

Advanced, Cross-Disciplinary & Integrated **M**edical **I**maging for all **EU**ropeans through a Network of **R**egional Clusters and Devel**OP**ment Strat**E**gies

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Table of acronyms

SWOT	Strength, Weakness, Opportunities, Threats
MI	Medical Imaging
AMI	Advanced Medical Imaging
BIH	Bosnia and Herzegovina
RS	Republic of Srpska
R&D	Research and Development
EU	European Union
COST	Cooperation in Science and Technology
FP7	Framework Programme 7
ERA	European Research Area
IU	Innovation Union
MSTRS	Ministry of Science and Technology Republic of Srpska
R&D&I	Research, development and innovation
S&T	Science and Technology
ICT	Information & Communication Technologies
MIPD	Multi-annual Indicative Planning Document
IPA	Instruments for Pre-Accession Assistance
BAM	Official designation of Bosnia and Herzegovina Convertible Mark
MZSZ	Ministry of health and social Security RS
RTD	Research Technology and Development
SME	Small and Medium size Enterprise
PPP	Public Private Partnership
GDP	Gross Domestic Product
NGOs	Non-Governmental Organizations
EIB	European Investment Bank
ROP	Regional Operational Programme
VCA	Value Chain Analysis
WP	Work Package

Introduction

The present document is deliverable D7.2 “Regional SWOT on Capacity Building and Value Chain Analysis Report on NordEst Region in Romania and the Republika of Srpska in Bosnia and Herzegovina”. This regional SWOT on Capacity Building and Value Chain Analysis aims at providing the regional context investigated in Republic of Srpska and NordEst Region and qualitative review of MI sector in Republic of Srpska / Bosnia and Herzegovina through observation of different programmes, policies, strategies, as well as review of public and private investment and other relevant actions.

This activity is executed in close co-operation with **tasks**:

T2.1 VALUE CHAIN ANALYSIS OF THE MEDICAL IMAGING SECTOR IN EUROPE

T3.6 AMI “Socio-Economic” S.W.O.T. Analysis

T4.5 AMI “Scientific” (RTD) S.W.O.T. Analysis

as well as **deliverables**:

D2.1 Value Chain Analysis of the Medical Imaging Sector in Europe

D3.5 Final AMI Socio-Economic SWOT Analysis Report

The **main goal** of this document is:

- to explain briefly the problem in question, its background and to give brief description of the Republic of Srpska related to status of Advanced Medical Imaging-AMI (scientific and non-scientific stakeholders, main policies, sources of funding, overall AMI capacities in region, available scientific and non-scientific projects related to AMI);
- to give a brief overview of the methodology used, to describe briefly the methodology of data collection and evaluation and to provide main strategic documents used for SWOT analysis;
- to provide a table with detailed SWOT analysis (Strengths, Weakness, Opportunities , Threats) with possible scenarios;
- to integrate the findings into the political, social, socio-economic and economical context of the Republic of Srpska;
- to give the comparison between main findings of Value Chain Analysis (D2.1) and SWOT for the Republic of Srpska, and
- to give recommendations for the improvement of AMI in the Republic of Srpska.

REGIONAL SWOT ON CAPACITY BUILDING AND VALUE CHAIN ANALYSIS ON REPUBLICA SRPSKA IN BOSNIA AND HERZEGOVINA

Executive summary

Within this regional SWOT analysis and Value Chain Analysis for the Republic of Srpska, Bosnia and Herzegovina region, different indicators for the field of medical imaging (MI) and advanced medical imaging (AMI) were observed and evaluated. This SWOT analysis arose as a result, or rather as the continuation of previous initial analysis for the same region, which mapped the most important strategies, policies and programmes that more or less relate to MI and the AMI Sector, but without the intention to make a more detailed evaluation or to make value assessment.

SWOT analysis was realized using a combined methodological approach, or the processed information was collected from different sources in order to have an overall review of the MI sector and to have an opinion from all relevant stakeholders.

SWOT analysis showed that the MI sector, and especially AMI, is faced with numerous challenges and difficulties that must be eliminated or minimized in order to expect further progress of healthcare system in the Republic of Srpska and the development of MI sector as its constitutive part.

The companies that based their business more or less on medical imaging are now faced with an undeveloped market, insufficient support within existing programmes and initiatives, weak networking with similar companies, networks and/or clusters, and with economic crisis and insufficient funds or investments from the public sector. Beside this, RTD institutions can be important partners to companies that suffer from weak technical equipping, significantly low level of investments from GDP in the sector of science, research and innovation, with minor participation in important European and regional research networks and programmes, weak links with European partner institutions and other unfavourable conditions.

The overall ambient for further development and investments in the MI sector is really unfavourable and asks for additional efforts and actions from all key stakeholders (public authorities in the Republic of Srpska, enterprises and associations, academies and the research sector, healthcare providers, creators of health policy and programmes, associations of patients and other healthcare service users), especially for further improvement of legislative framework for investments from private investors and foreign companies. A need for the further improvement of technical capacities of healthcare institutions and strengthening of supporting MI infrastructure in health sector is growing and it can be expected that in the next decade will grow for couple of times, which will for sure create higher pressure on decision makers. There are several positive examples (strengthening of public-private partnerships, additional and professional education of healthcare professionals, credit arrangements with international

institutions) in the Republic of Srpska that are resolving the problems, but it is still not sufficient to say that the MI field is developing and improving in accordance with the realistic and future needs of a public health system, as well as its users.

Besides the SWOT analysis, there was realized an additional comparative analysis against the most important conclusions from Value Chain Analysis of the Medical Imaging Sector in Europe (D2.1.) in order to identify all important indicators observed in both documents, but also eventual differences in findings from both of these analytical documents.

Within the scope of this SWOT analysis there were also identified additional short recommendations for the improvement of MI and the AMI sector that can be very useful for healthcare institutions and creators of health policies in Republic of Srpska during strategic planning and designing of relevant programmes.

Background information

Bosnia and Herzegovina (BiH) is located in the southeast Europe, decentralized and consisting of **two governing entities** - Federation of Bosnia and Herzegovina and Republic of Srpska, **and one district** - District Brcko. **BiH has a specific decentralized system with high independence of governing entities.**

The majority of the existing Research and Development (R&D) infrastructure is located at public universities, where most of these kinds of activities are being conducted in Bosnia and Herzegovina. Science, research and development Institutes in public and private ownership, in most of the cases, do not have any material and technical capacities, including human resources, required for conduction of activities they are registered for. In other words, **they are not engaged in the development of new products and new technologies, but more on expert and theoretical work.** Almost all science and research development institutes, which significantly contributed to the technological development of BiH, vanished. Most of them were demolished in the war, and the surviving ones have poor intensity of activities, doing mainly routine tasks and projects. The main problem for more-or-less all remaining institutes are available and qualified human resources, which are not good base ground for serious Science and Research work. More intensive intersectoral cooperation between institutes and industry is not possible because the majority of research laboratories are insufficiently equipped. Generally speaking, research for industrial purposes is at a very low level. Potentially usable science and research capacities are located at Universities, but because of the lack of financing they are not performing their main role - research. **Universities have mainly lost their science and research characteristic and turned into colleges for providing academic education with the absence of research activities performed by professors.**

Bosnia and Herzegovina is a potential candidate for EU membership. According to European Commission Bosnia and Herzegovina 2011 Progress Report, **some progress was made in the area of research and innovation policy** through participation in the Seventh EU Research Framework Programme (FP7), which slightly increased. Cooperation with COST and EUREKA started, some efforts were made to

integrate into the European Research Area (ERA) and contribute to the Innovation Union (IU), BiH joined the EURAXESS network aiming at mobility of researchers.

A framework for **defining health and health-research policy does not exist at the state level** due to the fact that on that level, there is no national Ministry of Health or any other national agency with the aim to create and carry on the activities connected with defining scientific-research policies in health. **The Ministry of Civil Affairs of BiH only** has a coordinative role in the process of scientific research in the field of health in the part referring to international cooperation.

The health care system in the **Republic of the Srpska (RS)** is **centralised** with overall power concentrated within the **Ministry for health and social welfare of the Republic of Srpska, the Public Health Institute and the Health Insurance Fund**. Financing of scientific researches is conducted and coordinated by the **Ministry of Science and Technology of the Republic of Srpska (MSTRS)**, together with mutual coordination with the **Ministry for health and social welfare of Republic of Srpska**. **Ministry of industry, energy and mining of Republic of Srpska** is the highest level of entity authority responsible for the SME sector, defining measures of economic and development policy to support different economic activities. **In the Republic of Srpska, there are no specialized associations directly involved in the field of AMI**. However, certain associations gather individuals (doctors and researchers) on various issues in the scope of health policy, education and research, such as **Chamber of doctors of medicine of Republic of Srpska, the Pharmacy Chamber of the Republic of Srpska, and the Doctors society of the Republic of Srpska**.

Generally, the R&D&I system in RS is coordinated fully by MSTRS, which is responsible for adopting necessary regulations, provision of financial support and necessary funds for RDI institutions. In RS there are 15 S&T institutes, two public and six private universities. Most research activities in the health sector are conducted at public universities in close cooperation with the University and Clinical Centres in Banja Luka and Foca. In accordance with legislation, these clinical centres are at the same time the scientific base for teaching and research staff of these universities. Most of the research projects and activities are implemented at these clinical centres.

It is important to mention that there are **no strategies/policies/programmes closely connected to medical imaging, nanomedicine, biotechnology and ICT for health**. These issues are just mentioned in parts of available general strategies/policies/programmes.

The Government of the Republic of Srpska has adopted the **Development Program of the Republic of Srpska 2007 - 2010**. This document has defined the vision, goals and priorities in economic development of RS in the period 2007 - 2010, with directions for accomplishing the goals and priorities in realistically estimated terms and conditions, and it will serve as the base ground for preparing the General Development Strategy of RS, and the National Development Plan as the obligatory document in the process of the accession of the country to the EU.

“Secondary and Tertiary Health Care Strategy in the Republic of Srpska” defines programmes and projects intended for the modernization of hospitals, new latest generation medical equipment produced by a well-known producer, introducing new technologies, providing preconditions for the

setting up of new procedures for diagnostics and medical treatment. Within this strategy overall strategic objectives are defined that are financed through grants and loans, such as **“Modernization of hospitals in BiH - Korea 1 and Korea 2”**.

The Commission of the European Communities adopted the Multi-annual Indicative Planning Document (MIPD) for the years 2009-2011 for Bosnia and Herzegovina. This document determines strategic lines in assisting Bosnia and Herzegovina for the utilization of available components. IPA is implemented in Bosnia and Herzegovina through the European Commission Delegation as a centralized managed programme.

The most important programme in Republic of Srpska is the **Programme for basic and applied research** that operates with available funds in an amount of over 3 Million BAM. For medical and health sciences 12.7% of this amount was dedicated, which is insufficient for significant research projects in the field of clinical medicine and medical imaging. In 2010, MSTRS jointly with MZSZ established thematic research projects devoted to the specific needs of the health sector in RS. There are still no specially dedicated funds to support medical imaging research and advanced medical imaging.

Definitions

Medical imaging - The production of any kind of visual representation of the human anatomy, histology, physiology, pathophysiology or pathology, at either the macroscopic or microscopic level, by any acquisition and processing technique for research, clinical purposes (diagnosis, therapeutic guidance, post-treatment monitoring) or teaching and training

Advanced medical imaging - The “Next Generation” of Medical Imaging is just here out of the integration and cross-disciplinary use of Nano-Medicine, Pharmacological breakthroughs, Bio-technologies for healthcare and ICT combined with standard Medical Imaging evolution

SWOT analysis (alternately **SLOT analysis**) - is a strategic planning method used to evaluate the Strengths, Weaknesses/Limitations, Opportunities, and Threats involved in a project or in a business venture. It involves specifying the objective of the business venture or project and identifying the internal and external factors that are favourable and unfavourable to achieve that objective. The technique is credited to Albert Humphrey, who led a convention at Stanford University in the 1960s and 1970s using data from Fortune 500 companies.

Value Chain Analysis - A value chain is a chain of activities for a firm operating in a specific industry. The business unit is the appropriate level for construction of a value chain, not the divisional level or corporate level. Products pass through all activities of the chain in order, and at each activity the product gains some value. The chain of activities gives the products more added value than the sum

of the independent activities' values. It is important not to confuse the concept of the value chain with the costs occurring throughout the activities. A diamond cutter, as a profession, can be used to illustrate the difference of cost and the value chain. The cutting activity may have a low cost, but the activity adds much of the value to the end product, since a rough diamond is significantly less valuable than a cut diamond. Typically, the described value chain and the documentation of processes, assessment and auditing of adherence to the process routines are at the core of the quality certification of the business, e.g. ISO 9001.

Methodology applied

In order to have regional SWOT, for Capacity building and Value Chain Analysis of the Republic of Srpska, written in the best possible way, a combined methodological approach was used for this activity. The methodology had the basis in previously performed initial analysis for the mentioned region within work package 7 and in Value Chain Analysis within work package 2. The following strategic documents were used: D7.1 Initial analysis report on Nordest region in Romania and the Republic of Srpska in Bosnia and Herzegovina and D2.1 Value Chain Analysis of the Medical Imaging Sector in Europe. Beside these, for the realization of regional SWOT analysis were used other available documents as previously analyzed strategies, policy and programmes, more or less related to the medical imaging sector.

The model of direct personal interview (based on previously created questionnaire in WP2) with stakeholders – managers of biggest healthcare institutions in Republic of Srpska was basic methodological model used and that gave most important qualitative indicators. The questionnaires treated different questions related to the level of achieved technical standards in the field of medical imaging and advanced medical imaging, questions of the strategic development of the health sector with special emphasis on MI and AMI, different challenges and opportunities for the MI and AMI sector and the level of funding invested from different state grants, programmes and incentives for the technical equipping of biggest healthcare institutions in Republic of Srpska. The questionnaires address various issues concerning estimations of both the market and product, specific challenges and opportunities of the market and the various Medical Imaging appliances. The answer possibilities vary from insertion of facts, over a 5-point scale system (absolutely disagree, disagree, neutral, agree, totally agree) to a 5-point scale representing the type and strength of different influence factors (very negative impact, negative impact, no impact, positive impact, very positive impact).

Beside this, within the mentioned report on the initial analysis (D7.1) an exhaustive analysis of strategies, policies and programmes closely related with the medical imaging sector, nanomedicine, biotechnology and ICT for health was produced. This analysis gave detailed insight in all national, regional and other strategies and programmes offering support to the development of health, SME and research sectors, especially in medical imaging. Except for the qualitative analysis of these documents, there was provided a quantitative review through level of investments, grants and different incentives for RTD, SME and health sector with focus on MI. An activity that had significant methodological value was AMI4Europe workshop titled “Imaging techniques for guiding and tracing of stem cells therapy and regenerative medicine” held in June 2011 in the Republic of Srpska. Through the workshop and interactive discussion with scientific and non-scientific national stakeholders valuable feedback data on all aspects of the value chain in MI field in Republic of Srpska/Bosnia and Herzegovina were collected, and summarized results that were initial point of this regional SWOT analysis.

SWOT Analysis

<p>Strengths:</p> <ul style="list-style-type: none"> • Regional level S&T programs are available, • Active engagement of the public authorities • Introduction of the PPP model (public-private partnership) in the public health sector in the Republic of Srpska. • Professional training of RS medical staff • Development capacities of the Republic of Srpska, • Low-cost labor force in general • Qualified workforce available 	<p>Weakness:</p> <ul style="list-style-type: none"> • Insufficiently developed institutional capacities of R&D and outdated and inadequate equipment at R&D institutions • No clearly defined stimulating or supporting measures for SMEs dealing with medical equipment • Insufficient participation of social partners in the decision making process • SMEs dealing with the MI issue are mainly distributors of main MI equipment producers • Low level of industrial R&D capacities in SMEs • Low level of industry-academia cooperation • Inadequate involvement of young researchers and experts in big R&D projects • No international validation of research results and evaluation of projects based on international experience • No access to relevant international magazines and databases • No partnerships with networks/cluster's partners • Lack of foreign investments in the MI field • Administrative procedures complex for start-up companies • Lack of trade policy • Low level of research activities commercialization • Low level of knowledge and expertise for participation in international projects and programs • Low utilization level of available EU programs for RTD
<p>Opportunities:</p> <ul style="list-style-type: none"> • Demand for MI equipment is high • Possibilities for networking with other clusters and organizations, through available funding schemes, as improvement factor • Possibilities for international and domestic academia-university cooperation for MI research and innovation • Full membership of BIH in FP7, COST and EUREKA • Recognized importance of further reform and modernization of the public health system • Medicine and health sciences within the S&T policy documents pointed as one of the priorities • Increased budgetary allocations for science and research • Developed network of higher education institutions • Unity of R&D work and teaching process established as legal principle • New legislation in the field of science and higher education 	<p>Threats:</p> <ul style="list-style-type: none"> • Weak interest from European and other international partners for cooperation with R&D institutions from RS in the field of advanced medical research • No precise identification of the action plans for the improvement of the existing public health infrastructure • Possible decrease of allocations for modern RTD infrastructure due to global financial crisis • Regional (RS) RTD program priorities far too general not providing action plans for the improvement of RTD activities • No serious attempts in the establishment of bilateral and multilateral functional mechanisms for researchers' mobility based on reciprocity principle from which healthcare institutions would benefit.

Explanation of findings in SWOT table

Strength

- At the **regional level S&T programs are available**, providing the possibility of financial support for basic and applied research in the field of medicine and MI area, as well as procurement of related equipment of lesser value.
- Significant progress has been made in the RS by the **active engagement of public authorities (Government of RS and Ministry of Health and Social Welfare of RS) in signing commercial agreements** with the Government of the Republic of Korea for supply of modern diagnostic equipment. The ultimate goal of this important and large project will be the establishment of modern diagnostic centres in most important health institutions at secondary and tertiary levels, the introduction of new technologies and the prerequisites for setting up of up-to-date procedures for diagnosis and treatment.
- Significant progress in the introduction of modern MI diagnostic equipment is the **introduction of the PPP model (public-private partnership) in public health sector in the Republic of Srpska**. The health sector in RS is one of the first to make the best use all the advantages of PPP models and thus significantly improved the level of health services (radiology, dialysis centres) and MI infrastructure; especially at University-clinical center Banja Luka.
- Considerable attention is given to the **professional training of RS medical staff** - courses for different schools and courses of ultrasound, MRI and other are periodically organized. In this regard, the support provided by professional associations in the educational process is very important. In this way, health care facilities have at their disposal qualified and trained staff monitoring the latest trends in the field of MI's.
- **Development capacities of Republic of Srpska**, which are giving attractiveness to certain international research projects with the participation of domestic institutions (social and economic research, research in the field of energy, environmental protection, health, agriculture and organic food production etc.)
- **Low-cost labour force in general** – the average salary of employees is one of the lowest in Europe, which makes these employees attractive as cheap workforce.
- **Qualified workforce available** – due to the recent developments in higher education, a qualified workforce for MI sector is available.

Weakness

- **Insufficiently developed institutional capacities of R&D and out-dated and inadequate equipment at R&D institutions** – as the consequence of war devastation and long absence of investments in scientific and education sector, domestic institutions came into the situation that they cannot be competitive in the European market. There is a very small number of research facilities, and worse, they are equipped with outdated equipment without capacities for more serious research projects for the future. Most of the laboratory equipment is very basic and only basic and ideal cases can be resolved with such equipment.

- **There are no clearly defined stimulating or supporting measures for small and medium enterprises dealing with medical equipment** – within the frame of initial analysis done for Republic of Srpska, it is obvious that available RTD programmes, strategies, initiatives and policies treated insufficiently SMEs that have an RTD component, and especially SMEs that are focused on biomedical research and MI.
- **Insufficient participation of social partners in the decision making process** (such as professional associations, trade unions, patient groups, etc.). During the process of creation of key documents and public consultations at regional level, participation and presence of external partners is insufficient and without requested exchange of experience between relevant stakeholders and social partners.
- **SMEs dealing with the MI issue are mainly distributors of main MI equipment producers.** They are providing equipment and services for the maintenance of sold equipment. However, there are no domestic companies producing MI equipment.
- **Low level of industrial R&D capacities in SMEs**, while in the MI sector in RS there is no such R&D company.
- **Low level of industry-academia cooperation** – frequently the best students staying at university are not going to companies and this is usually reason for “brain drain” due to various factors influencing the future of graduated students (low salaries in industry, inadequate possibilities for advancing in positions, uncertainty of market position for companies etc). The cooperation between companies and universities (partnership with universities and other HE institutions) and research centres is very limited and there are almost no examples in the practice of different joint cooperation (research or commercial projects, joint venture, PPP, etc) between industry and university centres. Insufficient level of science and research leadership and management, as well as unsatisfactory level of science entrepreneurship, expressed in a marginal percentage share in a non-budgetary source of financing.
- **Inadequate involvement of young researchers and experts in big R&D projects** – this is the problem that was not only a weak point in the RTD sector, but in the whole system of higher education in RS. Unfortunately, if one does superficial analysis of most of R&D projects, inadequate involvement of young research staff can be observed.
- **No international validation of research results and evaluation of projects based on international experience** – one of biggest weakness is lack of validation of achieved research results at the international level. Domestic researchers are not having opportunities to participate and to be active at international congresses and symposia and to publish papers in referent European and World magazines.
- **No access to relevant international magazines and databases** – domestic scientists do not have access to relevant European and World magazines, as well as to relevant databases.
- **No partnerships with networks/cluster partners** – at present no medical clusters in RS.
- **Lack of foreign investments in MI field** – except some rare cases of bilateral agreements and some donations, there were no significant foreign investments in can be observed MI field in RS.
- **Administrative procedures complex for start-up companies** – the time needed to establish a company is estimated at 15-30 days, declared to be too long and needs to be improved.

- **Lack of trade policy** – at the moment this field is not completely regulated.
- **Low utilization level of available EU programs for RTD** - low number of project applications, although there are significant funds given as entry fees to FP7, EUREKA and COST.
- **Low level of knowledge and expertise for participation in international projects and programmes** – it is very common that a researcher is at the same time administrative staff in international programmes and projects, which is unfavourable for researchers to participate in the projects. They are more willing to do research part of the project, especially experienced researchers, and there are supporting systems that could facilitate logistical and administrative issues in project realization such as project planning, implementation and reporting.
- **Low level of research activities in commercialization** - There are not enough research projects that involve commercial business. The projects end up with patents, new technology etc., but there is no final step – the commercialization of research activities.

Opportunities

- **New legislation in the field of science and higher education** – new Law on Higher Education RS (2010) and Framework law on Higher education in BiH (2007) are giving complete institutional freedom to higher education institutions to establish their own commercial companies for research purposes, centres for technology transfer, innovation centres, and technological parks and to achieve income from such commercial research. Also, the legislation that regulates a work of R&D institution was significantly improved and is regulating the work of R&D institutions in the Republic of Srpska.
- **Unity of R&D work and teaching process established as legal principle** – this basic principle gives accent to all legal acts on importance of R&D work and an unbreakable connection with teaching process in higher education.
- **Developed network of higher education institutions** (establishment of a large number of study departments) and organization of studies for bigger number of different scientific fields. The system of higher education in RS/BiH still has qualified teaching and researching staff, even these are mainly older researchers and university professors.
- **Increased budgetary allocations for science and research** – changes and amendments of Law on scientific and research activities in RS, for the first time the budgetary allocations are significantly increased for achievement of R&D programme budget for the realization of scientific-research programs have significantly increased and set at a minimum of 0.15% to a maximum of 1% of GDP. This is an important move in budget allocation for the needs of science and research in RS and the opportunity for further stimulation of R&D institutions, especially in the field of biomedical research. Thanks to achieved incomes from privatization of state capital, Government of RS enabled establishment of additional funds from RS budget for infrastructural investments, beside existing grants given by Ministry of science and technology.
- **Medicine and health sciences within the S&T policy documents indicated as one of the priorities:** multidisciplinary approach including fundamental research in natural sciences, guided integrated research in medicine Biotechnologies and technical – technological sciences contributing to development and adopting new diagnostic, therapeutic and information

technologies such as: diagnostics and therapy based on genes, manipulation of cells, tissues and organs, biosensors, etc.

- **Recognized importance of further reform and modernization of the public health system,** health insurance fund and as an ultimate goal of achieving greater efficiency and financial sustainability of health systems in the RS / BiH.
- **Full membership of BiH in FP7, COST and EUREKA since January 2009** – acquiring status of full or associated member in some international programmes, domestic institutions are able to use all possibilities and options which they could not until now, and also through different modalities to improve their infrastructure, knowledge transfer and experience with EU partners and to improve level of researchers mobility etc.
- **Possibilities for international and domestic academia-university cooperation for MI research and innovation** – opening entrance to various cooperation programmes with EU member states, the community (both academic and SMEs) have possibilities for joint cooperation and improvements. There is evident enormous interest of other institutions (clinical centres and other medical institutions, SMEs, NGOs and development agencies) for participation in different EU programmes for science and technological development.
- **Possibilities for networking with other clusters and organizations, through available funding schemes, as improvement factor** – such as previously mentioned, but this extends previous cooperation with foreign investments in production capacities and improvement of economic cooperation between sectors or clusters.
- **Demand for MI equipment is high** – domestic MI equipment market does not exist, but devastated and outdated equipment should be replaced with new one.

Threats

- **Weak interest from European and other international partners for cooperation with R&D institutions from RS in the field of advanced medical research** – as this is the case with other field, R&D sector is not interesting for cooperation with a certain number of international partners, due to low competitiveness and technological obsolescence.
- In the framework of existing strategies and policies there is **no precise identification of the action plans for improvement of the existing public health infrastructure** nor of possible funding sources
- **Possible decrease of allocations for modern RTD infrastructure due to the global financial crisis.** Even the recent changes in legislation have predicted increase of allocations for RTD sector yearly with final goal of 1% of GDP, the practice shows that due to financial obstacles and budgetary deficit this is not realized in practice.
- **Regional (RS) RTD program priorities far too general not providing action plans for improvement of RTD activities** - the definition of programme priorities in RS is done mainly according to their own needs without previous harmonization with European and regional program aims. The subjects defined in R&D papers are defined in the “bottom up” approach for publicly funded programmes. There is no regional priority where the respective ministry will undertake “top-down” approach for identification of programme priorities.

- **No serious attempts in the establishment of bilateral and multilateral functional mechanisms for researcher's mobility based on reciprocity principle of which healthcare institutions would benefit.**

Discussion of results

As expected, the SWOT analysis showed that the **MI (including AMI) sector in the Republic of Srpska is considerably weak** and with a lot of possibilities for improvement. These improvements cannot be done overnight due to the complex nature of these improvements.

Although the economic situation in the Republic of Srpska is very difficult and complex, still there are several strengths expressed in this analysis. The most important one is that the **Republic of Srpska has and is producing qualified workforce** for the MI and AMI sector. However, due to the economic situation this workforce is not paid as it is supposed to be, actually salaries are not attractive for these specialists. Besides a qualified workforce, the Republic of Srpska has the development potential to foster MI development and to strengthen the MI equipment market, even as producers or assemblers of MI equipment.

However, the list of weakness is far longer than the list of strengths. The reason for this finding of the analysis lies in the fact that **BIH is still an underdeveloped country** with a lot of social and economic problems, which are positioning themselves with more priority than MI or AMI. The major problem is the low **level of investments in the MI sector**, which is an essential precondition to have better MI infrastructure deployed. Recent investments in this sector were based on **PPP and proved as a successful model**. However, there is still a **lack of private investment in this sector** due to **complex administrative procedures and an unstable economical situation** in the market. The major companies in the MI market are representatives of major world-wide producers of MI equipment or just **resellers and distributors**. In some cases famous producers have representatives in Austria or Croatia who are also in charge for Bosnia and Herzegovina. This can be explained with the fact that BIH has in total 4 million inhabitants (unofficial figure), which is a rather small market despite increased market demand in the health sector for MI equipment.

From the scientific perspective, **a major problem is the lack of advanced research equipment**, but in some cases even basic research equipment needed for MI research. Another major issues causing a very difficult situation in MI scientific sector is that researchers do not have access to journals and magazines in order to acquire new knowledge. Another weakness is that **the industry-academia cooperation is on a very low level and there is a small number of SMEs with R&D capacities**, especially in the MI sector. The research in the MI sector is very limited due to the mentioned factors, although the researchers are trying to keep the pace with others. Thanks to continuous medical education that is obligatory for all medical doctors, they can follow up the newest developments in MI by participation to Congresses and to other similar events. Another very important weakness observed is the **low level of participation in available EU funds for S&T** (FP7, COST, and EUREKA). Namely, the academic community (including MI researchers) is not stimulated to participate in these projects and they see funding procedures

complicated from the perspective of researcher. The **researchers suffer a lack of project manager skills** and have problems to cope with different administrative procedures in project preparation, realization and reporting stages. From the other hand, **EU partners are reluctant to involve RS researchers in the projects** due to scarce and outdated equipment. Also, **most of the research work done recently is not commercialized but is more academically oriented**. Therefore the interest of SMEs to participate in joint projects with academia is very low.

However, there are significant possibilities or opportunities that can facilitate overcoming the mentioned problems. One of major opportunities from economical aspect is that the **demand for MI equipment in the domestic market is growing** due to the fact that this equipment provides fast and reliable diagnostics. There are “theoretically” skilful staffs that can work with this equipment and they need additional trainings in order to provide maximum services to patients. This demand can assure future investments in this sector. But this must be **accompanied with positive legislation provided by local and republic authorities**. Luckily, the RS Government has recognized the importance of the health sector (including the MI sector) and is investing efforts to facilitate advancing the healthcare sector. This is also a very important part of almost every new development strategy produced by RS authorities.

On the other hand, **researchers should use more available external sources of funds**, such as EU funded programmes for enlargement. Due to the Memorandum of understanding signed with the EC, BIH researchers can participate in FP7, COST, and EUREKA since 2009. Although there are problems participating in these programmes due to their competitive nature. Due to consequences of global economic crisis, the public investments in R&D are decreased. The budgets are reorganized to satisfy “more important” sectors, other than science and research. This is the main reason that domestic researchers should invest more efforts in applying to available EU funds and to participate in EU funded projects.

Although academia-industry cooperation is very low, still there is room for improvement of this cooperation, especially if SMEs take initiative and invest private funds into joint research projects with universities. There are qualified staffs on both sides that can be innovative and to make improvements in MI sector if join forces and resources. **The projects, such as AMI-4EUROPE and similar, can strengthen cluster cooperation and networking in order to participate in joint actions on mutual benefit**. The clustering and networking initiatives are officially and legally supported and there is positive legislation on clusters. Therefore, in order to foster inter-sector cooperation, clustering and networking are very useful to achieve mutual benefits.

Nevertheless, if the trend of low participation in international projects continues, then it can become very serious problem. Also, if the investments in the sector stop this will mean less interest in the sector and will cause bad provision of healthcare services in MI sector. This will lead to mistrust in the healthcare sector and will cause that patients go to other healthcare institutions in neighbouring countries for treatment and curing. All stakeholders in MI sector should join forces and resources in order to create and to implement action plans and strategy on improvement of MI sector. Only this way it is possible to overcome threats and to minimize weakness in the sector and with it to improve overall provision of healthcare services to citizens and patients.

Value chain analysis and SWOT comparison

After the realization of regional SWOT analysis for the Republic of Srpska/Bosnia and Herzegovina it is possible to withdraw some qualitative conclusions and recommendations for improvement of advanced medical imaging for this region. However, it is also interesting to make small comparative analysis between the conclusions obtained from document “Value Chain Analysis of the Medical Imaging Sector in Europe” (D2.1.), and especially in the part related to the Republic of Srpska/Bosnia and Herzegovina and the opinion of national experts on individual issues related to MI.

Both SWOT analysis and mentioned document, and opinion of national experts, have shown mainly coherent findings and opinions related to most conclusions:

- Available technical infrastructure and especially the one that refers to Advanced Medical Imaging is at an unsatisfactory level. Most of the technical equipment that research institutions have at their disposal is outdated, inadequate and insufficient for serious research work. Healthcare institutions are facing certain problems related to bad and inadequate infrastructure, fast communication and exchange of information with other research centres, availability of most modern MI devices and new methods.
- The partnership and level of cooperation between healthcare institutions and research and academic institutions is at a very low level and not well stimulated. There is a small number of institutional cooperation in serious research and development projects, exchange of knowledge and experience, as well as exchange of researchers. The cooperation is mainly done through the work of medical doctors and specialists working at the same time at clinics and public universities – medical faculties. Therefore, availability and closeness of research premises for biomedical research and nanomedicine and ICT is really bad.
- Although there are several initiatives for networking (financed and supported mainly by international donation programs), there are no samples of joining in clusters and similar, functionally similar institutions and companies, and especially in the sector of health and medical imaging.
- In the regional market are present MI companies that are not facing problems related to registration and business, but these are mainly distributive companies. There is almost no example of RTD oriented companies in health sector. Measures for stimulation and support of these or spin-off companies are insufficient especially for foreign companies that are considering this market not attractive for investments and opening of production capacities. An additional problem is the offer of qualified workforce from the domestic labour market.
- Existing demographic tendencies as well as policy in the field of social and health care in the Republic of Srpska will definitely present a challenge for public authorities and healthcare institutions in future especially increasing number of requests and level of healthcare quality especially in the field of MI. In that sense, over the last years investment into MI and other

health infrastructures has been more intensive through different models of investment (credit arrangements with Republic of Korea and EIB; public-private partnership model for dialysis centres etc.)

- Differing from opinions of national experts and conclusions given in Value Chain Analysis, performed SWOT analysis shows that funding and subventions for RTD structure and for necessary MI equipment are not adequate and sufficient. Namely, allocations within the existing national and regional programmes and grants does not allow further development of RTD infrastructure and equipment and are not sufficient for improvement of technical infrastructure in the health sector, especially in the segment of advanced medical technologies and biomedical researches.

Also, there is a disproportion of conclusions of VCA and SWOT related to segment of cooperation with funding facilities. Namely, compared to the opinion of national experts, SWOT analysis presented weakness in the availability of different funding instruments (public and private) for healthcare institutions related in order to meet MI sector's needs. Most of them are based on guarantees given by Government of the Republic of Srpska or other levels of authorities, while other models are insufficiently represented and unused, which in the end causes inconsistency between needs of healthcare and research centres for MI equipment and available funding instruments and possibilities within the frame of various programmes and grants.

Recommendations

Bearing in mind the conclusions obtained from SWOT analysis and Value Chain Analysis, the following recommendations could be deducted.

In order to improve the overall status of the MI sector and especially AMI in Republic of Srpska, it is necessary **to increase funds invested in this sector**. Namely, general investments in the medical sector are insufficient, but considering the importance of MI and AMI in the prevention of diseases and illnesses and further development of modern healthcare services, it is reasonable to expect further investments from public sector (municipalities, government). However, **private investments in MI and AMI should be further stimulated and encouraged**. Today, this kind of investment does not exist in the Republic of Srpska. The opportunity for the sector lies in **public-private partnerships** due to the very limited public budget. The cases of public-private partnerships already prove this hypothesis.

Moreover, the **MI and AMI market in the Republic of Srpska is not well developed and there are many possibilities available**. As such there's still room for improvement in investments, trade, utilization of qualified workforce etc. This market today consists mostly of resellers or distributors of MI equipment that are either autonomous or officially representative of major world-wide MI equipment producers, such as Fujinone, AGFA, GE, etc. There is a **strong demand in the market (especially by healthcare consumers) for this kind of equipment**, due to the fact that this equipment provides fast and reliable diagnostics, saving time and resources. Moreover, there is a strong demand from healthcare providers for improvement of necessary technical infrastructure, such as broadband Internet, fast data exchange, processing of MI images etc. Almost every general hospital in region is having significant number of patients that are waiting in long queues to have MRI or CT examination. In order to provide highly efficient healthcare, it is necessary to equip all hospitals with more MI and AMI equipment.

It is necessary **to continue with the positive practice of continuous medical education**, which is giving a constant upgrade of knowledge and further development of workforce skills. Only highly skilled and qualified staff will be able to utilize available MI and AMI equipment in order to provide quality healthcare to citizens. The constant update of knowledge and skills can be also achieved through the **intensification of participation in EU funded research programmes**, such as FP7, COST and EUREKA. This can be achieved with **more intensive collaboration with other clusters and networks of interest**. This collaboration can result in numerous positive effects- from the financial, but also from the scientific and educational point of view.

On the other hand, public authorities should be **more efficient in passing adequate legislative framework (laws and bylaws regulating this field) from the perspective of healthcare providers**. But also, public authorities should **facilitate and help strengthening the domestic MI and AMI market** in order to increase the level of investments of public and private origin. **Provision of specific incentives and measures for potential investors** should be insured in order to gain investments in the MI and AMI sector.

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REGIONAL SWOT ON CAPACITY BUILDING AND VALUE CHAIN ANALYSIS ON NORDEST REGION IN ROMANIA

Executive summary

According to the SWOT performed as part of this analysis, there are several conclusions & recommendations that can be drawn for the AMI related players and stakeholders:

There is a **relatively high number and diversity of hospital units**, clinics and dispensaries. This is a limited strength, given the poor availability of imaging in those units. However, in the conditions where a better availability of funding is found, the present infrastructure can be used also for improving the imaging resources.

The **growing private healthcare sector** is surely interested in the improvement of imaging services for the general population. Already, private practices offer a permanently larger gamut of imaging techniques to the general population. However, the relationship of these private practices with the national insurance company is unstable and highly unregulated.

The existence of **enterprises with innovation activities** is a bonus, given the immediate availability for response of the local infrastructure if the financial and legislative conditions change.

Existence in the region of specialized companies in producing software and IT services. The IT industry into the region on interest is a long-standing tradition. However, the degree of integration within the imaging and diagnostic services is low.

Adequate number of non-scientific stakeholders in North East Region on medical imaging sector. This is a strength which is connected to the growing private health-care sector. The private imaging companies have stagnated during the last two years, after a quick development due to good access to financing before the economic collapse.

Availability of funding the health sector through European and Governmental Funds. Even if lately the access to European financing has dwindled and the government funds are reduced due to a budget crisis and to the financial incertitude, there still are ample possibilities to access those funds for a determined institution, which might be able to ensure also the backing of private funds. Creation of a cluster towards these goals may be an important step in securing financing and further developing a network of imaging resources and finally bringing some high-end technology sorely missed in the area, like a PET-CT centrum.

A large majority of the healthcare units are in dire need of infrastructure investments. Usually public buildings are old, unmodernized, lacking in technical infrastructure. Many hospitals and clinics are outdated and highly depending on overstrained municipal budgets for repairs.

Reduced funding for drugs and prescription of expensive medication led to limited access of a large part of the population to compensated and free drugs provided by the health insurance system. The public healthcare units have a precarious situation, functioning in old buildings, generally unmodernized. Medical equipment of the public hospitals is generally old, physically outrun and technically outdated. The public scarce financing and the low uptake of private healthcare insurance currently hinder growth. In terms of medical equipment purchasing, some of the private players have shifted towards low-end or low-cost imaging equipment. NHIH funding is not sufficient, especially for new and more expensive investigations, such as tomography, NMR and angiography. Fees for service revenues remain fairly healthy, being the main driver of the sector.

Unequal accessibility to health services at regional level both from quality and geographical coverage points of view . There are also low levels of healthcare facilities and awareness in rural areas.

Insufficient qualified human resources and specialised in the use of new modern technologies of diagnostic and treatment

About one half of the stakeholders consider that the foreign competition is very strong and represent a market entry barrier. **Governmental regulations** are perceived as a market entry barrier only by 25% of the responders, while other 25% do not seem to be bothered by government interventions on the market. **Licensing requirements** seem to be a universal market entry barrier, perceived by almost 80 per cent by the responders.

In what concerns the location factor, local expert questioned have mixed opinions concerning the framework conditions, (Poor 34%, Acceptable 22%, Good 11%, Perfect 33%), while a common opinion on the technical Infrastructure sums 78% that consider it to be poor and very poor. Opinions are almost evenly divided among the responders in what concerns the **co-operation of stakeholders with the universities**, where almost half 53% considerate good and very good, while the other half consider it mediocre or even poor. Compared to the SWOT analysis, it can be considered among the strengths, but also it can be a caveat, concerning the inabilities of universities to cope with the ever-changing demands of the market.

The partnership with the network/cluster partners is seen as poor and rather mediocre by more than a half of the responders, which might mean that improved communication and a higher familiarity with the notion of cluster have to be implemented by the cluster decision-makers.

The quality of the scientific establishment is considered to be good and very good by the majority of the responders (78%), which is in agreement with the results of the SWOT analysis.

Collaboration with funding facilities is seen as very poor or lacking by most of the responders (78%), situation already apparent in the SWOT analysis.

Major investments in the infrastructure are necessary. As highlighted by the SWOT analysis, most of the healthcare facilities in the north/eastern Romania are old, outdated and frail, as most of them

were built centuries ago or in a period where speed and obedience were more important than quality or resistance

Investment toward personnel training: due to the weaknesses underlined in the SWOT analysis, trained personnel, physicians, nursing staff and support staff (chemists, biologists, physicists, specialists in IT) are difficult to find and recruit. A solution might be the funding of territorial learning facilities, task-oriented and ready to supply qualified personal on demand by the stake-holders. Such a unit could be able to school several dozens of students at a time, while the funding of the immediate study is endured by the employing company and the costs for the infrastructure and materiel are supported via government subsidies or European and private grants. These units could also function as semi-private medical research facilities.

As the need for advanced medical imaging is increasing, actors (European, national, cluster members and stakeholders) in the decisional process might envision the creation of a large diagnostic centre with the addressability for the whole region, encompassing the whole north-eastern Romania, with a population of about 4.5 million. To these patients might be added paying customers from the Republic of Moldova and Western Ukraine. Such an imaging diagnostic centre should be composed of a PET-CT facility, together with MRI, CT and nuclear imaging. Ultrasonic diagnostic could be added to all these possibilities, together with interventional imaging procedures, thus producing a very large pole of medical care, teaching and research, from which all the area might benefit.

Background information

In North East Region both public and private non-scientific stakeholders have been engaged, respectively County and Local Councils (12) and private medical clinics (21).

The County and Local Council play a major part in the modernization and endowment of the hospitals due to the fact that, after the reform of the health sectors, the hospitals are currently under their administration. The buildings belong to local authorities (local/county councils), the latter having the obligation of maintaining and rehabilitating them, while the coordination of human and material resources is at the level of the Ministry of Public Health. Consequently, the European funding projects for rehabilitation, modernisation of the hospitals must be realised the Country or Local Counties.

The role of County and Local Councils in medical imaging sector is related to the access to funding in order to improve the infrastructure and increase the quality of the medical act by acquiring the newest technologies.

On the other hand, in Romania it can be noticed that the private health sector is presently strengthening, especially due to the fact the public system has, generally speaking, shortcomings because of the precarious hospitals infrastructure contributing to a low quality of the medical act and also due to the deficiencies of settlement of the accounts with the National Health Insurance House.

In this context, a continuously increasing number of patients prefer to address to private medical clinics or hospitals in order to benefit of good quality hospitalisation conditions and performing diagnostic through new and modern medical equipments.

The main core competencies of the private non-scientific stakeholders are medical investigation based by MRI, CT, ultrasound, radiography, teleradiology, endoscopic exploration, and electrocardiography. Also, one non-scientific stakeholder is an ICT company with competences in e-health platform development.

The **scientific stakeholders** identified in North East Region are Medical Imaging providers, either public (10 hospitals/clinics) or private (9 private health services provider), end-user /beneficiary of Medical Imaging (9 public or private clinics/hospitals), 4 research institutions (2 research centres and 2 universities) and 8 ICT stakeholders.

The public hospitals have been divided into university and county hospitals. University Hospitals are Clinical Hospital, usually county/regional hospitals and specialized Medical Institutes in cities with a University of Medicine and in which there are also academic activities and medical research.

Both, public and private clinics/laboratories of Medical Imaging are usually Integrated Medical Imaging facilities with multiple imaging modalities available: conventional radiology, ultrasound, CT, MRI.

Included in the identified scientific stakeholders are the research institutes (independent or belonging to the public universities) which act both as R&D facilities in the field of Medical Imaging (i.e. nanotechnologies, advanced optics, physics etc) and as end-user facilities (using state of the art MRI, Spectroscopy, fluorescence microscopy, electron microscopy).

Private sector in Medical Imaging is developing fast with new and mid to high-end equipment. People are also seeking private medical care in general and medical imaging especially for various reasons. Generally it is considered that the increased interest of patients for the private sector is generated by better equipment and better expertise. With increased investments in public sector, although insufficient, the differences are not quite so high; also, the level of expertise is comparable since people working in the private sector are from or still working in the public sector. What makes the difference in favour of private sector is the attention to individual care, which is possible through higher investments in all the aspects from public relation to healthcare. In the mean time the public sector is flooded with patients without a real correlation in terms of personnel and medical expenses coverage.

University Hospitals are collaborating with Medicine Universities in research projects, and also with partners from abroad usually within clinical trials or international funded projects. Private clinics may also be found as partners in research programs or clinical trials on contract. County Hospitals may have punctual collaborations with various entities for research or trials but their activity is mostly limited to healthcare. All of them provide healthcare community services in Medical Imaging.

There are also Universities which include in the curricula some courses into Medical Imaging field or more generally, digital image processing.

Regarding the ICT stakeholders working on Medical Imaging, all founded stakeholders are working individually, there is no cooperation between them. As most of them are research or academic centres, the activity on the Medical Imaging is mostly a researching within the scope of PHD projects.

The ICT stakeholders are institutions which are activating into ICT field, especially in digital image processing: Computer graphics, Computer animation, Image Enhancement in the spatial domain, using the Fourier Transform for Image Enhancement in the frequency domain, Morphological Image Processing, Image Segmentation, Representation and Description, Image file format converters, Image filtering, Advance neural network and fuzzy logic for form recognition, GDI (Graphic Device Interface), DirectX programming

As a conclusion the scientific stakeholders identified are both united and competing in terms of providing Medical Imaging services to the community – which is the dominant part of their work, but there is no system or framework for collaboration in research or for developing large community projects, except at a smaller scale between Universities and the Hospitals in the area with academic activities. So, we feel there is need for a Regional Cluster in the field of Medical Imaging through which all partners may access knowledge, funds or be part of projects of development in the interest of the community.

Currently the collaborations between scientific and non-scientific stakeholders are only punctual and to our knowledge there are no important ongoing projects since there is little awareness of such need and we (at regional level) are mostly consumers of Medical Imaging appliances and related products and not producers.

In North East Region no activities have been developed on medical imaging based on cooperation between the scientific and non-scientific stakeholders, they are working individually based of each institutions responsibilities. To this situation, the fact that there are no projects developed in a private-public partnership also contributes.

Generally the only connection is caused by the possibility to access European funding, due to the fact that the property of the public hospitals has been transferred to the local authorities.

Programmes supporting MI sector

The **RDI National Strategy** has as main objective to diminish the current gaps between Romania and the European countries and prepare the Romanian RDI system in order to identify and strengthen, through an international openness, partnership and competition, those areas where Romania can excel.

National Plan, the main instrument for implementing the National Strategy for RDI is setting out the rules and principles of implementation, the component programmes, investment model and budget, and also the monitoring and evaluation indicators, both at the level of component programmes and the plan.

The **RDI National Plan** takes into account the results of prospective studies in science and technology, the economic situation, level of development of the RDI, the strategic objectives formulated by the National Strategic Reference Framework and the European Union recommendations.

The main programmes of RDI National Plan are the following:

1. **Programme HUMAN RESOURCES - Research Development and Innovation National Plan 2007-2013**, the **main objective** being the *Increase of the number of researchers and their professional performances*

Resources for the implementation: approx 3,1 millions euro for the period 2007-2013

Sectors: Manufacturing, Health and Social Work, ICT for Health, Biotechnologies, Nanomedicine

Beneficiaries: Research and development personnel and RDI entities

2. **Programme IDEAS - Research Development and Innovation National Plan 2007-2013**, having as **main objective** *Obtaining outstanding scientific and technological results, comparable to the ones obtained at the European level, reflected by the increase in international visibility and recognition of Romania research.*

Resources for the implementation - approx 630 millions euro

Sectors: Manufacturing, Health and Social Work, ICT for Health, Biotechnologies, Nanomedicine

Beneficiaries: R&D personnel, RDI entities and RDI entities consortia

3. **Programme CAPACITIES - Research Development and Innovation National Plan 2007-2013**, having as **main objective** *Developing the research capacities and opening the RDI system to the international scientific environment and national socio-economic environment.*

Resources for the implementation- approx 470 millions euro

Sectors: Manufacturing, Health and Social Work, ICT for Health, Biotechnologies, Nanomedicine

Beneficiaries: RDI entities, RDI entities consortia and Companies with their own RDI activity

4. **Programme Partnerships in priority S&T domains - Research Development and Innovation National Plan 2007-2013**, the **main objective** being *Increasing R&D competitiveness by stimulating partnerships in the main S&T domains, concretized in innovative technologies, products and services in order to solve complex problems and to create implementation mechanisms*

Resources for the implementation - approx 1260 millions euro

Beneficiaries: RDI consortiums: RDI entities, enterprises or public administrations, universities

Programme's focus: R&D activities; cluster or network; science industry cooperation; technology/knowledge transfer/ new and innovative products/ services/processes/ R&D management; dissemination and exploitation of results; creation of start ups and spin-off; research on medical imaging, nanomedicine, biotechnologies, ICT for health.

5. **Programme Innovation - Research Development and Innovation National Plan 2007-2013**, **having as main objective** *Increasing the innovation, technological development and production assimilation capacity of the results of the researchers, in order to improve the competitiveness of the national economy and to improve the quality of life.*

Resources for the implementation - approx 475 millions euro

Sectorial Operational Programme "Increase of Economic Competitiveness" has as general objective the increase of Romanian companies' productivity, in compliance with the principle of sustainable development, and reducing the disparities compared to the average productivity of EU.

The financial support will contribute to an increased efficiency of R&D activity in universities and research institutes by supporting the procurement of new modern equipments, instruments, software, the development of the existing R&D infrastructure and the creation of new infrastructures (laboratories, research centres, etc), the development of international R&D partnerships and the valorisation of the clustering potential in fields with comparative economic advantages.

The enterprises' technological development, as prime factor for increasing their competitiveness, is supported through R&D partnerships with R&D organizations that will generate results directly applicable in economy with the aim of creating new or improved products, technologies and services of high added-value.

The Regional Operational Programme (ROP) 2007-2013 supports the implementation of the national health strategy aiming at increasing the efficiency of health services, by modernisation and equipping of outdoor patient departments and by supporting hospital infrastructure.

ROP's field of intervention Rehabilitation, modernization and equipping of health services' infrastructure has as indicative operations:

- Rehabilitation, modernization and equipping of the county hospitals;
- Rehabilitation, modernisation, development and equipping of outpatient departments (hospitals and specialized outpatient).

On the other hand, the Regional Operational Programme supports the establishment and development of productive and service micro-enterprises, including health services. Furthermore, micro-enterprises are encouraged to use new technologies and innovations, IT equipments and services with an essential role in increasing competitiveness, productivity and quality of services.

Indicative operations focus on the support to micro-enterprises' development through

- Procurement of equipments and modern productive technologies, services, constructions;
- Procurement of IT systems (software and equipments);
- Use of new technologies in the current activities of micro-enterprises;
- Extension/ construction/ rehabilitation/ modernization of the micro-enterprises production spaces;

Definitions

Medical imaging - The production of any kind of visual representation of the human anatomy, histology, physiology, pathophysiology or pathology, at either macroscopic or microscopic level, by any acquisition and processing technique for research, clinical purposes (diagnosis, therapeutic guidance, post-treatment monitoring) or teaching and training

Advanced medical imaging - The “Next Generation” of Medical Imaging is just here out of the integration and cross-disciplinary use of Nano-Medicine, Pharmacological breakthroughs, Bio-technologies for healthcare and ICT combined with standard Medical Imaging evolution

SWOT analysis (alternately **SLOT analysis**) - is a strategic planning method used to evaluate the **S**trengths, **W**eaknesses/Limitations, **O**pportunities, and **T**hreats involved in a project or in a business venture. It involves specifying the objective of the business venture or project and identifying the internal and external factors that are favourable and unfavourable to achieve that objective. The technique is credited to Albert Humphrey, who led a convention at Stanford University in the 1960s and 1970s using data from Fortune 500 companies.

Value Chain Analysis - A value chain is a chain of activities for a firm operating in a specific industry. The business unit is the appropriate level for construction of a value chain, not the divisional level or corporate level. Products pass through all activities of the chain in order, and at each activity the product gains some value. The chain of activities gives the products more added value than the sum of the independent activities' values. It is important not to mix the concept of the value chain with the costs occurring throughout the activities. A diamond cutter, as a profession, can be used to illustrate the difference of cost and the value chain. The cutting activity may have a low cost, but the activity adds much of the value to the end product, since a rough diamond is significantly less valuable than a cut diamond. Typically, the described value chain and the documentation of processes, assessment and auditing of adherence to the process routines are at the core of the quality certification of the business, e.g. ISO 9001.

Methodology

The present document is deliverable 7.2 Regional SWOT on Capacity Building and Value Chain Analysis and it is based on the results of the activities 2.1 Value Chain Analysis of the Medical Imaging Sector In Europe, 3.6 AMI “Socio-Economic” S.W.O.T. Analysis and 4.5 AMI «Scientific» (RTD) S.W.O.T. Analysis, more specifically the deliverables D2.1 Value Chain Analysis of the Medical Imaging Sector in Europe and D3.5 Final AMI Socio-Economic SWOT Analysis Report.

In order to perform a comprehensive, in-depth analysis of the AMI environment in North East Region, there were identified non-scientific stakeholders, strategies, policies and programmes within WP 3 (D3.2 “Compendium of research and innovation programmes and initiatives”) and scientific stakeholders within WP 4. The partners used the method of secondary research described in details in D3.2 “Compendium of research and innovation programmes and initiatives”. Besides these data, ADR NE prepared a regional analysis report which was the base of D3.4 “Final EU AMI in Support of Health-related Economy and Regional Competitiveness Analysis Report” and for D3.5 Final AMI Socio-Economic SWOT Analysis Report”.

Related to the SWOT Analysis, the overall aim of this deliverable is to identify any key issues, current barriers, weaknesses and threats preventing AMI objectives become reality. The analysis was focused on a socio-economic and policy-making point of view in the North East Region. In order to have a coherent approach, NBANK realized a methodological tool by NBANK which guided the process of performing the SWOT Analysis and TWOS Matrix, together with the current knowledge and experience of North East RDA in realising regional development plans, which include SWOT analysis.

This document utilized also the results of the deliverable D2.1 “Value Chain Analysis of the Medical Imaging Sector in Europe” which aimed to analyze and compare the European market, the factors shaping it and the potential of the Medical Imaging sector to influence the countries’ economic growth. On the basis of the model value chain, questionnaires for the value chain analysis were produced centrally by the WP 2 leader and distributed to the stakeholders of the six AMI partner countries. All the Romanian partners have sent the questionnaires to the scientific and non-scientific stakeholders and processed the collected data into *Value Chain Analysis* and also produced documents based on desk research - *2.1.4 Demographic Trends Driving Medical Imaging Market and 2.1.5 Overall Implementation vs. Greater Adoption of Imaging Technologies*.

The data necessary for realising the present deliverable was collected from various strategic documents of ministries and also official statistical data of National Statistical Yearbook:

- National Authority for Scientific Research
- Ministry of Education and Research
- Ministry of Economy, Commerce and Business Environment
- Ministry of Public Health
- Ministry of Regional Development and Tourism

SWOT Analysis

Strengths	Statistical Data
<ul style="list-style-type: none"> Relatively high number and diversity of hospital units, clinics and dispensaries 	<ul style="list-style-type: none"> North-East Region has 68 hospitals (14.35 % from the national value), 11 polyclinics, 1 TB sanatoria and 1,781 medical clinics
<ul style="list-style-type: none"> Growing private healthcare sector 	<ul style="list-style-type: none"> 1,781 medical clinics from which 1317 are private (73.95%) Increased setting up private diagnostic clinics (including MRI, CT units) Increased turnover of the SMEs active in health and social assistance sector (from 78 thousand lei in 2005 to 264 thousand lei in 2008)
<ul style="list-style-type: none"> Enterprises with innovation activities 	<ul style="list-style-type: none"> 16.29% from the national value
<ul style="list-style-type: none"> Existence in the region of specialised companies in producing software and IT services 	<ul style="list-style-type: none"> 20.85% from the national value, recording the third turnover among the Romanian regions.
<ul style="list-style-type: none"> Adequate number of non-scientific stakeholders in North East Region on medical imaging sector 	<ul style="list-style-type: none"> 33 non-scientific stakeholders , 21 private healthcare units and ITC company, 12 local authorities with responsibilities in the funding of the public hospitals
<ul style="list-style-type: none"> Availability of funding the health sector through European and Governmental Funds 	<ul style="list-style-type: none"> 6 funding programmes related to the implementation of the Research Development and Innovation National Plan 2007-2013 Regional Operational Programme 2007-2013 Competitiveness Sectorial Operational Programme 2007-2013 38% of the private non-scientific stakeholders received funding for modern endowments
Weaknesses	Statistical Data
<ul style="list-style-type: none"> Inadequate funding to the health sector from public and private sources and low level of health expenditure per capita Reduced funding for drugs and prescription of expensive medication led to limited access of a large part of the population to compensated and free drugs provided by the health insurance system. 	<ul style="list-style-type: none"> Expenditures in the health sector in Romania have been traditionally low, compared to European level and even the former socialist countries. However, health budgets have increased from about 90 euros/capita at 200 euros/capita in recent years. Despite this growth, Romania continues to be one of the last places in the European Union in terms of resources allocated to health.
<ul style="list-style-type: none"> The public healthcare units have a precarious situation, functioning in old buildings, generally unmodernized 	<ul style="list-style-type: none"> The majority of hospitals need rehabilitation being older than 50 or 100 years and do not have functioning authorization (North-East Region - 61%), which affects the quality of the services provided and the safety of the hospitalised patients.
<ul style="list-style-type: none"> Medical equipments of the public hospitals are generally old, physically outrun and technically 	<ul style="list-style-type: none"> Healthcare services are confronted with operational problems as a consequence of outdate equipments

outdated.	and utilities, being more than 25 years old in most of the cases.
<ul style="list-style-type: none"> • Unequal accessibility to health services at regional level both from quality and geographical coverage points of view • Low levels of healthcare facilities and awareness in rural areas 	<ul style="list-style-type: none"> • The medical infrastructure is concentrated in Iasi, university and medical centre and weak development in small towns and rural communities • The physicians are not motivated to work in disadvantaged areas
<ul style="list-style-type: none"> • Insufficient qualified human resources and specialised in the use of new modern technologies of diagnostic and treatment 	<ul style="list-style-type: none"> • The density of physicians in European countries shows that Romania ranks 31 out of 33 countries, with a density of 1.9 doctors per 1,000 inhabitants, only Albania and Bosnia-Herzegovina recording densities lower than our country. • The density is critical also regarding the nurses (3.89 nurses per 1000 inhabitants), dentists (0.22 dentists per 1000 inhabitants) and pharmacists (0.06 pharmacists per 1000 inhabitants). <p>Source of information: World Health Organization Study 2008</p>
Opportunities	
<p>Good academic tradition due to the three university centres that include in as core activities scientific research invention, technological innovation and IT.</p> <ul style="list-style-type: none"> • The number of students in the three universities centres are : Iasi – 55.557, Suceava -9350, Bacau – 6792, representing as 10.65% out of the national level (2010) • The Medicine and Pharmacy University Iasi has among disciplines radiology, a Research Centre of Excellence for diagnostic and therapeutic techniques in gastroenterology and develops projects with European and Governmental funding in fields related to medical imaging 	
<p>Existence of the basic infrastructure for research, development, innovation and technological transfer</p> <ul style="list-style-type: none"> • 79 units recognised by the national authority (cca.12% from the total at national level) 	
<p>The delivery of health services has been decentralised, granting autonomy to the institutions with competences in health and medical assistance</p> <p>The property of the public health institutions have been transferred to the local authorities</p>	
Implementation of private health insurance system	
Collaboration projects at international projects providing transfer of know –how and potential to create clusters in medical sector	
Risks	
<p>Low level of living standard and health prevention information contribute to unfavourable medical statistics related to high incidence of contagious and chronic diseases.</p> <ul style="list-style-type: none"> • The lowest rate of GDP/capita from the Romanian regions - regional GDP/capita is 4014.29 euro, representing 61.72% out of the national (2008) 	

<ul style="list-style-type: none"> High rate of unemployment - 7.7% in North East Region compared to 6.9% at national level (2010)
<p>The population of North East Region and Romania has some of the worst health status indicators from the entire European area</p> <ul style="list-style-type: none"> Indicator relatively low of life expectancy at birth (from 73.14 years in 2009) Highest infant mortality rate of all the regions: 11.2‰ in 2010, but significantly decreased from 1990 when it was recorded the value of 29.7‰ Overall mortality is an increasing trend during 1990-2010, from 9.2 to 11.7 Due to the negative dynamics birth and mortality, natural growth rate in North East Region fell to negative values, from 7.3‰ a population in 1990 to a -1.2‰ in 2010. The birth rate decreased from 16.5‰ in 1990 to 10.5‰ in 2010 High infectious disease morbidity by comparison with the European level – 83.10 new cases/100.000 inhabitants, but decreasing as in 2002 the value was 116.2 The main causes of death in North East Region are diseases of the circulatory system - 56.58%, neoplasm 16.19%, diseases of the digestive system - 8.10%, diseases of the respiratory system - 6.03, injuries 5.51 (2010)
Unstable legislative framework due to several health sector reforms
Migration of qualified labour force to other regions and countries
The national strategic documents do not envisage explicitly the development of the medical imaging sector

TWOS Matrix

	Strengths	Weaknesses
	<ul style="list-style-type: none"> Relatively high number and diversity of hospital units, clinics and dispensaries Growing private healthcare sector Satisfactory number of non-scientific stakeholders in North East Region on medical imaging sector Availability of funding the health and RDI sectors through European and Governmental Funds Existence in the region of specialised companies in producing software and IT services Enterprises with innovation activities 	<ul style="list-style-type: none"> The public healthcare units have a precarious situation, functioning in old buildings, generally unmodernized Medical equipments of the public hospitals are generally old, physically outrun and technically outdated. Inadequate funding to the health sector from the state budget and low level of health expenditure per capita Reduced funding for drugs and prescription of expensive medication led to limited access of a large part of the population to compensated and free drugs provided by the health insurance system.

		<ul style="list-style-type: none"> • Unequal accessibility to health services at regional level both from quality and geographical coverage points of view • Insufficient qualified human resources and specialised in the use of new modern technologies of diagnostic and treatment • Low levels of healthcare facilities and awareness in rural areas
Opportunities	SO scenarios	WO scenarios
<ul style="list-style-type: none"> • Good academic tradition due to the three university centres that have as core activities scientific research, invention, technological innovation and IT. • Existence of the basic infrastructure for research, development, innovation and technological transfer • The delivery of health services has been decentralised, granting autonomy to the institutions with competences in health and medical assistance • The property of the public health institutions have been transferred to the local authorities • European collaboration projects providing transfer of know –how and potential to create clusters in medical sector • Implementation of private health insurance system • Medical system reform contributing to increased efficiency of the public insurance system 	<ul style="list-style-type: none"> • Development of the basic infrastructure for research, innovation and technological transfer by accessing the European and Governmental funds dedicated to health and RDI sectors • Increasing the performance of the non-scientific stakeholders from North East Region on medical imaging sector through European collaboration projects at international projects providing transfer of know –how and through the involvement in the medical sector clusters • Improvement of the medical services quality by the consolidation of the private healthcare sector and of the private health insurance system • Increasing the participation of the companies specialised in producing software, IT services and with innovation activities in European projects 	<ul style="list-style-type: none"> • Rehabilitation of the public healthcare units with a precarious situation and endowment with modern medical equipments in the context of the health system decentralisation and property transfer to the local authority • Increasing the population accessibility to health services and the level of health expenditure per capita by the implementation of the medical system reform • Improvement of the human resources competences in using the new modern technologies of diagnostic and treatment in the context of the good academic tradition
Threats	ST scenarios	WT scenarios
<ul style="list-style-type: none"> • Low level of living standard and health prevention information contribute to unfavourable medical statistics related to high 	<ul style="list-style-type: none"> • Development of the medical services of the hospital units, clinics and dispensaries in order to contribute to the improvement of the population 	<ul style="list-style-type: none"> • Implementation of tackling measures in order to stop the migration of qualified human resources

<p>incidence of contagious and chronic diseases.</p> <ul style="list-style-type: none"> • The population of North East Region and Romania has some of the worst health status indicators from the entire European area • Unstable legislative framework due to several health sector reforms • Migration of qualified labour force to other regions and countries • The national strategic documents do not envisage explicitly the development of the medical imaging sector 	<p>health status</p> <ul style="list-style-type: none"> • Absorption of the qualified labour force by the private healthcare units • Increase the level of health prevention awareness by implementing European and Governmental funded projects 	<ul style="list-style-type: none"> • Development of the public campaigns dedicated to increase the awareness of prevention methods contributing to a diminished need to use medication • Lobby for increasing the allocation from the state budget to the health sector aiming the improvement of the health indicators in North East Region • Promoting the inclusion of the medical imaging sector as priority measure in the national strategic documents and thus contributing to increased funding dedicated to upgrading the technical endowments of the public hospitals
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Discussion of results

According to the above-presented SWOT, there are several strengths but also weaknesses in the imaging resources available for our country.

There is a **relatively high number and diversity of hospital units**, clinics and dispensaries. This is a limited strength, given the poor availability of imaging in those units. However, in the conditions where a better availability of funding is found, the present infrastructure can be used also for improving the imaging resources.

The **growing private healthcare sector** is surely interested in the improvement of imaging services for the general population. Already, private practices offer a permanently larger gamut of imaging techniques to the general population. However, as the relationship of these private practices with the national insurance company is unstable and highly unregulated, due to a flawed frame of laws and methodologies, the greater part of the investigations rely on payments from patients, which vary greatly from unit to unit and of course, reduces in a significant way the general access of patients to quality diagnostic. The highest priority towards improving access to advanced diagnostic and imaging techniques would be the **establishing of a working framework of rules and regulations** through which the private practices to have access to insurance funding.

The existence of **enterprises with innovation activities** is a bonus, given the immediate availability for response of the local infrastructure if the financial and legislative conditions change. Foreign investors have a significant pool of local companies which can **assure the role of buffer** between the foreign investors, the European representatives and the local authorities and population. Also, they may

present innovative approaches to older problems, for which the already-known patterns of work are too expensive or too time-consuming to be employed.

Existence in the region of specialized companies in producing software and IT services. The IT industry into the region on interest is a long-standing tradition. However, the degree of integration within the imaging and diagnostic services is low, mostly due to the inability of the health authorities to formulate clear demands and to ensure the compliance of the medical actors with the ever-changing requests of the IT field. PACS systems are not integrated with historic and anamnestic data; patient information is spotty and lacks updating. All these situations may be resolved by using local IT and software companies.

Adequate number of non-scientific stakeholders in North East Region on medical imaging sector. This is a strength which is connected to the growing private health-care sector. The private imaging companies have stagnated during the last two years, after a quick development due to good access to financing before the economic collapse. The large integrated players and the more specialized services providers have fuelled the market with new and expensive equipment, with a view to acquire market share and build a good reputation. They have relied on the strong demand for such services which was backed by either cash payments or reimbursement funds from the National House of Insurances.

Availability of funding the health sector through European and Governmental Funds. Even if lately the access to European financing has dwindled and the government funds are reduced due to a budget crisis and to the financial incertitude, there still are ample possibilities to access those funds for a determined institution, which might be able to ensure also the backing of private funds. Creation of a cluster towards these goals may be an important step in securing financing and further developing a network of imaging resources and finally bringing some high-end technology sorely missed in the area, like a PET-CT centrum.

Weaknesses

- Inadequate funding to the health sector from public and private sources and low level of health expenditure per capita

As all budget expenditures, they are nowadays suffering due to the financial crisis and the fears concerning the financial evolution in the future. However, all preliminary steps have to be taken, in ensuring the necessary organization and paperwork of private/public organization to obtain European or governmental funds.

A large majority of the healthcare units are in dire need of infrastructure investments. Usually public buildings are old, unmodernized, lacking in technical infrastructure. Many hospitals and clinics are outdated and highly depending on overstrained municipal budgets for repairs.

- Reduced funding for drugs and prescription of expensive medication led to limited access of a large part of the population to compensated and free drugs provided by the health insurance system.
- The public healthcare units have a precarious situation, functioning in old buildings, generally unmodernized
- Medical equipment of the public hospitals is generally old, physically outrun and technically outdated. Growth is currently hindered by the public scarce financing and the low uptake of private healthcare insurance. In terms of medical equipment purchasing, some of the private players have

shifted towards low-end or low-cost imaging equipment. NHIH funding is not sufficient, especially for new and more expensive investigations, such as tomography, NMR and angiography. The fees for service revenues remain fairly healthy, being the main driver of the sector.

- Unequal accessibility to health services at regional level both from quality and geographical coverage points of view
- Low levels of healthcare facilities and awareness in rural areas
- Insufficient qualified human resources and specialised in the use of new modern technologies of diagnostic and treatment

Value chain analysis and SWOT comparison

After the initial survey of Romanian stakeholders, a series of information have been obtained that can be compared with the SWOT analysis.

The already established firms in the field are perceived by the stakeholders in a **percentage of 75% per cent to be a market entry barrier**.

About one half of the stakeholders consider that foreign competition is very strong and represents a market entry barrier. However, **the other half remains undecided**, which agrees with the SWOT analysis that many stakeholders consider foreign companies to be rather opportunities for collaboration than enemy on a fast-moving and highly individualized market.

Governmental regulations are perceived as a market entry barrier only by 25% of the responders, while other 25% do not seem to be bothered by government interventions on the market. The other half are not yet decided whether governmental impositions are deleterious or beneficial for the development of medical, software or consulting enterprises. The results are congruent with those of the SWOT analysis, as it being a weakness.

Licensing requirements seem to be a universal market entry barrier, perceived by almost 80 per cent by the responders, and also the trade policies are considered a major market entry barrier by the stakeholders (78%).

In what concerns the location factor, local expert questioned have mixed opinions concerning the framework conditions, (Poor 34%, Acceptable 22%, Good 11%, Perfect 33%), while a common opinion on the technical Infrastructure sums 78% that consider it to be poor and very poor. The availability of subsidies / state funding is also considered to be poor (33%) and very poor (45%), which confirms the results of the swot analysis

Opinions are almost evenly divided among the responders in what concerns the **co-operation of stakeholders with the universities**, where almost half 53% considerate good and very good, while the other half consider it mediocre or even poor. Compared to the SWOT analysis, it can be considered among the strengths, but also it can be a caveat, concerning the inabilities of universities to cope with the ever-changing demands of the market.

The partnership with the network/cluster partners is seen as poor and rather mediocre by more than a half of the responders, which might mean that improved communication and a higher familiarity with the notion of cluster have to be implemented by the cluster decision-makers.

The quality of the scientific establishment is considered to be good and very good by the majority of the responders (78%), which is in agreement with the results of the SWOT analysis.

Collaboration with funding facilities is seen as very poor or lacking by most of the responders (78%), situation already apparent in the SWOT analysis. Most of the responders considered that the proximity to research facilities could be better (45%), while the other considered themselves satisfied. Proximity to specific suppliers is considered to be “acceptable” by 33% of the responders, while 45% considered it lacking. This is a recommendation to be made toward authorities for modern legislative measures concerning the spending patterns of government and contractual funding, which is highly discouraging for specific suppliers, mainly when demand is reduced.

The situation on the work market is considered satisfying by most of the responders in the study, which is in agreement with the results of the SWOT. Access labour resources is considered to be good and perfect by 89% of the stakeholders, only 11% complained about the access to qualified personnel, while the proximity with the customers was considered good and satisfying by 89% of the responders.

Finally, there is a high degree of congruence between the conclusions of the SWOT and the result of the study.

Recommendations

Major investments in the infrastructure are necessary. As highlighted by the SWOT analysis, most of the healthcare facilities in the north/eastern Romania are old, outdated and frail, as most of them were built centuries ago or in a period where speed and obedience were more important than quality or resistance

European legislators and financing institutions should improve their knowledge of the local landscape and adapt the granting patterns to the local situations. Political influence is to be avoided, and the selection of the stakeholders has to be very carefully made.

While technical endowments may be sufficient in certain areas, mainly in the areas of medical universities or large county hospitals, their use is frequently reduced by deficits in supply with consumables, or lack of personnel. Private companies acting in the field of supply and externalized services should be supported, both financially and politically, as they are more capable of efficiently managing the resources and of selecting personnel.

Investment toward personnel training: due to the weaknesses underlined in the SWOT analysis, trained personnel, physicians, nursing staff and support staff (chemists, biologists, physicists, specialists in IT) are difficult to find and recruit. A solution might be the funding of territorial learning facilities, task-oriented and ready to supply qualified personal on demand by the stake-holders. Such a unit could be able to school several dozens of students at a time, while the funding of the immediate study is endured by the employing company and the costs for the infrastructure and materiel are supported via government subsidies or European and private grants. These units could also function as semi-private medical research facilities.

As the need for advanced medical imaging is increasing, actors (European, national, cluster members and stakeholders) in the decisional process might envision the creation of a large diagnostic centre with the addressability for the whole region, encompassing the whole north-eastern Romania, with a population of about 4.5 million. To these patients might be added paying customers from the Republic of Moldova and Western Ukraine. Such an imaging diagnostic centre should be composed of a PET-CT facility, together with MRI, CT and nuclear imaging. Ultrasonic diagnostic could be added to all these possibilities, together with interventional imaging procedures, thus producing a very large pole of medical care, teaching and research, from which all the area might benefit.

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