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EVENT REPORT

Europe's moment: advancing clinical research and health innovation

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Co-funded by the European Union

Co-organised with

Bristol Myers Squibb

Event summary

Clinical research is the backbone of Europe's life sciences sector and a bellwether of its global competitiveness. Yet in the past decade, Europe's share of global clinical trials has declined sharply, reflecting systemic inefficiencies and growing competition from the United States and China.

This Policy Insight convened experts from government, industry, investment and public-private partnership to assess the state of Europe's clinical research and innovation ecosystem. Their discussions underscored both the urgency of reform and the opportunities Europe holds if it acts intentionally. With robust health systems, scientific excellence and a commitment to universal healthcare, Europe is uniquely placed to shape a sustainable, patient-centred model of innovation.

The debate highlighted the need for harmonisation, faster regulatory processes, investment in digital and AI-driven tools and stronger collaboration across sectors. Above all, the message was clear: Europe's moment is now. Seizing it requires ambition, coherence and clarity of purpose.

Key takeaways

During the event, several priorities emerged for strengthening Europe's role in clinical research:

- **The EU Life Sciences Strategy should position competitiveness alongside public health goals**, ensuring clinical research serves both patients and innovation.
- **Regulatory processes must be accelerated** by harmonising approval timelines, streamlining ethics reviews and simplifying contract negotiations across member states.
- **Public-private partnerships (PPPs) should be expanded** to break down silos, pool expertise and scale up successful models such as decentralised and platform trials.
- **Artificial intelligence (AI) and digital tools can reduce the cost and complexity of clinical development**, particularly in later stages, while supporting more patient-centred trial designs.
- **A new European model of innovation is needed**, designed intentionally around patient needs, payer realities and cost-effectiveness, rather than relying on US approval pathways.
- **Reform will require broad collaboration** across governments, regulators, industry, academia, investors and patient groups to align ambitions with practical delivery.

A shifting global landscape

Europe's history in medicine and science is one of leadership. From vaccines to biomedical research, Europe has been a pioneer. But that legacy is under pressure. Clinical trials, the mechanism that transforms scientific ideas into safe, effective treatments are increasingly being conducted elsewhere.

Over the past decade, Europe's share of global clinical trials has dropped dramatically. As **Richard Robinson**, Head of European Policy and Government Affairs at Bristol Myers Squibb (BMS), warned, "Europe's share of global clinical trials has halved over the last decade from 18% to only 9% of global clinical research." The trend is unmistakable: the United States and China are attracting a growing share of research activity, while Europe lags behind. This decline is more than a statistical footnote; it signals deeper challenges in Europe's ability to convert scientific excellence into health and economic impact.

Clinical trials are more than an academic exercise. They provide patients with early access to potentially life-saving therapies and bring inward investment: in Europe's case, over €1.5bn annually. They also strengthen health systems by embedding innovation into practice. When trials falter, the consequences ripple widely – patients wait longer, investment goes elsewhere and Europe's influence in global innovation diminishes.

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A competitive race against time

Global competition in life sciences has never been fiercer. The US continues to dominate clinical research, powered by deep capital markets, large patient pools and streamlined regulation. China, too, has rapidly expanded its share, drawing in multinational companies with promises of speed and scale. By contrast, Europe's fragmented system, shaped by 27 different national regulations, multiple languages and uneven administrative practices, creates friction.

The EU's Clinical Trials Regulation (CTR) was designed to address this by introducing a single-entry portal and coordinated assessment processes. But implementation has been uneven and many sponsors say it has increased rather than reduced complexity. Ethics committee procedures still vary widely between member states. Contract negotiations remain slow and inconsistent with approval timelines for multinational trials in Europe exceeding 100 days, compared to 40 to 60 days in other parts of the world.

Speed matters in clinical research. A delay of even a few months can determine whether Europe secures a trial or loses it to another region.

These challenges form part of a wider picture: Europe's difficulty in translating scientific discoveries into commercial and health impact. Without reform, the risk is that Europe becomes a bystander in a field it once led.

Policy momentum: the EU Life Sciences Strategy

Against this backdrop, the European Commission has launched the EU Life Sciences Strategy, an ambitious framework to make Europe the leading hub for health innovation by 2030. The strategy explicitly recognises clinical research as a priority, linking it to both competitiveness and public health. At its heart is a recognition that competitiveness in clinical trials is not optional – it is essential.

Rainer Becker, Director for Medical Products and Innovation, European Commission Directorate-General for Health & Food Safety (DG SANTE) stressed why this matters for patients: "When clinical trials are conducted in Europe, patients have earlier access to medicines and launches happen more quickly." In this view, anchoring clinical research within Europe is as much about public health as it is about economic strength.

Clinical trials also strengthen Europe's ability to respond to future crises, as demonstrated during the COVID-19 pandemic, when the rapid mobilisation of research infrastructure made the development and deployment of vaccines possible at unprecedented speed.

The strategy also highlights the upcoming Biotech Act, which will provide an opportunity to streamline and accelerate regulatory frameworks, with a focus on making them simpler, faster and more predictable. Proposals under discussion include more proportionate, risk-based approaches to low-intervention trials; reinforced coordination between member states; and streamlined ethics reviews. The Commission has also launched a public consultation, inviting stakeholders to share their views on where improvements are most urgently needed.

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Public-private partnerships as a catalyst

If regulation sets the framework, collaboration provides the engine. Public-private partnerships (PPPs) are increasingly recognised as essential to making Europe's clinical research ecosystem more effective. Rather than operating in silos, PPPs bring together industry, hospitals, academic researchers, patient groups and regulators to co-create solutions that address shared bottlenecks.

Several initiatives were highlighted by **Nathalie Seigneuret**, Senior Scientific Officer at the Innovative Health Initiative Joint Undertaking (IHI-JU) during the debate:

Connect for Children (C4C): a pan-European network linking 250 hospitals and clinical sites across 21 countries to support paediatric trials. By creating a single point of contact, C4C allows sponsors to identify trial sites within two weeks and complete feasibility checks within six. This dramatically reduces the risk of delays and ensures that children, often underserved in clinical research, can access trials more quickly.

EU-PEARL: focused on platform trial protocols, EU-PEARL has developed a 'master protocol' that allows multiple treatments to be tested under a single structure. Already deployed in depression trials across six countries, this model reduces administrative burden and increases flexibility.

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> **Nathalie Seigneuret**, Senior Scientific Officer at the Innovative Health Initiative Joint Undertaking (IHI-JU)

Trials@Home: a project exploring decentralised clinical trials, using digital tools to reduce the need for patients to travel to trial sites. Its proof-of-concept study is generating recommendations that could shape the future of patient-centred, digitally enabled research in Europe.

These projects demonstrate Europe's potential to lead in innovative trial design. By piloting new approaches and proving their feasibility, PPPs provide evidence that can inform future regulation and scale successful models across the EU.

As Seigneuret emphasised: "An important aspect of public-private partnerships is that we break the silos. We bring all perspectives together, and we can do things at scale by leveraging expertise, experience, and resources from both the public and private sides. The idea is not only to run pilots, but to create frameworks that can be scaled up and used more widely in Europe."

Rethinking Europe's model

Investment is the lifeblood of innovation. Without it, even the most promising science cannot reach patients. Yet Europe's current business model for life sciences is showing its limits. For years, many European biotech firms have depended on gaining approval and pricing power in the US market to sustain growth. But that approach is increasingly unsustainable, as payer systems tighten and investors seek predictable returns closer to home.

Nina Rawal, Partner and Co-Head at Trill Impact Ventures and a European Young Leader (EYL40), argued that Europe must "be intentional in designing a new model that is based on European patient needs and payer realities." The challenge, she said, is not only to remain competitive, but also to redefine competitiveness in a way that reflects Europe's strengths.

The old approach, betting on US approvals and high pricing, is no longer viable. Instead, Europe should centre its strategy on patient needs, payer realities, and cost-effectiveness. This is also a key commercial opportunity, as many middle-income countries are building up their health systems and are similarly price-sensitive when it comes to medication. Europe could embrace this opportunity and carve out a leadership role in these new markets. Rawal identified three levers for change: harnessing AI to lower clinical development costs; achieving true regulatory harmonisation; and adopting smarter, risk-based regulation. She stressed that Europe's unique combination of universal health systems, diverse patient populations and strong science could allow it to innovate not only for itself, but also for other countries worldwide.

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> **Nina Rawal**,Partner and Co-Head at Trill Impact Ventures and a European Young Leader (EYL40)

Conclusion

The Policy Insight underlined both the urgency and the opportunity of reform. Europe can still be a global leader if it acts now: by harmonising systems, scaling PPP solutions, embracing AI and designing an innovation model aligned with its strengths. The costs of inaction are high: patients wait longer for innovative treatments, health systems lose opportunities for early evidence and investment flows elsewhere.

The speakers consistently highlighted that reform would require collaboration across governments, industry, academia, regulators and patient groups. Lessons from existing PPPs show that success depends on breaking down silos and piloting new models that can be scaled across the EU. Speakers also emphasised the importance of intentionality: Europe must proactively define its own approach to medical innovation, rather than reacting to trends set elsewhere. This means placing patient needs and health system sustainability at the centre, while ensuring Europe remains globally competitive.

Ultimately, the debate made clear that Europe stands at a crossroads. The choice is whether to seize this moment with coherence and ambition or risk slipping further behind in the global race for medical innovation.

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info@friendsofeurope.org
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