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Mission Statement

As ***centre of expertise*** and ***representative association*** of the ***innovative biopharmaceutical industry***, pharma.be acts as a ***trusted partner*** to contribute to the ***sustainable health of citizens, patients, and the economy*** in Belgium, through ***knowledge-sharing, collaboration and dialogue***.

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ALGEMENE VERENIGING VAN DE GENEESMIDDELENINDUSTRIE

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pharma.be: the voice of > 120 (bio)pharma companies in Belgium

Start-ups, small, mid-sized and multinational companies

Almost all Belgian companies with R&D activities joined pharma.be – R&D activities as well in preclinical as in clinical stage

pharma.be
126
members

88% have medicines on the market in portfolio

32% of the human members with medicines on the market have at least one orphan drug on the market

90% of the members focus on human health

10% of the members focus on animal health

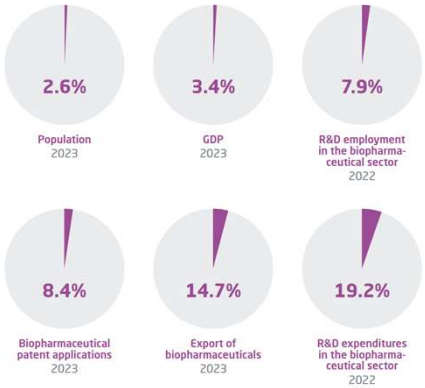
3

Key figures

The Belgian biopharmaceutical sector consistently in Europe's top 3

R&D	PATENTS[1]	JOBS	EXPORT
NO. 1 in R&D expenditures per capita (2022)	NO. 2 in patent applications per capita (2023)	NO. 3 in employment share (direct, indirect and induced[3]) relative to national employment rate (2022)	NO. 3 in export per capita (2023)
NO. 2 in R&D expenditures (2022)	NO. 2 in patent applications relative to all patent applications in the country (2023)[2]	NO. 3 in biopharmaceutical R&D jobs per capita (2022)	NO. 2 in export (2023)
NO. 2 in clinical trials per capita (2022)		NO. 2 in gross added value per employee (2022)	

Belgium's share within the European Union



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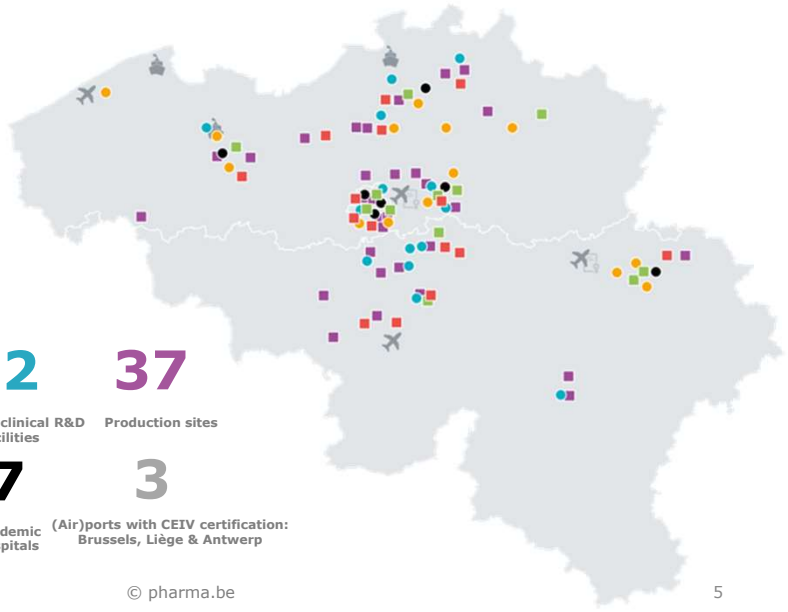
pharma.be companies are part of a strong innovation-driven ecosystem

- Headquarters of pharma companies
- Pharma R&D sites
- Pharma production sites
- Universities & research centres
- Bio-incubators
- Academic hospitals
- Ports
- Airports



126 pharma.be member companies

23 Headquarters

52 R&D and clinical R&D facilities

37 Production sites

18 Bio-incubators

14 Universities & research centres

7 Academic hospitals

3 (Air)ports with CEIV certification: Brussels, Liège & Antwerp

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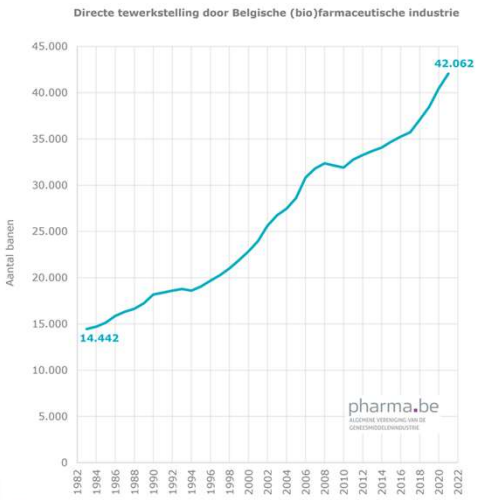
Direct jobs in Belgium



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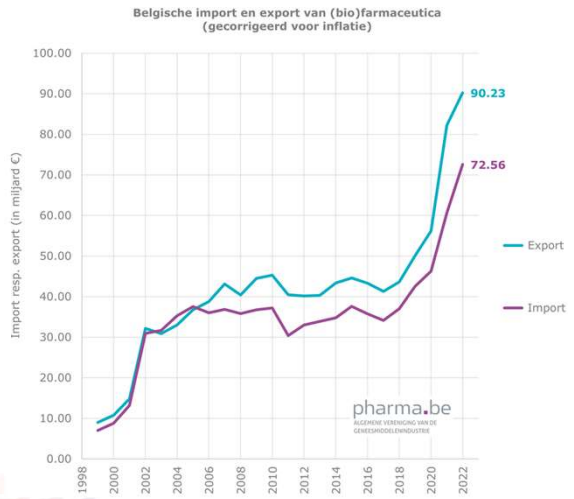
Import and export



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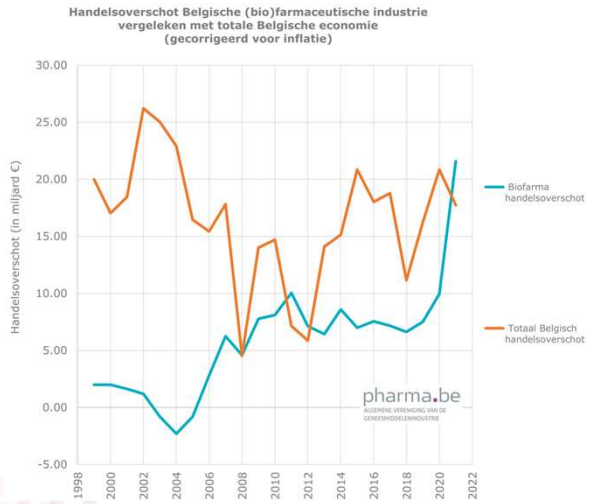
Belgian trade balance



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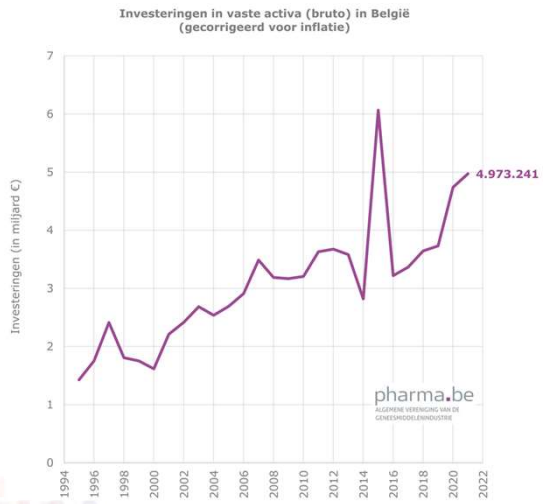
Fixed assets investments



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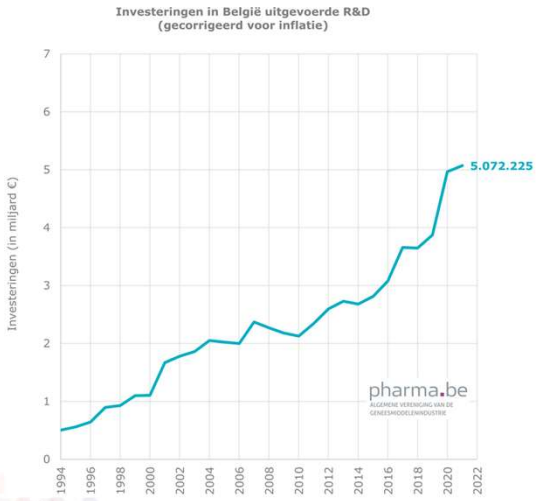
R&D investments



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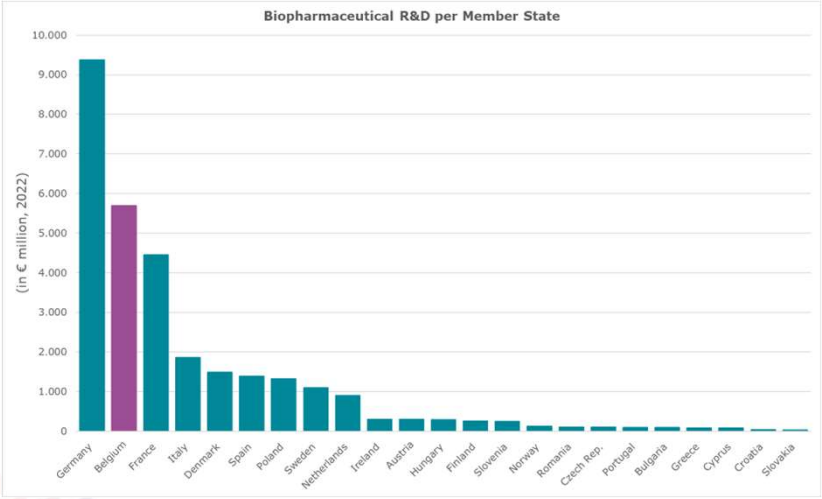
R&D investments



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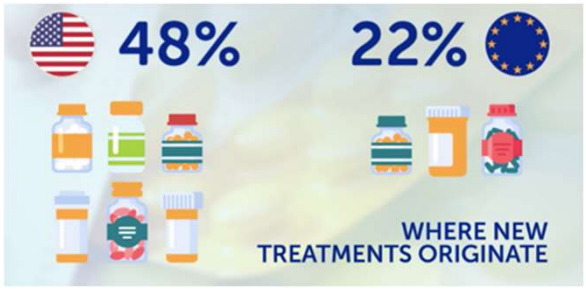
Slow but steady and profound shift out of Europe



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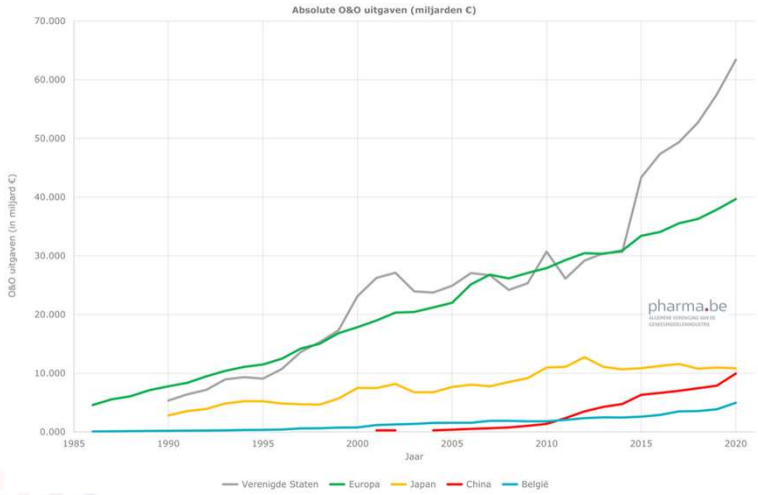
Absolute R&D spend



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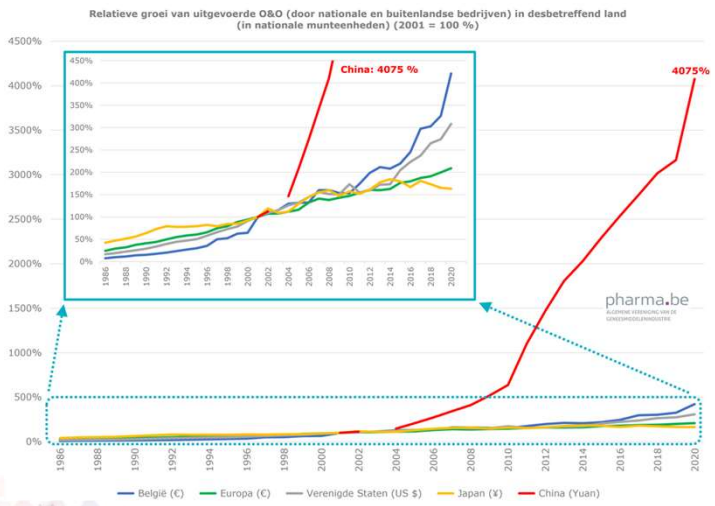
Relative growth of R&D



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In the news …

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In 2024, total biopharmaceutical exports were € 79.0 billion, down 1.4% from 2023.

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In the news …

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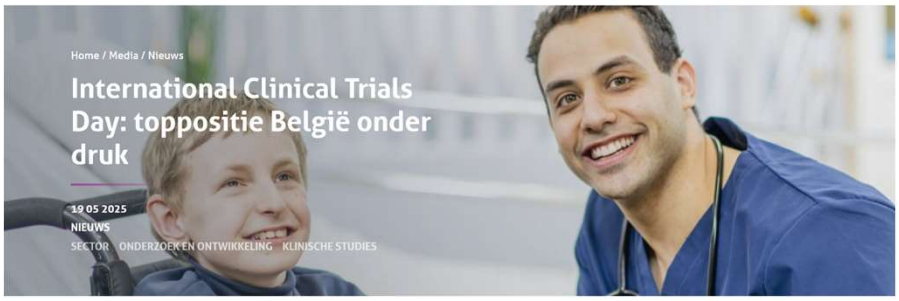
over ons expertise diensten media contact



De laatste tien jaar stond ons land telkens in de top drie van klinisch onderzoek in Europa. Dat is goed nieuws, want klinische studies stimuleren baanbrekende innovaties in de gezondheidszorg en redden letterlijk levens. Onze toppositie staat echter onder druk. Hoog tijd om de aantrekkelijkheid van België als locatie voor klinische studies te versterken, beklemtoont pharma.be, de koepelorganisatie van een 130-tal innovatieve farmaceutische bedrijven actief in België.

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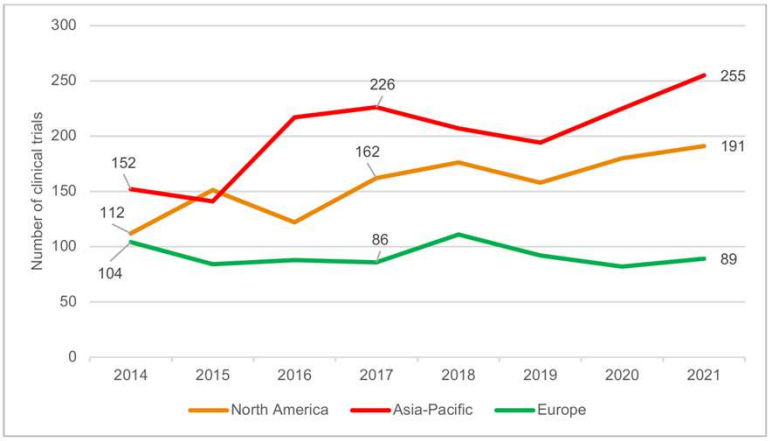
Advanced Therapy Medicinal Products (ATMPs)

Figure 5: The location of Advanced Therapy Medicinal Products (ATMP) clinical trials differ from the overall geographic pattern of biopharma clinical trial activity



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Belgian focus on ATMPs

Health

Belgium launches regulatory push for Advanced Therapy Medicinal Products

Belgium is scaling its regulatory and clinical systems for Advanced Therapy Medicinal Products (ATMPs) – academia's role will be crucial in bridging innovation and patient access.

Belgium has set 2028 targets for Advanced Therapy Medicinal Products (ATMP) readiness, with the Federal Agency for Medicines and Health Products (FAMHP) launching a dedicated spearhead domain to support ATMP development.

The move reflects growing political, scientific and industrial momentum to bring transformative cell, gene, and tissue therapies to patients.

National commitment to clinical research

In parallel, Belgium's 2025 new government agreement pledges to develop a national clinical trial network with a focus on ATMPs.

The political commitment aims to boost Belgium's position as a clinical research hub and improve access to early-stage trials. This complements the FAMHP's technical roadmap and reflects a whole-of-government approach.

The FAMHP's five-year roadmap also prioritises deeper involvement in clinical trial assessment, scientific advice, and regulatory alignment with European standards through the EMA.

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Source: https://www.euractiv.com/section/health-consumers/news/belgium-launches-regulatory-push-for-advanced-therapy-medicinal-products/, 20250408

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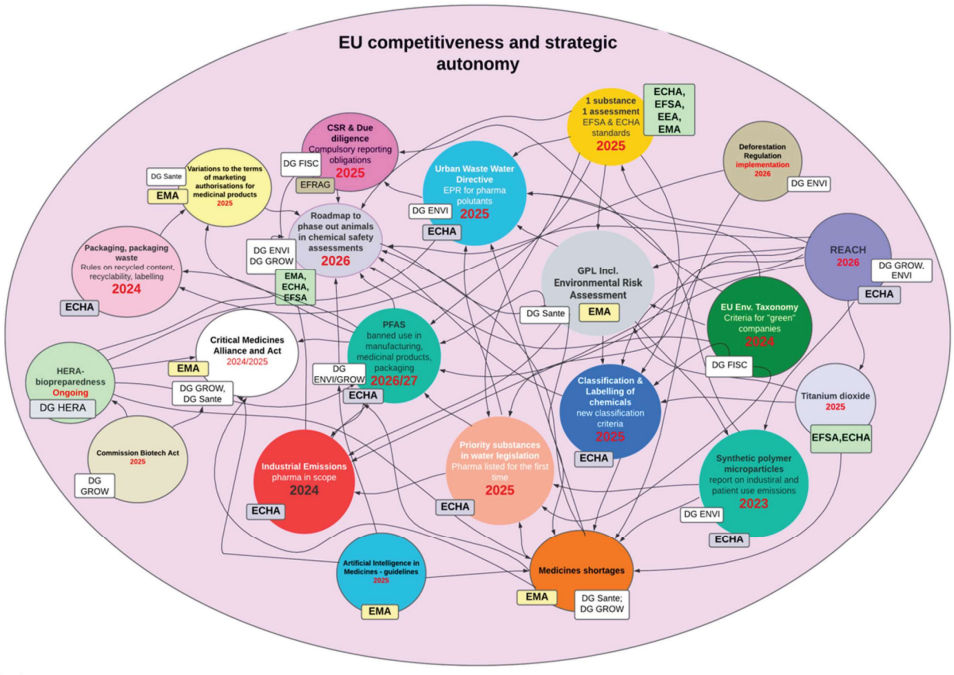
Competitiveness

State-of-play:

- Pressure from U.S.:
  - Inflation Reduction Act
  - US Tariffs under consideration – Goal: reshoring production and R&D to U.S.
  - US Executive Order – Goal: lowering prices in U.S.
- Intensified competition from China (and India)
- General pharmaceutical legislation (aim i.a. to strengthen EU competitiveness of sector) still under review
- Europe faces a complex regulatory environment, supply chain vulnerabilities, fragmented national policies, and slow approval processes, which undermine the region's ability to attract R&D investments and failing its ambition of being a leader in innovation.
- Difficulties in recouping R&D investments in Europe' – better valorisation required



The future of European competitiveness

Draghi Report

The future of European competitiveness – A competitiveness strategy for Europe (20240909)

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Proposals for biopharmaceutical sector

SUMMARY TABLE PHARMA PROPOSALS		TIME HORIZON[01]
1	**Maximise the impact of the EU Health Data Space**, e.g. by facilitating access to and the sharing of electronic health records, leveraging the DARWIN EU® network and scaling up genome sequencing capacities.	ST/MT
2	**Streamline the set-up and management of multi-country trials in the EU** to advance the EU as an attractive place for conducting clinical R&D.	MT
3	**Expedite access to markets** through coordinated action by medicines agencies, HTA authorities and public payers on guidance to industry, pricing and reimbursement as well as procurement.	MT
4	Provide clear and timely guidance on the use of AI in the lifecycle of medicines.	MT

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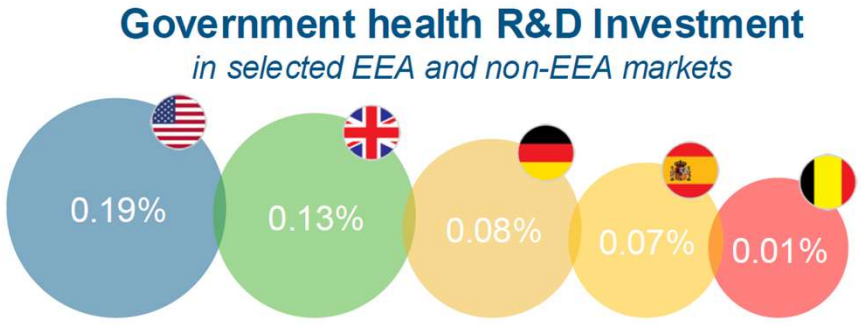
Proposals pharma (continued)

5	Rapidly and fully implement the HTA regulation and ensure the required resources are allocated to ensure the delivery of joint clinical assessments as of 2025, with the aim of establishing an EU agency in the long term.	ST/LT
6	Improve business predictability through a continuous evidence-based dialogue with stakeholders to underpin EU policy-making on protection mechanisms for novel medicines.	MT/LT
7	Increase and focus public R&D investment in the EU, e.g. supporting a number of world-class innovation hubs in life sciences for advanced therapy medicinal products (ATMPs).	MT
8	Mobilise private R&D investment in the EU and bolster the supporting environment.	MT
9	Develop strategic international partnerships to solidify and bolster the EU's international trade position in pharmaceuticals.	MT/LT

Governmental health R&D investment (% of GDP)

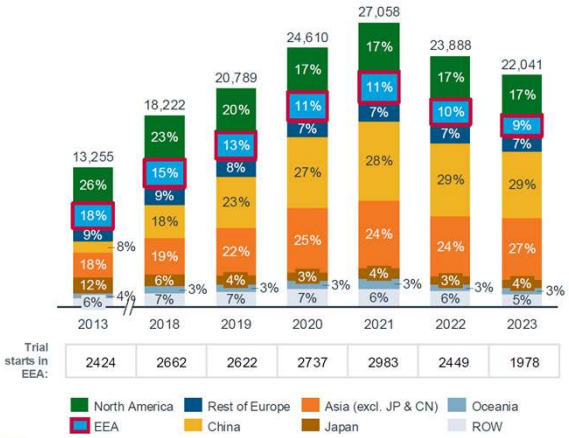


US government allocated 2x % GDP to health R&D than Germany and Spain, and 19x Belgium, highlighting major variation in foundational support within and outside of Europe

Source: Office of Life Sciences (UK), in: Assessing the clinical trial ecosystem in Europe. Final Report. (IQVIA, for EFPIA & Vaccines Europe, October 2024)

Global CT ecosystem: Europe's share declining, Asia emerging as major location for new CT starts

Number of global clinical trial starts by region (2013, 2018-2023; Phase 1-4)



EEA countries: Austria, Belgium, Bulgaria, Croatia, Republic of Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Iceland, Liechtenstein and Norway

25 Source: Assessing the clinical trial ecosystem in Europe. Final Report. (IQVIA, for EFPIA & Vaccines Europe, Oct. 2024)

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Phase 1 CTs declining

EEA has a relatively high share of Phase 2 & 3 trials, which are important for patients; however, the decline in Phase 1, may limit future trial opportunities

Number of global commercial clinical trial starts by phase (2013, 2018-2023; Phase 1-4)

Global commercial growth has mainly been fueled by the rise in Phase 1 trials, which have seen a 4.5% growth (2018-2023 CAGR), higher compared to overall 4% growth of commercial clinical trials

In the EEA, the trend contrasts with the global picture, as most trials are in Phase 2 and 3, with a slight decrease in Phase 1 trials in 2023.

Whilst Phase 2 and 3 trials are particularly important for patients, a reduction in Phase 1 trials may lead to a reduced 'pipeline' of future trials, particularly in areas where specialized knowledge or equipment is required to deliver the investigational therapy, which may be established during Phase 1.

Analysis from IQVIA Institute suggests EEA has seen relative or absolute decline in most categories of trials, such as:

- Phase 1 oncology and Phase 2/3 oncology
- Cell and Gene Therapy (CaGT)
- Biosimilars
- Rare diseases

Conversely, China has grown its global share, particularly through an increase in Phase 1 oncology, Phase 2/3 oncology, and cell and gene therapy trials

Note: Phase 2 includes Phase 1/2, 2a & 2b trials, Phase 3 includes Phase 2/3. Medical device trials and terminated/suspended trials were excluded. Trial with sites in multiple EEA countries were counted once within EEA
Abbreviations: CAGR: compound annual growth rate
Source: Clinical Trial Repository (Access Date: April 30th 2024)
IQVIA | EFPIA-VE | Assessing the Clinical Trial Ecosystem in Europe | Final Report | August 2024

IQVIA

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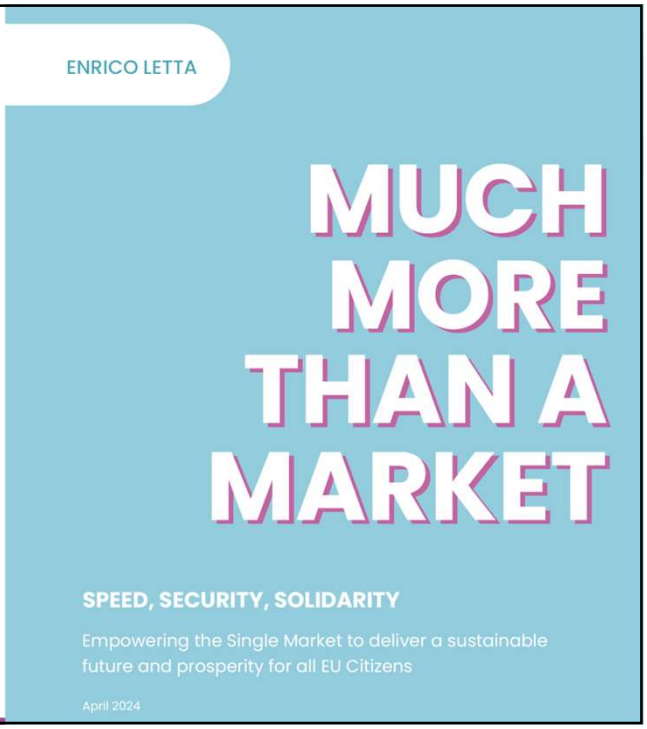
Letta report

- EU Single Market framework - four freedoms: free movement of people, goods, services and capital
- **Fifth freedom**: to enhance research, innovation and education in the Single Market - the freedom **of investigating, exploring and creating for the benefit of humankind without disciplinary or artificial borders and limitations**
- Among various sectors poised to benefit from the implementation of a fifth freedom, the healthcare sector stands out prominently. Its critical importance, underscored by the recent pandemic, positions it to greatly leverage this new framework which promises to enhance cooperation and drive innovation. This initiative is particularly vital as **European healthcare urgently requires significant revitalization**. The EU's increasing reliance on external suppliers for chemically synthesised active ingredients, components, and finished products has led to a steep decline in European production - from 53% in the early 2000s to less than 25% today. Moreover, the **migration of European talent in search of opportunities outside the EU** is severely undermining the Union's capacity for innovation



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Letta report

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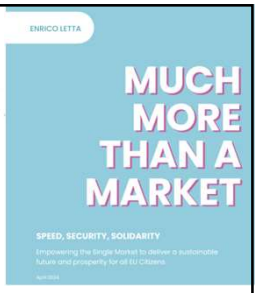

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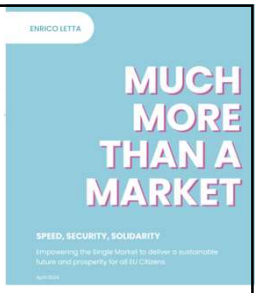
Full page on CTs!



- **Streamline clinical trial process**
- **Multi-country / EU-wide trials**: important factor for sufficient scale to compete with the US and other competitors. **Regulatory differences between Member States** pose a significant challenge in this regard.
- monitor CT legislation across Member States to **identify inconsistencies and promote alignment**
- **Fostering collaborations will accelerate innovation and speed up the path to market for novel treatments**
- Actively encourage **training of highly qualified pharmaceutical professionals** and **promote researcher mobility** - fifth freedom framework
- creation of **transnational networks between large research hospitals**

Future clinical trials require adapted or even new roles with specific competencies and capabilities

8 potential new roles required to conduct future clinical trials

As a **Health Data Scientist** in clinical trials, you will leverage advanced AI and quantum computing to delve into vast, complex datasets, uncovering patterns and insights that drive the next frontier of personalised medicine. Your role will be crucial in developing predictive models that transform raw data into breakthrough therapies, accelerating drug development towards the future of healthcare.

As a **Digital Health Coordinator**, you will be at the epicentre of integrating state-of-the-art wearable technologies and AI-driven health applications into clinical trials. Your efforts will enable continuous, real-time monitoring of participants, collecting invaluable data that enhances trial accuracy and brings futuristic healthcare solutions to life.

As a **Patient Engagement Manager**, you will utilise immersive virtual reality (VR) and AI-powered communication platforms to enhance the participant experience in clinical trials. Your innovative approaches will ensure that participants remain informed, motivated, and deeply engaged, building new paths in patient-centric research environments.

As a **Regulatory Innovation Officer**, you will pioneer the regulatory frameworks necessary to integrate next-gen technologies like AI, blockchain, and personalised genomics into clinical trials. Your strategic vision and regulatory acumen will facilitate the seamless approval of groundbreaking trials, steering in a new era of compliant and rapid medical research advancements.

As a **Genomic Data Analyst**, you will explore the cutting edge of genomic science, combining AI with genomic sequencing to uncover biomarkers and genetic patterns. Your work will be pivotal in crafting hyper-personalised treatment protocols, leading the march towards a future where therapies are tailored to the unique genetic makeup of each person.

As a **Remote Trial Coordinator**, you will orchestrate the complex logistics of decentralised clinical trials using advanced AI-driven management systems. Your role will ensure the seamless coordination of trials across a global network of participants, enabling unprecedented inclusivity and efficiency in futuristic clinical research.

As an **AI Ethics and Compliance Officer**, you will oversee the ethical deployment of AI and machine learning in clinical trials, crafting policies that balance innovation with integrity. Your forward-thinking leadership will safeguard the ethical standards of the future, ensuring that cutting-edge technologies are used responsibly and transparently.

As a **Cybersecurity Specialist**, you will join advanced encryption and AI-driven threat detection to protect sensitive clinical trial data. Your expertise will secure the digital landscape of clinical trials, ensuring the integrity and confidentiality of patient data, and maintaining trust in a world where data security is vital.

How to prepare the clinical trial workforce of the future, today?

All stakeholders play a critical role in preparing the clinical trial workforce for the future

BIOPHARMA COMPANIES	GOVERNMENT	REGULATOR	HOSPITALS	HIGHER EDUCATION INSTITUTIONS
• **Professional Development**: Implement ongoing training in emerging technologies • **Innovation Labs**: Establish labs for hands-on tech experience • **Education Collaboration**: Partner with universities for specialised courses	• **Education Investment**: Fund programs in AI, ML, digital health, genomics, cybersecurity • **Adaptive Regulations**: Develop flexible, robust regulatory frameworks • **Public-Private Partnerships**: Create internships, apprenticeships, and continuous learning opportunities	• **Specialised Training**: Train staff on the latest methodologies, AI, and digital health technologies • **Advanced Technology**: Invest in analytical tools to streamline trial approvals • **Collaborative Dialogue**: Engage with industry and academia to keep regulatory frameworks relevant	• **Clinical Training**: Conduct workshops on digital health tools, wearables, and AI-driven analysis • **Research Partnerships**: Collaborate with pharma, regulators, and academia to stay on the cutting edge • **Patient-Centric Training**: Train staff in AI-enhanced patient engagement techniques	• **Curriculum Modernisation**: Include courses on AI, digital health, genomics, and cybersecurity • **Industry Collaboration**: Develop joint programs and internships with pharma, regulators, and hospitals • **Interdisciplinary Programs**: Create courses integrating life sciences, engineering, data science, and bioethics

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How to strengthen Europe's CT ecosystem

EU's moment to reclaim its place as a global leader in life sciences innovation

Strengthening Europe's clinical trial ecosystem requires urgent, coordinated action.

1. **No extra national rules:** implement the EU Clinical Trial Regulation without adding national layers of complexity.
2. **Faster, harmonised processes for multi-country trials,** including how Ethics Committees work across Europe.
3. **Make CTIS work for users:** ensure the Clinical Trials Information System is simple, reliable, flexible, and user-friendly.
4. **Enable cross-border access,** so patients can join clinical trials anywhere in Europe.

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