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# Action Plan

**Cluster Techforlife**

## PART I – GENERAL INFORMATION

Project: Medtech4Europe

Partner organisation: Clustert Techforlife (ITA)

Other partner organisations involved (if relevant): Lombardy Region

Country: Italy

NUTS1 region: Lombardy-IT (IT25)

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## PART II – POLICY CONTEXT

- The Action Plan aims to impact:
- Investment for Growth and Jobs programme
  - European Territorial Cooperation programme
  - Other regional development policy instrument

Name of the policy instrument addressed: **ERDF Regional Operational Programme**

### Regional context

Lombardy has one of the strongest GDP PPS per capita of Lombardy and is the second richest region in Italy after South Tyrol, with a GDP per capita about 30% higher than the national and the EU average.

The economy of Lombardy is characterised by a wide variety of industries ranging from traditional sectors, such as agriculture and livestock to heavy and light industries. As the second quarter of 2020, in Lombardy there were 3036 start-ups (the highest value in Italy), representing 27.1% of total start-ups in Italy. In 2020, almost the 40% of the total firms of the region are based in Milan and its province, and the main sectors are: mechanical, electronics, metallurgy, textiles, chemicals and petrochemicals, pharmaceuticals, food, publishing, footwear and furniture. The service sector is also very well developed and mostly related to international trade and financial services.

Lombardy's knowledge-based system is extremely complex, specializes in a range of technical and scientific disciplines and includes skills and research groups of international ranking. In Lombardy there are 14 academic institutions and several top-ranking public and private research centers. 36 entities provide business accelerator / incubator services with over 200 start-ups.

The private R&D expenditure of Lombardy is one of the highest in the Italian economy (78% against a national average of 58%). The private R&D expenditure was concentrated, over the years, in health, energy and environment, advanced manufacturing, agrifood and ICT. The large private investment is paired with a great participation in European projects fundings which sees an SMEs participation of 53%, the highest in Italy.

The Lombardy Regional Administration (Directorate General Research, Innovation, University, Export and Internationalization) plays a central role in designing/implementing the RTDI policy. All representatives of the innovation ecosystem are involved in defining the technological pathways: representatives of the companies and research organizations, through Cluster Organizations (nine Lombardy-based technological clusters: life sciences; smart communities technology; living environment technology; aerospace; agri-food; green chemistry; energy, cleantech and sustainable building; smart factory; mobility) and specific sectoral working groups too.

### **MedTech in Lombardy**

Medtech represents roughly the 16% of the Regional Investments in the Research and Development field, with 286,1 Million Euros in the last 6 years and being the most relevant Specialization area of the ERDF Regional Operational Programme, which covers for the 51% of the total investments. The rest of the investments come from National assets (for the 19%) as well as from Europe Horizon 2020 program (30%).

The major topics of interests in the Medtech sector within the region are as follows:

- Orthoses, prosthesis and implantable devices
- Medical Robotics, biomedical instruments and products
- Alternative drug delivery systems
- Assistive Technologies of the disabled and the elderly
- Intelligent clinical information management
- Bioinformatics, in silico modelling and simulation
- Personal health, preventive healthcare, mobile health
- Medical imaging technologies
- Early diagnosis tools, Point-of-Care (PoC) testing

The Growth and Job Program of the ERDF Regional Operational Programme in the 2014-2020 time frame was funded with 970,4 Million euros which came from Lombardy Region for roughly 15% of the expenses. The 36% of these expenses were allocated in the First Axis, to empower Research, Innovation and the technical development of the Region, for a total of 349.2 Million Euros that were used within the Smart Specialization Strategy (S3).

The Third Axis has also its relevance with respect to the Project, being focused on increasing SMEs competitiveness with 30% of ERDF Regional Operational Programme economic resources.

### **Actions addressed in this action plan**

This action plan addressed the Medical Technology sectors, comprising a wide variety of products, services and which involves stakeholders that range from SMEs, to University and Research Organization as well as Clinical Centres.

In order to strengthen the Lombardy ecosystem, taking into consideration the lessons learned withing the Medtech4Europe project, this action plans aims at:

- Improving technological transfer, facilitating SMEs in reaching the marker with Innovative technologies and services
- Increasing ERDF funding for the SMEs and Research Organizations that operate in the medtech sector.
- Increasing the efficacy and effectiveness of the ERDF funding in Lombardy, assuring that research project reach the market for medical devices.
- Increase the presence of Lombardy within the international medtech networks, creating strong relations between other regions with similar or complementary research interests.
- Promoting a strategic collaboration with the province of Limburg (NL), as a follow up of the relationship established within the projetc, so to jointly identify appropriate connections in the respective ERDF Operational Programmes (e.g. as for transnational activities) as well as other relevant EU Programmes

## PART III – DETAILS OF THE ACTIONS ENVISAGED

### ACTION 1

Name of the action: **Clinical trials competence Centre**

#### 1. Relevance to the project

In many occasions, throughout the course of multiple stakeholders' meetings, one of the most recurrent themes and problems that projects partners were experiencing in their region was the difficulty in developing and accessing clinical studies. This problem, which is present also in the Lombardy Region and which will become even more central in the next years, finds its roots in a lack of connection and cooperation between the different actors that contribute to the medtech sector. In order to facilitate this process, it's necessary that researchers, universities, companies, clinicians and policy makers work together in order to push devices, services and new technologies to reach the market.

During the first phase of the project, the main occasions in which the need to strengthen the technological transfer through the empowerment of a solid and reliable clinical trial process have been the following:

1. During the Stuttgart visit in November 2018, some of the Good practices presented (i.e. "Trail Nation") raised the discussion regarding clinical trials, their effectiveness and how to improve it.
2. The Workshop on clinic-friendly environments in Maastricht, during the visit in March 2019
3. In February 2020, during the visit in Copenhagen, during which the topic of "Trial Nation" was largely presented.

#### 2. Nature of the action

Create a Virtual competence centre in Lombardy on Technological Transfer and Clinical Trials based upon the already existing technological infrastructures from Lombardy Region (Open Innovation platform). Through the Competence Centre, Research and Innovation in Lombardy Region will be boosted, facilitating the access to clinical trials from SMEs and Research Organization. The action will also improve technological transfer, improving the chance for new start-ups and SMEs to be spun out and off from the competitive Research Organizations that are already present in the Region's medtech ecosystem.

- The core of the platform should be a Board of experts composed by representatives of the Research, University, Clinical and SMEs world, in order to encompass all the aspects of the medtech sector.
- The first aim of the board will be offering its counselling, expertise, and network to facilitate, empower and strengthen clinical trials in the context of future, ongoing and previous projects financed through the Axis I “Research and Innovation” of the ERDF Regional Operational Programme. This activity will contribute to boost technological transfer and facilitate the adoption of research project’s outcomes in the clinical practice, improving projects’ impact over the Medtech sector.

Cluster Techforlife has started proposing this methodology with a subgroup of researchers from multiple research hospitals and research organizations within the context of a Axis I ERDF call from Lombardy Region: *Call HUB*. Cluster Techforlife was involved in the creation of the partnership and in the definition of the activities for sPATIALS3, an integrated HUB of research, development and innovation in the context of nutrition that aims to improve Agro-food Productions and to develop innovative technologies for a healthier, safer and more sustainable diet. Thanks to Techforlife activity, clinicians were involved in the design of the project proposal, helping in the definition of the project clinical aims and actively redirecting part of the budget towards clinical trials and product validation. Techforlife allowed and facilitated the interaction between the project partners and clinicians from multiple research hospitals, building a board of experts that could become the core of the Clinical Trial Competence Centre.

The Action proposed will continue in this activity, monitoring the effects and the benefits introduced by the collaboration with the board of experts and advisors and extending this collaboration with other beneficiaries of Lombardy ERDF Regional Operational Programme – Axis I “Research and Innovation”.

- A public forum hosted on Lombardy’s Open Innovation will be activated so that questions from the regional Medtech stakeholders regarding clinical trials could be collected and answered by the experts (individually or as a board). The Experts Board will also help identifying clinical populations in which the devices or services should be tested, providing useful contacts with corresponding clinics that might be willing to help the SMEs or Research Organizations in carrying on the trials’ procedure.
- Another aim of the board of experts will be the creation of a document comprising the scientific and legislative requirements for a scientifically sound clinical trial procedure,

underlying the most critical aspects to be considered and giving hints and suggestions to those who are willing to bring innovative products to the market.

### 3. Stakeholders involved

- Lombardy Region
- Lombardy's Cluster Techforlife and Life Science
- Lombardy's Research clinics
- Lombardy's Universities and Research Organizations
- SMEs and Start-ups with Innovative medtech products that would like to undergo clinical trials.

### 4. Timeframe

- January 2021 to July 2021: Using the already existing technological infrastructures of Lombardy's Open Innovation platform, the forum and the technological aspect of the Clinical trial Competence Centre will be prepared.
- February 2021 to May 2021: Start collaborations with beneficiaries of previous ERDF Calls to help strengthen the impact on the medtech sector.
- July 2021: Launch event of the Clinical trials competence Centre, reaching out for SMEs and presenting the board to Research Organizations in Lombardy
- September 2021: First document with challenges, suggestions, hints and key aspects of clinical trials will be proposed and shared on the platform.
- November 2021: Final version of the document and creation of the Frequently Asked Questions section on the Online Platform.
- December 2021: First survey about the Centre on the Open Innovation Platform. 6 months feedback meeting to evaluate interest in the platform, its adoption and its effects (number of visits, number of questions, number of clinical trials facilitated).

### 5. Indicative costs

- Total man months for the Clinical Trial web platform maintenance and update in the two years: 6 man-months = 8000€ (35€/h \* 38h/month\*6 months)
  - Experts to collect, structure and write the document with challenges, requirements and suggestions regarding clinical trials: 2000€
- Total expenses for the action: 10.000€



## 6. Indicative funding sources

The Action will be financed by own means of the partner.

## ACTION 2

Name of the action: **Cooperation Limburg and Lombardy**

### 1. Relevance to the project

Within the good practices Limburg's REGMEDXB project was introduced amongst the Medtech4Europe project partners. After an exchange of details between Limburg representatives and the Italian colleagues during the Stuttgart meetings in December 2018 the MIND (Milano Innovation District), initiative arose as an interesting case for cooperation. During a self-organised site visit organised by the Lombardy Region and Assolombarda in the framework of this project the Brightlands Materials Center, the Brightlands Chemelot Campus and the Province of Limburg were introduced to the developments of Arexpo/MIND in January 2020.

Since the MIND is still under development, the presentations have shown that there might be an interest for a transfer of knowledge about the governance (triple helix model and open innovation) of Brightlands to be to be strategic for the MIND governance. Therefore, a learning transfer organized in Limburg for Lombardy could be organised on the governance. This exchange can be bidirectional since MIND and MERLN Institute of the Maastricht University, as well as MUMC+ could also benefit from a scientific exchange of experiences that could lead to a closer operation on the regenerative medicine themes.

### 2. Nature of the action

The aim of this action is to build up and deepen an international network around MedTech between Limburg and Lombardy With the objective of further strengthening the existing collaboration, also through the definition and realisation of strategic projects under the new EU Programming Period 2021-2027.. In order to give shape to this cooperation, the Lombardy Region, together with the Province of Limburg, will give follow-up to the previous study visit occurred in 2020 in Milan. Accordingly, this action will address the implementation of the first forms of cooperation as envisaged and developed during the first study visit.

The action will include different initiatives, starting from a preparatory analysis phase (desk research, matchmaking, feasibility study) which will lead to a study visit in order to have the opportunity for a concrete interaction on strategic project ideas and/or other synergic activities. Through this direct exchange, the stakeholders from Lombardy and Limburg can get a better understanding of the areas for a stricter collaboration and the advantages they can reciprocally have. This paves also the way for a further development of additional project ideas at a later stage. By doing this more cross-border collaborations are thus possible, to be pursued also in other key relevant frameworks.

Visits to Milan and Limburg help to deepen the cooperation between Lombardy and Limburg. This will be further enhanced when the strengths of different parties are combined and parties from Limburg and Lombardy will work together in a MedTech project. Incorporating the possibility of exchanging project ideas in the study visit increases the possibility of setting up such a collaboration. In this way, by deploying the knowledge and expertise of both partners, a situation can be created from which both could benefit. This action will help in increasing the cooperation between the two regions within the context of the S3 platform, in which both regions are involved, creating a scientific and institutional bridge across Europe.

In addition to the in-depth exchange of good practices, cooperation also provides economies of scale and better access to different markets. Because of the European character of the cooperation, the European market is more accessible and because of the larger scale it is also possible to look beyond European borders.

Through the successful joint action between Lombardy and Limburg, the relevance of international collaboration will be highlighted as an added value that could be concretely operationalised through appropriate ERDF support, for example under future calls targeting interregional cooperation, or other relevant EU programmes, such as the Interregional Innovation Investment Initiative, Horizon Europe and/or EU4 Health. Such reference framework could indeed represent an appropriate context for the implementation of further collaboration activities, which will be explored during the matchmaking phase and feasibility study, and further defined during the following steps.

### 3. Stakeholders involved

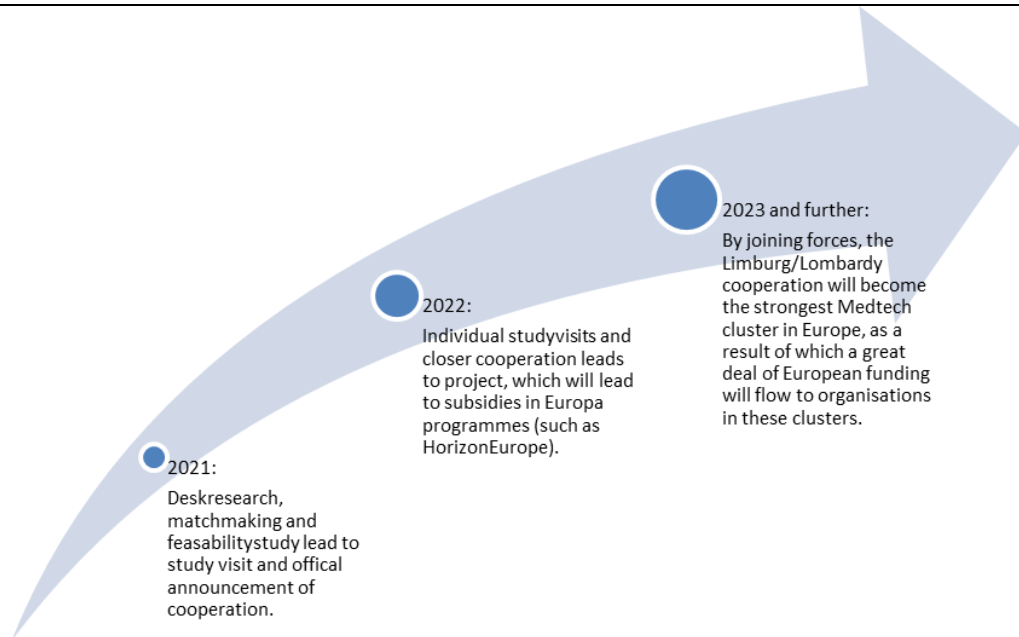
- Province of Limburg
- Maastricht University MERLN Institute
- REGMEDXB

- MUMC+ (University Hospital Maastricht)
- Arexpo/MIND
- Lombardy Region
- Assolombarda
- Politecnico di Milano
- Cluster Technologies for Living Environment (TechforLife)
- Brightlands Maastricht Health Campus

#### 4. Timeframe

In the next two years the following actions will take place to deepen this cooperation:

Date	Action
Quarter 1 2021	<b>Deskresearch:</b> During the desk research an overview of the medtech ecosystem in Lombardy and in Limburg will be drawn up. In this overview the organisations that are active in the Medtech, but also the specialisations of these organisations, are mapped out.
Quarter 2 2021	<b>Matchmaking:</b> This step investigates where there is overlap between organisations and activities in Limburg and Lombardy. This so that organisations can be linked together for cooperation.
Quarter 3 2021	<b>Feasibility study:</b> which parts of the ecosystem are we going to link? Based on the matchmaking, a feasibility study is drawn up to investigate whether cooperation can take place on these different subjects and between these organisations.
Quarter 4 2021	<b>Study visit (group):</b> A study visit is planned to complete the feasibility study. During this study visit, the various organisations will get to know each other and the official starting signal will be given for the cooperation between Lombardy and Limburg in the field of Medtech.
Quarter 1 2022	<b>Start of cooperation:</b> In the first quarter of 2021, the organisations will get to know each other for the first time at an individual level. Following the study visit to Milan, the partners from Lombardy will now be invited individually in Limburg to become acquainted with Limburg's work in Medtech. These are therefore individual visits, which will immediately allow the seed to be sown for further cooperation.
Quarter 2 2022	<b>Follow up of the start of the cooperation.</b> During this phase, the two ecosystems will be more linked. This is because, as a result of the visits, cooperation has got off the ground.
Quarter 3 2022	Initial project ideas are exchanged and, when opportunities exist within European programmes, the <b>first joint grant applications are prepared.</b>
Quarter 4 2022	The first joint grant applications (e.g. through Horizon Europe) will be <b>submitted.</b>



### 5. Indicative costs

Travel costs for this event will be €1.000 for each person who will participate in Milan's and Limburg's study visits. Forecast is that four persons will participate each study visit so the total cost of the study visit for each Region will be €4.000.

Costs are expected also for the Region that will host the visit, for its organization which we evaluate around 3000€ per visit.

Each Region is therefore expected to spend 7.000€ for the two study visits.

Limburg expenses: 7.000€

Lombardy expenses: 7.000€

Total expenses: 14.000€

### 6. Indicative funding sources

These costs will be paid out of own means from both partners.

## SIGNATURE

The managing Authority of ROP ERDF 2014-2020 of Lombardy Region herewith agrees to support and promote the implementation of the actions detailed in the present Action Plan.

I confirm that I have the required authority of my organization to do so and that the required authorization process of my organization has been duly carried out.

Date: *March 16<sup>th</sup> 2021*

Name and job Title: *DARIO SCIUNNACH  
ROP Lombardia ERDF MA*

Signature: *Sciunnach*

Stamp of the organisation: *Il dirigente  
(Dr. Dario Sciunnach)*



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