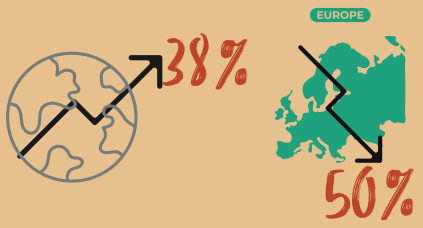
Lung Cancer Europe

Clinical Trials in Europe

Key Trends and Issues

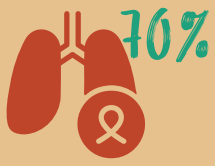
Participating in a clinical trial is a potential lifeline for many people in Europe. Clinical trials provide participants with early access to new medicines by up to 5-10 years before launch. But there are now 60,000 fewer spots in trials for people living in Europe.

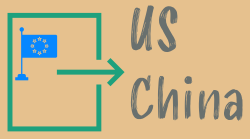
Half of all **clinical trials in the world** take place in just 4 countries: US, China, India and Japan



- Globally clinical trials have increased by 38% over the past 10 years while **Europe's share of these trials has dropped by half**.
- There are fewer oncology trials in Europe today than in 2018

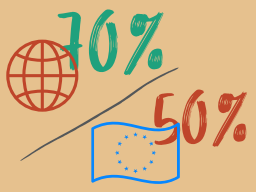
70% of all **lung cancer trials** since 1999 have taken place in China, US and Japan even though Europe has the poorest lung cancer outcomes (incidence/mortality) in the world





Europe is losing attractiveness for **commercial trial sponsors** compared to US and China due to regulatory barriers, unfavorable demographic trends, slower and less divese patient recruitment

Globally around 70% of clinical trials are sponsored by **non-commercial stakeholder**, while in EU only about 50% are



Number of clinical trials conducted in EU countries is highly inequitable and varies by income levels, yet it is rare for people to gain access to clinical trials beyond their home country

Lung Cancer Europe

Call to Action

Access to clinical trials is critically important for people with lung cancer. In Europe, access to trials is highly inequitable and is worse in countries with higher disease burden and lower income levels. Moreover, recruitment of participants remains slow and lacks diversity when compared to clinical trial leaders like the US. **As Europe is falling behind in the number of clinical trials, participants' access to trials and new medicines will follow this trend. Urgent policy action as well as investment is needed to course-correct.**

1. Governments in Europe collectively need to **increase the share of non-commercially sponsored clinical trials** in order to catch-up with market leaders like the US and China

2. **Multicountry trials in the EU need to be facilitated** by eliminating additional national requirements that go beyond the EU Clinical Trials Regulation and by supporting harmonized dossier reviews by National Competent Authorities and Ethics Committees across Europe

3. **People living with lung cancer need to be included in clinical research at an early stage** when they can meaningfully contribute to the definition of research questions, prioritisation, patient-relevant endpoints, trial design, inclusion and exclusion criteria and priorities in terms of benefit and risk.

4. **Barriers to cross-border access to clinical trials within EU need to be understood and addressed**, and participants' access to trials beyond their home countries needs to be facilitated

Frequently Asked Questions

What is a clinical trial?

According to the World Health Organization (WHO), a clinical trial is **any research study that assigns participants or groups of humans to health-related intervention(s) with the purpose of evaluating its effects on health outcomes**. Clinical trials may also be referred to as interventional trials. Health-related interventions include but are not limited to drugs, cells and other biological products, surgical procedures, radiologic procedures, devices, behavioural treatments, process-of-care changes, preventive care, etc.

WHO considers the registration of all interventional trials to be a scientific, ethical and moral responsibility.

Why do we need clinical trials?

For any health-related intervention to be approved and become available in the market, developers need to take it through strict clinical development to demonstrate:

Safety: minimal risk of side effects
Efficacy: ability of a medicine to provide a beneficial effect.

This happens in **4 phases** of clinical trials: **Phase I** tests new interventions on a small group of healthy people to determine safe dosages and identify side effects. **Phase II** tests the intervention on a larger group of people with the target disease to confirm the dose and assess efficacy and safety. **Phase III** is often the step right before a new treatment is approved and involves even larger populations across geographic regions, comparing the new treatment to a standard of care. **Phase IV** studies take place after approval when there is need for further testing in a wide population over a longer timeframe.

What is the importance of clinical trials for patients?

- The goal of clinical trials is to determine if a new test or treatment works and is safe. Some clinical trials also look at other aspects of care, such as improving the quality of life for people with chronic illnesses.
- **Clinical trials provide participants with the earliest access to new medicines, up to 5-10 years before launch.**
- Clinical trials offer hope for many people and an opportunity to help researchers find better treatments for others in the future.

What is the state of clinical trials* in the World and in Europe?

- In 1999, there were 5,346 clinical trials in the world. In 2024, this number had increased to 906,163.
- **50% of all clinical trials in the world take place in just four countries**: US, China, India and Japan, with the US leading the world in number of trials.
- Over the last 25 years, 12,540 or 1.69% of registered clinical trials have focused on lung cancer.
- Over **70% of all lung cancer trials have taken place in China, US and Japan**.
- **Within Europe, Germany leads** in the number of clinical trials conducted over the past 25 years at 54,902, followed by the UK and France. **Spain has also recently emerged as a leading EU country in clinical trials**. By contrast, the number of trials conducted in Bulgaria was 5,705 and Ireland was 4,637 indicating a significant differential between European countries.
- Oncology remains the dominant therapeutic area for commercial clinical trials in European Economic Area (EEA) accounting for 25% of the trials**.
- As of February 2025, the **EU Clinical Trials registry has 376 ongoing lung cancer clinical trials** of which 309 focus on Non-Small-Cell Lung Cancer.
- **Globally, clinical trials are predominantly sponsored by non-commercial stakeholders**, with a relatively stable 70% -30% split between non-commercial and commercial/pharma sponsored. Within the EU, non-commercial trials are around 50%.

*The figures included here are taken from trials listed in the WHO International Clinical Trials Registry Platform (ICTRP)
** Data from American oncology trials shows that 20% of oncology clinical trials fail to complete because of inadequate accrual. Patient accrual, or achieving the targeted sample size, is required for valid results, without which trials fail to reach intended goals. Lung cancer trials have comparatively poor accrual rates despite growing incidence of lung cancer.

Is Europe falling behind in clinical trials compared to other regions?

- Data from commercial research shows significant country-level variation within Europe; however, the number of trials has decreased in all but three countries, indicating a systemic challenge in the region.
- **Despite global clinical trials increasing by 38% over the past decade, the EEA's global share of trials has halved over the same period.** This translates to 60,000 fewer participants accessing a trial involving a country within the region, meaning people living in Europe could be missing out on the opportunity to access the latest medicines.

Why has Europe fallen behind in clinical trials?

- Clinical trials can be the most expensive and time-consuming part of the drug development process.
- Pharmaceutical industry research suggests that Europe's diminishing attractiveness for clinical research can be attributed to less favourable regulatory and funding environments as compared to the US and China, which slows down the set up and access to trials.
- **Conducting multi-country trials is challenging in Europe** (e.g. for innovative precision medicine) due to regulatory fragmentation and lack of coordination between countries. This often **pushes trial sponsors to choose other regions like the US and China which also benefit from larger populations**.
- As pharmaceutical industry is driven by global market forces and commercial priorities, multi-country or EU-wide trials are crucial for enabling medicines developers in Europe to achieve the necessary scale to compete with the US and other global competitors.

What is the state of oncology trials in Europe?

- While a quarter of all trials in Europe focus on oncology, there has been a relative or absolute decline in all phases of oncology trials in Europe, which are now below 2018 levels.
- By contrast, the US saw an increase in oncology trials in 2021. Pharmaceutical industry consider the EU In-vitro Diagnostic Regulation (IVDR) to pose operational challenges for multi-country trials in oncology.
- While Europe's Beating Cancer Plan can help provide better focus in this area, the plan itself risks getting deprioritized due to shifting health policy landscape in EU.

What policy measures has the EU instituted to support and promote clinical trials?

- European Union (EU) pharmaceutical legislation known as the **Clinical Trials Regulation (CTR**) entered into application on 31 January 2022 and **became fully applicable across all clinical trials in the EU on 31 January 2025**. It aims to ensure the EU offers a favourable environment for carrying out clinical research on a large scale, with high standards of public transparency and safety for clinical trial participants.
- Prior to the CTR, trial˜sponsors needed to submit clinical trial applications separately to national competent authorities and ethics committees in each country for regulatory approvals.
- The **CTR harmonises the processes for assessment and supervision of clinical trials throughout the EU by enabling trial sponsors to submit only one online application** via a single platform known as the Clinical Trials Information System (CTIS) for approval to run a clinical trial in several European countries.
- The Regulation also makes it more efficient for EU Member States to evaluate and authorise such applications together, via the Clinical Trials Information System.

Is the CTR enough to help EU catch-up in clinical trials with the US and China?

- Participant recruitment is much slower and challenging in Europe than in the US and China. In addition, **Europe also faces unfavorable demographic trends that cannot be addressed through changing regulation alone.**
- Industry/commercial trial sponsors think that more needs to be done to make Europe competitive in the multi-country clinical trial ecosystem, such as:
  - **Eliminating additional national requirements that go beyond the CTR** and support harmonized dossier reviews by National Competent Authorities and Ethics Committees across Europe for multi-country clinical trials
  - Standardizing the Ethics Committees' review process across Europe.
  - **Facilitating cross-border access to clinical trials by patients.**
- The **advocacy capacity of non-commercial trial sponsors, however, is weak**, which also means that commercial trial sponsors dominate lobbying efforts in shaping European clinical trials ecosystem.

What are some of the barriers for participants' access to clinical trials in Europe?

- Participating in a clinical trial is a possible lifeline for many people in Europe. **Lack of clinical trial options in their home country pushes many individuals, particularly those with life-threatening diseases like lung cancer, to seek options across borders**. This is especially true for people with lung cancer living in Eastern Europe where prevalence is high while the number of trials is comparatively low.
- Despite high demand, it is rare for potential participants to gain access to clinical trials beyond their home country. The **lack of an EU-wide legal framework or any guidance that defines the conditions for accessing clinical trials in another country creates high barriers for people with lung cancer** and healthcare professionals.
- Lack of educational resources (availability and accessibility across all EU countries), lack of awareness and scientific jargon also pose significant barriers to participants' access to trials.

What improvements are required to make clinical trials more people-centered?

- It is important to **involve people living with lung cancer in clinical research at an early stage when they can meaningfully contribute to the definition of research questions, prioritisation, patient-relevant endpoints**, trial design, inclusion and exclusion criteria and priorities in terms of benefit and risk.
- In clinical trials, it is important to **include patient reported outcomes (PROs)**. This reflects the participant's perception of the disease and treatment, covering symptoms, quality of life, health status, treatment adherence, and satisfaction.
  - PROs, if sufficiently incorporated, can inform the decisions taken at the stage following clinical trials i.e. Health Technology Assessment (HTA) by providing evidence to support things like cost-effectiveness analysis, market access, reimbursement, and pricing negotiations.
  - Implementing PROs in clinical trials remains challenging due to lack of standardized methods for data collection, analysis and interpretation. Moreovere, PROs don't always reflect the newer issues experienced by people on novel therapies.
- Additional efforts should **focus on streamlining, harmonising and reducing the complexity for potential participants to provide relevant information**.

Which initiatives in the EU are working to complement CTR implementation?

- Launched in 2022, the Accelerating Clinical Trials in the EU (ACT EU) initiative aims to develop the European Union further as a competitive centre for innovative clinical research. The European Commission, the European Medicines Agency (EMA) and the Heads of Medicines Agencies (HMA) run the ACT EU initiative together.
- The ACT EU initiative is complementary to the CTR. Among other priorities, it supports non-commercial trial sponsors, and includes perspectives of people living with diseases and other conditions.

Which initiatives in the EU are working to complement CTR implementation?

- Operationalized in 2024 and leveraging the EU Health Data Space, the EU is also promoting the use of real-world evidence from healthcare databases across the EU for the safety and effectiveness of health interventions. This is called the Data Analysis and Real World Interrogation Network (DARWIN EU®), and is supported by EMA and the European Medicines Regulatory Network. This complements clinical trials by assessing treatment effectiveness in real-life settings and diverse participant populations, helping with regulatory decision-making.
- The EMA has also taken some steps towards greater engagement with people impacted by disease.
- The EU Cross-Border Clinical Trials Initiative (EU-X-CT) is a multi-stakeholder initiative (including patients' organisations) aimed at systematically collecting information on the barriers to cross-border participation in clinical trials from all European countries -inside and outside the EU- and developing recommendations for enabling better access.

Prepared by **Talha Jalal**, EU Policy and Engagement Advisor
with contributions from **Chiara Antoniani**, EU Project Manager
For any questions reach out to talha.jalal@lungcancereurope.eu

LuCE Policy Briefings *are primarily developed for people with lung cancer and their caregivers. These accessible briefings focus on key policy issues and developments that affect their well-being and access to healthcare. This resource is aimed at building the capacity of advocates and their communities to influence policies and engage in change-oriented advocacy at both European and national levels.*