Roundtable on the European Clinical Trial Ecosystem

July 2025

Multi-stakeholder Report

High-level Summary

On 24 March 2025, a broad group of stakeholders—including academic and industry sponsors, investigators, and professional societies—met to review the state of clinical trials in Europe and discuss joint solutions to ongoing challenges. The roundtable came amid a continued decline in Europe's global share of clinical research, despite the introduction of the Clinical Trials Regulation (CTR), which aimed to harmonise processes and boost cross-border collaboration.

Participants stressed the urgent need for better regulatory alignment across Member States. Fragmented implementation of the Clinical Trials Regulation (CTR) added barriers for combination studies, inconsistent assessments, and complex requirements continue to delay trial launches and increase the administrative burden. There was broad consensus on the need for a more effective framework—one that embraces streamlined, risk-based approaches, particularly for investigator initiated, low-intervention and paediatric trials—and strengthens coordination between ethics committees and national regulatory authorities.

To sustain momentum, participants committed to ongoing collaboration and follow-up. Turning these discussions into concrete actions was seen as essential, with continued multi-stakeholder dialogue viewed as key to meaningful reform and a stronger clinical trial ecosystem in Europe.

Background and Objectives

Despite a 38% increase in global clinical trials over the past decade, Europe's share has dropped from 22% in 2013 to 12% in 2023[1]. This represents 60,000 fewer clinical trial opportunities for European patients.

Europe is losing ground due to a fragmented clinical trial ecosystem. While a few countries continue to perform well, the overall decline across most Member States points to structural rather than localised issues. Meanwhile, Asia is rapidly emerging as a major hub for clinical research.

Adopted in 2014 and implemented in January 2022, the Clinical Trials Regulation (CTR) was designed to streamline both national and multi-country trials through a single submission and coordinated assessment across Member States. While the CTR promises greater efficiency and reduced fragmentation, stakeholders report that key challenges remain.

In light of this, a broad group of stakeholders—including representatives from academic and industry sponsors, investigators and professional societies —gathered on 24 March 2025 to assess the current state of the European clinical research ecosystem. *A full list of participating organisations is available in the annex.*

The roundtable aimed to discuss urgent challenges and explore collaborative solutions. Participants agreed that, at their current pace, existing initiatives are not sufficient to address the issues effectively and that accelerated action is needed.

[1] https://www.efpia.eu/media/3edpooqp/assessing-the-clinical-trial-ecosystem-in-europe.pdf

Key Themes and Discussion Highlights

Clinical trials play a crucial role in advancing medical research and ensuring the availability of innovative treatments for patients. However, there are several challenges in the EU that impact their efficiency, accessibility, and overall success.

Regulatory simplification, harmonisation and streamlining

One of the main concerns raised was the slow and fragmented approval process, which varies across countries and regulatory bodies. This inconsistency between regulators leads to delays in trial initiation and ultimately slows the development of new therapies.

This issue contributes significantly to regulatory burden and delays, particularly due to the differing procedures of national ethics committees. Although the CTR aims to create a unified submission and evaluation process across Member States, some impose additional national requirements beyond those outlined in the legislation—contradicting its core objective. These discrepancies add further layers of administrative complexity.

Regulatory hurdles are especially challenging for investigator initiated (IITs), paediatric and rare disease clinical trials. Divergent and discordant views across multiple stakeholders involved in the approvals of these trials lead to additional burden specific for these niche population. As a result, the approval of new medicines for children lags nearly a decade behind adult authorisations. This delay restricts access to innovation, compromises treatment, and increases reliance on off-label medicines not authorised for paediatric use. Furthermore, traditional trial designs are often unworkable in small populations. Innovative approaches—such as adaptive trial designs and the use of real-world data—should be actively encouraged.

The lack of harmonisation also affects the In Vitro Diagnostic Regulation (IVDR). Administrative barriers related to the IVDR have disrupted clinical trials—for example, a rare ovarian cancer trial was delayed for 18 months and ultimately cancelled. Innovation has suffered as a result. According to the European Society for Medical Oncology (ESMO), 10 out of 55 early-phase oncology trials in just one European centre have been cancelled or faced year-long delays. This represents not only a competitive loss for Europe but also a missed opportunity for European patients.

High administrative burden

The clinical trial approval process is significantly hindered by a high administrative burden and excessive Requests for Information (RFIs), many of which focus on aspects unrelated to patient safety or scientific integrity. These non-critical RFIs add unnecessary complexity and cause substantial delays. The lack of a standardised system for triaging or prioritising RFIs results in inconsistencies and creates additional challenges for both sponsors and investigators. Moreover, the absence of clear guidance on what constitutes a critical versus non-critical RFI makes it difficult for sponsors to anticipate and address regulatory concerns effectively.

Investigators also face considerable administrative burdens that divert their time from clinical investigation and patient care. These include, but are not limited to, providing the same data in different forms, multiple signatures in delegation and training logs, notes to file to explain self-explanatory aspects, and add-ons to official documents such as the informed consent. This administrative burden is imposed particularly in registration trials but also when conducting low-interventional trials. Under the current regulation, low interventional trials have become increasingly complex due to a too restrictive definition. As a result, they are often subject to the same administrative requirements as interventional trials, despite involving approved medicines with established safety profiles. This reduces the appeal of low-interventional designs and undermines

their practical utility. Furthermore, the CTR does not align with OECD guidance, which recommends categorising trials into three groups—repurposing, innovative, and comparative—based on drug type. The European Commission has only adopted two categories, limiting the potential impact and uptake of low-interventional trials.

The CTR also lacks flexibility regarding protocol modifications. Sponsors and investigators are frequently required to undergo time-consuming re-evaluation processes even for minor amendments. Compounding the issue, the Clinical Trials Information System (CTIS) does not support the submission of multiple modifications simultaneously, which can delay substantial updates and the inclusion of additional Member States in ongoing trials.

Contracting is another area of persistent administrative burden, particularly for academic investigators. Lengthy delays in contract negotiations between sponsors, investigators, and trial sites often result in significant trial start-up delays.

Patient recruitment, representation and retention

Many clinical trials struggle to enroll a diverse and sufficient number of participants, often resulting in delays or early termination—particularly in paediatric trials. Contributing factors include low awareness among patients and healthcare professionals, logistical burdens such as frequent travel requirements, cross-border health insurance issues, concerns about the trial's impact on daily life, and limited knowledge among general practitioners on how to manage side effects.

There is also a growing need to enhance inclusivity and diversity in clinical research. Historically underrepresented populations continue to face barriers to participation, resulting in gaps in understanding how treatments affect different demographic groups. Improving representation is essential for developing therapies that are safe and effective for all patient populations.

One barrier to recruitment is the complexity of the informed consent form (ICF). Poorly drafted ICFs can make it difficult for patients to understand trial requirements and objectives, discouraging participation. Additionally, because national ethics committees must evaluate ICFs in line with local laws, cultural norms, and ethical standards, this process adds to the administrative burden.

Financial burden

The financial burden of conducting clinical trials remains a major obstacle. High costs related to site management, data collection, and regulatory compliance can discourage smaller organisations and academic institutions from participating in trials or contributing to clinical development.

This challenge is particularly acute for investigator-initiated trials and those led by academia or professional societies. Limited public funding often results in insufficient financial support for essential aspects such as trial planning, execution, regulatory navigation, and access to qualified professional staff. As a result, many valuable research initiatives struggle to move forward or reach completion.

Use of technology and data

Technology and digital innovation hold significant promise for improving the efficiency and effectiveness of clinical trial processes. Emerging tools and enablers such as the European Health Data Space (EHDS), real-world data (RWD), and artificial intelligence (AI) have the potential to optimise trial design, enhance patient monitoring, and accelerate data analysis.

However, to fully realise these benefits, several key challenges must be addressed—most notably those related to data privacy, including compliance with the General Data Protection Regulation (GDPR), as well as issues of interoperability and the regulatory acceptance of real-world evidence.

Beyond regulatory requirements, sponsors and investigators also face considerable complexity in managing (serious) adverse events ((S)AEs), including Suspected Unexpected Serious Adverse Reactions (SUSARs). These challenges are further exacerbated by the lack of harmonised data standards, making adverse event reporting more burdensome and less efficient.

Capacity and training gaps

A lack of training among key stakeholders emerged as a critical barrier to the effective implementation of the Clinical Trials Regulation and applicable clinical research legislative framework in general. Academic sponsors, ethics committee members, investigators, and other key stakeholders often have limited familiarity with regulatory frameworks, digital platforms such as the CTIS, and evolving trial models, including low-intervention and decentralised trials. This knowledge gap contributes to delays, misinterpretation of requirements, and inconsistent assessments across Member States.

Proposed Actions and Solutions

Addressing these challenges requires a coordinated, multi-stakeholder approach. Enhanced collaboration among regulatory agencies, ethics committees, pharmaceutical companies, healthcare providers, patient advocacy groups, academic institutions, professional societies, and policymakers is essential to building a more efficient, harmonised, and patient-centric clinical trial ecosystem. Co-sponsorship models could further support this by enabling shared responsibility, resources, and expertise across stakeholders.

To effectively improve the clinical trial landscape, a combination of harmonised regulations, digital innovation, enhanced patient engagement, and financial sustainability is essential. These measures can significantly accelerate the development of life-saving treatments for patients across Europe and beyond. Rather than reinventing the wheel, the EU should build on best practices from other regions to increase flexibility and efficiency in trial approval processes. Additionally, better use of RWE and data extrapolation—supported by streamlined and user-friendly operational guidelines—could help overcome many current regulatory barriers.

Solutions for Regulatory simplification, harmonisation and streamlining

Streamlined processes and stronger coordination among regulatory authorities could substantially shorten approval timelines. This coordination should also extend to ethics committees. The coexistence of multiple ethics committees at national and institutional (hospital) levels, combined with misalignment between ethics and public health authorities, creates inefficiencies—particularly in cross-border trials where multiple jurisdictions are involved.

To address challenges in paediatric clinical trials, participants proposed the development of a more effective and targeted regulatory framework. This could be achieved by further optimising the paediatric provisions in the ongoing revision of EU General Pharmaceutical Legislation (GPL), including streamlining the organisation and operations of the PDCO as proposed by the European Commission. Other suggested improvements included the introduction of regulatory sandboxes and pilots to promote innovation, and better use of extrapolation and RWE.

On the IVDR, several solutions were put forward to improve implementation. These included the creation of a harmonised single-entry application system, accelerated development of clear guidance, and EU-funded capacity-building initiatives for Member States. Additional proposals included a validated reference assay model, faster feedback mechanisms through the European Database on Medical Devices (EUDAMED), a time-limited regulatory sandbox, and targeted exemptions for high-impact or lower-risk trials. These changes aim to support innovation while maintaining robust regulatory oversight.

Solutions to Address the Challenges of High administrative burden

From the perspective of investigators, studies and respective protocols should be developed as fit for purpose, minimising the collection of data that is not essential, or will not be used in any step of the trial life cycle, thereby immediately reducing time and costs. The administrative burden imposed on the investigators needs to be reassessed, so their time can be dedicated to investigation and patient care. Expanding both the definition and practical understanding of non-interventional clinical trials is essential to avoiding unnecessary bureaucratic requirements for low-risk studies. Trials that involve only minor procedures—without added safety risks or significant deviations from standard clinical practice—should be classified as non-interventional. Furthermore, randomisation should be recognised as a methodological tool rather than automatically treated as an intervention, thereby preventing inappropriate reclassification of such studies and reducing the associated administrative burden.

In terms of site setup—particularly the contracting phase—a standardised and simplified contract framework would help expedite the process.

Solutions to Address the Challenges of Patient recruitment, representation and retention

Improving patient engagement is essential for increasing recruitment and retention in clinical trials. Strategies such as public (age-appropriate) education campaigns, decentralised trial models, and improved communication channels—particularly virtual platforms for informed consent—can strengthen connections between healthcare professionals, providers, and patients. These approaches not only streamline participation but also help build trust and transparency.

In the context of vaccine development, the EU and its Member States should take a more proactive and coordinated role in raising public awareness about the critical importance of volunteer participation in clinical research. Without volunteers, the development of new medicines, vaccines, and innovative health interventions is not possible. Regularly organised public information campaigns at both EU and national levels are vital for fostering public understanding, trust, and engagement in research that benefits society as a whole.

A major challenge highlighted is the underrepresentation of certain populations in clinical trials. Addressing this issue requires targeted outreach efforts, trust-building within underrepresented communities, and trial designs that are inclusive and adaptable to diverse populations.

Simplifying the informed consent process is another critical step. Clearer, more accessible consent forms can help patients better understand trial requirements and objectives. For paediatric trials, the use of age-appropriate materials and assent forms should be encouraged to support both ethical conduct and enrolment.

Solutions to Address the Challenges on Financial Burden

Exploring alternative funding models, offering financial incentives, and leveraging public–private partnerships could help ease the financial pressures associated with conducting clinical trials. Dedicated public funding should be made available to support professional societies, academic institutions, patient associations, and public investigators in conducting non-industry-sponsored trials. This is essential to strengthening independent research in Europe and ensuring a more balanced and sustainable clinical research landscape.

Solutions to Address the Challenges on Use of Technology and Data

To fully realise Europe's potential in harnessing its health data sources, the proper implementation of the European Health Data Space (EHDS) is essential. This requires, among other things, harmonised data formats and changes to the way data is collected across systems.

In particular, requirements for investigators related to adverse event reporting should be simplified. Rather than requesting individual notifications for each event, regulators could instead require periodic safety profile reports with pooled SUSAR data, or adopt biannual summary reports on adverse events. These adjustments would reduce the administrative burden while maintaining robust safety oversight.

Solutions to Address the Challenges on Capacity and Training gaps

To address capacity and training gaps, participants proposed the development of structured, cross-stakeholder training programmes focused on regulatory literacy, CTIS navigation, and evolving trial methodologies. These initiatives should engage professional societies, patient associations, academic institutions, regulators, and ethics committees to promote a shared understanding of requirements and ensure consistent interpretation across Member States. Co-designed workshops, continuing education modules, and closer engagement with regulatory bodies were identified as effective formats to build capacity, strengthen collaboration, and support the successful implementation of the Clinical Trials Regulation.

Conculsions and Next steps

As a concrete outcome of the roundtable, participants agreed to prepare a joint public statement highlighting the key challenges discussed and the proposed solutions. This statement will aim to raise awareness among decision-makers, regulators, and the broader clinical research community, and to advocate for an urgent and coordinated action at both EU and national levels.

Despite representing various sectors and perspectives, the group identified significant areas of overlap and several common challenges. There was broad agreement that Europe has many strengths to build on, and a strong willingness to help address current barriers by proactively proposing solutions.

To maintain momentum, participants committed to reconvening after the summer to review progress, exchange updates on ongoing initiatives, and explore further opportunities for collaboration. The follow-up meeting will also aim to broaden stakeholder engagement and deepen discussions on implementation strategies and policy alignment.

Annex – List of organisations represented at the Roundtable

- ECRAID: European Clinical Research Alliance for Infectious Diseases – https://www.ecraid.eu/
- ECRIN: European Clinical Research Infrastructure Network – https://www.ecrin.org/
- EATRIS: European Infrastructure for Translational Medicine – https://eatris.eu/
- EFPIA: European Federation of Pharmaceutical Industries and Associations – https://www.efpia.eu/
- EHA: European Haematology Association - https://ehaweb.org/
- EORTC: European Organisation for Research and Treatment of Cancer – https://www.eortc.org/
- EuropaBio: European Association for Bioindustries – https://www.europabio.org/
    - hollandbio: https://www.hollandbio.nl/
    - bioMerieux: https://www.biomerieux.com/corp/fr.html
    - BioMarin: https://www.biomarin.com/
- EUCOPE: European Confederation of Pharmaceutical Entrepreneurs – https://www.eucope.org/
- ESMO: European Society For Medical Oncology – https://www.esmo.org/

- ESPGHAN: The European Society for Paediatric Gastroenterology Hepatology and Nutrition – https://www.espghan.org/
- The Coalition for Reducing Bureaucracy in Clinical Trials - https://bureaucracyincts.eu/
- TEDDY: European Network of Excellence for Paediatric Research – https://www.teddynetwork.net/
- Vaccinopolis – Innovative vaccine research centre
- Vaccines Europe – https://www.vaccineseurope.eu/
- ACUMEN - https://acumenpa.com/