

Optimizing the impact of public policies in favour of research and innovation facilities in the field of medical technologies

**Medtech4
Europe**
Interreg Europe



Action Plan for the Region of Helsinki-Uusimaa

This Action Plan was generated by the Finnish project partner Helsinki-Uusimaa Regional Council, in 2020.



Helsinki-Uusimaa
Regional Council

VISMA Sign
www.vismasign.com

Part I – General information

Project: Medtech4 Europe

Partner organisation concerned: Helsinki-Uusimaa Regional Council

Country: Finland

NUTS2 region: Helsinki-Uusimaa FI1B

Contact person: Heikki Kallasvaara

Email address: heikki.kallasvaara@uudenmaanliitto.fi

Phone number: +358 40 1616794

1.1. The Medtech4 Europe project

The Medtech4 Europe project, which is implemented within the framework of the INTERREG Europe Program, aims to strengthen the Research, Development and Innovation (RDI) ecosystem in favor of the innovative medical technology industry, in order to generate economic growth, create jobs and provide solutions for patients and healthcare systems.

In the course of the project, the regional partners exchange experiences to identify best practices, and from those learnings, the partners create Action Plans in order to implement new solutions to improve their regional policies.

The project is implemented by local regional partners in France, Germany, the Netherlands, Poland, Hungary, Denmark, and Finland. This Action Plan was generated by the Finnish project partner Helsinki-Uusimaa Regional Council.

1.2. What is Medtech?

This action plan addresses a sector “Medical technology” that covers many different products, all intended to perform a therapeutic or diagnostic action on human beings to improve health. Medical technology is a regulated EU sector (2017/745, 2017/746) and covers:

- Medical devices (MDs) which are products, services or solutions that prevent, diagnose, monitor, treat and care for human beings by physical means
- In vitro diagnostics (IVDs) which are non-invasive tests used on biological samples (for example blood, urine or tissues) to determine the status of one’s health
- Tools and services for Digital Health and Care can be included, depending on sectorial definition and regulatory status

Medical technology is used to diagnose, prevent, monitor, treat or alleviate a disease or injury. In addition to the above, the Medtech4Europe project will also consider the link to Enabling technologies (ICT, manufacturing, materials...) that contribute to the improvement of MDs and IVDs.

1.3. Medtech is highly regulated to ensure safety and efficacy

The EU has a competitive and innovative medical device sector, characterized by the active role of small and medium-sized enterprises. It is supported by a regulatory framework that aims to ensure the smooth functioning of the internal market, taking as a base a high level of protection of health for patients, users and third parties. The European regulatory framework ensures the safety and efficacy of medical devices and facilitates patients' access to devices in the European market.

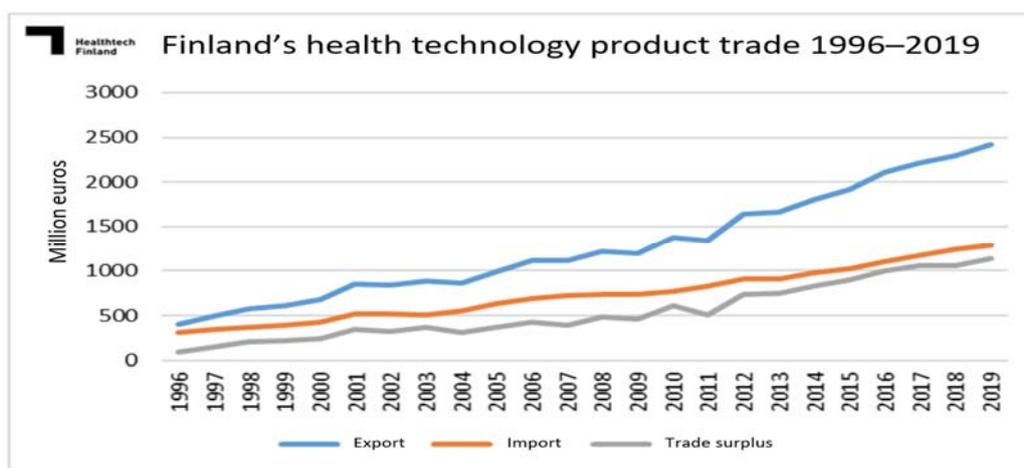
The medical device sector is essential to the provision of healthcare to citizens and is an important player in both the European and global economy. Medical devices and In Vitro Diagnostic medical devices (IVDs) have a fundamental role in saving lives by providing innovative healthcare solutions for the diagnosis, prevention, monitoring, prediction, prognosis, treatment or alleviation of disease. There are over 500 000 types of medical devices and IVDs on the EU market. Examples of medical devices are sticking plasters, contact lenses, X-ray machines, pacemakers, breast implants, software apps and hip replacements. IVDs are used to perform tests on samples, and examples include HIV blood tests, pregnancy tests and blood sugar monitoring systems for diabetics.

To align with sectoral developments over the last 20 years, the EU has substantially revised the legal framework governing medical devices and in-vitro diagnostics. The need to establish a robust, transparent and sustainable regulatory framework, ensuring a high level of safety and health whilst supporting innovation was recognized as a key priority. Two new regulations on medical devices and in vitro diagnostic medical devices were adopted by the Council and the Parliament and entered into force in May 2017. They will progressively replace the existing directives after a transition period.

In this action plan we address the urgent need for assistance and mentoring of medtech's SME's, startups and scaleups, who may not have the adequate resources to comply with the renewed regulatory framework.

1.4. The need for ecosystem thinking and cross-sectional collaboration in Medtech

Health technology is one of the fastest growing high-tech export sectors in Finland. In 2018 the value of health technology product exports from Finland grew by 3.4 % over 2017, and in 2019, the growth continued strongly, expanding 5.7 % from 2018. In the past 20 years, exports by the sector have increased five-fold with 12 billion euros trade surplus (Figure below, Source: Healthtech Finland 2020.)



Both healthcare and medtech innovation ecosystems in Finland and in the Helsinki-Uusimaa region are active and diverse, with multiple actors in the field. Unfortunately though, the organizations and activities are often fragmented and work separately or at least, not in harmony. We have professional research facilities, medical experts & quality hospitals, great startup communities, business advisory services, entrepreneurial, medical, and life-science educational programs, living labs and test-bed environments, private life science and medtech companies, and expertise in the commercialization of research, but these are not optimally working together in order to unleash the full potential of the networks.

For example, test-bed opportunities in Finnish hospitals work under different operators, feasibility rules and even on different pricings. (A systematic national approach to test-bed services in Finland is currently under development, led by Business Finland.) Also, Finland has (and is currently founding more) national specialty centers focusing on different medical (disease) areas, similar to Denmark, but unlike Trial Nation in Denmark, we don't yet have one point-of-access to these networks and services.

In addition to expertise in the areas of medicine and life-sciences, Finland also has great expertise and talent in data science, AI and engineering, but the experts from these two fields are too often separated and not working together as much as they could. This might be due to a number of reasons, for example the different cultures of the two fields; software development can be seen as 'fast', 'agile' and 'disruptive', when the medical industry is highly regulated and often slow to develop, i.e. the complete opposite. As the health and medtech industries are going more and more digital each day, we need to support and endorse such cross-sectional and multiprofessional thinking and working, with the goal of bringing together diverse sets of innovation skills and technological backgrounds.

From the learnings of the project, we have identified the tangible need to tackle these silos, which are causing bottlenecks to co-creation and collaboration between the various actors in the medtech scene. Improved coordination and better holistic view of collaboration opportunities among the medtech field is needed.

Better organization and co-operation in the field would not only minimize overlapping initiatives and work, but would also grow the business and create better health for the world more efficiently.

Part II – Policy Context in the Helsinki-Uusimaa Region

The Action Plan aims to impact: The action 4.1 seeks to increase the possibilities and efficacy of ERDF and the RIS3 in identifying and fostering cross-linking and co-creation between the sometimes siloed regional sub-ecosystems and networks in the field of medical technology. The action 4.2. seeks to improve the awareness of and capability to implement the substantially modified or totally new requirements demanded by the new EU medical devices (MDR) and in vitro diagnostic medical devices (IVDR) regulations. This need among especially start-ups and SMEs is not restricted to the Helsinki-Uusimaa Region nor to Finland only, but is common for all EU member states.

- Investment for Growth and Jobs programme
- European Territorial Cooperation (Interreg) programme
- Other regional development policy instrument

Name of the policy instrument(s) addressed:

- **'Sustainable growth and jobs 2014 - 2020 – Finland's structural funds programme'**
- **Helsinki-Uusimaa Regional Smart Specialisation Strategy**

Further details on the policy context and the way the action plan should contribute to improve the policy instrument:

Finland may claim to be a small giant in health technology: its health tech exports account for more than 95 % of its total health tech manufacturing output. In terms of medical technology, most activity and added value is generated in the southern Regions of Uusimaa and Finland Proper by both multinationals and domestic owned companies. Vibrant hotspots also exist around University City / University Hospital -combinations in Tampere, Oulu and Kuopio. Finland has for decades been one of the few countries that export significantly more health technology than they import. Finnish health tech solutions are not only developed but largely also manufactured in Finland.

Policywise, Business Finland (formerly Tekes) has been the agency providing long term investment in health technologies, lately though with decreased budget allocations, especially in the early phases of the innovation cycle. Business Finland has promoted national programmes on national Health Sector Growth Strategy for Research and Innovation Activities, Roadmap for 2016–2018. Two major programmes are running: The **Smart Life Finland Programme**, aims to promote personal, real-time and intelligent health and wellbeing solutions that are accessible anywhere and at any time. The **Personalized Medicine Programme** supports innovation and top-level research and creates new business around personalized healthcare areas, promotes growth and renews and creates new business life. The program also helps growth companies to raise venture capital and R&D funding.

Technological strengths in the Uusimaa Region range from monitoring, intensive care and imaging equipment to in vitro diagnostics. Particularly monitoring, electromedical and diagnostic imaging solutions require a profound understanding of patient physiology, on the one hand, and user requirements, on the other. This understanding takes time to build, and it is certainly one of the assets in the Uusimaa Region. A good part of the Healthtech Finland Member companies come from the Helsinki-Uusimaa Region, most having headquarters in the metropolitan Cities of Helsinki, Espoo and Vantaa.

Furthermore, this action plan fosters the possibilities of local healthcare startups' ability to combine different technologies and insight in clinical fields in novel ways, often relying on skills in software design and bioinformatics within the strict regulatory environment required by the new EU regulations and may turn a potential regulatory barrier into a competitive edge globally.

Part III – DETAILS OF THE ACTIONS ENVISAGED

3.1. ACTION 1: Improve and assess medtech innovation ecosystems taking advantage of the digital transition in healthcare

3.1.1. Learnings from the Medtech4 Europe project

From the learnings gained during project study visits and of the good practices identified in the project, this Action Plan adapts elements from the Brightlands Maastricht Health Campus (NL), the Copenhagen Health Ecosystem, especially Trial Nation (DK) and the CleverHealth Network in Helsinki (FI). We also want to note the impressive and inspiring Medtech4Health, one of the national Strategic Innovation Programmes of Sweden.

Learnings from Brightlands Maastricht Health Campus (Study Visit)

Brightlands Maastricht Health Campus is an open innovation community in Limburg, in the Netherlands. At Brightlands, over 9500 innovative entrepreneurs, researchers, and students work together with medical doctors on innovations in healthcare, medicine and life sciences. At the campus, (bio) medical research & education is combined with business with the goal of valorization of research results into products, processes, or services. In other words, at Brightlands, there are no borders between science and entrepreneurship.

The campus provides access to state-of-the-art R&D facilities, meeting spaces and offices, networking events, in-depth business support, an international network of experts, and sometimes even funding, to its community & companies arising from the campus.

For startups, the Brightlands Maastricht Health Campus offers also the The MedLim start-up program, which is unique as it provides support by world class experts in the field of business, medical device development, regulatory, IP & financing. The MedLim start-up program has been co-created in a unique partnership between Medtronic, Brightlands and LIOF (the regional development company of the Province of Limburg). These founding partners together provide unique and profound experience and knowledge to help start-ups: Medtronic has great knowledge regarding innovations and the treatment of physical conditions and has a relevant network of medical

professionals and key opinion leaders, the Maastricht University actively facilitates the development of innovations related to health and life sciences through the Brightlands Maastricht Health Campus, and LIOF has a lot of experience in investing in medical start-ups and strengthening the economic structure of the Limburg region.

The diverse community and the professional facilities and experts of the campus are what make the Brightlands such a unique place to start a company, innovate, or grow an existing company or organization. And for the next generation of experts, the campus offers numerous education programs, on all higher education levels. The education programs are built together with the business community and research institutes, in order for the students to get a sense of real working life challenges and processes already during their education.

The ecosystem is built on a Quadruple Helix-model of government, businesses, and educational institutions. The Campus itself is a company and has three shareholders: the Province of Limburg, Maastricht University, and Maastricht University Medical Center+. In addition, in the community, there are 120 active companies based at the campus and research programs embedded in 6 schools and 2 institutes. The co-creation between companies, knowledge institutes, and the government is essential to achieving innovations.

LEARNING: The Brightlands Maastricht Health Campus is a great example of a Quadruple Helix-model formed by the co-operation of government, businesses, and educational institutions. In addition to expediting the valorization of research results into products, this model also gives the students the opportunity to experience real working life challenges and processes already during their education. In other words, this model also ensures the supply of future talent for the medtech industry.

Learnings from Trial Nation in Copenhagen (Study Visit)

Trial Nation in Copenhagen is a great example of a well coordinated, national entry point for global companies, patient organisations and clinical researchers wishing to conduct clinical trials in Denmark. It is also a great example of a strong and continuous governmental support of the life science sector; the Trial Nation is funded by the Ministry of Industry, Business and Financial Affairs, The Ministry of Health and the five Regions in Denmark.

Private life science companies can apply for Trial Nation membership and gain easy access to leading hospital departments in seven national specialty centers and networks within oncology, haematology, dermatology, pediatrics, respiratory diseases, infectious diseases and dementia. Trial Nation also provides legal support for the companies, and access to a unified legal network of the healthcare regions in Denmark, which enables efficient negotiation of contracts relating to clinical trials. In addition, Trial Nation offers a quick and efficient feasibility process for companies and guarantees a streamlined assessment and start-up process for clinical trials. In other words, Trial Nation provides the industry with a single point of contact for national evaluation of any feasibility inquiries for clinical trials.

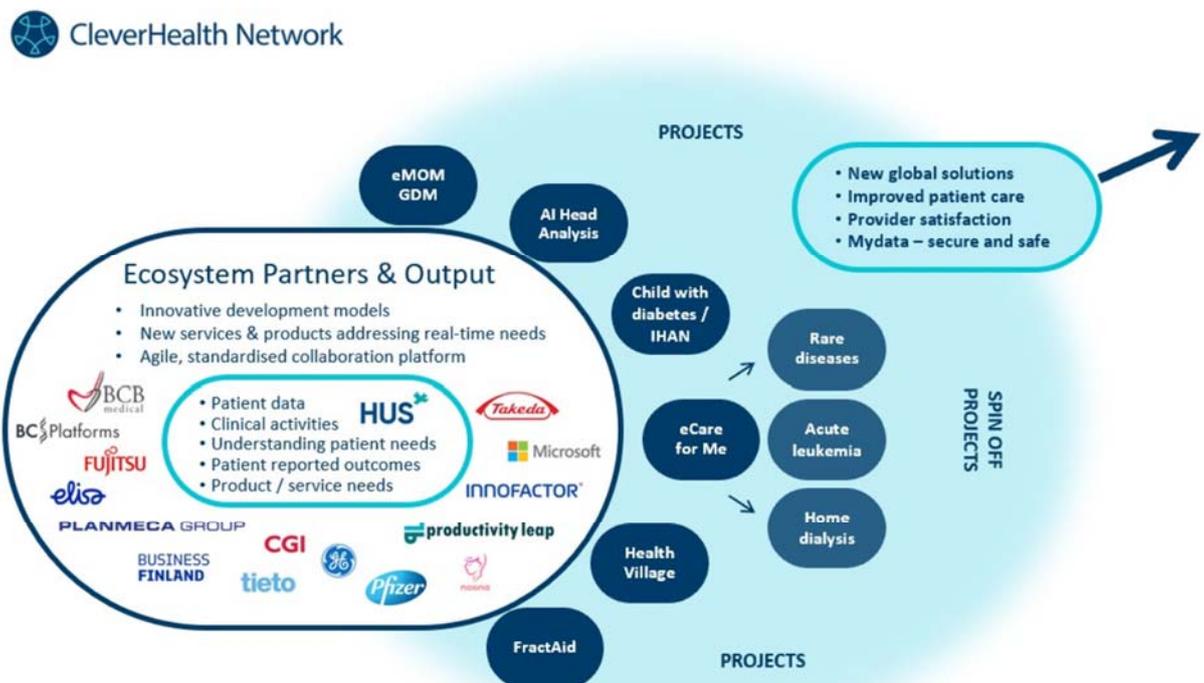
In a nutshell, Trial Nation co-operates with all the stakeholders of clinical trials; companies, hospitals, (clinical) scientists and patient networks, and the organization provides a national approach to increasing performance in clinical trials in Denmark.

LEARNING: Trial Nation offers a great example of a national approach and a single point of contact to clinical trials built together with national clinical specialty centers, public healthcare regions, patient organizations and private companies.

Learnings from CleverHealth Network

CleverHealth Network is a medical technology ecosystem in Finland in which companies and healthcare professionals develop better treatment and technological (software) solutions for healthcare.

In the CleverHealth Network, clinical professionals from the Helsinki University Hospital (HUS), top researchers from universities, and experts from small-to-large businesses from different technological fields develop new solutions together in response to well-defined clinical challenges. CleverHealth also supports SMEs in developing and successfully exporting their products. The network bases its products and service innovations on their extensive “health data lake”, a large mass of data built and analyzed by HUS.



For example, in the AI Head Analysis project, HUS, Planmeca and CGI are developing a clinically significant AI-based image analysis tool for physicians for more exact cerebral hemorrhage diagnostics and better care for patients. HUS Helsinki University Hospital has a digital archive of over 16 million scans, and these anonymous images can be utilized in the development work. In addition, the physicians and nurses from HUS provide their clinical expertise to the project, and Finnish technology companies provide their knowledge in artificial intelligence and image analysis. Interpreting the results of head imaging is demanding and requires experience. The AI and its applications provide support the physician can lean on during decision making, but it does not remove the significance of the human aspect (the CT scan results are still always analyzed by a physician). The results of the project are very promising; the AI-based algorithm identifies cerebral hemorrhage in the subarachnoid space with outstanding precision, but the ambitious work still continues.

The Clever Health Network is coordinated by HUS, with the help of the consulting company Spinverse, and funded by Business Finland & participating member companies. After the initial funding and launch in 2017, the ecosystem proved to be successful and was granted a significant amount of additional funding by Business Finland in June 2019.

LEARNING: The CleverHealth Network has proven that the cross-sectional co-operation between public healthcare providers, university research institutes and private companies in medtech is possible also in Finland and can be very successful. The co-operation model could be adapted also to developing medical devices, and expanded.

Learnings from the Medtech4Health programme (SE)

Medtech4Health Programme was designed to help fill the gaps in Sweden's current medtech innovation system. The patient, the healthcare service and the business community formulate the problems and the programme's dual focus is patient involvement in their own care and achieving a sustainable care and medical services system. Presently, the programme brings together Sweden's medtech industry, administrative regions and county councils, patient organisations, research institutes and universities in six Swedish regions. The Programme's several regional sections, Nodes, could well be piloted in the Helsinki- Uusimaa Region. Whilst Medtech4Health actors were not part of the Medtech4 Europe -project, both Helsinki and Copenhagen capital regions could clearly benefit from this well implemented, quadruple helix promoting resourceful project.

LEARNING: The Medtech4Health Programme is a great example of how public, private, research, academic and patient organizations can work together, showing how the helix approach can be implemented.

3.1.2. Nature of the action

Organized coordination of medical innovation activities in the region is needed in order to unleash the whole potential of existing expertise, insight, activities and organizational strengths.

Public Funding and policies should be directed into developing coordinated collaboration across various knowledge hubs, organisations, networks and stakeholders in the field of medical innovations.

The collaboration supporting interventions should address the relatively narrow development areas within the core medical technologies, instead of a wider health technology advancement. [Overarching system level development is also needed, but for this cohesion policy instruments in the relatively developed Uusimaa Region would not be sufficient.] Priority should be given to measures and projects bringing together diverse sets of innovation skills and technological backgrounds, enabling multiprofessional teaming experiences in medtech relevant domains, including electronics, biophysics and clinical disciplines. Further policy narrowing could be based on existing regional clinical strengths, for example in the fields of intensive care, oncology, CNS and dental/craniofacial imaging, and related diagnostics and therapy.

As multiple national speciality centers are currently under development in Finland, their development and strategies should go hand-in-hand with future policy measures, in order to enable the optimal environment, network and atmosphere for future medtech innovations and SME's.

3.1.3. Stakeholders involved

Actor	Role	Public/ Private
Helsinki-Uusimaa Regional Council	The intermediate body for the ERDF funds in Southern Finland	Public
National innovation & development agencies, Business Finland, Sitra (the Finnish Innovation Fund)	Providing access to business advisory services and funding, possibly the role of a coordinator of the ecosystem	Public
Ministry of Economic Affairs and Employment of Finland	Funding and expertise	Public
The National Institute of Health and Welfare	Providing access to data	Public
Healthcare providers	Providing healthcare professionals, medical data & expertise, connection to patients	Public/Private
Companies operating in healthcare	Providing their expertise and international networks	Private
SMEs & startups	Commercialization of innovations, with the help of advisors	Private
Startup communities	Community, access to SMEs & startups	Public/NGO
(Higher) education institutions	Education of future experts, employees for SMEs & startups	Public
Research institutes	Providing researchers and research facilities	Public

Educational institutes	Education of future experts and innovators	Public/Private
Testing facilities, Living labs & Test-beds	Providing validation possibilities	Public/Private
Regulatory authorities and experts	Providing certification, support, training and advise on medical device regulations	Public/Private
Investors	Funding for SMEs & startups	Private
Patient organizations	Providing connection to patients	NGOs

3.1.4. Timeframe, costs & funding sources

Depending on the funding availability, the policy measures suggested here could be carried out in 2 to 4 years. The ERDF managers can take these into account in last calls of the programming period, especially if the COVID19 -situation allows the ROP continuation. A typical ERDF project would be carried out in 24 months and would be in the magnitude of 100.000 to 200.000 €. RIS3 -based actions would be smaller, more agile and typically piloting new collaboration platforms.

3.2. ACTION 2: Support measures to SMEs and Start-ups to take advantage of the new regulatory context

3.2.1 Learnings from the project related to regulation

For a good reason, medtech is one of the most intensively regulated industrial sectors. A transition towards new regulations has been launched. The medtech community, industry, end-users and authorities alike support the goals of the new regulations – patient safety and reliability must come first. The actors have the right to expect that a workable implementation can be ensured, without adversely affecting time to market (and thus patient access).

The Medical Devices Regulation 2017/745 (MDR) and the in vitro Diagnostic Medical Devices Regulation 2017/746 (IVDR) significantly strengthen the decades old directive -based framework.

All medtech companies are impacted by the MDR or IVDR, and due to the significant resources needed for compliance with these regulations, smaller companies may struggle the most to transition to the new regime. Medtech4Europe project discussed options for policy measures helping especially startups, scaleups and SME´s to comply with the new demands. We suggest that at least to some degree, the adverse effects of the resource hungry safety policies could be mitigated by cohesion policy policies and measures.

3.2.2. Proposed Action

Background to the proposed action

Medical devices are critical for human healthcare. It is, therefore, totally understandable that the society strongly regulates both the development and manufacturing of the medical devices as well

as their use during the post-market phase. The products must be safe and fit for their intended medical use. The regulatory framework is thus complex and must be thoroughly interpreted and implemented not only at the medical device product level but also at the company level. E.g. the new EU MDR and IVDR have increased demands on risk classification, general safety and performance requirements, clinical evaluation and post-market surveillance as well as on the requirement of a quality management system based on the stringent ISO 13485:2016. As a significant part of the products are exported outside EU, not only the EU regulations must be

Not a single early stage medtech company or invention should fail due to lack of support to comply

considered but also the global regulations related to each country to which the products are exported. The new EU regulations, MDR and IVDR, are substantially more demanding than the previous directives, but are in line with global harmonization efforts. Compliance with the new regulations is, therefore, also enhancing the competitiveness of the EU medtech industry as well as it is increasing patient safety and device efficacy. However, the short remaining transition period in comparison with the considerably increased requirements are difficult to cope with for SMEs. The proposed actions seek to improve the awareness of and capability to implement the new EU regulations by SMEs. Eventually, the actions addressed in this action 4.2. aim to improve the global competitiveness of the EU medical device industry by removing some critical regulatory trade barriers.

Novel or enhanced mechanisms must be developed to effectively support SME's awareness to fully take into account regulatory requirements early enough during the product development of medical devices. The mechanisms must also support the medtech companies' capability to interpret and implement these regulations including not only product related requirements but also the demands on establishing a quality management system compliant with ISO 13485:2016. If a SME or a start-up company becomes aware of the demands only in later stages of the product development process, it means in practice that a significant part of the development work must be redone. This both prolongs considerably, may be 1-2 years, the time to market and constitutes a considerable economical risk as it increases costs and use of human resources.

Specific components of the Action 2 are:

Activities to influence on the following actors so that they improve information to the start-up companies about the relevance to implement the regulatory requirements as early as possible of the product development cycles:

- National Competent Authorities and Notified Bodies
- Governmental bodies and e.g, Science Park type organizations that are supporting the development of start-up companies and/or financing of specific development projects
- Business angels and other financial actors

The aim is to foster activities creating mechanisms and channels for efficient and timely information about new or modified regulatory requirements, tightly linked with wider understanding about their content and relevance. Sufficiently comprehensive training programs on a regional or national level are needed, based on common training material created on the EU level. The mechanisms and instruments must ensure that the SME's are able to interpret and implement the MDR or IVDR and their links to harmonized standards, but also their capability to continuously monitor, interpret and implement emerging guidance documents, possible implementing and delegated acts and possible common technical specifications.

Ideally, an educational program should be created, to ensure the availability and competence of Persons Responsible for Regulatory Compliance (PRCC). According to Article 15 in both the MDR and IVDR, medtech manufacturers "shall have available within their organisation at least one person responsible for regulatory compliance who possesses the requisite expertise in the field of medical devices". This person must have certain qualifications and as the PRCC is a key expert, this person must in practice have the knowledge of applicable regulations, their interpretations and must also be able to ensure that they are implemented and maintained.

Public support for medtech companies, especially for SMEs, should be made available to develop a comprehensive quality management system (QMS) which also captures all relevant reference to applicable regulatory requirements. It is critical that implementing this QMS is initiated early enough to enhance both an effective management of the innovative process and that regulatory requirements are correctly taken into account throughout this process. Lack of public investment, both economic and know-how, in this aspect weakens the European medtech SME's and slows down the innovativeness, growth and employment in the sector. Non-conformity to QMS requirements set forth in the applicable ISO 13485 standard may constitute an absolute trade barrier both for the EU CE-marking and for approaching the global market.

The quality management system requirements contain multiple extra requirements specific for the medtech industry. Therefore, the quite common assumption that developing a QMS is only a normal business development effort is faulty and devastating. The QMS for medtech companies must be compliant with ISO 13485, which is far more demanding and capacity-binding than the QMS standard, which is relevant for other kind of companies. The ISO 13485 is created "for regulatory purposes". In practice, a medtech company is expected to build all relevant regulatory requirements, that are demanded by the EU MDR or EU IVDR, into the quality management system. In case the company has a global approach, the regulatory requirements of each non-EU country must also be honored. Consequently, the lack of QMS, compliant with all regulatory requirements, is a true trade barrier, whereas an early enough adopted QMS approach is enhancing market entrance and the competitiveness of European medtech companies.

3.2.3. Timeframe, costs & funding sources

Depending on the funding availability, the policy measures suggested here could be carried out in 2 to 3 years. The ERDF managers can take these into account in last calls of the programming period, especially if the COVID19 -situation allows the ROP continuation. A typical ERDF project would be carried out in 24 months and would be in the magnitude of 50.000 to 100.000 €. RIS3 -based piloting actions would be shorter and more targeted.

3.3. Proposed Action: Fostering and coordinating Health Technology initiatives in line with the Helsinki-Uusimaa Region Smart Specialization Strategy

3.3.1 Relevance to the Project

The relevance of the Action to the the Medtech4Europe project lies i) in the broad awareness of the MedTech sector's European wide strengths, made visible by all partners and links to wider stakeholders that the projects opened for us and ii) in the insight and understanding of the fundamentally important public-private collaboration on the highly regulated MedTech sector.

3.3.2 Nature of the action

Helsinki-Uusimaa Regional Council has updated its S3 strategies in early 2020. Under the theme for *Industrial Modernisation and Innovative Services*, the strategy now recognizes the major role medtech sector and the broader health technology ecosystem plays in the Regions's economy with a specific reference, allowing medtech -related projects to be funded.

Digitalisation helps service-oriented models and decentralised healthcare to cut healthcare costs. The global digital health market is valued at ca 100 billion euros and is expected to grow significantly during 2021-2027 . Digital health is one cornerstone in managing the COVID-19 pandemic and health systems have changed more rapidly during the last months than in past years. By nature digitalisation is highly innovative and will change the way diseases are diagnosed, treated, prevented and monitored. This transformation, if adequately and wisely fostered, leads to better efficacy and impact of european health care systems and also offers cost containment possibilities.

The ERDF and the ESR are currently managed separately. Medtech sector would benefit from coordination between the two, as common related call objectives are identified and launched.

Stakeholders, will be more closely integrated into the medtech ecosystem development:
The Regional Management Committee: Supervision on RIS3 measures, synergy aspects;
Health Capital Helsinki Network: Networking measures and ecosystem building.

3.2.3. Timeframe, costs & funding sources

The benefits of this action and the underlying policy change on RIS3 are likely to exceed the current programming period. Within the Region, RIS3 will form a bridge between the 2014-2020 and the 2021-2027 ROP's.

The ERDF continuation measures, like the REACT -funding, are viable resources for this action. As the COVID-19 mitigation heavily relies on medical technology and diagnostics, this specific and severe pandemic challenge is likely to receive additional funding from various sources. Cost estimates can only be made when continuation measures and budget allocations are decided upon.

Medtech4 Europe - Optimizing the impact of public policies in favour of research and innovation facilities in the field of medical technologies

Action Plan for the Region of Helsinki-Uusimaa

Date: 2.2.2021

For the Helsinki Uusimaa Regional Council

e-signed

Ossi Savolainen, Regional Mayor

SIGNATURES**ALLEKIRJOITUKSET****UNDERSKRIFTER****SIGNATURER****UNDERSKRIFTER**

This documents contains 15 pages before this page

Dokumentet inneholder 15 sider før denne siden

Tämä asiakirja sisältää 15 sivua ennen tätä sivua

Dette dokument indeholder 15 sider før denne side

Detta dokument inneholder 15 sidor före denna sida

authority to sign

representative

custodial

asemavaltuus

nimenkirjoitusoikeus

huoltaja/edunvalvoja

ställningsfullmakt

firmateckningsrätt

förvaltare

autoritet til å signere

representant

foresatte/verge

myndighed til at underskrive

repræsentant

frihedsberøvende