REPORT
INDUSTRY CLINICAL TRIALS IN POLAND

Global Environmental Scan and Progress Review Through 2024

INFARMA POLCRO GCPpl Stowarzyszenie na Rzecz Dobrej Praktyki Badań Klinicznych w Polsce

REPORT: Industry Clinical Trials in Poland
Global Environmental Scan and Progress Review Through 2024

Commissioned by:
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Table of Contents

Foreword 4
Executive Summary 7
Introduction 8
Clinical Trials Market in Poland - Global Benchmarking 9
Market share and global trending 9
Socio-economic impact of industry CTs 11
Utilization of Poland by industry sponsors of CTs 13
Patient accessibility to industry clinical trials 15
Participation in development vs. participation in consumption of pharmaceuticals 16
Can Poland continue to defy gravity? 17
Impact of COVID & post-COVID on Industry Clinical Trials 19
COVID-19 trials by region and selected countries 2020-2024 19
Global iCTs 2008-2024 trending - the COVID-impact 21
How Shrinking Biotech Investment Is Shaping Global Clinical Trial Trends 23
Impact of the War in Ukraine 24
Other Factors Impacting Global iCTs: DEI Requirements 26
Assessment of the Impact of Implementation of the New EU CTR 27
Did Brexit insulate the UK from the EU's trouble? 30
Has GDPR played a role in reducing EU's iCT competitiveness? 31
EU's oncology clinical trials and IVDR 32
The China effect 32
Lessons from Spain 34
The clinical trials ecosystem in Spain 34
Spain's decade of clinical trials modernization 34
What can Poland learn from Spain? 36
Growth of Poland's Market Share Stifled? 37
Review of Implementation Status of Recommendations 38
Use of healthcare data to boost clinical trials 39
European Health Data Space (EHDS) regulation 40
National clinical trials strategy imperative 43
Conclusions 44
Glossary of Terms 45
ANNEX 1. Methodology, Data Sources and Model Assumptions 46
Clinical trials market share 46
Patient accessibility to clinical trial sites 46
Participation to consumption ratio 46
Calculation of country-level socioeconomic impact of iCTs 47
References 48
Report Authors 51

Foreword

Today, Poland is at a particular point in the development of the clinical trials sector - a key area for a modern economy based on knowledge, data and innovation. Clinical trials enable patients to access breakthrough treatments or therapies that are not yet available to the general public. They play a vital role in advancing medical knowledge, improving patient care and ultimately saving lives. Clinical trials provide patients with the earliest access to new medicines, up to 5-10 years before they reach the market, and healthcare systems in the European Economic Area gain USD 1-1.5 billion in connection with trial payments and savings on drug costs each year[1].

Clinical trials are the foundation of innovation in the European healthcare sector. It is clinical trials that contribute to building public health security. Innovation, research and development are crucial for economic growth, improving international competitiveness and building a resilient healthcare system. Therefore, they should be seen as a strategic element of Poland's development, both in terms of health and economy. They can be an important pillar of the development model of an economy based on knowledge and innovation, as they are not only a process of testing new medicines, but also a mechanism for transferring innovation, investment and knowledge, which can support the **country's long-term economic development** - provided that a stable, predictable and friendly regulatory and institutional ecosystem is created.

Based on the presented report, industry-led commercial clinical trials (iCT) bring tangible socio-economic benefits to our country. In 2024, the added value resulting from clinical trials amounted to almost USD 2.2 billion, and more than 26,800 Polish patients gained access to modern therapies, an increase compared to 2020. 9,400 high-quality jobs directly related to clinical trials were also created. These figures clearly indicate that the **clinical trial sector** can and should be one of the pillars of Poland's long-term economic strategy.

Despite the positive results in 2024, **Poland's share in the global clinical trials market has stopped growing since 2022** - bringing to a halt the upward trend that had lasted for more than two decades. Poland's situation reflects a wider European problem. According to the 2024 IQVIA report, Europe has lost more than 60,000 patient places in clinical trials in recent years, even though the number of research projects is growing globally. The European Economic Area's share in commercial trials - sponsored by pharmaceutical companies - decreased from 22% in 2013 to 18% in 2018 and to 12% in 2023. As much as 80% of newly initiated research went to China, the US and India, indicating a clear shift in the centre of gravity of global research away from Europe[2]. In the years 2018-2023, Poland remained relatively stable in the number of clinical trials, recording a decrease of 2%, compared to 6% for the EEA as a whole. The above indicates a negative trend that can be reversed by following the examples of other countries, e.g. as indicated in the Spanish report.

Today, in the face of declining EU competitiveness in the research market, geopolitical challenges and a global slowdown in biotechnology investment, Poland has a unique opportunity to respond to these challenges with a long-term strategy. The conclusions from **Enrico Letta's report** "Much More Than a Market" and **Mario Draghi's report**[3] point to the loss of the EU's competitiveness as an innovation centre and confirm the urgent need for action to make Europe the **location of R&D investments again**. Both reports emphasise the need for an effective regulatory system and streamlined processes for arranging and managing multinational clinical trials in the EU. This is essential for positioning the EU as an attractive and competitive location for clinical trials and development.

The recent initiatives of the European Commission - the Biotech Act, the Life Science Strategy, which aim to increase the competitiveness, strategic security and innovation of the European Union in the field of biotechnology and life sciences - are among the responses to these challenges. In turn, increasing the number and quality of clinical trials and accelerating the market uptake of innovations, including through new regulatory approaches and digitisation, are some of the specific objectives.

Taking into account the main findings of the report in the context of the above challenges, it should be emphasised that, especially in the present circumstances, there is a need to create a clinical trials strategy in Poland. It can be seen that simple growth reserves are being exhausted, and the

[1] Assessing the clinical trial ecosystem in Europe Final Report, October 2024, https://efpia.eu/media/3edpooqp/assessing-the-clinical-trial-ecosystem-in-europe.pdf
[2] Assessing the clinical trial ecosystem in Europe Final Report, October 2024, https://efpia.eu/media/3edpooqp/assessing-the-clinical-trial-ecosystem-in-europe.pdf
[3] Much more than market, https://www.consilium.europa.eu/media/ny3j24sm/much-more-than-a-market-report-by-enrico-letta.pdf; The Draghi report on EU competitiveness, https://commission.europa.eu/topics/eu-competitiveness/draghi-report_en

clinical research sector cannot rely solely on its current advantages for Poland to maintain its position. It is necessary to create a strategy similar to that adopted in Spain in December 2024, which is a joint document of several ministries and constitutes a comprehensive plan to strengthen the pharmaceutical sector. The purpose of the strategy is not only to improve public health, but also to strengthen Spain's position as a leader in biomedical research and pharmaceutical production, promoting innovation, the availability of medicines and the sustainability of the healthcare system. The adoption of such a strategy in Poland would also provide an opportunity to actively engage in **re-establishing leadership in clinical trials in the EU**, and through this our country could attract investments in research and production infrastructure, develop clinical trials as a pillar of innovation in the healthcare system and strengthen Poland's position as a regional biotechnology hub.

Michał Byliniak
Director General of INFARMA

Clinical trials are vital for developing new, safe, and effective methods of treating, preventing, and diagnosing illnesses. They also provide patients access to innovative therapies, especially when standard treatments are unavailable because of lack of any approved drug or lack of treatment reimbursement.

The **Clinical Trials Regulation (EU) 536/2014 (CTR)** was enacted in 2014 and aimed to harmonize clinical trial capabilities across Europe and make multi-country applications more streamlined to boost Europe's competitiveness in attracting clinical trials. The CTR aimed simplifying and harmonizing the clinical trial process, as well as improving timelines for regulatory approval, considering Europe had been already losing global market share. Whereas the CTR gave the clinical trial industry a hope for the successful future in 2014, the unexpected long time of its implementation and challenges with CTIS launch already decreased the related enthusiasm. Considering that full implementation of the CTR took over a decade, we all expected that its objective of increasing competitiveness of clinical trials in Europe would be finally accomplished. Instead, European market share has declined throughout 2014-2024.

In contrast and to the detriment of Europe, China launched a series of sweeping reforms starting in 2015 to modernize its regulatory environment. Historically, China, unlike Europe, was not a first-choice country to be included in global clinical trials due to long approval process (one year on average) and a backlog of applications. The "Opinion No. 44" issued in 2015 (so **at the similar time when the European Parliament and the Council passed the CTR**) initiated reforms in China to clear backlogs, improve trial quality, and enhance transparency. Key milestones included but were not limited to: adoption of ICH-GCP in 2017, acceptance of foreign clinical data and removal of site accreditation requirements in 2017-2019, and introduction of a 60-working-day silent approval rule in 2018. And finally in August 2024, a pilot program for optimizing the review and approval of clinical trials was initiated by the National Medical Products Administration (NMPA) for a year to reduce IND approval to 30 working days and begin patient enrollment in three months after China IND approval. Consequently, the number of global clinical trials in China has significantly increased since 2016, and China closely follows the US now, with over 1,000 industry-led trials annually and approximately 20% growth between 2020 and 2024. Number of commercial trials in China is approximately 4.5 and 1.5 times higher now than in 2015 and 2020, respectively, and accounts for a 22% share of global commercial clinical trials.

A top European country - **Spain**, meanwhile, just maintained a steady number of trials, although over the past decade, investment in clinical trials in Spain has risen at an average annual rate of 5.3%. Factors which cause that Spain attracts investment and continuously holds the highest number of commercial trials in Europe may include strong healthcare system, effective CTR implementation, and an effective commercial/ non-commercial clinical trial collaboration model.

Looking at the benchmarked data presented in the report, we have concerns if Europe can fully regain its position in the evolving clinical trials market, especially with the rise of Asian Pacific and Latin American countries market share. However, **Poland** still has potential. In 2024, over 26,800 Polish patients accessed innovative therapies through clinical trials. Yet, stagnant market share since 2022 meant over 3,000 patients missed such opportunities. To remain competitive, Poland must align its regulations with global trends and all stakeholders should collaborate on creating a **robust and well-developed strategy for clinical trials** in Poland. Organizations like POLCRO are ready to support this transition. Timely regulatory updates, new

infrastructure, and international collaboration are essential to ensure Polish patients and researchers benefit from real-time innovation.

Agnieszka Skoczylas
President of POLCRO

The presented report comes at a pivotal moment for the clinical research sector. It coincides with the completion of the transition of projects to the CTIS system, the upcoming revision of the ICH E6 guidelines, and the initial outcomes of the Medical Research Agency's activities. After a period of dynamic growth observed over the past four years, there is now a noticeable slowdown. This signals that the mere implementation of Regulation 536/2014 into national legislation is not sufficient to sustain momentum and competitiveness. Coordinated efforts between the industry and public authorities are essential to ensure that Poland remains an attractive location for conducting clinical trials.

To enhance the Polish market for clinical trials, still several key strategies can be implemented including fostering collaborations between industry players and public authorities to leverage resources and expertise, and promote patient-Centric Approaches. Enhance patient education and awareness about clinical trials to increase participation and trust is pivotal to continuously improve the patient experience in clinical trials.

Data and Technology integration seems crucial to utilized e-solutions (e.g e-consent, components of decentralized trials) and digital tools to optimize trial design, patient recruitment, and data management. Continued and enhanced dialogue between all stakeholders, including industry representatives, public authorities, researchers, and patients can sustain our growth in the clinical research sector, maintain our competitiveness, and continue to provide significant benefits to patients through access to innovative therapies.

Aneta Sitarska-Haber
Vice President GCPpl

Executive Summary

Poland derives very significant societal benefits from industry-sponsored biopharmaceutical clinical trials (iCT): in 2024 alone, the economic value Poland derived from iCTs reached nearly USD 2.2 billion, accounting for a substantial portion of Poland's total R&D investment. The sector also created approximately 9,400 jobs related to iCT and granted access to more than 26,800 Polish patients to novel and cutting-edge experimental therapies in that year alone.

The previous report, released in 2021 covered period through 2020 and recommended implementation of a range of measures, adoption of which was required to achieve stated growth opportunity (1). In this report we evaluate whether Poland remained competitive globally while facing new global challenges: another year of COVID pandemic, the short post-pandemic boom of global clinical trials, followed by a significant reduction of demand for clinical trial activities globally due to shortages in biotech funding. The on-going war in the neighboring Ukraine also presented a unique challenge. In addition, unexpected headwinds came also from the general and continuing decline in EU global competitiveness, which has somewhat ironically accelerated following adoption of the new EU CTR aimed at increasing EU's competitiveness. At the time of writing this report (May 2025) is still too early to evaluate the impact of the looming trade war triggered by the second Trump administration.

Despite the challenges and headwinds, since the last edition of this report (2020), Poland has initially continued to improve in market share ranking, both globally and within Europe. In the previous report, Poland ranked 11th globally and 7th in Europe, whereas it now holds the 9th and 6th positions, respectively.

However, Poland made most of its market share gains during the 2020–2022 period. Since then, its share has remained stagnant, in contrast to major European (Spain) and global (China, South Korea, Australia) competitors, which have continued to expand their market presence. Additionally, other countries such as Taiwan, Brazil, Argentina, and Turkey are rapidly closing the gap to the top 10 global markets with substantial gains of their own.

The adverse socioeconomic impact of this iCT market share stagnation over the past two years has been very significant for Poland: more than 600 R&D jobs have not been created, almost USD 250 million in economic value of R&D investment has been forgone, and more than 3000 patients could not gain access to cutting edge experimental therapies. These significant shortfalls should serve as a wake-up call for the key stakeholders in the country to adopt a set of far-reaching robust measures aimed at reinvigorating interest of clinical trials sponsors in Poland.

Our 2021 report provided a menu of growth-supportive measures, however, it appears that those have been heeded so far, and Poland paid a high socioeconomic price. Absence to act with resolve now would come with an even more significant negative price tag. One of the focus groups should be the new and rapidly growing segment of clinical trials sponsors - Emerging Biopharma (EBP) companies.

Introduction

Since the mid-1990s, Poland—alongside other Central and Eastern European (CEE) countries—has emerged as a significant hub for innovative biopharmaceutical clinical trials (iBPCTs). By 2019, Poland ranked 11th globally in iBPCT market share and recorded the 5th largest global market share gain between 2014 and 2019, following China, Spain, South Korea, and Taiwan (1).

The socioeconomic impact of this growth is substantial. In 2019, iBPCTs generated over USD 1.3 billion in economic value, representing 15% of Poland's total R&D investment. Around 9,000 jobs were directly related to iBPCTs, and over 25,000 Polish patients gained access to cutting-edge experimental therapies that year. Poland also ranked 12th globally in population-adjusted access to experimental treatments and 7th in the industry-country reputation index (1).

Several key factors have propelled Poland and the broader CEE region to this prominent position: higher site productivity compared to established markets, lower patient access to innovative treatment caused by more significant lag between drug approval and its reimbursement, lower overall costs (driven by labor and per-patient efficiency), reduced trial set-up expenses, and a strong reputation for quality. Poland's centralized healthcare system, motivated investigators capable of efficient patient recruitment and retention, and generally lower operational costs have further supported this growth.

However, the report also highlights several challenges where Poland lags behind global peers:

- A significant imbalance between pharmaceutical market share and clinical trial participation (7th largest globally), with nearly a 4x research bias.
- Weak medical research leadership, with Poland ranking 26th in the medical research prominence index, trailing many smaller countries, including Austria or Greece.
- Limited international collaboration in medical research.
- Lack of a national clinical trial infrastructure supported by modern technologies (e.g., EHR data mining)
- Under professionalization of many clinical trial sites
- Absence of government prioritization of iCTs—despite their substantial socioeconomic value.

The 2021 report outlined two potential future scenarios for Poland's iCT market:

1. **Growth Scenario:** A 3.5% annual market share increase from 2021 to 2030, aligning Poland's per capita iCT levels with those of Spain—a benchmark country in our analysis.
2. **Correction Scenario:** A market share decline of approximately 25% over the same period, driven by persistent structural imbalances mentioned earlier.

The difference between these scenarios amounted to an economic impact USD 6.3 billion during 2021 to 2030 period, with a USD 1.3 billion annual impact in 2030 alone.

As a key requirement to achieving the Growth scenario the 2021 report outlined adoption of bold, growth-focused measures aimed at increasing Poland's attractiveness among sponsors of iCTs. The proposed measures included development of nation-wide clinical trial infrastructure powered by technology, national and international promotion of Poland's clinical trial ecosystem, expansion of international research collaborations, as well as targeted financial incentives for sponsors and CROs. The report cautioned that in the absence of such bold growth-focused measures Poland's market share is likely to erode, a fate of the majority of its regional neighbors.

This report assesses whether Poland has managed to maintain its global competitiveness amid a series of recent challenges and opportunities. These include the COVID-19 pandemic, a brief post-pandemic surge in global clinical trial activity, and a subsequent downturn driven by a sharp decline in biotech funding. The ongoing war in neighboring Ukraine has added further complexity. Additionally, Poland has faced unexpected headwinds stemming from the broader, continued erosion of the EU's global competitiveness—an ironic development given that the newly adopted EU Clinical Trials Regulation (CTR), intended to enhance the EU's position, may have inadvertently contributed to this decline. In the final chapter we review implementation status of growth-focused measures implemented in Poland during the 2021-2024 period in support of iCTs.

Clinical Trials Market in Poland – Global Benchmarking

In the following chapters we examine iCT market in Poland across a range of parameters and benchmark Poland against other key global markets covering period 2020-2024.

Market share and global trending

Over the past 30 years, Poland has evolved as a major global player in the industry-sponsored biopharmaceutical clinical trials (iCT) sector. In 2024, Poland with iCT market share[4] of 2.68% ranked 9th globally in market share (Figure 1), maintaining and even improving its strong position among leading clinical trial destinations. Between 2020 and 2024, Poland's absolute iCT market share increased by 0.16 percentage points (Figure 2), representing strongest absolute market share gain in Europe. This translates to 6.2% growth in relative terms (Figure 3). This remarkable expansion places Poland 7th globally in absolute market share gain, ahead of all European peers. In contrast, traditional leaders such as the United States (US) and Germany saw declines, with the US losing 1.72 percentage points and Germany 0.82 percentage points market share. At this point we would also like express a cautionary note that Poland's market share remained stagnant during 2022-24, consequences of which are discussed in the chapter *"Growth of Poland's Market Share Stifled?"*.

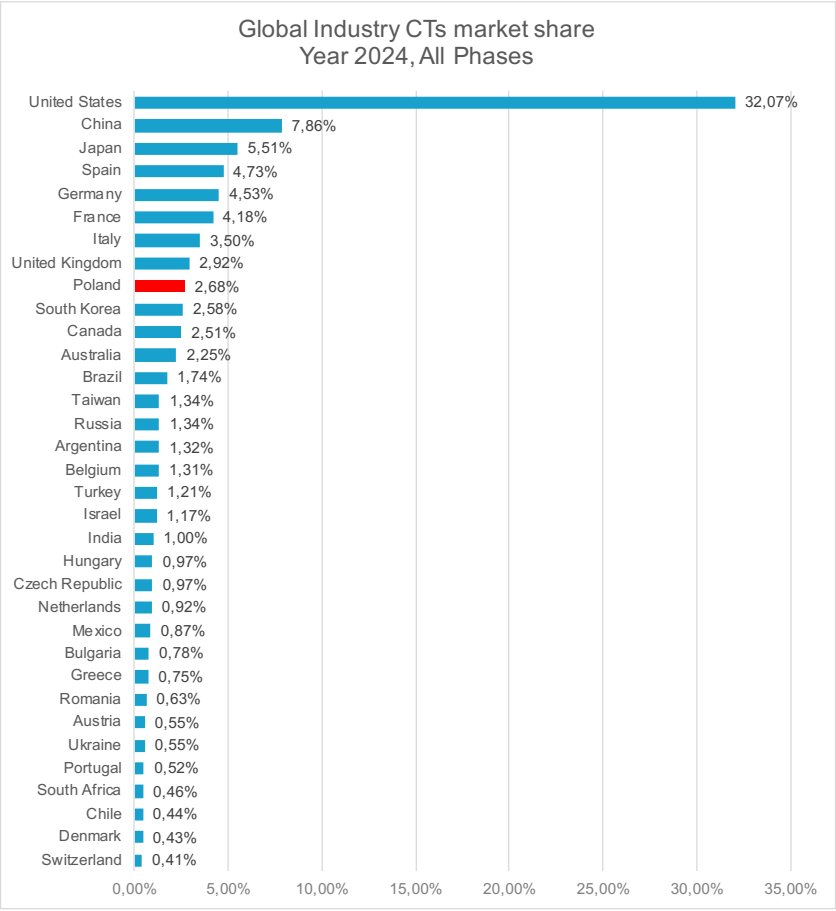


Figure 1. Industry sponsored Ct market share 2024; all phases. Mkt share in countries calculated as % of all global active CT sites in country. Source: LongTaal Informatics - data download 02 March 2025.

[4] For iCT market share definition and method of calculation see ANNEX 1. Methodology, data sources, and model assumptions.

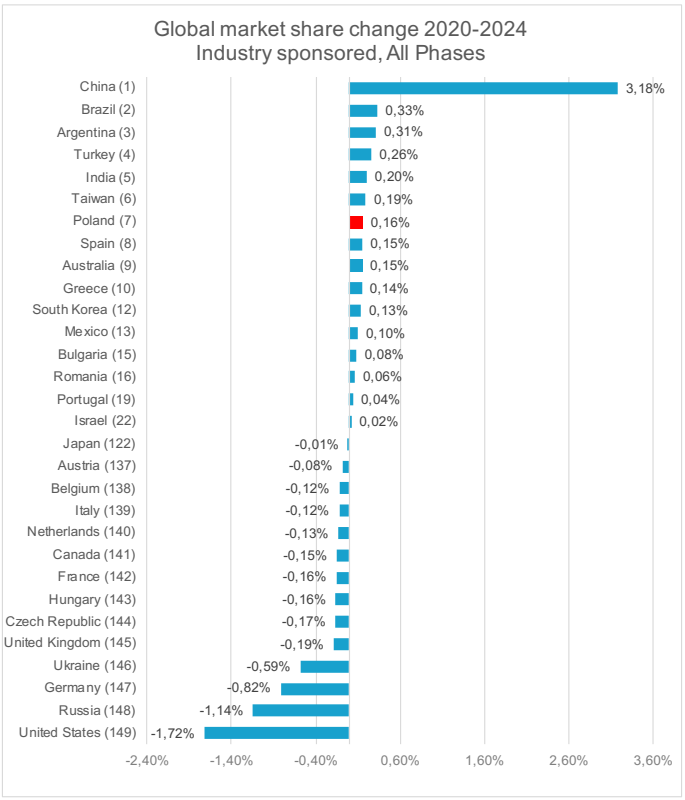


Figure 2. ICT market share trending 2020-2024. Calculated as = market share 2024 - market share 2020. Industry-sponsored CTS all phases = market share based on % of active ICT sites. Filtered to countries with at least 0.5% global market share in 2024. Source: LongTaal Informatics - data download 02 March 2025.

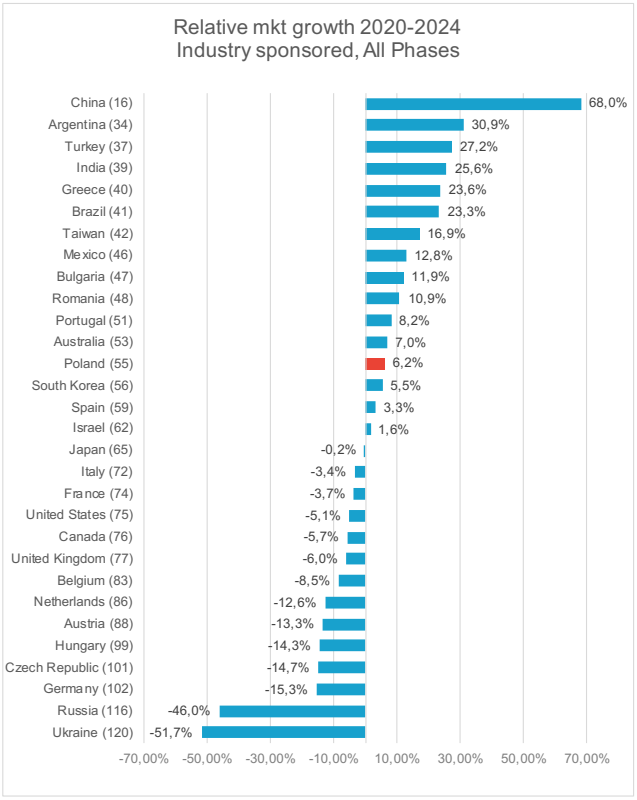
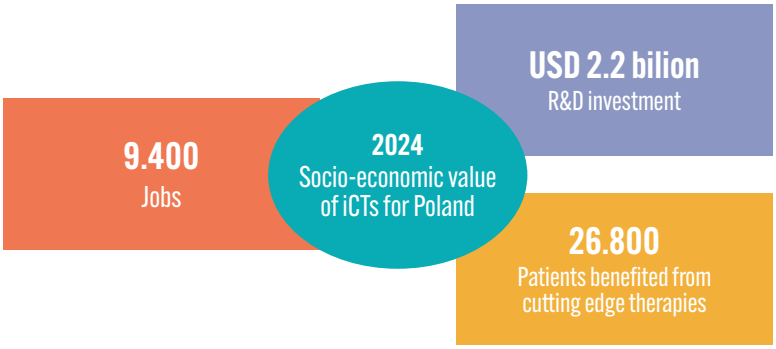


Figure 3. Relative iCT market growth 2020-2024 calculated as = Mkt share 2024/Mkt share 2020 - 1. Industry clinical trials all phases. Filtered to countries with at least 0.5% global market share in 2024. Source: LongTaal Informatics - data download 02 March 2025.

Socio-economic impact of industry CTs

Poland is deriving a very significant economic as well as societal benefits for conduct of industry-sponsored clinical trials (iCTs) in the country: in 2024 alone, the economic value Poland derived from iCTs reached nearly USD 2.2 billion, accounting for a substantial portion of Poland's total R&D investment. The sector also created approximately 9,400 jobs related to iCT and granted access to more than 26,800 Polish patients to novel and cutting-edge experimental therapies (Infographics 1)[5].



Infographics 1. Socioeconomic value of iCTs for Poland. Source: LongTaal Informatics - data download 02 March 2025.

The significance of these figures is best illustrated by evaluating alternative growth scenarios, as shown in Figure 4. Actual iCT market growth in Poland during 2020-2024 for economic value, job creation, and the estimated number of patients receiving advanced experimental therapies is denoted by a solid red line (ANNEX 1. Methodology, data sources, and model assumptions). The alternative growth scenarios are calculated by applying the annual growth rates of EU+ countries (blue dotted line) and CEE countries (yellow dotted line) respectively to the 2020 iCT market figures for Poland.

The embedded table presents a quantification of the cumulative 2020-2024 economic value, job creation, and the estimated number of patients receiving advanced experimental therapies, along with the delta between Actual and Alternative growth scenarios. The results are striking:

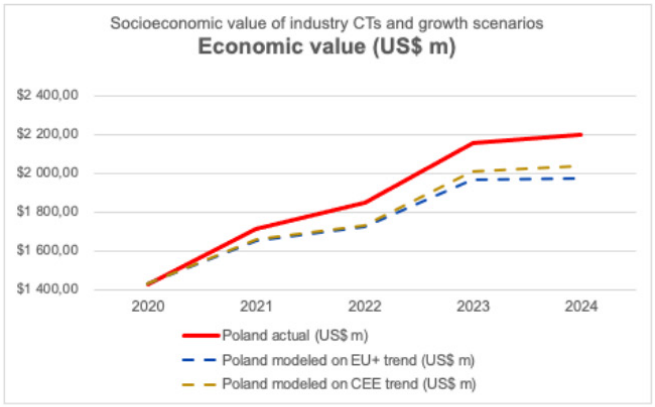
- If Poland's iCT market followed the growth trajectory of the CEE group of countries, it would have lost more than USD 400 million in economic value derived from iCTs during 2020-2024, approximately 700 iCT-related jobs would have been lost/would not have been created, and 6,300 fewer patients in Poland would have received advanced experimental therapies.
- If Poland's iCT market followed the growth trajectory of the EU+ group of countries, it would have lost more than USD 600 million in economic value derived from iCTs during 2020-2024, more than 950 iCT-related jobs would have been lost/would not have been created, and approximately 7,800 fewer patients in Poland would have received advanced experimental therapies.

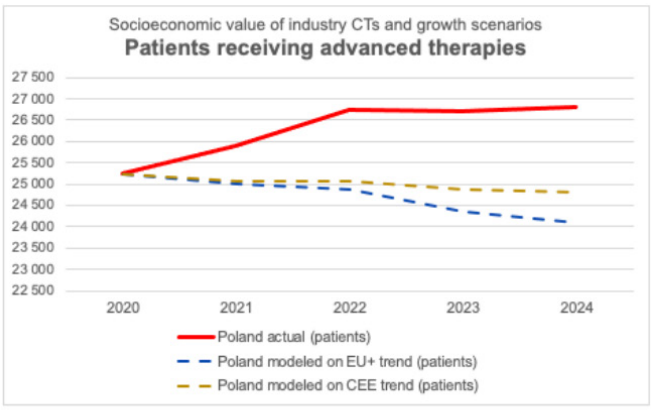
We can only speculate what made Poland different and more resistant to iCT market share loss which impacted all of its neighbors as well as a majority of CEE as well as European countries. We assume that Poland by virtue of being the most populous country with largest pharmaceutical market in CEE benefited longest from the strong trial reputation that the whole CEE region has built over almost twenty years starting from late 90's. Basis of this sound reputation were the centralized healthcare systems with motivated investigators resulting in rapid access to patients, including treatment-naïve patients and/or patients without prior treatment with advanced (e.g. biological) therapies in the course of routine care. Importantly, the CEE region provided reliable data quality and the cost, while rising rapidly over the past 20 years, remained below those in a majority of Western European countries.

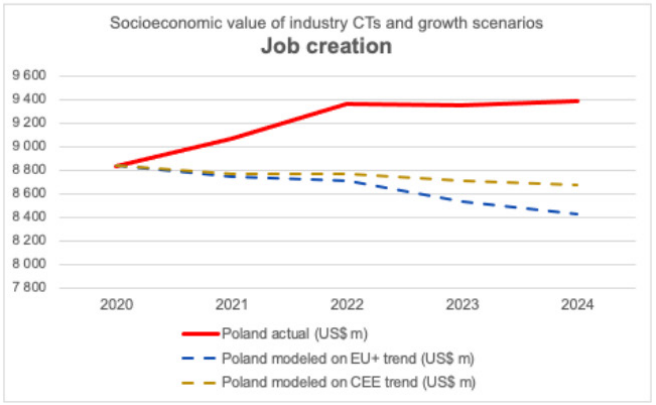
However, the CEE along with Poland with their market share (and the resulting biopharmaceutical R&D investments) significantly exceeding their pharmaceutical market significance (2,3) exposed these markets in growing global, mostly Asian, competition. This exposure and its consequences are discussed in greater detail in Participation in Development vs. Participation in Consumption of Pharmaceuticals - Clinical Trials Reputation Index chapter.

[5] See ANNEX 1. Methodology, data sources, and model assumptions for the methodology of estimating the socioeconomic value.

Therefore, assuming that Poland will continue to grow its market share (as it has done over previous two decades) and the associated societal and economic benefits is risky assumption. Indeed, as our data in the chapter entitled "Growth of Poland's Market Share Stifled?" demonstrate, during 2022-2024 period demonstrate Poland's iCT market share has been stagnating, which resulted in very significant socioeconomic opportunity losses. This is a powerful reminder that without a robust series of governmental and academic interventions, Poland's iCT market growth—along with all associated socio-economic benefits—could easily continue to stagnate or decline, as demonstrated by lessons from neighboring countries.







Economic value	2020	2024	Sum 2020-2024	Delta vs. actual
Poland actual (US$ m)	$1 427	$2 198	$9 343	-
Poland modeled on EU+ trend (US$ m)	$1 427	$1 975	$8 743	-$600
Poland modeled on CEE trend (US$ m)	$1 427	$2 033	$8 860	-$483
Job creation				
Poland actual (jobs)	8 835	9 381	546	-
Poland modeled on EU+ trend (jobs)	8 835	8 429	-405	-951
Poland modeled on CEE trend (jobs)	8 835	8 678	-157	-703
Patients				
Poland actual (patients)	25 242	26 802	131 393	
Poland modeled on EU+ trend (patients)	25 242	24 084	123 564	-7 828
Poland modeled on CEE trend (patients)	25 242	24 794	125 041	-6 352

Figure 4. Socio-economic impact of Industry CTs. The economic value (USD), job creation and number of patients receiving cutting-edge experimental therapies was estimated from iCT market share (see Methods in Annex 1). Source: LongTaal Informatics - data download 02 March 2025. Scenarios are calculated applying the annual growth rates of EU+ countries and CEE countries respectively to the 2020 revenues in Poland. Embedded Table: Quantification of the cumulative economic value, job creation, and number of patients receiving advanced experimental therapies in Poland and delta vs. Growth scenarios shown in the graphs.

Utilization of Poland by industry sponsors of CTs

As Table 1 shows, the largest industry sponsors globally (ranked by the number of CTs across all phases) **remain the dominant sponsors in Poland**. This group of sponsors now accounts for 43% of all active industry CT sites globally and 47% of active sites in Poland, reaffirming Poland's strong integration within global clinical research networks.

Table 1. Top Industry sponsors of iCTs in Poland and Globally (ranked by number of iCTs all phases). Sponsors' share of iCTs and iCT sites in Poland and Globally shown, as well as sponsor's Poland and Global ranking (ranked by number of studies). Source: LongTaal Informatics - data download 02 March 2025.

Rank Poland (studies)	Parent Sponsor	Mkt share Poland (studies)	Mkt share Poland (sites)	Rank Global (studies)	Parent Sponsor	Mkt share Global (studies)	Mkt share Global (sites)
1	AstraZeneca	7,2%	8,3%	1	AstraZeneca	2,7%	8,1%
2	Hoffmann-La Roche	5,9%	5,2%	2	Novartis	2,0%	3,7%
3	Merck Sharp & Dohme LLC	5,8%	5,4%	3	Pfizer	1,6%	3,2%
4	Johnson & Johnson	4,8%	6,6%	4	Merck Sharp & Dohme LLC	1,5%	4,9%
5	Bristol-Myers Squibb	3,5%	2,9%	5	AbbVie	1,5%	4,2%
6	Eli Lilly and Company	3,1%	4,8%	6	Johnson & Johnson	1,4%	4,3%
7	Novartis	3,1%	2,3%	7	Eli Lilly and Company	1,3%	4,1%
8	AbbVie	2,7%	2,7%	8	Hoffmann-La Roche	1,2%	3,7%
9	Sanofi	2,6%	2,0%	9	Bristol-Myers Squibb	1,1%	2,7%
10	GlaxoSmithKline	2,4%	2,4%	10	Sanofi	1,1%	2,4%
11	Pfizer	2,3%	4,0%	11	GlaxoSmithKline	1,0%	2,0%
	Top 11 Subtotal	**43,4%**	**46,6%**			**16,4%**	**43,3%**

However, as seen in Figure 5, there are notable differences in the way top industry sponsors utilize Poland. The majority of the top 30 sponsors (22 companies) allocate a higher share of their global clinical trial portfolio to Poland than the industry average, reinforcing Poland's appeal as a key research hub. At the same time, four of the largest global pharmaceutical companies currently do not have any active studies in Poland, indicating that while Poland is growing in significance, there remain opportunities to further expand engagement with select industry leaders.

Looking at depth of allocation (Figure 6) - the extent to which individual sites in Poland participate in sponsors' trials - there is a significant variation among the top 30 sponsors. About half of them (14 companies) allocate a higher proportion of their total trial sites to Poland compared to the global industry average, highlighting depth of utilization of Poland's sites among these iCT sponsors.

A key shift compared to the last version of this report is the emergence of **Chinese pharmaceutical companies among the top 30 largest industry sponsors globally**, reflecting China's expanding role in international clinical research not only as a recipient iCT market but also as exporter of iCTs. This trend may reshape competitive dynamics across Europe, as more sponsors from Asia-Pacific and from China specifically enter the global clinical trials landscape and their country selection biases may differ from those of traditional, mostly North American and West-European, sponsors.

Additionally, the increase in the number of sponsors conducting a single clinical trial in Poland—from 239 in 2020 to 285 in 2024—suggests a growing presence of **Emerging Biopharma (EBP)** companies. This aligns with global trends, where EBPs have significantly driven the growth in clinical trial initiations over the past decade (4). Poland's robust clinical infrastructure, supportive regulatory environment, and expanding pharmaceutical sector make it an attractive destination for these innovative enterprises.

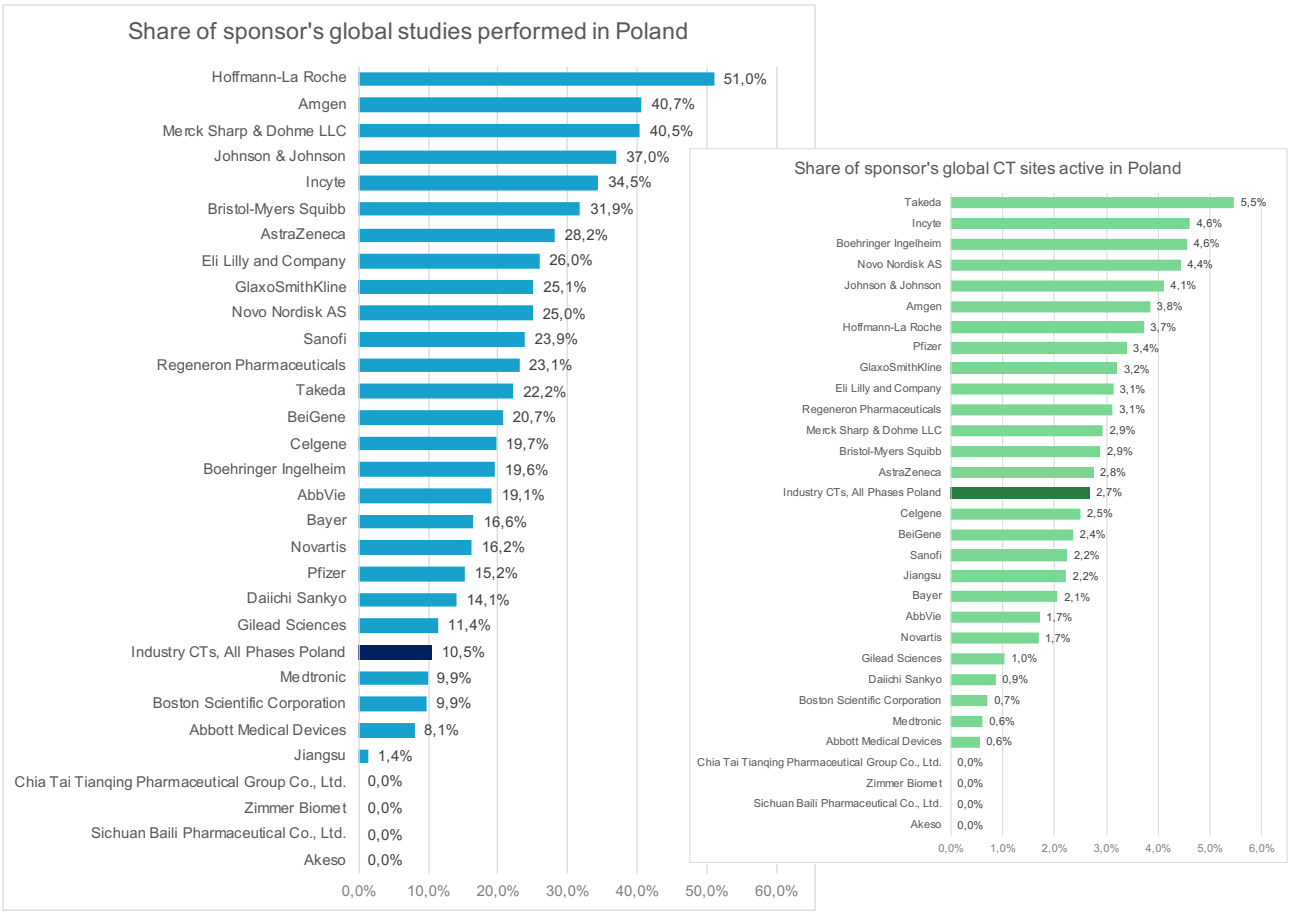


Figure 5. Sponsor-level utilization of iCT market in Poland (based on studies active in 2024): Share of sponsor's global studies performed in Poland (blue bars). Insert: Share of sponsor's global CT sites active in Poland (green bars). Darker shaded bars represent Poland's share of global industry CTs across all phases (2024 data). Source: LongTaal Informatics - data download 02 March 2025.

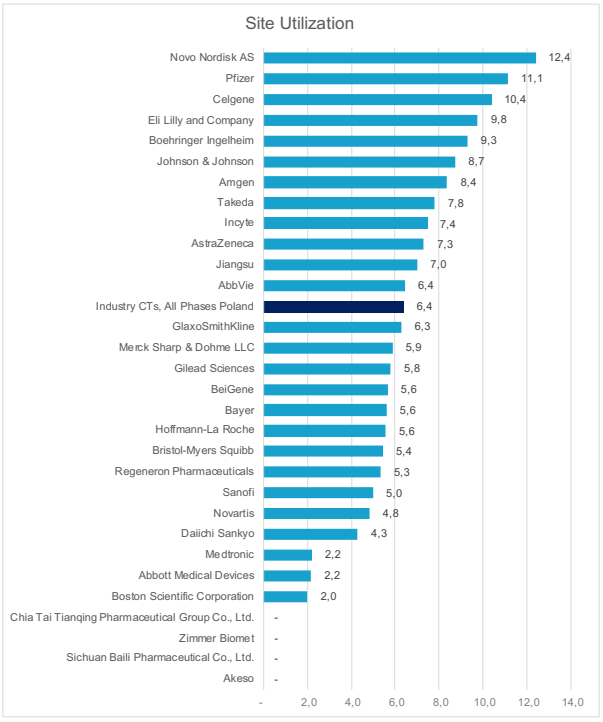


Figure 6. Study level site utilization by CT Sponsor: average number of Active Sites per Study by iCT sponsors in Poland, all Phases (2024 data). Source: LongTaal Informatics - data download 02 March 2025.

Patient accessibility to industry clinical trials

Patient accessibility to clinical trials has been calculated as described in the Methodology, Data Sources, and Model Assumptions chapter of this report. Accessibility to CTs is defined as the number of iCT sites per 1 million population, and expressed relative to the US levels.

As shown in Figure 7, Poland, with 103% accessibility relative to US levels, ranks 7th globally and 6th in Europe, placing it ahead of major research markets such as Germany (57%), France (64%), Italy (71%), and the Netherlands (60%). Poland also outperforms the CEE regional average (excluding Russia and Ukraine), which has an average accessibility of 88%.

Since 2019 Poland made a notable improvement in this parameter: while 2019 iCT Accessibility levels were 63% (1), it increased to 103% by 2023. This increase is a combination of increase of Poland's iCT market size and a decrease of the size of the US market (see Figure 2 and Figure 3).

Given that patients are the principal beneficiaries of novel treatment modalities, this is an important finding that merits further visibility. The results presented in Figure 7 counter concerns that Polish patients may carry an undue burden of pharmaceutical development, as several countries—including Belgium, Israel, and Spain demonstrate even higher accessibility levels. Given the high socioeconomic value of iCT including benefits to patients, high levels of accessibility are not something to fear of but instead governments and medical institutions should be adopting robust measures to increase trial accessibility to their patients.

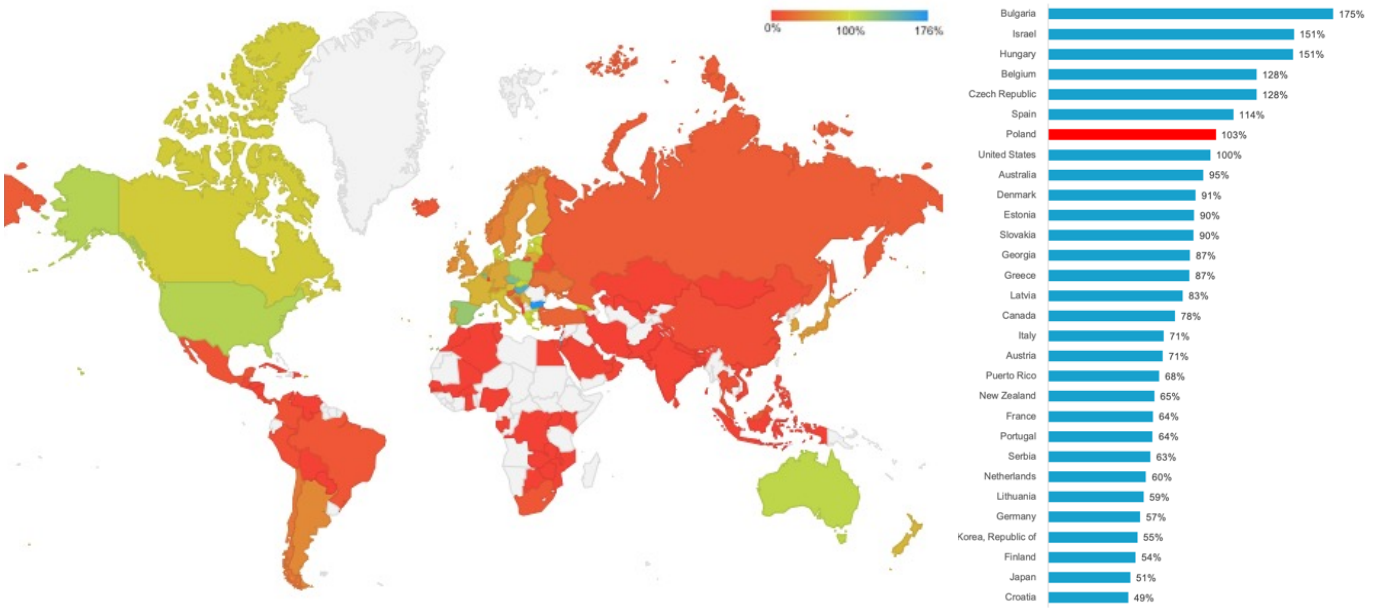


Figure 7. Accessibility to clinical industry clinical trials. calculated as number of clinical trial sites per 1m population relative to the US levels (US = 100%). Insert: Accessibility levels for selected countries (2023 Data). Source: LongTaal Informatics.

Participation in development vs. participation in consumption of pharmaceuticals

A country's market share of global prescription sales is generally a strong predictor of its market share of industry-sponsored clinical trials (iCTs), based on meta-analysis of industry trial allocation patterns (1). This relationship is well established, as exposure of key opinion leaders (KOLs) and prescribers to new therapies in Phase 2 and 3 clinical trials plays a critical role in shaping future prescribing behaviors, ultimately influencing the commercial success of pharmaceutical products post-launch (5) (6). Consequently, optimal return on investment (ROI) dictates that a significant portion of iCT budgets is directed toward markets that are expected to generate high prescription volumes.

For most established pharmaceutical markets, there is an alignment between their share of global iCTs and their share of global prescription sales.

However, a closer examination of country-level patterns reveals distinct clusters of markets based on their level of alignment between clinical trial activity and pharmaceutical consumption:

- **Countries with a research bias:** A select group of smaller pharmaceutical markets—including Bulgaria, Georgia, Hungary, Israel, and Poland—attract a disproportionately high share of iCTs relative to their pharmaceutical market size.
- **Countries with a consumption bias:** At the other extreme are markets where clinical trial activity is disproportionately low compared to pharmaceutical consumption. A majority of countries in the Middle East belong to this group. Indeed, as we have demonstrated elsewhere consumption bias in these countries is so significant that legitimate safety and efficacy concerns have been raised since patients in these countries are taking medications for which safety and efficacy has not been adequately ascertained for their ethnic group (7).

While Accessibility data (see heat-map in Figure 7) may flag potential under-representation in iCTs, they do not account for another essential variable: pharmaceutical consumption. Overlaying pharmaceutical consumption data with iCT participation data enables the identification of countries under-represented in pharmaceutical development (i.e., in iCTs) relative to their pharmaceutical consumption.

To evaluate these imbalances, we introduced the **Participation to Consumption Ratio (PCR)**[6]. Pharmaceutical consumption is expressed as the global market share of prescription medicine sales, while participation in the development of novel biopharmaceutical products is represented by the global share of active iCT sites (iCT market share).

$$PCR = \frac{\text{Industry CT market share (\% of global iCT sites)}}{\text{Share of prescription sales (\% of global sales)}}$$

The PCR index was adapted and modified from the **Participation to Prevalence Ratio (PPR)**, a concept introduced by Saltzman et al. to evaluate proportional representation of specific patient demographics in clinical trials for cell-based therapies (8).

Before discussing the findings, it is essential to provide guidance to the PCR results. A "normal" PCR range, where most countries land, is in the range $\in <0.5; 2>$. $PCR > 3$ indicates countries with research bias. $PCR < 0.3$ indicates countries with consumption bias. Certain countries or regions with $PCR < 0.1$ are likely to be significantly under-represented in the development of novel pharmaceuticals and patients in those countries may be consuming medications whose development did not adequately represent patients with similar ethnic or cultural profiles (3).

[6] As demonstrated previously this index is also reflection of country's reputation among sponsors of iCTs - with high iCT reputation = high research bias, likely based on perceived exceptional value in key aspects of clinical trial execution, including predictable study timelines, ease of site access, professional clinical trial support, investigator motivation, patient recruitment and retention efficiency, and logistical simplicity, sites capability to conduct clinical trials because of logistic aspects and access to specialize equipment or procedures. Conversely, countries that do not consistently deliver on these key factors tend to receive a lower-than-expected share of global clinical trials (high consumption bias = low iCT reputation) (1).

Figure 8 shows global heat-map of the PCR Index, with Poland, along with Israel and several CEE markets among countries with the highest research bias globally. The PCR index for Poland increased from 3.9 in 2019 to 4.5 in 2023. **While this clearly demonstrates endorsement of the iCT market in Poland by industry sponsors of iCTs, the wide and further increasing gap between Poland's share of global R&D clinical trials and the pharmaceutical importance of Poland (share of global pharmaceutical sales), also represents a downward risk if Poland does not continue to consistently outperform its global peers in global iCTs.** This risk is further analyzed in the next chapter.

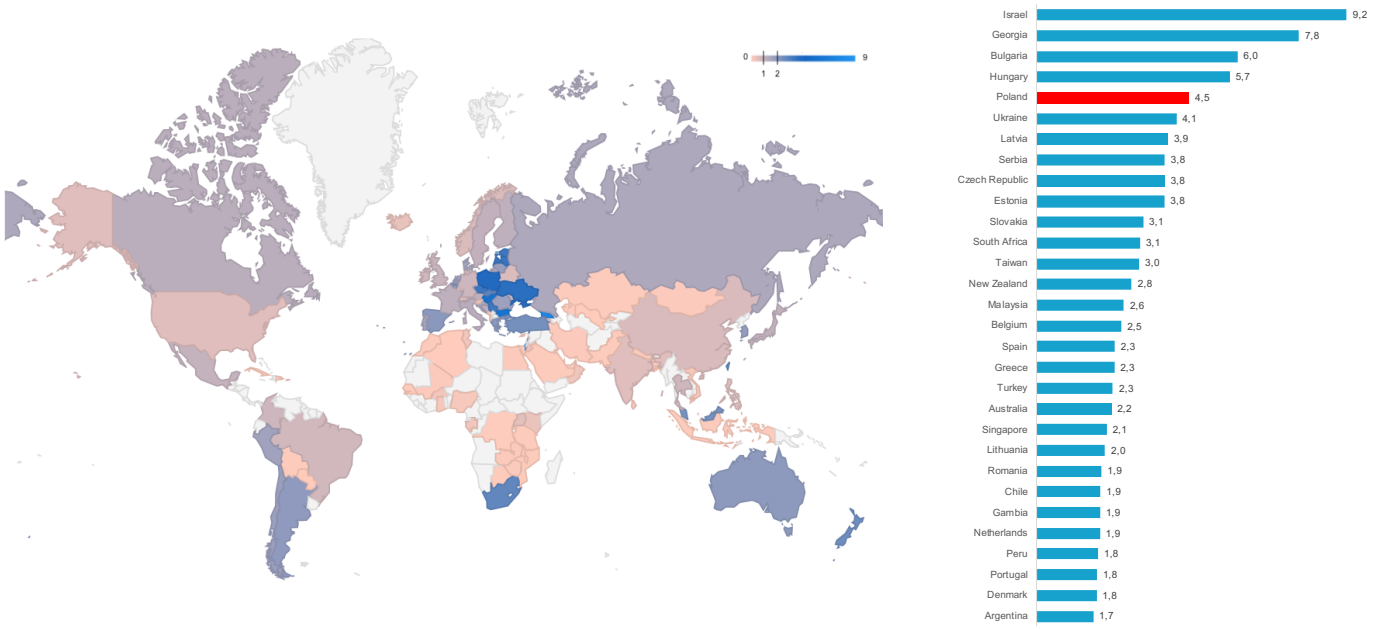


Figure 8. Participation in Development vs. Participation in Consumption of Pharmaceuticals - PCR index = Industry CT market share/Pharma sales market share. Insert: countries with highest PCR (highest research bias). 2023 data. Source: LongTaal Informatics.

Can Poland continue to defy gravity?

To fully appreciate the unique position of Poland, we have analyzed Poland's iCT market share relative to its pharmaceutical sales share alongside the trends across CEE markets[7] (Figure 9). In our previous report we reported the first signs of decline of the iCT market across CEE (starting from 2015), and as the data in Figure 9 show the decline of the CEE iCT market share continued during 2019-2023. However, such regional decline is not an unexpected correction, as the clinical trial allocations in the region have been progressively aligning more closely with the region's pharmaceutical market significance (i.e. global pharmaceutical market share).

Poland, however, continues to defy this broader regional pattern, maintaining a higher-than-expected allocation of global iCTs relative to its pharmaceutical market share (Figure 9).

The key question remains: can Poland sustain and further build on its strong reputation in iCTs, or will it eventually experience a correction, bringing its clinical trial share closer to its pharmaceutical sales share? The difference between these two scenarios is estimated to exceed USD 1.5 billion (expressed at 2024 values), demonstrating the magnitude of the adverse annual financial impact of such market adjustment.

This report revisits and updates recommendations from the previous report (1) to mitigate such risks and sustain Poland's position as a key global player in clinical research. As emphasized in this chapter's title, Poland continues boxing above its weight class in the global clinical trial market,

[7] In our previous report we compared Poland's market share trending in terms of iCT market share and pharmaceutical market market share relative to those of CEE. In the Central and Eastern European grouping of countries in 2019 we have included also Russia and Ukraine. We have devoted a separate chapter in this report focused entirely on the impact of the on-going war on iCT markets in these countries, thus in this report we define core CEE as a grouping of the following countries: Albania, Bosnia and Herzegovina, Bulgaria, Croatia, Czech Republic, Estonia, Hungary, Latvia, Lithuania, Moldova, Republic of Montenegro, Poland, Romania, Serbia, Slovakia, and Slovenia.

benefiting—historically alongside other CEE countries—from proximity to major European pharmaceutical hubs, centralized healthcare systems with broad patient access, and a strong base of motivated investigators.

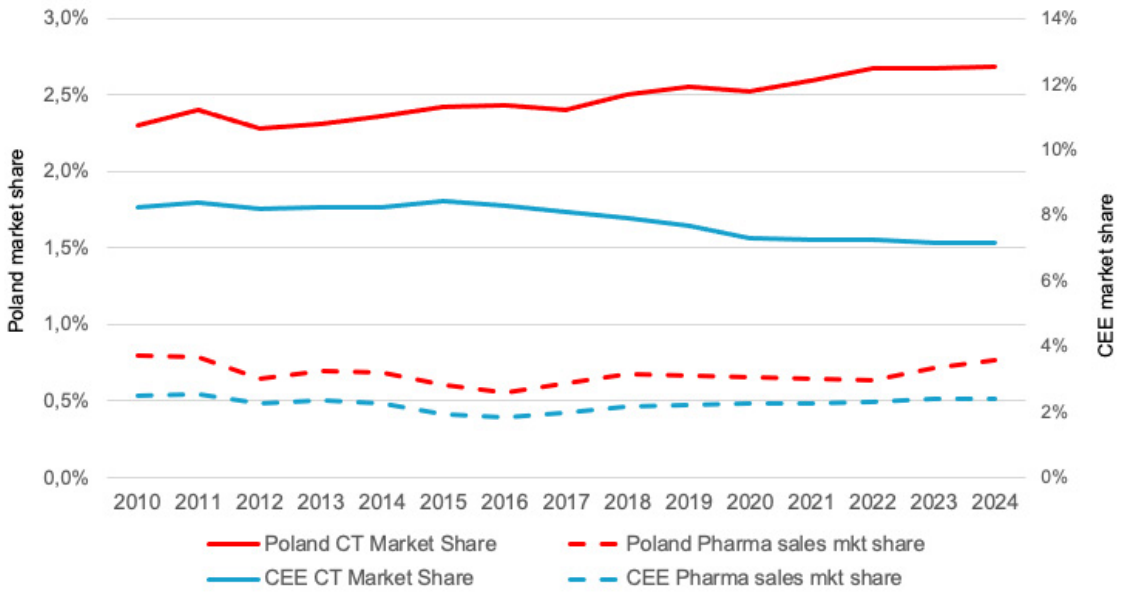


Figure 9. Comparison of Industry CT market share and Pharmaceutical sales market share trending 2010-2024 in CEE (Blue lines) and Poland (Red lines). Source: LongTaal Informatics - data download 02 March 2025.

Meanwhile, global market dynamics continue to shift. A growing number of "pharmerging" countries—such as China, South Korea, Turkey, Malaysia and most recently Saudi Arabia —are rapidly expanding their clinical trial footprint, while traditional pharma markets are implementing targeted policies to retain or regain their share of clinical trials [6][7](11)(12).

For Poland to continue securing a strong share of global clinical trials and their associated economic and societal benefits, it must remain focused on:

- Ensuring predictable and expedited study start-up processes,
- Providing access to a broad and well-equipped network of clinical trial sites,
- Enhancing professional support services for clinical trial execution,
- Maintaining a high level of investigator engagement and patient recruitment efficiency,
- Streamlining trial logistics, maintaining cost competitiveness, and ensuring trusted data quality.

Lack of ability to demonstrate value across majority of these parameters would almost inevitably lead to a loss of Poland's iCT market share, which has already impacted most other CEE markets.

However, if Poland is set to achieve its full potential it will not be sufficient to just retain status quo, or continue delivering trials predictably, it will need to introduce additional attractors to sponsors of clinical trials, detailed in the Recommendations chapter of this report.

Impact of COVID & post-COVID on Industry Clinical Trials

The global pandemic of COVID-19, which based on WHO criteria lasted from 30 January 2020 - 5 May 2023 (13), resulted initially in major disruptions to the global clinical trials. However, in the later stages of pandemic[8] and during the several months after the pandemic formally ended, provided a significant boost to global clinical trial activities (14) due to the confluence of the following factors:

- Delivery of COVID-19 trials (both vaccines and therapeutics)
- Restart of trials put on hold or those not submitted or initiated during 2020 and 2021
- Initiation of new trials of compounds which matured to clinical stage by 2021-23.

COVID-19 trials by region and selected countries 2020-2024

Assessment of global footprint of commercial COVID-19 trials (both vaccines and therapeutics) (Table 2 and Table 3) reveals the following facts about these trials:

- During the first year of COVID-19 pandemic – 2020 - 362 new COVID trials at more than 4000 sites were registered, which represented more than 7% of all new trials and almost 5% of all new sites. In terms of trial activities during the first pandemic year these percentages were significantly higher, since a vast majority of all new non-COVID trials was put on hold and not initiated. This topic is discussed in more detail in the chapter Global iCTs 2008-2024 Trending – COVID-impact below.
- The geographic distribution of COVID trials and sites did not mirror the footprint of non-COVID commercial clinical trials:
  - Not surprisingly, given the funding by the US government for vaccine development- Operation Warp Speed (15) during 2020 the vast share of COVID trials and sites were located in the US (46% of trials and more than 50% of global sites)
  - US was followed by EU (19% of trials and 12% of global sites).
  - Leading countries in Europe during 2020 were UK (7.5% trials, 3% sites), Germany (6% trials, 2% sites) and Spain (7% trials, 3% sites), which is not surprising given the strong pharmaceutical R&D bases in these countries.
  - Somewhat surprising was the high COVID trial allocation in Russia (8% of global trials and almost 6% of global during 2020).
  - Poland, along with the majority of CEE countries, was underrepresented in global COVID development (1% of trials and 0.5% of global sites), not only during 2020 but throughout the pandemic.
- Almost as rapidly as the new COVID trials emerged they disappeared from the development pipeline: by 2023 the volume of new trials decreased 74% and of sites almost 80%.

[8] In the US the elective healthcare resumed in most areas by mid-2021, while backlogs and staffing shortages continued, across Europe some elective procedures remained delayed until late 2021 (16).

Table 2. Industry-sponsored covid-19 trials (vaccines and therapeutics). Absolute number and share of global covid19 trials and sites by region and selected countries. Source: LongTaal Informatics - data download 02 March 2025.

	2020				2021				2022				2023				2024			
	New Trials	% Global	New Sites	% Global	New Trials	% Global	New Sites	% Global	New Trials	% Global	New Sites	% Global	New Trials	% Global	New Sites	% Global	New Trials	% Global	New Sites	% Global
North America	167	46.1%	2,229	52.5%	95	33.1%	975	33.2%	50	24.4%	972	45.7%	39	41.9%	743	77.8%	24	55.8%	335	67.3%
United States	161	44.5%	2,204	52.0%	90	31.4%	961	32.7%	48	23.4%	946	44.5%	38	40.9%	726	76.0%	23	53.5%	329	66.1%
Canada	12	3.3%	25	0.6%	7	2.4%	14	0.5%	6	2.9%	26	1.2%	2	2.2%	17	1.8%	1	2.3%	6	1.2%
Australia/NZ	9	2.5%	24	0.6%	8	2.8%	33	1.1%	12	5.9%	108	5.1%	3	3.2%	7	0.7%	4	9.3%	82	16.5%
Asia	78	21.5%	294	6.9%	107	37.3%	512	17.4%	94	45.9%	355	16.7%	42	45.2%	122	12.8%	11	25.6%	56	11.2%
Japan	14	3.9%	69	1.6%	15	5.2%	117	4.0%	3	1.5%	20	0.9%	3	3.2%	7	0.7%	2	4.7%	27	5.4%
China	21	5.8%	22	0.5%	46	16.0%	76	2.6%	44	21.5%	116	5.5%	26	28.0%	51	5.3%	5	11.6%	5	1.0%
India	20	5.5%	100	2.4%	8	2.8%	54	1.8%	8	3.9%	62	2.9%	1	1.1%	5	0.5%	-	0.0%	-	0.0%
South Korea	11	3.0%	35	0.8%	12	4.2%	103	3.5%	4	2.0%	14	0.7%	3	3.2%	15	1.6%	2	4.7%	12	2.4%
EU (per 2025)	68	18.8%	504	11.9%	48	16.7%	421	14.3%	27	13.2%	258	12.1%	2	2.2%	16	1.7%	2	4.7%	2	0.4%
Western Europe	79	21.8%	595	14.0%	50	17.4%	361	12.3%	31	15.1%	234	11.0%	4	4.3%	63	6.6%	2	4.7%	2	0.4%
Germany	23	6.4%	80	1.9%	10	3.5%	38	1.3%	5	2.4%	22	1.0%	1	1.1%	8	0.8%	1	2.3%	1	0.2%
United Kingdom	27	7.5%	132	3.1%	13	4.5%	82	2.8%	12	5.9%	39	1.8%	2	2.2%	46	4.8%	-	0.0%	-	0.0%
Spain	25	6.9%	142	3.3%	18	6.3%	96	3.3%	16	7.8%	82	3.9%	1	1.1%	4	0.4%	-	0.0%	-	0.0%
CEE	45	12.4%	348	8.2%	35	12.2%	406	13.8%	16	7.8%	151	7.1%	2	2.2%	10	1.0%	1	2.3%	1	0.2%
Poland	4	1.1%	22	0.5%	8	2.8%	37	1.3%	2	1.0%	3	0.1%	-	0.0%	-	0.0%	-	0.0%	-	0.0%
Bulgaria	2	0.6%	4	0.1%	6	2.1%	54	1.8%	3	1.5%	15	0.7%	-	0.0%	-	0.0%	-	0.0%	-	0.0%
Czech Republic	-	0.0%	-	0.0%	5	1.7%	14	0.5%	-	0.0%	-	0.0%	-	0.0%	-	0.0%	-	0.0%	-	0.0%
Hungary	5	1.4%	13	0.3%	5	1.7%	18	0.6%	3	1.5%	8	0.4%	-	0.0%	-	0.0%	-	0.0%	-	0.0%
Romania	4	1.1%	9	0.2%	4	1.4%	18	0.6%	3	1.5%	13	0.6%	-	0.0%	-	0.0%	-	0.0%	-	0.0%
Slovakia	-	0.0%	-	0.0%	-	0.0%	-	0.0%	2	1.0%	17	0.8%	-	0.0%	-	0.0%	-	0.0%	-	0.0%
Russia	30	8.3%	239	5.6%	15	5.2%	168	5.7%	5	2.4%	78	3.7%	1	1.1%	6	0.6%	1	2.3%	1	0.2%
Ukraine	8	2.2%	53	1.2%	9	3.1%	83	2.8%	1	0.5%	3	0.1%	1	1.1%	4	0.4%	-	0.0%	-	0.0%
Latin America	49	13.5%	551	13.0%	41	14.3%	409	13.9%	21	10.2%	188	8.8%	4	4.3%	4	0.4%	3	7.0%	8	1.6%
MEA	39	10.8%	196	4.6%	45	15.7%	243	8.3%	27	13.2%	118	5.6%	3	3.2%	6	0.6%	3	7.0%	14	2.8%
Total	**362**	**100.0%**	**4,242**	**100.0%**	**287**	**100.0%**	**2,940**	**100.0%**	**205**	**100.0%**	**2,126**	**100.0%**	**93**	**100.0%**	**955**	**100.0%**	**43**	**100.0%**	**498**	**100.0%**

Table 3. Industry-sponsored covid-19 trials (vaccines and therapeutics). Percentage of covid19 trials and sites from all new trials and sites. Source: LongTaal Informatics - data download 02 March 2025.

% COVID19 new trials & new sites from ALL new trials & new sites										
	2020		2021		2022		2023		2024	
	% New Trials	% New Sites	% New Trials	% New Sites	% New Trials	% New Sites	% New Trials	% New Sites	% New Trials	% New Sites
North America	**6.4%**	**6.9%**	**3.1%**	**2.6%**	**1.7%**	**2.7%**	**1.4%**	**2.2%**	**0.9%**	**1.3%**
United States	6.4%	7.2%	3.1%	2.8%	1.7%	2.8%	1.4%	2.3%	0.9%	1.3%
Canada	2.6%	1.4%	1.1%	0.5%	1.1%	1.2%	0.3%	0.7%	0.2%	0.3%
Australia/NZ	**1.8%**	**1.2%**	**1.4%**	**1.4%**	**2.2%**	**4.9%**	**0.6%**	**0.3%**	**0.7%**	**4.3%**
Asia	**4.7%**	**1.7%**	**4.8%**	**2.5%**	**4.6%**	**1.9%**	**1.9%**	**0.6%**	**0.6%**	**0.4%**
Japan	3.7%	1.2%	3.3%	2.0%	0.8%	0.4%	0.8%	0.2%	0.6%	0.8%
China	2.6%	0.4%	3.8%	0.9%	3.7%	1.4%	1.9%	0.5%	0.4%	0.1%
India	16.0%	12.4%	5.1%	4.6%	4.9%	5.5%	0.6%	0.4%	0.0%	0.0%
South Korea	2.3%	1.6%	2.2%	3.8%	0.8%	0.6%	0.6%	0.6%	0.5%	0.7%
EU (per 2025)	**4.6%**	**2.1%**	**2.6%**	**1.5%**	**1.5%**	**0.9%**	**0.1%**	**0.1%**	**0.2%**	**0.0%**
Western Europe	**5.0%**	**2.9%**	**2.5%**	**1.4%**	**1.7%**	**1.0%**	**0.2%**	**0.3%**	**0.1%**	**0.0%**
Germany	3.6%	2.0%	1.3%	0.9%	0.7%	0.5%	0.1%	0.2%	0.2%	0.0%
United Kingdom	4.8%	6.0%	1.7%	2.8%	1.8%	1.4%	0.3%	1.7%	0.0%	0.0%
Spain	4.1%	3.9%	2.3%	2.0%	2.2%	1.8%	0.1%	0.1%	0.0%	0.0%
CEE	**7.1%**	**3.7%**	**4.1%**	**3.9%**	**2.2%**	**1.8%**	**0.3%**	**0.1%**	**0.2%**	**0.0%**
Poland	1.2%	1.0%	1.6%	1.2%	0.5%	0.1%	0.0%	0.0%	0.0%	0.0%
Bulgaria	1.6%	0.6%	4.3%	6.2%	2.0%	1.6%	0.0%	0.0%	0.0%	0.0%
Czech Republic	0.0%	0.0%	2.0%	1.4%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Hungary	2.5%	1.4%	2.1%	1.8%	1.5%	0.9%	0.0%	0.0%	0.0%	0.0%
Romania	5.3%	2.2%	3.9%	3.6%	2.6%	2.0%	0.0%	0.0%	0.0%	0.0%
Slovakia	0.0%	0.0%	0.0%	0.0%	2.6%	5.0%	0.0%	0.0%	0.0%	0.0%
Russia	11.0%	10.2%	6.3%	10.4%	5.2%	12.8%	1.5%	0.7%	3.1%	0.3%
Ukraine	6.0%	5.8%	7.6%	10.5%	3.4%	1.9%	7.1%	5.6%	0.0%	0.0%
Latin America	**11.8%**	**14.0%**	**8.4%**	**9.2%**	**4.5%**	**3.9%**	**0.9%**	**0.1%**	**0.8%**	**0.2%**
MEA	**8.9%**	**7.6%**	**8.4%**	**7.5%**	**5.4%**	**4.1%**	**0.6%**	**0.2%**	**0.9%**	**0.8%**
Total	**7.1%**	**4.8%**	**4.5%**	**2.8%**	**3.3%**	**2.2%**	**1.6%**	**1.0%**	**0.8%**	**0.7%**

Global iCTs 2008-2024 trending - the COVID-impact

During the first year of COVID there were major disruptions to the global clinical trials due to stay home mandates, travel restrictions, and restriction of a majority of healthcare services (14,16). In response to these restrictions sponsors of clinical trials have halted new submissions of almost a majority of non-COVID trials, and halted site initiations, and largely paused recruitment of new patients in non-COVID trials. Monitoring of on-going trials with active patients continued mostly remotely.

This reduction of trial activities during the first year of pandemic was to a certain degree offset by the new COVID trials, which in 2020 represented more than 7% of all new registered trials (Table 3) and it caused a spike of newly registered trials during 2020-2023 period (Figure 10 a, b). In terms of a real clinical trials activity the impact of COVID trials was much more impactful, given that during 2020 and much of 2021 most non-COVID trials activities were significantly reduced and/or paused. We attempted to model the real activity impact in terms of site initiations during the COVID pandemic (Figure 10 d), using the following assumptions:

- Percentage of newly registered sites, those registered in the year of assessment and those registered but not initiated during the previous year(s), initiated during the assessment year:

	2020	2021	2022	2023	2024
Registration / Initiation conversion rate*	**15%**	**35%**	**90%**	**95%**	**100%**

*Assumptions: conversion rate pre-2020 was ~ 100%, conversion rate of all COVID trials was 100%.

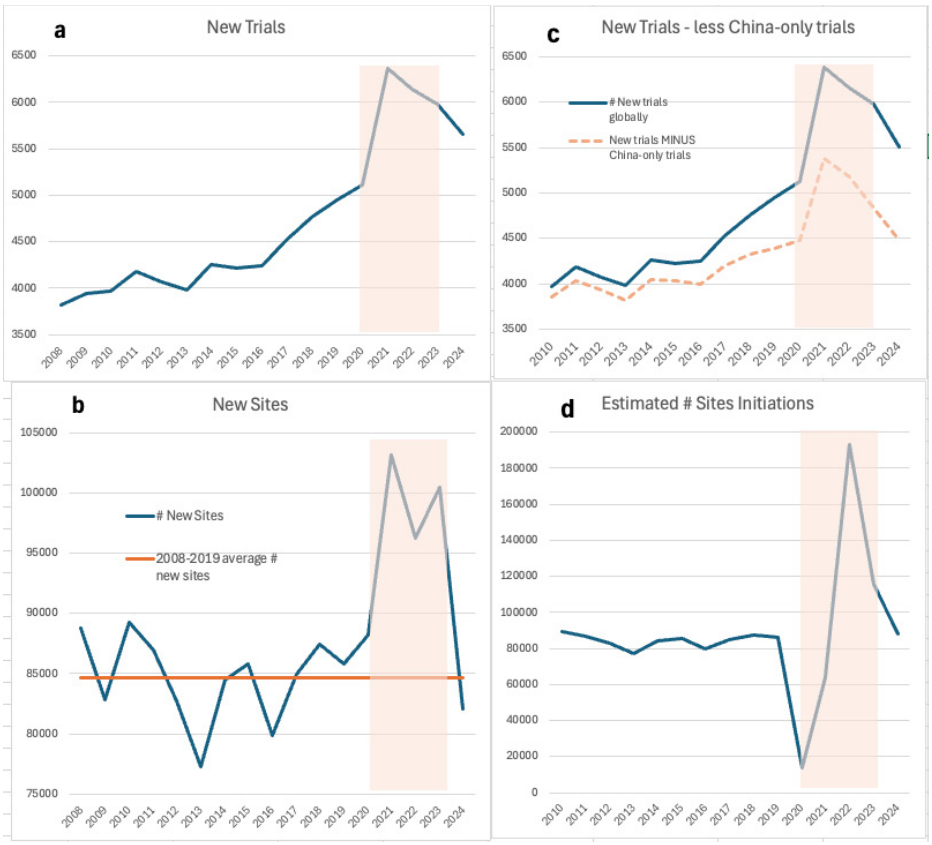


Figure 10. Global iCT trending 2008-2024 (a: new trials and b: new sites) - shaded is period impacted by covid. c: new trials trending - effect of exclusion of China-only trials (shaded red line). d: estimated site initiations - covid impact. Source: LongTaal Informatics - data download 02 March 2025.

The data in Figure 10 also reveal not only the COVID iCT spike but also the post-COVID decline (Figure 10 a, b, d). Noteworthy is that during 2024, the first full post-pandemic year the number of newly registered sites dropped below the 2008-2019 average (Figure 10 b).

These rapid and substantial changes in terms of iCT activities caused massive resourcing challenges: over-resourcing during 2020 (in organizations not running COVID trials), to massive incremental resourcing need during 2021-2023 or substantial over-resourcing in 2024. Crucially, the post-COVID resourcing need appears to be below or even well-below the historical the pre-pandemic levels, most likely a result of the following three factors:

1. Traditional model of regular on-site monitoring visits every 4-6 weeks, typical during the pre-pandemic period, has been replaced by a composite model of remote sites monitoring combined with directed visits (RBM model), which led to reduced resourcing need for monitoring for the same number of sites.
2. However, since the new sites registrations dropped below pre-pandemic levels (Figure 10 b) the number of sites declined below pre-pandemic levels which further reduced the resourcing need.
3. There is also a third phenomenon at play, which has not been described previously, i.e. the rapidly growing and increasingly impactful on a global scale segment of China-only trials (see The China Effect). When correcting the global registrations of new trials for China-only trials (Figure 10 c) the apparent sustained and substantial growth of new trials during much of 2008-2024 looks much less significant, which a near-zero net increase of new ex-China trials pre-COVID and post-COVID (Figure 10 c, dotted line). Correction for China-only trials further amplifies the pre-COVID vs post COVID decline in ex-China new sites registrations. This led to yet additional reduction of monitoring capacity demand.

The combined result of the three factors described above led to an unprecedented oversupply of monitoring as well clinical project management capacity globally, which manifests itself in the number of CRAs and clinical project managers searching for jobs and minimal to job openings for these positions at large CROs and pharma. This contrasts sharply with more than 20 pre-pandemic years of continuing seemingly unsatiable demand for new CRAs and clinical project managers / clinical leads and war on talent among the CROs.

How Shrinking Biotech Investment Is Shaping Global Clinical Trial Trends

As described in the previous chapter, by 2024 the volume of iCT activities started to slow down noticeably. Beyond the factors related to decline of activities after the COVID-related boom, there was one significant factor which has been adversely impacting industry trial pipeline: shortages in biotech funding caused by high yields in low-risk financial products: saving accounts, government bonds.

This resulted in outflow of investment money to biotechnology companies (biotech) from venture capital (VC) or from private equity firms (PE). Since biotech is the key breeding ground for pharmaceutical innovation on which big pharma pipeline depends significantly, this adversely impacted the entire industry pipeline. With the continuing reductions of the borrowing rates of the US treasury as well as the ECB during much of 2024, and buoyant stock market, it looked like 2025 may be a turning point for biotech. The prospect of this however is uncertain at the time of writing of this report (March 2025) since stock markets have entered into significant decline as investors appear concerned about the economic impact of the ongoing or still looming tariffs and trade wars the new US administration has engaged with much of the developed world, uncertain prospects of a cease fire in Ukraine and in Gaza, and ever more likely prospect of a recession in the US. With all these head winds many investors are opting to park their investments in safer harbors, such as commodities (particularly gold) or real estate.

At the time of completion of this report (May 2025) another significant adverse factor with a likely negative downstream impact on biopharmaceutical innovation emerged - the decision of the second Trump administration to freeze USD billions in federal funding of biomedical research (17). This decision is likely to have a very significant long-term negative impact on the development of new medicines, since government-funded research has been demonstrated to be essential for biomedical innovation: every new drug approved from 2010-2019 benefited from US government (NIH) funding (18).

The unprecedented confluence of the anemic private investment funding of the biotech industry, coupled with freezing of billions in government biomedical research funding is likely to have a long-lasting negative downstream effect on the global industry pipeline (both quality and quantity).

The weakness in the iCT market is very noticeable also in the hiring for key iCT positions, including CRAs and Clinical Project Managers, which were for decades in short supply: probably for the first time on over 20 years we have seen layoffs of experienced CRAs and CPMs and hiring for these positions has all but stopped by CROs and pharma, particularly in North America and Europe.

With these headwinds the size of the global iCT pie is getting smaller and maintaining or even growing the size of country's own slice even more precious. Therefore, it is even more important making Poland look attractive to sponsors of iCT. How this can be achieved is discussed in the final chapter of this report.

Impact of the War in Ukraine

The war in Ukraine initiated by Russia has far-reaching global consequences. The majority of the leading global economies have imposed tough economic sanctions against Russia. Many global brands, including, but not limited to, McDonald's, PepsiCo, Shell, Marriott, British American Tobacco, H&M, IKEA, Nestlé, or Nike, have closed their offices/stores in Russia and/or are suspending planned investments (19).

While the export of life-saving pharmaceuticals does not fall under sanctions for ethical reasons, all major pharmaceutical companies have vowed to stop new investments in Russia, including clinical trials (CTs) (20)(21)(22). Discontinuing the recruitment of new patients into ongoing CTs in which sites in Russia are participating and not placing new CTs in Russia was expected to have a dramatic impact on innovative biopharma CTs (iCTs) in Russia and the associated socioeconomic benefits they bring. The war is naturally also impacting iCTs in Ukraine: among the millions of refugees are active or potential iCT patients, investigators, and site staff; hospital infrastructures have been impacted directly and indirectly; importation of IP and CT supplies via air freight has become difficult or impossible, with only land routes remaining and distribution of supplies and well as collection of biospecimen to / from many CT sites is challenging.

As shown in Figure 11 the war in Ukraine and the sanctions against Russia had devastating impact on iCT markets in both Russia and Ukraine with a new study sites market decline of -65% and -70% in relative terms (-1% and -0.5% in absolute terms) and active study sites market share decline of -40% and -47% in relative terms (-0.9% and -0.5% in absolute terms).

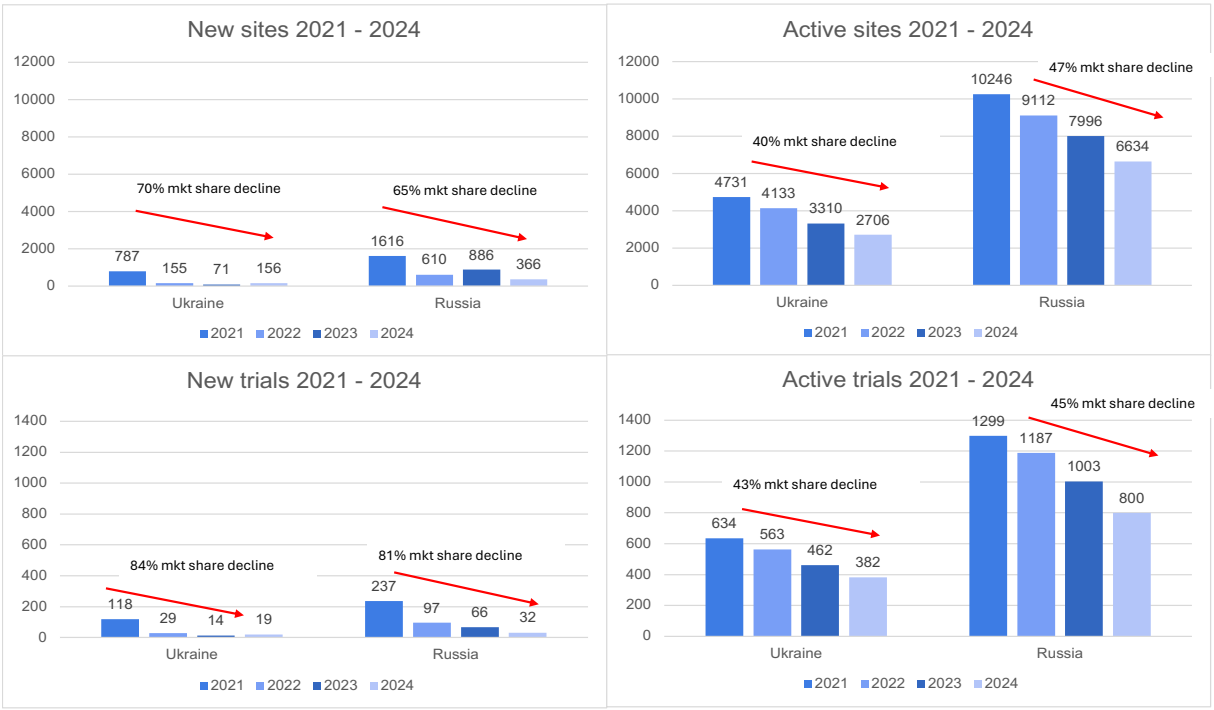


Figure 11. Impact of the war in Ukraine and sanctions against Russia on iCT markets in both countries (2021-2024 data). Source: LongTaal Informatics - data download 02 March 2025.

Our 2022 analysis quite accurately predicted the magnitude of decline of the iCT markets in both countries (23). In the same paper we made a prediction that the iCT capacity redirected away from Russia and Ukraine would be redistributed and absorbed locally, i.e. in Poland and across core Central Europe (23).

However, three years into the war that does not appear to have been tactic most sponsors followed: while between 2021 and 2024 the combined loss of new sites market share of Russia and Ukraine -1.5%, and the combined loss of active sites market share of Russia and Ukraine -1.4%, there core CEE market lost -0.4% new sites market share, and -0.1% active sites market share (Figure 9). There is also no sign of market upside in Poland: over

2021-2024 period new sites market share has not changed (0.0%) , and active sites market share of Poland increased only marginally (+0.09%) share (Figure 9).

We can therefore conclude quite definitively, that sponsors of iCT have not redirected their development pipelines within the CEE region or even within Europe, since the EU iCT market showed no sign of market share pickup and its market share continued declining throughout 2021-2024 period (Figure 13).

In this context we would like to highlight that while, as shown above, there was no measurable increase of iCT activities in Poland, anecdotally we are aware of multiple instances of transfers of patients enrolled in clinical trials in Ukraine, who fled the war and were directed to clinical trial sites in Poland but are unable to quantify these patient transfers.

In the context of the on-going war and on-going sanctions against Russia it is of interest to assess changes of the iCT markets in Ukraine and in Russia in terms of iCT pharmaceutical sponsor responses (Table 4).

Table 4. Top 10 iCT sponsors in Russia, Ukraine, and globally 2021 and 2024. Based on number of new studies and number of active studies. Source: LongTaal Informatics - data download 02 March 2025.

Top 10 Sponsors based on # Active Studies

Ukraine						Russia						Global			
2021		% Global	2024		% Global	2021		% Global	2024		% Global	2021		2024	
Merck Sharp & Dohme	57	25%	Merck Sharp & Dohme	52	16%	Hoffmann-La Roche	98	31%	AstraZeneca	104	19%	AstraZeneca	415	AstraZeneca	536
Hoffmann-La Roche	50	16%	AstraZeneca	32	6%	AstraZeneca	96	23%	Merck Sharp & Dohme	74	23%	Novartis	408	Novartis	394
Johnson & Johnson	41	11%	Hoffmann-La Roche	30	10%	Merck Sharp & Dohme	92	41%	Hoffmann-La Roche	55	18%	Johnson & Johnson	359	Merck Sharp & Dohme	317
AstraZeneca	34	8%	Johnson & Johnson	27	9%	Novartis	91	22%	Novartis	49	12%	Pfizer	321	Pfizer	315
AbbVie	33	14%	AbbVie	19	6%	AbbVie	58	24%	Johnson & Johnson	40	14%	Hoffmann-La Roche	319	Hoffmann-La Roche	300
Pfizer	25	8%	Sanofi	17	8%	Bristol-Myers Squibb	58	24%	Sanofi	35	15%	AbbVie	243	AbbVie	293
Sanofi	23	11%	Eli Lilly and Company	12	5%	Johnson & Johnson	58	16%	Bristol-Myers Squibb	33	15%	Eli Lilly and Company	243	Johnson & Johnson	291
Eli Lilly and Company	17	7%	Pfizer	12	4%	Sanofi	47	23%	AbbVie	31	11%	Bristol-Myers Squibb	242	Eli Lilly and Company	252
Bayer	15	8%	Novo Nordisk AS	11	6%	Pfizer	45	14%	Eli Lilly and Company	27	11%	Takeda	229	Bristol-Myers Squibb	226
Novo Nordisk AS	15	11%	Takeda	9	5%	Eli Lilly and Company	43	18%	Pfizer	23	7%	Merck Sharp & Dohme	226	Sanofi	226

Top 10 Sponsors based on # New Studies

Ukraine						Russia						Global			
2021		% Global	2024		% Global	2021		% Global	2024		% Global	2021		2024	
Merck Sharp & Dohme	16	28%	AstraZeneca	5	3%	Merck Sharp & Dohme	27	47%	AstraZeneca	8	5%	Novartis	143	AstraZeneca	163
Hoffmann-La Roche	8	12%	Merck Sharp & Dohme	2	3%	AstraZeneca	17	13%	Biocad	5	100%	Johnson & Johnson	130	Pfizer	90
Johnson & Johnson	8	6%	Alvotech Swiss AG	1	33%	Hoffmann-La Roche	17	26%	Valenta Pharm JSC	5	100%	AstraZeneca	129	Novartis	86
AstraZeneca	7	5%	Bayer	1	2%	Novo Nordisk AS	12	20%	Efferon JSC	3	100%	Pfizer	119	Merck Sharp & Dohme	78
Pfizer	5	4%	Dr. August Wolff GmbH & C	1	100%	Novartis	11	8%	Novartis	2	2%	Jiangsu	78	Eli Lilly and Company	74
Novo Nordisk AS	4	7%	Eli Lilly and Company	1	1%	Johnson & Johnson	10	8%	POLYSAN Scientific & Techno	2	100%	Eli Lilly and Company	74	AbbVie	71
Octapharma	3	60%	Formycon AG	1	25%	Eli Lilly and Company	7	9%	AO GENERIUM	1	100%	Takeda	72	Boehringer Ingelheim	69
Sanofi	3	5%	Nutra Harmony LLC	1	100%	GlaxoSmithKline	7	15%	GlaxoSmithKline	1	2%	Hoffmann-La Roche	66	Sanofi	64
BeiGene	2	13%	Octapharma	1	50%	Pfizer	7	6%	Materia Medica Holding	1	100%	Sanofi	63	Novo Nordisk AS	63
Celon Pharma SA	2	100%	Omeros Corporation	1	50%	Pharmtechnology LLC	6	100%	Neurotechnika	1	100%	Novo Nordisk AS	61	GlaxoSmithKline	62
														Hoffmann-La Roche	38

As seen from Table 4, all global sponsors have adhered to their pledges to significantly reduce R&D investments into Russia and have either discontinued or significantly reduced placements of new studies to Russia. Indeed, while in 2021 nine out of 10 companies in terms of the number of new studies in Russia were large US or European biopharmaceutical companies (biopharma), in 2024 only three large global biopharma made the top 10 list (AstraZeneca, Novartis, and GSK) and even those have substantially reduced their Russia footprint in new studies: AstraZeneca from 13.4% new global studies in 2021 to 4.9% in 2024, Novartis from 7.7% to 2.3%, and GSK from 5.9% to 1.6%. The other companies on the Top 10 new studies list in 2021 were all Russian, and majority of registered studies were bioequivalence rather than innovative R&D studies. In Ukraine the top sponsor in terms of new studies (5) was also AstraZeneca, and the only other sponsor with more than one registered new study in Ukraine in 2024 was Merck Sharp and Dohme (2 studies).

Other Factors Impacting Global iCTs: DEI Requirements

In its recent guidance to the industry, the US FDA highlighted concerns regarding the lack of diversity in industry-sponsored clinical trials (iCTs). Specifically, it pointed to the insufficient enrollment of participants from underrepresented racial and ethnic populations in the US. According to the FDA, these populations are often underrepresented in biomedical research, despite bearing a disproportionately high disease burden for certain conditions relative to their representation in the general population (32). Without corrective actions, this underrepresentation in US iCTs is likely to worsen in the coming years, particularly as the country is projected to become "minority (non-Hispanic) White" by 2045 (33).

To address this issue, the FDA has urged sponsors to develop and implement strategies to ensure more diverse participation in clinical trials. These measures aim to enhance the generation of safety and efficacy data across the entire US population. Examples of such strategies include offering financial reimbursement for expenses incurred during trial participation (e.g., travel and lodging), providing language support for participants with limited English proficiency, and collaborating with community-based organizations to support trial participants.

The challenge of insufficient representation of certain ethnic or racial groups in industry clinical trials (iCTs) is not unique to the US; it is a global issue. Several nations and ethnic groups remain underrepresented in the development of new drugs. In our earlier publications, we explored and quantified the extent of underrepresentation among Middle Eastern populations, particularly Arabic-speaking groups (3,24).

Given that historically white patients of European ancestry have been overrepresented in global industry clinical trials strict adherence to the DEI requirements by the FDA would increase demand for recruitment into clinical trials of non-white patients with expected reduced recruitment demand in Europe, including Poland. However, at the time of writing of this report the new US administration appears to be purging majority if not all government DEI initiatives and remains to be seen if the FDA will be enforcing the DEI requirements (and checking adherence to diversity plans). It is worth noting however, that as the Trump administration continues to target DEI practices, several large pharmaceutical companies reaffirmed their commitments to diversifying clinical trials (25).

Therefore, currently we are unable to assess whether the DEI adherence in the US (or lack thereof) would have any immediate impact in Europe. However, **the politics of this topic in the US notwithstanding, the diversity requirements as part of the development of new drugs is rooted in good science and undoubtedly over time will lead to increased recruitment of non-white patients into R&D clinical trials with a resulting downward pressure on European patients, including Poland**.

Assessment of the Impact of Implementation of the New EU CTR

Last year, Mario Draghi presented a comprehensive report on Europe's competitiveness, in which he warned that, among all global economies, Europe is particularly vulnerable to the most significant geopolitical shifts since World War II (26). The challenges outlined in Mr. Draghi's report, combined with new issues that have emerged since its publication—such as a looming trade war with the US and a fracturing transatlantic security alliance—have become even more pressing for Europe under the Trump administration.

One of the areas where Europe is critically lagging behind the US and China is R&D (26): EU companies spent around €270 billion less on R&D than their US counterparts in 2021 (26).

In 2024 biopharmaceutical sector was the second largest globally in terms of R&D investment, trailing only IT services, and accounted for 18.4% of total global R&D spending (27). As shown in Figure 12 European biopharmaceutical manufacturers lag significantly behind their US counterparts in R&D.

However, it is important to highlight that, due to the global nature of biopharmaceutical development—particularly clinical trials—a substantial portion of R&D spending, primarily in the development phase, follows the location of recruited trial participants. Therefore, as we have shown in chapter on Socio-Economic Impact of Industry CTs participation in clinical trials in is an opportunity for countries and regions to redirect a significant portion of the global pharmaceutical R&D into their countries or regions.

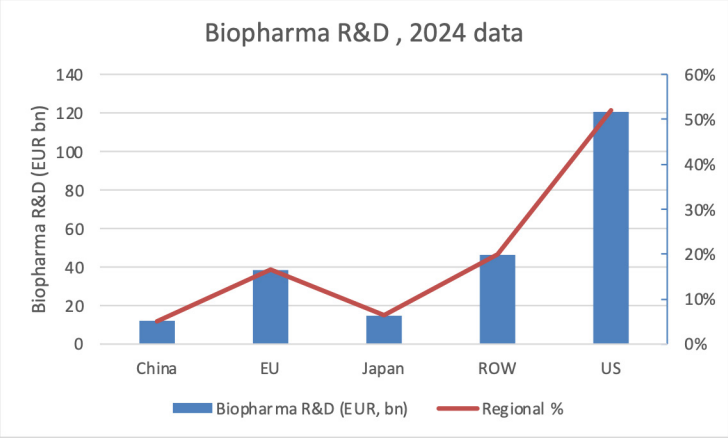


Figure 12. Global biopharmaceutical R&D. Source (27)

Thus, iCTs represent an opportunity for Europe to offset (at least part of the biopharmaceutical R&D spend gap vs. the US). In this chapter we analyze whether and to which extend Europe has been successful at accomplishing this task.

Before embarking on the data analysis and interpretation a few methodological points:

1. Europe's participation in global clinical trials was assessed across a range of parameters, including market share of newly registered global trials, market share of newly registered global iCT sites, market share of active global trials, market share of active global iCT sites. Using these complementary data sets allowed us to gain more granular insights into the evolving competitiveness of European countries and sites, compared to a recent report on this topic (28).
2. This analysis covers period 2010-2024 and to enable like-for-like comparisons across more than a decade, EU2025 was defined as a grouping of countries which include countries which have been members as of January 2025 (Austria, Bel-

gium, Bulgaria, Croatia, Republic of Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Poland, Portugal, Romania, Slovakia, Slovenia, Spain and Sweden), even when looking at prior years: thus, the UK is not part of the EU2025 data even for years preceding the Brexit date (Feb 1, 2020), and Croatia was considered part of the EU2025 grouping also prior to joining the EU (July 1, 2013).

3. To enable assessment of the performance of the UK post-Brexit we have included UK as a separate line item in this analysis.

EU2025, has been losing market share for well over a decade (Figure 13).

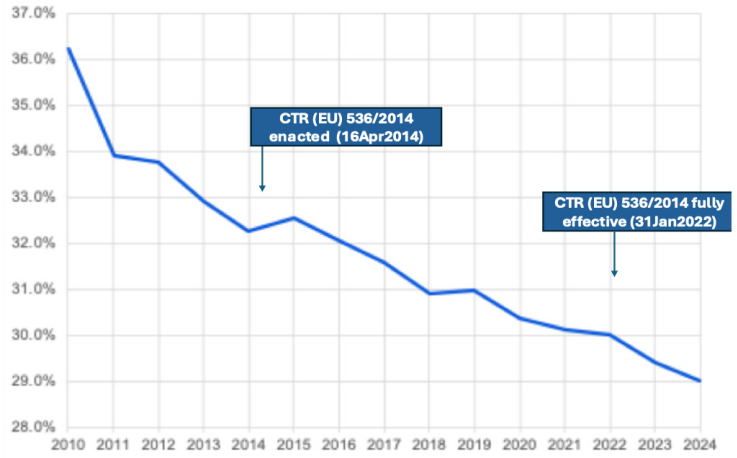


Figure 13. EU(2025) iCT market share trending 2010-2024. Source: LongTaal Informatics - data download 02 March 2025.

In response to declining global market share of iCT pipeline, with very significant adverse socioeconomic impact, the European Parliament enacted Clinical Trials Regulation (EU) 536/2014 (CTR) on clinical trials on medicinal products for human use on 16 April 2014, repealing Directive 2001/20/EC. The Clinical Trials Regulation (EU) 536/2014 was enacted to address shortcomings in the Clinical Trial Directive 2001/20/EC and to create a more harmonized, efficient, and transparent framework for conducting clinical trials across the EU (29,30). Key reasons for its enactment included:

1. Simplification and Harmonization
   - The previous directive led to a fragmented system with differing national rules, requiring sponsors to submit separate applications in each EU country where a trial was conducted.
   - The regulation established a single submission and assessment process via the Clinical Trials Information System (CTIS), streamlining approvals across EU/EEA countries.
2. Increased Transparency
   - The new regulation requires that clinical trial data, including results, be made publicly available in CTIS, enhancing transparency for researchers, patients, and the public.
3. Improved Timelines for Approvals
   - A coordinated assessment procedure ensures a more predictable and faster approval process, reducing administrative burdens for sponsors.
4. Facilitation of Multinational Trials
   - The previous directive created obstacles for trials conducted in multiple EU member states due to different national requirements. The regulation provides a harmonized framework for multi-country studies.
5. Better Protection for Participants
   - The regulation strengthens informed consent requirements and risk-based monitoring, ensuring the safety and well-being of participants.
6. Boosting Research and Innovation in the EU
   - Due to the complexity of the old directive, many sponsors, especially small and medium-sized enterprises (SMEs), academic researchers, and non-commercial sponsors, faced challenges in conducting trials in Europe.
   - The new regulation reduces administrative burdens, making the EU more attractive for clinical research.

Overall, Regulation (EU) 536/2014 was designed to improve the efficiency, transparency, and competitiveness of clinical trials in Europe while maintaining high standards for patient safety and data integrity (29,30).

However, as the data in Figure 13 demonstrate the stated objective of increasing competitiveness of clinical trials in Europe has not been accomplished: market share decline during 2010-2014 period preceding Regulation (EU) 536/2014, continued throughout 2014-2022 transitional period, and ironically (contrary to its stated objective), appears to have accelerated after the Regulation (EU) 536/2014 became fully effective (starting from 31 January 2022 sponsors of clinical trials with sites in any of the EU member states the EU need to utilize Clinical Trials Information System (CTIS) as a single point of entry for clinical trial applications).

As Figure 14 demonstrates the overall decline was visible across a majority member states but most accentuated in Germany, which over the past 15 year lost more than 4 percentage points of global iCT markets share. Only three countries in the EU 2025 - Spain, Italy and Poland - were able to gain market share during most of the past decade and a half. Spain has overtaken Germany in 2023 becoming Europe's largest iCT market 's continued to grow Italy's growth turned negative starting from 2020. Poland while outperforming in terms of growth most of the EU2025 member states until 2022, but during the last 3 years Poland's market share remained stagnant, as will be discussed in more detail in the chapter *Growth of Poland's Market Share Stifled?*.

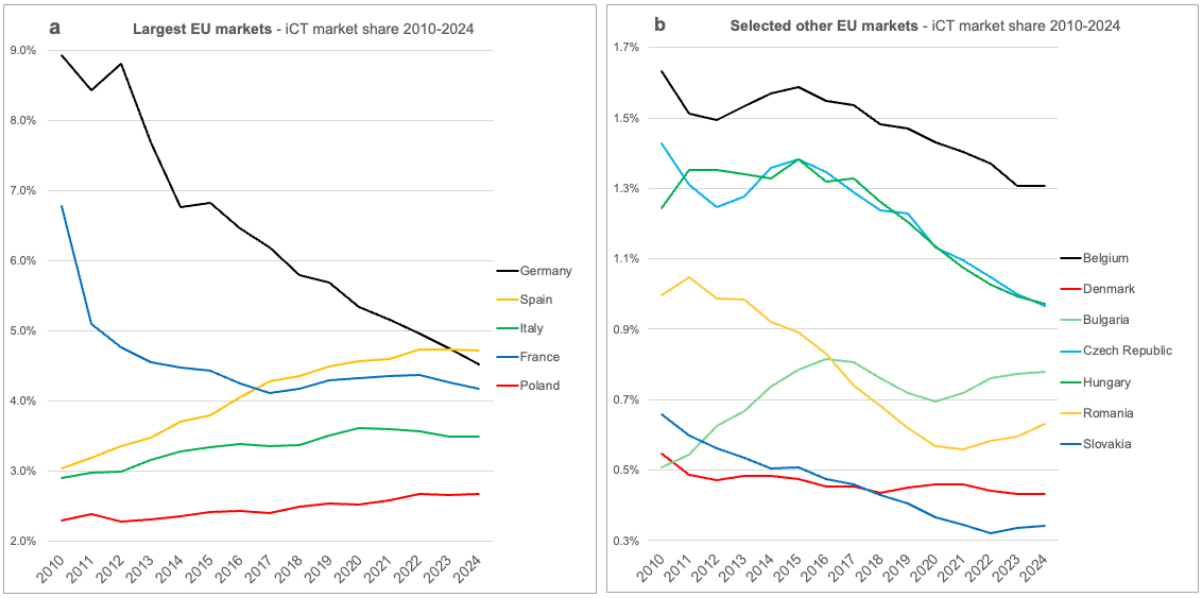


Figure 14. iCT Market share trends 2010-2024 of largest EU iCT markets (a) and selected other EU markets (b). Source: LongTaal Informatics - data download 02 March 2025.

The socioeconomic consequences of lack of its global competitiveness have been dire for the EU: between 2014, by 2024 EU lost over 11,000 R&D jobs, more than 150,000 patients have not been able to gain access to cutting edge therapies, and the adverse economic impact for the EU zone was EUR 10bn (Table 5).

Table 5. EU (2025) iCT market share trending 2010-2024 and the resulting socioeconomic implications. Source: LongTaal Informatics - data download 02 March 2025.

EU (per 2025 member states)	2010	2012	2014	2016	2017	2018	2019	2020	2021	2022	2023	2024
Active sites mkt share	36.2%	33.8%	32.3%	32.1%	31.6%	30.9%	31.0%	30.4%	30.1%	30.0%	29.4%	29.0%
iCT-related R&D jobs Jobs in the EU	126,838	118,184	112,917	112,237	110,572	108,244	108,496	106,377	105,432	105,015	102,889	101,567
Patients benefiting from iCTs	362,394	337,669	322,620	320,678	315,919	309,270	309,988	303,934	301,236	300,042	293,970	290,190
Annual biopharma R&D investment (EUR bn)*	€ 11.12	€ 11.10	€ 11.36	€ 12.46	€ 13.04	€ 13.73	€ 14.66	€ 15.48	€ 17.95	€ 18.68	€ 21.35	€ 21.43
Delta actual vs 2014 market share												
iCT-related R&D jobs Jobs in the EU	13,921	5,267	-	- 680	- 2,345	- 4,673	- 4,421	- 6,540	- 7,485	- 7,902	- 10,028	- 11,351
Patients benefiting from iCTs	39,774	15,049	-	- 1,942	- 6,701	- 13,351	- 12,632	- 18,686	- 21,385	- 22,579	- 28,650	- 32,430
Annual biopharma R&D investment (EUR bn)**	€ 1.22	€ 0.49	€ -	€ (0.08)	€ (0.28)	€ (0.59)	€ (0.60)	€ (0.95)	€ (1.27)	€ (1.41)	€ (2.08)	€ (2.39)

*Restated in EUR based on average ECB EUR / USD exchange rate
**Hypothetical; based on 2014 mkt share

Did Brexit insulate the UK from the EU's trouble?

The UK was an EU member state until it formally left the Union on 31 January 2020, concluding the protracted Brexit process. The following key Brexit milestones (31), appear to have played a significant role in shaping the UK's competitiveness—or lack thereof—in industry clinical trials:

- 23 January 2013: then-Prime Minister David Cameron announced in a speech that the Conservative Party would hold an in-out referendum on EU membership if they won the 2015 general election.
- 23 June 2016: The Brexit referendum was held
- 31 January 2020: the UK officially left the EU but remained in the EU single market and customs union during a transition period.
- 31 December 2020: transition period ended on 31 December 2020, and the UK exited the EU's legal framework.

Improving NHS funding and healthcare was one of the most prominent promises made by Brexit proponents—particularly during the 2016 referendum campaign. The most famous slogan was on the side of the Vote Leave campaign bus: "We send the EU £350 million a week. Let's fund our NHS instead."

This claim suggested that money previously sent to the EU could be redirected to the National Health Service (NHS) after Brexit, implying a major funding boost.

The post-Brexit reality looked quite different from the promises on the campaign trail (32-36):

1. NHS Funding: Government spending on the NHS has increased since 2016—but this cannot be clearly attributed to Brexit savings, as the UK did not "recover" £350 million per week in full. The UK still makes payments to the EU under the financial settlement ("divorce bill"). And some of the increase in NHS spending was already planned or part of wider budget priorities, independent of Brexit.
2. NHS Workforce and Services: Staff shortages have worsened, especially among nurses and social care workers. Fewer EU nationals are coming to work in the NHS due to immigration restrictions post-Brexit. Supply chain issues and access to medical research and treatments have also been affected.
3. Overall Quality and Performance: the NHS has faced increasing pressure since Brexit, compounded by the COVID-19 pandemic, aging population, and delayed reforms. Wait times, staffing levels, and patient satisfaction have generally declined or stagnated, not improved.

However, as our data in Figure 15 demonstrate, beyond the NHS problems related to Brexit mentioned above, the UK has apparently lost its luster among industry sponsors of clinical trials adding to the long list of adverse impacts on NHS.

Up until 2014 UK was one of the darlings of the clinical trials industry with significant iCT market share gains. One of the key contributing factors attracting industry players of clinical trials was the National Institute for Health Research (NIHR) which was created in 2007 to enable research and development within the National Health System (NHS) in order "to improve the health and wealth of the nation through research".

One of the key pillars of NIHR is the Clinical Research Network (CRN) developed with the aim to increase in the UK's world share of clinical trials patients. It provided national-level support to industry sponsors of clinical trials by helping to identify suitable sites with eligible patients utilizing EHR data from the NHS system across the country.

Overall CRN reduced complexity of administrative procedures and study start-up for sponsors of multi-centric studies, managed the approval process and speeds up start-up times. As a consequence, 96% of all NHS sites had active patient recruitment into clinical trials (37).

However, these benefits to sponsors of clinical trials clearly have not outweighed the risks perceived by sponsors of clinical trials during the process leading up to the Brexit referendum as well as after the Brexit completion. As Figure 15 demonstrates, like in many other economic areas with adverse Brexit impact, UK competitiveness for biopharmaceutical clinical trials (iCTs) eroded ever since plans to hold Brexit referendum were announced and continued through the formal completion of Brexit and beyond: during 2014 - 2024 UK's market share gains made during 2011-2014 have been wiped out along with £1.5bn of economic value from iCTs (Table 6).

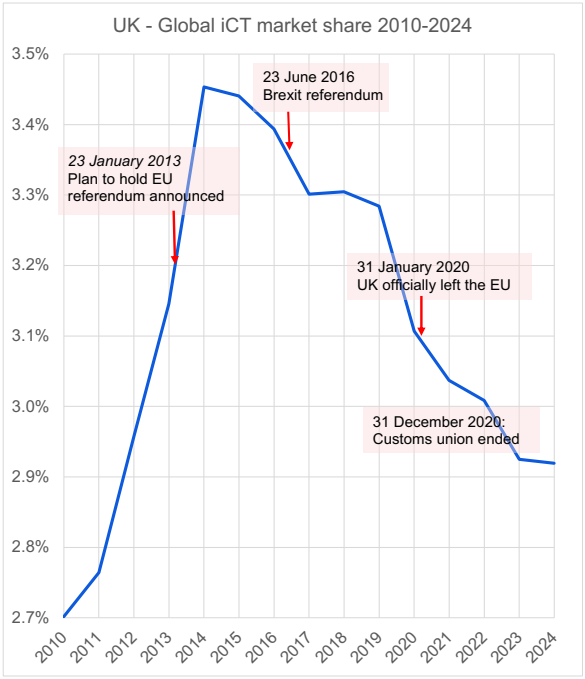


Figure 15. UK - Global iCT Market share trend 2010-2024. Major Brexit milestones are shown.
Source: LongTaal Informatics - data download 02 March 2025.

Table 6. UK - Global iCT market share trending 2010-2024 and the resulting socioeconomic implications. Source: LongTaal Informatics - data download 02 March 2025.

UK iCT market	2010	2012	2014	2016	2018	2019	2020	2021	2022	2023	2024	2014-2024 Impact
Active sites mkt share	2.70%	2.96%	3.45%	3.39%	3.30%	3.28%	3.11%	3.04%	3.01%	2.93%	2.92%	
iCT-related R&D jobs	9,456	10,354	12,086	11,878	11,565	11,495	10,873	10,630	10,529	10,238	10,218	
Patients benefiting from iCTs	27,017	29,583	34,531	33,938	33,044	32,843	31,067	30,371	30,084	29,251	29,194	
Annual biopharma R&D investment (GBP bn)*	£ 0.72	£ 0.84	£ 1.05	£ 1.14	£ 1.27	£ 1.35	£ 1.37	£ 1.57	£ 1.62	£ 1.84	£ 1.87	
Delta actual vs 2014 market share												
iCT-related R&D jobs			-	208 -	520 -	591 -	1,212 -	1,456 -	1,557 -	1,848 -	1,868	- 1,868
Patients benefiting from iCTs			-	593 -	1,487 -	1,689 -	3,464 -	4,161 -	4,448 -	5,280 -	5,338	- 27,980
Annual biopharma R&D investment (GBP bn)*			-£	0.02 -£	0.06 -£	0.07 -£	0.15 -£	0.22 -£	0.24 -£	0.33 -£	0.34	-£ 1.48

*Restated in GBP based on average GBP / USD 2024 exchange rate
**Hypothetical; based on 2014 mkt share
USD / GBP 1.280682

To conclude: not only Brexit did not insulate UK from the decline of clinical trial market share Europe has been facing, but UK's decline of clinical trial market share also appears to have been accelerated by Brexit and/or the process of leading up to Brexit.

Has GDPR played a role in reducing EU's iCT competitiveness?

Thus, we have clearly documented that EU has been continuously losing global competitiveness in iCT over more than a decade and the adoption of EU CTR aimed at reversing the trend has not yielded the stated objective. So far we did not discuss the possible root causes of if the declining competitiveness.

It appears that a strong contributing role in the reduction of EU's competitiveness in global clinical trials played the General Data Protection Regulation (GDPR). Several recent articles concluded that GDPR has, in practice, intensified administrative burdens, complicated by lack of legal harmonization across member states, thus prompting a shift in trial locations toward jurisdictions with less stringent data protection regulations (38–40).At the time of writing this report (April 2025) the European Commission announced plans to present a proposal to cut back the General Data Protection Regulation (GDPR). Slashing regulation is a key focus for Commission President Ursula von der Leyen, as part of an attempt to make businesses in Europe more competitive with rivals in the US, China and elsewhere (41). It remains to be seen if the changes will be sufficiently far-reaching and will help reduce some of the incremental data protection-related complexity of clinical trials in the EU.

EU's oncology clinical trials and IVDR

In 2021 European Commission released its Europe's Beating Cancer Plan as a political commitment "to turn the tide against cancer and another steppingstone towards a strong European Health Union and a more secure, better prepared and more resilient EU" (42).

In the Europe's Beating Cancer Plan European Commission pledged €4 billion of funding, including €1.25 billion from the future EU4Health programme (42).

Clinical trials are an integral part of good oncology treatment practice. There is compelling evidence that enrollment of patients in clinical trials produces treatment advances at a faster rate and concurrent survival increases and mortality reductions in the cancer population. In this context, the issue of clinical trial enrollment is viewed as foundational, lying at the heart of the cancer clinical trial endeavor (43).

Yet, despite commitments in the 'Beating Cancer Plan', oncology trial in Europe have fallen consistently since 2021, and are now below 2018 levels. This contrasts to the US, which saw an increase in 2021, and trial levels have been maintained (28).

While the observed decline in Europe's oncology clinical trials can be multifactorial, a likely contributing factor is the EU's In-Vitro Diagnostic Regulation (IVDR) (44). The IVDR transition period began in 2017, which introduced more stringent requirements for the designation of Notified Bodies, with increased control and monitoring by the national competent authorities and EU Commission (28). This regulation affects clinical trials using in-vitro diagnostics (e.g., for patient selection, allocation and monitoring), which is particularly relevant to oncology trials.

The China effect

Over the past decade China reformed its clinical trial regulations to boost global market competitiveness - and the impact of those changes has been far more impactful that those of the EU. In recent years, China has made substantial efforts to modernize its regulatory framework to promote the development of new drugs. Prior to 2016, China—unlike Europe—was not typically a preferred country for inclusion in global clinical trials. Due to a lengthy approval process, averaging around one-year, Chinese sites were often activated only after the global "last patient in" had already occurred.

One contributing factor to this long approval timeline was the backlog of drug applications in China, which included a large volume of generics and a limited number of reviewers at the Center for Drug Evaluation (CDE). As a result, foreign innovative drugs historically faced significant delays in approval. Recognizing that patients in China were not receiving timely access to new global therapies, the government-initiated reforms in 2015—around the same time the European Parliament and Council adopted the Clinical Trials Regulation (CTR).

Since then, China has implemented a series of swift and impactful regulatory reforms. A key milestone came in August 2015, when the State Council released the "Opinion on Reform of the Drug and Medical Device Approval System" (Opinion No. 44), which marked the beginning of this transformation. Its main objectives were to eliminate the application backlog, raise the quality of clinical trials, and enhance transparency and efficiency in the review process.

China began implementing ICH-GCP in June 2017, and the current version of China GCP has been effective since July 1, 2020. In response to Opinion No. 44, the National Medical Products Administration (NMPA)—the authority overseeing clinical trials—launched multiple regulatory initiatives. On October 8, 2017, the State Council issued "Opinions on Deepening Reforms on Drug and Medical Device Review and Approval System to Encourage Innovation" (Opinion No. 42), which laid out the vision for further reform. These included streamlining trial review and approval processes, accepting foreign clinical data, and removing the requirement for NMPA accreditation of trial sites.

Soon after, on October 10, 2017, the NMPA revised rules on imported drug registration to encourage foreign sponsors to pursue clinical development both within and outside China simultaneously. Then, on July 27, 2018, the NMPA introduced "Notice No. 50," establishing a 60-working-day silent approval policy for clinical trials, effectively reducing review timelines to under three months.

Another major change came in November 2019, when the NMPA announced that clinical sites in China would no longer require NMPA accreditation to conduct trials. As of December 1, 2019, any site meeting specified criteria could file with the NMPA without requiring formal approval, thereby expanding trial capabilities.

By July 2020, both the updated Drug Registration Regulation and the revised China GCP came into effect. When revising the regulation, the NMPA considered unmet medical needs, industry feedback, international best practices, and positive outcomes from the 2015 reforms. The 60-working-day trial review timeline was also codified into law.

Most recently, in August 2024, the NMPA launched a one-year pilot program aimed at optimizing the review and approval process for clinical trials, targeting a 30-working-day IND approval and first patient consent within three months of approval.

These sweeping reforms over the past decade have fueled a dramatic rise in industry-sponsored clinical trials (iCTs) in China. As shown in Table 7, the number of global clinical trials conducted in China has steadily increased since 2016. China now closely trails the US, conducting over 1,000 industry-led trials annually, with an average annual growth rate of nearly 20% from 2020 to 2024. The volume of commercial trials is now about 4.5 times higher than in 2015 and roughly 1.5 times higher than in 2020, representing a 22% share of global commercial clinical trials.

Table 7. Analysis of iCTs which include China. Source: LongTaal Informatics - data download 02 March 2025.

	2010	2011	2012	2013	2014	2015	2016	2017	2018	2019	2020	2021	2022	2023	2024
New trials (iCT) globally	3975	4181	4074	3979	4258	4227	4246	4523	4761	4948	5123	6382	6153	5976	5507
Trials (iCT) in which China was included	188	204	204	242	270	262	309	425	557	701	822	1221	1180	1369	1207
China-only trials (iCTs) (no other countries)	122	145	136	164	214	194	248	323	436	553	646	1000	975	1140	1028
% increase YoY		*19%*	*-6%*	*21%*	*30%*	*-9%*	*28%*	*30%*	*35%*	*27%*	*17%*	*55%*	*-3%*	*17%*	*-10%*
% of global iCTs which included China	5%	5%	5%	6%	6%	6%	7%	9%	12%	14%	16%	19%	19%	23%	22%
% of China-only trials from global iCTs	3%	3%	3%	4%	5%	5%	6%	7%	9%	11%	13%	16%	16%	19%	19%

Lessons from Spain

While China has been the biggest growth market globally for iCTs, in Europe Spain was the fastest growing market. As demonstrated in this report, Spain is not only the fastest growing clinical trials market in Europe but has been one of the countries globally with highest growth of industry-sponsored clinical trials for over a decade. Therefore, we explore here what makes Spain so exceptional as a country attractive to sponsors of global clinical trials.

Fehervary et al. in their recent paper compared clinical trial ecosystems in Hungary and Spain (45) and concluded that Spain has made significant strides in enhancing its clinical trials ecosystem through a comprehensive approach involving key stakeholders, strategic plans, and targeted investments in infrastructure.

Hungary, similarly to Poland and other countries in Central and Eastern Europe, has traditionally offered cost-effective trials with high regulatory standards but was lacking the effective multi-stakeholder process which has been powering Spain's success in industry-sponsored clinical trials (45),

In Spain, the clinical trial system is largely driven by academic institutions, and with close ties to government institutions and to industry, and with a strong link to public health priorities. A collaborative network of hospitals, research centers, and universities is key. The Spanish Clinical Research Network (SCReN) supports these collaborations, helping to integrate clinical trials into public health systems and academic research. This is closely related to Spain's public-private partnership model and notably has a strong industry element to its plans, with ongoing collaboration with Farmaindustria. In Spain, a vast majority of all clinical trials are initiated by pharmaceutical companies (45).

The clinical trials ecosystem in Spain

The Clinical Trial Landscape in Spain has become a prominent player in the global clinical trials landscape, with a well-established network of research institutions and hospitals. The current status of clinical trials in Spain is marked by a focus on innovation, with significant investments in areas such as personalized medicine and rare diseases. However, challenges such as regulatory delays and the need for more streamlined processes remain areas for improvement (14). In keeping with its academic/research driven model, Spain's clinical trial landscape is centered around major hospitals mainly located in Madrid, Barcelona, and Valencia. These include Hospital Clínic de Barcelona, Hospital Universitario La Paz in Madrid, and Hospital Vall d'Hebron in Barcelona, who carry a disproportionate share of trials for advanced therapies with strong research capabilities in oncology, neurology, and cardiovascular disease. Catalonia in particular has established itself as a 'pole' of the national ecosystem, including a policy leadership role. For Andalucia, Hospital Virgen del Rocío in Seville plays a significant role in clinical trials. Public-private partnerships are strongest in Catalonia and Madrid, creating opportunities to combine research with innovative market access approaches (45).

As the healthcare system in Spain is decentralized, each autonomous region has authority over its healthcare institutions, creating a diversity in approaches that must then be reconciled via a national plan and funding (see below). While the Spanish Agency of Medicines and Medical Devices (AEMPS) is the primary regulatory authority, the Spanish Society of Clinical Pharmacology (Sociedad Española de Farmacología Clínica) plays a crucial role in promoting research ethics and quality within clinical trials. Strong advocacy from the Spanish Association of Pharmaceutical Companies (Farmaindustria) has played an important role: it is one of the best organized trade associations of the industry in Europe and has served as an effective partner in advancing overall partnership. As noted above, the Platform for Clinical Research Units and Clinical Trials Networks (SCReN) is a public initiative aiming to promote high-quality clinical research across Spain offering support to researchers and institutions (45).

Spain's decade of clinical trials modernization

Over the past decade, Spain has emerged as a leader in modernizing its clinical trials ecosystem, largely due to its commitment to innovation, regulatory reforms, and the integration of advanced therapies. One milestone was the implementation of the 2015 Clinical Trial Regulation and alignment with the EU Clinical Trials Regulation (CTR), which together reduced the bureaucratic burden as well as significantly cutting costs and timelines. Two recent plans show Spain's commitment to this sector as well as to the innovation economy overall. They are the State Plan for Scientific, Technical and Innovation Research 2024-2027 (PEICTI) and the Spanish Science, Technology and Innovation Strategy 2021- 2027 (EECTI). According to the Ministry

of Science, PEICTI build on Spain's recent focus on research in personalized medicine, biotech and development of novel therapies, aligned with their overall goal of becoming a leader in highly innovative medicines. To this end, one key PEICTI objective is to improve the translation of research into successfully commercialized products, e.g. to bridge the "valley of death". To achieve this, the Ministry of Science advocates creating a more dynamic clinical trials environment, updating infrastructure are key and further enabling public-private partnerships (15) (45).

Compared to PEICTI, EECTI has broader aims which include industrial policy (supporting strategic industries), using science, technology and innovation to achieve the 2030 Sustainable Development Goals, and contributing to the EU's political goals, with the overall aim of achieving 3% GDP investment in R&D by 2030. The EECTI is strongly aimed at encouraging collaboration with Spain's business world, reflecting new dynamics between the government, academia and the private sector. Governance, coordination and capabilities are highlighted as key enabling elements, together with recognition of multidisciplinary approaches. The social dimension is not neglected, seeking to create a culture of open and inclusive science and innovation, also via improved public awareness campaigns (16). For clinical trials, specific measures include:

- Strengthening public-private partnerships with a focus on clinical trials, to make commercialization of research findings more likely (PEICTI)
- Promotion of translational research, to encourage collaboration between the pharmaceutical industry, universities, academic institutions, hospitals, to speed up development of new drugs and technologies
- Incentivizing clinical research networks, big data and AI, for better coordination and sharing of resources
- Digitalization of health research, also to assist with patient recruitment. Specifically, to develop digital platforms that allow for more decentralized and patient-centric trials (EECTI)
- Upgrading of infrastructure and supporting development of specialized clinical research units to support larger and more complex trials.

Selected other recent initiatives include the Strategic Action in Health, a vehicle for biomedical research projects (€138 million, to be managed by the Carlos III Health Institute), the Strategic Project for Economic Recovery and Transformation (PERTE) for Cutting-Edge Health (€137 million) and €130 million for Ramón y Cajal contracts which will finance -year grants for 500 outstanding researchers, and increase minimum salaries by 20%. Overall, the government has earmarked €3.991 billion for science and innovation (17). The Advanced Therapy Case Study (Spain) Spain's focus on becoming a leader in advanced therapies such as gene therapies via two initiatives launched in 2020, the Congressional Reconstruction Commission (Comisión para la Reconstrucción Social y Económica) and the Shock Plan for Science and Innovation (Plan de Choque por la Ciencia y la Innovación). A specific plan was developed, supportive legislation, regulation and funding was put into place, with close collaboration across involved ministries and other entities (18). Efforts are also made to align the plan with Spanish health priorities. In September 2024, Spanish Minister of Health Mónica García noted the plan had already succeeded in making Spain a world leader in CAR-T therapies. Minister Garcia noted targeting leadership in advanced therapies, as well as her conviction advanced therapies will transform the treatment of degenerative and genetic diseases (19) (45).

To further increase its global clinical trial competitiveness, the Spanish Agency for Medicines and Health Products (AEMPS) has recently introduced an accelerated evaluation process (fast-track) for early phase single-country trial (1). This process promised to reduce the timelines for studies which meeting the following criteria:

- Phase I clinical trial
- Sites solely in Spain
- Investigation of advanced therapy treatments
- Examination of seriously debilitating or life-threatening diseases lacking therapeutic alternatives
- Submission through the EU clinical trials database CTIS (Clinical Trial Information System) solely in Spain
- Presentation of the study to an Ethics Committee adhering to the fast-track process.

Alignment with the pharmaceutical industry has been important to drive focus on targeted therapies and those for rare diseases: 90% of such trials conducted in Spain are industry-financed, with an investment of €1.3 bn. Via the Strategic Plan for the Pharmaceutical Industry, presented by Farmaindustria to the Spanish Government in December 2022, the industry has committed to invest an incremental €8 billion in Spain over three years, with, biomedical research to account for more than half of this investment effort (€4.3 billion), aimed at strengthening Spain's leadership in clinical trials and enhance translational and preclinical research (20) (45).

What can Poland learn from Spain?

Drawing on the Spain model, Fehervary et al. made the following recommendations for Hungary (45), but they are equally applicable to Poland:

- A national clinical trials strategy: a dedicated plan developed in cooperation with key stakeholders can complement the existing framework of innovation plans, while sending a strong positive message to the international industry.
- Improved platforms for dialogue, for example the joint working group formed to oversee implementation of the Strategic Plan for the Pharmaceutical Industry 2023- 2025
- Adopting elements of Spain's public-private collaboration framework, as well as Spain's commitment across the development pathway from basic research towards commercial development of medicines.
- Using Spain's focus on digital health technologies and data management practices to further enhance trial design and monitoring as a reference, target areas such as precision medicine, personalized therapies, and digital health trials, supported by emerging technologies like artificial intelligence (AI) and big data analytics - areas in which the country shows potential.

Growth of Poland's Market Share Stifled?

Our previous report presented possible scenarios of Poland's market shared trending:

We also cautioned that while the Growth scenario may be achievable when setting Spain as market benchmark for Poland, however such growth trajectory would be contingent upon adoption of comprehensive set of pro-growth measures.

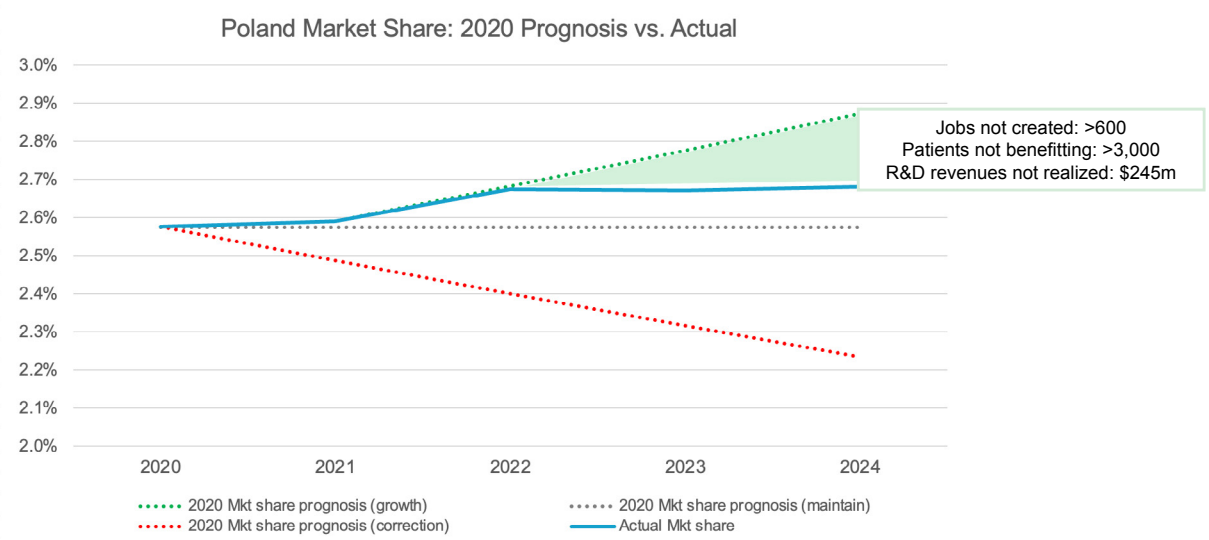


Figure 16. Poland's iCT market share prognosis made in 2020 (dotted lines), vs. actual performance (solid line). The green area between the 2020 growth projection and actual represents significant socioeconomic values which were not realized (text insert).

As our data demonstrate the growth of iCT market of Poland which lasted for over two decades seems to be stifling and stagnation is already visible (as described earlier in the report) which has very significant adverse socioeconomic impact (see Figure 16).

Resuming market growth should therefore be a matter of strategic importance for the economy, patient care, as well as job market. Given its importance we feel compelled to revisit expert recommendation made in the 2021 (1) and review the status of their implementation as presented in the following chapter.

Review of Implementation Status of Recommendations

For Poland to remain an attractive location for sponsors of clinical trials, emphasis should be placed on the following focus areas:

- Support for sponsors of CTs through CT Infrastructure and Technology
- International promotion of Poland as an attractive location for CTs (especially important for EBPs)
- Raising profile of Poland through international collaborations
- Financial incentives to reward R&D activity not just innovation

Recommendation 1 - Create support office for sponsors of CTs (both industry and academic):
We recommended that the current scope of ABM be expanded to include support for commercial clinical trials[9]. A support office would help commercial and academic sponsors of CTs with the following process and data:

1. Identify sites and patients for clinical trials by creating a Digital platform capable of data mining for de-identified EHR data from major hospitals around Poland to enable digital patient mining and improve speed and reliability of study planning. In addition to supporting study planning, providing access to this **data mining platform to sponsors of clinical trials could be monetized which would provide required funding for creation and maintenance of such system**.
2. **Support sponsors of CTs with study set-up and study conduct following examples of the UK, Denmark and South Korea outlined in this report.** CT support offices should be staffed with contract specialist and study coordinators. The support offices would charge participating sites transparent fees for their services. Available structural options:

Scheme	Pros	Cons
A single national CT support office (eg., under the ABM)	- Single point of contact for sponsors - Performance overview across Poland	- Support of sites would be virtual
Geographically aligned CT support offices to support CTs within their geographic area	- Better able to support sites through physical proximity	- Lack of national-level performance oversight
Therapeutic network-aligned CT support offices (see below)	- Single point of contact for sponsors in each major therapy area - Performance overview across Poland in each therapy area	- Support of sites would be virtual
Hybrid CT support: centralized office with study coordinating staff based locally across Poland	- This would provide the benefit of centralized approach with local support of sites	

Recommendation 1 - Implementation status:
In February 2025 ABM announced on its web page the launch of Sponsor Support Center. The new feasibility tool to support clinical trials sponsors. This promises several useful features for sponsors of clinical trials:

[9] Alternatively, a new organization could be established tasked with support of commercial CTs.

The Sponsor Support Center (SSC) at the MRA is an initiative to assist clinical trial sponsors in the process of identifying and selecting appropriate sites to conduct clinical trials. The SSC serves as a contact point allowing sponsors to access specialized sites collaborating within the Network.

Main task and functions of the Sponsor Support Center:

- Advice and support in the trial site selection process: advice on the selection of optimal study sites within the Polish Clinical Trials Network (PCTN)
- Access to the trial sites database of sites within the PCTN: information on the sites' infrastructure, specialties and experience.
- Site potential analysis: SSC offers assessment of the potential and capacity of trial sites to conduct a specific clinical trial, considering both scientific and logistic aspects.
- Logistic support and process monitoring during trial:
- The SSC assists in the logistic process involved in starting a collaboration with trial sites. Once sites have been selected, the SSC stays in constant contact with sponsors, monitoring the progress of the trial and supporting issue resolution.
- Developing cooperation between the public and private sectors: supporting cooperation between the public sector (trial sites) and the private sector (clinical trial sponsors), which contributes to promoting innovation and the development of medical research in Poland.

The SSC also recently (February 2025) announced the launch of a new tool - Poland Feasibility tool. According to the information on the AMB's web site this tool *has been designed for clinical trial sponsors – both commercial and non-commercial – to facilitate the identification of appropriate centers that provide healthcare services to patients with specific medical conditions based on ICD-10 classification.*

We very much welcome the creation of SSC and the Feasibility Tool. Together with SSN it appears to be addressing what we called for in Recommendation 1 under point #2 above and in our 2021 Report (1). Given the short time from the launch of these initiatives the member companies of POLCRO, INFARMA and GCPpl have not been able to gain enough experience of working with SSC and thus we are unable to provide any early user feedback. **Given the significant value these new tools and processes offer, we recommend a much broader domestic and international promotion of these support systems for clinical trial sponsors in Poland, along with an expansion of their scope.**

Use of healthcare data to boost clinical trials

What we have not seen or heard ABM to talk about are plans for using any of the super-rich health data sources available to the government:

Source 1 - EHR (Electronic Health Records) – both centralized and Hospital & Outpatient Information Systems (HIS) – localized with providers: Currently, and over a longer term these are the most promising and valuable source of health data for sponsors of clinical trials. Many countries already have parts implemented (such as ePrescriptions, eLabs, eImaging, eDischarge, eDisability, etc.).

- **Benefits:** Most detailed clinical data; Contextualized; Official and legally "binding" health records of patient; Both the inputting doctor and the patient are officially identified (with ID) and detailed access logs are kept; Data is immediately available.
- **Limitations:** Some of these data are often siloed at institutions (centralization eHealth projects are slow moving in many countries); Unstructured; Development led by governments which often means slower and more heavy-handed implementation.
- Clinical trial applications:
  - eClinicalTrials: Creation of eHealth module to target needs of clinical trials (eClinicalTrials). Investigator would submit inclusion / exclusion criteria to the central authority / office, which inputs these into eHealth. Upon visiting a specialist / GP / hospital the attending doctor will be alerted about potential patient eligibility for a trial (based on age, gender, previous medical history…) and can indicate interest in enrolling the patient, and/or referring the patient to the nearest trial site. This would significantly increase the targetable population and patient enrollment speed.
  - eHealth extension could also support data collection, as eHealth are official medical records, for enrolled patients the agreed upon data could be automatically available to investigators for input into eCRFs.

In Poland, the institution responsible for gathering and storing Electronic Health Records (EHRs) is the Centrum e-Zdrowia (CeZ), thus they need to be the enablers of their secondary use for research purposes.

Source 2 - Health insurance claims (HIC) data: Today HIC present one the most actionable and complete sources of health utilization data. Since providers are being reimbursed on the basis on submitted claims there is a high financial incentive to provide HIC in a timely manner (typically on a monthly basis = data lag 2 to 3 months).

- **Benefits:** Data available for nearly entire (98%+) population; Short time lag of a couple months; Integration of all aspects (inpatient, outpatient, GP, emergency, prescriptions, labs, rehab, death…); As insurance companies base payments on the data it is properly cleaned and monitored; Data contains not just health related information, but also the price; As insurance in many EU countries is based on income, health insurance companies have also socio-demographic patient data
- **Limitations:** Missing clinical depth (stage, grade, functional status, or lab results); Upcoding - fictional care claim, Incorrect diagnosis codes (suspected disease, genetic risk); Insurance companies do not share complete socio-demographic data; No out-of-pocket payments/care is available in the data; Short delay of a couple months.
- Clinical trial applications:
  - Using these data, a central office (eg the SSC at ABM) could, based on these data, significantly speed up feasibility and site/specialist identification.
  - Potential to create a streamlined system for reimbursements in clinical trials, billing of standard of care treatment.
  - Potential for innovative payment mechanisms for pharmaceuticals utilizing real-world evidence in Phase 4 trials.
- **Best practice from neighbors:** Czech Republic recently granted access to HIC to researchers.

In Poland, the institution responsible for managing and processing health insurance claims are Narodowy Fundusz Zdrowia (NFZ), thus they need to be the enablers of their secondary use for research purposes.

Source 3 - National health registries: in selected disease areas data for these have been collected annually but nowadays most countries are trying to gradually automate them by using data sources mentioned above. Because of the long gap (currently one or more years) at the moment registries offer limited value to sponsors planning or setting up a new clinical trial. This may change however, soon: as Registries they become more up to date, they could also become a useful source for clinical trials.

European Health Data Space (EHDS) regulation

An important enabler of the secondary use of the available electronic health data will be the recently approved European Health Data Space (EHDS) Regulation (46), which It entered into force on 26 March 2025, and which will:

1. Empower individuals to access, control and share their electronic health data across borders for the healthcare delivery (primary use of data);
2. Enable the secure and trustworthy reuse health data for research, innovation, policy-making, and regulatory activities (secondary use of data);
3. Foster a single market for electronic health record (EHR) systems, supporting both primary and secondary use.

Countries, which will be fast adopters of the secondary use of the electronic health data for research under EHDS Regulation will be rewarded either by monetizing such data for research purposes (for commercial subjects – for academic researchers the access could be provided free of charge), **or by attracting more clinical trials to their countries by providing access to trial sponsors their electronic health data. Given the outsized importance of industry clinical trials for Polish economy and healthcare we urge the government of Poland and its institutions to make this one of the national health priority focus areas.**

Recommendation 2 - Promotional activities and materials:
Task an organization (e.g., ABM with an expanded mandate would be most likely the most suitable) with increasing the profile of Poland among sponsors of clinical trials by regularly participating in and speaking at leading industry events in Europe, North America, China, and Japan, highlighting Poland's profile and promoting adoption of new measures to increase attractiveness of Poland to sponsors of CTs.

Recommendation 2 - Implementation status:
At the time of writing of this Report (May 2025) we are not aware of any systematic promotional activities for Poland's clinical trial ecosystems. As already mentioned in our comments on implementation status of Recommendation 1 above, raising domestic and international awareness about actions taken to support clinical trials in Poland (such as creation of SSC and the Feasibility Tool under AMB) is an essential component that will determine impact of the new measures or growth initiatives.

Recommendation 3 - Performance indicators:
In order to enable effective and up-to-date promotional material for the above-mentioned promotional activities, we recommend collecting and maintaining data about the performance of Polish sites in international studies. Towards that objective we recommend the creation of a data analytics team within ABM maintaining up-to-date performance data for Poland:

1. Productivity data: Upon study closure, sponsors would be required to submit (e.g., to ABM) information about study completion and provide a list of participating countries, with number of sites and number patients recruited in each country. This would enable maintaining up-to-date productivity data analogous to those shown in this report.
2. Study start-up data: de-identified global benchmarks to be submitted annually by large sponsors and CROs active in Poland (e.g., member companies of POLCRO and INFARMA)

Recommendation 3 - Implementation status:
Since the preparation of the 2021 Report (1), the new EU clinical trials register (EUclinicaltrials.eu), supported by the Clinical Trials Information System (CTIS), was launched on 31 January 2022. CTIS enables users to search for country- and site-level patient recruitment data for ongoing and completed trials. This makes it possible to compile and maintain recruitment productivity metrics for trials involving Poland as a participating country.

Given the accessibility of such data and its value in demonstrating the productivity of Polish sites, it is incumbent upon the ABM to develop and maintain live site productivity dashboards in a publicly accessible domain.

While CTIS does not provide country-level start-up data, such information is crucial for sponsors when selecting trial locations. Therefore, it should be collected annually through surveys conducted with participating companies.

Recommendation 4 - Educational activities:
Training of site staff and patient groups, which are activities typically performed by sponsors of CTs, vary substantially in terms of their quality and rigor. These educational activities could be streamlined and standardized e.g., under ABM or the Patient Ombudsman:

- Provide easy access to high-quality certified training for investigators and sites staff
- Engage and train representatives of Polish patient organizations to enable their active engagement of their patient communities

Recommendation 4 - Implementation status:
At the time of writing of this Report (May 2025) we are aware about ABM's initiative to set up Clinical Trial Support Centers (CTSC) across PCTN sites including provision of staff training at these facilities. Given the short time from the launch of the CTSCs the member companies of POLCRO, INFARMA and GCPpl have not been able to gain enough experience of working with these study coordination centers and thus we are unable to provide any early user feedback.

A positive example of educational activity is the "Patient in Clinical Trials" platform, which is operated by the ABM in collaboration with professional organizations.

Recommendation 5 - Therapeutic Networks and international collaboration:

1. The Ministry of Health should be tasked with formalizing the creation of therapeutic networks in major therapeutic areas with large development pipelines (oncology/hemato-oncology, neurology, psychiatry, metabolic/endocrinology, cardiovascular), which could provide access to large patient populations in these disease areas cross Poland. The therapeutic networks should become virtual SMOs with professional CT support (see recommendation on CT support offices above). Special focus should also be paid to pediatric clinical trials with their C4C program. (53). Representatives of these networks should regularly participate at leading therapeutic events and actively engage with international therapeutic networks and

consortia in Europe and the US, and actively participate in CTs led by international therapeutic networks and consortia.

2. Therapeutic networks to establish or broaden collaboration with academic clinical research organizations (AROs) (e.g., Duke Clinical Research Institute, TIMI, Berman Center for Outcomes in Clinical Research, Julius Clinical) and consortia (e.g., TRICALS) frequently tasked with identification of centers for sponsor trials.

Recommendation 5 - Implementation status:
At the time of writing of this Report (May 2025) we are aware about any formal establishment of one or more national therapeutic networks. However, the establishment of the Polish Clinical Trials Network (PCTN) in March 2021 appears to be addressing the some aspects of clinical trial sites readiness by making use of some of the network sites' data for trial planning purposes. Currently there are 23 public health facilities (mostly hospitals) supported by Clinical Trials Support Centers (CTSC), creation of which has been supported by several funding calls from ABM, totaling almost 200 million PLN. Of particular value from therapeutic perspective appears to be the creation of dedicated oncology and hemato-oncology CTSCs (OncoCTSCs). Since the largest portion of commercial clinical trials pipeline are oncology and hemato-oncology, promoting OncoCTSC network at international conferences, such as ASCO, would certainly generate significant interest among sponsors of clinical trials.

Recommendation 6 - Establish regulatory thought-leadership:
URPL to identify focus areas in which Poland has existing regulatory competencies and/or plans to develop them in order to be able act on behalf of other Member States as a *reporting Member State* (as per REGULATION (EU) No 536/2014 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL from 16 April 2014). Currently, within the CEE region it is the Czech and Hungarian authorities which are viewed as the strongest and have acted repeatedly as *Rapporteur* authorities under the VHP process under the EU Directive 2001/20/EC.

Recommendation 6 - Implementation status:
Given the full implementation of the EU's centralized regulatory submission process under EU CTR 536/2014, this is unlikely to directly enhance Poland's global competitiveness in industry-sponsored clinical trials (iCT). However, indirectly, strong national regulatory competence would support and reinforce Poland's ambition to remain among the global leaders in clinical research.

To this end, it is important to strengthen regulatory capacity by positioning Poland as a rapporteur country. Achieving this will require additional resources for the national regulatory agency, URPL, which currently appears to be underfunded and understaffed - factors that are negatively affecting both the speed and quality of application evaluations.

Recommendation 7 - Academic incentives to physicians for their participation in CTs:
Universities/research centers to introduce academic incentives as part of academic promotion, and professional recognition, by recognizing participation in CTs as an equivalent/part-equivalent to a *in-extenso* research publication in terms of academic merit assessment. The lack of such academic incentives has been identified as a barrier to greater participation in CTs by physicians at academic centers. (54)

Recommendation 7 - Implementation status:
At the time of writing of this Report (May 2025) we are not aware of any steps towards introduction of such academic incentives.

Recommendation 8 - Expand existing R&D tax incentives:
Ministry of Finance to allow CROs to claim R&D credit and incentivize multinational biopharma sponsors to set-up and/or expand their regional or global product development hubs, thus creating high-end R&D jobs in the country (e.g., global/regional study management) which has the potential to substantially increase the number of high-end R&D jobs in the country as well as raise the profile of the country from patient recruitment hub to, more broadly, a product development hub.

The IP Box has been established in Poland to reward innovation. The limitation is that it does not reward R&D process *per-se* - it rewards only the innovation. Given the high socioeconomic value of the R&D process, financial incentives should be provided to all organizations which carry out commercial CT activities (pharmaceutical companies, CROs, SMOs). Examples to follow in that regard would be e.g., France and the UK – both countries offering significant tax incentives which can be claimed also by CROs, not just innovative pharma. Broad incentives on the R&D process (not just the innovation part) would help to create additional R&D jobs in Poland and increase Poland's profile in global iCTs, as innovative pharmaceutical companies and CROs would be rewarded not only to carry our clinical trials at sites in Poland but also to create global/regional R&D hubs responsible for coordination CTs in other countries.

Recommendation 8 - Implementation status:
The scope of R&D tax credits or other financial incentives to those companies which bring and conduct clinical trials to Poland has so far not been broadened as proposed.

National clinical trials strategy imperative

The recommendations outlined above represent specific actions that the government and its institutions could undertake to foster a robust ecosystem for clinical trials in Poland. These efforts would help sustain and further strengthen this vital economic activity and its high-value contribution to healthcare and society.

Given the socioeconomic importance of commercial clinical trials, we propose the development of a coherent national strategy for biopharmaceutical product development and clinical research. This strategy should be coordinated across multiple ministries—including health, economy, science, finance, investment, and labor. Its formulation could draw inspiration from existing models such as Spain's national strategy (47) or the European Commission's more recent Strategy for European Sciences (48).

Only a government-wide, coherent strategy—one that recognizes the socioeconomic value of clinical research and actively promotes Poland as a destination for research investment—can ensure continued success. Predictable, strong, and enforceable intellectual property protections, along with a modern regulatory framework, should form core components of this strategy.

The Governmental Development Plan for the Biomedical Sector 2022-2031 (Rządowy Plan Rozwoju Sektora Biomedycznego na lata 2022-2031) was introduced to "support the national biomedical sector, with a focus on innovative projects that address strategic needs and have potential for rapid commercialization and scaling" (49). However, the plan currently lacks the necessary processes, funding mechanisms, and systemic support to effectively back one of the most significant—if not the largest—contributors to biomedical R&D in Poland: commercial clinical trials.

Conclusions

Poland is deriving a very significant economic as well as societal benefits for conduct of industry-sponsored clinical trials (iCTs) in the country: in 2024 alone, the economic value Poland derived from iCTs reached nearly USD 2.2 billion, accounting for a substantial portion of Poland's total R&D investment. The sector also created approximately 9,400 jobs related to iCT and granted access to more than 26,800 Polish patients to novel and cutting-edge experimental therapies (Infographics 1).

However, this report identified signals that the competitiveness of Poland as a clinical trial destination is beginning to show signs of weakness: during two consecutive years 2022-2024 Poland's market share, which was on a growth trajectory for over two decades, started stagnating, unlike its major European (Spain) and global (China, South Korea, Australia) competitors which continued to gain market share. Additionally, other countries such as Taiwan, Brazil, Argentina, and Turkey are rapidly closing the gap to the top 10 global markets with substantial gains of their own.

The adverse socioeconomic impact of this iCT market share stagnation over the past two years has been very significant for Poland: more than 600 R&D jobs have not been created, almost USD 250 million in economic value of R&D investment has been forgone, and more than 3,000 patients could not gain access to cutting edge experimental therapies. These significant shortfalls should serve as a wake-up call for the key stakeholders in the country to adopt a set of far-reaching robust measures with an overarching national clinical trials strategy aimed at reinvigorating interest of clinical trials sponsors in Poland.

Our 2021 report provided a menu of such measures, however, it appears that while some have been acted on (it is, however, too early to assess the utility and impact of those) large portion of the recommendations has not been heeded so far, and Poland paid a high socioeconomic price for lack of more robust actions already. **Absence to act with resolve now would come with an even more significant negative price tag.** While several growth measures have been proposed in this report, utilization of available super-rich data sources (primarily de-identified EHR) and support for commercial sponsors of clinical trials, with particular focus on Emerging Biopharma (EBP), appear to be set to provide highest returns on investment.

Glossary of Terms

ABM - Medical Research Agency (Agencja Badań Medycznych)

CDA – a Confidential Disclosure Agreement: a legal contract that protects proprietary information and binds the parties to hold information in confidence for a set period of time

CRO – contract research organization (a company providing support to the pharmaceutical, biotechnology, and medical device companies in the form of research services outsourced on a contract basis)

CTs – clinical trials

eCRF/IVRS - electronic case report form/ interactive voice response system

EHR – Electronic Health Records. Sometimes incorrectly used interchangeably with the term EMR (Electronic Medical Record) which is a digital version of a patient's chart. EMR contains the patient's medical and treatment history from one practice. By contrast, an EHR contains the patient's records from multiple doctors and provides a more holistic, long-term view of a patient's health.

EMR - Electronic Medical Record. A digital version of a patient's medical chart. EMR contains the patient's medical and treatment history from one practice.

eTMF - electronic trial master file

iCTs – innovative biopharmaceutical industry clinical trials – in the text also referred to as "commercial clinical trials" (does not include clinical trials of generic manufacturers and academic CTs)

MAA - Marketing authorization application

MeSH terms - Medical Subject Headings (MeSH) is used by ClinicalTrials.gov registry to classify which diseases are studied by trials registered in the registry

NFZ - National Health Fund (Narodowy Fundusz Zdrowia)

RPP – Rzecznik Praw Pacjenta (Patient Ombudsman) https://www.gov.pl/web/rpp

URPL - Urzad Rejestracji Produktów Leczniczych, Wyrobów Medycznych i Produktów Biobójczych

ANNEX 1. Methodology, Data Sources and Model Assumptions

For the purposes of analyses for this report and well as the previous report (1), LongTaal CT Informatics: proprietary big-data clinical trial informatics platform, which allows preparing bespoke comparative benchmarks for clinical trial markets globally, has been utilized as the primary data source for comparative benchmarking purposes.

Clinical trials market share

Unlike the methodology used by other authors which utilized number of **newly submitted** clinical trials sites into the registries (with considerable year-on-year changes), (50,51) (52)(53) the methodology we developed and utilized also in this paper enables determination of all **active** clinical trial sites in the country and has proven to be reliable source of determination of iCT market share of countries as a percentage of all active iCT sites in the country relative to all active iCT sites globally (54)(2)(1)(24)(23)(3).

Patient accessibility to clinical trial sites

Accessibility to industry clinical trial sites is defined as the number of iCT sites per 1 million population. For comparative purposes, iCT Accessibility is expressed relative to the U.S. levels (U.S. iCT Accessibility level being 100%). Source of the population data was the World Bank population databank (55).

Participation to consumption ratio

Participation in iCTs on a country level was approximated as a country's market share of global iCTs (see above). As a surrogate for the consumption of pharmaceuticals on a country level, a country's market share of global prescription sales was used. Participation to Consumption Ratio (PCR) is a parameter introduced and coined by these authors to quantify adequacy of representation of countries' populations in development of new pharmaceutical products relative to consumption of commercially available pharmaceutical products.

The Participation to Consumption Ratio (PCR) was adapted and modified from the **Participation to Prevalence Ratio (PPR)**, a concept introduced by Saltzman et al. to evaluate proportional representation of specific patient demographics in clinical trials for cell-based therapies (8).
Participation to Consumption Ratio has been computed as follows:

$$PCR = \frac{\text{Global iCT market share (\%)}}{\text{Global share of pharmaceutical consumption (\%)}}$$

Where iCT market share is calculated as shown above and pharmaceutical consumption market share has been calculated from (56).

A "normal" PCR range, where most countries land, is in the range $\in <0.5; 2>$. PCR > 3 indicates countries with research bias. PCR < 0.3 indicates countries with consumption bias. Certain countries or regions with PCR < 0.1 are likely to be significantly under-represented in the development of novel pharmaceuticals and patients in those countries may be consuming medications whose development did not adequately represent patients with similar ethnic or cultural profiles (3).

Calculation of country-level socioeconomic impact of iCTs

The socioeconomic impact presented in this paper (R&D job creation, number of patients participating in iCTs, and patient-related R&D investment) was estimated using the following assumptions.

Patients:

Average annual number of subjects recruited in clinical trials globally during 2012-2022 (excluding COVID19 trials and Ebola trials) was approximately 1,000,000 (57). Assumption was made that 1 percent iCT market share (calculated on the basis of active iCT sites as described above) corresponds to 10,000 patients.

Country-level R&D jobs:

According to a recent publication, the biopharmaceutical R&D created 1,000,000 jobs directly (58). Out of those 58% in development (clinical trials) (59), out of those 32-40% are linked to country- and site-level activities (60) (61), and additional ~50% of jobs linked to country- and site-level activities are outsourced (62). Thus, the estimated number of jobs linked to country- and site-level clinical trial activities globally is 350,000. It was assumed that 1 percent iCT market share (calculated on the basis of active iCT sites as described above) corresponds to 3,500 R&D jobs linked to country- and site-level clinical trial activities.

Country-level biopharmaceutical R&D investment estimate:

Estimated global biopharma R&D spend in 2024 was USD 306 billion - data extrapolated from (63) and from (64). Clinical development (mostly clinical trials) accounts for 50-58% of total R&D spend (59). Elements in clinical development (clinical trials) which are attributable to countries and sites where trials are performed are patient recruitment: 32% of total trials costs (61)), and clinical monitoring: up to 25% of total trial costs (65). Using these assumptions, we estimated the 2024 clinical development cost directly attributable to countries where trials are performed at approximately USD 82bn. On a more granular level this amount covers the following elements: patient-related hospital and investigator grants, patient expenses, costs of investigational product provided to patient, national regulatory fees, ethics committees/IRB fees, local safety laboratory fees, salaries of hospital clinical trial staff, e.g. study coordinators/nurse, in-country CRO start-up and monitoring fees, customs fees & logistics of study material, courier fees. Assumption was made that 1 percent iCT market share (calculated on the basis of active iCT sites as described above) in 2024 value corresponded to USD 820 million linked to country- and site-level iCT activities.

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Author of more than 60 research articles and book chapters in peer-reviewed journals, editorial board member at Applied Clinical Research, Clinical Trials and Regulatory Affairs journal, board member of DIA Core committee for clinical research. His current research focuses on various aspects of globalization of industry clinical trials. As a lead author of the Report Vladimir was not only able to tap into his experience of more than 30 years in biomedical R&D, during which he worked and served in multiple senior roles in North America, Europe, Middle East and Africa, and Asia, but also provided objective external global benchmarks utilizing big data analytics of LongTaal a clinical trial informatics company, which he founded and is managing.

Data analytics: Martin Bolecek

Lead, Digital Strategy & Transformation at AOP Health

Martin Bolecek is a digital health strategist with expertise in clinical trial analytics, innovation, and large-scale organizational transformation. At AOP Health, he leads the digital strategy and transformation agenda, driving innovation and the adoption of emerging technologies to enhance R\&D, commercial operations, and overall business performance. Previously, Martin served as Director of Innovation & Technology at IQVIA, where he led global initiatives to modernize real-world evidence operations. He spearheaded the development of analytics-driven, technology-enabled solutions that significantly improved operational efficiency and performance. Martin has co-authored multiple peer-reviewed publications on the globalization and ethics of clinical trials and has contributed data-driven insights to industry reports and articles focused on global clinical research trends and clinical development strategies.

Co-authors (in alphabetical order):

Anna Kacprzyk

Manager of Innovation and Business Ethics | The Employers' Union of Innovative Pharmaceutical Companies INFARMA

Experienced leader in innovation policy and business competitiveness, focused on finding solutions to enhance the innovativeness of industry and the Polish economy through multi-stakeholder cooperation across a variety of industries. Anna holds a PhD in economic sciences and has leadership experience in both public and private sector. She led departments at the Ministry of Economy and the Polish Agency for Enterprise Development, where she implemented programs related to innovation, intellectual property, science-business cooperation, foreign investment, and corporate social responsibility. Currently at INFARMA, she oversees areas including innovation, industrial investment, clinical research, intellectual property, and business ethics. She also leads projects related to national and European legislation relating to the industry.

Bartłomiej Kopacz

Vice-Chairman of the Clinical Trials Group, INFARMA

With over 15 years of international experience in clinical trials and the biopharmaceutical sector—spanning both Clinical Research Organizations and pharmaceutical companies Bartłomiej currently serves as Head of Clinical Operations for Poland and Central & Eastern Europe at GSK. He is deeply engaged in shaping the clinical trials landscape at both national and regional levels, acting as Vice-Chairman of the Clinical Trials Group at INFARMA and a Business Council Member at the Medical Research Agency. A dynamic and forward-thinking leader, with his solutions-driven attitude Bartłomiej consistently challenges the status quo to deliver impactful, patient-centric outcomes in clinical research and beyond.

Agnieszka Skoczylas

Global Director, Feasibility & Proposals, Country Manager - Poland at Medpace

President of POLCRO, the Polish Association of Clinical Research Organizations

Agnieszka currently holds a dual role as Global Director of Feasibility & Proposals and Country Manager for Poland at Medpace, where she leverages her extensive clinical operations expertise to develop effective enrollment strategies in response to requests for proposals. Since 2020, she has served as President of the Polish Association of Clinical Research Organizations (POLCRO), representing the interests of CROs in discussions with the Polish Regulatory Authority and the Medical Research Agency. She is a dedicated advocate for both Poland as a key destination for clinical research and Medpace as an industry leader. With over 25 years of international leadership experience in clinical research, Agnieszka is a strategic thinker who combines process orientation with a broad, global perspectives—enabling her to assess the impact of international trends on local clinical trial markets.

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