

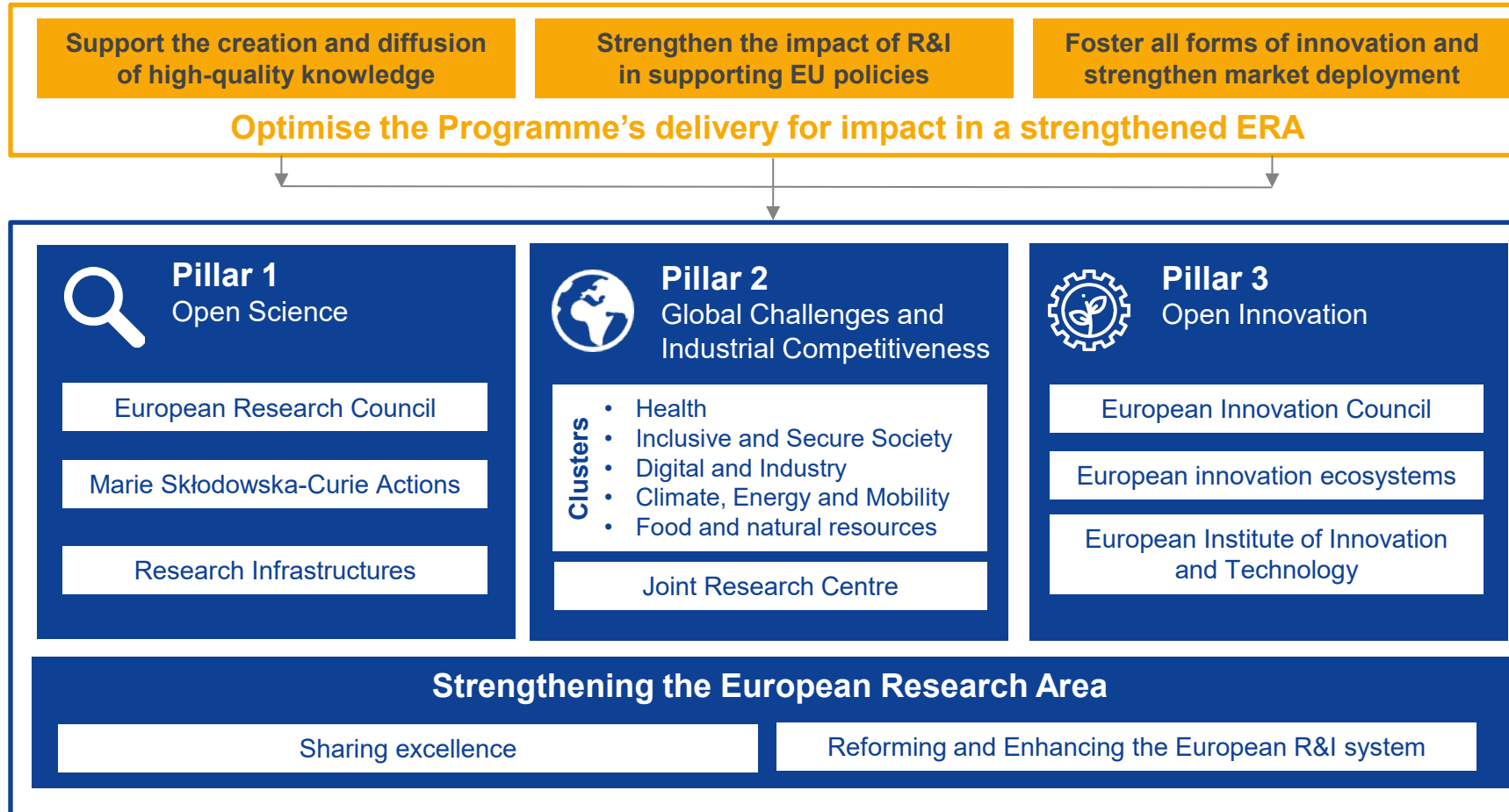


Horizon Europe funding programme - ATMPs

Anna-Pia Papageorgiou
Policy Officer
DG Research and Innovation

Rome, 15th of November

Horizon Europe is the EU's key funding programme for research and innovation with a budget of €95.5 billion



Celebrating 40 years of EU Research and Innovation

#EU40YearsRI



FP6

- Stem cells
- ATMP Regulation
- 59 projects
- 266 million €

FP7

- Regenerative medicine term
- 53 projects
- 349 million €

H2020

- 57 projects
- 356 million €
- Covid

Horizon

- 34 projects
- 225 million €
- 3 more years to go

Lessons learnt from projects embarking on clinical research

- obtaining cell manufacturing licence
- Authorisation needed: ethical, regulatory..etc
- Non-harmonisation of procedures across member states
- Lack of knowledge or experience of procedures involved in regulatory pathway, GMP grade cell production..etc.
- Contacts with the authorities are often left late in the game
- Diversity in business model and the therapeutic product
- Exploitation route not always clear anticipated
- recruiting patients is not always as straight forward

ATECT: (CAR-T cells)

- Two clinical trials (in adults) of anti-CD19 chimeric antigen receptor-modified (CAR) T-cell therapies using 'universal' CAR T cells
- UCART19 released for compassionate use resulted in molecular remission of B-ALL in two 18-month old infants
- the first-in-man genome edited allogeneic CAR T-cells.
- the first CAR T-cells manufactured by automated production.
- Last year Cellectis one of the partners in ATECT was awarded EIB financing of EUR 40 million that will support the Company's R&D investments



8 million EUR budget



2013-2018



6 partners



[Advanced T-cell Engineered for Cancer Therapy | ATECT](#)
[| Project | Fact sheet | FP7 | CORDIS | European Commission \(europa.eu\)](#)



CANCER IMMUNOTHERAPY

Baby's leukemia recedes after novel cell therapy

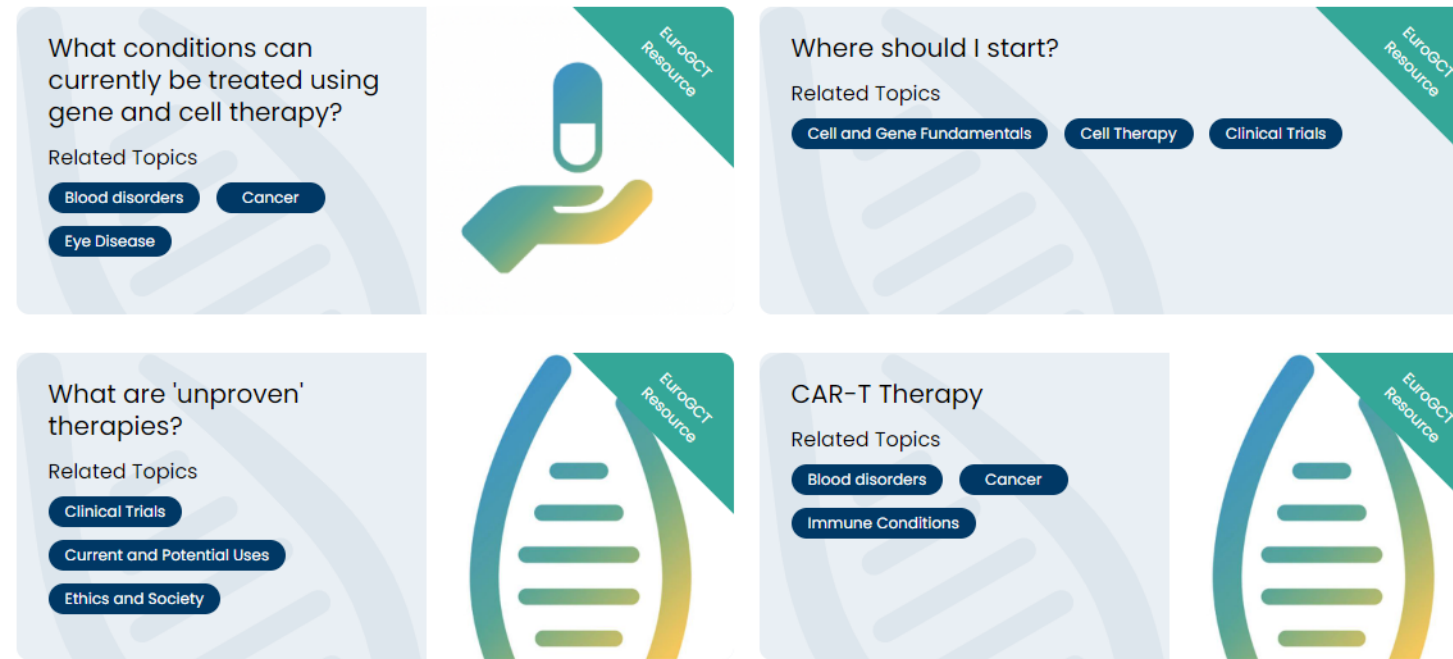
Gene editing used to create “off-the-shelf” T cells



Improving public acceptance of health biotechnologies



provide patients, people affected by conditions, healthcare professionals and citizens with detailed scientific, legal, ethical and societal information on cell and gene therapies



2 million EUR budget



2021-2026



46 partners

CAR T-cell development : T2EVOLVE



- **Objective of T2EVOLVE is to accelerate the process of developing CAR T-cell therapy in the European Union (EU) through this public private partnership:**
 - Selection of optimal lymphodepletion regimens to grant optimal reception of the therapy
 - Optimization of pre-clinical models for the best safety and efficacy prediction.
 - To involve and guide patients all over their clinical journey
 - Definition of gold standard analytical methods pre- and post-engineered T-cell infusion for the finest patient monitoring
 - To minimize unpredictable variables by Production of GMP guidance and establishment of standard product profiles.
 - To make excellent cancer therapies accessible to all European patients
- **Published in March 2024 some recommendations for cutting CAR-T therapy red tape**
 - Use an umbrella approach for evaluating multiple versions of a single product
 - Pioneering the ‘parent-child’ approach in Europe

T²EVOLVE



19 million EUR budget



2021-2025



27 partners

Access to EU FUNDING

Strategic Technologies for Europe Platform (STEP)

June 2024

WHAT IS STEP?

- The **Strategic Technologies for Europe Platform** (STEP) is a new EU initiative launched on 1 March 2024.
- It aims to strengthen EU's industrial competitiveness and reduce external dependencies by funding the **development** and **manufacturing** of **critical technologies in the EU**, reinforcing their **value chains**, and reducing shortages of essential **labour and skills**.
- It is estimated to boost investments by **up to EUR 50 billion** through existing EU instruments combined with other public and private funds.

STEP will help mobilise funding across **11 existing programmes financed by the EU**, namely: The Digital Europe Programme, European Defence Fund, EU4Health, Horizon Europe, Innovation Fund, InvestEU, the Recovery and Resilience Facility and cohesion policy funds including the Cohesion Fund, European Regional Development Fund, European Social Fund+ and Just Transition Fund. The sectors covered by STEP are:



**Digital and deep
innovation tech**

including artificial intelligence,
quantum technologies, advanced
connectivity.



**Clean and resource
efficient tech**

including carbon capture and
storage technologies, heat
pumps.

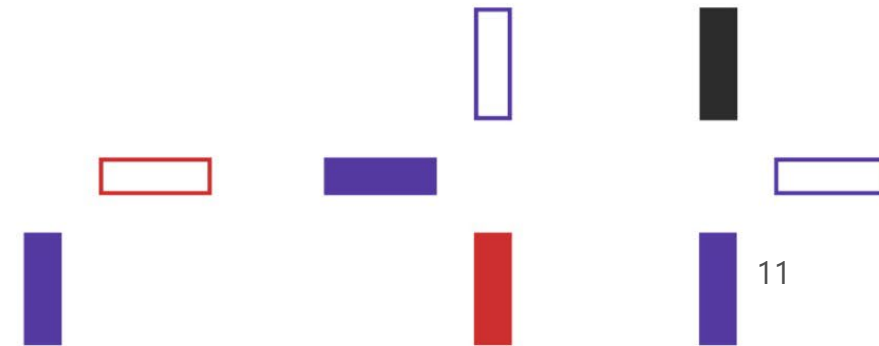
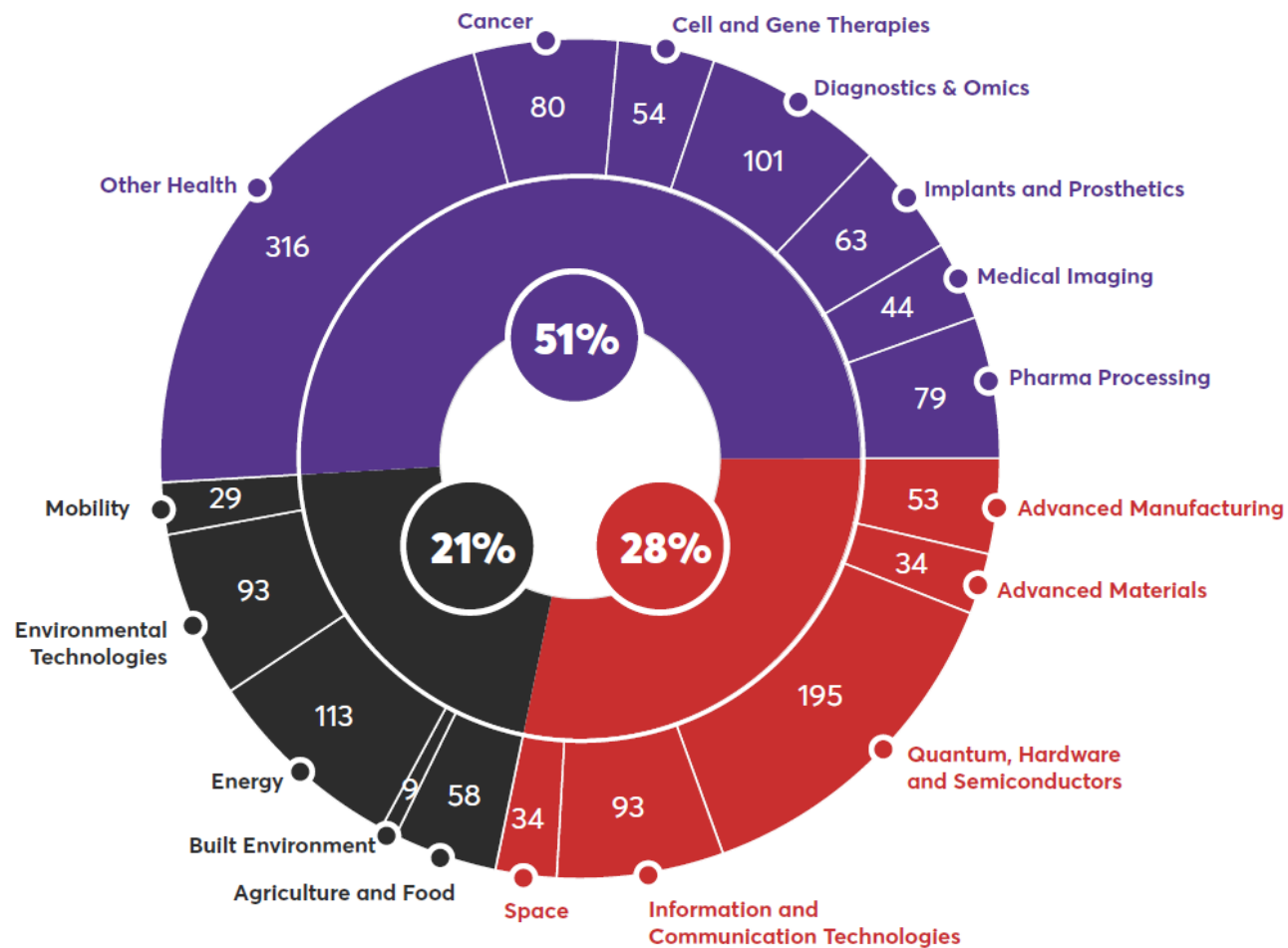


Bio tech

including molecular
biotechnology,
pharmaceuticals, crop biotech.

[Gateway to EU funding opportunities for strategic technologies](#)

EIC portfolio 2021 - 2023



€10.1

BILLION
2021 - 2027

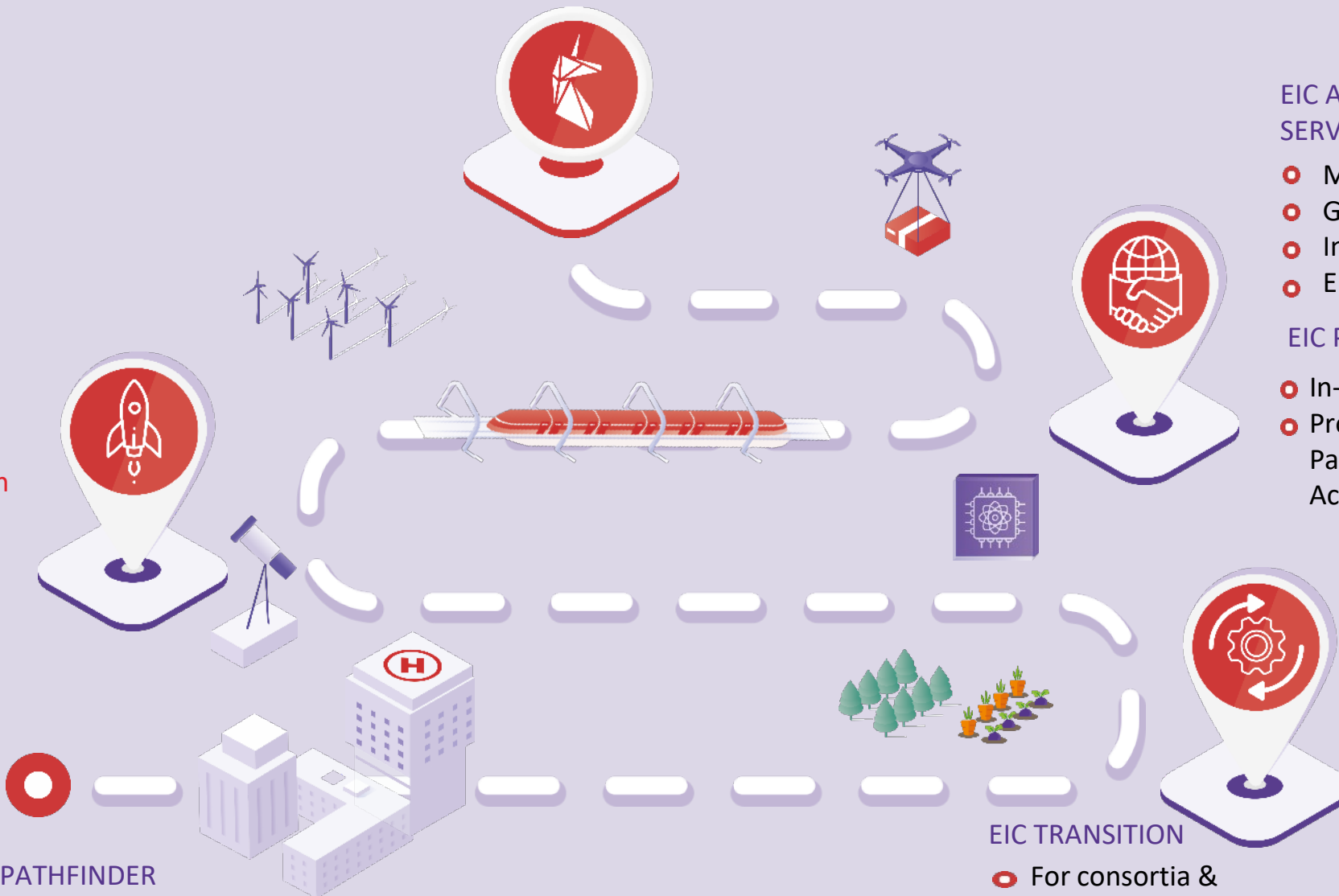
EIC ACCELERATOR

- For single companies
- Grants up to €2.5 million
- Equity up to €30 million or above
- To enter the market & scale-up (TRL 6-9)



EIC PATHFINDER

- For consortia
- Grants up to €4 million
- To research technology breakthroughs (TRL 1-4)



EIC ACCELERATOR SERVICES

- Mentors, coaches
- Global partners
- Innovation ecosystems
- EIC Community Platform

EIC PROGRAMME MANAGERS

- In-house Leading Experts
- Pro-actively managing EIC Pathfinder, Transition and Accelerator portfolios

EIC TRANSITION

- For consortia & single companies
- Grants up to €2.5 million
- To develop business cases (TRL 4-6)

BOOSTING BIOTECHNOLOGY AND MANUFACTURING IN THE EU

Commission européenne
European Commission



- **The Communication summarises the current challenges and barriers for biotechnology and biomanufacturing**
- **It proposes many actions (>20) to address each of these challenges in a timely manner, in line with the Communication on the Long-term competitiveness of the EU**
- **It also explores ways to foster engagement and collaboration, including through international dialogue and cooperation**

EU Biotech and Biomanufacturing initiative

A strategic action-plan to boost the biotech and biomanufacturing sector across Europe, enhance global competitiveness and innovation.

- **Potential EU Biotech Act:** Introducing sector-specific legislation, streamlining and simplifying the regulatory framework.
- **EU Biotech Hub:** Establishing a centralised support system to guide companies through regulatory processes and assist with scaling operations effectively.
- **Accelerating Clinical Trials in Europe (ACT EU):** harmonisation, improvement and streamlining of the clinical trial processes in the EU.
- **Stimulating Market Demand:** Implementing strategies to enhance market receptiveness and demand for biotech products, ensuring robust market growth.
- **Dedicated Funding from the European Innovation Council:** Allocating specific financial resources to support pioneering projects and technologies in the biotech sector.
- **Strengthening Biotech-related Skills:** Enhancing workforce capabilities through targeted education and training programs, addressing skill shortages in the biotech industry.

Keep in touch



commission.europa.eu/



europa.eu/



[@EU_Commission](https://twitter.com/EU_Commission)



[@EuropeanCommission](https://www.facebook.com/EuropeanCommission)



[European Commission](https://www.linkedin.com/company/european-commission/)



[europeancommission](https://www.instagram.com/europeancommission)



[@EuropeanCommission](https://twitter.com/EuropeanCommission)



[EUTube](https://www.youtube.com/EUTube)



[EU Spotify](https://open.spotify.com/playlist/37i9ZQAEWUu4y2R0p00000)

Thank you



© European Union 2023

Unless otherwise noted the reuse of this presentation is authorised under the [CC BY 4.0](#) license. For any use or reproduction of elements that are not owned by the EU, permission may need to be sought directly from the respective right holders.

Slide **xx: element concerned**, source: [e.g. Fotolia.com](#); Slide **xx: element concerned**, source: [e.g. iStock.com](#)