SWOT Analysis on ICT Theme
e-Health

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FORSEE
Regional ICT Foresight exercise for SEE countries

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1 Introduction

The 'FORSEE - Regional ICT Foresight exercise for Southeast European countries' project aims to introduce a sustainable mechanism for ICT foresight in the SEE area, attempting to tackle the absence of a regular process applied for technological future orientation and research policy review.The South East Europe (SEE) Programme Area includes 16 countries: Albania, *Austria*, Bosnia and Herzegovina, *Bulgaria*, Croatia, FYROM, *Greece*, *Hungary*, certain regions of Italy, Moldova, *Montenegro*, *Romania*, *Serbia*, Slovakia, *Slovenia*, and certain regions of Ukraine (Those in italics are represented in the FORSEE project).

E-health stands for the application of Information and Communication Technologies (ICT) to improve the access efficiency, effectiveness, and quality of clinical and business processes utilized by healthcare organizations, medical personnel, practitioners, patients, and consumers in an effort to improve the health status of patients.

A thorough analysis is performed aiming to identify the main internal and external driving forces and obstacles for positioning the whole SEE area in the future RTDI scene on "e-Health".

2 Theme description

The genesis of health care computing can be traced as far back as the early 1950s, when only mainframes were available and only the major hospitals of G7 countries could afford to house and use these machines. In that period, even the processing of a routine batch of health-related information took a considerable amount of coordinated effort among various health professionals and computer experts. Despite the demand on expertise, the end results were mostly fraught with mechanical and programming errors.

From the early 1960s through the 1970s, a new era of computing in health care emerged. Nonetheless, many of the early projects were almost complete failures: the complexity of the information requirements of a patient management system was gravely underestimated. Companies such a GE and Lockheed had to withdraw their participation due to a lack of continuing funding, interest, and management support. Many pioneering hospitals also had to fall back on their manual systems to keep their facility operating smoothly, and several of the hospital administrators had to make the difficult choice to abandon their hospital information systems project at a huge loss.

Nonetheless, these early successes were achieved at very high costs. Johns Hopkins Oncology Center, for example, acquired their first computer system in 1976 for a quarter million dollars; its processing power was only a fraction of today's desktop computers. Other successful early patient record systems include the Computer Stored ambulatory Record System (COSTAR), the Regenstrief Medical Record System (RMRS) and The Medical Record (TMR). COSTAR, a patient record system developed at Massachusetts General Hospital by Octo Barnett in the 1960s, was later extended to record patient data relating to different types of ailments (for example, multiple sclerosis (MS-COSTAR), and is used even today in several teaching hospitals and research universities across the globe. RMRS was a physician-designed integrated inpatient and outpatient information system implemented in 1972, and TMR is an evolving medical record system that was developed in the mid-1970s at Duke University Medical Center. Together with the success of the Technicon system, the efficiencies of these automated record systems soon provided considerable motivation for the integration of computing into health care systems.

By the early 1980s, computer miniaturization and cost reduction simultaneous with increases in processing power resulted in a dramatic move away from massive health data processing using mainframe or minicomputers to new and more efficient forms of health management information system (HMIS), office automation (OA), and networking technologies.

Health networking and telecommunications were soon discovered to be the most powerful pieces in the puzzle of an integrated health care information system, bringing together the different technological islands. The focus on these two technologies opened up interest in e-clinical decision support and e-medicine applications in the early 1990s. E-medicine was first tried in the 1970s via low-cost telephone technology, but interest in this area dwindled quickly due to lack of funding. In the mid-1990s, however, advances in health computing and networking technologies rekindled interest in e-medicine and other areas of e-health administrative, clinical, and financial applications, including e-commerce applications, e-clinical decision support and expert systems, e-nursing support systems, and other e-health applications such as e-home care systems.

While e-health constitutes only a tiny part of the lengthy history of the life and medical sciences, which, according to Jordan (2002), date back as far as 3,000 B.C., the wave of interest in and consumer-driven requests for e-health services on employers, clinicians, doctors and pharmacists in just the last several years is mind-boggling.

In general, e-health domains and applications can be divided into two primary clusters based on two key dimensions of systems integration characteristics. On one hand, systems that are characterized by a high degree of *internal integration* include applications such as Virtual patient records (VPR); Document management (DM); Geographical information systems (GIS); Group health decision support systems (group HDSS); Executive information systems (EIS); Data warehouses (DW); and Data mining. We define internal integration as the degree to which systems and technologies are integrated with one another within an organization.

On the other hand, systems that are characterized by a high degree of *external integration* include: Telecommunications, wireless and digital networks such as asynchronous transfer mode (ATM) networks; Community health information networks (CHIN); the Internet; intranets and extranets; health informatics; and telemedicine or e-medicine. External integration is defined as the degree to which systems and technologies interface with outside organizations and agency computer systems.

The basic function of an e-health system is to gather and exchange appropriate and accurate data from various sources to satisfy the administrative, clinical, and transactional needs of e-health providers, payers, and users. Proposing an e-health business is not exactly the same as proposing a brick-and-mortar health business, and it is vital to understand the factors and barriers that determine e-health business success or failure. The fundamental components of an e-health system include: its core value propositions; the characteristics of the e-health service model; the community of e-stakeholders involved; the potential to process a critical mass of transactions, to ensure enough revenue for sustainability and e-commercialization, that is, the potential for e-business ideas and models to thrive in a free online market system; and the potential to accommodate future features such as product or service expansion, profitability, growth, and global development.

Both the United States and Canada face rapidly increasing health care costs. Health care expenditures in the United States now exceed 14 percent of the country's gross national product (GNP), which implies that Americans spend roughly $2 billion a day on health care products and services. Yet despite these large expenditures on health care, millions of Americans are denied access to medical care because they lack medical insurance coverage. In Canada, where the majority of health care funding comes from the government, citizens and residents are experiencing long waits and bed closures due to shortages of nurses, family physicians, and various health specialists. Fortunately, the e-health paradigm shift has been supported by core value propositions that can help alleviate some of these problems by reducing costs and increasing efficiencies of processes in several areas. For example, e-health database management and on-line submission and processing of medical claims can vastly reduce the need for clerical personnel. In addition, on-line processing will eliminate many unnecessary clerical errors due to faulty transcription; the need to satisfy repeated requests on status of claim processing; and submissions of identical patient information for different interventions, as well as the failure to simultaneously update redundantly maintained patient records in various physical files located in different places (update anomalies).

Virtual patient records (VPR) is an integrated health database processing engine that links the accurate and rapid collection of various patient-related information and knowledge elements to generate an aggregated, well-classified, and organized set of administrative and clinical information and knowledge that e-health providers (primarily nurses and clinicians) can retrieve, exchange, and disseminate as needed for e-clinical decision making, e-control, analysis, e-diagnosis, e-treatment planning and evaluation, and many other e-health-related cognitive activities.

Another core value proposition of most e-health domains and applications is improving two-way or multiple-party communications, thereby significantly improving access to e-health care, especially for those located in rural or remote areas. For example, technologies such as e-mail, Blackberries (wireless devices with organizer features providing access to email, corporate data, phone, and the Web), secured Internet Web sites, personal data assistant (PDAs), virtual private networks (VPNs) and wireless cellular phones can enhance long-distance communications among e-health professionals or between e-health professionals and e-patients in different sectors, including communications between e-physicians and e-patients, laboratory test clinics and doctors, e-consumers and e-home care workers, e-physicians and e-pharmacists for verification of on-line prescription orders, and e-generalists and e-specialists for e-consultations on various subjects.

Aside from e-data management capabilities, improved communications, and tele-education, other core e-health value propositions include knowledge dissemination, intelligent support, better health decision making, and improved personal and community well-being. The use of the Internet, as well as intranets and extranets, to promote community learning and e-learning communities (e-communities), to increase virtual interactions between e-health experts and non-experts within a virtual health network environment, and to build partnerships among community and health care leaders can improve health service delivery. In addition, more effective implementations and uses of emerging e-technologies such as specialized Web services for intelligent health decision analysis and support – for example, helping an employer or employee choose among competing insurers and health maintenance organizations (HMOs) – can be of great benefit.

3 PESTLE analysis

The "opportunities" and "threats" part of the SWOT analysis for each of the ICT themes is approached in the form of a PESTLE analysis in the context of the FORSEE project. This allows capturing a broader yet clearer spectrum of factors and their relevant importance at present and in the future that affect the SEE area by analysing the macro-environment of the area in terms of political, economic, social, technological, legal, and environmental factors.

3.1 Political factors

Relevant ICT-related policies: technology, trade, research and innovation policies

Specific ICT strategies do not exist across all countries. ICT is often captured as a horizontal issue among for example lifelong learning and skills, support of entrepreneurship, improvement of the business environment, and extroversion of the economies. Specific ICT strategies hold for Romania (electronic communications, broadband, e-government), Greece (Digital Strategy), Montenegro (Strategy for the Development of Information Society), and Austria (ICT and quality of life).

In terms of innovation, the major policies common in the region mainly relate to: increase of support towards research-relevant actors, development of innovative infrastructure, centres of excellence, technology transfer, support to SMEs and entrepreneurship, and participation of the private sector in R&D activities. The situation is different in the case of Serbia and Montenegro where the innovation system is not harmonized with the EU innovation guidelines. The most common STI policy priorities relate to the support and improvement of scientific research and infrastructure, the support of innovation activities in SMEs, as well as the economic competitiveness of each country. In addition, the promotion of entrepreneurship and the increase of productivity levels are further common points.

The Electronic South Eastern Europe Initiative (eSEE Initiative) was founded as a coordinated effort to better integrate the Stability Pact for South Eastern Europe countries into the global, knowledge-based economy by regionally supporting the development of Information Society. One of the most important documents proposed is the "*eSEE Agenda+ for the development of Information Society in SEE 2007-2012*". The Agenda[1] states three region-specific priority areas for the Information Society development: the development of a Single SEE Information Space (high-speed broadband, rich online content, interoperability framework, harmonisation of rules for Information Society and Media), strengthening innovation and investment in ICT R&D (curriculum for ICT skills, vocational training in ICT, inclusion of ICT research among domestic research priorities, National Academic and Research Networks for regional interconnection) and achieving an inclusive Information Society (access to technology, ICT-enabled public services and e-government, e-business, digital libraries, and e-participation.

Since its adoption, all eSEE governments reported significant progress towards the agreed. A cabinet-

[1]The eSEE Agenda+ is signed by Albania, Bosnia and Herzegovina, Croatia, FYROM, Moldova, Montenegro, Romania, Serbia, and the UN Interim Administration Mission in Kosovo on behalf of Kosovo (in accordance with UNSCR 1244). The Agenda is available on http://www.eseeinitiative.org/images/stories/esee_agenda_plus_files/eSEE_Agenda_Plus_signed.pdf [last access 2012-09-21].

level body is already established in most SEE countries for the development of an Information Society. A central coordination body is a condition sine qua non. Thus, it is rather encouraging for the whole SEE area.

Overall funding patterns for ICT R&D and R&D/innovation and ICT innovation

In a number of SEE countries, the EU Structural Funds are largely the determining source for R&D and innovation, although there has not been much change in funding levels between 2009 and mid-2011. The dependence on the EU funds appears to be very strong in the case of Greece and important for others, such as Slovenia and Romania. In other EU-associated countries, such as Montenegro and Serbia, the total R&D and innovation funding is far below that of the EU average. The current level of R&D investment (including ICT) in the SEE area is less than 1% of GDP, compared to 2% of EU-27, 2.6% in the USA, and 3.4% in Japan.

Regarding the contribution of the private sector in RTDI funding, there seems to be a big gap: on the one side, there are countries in which its contribution is insignificant (such as Bulgaria and Greece) and on the other side, there countries in which its contribution is increasing (such as Romania, Austria, Hungary, and Slovenia). Public funding appears to be of high significance especially for Bulgaria, Romania, and Greece. The SEE area has to increase substantially its R&D expenditure. There are also significant inequalities among the countries: for example IT investment per capita in Serbia was 74 euros in 2008 while in Hungary it was 3.5 times higher.

Tax incentives assist RTDI only in certain countries. Business Expenditures for R&D specifically for ICT is quite notable in the case of Hungary and Romania (only recently, about 20%) while it is less than 10% for the rest of the countries. The share of public funding of ICT R&D in GDP (as an indicator of ICT R&D funding intensity) exceeds EU average in Austria and Slovenia (0.08%), while in the rest of the countries it falls below 0.04%. In more general terms, Gross Domestic Expenditure and Business Expenditure for R&D as percentage of GDP is significant for Austria and Slovenia (1.5-2%) while in the rest of the countries it falls under 1% (less than 0.5% in the case of business expenditure).

The SEE area is the fastest growing market and economy in Europe, although it exhibits a low level of Foreign Direct Investments. Financial incentives are provided in some SEE countries as to attract investments in ICT. Examples include income tax exemption for the IT specialists in Romania and reduced tax rates for ICT equipment in FYROM; Montenegro; and Serbia, and tax-free regime of enterprises in Moldova.

Overall R&D and innovation cooperation patterns including ICT RTDI

On a national scale, cooperation patterns are indicated through participation in EU funding programmes. Greece and Austria rank very high (over 3.5% each) while the rest of the countries' participation rate reaches 2.5% of the EU funding. On a national innovation level, most of the countries suffer from a rather weak collaboration of the research triangle. In more specific terms, the "University-industry collaboration in R&D"[2] indicator classifies Austria and Slovenia in considerable global rankings (18th and 37th respectively), which is distinctively different from the rest of the countries. Hungary and Montenegro score in medium terms. Greece (112th), Bulgaria (110th), and

[2]According to the Global Competitiveness report

Romania (102nd)rank among the last globally, indicating severe structural inefficiencies within their systems.

On a business level, cooperation patterns in innovation point towards cooperating with local partners in other countries[3] , market testing in other countries, and outsourcing activities. The public sector is not the preferred partner in the development of projects for innovative firms. The suppliers of equipment, clients or customers, other enterprises within the company group, and consultants are the most frequently selected cooperation partners. Universities also have an important role and are at the same level as consultants and commercial laboratories. In overall, knowledge flows in the region is considered a key disadvantage.

On a SEE level, the SEE-ERA.NET projects target the integration into the European Research Area of the West Balkan countries by supporting RTD and networking activities[4]. ICT-specific projects focused on software systems fore-learning and ICT for energy efficiency (five out of six projects on the latter relate to use of embedded systems for energy efficiency).

Theme-specific analysis

Each country implements its national RDI policy for ICT, aligned in a lesser or greater extend to the EU ones. There is currently no SEE-level government body encouraging a coherent ICT RDI agenda across the whole area. The varying approach of each country on ICT RDI is also reflected in participation to trans-national instruments supporting R&D in e-Health. Only a handful of EU-funded projects include participants from at least two SEE-area countries (see Annex II).

3.2 Economic factors

General Economic Indicators

Most of the countries under investigation currently face some critical challenges both in terms of an emerging economy which does not perfectly correspond to the new realities and of an industrial sector that needs to transit to a knowledge-intensive reality. The external balance in ICT trade is negative in most of the countries with the notable exception of Hungary, where ICT trade (exports) represents about 1/4 to 1/5th of its national trade.

The data are summarized in the following table.

	[5]AT	BG	HU	GR	RO	SI	RS	ME
Employmentgrowth (%)	1.0	-5.9	0.2	-2.1	-1.8	-2.2	1.0 (2008)	Jobless growth

[3]Specific survey in the context of the EU Innovation Scoreboard

[4]The participating countries of the SEE-ERA net consist of the Western Balkan countries, EU Member States (Austria, Bulgaria, France, Germany, Greece, Romania, and Slovenia), and Turkey.

[5]The abbreviations of countries used thereof are consistent with the Eurostat taxonomy and are represented as follows: Austria (AT), Bulgaria (BG), Hungary (HU), Greece (GR-EL), Romania (RO), Slovenia (SI), Serbia (RS) and Montenegro (ME)

Unemployment rate (%)	4.4	10.2	11.2	12.6	7.3	7.3	20	17.6 (2007)
Male (%)	4.6	10.9	11.6	9.9	7.9	7.5	19.2	n/a
Female (%)	4.2	9.5	10.7	16.2	6.5	7.1	21	n/a
GDP (100-base value)	139	20	40	83	23	72	n/a	41
Trade balance (%) , 2009	0.1	-2.6	3	-3.9	-2.6	-2	n/a	n/a
ICT goods exports (% of total), 2009	5.5	3.6	24.6	3.0	8.4	3.8	2.2	n/a
ICT goods imports (% of total), 2009	7.0	6.4	78.83	5.87	9.4	5.6	5.4	n/a
ICT service exports (%), 2009	6.6	5.6	8.3	2.2	18.9	7.2	6.7	n/a
High-tech exports (% of manufacturing exports), 2009	11.5	8.2	24.0	11.3	10.0	6.5	n/a	n/a

Access to capital in general and for ICT RTDI

Available data do not discriminate between accesses to capital in general and in the case of ICT RTDI, therefore only generic information is provided. In the EU-15 almost 80% of venture capital was allocated to buyouts, followed by 17% to the expansion and replacement stage and 3% to early-stage development.

Venture capital investment as a share of GDP is minimal. Specifically, Venture Capital Investments (VCI) at early stage is and less than 0.01% for Austria, Hungary, and Romania and 0% for Greece, according to EVCA Yearbook 2012. VCI at the expansion stage is less than 0.06% for the same set of countries. No information is available for the rest of the SEE area countries.

Loans remain the most important finance type and high-growth firms will likely need more loans than equity finance in coming years. Banks and leasing companies need to be prepared to be addressed as financiers for SMEs between 2011 and 2013. In specific, SMEs used bank products in the range of 45-53% in the SEE area.

The preferred type of external funding in the area is as follows[6]:

- Bank loans (ranging from 8.6% in Serbia to 66% in Austria and 82% in Slovenia).
- Loans from other sources (stakeholders, public sources, etc.). About 15-22% of SMEs in the SEE area use loans from other sources, with the exception of Slovenia and Serbia (<4%).
- Equity investment (including venture capital and business angels). The market is quite underdeveloped in the SEE area, with less than 10% of SMEs participating. Paradoxically, equity investment appears to be higher in Montenegro and Serbia (15-20% of SMEs).
- Subordinated loans, participation loans, and similar financing instruments. These schemes are notable in Greece, Montenegro, and Serbia (25-60%), while in the rest of the countries

[6]Source: FORSEE synthesis report and "The Survey on the Access to Finance of Small and Medium-sized Enterprises (SAFE)", 2011. European Commission and ECB data

the percentage falls under 3%.

Other factors: The economic crisis

The SEE countries responded differently to the crisis. In general, the trends indicate a decline in demand, capital and liquidity problems, limited access to funding, falling innovation expenditures and decreasing employment rates. However, some countries, like Austria, have increased funding for research and innovation, while in others it remained balanced. Cost cutting has been very widespread in Greece, due to the specific political and economic circumstances that may have undermined business and market confidence in the country. Bulgaria and Romania responded with unprecedented cuts. In Hungary, there was a disruption in funding. In many countries, funding provided to innovation agencies and departments has been maintained whilst in others, institutional budgets have been cut. Reallocations and consolidations between different government departments or agencies can also be observed. The ICT sector experienced a decline during the past years and therefore ICT policies need refinement in the crisis for quick recovery.

On a European level, differentiation strategies, the optimisation of assets and the fuelling of the national systems with young researchers have been proposed as to alleviate countries on the long term. It is also recommended that structural reforms need to be oriented towards supporting employment, improving flexibility, reducing administrative and regulatory burden on businesses, promoting entrepreneurship, and enhancing access to finance for businesses (loan subsidies, guarantees, start-ups and micro-enterprises).

Theme-specific analysis

The following table from OECD summarizes health expenditure and financing since 2000 in four countries of the SEE area. There is a clear trend for all countries on steadily increasing the relevant spending.

	Year 2000	Year 2003	Year 2005	Year 2010
Austria	22,620.5	24.053,6	25,551.2	28,902.7
Greece	12,593.4	16.300,7	18,652.0	20,045.5
Hungary	1,288,5	1,731,7	1,859,5	1,698,3
Slovenia	1,987.1	2,285.5	2,398.2	2,830.5

3.3 Social, Cultural and Demographic factors

Human resources for ICT and ICT use

Digital literacy is generally high in the region. There are however indications of scarcity of talent in RTDI (apart from Romania and Austria) and medium to low index of Human Resources in Research and Technology. Most countries suffer from high levels of unemployment in RTD personnel, despite satisfactory levels of tertiary education attainment. The educational structures of all countries serve a long-lasting tradition in science and therefore provide skilled workforce, especially in IT. In most of the countries, the innovation systems are not yet well-structured and mature enough as to enable absorption of researchers and highly-skilled personnel to stimulate research careers. This generates a skill gap that must be addressed and further reduce brain drain outside the area. On-the-job training and quality of education are long-lasting challenges in most of the countries (with the exceptions of Austria and Slovenia).

The links between education and RTDI can be better reflected in the percentages of employment in Knowledge-Intensive high-technology services as well as R&D personnel. The percentage of employment in knowledge-intensive activities in high technology represents a fraction of 1.5-3% on a country level. The development of e-skills is placed high on the political agenda but without specific ICT national curricula. Scientists' and engineers' percentage in total Human Resources in Science and Technology fluctuates around 20%, with the exception of Austria (10%). The available R&D personnel is higher in Austria and Greece (1.5-2% of total workforce), while in the rest of the countries it is less than 1.5%. The number or researchers generally falls between 15.000-25.000 per country in the SEE area but the percentages are incomparable to the EU's innovation leaders. In general, the annual growth in business researchers in the EU-27 has been higher than that of the business expenditure on R&D. However, no country-level data can confirm this statement for the SEE area. The 2005 Eurostat data illustrate that in Science and Engineering, the number of tertiary graduates has been increasing about 5% per annum in the SEE area (high extreme for Romania and low extreme for Hungary). Awarded PhDs. in "science, mathematics, and computing" in EU-27 increased by 2.8% per annum.

Statistics on ICT use

According to the Digital Agenda Observatory, the percentage of citizens buying online is about 16.5% in average, highest in Austria and lowest in Romania and Bulgaria. The average percentage of citizens buying online cross-border is 8% (highest in Austria, lower in Romania and Bulgaria). SMEs buying online reach about 13.6%, while SMEs selling online reach 7.5% accordingly. Regular Internet use reaches 51% in the area (33% in Romania though), while general Internet use reaches 53.6% (highest in Austria, lowest in Bulgaria). The use of e-government portals and services by citizens is about 22.3% (with extremely low percentages for Bulgaria).

Austria, Hungary, and Slovenia are more well-prepared markets with an advanced level of maturity in Internet and e-government use. The absorption level of enabled broadband technologies does not appear to benefit Greece, Bulgaria, and Romania, as these indicators fall behind. However, in e-commerce and buying online behaviour, all countries except Austria are lagging behind the targets set. Cross-border online commerce remains underdeveloped again with the exception of Austria.

ICT for societal challenges

ICT for societal challenges is included in the Digital Agenda for Europe, one amongst the flagship initiatives under the Europe 2020 strategy for growth. Some of the priority areas are targeted to concrete issues faced by citizens and society as a whole, such as ageing, health, digital skills, and climate change. The priorities are articulated as better and personalised healthcare, achieving at the same time relevant cost savings for patients and the society at large. Effective online public services for citizens and business' interactions with public authorities are expected to be integrated and effective, including cross-border services. Independent, active and safe living for older people addresses the ageing population and disadvantaged groups Also, ICT will help tackling environmental issues, such as energy saving, in the perspective of a sustainable growth.

Other international organizations, such as the OECD place innovation strategy in a framework that addresses global and social challenges. The OECD outlines new challenges for STI policy priorities in line with grand societal challenges which mainly evolve around green technology and innovation e.g., carbon pricing, taxation,regulation that reduces environmental externalities, encouragement of green inventions, as well as technology to manage disasters.

Theme-specific analysis

The ageing population is a major global challenge that is magnified in some parts of the SEE area by the migration of younger population towards countries outside the area leaving elderly behind. Sensing and intelligently reacting to received signals is in the core of addressing this challenge e.g., by monitoring human physiological signals and alerting a doctor when they fall beyond acceptable limits for each human.

3.4 Technological factors

The SEE countries dedicate on average 3-4% of their GDP to communications expenditure. Broadband penetration rate varies from about 15% in Bulgaria, Romania, and Greece to just over 20% in Hungary, Slovenia, and Austria. Romania, Bulgaria, and Greece mark the lowest percentage of households using a broadband connection (20-30%). Nevertheless, these countries have placed broadband and connectivity policies as instruments to foster economic growth. In the same countries, DSL national and rural coverage rates are quite different. Still, most of the countries have developed R&D infrastructures, such as national RTD networks, portals of public administration, and supercomputing and eScience centres in order to accommodate their future R&D needs. Some efforts are put in developing hard R&D infrastructures in the area, led by Austria, Hungary, Serbia, Bulgaria, and Greece, mainly in the area of connecting the National Research and Education Networks to the pan-European infrastructure of GEANT.

Theme-specificanalysis

EU Benchmarking survey (2010 data) provide a snapshot of ICT penetration in health services for the SEE area and the EU 27. The information indicates that SEE Hospital computer systemsare externally connectedthrough secure internet or proprietary infrastructure in over 75% (AT, BG, GR, RO, SI, and HU) of all cases which is very close or even above the EU27 average. Application integration in hospital computer systems is also above the EU27 average, ranging from 50-80% complete integration in SEE. The majority of SEE institutions hospital wide EPR system shared by all the clinical service departments is the main type of electronic patient record (EPR) used, while in some cases there is still use of multiple local/departmental EPR systems, which share information with a central EPR system. Data indicate that in EU member SEE countries there only few cases that electronic records (EPR) are not shared across departments and almost no cases in which EPR do not exist at all. Evidence is also presented that as in the majority of EU27, SEE Hospital EPR are not accessible online by the patients.

Electronic exchange of patient clinical care information appears to be common practice for Austria, around the EU27 average for Hungary, Slovenia and Romania, but still very low for Greece and Bulgaria. Evidence suggests that Austria, Romania and Hungary are active in providing security measures for stored and transmitted patient data through encryption methods, while other SEE countries are less than proficient in this respect.

Use of Picture Archiving and Communications System (PACS) is not so high in the selected SEE countries (EU members), which appear to be below EU27 average with the exception of Austria and Hungary. In almost all cases that PACS are in use, they correspond to standalone systems. An interesting observation is that PACS used in SEE can rarely be accessed at bedside, or in the ambulance or outside the hospital by own hospital staff.

Adverse health events reporting systemsare practically non-existing in SEE (except in Austria). Electronic service order placing systems are used in the majority of cases, except in Slovenia where utilisation is at 0%.

Wireless connectivity is provided in almost all cases to hospital medical workstations and staff members at a rate above the EU27 average, while connectivity for inpatients and outpatients or visitors are around the EU27 rates. Hungary and Slovenia appear to be champions at Tele-homecare or tele-monitoring services offered to outpatients at home, but still penetration of such services to the SEE are very low (around the EU27 average of 9%).

Tables of information from the 2010 EU Benchmarking survey on e-Health Services are presented in Annex I.

3.5 Legal factors

Regulation harmonization

According to "eGovernance and ICT Usage Report for South East Europe" (2nd edition, 2010) prepared by the eSEE Initiative, the legal infrastructure of the non-EU SEE countries has become appropriate for the development of an Information Society. Almost all these countries have adopted all of the major laws and related regulations and the next logical steps would be the harmonization with EC directives.

The pan-European fragmented legal system on intellectual property rights protection results in low patenting rates; the associated costs to file a patent in so many countries is prohibitively high and the market size at each SEE country is discouraging such investments. Still, some inequalities exist: Serbia and Hungary create revenues in their economies from patents (Austria and Romania in a lesser degree too), while Greece and Bulgaria create marginal ones.

Data protection and regulations

In 2012, a reform is expected in the EU's 1995 data protection rules to strengthen online privacy rights and boost Europe's digital economy, due to different enforcement modes by the Member states. The reform is expected to rectify current fragmentation and costly administrative burdens, leading to savings for businesses and the restoration of consumer confidence in online services, providing a much needed boost to growth, jobs, and innovation in Europe.

Relevant EU directives currently consist of: protection of individuals with regard to the processing of personal data by competent authorities, electronic communications networks and services, cooperation between national authorities, the retention of data generated or processed in connection with the provision of publicly available electronic communications, etc.

Data protection frameworks remain uncertain throughout the area, due to a very fragmented unified digital market. Privacy laws, IPR, and regulation enforcement remain at a national level. There are also nationally fragmented network regulations for telecommunication markets. To our knowledge, the countries have not managed to surpass these problems in the SEE area and in the EU as such.

Environmental regulations

Digitization of services can result in positive outcomes for the environment due to dematerialization (i.e., e-prescriptions vs. paper-based ones) and reduction of dangerous medical waste by utilizing electronic health records and avoiding repetition of already performed tests; yet these benefits must be offset by the introduced carbon footprint for operating all these ICT systems and networks.

Theme-specific analysis

Healthcare professionals are especially sensitive to privacy. They need to ensure medical records are kept confidential, owned by the healthcare professional and the patient, and are not unwillingly or unwittingly shared with the healthcare insurances or third parties. At the same time, healthcare professionals often have to share data with their peers. For instance, a General Practitioner (GP) often needs to share patient-related data with a specialist. An e-Health system has to provide healthcare professionals with a means to securely share information. In this context, securely sharing information means the sender and the recipient need to be authenticated, and may have to exchange data in an encrypted manner. Typically a system based on public key cryptography (PKI or Public Key Infrastructure) with digital signatures is the commonly accepted solution to this requirement.

There is currently considerable legal uncertainty in the e-Health domain. Interoperable e-Health services cannot be fully operational without the underpinning legal certainty. Legal certainty is a pre-requisite for businesses to invest in innovation and for buyers and users to take up new products and services for which they know in advance who has legal responsibility for each aspect of an application.

Uncertainties relate, among others, to issues such as the legal definition of e-Health products and services and their interoperability, patient mobility including cross-border mobility, and privacy and personal data.

There are a number of examples in the health area on which Member States cannot act alone effectively and where cooperative action at the EU level is indispensable, including regarding issues which a cross-border dimension or relating to the free circulation of persons within the single EU market.

The need for legal certainly has been highlighted in recent years through the increased political focus on cross-border care and patient mobility, of which the e-Health market can be a prime facilitator. Approximately 1% of total healthcare expenses is spent each year on cross-border care and, although the overall number or citizens using cross-border care remains relatively low, its importance for individuals can be high.

Nevertheless, telemedicine and free movement of electronic health data pose a series of open questions regarding: a clear definition of telemedicine services, harmonisation of diagnosis related groups that can be treated by telemedicine, accreditation of health professionals who provide telemedicine applications, a telemedicine providers' database, and reimbursement for telemedicine services. Greater legal certainty is needed as, in some circumstances, cross-border telemedicine falls under the existing regulations covering the free movement of patients and, in other situations, is covered by the rules regulating free movement of professionals or electronic commerce (e-Commerce Directive).

3.6 Environmental factors

Theme-specific analysis

Digitization of services can result in positive outcomes for the environment due to dematerialization (i.e., e-prescriptions vs. paper-based ones) and reduction of dangerous medical waste by utilizing electronic health records and avoiding repetition of already performed tests; yet these benefits must be offset by the introduced carbon footprint for operating all these ICT systems and networks.

4 SWOT Analysis

The "strengths" and "weaknesses" part of the SWOT analysis for each of the ICT themes is approached in the usual format of a SWOT analysis in the context of the FORSEE project. As to identify the strengths and weaknesses of the SEE area in the e-Health theme, the following questions emerge:

- Identify major global ICT technological trends in this domain. How do these trends occur in the EU and the SEE?
- Identify major global technological trends influencing ICT development and application potentials, need/demands for ICT RTDI, co-development, convergence with non-ICT technologies in the domain. How do these trends occur in the EU and the SEE?
- What is the impact of the above two questions in the EU and SEE (S&T, economic, societal, any other)?
- What are the current and potential R&D activities in this domain in the SEE?
- What are the R&D competences, resources, and performance in this domain in the SEE?
- What are the innovation competences, resources, and performance in this domain in the SEE?
- What are the major application/market trends in this domain (global, EU, SEE)?
- Which STI policy initiatives promote ICT RTDI activities relevant for this domain (EU, SEE, national)?
- What do the ICT policy-making structure and mechanisms look like in this domain?
- What regulations exist in this domain (EU, national, SEE level, if relevant)?
- What ethical issues, social norms, behavioural patterns and values of major actors/important social groups are relevant for the developments occurring in this domain?

In the next sections, we analyse each of the above questions, synthesizing the views of the SEE area experts and stakeholders for the ICT domain/theme of "smart embedded components and systems".

4.1 Major global ICT trends in the domain

In a global scale, three major ICT trends emerge for e-Health, namely: telemedicine, diagnostics, and augmentation. We briefly describe them in the following paragraphs.

<u>Telemedicine</u>

Global networks and mobile technologies remove the necessity for medical practitioners to be in the constant physical presence of their patients to make a diagnosis or perform procedures. Key technologies include: AI therapists, App-driven diagnostics, AR surgery assistance, data-driven diagnostics, data-driven patient communities, full-body simulation, full-brain simulation, m-Health, natural language processing, remote virtual presence, robotic healthcare assistants, robotic surgery, telemetrics, and virtual triage.

<u>Diagnostics</u>

The development and distribution of advanced sensors will turn diagnoses from knowledgeable guesses with incomplete information into idiosyncratic, data-driven procedures. Key technologies include: at-home sensors, big data, blood stream sensors, epidermal sensors, external sensors, in-clothes sensors, ingestible sensors, internal sensors, medical tricorder, non-invasive glucose sensors, open health records, question answering computing systems, rapid gene sequencing, and tissue-embedded sensors.

Augmentation

Technological replacements to human features can not only restore senses to those without, but could also enhance conventional attributes into remarkable capabilities. Key technologies include: auditory vision substitution, augmented hearing, augmented olfaction, enhanced metabolism, exoskeletons, hybrid assisted limbs, myoelectric prosthesis, neuroprosthetics, optogenetics, sensory augmentation, telescopic & microscopic vision.

4.2 Major global technological trends influencing ICT development

The advances in sciences such as medicine, pharmaceuticals, physics, and chemistry generate innovations that create demand for accelerated ICT development; for example, medical imaging generates demand for more advanced image processing techniques and genome sequencing generates demand for innovations in large-volume data processing and storage. The following major technological trends are identified:

- ICT solutions for improved efficiency and effectiveness of the healthcare systems that already cost too much (e.g., Hospital information systems and ERPs and e-Prescriptions), including better use of limited human resources for remote serving an ever-increasing population of elderly citizens (e.g., telemedicine and homecare)
- Technologies for independent and assisted living, especially for the elderly and disabled.
- Illness prevention (e.g., healthy living, virus outbreak control, disease information diffusion, sentinel surveillance, and preventive care) and patient support for “modern-living” diseases (e.g., obesity, diabetes, heart disease, and dementia).
- Re-use of public health information (e.g., government open data and social medicine) to develop novel applications and business models.

4.3 Impact in the EU and the SEE area

The issue of value creation by e-Health systems has been explored in several EU-funded projects. An initial consolidated attempt was undertaken by the European e-Health IMPACT study. Its objective was to devise a generic, adaptable assessment framework for e-Health applications and services focused on the cost-benefit analyses of 10 cases in Europe. Specific effort was made in collecting and analysing the direct and investment costs associated with the development and implementation of each case study, as well as in estimating the expected benefits in terms of quality, access and operational efficiency. The analysis also involved sensitivity analysis of multiple scenarios through different utilisation levels, estimation of annual and cumulative benefits and costs, productivity and distribution of benefits among the various stakeholders. The study concluded that identifying the economic and financial benefits of e-Health needs to take into consideration the overall operational context within which these applications and services lie.

A similar argument is substantiated by the US Congressional Budget Office. Building upon the critical analysis of the findings of two US-based endeavours in this domain, it concluded that e-Health systems and applications can lead to financial benefits, provided that a set of non-financial operational conditions are put into place. Still, their adoption has not been as rapid as expected, since the positive financial returns depend on different factors ranging from implementation challenges, evolving legislative and procurement processes to perceptions of the expected positive results among all involved stakeholders, among others.

The Financing e-Health study provided the basis for a more detailed analysis of evaluating the socio-economic impact of electronic health records as part of the Electronic Health Records (EHR) Impact research initiative. The study confirmed the need to examine the issue of effectiveness of e-Health systems using a multidisciplinary approach. In particular, it highlighted different adoption issues affecting the socio-economic impact of e-Health services, such as electronic health records and e-prescription; reimbursement mechanisms; organisational structures; networks; connectivity; and information governance.

The first issue emphasises that healthcare providers have to consider the potential of having their e-Health service reimbursed, although this may vary according to specific national systems. The second issue refers to the fact that the expected benefits of EHR and e-prescription require strong senior leadership and commitment. The last two factors (networks/interconnectivity and information governance) call for open and technologically neutral solutions when devising e-Health systems, so as to facilitate their present and future integration with other relevant systems. Still, it remains necessary to consider applicable national and international legislative requirements, including those relating to security and privacy. At the end, the strategic objective is to achieve positive network externalities, which state that the value of a specific network grows with the number of actors connected.

In 2006, the newly created Global Observatory for Health (part of the WHO) carried out a survey on the needs of States regarding e-Health services. In this context, policy makers, health workers, and academics were interviewed in 96 countries about the usefulness of e-Health tools for their nation. The results for developing countries were very eloquent as over 70% of non-OECD countries estimated all e-Health tools as either very or extremely useful.

Historically, in rich counties, technological innovation has tended to drive healthcare costs upwards. Overall costs rise as new, expensive products are diffused to increasingly broader segments of the patient population. It has proved difficult to control demand, even if the efficacy of the new product is not yet well demonstrated. For example, within the United States there are many market incentives for consumers to overuse new products, in turn driving overall costs up. Information technology may also fail to decrease the costs of health administration. Contrary to the overall experience of business and government enterprises outside of health, where ICT has increased productivity, a recent HIMSS survey showed that while U.S. hospitals have increased their use of IT, there was no indication that it lowered costs or streamlined administration.

It is a reasonable hypothesis, however, that the introduction of low-cost mobile technologies has the potential to reverse this trend, at least as far as delivering health services to poor, underserved populations in both rural and urban areas. The cost of mobile phones, other hand-held devices, and computers has declined dramatically over the last decade even as capabilities have increased.

European healthcare systems are the pillars of Europe's social infrastructure. Although they differ in terms of operational and financial structure, they share common goals and priorities such as universality, access to good quality care, equality and solidarity. More importantly, EU states also share common challenges. The first is population ageing with direct impact on the overarching dependency factor and pathological map of Europe. Ageing is changing disease composition, with a rise in chronic diseases. However, these are not only linked to ageing; it is also important to consider the rise of chronic diseases such as, for example, diabetes and cardiovascular conditions, which are directly related to unhealthy behaviour. At the same time, citizens as a whole are getting better information about healthcare issues, indirectly pushing national health systems to provide them with better quality and safety. This access to better information is one of the reasons for support for e-Health and healthy lifestyle approaches, in order to foster a better lifestyle for the prevention of chronic diseases. Nevertheless, these challenges do not come without financial implications, since they affect healthcare resource utilisation and expenditure with direct impact on general funding.

The European Commission recognised this pivotal role in its 2004 e-Health Action Plan, where it indicated a set of actions and initiatives to be taken at the EU and national levels. This was confirmed in the 2006 AHO report, "Creating an Innovative Europe", where the importance of ICTs in tackling specific healthcare challenges was seen as an area of action for European leadership, provided that appropriate policies were developed and legislative obstacles removed. This second report recognised Europe's weaknesses in specific e-Health domains such as infrastructure and clinical information systems. It also indicated the barriers for the development of pan-European e-Health services in Europe.

The possibility for geographical delocalisation of "healthcare" provision also requires access to patient data via health record systems based on commonly agreed standards.

The pivotal role of e-Health for Europe was confirmed at the 2009 EU Ministerial Conference in Prague and by the December 2009 conclusions of the European Council calling for the implementation of safe and efficient healthcare through e-Health. There has been a call for overarching governance structure so as to remove barriers to the development of e-Health in Europe. This last aspect is extremely important, since the socio-economic and policy developments previously indicated have created a large pan-European commercial market for e-Health solutions (as discussed in the following section).

4.4 SEE area current and potential R&D activities in the domain

The SEE countries involvement in R&D activities is mixed; some countries are established members in the European Research Area and actively participate and lead major multi-national projects with the Framework Programmes context. Still, other countries are in a catch-up phase.

The Strategic Research Agenda[7] of the I3E project (I3E SRA) identified health support, monitoring, diagnostics, and living assistance among the major application areas of embedded systems related R&D activities of interest for the SEE area.

As the integration efforts with the EU increase, so does the joint R&D activities with more advanced countries; in many cases, the deep expertise of the SEE members allows to take the lead of such activities. While contributing to generation of primary new knowledge, SEE countries also develop their expertise to innovate by adapting prior solutions to the specific needs of the countries and developing innovative area-, country-, or region-specific variations of global technological results.

4.5 SEE area R&D competences, resources, and performance in the domain

[7] http://www.i3e.eu/sra

The potential of the SEE area is quite high as it is characterised by a high growth rate, inexpensive labour force (GDP per capita is 25%-50% of the EU average), same business culture and proximity to the EU that can make it a favourable area for EU investment and common research and development endeavours. However the current level of R&D investment in SEE is well below the EU level (less than 1% of the GDP of the area, compared to 2% in EU, 2.6% in USA and 3.4% in Japan), which has to change. On the other hand SEE has to support long-term R&D instead of focusing on short term profitability, which is the general case.

4.6 SEE area innovation competences, resources, and performance in the domain

Europe's inferiority in terms of transforming the results of technological research and skills into innovations and competitive advantages has been described as the "European paradox" as early as the 1950's. The transformation of research results to innovative products, services, methods and processes in Europe is not guaranteed. Thus, Europe lies behind regarding its innovation competences compared to other poles of the global economy, such as the USA and Japan.

The situation in the SEE area is even worse. According to the Innovation Scoreboard, most of the SEE-area countries are classified as either *moderate* or *modest innovators*, with just Slovenia and Austria being classified as *innovation followers*, and no country being classified an *innovation leader*. With the exception of Austria, all countries lie below the EU average, including the highly-industrialized Italy. An innovation support framework is established in most of the SEE-area countries, yet with poor results with reference to the support and financing of innovation. The economic crisis has led to a further cut in available financing resources for innovation.

4.7 Major application and market trends in the domain

In terms of market size, the European e-Health industry has leading positions in emerging fields such as personalised health systems, medical equipment, and in several sectors of integrated e-Health solutions. The focus is on two main areas, telemedicine/homecare and clinical information systems in the primary healthcare sector. Those companies which have potential for success in these fields include both large European-based companies of specialised e-Health solutions that are world leaders in their fields as well as the estimated 5,000 European small- and medium-sized enterprises (SMEs) that operate in various sub sectors of e-Health.

The presence of EU industry is relatively weak in more traditional fields related for example to administrative and management systems or basic computing infrastructures, and its growth potential is diverse, from organic growth to high growth. For clinical information systems outside the care institutions such as general practitioner and pharmacy information systems, penetration and usage rate is very much dependent on the country/region. Hence, growth rates differ from organic to high.

A major hurdle for the further and quicker development of the e-Health sector in Europe is market fragmentation, which is often exacerbated by a lack of system interoperability (both technical and semantic). Market fragmentation in Europe, with its many small, differentiated markets, inevitably results in a lack of economies of scale for companies that offer e-Health related goods and services.

The combination of social and policy factors have created the basis for a strong European demand for e-Health services and applications. Based on an analysis undertaken by Capgemini Consulting, the

European e-Health market was estimated at EUR14.269 billion in 2008 and is projected to reach EUR15.619 million by 2012, with a compounded annual growth rate of 2.9%. A per-country analysis of the results confirms that France, Germany, Italy, Spain, and the United Kingdom are the principal European e-Health markets. However, the analysis also confirms that over the next three years all national e-Health markets will experience some form of growth in this area.

Capgemini Consulting has concluded that in 2008, Secondary Non-clinical Systems (SUNCS) accounted for 71.6% of the total e-Health market in Europe. Clinical Information Systems (CIS) represented about 13.6% of the total European e-Health market, while Integrated Health Clinical Information Networks (IHCIN) fare at about 5%. Finally, telemedicine accounted for a mere 0.9%. However, between 2008 and 2012 the situation is to evolve, with a major shift from Secondary Usage Systems to Clinical Information Systems (SUCIS). This suggests that e-Health systems are targeted more towards supporting the operational processes of healthcare 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. Together with CIS, IHCINs are expected to be responsible for about 80% of e-Health market growth in the period 2008-2012. More importantly, both segments promise the best prospect for the European e-Health industry in the medium and long term. Finally, the market for telemedicine systems and applications will continue to be small but growing, rapidly suggesting that true adoption of this technology by providers, professional and medical staff as well as patients will take significant time.

Closely related to issues of market fragmentation are issues concerning access to pump-priming funding for e-Health in an environment where health delivery is often funded through public bodies. Because there is not one owner of the various health systems (and therefore there is organisational fragmentation), it can be a challenge to introduce e-Health tools, such as disease management tools, into health systems so that the party responsible for making the investment reaps the benefits.

Significant and sustainable improvements in the quality and efficiency of health and social care can also be obtained through the procurement of R&D services that can lead to solutions and technologies that do not yet exist and that will outperform the solutions available on the market.

In addition, the e-Health market in Europe, like several other markets of innovations, suffers also from the fragmentation of public demand which in turn leads to a lack of exchangeability of products and services. The setting of different requirements by individual buyers at local, regional and national levels, the limited cooperation between procurers and between procurers and suppliers to develop solutions applicable across different member States are major barriers.

Despite the significant progress achieved in the use of ICT in health area, the reimbursement for cross-border services in e-Health is not regulated at the EU level. Although the existing regulations provide a well-established tool that has ensured social protection for workers, tourists and patients travelling within the EU, the system needs improvement in order to exploit the great potential for e-Health applications for the enhancement of safer, more efficient cross-border care.

Both existing and emerging disparities in member States legislation and case-law concerning healthcare prevent the smooth functioning of the internal market, in particular by impairing the development of cross-border services and producing distortions of competition.

4.8 STI policy initiatives promoting ICT RTDI activities in the domain

Several initiatives promote ICT RTDI activities relevant to the e-Health domain at EU level, including the Horizon 2020 i.e., the EU framework programme for research and innovation and its flagship initiatives of Innovation Union, Digital Agenda for Europe, and Industrial Policy for the Globalization Era; the 7th Framework Programme, being the EU's chief instrument for funding research until 2013; the Competitiveness Clusters, generating synergies in relation to common innovative projects; the Joint European Resources for Micro to medium Enterprises (JEREMIE); the Joint Action to Support Micro-finance Institutions in Europe (JASMINE); the Information and Communication Technologies Policy Support Programme (ICT-PSP); the Programme for the Competitiveness of enterprises and SMEs (COSME) 2014-2020; and the Entrepreneurship and Innovation Programme (EIP).

The SEE area is a mix of EU member and non-member states that may take benefit of the different initiatives at EU level. Further to these initiatives, the area is eligible for different cooperation programmes under the European Territorial Cooperation Objective, including: the South East Europe Programme; the Alpine Space Programme; the Central Europe Programme; and the Mediterranean Programme. Although these programmes do not support R&D directly, they offer support actions for innovation and networking, which are the fundamental steps of the overall R&D process. Furthermore, several cross-border bilateral cooperation programmes involve countries of the SEE area, including: Ellada-Boulgaria, Romania-Boulgaria, Ellada-Italia, Italia-Osterreich, Italia-Slovenija, Osterreich-Magyarorszag, Magyarorszag-Romania, Slovenija-Magyarorszag, Magyarorszag-Slovensko, Slovenija-Osterreich, and Slovensko-Osterreich.

At national level, different operational programmes (OP) support RTDI activities under the National Strategic Reference Frameworks (NSRF): in Greece, the OP "Competitiveness & Entrepreneurship", the OP "Digital Convergence", the OP "Education and Lifelong Learning", and the Regional OP (ROP) for each region; in Bulgaria, the OP "Competitiveness"; in Italy, the OP "Research and Competitiveness", the OP "Security", the OP "Networks and Mobility", and the ROPs; in Hungary, the OP "Competitiveness and Employment objective" and the OP "Convergence"; in Romania, the OP "Increase of Economic Competitiveness"; in Slovakia, the OP "Information Society", the OP "Competitiveness", and the OP "Research and Development".

Recurring public budgets dedicated specifically to e-Health are the exception (Austria, the UK, Spain), whereas there is widespread use of projects-based sourcing. Sometimes, private and public insurance companies or public technology or innovation agencies (for example Tekes, the Finnish Agency for Technology Development and Innovation) are involved in financing. Among the international sources of funding mentioned, EC RTD project co-financing as well as funding from European Structural and Regional Funds and the European Investment Bank are mentioned.

The topic of ex-ante impact assessment as well as formative and ex-post summative evaluations has gained considerable momentum across Europe. Whereas in 2006 only 5 countries reported related activities, in 2010 already a considerable majority of 21 countries mentions such undertakings – this is the largest increase in interest of all topics surveyed. The scope and procedures used are very diverse, however, and a systematic comparison of approaches, techniques/tools applied and specific applications or processes evaluated was not possible.

Six countries (under way in Ireland, England, and Switzerland; planned in France, Slovenia, and Slovak Republic) report on actual assessments of the impact of investments in the e-Health domain. As such analyses are expected to lead to an optimisation of resource allocations not only with respect to planned investments, but also for already running activities, one can expect more attention to be paid to such socio-economic and change management aspects in future.

Whereas most Member States by now realise the urgent need of evaluation activities to better prepare for and control policy progress and learn from experience. Further services high on the agenda are the electronic transfer of prescriptions or the provision of tele-health services, e.g., for doctors and patients in remote regions or for chronically ill patients at home. These are among the key activities identified in the EC's 2004 Health Action Plan.

4.9 ICT policy-making structures and mechanisms

The European policies in the e-Health domain are largely structured at intergovernmental level and expressed by the European Commission. At the national level, the policy making structure is at a governmental level expressed through the NSRF and its operational programmes.

Several countries have updated their older e-Health strategy documents, the most recent being Bulgaria ("Concept on E-health", 2011). In countries where the responsibility for the provision of healthcare is decentralised i.e., delegated to the regional level, strategy documents regarding e-Health have also been published by regional authorities.

Slovak Republic is an EU Member State which recently has developed a very detailed strategy and implementation plan, based on a comprehensive needs analysis for e-Health implementation. Some countries have published a more generic e-Government or Information Society policy document which refers to an ICT strategy in the healthcare sector as one of several priorities.

Allocation of responsibility for e-Health strategy development and their implementation is not uniform in EU Member States. In the majority of countries responsibility lies largely with the Ministry of Health. In others (e.g., Greece, Estonia, Italy, and Hungary), responsibility is more widespread across several ministries and/or agencies, such as those responsible for new technologies, innovation and/or telecommunications. In countries with decentralised health systems or in countries where several ministries are involved, there is a strong need for a concerted official e-Health strategy with common goals that are agreed among these different institutions.

By now, more than a dozen countries have established legal entities as specific consultative bodies or competent authorities under ministerial supervision. Their role is to develop, oversee and monitor the country's strategic goals, and/or implement and manage e-Health infrastructure and application projects. In the Slovak Republic, the National Health Information Centre (NHIC) was established as an e-Health "think-tank" body.

In the meantime, as part of their e-Health governance structures, many countries have advisory bodies involving professional associations, patient representatives, third party payers or care providers. Careful planning, organisational setup and stakeholder involvement are key success factors for e-Health (infrastructure) projects. A flawed institutional structure or ill-conceived processes can jeopardise an entire project because of deficient conflict-resolution procedures or competing centres of power whose rivalry jeopardises progress. In Austria, a success e-Health initiative was established in 2005 already. It represents an interesting example of early involvement of stakeholders in strategic shaping of a national e-Health project. Stakeholders were motivated to become involved in defining the goals and objectives to be achieved by the overall e-Health programme.

A strangely neglected field in the overall governance domain seems to be the continuous development of user skills, be they professionals like nurses and doctors, be they citizens as patients and informal carers.

4.10 Regulations

Legal and regulatory issues are among the most challenging aspects of e-Health: privacy, confidentiality, liability and data protection all need to be addressed in order to enable a sustainable implementation and use of e-Health applications. Rarely does a country report on a coherent set of laws specifically designed to address these diverse aspects of e-Health. Rather, in most countries the use of e-Health is currently regulated only by the general legal framework, in particular by laws on patient rights and data protection and by regulations on professional conduct. New legislation is often still in the process of being drafted and enacted. In 2006, the activities with a specific regard to handling e-Health issues were reported in 14 countries. Today, 22 countries are dealing with e-Health related legal regulations, showing that this topic is now widely recognised as an important enabler for progress in this sector.

With regard to the regulation of electronic health records, it can be noted that nearly all European countries legally enforce a duty to keep a carefully updated and safely stored health record, but most keep the option open of storing the health record on paper or electronically. If they have an electronic form, additional requirements concerning content, access, and security often apply. It is however expectedthat the obligation to store the records electronically will arise in more and more countries, if only because many are currently planning to roll out electronic health record-like systems that will become mandatory unless patients opt-out.

The extent of regulations concerning tele-health service delivery is presently considerably smaller than that of electronic health record systems. This is mainly because the usefulness of legal provisions dealing with tele-health specifically is being questioned. If regulated at all, the measures usually focus on whether to uphold the requirements to treat a patient initially in person and allow for tele-services only after a first direct contact, the fact that specific accreditation for such services is not available and liability issues, particularly in cross-border situations.

4.11 Ethical issues, social norms, behavioural patterns, and values

Social willingness to accept e-Health innovations is a decisive parameter for the wide acceptance and success. It is not easy to predict user acceptance, especially when such systems involve continuous monitoring of and interference with human activity at large. Security and privacy issues must be addressed beforehand and user engagement in the design of these systems is mandatory as to address the scepticism and concerns.

There is a lack of user (i.e., patients and healthcare professionals) awareness and confidence; most people prefer to see their doctor face to face and do not trust the safety of stored information.

Fragmentation within healthcare systems is a major barrier to e-Health deployment on a large scale.

There are particular challenges in relation to health and social care informatics. The small size of the buying entities such as GPs and single hospitals does not attract major commercials that tend to focus on large clients and cover smaller organisations via business partner models.

There is still lack of large scale evidence for potential improvements of healthcare processes; lack of a consolidated and systematic approach to monitor and benchmark the adoption and use of the whole spectrum of e-Health solutions; and lack of agreed metrics for measuring success, including the time period over which to look at costs/benefits and the comparability of different implemented systems.

The acceptance by healthcare professionals is still weak. The e-Health system design and implementation processes often fail to win over clinicians. Failure to engage with people in health management roles in charge of implementing new systems is also a significant barrier. Opportunities offered by e-Health should be introduced in a consensual way. It should be clear for whom e-Health is mostly intended and for what kind of activities or services it is not appropriate. In the case of doctors and other health professionals, it should be determined for what kind of duties it will represent a helpful solution.

5 SWOT table

Strengths	Weakness
Very high mobile penetration SEE achieved broadband coverage for all Digital Agenda target-Relatively high availability of broadband connectivity Average SEE internet use around EU27 average Policies/strategies in place for support of e-Health services in SEE RDI proven potential from results of FP7 ICT Programme: Challenge 5 - ICT for Health, Ageing Well, Inclusion and Governance Capacity of Innovation in e-Health to produce significant cost savings and operational benefits to the traditional healthcare system Good potential for scientific cooperation/co-publications, which enables knowledge transfer and sharing also at transnational level in SEE Inherent relationship between cost and mass production costs shared with non-health services Sizeable market to be targeted within the region Possibility to produce application/product innovation in domain even at small SME’s level without large investments for development	Low business R&D expenditure and low mobile broadband penetration. Little evidence currently exists to help countries decide if e-Health technologies can provide substantial savings to health care systems – Lack of investments’ impact assessments Low level of e-Health applications development in SEE Low level of SEE participation in EU research and innovation support programmes (with some exceptions) comparing to EU27 SEE countries present mostly followers part of innovation lifecycle Lack of e-Health system interoperability EU Health industry is relative weak in traditional heath sectors Major issues under debate on privacy and security Lack or low adoption of common legal/regulatory standards

Opportunities	**Threats**
General reforms to the NHS taking place (austerity measures, restructuring, etc.) Ageing population in Europe and SEE in particular Underserved populations among the poor or at remote locations can be seen as major markets 'Health, demographic change and wellbeing' is a societal challenge for which funding will be provided under Horizon 2020 Constant availability of research and development funding as a percentage of GDP. Digital Agenda (Europe 2020) targets support ageing citizens' lives and revolutionising health services (Action 76: Propose a recommendation to define a minimum common set of patient data, Action 77: Foster EU-wide standards, interoperability testing and certification of e-Health, Action 78: Reinforce the Ambient Assisted Living (AAL) Joint Programme) increased need for data sharing among delivery organisations and healthcare professionals – because of citizens' mobility Potential for follow-up innovation for SMEs participating in EU funded research projects Exploitation of new markets: development of concerted e-Health services in border regions for EU and candidate communes next to the service centres Niche, app-oriented, markets Increased computer literacy and ICT skills among SEE citizens	Low social willingness to accept e-Health innovations - Low level of early adoption capacity Reforms of NHS stopped (or reduced only to cut downs) when significant investments are needed because of economic crisis Austerity prevents increasing or even imposes a decrease in RDI financing Adoption of e-Health systems requires strong senior leadership support Adoption of e-Health systems often requires cooperation among Ministries and government bodies – bureaucracy implications Inability of SEE countries to participate with equal footing in the new European Research Area given the changes in EU support programmes for 2013-2020 limiting SEE innovation activities further. Still relatively low research and development expenditure as a percentage of GDP. Accreditation problems for Health professionals, especially in transnational cooperation fragmentation of public demand

Annex I

EU Benchmarking survey (2010 data) - ICT penetration in health services in the SEE area and the EU 27

Table 1: Hospital computer system externally connected

	Yes, through an extranet i.e. using a secure internet connection over the internet (%)	Yes, through an value added network or proprietary infrastructure (%)	Your computer system is not connected (%)	Do not know (%)
Austria	50	50	0	0
Bulgaria	53	20	7	20
Greece	75	13	13	0
Hungary	50	40	10	0
Romania	72	9	16	3
Slovenia	67	0	33	0
EU 27	50	30	19	1

Table 2: Application integration in hospital computer system

	Completely or nearly fully integrated (>60% of applications)	Partially integrated (26-60% of applications)	Not very integrated (0-25% of applications)	Not integrated at all	Do not know
Austria	79	14	0	7	0
Bulgaria	40	60	0	0	0
Greece	71	21	8	0	0
Hungary	50	40	10	0	0
Romania	53	34	9	3	0
Slovenia	67	33	0	0	0
EU 27	59	32	6	2	0

Table 3:Hospital-provided wireless Internet access to …

	Medical workstations inside the	Ambulances	Inpatients inside the hospital	Outpatients or visitors inside the	None	Do not know

	hospital			hospital		
Austria	100	8	38	23	0	0
Bulgaria	80	0	60	20	20	0
Greece	67	0	0	0	33	0
Hungary	67	0	67	33	33	0
Romania	71	0	29	14	29	0
Slovenia	100	0	100	100	0	0
EU 27	76	9	46	30	16	0

Table 4: Type of electronic patient record (EPR) mainly used in hospital

	A hospital wide EPR system shared by all the clinical service departments	Multiple local/departmental EPR systems, which share information with a central EPR system	Multiple local/departmental EPR systems, but they do not share information	None, we do not use EPR systems in our hospital
Austria	73	40	7	13
Bulgaria	47	13	7	33
Greece	54	15	23	19
Hungary	90	10	10	0
Romania	54	42	18	16
Slovenia	83	8	0	0
EU 27	64	25	11	19

Table 5: Online access to EPR by patients

	Yes, to everything	Yes, but only to certain data (e.g. results and protocols)	No	Do not know
Austria	0	0	100	0
Bulgaria	0	7	93	0
Greece	0	4	92	4
Hungary	20	0	80	0
Romania	3	3	95	0

Slovenia	0	0	100	0
EU 27	1	3	95	0

Table 6: Use of Picture Archiving and Communications System (PACS)

	Yes	No	Do not know
Austria	80	20	0
Bulgaria	40	60	0
Greece	23	77	0
Hungary	60	40	0
Romania	37	63	0
Slovenia	33	67	0
EU 27	61	38	0

Table 7: Type of PACS

	A hospital standalone system	A PACS system which is part of a national or regional network system	Do not know
Austria	75	25	0
Bulgaria	100	0	0
Greece	100	0	0
Hungary	67	17	17
Romania	86	0	14
Slovenia	100	0	0
EU 27	76	23	1

Table 8: Location PACS can be accessed from

	Bedside (accessible right next to the patien	On each ward	In the emergency room	In the operating room	In the ambulance	In the radiology department	In the outpatient department/in a consulting room	Anywhere inside the hospital (through a wirele	Outside the hospital by own hospital	Outside the hospital by external health care provid	Don't know

	t)							ss netw ork)	staff (on the mov e, at hom e..)	ers (prima ry care, other hospit als, GPs..)	
Austr ia	67	10 0	83	92	8	100	100	67	42	0	0
Bulg aria	0	83	0	17	0	33	33	17	33	0	17
Gree ce	17	50	33	33	0	83	50	17	0	17	0
Hung ary	0	0	100	100	17	100	83	17	50	17	0
Rom ania	7	21	71	43	21	86	50	14	14	14	0
Slove nia	0	10 0	100	100	0	100	100	0	0	0	0
EU27	36	77	78	73	6	93	83	37	40	27	*1

Table 9: Adverse health events reporting system exists

	Yes	No	Do not know
Austria	47	47	7
Bulgaria	7	93	0
Greece	4	88	8
Hungary	10	80	10
Romania	3	98	11
Slovenia	0	100	0
EU 27	39	54	7

Table 10: Computer-based system for electronic service order placing

	Yes	No	Do not know
Austria	60	40	0
Bulgaria	40	53	7

Greece	50	46	4
Hungary	80	20	0
Romania	32	63	5
Slovenia	0	100	0
EU 27	55	43	2

Table 11: Tele-homecare or tele-monitoring services offered to outpatients at home

	Yes	No	Do not know
Austria	0	100	0
Bulgaria	7	93	0
Greece	4	85	12
Hungary	20	80	0
Romania	3	95	3
Slovenia	17	100	0
EU 27	9	89	2

Table 12: Electronic exchange of patient clinical care information

	With a hospital or hospitals outside your own hospital system	External general practitioners	External specialists	Health care providers in other EU countries	Health care providers outside the EU countries	None	Do not know
Austria	40	67	67	0	0	33	0
Bulgaria	0	0	0	0	0	80	20
Greece	8	0	0	4	0	85	8
Hungary	50	30	10	0	0	40	10
Romania	16	16	21	8	5	74	3
Slovenia	0	33	33	0	0	67	0
EU 27	33	27	28	5	2	55	3

Table 13: Security measures for stored and transmitted patient data

	Encryption of all stored data	Encryption of all transmitted data	Workstations with access only through health professional cards	Workstations with access only through fingerprint information	Workstations with access only through a password	Data entry certified with digital signature	Other	Do not know
Austria	47	87	33	7	100	13	27	0
Bulgaria	13	13	0	0	93	13	27	0
Greece	8	12	8	0	96	4	19	0
Hungary	30	30	0	0	100	0	20	0
Romania	66	84	13	3	87	21	21	8
Slovenia	0	0	33	0	100	0	0	0
EU 27	38	63	20	4	93	29	11	2

Annex II

Related R&D Architectures (source: Linked2Safety project Requirements Analysis)

List of e-Health-related projects

Project Short Name	Project Full Title	Short domain description	SEE countries participating
Interoperability in e-Health			
ARTEMIS	A Semantic Web Service-based P2P Infrastructure for the Interoperability of Medical Information Systems	interoperability problem in the healthcare domain, ontologies based on prominent healthcare standards	Greece
HITCH:	Healthcare Interoperability Testing and Conformance	establish a roadmap towards an overall functionality and interoperability testir approach in the field of healthcare in Eu	None from SEE
RICORDO	Researching Interoperability using Core Reference Datasets and Ontologies for the Virtual Physiological Human	semantic interoperability between the meta-data of clinical models and datasets, development of new ontologies, in co-ordination with the OBO Foundry	None from SEE
RIDE:	A Roadmap for Interoperability of eHealth Systems in Support of COM 356 with Special Emphasis on Semantic Interoperability	European best practices for semantic interoperability in eHealth domain, a EU-wide semantically interoperable eHealth infrastructure	Greece
SemanticHEALTH		global roadmap for deployment and research in health-ICT, focusing on semantic interoperability issues of eHealth systems and infrastructures	Hungary
SemanticMining	**Semantic Interoperability and Data Mining in Biomedicine**	generic methods and tools supporting the critical tasks in medical and biomedical informatics, such as data mining, knowledge discovery, knowledge representation, abstraction and indexing of information, etc.	Greece, Hungary
Linked Data and e-Health			
CALBC	**Collaborative Annotation of a Large Biomedical Corpus**	Support Action	None from SEE
LATC	**The LOD Around-The-**	Support Action	None from SEE

	Clock		
LOD2	**Creating Knowledge out of Interlinked Data**	testbed and bootstrap network of high quality multi-domain, multi-lingual ontologies, machine algorithms for fusing data from the Web	Serbia (Mihalo Pupin)
Linked2 Health	**Secure Linked Data Medical Information Space For Semantically-Interconnecting Electronic Health Records and Clinical Trials Systems Advancing Patients Safety In Clinical Research**	novative semantic interoperability framework, a sustainable business model, and a scalable technical infrastructure & platform for the efficient, homogenized access to and the effective, viable utilization of the increasing wealth of medical information contained in the EHRs deployed	Greece, Romania
Granatum	**A SOCIAL COLLABORATIVE WORKING SPACE SEMANTICALLY INTERLINKING BIOMEDICAL RESEARCHERS, KNOWLEDGE AND DATA FOR THE DESIGN AND EXECUTION OF IN-SILICO MODELS AND EXPERIMENTS IN CANCER CHEMOPREVENTION**	homogenized, integrated access to the globally available information and data resources needed to perform complex cancer chemoprevention experiments and conduct studies on large-scale datasets.	Greece
Prevention, Identification and Monitoring of Medical Errors and ADRs			
AMICA	**Assembling Data and Knowledge at the Point-of-Care to Improve Medical Decision-Making and Prevent Errors**	preventing errors is the combination of data and knowledge stored in different distributed information systems.	Greece (hospital)
COCOON	**Building knowledge driven and dynamically networked communities within European healthcare systems**	semantic-based healthcare information infrastructure capable of seamlessly integrating medical information and eHealth services	None from SEE
EU-ADR/ALERT	**Early Detection of Adverse Drug Events by Integrative Mining of Clinical Records and Biomedical Knowledge**	the ALERT project generates signals using a variety of text mining, epidemiological and other computational techniques to analyse the EHRs. Moreover, it supplements the signal detection by means of	None from SEE

		current knowledge of biological mechanisms and in-silico prediction capabilities.	
PSIP	**Patient Safety through Intelligent Procedures in Medication**	The project develops innovative computer-based applications able to search databases, analyse medical data with innovative statistical tools and automatically identify ADE systematically associated with combinations of certain drugs and contexts	Romania, Greece
SAPHIRE	**Intelligent Healthcare Monitoring Based on a Semantic Interoperability Platform**	intelligent healthcare monitoring and decision support system on a platform integrating the wireless medical sensor data with the hospital information systems	Romania (2), Greece
Integrated Environment for Clinical Research			
ACGT	**Advancing Clinico-Genomic Trials on Cancer**	development of an integrated grid-enabled infrastructure that allow the cancer research community to seamless and secure integrate, access and analyse clinical and genomic data at different levels	Romania Greece(2),
ASSIST	**Association Studies Assisted by Inference and Semantic Technologies**		Greece (3)
EHR4CR	**Electronic Health Records for Clinical Research**	a State of the Art interoperable platform and a sustainable business model to enable heterogeneous EHR systems to reuse patient data for clinical research, in full compliance with applicable legislative, regulatory, ethical, and privacy protection requirements and policies across Europe	Greece
PONTE	**Efficient Patient Recruitment for Innovative Clinical Trials of Existing Drugs to other Indications**	SOA-based platform that offers intelligent, automatic identification of patients eligible to participate in clinical trials	Greece
SALUS	**Scalable, Standard based Interoperability Framework for Sustainable Proactive Post Market Safety Studies**	semantic interoperability infrastructure to enable reuse of EHRs in an efficient and effective way for enabling pro-active post-market safety studies	None from SEE
TRANSFORM	**Translational Medicine**	rapid learning healthcare system" driven by advanced computational	None from SEE

	and Patient Safety in Europe	infrastructure that can improve both patient safety and the conduct and volume of clinical research in Europe	
Ethical and Privacy-driven Research Projects			
CONTRACT	**Consent in a Trial and Care Environment**	impact of European legislation on informed consent (Clinical Trials Directive, Data Protection Directive) on translational research	Greece
ETHICAL	**Promoting International Debate on Ethical Implications of Data collection, use and retention for Biometric and Medical Applications**	an international consensus on the ethical use of personal data in the information society that leads to a secure environment with no compromise in human rights respect	None from SEE
RADICAL	**Road Mapping Technology for Enhancing Security to Protect Medical and Genetic Data**	requirements for enhancing security and privacy in the management of medical and genetic data	?

An indicative list of EU-funded projects in the field of e-Health and their corresponding area of focus appear below:

Research Project	Semantic interoperability	Linked Data	Decision support	Integrated environment reusing EHR data	AE detection	Clinical research support	Ethical, personal data and security
ARTEMIS	X						
HITCH	X						
RICORDO	X						
RIDE	X						
SemanticHEALTH	X						
SemanticMining	X		X				
CALBC	X	X		X			
LATC	X	X		X			
LOD2	X	X		X			
AMICA			X	X			
COCOON	X		X	X			
EU-ADR/ALERT				X	X		
PSIP	X		X	X	X		

SAPHIRE	X		X				
ACGT	X			X		X	X
ASSIST	X			X	X		X
EHR4CR	X			X		X	X
PONTE	X	X	X	X		X	
SALUS	X			X		X	X
TRANSFORM	X		X	X	X	X	
CONTRACT							X
ETHICAL							X
RADICAL							X
Linked2Safety	X	X	X	X	X	X	X