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Short term high quality studies to support activities under the Eastern Partnership

HiQSTEP PROJECT

HARMONISATION OF THE DIGITAL MARKETS IN THE EASTERN PARTNERSHIP

eHealth Study Report

December 2017

PREFACE

This report presents the findings of the study that investigated the state of play and a cooperation potential in eHealth in the EaP Partner Countries of Armenia, Azerbaijan, Belarus, Georgia, Moldova and Ukraine, as part of the EU initiative on the Harmonisation of the Digital Markets (HDM) in the Eastern Partnership. The study has been implemented in the framework of the project 'Short term high quality studies to support activities under the Eastern Partnership – HiQSTEP, EuropeAid/132574/C/SER/Multi', carried out by an international consortium under the leadership of Kantor Management Consultants.

The study was implemented between April and October 2017 by a team comprising ***Yuri MISNIKOV*** (Study Team Leader, Belarus), ***Nick GULDEMOND*** (Senior Expert, Erasmus School of Health Policy & Management, The Netherlands), : ***Vardan GEVORGYAN*** (National Expert, Armenia), ***Nariman HAJIYEV*** (National Expert, Azerbaijan), ***Mikhail DOROSHEVICH*** (National Expert, Belarus), ***Merab LABADZE*** (National Expert, Georgia), ***Ion COSULEANU*** (National Expert, Moldova), and ***Yuriy BUGAY*** (National Expert, Ukraine).

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The views presented in this report are those of the report authors only and do not represent the official position of the European Commission.

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LIST OF ACRONYMS AND ABBREVIATIONS

AAL:	Assisted Living Programme
AHA:	Active and Healthy Ageing
CEF:	Connecting Europe Facility
CIS:	Clinical Information Systems
DSM:	Digital Single Market
EaP:	Eastern Partnership
EC:	European Commission
eHDSI	eHealth Digital Service Infrastructure
eHN:	eHealth Network
EHR:	Electronic Health Records
eID:	Electronic Identification
EIP:	European Innovation Partnership
ENP:	European Neighbourhood Policy
epSOS:	European Patients Smart Open Services
EU:	European Union
GDPR:	General Data Protection Regulation
HDM:	Harmonisation of Digital Markets
HIV/AIDS:	Human Immunodeficiency Virus /Acquired Immune Deficiency Syndrome
ICT:	Information and Communication Technologies
IHCIN:	Integrated Health Clinical Information Networks
IHE:	Integrating the Healthcare Enterprise
IoT:	Internet of Things
MOH/MoH:	Ministry of Health
MS:	Member State
OOP	Once-Only Principle
PS:	Patient Summary
SUNCS:	Secondary Usage Non-Clinical Systems
USAID:	United States Agency for International Development
WHO:	World Health Organisation

EXECUTIVE SUMMARY

Study results at a glance: Main findings and recommendations.

***Three main findings**:*

1) *On the whole, all six Partner Countries can be described as being at the half-way point relative to the EU eHealth baseline, which is a good achievement in its own right.*
2) *Despite certain differences that exist between the Partner Countries, they have more common than different features and thus face similar eHealth challenges.*
3) *No cross-border interoperable eHealth services are available in the Partner Countries.*

Main recommendation 1: Four harmonisation roadmaps and pillars.

Regional and country-specific roadmaps are proposed for implementation along the following four harmonisation pillars:

- *eHealth regional networking.*
- *eHealth policy and governance.*
- *eHealth interoperability and standards.*
- *eHealth patient services and personal data protection standards.*

Main recommendation 2: Priority to common region-wide actions.

A common region-wide approach is prioritised as the most impactful and cost-effective way to start harmonisation of eHealth systems and services, especially in the area of interoperable ePrescriptions and Patient Records (Patient Summaries). It is recommended that the capabilities of the existing regional eHealth Network are substantially enhanced to become the main implementation vehicle for coordinated regional and country-specific activities

aiming at transforming the regulation of the eHealth sector in each Partner Country in line with the EU eHealth policy principles and via close collaboration with various European eHealth platforms and initiatives, such as eHealth Digital Service Infrastructure (eHDSI) and individual Member States. The regional eHealth Network's website should be created and operationalised as a common for all the Partner Countries entry point to start implementing the identified harmonisation actions under each pillar over the three-year period; for example, to provide access to an online meeting room available at the eHDSI website and connect to its eHealth communities engaged in developing and rolling out Patient Summaries and ePrescriptions as key use cases. Common regional guidelines and other policy documents need to be developed for translation into local contexts coupled with the organisation of relevant training and awareness-raising activities and supported by sharing good practices available in the EaP region.

Main recommendation 3: Meeting specific needs of individual Partner Countries.

It recommended that, in parallel with strengthening the EaP regional eHealth Network, supporting its Action Plan and implementing regional activities, the national eHealth communities will need to be organised in the form of eHealth Stakeholder Groups / Action Groups followed by the establishment in due course of the national eHealth Networks to start cooperation with the EU eHealth Network through the EaP regional eHealth Network. Assistance should be provided to individual Partner Countries upon demand to address their specific needs through targeted training, policy advice, study tours, twinning / experience exchange, piloting and other forms of support.

Objective and methodology.

The overall objective of the eHealth study has been to assess the readiness of the digital markets in Partner Countries for harmonisation with the EU's Digital Single Market in the field of eHealth, in line with the relevant EU norms, standards and practices.

More specifically, the study has:

- analysed the state of play of eHealth systems and markets in all six Partner Countries using as a baseline the EU legal framework, European best practices, ICT platforms in view of developing interoperable across borders national eHealth systems and services;
- identified challenges, obstacles, opportunities and benefits both for individual Partner Countries and the EaP region as a whole in order to accomplish the harmonised interoperable eHealth systems and services;
- proposed country-specific and regional roadmaps for harmonising the Partner Countries' eHealth systems and services with the EU's.

The eHealth study capitalises on the previous HDM study undertaken in 2014-2015 and applies a similar assessment methodology to investigate the state of eHealth in the Partner Countries. The approach dwells on building a set of benchmarks that reflect upon the key benefits of harmonisation with the EU. Such benchmarks describe and measure the state of play in eHealth in the Partner Countries and identify gaps relative to the existing EU baseline. Two types of the benchmarks were used in the study: (a) 13 aggregated ***benchmark indicators*** addressing the key aspects of the EU baseline and (b) 80 individual ***benchmark targets*** underpinning the baseline's specific features. The comparison of the gaps between the Partner Countries and the EU has helped identify both country-specific and common for the entire region areas for follow-up actions in the form of the eHealth harmonisation roadmaps.

The process of data collection was organised in the form of a questionnaire-based interviews with key actors in the eHealth sector in each Partner Country. The questionnaire included the benchmark indicator statements addressing the key strategic dimensions of the EU eHealth baseline that were further broken down into more detailed benchmark target questions asking to clarify particular aspects of the baseline. As many as 35 fully completed questionnaires were returned to the study team. In addition, several opinion-based questionnaires were also filled out (these were used as a source of additional information but were not included into processing and computation).

Main conclusions and recommendations.

The main conclusion of the study is that, on the whole, the ***Partner Countries are at the level of 50% relative to the EU eHealth baseline***, which is considered a good achievement. Despite certain differences – for example, the status of the association with the EU, as in the case of Georgia, Moldova and Ukraine – that exist between Partner Countries, ***they have more common than different features and face similar eHealth challenges***. The gaps are most evident in such benchmark areas as eHealth business models, Voluntary eHealth systems/services, Patient Consultation Systems/Services, Citizens' eHealth Literacy, ePrescription, Best Practice exchange, eHealth Cross-border Services, Patient Portal, Big Data and eHealth Business Models of Patient Service Suppliers – the gap here exceeds 60%.

Whereas no Partner Country has a clearly articulated and officially approved eHealth strategy aligned with the EU eHealth strategy, ***the topic of eHealth has become (rather recently) a policy priority although not always adequately enforced in practice and supported by strong and consistent political will***. It is typical that ***all the Partner Countries still rely on the legacy systems that generally lack innovation, interoperability, patient-centric services***, with the role of hardware still dominating over services and collaboration across government agencies. All the countries have a significant number of disparate medical registries and data bases, especially those specialised on certain diseases. Many of them were created long ago often using disparate software tools. Interoperability between them remains weak; when medical data are exchanged, it is often done on an ad-hoc basis (e.g. using inter-agency MoUs). Even though almost all the Partner Countries apply to a different degree the internationally recognised eHealth interoperability standards (such as the Open HL7 standard protocols of exchanging medical information)[1], no national full-fledged eHealth interoperability

[11] The HL7 refers to the highest level of the International Standards Organization's (ISO) communications model for Open Systems Interconnection (OSI). The application level addresses definition of the data to be exchanged, the timing of the interchange, and the communication of certain errors to the application. The HL7 protocol was developed to address this need for data sharing among medical applications. It is a computer communication "language" that allows clinical applications to communicate essential information about patients' demographics, medical history, financial information, diagnosis and procedures at different facilities. HL7 provides standards for exchange, management and integration of

frameworks have been developed or realised in practice. The ***EU's general interoperability standards are rarely used***. ***Cross-border services are absent***, also due to the lack of both legal (regulatory) clarity and operational (technical) capability to exchange medical data between countries (e.g. it is not clear how to electronically identify and authenticate foreign citizens); although, for instance, legally, cross-border interoperability is possible in Moldova. The ***issue of personal data protection is overall well addressed in legal terms*** but there is little experience of applying the existing laws in relation to patients' medical data, and especially for ensuring that patients have control over their personal medical data and privacy.[2]

This is also due to the ***absence of the well-functioning broader whole-of-government interoperability infrastructure and services from which the eHealth sector could and should benefit; likewise, the once-only interoperability principle[3] and privacy enhancing technologies are hardly used***. While the e-government interoperability infrastructure is gradually emerging (e.g. Armenia, Azerbaijan, Georgia, Moldova, Ukraine), it is not clear whether the eHealth sector will be part of it. At the moment, building the sector-specific eHealth infrastructure and related corporate networks remains a preferred choice in most of the Partner Countries. Almost all existing electronic medical registries and records require significant revision and upgrade to meet the new requirements of the Internet age (e.g. developing APIs[4] for building new services and applications). With the World Bank assistance (e.g. in Azerbaijan, Ukraine, Belarus, Moldova) such upgrades are likely to be implemented in the near future; however, whether or not it will be done according to the EU interoperability principles remains an open question and should be looked at carefully.

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data that supports clinical processes and patient care, along with management, delivery, and evaluation of healthcare services (http://ehealth.eletsonline.com/2007/10/11037/).

[2] In relation to the "old" GDPR (before 25 May 2018 when its new revised edition was effected).

[3] The Once-Only Principle is part of the Benchmark 4 on Interoperability; it is used to ensure that patients/health organisations do not supply the same information more than once (see more on pages 39-40 and further).

[4] Application Programming Interface (AP) is a software programme that defines methods, protocols, tools of communication between various software components that programmers use to develop new software applications and products. (https://en.wikipedia.org/wiki/Application_programming_interface).

The ***lack of eHealth interoperability prevents the development of patient-oriented records and services in line with EU practices and guidelines*** that emphasise the personalised and value-based care. For example, whereas ***ePrescriptions are planned in all six countries, in real life this service is available in just a few of them*** (Belarus and Georgia, with other countries planning to do so in future) where these are still in a test phase and have limited coverage. Yet, it is obvious that sooner than later ePrescriptions will become available in all the Partner Countries. However, ***cross-border ePrescriptions are not a priority as yet***. Overall, the lack of interoperability at a system and service level leads to the fragmentation of the national eHealth sectors.

While the eHealth markets exist, the ***role of the private sector as a key stakeholder is limited*** despite it being a springboard for many technology-driven innovations including ePrescriptions (e.g., it was originally the private sectors' idea in Belarus where this services is already available). The ***role of professional associations and civil society is small as well, except in Ukraine*** which is special in having the non-governmental sector (Transparency International) successfully driving the eHealth reform, in close cooperation with state authorities. Patient portals are available and operational to a different degree in Armenia, Azerbaijan and Georgia; health-related services are provided via the national e-government portals (although the number of such services is more informational). The functioning systems for patient consultation are lacking as well.

Personal medical data and records are protected by, as a rule, by the more general Personal Data Protection Laws (however, in Moldova, for example, there are direct references to the protection of medical data too). It is possible to view and exchange personal data but the patients' consent is needed to do so (except Belarus which does not have a dedicated law on personal data protection, with the provisions protecting such data being part of the Informatisation Law).

Another similarity between the Partner Countries is the uncertainty accompanying the ***national eHealth strategies which often exist as policy drafts yet to be officially approved***. In addition, ***all Partner Countries have experienced difficulties in implementing previous policies, often due to the lack of the sufficiently empowered and effectively functioning government agencies responsible for eHealth*** (coupled with the lack of resources to implement such polices). Ministries of healthcare usually lead national eHealth agendas but their capacities are scarce unless there is a dedicated institution in charge of eHealth. The study

also demonstrates that the ***European experience is hardly known in the region*** (the main players among international donors are the World Bank, USAID and also the WHO as a provider of policy support).

Whilst ***eHealth training opportunities exist in most countries, these are fragmented and not systematic*** being often part of specific projects (e.g. the World Bank). The quality of training is unclear. There are ***no mechanisms and tools for best practice and experience exchange*** neither between the Partner Countries nor between them and the EU. Activities aimed at increasing citizens' literacy in digital health are rare.

A gap mapping exercise was performed to better understand which eHealth challenges are common, partially common and country-specific (see section 4.1.3 for details). The gap between 40 and 80% is the most common in the region. The data demonstrate that the largest gap over 60% is typical for the benchmark *(5) Innovation, Research*. All the Partner Countries experience the gap over 40% for two benchmark areas: *(1) Policies, Regulation* and *(9) Capacity, Competence, Resources*, whereas five countries show the same gap for as many as five benchmarks, which are: *(2) Governance, Institutions, Networks* (except Belarus), *(4) Interoperability, Once-Only Principle* (except Armenia), (*6) Services, Progress* (except Armenia), *(8) Economy, Business, Market* (except Georgia) and *(11) Big/Open Data, IoT* (except Armenia). These are the most problematic eHealth areas that potentially qualify for the category of the common harmonisation projects undertaken at the region-wide level.

The sub-regional harmonisation level with the gap of over 40% includes such benchmark areas as *(3) Infrastructure, Technology, Systems* (except Armenia and Georgia), *(7) Maturity, Integration* (except Armenia and Georgia), *(12) EU Cooperation* except Azerbaijan and Moldova) and *(13) Projects, Initiatives* (except Armenia and Azerbaijan). The country-specific harmonisation level covers just one benchmark (*10) Privacy, Awareness, Security* with a special focus on Belarus (which demonstrates the largest gap of over 60% due to the absence of a data protection legislation, while for other countries the gap for this benchmark does not exceed 40% and which is even smaller for Moldova – less than 20%). These country groups and benchmark areas demonstrate that ***harmonisation can be best addressed at the regional and sub-regional levels***. The most impactful effect from harmonisation would be felt at the level of the whole region and, hence, the proposed actions cover all the EaP countries.

To ensure effectiveness and efficiency of the harmonisation activities at regional and sub-regional level, it is ***proposed that an intra-regional coordination mechanism is established***

within the existing regional eHealth Network to ensure that the future EU assistance would be beneficial for all the Partner Countries to ensure strong multiplying effects of such assistance. In parallel, a focused and dedicated support should be provided to certain countries with special needs and upon demand, also via engaging local experts from the most advanced in particular eHealth areas Partner Countries to share experience across the region. It is proposed, therefore, that ***the regional eHealth Network is adequately empowered as the main coordination and facilitation body***.

Recommendations

It is proposed that the future ***harmonisation initiatives in eHealth are grouped around four harmonisation pillars*** as follows:

1. eHealth regional networking.
2. eHealth policy and governance.
3. eHealth interoperability and standards.
4. eHealth patient services and personal data protection standards.

Each pillar contains specific project activities – or actions – at each implementation level, namely: 14 actions for Pillar 1; 18 actions within Pillar 2; 8 actions under Pillar 3, and 12 actions for Pillar 4. The actions were formulated and assessed using the SMART Goals framework. It is proposed, as mentioned above, that to facilitate cooperation between the EaP Countries and the EU it will be essential, first of all, to empower the EaP regional eHealth Network to undertake regional coordination and facilitation of cooperation with the EU, for at the moment no Partner Country has its national eHealth network which prevents from effective cooperation with the EU Member States that have such national eHealth Networks; and, secondly, to help ***establish National Stakeholder and Action Groups*** (no Partner Countries have such Groups) that would unite together all the key actors in eHealth, including the private sector business, as a first step towards the establishment of the national eHealth Networks. Such a regionally coordinated approach is seen as the most effective way of harmonising with the EU. The ***EaP eHealth Network's web site will need to be created to start sharing information and best practices*** and eventually becoming a ***regional platform connected to the EU key eHealth platforms and services as a common testbed for piloting cross-border services and technology access***.

For each harmonisation pillar a set of ***key milestones and timelines has been identified to provide synergy to the implementation of the proposed under each pillar harmonisation actions***. The implementation modalities include training and advisory services, twinning activities, regional networking, collaboration with specialised platforms, piloting cross-border services (ePrescriptions and patient electronic health records/summaries in the first place), participation in EU events and initiatives. As underlined above, at the initial phase, the main emphasis is placed on supporting the already established regional eHealth network to empower it as the main common entry point – and as the key implementation vehicle – for cooperation with the EU relevant platforms and initiatives, such as the eHealth Digital Service Infrastructure (eHDSI). On a practice level, the regional eHealth Network's website will offer collaboration opportunities to implement harmonisation actions within each pillar; for example, providing access to the online meeting room available at the eHDSI website to connect to its eHealth communities (operations, technical, semantic) communities engaged in developing and rolling out Patient Summaries and ePrescriptions as the key use cases. Codifying and sharing the existing experiences and eHealth solutions already available in the Partner Countries will be key to raising the overall impact of the proposed harmonisation activities.

It is also suggested to ***explore and utilise opportunities created by the EaPConnect project to improve eHealth infrastructure and services*** in the region thanks to the state-of-the art high-capacity broadband internet networks for research and education across the EaP Partner Countries. It is critical to benefit from the ultra-high speed broadband telecommunication channels as the benchmark on ICT-based innovation in healthcare system and solutions demonstrates one of the largest gaps across the region, for many innovative eHealth solutions require modern and fast broadband infrastructures.

The ***proposed harmonisation activities are planned for implementation during 2018-2020 (or 2019-2021)*** to start creating a critical mass for wider and deeper cooperation after 2021 increasingly at a country level. That will require building relevant national capacities for such cooperation. Their scope can be expanded through the strengthened collaboration between individual Partner Countries and the EU Member States, deeper involvement in the European eHealth Network, direct participation in eHealth large-scale projects.

The proposed roadmaps for individual Partner Countries are based on the regional roadmap and follow its logic. In addition, the roadmaps also include country-specific project activities,

priority topics, obstacles and, challenges when such information was provided by the Partner Countries during the validation workshop in Tbilisi, Georgia held in September 2017.

1 STUDY CONTEXT

1.1 Background

In November 2013, the Heads of State and representatives of the six Eastern Partnership countries and EU's Member States met in Vilnius for the Eastern Partnership (EaP) Summit. In the ***Vilnius Summit declaration***, they defined the jointly agreed political priorities for the future of the Eastern Partnership. Among others, they called for "*promotion of information society policies and continued capacity building in the EaP, related to the creation of interoperable cross-border services*". The Vilnius joint declaration has been preceded by a non-paper on 'Information and Communication technologies (ICT) development with EaP Countries', presented in July 2013 to the Council's Working Party on Eastern Europe and Central Asia (COEST) by Poland, Estonia, Finland, Lithuania, Sweden, Georgia and Moldova. With their non-paper these countries stressed the need for a "*comprehensive approach in exploring the role of ICT for creating a common room for interoperable pan-European services*".

Following the Declaration[5] of *the* ***Riga EaP Summit*** (May 2015) that welcomed the completion of the first HDM study and called for the establishment of the HDM Panel, the Declaration[6] of the **1st *EaP Ministerial Meeting on the Digital Economy*** (June 2015) identified eHealth as priority topic for digital cooperation in the EaP.

In October 2016, the Joint Statement[7] of the ***Ministerial level meeting on the Digital Community*** with the EaP partners endorsed the operational conclusions of the 2nd HDM Panel, including an *ad* hoc workshop to explore the creation of a EaP regional network "EU4Digital: eHealth" aimed at promoting interoperable digital Health services and processes among partners and with the EU. ***The participants also called for a new eHealth study to perform gap analysis in the Partner Countries and produce regional harmonisation***

[5] http://eeas.europa.eu/eastern/docs/riga-declaration-220515-final_en.pdf.

[6] https://ec.europa.eu/digital-agenda/en/news/first-eastern-partnership-ministerial-meeting-digital-economy.

[7] http://ec.europa.eu/newsroom/dae/document.cfm?doc_id=18495,

recommendations on this topic. Methodology and approach of the initial HDM study has served as input to this eHealth study to take stock of the current state of eHealth in the six EaP Partner Countries from the perspective of harmonisation with the EU. The assessment of existing gaps identified in this report has helped understand the potential benefits stemming from gap reduction for developing both common and country-specific recommendations to harmonise eHealth-related regulation, technical platforms, services, practices.

A 2nd meeting of the EU4Digital: eHealth Network (eHealth workshop) was held in Tbilisi, Georgia, during 14-15 September 2017 to present and discuss the pre-final results of the eHealth study. Apart from validating the study results, workshop participants helped to devise a set of recommendations for future harmonisation initiatives that laid the basis for developing both the regional and country roadmaps.

1.2 Geography

The geographical scope of the study covers six eastern European partner countries: Armenia, Azerbaijan, Belarus, Georgia, Moldova and Ukraine.

1.3 Objectives and Tasks

The overall objective of the eHealth study is to ***assess the readiness of the digital markets in Partner Countries for harmonisation with the EU's Digital Single Market in the field of eHealth***, in line with relevant EU norms and practices.

More specifically, the study has:

- analysed the state of play of eHealth systems and markets in the Partner Countries using as a baseline the EU legal framework, European best practices, ICT platforms, in view of developing interoperable across borders national eHealth systems and services;
- identified challenges, obstacles and benefits both for individual Partner Countries and the EaP area as a whole in order to accomplish the harmonised interoperable eHealth systems;
- proposed country-specific and regional roadmap for harmonising the Partners' eHealth systems with the EU.

The study has performed the following tasks as per the Terms of Reference:

- ***Task 1: Identification of the EU baseline***: includes relevant EU legislation, best

practices, standards, ICT platforms based on the consultation with EC officials from relevant DGs including DG CONNECT, DG SANTE and DG NEAR. Qualitative and quantitative benchmarks should be identified to formalise the EU baseline.

- ***Task 2: Stock taking in the 6 Partner Countries***: includes the examination of the state of play according to a set of 13 benchmark indicators and 80 benchmark targets, as described below, supplemented by the country-specific lists of key legislation/regulation, participating organisations and major ongoing and planned projects/initiatives. This task was carried out by national experts in line the detailed questionnaires and instructions developed by Team Leader who also performed quality assurance of the collected information.
- ***Task 3: Gap analysis***: includes the comparative analysis of the state of play at each EaP partner (established via task T2) with respect to the EU baseline (identified via task T1). As part of this task, the study defined a methodology and indicators for an independent monitoring of partners' harmonisation progress in eHealth.
- ***Task 4: Benefit analysis***: includes the assessment of economic, political, and social benefits that each Partner Country and the EaP can expect to gain from harmonisation in eHealth.
- ***Task 5: Regional and national roadmaps***: includes the identification of concrete steps for the development by the end of 2019 of harmonised interoperable national platforms for eHealth (interoperable among the Partners and with the EU); the steps comprise the necessary actions/reforms in the field of legislation, services and ICT or other infrastructure, identification of actors involved and an estimation of the corresponding costs. In addition, to complement the national roadmaps, the study proposes a regional (EaP) roadmap (joint actions) for improving the interoperability of the partners' eHealth systems, among them and with the EU. As mentioned under Task 3, the proposed roadmaps include specific objectives and indicators/targets for monitoring harmonisation progress, nationally and regionally, according to the methodology defined in task T3, as well as the modality of such monitoring. The proposed roadmaps are in line with existing international agreements involving the Partner Countries.

1.4 Expected Results

In accordance with the Terms of Reference, this report contains

- ***Gap and benefit analysis:*** Assessment of relevant legislation, best practices, standards, ICT platforms, organisations involved, decision-making process, national plans, international agreements, etc existing in Partner Countries (assessed against a well-defined and documented EU and international baseline). Estimated benefits that are expected in each Partner Country and the EaP as a whole from deeper harmonisation with the EU
- ***Roadmaps*****:** Six national (for each Partner) and a regional (EaP) roadmaps for the development by the end 2019 of harmonised interoperable national platforms for eHealth (interoperable among the partners and with the EU); includes actions/reforms (either nationally or jointly/regionally) in the field of legislation, services and ICT or other infrastructure, actors involved and estimated costs; also includes indicators and targets for monitoring the harmonisation progress.

2 DIGITAL TRANSFORMATION OF HEALTH CARE: EU BASELINE

2.1 Context

As stated above, the goal of this study is compare the state of eHealth in the six Partner Countries with that of the EU. The definition of EU baseline is based on documents, position papers and communications from the European Commission and related institutions on the requirements for (cross-border) eHealth systems and services. In this context, the EU baseline is viewed in broader terms than the actual level of maturity of eHealth systems and service in the EU Member States. The latter do not always and necessarily meet as yet the requirements set for the cross-border interoperability of such systems and services. Thus, this report is a benchmark evaluation on the European Commission's requirements for essential eHealth systems and services in the six Eastern Partnership countries rather than a benchmark evaluation with EU Member States. The EU baseline includes not only existing policies and practices but also those that have been established as desired norms yet have to be achieved by many EU Member States as well. In this context, the emphasis is placed on measuring the gap between the actual sate of play in the Partner Countries and the normatively declared eHealth policy objectives in the EU. Viewed from that perspective, the EU baseline was used to

formulate the benchmark statements (as listed in Table 2) against which the state of play is measured and assesses.

2.2 Key Documents and Sources

The eHealth baseline is based on the following EU documents broken into several categories, namely:

2.2.1 EU policy and associated initiatives

- eHealth Action Plan 2012-20[8] and Accompanying Staff Working Document.[9]
- eHealth Network[10] (established under Article 14 of Directive 2011/24/EU – see below).
- Joint Action to support the eHealth Network[11] (to prepare scientific and technical work of the eHealth Network).
- eHealth Stakeholders Group[12] (contributes to developing legislation and policy in the area).
- EU Green Paper[13] on Mobile Health & Consultation.[14]
- Commision Staff Working Document[15] on existing EU legal framework applicable to lifestyle & wellbeing apps (2014).
- eHealth Projects[16] (updated regularly).

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[8] http://ec.europa.eu/digital-agenda/en/news/ehealth-action-plan-2012-2020-innovative-healthcare-21st-century.

[9] http://ec.europa.eu/information_society/newsroom/cf/itemdetail.cfm?item_id=9157.

[10] http://ec.europa.eu/health/ehealth/policy/network/index_en.htm.

[11] http://jasehn.eu/.

[12] http://ec.europa.eu/digital-agenda/en/news/ehealth-stakeholder-group-members.

[13] http://ec.europa.eu/digital-agenda/en/news/green-paper-mobile-health-mhealth.

[14] https://ec.europa.eu/digital-agenda/en/public-consultation-green-paper-mobile-health.

[15] https://ec.europa.eu/digital-single-market/en/news/commission-staff-working-document-existing-eu-legal-framework-applicable-lifestyle-and.

- Digital Single Market strategy[17] (2015 and subsequent updates).
- EU Council Conclusions[18] on digital health "Health in the digital society – making progress in data-driven innovation in the field of health" (8 December 2017).
- Mid-Term Review of the Digital Single Market[19] of 10 May 2017 accompanied by the European Digital Progress Report and Digital Economy and Society Index (DESI)[20].

2.2.2 EU legislation and associated documents

- Directive 2011/24/EU[21] on the application of patients' rights in cross-border healthcare.
- EC Communication COM(2008)689 [22] on telemedicine for the benefit of patients, healthcare systems and society.
- COMMUNICATION[23] FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT, THE COUNCIL, THE EUROPEAN ECONOMIC AND SOCIAL COMMITTEE AND THE COMMITTEE OF THE REGIONS on the Mid-Term Review on the implementation of the Digital Single Market Strategy: A Connected Digital Single Market for All.
- General Data Protection Regulation (GDPR)[24] – approved by the EU Parliament on 14 April 2016 with the enforcement date of 25 May 2018 (heavy fines envisaged for non-

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[16] https://ec.europa.eu/digital-single-market/news/ehealth-projects-research-and-innovation-field-ict-health-and-wellbeing-overview.

[17] https://ec.europa.eu/growth/single-market/digital_en.

[18] http://data.consilium.europa.eu/doc/document/ST-14078-2017-INIT/en/pdf.

[19] https://ec.europa.eu/digital-single-market/en/news/digital-single-market-mid-term-review,

[20] https://digital-agenda-data.eu/datasets/desi/visualizations.

[21] http://eurlex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2011:088:0045:0065:EN:PDF.

[22] http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=COM:2008:0689:FIN:EN:PDF.

[23] http://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1496330315823&uri=CELEX:52017DC0228.

[24] https://www.eugdpr.org/.

compliance) replaces the Data Protection Directive 95/46/EC [25] of the European Parliament and of the Council of 24 October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data. The GDPR will harmonize data privacy laws across Europe to protect and empower all EU citizens data privacy and to reshape the way organizations across the region approach data privacy. The key articles of the GDPR, as well as information on its business impact, can be found throughout this site.

- European Union Agency for Network and Information Security (ENISA)[26] Regulation No 526/2013[27] of the European Parliament and of the Council of 21 May 2013, repealing Regulation (EC) No 460/2004.
- Directive (EU) 2016/1148[28] of the European Parliament and of the Council of 6 July 2016 concerning measures for a high common level of security of network and information systems across the Union.

2.2.3 EU eHealth (cross-border) interoperability and associated initiatives

- Commission has proposed an eHealth Interoperability Framework [29] with the endorsement of the eHealth Network in Brussels on 23 November 2015.
- Documents developed by the eHealth Digital Service Infrastructure (eHDSI) communities[30].
- Study on Economic Impact of Interoperable Electronic Health Records and ePrescription in Europe (01-2008/02-2009).[31]

[25] http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:31995L0046&from=EN.

[26] https://www.enisa.europa.eu/about-enisa/mission-and-objectives.

[27] http://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=OJ:JOL_2013_165_R_0041_01&qid=1397226946093&from=EN.

[28] http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32016L1148&rid=8.

[29] http://ec.europa.eu/health/sites/health/files/ehealth/docs/ev_20151123_co03_en.pdf.

[30] https://ec.europa.eu/cefdigital/wiki/display/EHOPERATIONS/eHDSI+Mission.

- eHealth Conformity Assessment Scheme for Europe in 2018.[32]

2.2.4 Large-scale EU pilot eHealth projects and initiatives

- CEF eHealth Digital Service Infrastructure.[33]
- epSOS,[34] Renewing Health,[35] United4Health,[36] CEF pilots.[37]
- Blueprint for digital Transformation of Health and Care.[38]
- ICT for Active and Healthy Ageing.[39]
- European Innovation Partnership on Active and Healthy Ageing.[40]
- European Scaling-up Strategy in Active and Healthy Ageing.[41]
- Active and Assisted Living Joint Programme.[42]
- EIT KIC on Healthy Living and Active Ageing.[43]

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[31] http://ec.europa.eu/information_society/activities/health/docs/publications/201002ehrimpact_study-final.pdf.

[32] https://ec.europa.eu/digital-single-market/en/news/eu1-million-more-interoperability-ehealth.

[33] CEF eHealth Digital Service Infrastructure.

[34] http://www.epsos.eu/.

[35] http://www.renewinghealth.eu/.

[36] http://www.united4health.eu/.

[37] http://ec.europa.eu/health/sites/health/files/ehealth/docs/ev_20160607_co01_en.pdf.

[38] http://ec.europa.eu/research/conferences/2016/aha-summit/index.cfm?pg=blueprint.

[39] http://ec.europa.eu/digital-agenda/en/policies-ageing-well-ict.

[40] http://ec.europa.eu/research/innovation-union/index_en.cfm?section=active-healthy-ageing&pg=silvereconomy.

[41] https://ec.europa.eu/research/innovation-union/pdf/active-healthy-ageing/scaling_up_strategy.pdf.

[42] http://www.aal-europe.eu/.

[43] https://eithealth.eu/.

- Joint Programming Initiative More Years – Better Lives.[44]
- European Innovation Summit on Active and Healthy Ageing.[45]
- EU Silver Economy Strategy.[46]
- EU Silver Economy Study.[47]

2.2.5 Main sources used

- eHealth Action Plan 2012-2020 -- Innovative healthcare for the 21st century.[48]
- Article 14 of Directive 2011/24 on the application of patients' rights in cross-border healthcare.[49]
- COMMUNICATION FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT, THE COUNCIL, THE EUROPEAN ECONOMIC AND SOCIAL COMMITTEE AND THE COMMITTEE OF THE REGIONS on the Mid-Term Review on the implementation of the Digital Single Market Strategy: A Connected Digital Single Market for All.[50]
- General Data Protection Regulation[51] – Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data.
- epSOS.[52]

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[44] http://www.jp-demographic.eu/.

[45] http://ec.europa.eu/research/conferences/2016/aha-summit/index.cfm?pg=home.

[46] http://ec.europa.eu/research/innovation-union/index_en.cfm?section=active-healthy-ageing&pg=silvereconomy.

[47] http://www.smartsilvereconomy.eu/home.

[48] https://ec.europa.eu/digital-single-market/news-redirect/9156.

[49] http://www.europarl.europa.eu/sides/getDoc.do?type=TA&reference=P7-TA-2011-0007&language=EN#BKMD-2.

[50] http://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1496330315823&uri=CELEX:52017DC0228.

[51] http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:31995L0046&from=EN.

- Business Models for eHealth: Final Report.[53]

2.3 Key Definitions

The World Health Organisation (WHO) defines eHealth as a "*cost-effective and secure use of information and communications technologies in support of health and health-related field, including health care services, health surveillance, health literature, and health education, knowledge and research*" (see Glossary section). According to the ***Commission Staff Working Document***[54] on existing EU legal framework applicable to lifestyle & wellbeing apps (2014), eHealth, in this context, means "*ICT tools and services for health. eHealth covers the interaction between patients and health-service providers, institution-to-institution transmission of data, or peer-to-peer communication between patients and/or health professionals. Examples include health information networks, electronic health records, telemedicine services, wearable and portable systems which communicate, health portals, and many other ICT-based tools assisting disease prevention, diagnosis, treatment and follow up*". Telemedicine is defined as the provision of healthcare services, through use of ICT, in situations where the health professional and the patient are present in different locations.

eHealth improves access to healthcare and boosts the quality and effectiveness of the services offered. eHealth describes the application of information and communications technologies across the whole range of functions that affect the health sector. eHealth tools or solutions include products, systems and services that go beyond simply Internet-based applications. They include tools for both health authorities and professionals as well as personalised health systems for patients and citizens; examples include health information networks, electronic health records, telemedicine services, personal wearable and portable communicable systems, health portals, and many other information and communication technology-based tools assisting prevention, diagnosis, treatment, health monitoring, and lifestyle management.

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[52] http://www.epsos.eu/home/about-epsos.html.

[53] http://ec.europa.eu/newsroom/dae/document.cfm?doc_id=2891.

[54] http://ec.europa.eu/information_society/newsroom/cf/itemdetail.cfm?item_id=9157.

eHealth end-users (according to the EU Active and Assisted Living Programme -- AAL)[55]:

- Primary end-user is the person who actually is using an AAL product or service, a single individual, "the well-being person". This group directly benefits from AAL by increased quality of life;
- Secondary end-users are persons or organisations directly being in contact with a primary end-user, such as formal and informal care persons, family members, friends, neighbours, care organisations and their representatives. This group benefits from AAL directly when using AAL products and services (at a primary end user's home or remote) and indirectly when the care needs of primary end-users are reduced;
- Tertiary end-users are such institutions and private or public organisations that are not directly in contact with AAL products and services, but who somehow contribute in organising, paying or enabling them. This group includes public sector service organisers, social security systems, insurance companies. Common to these is that their benefit from AAL comes from increased efficiency and effectiveness which result in saving expenses or by not having to increase expenses in the mid and long term

Mobile Health (mHealth) is a "*sub-segment of eHealth and covers medical and public health practice supported by mobile devices. It especially includes the use of mobile communication devices for health and well-being services and information purposes as well as mobile health applications. It is a rapidly developing field with over 100,000 mHealth apps are currently available on the European market. mHealth contributes to the empowerment of patients: they could manage their health more actively, live more independently thanks to self-assessment or remote monitoring solutions. mHealth can also support healthcare professionals in treating patients more efficiently as mobile apps can encourage adherence to a healthy lifestyle*".[56]

Health system interoperability is "*the ability, facilitated by ICT applications and systems to exchange, understand and act on citizens/patient and other health related information and*

[55] http://www.aal-europe.eu/.

[56] https://ec.europa.eu/digital-single-market/en/mhealth.

knowledge among linguistically and culturally disparate clinicians, patients and other actors and organisations within and across health system jurisdictions in a collaborative manner."[57]

HL7 protocol refers to the highest level of the International Standards Organization's (ISO) communications model for Open Systems Interconnection (OSI). The application level addresses definition of the data to be exchanged, the timing of the interchange, and the communication of certain errors to the application. The HL7 protocol was developed to address this need for data sharing among medical applications.[58]

2.4 State of play of the EU's eHealth Sector

2.4.1 The growing importance of eHealth

The healthcare expenditure in the EU's 27 Member States was on average 7.2% of GDP in 2010 and is expected to grow to 8.5% of GDP in 2060 due to the ageing population and other socio-economic development; for example, the working age contingent is expected to fall from 61% to 51% of the total population during 2010 and 2069, while the share of the elderly (65+) and very old (80+) population in the EU is projected to grow during this period from 17.4% to 30.0% and from 4.7% in 2010 to 12.1% respectively.[59]

Rapid developments in digital technologies could facilitate the transformation towards a better accessible, personalised, a more efficient, good quality and safe care. Health and care services increasingly depend on information technology and the digitisation of information-driven healthcare supply chain processes. Digital healthcare enables new services and interactions with stakeholders, i.e. users, providers, industry and payers. Digital health and care services could be available to people outside traditional care settings in terms of a relative independency from time, place and provider who delivers the service. This creates a digital market for new service and business models based on a different interplay between payers, provider networks (incl. suppliers and complementors) and consumers. Since health and care services often

[57] http://www.epsos.eu/faq-glossary/glossary.html, see page 3.

[58] http://ehealth.eletsonline.com/2007/10/11037/.

[59] eHealth Action Plan 2012-2020 -- Innovative healthcare for the 21st century https://ec.europa.eu/digital-single-market/news-redirect/9156.

consist of multiple contributors, one should look beyond the individual provider perspective and consider a business model as a collaborative effort of a provider network to offer a joint proposition to their consumers.

Evidence suggests that related digital health business models should map all key supporting activities, value network relationships, and dependencies impacted by the introduction of an eHealth service. The structuring and implementation of such a service and business model require leadership, a clear vision and related implementation and up-scaling roadmap, supported by strong senior management involvement throughout the design, development and delivery of an eHealth service. Staff involvement is also essential to ensure that business models reflect the interactions of those actors who are to use them in their day-to-day professional activities. Public policy and the role of the EC: Action requires the involvement of all stakeholders such as national healthcare authorities, health professional associations, healthcare delivery organisations, industry and the research community as well as European perspectives, so as to foster the sharing of applicable best practices and experiences. However, the provision of such pan-European services is not easy given that each EU Member State is responsible for the operational delivery and financial management of healthcare. To remove these barriers, this study calls on the EC to take on a vital coordinating role in the development and implementation of eHealth services through:

- Launching pilots to test or simulate e Health-related projects;
- Fostering the sharing of best practice in business models;
- Defining benchmarking indicators for cross-organisational comparisons;
- Supporting the development of best practice via specific incentives such as tax breaks and/or different reimbursement procedures or co-funding mechanisms;
- Bringing legal clarity as to facilitate safe exchange and authentication of healthcare data across national borders, as well as healthcare staff;
- Working towards the solution of technical issues and the facilitation of market developments via interoperability, common terminologies and stands for terminologies and data, and pre-procurement activities.

Already now two-thirds of Europeans think that the most recent digital technologies have a positive impact on society, the economy and their own lives.[60]

A mid-term review[61] undertaken to assess progress towards the implementation of the Digital Single Market, is accompanied by the 2017 European Digital Progress Reports[62] outlining the progress made at both EU and Member State level. Specifically, the report in a dedicated chapter assesses digital transformation of health and care. Its explicit goal is that EU citizens "*can transfer their basic medical information electronically when receiving treatment in another Member State and use e-prescriptions to get their medication dispense*". That goal should be operational by 2020 in most Member States. However, it is also stated that 'more needs to be done so that all citizens can, in full privacy and confidence, access and transfer their complete electronic health record when receiving healthcare abroad" (see more in Experience Demonstration Box 1).

Experience Demonstration Box 1. European Union: examples of eHealth objectives in the context of the Digital Single Market.

High performance computing can unlock the potential of big data for health through advanced data infrastructure and data analytics. The European Reference Networks created this year are a striking demonstration of what Europe can achieve by pooling medical expertise and data for faster diagnosis and treatment of rare and complex diseases. To extend this approach to other healthcare domains and make available on an EU wide scale, further action implementation and up-scaling is needed along with additional requirements. Health data generated in the EU and processed with patients' explicit consent or other legal grounds permitted by the GDPR (General Data Protection Regulation) and subject to appropriate safeguards, can advance research in an unprecedented way. It can also enable the early detection of infectious

[60] eHealth Action Plan 2012-2020 -- Innovative healthcare for the 21st century https://ec.europa.eu/digital-single-market/news-redirect/9156.

[61] COMMUNICATION FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT, THE COUNCIL, THE EUROPEAN ECONOMIC AND SOCIAL COMMITTEE AND THE COMMITTEE OF THE REGIONS on the Mid-Term Review on the implementation of the Digital Single Market Strategy: A Connected Digital Single Market for All http://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1496330315823&uri=CELEX:52017DC0228.

[62] European Digital Progress Report (EDPR) 2017, SWD (2017) 160.

outbreaks and accelerate development of medicines and medical devices, and stimulate innovative healthcare solutions such as telemedicine and mobile health applications.

Two new Regulations on medical devices were adopted in April 2017 and will become progressively applicable over the next five years. They foresee the establishment of a new comprehensive EU-wide database on medical devices ('Eudamed'), whose big data deployment will serve the development of innovative digital diagnostic and therapeutic solutions and the early detection of safety issues.

The Commission will adopt a Communication in 2017 addressing the need and scope for further measures in the area of digital health and care, in line with legislation on the protection of personal data, patient rights and electronic identification, in particular as regards:

- citizens´ secure access to electronic health records and the possibility to share it across borders and the use of e-prescriptions.
- supporting data infrastructure, to advance research, disease prevention and personalised health and care in key areas including rare, infectious and complex diseases.
- facilitating feedback and interaction between patients and healthcare providers, to support prevention and citizen empowerment as well as quality and patient-centred care, focussing on chronic diseases and on a better understanding of the outcomes of healthcare systems.

Source: COMMUNICATION FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT, THE COUNCIL, THE EUROPEAN ECONOMIC AND SOCIAL COMMITTEE AND THE COMMITTEE OF THE REGIONS on the Mid-Term Review on the implementation of the Digital Single Market Strategy: A Connected Digital Single Market for All http://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1496330315823&uri=CELEX:52017DC0228.

The General Data Protection Regulation[63] prohibits, with some explicit conditions, the use and processing of citizens' health data without their consent (see Experience Demonstration Box 2).

Experience Demonstration Box 2. European Union: Protection of personal health data.

[63] http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:31995L0046&from=EN.

Protection of personal health data and privacy is an important concern of European citizens. Accordingly, the EC took policy measures to formulate rules and regulation: e.g. article 8 The processing of special categories of data: 'Member States shall prohibit the processing of personal data revealing racial or ethnic origin, political opinions, religious or philosophical beliefs, trade-union membership, and the processing of data concerning health or sex life'.
Item (33): '… data which are capable by their nature of infringing fundamental freedoms or privacy should not be processed unless the data subject gives his explicit consent; whereas, however, derogations from this prohibition must be explicitly provided for in respect of specific needs, in particular where the processing of these data is carried out for certain health-related purposes by persons subject to a legal obligation of professional secrecy or in the course of legitimate activities by certain associations or foundations the purpose of which is to permit the exercise of fundamental freedoms;'
Source: Directive 95/46/EC; Article 1(3) General Data Protection Regulation

2.4.2 eHealth market perspectives and stakeholders

The European eHealth market area can be viewed from two perspectives. One is a narrower supplier perspective concerned with the commercial provision of single/stand-alone solutions to healthcare organisations – e.g. in the form of information systems.[64] The other one is a more holistic patient-centric perspective concerned with the provision of broader health services aimed at - together - payers, providers and consumers. The supplier perspective has generated such business models (along with respective market areas), as: Clinical Information Systems (CIS), Secondary Usage Non-Clinical Systems (SUNCS), Telemedicine, and Integrated Health Clinical Information Networks (IHCIN) – see definitions below. Capgemini Consulting has concluded that in 2008, Secondary Usage Non-Clinical Systems (SUNCS) accounted for 71.6% of the total eHealth market in Europe. Clinical Information Systems (CIS) represented about 13.5% of the total European eHealth market, while Integrated Health Clinical Information Networks (IHCIN) fare at about 5%. Finally, telemedicine accounted for only 8.9%. With time, the importance of the Clinical Information Systems is expected to grow relative to the Secondary Usage Systems. This suggests that eHealth suppliers increasingly target the operational

[64] Source: Business Models for eHealth: Final Report http://ec.europa.eu/newsroom/dae/document.cfm?doc_id=2891.

processes of healthcare organizations and professionals. In addition, Capgemini Consulting has identified a growing demand for integrated healthcare clinical information systems in light of an increasing need for data sharing among healthcare delivery organisations. The market for telemedicine systems and applications will continue to be small but rapidly growing suggesting that true adoption of this technology by providers, professional and medical staff as well as patients will take significant time.

Traditionally, healthcare is a single-provider-based service model. As said, increasingly the single-provider-based service delivery is developing into a more integrated service model in which multiple stakeholders work collaboratively through digital platforms with direct interaction of the consumer. Accordingly, the related business concept transforms from a single-provider-based model to a network-based model. This is also known as a multi-sided business model which aims at creating value for the actors involved in the service provision and for the consumer as well. The key elements of a multi-sided business model are 1) the service, 2) the technological infrastructure, 3) the network of service provider, intermediaries and/or suppliers, and 4) the cost structure. Such a service should be provided in a healthcare service market where the consumer (patient) can choose between providers of services and for which transparency with price and quality indicators is essential. Usually, a third party is responsible for the procurement and/or insurance of the services.

Contrary to these business models for stand-alone solutions provided by commercial suppliers, the providers of health services – rather than single solutions – are not based on particular business models but underline the importance of networking among various complementary actors and intermediaries following a more complex cost and revenue model. While this study is also interested to measure the availability of the supply-driven digital healthcare market, more important is to focus on the factors that set pre-conditions for its emergence not only from the industry perspective but all other stakeholders and their mutual relations, as illustrated below.

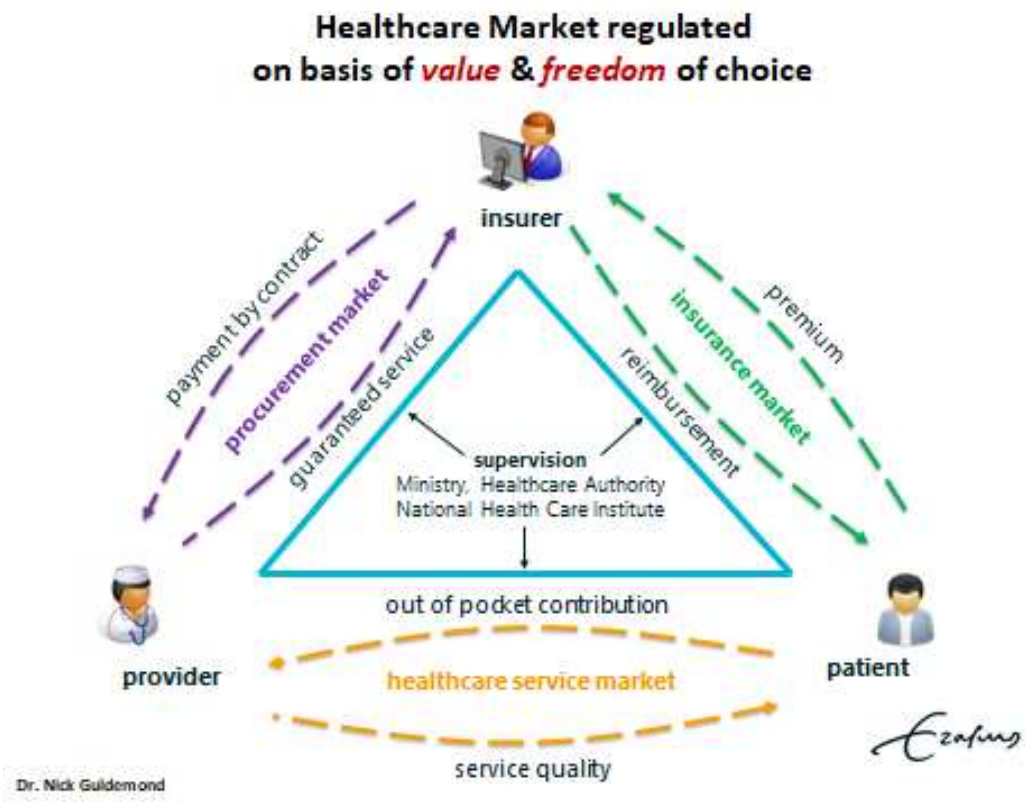


Figure 1. Digital health market

The success of the entire eHealth market depends on the relation and interaction of these three stakeholders – patients, healthcare providers, and insurers or payers. The rules of this playing field are set by the government, i.e. how the market is regulated. The rules include such major pre-conditions as:

- How patients can obtain his (eHealth) service?
- How patients will pay for it, e.g. via taxation policy, insurance, direct personal payment or a combination of those three;
- Does it apply to all related health services or some are excluded;
- Is there a freedom of choice between sets of eHealth services and payments schemes?
- Is there transparency in price and quality?
- Is the eHealth market open for competitors?

Suppliers/complementors can provide services indirectly through healthcare providers or directly to the consumer. In order to provide a level playing field for companies who dependent on exchange of information for their services and business models, it is important that these companies have access to platforms and relevant data.

2.4.3 Key objectives and benefits of eHealth

The main objectives of the EU eHealth sector can be summarised as follows:

- Achieving wider interoperability of eHealth services and related interoperability of IT infrastructure, (medical) devices, data, etc.
- Supporting research, development and innovation in eHealth and wellbeing to address the lack of availability of user-friendly tools, products (e.g. devices) and services.
- Facilitating uptake and ensuring wider deployment, with special emphasis placed on implementation and up-scaling of successful and impactful initiatives and projects.
- Promoting policy dialogue and international cooperation on eHealth at global level.
- Supporting self-management in health and disease monitoring, evaluation and control.

From the EU perspective, the benefits of eHealth lie in the interoperability of its solutions, which include[65]:

- "For healthcare professionals: improved quality and safety of care through strengthened coordination; up- to-date patient status information and evidence-based clinical guidelines to support decision-making procedures;
- For patients: enhanced safety of treatments received, delivery of care at the point of need, integrated care including quality and safe treatment abroad, e.g. in an emergency situation in another EU Member State;
- For users: interoperable systems result in significantly lower implementation and integration costs. For example, a MRI image from a hospital can be exchanged and used by various professionals and structures without the need to repeat tests;

[65] https://ec.europa.eu/digital-single-market/en/interoperability-standardisation-connecting-ehealth-services.

- For healthcare businesses: the use of a common eHealth EU Interoperability Framework (EIF) can help expand a digital single market for healthcare, opening up competition and reducing costs for developers. In this sense, cooperation is vital: a thorough and wide collaboration allows sharing costs and reduces future reinvestments to update systems".

Citizens also benefit from such healthcare services that are: more personalised and citizen-centric; effective and efficient thanks to better operational performance through information driven management and collaboration; helping reduce errors, as well as the length of hospitalisation; empowering patients through greater transparency, improved access to services and information and the use of social media for health, unlocking effective health data; improving well-being and mobility of the elderly; responding to the growing prominence of chronic diseases.

Economic benefits of eHealth solutions include: greater sustainability of healthcare efficiency where better use of resources is paramount; overcoming financial challenges to control overall healthcare spending; facilitating socio-economic inclusion and equality.

- Technological benefits lie in: developing technology-assisted therapies combined with a reciprocal benefit for science and development of new therapies; complementing routine clinical care and improving the cost-efficiency of the treatments; exchanging interoperable electronic health record among health organisations within the country and across borders; establishing electronic health records, patient summaries; connecting electronic registries; rolling out ePrescription systems, Electronic Health Records (HER), etc.

2.4.4 Key barriers for wider uptake of eHealth solutions

However, numerous barriers exist that hamper the wider uptake of eHealth solutions to maximise the value of their benefits. Such barriers include (but are not limited to) the following:

- Ensuring clear common responsibilities in respect of the provision of mechanisms for responding to harm arising from healthcare is essential to prevent lack of confidence in those mechanisms being an obstacle to taking up cross-border healthcare.
- Lack of awareness of, and confidence in eHealth solutions among patients, citizens and healthcare professionals.
- Lack of interoperability between eHealth solutions.

- Limited large-scale evidence of the cost-effectiveness of eHealth tools and services, in particular with regard to telemedicine services.
- Lack of legal clarity for health and wellbeing mobile applications.
- Lack of transparency regarding the utilisation of data collected by such applications.
- Inadequate or fragmented legal frameworks including the lack of reimbursement schemes for eHealth services.
- High start-up costs involved in setting up eHealth systems.
- Regional differences in accessing ICT services, limited access in deprived areas.
- Fragmented legislation.

2.4.5 Challenges of implementing eHealth solutions

eHealth solutions are seen as especially effective instruments for addressing such healthcare challenges as:

- Improving chronic disease and multimorbidity (multiple concurrent disease) management and to strengthening effective prevention and health promotion practices.
- Increasing sustainability and efficiency of health systems by unlocking innovation.
- Enhancing patient/citizen-centric care and citizen empowerment and encouraging organisational changes.
- Fostering cross-border healthcare, health security, solidarity, universality and equity.
- Improving legal and market conditions for developing eHealth products and services.

Experience Demonstration Box 3 below presents a case from the Czech Republic to demonstrate how these challenges, objectives, barriers, benefits can be handled in synergy at both national and regional levels.

Experience Demonstration Box 3. European Union: Maturity model for scaling-up – Experience of Olomouc Region, Czech Republic

The Czech National Strategy for eHealth includes 4 objectives: patient empowerment, health sector effectiveness, quality and access to HC services, infrastructure and governance incl. standards.

Key institution: National eHealth Centre (NTMC – founded in 2012)

Status: Medically driven unit, task force and association located at cardiology clinic. Leading expert centre for telemedicine in the CR

Main strategy: Bottom-up in innovations and to expand skills

ACTIVITIES:

- Coordinates activities in eHealth
- Participates in the development of the National eHealth strategy
- Co-founded a Platform for Electronic Healthcare – promotion of eHealth, debates, esp. in medical community in the CR
- Participates in key activity of Ministry of Labour and Social Affairs 'Support of assistive technologies (AT)' – evaluates AT and use of ICT in social care and healthcare in the CR and develops mechanisms for deployment of AT for citizens with social and health needs.
- Creates modular telemedicine program for a number of diseases and interventions in Olomouc Region
- Established a call centre
- Participates in the regional and interregional initiative for sharing medical records
- Maps and resolves issues of ICT use in medicine (and social care) – barriers, financing, reimbursement, acceptance by stakeholders, modification of current protocols of care that are face-to-face oriented
- Provides services – distant monitoring of pacemakers and defibrillators, later chronic diseases, e.g. diabetes, heart failure
- Teams up with stakeholders on national and regional level to progress from pilots/studies to regular use
- Integrates care vision for patients (seniors) with chronic diseases
- Educates for future, esp. medical personnel (University)

Source: ZDENEK GÜTTER, National eHealth Centre, University Hospital Olomouc, Czech Republic (presented at the WEBINAR ON B3 MATURITY MODEL, 10 NOVEMBER 2015)

3 ASSESSMENT METHODOLOGY

3.1 Assessment Approach

3.1.1 Gap assessment framework: benchmark indicators and targets

The eHealth study capitalises on the previous HDM study undertaken in 2014-2015 and applies a similar assessment methodology to compare eHealth in the Partner Countries. The approach dwells on building a set of benchmarks that reflect upon the key benefits of harmonisation with the EU. Such benchmarks describe and measure the state of play in eHealth in Partner Countries in the form of gaps in existing with the EU (as depicted in Figure 2).

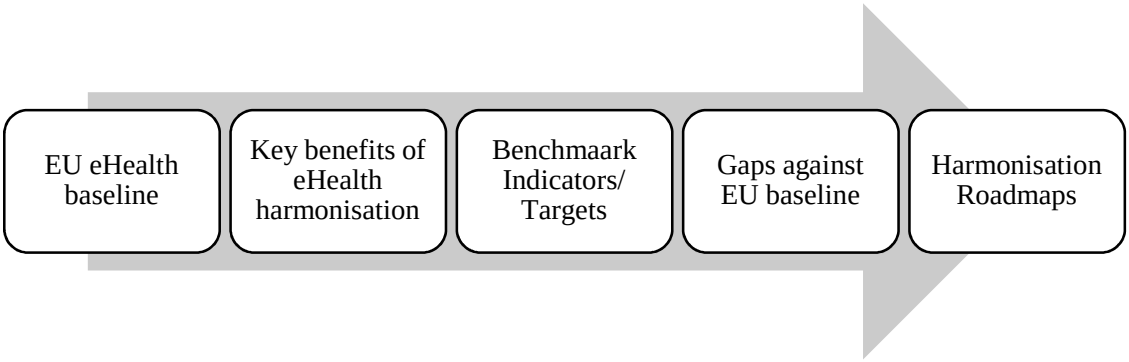


Figure 2. eHealth assessment process

There are two types of benchmarks used in the study: (1) 13 aggregated benchmark indicators and (2) 80 individual benchmark targets underpinning the EU baseline. The comparison of the gaps existing in individual Partner Countries with the EU baseline has helped identify both country-specific and common areas for follow-up actions in the form of the eHealth roadmaps.

Benchmark indicators include the following aspects of the EU eHealth baseline:

1. Policies, Regulation.
2. Governance, Institutions, Networks.
3. Infrastructure, Technology, Systems.
4. Interoperability, Once-only Principle.
5. Innovation, Research.
6. Services, Progress.
7. Maturity, Integration.
8. Economy, Business, Market.

9. Capacity, Competence, Resources.
10. Privacy, Awareness, Security.
11. Big Data, Internet of Things.
12. EU Cooperation.
13. Projects, Initiatives.

In turn, each benchmark indicator consists of more detailed benchmark targets as listed below in Table 1.

Table 1. List of benchmark indicators and targets

Benchmark indicators		Benchmark targets
1. Policies, Regulation	1.1	Availability of eHealth strategy
	1.2	Strategy for mHealth
	1.3	Regulation of Telemedicine
	1.4	Transparency of interoperability
	1.5	Regulation of Electronic Health Records (EHR)
	1.6	Regulation of software technology use
	1.7	Regulation of mHealth
	1.8	Ageing-related policies
	1.9	Policies encouraging innovation procurement
	1.10	Legal certainty of cross-border interoperability
	1.11	Legal certainty of in-country interoperability
	1.12	Strategy for interoperability
2. Governance, Institutions, Networks	2.1	Networks of healthcare providers
	2.2	Networks of healthcare professionals
	2.3	Coordination
3. Infrastructure, Technology, Systems	3.1	National health information system/infrastructure
	3.2	Use of Open Standards
	3.3	Availability of interoperability infrastructure
	3.4	Market-driven infrastructure
	3.5	Availability of electronic health record systems (EHR)
	3.6	Electronic Health Records levels
	3.7	Availability of the national health information system
	3.8	Availability of medical electronic registries
	3.9	Availability of specialised health information systems
	3.10	Patient consultation systems
	3.11	Availability of Big Data technologies
	3.12	Integration with e-government architecture/infrastructure
	3.13	eID-based access services
	3.14	Non-eID access services
	3.15	Availability of Internet of Things (IoT) technologies
	3.16	Health monitoring
4. Interoperability	4.1	Strategy for interoperability
	4.2	Application of whole-of-government approach to interoperability
	4.3	Possibility of in-country interoperability
	4.4	Possibility of cross-border interoperability
	4.5	Availability of interoperability infrastructure
	4.6	Legal certainty of cross-border interoperability

Benchmark indicators	Benchmark targets	
	4.7	Legal certainty of in-country interoperability
5. Innovation, Research	5.1	Support to eHealth research
	5.2	Participation in international research
	5.3	Research through business partnerships
	5.4	Research into ageing well-being
	5.5	Commercialisation of eHealth research
6. Services, Benefits, Progress	6.1	Patient Portal
	6.2	Availability of Electronic Health Records (EHR) services Availability of Patient Summary (PS) services
	6.3	Availability of ePrescription services
	6.4	Patient consultation services
	6.5	Emergency response services
	6.6	
7. Maturity, Integration	7.1	Connected eHealth systems/services
	7.2	Voluntary use of eHealth systems/services
	7.3	Mandatory use of eHealth systems/services
	7.4	Universal use of connected eHealth systems/services
8. Economy, Business, Markets	8.1	Business involvement
	8.2	Commercialisation of innovation
	8.3	Business models
	8.4	Market for eHealth/mHealth solutions/ products/ services/ systems
	8.5	Presence of industry players
	8.6	Presence of insurers
	8.7	Role of insurers
	8.8	Market openness
	8.9	Market for patients
	8.10	Freedom of choice
	8.11	Market for commercial suppliers of eHealth services
	8.12	Business model of eHealth service provision
	8.13	Market for commercial suppliers of eHealth information systems
	8.14	Market for suppliers of Clinical Information Systems
	8.15	Market for suppliers of Secondary Usage Non-Clinical Systems
	8.16	Market for Telemedicine systems
	8.17	Market for suppliers of Integrated Health Clinical Information Networks
9. Capacity, Competence, Resources	9.1	Availability of training
	9.2	Quality of training
	9.3	Availability of budgetary resources
	9.4	Citizens' digital health literacy
10. Privacy, Security, Awareness	10.1	Regulation of privacy protection
	10.2	Extent of privacy protection
	10.3	Patient's control over privacy protection
	10.4	Use of Privacy Enhancing Technologies
11. Big Data, Internet of Things	11.1	Availability of Big/Open Data technologies
	11.2	Regulation of Big/Open Data, IoT in health sector
	11.3	Collection and processing of Big/Open Data
12. EU Cooperation	12.1	List of cooperation projects/initiative
13. Projects, Initiatives	13.1	Best practice exchange
	13.2	List of national eHealth projects
	13.3	Pipeline eHealth projects

3.1.2 Measurement method: scoring scales and computation of gaps

The data collection was conducted t through questionnaire-based interviews with key actors in eHealth development in each Partner Country (see the questionnaire sample in Figure 4 below).

Each indicator is formulated as a statement intended to underline a particular dimension of the EU baseline relevant to the Eastern Partnership context (Table 2).

Table 2. List of benchmark statements

Benchmark 1: Policies, Regulation, Leadership	There is sufficient legal clarity/certainty in your country regarding eHealth as evidenced by the existing policies, laws and other regulation that create an enabling environment to advance patient-centric interoperable healthcare services including via mobile technology
Benchmark 2: Governance, Institutions, Networks	Your country has established an effective, responsive and participatory governance system that includes a fully empowered government structure specifically working on eHealth working in coordination with other government bodies and cooperation with professional associations and networks
Benchmark 3: Infrastructure, Technology, Systems	Your country has built or is in the process of building a national health information system and related eHealth infrastructure -- fully or partially based on Open Standards -- that enables the provision of healthcare services for consumers (patients, health organisations/professionals) and creates an attractive market for commercial suppliers of eHealth information systems/solutions
Benchmark 4: Interoperability, Once-only Principle	Your country's eHealth policy aims at building interoperable and technologically compatible systems, solutions and services based on the benefits of the once-only principle to ensure that patients/health organisations do not supply the same information more than once
Benchmark 5: Innovation, Research	There is a national eHealth science and technology innovation policy/strategy/programme realised in cooperation through business partnerships to develop and commercialise eHealth products
Benchmark 6: Services, Progress	The eHealth system in your country is making strong and sustainable progress to offer an increasing number of patient-centric services
Benchmark 7: Maturity, Integration	eHealth policy in your country aims at connecting systems and services in new ways to support integration of care by sharing health information and care plans across diverse care teams for continuous collaboration
Benchmark 8: Economy, Business, Market	Your country has an increasingly attractive and sustainable market for commercial providers of (a) eHealth services for patients and (b) eHealth information systems for healthcare organisations
Benchmark 9: Capacity,	Your country has the up-to-date ongoing pre- and in-service training programmes of good quality in eHealth for health professionals supported by the state budget

Competence, Resources	
Benchmark 10: Privacy, Awareness, Security	The patient's electronic medical data are protected in your country by relevant legal and regulatory policies, as well as by applying the principle of privacy by-design and by-default in technology development
Benchmark 11: Big Data, Internet of Things	Your country's eHealth systems include the use of Big Data and Internet of Things (IoT) technologies to improve the accuracy of health data and the quality of health services
Benchmark 12: EU Cooperation	Your country has an ongoing cooperation with the EU in the field of eHealth
Benchmark 13: Projects, Initiatives	Your country's health professionals and organisations are aware of local and international best practices in eHealth thanks to the available system of knowledge management and exchange

The level of relevance is measured on a five-point scoring scale, which comprises the following answering options: (1) Strongly disagree; (2) Disagree; (2) Uncertain; (4) Agree; and (5) Strongly agree. The answer demonstrates the proximity of the national state of play in eHealth to the EU Baseline for the entire benchmark indicator. To help answering the benchmark indicator statements, the latter are broken down into more specific benchmark targets in the form of questions requiring definitive answers 'Yes', 'No' or 'Don't Know'. Answers 'Yes' had to be supported by concrete evidence recorded in the special box.

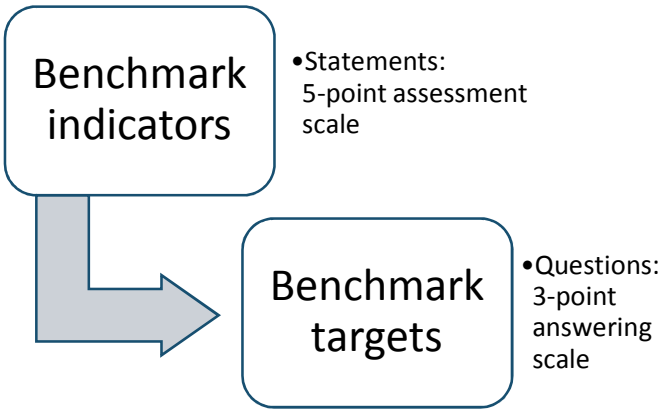


Figure 3. eHealth scoring system

If respondents were unable to provide a definitive answer 'Yes' or 'No' and preferred instead the option 'Don't know', they were invited to assess the likelihood of 'Yes' by answering the following question *Please check one box on a scale of 1 to 10, where 1 means 'Rather 'No'*

that ''Yes'' and 10 means 'Rather 'Yes' than 'No''; that is, the aim was to estimate whether there is still a possibility of 'Yes' according to the 10-point likelihood scale; as this was a personal opinion, no supporting evidence is needed.

The measurement was done by assigning scores to each answer according to the following assessment scales applied for benchmark indicators and targets (Tables 3, 4 and 5).

Table 3. System of scoring used for answers to opinion-based benchmark statements

Answer option to statements according to a 5-point scale	**Score – equivalent percentage of EU baseline (gap)**
(1) Strongly disagree	0%
(2) Disagree	25%
(2) Uncertain	50%
(4) Agree	75%
(5) Strongly agree	100%

As illustrated above, scoring is done by choosing on 0% to 100% likelihood scale meaning a degree of compliance with the EU baseline statement from "Strongly disagree" to "Strongly agree" for each benchmark. A "Strongly agree" response implies that the country is in line with the EU baseline benchmark and so scores 100% for the benchmark. A "Strongly disagree" response means that the country has no alignment with the EU baseline benchmark and so scores 0%. The assessment assumes choosing a score that is most appropriate to the status of a country on a particular benchmark, whilst the statement corresponds to the EU baseline level (objective or expected level).

For the fact-based questions, a three-point scoring scales was used implying a necessity to choose between three alternative answers 'Yes', 'No' or 'Don't know' (Table 4).

Table 4. System of scoring used for answers to fact-based benchmark questions

Answer option to questions according to a 3-point scale	**Score – equivalent percentage of EU baseline (gap)**
(1) Yes	100% = 1
(2) No	0% = nil
(2) Don't know	0% = nil

In the case of choosing the option 'Don't know', respondents were asked to clarify the hypothetical likelihood of 'Yes' (Table 5).

Table 5. System of scoring used for answers to opinion-based benchmark questions.

Answer option according to a 10-point likelihood scale from *1 to 10, where 1 means 'Rather 'No' that 'Yes'' and 10 means 'Rather 'Yes' than 'No''*	**Score – equivalent percentage of EU baseline (gap)**
Points (1) and (2)	-1 (as if answer No)
Points (3) and (4)	- 0.5
Points (5) and (6)	0
Points (7) and (8)	+ 0.5
Points (9) and (10)	+1 (as if answer Yes)

Note: In case the answer is 'Don't know' under Table 4.

The computation of gaps was done according to the following algorithm. Firstly, all answers 'Yes' (i.e. score = 1) were summed together based on all completed questionnaires for each benchmark question; if, for example, 5 completed questionnaires had 40 positive answers to 16 questions comprising the benchmark indicator 3 (Infrastructure, Technology, Systems – out of 80 possible for this indicator), the gap against the EU baseline was 50%. Secondly, this amount of 40 scores was further adjusted by the answers received in case of the "Don't know'

answering option using the scheme described in Table 5 (i.e., by way of either adding or subtracting scores equalled 0.5 and 1). As a result of such adjustment, the total number of scores became, for example, 35 (or 44% instead of the unadjusted 50%. Thirdly, this percentage was subsequently averaged (merged) with the percentage given to the opinion-based statements using a 5-point scale (see Table 3 above); for instance, if out of all five respondents, three marked the answer option 'Disagree' (25%), one respondent – gave 'Uncertain' (50%) and the third one answered 'Agree' (75%), the weighted average was 40%. And fourthly, that mean value was then combined as a simple average with 44% obtained from 40 answers 'Yes' to produce the final gap of 42% for the benchmark indicator number 3. All indicators were processed in the same manner. These results were further visualised with the help of select graphs. Figure 4 demonstrates a questionnaire design and the content sample (benchmark indicator 1 used as an example). All the completed questionnaires are annexed to this report.

Benchmark indicator 1: Policies, Regulation, Leadership

Answer options	Score				
	Strongly disagree	Disagree	Uncertain	Agree	Strongly agree
Enter your response (tick one score box only)	☐	☐	☐	☐	☐
Benchmark 1: Policies, Regulation, Leadership	There is sufficient legal clarity/certainty in your country regarding eHealth as evidenced by the existing policies, laws and other regulation that create an enabling environment to advance patient-centric interoperable healthcare services including via mobile technology				

Benchmark target 1.1: Strategy for eHealth

Does your country have a dedicated eHealth strategy/policy/programme or any other strategic document (including relevant action plans and/or implementation roadmaps)? If so, please specify in the Evidence & comment box below.

Yes ☐ No ☐ Don't know ☐

Please explain your answer:

If your answer is 'Don't know', please provide your personal assessment whether there is still a possibility of 'Yes' according to the following 10-point likelihood scale. *Please check one box on a scale of 1 to 10, where 1 means 'Rather 'No' that 'Yes'' and 10 means 'Rather 'Yes' than 'No''*

1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8 ☐ 9 ☐ 10 ☐

Figure 4. Questionnaire design and contents

3.1.3 Respondents and sources

The national experts in each Partner Country were responsible for identifying relevant institutions and respondents to be interviewed. While local circumstances varied from country to country, as a rule of thumb, it was advised that the following institutions and organisations are interviewed as the primary sources:

1. Ministry of Health Care or other cabinet-level body responsible for eHealth
2. Ministry responsible for broader e-Government policies and ICT infrastructure development
3. Local WHO and/or World Bank offices and other important international/bilateral donors providing aid assistance in eHealth
4. Professional associations/unions active in eHealth
5. Private sector software/application development companies active/interested in eHealth.

However, national experts were free to seek responses from additional actors so as to increase the number of questionnaires filled in for greater accuracy and validity. Since the number of fact-based questions to answer was substantial (80 target questions), national experts were advised to prefill the questionnaire wherever feasible with 'hard' facts by searching the internet and asking respondents to confirm or correct them (13 indicator statements were answered by respondents individually).

As many as 35 fully completed questionnaires with the fact-based questions were returned to the study team. In addition, several opinion-based questionnaires were also filled out (these were used as a source of additional information but were not included into computation). The organisations involved and interviewed were as follows:

- Armenia: Ministry of Healthcare; National Institute of Health; State Health Agency; Transparency International; eGovernance Infrastructure Implementation Unit -- EKENG CJSC; Masys Apahov LLC.
- Azerbaijan: Ministry of Healthcare; United Nations Population Fund – UNFPA; E&Y; Baku branch of M. Sechenov First Moscow State Medical University, Neuron Technologies LLC.
- Belarus: State Institution "Republican Scientific and Practical Centre for Medical Technologies, Informatisation, Administration and Management of Health" -- RSPC MT; Human Constanta Consulting Centre; Manpower-Belarus; Baltic Internet Policy Initiative; Infopark Association; Open Data Belarus; Ministry of Communications and informatisation; Institute of Economics of the National Academy of Sciences; BELISA; World Health Organisation (WHO).
- Georgia: Ministry of Labour, Health and Social Affairs; Data Exchange Agency (DEA) of

the Ministry of Justice; e-Government Unit of the Government Administration; National Centre for Disease Control and Public Health; MySoft LLC; Partners for Health NGO / Tbilisi State Medical University.

- Moldova: Ministry of Health; Ministry of ICT; Medical Emergency Institute; National Medical Insurance Company -- NMIC/CNAM; Association of Family Physicians; State University for Medicene and Pharmacy "N. Testemitanu"; National Centre for Health Management; Chisinau Municipal Public Health Centre; Netinfo SRL.
- Ukraine: Ministry of Health; World Health Organisation (WHO); Helsi Company; Network of People Living with HIV; State Agency for eGovernance.

4 RESULTS

4.1 Overview of the Region

4.1.1 State of play

The gap analysis demonstrates that despite certain differences that exist between the Partner Countries (one is, for example, the status of being associated with the EU in the case of Georgia, Moldova and Ukraine; the other is the level of socio-economic development), the actual difference in the eHealth state of play between them is far less obvious; that is, the countries are more alike than significantly different even though some counties fare better than others on some indicators. Figure 5 demonstrates that, overall, the patterns of the gap variance are quite similar for the Partner Countries.

For one, whereas no Partner Country has a clearly articulated and officially approved eHealth strategy aligned with the EU eHealth strategy, the topic of eHealth has become (rather recently) a policy priority; that is manifested in the World Bank's eHealth projects in Azerbaijan, Belarus, Ukraine (credit borrowing from the World Bank). Also, more typical than not, all the Partner Countries still have some sort of state policy which often looks like as a legacy "informatisation programme" of using ICTs in public institutions and sectors, including health care; such programmes are built on principles different from the EU (e.g. lack of interoperability, patient-centricity and respective services are not sufficiently prioritised while the role of hardware is largely overemphasised).

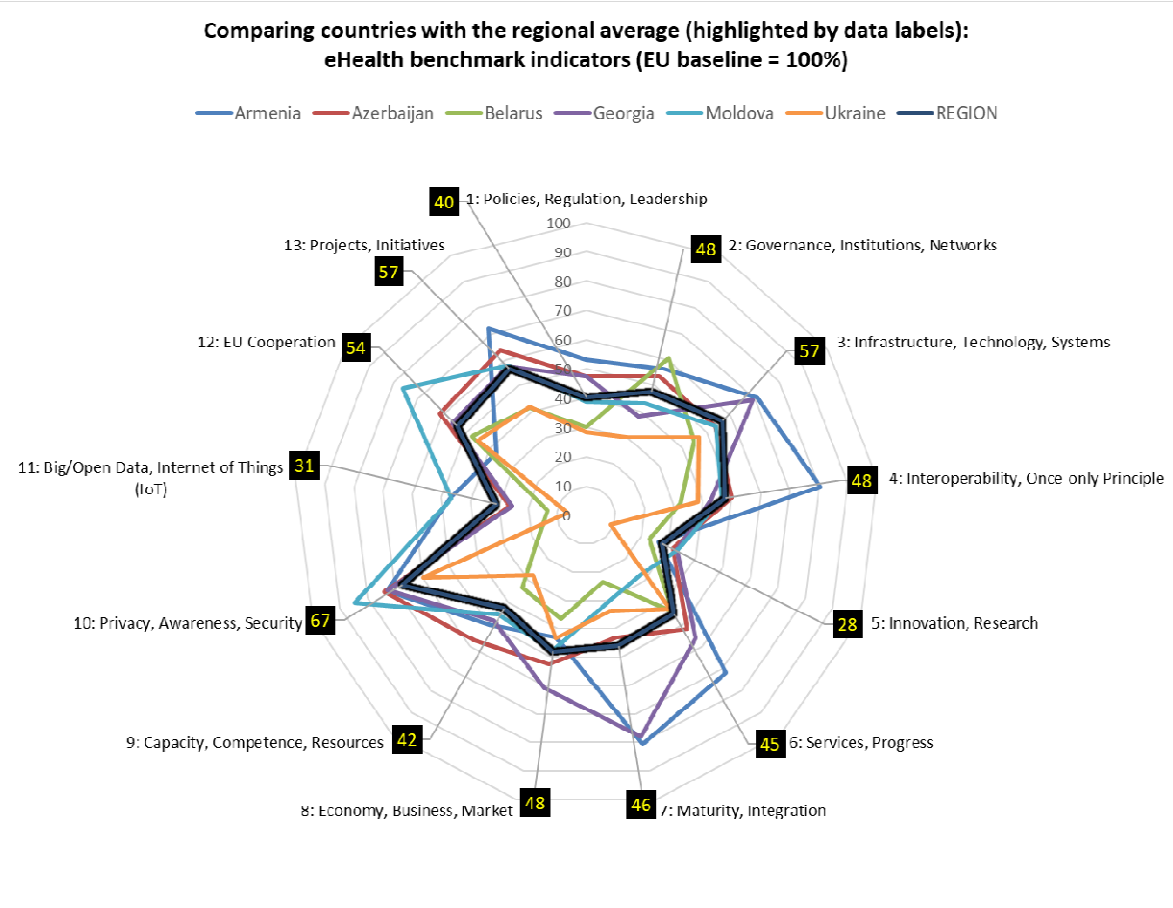


Figure 5. Country gaps against the regional average by main benchmark indicators

Another similarity is that when there is a clearer articulated eHealth strategy, it exists in a draft form, i.e. not officially approved which points at the lack of leadership to do so. In addition, all Partner Countries have experienced difficulties in implementing previous policies, which have failed to deliver the declared objectives and had to be overhauled, e.g. Ukraine. Ukraine stands out among other EaP Countries in terms of the currently scarce institutional capacity within the Health Ministry to advance eHealth agenda. In this light, civil society took the lead in setting the agenda by developing a regulation that provides legal definition of eHealth (the regulation awaits adoption by the Parliament) and performing de facto the government's function in this regard (temporarily until the government is ready to take over).

Another common feature is that all the countries have a significant number of disparate medical registries and data bases, especially the ones specialised on certain diseases. These were created quite long ago using now outdated software. There is little interoperability between

them; when medical data are exchanged, it is done on an ad-hoc basis (e.g. using inter-organisational MoUs). Whereas almost all Partner Countries apply to a different degree internationally available standards of eHealth interoperability (such as the Open HL7 standard protocols of exchanging medical information), no national eHealth interoperability frameworks exist. The EU standards are not used either. Cross-border services are absent as a result, also due to the lack of both legal (regulatory) clarity and operational (technical) opportunity to exchange medical data between countries; although, for example, cross-border interoperability is legally possible in Moldova.

This is also due to the absence of the functioning broader whole-of-government interoperability infrastructure and services from which eHealth could benefit. While such infrastructure is gradually emerging (e.g. Armenia, Azerbaijan, Georgia, Moldova, Ukraine), it is not clear whether eHealth sector will be part of it. At the moment, a sector-specific eHealth infrastructure and related corporate network remain a preferred choice. Almost all existing electronic medical registries and records require significant revision and upgrade to meet the new requirements of the Internet age (e.g. having APIs for building new services and applications). With the World Bank assistance, such upgrade is ongoing (e.g. in Azerbaijan, Ukraine, Belarus, Moldova) and the integration with the broader e-government interoperability infrastructure is planned or ongoing. Azerbaijan, for example, has implemented an Integrated Health Information System that relies on the whole-of-government interoperability infrastructure built under the aegis of the Ministry of Communications and High Technologies and is linked to the eHealth portal.

The lack of the full-fledged interoperability prevents the development of patient-oriented records and services. For example, while ePrescriptions are planned in all the six countries, in real life this service is available in few countries (Belarus and Georgia, with other countries planning to do so) on a limited scale being still in a test phase. Yet, it is obvious that sooner than later such a service will become available as one of many requirements for personalised integrated health and social care services.

Patient portals are available in Armenia, Azerbaijan and Georgia (although in the latter it is not operational at the moment); health-related services are provided via the national e-government portals (yet a lot of such services are more informational rather than functional in nature); the functioning systems for patent consultation are lacking as well.

Personal medical data and records are protected by more general Personal Data Protection Laws (in Moldova, for example, there are direct references to the protection of medical data too).

It is normal that to view and exchange personal data, one needs to obtain patients' consent (except Belarus which does not have a dedicated law on personal data protection, for the provisions to protect such data are part of the Informatisation Law).

Ministries of health usually lead the eHealth agenda but their capacities are limited unless there is a dedicated institution in charge of eHealth. Overall, whilst there is some training on eHealth issues, it is fragmented and not systematic and is often part of the ongoing projects (e.g. the World Bank) but the quality of training is unclear. There are no mechanisms and tools for best practice and experience exchange. Activities aimed at increasing citizens' literacy in digital health are virtually absent. eHealth markets exist and are open in all the countries, with main industry players (both local and international) being present; however, for smaller countries it is harder to maintain the market attractiveness and competitiveness. Hence, the economic benefits of eHealth services are not sufficiently understood.

Research into eHealth innovation, including the practice of procurement of eHealth innovation, is almost non-existent or small in scope and scale, partly as consequence of fragmented data and information sources. The potential of Big/Open Data and Internet of Things technologies is not exploited although some data are being collected (but the analytical capacity to process them is weak). Existing cooperation with the EU is scarce and sporadic.

The role of professional associations and networks in advancing eHealth is weak as well, just as the engagement of business community (which is seen rather as a vendor and software provider). Yet Ukraine has demonstrated recently that the role of such non-governmental stakeholders can be highly important and effective.

4.1.2 Gap analysis

Figures 5 above and 6 below demonstrate that on average the gap with the EU is around 50% ranging from 60-70% in 5. Innovation, Research; 11. Big Data, Internet of Things; 1. Policies, Regulation; 9. Capacity, Competence, Resources and dropping to 30-40% in 13. Projects, Initiatives; 3. Infrastructure, Technology, Systems; 10. Privacy, Awareness, Security.

Viewed from the perspective of benchmark targets (rather than aggregated composite indices), the gaps are most evident in eHealth business models, Voluntary eHealth systems/services, Patient Consultation Systems/Services, Citizens' eHealth Literacy, ePrescription, Best Practice exchange, eHealth Cross-border Services, Patient Portal, Big Data and eHealth Business Models of Patient Service Suppliers where the gap is over 60% (Figure 7). Smaller gaps – less

than 30% -- are observed in Ongoing and Future eHealth Projects/Initiatives; Patients' Control over their eHealth Privacy; Commercial Suppliers of Health Information Systems; Electronic Health Records/Medical Registries; eHealth Dedicated Institutions.

Figures 8 through 11 presenting the gaps within those particular benchmark indicators that are especially important for the EU baseline, such as general and cross-border interoperability, availability of medical information/registers, ePrescriptions. These figures suggest that while all the Partner Countries have various medical information systems, as well as health records (to a lesser extent), already in place, there is no distinction between primary, secondary and tertiary levels is absent. Overall, the regulation of health information is not advanced (Figure 8). Whilst, as mentioned, some sort of ad-hoc eHealth interoperability is being built (sector-specific rather than government-wide) and the gaps are smaller (see left-hand side of the radar chart in Figure 9), the cross-border gaps are far wider (the upper and right-hand side). Figures 10 and 11 are the case in point to reaffirm this conclusion arguing that even though the ePrescription service is emerging, it does not cover the entire country and health institutions and is not interoperable across borders.

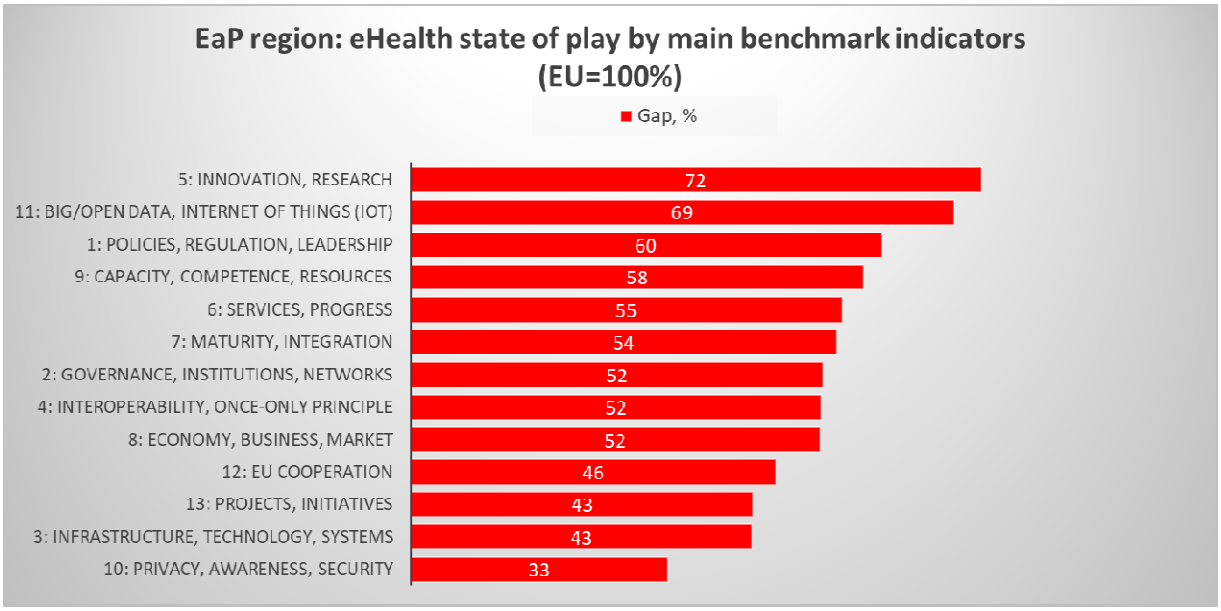


Figure 6. Gaps assessment of the EaP region by main benchmark indicators

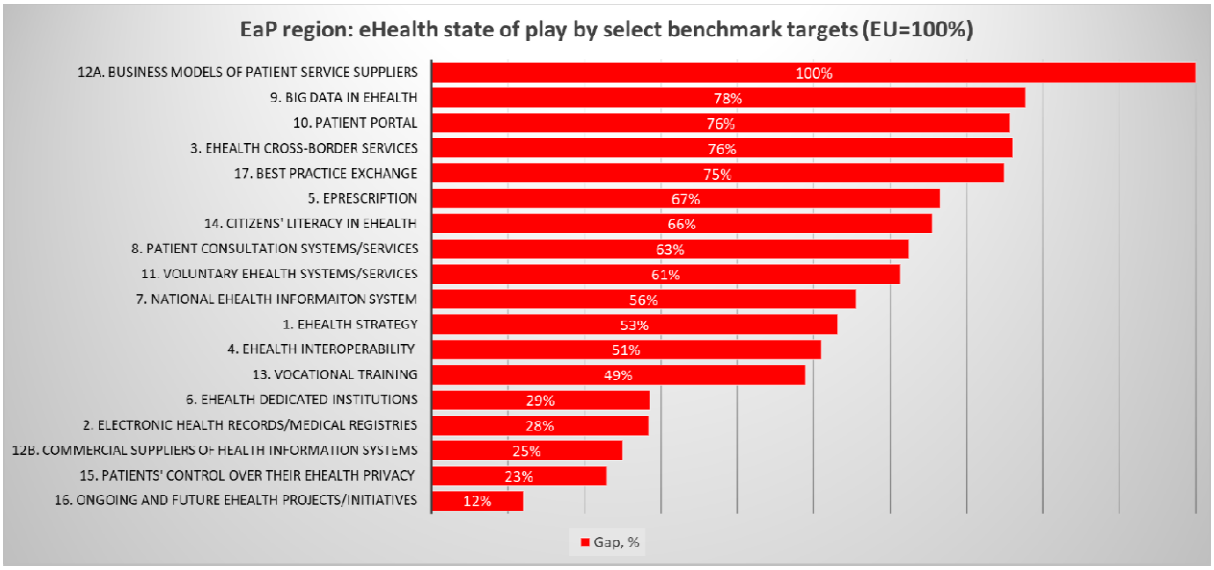


Figure 7. Gap assessment of the EaP region by specific benchmark targets

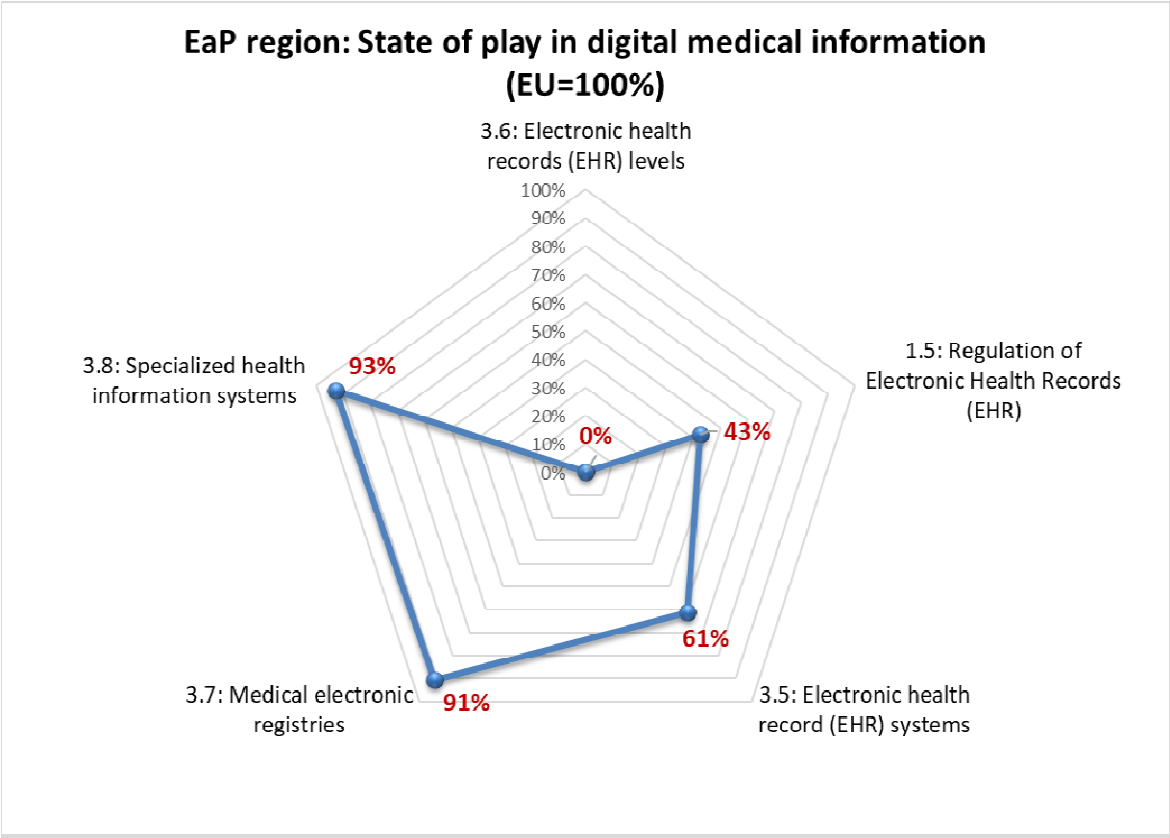


Figure 8. Gap assessment of the EaP region in digital health data.

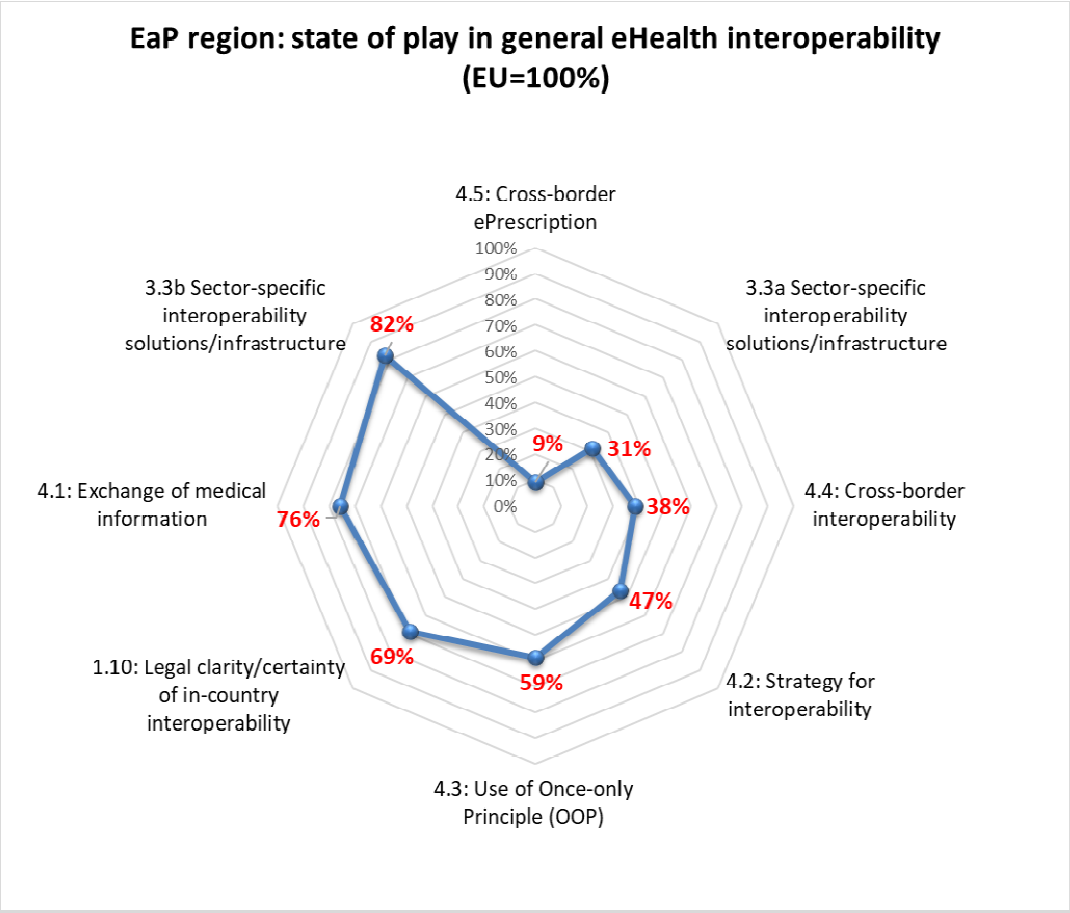


Figure 9. Gap assessment of the EaP region in eHealth interoperability

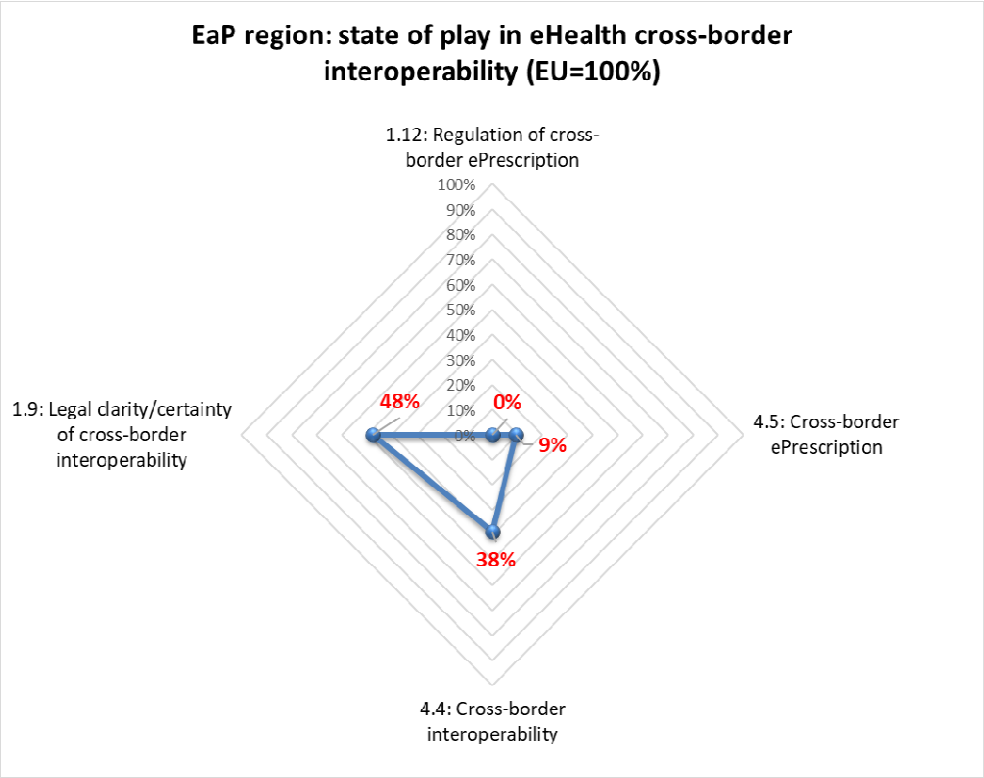


Figure 10. Gap assessment of the EaP region in cross-border eHealth interoperability.

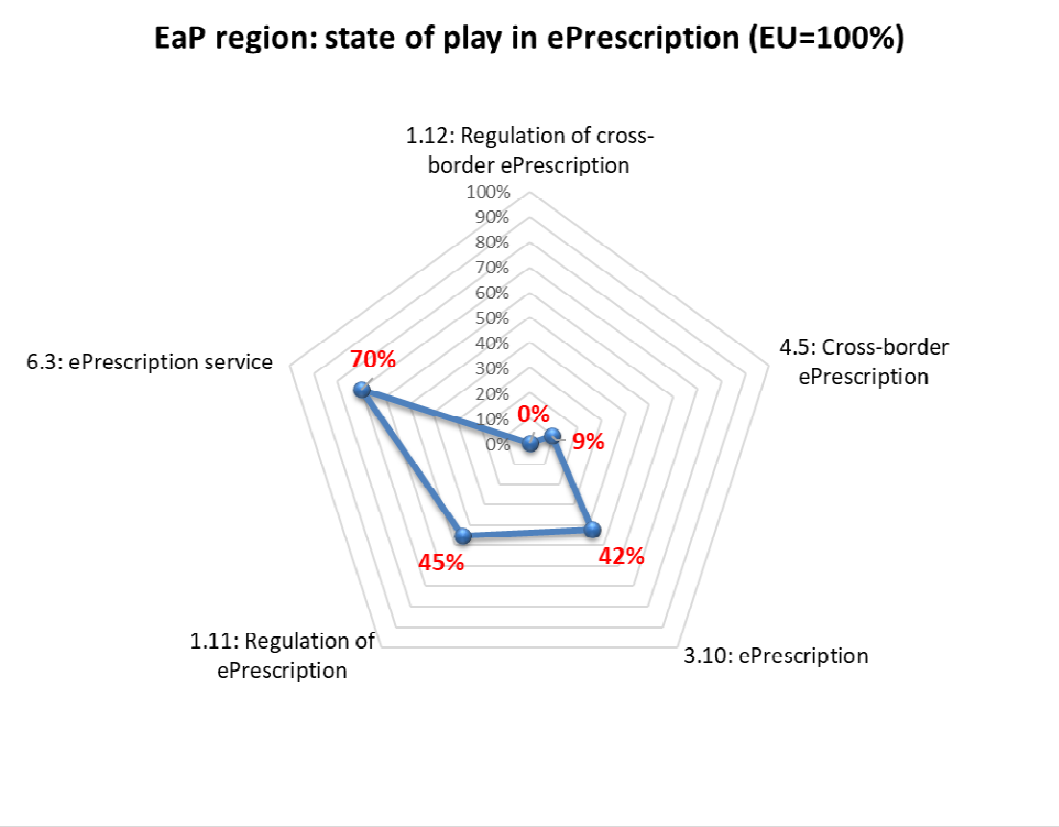


Figure 11. Gap assessment of the EaP region in ePrescription.

4.1.3 Gap mapping

A deeper gap mapping exercise has been performed to better understand which eHealth areas are common, partially common and country-unique. Tables 6 and 7 present the outcome of such mapping benchmark indicator measured through a 20% increment scale with each increment range individually coloured to visualise differences and commonalities better among the countries. Such a mapping has helped better understand which eHealth areas are common, partially common and country-unique. The gap between 40 and 80% is the most common for the region. The data demonstrate that the largest gap over 60% is typical for just one area, namely: *for (5) Innovation, Research*. All EaP Countries experience the gap over 40% in two areas: in *(1) Policies, Regulation* and in *(9) Capacity, Competence, Resources*. As many as five countries show the gap of over 40% in five areas: in *(2) Governance, Institutions, Networks* (except Belarus), *(4) Interoperability, Once-Only Principle* (except Armenia), *(6) Services, Progress* (except Armenia), *(8) Economy, Business, Market* (except Georgia) and (*11) Big/Open*

Data, IoT (except Armenia). These eHealth areas qualify for the category of the most common harmonisation projects at the regional level, i.e. the region-wide harmonisation level.

The sub-regional harmonisation level with the gap of over 40% is typically represented by four countries and includes such areas as *(3) Infrastructure, Technology, Systems* (except Armenia and Georgia), (*7) Maturity, Integration* (except Armenia and Georgia), *(12) EU Cooperation* except Azerbaijan and Moldova) and (*13) Projects, Initiatives* (except Armenia and Azerbaijan). The country-unique harmonisation level covers one area of (*10) Privacy, Awareness, Security* where Belarus demonstrates the largest gap of over 60% while for other countries the gap does not exceed 40% (and less than 20% for Moldova). These groups and areas demonstrate that the need for harmonisation can be best addressed at the regional and sub-regional levels. Thus, the most impactful effect from harmonisation would be felt at the level of the whole region and, hence, the proposed actions cover all EaP countries.

Table 6. Gap mapping matrix

Benchmark indicators	Armenia					Azerbaijan					Belarus					Georgia					Moldova					Ukraine					REGION				
	0-20%	21-40%	41-60%	61-80%	81-100%	0-20%	21-40%	41-60%	61-80%	81-100%	0-20%	21-40%	41-60%	61-80%	81-100%	0-20%	21-40%	41-60%	61-80%	81-100%	0-20%	21-40%	41-60%	61-80%	81-100%	0-20%	21-40%	41-60%	61-80%	81-100%	0-20%	21-40%	41-60%	61-80%	81-100%
1. Policies, Regulation, Leadership			1					1						1				1						1					1		0	0	3	3	0
2. Governance, Institutions, Networks			1					1				1							1				1						1		0	1	3	2	0
3. Infrastructure, Technology, Systems		1						1					1				1						1					1			0	2	4	0	0
4. Interoperability, Once-only Principle	1							1						1				1					1						1		1	0	3	2	0
5. Innovation, Research				1					1					1					1					1					1		0	0	0	6	0
6. Services, Progress		1						1					1					1						1				1			0	1	4	1	0
7. Maturity, Integration	1							1						1			1							1					1		1	1	1	3	0
8. Economy, Business, Market			1					1						1			1						1					1			0	1	4	1	0
9. Capacity, Competence, Resources			1					1						1				1					1						1		0	0	4	2	0
10. Privacy, Awareness, Security		1					1								1		1				1						1				1	4	0	0	1
11. Big/Open Data, IoT			1						1						1				1				1						1		0	0	2	3	1
12. EU Cooperation				1			1						1					1				1						1			0	2	3	1	0
13. Projects, Initiatives		1					1						1					1					1					1			0	2	4	0	0
																																3	**14**	**35**	**24**	**2**

Tables 7 and 8 below group countries in relation to the main aggregated gap ranges and harmonisation levels.

Table 7. Country groupings by gap range

Benchmark indicator	Gap		
	over 60%	**40-60%**	**20-40%**
1. Policies, Regulation	Belarus Moldova Ukraine	Armenia Azerbaijan Georgia	
2. Governance, Institutions, Networks	Georgia Ukraine	Armenia Azerbaijan Moldova	Belarus
3. Infrastructure, Technology, Systems		Azerbaijan Belarus Moldova Ukraine	Armenia Georgia
4. Interoperability, Once-only Principle	Belarus Ukraine	Azerbaijan Moldova Georgia	Armenia
5. Innovation, Research	Armenia Azerbaijan Belarus Georgia Ukraine Moldova		
6. Services, Progress	Moldova	Azerbaijan Georgia Belarus Ukraine	Armenia
7. Maturity, Integration	Belarus Moldova Ukraine	Azerbaijan	Armenia Georgia
8. Economy, Business, Market	Belarus	Armenia Azerbaijan Moldova Ukraine	Georgia
9. Capacity, Competence, Resources	Belarus Ukraine	Armenia Azerbaijan Georgia Moldova	
10. Privacy, Awareness, Security	Belarus		Armenia Azerbaijan Georgia Moldova Ukraine
11. Big Data, Internet of Things	Azerbaijan Belarus Georgia	Moldova	Armenia

	Ukraine		
12. EU Cooperation	Armenia	Belarus Georgia Ukraine	Azerbaijan Moldova
13. Projects, Initiatives		Belarus Georgia Moldova Ukraine	Azerbaijan Armenia

Table 8. Country groupings by harmonisation level (gap is over 40%).

Indicators	Countries
Common regional level 1: 5-6 countries	
1. Policies, Regulation 2. Governance, Institutions, Networks 4. Interoperability, Once-only Principle 5. Innovation, Research 6. Services, Progress 8. Economy, Business, Market 9. Capacity, Competence, Resources 11. Big Data, Internet of Things	Armenia Azerbaijan Belarus Georgia Moldova Ukraine
Sub-regional level 2: 2-4 countries	
3. Infrastructure, Technology, Systems; 7. Maturity, Integration	Azerbaijan Belarus Moldova Ukraine
12. EU Cooperation	Armenia Belarus Georgia Ukraine
13. Projects, Initiatives	Belarus Moldova Georgia Ukraine
Country-specific level 3: 1 country	
10. Privacy, Awareness, Security	Belarus

The gap analysis data demonstrate that future support projects would be most relevant at the common regional harmonisation level involving all countries in almost each eHealth area. Additional assistance could be provided at the sub-regional level to Azerbaijan, Belarus, Moldova and Ukraine in the field eHealth infrastructure and systems, while Belarus would need special support in protecting patient's privacy and control over personal medical information in line with EU regulation and practice. This mapping confirms the conclusion made during the

state of play analysis that the Partner Countries' eHealth needs are quite similar despite some contextual variations. In this light, the harmonisation initiatives and respective roadmaps should aim at the entire region across the board at least at the first phase of harmonisation. A certain intra-regional coordination mechanism should be established to ensure that the EU assistance -- provided via the European Commission's cooperation instruments and by individual Member States – benefits all the Partner Countries for greater impacts and multiplying effects. It is proposed that the regional eHealth Network is empowered as a coordination and facilitation body. Applying a coordinated regional approach would not preclude assistance provided to individual countries in parallel according to their special needs.

4.1.4 Common benefits of harmonisation with the EU

The study has identified several common for all EaP Countries benefits of harmonisation with EU in eHealth, such as:

- More personalised citizen-centric healthcare, more targeted, effective and efficient. Improved access to health information and to quality healthcare and high-performance services. Increasing the quality and effectiveness of communication between physicians and patients.
- Ease the work of doctors of all categories and increased efficiency of their activity. Patient empowerment through greater transparency, improved access to services and information connecting electronic registries. Rolling out ePrescription systems, etc. Medical institutions will benefit from increased service quality, minimisation of time and costs for provision of medical services through process automation and re-engineering and optimisation of referral procedures (reference system).
- Active contribution of all stakeholders to create new level of medicine in the country and ensure the enhanced level of services and communication between medical doctors and patient.
- More services for citizens, on-line programming for visits to doctor, telemedicine services in remote areas, use of ePrescription, etc. overcoming financial challenges to control overall healthcare spending.
- Increased number of young professional in responsible positions, accelerate implementation of new ICT technology based services. Improved well-being and mobility the ageing population.

- Improved communications between professionals. More efficient and fast diagnostics and patients service.
- Efficient use of invested resources (for example, once started and resources spent, projects have to be successfully finalised in spite of changes of personal involved).
- The Strategy will serve as main guide for 5-10 years in eHealth projects implementation including development partner assistance programs and projects formulation and financing, improving the health services.
- Facilitating cross-border and cross-country medical services enhancing the possibilities for patient to use EU and Partner Countries' facilities when necessary, exchanging interoperable electronic health record among health organisations within the country and across borders establishing electronic health records, patient summaries.
- Knowledgeable professionals supporting implementation of new eHealth technologies and services, wide awareness and training campaign among the elderly.

4.2 Overview of the Partner Countries

4.2.1 Armenia

State of play

Armenia has made a strong and sustainable progress over the past 3-5 years in providing patient-centric eHealth services. Armenian eHealth sector offers a number of services that can be voluntarily used across the country's healthcare, such as searching online for doctors or medical institution on a map, as well as making online appointments. With regard to the available mandatory services, the Ministry of Healthcare is in the process of developing and approving relevant regulation; for example, the mandatory use of eHealth solutions as a licensing requirement. As many as 470 medical institutions that provide medical services financed by the Ministry, are obliged (through contracts) to register medical records in the national eHealth system (as an example of using a mandatory service).

The country has an ongoing national eHealth programme approved by the government in November 2016, along with a respective implementation roadmap (this covers telemedicine and mHealth as well). The programme is top government priority for 2018-2022. It is expected that after the pre-implementation period – that included training medical and administrative staff, creating an enabling legal and regulatory environment and building a dedicated IT infrastructure – the programme will include all medical institutions by the end of 2017. The active

implementation is evidenced by the steady rise of the system's users whose number exceeds several thousand daily. There is a functioning portal for patients[66] to provide them eHealth services from one place.

Armenia has a law that protects personal data which also applies to personal medical information. While the Law on Medical Care and Service Provision to Population contains a section on privacy of medical data, it does not state any special requirements for eHealth-related data protection. The respective operating legal and regulatory acts need to be changed to reflect upon specific eHealth processes and demands that are already included into the national eHealth programme. In addition, Privacy Enhancing Technologies (PETs) are used to enhance medical information; e.g. it is required that the TORs for software development contain special references on privacy protection when contracting companies for developing related software. The national eHealth programme also includes a provision that allows for exchanging patients' health records. There is no legal act allowing the exchange of medical data with other countries. Medical institutions and health professionals have access to patients' Electronic Health Records (EHR) under condition of their consent to view and/or exchange personal medical information. These conditions are implemented in the eHealth national programme. Patients have the power to close their medical information from viewing and exchanging. In August 2017, the government designated an e-Health official operator to deal with these and other issues. The operator is operational since 1 September 2017. Also, in August 2017, the government introduced new changes in the licensing regime (will enter into force in early 2018) which will subject all the medical information about the patient, including EHRs, to mandatory registration with the eHealth operator.

ePrescription-specific regulation awaits government approval; at the moment, it is not possible to exchange prescriptions across borders.

There are no dedicated policies governing the problem of population ageing. Also, the policies that regulate the procurement of eHealth innovations to encourage the supply of new medical products, raise scalability and interoperability of effective eHealth solutions according to defined standards and common guidelines are lacking.

[66] www.armed.am.

There are no specialised eHealth associations/networks comprising healthcare providers and professionals. The Ministry of Health is the chief government institution responsible for eHealth in the country. It has enough power and authority to coordinate with all other stakeholders. The State Health Agency of the Ministry of Healthcare specifically oversees and funds eHealth services and medical records for further use by hospitals.

Armenia has a functioning national health information system as a common platform integrating other information systems developed by health organisations to exchange data among the professional care organisations. eHealth interoperability is enabled by the application of the Open HL7 standard protocols (ISO 13940). The platform will be used to enable data exchanges also between care organisations and their patients. Whilst the country continues developing its electronic health record system, it does not distinguish as yet between the (a) primary care facilities, (b) secondary care facilities, (c) tertiary care facilities. There are functioning health information systems and registries, e.g. in the area of HIV/AIDS. Patient consultation systems is going to be launched in 2018, just as an ePrescription system.

The country does not have a dedicated (state-funded) national research and development/science & technology programme in eHealth. Participation in international research projects, including with the EU is limited. There is no ongoing practice or schemes that involves business partnerships to support eHealth research and innovation.

There are no specific functioning eHealth/mHealth business models in the country, although Armenia has a strong presence of eHealth industry. It has well-developed, open and attractive market for IT companies that could have interest in developing eHealth services and solutions. However, the eHealth market does not include a similarly strong presence of insurance companies. Whereas they do not play a pivotal role in eHealth (since there is no compulsory medical insurance), insurance companies will be included in eHealth system as users still in 2017.

The role of commercial suppliers of eHealth information systems for healthcare organisations is limited. There is no market for commercial suppliers delivering Clinical Information Systems (CIS), Secondary Usage Non-Clinical Systems, Telemedicine systems, Integrated Health Clinical Information Networks (IHCIN).

Armenia has both pre-service and in-service training programmes for health professionals on the use of ICT in health care. The quality of the training is adequate. However, citizens' digital health literacy in health issues is weak.

Local trainings and workshops is the main vehicle of exchanging experience and learning from one another in eHealth. There is online training organised by the Ministry of Health in 2017 for health professionals. One of the main indicators of training and dissemination efficiency is that the volume of state funded medical services registered on the national eHealth system has grown significantly over a short period of time since May 2017. Yet there is no system to collect and disseminate international eHealth best practices.

Table 9. Organisations/institutions involved in eHealth development in Armenia

eHealth Organisations, Institutions	Level of involvement (H - for High, M - for Medium, L - for Low)						Description	Key functions per eHealth domains	Contact details (web site, officials)
	Training	Policy	Strategy	Technology	Executive	Innovation			
Organisation 1 (Ministry of Healthcare)	**H**	**H**	**H**	**H**	**H**	**H**	MOH is the governmental main body responsible for the overall governance of the health sector.	Acts as the main centre for leading the development of the e-health system, organisation of trainings, development of all related policy documents and regulations, monitors the process of integration of e-health into the country's health system.	www.moh.am
Organisation 2 (RA MOH National Institute of Health)	**M**	**M**	**M**	**L**	**L**	**L**	NIH is a MOH related agency, which is responsible for policy and strategy development, health care data gathering and analysis, and conducting programs on continuous	The NIH participates in the development of strategies and policies related to e-health. It also is the entity, which will analyse and make recommendations based on health care data provided by e-health.	www.nih.am

							professional development.		
Organisation 3 (EKENG CJSC)	**L**	**M**	**M**	**M**	**M**	**M**	**EKENG CJSC** is the coordinator of e-government projects in the Republic of Armenia. The company was founded by the Government of the Republic of Armenia on behalf of the Republic of Armenia.	Responsible for eHealth system purchasing process, testing and piloting the system, developing roadmap.	www.ekeng.am

Table 10. List of the key policies, regulations, strategies, laws relevant to eHealth in Armenia

Title and date	Brief description
Government Program 2018-2022, June 19, 2017	It is the government's plan of actions and main goals for next five years; it covers all spheres of governance including health care.
Government of Armenia's Plan of Actions and Priorities for 2017, January 12, 2017	It is the government's plan of actions and main priorities for the year of 2017. Covers main spheres of governance including the health care.
Law of RA on protection of personal data, June 13, 2015	States the rules concerning to personal information protection including medical information.
Law on Medical Assistance and Service to the Population, March 4, 1996	This Law establishes the legal, economic and financial grounds for organizing medical assistance and service that ensure the exercise of the constitutional right of a person to health care.

Gap analysis

As Figure 12 demonstrates, Armenia scores well across most of the benchmark indicators, especially in (3) Infrastructure, Technology, Systems; (6) Services, Progress; (13) Projects, Initiatives; (10) Privacy, Awareness, Security; (4) Interoperability/Once-only Principle where the gap with the EU baseline is the smallest (does not exceed 20-30%). The country also fares relatively well in developing eHealth policies and building capacities of participating medical institutions by improving their governance, promoting networking and increasing the adequate resource base (1) Policies, Regulation; 2. Governance, Institutions, Networks; (9) Capacity, Competence, Resources), where the gap – while substantial – does not exceed 50%. The

largest gaps revealed by the study concern eHealth economy and business, as well as in using the potential of Big Data to build new business models and harnessing the innovation offered by the Internet of Things technologies. Overall, eHealth research, including through cooperation with the EU, are the weakest.

As mentioned earlier, in comparison with the region, Armenia performs better along the most benchmark indicators lagging behind only in the area of cooperation with the EU and eHealth market development (Figure 13).

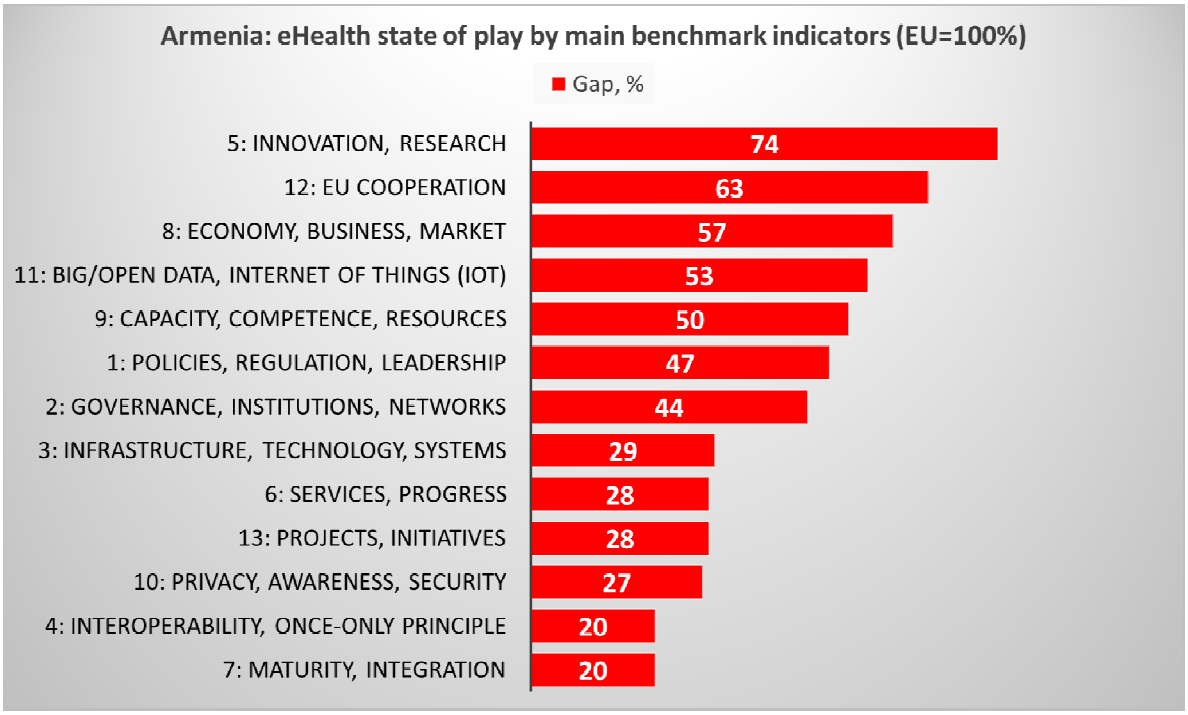


Figure 12. Armenia eHealth: gaps against EU baseline

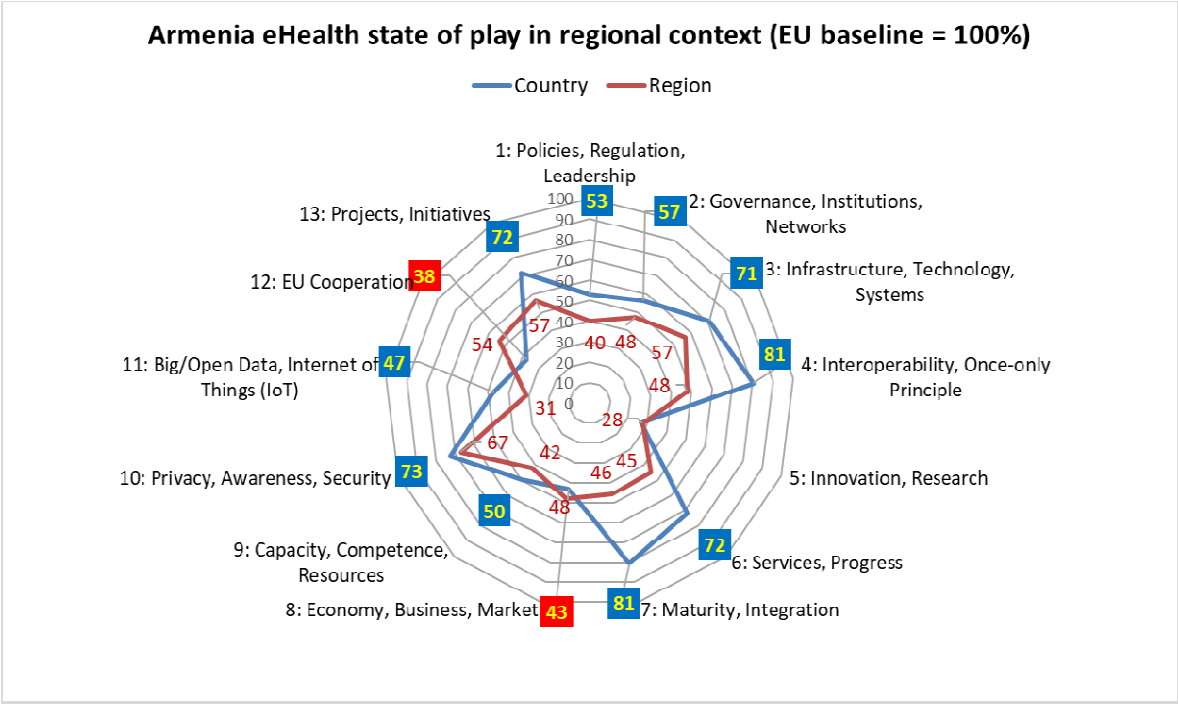


Figure 13. Armenia eHealth compared with the EaP regional average

4.2.2 Azerbaijan

State of play

Azerbaijan has implemented an Integrated Health Information System that relies on the whole-of-government interoperability infrastructure build under the aegis of the Ministry of Communications and High Technologies.[67] The eHealth portal[68] offers 39 e-services including 8 for medical staff, 15 for businesses and 8 for citizens, patients can make appointments and manage information stored on their eID cards. It is integrated with the national interoperability system; the once-only principle is applied. Patient's medical information is exchanged between government agencies such as the Ministry of Internal Affairs (eID card requests) and Ministry of Justice (new-borns and birth certificates). Also, there is a communication system between the Ministry of Health and the Ministry of Emergencies for emergency situations (must be enacted

[67] www.e-gov.az.

[68] http://www.e-health.gov.az/.

by the special order of the Cabinet of Ministers). The extent and volume of such exchanges is unclear.

In 2011, Azerbaijan has launched a (World Bank supported) Health Sector Reform Project which included the development of a strategy concept for creating an Integrated Health Information System. The latter includes such information systems as

- Citizen's eID health card system[69]
- Hospital management information system
- Infectious diseases system
- Blood bank system
- Hospital activity monitoring system (connects 468 medical institutions, including private)
- Ambulance dispatcher service system
- Personnel management system
- Medical certificates register
- Electronic medical registers

The eID health card contains the following information: visits, immunisation, diagnoses, surgeries, tests, prescribed medication (over 100,000 patients eligible for the state-subsidised medication are registered in the system). The hospital management information system that covers all medical institution's activities has been tested in 16 hospitals and one polyclinic. Medical examination eID card-based system (linked to health insurers) is connected to 76 hygiene and epidemiology centres and 95 medical examination cabinets (such cards have been given to over 300,000 citizens).

Azerbaijan has a number of strategic policy documents that support the development of digital society and economy in the country namely: national information society strategy 2014-2020 (approved by President's decision № 359 of 02 April 2014 along with the respective implementation action plan of 20 September 2016); the Government's decision №191 of 24. November 2011 regarding the provision of e-services); roadmaps for the economy's key sectors

[69] (http://e-health.gov.az/en/s/12/Electronic+Health+Card+System+of+Citizens.

(approved by Presidents' decree №1138 of 06 December 2016) including health care sector.[70] In the absence of a stand-alone national eHealth strategy, the Integrated Health Information System Concept Strategy serves at the moment as such a strategy. It includes several sub-systems on patients' health cards, medical examination, personal, hospital and drug management, blood bank.

The law On the Protection of Population's Health (2013) contains provisions in article 53 that grant citizens the right to allow or not to allow health professionals viewing and exchanging their personal medical information. Patients – via the patient portal[71] – have access to their electronic medical records (it is not clear though whether or not patients have the power to close such data from viewing/exchanging). Patient's electronic health records are regulated by the government decision №143 of 12 June 2006 on Health Electronic Cards. Such records cover health institutions at local and central levels (information is stored in centralised data bases). All information systems of the Ministry of Health send data to the centralised data base in real time (online). There are several medical e-registries for different categories of patients diagnosed with tuberculosis, chronic kidney disease kidney diseases, diabetics, thalassemia diabetes, hemophilia, as well as dedicated registries for the pregnant, medical personnel, blood donors.

The level of citizens' digital literacy is unclear (e.g. people may not be aware of their privacy protection rights in relation to their personal medical information). No dedicated policies exist to address the active and healthy ageing.

ePrescription service is regulated by the health sector roadmap of 2016 of 06 December 2016. There is a special module called Pharmacy within the drug management information system that enables issuing electronic prescriptions for patients diagnosed with diabetes only; prescribing medication online is planned in the future. Exchange of ePrescriptions with other countries is not available.

The eHealth market is open for all local and international vendors which play an important role (e.g. Siemens, GE). Overall, the market is occupied by the providers of Clinical Information

[70] More is here No.5: http://e-qanun.az/framework/25321, No.9: http://e-qanun.az/framework/25539, No.25: http://e-qanun.az/framework/26307, No.35: http://e-qanun.az/framework/27102, No.24/3: http://e-qanun.az/framework/27888

[71] www.e-sehiyye.gov.az.

System (CIS) and telemedicine systems. A number of eHealth business models have been implemented by the private sector, such as Mediclub, SOS, Grand City Hospital, Turkish-American Hospital. As the government established in 2016 a special agency for the development of mandatory medical insurance, the role of insurers may increase in future.

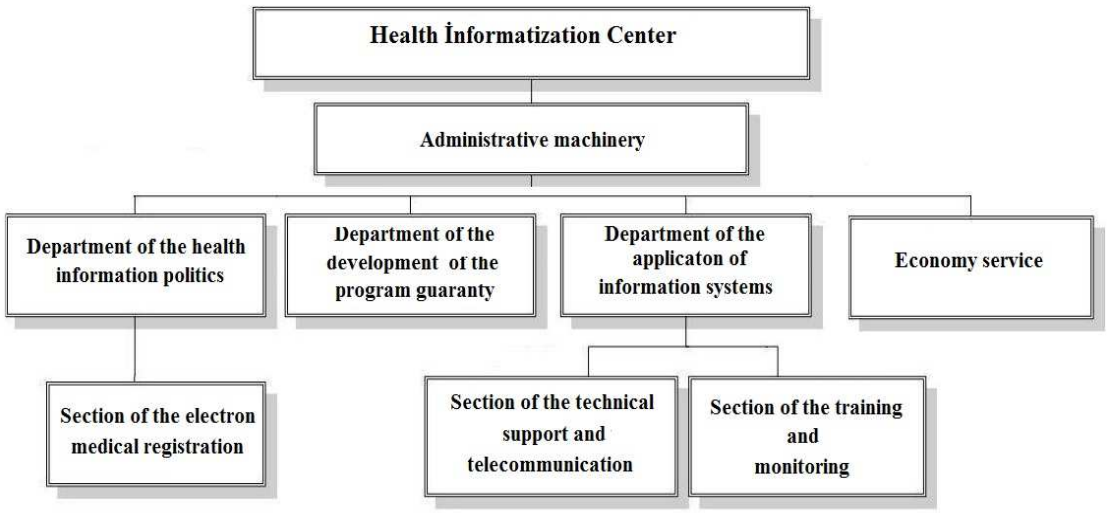
There is a state-funded training programme for medical professionals and students addressing, for example, a history of eHealth evolution and the use of new technologies. The Ministry of Health also cooperates with international organisations, including the UN (UNICEF, WHO, UNFPA, UNHCR) in capacity building.

Ministry of Health and the Centre for Healthcare Informatisation are key government institutions responsible for policy making in eHealth. The latter undertakes inter-agency coordination in consultation with the Ministry. The organisational structure is presented in Box 4 below.

Gap analysis

In general, the level of eHealth development in Azerbaijan is around 50% of the EU baseline measured against most benchmark indicators (see Figure 14). The smallest gap is observed in the area of (10) Privacy, Awareness, Security) where the country's legal and regulatory environment is sufficiently clear; the largest gaps are observed in (11) Big Data, Internet of Things and (5) Innovation, Research. The country fairs slightly better than the region, especially in (9) Capacity, Competence, Resources; (1) Policies, Regulation; (2) Governance, Institutions, Networks; (10) Privacy, Awareness, Security repeating generally the regional gap pattern (Figure 15). The country represents well the regional average indicators (except, indicators (11) Big Data, Internet of Things; (3) Infrastructure, Technology, Systems; and (7) Maturity, Integration, although the gap here is just few percentage points below respective regional trends)). The Experience Demonstration Box 4 describes the country's eHealth organisational structure.

Experience Demonstration Box 4. Azerbaijan: Institutional organisation of eHealth governance structure.



Source: Presentation of Emin Ismayilov at EU4Digital: eHealth, 1st Workshop, 20-21 February 2017, Tbilisi, Georgia

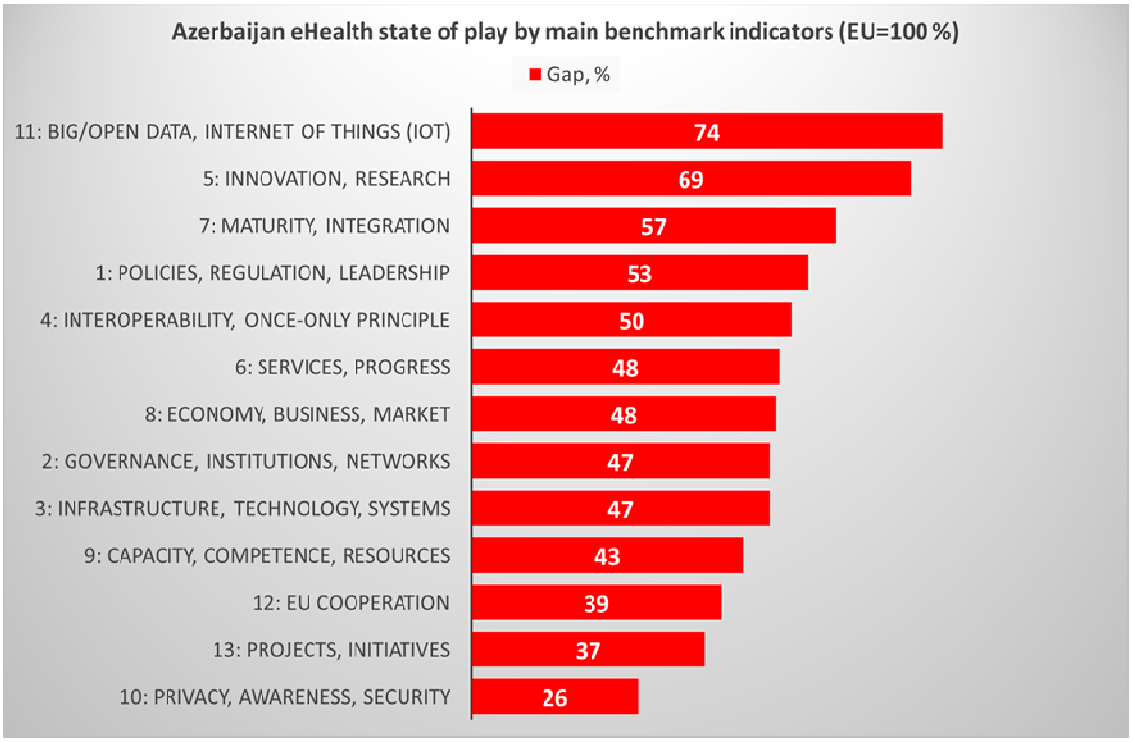


Figure 14. Azerbaijan eHealth: gaps against EU baseline

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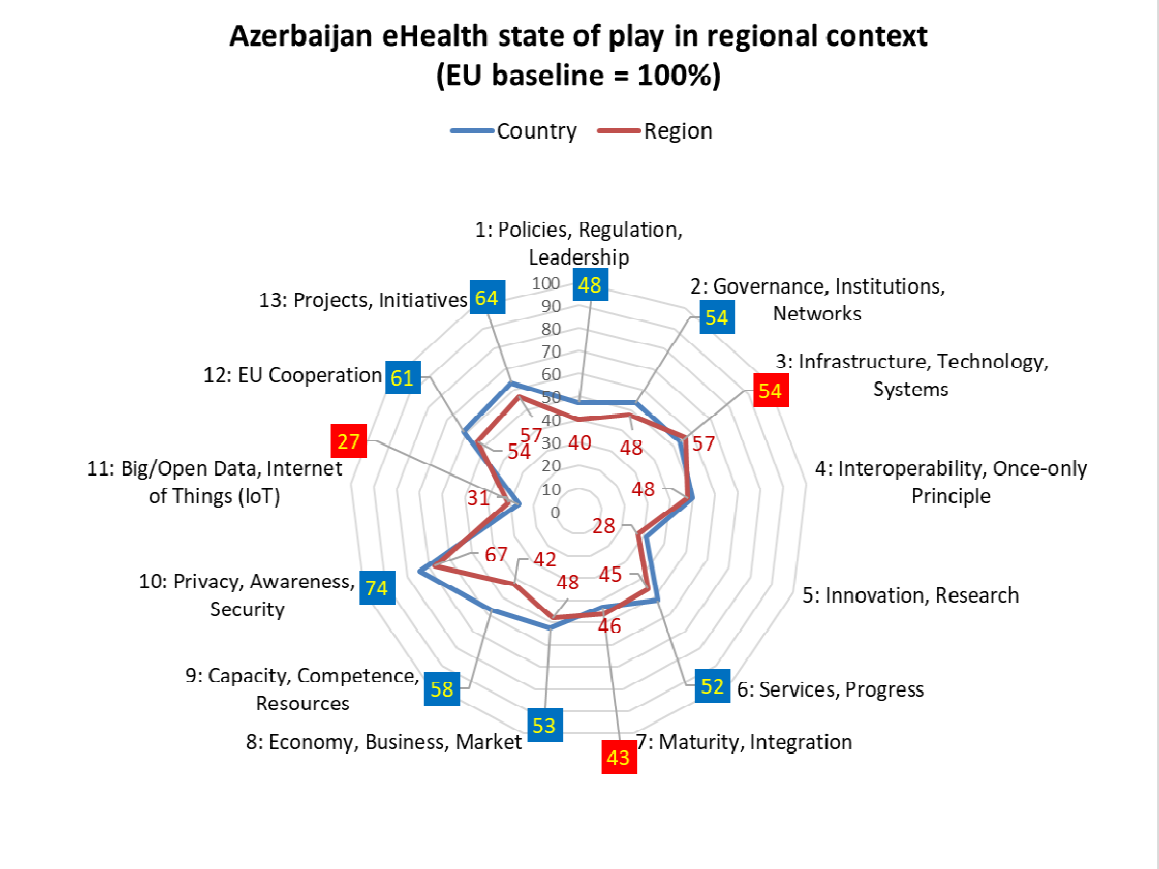

Figure 15. Azerbaijan eHealth compared with the EaP regional average

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4.2.3 Belarus

State of play

Belarus has prepared a draft eHealth concept which is currently under consideration by key stakeholders. The concept is expected to be approved at the end of 2017. In addition, some elements of e-Health are mentioned in such government programmes as

- National programme of socio-economic development of Belarus for 2016-2020 (http://www.government.by/upload/docs/program_ek2016-2020.pdf).
- Health of the nation and demographic security of the republic of Belarus for 2016-2020 (http://minzdrav.gov.by/ru/static/activities/nauchno-tehnicheskie_programmy).
- Development of digital economy and digital market for 2016 -2020 (http://www.government.by/ru/solutions/2435).

- Innovations development in Belarus for 2016-2020 (http://mshp.gov.by/programms/fdbac4b499a1dde8.html).

Ministry of Public Health (and its Republican Scientific and Practical Centre for Medical Technologies, Informatisation, Administration and Management of Health) is the government body responsible for eHealth policy development and coordination (a dedicated eHealth department was created in the Centre in June 2017).

There are no laws specifically designed for e-Health. Some aspects of e-health are addressed by other basic laws governing various aspects of health. Similarly, the rights of patients and the protection of confidentiality are regulated by other laws, such as: "On Health Care" (June 1993), On Medicines (July 2006) "On Social Assistance" (May 2000), "On Protection of Consumer Rights "(January 2002) and Resolution of the Council of Ministers No. 963 of 18 July 2002" On State Minimum Social Standards in the Field of Health Protection". Patients‘ consent to exchange personal medical information with other health organisations is not required by the Law on Healthcare, which states that such information can be provided without patients' consent in the case of formal requests in proper electronic form .[72] Regulation on the implementation and use of ICT in healthcare is governed by orders of the Minister of Public Health. These are, for example, the order of the Minister of Public Health of the Republic of Belarus "On some issues of telemedicine consulting in the Republic of Belarus" (October 2017), the orders regulating the circulation of electronic prescriptions, as well as other orders.

There is also no stand-alone law on data protection in Belarus. The Law on information, informatisation and information protection (10 November 2008 № 455-З) includes a provision on personal data protection and patient confidentiality; Part 1, article 18 states that no one has the right to demand provision of an individual's personal data including personal and family secrets, secrecy of communications and any other information on person's health.

Until now, neither the patient portal nor electronic medical records of patients are available. There is a section related to health on the portal of national electronic services .[73] At the moment, there is no market for medical electronic services. However, it is worth noting that the

[72] http://http://pravo.by/document/?guid=3871&p0=v19302435.

[73] http://portal.gov.by/PortalGovBy/faces/adminProcedures?_adf.ctrl-state=1cw3lt086t_4&_afrLoop=45497671191743.

websites of many health organisations have implemented the function of an Internet-based appointment system to visit a doctor. The portal "Clinics of Belarus"[74] was also created for foreign citizens to inform about possibilities of medical tourism in Belarus. In addition, the Ministry of Public Health initiated the creation of a portal "Healthy People" (https://24health.by/) with the aim to popularise healthy lifestyle.

The legislation on National ICT infrastructure includes:

- Law No 455-Z On information, informatisation and protection of information of 10 November 2008.
- Law No 113-Z On electronic document and digital signature of 28 December 2009.
- Law On electronic communication No.45-3 of 19 July 2005.
- Resolution of the Council of Ministers No. 1055 On Procedures for rendering electronic communications services of 17 August 2006.
- Presidential Decree of1 February 2010 No 60 On Measures to Improve the Use of the National Segment of the Internet includes requirements to protect public sector information.
- Resolution of the Ministry of Communications and Informatisation No 6 of 18 February 2015 approves Instruction on the procedure for shaping and storing data on the information resources (their constituents) of Internet-services, placed in the global computer Internet network.
- Council of Ministers' Decree No 2013/027/BY on Technical regulations of Information technologies.
- Decree of Operations and Analytical Centre (OAC) № 48 On Approval of the order of attesting of managers responsible for ensuring the protection of state secrets, and other employees of government agencies and other organisations working with state secrets, as for application of technological measures protecting state secrets of 9 June 2011.
- Safe operation and reliable operation of critically important objects of informatisation. General requirements (No 47) of 17 July 2014.

[74] https://www.clinicsbel.by.

- Order No 53 of 1 August 2013 On Approval of the Statute of the Core Certification Centre.

The country does not have any healthy ageing policies, although the state programme on social protection for 2016-2020 contains a section Social integration of persons with disabilities and the elderly aimed at creating a barrier-free environment for such citizens.[75]

In 2017, the country has launched a process of creating a national integrated health information system which is planned to be completed by 2021 with the credit of the World Bank project on health care system modernisation (the cost is 65 million USD; to be implemented by the Republican Scientific and Practical Centre for Medical Technologies, Informatisation, Administration and Management of Health.[76] To some extent, the strategy of this project can be considered as a national eHealth strategy.

At present, there is a dozen of operational stand-alone health information systems mainly in the form of clinical registers in the field of cancer, Chernobyl-affected population, tuberculosis, diabetics, safety accidents, people with disabilities, haematological diseases.[77] In addition, there are non-clinical health information systems designed to analyse medical information, manage personnel, run medication procurement, consult patients via telemedicine, issue prescriptions.[78] Electronic health records and registries are operational at the level of primary care facilities.

New electronic services are available to make appointments with doctors, prescribe medication, call doctors for home visits. Overall, the availability of clinical information systems within health institutions reaches 85% in the capital city Minsk and 45% in the country's regions (including such Information systems as *Lekar*', *Polyclinic* and others). The creation of such systems is seen as a step towards handling medical information fully electronically. It is planned to create a single space for health-related information and create a national telemedicine system.

There is no functioning whole-of-government interoperability system. Instead, medical information is exchanged directly between health institutions using a corporate health

[75] http://www.mintrud.gov.by/system/extensions/spaw/uploads/files/Programma-sodejstvija.pdf.

[76] http:/rnpcmt.belcmt.by/index.php; http://projects.worldbank.org/P156778?lang=en).

[77] http://minzdrav.gov.by/ru/static/informatization/informatization_common.

[78] http://www.ipps.by:9087/apex/f?p=124:201:0::NO.

telecommunication system and applying such international standards of information exchange in health sector as FHIR and Health Level 7 (HL7). It is not clear to which extent the new national health information system will be built on the broader e-government interoperability system (which is also being developed and expanded). The latter has been used to design and operationalise a card-based ePrescription system (part of the national programme on Digital Market and Information Society Development 2016-2020 – activity 21). While it is still in its test phase, it covers around 100 policlinics and some 650 state-owned pharmacies in 17 cities, with the majority being still in the capital city (covers about 30% of the entire population).[79] The card used for prescribing and getting medication can also be used to obtain other eHealth services including making appointments. The above-mentioned project of the World Bank will integrate the available information systems and create new ones including a clinical decision support system, tools for assessing performance and quality of health care, patient's records and the ability to manage personal medical information. It is planned to upgrade the current legal and regulatory environment too. While exchange of medical information is considered key for the creation of a national health information system, there is, however, no regulation of cross-border exchanges; it is not clear whether such cross-border exchange would be possible and to which extent a whole-of-government and once-only principles will be implemented. At present, for example, electronic prescriptions are available only within the country.

A dozen local companies are present on the local eHealth market offering various software solutions. There are five major medical informational systems (MIS) implemented by different IT developers in different regions in Belarus. Business representatives participate in discussing the future architecture of the national health information system.

eHealth research is part of the Subprogram "Digital Transformation" of the State Program for the Development of the Digital Economy and the Information Society.[80] However, its quality and scope is unclear.

The currently running projects include the following initiatives:

- e Prescription - covering the country's all polyclinics, as well as state-owned pharmacies. It is planned to connect several private pharmacy networks by the end of the year 2017.

[79] http://pharma.by/el_prescription.

[80] http://pravo.by/document/?guid=12551&p0=C21700215&p1=1&p5=0.

- Telemedicine within the framework of the “Health of the nation and demographic security of the Republic of Belarus”.
- eHealth as a part of the recently launched World Bank project on the modernisation of the health system of the Republic of Belarus.

The following organisations are involved in eHealth activities and projects:

- Ministry of Public Health.
- Direct subordinates of the Ministry of Public Health of the Republic of Belarus are: health care authorities of the regions of the Republic of Belarus (health departments of the regional executive committees and the health committee of the Minsk city executive committee), republican health organisations, including 17 republican scientific and practical centres, four medical universities, Belarusian Medical Academy of Postgraduate Education (BelMAPO), republican hospitals, unitary enterprises, etc. Under the jurisdiction of the regional and Minsk city health authorities are health organisations that provide inpatient, outpatient, and emergency medical care in the regions.
- National Centre of e-Services
- Ministry of Communications and Informatisation
- World Bank
- Infopark Association
- World Health Organisation, Regional office for Europe (collaboration on e-health and IT is included in the Biennial collaboration plan with the MOH for 2018-2019).

Gap analysis

On most benchmark indicators, Belarus is lagging behind the EU baseline except (2) Governance, Institutions, Networks (Figure 16). The largest gaps – in the range of 60-80%) – are observed for (11) Big Data, Internet of Things; (10) Privacy, Awareness, Security; (5) Innovation, Research; (7) Maturity, Integration; (1) Policies, Regulation; (4) Interoperability, Once-only Principle; (9) Capacity, Competence, Resources; (8) Economy, Business, Market. Likewise, the country also lags behind the regional trends on most indicators (Figure 17).

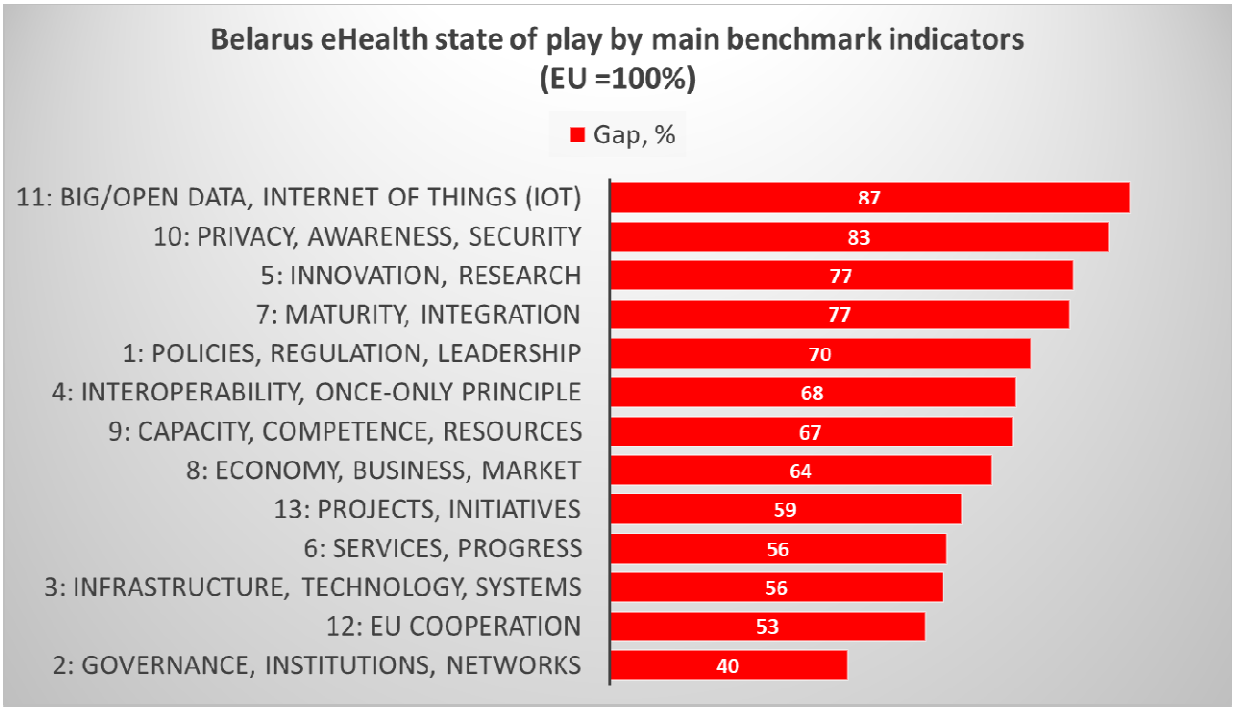

Figure 16. Belarus eHealth: gaps against EU baseline

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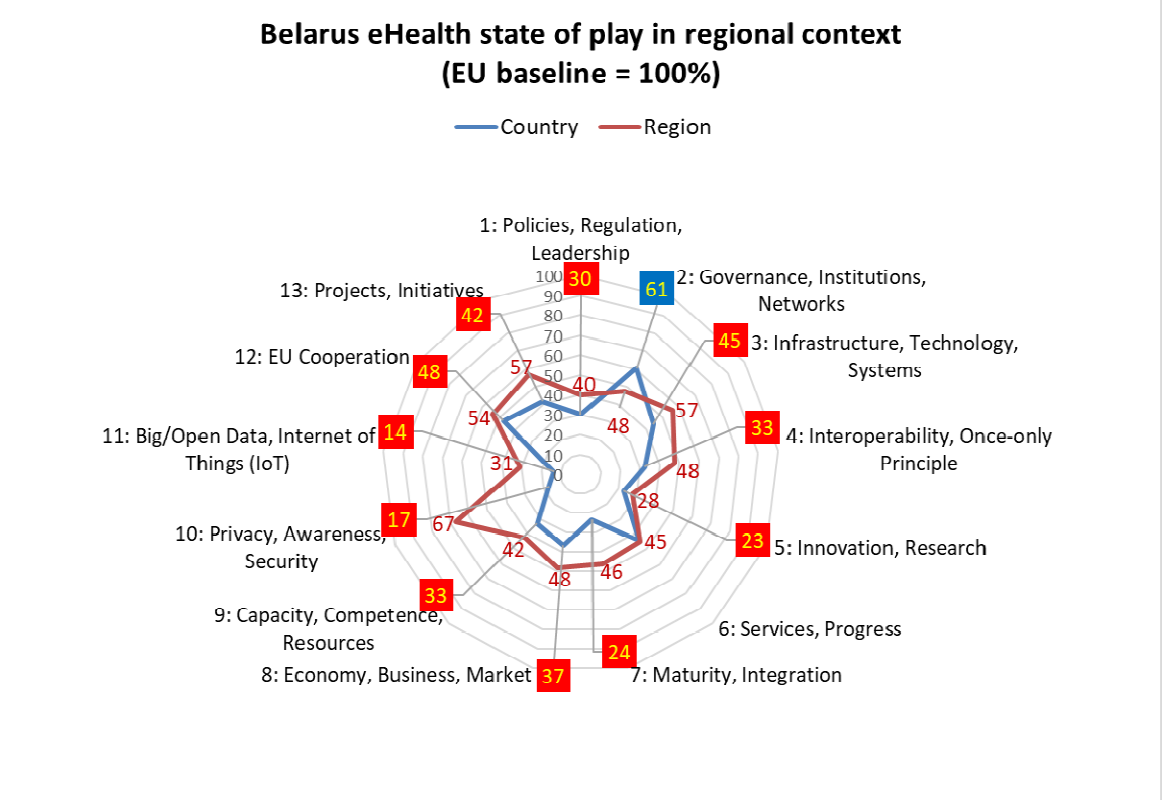

Figure 17. Belarus eHealth compared with the EaP regional average

4.2.4 Georgia

State of play

In general, there has been a decent progress made in advancing eHealth in Georgia, although the main plans are still to be put in practice. Joining its new phase would significantly advance the eHealth agenda. A national eHealth strategy is available and awaits approval by the Parliament. It includes a mobile health component (mPlatform).

The Georgian Ministry of Labour, Health and Social Affairs leads a programme of health care reform in the country aimed at:

- More accessibility to quality health services;
- Selective contracting for medical institutions (Includes commitment of involvement in e-prescription and EMR systems;
- New costing system for Healthcare;
- Reform of monitoring and claims management system;

- More access to medicines by providing consolidated procurement;
- Development of the primary healthcare, disease prevention and early detection systems;
- Introduction of EMR system in the whole country.

Georgia does not have any government structure specifically dedicated to eHealth (although the eHealth strategy gives such a recommendation); the functions of such agency are performed de-facto by the Ministry's departments for Healthcare Protection and IT. Inter-agency coordination is not formalised and realised at the working level with Data Exchange and Public Services Development agencies. At the moment, the Ministry runs Health Information Management System (HMIS) (www.eHealth.moh.gov.ge), Social Information Management System, Central Electronic Medical Records, a number of eHealth Modules. The HMIS Strategy "Healthy Georgia, Connected to you" was established in 2011 (with support of USAID) but its detailed implementation roadmap was not delivered. The system's modules provide e-tools for reporting to insurers, registration of beneficiaries and cases, finance and administration management, statistics collection. The system is used for taking evidence-based decisions by all doctors and 80% of the country's hospitals (has over 7,000 of active users), It has produced substantial savings thanks to the elimination of duplication in resolving beneficiary cases (around 100,000 patients served) leading to the reimbursement of 16 million USD to healthcare institutions in 2016.

Launched in 2016 by the Minister of Health Decree #01-29/n (26 July 2016), an ePrescription service has been implemented throughout the country in 2017. Also, a new project to test electronic medical records has been started in 2017; a similar initiative was already under implementation in 2011 but it was not considered successful. That raises an important question on both efficiency and effectiveness of electronic health records and wider clinical information systems in the absence of the clearly formulated success criteria applied in the properly undertaken evaluations. The lack in the past of well-defined eHealth policy has prevented from stronger progress in implementing eHealth initiatives on the ground. Mobile health and telemedicine are especially lagging. The lack of clear policies prevents stronger investment into eHealth research and innovation, which would mobilise wider community in support of electronic health projects. Insufficient knowledge and experience sharing with the EU is another obstacle for progress; in this context, learning from epSOS about cross-border interoperability, as well as joining its new phase would significantly advance the eHealth agenda.

At practice level, there have been two pilot projects implemented by Partners for Health NGO in m-Health thanks to grants from Shota Rustaveli National Science Foundation and CRDF-Global, directions: cardiology and dermatology. In 2014, Government of Georgia has adopted Decree #724 (26.12.2014) about 2014-2020 State Concept supporting "Universal Healthcare Plan and Quality Management for Patient's Rights Protection", which to a certain extent addressed the development of eHealth as well. The draft strategy recommends creating a national eHealth network. Patient's control over access to their personal medical records is not yet available in practice but is envisaged. In the absence of the dedicated policy to protect patient's medical data in electronic form, the latter are protected by the law on personal data protection (effective since 2014). The patient's consent to exchange their health information with other health organisations is not explicitly requested; it is rather assumed that such permission is granted by patients in the case of referral to a doctor. Software development companies pay attention to personal data protection and require its reflection in the developed systems.

Policies regulating EHRs have been prepared and are expected to be approved soon to operationalise them at the end of 2017 at the level of primary, secondary and tertiary care facilities. Several medical electronic registries exist (e.g. Doctors' registries, Clinics database, Medication registry) except for pharmacies. As mentioned above, the Ministry runs some two dozen specialised health information systems including in oncology, cardiology, financial management, Universal Healthcare Program and C-Hepatitis modules.[81] The National Centre for Disease Control and Public Health has developed e-registries in Mother and Children care (birth e-registry) and Cancer e-registry. In some other fields – Dermato-oncology, Asthma/COPD, Epilepsy – several leading institutions also have started e-registries. Some of them have been built using different software products which creates interoperability/miscommunication challenges, e.g. for integrating with the ministerial portal

Regulation exists on technology use; it is part of the draft eHealth strategy and applies, first of all, to HL7 technologies interoperability standards to enable integration with the central portal. However, while the use of HL7 is accepted, there is no sufficient knowledge available to exploit its full benefits. There is no dedicated healthy and active ageing policy; the emphasis is placed currently on services for patients with chronic diseases of all ages.

[81] (http://ehealth.moh.gov.ge/Hmis/Portal/List.aspxas.

eHealth interoperability will be implemented on the Ministry of Health platform – now, de-facto the exchange is realised via MOUs between health organisations – within the architecture of the planned eHealth portal; it is planned that in future it will rely on the broader infrastructure of Data Exchange Agency (at the moment it is not the case). The integration of eHealth infrastructure with other e-government infrastructures is an ongoing issue and awaits its fuller resolution, also in legal terms. Since the Patient Portal is not yet operational (technically, it is built but lacks content; the Ministry has an information portal[82] that provides information regarding Healthcare providers, Medical Equipment, Bed Capacity, Medical Services, Blood Bank, Healthcare professionals), the patient-related information will have to be integrated into the central e-Government portal my.gov.ge (using the Data Exchange Agency infrastructure). The Health Level 7 is used as a default open standard for eHealth interoperability solutions.

Patient consultation systems are not available but the planned Patient Portal will have a patent consultation functionality. An online medical consultation is available on www.mkurnali.ge, www.onlineclinic.ge, however, with limited interactive online functionality. Recently, a start-up project Online Hospital www.onlineclinic.ge has received a small grant from the Ministry of Economics to make the process of patient consultation more interactive.

Cross-border interoperability of electronic health information (records) is not yet possible. Same applies to ePrescriptions.

While there are no functioning data-driven platforms in health sector that use Big/Open Data and Internet of Things technologies, the Ministry considers decreeing a possibility for secondary use of depersonalised (anonymised) data for research. Data are collected but their processing is basic. No standards and rules exist for processing Big Data, which prompts unofficial practices. Lack of demand is also observed. Overall, there is little support from the state to eHealth research and innovation. Internet of Things technologies are not used. Participation of local researchers in international projects, including with the EU, is weak. The potential of the Horizon2020 and COST programmes has not been exploited.

Innovation procurement in eHealth is not a practice; but it is planned for 2018 with support from the Czech Republic. Health monitoring for epidemiology is well established. Work in progress to

[82] http://cloud.moh.gov.ge/Default.aspx.

offer a service for online application/renewal of driving license based on the medical check results.

Overall, Georgia has an open and growing market for eHealth solutions and products/services (but still not yet attractive as health care providers are not ready to pay adequate money for eHealth products), with strong presence of industry players (including Microsoft). However, policies and practices of involving the private sector in developing eHealth solutions and viable business models, as well as in product commercialisation are scarce. In-service training of adequate quality is available; it was especially effective during the rollout of the HMIS modules. But citizens' digital health literacy is insufficient. The ongoing and pipe-line projects include: online catalogue of clinics and doctors (with ratings); mobile apps to ePrescriptions; Psycho databanks; Clinical Support System that shall automatically provide advice for health professionals and support decision-making.

The country has a clear vision of existing barriers, challenges and benefits of harmonisation with EU, as well the priority cooperation areas to implement the harmonisation agenda (Experience Demonstration Box 5).

Experience Demonstration Box 5. Georgia's priorities for cooperation with EU

GEORGIA		
Major obstacles in national eHealth to harmonize with EU	**Major challenges to overcome obstacles**	**Major likely benefits of harmonization with EU for national eHealth development**
1. Foreign Patient Identification Issue	1. Develop common identification standards	1. Adopting EU standards in terms of interoperability
2. Legislation issue, Unknown rules of the game	2. Starting process of harmonization national legislation with EU directives	2. Adopting EU level eHealth legislation
3. Uncertainty in terms of information, which should be exchanged, harmonized	3. Develop common content of HER, which will be minimum necessary information, to be engaged in cross-border healthcare	3. Adopting EU standards in terms of HER content
4. Uncertainty, who will finance the project	4.	4. Better healthcare for our citizens in EU and EaP, because of the better access on their health information
5. patient information Protection issue	5.	5. Acceleration of eHealth development
6.	6.	6. Possibility to harmonize not only EHR, but other healthcare programs
Priority areas of cooperation with EU		
1. Identification and Authentication		
2. Legal area		
3. Patients' rights		
4. Electronic Health Record (EHR) development		
5. Patient's Portal development		
6. Online list of Health care facilities and their doctors and their ratings		
7. Telemedicine		
8. Mobile Medicine		
9. Medical decision Support systems		
10. ePrescription		

Gap analysis

For half of the benchmark indicators, Georgia exceeds a 50%-percent level of the EU baseline. The country performs particularly well in (7) Maturity, Integration; (10) Privacy, Awareness, Security; (3) Infrastructure, Technology, Systems (Figure 18). The largest gaps are observed in

(11) Big Data, Internet of Things; (5) Innovation, Research; (2) Governance, Institutions, Networks; (4) Interoperability, Once-only Principle.

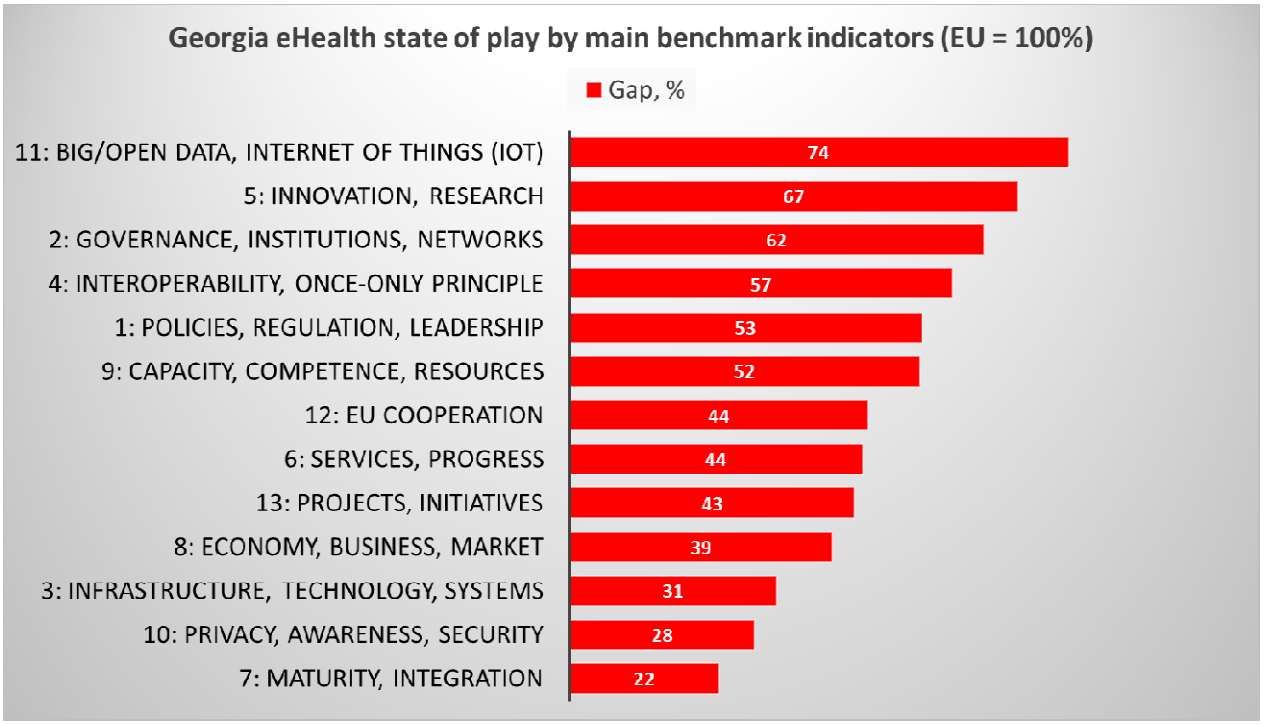

Figure 18. Georgia eHealth: gaps against EU baseline

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The country performs better than the region on average on most indicators except (2) Governance, Institutions, Networks; (4) Interoperability, Once-only Principle; (11) Big Data, Internet of Things (Figure 19).

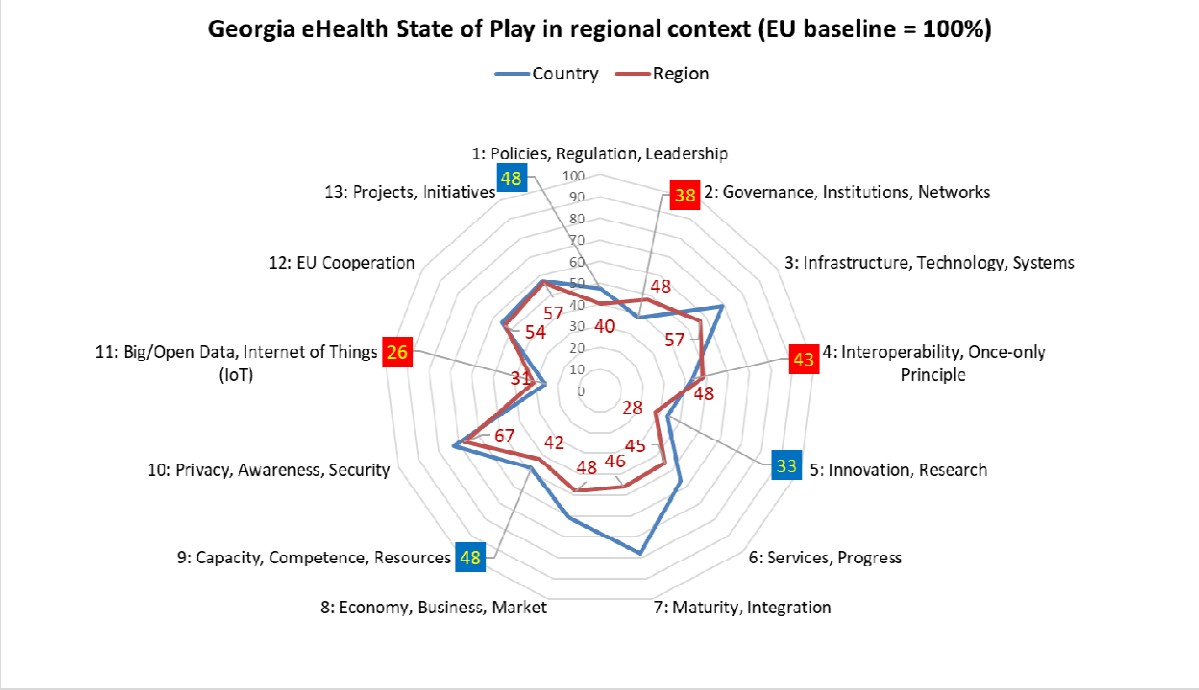

Figure 19. Georgia eHealth compared with the EaP regional average

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4.2.5 Moldova

State of play

Moldova does not have any approved eHealth strategy. There have been two failed attempts to endorse it in 2013 and 2016. The available draft of the National eHealth 2020 Strategy was elaborated as part of the negotiations with the World Bank for financing the Strategic Planning Reform of Health Information Management in Moldova (in the context of the Government Decision no. 710 of 20 September 2011 regarding the approval of the Strategic Technology Modernisation of Government – e-Transformation Program – and the Government Decision no. 857 of 31 October 2013 on the National Strategy for the Development of the Information Society "Moldova Digital 2020". The draft strategy also included provisions on mHealth and telemedicine, as well as contained references to active and healthy ageing.

eHealth-related elements are contained in the concept of the Integrated Medical Information System (SIMI) (Government Decision No. 1128 of 14 October 2004). The system must allow free access to information in international medical information centres, up-to-date information;

remote patient consultation, as well as exchange of information with colleagues from other localities and countries. It must be now either repealed or revised.

Although there has been some progress in eHealth, the lack of strategy makes such progress modest. The main drawback of Moldova's legal framework that governs the country's health sector in general and Health in particular is that it does not contain enforcement provisions. Regardless of the vast list of available policies, the legal and regulatory framework for eHealth remains incomplete, for those provisions important for e-Health are fragmented and create more impediments than incentives. The programme of the government technological modernisation (eTransformation) has become one of the pillars of public service reform in Moldova, including the eHealth sector. By widely applying information and communication technologies, the government aims to increase performance of authorities and transparency of state institutions, to increase access to information and to promote digitised services.

The Law on Personal Data Protection (no. 133 from 08 July 2011 http://lex.justice.md/md/340495/, Article 5. Processing of personal data) requires that the processing of personal data shall be carried out with the consent of the subject of personal data and that the subject of personal data can withdraw such consent at any time (the withdrawal of consent cannot have a retroactive effect).

While Moldova has an approved Programme on interoperability framework (Government Decision no. 656 of 05 September 2012 On the approval of the Program on Interoperability Framework) and has built a respective MCloud infrastructure, the actual use of interoperability solutions and infrastructure is at initial phase – few interoperable systems exist at the moment. The draft eHealth Strategy contains a separate chapter on interoperability. The once-only principle is applied in the Law on Registers stipulating that the "repeated registration of the object of the register, which has been registered in another state register, or repeated accumulation of the object data in the same register is forbidden".

Personal Data Protection Law contains dedicated article to personal medical data protection. The Law's Article 16 allows for cross-border transmission of personal data under condition that the respective state ensures an adequate level of protection of the person's rights. The level of protection is determined by the Centre of Personal Data Protection taking into account the conditions under which the transmission of data takes place, in particular the nature of the data, the purpose of the transmission and processing of data, the state of final destination, the law of the requesting State. It is done also based on mutual bilateral agreements between countries.

According to the Concept of the Integrated Medical Information System (Government Decision No. 1128 of 14 October 2004), the interoperability system allows also the exchange of information with colleagues from other localities and countries. The cloud-based national interoperability framework provides technical provisions for such exchange.

The Ministry of Health has developed a concept of the ePrescription system along the relationship family doctor - pharmacy - patient - National Health Insurance Company; however, the system is not yet approved nor implemented.

Electronic health record (EHR) are part of the Automated Information System in Primary care system. In the tertiary care facilities EHRs include an Information System for Monitoring and Evaluation of Tuberculosis; Integrated Hospital Information and Hospital Imaging System "Hospital Manager Suite"; Integrated Information System "Hippocrates"; Information System Hipocrates is an integrated management solution for all aspects of the National Emergency Medicine Practical Centre; Information System Monitoring the epidemiological situation; the Blood Service Automated Information System. There are functional medical electronic registers at the level of Centres of Family Physicians and Hospitals Medical Assistance, as well as the specialised medical electronic registers – the Register of patients with rare diseases – although not interoperable. Overall, there are many sspecialised health information systems (see Experience Demonstration Box 6).

Experience Demonstration Box 6. Moldova: Existing eHealth Systems.

- Primary Health Care Medex 2.0 – for collecting and monitoring patients' data.
- "Blood Service" – for managing information and flows within the National Blood Transfusion Centre.
- State Medicines Nomenclature – for monitoring activities of pharmaceutical companies and institutions in the area of the circulation of medicinal products.
- Public Health Surveillance Service – for collecting, transmitting, storing, processing and visualizing the information to solve public health problems.
- Primary Health Care, Cabimed Manager – for managing five basic modules in primary and specialised health care: (1) Module "Medical records"; (2) Patient Visits module; (3) "Reporting" module; (4) "Configuration" module (keeps track of application users, access rights); (5) "Prices and Accounts" (manages information and medical services provided to the patients).
- Integrated Hospital and Medical Imaging System "Hospital Manager Suite" – for managing hospital's clinical, economic, administrative and research activities.
- Monitoring and evaluation of tuberculosis in Moldova
- Monitoring and Evaluation of HIV and Sexually Transmitted Diseases in Moldova – for reporting on new STI cases.
- Payroll, Pricing, Cabinet Manager, 1C, Exim-Bank, Quick Statement, WinSmeta, SIERUSS, FoxPro-sp, ECAM, Hospital Manager, OLTP CNAM, Maip solarium card, CTS Manager – for financial management

- Patient Programming Information System – for both public and private medical staff in connection to the Single Program of Compulsory Health Insurance.
- Udi / Ident Information System – an Observatory for providing injectable drug users (RDI) beneficiaries with risk reduction services.
- HIV / Ident Information System – for evidence of the services offered to HIV-positive people and their families. Medical Statistics – Data Presentation System for comparing data and indicators of defined geographic or administrative areas and for a certain period of time.
- National Accounts in Health in the Republic of Moldova (ISHAM) – an on-line application with web interface for databases is located in the National Centre for Health Management.
- National Company for Medical Insurance Information Systems (CNAM) – includes several information systems:
- Compulsory Medical Assistance (SIA AOAM) – for allowing authenticated users to register and consult data about the beneficiaries of the medical insurance system (however, it does not meet new requirements).
- The register of persons registered in the medical institution providing primary health care services (registration with the family doctor) – a web access point accessible directly from the official web site of NHIC for verification of persons registered with the family doctor.
- Payment of Medical Services (SIA ASM) – for recording payments for medical services.
- Register of Reports on the fulfilment of the business-plan by the medical-sanitary institution from the compulsory health insurance funds – for helping contracted medical institutions to provide business plans and cost estimates.
- Evidence and reporting of medical services – for providing clients (hospitals) with the ability to connect to the application server and use the system according to their rights.
- Verifying the status of insured under compulsory health insurance – for web access to verify the status of the insured.
- Compensated Medicines Information System – for recording the offset medications partially or fully covered by insurance.

According to the draft eHealth strategy, Moldova has a nation-wide system for primary care (developed several years ago), even if this system is not fully implemented across the country (not all public institutions use it). Besides, private institutions from the primary care facilities are free to select any system, and there is no requirement for this system to be interconnected with government-owned solution. Regarding hospital care, majority of them do not have health information system on a country-wide level. Each hospital was free to select its own solution. This ended in 2017, when Ministry of healthcare decided to buy solution for biggest hospitals. In legal terms, the European standards for electronic health records have been officially declared as Moldovan standards but no steps have been taken in their implementation on the national scale.

The Moldova's Primary Healthcare Information System uses the principle of open standards (including HL7), which is applied to ensure both interoperability with external systems and the

retention of information (a draft concept for the Primary Medical Assistance Information system.[83] No Patient Portal is available.

The existing health information systems are not standardised, mutually integrated and therefore not interoperable. Many were built on outdated technologies that are no longer maintained causing serious information security concerns. Often, information systems duplicate each other in data collection. One of the key problems is the lack of a dedicated institution responsible for managing all e-health systems. The capacity of the Ministry of Health is not sufficient (there is only one official within the Ministry of Health to deal with e-transformation of Moldova's health care sector). There is also an insufficient number of ICT specialists in other medical institutions. The main body that collects and analyses medical data is the National Centre of Health Management (NCHM). The National Health Company for Medical Insurance Centre (CNAM/NHIC) manages a separate information system, monitors the coverage under Mandatory Health Insurance (MHI) and oversees other economic aspects of health service provision. Other information activities including the surveillance of public health are managed by the National Centre for Public Health (NCPH).

In 2008, with the support of the World Bank, the Ministry of Health created a National Health Accounts information system. Other international organisations helped create other information systems for monitoring and evaluation of communicable diseases and health security, TB, HIV/AIDS, STIs and drug use. There is also a dedicated information system designed to manage activities in support of reproductive health. A methodology for reporting and calculating health indicators has been adjusted to be in line with the WHO recommendations to implement the commitments made under the Moldova–European Union Action Plan and as a result of the evaluation of the national health information system (with support from the Health Metrics Network). Following this evaluation, a Strategic Plan for the Development of the National Health Information System 2008–2017 was developed and approved. However, due to the lack of sufficient financial resources, the Plan has not been adequately implemented causing health personnel to spend a lot of time for filling medical evidence forms manually. In 2011, the Ministry of Health reduced the volume of reporting burden (primary medical evidence forms).

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83 http://particip.gov.md/public/documente/140/ro_3945_proiectul-Hotariri-Guvernului-cu-privire-la-aprobarea-Conceptului-tehnic-i-Regulamentului-de-funcionare-al-SIA-AMP.docx).

Moldova has mandatory Health insurance managed by the National Company for Medical Insurance (CNAM). It is mandatory to use the Automated Information System for Primary Medical Assistance. The Big Data in health are collected and available on Date.gov.md, but no deep research exists; same applies to the use of IoT (Internet of Things) technologies and applications in health sector.

The eHealth market in Moldova is small but it is open for all players under the Public Procurement Law. The adoption of the eHealth strategy could help the market grow. There are several suppliers of eHealth products in the market. The use of technologies in the health sector is regulated by Law no. 92 of 26 April 2012 "On Medical Devices" and by the Government Decision no. 96 of 29 January 2007 regarding the establishment of the conditions for placing on the market and the use of medical devices. Participation in EU/international research is limited.

Gap analysis

As Figure 20 suggests, Moldova's state of play is within 30 to 50% of the EU baseline on the majority of benchmark indicators. The country is behind especially in (6) Services, Progress; (7) Maturity, Integration; (5) Innovation, Research. The country has made stronger progress in 3. Infrastructure, Technology, Systems; (13) Projects, Initiatives and excels in (10) Privacy, Awareness, Security.

To a significant extent, the country follows regional trends demonstrating better performance in (10) Privacy, Awareness, Security; (11) Big Data, Internet of Things; (12) EU Cooperation and lagging in (2) Governance, Institutions, Networks (Figure 21).

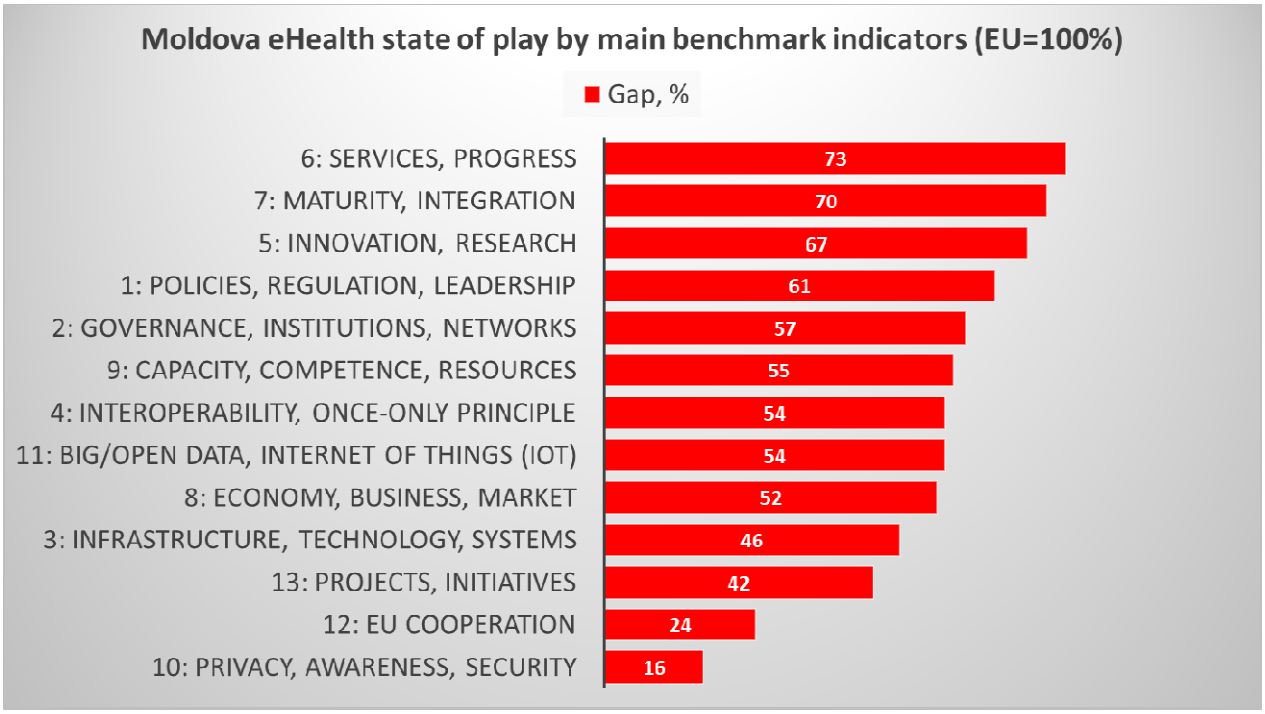

Figure 20. Moldova eHealth: gaps against EU baseline

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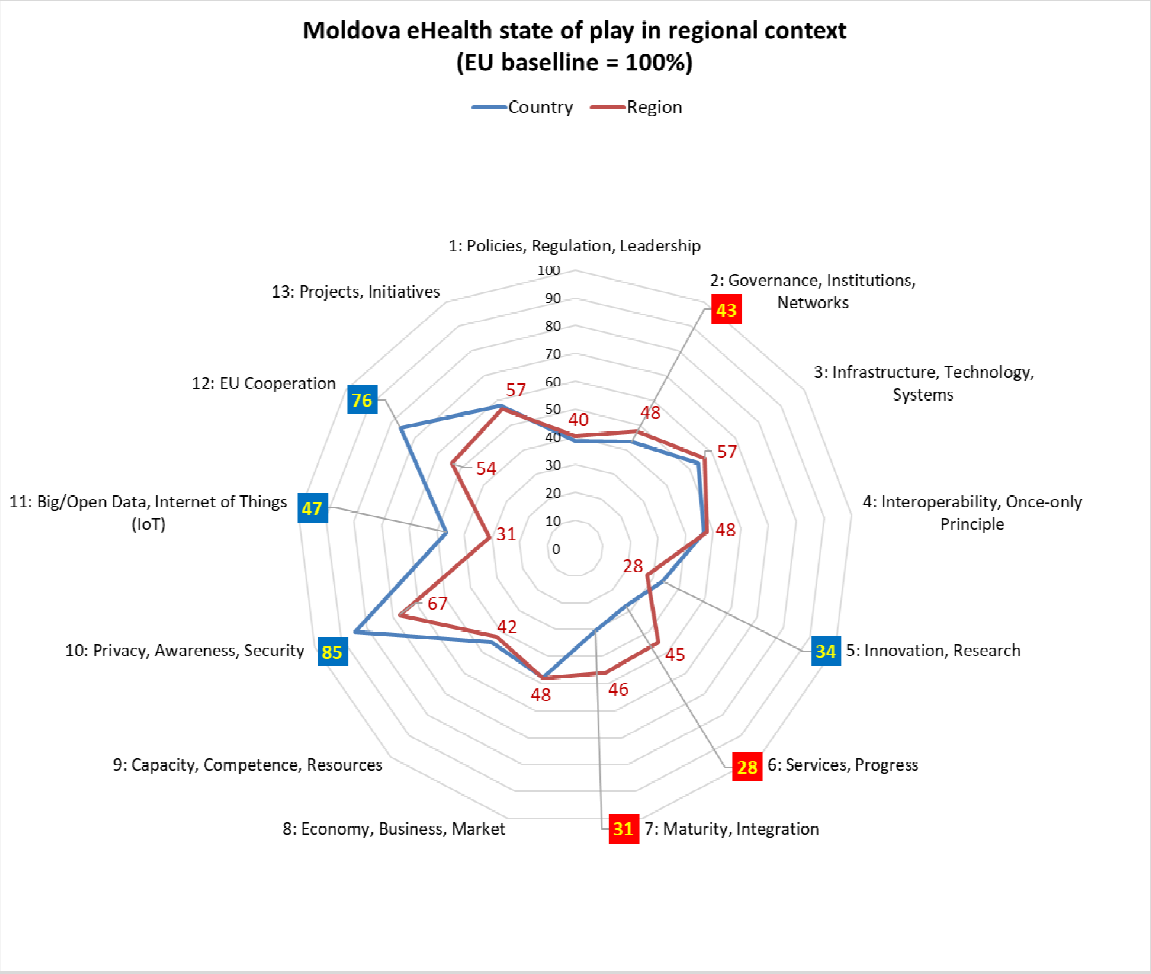

Figure 21. Moldova eHealth compared with the EaP regional average

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4.2.6 Ukraine

State of play

Ukraine has several policy documents in eHealth. The main one is the concept of the national programme of health care informatisation of 2013, the Law On the main principles of information society development 2007-2015, the state programme of health care informatisation 2013-2018,

the Law on the implementation of the national informatisation programme.[84] However, the concept has not been put into practical implementation. The previously developed plan for telemedicine has been abolished.[85]

eHealth policies are led by the Ministry of Health in broad partnership with many stakeholders. In 2015, a State Enterprise The eHealth Centre under the Ministry of Health was created to coordinate the implementation of eHealth initiatives (having such an agency was a condition of the World Bank eHealth project (http://projects.worldbank.org/P144893?lang=en). The Centre has been recently revamped (https://www.slideshare.net/secret/2RxA4BGHXIbsdJ).

With the concept on informatisation of the health sector adopted in 2013, Ukraine has a relatively short history of concerted effort to develop eHealth. However, while some progress has been made – such as, for example, preparing 246 medical forms for getting digitised – some key fundamentals are yet to be put in place. Emergency service information system is available in every region. The World Bank has started eHealth-related activities in one-third of Ukraine's 24 regions. All related procurement and bidding is realised at central level.

Still, the past legacy prevails, which includes:

- the existence of separate and not properly integrated population registries at the ministries of Justice, Social Policy, and Migration Service;
- disparate medical registries were created in different periods by using different software tools: medical staff and educators, donors, drugs and medical ware; cancer, HIV, tuberculosis, diabetes, and orphan diseases patients;
- while the electronic signature is available, it is not used in health care;
- a Unique record number in the registry (Unique Identifier) is only being created;
- primary statistics data are not of adequate quality and still paper-based (being translated afterwards into electronic format);
- medical information systems are developed privately by each facility and not interoperable – there are 5 large medical information systems and 15 smaller; yet, less than 5% of the primary health care institutions have them and cover mostly specialised

[84] http://uacm.kharkov.ua/download/2013_10/148-154_Konzepziya_10_sc_P.pdf/.

[85] http://www.moz.gov.ua/ua/portal/dn_20100326_261.html.

care;

- patient information systems are privately developed without adequate government oversight without enforcement of eHealth standards that are at early stages of approval.

In 2016, the government has embarked on a large-scale transformation of the health care sector with the adoption by the Cabinet of Ministers Ion 30 November 2016) of a Concept of Health Care Financing Reform (see Box 7). The reform will be implemented in stages. At the first stage, a first priority will be given to the primary health institutions. Applying eHealth instruments will be key to putting the reform plan into practice. The Ministry of Health leads the reform by observing the following principles:

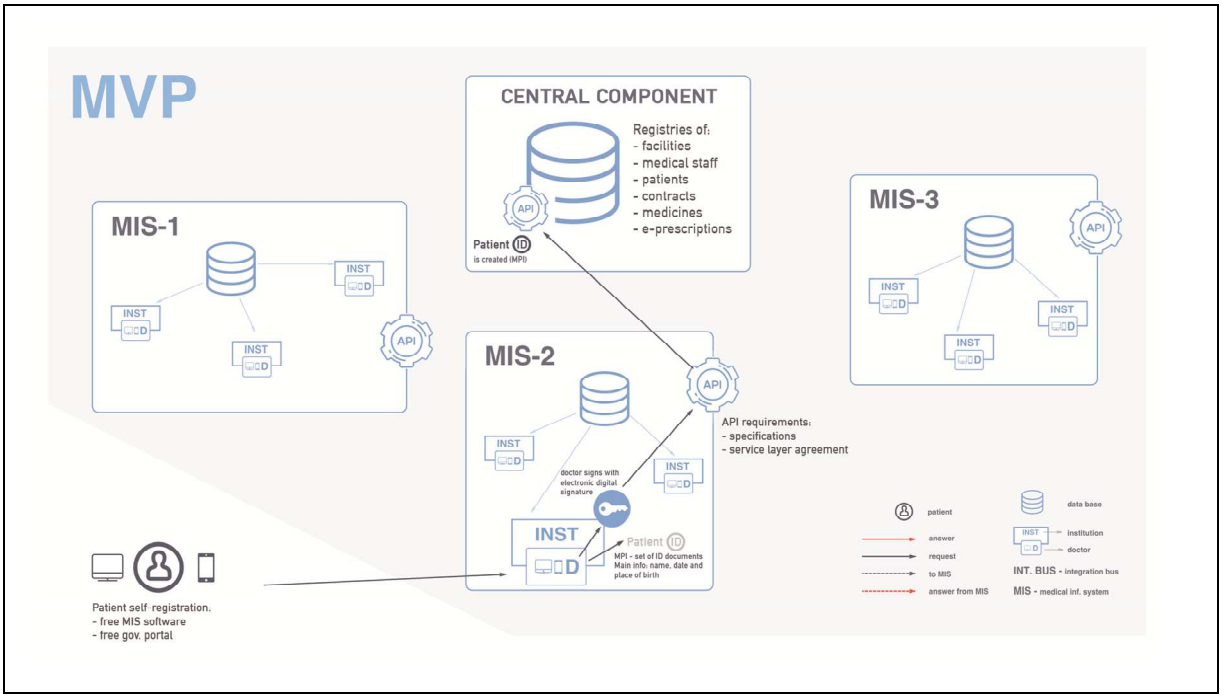
- Safety and security of information is a priority
- Consumer-orientation - utility and value for all actors
- Data audits
- Integrity and continuity of health records
- Equal access to information in all regions of Ukraine
- Convenience and reliability
- Management and financial transparency
- Information and knowledge management
- Interoperability and standardisation
- Free market and fair competition
- Possibility for further expansion of system's functionality

The main objective is to start piloting patient-oriented eHealth initiatives quickly, with the priority given to the following actions:

- Issuing IDs for all
- Creating APIs for service providers, patient registry, pharmacies
- Creating an interface for the National Health Service of Ukraine
- Creating: a registry of primary health care facilities and physicians; Patient registry; registry of declarations; registry of reimbursed molecules and diagnoses
- Establishing basic rules for reimbursement
- Launching an ePrescription and eAppointment services
- Creating eReferrals for further diagnostics
- Developing a development strategy for the secondary care institutions

However, the institutional capacity of the Ministry is not adequate at the moment to advance the national eHealth agenda. In this aspect, Ukraine stands out among other EaP. As a result, the local civil society took a lead in defining eHealth systems in legal terms – which should be followed up by developing a full-fledged eHealth strategy – and performing de facto the government's function in this regard (temporarily until the government is ready to take over). The entire healthcare project strategy relies on strong and direct involvement of such NGOs as the Transparency International Ukraine and Network 100% Life creating a project office within the Ministry of Health. The first priority will be to make the reorganised State Enterprise for eHealth a national Operator by implementing a Minimum Viable Product (MVP) pilot for the transparent and efficient electronic health system (see Experience Demonstration Box 7).

Experience Demonstration Box 7. Ukraine: eHealth Implementation Vision – A Minimal Value Product in eHealth



The scope of private medical information includes provisions requiring obtaining patient's consent according to the law on personal data protection .[86] Nevertheless, this law is already outdated and needs to be significantly reviewed in line with the GDPR.

Ukraine has a dedicated network of non-governmental organisations involved in eHealth support and development, such as: Public Association of eHealth product and service providers (*Громадська спілка "Асоціація постачальників товарів та послуг в сфері інформатизації охорони здоров'я "ІХЕЛС"*). Ukrainian Association Computer Medicine (http://uacm.kharkov.ua/ukr/index.html). In addition, eHealth project offices have been established at Transparency International Ukraine and Ukraine 100% Network in cooperation with the Ministry of Health and the National e-Government Agency.

The central component for ensuring equal access for eHealth services, solutions and producers by medical institutions will be based on Open Standards (http://docs.ehealthapi1.apiary.io/#).

Medical registries are mostly specialised, for example:

- National cancer register http://www.ncru.inf.ua;
- patients with tuberculosis and eTB-manager; http://phc.org.ua/pages/diseases/tuberculosis/register_of_patients;
- HIV/AIDS register;
- Diabetics register;
- Register of injured military force;
- Register of health professionals;
- Medication and drug register;
- Register of medical devices'
- Register of medical documentation and standards of health care assistance;
- Registers of analytical and statistical information.

The existing medical information systems are mainly at the primary level, such as the registers for doctor appointments and creating patient records.[87] Medical information systems and registries at the secondary level include hospital information systems.[88]

[86] http://zakon3.rada.gov.ua/laws/show/2297-17/page/.

ePrescription service is not yet available but is planned as part of the Minimal Product Value (MPV) implementation phase. Cross-border interoperability of medical information is not possible.

Ukraine, as the largest EaP country and the region's largest producer of IT products, has a big and attractive eHealth market with strong presence of many industry players. In spite of the existence of several clinical information systems (such as Health 24,[89] Laboratory information management system EmciLab[90]), its market is not mature enough. Interoperability between health information systems is lacking at the moment. The applied whole-of-government approach includes the establishment of the national e-government interoperability platform (to be operational in mod-2018) within a project EGOV4UKRINE supported by Sweden, Estonia and the European Commission.

Open/Big Data and Internet of Things technologies are not used in health sector. Research and innovation supported by the state funding and international donors is limited. The best practice exchange mechanisms in eHealth are absent. In addition to the mentioned project of the World Bank, the USAID is planning a five-year project that will also contribute to Health development in Ukraine. A new state enterprise for eHealth has been created to become the official operator of health care information systems.

Gap analysis

Ukrainian eHealth sector is below the European baseline level on all benchmark indicators except (10) Privacy, Awareness, Security where the gap is minimal at the level of 40%, while the gaps on such indicators as (4) Interoperability, Once-only Principle; (7) Maturity, Integration; (2) Governance, Institutions, Networks; (9) Capacity, Competence, Resources; (1) Policies, Regulation; (11) Big Data, Internet of Things reaches s over 60% (Figure 22).

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[87] https://helsi.me/; https://medics.com.ua/; https://vitagramma.com/; https://helsi.me/; https://medics.com.ua.

[88] For example, http://doctor.eleks.com/en/; http://www.mcmed.ua/ua; http://ciet.kiev.ua/solutions.php?p_id=92.

[89] https://health24.life/index.

[90] http://www.mclab.ua/en.

Due to these gaps, the country lags behind the regional trends, especially in (5) Innovation, Research; (7) Maturity, Integration; (9) Capacity, Competence, Resources; (11) Big Data, Internet of Things (Figure 23). The gaps with the region are less noticeable in (6) Services, Progress; (8) Economy, Business, Market; (11) Big Data, Internet of Things. The country fares well in engaging all major stakeholders from outside the government to design and implement new eHealth programme together with the World Bank.

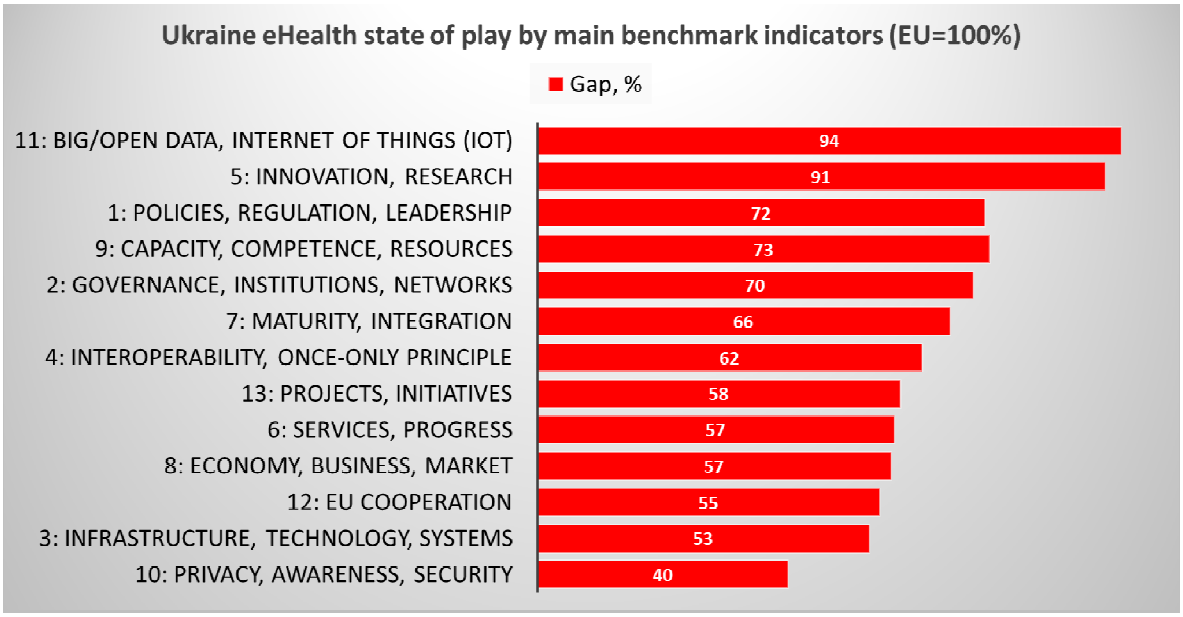


Figure 22. Ukraine eHealth: gaps against EU baseline

Figure 23. Ukraine eHealth compared with the EaP regional average

5 ROADMAPS

5.1 Roadmap for the Region

5.1.1 Harmonisation priorities: levels and pillars

Following the gap mapping exercise (see section 4.1.3 above), The Study Team recommends that the future HDM harmonisation initiatives in eHealth should be formulated and implemented at three main levels:

- Level 1: Projects common for the entire region i.e. all 6 partner countries;
- Level 2: Projects common for certain groups of Partner Countries;
- Level 3: Country-specific projects for individual countries.

Participants of the eHealth study validation workshop held in Tbilisi, Georgia, on 14-15 September 2017 agreed on four harmonisation pillars (domains) following deeper examination of existing barriers and the benefits of their removal.

The above indicators have been further aggregated into the four eHealth project harmonisation pillars that represent the EU baseline in a strategic manner and are applicable to the entire region based on the gap analysis. The proposed pillars are:

1. eHealth regional networking
2. eHealth policy and governance
3. eHealth interoperability and standards
4. eHealth patient services and data protection standards

Each pillar contains specific projects at each implementation level. The SMART objectives framework – as explained below – has been applied by the Study Team as a variation of the concept used for gap assessment to formulate the proposed harmonisation actions.

S = Specific, i.e. whether there is sufficient detail to address the challenge

M = Measurable, i.e. whether it is possible to measure progress and accomplish results

A = Attainable, i.e. whether challenges are recognised and objectives accepted by stakeholders

R = Realistic, i.e. whether objectives and challenges are attainable at reasonable cost;

T = Time-bound, i.e. whether the implementation period is clear

For each pillar, SMART objectives are defined and respective harmonisation actions are proposed as described in Tables 10 through 13.

A common region-wide approach is prioritised as the most impactful and cost-effective way to start harmonisation of eHealth systems and services, especially in the area of interoperable ePrescriptions and Patient Records (Summaries). It is recommended that the capabilities of the existing regional eHealth Network are substantially enhanced to become the main implementation vehicle for coordinated regional activities aiming at transforming the regulation of the eHealth sector of the Partner Countries in line with the EU eHealth policy principles via close collaboration with various European eHealth platforms and initiatives, such as eHealth Digital Service Infrastructure (eHDSI). On a practice level, the regional eHealth Network's website will offer collaboration opportunities to implement actions under each pillar; for example, providing access to the online meeting room available at the eHDSI website to connect to its eHealth communities (operations, technical, semantic) communities engaged in developing and rolling out Patient Summaries and ePrescriptions as key use cases.

Table 10. Pillar 1: Regional networking

Objective	Description of harmonisation action
Specific	• To facilitate cooperation between the EaP Countries with the EU *(no such cooperation exists)* • To empower and strengthen capacities of the EaP regional eHealth Network to undertake regional coordination and facilitation of cooperation with the EU (*no EaP Countries have their functioning national eHealth networks aligned with the European eHealth network)* • To help establish National Stakeholder (Action Groups) associated with the regional eHealth Network to enable specific groups of healthcare specialists cooperate with their partner groups in the EU (e.g. dentists cooperate with dentists who are also in our eHealth stakeholder group, radiologists with the European society of radiologists etc.) (*no EaP Countries have national Stakeholder and Action Groups and cooperation with European partners, where available, is ad-hoc)* • To help establish National eHealth Networks associated with the Regional Network, where feasible *(no EaP Countries are the members of the European eHealth network; no EaP Countries participate in the Joint Action to support the eHealth Network)*
Meaningful	**1.1.** The regional eHealth Network is empowered through assistance in setting up its portal (aligned with EU best practices) as a networking tool knowledge repository and eventually as a common Open Platform for piloting cross-border services **1.2.** Portal's networking effectiveness and impact is measured and demonstrated via web statistics **1.3.** A feasibility study is conducted to assess the legal and technical aspects of connecting the EU infrastructure (e.g. to eHDSI, European Electronic Health Record Exchange including identification/protocols, data exchange, functional

Objective	Description of harmonisation action
	modalities for eHealth services, administration, well-being/independent living, etc) with the regional eHealth portal to enable eHealth service provision **1.4.** Portal becomes a host and facilitator of exchanging eHealth solutions based on Open Standards and best EU practices and providing access to the eHDSI communities working on operational, semantic and technical issues of interoperable ePrescriptions and Patient Records (Summaries). **1.5**. Each Partner Country establishes its (a) Stakeholder and Action Group aligned with those of the EU and (b) eHealth Network linked with the EU eHealth Network via the Regional eHealth Network **1.6.** Pilot cross-border services in ePrescription and Patient EHR (Patient Summaries) are tested on the regional common Portal
Attainable	• All countries establish a stakeholder Task force/Working group to support eHealth policy harmonisation process to align with EU best practices and standards (e.g. aligned with the EU eHealth Stakeholders Group)
Realistic	• All countries have clear plans – whether in draft form or approved – to have their eHealth strategies implemented • All countries have government agencies dealing with eHealth issues
Time-bound	• 2018/2019 -2020/2021

Table 11. Pillar 2: eHealth policy and governance

Objective	Description of harmonisation actions
Specific	• To help develop/approve eHealth policies aligned with principles of the eHealth Action Plan 2012-2020 (*no countries have eHealth policies fully aligned principles of the eHealth Action Plan 2012-2020; in most EaP Countries draft eHealth policies exist or are being developed but these are not necessarily formulated in line with the principles of the eHealth Action Plan 2012-2020)* • To help establish dedicated and well-functioning government institutions responsible for eHealth *(not all EaP Countries have such institutions; the effectiveness. Efficiency and openness of those that exist is unclear; a functional analysis is needed to assess their performance).*
Meaningful	**1.1.** Those countries that have their eHealth policies already formulated and approved are assisted in aligning them with the principles of the eHealth Action Plan 2012-2020 – 2018/2019 (e.g. with support from the EU eHealth Stakeholders Group) **1.2.** Those countries that have their eHealth policies aligned with the principles of the eHealth Action Plan 2012-2020 are assisted in launching national eHealth networks aligned with the European eHealth network – 2018/2019 – 2019/2020 (e.g. with support from the EU eHealth Stakeholders Group) **1.3.** Those countries that have their eHealth policies aligned with the principles of the eHealth Action Plan 2012-2020 and that have established their national eHealth networks in line with the principles of the European eHealth network are assisted to become members of the latter and participate in the Joint Action to support the eHealth Network – 2019/2020 (e.g. with support from the EU eHealth Stakeholders Group) **1.4.** Those countries that have eHealth policy drafts are assisted in finalising them in line with the principles of the eHealth Action Plan 2012-2020 (e.g. with

Objective	Description of harmonisation actions
	support from the EU eHealth Stakeholders Group) **1.5**. Those countries that don't have dedicated government eHealth institutions, establish them in line with EU best practices and standards **1.6.** Those countries that already have the dedicated government eHealth institutions, develop a system of performance assessment and set stakeholder/ partnership platforms in line with EU best practices
Attainable	• All countries establish a stakeholder Task force/Working group to support eHealth policy harmonisation process to align with EU best practices and standards (e.g. aligned with the EU eHealth Stakeholders Group, eHDSI))
Realistic	• All countries have clear plans – whether in draft form or approved – to have their eHealth strategies implemented • All countries have government agencies dealing with eHealth issues
Time-bound	• 2018/2019 – 2020/2021

Table 12. Pillar 3: eHealth interoperability framework and standards

Objective	Description of harmonisation actions
Specific	• To help develop eHealth interoperability systems aligned with the European eHealth Interoperability Framework to exchange health data domestically and across national borders, including the application of the once-only principle *(most EaP Countries either have plans or are have ongoing projects to develop such systems in eHealth; not all EaP Countries have implemented the whole-of-government of information exchange and a once-only principle of information reuse; no countries have cross-border interoperability of eHealth services and systems; no EaP Countries have access to the European Electronic Health Record Exchange and eHDSI)* • To help developer interoperable ePrescription and Patient Records (Summaries) services aligned with the work being done under the eHealth Digital Service Infrastructure (eHDSI).
Meaningful	**2.1.** All countries are assisted in building their eHealth interoperability systems aligned with the principles of the EU eHealth Interoperability Framework, best practices and standards – 2018/2019 – 2019/2020 **2.2.** The countries that have aligned their eHealth interoperability systems with the principles of the eHealth Interoperability Framework are assisted in joining the EU major eHealth initiatives (e.g. large-scale projects such as the next edition of epSOS) – 2019/2020 **2.3.** The countries that have aligned their eHealth interoperability systems with the principles of the eHealth Interoperability Framework are assisted to get access to eHDSI, European Electronic Health Record Exchange – 2019/2020 **2.4.** The countries that have aligned their eHealth interoperability systems with the principles of the eHealth Interoperability Framework are assisted in cross-border interoperability of eHealth services and systems
Attainable	• All countries establish a Task force/Working group to advance eHealth policy harmonisation process to align with EU standards (e.g. aligned with the EU eHealth Stakeholders Group, eHDSI)

Objective	Description of harmonisation actions
Realistic	• All countries have clear plans to build their eHealth interoperability systems
Time-bound	• 2018/2019 – 2020/2021

Table 13. Pillar 4: eHealth patient services and data protection standards

Objective	Description of harmonisation actions
Specific	• To help align with the EU new General Data Protection Regulation that will become effective as of 25 May 2018 replacing the Directive 95/46/EC *(while all EaP Countries have laws protecting personal data the existing laws and regulations are not sufficiently aligned; not all countries have data protection laws explicitly protecting health data; not all countries have data protection laws explicitly requiring the patients' consent to exchange personal health data including patients' power to protect personal data from viewing and exchanging in line with EU best practices and standards (not all countries adequately enforce the implementation of data protection laws in relation to personal health data)* • To help develop cross-border services *(EaP Countries have no access to the key elements of the European eHealth system, such as the European Electronic Health Record Exchange and the digital access to citizens' EHR; no countries provide eHealth services across borders; in most countries Patient Portals are either established or are planned; most countries provide certain eHealth services to citizens and have already implemented (fully or partially) ePrescription services; some countries have legal provisions in place for providing eHealth services across borders)* • To help align with the EU data security standards and practices by cooperating with ENISA (European Network and Information Security Agency), especially through training and awareness-raising activities (no EaP country (*EaP Countries do not cooperate with ENISA and its products and services are largely unknown in the EaP region in general and among health practitioners in particular)*
Meaningful	**3.1.** Those countries that have dedicated data protection laws already in place are assisted to align them with EU best practices and standards (e.g. the new GDPR regulation as of 25 May 2018) – 2018/2019 **3.2.** Those countries that don't yet have dedicated data protection laws are assisted to formulate them in line with EU best practices and standards (e.g. the new GDPR regulation as of 25 May 2018) – 2018/2019 **3.3.** Those countries that have digital access to citizens EHRs and have aligned with the General Data Protection Regulation principles concerning the access to personal health data are assisted to get access to the European Electronic Health Record Exchange – 2019/2020 **3.4**. Those countries that have aligned their eHealth interoperability with the EU eHealth interoperability Framework are assisted in cross-border interoperability solutions – 2019/2020 • **3.5.** Assistance on demand provided in ePrescription services – 2018/2019 • **3.6.** Assistance on demand provided in setting up Patient Portals – 2018/2019 – 2019/2020 **3.7.** Those countries that have aligned their eHealth interoperability with the EU eHealth interoperability Framework are assisted in cross-border ePrescription

Objective	Description of harmonisation actions
	services – 2019/2020 **3.8.** Those countries that have aligned their eHealth interoperability with the EU eHealth interoperability Framework are assisted in cross-border exchanges of patient EHRs – 2019/2020
Attainable	• All countries establish a Task force/Working group to advance eHealth policy harmonisation process to align with EU standards (e.g. aligned with the EU eHealth Stakeholders Group)
Realistic	• All countries have offer eHealth services to citizens and have plans to offer more, e.g. ePrescriptions including via Patient Portals
Time-bound	• 2019/2020 – 2020/2021

5.1.2 Harmonisation milestones

Figures 24, 25, 26 and 27 below demonstrate the planned harmonisation milestones for each pillar.

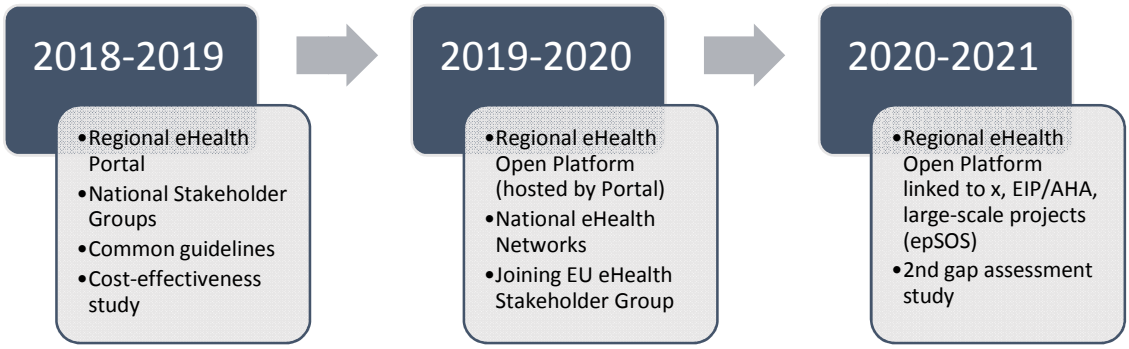


Figure 24. Milestones for Pillar 1 Regional networking and cooperation

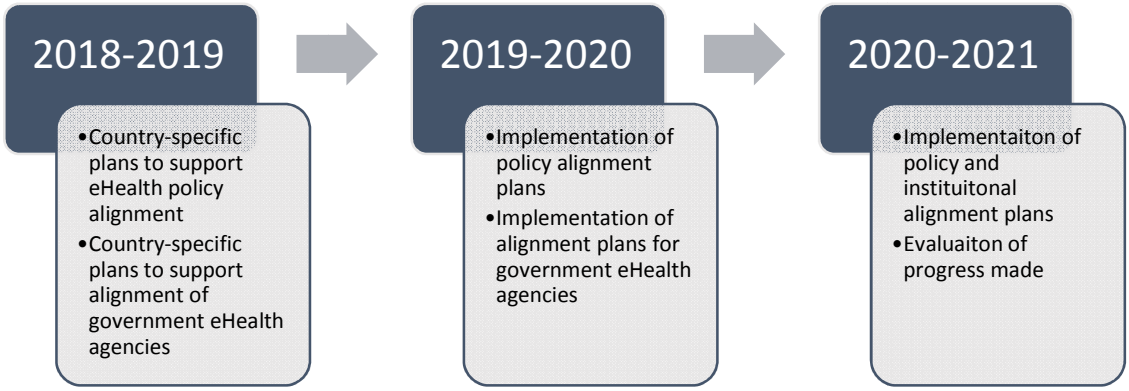


Figure 25. Milestones for Pillar 2 eHealth policy and governance

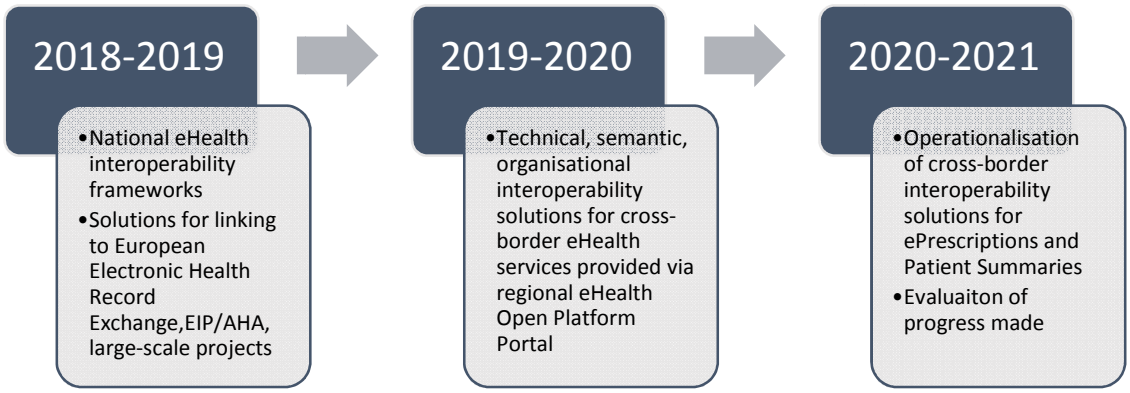


Figure 26. Milestones for Pillar 3 eHealth interoperability framework and standards

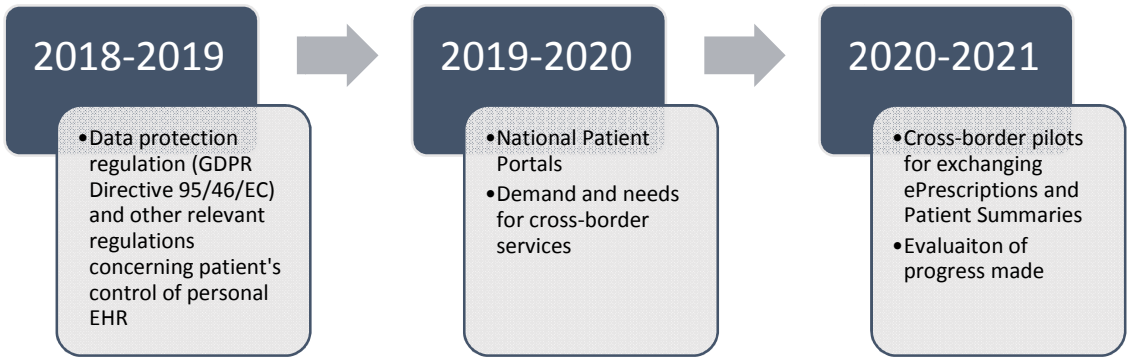


Figure 27. Milestones for Pillar 4 eHealth patient services and data protection standards

5.1.3 Harmonisation actions/projects

The following project activities are proposed under each harmonisation pillar.

Pillar 1: Regional networking and cooperation

2018 - 2019

Action 1.1: Set up regional Portal for EaP eHealth Network and populate it with knowledge depositary, forum and link it to the eHDSI technical, operational and semantic communities working on interoperable ePrescripiton and Patient Summary use cases; ***Action 1.2***: Elaborate common guidelines, standards and principles for establishing national eHealth Stakeholder Groups; ***Action 1.3***: Set up national eHealth Stakeholder Groups whose representatives will form a regional Stakeholder Group as part of the regional eHealth network; ***Action 1.4***: Elaborate common guidelines, standards and principles for establishing national eHealth Networks in line with European eHealth Network; ***Action 1.5***: Undertake a cost-effectiveness study of eHealth projects to create a repository of good practices

↓

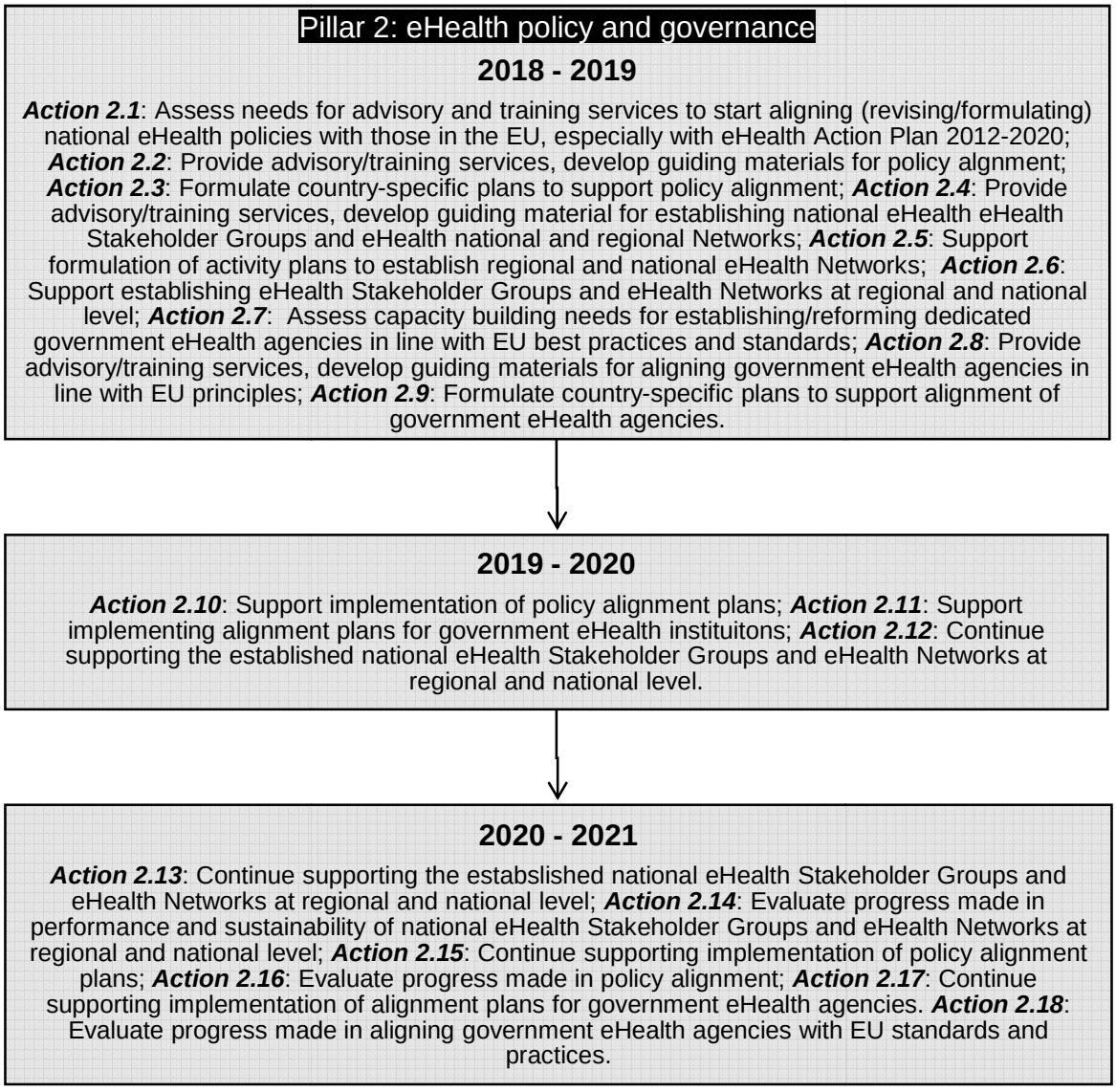
2019 - 2020

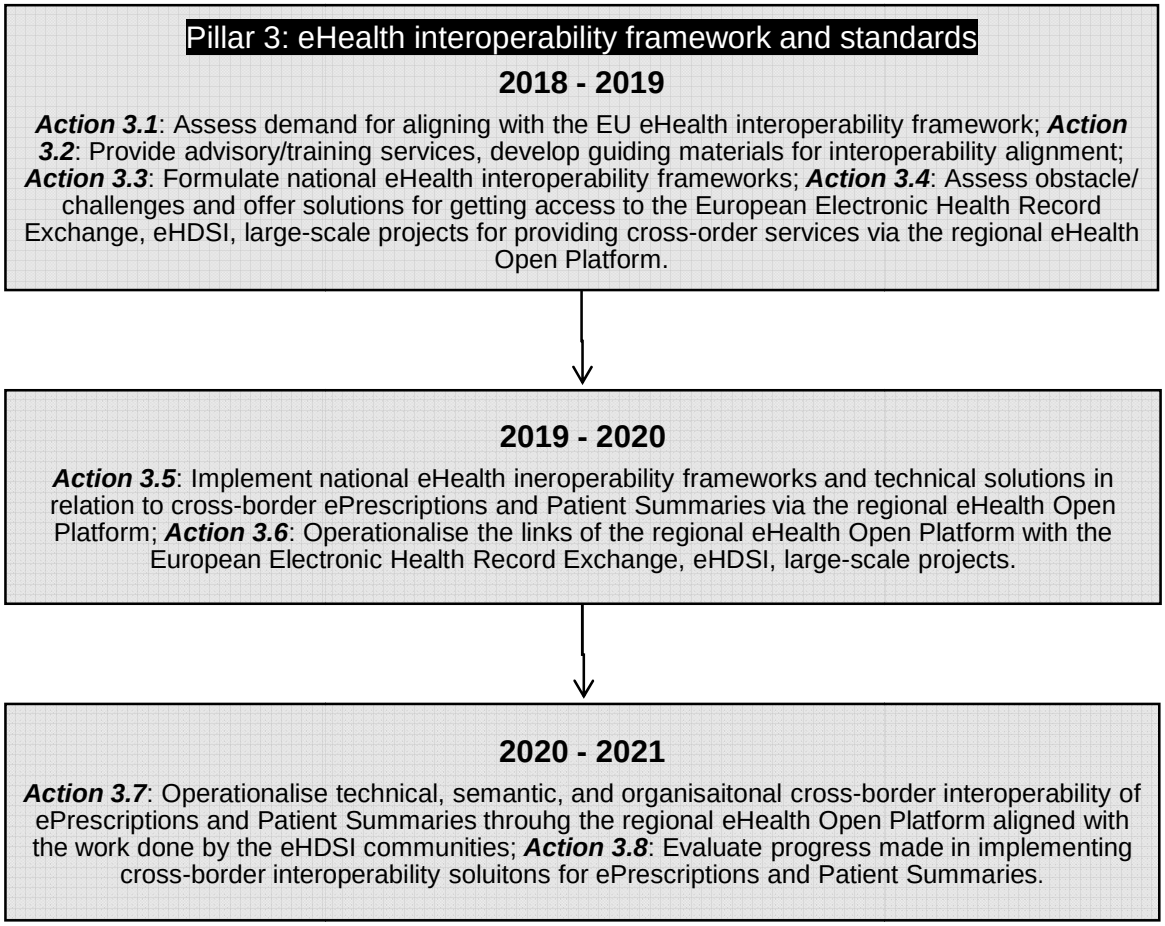
Action 1.6: Create an Open eHealth Platform on the regional Portal with the functionality allowing for sharing eHealth interoperability solutions; ***Action 1.7***: Start establishing national eHealth Networks; ***Action 1.8***: Provide advisory/ training services, develop and offer organisational and technical guidance for establishing national eHealth Networks; ***Action 1.9***: Establish national eHealth portals linked with the regional Open Platform Portal; ***Action 1.10***: Provide advisory/ training services, develop and offer organisational and technical guidance for creating functionality to exchange Patient Summaries and ePrescriptions via the regional Open Platform; ***Action 1.11***: Provide advisory/ training services, develop and offer organisational and technical guidance for linking the regional Open Platform with the European Electronic Health Record Exchange, EIP (on AHA), large-scale projects (e.g.epSOS).

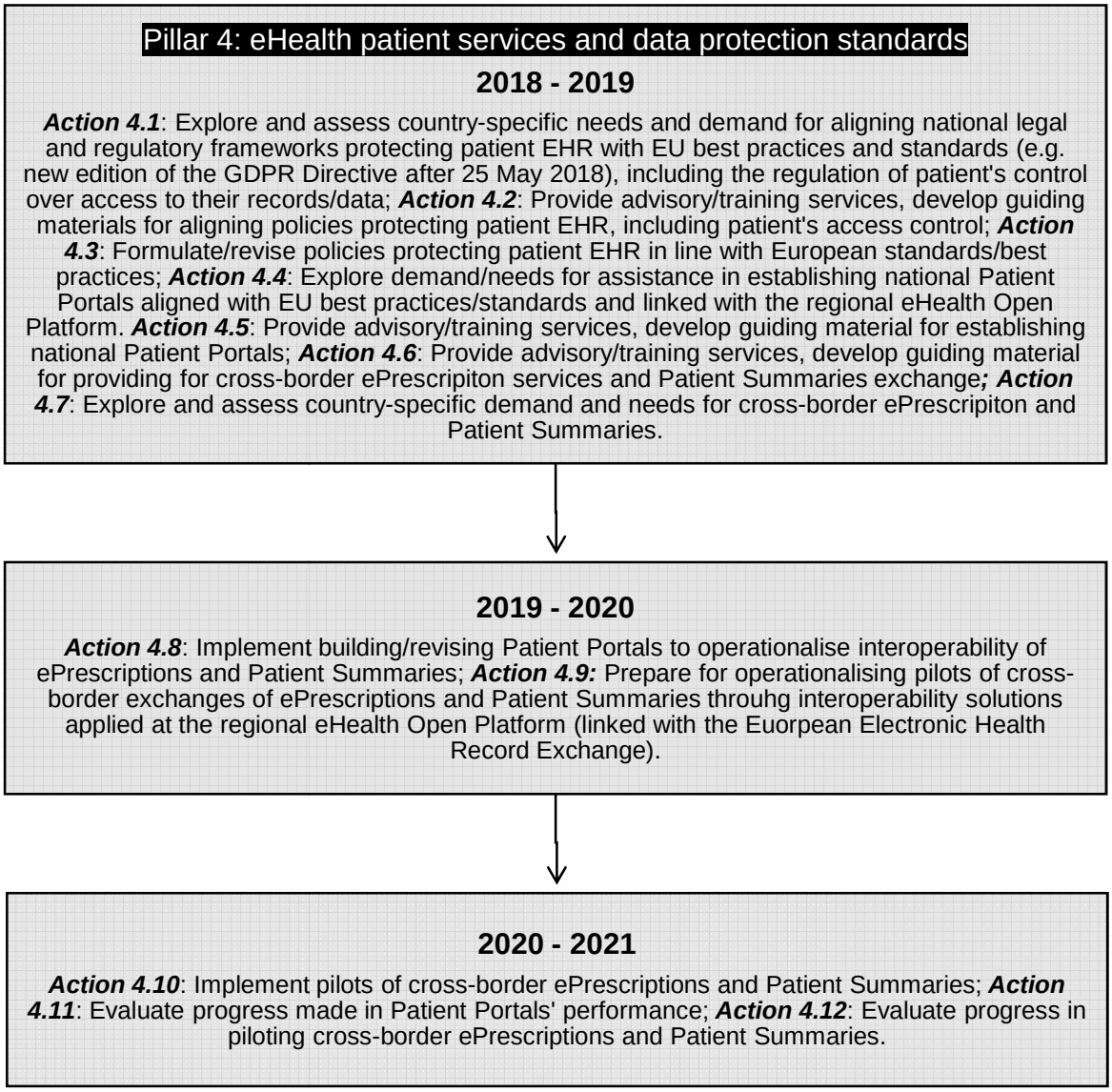
↓

2020 - 2021

Action 1.12: Link regional eHealth Open Platform to the European Electronic Health Record Exchange, EIP, relevant large-scale projects to pilot cross-border ePrescription and Patient Summaries; ***Action 4.13***: Evaluate performance, impact and outreach of the reigonal eHealth Open Platform; ***Action 4.14***: Undertake a second gap assessment study to evaluate progress of harmonisation.


Pillar 2: eHealth policy and governance
2018 - 2019
Action 2.1: Assess needs for advisory and training services to start aligning (revising/formulating) national eHealth policies with those in the EU, especially with eHealth Action Plan 2012-2020; Action 2.2: Provide advisory/training services, develop guiding materials for policy algnment; Action 2.3: Formulate country-specific plans to support policy alignment; Action 2.4: Provide advisory/training services, develop guiding material for establishing national eHealth eHealth Stakeholder Groups and eHealth national and regional Networks; Action 2.5: Support formulation of activity plans to establish regional and national eHealth Networks; Action 2.6: Support establishing eHealth Stakeholder Groups and eHealth Networks at regional and national level; Action 2.7: Assess capacity building needs for establishing/reforming dedicated government eHealth agencies in line with EU best practices and standards; Action 2.8: Provide advisory/training services, develop guiding materials for aligning government eHealth agencies in line with EU principles; Action 2.9: Formulate country-specific plans to support alignment of government eHealth agencies.
2019 - 2020
Action 2.10: Support implementation of policy alignment plans; Action 2.11: Support implementing alignment plans for government eHealth instituitons; Action 2.12: Continue supporting the established national eHealth Stakeholder Groups and eHealth Networks at regional and national level.
2020 - 2021
Action 2.13: Continue supporting the establslished national eHealth Stakeholder Groups and eHealth Networks at regional and national level; Action 2.14: Evaluate progress made in performance and sustainability of national eHealth Stakeholder Groups and eHealth Networks at regional and national level; Action 2.15: Continue supporting implementation of policy alignment plans; Action 2.16: Evaluate progress made in policy alignment; Action 2.17: Continue supporting implementation of alignment plans for government eHealth agencies. Action 2.18: Evaluate progress made in aligning government eHealth agencies with EU standards and practices.


Pillar 3: eHealth interoperability framework and standards
2018 - 2019
Action 3.1: Assess demand for aligning with the EU eHealth interoperability framework; Action 3.2: Provide advisory/training services, develop guiding materials for interoperability alignment; Action 3.3: Formulate national eHealth interoperability frameworks; Action 3.4: Assess obstacle/ challenges and offer solutions for getting access to the European Electronic Health Record Exchange, eHDSI, large-scale projects for providing cross-order services via the regional eHealth Open Platform.
2019 - 2020
Action 3.5: Implement national eHealth ineroperability frameworks and technical solutions in relation to cross-border ePrescriptions and Patient Summaries via the regional eHealth Open Platform; Action 3.6: Operationalise the links of the regional eHealth Open Platform with the European Electronic Health Record Exchange, eHDSI, large-scale projects.
2020 - 2021
Action 3.7: Operationalise technical, semantic, and organisaitonal cross-border interoperability of ePrescriptions and Patient Summaries throuhg the regional eHealth Open Platform aligned with the work done by the eHDSI communities; Action 3.8: Evaluate progress made in implementing cross-border interoperability soluitons for ePrescriptions and Patient Summaries.



Below is an example of how harmonisation activities could look like under Pillar 2.

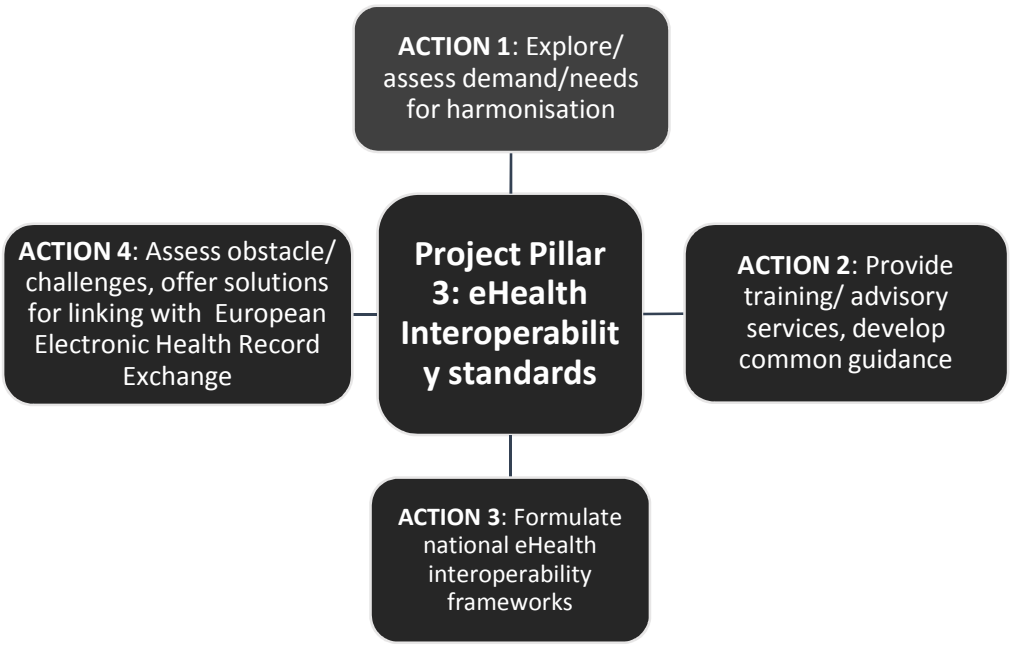


Figure 28. Proposed activities under harmonisation Pillar 3 on eHealth interoperability

Figure 30 below proposes a mix of implementation modalities that could be used within each harmonisation pillar to deliver specific projects.

Figure 29. Project harmonisation modalities

The proposed harmonisation activities serve as an entry point for the common activities over the next three years 2018-2020 in line with the planned timeframe of a possible support that could be provided through the European Neighbourhood Policy (ENP) assistance instruments.. The proposed actions in eHealth aim at cooperation at the regional level, especially in addressing the interoperable solutions for ePrescriptions and Patient Records, to create a critical mass for wider and deeper cooperation after 2020 which would have a stronger country level dimension. In parallel with the proposed regional activities, technical assistance and policy advice are proposed to be used as additional support tools for individual EaP Countries. Twinning activities when applicable (the ENP East twinning page[91] mentions Armenia, Azerbaijan, Georgia, Moldova and Ukraine as eligible for bilateral twinning projects with the EU Member States) can be used to share experiences and good practices. Besides regional networking and cooperation, much can be gained through strengthened collaboration/interaction with the EU bodies on standardisation dealing with healthcare, ICT, interoperability, services e.g. CEN, ISO). Partnerships with EIP-AHA, IHE[92] by attending important meetings for knowledge exchange and twinning on topics such as SNOMED and HL7 implementation as well as eHealth service provision.

As far as eHealth innovation is concerned, the Study Team also recommends to that the opportunities created by the EaPConnect project should be fully utilised to improve eHealth infrastructure and services in the region thanks to the state-of-the art high-capacity broadband internet networks for research and education across the EaP Partner Countries. Innovation in eHealth which seriously demonstrates one of the largest gaps across the board and cooperation with this project could be especially beneficial.

In addition to common activities, the Study Team proposes to create in 2018 a ‘fast-lane’ umbrella project dedicated to quickly responding to the courtiers’ specific needs on a demand-driven basis, as illustrated in Figure 31.

[91] https://ec.europa.eu/neighbourhood-enlargement/tenders/twinning_en.

[92] https://ec.europa.eu/eip/ageing/home_en.

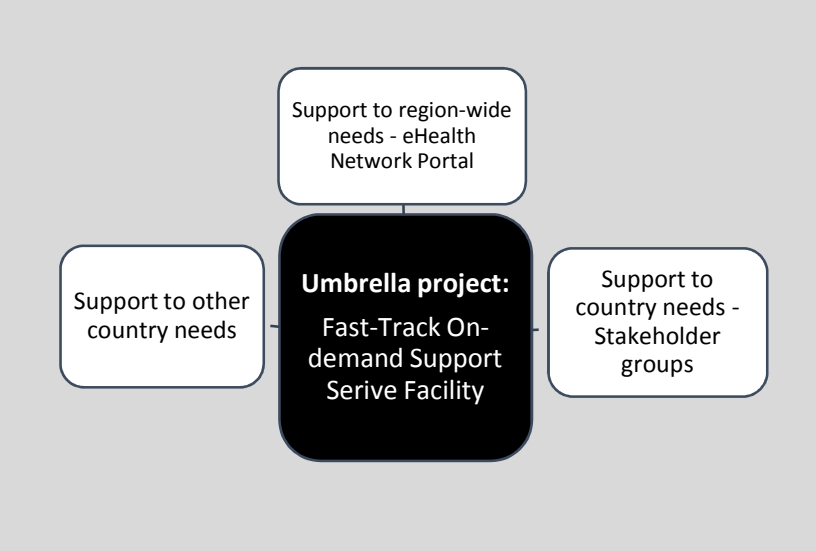


Figure 30. A fast-track support facility project

Such a needs-driven support can facilitate the wider uptake of the harmonisation activities, strengthen the credibility of the proposed agenda in the eyes of the Partner Countries and mobilise other donors as well.

5.2 Roadmaps for Partner Countries

The roadmaps for individual Partner Countries are based in the first place on the proposed regional roadmap and follow its logic. In addition, the roadmaps for Armenia and Ukraine also include – as part of the priority areas of cooperation with the EU – specific projects that were proposed by the national eHealth authorities (presented in the summarised form). A range of concrete obstacles and challenges to meet were identified for Belarus, Georgia and Moldova.

5.2.1 Roadmap for Armenia

Priority areas/projects of cooperation with EU:

Project 1: Fund raising for purchasing the necessary IT equipment for medical centres

Goal:	Purchasing the necessary number of computers, ID readers, printers and other equipment for implementation of e-health in Armenia
Outcome:	Having the opportunity to start implementation of e-health in all medical centres (included in rural areas), which will ensure the implementation of EMR of citizens and ePrescription.

Implementation mode:	Advice
Target beneficiaries:	Ministry of Health/state medical centres.

Project 2: Creation of legal framework for harmonisation and exchanging medical information with EU

Goal:	Creation of comprehensive legislation regulating eHealth processes
Outcome:	Learning from EU best practices in this field for development of legal framework for eHealth implementation in national level and exchanging Electronic Health Records with EU platforms.
Implementation mode:	Legal advice
Target beneficiaries:	Ministry of Health.

Participation in common actions of the regional roadmap.

Pillar 1: Regional eHealth networking and cooperation

2018 - 2019

- Action 1.3: Set up national eHealth Stakeholder Groups.
- Action 1.4: Elaborate common guidelines, standards and principles for establishing national eHealth Networks in line with European eHealth Network.

2019 - 2020

- Action 1.7: Establish national eHealth Networks.
- Action 1.10: Provide advisory/ training services, develop and offer organisational and technical guidance for creating functionality to exchange Patient Summaries and ePrescriptions via the regional Open Platform.

2020 - 2021

- Action 1.12: Link regional eHealth Open Platform to the European Electronic Health Record Exchange, EIP, relevant large-scale projects to pilot cross-border ePrescription and Patient Summaries.

- Action 1.14: Undertake a second gap assessment study to evaluate progress of harmonisation.

Pillar 2: Policy and governance

2018 - 2019

- Action 2.1: Assess needs for advisory and training services to start aligning (revising/formulating) national eHealth policies with those in the EU, especially with eHealth Action Plan 2012-2020.
- Action 2.2: Provide advisory/training services, develop guiding materials for policy alignment.
- Action 2.4: Provide advisory/training services, develop guiding material for establishing national eHealth Stakeholder Groups and eHealth national and regional Networks.

2019 - 2020

- Action 2.11: Support implementing alignment plans for government eHealth institutions.
- Action 2.12: Continue supporting the established national eHealth Stakeholder Groups and eHealth Networks at regional and national level.

2020 - 2021

- Action 2.17: Continue supporting implementation of alignment plans for government eHealth agencies.

Pillar 3: Interoperability framework and standards

2018 - 2019

- Action 3.3: Formulate national eHealth interoperability frameworks.
- Action 3.4: Assess obstacle/ challenges and offer solutions for getting access to the European Electronic Health Record Exchange, large-scale projects for providing cross-order services via the regional eHealth Open Platform.

2019 - 2020

- Action 3.5: Implement national eHealth ineroperability frameworks and technical solutions in relation to cross-border ePrescriptions and Patient Summaries via the regional eHealth Open Platform.

2020 - 2021

- Action 3.7: Operationalise technical, semantic, and organisational cross-border interoperability of ePrescriptions and Patient Summaries through the regional eHealth Open Platform.
- Action 3.8: Evaluate progress made in implementing cross-border interoperability

solutions for ePrescriptions and Patient Summaries.

Pillar 4: eHealth patient services and data protection standards

2018 - 2019

- Action 4.1: Explore and assess country-specific needs and demand for aligning national legal and regulatory frameworks protecting patient EHR with EU best practices and standards (e.g. GDPR Directive 95/46/EC), including the regulation of patient's control over access to their records/data.
- Action 4.4: Explore demand/needs for assistance in establishing national Patient Portals aligned with EU best practices/standards and linked with the regional eHealth Open Action 4.5: Provide advisory/training services, develop guiding material for establishing national Patient Portals; Platform.
- Action 4.6: Provide advisory/training services, develop guiding material for providing for cross-border ePrescription services and Patient Summaries exchange.

2019 - 2020

- Action 4.8: Implement building/revising Patient Portals to operationalise interoperability of ePrescriptions and Patient Summaries
- Action 4.9: Prepare for piloting cross-border exchanges of ePrescriptions and Patient Summaries through interoperability solutions applied at the regional eHealth Open Platform (linked with the European Electronic Health Record Exchange).

2020 - 2021

- Action 4.11: Evaluate progress made in Patient Portals' performance
- Action 4.12: Evaluate progress in piloting cross-border ePrescriptions and Patient Summaries.

5.2.2 Roadmap for Azerbaijan

Participation in common actions of the regional roadmap.

Pillar 1: Regional eHealth networking and cooperation

2018 - 2019

- Action 1.1: Set up regional Portal for EaP eHealth Network and populate it with knowledge depositary, forum.
- Action 1.2: Elaborate common guidelines, standards and principles for establishing national eHealth Stakeholder Groups.
- Action 1.3: Set up national eHealth Stakeholder Groups.

- Action 1.4: Elaborate common guidelines, standards and principles for establishing national eHealth Networks in line with European eHealth Network.
- Action 1.5: Undertake a cost-effectiveness study of eHealth projects to create a repository of good practices.

2019 - 2020

- Action 1.6: Create an Open eHealth Platform on the regional Portal with the functionality allowing for sharing eHealth interoperability solutions.
- Action 1.7: Establish national eHealth Networks.
- Action 1.8: Provide advisory/ training services, develop and offer organisational and technical guidance for establishing national eHealth Networks.
- Action 1.9: Establish national eHealth portals linked with the regional Open Platform Portal.
- Action 1.10: Provide advisory/ training services, develop and offer organisational and technical guidance for creating functionality to exchange Patient Summaries and ePrescriptions via the regional Open Platform.
- Action 1.11: Provide advisory/ training services, develop and offer organisational and technical guidance for linking the regional Open Platform with the European Electronic Health Record Exchange, EIP (on AHA), large-scale projects (e.g. epSOS).

2020 - 2021

- Action 1.12: Link regional eHealth Open Platform to the European Electronic Health Record Exchange, EIP, relevant large-scale projects to pilot cross-border ePrescription and Patient Summaries.

Pillar 2: Policy and governance

2018 - 2019

- Action 2.1: Assess needs for advisory and training services to start aligning (revising/formulating) national eHealth policies with those in the EU, especially with eHealth Action Plan 2012-2020.
- Action 2.2: Provide advisory/training services, develop guiding materials for policy alignment.
- Action 2.3: Formulate country-specific plans to support policy alignment.
- Action 2.4: Provide advisory/training services, develop guiding material for establishing national eHealth Stakeholder Groups and eHealth national and regional Networks.
- Action 2.5: Support formulation of activity plans to establish regional and national eHealth Networks.
- Action 2.6: Support establishing eHealth Stakeholder Groups and eHealth Networks at

regional and national level.

- Action 2.7: Assess capacity building needs for establishing/reforming dedicated government eHealth agencies in line with EU best practices and standards.
- Action 2.8: Provide advisory/training services, develop guiding materials for aligning government eHealth agencies in line with EU principles.
- Action 2.9: Formulate country-specific plans to support alignment of government eHealth agencies.

2019 - 2020

- Action 2.10: Support implementation of policy alignment plans.
- Action 2.11: Support implementing alignment plans for government eHealth institutions.
- Action 2.12: Continue supporting the established national eHealth Stakeholder Groups and eHealth Networks at regional and national level.

2020 - 2021

- Action 2.13: Continue supporting the established national eHealth Stakeholder Groups and eHealth Networks at regional and national level.
- Action 2.14: Evaluate progress made in performance and sustainability of national eHealth Stakeholder Groups and eHealth Networks at regional and national level.
- Action 2.15: Continue supporting implementation of policy alignment plans.
- Action 2.16: Evaluate progress made in policy alignment.
- Action 2.17: Continue supporting implementation of alignment plans for government eHealth agencies.
- Action 2.18: Evaluate progress made in aligning government eHealth agencies with EU standards and practices.

Pillar 3: Interoperability framework and standards

2018 - 2019

- Action 3.1: Assess demand for aligning with the EU eHealth interoperability framework.
- Action 3.2: Provide advisory/training services, develop guiding materials for interoperability alignment.
- Action 3.3: Formulate national eHealth interoperability frameworks.
- Action 3.4: Assess obstacle/ challenges and offer solutions for getting access to the European Electronic Health Record Exchange, large-scale projects for providing cross-order services via the regional eHealth Open Platform.

2019 - 2020

- Action 3.5: Implement national eHealth interoperability frameworks and technical

solutions in relation to cross-border ePrescriptions and Patient Summaries via the regional eHealth Open Platform.

- Action 3.6: Operationalise the links of the regional eHealth Open Platform with the European Electronic Health Record Exchange, large-scale projects.

2020 - 2021

- Action 3.7: Operationalise technical, semantic, and organisational cross-border interoperability of ePrescriptions and Patient Summaries through the regional eHealth Open Platform.
- Action 3.8: Evaluate progress made in implementing cross-border interoperability solutions for ePrescriptions and Patient Summaries.

Pillar 4: eHealth patient services and data protection standards

2018 - 2019

- Action 4.1: Explore and assess country-specific needs and demand for aligning national legal and regulatory frameworks protecting patient EHR with EU best practices and standards (e.g. GDPR Directive 95/46/EC), including the regulation of patient's control over access to their records/data.
- Action 4.2: Provide advisory/training services, develop guiding materials for aligning policies protecting patient EHR, including patient's access control.
- Action 4.3: Formulate/revise policies protecting patient EHR in line with European standards/best practices.
- Action 4.4: Explore demand/needs for assistance in establishing national Patient Portals aligned with EU best practices/standards and linked with the regional eHealth Open Platform Portal.
- Action 4.5: Provide advisory/training services, develop guiding material for establishing national Patient Portals; Platform.
- Action 4.6: Provide advisory/training services, develop guiding material for providing for cross-border ePrescription services and Patient Summaries exchange.
- Action 4.7: Explore and assess country-specific demand and needs for cross-border ePrescription and Patient Summaries.

2019 - 2020

- Action 4.8: Implement building/revising Patient Portals to operationalise interoperability of ePrescriptions and Patient Summaries.
- Action 4.9: Prepare for piloting cross-border exchanges of ePrescriptions and Patient Summaries through interoperability solutions applied at the regional eHealth Open Platform (linked with the European Electronic Health Record Exchange).

2020 - 2021

- Action 4.10: Implement pilots of cross-border ePrescriptions and Patient Summaries.
- Action 4.11: Evaluate progress made in Patient Portals' performance;
- Action 4.12: Evaluate progress in piloting cross-border ePrescriptions and Patient Summaries.
- Action 4.13: Evaluate performance, impact and outreach of the regional eHealth Open Platform.
- Action 4.14: Undertake a second gap assessment study to evaluate progress of harmonisation.

5.2.3 Roadmap for Belarus

Priority areas of cooperation with EU:

- Mainstreaming EU strategic approaches into the national eHealth domain.
- Researching the choices between an array of possible policy instruments and programme intervention, including a research into a cost-effectiveness analysis of Health solutions.
- Advising on new legislation to better protect patients‘ data and privacy.

Obstacles to overcome, challenges to meet:

- Lack of knowledge and understanding of comprehensible eHealth strategies adopted in EU.
- Absence of documented economic benefits and cost–effectiveness of eHealth solutions.
- Insufficient legislative and regulatory framework.
- Hampered policy implementation process.
- Absence of adequate evaluation and monitoring methodologies for eHealth projects implementation.
- Absence of both Russian or Belarusian language versions of strategic documents.
- Lack of forward-looking feasibility studies for developing and adopting key strategic priorities and absence of cost-effectiveness analysis of the existent solutions, including patients’ demand.
- Patients’ privacy and data protection are not sufficiently protected by law.
- Lacking patients’ centric approach to eHealth.
- Research and policy are not aligned to produce useful, evidence-based outcomes.

Participation in common actions of the regional roadmap.

Pillar 1: Regional eHealth networking and cooperation

2018 -2019

- Action 1.1: Set up regional Portal for EaP eHealth Network and populate it with knowledge depositary, forum.
- Action 1.2: Elaborate common guidelines, standards and principles for establishing national eHealth Stakeholder Groups.
- Action 1.3: Set up national eHealth Stakeholder Groups.
- Action 1.4: Elaborate common guidelines, standards and principles for establishing national eHealth Networks in line with European eHealth Network.
- Action 1.5: Undertake a cost-effectiveness study of eHealth projects to create a repository of good practices.

2019 - 2020

- Action 1.6: Create an Open eHealth Platform on the regional Portal with the functionality allowing for sharing eHealth interoperability solutions.
- Action 1.7: Establish national eHealth Networks.
- Action 1.8: Provide advisory/ training services, develop and offer organisational and technical guidance for establishing national eHealth Networks.
- Action 1.9: Establish national eHealth portals linked with the regional Open Platform Portal.
- Action 1.10: Provide advisory/ training services, develop and offer organisational and technical guidance for creating functionality to exchange Patient Summaries and ePrescriptions via the regional Open Platform.
- Action 1.11: Provide advisory/ training services, develop and offer organisational and technical guidance for linking the regional Open Platform with the European Electronic Health Record Exchange, EIP (on AHA), large-scale projects (e.g.epSOS). .

2020 - 2021

- Action 1.12: Link regional eHealth Open Platform to the European Electronic Health Record Exchange, EIP, relevant large-scale projects to pilot cross-border ePrescription and Patient Summaries.
- Action 1.13: Evaluate performance, impact and outreach of the regional eHealth Open Platform.
- Action 1.14: Undertake a second gap assessment study to evaluate progress of harmonisation.

Pillar 2: Policy and governance

2018 - 2019

- Action 2.1: Assess needs for advisory and training services to start aligning (revising/formulating) national eHealth policies with those in the EU, especially with

eHealth Action Plan 2012-2020.

- Action 2.2: Provide advisory/training services, develop guiding materials for policy alignment.
- Action 2.3: Formulate country-specific plans to support policy alignment.
- Action 2.4: Provide advisory/training services, develop guiding material for establishing national eHealth Stakeholder Groups and eHealth national and regional Networks.
- Action 2.5: Support formulation of activity plans to establish regional and national eHealth Networks.
- Action 2.6: Support establishing eHealth Stakeholder Groups and eHealth Networks at regional and national level.
- Action 2.7: Assess capacity building needs for establishing/reforming dedicated government eHealth agencies in line with EU best practices and standards.
- Action 2.8: Provide advisory/training services, develop guiding materials for aligning government eHealth agencies in line with EU principles.
- Action 2.9: Formulate country-specific plans to support alignment of government eHealth agencies.

2019 - 2020

- Action 2.10: Support implementation of policy alignment plans.
- Action 2.11: Support implementing alignment plans for government eHealth institutions.
- Action 2.12: Continue supporting the established national eHealth Stakeholder Groups and eHealth Networks at regional and national level.

2020 - 2021

- Action 2.13: Continue supporting the established national eHealth Stakeholder Groups and eHealth Networks at regional and national level.
- Action 2.14: Evaluate progress made in performance and sustainability of national eHealth Stakeholder Groups and eHealth Networks at regional and national level.
- Action 2.15: Continue supporting implementation of policy alignment plans.
- Action 2.16: Evaluate progress made in policy alignment.
- Action 2.17: Continue supporting implementation of alignment plans for government eHealth agencies.
- Action 2.18: Evaluate progress made in aligning government eHealth agencies with EU standards and practices.

Pillar 3: Interoperability framework and standards

2018 - 2019

- Action 3.1: Assess demand for aligning with the EU eHealth interoperability framework.

- Action 3.2: Provide advisory/training services, develop guiding materials for interoperability alignment.
- Action 3.3: Formulate national eHealth interoperability frameworks.
- Action 3.4: Assess obstacle/ challenges and offer solutions for getting access to the European Electronic Health Record Exchange, large-scale projects for providing cross-order services via the regional eHealth Open Platform.

2019 - 2020

- Action 3.5: Implement national eHealth interoperability frameworks and technical solutions in relation to cross-border ePrescriptions and Patient Summaries via the regional eHealth Open Platform.
- Action 3.6: Operationalise the links of the regional eHealth Open Platform with the European Electronic Health Record Exchange, large-scale projects.

2020 - 2021

- Action 3.7: Operationalise technical, semantic, and organisational cross-border interoperability of ePrescriptions and Patient Summaries through the regional eHealth Open Platform.
- Action 3.8: Evaluate progress made in implementing cross-border interoperability solutions for ePrescriptions and Patient Summaries.

Pillar 4: eHealth patient services and data protection standards

2018 - 2019

- Action 4.1: Explore and assess country-specific needs and demand for aligning national legal and regulatory frameworks protecting patient EHR with EU best practices and standards (e.g. GDPR Directive 95/46/EC), including the regulation of patient's control over access to their records/data.
- Action 4.2: Provide advisory/training services, develop guiding materials for aligning policies protecting patient EHR, including patient's access control.
- Action 4.3: Formulate/revise policies protecting patient EHR in line with European standards/best practices.
- Action 4.4: Explore demand/needs for assistance in establishing national Patient Portals aligned with EU best practices/standards and linked with the regional eHealth Open Platform Portal.
- Action 4.5: Provide advisory/training services, develop guiding material for establishing national Patient Portals; Platform.
- Action 4.6: Provide advisory/training services, develop guiding material for providing for cross-border ePrescription services and Patient Summaries exchange.
- Action 4.7: Explore and assess country-specific demand and needs for cross-border ePrescription and Patient Summaries.

2019 - 2020

- Action 4.8: Implement building/revising Patient Portals to operationalise interoperability of ePrescriptions and Patient Summaries.
- Action 4.9: Prepare for piloting cross-border exchanges of ePrescriptions and Patient Summaries through interoperability solutions applied at the regional eHealth Open Platform (linked with the European Electronic Health Record Exchange).

2020 -2021

- Action 4.10: Implement pilots of cross-border ePrescriptions and Patient Summaries.
- Action 4.11: Evaluate progress made in Patient Portals' performance;
- Action 4.12: Evaluate progress in piloting cross-border ePrescriptions and Patient Summaries.

5.2.4 Roadmap for Georgia

Priority areas of cooperation with EU:

- Identification and authentication.
- Legal framework.
- Patients' rights.
- Electronic Health Record (EHR) development.
- Patient's Portal development.
- Online list of Health care facilities and their doctors and their ratings.
- Telemedicine.
- Mobile Medicine.
- Medical decision Support systems.
- ePrescription.
- Joint planning of eHealth policy and strategy development via building joint EU-Georgia teams of experts, e.g. from the Baltic Member States (to make the Georgian healthcare system interoperable with the EU).
- Developing eHealth project ideas for the South Caucasus/ Black Sea regions for participation in the future Horizon2020 or COST programmes calls.
- Organising regional eHealth conferences, workshops and expos with participation and co-funding from EU, establishing new networks and eHealth incubator in Tbilisi.
- Engaging in Active and Health Aging (AHA) and Assisted Ambient Living (AAL) programmes.
- Realising patient empowerment through greater transparency, improved access to

services and information and the use of social media for health, unlocking effective health data.

- Supporting research, development and innovation in eHealth and wellbeing to address the lack of availability of user-friendly tools and services.
- Fostering cross-border healthcare, health security, solidarity, universality and equity.
- Facilitating socio-economic inclusion and equality in eHealth.
- Responding to the growing prominence of chronic diseases.
- Developing a roadmap of joint activities with local promoters of change (e.g. Partners for Health [93] NGO, Institute of Neurology and Neuropsychology [94], Association of Dermatooncology, Dermatoscopy and Skin Optical Diagnostic[95] (ADDaSOD); launching pilots to test or simulate eHealth-related projects, e.g. in cooperation with Shota Rustaveli National Science Foundation (possibility of joint calls).

Obstacles to overcome, challenges to meet:

- Lack of clarity of how to identify foreign patients in both technical and legal terms (e.g. uncertainty in terms of what information to exchange / harmonise; how to protect personal data; how to develop common identification standards; how to finance such a project).
- Develop common content of Electronic Health Records (EHR) as a minimally necessary information to be engaged in cross-border healthcare.
- No well-defined eHealth policy and strategy.
- Lack of patent's centricity in the health information systems that focus more on management and statistical data collection than on patients.
- No proper assessment of CIS, EMR and e-Registries developed in the private healthcare sector (hospitals clinics, insurance companies); there has been one project for EMR development started by the previous government in 2011, but its results are not discussed.
- Lack of the forward-looking vision for using eHealth in patient-centred healthcare model (preventive medicine and patient-centred healthcare are not yet put into a real-life practice (the Health Ministry, the universal healthcare insurance, private insurance companies seem to be ready to apply a patient-centred eHealth models and applications).
- Lack of domestic and cross-border interoperability (in-country interoperability is still a

[93] http://pfh.org.ge/.

[94] http://www.inn.org.ge/.

[95] http://www.oncodermatology.ge/.

challenge due to the lack of inter-agency coordination, lack of understanding how to integrate with then EU interoperability projects, e.g. epSOS).

- No specific programme and funding for eHealth scientific and research projects. Government ministries, National Science Foundation and Georgian Technology and Innovation Agency so far show no rapid changes in the creation of specific niche for eHealth innovation.
- Similarly, most well-known EU Horizon2020 Programs – Active and Health Ageing and Ambient Assisted Living – are not known to Georgian researchers; lack of research and science policy and funding mechanisms to support eHealth innovation.
- No policy, vision, strategy and funding for mobile health related activities (lack of clarity how to integrate mobile health into telemonitoring and prevention).
- Lack of legal clarity, regulatory documents regarding EMR, patient data protection, telemedicine regulations and mobile health (legal reform of Healthcare sector has not addressed these issues since 2000-2001).
- High start-up costs involved in setting up eHealth systems (there are no incentives from the Universal Healthcare Programme, contracting institutions, tax agencies to implement eHealth solutions and spend more on hardware and software).
- Lack of awareness of, and confidence in eHealth solutions among patients, citizens and healthcare professionals (some healthcare institutions see eHealth and EMRs as increasing costs leading to maximum level of sharing of patient's information that may cause the "leakage of patient data" to competitors; some patients and citizens question eHealth effectiveness, although accept the related benefits).
- Limited usage of ePrescription.

Participation in common actions of the regional roadmap.

Pillar 1: Regional eHealth networking and cooperation

2018 - 2019

- Action 1.1: Set up regional Portal for EaP eHealth Network and populate it with knowledge depositary, forum;
- Action 1.2: Elaborate common guidelines, standards and principles for establishing national eHealth Stakeholder Groups;
- Action 1.3: Set up national eHealth Stakeholder Groups;
- Action 1.4: Elaborate common guidelines, standards and principles for establishing national eHealth Networks in line with European eHealth Network;

  Action 1.5: Undertake a cost-effectiveness study of eHealth projects to create a repository of good practices

2019 - 2020

- Action 1.6: Create an Open eHealth Platform on the regional Portal with the functionality allowing for sharing eHealth interoperability solutions;

- Action 1.7: Establish national eHealth Networks;
- Action 1.8: Provide advisory/ training services, develop and offer organisational and technical guidance for establishing national eHealth Networks;
- Action 1.9: Establish national eHealth portals linked with the regional Open Platform Portal;
- Action 1.10: Provide advisory/ training services, develop and offer organisational and technical guidance for creating functionality to exchange Patient Summaries and ePrescriptions via the regional Open Platform;
- Action 1.11: Provide advisory/ training services, develop and offer organisational and technical guidance for linking the regional Open Platform with the European Electronic Health Record Exchange, EIP (on AHA), large-scale projects (e.g. epSOS).

2020 - 2021

- Action 1.12: Link regional eHealth Open Platform to the European Electronic Health Record Exchange, EIP, relevant large-scale projects to pilot cross-border ePrescription and Patient Summaries;
- Action 1.13: Evaluate performance, impact and outreach of the regional eHealth Open Platform;
- Action 1.14: Undertake a second gap assessment study to evaluate progress of harmonisation.

Pillar 2: Policy and governance

2018 - 2019

- Action 2.1: Assess needs for advisory and training services to start aligning (revising/formulating) national eHealth policies with those in the EU, especially with eHealth Action Plan 2012-2020.
- Action 2.2: Provide advisory/training services, develop guiding materials for policy alignment.
- Action 2.3: Formulate country-specific plans to support policy alignment.
- Action 2.4: Provide advisory/training services, develop guiding material for establishing national eHealth Stakeholder Groups and eHealth national and regional Networks.
- Action 2.5: Support formulation of activity plans to establish regional and national eHealth Networks.
- Action 2.6: Support establishing eHealth Stakeholder Groups and eHealth Networks at regional and national level.
- Action 2.7: Assess capacity building needs for establishing/reforming dedicated government eHealth agencies in line with EU best practices and standards.
- Action 2.8: Provide advisory/training services, develop guiding materials for aligning government eHealth agencies in line with EU principles.

- Action 2.9: Formulate country-specific plans to support alignment of government eHealth agencies.

2019 - 2020

- Action 2.10: Support implementation of policy alignment plans.
- Action 2.11: Support implementing alignment plans for government eHealth institutions.
- Action 2.12: Continue supporting the established national eHealth Stakeholder Groups and eHealth Networks at regional and national level.

2020 - 2021

- Action 2.13: Continue supporting the established national eHealth Stakeholder Groups and eHealth Networks at regional and national level.
- Action 2.14: Evaluate progress made in performance and sustainability of national eHealth Stakeholder Groups and eHealth Networks at regional and national level.
- Action 2.15: Continue supporting implementation of policy alignment plans.
- Action 2.16: Evaluate progress made in policy alignment.
- Action 2.17: Continue supporting implementation of alignment plans for government eHealth agencies.
- Action 2.18: Evaluate progress made in aligning government eHealth agencies with EU standards and practices.

Pillar 3: Interoperability framework and standards

2018 - 2019

- Action 3.1: Assess demand for aligning with the EU eHealth interoperability framework.
- Action 3.2: Provide advisory/training services, develop guiding materials for interoperability alignment.
- Action 3.3: Formulate national eHealth interoperability frameworks.
- Action 3.4: Assess obstacle/ challenges and offer solutions for getting access to the European Electronic Health Record Exchange, large-scale projects for providing cross-order services via the regional eHealth Open Platform.

2019 - 2020

- Action 3.5: Implement national eHealth interoperability frameworks and technical solutions in relation to cross-border ePrescriptions and Patient Summaries via the regional eHealth Open Platform.
- Action 3.6: Operationalise the links of the regional eHealth Open Platform with the European Electronic Health Record Exchange, large-scale projects.

2020 - 2021

- Action 3.7: Operationalise technical, semantic, and organisational cross-border interoperability of ePrescriptions and Patient Summaries through the regional eHealth Open Platform.
- Action 3.8: Evaluate progress made in implementing cross-border interoperability solutions for ePrescriptions and Patient Summaries.

Pillar 4: eHealth patient services and data protection standards

2018 - 2019

- Action 4.1: Explore and assess country-specific needs and demand for aligning national legal and regulatory frameworks protecting patient EHR with EU best practices and standards (e.g. GDPR Directive 95/46/EC), including the regulation of patient's control over access to their records/data.
- Action 4.2: Provide advisory/training services, develop guiding materials for aligning policies protecting patient EHR, including patient's access control.
- Action 4.3: Formulate/revise policies protecting patient EHR in line with European standards/best practices.
- Action 4.4: Explore demand/needs for assistance in establishing national Patient Portals aligned with EU best practices/standards and linked with the regional eHealth Open Platform Portal.
- Action 4.5: Provide advisory/training services, develop guiding material for establishing national Patient Portals; Platform.
- Action 4.6: Provide advisory/training services, develop guiding material for providing for cross-border ePrescription services and Patient Summaries exchange.
- Action 4.7: Explore and assess country-specific demand and needs for cross-border ePrescription and Patient Summaries.

2019 - 2020

- Action 4.8: Implement building/revising Patient Portals to operationalise interoperability of ePrescriptions and Patient Summaries.
- Action 4.9: Prepare for piloting cross-border exchanges of ePrescriptions and Patient Summaries through interoperability solutions applied at the regional eHealth Open Platform (linked with the European Electronic Health Record Exchange).

2020 - 2021

- Action 4.10: Implement pilots of cross-border ePrescriptions and Patient Summaries.
- Action 4.11: Evaluate progress made in Patient Portals' performance;
- Action 4.12: Evaluate progress in piloting cross-border ePrescriptions and Patient Summaries.

5.2.5 Roadmap for Moldova

Priority areas of cooperation with EU:

- Strengthening of the public health system of the Republic of Moldova, in particular through implementing health sector reform, ensuring high-quality primary healthcare, improving health governance and healthcare financing (part of the Association Agreement).
- Epidemiological surveillance and control of communicable diseases, such as for example HIV/AIDS, viral hepatitis and tuberculosis, as well as increased preparedness for public health threats and emergencies (part of the Association Agreement).
- Prevention and control of non-communicable diseases, mainly through exchange of information and best practices, promoting healthy lifestyles and addressing major health determinants, such as nutrition, addiction to alcohol, drugs and tobacco (part of the Association Agreement);
- Quality and safety of substances of human origin (part of the Association Agreement).
- Health information and knowledge (part of the Association Agreement).
- Full and timely implementation of international health agreements, in particular the International Health Regulations and the Framework Convention on Tobacco Control of 2003. The progressive integration of the Republic of Moldova into the European Union's health related networks (part of the Association Agreement).
- The progressive enhancement of interaction between the Republic of Moldova and the European Centre for Disease prevention and Control (part of the Association Agreement).
- Legal and regulatory framework in health field harmonisation including standardisation and Medical Metadata harmonisation (Suggested by draft eHealth Strategy).
- Support in Implementation of the Information System "Integrated Patient Electronic Data Sheet" and Development of Integrated National Medical Information system (Suggested by draft eHealth Strategy).
- Implementation of cloud based approach and management of eHealth services (based on discussions with eGovernment Centre).

Obstacles to overcome, challenges to meet:

- Outdated, fragmented legislation – includes challenges of having a political will to foster legislation (updating and harmonising) as basis for improving chronic disease and multimorbidity (multiple concurrent disease) management; raising the effectiveness of disease prevention and dissemination of health promotion practices; increasing sustainability and efficiency of health systems by unlocking innovation.
- Fragmented IT infrastructure – includes challenges of overcoming the lack of political will; ensuring mandatory regulation and the application of standard operational procedures, interoperability; introducing a cloud approach; raising financial resources and overcoming resistance of some medical institutions' managers at different levels to implement integrated information systems; making competition in procurement procedures more open and transparent to select most innovative IT infrastructure

solutions/providers.

- Mentality of the Leadership and resistance to changes – includes challenges of accepting eHealth as a policy priority by leadership and professionals; lacking opportunities of learn about best practices, undertaking study visits, participating in training, exchanging specialists; changing the mentality of health care policy-makers, service providers, and general public so that health services are no longer perceived as mere disease-fighting actions, but a mechanism that places the emphasis on the promotion of health and well-being.
- Lack of capacities (human, financial, infrastructural – e.g. insufficient capacity of the Ministry of Health, Labour and Social Protection in the domain of e-government and eHealth (only 1 official from the Ministry is involved in e-Transformation / eHealth service) – includes challenges of optimising available resources and capacities; strengthening the eHealth/eTransformation service capacities within the Ministry of Health, Labour and Social Protection, and within other health institutions.
- A Pre-retirement age of many health professionals and population aging – includes challenges of creating supportive environment in health sector for young professionals and their promotion; organising awareness campaigns and training for pre-retirement professionals.
- Lack of intersectoral and interagency cooperation, fragmented systems of data collection and duplication of the date collected – includes a challenges of organising cooperation among different agencies through cooperation agreements, workshops, teambuilding events, working groups on specific common tasks.
- Frequent change of public officials responsible for health, lack of institutional memory – includes a challenge of establishing the system of continuity in public health institutions including among of ICT/eHealth professionals.
- Lack of the approved e-Health Strategy – includes challenges of placing the Strategy approval on the government agenda by the newly reformed Ministry of Health, labour and Social Protection; creating a new authority for e-Health in the times of cutting the number of government institutions.

Participation in common actions of the regional roadmap.

Pillar 1: Regional eHealth networking and cooperation

2018 - 2019

- Action 1.1: Set up regional Portal for EaP eHealth Network and populate it with knowledge depositary, forum.
- Action 1.2: Elaborate common guidelines, standards and principles for establishing national eHealth Stakeholder Groups.
- Action 1.3: Set up national eHealth Stakeholder Groups.
- Action 1.4: Elaborate common guidelines, standards and principles for establishing national eHealth Networks in line with European eHealth Network.
- Action 1.5: Undertake a cost-effectiveness study of eHealth projects to create a

repository of good practices.

2019 - 2020

- Action 1.6: Create an Open eHealth Platform on the regional Portal with the functionality allowing for sharing eHealth interoperability solutions.
- Action 1.7: Establish national eHealth Networks.
- Action 1.8: Provide advisory/ training services, develop and offer organisational and technical guidance for establishing national eHealth Networks.
- Action 1.9: Establish national eHealth portals linked with the regional Open Platform Portal.
- Action 1.10: Provide advisory/ training services, develop and offer organisational and technical guidance for creating functionality to exchange Patient Summaries and ePrescriptions via the regional Open Platform.
- Action 1.11: Provide advisory/ training services, develop and offer organisational and technical guidance for linking the regional Open Platform with the European Electronic Health Record Exchange, EIP (on AHA), large-scale projects (e.g. epSOS). .

2020 - 2021

- Action 1.12: Link regional eHealth Open Platform to the European Electronic Health Record Exchange, EIP, relevant large-scale projects to pilot cross-border ePrescription and Patient Summaries.
- Action 1.13: Evaluate performance, impact and outreach of the regional eHealth Open Platform.
- Action 1.14: Undertake a second gap assessment study to evaluate progress of harmonisation.

Pillar 2: Policy and governance

2018 - 2019

- Action 2.1: Assess needs for advisory and training services to start aligning (revising/formulating) national eHealth policies with those in the EU, especially with eHealth Action Plan 2012-2020.
- Action 2.2: Provide advisory/training services, develop guiding materials for policy alignment.
- Action 2.3: Formulate country-specific plans to support policy alignment.
- Action 2.4: Provide advisory/training services, develop guiding material for establishing national eHealth Stakeholder Groups and eHealth national and regional Networks.
- Action 2.5: Support formulation of activity plans to establish regional and national eHealth Networks.

- Action 2.6: Support establishing eHealth Stakeholder Groups and eHealth Networks at regional and national level.
- Action 2.7: Assess capacity building needs for establishing/reforming dedicated government eHealth agencies in line with EU best practices and standards.
- Action 2.8: Provide advisory/training services, develop guiding materials for aligning government eHealth agencies in line with EU principles.
- Action 2.9: Formulate country-specific plans to support alignment of government eHealth agencies.

2019 - 2020

- Action 2.10: Support implementation of policy alignment plans.
- Action 2.11: Support implementing alignment plans for government eHealth institutions.
- Action 2.12: Continue supporting the established national eHealth Stakeholder Groups and eHealth Networks at regional and national level.

2020 - 2021

- Action 2.13: Continue supporting the established national eHealth Stakeholder Groups and eHealth Networks at regional and national level.
- Action 2.14: Evaluate progress made in performance and sustainability of national eHealth Stakeholder Groups and eHealth Networks at regional and national level.
- Action 2.15: Continue supporting implementation of policy alignment plans.
- Action 2.16: Evaluate progress made in policy alignment.
- Action 2.17: Continue supporting implementation of alignment plans for government eHealth agencies.
- Action 2.18: Evaluate progress made in aligning government eHealth agencies with EU standards and practices.

Pillar 3: Interoperability framework and standards

2018 - 2019

- Action 3.1: Assess demand for aligning with the EU eHealth interoperability framework.
- Action 3.2: Provide advisory/training services, develop guiding materials for interoperability alignment.
- Action 3.3: Formulate national eHealth interoperability frameworks.
- Action 3.4: Assess obstacle/ challenges and offer solutions for getting access to the European Electronic Health Record Exchange, large-scale projects for providing cross-order services via the regional eHealth Open Platform.

2019 - 2020

- Action 3.5: Implement national eHealth interoperability frameworks and technical solutions in relation to cross-border ePrescriptions and Patient Summaries via the regional eHealth Open Platform.
- Action 3.6: Operationalise the links of the regional eHealth Open Platform with the European Electronic Health Record Exchange, large-scale projects.

2020 - 2021

- Action 3.7: Operationalise technical, semantic, and organisational cross-border interoperability of ePrescriptions and Patient Summaries through the regional eHealth Open Platform.
- Action 3.8: Evaluate progress made in implementing cross-border interoperability solutions for ePrescriptions and Patient Summaries.

Pillar 4: eHealth patient services and data protection standards

2018 - 2019

- Action 4.1: Explore and assess country-specific needs and demand for aligning national legal and regulatory frameworks protecting patient EHR with EU best practices and standards (e.g. GDPR Directive 95/46/EC), including the regulation of patient's control over access to their records/data.
- Action 4.2: Provide advisory/training services, develop guiding materials for aligning policies protecting patient EHR, including patient's access control.
- Action 4.3: Formulate/revise policies protecting patient EHR in line with European standards/best practices.
- Action 4.4: Explore demand/needs for assistance in establishing national Patient Portals aligned with EU best practices/standards and linked with the regional eHealth Open Platform Portal.
- Action 4.5: Provide advisory/training services, develop guiding material for establishing national Patient Portals; Platform.
- Action 4.6: Provide advisory/training services, develop guiding material for providing for cross-border ePrescription services and Patient Summaries exchange.
- Action 4.7: Explore and assess country-specific demand and needs for cross-border ePrescription and Patient Summaries.

2019 - 2020

- Action 4.8: Implement building/revising Patient Portals to operationalise interoperability of ePrescriptions and Patient Summaries.
- Action 4.9: Prepare for piloting cross-border exchanges of ePrescriptions and Patient Summaries through interoperability solutions applied at the regional eHealth Open Platform (linked with the European Electronic Health Record Exchange).

2020 - 2021

- Action 4.10: Implement pilots of cross-border ePrescriptions and Patient Summaries.
- Action 4.11: Evaluate progress made in Patient Portals' performance;
- Action 4.12: Evaluate progress in piloting cross-border ePrescriptions and Patient Summaries.

5.2.6 Roadmap for Ukraine

Priority areas/projects of cooperation with EU:

- Establishment and capacity building of a national administrator and regulator for eHealth
- GDPR implementation in Ukraine and adjustment of the legal framework
- ePrescription
- Telemedicine
- Alignment of interoperability standards
- Online list of Health care facilities, doctors and their ratings
- Support with development of a long-term action plan for development of eHealth
-

Obstacles to overcome, challenges to meet:

- Absence of legal framework for eHealth
- Absence of institutions, responsible for eHealth coordination
- Outdated regulation for person data protection
- Absence of strategy for eHealth development and implementation
- Political instability
- Lack of resources
- Lack of local expertise
- Lack of skills of medical personnel

Project 1: GDPR implementation in Ukraine and adjustment of the legal framework

Goal:	Align data protection policies between EU and Ukraine, setting up a background for further cross-border integration
Outcome:	Setting up a legal framework for further cross-border cooperation in exchange of personal and medical data
Implementation mode:	Policy advice and training

Target beneficiaries:	State Agency for e-Governance, Ministry of Justice, State Service of Special Communication and Information Protection of Ukraine, Ministry of Health, NGOs

Project 2: Establishment and capacity building of a national administrator and regulator for eHealth

Goal:	Enhance capacities of the national regulator in the sphere of eHealth
Outcome:	Establishment of a specific counterpart for eHealth coordination between Ukraine and EU countries for further development of cross-border cooperation, e.g. in patient summary and ePrescriptions exchange
Implementation mode:	Policy advice, training, and study tours
Target beneficiaries:	Ministry of Health, SOE on eHealth, eHealth Project Office

Participation in common actions of the regional roadmap.

Pillar 1: Regional eHealth networking and cooperation

2018 - 2019

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- Action 1.2: Elaborate common guidelines, standards and principles for establishing national eHealth Stakeholder Groups.
- Action 1.3: Set up national eHealth Stakeholder Groups.
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- Action 1.5: Undertake a cost-effectiveness study of eHealth projects to create a repository of good practices.

2019 - 2020

- Action 1.6: Create an Open eHealth Platform on the regional Portal with the functionality allowing for sharing eHealth interoperability solutions.
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- Action 1.8: Provide advisory/ training services, develop and offer organisational and technical guidance for establishing national eHealth Networks.

- Action 1.9: Establish national eHealth portals linked with the regional Open Platform Portal.
- Action 1.10: Provide advisory/ training services, develop and offer organisational and technical guidance for creating functionality to exchange Patient Summaries and ePrescriptions via the regional Open Platform.
- Action 1.11: Provide advisory/ training services, develop and offer organisational and technical guidance for linking the regional Open Platform with the European Electronic Health Record Exchange, EIP (on AHA), large-scale projects (e.g. epSOS).

2020 - 2021

- Action 1.12: Link regional eHealth Open Platform to the European Electronic Health Record Exchange, EIP, relevant large-scale projects to pilot cross-border ePrescription and Patient Summaries.
- Action 4.13: Evaluate performance, impact and outreach of the regional eHealth Open Platform.
- Action 4.14: Undertake a second gap assessment study to evaluate progress of harmonisation.

Pillar 2: Policy and governance

2018 - 2019

- Action 2.1: Assess needs for advisory and training services to start aligning (revising/formulating) national eHealth policies with those in the EU, especially with eHealth Action Plan 2012-2020.
- Action 2.2: Provide advisory/training services, develop guiding materials for policy alignment.
- Action 2.3: Formulate country-specific plans to support policy alignment.
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- Action 2.5: Support formulation of activity plans to establish regional and national eHealth Networks.
- Action 2.6: Support establishing eHealth Stakeholder Groups and eHealth Networks at regional and national level.
- Action 2.7: Assess capacity building needs for establishing/reforming dedicated government eHealth agencies in line with EU best practices and standards.
- Action 2.8: Provide advisory/training services, develop guiding materials for aligning government eHealth agencies in line with EU principles.
- Action 2.9: Formulate country-specific plans to support alignment of government eHealth agencies.

2019 - 2020

- Action 2.10: Support implementation of policy alignment plans.
- Action 2.11: Support implementing alignment plans for government eHealth institutions.
- Action 2.12: Continue supporting the established national eHealth Stakeholder Groups and eHealth Networks at regional and national level.

2020 - 2021

- Action 2.13: Continue supporting the established national eHealth Stakeholder Groups and eHealth Networks at regional and national level.
- Action 2.14: Evaluate progress made in performance and sustainability of national eHealth Stakeholder Groups and eHealth Networks at regional and national level.
- Action 2.15: Continue supporting implementation of policy alignment plans.
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Pillar 3: Interoperability framework and standards

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- Action 3.3: Formulate national eHealth interoperability frameworks.
- Action 3.4: Assess obstacle/ challenges and offer solutions for getting access to the European Electronic Health Record Exchange, large-scale projects for providing cross-order services via the regional eHealth Open Platform.

2019 - 2020

- Action 3.5: Implement national eHealth interoperability frameworks and technical solutions in relation to cross-border ePrescriptions and Patient Summaries via the regional eHealth Open Platform.
- Action 3.6: Operationalise the links of the regional eHealth Open Platform with the European Electronic Health Record Exchange, large-scale projects.

2020 - 2021

- Action 3.7: Operationalise technical, semantic, and organisational cross-border interoperability of ePrescriptions and Patient Summaries through the regional eHealth Open Platform.
- Action 3.8: Evaluate progress made in implementing cross-border interoperability solutions for ePrescriptions and Patient Summaries.

Pillar 4: eHealth patient services and data protection standards

2018 - 2019

- Action 4.1: Explore and assess country-specific needs and demand for aligning national legal and regulatory frameworks protecting patient EHR with EU best practices and standards (e.g. GDPR Directive 95/46/EC), including the regulation of patient's control over access to their records/data.
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- Action 4.3: Formulate/revise policies protecting patient EHR in line with European standards/best practices.
- Action 4.4: Explore demand/needs for assistance in establishing national Patient Portals aligned with EU best practices/standards and linked with the regional eHealth Open Action.
- Action 4.5: Provide advisory/training services, develop guiding material for establishing national Patient Portals; Platform.
- Action 4.6: Provide advisory/training services, develop guiding material for providing for cross-border ePrescription services and Patient Summaries exchange.
- Action 4.7: Explore and assess country-specific demand and needs for cross-border ePrescription and Patient Summaries.

2019 - 2020

- Action 4.8: Implement building/revising Patient Portals to operationalise interoperability of ePrescriptions and Patient Summaries.
- Action 4.9: Prepare for piloting cross-border exchanges of ePrescriptions and Patient Summaries through interoperability solutions applied at the regional eHealth Open Platform (linked with the European Electronic Health Record Exchange).

2020 - 2021

- Action 4.10: Implement pilots of cross-border ePrescriptions and Patient Summaries.
- Action 4.11: Evaluate progress made in Patient Portals' performance.
- Action 4.12: Evaluate progress in piloting cross-border ePrescriptions and Patient Summaries.

Proposed system of measurement and monitoring of eHealth harmonisation

The Study Team proposes that a similar study using the same or similar set of benchmark indicators and targets should be conducted at the end of 2020 to assess the impact of harmonisation activities on gap reduction and the overall progress. The effectiveness of

common and country-specific roadmaps will be evaluated via an independent evaluation and according to the requirements of the relevant funding schemes.

6 GLOSSARY, KEY TERMS, DEFINITIONS[96]

General

- **Eastern European Partnership** - is a joint initiative of the EU and its Eastern European partners: Armenia, Azerbaijan, Belarus, Georgia, the Republic of Moldova and Ukraine. Launched in 2009 at the Prague Summit, it brings our Eastern European partners closer to the EU.
- **Partner country** – one of the 6 Eastern Partnership countries (Armenia, Azerbaijan, Belarus, Georgia, Moldova, Ukraine)
- **Region** - 6 Eastern Partnership countries collectively
- **Community-based services**: Support and services such as health care, long-term care, preventive actions and support for activities of daily life, all of which are necessary for people to be able to fully experience productive participation, should be rooted in communities to secure user accessibility and to enhance provider responsibility and coherence.
- **Healthcare**: Health services provided by health professionals to patients to assess, maintain or restore their state of health, including the prescription, dispensation and provision of medicinal products and medical devices.
- **Health professional:** a doctor of medicine, a nurse responsible for general care, a dental practitioner, a midwife or a pharmacist within the meaning of Directive 2005/36/EC, or another professional exercising activities in the healthcare sector which are restricted to a regulated profession as defined in Article 3(1)(a) of Directive 2005/36/EC, or a person considered to be a health professional according to the legislation of the Member State of treatment.

[96] In most cases the sources are: Directive 2011/24/EU http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32011L0024; eHealth Action Plan 2012-2020 https://ec.europa.eu/digital-single-market/news-redirect/9156; Business Models for eHealth: Final Report http://ec.europa.eu/newsroom/dae/document.cfm?doc_id=2891.

- **Healthcare provider**: Any natural or legal person or any other entity legally providing healthcare on the territory of an EU Member State; healthcare providers provide relevant information to help individual patients to make an informed choice, including on treatment options, on the availability, quality and safety of the healthcare they provide in the EU Member State of treatment.
- ***Healthcare Provider Organisations*:** associations, or federations of healthcare providers, that search a benefit from coordinating or associating among them. Health services provider organisations can include general practitioner practices, general hospitals, specialised hospitals, teaching and university hospitals, social care organisations, and so on
- **Health technology**: A medicinal product, a medical device or medical and surgical procedures as well as measures for disease prevention, diagnosis or treatment used in healthcare.
- **Integrated health services**: continuum of services that are managed and delivered at different levels and sites within the health system
- **Medical records**: All the documents containing data, assessments and information of any kind on a patient's situation and clinical development throughout the care process. Systematic documentation of a patient's medical history and care. The term is used both for the physical folder for a patient and for the body of information which comprises the total of a patient's health history. Medical records are personal documents and all data collected in medical records shall be regarded as sensitive personal data and processed accordingly.
- **mHealth**: mHealth (also known as mobile health) is the use of mobile devices, such as mobile phones, patient monitoring devices, Personal Digital Assistants (PDAs), and wireless devices, for medical and public health practice. mHealth applications include examples such as treatment adherence, community mobilisation, collecting community and clinical health data, wellness and self-care, chronic disease management and remote patient monitoring.
- **Medical records**: All the documents containing data, assessments and information of any kind on a patient's situation and clinical development throughout the care process. Systematic documentation of a patient's medical history and care. The term is used both

for the physical folder for a patient and for the body of information which comprises the total of a patient's health history. Medical records are personal documents and all data collected in medical records shall be regarded as sensitive personal data and processed accordingly.

- **Once only principle (**OOP**)** [97] : The Once-only principle means that individual users/businesses should not be required to supply the same information more than once. For instance, if information has already been submitted to one public administration, individual users/businesses should not be required to submit that information again to another public administration.
- **Patient**: Any natural person who seeks to receive or receives healthcare in an EU Member State
- **Patient-centered care**: Providing care that is respectful of and responsive to individual patient preferences, needs, and values and ensuring that patient values guide all services provided.
- **Patient empowerment**: A process to help people gain control, which includes people taking the initiative, solving problems, and taking decisions, and can be applied to different settings in health and social care, and self-management"
- **Personal Data:** Any information relating to an identified or identifiable natural person ('data subject'); an identifiable person is one who can be identified, directly or indirectly, in particular by reference to an identification number or to one or more factors specific to his physical, physiological, mental, economic, cultural or social identity.

eHealth-related

- **eHealth:** Electronic health / electronic healthcare. The term eHealth may refer to ICT tools and services for health, used by healthcare professionals, institutions and administrations as well as utilities which provide patients directly with services related to healthcare

[97] https://ec.europa.eu/digital-single-market/en/glossary#letter_o.

- **eHealth services**: Services and technology-enabled solutions to improve overall healthcare delivery
- **Maturity model of ICT-enabled integration of care** (eHealth Information & eHealth services dimension): A conceptual model intended to show how healthcare systems are attempting to deliver more integrated care services for their citizens. Integrated care requires, as a foundational capability, sharing of health information and care plans across diverse care teams which, in turn, leads progressively to systems for enabling continuous collaboration, measuring and managing outcomes. That also enables citizens to take a more active role in their care. This means building on existing eHealth services, connecting them in new ways to support integration, and augmenting them with new capabilities, such as enhanced security and mobility. Main features of maturity model:
  - Essential components to enable information-sharing, based on secure and trusted services, are in place;
  - 'Digital first' policy is applied (where possible, move phone and face-to-face services to digital services to reduce dependence on staff and promote self-service);
  - Fundamental building blocks (such as Unique citizen ID, linked health records; regional/national longitudinal electronic health record; at-Scale teleservices; ability to combine health and social care information; care collaboration platforms – please specify which) to enable eHealth and eServices ('infostructure') are available;
  - Confidentiality and security designed into patient records, registries, online services etc. are applied across the board;
  - New channels for healthcare delivery to replace face-to-face and telephone contact are enabled. Indicators of maturity: Unique citizen ID; linked health records; regional/national longitudinal electronic health record; at-Scale teleservices; ability to combine health and social care information; care collaboration platforms.
- **eHealth IT supply-driven business model/market**: Needed for developing and implementing a value-creating and sustainable eHealth service. eHealth business

models map all key supporting activities, value chain relationships and dependencies impacted by the introduction of an eHealth service. Successful business models require:

  - strong senior management involvement throughout the various phases of the design, development and delivery of an eHealth service having a clear vision of what its healthcare delivery organisation wants to achieve with a specific eHealth service and system, and leading the required operational steps;
  - staff involvement in designing a business model of an eHealth service;
  - evolving technological and organisational change following an evaluation aimed at measuring the potential and current impact of the eHealth system; this may require data collection concerning activity, costs and benefits (Source: Business Models for eHealth: Final Report)

- **eHealth service demand-driven business model/market**: Gives priority to the interaction between major eHealth stakeholders – healthcare providers, insurers, patients; that is, those who provide healthcare services; those who consume them; and those who pay for such services. The suppliers of stand-alone solutions from the industry can be considered part of broader healthcare services. The rules of this playing field are set by the government i.e. how the market is regulated. These include such key pre-conditions as: (a) how patients can obtain his (eHealth) service? (b) how patients will pay for it, e.g. via taxation policy, insurance, direct personal payment or a combination of those three; (c) do it apply to all related health services or some are excluded; (d) is there a freedom of choice to choose between sets of eHealth services and payments schemes? (e) is there sufficient transparency in price and quality? (f) is eHealth market open for competitors? Suppliers/complementors can provide services indirectly through healthcare providers (B2B2C) or directly to the consumer (B2C).
- **eHealth value**: an eHealth service whose functionalities bring socio-economic and healthcare value to patients and/or healthcare professionals. These involve specific elements such as better clinical care, safety, timeliness of care, quality, effectiveness and efficiency (Source: Business Models for eHealth: Final Report).[98]

[98] http://ec.europa.eu/newsroom/dae/document.cfm?doc_id=2891.

- **eHealth Network (eHN):** The eHealth network was established by article 14 of the 'Directive (2011/24/EU) on patients' rights in cross-border healthcare'. The voluntary network connects national authorities responsible for eHealth designated by the Member States and shall support and facilitate cooperation and the exchange of information among Member States.
- **EHR (Electronic Health Record):** A comprehensive medical record or similar documentation of the past and present physical and mental state of health of an individual in electronic form, and providing for ready availability of these data for medical treatment and other closely related purposes.
- **Electronic Health Record System:** A system for recording, retrieving and manipulating information in electronic health records
- ***ePrescription*** **(Electronic Prescription):** A prescription for medicines or treatments, provided in electronic format.
- **eDispensation (Electronic Dispensation):** An act of electronically retrieving a prescription and giving out the medicine to the patient as indicated in the corresponding ePrescription. Once the medicine is dispensed, the dispenser shall report via software the information about the dispensed medicine(s).
- ***eHealth systems***
  - ***Interoperability*** **systems**: The ability, facilitated by ICT applications and systems to exchange, understand and act on citizens/patient and other health related information and knowledge among linguistically and culturally disparate clinicians, patients and other actors and organisations within and across health system jurisdictions in a collaborative manner.
  - **eHealth system sustainability/viability**: an eHealth system which has passed the pilot phase and is fully operational to provide data for assessing its overall performance in line with a set of predefined benchmarks and indicators. Value creation and sustainability require eHealth services to be supported by business models reflecting the interests of all the involved stakeholders. More importantly, these business models need to detail the interactions and interdependencies among all of the stakeholders and how the introduction of an IT service is going to affect them

- **Clinical Information System (CIS)**: (a) Specialised tools for health professionals within healthcare institutions (e.g. hospitals). Examples are radiology information systems, nursing information systems, medical imaging, computer-assisted diagnosis, surgery training and planning systems; (b) Tools for primary care and/or for outside care institutions, such as general practitioner and pharmacy information systems (example: Telemedescape).
- **Secondary Usage Non-clinical Systems (SUNCS)**: This category includes: (a) systems for health education and health promotion of patients/citizens, such as health portals or online health information services; (b) specialised systems for researchers and public health data collection and analysis, such as biostatistical programs for infectious diseases, drug development and outcomes analysis; (c) support systems, such as supply chain management, scheduling systems, billing systems, administrative and management systems, which support clinical processes but are not used directly by patients or healthcare professionals (example: Centro Unico di Prenotazione Umbria).
- **Telemedicine**:
    - the practice of medicine at a distance, i.e. the delivery of health care services, where patients and providers are separated by distance. Telehealth uses ICT for the exchange of information for the diagnosis and treatment of diseases and injuries, research and evaluation, and for the continuing education of health professionals. Telehealth can contribute to achieving universal health coverage by improving access for patients to quality, cost-effective, health services wherever they may be. It is particularly valuable for those in remote areas, vulnerable groups and ageing populations http://apps.who.int/iris/bitstream/10665/252529/1/9789241511780-eng.pdf?ua=1
    - Personalised health systems and services, such as disease management services, remote patient monitoring (e.g. at home), teleconsultation, telecare, telemedicine and teleradiology (example: Tactive/University City London Hospital (UCLH)).

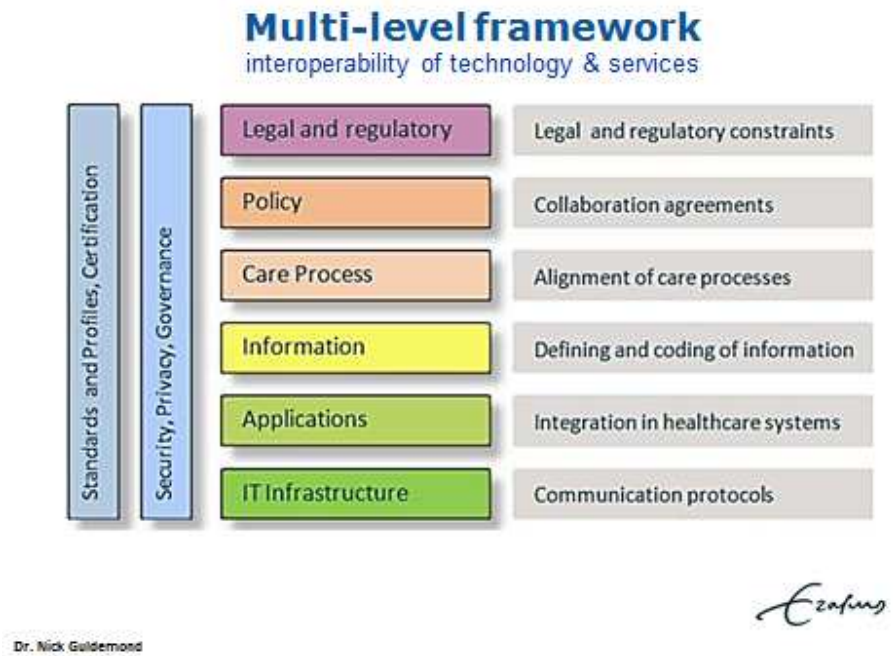
  - **Integrated Health Clinical Information Network (IHCIN)**: Distributed electronic health record systems and associated services such as ePrescriptions or eReferrals (example: Naviva).

- **ICT:** Information & Communication Technology
- **Authentication:** in the context of eHealth information security, refers to the confirmation of the identity of a user demanding access to eHealth services. Its purpose is to verify whether or not the user really is who he/she claims to be. Authentication is not to be confused with Authorisation, which deals with rights particular users or user groups may or may not have. While Authentication deals with questions like: “Is this person really Dr. X?“, Authorisation might ask “Does Dr. X have the right to access this specific kind of data?“.
- **Authorisation:** in the context of eHealth information security, refers to rights a particular user (e.g., health professional) has with regards to eHealth service systems. Authorisation is not to be confused with Authentication, which deals with the question of whether the user demanding access to eHealth service systems really is the person he/she claims to be. hile Authorisation deals with questions like: “Does Dr. X have the right to access this specific kind of data?“, Authentication might ask “Is this person really Dr. X?“.
- **EU eHealth Network**: Set up by Directive 2011/24/EU is the main strategic and governance body at EU level to work towards interoperability of cross-border eHealth services. The Network has the task of producing guidelines on eHealth, as foreseen in the same Directive, and on an interoperability framework for cross border eHealth services. It provides a platform of Member States' competent authorities dealing with eHealth.
- **Cross-Border eHealth Information Services** (CBeHIS): The infrastructure and the operations used to exchange of real patient related data, in particular health data, between its members.
- **Patient Summary (PS)**: Concise clinical document that provides an electronic patient health data set applicable both for unexpected, as well as expected, healthcare contact. A PS provides a health professional with essential information needed for healthcare coordination and, in case of an unexpected need, for the continuity of care, or when the

patient consults an health professional other than his regular contact person (e.g. the general practitioner he/she is registered with).

- **Interoperability**: Two or more eHealth applications (e.g. EHRs) can exchange, understand and act on citizen/patient and other health-related information and knowledge among linguistically and culturally disparate clinicians, patients and other actors or organisations within and across health system jurisdictions, in a collaborative manner.
- ***Cross-border interoperability***: Interoperability between neighbouring and non-neighbouring EU Member States and their entire territories.
- **Semantic Interoperability:** Ensuring that the precise meaning of exchanged information is understandable by any other system or application not initially developed for this purpose. Also: Ability of two or more systems or components to exchange information and to use the information that has been exchanged.

The comprehensive interoperability model which depicts the different aspects/levels (from data to policy) of interoperability can be illustrated as follows to emphasise the importance of the interplay between interoperability levels which is needed for a well-functioning digital health market.



ANNEXES – COUNTRY QUESTIONNAIRES

Annex 1 – Armenia Questionnaires

Annex 2 – Azerbaïdjan Questionnaires

Annex 3 – Belarus Questionnaires

Annex 4 – Georgia Questionnaires

Annex 5 – Moldova Questionnaires

Annex 6 – Ukraine Questionnaires