



# FOCUS-EU

HEALTH

February 2020

Overview of EU and global policy developments

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Commission

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## European Commission

### Revised enlargement methodology

The European Commission has proposed a revised methodology for enlargement which puts public administration reform on an equal footing with the other fundamentals (functioning of democratic institutions, economic reforms, etc). A stronger focus is placed on rule of law in the accession negotiations, for example through anti- corruption work being main-streamed where relevant. Negotiations in the area of fundamentals will be opened first and closed last and progress on the fundamental reforms will determine the overall pace of accession negotiations.

Source: <https://ec.europa.eu/enlargement>

### Artificial Intelligence and Intellectual Property

A report by the Joint Research Centre (JRC) of the European Commission highlights the need for reflection on the possible implications of the development and adoption of AI within the intellectual property (IP) framework in areas such as:

- copyright and the use of data for training AI (i.e. feeding algorithms);
- the IP protection of assets generated by AI;
- the relationship between ethical requirements of transparency and explainability; and
- the interests of rights holders, users and society at large.

*The Joint Research Centre (JRC) is the European Commission's science and knowledge service which employs scientists to carry out research in order to provide independent scientific advice and support to EU policy.*

Source: <https://publications.jrc.ec.europa.eu/ipfinal.pdf>

### eHealth Stakeholder Group renewed

The Commission has announced the new member organisations of the eHealth Stakeholder Group with a mandate until 2022. Members are all umbrella organisations/associations with a European outreach, representing the Health Tech industry, patients, healthcare professionals and the research community. The group will support the Commission in the development of actions for the digital transformation of health and care in the EU in the following areas:

- Health Data, including the European Electronic Health record exchange format and the baseline set of technical specifications and better interoperability
- Digital health services
- Health data protection and privacy issues
- Cybersecurity for health and care data
- Digital tools for citizen empowerment and person centred care
- Artificial intelligence and health
- Cross cutting aspects such as financing and investment proposals and enabling technologies

The first meeting of the renewed Group is planned for 13 March 2020 in Brussels.

For information on selected organisations, meetings, including agenda and minutes:

[https://ec.europa.eu/register\\_CommissionExpertGroups](https://ec.europa.eu/register_CommissionExpertGroups)

Source: <https://ec.europa.eu/ehealth-stakeholder-group>

### European Health Data Space

Work has started on the European Health Data Space (EHDS), one of the priorities of the new Commission mandate. The aim of the EHDS is to foster the exchange, and sharing of different kinds

of health data (electronic health records, genomics, registries, etc.) across Europe for both primary and secondary uses in a way that it protects citizens' data while supporting the delivery of primary care and the development of new interventions and services. A series of three workshops will explore potential gaps and needs regarding health data usage within the EU; how Member States are implementing the GDPR for the protection of personal data in the field of health, in order to identify possible differences; and the impact of such differences on the cross-border exchange of health data.

The discussions will address citizens' access to their personal data and the portability of such data to other operators.

Discussions will also explore different national governance models, databases and codes of conduct for secondary use of health data (used for research, policymaking and development of private services in the field of health).

The Commission is currently working with the Member States and stakeholders to define the best governance structure and set up the appropriate infrastructure for the EHDS; and address existing regulatory gaps regarding Member States implementation of the GDPR for the secondary use of data.

Source: <https://ec.europa.eu/protection-personal-data-health>

## Progress report on AMR

The European Commission published its 4th progress report on the implementation of the European One Health Action Plan against Antimicrobial Resistance (AMR), which was adopted in June 2017.

This follows the publication of two overview reports respectively on measures to tackle AMR through the prudent use of antimicrobials in animals and on a series of audits carried out in 2017 and 2018 in order to evaluate the monitoring and reporting of AMR in zoonotic and commensal bacteria in certain food-producing animal populations and food. The next progress report is planned to be published by the end of 2020.

Full report: [https://ec.europa.eu/amr\\_actionplan-progress.pdf](https://ec.europa.eu/amr_actionplan-progress.pdf)

One Health Action Plan: [https://ec.europa.eu/amr\\_action-plan.pdf](https://ec.europa.eu/amr_action-plan.pdf)

## AI testing facilities

The European Commission has proposed a limited number of world-class, large-scale reference AI Testing and Experimentation Facilities. These facilities will be made available to all actors across Europe in order to make products market-ready while ensuring compliance with safety standards and security by design and they may include regulatory sandboxes (areas where regulation is limited or favourable to testing new products and services).

The exact number and model of facilities should be adapted to the needs of the health sector, and can have different sizes and locations. One given facility could be a network of physical locations. The intention is to make economies of scale, but it does not exclude a certain number of similar sites either, for instance to guarantee easy access to all regions in Europe. The regulatory

environment might also be a factor to select the location/number of facilities.

Source: <https://ec.europa.eu/AI-testing-facilities-health>

## European Green Deal

The European Green Deal is a new growth strategy towards achieving sustainable green transition with the involvement of the public and of all stakeholders. It is supported by investments in green technologies, sustainable solutions and new businesses; its measures range from ambitiously cutting emissions, to investing in cutting-edge research and innovation, to preserving Europe's natural environment. The vision is to set a path for a just and socially fair transition leaving no individual or region behind in the planned transformation.

Source: <https://ec.europa.eu/european-green-deal.pdf>

## Across the World

### FDA: Gene therapy for Retinal Disorders

The Food and Drug Administration has announced the availability of a final guidance entitled "Human Gene Therapy for Retinal Disorders; Guidance for Industry." The guidance provides recommendations to sponsors developing human gene therapy (GT) products for retinal disorders affecting adult and pediatric patients. The guidance finalises the draft guidance of the same title dated July 2018 and focuses on issues specific to GT products for retinal disorders with recommendations related to product development, preclinical testing, and clinical trial design for such GT products.

The final version for retinal disorders includes:

- new details on safety considerations;
- explanation of why a single administration of a gene therapy product in each eye may not always be sufficient and
- information on the separation of clinical evaluators and personnel involved in product administration and the sham procedure.

The guidance document:

<https://www.fda.gov/human-gene-therapy-retinal-disorders>

Source: <https://www.raps.org/fda-finalizes-gene-therapy-guidance>

## Other

### European Human Exposome Network

The European Human Exposome Network has been launched. It is the world's largest network of projects studying the impact of environmental exposure on human health. The Network is rooted in international and regional frameworks, such as the United Nations Sustainable Development Goals and the strategic cooperation on environment and health between the European Commission and the World Health Organization (WHO) Europe. The network has emerged from three decades of work towards better integration of environment and health in research. It brings together 9 research projects, receiving over €100 million from Horizon 2020 running for five years from 2020 until 2024 on issues such as exposures to air quality, noise, chemicals, urbanisation etc. The research will inform preventive policies and will contribute to the European Green Deal, the EU's pledge to protect citizens' health and well-being from pollution and environmental deterioration.

*The Human Exposome is an emerging area of research that explores how exposure to environmental factors (pollution, diet, lifestyle, socioeconomic factors, work, environment, infections etc.) impacts our health and wellbeing throughout life, starting from conception and pregnancy. Research on the Human Exposome aims for a better understanding of the cause of many common diseases and ultimately improve disease prevention and health promotion.*

To access presentations from launching event:

<https://ec.europa.eu/info/exposome-event-2020-presentations.pdf>

Sources: <https://www.humanexposome.eu>  
[https://ec.europa.eu/environment&health\\_en](https://ec.europa.eu/environment&health_en)

### EUTOPIA is looking for researchers

EUTOPIA (European University Alliance) is launching a postdoctoral programme worth €10.2 million, with €5.6 million coming from EU's Horizon 2020 programme and another €4.6 million put forward by the universities in the alliance. The universities will offer grants to 76 post-doctoral researchers working on data and artificial intelligence, health and disease, and energy and sustainability involving international collaborative research and teaching over five years. Researchers are expected to work with local governments and businesses and collaborate across international divides and traditional disciplinary boundaries. Their work would also be aligned with the private sector and other organisations to deliver real benefits to society. The programme is looking for researchers willing to work on practical challenges such as developing new and sustainable materials, antimicrobial resistance, assessing the impact of big data and artificial intelligence and addressing inequality. Fellows will have access to expert mentoring and state-of-the-art research infrastructure. More than 45 companies, local authorities and non-profit organizations will train or host

researchers on secondments to support the programme. The first call for applications will be published in autumn.

*EUTOPIA is one of the alliances to have recently been included in a pilot project by the European Commission to build "European Universities." Its members are Free University Brussels, CY Cergy Paris University, University of Gothenburg, University of Ljubljana, Pompeu Fabra University in Barcelona and the University of Warwick.*

For more information contact: <https://eutopia-university.eu>

Source: <https://sciencebusiness.net/european-university-alliance>

## Calls

### Call for proposals on new infrastructures (ESFRI)

**Deadline: 5 May 2020**

ESFRI Guide: <https://ESFRI-Roadmap2021-Public-Guide.pdf>

Health Research Infrastructures: <http://esfri>

### Open Call SC1-HCO-19-2020: Reliable and Accessible Information on Cell and Gene-Based Therapies

**Deadline: 7 April 2020**

For topic conditions, documents and submission service: <https://ec.europa.eu/funding/sc1-hco-19-2020>

### Open Call SC1-HCO-20-2020: Coordination of Clinical Research Activities of the European Reference Networks

**Deadline: 7 April 2020**

For topic conditions, documents and submission service: <https://ec.europa.eu/funding/sc1-hco-20-2020>

### IMI 20th Call

**Deadline: 21 April 2020**

Rules and how to apply: [IMI website](http://IMI-website).  
IMI webinars to inform about the open topics: [here](http://IMI-webinars).

Source: <https://www.euresearch.ch/IMI>

### Open Call DT-ICT-12-2020: AI for the smart hospital of the future

**Deadline: 22 April 2020**

For topic conditions, documents and submission service: <https://ec.europa.eu/fundingdt-ict-12-2020>

**Open Call SC1-HCC-10-2020:  
Towards a Health Research and Innovation Cloud:  
Capitalising on Data Sharing Initiatives in Health  
Research**

**Deadline: 7 April 2020**

For topic conditions, documents and submission service:  
<https://ec.europa.eu/sc1-hcc-10-2020>

**Open Call SC1-BHC-06-2020:  
Digital Diagnostics - Developing Tools for Supporting  
Clinical Decisions by Integrating Various Diagnostic  
Data**

**Deadline: 7 April 2020**

For topic conditions, documents and submission service:  
<https://ec.europa.eu/funding-tenders/sc1-bhc-06-2020>

**Open Call SC1-BHC-20A-2020:  
Pre-Commercial Procurement (PCP) for Integrated  
Care Solutions**

**Deadline: 7 April 2020**

For topic conditions, documents and submission service:  
<https://ec.europa.eu/funding-tenders/sc1-bhc-20a-2020>

**Open Call SC1-DTH-12-2020:  
Use of Real-World Data to Advance Research on the  
Management of Complex Chronic Conditions**

**Deadline: 7 April 2020**

For topic conditions, documents and submission service:  
<https://ec.europa.eu/info/funding-tenders/sc1-dth-12-2020>

**Open Call SC1-HCO-19-2020:  
Reliable and accessible information on cell and gene-  
based therapies**

**Deadline: 7 April 2020**

For topic conditions, documents and submission service:  
<https://ec.europa.eu/funding/sc1-hco-19-2020>

**Open Call SC1-DTH-06-2020:  
Accelerating the uptake of computer simulations for  
testing medicines and medical devices**

**Deadline: 22 April 2020**

For topic conditions, documents and submission service:  
<https://ec.europa.eu/funding/sc1-dth-06-2020>

## Consultations & Events

### Free online course on AI

Finland is to invest in the future skills of Europeans – training one per cent of EU citizens in the basics of artificial intelligence. During 2020–2021, Finland will provide European citizens with free access to a successful online course, the Elements of artificial intelligence. The course will be made available in all the official EU languages. This initiative by the Finnish Presidency aims to respond to the challenges posed by the transformation of work and to reinforce the digital leadership of the EU.

Access the course: <https://www.elementsofai.com>

Source: <https://ec.europa.eu/finland-skills-basicsAI->

### WEBINARS

#### Data Sharing in Digital Healthy Ageing Projects 18 February 2020

This webinar is on how to handle data sharing in compliance with the latest regulations and ethics in research projects on healthy ageing. The webinar builds on the experience of three European research projects (NESTORE, EMPATHIC and CAPTAIN) which are developing personalised coaching solutions for ageing well.

Registration: <https://ec.europa.eu/webinar-data-sharing>

#### Calls 2020 of EU Health Programme 4 March 2020

Join to hear about the Calls 2020 and the Annual Work Plan of the EU Health Programme.

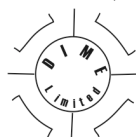
Registration info: [https://ec.europa.eu/annual\\_work\\_plan.pdf](https://ec.europa.eu/annual_work_plan.pdf)

**The EU EYE continues to be a partner of the European Innovation Partnership on Active and Healthy Ageing (EIP-AHA) with a commitment to the B3 Action Group on Integrated care accessible at: <https://ec.europa.eu/eip/b3/>**

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