining approvals through a centralized authority and online portal would reduce delays. Investments in infrastructure, such as expanding GCP-certified sites, developing Clinical Trials Units (CTUs), and workforce training programs, can build the required capacity. Public-private partnerships, modeled on successful frameworks in Taiwan and Brazil, could share risks and resources, accelerating progress.

Impact

Implementing these reforms could transform Vietnam's clinical trial landscape. Projections suggest the market could reach USD 749.5 million by 2029, driven by increased trial activity. This growth would create thousands of high-quality jobs, from research coordinators to data analysts, while improving healthcare outcomes by providing Vietnamese patients faster access to innovative treatments.

Recommendation

Key actions include centralizing ethical reviews to ensure consistency, establishing a government-backed clinical trial fund to incentivize investment, and enhancing international collaborations with global research networks for knowledge and technology transfer. A summary of recommendations is provided below, dividing between Policy and Non-Policy Recommendations across the short, medium and long term.

Strategy Roadmap for Vietnam's clinical trial hub

Strategy Roadmap for Vietnam's clinical trial centre will divide into policy and non-policy recommendations

	Policy recommendations	Non-policy recommendations
Short-term *(2025)*	**Mandate dual-language documents** to simplify processes for international sponsors **Amend the legal documents in the direction of simplifying the import procedures for medical devices and ePRO equipment,** similar to the drug import regulations stipulated in the amended Pharma Law **Fostering the PPP model** **Adopt the risk-based approval process**	**Establishing a National Center of Excellence (CoE),** serving as a central hub for training clinical staff and clinical researchers **Partnerships between hospitals, academic and research institutions, and private companies with international universities** **Public-Private Collaborations**
Medium-term *(2026 - 2027)*	**The online portal** will be served as a centralized platform for clinical trial submissions **Centralize the ethical review process under NECBR** for all clinical trial ethical reviews **Having a dedicated clinical trial fund** to focus on financing key areas of R&D, particularly in priority medical fields such as oncology	**Establish a network of GCP-certified hospitals and pharmaceutical companies** **Implement GCP-compliant training and continous professional development programs** **Build regional infrastructure through targeted grants and establish research hubs** **Develop Clinical Trial Units (CTUs)** to drive academic clinical trials
Long-term *(2028-2029)*	**Implement fast-track approval pathways** for trials already approved in jurisdictions with advanced regulatory systems such as EU, US, or other advanced nations	**Foster digitalization in Vietnam's clinical trials** **Implement Electionic Medical Records to support building clinical trial database** **Develop a clinical trial database/registry** **Improve digital literacy among HCPs and government agency staffs** **Develop specialized clinical trial consultancy services**

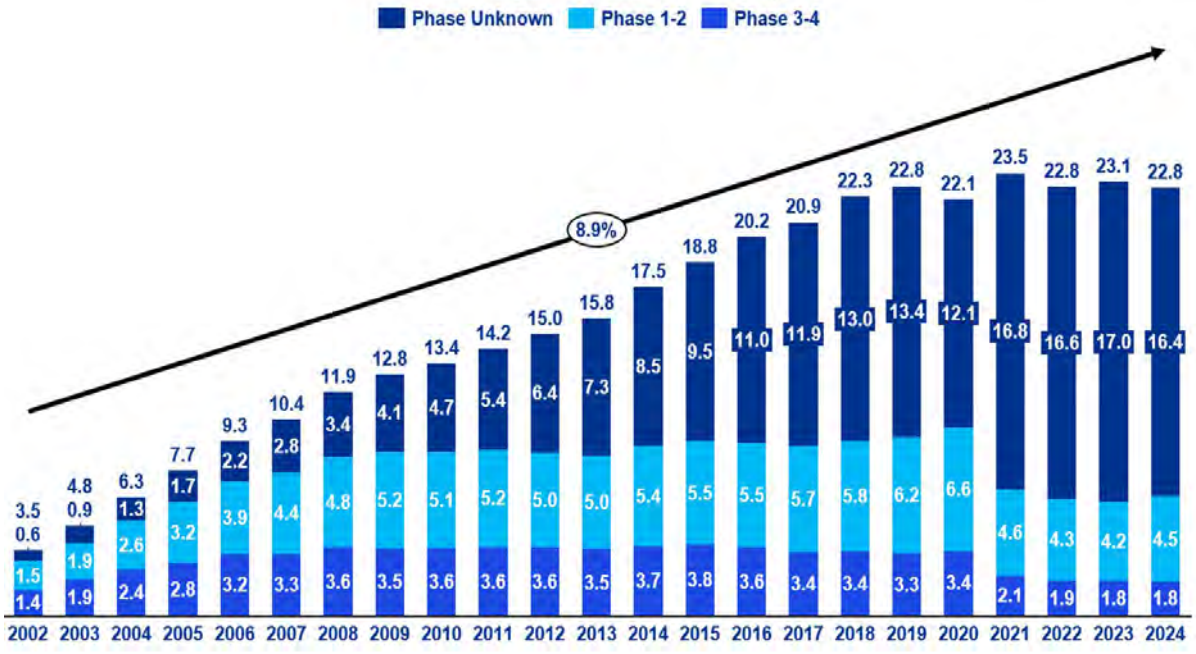
By pursuing these reforms, Vietnam can capitalize on its clinical trial potential, fostering economic development and advancing public health.

2. Current state analysis

2.1. Key Global and Regional Trends of Clinical Trial Development

The global clinical trials landscape is undergoing a significant transformation, with Asia, particularly Southeast Asia (SEA) emerging as a key hub for research and innovation. As pharmaceutical companies seek more efficient, cost-effective, and diverse trial sites, Vietnam has a unique opportunity to capitalize on this shift and position itself as a premier destination for clinical research.

Number of new clinical trials globally from 2002 to 2024 (unit: thousands)



Source: Clinicaltrials.gov

Global trend and market shifts

Over the past two decades, the number of clinical trials worldwide has expanded dramatically, reflecting increased investment in drug development and medical innovation. Between 2002 and 2019, global trials grew from approximately 3,000 to 22,800 annually, with the highest activity concentrated in the United States, Western Europe, and East Asia. However, since 2019, the overall number of new trials has plateaued at around 23,000 per year due to regulatory constraints, rising costs, and shifting industry priorities.[1]

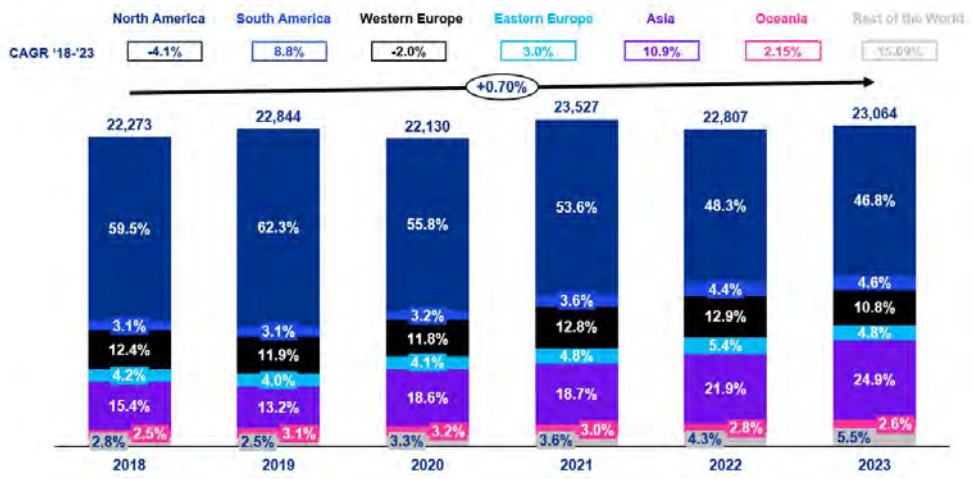
- **Early-phase trials (Phases 1 & 2)** have maintained steady growth, peaking in 2020 before stabilizing at around 4,500 new trials annually.
- **Late-stage trials (Phases 3 & 4)** have declined since 2017, driven by increasing complexity, rising costs, and a strategic shift toward more efficient trial models such as decentralized clinical trials.[2]

Despite these challenges, the global clinical trials market remains a critical driver of medical innovation, with continued expansion into emerging markets, particularly in Asia.

[1] *Frost & Sullivan (2017), 'Asia: Preferred Destination for Clinical Trials', Frost & Sullivan, Available at Link*
[2] *Frost & Sullivan (2017), 'Asia: Preferred Destination for Clinical Trials', Frost & Sullivan, Available at Link*

Asia's significant growth in new and multi-country clinical trials reflects its emerging role as a global hub for clinical research and innovation

Number of new clinical trials globally by region from 2018 to 2023



Source: Clinicaltrials.gov

Asia has emerged as the fastest-growing region for clinical research, achieving a compound annual growth rate (CAGR) of 10.9% from 2018 to 2023. Key drivers of this growth include:

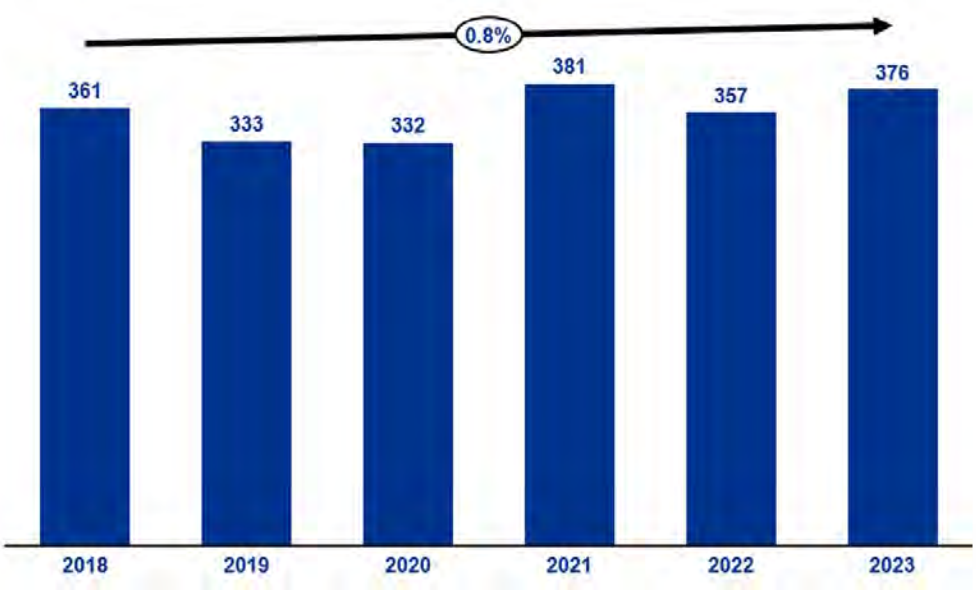
- **Expanding patient pools:** Asia is home to over 4 billion people, offering a vast and diverse population for trials.
- **Lower operational costs:** Conducting trials in Asia is 30–40% cheaper than in the U.S. and Europe. [1]
- **Regulatory improvements:** Countries such as China, Taiwan, and Singapore have introduced fast-track approval processes, boosting their appeal to global sponsors.

This trend has significantly increased Asia's share of global clinical trials, growing from 15.4% in 2018 to 24.9% in 2023. Meanwhile, North America's market share has declined due to operational barriers such as high competition for trial participants, rising costs, and extensive regulatory requirements.[3]

[3] *Sheraz Ali, Oluwaseun Egynsola, Zaheer Ud Din Babar, Syed Shahzad Hasan (2019), 'Clinical trials in Asia: A World Health Organization database study', Sheraz Ali, Oluwaseun Egynsola, Zaheer Ud Din Babar, Syed Shahzad Hasa, Available at Link*

Southeast Asia: The Next Frontier for Clinical Research

Number of new clinical trials in Southeast Asia region from 2018 to 2023



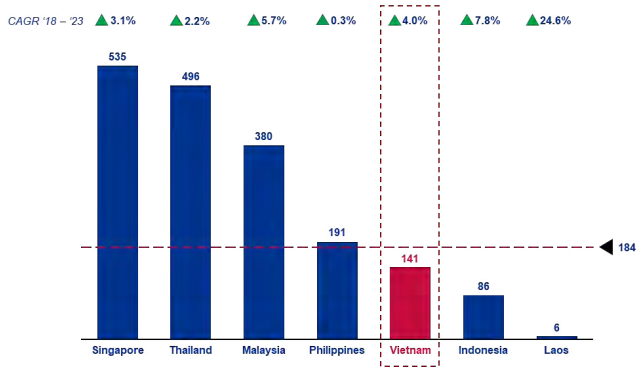
Note: Data is inclusive of commercial and academic clinical trials
Source: GSO; BMI Fitch Solutions

While Southeast Asia is emerging as a major destination for clinical research, the pace of growth varies significantly across the region. [4]

- **Thailand and Malaysia** have led in new trial starts, leveraging strong regulatory frameworks and well-established research ecosystems.
- **Singapore and Indonesia** continue to expand their clinical trial pipelines, benefiting from government-backed incentives and improving research infrastructure.
- **Vietnam,** however, has struggled to keep pace.

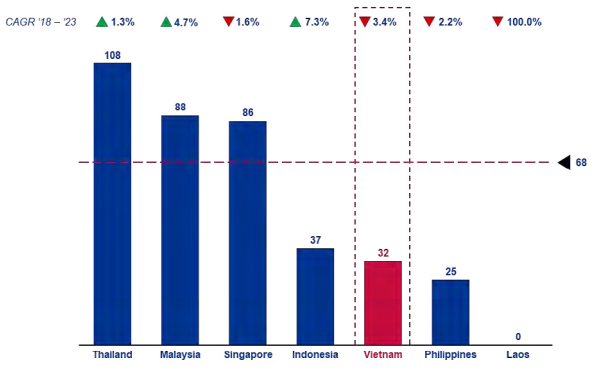
From 2018 to 2023, Vietnam's clinical trials industry experienced a decline, with fewer than 40 new trials annually and a negative Compound Annual Growth Rate (CAGR) of -3.4%. Persistent regulatory challenges, a shortage of GCP-certified facilities, and underdeveloped funding mechanisms have reduced investor and trial sponsor confidence and weakened Vietnam's competitiveness as a research destination. Without targeted reforms to streamline approvals, expand infrastructure, and create incentives for trial sponsors, Vietnam risks losing ground in the regional race to become a clinical research hub.

Number of active clinical trial starts by Southeast Asian countries in 2023



Source: GSO; BMI Fitch Solutions

Number of new clinical trial starts by Southeast Asian countries in 2023



Source: GSO; BMI Fitch Solutions

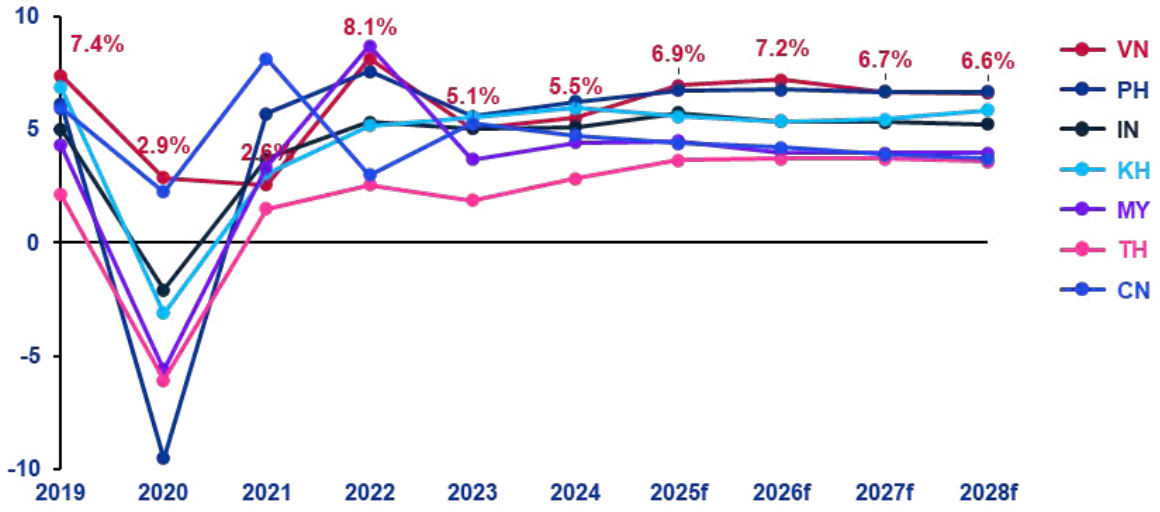
[4] *CAGR refers to the Compound Annual Growth Rate. It represents the mean annualized growth rate for compounding values over a given timeframe. This smooths the volatility of periodic values.*

2.2 Current clinical trial market landscape in Vietnam

2.2.1. Macroeconomics and industry conditions

Vietnam's Economic Growth Fuels the Future of Clinical Trials

GDP growth of selected countries from 2019 to 2028 (%)



Source: GSO; BMI Fitch Solutions [5]

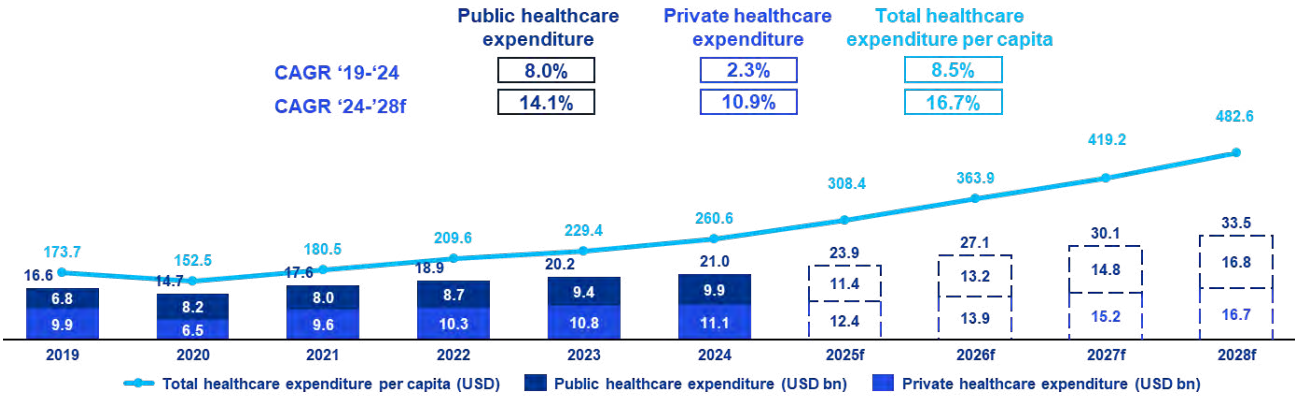
Vietnam is one of Southeast Asia's fastest-growing economies, consistently achieving strong GDP growth from 2020 to 2024. A diverse workforce, expanding middle class, and increasing foreign investment have contributed to a stable economic outlook, reinforcing Vietnam's potential as a destination for clinical research.

Several economic factors support the country's ability to attract clinical trials:

- **A large and growing population**: Nearly 100 million people, Vietnam provides a diverse patient pool, which is a key advantage for global sponsors.
- **Increased foreign direct investment (FDI)**: Government policies have improved the business environment, attracting global pharmaceutical companies and contract research organizations (CROs).

Despite these challenges, the global clinical trials market remains a critical driver of medical innovation, with continued expansion into emerging markets, particularly in Asia. Asia's significant growth in new and multi-country clinical trials reflects its emerging role as a global hub for clinical research and innovation

Public and private healthcare expenditure in Vietnam from 2019 to 2028



Source: BMI Fitch Solutions

[5] *Forecast year: Vietnam (2025), Philippines (2025), Indonesia (2025), Malaysia (2025), Thailand (2025), China (2025).*

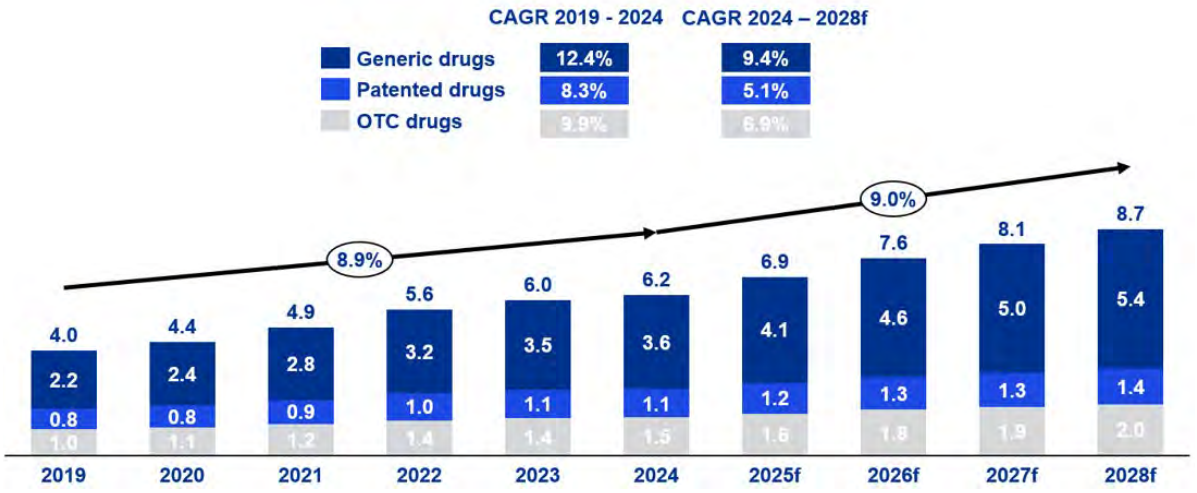
Healthcare Demand and Its Role in Clinical Research

Vietnam's growing middle class and improving healthcare access are leading to higher demand for pharmaceuticals, specialized treatments, and clinical research. As more individuals seek better medical care, the need for new treatment options and drug development increases.

This economic shift presents opportunities to:

- Growing private healthcare with a projected 10.9% CAGR
- Expand clinical research operations to meet rising demand for new treatments.
- Leverage Vietnam's large, treatment-naïve population for multi-phase trials.
- Develop partnerships with local healthcare institutions and academic researchers to support trial efficiency and patient recruitment.

Market value of Pharmaceutical industry in Vietnam from 2020 to 2028f (USD bilion)



Source: GSO; BMI Fitch Solutions.

Vietnam's Pharmaceutical Market: A Key Driver for Clinical Trials

Vietnam's pharmaceutical market is expanding, supported by increased healthcare spending and demand for new drug development and innovation. The market, which includes generic drugs, patented medicines, and over-the-counter (OTC) products, is projected to grow at a CAGR of 9.0% from 2024 to 2028.[6]

Several industry trends are shaping clinical trial activity in Vietnam:

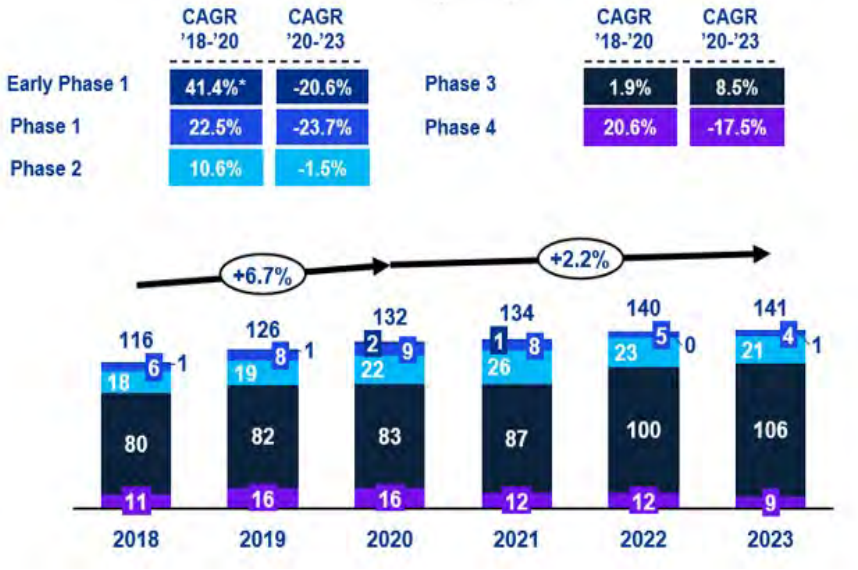
- **Generic drugs remain the dominant segment,** growing at 12.4% CAGR, driven by affordability and government support for locally manufactured medicines.[7]
- **Patented drug sales have grown at an 8.3% CAGR from 2020 to 2024,** reflecting rising demand for advanced treatments and innovative therapies. This is impressive growth, but still lags behind peer markets such as Thailand and Malaysia in terms of total market value and penetration rate.

The continued growth of the pharmaceutical sector creates opportunities to attract more clinical trials, particularly in therapeutic areas aligned with Vietnam's public health priorities.

[6] *Market value of the pharmaceutical industry includes the market value of generic drugs, patented drugs and OTC products*
[7] *Vietnam News (2022) 'Clinical research and applications improves cardiovascular-renal-metabolic care in Việt Nam: experts', Vietnam News, Available at Link*

2.2.2. Market Overview

Number of active clinical trials by phase from 2018 to 2023 (cases)



Source: GSO; BMI Fitch Solutions.

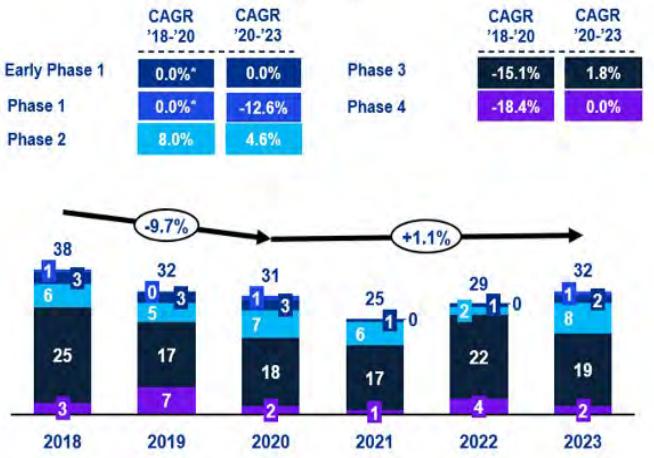
Current Trends in Vietnam's Clinical Trials Market

From 2018 to 2023, Vietnam's clinical trial market has grown slowly in recent years, but infrastructure, regulatory complexity, and patient participation remain challenges. While trial activity has grown across different phases, maintaining consistent progress has been difficult due to complex approval processes, recruitment barriers, and market conditions. With the revision of the Law of Pharmacy in 2016-2017, new drugs do not require to undergo clinical trials to be registered in Vietnam. This could lead to a decline of clinical trials conducted, however in recent years, the number of clinical trials conducted in Vietnam has increased slightly.

The COVID-19 pandemic had a significant impact on clinical research in Vietnam, as it did globally. Lockdowns, strained healthcare resources, and shifting research priorities led to delays in trial initiation, recruitment challenges, and regulatory bottlenecks. Many non-COVID-related studies were postponed or canceled, disrupting momentum across multiple therapeutic areas.

Trends Across Trial Phases

Number of new clinical trials by phase from 2018 to 2023 (cases)



Source: GSO; BMI Fitch Solutions

Between 2018 and 2020, clinical trials in Phase 1, Phase 2, and Phase 4 increased, reaching 9, 22 and 16 clinical trials in 2020, respectively. This growth was driven by:

- Increased interest from international sponsors.
- Rising demand for clinical research in Vietnam.
- Initial regulatory improvements that encouraged more trials.

This momentum slowed in from 2021 to 2023 due to:

- **Low patient participation rates,** which remain at 1–2% of total patient population due to limited awareness and cultural reluctance.[8]
- **Approval delays**, which make trial planning and execution more complex.
- **Recruitment difficulties,** especially for early-phase trials requiring specific patient groups.

While Phase 3 trials have maintained steady growth, Vietnam continues to face challenges in establishing itself as a preferred location for large-scale trials.

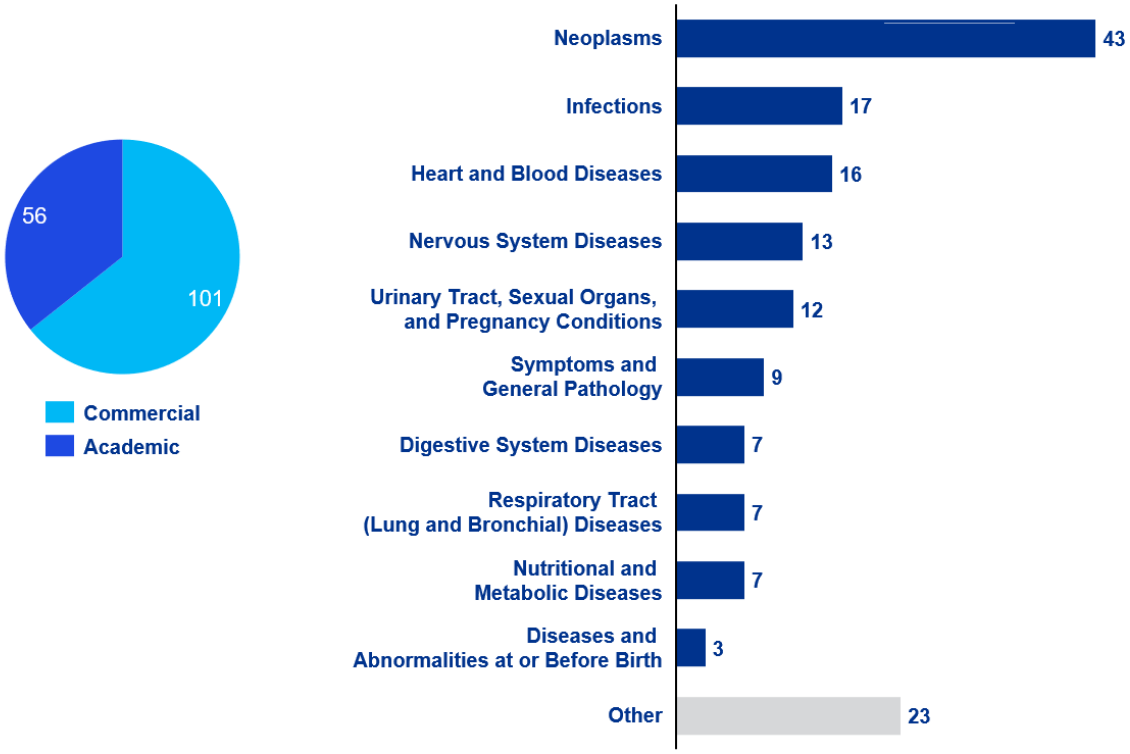
[8] *Vietnam News (2023) 'Patients in Vietnam are reluctant for drug testing', Vietnam News, Available at Link*

Decline in New Trial Starts and Signs of Recovery

Between 2018 and 2023, Vietnam saw a fall in new clinical trials, with fewer than 40 new trials annually and a negative CAGR of -3.4%[9]. The fall was most pronounced in Phase 3 and Phase 4 trials, which likely reflect Vietnam's reduced attractiveness for sponsors.

Despite this decline, between 2020 and 2023, the market shows some recent early signs of recovery, with a 1.1% CAGR. Phase 2 and Phase 3 trials expanded, indicating Vietnam may have the potential to attract more late-stage clinical research if regulatory and infrastructure improvements continue.

Top 10 therapeutic areas conducting clinical trials in Vietnam by number of studies as of December 2023



Note: There are duplicated case studies for therapeutic area, meaning one study can cover two or more areas
Source: Clinicaltrials.gov, KPMG Research and Analysis

Key Therapeutic Areas: Oncology and Infectious Diseases

It is important to acknowledge that industry clinical trials and academic clinical trials have different focus and emphasis. While industry-sponsored clinical trials target high-burden therapeutic areas such as oncology, cardiovascular, metabolic disorders, driven by the large patient population and significant market potential. Meanwhile, academic clinical trials often focus on more niche areas, including rare diseases, certain infectious diseases, and public health interventions, which address unmet medical needs and evidence gaps.

A similar pattern is displayed as Vietnam's clinical trials focus primarily on:

- Oncology (cancer research)
- Infectious diseases (COVID-19, tuberculosis (TB), hepatitis, dengue, drug resistant infections)
- Cardiovascular diseases
- Respiratory conditions

The emphasis on oncology and infectious diseases reflects both local healthcare priorities and alignment with global research trends.

[9]AMS 'Why Are There So Few Clinical Trial Service Providers in Vietnam?, AMS, Available at Link

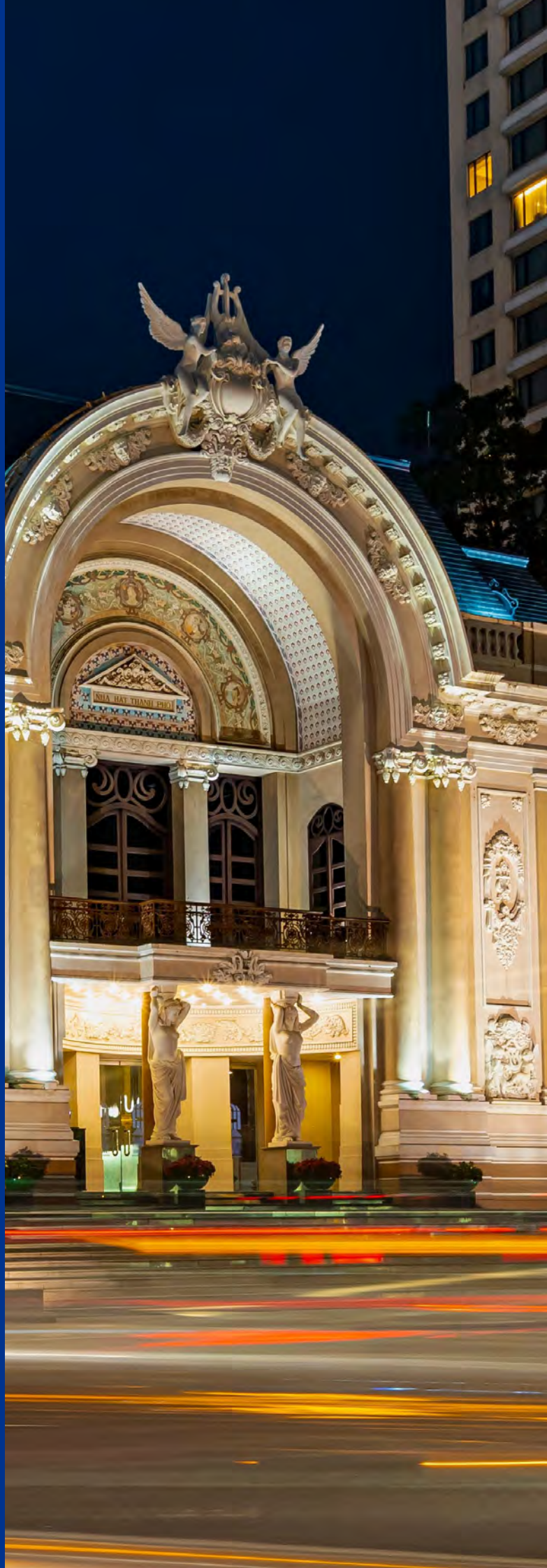
Key Industry Sponsors and Research Institutions

Pharmaceutical companies (industry-sponsored) account for 60% of all clinical trials in Vietnam, while academic institutions account for the other 40%. Leading sponsors include

- **AstraZeneca** – Oncology, respiratory, and gastrointestinal diseases.
- **Novartis** – Oncology, immunology, dermatology, gene therapy, infections.
- **Sanofi** - Aventis – Oncology, diabetes, and infections.
- **Pfizer** – Epidemiology, cardiovascular, respiratory.

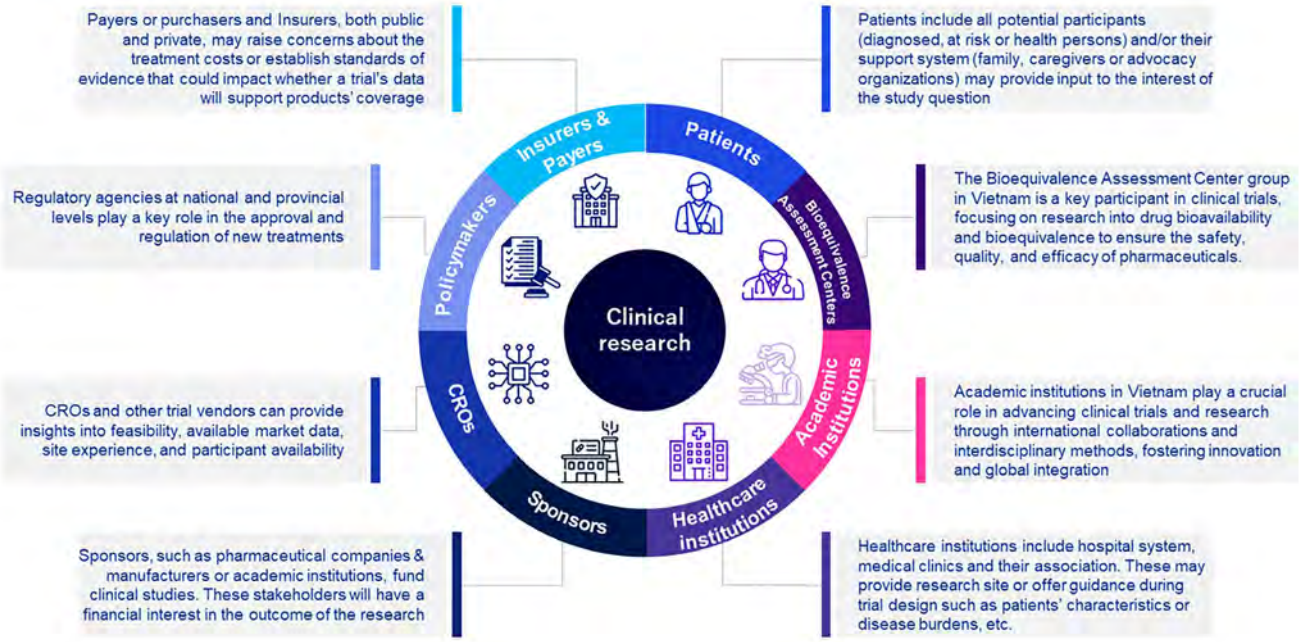
Academic institutions play a critical role, particularly in infectious disease research. Major contributors include:

- **Hanoi Medical University** – Infectious diseases, oncology, and neurology, with a focus on public health interventions and epidemiology.
- **The University of Medicine and Pharmacy at Ho Chi Minh City (HCMC)** – Clinical pharmacology, chronic disease management, and vaccine development, collaborating with both government and international research institutions.
- **Oxford University Clinical Research Unit (OUCRU)** – Infectious diseases, tropical medicine, antimicrobial resistance, and emerging pathogens, playing a key role in regional public health initiatives.
- **University of Sydney Vietnam Institute** – Multidisciplinary research, focusing on non-communicable diseases, cancer research, rural health, and nutrition, while fostering collaborations between Australian and Vietnamese researchers.
- **Vietnam's leading public hospitals** – Cardiology, endocrinology, and rare diseases, supporting nationwide healthcare improvements.



2.2.3. Key Stakeholders in Vietnam's Clinical Trials

Clinical trial success in Vietnam depends on the collective efforts of diverse stakeholders, each bringing distinct expertise, responsibilities, and perspectives



Source: Ministry of Health, KPMG Research and Analysis

The success of Vietnam's clinical trial sector hinges on the coordinated efforts of various stakeholders, each bringing unique expertise and facing specific challenges. While the sector shows significant promise, addressing obstacles such as regulatory inefficiencies, funding constraints, and capacity gaps will be critical. Below are the core stakeholder groups, their roles, the hurdles they face, and the opportunities for international collaboration that can accelerate their objectives.

POLICYMAKERS

Particularly the Ministry of Health (BYT), the National Ethics Committee for Biomedical Research (NECBR), the Administration of Science, Technology, and Training (ASTT), and the Institutional Review Board (IRB), establish Vietnam's regulatory framework and ethical standards for clinical trials. They play a pivotal role in aligning Vietnam with global best practices, such as Good Clinical Practice (GCP). Internationally, organizations like the World Health Organization (WHO) support regulatory advancements through initiatives such as Resolution WHA75.8, which fosters innovative, collaborative efforts to strengthen clinical trials worldwide.

KEY CHALLENGES:

- Multi-layered approval processes, leading to extended timelines.
- Limited digital infrastructure for trial oversight.
- Inconsistent local interpretations of national regulations.

OPPORTUNITIES FOR COLLABORATION:

- Partnering with global regulatory agencies and the WHO to streamline approvals, adopt shared databases or e-portals, and reduce approval timelines.
- Engaging in knowledge exchange initiatives that can boost Vietnam's attractiveness for international research.

INSURERS & PAYERS

Insurers, both public and private, along with payers such as Vietnam Social Security (VSS), decide how and whether new treatments arising from trials are reimbursed. Their decisions significantly affect patient access and the commercial viability of clinical research. Currently, patients who enroll in a clinical trial lose their government health insurance coverage for that condition, shifting all healthcare costs onto sponsors, especially burdensome for hospitalized patients. This is a major challenge and disincentive to sponsors, especially when conducting trials in hospitalized or critically ill patients.

KEY CHALLENGES:

- Lack of clear pathways for adding trial medicines to national reimbursement lists.
- High financial burden on sponsors due to patients' loss of insurance during trial participation.
- Limited data on real-world outcomes, impeding evidence-based coverage decisions.

OPPORTUNITIES FOR COLLABORATION:

- Adopting advanced reimbursement models, such as outcomes-based agreements, through learnings from countries with mature health technology assessment (HTA) systems.
- Developing pilot programs or policy exceptions to reduce the cost burden on sponsors and expand patient access.

CONTRACT RESEARCH ORGANIZATIONS

Such as IQVIA, Parexel, and local providers like Big Leap Research, SmartResearch, CRI Vietnam Ltd., handle trial logistics from regulatory filings and site selection to patient recruitment and data management. They link sponsors with trial sites and ensure adherence to Good Clinical Practice (GCP). However, Vietnam's CRO landscape is relatively underdeveloped, limiting the country's capacity to manage complex trials.

KEY CHALLENGES:

- **Underdeveloped CRO Sector:** Local providers often lack the resources, expertise, and networks found in global CROs.
- **Regulatory Complexity:** Aligning site capabilities with evolving local regulations and meeting international sponsor standards can be difficult.
- **Talent Retention:** Skilled project managers and coordinators are in short supply, as professionals may leave for more established markets.

OPPORTUNITIES FOR COLLABORATION:

- **Strengthening Local Clinical Research Units (CRUs):** Robust, homegrown CRUs can guide sponsors through Vietnam's regulatory landscape and build trust with local investigators. Tam Anh Research Institute (TAMRI) exemplifies a new model that integrates research coordination, training, and patient care under one roof.
- **Global Partnerships:** Collaborating with international CRO networks to adopt best practices, use advanced monitoring tools, and diversify sponsor pipelines can accelerate local CRO development.
- **Academic–Hospital Alliances:** Joint ventures with major hospitals and academic institutions can bolster infrastructure, shorten trial start-up times, and nurture specialized talent.

SPONSORS

often pharmaceutical companies, medical device manufacturers, and academic bodies, design, fund, and oversee clinical research to develop new treatments. In Vietnam, this includes both multinational corporations and leading universities such as the **University of North Carolina, Oxford University, University of Sydney,** and **VinUniversity**[10] , which bring specialized expertise, training programs, and advanced research methods. [11]

KEY CHALLENGES:

- **Complex Import Regulations:** Evolving policies for investigational medicinal products slow trial initiation.
- **Lengthy Approval Timelines:** Multi-layered ethics reviews and administrative hurdles prolong research progress and often introduce major delays to trial initiation.
- **Reimbursement Uncertainties:** Limited clarity on how trial outcomes transition into wider commercial availability can deter large-scale investments.

OPPORTUNITIES FOR COLLABORATION:

- **Alliances with CROs and Local Stakeholders:** Shared risk, cutting-edge trial designs (e.g., decentralized or adaptive), and robust data management can streamline Vietnam-based studies.
- **Integration with Academic Institutions:** Leveraging patient registries, training initiatives, and cross-border networks through universities enhances innovation and scales research capacity.
- **Policy Engagement:** Working closely with policymakers and payers to establish fast-track approvals and clearer reimbursement pathways will attract more multinational sponsors and academic-led collaborations to Vietnam's developing clinical trial landscape.

HEALTHCARE INSTITUTIONS

Both public and private, play a central role by providing the facilities, patient populations, and clinical expertise needed for trials. Government institutions, such as the National Hospital of Dermatology & Venereology, Vietnam National Cancer Hospital (K Hospital), Hanoi Oncology Hospital, and the Ho Chi Minh City Pasteur Institute, often lead multi-center studies addressing critical areas like dermatology, oncology, and communicable diseases. Meanwhile, private institutions like My Duc Hospital (through its Hope Research Center) and Tam Anh Hospital (through its Tam Anh Research Institute) target specialized fields such as reproductive medicine, gynecology, and chronic metabolic conditions, highlighting a diverse yet fragmented research ecosystem.

KEY CHALLENGES:

- **Inconsistent GCP Compliance:** Many facilities lack uniform adherence to Good Clinical Practice standards, affecting confidence among international sponsors.
- **Staff Training Gaps:** Busy medical professionals often have limited time, incentives, or structured programs to develop research-specific skills.
- **Resource Constraints:** High patient volumes and limited infrastructure can slow enrollment and data collection, particularly in complex or multi-center trials.

OPPORTUNITIES FOR COLLABORATION:

- **Twinning Programs with Established Research Centers:** Partnerships with leading hospitals worldwide can introduce new technologies, streamline protocols, and enhance on-site clinical training.
- **Focused Investments in Digital Systems:** Electronic health records, telemedicine platforms, and integrated patient registries can improve data accuracy, patient follow-up, and overall trial management.
- **Synergy with CROs and Academic Institutions:** Co-developing investigator training programs, research protocols, and patient recruitment strategies boosts clinical trial quality, making Vietnam a more attractive destination for global sponsors.

[10]HM, (2024), Clinical trials contribute to the development of new treatment methods, HM, Available at Link
[11]UNC is involved in multiple clinical trials in Vietnam in areas such as Human Immunodeficiency Virus (HIV) and TB, all trials available at Link

ACADEMIC INSTITUTIONS

Academic Institutions underpin the nation's clinical research efforts through multidisciplinary collaborations, extensive training programs, and a focus on high-impact studies. Alongside well-known public universities, such as **Hanoi Medical University (HMU)** and the **University of Medicine and Pharmacy at Ho Chi Minh City (UMP)**, a growing number of public and private institutions are expanding Vietnam's research capacity and global presence.

KEY CHALLENGES:

- **Funding Gaps:** Limited grants and infrastructure investments restrict large-scale or specialized research.
- **Administrative Complexities:** Multi-center studies may be delayed by overlapping approvals and inconsistent coordination.
- **Balancing Priorities:** Universities can struggle to reconcile pure research objectives with industry-driven timelines and commercial targets.

OPPORTUNITIES FOR COLLABORATION:

- **Investigator-Initiated Trials:** Targeting local disease burdens through tailored studies can attract both domestic and international funding, while advancing healthcare outcomes in Vietnam.
- **Global Partnerships and Knowledge Sharing:** Expanded engagements with the University of Sydney, Oxford University, and others open channels for data exchange, joint funding applications, and adoption of modern clinical trial methodologies.
- **Curriculum Integration:** Embedding clinical research components into medical and graduate education fosters a research-oriented culture, ensuring a continuous pipeline of qualified clinical trial professionals.

COLLABORATION ROLE:

- **Oxford University Clinical Research Unit (OUCRU) and the University of Sydney:** The University of Oxford, through OUCRU, and the University of Sydney, through its Vietnam Institute, undertake research on key public health challenges, including tuberculosis and antimicrobial resistance, whileproviding training in advanced clinical trial methodologies.[12]
- **108 Military Central Hospital & Institute of Tropical Medicine in partnership with the University of Tübingen, Germany:** Engage in oncology research and modern diagnostic technologies, facilitating scientific publications and investigator-led studies.
- **Vinmec International Hospital with the Perelman School of Medicine, University of Pennsylvania:** Operate an Oncology & Cardiology Center of Excellence, merging clinical and population-based research with innovative technologies.
- **VinUni-Illinois Smart Health Center (VISHC) with the University of Illinois**: Conduct high-impact research in biomedical sensing, informatics, and telehealth using artificial intelligence.
- **University of Medicine and Pharmacy at Ho Chi Minh City (UMP):** Conducts clinical trials on tropical and emerging infectious diseases, offering training programs for local investigators. [13]

BIOEQUIVALENCE ASSESSMENT CENTERS

Bioequivalence assessment centers ensures that drugs in Vietnam meet internationally recognized safety, quality, and efficacy standards through rigorous bioavailability and bioequivalence testing. Key institutions include the **National Institute of Drug Quality Control (NIDQC) and the Institute of Drug Quality Control Ho Chi Minh City (IDQC HCMC).** Their work underpins both national regulatory decisions and the global credibility of Vietnam's pharmaceutical products.

KEY CHALLENGES:

- **Funding and Modern Equipment:** Limited, inconsistent financial support constrains the acquisition and upkeep of cutting-edge laboratory infrastructure.
- **Skilled Workforce:** Recruiting and retaining specialized technical staff remain a hurdle, particularly with competition from private labs and global organizations.
- **Method Standardization:** Without unified testing protocols across regions, bioequivalence results may lack consistency or international comparability.

OPPORTUNITIES FOR COLLABORATION:

- **International Regulatory Alignment:** Partnering with bodies like the U.S. Food and Drug Administration (FDA) or the European Medicines Agency (EMA) can help adopt and harmonize global testing standards.
- **Pharmaceutical Industry Partnerships:** Collaborations with local and multinational drug companies can provide technical training, equipment funding, and knowledge transfer.
- **Regional Centers of Excellence:** Establishing dedicated training hubs and pooled resources could raise the overall quality of bioequivalence research, strengthening Vietnam's position in the pharmaceutical value chain.

[12] *The University of Sydney, (n.d), Clinical Trials, The University of Sydney, Available at Link*
[13] *Ho Chi Minh City Medicine and Pharmacy University, (2023), Infectious Diseases Research Department, Ho Chi Minh City Medicine and Pharmacy University, Available at Link*

PATIENTS

Patients diagnosed inviduals, those at risk, or healthy volunteers, are the heart of every clinical trial, offering essential feedback on study designs and gaining early access to potentially life-saving therapies. Their active participation can shape trial outcomes and impact future health policy decisions. However, in Vietnam, low public awareness, cultural reluctance, and uncertainties about trial safety limit patient participation and can impede timely enrollment.

KEY CHALLENGES:

- **Limited Awareness and Education:** Many patients are not fully informed about clinical trials, missing out on early treatment access and cutting-edge therapies.
- **Cultural Barriers:** Certain communities may view experimental treatments with suspicion, delaying consent and enrollment.

OPPORTUNITIES FOR COLLABORATION:

- **Patient Advocacy Groups:** Strengthening local advocacy networks and collaborating with global organizations can improve recruitment, informed consent practices, and long-term follow-up.
- **Community Engagement Campaigns:** Public education initiative via media, hospitals, or local health volunteers can demystify clinical trials and foster trust in new treatments.
- **Policy Reforms:** Aligning insurance regulations to protect or partially retain patient benefits during trials could encourage broader participation and reduce financial strain on sponsors, ultimately improving Vietnam's research environment.
- **Creating a clinical trial database:** similar to the well-known American platform, clinicaltrials.gov. This solution will involve sharing comprehensive information on various studies, including details on the study team and therapeutic areas. This resource will empower patients to assess whether a trial aligns with their needs, potentially enhancing patient recruitment for clinical trials in Vietnam.

2.2.4. Key existing Government's policies and initiatives on clinical trial development in Vietnam

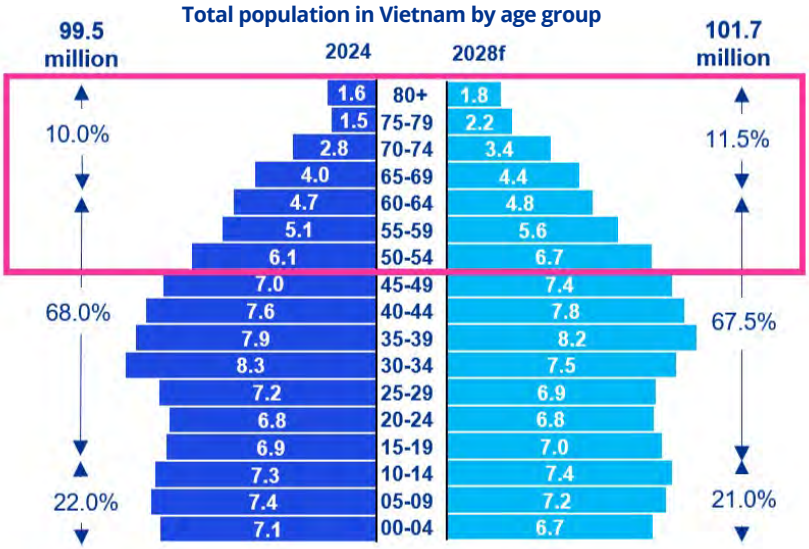
YEAR	POLICIES	DESCRIPTION	IMPACT ON THE CLINICAL TRIAL SECTOR
2012	**On Guiding Clinical Drug Trial** Circular No. 03/2012/TT-BYT	Sets requirements for trial facilities, drug labeling, and ethical assessments, ensuring compliance with biomedical ethics in participant selection.	Establishes a transparent, stable regulatory framework, promoting clinical trial operations and ethical oversight in Vietnam.
2014	**On Providing for activities supporting clinical trial research in Vietnam** Circular No. 08/2014/TT-BYT	Mandates registration for contract research organizations (CROs) and site management organizations (SMOs), along with periodic inspections for compliance.	Improves the clinical study environment by enforcing regulations on CROs and SMOs, offering better technology and standardized practices for trial conduct.
2015	**On Clinical Trial recognition for Medical Techniques** Circular No. 55/2015/TT_BYT	Establishes guidelines for recognizing new medical techniques by defining trial phases and classifying techniques based on risk levels.	Strengthens Vietnam's research framework, ensuring systematic evaluation of new medical methods while maintaining safety standards.
2016	**On Medical Device Management** Decree 36/2016/ND_CP	Lays the foundation for medical device oversight, including clinical trials through recognized ethics committees (RECs).	Provides structured governance for device research approvals, enabling clear pathways for device-related clinical trials.
	Law of Pharmacy Law No. 105/2016/QH13	Outlines the responsibilities and documentation requirements for entities conducting clinical studies in Vietnam.	Enhances transparency and encourages research efforts by establishing a solid legal framework for clinical study operations.
2018	**On Clinical Trial of Drugs** Circular No. 29/2018/ TT-BYT (to amend Circular No. 03/2012/ TT-BYT)	Regulates the application of Good Clinical Practice (GCP) standards, introducing a tiered assessment for clinical trial facilities (full, partial, or non-compliance).	Improves clinical trial quality by formally integrating GCP into Vietnam's regulatory system, making the country more attractive to trial sponsors.
2021	**On Approving the Development Program for Pharmaceutical Industry and Domestically Produced Herbal Ingredient until 2030 and vision to 2045** Decision No. 376/QD-TTg	Sets targets to boost domestically produced medicines to 80% of volume and 70% of market value, supporting local pharmaceutical R&D.	Streamlines the clinical trial pathway for medical devices except laboratory kits and supplies, providing more clarity and efficiency for sponsors and researchers.

YEAR	POLICIES	DESCRIPTION	IMPACT ON THE CLINICAL TRIAL SECTOR
2023	**Law on Medical Examination and Treatment** Law No. 15/2023/QH15	Clinical trials must be conducted at MOH-approved facilities, with mandatory biomedical ethics committee review (Article 99).	Ensures participant rights, safety, and compliance with GCP standards, promoting rigorous oversight and innovation.
	Protection of Personal data Decree No.13/2023/ND-CP	Requires transparent data processing, patient consent, and oversight by the Ministry of Public Security.	Strengthens data privacy and aligns clinical research with international data protection norms.
	On elaboration of the law on Medical Examination and treatment Circular No. 32/2023/TT-BYT	Mandates detailed ethical committee procedures, trial records (10–15 years), and robust GCP compliance.	Streamlines trial protocols, safeguards participant safety, and enforces high data integrity standards.
	National Strategy for the Development of the Vietnamese Pharmaceutical Sector to 2030, with a vision to 2045 Decision No. 1165/QD-TTg	This national plan aims to establish Vietnam as a high-value pharmaceutical hub in ASEAN by 2030 and anticipate contributing about USD20 billion to total GDP. It also expects to ensure timely support of safe and effective medicines, support national health security and socioeconomic development.	This national strategy promotes the need to increase access to high-quality and effective medicines where clinical trials would contribute largely by elevating research and innovation capacity.
2024	**Amendments to certain articles of the Law on Pharmacy** Law No. 44/2024/QH15	Expands drug definitions, controls substances, and promotes digital transformation.	Positions Vietnam's pharmaceutical industry as a key economic driver by focusing on research, clinical trials, technology transfer, and establishing centers for drug development, bioequivalence, and biosimilar testing.
	Regulations on the establishment, organization and operation of Ethics Council in Biomedical Research Circular No. 43/2024/TT-BYT	The circular helps standardize biomedical research in Vietnam, enhancing quality and transparency in ethical research management through high standards and specialized regulations, while protecting participants' rights.	Ensuring that research and clinical trials in Vietnam align with international standards facilitates global cooperation, fostering sustainable growth for this sector in Vietnam.
	Regulations on breakthroughs in the development of science, technology, innovation, and national digital transformation Resolution No. 57-NQ/TW	Positions Vietnam to invest in science, technology, and digital transformation, with gradual increases in research funding	Encourages innovation and technology adoption, paving the way for more advanced clinical trials.
	Decree No. 96/2023/ND-CP guiding the Law on Medical Examination and Treatment	Establishes a clear, step-by-step process for evaluating and integrating new medical techniques.	Faster adoption of innovative methods, improved standardization, and a more efficient regulatory pathway.
2025	**Decree on the Functions, Tasks, Powers and organizational structure of the Ministry of Health** Decree No. 42/2025/ND-CP	The Department of Science and Technology Management may oversee clinical trial approvals and compliance, while the Drug Administration Department could regulate drug use to ensure safety and efficacy.	The decree strengthening regulatory oversight, training requirements, and drug management, leading to stricter compliance, improved safety, and higher research standards in Vietnam.

Source: Thuvienphapluat; KPMG Research and Analysis

2.2.5. Vietnam's key strengths in its clinical trials market

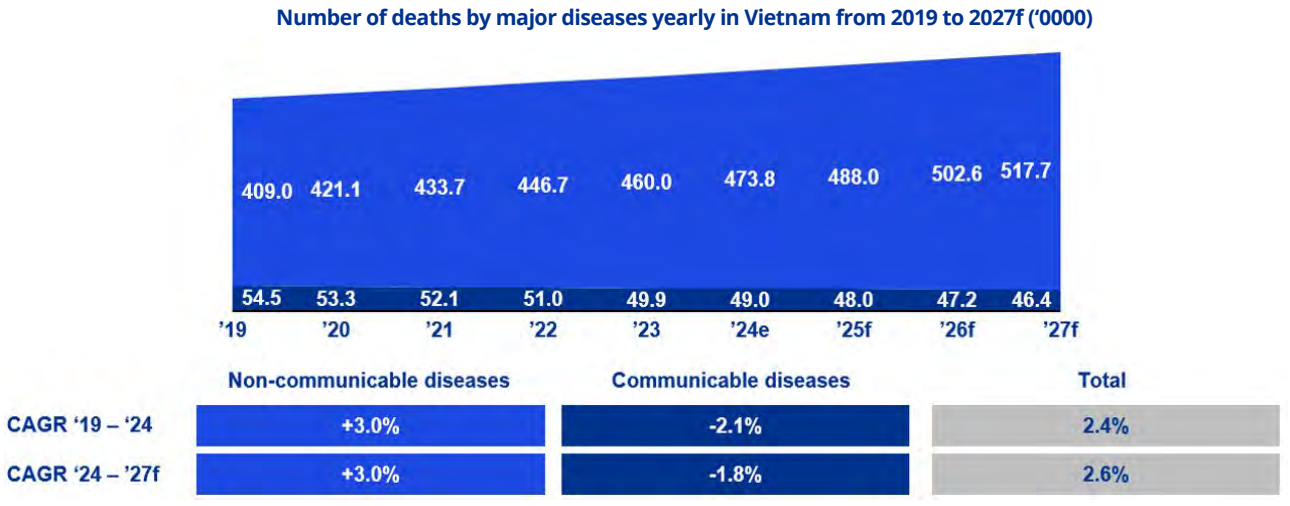
Vietnam possesses a growing and diverse patient pool for clinical trials thanks to its large population and rapidly aging population



Source: GSO, BMI Fitch Solutions

Vietnam's evolving demographic landscape positions the country as a promising hub for clinical research, thanks to an expanding, diversifying patient pool. Between 2024 and 2028, the population is projected to grow by 2.2 million, thereby increasing the number of potential participants for clinical trials. While this demographic shift will drive higher demand for healthcare services, including specialized and advanced treatments, it also opens opportunities for trials targeting age-related conditions and chronic diseases.

Vietnam's diverse disease landscape provides an opportunity for clinical trials



Source: BMI Fitch Solutions

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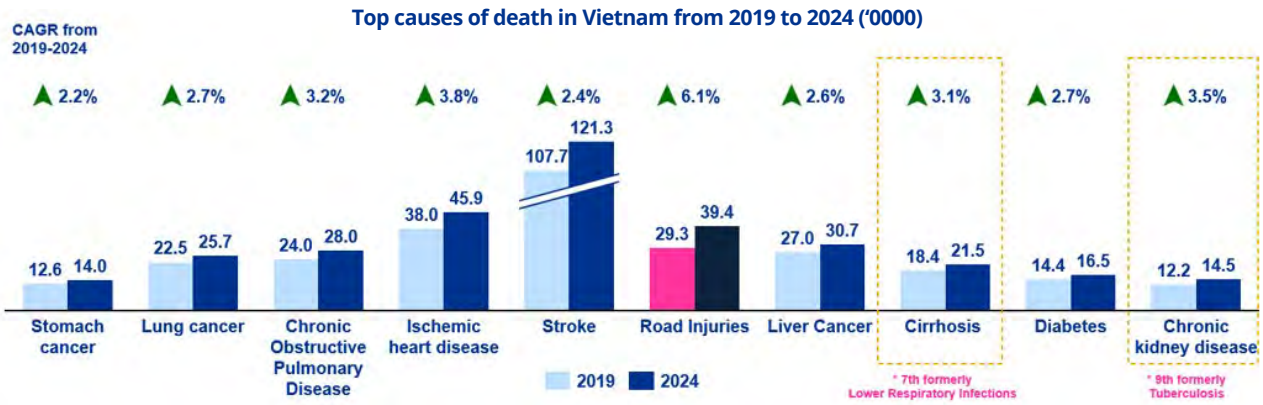


Source: BMI Fitch Solutions
Note: Road Injuries are marked with a different color because deaths from road injuries are not classified as NCDs

The growing prevalence of non-communicable diseases (NCDs) is expected to continue in the coming years. Major NCD categories: cardiovascular diseases (such as heart attacks and stroke), lung cancers, and chronic respiratory conditions, together account for roughly 70% of all disease-related deaths. As a result, Vietnam offers a supportive environment for companies to conduct specialized clinical trials in these high-burden therapeutic areas.

Regulatory reforms will strengthen Vietnam's clinical trial industry and attract global investment

Vietnam has significantly reformed its clinical trial regulations since 2012, most notably through Circular No. 03/2012/TT-BYT (Guiding Clinical Drug Trial) and Circular No. 29/2018/TT-BYT (Clinical Trial of Drugs). The first established core standards for trial facilities, drug labeling, and ethical oversight, aligning Vietnam with international practices for participant protection and data integrity. By 2018, Circular No. 29 further strengthened these regulations, representing a major milestone toward global compliance and credibility for Vietnam's clinical trials industry.

Alongside these regulatory reforms, the establishment of dedicated clinical trial units has further bolstered Vietnam's medical research landscape. The Oxford University Clinical Research Unit (OUCRU), founded in 1991, has completed 178 clinical trials and published over 2,500 academic papers, collaborating with more than 80 local
partners. The University of Sydney Vietnam Institute, launched in 2023, specializes in trial design and execution across tuberculosis, respiratory health, antimicrobial resistance, AIDS, lung disease, breast cancer, and cerebral palsy. By ensuring compliance with both local and international regulations, the institute integrates healthcare, biotechnology, and policy objectives. Meanwhile, the Tam Anh Medical Research Institute (TAMRI), established in May 2023, embodies a collaborative model that unites hospitals, universities, and private industries. With a focus on driving tangible healthcare innovations, TAMRI provides researchers with the resources needed to make a lasting impact on patient outcomes and public health.

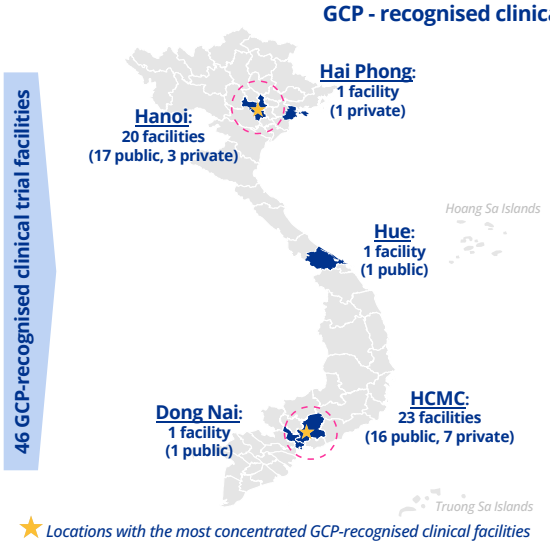
Together, these regulatory enhancements and expanding research capabilities yield substantial advantages for stakeholders across Vietnam's clinical trials ecosystem. For sponsors, clearer guidelines and standardized processes reduce administrative burdens, lower costs, and accelerate study timelines. These are critical factors when developing new treatments. As a result, the Vietnamese government, local citizens, and international partners can all share in the economic and social benefits, including potential increases in foreign investment, higher tax revenues, and marginal growth in GDP. By strengthening its clinical trial framework and fostering collaboration among research institutions, Vietnam positions itself as an increasingly attractive destination for both regional and global sponsors[14].

[14]*Global Journal of Management and Business Research (2011), 'Impact of Foreign Direct Investment on Gross Domestic Product', accessed 03 February 2025, available at: Link*

2.2.6. Vietnam clinical trials market's limitations

Despite Vietnam's growing healthcare infrastructure, there is an uneven distribution of GCP-certified facilities and regional disparities hinder its clinical trial market

GCP - recognised clinical trial facilities in Vietnam by 2024



	PUBLIC	PRIVATE
NORTH	15 Hospitals 11 National hospitals 4 Provincial hospitals 2 Institutions	3 Hospitals 1 University Central
CENTRAL	1 Hospital 1 National hospital	N/A
SOUTH	15 Hospitals 4 National hospitals 11 Provincial hospitals 3 Institutions	6 Hospitals

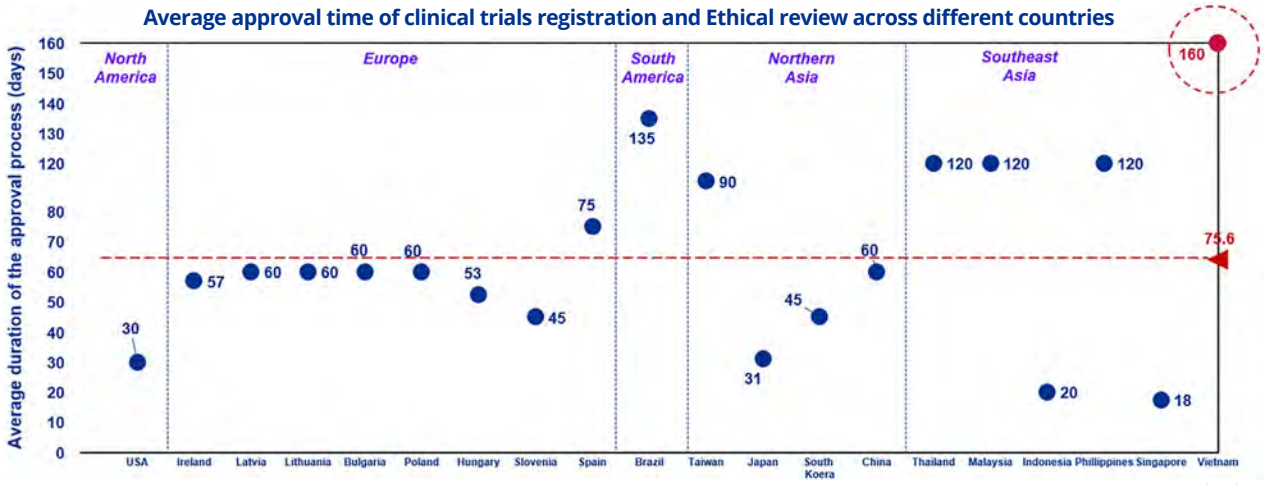
Source: KPMG Research and Analysis

As of 2024, 41 hospitals and 5 institutions in Vietnam possess government-approved Good Clinical Practice (GCP) certification, a small fraction of the nation's total healthcare network. This limited adoption stems from constrained financial resources and a shortage of trained personnel capable of conducting complex clinical studies. GCP-certified sites remain concentrated in Hanoi and Ho Chi Minh City, where the largest trial participant pools are located, underscoring significant regional gaps in clinical trial infrastructure. While this underdevelopment and lack of advanced technology pose formidable barriers to market expansion, the Ministry of Health's renewed focus on strengthening GCP standards offers a promising pathway for future growth.

In contrast, countries such as Taiwan, Poland, and Brazil feature a more evenly distributed network of GCP sites across provinces, enhancing accessibility and facilitating robust recruitment. Although no universally accepted "golden number" for GCP-certified sites exists, an optimal approach for the nation would involve a balanced ratio of GCP sites relative to regional population densities. Adopting such an approach could relieve urban facilities, drive broader participation, and ultimately strengthen Vietnam's overall clinical trial infrastructure.

Vietnam still lags behind many countries in clinical trial approval times, highlighting the need to streamline its regulatory framework and adopt internationally recognized standards

Average approval time of clinical trials registration and Ethical review across different countries



Source: KPMG Research and Analysis

Note: The approval time for Vietnam only reflects the approval time at MOH level. In reality, the entire process encompasses with seeking for approval at local level (which takes 3 – 12 months depending on the number of sites) and at MOH level (which takes 3 – 5 months on average) and then import permits for drug (for drug trial) (which takes 3 – 4 months).

On average, Vietnam's clinical trial approval and ethical review process takes nearly 160 days, significantly longer than global benchmarks and is the longest among regional peers. This extended timeline affects the country's overall market attractiveness. Multiple factors contribute to the delay, including a regulatory framework requiring separate reviews by both central and local ethics committees, extensive documentation demands, and limited staffing and infrastructure within relevant agencies. Streamlining these steps, and better aligning them with international standards, is vital for Vietnam to enhance its competitiveness and attract more clinical trials.

3. Barriers to clinical trials

3.1. Overview

Despite Vietnam's increasing recognition as a promising site for clinical trials, there are several critical barriers that hinder the country's ability to fully realize its potential, which can be broadly categorized into **Regulatory, Infrastructure, Human resources, Funding.**

Regulatory and Incentives

Lengthy approval process: Delays in obtaining regulatory approvals slow down clinical trial initiation and overall timelines

Unclear inport regulations: Lack of clarity around the importation of investigational products and materials

Lack of incentive: Limited government or regulatory incentives slow down investments in clinical trials and related infrastructure

Human Resources

Shortage of trained personnel: A limited pool of skilled professionals

Lack of adequate training opportunities: In need of programs for training clinical researchers and healthcare workers

Infrastructure

Limited availability of GCP-certified facilities: The lack of facilities adhering to Good Clinical Practice (GCP) standards

Limited availability of Clinical Trials Units (CTUs): few dedicated CTU exist in Vietnam, limiting trial delivery and governance

Absence of comprehensive disease registries: The lack of reliable disease registries makes patient identification and recruitment for trials more challenging

Geographic disparities: Uneven infrastructure development across regions limits access to research facilities, affecting scalability

Funding

Payment delays: Slow disbursement of funds affects trial continuity and stakeholder motivation

Lack of financial incentives: Limited menetary support for clinical research

3.2. Regulatory challenges

Lengthy approval processes

Vietnam's sequential clinical trial approval process is a key factor contributing to delays and inefficiencies in the country's research ecosystem. Unlike Malaysia and Singapore, which conduct parallel ethical reviews, Vietnam requires each step to be completed before the next phase can begin. This creates unnecessary bottlenecks, slowing down the initiation of clinical trials and making Vietnam less attractive to international sponsors.

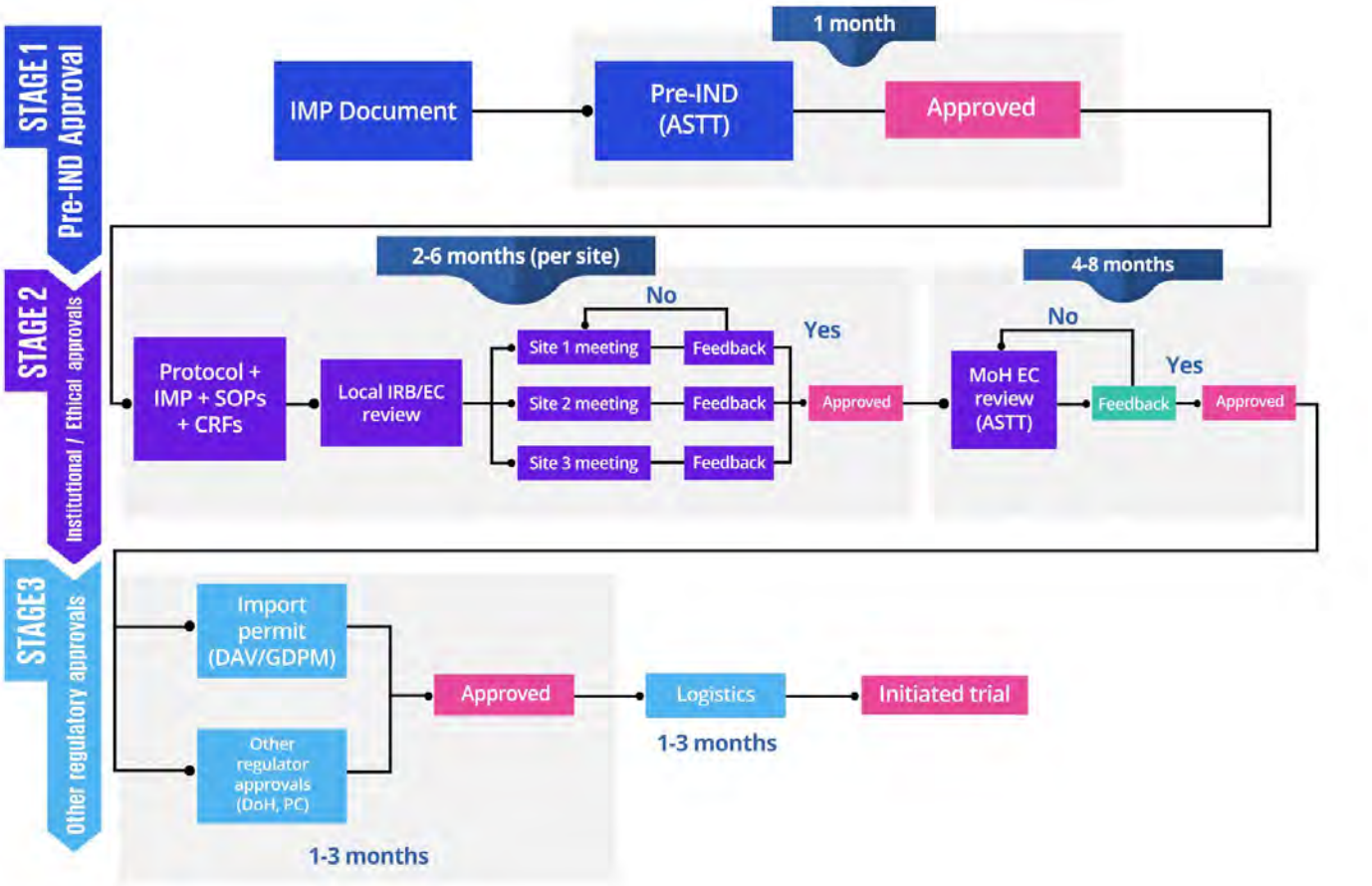
Currently, the clinical trial approval process in Vietnam consists of three main steps:

1. Pre-IND approval: Administration of Science, Technology, and Training (ASTT) will review IMP dossier, approval given within a month

2. Institutional / Ethical approvals: The process will begin with scientific and ethical review at local sites, where full dossier can be parallel submitted to all local sites, but approval time is varied at each local site, ranging from 2-6 months per site. Local review process requires full board face to face meetings with the study PI. Protocol revisions and re-meeting may be required, ensuring all sites have the same approved protocol version before moving to BYT approval. The local approvals and the approved dossier will then be sent to ASTT and NECBR for a legal check, and another ethical review conducted at a meeting within a month. Any response/ revision should be submitted back within 90 days. The whole BYT approval takes from 4-8 months. This main step is required for every subsequent protocol amendment.

3. Other regulatory approvals: Such as IMPs, labkit, equipment import permits or **DoH/ People Committee Level approvals**: sites must submit BYT approvals together with appropriate documents to relevant departments to get import permits of IMP/ labkit or to have "green" signal to initiate the study at the site. This step will take 1-3 months to complete.

In addition to these multiple levels of approval, the NECBR's protocol review is initiated by the MOH as part of the ASTT's procedures for evaluating study approval dossiers. This means the ASTT cannot complete its review until NECBR approval is granted, further prolonging timelines. According to Circular No. 29/2018/TT-BYT on Clinical Drug Trials and Law No. 105/2016/QH13 on Pharmacy, final MOH authorization is only granted once all prior approvals are secured. The overall flow of the process can be visualized as the chart below.



Challenges with the Current System

- **Repeated Reviews:** Approval for clinical trials in Vietnam requires various rounds of reviews and approvals, which are repetitive as questions are similar across the rounds and can take more than 1 year, which slows down the process unnecessarily and can discourage investors and other stakeholders to participate.
- **Strict Correction Windows:** Sponsors have limited timeframes (60–90 days) to submit corrections. If they fail to meet these deadlines, they must restart the process, leading to further delays.
- **Lack of a Defined Timeline for MOH's and local site level's approval:** Unlike the earlier review stages, the final approval by the MOH (including EC approval and import permits) as well as local-level sites do not have a guaranteed timeframe, making the overall process unpredictable for sponsors.
- **Resource Limitations:** Limited staffing within regulatory agencies leads to further processing delays, while paper-based submission systems slow document tracking and approvals.

Impact on Vietnam's Clinical Trial Landscape

This multi-layered approval system places Vietnam at a disadvantage compared to regional competitors, where clinical trials can move forward faster. The lack of a streamlined, predictable approval process discourages international sponsors and increases administrative costs. As a result, Vietnam risks missing out on valuable investment and research collaborations.

It is observed that clinical trials for drugs, medical devices, and vaccines have different regulations and requirements with challenges vary across each area.

CATEGORY	KEY REGULATIONS	STUDY REQUIREMENTS	KEY CHALLENGES	OPPORTUNITY FOR REFORM
Drugs	Law of Pharmacy, Decree No. 54/2017/ND-CP, Circular No. 08/2022/TT-BYT (exemptions for urgent needs, reference agency approvals)	Phases I-IV, informed consent, local ethics review, GCP compliance	Complex alignment with local and international standards for multinational trials	Centralize ethics reviews (e.g., Taiwan's TFDA model)
Medical Devices	Decree No. 98/2021/ND-CP (effective 2022), managed by Infrastructure and Medical Device Administration (IMDA) (previous name as DMEC); 3-phase trials (pre- and post-registration)	Phases 1-2 (safety/efficacy pre-registration), Phase 3 (post-approval, real-world safety/efficacy)	Focus mainly for medical devices and unclear importation guidance for laboratory kits or supplies used in a clinical trial. Device - specific protocol design, patient safety for invasive devices, adapting to new regulations	Fast-track pre-registration phases, clarify post-approval rules
Vaccines	Law of Pharmacy, Circular No. 08/2022/TT-BYT (registration as biologicals)	Similar to drugs, with emphasis on large-scale efficacy/safety due to public health implications	Large-scale production, efficacy vs. evolving pathogens, public perception	Leverage PPPs for funding and scale (e.g., Poland's ABM)

Unclear import regulation

Vietnam's unclear import regulations present a major obstacle for clinical trial sponsors, particularly in the importation of investigational medicinal products (IMPs), lab kits used in a clinical trial, and other critical trial equipment. The lack of clearly defined requirements and the need to obtain multiple import licenses result in inconsistent and time-consuming approval processes.

A key challenge is the ambiguity in required documentation. Sponsors are typically required to submit a combination of documents, such as product registration certificates, quality control documents, and clinical trial approval letters. However, the specific requirements often vary depending on the interpretation of different regulatory bodies, leading to unpredictability in the approval process. Additionally, overlapping jurisdiction between multiple entities including the ASTT, customs authorities, and local health departments further complicates the importation process by introducing redundancies and procedural delays.

Addressing these inefficiencies by implementing standardized and transparent import regulations would help reduce administrative burdens and improve Vietnam's attractiveness as a clinical trial destination. Streamlining coordination among regulatory agencies and aligning import requirements with international best practices could significantly accelerate trial initiation and encourage greater foreign investment in the sector.

Lack of incentives

Vietnam has implemented only modest policies and initiatives to attract multinational pharmaceutical companies to conduct clinical trials, limiting its competitiveness in the regional clinical research landscape. In contrast, countries such as Taiwan have proactively introduced measures like streamlined approval processes and the inclusion of trial drugs in procurement lists, making them more attractive destinations for clinical research.

One of the key shortcomings in Vietnam's current framework is the lack of a sufficiently robust "fast-track" mechanism. While an expedited approval pathway exists, it lacks the efficiency and comprehensive incentives seen in more developed regulatory systems. This is particularly problematic for critical studies focused on developing medicines for urgent public health needs, where rapid trial activation is essential.

Compounding this issue is the absence of a clearly defined and reliable timeline for clinical trial approvals. Uncertainty surrounding approval durations creates significant challenges for pharmaceutical companies and academic institutions, making it difficult for them to effectively plan and execute research and development strategies. Without greater predictability and incentives, sponsors may opt to conduct trials in countries with more efficient regulatory environments.

Addressing these structural barriers is essential for Vietnam to enhance its attractiveness as a clinical trial hub. By improving regulatory transparency, strengthening fast-track mechanisms, and introducing targeted incentives such as tax benefits, subsidies, or priority review for trials addressing high-burden diseases, Vietnam can better position itself as a competitive player in the global clinical research landscape.

3.3. Infrastructure

Limited availability of GCP-certified facilities

Currently, only a small number of hospitals in urban centers meet Good Clinical Practice (GCP) standards as they lack the infrastructure and resources required to meet the standards such as advanced laboratories, storage for IMPs, and specialized equipment. This low number of GCP-certified facilities limits the capacity for trials to expand into smaller or less-equipped hospitals. This creates a concentration of trial activities in urban areas.

Limited availability of Clinical Trials Units in Vietnam

Vietnam has very few dedicated Clinical Trials Units (CTUs), which are essential for coordinating and governing clinical research. Unlike CROs, which focus on outsourced trial management, CTUs provide structured support for both academic and industry-sponsored trials and they build critical local capacity and expertise. Their absence creates inefficiencies in trial execution, affecting regulatory compliance, research quality, and Vietnam's attractiveness for international clinical studies. Without CTUs, trial coordination become fragmented, increasing the risk of delays and inconsistencies in Good Clinical Practice (GCP) adherence. The lack of CTUs, also limits investigator-led research and participation in multi-center and international trials. In developed markets, CTUs streamline study execution across multiple sites, ensuring standardized processes and high-quality data collection. Without them, Vietnam faces challenges in integrating into large-scale, multinational trials. Additionally, the burden of managing trials falls on hospitals and universities, which often lack the administrative infrastructure to efficiently oversee research, potentially causing inconsistencies in trial quality and operations. Developing CTUs could be a simple way for Vietnam to dramatically accelerate the development of not only clinical trials capacity, but also its overall life sciences development capabilities.

Absence of comprehensive disease registry

The absence of a comprehensive disease registry, such as cancer databases, which makes it challenging to identify eligible patients and streamline recruitment and planning. Vietnam's healthcare institutions collect patient data independently, often in incompatible formats, leading to fragmented records spread across multiple hospitals and clinics. At the same time, the digital transformation of Vietnam's healthcare sector is still in its development stage and many facilities lack the technology required to establish or contribute to a centralized disease registry.

Geographic disparities

Trial activities are primarily focused on big cities such as Hanoi, Ho Chi Minh City and Danang, leaving rural provinces with significant patient pools underutilized. Expanding trial operations in these areas is constrained by limited infrastructure as there is a lack of GCP-certified sites with advanced diagnostic equipment. Many facilities in these areas and underfunded and poorly equipped which are not suitable for the rigorous demand of conducting clinical trials. This is further exacerbated by the shortage of trained personnel to execute trials as there are limited training opportunities.

3.4. Human resources

Lack of training opportunities:

Participation in clinical trial training remains low due to conflicting time demands, as doctors and nurses may sensibly prioritize patient care over additional training. Many medical institutions also lack structured support or incentives, making it difficult for healthcare professionals to engage in specialized programs.

However, several institutions are working to address this gap. VinUniversity, for example, has developed clinical research programs in partnership with global institutions, focusing on Good Clinical Practice (GCP) compliance and research methodologies. Other universities and research centers are also expanding their training initiatives to build a more skilled workforce.

To improve participation, Vietnam could integrate clinical trial education into medical curricula, offer incentives, and establish national accreditation for clinical research professionals.

Shortage of trained personnel:

Most healthcare workers in Vietnam lack familiarity with clinical trial procedures. Junior doctors and nurses, especially those in early careers, face a steep learning curve when introduced to the clinical trial process. The complexity of managing trial protocols, ensuring patient safety, adhering to ethical guidelines, and managing trial documentation can overwhelm less-experienced healthcare professionals. Additionally, balancing clinical duties with trial-related responsibilities can be a deterrent for healthcare professionals, particularly those earlier in their careers.

3.5. Funding

Vietnam has encountered critical funding barriers in its clinical trials sector, which have posed challenges to its advancement. The funding barriers primarily stem from time-consuming contract approval processes, payment delays and the lack of financial incentives for clinical research. These issues affect the capacity of the country to conduct high-quality and large-scale clinical trials.

Payment delays:

In Vietnam, the primary financial challenge is not simply delays in receiving funds from sponsors, but bottlenecks in disbursing those funds from local institutions to trial sites, investigators, and research teams. Once funding is secured, contractual complexities, administrative inefficiencies, and inconsistent approval workflows across different institutions slow down the transfer of funds, disrupting trial operations and delaying patient recruitment. These barriers also discourage healthcare professionals from participating in research.

Lack of financial incentives:

Beyond disbursement delays, securing funding itself remains a challenge. Vietnam lacks structured financial incentives such as government grants, tax benefits, or dedicated research funding programs. Unlike other regional markets, sponsors and institutions face limited financial support to offset the high costs of patient recruitment, site management, data collection, and regulatory compliance.

The financial burden of conducting clinical trials is significant, with global costs averaging USD 4 million for Phase 1 trials, USD 13 million for Phase 2, and USD 20 million for Phase 3. Additionally, pivotal Phase 3 trials for FDA-approved drugs have a median per-patient cost of USD 41,117. While clinical trial costs in Asia are generally 30-40% lower than in the U.S. and Europe, expenses in Vietnam remain substantial. Addressing these financial challenges through streamlined fund disbursement processes and targeted incentives would enhance Vietnam's attractiveness as a clinical trial destination.

Unlike other regional markets, Vietnam lacks structured funding mechanisms and tax incentives specifically designed to support clinical trial sponsors. In contrast to countries that offer comprehensive tax benefits for clinical research, Vietnam does not provide targeted financial relief to offset the high costs associated with patient recruitment, site management, data collection, and regulatory compliance. Additionally, government and institutional grants dedicated to supporting clinical trials remain scarce.

For example, Taiwan has successfully positioned itself as a competitive clinical trial destination by offering R&D tax credits and integrating clinical trial drugs into national procurement lists, reducing financial risks for sponsors. Similarly, Singapore provides research grants and government co-funding programs that directly support clinical trials, ensuring predictable financial backing for both public and private sector research.

The absence of such incentives in Vietnam makes the country less competitive compared to markets that actively subsidize trial costs, streamline regulatory expenses, or offer tax reductions to attract research investments. If Vietnam aims to establish itself as a regional R&D hub, it must consider adopting similar policies, including tax incentives, co-funding initiatives, and streamlined financial regulations, to enhance its attractiveness for clinical trials. These and other structural improvements will be essential for Vietnam to compete effectively with its regional peers in the global clinical research landscape.

3.6. Comparison of Vietnam's barriers to other comparable markets

To highlight the necessity of addressing Vietnam's existing market barriers in the clinical trials market, a benchmarking exercise has been conducted between Vietnam, Singapore and Thailand. This helps policymakers to understand what barriers need to be prioritized to make Vietnam's clinical trials industry to grow at the same pace with 2 leading countries of this field in Southeast Asia.

Comparison of the priority levels for market barriers in the peer markets' clinical trials sector

	1	2	3	4
Vietnam	Regulatory and Incentives	Infrastructure	Human Resources	Funding
Singapore	Infrastructure	Human Resources	Regulatory and Incentives	Funding
Thailand	Human Resources	Regulatory and Incentives	Infrastructure	Funding

3.6.1. Singapore

Singapore initially faced several challenges in establishing itself as a clinical trial hub, including limited research infrastructure, a shortage of skilled human resources, regulatory inefficiencies, and constraints in clinical trial funding. Despite having an advanced healthcare system, the country struggled with outdated research facilities and a lack of cutting-edge equipment, restricting its ability to conduct complex clinical trials. Recognizing this, the government invested over USD 2.2 billion in biomedical sciences between 2000 and 2006, leading to the creation of Biopolis, a dedicated research hub with seven research centers and 2,000 researchers, which significantly expanded the country's research capabilities.

In parallel, Singapore prioritized human resource development by launching initiatives such as the National Medical Research Council's (NMRC) training programs and collaborations between institutions like Duke University and SingHealth to build a sustainable biomedical workforce. On the regulatory front, Singapore implemented a fast-tracked clinical trial approval process (5 to 30 days), aligning its framework with evolving global standards to attract more research investments. While funding constraints existed, they were addressed through Clinical Trial Grants (CTG) and other incentive schemes, enabling clinicians to advance new therapies.

This strategic combination of infrastructure investment, workforce development, streamlined regulations, and targeted funding positioned Singapore as a leading clinical trial hub in Asia. This is an approach that Vietnam could adapt to strengthen its own clinical research ecosystem.

3.6.2. Thailand

Thailand initially faced significant barriers in human resources, regulatory efficiency, infrastructure, and funding, limiting its potential as a clinical trial hub.

Human resources were the most critical challenge, with a shortage of professionals trained in clinical trial management and advanced therapeutic areas. This gap affected trial design, patient recruitment, and execution. To address this, Thailand partnered with pharmaceutical companies, international organizations, and local institutions to provide specialized training and workshops, improving workforce expertise and expanding the talent pool.

Regulatory reforms have played a key role in Thailand's progress. The Thai Food and Drug Administration has worked to streamline approval processes, reducing clinical trial approval times to 3–5 months, which was a significant improvement that has enhanced Thailand's appeal for sponsors. While regulatory efficiency remains a priority, these reforms have positioned Thailand as a more competitive destination for research.

Infrastructure limitations, particularly in rural areas, posed another challenge. Well-equipped hospitals and research centers were mostly concentrated in major cities, making it difficult to expand trials to underserved regions. Logistical barriers, including delays in transporting trial materials, further disrupted research activities. However, ongoing improvements to research facilities and transportation networks have helped to mitigate these constraints.

Funding was historically limited but became more accessible as regulatory improvements, workforce development, and infrastructure expansion increased investor confidence. While private investment grew in response to these advancements, government support through grants from the National Research Council of Thailand has also contributed to sustaining the country's clinical research ecosystem.

By addressing these barriers through strategic investments, regulatory streamlining, and workforce development, Thailand has strengthened its position as a regional clinical trial hub.

Key takeaway

Vietnam faces many of the same barriers that Singapore and Thailand encountered in their early stages of clinical trial development. However, unlike these countries, Vietnam does not need to prioritize large-scale investments in attracting foreign sponsors. Many multinational pharmaceutical companies are already interested in conducting trials in the country. Instead, the biggest bottleneck is Vietnam's complex and inefficient regulatory environment, which significantly slows trial approvals and discourages investment.

To accelerate its clinical trial market growth, Vietnam should focus on regulatory reforms as a top priority, drawing from successful models in Singapore and Thailand. Key actions include:

- **Streamlining the Approval Process:** Implementing parallel ethical reviews, similar to Singapore and Malaysia, can significantly reduce approval timelines. Additionally, Bangladesh recently introduced a single-window regulatory approval system to simplify submissions for sponsors. A similar approach in Vietnam could reduce redundancies and improve coordination between regulatory bodies.
- **Strengthening Clinical Trial Infrastructure**: While not as critical as regulatory reform, targeted investment in GCP-certified sites beyond Hanoi and Ho Chi Minh City would improve trial accessibility. Expanding digital infrastructure for trial oversight can also improve efficiency.
- **Developing a Skilled Workforce:** Vietnam should expand structured training programs for clinical trial professionals through partnerships with academic institutions and international organizations, following Thailand's model of clinical research training programs.
- **Establishing Incentives for Sponsors:** To remain competitive with regional peers, Vietnam should introduce tax benefits, research grants, and funding mechanisms to offset trial costs for sponsors, as seen in Singapore and Thailand.

If Vietnam acts quickly to implement these reforms, it can catch up to and even surpass its Southeast Asian peers, positioning itself as a premier hub for life sciences innovation and clinical research. With the right regulatory improvements, Vietnam has the potential to become the go-to destination for pharmaceutical R&D in the region, driving both economic growth and advancements in healthcare.

4. Peer market benchmarking

4.1. Screening and Shortlisting Preliminary Result

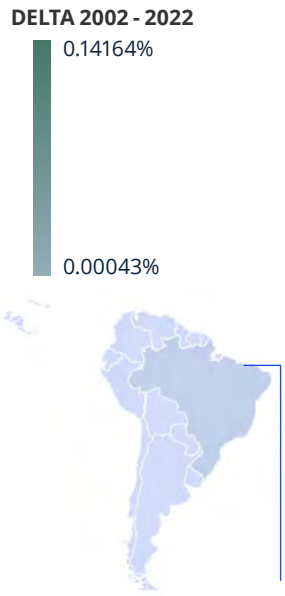
Vietnam is at the start of a journey to becoming a regional hub for clinical trials. With the right reforms in regulation, infrastructure, and research capacity, the country can attract global sponsors and contribute to medical innovation. This transition will be challenging, but Vietnam is not alone, other markets have faced similar obstacles and offer valuable lessons.

Before examining the detailed case studies of Taiwan, Brazil, and Poland, this section will first highlight regional solutions to common challenges in clinical research. These insights will provide a broader perspective on how markets across Asia have improved regulatory efficiency, research infrastructure, and industry collaboration.

By learning from both regional and global best practices, Vietnam can develop a practical roadmap for growth, positioning itself as a competitive destination for clinical trials.

4.1.1. Screening

Using a structured screening approach, 194 countries were analyzed to identify the 10 most comparable clinical trial markets to Vietnam. The selection was based on growth in clinical trials per capita and the size of the addressable patient pool (total population). The following diagrams provide an overview of these comparable markets.



POLAND

Poland has significantly advanced trial development since 2024, improving its **regulatory framework and trial efficiency.**

Polish Government supported through **NCBR programs (2024)** fostered innovation.

The 2023 EU-CTR introduced a centralized database for submissions, enhancing coordination and transparency across EU member states.

Clinical Trials Act 2023 **aligned Poland's legislation with EU Regulation 536/2014.**

HUNGARY

Hungary is a strong case study because it overcame several barriers to successfully positioned itself as a key player in Europe's clinical trial landscape.

Hungary initially faced slow approval processes and complex regulatory requirements. But later on, the country reformed its regulatory framework to align with EU clinical trial directors and adopted centralized ethics committees, significantly reducing approval time.

BRAZIL

Brazil has worked to streamline the regulatory appoval process for clinical trials, making it more efficient for sponsors to initiate and conduct studies.

The country has actively harmonized its regulatory framework with international standardsm such as Good Clinical Practice (GCP) guidelines, ensuring global recognition and trust in Brazillian clinical trials.

The government has fostered collaboration between public research institutions, private pharmaceutical companies, and healthcare providers to drive innovation and accelerate clinical research.

SPAIN

Spain's success is mainly due to the implementation of the European clinical trial regulation (CTR), which Spain was the first to adopt since 2016 investment in this area has grown at a rate of 5.7% per year from 479 milion in 2012 to 834 milion in 2022.

Spain has adopted a proactive, coordinated and cross-cutting approach to building its clinical trials ecosystem, driven by increased investment.

Note: KPMG has performed the analysis on all countries in the world to evaluate the growth of the clinical trials market in each country
Source: KPMG Research and Analysis

SOUTH KOREA

The Ministry of Food and Drug Safety (MFDS) introduced the Clinical Trial Authorization (CTA) process in the mid-2000s.

With research hospitals like Samsung Medical Center and advanced IT systems, South Korea ensures trial quality. Continuous researcher training programs support a highly skilled clinical trial workforce.

Adoption of decentralized trials and telemedicine since 2015 has improved patient recruitment and retention rates, further boosting trial efficiency.

THAILAND

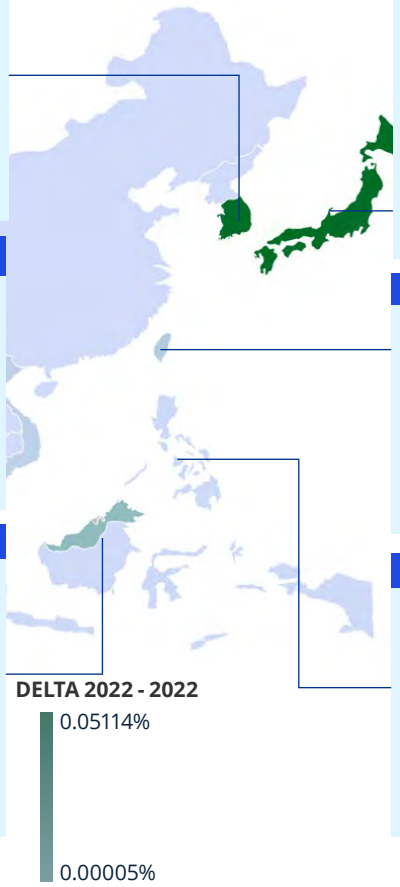
Thailand offers a compelling environment for clinical trials, combining rapid regulatory approval processes with significant cost savings. The Thai FDA's streamlined approach accelerates approvals, reducing time-to-market for new therapies.

Moreover, Thailand's lower operational costs, affordable healthcare services, and efficient patient recruitment contribute to substantial cost savings compared to Western countries, making it an attractive destination for pharmaceutical companies.

MALAYSIA

Malaysia's Ministries and Government Agencies offer various facilities and initiatives, including testing and certification, simplified licensing, tax incentives and funding assistance, training and consultancy services, and skills upgrading programmes.

Clinical Research Malaysia (CRM), a government-owned non-profit organization, was founded in 2012 to promote Malaysia as a leading destination for clinical trials. CRM aims to support the industry by providing services such as regulatory guidance, site management, and training.



JAPAN

Japan's Pharmaceuticals and Medical Devices Agency (PMDA) implemented fast-track approval systems and International Council for Harmonisation (ICH) harmonization starting in 2023, enabling quicker reviews and aligning with global standards.

The 2015 establishment of The Japan Agency for Medical Research and Development (AMED) has significantly funded partnerships in advanced medical research, enhancing Japan's clinical trial ecosystem.

Leveraging IT systems for trial monitoring and patient registries since 2010 has improved recruitment and compliance.

TAIWAN

The Center for Drug Evaluation (CDE) introduced expedited review pathways in 2005, while centralized IRBs standardized ethical reviews, boosting trial efficiency.

Tax incentives since 2010 and partnerships with global regulatory bodies have positioned Taiwan as a hub for international clinical trials.

Adoption of modern patient-centric technologies has significantly enhanced trial accessibility and engagement since 2015.

PHILIPPINES

From 2011 to 2015, the Philippines aligned clinical trial regulations with ASEAN Good Clinical Practice (GCP), boosting international compliance and partnerships.

The 2015 establishment of the Nation Clinical Trials and Translation Center (NCTTC) improved infrastructure and supported investigator-led trials nationwide.

During COVID-19 (2020), expedited approvals and tax incentives increased clinical trial activitym emphasizing the country's rapid response capacity.

4.1.2. Notable achievements and policies from regional peers

Vietnam's clinical trials sector faces several barriers that have slowed its growth and limited its competitiveness in the region. However, other markets in Asia have successfully navigated similar challenges, implementing policy reforms, infrastructure investments, and industry collaboration models that Vietnam can learn from.
This section highlights three major barriers currently limiting Vietnam's clinical research potential and examines specific policy solutions implemented in other countries that could serve as models for Vietnam.

Barrier 1: Regulatory Bottlenecks and Approval Delays

VIETNAM'S CHALLENGE: Vietnam's clinical trial approval process is lengthy and fragmented, requiring approvals from multiple agencies, sequential ethics reviews, and varied interpretations of regulatory requirements. The absence of a centralized approval system results in inefficiencies that discourage sponsors from investing in early-phase trials or expanding trial operations.

How Other Countries Addressed This Issue:

- **South Korea South Korea introduced the IND-Integrated** Review System under the Ministry of Food and Drug Safety (MFDS). This policy streamlined the approval process by allowing parallel review of clinical trial applications and investigational drug registration. Previously, these steps were handled separately, creating long delays. With the integrated review system, South Korea reduced trial start-up times by nearly 40%, making it a preferred destination for early-phase research.
- **Singapore implemented the Clinical Trials Authorization (CTA)** scheme under the Health Sciences Authority (HSA). The CTA process introduced a single application system that consolidated regulatory approvals across agencies, eliminating duplicate reviews. Additionally, Singapore introduced the National Healthcare Group (NHG) and SingHealth Centralized Institutional Review Boards (CIRB), allowing multi-site ethics review. This means that a single ethics approval can apply across multiple trial sites, instead of requiring separate approvals for each hospital, reducing trial initiation times by 30–40%.
- **China's National Medical Products Administration (NMPA)** addressed approval delays by introducing pre-submission consultations, allowing sponsors to engage with regulators early and address concerns before submitting formal applications. Additionally, China established fast-track approval pathways for priority therapeutic areas, such as oncology and rare diseases. These pathways cut the average approval time from 12–18 months to under three months, significantly improving China's competitiveness in attracting global trials.

Barrier 2: Limited Clinical Trial Infrastructure and CRO Development

VIETNAM'S CHALLENGE:
Vietnam's contract research organization (CRO) ecosystem remains underdeveloped, with most large-scale trials relying on foreign CROs. This dependency slows execution, increases costs, and limits Vietnam's ability to expand its clinical research capacity. Additionally, few hospitals have dedicated clinical trial units (CTUs), making research coordination inefficient. The lack of site management organizations (SMOs) also creates inconsistencies in trial execution across different locations.

How Other Countries Addressed This Issue:

- Malaysia established Clinical Research Malaysia (CRM) under the Ministry of Health Malaysia (MOH) to provide site management services, investigator training, and regulatory support. CRM acts as an intermediary between sponsors and trial sites, ensuring trials run efficiently. The government also launched the National Phase 1 Realization Project, which provides funding and infrastructure support to expand early-phase clinical trial capabilities, ensuring that Malaysia is not only conducting late-stage trials but also contributing to global drug development pipelines.
- Thailand developed the Excellence Center for Clinical Trials (ECCT) in collaboration with the Thai Food and Drug Administration (Thai FDA). The ECCT is a centralized trial coordination unit that supports protocol development, investigator training, and trial site accreditation to ensure high-quality research environments. Additionally, Thailand introduced financial incentives for hospitals to establish dedicated Clinical Trial Units (CTUs), increasing the country's ability to conduct multi-site clinical trials efficiently.
- India focused on simplifying CRO accreditation requirements, removing bureaucratic barriers that previously made it difficult for local CROs to compete with international firms. By increasing government funding for hospitals to establish Clinical Trial Units (CTUs) and providing subsidies for clinical trial site expansion, India has increased its trial capacity significantly.

VIETNAM'S EMERGING MODEL: Vietnam's Tam Anh Research Institute is pioneering a hospital-integrated clinical trial management model, demonstrating how local research units can streamline trial coordination and reduce reliance on foreign CROs. This model represents a potential path forward for scaling Vietnam's trial execution capabilities while ensuring regulatory compliance and site management efficiency.

Barrier 3: Low Patient Recruitment and Public Awareness

VIETNAM'S CHALLENGE:
Vietnam has one of the lowest patient participation rates in clinical trials (1–2%) due to limited awareness, cultural reluctance, and logistical barriers. Sponsors often face slow recruitment, high dropout rates, and difficulties in identifying eligible participants, increasing costs and extending trial timelines.

How Other Countries Addressed This Issue:

- **Japan**'s Ministry of Health, Labor and Welfare (MHLW) launched nationwide public awareness campaigns to educate citizens on the benefits and safety of clinical trials. These campaigns were complemented by the Japan Registry of Clinical Trials (JRCT), an online platform where patients can search for relevant trials, increasing transparency and participation.
- **Australia** introduced the Australian New Zealand Clinical Trials Registry (ANZCTR), a publicly accessible database where patients can search, register, and enroll in clinical trials. Additionally, Australia integrated electronic health records (EHRs) with trial recruitment platforms, allowing researchers to identify eligible patients automatically based on medical history, improving recruitment efficiency.
- **Taiwan**'s government provides financial incentives to hospitals that successfully integrate clinical trials into routine patient care. Hospitals that meet clinical trial recruitment targets receive additional funding, ensuring that healthcare providers actively refer eligible patients into research studies.

4.1.3. Benchmarking

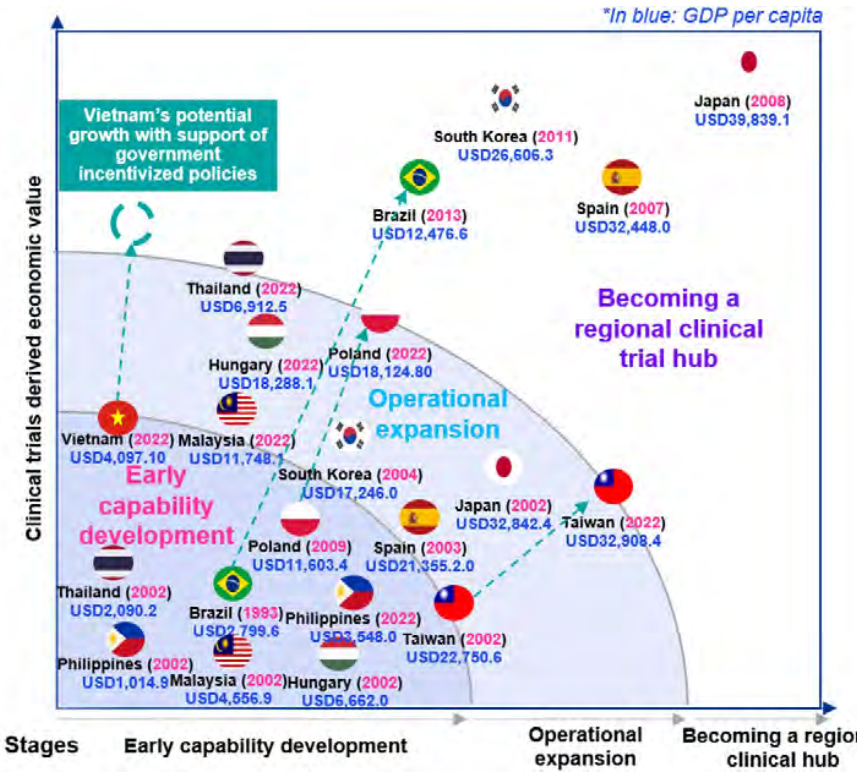
Vietnam is not alone in its ambition to become a leading destination for clinical trials. Many countries that now host large volumes of research once faced similar challenges, including slow regulatory approvals, limited research infrastructure, and difficulty attracting global sponsors. However, through targeted policy reforms, industry collaboration, and investment in clinical trial infrastructure, these markets successfully transformed into competitive research hubs.

This section examines Taiwan, Brazil, and Poland, three countries that have overcome bureaucratic inefficiencies, research capacity limitations, and low industry engagement. Each case study highlights the key strategies and policies that helped these countries expand their clinical trial sectors, offering Vietnam a blueprint for reform and growth.

4.2. Key lesson learnt for Vietnam

What are economic and social values that the countries can realize in each stage

Vietnam is in a similar position to where comparable markets were when they began industry development. Vietnam can learn from the development of its peers to inform its industry policies



STAGE 1 | EARLY CAPABILITY DEVELOPMENT

- Regulations standardization
- Improvement in clinical trials infrastructure
- Workforce/ Human resources training

STAGE 2 | OPERATIONAL EXPANSION

- Improved patient outcomes through faster drug development
- Improve individual patient care quality
- Public health benefits
- HCPs' capabiltity development
- Academic publications

STAGE 3 | BECOMING A REGIONAL CLINICAL TRIAL HUB

- Increase in GDP and Tax
- Increase in employment rate
- Improved national clinical trials capability
- R&D spillover
- Increase in FDI investments
- PPP in research

Development trajectory through each phases

Source: KPMG Research and Analysis

The clinical trial landscape has evolved significantly over the past two decades, with the global volume of trials increasing as more countries develop their regulatory frameworks and research capabilities. To better understand how clinical trial markets mature, a review of 10 countries were selected for in-depth study, revealing three distinct stages of clinical trial market development.

STAGE 1
EARLY CAPABILITY DEVELOPMENT

Vietnam's current stage: Countries in this stage are in the early phases of clinical trial development, with evolving regulatory systems, limited trial infrastructure, and relatively low trial participation. Most research is concentrated in late-stage (Phase 3 and 4) trials, as early-phase research remains limited. Expanding trial capacity, improving regulatory efficiency, and attracting industry partnerships are key priorities. Vietnam is currently in this stage, with a growing clinical trials market but challenges in trial approvals, CRO/CTU capacity, and patient recruitment.

STAGE 2
OPERATIONAL EXPANSION

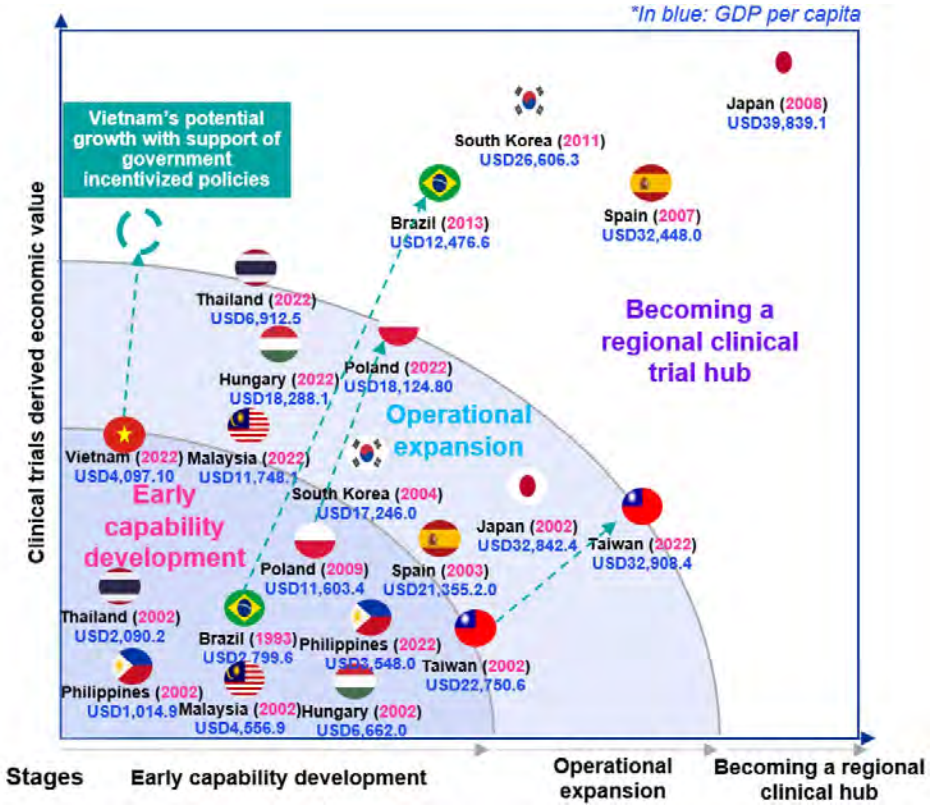
Countries in this stage have established regulatory frameworks and growing research capacity, enabling them to attract a higher volume of international clinical trials. Streamlined approval processes, better patient recruitment strategies, and the expansion of contract research organizations (CROs) characterize this phase. Countries like Malaysia, Thailand, and Poland have successfully transitioned to this stage, increasing their clinical trial competitiveness. For Vietnam, progress toward this stage will require regulatory reform, stronger industry partnerships, and investment in trial site infrastructure.

STAGE 3
BECOMING A REGIONAL CLINICAL TRIAL HUB

At this stage, countries have highly developed research ecosystems and are preferred destinations for early-phase and high-value clinical trials. These markets feature fast-track regulatory pathways, strong domestic CRO networks, and seamless integration of clinical trials into healthcare systems. Countries like Taiwan, South Korea, and Singapore have achieved this status by investing in regulatory excellence, digital trial systems, and international research collaboration. Vietnam aspires to reach this level in the future but will need long-term investments in infrastructure, workforce development, and policy modernization.

WHICH COUNTRY ALSO FACED THE SAME CHALLENGES like Vietnam did when they first developed their clinical trials industry.

Vietnam is in a similar position to where comparable markets were when they began industry development. Vietnam can learn from the development of its peers to inform its industry policies



Common barriers faced by other countries during the development of their clinical trials market *(by level of priority of the barriers that Vietnam is facing)*

Type Barriers Faced by EARLY DEVELOPING COUNTRIES

Unclear regulations (including import)

Lengthy approval processes

Lack of non-financial incentives

Lack of financial incentives for clinical trials

Lack of trained HCPs

Limited availability of GCP-certified facilities/CTU

Absence of comprehensive disease registries

Lack of adequate training opportunities

Geographic disparities in clinical trials infrastructure

Opportunity cost for HCPs

Type Barriers Faced by OPERATIONAL EXPANSION COUNTRIES

Low patient enrolment rate

Time-consuming funding contract approval process

Low patient recruitment and retention rate

Payment delays of clinical trials funding

Concentration of patient pool in urban areas

In order to overcomes those barriers, what are the notable solutions that each country has done in each phase?

	PHASE 1 EARLY CAPABILITY DEVELOPMENT	PHASE 2 OPERATIONAL EXPANSION	PHASE 3 BECOMING A REGIONAL CLINICAL TRIAL HUB
TAIWAN	**Establishment of TIHTC** Taiwan International Healthcare Training Center was created to intergrate medical expertise and resources, provides continous training for HCPs ★	**Robust multiple partnerships** The establishment of Taiwan Clinical Trial Consortium bringing together 12 disease-specific consortium involving 300+ experienced investigators and medical professionals ★	**Reimbursement policy set by National Health Insurance Administration**: Which helped hospitals cover the costs of most drugs and for pharmaceuticals companies when conducting clinical trials and making investments for development ★
BRAZIL	**Establishment of National Health Surveillance Agency (ANVISA)**: Established a dedicated government agency to oversee, manage and approve all clinical trials ★	**Development of national clinical trials registry**: Development of Brazilian Registry of Clinical Trials (ReBEC) to provide free access to all records on clinical trials in Brazil ★	**Establishment of dedicated training associations for clinical trials**: Including Brazilian Society of Clinical Pharmacology and Brazilian Association of CRO ★
POLAND	**Poland emphasizes GCP certification**, supported by partnerships with universities and CROs **Medical Research Agency** supports research acitivites, public awareness, etc. ★	The Office for Registration of Medical Products, Medical Devices, and Biocidal Products (URPL) centralizes the approval processes ★	**Regulatory reform:** On April 14, 2023, Poland enacted the Clinical Trials Act, aligning with EU Regulation 536/2014 to streamline legislation and boost clinical trial appeal, addressing low regional trial density
SPAIN	**Inauguration of new regulations:** the implementation of the Royal Decree to reduce times, increase transparency, and develops clinical trial registry.	**Implement talent development programs:** ICON and CROs offer early talent programs designed to provide talents skills and exposure to reinforce their clinical trial capabilities ★	**Fast track approval for studies:** the AEMPS accelerated approval process to enhance Spain's appeal for research on innovative medicines. ★
JAPAN	**Enforcement of Clinical Trial Act:** Developed comprehensive regulation to regulate the clinical trials industry and ensure compliance with GCP	**Financial grants for academia-industry partnership:** Offered Kakenhi Grants to encourage academia-industry collaboration in clinical trials	**Public-Private Partnership Funding:** Japan Agency for Medical Research and Development (AMED) has collaborated with the private sector for clinical innovation accelators
SOUTH KOREA	**Clinical trials national organization establishment:** Established KoNECT to strengthen Korea's clinical trials capability ★	**Centralization of Review and Ethics Committee:** Assigned Ministry of Food and Drug Safety as the primary approver for clinical trials	**Global collaboration organization establishment:** Established KoNECT Collaboration Center to facilitate cross-border clinical trials
THAILAND	**Redevelop rules:** Clarifying the definition of clinical studies and ensuring adherence to ICHGCP guidelines for all the applications	**Training Collaborations:** Collaborate with international organizations and pharmaceutical companies to provide training and workshops ★	**Decentralized clinical trials:** Facilitates online patient recruitment and simplifies multi-national trials conduction in Thailand

★ *Applicable for Vietnam*

	PHASE 1 EARLY CAPABILITY DEVELOPMENT	PHASE 2 OPERATIONAL EXPANSION	PHASE 3 BECOMING A REGIONAL CLINICAL TRIAL HUB
PHILIPPINES	**DA Regulatory Alignment:** Aligned framework with international standard like GCP guidelines to ensure global recognition	★ **Fostering PPP:** to boost its clinical research. These partnerships are accelerating clinical trials, and attracting international investment.	
MALAYSIA	**Awareness Campaigns:** several campaigns have been launched to educate the public on the benefits of clinical trials.	**Personalized Care:** Providing personalized care and attention to participants can enhance their experience and increase retention.	
HUNGARY	**Hungary complies with EU CTR,** with ethics committees reviewing protocols within strict timelines.	Centralized health system and excellent infrastructure. The centralized nature of Hungary's health care system assists rapid patient recruitment.	

Source: KPMG Research and Analysis

★ *Applicable for Vietnam*

4.3. Country profiling

4.3.1. Taiwan

4.3.3.1. Key actions taken to become a clinical trial hub

Taiwan has developed a robust healthcare system and a rapidly expanding clinical trial ecosystem, positioning itself as a competitive destination for clinical research in the Asia-Pacific region. The country benefits from universal health coverage, advanced medical infrastructure, and a highly skilled workforce, attracting a growing number of multinational pharmaceutical companies and Contract Research Organizations (CROs).

Major global players have recognized Taiwan's potential. Moderna announced in December 2022 that Taiwan would serve as a key site for clinical trials to refine its mRNA technology, integrating the country into its multicenter trial strategy. BioNTech has expanded its clinical footprint in East Asia, accelerating the development of its cancer immunotherapy pipeline.

Taiwan's increasing number of Principal Investigators (PIs) further strengthens its research ecosystem. The number of PIs grew from 459 in 2018 to 562 in 2023, reflecting a more experienced and capable research community. This growth has enhanced Taiwan's ability to conduct high-quality, efficient, and innovative clinical trials, making the country an increasingly attractive destination for global pharmaceutical investment.

Taiwan - Clinical trial network and bodies

	BARRIERS	SOLUTION	WHY IT IS APPLICABLE FOR VIETNAM?
PHASE 1	**Human Resources** Lack of trained HCPs **Human Resources** Opportunity cost for HCPs	★ **Establishment of National Training Center** to equip medical professionals with essential skills to conduct research and trials	Have experienced shortage of HCPs like Vietnam Having **a national training** center can standardize and elevate skill levels of local practitioners as a solid foundation
PHASE 2	**Patient Pool -** Low patient recruitment and retention	★ **Establishment of Taiwan Clinical Trial Consortium** bringing together 12 disease-specific consortiums involving 300+ experienced investigators and medical professionals	A joint-effort between relevant stakeholders such as a **clinical trial consortium** in Vietnam is critical to enhance patient recruitment and promote more clinical trials
PHASE 3	**Financial** - Lack of financial incentives for clinical trials	★ **The National Health Insurance Administration's (NHIA) reimbursement policy** provided crucial financial support, facilitating clinical trials and further advancing Taiwan's capabilities	Taiwan previously experienced the lack of financial incentives to conduct clinical trials Having the reimbursement policy in place will support institutions to alleviate costs to facilitate clinical research and trials

★ *Applicable for Vietnam*

4.3.1.2. Timeline of key policies and initiatives for clinical trial industry

YEAR	POLICY	KEY IMPACT
1997	**Good Clinical Practice (GCP) Adoption**	Established ethical and scientific standards for clinical trials.
2002	**Taiwan International Healthcare Training Center (TIHTC)**	Positioned Taiwan as a training hub for clinical trial capacity building.
2009	**Regulations on Human Trials**	Strengthened ethical compliance and participant protections.
2010	**Taiwan Food and Drug Administration (TFDA)**	Improved regulatory oversight and global alignment.
	Clinical Trial Notification (CTN) System	Reduced trial startup times from ~160 days to <30 days.
2011	**Taiwan Clinical Trial Consortium (TCTC)**	Enhanced trial efficiency and attracted global pharmaceutical investment.
2013	**Human Subjects Research Act**	Strengthened participant rights and ethical compliance.
2015	**International Council for Harmonization Good Clinical Practice (ICH-GCP) Alignment**	Facilitated multinational trial operations.
2016	**Biomedical Industrial Innovation Promotion Program**	Increased investment in clinical trial infrastructure and global collaboration.
2018	**Reimbursement Reform** National Health Insurance Administration **(NHIA)**	Supported post-market validation and accelerated drug access.
2023	**Decentralized Clinical Trial Framework**	Expanded access and trial flexibility.
	UK's National Institute for Health and Care Excellence (NICE) Partnership	Strengthened international collaboration and trial outcome evaluations.
	Conditional Listing	Improved access to critical treatments before full Phase III approval.
2024	**Center for Health Policy & Technology Assessment (CHPTA)**	Accelerated reimbursement decisions for new drugs.
	Parallel Review Measures	Shortened timelines for drug registration and reimbursement.

4.3.1.3. Key actions taken to become a clinical trial hub

National Training Centers: Building Clinical Trial Capabilities

Taiwan established the Taiwan International Healthcare Training Center (TIHTC) in 2002 under the Ministry of Health and Welfare (MOHW) to advance its global healthcare leadership. TIHTC collaborates with major academic institutions and medical centers to provide specialized training programs for healthcare professionals. These programs enhance clinical trial expertise, expand Taiwan's trial capacity, and position the country as a global hub for clinical research and training.

Reimbursement Policy Reduces Financial Barriers, Boosting Trials

Taiwan's NHIA implemented reimbursement policies to balance healthcare affordability with access to innovative therapies. In 2018, it introduced risk-sharing mechanisms, linking reimbursements to drug efficacy and financial outcomes. Developed collaboratively with the MOHW, TFDA, and CROs, these policies included conditional listing for urgent treatments, coverage for routine trial costs, and expedited reimbursement approvals. By reducing financial barriers for participants and sponsors, Taiwan attracted multinational pharmaceutical companies and strengthened its position as a global clinical trial hub.

Global Collaborations Strengthen Taiwan's Clinical Trial Capabilities

Taiwan launched the Taiwan Clinical Trial Consortium (TCTC) in 2011 under the National Research Program for Biotechnology to strengthen its clinical trial ecosystem. TCTC serves as a unified network of specialized research centers, collaborating with pharmaceutical sponsors to advance patient care and provide clinical coordination services. The consortium includes more than 16 disease-specific clinical trial groups and over 300 experienced clinical trial doctors and principal investigators (PIs). Funded by Taiwan's National Council of Science and Technology, TCTC supports new drug and medical device trials, bioavailability and bioequivalence (BA/BE) studies, and clinical research. By consolidating expertise and fostering partnerships between academia, industry, and government, TCTC enhances Taiwan's capacity to conduct large-scale, high-quality clinical trials.

4.3.2. Brazil

4.3.2.1. Overview

Brazil is a key player in global clinical trials, ranking 13th in registered trials and the 6th largest pharmaceutical market. Oversight from AREE (Equivalent Foreign Regulatory Authorities) and the Ministry of Health ensures strict regulatory control, particularly prioritizing neglected diseases, health emergencies, pediatric trials, and locally manufactured Phase I studies. In 2021, Brazil contributed 1.7% of global clinical trials, with oncology as the primary focus. However, challenges persist, including dependence on foreign inputs and scientific colonialism, limiting national entities to a lower market share.

Despite these obstacles, Brazil's strengths include a diverse population, skilled human resources, and a well-established regulatory framework. The clinical trial sector saw strong early growth (CAGR 28.1% from 2002–2012), followed by steady expansion (CAGR 3.3% from 2012–2022), reaching 1,426 trials by 2022. Major pharmaceutical companies, particularly Roche, Pfizer, BMS, Merck, AstraZeneca, and Novartis, have established a strong presence in oncology research. While trial numbers declined slightly post-2019, Brazil remains a leading destination for clinical research in Latin America, particularly for oncology drug development.

Brazil – Regulations reform

	BARRIERS	SOLUTION	WHY IT IS APPLICABLE FOR VIETNAM?
PHASE 1	**Regulations** - Unclear regulations (including import) **Regulations** - Lengthy approval processes **Regulations** - Lack of government support for clinical trials	★ **Establishment of National Health Surveillance Agency (ANVISA):** Appointed a dedicated government agency to oversee, manage and approve all clinical trials	Have gone through similar growth pattern with Vietnam National Clinical trials registry is critical for Vietnam to attract sponsors Having a dedicated government agency to oversee and develop incentives for clinical trials will help in improving the current status quo
PHASE 2	**Administration -** Absence of comprehensive disease registries	★ **Development of national clinical trials registry:** Development of Brazilian Registry of Clinical Trials (ReBEC) to provide free access to all records on clinical trials in Brazil	
PHASE 3	**Capability -** Lack of trained HCPs **Capability -** Opportunity cost for HCPs **Capability -** Geographic disparities in clinical trials infrastructure	★ **Establishment of dedicated training associations for clinical trials:** including Brazilian Society of Clinical Pharmacology and Brazilian Association of CRO	

★ *Applicable for Vietnam*

4.3.2.2. Timeline of key policies and initiatives for clinical trial industry

YEAR	POLICY	DESCRIPTION & IMPACT
1967	**FINEP – Financier of Studies and Projects**	Provides funding for research institutes and technology-based companies, supporting clinical trial infrastructure and modernization.
1979	**Brazilian Society of Clinical Oncology (SBOC)**	Implements training programs and research funding to expand clinical trials beyond major urban centers.
2004	**Resolution of the Collegiate Board (RDC) 219/2004**	Established Brazil's initial clinical trial regulations, but lengthy review timelines led to delays.
2005	**National Clinical Research Network (RNPC)**	Connected 32 research centers, decentralizing trials and improving study completion times.
2008	**Resolution RDC 39/2008**	Standardized clinical trial registration across all phases, improving regulatory oversight.
2010	**Brazilian Clinical Trials Registry (ReBEC)**	Created a national database to improve trial transparency and patient recruitment.
2014	**PRONON –** National Program of Oncological Attention	Expanded cancer research capacity and improved patient recruitment.
	EBSERH – Federal University Hospitals Research Program	Standardized clinical research management in public hospitals, aligning with global GCP standards.
2015	**Resolution RDC 9/2015**	Reduced clinical trial approval timelines from 12 months to 90 days, improving efficiency.
2017	**Resolution RDC 205/2017**	Introduced streamlined approval processes for rare disease treatments.
2018	**Resolution RDC 214/2018**	Established regulations for advanced therapies, aligning Brazil with global standards.
	National Clinical Research Action Plan	Strengthened ethics review, regulatory policies, and workforce training.
2021	**Resolution RDC 533/2021**	Fast-tracked COVID-19 vaccine approvals and imports.
2024	**Resolution RDC 945/2024**	Introduced a tiered clinical trial review system to enhance regulatory efficiency and global alignment.

4.3.1.3. Key actions taken to become a clinical trial hub

Transformative Regulatory Changes Drive Efficiency in Trial Approvals

Since 2004, Brazil has progressively strengthened its clinical trial regulations through systematic reforms. The initial framework, RDC 219/2004, established Good Clinical Practice (GCP) standards, introduced registration requirements, and formally recognized Representative Clinical Research Representative Organizations (ORPCs).

A major breakthrough came in 2015 with RDC 9, which reduced approval timelines from 12 months to 90 days, implemented risk-based oversight, and improved coordination between clinical trial and drug registration processes. By 2016, these changes significantly cut review timelines, National Research Ethics Committee (CONEP) reduced its approval period from 322 days to 81 days, while ANVISA shortened its analysis from 342 days to 177 days. The overall approval process streamlined to approximately 4.5 months, a major improvement in regulatory efficiency.

These reforms have transformed Brazil into a competitive global clinical trial destination. Faster approvals have attracted major pharmaceutical companies, strengthened Brazil's ability to conduct large-scale studies, and positioned the country as a leading site for clinical trials in Latin America.

Building a national clinical trial registry enabled transparency, thus facilitating more clinical trials

Established in 2010, the Brazilian Clinical Trial Registry (ReBEC) enhances transparency, accessibility, and coordination in clinical research. Developed by the Oswaldo Cruz Foundation (Fiocruz) in collaboration with the Brazilian Ministry of Health and supported by the World Health Organization (WHO), ReBEC aligns with global standards to ensure ethical and scientific integrity. As a publicly accessible platform, it increases Brazil's visibility as a credible research hub, fosters collaboration among researchers, and attracts international investment. Additionally, ReBEC empowers patients and healthcare providers by providing access to trial information, improving participation and trust in clinical research.

Comprehensive Policy Framework and Professional Associations Drive Brazil's Clinical Trial Transformation

Brazil's clinical trial evolution demonstrates how targeted policy reforms and infrastructure development can transform an emerging market into a global research hub. ANVISA's regulatory improvements and a nationwide research network have driven market growth, while initiatives like the Brazilian Association of Clinical Research Representative Organizations (ABRACRO) have strengthened industry collaboration and operational standards. Brazil's ability to attract major pharmaceutical investment underscores the importance of credible research infrastructure. Its success in balancing regulatory oversight with efficiency offers valuable lessons for other emerging markets aiming to expand their clinical trial sectors.

4.3.3. Poland

4.3.3.1. Overview

Poland has emerged as a leading clinical trial hub in Central and Eastern Europe, accounting for 21% of the region's trials. The country offers strong infrastructure, skilled medical professionals, and a diverse patient population, making it an attractive research destination. With EU-aligned regulations, efficient trial approvals, and modern medical facilities, Poland ensures high-quality data while maintaining relatively low operational costs compared to Western Europe.

From 2002 to 2012, Poland's clinical trial market grew at a CAGR of 24.5%, reaching approximately 800 trials annually. This number steadily increased to 1,203 trials by 2022, with a peak of 1,516 trials in 2021 due to COVID-19 studies. Regulatory efficiency, evidenced by the doubling of Investigational Medicinal Product (IMP) studies between 2020 and 2021, has solidified Poland's global research standing.

The number of active trial sites expanded significantly between 2009 and 2020. While hospitals initially dominated, dedicated research centers and ambulatory sites have grown rapidly, reflecting a shift towards more efficient, well-managed trial environments. Improved administrative processes, streamlined contracting, and dedicated study teams have optimized trial execution, enhancing Poland's attractiveness for multinational sponsors.

Poland – Regulatory Reform

	BARRIERS	SOLUTION	WHY IT IS APPLICABLE FOR VIETNAM?
PHASE 1	**Infrastructure** Limited availability of GCP-certified facilities	Poland emphasizes building a skilled workforce, supported by partnerships with universities ad CROs ★ Medical Research Agency supports research activities, public awareness, etc	Poland's emphasis on university partnerships has built a skilled workforce for clinical trials. Vietnam can work to foster similar collaborations
PHASE 2	**Regulatory** Lengthy approval processes	The Office for Registration of Medicinal Products, Medical Devices, and Biocidal Products (URPL) centralizes the approval processes ★	Poland centralized clinical trial approvals through The Office for Registration of Medicinal Products, Medical Devices, and Biocidal Products (URPL) to reduce delays and increase transparency. Vietnam could use this approach to amend its inefficient system
PHASE 3	**Regulatory** Time-consuming funding contract approval process **Patient pool** Low patient recruitment and retention rate	Poland enacted the Clinical Trials Act in 2023 which aligns with EU Regulation 536/2014. This streamlined legislation and boosted clinical trial appeal, addressing low regional trial density	Poland's reform of the 2023 Clinical Trials Act increased global compliance and appeal to sponsors. This provides a model for Vietnam in the long run

★ *Applicable for Vietnam*

4.3.3.2. Timeline of key policies and initiatives for clinical trial industry

YEAR	POLICY	IMPACT ON THE CLINICAL TRIAL SECTOR
2001	**Pharmaceutical Law Act**	Established a regulatory framework for trial approvals, drug safety, and compliance.
2002	**Office for Registration of Medicinal Products (URPL)**	Strengthened trial oversight, improving quality and regulatory compliance.
2012	**Regulation on Clinical Trial Inspections**	Improved trial quality by enforcing Good Clinical Practice (GCP) standards.
2018	**Amendment to the Pharmaceutical Law Act**	Reduced approval times, increasing Poland's attractiveness for clinical trials.
2019	**Medical Research Agency (ABM)**	Provided funding and organizational support, strengthening research capabilities.
2021	**Polish Clinical Trials Network (PCTN)**	Standardized procedures, enhancing collaboration and market competitiveness.
2022	**Biomedical Sector Development Plan (2022-2031)**	Strengthened infrastructure, fostered innovation, and attracted global research.
2023	**Act on Clinical Trials of Medicinal Products**	Aligned Poland's regulations with EU standards, improving governance and efficiency.
	Polish Clinical Scholars Research Training (P-CSRT)	Enhanced trial quality through specialized researcher training.

4.3.3.3. Key actions taken to become a clinical trial hub

Introducing a dedicated Research Agency helped Poland to advance clinical trials

The Medical Research Agency (MRA) was established in 2019 to strengthen Poland's biomedical and clinical research sector. Driven by the Polish Ministry of Health, the agency provides funding, fosters innovation, and coordinates global research efforts. Key initiatives include the Polish Clinical Trial Networks (PCTN), which streamlines collaboration between research centers, and the Polish Clinical Scholar Research Training (P-CSRT) program, which enhances researcher expertise. These initiatives have positioned Poland as a competitive clinical trial hub, driving economic growth and improving healthcare outcomes.

Regulatory reforms enhanced Poland's clinical trial competitiveness.

The Office for Registration of Medicinal Products, Medical Devices, and Biocidal Products (URPL) has regulated Poland's clinical trial framework since 2022, ensuring compliance with EU standards. Its establishment streamlined approvals, enhanced regulatory clarity, and increased confidence among international sponsors, strengthening Poland's role in global clinical research.

In 2023, Poland enacted the Act on Clinical Trials of Medicinal Products for Human Use, aligning with EU Regulation 536/2014. Key reforms included:

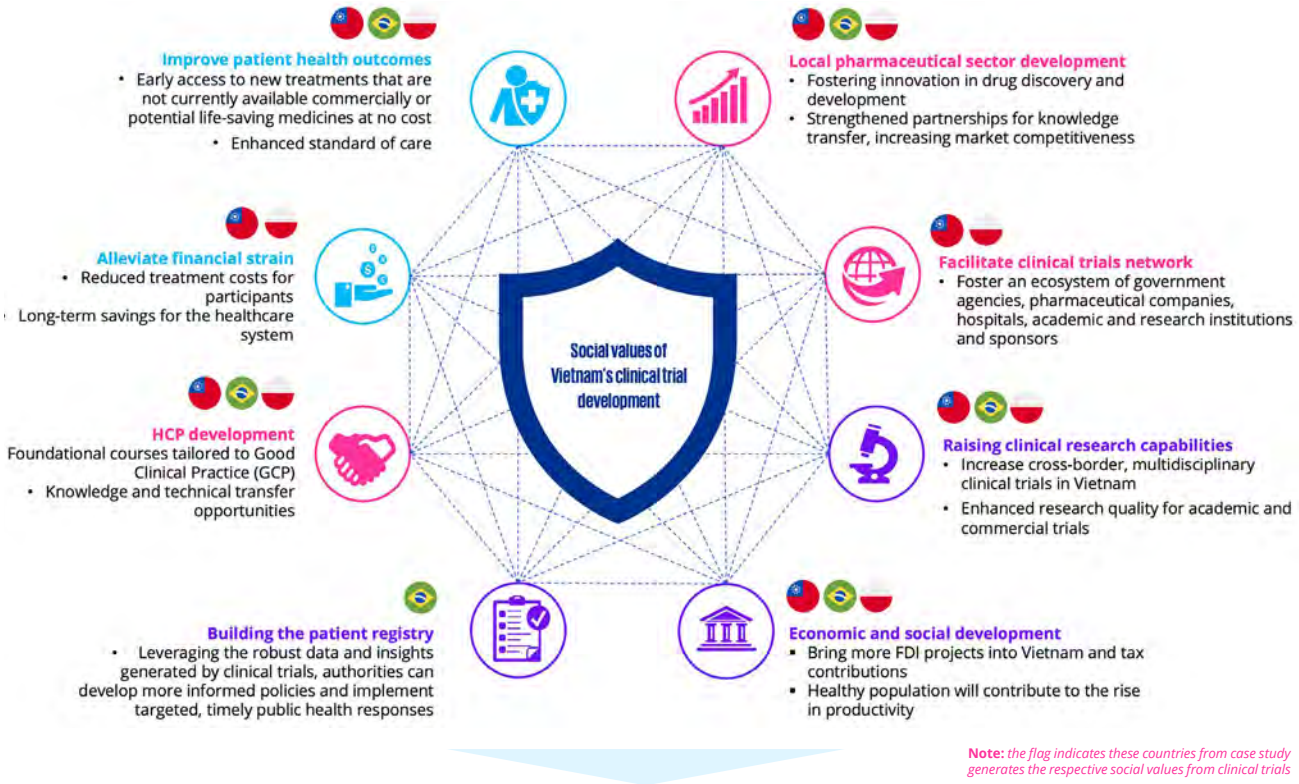
- **Non-commercial trials** – Allowed commercialization of publicly funded trial data.
- **Clinical trials compensation fund** – Created to expedite support for trial participants.
- **Ethical assessment** – Introduced the Supreme Bioethics Committee to oversee trial evaluations.

These reforms enhance efficiency, participant protection, and competitiveness, making Poland a more attractive destination for clinical research.

5. Future economic contribution

5.1. Overview

Social values of Clinical trial sector in Vietnam: rising to become a regional hub



Note: *the flag indicates these countries from case study generates the respective social values from clinical trials*

1. PATIENT BENEFIT

- Improve patient health outcomes
- Alleviate the financial strain on patients

2. GOVERNMENT BENEFIT

- Better informed policy decisions and public health responses
- Enhance the appeal of the country's research and development sector
- Economic and social development driven by a healthier population

3. INDUSTRY BENEFIT

- Support the pharmaceutical industry development through advancement of medicines
- Form strategic partnerships, collaborations, and secure investments in clinical research
- Develop the pool of specialized researchers

Vietnam's Growing Clinical Trial Sector Creates Broad Social Benefits
Clinical trials provide significant social benefits for patients, the government, and the pharmaceutical industry. Patients gain access to innovative, potentially life-saving treatments while reducing financial burdens on both individuals and the healthcare system. For the government, a stronger clinical trial ecosystem supports public health, informs better policy decisions through improved patient registries, and enhances Vietnam's reputation in global research. The pharmaceutical industry benefits from workforce development, local drug innovation, and increased foreign investment. Collectively, these factors position Vietnam as a competitive hub for clinical trials, driving long-term healthcare and economic growth.

5.2. Value propositions

5.2.1. Patient benefits

Improve patient health outcomes
Expanding clinical trials in Vietnam can significantly improve patient outcomes by introducing new treatments, medications, and therapies. Proven innovations from trials provide more effective treatment options, replacing outdated methods that may be less effective. Additionally, medical advancements from trials help integrate new therapies into standard care, offering patients better, faster, and more convenient treatment options. A 2022 study[15] found that medical innovations reduce recovery times and side effects, leading to improved long-term health outcomes tailored to patient needs.

Alleviate the financial strain on patients
Expanding clinical trials in Vietnam can reduce financial burdens on patients by providing free access to treatments, medications, and regular healthcare checkups. A 2022 study[16] found that patients in developing countries like Vietnam often face high out-of-pocket healthcare costs. Clinical trials help alleviate these expenses for participants while also driving long-term affordability. As new therapies emerge and become widely available, competition can lower prices, making innovative treatments more accessible, even for low-income patients. Ultimately, a stronger clinical trial sector will improve healthcare affordability and access across Vietnam.

5.2.2. Government benefits

Enhance the appeal of the country's research and development (R&D) sector
Expanding clinical trials can elevate Vietnam's R&D sector, positioning the country as a key player in global medical research. A supportive trial environment will attract international partners and foster collaboration between local researchers and institutions. A 2023 study[17] highlighted that increased R&D investment has led to groundbreaking therapies, particularly in areas with unmet medical needs. Strengthening Vietnam's R&D focus will drive innovation, advance population-specific treatments, and enhance the country's global reputation in medical research.

Building the patient registry:
Leveraging data from clinical trials to build a comprehensive patient registry can equip Vietnam's government with a powerful tool for evidence-based policymaking and targeted public health interventions. A national registry would track disease prevalence, treatment outcomes, and adverse events in real time, helping policymakers allocate resources effectively and address emerging health trends. The United Kingdom's (UK) National Disease Registration Service (NDRS) has successfully driven policy improvements in cancer prevention, early detection, and treatment. By adopting a similar approach, Vietnam can strengthen its healthcare infrastructure, enhance disease management programs, and ensure that public health decisions are data-driven and responsive to population needs.

Economic and social development driven by a healthier population
The health benefits of clinical trials extend beyond healthcare, driving Vietnam's economic and social development. A 2024 study[18] found that delays in innovative medicines worsen disease burdens, while clinical trials introduce more effective treatments, improving population health. A stronger healthcare system reduces public health expenditures, freeing government resources for other priorities. A healthier workforce enhances productivity, lowers absenteeism, and reduces healthcare costs, ultimately boosting economic stability, increasing tax revenues, and supporting long-term growth.

[15] *International Federation of Pharmaceutical Manufacturers & Associations – IFPMA (2022), "The Pharmaceutical Industry and Global Health: Facts and Figures 2022", available at link*
[16] *International Federation of Pharmaceutical Manufacturers & Associations – IFPMA (2022), "The Pharmaceutical Industry and Global Health: Facts and Figures 2022", available at link*
[17] *Reddy, P., & Singh, M. (2023). The Impact of Research and Development Investments on Drug Development Outcomes and Health Improvements. International Journal of Responsible Artificial Intelligence, 13(12), 1–10. Available at link*
[18] *Theiakou, F., Kastanioti, C., Zavras, D., Rekkas, D., & Kontodimopoulos, N. (2024). Quantifying the Societal Impact of Delayed Access to Innovative Medicines: A Mathematical Framework for Health Policy Decision-Making. Preprints. Available at link*

5.2.3. Industry benefits

Supporting pharmaceutical industry development through the advancement of medicines

Clinical trials are essential for pharmaceutical sector growth in Vietnam, fostering innovation and expanding research capabilities. A 2018 study[19] highlighted their role in addressing disproportionately high disease burdens in developing countries, underscoring the need for Vietnam to advance treatments for its unique healthcare challenges. Strengthening clinical research will not only improve local healthcare but also enhance Vietnam's reputation as a global hub for pharmaceutical innovation.

Formation of strategic partnerships, collaborations, and securing further investments

International collaboration in Vietnam's clinical trials enhances innovation and fosters knowledge exchange. Participation in global trials also gives international pharmaceutical companies deeper insights into Vietnam's market, creating opportunities for product launches and investment. A 2021 study[20] found that biopharmaceutical companies invested over one trillion USD in R&D globally. Capturing a larger share of this investment could drive significant economic growth in Vietnam.

An attractive clinical trial environment will allow Vietnam to develop and maintain a skilled pool of specialized researchers

The expansion of clinical trials in Vietnam will attract skilled professionals, strengthening the country's research capabilities and global competitiveness. This growth facilitates technology transfer and enhances local expertise in international standards such as Good Clinical Practice (GCP). A robust talent pool will draw further foreign investment from global pharmaceutical companies, creating new job opportunities. A 2019 study[21] found that each job in the biopharmaceutical sector supports five additional jobs in related industries, highlighting the sector's potential to drive Vietnam's economic development.

5.3. Map of Vietnam's clinical trials value and sector development goals

Mapping of Vietnam's clinical trials value and sector development goals

	MACRO ECONOMY	SECTOR FOCUS	PATIENT FOCUS
	1.Improving Business Environment and enhance national competitiveness (Resolution No. 2/ NQ-CP)	2. National Strategy for Vietnam's pharmaceutical industry development (Decision No. 1165/QD-TTg)	3.National Strategy for protection, care and improvement of people's health (Decision No. 89/ QD-TTg)
OVERALL OBJECTIVES	**Improve domestic business environment and competitiveness amongst ASEAN nations**	**Foster sustainable development of Vietnam's pharmaceutical industry to ensure drug security and facilitate deeper integration into the global pharmaceutical supply chain**	**Ensure public accessibility to high quality and affordable healthcare services and contribute to the improvement of public life quality**
SHORT TERM	**Enhancement of Global Innovation Index by WIPO:** Improve ranking from 3 – 10 places	***Objectives by 2030*** **Proactive and timely supply for 100% of drugs** to meet the public need for disease prevention and treatment **Increase domestic drug production capacity to meet 80% of the demand and 70% of the market value** by 2030 **Become a high-value pharmaceutical production hub in the region and meet with WHO's level 3 or higher certification** of drug production capacity	Improve the prevention and control of epidemics to ensure health security Improve the quality of healthcare facilities from central to provincial level and increase PPP in medical services Improve the quantity and quality of HCP workforce Improve scientific research and apply high technologies to prevent, discover, diagnose and treat disease Promote R&D activities of pharmaceutical products and medical devices Ensure accessibility and availability of quality and affordable medicines and vaccines to meet with public needs.
LONG TERM	**Achieve the Top 50 position in the Sustainable Development Ranking by United Nations** **Enhancement of Global Innovation Index by WIPO:** Improve ranking from at least 3 places	***Objectives by 2045*** **GDP contribution of the pharmaceutical industry will reach over USD20 billion** **Achieve the same standards of other developed countries** in drug testing, drug distribution, clinical pharmacy and pharmacovigilance **Meet domestic demand and increase export value** for pharmaceutical drugs to integrate into the global pharmaceutical supply chain	

Source: Thuvienphapluat

[19] *Alemayehu, C., Mitchell, G., & Nikles, J. (2018). Barriers for conducting clinical trials in developing countries- a systematic review. International Journal for Equity in Health, 17(1). Available at link*
[20] *International Federation of Pharmaceutical Manufacturers & Associations – IFPMA (2022), "The Pharmaceutical Industry and Global Health: Facts and Figures 2022", available at link*
[21] *Tecnomy Partnes LLC & PhRMA (2019) The Economic Impact of the US Biopharmaceutical Industry: 2017 National and State Estimates, p 1. Available at link*

OUR STUDY'S FOCUSED PILLARS	GOVERNMENT- WIN | Domestic capabilities	
Values of the clinical trial industry	**As set out in Resolution No. 2 on Improving Business Environment and enhance national competitiveness**	
ENHANCING PATIENT OUTCOMES		
ALLEVIATE FINANCIAL BURDEN		
HCP DEVELOPMENT	Participating in global clinical trials exposes domestic HCPs to cutting-edge research, and new technologies. An upskilled pool of HCPs leads to improved quality of care.	Clinical trials can help to attract and retain a skilled workforce of HCPs, often including international staff. Their capabilities have spillover effects onto local professionals, improving Vietnam's healthcare system.
LOCAL PHARMA SECTOR DEVELOPMENT	A growing pharmaceutical sector creates more high-skilled jobs and opportunities for collaboration. This fosters an innovative culture within Vietnam, improving its reputation as a site for research.	As Vietnams pharmaceutical sector becomes more attractive to international players it will be able to attract more foreign investment. This boosts Vietnam's economic growth, generating government revenue.
FACILITATE CLINICAL TRIAL NETWORK	Collaboration between research institutions will be bolstered by having a supportive environment for clinical trials. This increases efficiency and knowledge transfer within Vietnam.	Being an active participant in global clinical trials could influence more pharmaceutical companies to choose Vietnam as a site for future clinical trials. This will allow it to catch up to its Southeast Asian competitors.
BUILDING THE PATIENT REGISTRY	A complete patient registry will allow the government to access health data from the broader population. This can be leveraged by the government to make more informed policy decisions.	Clinical trials data can be used to track long-term evidence and improve the governments understanding on disease trends in Vietnam.
RAISING CLINICAL RESEARCH CAPABILITIES	Government support for clinical research can lead to enhanced infrastructure and HCP capability. These investments feed back into Vietnam's healthcare ecosystem, delivering more efficient and higher quality care.	Developing its clinical trials research capabilities will help Vietnam to become globally competitive in the international research landscape. This can enhance Vietnam's standing on the Global Innovation Index.
ECONOMIC AND SOCIAL DEVELOPMENT	Clinical trials create job opportunities for skilled workers both directly and indirectly. This pushes Vietnam forward in developing a more knowledge-based economy, diversifying the countries sector capabilities.	An environment supportive of clinical research results in better insights into Vietnam's health trends. This has positive implications for public health outcomes and quality of life.

Vietnam has emerged as one of Southeast Asia's fastest-growing economies, attracting increased multinational investment. In response, the government introduced Resolution No. 2/NQ-CP (2024) to enhance the business environment and improve national competitiveness within Association of Southeast Asian Nations (ASEAN). A key objective is to advance Vietnam's Global Innovation Index ranking by at least three places. By fostering a more investment-friendly climate, Vietnam can attract greater global participation in its clinical trial sector, accelerating high-value projects and leveraging international expertise to drive market growth.

OUR STUDY'S FOCUSED PILLARS

INDUSTRY – WIN | Clinical trials development

Values of the clinical trial industry	As set out in Decision No. 1165 on the National Strategy for Vietnam's pharmaceutical industry development	
ENHANCING PATIENT OUTCOMES		
ALLEVIATE FINANCIAL BURDEN		
HCP DEVELOPMENT	Clinical trials can help to enhance the capacity of Vietnam's domestic sector. The broader healthcare industry will benefit from a more capable workforce as HCPs move across hospitals or throughout the industry.	Participating in global clinical trials can help to transfer knowledge to Vietnam's HCPs. This could be in the form of complying with international standards such as good clinical practice (GCP) which will enhance industry performance.
LOCAL PHARMA SECTOR DEVELOPMENT	Training and international collaboration will facilitate knowledge transfer, contributing the a more robust pharmaceutical industry. In the long run, this will ripple across the industry as HCPs move between institutions.	As Vietnam's clinical research becomes more harmonized with international standards for it can achieve mutual recognition. This creates a better functioning, more efficient pharmaceutical industry.
FACILITATE CLINICAL TRIAL NETWORK	Participating in global clinical trials provides Vietnam with an opportunity to develop its international network. This can lead to technology transfer from nations with more developed clinical trials industries.	
BUILDING THE PATIENT REGISTRY	A robust patient registry could allow for a more streamlined clinical trials process. For example, it can speed up the patient recruitment process. This can also improve the design of future clinical trials.	If Vietnam's data management can achieve international standards, it can contribute to the global pool of high-quality research. This improves Vietnam's global standing as a site for research activities.
RAISING CLINICAL RESEARCH CAPABILITIES	Enhanced clinical research capabilities lead to innovative drugs becoming available on the market at a faster rate. This boosts the proficiency of pharmaceutical enterprises within Vietnam.	Global clinical trials must adhere to more standardized procedures as they work across multiple international trial sites. This means Vietnam's local clinical research environment will adopt improved data management and quality control practices.
ECONOMIC AND SOCIAL DEVELOPMENT	Vietnam's global reputation will improve as it develops its clinical trials sector. This can attract further foreign investment, increasing job opportunities and ultimately GDP growth.	

Vietnam's National Strategy for Developing the Pharmaceutical Industry to 2030 and Vision to 2045 aims to elevate the country's pharmaceutical sector to regional standards while ensuring affordable access to high-quality medicines. This roadmap positions Vietnam as a pharmaceutical production and technology transfer hub in ASEAN, enhancing domestic supply, boosting exports, and integrating into global value chains.

Key 2030 Objectives and Clinical Trial Alignment:

- Ensure 100% drug supply for disease prevention and treatment, improving patient health outcomes by expanding access to innovative medicines.
- Increase domestic drug production to meet 80% of demand and 70% of market value, targeting WHO Level 3 certification or higher. A strengthened clinical trial sector will introduce more effective therapies, driving Vietnam's reputation as a research hub and advancing global pharmaceutical innovation.

Key 2045 Targets and Economic Impact:

- Pharmaceutical industry GDP contribution to exceed USD 20 billion, with clinical trials playing a key role in economic and social development.
- Achieve global standards in drug testing, distribution, clinical pharmacy, and pharmacovigilance.
- Expand pharmaceutical exports by integrating into the global supply chain, leveraging high-value treatments emerging from Vietnam's clinical trial ecosystem.

By aligning with these national objectives, Vietnam's growing clinical trial sector can accelerate healthcare advancements, attract international investment, and position the country as a competitive force in pharmaceutical innovation.

OUR STUDY'S FOCUSED PILLARS	PATIENT – WIN | Health outcomes
Values of the clinical trial industry	**As set out in Decision No. 89 on the National Strategy for protection and care and improvement of people's health**
ENHANCING PATIENT OUTCOMES	Patients gain access to cutting edge treatments and novel therapies. Additionally, localized clinical trials allow for research into diseases that specifically effect Vietnam's population. In the long term, this improves public health outcomes.
ALLEVIATE FINANCIAL BURDEN	Clinical trials will help to ensure equality in public access to healthcare. Many clinical trials cover the cost of specific treatments which can reduce out of pocket expenditure for patients.
HCP DEVELOPMENT	Clinical trials can give HCPs the opportunity to upskill through collaborations and training sessions. This will improve the capability of Vietnam's local medical staff, providing better patient outcomes.
LOCAL PHARMA SECTOR DEVELOPMENT	Fostering an innovative culture through clinical trials will improve healthcare practices and efficiency. For patients, this means an improved healthcare system with access to a broader range of treatments.
FACILITATE CLINICAL TRIAL NETWORK	
BUILDING THE PATIENT REGISTRY	
RAISING CLINICAL RESEARCH CAPABILITIES	Enhancing Vietnam's capacity for clinical research will provide doctors with improved diagnostic and preventative strategies. This translates into doctors with stronger capabilities and therefore better quality of care.
ECONOMIC AND SOCIAL DEVELOPMENT	As clinical trials improve Vietnam's healthcare outcomes, a greater share of the population can remain productive. Having a more productive labor force will increase Vietnam's economic growth.

Vietnam's National Strategy for Protection, Care, and Improvement of People's Health aims to strengthen healthcare accessibility, infrastructure, and human resources, contributing to the growth of Vietnam's pharmaceutical and clinical trial market. Several economic and social benefits of clinical trials align with this strategy:

Key Objectives and Clinical Trial Contributions:

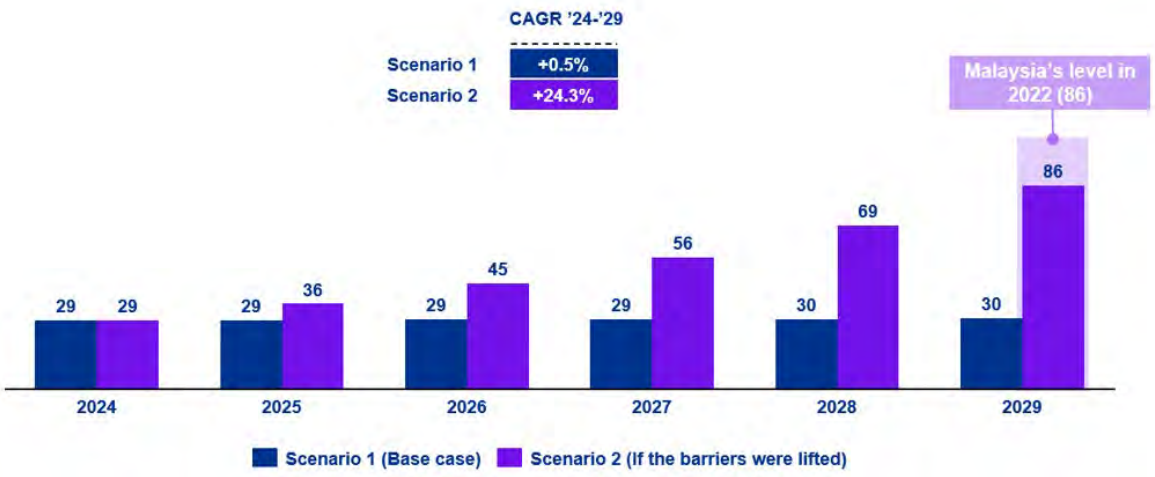
- **Enhancing healthcare infrastructure and Public-Private Partnerships (PPPs):** Clinical trials require GCP-certified facilities and advanced equipment, accelerating investments in healthcare infrastructure. PPPs can further expand Vietnam's capacity to conduct high-quality research.
- **Building a skilled healthcare workforce:** Clinical trials drive partnerships between academia, hospitals, and research institutions, fostering GCP-compliant training programs that strengthen Vietnam's clinical research capabilities.
- **Advancing scientific research and medical innovation:** A strong clinical trial sector positions Vietnam as an R&D hub, attracting global investment and fostering high-quality research publications that enhance its reputation in clinical research.
- **Strengthening epidemic prevention and access to medicines:** Clinical trials increase access to innovative treatments at no cost, reducing patient financial burdens while supporting vaccine and therapy development to improve health security. Over time, wider adoption of trial-developed treatments can lower costs, making healthcare more affordable for all.

5.4. Projected future economic contribution

5.4.1. Future market volume and value of the clinical trials market in Vietnam

The future outlook of Vietnam's clinical trials market is promising once the existing market barriers can be eliminated

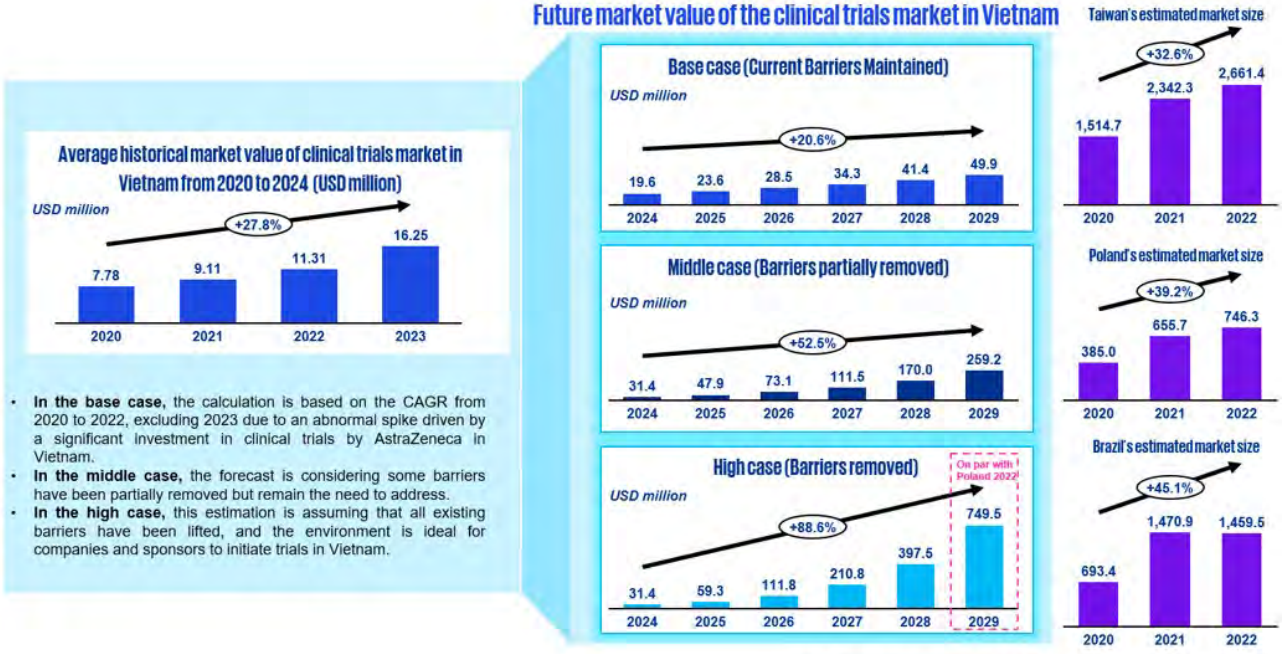
Forecast number of new clinical trials in Vietnam (cases) (*)



Source: Interviews with leading clinical trials companies in Vietnam, KPMG Estimation

Note: The estimation is based on the proportion of interviewed companies relative to the total number of new clinical trials in Vietnam and their forecasted growth in trial numbers if barriers were lifted

Estimated market value of the clinical trials industry in Vietnam from 2024 to 2029 (USD million)



- **In the base case,** the calculation is based on the CAGR from 2020 to 2022, excluding 2023 due to an abnormal spike driven by a significant investment in clinical trials by AstraZeneca in Vietnam.
- **In the middle case,** the forecast is considering some barriers have been partially removed but remain the need to address.
- **In the high case,** this estimation is assuming that all existing barriers have been lifted, and the environment is ideal for companies and sponsors to initiate trials in Vietnam.

**Note: This estimate is provided by KPMG and is based on the PPP conversion applied to the value calculations from the Vietnam trials.*

Note: The estimation is based on the proportion of interviewed companies relative to the total number of new clinical trials in Vietnam and their forecasted growth in trial numbers if barriers were lifted
Source: Interviews with leading clinical trials companies in Vietnam, KPMG Estimation

Projected Growth of Vietnam's Clinical Trials Market

If existing barriers remain unchanged, Vietnam's clinical trial volume is expected to grow modestly at a CAGR of 0.5%, reaching 30 trials by 2029, and a direct market value of USD 49.9 million. However, this modest growth underscores untapped market potential and missed economic opportunities for the industry.

Potential Market Expansion with Barrier Removal

If Vietnam successfully addresses regulatory delays, improves investigator training, expands GCP-certified facilities, and strengthens CTUs and CROs, the industry could grow substantially:

- **Clinical trial volume** could reach 86 trials by 2029, with a CAGR of 24.3%.
- **Market value** could rise to USD259.2 million (middle case) with CAGR of 52.5%, and up to USD 749.5 million (high case) with a CAGR of 88.6%.
- When comparing with the estimated historical market size of selected countries for case study, the expected value from the high case in 2029 of Vietnam would be on par with other developed nations such as Poland in 2022 (at USD746.3 million). Despite there is still a large gap comparing to other advanced countries, Vietnam can realize its clinical trials potential, reaching to the level of countries such as Poland and Taiwan once the barriers are overcome.
- **Higher-value clinical trials**, such as gene, radioligand therapy studies, would complement oncology research, further increasing market attractiveness.

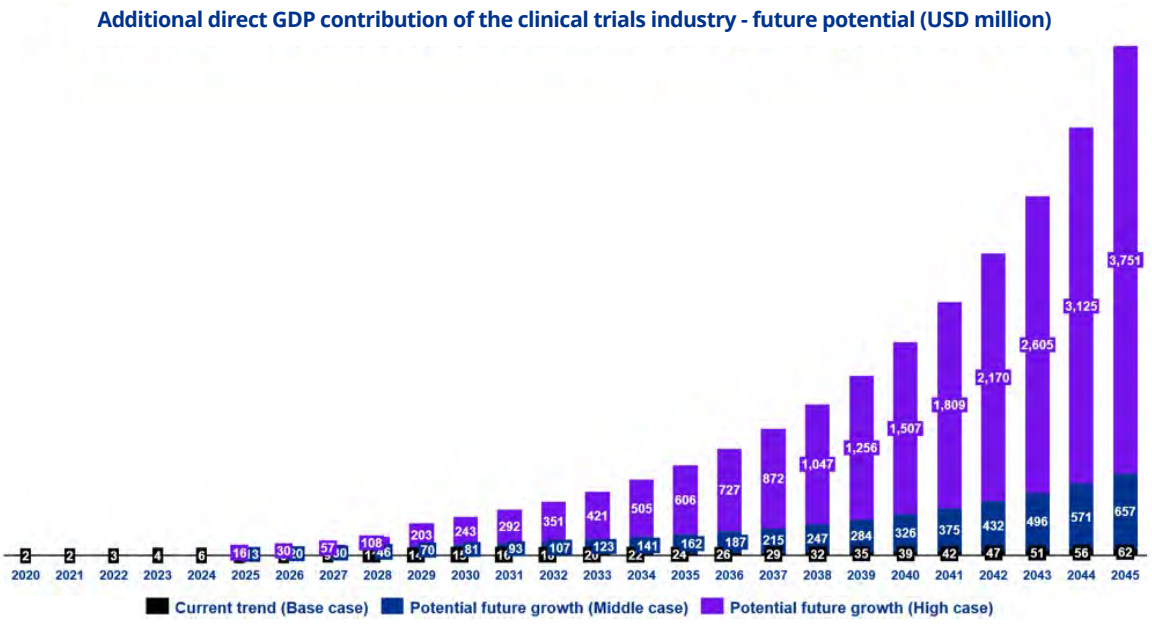
Vietnam's Competitive Edge and Future Outlook

Vietnam's diverse patient pool, cost-effective operations, and ongoing regulatory reforms, including the updated Law on Pharmacy (2024), are positioning the country as a rising clinical research hub. Continued investment in infrastructure, workforce development, and regulatory streamlining will not only drive market expansion but also deliver long-term economic and healthcare benefits, solidifying Vietnam's role in global clinical trials.

5.4.2. GDP contribution

Expanding Vietnam's clinical trial activity to nearly 100 trials per year could generate a direct GDP contribution ranging from USD62 million to USD3,751 million by 2045

Additional direct GDP contribution of the clinical trials industry - future potential (USD million)



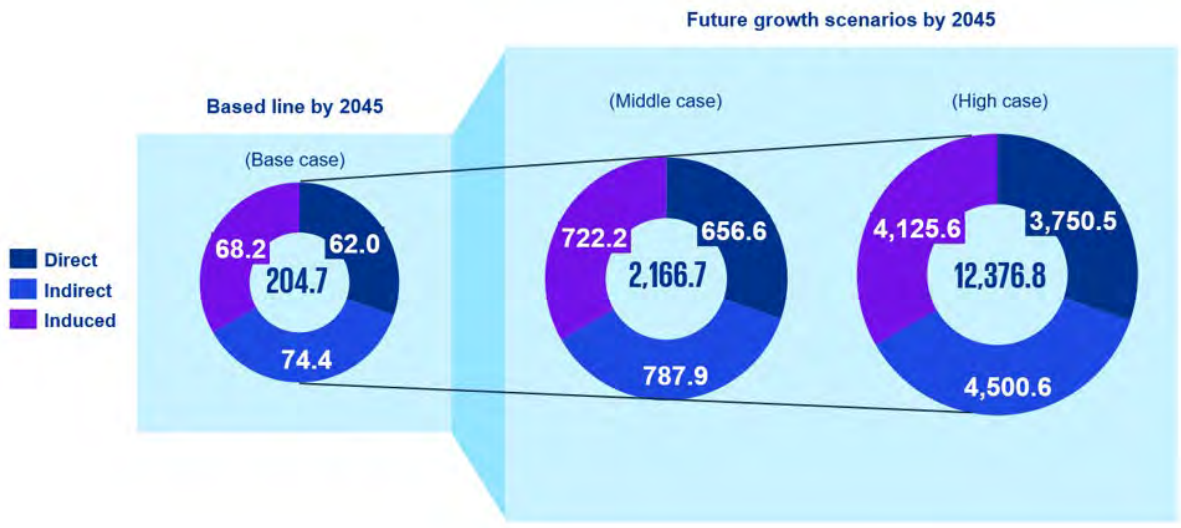
Source: KPMG Analysis and Estimation

Under current market conditions, Vietnam's clinical trials sector is projected to grow at a modest rate, with its direct GDP contribution increasing from USD 6.4 million in 2025 to USD 62.0 million by 2045. However, coordinated efforts between the public and private sectors to enhance market competitiveness could unlock significantly greater economic potential.

By streamlining regulations and introducing more attractive incentives for foreign investment, Vietnam's clinical trials market could achieve higher commercial growth, leading to a stronger economic impact. In the middle case, the sector's direct GVA could expand from USD 13.0 million in 2025 to USD 656.6 million by 2045. In a more ambitious scenario, where key barriers are fully removed and market expansion reaches its full potential, the direct GVA could increase from USD 16.0 million in 2025 to USD 3,750.5 million by 2045.

These projections highlight the significant economic benefits that a well-developed clinical trials industry could bring, reinforcing Vietnam's position as a competitive hub for global research and innovation.

Additional total GDP contribution from the clinical trials industry - future potential (USD million)



Source: KPMG Analysis and Estimation

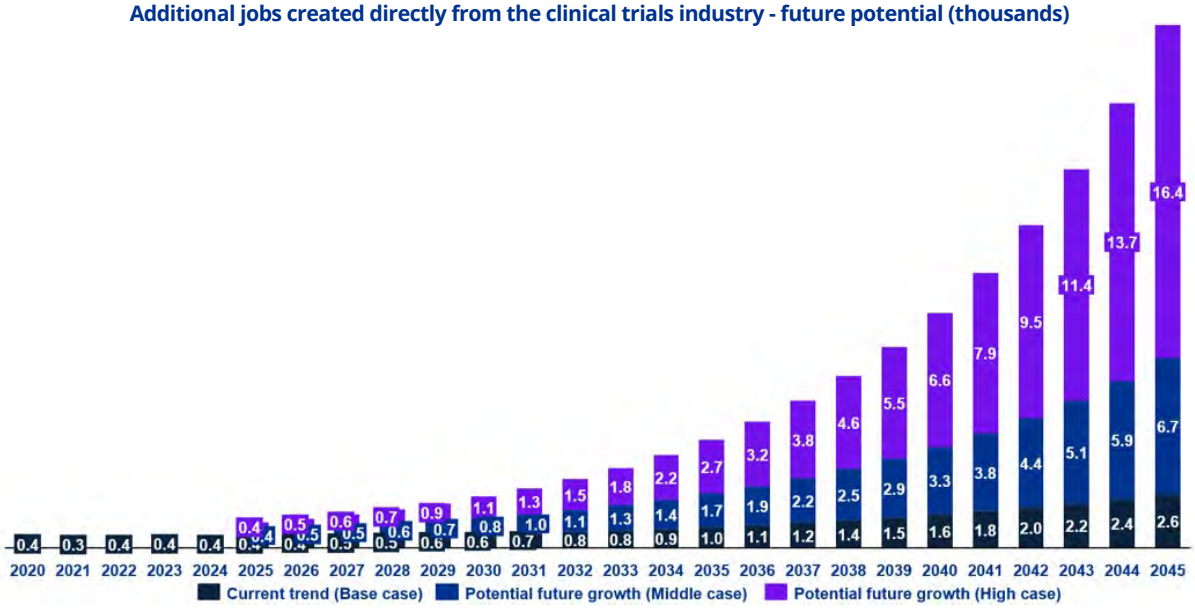
If current market conditions remain unchanged, Vietnam's clinical trials sector is projected to contribute USD204.7 million to the local economy. However, if Vietnam capitalizes on its market opportunities and removes existing barriers, the industry's GDP contribution could rise significantly to USD2,166.7 million at the middle case.

More importantly, if Vietnam's clinical trials sector grows at a pace comparable to Malaysia or Thailand (more than 20% annually), its GDP contribution could reach approximately USD 12,376.8 million, solidifying the country's position as a leading clinical research hub in the region. Beyond direct GDP impact, the expansion of clinical trials would also generate substantial tax revenue, further reinforcing the industry's broader economic benefits for Vietnam.

5.4.3. Employment

The sustainable growth of the clinical trials market in Vietnam will result in the creation of high-quality jobs for 2,600 to 16,400 direct employees by 2045

Additional jobs created directly from the clinical trials industry - future potential (thousands)

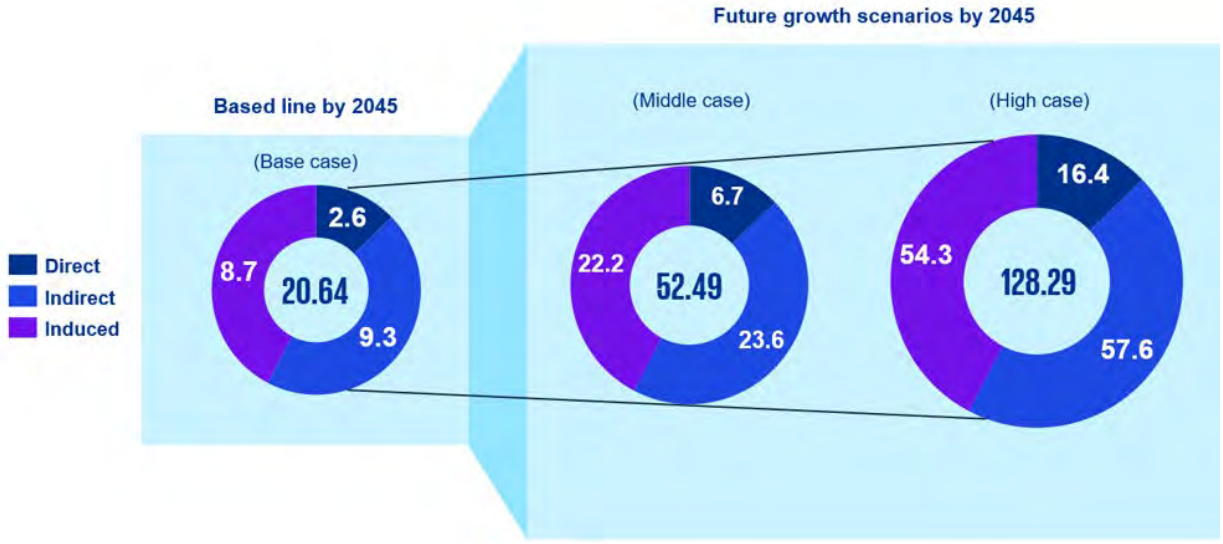


Source: KPMG Analysis and Estimation

The growth of Vietnam's clinical trials industry will directly enhance the quality and availability of highly skilled healthcare professionals (HCPs). At the base case, with existing human resource barriers unchanged, the sector is expected to create 400 new jobs in 2025 and 2,600 jobs by 2045.

However, with increased investment in training programs aligned with international standards and financial incentives for HCP participation, job creation could rise to 6,700 by 2045 at the Middle case. In a more ambitious scenario, where regulatory, infrastructure, and workforce challenges are fully addressed, the industry could generate up to 16,400 new jobs by 2045. This highlights the potential for Vietnam to develop a highly skilled workforce, making the country an increasingly attractive destination for global clinical research investments.

Additional total jobs created from the clinical trials industry - future potential (thousands)



Source: KPMG Analysis and Estimation

By 2045, Vietnam's clinical trials industry is expected to generate substantial employment opportunities beyond direct hires. Under a business-as-usual scenario, the sector will create 9,300 indirect and 8,700 induced jobs, totaling 20,640 jobs.

However, if key barriers are removed, job creation will expand significantly:

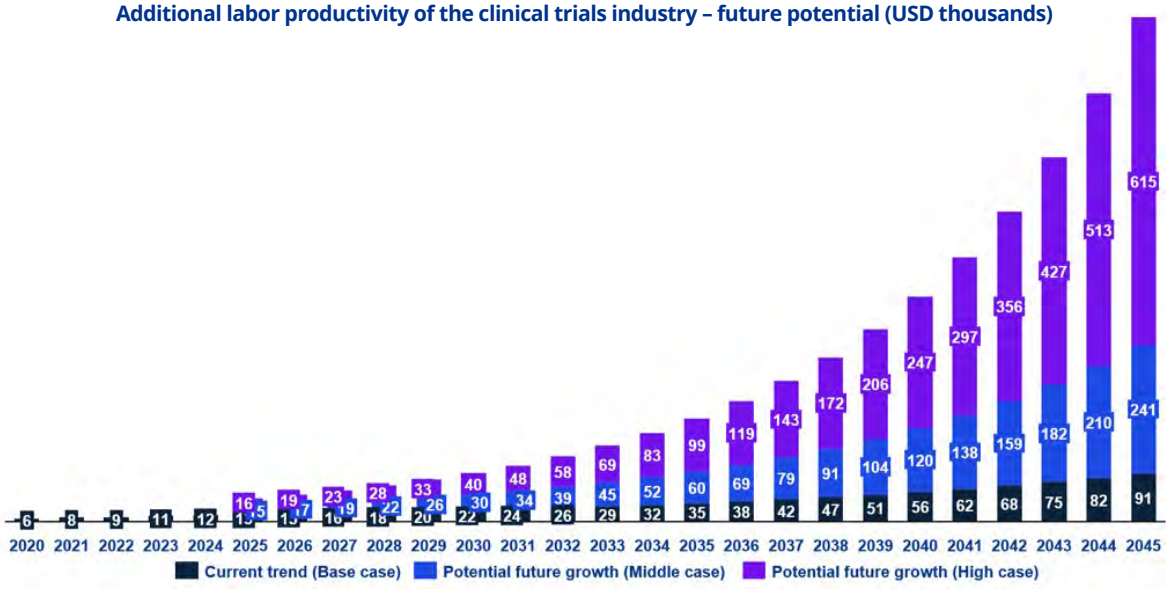
- **At the Middle case** if barriers are partially removed, the industry could support 23,600 indirect and 22,200 induced jobs, leading to 52,490 total new jobs.
- **At the High case** if barriers are fully removed, the sector could generate 57,600 indirect and 54,300 induced jobs, reaching 128,290 total jobs.

This highlights Vietnam's strong potential to become a high-value employment hub in clinical research. Strategic investments in regulatory efficiency, infrastructure, and workforce development will not only drive job growth but also position Vietnam as a leading destination for clinical trials in Asia.

5.4.4. Productivity

GVA and employment growth will drive higher labor productivity in clinical trials by 2045

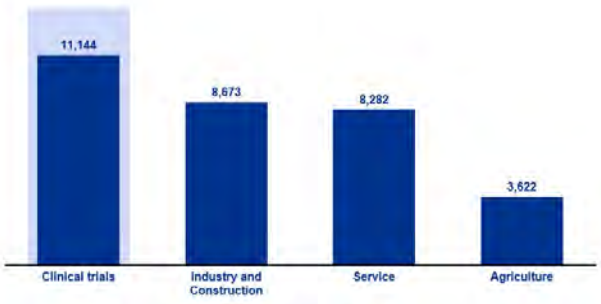
Additional labor productivity of the clinical trials industry – future potential (USD thousands)



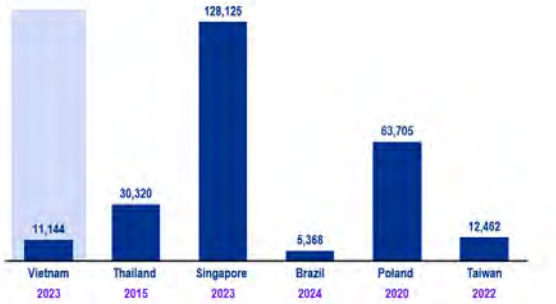
Source: KPMG Analysis and Estimation

Under normal conditions, labor productivity per employee in Vietnam's clinical trials industry is projected to grow from USD 13,00 in 2025 to USD 91,000 by 2045 at the Base case. Compared to other sectors in Vietnam, the clinical trials industry already demonstrates a strong economic advantage, with a higher labor productivity rate of USD 11,144 in 2023.

Benchmarking of labor productivity of clinical trials industry to other industries in 2023 (USD)

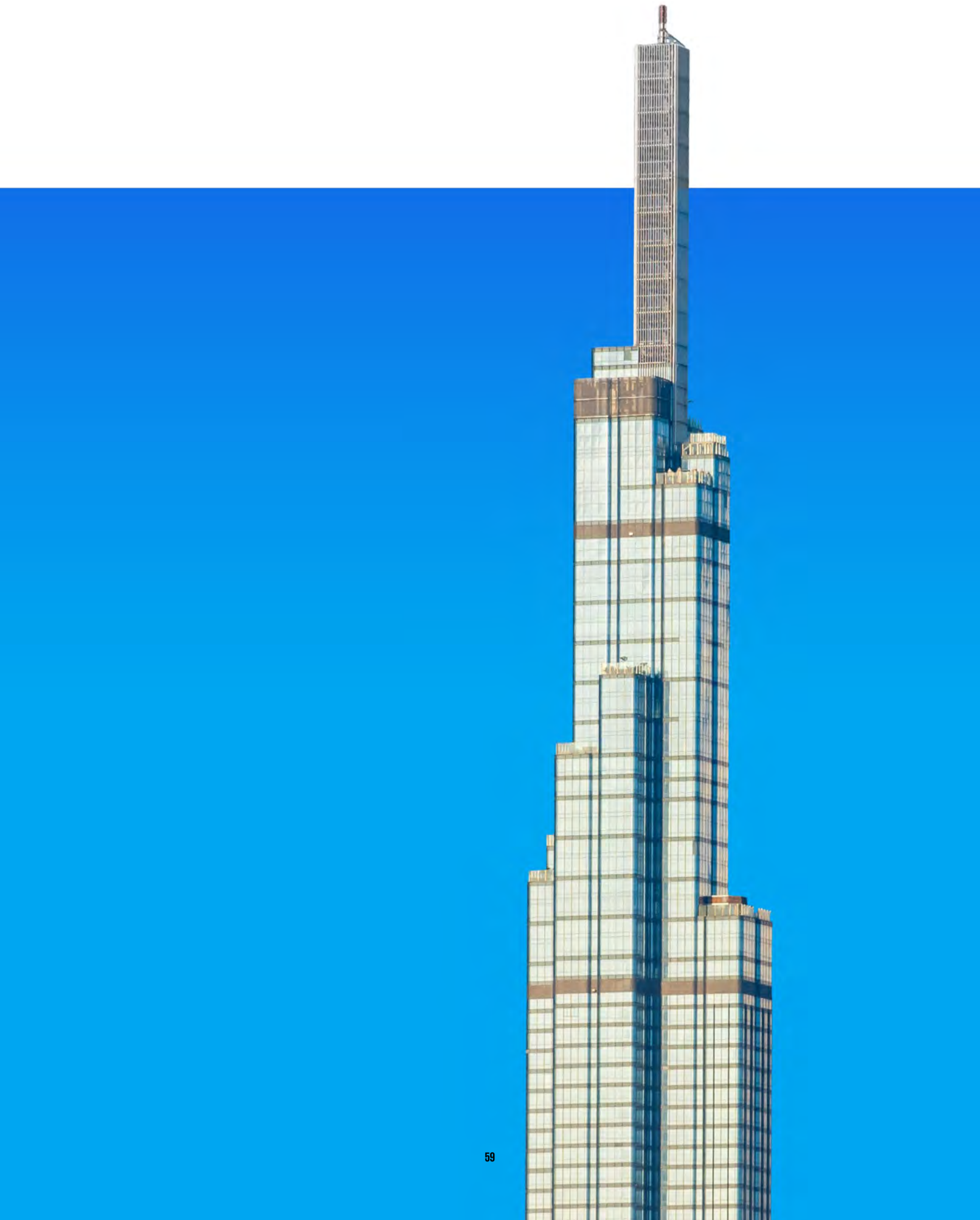


Benchmarking of labor productivity of clinical trials industry to other countries (USD)



Source: KPMG Analysis and Estimation

Implementing effective policies and solutions will drive increased business activity among pharmaceutical companies and research institutions, significantly boosting labor productivity in Vietnam's clinical trials sector. At the Middle case, labor productivity per employee is projected to reach USD 241,000 by 2045. If Vietnam's clinical trials industry reaches Malaysia's level, productivity could rise to USD615,000 per employee. This underscores the industry's high commercial value and strong social impact, reinforcing its potential as a key driver of economic growth.



6. Recommendations

Strategy Roadmap for Vietnam's clinical trial hub

Strategy Roadmap for Vietnam's clinical trial centre will divide into policy and non-policy recommendations

	Policy recommendations	Non-policy recommendations
Short-term *(2025)*	**Mandate dual-language documents** to simplify processes for international sponsors **Amend the legal documents in the direction of simplifying the import procedures for medical devices and ePRO equipment,** similar to the drug import regulations stipulated in the amended Pharma Law **Fostering the PPP model** **Adopt the risk-based approval process**	**Establishing a National Center of Excellence (CoE),** serving as a central hub for training clinical staff and clinical researchers **Partnerships between hospitals, academic and research institutions, and private companies with international universities** **Public-Private Collaborations**
Medium-term *(2026 - 2027)*	**The online portal** will be served as a centralized platform for clinical trial submissions **Centralize the ethical review process under NECBR** for all clinical trial ethical reviews **Having a dedicated clinical trial fund** to focus on financing key areas of R&D, particularly in priority medical fields such as oncology	**Establish a network of GCP-certified hospitals and pharmaceutical companies** **Implement GCP-compliant training and continous professional development programs** **Build regional infrastructure through targeted grants and establish research hubs** **Develop Clinical Trial Units (CTUs)** to drive academic clinical trials
Long-term *(2028-2029)*	**Implement fast-track approval pathways** for trials already approved in jurisdictions with advanced regulatory systems such as EU, US, or other advanced nations	**Foster digitalization in Vietnam's clinical trials** **Implement Electionic Medical Records to support building clinical trial database** **Develop a clinical trial database/registry** **Improve digital literacy among HCPs and government agency staffs** **Develop specialized clinical trial consultancy services**

By pursuing these reforms, Vietnam can capitalize on its clinical trial potential, fostering economic development and advancing public health.

KPMG and OUCRU have developed a strategic set of recommendations to position Vietnam as a leading regional clinical trial hub. These recommendations are categorized into policy and non-policy measures, structured across short-, medium-, and long-term timeframes.

- **Policy recommendations** focus on regulatory reforms, streamlined approval mechanisms, and investment incentives.
- **Non-policy recommendations** address infrastructure improvements, workforce and R&D capability development, dedicated clinical trial support and public-private partnerships.

Each recommendation identifies key stakeholders responsible for implementation and is supported by successful examples from other countries. By aligning Vietnam's strategy with proven global models while considering its unique market conditions, this roadmap provides a clear path to unlocking the full potential of the country's clinical trial industry.

6.1. Implications for Policy Makers

Policy recommendations

BARRIERS	SOLUTIONS: SHORT-TERM	SOLUTIONS: MEDIUM-TERM	SOLUTIONS: LONG-TERM	KEY INVOLVED STAKEHOLDERS
LENGTHY APPROVAL PROCESSES	**Mandate dual-language documents** to simplify processes for international sponsors **Adopt the risk-based approval process** ★	**The online portal will be served as a centralized platform for clinical trial submissions** **Centralize the ethical review process** under NECBR for all clinical trial ethical reviews ★	**Implement fast-track approval pathways** for trials already approved in jurisdictions with advanced regulatory systems such as EU, US, or other advanced nations ★★	Ministry of Health (MOH) Administration of Science Training and Technology (ASTT) National Ethics Committee for Biomedical Research (NECBR) International Regulatory Bodies (FDA, EMA, PMDA, MHRA)
UNCLEAR IMPORT REGULATIONS	**Amend the legal documents in the direction of simplifying the import procedures for medical devices and ePRO equipment,** similar to the drug import regulations stipulated in the amended Pharma Law ★			Ministry of Health (MoH) Ministry of Science and Technology (MoST) Drug Administration of Vietnam (DAV), Infrastructure and Medical Device Administration (IMDA) Clinical trial sponsors
LACK OF FUNDING MODEL	**Fostering the PPP model** can leverage private sector expertise, infrastructure, and funding to complement public sector efforts ★	**Having a dedicated clinical trial fund** to focus on financing key areas of R&D, particularly in priority medical fields such as oncology ★★		**Public sector:** Ministry of Health (MOH), Ministry of Finance **Private sector:** Pharmaceutical companies, CROs, Academic institutions

★ Recommendations impact on industry clinical trials ★ Recommendations impact on academic clinical trials

The government plays a pivotal role in advancing Vietnam's clinical trial sector by addressing three key barriers: lengthy approval processes, unclear import regulations, and the absence of a structured funding model.

Each barrier is matched with a targeted solution, drawing from interviews, case studies, and insights from key industry players. These solutions are further aligned with key stakeholders responsible for driving policy and initiative development, ensuring a coordinated approach to regulatory and industry improvements. By implementing these measures, Vietnam can enhance its clinical trial ecosystem, attract greater investment, and accelerate access to innovative treatments.

Proposed Solution: Streamlining Ethical Review Processes

Vietnam's lengthy approval process significantly reduces its attractiveness for clinical trials, as multiple layers of review create unpredictability and delays that push multinational sponsors to prioritize other markets with more efficient regulatory frameworks. Addressing this issue requires a streamlined and centralized approach to ethical approvals, supported by digital infrastructure and globally aligned policies. The following steps are recommended:

1.

Centralized Ethical Review Authority under the MOH or establish as a separate entity

Consolidate the approval process through the National Ethics Committee for Biomedical Research (NECBR) under the MOH or establish as a separate entity to ensure consistent decision-making, adherence to global standards, and reduced administrative redundancies. The current system, which involves separate approvals from local ethics committees, creates unnecessary variability and delays in trial initiation. A single, national approval process will provide greater efficiency, predictability, and transparency for sponsors and research institutions.

2.

Online Submission Portal

Establish a digital platform for clinical trial submissions to improve transparency, efficiency, and real-time monitoring by the Ministry of Health (BYT). A national clinical trial registry integrated into this platform will facilitate easier tracking of ongoing research, streamline compliance, and increase Vietnam's global appeal as a highly regulated and well-monitored research destination.

3.

Dual-Language Documentation.

Require key regulatory documents to be available in both English and Vietnamese to reduce translation delays and improve accessibility for international sponsors. Currently, most clinical trial documents are submitted in Vietnamese, except for certain materials (e.g., informed consent forms). By following best practices from Singapore and the Philippines, which allow full submission in English, Vietnam can attract more global research investments and accelerate international collaboration.

4.

Fast-Track Approval for Global Trials

Implement an expedited review pathway for clinical trials already approved in leading regulatory jurisdictions such as the US (FDA), EU (EMA), UK Medicines and Healthcare products Regulatory Agency (MHRA), and Japan's Pharmaceuticals and Medical Devices Agency (PMDA). Taiwan's TFDA model provides a successful precedent, allowing trials approved in ten recognized countries to bypass full technical evaluations and undergo only an administrative review, significantly reducing approval times and increasing global interest in Taiwan's research ecosystem.

5.

Risk-Based Approval Process

Introduce a tiered approval system that prioritizes fast-tracking low-risk trials while maintaining rigorous oversight for high-risk studies. This system aligns with WHO-driven risk-based evaluation frameworks, enabling regulatory agencies to allocate resources efficiently and focus on patient safety while accelerating lower-risk studies.

Given the recent Directives No. 05/CT-Ttg on key tasks and solutions to promote economic growth of 8% in 2025, the government has instructed to streamline administrative processes to reduce inconvenience, improve investment climate and expedite administrative procedures, which by 2025 the government aims to reduce administrative processing time and costs by at least 30%, eliminate at least 30% of unnecessary business conditions, ensuring all enterprise-related procedures are conducted online seamlessly and transparently. As this Directive becomes effective, it is expected that clinical trial approval procedures could reduce at least by a third of the current timeline, which could reduce from 3 to 4 months.

INTERNATIONAL BEST PRACTICES: TAIWAN'S TFDA MODEL

Taiwan transformed its clinical trials sector by consolidating ethical and regulatory reviews under a single authority - the Taiwan Food and Drug Administration (TFDA). Key measures included:

- Combining ethical and regulatory approvals into a streamlined process under one governing body.
- Establishing clear, predictable approval timelines to provide regulatory certainty for sponsors.
- Launching an online submission system that simplifies document handling and improves communication between sponsors and regulators.
- Implementing a fast-track approval pathway for global trials that meet stringent international regulatory standards.

By adopting similar policies, Vietnam can cut down approval timelines, enhance global research partnerships, and improve its attractiveness for investment in high-value clinical trials.

WHO's best practices: according to WHO's latest guidelines on best practices for clinical trials, there are some notable best practices that is recommended for countries to enhance regarding ethical review and capacity building. These recommendations include:

- The country should consider setting up national ethics committees to promote consistency and avoid unnecessary duplication of work in regions where several Regional Ethic Committees (RECs) exist. Regions or countries should consider having joint RECs or common reviews for multicenter research.
- RECs should examine their internal processes to reduce unnecessary bureaucracy, streamline their functions and harmonize processes with those of other RECs in the country or region. Regional or national forums, databases or registries should be encouraged to allow for communication and coordination between RECs.
- Review by an REC should be based on the protocol and complete, up-to-date supporting information and should include a determination of whether the proposed clinical study is scientifically sound, justified, proportionate and risk-based.
- The nation, international organizations and sponsors of research projects should invest in capacity-building for RECs in resource-limited settings, include training in scientific research and the key scientific and ethical considerations for good clinical trials, training for expedited and rapid reviews, and proportionate risk-based monitoring and evaluation.

STAKEHOLDERS FOR IMPLEMENTATION:

- **Ministry of Health (BYT)** – Leads regulatory reform and implementation.
- **Administration of Science, Technology, and Training (ASTT)** – Oversees policy execution.
- **International Regulatory Bodies (FDA, EMA, PMDA, MHRA)** – Provides technical guidance and validation for Vietnam's fast-track initiatives.

By implementing centralized approvals, digital solutions, dual-language policies, and fast-track pathways, Vietnam can reduce approval times, enhance regulatory efficiency, and solidify its position as a preferred clinical trial destination in Southeast Asia.

Proposed Solution: Simplifying Import Procedures for products that facilitate clinical trials

Vietnam's fragmented and unclear import-related approval process for Investigational Medicinal Products (IMPs) and clinical trial materials creates unnecessary delays and discourages foreign investment in clinical research. Multiple government bodies oversee import approvals, leading to redundant reviews, inconsistent timelines, and procedural bottlenecks.

Recommendations for Streamlining Import Approvals:

1. Amend the legal documents in the direction of simplifying the import procedures for medical devices and ePRO equipment

- Introduce a new legal policy mirroring the Revised Pharma Law to allow unregistered devices include ePRO solutions to be imported without a separate import license from DAV, based on MOH-approved trial protocol.
- Define clear exemptions (e.g. non-implantable devices, software tools) and carve out controlled-risk categories.
- Have DAV and IMDA (previously DMEC) together publish guidance on exercising the new import waiver for devices/ePRO, specifying dossier requirements, workflows and exceptions.
- Roll-out workshops for customs, hospitals, and CROs on the new "protocol-based" device import process.

2.Establish Transparent SOPs and Defined Timelines

- Develop standardized operating procedures (SOPs) outlining clear requirements, processing timelines, and documentation for sponsors.
- Introduce fast-track approval mechanisms for urgent medicines and critical trial materials.

3. Remove Grassroots-Level Review to Reduce Bottlenecks

- Eliminate local-level approvals, which are often a source of inconsistencies and prolonged decision-making.
- Shift approvals to national-level regulatory bodies for a more predictable and efficient process.

International Best Practices: Lessons from Taiwan and Brazil

TAIWAN

Special import approval for trials

- **Taiwan's Medical Devices Act (effective May 2021) provides a special clinical-trial import pathway.** Article 35 allows the health authority to grant "special approval for import" of investigational medical devices (defined as devices used solely in trials)
- In practice, a sponsor submits the trial protocol and device documentation to Taiwan FDA (TFDA). If TFDA grants approval, it issues a trial-specific import authorization. This replaces the normal registration process and import license. Thus, TFDA has established a Facilitated Customs Procedure for clinical use (similar to personal import rules) so that investigational devices can enter under this special approval.
- As a result, investigational systems (for example, an ePRO tablet or monitoring device) can be brought into Taiwan under the trial plan without undergoing full registration or a separate permit process. This streamlined path cuts weeks or months of processing, making Taiwan relatively attractive for device trials.

BRAZIL

Special import approval for trials

- **National Health Surveillance Agency (ANVISA)** was established as Brazil's single regulatory agency managing all import/export approvals.
- Sponsors apply for import/export approval simultaneously with submitting their Dossier for Development of Clinical Medicines (DDCM).
- An electronic system (SISCOMEX) processe documentation, enabling faster approvals (imported goods are released within 48 hours if compliant).
- These changes streamlined approvals, reduced delays, and ensured compliance with global standards.

STAKEHOLDERS FOR IMPLEMENTATION:

- **Ministry of Health (BYT)** – Oversees policy changes and regulatory alignment.
- **Drug Administration of Vietnam (DAV), Infrastructure and Medical Device Administration (IMDA, previously DMEC), and the Ministry of Science and Technology** – Implements and manages centralized import approvals.
- **Clinical Trial Sponsors** – Provide insights into current pain points and advocate for a more efficient system.

Proposed Solution: Establishing Sustainable Funding for Clinical Trials

Vietnam faces significant funding challenges for high-quality, large-scale clinical trials. Many studies, particularly those conducted in academic and research institutions, rely heavily on-site funding, forcing institutions to balance financial resources between normal operations and clinical research. This lack of stable financial backing often leads to delays or disruptions in trials. To address these funding gaps, two key initiatives are recommended:

1. Establish a Dedicated Clinical Trial Fund

A government-backed clinical trial fund would ensure consistent financial support for research in high-priority therapeutic areas such as oncology and infectious diseases. This fund could:

- Provide grants for early-phase and investigator-initiated trials, which often lack initial capital.
- Support capacity-building efforts, including GCP-certified facilities and training programs.
- Secure funding from multiple sources, including government budgets, international grants, and private sector contributions.

International Best Practice: Poland's Medical Research Agency (ABM)

- Poland established a dedicated clinical trial fund under the Medical Research Agency (ABM).
- The agency introduced a €95 million grant program for non-commercial trials on medicinal products and medical devices.
- 75% of the fund was allocated to academic and research institutions, while the remainder co-financed commercial research.
- This funding model reduced the financial burden on trial sites and enhanced Poland's research infrastructure, attracting greater participation from global sponsors.

2. Encourage Public-Private Partnerships (PPPs) for Clinical Trials

A structured PPP framework for clinical trials would leverage resources from both public and private sectors, filling funding gaps and encouraging investment. Key components include:

- Risk-sharing mechanisms to incentivize private investment.
- Government-led PPP framework outlining eligible projects, funding mechanisms, and regulatory support.
- Pilot PPP projects focused on high-cost therapeutic areas such as gene therapy, oncology, and infectious diseases.
- Tax benefits, co-investment opportunities, and fast-track regulatory processes to attract private sector participation.

International Best Practice: Taiwan's Taipei Medical University (TMU) & DCT Japan

- TMU partnered with DCT Japan to integrate decentralized clinical trials (DCTs) into Taiwan's healthcare system.
- DCT Japan provided technological expertise and digital platforms for remote monitoring and data collection.
- TMU contributed clinical sites and patient pools, facilitating broader patient access and reduced trial costs.
- The collaboration improved trial efficiency and attracted more international sponsors

STAKEHOLDERS FOR IMPLEMENTATION:

- **Ministry of Health (BYT)** – Develops and implements the clinical trial fund.
- **Ministry of Finance** – Oversees PPP incentives and investment policies.
- **Academia, Research Institutions & Hospitals** – Partner with private entities to facilitate clinical research.
- **Global Organizations (WHO, international investors)** – Provide technical assistance and funding for high-priority research.

6.2. Implications for Non-policy Makers

BARRIERS	SOLUTIONS: SHORT-TERM	SOLUTIONS: MEDIUM-TERM	SOLUTIONS: LONG-TERM	KEY INVOLVED STAKEHOLDERS
SHORTAGE TRAINED PERSONNEL	★ **Establishing a National Center of Excellence (CoE),** serving as a central hub for training clinical staff and clinical researchers ★ **Partnerships between hospitals, academic and research institutions, and private companies with international universities**			Government: Ministry of Health (MOH), Administration of Science Training and Technology (ASTT), National Ethics Committee for Biomedical Research (NECBR) Private sector: pharma companies, academic institutions WHO, universities, CROs
LIMITED CLINICAL TRIAL INFRASTRUCTURE AND SUPPORT SERVICES		★ **Establish a network of GCP-certified hospitals and pharmaceutical companies** ★ **Implement GCP-compliant training and continuous professional development programs** ★ **Develop Clinical Trial Units** ★ **Develop clinical trial consultancy services**	★★ **Implement Electronic Medical Records** to support building the clinical trial database ★★ **Develop a clinical trial database** to track trends and patient enrolment ★★ **Improve digital literacy** among HCPs and government agency staff	Ministry of Health (MOH) Drug Administration of Vietnam (DAV) International organizations Academic and research institutions Hospitals
GEOGRAPHIC INFRASTRUCTURE DISPARITIES	★★ **Public-Private Collaboration:** Foster co-investment models that combine resources and expertise from both the public and private sectors to upgrade and expand infrastructure	★ **Strengthen Local Capacity:** Build regional infrastructure through targeted grants and establish research hubs, ensuring that clinical trial facilities are accessible across the country	★★ **Foster digitalization in Vietnam's clinical trials:** execute electronic health records and technology systems to enhance trial	Ministry of Finance (MOF) Ministry of Health (MOH) Pharmaceutical companies, CROs and hospitals Academic and research institutions

★ Recommendations impact on industry clinical trials ★ Recommendations impact on academic clinical trials

While the government plays a crucial role in reshaping the regulations and policies aspects, extensive collaboration from various stakeholders is essential to overcome existing challenges and propel the clinical trials sector forward. These stakeholders, including private companies, academic and research institutions, hospitals, and investors, each play unique and complementary roles in developing the landscape of clinical trials in Vietnam.

Proposed Solution: Building a Center of Excellence (CoE) while implementing exchange programs with international universities

Vietnam faces a critical shortage of trained professionals in clinical trials, with limited training opportunities and institutional support hindering growth. Addressing this challenge requires two key initiatives:

1. Establishing a Center of Excellence (CoE) for Clinical Research

- Acts as a hub for training, research, and innovation in clinical trials.
- Provides specialized training in GCP, trial design, data management, and regulatory compliance.
- Offers certifications and mentorship programs led by experienced investigators.
- Facilitates high-priority clinical trials and pilots new methodologies, including decentralized clinical trials (DCTs).

GLOBAL EXAMPLES:

- Taiwan's NTUH CoE has expanded multidisciplinary clinical trials.
- Poland's CRSC at MUG enhanced research quality, boosted non-commercial trials, and established an Academic Clinical Research Organization.

2. Expanding International Collaboration and Exchange Programs

- Enables Vietnamese professionals to train at top global institutions.
- Brings international experts to Vietnam to upskill local healthcare professionals.

CASE STUDIES:

- Poland's P-CSRT with Harvard Medical School enhanced HCP competencies.
- Brazil's partnerships with LACOG, Fiocruz, and Dana-Farber Cancer Institute fostered a research culture.
- Taiwan's TCTC strengthened training programs through academia-industry collaborations.

STAKEHOLDERS FOR IMPLEMENTATION:

- **Government:** MOH, NECBR, public hospitals – to fund and support policy development.
- **Private Sector:** Pharma companies, academic institutions – to co-build the CoE and offer training.
- **International Organizations:** WHO, universities, CROs – to provide expertise and global best practices.

By establishing a CoE and expanding partnerships, Vietnam can significantly enhance its clinical trial workforce, improve research capacity, and position itself as a leading site for global clinical trials.

Proposed Solution: Establish a network of GCP-certified hospitals and pharmaceutical companies while providing continuous professional development programs tailored for clinical trials, developing Clinical Trial Units (CTUs), build a clinical trial database and introduce clinical trial consultancy services

Vietnam's growing clinical trial sector requires strong infrastructure and support services, but insufficient GCP-certified facilities, limited training programs, and a lack of Clinical Trial Units (CTUs) continue to hinder progress. To address these bottlenecks, three key initiatives are recommended:

1. Establishing a Network of GCP-Certified Hospitals and Research Institutions

- Identify and upgrade hospitals with potential to meet GCP standards by providing funding and technical support.
- Foster partnerships between certified hospitals, CROs, and pharmaceutical companies to share resources, expertise, and diagnostic equipment, enhancing trial quality.
- Encourage the development of CROs to provide specialized support services and operational efficiency, following Brazil's ABRACRO model, which strengthened trial infrastructure by integrating CROs into clinical research networks.

2. Expanding GCP-Compliant Training and Workforce Development

- Develop standardized GCP training programs for healthcare professionals, trial investigators, and researchers to enhance regulatory compliance, patient safety, and trial efficiency.
- Mandate continuous professional development through regular refresher courses, ensuring that clinical trial staff stay updated with international best practices.
- Introduce trainings on advanced trial methodologies, including Decentralized Clinical Trials (DCTs), to modernize Vietnam's research capabilities.
- Follow Taiwan's TCTC model, which integrates regular training courses and workshops to improve clinical trial operations.

3. Developing Clinical Trial Units (CTUs) in Academic Institutions and Hospitals

- CTUs will serve as dedicated hubs within universities and leading hospitals, streamlining trial operations from protocol design to patient recruitment and data management.
- Standardized best practices and centralized coordination will improve compliance with international regulations, ensuring efficient multi-center trial execution.
- Leverage global models, such as Taiwan's National Taiwan University Hospital and Poland's Clinical Trial Network, which successfully integrated CTUs into healthcare and research ecosystems.

4.Develop clinical trial consultancy services

Two main objectives for this solution are:
1. Enhance the quality of consultancy services among domestic CROs through capacity building,

2. Attract foreign CROs to facilitate clinical trials in Vietnam

Objective 1: Enhance the quality of consultancy services among domestic CROs (long-term solution)

- **Assessment and benchmarking:** evaluate existing domestic CROs to identify strength and limitations, and areas of improvement relative to international standards
- **Training programs:** Develop and implement comprehensive training programs focusing on regulatory compliance, trial design, data management, and qualty assurance
- **Knowledge transfer:** Establish partnerships with academic institutions and international organizations to facilitate knowledge exchange and best practices
- **Accreditation and quality framework:** Create a standardized accreditation process and quality assurance framework to ensure domestic CROs meet global benchmarks.

Objective 2: Attract foreign CROs to facilitate clinical trials in Vietnam (medium-term solution)

- **Fiscal incentives:** develop targeted incentives such as tax breaks, subsidies, and reduced administrative burdens to lower entry barriers for foreign CROs
- **Stakeholder engagement:** collaborate with government agencies, industry associations, and local research institutions to demonstrate Vietnam's market potential and readiness
- **Strategic partnerships:** initiate discussions for strategic alliances with leading global CROs such as IQVIA, Medpace to share expertise and resources

Vietnam can learn models in established markets, such as the comprehensive consultancy services offered by global firms such as Medpace, Paraxel and IQVIA. A prominent example with the involvement of Medpace is helping the International Sponsors to navigate regulatory requirements in South Korea and Japan, which Medpace was able to support timely site activation, developed a robust communication plan and cohort management to ensure smooth communications, and modify study plans and sites communications to ensure local enrollment requirements were complied.

5. Implement Electronic Medical Records (EMRs)

- Developing and deploying a secure, interoperable EMR system that integrates patient data from hospitals and clinics is essential.
- Concurrently, standardizing data formats and establishing protocols for data sharing will ensure consistency and compliance with international standards so all data can be used to roll out the clinical trial database.

6. Create a clinical trial database

- Create a standardized, digital platform similar to clinicatrials.gov to aggregate and monitor data on clinical trials across Vietnam.
- Key activities to achieve this include designing and developing database architecture, integrating data from multiple sources and implement robust analytics to track trends and patient enrollment.
- America's clinicaltrials.gov and Taiwan's clinical trial registry exemplifies a good case for Vietnam to craft a clinical trial database.

7. Improve digital literacy for HCPs and government agency staff

- The adoption of clinical trial database requires digital literacy to familiarize with the system. This solution requires comprehensive training programs, workshops, and continuous professional development courses focused on the EMRs, clinical trial database.
- Collaboration with academic institutions, international organizations, and professional associations will help develop tailored curricula and certification programs

STAKEHOLDER ENGAGEMENT FOR IMPLEMENTATION

- **MOH & Public Hospitals:** Designate clinical trial infrastructure and training as priorities, establish a centralized database of certified sites and trained personnel.
- **Pharmaceutical Companies, CROs & Private Hospitals:** Mobilize resources, co-finance infrastructure development, and integrate GCP training into medical education.
- **Technology companies:** to help build the platforms for managing Electronic Medical Records (EMRs) and to help integrate the EMRs to a dedicated clinical trial database.
- **International Sponsors & NGOs:** Secure funding and provide technical expertise for cross-border, multidisciplinary trials.

By establishing a GCP-certified research network, expanding workforce training, and integrating CTUs, together with implementing EMRs, creating a clinical trial database and develop specialized clinical trial consultancy services, Vietnam can rapidly enhance its clinical trial ecosystem, positioning itself as a leading research destination in Southeast Asia.

Proposed Solution: Building regional infrastructure through target grants and establish research hubs, co-investment with the PPP model and implementing decentralized clinical trials

To address this gap, three key initiatives are recommended:

1. Expanding Regional Infrastructure Through Targeted Grants and Research Hubs

- Allocate government grants to develop clinical trial centers in underserved areas, equipping them with laboratories, recruitment centers, and training facilities.
- Establish regional research hubs, modeled after Poland's Medical Research Agency (MRA), which successfully funded Clinical Trial Support Centers nationwide to boost research accessibility.
- Encourage collaboration between urban and rural institutions to share expertise, resources, and patient recruitment networks.

2. Strengthening Public-Private Partnerships (PPP) for Infrastructure Development

- Leverage PPP models to co-finance the expansion of clinical trial facilities in rural regions, ensuring access to cutting-edge research.
- Encourage pharmaceutical companies and private hospitals to invest in rural trials through tax incentives, regulatory fast-track mechanisms, and co-funding schemes.
- Follow successful models, such as Taiwan's TCTC, Brazil's ABRACRO, and Poland's PTCN, where government and private sponsors collaborated to expand infrastructure and improve market attractiveness.

3. Digitalizing Clinical Trials to Expand Access

- Adopt telemedicine platforms, electronic health records (EHRs), and mobile applications to support decentralized clinical trials (DCTs), allowing remote patient monitoring and telehealth consultations.
- Develop a centralized digital platform for trial management, integrating e-consent, patient tracking, and data analysis to enhance efficiency.
- Train healthcare professionals (HCPs) in digital trial management, ensuring standardized adoption across regions.
- Leverage international best practices, such as Taiwan's use of digital tools to streamline approvals and Brazil's remote monitoring systems in leading hospitals, ensuring geographic diversity in trial participation.

STAKEHOLDER ENGAGEMENT FOR IMPLEMENTATION

- **MOH & Provincial Health Departments:** Provide policy incentives (e.g., tax benefits) to encourage private investment in rural clinical trial sites.
- **Pharmaceutical Companies, CROs & Hospitals:** Support co-financing, establish GCP-compliant training, and integrate digital solutions for decentralized trials.
- **Academic & Research Institutions:** Expand workforce training and align rural healthcare professionals with clinical trial best practices.

By expanding infrastructure, leveraging PPPs, and digitalizing clinical trial processes, Vietnam can overcome geographic disparities, enhance trial accessibility, and position itself as a competitive clinical research hub in Southeast Asia.

Parting Words

Vietnam has the potential to become a leading clinical trials hub. The benefits of a well-developed clinical research ecosystem extend far beyond immediate economic gains. Clinical trials bring life-saving treatments to patients, strengthen the healthcare system, attract global investment, and drive innovation in the pharmaceutical and academic sectors. While the challenges Vietnam faces today, regulatory inefficiencies, infrastructure gaps, and workforce constraints are significant, they are not unique. Countries such as Taiwan, Brazil, and Poland have successfully overcome similar obstacles, proving that strategic reforms and strong public-private collaboration can rapidly transform a clinical trials market.

Vietnam does not have to navigate this journey alone. Global pharmaceutical companies, research institutions, and international organizations are eager to invest, collaborate, and provide expertise to help Vietnam build a sustainable and thriving clinical trials industry. By acting decisively, fostering global partnerships, and leveraging lessons from successful markets, Vietnam can accelerate its clinical trial development and position itself as a key player in the global research landscape, not just catching up to its regional peers but potentially surpassing them as a go-to destination for life sciences innovation.

Contact

Warrick Cleine
Chairman & CEO
warrickcleine@kpmg.com.vn

Luke Treloar
Partner, Head of Strategy Group
Head of Infrastructure, Government and Healthcare (IGH)
luketreloar@kpmg.com.vn

Guy Thwaites
Director, Oxford University Clinical Research Unit
gthwaites@oucru.org

Vo Thi Kim Ngan
Director, Strategy Group
nganvo@kpmg.com.vn

Evelyne Kestelyn
Head of Clinical Trials Unit
Oxford University Clinical Research Unit
ekestelyn@oucru.org

Offices

HANOI

46th Floor, Keangnam Hanoi Lanmark Tower
72 Building, Plot E6, Pham Hung Street
Cau Giay New Urban Area, Me Tri Ward
South Tu Liem District, Hanoi, Vietnam

T: +84 (24) 3946 1600
F: +84 (24) 3946 1601
E: kpmghanoi@kpmg.com.vn

HO CHI MINH CITY

10th Floor, Sunwah Tower
No. 115, Nguyen Hue Street
Ben Nghe Ward, District 1
Ho Chi Minh City, Vietnam

T: +84 (28) 3821 9266
F: +84 (28) 3821 9267
E: kpmghcmc@kpmg.com.vn

DANANG

Unit D3, 5th Floor, Indochina Riverside Tower
No. 74, Bach Dang Street, Hai Chau 1 Ward
Hai Chau District, Danang, Vietnam

T: +84 (236) 351 9051
E: kpmgdanang@kpmg.com.vn

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