FOCUS-EU

HEALTH

May 2020

Overview of EU and global policy developments

Retinal findings in patients with COVID-19

A Lancet report of retinal and OCT changes possibly associated with COVID-19 infection in humans.

Source: https://www.thelancet.com/PIIS0140-6736(20)31014-X

Covid-19 Disease Map

The Covid-19 Disease Map is an international effort of 31 countries. It organises the molecular processes underlying the virus-host interactions in COVID-19 to allow visual exploration and computational analyses of molecular processes involved in virus entry, replication, and host-pathogen interactions, host cell recovery and repair mechanisms. The resource will speed up the development of efficient diagnostics and therapies, developing robust disease models and repositioning of existing drugs.

The Covid-19 Disease Map is led by ELIXIR Luxembourg. ELIXIR is an intergovernmental organisation that brings together life science resources from across Europe to form a single sustainable infrastructure for biological information and it includes databases, software tools, training materials, cloud storage and supercomputers.

Sources: https://elixir-europe.org/covid-19-disease-map

Transport and tourism package 2020

The Commission package on tourism and transport in 2020 has been announced allowing businesses to reopen and cross-border travel to be resumed. The package includes common criteria and principles for gradually and safely restoring transport and hospitality industry activities.

Tourism and transport package:

https://ec.europa.eu/qanda_20_870

European Parliament

COVID-19: MEPs free up over €3 billion to support EU healthcare sector

The European Parliament has approved a total of €3.08 billion from the EU budget to cover increased needs of healthcare systems in EU member states due to the pandemic; allow the procurement of urgent medical supplies, and the transport of patients and medical equipment in cross-border regions; and finance the recruitment of additional healthcare professionals to be deployed to hotspots across the European Union, as well as helping member states to construct mobile field hospitals.
The package will be channelled mainly through the Emergency Support Instrument (€2.7 billion) and through rescEU (€380 million) and it includes additional funds to finance repatriation flights (€45 million) under EU Civil Protection Mechanism to reunite families stranded in third countries; to provide more resources for the European Centre for Disease Prevention and Control (€3.6 million); to help Greece deal with increased migratory pressures (€350 million); and to support Albania's post-earthquake reconstruction (€100 million).

Source: https://www.europarl.europa.eu/3-billion-to-healthcare

European Commission

European Semester: resilience of health systems

The Commission has adopted proposals for country-specific recommendations that require all Member State to take steps to strengthen the resilience, accessibility and efficiency of their national health systems in the wake of the ongoing COVID-19 crisis. Among the longer-term issues highlighted in the wake of

the COVID-19 crisis are:

- the working conditions of doctors and nurses;
- shortages of health workers;
- insufficient financing of segments of health system;
- high out-of-pocket payments;
- unmet needs for medical care for patients disproportionately affecting the most vulnerable;
- insufficient capacity of the primary care sector.

The crisis also brought to the fore the untapped potential for the deployment and use of e-Health services, with insufficient coordination and cooperation between health care providers, and a limited integration of health and social care services, in particular elderly care.

Source and details on country specific recommendations: https://ec.europa.eu/EuropeanSemesterMemberStates

Updated guidance on management of Clinical Trials during Covid-19

The European Commission, EMA and the Heads of Medicines Agencies have published the third version of the guidance on managing clinical trials during the pandemic. The updated document addresses sponsor communication with authorities and contain new recommendations on the distribution of investigational medicinal products and data verification under social distancing measures and resource limitations. Remote source data verification can be considered for trials on treatment or prevention of COVID-19 or in the final data cleaning steps for pivotal trials of products for serious or life-threatening conditions that lack sufficient treatment options. The guidance will be revoked once the crisis in Europe has passed.

Sources:
https://ec.europa.eu/guidanceclinicaltrials_covid19_en.pdf
https://ec.europa.eu/docsroom/documents/41183?locale=en

Guidance on safety reporting for medical devices

A new guidance has been released by the Medical Device Coordination Group of the European Commission on safety reporting until the electronic system of Eudamed becomes fully functional. The guidance outlines the procedures for premarket clinical investigations of non-CE marked devices, CE marked devices used outside their intended uses and device studies covered under MDR Article 82. The guidance also applies to certain post-market clinical follow-up investigations, specifically those that involve procedures outside the normal conditions of use of the device and those that impose additional procedures that are invasive or burdensome. The guidance also clarifies what events are considered reportable under MDR Article 80(2); who should report and to whom; and within what timelines depending on the seriousness of the event.

Access the guidance: https://ec.europa.eu/device_safereporting

Across the World

Telemedicine Transforms Response to COVID-19 Pandemic in Disease Epicentre

An article on the study of the dramatic increase in the use of telemedicine in the USA and the transformations in work practices including the role of insurers and regulators with U.S. insurers expanding coverage to include all telemedicine visit types; states relaxing licensing requirements to allow cross-state care delivery; and the U.S. Department of Health and Human Services allowing the use of consumer audio and video communication for telemedicine visits.

Source: https://www.ehealthnews.eu/telemedicine-transforms

FDA updates guidance on clinical trials amid COVID-19

The updated guidance of the US Food and Drug Administration (FDA) on conducting clinical trials during the pandemic has highlighted the need for training of investigators and study personnel on using telemedicine, and the need for procedures to protect participant privacy and to confirm the investigators' and participants' identities.

Source: https://www.fda.gov/clinical-trials-covid-19

Other

ERN-EYE Update

The ERN-EYE has launched a page dedicated to COVID-19 in their website including a new section dedicated to frequently asked questions from patients.
Source: https://www.ern-eye.eu/covid-19-patients

Lithuania joins BBMRI-ERIC

Lithuania has officially joined the Biobanking and BioMolecular resources Research Infrastructure – European Research Infrastructure Consortium (BBMRI-ERIC) as Observer with the Ministry of Education, Science and Sport as the coordinating

institution and the National Cancer Institute hosting the new BBMRI-ERIC National Node.

Source: https://www.bbmri-eric.eu/lithuania

Seasonality vs public health interventions on COVID-19 epidemiology

A prospective cohort study performed of all 144 geopolitical areas throughout the world with at least 10 cases and local transmission as of March 20, 2020, excluding China, South Korea, Iran and Italy suggest that seasonality is likely to play only a minor role in the epidemiology of COVID-19 compared to public health interventions (school closures, restricting mass gatherings, social distancing). However the effect of public health interventions needs to be weighed carefully against potential economic and psychosocial harms when deciding when and how to lift restrictions.

Source: https://www.cmaj.ca/

Expanding compassionate use for Covid-19 patients

EMA's human medicines committee (CHMP) has recommended expanding the compassionate use of the investigational medicine remdesivir to patients not on mechanical ventilation. EMA is currently evaluating these data in the context of the rolling review of remdesivir. Remdesivir is not yet authorised for marketing in the European Union. When the evaluation is complete, EMA will make a recommendation on whether or not remdesivir should receive a marketing authorisation.

Source: https://www.ema.europa.eu/remdesivir-compassionate

Register your pharmacoepidemiological studies

If you or your research group have started or are planning observational studies related to the utilisation and effects of drugs in relation to the Covid-19 pandemic, consider registering your study in the EU PAS Register in order to support the sharing of information on performed or planned studies and increase the efficiency of research. The EU PAS Register is the European Union electronic register of Post -Authorisation Studies run by the EMA and the European Network of Centres for Pharmacoepidemiology and Pharmacovigilance (ENCePP)

More information and registration details: http://www.encepp.eu

Member States presented interoperability guidelines for approved contact tracing apps in the EU

The EU Members States, with the support of the European Commission, adopted interoperability guidelines for approved contact tracing mobile applications in the EU necessary for their national COVID-19 crisis management strategy by enabling the tracing of cross-border infection chains. This is the first follow-up action envisaged by the Union toolbox for the use of mobile apps to support contact tracing in response to the coronavirus pandemic. A key principle of the guidelines is that users should be able to rely on a single app wherever they are in the EU at a certain moment. The idea is to prevent the possibility for the identification of app users, whether infected, exposed or otherwise, unless the individuals in question have voluntarily provided that information or want to contact the health authority. Contact tracing apps are voluntarily installed by citizens and are based on Bluetooth proximity technology that does not enable tracking of people's locations. These apps alert people who have been in proximity to an infected person for a certain duration, in order to self-isolate and to get tested. This way they help to interrupt the transmission chain. The longer the contact and the closer the infected person, the higher the risk of infection. App users' privacy and data will be safeguarded. **Next steps:** The guidelines will be complemented by interoperability specifications for cross-border transmission chains between approved apps. This will be supported by structured discussions between Member States through the eHealth Network. The work of Member States to develop and validate the apps will be supported by the New Generation Internet and m-health communities.

Source: https://ec.europa.eu/archive-issue

Calls

A note to our readers
Click on **Call title** for more information on how to apply

ERC Open Calls

ERC Advanced Grants 2020
Deadline: 26 August 2020
This call is for established researchers and for ground-breaking, high-risk project; €2.5 million over 5 years.

Information for applicants Advanced Grants

Timeframe Advanced Grants

Get Support from Your National Contact Points

Proof of Concept 2020
Deadline: 17 September 2020
This call is for ERC grant holders who are looking to establish proof of concept of an idea generated in the course of their ERC-funded project.

Information for Applicants Proof of Concept

Timeframe Proof of Concept

Co-funding of regional, national & international programmes
Deadline: 29 September 2020
For early-stage researchers' training, mobility and career development for doctoral programmes addressing the development and broadening of research competencies; and fellowship programmes for individual research training and career development for experienced researchers.

Call for proposals of EU Health Programme - Support to reforms in health workforce - initiative on task shifting
Deadline: 10 June 2020

Open Call SC1-HCO-19-2020: Reliable and Accessible Information on Cell and Gene-Based Therapies
Deadline EXTENDED: 4 June 2020

Call for proposals on new infrastructures (ESFRI)
Deadline EXTENDED: 9 September 2020
ESFRI Guide: https://ESFRI-Roadmap2021-Public-Guide.pdf
Health Research Infrastructures: http://esfri

Open Call SC1-HCO-18-2020: Developing methodological approaches for improved clinical investigation and evaluation of High-Risk Medical Devices
Deadline EXTENDED: 4 June 2020

Open Call DT-ICT-12-2020: AI for the smart hospital of the future
Deadline EXTENDED: 17 June 2020

Open Call SC1-HCC-10-2020: Towards a Health Research and Innovation Cloud: Capitalising on Data Sharing Initiatives in Health Research
Deadline EXTENDED: 4 June 2020

Open Call SC1-BHC-06-2020:Digital Diagnostics - Developing Tools for Supporting Clinical Decisions by Integrating Various Diagnostic Data
Deadline EXTENDED: 4 June 2020

Open Call SC1-DTH-12-2020: Use of Real-World Data to Advance Research on the Management of Complex Chronic Conditions
Deadline EXTENDED: 4 June 2020

Open Call SC1-DTH-06-2020: Accelerating the uptake of computer simulations for testing medicines and medical devices
Deadline EXTENDED: 18 June 2020

Consultations & Events

IP Management in ICT Projects

03.06.2020, Webinar

The webinar will discuss specific issues when using or developing ICT in EU projects, such as knowledge management and protection, exploitation, and maximising impact.

Webinar link:
https://www.iprhelpdesk.eu/webinar-ip-management-ict-projects

White Paper on AI

Deadline: 14 June 2020

The European Commission has published a White Paper on Artificial Intelligence. The paper sets out principles for a legislative framework for trustworthy AI and it is open for comments.

Source: https://ec.europa.eu/White-Paper-AI

Free online course on AI

Finland offers European citizens a free online course, the Elements of artificial intelligence in all the official EU languages.

Access the course: https://www.elementsofai.com
Source: https://ec.europa.eu/finland-skills-basicsAI-

Biobanking in Times of Covid-19

A BBMRI webinar on biobanking during the pandemic for information on quality standards, guidelines and research studies.

Webinar: https://www.bbmri-eric.eu/covid-19

Information on biobanking standards and pre-analytical sample processing: https://www.bbmri-eric.eu/services/standardisation/)

BBMRI response to Covid-19: https://www.bbmri-eric.eu/response-to-COVID.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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