Introducing Initiatives to Bring more Clinical Trials to Europe

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Organisers: THE CYPRUS INSTITUTE OF NEUROLOGY & GENETICS
DEPUTY MINISTRY OF RESEARCH, INNOVATION AND DIGITAL POLICY
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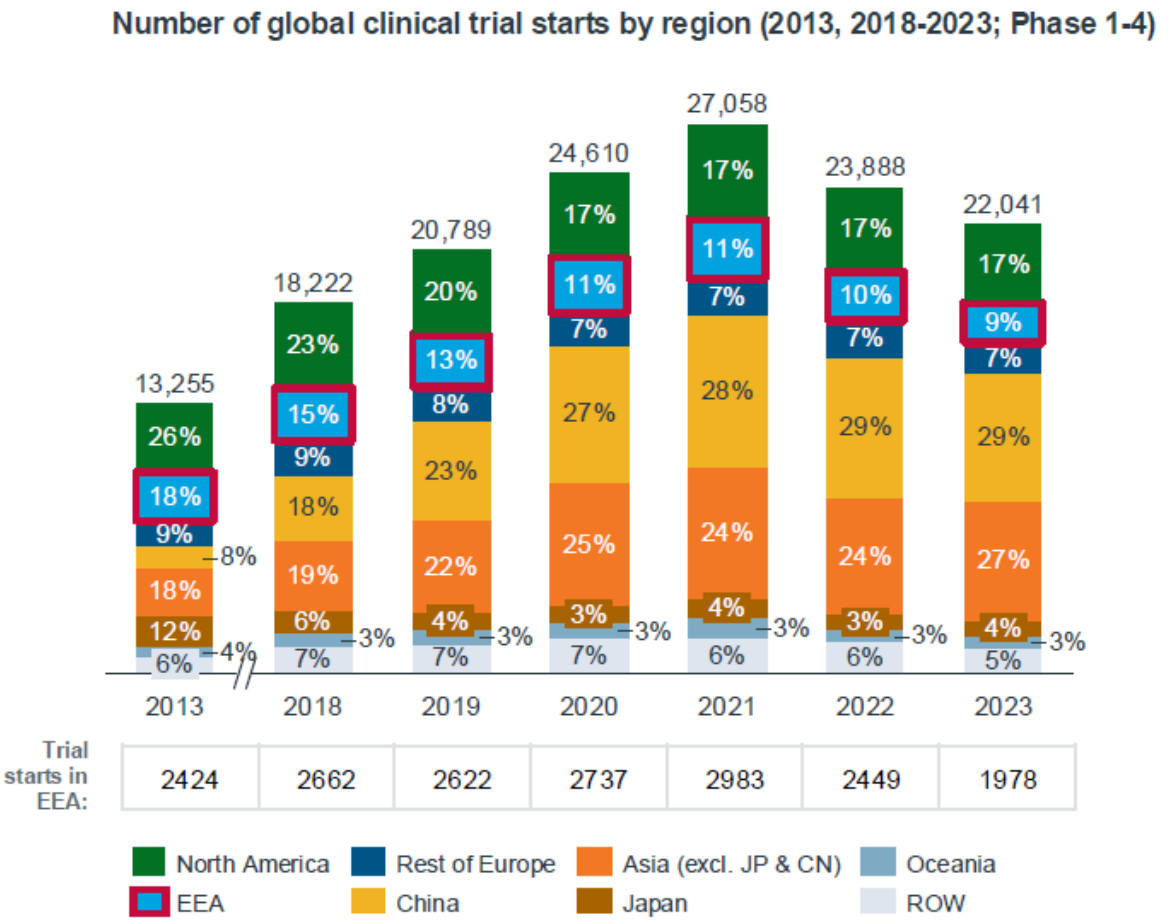
Context (1)

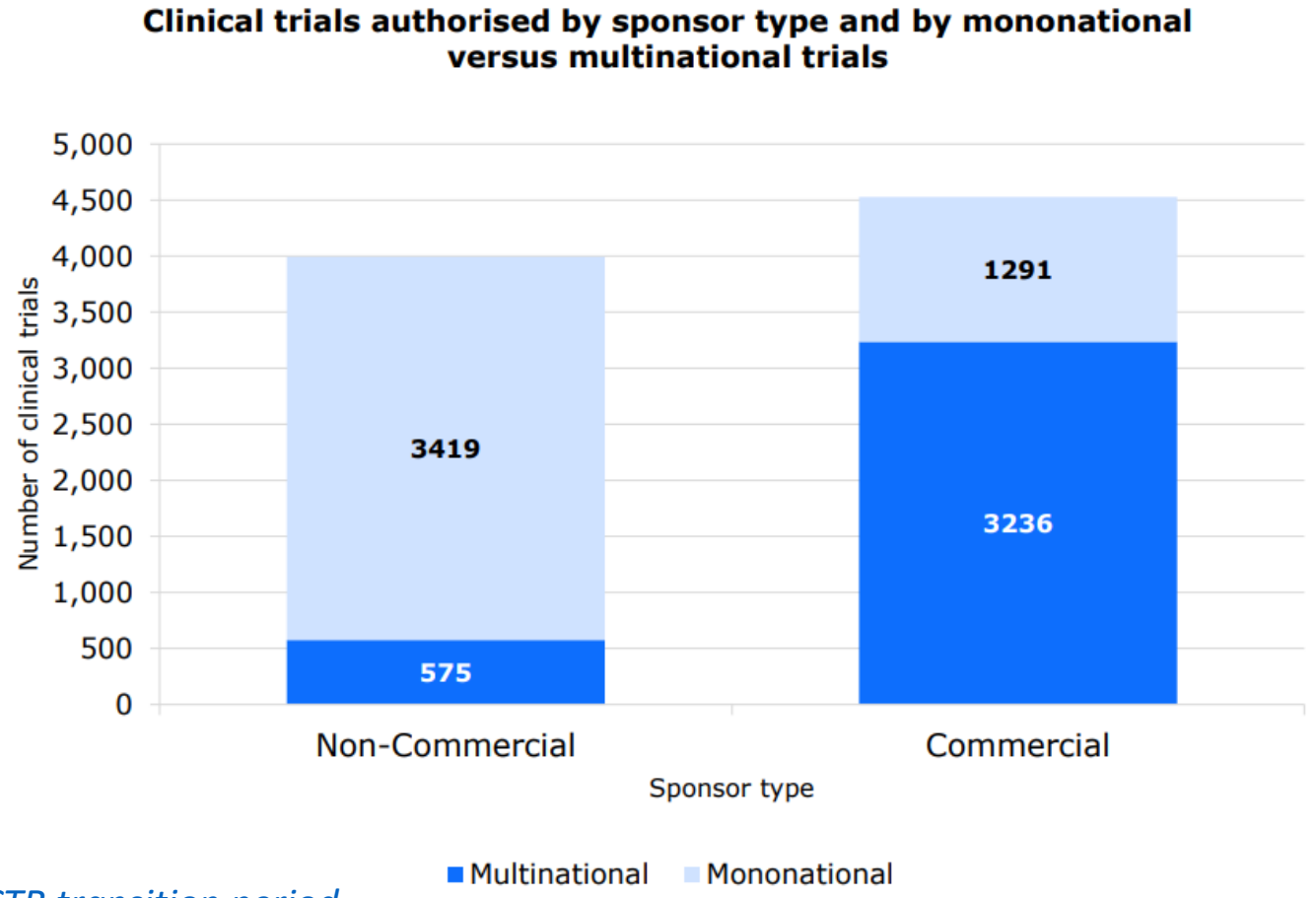
- Number of clinical trials in Europe stable, but declining worldwide share
- Asia emerging as a major location for new clinical trials
- In Europe and US clinical trials are almost evenly split between commercial and non- commercial trials
- Most of the trials in China have a non-commercial sponsor



Source: [IQVIA | EFPIA-VE | Assessing the Clinical Trial Ecosystem in Europe | Final Report | August 2024](#).

Context (2)

- Thanks to its large population, rich genetic diversity and scientific excellence, **Europe has unique advantage**s for conducting clinical research
- **But these advantages are not fully exploited** as most non-commercial clinical trials are conducted in just one country



Source: [ACT EU - Report EU clinical trials during the 3-year CTR transition period](#).

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A) Building on the legacy: ongoing and planned initiatives

EU Research & Innovation actions to facilitate clinical trials addressing patient needs across the EU:

1. Establish clinical trial networks and coordination
2. Maximise public health impact through adequate trial design
3. Team up with EU Member States and beyond
4. Strengthen regulatory environment
5. Support through (research) infrastructures

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1. Establish clinical trial networks and coordination

EU-PEARL
EU PATIENT-CENTRIC CLINICAL TRIAL PLATFORMS

- 42 months project (1st Nov 2019 start)

INTEGRATED RESEARCH PLATFORMS (IRPs)

A framework to carry out a patient-centric platform trial which includes:

- Shared master protocol and methodology.
- Scientific, legal, regulatory and ethical requirements.
- Network of hospitals, clinicians and researchers.
- Data governance policies and procedures.
- Regulated access to patient electronic health records and patient cohorts.
- Pathway for patients' participation in trials design.

conect4children
COLLABORATIVE NETWORK FOR EUROPEAN CLINICAL TRIALS FOR CHILDREN

Collaborative Network for European clinical trials for children (IMI2 JU)

- 6 years project (1st May 2018 start)

To generate a sustainable infrastructure that optimises the delivery of clinical trials in children :

- a single point of contact for all sponsors, sites and investigators;
- efficient implementation of trials adopting consistent approaches, aligned quality standards and coordination of sites at national and international level;
- collaboration with specialist networks;
- high-quality input to study design and preparation through rigorous strategic and operational feasibility assessment;
- the promotion of innovative methodologies.

Realise D

Comprehensive methodological and operational approach to clinical trials in rare and ultra-rare diseases (IHI)

- 5 years project (2025-2029)

Objectives:

- Change the paradigm for clinical trials in ultra-rare diseases. Catalyse the development and acceptance of innovative approaches for designing trials, (re-)using, analysing and interpreting data.
- Generate patient referral strategies to boost enrolment in future ultra-rare disease trials, and will set up a certification system to identify clinical trial sites capable of running studies on ultra-rare diseases.
- Work with several European Reference Networks (ERNs)

imi innovative medicines initiative

European Commission

innovative health initiative

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ERICA: the European Rare Disease Research Coordination and Support Action to support clinical research efforts of the 24 European Reference Networks (2021-2026)

The aim of the **European Rare Disease Research Coordination and Support Action** consortium (ERICA), in which all 24 European Reference Networks (ERNs) take part, is to build on the strength of the individual ERNs and create a platform that integrates all ERNs research and innovation capacity.

Through knowledge sharing, engagement with stakeholders in the rare disease domain and assembly of transdisciplinary research groups working across the global health spectrum, ERICA strives to reach the following goals:

- new intra- and inter-ERN rare disease competitive networks
- effective data collection strategies
- better patient involvement
- enhanced quality and impact of clinical trials
- increased awareness of ERNs innovation potential.

https://erica-rd.eu/

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2. Support innovative clinical trial designs

Collaborative projects supporting methodologies for clinical trials in small populations / rare diseases: build on FP7 legacy - 3 projects on 'new methodologies for clinical trials for small population groups' (2013-17):
- ASTERIX (Advances in Small Trials dEsign for Regulatory Innovation and eXcellence)
- IDEAL (Integrated DEsign and AnaLysis of small population group trials)
- INSPIRE (Innovative methodology for small populations research)

→ Realise D **is now building on this legacy and combining it with the strengths of the European Reference Networks (ERNs)**

Pragmatic clinical trials to optimize treatments for patients - under the Cancer mission → 10 projects supported (2023-2028), in various cancer field, including paediatric cancer
Objective: support academic investigator-driven clinical trials in cancer, trials with the potential to start changing clinical practices already NOW; Focus: quality of life of patients.

Support a pragmatic clinical trial programme by cancer charities → 1 project (2025-2029): FORCE (Fostering Oncology Research by Charities in Europe), a network of 15 European charities across 12 European countries

3. Team up with EU Member States and beyond – notably with co-funded European Partnerships

Fostering a European Research Area for Health (ERA4Health Partnership)

ERA4Health Partnership

Specific objectives:

- Support relevant medical research including clinical fields and intervention areas (prevention, diagnosis, treatment)
- Improve the use of existing health technologies in clinical practice
- Build capacity, in particular in conducting multi-country Investigator-Initiated Clinical Studies at European scale
- Implement and develop responsible research and innovation

Consortium:

- **48 Partners (including Funding Organisations)** covering:
  - 40 in 20 EU Member States
  - 5 in 4 Third Countries Associated to Horizon Europe
  - 3 in 3 Third countries (Egypt, Taiwan, USA)

= totally **27 countries**

Phase 1 (2022-2024)

Phase 2 (2025 -2034)

Main activities:

- Launch of Joint Transnational Calls (JTCs) on **nutrition, diet and healthy lifestyles, cardiovascular diseases and nanomedicine (*pre-clinical research*)**
- Development of a framework to support **multi-country Investigator-Initiated Clinical Studies (IICS)**
- Launch of JTCs on **multi-country IICS** in health technologies addressing public health needs ***(clinical research)***

Budget: **EU Budget: € 102,6 million**

(Phase 1: € 33 million + Phase 2: € 69,6 million)

EU co-funding: 30%

Advancement of Treatments FOR RARE DISEASES

European Rare Diseases Research Alliance (ERDERA)

Building upon the legacy of EU-funded projects EJP RD, ERICA, Solve-RD

Specific objectives:

Mission: Transforming research and care in rare diseases

Working hand in hand with patients and all stakeholders, ERDERA:

- Aligns national and European funding and strategies, creating a seamless research-to-care continuum;
- Closes the translation gap so that laboratory discoveries become cost-effective solutions for patients;
- Reduces the fragmentation of knowledge and data through a federated, FAIR* ecosystem. (*FAIR = findable, accessible, interoperable and reusable)

Consortium:

- *So far:* **180 Partners (including Funding Organisations)** covering:
  - 153 in **26** EU Member States
  - 25 based in 11 Third Countries (partially) Associated to Horizon Europe
  - 2 based in 2 Third countries

= totally **39 countries !**

Phase 1 (2024-2027)

Phase 2 (2027 -2034)

Main activities:

- Launch of yearly Joint Transnational Calls (JTCs)
- Training and capacity building
- National Mirror Groups
- Integrative activities including ***clinical research***
- Launch of a Clinical Trial Call for rare diseases ***(clinical research)***
- and much more (ATMPs, regulatory…) !!

Budget: **EU Budget: € 150 million**

(Phase 1: € 57 million + Phase 2 *(to come)*: € 93 million)

EU co-funding: 50%

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https://cordis.europa.eu/project/id/101156595

https://erdera.org/

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ERDERA Clinical Trial Call 2026: pre-announcement and key dates - ERDERA

ERDERA will launch its Clinical Trial Call 2026 (ECTC) on 1 July 2026, supporting multinational, GCP-compliant early-phase interventional clinical trials in rare diseases.

Scope and strategic encouragements: Applications addressing all eligible rare diseases are welcome. The call particularly encourages proposals targeting: Paediatric rare diseases, rapidly progressive rare diseases, rare diseases lacking approved therapeutic options or with substantial residual unmet medical need despite existing treatments.

The ECTC is expected to follow a **multi-stage process**, beginning with a mandatory Stage 0 Expression of Interest (EOI). Indicative key dates:

Stage 0 – EOI (mandatory): 1/7 – 10/9/2026

Stage 1 – Short Proposal: 15/9 – 29/10/2026

Stage 2 – Support Stage: 1–7/2027

Stage 3 – Full Proposal: 7–9/2027

Funding decisions: 2/2028

Also useful for

RD clinical trials:

IRDiRC RECOGNIZED RESOURCES

Cr Clinical Research E:DERA

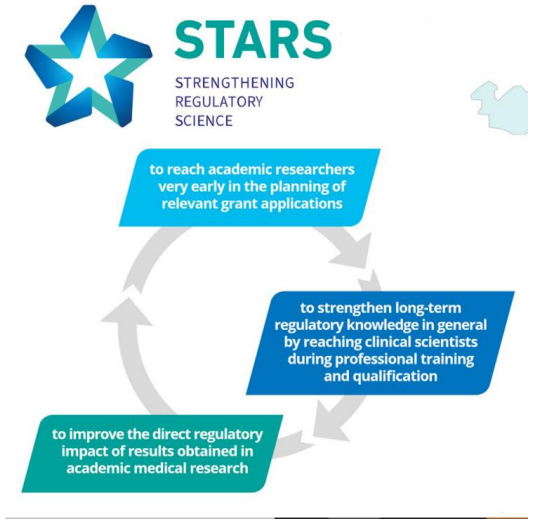
https://erdera.org/clinical-research/rare-diseases-clinical-trials-toolbox/

Rare Diseases Clinical Trials Toolbox

This Toolbox has been developed as a practical aid for developers of clinical trials on medicinal products for human use regardless of therapeutic area

4. Strengthen regulatory environment through coordinated actions…

Coordination and Support Action
STARS (2019 – 2022)



Accelerating Clinical Trials in the EU (ACT EU)

HMA Heads of Medicines Agencies

European Commission

EMA EUROPEAN MEDICINES AGENCY

ACT EU multi-annual
Workplan 2022-2026

Better, faster, smarter clinical trials

Improving the clinical trials environment in the European Union through harmonisation, innovation and collaboration with stakeholders.

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.

https://www.ema.europa.eu/en/human-regulatory-overview/research-development/clinical-trials-human-medicines/accelerating-clinical-trials-eu-act-eu

ACT EU: Vision and Goals

Vision:

Transform the EU into a region that supports **clinical trial development** and enables **collaboration and innovation** at all stages of the clinical research lifecycle. Seamless coordination among stakeholders, regulators and ethics committees will lead to more cross-border collaboration.

The result will be better, more impactful clinical trials, **benefitting patients and healthcare in Europe** in the process.

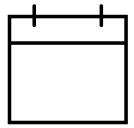
Goals:

500 more multi-national trials authorised by 2030

An additional 500 multinational clinical trials are added to the current average of 900 that are already authorised each year (i.e. an estimated 100 per year)

Increased attractiveness of the EU

Progress is measured by monitoring the number of authorised multi-national clinical trials each year.



66% of trials start recruitment in under 200 days from application submission

Faster access to treatment

Progress is measured by monitoring the time from submission of a clinical trial application to the start of patient recruitment at the first Member State concerned. **This is in comparison to only 50% of clinical trials today.**

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New targets for clinical trials in Europe | European Medicines Agency (EMA)

4. Strengthen regulatory environment

… via collaborative research

A specific topic funded under Horizon Europe, Health cluster WP2023 -2024:

"**Modelling and simulation to address regulatory needs in the development of orphan and paediatric medicines**" (HORIZON-HLTH-2023-IND-06-04:)

Scope: Assess the utility of mature computational models, to support the design of innovative clinical trials for small populations and regulatory decisions on the development of orphan and/or paediatric medicines; Benchmark diverse computational models by showcasing their performance and credibility in use cases representing well-justified group(s) of rare and/or paediatric diseases with commonalities.

- ERAMET (2024-2027) Ecosystem for rapid adoption of modelling and simulation METhods to address regulatory needs in the development of orphan and paediatric medicines https://www.erametproject.eu/
- INVENTS (2024-2028): Innovative designs, extrapolation, simulation methods and evidence-tools for rare diseases addressing regulatory needs https://invents-he.eu/

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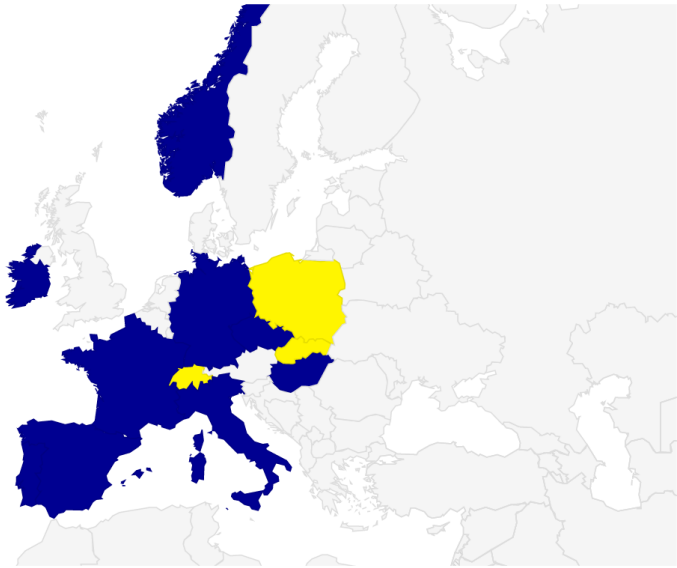
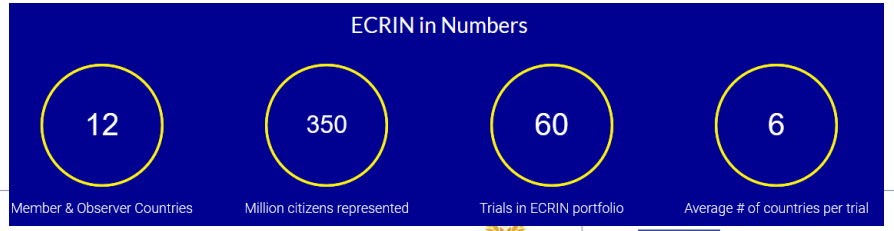
5. Support through research infrastructures

such as: European Clinical Research Infrastructure Network (ECRIN)





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The EU Rare Disease Registration Platform developed by the European Commission (Joint Research Centre)

This allows for GDPR-compliant access, search & sharing of interoperable patient data in rare diseases registries, including cohorts and clinical studies

Searchable, findable rare disease registry data

European Rare Disease Registry Infrastructure (ERDRI)

European standards for data collection and data sharing

Trainings, Resources and Latest news

List of participating RD registries with their main characteristics and description

Descriptive metadata - eight sections with 38 data fields related to a registry of which 23 are obligatory
- **specific rare disease addressed**
- **scope**
- **operating institution**
- **contact information**

Data input is performed by registry owners

List of the data elements collected by the registries according to the ERDRI.mdr:
registry-specific data scheme

https://eu-rd-platform.jrc.ec.europa.eu

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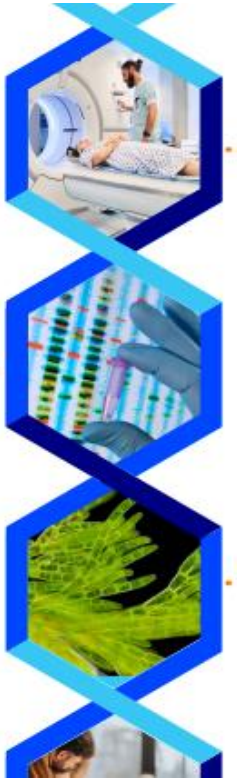
B) New initiatives for more & better clinical trials in Europe

Advancement of Treatments FOR RARE DISEASES

A new strategy for European life sciences

Main flagship actions

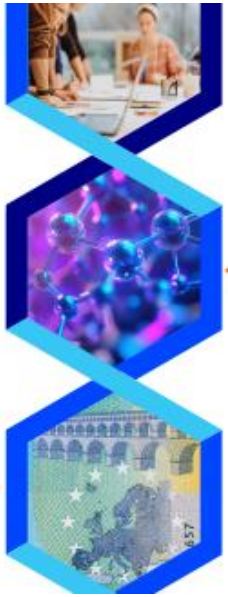


Clinical Research Investment Plan
Facilitate funding for multi-country clinical trials.

Support for advanced therapies
Coordinate the development of centres of excellence with Member States

One-Health* Microbiome Initiative
Make the EU a world-class innovator in microbiome-based solutions.

Life Sciences career development through Choose Europe
Attract and retain talent in synergy with Member States' activities.



EU Biotech Act
Foster innovation by simplifying rules and providing supportive measures.

Life Sciences Investors Interface
Connect startups, industry and investors.

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CLINICAL RESEARCH INVESTMENT PLAN

Flagship action under the **Choose Europe for Life Science Strategy**

Main focus:

- Facilitate **funding** for multi-country clinical trials, in compliance with competition rules.
- Further develop and streamline **European research infrastructures** in the field of clinical research.

Vision: Advancing towards a **single market for clinical research**

Impact on **commercial** and **non-commercial** studies

Non-regulatory initiative complementing regulatory measures in the EU Biotech Act

Alignment with other initiatives – ACT EU (EC, EMA & HMA), Joint Actions EU4HEALTH, HE Health Partnerships, etc.

Support for advanced therapies

Establishing a European network of Centres of Excellence (CoEs) for Advanced Therapies Medicinal Products (ATMPs) (HORIZON-HLTH-2026-01-TOOL-07)

→3 proposals submitted, 1 to be funded, evaluations ongoing

ATMPs represent a frontier in medicine, offering groundbreaking treatments such as gene therapies, cell therapies, and tissue-engineered products that hold the promise of addressing complex and previously untreatable conditions. The European ATMP landscape is dynamic and promising (28 products with marketing authorisation and many more in the pipeline).

The development of specialised infrastructures in Europe for these cutting-edge therapies is crucial for fostering innovation and ensuring fast and efficient delivery to patients in an equitable way.

Proposals should be of limited duration (2027-2030).

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Establishing a European network of Centres of Excellence for ATMPs

Proposals should cover at a minimum the following activities:

- **Identify common needs and challenges related to ATMP R&D**, as well as **develop relevant policy recommendations related to clinical trials**, manufacturing, logistics, regulatory (including harmonisation of market access authorisation and reimbursement procedures), public acceptance, policies for transnational care, and coordination with national/regional healthcare systems etc.
- **Develop a roadmap** to ensure that Europe becomes the global leader for ATMP R&I by 2035, with clearly defined milestones, targets and Key Performance Indicators (KPIs). The roadmap should align with national R&D plans and include a long-term funding strategy. […]
- Create an **advisory board with diverse stakeholders**, as a forum to provide guidance and advice for ensuring maximum utility of the generated outputs.
- Develop **common education and training programmes** for the next generation of scientists including outreach activities to better inform i) the public and patients on the benefits of ATMPs and ii) the stakeholders about access to the CoEs facilities and support.

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Advancement of Treatments FOR RARE DISEASES

The European Biotech Act

KEY FIGURES

- The EU biotechnology industry has grown more than **twice as fast** as the overall EU economy.
- **75% of biotechnology jobs** in the EU are in health biotech, totaling 685 000 jobs.
- **21% of the world's top biotech publications** are authored by EU scientists.
- **40% of all medicines** sold in the EU are bio-medicines (including biosimilars).

THE EUROPEAN BIOTECH ACT WILL

- **Accelerate and enable EU-clinical trials authorisations**
- **Encourage innovation** with increased support, one regulatory pathway and regulatory sandboxes
- **Support funding, investment** and access to capital, in a pilot together with the EIB Group
- **Boost bio-manufacturing capacity**
- **Foster the use of artificial intelligence (AI)** in health biotechnology
- **Enhance EFSA's capacity** to provide scientific advice to companies
- **Incentivise human and veterinary biotech medicine** with high added value
- **Reinforce security** by preventing the misuse of biotech and strengthen biodefence

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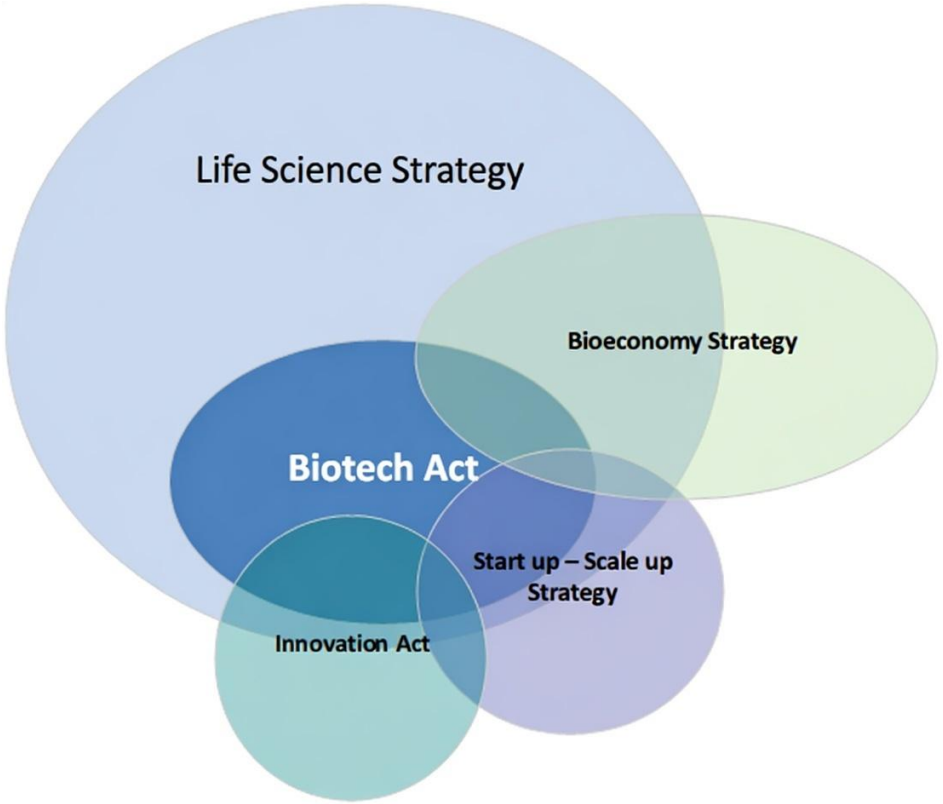
Conclusion: a dynamic policy context

- Pharma Package
- European Health Data Space (EHDS)
- Health Technology Assessment (HTA)
- …



- On 16 July 2025, the Commission presented its proposal for an ambitious and dynamic **Multiannual Financial Framework (MFF)** amounting to almost EUR 2 trillion.
- On 3 September 2025, the Commission adopted **a second package of sectoral proposals**, completing the framework for the next long-term EU budget for 2028-2034. Including:

A **new European Competitiveness Fund (ECF)** will invest in strategic technologies, with focus on four areas: clean transition and decarbonization; digital transition; **health, biotech**, agriculture and bioeconomy; defence, and space.
In close connection with the ECF, the renowned **EU research framework, with its flagship Horizon Europe worth EUR 175 billion,** will continue to fund world-class innovation.

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Thank you for your attention !

EU research & innovation on rare diseases: https://research-and-innovation.ec.europa.eu/research-area/health/rare-diseases_en

Cordis (database of EU-funded research projects): https://cordis.europa.eu

ERDERA: https://erdera.org ; https://cordis.europa.eu/project/id/101156595

RealiseD: https://realised-ihi.eu ; https://cordis.europa.eu/project/id/101165912

ACT EU: https://accelerating-clinical-trials.europa.eu/

Strategy for European Life Sciences: https://research-and-innovation.ec.europa.eu/strategy/strategy-research-and-innovation/jobs-and-economy/strategy-european-life-sciences_en

Biotech Act: https://health.ec.europa.eu/publications/proposal-regulation-establish-measures-strengthen-unions-biotechnology-and-biomanufacturing-sectors_en

Next Multiannual Financial Framework: https://commission.europa.eu/strategy-and-policy/eu-budget/long-term-eu-budget/eu-budget-2028-2034_en

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