Competitive Advantage of Nations – Romania's Clinical Research Capabilities in 2025

Developed by

THE INSTITUTE FOR BUSINESS ADMINISTRATION IN BUCHAREST

(ASEBUSS)

With the support of

ROMANIAN SOCIETY OF CLINICAL RESEARCH CENTERS

(RSCRC)

- September 2025 -

Executive Summary

Romania's clinical trials sector has emerged as a competitive force within the European Union, leveraging its strategic position in Central and Eastern Europe (CEE). The purpose of this report is to provide an overview of Romania's clinical research ecosystem and to assess its competitive position in comparison with other European countries**.** Although the sector demonstrates considerable growth potential and has the capacity to attract international sponsors and contract research organizations (CROs), it remains confronted with structural limitations and competitive pressures that challenge its sustainable development.

This analysis, undertaken by **ASEBUSS (Romanian-American Business School)** in collaboration with **SRCCC | RSCRC (Romanian Society for Clinical Research Centers)**, employs **Michael Porter's Diamond Model** (Porter, 1990) to assess Romania's national competitive advantage in clinical trials. The study captures the current state of Romania's clinical research ecosystem and evaluates its competitive standing within the European Union, with a particular focus on *factor conditions*, *demand conditions*, *related and supporting industries*, *firm strategy and rivalry*, and the exogenous influences of *government* and *chance*.

Drawing from from extensive research, including industry statistics, regulatory analyses, and international benchmarks (European Federation of Pharmaceutical Industries and Associations [EFPIA], 2025, 2024, 2023; European Medicines Agency [EMA], 2025; Organization for Economic Co-operation and Development [OECD], 2024; 2023;), the findings highlight Romania's strengths in cost-efficient operations, a sizeable medical workforce that can be trained, and regulatory convergence with EU standards. At the same time, critical constraints persist, including uneven infrastructure, workforce migration, talent retention, and regulatory bottlenecks that limit patient recruitment.

The present analysis benchmarks Romania's clinical research ecosystem against selected European Union comparators—most notably Poland, Spain, Germany, France, and neighbouring Eastern European states—in order to systematically delineate Romania's relative competitive strengths and structural vulnerabilities.

Key findings indicate that Romania's clinical research sector is characterized by a paradoxical combination of strengths and systemic barriers. On the one hand, Romania benefits from a cost-effective and sizeable medical workforce, a strong IT sector, and a diverse patient pool that provides a solid basis for clinical trial activity. On the other hand, several bottlenecks persist. First, **the absence of a standardized academic curriculum for training clinical research professionals** significantly limits the development of highly skilled investigators, study coordinators, and trial support staff (Health Innovation Hub, 2024). Second, **regulatory and communication barriers** have historically constrained direct patient recruitment, contributing to suboptimal enrollment outcomes in many studies. Third, **structural imbalances between public and private trial centers** continue to distort the competitive environment. Public hospitals dominate approximately half of the market, often operating under asymmetric conditions that restrict the capacity and growth of private-sector sites.

Consequently, Romania lags considerably behind both regional and Western European peers. As of September 2025, the country hosted approximately 656 clinical trials—far fewer than Poland (~2,149 trials) and significantly trailing leading EU countries such as Spain, France, and Germany, each with more than 3,000 trials (European Union Clinical Trials Information System [CTIS], 2025; ClinicalTrials.gov, 2025; EU Clinical Trials Register [EU CTR], 2025).

The ongoing digitalization and decentralization of clinical research represent a paradigm shift for the global industry. Romania, however, faces incremental challenges in this transition. Two key barriers stand out: **reluctance** and, in some cases, outright resistance among existing clinical research teams **to adopt and operate eSource/ Electronic Data Capturing (EDC)** platforms in daily practice, and **limited enthusiasm from industry stakeholders with regards to digitalization of clinical trial activities**, largely due to perceived increases in implementation costs and concerns about technical reliability and data quality.

Despite these constraints, **international evidence proves that full integration of trial activities into eSource/EDC systems is both irreversible and strategically advantageous** (U.S. Food and Drug Administration [FDA], 2022). Consequently, Romania should consider leapfrogging incremental approaches and positioning eSource as the national "gold standard" for clinical trial

operations, **supported by regulatory and financial incentives from both authorities and industry partners**.

To strengthen Romania's competitive position in the European and global clinical research landscape, three strategic priorities emerge.

First, developing formal education and training programs in clinical research. Romania currently lacks a standardized academic curriculum for clinical trial professionals, resulting in a narrow and overstretched cadre of investigators and coordinators. Embedding dedicated curricula within medical universities and establishing accredited certification programs for roles such as study coordinators and clinical research nurses would broaden the talent pipeline, improve quality standards, and mitigate physician migration, which has been one of Romania's persistent challenges (OECD, 2024; 2023).

Second, aligning regulatory practices with EU best practices to enable and promote direct patient recruitment and engagement. While the adoption of the EU Clinical Trials Regulation (CTR No. 536/2014) has harmonized basic approval procedures, Romania continues to lag in enabling direct-to-patient recruitment and awareness campaigns (CTIS, 2025). Modernization should include the ethical liberalization of recruitment practices (mass media, social media, registries), the establishment of national disease-specific patient registries, and the simplification of consent procedures, while safeguarding transparency and data protection standards (EMA, 2025). Empowering clinical research staff—including early career professionals—to take on active roles in patient engagement and trial coordination is equally critical.

Third, rebalancing public–private trial infrastructure. Romania's clinical trial ecosystem is skewed toward public hospitals, which often operate under bureaucratic constraints and capacity bottlenecks. Incentivizing public–private partnerships and funding site capacity across both sectors would expand national capabilities. Comparative evidence from Poland highlights the benefits of establishing a dedicated governmental capability (e.g., Poland's Medical Research

Agency), which has successfully coordinated funding, training, and infrastructure development while promoting international competitiveness (Kosiński et al., 2023). Romania could benefit from a similar dedicated governmental capability or initiative to support clinical research, tasked with national coordination, funding investigator training, simplifying trial approvals, and strategic promotion abroad.

By advancing these reforms, Romania can enhance its attractiveness for global clinical trial investments, accelerate patient access to innovative therapies, and reduce its performance gap relative to Central and Western European peers. This analysis therefore positions Romania's clinical research sector at an inflection point: its inherent strengths—large but under-utilized number of clinicians, in need of clinical research academic curriculum, a cost-competitive environment, and a diverse patient population—must now be matched with systemic investments in education, digitalization, regulation, and infrastructure if the country is to evolve into a credible regional hub.

The subsequent sections elaborate Romania's performance across Porter's Diamond dimensions, benchmarked against European comparators, and provide actionable recommendations to drive sustainable growth and innovation in clinical trials.

I. Overview of the Clinical Trials Industry in the EU and Romania

Clinical research—particularly the conduct of clinical trials— is a highly globalized industry in which countries compete to attract investments, expertise, and access to innovative therapies for patients (OECD, 2024, 2023). The European Union (EU) has historically represented a major hub for clinical trials, yet its global share has declined in the face of rising competition from regions such as Asia (EFPIA, 2024). Within Europe, substantial disparities exist in the capacity and performance of national clinical research systems. Western European states such as **Spain, France, and Germany** continue to host the largest volumes of trials, each with over 3,000 active studies in 2025 (PharmaLinkage, 2025). At the same time, several **Central and Eastern European (CEE) countries have strengthened their ecosystems and** have become attractive locations for sponsors due to competitive costs and faster recruitment. **Poland** currently leads the CEE region, with approximately 2,149 active trials in 2025, followed by the Czech Republic and Hungary, both of which have developed efficient and reliable infrastructures for trial operations (ClinicalTrials.gov, 2025).

Figure 1. Number of clinical trials in EU

Source: European Union Clinical Trials Register (2025)

Romania's clinical trial ecosystem has undergone significant transformation since EU accession in 2007. Integrated into a pharmaceutical market that generated **€5.2 billion** in revenue

in 2023—making Romania the second largest in CEE after Poland (Statista, 2025; EFPIA, 2024) - the sector contributes both directly, through sponsor and CRO investments, and indirectly, by enhancing patient access to innovative therapies and alleviating pressures on the national insurance system.

The ***Strategic Plan for the Development of Clinical Trials in the Field of Medicines for Human Use*** estimated that Romania's clinical trials market was valued at €45–50 million in 2022, with projections to triple by 2026 to approximately €150 million annually (Health Innovation Hub, 2024). This includes revenue from trial contracts and the associated economic contribution. Also, the ACT EU initiative by EMA and the European Commission also outlines efforts to transform clinical trials across the EU, including Romania. (EMA, 2025).

As of September 2025, Romania hosted more than 656 ongoing trials, with oncology accounting for the largest share, followed by cardiology, neurology, and infectious diseases (EU Clinical Trials Register, 2025). As an EU member state, Romania benefits from harmonized regulations under the **Clinical Trials Regulation (EU) No 536/2014**, fully applicable since January 2023, through the **Clinical Trials Information System (CTIS) (CTIS,** 2025), which harmonizes multinational approvals.

Romania's key strengths include a population of 19 million offering large treatment-naïve patient pools, **high recruitment rates** compared to Western Europe, and and a growing workforce of over **1,500 professionals** engaged in clinical research. Major global CROs and sponsors are already active in the country.

Nonetheless, Romania continues to face structural challenges. Lack of trained workforce, uneven infrastructure, and regulatory delays constrain its ability to compete with regional peers. In parallel, the digital transformation of clinical research has been slow: reluctance to adopt eSource and electronic data capture platforms, coupled with limited stakeholder investment, risks marginalizing Romania in a global landscape increasingly shaped by decentralized and digitalized trial models (International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use [ICH], n.d; FDA, 2022).

Addressing these challenges will be critical if Romania is to fulfill its strategic objective of becoming a more competitive and attractive destination for clinical research within Europe. Beyond digitalization, persistent systemic bottlenecks also undermine competitiveness, including disparities between public and private sites, delays in regulatory timelines, and the absence of a standardized national curriculum for training clinical research professionals.

II. Porter's Diamond Model Application

The present study employs **Michael Porter's Diamond Model -** first articulated in *The Competitive Advantage of Nations* (Porter, 1990) - as a conceptual framework to analyze Romania's clinical trials industry, a dynamic and strategically relevant segment of its healthcare sector. The model conceptualizes national competitiveness as the outcome of interactions among four interdependent attributes: **factor conditions**, **demand conditions**, **related and supporting industries**, and **firm strategy, structure, and rivalry**. These are complemented by two exogenous factors, **government and chance**, which together form the analytical "**diamond**."

Originally developed to explain why certain nations achieve sustained leadership in specific industries, the framework has since been widely applied across diverse sectors, including healthcare and pharmaceuticals, to explain why certain nations excel in global markets. Therefore, we apply the Diamond Model to Romania's clinical trials industry, a burgeoning segment of its healthcare sector. Clinical trials, as systematic studies evaluating the safety and efficacy of medical interventions, constitute a cornerstone of global drug development and represent both an economic and public health opportunity. With its EU membership, harmonized regulatory environment, and strategic location in Central and Eastern Europe, Romania has emerged as an attractive destination for sponsors and CROs, hosting more than 656 studies as of September 2025 (ClinicalTrials.gov, 2025).

The structure of this study follows the Diamond Model's six elements, beginning with an overview of Romania's clinical research ecosystem and concluding with comparative insights and policy recommendations.

Michael Porter's Diamond Model offers a structured framework to analyze why certain industries achieve competitive success in specific countries. The model posits that **four primary determinants**—factor conditions, demand conditions, related and supporting industries, and firm strategy, structure, and rivalry—interact dynamically to shape national advantage. In addition,

Porter emphasizes the importance of **two secondary influences: government policy and chance events**, which can either reinforce or undermine the competitive position of an industry.

Applied to the clinical research sector, this framework provides a comprehensive lens through which to assess Romania's current position and its comparative performance relative to peer countries. By systematically examining these six interrelated dimensions, it becomes possible to identify both the **structural strengths** and the **systemic weaknesses** that define Romania's clinical research ecosystem.

A. Factor Conditions: Romania's Resources for Clinical Research

Factor conditions, as defined by Porter (1990), refer to a nation's factor endowments, which include basic factors (e.g., natural resources, climate, geographic location, and unskilled labor) and advanced factors (e.g., skilled labor, research capacity, infrastructure, and technological capabilities). Porter emphasizes that **sustained competitive advantage derives primarily from advanced factors**, which are created and continually upgraded through investment, innovation, and institutional development.

In the context of clinical trials, Romania presents a paradoxical profile: *although quantitatively endowed with significant resources, its competitiveness is constrained by qualitative and structural deficiencies.*

Human Capital (Workforce and Skills)

Romania's medical workforce constitutes one of its most significant structural advantages in clinical research, though qualitative gaps persist. In 2023, the country reported approximately **74,400 physicians** and thousands of other healthcare professionals, providing a substantial pool of potential investigators and support staff (National Institute of Statistics [INSSE], 2025). Educational output in medicine and nursing is among the highest in the European Union on a per capita basis. In 2021, Romania registered 5,006 medical graduates (26.2 per 100,000 population, compared with the EU average of 17.5 per 100,000) and 20,763 nursing graduates (108.6 per

100,000 population, versus an EU average of 44.3 per 100,000) (OECD & European Observatory on Health Systems and Policies, 2023). Romanian medical education is well regarded in terms of core clinical training, and many graduates possess strong foreign-language skills, which facilitates participation in multinational studies.

Cost competitiveness further enhances Romania's workforce advantage. Historically, **labor costs have been 30–40% lower** than in Western Europe for comparable qualifications, making the country attractive for clinical trial staffing (Health Innovation Hub, 2024). However, the 2018 **public-sector reform substantially increased physician salaries** (~ 70–172% increases), **narrowing the differential with regional peers** (Mosca et al., 2023). Even so, Romania remains relatively cost-efficient for international sponsors (EFPIA, 2024).

Despite these quantitative advantages, a critical weakness lies in **the absence of formal, standardized training pathways in clinical research**. Unlike peer countries such as France or the UK, which provide specialized curricula and certifications in trial management, Romania historically **lacked academic programs dedicated to training investigators and clinical research staff**. Consequently, research competencies are often acquired through experiential practice, potentially delaying trial initiation and affecting procedural consistency (EFPIA, 2024).

A recent initiative introduced a Master's program in clinical trial monitoring at Carol Davila University of Medicine and Pharmacy in Bucharest (Health Innovation Hub, 2024), but this program is narrowly focused on preparing trial monitors for contract research organizations. It does not address the broader need to train principal investigators, study coordinators, data managers, and research nurses across the country (National Agency for Medicines and Medical Devices of Romania. Agenția Națională a Medicamentului și a Dispozitivelor Medicale din România [ANMDMR], 2024). Consequently, most physicians and nurses acquire trial competencies in the active centers - "on the job" - which prolongs start-up times, constrains quality assurance, and limits the pipeline of new investigators. Romania still **lacks a nationwide, standardized curriculum or certification pathway** for clinical research professionals, unlike France or the UK, where multiple universities offer such programs (Health Innovation Hub, 2024).

Regulatory practices have further constrained workforce availability. Until 2025, Romanian authorities required sub-investigators to demonstrate specific medical specializations or extensive prior research experience—**requirements not typically imposed in other EU countries**. Without broad training opportunities to expand the talent base, such criteria significantly reduced the pool of eligible research personnel.

In the context of the industry moving forward with the digitalization and decentralization of clinical research activities, Romania is facing an incremental challenge posed by the reluctance and, in some cases, resistance of current clinical research team members to learning and operating eSource and Electronic Data Capture (EDC) platforms used for daily trial operations. While these systems are now considered the international benchmark for data integrity, efficiency, and compliance with Good Clinical Practice (GCP), their uptake in Romania has remained limited (EMA, 2025; FDA, 2022).

The global trend to integrate all trial activities into eSource/EDC digital platforms is irreversible, with regulatory authorities such as EMA, FDA, and ICH explicitly endorsing their use to support decentralized and hybrid trial models (ICH, n.d). **As such, Romania should leapfrog incremental approaches and adopt eSource as the national golden standard for clinical trial activities.** This transition should be **strongly supported and incentivized by both industry and regulatory authorities**.

In addition, **brain drain** remains a significant obstacle. World Health Organization estimates that **up to 15% of Romanian physicians emigrate annually**, for better opportunities, one of the highest rates in Europe (World Health Organization [WHO], 2023, 2022). The combination of insufficient local training and ongoing physician migration means that, despite its substantial numeric workforce, Romania frequently lacks an adequate pool of *research-experienced* investigators and specialized support staff, including study coordinators and data managers (OECD, 2024, 2023; WHO, 2023, 2022). By contrast, **Poland's medical workforce is nearly double in size** and benefits from structured training initiatives sponsored by its Medical Research Agency (MRA), which have significantly expanded the pool of clinical trial professionals

(Medical Research Agency [MRA/ ABM], 2025, 2023). Western European countries such as Germany and France not only maintain larger physician bases—for example, Germany registered over 400,000 physicians in the mid-2020s (OECD, 2024, 2023) - but also sustain more mature research training ecosystems and established career pathways in clinical investigation, thereby reinforcing their long-term competitiveness in clinical research (PharmaLinkage**,** 2025).

Infrastructure and Sites

Romania's healthcare infrastructure provides a foundational base for clinical trial activity, though its quality and capacity remain uneven. The country maintains a network of public hospitals—including large academic centers in Bucharest, Cluj-Napoca, Iași, and Timișoara—alongside a growing private hospital sector. Key therapeutic areas, such as oncology, are supported by well-established reference centers. As of September 2025, **369 clinical trial sites were active in Romania**, reflecting a moderate geographic distribution of trials across centers (CTIS, 2025).

Despite this base, several challenges constrain performance. Research capacity varies significantly: many regional hospitals have limited trial experience, some public institutions operate with outdated facilities or equipment, and hospital-level **bureaucratic processes**—particularly in contracting and ethics approvals—frequently delay trial initiation (ANMDMR, 2024).

By comparison**,** countries such as **Poland and Germany maintain more extensive and research-specialized infrastructures.** Poland operates roughly 600 hospitals (versus ~500 in Romania), many of which host dedicated clinical research units. Moreover, its **Medical Research Agency (MRA)** has strategically invested in infrastructure modernization and developed a network approach that integrates public and private sites (MRA/ ABM, 2025, 2023).

Germany and France maintain extensive university hospital networks—such as France's comprehensive cancer centers and Germany's Coordinating Centers for Clinical Trials—which collectively provide highly specialized, research-oriented environments for clinical investigation. Beyond hospital infrastructure, these countries benefit from well-developed **ancillary systems**,

including accredited laboratories for biological sample analysis, national biobanks, and reliable supply chains for investigational medicinal products, all of which contribute to trial quality and efficiency (EMA, 2025).

In contrast, Romania's healthcare infrastructure, while relatively robust in major urban centers, requires substantial upgrading and targeted expansion in research-specific functionalities to reach comparable standards. Limitations are particularly evident in regional and rural sites, where insufficient equipment and limited research capacity restrict participation in multi-site or decentralized clinical trials (ANMDMR, 2024).

Technological and Data Capabilities

Romania benefits from a latent yet significant advantage in its strong information technology (IT) sector, which employs approximately 200,000 professionals nationwide (European Commission, 2024; CES Bucharest, n.d.). This resource has direct implications for clinical research, as contemporary trials increasingly depend on digital tools such as eSource systems, electronic data capture (EDC), remote monitoring, and advanced data analytics (EMA, 2025). The presence of a highly skilled technology workforce has already fostered the emergence of local vendors and start-ups offering eClinical software and data management solutions. Moreover, Romania's population demonstrates high levels of internet and mobile penetration, creating favourable conditions for the expansion of digital health solutions and, potentially, **decentralized clinical trial models** (e.g., telemedicine visits, electronic patient-reported outcomes) (HIMSS, 2023).

Despite these strengths, Romania has yet to fully channel its technological capacity into clinical research. Barriers include the relatively high entry costs of eSource and EDC adoption, limited training opportunities for clinical research professionals, and regulatory conservatism that constrains the use of telehealth or digital recruitment strategies in trial contexts (ANMDMR, 2024).

By contrast, leading European countries have systematically capitalized on digital integration. **The Netherlands and Denmark, for instance, have implemented online trial**

platforms and centralized data infrastructures, enabling trial start-up approvals in under 30 days and piloting fully remote, decentralized trial processes (PharmaLinkage**,** 2025; OECD, 2024, 2023). Romania has the requisite human capital to follow similar pathways, but this will require coherent policy support, institutional investment, and structured training programs to translate IT sector capacity into competitive clinical research infrastructure.

Natural and Epidemiological Factors

Although not 'natural resources' in the traditional sense, a country's epidemiological profile can be considered a critical factor condition for clinical trials (Porter, 1990). Romania's patient population demonstrates a high incidence of certain diseases (e.g., hepatitis C, selected oncological conditions, and cardiovascular disorders). Importantly, a significant proportion of Romanian patients remain treatment-naïve or have unmet medical needs, largely due to systemic resource constraints in the public healthcare system (OECD, 2024, 2023;WHO, 2023, 2022).

This combination of **diverse pathology and the prevalence of both common and rare diseases,** and treatment gaps creates an environment attractive to sponsors seeking accessible patient pools for clinical research. The relatively low uptake of certain innovative therapies within Romania's public health system means that many eligible patients remain treatment-naïve, which simplifies eligibility criteria and facilitates accelerated recruitment into trials (OECD, 2024, 2023).

With a national population of approximately 19 million, Romania offers not only numerical scale but also clinical diversity, enabling the formation of heterogeneous patient cohorts that align with global sponsors' requirements for robust and generalizable trial outcomes.

Romania's factor conditions present a dual profile: **abundant in human resources, cost advantages, IT capabilities,** and **epidemiological diversity**, yet undermined by **insufficient specialized training, persistent physician emigration, uneven infrastructure, and slow digital integration.** Taken together, these conditions place Romania at a *moderate competitive position*, requiring targeted interventions to convert latent assets into sustainable advantages.

B. Demand Conditions: Clinical Trial Demand in Romania vs. Europe

According to Porter's framework, demand conditions influence how industries develop by shaping the scale, structure, and sophistication of local and international markets (Porter, 1990). In the context of clinical research, Romania's demand conditions can be assessed along two dimensions: **international demand** (trials sponsored by global pharmaceutical and biotechnology companies choosing Romania) and **domestic demand** (trials initiated by local sponsors, research institutions, or driven by national healthcare needs).

International Demand and Patient Enrollment

Global pharmaceutical and biotechnology companies have shown sustained interest in Romania as a clinical trial location, primarily due to its **large patient pool** and **cost advantages** (EFPIA, 2024). As of September 2025, there were **656 clinical trials** registered in Romania across multiple therapeutic areas (CTIS, 2025). Many of these studies are components of **multinational research programs**, with Romania serving as one of several participating countries. Sponsors are particularly attracted by Romania's **population of 19 million**, which encompasses both urban and rural patients, many of whom are willing to participate in trials to gain access to innovative therapies otherwise unavailable in the national health system (OECD, 2024, 2023). In therapeutic areas such as **oncology, cardiology, and infectious diseases**, Romania's **epidemiological profile and treatment-naïve patient populations** create strong enrollment potential. For instance, oncology trials are especially appealing since standard-of-care options for some cancers remain limited, making **clinical trial participation a crucial alternative** for patients.

Domestic demand is further reinforced by demographic and health trends, notably an **aging population** and the **high prevalence of chronic conditions**. Approximately **20% of Romanians are affected by cardiovascular diseases**, which increases the pool of eligible trial participants (OECD & European Observatory on Health Systems and Policies, 2023).

Despite this potential, **patient recruitment performance in Romania remains suboptimal**. A significant proportion of trials have historically struggled to meet their enrollment targets. One major factor, as highlighted by local experts, has been **regulatory and communication barriers to direct patient recruitment**. Prior to the implementation of the EU Clinical Trials Regulation (CTR No. 536/2014) in 2023, Romanian regulations severely **restricted direct-to-patient advertising or outreach for clinical trials through mass media and digital platforms**. In practice, this meant that sponsors and contract research organizations (CROs) could not promote trials via **television, radio, or social media**, unlike in countries where carefully regulated patient-facing campaigns were permissible (EMA, 2025). Recruitment therefore relied primarily on **physician referrals** or **clinic-based postings**, approaches which limited both outreach and recruitment speed.

Since 2023, however, following the adoption of CTR and updated national guidance, as the national authorities finally understood the permissive framework imposed by CTR, **digital recruitment campaigns are now permitted**, provided they adhere to transparency and ethics standards (ANMDMR, 2024). Nevertheless, such campaigns are not yet broadly implemented across **mass media channels** such as TV, radio, or outdoor advertising.

A further limitation is the **absence of a national clinical trial registry or public-facing portal in the Romanian language**, which reduces patient awareness. While the EU's **CTIS portal** is accessible, it is little known among the general public (CTIS, 2025). By contrast, other EU member states have adopted proactive models to facilitate recruitment. Spain's **national registry (REEC)** provides accessible trial listings and supports collaboration with patient associations, while Denmark's **"Trial Nation"** platform functions as an integrated trial-matching service between patients and sites (Agencia Española de Medicamentos y Productos Sanitarios [AEMPS], 2024, 2015; Trial Nation, 2023; Distefar del Sur, n.d.).

Romania is currently at an **early stage of reform** in this area, with **strategic proposals** under discussion to create online portals and patient registries for clinical trials (Health Innovation Hub, 2024). However, these initiatives remain **aspirational rather than operational**, leaving the

country at a disadvantage compared with peers that have already institutionalized patient-centered recruitment mechanisms.

Domestic Demand and Local Sponsorship

A striking feature of Romania's clinical trial landscape is the **very low share of locally sponsored studies**. Only a **marginal percentage of active trials in Romania are initiated or funded by domestic organizations**—whether pharmaceutical companies, research institutions, or investigator-initiated projects (Health Innovation Hub, 2024). By contrast, the **vast majority of trials are sponsored by international entities**, reflecting weak internal demand for clinical research.

In comparison, **Poland reports approximately 15–20% locally sponsored trials**, supported by a more dynamic biotech/pharmaceutical sector and direct governmental investment through the **Medical Research Agency (MRA)** (MRA/ABM, 2023). In Western Europe, domestic sponsorship rates are significantly higher, driven by **large pharmaceutical companies** (e.g., Sanofi in France, Bayer in Germany) and sustained **public research funding** through national networks such as France's *Programme Hospitalier de Recherche Clinique* (PHRC) or Germany's university hospital consortia.

Romania's pharmaceutical industry remains **relatively small and primarily oriented toward generic drug production**, with limited capacity for innovative R&D. Furthermore, **academic research is chronically underfunded**, resulting in very few investigator-initiated trials. This structural weakness means that internal demand does not substantially propel Romania's trial activity; instead, the country functions largely as a **host site for foreign-led studies** (EFPIA, 2024).

The causes of low domestic demand are multifactorial. First, **Romania's gross domestic expenditure on R&D (GERD)** is among the lowest in the EU—around **0.5% of GDP in recent years**—which directly limits capacity for home-grown clinical trials (European Commission, Directorate-General for Research and Innovation, 2025; Eurostat, 2024). Second, unlike Poland,

Romania has **no governmental programs dedicated to non-commercial trials**; Poland's MRA allocates approximately **€100 million annually** to clinical research funding, with a particular focus on academic and rare-disease studies (European Commission, n.d.; MRA/ ABM, 2025, 2023).

Third, Romania lacks a supportive **venture capital ecosystem or biotech start-up base**, which elsewhere serve as key engines for early-phase trials. Taken together, these conditions underscore that Romania's clinical trial activity is structurally dependent on **foreign sponsorship**, in sharp contrast to countries that have succeeded in cultivating robust **domestic demand** as a driver of competitiveness.

Demand Sophistication and Trends

In clinical research, the **quality of demand is as critical as its quantity** (Porter, 1990). In Romania, both investigators and patient advocacy groups have increasingly called for clinical trials that address **locally prevalent health burdens**, including multidrug-resistant tuberculosis (Romania continues to report the highest incidence rate in the EU) and neurological disorders such as epilepsy and multiple sclerosis (ECDC, 2022; WHO, 2023, 2022). This shift reflects a growing recognition that aligning trial activity with national epidemiological needs would generate both public health and scientific value.

At the same time, **patient awareness and willingness to participate in trials have improved compared to a decade ago**, partly due to greater exposure to international collaborations and the availability of innovative therapies otherwise inaccessible through the national health system (Health Innovation Hub, 2024). Nevertheless, **public trust in clinical research remains fragile**, and enhancing it requires structured education campaigns targeting both patients and healthcare providers. The **Romanian Clinical Trials Development Plan (2024)** explicitly identifies **patient education and engagement as a strategic priority**, underscoring the need to normalize participation and clarify safety standards (ANMDMR, 2024; Health Innovation Hub, 2024).

On the international front, **Europe's new regulatory regime has reshaped demand dynamics**. The EU Clinical Trials Regulation (Regulation (EU) No. 536/2014), fully effective since January 2023, introduced the **Clinical Trials Information System (CTIS)**, enabling sponsors to submit a single application for multinational studies. This has significantly lowered administrative barriers to including countries like Romania. Early results confirm this trend: Spain's regulatory agency coordinated **350 multinational trial approvals in the first year of CTR**, ahead of Germany (314) and France (248), demonstrating how centralization can expand participation to newer markets (AEMPS, 2024; Distefar del Sur, n.d.). Spanish authorities explicitly noted that CTIS facilitated growth in countries that previously had minimal trial involvement, including Romania (European Commission, 2023; Distefar del Sur, n.d.).

In summary, Romania's demand conditions for clinical research remain moderate. International sponsors continue to bring a steady inflow of Phase II–III trials, particularly those requiring large patient pools at lower relative cost. However, the **conversion efficiency of sponsor interest into actual recruitment** is still limited by outreach barriers, low visibility of trials among patients, and infrastructural constraints. Domestic demand remains **structurally weak**, given the absence of strong local pharmaceutical R&D and underfunded academic initiatives. Strengthening demand—through liberalization of patient recruitment strategies, building local sponsor capacity, and active international promotion of Romania's advantages—will be essential for Romania to achieve long-term growth in the clinical research sector.

C. Related and Supporting Industries

The performance of a country's clinical research industry is strongly shaped by the robustness of **related** and **supporting industries**, including healthcare delivery, pharmaceuticals, biotechnology, contract research services, and information technology (Porter, 1990). Romania presents a **heterogeneous profile**: while certain sectors—most notably information technology and, to some extent, healthcare delivery—are relatively strong, others such as domestic

pharmaceutical R&D, site management organizations (SMOs), and national clinical research networks remain underdeveloped. This imbalance results in an overall **partially enabling but fragmented ecosystem**.

Healthcare System and Hospitals

As the primary source of patients and investigators, the healthcare sector represents the most critical supporting industry for clinical trials. Romania's system combines a network of **public hospitals/clinics**, coordinated by the Ministry of Health and local authorities, with a **growing private healthcare sector**. Clinical trials are concentrated in public university hospitals located in major urban centers (e.g., Bucharest, Cluj-Napoca, Iași, Timișoara), which benefit from large patient flows and medical specialization. However, these hospitals face **chronic underfunding, staff shortages, and lack of dedicated research units**, leaving clinical trial responsibilities as an added burden for physicians. (ANMDMR, 2024). **An absence of structured clinical research teams** in Romanian hospitals results in **overextended investigators** and **variable trial execution quality**. Clinical trial duties are often added to physicians' routine clinical workloads without dedicated support staff, reducing both efficiency and quality of research outputs (Health Innovation Hub, 2024). In recognition of these systemic gaps, Romanian experts have recommended the establishment of **dedicated clinical trial departments or units** within large hospitals (ANMDMR, 2024).

By comparison, international benchmarks highlight more advanced organizational models. The **UK National Health Service (NHS)** routinely maintains **Research & Development offices** and employs **research nurses** to support protocol implementation and patient engagement (NIHR, 2023). Similarly, Italy's leading oncology centers operate with **dedicated research staff** and often embed **specialized clinical trial units** within hospital infrastructure, ensuring institutionalized continuity and higher-quality trial management (Health Innovation Hub, 2024). Such organizational frameworks remain largely absent from Romania's hospital system at present.

On the positive side, Romania's hospitals provide **wide geographic coverage and substantial patient access**. Moreover, **patient trust in physicians is high**, meaning that when doctors endorse trial participation, patients are often receptive (Health Innovation Hub, 2024). This underscores the importance of **educating physicians** to actively contribute to clinical research, a practice that remains insufficiently widespread in Romania compared to international peers.

Pharmaceutical and Biotechnology Industry

A strong local pharmaceutical or biotech sector can act as a driver for clinical trials through direct sponsorship and strategic partnerships with global firms. Romania's pharmaceutical industry consists mainly of R&D based companies, generic drug manufacturers, importers, and distributors (OECD, 2024, 2023). The biotechnology sector is represented by a small number of start-ups and academic spin-offs, most of which are still at the preclinical stage and not yet engaged in trial sponsorship (EFPIA, 2024). Unlike France (Sanofi), Germany (Bayer), or even Poland, where an emerging biotech ecosystem is supported by targeted government investment, Romania lacks large innovative pharmaceutical companies capable of initiating early-phase or investigator-driven trials. Consequently, the domestic pharmaceutical industry provides only **limited support** for advancing Romania's position as a clinical research hub.

Contract Research Organizations (CROs) and Site Networks

Contract Research Organizations (CROs), Site Management Organizations (SMOs), and Clinical Research Networks constitute a vital layer of clinical research infrastructure, providing regulatory, monitoring, data management, and site coordination services. Romania hosts operations of nearly all major **global CROs**, typically integrated into their Eastern European clusters, alongside a number of smaller **local CROs,** competing for smaller projects or local management of trials.

This competitive presence represents a significant strength, as it enables sponsors to access experienced operational partners directly within Romania. However, the competitive landscape is uneven: **global CROs dominate large, multinational studies**, while **local CROs**

increasingly face operational and financial pressures, driven by rising costs and the complex adaptation to new regulatory frameworks such as the EU Clinical Trials Information System (CTIS) (EMA, 2025). This dynamic places smaller domestic CROs at risk of marginalization. At the same time, **Site Management Organizations (SMOs) and emerging Clinical Research Networks** are beginning to appear in Romania, offering the potential to harmonize trial operations and strengthen national research capacity through private-sector innovation, similar to models seen in Belgium and Denmark (Trial Nation, 2023).

In terms of site networks, Romania remains behind countries like Belgium, which has developed a **national Clinical Trials Network** (BCTN), and Denmark, with its **"Trial Nation"** public–private partnership that connects sites to streamline trial setup (PharmaLinkage, 2025; Trial Nation, 2023). Poland again provides a useful reference: its **Medical Research Agency (MRA)** has co-financed trial coordination centers and developed mechanisms to harmonize public and private trial operations, ensuring scalability and sustainability (MRA/ ABM, 2025, 2023).

Romania's recent establishment of the **Romanian Society of Clinical Research Centers (SRCCC | RSCRC)** represents a nascent but important step toward creating a unified voice for clinical trial centers across both public and private healthcare institutions.

Information Technology and Data Services

As highlighted under factor conditions, Romania's IT sector remains a relative strength and represents an important enabler for clinical research. This capacity extends to supporting services for clinical trials, including international eSource and electronic data capture (EDC) platforms, as well as clinical trial management systems (CTMS), which are already in use in several Romanian sites. The country also benefits from a large pool of IT professionals who can be employed in data management, monitoring, and advanced analytics. An emergent but promising area is data analytics, with a few Romanian companies and academic groups beginning to explore the use of "real-world data" (RWD) and electronic health information to improve feasibility assessments and patient recruitment strategies (OECD, 2024, 2023).

Despite these strengths, the **broad use of electronic health records (EHRs) in hospitals remains limited**, which constrains the ability to implement data-driven recruitment (e.g., mining databases for eligible patients). Furthermore, the EHR systems used by public and private hospitals are designed primarily to interface with the Romanian National Health Insurance House, and their current architecture does not permit advanced searches or trial participant identification. By contrast, countries such as **Estonia and the United Kingdom have leveraged national EHR systems** to rapidly identify and recruit trial participants, significantly accelerating study timelines (EMA, 2025; European Commission, 2022). Romania could replicate these best practices by channelling its IT talent into the development of interoperable eHealth solutions dedicated to clinical research.

Patient Organizations and Advocacy

An often-overlooked but strategically important supporting sector for clinical trials is the ecosystem of patient advocacy groups. In Romania, such organizations exist for various conditions—including cancer, rare diseases, immune disorders, and diabetes—and some are increasingly active in disseminating trial information. However, with few exceptions (e.g., FABC, APAA, COPAC), Romanian patient organizations tend to lack representativeness due to their relatively small membership base. These groups can support recruitment and ensure trials address patient needs. International evidence shows that **strong patient advocacy involvement can accelerate trial recruitment, improve study design, and ensure that research outcomes address patient needs** (European Patients' Academy on Therapeutic Innovation [EUPATI], 2022). In Western Europe, for example, oncology and HIV trial networks in France and Germany routinely include patient representatives, contributing to both recruitment efficiency and trial relevance (OECD, 2024, 2023). By comparison, Romania is only beginning to formalize such mechanisms of structured patient engagement.

Overall Assessment

Romania's related and supporting industries **provide a partial foundation for clinical research but fall short of constituting a fully enabling ecosystem**. While the IT sector and healthcare infrastructure are notable strengths, systemic gaps in patient advocacy and site management organizations remain evident. Poland, for example, benefits from a larger hospital network and targeted support from its Medical Research Agency (MRA), which links training, funding, and network-building into a cohesive national strategy (MRA/ABM, 2025, 2023). Western European countries also excel in this regard: France's dense network of specialized research institutions and trial units significantly contributes to its international competitiveness in clinical trials (OECD, 2024, 2023).

For Romania, **key steps forward include fostering integration between healthcare and research (e.g., dedicated research units within hospitals), supporting domestic pharma/biotech innovation, encouraging the growth of private SMOs and Clinical Research Networks, and leveraging its IT capacity for clinical research digital services.** Without these, the system risks remaining fragmented; with them, Romania could transition toward a fully enabling clinical research ecosystem.

D. Firm Strategy, Structure, and Rivalry

This dimension of Porter's Diamond examines how companies and institutions in Romania's clinical research ecosystem are structured, governed, and how they compete or collaborate. In this context, the "firms" include local affiliates of multinational pharmaceutical companies, contract research organizations (CROs), academic research centers (universities and medical institutes), Site Management Organizations (SMOs) and Clinical Research Networks, as well as clinical trial sites (ones within hospitals and private centers). The strategic behaviour and

competitive interactions among these actors shape both the efficiency and the absorptive capacity of the national clinical research industry.

Pharmaceutical Company Operations

Major multinational pharmaceutical R&D companies maintain a presence in Romania, though typically in the form of commercial or marketing and sales affiliates rather than fully developed local R&D headquarters (IQVIA Institute, 2022). Clinical trial operations are generally coordinated within broader regional clusters (e.g., South-East Europe groups), with Romanian affiliates competing internally to secure inclusion in global trials. Decisions are often influenced by perceived advantages such as faster patient recruitment or significant unmet medical need.

Historically, Romania has been regarded by many multinational companies as a **"moderate performer"**: while **capable of delivering satisfactory enrollment figures,** the country has frequently been **constrained by slow trial start-up and regulatory inconsistencies**. (EFPIA, 2023). This reputation persisted until at least 2023, when the implementation of the **EU Clinical Trials Regulation (CTR 536/2014)** through the EU Clinical Trials Information System (CTIS) placed Romania on a more level playing field with other EU member states. Even so, internal corporate strategies often restricted the allocation of Romanian sites in multi-country trials until performance was demonstrably reliable.

By contrast, countries such as **Spain** and **Poland** (AEMPS, 2024; MRA/ ABM, 2025, 2023)., which consistently meet or exceed recruitment targets and demonstrate greater regulatory efficiency, tend to secure a larger number of sites per trial. Romania's challenge, therefore, lies not only in improving structural conditions (e.g., regulatory predictability, workforce training) but also in how local affiliates **strategically advocate** for the country as a competitive trial destination within their global corporate networks. Encouragingly, some Romanian affiliates have begun investing in dedicated **feasibility teams** and **site relationship managers**, a move that strengthens Romania's credibility and positions it more favorably for inclusion in future global research portfolios.

CRO and Site Competition

Romania hosts more than 30 CROs, including subsidiaries of global firms and local operators, reflecting a competitive market for clinical trial management services. This competitive presence benefits sponsors by ensuring cost efficiency, operational capacity, and localized expertise, which are critical in the context of increasingly complex clinical trial protocols (IQVIA Institute, 2022). Romania's trial structure is currently a hybrid of **public-sector hospital sites and private independent research centers.**

In many countries—particularly the United States but also increasingly across Europe—dedicated private research clinics or networks organized under SMO/Clinical Research Network models have become central to the trial landscape, especially in outpatient settings (EUCROF, 2020). In Romania, clinical trial sites hosted in public hospitals or clinics are typically staffed by investigators who are government-employed physicians. The private sector is represented by private centers embedded in large integrated healthcare networks, such as Regina Maria, MedLife, Medicover, Affidea, as well as stand-alone multidisciplinary clinics and small hospitals. This dual structure reflects the traditional dominance of public hospitals in providing access to patient populations, coupled with the gradual emergence of private-sector capacity.

This landscape is beginning to evolve with the emergence of organized SMOs and Clinical Research Networks, which aim to build more efficient and scalable private trial ecosystems with unified governance and centralized quality oversight. However, most remain regionally limited or concentrated in only a few therapeutic areas. Consequently, private centers continue to capture a smaller portion of studies. This has been described as a form of "**asymmetric competition**" favoring public hospitals, which benefit from built-in patient pipelines, institutional prestige, and academic visibility that attract trials (EFPIA, 2023). By contrast, private centers often struggle with referrals and external recognition, despite greater agility. At the same time, public hospitals are burdened by administrative delays, complex contracting, and rigid internal processes, which private centers—particularly those integrated within SMO networks—can navigate more efficiently (EMA, 2025).

An ideal competitive environment would enable both public and private trial sites to thrive and complement one another, thereby expanding national trial capacity. **Poland provides a relevant comparator: its Medical Research Agency (ABM) has actively promoted a better public–private balance** by funding shared training programs and facilitating resource-sharing initiatives across sectors (MRA/ ABM, 2025, 2023).

Competition among sites for clinical trials in Romania exists but remains relatively limited in intensity. Investigators frequently accept whichever studies become available, and there has been little structural pressure for sites to develop specialization in defined therapeutic niches (e.g., early-phase oncology, neurology, or rare diseases). This pattern reflects Romania's overall moderate trial volume, which reduces incentives for differentiation or reputation-building among institutions (Health Innovation Hub, 2024).

By contrast, countries such as Belgium and the Netherlands illustrate how higher trial density fosters site specialization and healthy competition. In Belgium, certain hospitals have developed strong reputations as centers of excellence for early-phase oncology or rare disease research, while the Netherlands has consolidated expertise through academic medical centers and coordinating networks (PharmaLinkage, 2025; EUCROF, 2020). These reputational advantages not only attract more complex multinational trials but also create positive spillovers in training, infrastructure, and patient engagement.

Romania may gradually experience similar dynamics as its clinical trial activity expands under the EU Clinical Trials Regulation (CTR No. 536/2014), particularly if policy incentives encourage therapeutic specialization and capacity-building. Such developments could enhance both competitiveness and trial quality by fostering rivalry between sites while ensuring consistent adherence to international standards (EMA, 2025).

Regulatory and Structural Constraints

Firm strategy in Romania is strongly influenced by the regulatory environment. Prior to the full implementation of the EU Clinical Trials Regulation (CTR No. 536/2014), the national approval process was characterized by procedural complexity, requiring both central submissions and site-level authorizations. In practice, this often extended timelines to more than one year, despite the legal framework stipulating a maximum of 60 days (European Commission, 2021). While such durations were not excessively long by global standards, they nevertheless demanded strategic navigation by companies and contract research organizations (CROs).

The introduction of the EU CTR and its centralized Clinical Trials Information System (CTIS) simplified many of these steps. However, **local interpretations by Romanian authorities occasionally introduced additional requirements**, **prolonging processes and undermining harmonization** (ANMDMR, 2024). A particularly restrictive measure was the temporary requirement that sub-investigators demonstrate specific qualifications or academic titles—an idiosyncratic national rule not found in other EU jurisdictions. Industry stakeholders frequently cited this as a barrier to rapid site activation. Fortunately, the provision was eliminated in late spring 2025, but its existence illustrates how regulatory "gold-plating" can erode competitiveness.

By contrast, peer countries have introduced reforms explicitly designed to accelerate trial initiation. **Germany's *Medical Research Act* (2023) reduced authorization timelines from 45 to 26 days** (PharmaLinkage, 2025; BfArM, 2023), while **France's process reforms shortened time-to-first-patient by several months** (PharmaLinkage, 2025). Poland's Medical Research Agency (MRA) has also invested in training ethics committees and harmonizing regulatory procedures to streamline CTR adoption (MRA, 2023). In this comparative context, Romanian clinical trial centers and CROs must adapt strategically to achieve timelines competitive with European leaders. Otherwise, Romania risks being overlooked by sponsors prioritizing speed and predictability in study start-up.

Collaboration and Clustering

A positive dimension of Romania's clinical research ecosystem is the **gradual emergence of collaboration among key stakeholders.** The establishment of the Romanian Society of Clinical Research Centers (SRCCC | RSCRC) illustrates this trend, as it was co-founded by representatives from industry, academia, and patient organizations, with the explicit goal of providing a unified national voice, representing the interests of trial sites, and disseminating best practices. In parallel, **informal investigator networks**—for example, collaborations among oncology investigators at national conferences or knowledge exchange among infectious disease researchers—further support the diffusion of expertise and mentorship for less experienced clinicians.

Such collaboration is vital in a country seeking to scale up its clinical research capacity, as it facilitates both the pooling of knowledge and the recruitment of patients across institutions. Comparative experience underscores the importance of structured networks: Spain's *BEST Project*, coordinated by Farmaindustria, has demonstrated how formalized partnerships between hospitals, academia, and sponsors can enhance recruitment rates and trial quality (PharmaLinkage, 2025; Farmaindustria, 2023, 2022). While Romania's clinical research market may not yet justify such a large-scale initiative, the strategic **clustering of sites** and the development of coordinated trial networks could substantially improve national competitiveness, aligning Romania more closely with established European leaders.

Rivalry versus Cooperation

Porter's Diamond Model emphasizes that **domestic rivalry is a key driver of continuous improvement and innovation** (Porter, 1990). In Romania, however, competitive dynamics among clinical trial centers remain limited, largely due to the relatively modest volume of trials conducted nationally. Many large hospitals are underutilized, which reduces incentives for direct competition. Nevertheless, as the number of trials increases, **healthy rivalry—such as competing to become the top-enrolling site nationally or securing contracts from international sponsors—could stimulate faster patient recruitment and higher data quality** (EFPIA, 2024).

At present, Romania's research ecosystem remains fragmented, requiring significant cooperation to ensure trial execution. The limited pool of experienced investigators often necessitates **informal mentorship and knowledge transfer**; for instance, senior investigators in Bucharest or Cluj frequently support colleagues in smaller cities in navigating regulatory submissions or protocol adherence.

By contrast, countries such as Poland demonstrate how structured frameworks can foster both rivalry and cooperation. Poland's Medical Research Agency (MRA) has institutionalized mechanisms such as **site performance benchmarking and dedicated Clinical Trial Support Centers**, which have improved both competition and coordination across sites (MRA/ ABM, 2025, 2023).

Romania's clinical research sector is therefore best characterized as a **still-maturing competitive ecosystem**, with limited public–private integration and slower adaptation to professionalized trial management models compared to its peers. Closing this gap Romania **must foster an environment where both public and private clinical trial operators can grow** and will require deliberate policies: targeted incentives, research grants, infrastructure subsidies, and the **publication of site performance metrics** to encourage healthy competition. At the same time, the establishment of **Centers of Excellence** could provide focal points of expertise while fostering collaboration across regions. Ultimately, eliminating unnecessary regulatory hurdles and strengthening institutional coordination will be essential to improving firm strategies and positioning Romania more competitively within the European clinical trial landscape.

E. Government's Role in the Clinical Research Ecosystem

Government policy and regulatory oversight play a decisive role in determining a country's attractiveness for clinical trials, directly influencing regulatory timelines, sponsor confidence, and overall system efficiency. In Romania, the government's involvement reflects a

mixed profile: on one hand, gradual alignment with EU standards—particularly through the implementation of the EU Clinical Trials Regulation (Regulation (EU) No. 536/2014, effective since 2023)—and on the other, persistent delays in supportive initiatives such as dedicated funding mechanisms, infrastructure investment, or systematic workforce development. To fully assess Romania's position, it is necessary to evaluate **legislative frameworks, regulatory authority performance, levels of public investment, and complementary governmental actions**, and to compare these with peer countries such as Poland, Spain, and Germany, where stronger public–private policies and sustained national strategies have accelerated competitiveness.

Regulatory Framework Alignment

Romania, as a member of the European Union, is subject to the EU Clinical Trials Regulation (CTR) No. 536/2014, which replaced the earlier Clinical Trials Directive 2001/20/EC. The country completed its transition to the EU CTR in January 2023, meaning all new trial applications are now submitted via the EU Clinical Trials Information System (CTIS) with coordinated review across member states (EMA, 2025). In principle, this harmonization should ensure that Romania operates under the same regulatory framework as its peers, creating a level playing field for sponsors. **The National Agency for Medicines and Medical Devices (NAMMD)**, together with the **National Commission for Bioethics of Medicines and Medical Devices**, act as Romania's competent authorities for clinical trials. By 2023, Romania had updated its legislation to reflect the EU CTR, including eliminating the prior requirement for separate local authorizations of Phase II–III sites. Nevertheless, authorization of clinical trial sites for clinical trial phase I is still required.

Despite these updates, **certain local regulatory practices have persisted and remain only partially aligned with EU provisions.** The Romanian Society of Clinical Research Centers (SRCCC | RSCRC, 2025) has noted that **some decisions by national authorities imposed additional constraints beyond EU CTR requirements**—for example, earlier rules demanding specific qualifications for sub-investigators, which were not stipulated in the regulation. This requirement, which created delays in assembling trial teams, was finally abolished in spring 2025. Additionally, Romania's interpretation of certain ethics requirements has been conservative,

particularly regarding trial advertising and the content of patient-facing materials. These small misalignments can extend approval or startup times in Romania relative to more flexible EU peers.

By contrast, other EU member states have demonstrated how proactive alignment can generate competitive advantages. Spain anticipated the CTR with Royal Decree 1090/2015, which streamlined approvals and positioned the country as a European leader in multinational trial coordination (Distefar del Sur, n.d). Germany's Medical Research Act (2023) has further reduced authorization deadlines internally (PharmaLinkage, 2025), while Poland's Office for Registration of Medicinal Products (URPL), in partnership with the Medical Research Agency (MRA), has invested in CTIS adaptation, resulting in shorter approval timelines and improved sponsor confidence (MRA/ ABM, 2025, 2023). To maximize competitiveness, Romania must continue refining its regulatory framework by eliminating residual "gold-plating" requirements that do not contribute directly to patient safety or trial quality.

Approval Timelines and Bureaucratic Barriers

Under the EU Clinical Trials Regulation (CTR) No. 536/2014, a harmonized maximum timeline of 60 days is established for clinical trial authorization, with limited clock-stops permitted for specific clarifications. In practice, however, performance varies substantially across EU member states depending on the efficiency of their internal workflows. For example, the **Netherlands frequently completes approvals in under 30 days** (PharmaLinkage, 2025), while **Denmark has set an ambitious target of 14 days for Phase I trials** by assigning dedicated ethics committees (PharmaLinkage, 2025).

By contrast, Romania's historical performance before CTR implementation was far less favorable. Although national legislation nominally required authorization within 50–60 days, in practice, the effective approval timeline often extended to 12–18 months due to administrative bottlenecks, fragmented procedures, and sequential rather than parallel reviews. While no systematic post-CTR performance data have yet been published, Romanian authorities are now formally bound by the EU's 60-day limit, which represents an improvement on paper.

Nevertheless, additional procedural layers remain an obstacle. Even after regulatory approval, sponsors must secure hospital contracts and obtain further endorsements (e.g., from hospital managers or local health authorities), which can add weeks or even months before patient recruitment begins. Romania could benefit from adopting standardize clinical trial contracting procedures and timelines across public centers – something **France and Italy have attempted by introducing standardized contracting procedures and timeline** (OECD, 2024 2023; Ministère de la Santé, 2022).

Investments and Funding

One of the most striking differences between Romania and comparator countries lies in the level of **public investment in clinical research infrastructure, education, and non-commercial trial support**. Romania has **not significantly invested in systematic training programs for clinical research personnel**, nor has it developed robust grant mechanisms to fund investigator-initiated trials or dedicated research centers. Research allocations from the Ministry of Education and Research remain limited and largely oriented toward basic science rather than applied clinical studies, resulting in a persistent funding gap that weakens national capacity.

By contrast, **Poland** has undergone a transformation since the establishment of the **Medical Research Agency (MRA) in 2019,** which has significantly contributed to the development of the country's clinical research landscape. Over its first five years, the MRA signed 315 co-financing agreements totaling more than USD 1.03 billion (PLN 4.3 billion), averaging approximately USD 3.3 million (€3 million) per project. These projects have enrolled over **51,000 patients**, including more than 13,000 with rare diseases (MRA, 2025; Kitala et al., 2024). Beyond funding, the Agency has delivered structured **training to 7,731 researchers, students, patients, and patient advocates** (MRA, 2025) and launched the **Polish Clinical Scholar Research Training (P-CSRT)** in partnership with Harvard Medical School, aiming to train 500 professionals by 2027 (Harvard Medical School, n.d.). In addition, the MRA has allocated PLN 195 million (~€42 million) (MRA/ABM, 2025, 2023) to establish 23 **Clinical Trial Support Centers (CTSCs)**, which now serve as nodes of excellence for trial coordination and quality oversight (MRA, 2025).

Comparable Western European initiatives illustrate how sustained public investment shapes national competitiveness. In the **United Kingdom**, the **National Institute for Health Research (NIHR)** is the leading source of public funding for clinical and translational research, with an annual budget exceeding £1.2 billion (2020–2021), much of which directly supports studies embedded in the NHS and public health institutions (NIHR, 2022). In **France**, the **Programme Hospitalier de Recherche Clinique (PHRC)** allocates roughly €90 million annually to hospital-based clinical trials, covering oncology, inter-regional collaborations, and national research calls (Letourmy, et.al., 2023; Ministère de la Santé, 2022). These schemes not only generate scientific output but also provide structured environments where young investigators gain trial experience, creating a self-sustaining research workforce.

Romania has had *very limited grant programs* for clinical trials – research funding from the Ministry of Education and Research is scant and typically oriented to basic science. The lack of public funding means Romania is missing an opportunity to shape research towards national health needs and to build capacity (since funded projects are often where young investigators get experience). Romania's absence of comparable programs represents a critical missed opportunity. Without targeted public investment, the country risks remaining dependent on foreign-sponsored trials, while lacking the capacity to prioritize research that directly addresses pressing national health needs such as cardiovascular disease, cancer, or infectious diseases.

Policy Initiatives and Strategic Plans

On a positive note, Romanian authorities have begun to formally acknowledge the systemic barriers affecting the country's clinical research landscape. In 2023–2024, a ***Strategic Plan for the Development of Clinical Trials in Romania*** was drafted. The plan outlines priority interventions, including the creation of patient education platforms, the modernization of recruitment processes, structured development of human resources, international promotion of Romania as a trial destination, and the introduction of economic incentives (Health Innovation Hub, 2024). While, as of mid-2025, these remain at the level of recommendations rather than fully enacted policies, they signal an important recognition at the policy level that active and sustained measures are required.

Comparative experiences from peer countries show that decisive government action can yield tangible results. Germany, for instance, responded to a decline in trial activity through legislative reform—the ***Medical Research Act (2023)***—which reduced authorization timelines and simultaneously funded a federation of university trial centers to strengthen infrastructure. Similarly, Belgium established a *Concertation Platform* to coordinate biopharma R&D stakeholders with government bodies, aiming to streamline processes and attract investment. These examples highlight that government leadership, when coupled with targeted policy instruments, can catalyze improvements in national competitiveness. For Romania, the challenge now lies not in drafting strategies but in institutionalizing and funding them.

Regulation of Public Sector vs. Private Sector and Incentives

Government policy also significantly shapes how the public and private sectors interact in clinical research. In Romania, public hospitals fall under Ministry of Health regulations that historically have not prioritized research activities. For example, hospital performance metrics rarely include research output or participation in clinical trials, which diminishes institutional incentives to allocate resources for research. Revising such policies—for instance, by incorporating research performance indicators into hospital evaluations and allowing hospitals to retain a portion of trial-generated revenue—could encourage stronger institutional engagement and sustainability of trial operations.

The government could also play a catalytic role by facilitating **public–private partnerships (PPPs)** in research. Through EU-funded programs, Romania has the opportunity to establish *clinical research centers of excellence* involving also universities and private sponsors. Several Eastern European countries have successfully leveraged EU structural funds for this purpose; for example, the Czech Republic invested European Regional Development Fund resources to create advanced clinical and translational research centers (European Commission, 2021). Romania should actively explore similar funding avenues to expand infrastructure and research capacity.

Furthermore, fiscal and economic incentives can play a decisive role in attracting clinical trial activity. **Countries such as Ireland, and more recently Hungary and Slovakia, have introduced tax credits, or reduced R&D fees to incentivize clinical research** (OECD, 2024, 2023). By contrast, Romania's policy framework remains largely neutral: trial sponsors pay regulatory fees, but there are no dedicated tax advantages for sponsors, investigator-led studies, or clinical trial centers. Introducing targeted incentives—even on a temporary basis—could stimulate a measurable increase in trial activity, improve site competitiveness, and align Romania with best practices observed in comparator countries.

Quality and Pharmacovigilance Oversight

An essential governmental responsibility in clinical research is ensuring that trials are conducted ethically and that the resulting data are credible and internationally recognized. In recent years, there have been no major international concerns or quality issues linked to Romanian trial sites, a finding corroborated by inspections from foreign regulators such as the U.S. Food and Drug Administration (FDA) and the European Medicines Agency (EMA), which Romanian sites have generally passed successfully (EMA, 2025; FDA, 2022). This represents a ***quiet strength*** of Romania's research ecosystem: trial data generated locally are accepted by global sponsors and regulators. Maintaining this reputation requires continued adherence to **Good Clinical Practice (GCP)** standards, robust pharmacovigilance, and active participation in EU-wide inspection and harmonization initiatives (ICH, n.d.). Romania's involvement in the voluntary harmonization procedure and, more recently, in the common assessment processes under the EU Clinical Trials Regulation (CTR) has helped ensure consistency and shared expertise across member states (European Commission, 2023)

Summary

Government action in Romania has thus far been **necessary but insufficient**. Alignment with EU rules through CTR implementation was essential to avoid exclusion from multinational research, and this milestone has been achieved. However, Romania has yet to develop **proactive**

support mechanisms that go beyond regulatory compliance. By contrast, Poland has demonstrated how an active government research agency—the Medical Research Agency (MRA)—combined with supportive regulatory reforms can significantly elevate a country's attractiveness as a clinical research hub (MRA, 2025, 2023). Western European leaders such as Germany and France provide additional examples, where decades of consistent policy emphasis on research and innovation have created durable systemic advantages (OECD, 2024, 2023).

For Romania to move from a "passive regulator" to an **active enabler of clinical research**, strategic policy shifts are needed. These include sustainable public funding programs for workforce training and non-commercial trials, streamlined and transparent regulatory procedures, targeted incentives for clinical research centres, and national public engagement campaigns to build awareness of the value of clinical research. Without these, Romania risks remaining a peripheral player in the European clinical research landscape.

F. Chance Factors: External Events and Trends

In Porter's Diamond framework, **chance,** refers to unforeseen events and exogenous trends that can positively or negatively influence a nation's competitive advantage in a given industry (Porter, 1990). For Romania's clinical research ecosystem, several recent events and broader trends—largely outside the direct control of national actors—have exerted significant influence on the clinical trial landscape.

COVID-19 Pandemic (2020–2022)

The COVID-19 pandemic (2020–2022) was a major disruptor of global clinical trials, halting or slowing thousands of studies while prompting the urgent initiation of others, particularly vaccine and therapeutic trials. Romania participated in several COVID-19 treatment and vaccine studies, yet the more lasting impact was the forced adoption of remote and decentralized trial practices—

such as telemedicine visits, remote monitoring, and digital data capture—during periods of lockdown (FDA, 2022). This accelerated a global shift toward digitalization in clinical research.

Countries that adapted quickly gained reputational advantages: for example, the UK pioneered virtual trial approval pathways (MHRA, 2021), while Spain leveraged its robust hospital networks to conduct a high volume of COVID-19 studies, contributing to its position as the European leader in trial starts by 2023 (Farmaindustria, 2023; Distefar del Sur, n.d). Romania, by contrast, had a less flexible system and saw many non-COVID trials paused, with difficulties in launching new studies during the pandemic.

Nevertheless, the experience challenged conservative practices and nudged Romanian regulators and sites to consider decentralized and remote elements. The opportunity now lies in Romania's ability to leapfrog directly into modern trial models by embracing these approaches, now that the conservative mindset was challenged by necessity. At the European level, the **ACT EU (Accelerating Clinical Trials in the EU)** initiative, launched in 2022, is institutionalizing lessons from the pandemic and modernizing regulatory and operational processes (PharmaLinkage, 2025; European Commission, 2022) Romania stands to benefit from ACT EU's workstreams, which promote innovation-friendly regulations, digital integration, and patient-centered trial designs across member states.

EU Clinical Trials Regulation (CTR) Implementation (2022–2023)

The full implementation of the EU Clinical Trials Regulation (CTR, Regulation (EU) No 536/2014) in 2022–2023 represents a structural external development that has transformed clinical research operations across Europe (EMA, 2025). Its primary impact has been the **harmonization and simplification of multi-country trial** submissions through the Clinical Trials Information System (CTIS), replacing the fragmented procedures under the previous Clinical Trials Directive.

For Romania, this regulatory shift constitutes a major opportunity. Sponsors can now include Romanian sites within pan-European applications under a single, coordinated

assessment, reducing the historical bias of exclusion linked to Romania's previously complex and protracted approval processes (European Commission, 2022). Early evidence from the first year of CTR implementation suggests a more equitable distribution of clinical trials across EU member states, including to countries such as Romania that were previously underrepresented (Farmaindustria, 2023; Distefar del Sur, n.d).

If Romania can position itself to take advantage—by meeting timelines and recruiting effectively—the **CTR could represent a boon that was not directly orchestrated by Romania's domestic policies, but rather by EU-wide regulatory change**.

Geopolitical Context: War in Ukraine (2022–present)

The outbreak of war in Ukraine in 2022 represents a critical chance event with both risks and opportunities for the clinical trial landscape in Eastern Europe. Romania, sharing a direct border with Ukraine, **has inevitably been affected by perceptions of regional instability**. Sponsors have expressed caution in initiating new trials across the region due to concerns about potential spillover effects and operational continuity under uncertain conditions (EFPIA, 2023).

Prior to the war, Ukraine had become an increasingly attractive location for clinical research, particularly in oncology and infectious diseases, hosting hundreds of industry-sponsored studies. With the disruption of trial operations, many sponsors were forced to relocate ongoing or planned studies. Poland absorbed a significant share of these, leveraging its established Medical Research Agency (MRA) infrastructure and dense hospital networks to offer continuity and stability (OECD, 2024, 2023). Romania, as an EU and NATO member state, was also theoretically well-positioned to attract relocated trials; however, concerns about proximity to the conflict zone and Romania's own bureaucratic hurdles limited its ability to capture the full opportunity (Health Innovation Hub, 2024).

If the conflict stabilizes without involving Romania, the country could experience a neutral or even positive effect through redistribution of trials seeking stable EU jurisdictions. Conversely, any escalation or prolonged geopolitical tension could depress trial investment across the region,

as risk-averse sponsors might prefer locations perceived as safer and further removed from the conflict, such as Spain or Western European hubs (EFPIA, 2025; EMA, 2025).

Ultimately, Romania's influence over these dynamics is limited; however, the country can strategically mitigate perceived risks by emphasizing its NATO and EU security guarantees, highlighting political stability, and showcasing its capacity for high-quality, GCP-compliant research. Such positioning could reassure sponsors and increase Romania's attractiveness as a credible host country for clinical trials in a volatile regional environment.

Global Shift of Clinical Research to Asia

Over the past decade, a significant global trend has been the rise of China and other Asian countries in clinical trial activity. Europe's share of global trials declined from approximately 25% in 2013 to around 19% in 2023 (EFPIA & IQVIA, 2024). This macro-level shift affects all European countries, including Romania (PharmaLinkage, 2025). Key drivers include faster patient recruitment in Asia, access to large treatment-naïve populations, and substantial R&D investments by Asian governments and companies (OECD, 2024, 2023).

For Romania, this trend underscores the importance of carving out a competitive niche—potentially by specializing in particular trial phases or therapeutic areas aligned with its epidemiological strengths. Moreover, Western sponsors often seek to diversify trial geographies to ensure broader representation for regulatory purposes, particularly to meet EMA approval requirements (EMA, 2025). Romania, as an EU member state with relatively untapped patient pools, could strategically position itself to capture part of this redirected demand—provided that structural reforms in training, digitalization, and regulatory efficiency are implemented.

Technological Advances: AI, Genomics, and Advanced Therapies

The emergence of new medical technologies and trial methodologies represents another critical chance factor shaping global clinical research. Precision medicine and advanced therapies, such as gene and cell-based treatments, increasingly require specialized infrastructures (EMA,

2025). Countries such as **Belgium and the United Kingdom have been early adopters, establishing regulatory sandboxes, innovation offices, and dedicated support programs for advanced therapy medicinal products** (ATMPs), thereby facilitating the rapid initiation of cutting-edge trials (MHRA, 2023).

Romania currently hosts only a limited number of high-innovation studies—CAR-T cell therapy trials, for example, remain concentrated in Western European hubs with established infrastructures (European Commission, 2023). However, the democratization of scientific knowledge through global collaborations offers Romanian researchers pathways to join such projects. Realizing this potential requires targeted investment in infrastructure such as biobanking facilities, genomic testing platforms, and digital health ecosystems.

In the longer term, if Romania channels resources into areas such as cancer genomics, AI-driven clinical decision tools, or digital health trial models, the country could significantly enhance its attractiveness for sponsors seeking trial environments aligned with precision medicine and next-generation therapeutic domains.

Public Health Needs and Epidemiologic Shifts

A country's competitive advantage in clinical research can also emerge from its epidemiological profile, particularly when global sponsors prioritize diseases with high local prevalence. Romania faces a disproportionately high burden of certain infectious diseases such as hepatitis B and C, tuberculosis (TB), compared to Western Europe (ECDC, 2022). Additionally, demographic characteristics, including the presence of relatively genetically homogeneous or rare genetic populations in certain rural regions (due to historically lower migration), may present unique opportunities for precision-medicine and rare-disease trials.

These epidemiologic realities create potential niches for Romania in multinational clinical studies. To capitalize on these opportunities, Romania must remain strategically aligned with global health research agendas. This requires continuous epidemiological surveillance, prioritization of national health needs within research policy, and readiness to participate in trials addressing

emerging health crises—opportunities often catalysed by scientific breakthroughs or unforeseen global events.

Romania's 'Chance' factor must be assessed by acknowledging both positive and negative external influences on its clinical research environment. Poland, for instance, is marginally less exposed geopolitically and has adopted new technologies at a faster pace (European Commission, 2023). Western European countries benefit from stronger domestic pharmaceutical pipelines and more agile governmental responses to crises—Spain's rapid implementation of the EU Clinical Trials Regulation (CTR) is a notable case where regulatory adaptation translated directly into competitive advantage (AEMPS, 2024).

Ultimately, while Romania cannot control global exogenous events—whether pandemics, geopolitical instability, or macro-level shifts in clinical research—it can influence **how it responds** to them. Proactive adaptation, such as institutionalizing remote and decentralized trial methodologies introduced during the COVID-19 pandemic, or leveraging EU-level initiatives like the *Accelerating Clinical Trials in the EU (ACT EU)* program, will be decisive in determining whether such "chance" events materialize as opportunities or setbacks for Romania's clinical research industry.

III. Strategic Challenges for Romania's Clinical Research Competitiveness

The preceding analysis highlights several interrelated structural barriers that constrain Romania's competitiveness in the clinical research arena. Four **strategic challenges** emerge as pivotal constraints on Romania's ability to attract sponsors, deliver high-quality trial outcomes, and align with European best practices.

1. Absence of a Standardized Academic Curriculum for Clinical Research Professionals

Romania's lack of formal education and training pathways in clinical research remains a fundamental challenge. Historically, the country has not offered dedicated academic programs, certifications, or residency tracks focusing on clinical trial methodology, Good Clinical Practice (GCP), or research management. This gap has led to a **chronic shortage of qualified investigators and research staff** proficient in contemporary trial practices. Although Romania trains thousands of capable physicians annually, the absence of standardized research training significantly limits their ability to efficiently lead and conduct trials (OECD, 2024, 2023; Eurostat, 2023).

The issue is self-perpetuating: with few structured training programs, there are fewer new investigators entering the field, which in turn overextends the same small cadre of experienced researchers. Consequently, many promising young clinicians never transition into research. A recent initiative—the launch of a Master's program for clinical trial monitors at *Carol Davila University of Medicine and Pharmacy*—represents progress, yet it remains a single institutional effort. Moreover, this program targets clinical research associates (CRAs) and monitoring personnel from contract research organizations (CROs), rather than systematically qualifying the physicians, study coordinators, or research nurses who conduct day-to-day trial activities.

By contrast, in countries such as **France, the UK, or Sweden**, **multiple universities offer accredited postgraduate programs in clinical research** (Health Innovation Hub, 2024). French universities (e.g., Sorbonne, Paris-Saclay) provide dedicated diplomas in clinical investigation, while in the UK, research training has been integrated into medical residency pathways through *National Institute for Health and Care Research (NIHR)* initiatives (NIHR, 2022). Sweden likewise incorporates research methodology into clinical curricula, reinforcing trial literacy early in medical and nursing education. Poland provides a regional model: since 2019, its *Medical Research Agency (MRA)* has funded academic programs training ~5,000 researchers annually, a systematic approach to bridging the skills gap (MRA/ ABM, 2025, 2023). (See **Appendix 1 - International Models for Clinical Research Training**).

Without decisive action, Romania risks widening its knowledge gap. Modern trial designs—such as adaptive, remote or decentralized models—and increasingly complex regulatory requirements (e.g., GDPR compliance in clinical research) demand specialized expertise. The absence of a standardized national curriculum also results in no formal recognition of trial-specific roles such as "principal investigator," "study nurse," or "study coordinator" within Romania's professional qualifications framework. Indeed, Romania's *Strategic Plan for the Development of Clinical Trials* (2023–2024) explicitly acknowledges that clinical trial roles are missing from the *Nomenclature of Qualifications*, creating structural barriers to hiring, role recognition, and career progression for research staff.

2. Regulatory and Communication Barriers to Direct Patient Recruitment

Efficient patient recruitment is the lifeblood of clinical research. In Romania, regulatory and communication barriers have historically undermined recruitment efficiency. Until 2023, restrictive interpretations of national regulations prohibited most public-facing advertising for clinical trials (National Commission for Bioethics of Medicines and Medical Devices [NCBMMMD],

2024). As a result, recruitment relied heavily on physician referrals, flyers, and limited hospital-based postings—methods ill-suited to achieving ambitious enrollment targets.

The consequences are measurable: Romanian trials frequently fail to meet recruitment goals, with some estimates suggesting that up to one-third of studies under-enroll (Health Innovation Hub, 2024). By contrast, leading countries leverage digital and centralized recruitment systems, such as digital recruitment, including centralized trial registries, condition-targeted advertising, and online pre-screening solutions. US efficiently uses online pre-screening tools and patient databases. Spain's national registry (REEC), launched in 2013, integrates clinical trial listings in patient-friendly language and collaborates with oncology associations to advertise studies nationally (AEMPS, 2024). The UK's National Institute for Health and Care Research (NIHR) developed campaigns such as *"OK to Ask"*, which normalize participation and provide lay-accessible trial information across NHS channels (NIHR, 2023). Poland permits digital recruitment campaigns, as long as the content and consent process are Ethics Committee–approved, thus aligning with international standards (MRA/ ABM, 2023).

Romania has recently taken a step forward. Updated guidance from national ethics committees in 2025 clarified that digital recruitment campaigns are permissible, provided content is approved and transparent (NCBMMMD, 2024). This regulatory evolution aligns Romania with broader European norms and introduces the possibility of social media advertising, online pre-screening platforms, and direct-to-patient outreach.

Nevertheless, critical structural gaps remain. Romania lacks a centralized patient registry or national portal in the Romanian language, leaving patients dependent on EU-wide CTIS listings that are largely unknown to the public and linguistically inaccessible (CTIS, 2025). Cultural barriers also persist: limited public awareness and lingering distrust of clinical research continue to constrain participation. Comparative experiences suggest that sustained public engagement campaigns, co-led by government and patient organizations, are necessary to normalize trial participation.

If scaled and accompanied by public education, Romania's new regulatory openness could transform patient recruitment from a systemic weakness into a competitive advantage.

In the digital age, online recruitment of patients for clinical trials via social media, dedicated platforms, and broad outreach campaigns has become standard practice in leading research countries. When conducted ethically and with proper oversight, such approaches improve enrollment rates, reduce screening failures, and shorten trial timelines. Unfortunately, **Romania's regulatory and communication environment has struggled to adapt to this trend, thereby limiting trial enrollment capacity**.

By comparison, countries with strong research ecosystems have embraced digital recruitment, including centralized trial registries, condition-targeted advertising, and online pre-screening solutions. The US and UK routinely use centralized trial registries, condition-targeted advertising, and online pre-screening tools (NIHR, 2022). Spain's health authorities partnered with patient associations to promote oncology trials nationally, while in Poland, digital recruitment is explicitly permitted, provided Ethics Committees approve the campaign content (MRA/ ABM, 2025). Language accessibility is also critical: many EU trial listings remain in English or overly technical formats. Romania could significantly increase inclusivity by providing Romanian-language, patient-friendly trial information and consent materials, that are easily understandable, to broaden participation beyond the urban, educated class.

Until recently, Romania lagged far behind in this area. Regulations were long interpreted to prohibit or heavily restrict public-facing trial advertisements. As a result, common tools elsewhere—such as trial-specific Facebook pages, targeted online patient ads, or intuitive national trial registries—were absent. Even after the implementation of the EU Clinical Trials Regulation (CTR) in 2023, which should have opened the door to these tools, unclear interpretations and conservative applications of its provisions maintained historical barriers. Consequently, patient recruitment relied mainly on traditional methods: physician referrals, hospital flyers, or informal outreach. These approaches are labour-intensive, geographically limited, and often inadequate for

meeting diverse enrollment needs. The fact that **many Romanian trials underperform on enrollment targets illustrates the systemic consequences** (OECD, 2024, 2023).

A significant regulatory shift occurred in late spring 2025, when Romanian Ethics Committees clarified that digital recruitment campaigns are permissible if conducted transparently, ethically, and with pre-approved campaign content. This alignment with European practice represents a major opportunity for modernization. Digital recruitment enables patients to be matched to trials based on eligibility criteria and reduces recruitment delays while democratizing access—allowing patients to identify and volunteer for studies regardless of geographic location or hospital affiliation.

Nonetheless, broader structural deficits persist. Romania still lacks a centralized, government-backed patient registry to facilitate trial matching. Trial listings often remain non-intuitive for laypersons, and much of the content is not adapted to the Romanian language or literacy levels (Health Innovation Hub, 2024). Language accessibility remains a significant barrier: EU-wide clinical trial registries frequently present information exclusively in English or employ highly technical terminology that is not easily understood by lay audiences. Enhancing inclusivity therefore requires the simplification and localization of trial information into Romanian, accompanied by patient-friendly summaries that are clear, accessible, and tailored to varying levels of health literacy.

Another critical dimension concerns communication flow, transparency, and cultural context. In Romania, both patients and many physicians often lack adequate awareness of available clinical trials. The absence of a national registry—Romania currently relies on the EU register, which is not widely known to the general public—results in missed opportunities for patient enrollment. Furthermore, low public awareness and persistent skepticism toward clinical trials—frequently perceived as forms of “medical experimentation”—continue to function as soft barriers to participation. Overcoming these challenges requires systematic patient and physician education combined with transparent communication strategies. This highlights the urgent need for coordinated public education campaigns. Unlike countries such as the United Kingdom, where

the NIHR's "*Ok to Ask*" campaign successfully promoted patient engagement, or the United States, where the *NIH* has long supported public outreach, Romania has yet to implement comparable initiatives. **Developing similar nationally coordinated campaigns, endorsed by government agencies and professional societies, would strengthen public trust and normalize clinical trial participation.**

In conclusion, Romania is at a pivotal inflection point. With the National Commission for Bioethics of Medicines and Medical Devices (NCBMMD) now supporting digital recruitment, the regulatory tools are in place. What is urgently needed is implementation at scale, integration into national systems, and coordinated public communication. By leveraging this momentum, Romania could make clinical trial participation more inclusive, efficient, and attractive to global sponsors, positioning itself closer to European best practice.

3. Digitalization and Decentralization of Clinical Trial Activities

In Romania, the digitalization of clinical research remains underdeveloped; with few exceptions, trial sites continue to rely predominantly on paper-based records, which limits efficiency and constrains the ability to attract complex, data-intensive studies. This infrastructure gap has been explicitly recognized as a barrier to competitiveness in the European research landscape (OECD, 2024, 2023; EFPIA, 2024).

As the global clinical research ecosystem advances through **digitalization and decentralization**, Romania faces a dual challenge. On one hand, industry stakeholders have demonstrated **limited interest** in investing in **digitalization of clinical trial activities**, citing incremental implementation costs, and technical constraints. On the other hand, clinical research professionals often exhibit **hesitation**—or even resistance—**toward adopting and effectively using eSource and Electronic Data Capture (EDC) platforms in daily operations**, reflecting insufficient training and institutional support.

Given the irreversible global shift toward digital ecosystems, integrating eSource and EDC solutions has become a defining standard of clinical trial conduct (EMA, 2025; FDA, 2022). Romania therefore has a strategic opportunity to leapfrog by **positioning eSource adoption as the national gold standard** for trial execution. This transition requires coordinated efforts: industry stakeholders must view digitalization as a long-term efficiency driver, while regulatory authorities should actively encourage, support, and incentivize uptake. Such alignment with international best practices would not only enhance operational quality and regulatory compliance but also significantly strengthen Romania's attractiveness as a host country for global clinical trials.

4. Competitive Imbalances Between Public and Private Clinical Trial Centers

Romania's clinical trial landscape is skewed towards public healthcare institutions, with private sector involvement in trials being comparatively limited. Public hospitals - especially large academic and specialty centers - conduct a good part of studies, while private hospitals and independent research sites play a lesser role.

This imbalance generates several systemic challenges:

- **Capacity Constraint and Backlogs.** Public hospital sites often face very high patient loads in routine care and have limited staff dedicated to research activities. As highlighted by OECD (2023), physician-to-patient ratios in Romania are below the EU average, which constrains trial capacity. Consequently, public hospitals can only take on a limited number of trials before overstretching. When these centers become bottlenecked, national trial growth stagnates. Meanwhile, private clinics—often more flexible and potentially better resourced for rapid study initiation—remain underutilized.

- **Administrative Rigidity.** Public institutions operate under strict government procedures (e.g., procurement rules, multi-layered approvals). By contrast, private

centers can negotiate contracts and initiate activities more quickly, a factor emphasized in EU reports on clinical research competitiveness (European Commission, 2023). However, since the majority of Romanian trials are concentrated in public hospitals, the operational efficiencies and flexibility typically associated with private centers remain largely underutilized. Moreover, compliance with the EU Clinical Trials Regulation (CTR) has introduced additional administrative and financial burdens, disproportionately impacting smaller private centers and local CROs, while larger public hospitals are partially buffered by state support.

- **Financial Imbalance:** Trial budgets in Romania are negotiated directly with sites. Public hospitals often charge relatively low fees—partly because clinical research is not regarded as a profit-generating activity, partly due to the absence of transparent cost-accounting systems that would allow research-related expenditures to be tracked, and partly due to limited institutional experience in contract negotiation. By contrast, private sites must request higher fees to remain financially sustainable, as they lack access to state subsidies for overheads or to publicly funded medical infrastructure. Consequently, sponsors accustomed to the lower-cost environment of public hospitals may perceive private sites as less attractive, thereby perpetuating their underutilization.

- **Quality and Consistency:** Concentrating clinical trials within a limited number of large public hospitals may ensure high-quality data output when these centers are experienced; however, quality is not uniformly consistent across all institutions. This concentration also risks reducing the external validity of results, as trial populations may not fully represent the demographic and epidemiological diversity of Romania. Expanding trial activity to private centers—including those embedded in community or regional settings—could enhance representativeness, improve inclusivity, and generate findings that are more generalizable to the broader population. Moreover, increased participation of private sites could foster constructive competition, which in

turn may incentivize public hospitals to strengthen trial management practices and operational efficiency. In health systems research, competition between providers has often been linked with improved innovation and organizational performance.

Poland's situation in this regard is instructive: it faced similar challenges in the past, but the Medical Research Agency (MRA) introduced policies that explicitly encourage public hospitals to partner with or emulate private-sector efficiencies, including funding research-dedicated positions such as study nurses at public sites (MRA/ AMB, 2025, 2023). Furthermore, Poland has seen the expansion of Site Management Organizations (SMOs) that enable smaller clinics to participate in trials, thereby distributing research activity more evenly across the system.

In Romania, comparable networks remain scarce, though some initiatives have recently begun to emerge. This structural imbalance means that Romania is not fully exploiting its patient pool: patients who seek care in private clinics may never be offered opportunities to participate in trials at public hospitals, and vice versa. The result is fragility—if a handful of key public centers reduce their trial activity, whether due to leadership changes or institutional reprioritization, national output could decline sharply.

Addressing these **challenges—through workforce training, more efficient direct patient recruitment, accelerated digitalization of clinical research activities, and a better balance between the public and private sectors**—is essential if Romania is to leverage its intrinsic strengths and improve its standing as a competitive location for international clinical research.

International comparative evidence demonstrates that countries systematically investing in education, digitalization, direct patient engagement, and public–private integration achieve significant competitive gains (OECD, 2024, 2023; EMA, 2025).

The following section of this paper will outline **strategic recommendations** to address these barriers, drawing on best practices from comparator countries and tailoring solutions to Romania's specific context.

IV. Strategic Recommendations For Enhancing Romania's Competitiveness in Clinical Research

To transform Romania's clinical research industry and effectively address the strategic challenges identified, a comprehensive and multifaceted approach is required. The following recommendations are aligned with the key barriers outlined in this analysis while also encompassing broader measures designed to strengthen Romania's overall competitive position in the global clinical research landscape. These recommendations draw on international best practices (**see Appendix 2 – *Country Case Studies: Successful Clinical Trial Reform Examples***) and are tailored to the specific institutional, regulatory, and healthcare context of Romania.

1. Develop and Institutionalize a Clinical Research Education & Certification Framework

- ***Create Formal Academic Programs and Certifications.***

Romania should urgently integrate clinical research training into its higher education and professional development systems to address the acute shortage of trained professionals in this field. **The Ministry of Education**, in collaboration with the **Ministry of Health**, should actively support the establishment of accredited academic programs across 5–6 major universities nationwide. These programs could include **postgraduate professional certifications in Clinical Research as well as Master's degrees**, tailored to specific roles such as Principal Investigator, Clinical Research Coordinator (Study Coordinator), or Study Nurse. Curricula should comprehensively cover core domains including Good Clinical Practice (GCP), clinical trial design, regulatory compliance, research ethics, biostatistics, data management, and operational coordination (EMA, 2025). The **Romanian Society of**

Clinical Research Centers (SRCCC | RSCRC) can play a pivotal role in coordinating this process. In partnership with national academic institutions, SRCCC could help standardize curricula, accredit training providers, and ensure that certifications carry national and international recognition. Such a joint initiative would raise professional standards, expand the pool of trial-ready personnel, and send a strong signal to international sponsors that Romania is committed to building a sustainable, highly qualified workforce to support the long-term growth of clinical research (Health Innovation Hub, 2024; OECD, 2024, 2023).

- ***Include Clinical Research in Medical and Nursing Curriculum***

At the undergraduate level, medical and nursing schools in Romania should integrate mandatory modules on clinical trial methodology and evidence-based medicine. This would ensure that every new physician and nurse develops at least a foundational understanding of how clinical trials are designed, conducted, and monitored, as well as their relevance for advancing patient care. Over time, such integration fosters a professional culture in which clinical research is regarded as an intrinsic component of healthcare practice. The current national strategic plan has already suggested adding a research training course for all medical specialties during residency. Implementing this measure would guarantee that new specialists—for example, oncologists, cardiologists, or neurologists—are equipped not only to participate in but also to lead clinical trials as part of their professional trajectory. This aligns with international best practices, where residency and specialty training programs in countries such as the UK and France embed research exposure to build sustainable clinical trial capacity.

- ***Define Clinical Research Roles in Legislation and Clinical Research Centers HR Structure***

The Romanian government should revise the ***Nomenclature of Qualifications*** to explicitly include roles such as *Clinical Research Nurse, Trial Coordinator, Data Manager, and Clinical Research Associate* as recognized professional positions. (Health Innovation Hub,

2024). This measure would provide institutional legitimacy, create career pathways, and align Romania with international standards where such roles are long established (OECD, 2024, 2023). In parallel, hospitals—particularly large academic and specialty institutions—should establish dedicated ***Clinical Research Departments or Units*** staffed by professionals trained for these functions. A regulatory mandate or incentive scheme could require any hospital with a significant clinical trial portfolio (e.g., >5 trials per year) to maintain a minimum dedicated research team, including at least one research director and designated coordinators. Such provisions would mirror international best practices, where research-active hospitals embed structured research offices to ensure compliance, quality, and efficiency (Health Innovation Hub, 2024). Legislative adjustments to enable the hiring and sustainable funding of these positions would be essential. Beyond strengthening trial management, this would improve internal organization, reduce administrative delays, and enhance the overall quality of medical services.

- ***Leveraging International Partnerships for Academic Training Programs***

Romania should actively pursue partnerships with established international institutions to accelerate capacity-building in clinical research education. **Fellowship programs** could be designed to allow Romanian clinicians and research staff to spend 3–6 months in leading research centers in countries such as France, the UK, or the US, with the clear requirement that they return and disseminate their expertise locally through structured "train-the-trainer" models. This approach has been successfully applied in Poland through the Medical Research Agency's collaboration with Harvard Medical School, which created the Polish Clinical Scholars Research Training program (MRA/ ABM, 2025, 2023).

In addition, Romania could strengthen its knowledge base by inviting international experts to deliver teaching modules within Romanian universities or to co-develop joint curricula. This model has been adopted by several Central and Eastern European countries, where universities partnered with UK and Dutch institutions to introduce accredited Master's programs in clinical research and evidence-based medicine. Such exchanges would not

only accelerate knowledge transfer but also signal Romania's alignment with global standards in clinical research education, thereby improving its attractiveness to international sponsors.

- ***Secure Funding for Academic Training Initiatives***

None of the above initiatives can succeed without dedicated and sustainable funding. The Romanian government should consider establishing a ring-fenced budget line—such as a ***Clinical Research Capacity Fund***—to provide predictable financial support for workforce development. Even a modest allocation of a few million euros annually could catalyze progress by subsidizing new university programs, funding scholarships for clinical research training, and supporting the creation of research staff positions in hospitals. In parallel, engaging the pharmaceutical industry and other private stakeholders through structured public–private partnerships (PPPs) would be an efficient way to leverage additional resources. International best practices demonstrate that such co-financing mechanisms are both feasible and impactful. For example, the UK's National Institute for Health and Care Research (NIHR) operates in close collaboration with the biopharmaceutical sector, funding infrastructure and training through blended models (NIHR, 2022). By adopting a similar framework, Romania could attract industry partners willing to invest in the professionalization of investigators.

By **implementing a standardized academic training framework** and formalizing research careers, Romania can expand its pool of **skilled professionals** and demonstrate to international sponsors that it possesses the **human capital required to support high-quality clinical trials**. Over time, this approach is also likely to mitigate the ongoing physician exodus, as more competitive and attractive career opportunities in clinical research become available domestically. Evidence from other EU countries suggests that when research is integrated into medical careers, retention improves: for example, the UK's NIHR has shown that offering

structured research pathways within the National Health Service increases job satisfaction and reduces workforce attrition (NIHR, 2022). Similarly, France's hospital-based research programs have created stable research-oriented career tracks that help retain medical specialists.

2. <u>Modernize Regulatory Policies and Infrastructure to Enable Direct Patient Engagement in Trials</u>

- ***Ensure the righteous implementation of the Regulations to Allow Ethical Patient Outreach***

  This includes permitting advertisements about clinical trial opportunities in mass media and online, TV, radio, indoor, or outdoor, provided that the content of the campaigns is IRB-approved and not misleading—focusing on trial information and eligibility criteria rather than coercive messaging. Drawing on international practice, regulations can be designed to ensure that patient outreach is conducted transparently; for example, requiring that any advertisement directs potential participants to accredited trial centers for complete information. The overarching goal is to establish a "**responsible communication**" **framework**, with content duly reviewed and authorized by the competent regulatory authorities.

- ***Establish a National Clinical Trials Registry/Portal in Romanian***

  The government—or alternatively a consortium including the Romanian Society of Clinical Research Centers (SRCCC | RSCRC) - should establish an official national online platform where all actively recruiting clinical trials in Romania are listed in the Romanian language, with clear, patient-friendly information and direct contact points. Such a portal could technically interface with the EU CTIS database but present the information in a more accessible, user-centered format. Notably, Objective #1 of Romania's **Strategic Plan for the Development of Clinical Trials** explicitly calls for the creation of such a patient

platform, which should therefore be prioritized and implemented with urgency (Health Innovation Hub, 2024).

The portal should also enable patients to register their interest in participation, allowing trial sites to conduct outreach while fully respecting data privacy principles (e.g., GDPR-compliant opt-in contact). Over time, the platform could be integrated with electronic health records (EHRs) to proactively match eligible patients with ongoing studies—an approach already demonstrated in advanced systems such as the UK's **NIHR Clinical Research Network** or Denmark's **Trial Nation** initiative.

- ***Leverage Social Media and Patient Networks***

With appropriate regulatory approval, stakeholders—including sponsors, site management organizations (SMOs), and patient advocacy groups—should capitalize on Romania's high rates of social media usage to support ethical patient outreach. For example, existing Romanian Facebook groups dedicated to various diseases could be leveraged to host moderated Q&A sessions on clinical trial opportunities, eligibility, and patient rights. Furthermore, national authorities such as the Ministry of Health or the National Agency for Medicines and Medical Devices (NAMMD) could organize evidence-based public campaigns on social media to counteract misinformation and build trust in clinical research, ideally timed around **International Clinical Trials Day (May 20th)** to maximize visibility and symbolic impact.

Public–private collaboration represents an important mechanism in this regard. Pharmaceutical companies could co-fund awareness campaigns that are co-branded with patient associations, ensuring that content remains balanced, patient-centered, and in compliance with ethical and regulatory standards.

- ***Implement Patient Registries and Referral Systems***

Another recommendation from the national strategic plan is the development of **patient disease registries** that can actively support clinical trial recruitment (Health Innovation Hub, 2024). Romania should accelerate the creation and enhancement of registries for major therapeutic areas—such as oncology, diabetes, rare diseases, and autoimmune disorders—integrated within its healthcare system. When appropriately consented for research purposes, such registries can serve as powerful tools to identify eligible trial candidates. For instance, an oncology registry could flag patients who meet the eligibility criteria for an upcoming immunotherapy trial. Notifications could then be sent either to their treating physician or, where consent allows, directly to patients, thus facilitating recruitment and reducing screening failures. However, implementing such a system requires significant **data infrastructure improvements**, including interoperability of electronic health records (EHRs), standardized coding practices, and robust data governance frameworks to ensure privacy and ethical compliance. International experience shows the value of such registries: in Sweden, the national cancer registry has been successfully used for trial feasibility and recruitment, while in the US, disease-specific registries supported by the NIH have accelerated enrollment in precision medicine studies

- ***Empower General Practitioners (GPs) in Recruitment***

In Romania's healthcare system, specialists in hospitals currently lead most clinical trials, while family physicians (general practitioners, GPs) are responsible for the majority of the population's routine care. Developing a structured program to involve GPs in **referring eligible patients to clinical trials** could significantly broaden recruitment, ensuring access to more diverse and representative patient groups. Such a program would require appropriate training, clear communication channels with trial centers, and potentially compensation for the additional time and responsibilities associated with trial-related activities. For example, a GP could inform an asthma patient about an ongoing clinical trial at a nearby center, thereby facilitating earlier recruitment and improving trial inclusivity. International models demonstrate the feasibility of this approach: in the United Kingdom,

the National Institute for Health and Care Research (NIHR) has successfully embedded research in primary care through its Clinical Research Network, while in the Netherlands, structured GP networks actively contribute to trial referrals and patient enrollment. Romania could follow such examples.

By embracing direct patient outreach, especially **digital recruitment tools** and fostering **proactive patient communication**, Romania has the potential to significantly enhance its clinical trial enrollment capacity. Faster and more efficient recruitment not only increases the country's attractiveness to international sponsors—given that **shorter recruitment timelines are a top priority for trial organizers**—but also contributes to the **democratization of access to clinical trials**, offering Romanian citizens expanded opportunities for innovative therapies and improved healthcare options.

To fully realize these benefits, Romania must ensure the **consistent and correct implementation of EU legislation**, particularly the Clinical Trials Regulation (CTR), while continuously monitoring and fine-tuning outreach practices to uphold the highest **ethical and methodological standards**. Evidence shows that integrating digital strategies in patient recruitment, when ethically managed, reduces screening failures and accelerates time-to-first-patient-in.

3. Strengthen Public-Private Collaboration and Level the Playing Field for Trial Sites

- ***Equalize Competitive Conditions***

Competent authorities should ensure that **regulatory, commercial, and fiscal frameworks** are applied **consistently and equitably** across both public and private

clinical trial sites. Such alignment reduces structural imbalances and ensures that private centres are not disproportionately disadvantaged relative to public hospitals. Furthermore, fostering **collaborative models** between public and private entities could enhance capacity—for example, a private site partnering with a public hospital department to jointly conduct a trial, thereby **sharing patient pools, infrastructure, and responsibilities**.

To encourage efficiency and accountability, **transparent performance benchmarking** should be introduced. The Government, or professional associations such as the **Romanian Society of Clinical Research Centers (SRCCC | RSCRC)**, could publish an **annual national report on clinical trials** by site, detailing the number of trials conducted, recruitment performance, and adherence to timelines. International experience suggests that publishing such performance indicators stimulates healthy competition, motivates quality improvements, and builds sponsor confidence in site reliability.

- ***Establish Public-Private Clinical Trial Centers of Excellence***

The Romanian government, in collaboration with industry stakeholders, should co-invest in the development of **flagship clinical trial centers of excellence** built on public–private partnerships. A feasible model would be to select two major university or regional hospitals in different geographic areas of the country and establish **Clinical Research Units (CRUs)** that are jointly managed by the hospital administration and a consortium of sponsors. These units should be equipped with **state-of-the-art infrastructure**—including dedicated patient examination rooms, monitoring facilities, and specialized pharmacies for investigational products—and staffed by mixed teams of public sector clinicians and privately funded research professionals. Unlike traditional hospital departments, CRUs could operate **extended hours** to accommodate trial participants, thereby increasing accessibility and efficiency.

Such centers would serve not only as **trial execution hubs** but also as **training grounds for clinical research personnel**, promoting capacity building and diffusion of best practices

throughout the healthcare system. Evidence from other countries supports the value of this model: for instance, Poland's **Medical Research Agency (MRA)** has successfully funded and coordinated specialized research units that facilitate collaboration between public hospitals and private sponsors, leading to measurable improvements in trial quality and recruitment efficiency (MRA/ ABM, 2025, 2023). For Romania, adopting a similar approach—whether through **direct public funding, EU structural funds, or co-financed agreements with sponsors**—could accelerate its integration into the European clinical research ecosystem and strengthen its reputation as a reliable host for complex, high-quality studies.

- ***Incentivize Public Hospitals to Support Trials***

The Ministry of Health could institute incentive mechanisms for public hospitals to strengthen their engagement in clinical research. For instance, **hospital managers could be partially evaluated based on research performance indicators** such as the number of clinical trials conducted, patient enrollment rates, and adherence to quality standards. Another measure would be the establishment of **dedicated Clinical Research Units (CRUs) within hospitals, with separate profit-and-loss (P&L) accounts**, allowing institutions to retain a portion of indirect cost recovery from trials. These funds could then be reinvested into upgrading facilities, digital infrastructure, and specialized staff training. Evidence from international contexts shows that this approach leads to public centres prioritizing and professionalizing their research operations (NIHR, 2022).

Furthermore, Romania should consider introducing a **formal "researcher-physician" career track** within hospitals, whereby clinicians are allowed to allocate a defined percentage of their time to research activities while maintaining job security and clinical responsibilities. This dual-track model—already practiced in leading health systems such as the UK's NHS (through NIHR-funded Clinical Research Networks) and France's *Hospital-University Institutes*—provides clinicians with both institutional recognition and workload adjustments for research commitments (NIHR, 2022). At present, many

Romanian physicians conduct trials informally or as secondary activities ("side work"). Formalizing research roles would not only improve trial capacity and quality but also contribute to the **professionalization and retention of the medical workforce**, reducing reliance on a small cohort of overburdened investigators.

- ***Encouraging SMOs and Clinical Research Networks that collaborate with local physicians is a strategic priority.***

  These organizations assume much of the administrative workload and ensure compliance with Good Clinical Practice (GCP), enabling physicians in private practice to contribute effectively to clinical research. By streamlining operations, these entities can expand trial capacity beyond the major public hospitals and foster broader participation across healthcare settings. Romania could support this development through **targeted grants, incubator programs, or fiscal incentives** for entrepreneurs establishing SMOs. International models provide evidence of success: in **Turkey** and **India**, SMOs have significantly increased clinical trial capacity and quality, integrating private practices into global research networks.

Implementing these measures will enable Romania to gradually transition from an over-reliance on a limited number of public institutions to a broader and more resilient network of clinical trial sites that integrates private sector efficiency. This diversification will enhance the system's ability to accommodate larger trial volumes, distribute workload more evenly, and prevent bottlenecks that currently constrain trial activity.

Crucially, such a model would leverage Romania's entire healthcare ecosystem—both public and private—to support clinical research, thereby increasing patient access and expediting trial execution. International evidence shows that countries which successfully integrate public and private resources achieve superior trial efficiency, inclusivity, and patient diversity. By adopting similar strategies, Romania can position itself as a more attractive destination for global sponsors, improve trial quality, and provide broader therapeutic opportunities for its patient population.

Timeline and Prioritization. Some recommendations can generate **short-term impact**, such as regulatory adjustments to permit ethical patient outreach through advertising, which could yield measurable effects within a year, or the establishment of a national clinical trial registry portal, which might be operational within one to two years. Other measures are **medium- to long-term**—for example, developing accredited academic training programs in clinical research—which will require several years to produce a skilled workforce and sustainable institutional capacity.

It is therefore recommended that Romania prioritize **near-term enablers** (e.g., regulatory streamlining, creation of a national portal) while **concurrently investing** in education, workforce development, and infrastructure. This phased approach balances immediate improvements in trial attractiveness with the long-term structural reforms necessary for sustainable competitiveness. International best practices confirm that combining "quick wins" with structural reforms yields the most resilient outcomes in clinical research systems (OECD, 2024, 2023).

V. Conclusion

Romania stands at a critical juncture in its development as a player in the global clinical research industry. The analysis based on Porter's Diamond Model demonstrates that while Romania possesses valuable assets—a large and diverse patient population, dedicated healthcare professionals, cost advantages, and a growing technology sector—it continues to be constrained by systemic shortcomings in education and training, regulatory flexibility, and the structural organization of its clinical research ecosystem (Health Innovation Hub, 2024).

Comparisons with EU peers such as Poland, Germany, and France underscore both the considerable gap Romania must close and the feasible pathways forward, as these countries have implemented targeted reforms to strengthen competitiveness.

Romania's **competitive advantages can only be realized if the country addresses its strategic challenges head-on**. The absence of a standardized academic curriculum for clinical research is a solvable barrier: through educational reform and investment, Romania can cultivate a new generation of investigators and research staff, reducing dependence on ad hoc learning and mitigating the brain drain of medical talent. Similarly, regulatory and communication barriers that hinder patient recruitment are within Romania's power to reform. By modernizing its approach to patient outreach and fully embracing digital tools, Romania can accelerate trial enrollment and appeal to sponsors with faster, more predictable timelines. The imbalance between public and private trial centers also requires policy and cultural shifts to foster collaboration and efficiency, leveraging the strengths of both sectors to expand trial capacity without compromising quality.

The **strategic recommendations outlined in this report form an integrated agenda** to strengthen Romania's clinical research position. These measures are mutually reinforcing: better-trained personnel will make the implementation of digital recruitment strategies more effective; a

more collaborative public-private environment will provide the settings where newly trained researchers can operate effectively across diverse sites.

Transforming a country's clinical research ecosystem is a **complex undertaking requiring cross-sector coordination** among government ministries, regulatory agencies, academic institutions, industry associations, hospitals, private entities, and patient organizations. The experience of Spain—now a European leader after embracing regulatory reform and public-private partnerships—and Poland—which rapidly improved its profile through sustained investment in people and processes—illustrates that concerted, well-funded efforts yield measurable results (PharmaLinkage, 2025). Romania can draw lessons from these models, but must tailor solutions to its local context, as already signaled through its recent strategic planning initiative.

The **benefits of successfully strengthening Romania's clinical research sector are manifold.** Romanian patients would gain earlier access to innovative therapies and more opportunities to participate in potentially life-saving trials. **The healthcare system** would benefit from trial-related resources and the upskilling of medical personnel, thereby raising standards of care. **Economically**, a more vibrant clinical trials market would attract increased investment from global pharmaceutical companies, create high-skilled jobs, and position Romania as a destination for health innovation. At the European level, Romania's emergence as a clinical research hub in Eastern Europe would reinforce the EU's collective capacity to compete globally in medical innovation.

In conclusion, Romania's potential competitive advantages in clinical research—cost-effectiveness, human capital, and patient availability—can be fully realized only through deliberate investments in education, regulatory modernization, and infrastructure. With strong leadership, adequate funding, and sustained collaboration across sectors, Romania can transition from an underutilized player to a rising competitor in European clinical research. The trends of 2025 show both the rewards for proactive nations and the risks of inertia. Romania has recognized its challenges; this paper provides a roadmap. Implementing these recommendations

will require effort and commitment, but the payoff would be a robust and sustainable competitive advantage for Romania's science, economy, and public health.

Appendix 1

International Models for Clinical Research Training

A key barrier to Romania's competitiveness in clinical research is the absence of a standardized academic curriculum for training clinical research professionals - investigators, study coordinators, and support staff. This structural gap limits both the quality and scalability of the clinical trial workforce. By contrast, several countries have institutionalized education and certification pathways that professionalize research roles and create sustainable pipelines of talent. This appendix provides a comparative overview of international models from the United States, Austria, Poland, France, Spain, Belgium, and the Netherlands, highlighting lessons that Romania could adapt to its own context.

- **United States: Modular Certifications and University-Led Programs.**

The United States has developed a highly diversified ecosystem of clinical research training, with programs offered at both university and professional levels. Harvard Medical School's *Foundations of Clinical Research* is a six-month certificate program delivered online, combining epidemiology, biostatistics, trial design, ethics, and scientific writing with interactive workshops and capstone projects (Harvard Medical School, 2023). Graduates are prepared for careers as investigators or clinical research managers. In parallel, industry-recognized certifications—such as those provided by the Clinical Research Training & Professional Services (CCRPS)—offer role-specific credentials for Clinical Research Coordinators (CRC), Associates (CRA), and Regulatory Affairs professionals (CCRPS, n.d).

Relevance for Romania: The U.S. demonstrates the value of modular, flexible, and role-specific certifications that can scale rapidly without requiring full degree programs, a model that Romanian universities could emulate through postgraduate certificates.

➢ **Austria: Vienna School of Clinical Research (VSCR).**

Austria has pioneered postgraduate education through the Vienna School of Clinical Research (VSCR), which offers 14 short courses covering all aspects of trials, from design and approval to monitoring and pharmacovigilance. Completion of six modules yields a Diploma in Clinical Research, while ten modules confer an Advanced Diploma. Courses are tailored for investigators, ethics committee members, and regulatory staff, and are available online or in-person. (VSCR, n.d.).

Relevance for Romania: The VSCR model illustrates how structured, modular programs linked to diplomas can professionalize diverse roles within the trial ecosystem, and could serve as a blueprint for Romanian universities and medical societies.

➢ **Poland: Government-Led Transformation via the Medical Research Agency (MRA).**

Poland's Medical Research Agency (MRA) has played a transformative role in reshaping the country's clinical research ecosystem. A flagship initiative is the **Polish Clinical Scholars Research Training Program**, developed in collaboration with **Harvard Medical School**. (Harvard Medical School & MRA, 2021). This year-long postgraduate certificate program combines in-person workshops in Poland and Boston with online modules and capstone projects, aiming to equip participants with advanced competencies in **clinical trial design, biostatistics and data analysis, grant writing, and leadership in research management**. Over five years, the program is expected to train approximately **500 clinicians and research professionals**, significantly strengthening Poland's human capital for clinical research (Harvard Medical School, n.d.; MRA, 2023).

Beyond training, the MRA has **funded Clinical Trial Support Centers (CTSCs)**, which provide dedicated infrastructure, professional staff, and operational support for trials. Crucially, the agency has also invested **over USD 1 billion in non-commercial trials**, particularly in high-need therapeutic areas such as oncology and rare diseases. These measures have created both a **pipeline of trained professionals** and a robust **institutional infrastructure** that together underpin Poland's rapid rise as a leading European hub for clinical research.

Relevance for Romania: Poland's example shows how dedicated government funding and international partnerships can rapidly elevate national clinical research capacity.

- **France: Graduate Programs in Clinical Sciences.**

France has embedded clinical research education within its mainstream university system. Université Paris-Saclay coordinates a *Graduate Program in Clinical Sciences* with multiple Master's and doctoral tracks, covering translational medicine, e-health, imaging, and personalized medicine. These programs are interdisciplinary, open to physicians, pharmacists, engineers, and scientists, and are designed to foster integration between academic research and clinical care. They place a strong emphasis on interdisciplinary collaboration and embed clinical research within the broader framework of health sciences education. (Université Paris-Saclay, n.d.)

Relevance for Romania: France's model demonstrates how embedding clinical research in broader health sciences education ensures sustainability and elevates the prestige of research careers—an approach Romania could adopt to normalize research training within medical and nursing curricula.

- **Spain: Master in Applied Clinical Research – Global Health Track.**

The University of Barcelona, in collaboration with ISGlobal, offers a one-year *Master of Applied Clinical Research – Global Health Track* (University of Barcelona & ISGlobal, 2023). The one-year program combines theoretical modules with hands-on research participation, preparing graduates for doctoral studies and careers in global health. A particular strength is its emphasis on vulnerable populations and health equity (ISGlobal, n.d.).

Relevance for Romania: Spain highlights the importance of aligning training with national and global health priorities. For Romania, programs focusing on local epidemiologic burdens (e.g., tuberculosis, cardiovascular disease) could both serve public health and attract international sponsors.

➢ **Belgium: CliniX Program – Bridging Academia and Industry.**

Belgium's **CliniX program**, organized by the Université Libre de Bruxelles (ULB), represents a structured initiative to expand the clinical research workforce. The program consists of a **3-month intensive training course**, followed by a **3-month internship** in clinical research settings. Its primary target group is **jobseekers** seeking to transition into specialized roles, thereby simultaneously addressing employment and workforce shortages in clinical trials. The curriculum covers both theoretical and practical dimensions of clinical research, with dedicated modules on **Good Clinical Practice (GCP)**, **clinical trial design**, **pharmacovigilance**, **regulatory affairs**, **health economics**, and **medical writing**. Delivered in English, the program ensures alignment with international standards and prepares graduates for globally competitive roles such as **trial coordinators, data managers, regulatory specialists, and clinical research associates**. (Université Libre de Bruxelles, n.d.)

By combining academic instruction with practical internships, CliniX strengthens Belgium's reputation as a **hub for high-quality clinical research training**, aligning with EU-wide strategies to address the shortage of qualified clinical research professionals (European Commission, 2022; OECD, 2023). It also illustrates how **short-cycle, practice-oriented programs** can complement traditional postgraduate education in developing a sustainable research workforce.

Relevance for Romania: CliniX exemplifies how short, practice-oriented programs can rapidly expand the clinical trial workforce while bridging academic learning with industry placement—a strategy that could be highly impactful in Romania's current labor market.

➢ **Netherlands: Research Master in Clinical Research.**

Erasmus University Rotterdam offers a **Research Master in Clinical Research**, now integrated within its broader **Health Sciences program**. This **two-year, full-time degree** (120 ECTS) is explicitly designed to prepare students for academic and professional careers as **clinical investigators**. The curriculum combines rigorous training in **clinical trial**

methodology, advanced biostatistics, and translational medicine, thereby equipping graduates with the skills necessary to design, conduct, and critically evaluate clinical studies.

The program primarily targets **medical students and early-career professionals** who intend to pursue academic careers in medicine and health sciences, ensuring they acquire both methodological expertise and hands-on research experience. Its structure reflects European standards for postgraduate education in clinical research and aligns with the EU's strategic objectives of strengthening research capacity and integrating clinical and translational science (European Commission, 2022; Erasmus University Rotterdam, n.d). By integrating clinical research training into the **Health Sciences framework**, the program fosters an **interdisciplinary approach**, bridging medicine, epidemiology, and biomedical sciences. This positions graduates to contribute not only to clinical trial design and execution but also to advancing **evidence-based medicine and health innovation** at both national and international levels.

Relevance for Romania: The Dutch model underscores the value of integrating research methodology into formal graduate degrees, creating clear career trajectories for clinical scientists—a long-term measure Romania should consider to ensure sustainability of expertise.

Synthesis and Implications for Romania

Across these diverse contexts, three common features emerge:

1. **Integration into higher education and certification systems** – whether through short diplomas (Austria), Master's/doctoral programs (France, Netherlands), or modular certificates (U.S., Belgium).
2. **Collaboration across government, academia, and industry** – exemplified by Poland's MRA and Spain's ISGlobal partnership.
3. **Sustainable funding and incentives** – ensuring continuity and scalability.

For Romania, adopting a hybrid approach is both feasible and necessary: integrating clinical research into university curricula, launching academic training programs for specific roles found in a clinical research team, and establishing government-backed funding mechanisms in partnership with industry and international institutions. Without such reforms, Romania risks perpetuating its skills deficit; with them, it could create a robust and internationally competitive workforce to support its growing clinical trials sector.

Appendix 2

Country Case Studies: Successful Clinical Trial Reform Examples

To contextualize Romania's challenges and opportunities, it is instructive to examine international examples of systemic reform in clinical research. This section analyzes three case studies—**Poland,** the **United Kingdom,** and **Spain**—highlighting distinct trajectories that demonstrate how policy, governance, and stakeholder coordination can significantly enhance national competitiveness in clinical trials.

A. Case Study 1: Poland - Building a Clinical Research Ecosystem from the Ground Up

Background. In the early 2010s, Poland was considered a moderate player in the European clinical trial landscape. While industry-sponsored studies were relatively common, the country lacked centralized governance, sustainable funding, and substantial non-commercial research capacity. By 2018, Poland authorized approximately 450–500 new clinical trials annually, reaching a record of 603 in 2019 (Polish Ministry of Health, 2020). Yet, many patients continued to seek innovative therapies abroad due to restricted domestic access, underscoring systemic deficiencies. Recognizing these limitations, the government established the ***Medical Research Agency*** (*Agencja Badań Medycznych*, ABM) in 2019 as an independent body tasked with coordinating and financing clinical research, particularly in areas of high unmet medical need (Kitala et al., 2024).

Policy Interventions. Poland's reforms centered on the ***Medical Research Agency***, which catalyzed a broad transformation:

- **Central Governance and Funding.** The Medical Research Agency (ABM) was mandated to support especially **non-commercial clinical trials**. In its first five years, it funded nearly 280 projects with a cumulative value exceeding PLN 3.5 billion (~€770 million), representing an unprecedented level of public investment in this domain. These initiatives

prioritized areas of high unmet medical need, such as oncology and rare diseases, and actively engaged academic institutions as trial sponsors (Kitala et al., 2024; MRA, 2023).

- ***Infrastructure Development.*** By 2023, Poland's **Medical Research Agency (ABM)** had established **23 Clinical Trials Support Centres (CTSCs)** within major hospitals, designed as dedicated units that provide infrastructure, trained research staff, and professional management for clinical trials. Each CTSC operates as a **one-stop shop** for trial implementation, thereby standardizing processes, improving site quality, and enhancing patient access to studies. In parallel, ABM created **18 Regional Digital Medicine Centres (RDMCs)** to integrate health data at the regional level, supporting both clinical care and research by enabling, for example, the rapid identification of eligible patients through hospital electronic health records (Kitala et al., 2024; MRA/ ABM, 2023; OECD, 2024, 2023).
- ***Training and Workforce.*** A central pillar of ABM's strategy has been the systematic education of a new cadre of clinical researchers. The Agency organized nationwide training programs in **Good Clinical Practice (GCP)** and clinical trial operations, reaching several thousand participants across Poland (Kitala et al., 2024). In addition, ABM partnered with **Harvard Medical School** to establish the *Polish Clinical Scholars Research Training (P-CSRT) program*, designed to provide advanced research education for physicians and allied professionals. The program aims to train **at least 500 clinicians by 2027**, equipping them with expertise in trial design, conduct, and regulatory compliance. This sustained investment in human capital is intended to ensure that Poland develops a **critical mass of skilled investigators, research nurses, and study coordinators**, thereby reinforcing the country's capacity to conduct complex, high-quality clinical trials (Kitala et al., 2024; MRA/ ABM, 2023; Harvard Medical School & MRA/ ABM, 2021).
- ***Regulatory and Legislative Reform.*** Poland has undertaken significant reforms to create a more trial-friendly regulatory environment. The **Clinical Trials Act (2022)** harmonized national legislation with the **EU Clinical Trials Regulation (CTR 536/2014)**, thereby streamlining ethics committee operations and eliminating previous ambiguities that often delayed approvals. This alignment not only enhanced transparency but also increased

regulatory predictability and patient safety, making Poland a more attractive destination for international sponsors. In parallel, the **Medical Research Agency (ABM)** collaborated with the **Ministry of Health** to simplify administrative procedures, including the import and export of investigational medicinal products, and to ensure that trial authorization timelines complied with EU standards. Collectively, these measures have positioned Poland as one of the most **regulatory-efficient ecosystems for clinical research in Central and Eastern Europe**, contributing to its rapid growth in both commercial and non-commercial trials (Kitala et al., 2024; European Commission, 2023).

- ***Public–Private Collaboration.*** The Polish government has actively fostered structured collaboration with the life sciences industry, recognizing that sustainable clinical research ecosystems require alignment between public and private stakeholders. The **Medical Research Agency's (ABM) Strategic Council** includes representatives from pharmaceutical companies, contract research organizations (CROs), and academic institutions, thereby institutionalizing dialogue and trust across sectors (MRA/ ABM, 2025, 2023). Moreover, Poland published a **Clinical Trials Development Plan 2020–2030**, a policy roadmap emphasizing transparent public–private partnerships and concrete measures to support the establishment and professionalization of clinical research centers (OECD, 2025). This plan, which was noted in the **OECD Science, Technology and Innovation Policy Database**, was developed with broad stakeholder consultation, ensuring its legitimacy and relevance. To further demonstrate commitment and increase visibility to sponsors, Poland has organized high-profile promotional initiatives such as the **annual Clinical Trials Congress**, which convenes policymakers, academics, patient associations, and industry leaders to discuss progress and align strategies. Collectively, these initiatives highlight Poland's proactive stance in positioning itself as a **regional leader in clinical trials** through effective public–private collaboration (Kitala et al., 2024)

Outcomes. The reforms implemented in Poland have profoundly reshaped its clinical trial ecosystem within just a few years, positioning the country as one of the most dynamic markets in Europe (MRA/ ABM, 2023; Kitala et al., 2024):

- **Growth in Trial Activity.** Between 2019 and mid-2023, Poland initiated more than **1,300 new clinical trials**, ranking among Europe's fastest-growing trial markets. This expansion places Poland closer to traditional Western European leaders in terms of clinical trial density and volume. (Cromos Pharma, 2024)
- **Expansion of Non-Commercial Research.** Perhaps the most transformative change has been the rise of **academic-led, non-commercial trials**. Prior to the establishment of ABM, Poland had "at most a dozen" active non-commercial studies. By 2022–2023, this figure increased to more than **50 new academic-led trials per year**, marking a more than threefold expansion and broadening the country's research agenda beyond industry-sponsored projects (MRA/ ABM, 2025, 2023).
- **Expanded Capacity and Patient Access.** The creation of **Clinical Trial Support Centres (CTSCs)** enabled clinical research to extend beyond traditional metropolitan hubs. Over **900 healthcare units** (including hospitals and clinics) across Poland have participated in ABM-funded trials, providing more than **60,000 patients** with access to innovative therapies, including advanced oncology and rare disease interventions (MRA/ ABM, 2025, 2023).
- **Faster Timelines.** While exact benchmarks remain proprietary, early sponsor reports indicate that the establishment of CTSCs and agency oversight reduced **contract negotiation and site initiation delays**. Following Poland's full transition to the EU **Clinical Trials Information System (CTIS)** in 2022, ethics approvals were routinely processed within the maximum 60-day limit, aligning Poland with the most efficient EU peers.
- **International Recognition.** Poland has increasingly been recognized as a **regional hub for clinical research**. Major global CROs expanded their operations in Poland, citing its large and diverse patient pool, improved regulatory environment, and predictable approval timelines (Cromos Pharma, 2024). Several multinational pharmaceutical companies have relocated regional clinical trial management functions to Poland. The country also became a full member of **ECRIN (European Clinical Research Infrastructure Network)** in 2022, further embedding itself in Europe's research fabric (ECRIN, n.d.).

- **Sustainability and Academic Output.** Investments in human capital have produced a pipeline of **certified investigators, trial coordinators, and research nurses**, thereby improving trial quality and scalability. Polish researchers have increased their scientific visibility, publishing a growing number of trial results in high-impact international journals. A **2024 analysis in *The Lancet Regional Health – Europe*** highlighted Poland's rise as an Eastern European leader in clinical trial output (Kitala et al., 2024; Poland Daily 24, 2024). Importantly, the Polish government institutionalized funding for ABM with multi-year budgetary commitments, ensuring continuity and resilience beyond electoral cycles.

In summary, Poland's trajectory illustrates how a relatively underutilized research environment can be transformed into a robust and internationally competitive clinical research hub in less than a decade. This case underscores the importance of **implementing academic training programs**, **adequate funding, strong governance, and sustained public–private collaboration**. Romania's policymakers are already referencing Poland as a **benchmark model**, and the evidence validates this approach as both credible and achievable in the Romanian context.

B. Case Study 2: United Kingdom – Reinventing Clinical Trials in a Mature System

Background. The United Kingdom has historically been regarded as a **global leader in clinical research**, underpinned by the unique infrastructure of the **National Health Service (NHS)** and the research excellence of its universities. However, between 2017 and 2021, the UK's share of global clinical trial activity declined significantly. A **2023 ABPI review** reported that the number of new industry-sponsored trial starts fell by **44%**, with the country slipping from **4th to 10th place worldwide** in terms of trial volume (Clinical Trials Arena, 2025; ABPI, 2024).

Key challenges contributing to this decline included **slow trial set-up in hospitals**, a **regulatory backlog** at the **Medicines and Healthcare products Regulatory Agency (MHRA)**, and intensifying competition from faster-growing regions. For example, the **median time from trial application to first patient** exceeded **250 days in the UK**, compared with approximately **155 days**

in the United States (NIHR, 2023). The additional regulatory complexities introduced by **Brexit** further disrupted trial operations and sponsor confidence.

The COVID-19 pandemic paradoxically demonstrated both the **strengths and weaknesses** of the UK research system. On the one hand, the landmark **RECOVERY trial** was globally recognized as a model of adaptive, high-impact research, delivering practice-changing results at unprecedented speed. On the other hand, many non-COVID trials were suspended or significantly delayed, exposing systemic vulnerabilities in trial resilience and continuity.

In response to these challenges, the UK government and its research ecosystem launched a **major reform agenda** aimed at rejuvenating the country's clinical trial infrastructure and ensuring the UK remains a **preferred destination for global research investment**. This includes targeted measures to streamline regulatory processes, improve site readiness, expand digital tools, and strengthen collaboration between industry, academia, and the NHS.

Policy Interventions. The UK's clinical trial reforms have been **multi-faceted and strategically coordinated**, guided by a clear national vision and anchored in evidence-based policy frameworks.

- **Strategic Vision and Leadership.** In 2021, the UK government launched *The Future of UK Clinical Research Delivery* – a **10-year strategy** aimed at streamlining study setup, accelerating recruitment, and embracing innovation across the trial lifecycle (Department of Health & Social Care, 2022; NIHR, 2022). The plan articulated four high-level goals: (1) reducing bureaucratic delays in trial setup, (2) enabling modern and adaptive trial designs, (3) improving recruitment speed and inclusivity, and (4) embedding research more strongly in community-based healthcare. A 2022 update (*Phase 2 of the vision*) translated these goals into **concrete actions through 2025**, with progress tracked by the National Institute for Health and Care Research (NIHR).
- **Regulatory Reform (MHRA).** A critical intervention addressed inefficiencies in the **Medicines and Healthcare products Regulatory Agency (MHRA)**. In 2023, the agency launched an emergency operation to clear a backlog of **966 trial applications**, successfully eliminating it within six months. By September 2023, MHRA reported compliance with

service standards, processing ~2,100 applications in three months (MHRA, 2023; Department of Health & Social Care, 2023). Concurrently, the **Medicines and Medical Devices Act 2021** empowered MHRA with more regulatory flexibility, while subsequent amendments culminated in the **UK Clinical Trial Regulations (2024)**. These introduced a **notification-only pathway for low-risk trials**, capped combined MHRA and ethics approvals at **30 days**, and mandated proportional review timelines – all measures designed to align with international benchmarks while retaining high ethical standards.

- **Streamlining Trial Setup in the NHS.** The UK recognized that delays often occurred not at the regulatory stage, but between **approval and first patient enrollment**, which previously exceeded 200 days. (Odelle Technology. (n.d.)).

  To address this, the **Study Start-Up Improvement Programme** was launched, including:

  - a **centralized costing tool** developed by NIHR to standardize and accelerate budget negotiations;
  - national targets, such as **"first participant in within 70 days"**, alongside a broader ambition to reduce setup time to **150 days from submission to first patient**; (Department of Health & Social Care, 2025).
  - performance monitoring with **Trust-level reporting**, introducing competitive benchmarking to incentivize compliance.
- **Investing in Infrastructure and Capacity.** To ensure sustainability, the UK invested heavily in expanding trial delivery capacity:
  - **Clinical Research Facilities (CRFs):** In 2022, £161M was allocated to **28 NIHR CRFs** dedicated to early-phase research (CRFs -hospital units dedicated to early-phase trials). (NIHR, 2022)
  - **Research Delivery Networks:** The NIHR Clinical Research Network was restructured into the **Research Delivery Network (RDN)**, with additional funding for research nurses and trial officers in under-resourced areas.
  - **New Regional Hubs:** In 2023, as part of the *Voluntary Scheme for Branded Medicines Pricing and Access (VPAG)* – a £400M public–private investment agreement between the UK government and the pharmaceutical industry – an initial

£100M was allocated to establish up to **20 new Clinical Research Delivery Centres (CRDCs)** across the UK (UK Department of Health and Social Care, 2024). These centers, strategically located in regions that historically hosted fewer trials, are designed to provide **dedicated research staff, infrastructure, and facilities** specifically for late-phase commercial studies. By expanding research capacity beyond traditional metropolitan hubs, the initiative aims to reduce geographic inequities in trial participation, accelerate patient recruitment, and ensure that diverse populations are represented in clinical research (ABPI, 2024; NIHR, 2023; Odelle Technology. (n.d.)).

- **Embracing Innovation (Digital & Decentralized Trials).** The reforms emphasize **patient-friendly, technology-driven trial models**:
    - The MHRA and NIHR have jointly issued **guidance for decentralized and hybrid clinical trials**, incorporating tools such as telemedicine, remote monitoring, and home visits to make studies more patient-centered and accessible. These approaches were accelerated during the COVID-19 pandemic, when many ongoing trials had to pivot to remote methodologies, and the UK is now institutionalizing these lessons as part of routine practice. The shift is intended to enhance trial inclusivity, reduce patient burden, and shorten recruitment timelines—objectives strongly aligned with international trends in modern trial design (RAPS, 2025; MHRA, 2023; NIHR, 2023; FDA, 2022).
    - The NHS is increasingly leveraging its integrated health data to accelerate clinical trial recruitment. Through initiatives such as **NHS DigiTrials**, centralized electronic health records (EHRs) are securely accessed (with patient consent) to identify individuals meeting trial eligibility criteria and, in some cases, directly invite them to participate. The strategic vision is to make digital recruitment—supported by population-level EHR infrastructure—a routine component of most trials conducted in the UK. This aligns with broader international trends emphasizing the secondary use of health data for clinical research under strict ethical and legal safeguards (Department of Health & Social Care, 2025b; OECD, 2021).

- The UK has also established an **Innovative Trial Design Working Group**, tasked with advancing modern approaches such as **platform trials, basket trials, and the application of artificial intelligence (AI) in trial management**. These methodologies, already endorsed by international regulatory agencies such as the EMA and FDA for their efficiency in oncology and rare disease research, enable simultaneous evaluation of multiple therapies or adaptive modifications during trial conduct. To further accelerate processes, the UK has piloted a **combined review pathway**, whereby ethical review and MHRA assessment occur in parallel, thereby reducing approval timelines. Moreover, policymakers are considering the establishment of a **"rapid research" unit**, designed to authorize urgent trials within weeks—building upon the precedent set during the COVID-19 pandemic, when vaccine and therapeutic studies were approved within days. These innovations position the UK at the forefront of regulatory agility in Europe, making it a benchmark for other countries seeking to modernize their trial ecosystems. (Morgan, 2025; Beaney, 2023).

- **Patient and Public Involvement.** A central component of the UK's reforms has been the explicit emphasis on **making clinical research more accessible, inclusive, and representative**. The National Institute for Health and Care Research (NIHR) launched dedicated campaigns to enhance participation among **under-served and minority communities**, aiming to **quadruple the number of individuals enrolled in commercial trials by 2026** (NIHR, 2022). One flagship initiative is the **"Be Part of Research"** portal, which provides a user-friendly interface for the public to search ongoing studies, register interest, and connect directly with trial centers. Furthermore, sponsors are now required to submit **inclusion and diversity strategies** within trial protocols, ensuring proactive measures are taken to broaden participation across socio-economic, ethnic, and geographic groups. This approach reflects an international best practice, supported by growing evidence that diverse participation enhances both the **generalizability and equity** of clinical trial outcomes (Health Innovation Hub, 2024; NIHR, 2023).

Outcomes. The UK's reform agenda, although relatively recent, has already begun to deliver measurable improvements across multiple dimensions of its clinical research ecosystem:

- **Improved Approval Times.** MHRA reports indicate that by 2023 the **median approval time for new clinical trial applications stabilized at approximately 30 days**, representing a substantial improvement compared to 2021 and positioning the UK competitively at the international level (MHRA, 2023). Furthermore, the new UK Clinical Trials Regulations set the **maximum duration for ethics review at 30 days**, which in practice is expected to maintain the overall approval process within **60 days**. This alignment with international best practices not only enhances the UK's credibility as a research destination but also strengthens its attractiveness to global sponsors seeking predictable and efficient regulatory pathways (Manfrin, 2025).
- **Reduction in Site Setup Delays.** A 2023 stage-one pilot of the **National Contract Value Review (NCVR)** demonstrated measurable improvements in site activation efficiency. More than 60 late-phase industry-sponsored trials achieved site setup in an **average of 194 days**, representing a **36% reduction compared to the 305-day average** observed in the 12 months prior to NCVR implementation (NIHR, 2023). The streamlining measures—specifically the elimination of redundant R&D checks at trial sites and the adoption of a **standardized contracting process**—significantly shortened timelines by removing repetitive negotiations. Several large sponsors have acknowledged that the UK's trial initiation performance is converging with **U.S. benchmarks** (median start-up ~155 days in the U.S. vs. 253 days in the UK in 2020), suggesting that the regulatory and operational gap is narrowing (ABPI, 2024; Odelle Technology. (n.d.)).
- **Rise in Trial Numbers and Participants.** Following the pandemic-related decline, the **UK clinical trials sector is showing clear signs of recovery**. Data from the Association of the British Pharmaceutical Industry (ABPI, 2024) indicate that by late 2023 the number of **commercial trial initiations increased year-on-year**, reversing the downward trend. More importantly, patient enrollment in industry-sponsored trials expanded from approximately 36,000 in 2021/22 to nearly 46,000 in 2022/23, representing a **28% increase**. However, participation levels remain below the pre-pandemic peak of ~58,000 patients recorded in

2017/18. The UK government has set an ambitious goal of involving **1 million citizens in health research by 2025**, and current trajectories suggest that this target is achievable if momentum is maintained (NIHR, 2023; ABPI, 2024).

- **Restored Industry Confidence.** There are clear qualitative signs of **regained momentum in the UK clinical research sector**. In 2023, global pharmaceutical companies such as **Moderna** and **Novartis** announced **new investments in UK trial centers**, explicitly citing the government's supportive reforms and streamlined regulatory processes as decisive factors. The former UK Health Minister who led the clinical trials review described the progress as *"remarkable"*, underscoring the **improved performance of the MHRA** and its increased regulatory flexibility—such as the acceptance of **summary data in place of full datasets** for certain trial approvals, a measure designed to accelerate initiation timelines. These developments highlight that the UK's reforms are not only improving operational metrics but also **restoring industry confidence**, a critical element for sustaining long-term competitiveness (Beaney, 2025; ABPI, 2024; MHRA, 2023).
- **Notable Quick Wins.** A concrete example of the **impact of the UK's reform agenda** is the generalization of the **RECOVERY trial model**, an adaptive platform trial originally designed for COVID-19 treatments. By 2024, the UK successfully extended this approach to other therapeutic areas, including **multiple long COVID trials** and **oncology adaptive studies**, leveraging the extensive NHS research infrastructure. Importantly, these trials were initiated within **weeks rather than months**, reflecting the efficiency gains enabled by new organizational and regulatory structures. The UK's ability to rapidly scale adaptive trial methodologies demonstrates how **system-level reforms can foster methodological innovation and accelerate patient access to cutting-edge therapies** (Beaney, 2025; NIHR, 2024).
- **Global Competitiveness.** In 2023, the UK reinforced its position in the global research ecosystem by **joining the EU's Horizon Europe research funding program** and by establishing a **regulatory cooperation plan with the US Food and Drug Administration (FDA)**. These strategic moves provide reassurance to researchers and sponsors that **UK clinical trials remain internationally integrated**, facilitating cross-border collaboration,

access to funding streams, and alignment with global regulatory standards. Such initiatives are widely recognized as critical for sustaining the UK's competitiveness in biomedical research and ensuring that the NHS and academic institutions remain attractive partners for multinational trials (European Commission, 2023; UK Government, 2023; FDA, 2022).

In essence, the UK's ongoing reforms highlight that **even mature clinical research systems must continuously adapt and innovate to remain competitive**. For Romania, which is still in the process of consolidating its clinical research ecosystem, adopting a forward-looking mindset from the outset—emphasizing regulatory efficiency, innovation in trial design, and patient-centered access—could enable it to bypass some of the structural bottlenecks and delays that the UK has faced. The UK's trajectory also demonstrates that setbacks, such as a temporary decline in trial volume, can be successfully reversed through coordinated reforms, strategic investments, and stakeholder collaboration. This provides an encouraging lesson for countries like Romania, which aim to strengthen their global position in clinical research.

C. Case Study 3: Spain – Streamlining Processes to Become Europe's Trial Leader

Background. Spain has recently emerged as one of Europe's leading hubs for clinical research, surpassing traditionally dominant countries such as the UK, Germany, and France on certain performance indicators. This outcome was far from evident two decades ago: in the early 2000s, Spain maintained a modest clinical trial presence but lagged behind Western European leaders in industry-sponsored studies. Several barriers contributed to this situation, including the existence of multiple regional ethics committees and the mandatory translation of study documentation into Spanish, which slowed down the approval of multinational trials.

Over the last 15 years, Spain has implemented gradual yet transformative reforms to streamline clinical trial oversight. By leveraging its unified National Health System (NHS), standardizing regulatory procedures, and committing to operational efficiency, Spain has repositioned itself as an attractive, high-volume destination for clinical research. The culmination of these reforms came in 2024, when **Spain authorized more clinical trials than any other EU country (930 new trials),**

marking a milestone that reflects the effectiveness of its policies and structural modernization (Invest in Spain, 2025; AEMPS, 2024; OECD, 2024, 2023; Distefar del Sur. (n.d.)).

Policy Interventions. Spain's trajectory in clinical research has been defined by incremental, steady improvements rather than a single sweeping reform. This gradualist approach enabled progressive alignment with international best practices while maintaining regulatory stability and stakeholder confidence (AEMPS, 2024; OECD, 2024, 2023).

- ***Centralizing and Harmonizing Ethics Approvals.*** A pivotal reform was introduced through **Royal Decree 1090/2015**, which reorganized Spain's clinical trial regulation. The decree established that for multicenter trials, a single Central Ethics Committee opinion—issued via one of the accredited *Comités de Ética de la Investigación con medicamentos* (CEIms)—would suffice nationwide, thereby replacing the previously fragmented system that required separate approvals in each autonomous region. This harmonization markedly reduced redundancy and inefficiency, and it anticipated the EU Clinical Trials Regulation (Regulation (EU) No. 536/2014), which later mandated single ethical opinions at the European level.
- ***Accelerating Regulatory Timelines.*** Even prior to the implementation of the EU Clinical Trials Regulation (CTR 536/2014), Spain's regulatory authority (*Agencia Española de Medicamentos y Productos Sanitarios*, AEMPS) proactively pursued shorter evaluation timelines. Spain was an early and enthusiastic participant in the **Voluntary Harmonization Procedure (VHP)**, which—before CTR harmonization—enabled coordinated multinational assessments within the EU (AEMPS, 2012). Through this mechanism, AEMPS gained a reputation for efficiency and scientific rigor, frequently issuing approvals well ahead of statutory deadlines (European Medicines Agency, 2019). Following the entry into force of the EU CTR in 2022, which established a standard 60-day default approval period, Spain consistently managed to authorize many trials in significantly less time. Building on this momentum, in mid-2024 AEMPS launched an **Accelerated Evaluation ("Fast-Track") pathway**, specifically for high-priority studies such as early-phase trials, advanced therapy medicinal products (ATMPs), and trials addressing life-threatening conditions. Under this

pathway, evaluations are completed within **26 days post-validation**, positioning Spain among the fastest regulators globally for initial clinical trial approval (AEMPS, 2024). This initiative illustrates Spain's strategic commitment to regulatory agility and competitiveness in clinical research.

- ***Public Healthcare Integration*.** Spain's National Health System (SNS) provides universal healthcare coverage through its regional health services, creating a strong institutional backbone for clinical research. Over the past two decades, clinical research has become increasingly integrated into routine hospital care. Leading hospitals such as **Vall d'Hebron University Hospital in Barcelona** and **Hospital Universitario 12 de Octubre in Madrid** have established dedicated Clinical Research Units that facilitate both commercial and academic trials. The Ministry of Health further supported the creation of national research networks, including **CAIBER (Consorcio de Apoyo a la Investigación Biomédica en Red),** which initially focused on early-phase trials, and **SCReN (Spanish Clinical Research Network)**, a more comprehensive infrastructure launched with EU and national funding to coordinate hospital-based trial units and harmonize procedures (SCReN, n.a.; Aldea Perona et.al, 2012). These **publicly funded networks** ensure that not only commercially attractive studies but also **academic-led and investigator-initiated trials** benefit from sufficient infrastructure, quality oversight, and professional support. By embedding clinical research within the SNS, Spain has effectively expanded its trial capacity, enhanced site professionalism, and institutionalized research as a component of healthcare delivery.
- ***Training and Accreditation*.** Spain has strategically invested in **human capital development** to strengthen its clinical research ecosystem. The **Spanish Agency of Medicines and Medical Devices (AEMPS)**, together with the **Fundación Española de Medicamentos y Productos Sanitarios (Fundación AEMPS)**, regularly organizes **Good Clinical Practice (GCP) training, certification programs, and research methodology courses** to ensure that investigators and trial staff meet international standards (AEMPS, 2024). In parallel, many large hospitals have established **dedicated clinical trial units**, often embedded within broader research institutes, which provide continuous professional training for study coordinators, research nurses, and data managers. Over time, several

hospitals—particularly in **oncology (e.g., Vall d'Hebron Institute of Oncology, Hospital Clínic de Barcelona)** and **rare diseases (e.g., Hospital Universitario La Paz, Madrid)**—have become recognized **centers of excellence**, attracting **international multicenter trials** and positioning Spain as a competitive hub in specialized therapeutic areas (SCReN, n.a.).

- ***Patient Engagement and Recruitment*.** Spain has placed significant emphasis on **patient engagement** as a cornerstone of its clinical research strategy. Recognizing cultural barriers, including the persistent misconception of trial participants as "guinea pigs," regulators and stakeholders collaborated with **patient advocacy groups** to promote the value of clinical research. National campaigns led by **Farmaindustria** and federations of patient associations have played a critical role in **building trust, transparency, and awareness** about trial participation (Farmaindustria, 2022). At the operational level, several regions have established **volunteer research registries** and integrated **disease-specific databases** into recruitment workflows. For example, the **Catalan Health Service (CatSalut)** developed a digital tool that enables investigators—subject to patient consent—to search across primary care databases for eligible participants in specific trials. This innovation has significantly facilitated recruitment efficiency and broadened patient inclusion beyond tertiary hospital settings (Government of Catalonia, Ministry of Health, 2016).
- ***Incentives for Industry*.** Spain has systematically created an environment attractive to pharmaceutical sponsors by combining **financial incentives, institutional support, and regulatory reliability**.
    - The **national and regional governments** frequently co-fund clinical research positions in hospitals, ensuring that trial sites are adequately staffed. This arrangement reduces operational burdens on sponsors and improves site readiness (OECD, 2021).
    - Spain provides R&D tax credits that companies can apply directly to clinical trial costs, making investments in Spanish trials fiscally advantageous (European Commission, 2022; Odelle Technology. (n.d.)).

- Equally important, Spanish trial sites have built a reputation for **reliable performance**. In oncology in particular, Spanish centers consistently meet or exceed enrollment targets, reinforcing sponsor trust and leading to repeat allocations of studies.
- The **Spanish Agency of Medicines and Medical Devices (AEMPS)** has adopted a collaborative, science-driven approach. It engages in **early dialogue with sponsors**, provides **scientific advice for novel therapies**, and pioneered **rolling trial reviews** during the COVID-19 pandemic—balancing regulatory rigor with sponsor-friendly processes (AEMPS, 2024).This combination of fiscal incentives, skilled workforce, and **regulatory agility** positions Spain as one of Europe's most competitive environments for complex trials, including advanced therapy medicinal products (ATMPs) such as CAR-T cell therapies.

Outcomes. The outcomes of Spain's sustained reforms are both significant and measurable, underscoring its rise as a European leader in clinical research.

- **Top in Europe for Trials.** In 2024, Spain authorized **930 new clinical trials**, the highest among all European Medicines Agency (EMA) member states (Invest in Spain, 2025). This placed Spain ahead of larger countries such as France and Germany, consolidating a trajectory already evident in 2021, when Spain accounted for **16% of all European trials** (AEMPS, 2024; EFPIA, 2023; ALCIMED, 2023). Spain has firmly established itself on the "European podium" for trial activity, alongside or even ahead of traditional leaders.
- **Oncology and Advanced Therapies Leadership.** Spain demonstrated particular strength in oncology, hosting **336 oncology trials in 2024**, representing **37.6% of its trial portfolio**, the highest proportion in Europe (Invest in Spain, 2025). Globally, Spain is involved in **19% of oncology drug trials**, placing it in the world's top tier (ALCIMED, 2023). Moreover, in **advanced therapy medicinal products (ATMPs)**, Spain authorized **52 trials in 2024**, again ranking among Europe's leaders (Invest in Spain, 2025). These figures reflect the effectiveness of Spain's specialized trial centers and the adoption of fast-track processes for cutting-edge therapies (EMA, 2025).

- **Efficient Processes (CTIS and Reference Member State Role).** Spain adapted swiftly to the **EU Clinical Trial Information System (CTIS)** (Invest in Spain, 2025). Through intensive preparation, AEMPS ensured a seamless transition of ongoing trials and trained site staff effectively. By 2024, Spain acted as **Reference Member State (RMS) in 28% of multinational trials** in CTIS, demonstrating sponsors' trust in Spain's **quality, consistency, and speed of regulatory assessments** (AEMPS, 2024).
- **Patient Access and Benefits.** Spain's trial capacity has had a direct patient impact. More than **22% of trials in Spain target rare diseases (**Invest in Spain, 2025), thereby expanding access for patients with limited therapeutic options. Participation in trials has also reduced the gap between EMA drug approval and patient access in Spain, ensuring earlier availability of innovative therapies (AEMPS, 2024).
- **Economic and Scientific Gains.** Spain's leadership translates into measurable socio-economic impact. According to Farmaindustria (2022), clinical trials generate approximately **€1.2 billion annually** and support thousands of high-skilled jobs (Farmaindustria, 2023). Many global pharmaceutical companies, including Pfizer and Roche, have established or expanded European trial coordination offices in Spain. On the scientific front, Spanish investigators are increasingly represented as co-authors on pivotal trial publications, reflecting the integration of research into routine hospital practice.
- **Consistency and Resilience.** Even during the COVID-19 pandemic, Spain's infrastructure proved **resilient**. Spain not only launched and led large-scale COVID-19 trials but also **recovered quickly in non-COVID studies**, surpassing **700 authorized trials by 2021**. This continuity reinforced Spain's reputation among global sponsors as a reliable and adaptable research environment.

Spain demonstrates that being proactive and responsive in clinical trial regulation yields substantial dividends. For Romania—currently ranking at the bottom in the EU in terms of trials per capita (only **12 per million people in 2022**, according to EMA data)—adopting elements of "the Spanish approach," characterized by **efficient approval processes and the integration of clinical research into healthcare delivery**, could significantly improve its position. In essence, Spain

showed that lowering administrative barriers and embedding research into the health system directly attracts trial activity; Romania has the potential to replicate this trajectory if reforms are pursued decisively (Health Innovation Hub, 2024; AEMPS, 2024; EFPIA, 2023).

Each of the case studies discussed—**Poland's systemic capacity-building, the UK's targeted regulatory overhaul, and Spain's streamlined and patient-centered integration**—offers a distinct blueprint for strengthening the clinical research ecosystem. Despite their differences, a unifying theme emerges: **strong governance, adequate investment, and a commitment to efficiency and quality are essential prerequisites for competitiveness** (OECD, 2024, 2023; European Commission, 2022).

Romania can selectively draw from these experiences to craft a reform strategy tailored to its national context:

- From **Poland**, the importance of **dedicated funding and workforce development**;
- From the **UK**, the imperative to **cut bureaucratic delays, invest in infrastructure, and embrace digital innovation**;
- From **Spain**, the value of a patient-centric and agile regulatory environment.

Appendix 3

Comparison Romania vs. Poland in Clinical Research -

Diamond Scorecard and Data Validation

To ground the analysis in robust evidence, **key clinical research metrics** for Romania and Poland were compiled, focusing on the period **2022–2025**. This section provides validated comparative data on **clinical trial volumes, workforce training and educational capacity, ethics and regulatory approval timelines, as well as policies regarding direct patient outreach and digital recruitment**. By systematically benchmarking these indicators, the analysis allows for a more rigorous application of Porter's Diamond Model to the two countries.

Such a structured comparison not only highlights **quantitative differences** (e.g., number of trials initiated, patient participation rates, trained investigators) but also underscores **qualitative dimensions**, such as the maturity of regulatory frameworks, the existence of national training programs, and the integration of digital tools in trial recruitment. This dual focus provides a balanced and evidence-based foundation for assessing Romania's relative competitive position vis-à-vis Poland in the European clinical research landscape (EMA, 2025; CTIS, 2025; OECD, 2024, 2023; EFPIA, 2024; MRA/ ABM, 2023).

Comparison of Key Metrics (Romania vs. Poland):

- ***Annual Clinical Trial Volume*.**

  Romania authorized **233 clinical trials in 2022** (a decline from ~250 in 2021), which corresponds to approximately **12 trials per million inhabitants** (Health Innovation Hub, 2024). This represents one of the lowest rates in Europe. For context, smaller neighboring countries reported significantly higher volumes: **Bulgaria authorized 319 trials** and **Hungary ~461 trials** in 2022 (Health Innovation Hub, 2024; EFPIA, 2023). By contrast, Poland authorized **approximately 600–650 trials in 2022**. Poland had already reached a

record high of **603 new trial registrations in 2019**, and although activity dipped slightly during the COVID-19 pandemic, it consistently remained above 500 per year (INFARMA & POLCRO, 2022). Moreover, between **January 2022 and mid-2023, Poland initiated 1,307 new trials**, underscoring a marked acceleration following the implementation of structural reforms (Cromos Pharma, 2024; MRA/ ABM, 2023).

In comparative terms, Poland's clinical trial activity is **2.5–3 times higher than Romania's in absolute numbers**, and approximately **2.1 times higher per capita** (Poland ~25 trials per million vs. Romania ~12 per million in 2022). This gap reflects both stronger institutional support mechanisms and more proactive policy interventions in Poland.

Ilustrativ 11. Număr de studii clinice la un milion de locuitori [2022] [1] [8]

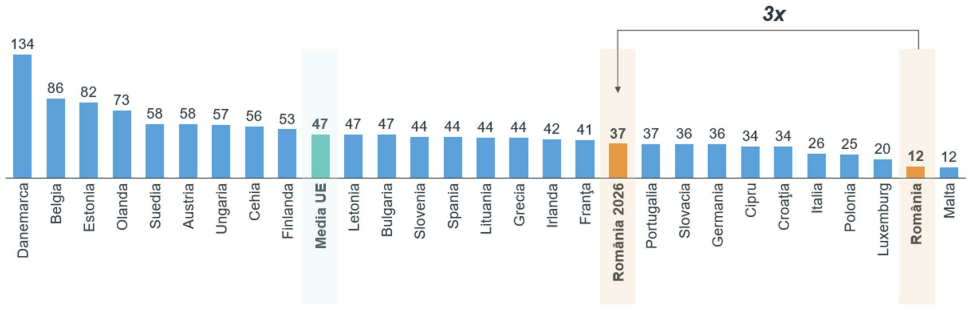


Figure 2. Number of clinical trials per one million inhabitants in selected EU countries (2022).

Source: Health Innovation Hub, 2024

hubinovatie.ro

Ilustrativ 12. Număr de studii clinice [2022] [8]

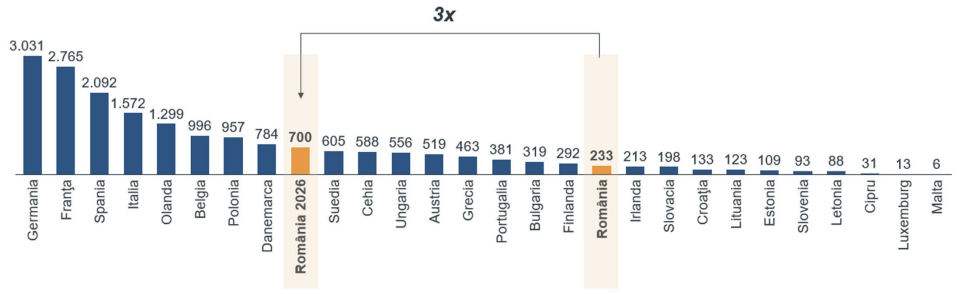


Figure 3. Number of clinical trials by country (2022).

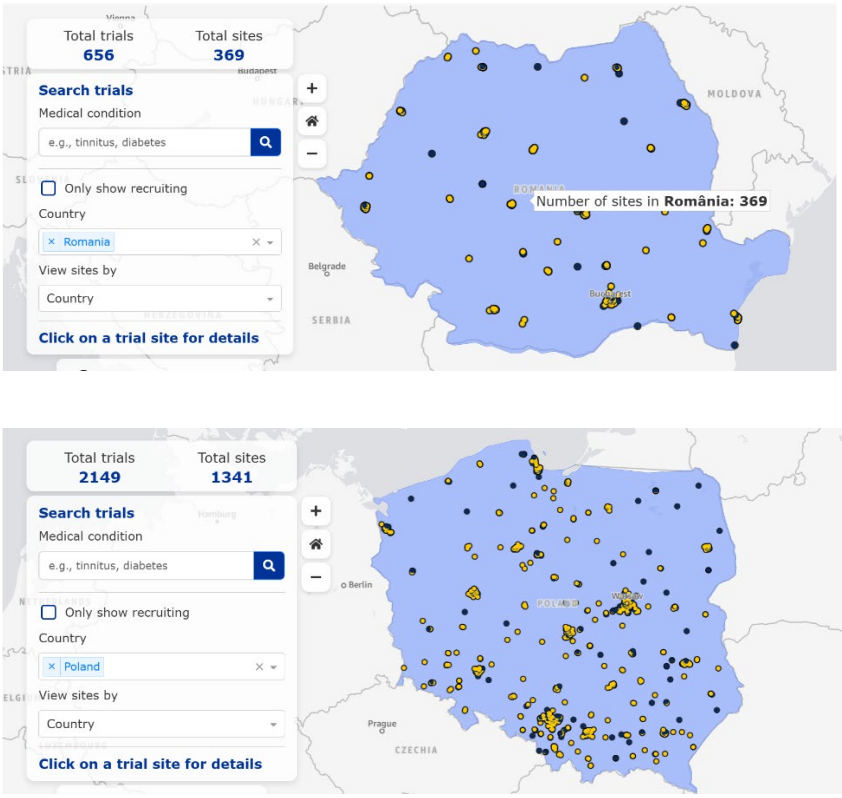
Source: Health Innovation Hub, 2024

hubinovatie.ro

Recent data indicate that Romania is beginning to show progress. By March 2024, the number of trials recorded since the entry into force of the EU Clinical Trials Regulation (CTR) on January 31, 2022 had risen to **189** (from 140 in December 2023)—a **35% increase** in just three months, suggesting an acceleration in activity (Health Innovation Hub, 2024).

Poland, however, has maintained a significantly stronger trajectory. According to official reports from the Medical Research Agency (MRA), the number of non-commercial trials has **increased threefold** nationwide since 2019, reflecting both institutional investment and policy effectiveness (MRA/ ABM, 2025, 2023).

The latest data from September 2025 confirm continued progress for both Romania and Poland. Nevertheless, the relative gap remains largely unchanged, as Romania's growth, while real, still lags behind Poland's sustained expansion in both volume and diversity of trials.



Info retrieved on 20.09.2025 from https://euclinicaltrials.eu/search-for-clinical-trials/trial-map/

Figure 4. Active clinical trials (Romania vs. Poland, Sept 2025).

Source: CTIS, 2025

- ***Clinical Research Workforce & Academic Training Programs.***

  Romania continues to face a pronounced **shortage of personnel** with expertise in clinical research. The country has **fewer doctors and nurses per capita than the EU average** (Health Innovation Hub, 2024; OECD, 2024, 2023), and this deficit extends directly to clinical research staff. At present, **Romania lacks dedicated academic curricula for clinical research teams**. Training is predominantly acquired **on the job**, with investigators relying on experiential learning rather than structured education in Good Clinical Practice (GCP), trial design, or research management. To address this structural weakness, Romania must prioritize the ***development of academic training programs for clinical research professionals***, integrating such curricula into universities and residency pathways.

  In contrast, **Poland's clinical research workforce is larger, more distributed, and better supported institutionally**. The country has **over 900 trial sites and units** actively engaged in studies (MRA/ ABM, 2023), reflecting a broad base of investigators and support staff. Through initiatives led by the **Medical Research Agency (MRA)**, more than **7,700 professionals (physicians, nurses, coordinators, and other staff)** have received structured training in GCP and trial methodology since 2021 (Kitala et al., 2024; MRA/ ABM, 2023). Furthermore, Poland's **Harvard-affiliated Polish Clinical Scholars Research Training Program** aims to train an additional **500 highly skilled clinical researchers by 2027** (Kitala et al., 2024). Poland has also institutionalized **multiple educational pathways**: for example, **Jagiellonian University in Kraków** offers a **postgraduate diploma in Clinical Trials**, while other universities and private providers offer certifications accessible nationwide. Crucially, the MRA has funded **13 postgraduate programs in biomedical sciences** that explicitly include modules in clinical research, demonstrating a **systemic approach to education and workforce development**. Complementing this, the **Polish Clinical Research Campus in Warsaw** partners with international institutions to deliver advanced training, further strengthening global integration.

  In summary, Poland's academic and professional training ecosystem—spanning physicians, study coordinators, and study nurses—is significantly more mature and

comprehensive than Romania's **still nascent and fragmented efforts**. This systemic investment in human capital has positioned Poland as a regional leader in clinical trial readiness and capacity.

- **Trial Approval & Start Timelines.**

  Under the **EU Clinical Trials Regulation (CTR 536/2014)**, both Romania and Poland are formally bound by a **maximum of 60 days for Part I review** (scientific and regulatory) and an additional **15 days for Part II ethics assessment**, excluding any clock-stops for sponsor responses. In principle, this harmonization ensures comparable timelines across the EU. However, in practice, cross-country differences persist.

  - **Romania**: Historically, Romania has been perceived as **slow and unpredictable in initiating clinical trials**, largely due to administrative bottlenecks in hospitals, protracted contracting processes, and layered approvals. This reputation of a "*history of difficult approval of clinical trials*" has contributed to Romania's relatively low attractiveness for sponsors (Health Innovation Hub, 2024). The recent adoption of the **EU CTIS portal** is expected to streamline procedures and reduce redundancies. As of late 2024, no comprehensive public data on average trial approval or site start-up timelines under the CTR have been released for Romania. Nonetheless, regulatory officials have stated their intention to align national performance with the EU average, suggesting gradual improvement in the near term.
  - **Poland**: Prior to reforms, Poland also faced delays. A multi-country benchmarking study reported that in 2019–2020, the **average time from submission to first patient ranged from 96 to 251 days**, depending on sponsor efficiency and site readiness (INFARMA & POLCRO, 2022). With the establishment of the **Medical Research Agency (ABM)** and subsequent reforms, significant progress has been achieved. Poland's **2022 Clinical Trials Act**, aligned with the EU CTR, has streamlined procedures, standardized ethics operations, and improved transparency. According to **ABM pilot reports**, certain **non-commercial trials were initiated in under 90 days** from authorization to first patient recruitment,

highlighting accelerated pathways for academic-led studies. For commercial industry-sponsored trials, unofficial expert estimates suggest **first-patient-in can now often occur within 120–150 days** for straightforward studies, which is competitive by EU standards.

Comparative Assessment: At present, Poland's regulatory and operational timelines appear **closer to the EU benchmark**, reflecting the effects of targeted governance and investment. Romania, while benefiting from CTR harmonization, may still be **lagging slightly behind** until recent reforms (e.g., streamlined contracting, clarified ethics procedures) are fully implemented. Continued monitoring and transparent publication of approval metrics will be essential for Romania to signal reliability to global sponsors.

- **Digital Recruitment and Decentralized Trial Policies**

  The integration of digital tools for **patient recruitment** and the implementation of remote activities or **decentralized clinical trial (DCT) policies** represent a key area of divergence between Romania and Poland.

  - **Romania**: For many years, Romanian regulations were interpreted as **restricting or even prohibiting public-facing promotion of clinical trials**, which meant that tools widely used in other countries—such as trial-specific social media pages, targeted online outreach to patients with defined conditions, or patient-searchable registries—were largely absent. A notable regulatory shift has, however, taken place. With the full implementation of the **EU Clinical Trials Regulation (CTR 536/2014)** and updated guidance from the National Commission for Bioethics of Medicines and Medical Devices (NCBMMD), **digital recruitment campaigns are now explicitly permitted**, provided that they are **transparent, ethical, and their content is pre-approved by ethics committees**. This step brings Romania closer to EU best practice and opens the door to modern, patient-centered engagement strategies.

    Despite this progress, Romania still **lacks comprehensive digital infrastructure and formal policies on decentralized trials**. As highlighted in expert roundtables, there are not enough **national disease registries** or **integrated electronic medical**

records to enable systematic patient identification (Health Innovation Hub, 2024). Patient data remains fragmented across hospitals (Health Innovation Hub, 2024), some of which still rely on paper records and non-uniform coding systems (parallel use of ICD-10 and local codes), making recruitment inefficient and limiting big data applications in research (Health Innovation Hub, 2024). Furthermore, **official guidance on DCTs** has not yet been issued by the Romanian regulator; remote elements such as telemedicine visits or virtual follow-ups are handled on an ad hoc basis by sponsors and investigators. Similarly, adoption of **eSource and Electronic Data Capture (EDC) systems** remains limited, with only a small number of sites beginning to implement such platforms.

In summary, Romania is only at the early stages of digital integration in clinical research; while discussions within the Innovation Hub suggest that **e-consent and virtual trial components** may be introduced in upcoming strategies, as of 2025 no binding regulations are in place.

- **Poland**: Poland is significantly more advanced in digital integration. The **Medical Research Agency (ABM/MRA)** has established **Regional Digital Medicine Centres (RDMCs)** designed to unify healthcare and research data infrastructures (Kitala et al., 2024). These centers enable, for example, the secure mining of hospital databases to match eligible patients with trial inclusion criteria, thereby **streamlining recruitment and reducing timelines**. In parallel, Poland developed a **national "Patient in Clinical Trials" portal**, coordinated by the MRA, which provides transparent trial listings and information directly accessible to patients (MRA/ABM, 2025, 2023).

On the decentralized trials front, while Poland's regulations still require in-person visits for most interventions, the regulatory authorities have expressed openness to hybrid and remote models. The **ICTD 2023 conference in Warsaw** emphasized decentralized trial methodologies, signalling institutional commitment to DCT adoption (ECRIN, 2023). Polish sites, particularly during COVID-19, successfully piloted **telemedicine consultations** and limited remote monitoring, and the MRA

has since indicated that forthcoming guidelines may formally enable **home nursing visits and electronic consent procedures**. Importantly, Poland's strong e-health infrastructure—such as the universal e-ID system and nationwide adoption of **electronic prescriptions (e-prescriptions)**—provides a robust foundation for further digitalization of trial conduct.

Comparative Assessment: While Romania has only recently begun to align with EU norms on digital recruitment, its fragmented infrastructure, reluctances to adopt eSource and EDC platforms, and lack of formal DCT policies continue to limit competitiveness. Poland, in contrast, is already **integrating e-health with clinical research**, positioning itself to adopt decentralized methods and advanced digital recruitment tools at scale. This gives Poland a **clear competitive advantage**, while Romania will need targeted investments in health IT, standardized registries, and regulatory guidance to bridge the gap.

Diamond Scorecard: Romania vs. Poland in Clinical Research

Scoring: We assess each Diamond factor on a **1–10 scale** (1 = very weak, 10 = very strong relative to international best practices) for how well it supports clinical research competitiveness, based on comparative evidence from the above indicators. Below is a comparative **scorecard** for Romania and Poland on each factor, with scores reflecting the countries' relative strengths as of 2025.

	Romania	Poland	
Factor Conditions (Talent, Infrastructure, Capital)	**6 (Fair / Moderately Supportive)**	**8 (Strong)**	**Romania** - Romania has a large human resource but struggles with physician and nurse shortages which leaves a smaller pool available for research. It lacks dedicated clinical trial centers and has a shortage of research-trained staff. Romania **lacks a nationwide, standardized curriculum or certification pathway** for clinical research professionals. Also, in Romania, the **digitalization of clinical research activities (e.g. usage of eSource) is lacking**. **Poland –**Poland's larger skilled workforce and investments enable over 600 trials annually. The country has built **CTSCs** nationwide to provide state-of-the-art trial infrastructure. Around **900+ trial sites/units** operate across Poland, collectively enrolling tens of thousands of patients. Poland has invested in digital infrastructure, enabling electronic data capture and telemedicine integration in trial. Crucially, Poland has invested in training hundreds of new clinical investigators. Substantial government funding has flowed into research and training programs since 2019, making Poland's talent pipeline very robust. The net effect is that Poland has many experienced principal investigators and study coordinators available **– a competitive advantage** – whereas Romania has very few (the lack of clinical research personnel represents a bottleneck). **This disparity is reflected in each country's ability to host trials**.

Demand Conditions (Patient Pool, Health Needs, Market Demand)	**5 (Average)**	**7 (Good)**	**Romania –**Romania has significant latent demand for clinical trials due to its healthcare needs, but this demand is not yet fully realized. The country's population faces **high unmet medical needs** – for instance, Romania has the worst treatable mortality rate in the EU (255 per 100k vs ~93 EU average) (LAWG, n.d.)., indicating many patients could benefit from new therapies. However, in Romania, this potential has not yet translated into proportional trial activity – partly because **the healthcare system has not actively connected patients to trials**. Patient engagement remains limited: **public awareness of clinical research is low,** and distrust persists (e.g. fear of being treated like "guinea pigs" still needs to be overcome). Furthermore, **limitations in the direct recruitment of patients in clinical trials through all media communication channels** affect the results of the studies (a significant percentage of studies do not achieve their enrollment goals). **Poland –** Poland exhibits strong and growing demand for clinical research. With a **population of ~38 million** and a heavy burden of chronic and serious diseases, Poland has ample candidates for trials. Poland managed to **leverage these needs into concrete demand for trials by creating pathways for patients to access studies**. Public interest in accessing new treatments is high – in 2024, **over 26,000 Polish patients in commercial trials** gained early access to innovative therapies (EURACTIV, 2025) and more than 13,000 patients with rare diseases were slated to enroll in ABM-funded trials (Harvard Medical School, n.d.). Patient awareness and trust in trials have improved due to outreach and education (the Medical Research Agency runs a patient-facing portal and training initiatives). Poland's local pharmaceutical and biotech companies are increasingly sponsoring or collaborating on trials, adding domestic market pull. These conditions create a sophisticated home-demand for clinical research. Nevertheless, some gaps in awareness remain in Poland – e.g. a portion of the public still lacks understanding of trials (EURACTIV, 2025) – but overall demand-side factors are strong.

Related & Supporting Industries (CROs, Labs, Pharma/Biotech ecosystem)	**6 (Fair / Moderately Supportive)**	**8 (Strong)**	**Romania –** Romania's related and supporting industries provide a foundation, but not yet a fully enabling ecosystem. This weaker support infrastructure in Romania is an impediment, whereas Poland's more complete service ecosystem supports its higher trial throughput. Overall, Romania's trials still rely a lot on external support structures, reflected in this moderate score. **Poland –**Poland has a well-established network of supporting industries that bolster its clinical research. These related and supporting industries provide a robust backbone for clinical trials in Poland. Poland scores slightly below the top tier globally due to its still-growing biotech sector, but it remains one of the strongest environments in Eastern Europe.
Firm Strategy, Structure & Rivalry	**5 (Average)**	**7 (Good)**	**Romania –**Asymmetric competition between public and private centers limits the ability to capture the opportunity. However, this landscape is beginning to shift with the emergence of organized SMOs aiming to build a more efficient and scalable private trial ecosystem. In terms of collaboration and clustering, a positive aspect of Romania's clinical research structure is the emerging collaboration among stakeholders. This collaboration is essential in a country trying to scale up its research footprint, as it allows the pooling of knowledge and possibly patients. This score was given, acknowledging the first positive steps from a previously dismal situation. **Poland –** Poland's strategy and structure for clinical research are showing proactive support. Moreover, **institutional rivalry and collaboration** in Poland work hand-in-hand. Many hospitals and universities actively compete to attract sponsored trials – for prestige, funding, and patient benefit – which drives them to improve quality and efficiency. Many institutions have embraced clinical trials as a core activity. Over the past decade, numerous Polish hospitals set up dedicated clinical trial units and research management departments, and they participate in networks to share best practices. At the same time, public-private partnerships are strongly encouraged.

Government (Policy, Regulation, Funding, Support)	**5 (Average)**	**7 (Good)**	**Romania –** Traditionally, Romania's clinical research landscape suffered from poor strategy and organization. Although Romania has aligned itself with the **EU CTR**, regulatory constraints persisted through decisions of local competent authorities that are not aligned with the provisions of the European Regulation. Also, the government structures in Romania have not invested in training programs for clinical research staff. The authorities are beginning to involve private stakeholders (industry working groups, patient organizations) in policymaking. However, these reforms are very recent and have yet to fully change on-the-ground behavior. As of 2025, Romania's regulatory and institutional framework for trials, while better than before, still **lags behind** and the country's low share of EU trials. **Poland – Regulatory efficiency** is high. As a result, Poland's approval and startup timelines have become very competitive. The government made clinical trials a priority with the creation of the **Medical Research Agency (ABM) in 2019**, which coordinates non-commercial trials funding and policy. A clear national strategy guides investments and goals. The MRA also funds formal academic training programs through which ~5000 researchers pass annually. Funding for research and development in Poland is balanced between public and private.
Chance (External Shocks and Unpredictable Events)	**6 (Fair / Moderately Supportive)**	**7 (Good)**	**Romania** -During **COVID-19** trials were disrupted and Romania struggled more than Poland to pivot to digital/decentralized approaches. **EU CTR** (2022) was a "positive shock" that forced harmonization and gave Romania an external push to reform. The **geo-political context**, especially proximity with the war in Ukraine, can be an advantage. Overall, shocks created both setbacks and opportunities, but Romania capitalized only partially. **Poland** – During **COVID-19** trials were initially disrupted, but Poland leveraged the crisis to accelerate regulatory modernization and highlight its patient pool. Enrollment rebounded quickly post-2020. **EU CTR**: Poland adapted rapidly and turned it into an advantage by aligning national law early and building capacity around it. **Geopolitical context**: The war in Ukraine shifted some regional trial activity to Poland (seen as a stable CEE hub), indirectly

			benefiting it. Poland turned chance events into a relative advantage, though shocks still created temporary disruptions.

Comparative Synthesis and Implications

The comparative data provide a clear conclusion: **Poland significantly outperforms Romania across most clinical research metrics**, although Romania has begun to demonstrate incremental improvements. Poland conducts nearly three times as many clinical trials as Romania in absolute terms and has developed a substantially larger pool of trained researchers and accredited trial sites. Its coherent strategy has generated a **self-reinforcing cycle**: **clear governmental vision, efficient regulatory frameworks, motivated institutions, and strong public–private collaboration.** Together, these elements have enabled Poland to reach an environment comparable to that of Western Europe's leaders in clinical trials (MRA/ ABM, 2025, 2023; OECD, 2024).

By contrast, Romania remains near the bottom of the EU both in total trial numbers and in trials per capita. Its **limited workforce capacity**, combined with slower administrative processes, reflects a much weaker baseline. This gap underscores why, despite comparable population and geopolicitical conditions and EU membership, Poland has successfully positioned itself as a **regional clinical research hub**, while Romania is only now beginning to emerge from relative obscurity in the clinical trials field.

Nevertheless, Romania's **trajectory is cautiously optimistic**. The adoption of the EU Clinical Trials Information System (CTIS) and recent administrative reforms have already resulted in an uptick in trial authorizations. If sustained, this momentum could translate into further growth in trial volume and gradual reductions in site start-up timelines.

For Poland, the outcomes of reform are clear: **stable growth in trials, a strong expansion of support infrastructure, and the active participation of tens of thousands of patients**. This demonstrates how ecosystem-level improvements directly translate into public health benefits. By contrast, Romanian patients currently have **fewer opportunities to access innovative therapies through trials**, highlighting what is at stake: bridging this gap could improve not only Romania's competitiveness but also its health outcomes and research visibility (ECRIN, 2023).

One area where both countries face ongoing challenges is the **digital transformation of clinical research**. Poland has a head start, thanks to its investment in **Regional Digital Medicine Centres** and patient trial portals, but all EU member states continue to grapple with the integration of decentralized trial methodologies and health IT. Romania's **lack of interoperable e-health infrastructure** poses a particular risk, as it may be overlooked for cutting-edge decentralized trials requiring robust digital capacity. Addressing this should be a strategic priority.

Conclusion: Porter's Diamond analysis shows that **Poland currently holds markedly stronger competitive advantages** across all dimensions of the model. Poland has built a conducive ecosystem – characterized by a well-trained workforce, robust infrastructure, high levels of patient engagement, strong supporting industries, and a clear pro-research policy framework – which has made it a preferred destination for clinical research in Central and Eastern Europe. Romania, although endowed with substantial inherent potential (large patient needs and decent medical expertise), has historically lacked the enabling environment to leverage these strengths.

Recent reforms suggest that Romania's **Diamond profile may improve in the coming years**, but as of 2025 it remains at a competitive disadvantage relative to Poland. Closing this gap will require **systematic investment in factor conditions** (expanding investigator training, building specialized trial centers, and increasing research funding), **activating domestic demand** (through patient education and stronger engagement of the local pharmaceutical industry), **developing supporting industries** (attracting CROs, improving laboratory infrastructure, joining international research networks), and **strengthening firm strategy and structure** (streamlined regulatory practices, incentives for innovation). Poland's rapid transformation illustrates what can be achieved in a relatively short period through **political will, sustained funding, and coordinated governance**. Within five years, it moved from a middling position to a **top-tier European research hub**. Romania is now at the beginning of a similar journey. The lesson for policymakers and stakeholders in both countries is that **long-term collaboration, investment, and patient-centered policies** are essential to fully realize the potential of their clinical research sectors.

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