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Scenarios as collaborative tool empowering the policymaking process. The case of MedTech sector in Europe

Abstract: In the paper, we analyse trends that impact the transition of the MedTech clusters in Europe to formulate growth scenarios and propose associated policy measures addressing the MedTech ecosystems while on their way to supporting Sustainable Development Goals. The study directly builds on the lessons learned within the S3martMed alliance, grouping the renowned European cluster organisations in MedTech. The research-oriented objectives of the paper are (i) to present the scenario method as a collaborative, knowledge-enabling tool for clusters and cluster policies and (ii) to identify contemporary scenarios for the MedTech sector willing to add value to transition paths of Regional Innovation Systems. Thus, the presented method and the paper itself are not retrospective but future-oriented to envisage new opportunities for SMEs, business support organisations, RTOs, and the users of MedTech products and services. The paper posits that sustainable ecosystems can be fostered by collaborative achievements of MedTech stakeholders on the condition that they keep on foreseeing the external driving forces to help policymakers to converge them into evidence-based policies.

Key words: scenarios, policy measures, cooperation, MedTech, clusters, ecosystems, Regional Innovation Systems, S3, sustainable transition

Introduction

Today, the world is facing many multi-scale and interrelated global challenges. The magnitude of societal, technological, and environmental challenges together with current and future multiplicative impacts of the COVID pandemic have certainly unveiled vast number of recovery paths pointing to transitions and transformative actions in territories (https://www.oecd.org/coronavirus/policy-responses/the-territorial-impact-of-covid-19-managing-the-crisis-across-levels-of-government-d3e314e1), a variety of ecosystems (Ibn-Mohammed et al.

2021) or regional innovation systems (Asheim etm al. 2020, Tereshko, Gintciak 2020). Thus, sustainability and sustainable development gained an outstanding focus with the global eyes looking at the Sustainable Development Goals for nations (Hege et al. 2019, Sachs et al. 2019) and cities (Zinkernagel et al. 2018, Hawken 2021) as well as smart specialization strategies (Nakicenovic et al. 2021) and resilience plans (Béné et al. 2014, Croese et al. 2020).

As we can read in the SDG Report 2019 (United Nations, p. 42) "For sustainable development, the greatest asset is people. They need to be empowered and engaged in community life to enjoy a high level of satisfaction with life and to age in dignity and good health. If they are to cope with emerging technologies, they need the necessary capacities. That means raising the bar in terms of learning opportunities, health care, and resources for innovation." Here we see the critical role of the MedTech clusters and their ecosystems with the quadruple helix notion forming alliances and creating endogenous and exogenous synergies between the range of stakeholders as well as allowing to boost a vehicle to transformative actions at the level of each of the ecosystems, in-between them as well as in the regional innovation systems they co-create. For this reason, there is a strong need not only for scrutinising the existing data and patterns of behaviours but mainly for using the experience of major players to envisage the future. The abovementioned report (p.43) elaborates that "Achieving all the Sustainable Development Goals requires more forceful action and transformation in the ways that societies foster human well-being and build human capabilities. That is especially true for Goal 1 (eliminating poverty); Goal 3 (good health and well-being); Goal 4 (quality education); Goal 5 (gender equality); Goal 6 (clean water and sanitation); and Goal 10 (reducing inequalities). Guided by evidence, governments, the private sector, civil society, individuals, and scientists can initiate new forms of cooperation." Well-organised processes of collective future-oriented thinking and co-creation might play a vital role in facilitating this cooperation. The selection of foresight tools proves helpful in the strategic alignment of stakeholders.

Having this in mind, in this paper we propose an insight into the empirically tested application of the scenario method. As a background, we have used knowledge of the S3martMed alliance built around 5 European MedTech cluster organisations (located in Belgium, France, Germany, Italy, and Poland) as well as their members. All stakeholders have a sound track record in business and in expertise sharing for the sake of innovation and industrial policy in their countries. As such, the previous experiences were considered the *sine qua non* condition for entering the process. Nevertheless, in detail, they were not meant to specifically impact the study. Neither were they the subject of analysis nor comparison.

In Europe, the MedTech industry, one of the key emerging industries, is composed of around 95% of SMEs (i.e., nearly 29.000) (https://www.medtecheurope.org/resource-library/medtech-europes-facts-and-figures-2021/). These SMEs, with their drive and inventive spirit, are strongly contributing to the advances in the medical field and, thus, the well-being of the overall population. Thus, we consider MedTech stakeholders (i.e., the ecosystems involved in the value chain of medical devices, in vitro diagnostics and digital health tools and services) not

only as those building strong economy but also as creators of products, services or solutions used to save and improve people's lives.

To set the framework of transformative dynamics of those clusters and how they are placed towards threats and opportunities of territorial development related to sustainability challenges, we propose to position the clusters in the logic of path renewal and creation in specialized regional innovation systems as discussed by Chaminade et al. (2019) who elaborate on the new regional industrial path development.

MedTech clusters are directly challenging the threats of ageing society, cardiological and oncological diseases and many other civilizational problems and thus they allow to bolster productivity and human well-being. Of course, there is criticism aligned with that, including for instance the arguments by Mazzucato (2018) who sees the pharmaceutical industry (so, not directly the MedTech) as appropriating the creation of value. We posit that the MedTech clusters or ecosystems should be seen as actors and institutions of the territories in helping the constant transition from product-oriented innovations to territorial-oriented innovations (Kebir et al. 2017) since they are creators of new opportunities for reaching out those abovementioned Sustainable Development Goals. There are differences between path renewal or extension and path creation. In fact, they require various levels of endogenous and exogenous forces. For our case, the ecosystems are rather built around shared visions of transformation allowing to boost the path creation through access to knowledge gathered around intra and extra-regional networks (Chaminade et al. 2019). Since MedTech ecosystems are very much cross-domain oriented with health, IT, bio-economy and other domains leading to sharing and learning based on related and unrelated variety (Asheim et al. 2011) it makes the intra-and extra-regional sharing of knowledge even more important.

Lin and Hu (2017) pinpoint that while symbolic or encoded tacit knowledge can be shared via formal or informal systems; the most non-symbolic knowledge, such as technology and revised tacit knowledge, requires interactive learning to be achieved. For this reason, territorialised cluster organisations need to boost their transformative dynamics if they want to remain efficient in business terms and relevant in the context of regional policy (e.g., as stakeholders of the smart specialisations). This is especially important for clusters dealing with a large share of social innovation (like the MedTech clusters addressed in the paper). First, it is because of fact that the need for social innovation is common around the world – and as such, the global competitive and collaborative arena is huge and full of actors. But also, social innovation is expected to showcase sustainable solutions and fuel sustainability transitions in communities. To move forward clusters need to revise their approach to organisational ambidexterity consisting of exploitative and exploratory approach to learning (March 1991) and leading to inside-out, outside-in and coupled open innovation processes (Gassmann, Enkel 2004). But they also need to target their dynamic capabilities (Teece et al. 1997) such as absorptive capacity, innovative capacity, and adaptive capacity (Wang, Ahmed 2007) related to sensing, seizing, and reconfiguring (Teece 2007) skills,

resources, and competencies. So that they could remain ahead or up to date with the nature of the sector, product, and technology life cycle curve as well as source from and contribute to sustainable innovation (with transformative focus) and sustainable innovation systems (Gerstlberger 2004, Kebir et al. 2017, Chaminade, Randelli 2020).

All that must be done in an international setup that allows local pooling for achieving global impact thanks to cooperation with partners from other parts of the world. Thus, a stable and forward-looking system of knowledge learning and collective intelligence governing, and policymaking is needed as a basis for sustainable transition of regional innovation systems.

Here comes the normative concept of smart specialisation. Since the introduction of the concept of smart specialisation (Foray et al. 2009) as well as smart specialisation strategies (S3) (Foray 2014), the place-based approach to territorial development (Vázquez-Barquero 1999, Barca et al. 2012,) started to gain attention by means of both planning and entrepreneurial discovery logic. In many regions around Europe and Africa smart specialisation strategies were created to boost new opportunities and new specialities in the economy by means of "… diversification through the local concentration of resources and competences in a certain number of new domains that represent possible paths for transformation of productive structures" (Barca et al. 2012, p. 492–493).

The implementation of a new European regulation for medical device (MDR); that was adopted in May 2017; imposed strict demands on medical device manufacturers. With the aim to protect public health and ensure safety and performance, the most significant changes in the regulation included more rigorous clinical evidence for class III and implantable medical devices as well as systematic clinical evaluation of Class IIa and Class IIb medical devices together with rigorous post-market oversight. Therefore, the changes in the regulation have raised additional barriers to innovation for some manufacturing SMEs. On the other hand, the situation regarding the strategies (and or) policies implemented around Europe with regards to supporting MedTech sector have been predominantly built on smart specialisation policies and tailor-made instruments essentially supporting the funding of research and development projects and enhancing the innovative potential of MedTech products and services.

Majority of the provided support is linked to the EU-based instruments, such as ERDF 2021–2027 (European Regional Development Fund) aiming at investments into medical care to reduce the inequalities between European regions. Here, the improvement of healthcare infrastructure and sustainable systems, promotion programmes, health coverage, ageing population and e-health are targeted. Also, the Horizon Europe – Health Cluster addresses some of the key areas such as EU scientific knowledge to better understand health and diseases and innovative technological solutions to better manage health and diseases and designing sustainable approaches for the digital transformation and delivery of integrated, person-centred, and equitable health and care services. The other instruments, basically providing funding and RTO2SMEs collaboration options, and they included: ERA-Nets calls (IRA-SME), EIT Health, Eurostars,

and CORNET programme, as well as Pathfinder, Fast Track to Innovation and EUREKA initiatives.

The most significant regional options for investment and internationalization opportunities included *inter alia* R&D Booster (collaborative effort – regional level for TRLs at 5–9) as well as bilateral funding schemes between Banque Public D'investissements and other national agencies (France, Auvergne-Rhône-Alpes); grants for industrial research projects: company alone or in collaboration (between 30% and 80% of eligible expenses) as well as export subsidies and assistance (Belgium, Wallonia); a voucher system available for Piedmont SMEs to access RTOs with up to 300 thousand EUR (Piedmont, Italy); start-up support system by means of Innovationsgutschein Hightech Start-up (with 20 thousand EUR) as well as ZIM international with up to 500 thousand EUR for international collaboration projects (Baden-Württemberg, Germany) and last but not least a national programme for co-financing of training, education of SMEs by means of "Competences for sectors: an offer for entrepreneurs" as well as dedicated internationalization initiatives such as GoGlobal (Slaskie, Poland). On top of that, private venture capital or seed capital projects were available including acceleration programmes for investment.

Finally, in 2021 European Commission made a rapid decision on the tailor-made measures with the spread of COVID-19, including the EU4health programme as a dedicated one to build resilient health systems.

Building on that, we propose a broader perspective of applied foresight study; namely, scenario learning process as a nexus of widening knowledge on inner and external critical factors enabling the development of various ecosystems as well as creating new opportunities to cross-fertilize and unfold the plans to act within the sustainable notion of the regional innovation systems with strong MedTech ecosystems. Utilizing Foray's notion of transformative activity conceptualization (Foray et al. 2021) we assume that all the stakeholders of the ecosystem are involved in the same direction of structural changes, by means of governing the complementarity of actions as well as being part of the collective intelligence (Komninos, Panori 2019) discussed by Foray as the potential to provide knowledge and information spillovers (thereafter). Thus, the process of generating desired structural changes within the framework of a sustainable regional innovation systems needs a multifaceted process of exploring and creating changes with extensive knowledge on futures (Godet, Roubelat 1996) That requires collective knowledge and dialogue in the ecosystem as well as between the ecosystems in a networking and collaborative mode. Scenario development can be therefore acknowledged as a collaborative action for sustainability challenges and cluster policy developments in MedTech.

The paper is therefore structured as follows. The action research study over a collaborative approach to the pursuit of key external driving factors influencing MedTech clusters and their ecosystems will allow to elaborate and introduce technology-based and public-led scenarios. The conclusions will refer to discussing how they can be converted into policy measures for sustainable transitions including those implemented within Regional Innovation Systems or even EU policies.

Materials and Methods

The study presented in the paper is anchored in the philosophy of action research (Lewin 1946, Adelman 1993) especially in the notion of participatory action research. As such the key orientation was a collective and self-reflective inquiry undertaken by the researchers and participants to understand and improve practice (Baum et al. 2006). The collective action was undertaken to formulate several scenarios that explain potential and most probable futures deeply influencing the MedTech sector. These scenarios were built on knowledge from small and medium-sized enterprises and their liaison organisations clustered in several European countries. All participating stakeholders had equal voice opportunities independently of the details of their track record and of their countries or regions of origin. As the research was meant to address pan-European challenges that the MedTech sector is going to face in the future, the inclusion of case- and country-specific factors, as well as the inter-country comparisons, were minimised on purpose.

One of the main goals of strategic planning is to become knowledgeable on the internal and external perspectives on the future. To better prepare for sustainable growth, one should not only create a vision of strategic changes but also identify key change factors that will most probably influence the actions. The scenario writing is applied here. Godet (1982) mastered the term "la prospective" to designate a discipline that seeks enlightened anticipation by clarifying actions made in the present through the thoughtful examination of both possible and desirable futures. He followed the philosopher Gaston Berger who is considered the spiritual father of "la prospective" as he outlined the fundamentals of the discipline in the 40s and 50s of the XX century (Tournier 1961). The original subject of "la prospective" is taking effective action considering human desire. However, it became a practical science that goes beyond merely applying scientific methods to human problems.

Following Godet's seminal methods, the dynamic picture of the external forces, trends and processes was translated into scenarios through analysis of interdependences. It allowed, then, to identify policy measures needed to boost the positive and diminish the negative factors and effects. We have run the study with the beforementioned S3martMed alliance.

The process of describing the input factors has been set in several steps and included clarification rounds as well as reformulation of the variables (Tab. 1). Some of them were deleted during discussions while new have been introduced; also, with attention given to the post-Covid reality (the collective inquiry had been started before the Covid-19 outbreak and was continued in the pandemic period).

A scenario is a description (usually of a possible future) that assumes the intervention of several key events or conditions which will have taken place between the time of the original situation and the time in which the scenario is set. Scenarios are formulated not to observe the future from the present, but rather to observe the present from the future (Schoemaker 1993).

Table 1. External processes – list of verified variables

Category	Factor
P1	Inefficient governmental activities towards the stabilization of financial underpinnings of the national health system
P2	Significant money has been and will be transferred to fight the COVID implications with the [MedTech] businesses
P3	Commitment of EC to boost new interregional /pan-European funding instruments in the forthcoming financial budgetary perspective – new possibilities of funding and collaboration
P4	Regulatory environment focused on the pandemic situation that in fact has forced medical--healthcare assistance to be increasingly moved into the e-health systems (with the global technological trend: emergence of smart devices that directly connect end users to healthcare)
P5	Limits in import/export flows of medical devices /equipment due to protective policies imposed by state authorities
P6	Decreasing accessibility of direct contacts due to policy regulations (esp. valid for mobilizing new, international collaborations)
P7	Long innovation processes in MedTech and requirements for heavy investments due to regulatory environment that is more and more demanding (new EU MDR, certification and labelling according to ISO13485)
P8	Business support systems targeting predominantly medium TRL levels and disfavouring low TRLs
E1	Decreasing accessibility to excellent healthcare providers due to increased overload and costs of staff
E2	Growth of companies active in the medical technologies market in Europe – leading to higher competition but also to more co-operation possibilities
E3	Society that becomes richer and more willing to pay for private – i.e., individual and more sophisticated – medical treatment
E4	Availability of vast array of seed funding, acceleration, and consultancy instruments for MedTech companies that have been financed mostly by states and EU and to some extent by private capital (however, there is sparse information on it, problematic application due to different evaluation criteria, possibly too many/multiple intermediaries)
E5	The 2021–2027 ESF+ Programme most probably facilitating synergies with other EU instruments that provide financing to health-related projects (worth only EUR 413 million)
E6	Digital Europe Programme financing projects with most probably ca. EUR 9 billion – as a chance to find synergies
E7	Growing importance of tax schemes addressing technological growth of SMEs
E8	Forthcoming development of private venture capital in Europe to complement funding through banks, personal investments, or public funding
E9	Growing excellence of few EU countries in MedTech related to high success rate in EU programmes (Horizon, SME instruments)
E10	Low accessibility of external financing perceived by start-ups and SMEs
S1	The burden of chronic diseases in the society – an increase of number of patients and extra specificity of medical treatment
S2	Decoupling in style of living that leads to superior health inequalities between different consumers – from healthy living to extensive consumerism resulting in unhealthy living
S3	Demographic pressures – new types of medical devices/services needed
S4	Health systems responsible for a high level of unmet needs in medical treatment and long waiting lists of elective medical procedures

Category	Factor
S5	Most of the diseases can be attributed to behavioural risk factors, including for example alcohol, smoking, lack of sports, etc.
S6	Latency time among health professionals in the demand and appropriation of innovative health solutions
S7	Shortage of qualified personnel for MedTech companies
S8	Growing digital competences of the society
T1	Impressive evolution of medical technology sector over the last years due to growth of patenting and applications
T2	5G technology allowing for example to master distant surgery procedures with higher quality of data transfers
T3	Growing skills in the use of big data – as a backbone for medical and health treatment procedures
T4	Enhancement of nanotechnologies and nanodevices – new standards of medical devices and treatments
T5	Massive adoption of additive technologies in various sectors, incl. MedTech and medical treatment
T6	Fast development of various technologies enabling customized treatment (3d scanning, genotype identification etc.)
T7	The development and business models of different types of innovation (chemistry, biology, cell genetics, medical devices, artificial intelligence, etc.) require sophisticated infrastructures, a complex chain of players and cutting-edge expertise.
EN1	Climate change leading to new types of diseases / increase of civilization diseases and medical treatment procedures that are needed
EN2	Market dynamics and value of MedTech businesses increased due to COVID and its consequences
L1	Implementation of HEIs' reforms to overcome the lack of medical staff in numerous countries across Europe
L2	Limited responsibility of medical devices' operators – no regulations regarding liability for any medical errors in procedures involving medical robots
L3	Implementation of MDR regulations – the need for more knowledge on the regulations
L4	EU Health Actions and Programmes that have been promoting good health and preventing diseases as well as supporting innovation and sustainability in EU countries' health systems
L5	Challenging administrative burden to acquire money from public funding (for innovations in MedTech, new services, etc.)

Source: own elaboration for S3martMed alliance.

The elaboration of scenarios offers numerous advantages (Perveen 2019). Starting with any given situation, they allow users to consider multiple possible futures without getting caught in the trap of simply describing trends. They require users to consider the interdependence of the elements of the system under study and they help users identify problems, relationships, or forgotten questions – or those voluntarily set aside because they are simply too controversial. Scenarios are not a requisite part of prospective, and prospective and scenario are not synonymous. However, a scenario is not an end in itself – it only has meaning as an aid to decision-making in so far as it clarifies the consequences of current decisions. Here – with the scenario writing applied to the MedTech sector, it

should be seen as a helpful tool allowing better-informed decision-making in businesses and their clusters. They might also be seen as the backbone for creating instruments of public policy interventions supporting the sector.

Deriving scenarios upon the variables was possible by applying a cross-impact analysis to identify the direct and indirect links between them. The matrix of direct interdependencies consisted of 1560 possible influences and dependencies (as the variable can either steer the others or it can be influenced by them). Further, the MICMAC (*Matrice d'Impacts Croisés Multiplication Appliqués à un Classement*) free software was used to unveil both direct and indirect relations. As a result, each of the variables was given its place within the dependence-influence matrix (Prospective stratégique… 2008).

The classification of variables allowed identification of the ones that have above-average influence capacity and below-average dependency. Those are the drivers of changes responsible for most changes. The variables that have both above-average influences and dependencies are called intermediaries as they act both as influences and dependents. In fact, those factors react to drivers and transmit some of the processes onto the resulting variables (above-average dependency; below-average influence). The variables with low influence and low dependency were considered autonomous and skipped in further analysis. The classification of variables agreed by the S3martMed alliance as valid to describe present and future external conditions for the growth of MedTech clusters is presented in the Supplementary Materials [Graph 1].

Based upon the results of the application of the presented methods we have elaborated the model of external processes influencing the MedTech sector and built scenarios on it. The scenarios were afterwards validated with stakeholders in clusters. Finally, policy recommendations have been drafted to be used with regional and national policymakers for establishing the support framework for clusters' growth and emergence/strengthening of sustainable ecosystems.

Results

Out of the listed variables, we identified: the drivers (T2, T3, L4, P3, S7); the intermediaries (T1, T7) and the resulting variables (P1, P7, S4, S6, T6, E2, E9). With the use of the MICMAC software, the strengths of their interrelations were tested and depicted [Supplementary Materials: Graphs 2–5]. Altogether these observations can be simplified and aggregated into a scheme of the interdependent processes which will most probably influence the MedTech sector and its growth (Fig. 1).

This scheme is a bridge between the analysed variables and the scenarios. What we can see is the dual notion of the drivers. Namely, first of all, the two technological variables T2 and T3 should be seen as moving the **technology scenario** that will highly influence the specificity of application of the intermediary process T1 that is, in fact, in close relation to T7, and that they will be finally resulting in the processes of the bottom line (P1, P7, S4, S6, T6, E2 and E9).

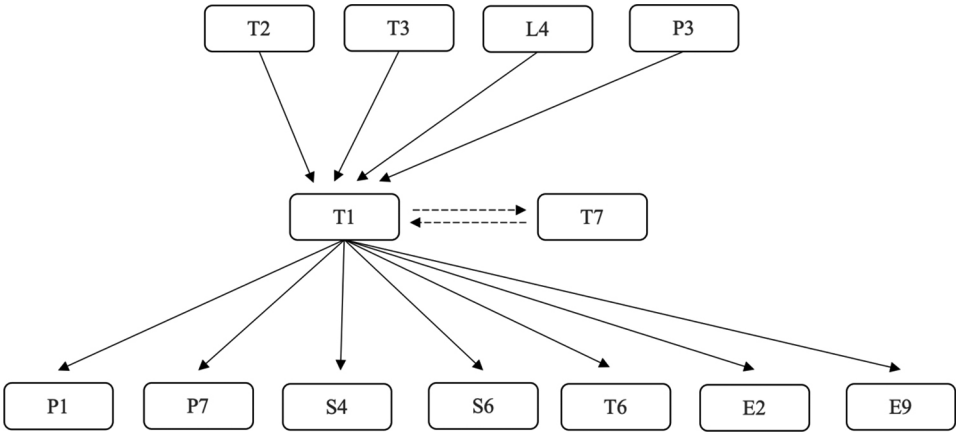

Fig. 1. The scheme of interdependent processes influencing the MedTech sector
Source: own elaboration for S3martMed alliance.

Secondly, the policy/legal environment will form the second possible future for the MedTech sector – seen as a **public intervention scenario** with L4 and P3 drivers linked to the same intermediaries and resulting factors as in the technology scenario. We can therefore call these two futures substantial for boosting operations in the MedTech business.

Considering 5G technology as a foundation for new technologies applied in various fields of business, including MedTech as well as growing skills of the European IT sector in the use of big data, one can observe **the positive scenario of** a **data technology revolution**. This scenario should, on the one hand, stimulate new applications in products and services extending the impressive evolution of the medical technology sector happening over the last years due to the growth of patenting and applications. However, it is conditioned by the availability of dedicated infrastructures, complex chains of players and cutting-edge expertise in different types of innovation.

The second group of drivers (i.e. the development of EU Health Actions and Programmes that have been and will be promoting good health to prevent diseases as well as supporting innovation and sustainability in EU countries' health systems together with the EC commitment to boost new interregional/pan-European funding instruments in the forthcoming financial budgetary perspective) will rejuvenate new areas for MedTech sector and it is believed to deliver new possibilities of funding and collaboration. **This positive scenario of public stimulation** to enable a healthier society will facilitate the pursuit of new patents and applications and should allow for growth in pan-European infrastructures and smooth networking for the benefit of the expertise of the sector professionals.

The two scenarios are not mutually exclusive, and the more efforts are made to maintain the technological advancement of data flows applied in health systems, its speed and security, the more excellency we should obtain by allowing the funding and full use of the infrastructures enabled by the EU policies.

Referring to the results of the scenarios, we can expect that there could be possibly faster compensation of the financial situation of some European national health systems. The more public and private investments are made to new types of infrastructure and services based on data transfer and the use of digital technologies, the better for the future of the systems. Prevention and learning based on AI solutions could save money in the national health systems. Also, more and more private health schemes are offered to prevent and cure. The rebuilt and digitally supported health systems should also better react to needs in medical treatment and cut on the long waiting lists of elective medical procedures through better and more prospective management of the services. The regulatory environment has been already heavy for MedTech. In fact, the variety of collaborative opportunities that should emerge from the public stimulation scenario and the growing knowledge of the regulations should ease the sector; on condition innovation processes continued to speed up.

The implementation of the two scenarios should also strengthen the growth of patenting and applications that will result in the market growth of the sector, already having the lead role in Europe. It should be seen as the enabling factor for higher competition in business but with regards to the expectation of European regions more actively collaborating, it should bring more business and non-business co-operation opportunities. There is an extra economic benefit for the EU, with possibly more countries entering the excellence in MedTech and enjoying the dissemination of new options allowed by public funding schemes highly sustained by private co-funding.

Finally, we can expect those scenarios to levy the link – patenting / new innovative products and readiness to implement the solutions by health professionals. Speedy dissemination of knowledge, artificial intelligence and data-driven algorithms predicting the application needs as well as improved public/market solutions for cutting on the latency time in the implementation of new services and products will serve for the benefit of patients and society. It should also enhance the development of various technologies enabling customized treatment (3d scanning, genotype identification etc.) and lead to even higher awareness of people in the options they have in prevention and medical treatment as well as knowledgeable creation of demand in products and services.

Conclusions

The scenarios presented above focus on policy improvements aimed at boosting the innovation and competitiveness potential of the European regions and their sustainable ecosystems. They are oriented on the MedTech sector and the long-term partnerships in its value chain(s) to enable better performance of companies (especially small and medium-sized enterprises), research and development as well as higher education institutions, technological observatories, technology transfer offices and other business support organisations. On top of that, they contribute to boosting growth led by sustainable MedTech ecosystems in

five regions of the S3martMed alliance and their regional innovation systems by means of unveiling necessary EU policy measures and transformative actions allowing to secure health-targeting smart specialisation strategies.

The structure of the proposed policy recommendations is logically linked to the scenarios. Five policy initiatives are derived regarding the drivers of both identified scenarios. They are the so-called "The Long Run" option that makes use of interdependencies within the scenarios to trigger change needed in a perspective of challenges being in the background of the result factors. Moreover, two policy initiatives are proposed as "The Short Track" option focused on the continuation of the existing measures enabling absorption of innovation. These initiatives directly address some of the resulting variables to provide improvements needed in a short-time perspective. Overall, the framework of the recommendations is presented in Figure 2. Recommendation fiches containing more detailed descriptions are presented in the Supplementary Materials [Fiches 1–7].

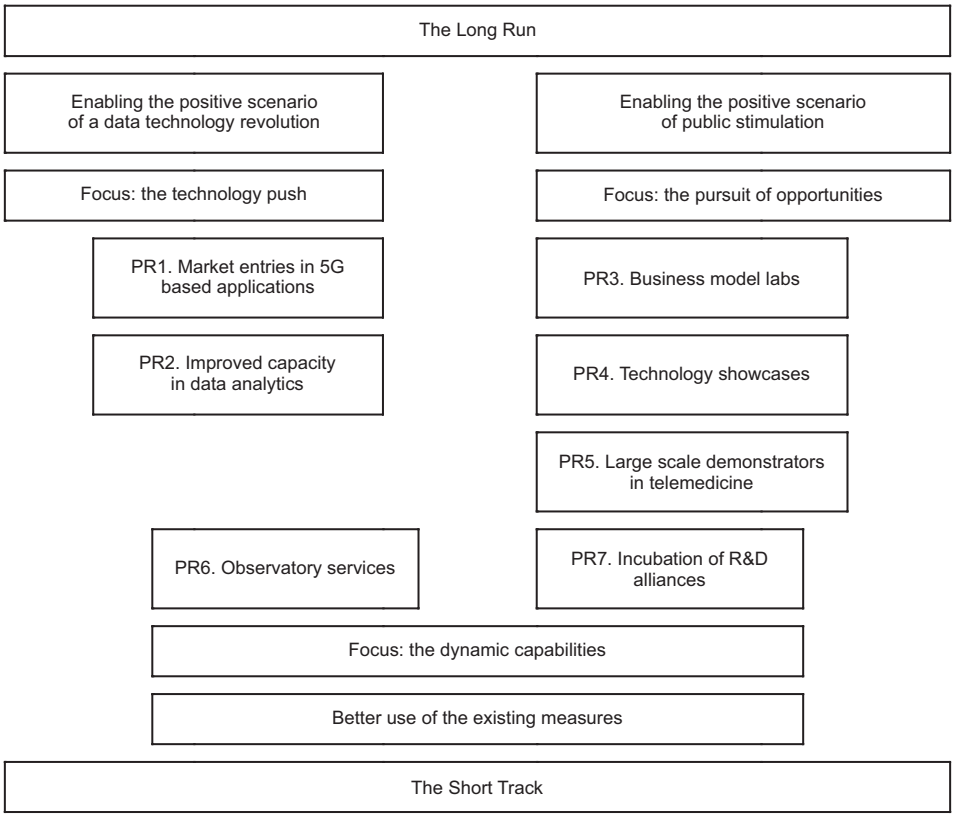

Fig. 2. The framework of policy recommendations originating from scenarios
Source: S3martMed alliance.

As such, building on the collaborative approach to a more knowledgeable decision and policymaking, we propose a methodological toolkit that can be applied to the other sustainable ecosystems – for instance, Industry 4.0+ as described by Bellandi and De Propris (2021) – in their pursuit of growth. The scenarios can be used as a mapping exercise, bringing knowledge on the impacts that define the probable future of the clusters, ecosystems, or sectors as well as a process enabling learning opportunities to the policymakers and other meaningful stakeholders. Even though an approach like this is always a kind of an expert view on the measures-to-be, we believe that it could significantly improve the process of decision-making and the evidence-based policy (Churski et al. 2017) if only built as a common approach to ecosystems' learning on present and the future socio-cultural, economic, technology, environmental and legal change factors.

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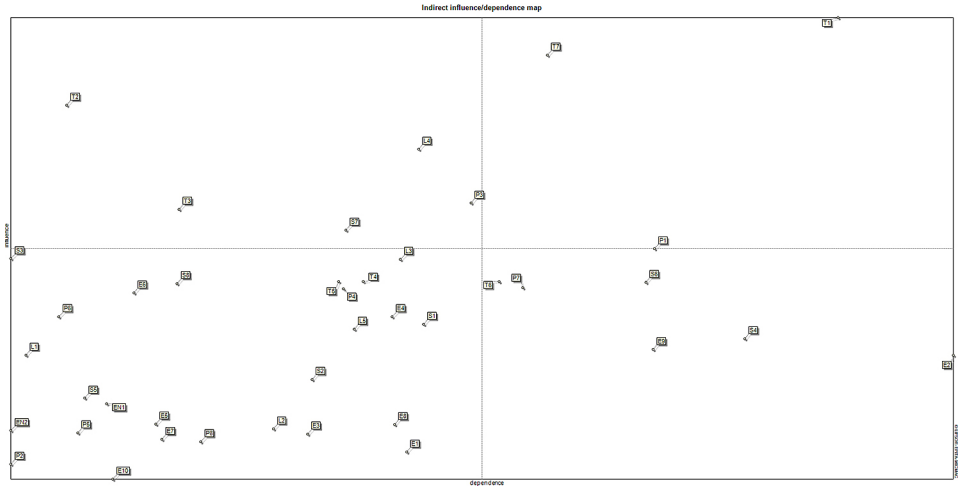
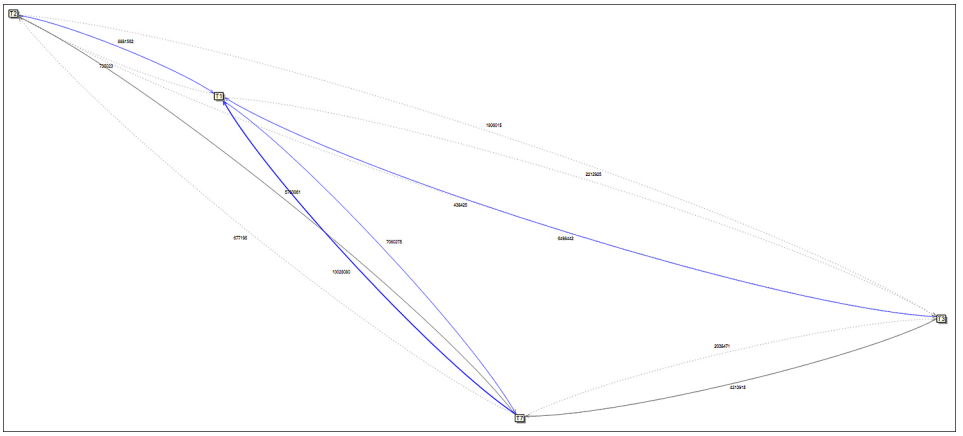
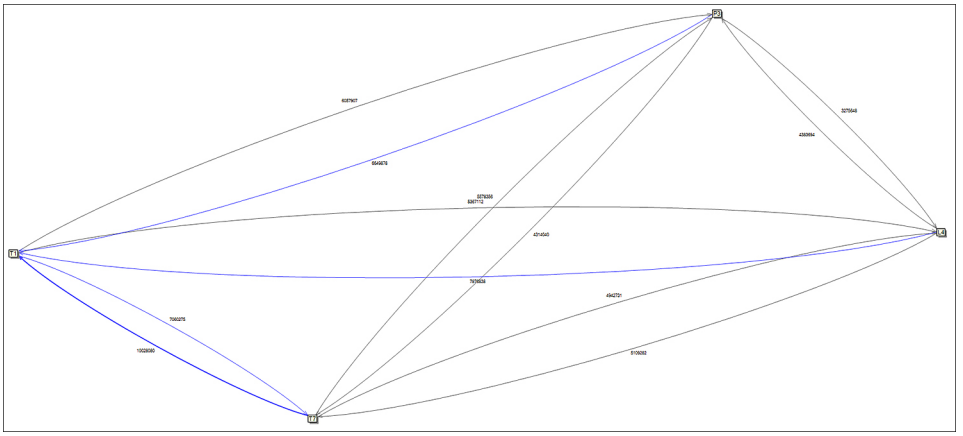
Supplementary Materials



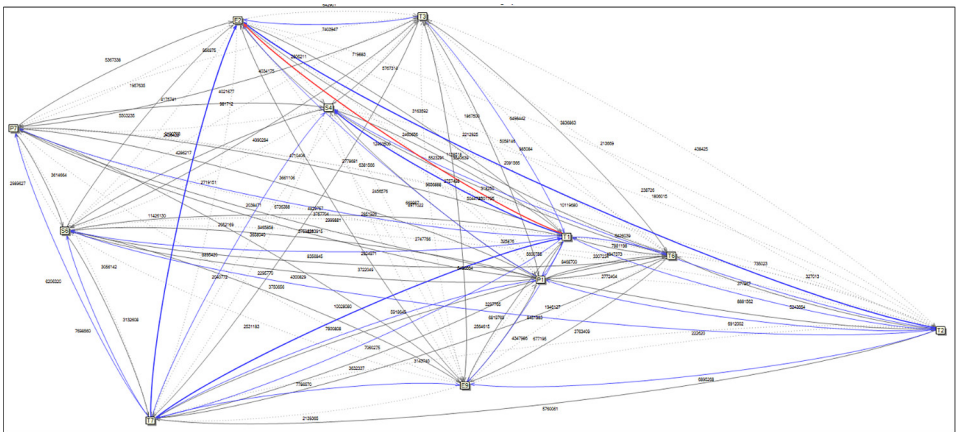
Graph 1. Influence/dependence of variables
Source: own elaboration for S3martMed alliance (with the use of MICMAC software).



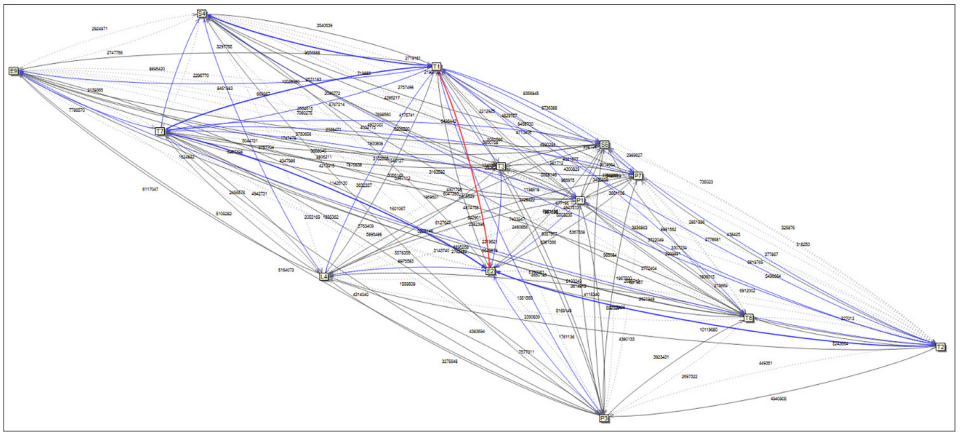
Graph 2. Relations between drivers: T2, T3 and intermediaries: T1 and T7
Source: own elaboration for S3martMed alliance (with the use of MICMAC software).



Graph 3. Relations between drivers: L4, P3 and intermediaries: T1 and T7
Source: own elaboration for S3martMed alliance (with the use of MICMAC software).



Graph 4. Relations between intermediary T1 and resulting: P1, P7, S4, S6, E2, E9 and T6
Source: own elaboration for S3martMed alliance (with the use of MICMAC software).



Graph 5. Relations between intermediary T7 and resulting: P1, P7, S4, S6, E2, E9 and T6
Source: own elaboration for S3martMed alliance (with the use of MICMAC software).

Fiche 1. Policy recommendation 1: Market entries in 5G based applications

Policy recommendation 1	Market entries in 5G based applications
Fits in the scenario:	The positive scenario of data technology revolution
Triggers the input factor:	5G technology allowing for example to master distant surgery procedures with higher quality of data transfers
Aim:	To encourage smooth market entries of businesses that utilise 5G technologies for MedTech applications.
Policy level:	National
Type of intervention:	Market-based – financial instruments with private co-financing
Scope:	Co-investments with seed capital and venture capital funds to promote RTD in MedTech applications relying upon data transfer in 5G networks. Where possible the co-funding schemes should be supported by 5G operators to achieve higher impact, increased credibility, and prompt scale-up. The intervention should encompass: • proof of principle, • proof of concept, • minimum viable product, • market entry and scale-up.
Potential beneficiaries:	Start-ups SME and R&D spin-offs
EU policy fit:	PO1. A smarter Europe by promoting innovative and smart economic transformation: (i) enhancing research and innovation capacities and the uptake of advanced technologies (ii) reaping the benefits of digitisation for citizens, companies and governments
Results in (regarding the scenario):	A higher share of market monies in the technological change of the national health systems. Shortened innovation processes in MedTech due to learning curve effects at seed and venture funds. Increased number of companies active in MedTech, leading to co-opetition and fostering excellence. Reduced latency time among health professionals in technology adoption.

Source: own elaboration for S3martMed alliance.

Fiche 2. Policy recommendation 2: Improved capacity in data analytics

Policy recommendation 2	Improved capacity in data analytics
Fits in the scenario:	The positive scenario of data technology revolution
Triggers the input factor:	Growing skills in the use of big data – as a backbone for medical and health treatment procedures
Aim:	To deliver better science-based methods and applications concerning data analytics in MedTech.
Policy level:	National
Type of intervention:	R&D grants
Scope:	Setting up two-fold R&D grant schemes tailored with MedTech industry representatives to focus on: • level A: supporting developments in computational science, leading to better data analytics algorithms potentially applicable to MedTech, • level B: co-financing applications of new data analytics methods in SMEs in MedTech.
Potential beneficiaries:	R&D and HE institutions Start-ups SME and R&D spin-offs
EU policy fit:	PO1. A smarter Europe by promoting innovative and smart economic transformation: (i) enhancing research and innovation capacities and the uptake of advanced technologies (ii) reaping the benefits of digitisation for citizens, companies, and governments
Results in (regarding the scenario):	A higher share of market monies in the technological change of the national health systems. Increased number of companies active in MedTech, leading to co-opetition and fostering excellence. Shortened medical diagnostics leading to better access to medical procedures. Reduced latency time among health professionals in technology adoption. Further development of technologies enabling customized treatment.

Source: own elaboration for S3martMed alliance.

Fiche 3. Policy recommendation 3: Business model labs

Policy recommendation 3	Business model labs
Fits in the scenario:	The positive scenario of public stimulation
Triggers the input factor:	Commitment of EC to boost new interregional / pan-European funding instruments in the forthcoming financial budgetary perspective – new possibilities of funding and collaboration
Aim:	To promote the application of new business models in MedTech via the interregional share of experiences.
Policy level:	Interregional
Type of intervention:	Co-ordinating actions
Scope:	Organising international partnerships of SMEs (and their supporting institutions e.g., TT offices, clusters) to enable: • best practice presentations, • SME training, • SME advisory concerning the business models relevant to the contemporary needs of the MedTech sector. Furtherly the aggregated experiences of the partnerships should be used for policy improvements.
Potential beneficiaries:	SMEs
EU policy fit:	European territorial cooperation goal (Interreg): 4. interregional cooperation to reinforce the effectiveness of cohesion policy PO1. A smarter Europe by promoting innovative and smart economic transformation: (iv) developing skills for smart specialisation, industrial transition, and entrepreneurship
Results in (regarding the scenario):	Shortened innovation processes in MedTech due to peer-to-peer learning. Increased number of companies active in MedTech, leading to co-opetition and fostering excellence. Increased SME capacity to fill in the gaps concerning the access to medical treatment as well as to improve the reliability of the innovative solutions in the eyes of health professionals.

Source: own elaboration for S3martMed alliance.

Fiche 4. Policy recommendation 4: Technology showcases

Policy recommendation 4	Technology showcases
Fits in the scenario:	The positive scenario of public stimulation
Triggers the input factor:	EU Health Actions and Programmes that have been promoting good health and preventing diseases as well as supporting innovation and sustainability in EU countries' health systems
Aim:	To promote technological advances in MedTech to the general society.
Policy level:	Regional
Type of intervention:	Co-ordinating actions
Scope:	Presenting the contemporary MedTech products to a wide audience attractively and understandably, associated with the creation of opportunities for product testing and receiving the user feedback. As a rule of a thumb, accessing the public should cover three areas of action: • day-to-day communication, especially in social media and popular press, • innovation showrooms focused on user experience and reducing barriers concerning the use of technologies, • living labs set up to enable low-threshold testing/feedback for SMEs.
Potential beneficiaries:	General society Start-ups SMEs R&D and HE institutions Clusters
EU policy fit:	PO1. A smarter Europe by promoting innovative and smart economic transformation: (iii) enhancing growth and competitiveness of SMEs (iv) developing skills for smart specialisation, industrial transition, and entrepreneurship
Results in (regarding the scenario):	Increased user demand and technology pull, speeding up the absorption of new technologies by health care institutions and professionals. Faster development of various technologies due to user feedback in the living labs.

Source: own elaboration for S3martMed alliance.

Fiche 5. Policy recommendation 5: Large scale demonstrators in telemedicine

Policy recommendation 5	Large scale demonstrators in telemedicine
Fits in the scenario:	The positive scenario of public stimulation
Triggers the input factor:	EU Health Actions and Programmes that have been promoting good health and preventing diseases as well as supporting innovation and sustainability in EU countries' health systems
Aim:	To scale-up existing pilot projects in telemedicine.
Policy level:	National
Type of intervention:	Scale-up grants
Scope:	Co-financing the large-scale implementation of certain already pilot-tested telemedical solutions to demonstrate their proficiency, reliability and feasibility. Industry-based partnerships with the networks of medical centres should be co-financed to anchor successful projects in medical routines.
Potential beneficiaries:	SMEs Medical centres
EU policy fit:	PO1. A smarter Europe by promoting innovative and smart economic transformation: (i) enhancing research and innovation capacities and the uptake of advanced technologies (ii) reaping the benefits of digitisation for citizens, companies, and governments
Results in (regarding the scenario):	A higher share of market money in the technological change of the national health systems. Growth of certain MedTech businesses, promoting their way to European/global leadership. Better access to medical procedures and prompt rescue. Reduced latency time among health professionals in technology adoption. Further development of technologies enabling customized treatment.

Source: own elaboration for S3martMed alliance.

Fiche 6. Policy recommendation 6: Observatory services

Policy recommendation 6	Observatory services
Complements the scenarios:	The positive scenario of data technology revolution The positive scenario of public stimulation
Aim:	To improve the regional knowledge base for smart specialisations in MedTech.
Policy level:	Regional
Type of intervention:	Co-ordinating actions
Scope:	Further development of regional cluster organisations and technology transfer offices in their role of MedTech observatories. The observatories should play a vital role in gathering, aggregating, and transmitting knowledge concerning technology development and market opportunities for: • SMEs in MedTech, • SMEs in the other sectors willing to enter MedTech for cross-industry innovation. Where possible the observatories should extend their offers by adding training and advisory services.
Potential beneficiaries:	Start-ups SMEs
EU policy fit:	PO1. A smarter Europe by promoting innovative and smart economic transformation: (iv) developing skills for smart specialisation, industrial transition and entrepreneurship
Results in (regarding the scenario):	Shortened innovation processes in MedTech due to access to knowledge. Increased number of companies active in MedTech, leading to co-opetition and fostering excellence.

Source: own elaboration for S3martMed alliance.

Fiche 7. Policy recommendation 7: Incubation of R&D alliances

Policy recommendation 7	Incubation of R&D alliances
Complements the scenarios:	The positive scenario of data technology revolution The positive scenario of public stimulation
Aim:	To boost participation of SMEs and HE + R&D institutions from transition regions in the international RTD consortia and projects.
Policy level:	Interregional
Type of intervention:	Co-ordinating actions
Scope:	Increased networking activity among regional clusters and technology transfer offices from transition regions and well-developed regions to bring together business, R&D and medical centres representatives from different parts of Europe for the sake of mutual collaboration over MedTech applications to Horizon Europe. Following measures should be applied: • partner search, • networking and planning workshops, • co-financing pilot actions, • advisory on issues related to the IPR and financing, • support in the preparation of consortia documentation and applications.
Potential beneficiaries:	SMEs R&D and HE institutions Medical centres
EU policy fit:	European territorial cooperation goal (Interreg): 4. interregional cooperation to reinforce the effectiveness of cohesion policy 5. interregional innovation investments through the commercialisation and scaling up of interregional innovation projects having the potential to encourage the development of European value chains PO1. A smarter Europe by promoting innovative and smart economic transformation: (iv) developing skills for smart specialisation, industrial transition, and entrepreneurship
Results in (regarding the scenario):	Shortened innovation processes in MedTech due to rigorous RTD projects implemented by strong R&D consortia. Co-opetition and excellence in European MedTech. Alternative ways to improve treatment and access to treatment. Reduced latency time among health professionals in technology adoption. Further development of technologies enabling customized treatment.

Source: own elaboration for S3martMed alliance.

Scenariusze jako narzędzie wspomagające proces tworzenia polityki. Studium przypadku sektora MedTech w Europie

Zarys treści: W artykule poddano analizom trendy, które determinują transformację klastrów technologii medycznych (MedTech) w Europie. Analizy te były podstawą sformułowania scenariuszy uwarunkowań i wynikających z nich propozycji instrumentów polityki wspierania ekosystemów MedTech, w kontekście celów zrównoważonego rozwoju (SDG). Badania dotyczące uwarunkowań bezpośrednio sięgają do doświadczeń aliansu S3martMed łączącego renomowane europejskie organizacje klastrowe w obszarze MedTech. Celami badawczymi artykułu są (i) prezentacja metody scenariuszowej jako narzędzia współpracy, umożliwiającego pozyskiwanie wiedzy niezbędnej dla formułowania polityk klastrowych oraz (ii) przygotowanie scenariuszy uwarunkowań dla sektora MedTech, który zdolny jest do wnoszenia wartości dodanej na rzecz regionalnej transformacji w warunkach rozwijania inteligentnych specjalizacji i promowania celów zrównoważonego rozwoju. Jak wykazano w artykule, rozwój sektora MedTech w Europie wymaga tworzenia instrumentów polityki opartej na dowodach. Wspólna praca nad scenariuszami pozwala nie tylko na podejmowanie przez władze lepszych decyzji, ale także jest podstawą do identyfikowania nowych możliwości przez firmy, organizacje wspierające biznes, jednostki badawcze czy też użytkowników produktów i usług tego sektora.

Słowa kluczowe: scenariusze uwarunkowań, instrumenty polityki, klastry, ekosystemy, regionalne strategie innowacji, transformacja