



eHealth Network Guidelines

to

the EU Member States and the European Commission

on

an interoperable eco-system for digital health and
investment programmes for a new/updated generation of
digital infrastructure in Europe

eHealth Network

The eHealth Network is a voluntary network, set up under article 14 of Directive 2011/24/EU. It provides a platform of Member States' competent authorities dealing with eHealth. The Joint Action supporting the eHealth Network (eHAction) provides scientific and technical support to the Network.

Adopted by consensus by the eHealth Network, Bucharest, Romania, 12 June 2019

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1. INTRODUCTION

Background

Several **Council Conclusions**¹ in the past have already highlighted the central importance of digitalisation in the healthcare sector and the **European Parliament**² has adopted similar documents in this field as well. The **UN**³ has identified good health and well-being as one of its 17 sustainable development goals, with the aim of ensuring healthy lives and promoting well-being for all at all ages. In the context of the Digital Single Market Strategy and the related Communication *on enabling the digital transformation of health and care*⁴, the **European Commission** has identified three priority pillars⁵, all of which aim to contribute to the further development of patient-centered digitalisation in the healthcare sector.

It is therefore clear that digitalisation of health and care, if designed to meet the needs of people and health systems and thoughtfully implemented, has the potential to significantly improve health and care outcomes.

Modern laboratory or diagnostic imaging is made possible by digitalisation. Internal processes as well as out-patient and in-patient healthcare providers are for the most part IT-based. While patient documentation or invoicing electronic support systems have long become indispensable, there are promising applications in the field of telemedicine or telemonitoring for instance. It has been proven that the sharing of digital health data leads to improved and faster availability of medical information. This in turn contributes to higher quality therapeutic decision-making and treatment as well as to an increase in the process and performance quality of health services.⁶ Politically and legally it is increasingly acknowledged that citizens have a right to access their own personal health data. This will be difficult to achieve without digital assistance.

The provision and use of digital health data are also of enormous significance for research and science. This is particularly true in the medical and nursing fields – where research on health data can bring about more targeted and personalised interventions and boost prevention – but also in terms of gaining a better understanding and potential improvement of the functioning and efficiency of complex health systems. Without the consideration and evaluation of health data, an increase in both process and performance quality as well as in organizational and economic efficiency is inconceivable.

¹ Council Conclusions of 1 December 2009 on safe and efficient healthcare through eHealth (OJ C 302, 12.12.2009, p.12); Council Conclusions of 8 December 2017 on health in the digital society – making progress in data-driven innovation in the field of health (OJ C 440, 21.12.2017, p.3)

² See, for example, the resolution of the European Parliament of 19 May 2015 on safer healthcare in Europe: improving patient safety and fighting antimicrobial resistance (P8 TA[2015]0197).

³ <https://www.un.org/sustainabledevelopment/sustainable-development-goals/>

⁴ Commission Communication on enabling the digital transformation of health and care in the Digital Single Market – Empowering citizens and building a healthier society: <https://eu-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52015DC0192&from=EN>

⁵ Pillar 1 Citizen's secure access to and sharing of health data; Pillar 2 Better data to promote research, prevention and personalised health and care; Pillar 3 Digital tools for citizens' empowerment and for person-centered care.

⁶ See § 13 Para.1 of the Austrian Federal Law on data protection measures in the processing of electronic health data and genetic data StF: BGBl. I No. 111/2021.

*Existing barriers***Insufficient use is being made of the potential for digital data exchange in the health sector.⁷**

It is becoming increasingly clear that exchange of data can contribute to raising quality of care. Yet large parts of the actually existing digital infrastructure in the healthcare system is not, or is only to a limited extent, suitable for data exchange outside of a specific organization. This affects in particular medical software used by doctors working in general practice, healthcare professionals in the outpatient sector and also many hospital information systems.

Need to remove barriers with financial incentives

Because health data is predominantly generated in out-patient care facilities and in hospitals, the overall goals of the health system is to **focus on the numerous individual “data generators” to bring them up to date with a new generation of or updated digital infrastructure to establish an interoperable eco-system for digital health in Europe.**

The most important prerequisite to enable a common interoperable eco-system for digital health for the EU Member States is to act within the same framework for interoperability, standardization and also security. The **Refined eHealth European Interoperability Framework⁸** which has been adopted by the eHealth network in 2015 foresees six interoperability layers (see figure 1). All six layers play an essential role in the European interoperable eco-system for digital health and should be all addressed to ensure full interoperability. These serve also as the basic structure to apply the necessary standards (see Annex 1) for health data exchange.

As there is a strong public interest in the exchange of health data, public funding also needs to actively support the interoperability of private and public healthcare facilities via the financing of digital infrastructure. **Achieving this interoperable eco-system for digital health in Europe will not be possible without the incentive provided by public funding.** This incentive should be provided by the EU Member States and the European Commission through different financing instruments to be made available to healthcare providers. The purpose of the financial means to be made available is to fund a new generation of/updated digital infrastructure among healthcare providers that ensure interoperability between them in a national and cross-border setting.

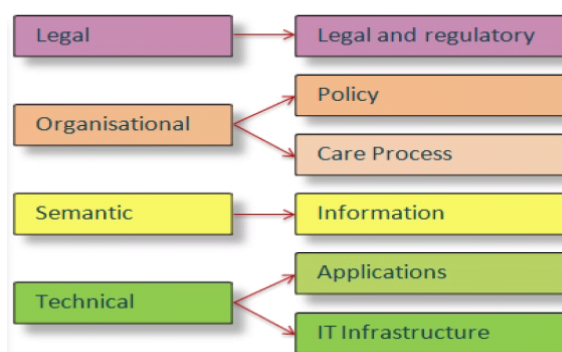


Figure 1: Refinement of the EIF model from four to 6 layers

⁷ See para. 22 of the Council Conclusions of 8 December 2017 (FN 2), where it is emphasized that “the removal of barriers for the stronger use of the potential of digital health and of the potential of digital healthcare and internet-supported care calls for a comprehensive package of measures, which build on the opportunities of the digital single market and the principle of free movement of data as well as the principles in accordance with the EU eGovernment Action Plan”.

⁸ https://ec.europa.eu/health/sites/health/files/ehealth/docs/ev_20151123_co03_en.pdf

Why remove barriers?

Health data that is generated by healthcare providers should be

1. exchanged with other healthcare providers nationally and cross-border, for the **continuity of care of patients**;
2. suitable for the **building of knowledge databases** by interacting with other data bases, registries, etc. to enable the potential of AI, big data, etc.

Purpose and scope of these guidelines

To build forth on the outcomes of previous political discussions (such as the informal meeting of health ministers in September 2018; etc.), the eHealth Network should use its role to foster common approaches, and to encourage the EU Member States and the European Commission to enhance their understanding regarding

- what constitutes an interoperable eco-system for digital health, especially when it comes to functional requirements and specifications, technical specifications, standards and profiles;
- the conditions under which public funding should be granted to support the creation and the future sustainability of a European interoperable eco-system for digital health;
- funding criteria and conditionalities that have to be fulfilled by the funding recipients, when obtaining public funding to update or establish their digital infrastructure for the management of patient information.

2. FINANCIAL SOURCES AND PROGRAMMES

Overview with status April 2019

While the below table provides a brief overview of the financial instruments and programmes proposed under the **EU's next multi-annual financial framework (MFF) 2021-2027**, Annex 2 provides a more in depth analysis with further explanations of those. It is to be noted that these amounts represent the overall draft allocation foreseen in COM proposal; the final amounts are still to be determined because the below listed programmes are still under negotiation. The allocation for digital health will be established more precisely during implementation and also depending on the member states' priorities (for shared management funds).

Name of main financial instrument or programme	Name of relevant sub instrument or programme	Types of investments/activities foreseen under the financial instrument or programme	Proposed amount in EURO
Shared management funds relevant for eHealth under the new MFF are managed by the Member States, through their managing authorities ⁹ → also linked with the European Semester Process through the Country-Specific Recommendations	European Regional Development Fund (ERDF)	Investments in infrastructure; investment in access to services; productive investments in SMEs; equipment, software and intangible assets; information, communication, studies, networking, cooperation, exchange of experience and activities involving clusters; technical assistance	<u>200.6 billion</u>
	European Social Fund Plus (ESF+)	Strand for the European Social Fund Plus	<u>100 billion</u>
		Strand for Health: analytical activities; policy implementation; capacity building; communication and dissemination activities	<u>413 million</u>
Direct/indirect management funds relevant for eHealth under the new MFF	The Digital Europe Programme (DEP)	High performance computing	<u>2.7 billion</u>
		Artificial Intelligence	2.5 billion
		Cybersecurity and trust	2.0 billion
		Advanced digital skills	700 million
		Deployment, best use of digital capacity and interoperability	1.3 billion
	Connecting Europe Facility (CEF)	Digital connectivity infrastructure	<u>3.0 billion</u>
	The Invest EU Programme (InvestEU)	Sustainable infrastructure	<u>11.50 billion</u>
		Small businesses	11.25 billion
		Research, innovation & digitisation	11.25 billion
		Social investment & skills	4.0 billion
	The Reform Support Programme	Financial and technical support to implement reforms	<u>25.0 billion</u>
	The Horizon Europe Programme (HE)	Open Science	<u>25.8 billion</u>
		Global Challenges and Industrial Competitiveness	52.7 billion
Open Innovation		13.5 billion	

⁹http://ec.europa.eu/regional_policy/en/atlas/managing-authorities/

3. eHEALTH NETWORK GUIDELINES

The eHealth Network,

TAKING INTO ACCOUNT

(1) Article 168 (1) of the Treaty on the Functioning of the European Union (TFEU), which provides that a high level of human health protection is to be ensured in the definition and implementation of all Union policies and activities;

(2) Directive 2011/24/EU of the European Parliament and of the Council of 9 March 2011 on the application of patients' rights in cross-border healthcare, in particular Article 14 (2) (a) thereof, which provides that the eHealth Network shall work towards delivering sustainable economic and social benefits of European eHealth systems and services and interoperable applications, with a view to achieving a high level of trust and security, enhancing continuity of care and ensuring access to safe and high-quality healthcare;

RECOMMENDS

(3) That, to meet the patients interests that during the continuity of care the right information is available at the right place and the right time, the purpose of an interoperable eco-system for digital health in Europe has to be based on functional requirements of health information domains¹⁰. This also enhances the quality of the processes and outcomes of healthcare. Functional specifications of IT-solutions could be derived from functional requirements. Strategic and political decisions building upon an interoperable eco-system for digital health in Europe may be based on such functional requirements in the healthcare sector.

(4) That the principles laid down in the Refined eHealth European Interoperability Framework¹¹ (legal and regulatory, policy, care process, information, applications, IT infrastructure) be considered a basis for a European interoperable eco-system for digital health where healthcare providers are able to share health data outside of their organization.

(5) That, as a starting point, to enhance interoperability, technical specifications, standards and profiles as laid out in Annex 1 should be considered for already agreed health information domains. For further and new health information domains, the interoperability should be based on sound analysis of functional requirements and should be agreed upon by the eHealth network in accordance with (8), so continuously amending Annex 1. Thereby, the Commission Recommendation (C(2019)800) of 6 February 2019 on a European Electronic Health Record exchange format is to be considered a reference for developing the health information domains.

(6) That public funding is made available by the EU Member States and the European Commission to be used for updating existing or establishing new digital health infrastructures used particularly by health professionals and healthcare providers but also to enable patient access to and management of their health data. It should be ensured that those public funds are thereby used to support the

¹⁰ Functional requirements of health information domains for the existing use cases (patient summaries and e-prescriptions) and for other, to be defined, use cases, such as medical images and reports, laboratory results and hospital discharge reports.

¹¹ https://ec.europa.eu/health/sites/health/files/ehealth/docs/ev_20151123_co03_en.pdf

establishment of a European interoperable eco-system for digital health, while taking into account the national interoperability strategies.

(7) That, in order to guarantee interoperability, applicants and recipients of all types of public and EU funding ensure to act in line with (3), (4), (5) and (6).

(8) That, in reference to (3) and (5) and, in order to commonly agree on how to advance interoperable eco-systems for digital health, a Joint Coordination Process between the EU Member States and the European Commission is to be established. Such process should take into account contributions from Member States and competent authorities responsible for digital health, the European Commission, stakeholders (including patient organizations, professional and scientific organizations) and international Standards Developing Organisations), at both EU and national level. The details of the Joint Coordination process should be designed by the Member States and the Commission and adopted by the eHealth Network.

(9) That all public procurers, national competent authorities in the EU Member States and the European Commission make reference to the Refined eHealth European Interoperability Framework and the technical specifications, standards and profiles as laid out in Annex 1, as points of orientation for public procurements and when formulating their tender documents or calls for proposals, as well as when defining the conditions for EU funds, including enabling conditions for structural and cohesion funds (article 11 of the draft Regulation 2018/0196 (COD))¹². This does not exclude the compliance to already existing national regulations.

(10) That these guidelines and their corresponding technical specifications, standards and profiles as listed under Annex 1 are included in the European Catalogue for ICT procurement¹³.

(11) That Member States develop a national approach to support the implementation of these guidelines, while respecting meaningful margin of discretion.

(12) That the Council is invited to express its support to these guidelines.

4. TIMEFRAME

Meeting:	Action at meeting:	Follow-up expected:
eHAction Steering Council meeting – 17.04.2019	Discussion & feedback by EU Member States on the Guidelines	Potential revision or update of Guidelines
15 th eHealth Network meeting – 11./12.06.2019	eHN discussion & adoption of the Guidelines	Depending on eHN discussion, potential final revision of the Guidelines
16 th eHealth Network meeting - November 2019	eHN adoption of the Joint Coordination Process	
Formal Council meeting – December 2019	Have the Guidelines on the agenda for discussion	Possibly Council Conclusions or any other kind of formal document

¹² Regulation of the European Parliament and of the Council laying down common provisions on the European Regional Development Fund, the European Social Fund Plus, the Cohesion Fund, and the European Maritime and Fisheries Fund and financial rules for those and for the Asylum and Migration Fund, the Internal Security Fund and the Border Management and Visa Instrument.

¹³ <https://joinup.ec.europa.eu/collection/ict-standards-procurement/about>

ANNEX

ANNEX 1 – LIST OF TECHNICAL SPECIFICATIONS, STANDARDS AND PROTOCOLS TO BE USED FOR ALREADY EXISTING USE CASES (state: 2019)

ANNEX 1.1 – BASED ON THE EUROPEAN ELECTRONIC HEALTH RECORD EXCHANGE FORMAT (EHRxF)

Specifications of the European EHR Exchange Format

The European EHR Exchange Format comprises specifications for:

1. Health information domains to be exchanged;
2. Interoperability specifications;
3. Cross border exchange profiles

Health information domains

The set of healthcare information categories and associated data reference models should be as follows: Tables A and B contain a set of recommended interoperability specifications for content structuring and representation¹⁴.

2.2.1 Table A: Content structuring and representation for health information domains for which the eHealth Network have adopted guidelines

Health information domains	Clinical information for cross-border exchange	Content representation for cross-border exchange
Patient Summary	Structured according to the provisions in the “GUIDELINE on the electronic exchange of health data under Cross-Border Directive 2011/24/EU Release 2 – Patient Summary for unscheduled care” adopted by the eHealth Network on 21 November 2016 ⁵	Health Level Seven (HL7) Clinical Document Architecture (CDA) Release 2 ⁶ <i>Level 3 and Level 1 (PDF⁷/A)</i>
ePrescription/eDispensation	Structured according to the provisions in the “GUIDELINE on the electronic exchange of health data under Cross-Border Directive 2011/24/EU Release 2 – ePrescriptions and eDispensations” adopted by the eHealth Network on 21 November 2016 ⁸	Health Level Seven (HL7) Clinical Document Architecture (CDA) Release 2 <i>Level 3 and Level 1 (PDF⁷/A)</i>

¹⁴ <https://ec.europa.eu/digital-single-market/en/news/recommendation-european-electronic-health-record-exchange-format>

2.2.2 Table B: Content structuring and representation for other health information domains

Health information domain	Clinical information for cross-border exchange	Content representation for cross-border exchange
Laboratory results	<p><i>Enable cross-border exchange according to the clinical information structure currently used by the sender electronic health record system, while common clinical information structures for cross-border exchange are developed and agreed.</i></p>	<p><i>For laboratory results, medical imaging reports and hospital discharge reports</i></p>
Medical imaging and reports		<p>Health Level Seven (HL7) Clinical Document Architecture (CDA) Release 2</p> <p>Level 3 or Level 1 (PDF⁷/A)</p>
Hospital discharge reports		<p><i>For medical imaging</i></p> <p>Digital Imaging and Communications in Medicine (DICOM)</p>

Exchange protocols

In order to be able to fulfil requests for the exchange of healthcare information categories across borders, the following specifications should be considered (based on the Commission Decision (EU) 2015/1302 of 28 July 2015 on the identification of ‘Integrating the Healthcare Enterprise’ profiles for referencing in public procurement)¹²:

No	Purpose	Specifications
1	To use patient identifiers for locating communities which hold patient relevant health data.	IHE XCPD - Cross-Community Patient Discovery ¹³
2	To retrieve patient relevant health data held by other communities.	IHE XCA - Cross-Community Access ¹⁴
3	For document interchange using a reliable messaging system and permit direct document interchange between EHRs, PHRs, and other healthcare IT systems in the absence of a document sharing infrastructure such as XDS Registry and Repositories.	IHE XDR - Cross-enterprise Document Reliable Interchange ¹⁵
4	To facilitate the registration, distribution and access, across health enterprises of patient electronic health records.	IHE XDS - Cross-Enterprise Document Sharing ¹⁶

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5	For the establishment of relevant security measures and together with the Security Policy and Procedures, provide patient information confidentiality, data integrity and user accountability.	IHE ATNA - Audit Trail and Node Authentication ¹⁷
6	To support authentication in cross-enterprise transactions.	IHE XUA - Cross-Enterprise User Assertion ¹⁸
7	For the sharing of laboratory reports among a community of healthcare settings and care providers.	IHE XD-LAB - Sharing Laboratory Reports ¹⁹
8	To provide a mechanism to record the patient privacy consent(s) and a method for Content Consumers to use for enforcing the privacy consent appropriate to the use. This profile complements XDS by describing a mechanism whereby an XDS Affinity Domain can develop and implement multiple privacy policies, and describes how that mechanism can be integrated with the access control mechanisms supported by the XDS Actors (e.g. EHR systems).	IHE BPPC - Basic Patient Privacy Consents ²⁰
9	To query and retrieve patient relevant medical imaging data held by other communities. The XCA-I Profile extends the XCA Profile by providing access to the images referenced in the imaging manifests.	IHE XCA-I - Cross-Community Access for Imaging ²¹
10	For publishing, finding and retrieving imaging documents across a group of affiliated enterprises. This profile extends XDS in order to share images, diagnostic reports and related information across a group of care sites.	IHE XDS-I.b -Cross-enterprise Document Sharing for Imaging ²²

No	Technical Frameworks
1	IHE Technical frameworks ²³

ANNEX 2 – FINANCIAL SOURCES AND PROGRAMMES

Financial instruments and programmes foreseen under the EU's next multi-annual financial framework, 2021-2027 (subject to decisions by co-legislators)

The proposals for the EU's next multi-annual financial framework (MFF)¹⁵ for the period 2021-2027 include a number of funding instruments which could support targeted investment in the area of eHealth. The EU is currently in the process of negotiating the terms of these instruments¹⁶.

Given that the coming months will be decisive – both from the perspective of the EU as well as for Member States – in determining many of the details of these instruments, this document concentrates on identifying those most likely to be of relevance for eHealth, as well as on advising what strategic preparations Member States can make ahead of the next budgetary period.

Close attention should be paid to the details finally agreed for each instrument, once the political negotiations have concluded.

Financial instruments proposed under the next MFF may be divided into two main categories:

- **Shared management funds:** instruments whose management is shared between the EU and the Member States. In practice, Member States assume a large part of the responsibility for managing and distributing these funds via national implementing programmes, which are agreed and supervised by the Commission. The bulk of EU funds fall under this category.
- **Direct/indirect management funds:** instruments which are managed centrally and directly/indirectly by the European Commission, e.g. for research.

1.1. SHARED MANAGEMENT FUNDS relevant for eHealth under the new MFF

i. Proposed ERDF and ESF+

The shared management funding instruments most likely to be of relevance for the area of eHealth are the European Regional Development Fund (ERDF) and parts of the European Social Fund Plus (ESF+)¹⁷. Both of these fall under the umbrella of the EU's 'Regional Development and Cohesion Policy' funds. More details can be found underneath:

¹⁵ The multiannual financial framework (MFF) is the EU's long-term budget. It sets the limits for EU spending - as a whole and also for different areas of activity - over a period of at least five years. Recent MFFs usually covered seven years.

¹⁶ At the time of drafting, i.e. March-June 2019.

¹⁷ The Regional Development and Cohesion Policy funds encompass seven funding instruments in total: ERDF, ESF+, the Cohesion Fund, the European Maritime and Fisheries Fund, the Asylum and Migration Fund, the Border Management and Visa Instrument and the Internal Security Fund.

The concrete investment areas (including e-health) are subject to negotiations between Member States and the Commission and should be included in the roadmaps (first drafts likely in June this year), partnership agreement and operational programmes (negotiations on these are set to begin around June). Managing Authorities http://ec.europa.eu/regional_policy/en/atlas/managing-authorities/ and other relevant governmental bodies should be contacted in order to ensure that e-health is included among the priorities for investment.

While the ERDF and the ESF+ have their own specific objectives, both are required to support the following high-level policy objectives (PO):

- **PO 1: a smarter Europe**
- **PO 2: a greener Europe**
- **PO 3: a more connected Europe**
- **PO 4: a more social Europe (all ESF+ specific objectives fall under PO4)**
- **PO 5: a Europe closer to citizens**

Potential funds for eHealth can be envisaged under **PO1, PO3 and PO4**.

- **The proposed European Regional Development Fund (ERDF)**

A budget of **€200 629 billion** is foreseen for the **ERDF programme** for the period 2021-2027.

Specific ERDF objectives

A number of its specific objectives¹⁸ have particular relevance for the area of eHealth:

(Under **PO1 – ‘a smarter Europe’**)

- **enhancing research and innovation capacities and the uptake of advanced technologies;**
- **reaping the benefits of digitisation for citizens, companies and governments;**
- **enhancing growth and competitiveness of SMEs;**
- **developing skills for smart specialisation, industrial transition and entrepreneurship;**

(Under **PO3 – ‘a more connected Europe’**)

- **enhancing digital connectivity;**

(Under **PO4 – ‘a more social Europe’**)

- **ensuring equal access to health care through developing infrastructure, including primary care.**

¹⁸ https://eur-lex.europa.eu/resource.html?uri=cellar:8d2f7140-6375-11e8-ab9c-01aa75ed71a1.0001.02/DOC_1&format=PDF

Types of investments possible under ERDF

The types of investment that ERDF will support include: (a) investments in infrastructure (i.e. *electronic health records, telemedicine etc.*); (b) investments in access to services; (c) productive investments in SMEs; (d) equipment, software and intangible assets; (e) transformational changes in health system; (f) information, communication, studies, networking, cooperation, exchange of experience and activities involving clusters¹⁹; and (g) technical assistance.

The ERDF may also be used to support development of skills for smart specialisation, industrial transition and entrepreneurship.

- **The proposed European Social Fund Plus (ESF+)**

A budget of **€101 billion** is foreseen for the **ESF+ programme** for the period 2021-2027. The ESF+ will be the EU's main financial instrument to strengthen Europe's social dimension. Its specific objectives are based on the principles set out in the European Pillar of Social Rights.

ESF+ strands and funding distribution methods

The ESF+ will have three strands:

- (i) the European Social Fund Plus strand (**€100 billion**)
- (ii) the Employment and Social Innovation strand (**€761 million**) and;
- (iii) the Health strand (**€413 million**. *The Health strand will replace the current EU Health Programme*)

Strand (i) will be distributed via **shared management** while strands (ii) and (iii) will be distributed via **direct/indirect management**.

Opportunities to fund eHealth investment are most likely to occur across strands (i) and (iii).

Specific ESF+ objectives

A number of specific objectives of ESF+ have particular relevance for the area of eHealth (provided that the relevant investments foster the affordability and accessibility of healthcare for vulnerable groups and do not support general healthcare reforms or are used to substitute national investments):

- improve the quality and effectiveness of education and training systems, to support acquisition of key competences including digital skills;
- improve accessibility, effectiveness and resilience of healthcare systems and long-term care services;
- (*under the Health strand*) support health promotion and disease prevention, contribute to effectiveness, accessibility and resilience of health systems, make healthcare safer, reduce health inequalities, protect citizens from cross-border health threats, and support EU health legislation

¹⁹ In the scope of Interreg programmes

The Health Strand

The Health strand has a number of operational objectives²⁰ of particular relevance for the area of eHealth:

- Support the digital transformation of health and care;
- Support the development of a sustainable Union health information system; *and*
- Support the implementation of Union legislation in the area of cross-border healthcare.

Types of activities possible under the Health strand

The types of activities that the Health strand will finance include (i) analytical activities; (ii) policy implementation; (iii) capacity building (*including via support for the deployment, operation and maintenance of an IT infrastructure for data exchange*) and (iv) communication and dissemination activities.

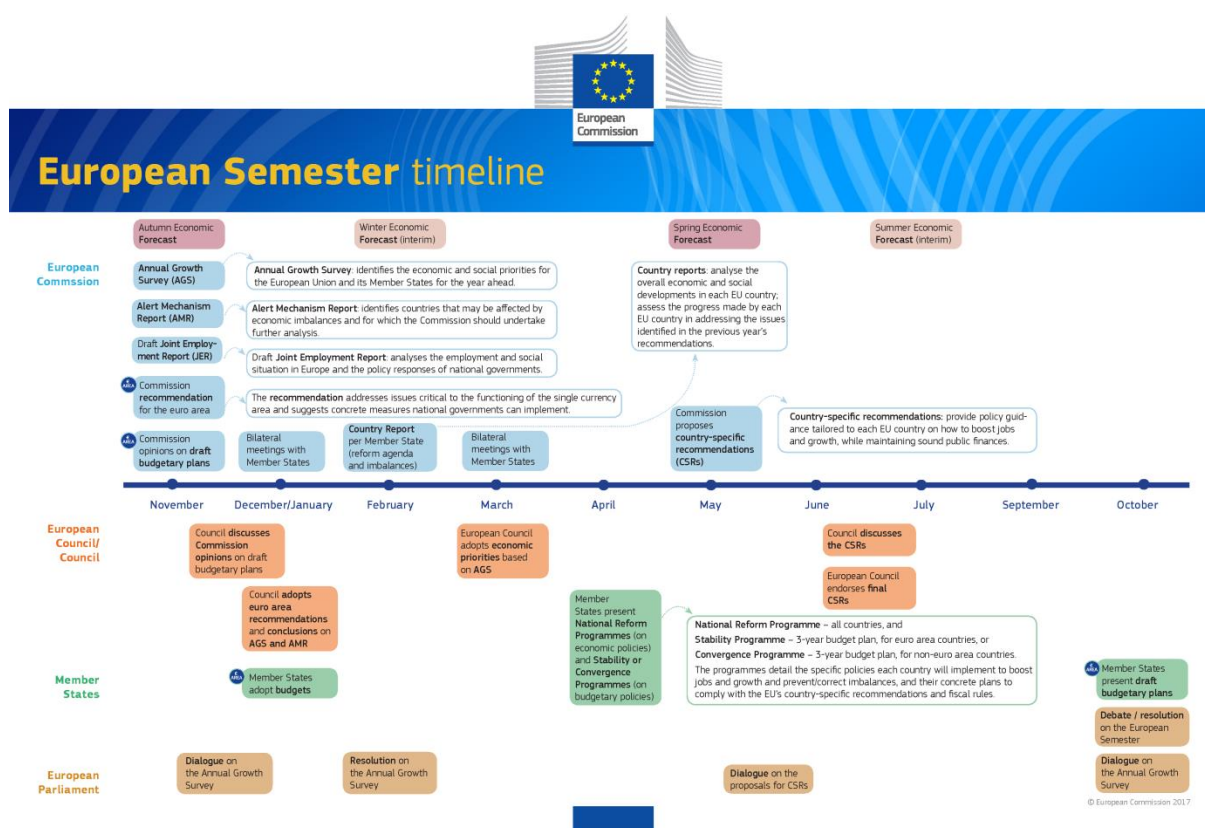
<p style="text-align: center;"><u>Link to the European Semester process</u></p>

The distribution of Regional Development and Cohesion Policy funds under shared management (including ERDF and the European Social Fund Plus strand of the ESF+) is set to be even more closely linked to the European Semester Process in the period 2021-2027, but in a simplified manner: each Member State's '**Country-Specific Recommendations**' (CSRs) related to investments will be taken into account twice over the budgetary period, both at the beginning (when agreeing the design of the funds' implementing programmes at national level), and during the mid-term review (at the end of 2024). In addition, to help remove barriers to investments, a number of general and specific '**enabling conditions**'²¹ (i.e. prerequisite conditions) must be met in order for funding to be granted.

The following table provides an indicative annual timeline of key steps in the European Semester process:

²⁰ The operational objectives must serve to implement the overall specific objectives.

²¹ Enabling conditions (both horizontal and thematic) for the specific objectives of the Cohesion Policy instruments are laid down in Annexes III and IV of COM(2018) 375 final



European Semester Process 2019

Following the publication in November last year of the Annual Growth Survey²² and the recommendation on the economic policy of the euro area²³, which set out the priorities at European level, in February 2019 28 **Country Reports**²⁴ were published by the Commission. These outline the Commission's annual assessment of the economic and social situation in each Member State and identify key imbalances to be addressed.

The publication of the Country Reports will be followed by a series of bilateral meetings between Member States and the Commission (circa March-April 2019) and the presentation by Member States of their **National Reform Programmes** to the Commission (April 2019). These programmes detail the specific policies and plans they will implement to correct the imbalances identified by the Commission in the Country Reports.

Based on the above steps, the Commission will publish **Country Specific Recommendations (CSRs)** related to investments for each Member State (June 2019). These CSRs will be one of the key criteria taken into account by the Commission when agreeing the design and distribution of the shared management funds with Member States for the period 2021-2027, both at the beginning of the period and during the mid-term review.

Member States must then draw up strategic plans with their investment priorities. These are sketched firstly in roadmaps, and then mapped fully in Partnership Agreements (PAs). Details of the

²² https://ec.europa.eu/info/publications/2019-european-semester-annual-growth-survey_en

²³ https://ec.europa.eu/info/publications/2019-european-semester-recommendation-euro-area_en

²⁴ https://ec.europa.eu/info/publications/2019-european-semester-country-reports_en

objectives Member States intend to achieve with the available resources are then set out in national and/or regional Operational Programmes (OPs).

Member States are expected to produce a first draft of their roadmaps by June this year. Negotiations on PAs and OPs between the Commission and Member States will begin immediately after the publication of the CSRs, i.e. also in June. It is likely that these documents will be approved in the course of 2020, before the beginning of the next budgetary period in 2021.

The negotiations for the Partnership Agreements and Operational Programmes (OPs) between the Commission and Member States will begin immediately after the publication of CSRs.

eHealth in Annex D of the 2019 Country Reports

(Published February 2019)

Annex D of the 2019 Country Reports sets out a Commission analysis of key investments needs in each Member State, which could be addressed by Cohesion Policy Funds during the period **2021-2027**.

eHealth has been mentioned (either directly or indirectly) as an investment priority for 17 Member States²⁵. **It will be up to these countries to make strategic use of this reference in their internal prioritisation of investment needs and subsequent negotiations of their Partnership Agreements and Operational Programmes with the Commission and EU Institutions, to ensure that eHealth receives financial support from Cohesion Policy Funds.**

Countries for which eHealth was not specifically listed as an investment priority in Annex D²⁶ may also internally prioritise eHealth, in the same spirit as above, in view of the negotiation of their Partnership Agreements and Operational Programmes with the Commission.

Accessing the funds

Where to apply: Shared management funds are managed by the Member States, through their **managing authorities**²⁷. Applications for funding should therefore be made via the relevant managing authority, which will be responsible for deciding whether funding is granted.

Eligibility: Those eligible to receive funding include, but are not limited to, **public bodies**, some private sector organisations (in particular small businesses), universities, associations, NGOs and voluntary organisations. Funding is most commonly granted to projects, with financial instalments provided at different stages of the process.

First step: Include the activities in the **operational programmes**²⁸ of the relevant Member State and/or region (likely to be approved and published in the course of 2020). All funding applications must meet the selection criteria and investment priorities set out in these documents.

²⁵ CY, CZ, DE, EE, EL, ES, FI, HR, IT, LT, LV, MT, PL, PT, RO, SI and SK (mentioned under PO1 of the investment guidance, **A Smarter Europe**. For 6 of these Member States, EL, ES, HR, PL, RO, SK, it is also mentioned under PO4 of the investment guidance, **A More Social Europe**).

²⁶ AT, BE, BG, DK, FR, HU, IE, LU, NL, SE, UK

²⁷ http://ec.europa.eu/regional_policy/en/atlas/managing-authorities/

²⁸ https://ec.europa.eu/regional_policy/en/atlas/programmes/

Application deadlines (once the process has opened): Some managing authorities have open-ended application deadlines, while others accept applications at certain times only. The website of the relevant [managing authority](#) should be consulted for precise details.

1.2. DIRECT/INDIRECT MANAGEMENT FUNDS relevant for eHealth under the new MFF

ii. The proposed Digital Europe Programme (DEP)

The DEP will support the digital transformation of the European economy and society and help bring its benefits to European citizens and businesses. The Programme will reinforce Europe’s capacities in key digital technology areas through large-scale deployment. It will widen their diffusion and uptake in areas of public interest and the private sector.

While all of the above SOs are likely to be of relevance for the area of eHealth, **SO5** in particular is intended to ensure that **areas of public interest**, including health and care, can deploy and access state-of-the-art digital technologies, and that trans-European interoperable Digital Service Infrastructures can be deployed, operated and maintained.

The DEP will take over funding of the eHealth Digital Services Infrastructure from the current CEF programme.

iii. The proposed Connecting Europe Facility (CEF)

In addition to funding for transport and energy, the new proposed CEF programme foresees **€3 billion** to fund digital connectivity infrastructure from 2021-2027.

The proposed DEP has a total budget of €9.2 billion. This will be distributed across its five specific objectives (SO):

- SO1:** High performance computing (€2.7 billion)
- SO2:** Artificial Intelligence (AI) (€2.5 billion)
- SO3:** Cybersecurity and trust (€2 billion)
- SO4:** Advanced digital skills (€0.7 billion)
- SO5:** Deployment, best use of digital capacity and interoperability (€1.3 billion)

Three key objectives in this area will be prioritised:

- to set a high capacity broadband infrastructure enabling the digital transformation of society and economy;
- to support project essential for the Digital Single Market and providing Gigabit connectivity of socio socio-drivers, like hospitals, medical centres and research centres;
- to provide a high level of wireless connectivity to local communities.

iv. The proposed Invest EU Programme (InvestEU)

The InvestEU Programme will combine several funds to offer tailor-made investment support for a broad range of applicants from individuals to governments. It builds on the successful experience of the current European Fund for Strategic Investments (EFSI) and will be composed of four legs: (i) the

InvestEU Fund (providing for the EU guarantee); (ii) the InvestEU Advisory Hub (providing in particular project development-related technical assistance); (iii) the InvestEU Portal (providing an easily accessible data-base for promoting projects in search for financing); and (iii) blending operations

The proposed InvestEU foresees a guarantee fund of **€38 billion**, intended to reinforce four policy areas:

	Policyarea	Budget
1	Sustainable infrastructure	€ 11.50 billion
2	Small businesses	€ 11.25 billion
3	Research, innovation & digitisation	€ 11.25 billion
4	Social investment & skills	€ 4 billion

The InvestEU Fund constitutes an EU budget guarantee that will back the financial products (such as loans and equity financing) provided by the 'implementing partners' (such as the EIB group and others chosen by the Commission or proposed by the Member States, after passing successfully an assessment exercise).

Regarding **Research, development and innovation**, the fund will encourage investments in new effective healthcare products, including pharmaceuticals, medical devices and advanced therapy medicinal products.

On the deployment/implementation front, the fund will encourage investments in health and long-term care infrastructure (including clinics, hospitals, primary care, home services and community-based care); and innovative health solutions, including health services and new care models.

Regarding eHealth it offers opportunity to deploy a digital connectivity infrastructure through projects supporting deployment of very high capacity digital networks. Moreover digital technologies and services may advance through artificial intelligence (AI), cybersecurity and network protection infrastructures, internet of things, blockchain, advanced digital skills.

The InvestEU programme is expected to **mobilise more than EUR 650 billion of additional investment** across Europe. Its uniqueness lies in the large scope of its potential applicants, which may be an individual with an idea, a small enterprise or even a public authority.

Use of EFSI funds under current MFF for eHealth: Case of Ireland

In 2018, the European Investment Bank agreed to provide EUR 225 million to support the roll-out of Ireland’s eHealth programme. The new nationwide electronic health and information programme is intended to improve delivery of health services for the entire population of Ireland over the next decade²⁹.

v. The proposed Reform Support Programme

Building on experience of the current Structural Reform Support Programme (SRSP), the Reform Support Programme will offer a comprehensive set of tools to support faster **implementation of structural reforms** across EU Member States. It will contain three instruments:

Participation by Member States is **voluntary**.

The Reform Support Programme may be availed of to encourage and accompany healthcare reforms from design to completion. It is open to all Member States. The technical support instrument will provide access to best practices, and support their application to the Member State's unique socio-cultural context. It will provide technical support by encouraging convergence, and building bridges to other Union policies.

- I.** the reform delivery tool: offering financial support, based on identified European Semester challenges;
- II.** the technical support instrument; offering tailored technical support with a wider scope for intervention; and
- III.** the convergence facility: supporting adoption of the Euro

vi. The proposed Horizon Europe Programme (HE)

The HE programme is intended to strengthen research and innovation in the EU. With a budget of €100 billion foreseen for the period 2021-2027, it is the EU's most ambitious research and innovation funding programme yet.

The HE programme has a dedicated cluster for health funding (falling under Pillar II). The Health cluster will have six main areas of intervention, two of which are likely to be of particular relevance for eHealth:

The HE programme will be implemented through three pillars:

- I.** Open Science (€25.8 billion);
- II.** Global Challenges and Industrial Competitiveness (€52.7 billion); and
- III.** Open Innovation (€13.5 billion).

²⁹ <https://www.eib.org/en/infocentre/press/releases/all/2018/2018-249-eib-confirms-eur-225-million-backing-for-irish-ehealth-programme.htm>

- **New tools, technologies and digital solutions in health and care:** supporting aspects including *integrated solutions for health incl. mobile and tele-health; piloting and large-scale deployment of healthcare technologies and tools in real-life settings; safety, efficacy, quality and ethical and social impact; regulatory science.*
- **Health care systems:** supporting aspects including *public health systems /policy reform; new models for health and care and future workforce; use of health data respecting security, privacy and interoperability; health systems resilience – crises and disruptive innovation; patient empowerment, self-monitoring, user-centered integrated care.*