



## Central and Eastern Europe: A crucible for clinical cancer innovation? ☆

Mark Lawler<sup>a,j,\*</sup>, Susan Bhatti<sup>b</sup>, Pawel Przewieźlikowski<sup>c</sup>, Birgit Wolf<sup>d</sup>,  
Joanna Frątczak-Kazana<sup>e</sup>, Piotr Rutkowski<sup>f,1</sup>, Peter Šišovský<sup>g</sup>, Lidia Zielińska<sup>h</sup>,  
Axel Glasmacher<sup>i,j</sup>

<sup>a</sup> Johnston Cancer Research Centre, Queen's University Belfast, BT9 7AE, UK

<sup>b</sup> Merck BV, Director EU Global Regulatory and Scientific Policy, Global Regulatory Affairs, Tupolevlaan 41-61, Schiphol-Rijk 1119 NW, the Netherlands

<sup>c</sup> Ryvu Therapeutics S.A, 2 Sternbacha Street, Krakow 30-394, Poland

<sup>d</sup> Bayer AG, Global Regulatory Leader, Research & Development Pharmaceuticals, Regulatory Policy & Science, Berlin 13353, Germany

<sup>e</sup> Alivia Cancer Foundation, Ul. Niedźwiedzia 4c, Warsaw 02-737, Poland

<sup>f</sup> Maria Skłodowska-Curie National Research Institute of Oncology, Roentgena 5, Warsaw 02-781, Poland

<sup>g</sup> State Institute for Drug Control in Slovakia, Non-clinical and Clinical Assessment Department, Kvetna 11, Bratislava 825 08, Slovakia

<sup>h</sup> Melanoma Patient Network Europe & Sarcoma (Association for the Support of Patients with Sarcomas and Melanomas), ul. Mickiewicza 63 pok, Warsaw 301 01-625, Poland

<sup>i</sup> Department of Internal Medicine III, Univ. of Bonn, Germany

<sup>j</sup> Cancer Drug Development Forum, Clos Chapelle-aux-Champs 30, Brussels 1200, Belgium

### ARTICLE INFO

#### Keywords:

Central & Eastern Europe (CEE)

Clinical trials

Cross-border access

Precision oncology

Patient-focused drug development

### ABSTRACT

Clinical research in oncology is essential for improving patient outcomes; however, cancer care provision and access to novel therapies remains highly heterogeneous across Europe, particularly between Western and Eastern EU27 regions. This has been further compounded by the Russian invasion of Ukraine, severely disrupting regional cancer treatment, research infrastructures and clinical trials activity. Challenges to clinical research in the Central and Eastern regions of the European Union (EU27-CEE) are multifactorial, relating to patient access, local implementation and conduct of trials, education, infrastructure and regulatory procedures. Nevertheless, EU27-CEE comprises a very active clinical trial landscape with its specialist workforce, high productivity and quality of data, empowering a growing regional pharmaceutical industry and establishing itself as an important clinical cancer research hub for conducting global trials. Consequently, patients recruited in EU27-CEE exercise an important impact on global cancer drug development. Poland has proven to be a model for biomedical innovation, serving as the region's blueprint for a productive clinical trials ecosystem. Multi-stakeholder collaboration and patient-centric approaches are required to streamline procedures for quicker trial initiation, simpler trial conduct, and better cross-border access. Recognizing these challenges and opportunities, we have developed, through a consultative approach, a Call to Action that, if implemented, would enhance the cancer clinical trials landscape in EU27-CEE countries and empower patient access to the latest advances and therapies in cancer drug development.

### 1. Introduction

The Central and Eastern European region of the European Union (EU27-CEE), – comprising 11 Member States and approximately 23 % of

the EU population (ca. 101 million inhabitants) [1,2] – represents a distinct and increasingly relevant segment of the European health and research landscape. Following successive EU enlargements between 2004 and 2013, countries including Poland, Hungary, Romania, Czechia

\* The views and opinions expressed in this publication are those of the individual co-authors and may not be understood or quoted as being made on behalf of or reflecting the position of any organization, committee, working party or group with which a co-author is affiliated.

\* Corresponding author at: Johnston Cancer Research Centre, Queen's University Belfast, BT9 7AE, UK.

E-mail addresses: [mark.lawler@qub.ac.uk](mailto:mark.lawler@qub.ac.uk) (M. Lawler), [susan.bhatti@merckgroup.com](mailto:susan.bhatti@merckgroup.com) (S. Bhatti), [pawel.przewieźlikowski@ryvu.com](mailto:pawel.przewieźlikowski@ryvu.com) (P. Przewieźlikowski), [birgit.wolf@bayer.com](mailto:birgit.wolf@bayer.com) (B. Wolf), [joanna.kazana@alivia.org.pl](mailto:joanna.kazana@alivia.org.pl) (J. Frątczak-Kazana), [peter.sisovsky@sukl.sk](mailto:peter.sisovsky@sukl.sk) (P. Šišovský), [lidia.zielinska@sarcoma.pl](mailto:lidia.zielinska@sarcoma.pl) (L. Zielińska), [axel@cddf.org](mailto:axel@cddf.org) (A. Glasmacher).

<sup>1</sup> nio.gov.pl

and others have transitioned from centrally-planned to market-based healthcare systems. While substantial progress has been made in modernizing infrastructure and aligning regulatory frameworks, structural weaknesses and differences in access to innovative drugs remain [3]. Health expenditure per capita in most EU27-CEE countries remains well below the average of the 38 member countries of the Organization for Economic Co-operation and Development [OECD38], and delays in the uptake and reimbursement of innovative oncology treatments are common in this region [4,5]. On average, the region’s purchasing-power-adjusted gross domestic product (GDP) per capita stands at 79 % of the EU mean [6], reflecting both economic progress and persistent disparities. These factors affect not only access to care, but also the broader capacity for clinical research and innovation.

At the same time, the region plays a vital and growing role in global oncology research. A pre-pandemic analysis showed that 15 % of all patients enrolled in global clinical trials submitted to the U.S. Food and Drug Administration (FDA) were recruited from EU27-CEE countries; therefore patients recruited in EU27-CEE have an important impact on global cancer drug development [7]. Among clinical trials currently planned/recruiting in EU27-CEE (up to June 2025), Poland has over 1350 registered trials, followed by the Czechia with ~800 trials, and Hungary with ~540 trials [8] (Fig. 1), demonstrating a very active clinical trial landscape in EU27-CEE. The region’s combination of population size, well-trained clinical staff, and available patient pools has led pharmaceutical companies to establish major clinical operations hubs in several countries – particularly Poland, where AstraZeneca, Merck Sharp & Dohme, Sanofi, and others maintain large research and development presences [9]. Several EU27-CEE countries, including Poland, Slovenia, and Croatia, have recorded some of the fastest economic growth within the EU in recent years [10,11]. This has been accompanied by significant growth in pharmaceutical markets, with regional revenues increasing from €21.5 billion in 2019 to €31.8 billion in 2023 [12]. These developments suggest both an improving landscape for access to cancer medicines and expanding opportunities for research partnerships.

Cancer patients who are treated in research-active hospitals display better outcomes than those who are not, emphasizing the key role of research in 21st century cancer care [13]. Additionally, there is growing

evidence that increased clinical research activity in oncology contributes to earlier access to innovative therapies and broader improvements in cancer care. Participation in clinical trials allows patients to benefit from cutting-edge treatments and protocolised care, which has been associated with improved outcomes in various malignancies [14]. Additionally, the 2024 clinical trial ecosystem assessment performed by the European Federation of Pharmaceutical Industries and Associations (EFPIA) noted that trials can deliver innovative medicines to patients up to 5–10 years before commercial launch and generate system-level benefits—such as enhanced diagnostics, better data infrastructure, enhancement of workforce skills, and cost savings—thereby strengthening overall care capacity [9]. Although clinical trial access is a key measure of quality-of-care and a fundamental right of the patient, it remains an important unmet need globally – only around 9 % of patients in the US, and even less globally, enter clinical trials [15]. In the EU27-CEE region, where health systems often operate under resource constraints, clinical trials have provided not only early access to innovation but also capacity-building effects, particularly in countries like Poland and Czechia [16].

However, research activity alone does not ensure broad patient access, as significant delays in national reimbursement of European Medicines Agency (EMA)-approved drugs persist across much of the region [5]. The ongoing war in Ukraine has had a multifaceted impact on the region. EU-CEE countries neighboring Ukraine – most notably Poland, Slovakia, and Romania – have faced additional pressure on their health systems due to large-scale refugee inflows and the closure of clinical study sites in Ukraine [13,17,18]. Simultaneously, the conflict has introduced new uncertainties for regional research collaboration and supply chain stability, while also underscoring the strategic importance of resilient health and research infrastructures in Europe’s eastern borderlands [13,18].

This paper, informed by a multi-stakeholder workshop convened by the Cancer Drug Development Forum (CDDF) in Kraków, Poland, in April 2024, provides an in-depth assessment of cancer clinical research and care in the EU27-CEE region. It synthesizes insights from patient advocates, clinical investigators, regulators, and industry stakeholders, and highlights best practices – particularly from Poland – that can inform policy and practice across the region. These insights form the

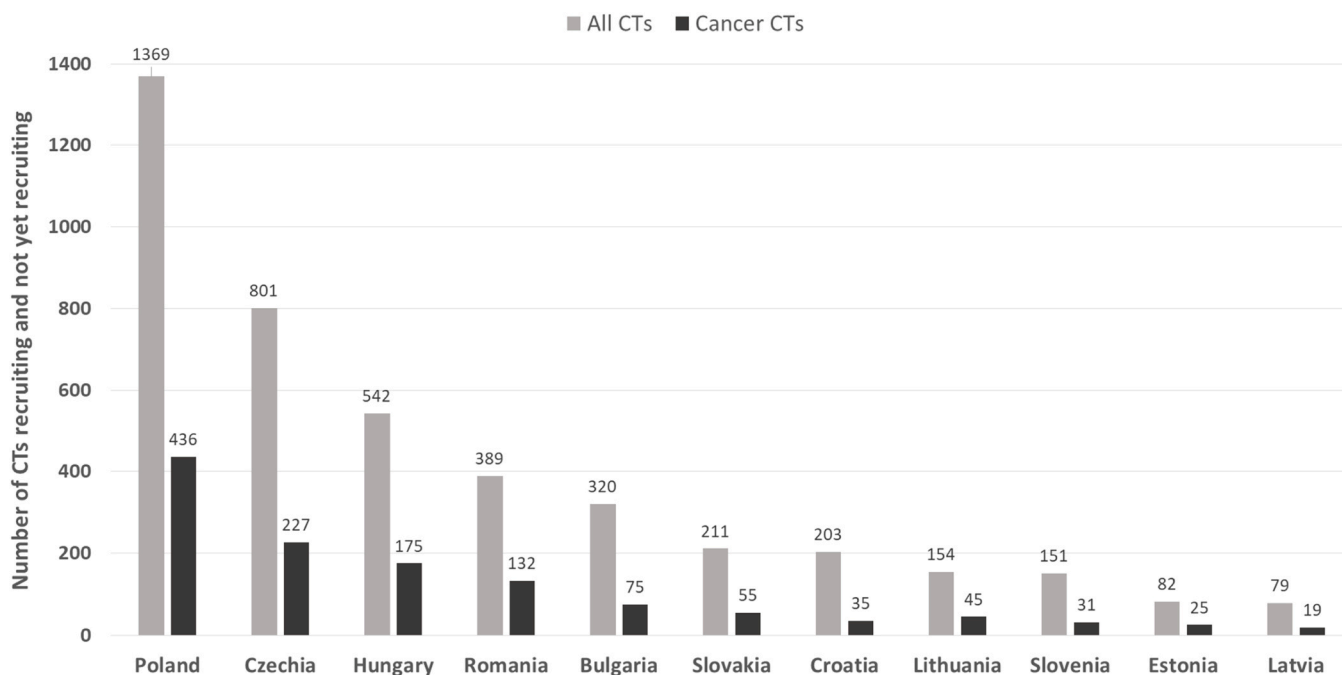


Fig. 1. Comparing clinical trials activity in EU27-CEE\*. \*Per Clinicaltrials.gov on 30 June 2025. EU27-CEE, Central and Eastern European countries in the European Union; CTs, clinical trials.

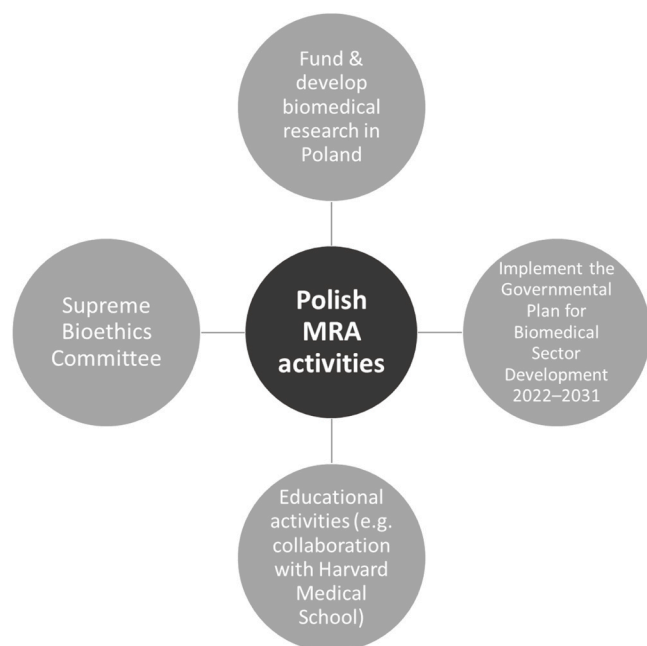
basis for a Call to Action to enhance clinical research and innovation activities in the region (Figs. 2 and 3).

## 2. Current status of oncology care and clinical research in EU27-CEE

### 2.1. Cancer care inequalities across Europe

Recent surveys have highlighted the inconsistencies in access to precision oncology drugs and high-quality biomarker testing across Europe, with important disparities noted between Western and many EU27-CEE countries [19,20]. Notably, there are higher aged-standardized cancer-related mortality rates in EU27-CEE countries than in other EU countries [20]; the highest cancer-related mortality rates observed among OECD38 (2021) were in Hungary, Slovakia, Slovenia, Latvia, and Poland [4]. Furthermore, the average time-to-market for a newly registered oncology drug (time from date of EU-wide approval to date of first sale) in many EU27-CEE countries has been below the European average of 398 days (2011–2018) [5]. Provision of cancer care, including adoption of novel therapies, enhanced biomarker testing, and robust infrastructure capacity to deliver more advanced therapies, is highly heterogeneous across Europe, particularly between Western and Eastern EU regions [19–22].

Clinical trials are an important part of healthcare provision by enabling access to innovative therapies that may not yet be available, and can also alleviate costs to public payers [13,14]. Cancer clinical research directly impacts on patient survival and is thus an essential part of modern European cancer care. There is an unmet need for clinical research to close the regional divide that has been observed, and an opportunity for clinical trials to help bridge the gap between innovative precision oncology therapies and patients' access, especially in EU27-CEE, where the research gap is at its widest [13].



**Fig. 2.** Objectives and activities of the Medical Research Agency (MRA) of Poland. The MRA was founded in 2019 with a vision to establish Poland as a leading site for clinical research both in CEE-EU and globally, by building the necessary capacity and infrastructure to ultimately increase the attractiveness of conducting clinical trials in Poland among its sponsors, but also to all stakeholders. CEE-EU: Central and Eastern European countries in the European Union; MRA: Medical Research Agency of Poland.

### 2.2. Challenges with conducting precision oncology clinical research in EU27-CEE

Based on multi-stakeholder perspectives from patients, investigators and industry, there are several barriers to establishing EU27-CEE as a region for the effective conduct of clinical trials, some of which are EU-wide (Table 1) and others being specific to EU27-CEE. In order to improve trial recruitment and patient access in EU27-CEE, there is a crucial need to raise awareness and understanding among patients and doctors that clinical trials are fundamental to medical progress and to access innovative treatment approaches. Importantly, clinical trials provide an opportunity to improve patients' outcomes whilst enhancing and saving money to healthcare systems, and trial participation should be considered as one of many options across national and global recommendations, rather than just a last resort as is currently often the case. Similarly to other EU regions, patients in EU27-CEE are missing comprehensive discussions about relevant trials with their doctors, notably on potential benefits and risks of precision oncology treatments; reciprocally, medical professionals in EU27-CEE must be educated to be better equipped to guide patients through decision-making processes.

A resounding consensus gleaned from regional patient advocates is that it is often unclear where to find a relevant clinical trial taking place in EU27-CEE, given the delayed implementation of the EU Clinical Trials Register (EU-CTR) in national languages (Table 1) and no accessible public database of available clinical trials (commercial/non-commercial/investigator-initiated). Accordingly, there is an important unmet need for a user-friendly, informative and up-to-date EU-wide clinical trials registry available in EU27-CEE local languages, including information on specific enrolment sites (e.g. contact details, trial eligibility and whether trial is open/closed), and updated with key trial results (ideally also with data from preceding earlier phase trials). Finally, specific concerns have been raised by local clinical trial investigators and study coordinators running clinical trials at academic research sites in EU27-CEE, with increasingly complex clinical trial procedures becoming very challenging for site staff, and a call to trial sponsors to provide more support and resources [23,24].

### 2.3. Regulatory hurdles within the EU

Despite significant efforts over the past years, there still remains a large gap between the EMA's aspirations and the realities on the ground in individual EU countries, notably in EU27-CEE, characterized by a lack of harmonization with regards to the registration and conduct of clinical trials across the region. There is a general consensus on the urgent need to reduce bureaucratic burdens by simplifying EU-wide regulatory and operational processes, including tackling the multiplicity of guidance documents and legal frameworks (e.g. Pharmaceutical Legislation or Medical Devices regulation) and asynchronous approval processes slowing down trial registration and conduct (e.g. separate assessments for *in vitro* diagnostics used in clinical trials). Furthermore, the Clinical Trials Information System (<https://euclinicaltrials.eu/>) submission and approval process, as required for all clinical trial applications in the EU/European Economic Area by end of 2025, must be streamlined and simplified.

National health agencies and ethics committees often have additional country-specific requirements that go beyond those in the EU legislation for clinical trial applications. For example, the administrative burden in some EU27-CEE national healthcare systems could be reduced by shortening the contracting stage at different national sites to speed up trial initiation. Similarly, capacity constraints within some EU27-CEE health authorities due to insufficient human resources could be alleviated by workload sharing between agencies across the EU. Ultimately, there is a need to continue to strive for better regulatory alignment and consistency between EU Member States, therefore simplification by harmonizing and reducing processes is much needed to save time and ultimately ensure trials can initiate more promptly, particularly for

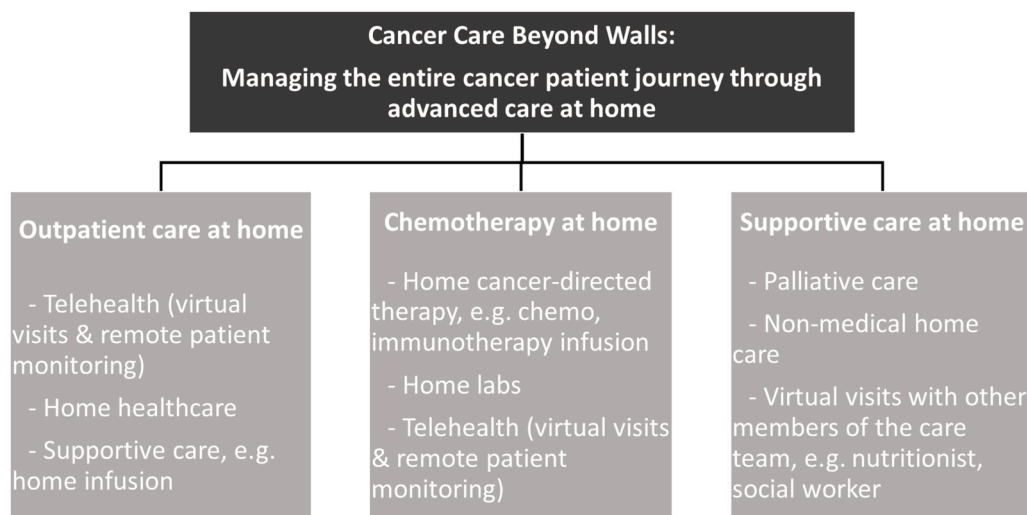


Fig. 3. The Mayo Clinic ‘Cancer Care Beyond Walls’ Program.

multi-regional trials across the EU27-CEE.

### 3. Fostering a favorable environment for oncology clinical research in EU27-CEE

#### 3.1. Poland as a model for a clinical trials ecosystem

Data on the pharmaceutical market in the region show that Poland is by far the most active EU27-CEE country, with a revenue of > €10.5 billion (2023), followed by Romania (€5.2 billion), Czechia (>€4.4 billion), and Hungary (€3.2 billion) [25]. Among 15 CEE countries (beyond the EU, 1999–2024), Poland conducted the highest number of clinical trials (16,247, ~2% of all clinical trials worldwide, with oncology being the top indication), followed by Czechia (11,941), Hungary (11,038) and Russia (10,434; the remaining countries conducted under 6000 clinical trials) [26], demonstrating that a number of biomedical organizations have noticed Poland’s potential in this sector.

The steady increase in the number of clinical trial applications for medicinal products in Poland can be attributed to various factors (Table 2), including by achieving high standards, with Poland ranked fifth top country for relative site productivity (148% versus 80% for the US) [27]. Quality also keeps pace: results of the FDA Bioresearch Monitoring inspections (2014–2020) showed that 73% of the inspections for Poland ended with no actionable findings (versus the US 67%, Germany 80%, and UK and France both 74%), confirming Western-grade data integrity [28,29]. These data demonstrate very positive results on the conduct and reporting of clinical trials in Poland, being comparable or better than countries with a more mature clinical trial landscape.

Additionally, recent governance reforms –chiefly the 2023 Clinical Trials Act and the government-based Medical Research Agency (MRA)’s implementation of EU-CTR – have compressed combined ethics-plus-regulatory review to roughly 60 days, giving Poland one of the fastest study start-up clocks in the region [30,31]. Public sentiment in Poland is also favorable – 68% of adults view trial participation positively and more than half would consider enrolling, according to a 2025 nationwide survey [32]. Several crucial socio-economic factors have also contributed to Poland becoming a promising prospect for a global R&D hub (Table 2). Poland is the largest economy in EU27-CEE, and the sixth largest economy in the EU behind Germany, France, Italy, Spain and Netherlands [33]. Strong and stable GDP growth provides a favorable economic base for further development, making Poland a regional economic leader with a high potential for dynamic future growth. Another key factor is Poland’s human capital of life science talent from a

productive university base and qualified R&D labor force.

Although Poland’s poor healthcare expenditure is currently one of the lowest among OECD countries and delayed reimbursement remains a key unmet need in Poland [4], these factors also comprise an opportunity for clinical trials to fill this gap by offering innovative treatments to patients. Furthermore, public clinical sites must continue to work towards eliminating some existing constraints, notably atypical requirements at contracting stages (e.g. requests for detailed excerpts from commercial registers, even from pharmaceutical companies with an international reputation). However, taken together, Poland’s blend of scale, recruitment efficiency, streamlined regulation and proven quality means Poland is usually placed in the first wave of global protocols, while neighboring EU27-CEE countries serve mainly as complementary add-on markets. But Poland could also act as a model for other EU27-CEE countries to emulate.

#### 3.2. Cross-border access

Clinical trials are an important element of healthcare, especially for patients with life-threatening and/or rare diseases, for which this avenue might be the only therapeutic option [14,34]. Patients should be able to access clinical research across Europe, but opportunities for patients to join a clinical trial differ greatly depending on the EU country they live in, with most trials still conducted in Western Europe [9]. Although joining a clinical trial abroad is theoretically possible per European legislation, there is no specific guidance to facilitate cross-border trial participation (formal national legal/regulatory/ethical frameworks do not seem to exist for this specific setting) [34], and thus unsurprisingly, EU cross-border access to clinical trials rarely occurs [9,35]. There is an overwhelming need to facilitate approaches that support better cross-border access, notably across EU27-CEE, such as decentralization of care delivery, to be closer to where patients live by using local laboratories, providers and support systems. The European Forum for Good Clinical Practice and EFPIA jointly started the EU Cross-border Trials Initiative, EU-X-CT (eu-x-ct.eu), to enable cross-border access to clinical trials when there is no option for patients to join a trial in their own country by addressing the key hurdles (e.g. legal/regulatory and ethical constraints, financial/reimbursement hurdles, or operational challenges at clinical sites).

### 4. Conclusions

Productive clinical cancer research is fundamental to improving patient outcomes, but access to the latest advances remains highly

**Table 1**  
Suggested improvements for overcoming the barriers to clinical research in EU27-CEE from the perspective of different stakeholders.

Category/perspective	Suggested improvements
<b>Patients' perspective*</b>	<ul style="list-style-type: none"> <li>• Create an accessible and regularly updated Europe-wide clinical trials database, accessible to both patients and HCPs in EU27-CEE countries</li> <li>• Devise more patient-friendly clinical trials for EU27-CEE countries with greater convenience (e.g. exploiting the benefits of remote technology)</li> <li>• Include EU27-CEE patients as equal partners in the trial design process</li> </ul>
<b>Investigators' perspective†</b>	<ul style="list-style-type: none"> <li>• Strengthen the partnership of different EU27-CEE stakeholders (patient organizations, public institutions and investigators) to create and implement long-term patient education projects in the area of clinical trials and the applications of new technologies</li> <li>• Mandate that study sponsors minimize the number of non-urgent emails sent to EU27-CEE investigators to 1–2 email per project per week</li> <li>• Ensure additional human resources in EU27-CEE countries to alleviate the increasing operational/logistical tasks imposed on investigators, such as:             <ul style="list-style-type: none"> <li>◦ Managing study drug supplies</li> <li>◦ Ensuring medication availability</li> <li>◦ Collecting all relevant certificates</li> <li>◦ Making Patient Reported Outcomes (PROs) (notably electronic ones) available to the patients</li> <li>◦ Determining travel cost reimbursement</li> <li>◦ Calculating payments for visits and procedures (information which should already be on the sponsors' systems)</li> </ul> </li> <li>• Educate the medical community in EU27-CEE countries on the option to refer patients to CTs as an alternative treatment approach by:             <ul style="list-style-type: none"> <li>◦ Raising awareness of the collective benefits of referring patients to a CT</li> <li>◦ Alleviating fears from EU27-CEE doctors that they may lose business if they refer a patient to a CT</li> </ul> </li> <li>• Raise awareness and increase trust among EU27-CEE patients on the benefits of clinical trials by communicating that:             <ul style="list-style-type: none"> <li>◦ A CT is an ethically approved, safe and well-monitored process</li> <li>◦ Through CTs, patients can gain early access to new technologies</li> <li>◦ Patients enrolled in CTs will receive 'extra care', such as assistance from study coordinators to navigate the patient journey (e.g. scheduling of their activities and medical procedures), and reimbursement for travel and meal costs</li> </ul> </li> </ul>
<b>Study coordinators' perspective‡</b>	<ul style="list-style-type: none"> <li>• Ensure additional human resources from sponsors to alleviate the increasing administrative burden in EU27-CEE countries including:             <ul style="list-style-type: none"> <li>◦ Providing support to assist in the provision of reports</li> <li>◦ Monitoring kits and stocks of investigational products</li> <li>◦ Assembling kits manually</li> <li>◦ Sending images, drug accountability, PROs, and local laboratory results through various online systems (there may be 3–10 platforms per protocol)</li> <li>◦ Managing travel reimbursement</li> </ul> </li> </ul>
<b>Regional infrastructure and health systems§</b>	<ul style="list-style-type: none"> <li>• Enhance digitalization of the health system in EU27-CEE region</li> <li>• Invest in clinical research personnel in EU27-CEE region</li> <li>• Invest in more specialized equipment in EU27-CEE countries, often needed for certain types of clinical trials</li> </ul>

**Table 1 (continued)**

Category/perspective	Suggested improvements
	<ul style="list-style-type: none"> <li>• Simplify overall bureaucracy</li> <li>• Shorten the contracting stage with clinical sites in EU27-CEE countries             <ul style="list-style-type: none"> <li>◦ For example, both the UK and France have introduced nation-wide systems to standardize costing and contracting processes for each site across the country, shortening clinical trial initiation by several months</li> </ul> </li> <li>• For partnering agreements for drugs discovered in EU27-CEE, develop creative schemes to ensure future access to drugs for EU27-CEE patients at a price level acceptable to the EU27-CEE payers</li> </ul>
<b>Regulatory perspective§</b>	<ul style="list-style-type: none"> <li>• Achieve regulatory and procedural alignment in implementing the CTR across the EU (including the EU27-CEE region) – ensure simplification and harmonization</li> <li>• Improve patient-centricity including through consultation, participation and information provision, and by advancing uptake of innovative trial design and technologies in EU27-CEE region</li> <li>• Reduce the bureaucratic burden and support more academic trials for questions that go beyond drug approval</li> <li>• Share workload among EU Member States to increase efficiency of CTs applications assessment (e.g. multinational assessment teams)</li> </ul>

EU27-CEE, Central and Eastern European countries in the European Union; CT, clinical trial; CTR, Clinical Trials Regulation; HCPs, healthcare practitioners; PROs, patient-reported outcomes

\*Consensus at the workshop through the patient advocate stakeholders' perspective.

† Consensus at the workshop through the investigator/study coordinator stakeholders' perspective.

‡Consensus at the workshop through the health system stakeholders' perspective.

§Based on the general consensus from the panel discussions at the workshop.

heterogeneous across the EU, with an imbalance between Western Europe and EU27-CEE. However, clinical trials across the latter region can help bridge the healthcare gaps by providing patient access to novel precision oncology medicines and innovative interventions, and enhance representativeness of all EU patients in clinical trials. Furthermore, with its specialist workforce, high productivity and quality of data outputs, EU27-CEE is also an attractive region to conduct global clinical trials, as exemplified by Poland with its steady economic growth, governmental support for both commercial and non-commercial trials and the establishment of a national clinical trials network. Finally, multi-stakeholder collaboration is required to streamline procedures for quicker trial initiation and simpler trial protocols/conduct, providing an opportunity for the EU27-CEE region to enhance their clinical trial portfolio.

Panel: Call to Action for more equitable patient access to precision oncology therapies across Europe

In order to address the myriad challenges we have highlighted, a series of policy recommendations were developed (Panel 1), informed by data intelligence and achieved by consensus through the panels that were convened at the Cancer Drug Development Forum (CDDF) multi-stakeholder workshop "Clinical Research in Central and Eastern Europe: New Approaches for the Next level of Development" <https://cddf.org/events/past-events/cddf-meetings-2024/cddf-workshop-april-2-024/>

1. Deliver a multi-tiered and collaborative approach to increase patient access to clinical trials in the EU's Central & Eastern European region (EU27-CEE).

1.1. Increase availability of oncology clinical trials for greater European diversity representation.

The emergence of EU27-CEE sites should be fostered and

**Table 2**  
Factors contributing to Poland as a leading partner for the international biomedical industry.

Aspect	Factors/reasons
<b>Favorable socio-economic conditions*</b>	<ul style="list-style-type: none"> <li>• Favorable economic base for further development:                             <ul style="list-style-type: none"> <li>o Poland has a large and stable economy with strong GDP growth, and is expected to record the largest GDP growth among Europe's big economies in 2025</li> <li>o Strong domestic market, low private debt, low unemployment rate and flexible currency</li> </ul> </li> <li>• Research funding support from the European Union</li> <li>• Human resources with specialist training as a result of access to a strong caliber of universities teaching biomedical sciences/biotechnology                             <ul style="list-style-type: none"> <li>o Poland ranked 5th in the EU by numbers of scientists (in 2022)</li> </ul> </li> <li>• Short-term growth engine: Labour cost arbitrage                             <ul style="list-style-type: none"> <li>o E.g. business process outsourcing centers for patient enrollment, contract research on drugs, clinical trials, bioinformatics services, and production of high-value-added drugs (difficult-to-synthesize generics, biosimilars)</li> </ul> </li> <li>• Long-term growth engine underpinned by innovation                             <ul style="list-style-type: none"> <li>o Strong heritage in biomedical discoveries over the last centuries</li> <li>o Polish innovative drugs approach empowered by collaborative research with international institutions</li> <li>o Presence of AI-driven precision medicine (screening for proprietary targets and strong academic collaborations)</li> </ul> </li> </ul>
<b>Investigator's perspective: Poland's strong position in clinical research†</b>	<ul style="list-style-type: none"> <li>• Establishment of the Polish Medical Research Agency                             <ul style="list-style-type: none"> <li>o Governmental financial and infrastructural support, including the Polish Clinical Trials Network</li> <li>o Large push from the government for non-commercial CTs since 2019</li> <li>o Better organization and centralization of some existing cancer centers</li> </ul> </li> <li>• Steady increase in numbers of CT registrations in Poland can be attributed to:                             <ul style="list-style-type: none"> <li>o Attractiveness of the market in view of future sales</li> <li>o High speed of return of feasibility questionnaires</li> <li>o Presence of nationally and internationally recognized investigators in Poland</li> <li>o Availability of a defined patient population</li> <li>o Access to equipment required by the protocol at clinical sites</li> <li>o High site productivity and robust quality of data</li> <li>o Advances in medical technology (AI and machine learning in drug discovery and development; personalized medicine)</li> <li>o Increase in the number of diseases being studied</li> <li>o Recognition of the need for new treatments and vaccines, especially in response to global health crises</li> </ul> </li> </ul>

**Table 2 (continued)**

Aspect	Factors/reasons
<b>Industry perspective: Poland's strengths as a clinical trial location‡</b>	<ul style="list-style-type: none"> <li>• Higher productivity of clinical trial sites in relation to other markets</li> <li>• Centralized healthcare system with competent researchers attracting and retaining large numbers of patients for clinical trials</li> <li>• Lower costs of conducting clinical trials compared to other markets, including lower start-up costs</li> <li>• Still a relatively small saturation of clinical trials to country population, compared to other EU27-CEE countries</li> <li>• Established and well-respected Polish Clinical Trials Network (PCTN)</li> </ul>

AI, artificial intelligence; EU27-CEE, Central and Eastern European countries in the European Union; CT, clinical trial; GDP, gross domestic product

\*Consensus at the workshop through the socio-economic perspective.

† Consensus at the workshop through the investigator stakeholder perspective.

‡ Consensus at the workshop through the industry stakeholder perspective.

encouraged, given their proven consistency in producing high-quality data – not only to increase patient access and numbers treated, but also to improve patients' outcomes.

1.2. Create an accessible, informative and regularly updated patient- and practitioner-facing EU-wide clinical trials registry.

The clinical trials register should be available in local languages, with obligatory inclusion of site contact information (i.e. name of site, contact email), clear eligibility criteria and enrolment status, and timely updates of trial results (including data from the preceding Phase 1–2 trials, where possible). The Registry should be urgently embedded in national cancer strategies, with a multi-stakeholder agreement on how it can be funded.

1.3. Urgently address the critical need for better cross-border access to clinical trials across the EU with a specific emphasis on patients in EU27-CEE.

Numerous challenges and outstanding questions remain to be solved (e.g. financial, regulatory/ethical and logistical aspects), however the feasibility of cross-border access can be increased if planned upfront in the trial design and protocol.

1.4. Implement patient-centric approaches in trial protocol designs and regulations, including through decentralization of care delivery to be closer to patients in EU27-CEE countries.

Achieve EU-wide harmonized regulatory requirements on decentralized trial elements, including use of digital tools to facilitate uptake of innovation, new technologies and participation in patient-centered clinical trials, with a particular emphasis on EU27-CEE countries.

1.5. Develop country-level educational campaigns for physicians across the EU27-CEE region to increase awareness of clinical trials as a possible treatment option, rather than just a rescue treatment.

Clinical research needs to be integrated as one of the pillars for healthcare education, alongside national treatment guidelines that include the latest treatment innovations.

1.6. Increase efforts to fund non-commercial trials in certain EU27-CEE countries to increase patients' opportunity to access to treatment.

This will also facilitate collection of data on special populations (e.g. rare cancers, pediatric oncology), allowing this intelligence to contribute to the overall effort in maximizing the development of new and improved therapies

2. Harmonize clinical trial protocols and submissions, EU regulatory processes, and study initiation and conduct

2.1. Adapt clinical trial protocols, ranging from straightforward to more complex, in order to answer questions rapidly and simply in EU27-CEE countries.

Focus on what matters most to patients (e.g. survival, quality-of-life) and minimize protocol deviations, particularly for trials combining

existing therapies – greater interaction is needed between the US Food and Drug Administration and the EU's European Medicines Agency (EMA) to work together towards this objective (e.g. pragmatic trials).

2.2. Simplify EU-wide regulatory and operational processes through harmonization to reduce overall requirements and promote workload sharing across the EU.

This approach should be deployed particularly for smaller country health agencies, in order to mitigate potential human capacity constraints.

2.3. Streamline the EMA's Clinical Trials Information System submission process to shorten the authority response timelines for initial approval and amendments.

This approach can help ensure the EU region remains competitive in global clinical research.

2.4. Alleviate the administrative burden imposed by national healthcare systems, notably across EU27-CEE.

Introduce country-wide systems to standardize costs and contracting processes for each site, to improve trial start-up times by several months (e.g. as implemented in France and the UK).

2.5. Bridge the gaps between sponsors and local investigators/contract research organizations (CROs) to improve collaboration and increase efficiency of conducting clinical trials, with a particular focus on EU27-CEE.

This could be achieved, for example, by sponsors providing a communication platform to facilitate their interaction with CROs, and with additional human resources to alleviate the local administrative burdens.

2.6. Increase patients' and communities' trust in clinical cancer research, by providing more opportunities for dialogue between patients and doctors.

This should replace the monologue by the doctor to the patient by implementing a 'no time, no trust' approach with patients as active participants rather than passive recipients.

2.7. Increase transparency of clinical trials by making information promptly available to patients.

This can be achieved through the timely public release of lay summaries in parallel with the first presentation of trial results at scientific conferences, and by encouraging active dialogue between the public and pharmaceutical companies to enable public scrutiny.

3. Conduct more publicly-funded research on available therapeutic interventions

3.1. Provide opportunities for clinicians in EU27-CEE countries to engage in clinical research and drive investigator-led clinical trials.

Incentivize and support investigator-led clinical trials and clinical research studies.

3.2. Ensure appropriate training and mentorship support for early-stage clinician scientists in EU27-CEE countries to deliver academic-led clinical studies.

Ensure both support and protected time are available to empower early career clinicians with an interest in research.

3.3. Increase EU27-CEE physicians' willingness to engage in clinical research, by seeking greater input from expert physicians at the earliest stages of protocol/study design, to ensure that procedures are user-friendly.

Ensure realistically feasible and applicable to local clinical practice, before final approval of the protocol.

### CRedit authorship contribution statement

**Mark Lawler:** Writing – review & editing, Validation, Conceptualization. **Susan Bhatti:** Validation, Conceptualization. **Joanna Frączak-Kazana:** Validation. **Paweł Przewieźlikowski:** Validation, Conceptualization. **Birgit Wolf:** Validation, Conceptualization. **Lidia Zielińska:** Validation. **Axel Glasmacher:** Validation, Conceptualization. **Piotr Rutkowski:** Validation. **Peter Šišovský:** Validation.

### Declaration of Competing Interest

ML reports having received honoraria from Pfizer for presentations unrelated to this paper.

SB is an employee of Merck BV and managing director of Merck Europe BV.

PP is an employee of Ryvu Therapeutics, and sits on boards of Ryvu, Selvita and Ardigen. He also holds shares in Ryvu and Selvita.

BW is an employee of Bayer AG, Berlin Germany.

JFK is an employee of Alivia Cancer Foundation and reports no conflicts of interest directly related to this paper.

PR has received honoraria for lectures and Advisory Boards from BMS, MSD, Novartis, Pierre Fabre, Genesis Pharma, Medison Pharma outside of the scope of this report.

PS reports no conflicts of interest relevant to this paper.

LZ reports no conflicts of interest relevant to this paper.

AG reports no conflicts of interest relevant to this paper.

### Acknowledgements

This paper is informed by the multi-stakeholder Cancer Drug Development Forum (CDDF) Workshop 'Clinical Research in Central and Eastern Europe – New Approaches for the Next Level of Development' (April 15–16, 2024), sharing insights from industry leaders, regulators, academics, patient groups and non-commercial organizations. CDDF asbl ([www.cddf.org](http://www.cddf.org)), a non-profit organization dedicated to improve the development of anti-cancer drugs, sponsored this multi-stakeholder workshop and provided support for the preparation of this article. The authors acknowledge administrative support from the CDDF Office staff, writing support from Tania Kapoor, and the contributions from the following speakers, session chairs and discussion panel members at this CDDF workshop: Keiu Heinla, Alexander Hope, Laura Huggins, Wiktor Janicki, Chitkala Kalidas, Ewa Kalinka, Olga Kholmanskikh, Teodora Kolarova, Ewa Mark-Pawlowicz, Hendrik Nogai, Karolina Nowak, Grzegorz S. Nowakowski, Richard Pazdur, Francesco Pignatti, Eva Hrušková Reinová, Radek Spisek.

### References

- [1] EuroVoc, EUR-Lex 2024. ([https://eur-lex.europa.eu/browse/eurovoc.html?params=7,7206,5781#arrow\\_5781](https://eur-lex.europa.eu/browse/eurovoc.html?params=7,7206,5781#arrow_5781)) (accessed 30 June 2025).
- [2] Worldometer, European Countries by population, 2024. (<https://www.worldometers.info/population/countries-in-europe-by-population/>). (accessed 30 June 2025).
- [3] M. Costa, D. Collingridge, Groundshot: a pan-European, patient-centred, and data-driven approach to tackling cancer, *Lancet Oncol.* 24 (1) (2023) 5–6.
- [4] OECD, Health at a Glance 2023: OECD Indicators. <https://doi.org/10.1787/7a7afb35-en> (accessed 5 December 2024).
- [5] C.A. Uyl-de Groot, R. Heine, M. Krol, J. Verweij, Unequal access to newly registered cancer drugs leads to potential loss of life-years in Europe, *Cancers* 12 (8) (2020) 2313, <https://doi.org/10.3390/cancers12082313>.
- [6] Eurostat, Purchasing power parities and GDP per capita - preliminary estimate, 27 March 2025. ([https://ec.europa.eu/eurostat/statistics-explained/index.php?title=Purchasing\\_power\\_parities\\_and\\_GDP\\_per\\_capita\\_-\\_preliminary\\_estimate](https://ec.europa.eu/eurostat/statistics-explained/index.php?title=Purchasing_power_parities_and_GDP_per_capita_-_preliminary_estimate)) (accessed 30 June 2025).
- [7] Food and Drug Administration (FDA), 2015–2019 Drug Trials Snapshots, Summary Report: Five-Year Summary and Analysis of Clinical Trial Participation and Demographics (November 2020). file:///D:/Downloads/fda-drug-trials-snapshots-report-november-2020.pdf (accessed 30 June 2025).
- [8] Clinicaltrials.gov, 2024. (<https://clinicaltrials.gov/>) (accessed 30 June 2025).
- [9] IQVIA for European Federation of Pharmaceutical Industries and Associations (EFPIA) and Vaccines Europe (VE). Assessing the clinical trial ecosystem in Europe, Final Report (October 2024). (<https://www.efpia.eu/media/3edpooqg/assessing-the-clinical-trial-ecosystem-in-europe.pdf>) (accessed 30 June).
- [10] Organisation for Economic Co-operation and Development (OECD), Economic Outlook – An unfolding recovery, May 2024. (<https://www.oecd.org/economic-outlook/may-2024/>) (accessed 30 June 2025).
- [11] European Commission, Spring 2024 Economic Forecast: A gradual expansion amid high geopolitical risks, 15 May 2024. ([https://economy-finance.ec.europa.eu/economic-forecast-and-surveys/economic-forecasts/spring-2024-economic-forecast-gradual-expansion-amid-high-geopolitical-risks\\_en#gdp-growth-map](https://economy-finance.ec.europa.eu/economic-forecast-and-surveys/economic-forecasts/spring-2024-economic-forecast-gradual-expansion-amid-high-geopolitical-risks_en#gdp-growth-map)) (accessed 30 June 2025).
- [12] Statista. Revenue of pharmaceutical markets in Central and Eastern Europe from 2021 to 2023, December 2024. (<https://www.statista.com/statistics/458901/phar>

- maceutical-markets-turnover-central-and-eastern-european/) (accessed 30 June 2025).
- [13] M. Lawler, L. Davies, S. Oberst, K. Oliver, A. Eggermont, A. Schmutz, et al., European groundshot – addressing Europe’s cancer research challenges: a lancet oncology commission, *Lancet Oncol.* 24 (1) (2023) e11–e56, [https://doi.org/10.1016/S1470-2045\(22\)00540-X](https://doi.org/10.1016/S1470-2045(22)00540-X).
- [14] J.M. Unger, E. Cook, E. Tai, A. Bleyer, The role of clinical trial participation in cancer research: barriers, evidence, and strategies, *Am. Soc. Clin. Oncol. Educ. Book* 35 (2016) 185–198.
- [15] A. Occa, A. Leip, A.S. Merritt, J.L. Stapleton, Prevalence and correlates of invitation to participate in clinical trials among US adults, *Prev. Med. Rep.* 26 (2022) 101742, <https://doi.org/10.1016/j.pmedr.2022.101742>.
- [16] IQVIA Institute Research Highlights 2022. (<https://www.iqvia.com/blogs/2023/02/iqvia-institute-research-highlights-2022>) (accessed 30 June 2025).
- [17] A. Charalambous, D. Pyle, R. Sullivan, N. Couespel, E. Venegoni, M. Lawler. Cancer services disruptions during the war in Ukraine. Results from a joint multidisciplinary survey. European Cancer Organisation, Brussels. (<https://www.europecancer.org/resources/289:cancer-services-disruptions-during-the-war-in-ukraine-results-from-a-joint-multidisciplinary-survey.html>) (accessed 8 April 2025).
- [18] I. Bondarenko, A. Agarwal, M. Van Hemelrijck, M. Lawler, M. Zubaryev, R. Sullivan, Far-reaching impact of the Russian invasion of Ukraine on global cancer research, *Eur. J. Cancer* 183 (2023) 95–97, <https://doi.org/10.1016/j.ejca.2023.01.020>.
- [19] N. Normanno, K. Apostolidis, A. Wolf, R. Al Dieri, Z. Deans, J. Fairley, et al., Access and quality of biomarker testing for precision oncology in Europe, *Eur. J. Cancer* 176 (2022) 70–77, <https://doi.org/10.1016/j.ejca.2022.09.005>.
- [20] A. Bayle, J. Bonastre, D. Chaltiel, N. Latino, E. Rouleau, S. Peters, et al., ESMO study on the availability and accessibility of biomolecular technologies in oncology in Europe, *Ann. Oncol.* 34 (10) (2023) 934–945, <https://doi.org/10.1016/j.ejca.2022.09.005>.
- [21] C. Berchet, G. Dedet, N. Klazinga, F. Colomb, Inequalities in cancer prevention and care across Europe, *Lancet Oncol.* 24 (1) (2023) 10–11, [https://doi.org/10.1016/S1470-2045\(22\)00746-X](https://doi.org/10.1016/S1470-2045(22)00746-X).
- [22] IQVIA Institute of Human Data Science. Global Oncology Trends 2023, Outlook to 2027, May 2023. (<https://www.iqvia.com/insights/the-iqvia-institute/reports-and-publications/reports/global-oncology-trends-2023>) (accessed 30 June 2025).
- [23] M. Sekeres, Contract research agonizations. *ASH Clinical News*, American Society of Hematology, 2017. (<https://ashpublications.org/ashclinicalnews/news/3109/Contract-Research-Agonizations>) (accessed 30 June 2025).
- [24] J.L. Perez-Gracia, N. Penel, E. Calvo, A. Awada, H.T. Arkenau, T. Amaral, Streamlining clinical research: an ESMO awareness call to improve sponsoring and monitoring of clinical trials, *Ann. Oncol.* 34 (1) (2023) 70–77, <https://doi.org/10.1016/j.annonc.2022.09.162>.
- [25] Sas A. Revenue of pharmaceutical markets in Central and Eastern Europe 2021–2023, December 2024. (<https://www.statista.com/statistics/458901/pharmaceutical-markets-turnover-central-and-eastern-european/>) (accessed 30 June 2025).
- [26] World Health Organization (WHO). Number of clinical trial registrations by location, disease, phase of development, age and sex of trial participants (1999–2024), December 2024. (<https://www.who.int/observatories/global-observatory-on-health-research-and-development/monitoring/number-of-trial-registrations-by-year-location-disease-and-phase-of-development>) (accessed 30 June 2025).
- [27] V. Misik, B. Jarosz, L. Bęczkowski, M. Czarnecka, T. Dąbrowski, D. Drake, et al. Report on industry clinical trials in Poland – possibilities to increase number and scope of trials in Poland, 2021. (<https://longtaal.com/report-industry-clinical-trials-poland/>) (accessed 30 June 2025).
- [28] Food and Drug Administration (FDA), Inspection Classification Database, September 2024. (<https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/inspection-classification-database>) (accessed 30 June 2025).
- [29] J. Gelfand, K. Dutchak, Clinical trials in central & Eastern Europe: keeping up with global competition, *J. Clin. Stud.* 9 (2) (2017) 36–38. (<https://journalforclinicalstudies.com/wp-content/uploads/2017/04/Clinical-Trial-in-Central-and-Eastern-Europe.pdf>).
- [30] D. Kitala, K. Kaczmarska, J. Kornacka, K. Górski, E. Bylina, K. Nowak, et al. Medical research agency: 5 years of reshaping the clinical trials ecosystem in Poland. *Lancet Reg. Health Eur.* 48 (101175) (2024). doi: 10.1016/j.lanepe.2024.101175. eCollection 2025 Jan.
- [31] P. Ledesma. Clinical trials in Poland: A land of opportunities. ([https://www.sofpro.com/clinical-trials-in-poland-a-land-of-opportunities?utm\\_source=chatgpt.com](https://www.sofpro.com/clinical-trials-in-poland-a-land-of-opportunities?utm_source=chatgpt.com)) (accessed 30 June 2025).
- [32] A. Kozakiewicz, J. Mazur, M. Szkulcka-Dębek, M. Białorudzki, Z. Izdebski, Public perception of clinical trials and its predictors among Polish adults, *J. Clin. Med.* 14 (10) (2025) 3279.
- [33] CountryEconomy.com. (<https://countryeconomy.com/countries/groups/european-union>) (accessed 30 June 2025).
- [34] European Forum for Good Clinical Practice (EFGCP). (<https://efgcp.eu/project?initiative=EU-X-CT>) (accessed 30 June 2025).
- [35] T. Lalova, C. Padeanu, A. Negrouk, D. Lacombe, J. Geissler, I. Klingmann, et al., Cross-border access to clinical trials in the EU: exploratory study on needs and reality, *Front. Med.* 7 (2020) 585722, <https://doi.org/10.3389/fmed.2020.585722>.