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Public Questionnaire informing the European Biotech Act

Fields marked with * are mandatory.

Introduction

The European Biotech Act

Biotechnology and biomanufacturing hold great promise for advancing competitiveness and innovation within the European Union (EU). As previously acknowledged in the Communication on Biotechnology and Biomanufacturing (March 2024) and the reports by Enrico Letta (April 2024) and Mario Draghi (September 2024), it is necessary to address the challenges faced by European companies, users and consumers, and all stakeholders involved to boost the technological advancement, competitiveness and economic growth of the EU.

To this end, the Commission has announced in the 2024-2029 political guidelines a new European Biotech Act, aimed at creating an enabling environment to make it easier to bring biotech products from the laboratory to the factory and then onto the market, while maintaining the highest safety standards for the protection of the population and the environment.

EU policy initiatives relevant for this sector are for example the Strategy for European Life Sciences, the Competitiveness Compass, new EU Bioeconomy Strategy, the AI in science Strategy, the Vision for Agriculture and Food, the European Innovation Act, the EU Start-Up and Scale-up Strategy, the Union of Skills and the Savings and Investment Union. Some of these are currently still under development and the European Biotech Act will be defined in synergies with them.

The public consultation

The European Commission is launching a **public consultation** on the European Biotech Act in the form of an online questionnaire. The aim is to gather evidence and views from stakeholders across all relevant sectors of biotechnology and biomanufacturing, including the medical and pharmaceutical, agricultural, food and feed, industrial, environmental and marine sectors. Your feedback is crucial for identifying the most important challenges and barriers that could be addressed by the Act and for shaping targeted policy actions.

Instructions

The first section of the questionnaire contains questions about you or the organisation you represent, which is then followed by questions on the regulatory and non-regulatory environment in the EU to inform the policy-

making process of the European Biotech Act.

Whenever possible, please substantiate your replies with data and sources of information or practical examples.

This questionnaire is available in all EU official languages and you can reply in any EU official language. You can pause at any time and continue later. You can download your contribution once you have submitted your answers.

About you

* Language of my contribution

- Bulgarian
- Croatian
- Czech
- Danish
- Dutch
- English
- Estonian
- Finnish
- French
- German
- Greek
- Hungarian
- Irish
- Italian
- Latvian
- Lithuanian
- Maltese
- Polish
- Portuguese
- Romanian
- Slovak
- Slovenian

- ○ Spanish
- ○ Swedish

* I am giving my contribution as
  - ○ Academic/research institution
  - ○ Business association
  - ○ Company/business
  - ○ Consumer organisation
  - ○ EU citizen
  - ○ Environmental organisation
  - ○ Non-EU citizen
  - ◉ Non-governmental organisation (NGO)
  - ○ Public authority
  - ○ Trade union
  - ○ Other

Do you identify yourself as a private investor (e.g. venture capitalist, business angel)?
- ○ Yes
- ◉ No
- ○ I don't know/I'd rather not say

* This questionnaire covers **all areas of biotechnologies.** Please indicate the **sector s** that are relevant to you or the organisation you represent, or which you have most knowledge on.

You can select multiple sectors.

Please note that your answers to the questionnaire will be analysed in relation to the sector(s) you have selected.
- ☑ Medical/pharmaceutical
- ☐ Agricultural
- ☐ Food/feed
- ☐ Industrial

- [ ] Environmental
- [ ] Marine
- [ ] Bioinformatics
- [ ] Biotechnology for defence and security
- [ ] Other areas of biotechnology
- [ ] Not applicable

If a different sector of biotechnology is relevant to you or the organisation you represent, please specify.

*First name

Toma

*Surname

Mikalauskaite

*Email (this won't be published)

Toma@cancer.eu

*Organisation name

255 character(s) maximum

Association of European Cancer Leagues (ECL)

*Organisation size

- (•) Micro (1 to 9 employees)
- ( ) Small (10 to 49 employees)
- ( ) Medium (50 to 249 employees)
- ( ) Large (250 or more)

Transparency register number

Check if your organisation is on the transparency register. It's a voluntary database for organisations seeking to influence EU decision-making.

19265592757-25

* Country of origin

Please add your country of origin, or that of your organisation.

This list does not represent the official position of the European institutions with regard to the legal status or policy of the entities mentioned. It is a harmonisation of often divergent lists and practices.

- Afghanistan
- Åland Islands
- Albania
- Algeria
- American Samoa
- Andorra
- Angola
- Anguilla
- Antarctica
- Antigua and Barbuda
- Argentina
- Armenia
- Aruba
- Australia
- Austria
- Azerbaijan
- Bahamas
- Bahrain
- Bangladesh
- Djibouti
- Dominica
- Dominican Republic
- Ecuador
- Egypt
- El Salvador
- Equatorial Guinea
- Eritrea
- Estonia
- Eswatini
- Ethiopia
- Falkland Islands
- Faroe Islands
- Fiji
- Finland
- France
- French Guiana
- French Polynesia
- French Southern and Antarctic Lands
- Libya
- Liechtenstein
- Lithuania
- Luxembourg
- Macau
- Madagascar
- Malawi
- Malaysia
- Maldives
- Mali
- Malta
- Marshall Islands
- Martinique
- Mauritania
- Mauritius
- Mayotte
- Mexico
- Micronesia
- Moldova
- Saint Martin
- Saint Pierre and Miquelon
- Saint Vincent and the Grenadines
- Samoa
- San Marino
- São Tomé and Príncipe
- Saudi Arabia
- Senegal
- Serbia
- Seychelles
- Sierra Leone
- Singapore
- Sint Maarten
- Slovakia
- Slovenia
- Solomon Islands
- Somalia
- South Africa
- South Georgia and the South Sandwich Islands

- Barbados
- Belarus
- Belgium
- Belize
- Benin
- Bermuda
- Bhutan
- Bolivia
- Bonaire Saint Eustatius and Saba
- Bosnia and Herzegovina
- Botswana
- Bouvet Island
- Brazil
- British Indian Ocean Territory
- British Virgin Islands
- Brunei
- Bulgaria
- Burkina Faso
- Burundi
- Cambodia
- Cameroon
- Canada
- Cape Verde
- Gabon
- Georgia
- Germany
- Ghana
- Gibraltar
- Greece
- Greenland
- Grenada
- Guadeloupe
- Guam
- Guatemala
- Guernsey
- Guinea
- Guinea-Bissau
- Guyana
- Haiti
- Heard Island and McDonald Islands
- Honduras
- Hong Kong
- Hungary
- Iceland
- India
- Indonesia
- Monaco
- Mongolia
- Montenegro
- Montserrat
- Morocco
- Mozambique
- Myanmar/Burma
- Namibia
- Nauru
- Nepal
- Netherlands
- New Caledonia
- New Zealand
- Nicaragua
- Niger
- Nigeria
- Niue
- Norfolk Island
- Northern Mariana Islands
- North Korea
- North Macedonia
- Norway
- Oman
- South Korea
- South Sudan
- Spain
- Sri Lanka
- Sudan
- Suriname
- Svalbard and Jan Mayen
- Sweden
- Switzerland
- Syria
- Taiwan
- Tajikistan
- Tanzania
- Thailand
- The Gambia
- Timor-Leste
- Togo
- Tokelau
- Tonga
- Trinidad and Tobago
- Tunisia
- Türkiye
- Turkmenistan

- Cayman Islands
- Central African Republic
- Chad
- Chile
- China
- Christmas Island
- Clipperton
- Cocos (Keeling) Islands
- Colombia
- Comoros
- Congo
- Cook Islands
- Costa Rica
- Côte d’Ivoire
- Croatia
- Cuba
- Curaçao
- Cyprus
- Czechia
- Democratic Republic of the Congo
- Denmark
- Iran
- Iraq
- Ireland
- Isle of Man
- Israel
- Italy
- Jamaica
- Japan
- Jersey
- Jordan
- Kazakhstan
- Kenya
- Kiribati
- Kosovo
- Kuwait
- Kyrgyzstan
- Laos
- Latvia
- Lebanon
- Lesotho
- Liberia
- Pakistan
- Palau
- Palestine
- Panama
- Papua New Guinea
- Paraguay
- Peru
- Philippines
- Pitcairn Islands
- Poland
- Portugal
- Puerto Rico
- Qatar
- Réunion
- Romania
- Russia
- Rwanda
- Saint Barthélemy
- Saint Helena Ascension and Tristan da Cunha
- Saint Kitts and Nevis
- Saint Lucia
- Turks and Caicos Islands
- Tuvalu
- Uganda
- Ukraine
- United Arab Emirates
- United Kingdom
- United States
- United States Minor Outlying Islands
- Uruguay
- US Virgin Islands
- Uzbekistan
- Vanuatu
- Vatican City
- Venezuela
- Vietnam
- Wallis and Futuna
- Western Sahara
- Yemen
- Zambia
- Zimbabwe

The Commission will publish all contributions to this public consultation. You can choose whether you would prefer to have your details published or to remain anonymous when your contribution is published. **For the purpose of transparency, the type of respondent (for example, 'business association, 'consumer association', 'EU citizen') country of origin, organisation name and size, and its transparency register number, are always published. Your e-mail address will never be published.** Opt in to select the privacy option that best suits you. Privacy options default based on the type of respondent selected

* Contribution publication privacy settings

The Commission will publish the responses to this public consultation. You can choose whether you would like your details to be made public or to remain anonymous.

- **Anonymous**

  Only organisation details are published: The type of respondent that you responded to this consultation as, the name of the organisation on whose behalf you reply as well as its transparency number, its size, its country of origin and your contribution will be published as received. Your name will not be published. Please do not include any personal data in the contribution itself if you want to remain anonymous.

- **Public**

  Organisation details and respondent details are published: The type of respondent that you responded to this consultation as, the name of the organisation on whose behalf you reply as well as its transparency number, its size, its country of origin and your contribution will be published. Your name will also be published.

☑ I agree with the personal data protection provisions

Questions regarding a future European Biotech Act

*Mandatory questions are indicated with an *.*

Please note that the answers to the questionnaire will be analysed in relation to the area(s) you have selected in the 'About you' section.

Section 1 - General views on biotechnology

Biotechnology can be defined as the application of science and technology to living organisms, as well as parts, products and models of them, to alter living or non-living materials for the production of knowledge, goods and services.

Biomanufacturing is the use and conversion of biotechnology and biological resources into chemicals, products and energy.

Q1. Considering **biotechnology and biomanufacturing products overall,** to what extent do you agree with the following:

	Strongly disagree	Disagree	Neutral	Agree	Strongly agree	Not applicable/I don't know
* Biotechnology and biomanufacturing products can **positively impact the EU economy**	○	○	○	○	◉	○
* Biotechnology and biomanufacturing can **positively impact the EU society**	○	○	○	○	◉	○
* Biotechnology and biomanufacturing can **positively impact the environment**	○	○	◉	○	○	○
* Biotechnology and biomanufacturing products that reach the EU market are **safe and secure**	○	○	○	◉	○	○
* **Information to users and consumers** on biotechnology and biomanufacturing is available and accessible	○	◉	○	○	○	○
* Consumes are **willing to pay a price premium** for biotechnology and biomanufacturing products	○	◉	○	○	○	○

Section 2 - The regulatory environment in the EU

The following questions seek to collect views on the regulatory environment in the EU, in particular the perceived regulatory barriers.

Q1. Taking into account recent initiatives and legislation adopted or under discussion at EU level, to what extent do you agree with the following statement: **EU rules lead to regulatory barriers for biotechnology and biomanufacturing products to reach the market in the following phases:**

Not all phases may be applicable to all biotechnology and biomanufacturing products.

This specific question covers EU rules, i.e. legislation stemming from the European Union.

	Strongly disagree	Disagree	Neutral	Agree	Strongly agree	Not applicable/I don't know
* In early-stage or pre-clinical development	○	○	○	◉	○	○
* In product development	○	○	○	◉	○	○
* In pre-commercial testing or clinical trials	○	○	○	◉	○	○
* In the assessment and in obtaining authorisation to market products	○	○	◉	○	○	○
* In techno-economics (outside of health) or health technology assessment	○	○	○	◉	○	○
* In commercialising products	○	○	○	◉	○	○
* In scaling-up production or manufacturing	○	○	◉	○	○	○
* In post-market activities, including monitoring and surveillance	○	○	◉	○	○	○

Q2. Please indicate **other phases of the innovation and manufacturing cycle** where there are **regulatory barriers** caused by EU rules.

600 character(s) maximum

Cross-border access and interoperability of clinical trial data remain fragmented. Differences in ethical review procedures and delays in data-sharing across countries create additional barriers. In oncology, these inconsistencies delay trial initiation and evidence generation, slowing patient access to innovation. In addition, cross-border access to therapies developed under Hospital Exemption is an issue. Finally, regulations defining which human models are validated and accepted for the submission of toxicology and PK/PD data currently pose a barrier to the adoption of alternative models.

Q3. Please substantiate your statements with **additional evidence** on the **challenges** resulting from the **EU regulatory environment**.

600 character(s) maximum

For cancer patients, delays in clinical trial approvals, divergent health technology assessment (HTA) across EU countries and launching strategies of pharmaceutical companies mean unequal and late access. Studies show median time-to-market for oncology medicines can differ by years between member states. These regulatory inefficiencies undermine the goals of faster and equitable access to innovation.

The following questions seek to collect views on possible ways forward to simplify and streamline the EU regulatory environment applicable to biotechnology and biomanufacturing products.

* **Q4.** In your view, what **actions at EU level** are necessary to **improve the regulatory environment for biotechnology and biomanufacturing** in the EU? Please substantiate your statements with views and evidence on the ways forward.

600 character(s) maximum

There is a need to harmonise and streamline HTA and pricing/reimbursement processes, ensure predictable timelines, and strengthen coordination between the European Medicines Agency (EMA), HTA bodies and payers. Fast-track procedures should be available for therapies addressing high unmet medical needs such as cancer. Patient organisations should be systematically involved in regulatory design.

The following questions refer to views or experience with regulatory environments in countries outside of the EU and of the EEA (Norway, Iceland and Liechtenstein).

Q5. To what extent do you agree that the EU regulatory environment in comparison with some of the countries outside of the EU...:

For each statement, you will have the possibility to indicate the third country(ies) your answer refers to.

	Strongly disagree	Disagree	Neutral	Agree	Strongly agree	Not applicable/I don't know
... is more **predictable**	○	◉	○	○	○	○
... is **less complex and clearer**	○	◉	○	○	○	○
... leads to lower **costs** for **complying** with the regulation	○	◉	○	○	○	○
... **enables** biotechnology and biomanufacturing products to **reach the market faster**	○	◉	○	○	○	○
... ensures a **higher level of safety and security**	○	○	◉	○	○	○

Q5a. Regarding predictability: Please indicate the reasons why, and in which third-country(ies) this applies.

600 character(s) maximum

Compared with the U.S. Food and Drug Administration (FDA), EMA procedures are predictable, but fragmentation in national HTA makes the overall EU environment less so. In oncology, this causes uncertainty for innovators and delays for patients.

Q5b. Regarding complexity and clarity: Please indicate the reasons why, and in which third-country(ies) this applies.

600 character(s) maximum

EU has multiple regulatory layers (EMA approval + 27 national HTA/pricing and reimbursement decisions). This creates complexity compared to the US, where regulatory and reimbursement frameworks are more centralised.

Q5c. Regarding compliance costs: Please indicate the reasons why, and in which third-country(ies) this applies.

600 character(s) maximum

In the US the single centralised approval reduces duplicative costs, while in the EU biotech companies need to deal with different HTA, pricing and reimbursement in each member state, increasing the cost and time.

Q5d. Regarding speed of reaching the market: Please indicate the reasons why, and in which third-country(ies) this applies.

600 character(s) maximum

Oncology products often reach US patients 6-12 months earlier than EU due to faster FDA reviews and less fragmented HTA. EU patients face delays despite equal or greater need.

Q5e. Regarding the level of safety and security: Please indicate the reasons why, and in which third-country(ies) this applies.

600 character(s) maximum

EU ensures high safety standards, particularly post-market surveillance. This is a comparative strength and should not be compromised in efforts to accelerate access.

Q6. Please indicate any **other relevant factors that characterise the regulations in non-EU countries** and that are applicable to biotechnology and biomanufacturing products.

600 character(s) maximum

Section 3 - Access to capital

The following questions seek to collect views on access to public and private capital and related barriers.

Q1. To what extent do you agree it is **easy to access the following types of public investments in the EU:**

	Strongly disagree	Disagree	Neutral	Agree	Strongly agree	Not applicable /I don't know
* Grants and subsidies (e.g. at EU level: HORIZON, EU4Health)	○	○	○	◉	○	○
* Debt and equity instruments (e.g. European Innovation Council, European Investment Bank, Strategic Technologies for Europe Platform)	○	○	◉	○	○	○
* Commercialisation support	○	○	○	○	○	◉
* Support to capacity expansion	○	○	○	○	○	◉

Q2. To what extent do you agree it is **easy to access the following types of private investments in the EU:**

	Strongly disagree	Disagree	Neutral	Agree	Strongly agree	Not applicable/I don't know
* Angel investors	○	○	○	○	○	◉
* Venture capital: Start-up/early stage (Series A)	○	○	○	○	○	◉
* Venture capital: Expansion stage (Series B)	○	○	○	○	○	◉
* Venture capital: Growth stage (Series C, etc)	○	○	○	○	○	◉
* Debt financing	○	○	○	○	○	◉
* Private equity	○	○	○	○	○	◉
* Strategic research or sales partnerships and collaborations	○	○	○	○	○	◉
* Publicly listing (Initial Public Offering (IPO))	○	○	○	○	○	◉
* Capital markets/shareholders	○	○	○	○	○	◉
* Corporate funding (from other companies in the market)	○	○	○	○	○	◉

* **Q3.** In your views, are there **other financial instruments** relevant for the biotechnology sector in the EU?

- (●) Yes
- ( ) No
- ( ) I don't know

Q3a. Please indicate **other relevant private and public financial instruments**.

600 character(s) maximum

Philanthropic sector of different member states is especially important for specific funding for non-commercial clinical trials or early-stage spin offs of academic origin and support for high-risk research, such as advanced therapies for rare cancers.

Q4. Based on your experience, to what extent do you agree that the following factors **drive investment in a biotechnology company**?

	Strongly disagree	Disagree	Neutral	Agree	Strongly agree	Not applicable /I don't know
* Innovative science	( )	( )	( )	( )	(●)	( )
* Groundbreaking technology (e.g. health biotech: a breakthrough that significantly improves upon existing therapies or addresses unmet medical needs; food biotech: solution that can boost food security)	( )	( )	( )	( )	(●)	( )
* Scientific evidence, including data, concerning innovation	( )	( )	( )	( )	(●)	( )
* Access to data held by public sector bodies	( )	( )	( )	( )	(●)	( )
* Experienced management team	( )	( )	( )	( )	(●)	( )
* Robust supply chain	( )	( )	( )	( )	(●)	( )

* Regulatory certainty (e.g. length and predictability of authorisation process)	○	○	○	○	◉	○
* Sufficient protection of intellectual property	○	○	◉	○	○	○
* Financial health and projections	○	○	○	○	◉	○

Q5. Please indicate **other factors that drive investment** in a biotechnology and/or biomanufacturing company here.

1000 character(s) maximum

For cancer-related biotechnology, investment is strongly driven by the potential to address unmet medical needs, particularly rare and aggressive cancers. The level of patient involvement in research design, the availability of real-world data, and new partnerships with hospitals, universities, and NGOs increase the attractiveness for investors. Also, strong cross-border collaborations and the evidence of added value for society, such as improved survival rates and reduced inequalities in access to innovation. Investment in biotechnology and biomanufacturing is strongly driven by the technology readiness level (TRL), as higher TRLs make technologies more attractive to private investors and commercial partners. Strengthening funding mechanisms that help early-stage, fundamental, and pre-clinical research progress toward market readiness would de-risk innovation and stimulate private investment, particularly in promising cancer technologies.

Q8. Please substantiate your statements with **additional evidence** on the **challenges** related to **access to finance in the EU**.

600 character(s) maximum

The following questions seek to collect views on possible ways forward to support access to finance in the EU.

* **Q9.** In your view, what **actions at EU level** are necessary for the public sector **to attract/derisk private investments in biotechnology and/or biomanufacturing**? Please substantiate your statements with views and evidence on the ways forward.

You can provide references of successful schemes existing at EU level, national level or in other jurisdictions to attract private capital in biotechnology.

600 character(s) maximum

A continuation of the EU Cancer Mission with a dedicated budget for EU cancer innovation could support projects that address unmet needs, particularly in rare cancers. The EU should expand public-private co-funding schemes that reduce risk for investors while ensuring social impact. For example, more grants with guaranteed mechanisms could enhance the investment in oncology research.

* **Q10.** In your view, what **actions at EU level** are necessary to prioritise **funding for high-risk and high-reward biotechnology research and innovation?** Please substantiate your statements with views and evidence on the ways forward.

600 character(s) maximum

The EU should consider specific funds for high-risk and high-reward oncology projects, particularly immunotherapies and other advanced therapies, personalised medicine, prevention and AI-diagnostics. The EU should also simplify access to those funds for NGOs and hospitals to ensure therapies for rare cancers will also be developed when commercial incentives are missing. Fast-track funding and flexible reporting would encourage researchers to participate while ensuring patient involvement throughout the process.

* **Q11.** In your view, what **other actions** are necessary at EU level? Please substantiate your statements with views and evidence on the ways forward.

600 character(s) maximum

Ensure that the EU financing mechanisms integrate health equity and fair prices as a crucial criterion, so that investments lead to better access for patients across all member states. Increase the support for non-commercial clinical trials, prevention programmes and rare cancers. Increase cross-border funding for collaborative platforms that bring together academia, industry and patient associations to accelerate innovation against cancer.

Section 4 - Biotechnology clusters and/or cluster organisations

The following questions seek to collect views on biotechnology clusters and/or cluster organisations in the EU.

'**Clusters** are groups of firms, related economic actors, and institutions located near each other and with sufficient scale to develop specialised expertise, services, resources, suppliers and skills.' [**link to definition of clusters**]

'**Cluster organisations** are the legal entities that support the strengthening of collaboration, networking and learning in innovation clusters and act as innovation support providers by providing or channelling specialised and customised business support services to stimulate innovation activities, especially in SMEs. They are usually the actors that facilitate strategic partnering across clusters.' [**link to definition of cluster organisations**]

Q1. To what extent do you agree that biotechnology clusters and/or cluster organisations in the EU face the **following barriers** in order to reach their full potential?

	Strongly disagree	Disagree	Neutral	Agree	Strongly agree	Not applicable /I don't know
* Insufficient number of academic institutions with long standing expertise in the area of biotechnology	○	○	◉	○	○	○
* Insufficient presence of industrial players	○	○	○	◉	○	○
* Insufficient higher education or vocational training institutions	○	○	◉	○	○	○
* Insufficient startup incubators or business support infrastructure (providing for example regulatory affair support)	○	○	○	◉	○	○
* Lack of technology transfer offices	○	○	○	◉	○	○
* Incapacity to reach a critical mass of stakeholders	○	○	○	◉	○	○
* Insufficient public support	○	○	○	○	◉	○
* Insufficient collaboration among existing clusters	○	○	○	○	◉	○
* Insufficient financial support	○	○	○	○	◉	○

Q2. Please indicate **other factors impacting biotechnology clusters and/or cluster organisations** in the EU.

1000 character(s) maximum

For cancer-related biotechnology, clusters are fragmented and sometimes driven by commercial interests. Patient involvement is often missing in clusters. Without including civil society, clusters risk pursuing innovation that does not align with public health priorities. Regional disparities also mean that some countries benefit far more than others.

Q3. Please substantiate your statements with **additional evidence** on the **challenges** faced by **biotechnology clusters and/or cluster organisations** in the EU.

600 character(s) maximum

Cancer-focused biotech clusters often fail to translate discoveries into practice because of fragmented governance and lack of patient input. This slows uptake of promising diagnostics and therapies across member states.

The following questions seek to collect views on possible ways forward to support biotechnology clusters and/or cluster organisations in the EU.

* **Q4.** In your view, what **actions at EU level** are necessary to **enhance the impact of biotechnology clusters and/or cluster organisations in the EU**? Please substantiate your statements with views and evidence on the ways forward.

600 character(s) maximum

A stronger focus on publicly funded health research is essential to drive innovation & ensure equitable access to new therapies. Evidence from the U.S. shows that 99% of all drugs approved by the FDA in 2010-2019 relied on NIH-funded research, demonstrating the effectiveness of sustained public investment in medical innovation. Strengthening collaboration between national research institutes, academia, & industry through European frameworks would help bridge the gap between early-stage discovery and market-ready solutions, ultimately reinforcing Europe's health sovereignty and competitiveness.

* **Q5.** In your view, what **actions at EU level** are necessary to create more **synergies** between existing clusters and/or cluster organisations and facilitate **pooling of expertise and resources** in the EU? Please substantiate your statements with views and evidence on the ways forward here.

600 character(s) maximum

Facilitate European network of oncology clusters, with joint data platform and shared expertise. Joint platforms for cross-border clinical trials and technology transfer could accelerate equitable access to innovation and advanced treatments for all EU patients. Encourage collaboration over competition and include patient organisations in governance structures.

Section 5 - Biotechnology manufacturing

The following questions seek to collect views on biotechnology manufacturing in the EU.

Q1. To what extent do you agree that biotechnology manufacturing in the EU faces the following challenges:

	Strongly disagree	Disagree	Neutral	Agree	Strongly agree	Not applicable /I don't know
* Length and/or complexity of permitting processes for new facilities	○	○	○	◉	○	○
* High cost of raw material and/or of the operations	○	○	○	◉	○	○
* High energy costs	○	○	○	◉	○	○
* Other operational costs	○	○	◉	○	○	○
* Limitations in logistics and physical infrastructure	○	○	○	◉	○	○
* Vulnerabilities in supply chains and strategic dependencies	○	○	○	○	◉	○
* Labour costs	○	○	◉	○	○	○
* Inconsistent environmental and sustainability policies or lack of a policy	○	○	◉	○	○	○
* Taxation and customs barriers (e.g. tax credits, import duties)	○	○	◉	○	○	○
* Global competition	○	○	○	◉	○	○
* Difficulty scaling up from pilot to industrial production	○	○	○	◉	○	○
* Maintaining product quality and consistency at scale	○	○	◉	○	○	○

Q2. Please indicate **other challenges impacting biotechnology manufacturing in the EU**.

600 character(s) maximum

The manufacturing capacity for producing advanced therapies, such as CAR-T, varies significantly and is unequal across different countries. For cross-border clinical trials in such therapeutic approaches, the difficulty is even greater as the shipment and extension of the permission for production is not the same for all member states, and it is a burden for research due to the different manufacturing times and conditions.

Q3. Please substantiate your statements with **additional evidence** on the **challenges impacting biotechnology manufacturing in the EU**.

600 character(s) maximum

Repeated shortages of cancer drugs across EU member states have been well-documented, undermining equal access. EU level action on critical medicine production capacity is urgent.

The following question seeks to collect views on possible ways forward to support biotechnology manufacturing in the EU.

* **Q4.** In your view, what **actions at EU level** are necessary to **enhance the impact of biotechnology manufacturing in the EU?** Please substantiate your statements with views and evidence on the ways forward.

600 character(s) maximum

One action would be to increase the investment in biomanufacturing platforms accessible to hospitals and research centres, not only industry. Another could be increasing also the access to grants for public-private partnerships, which are essential for the manufacturing of cancer therapies. Moreover, the creation of EU strategic reserves and manufacturing capacity for essential medicines, including oncology, would allow the sustainability of the supply chain across different member states.

Section 6 - Availability, upskilling and reskilling the biotechnology workforce

The following questions seek to collect views on the needs of the workforce in biotechnology in the EU.

Q1. To what extent do you agree that **the EU workforce for biotechnology** faces the following **challenges?**

	Strongly disagree	Disagree	Neutral	Agree	Strongly agree	Not applicable /I don't know
* Shortage of vocational skills especially for biotechnology and biomanufacturing (e.g. lab technicians, operators, etc.)	○	○	○	◉	○	○
* Insufficient STEM education graduates (STEM: Science, Technology, Engineering, Mathematics)	○	○	◉	○	○	○
* Insufficient research and technical skills	○	○	◉	○	○	○
* Insufficient regulatory and quality assurance expertise	○	○	○	○	◉	○
* Insufficient digital and data science skills	○	○	○	◉	○	○
* Insufficient intellectual property skills	○	○	◉	○	○	○
* Limited financial, entrepreneurial skills and mindsets	○	○	○	◉	○	○
* Other	○	○	○	◉	○	○

Q2. Please indicate **other challenges faced by the workforce for biotechnology in the EU**.

600 character(s) maximum

There is a lack of training in advanced therapies in the oncology field, together with the low level of understanding of regulatory aspects and intellectual property rights within that field, it makes patient-centred non-commercial clinical research difficult, especially in the accessibility of the clinicians to training opportunities in that field, and therefore, making this research unequal and poorer than other regions of the world. Moreover, gender imbalance and limited career pathways for young researchers also reduce talent retention within the EU.

Q3. To what extent do you agree that **the following factors** lead to the EU workforce facing the above-mentioned challenges?

	Strongly disagree	Disagree	Neutral	Agree	Strongly agree	Not applicable /I don't know
* Difficulty in attracting, developing and retaining global talent	○	○	○	◉	○	○
* Misalignment between education and industry needs	○	○	○	◉	○	○
* Regional disparities in the availability of skilled workers in the EU (for example as a result of brain drain or lack of availability of training courses)	○	○	○	◉	○	○
* Insufficient public and private investment in skilled workforce	○	○	○	◉	○	○

Q4. Please indicate **other factors** leading to the **EU workforce facing the above-mentioned challenges**.

1000 character(s) maximum

Biotech careers in Europe often seem less appealing than in the US or Asia, mainly because salaries are lower, there are fewer opportunities to start businesses, and career growth is slower. In cancer research, many doctors struggle to combine patient care with research, which reduces the number of clinician researchers, who are key for the research of new treatments. Moreover, training opportunities are also unequal across the different EU countries, leaving some regions behind. Also, NGOs are often excluded from training, even though their role is crucial for patient-centred innovation.

Q5. Please substantiate your statements with **additional evidence on the challenges faced by the workforce for biotechnology in the EU**.

600 character(s) maximum

As mentioned above, the salary of a research career in the EU is much lower than in the USA, for instance, and also the opportunities for career progression are limited. Thus, there are many EU researchers who are leaving for the USA or the UK. Also, training programmes in the EU are valuable but often too competitive or fragmented, leaving gaps in areas like bioinformatics and clinical trial design, which makes the translational research more difficult and increases the 'valley of death'.

* **Q6.** In your view, what **actions at EU level** are necessary to **enhance specialised training programmes/curricula?** Please substantiate your statements with views and evidence on the ways forward.

600 character(s) maximum

The EU should invest more in bioinformatics and digital health training for researchers with patient-centred modules, making the curricula of researchers stronger in clinical and regulatory expertise to be able to apply knowledge in the translation between the laboratory and industry. Promote joint degrees across universities and training placements in regulatory bodies.

* **Q7.** In your view, what **actions at EU level** are necessary to **enhance support for scientists to launch a business** (e.g. through incubators, pilot facilities for knowledge transfer and idea testing, etc.)? Please substantiate your statements with views and evidence on the ways forward.

600 character(s) maximum

Support incubators and pilot facilities that allow oncology researchers to test ideas without immediate commercialisation pressure. Patient organisations should be included as partners in early-stage projects.

* **Q8.** In your view, what **actions at EU level** are necessary to support **programmes to attract talent from other geographical areas**? Please substantiate your answers with views and evidence on the ways forward.

600 character(s) maximum

One action could be to reduce the bureaucratic burden in Visas and the homologation of academic titles. Also, specific fellowships with attractive conditions, such as family support and long-term career opportunities, could help the EU to compete with the US and Asia in attracting talent worldwide.

* **Q9.** In your view, what **other actions at EU level** are necessary for the availability, upskilling and reskilling of the biotechnology workforce? Please substantiate your statements with views and evidence on the ways forward.

600 character(s) maximum

Increase the investment to promote professional development in cross-functional areas such as AI in combination with biological sciences, facilitate the combination of practice and research for clinicians, with a correct gender balance, and include patients' perspectives in the training. Encourage interdisciplinary training including ethics, patient engagement and health economics. These are vital for responsible translation of biotech to patient benefit.

Section 7 - Data and Artificial Intelligence

The following questions seek to collect views on the challenges related to access to data and on the development, deployment and use of Artificial Intelligence (AI) in biotechnology.

* **Q1.** Are you or the organisation you represent having difficulties in **accessing or using relevant data** for the development of biotechnology or biomanufacturing products?

- ○ Yes
- ○ No
- ○ Partially
- ◉ Not applicable/I don't know

* **Q2.** Are you or the organisation you represent relying on **data sourced from outside of the EU/EEA** for the development of biotechnology and biomanufacturing products and services?

- ○ Yes
- ○ No
- ◉ Not applicable/I don't know

Q3. To what extent do you agree that **data synthetisation** is a viable means to overcome data scarcity in the EU?

- ○ Strongly disagree
- ○ Disagree
- ◉ Neutral
- ○ Agree

- ○ Strongly agree
- ○ Not applicable/I don't know

The next set of questions specifically cover the implementation of the European Health Data Space (EHDS) and consequently focus on health data.

In the health domain, the EHDS aims to alleviate challenges in accessing data for secondary use by establishing a legal framework facilitating the reuse of health data for research and innovation, including in the biotechnology sector. The EHDS Regulation entered into force on 26 March 2025 and its key provisions will enter into application and be operational by March 2029.

Q4. Regarding the health biotechnology sector, are you or the organisation you represent **actively preparing for the entry into application of the EHDS?**

- ◉ Yes
- ○ No
- ○ Not applicable/I don't know

* **Q4a.** In what capacity does your organisation expect to be involved in the European Health Data Space? Please select the capacity(ies) that is/are most relevant for you.

- ☑ Data user
- ☐ Data holder
- ☐ Health Data Access Body
- ☐ Authorised participant to HealthData@EU infrastructure (e.g. as a health-related research infrastructure or other data-sharing infrastructure)
- ☐ Health Data Intermediation Entity
- ☐ Single Trusted Data Holder
- ☐ Cross-border registry
- ☐ Other

Q4b. What are the specific challenges related to the implementation of the EHDS that you or the organisation you represent encounter?

600 character(s) maximum

The principal concerns are ensuring patient privacy, ensuring their consent for secondary use, and making access to that data available and affordable for NGOs, hospitals and researchers and not only for industry. Also, the 2029 date puts cross-border clinical trials at high risk, as these trials need data-sharing and are crucial for the oncology research of today.

Q5. Which types of services of research and health data infrastructures (e.g. biobank research infrastructures) are currently used in the biotechnology sector?

600 character(s) maximum

Cancer registries, hospital-based clinical databases and EU biobank infrastructures.

The following questions specifically concern the transformative potential of AI for biotechnology.

In the following questions, a distinction is made between two categories of AI use in biotechnology, representing different phases of the innovation cycle:

1. Use of AI in Research and Development (R&D): Biotech companies using AI toolsto support or accelerate their R&D processes (e.g. using AI to identify drug targets or design new molecules, applying machine learning to analyse omics data, etc).

2. Deployment and scale-up of AI-based Biotechnology Products: Biotech companies developing AI-powered products or services and deploying these products into real-world settings (e.g.AI-powered biomanufacturing platforms aimed to be integrated in production facilities, AI powered diagnostic tool that analyses blood based biomarkers to detect early stage cancer using a biological model of tumour progression, etc).

Q6. To what extent do you agree that **the use of AI in R&D** is facing the following challenges:

	Strongly disagree	Disagree	Neutral	Agree	Strongly agree	Not applicable /I don't know
* **Technological challenges, access and use of data** (e.g. outdated infrastructure to support the integration of AI tools, lack of interoperability, lack of local validation (performance testing), lack of post-deployment monitoring mechanisms, lack of AI transparency and explainability etc)	○	○	○	◉	○	○
* **Challenges in the implementation of regulatory frameworks** (e.g. complex regulatory landscapes for AI users and/or deployers, concerns over liability, concerns surrounding data security and privacy etc)	○	○	○	◉	○	○
* **Organisational and business challenges** (e.g. lack of end-user involvement in the development and deployment of AI tools, lack of added value assessment in deploying AI, lack of AI strategy for use/deployment in the entity)	○	○	○	◉	○	○
* **Social and cultural challenges** (e.g. lack of trust in AI tools, lack of digital literacy among users/deployers/the public, concerns on job security, concerns surrounding overreliance on AI tools, etc	○	○	○	◉	○	○

Q7. To what extent do you agree that **the deployment of AI-based biotech products** is facing the following challenges:

	Strongly disagree	Disagree	Neutral	Agree	Strongly agree	Not applicable /I don't know
* **Technological challenges, access and use of data** (e.g. outdated infrastructure to support the integration of AI tools, lack of interoperability, lack of local validation (performance testing), lack of post-deployment monitoring mechanisms, lack of AI transparency and explainability etc)	○	○	○	◉	○	○
* **Challenges in the implementation of regulatory frameworks** (e.g. complex regulatory landscapes for AI users and/or deployers, concerns over liability, concerns surrounding data security and privacy etc)	○	○	○	◉	○	○
* **Organisational and business challenges** (e.g. lack of end-user involvement in the development and deployment of AI tools, lack of added value assessment in deploying AI, lack of AI strategy for use/deployment in the entity)	○	○	○	◉	○	○
* **Social and cultural challenges** (e.g. lack of trust in AI tools, lack of digital literacy among users/deployers/the public, concerns on job security, concerns surrounding overreliance on AI tools, etc	○	○	○	◉	○	○

Q8. Please substantiate your statements with **additional evidence** on **access to data, the use of AI in R&D,** and **deployment of AI-based biotech products in the EU biotechnology sector** here.

600 character(s) maximum

If the datasets are fragmented and incomplete, patients and clinicians could mistrust AI-based diagnostics that are based on them, especially if transparency and explainability are missing. These barriers limit both research progress and clinical uptake.

The following questions seek to collect views on possible ways forward to support the deployment and use of AI and data in biotech.

* **Q9.** In your view, what **actions at EU level** are necessary to enhance **the use of AI in R&D in biotechnology** in the EU?

600 character(s) maximum

Create secure access to annotated cancer datasets, support controlled regulatory test environments, and fund validation of AI models in real-world oncology settings. The involvement of patients and NGOs in the early stages of AI projects will also help build trust and transparency in the field.

* **Q10.** In your view, what **actions at EU level** are necessary to enhance the **deployment of AI-based biotechnology products** in the EU?

600 character(s) maximum

Establish EU-wide certification for AI tools, focusing on transparency and explainability. Fund implementation pilots in hospitals to build trust and assess added value. The involvement of patients and NGOs in the early stages of AI projects will also help build trust and transparency in the field.

Q11. In your view, what **other actions** should be prioritised **at EU level** related to **data and AI in the field of biotechnology and biomanufacturing** (e.g. on data, on use of high-performance computers (HPC), etc.)?

600 character(s) maximum

Ensure the EHDS integration with AI tools, invest in advanced computing capacity, and enforce equity in access to datasets across member states. Provide funding and training for clinicians and researchers, as well as for hospitals and their centers to adopt AI in oncology. Also, promote data-sharing frameworks to encourage collaboration that is easily accessible.

Q12. The European Commission is supporting the creation of **AI Factories** to accelerate trustworthy AI development. AI Factories are dynamic ecosystems bringing together computing power, data, and talent to create cutting-edge AI models and applications across various sectors (e.g. health, manufacturing, climate etc.).

In your views, how can the AI factories be leveraged to advance biotechnology innovation in Europe?

	Yes	No	Not applicable /I don't know
* Host public-private AI model development for biotech use cases	◉	○	○
* Support validation and certification of AI tools in the biotech field	◉	○	○
* Secure and high-performance processing of health data made available through the EHDS for development of innovative products and tools for the biotech sector	◉	○	○
* Provide access and/or facilitate the use of high-quality datasets through 'data labs'	◉	○	○
* Other	◉	○	○

Q12a. If you would like to indicate other factors, you can do so here.

600 character(s) maximum

Provide training for clinicians, researchers, and patient advocates to increase trust in AI, facilitating its use.

Q13. To what extent do you agree that the following types of support would help biotech companies, particularly SMEs, **develop and deploy AI solutions more effectively** in the EU?

	Strongly disagree	Disagree	Neutral	Agree	Strongly agree	Not applicable /I don't know
*						

Dedicated funding instruments for biotech-related AI research and development	○	○	○	○	◉	○
* Access to annotated datasets (e. g. biological, clinical, genomic data)	○	○	○	○	◉	○
* Access to synthetic datasets	○	○	○	○	◉	○
* Regulatory sandboxes for testing biotech-related AI models	○	○	○	○	◉	○
* Partnerships with public research institutions or AI hubs /factories	○	○	○	○	◉	○
* Simplified IP and data-sharing frameworks	○	○	○	○	◉	○
* Skills development and AI training for biotech personnel	○	○	○	○	◉	○
* Roadmaps for implementation and scalability of AI tools in the EU ecosystem	○	○	○	○	◉	○
* Other	○	○	○	○	◉	○

Q13a. Please indicate other factors here.

600 character(s) maximum

Focus these AI projects on solutions to address unmet clinical needs, such as cancer prevention, early detection, and advanced therapies for rare cancers. Also, the funding for non-commercial and patient-centered AI projects is essential.

Q14. If you would like to substantiate any of your statements with additional evidence on **the ways forward** to **support the deployment and use of data and AI in biotechnology,** you can do so here.

600 character(s) maximum

AI tools have high potential in cancer research. However, it is critical to ensure equal access to data and clear and transparent rules, as well as allow formation for clinicians, researchers and patient advocates to promote innovation not restricted to big industrial players.

Section 8 - Defence and security

Advanced biotechnological possibilities including development of synthetic pathogens, aided by AI-driven software systems, are creating new risks related to future health preparedness and potential of weaponisation by State or non-State actors (Sauli Niinistö report, October 2024).

The following questions seek to collect views on biotechnology for defence and security in the EU.

Q1. To what extent do you agree that application of **biotechnology in defence and security related areas** faces the following **challenges in the EU**?

	Strongly disagree	Disagree	Neutral	Agree	Strongly agree	Not applicable /I don't know
* Threats related to biosecurity and biosafety, including misuse of biotechnology	○	○	○	○	◉	○
* Risks to strategic autonomy in biomanufacturing, and availability of medical and non-medical countermeasures	○	○	○	◉	○	○
* Vulnerabilities in the resilience of biotech supply chains	○	○	○	◉	○	○
* Insufficient civil military cooperation in biotechnology sector	○	○	◉	○	○	○
* Cybersecurity risks to biotech infrastructure and AI tools used in biotechnology	○	○	○	◉	○	○
* Other	○	○	○	○	○	◉

* **Q2.** Please indicate **other challenges** impacting biotechnology for defence and security in the EU.

600 character(s) maximum

N/A

Q3. To what extent do you agree that **biotechnology for defence and security** is creating the following **opportunities in the EU**?

	Strongly disagree	Disagree	Neutral	Agree	Strongly agree	Not applicable /I don't know
* Facilitate detecting biological and chemical threats, including via availability of biosensors	○	○	○	◉	○	○
* Opportunity to revolutionise defence logistics with biotechnology products (including food) manufacturing close to its point of use	○	○	◉	○	○	○
* Development of new innovative medical countermeasures including vaccines and antidotes	○	○	○	◉	○	○
* Developments of materials with new functions and/or improved characteristic	○	○	◉	○	○	○
* Increased food security	○	○	◉	○	○	○
* Other	○	○	○	○	○	◉

The following questions seek to collect views on possible ways forward to support biotechnology for defence and security in the EU.

* **Q4.** In your view, what **other actions at EU level** are necessary to **enhance the impact of biotechnology for defence and security in the EU**? Please substantiate your statements with views and evidence on the ways forward.

600 character(s) maximum

There is a need for higher coordination between sectors such as health and defence, with the need to increase the ethical supervision of the misuse of biotechnology, without preventing its use in the positive health applications it could have. The EU funding should prioritise the sustainability of the health system with a patient-centred vision, increasing the R&D budget instead of increasing the defence budget.

Section 9 - Additional information

Is there anything else you would like to add that has not been covered by this consultation?

We welcome the European Biotech Act as an opportunity to ensure that biotechnology innovation translates into real benefits for patients. In the oncology field, access to new treatments and advanced therapies is crucial, particularly when addressing unmet clinical needs. Therefore, the simplification of regulatory processes to enable cross-border clinical trials, greater harmonisation among member states, equal access to medicines, and transparency with patient involvement in AI-driven research projects are urgent priorities. In addition, market failures can be observed in the domain of advanced therapy medicinal products (ATMPs). Therefore, academic development of ATMPs should be supported; see attached ECL paper on this topic. To enable this, initiatives such as EMA's pilot offering enhanced support to academic and non-profit developers of ATMPs should be sustained and reinforced. In this context, it is essential to establish financing mechanisms that combine competitive public funding, philanthropy, and private capital. The European Biotech Act should allocate specific funds for cancer and other diseases with a high social burden, while also increasing R&D investment to support non-commercial clinical trials, prevention, and early detection. Above all, any support measure for biotechnology applied to cancer must translate into tangible patient benefits - prevention, early diagnosis, innovative treatments, and equitable access. Innovation must reach all patients, regardless of geography or socioeconomic status, and its value should be measured not only in economic return, but also in life years gained, improved quality of life, reduced inequities, and the sustainability of healthcare systems, which entails fair prices.

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