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Action Plan

**Steinbeis-Europa-Zentrum | Steinbeis
Innovation gGmbH**



PART I – GENERAL INFORMATION

Project: Medtech4Europe

Partner organisation: Steinbeis-Europa-Zentrum der Steinbeis Innovation gGmbH

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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:

Policy Instrument supporting research and development infrastructure in the medical technology sector

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

Regional economic context and Political Priorities

Baden-Württemberg (*hereafter BW*) is one of the economically strongest regions in Germany and in Europe with an above average share of industry research & development (R&D) investment and patent applications. Apart from industrial giants such as Daimler and Bosch, the region's economic strength is carried by a high number of small and medium-sized companies (SMEs), which are very successful in their respective segments, often worldwide market leaders, and have their headquarters in BW. The health economy is one of the region's main economic sectors and includes the medtech, pharmaceutical and biotechnology industries. With a share of nearly 17 % of all employees in BW, the health economy is the strongest economic sector in terms of employment. In addition, the health economy has experienced constant economic growth in the past years and is the third-largest export sector in BW, underlining its regional economic and international importance.¹

The overall economic structure in BW is mirrored by the regional Medtech industry which features not only large industrial players, for instance Aesculap AG, Karl Storz, or Stryker Leisinger GmbH, but also numerous SMEs. In total, 840 companies are active in the Medtech industry. The Medtech industry in Baden-Württemberg is highly successful with a continuous increase in revenues over the past years and a strong sense of innovation.²

¹ see Staatsministerium Baden-Württemberg (Hrsg.) (2019): Erster Jahresbericht Forum Gesundheitsstandort Baden-Württemberg, Juli 2019, p.11.

² see *Ibid.*, p.11.

In terms of R&D in the health sector, universities, non-university research institutes and 5 university clinics carry out research. Among the 21 non-university research institutes, there are large research institutions, such as the European Molecular Biology Laboratory (EMBL) and the German Cancer Research Center (DKFZ) as well as the institutes of the Max-Planck, Fraunhofer, Leibniz and Helmholtz research associations. Furthermore, 13 excellent non-university research institutions are assembled in the Innovation alliance Baden-Württemberg. Translational research, i.e. the efficient implementation of pre-clinical research into clinical development, plays an important role and has been established as a research focus by university medicine as well as non-university research institutes.³

Involving and connecting all actors in the innovation process, i.e. industry, R&D, technology transfer institutions as well as intermediaries, such as clusters, is a key element of BW's regional innovation policy. Since 2011, smart specialization in BW is focused on four growth areas (1. Sustainable mobility concepts, 2. ICT, green IT and intelligent products, 3. Health, 4. Environmental technologies, renewable energies and & resource efficiency), which are the basis of the policy instrument's priorities. These growth areas are clearly visible in the updated *Innovation Strategy Baden-Württemberg (2020)* naming

- Digitalization, Artificial Intelligence (AI), Industry 4.0;
- Sustainable Mobility;
- Health Industry;
- Resource efficiency and energy transition; and
- Sustainable bioeconomy

as key areas addressed by regional innovation policy.

Within the Innovation Strategy, other regional strategies are embedded, which are likewise strongly connected to the health industry: The State's *Digitalization* strategy sets regional priorities with respect to digital transformation, among these "Digital start-ups" and "Digital Health applications" are connected to the health industry. Another key strategy is the *Strategy for Artificial Intelligence*, focusing on the potential of AI along the value chain. In addition, BW has recently laid a dedicated political focus on the health economy by launching the *Forum Health Location Baden-Württemberg* in June 2018, a cross-ministerial and interdisciplinary strategic process aimed at identifying cross-sectoral ideas and

³ see Ibid., p.8.

projects, putting them to the test and implementing them with the overall objective of creating a better healthcare, and an increase in value added and employment in the health industry. For this purpose, a common exchange platform has been established featuring regional players, from science, economy and healthcare including BW's state agency BIOPRO, chambers of commerce, clusters and networks connected to the health economy.

Actions

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.

In line with regional policy priorities, notably smart specialization, this action plan aims at:

- supporting the cooperation between stakeholders from the health industry with a specific focus on Medtech stakeholders, within BW and within the interregional scope of the Medtech4Europe partnership;
- lowering the barriers for SMEs to engage in R&D, notably with respect to clinical trials and thus encourage innovation as well as a closer linkage of innovation actors in the regional Medtech ecosystem; and
- ensuring and reinforcing the leading economic position of BW's Medtech and Health Industry in Europe.

To achieve these objectives, the following two actions are developed:

1. Improve access to clinical trials by providing a centralized source of information and support; and

2. Fostering international cooperation in the Medtech sector through the co-organization of webseminars with project partners (initiative by the Province of Limburg/NL).

PART III – DETAILS OF THE ACTIONS ENVISAGED

ACTION 1

Name of the action: Improve access to clinical trials by providing a centralized source of information and support

1. **Relevance to the project** (*please describe how this action derives from the project and in particular from the interregional exchange of experience. Where does the inspiration for this action come from?*)

The difficulty in accessing clinical studies, mainly in terms of information, has been a recurrent point raised by stakeholders in stakeholder meetings. In terms of overall project objectives, improving access to information on clinical studies contributes to *strengthening the innovation ecosystem for the Medtech sector*, as this requires to establish or reinforce links between multiple actors of the regional ecosystem, such as clinicians / clinics, and companies. Clinical studies themselves are crucial in bridging the gap between research and actual market product.

In the exchange with partners, e.g. during the study visits and workshops, challenges related to clinical studies have been analysed during:

- The **workshop on ecosystems in Maastricht** in March 2019, specifically in the "Workshop on clinic-friendly environment"
- The **study visit in Copenhagen in February 2020**, where project partners had the opportunity to get a more detailed picture of the Danish Good Practice "Trial Nation", an initiative which received particular attention from Baden-Württemberg stakeholders during the stakeholder meeting in January 2020. In addition, the exchange of partners on the status quo of their respective action plans was very helpful in narrowing down potential actions for Baden-Württemberg in the context of clinical studies.

Furthermore, in a more general context, clinical studies have been addressed in the context of Medtech regulation in the **State-of-Play** and the **Joint Cross analysis**, both emphasizing the pressure on SMEs / RDIs to comply with high(er) regulation standards, specifically regarding the new Medical Device Regulation (MDR).

The various analysis in workshops, documents and discussions with partners have confirmed the need for more informational support in the area of clinical studies, while the Danish Good Practice "Trial Nation" has provided a good example of overall organizational support in this field.

While the financial burden of clinical studies is indeed a significant obstacle for SMEs and RDIs in advancing their innovations, support is also needed in terms of information and establishing contact with clinical study centers.

2. Nature of the action (please describe precisely the content of action 1. What are the specific activities to be implemented?)

The aim of the policy action is to **continue and further establish** an initiative on clinical trials for medical devices. In Baden-Württemberg, this task is performed by the regional state agency 'BIOPRO Baden-Württemberg GmbH' (hereinafter BIOPRO), as one of five measures of the "MDR fast track support BW". The program has been started in summer 2019 and is funded by the Ministry of Economic Affairs, Labour and Housing of the State of Baden-Württemberg. It is intended to provide support to regional companies in implementing the Medical Device Regulation EU 2017/745 (MDR), notably to the many SMEs, which are the backbone of the Medtech sector in Baden-Württemberg. BIOPRO, an organisation that comes under the auspices of the Baden-Württemberg government, coordinates the program.

Clinical trials, as point of major concern for Medtech companies in general and specifically in consideration of the increased requirements set by the MDR, are addressed within the program's measure "Improved access to clinical study centres". The measure will be implemented by building a centralized platform acting as a contact and information point for Medtech and other Health industry stakeholders seeking information for organizing clinical trials. This "Clinical study guide BW" is developed in exchange with other stakeholders and will be performed and coordinated by BIOPRO.

The "MDR fast track support BW" started in 2019 and will run until the end of 2021. The policy action addresses the **continuation of the "Clinical study guide BW" from December 2021** on which will profit from the experiences and feedback gathered between 2019 until December 2021. These will be used to identify how the management of the "Clinical study guide BW" can be optimized.

Clinical trials will remain a key issue in the Medtech sector in complying with regulations and in bridging the gap between research, product development and market access as well as the persistence of products on the market. It is therefore important to ensure the long-term perspective of the "Clinical study guide BW". The "Clinical study guide BW" is to be available to interested parties even after the "MDR fast track support BW" has ended. Under this action, BIOPRO has planned the continuation of its activities and potentially the deepening of individual priorities.

The "Clinical study guide BW" will not only provide access to information for organising clinical trials, but also offer opportunities for strengthening the cooperation between Medtech stakeholders in Baden-Württemberg.

3. Stakeholders involved (please indicate the organisations in the region who are involved in the implementation of the action 1 and explain their role)

- **BIOPRO Baden-Württemberg GmbH:** Development, Running and Coordination of the "Clinical study guide BW"
- **BW Clinical Study Centres:** Contact and support in coordination and organisation of clinical trials at the associated clinics
- **BW University clinics:** Conducting clinical trials
- **BW Clinical Research organizations (CROs):** Clinical trial management and related services
- **BW Health Clusters:** Contact and interface for Medtech companies

- Local SMEs: As a manufacturer of medical devices, affected by the increasing requirements of the MDR including the conduct of clinical trials and if necessary sponsor of a clinical trial

4. Timeframe (please specify the timing envisaged for action 1)

End of December 2021 until the end of December 2022.

5. Indicative costs (please estimate the costs related to the implementation of action 1)

N/A

6. Indicative funding sources (please describe how action 1 will be financed. Is it through the policy instrument(s) indicated in part II):

While the currently running "Clinical study guide BW" is financed under the "MDR fast track support BW", the optimized continuation of the policy instrument will be financed from the basic financial resources of BIOPRO. BIOPRO is a central contact point for companies, research institutions as well as clusters and networks in the healthcare industry (biotechnology, medical technology, pharmaceutical industry) in Baden-Württemberg. These activities are financed by the Ministry of Economic Affairs, Labour and Housing of the State of Baden-Württemberg.

ACTION 2

Name of the action: Fostering international cooperation in the Medtech sector

- 1. Relevance to the project** (*please describe how this action derives from the project and in particular from the interregional exchange of experience. Where does the inspiration for this action come from?*)

Medtech stakeholders from Baden-Württemberg have confirmed the value of international knowledge exchange in the context of the project's study visits in Limburg, Upper Silesia, Pécs and Copenhagen. BW stakeholders have either benefitted from this exchange by directly participating in the study visits, or indirectly by participating in one of the regional stakeholder meetings, where experiences from the study visits and regional Good Practices have been presented by Steinbeis-Europa-Zentrum. In this regard, the 3rd and the 4th stakeholder meeting have been particularly valuable, as Good Practices from the partner regions were presented to the participants. In addition, the project has also stimulated interregional cooperation between Medtech stakeholders beyond project activities, thus further strengthening international exchange. Given this positive feedback from stakeholders, a dedicated action aimed at fostering international cooperation in the Medtech sector has been drawn up.

- 2. Nature of the action** (*please describe precisely the content of action 2. What are the specific activities to be implemented?*)

Following an initiative by the Province of Limburg (NL), Steinbeis-Europa-Zentrum will participate in an action, which continues and expands the exchange between Medtech stakeholders across the Medtech4Europe partner regions and offers opportunities for further international cooperation. Through linkages with other health hubs, Steinbeis-Europa-Zentrum will also attract European health stakeholders beyond this geographical scope, thus increasing the impact of the action. In addition, results of the exchange – where suitable – can be communicated to the regional and European policy-level through the organizations' linkages to the Commissioner for Europe of the Minister of Economic Affairs, Labour and Housing Baden-Württemberg. The continued exchange of information will be implemented in the form of webseminars, a digital format, which has proven to be a valuable tool for stakeholder exchange in the context of the Covid-19 pandemic and ensures easy communication independent of geographical distance. The webseminars will take place every 3 months, an according calendar of webinar dates will be set up by the Province of Limburg in accordance with project partners. Depending on the topic, the webseminars may slightly differ in time length, however, they will generally last around 1.5 hours and offer stakeholders room for questions and discussions.

Each region will motivate their own Medtech and Health stakeholders to take part in the webseminars. Beyond stakeholders from Baden-Württemberg, Steinbeis-Europa-Zentrum will also reach out to stakeholders from the Enterprise Europe Network (EEN) sector group "Healthcare" assembling European health stakeholders. In addition, Steinbeis-Europa-Zentrum will involve stakeholders from the eHealth Hub, a networking platform with a focus on European eHealth SMEs (<https://www.ehealth-hub.eu/ehealth-hub/>)

which is intended to be continued beyond the project as legal entity providing services for digital health companies.

As Steinbeis-Europa-Zentrum is connected to Steinbeis 2i GmbH which is part of both initiatives, it is in close contact with according stakeholders. For each webseminar, Steinbeis-Europa-Zentrum will only contact those stakeholders which have knowledge and experiences regarding the respective topic. This will guarantee that the exchange is of high quality and fruitful for participating stakeholders.

In addition, Steinbeis-Europa-Zentrum has a direct link to the Commissioner for Europe of the Minister of Economic Affairs, Labour and Housing Baden-Württemberg who is also the Head of Steinbeis-Europa-Zentrum. The Commissioner can, when and where applicable, communicate the results of the exchange to the regional and European policy level in terms of challenges and framework conditions.

Furthermore, the webseminars will be designed in a way to ensure maximum involvement of stakeholders, who will determine the content, presentation and direction of discussion. Project partners will take turns in organizing the webseminars and finding a subject of common interest among stakeholders in consultation with them; the Province of Limburg will take a coordinating role and monitor the topics covered to ensure that no topic comes up twice. Project partners are therefore only acting as enablers and organizers of the webseminars, the actual exchange is fully in the hands of stakeholders.

Among possible webseminar subjects, Steinbeis-Europa-Zentrum will propose “Digitalization of supply chains in the Medtech sector”, thus highlighting a key topic which has become increasingly important in the context of the Covid-19 pandemic. Through a contract with the State Ministry of Baden-Württemberg (*Staatsministerium*), Steinbeis 2i GmbH, together with other consortial partners including the state agency BIOPRO, will support SMEs active in the health and bioeconomy sector in the Danube region in digitalizing their supply chains. The objective is to make them more competitive and resilient to crisis situations such as the current pandemic. According activities are to be carried out between November 2020 and December 2022 which means that insights gathered could be transferred to Medtech stakeholders in the webseminars likewise planned to take place from the end of 2020.

The planned webseminars will complement an existing exchange format between stakeholders from the health sector, the “Meet & Match” events by BIOPRO which are topic-specific and offer stakeholders from the health and bioeconomy sector a platform for exchange. Stakeholders include research institutes, universities and companies. Apart from regional “Meet & Match” events, BIOPRO also organizes a trinational “Meet & Match” series in cooperation with the French Life Science Cluster Alsace Bio-Valley assembling stakeholders from the regions Alsace, Northwestern Switzerland and Baden-Württemberg. These meet-ups usually take place in physical form but have been organized virtually due to the Covid-19 pandemic.

While the “Meet & Match” events have been a very successful format, the planned webseminars have a dedicated focus on Medtech stakeholders and are built on well established and large spanning international partnerships which go beyond the trinational focus of the “Meet & Match” events. Therefore, they represent

a valuable improvement of the status quo in terms of a new geographically extended and Medtech-focused exchange and networking platform in Baden-Württemberg.

3. Stakeholders involved (please indicate the organisations in the region who are involved in the implementation of the action 2 and explain their role)

- Steinbeis-Europa-Zentrum:
 - technical organization of webinars and time planning (precise dates)
 - overview of potential relevant Medtech subjects and which stakeholders are suitable for presenting them – particular focus on RDIs
 - reaching a consensus on specific webseminar topic with stakeholders
 - attract interest and active participation of BW's Medtech stakeholders as well as stakeholders from eHealthHub and the EEN sector group "Healthcare"
 - in cases of topics/ discussions of systemic interest, e.g. discussions on framework conditions, results of the exchange could be communicated to the regional and European policy level via the Commissioner for Europe of the Minister of Economic Affairs, Labour and Housing Baden-Württemberg
- Province of Limburg:
 - Time Planning / Setting up of webseminar calendar in accordance with project partners
 - Monitoring and coordination of webseminar topics
 - Overall coordinator of the action
- All project partners
 - Co-organization of webseminars and time planning
 - Co-organization and coordination of webseminar topics
 - Mobilization of own Medtech stakeholders
- Medtech stakeholders from all partner regions
 - Participation in webseminars
 - Determine webseminar topic, presentation and discussion
- Multipliers / Key Medtech stakeholders in Baden-Württemberg, e.g. BW health clusters, state agency BIOPRO, Life Science accelerators
 - Dissemination of webseminar invitations to relevant stakeholders in respective networks
 - Possibly participation in webseminars if relevant for topic

4. Timeframe (please specify the timing envisaged for action 2)

- Pilot of the action is scheduled for the end of 2020.
- Every three months a webinar will be organised starting from the beginning of 2021

5. Indicative costs (*please estimate the costs related to the implementation of action 2*)

For Baden-Württemberg, the costs are indicated on 1 man month and are estimated around € 7,500 for the next two years.

6. Indicative funding sources (*please describe how action 2 will be financed. Is it through the policy instrument(s) indicated in part II*):

Internal resources of Steinbeis-Europa-Zentrum

Endorsement

Approval of the action plan for PP8 Steinbeis Innovation gGmbH - Steinbeis-Europa-Zentrum

Date: 3. Dezember 2020

Signature: S. Jaumann

Stamp of the organisation (if available): _____

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