Bluepoint Building

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FEBRUARY 2021



Last month, we shared our first newsletter with you, with the emphasis on digital health. This month, we will focus on EU funding opportunities for SMEs.

This is a worrying time for many businesses of all sizes; companies need to look for opportunities to sustain their activities. Aware of these challenges to the European economy and societies, the European Union is providing an unprecedented €1.8 trillion of funding over the coming years. This is designed to support recovery following the COVID-19 pandemic and to help the EU meet its long-term priorities in a range of different policy areas.

The detailed mechanisms and contents of the different funding and investment programmes are currently still under development. They will range from support for research and innovation, through investment in digital infrastructure to funding for regional and local procurement.

We strongly believe that information on these mechanisms will be highly valuable for your organisations, allowing you to identify potential opportunities and where you can find more information.

Please note this is our last complimentary newsletter. If you express interest to receive important information from COCIR, please let us know. You can express your interest by clicking here.

Wishing you a wonderful 2021!

Nicole DENJOY

COCIR Secretary General

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IN CASE YOU WANT MORE INFORMATION ON COCIR ACTIVITIES, PLEASE CONTACT US: WWW.COCIR.ORG / INFO@COCIR.ORG

#02 FEBRUARY 2021



1. DEEP DIVE:

CURRENT EU FUNDING OPPORTUNITIES FOR SMEs IN HEALTHCARE

RESEARCH AND INNOVATION: HORIZON 2020



FUNDING FOR RESEARCH, DEVELOPMENT AND INNOVATION

Horizon 2020, the EU's research and innovation funding programme, runs from 2014-20 with a budget of €80 billion. It provides research and innovation funding for multi-national collaboration projects as well as for individual researchers and supports SMEs with a special funding instrument.

WHAT'S HAPPENING?

In preparation of the next Framework Programme, the European Commission has launched a pilot for the so-called European Innovation Council (EIC). The EIC supports researchers and innovators developing breakthrough innovations with the potential to create new markets and boost jobs, growth and prosperity in Europe. You can access an overview of the EIC pilot here.

NEXT STEPS:

IMPLICATIONS FOR SMEs:

EU-funded research projects provide an opportunity for SMEs to conduct research and innovation that may otherwise be too risky or costly. In addition, the European networks create opportunities to discover new suppliers and / or customers. The European Innovation Council pilot also provide mentoring and visibility for SMEs.

REGIONAL INNOVATION: EUROPEAN STRUCTURAL AND INVESTMENT FUNDS

SUPPORT FOR REGIONAL INVESTMENT AND INNO-VATION IN HEALTHCARE.

The <u>European Structural and Investment Funds</u> are designed to work together in order to support economic development in all EU countries. They are not specifically targeted at innovation, digitisation, health or SMEs. <u>Every EU region</u> may benefit from the ERDF and ESF. However, only less-developed regions may receive support from the Cohesion Fund.

During the period 2021-27, the REACT-EU package will provide €47.5 billion of additional funds in 2021-22 from Next Generation EU. These will be made available to the 2014-20 European Regional Development Fund (ERDF) and the European Social Fund (ESF), as well as the European Fund for Aid to the Most Deprived (FEAD). Funding is in the form of loans, equity and/or grants.

WHAT'S HAPPENING

In the period 2014-20 the Regional Cohesion Funds channelled almost half of their <u>budget</u> to SMEs. In the

2021-27 period, in addition to the Multiannual Financial Framework (MFF) budget, the REACT-EU will target:

- Healthcare systems;
- The provision of working capital and investment support for SMEs;
- The digital transition and the Green Deal.

NEXT STEPS:

The Regional Cohesion policy budget is executed by the <u>Member States</u>, under the <u>Partnership Agreements</u> between the European Commission and individual EU countries, based on national priorities. These Agreements are concluded at the start of every MFF.

IMPLICATIONS FOR SMEs:

<u>Applications</u> for regional funding are submitted to the authority managing the relevant regional programme. That body will evaluate the project and decide whether to grant funding.







ACCESS TO FINANCE FOR SMEs

COSME aims to make it easier for SMEs to access finance during all phases of their lifecycle, be it creation, expansion or business transfer.

WHAT'S HAPPENING?

Businesses will have easier access to guarantees, loans and equity capital. EU 'financial instruments' are channelled through local financial institutions in EU countries. You can find more information here.

NEXT STEPS:

If you are an SME or an entrepreneur looking for debt or equity finance, you can find out which financial inter-

mediaries are working with COSME on the <u>Access to</u> Finance portal.

The <u>'EU financing - real benefit for businesses' brochure</u> offers information on the COSME/EFSI results as of December 2018. It also offers case studies that highlight the wide diversity of projects and businesses supported. You can see more on our <u>case study overview feed</u> and on the <u>EIF website</u>.

IMPLICATIONS FOR SMEs:

The programme is tailored specifically to SMEs to access funding relevant to them, including access to finance, markets and entrepreneurship support.

2. OUTLOOK TO THE NEXT FUNDING FRAMEWORK

The European Commission published, on 27 May 2020, its new proposals for the revised MFF, the EU's long-term budget. It sets the limits for EU spending - as a whole as well as for specific areas of activity - over a seven year period.

Initial proposals for this funding period were already published in 2018. However, as a consequence of the COVID-19 crisis, EU institutions recognised the need to revise and reinforce this long-term budget. The Com-

mission is therefore aiming – exceptionally - to borrow on behalf of the Union for measures over the period 2021-2024, by issuing bonds.

EU funding will be available for a diverse range of programmes and policy areas, spanning agriculture to migration. In addition, the Commission is proposing to raise funds on the financial markets for a temporary boost to selected programmes in the MFF. These additional funds will be frontloaded to the end of 2024.

RESEARCH AND INNOVATION: HORIZON EUROPE



MAINTAINING EUROPE'S HEALTH INNOVATION LEADERSHIP FOR THE NEXT DECADE

As the successor to Horizon 2020, <u>Horizon Europe</u> will be the world's largest funding programme for research, development and innovation, with a budget of €95.5 billion.

WHAT'S HAPPENING?

The programme offers different types of R&D&I support for SMEs. This can be both as members of a consortium

with other companies and academia or as an individual company. Relevant instruments include:

- Funding of collaborative research and innovation projects conducted by transnational consortia, for example in the areas of health or digital innovation.
- European Innovation Council funding for advanced research on breakthrough technologies, support for individual companies to develop and scale-up highrisk and high impact breakthrough innovations as well as with Business Acceleration Services.



 A to-be-created public-private partnership dedicated to health innovation will provide opportunities for SMEs and start-ups to engage in research and innovation projects alongside leading medical technology, pharmaceutical and digital health companies, as well as academics and end users. The first call of the new Public-Private Partnership for Health Innovation is expected to be launched at the end of 2021. Information is made available regularly here.

NEXT STEPS:

The Work Programmes for the relevant parts of the main programme (health, digital, industry and space, European Innovation Council) will be published in April 2021. Informal draft versions can be found here (site regularly updated).

IMPLICATIONS FOR SMEs:

EU-funded research projects provide an opportunity for SMEs to conduct research and innovation that may otherwise be too risky or costly. In addition, the European networks create opportunities to discover new suppliers and / or customers.

DIGITAL INNOVATION: DIGITAL EUROPE



A new initiative for the digital transformation of European healthcare systems

The <u>Digital Europe Programme</u> is a new, dedicated programme that aims to support the digital transformation (cross-sector) by building strategic digital capacities and to facilitate the wider deployment of digital technologies. The Digital Europe Programme is considered an essential element in bridging the gap between research, innovation and development and the large-scale uptake of digital technologies.

WHAT'S HAPPENING?

While the Digital Europe Programme is mainly technology focused and does not target any single sector specifically, health is mentioned several times as one

of the sectors to be covered. Targeted technology areas include high performance computing, Artificial Intelligence (AI) and cybersecurity as well as digital skills.

NEXT STEPS

The Work Programmes for the first calls will be published in April 2021.

IMPLICATIONS FOR SMEs:

SMEs may profit from additional procurement opportunities at national level, as well as updated digital infrastructures, including testing and experimentation facilities.

DIGITAL INFRASTRUCTURE: CONNECTING EUROPE FACILITY



CREATING THE INFRASTRUCTURE FOR DIGITAL TRANSFORMATION

The Connecting Europe Facility (CEF) Programme supports large infrastructure projects with a cross-border impact, building interoperable trans-European networks of strategic importance in realising the Commission's green and digital agendas.

WHAT'S HAPPENING?

The Connecting Europe Facility Programme defines criteria for projects of common interest in the area of digital connectivity infrastructure and refers to an indicative list of eligible projects. This list considers projects related to

- Gigabit connectivity;
- Wireless connectivity in local communities;
- 5G corridors along major transport networks.



One of the two priority actions in this area is the gigabit connectivity for hospitals and medical centres. This will be vital in supporting the European Commission's strategy for the digital transformation of health and care.

NEXT STEPS

Funding will become available later in 2021.

IMPLICATIONS FOR SMEs:

SMEs may profit from additional procurement opportunities at national level, as well as updated digital infrastructures in hospitals and healthcare systems.

REGIONAL INNOVATION: STRUCTURAL AND COHESION FUNDS



SUPPORT FOR REGIONAL INVESTMENT AND INNOVATION IN HEALTHCARE.

In the MFF 2021-2027, Cohesion policy becomes simpler, with the potential for synergies with Horizon Europe. The European Regional and Development Fund and the Cohesion Fund support projects in the Member States through loans, guarantees and equity. Funding can also be granted to projects; to access this, one needs to develop a project to be eligible for funding, which you will then receive at various stages of the process.

Investment areas include ICT, Research and Innovation.

WHAT'S HAPPENING

At the beginning of each MFF, Member States prepare and negotiate with the Commission their so-called

'Partnership Agreements'. These are the strategic plans covering the five European Structural and Investment Funds.

NEXT STEPS

Following the conclusion of the Partnership Agreements, Operational Programmes are adopted that break down the investment priorities and objectives of the Agreements into concrete actions.

IMPLICATIONS FOR SMEs:

The Funds are managed by national <u>Managing</u> Authorities. These can provide information on who may apply in each EU region and for which aspects.

EU4HEALTH PROGRAMME



INCREASED SUPPORT FOR HEALTHCARE POST-COVID-19

EU4Health is EU's response to COVID-19, which has had a major impact on Europe's medical and healthcare staff, patients and health systems. By investing €5.1 billion -the largest health programme ever in monetary terms - EU4Health will provide funding to EU countries, health organisations and health NGOs.

WHAT'S HAPPENING?

EU4Health will support the creation of medical supplies reserves for crises preparedness, as well as a reserve of healthcare staff and experts that can be mobilised in response to crises throughout the EU. It also aims to

strengthen health systems, including by supporting their digital transformation and promoting medical and pharmaceutical innovation and greener manufacturing.

NEXT STEPS

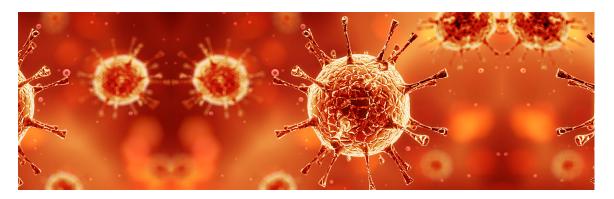
Applications for funding will be open in 2021.

IMPLICATIONS FOR SMEs:

EU4Health may create additional procurement opportunities at national level as stockpiles are being created and healthcare systems receive funds to take up digital tools and services, including Artificial Intelligence.



3. EU SUPPORT FOR THE FIGHT AGAINST COVID-19



In response to the COVID-19 crisis, the European Union has mobilised existing instruments to support Member States and other actors. Activities include legislative and policy initiatives, technical support along with funding and financing opportunities.

A general overview of the EU's Coronavirus response activities, continuously updated, is available here. The European Centre for Disease Control (ECDC) has also developed a dedicated web page, where they publish information on the outbreak and issue regular epidemiological updates and risk assessments.

In addition, in order to keep our members - and the public - informed, COCIR has also created its own COVID-19 Information Centre. Here, you can find the latest news and information from COCIR on developments in tackling this pandemic, including:

- Latest developments;
- Steps taken by COCIR and its members;
- COCIR statements on COVID-19.

There are a number of direct and indirect opportunities for SMEs to support their activities in the fight against COVID-19 via several EU funding instruments. These include:

- Horizon 2020
- Joint Procurement of medical countermeasures
- Emergency Support Instrument
- EU Civil Protection Mechanism/rescEU
- Matchmaking Platform
- Coronavirus Response Investment Initiative

All funding opportunities and tenders provided directly by the EU can be accessed here. In addition, there are several instruments making financing available to Member States to support them in responding to the crisis and reinforcing their healthcare systems. You can access an overview of open COVID-19-related tenders for medical equipment at country-level here.

The European Research Area corona platform is a one-stop shop that provides comprehensive information on funding opportunities for Coronavirus-related Research and Innovation at EU and national level. It offers continuously updated information about extensions to Horizon 2020 call deadlines, both specific and related to Coronavirus-funded and ongoing projects along with FAQs and other useful links. In cooperation with country correspondents, the platform maintains a dedicated section on national activities, funding opportunities, initiatives and projects within the Member States and other European countries.

Funding to provide support and relief for some 100,000 businesses hit by the economic consequences of the Coronavirus will be available as of April 2020, as the European Commission and the European Investment Fund unlock €8 billion from the European Fund for Strategic Investments. Business can directly apply for support at local banks and/or lenders participating in the scheme, a list of which is available on www.access2finance.eu.



4. LATEST EU POLICY DEVELOPMENTS

EU FINDS COMMON GROUND FOR SHARING VACCINATION INFORMATION

FIRST EUROPEAN GUIDELINES FOR PROOF OF VACCINATION

As we enter into a new phase of the pandemic response, attention and resources are being shifted to vaccination. Information exchange on vaccination is important for clinical purposes and is likely to become increasingly important in opening up our societies again. Therefore EU coordination – and effective methods for this cooperation - is essential.

WHAT'S HAPPENING?

The eHealth Network has agreed guidelines on the proof of vaccination for medical purposes. These guidelines establish a minimum required dataset, including a unique identifier for vaccination certificates. The dataset will consist of identification of the individual, information on their vaccination status and certificate metadata.

NEXT STEPS:

Further details of the trust framework needed for establishing the authenticity and validity of vaccination certificates presented by certificate holders will be set out in the coming weeks, and will take into consideration data protection issues and security measures. There will also be further work undertaken in the area of vaccination registration and interoperability in general. In the longer term the proof of vaccination could be integrated into the patient summary.

IMPLICATIONS FOR SMEs:

Current guidelines set out the basic interoperability elements for proof of vaccination. This will be important for those SMEs that integrate or exchange information with EHR software.

HANDLING DATA PROTECTION AND CYBERSECURITY IN HEALTHCARE

FOSTERING TRUST THROUGH DATA PROTECTION AND CYBERSECURITY

Trust is hard to win but can be quickly – and easily lost. With health data understandably considered to be some of the most sensitive personal data, it is of utmost importance to take appropriate measures when it comes to data protection and cybersecurity.

WHAT'S HAPPENING?

The European Data Protection Board (EDPB) has issued <u>Guidelines 01/2021</u> providing practical examples of what to do in the event of a data breach. An example of a ransomware attack in a hospital setting is included.

The EU Agency for Cybersecurity (ENISA) has issued a report with an overview of <u>pseudonymisation techniques</u> and use cases for healthcare. In addition, ENISA has published a <u>report</u> providing a set of guidelines for ensuring security and protection when procuring cloud

services for healthcare. It includes three specific use cases: electronic health records, remote care and medical devices. The report also offers an overview of cloud security measures and good practices.

NEXT STEPS:

The EDPB has launched a public <u>consultation</u> on the data breach notification examples. Stakeholders can provide input until 2 March 2021.

IMPLICATIONS FOR SMEs:

SMEs should be aware of the latest technological and policy developments to ensure they have adequate data protection and cybersecurity measures in place. So doing will ensure legal compliance and reduce their business risks and maintain the trust of their customers and stakeholders.

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5. NEWEST COCIR ACTIVITIES ON DIGITAL HEALTH

SHAPING THE FUTURE FOR HEALTH DATA USE

BUILDING THE FRAMEWORK - DATA GOVERNANCE ACT AND EUROPEAN HEALTH DATA SPACE

The <u>European Data Strategy</u>, announced in February 2020, set out the concept of common European data spaces. This foresees establishing a European data space for various sectors with the aim of making data more easily available and accessible in order to support Europe's digital economy. Identified as a key priority, work on a <u>European Health Data Space</u> is expected to kick off in 2021.

The European Commission has launched a <u>proposal</u> for a Data Governance Act that would establish common data governance rules for all data spaces. COCIR has provided feedback to the proposal.

In addition, the Commission has published its <u>initial views</u> for a European Health Data Space. COCIR

has provided <u>preliminary input</u> and will work with the Commission, Member States and other stakeholders to create an enabling framework that would make health data available for research and innovation purposes. This would allow the development of health solutions that would greatly benefit patients and the health system.

IMPLICATIONS FOR SMEs

The Data Governance Act aims to open up access to more-sensitive public sector data and increase trust in data-sharing service providers. The European Health Data Space legislative framework will, in turn, create a more integrated approach to sharing health data, making it more accessible and available for companies to power their research, innovation or Al developments.

BUILDING TRUST IN mHEALTH SOLUTIONS

CURRENT STATE OF PLAY AND CHALLENGES FOR AN mHEALTH CODE OF CONDUCT

European Commission organized recently a webinar on mHealth and asked COCIR to present the current state of play on an mHealth Code of Conduct for data protection.

COCIR highlighted the various challenges the drafting team is experiencing. These arise from the complexity of the mHealth ecosystem and the ongoing lack of clarity on the Commission's intent to address the fragmented GDPR implementation across Member States, particularly on the secondary use of data.

COCIR remains committed to improve the credibility of mHealth solutions. It will continue to engage with all relevant stakeholders to help develop tangible tools and approaches to compliance and communication.

IMPLICATIONS FOR SMEs

There are already numerous existing health and well-being apps. A Code of Conduct for data protection might create transparency for users and authorities. From a sectoral point of view, it would help to achieve consensus on practical questions on GDPR compliance.



'HOW CAN DIGITAL HEALTH DRIVE COHESION IN EUROPE?' - FINAL EVENT REPORT

The <u>event</u>, hosted by COCIR in partnership with Siemens Healthineers in October 2020, brought together a number of key representatives from EU Institutions and Member States, from regions and cities, from patient organisations, from the healthcare professions, innovators as well as industry. Discussions focused on funding in healthcare, with an emphasis on digital health and integrated care, as well as training and education for

healthcare professionals.

COCIR has now published the full report of the event. This includes the key takeaways from the meeting and COCIR's policy recommendations for how to unlock additional EU Cohesion and Structural Funds for the digitalisation of healthcare systems.

Download the full event report here.



6. UPDATES ON COCIR INVOLVEMENT IN EUROPEAN PROJECTS



X-eHEALTH

COCIR is a collaborative partner in the X-eHealth project, which aims to enhance the European exchange format for electronic health records in new domains. COCIR is bringing its expertise to this area, and is currently reviewing the technical specifications for medical imaging, lab results and hospital discharge reports.

IMPLICATIONS FOR SMEs

The X-eHealth project will define the future European exchange formats for imaging, laboratory and hospital discharge reports. These will not only be used for cross-border exchange but will also become integrated and routine at a more local level over time.



UNICOM

<u>UNICOM</u> is an EU-funded project aimed at improving the uptake of ISO IDMP standards that allow for the unequivocal identification of medicinal products. As a project partner, COCIR will organise a validation workshop specific for EHR vendors that will better frame the challenges and opportunities of ISO IDMP uptake.

IMPLICATIONS FOR SMEs

Companies will have the opportunity to exchange views on the added value of ISO IDMP implementation during a validation workshop that will take place in March. This will also allow them to indicate the barriers they face and the incentives needed to increase deployment of ISO IDMP standards in EHR packages.

7. FUTURE COCIR EVENTS

COCIR/DITTA VIRTUAL EVENT

"WORKING TOGETHER AGAINST CERVICAL CANCER"

THURSDAY 18 MARCH 2021, (14H00 to 16H30 CET) - REGISTER HERE

Although there are several current events on cervical cancer being organised, this COCIR - DITTA event will be different, important and timely. The problem - as we see it - is that the general, global focus is being placed almost exclusively on HPV vaccines. Yet this means that

the importance of diagnosis and treatment is frequently neglected. This is why we want to discuss how we can advance the fight against cervical cancer on this front also and how COCIR members' solutions can play a role.





COCIR WEBINAR

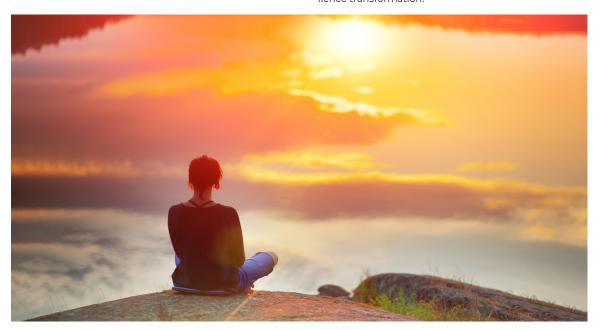
RECOVERY FROM COVID-19 - DRIVING HEALTHCARE RESILIENCE IN THE EU

WEDNESDAY **24 MARCH 2021** (14:00 to 15:30 CET) - **REGISTER** <u>HERE!</u>

The European Union has responded to the challenge posed by the pandemic with its historic 'Recovery and Resilience Package', which is set to make €672.5 billion in grants and loans available to EU Member States over the coming three years. National governments now have until 30 April to submit their national recovery and resilience plans to the European Commission for approval. The aim is to make European economies and societies

more sustainable, resilient, and better prepared for the challenges and opportunities of the green and digital transitions.

With this webinar, we want to discuss the significant role that healthcare will play in helping fulfil the EU's objectives and what investments in healthcare will be required necessary to drive the relevant digital and resilience transformation.



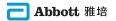
COCIR is the European Trade Association representing the medical imaging, radiotherapy, health ICT and electromedical industries.

Founded in 1959, COCIR is a non-profit association headquartered in Brussels (Belgium) with a China Desk based in Beijing since 2007. COCIR is unique as it brings together the healthcare, IT and telecommunications industries.

Our focus is to open markets for COCIR members in Europe and beyond. We provide a range of services in the areas of regulatory, technical, market intelligence, environmental, standardisation, international and legal affairs.

COCIR is also a founding member of DITTA, the Global Diagnostic Imaging, Healthcare IT and Radiation Therapy Trade Association (www.globalditta.org).

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