



# The European Biotech Act

December 2025  
#EU4Health #HealthUnion

## 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).



## WHY A BIOTECH ACT ?

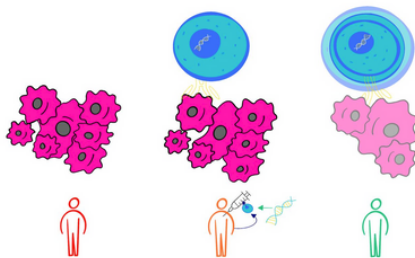
- **EU Competitiveness** - Enhancing the EU's ability to compete globally and as a leader in biotech.
- **Availability of treatments** - Accelerating the development and delivery of groundbreaking treatments.
- **Job Creation** - Creating thousands of quality jobs and boosting European economies.
- **Innovation and Investment** - Enabling innovative companies to thrive and drive healthcare and tech breakthroughs.
- **Biosecurity** - Ensuring clear rules preventing the misuse of biotechnologies.

## 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

## HOW BIOTECHNOLOGY IMPROVES OUR LIVES

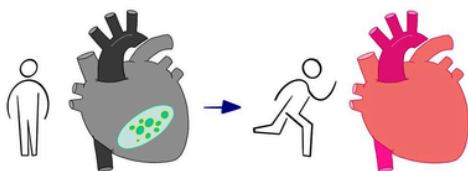
### Examples of innovative health biotechnologies



**CAR-T cells** are engineered immune cells that recognise and destroy cancer. They can eliminate tumors quickly and may offer long-term remission or even cures.



**Monoclonal antibodies** are lab-made antibodies that help your immune system fight harmful or faulty cells, treating diseases from cancer to neurological conditions.



**A smart stem-cell heart bioengineered patch** places healing stem cells directly on damaged heart tissue to aid repair and reduce scarring.