

Consultation on the White Paper on Artificial Intelligence - A European Approach

Fields marked with * are mandatory.

Introduction

Artificial intelligence (AI) is a strategic technology that offers many benefits for citizens and the economy. It will change our lives by improving healthcare (e.g. making diagnosis more precise, enabling better prevention of diseases), increasing the efficiency of farming, contributing to climate change mitigation and adaptation, improving the efficiency of production systems through predictive maintenance, increasing the security of Europeans and the protection of workers, and in many other ways that we can only begin to imagine.

At the same time, AI entails a number of potential risks, such as risks to safety, gender-based or other kinds of discrimination, opaque decision-making, or intrusion in our private lives.

The [European approach for AI](#) aims to promote Europe's innovation capacity in the area of AI while supporting the development and uptake of ethical and trustworthy AI across the EU. According to this approach, AI should work for people and be a force for good in society.

For Europe to seize fully the opportunities that AI offers, it must develop and reinforce the necessary industrial and technological capacities. As set out in the accompanying European strategy for data, this also requires measures that will enable the EU to become a global hub for data.

The current public consultation comes along with the [White Paper on Artificial Intelligence - A European Approach](#) aimed to foster a European ecosystem of excellence and trust in AI and a Report on the safety and liability aspects of AI. The White Paper proposes:

- Measures that will streamline research, foster collaboration between Member States and increase investment into AI development and deployment;
- Policy options for a future EU regulatory framework that would determine the types of legal requirements that would apply to relevant actors, with a particular focus on high-risk applications.

This consultation enables all European citizens, Member States and relevant stakeholders (including civil society, industry and academics) to provide their opinion on the White Paper and contribute to a European approach for AI. To this end, the following questionnaire is divided in three sections:

- **Section 1** refers to the specific actions, proposed in the White Paper's Chapter 4 for the building of an ecosystem of excellence that can support the development and uptake of AI across the EU economy and public administration;
- **Section 2** refers to a series of options for a regulatory framework for AI, set up in the White Paper's Chapter 5;
- **Section 3** refers to the [Report on the safety and liability aspects of AI](#).

Respondents can provide their opinion by choosing the most appropriate answer among the ones suggested for each question or suggesting their own ideas in dedicated text boxes.

Feedback can be provided in one of the following languages:

[BG](#) | [CS](#) | [DE](#) | [DA](#) | [EL](#) | [EN](#) | [ES](#) | [ET](#) | [FI](#) | [FR](#) | [HR](#) | [HU](#) | [IT](#) | [LT](#) | [LV](#) | [MT](#) | [NL](#) | [PL](#) | [PT](#) | [RO](#) | [SK](#) | [SL](#) | [SV](#)

Written feedback provided in other document formats, can be uploaded through the button made available at the end of the questionnaire.

The survey will remain open until 14 June 2020.

About you

* Language of my contribution

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

* I am giving my contribution as

- Academic/research institution
- Business association
- Company/business organisation
- Consumer organisation
- EU citizen
- Environmental organisation
- Non-EU citizen
- Non-governmental organisation (NGO)
- Public authority
- Trade union
- Other

* First name

Paul

* Surname

DE RAEVE

* Email (this won't be published)

efn@efn.be

* Organisation name

255 character(s) maximum

European Federation of Nurses Associations - EFN

* Organisation size

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

Transparency register number

255 character(s) maximum

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

87872442953-08

* Country of origin

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

- | | | | |
|-------------------------------------|--------------------------------|-------------------------------------|------------------------------------|
| <input type="radio"/> Afghanistan | <input type="radio"/> Djibouti | <input type="radio"/> Libya | <input type="radio"/> Saint Martin |
| <input type="radio"/> Åland Islands | <input type="radio"/> Dominica | <input type="radio"/> Liechtenstein | <input type="radio"/> |

- Albania
- Algeria
- American Samoa
- Andorra
- Angola
- Anguilla
- Antarctica
- Antigua and Barbuda
- Argentina
- Armenia
- Aruba
- Australia
- Austria
- Azerbaijan
- Bahamas
- Bahrain
- Bangladesh
- Barbados
- Belarus
- Belgium
- Belize
- Benin
- Bermuda
- Bhutan
- Bolivia
- Bonaire Saint Eustatius and Saba
- Bosnia and Herzegovina
- Botswana
- Bouvet Island
- Brazil
- 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
- Gabon
- Georgia
- Germany
- Ghana
- Gibraltar
- Greece
- Greenland
- Grenada
- Guadeloupe
- Guam
- Guatemala
- Guernsey
- Guinea
- Lithuania
- Luxembourg
- Macau
- Madagascar
- Malawi
- Malaysia
- Maldives
- Mali
- Malta
- Marshall Islands
- Martinique
- Mauritania
- Mauritius
- Mayotte
- Mexico
- Micronesia
- Moldova
- Monaco
- Mongolia
- Montenegro
- Montserrat
- Morocco
- Mozambique
- Myanmar /Burma
- Namibia
- Nauru
- Nepal
- Netherlands
- New Caledonia
- New Zealand
- 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
- South Korea
- South Sudan
- Spain
- Sri Lanka
- Sudan
- Suriname
- Svalbard and Jan Mayen
- Sweden
- Switzerland
- Syria
- Taiwan
- Tajikistan
- Tanzania

- British Indian Ocean Territory
- British Virgin Islands
- Brunei
- Bulgaria

- Burkina Faso
- Burundi

- Cambodia

- Cameroon

- Canada
- Cape Verde
- 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

- Guinea-Bissau
- Guyana
- Haiti
- Heard Island and McDonald Islands
- Honduras
- Hong Kong
- Hungary
- Iceland
- India
- Indonesia
- Iran
- Iraq
- Ireland
- Isle of Man
- Israel
- Italy
- Jamaica
- Japan
- Jersey
- Jordan
- Kazakhstan
- Kenya
- Kiribati
- Kosovo
- Kuwait
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- Laos
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- Nicaragua
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- Nigeria
- Niue
- Norfolk Island
- Northern Mariana Islands
- North Korea
- North Macedonia
- Norway
- Oman
- Pakistan
- Palau
- Palestine
- Panama
- Papua New Guinea
- Paraguay
- Peru
- Philippines
- Pitcairn Islands
- Poland
- Portugal
- Puerto Rico
- Qatar
- Réunion
- Romania
- Russia
- Rwanda
- Saint Barthélemy
- Thailand
- The Gambia
- Timor-Leste
- Togo
- Tokelau
- Tonga
- Trinidad and Tobago
- Tunisia
- Turkey
- Turkmenistan
- 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

- Democratic Republic of the Congo
- Lesotho
- Saint Helena Ascension and Tristan da Cunha
- Zimbabwe
- Denmark
- Liberia
- Saint Kitts and Nevis
- Saint Lucia

*** 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 your type of respondent, country of origin and contribution will be published. All other personal details (name, organisation name and size, transparency register number) will not be published.
- Public**
Your personal details (name, organisation name and size, transparency register number, country of origin) will be published with your contribution.

I agree with the [personal data protection provisions](#)

Section 1 - An ecosystem of excellence

To build an ecosystem of excellence that can support the development and uptake of AI across the EU economy, the White Paper proposes a series of actions.

In your opinion, how important are the six actions proposed in section 4 of the White Paper on AI (1-5: 1 is not important at all, 5 is very important)?

	1 - Not important at all	2 - Not important	3 - Neutral	4 - Important	5 - Very important	No opinion
Working with Member states	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Focussing the efforts of the research and innovation community	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>
Skills	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>
Focus on SMEs	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Partnership with the private sector	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Promoting the adoption of AI by the public sector	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>

Are there other actions that should be considered?

500 character(s) maximum

The engagement of the frontline nursing workforce should be included. They should be pro-actively engaged in the co-design process formulating end-user requirements that guide digital developments and innovation, ensuring fit-for-purpose solutions.

Revising the Coordinated Plan on AI (Action 1)

The Commission, taking into account the results of the public consultation on the White Paper, will propose to Member States a revision of the Coordinated Plan to be adopted by end 2020.

In your opinion, how important is it in each of these areas to align policies and strengthen coordination as described in section 4.A of the White Paper (1-5: 1 is not important at all, 5 is very important)?

	1 - Not important at all	2 - Not important	3 - Neutral	4 - Important	5 - Very important	No opinion
Strengthen excellence in research	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>
Establish world-reference testing facilities for AI	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>
Promote the uptake of AI by business and the public sector	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Increase the financing for start-ups innovating in AI	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>
Develop skills for AI and adapt existing training programmes	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>
Build up the European data space	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>

Are there other areas that that should be considered?

500 character(s) maximum

EU Member States should proactively engage with the frontline nursing workforce. That would ensure that the deploy of AI tools and systems that reduce the workload of nurses and safeguard the quality of care. AI should go beyond the traditional perspective of the medical model and be more inclusive towards all healthcare professions in the health and social care ecosystems.

A united and strengthened research and innovation community striving for excellence

Joining forces at all levels, from basic research to deployment, will be key to overcome fragmentation and create synergies between the existing networks of excellence.

In your opinion how important are the three actions proposed in sections 4.B, 4.C and 4.E of the White Paper on AI (1-5: 1 is not important at all, 5 is very important)?

	1 - Not important at all	2 - Not important	3 - Neutral	4 - Important	5 - Very important	No opinion
Support the establishment of a lighthouse research centre that is world class and able to attract the best minds	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>
Network of existing AI research excellence centres	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>
Set up a public-private partnership for industrial research	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Are there any other actions to strengthen the research and innovation community that should be given a priority?

500 character(s) maximum

Nursing research input is key to make deployment of AI frontline more fit-for-purpose. Building trust with the end-user is key to make research findings implemented. Implementation research is key to build trust!

Focusing on Small and Medium Enterprises (SMEs)

The Commission will work with Member States to ensure that at least one digital innovation hub per Member State has a high degree of specialisation on AI.

In your opinion, how important are each of these tasks of the specialised Digital Innovation Hubs mentioned in section 4.D of the White Paper in relation to SMEs (1-5: 1 is not important at all, 5 is very important)?

	1 - Not important at all	2 - Not important	3 - Neutral	4 - Important	5 - Very important	No opinion
Help to raise SME's awareness about potential benefits of AI	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>
Provide access to testing and reference facilities	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>
Promote knowledge transfer and support the development of AI expertise for SMEs	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>
Support partnerships between SMEs, larger enterprises and academia around AI projects	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>
Provide information about equity financing for AI startups	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>

Are there any other tasks that you consider important for specialised Digital Innovations Hubs?

500 character(s) maximum

SME need to build their work, development on end-user engagement, a co-creation and co-design approach, to make sure investments lead to concrete fit-for-purpose outcomes. End-user requirement are key: listen to what the nurses need and want!

Section 2 - An ecosystem of trust

Chapter 5 of the White Paper sets out options for a regulatory framework for AI.

In your opinion, how important are the following concerns about AI (1-5: 1 is not important at all, 5 is very important)?

	1 - Not important at all	2 - Not important	3 - Neutral	4 - Important	5 - Very important	No opinion
AI may endanger safety	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

AI may breach fundamental rights (such as human dignity, privacy, data protection, freedom of expression, workers' rights etc.)	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
The use of AI may lead to discriminatory outcomes	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
AI may take actions for which the rationale cannot be explained	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
AI may make it more difficult for persons having suffered harm to obtain compensation	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
AI is not always accurate	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

**Do you have any other concerns about AI that are not mentioned above?
Please specify:**

500 character(s) maximum

end-user co-creation is key to develop a regulatory framework; Nursing Regulators are key to translate nurses needs into an AI regulatory framework build on TRUST.

Do you think that the concerns expressed above can be addressed by applicable EU legislation? If not, do you think that there should be specific new rules for AI systems?

- Current legislation is fully sufficient
- Current legislation may have some gaps
- There is a need for a new legislation
- Other
- No opinion

If you think that new rules are necessary for AI system, do you agree that the introduction of new compulsory requirements should be limited to high-risk applications (where the possible harm caused by the AI system is particularly high)?

- Yes
- No
- Other
- No opinion

Do you agree with the approach to determine “high-risk” AI applications proposed in Section 5.B of the White Paper?

- Yes
- No
- Other

- No opinion

If you wish, please indicate the AI application or use that is most concerning (“high-risk”) from your perspective:

500 character(s) maximum

Nurses experiences to make informed decisions in the clinical pathways, that impact on human activities and behaviour, are AI high-risk areas: machine learning and clinical expertise need to be complementary, not competitive and disruptive.

In your opinion, how important are the following mandatory requirements of a possible future regulatory framework for AI (as section 5.D of the White Paper) (1-5: 1 is not important at all, 5 is very important)?

	1 - Not important at all	2 - Not important	3 - Neutral	4 - Important	5 - Very important	No opinion
The quality of training data sets	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>
The keeping of records and data	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>
Information on the purpose and the nature of AI systems	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>
Robustness and accuracy of AI systems	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>
Human oversight	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>
Clear liability and safety rules	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>

In addition to the existing EU legislation, in particular the data protection framework, including the General Data Protection Regulation and the Law Enforcement Directive, or, where relevant, the new possibly mandatory requirements foreseen above (see question above), do you think that the use of remote biometric identification systems (e.g. face recognition) and other technologies which may be used in public spaces need to be subject to further EU-level guidelines or regulation:

- No further guidelines or regulations are needed
- Biometric identification systems should be allowed in publicly accessible spaces only in certain cases or if certain conditions are fulfilled (please specify)
- Other special requirements in addition to those mentioned in the question above should be imposed (please specify)
- Use of Biometric identification systems in publicly accessible spaces, by way of exception to the current general prohibition, should not take place until a specific guideline or legislation at EU level is in place.

- Biometric identification systems should never be allowed in publicly accessible spaces
- No opinion

Please specify your answer:

EHR developments and consent are key in clinical pathways - informed consent is key in nursing care.

Do you believe that a voluntary labelling system (Section 5.G of the White Paper) would be useful for AI systems that are not considered high-risk in addition to existing legislation?

- Very much
- Much
- Rather not
- Not at all
- No opinion

Do you have any further suggestion on a voluntary labelling system?

500 character(s) maximum

Building trust is key! End-user engagement builds trust! Listen careful to what the end-user needs so tools become fit-for-purpose.

What is the best way to ensure that AI is trustworthy, secure and in respect of European values and rules?

- Compliance of high-risk applications with the identified requirements should be self-assessed ex-ante (prior to putting the system on the market)
- Compliance of high-risk applications should be assessed ex-ante by means of an external conformity assessment procedure
- Ex-post market surveillance after the AI-enabled high-risk product or service has been put on the market and, where needed, enforcement by relevant competent authorities
- A combination of ex-ante compliance and ex-post enforcement mechanisms
- Other enforcement system
- No opinion

Please specify any other enforcement system:

500 character(s) maximum

Engaging with the nursing workforce and with the end-users in the deployment of AI tools. A co-creation process is key.

Do you have any further suggestion on the assessment of compliance?

500 character(s) maximum

Make systems deployable, easy to use, so that tools decrease nurses workload!

Section 3 – Safety and liability implications of AI, IoT and robotics

The overall objective of the safety and liability legal frameworks is to ensure that all products and services, including those integrating emerging digital technologies, operate safely, reliably and consistently and that damage having occurred is remedied efficiently.

The current product safety legislation already supports an extended concept of safety protecting against all kind of risks arising from the product according to its use. However, which particular risks stemming from the use of artificial intelligence do you think should be further spelled out to provide more legal certainty?

- Cyber risks
- Personal security risks
- Risks related to the loss of connectivity
- Mental health risks

In your opinion, are there any further risks to be expanded on to provide more legal certainty?

500 character(s) maximum

healthcare service liability stays with the healthcare provider

Do you think that the safety legislative framework should consider new risk assessment procedures for products subject to important changes during their lifetime?

- Yes
- No
- No opinion

Do you have any further considerations regarding risk assessment procedures?

500 character(s) maximum

clinical risk assessment procedures are key to be developed by the regulatory body of the profession.

Do you think that the current EU legislative framework for liability (Product Liability Directive) should be amended to better cover the risks engendered by certain AI applications?

- Yes
- No
- No opinion

Do you have any further considerations regarding the question above?

500 character(s) maximum

Engage the nursing profession regulation in this development.

Do you think that the current national liability rules should be adapted for the operation of AI to better ensure proper compensation for damage and a fair allocation of liability?

- Yes, for all AI applications
- Yes, for specific AI applications
- No
- No opinion

Do you have any further considerations regarding the question above?

500 character(s) maximum

EU coordination is key for the healthcare sector in the EU

Thank you for your contribution to this questionnaire. In case you want to share further ideas on these topics, you can upload a document below.

You can upload a document here:

The maximum file size is 1 MB

Only files of the type pdf,txt,doc,docx,odt,rtf are allowed

Contact

CNECT-AI-CONSULT@ec.europa.eu