Medtech4 Europe
Interreg Europe

European Union
European Regional Development Fund

JOINT CROSS ANALYSIS

Between Regions

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CONTENTS

Introduction and project objectives

The main goal of Medtech4 Europe (MT4E) project is to improve implementation of policies and programmes to support RDI facilities and infrastructures in the Medical Technology (Medtech) sector. Thanks to their experiences, successes and lessons learnt from mistakes, MT4E partners will progress to improve their support to Research and Innovation investments and projects. This will serve their overall ambition to develop the potential of innovation growth and keep their competitive advantage in the global competition.

Partners expectations regarding this benchlearning process are:

- To strengthen the innovation Medtech ecosystem thanks to policy support, on the following challenges: better organised ecosystems, better understanding of successful processes to be developed, role of RDI infrastructures in Medtech, accessibility and governance of RDI facilities and how they could better facilitate collaboration between firms, labs, hospitals or healthcare institutions.
- To study the business models of RDI facilities in order to facilitate accessibility of RDI to SMEs, and sustainability of these models
- To initiate potential collaboration by identifying complementary strong domains in each region, given the wide range of specialised technologies.

During phase 1 *"Exchange of Experiences"* a State of Play of capabilities of each region has been elaborated by each partner in cooperation with its stakeholders group and other experts (from July to December 2018). From these 8 reports a comparative and benchmarking analysis has been done by CEA to provide the Joint Cross Analysis (present document).

The initial Terms of Reference in the proposal were the following:

- the regional Medtech innovation ecosystems showing a picture of the relationships between RDI infrastructures and the rest of the value chain.
- the description of existing business models for the RDI facilities
- the identification of the main excellence application domains in Medtech and their potential complementarities.

To write their own State of Play, partners have followed the same template, indicated on the following table. The template has been defined after a Methodology Workshop led by CEA. Chapters cover the main tasks defined by the proposal:

- The general innovation ecosystem
- Existing business models
- Supporting policy tools
- Mapping of the excellence application domains
- Self-assessment of the public policies in favour of R&D infrastructures
- Strengths and weaknesses
- Gaps
- Interesting tools for in-depth analysis that could be useful for the other partners (Good Practices)

The 10 chapters of the State of Play reports constitute the 10 criteria of benchmarking and comparison. The present Joint Cross Analysis identifies convergences, elements of improvement, best practices and

recommendations that could be useful for the partnership to elaborate the basement of new models and the writing of the action plans.

The preliminary conclusions of this analysis have been presented and discussed during the Interregional Seminar in Stuttgart on December 12th, 2018. Good practices have been presented and some of them have been chosen to be further analysed in the next steps of phase 1 (Study visits and thematic workshops).

Table 1 - Template of the State of Play for each Region

Chapter	Objective	Suggestions to partners
1. Context: Regional Innovation Ecosystem	Brief overview of the policy context of innovation. To better understand the historical, economical and social context in which Medtech 4Europe takes place.	*We advise to refer to the Committee of Regions report on pioneering regions and cities[1]. A model of a successful Regional Innovation Ecosystem, as studied by the CoR is described in annex 2.* *Suggested topics :* - *Historical background, industrial assets and leading/decreasing activities, research skills, educational strengths…Where do you come from ? What are your capabilities now?* - *Narration about the recent transformations of the ecosystem (e.g. political context, S3 description, topics chosen for specialisation…)* - *Does the regional innovation ecosystem produced the expected results? If no or not yet, why?* - *Key stakeholders, decision-makers in this regional innovation ecosystem*

2. The Medtech Regional Innovation Ecosystem	Description of the main features of regional medtech innovation ecosystem.	*Suggested topics :*
		- *Medtech sector in your region… and in a creative way[2] ☺*
		  ○ *Regional companies in medical technology products and services (large, medium, small), S&T research facilities and centers*
		  ○ *Care providers and clinical research centers (addressing medtech aspects), patient organisations*
		  ○ *Regional authorities involved in medtech regulation (health agencies, notified bodies…)*
		  ○ *Funding partners (private funds, foundations…)*
		  ○ *Formal relationships between all above (if any)*
		  ○ *Bridges between stakeholders: transfer offices, clusters, economic development agencies…*

[1] Regional innovation ecosystems, CoR guide: learning from the EU's cities and regions, Published by the European Committee of Regions, 2016 https://publications.europa.eu ISBN 978-92-895-0877-3

[2] You can be inspired by a triple helix, a quadruple helix, a value added chain, or simply…your own creative representation! Excel tables to avoid…

		○ *International features of this ecosystem (most important partnerships, suppliers, networks, companies etc)* - *Quantitative information to describe this innovation ecosystem (turnover, jobs, publications, patents, start-ups created, private or public money invested, all available and useful information you may have)* - *Success stories*
3. Regional medtech Excellent Application Domains	Description/justification of the regional Excellent application domains in medtechs	*Please justify in each case why you consider it is an excellent one. Your arguments could be either subjective (in this case you might be questioned by other members) or objective (quantitative assessment). Excellence has to be proven (written document, publication, workshop results). If excellence results from your own calculation, please describe how you did it.*
4. Evolutions of your medtech innovation ecosystem	Objectives for transformation, enhancement, improvement of medtech ecosystem in the next months or years.	
5. List of RDI infrastructures and facilities in medtech	Description of the main infrastructures dedicated to medtech innovation activities: objectives and active stakeholders (founders, partners, users, members, customers)	*Definition:* ***a physical place where research, development of new services and products, and innovation activities are conducted, to the benefit of medtech sector.*** *However, a RDI infrastructure in medtech can also be a technological RDI infrastructure such as robotics, cybersecurity, smart textiles, 3D printing, ...****if only it has well defined medtech customers/users.*** *If it is relevant from your point of view, consider also extended definitions of RDI infrastructure in medtech such as:* - *a temporary virtual infrastructure (i.e. a digital network allowing experimental telemedicine)* - *a data center, collecting and using medical records, or a biobank, to develop new healthcare services provided by medtech sector* - *a liaison office between RDI people and medtech companies (service)* - *a virtual partnership among research groups of different research facilities regulated by a written agreement*
6. Features and business models of RDI infrastructures in medtech	In-depth analysis of features and business models of your RDI infrastructures in medtech	*In general, a RDI infrastructure in medtech presents the following essential features:* - *It is open, but on a contract base: organisations can access to the facility if a contract is signed (with or without financial contribution)* - *It is aimed at demonstrating new medical technology product or service for health professionals*

		It can also be publicly-owned or privately-owned, include educational purposes among its objectives, be open to patients or healthy people to get a user experience (such as a living lab for instance)… *Suggested business model description: funding, shareholders structure, customers/users, activities provided and services, staff employed, impacts for companies, for region…(for that purpose, do not hesitate to use story telling: tell us your most impactful results!) and return on investment if any.*
7. Summary of sections 1 to 6: Strengths and Weaknesses	3 strengths and 3 weaknesses to summarise the previous sections	*Take the most important from your point of view, either about medtech ecosystem, excellent (or not!) application domains, RDI facilities*
8. Policy instruments and programmes	Description of innovation policy instruments, and how they are used to support medtech RDI infrastructures.	*A general definition of "Policy instrument" for the Interreg Europe programme is given in annex 3.* *The suggested description has 4 parts for each instrument listed:* - *The context: in what environment the policy is built?* - *The time frame: not necessarily the ERDF time frame (start/end date)* - *Targeted innovation chain / stakeholders by the policy instrument. Different levels addressed (instruments can be flexible to address more than one)* ▪ *Generic support (to SMEs, infrastructures…) most often linked to S3* ▪ *Specific support to medtech sector* ▪ *Specific support to RDI infrastructures in medtech* - *Expected added value and challenges addressed by policies at 3 levels* *Examples of projects resulting from these policies are more than welcomed to illustrate your practice.*
9. Good practices related to policy instruments	Description of a limited number of good practices.	*Good practice is defined as an initiative (e.g. project, process, technique):* - *undertaken in one of the programme's priority axes* - *which has proved to be successful in a region and* - *which is of potential interest to other regions.* *"Proved successful" is where the good practice has already provided tangible and measurable results in achieving a specific objective.*
10. Worst mistakes and lessons learned		*Learning processes are also linked to mistakes, to be avoided by others.* *Feel free to comment this section as you want.*

Joint Cross Analysis

1. Introduction – Analysis of partners expectations from the proposal

Partners did not have the same goals and expectations regarding the project: most of them share the general objectives of Interreg Europe collaborative projects, such as a better implementation of existing policy instruments (improve what exists), inspiration for new RIS3, interregional cooperation and interconnections, improvement of policies regarding RDI infrastructures. Some others have more detailed goals, such as to strengthen research capacities, strengthen RDI impact, strengthen knowledge and technology transfer, or to invent new governance for policies in disruptive areas such as digital health, to better adapt to safe compliance gateways, or for the larger regions, a better coordination of the abundant research capacities.

In terms of learning, expectations are relatively well shared: partners want to learn about each others' good practices, projects, models, ideas, feedbacks from experiences, in particular to achieve a better efficiency of their ecosystems. They consider that their objective is to achieve ecosystems more connected and to improve/upgrade medtech innovation infrastructures. To develop synergies, cooperation between regions is also a shared expectation. One region expresses a different expectation for its future policy instruments: to get a better level of interoperability between social care and healthcare processes, due to age related challenges that all Europe meets. This link between social objectives and economic/innovation objectives will be developed later on.

Regarding self-defined performance indicators, each region provides a different one:

Auvergne Rhone Alpes	Number of medtech projects accompanied by regional RDI platfoms
Province of Limburg	Number of joint excellent research projects in medtech (European level)
South Transdanubia	Number of researchers in medtech +2
Region Copenhagen	Number of new partnerships in the triple helix ecosytem
Upper Silesia	Number of new projects born from the cooperation between RDI infrastructures and firms in health, ICT, medtech
Helsinki Uusimaa	Policy suggestions, action lines retained and implemented in the future RIS3
Lombardy	Increase the number of project products (reports/papers/patents) in research centers
Baden Württemberg	Number of R&D institutions in medtech involved in the policy instruments

These indicators reflect the various expectations of regions regarding the benchlearning process that drives the future action plans. Prior to the project, all regions wanted to get more insight about improvement of ecosystems (research projects, partnerships) in Medtech, but few related this objective to their RDI infrastructures/facilities.

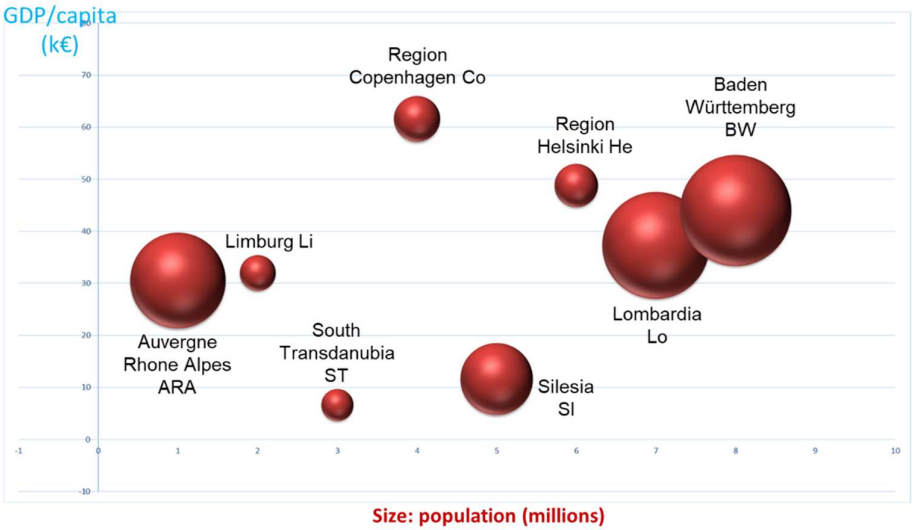
Expectations towards the project are therefore broader than learning about business models of RDI infrastructures in Medtech. The Good Practices catalogue that all partners have contributed to build, will show **the broad scope of their exchanges and reflect the need to extend their learning process to a more contextual vision of medtech RDI infrastructures, as seen as consequences of effective policies**.

2. Starting point: Regional Innovation Ecosystems, focus on industry

A general description of regional innovation ecosystems is needed in order to 1. better understand their particular economic and social environments and 2. allow a relevant comparison between partners.

Economic indicator #1: GDP/capita

From the very basic economic data (GDP- Gross Domestic Product/capita[3]) and population, the partnership is formed of diverse regions in size and wealth.



The EU28 average GDP/capita is 27700€ in 2017. 2 regions (Silesia and South Transdanubia) form a group of those below the average, all others can be clustered as above average regions.Copenhagen Region and Helsinki Region being the Capital Regions of two of the wealthiest countries in EU28, they benefit from a different environment.

South Transdanubia is placed below the Hungarian ratio. Auvergne Rhone Alpes, Limburg and Silesia are close to their respective national GDP/c.

The four other regions are far above this national indicator.

[3] Provided by partners and checked on Eurostat database here

This has to be kept in mind when analysing the different practices, instruments, ecosystems related to innovation, although this is perfectly clear that this single/simple indicator doesn't not reflect the future potential of regions, neither their attractiveness.

Economic indicator #2: R&D expenditure and R&D intensity

In terms of innovation capacity, a traditional and simple indicator is the R&D expenditure (when compared to GDP). Strong innovators are above 3 %. In the partnership, and given the data provided, South Transdanubia and Silesia are modest innovators, Lombardy, Auvergne Rhone Alpes and Limburg are moderate / average innovators, and Baden Wurttemberg (4,9%), Copenhagen and Helsinki are strong innovators. With a specific innovation index, Baden Wurttenberg is also considered as a European Region with the highest innovation potential before Bavaria and Ile de France. As for GDP/c, the R&D intensity doesn't reflect the reality of regions, since national systems funding (of various maturity) can change it significantly.

Benchmark about regional ecosystems from State of Play reports

Restructuring/transformation of economy are good incentives for boosting innovation

Upper Silesia and Limburg regions faced a significant restructuring of their industry, leading to a growing investment on innovation. Helsinki region had also suffered from a decrease in the ICT sector, although it was a growth purely based on innovation, that forced companies to significant changes and adaptations. These three regions present positive results and are well positioned in the Medtech sector now (see next chapter).

In Upper Silesia, in the recent years, together with the gradual financing of restructuring processes on the heavy industry and the conversion in the mode of organizing public services, innovative communities emerged. They are related with both traditional branches such as mining industry, energetics or metallurgy, and new ones as chemistry, environmental protection, automotive production, logistics and medicine. In the beginning of the 21st century, foundations of pro-innovative policy have been created. Restructuration of economy became an impulse for changes in the research and development sector. Region's research institutes adapt their offer and intensify international cooperation.

In Limburg, the manufacturing industry sector is relatively large, as are agriculture, wholesale and the public sector. The closure of the coal mines in the 1960s led to high unemployment (100,000 jobs lost in a short period) and started a process of economic restructuring focusing on industry and public services. Although this process of restructuring was rather successful, some current characteristics of the region can still be traced back to this history (e.g. due to an ageing population the south of the province has a decreasing population).

In Helsinki Uusima region, as in Finland, the 2009 recession contributed to a deep restructuring of the information and communication technology (ICT) industry and the downsizing of traditional sectors that have weighed on the economy, productivity growth and international competitiveness.

In these three regions, policy support to research, development and innovation is considered as a strategic asset to accompany industrial transition.

Roadmapping and foresight exercises to help strategic thinking

Two regions have conducted structured strategic exercises with their ecosystem partners, in a bottom-up approach.

Limburg: RIS3 lies on strategic pillars provided by

- the Brainport 2020 strategy;
- the Strategic Board Zuidwest-Nederland Agenda;
- three provincial economic agendas and programs;
- the implementation programs of the triple helix organisations in the southern sub regions of the Netherlands;
- roadmaps and innovation contracts of the relevant top sectors;
- various studies and benchmark reports, in particular from OECD.

Silesia: based on findings of Regional Innovation Strategy and technological foresight, the Voivodeship began in 2009 to implement 8 Technology Development Programmes for the years 2010-2020. The focus of the document was on the establishing of conditions for the particular components of technologies derived from road maps, developed under foresight (SWOT analyses were also conducted). Technology Development Programme is a sort of guide to the advancement of the state of technology development in particular technological branches, and it delimits the fields of region's technological specialization.

Diversity or specialisation: a matter of size… or a strategic choice?

Large regions such as Baden Wurttemberg, Auvergne Rhone Alpes, Lombardy, have diverse industry sectors, well developed historically and with a critical mass of companies that provide significant growth. It corresponds to high numbers of industrial jobs: 526 000 in Auvergne Rhone Alpes, 1,37 millions in Lombardy. These regions have industrial giants: Michelin, Sanofi-Pasteur, Renault trucks, ST Microelectronics in Auvergne Rhone Alpes, Bosch, Daimler, IBM in Baden Wurttemberg. Baden Wurttenberg as a classic industrial state with strong economic power hosts SMEs that often "hidden champions", very successful on global markets and with a high export orientation.

Economic diversity doesn't go systematically with a focused specialisation strategy: Auvergne Rhone Alpes builds its economic strategy on 8 smart specialisation domains, Lombardy quotes 7 specialisation areas, but Baden Wurttemberg, although the biggest region in terms of population and industry jobs, has defined only 4 focus areas (sustainable mobility, ICT, Health, Environment). Diversity is a strength for developing balanced innovation strategies between sectors, mitigating the risks of a significant crisis on one of them. However, it might be complex to focus policy instruments on large ecosystems because of potential competition between supporting measures. Also it is not so simple to make these complex and diverse ecosystems to collaborate and at least to coordinate. This will be detailed later on the "Strengths and Weaknesses" chapter.

At the opposite of spectrum, Limburg and Helsinki due do their limited size and populations have defined excellence domains as key sectors (high tech sector, ICT and healthtech in Helsinki, healthtech, Agro&Food, wholesale, logistics in Limburg). This has led to a directional innovation strategy, that focuses on few assets and provides the necessary infrastructures and support to make it work efficiently.

Silesia has transformed its economic pattern from a monocultural industrial region (mining and metallurgy) to a multisectoral region, including by attracting firms in totally new areas and included in global supply chains. The voivodeship has defined 8 technological branches (see above) as bases for the innovative potential of the region (among which medicine and medical technology). These 8 are priority fields and regional Specialised Observatories have been defined (this will be detailed in the Good Practices of Silesia). Silesia is therefore a specific region in its approach, not highly specialised,

neither very diverse, but trying to focus on **technological enablers** in order to find its own way to build dynamic innovation ecosystems.

South Transdanubia is a rural region, with 66h/km², a modest innovator region, characterized by relatively low share of manufacturing and foreign direct investment, few innovative companies and low grant absorption capacity. Despite substantial investment in R&D infrastructure and in new technology, the region is among the bottom 20% of the European regions in most aspects. Regional Innovation strategy addresses health industry as one of the main directions of regional R&I activities, and this will be based upon research capacities and transformation of SMEs (see following chapters).

Only 2 regions describe their ecosystem as performant in exportation

Baden Wurttenberg and Limburg are good at exportation and consider this asset as a key success factor of their growth. Limburg is an important link between the ports of Antwerp and Rotterdam, and also the knowledge institutes and production sites in the adjoining regions of Flanders (Belgium) and North Rhine Wesphalia (Germany). Beyond exportation, that is high ranked (as in general for Dutch sectors), Limburg builds its strategy also on the collaborative framework established at the international level.

Key players of regional innovation ecosystem are regarded differently by regions

The triple helix concept (Industry, Research, Education) is well described by all regions, although the role of the different parts is not recognised equally.

Industry leaders, when they exist, are the first key players of innovation ecosystems, with the highest impact. All regions consider also that spin-offs, SMEs, incubators/accelerators are important ingredients of a good recipe for boosting local innovation. Although not fully described in the State of Play, the general conditions of a “friendly business environment” is certainly a major goal for all of them.

Research institutes and universities conducting research are described as key players in all regions, although it remains difficult to understand from this description, what are the key ingredients of success for regional innovation ecosystems, when talking about research capacities. Except for South Transdanubia which has only one university (University of Pécs) as a key player, all other regions have many research labs (550 in Auvergne Rhone Alpes, 234 in Silesia) from 11 to 32 universities (including applied sciences) and a considerable numbers of research indicators (patents, spin offs from universities, number of labs…) that are simply not comparable. It raises the issue of the efficiency of the helix research of innovation ecosystems. Do the big figures guarantee that hundreds of research labs have an big impact on the performance of ecosystem?

Limburg focuses on the ability to attract key players like KICs of EIT (European Institute of Technology), Baden Wurttemberg considers that among research institutions, those which are oriented towards industry are noticeable (30 in this region). Silesia adds living labs on the long list of research capacities.

Besides research, **education and higher education** is the third helix, not fully recognised beyond key figures (nr of students or nr of universities). There are some interesting approaches in two regions: Silesia, about the close relationship with economic development, through the regional Observatory initiatives, and Limburg that stresses the leveraging role of KIC-EIT between education and business sector, around key societal issues. The role of universities of Applied Sciences in Limburg is also considered as critical (Regional Training Centers and Centres of Expertise, Centers for Innovative Craftmanship) to create a link with the labour market needs of the priority sectors.

Clusters - or networks, or initiatives, can be all names, all based on a collaborative spirit, improvement of collective actions to combine forces in the considered region - appear as the “cherry on the cake”

integrating all dimensions with more or less success and trying to reinvent new models of cooperation. In small regions, clusters can be national. In bigger ones, or very innovative ones, there are many clusters and it raises some issues about the coordination of all these clusters if too independent from the innovation strategy.

Finally, only Limburg defines the key role of its **campuses** in the innovation ecosystem: campuses are the place where the triple helix is really taking place. For Limburg, campuses act

- *"as actual locations with good possibilities and facilities for establishing businesses; especially availability of infrastructure (labs, pilotplants) highly contributes to innovation;*
- *with the focus on R&D and knowledge-intensive activities;*
- *with the presence of manifest knowledge carriers;*
- *and as an environment for active open innovation"*

2. Medtech regional ecosystems

(Without Copenhagen)

The Medtech regional ecosystems are mostly described as rather static pictures of stakeholders. A comparative analysis of these pictures is interesting and raises some questions, but it's not possible to figure out how the ecosystems perform. Beyond the description below, we let some questions open for the thematic workshops and study visits of phase 1 in 2019.

The tables below present the main stakeholders described by region for the 4 categories:

- Companies
- University Hospitals, Medicine faculties conducting medical research and clinical trials, Hospitals and important/specialised care centers
- High education institutions, mainly universities
- Research organisations active in Medtech.

General overview by region

Auvergne Rhone Alpes	Strong diversity of sectors is an asset for medtech: many different technologies co-exist (biomaterials, chemistry, textile, plasturgy, computing, microelectronics…) Diverse and innovative landscape of partnerships, helps technology integration into the medtech sector. Originally focused on vaccines and in vitro diagnostics the medtech innovation ecosystem became a interconnected network between sub-regional assets, each located in a specific geographical area.
Province of Limburg	Core asset is Brightlands initiative (Knowledge crossing barriers), brand name, connects 4 campuses, focus Health and Sustainability. Triple Helix Science, business and education. Public/Private partnership. Brightlands Maastricht Health Campus (BMHC) 720000m² A local ecosystem for health and clinical medicine Focus on Imaging MRI 3T, 7T, 9,4T and CardioVascular related technologies (Medtronic support). Excellent application domains: regenerative medicine, precision medicine, the entire value chain in cardiovascular

South Transdanubia	There is a need for cooperation between R&I medtech / supply side and demand side (university and companies). Medtech companies are small size and followers rather than innovators. Bridge with research starts but not fully efficient, it doesn't match completely (need of more technological research or technical centers?)
Region Copenhagen	nd
Upper Silesia	Numerous stakeholders in medicine, research, training, engineering etc Strong export capacities for companies A key cluster MedSilesia
Helsinki Uusimaa	*Landscape of healthtech is given for Finland (can be extended to Helsinki)* High exportation capacity (95% of total manufacturing output) Trade balance more than positive. High growth of export these last years in healthtech. A strong ability to build medtech companies from the life sciences/biotech sector
Lombardy	High concentrated R&D expenditure in large companies shifts towards regional SMEs, that constitute the basic asset of medtech ecosystem. A strong national association is Assobiomedica (within Cofindustria) which connect all stakeholders involved in a very diverse fabric of products and technologies.
Baden Württemberg	Highly concentrated on health industries (a success story is the City of Tuttlingen 12000 employees in medtech on 35000 inhabitants). The ecosystem is made of technology research centers, technical universities, many companies of all sizes, clusters all strongly interlinked through innovation policies at the regional and federal levels.

Companies by region

	Companies	**Among which recognised leaders** (TOP20 sales in medtech – source Evaluate medtech 2018)
Auvergne Rhone Alpes	251 companies, 17500 jobs Leaders: bioMerieux, BD, Depuy (J&J), Stryker, Fresenius, Tornier, Medtronic	BD Stryker – Medtronic – J&J (small units)
Province of Limburg	103 companies, 9541 jobs, LONZA NL: CMO for cellular therapies and reg. medicine Start-ups in reg. medicine (Neuroplast, Mosameat, CiMaas, Materiomics) Start-ups in precision medicine: PSMedtech, ptTheragnostic, pathoFinder, Digitale Dermatoloog Leader in cardiovascular medtech Medtronic Start-ups in cardiovascular: ACS biomarker, Glycocheck, MyDiagnostick, FABpolous, VitaK,	Medtronic

	PieMedical Imaging, Synapse, Mirabilis, TripleMed, Bioactor	
South Transdanubia	Companies with R&D capacities: CorvusMed, OrthoprofilMed, Small equipment manufacturers (prosthesis, rehab. equipt, bandages, home nursing and assistive) often retailers of foreign companies	
Region Copenhagen	Nd	
Upper Silesia	120 medtech producers Production value 6,5 bn PLN 2013, tripling the export (60% to GE, DK and FR) mainly for hospital furniture, precise surgical instruments, medical materials, implants MEDENINMED (medical equipment, rehabilitation equpt)	
Helsinki Uusimaa	Main asset: electromedical and diagnostic imaging solutions require a profound understanding of physiology and user requirement: it takes time. Export giants: Planmeca, Orion. New players: Fimmic, BC Platforms, Blueprint genetics, Noona Healthcare, Disior Oy	
Lombardy	GLOREHA group of 11 SMEs in rehabilitation devices Officine Ortopediche Rizzoli *Also several companies not active in medtech have been quoted: DOMPE (biopharma), MOXOFF (software, analytics)*	
Baden Württemberg	600 companies The most important ones: Aesculap, Karl Storz, Henke-Sass, Wolf, Stryker, Zrinski Aesculap and the City of Tuttlingen - the city of medtech (12000 jobs, 600 companies)	Aesculap (division of BBraun) Stryker

Hospitals and medical centers by region

	University Hospitals, Medicine Faculties conducting Clinical trials in Medtech	**Hospitals and Medical Centers (care only)**
Auvergne Rhone Alpes	Lyon, Grenoble, Clermont-Ferrand, Saint Etienne	

Province of Limburg	Maastricht University Medical Center+, excellence center for clinical medicine and medical research. Interaction between prevention, treatment and aftercare to strengthen public health and healthcare chain. Scannexus: UHF MRI MAASTRO clinic: proton therapy and radiotherapy	
South Transdanubia	University of Pécs Medical School	13 hospitals, 7 healthcare centers
Region Copenhagen	Nd	
Upper Silesia	Medical University of Silesia Silesian Center for Heart Diseases Rehabilitation Center repty	Many therapeutic units for medical rehabilitation, Orthopaedics, Cardiology, Paediatric Oncology and Haematology
Helsinki Uusimaa	University of Helsinki Comprehensive Cancer Center	
Lombardy	Foundation Don Carlo Gnocchi (IRCCS Milano) (rehabilitation) INRCA translational research and care Istituti Clinici Scientifici Maugeri Instituti Auxologico (hospital and biomedical research)	MEDEA Association "La Nostra Famiglia" Valduce Hospital (Rehabilitation medicine) Clinical Center Nemo (Neuromuscular Omnicentre)
Baden Württemberg	Freiburg, Heidelberg, Tübingen, Ulm 30000 employees, 4200 doctors, €2,4bn turnover 14000 medical students	

Higher education by region

Auvergne Rhone Alpes	5 universities in science 12 engineering schools
Province of Limburg	6929 students - Maastricht University
South Transdanubia	University of Pécs
Region Copenhagen	nd
Upper Silesia	Silesian University of Technology Silesian University in Katowice

Helsinki Uusimaa	University of Helsinki Aalto University Laurea University of Applied Sciences Metropolia University of Applied Sciences
Lombardy	Politecnico di Milano (engineering) Univ Milano Bicocca (School of Surgery and Medicine) Univ Cattolica Sacre Cuore (psychology, Engageminds-HUB) Univ di Brescia (translational medicine, surgery, clinical medicine, public health)
Baden Württemberg	University of Applied Sciences Furtwangen (Medical and Life Sciences) University of Konstanz (health informatics) University of Ulm (Laser technology in medicine)

Research Institutes, research centers active in medtech, by region

Auvergne Rhone Alpes	National labs: CEA, INRIA, INSERM, CNRS Specialised labs: TIMC-IMAG, Labtau, INL, CREATIS, CIS, CRNL, ISA, LIRIS, 3DFAB, Institut Pascal *(see the State of Play for acronyms)*
Province of Limburg	MERLN (technology-inspired regenerative medicine institute) Virtual lab RegMed XB (cross border NL BE) CARIM (Cardiovascular research) M4I molecular imaging (personalised medicine and diag) Scannexus ultra high field human MRI center Medtronic Bakken Research Center (300p) - cardiac rythmn and heart failure. The only one private research center in the partnership.
South Transdanubia	University of Pécs
Region Copenhagen	Nd
Upper Silesia	Silesian Univ of Technology (Fac of Biomedical Engineering) Center of Polymer and Carbon materials Polish Ac of Sc Silesian University in Katowice Institute of Medical technology and Equipment ITAM Silesian Park of Medical Technology KardioMed Silesia Pr Zbigniew Religa Foundation for Cardiac Surgery
Helsinki Uusimaa	VTT
Lombardy	CNR Politecnico di Milano
Baden Württemberg	Innovationsallianz Baden Württemberg (alliance of 13 research institutes) Natural and Medical Sciences Institute (NMI) (Univ Tubingen)

Only 2 regions have **Clinical Training Centers** (education of Health Professionals and Surgeons): Limburg (European Medical Training Center (EMTRAC) part of Cardiovascular Center Maastricht) and Silesia (Pr Zbigniew Religa Foundation for Cardiac Surgery) both for cardiovascular and cardiac surgery.

Clusters, trade associations, networks are part of Medtech regional ecosystems. Most regions present clusters developing services for medtech companies, sometimes several clusters in medtech for one large region (5 in Auvergne Rhone Alpes, 3 in Lombardy, 3 in Baden Wurttemberg).

Technology transfer and business development offices are also present in developed regions (beyond the traditional patent/licensing offices of universities). The experience of Maastricht valorisation center, and its specific team of business developers, or the Open Innovation Platform and LTC state room in Lombardy, or Steinbeis Europa Zentrum and BioPro in Baden Wurttemberg could be discussed later on in the project meetings.

Only South Transdanubia and Lombardy refer also, as stakeholders of the medtech ecosystem, to the the **Health insurance/payers organisations**: the National Health Insurance Fund of Hungary, that plays a key role for purchasing products and services and ATS Brianza, as a controlling organistion for health services. If the term “value added chain” is often used, only 2 regions describe this chain until the end (market).

As previously, only Limburg refers to its main **Campus** Brightlands Maastricht Health Campus, as the cornerstone of its Medtech innovation ecosystem. The Campus favours the continuum of knowledge transfer from initial ideas developed by research to market introduction. BMHC hosts several key infrastructures and centers that are magnets for international cooperation, businesses, clinical research.

This benchmark shows that all regions describe more or less on the same data/inputs their innovation medtech ecosystem, but only Limburg at that stage describes the potential interaction between players, and the determinants of a successful interaction.

Some key questions to be asked and discussed on this specific point of interactions between players:

- Is there some incentives to create a leveraging effect between large/leading companies and SMEs in a region? How do the leaders work with the local SMEs and start-ups? Do they take part to the region’s efforts to support these companies?
- How do Clinical Research/Clinical care centers interact with other players in the ecosystem? Do they have incentives to work together, to develop projects with local assets? If no what do they expect from the ecosystem? Do they consider themselves as full players of the medtech ecosystem?
- How does the region articulate the challenges of care and those of economic development?
- What is the position of payers/insurances?
- Are there demonstrations, pilot cases, to experiment innovative technologies in hospitals, in care centers, rehabilitation centers or simply at home?
- To what extent are Medical Schools involved in medtech development and new technology learning? Do private organisations (care structures or companies) invest in training for young physicians or health professionals education?

- Which are the key ingredients to make a research center well integrated in a medtech regional ecosystem? Are transfer structures a sustainable solution?
- What is the role of RDI infrastructures to attract companies in research and innovation? Do the clusters sell these infrastructures and skills?
- What could be the ideal process for a less developed region such as South Transdanubia? From which point to start and what could be reasonably achieved in a short time frame (5 years)?
- Does the network established in the medtech innovation ecosystems play a role in human resources management (attraction of talents, share of staff between universities and SMEs, traineeships for students or apprenticeship…)

3. Application excellent domains

(without Copenhagen)

The table below presents the main excellence Application Domains as quoted by regions. South Transdanubia and Helsinki underline some important links with biotech companies that stimulate new instrumentation tools, which cannot be strictly considered as medtech products, even if the technology used for life sciences instrumentation and medtech sector strictly speaking is very similar (based on interaction between living objects and physical objects).

However, the rising importance of genomics can be a real asset for medtech development if this excellent domain is present: the convergence towards personalised medicine and health data related information (digital markers for instance) is a powerful trend for the next years, as underlined by Helsinki.

Table 2 – Excellent application Domains in Medtech for each region

	ARA	Li	ST	Co	SI	He	Lo	BW
Diagnostics IVD, monitoring devices, precision medicine, molecular diagnostics	■	■					■	
Rehabilitation, orthopaedics, prosthesis, implants			■		■		■	
Regenerative medicine (biomedical engineering and cellular therapies)		■						
Materials, biomaterials	■				■			
Cardiovascular, cardiac surgery		■			■			
Surgical instruments and implantable devices (incl semi-impantable endoscopy)								■
E-health services, telemedicine					■	■	■	■
Medical imaging	■	■	■			■		
Data analytics and connected health						■		
Computer assisted surgery, medical robotics, 3D planning	■		■		■			

4. Evolution of medtech ecosystems

(without Copenhagen)

Improvements are basically function of departure point.

Six different expected evolutions have been addressed

- **Leadership and reinforcement** (Auvergne Rhone Alpes, Limburg)
- **Initial development** (South Transdanubia) with transfer of research results to innovative production, financing and IP, innovative projects as demonstrators
- **Acquire complementary asset**s
    - Either the missing or weak parts of the value chain:
        - Clinical trials (Limburg)
        - Regulatory education/resources (Helsinki, Baden Wurttemberg, Auvergne Rhone Alpes)
    - Or technologies/new models for healthcare that sound promising and needed, such as Cardiac devices, regenerative medicine, data analytics, surgery systems, microchips, nanomaterials, photonics (Silesia), Connected health and data, Addressing Ageing challenges and needs (Helsinki)
- **Better coordination** between the various components of innovation ecosystem (Medtech and the rest), especially for digital sector and genomics (Limburg, Helsinki, Silesia)
- **Better coordination and synergies between RDI components in medtech** (facilities, research centers, better access to RDI facilities by SMEs) Auvergne Rhone Alpes, Baden Wurttemberg, Silesia)
- **Extended understanding of policies**: "*Closer relationship between policy makers esp EU and industry to better understand core problems"* (BW)

5. RDI Infrastructures in medtech

(without Copenhagen)

There is no unified vision of what a medtech RDI infrastructure is. Although the definition seems to be clear *(a physical place where RDI activity is conducted to the benefit of medtech sector, i.e. companies)* most regions (except Auvergne Rhone Alpes and Limburg, which have been really selective for the medtech application) are considering that a university, a hospital or a research institute or even a specialised lab active in biomedical research or life sciences research is called a medtech RDI infrastructure. **Physical place where medical research is conducted is not necessarily related to the medtech sector** (most of them relate to drug development or fundamental understanding of diseases).

This point should be discussed in the next steps of MT4E in order to adapt the benchlearning experience to the specific context of regional infrastructures in medtech, with a clear definition of what medtech products are:

Products intended to perform a therapeutic or diagnostic action on human beings by physical means. *Include in-vitro medical devices - products which provide medically useful diagnostic information by examination of a specimen derived from the human body.*

It is likely that unless a very strict definition is accepted, policy instruments regarding the support to these infrastructures might be very different. If the goal is to create and transfer knowledge, prototypes, testing, training immediately usable by companies to shorten their market access time with innovative products and services, it is probable that funding to academic research labs in medical

research will have a very limited impact. But if in the same place (e.g. a campus) biomedical research is conducted together with engineering research, it increases the chances to provide successful inputs to the medtech sector.

Surprisingly, campuses are not considered as large infrastructures, although investment needs related to their operation and attractiveness may be very high.

Some infrastructures provided by partners have been suppressed from the list because not strictly related to medtech, except for genomics / biobank infrastructures that can be linked to medtech sector[4]. Clusters and networks are in italic in the table below.

List of 46 RDI infrastructures in Medtech provided by partners

Auvergne Rhone Alpes	ECCAMI (Excellence Center for Computer Assisted Medical Intervention) CIC-IT (Clinical Investigation Center for technology Innovation) CETIM (Mechanical Engineering) CEA LETI HEALTH (Technological Research in Medical Devices) CLINATEC (Clinical facility for implanted medical devices) NANOBIO (Micro and nanobiotech) CERMEP (In vivo imaging) GIN (Grenoble Neurosciences Center – includes research on medical Imaging) Mines Tech#future medicine (engineering) IVTV (engineering and aging of living tissues) IN2P3 Computing Center and data analysis
Province of Limburg	Scannexus MRI facility open for research Bakken Research Center (Medtronic)
South Transdanubia	University of Pécs - Medical School Szentágothay János Research Centre (multidisciplinary Institute) 3D imaging lab (biomedical research) MediSkill lab (training and simulation facility at univ Pécs)
Region Copenhagen	Nd
Upper Silesia	Pr Zbigniew Religa Foundation for Cardiac Surgery Development Center for Biocompatibility and Biobank *(created?)* MedicaSilesia BioLab (*created?*) AssistMedSport Silesia Lab (*created?*) Silesian Univ of Technology (Fac of Biomedical Engineering) Institute of Medical technology and Equipment ITAM Silesian Park of Medical Technology KardioMed Silesia *GAPR (Agency)*

[4] NMS Group (related to drug development), Biorep, Multmedica (oncology association), in Lombardy, Hochschule Albstadt Sigmaringen (entrepreneurship)

Helsinki Uusimaa	University of Helsinki HILIFE (life sciences) University of Helsinki FIMM (Finnish Institute of Molecular Medicine (human genomics, personalised medicine, technology center, biobank) Univ Helsinki FinGen (Large Scale Genomic Project in PerMed) Aalto University Health Platform *Health Capital Helsinki (network)*
Lombardy	BBMRI biobanking National Center of Oncological Hadrontherapy Lecco Innovation Living Lab Politecnico Milano Auxologico Institute Carlo Besta Neurological Institute
Baden Württemberg	*Innovationsallianz Baden Württemberg (alliance of 13 research institutes)* Natural and Medical Sciences Institute (NMI) (Univ Tubingen) Hahn-Schickard Gesellschaft Fraunhofer Institutes (IPA, IGB) *Medical Mountains (network)* *Technology Mountains (network)* *MicroTEC Sudwest (Cluster)* IHK Schwarzwald Baar Heuberg Landesinnung für Chirurgiemechanik Hochschule Furtwangen

6. Business models of infrastructures

Only Lombardy has provided information about funding models for certain infrastructures for instance mixed between public funds (grants, collaborative projects) and private funds (contracts with companies, donations). Baden Wurttemberg, Lombardy and Auvergne Rhone Alpes have provided information about customers/users, that are mainly researchers, companies, clinical researchers, clinical practitioners, and in Baden Wurttemberg, municipalities. Governance models are not described.

Although this point is a key objective of the project, it is indeed very difficult, almost impossible to describe. First because of confidentiality reasons, and second because it would be very difficult to access to information, as partners do not really interface with the operational management of these infrastructures. However, a dedicated workshop in June 2019 (organised by GAPR) has tried to dig in this important issue (see Upper-Silesia workshop report June 2019).

7. Strengths and weaknesses (S/W)

(without Copenhagen and South Transdanubia)

There are some discrepancies between regions: some regions did the analysis of S/W strictly applied to the regional medtech ecosystem and infrastructures, others have described more general S/W for the regional ecosystem. This makes the comparison difficult.

	Strengths	Weaknesses
Auvergne Rhone Alpes	• A very rich and diverse industrial fabric (SMEs vs big companies, strong related sectors (digital, electronics, mechanics) • A lot of skills (scientific, medical, technological, education/training) all along the value chain • A strong political will to support the health sector	• Lack of a common strategy (due to a lack of common objectives) • Support organisations are too scattered and there is a lack of coordination between the different actors and territories • Low visibility of the medtech sector (fragmented industrial fabric, technological and geographical fragmentation)
Province of Limburg	• Unique open innovation system and strong international knowledge position • Worldwide competitive supply chains • Triple helix cooperation	• Public R&D expenditures below critical boundary • Shortage of skills from the area, unflexible labor market • Utilisation of European cooperation potential
South Transdanubia	• High quality RDI human capacities and equipment facilities • Availability of funds for conducting tailored product and service development • Demographic changes (ageing population, increased need for rehabilitation)	• Lack of capacities / trust for successful academia – business transfer • Low technological development of the region hinders an effective articulation of medtech research with government and business • Few medtech products and services have potential to penetrate foreign markets
Region Copenhagen		
Upper Silesia	• launching new technologies • demographic changes also force the use of new technologies, • response to market demand, • participation in research projects (NCBR, NCN) and applications in EU projects, • possibility to acquire international patents, • cooperation with research institutions/ R&D institutes from abroad • leading universities and research institutes available and acting in Śląskie (R&D potential - second biggest in Poland)	• lack of funding in the early stages of development • undefined user, • current low technological development of the region/country • moderate experience in running joint projects of representatives of science and business • moderate skills of scientists in the commercialization of scientific research
Helsinki Uusimaa	• Skill, education structures on all levels	• resources, knowledge silo's, lack of coordination, lack of multidisciplinary collaboration

	• scientific mobility, data structures and registers • start up communities and evolving entrepreneurial spirit • Export orientation of spearhead companies • ICT capabilities	• sub-ambitious short-term projects • only few industrial operators of international weight • ineffective public incentives • thin VC and capital presence • early start-ups buy outs causing loss of IP, knowledge
Lombardy	• Successful implementation of quadruple helix innovation system, innovative policy mix • Highest concentration of university hospitals in italy • Private R&D expenditure among the highest in Italian economy	• Lower chances to access to EU calls for SMEs (not enough support?) • Great difficulties for SMEs to reach EU market • Networking should be better supported
Baden Württemberg	• Industry oriented research institutions • High potential for specialists • High degree of innovation	• Some of the institutions specialise in basic research, good for reputation, but not industry oriented • Expandable cooperation between science and industry • High requirements/standards for approvals (not enough prepared?)

Weaknesses have great value to understand the lines where regions will try to learn from each other. The most recognised weaknesses are

- W1: the lack of coordination (even for small regions) among actors or between research and industry, not enough multidisciplinary cooperation, networking not enough supported
- W2: the lack of public funds, or the inefficiency of public incentives, sub-ambitious research projects,
- W3: international weak capacity, especially for SMEs, and difficult access to EU projects
- W4: shortage of skills, labor force
- W5: all barriers specific to medtech SMEs (access to EU calls, market access, regulatory approval…)
- W6: Low technological development in some sectors

This respectively corresponds to the following strengths of these regions:

- S1: successful triple helix or quadruple helix systems: Limburg, Lombardy (strong clinical research), start-up communities: Helsinki; research institutes oriented towards industry: Baden Wurttenberg
- S2: efficient public incentives: ?
- S3: strong international position, competitive supply chains, international cooperation: Limburg, Silesia
- S4: good skills for medtech sector, diverse and well adapted, well educated: Auvergne Rhone Alpes, Helsinki,
- S5: SMEs friendly environment and specific measures to help them to overcome the specific barriers of the medtech sector:?

- S6: competitive industrial sectors, highly innovative, to work with: Auvergne Rhone Alpes, Baden Wurttemberg, Helsinki for ICT

Strengths not identified by partners:

Efficient public incentives: there is no region reporting as a strength its general public incentives or policy supporting measures, in absolute terms because of the difficulty to assess what is an efficient public incentive. To better discuss this critical issue for Interreg projects, it is necessary to figure out the main features of "efficient" policies and public incentives. How do we measure the real success? How do we define the most impactful measures? To what time scale should we evaluate the potential impact? What kind of impact?

Help SMEs to overcome the specific barriers of medtech sector: this is also like an unsolved concern, no region reports its specific environment as a strength to tackle this challenge, although it is clearly a key challenge. Are regions well informed of the specific obstacles that medtech SMEs will meet during their innovation journey? Do they try to deliver specific support measures?

Surprisingly, no region reports about **the excellence of its RDI medtech infrastructures**, and the efficient service they provide to medtech companies, despite the high number of these infrastructures (46). Would that mean that these infrastructures are not completely dedicated to support the medtech sector, its companies, its innovative forces?

8. Policy instruments

There is no specific policy instrument managed by regional authorities for the medtech sector.

Few regions have specific instruments besides the ERDF/ESF general instrument.

2 regions undergo major political reforms that limit their ability to project their current policy instruments (Copenhagen and Helsinki) for the future MFF.

Among the regional specific policy instruments that could be well adapted to the specific issues met by medtech companies and researchers, there are 4 interesting initiatives:

- A dedicated call for proposals for shared RDI facilities, open to SMEs (Auvergne Rhone Alpes - IRICE)
- Innovation vouchers and digitalisation premium grants for SMEs (Baden Wurttemberg)
- Innovative Pre Commercial Procurement (Lombardy).

Baden Wurttemberg is the only one region that includes in its policy instruments the public funding for innovative projects from the Federal Ministeries (Research BMBF and Industry BMWi), fully dedicated to the medtech innovation challenges.

Policy instruments of all regions are oriented towards innovation, strengthening research capacities, technology transfer, collaborative projects, excellence research development, skills and education, clusters etc. Although all regions invest in these critical areas, there is in general no impact assessment associated, no guarantee that at long term these incentives have been efficient and have produced the promised expected results. It makes it tricky to learn from mistakes in order to avoid to duplicate what has been somehow "unefficient".

9. Good practices

Good practices have been extensively described and discussed at the Interregional Seminar in Stuttgart on 12 december 2018. Helsinki and Copenhagen have added some other good practices as well as Limburg and Baden Wurttemberg.

The catalogue includes 39 good practices from the 8 regions. They are sorted by objective in the following table (contents of the Good Practice catalogue, each line is detailed by a specific page on the same format).

	Reference	Name	
ENT – RDI support to enterprises, in particular SMEs			
FR	ENT 01	Easytech “Easy innovation for SMEs”	
FR	ENT 02	Innovation vouchers for companies	
FR	ENT 03	RDI projects labelled by competitivity clusters	
FR	ENT 04	Technology transfer through shared equipment concept	
HU	ENT 05	Baross Gábor Regional Research-Innovation Fund	
DK	ENT 06	Smart Innovation	
DK	ENT 07	Trial Nation – Clinical Trials Denmark	
IT	ENT 08	Ecosistema Innovazione Lecco	
GE	ENT 09	CleanMed Project	
FI	ENT 10	Embracing the skills and technologies from other Verticals / DIGITAL	
FI	ENT 11	Mediators building on the open innovation spirit among the startups	
FI	ENT 12	Testing facilities and willingness to validate health tech innovation	
RES – Research-based initiatives (networks, virtual institutes, excellence centers, clinical research)			
FR	RES 01	Clinical Investigation Center for Technology Innovation (CIC-IT	
NL/BE	RES 02	RegMed XB	
NL	RES 03	Scannexus	
NL	RES 04	Maastricht Imaging Valley	
HU	RES 05	János Szentágothai Research Centre	
HU	RES 06	Active participation in Federation of European Neuroscience Societies (FENS)	
PL	RES 07	Assist Med Sport Silesia (flagship project – science-business)	
PL	RES 08	Silesia LabMed (flagship project – science-business)	
PL	RES 09	MONITEL – HF project	
PL	RES 10	RH ROT project	
EDU – Training, education for students or professionals			
FR	EDU 01	EIT Health Summer School	
PL	EDU 02	Medi Skills Lab	
DK	EDU 03	The Capital’s Entrepreneurship Program	
DK	EDU 04	Copenhagen Health Innovation CHI Health Innovation Through Education	
GE	EDU 05	BIOLOX® App and BIOLOX® motions: Surgeon consultation and training with interactive media for the handling of ceramic hip prostheses	
OIC – Open innovation campuses or facilities			
FR	OIC 01	CEA Technology Innovation Showroom	
NL	OIC 02	Brightlands Ecosystem	
NL	OIC 03	AMIBM	
NL	OIC 04	Brightlands Innovation Factory	
NL	OIC 05	Chemelot InSciTe – Technical Validation Institute	
GE	OIC 06	Wissenschaftsoffensive (Science Offensive)	
PRO – Procurement for innovative products/services			
IT	PRO 01	Public Pre-Commercial Procurement	
POL – Policy framework/organisation/forum for innovation			
IT	POL 01	Accordo Quadro Regione Lombardia – CNR (2016-2018)	
GE	POL 02	Forum Health Location Baden-Württemberg	
PL	POL 03	Regional Specialized Observatories	
EXP – Real life experimentation supported by public funds			
FR	EXP 01	Digital care territories – Auvergne Rhone Alpes services (Pascaline)	
PL	EXP 02	Silesian Medical Digital Platform eCareMed - Telemedicine and exploration of medical data	

10. Worst mistakes and lessons learned

(Without Limburg and Baden Wurttemberg)

Several risks when addressing policies toward RDI infrastructures are identified. A bad assessment of these risks leads to failures or limited 'mistakes' in terms of targeted efficiency and use of public funds.

- When support is given to a RDI infrastructure, by definition the business model is not known. Either a bad evaluation of this business model, or more likely the lack of follow-up related to the learning process related to this business model are the most important risks.
- Once the infrastructure is operational, there is also a risk to have over or under estimated its usability by its customers and partners. To mitigate this risk, a stepwise approach might be of interest, including for investment in buildings and equipement.
- Duplication is also a risk (only for large and rich regions). It introduces confusion, a waste of energy to coordinate similar initiatives (clusters, networks, infrastructures). The way to avoid this risk is to maintain a good flow of strategic discussions inside the ecosystem (and it's particularly difficult when related to the cross disciplinary domain of medtech).

Traditional limitations of public policies are also underlined:

- A classical pitfall is the underestimation of time/money required to achieve good projects with a strong impact. In trying to satisfy all stakeholders, policy instruments might not have the right ambition or the right dimension to address these challenges. Thin spread of funds limits impacts (larger projects are better). Therefore mutualise policy instruments seems to be a possible solution (at the national, cross border or European level). Subcritical investments do not produce miracles.
- Another one is the rigidity of support programmes that doesn't allow a reorientation of budget or objectives during implementation. It is obvious that public aids should better accommodate with the intrinsic risky nature of projects, and thus allow budget reallocation during the course of project. A too strict regulation doesn't serve its goals.
- Also the lack of orchestration, the lack of coordination might underperform good ecosystems which have all assets in place.

There is also a big trap related to the very innovative nature of medtech: if the regional ecosystem doesn't capitalise its results, successes, outputs, experiences, a lot of ideas or experimentations are lost. The lack of capitalisation from experience is also a well-known pitfall.

SMEs are constituting the most important part of industry sector. Thus to adapt policy instruments and programmes to their specific needs, especially simple application procedures, short delay of reponse, pragmatism and lowering complexity at all stages, appropriate amount of funding to achieve good results, all are necessary. This can include actions towards new products and services, traditionally served by innovation support policies, but it is also of interest to support mentorship, education, training, help to connect to other ecosystems etc.

The measuring of effects are also somehow problematic, due to the lack of a clear ex-ante picture.

Discussion and open questions

During the meetings of phase 1, partners will discuss, among other questions the following topics defined in the Application Form:

1. How to make the R&D ecosystem more efficient to suit the needs of the medtech sector or even to think together to new models?
2. The best policy instruments to support relevant business models of RDI infrastructures in the medtech sector (new tools, new funding or co funding etc.)
3. Feasibility and proposals of mutualisation between excellence RDI services and facilities among the partnership to satisfy the territorial needs of the medtech sector

Medtech RDI raises issues that are complex for regional authorities: it gathers many different concerns, that could be starting points for thematic workshops and learning. Thanks to the previous Joint Cross Analysis, we suggest to open the above 3 topics in order to integrate the following key issues

1. Efficiency of ecosystems in medtech
2. Efficiency and impact of policy instruments to support medtech sector, among which RDI infrastructures
3. Cooperation between partners, complementarities

1. Efficiency of ecosystems in medtech

Strategic issues

Economic development and weight of medtech: the medtech sector growth is obvious (high demand, good position of European companies, large market, increasing need of ICT in healthtech solutions…). Regions would like to take advantage of this opportunity for their companies. For those which are already specialised or strong (Limburg, Helsinki, BW) the momentum should be kept. For others, how to implement good policies for medtech without threatening other sectors? How to integrate these very specific policies among so many objectives? Although our project is focused on medtech, there are strong links with life sciences economy (pharma, biotech, genomics…) and more traditional sectors (mechanical engineering, materials, electronics…).

Knowledge based economy and role of medtech: many technologies are concerned. Universities and research organisations, even far from medtech initially, have developed initiatives to apply their basic or applied knowledge to the health sector. Therefore RDI policies are complex and multidimensional: each investment could lead to a stronger position in medtech (for instance investments done in materials, ICT, genomics, environmental topics), directly or undirectly, but also to an unsuccessful diversification. Most of regions recognise medtech as a strong asset to develop their knowledge based economy and increase their attractivity. The quality of transfer to economical world is therefore mandatory to transform knowledge in economic impact. How to organise such cooperation between sectors? How to define the most powerful technological enablers (as Silesia did) for medtech, but also for other sectors?

Implementation issues

Public-private partnerships at the regional level: from the State of Play, only one region shows a medtech ecosystem with the strong support of private sector, in particular for funding, governing and operating RDI infrastructures (Limburg). At the same time Limburg addresses this apparent strength with the corresponding weakness: public funds below critical boundary. The balance between public and private is particularly critical for the next years. How could regions find an efficient and streamlined process to share risks with companies and private investors to provide sustainable, excellent and highly specialised RDI facilities? How this works with the need to provide support to SMEs? How regions can leverage their investment together with national and international private funds related to RDI investment? For instance charities and private foundations are not quoted by regions as part of ecosystems, on the research and clinical side, although we know that private investment players are already very active in the process of start-up growth. Would it be possible to achieve this goal of positive PPPs for innovation in the framework of the next MFF (multiannual financial framework of EU)?

Efficiency of knowledge transfer: all partners have a strong commitment to research, on any form: research can be conducted by or/under supervision of a single major university (Pécs University in ST) or done by numerous research organisations (universities, clinical research, research institutes). One of the most frequent weakness is the ability of research stakeholders to transfer efficiently their knowledge to companies, especially SMEs. This process is at the core of regional policy instruments and should be analysed carefully during the visits. What are the right ingredients to enhance transferability of results? Difficult to answer, we miss some information about medtech infrastructures business models: how do they work, is it efficient, is it of easy access for SMEs? Do they even know the capacities of these regional infrastructures? How do researchers or students contribute to the technology transfer process?

Infrastructures: The issue of dedicated RDI infrastructures is raised only if the region is specialised in medtech. If not, any multidisciplinary or cross sectoral initiative can contribute to medtech economic performance with or without fully dedicated RDI infrastructure. There is a bias in our survey due to the difficult definition of infrastructure (see section 5.) However we could also question this statement: how sustainable the medtech sector would be in a region without dedicated physical infrastructures that would attract – in a triple helix process – investment and skills? The better example is Brightlands Campus in Maastricht, where political engagement took over the existing strengths. What would happen without any campus? Is the Campus the perfect and ideal infrastructure? Good practices from Limburg show that the campus is linked to Open Innovation good practices, and by consequence to many positive feedbacks from industry and international collaboration.

Internationalisation: there are 2 ways. The first goes through the scientific and medical networks. The second with the ability of companies to be good exporters. Both are complementary, but if there is no excellent tech transfer practice between research/science skills and economy, this international capacity will stay at the level of people, not GDP. On this point, the medtech sector raises very specific issues that are not yet fully integrated by regions: market acces in Europe is not unified, although the regulations are. Each country has its own tracks, reimbursement schemes and social insurance rules, as well as distribution chains. Any policy dedicated to internationalisation of existing medtech SMEs has to adapt to this specific market barriers. This point is definetly not developed by regions (no good practice on this chapter)

2. Efficiency of policy instruments towards medtech sector

2 unsolved issues not addressed by regions

Efficient public incentives and their economic impact: Policy instruments of all regions are oriented towards innovation, strengthening research capacities, technology transfer, collaborative projects, excellence research development, skills and education, clusters etc. Although all regions invest in these critical areas, assess and evaluate the money spent, it is still very difficult to evaluate the synergy effect brought by ecosystem "efficient" organisation. It makes it tricky to learn from mistakes in order to avoid to duplicate what has been somehow "unefficient".

No region reports as a strength its general public incentives or policy supporting measures, certainly because of a low level of knowledge of what is done by others, but mainly in absolute terms because of the difficulty to assess what is an efficient public incentive. To better discuss this critical issue for Interreg projects, it is necessary to figure out the main features of "efficient" policies and public incentives. How do we measure the real success? How do we define the most impactful measures? To what time scale should we evaluate the potential impact? What kind of impact?

Help SMEs to overcome the specific barriers of medtech sector: this is also like an unsolved concern, no region reports its specific environment as a strength to tackle this challenge, although it is clearly a key issue. Are regions well informed of the specific obstacles that medtech SMEs will meet during their innovation journey? Do they try to deliver specific support measures?

Social issues, especially healthcare burden: the capacity of regions to support the development and implementation of new healthcare solutions is also an important point. It's not all about technology and manufacturing and value and jobs. Important expectations exist to make use of local companies or local skills to implement specific solutions to take care of population, especially when it comes to ageing. Hospitals are obviously key stakeholders, but not always. Some university hospitals with strong research capacities are biased by their academic objectives, and smaller structures, dedicated to care, can also play a determinant role as "end-users" to challenge research and innovation on easier marketable solutions (vs implantable devices for instance); It is already the case for rehabilitation in several regions (Lombardia, Upper Silesia, ST). This point is not fully recognised by regions. It still lacks of coherence with the above points in terms of policies.

Digital Health: the converging process between digital technologies and healthcare sector brings many issues to be anticipated and managed in the RDI policies. First because existing positions can be threatened, even for leading companies, second because digital "smart, anything, everywhere" reinforces the urgent need to tackle some technical or regulatory issues such as cybersecurity, data ownership models, ethical issues and predictive purposes of early diagnostics. Due to its particular ICT specialisation, only Helsinki has raised this concern so far. Regions often consider that digital is related to e-health or telemedicine, for remote services or user-friendly apps. Actually the digital dimension goes far beyond this, through the abundance of data generated by genomics approaches, wearable devices etc. For instance frontiers with the well-being/wellness sector will blur: healthcare solutions might be provided by new intrants such as large digital companies which own or acquire personal data. This will deeply impact the medtech sector. Digitisation of manufacturing processes is however well understood in several regions with strong industrial background (BW, AuRA, Lom) as a general trend for the whole industry. In that sector, the health providers play a dominant role and incentives should be on the demand side, if we want to generate some growth from digital health solutions. Health providers at the regional level can obviously be a game changer. Innovative procurement is a first attempt, only Lombardy has developed a good practice about it.

Regulation: there is a very high pressure on medtech SMEs to comply to new European regulations, and this pressure might lessen their innovation capacities in the coming years. Helsinki, Aura and BW have clearly identified this key issue.

3. Cooperation between regions

European territorial cooperation: do we talk only about exchanging good practices, to learn and maybe to adapt a local implementation (that will be highly inspiring anyway), or imagining to create new and different added value thanks to the complexity of medtech ecosystems? All ingredients cannot be present in all regions for all reasons above, except maybe for the wealthiest. On the added value chain of players – from science idea to patient – how could these 8 regions penetrate in each other 's ecosystem without threatening what exists or is still fragile, to create value?

Four possibilities:

1. Cross experimentation of healthtech solutions, in the real world of care, not so developed so far. There are numerous possibilities to fight against medical deserts, initiatives related to telemedicine, assistive technologies, rehabilitation, monitoring of chronic diseases etc…This would not only help healthcare providers and mitigate the risks associated with experimentation, not so developed in good practices but also highly support SMEs that provide innovative solutions to answer to well identified needs. They would certainly have better knowledge of European markets thanks to limited deployment in various regions.
2. Cross educational projects targeting entrepreneurship, healthcare professionals and student programmes. AURA, Copenhagen, Upper Silesia, Helsinki can help other regions in providing ready to use programmes
3. Research staff exchange between regions to facilitate knowledge of local assets, dialogue and transfer of experience. To target SMEs and start-ups would really be an added value for the medtech sector.
4. Complementarity between manufacturing sub-contractors and first rank/second rank industry suppliers in each region, to gain efforts and time in qualifying and certifying the upstream chain, that is subject to scrutiny from regulation authorities. This supply chain is critical for market access. If regions could envisage a shared map of qualified suppliers and expertise in critical technologies/components for future medtech products and services, it would certainly help their companies. For instance, microfluidic platforms, or cybersecurity expertise related to medical devices (incl. software) are critical technologies.

These four are non-competitive areas where sooner or later, a strong economic impact may be expected to the benefit of all.

ANNEX – THE MEDTECH SECTOR: KEY FIGURES

Medtech4 Europe
Interreg Europe

Medical technology = medical devices

Products intended to perform a therapeutic or diagnostic action on human beings by physical means.

Include in-vitro medical devices - products which provide medically useful diagnostic information by examination of a specimen derived from the human body.

Source Medtech Europe

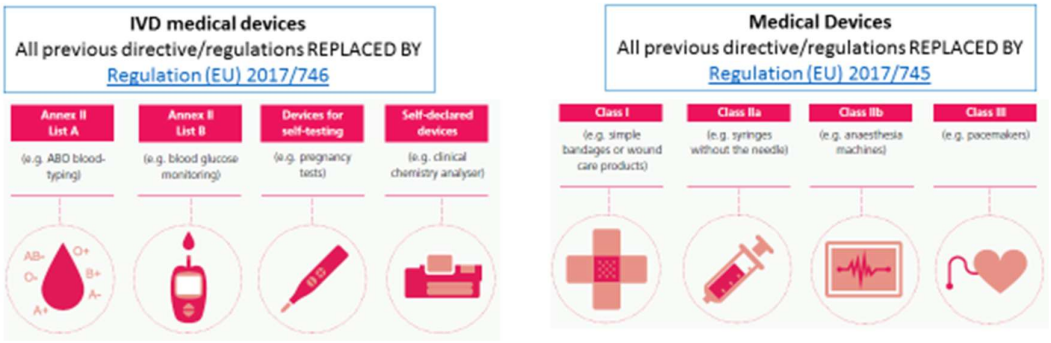
There are more than 500,000 medical technologies registered. These fall within 16 categories of products, as determined by the Global Medical Devices Nomenclature (GMDN) Agency[3]

Code	Classification	Example
01	Active implantable technology	Cardiac pacemakers, neurostimulators
02	Anesthetic respiratory technology	Oxygen mask, gas delivery unit, anesthesia breathing circuit
03	Dental Technology	Dentistry tools, alloys, resins, floss, brushes
04	Electromechanical medical technology	X-ray machine, laser, scanner
05	Hospital hardware	Hospital bed
06	In vitro diagnostic technology	Pregnancy test, genetic test, glucose strip
07	Non-active implantable technology	Hip or knee joint replacement, cardiac stent
08	Ophthalmic and optical technology	Spectacles, contact lenses, intraocular lenses, ophthalmoscope
09	Reusable instruments	Surgical instruments, rigid endoscopes, blood pressure cuffs, stethoscopes, skin electrodes
10	Single use technology	Syringes, needles, latex gloves, balloon catheters
11	Technical aids for disabled	Wheelchairs, walking frames, hearing aids
12	Diagnostic and therapeutic radiation technology	Radiotherapy units
13	Complementary therapy devices	Acupuncture needles/devices, bio-energy mapping systems/software, magnets, moxibustion devices, suction cups
14	Biological-derived devices	Biological hearth valves
15	Healthcare facility products and adaptations	Gas delivery systems
16	Laboratory equipment	Most IVD which are not reagents

Source Medtech Europe

A regulated market

In the European Union, medical technologies are tightly regulated by laws that govern the safety and performance of devices across their lifetime, pre- and post-market. Over the next few years, the sector will transition from being regulated under the current medical devices directives to two new regulations.

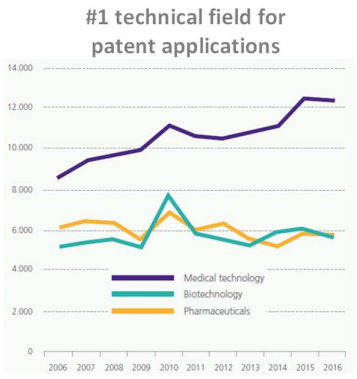


Source Medtech Europe

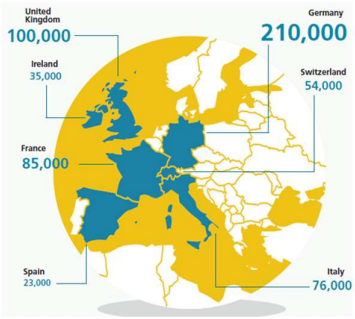
Application domains

Application domains *(Vanguard questionnaire 2016)*	Device areas *(Evaluate 2017)*	SNITEM (French Industrial association) *(2017)*
• IVD (In Vitro Diagnosis) • Medical Imaging • Connected health • Biomaterials & implants • Drug delivery • Orthopaedics • Medical textiles • Computer assisted medical intervention • HIFU • Other	• In Vitro Diagnostics IVD • Diagnostic Imaging • General and Plastic Surgery • General Hospital and Healthcare supply • Endoscopy • Drug delivery • Cardiology • Orthopedics • Ophtalmics • Dental • Wound management • Diabetic Care • Nephrology • Neurology • Ear Nose and Throat (ENT)	• Medical device for individual use • Medical device so-called equipment (including e-health) • IVD medical device

2016 - Key figures



Pharma 740 000

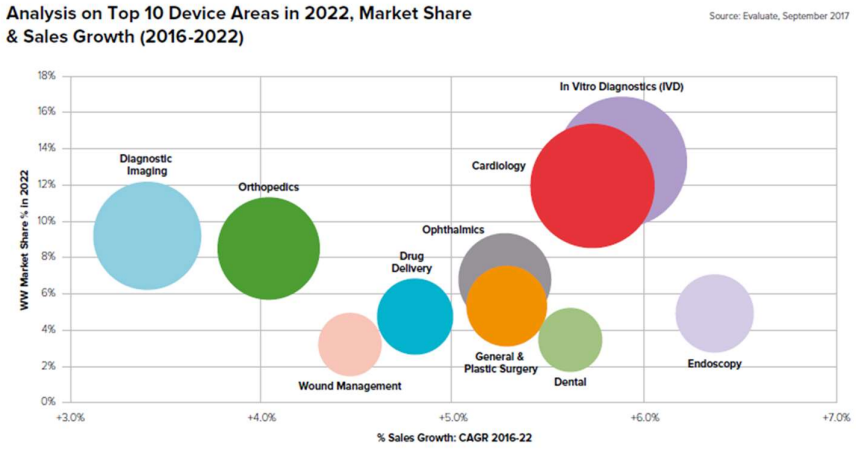


29% of global market

Source Medtech Europe

Market forecasts

Worldwide medtech sales forecast to grow by 5.1% to $522bn by 2022; in vitro diagnostics retains its number one spot in 2022



Medtech4 Europe
Interreg Europe

Top 15 device areas - worldwide medtech sales and forecasts

Rank	Device Area	WW Sales ($bn) 2016	2022	CAGR % Growth
1.	In Vitro Diagnostics (IVD)	49.4	**69.6**	+5.9%
2.	Cardiology	44.6	**62.3**	+5.7%
3.	Diagnostic Imaging	39.2	**48.0**	+3.4%
4.	Orthopedics	35.0	**44.4**	+4.0%
5.	Ophthalmics	26.0	**35.4**	+5.3%
6.	General & Plastic Surgery	20.4	**27.8**	+5.3%
7.	Endoscopy	17.8	**25.7**	+6.4%
8.	Drug Delivery	18.6	**24.6**	+4.8%
9.	Dental	12.8	**17.8**	+5.6%
10.	Wound Management	13.0	**16.9**	+4.5%
11.	Diabetic Care	11.0	**16.2**	+6.6%
12.	Nephrology	11.1	**14.6**	+4.6%
13.	General Hospital & Healthcare Supply	11.0	**12.8**	+2.5%
14.	Neurology	7.4	**11.6**	+7.8%
15.	Ear, Nose & Throat (ENT)	8.0	**11.1**	+5.5%
	Top 15	325.4	**438.6**	+5.1%
	Other	61.4	**83.3**	+5.2%
	Total WW Medtech Sales	386.8	**521.9**	+5.1%

End introduction